European Federation of Pharmaceutical Industries and Associations

EFPIA response to the consultation on a legislative proposal for a European Health Data Space (EHDS)

Version: FINAL

About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 38 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

Executive summary

The legislative proposal on a European Health Data Space (EHDS) and respective horizontal proposals provide an unprecedented opportunity to shape the future health data and digital ecosystem. Digital transformation has the potential to increase the innovation and productivity of the EU economy and ensure that Europe remains an innovator and world leader in the development and manufacture of medicines, supporting faster access to care for patients.

EFPIA supports the EU's efforts to increase citizen and patient control of, and access to, their health data, while at the same time giving policymakers, researchers and innovators the opportunity to realise the potential of health data in a trusted and secure way. Removing the barriers to health data for scientific research and development activities will mean patients can benefit from the discovery of innovative treatments, medical devices and diagnostics, and it will unlock a sustainable, resilient healthcare system paving the way for more preventive, personalised healthcare.

We welcome the proposed participatory governance model with the right to request access to data for secondary re-use (under strong safeguards for security and privacy) not limited by the type of user, but rather based on the purposes of data access and use set out in the Regulation (which includes scientific research, development and innovation activities). We are supportive towards the mandatory creation of health data access bodies in all Member States (MS) for the assessment and granting of data access requests. They are a key step to enable the vision set out in the EHDS draft; to promote and facilitate the reuse of health data whilst ensuring strong safeguards for security, privacy and IP rights. **It will be critical to ensure consistency across different Member State health data access bodies to avoid fragmentation.**

EFPIA acknowledges the potential for the EHDS to unleash the value of data for the economy. To achieve this, the EHDS must strike the right balance between facilitating data access (for data users) and responsibilities of sharing data (as a data holder). **The EHDS must give clearer assurances on the conditions for sharing data, including around how IP and trade secrets will be protected when data is requested from a data holder** (such as pharmaceutical companies), including in times of public emergency. The current definition of data falling under the scope of EHDS is broad and ambiguous,

leading to challenges in understanding which categories of data fall under this definition and which do not.

Intellectual property rights (IPR) are imperative to maintain a competitive innovation ecosystem in the EU; IPR enable the pharmaceutical industry to invest in R&D that will ultimately benefits patients through the discovery of new medicines and technologies. Companies' trade secrets and proprietary information must remain secure from disclosure to competitors; disclosure of this information would limit the EU's ability to maintain a sustainable, competitive research ecosystem.

Further clarification is also needed on the conditions for which data holders will be required to share clinical trial data under the EHDS. **Industry already adheres to clinical trial transparency and data sharing standards and policies[1] which balance making data available with the need to protect the validity of trials and IP rights – it is vital the EHDS does not circumvent this.** The legal basis for data sharing and access for secondary use should also be clarified. This will help to ensure that the EU remains competitive in R&D and encourage continued investment in innovation, enabling the development of innovations that will benefit citizens and patients

EFPIA acknowledges the ambition of the EHDS proposal, however, the ability to address the current legal and technical fragmentation is dependent on the implementation of standardised procedures and common specifications that are to be defined in the delegated (12) and implementing acts (24). More clarity on the aspects that will be addressed in these acts should be provided at an early stage and jointly agreed by institutions. The coordination of requests between national access bodies and common rules facilitating handling of data access must be ensured. If the EU fails in this endeavour, another layer of fragmentation may be added which would hinder the goals of the EHDS and become yet another barrier to scientific research. Overall, consistency with other data related initiatives (GDPR, AI Act, Data Governance Act, Data Act) is imperative to avoid additional bureaucracy.

The proposal envisages the creation of a European Health Data Space Board (EHDS Board) that will facilitate the cooperation between digital health authorities and health data access bodies. The Board should also contribute to the consistent application of the EHDS Regulation throughout the EU and ensure mutual recognition and consistency in how health data access bodies operate. Involvement in the Board for all stakeholders, including industry as innovator, is necessary to benefit from their experience and knowledge and to understand the challenges different stakeholders face. The pharmaceutical industry has a long legacy of transparent, respectful and privacy-compliant management of patient data from clinical trials and registries, as well as Real-World Evidence (RWE) generated from other sources, which requires novel research methods, including governance, ethics and legal implications. Hence, we would like to contribute to a better public understanding of the value of health data and enhance confidence and trust in how data is collected and used to foster health innovation. The success of the EHDS relies on the availability of and access to rich, high-quality, interoperable data.

