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European Health Care Systems and the potential for Big Data

Workshop "DIGITALISATION AND BIG DATA: IMPLICATIONS FOR THE HEALTH SECTOR" that will be held at the European Parliament, Brussels

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European Alliance for Personalised Medicine

19.06.2018,

What is Innovation ?

Innovation = translation of knowledge and insight to <u>value</u>

Value=

- **Value to patients**
- **Value to Society**
- **Return on Investment**

The Translational Challenge

- There is a **wide research-to-market gap in Europe**. The latest EU innovation scoreboard, published in June 2017, noted that although the innovation performance of the EU is improving, **progress is too slow**. Many of our global competitors are increasing their innovation performance at a faster pace, moreover, **performance gaps remain wide within the EU** itself. Europe's comparative advantages in education, research, broadband infrastructure and ICT training are **not matched by venture capital investments and the number of SMEs introducing innovations, both of which are declining strongly.**
- Europe still faces harsh choices about **whether it is actually going to do what it has so often discussed.**

Extracts from Horgan et a, IBiomed Hub 2017;2(suppl 1):481130

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BUT, healthcare systems …

Function nationally

Have national efficiency as their highest priority

Produce data in incompatible silos

Secondary use of data is subject to data protection laws

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"Drug innovation has also transformed the treatment of grievous illnesses, such as cancer - where we have seen significant value delivered at societal and individual patient level, with the promise of more to come"

Experts estimate that innovative cancer drugs introduced between 1975 and 1995 have:

- Increased the 1-year crude cancer survival rate from 69.4% to 76.1%, the 5-year rate from 45.5% to 51.3%, and the 10-year rate from 34.2% to 38.1%
- Accounted for **~ 50-60% of the increase in age-adjusted survival rates in the first 6 years after diagnosis**
- **Added > 1 year of life to patients diagnosed with cancer in 1995**
- Increased the life expectancy of the *entire U.S. population* by 0.4 years (since lifetime risk of being diagnosed with cancer is ~ 40%)
- Recent research suggests the value to the patient of a life year saved **in cancer is actually closer to ~$300K, well above the typical $30-75K QALY values used in health economics**

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Science has evolved but health systems lag behind

Challenges for society with potential emergence of tiered health systems...

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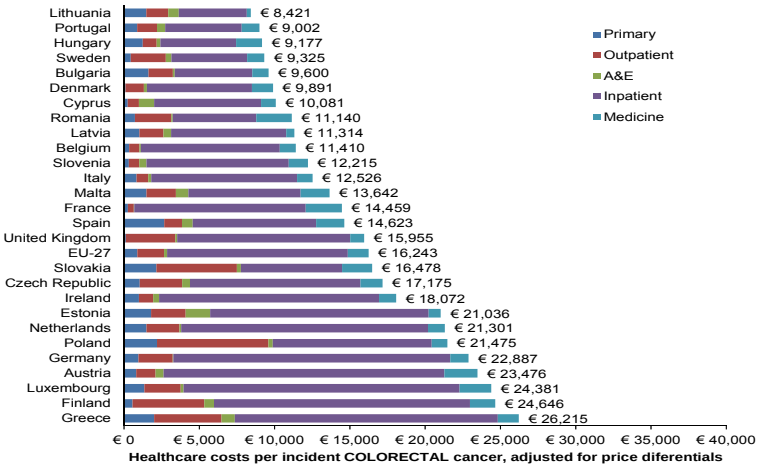
Massive variation in direct spend on cancer care across Europe: *major*



