EU health data centre and a common data strategy for public health

STUDY

Panel for the Future of Science and Technology

EPRS | European Parliamentary Research Service

Scientific Foresight Unit (STOA)

PE 690.009 – September 2021

EN

EU health data centre and a common data strategy for public health

Regarding health data, its availability and comparability, the Covid-19 pandemic revealed that the EU has no clear health data architecture. The lack of harmonisation in these practices and the absence of an EU-level centre for data analysis and use to support a better response to public health crises is the focus of this study. Through extensive desk review, interviews with key actors, and enquiry into experiences from outside the EU/EEA area, this study highlights that the EU must have the capacity to use data very effectively in order to make data-supported public health policy proposals and inform political decisions.

The possible functions and characteristics of an EU health data centre are outlined. The centre can only fulfil its mandate if it has the power and competency to influence Member State public-health-relevant data ecosystems and institutionally link with their national level actors. The institutional structure, its possible activities and in particular its usage of advanced technologies such as AI are examined in detail.

Policy options on how to set-up such an EU health data centre and a common strategy for health data are put forward as ways to achieve a public health datafication multi-level process in the EU, and create a central coordination and support structure with advanced digital public health functions, that bear the potential to significantly alter public health in the EU, for smouldering public health crises such as cancer, mental health and obesity, as well as cross-border large-scale threats.

AUTHORS

This study has been written by Henrique Martins of ISCTE-Lisbon University Institute and Faculty of Medical Sciencies, UBI Portugal, at the request of the Panel for the Future of Science and Technology (STOA) and managed by the Scientific Foresight Unit, within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament.

ADMINISTRATOR RESPONSIBLE

Mihalis Kritikos, Scientific Foresight Unit (STOA)

To contact the publisher, please e-mail stoa@ep.europa.eu

LINGUISTIC VERSION

Original: EN

Manuscript completed in June 2021

DISCLAIMER AND COPYRIGHT

This document is prepared for, and addressed to, the Members and staff of the European Parliament as background material to assist them in their parliamentary work. The content of the document is the sole responsibility of its author(s) and any opinions expressed herein should not be taken to represent an official position of the Parliament.

Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the European Parliament is given prior notice and sent a copy.

Brussels © European Union, 2021.

PE 690.009
ISBN: 978-92-846-8151-8
doi: 10.2861/70808
QA-03-21-262-EN-N

http://www.europarl.europa.eu/stoa (STOA website)
http://www.eprs.ep.parl.union.eu (intranet)
http://www.europarl.europa.eu/thinktank (internet)
http://epthinktank.eu (blog)

Executive summary

The COVID-19 pandemic bought about such significant societal impacts in the European Union (EU) and beyond that only time and distance will allow us to grasp their full extent (1). This study is a humble attempt to take a picture of an incredibly fast-moving object, the size of the Union, and impacting each and every one of its millions of inhabitants in unique, unforeseen, radical and life-changing (for some, unfortunately, life-taking) ways.

> *"Early lessons learnt with COVID-19 have shown that the current system has not ensured an optimal response at EU level to the COVID-19 pandemic"* (2)

This statement forms part of the opening of a document that launches the proposal for major changes to the EU response to serious cross-border health threats. This time, changes to the Union's legal armament happen not one or two years after the crises but, literally, during its peak. Now most EU territories are fighting an unprecedented pandemic, tainting red the Union's maps in the recent European Centre for Disease Prevention and Control (ECDC) online reports [1]. These took months to set up, and clearly show how fragmented the health sector is, including differences in Member States (MS) reporting only national level data, while others display regional level data, with striking relevant differences (3). Alemanno advances a set of provisional explanations of what he calls "*the global suboptimal response to an essentially foreseeable outbreak such as a pandemic*" (4). He suggests one explanation is "*the inability to mobilise the unprecedented wealth of data collected today to counter the virus due to the absence of a data governance and data-sharing culture as well as public–private infrastructure*". This refers to data relevance in public health. In its official position, the European Parliament, in its resolution of 10 July 2020 on the EU's public health strategy post COVID-19 (5), called for a strong push on a European Health Union, where data is central to this construct.

Despite the EU MS sharing a set of health system common values, reiterated by the European Council in its 2006 conclusions (6), the best word that has characterised the EU response since the first day is: ***Heterogeneity***. From the wide range of organisational capacity complications and asymmetries in the different MS to the dispersed and heterogenous nature of public health measures and political positions, which started to converge more out of imitation than coordination (7). Regarding data, its availability and comparability, the COVID-19 pandemic revealed that ***the EU has no clear health data architecture***, and that even simple statistics on elements like intensive care beds, number of active cases under surveillance or availability of professionals, were limited by national and even regional idiosyncratic differing interpretations.

The lack of harmonisation in these practices is also a result of the lack of national comparable data, and the absence of multi-lateral collaboration on data analytics. The problems with differing criteria for recording, documenting and using populational health data have long been identified by a series of European Commission (EC) funded projects and collaboration networks. On 11 November 2020, just eight months after the day the World Health Organization (WHO) declared COVID-19 as a pandemic, a pack of legislative proposals, under the 'European Health Union' umbrella, was presented. More recently the EC also proposed the creation of a new European Health Emergency Preparedness and Response Authority (HERA)[2]. These proposals constitute useful elements for this

[1] The new system to present the evolution of the pandemic, was only launched in September after a complex process of agreeing on structured of reporting data, and the mechanism. Please see link for the maps – https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement These maps are published by ECDC every Thursday in support of the "Council Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic", which was adopted by EU MS on 13 October 2020. The maps are based on data reported by EU MS to The European Surveillance System (TESSy) database by 23:59 every Tuesday.

[2] For details on the HERA proposal please see: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-

study, and this report has been written considering that it may be useful for Members of the European Parliament (MEPs) participating in the analysis and voting on such EC proposals.

Objectives and Methods

The study focussed on addressing the key objectives as outlined in the study specifications and detailed in the methodology section. During this process, and as a reflection of the intricacy of the issues at hand, on his own responsibility the author made two detours:

1. The analysis and advancement of proposals not just regarding a centralised governance structure for health data use, but more broadly regarding the coordination and response in crisis management.
2. A transient health data processing and central structure is arguably compatible with a second idea of exploring how a well-defined strategy for collecting data in the different phases of a Europe-wide public health crisis could be conceived.

Extensive desk research was used. A set of interviews with key actors in the public health information ecosystem and emergency response, as well as EC/agencies was performed. An enquiry into experiences from a selected group of countries from outside the EU and European Economic Area (EEA) was undertaken including Japan, South Korea, Hong Kong (China), Singapore and the United States.

Findings

Systematic problems with heterogeneous public health data have been identified as a challenge and a barrier to robust health indicators (even at aggregated level). Significant semantic differences and subsequent differences in public health indicators are a result of national interpretations about data elements to send over to the EU institutions. This was often referred to and clearly not an issue in places like Hong Kong, Singapore and South Korea, leaving the respective geographical areas with high quality data, of daily or hourly freshness, to be the basis for fast and effective public health policies and decisions. In summary, **there is NO comprehensive health data governance at the EU level, and very few MS could be said to have one at the national level as well**. This impacts the holistic thinking of data usage and information systems. In a way, this is the first main element blocking the conceptualisation of an "EU Data Centre" or "establishing a common European strategy on how to collect data". This is, on the other hand, an opportunity for policy-making at the EU level.

First, because EU and MS health data governance does not necessarily imply a conflict with the Treaties; rather it may require a legal clarification and a positive legal solution.

Second, because in today's world, with learnings from the COVID-19 pandemic and foresight into larger, possibly hybrid, cross-border threats, ***all data may be needed to prevent, perceive, detect, alert, respond and recover***. Even with such a holistic and encompassing view of data usage, MS freedom and responsibility for organising their health systems may not be disturbed as much as needed for public health safety, a responsibility which they also have, and that, increasingly, can only be met in multilateral work, even in inter-critical periods.

A centralised governance structure for dealing with large EU public health crises is needed. Not just for the "governance of data and how it helps emergency coordination and response", but to guide the overall EU-level response. Without a coherent drive on the EU-level response it is more dificul to conceptualize and implement a consistent data governance for emergency coordination and response. A centralised governance structure in a crisis must have the capacity to use data very effectively in order to make data-supported public health policy proposals and inform political decisions. It would nevertheless rest on a complex high-level set of aggregator sub-leadership intelligence hubs to include, *inter alia*, the ECDC, DG SANTE, EC President's Cabinet, Emergency Response and Coordination Centre (ERCC). Four preliminary options about this are outlined.

Findings on gaps and challenges when sharing data at the EU level in health emergencies in terms of the quality, consistency and comparability of data, methodologies and protocols were obtained from interviews with both national level experts and authorities responsible to send data, as well as, the ECDC itself and interviewees in different EU-level functions, at both the EC and JRC as non-official posts. For the purposes of this study the following broad types of public health data are considered: 1. Data on Communicable Diseases (DCD); 2. Data on Non-Communicable Diseases (DNCD); 3. Data about the Health System (DHS); 4. Data with a public health relevance (DPHR), which means non-health data with the potential to be relevant for public health functions. A more harmonised interpretation, preferably sanctioned by EU-level institutions, was considered to have the potential to facilitate their collection and eventually contribute to their utilisation at European level. To consider the utilisation of health data at the EU level for better dealing with cross-border health threats, a centralised governance structure for dealing with data in a crisis needs to ensure several functions which have been outlined.

There is no well-defined or even ill-defined common European strategy on how to collect data. Simply **there is NO strategy which could be considered "common" on data collection**. As the EU discusses the recently proposed 'Data Governance Act' (8), and has a scheduled legal discussion on the European Health Data Space, it is worth mentioning that both can be legal umbrellas for a 'Health (Public Health) Data Governance Act" only if there is a wider understanding of its complexities and necessities as subsequent legislation. An alternative policy option is to have a stand-alone, albeit articulated, legal and organisational stream dedicated only to "health data" understood in a broad sense and not in a narrow classical public health perspective. A set of policy solutions to the present absence of a common European strategy on data collection was offered as **four preliminary options were formulated in advance**.

The EU legal and regulatory framework in the fields of data collection/exchange, testing/reporting methodologies and public health and particularly the law of "cross-border" health (threats) was reviewed. The assessment of adequacy of current EU institutional structures was performed and options suggested for *w*hat could be, the institutional "home" for a new EU structure and what its scope would be. **Four further preliminary options are worth exploring regarding the institutional frame for an EU health data centre.**

The study examined the requirements for a centralised governance structure. It is clear that the concept of such a structure is not irrelevant to its capacity both to really add value to the current EU-level institutional ecosystem, but also, to help, develop, mature and sustain readiness for public health data advanced usage capacity in Member States. **So whether the structure is a "temporary assemblage" or a permanent entity is not an irrelevant policy option**, although arguably a difficult one. There is support for the need for a structure capable of centralising the governance and usage of data for public and populational health in order to help better management of public health emergencies but also to further the protection of human health for EU citizens. **The possible functions and characteristics of an EU health data centre were outlined**. Table 1 (page 33) displays those functions and characteristics in brief and presents their description. Based on this set of characteristics a further analysis into whether a temporary "structure" or a more permanent structure is better suited for the propose of lending more support to a coordination and emergency response was conducted, and favoured a more permanent one.

The centre can only fulfil its mandate if it has power and competency on influencing MS public-health-relevant data ecosystems and institutionally linking with their national level actors. Such a response structure needs to be of permanent continuous activity and not only "actionable when crisis is declared", capable of driving the EU health data strategy and agenda, and capable of liaison with MS internal public health data structures and authorities to ***establish functional public health relevant data pipelines by building technical connectivity and upskilling the workforce in digital health and data science***. The **institutional structure can be located inside an agency or as a**

stand-alone agency, bearing a mix of regulatory agency and technical competence centre attributes. Inspirational examples could be European Agency for Cyber Security (ENISA) under the umbrella of the new Cyber Security Act[3] and the NIS Directive (9), the US Centre for Disease Control and Prevention (CDC)[4] in respect of its technical competence, data aggregation (both communicable and non-communicable diseases) mandate and scientific and data science powerhouse, or the exemplary information technology architecture (10) and centralisation (11) capacity of the Hong Kong Hospital Authority (HKHA). The legal formats possible have been discussed in provisional options 2. A central structure dealing with health data at EU level, particularly if it covers public health data understood in the broader sense and with a permanent rather than transient nature during a crisis, ***will fill a severe actual governance gap***. However, to really have an impact on public health preparedness and betterment of populational health in the EU, such a structure should tackle different types of health data and support multiple EU-Level actors/agencies. For this it would require the access and the capacity (both technical and legal) to process **four large sets of data/health information** from the MS detailed in this study.

An EU health data centre can help a more effective response and so **strengthen European risk management response to crossborder threats.** A better response can be broken down into components such as: preparedness, detection, sense-making, decision-making, coordination, meaning-making, communication and accountability. Positive effects were identified in all. **While a temporary structure would add value,** it may fail to support preliminary and anticipatory decisions, as well as it may prove "short-sighted" for future risks and inevitable next public health crises. **A permanent structure is needed for full effect**.

Without prejudice to the existing allocation of competences between the EU and its Member States ***it is possible to advance an effective and well-coordinated response structure***. It bears the potential to strengthen the European risk management response to cross-border health threats, if it can serve as a ***data hub to support many relevant public health functions that, as of today, are mostly inexistent at EU level***, or even at most MS levels. To show how the structure would undertake its role and serve its mission during a crisis and in between crises, an illustrative set of main operational activities/services it would entertain are shown in table 4 (page 41) which shows a non-exhaustive list of EU health data centre/European Health Data Agency regular and emergency activities. The impact of a structure like this on the overall (existing or potential) EU response was simulated for various combinations of options to understand its expected effect on what could be an EU Overall Coordination and Emergency Response Capacity.

The study outlines the main tenets for a "European strategy on how to collect data for preventing, detecting and curing diseases". Such a strategy would need to include, *inter alia*, the following elements:

1. Definition of the care processes associated with certain data elements
2. Definition of the acceptable technical and semantical requisites
3. Definition of the minimum privacy and cyber-security preserving processes
4. Definition of minimum standards for interoperability and health data quality control
5. Roadmap developments and investments needed
6. Definition of the data areas and sources, including non-health sector data
7. Establishment of interorganisational and interlevel trust in data sharing

[3] Ironically the Cyber Security Act also expanded ENISA's mission in the aftermath of the crisis caused by the WannaCry (cyber)virus which created a significant disruption in the EU economy and showed its vulnerability. For details on the Act and ENISA see: https://ec.europa.eu/digital-single-market/en/eu-cybersecurity-act

[4] US Centre for Disease Control website: https://www.cdc.gov/

8. Ensuring accountability to citizens and securing their participation and support.

A full European strategy on how to collect data for preventing, detecting and curing diseases will need to encompass a set of key strategic elements, such as: preparedness; capacity building; reporting and utilising all types of data relevant for health; technology-based public health functions; advanced insights; foresight and horizon scanning for emerging health threats; datafication of vertical public health data pipelines; expanding health data law. The proposed strategy is not only on how to **collect data** because that would not solve the main problem: lack of data harmonisation, lack of public health process datafication and lack of interoperable and steady data pipelines. It must aim higher to be effective. **Opportunities for strategy implementation exist in the current 'European Health Union' package proposed by the EC, particularly regarding preparedness plans and its audit regimes**. Regarding the legal and operational definitions of who does what, how and when under EU law in an emergency, then the best legal and operational setting is to make the data authority participate at the highest possible decision-making levels. This should be the case if all elements proposed are in place such as: (i) an established authority – part of an Agency or a stand-alone EHDA; (ii) a published and sustained common strategy for health data; and (iii) an ongoing modernisation and datafication process at all four levels of the public health data ecosystem.

The legal mandate of the EU health data centre should contain the provisions for 'emergency-only' digital services, such as some advanced analytic solutions and, definitely, personal surveillance via digital and AI powered tools, as well as the provision of digital therapeutics and digital interaction services directly to EU citizens. **These services are to be run under the strictest protocols and the data to be used must be destroyed as soon as circumstances immediately allow**, even if this reduces the usefulness of the solutions, subject to proportionality considerations as to which data protection and court authorities should be invited to participate. The concept, scoping, clear description, and legal ethical and cybersecurity safeguards of "emergency-only public health digital services" should be formalised and formally approved beforehand. These should be tested, simulated, and shown to the public as part of general preparedness schemas run by the EC. In addition to general communication to the public, the agency responsible for these services must ensure an open individual accountability policy. Explaining these services to each citizen should be guaranteed during and before emergencies, and when they utilise AI.

Irrespective of its scope, mission, capacity, institutional home or of its temporary *versus* permanent nature, the EU health data centre/European Health Data Agency is expected to have to engage with the usage of AI technologies in the context of the "**gradual establishment of a cyber-secure, risk-free, privacy-strict data space that will be able to help the EU to *collect vital data and algorithmically use it*".** The issues around this progressive establishment would be worthy of a complete separate study due to its complexity and ramifications. The current ongoing work for the conceptualisation of the European Health Data Space (EHDS) will obviously require such in-depth considerations. Issues around the progressive establishment of a cyber-secure, risk-free, privacy-strict data space to collect vital data were briefly analysed and suggestions included. Algorithmic use of data encompasses the use of simple and basic algorithms, or the use of AI tools. Both have invaluable potential use for exploring health data. The former have well documented extensive evidence supporting their usefulness and raise less ethical and societal issues than the less well-established AI-based technologies and methodologies. **Issues related to AI usage in processing such vital data were outlined**. Finally, an analysis was conducted of Article 14 of the new proposal for a regulation on serious cross-border threats to health, repealing Decision No 1082/2013/EU (2). This entails a completely new provision called 'Surveillance Platform', which is studied for its pertinence, risk and because it can be the legal leverage point for the establishment of the described space, or actually become a lost opportunity to devise such a space adequately and in due coordination with other EU legal initiatives.

Final set of individual policy options

Three final sets of options create 12 individual options. These were analysed for compatibility and synergy, and combined into main options which were further subjected to a viability and comparison testing resulting in the three final study options.

About the functions necessary for a more effective EU-level broad governance of public health crises

A centralised governance structure operating as a **sort of cockpit function** would be beneficial. Four options are outlined:

1. Do nothing scenario.
2. Approve, with some changes, the proposals by the EC under the package 'European Health Union'.
3. Approve, with changes, the proposals by the EC under the pack 'European Health Union' and **explore the idea of the HERA agency, taking an "all-of-health" perspective** rather than focusing on emergency response and medical countermeasure response.
4. European Public Health Authority.

About the institutional frame for an EU health data centre

Accounting for all presented material and the complexity of the institutional ecosystem, four options are worth exploring regarding the institutional frame for an EU health data centre:

1. **Do nothing scenario**. Maintain existing functions in the different institutions and no horizontal health data coordination function.
2. **Using same institutional arrangements.** Maintaining the existing functions in the different institutions. Establishing four functional regimes via different arrangements
3. Reinforcing the **role of the ECDC in the EHDS (the centre would be part of the ECDC)**. The ECDC would be the main institution responsible for all public-health-related data topics, including not only crisis (and in between crises) relevant data use, but also public health indicators (and functions on 2).
4. Establishing a **European Health Data Agency (EHDA).** Its mission would be to aggregate all existing capacities and digital health EC competencies (and functions in 3) while acting as the main governance agency on the European Data Space on behalf of the "health sector" more broadly.

About solutions for a common European strategy on Health data collection

Regarding a policy on a common European strategy on data collection four options were outlined:

1. Do nothing scenario,
2. Frame such strategy under the umbrella of the Data Governance Act,
3. Frame such strategy under the umbrella of the European Health Data Space Act,
4. Develop a **Health (public Health) Data Governance Act** as a basis for a sustainable strategy

Final study Policy Options

Combining the best options regarding the setting-up of a EU health data centre and a Common European strategy to collect health data to help coordination and emergency response to a serious cross-border threat, a final set of main options, which include a combination of three organisational arrangements and two levels of strategy formalisation, are as follows:

1. Main Option 2 - "Current proposals"/ ***"temporary centre"***: It captures the option of co-legislation on current proposals under the 'European Health Union' package only, with no significant changes, or at least not significant enough to establish an identifiable central coordination structure. Some increased horizontal coordination mechanisms for better liaising among the different EU-level bodies during a crisis with regard to their cooperative usage of health data could be included. This option entails that, at a strategy level, there may be some opportunities and components under the coming European Health Data Space Regulation/Act. The expanded role of the ECDC may help slightly, but Art. 14 of the new regulation, or other dispersed legal elements, have only a limited capacity to exert harmonisation influence and should not be confused with a comprehensive and coherent health data strategy.
2. Main Option 3 – Embedded EU health data centre: In this case, a full-fledged centre is conceived as a part of an existing (ECDC) or new agency (HERA):
    a. Main Option 3a where the centre would be a part of the ECDC;
    b. Main Option 3b where the centre would be a part of the future HERA. - This is perhaps a more viable legal option, as HERA is still open to foundational reconceptualisation.
3. Main Option 4 – Stand-alone EU health data centre: In this case, a new agency – European Health Data Agency (EHDA) is created. ***EHDA is created as a stand-alone agency***, not just to use public-health-relevant data during a public health crisis, but to fundamentally collect, use and analyse the four main types of health data in crisis and inter-critical periods. HERA's remit and ongoing development stays for the most part unaltered, with the exception that it becomes another consumer of data aggregated and shared via the common public health data pipeline and channelled through EHDA.

Figure 2 (page 68) summarises the three options for the EU health data centre, depicts how this centre would support the top main decision-making institutions in coordinating the EU response to a cross-border health threat crisis, and broad data types required for maximum response.

Conclusions

The future is a mystery, but worst and more likely hybrid threats (bio and cyber viruses or other) loom on the horizon. Nonetheless, policy options made to prepare for these can better protect us. They can also provide significant public health value in areas such as cancer, mental health and many other smouldering public health crises that never come to be called emergencies. The European Union's health digital integration ***may take small steps based on shy policy options, with pallid and intangible consequences for citizens a decade after, or large incredible world-astonishing leaps, through courageous legislation and institutional reshaping to achieve real effective public health safety for its inhabitants***.

Table of contents

1. Introduction _____ 1

2. Methodology and resources used _____ 5

3. Synthesis of the research work and findings _____ 8

3.1. In-depth analysis of the challenges associated with the lack of a centralised structures and the absence of a well-defined common European strategy on how to collect data. _____ 8

3.1.1. Challenges due to the lack of a centralised governance structure for the overall crisis response _____ 10

3.1.2. A reflection on a "more effective EU level broad governance of public health crises" _____ 12

3.1.3. Preliminary options 1 _____ 14

3.1.4. Challenges associated with the use of data for emergency coordination and response ___ 14

3.1.5. A Capacity to use the data at EU level – Centralised governance structure _____ 16

3.1.6. Preliminary options 2 _____ 16

3.1.7. Challenges due to an ill-defined common European strategy on how to collect data _____ 17

3.1.8. Absence of a common European strategy and MS high health data/information heterogeneity _____ 18

3.1.9. Preliminary options 3 _____ 19

3.2. Brief review of the EU legal and regulatory framework in the fields of data collection/exchange, testing/reporting methodologies and public health. _____ 20

3.3. Assessment of the adequacy of the existing EU institutional structures to provide a common European Health Data Space (EHDS) and a coordinating structure for emergency responses _____ 23

3.3.1. How the EHDS may relate with public health data needs _____ 23

3.3.2. Working concept of a "coordinating structure for emergency responses", an EU health data centre _____ 25

3.3.3. Assess the adequacy of current EU institutional structures _____ 26

3.3.4. Preliminay options 4 _____ 27

3.4. Examination of the requirements for a centralised governance structure _____ 28

3.4.1. Preliminary considerations _____ 28

3.4.2. Requirements for a centralised governance structure _____ 34

3.4.3. Powers, competences, institutional structure, and legal format _____ 36

3.5. How can an EU structure contribute to the European risk management response to cross-border health threats ____ 36
3.5.1. Filling an actual governance gap ____ 36
3.5.2. Potential for strengthening the European risk management response to cross-border health threats ____ 38
3.5.3. Proposal for an effective and well-coordinated response structure at the EU level ____ 41
3.6. A "European strategy on how to collect data for preventing, detecting and curing diseases" ____ 45
3.6.1. Outline of the main tenets for a "European strategy on how to collect data for preventing, detecting and curing diseases" ____ 45
3.6.2. Strategy implementation and emergency context ____ 47
3.7. Outlining the potential and challenges of a EU Public Health Data Space and its usage of Artificial Intelligence ____ 49
3.7.1. Issues around the progressive establishment of a cyber-secure, risk-free, privacy-strict data space to collect vital data ____ 50
3.7.2. Potential and challenges associated with using AI for public health crisis ____ 51
3.7.3. The new article 14 - "Surveillance platform", AI and a broader EU public health data strategy 55
4. Policy options ____ 58
4.1. General considerations on option analysis ____ 58
4.2. Preliminary policy options ____ 60
4.3. Final set of individual policy options ____ 61
4.3.1. Individual options about the functions necessary for a more effective EU-level broad governance of public health crises ____ 61
4.3.2. Individual options about the institutional frame for an EU health data centre ____ 61
4.3.3. Individual options about solutions for a common European strategy on health data collection ____ 61
4.4. Compatibility and synergy testing ____ 62
4.4.1. Options on an EU data centre in the context of an overall EU response to public health crises 62
4.4.2. Options on an EU data centre for emergency coordination and response in the context of a common European strategy on how to collect data ____ 62
4.5. Main options viability testing ____ 65
4.6. Final study policy options ____ 68
5. Conclusions ____ 70
6. References ____ 75

List of figures

Figure 1 – Non-exhaustive chronological representation of the major EU Law marks in EU Emergency response to serious cross-border threats to human health. 22

Figure 2 – Summary of three Main Policy Options for an EU health data centre and a common European Strategy for health data collection 69

List of tables

Table 1 – The EU health data centre – functions and characteristics 34

Table 2 – Comparison of two options regarding a EU health data centre for Coordination and Emergency Response 35

Table 3 – Analysis of how an EU health data centre, with permanent functions, could positively impact a more effective response to a public health crisis 40

Table 4 – Non-exhaustive list of EHDA's/The centre regular and emergency activities 42

Table 5 – Potential effects of the centre on existing or potential EU overall emergency response capacity 44

Table 6 – Combining preliminary options on the institutional frame for an EU health data centre with preliminary options for a common European Strategy on Health data Collection 64

Table 7 – Four Main Options on the establishment of an EU health data centre and a common European strategy to collect health data: Dimensions and comparison against STOA studies criteria 67

List of abbreviations

DCD	Data on Communicable Diseases
DNCD	Data on Non-Communicable Diseases
DHS	Data about the Health System
DPHR	Data with a public health relevance
CDC	Centre for Disease Control and Prevention of the United States
CJEU	Court of Justice of the European Union
ECB	European Central Bank
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
EC	European Commission
EDPS	European Data Protection Supervisor
EHDA	European Health Data Agency
EHDS	European Health Data Space
EHR	Electronic Health Record
EEA	European Economic Area
ERCC	Emergency Response and Coordination Centre
EU	European Union
ENISA	European Union Agency for Cybersecurity
ERIC	European Research Infrastructure Consortium
FAST DATA	Fast Abundant Standardized Total Data
HSC	Health Security Council
IT	Information Technology
JRC	Joint Research Centre
MEPs	Members of the European Parliament
MS	Member States
NLP	Natural language processing
STOA	Panel for the Future of Science and Technology
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organization

1. Introduction

The COVID-19 pandemic brought about so significant societal impacts inside and outside of the European Union (EU) that only time and distance will allow us to grasp its full extent(1). This study is a humble attempt to take a picture of an incredibly fast-moving object, the size of the Union, and impacting each and every one of its millions of inhabitants in unique, unforeseen, radical and life-changing (for some, unfortunately, life-taking) ways.

The EU, and its Member States (MS) face undoubtedly the biggest challenge since its inception. This study was started 15th October 2020 not at the end of that test but rather at its peak, as a second wave of the pandemic was rising to take the life of thousands of Europeans per day and is being finished after one of the deadliest months of January and February in the history of our continent. Using an airplane metaphor, the difficulty is to capture this picture of the plane while trying to understand the pilots and the crews, their coordination processes, and what input data they are getting from central to distal parts of the aircraft. Trying to anticipate what could have been the effects of "alternative" ways, the options available and their respective consequences. This study is not an historical account, a retrospective narrative, or a detached analysis. Materials of dense content and pertinence continue to be created. Intentions, communications and legal proposals sprout. The people involved, who would be key for some insights, are too busy dealing with the crisis to be available for conversations and distractions with a researcher. This is also a sort of "action research" or "active-research" as the camera, needs to "follow" the vehicle or it loses its capacity to film the events inside. The lenses of our camera have been: legal & regulatory; organizational & managerial, and technical & informational. Rather than trying to capture all that context, there was a focus on the substantive elements of the question: *"Could we have a better coordination of response to a crisis ("such" as this one or larger) and how can different health data use contribute to this and what can the EU do about it?"*. In a nutshell, this is what this study is all about.

