RWE4Decisions response to the TEHDAS2 Public Consultation 5 on "*Draft guideline for Health Data Access Bodies on the procedures and formats for data access*"

OVERVIEW OF THE PUBLIC CONSULTATION & RWE4DECISIONS' RESPONSE

TEHDAS2 is a joint action dedicated to creating guidelines and technical specifications for using health data across countries for a better implementation of the European Health Data Space Regulation.

Its second public consultation (closed on 30 November 2025) included the collection of feedback on 11 draft guidelines. RWE4Decisions participated in the fifth one on the "*draft guideline for health data access bodies on the procedures and formats for data access*" as it directly addresses how quickly and transparently data access requests can be processed, which is vital for payers and other stakeholders who rely on timely evidence generation.

Our response builds on RWE4Decisions' long-standing commitment to a robust EHDS framework and implementation, reinforced by our active participation in policy discussions including through an informal EHDS stakeholder group and contributions to the European Commission public consultations (available here).

The consultation was structured in 36 questions addressing each section of the guideline and its annexes. Overall, our feedback to the draft guideline was positive as we found it easy to understand. Nevertheless, RWE4Decisions stressed the need for clearer guidance and practical tools to make implementation feasible. We proposed adding explanatory materials for decision pathways, and structured feedback loops between Health Data Access Bodies and data users. We also recommended machine-readable templates and simplified processes to support SMEs and ensure inclusivity. These additions aim to reduce administrative burden, accelerate timelines, and foster cross-border collaboration.

Below are the answers we submitted to TEHDAS2.

Next steps include:

- *Q1 2026*: TEHDAS2 to publish final versions of guidelines based on the second public consultation
- *May-June 2026*: TEHDAS2 third public consultation, focusing on the collaboration with third countries, data enrichment and informing citizens.

GENERAL QUESTIONS

7. Is the document easy to understand? 4

1: Not clear nor easy to understand
4: Very clear and easy to understand

8. How well does the document address the key issues related to its subject matter? 4

1: Not well
4: Very well

9. How feasible do you find the guidelines or technical specifications to implement, as outlined in the document? 3

1: Not feasible and implementable at all
4: Very feasible and implementable

10. Generic feedback - Do you have any suggestions for improving the document? Are there any additional topics or areas that should be covered?

RWE4Decisions welcomes the comprehensive and operationally detailed draft guideline developed under TEHDAS2. We appreciate the effort to harmonise procedures across Member States and support the implementation of the EHDS Regulation. To further strengthen the document, we suggest the following additions and clarifications:

- First, Payers represent key stakeholders in the development of innovative health technologies, with specific requirements relating to timeliness and cross-border collaboration which differ from regulators and policymakers. We recommend that Payers' specificities are acknowledged in the guideline, with tailored provisions to consider their data needs and timelines over the process.
- Efforts towards adopting a holistic approach should take account of the use of real-world data into the full life cycle of health technologies. This includes strengthening the European-level coordination among HDABs. We recommend including examples, perhaps in a dedicated subsection, of how HDABs can support access to data for generating real-world evidence, particularly for regulatory decision-making, HTA, post-market surveillance and optimisation of treatment use. This would help clarify the relevance of real-world evidence within the EHDS framework. The guideline could also be more explicit on how HDABs assess and communicate data quality. This is particularly important for secondary use in research and regulatory contexts, where data provenance and reliability are critical.
- The guideline should include simplified pathways and practical examples for SMEs, as resources constraints differ significantly from large organisations. Without tailored guidance, smaller entities may face disproportionate administrative and financial burdens.
- While ethical considerations are referenced, we would also recommend expanding on how HDABs should engage with ethics committees and communicate safeguards to the public. Secure Processing Environment (SPE) requirements and associated

costs should also be clearly communicated upfront to avoid unpredictability for SMEs. This would help build trust and ensure transparency in secondary data use.

- We propose that HDABs implement structured feedback loops with data users and holders to improve processes over time. This could include periodic surveys or stakeholder workshops.
- Finally, all templates should be machine-readable to enable automation and reduce administrative burden. Digitalisation of these processes would allow applicants to pre-populate forms, integrate with compliance tools, and streamline submissions.

QUESTIONS ON CHAPTER 5 OF THE GUIDELINE

Chapter 5 describes the application completeness check phase. This is recommended to ensure that an application is complete before entering the actual application assessment process.

