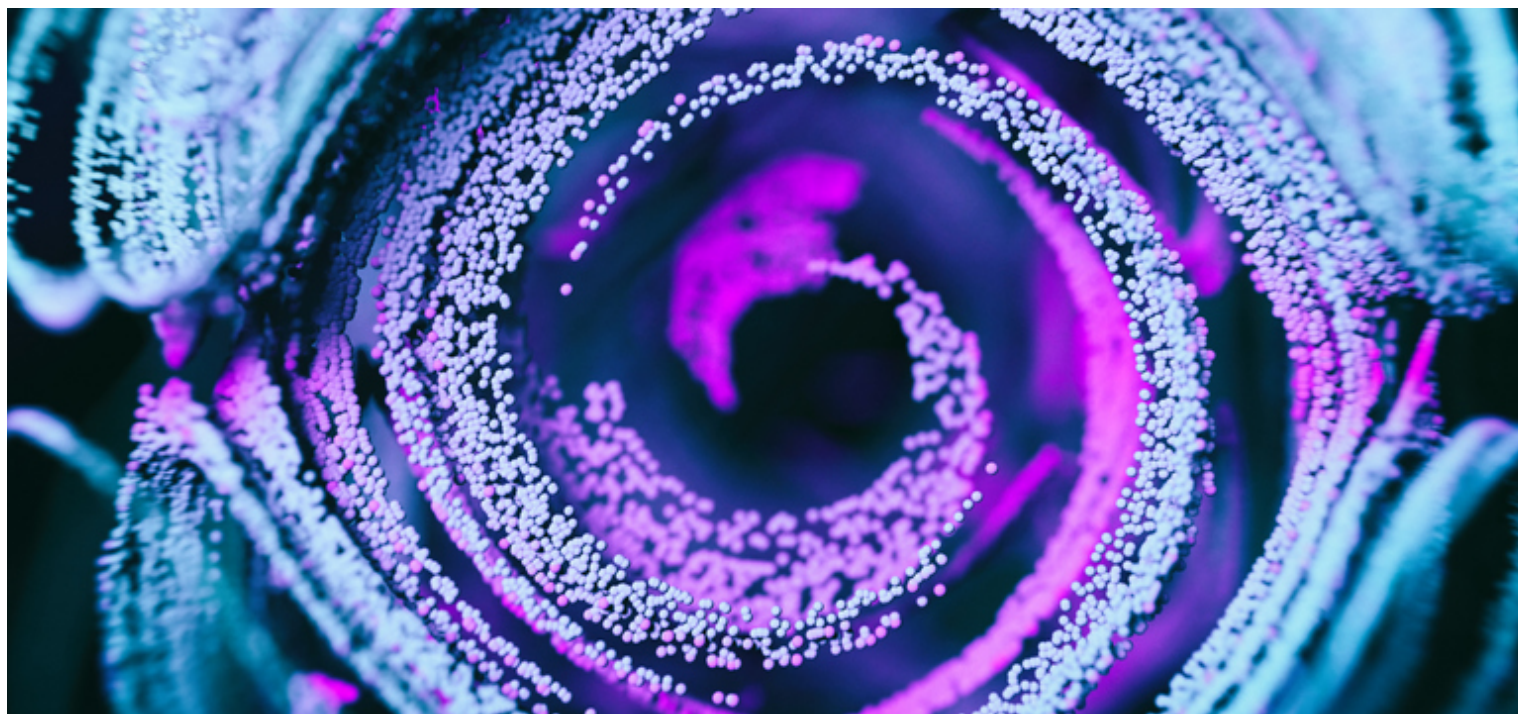


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EU: Impact of proposed European Health Data Space Regulation on use of health data for secondary research

On 3 May 2022, the European Commission issued its proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space¹ ('the Draft Regulation'). At a high level, the Draft Regulation – which is expected to come into force in 2025 – seeks to: (i) provide individuals with increased control over, and access to, their electronic health data ('EHD'); (ii) enable the secure cross-border sharing of such EHD between national EU healthcare systems; and (iii) facilitate the trustworthy and secure sharing of EHD for secondary research purposes ('Secondary Use'). William RM Long, Francesca Blythe, and Zina Chatzidimitriadou, from Sidley Austin LLP, discuss certain key issues presented by the Draft Regulation, such as what data qualifies as EHD and the international data transfers.



The Draft Regulation has been welcomed by industry as an ambitious attempt to remove the barriers to health data for scientific research. However, a large number of legal and policy issues still need to be addressed to ensure the resulting regulation is workable for industry and achieves its stated objectives. When addressing these issues it is essential that the provisions and definitions in the Draft Regulation, and also the proposed delegated acts, are aligned not only with existing EU and Member State laws (for example, the General Data Protection Regulation (Regulation (EU) 2016/679) ('GDPR')) but also with other (proposed) digital data laws, such as, the Data Governance Act ('DGA'), the proposal Regulation on harmonised rules on fair access to and use of data ('the Data Act'), and the proposal for a regulation on laying down harmonised rules on artificial intelligence ('the AI Act').