In most countries, population is growing old (12), which, associated to unhealthy lifestyles, increases healthcare needs, leading to healthcare systems sustainability challenges (13). These needs remain but the sudden onset of the COVID-19 pandemic has significantly altered focus, attention, and priorities. A significant number of very important studies (14) and reports are starting to be produced and will continue over next few years casting light on the consequences of this incredible worldwide crisis(15)(16). Contemporary debates accumulate, from the safety of vaccines [5] and their capacity to deal with relevant viral strain variants, to the lack of countermeasures in the first months of the pandemic in the EU and its health and economic sovereignty[6]. Despite the EU MS sharing of a set of health systems common values, reiterated by the European Council in its 2006 conclusions (6), the best word that characterizes the EU response since the first day is: ***Heterogeneity***. From wide range of organizational capacity perplexities and asymmetries in the different Member States (MS), to the disperse and heterogenous nature of public health measures and political positions, which started to converge more out of imitation than coordination (7). Regarding data, its availability and comparability, COVID-19 pandemic evidenced that ***the EU has no clear health data architecture***, and that even simple statistics on elements like intensive care beds, number of active cases under surveillance or availability of professionals were limited by national and even regional idiosyncratic distinct interpretations.

[5] Please see EMA - https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-march-2021_en.pdf

[6] Please see European Council on Foreign Relations - https://ecfr.eu/publication/defending_europe_economic_sovereignty_new_ways_to_resist_economic_coercion/

A range of ongoing projects (many funded by the EU) not just to "fight" the pandemic, but to learn from it, have been launched[7], the results of which can further inform policy options directly or indirectly related to this study. Time, however, has not yet allowed for those findings to come to light. Many research findings are yet to be published. A range of interesting opinion and review articles (3,4,17) in risk studies or policy related academic fields (18), however, have enlighten our understanding, particularly in relation to areas such as response but also the possibilities of the EU to take more decisive actions in coordination as well as with regards to data utilization.

Several response measures to this crisis (and societal responses to them) both at each MS level (such as confinement strategies or testing strategies, for example) have propelled debates and questions of comparative nature between the differing MS decisions (16) and at their scoping at the EU level (3). Total lockdown decisions, relief of first lockdown, hospital/systems capacities, unstaffed health services, insufficient beds/data/medical countermeasures are, but a few, of the dilemmas and controversies under debate. During December 2020 we saw different "Christmas strategies" in each MS but a "EU vaccination days" campaign illustrating how weekly topics steer hot discussions in MS and at the EU level. In January and February 2021, we again saw very different lock-down associated decisions and mechanisms. There is no visible common roadmap, resulting in a ECDC incidence map where high and low regional incidence scores seem to alternate endlessly. Examples of desynchrony were very salient in the early months, what is less explainable is that they persist in small things one year later. For example, different criteria for the requirements about holding a negative PCR-test for the entrance in an EU Member State are inexplicable. Namely the age limit below which this test is dispensed varies from 13 years, in the Netherlands to 12 in Denmark, 11 in France, 6 in Germany, Belgium, Spain, Ireland and Luxemburg, to as low as 2 years in Portugal. This heterogeneity cannot be based on science, it damages communication with Europeans and contributes to the discredit of the EU as a health protection and free-movement space. **This heterogeneity is much more the result of different perspectives from national public health authorities and a tradition to decide based on national data, experts, or history. The lack of harmonization in these practices is also a result of the lack of national comparable data, and the absence of multi-lateral collaboration on data analytics.**

The problems with differing criteria for recording, documenting and using populational health data have long been identified by a series of EC funded projects and collaboration networks, such as Bridge Health[8] and more recent Inf-Act Joint Action (which inherited a long set of assets, identified issues, causes and consequences)[9]. The Expert Group on Health Information (EGHI)[10], Inf-Act experts and others have been advocating for a long time on a need for a common approach to health data (more broadly) or populational health information (more narrowly). Pointing this as an area where MS need the coordination role of the EC to advance. EC in turn, points to MS as the tenets of the solution by asking them to fund a more intense collaboration and secure the political will to create the necessary common structures and strategies. Different mechanisms have been proposed, but no significant advancement has happened with the EC outsourcing to the OECD the production of the flagship report on Health Status of EU MS, the Health at a Glance report[11], or trying to sustain

[7] Please refer to a all set of projects and initiatives by the EC at - https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/covid-19

[8] For details and deliverables of Bridge Health project please see BridgeHealth (bridge-health.eu)

[9] For details and deliverables of Inf-Act Joint Action please see https://www.inf-act.eu/

[10] The Expert Group on Health Information (EGHI) is an advisory group for evidence-based policy made up of representatives from EU countries, European Economic Area countries, possible future EU members, and international organisations. For details on the past activities, meetings and deliverables of the EGHI, and a set of health indicators see https://ec.europa.eu/health/indicators_data/eghi_en

[11] Funded by the EC via DG SANTE The *Health at a Glance: Europe* report series gauges progress towards effective, accessible and resilient health systems across the EU. The report – which is published every two years – provides a

with scarce resources some online European Core Health Indicators considered by the EGHI as outdated and needing profound EU and National level workup[12]. The EC struggles to make sense of data sent by MS of irregular quality and often with years of delay, as is the case of the cancer registry data, as examples. It is against this backdrop of national and regional absence of systematically collected and readily available data with a public health relevance (DPHR) and a poorly digitalized public health administration that the difficulties of using data for better decisions to fight COVID-19 pandemic need to be understood.

If there is something healthcare organizations and Member States in Europe have learnt from COVID-19 pandemic is how ill prepared they were to use health data more effectively, how uncapable to serve their citizens through telehealth, to integrate and interoperate care services via electronic healthcare records exchange, or to implement task-shifting or rearrange teams assuming all members of staff could access, understand and explore semantically compatible electronic patient records.

In the past, H1N1 pandemic or the Ebola Crisis stimulated changes in EU legislation related to cross-border health threats about two years later. In 2020, the EC was fast in suggesting novel actions, communicating vision for changes, and presenting concrete, and quite significant (albeit narrow focused as will be discussed throughout this study) changes for the after-COVID-19 epoch. In the 11th of November the EC presented a pack of proposals under the "European Health Union" umbrella, just 8 months after the WHO declared COVID-19 as a pandemic. These proposals constitute useful elements for this study, and this report has been written considering that it may be useful for MEPs participating in the analysis and voting of such EC proposals. More recently, in late February 2021, as vaccine shortage threatened previous plans and a the proposal of a narrow-focused new European Health Emergency Preparedness and Response Authority (HERA)[13] was greeted with great enthusiasm while its capacity to be operational before pandemic is over is neglectable. Such opportunist policy option choices do benefit from a more distanced reflection as well as strategic thinking on how much further reaching they may need to be if they are to really be effective in a next similar crisis.

One of the final dimensions of the study is **the degree and mechanism through which secure and AI-based information and communication technologies can allow better use data for dealing with public health threats**. This is an acknowledgement that solutions to the previously existing and growing need for change and efficiency in health and care to attain safer health for large populations are to be found in the implementation of 'smart' healthcare technologies. Health 4.0 technologies and processes (19) mean possibilities for organizational change through the implementation of new digitalization strategies and advanced information technology, such as Artificial Intelligence Systems. "Digital Health" is a priority worldwide (20) and is expected to increase quality of care and clinical safety. A higher use of AI technologies is said to potentially bring more efficiency and effectiveness to health and care. Moreover, the current pandemic showed how useful AI/Robots can be during a crisis as they have been used in different tasks[14].

---

neutral, descriptive comparison of all EU countries based on publically available data and indicators. See - https://ec.europa.eu/health/state/glance_ga?2nd-language=en

[12] For online European Core Health Indicators refer to: https://ec.europa.eu/health/indicators_data/indicators_en

[13] See online consultation for the launch of HERA - https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-

[14] Non-scientific literature and news on this have emerged such as: Parrock, Jack. "Belgium Hospital Employs Robot to Protect against Spread of COVID-19." Euronews, 2 June 2020; https://www.euronews.com/2020/06/02/coronavirus-belgium-hospital-employs-robot-to-protect-against-covid-19; Scalzo, Flavio Lo. "Covid-19: Tommy the Robot Nurse Helps Keep Italy Doctors Safe from Coronavirus." The Star Online, 1 Apr. 2020, www.thestar.com.my/tech/tech-news/2020/04/02/covid-19-tommy-the-robot-nursehelps-keep-italy-doctors-safe-from-coronavirus#.XobfCpIdTLc.twitter; Cat Clifford "Look inside the Hospital in China Where Coronavirus Patients Were

Multiple definitions of AI exist and are often re-elaborated. In its Communication on AI for Europe the Commission(21) provided a first definition of AI[15].This definition was further refined by the High Level Expert Group[16]. The goal of AI research, a subset of data science, is to give machines human-like cognition meaning they can "think" and recommend actions based on that thinking, they can predict outcomes, and they can learn. Amongst other technologies(22) AI has been identified as a promising technology for advancing the fight against COVID-19 pandemic and similar threats. The same author points out for the relevant role of universities and research institutes in as creators of technologies which in turn call for regulation(22). On the other hand, anticipatory policymaking is needed in areas such as AI use in (public) health where experimentation is likely to grow exponentially. Well established and well-known datafication(23) strategies for digital systems and health data use allow better alignment and joint efforts between policy and research. Legal and ethical issues are significant and several policy options for pragmatic solutions in this area, such as ethical technology assessment (eTA), have been recently advanced(24). These reflections help gain a more informed perspective on the subject for this particular study.

Treated by Robots." CNBC, CNBC, 23 Mar. 2020, www.cnbc.com/2020/03/23/video-hospital-in-china-where-covid-19-patientstreated-by-robots.html

[15] "Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications)."

[16] "Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions." (61)

2. Methodology and resources used

The study focussed on addressing the **key objectives** as outlined in the study specification:

> *-perform an in-depth analysis of the challenges associated with the lack of a centralised governance structure for emergency coordination and response as well as the absence of a welldefined common European strategy on how to collect data in a public health emergency context;*
>
> *-identify the gaps and challenges when sharing data at the EU level in health emergencies in terms of the quality, consistency and comparability of data, methodologies and protocols;*
>
> *-identify the main actors involved in the eco-system of data collection and processing in public health emergencies;*
>
> *-review the existing EU legal and regulatory framework in the fields of data collection/exchange, testing/reporting methodologies and public health, and assess the adequacy of the existing EU institutional structures (JRC, ENISA, ECDC etc.) to provide a common European health data space and a coordinating structure for emergency responses; -examine in detail the requirements and the added value associated with the development of a centralised governance structure;*
>
> *-examine whether the establishment of an EU structure of this kind fills in an actual governance gap and carries the potential for strengthening the European risk management response to crossborder health threats and propose an effective and well-coordinated response structure at the EU level without prejudice to the existing allocation of competences between the EU and its Member States that could strengthen the European risk management response to cross-border health threats.*
>
> *-devise the main tenets of a European strategy on how to collect data for preventing, detecting and curing diseases, which could legally and operationally define who does what, how and when under EU law in an emergency context;*
>
> *- develop a wide range of realistic and thought-provoking policy options that could address the effects of the fragmented and uncoordinated response to COVID-19.*

During the study the author entertained two detours in addition to these set objectives:

5. The analysis and the advancement of proposals was extended to EU level overall coordination and response for the crisis. It is not ideal to conceive a centralised EU data structure without understanding the requirements of top decision making. The analysis of the overarching EU mechanism for dealing with serious cross-border threats (included in Decision No 1082/2013/EU, and the Regulation establishing the ECDC, as well as the EC latest proposals to changes in such mechanisms (the proposal for a REGULATION on serious cross-border threats to health and repealing Decision No 1082/2013/EU, and changes to ECDC, EMA and a the HERA agency) was outside the scope of this study. However, from an IT perspective, studying the role and functions of a centralized unit for handling data without understanding or creating scenarios/policy options of what its "client" and institutional users look like is not a good enterprise architecture practice and from a COBIT® framework[17] it is actually considered less optimal. In other words, ignoring the contours of the "overarching governance function" that will use the outputs, and pose requests to the idealized central structure, makes it significantly more difficult to delineate its characteristics. Even if there is no precise knowledge of this "management entity" due to its undefinition or evolving

[17] The COBIT®framework is an advanced and well recognised information technology governance framwork and it postulates that IT structures and processes always have to be adjusted to top management/decision makers aims and goals for the organization. More detailes can be found at: https://www.isaca.org/resources/cobit

nature, scenarios (policy options) can be created to help understand how one structure would relate to the other. This methodology was the one followed.

6. While the study specifications suggest a "temporary" nature of such health data processing and central structure, this is arguably compatible with the second idea of exploring how a well-defined strategy for collecting data for the different phases of a European wide public health crisis.

Extensive desk research was used. To guide this, the following areas of enquiry were considered:

7. Legal background on cross-border serious threats to health in the EU(25), as well as emergency civil response in general (26) – mostly legal and grey literature;
8. Legal text under current relevant proposals such as (the EC Communication on Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats (1); the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control (27); the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU (2); and the proposal on European Data Governance (Data Governance Act) (8);
9. Background on data usage at EU level: legal and policy initiatives by the EC, including ongoing discussions in projects around the European Health Data Space (EHDS)[18]. Mostly grey literature, but also projects (Horizon 2020, Joint Actions) materials;
10. Public Health at the EU, main priorities, the EU4Health plan, and the area of work under the topic of public health information/health indicators;
11. ECDC related information: institutional setting, ongoing audit reports and strategic planning;
12. Technological solutions. Material on AI usage at EU level, AI and technical solutions for COVID-19, and AI usage in Public health more broadly. Mostly technical-scientific reports or peer reviewed literature;
13. Crisis preparedness (pre-2020) phase, understanding the role and function of the ECDC and ongoing activities in health crisis preparedness; Exploring equally EU-funded projects like TransCrisis[19] on EU preparedness for crisis more broadly;
14. Crisis response phase: EU institutions produced documents on response coordination;
15. Crisis response phase: Peer-reviewed academic publications about the EU institutions actions, especially by the EC/agencies;
16. Crisis reaction and policy proposals for "changes" in the EU capacity for dealing with similar crisis in future. Mostly Grey literature and concrete legal proposals or relevant official positions such as the European Parliament resolution of 10 July 2020 on the EU's public health strategy postCOVID-19 (5);

[18] European Health Data Space discussion has been taking shape, the author views result from Interview with DG SANTE on this topic, the participation of an open session on the EHDS on 25th January 2021, and the information available for online consultation at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space

[19] TransCrisis is a three-year international research collaboration on EU transboundary crisis-management. For more information on Trans.Crisis https://www.transcrisis.eu/

17. Better regulation and foresight science as inputs for better policy proposals.

A set of interviews to key actors of the public health information ecosystem and emergency response, as well as EC/agencies was envisioned. An enquiry of experiences from a selected group of countries from outside the EU/EEA area was considered including Japan, South Korea, Hong Kong (China), Singapore, Australia and the United States. Regarding the set of interviews, the following groups were considered, and the number of interviews conducted with representatives is indicated in brackets:

18. Academics from the area of EU law and policy (1) and AI technology (1);
19. EC/Agencies[20]: DG SANTE[21] (2); DG CNECT (2); DG DIGIT (3); JRC (3); ECDC (1)
20. Member states, namely in two dimensions; (i) Public Health authorities, or National Public Health experts (Italy, Portugal, Malta, Norway) (4); (ii) Data permit authorities or eHealth Network representatives (2) from: Finland – Findata; and France – French data hub
21. Public health experts: From Portugal (2) the acting head for information division at DGS (Portuguese National Public Health Authority) and the President of the Public Health Doctors Association. From Belgium (1). From the OECD (1) and with past experience at a national public health agency, now at WHO (1).
22. Non-EU entities and experiences: US Center of Disease Control (CDC) (2); Hong Kong Hospital Authority (1)

Overall, 25 semi-structured interviews were conducted via videoconference with an average duration of one hour. These were not taped; notes were taken and replies to email follow-ups with reference materials and further clarifications helped obtain additional relevant information. With regards to non-EU/EEA area information on public health information systems, response to COVID-19 pandemics and vertical integration of health data for supporting pandemic response was solicited. Ministerial level representatives in eHealth were used as first contact to reach relevant respondents. Study scope and a set of questions (Annex 1) was sent. In the case of Japan a written reply was received, for Singapore an informal interview with a former Ministry of Health official involved in data and systems utilization for COVID-19 until September was conducted. From Hong Kong the Hospital Authority provided relevant material and was available for interview, South Korea also provided a set of relevant documents, while Australia did not contribute in time of the closing of this report. In the case of the United states, a short feedback by email was obtained from the Office of the National Coordinator (for eHealth), and a set of interviews with the CDC (2) were conducted.

[20] Despite more than one contact, EMA never accepted the invitation for interview.

[21] There was no capacity to interview representatives from DG SANTE (Unit C3) which limits proper understanding of issues related to the dynamics of the Health Security Council (HSC), vaccination and the new HERA proposal in more detail than that which is provided in the document published for consultation.

3. Synthesis of the research work and findings

The following sections will deal with the overall context and challenges related to the lack of lack of a centralised governance structure for emergency coordination and response as well as the absence of a well-defined common European strategy on how to collect data in a public health emergency context, but also what is the legal and institutional backdrop, while advancing a set of preliminary options that are the basis for the policy options to be presented towards the end of the study.

3.1. In-depth analysis of the challenges associated with the lack of a centralised structures and the absence of a well-defined common European strategy on how to collect data.

This section will present an in-depth analysis of current challenges due to lack of a centralised governance structure for overall crisis response. Due to lack of a centralized structure for data use in support of emergency coordination and response ("the eventual "EU Data Centre"). Finally challegues associated with an ill-defined common European strategy on how to collect data. This will allow the establishment of the points to be addressed by a proposal for the centralized governance functions (particularly on data aspects) and a well-defined common European strategy on how to collect data to be outlined in section 3.6. The study would be somehow inconsistent and incomplete if it contained no proposals on the overarching EU governance mechanism for cross border serious health threats. As such, although outside the scope of the study, a proposal on elements that could potentially be improved and what policy options for improvement would look like has also been included. Consequentially, this section is broken into three components.

1. Challenges due to lack of a centralised governance structure for the overall crisis response,
2. Challenges associated with the use of data for Emergency Coordination and Response,
3. Challenges due to an ill-defined common European strategy on how to collect data.

Challenges are measurable only in relative terms, in this case to a certain aim or target. Regarding emergency coordination and response to a cross-border serious threat to human health such target is to protect human health and public health more concretely as emerging from Article 168 of the Treaty on the Functioning of the European Union (TFEU). For each of these challengues a set of premilinary policy options is proposed.

Perhaps the first challenge is the interpretation of the role of the EU institutions and that of member states with regards to the Lisbon Treaties, as that seems to determine a significant degree of institutional "hesitation", but also, lack of clear reporting/abiding duties. Findings from interviews with MS as well as EC did not, however, show that such legal barriers seem to be a significant deterrent to data being made available at the onset of the crisis. However, they were considered relevant to account for a lower level of response to ECDC, the level of preparedness initiatives, and regular (inter-critical) data gathering processes. Under the TFEU, public health is a policy area where the Union supports, complements, or supplements the actions of the Member States (Article 6 TFEU). However, the "problem" arises as common safety concerns in public health matters are an area where competence is shared between the Union and the Member States (Article 4 TFEU). The dual nature of the competences, in public health, is reflected in the different types of measures that the EU can take under article 168 TFEU:

1. On the one hand the EU may adopt harmonisation measures setting high standards of quality and safety for organs, substances of human origins and medicinal products and

devices, and also adopt protective measures in the sanitary and phytosanitary fields [art. 168 (4) TFEU];
2. On the other hand, the EU may also adopt incentive measures in other matters pertaining to the protection and improvement of human health, i.e. for combating major cross-border health scourges, monitoring, early warning of and combating serious threats to health as well as measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol. Nonetheless, the harmonisation of national laws and regulations is excluded in these fields [art. 168 (5) TFEU];
3. Finally, the EU can encourage and support cooperation between the Member States in Public Health through the open method of coordination [art. 168 (2) TFEU].

The EU Treaties acknowledge that Member States remain responsible for the definition of their health policy and the organisation and delivery of health services and medical care, including the management of health services, medical care and the allocation of resources assigned to them. Findings show this means a significant heterogeneity in the data gathering processes regarding communicable diseases even though the list of those that are subject to compulsory reporting is quite similar across MS. The variation is in format (paper, online formularies, partially or fully embedded Electronic Health Record (EHR) solutions) but also, in clinical detail, processes of care, and when relevant, laboratory work and consequentially laboratory data and in other non-clinical data. Finally case definitions vary, and in the case of COVID-19, interviewees agreed that these case definition variation was so frequent and heterogeneous that it conditioned effective use of information systems at times, and even the capacity of clinicians to adjust and capture relevant data.

The way the TFEU can be interpreted regarding high-level public health matters does bring about two fundamental questions for this study:

1. Is "data harmonization" at member states level excluded from the treaty, by way of [art. 168 (5) TFEU] or, accepting that such is, or can become, critical to the attainment of high levels of protection from public health threats, under a broader interpretation of the TFEU, then data harmonization is acceptable. If so, as public health is a policy area where the Union supports, complements or supplements the actions of the Member States (Article 6 TFEU) and MS cannot, without the Union, harmonize such data, such would establish legal footing for that harmonization.
2. Decision-making as a process in public health – and in public health cross-border crisis in particular – can result in decisions with an EU-wide range of application. In other words, are these decisions, or are some of them, capable of being directly applicable in Member States legal order, as regulations are, or, are they more like directives which are to be "transposed" to MS legal orders. The first would then mean the restriction of certain contradicting decisions by individual MS themselves.

While these may seem high-level discussions, they are directly linked to the issues at hand, and bear significant weight in pondering policy options available. The role of the European Commission seems at times inconsistent and hesitant, much because this dialectic clarification may have inhibited concrete action. For example, if the ECDC does not receive information from a particular MS, it has no legal instrument to demand such information. Likewise, if the quality of the data is not good enough, there is no instrument to impose a harmonization of data collection processes or the procedures associated with it. This has meant that systematic problems with heterogeneous public

health data have been identified as a challenge and a barrier to robust health indicators (even at aggregated level). In addition, significant semantic differences, and then epidemiological differences as a result of national interpretations of data elements to send over to EU institutions. This was often referred in findings, and clearly not an issue in places like Hong Kong, Singapore or South Korea, leading these respective geographies with high quality data, of daily or hourly freshness to be the basis for fast and effective public health policies and decisions.

In summary, **there is NO comprehensive health data Governance at the EU level**, and very few MS could be said to have one at the National level as well. This impacts severely any holistic thinking of data usage and information systems. In a way, this is the first main element blocking the conceptualization of an "EU Data Centre" or "establishing a common European strategy on how to collect data". This is, on the other hand, **an opportunity for policy making at the EU level. First, because an EU and MS health data governance does not necessarily imply a conflict with the treaties**, rather it may require a legal clarification and a positive law solution. Second, because **in todays' world, with learnings from COVID-19 pandemics and foresight into larger, possibly hybrid, cross-border threats, all data may be needed to prevent, perceive, detect, alert, respond and recover**. Even with such an holistic and encompassing view of data usage, MS freedom and responsibility for organizing their health systems may not be disturbed in as much as needed for public health safety, a responsibility which they also have, and that increasingly can only be met in multilateral work, even in inter-critical periods.

3.1.1. Challenges due to the lack of a centralised governance structure for the overall crisis response

Building on scholarly work (4,16) and findings of the European Court of Auditors (ECA) (28), in a necessarily brief overview of challenges due to the lack of a more centralized EU level governance structure dealing with the pandemic crisis several can be listed. Some more salient in the beginning of the pandemic but many persist one year later. These are:

3. **No clear leadership**. When there is no centralized governance structure for emergency coordination and response, it is not possible to know, without a doubt, what official body, and ultimately what face – who – is leading. Vast management and leadership literature points univocally for the need of a strong and clear leadership and line of command especially in crisis . It is evident that the first challenge that arises from the lack of a centralized governance is that no one takes the (hard) role of being the leader during the crisis. In concrete terms, this results in some of the following gaps/challenges.
4. **Different priorities**. At times there was a sort of leadership competition on who was the best MS leader with regards to the response and measures in his/her MS.
5. **Conflicting decisions**. Such often can result in a worst-off outcome. This is explained by Game Theory in its typical prisoners dilemma (29). Both players make suboptimal choices with the fear that the counterpart choices may endanger their results, therefore both achieve a less than ideal result for both that would be avoided if there was effective coordination and decision. The EC in public health, and in the health area in general, has played a coordination role, for example, chairing a meeting like the ones of the Health Security Council (HSC). However, many times it is necessary to decide A or B or propose a solution. Coordination alone is not enough. This cannot depend always on meetings and voting; otherwise a coherent steering of the crisis may not come as a logical result of a series of vote-based micro-management decisions.

6. **Absence of an identifiable "unified" approach**. The lack of a plan for responding to the crisis potentially impacts many decisions on the response and recover phases but also regarding the use of data and information for sense-making and decision making.
7. **New methods of looking and studying existing data and information.** While examples of new work on exploring EU level data was conducted by the JRC "crisis taskforce" and DG DIGIT helped supply clould digital services and experts to mature some new data exploration these were mostly ah-hoc, research-led initiatives with few policy guidance links and consequences.
8. **Challenging existing feedback loop information** by demanding and deciding in the obtainance of new data and information, from the same or new sources. New ways/approaches to dealing with the crisis that can be seen to complement the ongoing strategy because, that is not made obvious;
9. **Joining, in a logical way, the key communication elements**: decisions, their rational and the arguments for their defence. Avoiding disperse, erratic, and ineffective communication. Messages to citizens in the EU need to be more and more "*about one same thing*", this means considering three relevant modern trends:
10. **Tackle the fact that citizens get information from multiple international sources**. They get it from "their" home country but also from other countries. One good example: what to do during Christmas Eve? In some countries, with the "same data/epidemiological status" some citizens could, and others could not go and visit their family members. In some, the maximum number "at dinner table" was six in others it was eight or the "nuclear family" or the "enlarged nuclear family". This erodes authority, not just of national public health "authorities", but that of the EU as a collective political entity.
11. **Communication is increasingly more direct**. Large companies like Facebook® or Google®, "contact" more humans directly that those who live in the EU. They send a clear univocal email. As an EU citizen I have not received one single email from the EC about COVID-19. Not even as a registered EC portal user. While privacy concerns are always useful and handy to justify this inertia, the reality is: there are more than 27 contact tracing apps, none of which is from the EC, this could be a way to communicate to citizens. There are multiple informational websites from as many as 27 public health "authorities", as if the main elements of dealing with COVID-19 were not the same, as if the virus was Belgian, Greek or Finnish.
12. **Communication with citizens is bidirectional and digital**. This means it is a source of very relevant data per se. Using sentiment analysis, natural language processing (NLP) for AI analysis of text or other technologies and methodologies can produce valuable insights. Such allows better tailoring of messages, especially on how to communicate the ratio of certain decisions but also the arguments supporting those decisions. Communicational data, and response feedback, can both be useful for monitoring, and surveillance of reactions (for example to Vaccines), of new concerns (post-Covid-19 syndrome).
13. **No clear anticipatory strategy for next phase preparedness**. Leaders and good governance "anticipate". In a "response" to a crisis the first line is anticipatory action. This entails: overall prevention of the crisis, or effective containment/mitigation in small scale. Yet this does not terminate the need for anticipating next "steps"/elements of the ongoing crisis. With COVID-19 pandemic, the "second wave" was identified as an issue as early as April. There would have been benefits to a well-organized, dedicated, governance structure to

monitor MS preparedness for that phase, and well before the September/October EC and Council positions.

14. **No clear list of strategic questions**. To make meaningful and purposeful use of data, particularly when considering the use of AI-based analytics, a good set of questions and the priority ranking of their importance and timeliness is key. Such are questions to be answered by data (existing or to be quickly sourced) by a given date/moment and expected from a set of sources. This allows the usage of data utilization permits, legal and ethical processes to be processed in an expedite manner.
15. **Need for high level patronage**. The EC, the Council and the European Parliament cannot continuously improvise the support to a varying-geometry body coordinating the response. If a centralized governance structure – a sort of EU Public Health "Authority" – existed, the three main institutions of the UE would previously or at worst in an *ad-hoc* manner have established a "stable" relationship with such structure and made that authoritative linkage "visible to Europeans". This is key, to ensure the democratic and rule of law link between the decisions outputted by such governance structure and citizens of all the EU. This is as critical during the crisis, as in its aftermath, inter-crisis periods and preparatory stages for a next crisis, which may not take that many years to materialize.

It would follow that a "truly centralized" governance structure for dealing with these types of crisis is needed. Just a structure for "governance of data and how it helps emergency coordination and response" but for the "governance of the overall EU-level response". Without the last, the first is more difficult apprehend. On the other hand, if no "centralized governance of the overall EU-level response" is envisioned or possible to be conceived then, have disperse "high level decision makers" EU runs a lesser risk of dispersion and contradiction, if indeed it has a "centralized command" at least at the level of data aggregation, use and analysis during an emergency or in preparation for one.

