



Plenary sitting

A9-0069/2023

23.3.2023

REPORT

on discharge in respect of the implementation of the budget of the Innovative Health Initiative Joint Undertaking (before 30.11.2021 the Innovative Medicines Initiative 2 Joint Undertaking) for the financial year 2021 (2022/2131(DEC))

Committee on Budgetary Control

Rapporteur: Ryszard Czarnecki

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1. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

**on discharge in respect of the implementation of the budget of the Innovative Health Initiative Joint Undertaking (before 30.11.2021 the Innovative Medicines Initiative 2 Joint Undertaking) for the financial year 2021
(2022/2131(DEC))**

The European Parliament,

- having regard to the final annual accounts of the Innovative Health Initiative Joint Undertaking for the financial year 2021,
- having regard to the Court of Auditors' annual report on the EU Joint Undertakings for the financial year 2021, together with the Joint Undertakings' replies¹,
- having regard to the statement of assurance² as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2021, pursuant to Article 287 of the Treaty on the Functioning of the European Union,
- having regard to the Council's recommendation of 28. February 2023 on discharge to be given to the Joint Undertaking in respect of the implementation of the budget for the financial year 2021 (06252/2023 – C9-0113/2023),
- having regard to Article 319 of the Treaty on the Functioning of the European Union,
- having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012³, and in particular Article 71 thereof,
- having regard to Council Regulation (EC) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking⁴, and in particular Article 12 thereof,
- having regard to Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014⁵, and in particular Article 26 thereof,

¹ OJ C 433, 15.11.2022, p. 52.

² OJ C 433, 15.11.2022, p. 52.

³ OJ L 193, 30.7.2018, p. 1.

⁴ OJ L 169, 7.6.2014, p. 54.

⁵ OJ L 427, 30.11.2021, p. 17.

- having regard to Commission Delegated Regulation (EU) 2019/887 of 13 March 2019 on the model financial regulation for public-private partnership bodies referred to in Article 71 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council⁶,
 - having regard to Rule 100 of and Annex V to its Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control (A9-0069/2023),
1. Grants the Executive Director of the Innovative Health Initiative Joint Undertaking discharge in respect of the implementation of the Joint Undertaking's budget for the financial year 2021;
 2. Sets out its observations in the resolution below;
 3. Instructs its President to forward this decision and the resolution forming an integral part of it to the Executive Director of the Innovative Health Initiative Joint Undertaking, the Council, the Commission and the Court of Auditors, and to arrange for their publication in the *Official Journal of the European Union* (L series).

⁶ OJ L 142, 29.5.2019, p. 16.

2. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on the closure of the accounts of the Innovative Health Initiative Joint Undertaking (before 30.11.2021 the Innovative Medicines Initiative 2 Joint Undertaking) for the financial year 2021 (2022/2131(DEC))

The European Parliament,

- having regard to the final annual accounts of the Innovative Health Initiative Joint Undertaking for the financial year 2021,
- having regard to the Court of Auditors' annual report on the EU Joint Undertakings for the financial year 2021, together with the Joint Undertakings' replies¹,
- having regard to the statement of assurance² as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2021, pursuant to Article 287 of the Treaty on the Functioning of the European Union,
- having regard to the Council's recommendation of 28. February 2023 on discharge to be given to the Joint Undertaking in respect of the implementation of the budget for the financial year 2021 (06252/2023 – C9-0113/2023),
- having regard to Article 319 of the Treaty on the Functioning of the European Union,
- having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012³, and in particular Article 71 thereof,
- having regard to Council Regulation (EC) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking⁴, and in particular Article 12 thereof,
- having regard to Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014⁵, and in particular Article 26 thereof,
- having regard to Commission Delegated Regulation (EU) 2019/887 of 13 March 2019

¹ OJ C 433, 15.11.2022, p. 52.

² OJ C 433, 15.11.2022, p. 52.

³ OJ L 193, 30.7.2018, p. 1.

⁴ OJ L 169, 7.6.2014, p. 54.