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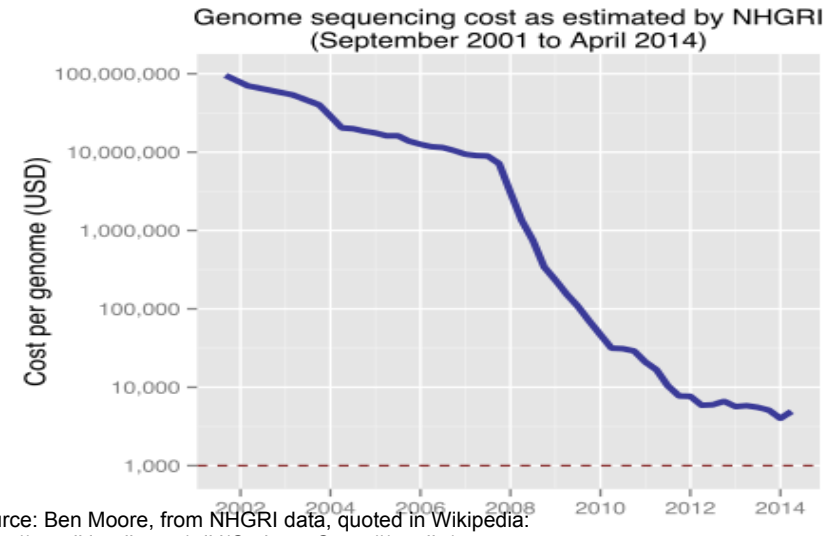
Rapidly falling cost of gene sequencing



Source: Ben Moore, from NHGRI data, quoted in Wikipedia: https://en.wikipedia.org/wiki/Carlson_Curve#/media/

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Interoperability of digital solutions: a challenge for Big Data

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over 900 healthcare units from 26 countries

24 thematic networks

European Reference Networks

5 000 – 8 000 RARE DISEASES INCLUDING 300 RARE CANCERS AFFECT 30 MILLION PEOPLE IN THE EU

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Real world data in health care

Multiple sources of data:

- Clinical databases (prescriptions, EHR, registries)
- Clinical trials
- Imaging data
- 'Omic data'
- Published literature
- Regulatory pharmacovigilance data
- Social media/mHealth data

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"Towards access to 1 million Genomes in the EU by 2022"

Joint Declaration indicating political support for linking* existing and future genomic databanks (on a voluntary basis) in order to reach a cohort of 1 million sequenced genomes accessible in the EU by 2022. This joint commitment will make it possible to:

- **Bring together fragmented infrastructure and expertise supporting** a shared and tangible goal (1 million sequenced genomes accessible in the EU by 2022),
- **Leverage and maximise** the investments already made by Member States at national and EU level, particularly in sequencing, biobanking and data infrastructure,
- **Reaching a larger cohort** that will provide sufficient scale to inform the significance of "signals" identified in genomic and associated data, leading to new clinically impactful associations.

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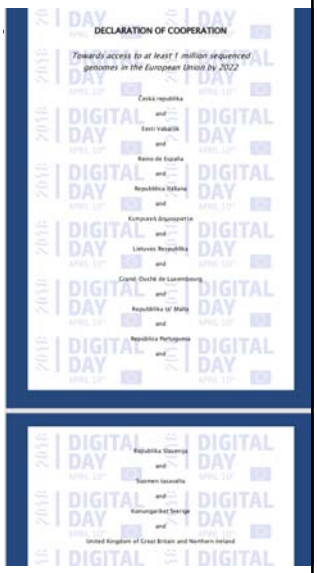
Member States signed – States Signed

- Italy
- Croatia, Bulgaria, Lithuania
- Czech Republic Luxembourg, ,
- Estonia, Spain, Malta, Sweden, Slovenia, Greece, Cyprus, UK, Finland, Portugal



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POLITICAL COMMITMENTS I

- **Define a voluntary coordination mechanism** of national, regional and local public authorities to link ongoing genomic medicine initiatives and to steer the activities stemming from this declaration;
- **Ensure distributed, authorised and secure access to national and regional banks of genetic and other relevant data for the advancement of science and innovation**, while taking appropriate measures to protect the privacy of individual data donors;

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POLITICAL COMMITMENTS II

- **Access provided in a federated** (not centralised) network to genomics data-sets at national / regional level.
- **Define a governance model** of cooperation, particularly concerning the **terms and conditions** for distributed access to genomic data across borders, usage of the data and other aspects deemed necessary by the signatories;

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POLITICAL COMMITMENTS III

- **Support the development of technical specifications** for secure access and cross-border exchange of genomic datasets and facilitate interoperability of relevant registries and databases to support research;
- **Develop a secure infrastructure and tools** to enable cross-border sharing or analysis of genetic and other data-sets, anonymised as appropriate, from multiple Member States, building upon existing infrastructure;