3.1.2. A reflection on a "more effective EU level broad governance of public health crises"

A centralised governance structure in a crisis must have the capacity to use data very effectively and make data-supported public health policy proposals and inform political decisions. Such public health centralized governance structure may have role in "the actual governance" of the actions the EU needs to see taken for controlling of a serious cross-border threat. This element depends on how the political arrangement and agreement can be created (before a crisis) on the role of a public health EU-level authority. It is relevant to note, however, that power is something that can only be fully appreciated when and upon its exertion. The current crisis has shown that in many MS the formal outlines of what could have been expected as the role of "national public health authorities" and "science-based health policy" was very often highjacked by political decisions(16). This happened in MS with a variety of institutional outlines and institutional power interrelations. It is naïve to assume an EU public health authority, even if such was to exist, would not encounter similar issues. Nevertheless, it is safe to say that this "centralized governance structure" would more likely need to be a combination of the following elements:

1. Pre-established legal frame and terms of reference for meetings and decision-making timings.
2. So called "emergency law", a set of rules and legal definitions that enter into force upon pre-existing legal order as a set of triggers and mechanisms have been activated.
3. Legal and operational rules for compensation action. With a centralized governance structure, significant unintended consequences can arise from large scale implementation of, naturally fast and insufficiently matured decisions. Legal and operational countermeasures need to be possible and not depend on the ordinary legal proceedings of the EU institutions. Such repair function introduces a system of compensation that allows more audacious early on decisions to be taken, as decision makers, both political and public health related, known that, to a certain extent they have equally fast mechanism to recalibrate and mitigate possible side-effects.
4. A institutional "decision making cockpit" needs to exist. It is questionable if it would require a change to the Lisbon treaties. It should include four basic elements:
    a. A public Health collective decision-making body (27 MS+ECDC)
    b. Participation of the EC (DG SANTE; EMA; "and any other new dedicated agencies")
    c. European council (direct representatives from MS leaders, which means their ministers of health, or a minister appointed for this function)
    d. The appointment of an EU spokesperson (rather then, or in articulation with, the 27 MS leaders, president of the EC and the president of the European Council)
5. Finally, direct citizen participation via relevant stakeholders is very important for trust building. This would serve as pressure valve and legitimization functions. If a centralized "powerhouse" is conceived, a balancing power needs to be ensured, here the European Parliament could have a role[22], namely for example via:
6. The activation of "emergency" MEPs committees which have been predefined regarding the need for: acting new emergency legislation, counterbalancing legislation, and emergency reflection, is, *inter alia*, possibly desirable, and to many extents extraordinary activity did happen in current pandemic, which serves as inspiration.
7. Creation of an emergency representational function, with the capacity to listen, collect and identify relevant societal voices and pressure elements, channelling this more adequately to the core decision making of the centralized governance structure. This societal buffer and sensing function may prove essential to up-hold emerging human rights tensions as the crisis prolongs from months to years and ensure trust by citizens the EU rule of law. Such breach in the "democratic contract" has been identified as a underlying issue and raising

BOX OF LEGAL IDEAS OUTSIDE THE BOX

New form for emergency law clauses. As often the problem is delayed activation of emergency decision-making mechanisms. This can be partially solved by inverting the paradigm of "exceptionality law". A possible solution is to have a legal provision of "permanent emergency", which is "held back" by a regular (ever 2 weeks for example) confirmation of a state of no existence of a cross-border public-health threat. This means that at regular intervals the system has to "proactively search for evidence" of no signs of alert or rising risk or established national level crisis with a significant probability of becoming a serious cross-border threat.

[22] This study did aim to include a detailed research into the European Parliament response to the pandemic crisis, its actions, and reactions.

tension in later months of the pandemic, and an aspect that some scholars believe then led to representational and power equilibrium consequences after the emergency nature of the pandemic is no longer accepted by large sectors of European liberal democracies (14).

3.1.3. Preliminary options 1

The functions necessary for a more effective EU level broad governance of public health crisis do not seem to be secured by the current arrangement of EC, EU-level independent agencies, in conjunction with MS via the Health Security Council (HSC) and European Council. This assemblage is just not centralized enough. The day-to-day decisions and management of COVID-19 showed this clearly. A centralized governance structure operating as a sort of cockpit function would be beneficial. It would nevertheless rest on a complex high-level set of aggregator sub-leadership intelligence hubs (ECDC, DG SANTE, EC president Cabinet, ERCC etc). Four preliminary options can be outlined:

1. Do nothing scenario: Maintain existing "governance" agreements under the current Regulations (for dealing with serious cross-border threats to human health; and on the establishment of the ECDC).
2. Approve, with some changes, the proposals by the EC under the pack "European Health Union". Changes to better clarify some of the "leadership functions" outlined could reinforce a more unified approach hence strengthening a steering function during a crisis.
3. Approve, with changes, the proposals by the EC under the pack "European Health Union" and explore the idea of the HERA agency, taking a "all-of-health" perspective rather than focusing on emergency response and medical countermeasures response.
4. European Public Health Authority. With full-fledged powers to be activated under certain conditions and in strict articulation with the president of the EC and the president of the Council.

3.1.4. Challenges associated with the use of data for emergency coordination and response

Findings on gaps and challenges when sharing data at the EU level in health emergencies in terms of the quality, consistency and comparability of data, methodologies and protocols were obtained from interviews with national level experts and interviewees from authorities responsible to send data, the ECDC itself, EU level functions (the EC, JRC) and non-officials.

In general, consensus could be said to orbit around a set of point of a clearly very heterogenous landscape, characterized by the following observations:

1. Several MS have different reporting systems, based on Information Technology (IT) tools or more or less relying on paper. In the words of one interviewee: "there are as many systems, formats, case definitions, sets of national and regional data, as there are MS in the EU". Some interviewees also pointed out to the need to quickly adjust or even implement digital or more digitally advanced reporting systems. IT tools in public health administrations were either obsolete, non-existent, or inadequate to the volume of the cases to be reported and the details being asked by the ECDC and the EC in the first few months were greatly enlarged.
2. Criteria for quality and data consistency are practically non-existent at the EU level and even at the Member State level, the consistency and effectiveness of data quality

verification processes is poorly known. Data consistency is reported as missing in many MS, particularly in those that had the "courage" to provide extensive access and open access to data to academia. Even the JRC refers to poor quality of data as a major challenge, and certainly one that their *a posteriori* positioning cannot solve. Criticism to the non-binding nature of guidelines from ECDC and even JRC came more from public health specialists than from MS representatives although some of these actually acknowledged that a stronger "EU mandated" requirements could have had an impact in preparedness and the base-line capacity to collect data that may be relevant to public health.

3. Comparability of data between regions and MS is practically non-existent for two sets of reasons: i. the lack of capacity to change data capture processes and methodologies as the crisis settles due to inexistence of definitions and clear technical specifications and interpretation rules defined *a priori*; ii. the inability of the ECDC to impose on MS authorities hence inconsistent data reporting continues.
4. Scattered methodologies, based on national interpretations of scientific advice and even WHO recommendations/guidance, are not harmonized as MS do not recognize any authority in the EU for establishing binding rules on methodologies. For example, counting individuals deceased due to COVID-19, or common criteria for accessing the need for "admission to intensive care".
5. EU-level protocols are non-existent for many relevant healthcare processes that result in data outputs, except for "protocol proposals" by some European medical and scientific societies. ECDC recommendations, which in some cases could establish common protocols, have again a "recommendation" status, limiting severely their effectiveness.

These aspects have resulted in a traditionally low capacity at EU level to work with detailed datasets as not all countries can provide data with such granularity, but also as capacity in ECDC, JRC and particularly DG SANTE has been limited by staff and budget constraints. Where this was not the case the often voluntary and optional nature of the relationship with MS data sources meant patchy data sets have been made available. Finally, EU level aggregation platforms for the most part were not designed to receive real-time data (sent with a frequency of seconds or maximum 5 min refresh intervals) nor even near real (1h refresh intervals).

A working definition of "public health data"

Another element that become obvious from the different sources studied and findings from interviewees was that the interpretation of health data, public health data, and data that could/would otherwise have been useful for dealing with a public health crisis such as the COVID-19 pandemic was by no means the same. If anything, it was quite different. Perhaps the exception was the apparently well established divide between data on Communicable and Non-Communicable diseases where there was not conceptual disagreement but was again a quite relevant separation about whether, and to what extent, data about non-communicable diseases health status was useful and necessary in dealing with a cross-border public health threat. The following broad types of public health data should be considered:

1. Data on Communicable Diseases (DCD)
2. Data on Non-Communicable Diseases (DNCD)
3. Data about the Health System (DHS)

4. Data with a public health relevance (DPHR), which means non-health data with the potential to be relevant for public health functions

The lack of consensus or even awareness of the usefulness of these different types of public health data, as well as, the fact that they are to be obtained from multiple local, regional, and national actors, is clearly a challenge. A more harmonized interpretation preferably sanctioned by EU-level institutions would have facilitated their collection and eventually contributed to their utilization at European level.

3.1.5. A Capacity to use the data at EU level – Centralised governance structure

The capacity to use public health data collected from MS at an European level was considered as limited by the fact that different EU agencies and services hold different datasets, networks of MS representatives, and interpretations of how health data can be exploited. Also, between themselves sharing and joint exploration of all possible data analysis opportunities has not been fully realized.
If we consider the utilization of health data at the EU level for better dealing with cross-border health treats, a centralized governance structure needs to ensure, *inter alia*, that:

1. Good data collection methods, flux, and consistency, for example:
2. Data is obtained with a minimum effort loaded onto busy field workers, including the data elements of new case description.
3. Quality of data, and data collection processes are the least intrusive on healthcare.
4. Data on non-(new disease) cases continues to be captured.
5. Data on real time health systems capacity (e.g. hospital beds, critical equipment).
6. Data collected flows through a sustainable and scalable data pipeline from local/hospital systems to regional, national, and European levels.
7. That such "data pipelines" have been created inside MS, both from an organizational as well as technical interoperability perspective, have been tested in preparedness exercises, are secured by sufficient and skilled workforce, legal and funding basis.
8. There are clear data "aggregation", "anonymization", "tokenization" and "curation" processes and points previously defined for these.
9. Analytics is run on data from anonymous or identifiable sources, or even in direct interactions between EU-structure and individuals, upon clearance of legal and ethical requirements.
10. Data can be used for modelling during the crisis, but perhaps more importantly for anticipating trends, predicting public health threats or their early evolution path and foresight complications (for example the emergence of a virus variant strain).
11. Mix and use in multiple hybrid analysis data from health sector, and traditional public health datasets, with non-health data with a public health relevance (DPHR). For example: (i) mobility data, (ii) air traffic data, or (iii) public space utilization data.

3.1.6. Preliminary options 2

The study request suggests a focus on a EU Health data Centre, as a centralized structure dedicated to "temporarily" using health data to better coordinate and respond to public health crisis. However, at this stage I would argue it is beneficial to explore at least the temporary *versus* permanent aspects of such a centralized structure. Whether this structure is "located" at the ECDC, in its current capacity and structure, or under its future (28) configuration, or even in any other institutional home existing

or to be created (for example, HERA) is also an aspect to be dealt with in section 4. So as preliminary options I propose the following four should be considered:

1. Do nothing scenario: Maintain existing "governance", where the collective of EC services /Agencies poll their capacity in an *ah-hoc* manner as the crisis unfolds, with varying degrees of effectiveness and definitely no anticipatory joint efforts, particularly when addressing MS needs, challenges and results regarding data collection. Low capacity for advanced data exploration.
2. The centralized governance structure as a temporary function performed by the ECDC.
3. Devise a full-fledged central governance structure that sits on top of all relevant EU health public health data stakeholders to coordinate and govern temporarily the use of such data for better dealing with a serious cross-border threat.
4. Devise a full-fledged central governance structure as an independent EU agency (an "European Health Data Agency"- EHDA) or as core part of one (ECDC or HERA) that relates with relevant EU public health data stakeholders to coordinate and govern in a more permanent way the use of such data for better dealing with a serious cross-border threat.

3.1.7. Challenges due to an ill-defined common European strategy on how to collect data

There is no such thing as an ill-defined common strategy. Simply because there is no common European strategy on how to collect health data. What are the elements and foundational tenets for such a strategy is the object of section 6, so for now we will focus on identifying what challenges arise from the absence of such a strategy, or the ill-functioning of the existing eco-system of data collection and processing in public health emergencies. For this eco-system to be characterized it needs to first be delineated into its actors and the data types in question.

It can be sustain that it is not beneficial to discriminate whether the eco-system of data for public health is "particular" or whether all four types of data previously outlined can actually be useful and that it makes sense to actually have them all collected in one way or another, continuously or on demand under certain temporary criteria. The last concept could be called temporal or temporary search or contextual health data collection.

There are some characteristics in the eco-system of data collection and processing in public health emergencies, that have been emerging and move the topic away from the traditional public health data pipeline very centred on reporting cases, indexing contacts and identifying epidemiological links and other data about disease evolution in a population. Some of these emerging characteristics are also present challenges as local, regional, national, and even European systems have not been designed to capture data under these paradigms. For example:

1. Different and "new" sources of "non-health" data. These not traditionally considered sources of public health relevant data are increasingly more important and available. For example, projects using data from smart cities projects or open data from municipalities were supported by DG DIGIT services and shown to be useful in studying the compliance to lockdown measures for example. Another example has been the usefulness of data from mobile phone companies (30) as well as transportation authorities to understand movement of collective groups of people.
2. Heterogeneity of health data sources. This element has been described regarding the lack of harmonization and associated data quality. Here the issue is that the sources and supports

are themselves very heterogenous as health sector organizations still face different degrees of digitalization in and between member states.

3. Limitations to personal data associations. In a mix result from lack of digital media, lack of robust digital identification and privacy preserving culture by isolation and silo creation, in most MS, it is very difficult if not at all impossible to "create" a "digital health twin" for each person based on his/her health data. While profiling is not only limited by GDPR as well as most national data protection regimes, in a somehow partial form, it could be relevant to assert real risk pattens of both individuals but also of communities.

Identify the main actors involved in the eco-system of data collection and processing in public health emergencies

Regarding the main actors involved it is very important to list them in order to identify the challenges and later to outline a possible strategy. A common European Strategy on health data collection is about who to engage, and how one may legally and technically want to connect them and the data under their control. The main actors involved (as data producers, consumers, or both) are:

1. At the international level (WHO, OECD, third countries, namely neighbouring countries)
2. At the EU level
3. EC (different DGs are involved, namely: DG SANTE; DG DIGIT, and the ERCC) as well as the ECDC; EMA; JRC
4. The European Council
5. The European Parliament
6. At the National level (Governments; National Parliaments; Ministries of Health; Ministries in charge of border control, internal administration (law enforcement); Public Health Authorities; Reference Laboratories; eHealth/digital health agencies; Emergency/Civil protection; National drug agencies; Media)
7. At regional or local and institutional level (Regional health authorities; Municipalities; Hospitals; Primary care facilities and other small Healthcare Providers; Pharmacies; Laboratories/testing centres; Local public health units)

3.1.8. Absence of a common European strategy and MS high health data/information heterogeneity

The absence of a well-defined common European strategy on how to collect data, or at best the existence of an ill-defined strategy is the current reality. The work carried out by projects such as Bridge Health highlighted significant problems in MS, limiting the quality and availability of health data ready to be collected. Particularly relevant are some of the infrastructure, governance and communication ones cited in this project:

> *"Many barriers related to infrastructures, governance and communication within and between institutions were mentioned as obstacles for building health information systems. They were also seen to interact with the challenges of the 3 domains mentioned above, since lack of political will and policies, the complexity of data protection and privacy regulations and lack of knowledge are particularly detrimental when infrastructure and governance are poor. Further, it was mentioned that in some countries, the parallel development of a national and a private healthcare system also hinders the collection of national and comparable data. The specific barriers raised by respondents included:*
>
> *– The absence of sustainable infrastructure (and funding).*
>
> *– Regional and local governance of health databases, thereby making collection of national level data challenging.*

– The expense of creating new health information systems or adding items to existing health systems

– An absence of optimal linkage between data sources.

– No established health information administrative structures that provide coordination between institutions or take charge of using data for surveillance.

– Difficulties communicating between different administrations that are responsible for health information and policy.

– Lack of explicit policy on secondary use of data, consequently leading to minimal translation into long-term investment.

– Budgetary constraints heading money to different priorities other than health information.

– Absence of public accountability and evaluation for improvement of existing HI systems. This creates a vacuum in which inefficient and unproductive systems continue to operate.

– The need for multidisciplinary input, as there needs to be necessarily clinical, statistical and technological expertise involved"

For many years MS and DG SANTE have had meetings, working groups, and EC-funded projects, and there is not, at present, any clear agreements on an overarching health data strategy for relevant public health data. The first observation worthy of note is that this would encompass different types of data, and different EU-level actors (DG SANTE, ECDC, EUROSTAT, EMA). Such as been extensively pointed out by the Expert Group on Health Information (EGHI), the current joint action Inf-Act has explored some of the impacts and possible ways forward, in a sequence of more than a decade of ongoing reflection and building common-ground. The main argument of this group of MS experts (some of them representing MS authorities) is that a central health statistics and public health data unit should exist. Problems of indicators definitions, open issues on what is relevant data to be collected and how to process it remain. Capacity both human and technological at national and EU level has been identified as a salient problems. Interestingly, the "main" issue identified by these groups is the inability to make final decisions, "determine", and dictate/regulate health data collection. On the other hand, the data and health indicators that concern the EGHI, are traditionally aggregated data elements, population surveys, normally on non-communicable disease or other public health data/indicators. This is in a stark contrast to ECDC requested information on case reports, often individually (anonymously), and focussing on communicable diseases. Data on medicines use and adverse drug reactions, tends to be collected on a "voluntary" doctor/nurses or patient basis, and centralized in EMA. Lastly, vaccination coverages tend to be reported as aggregated indicators, with no standardized cross-EU methods, over to a different unit within DG SANTE.

Different "sets" of "public health" data are being collected by different routes from local to national and then to EU level. Here, these data sets often remain siloed in different EC DG units and Agencies, depending on interpreted competences and historical reasons. Such data may be in different data centres, servers and under the control of different teams with no one having a "map" of where and what data is with whom and for what purpose exactly – what is commonly known as an Enterprise Architecture blueprint. There is no well-defined or ill-defined common European Strategy on how to collect data. Simply there is NO strategy which could be considered "common" on data collection.

3.1.9. Preliminary options 3

As the EU discusses the recently proposed "Data Governance Act" (8), and has a scheduled legal discussion on the European Health Data Space, it is worth mentioning that both can be legal umbrellas for a "Health (public Health) data governance act" only if, there is a wider understanding of its complexities and necessities as subsequent legislation. Alternative policy option is to have a standalone, albeit articulated, legal and organizational stream dedicated only to "health data"

understood in a broad sense and not in a narrow, classical public health perspective. It follows that regarding a policy solution to the present absence of a common European strategy on data collection four preliminary options can be anticipated:

1. Do nothing scenario,
2. Frame such strategy under the umbrella of the Data Governance Act,
3. Frame such strategy under the umbrella of the European Health Data Space,
4. Develop a Health (public Health) data governance act as a basis for a sustainable strategy

Regarding 2. and 3. it is just relevant to consider that the current proposals (2.) and the ongoing discussions and envisioned perspectives (3.) do not go to the detail, and authoritative stance, required to full-fill the aforementioned criteria and elements. Option number 4. would entail a long, warm, but potentially very clarifying debate, not just about health data, but about the healthcare results and outcomes in the Union. Such is a worthwhile debate. ***A strategy without an operational leader or organizational backdrop is no more than a policy and likely to product limited tangible outcomes***. Hence preliminary options here need to be analysed taking into consideration what structures exist or any new EU structure, which would take up as its mission to follow, detail and renew such a strategy looking forward.

3.2. Brief review of the EU legal and regulatory framework in the fields of data collection/exchange, testing/reporting methodologies and public health.

The current health security arrangements, as established by Decision No 1082/2013/EU on serious cross-border threats to health, provide a limited legal framework for EU level coordination, based essentially on the Early Warning and Response System (EWRS) and the exchange of information and cooperation within the Health Security Committee. This is the result of a slow, but incremental effort of the Union to defend its MS from serious cross-border threats. A non-exhaustive list (shown in Figure 1) highlights the following elements:

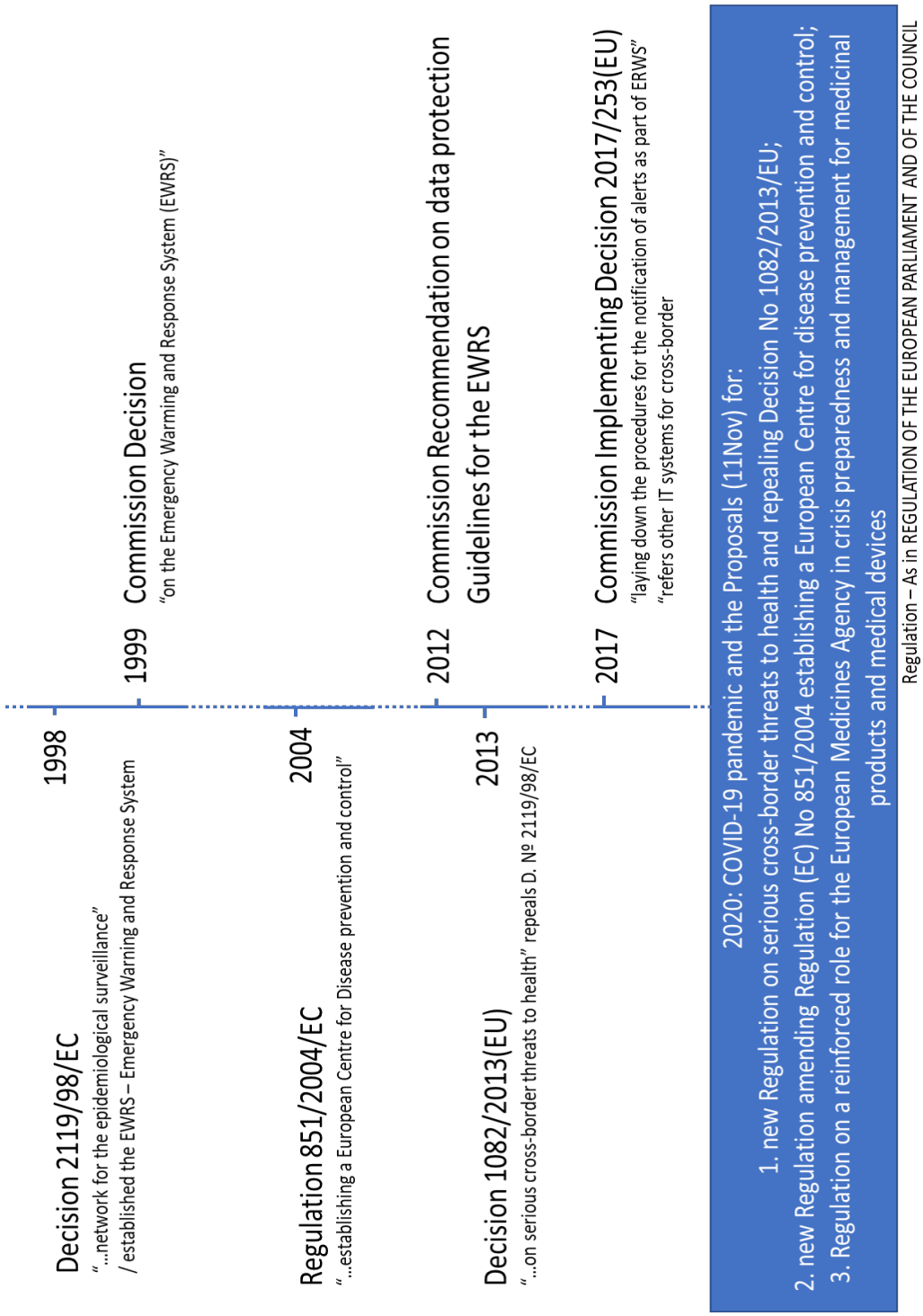
1. Impulses seemed linked to major crisis: "Mad-cows disease" Crisis – decision 2119/98/EC; H1N1 flu pandemic – decision 1082/2013/EU; and, COVID-19 – Decision(proposal) COM (2020) 727 final;
2. Addition of elements, increased number of "systems" and processes, progressive but delayed/not detained enough usage of information technology;
3. Reduction of "adhocism", "voluntarism", and increasing of obligations to MS;
4. Usage of technical experts to corroborate decisions that are in many ways political;
5. No, or limited, regime for the "inter-critical" periods, until the current proposal.

In addition to this legal block, another EU Directive worth mentioning, as it marks the first legal instrument relating to national level health services regulating aspects of cross-border healthcare, is the Directive 2011/24/EU. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between MS, in full respect of national competencies in organising and delivering healthcare (Article 1(1)), and apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed (Article 1(2)). This means the EU legislator, created a mechanism to ensure the provision of healthcare to moving patients, even though it had to respect the subsidiarity principle. In so doing the directive, *inter alias*, ensures the reimbursement of healthcare, mutual recognition of medical prescriptions and sets the scene for eHealth services, namely patient summary, electronic prescription and a common health information systems interoperability agenda. All of these have the potential to be highly useful for surveillance systems. Member States are obliged, or have self-

committed for most non-communicable diseases, to provide data, mostly by self-reporting mechanisms (sometimes disease specific, and requiring manual input) or sending files to many EU and international Institutions, namely to EU agencies and the European Commission, such as Eurostat, European Centre for Disease Prevention and Control (ECDC) or the Joint Research Centre (JRC), and to other international organisations, such as the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation Regional Office for Europe (WHO-EUR). In the case of reporting to ECDC the TESSy system and platform[23] is an obligatory tool, yet in practice delays are significant, inconsistency frequent and no effective enforcement mechanism is available to the ECDC for improvement of MS compliance.

[23] TESSy platform - https://www.ecdc.europa.eu/en/publications-data/european-surveillance-system-tessy

Figure 1 – Non-exhaustive chronological representation of the major EU Law marks in EU Emergency response to serious cross-border threats to human health.



Bridge Health project found[24] that two key issues inhibit the availability and use of health information from MS for research and policy-making (including public health policy):

1. Gathered evidence and knowledge is dispersed, incomplete and difficult to access,
2. Large differences can be found in terms of quality and, as a consequence, comparability of health information between and within EU countries.

Following from a set of EU funded projects the same consortium proposed the creation of an alternative structure to collect relevant populational health data. It suggested "the creation of a European Research Infrastructure Consortium (ERIC) to collect, process, analyse, report, and communicate health information can overcome these obstacles and can facilitate the governance of health information activities in the EU to allow comparative descriptive analyses and to facilitate research for multi-level policy use and targeted investments". This gained significant support from a few member states but not materialized in 2018. A decision to continue the reflection and conceptualization was made by the EC by advancing a Joint Action on Health Information. The proposal for an ERIC was a second alternative on a option study realised at the time and put forward to the EGHI, at the time the creation of any new agency was "unacceptable". Now, however, once HERA proposal is a political reality, this "tabu" is no longer true, and hence it opens the door to exploring the idea of a "centralizing health data agency" that could cater for the four sets of data/health information.

Lastly, and particularly relevant for most biologically related cross-border threats is a particular subtype of data - Laboratory data. There is no EU-wide system for sharing laboratory data. There are reference laboratories in the JRC, yet it has no mandate to standardize and harmonize neither the laboratory methods nor the way laboratory data must be communicated within the EU. These facts were referred as significantly limiting EU capacity to know and learn from quite rich and relatively easier to collect laboratory datasets when compared with EHR data or epidemiological and community public health data.

3.3. Assessment of the adequacy of the existing EU institutional structures to provide a common European Health Data Space (EHDS) and a coordinating structure for emergency responses

An assessment of the adequacy of EU institutional structures calls for a better understanding of (i.) how the EHDS, under current discussion, may relate with public health data needs, and (ii.) what is our working concept of a "coordinating structure for emergency responses". If this is a temporary central structure focussing on public health relevant data aggregation, utilization, and exploration to support coordination and emergency responses or a permanent structure with the same purpose. In short: What is the EU health data centre? Once these have been clarified it is possible to address the question of ***whether the current EU institutional structures are adequate for providing the two elements described***.

3.3.1. How the EHDS may relate with public health data needs

Regarding the EHDS, and to elucidate existing structures adequacy, we need to look into:

a. the "elements" that could characterize such space,
b. its essential features,

[24] For the full report and proposal for an ERIC please see: Technical_and_Scientific_Description_HIREP-ERIC_final_draft.pdf (bridge-health.eu)

c. and then how it could or not sustain and support public health needs, in particular those relating to emergency situations.

Then, we need to see how institutional structures can or cannot provide for a "meaningful and useful EHDS" for serious cross-border threats to human health.

The ongoing discussions on the EHDS have started in November 2019, mostly propelled by DG SANTE, in the context of a broader discussion on the European Data Space (led by DG CONNECT) of which the EHDS is to form part. The first palpable outcome of the efforts on the European Data Space is the recent EC proposal on a European Data Governance Act, but this is not laying the foundations of the space, how the commission services/agencies organize to provide the digital services needed nor does it clearly sets out a governance structure with the detail needed to curl up the gaps and problems already identified with health data collection.