⁵ OJ L 427, 30.11.2021, p. 17.

on the model financial regulation for public-private partnership bodies referred to in Article 71 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council⁶,

- having regard to Rule 100 of and Annex V to its Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control (A9-0069/2023),
1. Approves the closure of the accounts of the Innovative Health Initiative Joint Undertaking for the financial year 2021;
 2. Instructs its President to forward this decision to the Executive Director of the Innovative Health Initiative Joint Undertaking, the Council, the Commission and the Court of Auditors, and to arrange for its publication in the *Official Journal of the European Union* (L series).

⁶ OJ L 142, 29.5.2019, p. 16.

3. MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the Innovative Health Initiative Joint Undertaking (before 30.11.2021 the Innovative Medicines Initiative 2 Joint Undertaking) for the financial year 2021 (2022/2131(DEC))

The European Parliament,

- having regard to its decision on discharge in respect of the implementation of the budget of the Innovative Health Initiative Joint Undertaking for the financial year 2021,
 - having regard to Rule 100 of and Annex V to its Rules of Procedure,
 - having regard to the report of the Committee on Budgetary Control (A9-0069/2023),
- A. whereas, in November 2021, Regulation (EU) 2021/2085, setting up the Innovative Health Initiative (IHI) Joint Undertaking to replace Innovative Medicines Initiative 2 (IMI2) Joint Undertaking under the Horizon Europe programme for the period ending on 31 December 2031, was adopted;
- B. whereas the IHI Joint Undertaking is a public-private partnership for health research and innovation; whereas the goal of the IHI Joint Undertaking is to help create a Union-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations; whereas those innovations should cover prevention, diagnostics, treatment and disease management;
- C. whereas its founding members are the Union, represented by the Commission, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry, Advancing Healthcare, the European Federation of Pharmaceutical Industries and Associations including Vaccines Europe (EFPIA), the European Association for Bioindustries and MedTech Europe (the European trade association for the medical technology industry including diagnostics, medical devices and digital health); whereas the IHI Joint Undertaking follows a bipartite model, with the Commission and private members from industry and research represented on the governing board and contributing to the IHI Joint Undertaking's operational activities;
- D. whereas the IHI Joint Undertaking's total budget for the period 2021-2027 is EUR 2,4 billion, of which half comes from the Horizon Europe programme; whereas the Union financial contribution from Horizon Europe, including European Free Trade Association appropriations, will cover administrative costs and operational costs up to EUR 1,2 billion, including up to EUR 30,2 million for administrative costs; whereas, between 2021 and 2028, the Union will further contribute an amount of up to EUR 22,3 million to the administrative budget, representing the carryover from the IMI2 Joint Undertaking;

Budgetary and financial management

1. Welcomes the fact that, according to the report of the Court of Auditors (the ‘Court’s report’), the accounts of the IHI Joint Undertaking for the year ended in 31 December 2021 present fairly, in all material respects, the financial position of the IHI Joint Undertaking at 31 December 2021, the results of its operations, its cash flows, and the changes in its net assets for the year that ended, in accordance with its Financial Regulation and with accounting rules adopted by the Commission’s accounting officer; highlights, moreover, the fact that, according to the Court’s report, the transaction underlying the accounts are legal and regular in all material respects;
2. Notes that Horizon Europe envisages ambitious goals for the IHI Joint Undertaking, which can only be achieved if effective solutions that address the weaknesses in the internal control systems of the IHI Joint Undertaking and prepare for the future challenges arising from increased responsibilities, e.g. in the area of human resources management and planning, are designed and implemented; points out, in this context, that particularly complicated and burdensome calculations and reporting requirements represent a significant risk of error and calls, therefore, for the possibilities for simplification wherever possible and compatible with the existing legal framework to be explored;
3. Notes that the final IHI Joint Undertaking available budget for 2021, including unused appropriations of previous years, which the IHI Joint Undertaking re-entered in the budget of the current year, assigned revenues and reallocations to the next year was EUR 11,0 million in commitment appropriations and EUR 210,4 million in payment appropriations; notes that the budget execution of the commitment appropriations and the payment appropriations reached 75,91% (98,66% in 2020) and 95,39% (97,08% in 2020) respectively;
4. Notes that there is no harmonised definition of ‘administrative costs’ among the Joint Undertakings, which is a basis for calculating the financial contributions of its members and a precondition for the purpose of comparable figures; calls, with this in mind, for common guidelines to be adopted so that all Joint Undertakings take a harmonised approach for the classification of certain administrative cost expenditure categories, such as expenditure for consultations, studies, analyses, evaluations, and technical assistance;
5. Is concerned that the IHI Joint Undertaking’s level of achievement of members’ contribution targets is relatively low; notes, however, that this is due to the long project duration required by the nature of the IHI Joint Undertaking’s research in the area of innovative health, and the scale of global consortia implementing projects; notes that the IHI Joint Undertaking still has to pay EUR 84,3 million for ongoing Seventh Framework Programme projects in the coming years;
6. Draws attention to the fact that the increasing number of ongoing projects from multiple Multiannual Financial Framework programmes being implemented simultaneously presents the risk that administrative resources needed for the efficient management of those funds may not be sufficient; is pleased that the follow-up on the 2020 discharge has led to actions addressing this issue and that the IHI Joint Undertaking will report on details of the process in the Consolidated Annual Activity Report for 2022;
7. Notes, as regards the IHI Joint Undertaking’s operational obligations at the end of 2021,