Our detailed feedback on provisions of the EHDS proposal is provided below.

[1] Sharing clinical trail information

Primary use of data (Chapter II)

Safe access, handling and sharing of data are crucial for the delivery of timely, effective, and good quality healthcare to patients, and help guarantee patients' safety. Not only is data fundamental for responding to citizens and patients' needs, but it also helps in defining public health policy development and improving patient care. The intent of the primary use of data is to empower citizens to better control and exercise their rights over their own data, to be able to share it with healthcare providers of their choice, nationally and across borders throughout the EU. Trust, including in data security, is a central component of the success of this endeavour. The ability to demonstrate the value of the single market for data to citizens is key, as this will ensure the availability of rich, high-quality data for secondary use. When asked to provide their health data, citizens and patients should be able to do so without concern that their data is being sold and used for purposes other than public health research, such as insurance or targeted advertising.[2] Data protection policies must ensure citizens and patients' data is used for healthcare-related purposes and actively enabled, by putting safeguards in place that preserve the confidentiality of the patient and respect ethical standards.

EHRs (Chapter III)

EFPIA welcomes the establishment and mandatory self-certification scheme for European Health Records (EHR) Systems to ensure standardised requirements for interoperability, security, safety and privacy. **It is paramount that the common specifications are defined at an early stage of the examination of the EHDS proposal to avoid different approaches that would further fuel fragmentation.** The common format of the European Electronic Health Record Exchange should be prioritised to strengthen the fundamental freedoms of EU citizens in the area of cross-border healthcare and ensure better interconnectedness and quality of the available data for secondary use. Furthermore, while the legislative proposal explicitly refers to the importance of supplementary and interoperable infrastructures in cases of public health emergencies, such as support for vaccination card functionalities, the industry believes that attention should also be put on collection, sharing and access to vaccination data in real time, both at EU and national level, outside of pandemic context. The 2018 European Commission Roadmap already outlined the importance of common vaccination cards that should be compatible with electronic immunisation information systems and recognised for use across borders.

We would like to emphasise that the definition of the EHR System in the EHDS proposal is very broad and does not define the term of the 'health system', which could potentially encompass any software that stores electronic health data for healthcare professionals. In the case of more complex products that would qualify as a medical device and an EHR system which also uses AI to achieve the device's intended purpose, more clarity should be provided on the roles and responsibilities and under which regulation (MDR, AI Act, EHDS Regulation) the conformity assessment should be conducted.

[2] Public trust in health data sharing has sharply declined, survey reveals | Imperial News | Imperial College London

Furthermore, the applicability of the EHDS proposal to data generated by diagnostics regulated under the In-Vitro Diagnostics Regulation (IVDR 2017/746) should be clarified.

Secondary use of data (Chapter IV)

a) Scope and definitions

EFPIA welcomes the establishment of the minimum categories of data to be shared for secondary use. However, the **current text does not provide clarity on the scope of the data that is covered and does not set any time limit for the requested data**. It is recommended that - in consultation with stakeholders - more information is provided on different limits depending on the category of electronic health data. In addition, the EHDS should set out any grace period during which no electronically structured data has to be shared for specific situations.

Moreover, the definition of the '*data holder'* is unclear and more certainty would be welcomed on the meaning of the *'data that is in scope*' and the '*entity that performs research with regards to the health sector',* and if the pharmaceutical industry will be classified as such.