Additionally, the EC launched a two years joint action – TEHDAS Joint Action[25] –, started on January 2021 to explore and propose the different dimensions of the EHDS proposal and early set up. So far discussions have centred on the distributed nature of the proposed architecture, there has have been no clear governance decisions, except that perhaps MS would relate to the EHDS via data permit authorities. Discussions have shown that MS themselves do not have a clear data aggregation strategy/architecture nor, in most cases, a holistic health data governance, with more than one representing institution having siloed access to parts of the health data ecosystem. The EC is planning to propose legislation to Parliament and the Council in the 4th quarter of 2021 specifically on the EHDS. The extent to which such legislation will set the foundations for concrete definitions lacking in health data (as explained extensively before) is unknown. It can regulate this at mainly two levels, the second of which with significant impact on MS health data interoperability:

6. at a superficial level (somehow stopping at "the door of MS" focussing on the cross-border use and aggregated data use of anonymized datasets), or
7. at a deeper level, entering into national level definitions, insofar as needed for data quality and comparability to be possible. This could provide invaluable to solve the many issues associate with poor harmonization of health data collectable from MS.

If the first level is chosen existing structures are likely to be sufficient particularly if DG DIGIT and or JRC are made technically much more robust, and if DG SANTE has a Unit dedicated to being the governance hub for the EHDS from a policy and public health programmatic perspectives. The ECDC, as a "element" using such space would be in a somehow fragile position, particularly if its mission changes for the new roles and expectations that the proposed regulation anticipates. In this case, the existing structures are possibly adequate, but the resulting EHDS may not significantly add value to the Public Health data ecosystem critical for Emergency Response. If a deeper level approach is followed, significant initial resistance is to be anticipated and needs to be overcamo, this falls under the scope of the more ambitious policy options presented before. In this case, data quality, consistency, reporting, methodologies and protocols may find themselves object of such extensive legal act, and the resulting governance will be able to mould the necessary systems processes and people over time, to ensure the data consistency and breath that is needed (as COVID-19 pandemic showed) to deal with a crisis, at least as big and complex, as the current one. In this case, legislation will need to be followed by institutional reforms to accompany this data modernization in (public) health option. Such ***reforms would need to guarantee that a set of capabilities is available at the EU level with a mandate to influence at national levels*** the following aspects:

[25] More information about the TEHDAS Joint Action can be obtained from their website at: Website - Joint Action Towards the European Health Data Space – TEHDAS - Tehdas

1. Health data standardization capacity
2. National health information systems development

8. Data science training (could use EC transversal capacity)
9. Data quality assertion

With a high-impact high-reach EHDS the definition of **four main EU-level health data usage regimes** (with different governance structures and data ecosystems) are likely to be needed:

1. "non-crisis" regular data collection processes and purposes. These would mostly deal with regular activities like the production of Eurostat useful information, Health Indicators, data to support public health policies, supporting research across the EU, and research with EU datasets, both by JRC, Academia and Industry (eg. Pharma)
2. *Ad-doc* data collection processes and purposes. Non-crisis but occasional and non-regular data collection or usage projects
3. Public health inter-crisis periods. Particularly for preparedness and active surveillance
4. Public health crisis. Supporting ECDC and HSC needs to their many functions when coordinating the response to public health crisis

3.3.2. Working concept of a "coordinating structure for emergency responses", an EU health data centre

As interpreted from the study plan the "structure" is more likely to be like a ***temporary central structure focussing on public health relevant data aggregation, utilization, and exploration to support coordination and emergency responses.*** The EU (Health) Data Centre under scrutiny, would relate to the following "preliminary descriptors":

> *The establishment of an EU Data Centre for Emergency Coordination and Response* ***should allow the seamless concentration of data and their algorithmic use to provide immediate solutions in an absolutely secure space****. The Centre would* ***operate in pre-determined times of emergency in coordination with the Member States, which will also be co-owners of the Centre****. In its operational structure,* ***the Centre would operate with the maximum discretion and mechanisms that can "delete" the digital traces and the meta-data of the engagement of the Centre with citizens, so as to guarantee their maximum privacy and incentivise their maximum collaboration****. (…) The powers, competences, institutional structure and legal format of such a Centre* ***that could coordinate with existing non-executive agencies in specific sectors*** *need to examined in detail.*

A structure with a limited mandate to "operate in pre-determined times of emergency" is very likely to ***be insufficient and very weakly capable*** of significantly adding value to EU public health crisis management broadly speaking. Perhaps an alternative policy option is to look at this as a ***more permanent structure with the same purpose***. I will argue why. In such case we would be talking of a "European Health Data Authority/Agency" – EHDA. Amongst other reasons to be further outlined only a more permanent structure would be in the position to address the following requirements also advanced:

> *Whether the establishment* ***of an EU structure of this kind fills in an actual governance gap and carries the potential for strengthening the European risk management response to cross-border health threats*** *including* ***the development of harmonised testing methodologies and reporting protocols and the shaping of a common and well coordinated data collection, reporting and testing framework****. The study should consider ways of scaling up cross-border exchange of health data in public health emergency settings; also ways of linking and using, through secure, federated repositories, specific kinds of health information in compliance with the GDPR*

including a mechanism to prioritise standardisation activities and ***to work towards a more harmonised description and overview of datasets, data objects and identifiers to foster data interoperability between sectors and, where relevant, within sectors****.*

Irrespective of the temporary or permanent nature of an EU Data Centre for supporting Coordination and Emergency Response it is invaluable to list possible ways on how data could be used at the EU level to improve decision-making, anticipation and even communication to patients and citizens. This will be extensively detailed in section 4 under "possible functions and characteristics of the EU health data centre and distinctions between a temporary centre and a permanent structure". For the moment **it is enough to understand that depending on a temporary or more permanent the adequacy of existing EU structures change**, which may determine different preliminary policy options. Finally, two core competencies have to be ensured in such a Centre, one looking inwards and one extending outward all the way across the data pipeline to public health practitioners and patient encounters where relevant data is generated and needs to be captured. These are:

1. Trust, cybersecurity, and ethical(24) core values and practices.
2. Datafication and capacity building in health systems and particularly public health units, including data science and advanced digital health education.

3.3.3. Assess the adequacy of current EU institutional structures

The current EU institutional structures are not fit for purpose if we are to take a broad perspective into a common EHDS, and certainly not for a "new" coordinating structure for emergency responses whatever form it is conceived as. The first part of the statement may seem bold when at present the EC (via DG SANTE in cooperation with DG CNECT) is launching a debate on the new legal proposal for an EHDS and it does not outline any intention for changes to current EU institutional structures. However, debates and feedback on this proposal have been revolving at times around the governance of the EHDS. How and who could enact it, as well as, the operational elements it would entail. Following such debates, it seems unlikely that a full-fledged EHDS could come to exist without some changes to current structures and even the creation of new arrangements. No adequacy was found in current EU institutional structures that could take up the functions of an EU health data centre for Coordination and Emergency Response. This would be a new structure and it follows from previous arguments that the capacity to set-up, maintain, operate technically and legally, and mature such broad and intrusive use of health and public-health relevant data, does not sit under any structure as defined in current Regulations. Even looking at the ambitious EC proposed documents under the "European Health Union" 11th November pack (1) and the HERA Regulation under current discussion. The institutional structures to be consider are: 1) DG SANTE/CONNECT/DIGIT (namely units dealing with Digital Health, AI, Health data); 2) JRC; 3) ECDC; 4) EMA. We can also consider HERA, as an emerging structure. Regarding institutional adequacy perhaps the role and participation of ENISA (regarding cybersecurity) can be further enhanced and we can anticipate that a special relation with the European Data Protection Supervisor (EDPS) may be needed, for quick data protection decisions.

What could be the institutional "home" for this new EU structure?

Homing the EU health data centre in EMA is not logic due to the specialized nature of this agency, a similar argument could be said of HERA in its current proposed mission and outline. Despite that the centre would need a significant amount of data from agencies and input with information and insights it will produce. The JRC has technical and scientific data analytic strength and capacity to scale it up as needed, but it has no public health knowledge base or authority in the context of public health, particularly in communicable diseases and in the more common and historical cross-border threats. The ECDC emerges from this analysis as the agency where such a function could be located or co-located, it has the public health knowledge and focus, it lacks IT capacity (31)(32), staff size and

specialization in data science. It also has had, until 2020, a rather "observatory and counselling role" seen as lacking the capacity to implement, and for top-down decision making(28). Something which may become a critical success factor for such type of structure particularly during crisis periods. The EC itself (via DG SANTE) could theoretically be in an ideal middle ground position, however it historically has struggled with the capacity to retain, hire and develop long lasting teams with hybrid technical capacity (data scientists, epidemiologists, communication and IT experts, management and decision-science specialists) critical for success. This has been the reason behind the creation of so many specialised EU agencies, particularly in the health area. Finally, the EHDS, if it evolves to include a central unit with stable and sustained staff, expertise and authority, then from an institutional topology perspective, it would be ideally iso-located to other structures. It could, if given that authority, perform critical functions needed, such as coordination, command and control, and governance on MS public health data ecosystem. However, as discussion go regarding the governance of the EHDS, a distributed architecture and governance is currently the mainstream idea, which would contradict the above. Alternatively**, it is possible to assume that a core central health data function is needed at the EU level, and that this is the moment to solve that gap**. Providing a home not just to a structure having the responsibility for better use of health data for Coordination and Emergency response but beyond that. To explore populational health data issues, synergize communicable and non-communicable disease datasets and create the conditions to use data on health systems and non-health public health relevant data in ways that can create more resilient health systems and hence anticipate and prevent future hybrid or even more difficult health crisis than the current one.

3.3.4. Preliminay options 4

Accounting for all presented material and the complexity of the institutional ecosystem four preliminary **options** are worth exploring regarding the institutional frame for a EU health data centre (these somehow incorporate preliminary options 2 advancing them further):

10. **Do nothing scenario**. Maintain existing functions in the different institutions and no horizontal health data coordination function.
11. **Using same institutional arrangements.** Maintaining the existing functions in the different institutions. Establishing four functional regimes via different arrangements of the different elements and a respective governance. Adding capacities by the creation of four horizontal health data coordination units: 1) a health data standardization unit; 2) national health information systems accompanying unit; 3) data quality audit unit; 4) data science training and development unit.
12. **Reinforcing the role of the ECDC in the EHDS**. The ECDC would be the main responsible institution for all public health related data topics, including not only crisis (and in between crisis) relevant data use, but also public health indicators. The remaining aspects would be run under the ***governance schemes to be established as in 2***. In this option the ECDC would be operating much like the CDC in the US, with two high-level legal regimes: One on Cross-Border public health, mostly communicable diseases related activities; and one on public-health indicators (presently under DG SANTE), national health systems indicators and non-communicable diseases information collection and exploration. The advantage would be the usage of resources and connections established under the Data Act and the legal regime of the EHDS for merging communicable and non-communicable disease information both for preparedness as well as crisis response and recovery.
13. **Establishing a European Health Data Agency (EHDA)**. It mission would be to aggregate all existing capacities and digital health EC competencies (units from DG CNECT and units of DG SANTE, as in 3.), as well as Public Health Indicator activities, include additional ones

needed (as in 2.) and serve both the EC as well as its different specialized agencies: the ECDC and EMA (but also EMCDDA [26] and EFSA [27]), while acting as the main governance agency on the European Data Space on behalf of the "health sector" more broadly.

3.4. Examination of the requirements for a centralised governance structure

An examination of the powers, competences, institutional structure, and legal format of such a Centre that could coordinate with existing non-executive agencies in specific sectors was asked from this study. As a summary from last section, definitely a new centralized structure to better exploit health data, particularly to provide support to coordination and emergency response is needed for a better EU response to pandemics such as the COVID-19 pandemic and specially even more dangerous scenarios. It is also clear the concept of such a structure is not indifferent to the capacity it can have in practice both to really lead added value to current EU-level institutional ecosystem, but, as particularly to help, develop, mature and sustain readiness for public health data advanced usage capacity in Member States. **So whether the structure is a "temporary assemblage" or a permanent entity is not an indifferent policy option**, although arguably a difficult one. With this caveat the next subsection will examine as requested the requirement for such a centralized governance, assuming it can take a "temporary" nature, or a "permanent" one.

3.4.1. Preliminary considerations

Preliminary considerations on whether this should be temporary or permanent and a set of previous aspects that better inform the requirements of such centralised governance structure will be presented. This is important backdrop for the conceptualization of a structure that adds significant value to the five stages (prevention, detection, alert, response and recover) of dealing with a large European Public Health crisis. Lastly, the listing of the requirements is to be presented. A preliminary examination of the powers, competences, institutional structure, and legal format of such a Centre is summarized. Exploring their differences regarding the limitations of a temporary solution *versus* a more permanent one has already been presented. A Centre with more permanent functions can of course additionally run all temporary functions on top of its underlying continuous activity. The decision for one or the other is a policy option. Both can be legally sustained within the scope of the Lisbon Treaties. The requirements and the need for a centralized governance structure for health data collection and utilization in public health can be informed by a set of relevant previous work.

3.4.1.A Previous audit work

The audits by the European Court of Auditors in 2016 (33) and in 2006 on "Dealing with serious cross-border threats to health in the EU" (28) started from the acceptance that: "*Implementing the decision on serious cross-border threats to health and the related framework is complex in view of the competences of the EU and the Member States, and the fact that serious threats keep emerging*", and assessed:

1. whether the EU framework for protecting citizens from serious-cross-border threats to health was adequately implemented.

2. And examined:

14. whether the innovations introduced by the decision are effectively implemented;

[26] https://www.emcdda.europa.eu/emcdda-home-page_en

[27] https://www.efsa.europa.eu/

15. whether the existing systems for early warning and response and epidemiological surveillance are adequately managed and implemented;
16. whether the EU health programmes are making effective contributions to protecting citizens from threats to health;
17. whether the Commission's internal coordination in terms of health security funding and public health crisis management is adequate.

3. To conclude (regarding only the main aspects core to this study) that:
    a. significant weaknesses at Member State and Commission level affect the implementation of the decision and the related EU framework
    b. the work and role of the HSC have proven to be very important, but it is facing strategic and operational challenges which need to be tackled, including in relation to the coordination of response rules.
    c. the effective implementation of the existing systems for early warning and response and epidemiological surveillance, we found overall that these systems have been operational for years and that their important role at EU level is widely recognised by stakeholders. However, there is scope for making certain upgrades to the Early Warning Response System (EWRS) and related procedures.
    d. the audit revealed that a number of gaps existed in relation to the Commission's internal coordination of health security activities across different services and programmes. We also found that more work needs to be done to make agreements for cooperation between Commission crisis management structures fully operational, and that DG Health and Food Safety's management of its Health Emergencies Operations Facility showed weaknesses that might hamper its performance.
4. From the interview to the ECDC representative and the new proposed regulation on the ECDC (27) the following points in c) were being addressed with a new IT tool (3.c) and those in 3.b might benefit from the enactment of the new regulation repealing Regulation Nº1082/2013.

The audit of the ECA to the ECDC in 2019 (31) and in particular the Third Independent Review of the ECDC and the response Management Board conclusions[28] have highlighted that:

1. ECDC has been well managed, follows its mission within its given scope. Staff numbers have been constantly below 300 and comments over time have stressed the need for the ECDC to relate more with MS.
2. The Third Independent Review recommendation 9 ("Extension of the mandate of ECDC") suggested: "*(….)the possibility of extending the remit of ECDC should be further considered via the competition of a full impact assessment to be undertaken to assess the level of this need. Given the identified evidence of needs for strengthened EU-level activities in the area of noncommunicable diseases and the potential strengths and opportunities of ECDC for taking on these additional tasks, a full Impact Assessment should be undertaken. This should be in line with the European Commission Better Regulation Guidelines. The Impact assessment should be able to further define the needs (problems, drivers,*

[28] The Third External Evaluation report can be accessed at https://www.ecdc.europa.eu/en/publications-data/third-external-evaluation-ecdc-2013-2017 the Conclusions and recommendations of the Management Board based on the Third External Evaluation of ECDC (Approved by the ECDC Management Board at its Forty-ninth meeting, 17 June 2020) can be accessed at: https://www.ecdc.europa.eu/sites/default/files/documents/Conclusions-Recommendations-Third%20External-Evaluation.pdf

consequences), the corresponding policy objectives and then consider the options of: no change, extension of ECDC's mandate to these areas, or establishing a new EU Agency with a mandate in the areas considered. The Impact Assessment should also consider other areas where ECDC's mandate can be revised – in the areas of international activities and cross-border threats to health other than from communicable diseases".

3. The ECDC Board responded, in 2020, to this recomendation in the following terms: *"In comparison to the second external evaluation, the recommendation concerning the changes of the mandate of ECDC was considered through a number of different perspectives: • other cross border health threats than infectious diseases related threats • NCD surveillance, health monitoring and health information • risk management • health determinants • health behaviour and health promotion. The Management Board notes that for none of the areas mentioned above, is there a consensus on the extension of the mandate of ECDC. However, their specific focus was on the two first issues in the list - health threats and NCD surveillance - as the evaluation report considered these two as the most key". To conclude that: "having considered the possible need to extend the scope of the Centre's mission to other Community level activities in the field of public health, in particular health monitoring, that such an extension cannot be justified only on the basis of the current external evaluation. Instead, the Management Board requests the Commission to consider to propose how to put the question forward, for example based on a scoping analysis."*

3.4.1.B Challenges in EU-level governance during COVID-19 public health crisis

Gaps and challenges identified regarding an EU-level governance of public health crisis which could be better supported by such a Centre and improved mandate on harmonization of public health data in MS (in section 1), include: i) No clear leadership; ii) Different priorities; iii) Conflicting decisions; iv) Absence of an identifiable "unified" approach; v) Disperse, erratic, and ineffective communication; vi) No clear anticipatory strategy for next phase preparedness; vii) No clear list of strategic questions; and vii) Need for high level patronage.

3.4.1.C The "European Health Union" pack

The 2020 EC Communication and three Regulation proposals, under the "European Health Union" pack, of which a brief detailed analysis is presented in next section, shows determination by the EC. Although in the right direction regarding digital health and health data, the proposed changes are timid and not capable of inducing necessary changes at MS level on health data collection capacity without additional legal acts and without a dedicated central structure not just to verify conformance but particularly to serve as a expertise hub and a public health datafication institutional driver.

3.4.1.D Lessons learned from other countries/experiences outside the EU

Findings from interviews, desk research and material received from the MoH permit learnings from best practices:

18. In Hong Kong, the establishment of a weekly daily for running the response to the present pandemic, with all major leaders (public health authority, head of major hospital clusters, and others). This was made significantly more effective due to the presence of both the leader of the centralized IT function (at the HKHA), capable of executive follow-up action and consequential changes in IT and data availability, and readily available and analysed real-time data. This was possible due to the support of setting of advanced digital capacity tools and teams, capable of altering the IT systems, and or mandating changes in a matter of days, following the meetings, and in alignment with clinical care process transformation and/or public health measures refinements.

19. In Singapore, the capacity to link up citizens and laboratory data though a set of citizen centric digital solutions (like TraceTogether APP) meant that centralized IT function could gather data not just from conventional health system organizational information systems but also and directly from individuals under quarantine rules, under investigation or at risk, with a bidirectional educational effect.
20. In Japan, the Contact Confirmation APP, subject to patient consent, uses the proximity communication function (Bluetooth) to ensure your privacy much like the EU eHealth Network approved guidelines[29].
21. In Korea, the implementation of a "Smart quarantine (Entry Screening)" was facilitated by a combination of extensive lab testing (in first 15 days, homogenous and with all laboratories linked in network, and with a results time in about 6h) and a Self-health check application – with the personal (passport ID) identification. This allowed linking of results and symptom automatically.
22. In the US, the public health modernization initiative is fuelling a set of digital transformation and upskilling of the public health data ecosystem organizations and people, with visible impacts in their capacity to increase interoperability of their solutions. This has not been met with federal level public health measures and additional requests which could have resulted in a further acceleration of the maturation of such digital ecosystem.
23. In both US and HK, the usage of AI for limited public health functions has been mostly done ad-hoc, in academia or in some experimental private settings. Legal and institutional uncertainty, and the low level of sophistication on the public health authorities on how to "ask relevant questions" that can only be answered by such systems were identified as two clusters of deterrents from higher technical and leadership attention to AI usage for flighting the current pandemic.

3.4.1.E. Strategic Foresight activity

Europe faces structural risks that have started to be mapped, for example by a recent STOA study "Towards a more resilient Europe post-coronavirus" (34). If this study is to follow a anticipatory-policy perspective then there is a need to prepare the EU for dealing better with a next public health crisis the size and complexity of COVID-19 pandemic and its societal consequences, and whatever devices we conceive have to be able to support and embrace strategic foresight (35) and data-informed foresight. ***Simulation of large scale crisis, as well as public health stress tests***, like those the European Central Bank (ECB) has imposed upon the banking sector[30], are the only way to ensure we are better prepared next time, and that we know we are, or what are the areas in which we still have collective work to do.

So, building on past EU experience in foresight units and on the Eurozone experience and model, ***a truly authoritative exercise schema, using simulated data and synthetic patients and large digital simulation environments for decision-making, is the best way to ensure a sustained MS and EU-level investment in public health resilience after the pandemic is over and the attention to such topics drastically diminish like history has recurrently has shown***. This model can benefit from inspiration to be found in banking stress tests (organized, mandatory, and supervised by a strong EU institution – the ECB) and in EU-wide cybersecurity drills (organized by ENISA in

[29] Interoperability guidelines for approved contact tracing mobile applications in the EU https://ec.europa.eu/health/sites/health/files/ehealth/docs/contacttracing_mobileapps_guidelines_en.pdf

[30] For more details on the European Central Bank stress tests policy see: https://www.bankingsupervision.europa.eu/banking/tasks/stresstests/html/index.en.html

articulation with several DGs in the EC)[31]. In both cases, a strong capable central structure is key in creating the test, obtaining, and analysing findings, and extracting lessons learnt which, if relevant, they have the capacity to transform into guidance, soft regulation or even hard regulation proposals.

3.4.1.F. Proposed changes to the regime on EU response to serious cross-border health threats: diluted decision-making, little room for data-influenced, data-based public health decisions.

The "European Health Union" pack of legislative proposals ***advances a series of weaknesses*** it sets to address, namely, the lack of a "*comprehensive legislative framework to govern action at Union level on preparedness, surveillance, risk assessment, and early warning and responses*"; and a need for enhancing "*the Union's guidance in the adoption of common measures at EU level to face a future cross-border health threat*". (2). The changes to the regime have the following declared aims:

> *"to provide EU added value through the development of an EU health crisis and pandemic preparedness plan, complemented by: national plans and transparent reporting of capacities; strengthened, integrated surveillance systems; enhanced risk assessment for health threats; increased power to enforce a coordinated response at EU level through the Health Security Committee; and, an improved mechanism for recognition of and response to public health emergencies"*

This means this regime is not prioritizing health data usage coordination beyond dealing with it as an instrument, which signifies that it cannot be seen in any way as setting strategy and leadership to propel data use for public health. Regarding Article 1 (subject matter) it is significantly longer and more detailed than its predecessor. Of particular interest is the detail on the rules for preparedness and response planning, increasing visibility to elements such as "*reporting and auditing of preparedness*" whereas topics of data use, automation and the establishment of an pan-European digital surveillance mechanism (detailed in Article 14) is not even allured to. This cannot be an accidental omission. The Article sets the subject matter of the decision to include the establishment (Article 1(2)) of new "bodies", namely: i) a network of EU reference laboratories for public health; ii) a network for substances of human origin; [and] an advisory committee for the occurrence and recognition of emergency situation at Union level. These bodies, together with a revamped Health Security Committee (Article 1, nº1(a)) create a significantly more complex and inter-networked governance mechanism. Nevertheless, they ***give no significant role to a central structure to help foster the use of health data in coordination and emergency response***.

It seems the proponent believes better coordination will come from establishing a dual-level Health Security Committee (Article 4(1)), along site an Advisory Committee, and two "parallel" networks. On one hand, this may increase the participation of experts, member state agents, and even EC services and Agencies from the EU but on the other, it can create high level of complexity in ensuring the "aimed" orchestration and avoiding the "lessons learnt from the COVID-19". Alternatively, there is a central orchestration "function" within the EC not made transparent and there is surely a higher need for negotiations. This option for a "marbled" structure of "experts" appointed by the EC but "accepted" by MS representatives, or a committee of MS representatives chaired by the EC (with a rule of decision by consensus) represents a clear attempt to find a dynamic and elaborate balance between the state and supra-state level, without offending the subsidiarity principle, in an attempt for a proportional, and yet, operational governance mechanism.

[31] For more details on the ENISA cybersecurity EU-wide exercises see: https://www.enisa.europa.eu/topics/cyber-exercises

The scope for a data analytics working group and its limited authority

Another example of a clear move from a "information and experience sharing" culture of the earlier regime, to a proactive stance, results from the analysis of the new proposed Article 4(2)(a) which reads "*The HSC shall have the following tasks: (a) enabling of coordinated action by the Commission and the MS for the implementation of this Regulation*" against its predecessor Article 17(2). *The newer proposed version* means the HSC evolves from "sharing" to ***become an "executive" body***. Article 4 (5)(6) in the proposal is the same as Article 17(4)(5). In its number 3, however, it introduces an enigmatic text: "*As far as possible, the group shall adopt its guidance or opinions by consensus. In the event of a vote, the outcome of the vote shall be decided by simple majority of the members. The members that have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the guidance or opinions*". Enigmatic for two reasons: i) it is unclear if "the group" is referring to the HSC, in which case "the committee" should have been chosen for legal clarity and certainty, or if it refers to "the groups" as in, Article 4(1)(b) "the technical working groups"; ii) if the first option would be true then there is an obvious conflict of decision-making rules: Consensus versus two-thirds majority. As no other information allows us to fully understand the intent of the proponent, if there is a typo (an "s" maybe missing) or any other alternative, I assume it refers to the decision-making processes of the working groups. Although their existence is foreseen in the 2013 decision Article 17 (5) "the procedures for plenary meetings at high level and ***working groups***", these technical working groups are no further detailed, nor it is clear how their decision-making operates. The new proposed version, if corrected for "the groups" would then add density to their function and how they decide. ***These working groups provision could create the legal link between this regulation and much needed MS health data harmonization and improved data collection capabilities.*** This would however be a significantly weak legal instrument to foster the scale and scope of public health digital transformation and its follow-up that seems to be required, for an effective and empowering use of health data at the EU level. Some provisions under the proposed ECDC regulation open the door to a more proactive role, but the dimensions of mission change regarding general preparedness and the limited scope of staff size and budget changes, limit the potential of those legal devices.

Article 14, on the surveillance platform, will be analysed extensively in section 7 with in a broader discussion on the usefulness of advanced digital technologies for public health including AI. Finally, Article 7(2)(3) creates the conditions for "governance by influence or use of indicators". The rise of indicators, benchmarking and "shame-and-blame" approaches in global governance has been identified as a growing trend (36). In this case, it also has another operative effect, by extensively covering the elements of the report (article 7(1)) and then giving power to the EC, by means of implementing acts (Article 7(3), to define the templates to be used when providing the information in (1), Article 7 enforces in effect a "template/report"-based governance. However, ***this is only as effective as the EU-level capacity to produce such indicator descriptors, update them to make them relevant to capture aspects of reality that are worth managing, and process them in time and detail to inform policy options and tactical plans***. If based on self-reporting and late reporting, as has been traditionally the relationship between national public health data sources and authorities and the ECDC and DG SANTE health information (public health and populational health) ecosystems, these provisions will have no tangible effect on crisis management. A stronger mandate is needed to make and capacitate MS to collect and share relevant data and to have EU-level institutions making good and speedily use of such data to inform the complex array of decision-making. As conclusion from this sub-section, extensive background and arguments support the need for a structure capable of centralizing the governance and usage of data for public and populational health in order to support better management of public health emergencies but also to further the protection of human health for EU citizens.

3.4.2. Requirements for a centralised governance structure

Possible functions and characteristics of an EU health data centre were conceived from research conducted. A set of them is outlined in Table 1 together with their brief description.

Table 1 – The EU health data centre – functions and characteristics

Function/Characteristic	Description
Data utilization during a crisis	How capable the structure is to use data during a public health crisis
Network of actors	How does the "EU Data Centre" relate with the other health data actors within the frame of the European Health Data Space (EHDS) and non-health spaces
Data harmonization/ common European strategy on how to collect data	How capable is this option in addressing the persisting problem of low health data interoperability and reduced data utility for public health due to problems in harmonization of processes and data capture
Emergency Coordination and Response	Capacity to support the Emergency coordination and response mechanism irrespective of its present and future options/nuances; Visualization tools
Using AI tools	Capacity to use and explore AI-based technologies to produced advanced digital insights
Data-based forecasting and predictive analytics	Use of data analytics for future trends predictions and other techniques for disease outbreak anticipation, prediction, and evolution during a pandemic
Advanced-telehealth capacity	Usage of digital services to provide tele-health or information about the crisis or connect data from populations in real time (e.g. chatbots and digital presence)
Real-time personal/case surveillance	The usage of digital tools (AI based and telematic) to track, monitor and follow-up individuals with or at risk of a given disease
Utilization of data on health systems	Capacity to make use of data from MS health systems to improve coordination and management of the emergency response
Utilization of any data with a public health relevance (DPHR)	Capacity to utilize non-health data, that may however provide valuable public health insights during a crisis

Based on this set of characteristics a further analysis into whether a temporary "structure" or a more permanent structure is better suited for the propose of lending more support to a Coordination and Emergency Response was conducted which favours a more permanent one (presented in table 2).

