

Research and Recommendations from the PhUSE Data Transparency Working Group GDPR Project

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Introduction and Background

The General Data Protections Regulation (GDPR) from the European Parliament was published in 2016 and became enforceable in 2018, standardizing data privacy laws across Europe. GDPR's purpose is to ensure privacy and security of personal data collected in the process of any business operation, including clinical research. GDPR grants significant new rights to citizens of European countries, including the right to be forgotten, as well as promoting transparency on how patient data is collected and used. The interpretation and application of the regulation in clinical research has been a hot topic of conversation.

PhUSE convened a GDPR data transparency working group project in 2018 to research and discuss GDPR compliancy. Three sub-teams were formed to research different aspects of GDPR's impact on clinical research. Those sub-teams were: Data Collection and PII, Safeguard and Processes, and Data Breach. Ultimately, all three sub-teams merged back together and are collectively reviewing research results pertaining to GDPR.

This poster will introduce the ongoing guidance and recommendations of the GDPR Project including a description surrounding the process of research behind the white paper.

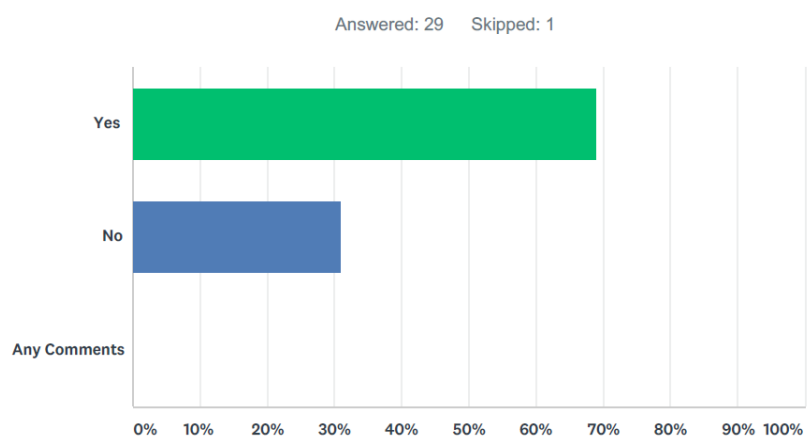
Research Overview

Data Collection and PII

The **Data Collection and PII** sub-team researched data collection practices related to GDPR including how to handle the collection of personally identifying information (PII) such as birth date or age across age ranges and study types, and what not to collect differently in any study. As part of their research they did a public survey on current industry practices around the collection of birth date and age.

Of the 30 respondents who were mostly from Sponsor organizations, 69% said they would continue to collect at least some component(s) of Birth Date under GDPR.

Under GDPR, do you plan to continue collecting any components of Birth Date in any of your data, including EDC, lab requisitions, ePRO/eCOA, etc?