If pharmaceutical companies qualify as a data holder, we understand that real world data i.e. from registries, EHRs and data from interventional clinical trials – which is included in the minimum categories – should be shared. We urge the decision makers to define in consultation with industry and other stakeholders the specificities related to the scope of this provision. Other sources could also be captured, for example from Art. 33 (k) "*medical devices*" which could include data collecting apps that pharmaceutical companies may use and also Art. 33 (l) "*research cohorts, questionnaires and surveys related to health*" which could impact non-clinical research and RWE efforts. It also covers genetic data and Patient Support Program data which presents both risks to individuals as well as revealing research interests/potential drug targets at an early stage in development.

The proposal seems to cover all electronic health data including data from clinical trials and registries that companies have, but also all EHR systems that are operational and all biobanks in operation. **A lack of clear thresholds for what electronic health data is in scope will only increase uncertainty on the roles and responsibilities of different actors within the EHDS**. Given the existing European requirements around sharing of clinical trials data that is strictly regulated, further clarification is needed on the expected contribution for sharing of clinical trial data under the EHDS, as this is not clear at this stage. Public disclosure of clinical trial information and documents is required in countries and regions around the world with the EU requiring the most extensive regulatory document public disclosure. **The current obligations of the pharmaceutical companies for sharing clinical trials data (aggregated and patient level) are sufficient to enable innovation, hence the legislator intention for this provision should be clarified**.

b) Disclosure of IP and Trade Secrets

The Commission should specify how data holders' IP and trade secrets will be protected within the EHDS. While the main focus is on the IP/trade secrets for clinical trial data, there will be other situations to consider for pharmaceutical companies – such as secondary use of data collected through product/clinical support tools (AI or otherwise).

There are examples of how to balance the public interest to access certain data sets and the commercial interest to protect intellectual property and trade secrets. The draft EU Data Act includes

a prohibition on using the accessed data for the purpose of building a competing product (draft EU Data Act, Art. 6(2)(e)[3]). A similar provision should be included in EHDS to protect the data holder/owner. Additionally, inspiration can be drawn from the European Medicines Agency (EMA) policy on publication of clinical data for medicinal products for human use (Policy 0070) including the external guidance on the implementation issued by the EMA; and EMA policy on access to documents (related to medicinal products for human and veterinary use) (Policy 0043).

Looking at e.g., clinical trial or registry-related data, we expect that sharing these categories of data would take the form of contractual protections (non-disclosure or confidentiality agreements). The EHDS proposal suggests that IP and trade secrets should not be an obstacle to data sharing (e.g., Art. 33(4)), but that measures can be put in place to offer protection that will continue to motivate clinical research in the EU. **The proposal should also clarify <u>what</u> data is to be shared – i.e. raw/source data only (which may need to be defined/explained), as opposed to processed/derived data and insights (which in themselves are IP/trade secrets and also could reveal IP/trade secrets used to process the data and/or find those insights).** Further clarification is required on when and to whom the data entailing intellectual property and trade secrets is expected to be shared, on which principles commercially sensitive data is expected to be shared, and what mechanism will be applied to ensure its protection.

Clinical trial data should not be accessible before study completion or market authorisation. Any requirements going beyond what is required to be disclosed under existing EU law will detract from innovation taking place in the EU, which is the opposite of the objectives set up in the EHDS.

Data holders should have a say in who can/cannot access data and/or setting conditions for access (for example, to limit access to data by competitors or technology companies, or to ensure researchers will agree to appropriate contractual/technical measures to protect IP/trade secrets).

The EHDS should be more specific on the level of transparency of the data user. For example, if a third party is making a data request on behalf of a competitor, that third party should be compelled to disclose the real party of interest behind the data request. The same level of transparency should be applied independently on the type of the user i.e. public or private.

Measures and mechanisms integrated to an administrative procedure are crucial so that in case IP, confidential information, trade secrets and any other kind of commercially sensitive information are in scope, each data holder can efficiently defend against the disclosure obligation, even before a court as a last resort. The disclosure obligation under EHDS must be balanced against data holders' other legal obligations, including EU competition law requirements, according to which crucial business information cannot be disclosed freely among competing companies. Given the sensitivity of data and the implications for trade secrets and IPR, appropriate measures that can lead to penalties or temporary or definitive exclusions from the EHDS framework of the data users or data holders that do not comply with their obligations should be well-defined and enforced accordingly.