12. Were the points to be checked presented clearly? 3

1: Not clear nor easy to understand
4: Very clear and easy to understand

13. Do you consider the checklists for data access application and data request completeness check (annexes 7 & 8) helpful in performing the completeness check? 4

1: Not helpful
4: Very helpful

14. Do you have suggestions for improving section 5? Was something missing or was something unnecessary?

First, we note that the completeness check does not account for the iterative nature of many real-world evidence projects. For example, definitions or strategies may evolve as feasibility assessments progress. The guideline should consider Payer-specific requirements (including timeliness and cross-border collaboration) and allow for provisional completeness in certain cases, with a pathway for amendment or clarification during the assessment phase. Coordination mechanisms across HDABs should be clearly defined to ensure consistency and avoid delays. The guideline should also introduce a formal mechanism for provisional completeness, allowing SMEs to submit initial applications and update them without restarting the process. This flexibility is critical for smaller companies with limited resources and would help ensure that administrative requirements do not become a barrier to participation in the EHDS ecosystem.

The guideline could also more explicitly address how completeness checks interact with multi-country applications. While the HealthData@EU platform is mentioned, the operational implications of coordinating completeness checks across HDABs in different jurisdictions are not fully explored. Clarifying how HDABs should handle discrepancies

or delays in completeness validation across borders would strengthen the section's practical utility.

The guideline should address ambiguity in the different purposes of data use, such as how HDABs should collaborate on clear criteria for what qualifies as public interest or other ambiguous purposes. The guideline should clearly indicate what areas qualify as public interest, what areas do not, and how issues that fall between these options are resolved. It should also specify who has the authority to make these determinations and how that authority is communicated across the HDAB network to ensure harmonisation. The document could better acknowledge the diversity of data users. For example, some applicants may not have access to sophisticated systems or legal teams to pre-validate attachments or formats. Including guidance on how HDABs can support applicants during this phase would align with the EHDS's goal of equitable access. Additionally, the guideline could be strengthened by including examples of common completeness issues and how they were resolved. This would help applicants self-assess their submissions and reduce the burden on HDABs.

Finally, the guideline could recommend periodic review and updates of the templates in annexes to reflect evolving regulatory requirements, user feedback and technological developments. This would ensure that the tools remain fit-for-purpose and responsive to stakeholder needs.

QUESTIONS ON CHAPTER 6 OF THE GUIDELINE

Chapter 6 describes the application assessment process that begins after the application has been deemed complete in the completeness check phase. The application contents are reviewed, and it is evaluated whether a data permit can be granted, or a data request approved.

15. Were the different aspects to be reviewed presented clearly? 3

1: Not clear nor easy to understand
4: Very clear and easy to understand

16. Were the "What to check" points helpful and concrete? 4

1: Not helpful nor concrete
4: Very helpful and concrete

17. Do you have suggestions for improving section 6? Was something missing or was something unnecessary?

This section could better articulate the balance between regulatory compliance and scientific or societal value. While the procedural steps are well-defined, the document puts less emphasis on how HDABs can assess the potential public health or innovation impact of a proposed data use. For stakeholders working in real-world evidence generation, this is a critical dimension. We suggest that the guideline explicitly encourages HDABs to consider the societal relevance and potential health system benefits (including for patients' safety) of the proposed data use.

We also note that the guideline assumes a relatively static application structure. In practice, many real-world data projects evolve over time, especially in multi-country or multi-source contexts. The guideline could acknowledge this by allowing for iterative refinement of applications during the assessment phase and by committing to update templates regularly based on stakeholder feedback and technological developments. This is particularly critical for SMEs developing novel therapies, as they rely on adaptive processes to keep pace with innovation and avoid unnecessary administrative barriers.
The subsection 6.4 on communication could be expanded to clarify the nature and purpose of the interaction. It should specify that communication is not merely administrative but should serve as a structured dialogue to resolve ambiguities, clarify technical requirements, and ensure alignment between HDABs and applicants. This communication should include clear timelines, pathways for unresolved issues, and guidance on how HDABs coordinate responses across jurisdictions for multi-country applications.

Finally, as for Section 5, Section 6 could better reflect the diversity of data users and provide explanatory notes, pre-assessment consultation options, and simplified pathways for low-risk research projects to help SMEs navigate complex requirements. While it assumes a high level of technical and legal literacy, many applicants may need additional support. The guideline could recommend that HDABs provide explanatory materials, templates or pre-assessment consultations to ensure fair access.

18. Was the distinction between the completeness check phase and the application assessment phase clearly presented? 4
1: Not clear nor easy to understand
4: Very clear and easy to understand

19. Would the distinction need to be clarified further? If yes, please provide suggestions.
While the guideline explains both the completeness check phase and the application assessment phase, the current text may still be challenging for SMEs and resource-limited applicants. We recommend introducing a comparative summary table that presents a side-by-side overview of the two phases, including objectives, key checks, responsible parties, and expected outputs. This would make the differences intuitive and reduce ambiguity for applicants unfamiliar with regulatory processes.