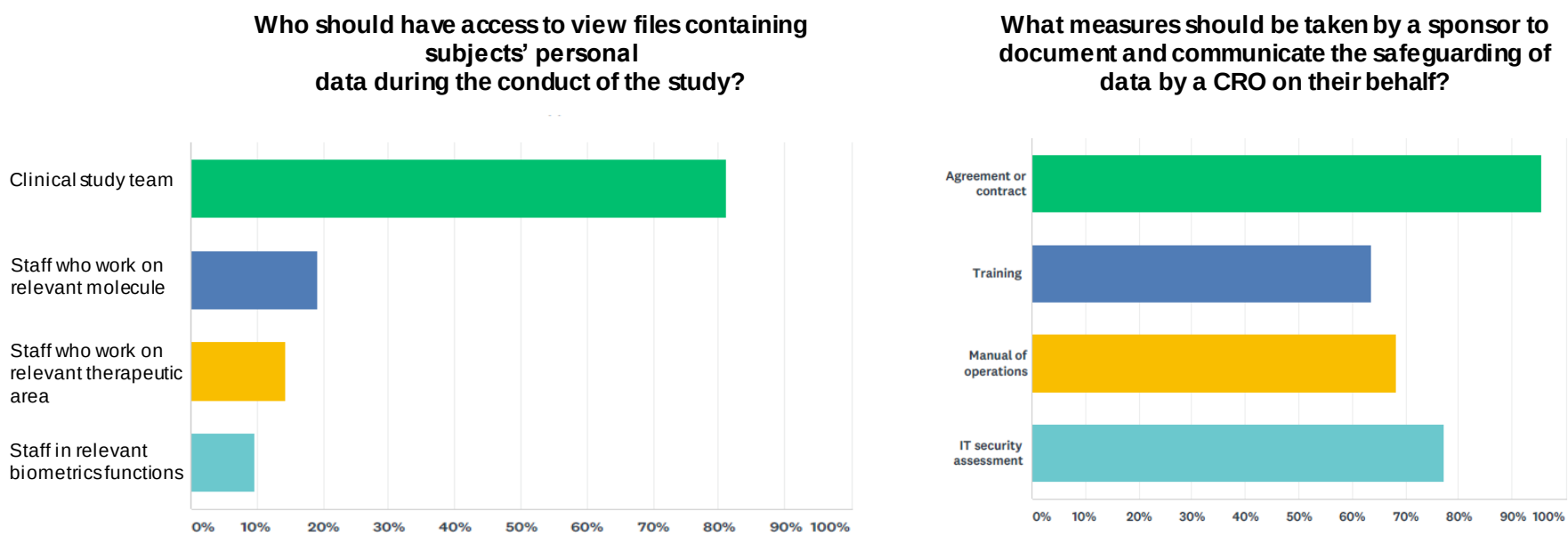


Research Overview

Safeguard and Processes

The **Safeguard and Process sub-team** identified areas of research including clinical data access and restrictions, documentation, process and training specific to safeguarding patient level data, as well as clinical data retention periods. Continued discussion includes plausible data breach scenarios, data anonymization, and GDPR implications on past, ongoing and completed clinical studies. A separate public survey was conducted to gather cross-industry GDPR interpretation on these topics:

- 80.95% of respondents agree that subject level clinical data should be restricted to only clinical study team members. Exceptions can be made with appropriate approval and access to colleagues who require to conduct review or analysis
- Dependent on data users role, only provide access to a subset of required subject level data
- 80% of respondents recommend to anonymize subject level data after allocated retention period, if consented
- Continued survey summarization is being completed on data breach preventative measures, communication, training and documentation to protect patient privacy



Recommendations

Survey results are currently being reviewed and evaluated, and support the GDPR Project's draft recommendations for data collection and PII, safeguard and processes:

- Continue to follow predicate data integrity and provenance Rules, which are not replaced by GDPR
- Evaluate your data collection needs carefully, and only collect data that are actually needed for your study
- Take appropriate measures to safeguard and protect patient privacy to ensure GDPR compliancy by setting subject level clinical dataset restrictions, anonymize when appropriate and if consented, provide transparency on how subject level data will be used, follow appropriate GCP (Good Clinical Practices), update training and contractual agreements to align with GDPR, and ensure best practices when sharing and discussing subject level data

In addition to these high level recommendations, a discussion about the risks and mitigation plans for various data collection modalities and data sources is being prepared for the GDPR White Paper. As an example, the team identified data from wearables as a risk because the wearer's name, street address and other PII may be integrated into the data that is transferred from the wearer to the vendor. One potential mitigation of this risk is to address which data points should be included and excluded when you develop your Data Transfer Agreement with the vendor. Further recommendations surrounding safeguarding and process will be included in the GDPR White Paper.

Public Comment on Draft GDPR White Paper

A draft White Paper will be published for public comment in 3Q-4Q of 2019. The PhUSE Data Transparency Working Group will seek input during this public comment period on the following aspects of the White Paper:



References

https://ec.europa.eu/info/law/law-topic/data-protection_en