[3] Draft Data Act

c) Legal basis and GDPR

EFPIA welcomes that the EHDS proposal provides a legal basis under GDPR for processing of sensitive data for secondary use by data holders and access bodies. The complex legal landscape at Member State level, together with the legal uncertainty faced by data holders, has been an important factor preventing data access for researchers. The inception of the EHDS is an opportunity to resolve this challenge for the future. This will require MS and the European Data Protection Board (EDPB) to align behind the approach put forward by the EHDS and clarify in clear terms that Articles 6(1), points (e) or (f) and 9(2)(h), (i) or (j) are the appropriate legal basis for processing of sensitive data for secondary research purposes across the EU. In order to streamline the conduct of scientific research, we advise prioritising the development of GDPR guidelines to offer practical support for compliance in the healthcare and consumer sectors.

More clarity is needed on how the EHDS will reconcile with requirements set out under Clinical Trial Regulations, MS' laws relating to genetic data, as well as ethics committee requirements. These could act as a barrier to pharmaceutical companies being able to share clinical trial and genetic data, as intended under EHDS.

d) EFPIA comments on specific Articles related to Chapter IV, secondary use (Articles 35, 36, 37, 38, 39, 42, 45, 46, 62, 63):

- **Regarding prohibited use of electronic health data (Article 35)**
  - Reconsideration of the prohibition for promotional activities towards healthcare professionals would be welcomed, considering the fact that studies based on real world data and clinical trials may be considered a source of commercial claims used by pharmaceutical companies in promotional activities. These are legitimate sources to inform the prescribing information that is part of all promotional material for medicinal products.

- **Regarding health data access bodies (Article 36)**
  - For a successful and consistent functioning of the EHDS across the EU regarding the secondary re-use of data, it will be critical that all MS ensure health data access bodies are provided with sufficient human, technical and financial resources to enable optimal set up and performance.

- **Regarding the tasks described of health data access bodies (Article 37)**
  - Specific to the task to decide on data access applications (1.a)
    - The actual decision-making processes related to assessing applications for access to data and the subsequent granting of data permits requires greater clarity, as the specific criteria to be used for a decision (at least a basic framework) has not been described in the EHDS. Therefore, EFPIA recommends that the implementation of the decision-making processes and criteria be clarified, transparent and available to all potential data users.

- Additionally, EFPIA recommends that these processes and criteria should be aligned, if not very similar, across all MS and health data access bodies to ensure consistent governance models are in place across the EU for all access to health data. This is integral in encouraging participation from all stakeholders in the EHDS, otherwise overburdensome and fragmented processes across health data access bodies and MS could create unintended barriers to access and therefore stakeholder participation. Accreditation of these processes could serve as a mechanism to help ensure harmonised implementation. It is paramount to avoid the scenario with the implementation of GDPR with a number of inconsistencies in its application across the EU.
- Processes should be streamlined to provide a single access point for data users. Mutual recognition between heath data access bodies should be ensured, so that data users are not able to be denied a permit by one health data access body and accepted by another.

- Specific to the task of making national dataset catalogue public (1.q)
  - EFPIA believes this point is critical given the importance of creating broad awareness to all potential data users which datasets exist in each Member State and information on their properties. If such information is not broadly known, the overall value derived from the EHDS will be impacted. This important activity will also support FAIR data principles (findable, accessible, interoperable, and reusable), specifically that of making data "findable". Use of such principles provides the framework to utilise the benefits of a federated data network, enabled by the use of Common Data Models, metadata, standardised analytical tools and fit-for-purpose methodologies. The IMI EHDEN project is a good example of data partner catalogues that utilise OMOP CDM across the European region.
  - In addition, data quality is critical for secondary use of data in research, regulation and policymaking. The "reliability, relevance, timeliness, coherence, coverage and completeness should be adopted as measurable dimensions" of data quality as per TEHDAS recommendations[4].
  - We also believe the additional following criteria are equally important:
    - Accuracy - data reflects an event as it happened
    - Consistency - data is consistent across datasets, and over time
    - Transparency - data retention and expiration policies defined and agreed upon
  - EFPIA supports the intention to expand the availability of additional health datasets to support the development of Artificial Intelligence/Machine Learning, as it could enable continuous validation of computational models and Artificial Intelligence/Machine Learning.

