

PP07-Recommendations for General Data Protections Regulation (GDPR) Compliancy by the PHUSE Data Transparency Working Group

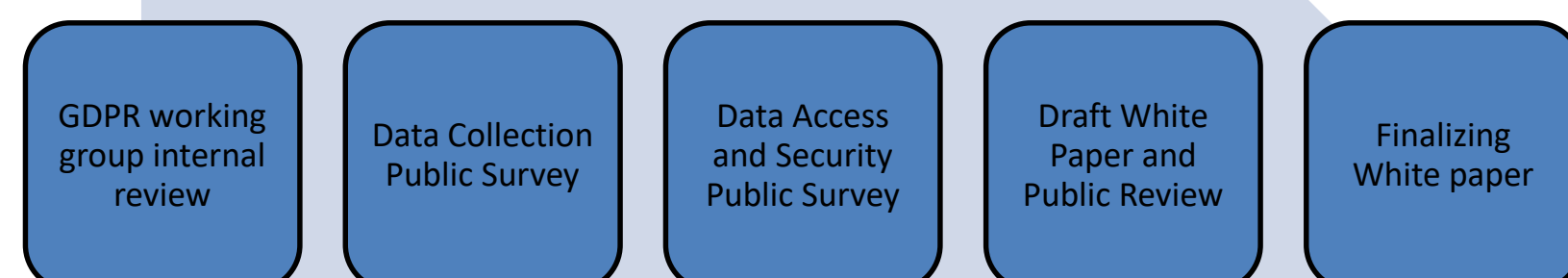
Author: Arlene Coleman (Pfizer)

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.

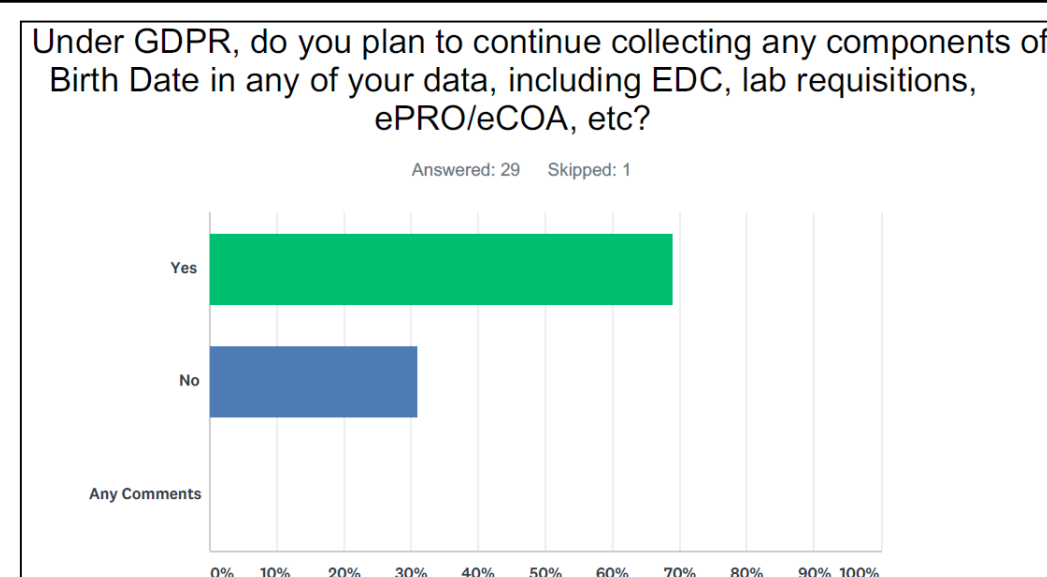
PhUSE convened a GDPR data transparency working group project in 2018 to research and discuss GDPR compliancy. This poster will summarize the process of research behind the GDPR project white paper along with survey result recommendations.

Research Process



Data Collection and Personal Identifiable Information Survey Results

Investigate how organizations plan to handle the collection of personally identifying information (PII) such as birth date or age across age ranges and study types