Table 2 – Comparison of two options regarding a EU health data centre for Coordination and Emergency Response

Function/ Characteristic	Description	"EU DATA CENTRE" – as "temporary Centre"	"EU DATA CENTRE" – as EHDA
Data utilization during a crisis	How capable the structure is to use data during a public health crisis	This is its main activity	It is part of its activity. It also develops preparatory activity to ensure data is ready to be utilized, up-to-date human skills and processes exist
Network of actors	How does the "EU Data Centre" relate with the other health data actors within the frame of the European Health Data Space (EHDS) and non-health spaces	Has to have capacity to activate and secure attention from ad-hoc relationships and temporary data usage protocols and engaement. Exploratory relationship	Long term relationships, permanent MS representatives, educational network
Data harmonization/data authority (common European strategy on how to collect data)	How capable is this option in addressing the persist problem of low health data interoperability and reduced data utility for public health due to problems in harmonization of processes and data capture	(+) Via Art 14 and Art(s) on preparedness (new regulation to repeal Decision N0 1082/2013/EU); It can induce the adoption of data standards indirectly but can only verify if MS actually adopted them as the crisis unfolds. It cannot ensure testing, preparedness exercices or capacity apraisal	(++) or (+/-) if the scope and authority over non-Communicable Disease data, Health System data and non-health relevant data is not clear, reinforced and followed by capacity enhancement then there is a risck; Several strategy leaders
Emergency Coordination and Response	Capacity to support the Emergency coordination and response mechanism irrespective of its present and future options/nuances. Visualization tools	Capable of limited contribution to Coordination and Emergency response with a temporary data processing and authority mandate	Capable of extensive contribution to Coordination and Emergency response due to a extended data processing and authority mandate
Using AI tools	Capacity to use and explore AI-based technologies to produced advanced digital insights	Very limited. The accumulation of data is very restricted, articularly if discard&delete data policy options are pursuit. Horizontal/transversal datasets and analytics is possible. Vertical and longitudinal is not facilitated.	Accumulation of data is not so restricted,. Easier to implement selective discard and delete data policy options for certain real person data. Horizontal/transversal datasets and analytics is possible; vertical and longitudinal datasets are equally possible.
Data-based forecasting and predictive analytics	Use of data analytics to develop future trends predictions and other forecasting techniques for disease outbreak anticipation, prediction and evolution during a pandemic	(++)	(++++) A long-term operation, consolidated data, and more dedicated data science staff, makes this structure much more capable of achieving tangible results. Preparedness and future crisis outlook activity.
Advanced-telehealth capacity	Usage of digital services to provide tele-health or information about the crisis or connect data from populations in real time (e.g. chatbots and digital presence)	(++)	(+++) If more permanent structure exists linking to national online and digital therapeutic services can be envisioned, as well as telehealth/call centre for harmonization of information and support
Real-time personal/case surveillance	The usage of digital tools (AI based and telematic) to track, monitor and follow-up individuals with or at risk of an give disease	(+++)	(+) The ethical and legal risk of this activity in a permanent structure is too high. Significant control mechanisms need to be set in place-
Utilization of data on health systems	Capacity to make use of data from MS health systems to improve coordination and management of the emergency response	(++)	(+++) This will required significant preparation time, resources and process harmonization as well as interoperability work in non-conventional IT systems (e.g. bed management, or OT systems)
Utilization of any data with a public health relevance (DPHR)	Capacity to utilize non-health data, that may however provide valuable public health insights during a crisis	(+)	(+++) This requires significant time, resources and relationship building

3.4.3. Powers, competences, institutional structure, and legal format

A detailed examination of the powers, competences has been presented in section 3.4.2 with regards to the capacity of using and exploring public health data to the level of highly advanced data analytics, not just based on traditional non-communicable disease data but from all four types of health data deemed relevant to public health. ***The centre can only fulfil its mandate if it has power and competency on influencing MS public health relevant data ecosystems and institutionally linking with their national level actors***. Such response structure needs to be of permanent continuous activity and not only "actionable when crisis is declared", capable of driving the EU health data strategy and agenda, and ***capable of liaison with MS internal public health data structures and authorities to establish functional public health relevant data pipelines by building technical connectivity and upskilling workforce in digital health and data science***.

The **institutional structure can be located inside an agency or as a stand-alone agency**, bear a mix of regulatory agency and technical competence centre attributes. Inspirational examples could be ENISA under the umbrella of the new Cyber Security Act[32] and the NIS Directive (9), the US CDC[33] in respects to its technical competence, data aggregation (both communicable and non-communicable disease) mandate and scientific and data science powerhouse, or the exemplar information technology architecture (10) and centralization (11) capacity of the Hong Kong Hospital Authority (HKHA). The legal formats possible have been discussed in provisional options 2. These options should be combined with: (i) the analysis of the EU institutional structure adequacy (section 4.) which presented 4 final options regarding the institutional "homing" for the Centre, (ii) the findings of the ECA reports, and the Third ECDC internal audit report, and, (iii) the new set of competencies proposed for the ECDC, which is already struggling with budget limitations, staff size and retention, and a communicable disease focus and capacity. The legal format could be a very significantly reinforced ECDC mandate, budget, staff, and structure change which has a high risk of failure due to all the other changes already proposed for this Agency by the EC. A new EHDA agency, either combining this with the current ideas about the future HERA, or actually advancing to a dedicated digital health agency with a focus on advanced analytics and capabilities particularly concentrated on public health data and supporting EU-level public health functions. EMA and the medicinal drug regulatory multi-level ecosystem could be an inspiration.

3.5. How can an EU structure contribute to the European risk management response to cross-border health threats

This section will examine whether the establishment of an EU structure of this kind **fills in an actual governance gap** and **carries the potential for strengthening the European risk management** response to cross-border health threats. **Propose an effective and well-coordinated response structure at the EU level,** without prejudice to the existing allocation of competences between the EU and its Member States, that could strengthen the European risk management response to cross-border health threats.

3.5.1. Filling an actual governance gap

A central structure dealing with health data at EU level, particularly if it covers public health data understood in the broad sense and have a permanent rather than transient nature during crisis, ***will***

[32] Ironically the Cyber Security Act also expanded ENISA's mission in the aftermath of the crisis caused by the WannaCry (cyber)virus which created a significant disruption in the EU economy and showed its vulnerability. Details on the cyber security act and ENISA's expanded mission are to be found at: https://ec.europa.eu/digital-single-market/en/eu-cybersecurity-act

[33] US Centre for Disease Control website: https://www.cdc.gov/

fill a severe actual governance gap. However, to really have an impact on public health preparedness and betterment of populational health in the EU, such structure should tackle different types of health data and support multiple EU-Level actors/agencies. For this it would require the access and the capacity (both technical and legal) to process the following four large sets of data/health information:

1. Communicable disease related data, to support the mission of the ECDC, EMA, and "HERA", the JRC, DG SANTE and other "crisis coordination bodies";
2. Non-Communicable disease related data, and population health data and health information systems (classically build based on surveys and other data collection tools, but that can be progressively gathered from EHRs, Patient reported/provides health/behavioural data, non-health sector but health-relevant datasets).
3. Data "about healthcare systems", e.g. number of available ICU beds, critical equipment critical teams etc.
4. Non-health data that is of high value to public health.

Such governance gap is not covered by any of the existing or recently proposed structures, not even the EHDS in its present preliminary outline. The consequences have been identified and the outcomes became obvious during COVID-19 pandemic. No organization at the EU level has a mandate strong enough to trigger much needed national level effects such as:

1. Intense public health datafication and data usage modernization
2. Harmonization of health data sets
3. Preparation of Information Systems to on-demand data access, under pre-determined crisis conditions
4. Data analytics and data science capacity, as well as, data capture and public health data expertise capacity building

These four elements have been identified systematically by interviewees as missing in most EU MS and the hope of many of them is that an EU-level mandate could trigger the necessary investment and leadership attention. Only through a powerful EU health data centre, operating as a true European Health Data Agency (EHDA) can some of these influences be strong enough and sustained enough to deliver tangible results. This has been pointed out by numerous scholars and some EC funded projects like Bridge Health. Only throught health data governance effects on the four public health data levels: i) local/hospital; ii) Regional; iii) National and iv) European, can data be collected of sufficient quality quantity and timely to be effectively used to support advanced information management and supporting critical EU-level public health decisions, monitoring, preparedness and anticipation of future crisis. This sort of vertical governance does not mean all aspects are to be governed at the centre. The governance of medicinal drugs is an excellent example and can serve as an inspiration. No doubt the complex multilevel system we have today, with quite clear and well-articulated competencies between EU, and National and regional levels, for managing medicinal drugs would not be as consistent, or even existing at all, if there had not been a bold and forward looking decision to create EMA, and its regulatory ecosystem.

At least so far, the EHDS has not been conceived as a vertical governance space. Its discussions have included governance dimensions mostly related to the interplay between the different parties that could connect to the EHDS, as nodes at the EU level. The big problem however that our findings highlighted was the vertical public health pipeline, being often insufficient, delayed, and above all heterogenous in data quantity quality format and technical support making its usability at the EU level very difficult, costly, unprecise and impossible for some advanced analytics and predictive tools.

3.5.2. Potential for strengthening the European risk management response to cross-border health threats

Contrary to previous crisis, that triggered legal changes in the EU's capacity to respond to serious cross-border threats (3), this time, changes to the Union's legal armament happen not one or two years after the crisis but, literally, during its peak. Now most of the EU territories fight an unprecedented pandemic, tainting red the Union's maps in the recent ECDC online reports[34]. These took months to set up, and clearly show how fragmented the health sector is, including differences in MS reporting only national level data, while others display regional level data, with striking relevant differences. The acknowledgement by the EC that optimal response at the EU level was not guaranteed is attributed to a defect of the "current system". This is a position many scholars contest as they suggest(17), legal interpretation and different acting based on existing legal frameworks was possible and desirable in the early pandemic months (4), and remains as such for the months of autumn and coming winter (7). Some equally point out that the "argument" of surprise and the unexpected nature of this crisis was "expectable" and, hence, should have been taken into consideration by EU institutions significantly earlier (15).

According to many critiques the response from the EU, and its main "governing" bodies, the EC and the Council, has been weak, uncoordinated, and somehow erratic. It is said that multiple discussions have taken place with MS including at health ministers' level, have seen calls for a more consistent and coordinated approach to preparing for and managing health crises in the EU. ALEMANNO advances a set of provisional explanations of what he calls "the global suboptimal response to an essentially foreseeable outbreak such as a pandemic"(4). He suggests eight, of which four are more relevance to our study:

1. the lack of an effective global alarm response capacity in an highly interdependent yet geopolitically volatile world;
2. widespread unpreparedness of our respective health systems, in particular their inability to cater for a surge in capacity;
3. the inability to mobilise the unprecedented wealth of data collected today to counter the virus due to the absence of a data governance and data-sharing culture as well as public–private infrastructure;
4. [and] the lack of evidence-based communication to – and engagement with – the public at a time of unprecedented disinformation."

The first refers to the issue of global articulation and global health regulatory regimes and responses, the second touches upon the issue of seeing health and care almost only as a "national prerogatives" an area where EU level law and decision making can hardly enter. According to some scholars such limitation of EU mandate has been, to some extents, overrated (a sort of EU "urban myth" that sees health as an untouchable national prerogative) and consequently that has prevented the exploration of the true boundaries but also possibilities for health law under the treaties(17) . The fourth has been mostly downplayed and could have been better tackled if there was an EU-level Health Data Agency and a stronger Authority as discussed in Provisional Options 1. The third point

[34] System created to present the evolution of the pandemic, launched only in September 2020 after a complex process of agreeing on the structure and mechanism for reporting data. Maps are available at: https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement
These maps are published by ECDC every Thursday in support of the "Council Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic", adopted by EU MS on 13 October 2020. The maps are based on data reported by EU MS to The European Surveillance System (TESSy) database by 23:59 every Tuesday.

refers to data, in essence it resumes how an EU health data centre function at the EU-level could have made a difference.

3.5.2.A How does the EU health data centre help a more effective response?

Table 1 summarized the characteristics and functions that an EU health data centre could have. Ignoring the temporary or permanent nature of this structure it is possible to hypotese how it could help a more effective response. A better response can be broken down into different components for analytical purposes. Building the TransCrisis project work on better "crisis management" in preparedness stage as well as during all seven capacities for crisis management suggested by Stoto et al. (37), we can identify eight steps where a better use of health data, and specially a coordinated EU-level use, could have a significant impact in a more effective response, not only of EU-level authorities, but also National Authorities has they gain a new perspective – a comparison and benchmarking perspective – into the phenomena. These eight elements are: i) Preparedness; ii) Detection; iii) Sense-making; iv) Decision-making; v) Coordination; vi) Meaning-making; vii) Communication; and, viii) Accountability. Table 3 shows how the different capabilities provided from the existence of a strong permeant EU health data centre can impact differently but significantly in the different elements associated with an effective response.

Table 3 – Analysis of how an EU health data centre, with permanent functions, could positively impact a more effective response to a public health crisis

"EU DATA CENTRE" – as EHDA			More effective response to public health crisis							
Function/Characteristic	Capacity	Comments on capabilities to help and conditions	Preparedness	Detection	Sense-making	Decision-making	Coordination	Meaning-making	Communication	Accountability
Data utilization during a crisis	How capable the structure is to use data during a public health crisis	It is part of its activity. It also develops preparatory activity to ensure data is ready to be utilized, up-to-date human skills and processes exist	(++)	(++)	(+++)	(+)			(+)	(+)
Network of actors	How does the "EU Data Centre" relate with the other health data actors within the frame of the European Health Data Space (EHDS) and non-health spaces	Long term relationships, permanent MS representatives, educational network	(++)			(+)	(+++)	(+)	(+)	
Data harmonization/data authority (common European strategy on how to collect data)	How capable is this option in addressing the persist problem of low health data interoperability and reduced data utility for public health due to problems in harmonization of processes and data capture	(++) or (+/-) if the scope and authority over non-Communicable Disease data, Health System data and non-health relevant data is not clear, reinforced and followed by capacity enhancement then there is a risk of several strategy leaders.	(++)	(++)	(+++)		(+++)	(++)		(+++)
Emergency Coordination and Response	Capacity to support the Emergency coordination and response mechanism irrespective of its present and future options/nuances. Visualization tools	Capable of extensive contribution to Coordination and Emergency response due to a extended data processing and authority mandate			(+)	(+++)	(+++)	(+++)	(+)	
Using AI tools	Capacity to use and explore AI-based technologies to produced advanced digital insights	Accumulation of data is not so restricted,. Easier to implement selective discard and delete data policy options for certain real person data. Horizontal/transversal datasets and analytics is possible; vertical and longitudinal datasets are equally possible.	(++)	(+++)				(++)		
Data-based forecasting and predictive analytics	Use of data analytics to develop future trends predictions and other forecasting techniques for disease outbreak anticipation, prediction and evolution during a pandemic	(++++) A long-term operation, consolidated data, and more dedicated data science staff, makes this structure much more capable of achieving tangible results. Preparedness and future crisis outlook activity.				(+++)	(++)		(++)	(+)
Advanced-telehealth capacity	Usage of digital services to provide tele-health or information about the crisis or connect data from populations in real time (e.g. chatbots and digital presence)	(+++) If more permanent structure exists linking to national online and digital therapeutic services can be envisioned, as well as telehealth/call centre for harmonization of information and support		(++)					(++)	(++)
Real-time personal/case surveillance	The usage of digital tools (AI based and telematic) to track, monitor and follow-up individuals with or at risk of an give disease	(+) The ethical and legal risk of this activity in a permanent structure is too high. Significant control mechanisms need to be set in place-		(++)			(++)		(+++)	
Utilization of data on health systems	Capacity to make use of data from MS health systems to improve coordination and management of the emergency response	(+++) This will required significant preparation time, resources and process harmonization as well as interoperability work in non-conventional IT systems (e.g. bed management, or OT systems)	(+++)			(+++)				(++)
Utilization of any data with a public health relevance (DPHR)	Capacity to utilize non-health data, that may however provide valuable public health insights during a crisis	(+++) This requires significant time, resources and relationship building			(++)	(++)	(++)	(++)	(++)	

Definitely elements regarding preparedness and detection can be very positively impacted by more extensive availability and advanced use of health data at the EU level. Likewise, coordination can be boosted from elements that work progressively over time such as the establishment of productive long-term relationships, permanent MS representation and more importantly an educational network on data use and data science. On the other hand, for example, the capacity for real-time personal or case surveillance, although, facing ethical and legal challenges, particularly with regards to preservation of identifiable data and direct personal data linkage, has the potential to impact positively on detection and communication with citizens. The later can be further enhanced by the availability of advanced telehealth capacity, something that can help in overloaded healthcare systems, and serve to communicate with citizens. While clearly a temporary structure would already add value, it may fail to support preliminary and anticipatory decisions, as well as it may prove "short-sighted" for future risks and inevitable next public health crisis. A permanent structure is needed.

3.5.3. Proposal for an effective and well-coordinated response structure at the EU level

Without prejudice to the existing allocation of competences between the EU and its Member States ***it is possible to advance an effective and well-coordinated response structure***. It bears the potential to strengthen the European risk management response to cross-border health threats, if it can serve as a ***data hub to support many relevant public health functions that as off today are mostly inexistent at EU level***, or even at most MS levels. Namely, preparedness simulation and audit, establishing base-line information about the readiness and resilience of each MS health system and particularly its public health ecosystem by way to the data it is able to process, the health information which is generated, and the way non-health data can help inform aspects of populations behaviours that help predict and detect threats as well as how such populations deal with measures implemented.

As emphasised before such response structure needs to be of permanent continuous activity and not only "actionable when crisis is declared". The reasons for this have been elucidate earlier. So consolidating provisional proposals 1.2 and 1.3, having conducted a gap analysis regarding need for further governance and how such a structure could indeed significantly increase the EU capacity to KNOW about its public health, and PREVENT, PREPARE, DEFEND, RESPOND and RECOVER from a cross-border public health crisis I anticipate a final set of policy options regarding the setting up of a permanent structure to support Coordination and Emergency Response. Two good ways to explain and show on an effective and well-coordinated structure could help the EU in public health more broadly and specially during a public health crisis is to:

1. Depict the structure's main activities assuming a "full" policy option is taken
2. Map the preliminary options on the structure with the current or future options regarding the overall EU response to a cross-border health threat

3.5.3.A Understanding EHDA/"the center" activities

To show how the structure would undertake its roles and serve its mission during a crisis and in between crisis, an illustrative set of main operational activities/services it would entertain are shown in table 4. These are just illustrative and do not aim to be exhaustive. The rational for the emergency activities is presented to the right, to allow the linking with the following topic. Helping to clarify how could this structure add value to already existing tools, processes, and digital services.

Table 4 – Non-exhaustive list of EHDA's/The centre regular and emergency activities

"EU DATA	Activities of the Centre		
Function/ Characteristic	Main Regular Activities	Main Emergency Activities	Rational in emergency
Data utilization during a crisis	Preparatory activities with EU agencies and MS on "crisis" data labelling, testing emergency data collection. Update skills and processes in MS	Collection of emergency (FAST) data. New dataset definition. Quick decision on dataset update. Technical and quality data control	Fast, Abundant, Standardized and Total Data (FAST DATA) is needed
Network of actors	Sustain networking, run data collection and utilization scenarios, mature education and data science culture	interpretation meetings; Trouble shoot legal, political and technical data blocks. Provide data and data analytics services	Providing value to ecosystem actors is key
Data harmonization/data authority (common European strategy on how to collect data)	Work though existing, or autonomous policy/political sructures to harmonize data related proceses. Follow up on public health datafication strategy. Network with Horizon Europe; DEP and	Emergency harmonization of "new" datasets: Emergency case definitions; data associated with new tests; new treatments/vacines/procedures. Emition of mandatory data collection standards	Capacity to gather new data fast, but with similar
Emergency Coordination and Response	Testing and Simulation exercises	Main Focus of leadership attention	Focus on supporting EU-level and EU-contextualized decision making
Using AI tools	testing and development. Colaboration wih academia. Maturing "emergency" ethical and legal protocols. Data science education. Building public trust	USING AI tools for continous modeling of the crisis, activate protocols and recalibrate algoritms	Demonstrate the usefulness of AI modeling. AI obsolencence, bias, ethical and legal risks mitigation.
Data-based forecasting and predictive analytics	Explore data for predicting, antecipating and continous horizon scanning for new detection Ai-based/data based techniques. Forecast health system capacity and resilience.	Predictive analytics and AI modeling and visualization of day-to-day evolution	Daily added-value
Advanced-telehealth capacity	Explain the concepts. Educate, Build capacity for advanced-telehealth services deployment. Work legal and regulatory MS backdrop. Train and simulate.	Activate advanced telehealth capacity in articulation with national telehealth or phone support services. Cater for indidual services. Deploy large scale digital-only operations.	Workforce depletion, burnout or distribution assimetry can be compensated partialy by automated mass healthcare
Real-time personal/case surveillance	Pre establish the ethical and legal conditions. Negotiate with society. Simulate. Devise triggers and controls.	Activate real-time individuals/case surveillance services; Activate misuse continous audit team. Use XAI methods to inform individuals	This is the higest powered digital tool of the Centre. Its control and explaining is key.
Utilization of data on health systems	Gather and harmonize health system data; Build capacity and resilience maps, models and simulations	Track health system capacity and resistance in real-time. Antecipate supply and demain of health services mismatch	Antecipate health system demands and crashs to guide EU emergency aid plans
Utilization of any data with a public health relevance (DPHR)	Explore and study novel (non-health) datasets with potential value in preparednes and emergency. Test such systems. Link with academia.	Active non-health data collection, use tested systems, coordinate the involvement of non-health actors	Only in emergency will non-health actors really see the value of these efforts. Better monitoring of confirment and other social measures

3.5.3.B Impact of a structure like this on the overall (existing or potential) EU response

If we combine policy options regarding overall public health crisis management regimes (provisional options 1 (Page 28) with the proposed institutional vehicles for an EU health data centre (provisional options 4. (page 42) we can simulate the obtained effect on what could be an EU overall coordination and emergency response capacity (Table 5 shows a summary of the exercise). As can be observed not all combinations are possible, and some are more capable of theoretically contributing to a stronger EU level capacity than others.

The most capable of achieving maximum Coordination and Response capacity at EU level, simultaneously having foresight capacity and prevention mobilization capacity is the combination of a European Public Health Authority (EPHA) with a European Health Data Agency (EHDA).

Although very different, both the combination of a European Public Health Authority (EPHA) with a lesser powerful option for the "Reinforcing the role of the ECDC in the EHDS", or the combination of a EDHA option as inside HERA, and supporting the new Regime for responding to public health threats based on changes to proposals by the EC under the pack "European Health Union", making sure HERA mission is broader rather than focusing on emergency response and medical countermeasures response only, can result in a Higher Coordination and Response capacity at EU level, with some foresight capacity.

The option to Approve, with some changes, the proposals by the EC under the pack "European Health Union" – better clarifying some of the "leadership functions" outlined – when combined with either with the option of "Reinforcing the role of the ECDC in the EHDS", or with the option of establishing a stand-alone EHDA, can be a lesser but still effective mechanism to improve Coordination and Emergency Response. The reduction on the effect is not so much due to data utilization but to how effectively data-based decisions could be mandated (on this please refer to discussion on last part of section 4.1).

Lastly, even if there was no decision to co-legislate on the EC proposed pack, any one of the options for a central structure to deal with health data for public health could mean an effect, albeit modest, in overall capacity. It would, however mean underutilizing capacity in the case of an option for EHDA.

Table 5 – Potential effects of the centre on existing or potential EU overall emergency response capacity

		Preliminary options 4. Regarding the institutional frame for an EU Health Data Centre			
		1. **Do nothing scenario**. Maintain existing functions in the different institutions.	2. **Using same institutional arrangements.** Maintaining the existing functions in the different institutions. Establishing four functional regimes via different arrangements	3. **Reinforcing the role of the ECDC in the EHDS**. The ECDC would be the main responsible institution for all public health related data topics, including not only crisis (and in between crisis) relevant data use, but also public health indicators. (plus functions on 2.)	4. **Establishing a European Digital Health Agency (EDHA)**. It mission would be to aggregate all existing capacities and digital health EC competencies (and functions in 3.) while acting as the main governance agency on the European Data Space on behalf of the "health sector" more broadly.
Preliminary options 1.1 The functions necessary for a more effective EU level broad governance of public health crisis	1. **Do nothing scenario**: Maintain existing "governance" agreements under the current Regulations (for dealing with serious cross-border threats to human health; and on the establishment of the ECDC).	AS IS status	Slight improvement in usage of existing EU level information. No increased collection of public health information	Increased utilization of available information with a focus on Comunicable disease and based on low quality MS data	Increased availability of good quality data including non-health data sets; Low usage of digital and data capabilities for decision making
	2. **Approve, with some changes, the proposals by the EC under the pack "European Health Union".** Changes to better clarify some of the "leadership functions" outlined could reinforce a more unified approach hence strengthening a steering function during a crisis.	N/A	Slight improvement in Coordination and Response Capacity	There is an increase in EU-level overall coordination and response capacity but limited to quality of data MS make available (less limited if ECDC leads and use the EHDS for all public health related exchanges then it can benefit form more data being made available to it).	Increased Coordination and Response capacity at EU Level
	3. Approve, with changes, the proposals by the EC under the pack "European Health Union" and **explore the idea of the HERA agency, taking a "all-of-health" perspective** rather than focusing on emergency response and medical countermeasures response.	N/A	N/A	Not compatible options	Very high Coordination and Response capacity at EU level and significant outlook into public health and population health landscape in the EU. Foresight capacity.
	4. **European Public Health Authority**. With full-fledged powers to be activated under certain conditions and in strict articulation with the president of the EC and the president of the Council.	operational, due to the lack of consistent EU-level public	Non-operational, due to the lack of consistent EU-level public health data	Possible improvement in coordination. The ECDC would have access and explore public health data while the EPHA would have the dcision-making and coordination role	Maximum Coordination and Response capacity at EU level. Foresight capacity and prevention mobilization capacity.

3.6. A "European strategy on how to collect data for preventing, detecting and curing diseases"

This section covers the *outlining of* ***the main tenets of a European strategy*** *on how to collect data for preventing, detecting and curing diseases, which could legally and operationally define who does what, how and when under EU law* ***in an emergency context.*** It does so by looking at two distinct, but obviously related, sub-sections. As a preliminary note it is important to highlight that it is not possible for data to be "collected" in a public health emergency context effectively and rapidly, if no "preparatory actions" are ensured, though technological artifacts, rules, procedures and harmonization on data storage and collection from primary sources. Findings from our interviews show this was THE main problem in March-September 2020. There was data in many MS about many aspects relevant to prevent detect and help stop COVID-19 disease from spreading more widely, but it represented different healthcare processes, different case interpretations, was stored in different formats and often scattered into inaccessible non-interoperable manners. Hence, ***any effective strategy for collecting data and using it FOR a public health emergency, it must cover the period of pre-emergency***, the inter critical periods. In this sense it is no different from a preparedness strategy and initiatives. On the other hand, ***if such strategy is to be capable of "preventing" diseases, it must be able to support public health foresight***, and not just merge early detection and alert.

3.6.1. Outline of the main tenets for a "European strategy on how to collect data for preventing, detecting and curing diseases"

A thorough health data strategy outline is far beyond the scope of this study, critical though it is, it would require an extensive study and space for its explanation. Outlining, however, the criteria that would be required for us to be able to say we have or not such common strategy is quite useful. These criteria are, that such strategy is:

1. **European**. This means considering local, regional, national/federal and EU levels. **Common**. There is mutual agreement on the data collection processes and the "meaning" of the context from which data is obtained, this is essential to interpretation, sense-making and building of common information, from sets of commonly obtained data;
2. **Strategic**. Entailing progressive alignment steps, incentives (both financial as well as regulatory), decision-making and priority setting capacities.
3. about **Collection** (focused and not creation-focused). This means that professionals and patients should not be asked to fill in questionnaires or reporting forms. There is a growing need for using automated elements and there should be a minimization of human intervention. Verification and confirmation processes are required, done by humans eventually using semi-automated methodos and tools.
4. about public-health relevant **Data**. Agreement of what data is relevant for public health is a necessity as this can be multiple, depending on the scope of the interpretation of "relevant", which again needs to be commonly agreed. Does it entail only communicable disease data. Is there value in non-communicable disease data, non-health sector data, or even data on behaviours in the digital space?