[4] TEHDAS Recommendations on data quality

- The details for the data in any such catalogue should also be without prejudice to IP/trade secrets.

- **Regarding the obligations of health data access bodies towards natural persons (Article 38)**
  - Specific to informing on the conditions under which electronic health data is made available for secondary use:
    - EFPIA supports the role outlined in Article 38 for the national access bodies to be an information hub for data subjects and the role set out for the EHDS Board in article 65 (2) in coordinating practices to ensure consistent application of the Regulation.
  - Specific to making results or outcomes of projects for which health data were used publicly available (1.e):
    - EFPIA recommends that consideration be given to when results or outcomes of the projects for which data is used can be shared. For instance, in the context of research and development this information cannot be shared while it is still considered commercially sensitive. More clarity on the definition of the terms *results* and *outcomes* is recommended to understand the obligations of the Data Users has when they potentially identify innovations derived from the use of the data.
    - EFPIA members continue to be fully committed to transparent data sharing and to disclose results of clinical trials as soon as appropriate and in line with existing rules and regulations for legitimate reasons of supporting innovation and research for the benefit of patients. We recommend specifying parameters for minimum outcomes information that will be shared. EFPIA together with the European Forum for Good Clinical Practice (EFGCP) published the *Good Lay Summary Practice (GLSP) Recommendations*[5] that provides recommendations on how to prepare, write, translate, and disseminate summaries of clinical trial results in lay language. This is a mandatory requirement laid out in Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use ("EU CTR") and a transparency obligation to all trial participants and the interested public.
  - Specific to informing the public about the role and benefit of health data access bodies (4.):
    - EFPIA strongly supports this proposed provision. Broadly communicating the benefits of establishing health data access bodies will further encourage citizens' participation in the EHDS and reinforce its added value to both the MS and the EU.

- **Regarding Fees (Article 42, 43)**
  - Specific to the charging of fees (1)

[5] Good Lay Summary Practice Recommendations

- EFPIA would encourage a standardised fee *structure* across the MS but recognises underlying costs can vary between MS. Any fee should be proportionate to the cost associated with the individual data permit.

Specific to transparent and proportionate fees (4)

- EFPIA recommends considering the introduction of a fee reduction mechanism for data users who are also data holders, to compensate financial efforts and to motivate participation in data sharing.

- Specific to disagreements of level of fees (5)
  - EFPIA recommends that any framework established should consider processes to negotiate disagreement and how requests outside of standard requests should be assessed and the appropriate fee set.
- Specific to fines established as penalties by health data access bodies (art. 43 (54))
  - EFPIA recommends establishing processes to ensure that data holders may defend themselves against established penalties by demonstration of a justifiable reason they might have for the electronic health data withhold (e.g. protection of trade secrets or other sensitive commercial information).

- **Systematically anonymised data (Article 44, 2, 3)**
  - The health data access bodies will provide the electronic health data in an anonymised format, or pseudonymised where the purpose of the data user's processing cannot be achieved with anonymised data (Article 44, 2, 3). Consistency across MS will be needed on when pseudonymised data may be requested, how the decision is made on whether it is provided and on the form of any anonymised data that is provided. It is unclear from the current text of the EHDS Regulation on how such requests will impact timelines for making anonymised health data available to data users.
  - Conflicting interpretation of terms in the GDPR such as "scientific research", "secondary use of data", "anonymisation" and "pseudonymisation" and uneven interpretation of the GDPR among national data protection authorities in the EU (e. g. concerning the legal basis for the processing of personal data collected in the context of clinical studies, the role of investigational sites as data controllers or processors, etc.) are proving to be a major obstacle in enabling access to data and conducting research in Europe. Efforts fostering uniformed interpretation of legal terms would streamline research processes, make Europe more attractive for R&D investments and boost its competitiveness at the global level. With this aim, EFPIA proposes that the EHDS Regulation requires the European Commission to issue guidance on the standard of anonymisation required, or at least that the EHDS Board should issue guidance on the principles of anonymisation and pseudonymisation, as they should be applied in a health research context.