Most companies will continue to collect birth year

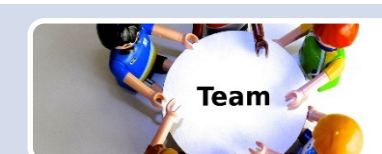
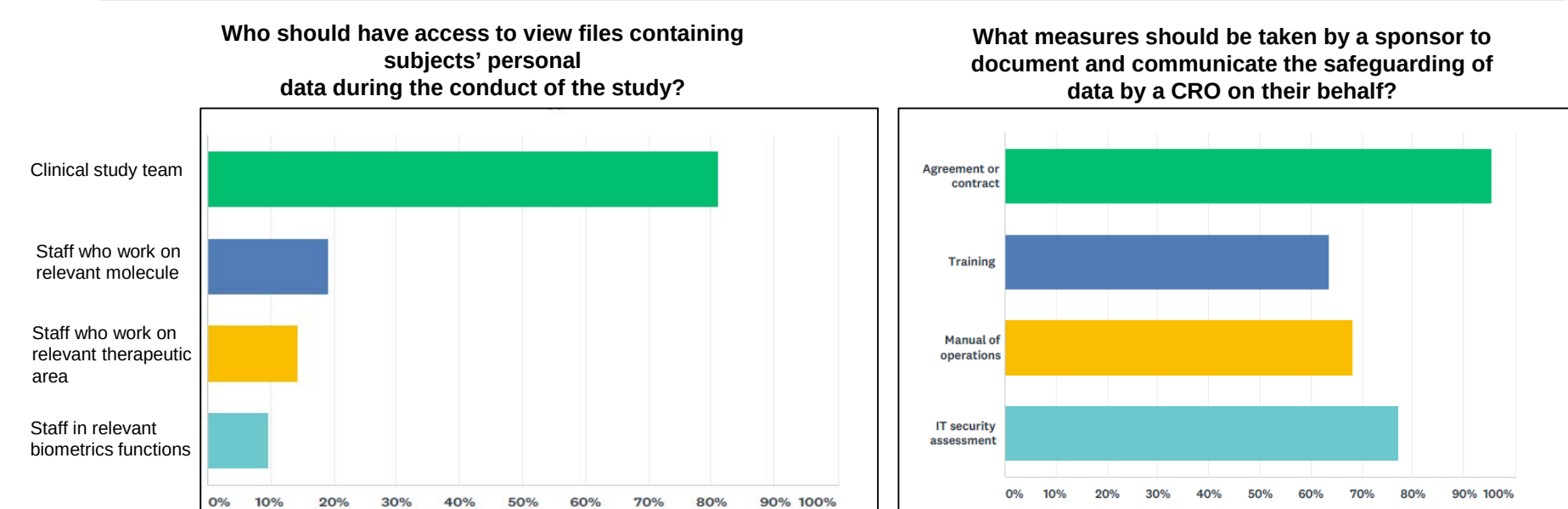
Complete birth dates may continue to be collected for pediatric studies

Collection of age dependent on need for precise age in analysis and eligibility

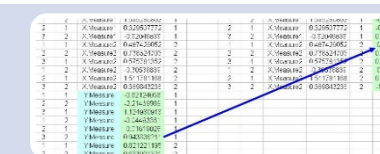
Dependent on Country restrictions and requirements

Safeguard and Processes Survey Results

Investigate clinical data access and restrictions, documentation, process and training specific to safeguarding patient level data, as well as clinical data retention periods, data breach scenarios and data anonymization



Restrict subject level clinical data to clinical study team members. Exceptions to appropriate approval and access for conduct review or analysis



Dependent on data users role, only provide access to a subset of required subject level data



Recommend to anonymize subject level data after allocated retention period, if consented



Periodic training, secure IT systems, proper audit trails, user-friendly SOPs, anonymized/approved data sharing. Standing data security/data privacy policy

Additional Recommendations

Continue to follow data integrity and provenance rules, which are not replaced by GDPR

Informed consent forms should be updated with new GDPR requirements and informed consent language

Conduct Privacy Impact Assessments to assess the risk of clinical trial data processing in your company

Consider novel data processing activities such as artificial intelligence and application of machine learning using previously collected real data

Assess creation and governance of large-scale data repositories for access and analysis, e.g. "Data Lake"

Conclusions

The wide scope and general nature of the principles of the GDPR leave room for differences in its practical application in the clinical study context

The overall intent is clear: To respect individuals, especially as technological advances change the way data can be used

A final white paper will be published approximately 1Q-2Q of 2020, focusing on how best to handle the data of clinical study participants to ultimately contribute to the furtherance of human health and well being

References and Acknowledgments

GDPR Website:

https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en

PhUSE Data Transparency Working Group Wiki:

https://www.phusewiki.org/wiki/index.php?title=Data_Transparency

Special thank you to Shannon Labout (Data Science Solutions LLC), PHUSE Data Transparency Working Group, and to Stuart Pearce (Pfizer) and Patti Compton (Pfizer)