Such a strategy would need to include, *inter alia*, the following elements:

1. Definition of the care processes associated with the generation of certain data elements. This definition does not have to harmonize care processes interfering with MS health subsidiarity

principle and the prohibition for harmonization. Rather it needs to define the "data outputs" of such processes, from the point of view of public health;

2. Definition of the acceptable technical and semantical requisites for information systems supporting such activities so they can capture the data elements;
3. Definition of the minimum privacy and cyber-security preserving processes and technologies to ensure data is kept safe and uncorrupted in local/regional/national information systems, and ready for data collection;
4. Definition of minimum standards for interoperability and health data quality control, associated with establishing the (legal and European know-how) basis for supporting enforcement authorities and activities of such standards;
5. Roadmap developments and investments needed and, thus, establish a "public health data modernization agenda", with targets, KPIs and a joint MS and EC investment plan.
6. Define the data areas and sources, including non-health sector data. Having an holistic view of public health data needs, not just for longer term, policy guiding health indicators, vaccination coverages, communicable or non-communicable diseases, but rather in an integrated manner. Also, realizing that data relevant to public health threats may include:
    a. Extensive data from non-health sectors
    b. *Impacts and socio*-economical data in real time
    c. Data obtained before the crisis
7. Establish interorganizational and interlevel trust in data sharing. Trust does not come from legislation, or emergency needs. Trust in data sharing is a result of prolonged uneventful relationships and shared meaning.
8. Ensure accountability to citizens, to secure their participatory and legitimizing democratic support. This is vital as an extensive arrangement in health data use is foreseen, even if data can be tokenized and anonymised, and that legal basis can bypass citizen participation. Citizens capacity to trust result from active role of scrutiny agents on their behalf, transparent processes, and sharing of information on risks and benefits.

A full European strategy on how to collect data for preventing, detecting and curing diseases will need to encompass a set of key strategic dimensions, such as: i) Preparedness; ii) Capacity building; iii) Reporting and utilizing all types of data relevant for health; iv) Technology-based public health functions; v) Advanced insights; vi) Foresight and horizon scanning for emerging health threats; vii) Datafication of vertical public health data pipelines; viii) Expanding health data law.

It follows from the previous paragrahs that ***such proposed strategy cannot be limited to be a strategy about how to collect data*** "as is". This would not solve the main four problems: i) lack of data harmonization, ii) lack of public health processes datafication and lack of interoperable and steady data pipelines. In most MS, data in current siloed within health systems, for the most part disconnected even within the health sector authorities, and also even more segregated from relevant data for public health residing in municipal administration or other non-health public administration sectors, or, even worst, when in data may be from relevant private entities (transportation or communication companies). It must ***aim higher to be effective, ensuring ways to reach a data interoperable ecosystem that is relevant for the provision of care in both communicable and non-communicable disease settings, as well as during crisis and in between them*** ensuring a more effective and less burdened health system with regards to data collection and benefiting from its consistency.

3.6.2. Strategy implementation and emergency context

3.6.2.A Opportunities for strategy implementation in current EC proposals

Preparedness Plans

It is during preparedness that strategy makes full sense. Although preparedness was already a concern on the existing legal frame, the proposed decision places this in a much more central stage, as well as, at a much higher level in terms of demands and accountability. While many aspects of preparedness would seem to mix with the competency of MS to organize their health systems, the formulations proposed try to circumvent this is more than one way. Proposed Article 5 benefits to be compared to article 4 in current version[35], bearing in mind the content and set-up of an audit framework on preparedness and response planning (article 8), which includes:

a. A regularity of every 3 years,
b. The ECDC as the agency charged for "conducting audits ***in the*** MS",

   That such audits shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).

The discussion of how an eminently scientific advisory Agency – the ECDC – becomes an auditor of States and their plans, and therefore an international regulator is relevant. Its mission and competencies are equally subject to proposal for changes, new elements that clearly are outside the scrutiny of this study. It is evident that Article 8, add a very heavy and new meaning to the sharing of, and articulation between MS about their "preparedness plans". It is interesting that no regular audits of Union level plans, under the responsibility of the EC itself, seem visible in the proposal. Article 5 of the proposed decision can be compared with Article 4 (of the current decision). While in the existing legal order, MS and the Commission consult "each other", with view to coordinating "their" efforts, the new version proposes that the commission (in cooperation) with MS and the relevant Union Agencies shall establish a Union health crisis and pandemic plan[36]. Article 5(2) and Article 6 create the frame for the national plans, which are to be "prepared" in coordination with the EC for reasons of "consistency". Now, if one looks at the wording of the current and corresponding predecessor, articles 5 and article 4, it its clear to see a paradigm shift, visible in three examples:

1. From "informing and sharing" plans to "centrally coordinate" the preparation of the preparedness plans;
2. From "maintaining their [MS] capacities to "**promote effective and coordinated response**";
3. From a position where MS are expected to "respond" to a state of "Union preparedness and response".

How to achieve this homogeneity of national plans so that they together for part of a Union's response that is coherent and coordinated from the centre without conflicting with the non-harmonization golden rule (TFEU Article 168 (5))?[37]. As such, the EC does not propose legislation to

[35] The regime in the newly proposed Articles 5-8 is substantially different and much more complex then to the one in Article 4 of the current decision.

[36] The term *pandemia* plan is too narrow as it would not apply to non-biological cross-borders non-biological agents

[37] TFEU Article 168 (5)) "…The European Parliament and the Council (…) may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, (…) excluding any harmonisation of the laws and regulations of the MS."

harmonize laws and regulations of the MS in this area, but, by enforcing a process output (data, capacities, human resource availability, etc) it achieves that purpose. It is difficult to foresee how such can be achieved in one year (the preparedness plans are to be submitted by November 2021) without any laws or regulations in MS to create those conditions. Likewise, a common audit framework, does not in itself, harmonize legislation or regulation, but by auditing a significantly detailed set of national health organizational elements, it does, in fact induce some "process" harmonization, which no doubt, is key to a successful national plans integration approach and the realization of a Union response rather than 27 "articulated" national responses. It is worth noting this "relationship" is asymmetric as audits to EC plans are not foreseen. Here perhaps the role of the Court of Auditors (TEU Article 13; TFEU Article 285-287) "*is relevant as its main task is to carrying out the Union's audit with the dual aim of improving financial management and reporting to the citizens of Europe*"[38]. Equally while MS have to "by the end of November 2021 and every 2 years thereafter provide the Commission with a report on their preparedness and response planning and implementation at national level" the commission only needs to report to the Council and the European Parliament in 2025, and every 5 years thereafter (Article 29) about the implementation of the Decision as a whole, and has some "editing and publisher" function of the MS and Agencies received plans (Article 7 (2)).

Governance through reporting and data

Two additional "harmonization" or "integration" processes, using structured reporting and data reporting, result from Articles 7 and 14. Article 7(2)(3) creates the conditions for governance by influence or use of indicators. Article 7 enforces in effect a "template/report"-based governance. Dissecting the new highly advanced Article 14 (Platform for Surveillance) will be detailed in coming section 7. At this point it is enough to say, that its provisions together with the allowed implementing decisions, create the conditions for a pan-European health information network that could extend literally from every healthcare providers IT system, to EC services and even the Union Agencies. Namely number 6 clearly creates conditions for interoperability setting rules in vast array of healthcare datasets. Setting interoperability rules on data, indirectly can influence documentation and even care processes. Again, this can be seen as a very subtle, yet potentially quite powerful way to "harmonize" certain healthcare practices.

Governance (network/influence), legitimacy and data law

Concentration of power by the EC is evident in the proposals advanced. It seeks to occupy a power vacuum that was always there in the previous regimes. The collegial nature of the decision-making architecture, with no central driver but rather a "moderator" function, is capable of dealing with inter-crisis processes and decisions. When strong, and fast decisions had to be made, the regulatory regime under Decision 1082/2013, has proven to fail significantly. The Council and the Commission, through other mechanisms and its core powers, were forced to step in. By April 2020, and then subsequentially, more coherent efforts started to show. This was partly the result of late, but decisive, action by the EC, and partly by a process that ALEMANNO calls Regulatory Emulation (7), and that could be looked as governance by network/influence, present in many global regulatory regimes (36)

When analysing the emergent nature of a "network governance" two elements stand out with regards to the position of states. One is the formulation, in Article 7 (1), where States are placed at the same level as Union Agencies *vis-à-vis* the EC, in "The Commission, in cooperation with MS and the relevant Union agencies". The second, perhaps even more worthy of attention, is that according to Article 8(1) it is not the EC itself (a Union institution according to Article 13 of TFEU(1)) but rather an agency that will conduct audits "in the Member States". How accountable is the ECDC politically

[38] Court of Auditors website - https://www.eca.europa.eu/en/Pages/LegalFramework.aspx

to MS? What is its participatory ethos? What are the reporting lines from the ECDC to the Council or the European Parliament? These issues are fundamental as basis for the legitimacy that will be required. No longer solid scientific track record will be enough, as used to be the case when the ECDC was mainly a scientific advisory agency, rather political legitimacy of some sort. This is needed to lend support to audit criteria and processes, proposals for guidance and advice, and, during crisis, to uphold a central role in decision-making. Conscious of this, the EC proposes a simultaneous change of the Regulation that established the ECDC, 15 years after its onset. Law regarding data use is often associated with data protection, but this study opens a research window into the study of a new element. That of using data flows, compulsory reporting and audits, as law enforcing-mechanisms for exerting indirect (governance) influence onto "processes" that are national, hence "subsidiarity unreachable". I call this international regulatory regime as "Data Law".

3.6.2.B Legal and operational definitions of who does what, how and when under EU law in an emergency

During an emergency context, if all elements proposed [(i)an established authority – part of an Agency or a stand-alone EHDA; (ii) a published and sustained Common Strategy for Health data, and (iii) an ongoing modernization and datafication process of all four levels of the public health data ecosystem) are in place the best legal and operational setting is to make the data authority participate at the highest possible decision making levels (the HSC and even at some critical EC/EU Council high-leadership decision making forums).

The legal mandate of either HERA (understood with a border mission then presently under discussion) or a EHDA should contain the provisions for "emergency" only digital services, such as some advanced analytic solutions, definitely persons surveillance via digital and AI powered tools, and the opening of digital therapeutics and digital interaction services direct to EU citizens. These services are to be run under the most strict protocols and the data to be used must be destroyed as soon as circumstances immediately allow even if this reduces the usefulness of the solutions pondering proportionality judgements to which data protection and courts authorities should be invited to participate.

The concept, scoping, clear description, and legal ethical and cybersecurity safeguards of "emergency only public health digital services" should be formalized, formally approved beforehand. These should be tested, simulated, and show to the public as part of general preparedness schemas run by the EC. In addition to general communication to the public agency responsible for these services must ensure an open individual accountability policy. Explaining these services to each citizen should be guaranteed during and after emergency, and when they utilize AI, explainable AI (XAI) methodologies should be ensured(38).

3.7. Outlining the potential and challenges of a EU Public Health Data Space and its usage of Artificial Intelligence

Irrespective of the scope, mission, capacity, institutional home or of its temporary versus permanent nature the EU health data centre/European Health Data Agency, is foreseen to have to engage with the usage of AI technologies in the context of the "gradual establishment of a cyber-secure, risk-free, privacy-strict data space that will be able to help the EU to *collect vital data and* ***algorithmically use it".*** The study order expected that it could:

> *prove vital in helping to* ***understand both the potential but also the challenges*** *associated with the gradual establishment of a cyber-secure, risk-free, privacy-strict data space that will be able to help the EU to collect vital data and* ***algorithmically use them to identify behavioural patterns, flows of people, spot necessities, locate them, identify dynamics and run predictive analytics.***

This section will first deal with the issues around the progressive establishment of a cyber-secure, risk-free, privacy-strict data space to collect vital data is a very superficial manner. The follow sub-section will explore the aspects related to AI usage in processing such vital data. Finally, it is relevant to analyse Article 14 in the new proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU (2) as it entails a completely new provision called "Surveillance Platform" which can be the legal leverage point for the establishment of the described space, or actually become a lost opportunity to devise such a space adequately and in due coordination with other EU legal initiatives such as the forthcoming Regulation on the European Health Data Space or the Regulation to establish HERA.

3.7.1. Issues around the progressive establishment of a cyber-secure, risk-free, privacy-strict data space to collect vital data

The issues around the progressive establishment of a cyber-secure, risk-free, privacy-strict data space to collect vital data would be worthy of a complete separate study due to its complexity and ramifications. The current ongoing work for the conceptualization of the EHDS will obviously require such in-depth considerations. At this stage, and for the purposes of public health response there are only a few elements I would like to raise awareness to as a humble contribution:

1. There is no absolute cyber-secure space. This is of course obvious, but it also means that if hybrid (public health and major cyber-incident) threats are to be mitigated than, any digital system on which the Coordination and Emergency Response has to relay upon needs to be conceived, maintained, stress-tested, and defended as a CRITICAL infrastructure at the EU and MS level, which follows from NIS Directive and ENISA's guidelines and action but more importantly it has to be resilient, capable of running it in an emergency mode, while supporting maximum demand for its services. This means digital services "emergency" more under a cyber incident, cannot be designed at the expense of a reduction in its inherent function as a "emergency" support system. Otherwise the system is resilient, but at the expense of compromising public health response resilience. How can this be achieved? Redundant IT solutions, by-pass mechanisms, and contingency design, testing and infrastructural capacity.
2. There is no risk-free data space. If we are covering cyber risks, data protection risks, human rights and discrimination risks or simply the risk that such a space does not serve its originally intended purpose – i.e. it under performs – the only thing we can do to really build resilience is to: 1) accept these risks do exist, and have associated probabilities; 2) these risks can be measured in anticipation; 3) a risk management plan, devising restore and repair actions as well as risk minimization initiatives is more realistic that assuming a risk-free space can be designed and sustained.
3. Privacy is a contextual variable. In one moment, what is private, may cease to be so depending on personal trade-offs and or legally induced personal trade-offs. This means that a privacy-strict data space holding vital data in the EU, can only be clearly conceptualized if EU-level clarification on what constitutes privacy rules for public health data and vital data stored or processes by a EU central structure is attained. Otherwise, different interpretations of MS constitutional and GDPR and related law, could mean that the criteria to be full-filed are different, which would create grounds for legal insecurity undermining trust in the strategy and its final purpose: to use such EU aggregated data in advanced analytical ways to advance public health protection and promotion, particularly in cases of cross-border health threats. The preliminary opinion 8/2020 (39) on the EHDS emitted by the European

Data Protection Supervisor (EDPS) is a quite useful piece of guidance and additional focused opinions should be formally requested.

3.7.2. Potential and challenges associated with using AI for public health crisis

This subsection will deal with a preliminary analysis of the potential and the challenges associated with the ability at the EU level to ***algorithmically use*** vital data collected for six public health purposes.

Algorithmic use of data encompasses the use of simple somehow static algorithms, or the use of AI tools. Both have invaluable potential use for exploring health data. The first have well documented extensive evidence supporting their usefulness and raise less ethical and societal issues, then the less well establish AI-based technologies and methodologies. AI can be characterised by four broad technologies:(40)[39] AI is primarily used to augment human decision-making, and significant benefits are forecasted if AI is implemented profusely in health systems in five main domains (41)[40].

3.7.2.A Brief overview of AI usage for multiple public health purposes

Artificial intelligence potential include, among others, improved and faster diagnoses, improved clinical decision-making, tailored treatment interventions (personalised care), new treatment opportunities, improved health care delivery with higher efficiency and assisting in tackling staff shortages (42) (43). AI in general, and Machine Learning-Clinical Decision Support Systems (ML-CDSSs) in particular, has the potential to better exploit the vast amount of data that flows to hospital EHRs 16) or other systems for supporting clinicians in diagnosis, triage and choice of treatment as well as public health professionals in their attempt to process large amounts of heterogenous data. Of undoubtedly necessity, a fully detailed study on this is outside the scope and size of this report. Different AI techniques have been started to be experimented with good results in medicine (44)(45). EI XING et. AI describe in detail the future landscape of AI in medicine and its new challenges(46) including in the fields related to public health. AI has been used for Surveillance in Public Health in general (47) encompassing identify behavioural patterns, flows of people, spot necessities and locate necessities (48) and forecasting, for example in seasonal flu (49). It has been used by researchers in fields like urban mobility as well as telecom industry to study the flows of people, but regulatory, social and ethical issues of different nature arise in its application in medicine in general (38) and public health in particular.

3.7.2.B Legal dimensions and AI for public health

We can look at AI-based technology as a commercially available product in the EU, hence subject to Product Liability Directive (PLD) and related liability law, and, because its use is anticipated in the health area, it can potentially fall under the Medical Device categorization with its profound legal

[39] Four broad AI technologies are: *Natural language processing (NLP).* The ability to parse human language, extract meaning and sentiment, and reply intelligibly is transforming communication with each other and with machines; *Computer vision.* It comprises the extraction of information from images; *Machine learning.* Comprises programmes and tools, like neuronal networks or deep-neuronal networks, that recognise patterns in data and make predictions based on those patterns. -learning from data. The distinctive feature is that the system must learn the mapping from input to output by itself – there is no explicit *a priori* model provided to the machine; and, *Robotics.* Covers machines' physical interactions with the human world. In a simplistic way it is basically ***hardware moving under the control of AI software***.

[40] Five domains of high expectations for AI in health include are: 1. **Better forecast population trends**: Data science can more accurately predict disease burden and costs, identify high-risk patient groups, and target prevention therapies. 2. **Deliver more preventative care:** Most healthcare expenditure today is focused on treatment rather than prevention. 3.**Further personalise treatments:** Using results from large population studies, AI could combine genetics, biology, behaviour, and patient preference to select the most effective and appropriate treatment pathways. 4.**Improve the user experience:** In the future, virtual assistants will provide clinicians with the latest research at a single voice command. Patients, too, will have access to health advice and lifestyle support from their mobile phones. 5. **Improve productivity and reduce costs:** AI can automate and optimise tasks across a hospital.

ramifications. The second way to explore legal implications, which may be more relevant to AI usage to explore data for public health purposes relates to the fact that these products are built on data (in the case of health, a specially protected type of data – personal health-related data). In addition, to provide personalized outcomes, they need nominal data, and profiling of everyone, to eventually provide an automated decision, based on a ML algorithm. In summary:

1. Regimes ***aiming to protect individuals from risks of harm to their health/life*** due to defective products and or inappropriate/inadequate use/safe use of AI-based medical devices – PLD and MDR related regimes, which are to some extents less relevant for this study, hence, will not be covered any further, [and],
2. Regimes ***aiming to protect individuals from risks of harm to their rights regarding the processing of personal data*** and to other fundamental EU/national rights – CFR, GDPR and NIS Directive related regimes.

A profound in-depth discussion on legal aspects of AI usage in health is outside the scope of this study and could constitute a useful study, particularly if options towards dedicated legal instruments on health data are pursuit. Some elements are, nevertheless useful as they are relevant to inform policy options on the use and the extent of use of AI for defending public health, in particular serious cross-border threats to human health, and when these options may imply new or adapted legal instruments.

As healthcare digitalization progresses, and more processes start to relay on AI-based information systems this will lead to increasing problems in health and care services, with higher potential, and real, impactful harm to individual humans' health and life. Such increased the relevance of looking at liability implications of when things do not go so well or very wrong with a powerful yet quite unknown technology.

AI technology is considered to have the potential to revolutionize health and care, however, one most ensure proper protection to all relevant legally protected interests is set in place. White paper by the EC point to numerous benefits as well as challenges for societal use of AI (50). It refers healthcare examples, namely imaging AI software and identifies health and public sector as areas of high relevance and complexity, due to the potential to help save lives and provide better care alongside the challenges of safety risks and privacy concerns.

When considering AI use in health, other risks to legally protected interest exist that extrapolate those directly related with defective products supplied by AI-based product manufactures. There are two reasons for this:

1. AI-based products are used by professionals, who can make decisions regarding all aspects of medicine, public health, and decisions of resource allocation and prioritization. This means there is a risk that results from medical malpractice or public health inadequate decisions due to defective AI suggestions/decisions, or due to defective use of these AI-based tools.
2. These products use, and explore data, which in the case of health, is not just personal data, it is health data, a specially protected type of personal data under the GDPR. Risks to privacy and harm to other rights protected by the GDPR, namely in relation to the use of automated decisions and profiling are always major issue but become even more salient in health.

This is particularly interesting and relevant if we are not talking about fully anonymised data sets as a basis for AI analytics but rather exploring AI to address public health issues of particular individuals, or groups of individuals (for example exposed to an index case or at a particular selected higher risk of contact with a contagious disease). We enter a personalised data remit where the legal regime is naturally more challenging.

Legal regimes related with risks of AI use in health to legally protected interests of citizens: rights of the data subject

The 2016 General Data Protection Regulation (51) implies a new set of rules, with stronger enforcement on health data classified as a special category of personal data (art. 9º) specially obligations in case of data security breaches (52). Artificial Intelligence and the protection of personal data are intertwined. Artificial Intelligence applications in many ways is therefore subject to the GDPR.

The Regulation applies when the controller or processor is established in the European Union (EU) or when the processing activities relate to data subjects in the EU (GDPR, article 3). Therefore, it clearly applies to public sector health in the EU. Controllers are subject to the principle of accountability (GDPR, article 24). In practice, he or she shall "implement appropriate technical and organizational measures" to ensure compliance with the Regulation's requirements (ex: encryption or pseudonymisation). These measures will be determined on a case-to-case basis depending on the type of business, the number of data subjects, the type of data processed and so forth. This means that any absence in necessary diligence in data protection is made unlawful or illicit by GDPR and regardless of national law due to the nature of the regulation. The appropriate measures must also be determined by carrying out a data protection impact assessment when the processing "is likely to result in a high risk to the rights and freedoms of natural persons" in regard to the nature, scope, context and purposes of the processing (GDPR, Article 35). Article 29 Working Party (WP29) published guidelines regarding data protection impact assessment on October 4th, 2017. This new obligation under the Regulation reinforces the accountability of data controllers.

In practice, data controllers such as public sector health organizations, have the responsibility to adapt their procedures to conform to the Regulation and may have to incorporate or modify their organisational and technical measures accordingly. If this is evident for older technologies like EHRs, it is perhaps even more so with regards to AI-based technologies. Because some of the principles within the GDPR are particularly challenging for the very nature of AI technology and because explicit legal grounds are needed for lawful use of health data, and especially for machine made decisions (which includes profiling or in addition to profiling). Article 5 of the GDPR lists the principles relating to processing of personal data. It namely holds that the personal data must be processed in a *transparent manner* in relation to the data subject. It also holds the *principle of data minimization* under which only "adequate, relevant and limited" personal data can be processed in relation with the purposes of the processing. However, this principle seems in contradiction with the essence of Artificial Intelligence. Another aspect to consider is the right of data subjects "not to be subject to a decision based solely on automated processing, including profiling" (GDPR, article 22) AI technologies are directly concerned as an automated process.

The WP29 has published a very important guideline on Automated Decision Making and Profiling s (53), thus providing an official interpretation of many of the issues regarding AI and GDPR. Since most AI applications depend on either Automated Decisions (as their desired output, even if using a rules-based system and not Machine Learning-type algorithms) or the building of a personal profile – profiling – to allow prediction to be made for a particular individual based on statistical inferences from similar sub-groups/clusters or cohorts of individuals, clearly Article 22nd is pivotal to understand AI-technology use in health. So no doubt that profiling fits Article 22 criteria, and yet, the usage of AI can be applied assuming an lawful exception is evoked. The exceptions include:

1. necessary for the performance of or entering into a contract;
2. authorised by Union or Member State law to which the controller is subject, and which also lays down suitable measures to safeguard the data subject's rights and freedoms and legitimate interests; or

3. based on the data subject's explicit consent.

It seems that only under Union or Member State law with details on the "suitable" safeguard measures. Actually, recital 71 presents examples of situations where such laws could make sense, for example, "for monitoring and preventing fraud and tax-evasion, or to ***ensure the security and reliability of a service*** provided by the controller". Clearly the implementation of AI in public health is aiming towards ensuring its security and increasing is accuracy and therefore the reliability of public health services/decisions, as a service that needs to remain safe (low false negatives and low false positives) and worthy of trust by the population as well as by healthcare professionals. In any case "appropriate safeguards" are required, and these include:

1. the right to be informed (addressed in Articles 13 and 14 – specifically meaningful information about the logic involved, as well as the significance and envisaged consequences for the data subject),
2. the right to obtain human intervention
3. the right to challenge the decision (addressed in Article 22(3).

Since this is considered always a processing likely to result in a high risk to data subjects the additional requirement to the controller is that it needs to carry out a Data Protection Impact Assessment (DPIA). Finally, an automated decision-making (described in Article 22(1)) that involves special categories of personal data (such as health data) is only allowed under the following cumulative conditions (Article 22(4)): (i) there is an applicable Article 22(2) exemption, and, (ii) point (a) or (g) of Article 9(2) applies.

Regarding 9(2) (a) - the explicit consent of the data subject – this is problematic in triage situation, as in many other acute care settings and in this case data subjects will have ***the right to obtain human intervention on the part of the controller***, to express his or her point of view ***and to contest the decision***. This is obviously impractical in an emergency triage setting. They have the right to receive a justification of the automated decision. An issue arises when AI becomes so complex and processes such voluminous data that a justification cannot be given. Some authors (54)(55) have suggested for example the use of counterfactual explanations as a method to help solve this "black-box" problem. Regarding 9(2) (g) - processing necessary for reasons of ***substantial public interest***, on the ***basis of Union or Member State law*** which shall be ***proportionate to the aim pursued***, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and interests of the data subject – it is conceivable for the public administration to justify a substantial public interest in more adequate triage, and better use of available public resources in hospitals, it would need to be supported by a Member State law, which creates the lawfulness conditions for such public administration use of AI in triage, as in many other areas of healthcare one can generalize.

In summary, using **automated decisions and profiling is possible**, but since, particularly reinforced for health data, there is a general prohibition principle and such type of processing can only be lawful, ***if adequate exceptions are chosen and safeguards are guaranteed***. If these exceptions do not apply to the particular case, or if they do apply but the data processor does not ensure and comply with all safeguards, then such processing is breaching GDPR regulation and the data owner and data processor may be liable under GDPR liability regime. AI systems used for public health, that are based the creation of individual profiles - profiling techniques - even if temporary in nature, fall under data processing mechanisms for high sensitive data. They are forbidden in principle, and possible under two relevant exceptions:

1. The provision of valid consent to be subject to automatic decision – this means Explainable Artificial Intelligence (XAI) methodology provisions need to be clear, and

doubts about which healthcare settings create conditions for an open, comprehensive, and free consent exist. The right to object is an additional issue. This exceptional route does not seem to be the most viable option in healthcare, as trade-offs between consenting and receive care, especially in emergency situations, may raise additional legal and ethical issues. However, for situations like active surveillance post diagnosis for example using remote sensor technologies coupled with AI technologies for "overseeing" large numbers of patients this could be an ideal solution.

2. If this data processing is necessary for reasons of public interest (where public health and in particular serious cross-broader treats to human health), according to EU or national law, in proportion to the aim/purpose, respect the essence of the right to personal data protection and if the adequate and specific measures are ensured to safeguard the fundamental rights and the interests of the data subject, which may include technical developments within XAI methodologies still somehow.

One of the major risks to data privacy, but equally to the performance of an AI system is the cluster of cybersecurity risks, or more generally information security risks. In fact, not only cyber threats can expose otherwise well processed data, allowing for non-authorized access to happen and a series of potential and real harms, but also, and more worrisome, cyber incidents can compromise the functioning of an AI solution, with or without an immediately noticeable trace. In this second case, outcomes of the AI algorithms could be defective and lead to human misjudgements, for example, in semi-autonomous decision-making systems, as is likely to be the case in AI-based triage systems. To provide protection against these illicit third-party influences in information systems EU law has advanced a Directive targeted to reduce cybersecurity risks, but also to set in motion a responsibility and awareness framework.

The Directive (EU) 2016/11481 shortly known as the NIS Directive, is the first European legal document specifically targeting the improvement of cybersecurity throughout the EU. It includes health as an essential service, and it sets up a Cooperation Group. Member states must create a legal framework and identify Operators of Essential Services (OES) in their territory and comply with several binding provisions defined nationally and ensure to take appropriate cybersecurity measures. The directive recognizes healthcare providers (HCPs) – hospitals and private clinics – as OES. Criteria for their identification is not clear. Possibly any system at EU level that deals with public health data needs to be consider as an OES.

3.7.3. The new article 14 - "Surveillance platform", AI and a broader EU public health data strategy

The topic of AI has been extensively reported to the EP by a set of relevant studied (24) and its use associated to conventional data mining tools to explore data in EHRs is increasing (56). This points out to the value of these technologies, its dangers and the set of technical and human resources needed to make it use safe ethical while at the same time effective and forward looking. In article 14, algorithmic use and AI are not a substantial part of the text, yet its reference, particularly in the context of the word "surveillance platform", may trigger significant reactions and backlash hence its analysis is worth detailing. Any significant legislative mistake or lost opportunity here could risk jeopardizing many of previously discussed AI-based digital services useful, in certain contexts under strict conditions, to help in emergency public health contexts. The second reason why such detailed consideration should be undertaken is that this article is so far the ***closest legal text to a "EU public health data strategy"*** that we can find proposed by the EC and under present reading by the European Parliement but it is very far from what is needed as explained extensively in this study. MEPs should be made aware of this distance so as not to be surprised by the humble results that may come to fruition a few years later when we may come to realise how a full-fledged strategy was

really needed. Nevertheless, in the correct frame and followed by additional policy choices it can be an embryo and a link between strategically scoped legal acts and operational and concrete ECDC and EU public health tactical needs.