- **Regarding Data Access Applications (Article 45)**
  - Specific to inclusion of a description of the requested health data (2.b)
    - Recognising a permit applicant may not be fully aware of data that is available/exists, who holds it, in which format and where it is located, EFPIA recommends this aspect of the application may require some flexibility.

        - Additionally, in the implementation/establishment of health data access bodies, EFPIA recommends consideration be given to how to make this information available to permit applicants. This serves as another reason for alignment and collaboration among health data access bodies, as health data access bodies in the instance geographic location of data is required, access to this information across MS will be needed. This links with our comment made for Article 37 (1.q).
    - Specific to reasons for requesting access to pseudonymised format data (2.d)
        - EFPIA recommends setting out a framework with guardrails as to what are the conditions, criteria and context in which access to pseudonymised data would be acceptable and ensuring harmonisation of these guardrails across health data access Bodies. In the case of pharmaceutical companies, expectations or requirements from health authorities of traceability and the possibility to reproduce research results may be a reason for requesting access to pseudonymized data.
    - Specific to assessing ethical aspects of processing data in pseudonymised format (4.b)
        - EFPIA recommends that in support of an assessment of ethical aspects of the processing of data access applications, a transparent, consistent and agreed structured framework to make this assessment would support harmonised implementation of this process across MS.

- **Regarding Data Permits (Article 46)**
    - Overall, further clarification is needed regarding timelines as set out in this section. For instance, clarity is needed on whether the timeline includes the 15 days notification period to health data access Bodies located in other MS, or whether this timeline includes a stop-the-clock clause when data access applications need clarification.
    - Specific to assessing data permit requests (1)
        - EFPIA recommends that the assessment, criteria and decision-making processes in deciding if the requested data is necessary for the purpose listed be transparent and publicly available to all data permit applicants.
        - The timeline of 2 months for the data holder to make the requested data available to the data access body should be considered and evaluated on a case-by-case basis to ensure appropriateness. Also, the 'exceptional cases' under which this may be extended for an additional 2 months should be further clarified (article 41, 4)), e.g. if it applies to anonymisation and other similar situations. In addition, the possibility of receiving multiple regular requests may be burdensome and expensive for some data holders which could prevent them from making the data available in the timeline of 2 months.
        - EFPIA also recommends that consideration be given in the data permit request and application processes as to whether or not disclosure of the full application is appropriate. For data users, companies request to access data as part of future product development programmes could constitute

competitive market intelligence about competitors' intentions to launch new development programmes and beyond. In this instance, partial or high-level disclosures should be considered as more appropriate ("disclosure to the extent necessary").

- Specific to delaying or refusing a data permit (3)
  - EFPIA recommends that it is made clear in advance of making an application what criteria may delay an application or lead to a refusal. This will support more effective applications and a more efficient overall process.
- Specific to the requirement of data users to make public the results or output of secondary use of data no later than 18 months after completion of data processing (11.)
  - EFPIA acknowledges that transparency is an important aspect of the EHDS but highlights that more discussion is needed to explore the extent to which existing transparency obligations should be complemented by the provisions in the EHDS. EFPIA supports sharing the outputs of our secondary use of electronic health data, however this can only be done within a timeframe which preserves the integrity of clinical trials and protects commercially sensitive data. Noting that clinical trial data is included, the provisions of the EHDS should be reviewed to ensure that they align with existing laws and policies that specifically apply to clinical trials, but also takes into consideration the principles of competition laws and regulations.
  - The requirement for data users to make public the results or output of the secondary use no later than 18 months after the completion of the data processing or after having received the answer to the data request (Article 46, 11) creates some uncertainty. A data permit can last for up to five years, so the publication obligation could apply as of five years plus 18 months. However, the latter part of the statement may imply that researchers would have 18 months to do the research on those results and produce a report. As the provision does not include "whichever time is shorter", its intention and added value is unclear. Furthermore, consideration should be given to the timelines and extent of transparency in cases where the research is directed towards new innovation.
  - Moreover, more specificity should be provided in the context of the use of requested data for the creation of AI models and the ownership of and access to the data after the permit expiry.