Additionally, the guideline should include a visual flowchart or process diagram illustrating the transition from completeness check to assessment. This diagram should show timelines and decision points, helping applicants understand the sequence of steps. Visual aids are particularly valuable for smaller organisations that lack dedicated compliance teams.

Finally, the guideline should explicitly state what the applicant does versus what the HDAB does in each phase. Clear presentation of responsibilities will prevent misunderstandings and ensure that applicants can prepare effectively without unnecessary delays.

20. Was the distinction between assessing data access applications and data requests clear? 4

1: Not clear nor easy to understand
4: Very clear and easy to understand

21. Would the distinction need to be clarified further? If yes, please provide suggestions.

The guideline should include plain language definitions of both data access applications and data requests within the main text and in the templates for applicants to understand the fundamental differences.

Additionally, a flowchart should be included to illustrate when to use each pathway and what steps follow. This visual aid should clearly show the decision points and timelines for each pathway, making the process intuitive and reducing complexity for smaller organisations.

QUESTIONS ON CHAPTER 7 OF THE GUIDELINE

Chapter 7 describes the steps after the decision and the actions the HDABs need to take. Many of the topics are described in detail in other TEHDAS2 guidelines.

22. Were the responsibilities and actions to be taken after the decision presented clearly and on a sufficient level? 4

1: Neither clear nor on sufficient level
4: Very clear and on sufficient level

23. Do you have suggestions for improving section 7? Was something missing or was something unnecessary?

Following the comments for previous sections, section 7 could better reflect the iterative nature of data preparation and use and introduce a mechanism for ongoing dialogue between HDABs and applicants after permit issuance. It currently presents the post-decision steps as linear, but in practice, data users may need to clarify and adjust variables after initial extraction of data. Including a mechanism for post-decision dialogue between HDABs and data users would support more flexible and responsive data access.

The integration of user timelines and expectations could also be strengthened. While the section outlines what HDABs must do after issuing a permit or approval, it does not sufficiently address how applicants will be kept informed throughout these steps. Clearer guidance on expected timeframes for data delivery or notifications of delays would enhance transparency and user experience. This is particularly important for SMEs and real-world evidence projects that often operate under regulatory or funding deadlines.

Finally, the invoicing section is functional but could be more transparent. Applicants would benefit from clearer guidance on how fees are calculated (including SPE costs and data preparation fees), what constitutes a reasonable cost, and whether fee waivers or reductions are available for public-interest research.

OPEN QUESTIONS AND UNRESOLVED ISSUES OF CHAPTER 9 OF THE GUIDELINE

24. Should the full applications, data permits and data request approvals be published in the transparency portal or only certain information from these? If the full documents should be published, sensitive information related to e.g. the persons entitled to process the data, the detailed description of the granted data sets or other sensitive information might need to be transferred to a non-public annex or similar. The HDAB must justify all omissions.

Publishing full applications, data permits, and data request approvals risks exposing intellectual property and trade secrets, even if sensitive elements are moved to non-public annexes. While transparency is essential, a more balanced approach would be preferable. We recommend publishing summary-level information only, such as the purpose of data use, dataset categories, duration of the permit, and the name of the HDAB, while keeping sensitive details confidential.

EHDS Article 68(2) states that the HDAB shall take into account (a) risks for national defence, security, public security and public order and (b) the risk of undermining the confidentiality of data in governmental databases of regulatory authorities.

25. What specific points should be considered when assessing the aforementioned risks? On what level these should be assessed?

We believe the guideline should detail a specific approach to risk assessment, ideally supported by a standardised checklist for HDABs to ensure consistency across Member States. Points to consider could include whether the requested data includes information on military personnel, national security infrastructure, or sensitive populations.

In terms of public order and security, the HDAB should consider if the intended use of the data could lead to social discrimination or misuse in politically sensitive contexts. For example, projects that aim to analyse health outcomes by ethnicity, religion, or migration status may require additional scrutiny.

We recommend that these risks are assessed at the HDAB level through internal review and expert consultation, and in coordination with designated national authorities responsible for defence, security or regulatory oversight. The guideline should clarify when and how HDABs should submit applications for external review, and what timelines apply to such referrals.

Finally, the guideline should emphasise that risk assessment must be proportionate. It should not become a barrier to legitimate research or innovation, especially in the field of real-world evidence, where access to granular data is essential.