The discussion on this topic results from four main sources. Interviews with EC and MS representatives; insights from interviews with US CDC data experts; findings and experiences obtain from non-EU non-US countries such as South Korea, Hong Kong and Singapore/Japan; and , finally, the author's experience in national level AI projects, and his research legal aspects of AI in health. An in-depth study of the proposal should be done regarding its scope, the AI elements and the harmonization potential and instruments.

3.7.3.A Brief preliminary analysis of aspects of article 14 (version of 11 november 2020)

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU (2) contains an completely new provision under article 14, this is:

Article 14 Platform for surveillance

1. The ECDC shall ensure the further development of the digital platform ***through which data are managed and automatically exchanged****, to establish* ***integrated and interoperable surveillance systems enabling real-time surveillance where appropriate****, for the purpose of supporting communicable disease prevention and control.*
2. The digital platform shall
(a) enable the ***automated collection of surveillance and laboratory data****, make use of information from electronic health records, media monitoring, and* ***apply artificial intelligence for data validation, analysis and automated reporting****;*
(b) allow for the computerised handling and exchange of information, data and documents.
3. Member States are ***responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely and complete information, data and documents*** *transmitted and exchanged through the digital platform.*
4. The ECDC shall
(a) ***monitor the functioning of the integrated surveillance system and share regular monitoring reports*** *with the Member States and the Commission;*
(b) regularly inform the HSC on the ***timeliness, completeness and quality of the surveillance data*** *reported to the ECDC and transmitted and exchanged through the digital platform.*
5. For epidemiological purposes, ***ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes****.*
6. The Commission ***shall adopt implementing acts for the functioning of the surveillance platform which lay*** *down:*
(a) the ***technical specifications of the platform****, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures,* ***data dictionaries, exchange of protocols and procedures****;*
(b) the specific rules for the functioning of the platform, including to ensure protection of personal data and security of exchange of information;
(c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;
(d) the cases where, and the conditions under which the ***third countries and international organisations concerned may be granted partial access to the functionalities*** *of the platform and the practical arrangements of such access;*

(e) the cases where, and the conditions under which the data, information and documents referred to in Article 13 are to be transmitted using the platform and the list of such data, information and documents; and

(f) the conditions under which the ECDC can participate and be granted access to health data accessed or exchanged through the digital infrastructures referred to in paragraph 5.

Regarding Nº1 three general observations are due: (i) the proposal is bold, when read in all its amplitude and under a "broad interpretation", (ii) it has data and health data ramifications that go significantly beyond the scope and purpose of this study and indeed even its intended intention, and, (iii). without a significand development both in a legal as well as organization maturation, this surveillance platform may result in just a slight improvement and visibility to projects already under way by the JRC or some universities where AI is used to help alert systems.

Depending on the level of detail and the decisions of what constitute relevant health data and data about healthcare, the platform may be collecting a little more than current TESSy and EWRS systems do, highly dependent of irregular quality and frequency of data outputs from MS, or it can literally "set to receive" very detailed health data of many human healthcare encounters, laboratory data and even personal data not immediacy associated with health and diseases, but that, upon the onset of a health crisis can become relevant, such as data on personal mobility, data on person-to-person interactions, data on travel options (planes, trains, bus, metro stations and even metro doors utilized). On the other hand, when combining "real-time surveillance" with "for the purpose of supporting communicable disease prevention" (nº1), and the utilization of AI for data analysis (nº 2 a)) one can anticipate the capacity of a AI-based IT platform with the capacity to (in real time) suggest the control of certain human actions in the vicinities of a case or a potential case (of an emerging new disease). This is as exciting for real-time digital-powered public health – personalized public health (57) – as it is potentially scary.

4. Policy options

4.1. General considerations on option analysis

The effects of the fragmented and uncoordinated response to COVID-19 are obvious and they call for new realistic, yet audacious decisions upon presented and substantiated thought-provoking policy options that could address the effects of the fragmented and uncoordinated response to COVID. Upon the detailed analysis of the many interrelated topic regarding the study of a EU Data Centre for Emergency Coordination and Response, and the establishment of a common European strategy on how to collect data many options and ideas have been identified regarding particular subtopics, but that need to be aggregated into logical and consequential "**option composites scenarios" or MAIN OPTIONS, so these can be subject to a viability test.** In these the four data functions are considered together in their capacity to lend support to a more agile EU-level decision-making capacity in preventing, detecting, alerting, responding, and recovering to large cross-border crisis. These four data functions are:

1. Datafication of public health, and other relevant health contexts;
2. Harmonization of health data
3. Effective and reactive data pipelines
4. Advanced insightful data analytics capacity

Policy options were asked with regards to:

1. Create an "EU Data Centre for Emergency Coordination and Response"
2. Establish a common European strategy on how to collect data

Initial study specifications asked this study to broadly:

> *(…) perform an in-depth analysis of the challenges associated with the lack of a centralised governance structure for emergency coordination and response as well as the absence of a well-defined common European strategy on how to collect data in a public health emergency context.*
>
> *The development of a centralised governance structure that will allow the seamless gathering of credible and comparable data and contribute to the shaping of a common and well-coordinated data collection, reporting and testing framework especially in the context of a public health emergency needs to be examined in detail.*
>
> *The study should examine whether the establishment of an EU structure of this kind fills in an actual governance gap and carries the potential for strengthening the European risk management response to cross-border health threats.*
>
> *Such a structure should be grounded on an elaborated European strategy on how to collect data for preventing, detecting and curing diseases. The study should also devise the main tenets of such a strategy that could legally and operationally define who does what, how and when under EU law in an emergency context.*

And in detail to see how:

> *The establishment of an EU Data Centre for Emergency Coordination and Response* ***should allow the seamless concentration of data and their algorithmic use*** *to provide immediate solutions in an absolutely secure space.* ***The Centre would operate in pre-determined times of emergency in coordination with the Member States, which will also be co-owners of the Centre****. In its operational structure, the Centre* ***would operate with the maximum discretion and mechanisms that can "delete" the digital traces and the meta-data of the engagement of the Centre with citizens****, so as to guarantee their maximum privacy and incentivise their maximum collaboration.*

Within this frame, the study should ***give consideration to having in place criteria, indicators, monitoring systems and accompanying measures including a robust surveillance strategy based on enhanced testing, which thoroughly and continuously monitors the epidemic by gathering comparable data among Member States****.*

Given the recent Commission's initiatives towards the gradual establishment of a common data collection narrative and reporting hub, the study is expected to develop a wide range of realistic and thought-provoking policy options that could address the effects of the fragmented and uncoordinated response to COVID-19 and ***propose an effective and well-coordinated response structure at the EU level without*** *prejudice to the existing allocation of competences between the EU and its Member States.*

Main aspects with regards to the elements sought by the study can be summarise in:

1. No structure with the outline of "such a centralized structure" as asked for by the study currently exists, or can be said to be envisioned in currently communicated and proposed texts by the European Commission, or being conceived in the same manner in any research or EU funded project.
2. No EU health data strategy exists as of today.
3. Significant and abundant academic and grey literature as well as interviewed experts and authorities agree that the lack of well harmonized, timely, analysable, and sharable data could have had significant impact in early COVID-19 pandemic response. Even more in the ongoing management, anticipation of 2nd and 3rd wave and coordination of more effective EU-level measures and anticipation of steps.
4. No clear, effective, and participated EU-level coordination mechanism existed nor was it supported by state-of-the-art digital technology, AI-based tools, and good quality data and data science and analytic capacity.

Existing legal proposals, both from the perspective of a European Health Union, and from the perspective of the Data Act and AI-related legislation, or current debates on the European Health Data Space initiative and legislation intention contain no elements that show these alone can create the legal and organizational conditions at the EU level to address aforementioned points 1. and 2. with the views to avoid what happened and is happening as described in 3. through a better use of health data at EU level (point 3.)

Additionally, the study sought for contributions regarding the way the structure could operate in emergency circumstances and how it could use data effective securely, ethically, and algorithmically exploring AI potential. Those considerations have been extensively detailed and have the following implications for option analysis:

1. It is easier to concentrate high technical expertise and retain staff exquisite knowledge required to operate such advanced digital technologies in a critical context under intense scrutiny and stringent legal, ethical and accountability conditions, than to have different data processing functions distributed across organizations
2. There are significant insecurities and uncertainties related with advance data technologies used in public health, particularly in crisis circumstances, that benefit from a clear mandate to prepare them, technically and sociologically, as well as to test and simulate their effects.
3. Strong policy and legal arguments will be required to effect significant changes to data ecosystem within MS. Guidelines, available standards, even occasional investment have not been prized with interoperable easy to collect health data. Datafication of public

health requires education, investment, and powerful legal incentives. A strategy that has a weak legal basis will mostly likely produce some change in digital public health but may not result in the Fast, Abundant, Standardized and Total Data (FAST DATA) which is needed for significantly impact on EU-level and MS-level data-driven public health action, during and in-between crisis.

4.2. Preliminary policy options

Framed in the context of "*the recent Commission's initiatives towards the gradual establishment of a common data collection narrative and reporting hub*", the study was expected to "*develop a wide range of realistic and thought-provoking policy options that could address the effects of the fragmented and uncoordinated response to COVID-19 and propose an effective and well-coordinated response structure at the EU level without prejudice to the existing allocation of competences between the EU and its Member States*".

Accepting this frame, and that no changes to the allocation of competences between the EU and its Member States[41] are to be considered, supported in all previously presented material the following options seem to be available for policy with regards to:

1. An EU level Overall coordination mechanisms (as a background for different requirements and *modus operandi* with relation to an EU data centre and a common European Strategy)
2. An EU data centre for emergency coordination and response in the context of a common European strategy on how to collect data

In more concrete terms the study resulted in four sets of preliminary policy options, which consolidated (preliminary options 2 were transformed in preliminary options 4.) into three sets:

1. Preliminary options 1 – The functions necessary for a more effective EU level broad governance of public health crisis
2. Preliminary options 4 – The institutional frame for an EU health data centre
3. Preliminary options 3 – Solutions for a common European strategy on Health data collection

While all these options, help policy makers to think of the different nuances and elements that can be beneficial or detrimental in each. However, these options, are not all mutually exclusive nor can they be combined in all possible configurations. Some combinations are illogical (Not Acceptable) or highly likely to result in a very weak policy solution due to inherent incoherence.

Lastly, once a set of main options is reached then a Viability test also should be performed. STOA methodology suggests a minimum of criteria against which well-developed options allow policy-makers to differentiate between them on the basis of their performance against: i) Cost and benefits; ii) Feasibility and effectiveness; iii) Sustainability; iv) Risks and uncertainties (that may occur at some point in the future and have the potential to impact the policy and its objectives); v) Coherence with EU objectives; vi) Potential ethical, social and regulatory impacts.

[41] This is worthy of a brief note as an equally relevant study could have been conceived on the value, opportunity and, indeed, necessity of a more profound change regarding a true "Health Union", with central control mechanisms, goals and policy setting, as a way, or eventually the best way to actually secure Europeans against relevant smouldering public health crisis (like obesity, mental health and other non-communicable diseases) as well as sudden crisis, like a pandemic, or other more dangerous, potentially hybrid, sudden cross-border threats.

4.3. Final set of individual policy options

This part recapitulates from main text the three final sets of options create 12 options, without detailing their rational has that has been extensively covered before.

4.3.1. Individual options about the functions necessary for a more effective EU-level broad governance of public health crises

A centralized governance structure operating as a **sort of cockpit function** would be beneficial. It would nevertheless rest on a complex high-level set of aggregator sub-leadership intelligence hubs (ECDC, DG SANTE, EC president Cabinet, ERCC etc). Four options are outlined:

4. **Do nothing scenario**: Maintain existing "governance" agreements under the current Regulations (for dealing with serious cross-border threats to human health; and on the establishment of the ECDC).
5. **Approve, with some changes, the proposals by the EC under the pack "European Health Union".** Changes to better clarify some of the "leadership functions" outlined could reinforce a more unified approach hence strengthening a steering function during a crisis.
6. Approve, with changes, the proposals by the EC under the pack "European Health Union" and **explore the idea of the HERA agency, taking a "all-of-health" perspective** rather than focusing on emergency response and medical countermeasures response.
7. **European Public Health Authority**. With full-fledged powers to be activated under certain conditions and in strict articulation with the president of the EC and the president of the Council.

4.3.2. Individual options about the institutional frame for an EU health data centre

Accounting for all presented material and the complexity of the institutional ecosystem four **options** are worth exploring regarding the institutional frame for a EU health data centre:

5. **Do nothing scenario**. Maintain existing functions in the different institutions and no horizontal health data coordination function.
6. **Using same institutional arrangements.** Maintaining the existing functions in the different institutions. Establishing four functional regimes via different arrangements
7. Reinforcing the **role of the ECDC in the EHDS (the centre would be part of the ECDC)**. The ECDC would be the main responsible institution for all public health related data topics, including not only crisis (and in between crisis) relevant data use, but also public health indicators. (plus functions on 2.)
8. Establishing a **European Health Data Agency (EHDA).** It mission would be to aggregate all existing capacities and digital health EC competencies (and functions in 3.) while acting as the main governance agency on the European Data Space on behalf of the "health sector" more broadly.

4.3.3. Individual options about solutions for a common European strategy on health data collection

Regarding a policy solution to the present absence of a common European strategy on data collection four options were outlined:

1. Do nothing scenario,
2. Frame such strategy under the umbrella of the Data Governance Act,
3. Frame such strategy under the umbrella of the European Health Data Space Act,
4. Develop a **Health (public Health) Data Governance Act** as a basis for a sustainable strategy

4.4. Compatibility and synergy testing

Options on an EU data Centre should be verified for compatibility and synergy regarding both how it could positively health an Overall EU response to public health crisis (accepting this can take different future forms) and how they relate to options about a Common Strategy on how to collect health data.

4.4.1. Options on an EU data centre in the context of an overall EU response to public health crises

While the focus of this study was not to analyse in depth the elements of EU-level coordination mechanism to address serious cross-border threats, however some of its aspects were indeed asked, and to some extents that is at the end, the public interest and public purpose of any policy changes to be introduced in this area. If the EU Data Centre or a Common strategy to collect health data would not result in added value to that Overall Response than that defeats its purpose and TFEU article 168º could not be invoked as such changes would not be furthering a public purpose. Finally the way the EU could decide on changes to such mechanisms, particularly as the proposals from the EC on new regulations for overall mechanism (repelling Decision No 1082/2013/EU) as well as the changes to the Regulation of the ECDC, EMA, and the new "HERA" agency, should take into consideration the interdependencies with the raising value and opportunity advanced data use in public health can mean.

The different options conceived, presented and explored (section 1), constitute a background against which different requirements and *modus operandi,* with relation to an EU data centre and a common European Strategy, would emerge. In other words, there are interdependencies in how the EU choses regarding options on an EU Data Centre and Common European Strategy on how to collect data, and how it matured, evolved and finally co-legislates about the way it organizes itself under an new Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU, and other related legal acts, currently under discussion and envisioned (such as the creation of the HERA agency).

If we combine policy options regarding overall public health crisis management regimes (provisional options 1) with the proposed institutional vehicles for an EU health data centre (provisional options 4) we can simulate the obtained effect on what could be an EU Overall Coordination and Emergency Response Capacity (Table 5 in page 59 shows a summary of the exercise). Regarding the cells were synergy exists and which justify the argument that indeed an EU health data centre, particularly an advanced version, can indeed make a difference to the Overall EU response. All the remaining black non-coloured cells represent situations where option combinations are either illogical, incompatible, non-operational or just simple represent an AS IS status where no significant change would come as a result of their implementation.

4.4.2. Options on an EU data centre for emergency coordination and response in the context of a common European strategy on how to collect data

When combining preliminary options regarding the institutional frame for an EU health data centre with preliminary options for a common European Strategy on Health data Collection, effects on the

impact of the strategy and the capacity to generate good data for public health in the EU and for supporting cross-border health threat risk management, coordination and response can be considered (please see table 6). The cells coloured with green represent policy option combinations that are synergic, the darker the green the more powerful the effect and the capacity of data to be made available, used and support coordination and emergency response, in the multiple ways anticipated in section 5. on the activities and capabilities of an EU health data centre.

In summary, either framing such strategy under the umbrella of the European Health Data Space Act or develop a Health (public Health) data governance Act as a basis for a sustainable strategy create the conditions for positive effect either when the EU Health Data Center is a part of the ECDC and this entity as a reinforced role in the EHDS in the area of public health, or when there is a stand-alone EHDA. When the development of a strategy would result from a Health (public Health) data governance Act and an dedicated Agency to Health Data and Digital Health would be equally created by Regulation then a maximum EU-level capacity to use health (public health) data because its legally and technically made available by MS and there is inbuilt sustained technical expertise (in this case it is advisable that both Acts are created together for maximal legislative efficiency and coherence).

Table 6 – Combining preliminary options on the institutional frame for an EU health data centre with preliminary options for a common European Strategy on Health data Collection

		Preliminary options 4. Regarding the institutional frame for an EU Health Data Centre			
		1. **Do nothing scenario.** Maintain existing functions in the different institutions.	2. **Using same institutional arrangements.** Maintaining the existing functions in the different institutions. Establishing four functional regimes via different arrangements	3. **Reinforcing the role of the ECDC in the EHDS**. The ECDC would be the main responsible institution for all public health related data topics, including not only crisis (and in between crisis) relevant data use, but also public health indicators. (plus functions on 2.)	4. **Establishing a European Digital Health Agency (EDHA)**. It mission would be to aggregate all existing capacities and digital health EC competencies (and functions in 3.) while acting as the main governance agency on the European Data Space on behalf of the "health sector" more broadly.
Preliminary policy 1.3 Solutions for a common European strategy on Health data collection	1. Do nothing scenario,	AI IS scenario	No significant impact on MS public health data, no expected improvement on public health data pipeline	Explore existing provisions under Art 14 of the new proposed Regulation as a strategic leverage. Weak alignment and mostly covering only comunicable diseases	Low capacity to work with MS and carry on its mission, except if the Regulation establishing the Agency gives it strategic decision making capacity, which is not desirable
	2. Frame such **strategy under the umbrella of the Data Governance Act,**		Possible impact on MS public health data, limited improvement on public health data pipeline	Possible impact on MS public health data, significant improvement on EU-level data usage may be limited by MS willingness to share data in the EHDS	High impact. Risk of disaligment with the EHDS strategy and lesser integration with non-health sectors and data pipelines. Capacity to alter MS interna health data ecosystem is low.
	3. Frame such **strategy under the umbrella of the European Health Data Space Act**			Good alignment. There would be a strategic leader duo (DG Sante-ECDC) and a legal (via EHDS Act) and operational (via the EHDS infratructure and governance) to enhanct the strategy	Good alignment, more policy independency via one strategic leader (EDHA). A legal (via EHDS Act) and operational (via the EHDS infratructure and governance) to enhanct the strategy
	4. Develop a **Health (public Health) data governance Act** as a basis for a sustainable strategy		Low impact. EU-level capacity to use health (public health) data is underminned not because data is not legally and tecnically made available by MS but because there not enough concentraed technical expertise to utilize it.	High impact. EU-level capacity to use health (public health) data because its legally and tecnically made available and but there is a risk of not enough core sustained technical expertise, to cope with all legal posibilities. Useful for MS public health datafication	Maximum EU-level capacity to use health (public health) data because its legally and tecnically made available by MS and there is inbuilt sustained technical expertise. Both Acts should be created together for maximal legislative eficiency

4.5. Main options viability testing

A necessarily brief comparison of the main four policy options for an EU health Data Centre in the context of a common European strategy for collecting health data was performed (table 7 represents the results of this analysis). To compare and viability test each option has been further described regarding a set of dimensions and then compared against the six criteria suggested for STOA studies. The dimensions were:

1. Institutional frame – as outlined in individual options about the institutional frame with the exception of Main Option 3 where the possibility of HERA as a homing agency has been considered. This results in a breaking down into 2 sub-options:
2. Main Option 3a where the Centre would be a part of the ECDC
3. Main Option 3b where the Centre would be a part of the future HERA.
4. Governance/Specialization/Accountability/Auditability – How such option would playout regarding easy and clear governance, promote specialization, be easily held accountable to EU citizens and be auditable by CJEU/ECA
5. Network of actors – How does the "EU Data Centre" relate with the other health data actors within the frame of the European Health Data Space (EHDS)
6. Legal/treaties – Compatibility with legal frames of reference, existing EU treaties, interpretation and necessary political will
7. Emergency Coordination and Response – Capacity to support the Emergency coordination and response mechanism irrespective of its present and future options/nuances
8. Capacity – What is the installed capacity and what are expected capacity-building investments
9. Data harmonization/data authority – How capable is this option in addressing the persist problem of low health data interoperability and reduced data utility for public health due to problems in harmonization of processes and data capture.
10. Common European strategy on how to collect data – What options, from the set of final options on strategy, are compatible with this organizational structure.

The four Main Options to be comparison are:

1. Do Nothing Scenario
2. Main Option 2 - "Current proposals"/ ***"temporary Centre"*** – basically it reflects the option of co-legislation on current proposals under "European Health Union" pack only, with no significant changes, or at least not significant enough to establish a identifiable central coordination structure such as the one outlined in this study, except perhaps some increased horizontal coordination mechanisms for better liaising the different EU-level bodies during a crisis with regards to their cooperative usage of health data. This option entails that at a strategy level, there may be some opportunities and components under the European Health Data Space Regulation/Act in the making. The expanded role of the ECDC may help lightly but Art. 14 of the new regulation, as well as other disperse legal elements with a capacity to exert positive harmonization influence should not be confused in any way with a coherent and sustained health data strategy for public health due to their either instrumental or narrow focus nature.

3. Main Option 3 – Embedded EU health data centre – in this case a full-fledged Centre is conceived as a part of an existing (ECDC) or new agency (HERA)
    a. Main Option 3a where the Centre would be a part of the ECDC
    b. Main Option 3b where the Centre would be a part of the future HERA. - This is a viable legal option as the new HERA (an agency being advocated by the EC, mostly inspired in the US BARDA[42] agency is currently under pre-proposal stages and therefore open to foundational reconceptualization.
4. Main Option 4 – Stand-alone EU health data centre – in this case through the creation of a new agency – European Health Data Agency (EHDA). ***EHDA is created as a stand-alone agency***, not just to use public health relevant data during a public health crisis, but to fundamentally collect, use and analyse the four main types of health data in crisis and inter-critical periods. HERA remit and ongoing elaboration stays for the most part unaltered with the exception that it becomes another consumer of data aggregated and shared via the common public heath data pipeline and channelled through EHDA.

There is not clear tactic difference regarding option 3.b or option 4. since both could equally support a much more sophisticated harmonization, collection, and analysis of data relevant for a public health pan-EU crisis. The difference lays in a strategic outlook and interpretation of the EU treaties regarding its role in protecting health. At present, ***option 3.b would seem more likely to be politically and financially possible***, the "Emergency" element of the Agencies mission means, however, these processes of using, processing and exploring value from public health data and supporting better decisions would be somehow "transitory". High costs of simulation, permanent exercises and low level of ongoing relationship and commitment to existing or future public health data pipelines in MS and indeed other EC services/agencies, could ***result in this "surge capacity" not being ready fast enough or with as relevant datasets and processes*** as it would otherwise under a sort of "continuous" operation mode.

Organizations are its people, their processes, and their skilful use of technologies. Option 4., means a more serious commitment to a common future with regards the use of health data. Not just for supporting transitory complex decision-making when the EU is to face serious public health (mostly communicable diseases) threats, but rather to be capable of supporting public health policy also when in face of smouldering public health problems, or hybrid threats. Such an option means a choice about how the EU wants to foster health quality and outcomes comparison with the aim to ensure higher attainment of Art. 168 of TFEU, where a "protection of the human health" should be broadly interpreted.

Obviously main option 1 is not acceptable, as there are already EC initiatives in the European Parliament to legislate for a "European Health Union" pack. So this should be disregarded except if to say that no support would be lend to such proposals which would be in contradiction to the parliament previous calls for proposals from the EC in this area (5).

[42] BARDA - Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). See: https://www.phe.gov/about/barda/Pages/default.aspx

Table 7 – Four Main Options on the establishment of an EU health data centre and a common European strategy to collect health data: Dimensions and comparison against STOA studies criteria

	Main Option1	Main Option2	Main Option 3a and 3b		Main Option 4
Dimensions /criteria	**Do nothing**	**"Current proposals"/ "temporary Centre"**	**Embedded "EU HEALTH DATA CENTRE"**		**Self-standing "EU HEATH DATA CENTRE"**
Institutional frame		Using same institutional arrangements. Establishing 4 functional regimes	Centre as part of the ECDC or HERA. Reinforcing the role of the ECDC (3.a) or HERA(3.b) in the EHDS.		Establishing a European Health Data Agency (EDHA).
Governance/Specialization/ Accountability/Auditability		+	+/- (there is a risk of "functional focus and narrow approach to data collection methods and scope)		+++
Network of actors		Connected as "one amongst equals"	Connected via EHDSpace as part of the ECDC (3.a) or HERA (3.b) node		Equidistance; via EHDSpace but as its Core Node
Legal/Treaties		Compatible	Compatible – interpretation of subsidiarity vs health protection		Compatibility test – data for public health protection, quality of health care as a surrogate of EU readiness to protect health of its citizens when facing a similar to COVID-19 or worst crisis (incl. hybrid)
Emergency Coordination and Response		+	+++ (if it is a Communicable Disease crisis) ++ (if it is a Hybrid crisis)		+++
Capacity		++	+		+++
Data harmonization/data authority		(+) Via Art 14 and Art(s) on preparedness (new regulation to repeal Decision No 1082/2013/EU); Several strategy leaders	(++) or (+/-) if the scope and authority over non-Communicable Disease data, Health System data and non-health relevant data is not clear, reinforced and followed by capacity enhancement; Several strategy leaders		(+++) Assuming this centre caters for both crisis and inter-critical data gathering and sharing, for all 4 broad data types; Vertical Strategy
Common European strategy on how to collect data		As part of the European Health Data Space Act	European Health Data Space Act or a Health (public Health) data governance Act		European Health Data Space Act or a Health (public Health) data governance Act
STOA studies criteria					
Cost and benefits	N/A	Low cost/Low benefit	Low cost/High Benefit		High Cost/High Benefit
Feasibility and efectiveness	N/A	High/Low efectiveness	Lower (3.a) High (3.b)/Medium efectiveness		High/High efectiveness
Sustanability	N/A	Low	Medium		High
Risks and uncertainties	N/A	Low	Low		Medium
Coherence with EU objecives	N/A	Yes	Yes		Yes (Next Generation EU/Digital Europe)
Potential ethical, social and regulatory impacts	N/A	Low	Medium		High

Regarding costs and benefits clearly Option 4 would mean a significantly higher investment but while for sure the benefits will be higher, the economical sustainability may also be there, as many of its services do not necessarily have to be free. Education and training from a highly specialized and authoritative centre can be a source of valuable income, as well as others, and this is facilitated by the stand-alone nature of the structure. All three options are equally feasible with the exception of option 3.a as the ECDC MB has already recently voiced their opinion against an enlargement of the ECDC role, and this was due during the current pandemic and on top of that much other functions are being considered under the recent EC proposals making this "data responsibility" expansion less feasible form that point of view.

Option 4 is associated with higher risks and uncertainties as it needs to explore advanced technologies, original digital services, and establish a governance structure, however, this in itself may be allow new social and stakeholder arrangements from the beginning with links to patient associations, professional associations, networks of researcher in data science, populational health, ethical and legal academics to help compensate for the high expected potential impacts. Alternatively, a more conservative approach is that proposed in Option 2. It is a low risk but also lower benefit option. It does not address some of the more significant public health data issues outlined throughout the study. It does not significantly alter technical and data utilization EU-level capacity and without such polling of expertise and concentration of data we are likely to have pretty much the same public health information outputs as we have been having during COVID-19 pandemic.

4.6. Final study policy options

Combining the best options regarding the setting up of a EU HEALTH DATA CENTRE and a Common European strategy to collect health data to help Coordination and Emergency response in case of a serious cross-border threat this author suggests a final set of final Policy Options, which is a combination of 3 organizations arrangements and 2 levels of strategy formalization.

Figure 2 summarizes these three options (corresponding to Main Options 2,3a,3b, and 4.) for the EU HEALTH DATA CENTRE, depicts how this Centre would support the top main decision makers institutions coordinating EU response to a Cross-Border Health threat crisis, and the broad data types required for maximum response. This support would happen via the collection and usage of health data from MS-level and other EU institutions via future European Health Data Space. It also tries to capture the notion that vertical public health relevant data pipelines could emerge from a strong and coherent common European Strategy which could be materialized by either one of the two possible scoping and legal options, a more modest one focusing on "traditional public health data"/"data needed to support immediate crisis management" or a more broad interpretation of health data (the previously described four types) expanding significantly its scope both in terms of what it would mean at MS level, but, and perhaps more important for the EU Health data Centre, what it would mean for the possibilities (listed as exemplar activities of the Centre) of new Digital Public Health Services, through advanced digital technologies.

