Centre for Information Policy Leadership (CIPL), European Federation of Pharmaceutical Industries & Associations (EFPIA) and Future of Privacy Forum (FPF) Joint Workshop

Can GDPR work for Health Research?

Renaissance Hotel
Rue du Parnasse 19
1050 Brussels, Belgium
22 October 2018 | 10:00 – 17:00

WORKSHOP AGENDA

10:00 **Registration**

10:30 **Opening Remarks**

- Cecilia Álvarez, European Data Protection Officer, Pfizer

10:45 **The Scope of Life Sciences Research**

- Brendan Barnes, EFPIA

11:00 **Session I - CLINICAL TRIALS**
Overview of the Regulatory Framework for Clinical Research

Charlotte Ryckman, Covington

11:30 **Break**

11:45 **Reflection on the GDPR/CTR Interaction**

- Christian Dierks, CEO and Founder, Dierks & Co.

12.15 **Operating Challenges in the Post-GDPR Environment**

- Cecilia Álvarez, European Data Protection Officer, Pfizer

12:45 **Panel Discussion : How to perform GDPR proof Clinical Trials ?**

Private and public sector researchers are facing difficulty in understanding how to comply with GDPR, when conducting clinical research. Views differ regarding what should be the basis for processing special categories of personal data in scientific research and the divergences are, if anything, widening. It was the legislator's intention in GDPR to support research while ensuring harmonization; however, aligning GDPR's goals and research needs is proving much harder than expected. What is the best way forward?

Key Questions:

- Is processing based on consent feasible under GDPR?
- Is a hybrid – consent under CTR & another basis under GDPR – feasible?
- What are the barriers to moving to other bases for processing?
- What role could legitimate interest play in a clinical trials context ?

❖ Moderator: Bojana Bellamy, President, Centre for Information Policy Leadership
❖ Cecilia Álvarez, European Data Protection Officer & Spain Legal Director, Pfizer
❖ Christian Dierks, CEO and Founder, Dierks & Co.
❖ Gabriela Zanfir-Fortuna, Policy Counsel, Future of Privacy Forum

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13:30 **Lunch**

14:15 **<u>Session II : SECONDARY USE OF DATA FOR RESEARCH</u>**
Reminder of Context

❖ Johan Wisenborn, Head of Data Privacy Country Operations, Novartis

14:30 **Case Studies of Re-use of Data Generated in Clinical Trials for New Scientific Purposes**

❖ Janice Carling, TEVA

15:00 **Reflection on Legal Issues**

❖ Christian Dierks, CEO and Founder, Dierks & Co.

15:30 **Break**

15:45 **Panel Discussion: How to reuse personal data for secondary scientific research purposes under GDPR?**

Data gathered in clinical trials have continuing value in scientific research. The secondary use of such data cannot be anticipated in advance, nor can it be assumed that such data is only of interest to the group that carried out the primary research. The future of scientific research is tied to the secure sharing of personal health data between researchers. Extensive safeguards are adopted by the research community to protect the individual interests of participants..

Key Questions:

- In what way does "deemed compatibility" facilitate secondary research?
- What role should safeguards play in supporting access to data for secondary research?

- What role could legitimate interest play in a research context ?

❖ Moderator: Stan Crosley, Senior Fellow, Future of Privacy Forum
❖ Nick Tyler (Takeda)
❖ Kristof Van Quathem, Special Counsel, Covington & Burling LLP
❖ Bojana Bellamy, President, Centre for Information Policy Leadership

16:45 **Closing Remarks**

❖ Cecilia Álvarez, European Data Protection Officer, Pfizer

17:00 **End of Workshop**