EHDS states that if a data permit needs to be amended, the health data user shall submit an amendment request. Further, EHDS separately mentions two topics that an amendment can concern: extending the data permit validity period once or modifying the authorised persons with access rights to the electronic health data in a secure processing environment.

26. Do you foresee some other points in the data permit that should be allowed to be subject to amendment requests? What kind of implications this would have in your member state?
Potential options could include e.g. transferring the data to another secure operating environment, extracting additional variables from the datasets included in the original permit, and extending the period from which the data are extracted (i.e. extracting more data from the datasets included in the original permit). The original datasets and purpose of use should be maintained.

We support the idea that additional elements of a data permit should be eligible for amendment requests. We agree with the potential options mentioned as they reflect the realities of real-world evidence generation, where project needs may evolve due to feasibility assessments, technical constraints, or emerging scientific insights.

Flexibility is essential to adapt to evolving scientific requirements without restarting the entire application process. This is particularly important for SMEs and innovative projects operating under tight timelines and regulatory constraints. Additionally, the guideline should provide digital forms and automated checks for amendment requests to reduce administrative burden and accelerate processing.

There should also be a greater recognition of the risk of not advancing data use with appropriate protections. A plausible model addressing this tension is being piloted in Alberta, which recognises data-related harms and balances individual, community, and health system administrator interests (see https://www.networkedhealth.org/_files/ugd/3eb345_85ada6635d334c2ba6c102bdd57f20e2.pdf for reference). Including such considerations would help ensure that amendment processes do not unintentionally create barriers to beneficial data use.

QUESTIONS ON ANNEXES 5-6 OF THE GUIDELINE

Annexes 5-6 of this deliverable are templates for the common European data access application and data request, respectively, to be utilised when applying for data under the EHDS both through the HealthData@EU central platform and national HDABs.

27. Was annex 5 (the data access application template) clear and easy to understand? 4

1: Not clear nor easy to understand
4: Very clear and easy to understand

28. Do you have any feedback related to annex 5 (the data access application template)? Please elaborate.

We recommend including sample completed templates for different applicant profiles, such as SMEs, academic institutions, and larger pharmaceutical companies. These examples would help ensure consistent interpretation of requirements.

Additionally, the guideline could introduce a simplified version of the template for low-risk research projects. This would significantly reduce administrative burden for smaller organisations and projects that pose minimal privacy or security risks.

29. Was annex 6 (the data request template) clear and easy to understand? **4**

1: Not clear nor easy to understand
4: Very clear and easy to understand

30. Do you have any feedback related to annex 6 (the data request template)? Please elaborate.

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QUESTIONS ON ANNEXES 9-10 OF THE GUIDELINE

Annexes 9-10 of this deliverable are templates for the data permit and data request approval, to be utilised by the HDABs or the European Commission when granting access to data.

31. Was annex 9 (the data permit template) clear and easy to understand? **3**

1: Not clear nor easy to understand
4: Very clear and easy to understand

32. Do you have any feedback related to annex 9 (the data permit template)? Please elaborate.

The structure could be more intuitive if the scenarios covered were separated into distinct sections or templates. This would help ensure that only relevant fields are completed.

The fee section could also be improved by including a standardised format and guidance on how to communicate fee changes or additional charges.

33. Was annex 10 (the data request approval template) clear and easy to understand? **3**

1: Not clear nor easy to understand
4: Very clear and easy to understand

34. Do you have any feedback related to annex 10 (the data request approval template)? Please elaborate.

The fee section could include clearer guidance on how recurring extractions are priced and invoiced. For example, if the applicant requests quarterly updates, the template should specify whether each extraction requires a separate approval or whether the initial approval covers the full period.

The template could include a summary of the applicant's obligations post-approval, such as timelines for publishing results and informing the HDAB of outputs to reinforce accountability and transparency goals.

QUESTIONS ON ANNEXES 11 OF THE GUIDELINE

Annex 11 describes the key recommendations for electronic contractual arrangements that may be used by health data holders and health data users for the sharing of data containing information or content protected by intellectual property rights or trade secrets.

35. Was annex 11 (the key recommendations for electronic contractual arrangements) clear and easy to understand? 4

1: Not clear nor easy to understand
4: Very clear and easy to understand

36. Do you have any feedback related to annex 11 (the key recommendations for electronic contractual arrangements)? Please elaborate.

Annex 11 could be more explicit on how to distinguish if a data is protected or not. In practice, many datasets contain a mix of data, and it is not always clear which parts require contractual safeguards. Including examples or criteria for identifying protected content would help both data holders and users navigate the form.