that the IHI Joint Undertaking had fully committed EUR 966 million of the maximum Union contribution for signed Seventh Framework Programme grant agreements, out of which around EUR 84,3 million (or 8,7 %) remains to be paid in the coming years; notes that private members provided in-kind contributions at the same level; notes that the implementation rate for the IHI Joint Undertaking's 2021 payment budget available for Seventh Framework Programme projects was 80 %; notes, moreover, that the IHI Joint Undertaking had almost no 2021 operational commitment appropriations, as it had finished its last call for proposals by the end of 2014;

8. Notes that, at the end of 2021, the IHI Joint Undertaking had committed EUR 1 452,1 million or 91 % , of EUR 1 595,4 million of the maximum Union contribution for signed Horizon 2020 grant agreements; notes that this was due to the fact that the 2019 call for proposals could not cover all topics planned and the Union budget had been reduced accordingly by decision of the governing board; notes that, of this committed amount, around EUR 616,8 million (or 42,5 %) remains to be paid in the coming years; notes, in addition, that the IHI Joint Undertaking's private members had legally committed to provide in-kind contributions of EUR 1 520,7 million;
9. Underlines the fact that the implementation rate for the IHI Joint Undertaking's 2021 payment budget available for Horizon 2020 projects was 97% and that the IHI Joint Undertaking had almost no 2021 operational commitment appropriations, given that Regulation (EC) No 557/2014 required that all commitments be made before the end of 2020, and Regulation (EU) 2021/2085 only came into force at the end of 2021, no calls were launched in 2021;

Performance

10. Notes, from the annual report, that in 2021 the completion of the IMI2 Joint Undertaking project portfolio, with the signature of the last 15 IMI2 Joint Undertaking project grant agreements, was achieved; notes that the 15 newly created projects have a total budget of EUR 413 million, with around half of that amount coming from the Union's Horizon 2020 programme and the rest coming from EFPIA contributions and IMI2 Joint Undertaking associated partners as well as other sources;
11. Notes with appreciation that the IHI Joint Undertaking's projects have generated 275 assets that completed a significant milestone during the project lifecycle (the target was 50); notes that those assets include, amongst others, tools, methodologies, processes, services, training materials; notes that examples of milestones are: key clinical trial phases, animal models, prototypes, commercialisation, patents and publications; notes, moreover, that industry participants in many of the IHI Joint Undertaking's projects are making use of new tools and processes generated by the projects, such as animal models, standards, biomarkers, standard operating procedures, use of screening platforms, and clinical trial networks;
12. Highlights the fact that, as regards visibility, the IHI Joint Undertaking continued to demonstrate Union added value through assertive communication to target audiences with emphasis on the openness, transparency, relevance, and coherence of the IHI Joint Undertaking's activities; notes that it continued to disseminate the project results and success stories by boosting the diversity of their output to include over 100 written articles in different styles, as well as short, accessible videos for promotion via social

media, and that in addition all of the IMI2 Joint Undertaking project factsheets were added to the newly created IHI Joint Undertaking website, to facilitate their promotion in the future; encourages the IHI Joint Undertaking to share any successful visibility strategies with other Joint Undertakings in order to present their added-value to citizens;