For purposes of this article, we have focused on certain key issues presented by the Draft Regulation as it relates to the Secondary Use of EHD. For context, the Draft Regulation requires companies processing EHD ('Data Holders') to - on request from a national health data access body ('HDAB') - make this data available to other organisations, companies, or researchers ('Data Users') for prescribed Secondary Use purposes (including, scientific research, and the training and testing of algorithms including as found in AI systems and MedTech devices). The access by the Data User is, however, subject to the Data User having applied for and received a permit from a national HDAB to access the EHD. Upon receipt of a request to disclose EHD, a Data Holder will have just two months to comply with the request (i.e., convert the EHD into the desired format and upload it onto an interoperable decentralised platform) or otherwise potentially face a fine.

What data qualifies as EHD?

As drafted, the categories of EHD which a Data Holder may need to disclose include a very broad set of data i.e., both personal and non-personal data, from a wide variety of sources (e.g., from clinical trials, EHR systems, biobanks, connected devices). In turn, identifying the relevant EHD to be disclosed and then taking steps to ensure such data is disclosed in a compatible format could potentially be burdensome for Data Holders. Further, it should be clarified where anonymous EHD is being disclosed, and the anonymisation standard that then needs to be used.

Who is a Data Holder?

The definition of who may constitute a Data Holder under the Draft Regulation is also very broad and, as acknowledged by the European Data Protection Board ('EDPB') and the European Data Protection Supervisor ('EDPS') in their Joint Opinion on the draft Regulation ('the Joint Opinion'), 'does not allow to clearly identify who would qualify as data holder and to understand what the interplay is with the definition of data holder provided in the Data Act and the [Data Governance Act]'.

Importantly, the Draft Regulation also fails to clarify the potential territorial scope e.g., would a clinical trial sponsor located outside of the EU and processing EHD originating from clinical trials conducted in the EU qualify as a Data Holder?

What is the scope of the data permit?

As mentioned above, Data Users will need to apply for a permit from an HDAB before being granted access to the EHD. The permit could grant access to multiple datasets from one or more Data Holders, either directly or through an HDAB. However, as drafted, it is not clear whether the scope of the data permit can be subsequently revisited or amended, given the dynamic nature of clinical research and development of analytical tools, especially for more complex types of research and nuanced Secondary Use (e.g. retrospective application of biomarkers). The Draft Regulation also fails to address what will happen in the event, for example, there is disagreement on whether a particular use is covered in the data permit.

What format should the EHD be converted into by Data Holders?

Whilst the benefits of promoting interoperability are clear, as drafted, there is insufficient technical information as to how in practice Data Holders will upload and share EHD. The publication of information in this regard should be prioritised as meeting these obligations could potentially be very time and resource intensive for Data Holders.

Can Data Holders withhold commercially sensitive information?

The protection of intellectual property rights ('IPRs') and confidential information is a priority for Data Holders. Indeed, whilst the Draft Regulation requires that IPRs and trade secrets are respected when responding to data access and disclosure requests, it does not explicitly provide for the protection of commercially confidential information ('CCI'). This is not consistent with other EU frameworks, such as the clinical trial transparency policy and the DGA, which include carve-outs for CCI.

The Draft Regulation is also not clear in terms of when and how a Data Holder can resist a request to disclose certain EHD where it considers this to constitute commercially sensitive information. As drafted, it is the HDABs who will have the remit to determine whether a set of EHD constitutes data which can be exempted from disclosure for these reasons. This could, in turn, lead to uncertainty and different approaches being taken by HDABs in different Member States.

What does the Draft Regulation say about international transfers?

As with the Data Act, the Draft Regulation extends the restrictions on cross-border transfer of data so that they apply also to non-personal data. In addition, the Draft Regulation permits Member States to implement further national conditions on international access and transfers of personal EHD. Whilst such a provision

allowing national conditions already exists in the GDPR, this may add to the variation across EU Member States that is currently seen, in how national laws are applied to the processing of health data.

How will Data Holders and Data Users meet their GDPR fair and lawful processing obligations?

The GDPR requires that a company identify a lawful basis for the processing of personal data. Whilst the Draft Regulation does provide a lawful basis for Data Holders to process personal data for Secondary Use, it does not identify a lawful basis for Data Users. However, the provision of a lawful basis for the processing of personal data for Secondary Use may facilitate the ability to carry out such Secondary Use more generally under the GDPR.

In terms of transparency, the Draft Regulation exempts HDABs from providing a data protection notice to data subjects (i.e. under Article 14 of the GDPR). However, the position as regards Data Holders and Data Users is not clear. To the extent this is not addressed, this could prove to be problematic for Data Holders. For example, would a Data Holder be expected to start updating all its data protection notices now in anticipation of any potential disclosure under the Draft Regulation and will Data Users be able to rely on an exemption under Article 14(5) of the GDPR where the provision of information is not required if it would involve a disproportionate effort.

Next steps

The public consultation on the Draft Regulation ended on 28 July 2022. The Draft Regulation will now, over the coming months, be discussed in the European Parliament and the Council. It will be important for life sciences companies to consider what impact the Draft Regulation may have on their operations and what steps they will need to take in order to meet the requirements of the Draft Regulation once adopted.

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1. See: https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en