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POLITICAL COMMITMENTS IV

- **Develop a coordinated data governance** framework necessary to facilitate Europe-wide large-scale processing of health and related data in compliance with the **applicable data protection legal framework,** in order to support shared health policy goals; notably to achieve better health for citizens, future sustainability of health systems, and to boost large-scale data-driven biomedical and clinical R&D in Europe;

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POLITICAL COMMITMENTS V

- **Promote the use of open standards and data management systems** to ensure interoperability of genomic and other health data with a view to enhance research on personalised medicine and genetic diseases;
- **Strengthen cooperation on the implementation** of the General Data Protection Regulation particularly as this concerns the further processing of personal data related to health.

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Clarify the gap that needs to be closed by country and in relation to cross-country collaborative efforts by aligning the various stakeholders to facilitate delivery including relevant academic/research groups; commercial partners (large and small companies); clinical experts; patient groups; payers; and regulators.

To do this a series of Expert Committees will be established:

- **Committee 1. Clinical and Scientific**
- **Committee 2. Ethical Legal and Social Implications**
- **Committee 3: Education, Engagement and Communications**
- **Committee 4: Data and Informatics**
- **Committee 5: Sequencing**

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Communication on the Digital Transformation of Health and Care

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Role of Innovation and Financing

- As a result of rapid diffusion, governments have faced unprecedented challenges in balancing high quality and innovative care with other dual concerns.
  - **Managing health care budgets and scarce resources**.
  - **Safeguarding basic principles of access, equity, and choice**.
- Consequently, governments are increasingly required to strategically manage scarce resources by investing in services that deliver the best value for investment.
- To help meet this challenge, various Member States have developed HTA systems.
  - Overall, HTA systems seek to ascertain **the relative effects of technology on health, the availability and distribution of resources, and other aspects of the health system**.
  - Helps to identify both **cost-effective and cost-*in*effective technologies and health services.**
- HTA provides a range of stakeholders **with evidence-based information for decision-making** (e.g., reimbursement, pricing) and priority-setting.

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Why an HTA initiative?

More than 10 years of cooperation: projects, joint actions

ACHIEVEMENTS

- **Trust** between HTA bodies
- **Capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting **joint work** (e.g. early dialogues, joint assessments)

LIMITATIONS

- **Low uptake of joint work** ⇒ duplication of work
- Differences in the **procedural framework** and administrative capacities of Member States
- Differences in national **methodologies**
- **Unsustainability** of current cooperation model

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HTA across EU

Differences in:
- Procedural framework
- Methodology

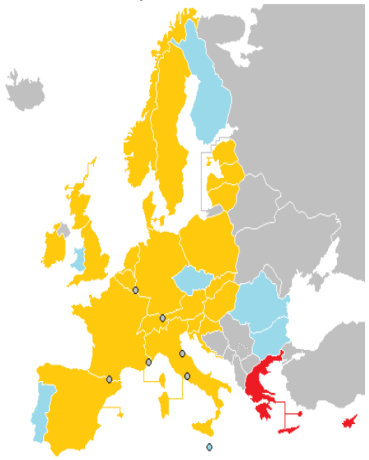
Scope
- Medicinal products

→ 26 MS and NO
- Medical devices

→ 21 MS* and NO
- Under development

→ 2 MS

Figure 2: Overview of HTA activity



Key: N=31 countries with England, Scotland and Wales counted separately; red = no current HTA procedure; blue = pharmaceuticals only; yellow = both pharmaceuticals and non-pharmaceuticals

* In Wales HTA on medical devices is under development

(EUnetHTA, WP7 report, 20

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Article 1

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

- The Regulation establishes:
  - **support framework** and procedures for cooperation on health technology assessment at Union level
  - **common rules** for clinical assessment of health technologies

The Regulation **shall <u>not</u> affect** the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them.

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Cowboys and Pit crews*

The Project Culture:

Could the Health Care system be organized in a Matrix centered around the patient and with a defined Project leader?

** A. Gawande, the New Yorker, 2011*

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Thank you!
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