Recruitment and staff

13. Notes that the staff establishment plan provides for 39 temporary agents, 15 contract agents and 2 seconded national experts (SNEs), in total 56 staff members; notes that, on 31 December 2021 there were 50 positions occupied: 36 out of 39 temporary agents (TAs) (92,30 %), 13 out of 15 contract agents (86,70 %) and 1 out of 2 SNEs (50 %); notes, in addition, that, as regards TAs, the empty posts were to be filled in 2022 as two selection procedures were on-going and that, in 2022, 1 (SNE post was to be cut;
14. Welcomes the fact that the IHI Joint Undertaking has maintained a good geographical balance (20 different countries) and a good gender balance (22 women, 17 men) when external experts were consulted;
15. Notes with concern that during the period from 2018 to 2021 the average annual rate of interim staff for all Joint Undertakings remained high, at around 11 % of statutory staff; recalls that the high level of contractual staff tends to significantly increase the IHI Joint Undertaking's staff turnover rate and further destabilises the staffing situation; emphasises, moreover, that the use of interim staff should remain a temporary solution, otherwise it could negatively affect the IHI Joint Undertaking's overall performance, such as the retention of key competences, unclear accountability channels, possible judicial disputes and lower staff efficiency;
16. Notes from the annual activity report 2021 that there is an appropriate gender balance with 66% of staff being female: 50% of members on the governing board, 61,5% of appointed nominees at the States representatives group and 41,7% of full members in the scientific committee are women; encourages the IHI Joint Undertaking to maintain this balance;
17. Appreciates the fact that the continuous improvements in the project management workflow and the coordinated effort made by the IHI Joint Undertaking's staff led to the difficulties linked to the COVID-19 pandemic period being overcome, thereby ensuring business continuity and resulting in a considerable 96,04 % of operational budget execution in 2021;
18. Notes that the employers' contributions for the staff of the Joint Undertakings corresponding to the ratio of their non-Union subsidised revenues to their total revenues, have not been paid by the Joint Undertakings to the Union pension scheme since 2016, as the Commission has neither provided for this expenditure in the budget of the Joint Undertakings nor formally requested the payments; calls on the Commission to take steps to avoid similar issues in the future;

Internal control systems

19. Notes that, for Seventh Framework Programme interim and final payments, the IHI

Joint Undertaking performs ex-post audits, whilst for Horizon 2020 payments, the Common Audit Service of the Commission's DG RTD is responsible for the ex-post audits; notes that, based on the ex-post audit results available at the end of 2021, the IHI Joint Undertaking reported a representative error rate of 1,9 % (2,16% in 2020) and a residual error rate of 0,8 % (1,14%) for its Seventh Framework Programme projects, and a representative error rate of 0,97 % (1,13% in 2020) and a residual error rate of 0,6 % (0,74% in 2020) for Horizon 2020 projects (clearings and final payments);

20. Notes that, to assess the operational payment controls of the IHI Joint Undertaking, the Court audited randomly sampled Horizon 2020 payments made in 2021, at the level of the final beneficiaries, to corroborate the ex-post audit error rates; notes that, in one case, the Court found and quantified a systemic error related to personnel costs resulting from the use of incorrect hourly rates that were not based on a completed financial year, and in another case, an error resulting from the lack of appropriate supporting evidence for declared equipment and travel costs;
21. Emphasises that the Court's finding confirmed persistent systemic errors for declared personnel costs and that in particular, small and medium-sized enterprises (SMEs) and new beneficiaries are more error-prone than other beneficiaries; highlights the fact that those errors have also been regularly reported in the Court's previous annual reports since 2017; emphasises, therefore, that streamlining of the Horizon 2020 rules for the declaration of personnel costs and wider use of simplified cost options is a precondition for stabilising error rates to below materiality level; emphasises that the IHI Joint Undertaking should strengthen its internal control systems to address the increased risk regarding SMEs and new beneficiaries and strongly encourage the use of the personnel costs calculation wizard by certain categories of beneficiaries that are more prone to errors, such as SMEs and new beneficiaries; welcomes the fact that, in 2022, all Joint Undertakings started implementing actions for error rate reductions in line with the action proposed by the Court, including exploring the options of simplified forms of costs such as unit costs, lump sums and flat rates;
22. Notes that, given the multi-annual nature of both programmes and individual research projects, the residual error rate calculated on the duration of the programme provides the most meaningful indication of the financial impact of errors and that it takes into account the corrections made by the IHI Joint Undertaking and the fact that the IHI Joint Undertaking extrapolates the systematic findings of the audits, significantly increasing the cleaning effect of audits; highlights, moreover, the fact that as the programmes advance, beneficiaries learn from their errors and that drawing from the lessons learned from the audit findings, the IHI Joint Undertaking also works continuously to better inform beneficiaries of any pitfalls to help them report their costs correctly, thereby preventing errors;