Figure 2 – Summary of three Main Policy Options for an EU health data centre and a common European Strategy for health data collection

Dimensions	Option 2 "Current proposals"/"Temporary Centre"	Option 3 (.a or .b) Embedded "EU Health Data Centre"	Option 4 Self-Standing "EU Health Data Centre"
Institutional Frame	Using same Institutional arrangements. Establishing 4 functional regimes	Centre is part of ECDC (3.a) or "HERA" (3.b), reinforcing their role in the EHDS	Establishing a European Health Data Agency (EHDA)
Governance/Specialization/Accountability /Auditability	+	+/- (risk of "functional" focus and narrow approach to data collection methods and scope)	+++
Emergency coordination & response	+	+++ (Communicable disease crisis) ++ (hybrid crisis)	+++
Data harmonization/Data authority	(+) via Art14 & Art(s) on preparedness (new regulation to repeal Decision n. 1082/2013/EU; Several strategy leaders	(++) or (+/-) if the scope and authority over DNCD, DHS, and DPHR is not clear, reinforced and followed by capacity enhancement; several strategy leaders	(+++) Assuming this centre caters for crisis and inter-critical data gathering and sharing for all 4 broad data types; Vertical Strategy
Common European strategy on data collection (for public health)	As part of the European Health Data Space Act	European Health Data Space Act or a Health (Public Health) Data Governance Act	European Health Data Space Act or a Health (Public Health) Data Governance Act

5. Conclusions

This study set out to investigate and examine:

> *"the challenges associated with the lack of a centralised governance structure for emergency coordination and response as well as the absence of a well-defined common European strategy on how to collect data in a public health emergency context. It should detail on the development of a centralised governance structure that will allow the seamless gathering of credible and comparable data and contribute to the shaping of a common and well-coordinated data collection, reporting and testing framework especially in the context of a public health emergency. And it should clarify* ***whether the establishment of an EU structure of this kind fills in an actual governance gap and carries the potential for strengthening the European risk management response to cross-border health threats****. Such a structure should be grounded on an* ***elaborated European strategy on how to collect data for preventing, detecting and curing diseases****. The study should also* ***devise the main tenets of such a strategy*** *that could legally and operationally define who does what, how and when under EU law in an emergency context. The study was* ***expected to develop a wide range of realistic and thought-provoking policy options that could address the effects of the fragmented and uncoordinated response to COVID-19 and put forward an effective and wellcoordinated response structure at the EU that could enhance resilience and responsiveness"****.*

All these have been accomplished to the degree of detail allowed by time, space and the extension of the complex subject matter and the uneven and fast-changing ground of the issues and initiatives at stake. An attempt was made to balance an analysis that was simultaneously updated but not too constrained by the present, but also could look ahead for post-COVID-19, and towards more mature data rich public health EU landscape.

Regarding its key objectives the following bulleted conclusions can be extracted:

1. Study shows there are different political and technical challenges associated with the lack of a centralised governance structure for emergency coordination and response. There is an absence of a welldefined common European strategy on how to collect data in a public health emergency context. The lack of a centralized governance on health data, and an uncoordinated overall EU response to public health crisis seem interrelated, and a better strategy to collect four types of public health data could have provided better support to EU level decision makers.
2. Gaps and challenges when sharing data at the EU level in health emergencies in terms of the quality, consistency and comparability of data, methodologies and protocols as well as the identification of the main actors involved in the eco-system of data collection and processing in public health emergencies was conducted. The main finding is that there is a very high level of heterogeneity, paucity of public health datafication in MS, and that main EU-level past initiatives have resulted in few tangible results in health data harmonization and increased availability for policy and public health decision-making.
3. The review of the existing EU legal and regulatory framework in the fields of data collection/exchange, testing/reporting methodologies and public health was undertaken. This resulted in the finding data no strategy or regulatory frame exists except for some, difficult to enforce, rules regarding ECDC/Communicable disease related information. This also included upcoming/in discussion regulation like the new EHDS regulation which can be a limited vehicle for the degree and level of data harmonization and readiness deemed needed.

4. The study was expected to "assess the adequacy of the existing EU institutional structures to provide a common european health data space and a coordinating structure for emergency responses". Such assessment produced two relevant sets of findings. On one hand that existing institutional structures and the current EC proposals under the "European Health Union" pack, together with upcoming proposal on the EHDS, and the Data Governance Act, can serve for a temporary weaker coordinating structure for emergency responses the effectiveness of which, on the EU-level overall response to a public health crisis was deemed too low. Alternatively, the exploration of the concept of a more permanent and fully-fledged EU health data centre was entertained. The alternative EU institutional arrangements that could home such a structure were outlined. A full-fleged centre was considered relevant for higher efficacy on strategy implementation (particularly with regards to data harmonization, and public health services datafication at MS level) and ultimately better collection and usage of such data for truly supporting EU-level decision making and crisis management with advanced digital public health services.
5. The detailed examination of the requirements and the added value associated with the development of a centralised governance structure was concluded. The advancement and breakdown of a set of 10 lines of activity (in and between crises) for the Centre was equally entertained.
6. Asked to examine whether the establishment of an EU structure of this kind fills in an actual governance gap and carries the potential for strengthening the European risk management response to crossborder health threats and propose an effective and well-coordinated response structure at the EU level without prejudice to the existing allocation of competences between the EU and its Member States that could strengthen the European risk management response to cross-border health threats. **This study concludes that an actual gap would be filled, particularly with a full-fledged EU health data centre, which would have the capacity to help not just the EU institutions during the Coordination and Emergency response phase but throughout the entire crisis and risk management cycles.** This would additionally have a significant impact in preparedness stages at the MS level, is coupled with a public health data and datafication strategy.
7. The main tenets of a European strategy on how to collect data for preventing, detecting and curing diseases, where outlined and identified as highly relevant for the creation of both a interoperable health data ecosystem at healthcare provision level as well as creating the conditions for the harmonized collection of relevant public and populational health data. This strategy should legally and operationally define who does what, how and when under EU law in an emergency context. An appreciation of EU law in this regard was done and a set of conditions for "emergency law" and for using advanced public health digital services were outlined, with a particular attention to the usage of AI as it is considered to be a raising trend bringing about complex socio-technical challenges.
8. As was anticipated the study could prove vital in helping to understand both the potential but also the challenges associated with the gradual establishment of a cyber-secure, risk-free, privacy-strict data space that will be able to help the EU to collect vital data and algorithmically use them to identify behavioural patterns, flows of people, spot

necessities, locate them, identify dynamics and run predictive analytics. Such issues were subject to a necessarily incomplete analysis. Besides identifying cautionary step in this area the study also concludes that careful legislation of proposed Article 14º "surveillance platform" of the proposal for a new regulation on cross border health threats may be needed as it can be a useful embryo for a much needed EU-wide interconnected public health information system but it also harbours some legal, ethical and technical risks.

9. Finally, the study was asked to develop a wide range of realistic and thought-provoking policy options that could address the effects of the fragmented and uncoordinated response to COVID-19. These have been accomplished and can be summarized into three Main Options build after a careful analysis of a set of 12 individual options regarding three main areas:
10. Preliminary options 1 – The functions necessary for a more effective EU level broad governance of public health crisis
11. Preliminary options 4 – The institutional frame for an EU health data centre
12. Preliminary options 3 – Solutions for a common European strategy on Health data collection

The final study policy options combined the best options regarding the setting up of a EU HEALTH DATA CENTRE and a Common European strategy to collect health data to help coordination and emergency response in case of a serious cross-border threat in a combination of three organizations arrangements and two levels of strategy formalization.

1. Main Option 2 - "Current proposals"/ ***"temporary Centre"*** – basically it reflects the option of co-legislation on current proposals under "European Health Union" pack only, with no significant changes, or at least not significant enough to establish a identifiable central coordination structure such as the one outlined in this study, except perhaps some increased horizontal coordination mechanisms for better liaising the different EU-level bodies during a crisis with regards to their cooperative usage of health data. This option entails that at a strategy level, there may be some opportunities and components under the European Health Data Space Regulation/Act in the making. The expanded role of the ECDC may help lightly but Art. 14 of the new regulation, as well as other disperse legal elements with a capacity to exert positive harmonization influence should not be confused in any way with a coherent and sustained health data strategy for public health due to their either instrumental or narrow focus nature.
2. Main Option 3 – Embedded EU health data centre – in this case a full-fledged Centre is conceived as a part of an existing (ECDC) or new agency (HERA)
    a. Main Option 3a where the Centre would be a part of the ECDC
    b. Main Option 3b where the Centre would be a part of the future HERA. - This is a viable legal option as HERA mission is not closed and is under discussion).
3. Main Option 4 – Stand-alone EU health data centre – in this case through the creation of a new agency – European Health Data Agency (EHDA). ***EHDA is created as a stand-alone agency***, not just to use public health relevant data during a public health crisis, but to fundamentally collect, use and analyse the four main types of health data in crisis and inter-critical periods. HERA remit and ongoing elaboration stays for the most part

unaltered with the exception that it becomes another consumer of data aggregated and shared via the common public health data pipeline and channelled through EHDA.

Regardless of the options to be followed or not it is very important to continue to study this important EU policy area. That of Health Data at the EU level, in particular how it can be used to foster better health systems and through this mechanism help fulfil EU treaties established responsibilities on human health protection. Further attention to the following aspects is advisable:

1. Use of AI for public health threats – the detailed exploration of the technical possibilities, and the ethical and legal context of AI use in public health
2. Further analysis and detailing of the implications of Art 14 "surveillance platform" on the new Regulation Proposal with the eventual production of timely contributions to the European Parliament readings of the legal document.
3. Devise an urgent public health administration modernization agenda and MS datafication strategy, where common building blocks from the EC (e.g. DG Digit), structural funding and Horizon Europe as well as Digital Europe Program.
4. Devise a mechanism for the establishment of data science and data education for public health staff and authorities.

The study was presented to the STOA panel on the 19th of March 2021[43] from the many issues raised by MEPs trust, citizen oversight and participation as well as eventual obstacules were amongst the more salient. It was argued that trust and even citizen engagement is more easily ensured in situations where health data strategy leadership as well as its EU level use is institutionalized into a tangible organization, then when it rests on a complex maze of inter-institutional collaboration networks. It is easier to appoint patients and other health stakeholders to advisory and even supervisory boards of an eventual Centre, then when it is a rather disperse set-up. Some of the obstacles discussed were national level obsolete or inexistent public health data infrasrutures and lack of public health workforce competencies on data, data science and on digital health more broadly. Again a common strategy that is not just about data collection but about public health datification, led by a visible and empowered agency was defended as a possible mitigation mechanism while creating the grounds for better usage of public health data for national and regional management of the health status of the populations.

The COVID-19 pandemic has shaken the foundations of the EU collaboration and citizens' trust. It also showed that unheard-of effort is sometimes required to sustain the most important of all EU recognised fundamental rights (58) the right to health and life in a free space. It also showed intense cooperation between MS to the level of individual patient's bedside. Making doctors and nurses from other MS indispensable to save life in often non-digitally connected healthcare facilities ten years after a directive (59) that suggested a patient summary, as a minimum, should follow Europeans when needed cross-border care. Ironically, many did not move from their hometown, but the EU brought them a doctor. Many did, as they were moved to other MS for healthcare while those doctors could not even access their past medical history or their patient summary from their home country electronically. The 2011 idea of cross-border patient summary had it materialized could have helped. The idea was good, the policy option clear, the legal and institutional instruments too weak for results.

The future is a mystery, but worse and more likely hybrid threats (bio and cyber viruses or other) loom on the horizon. However the EU can prepare for these by using health data much better.

[43] For compreenhsive review of the presentation and following discussion please access the online video at: Panel for the Future of Science and Technology - Multimedia Centre (europa.eu)

While doing that, it can add public health value in areas of public health smouldering crises that never come to be called emergencies (such as cancer or mental health). Working for population's health by reiforicng a cognitive health systems approach (60).

Impossible though it was to capture all issues, the substantive question: "Could we have a better coordination of response to a crisis ("such" as this one or larger) and how can different health data use contribute to this and what can the EU do about it?" has been answered in these pages. Yes, we can have it, **there are many steps necessary and the EU can decide upon a ray of policy options that vary in their integrationist ambition. In ten years, hopefully these will have made a difference**.

The European Union's health digital integration **may take small steps based on shy policy options, with pallid and intangible consequences for citizens a decade after, or large incredible world astonishing leaps, through courageous legislation and institutional reshape to achieve real effective public health safety for its inhabitants**.

6. References

1. European Commission. Communication From the Commission - Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats. COM(2020) 724 Final. 2020;
2. European Commission. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU. COM(2020) 727 final; 2020.
3. Pacces AM, Weimer M. From Diversity to Coordination: A European Approach to COVID-19. Eur J Risk Regul [Internet]. 2020 Jun 16 [cited 2020 Nov 4];11(2):283–96. Available from: https://www.cambridge.org/core/product/identifier/S1867299X20000367/type/journal_article
4. ALEMANNO A. Taming COVID-19 by Regulation: An Opportunity for Self-Reflection. Eur J Risk Regul [Internet]. 2020 Jun 24 [cited 2020 Nov 4];11(2):187–94. Available from: https://www.cambridge.org/core/product/identifier/S1867299X20000434/type/journal_article
5. Parliament TE. The EU ' s public health strategy post-COVID-19. 2020;
6. Union C of the E. Council Conclusions on Common values and principles in European Union Health Systems (2006/C 146/01) [Internet]. 2006. p. 1–3. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:146:0001:0003:EN:PDF
7. Alemanno A. The European Response to COVID-19: From Regulatory Emulation to Regulatory Coordination? Eur J Risk Regul [Internet]. 2020 Jun 28 [cited 2020 Oct 30];11(2):307–16. Available from: https://www.cambridge.org/core/product/identifier/S1867299X20000446/type/journal_article
8. European Commission. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) [Internet]. COM(2020) 767 final; 2020. Available from: https://eur-lex.europa.eu/resource.html?uri=cellar%3A91ce5c0f-12b6-11eb-9a54-
9. European Parliament. DIRECTIVE (EU) 2016/1148 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union [Internet]. 2016. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L1148&from=EN
10. Cheung N-T, Fung V, Kong JHB. The Hong Kong Hospital Authority's information architecture. Stud Health Technol Inform. 2004;107(Pt 2):1183–6.
11. Cheung N-T, Lam A, Chan W, Kong JHB. Integrating images into the electronic patient record of the hospital authority of Hong Kong. Comput Med imaging Graph Off J Comput Med Imaging Soc. 2005;29(2–3):137–42.
12. OECD. OECD Regions and Cities at a Glance 2018 [Internet]. 2018. 160 p. Available from: https://www.oecd-ilibrary.org/governance/oecd-regions-and-cities-at-a-glance-2018_reg_cit_glance-2018-en%0Ahttps://www.oecd-ilibrary.org/governance/oecd-regions-and-cities-at-a-glance-2018/summary/korean_df4c6360-ko
13. Health at a Glance 2019 [Internet]. OECD; 2019 [cited 2020 May 31]. (Health at a Glance). Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2019_4dd50c09-en
14. Crego MD, Kotanidis S. States of emergency in response to the coronavirus crisis. EPRS | European Parliamentary Research Service; 2020.
15. Platje J, Harvey J, Rayman-Bacchus L. COVID-19 – reflections on the surprise of both an expected and unexpected event. Cent Eur Rev Econ Manag. 2020;4(1):149–62.
16. Dobbs M. National Governance of Public Health Responses in a Pandemic? Eur J Risk Regul [Internet]. 2020 Jun 21 [cited 2020 Nov 20];11(2):240–8. Available from: https://www.cambridge.org/core/product/identifier/S1867299X20000392/type/journal_article
17. Purnhagen KP, De Ruijter A, FLEAR ML, HERVEY TK, HERWIG A. More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak. Eur J Risk Regul [Internet]. 2020 Jun 16 [cited 2020 Oct 30];11(2):297–306. Available from:

https://www.cambridge.org/core/product/identifier/S1867299X20000355/type/journal_article
18. Greer SL. The three faces of European Union health policy: Policy, markets, and austerity. Policy Soc [Internet]. 2014;33(1):13–24. Available from: http://dx.doi.org/10.1016/j.polsoc.2014.03.001
19. Bause M, Khayamian Esfahani B, Forbes H, Schaefer D. Design for Health 4.0: Exploration of a New Area. Proc Des Soc Int Conf Eng Des [Internet]. 2019 Jul 26 [cited 2020 May 31];1(1):887–96. Available from: https://www.cambridge.org/core/product/identifier/S2220434219000933/type/journal_article
20. World Health Organization. Global strategy on digital health 2020 – 2024 [Internet]. 2020. Available from: https://www.who.int/health-topics/digital-health#tab=tab_1
21. European Commission. Artificial Intelligence for Europe COM(2018) 273 final. COM(2018) 273 Final. 2018;
22. Kritikos M. Ten technologies to fight coronavirus. Eur Parliam Res Serv [Internet]. 2020;(April):1–20. Available from: https://www.europarl.europa.eu/RegData/etudes/IDAN/2020/641543/EPRS_IDA(2020)641543_EN.pdf
23. Hoeyer K, Bauer S, Pickersgill M. Datafication and accountability in public health: Introduction to a special issue. Soc Stud Sci [Internet]. 2019;49(4):459–75. Available from: https://doi.org/10.1177/0306312719860202
24. van Wynsberghe A. Artificial intelligence: From ethics to policy [Internet]. European Parliamentary Research Service. 2020. Available from: https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641507/EPRS_STU(2020)641507_EN.pdf
25. The European Parliament Council. DECISION No 1082/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC. Off J Eur Union [Internet]. 2013;(L 293/1):1–15. Available from: http://europa.eu.int/eurolex/pri/en/oj/dat/1998/l_268/l_26819981003en00010006.pdf
26. European Parliament and the Council. DECISION No 1313/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 December 2013 on a Union Civil Protection Mechanism. Off J Eur Union. 2013;(L 347):924–47.
27. European Commission. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control. COM(2020) 726 final. 2020.
28. Court E, Auditors OF. Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done. 2016.
29. Heuer L, Orland A. Cooperation in the Prisoner's Dilemma: An experimental comparison between pure and mixed strategies. R Soc Open Sci. 2019;6(7).
30. Oliver N, Letouzé E, Sterly H, Delataille S, de Nadai M, Lepri B, et al. Mobile phone data and COVID-19: Missing an opportunity? arXiv. 2020;
31. Court E. Report on the annual accounts of the European Centre for Disease Prevention and Control (ECDC) for the financial year 2019 ,. 2019;
32. PWC. The third external evaluation of the European Centre for Disease Prevention and Control (ECDC). 2019.
33. European Court of Auditors. Union Civil Protection Mechanism: the coordination of responses to disasters outside the EU has been broadly effective [Internet]. 2016. 8–10 p. Available from: https://www.eca.europa.eu/Lists/ECADocuments/SR16_33/SR_DISASTER_RESPONSE_EN.pdf
34. European Parliament. Towards a more resilient Europe post-coronavirus. 2020.
35. Wilkinson A. Strategic Foresight Primer. Eur Polit Strateg Cent [Internet]. 2017;1–40. Available from: http://ec.europa.eu/epsc/sites/epsc/files/epsc_-_strategic_foresight_primer.pdf
36. Cassese S, D´Alterio E. Introduction: the develpment of Global Administrative Law. In: Cassese S, editor. Research Handbook on Global Administrative Law. Elgar; 2016.
37. Stoto MA, Nelson C, Savoia E, Ljungqvist I, Ciotti M. A Public Health Preparedness Logic Model:

Assessing Preparedness for Cross-border Threats in the European Region. 2017;15(5).
38. Shearer E, Cho M, Magnus D. Chapter 23 - Regulatory, social, ethical, and legal issues of artificial intelligence in medicine. In: Xing L, Giger ML, Min JKBT-AI in M, editors. Academic Press; 2021. p. 457–77. Available from: https://www.sciencedirect.com/science/article/pii/B9780128212592000235
39. Supervisor EDP. Preliminary Opinion 8/2020 on the European Health Data Space. 2020.
40. Hoffmann-Riem W. Artificial Intelligence as a Challenge for Law and Regulation. In: Wischmeyer T, Rademacher T, editors. Regulating Artificial Intelligence [Internet]. Cham: Springer International Publishing; 2020. p. 1–29. Available from: https://doi.org/10.1007/978-3-030-32361-5_1
41. Colclough G, Dorling G, Riahi F, Ghafur S, Sheikh A. Harnessing Data Science and Ai in Healthcare [Internet]. 2018. Available from: https://www.wish.org.qa/wp-content/uploads/2018/11/IMPJ6078-WISH-2018-Data-Science-181015.pdf
42. Horgan D, Romao M, Morré SA, Kalra D. Artificial intelligence: Power for civilisation - and for better healthcare. Public Health Genomics. 2020;22(5–6):145–61.
43. Cossy-Gantner A, Germann S, Schwalbe NR, Wahl B. Artificial intelligence (AI) and global health: How can AI contribute to health in resource-poor settings? BMJ Glob Heal. 2018;3(4):1–7.
44. Gennatas ED, Chen JH. Chapter 1 - Artificial intelligence in medicine: past, present, and future. In: Xing L, Giger ML, Min JKBT-AI in M, editors. Academic Press; 2021. p. 3–18. Available from: https://www.sciencedirect.com/science/article/pii/B9780128212592000016
45. Erickson BJ. Artificial intelligence in medicine: Technical basis and clinical applications. In: Xing L, Giger ML, Min JKBT-AI in M, editors. Artificial Intelligence in Medicine [Internet]. Elsevier; 2021. p. 19–34. Available from: https://www.sciencedirect.com/science/article/pii/B9780128212592000028
46. Xing L, Kapp DS, Giger ML, Min JK. Chapter 25 - Outlook of the future landscape of artificial intelligence in medicine and new challenges. In: Xing L, Giger ML, Min JKBT-AI in M, editors. Academic Press; 2021. p. 503–26. Available from: https://www.sciencedirect.com/science/article/pii/B9780128212592000259
47. Thiébaut R, Cossin S, Informatics SE for the IYS on PH and E. Artificial Intelligence for Surveillance in Public Health. Yearb Med Inform [Internet]. 2019/08/16. 2019 Aug;28(1):232–4. Available from: https://pubmed.ncbi.nlm.nih.gov/31419837
48. Desai RJ, Wang S V, Vaduganathan M, Evers T, Schneeweiss S. Comparison of Machine Learning Methods With Traditional Models for Use of Administrative Claims With Electronic Medical Records to Predict Heart Failure Outcomes + Supplemental content. JAMA Netw Open [Internet]. 2020;3(1):1918962. Available from: https://jamanetwork.com/
49. Ertem Z, Raymond D, Meyers LA, Tanaka MM. Optimal multi-source forecasting of seasonal influenza. 2018; Available from: https://doi.org/10.1371/journal.pcbi.1006236
50. European Commission. White Paper on Artificial Intelligence - A European approach to excellence and trust. COM(2020) 65 Final. 2020;
51. European Parliament. Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – GDPR). REGULATION (EU) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protec 2016.
52. Pinheiro AS. Cometário ao Regulamento Geral de Proteção de Dados. Almedina, editor. Coimbra; 2018.
53. ARTICLE 29 DATA PROTECTION WORKING PARTY. Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679. 2018.
54. Wischmeyer T. Artificial Intelligence and Transparency: Opening the Black Box. In: Wischmeyer T, Rademacher T, editors. Regulating Artificial Intelligence [Internet]. Cham: Springer International Publishing; 2020. p. 75–101. Available from: https://doi.org/10.1007/978-3-030-32361-5_4
55. Wachter, Sandra Mittelstadt B, Russell C. No Counterafctual explanations without opening the

black box: automated decisions and the GDPR. Harv J Law Technol. 2018;

56. Lin AL, Chen WC, Hong JC. Chapter 8 - Electronic health record data mining for artificial intelligence healthcare. In: Xing L, Giger ML, Min JKBT-AI in M, editors. Academic Press; 2021. p. 133–50. Available from: https://www.sciencedirect.com/science/article/pii/B9780128212592000089
57. Taylor-Robinson D, Kee F. Precision public health—the Emperor's new clothes. Int J Epidemiol [Internet]. 2019 Feb 1;48(1):1–6. Available from: https://doi.org/10.1093/ije/dyy184
58. European Union. Charter of Fundamental Rights of the European Union. 2012.
59. The European Parliament and the Council. Directive 2011/24/EU: The application of patients' rights regarding cross-border healthcare.
60. Coiera E. The cognitive health system. Lancet [Internet]. 2020;395(10222):463–6. Available from: http://dx.doi.org/10.1016/S0140-6736(19)32987-3
61. European Commission - Expert Group on Liability and New Technologies – New Technologies Formation. Liability for Artificial Intelligence Report from the Expert Group on Liability and New Technologies-New Technologies Formation. 2019.

ANNEX

Set of questions sent to Hong Kong, Japan, Singapore, South Korea and Australia. The questions posed to the CDC in the United States were more targeted but around same topics.

Questions to exchange experiences from outside EU

For the STOA (European Parliament) Study on:

EU Data Centre for Emergency Coordination and Response Establishing a common European strategy on how to collect data[44]

Henrique Martins

Context:

The study is looking mostly at the "coordination of response between the EU level and its Member States", but specially at ways in which new IT tools could better: early detect cross-border health threats (like epidemics/pandemics), abnormal surges in disease patterns, other trends even if from non-medical/healthcare data sources. The EU is pondering the creation of a more automatic means of surveillance of outbreaks, by a combination of methods or technologies (this is in the EC proposal to the European Parliament), namely linking information systems better, using AI, and exploring automatic reporting systems.

Main questions:

1. Is there a national information system for communicable diseases (eventually integrating clinical reporting, lab reporting, automated lab reporting, etc) that allows the National level Authorities to have direct information on Communicable diseases (in particular COVID-19)?
2. How this is this system linked up from local (laboratory/EHR level) to organizational/regional/national levels?
3. Is there any legal basis/law/degree supporting the system?
4. Are there any published reports/papers refereeing to this system (architecture, implementation etc), or that make use of data from this system?
5. What were some of the implementation/usage challenges before, and during early COVID-19 months (Feb-May)?
6. How far (in percentage and scope) does the system cover communicable diseases information?
7. And how far does it use/integrate some non-communicable disease information/resource availability information for supporting logistics decisions as well as decisions on risk (patient or group) based on non-communicable disease loads?
8. How is the system set-up - outlined enterprise architecture/ its elements (you can referee to any published paper (possibly engineering area or medical/health informatics)?

[44] AIMS of the study first paragraph: *The main idea behind the study is to perform an in-depth analysis of the challenges associated with the lack of a centralised governance structure for emergency coordination and response as well as the absence of a well-defined common European strategy on how to collect data in a public health emergency context. Within this frame, the study should review the existing EU legal framework in the fields of data collection/exchange, testing/reporting methodologies and public health and assess the adequacy of the existing EU institutional structures (JRC, ENISA, ECDC, etc) to provide a common European health data space and a coordinating structure for emergency responses. The development of a centralised governance structure that will allow the seamless gathering of credible and comparable data and contribute to the shaping of a common and well-coordinated data collection, reporting and testing framework especially in the context of a public health emergency needs to be examined in detail.*

9. Who (department/agency, team) is mostly responsible for maintaining and further implementing the system?
10. Is there a legal basis/law/degree supporting the system/was there a need to update it?
11. How important and for what do you see the existence of information systems to support the decision-making teams in terms of public health department/Ministry of Health
12. It there any experience in your country on the use of AI systems in non-medical/health related data/information for spotting important trends to be further analysed
13. Have you had any lessons learnt in terms of big data use/secondary use of data for exploring and integrating data from different health sectors/regions, difficulties, challenges, success stories (you can refer to any published material/website (even if in your own language).
14. What is your view on experiences, difficulties or advantages of using IT/eHealth standards for linking up different levels of health IT?
15. How do you link COVID-19 trace apps to general system as a whole?
16. Could you provide any suggestions for the European Union (EU) handling of this crisis in terms of COVID-19 management overall, and the use of health data in particular?
17. What would you like to learn back from the creation of a panEU system?

Feel free to add any additional information or useful links/websites that you think might help he understand and learn from how your country as coordinated response to COVID-19, in particular, how it used health data in that process.

THANK YOU SO MUCH

HENRIQUE MARTINS

OA-03-21-262-EN-N

Regarding health data, its availability and comparability, the Covid-19 pandemic revealed that the EU has no clear health data architecture. The lack of harmonisation in these practices and the absence of an EU-level centre for data analysis and use to support a better response to public health crises is the focus of this study. Through extensive desk review, interviews with key actors, and enquiry into experiences from outside the EU/EEA area, this study highlights that the EU must have the capacity to use data very effectively in order to make data-supported public health policy proposals and inform political decisions.

The possible functions and characteristics of an EU health data centre are outlined. The centre can only fulfil its mandate if it has the power and competency to influence Member State public-health-relevant data ecosystems and institutionally link with their national level actors. The institutional structure, its possible activities and in particular its usage of advanced technologies such as AI are examined in detail.

This is a publication of the Scientific Foresight Unit (STOA)
EPRS | European Parliamentary Research Service

This document is prepared for, and addressed to, the Members and staff of the European Parliament as background material to assist them in their parliamentary work. The content of the document is the sole responsibility of its author(s) and any opinions expressed herein should not be taken to represent an official position of the Parliament.

ISBN 978-92-846-8151-8 | doi:10.2861/70808 | QA-03-21-262-EN-N