Additional actions (Chapter V)

- **International transfer of data (Articles 62, 63)**

The EHDS, as an enabler of cross-border health data flows, should also maintain international data flows to foster greater research and innovation globally. It should also support medicines approval and pharmacovigilance processes. The EHDS should clearly define processes for requesting access to the EHDS by third parties outside of the EU, such as external researchers (e. g. what is the legal instrument to transfer such data, in particular when there is a risk of re-identification).

With respect to the development of medicinal products, the EHDS will also prove essential to the conduct of clinical trials and studies globally (e.g. to help identify and establish clinical trial sites, identify clinical trial participants, monitor the conduct of clinical trials, generate real world evidence of medicine and vaccine effectiveness, safety, and value). In alignment with the requirements of ICH E17, global trials are needed to generate data that are representative of different populations and can be accepted by multiple regulatory authorities to support the approval of new medicines, notably by reducing potential delays in making a drug available in key markets and improving patient access to new transformative treatments. Hindrances on data flows and other barriers to cross-border digital services can therefore interfere with drug discovery and development at global level, considering the need to submit patient level data to key international regulators while making it more difficult for patients worldwide to benefit from digital tools that enhance patient care. We should avoid the issues that arose after the ECJ Schrems II decision[6], after which some data protection authorities seemed to follow a very restrictive interpretation, suggesting any potential form of access to EU data by a non-EU authority may be questioned or challenged. This could result in tension for international data sharing for research purposes.

We therefore call for European policymakers to work with third countries to support the enabling of international data transfers and to avoid making such transfers more difficult.

More specifically:

- EFPIA is concerned by the proposal to create a new standard of protection for non-personal data, going beyond accepted standards of anonymisation. The problem the Commission is trying to address – the specific vulnerability to re-identification of certain datasets – can be better met through a proper risk-based approach to anonymisation applied by data exporters, rather than regulatory intervention. With reference to Art. 62(4), EFPIA would welcome more clarification on the concept of minimum amount of data to be shared and of the meaning of a "reasonable interpretation" of the request.
- EFPIA recognises that Art. 9(4) of Regulation (EU) 2016/679)) provides latitude for MS to introduce national measures governing the processing of health data. However, we do not believe that it was the intent that this should be applied to international transfers and the downsides of the proposal are significant, **adding further complexity to an already complex landscape**. **EFPIA would like more details on the potential further conditions that can be imposed by MS in the context of international access and transfer of personal electronic health data. More specifically, can a single Member State deny access to electronic health data (originated in that Member State) to a third country.**

[6] ECJ Schrems II decision

European Governance and Coordination (Chapter VI)

- **Article 64: European Health Data Space Board (EHDS Board)**

The selection process for the participation in the EHDS Board should ensure equal representation across stakeholders and MS. There needs to be consensus on how the Board is established so that representation is fair, balanced, and effective in advancing efforts of the EHDS. As potential data partners and a key stakeholder group in the broader health data ecosystem, industry should be represented within the EHDS Board. Equally, patients' representation should be guaranteed either through a patients' driven initiatives such as Data Saves Lives or individual representatives as another key stakeholder group. The EHDS Board should be provided with sufficient resources allowing to coordinate its activities and track the implementation of its recommendations.

EFPIA's strategic aim in the digital health space is to support transformation of European healthcare for the benefit of patients and to facilitate that digital evolution enables a move towards effective, data-driven healthcare systems, ensuring the continued competitiveness of the EU. EFPIA looks forward to dialogue with stakeholders to support the development and implementation of crucial components of the EHDS, that will be pivotal to the ongoing modernisation and enhancement of European Healthcare.