Prevention and management of conflict of interests, and anti-fraud strategy

23. Notes that IHI Joint Undertaking has an anti-fraud strategy aligned with the Commission anti-fraud strategy (CAFS 2019) and the Common anti-fraud strategy for the research family (RAFS 2019), complemented by additional anti-fraud actions related to service contract management and administration;
24. Notes that actions implemented on grants and operational activities are coordinated with

DG RTD and other research agencies through a multiannual action plan coordinated by the Fraud and irregularity in research (FAIR) Committee;

25. Notes that, in 2021, the IMI 2 Joint Undertaking's anti-fraud activities covered cooperation with the FAIR Committee activities, increasing staff awareness on anti-fraud, including participation in the European Anti-Fraud Office's conference 'United against corruption – Upholding the ethical standards of EU Institutions' and fraud risk assessment exercise; notes in addition that that task was twofold, one task embedded in the annual anti-fraud cycle and one, more extensive and detailed, to set the basis for the revision of the overall anti-fraud strategy for the IHI Joint Undertaking;
26. Welcomes, moreover, the fact that regular information on fraud-related risks and on the procedures to be used in the event of suspicion of fraud/irregularities was communicated to the entire staff of the IHI Joint Undertaking and that attention was given to cross-sectional issues such as risks linked with conflict of interests, delegation of authority and segregation of duties.

INFORMATION ON ADOPTION IN COMMITTEE RESPONSIBLE

Date adopted	28.2.2023
Result of final vote	+ : 21 - : 6 0 : 0
Members present for the final vote	Gilles Boyer, Olivier Chastel, Caterina Chinnici, Corina Crețu, Ryszard Czarnecki, José Manuel Fernandes, Luke Ming Flanagan, Daniel Freund, Isabel García Muñoz, Monika Hohlmeier, Jean-François Jalkh, Mislav Kolakušić, Joachim Kuhs, Alin Mituța, Jan Olbrycht, Markus Pieper, Michèle Rivasi, Sándor Rónai, Petri Sarvamaa, Eleni Stavrou, Angelika Winzig, Lara Wolters, Tomáš Zdechovský
Substitutes present for the final vote	Eider Gardiazabal Rubial, Elżbieta Rafalska
Substitutes under Rule 209(7) present for the final vote	Fabienne Keller, Katrin Langensiepen

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

21	+
ECR	Ryszard Czarnecki, Elżbieta Rafalska
ID	Jean-François Jalkh
PPE	José Manuel Fernandes, Monika Hohlmeier, Jan Olbrycht, Markus Pieper, Petri Sarvamaa, Eleni Stavrou, Angelika Winzig, Tomáš Zdechovský
Renew	Gilles Boyer, Olivier Chastel, Fabienne Keller, Alin Mituța
S&D	Caterina Chinnici, Corina Crețu, Isabel García Muñoz, Eider Gardiazabal Rubial, Sándor Rónai, Lara Wolters

6	-
ID	Joachim Kuhs
NI	Mislav Kolakušić
The Left	Luke Ming Flanagan
Verts/ALE	Daniel Freund, Katrin Langensiepen, Michèle Rivasi

0	0

Key to symbols:

+ : in favour

- : against

0 : abstention