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Data Privacy

Data privacy may seem at first glance a topic to be addressed and, considering the level of complexity it may have in an international - even European - context, to be sorted out by specialist lawyers. However, beyond regulatory compliance, the protection of personal data from patients and subjects participating into clinical research projects, is one of the keys that allows to overcome the barriers that are currently faced by innovators. As a matter of fact, it contributes to building the trust from public, which is paramount in order to get active participation from persons when it comes to:

- Recruiting patients into clinical trials
- Recruiting donors for bio-banking projects
- Making secondary use of healthcare data for research purposes
- Delivering digital applications to patients

In parallel, the demand for public clinical trial data disclosure is growing, calling for safeguards to data privacy before making the data available. Even though this might be as per a requirement from regulators, this remains under the responsibility of the sponsors of clinical research projects, and constitutes an ethical commitment as well.

“Privacy by Design” is a concept imposed by the new EU General Data Protection Regulation (GDPR), which will have to start being applied as of May, 25th 2018. It means that privacy and protection of personal data is no longer an after-thought, and should be instilled in the practices from clinical development teams from the project onset. Changing the mind-set from people to embrace this concept proceeds from the same small cultural revolution as getting them to embrace the concept of Quality by Design.

We will learn that the topic is however easily accessible to everyone, providing that:

- The main differences between the type of laws adopted throughout the world are understood
- Some basic definitions are known
- A general culture regarding data privacy / data protection principles is developed

We present the specifics of implementing data protection in the context of GCP studies, public clinical trial data disclosure and secondary use of healthcare data. We shed a light on these topics by making use of real life experience. For instance, the importance of mastering the data flow from clinical study data will be highlighted from the lessons learnt after the invalidation of the Safe Harbor agreement between EU and US by the European Court of Justice, and its recent replacement by the new EU-US Privacy Shield framework for transatlantic data flows.