

What You Need to Know About the EU's New Data Protection Law



The EU's new data protection law is going to have a great impact on companies worldwide, including those involved in clinical trials. Here's what you have to know and how to act!

In May 2018, the European Union's new data protection law, the General Data Protection Regulation (GDPR), is set to replace the current Data Protection Directive (DPD). Although this just sounds like a bunch of complicated words, it will actually have a wide-reaching effect on companies worldwide.



You may read this and wonder why you should care. Well, if your company handles personal data of any sort, then you will likely be affected. One of the sectors hit especially hard by the new changes to the data protection law is the drug development industry. Namely, anyone who is involved in a clinical trial, from sponsors and investigators to CROs and vendors. Starting in Spring next year, companies will be facing a long list of changes that they have to follow in order to comply with the GDPR. In light of looming, strict penalties, companies will be forced to observe the EU's new law.

The GDPR is set to come into effect on May 25th, 2018, and is aimed at improving the existing Data Protection Directive (DPD) by fixing the fragmented implementation of data privacy laws amongst EU member states, and setting forth a robust common baseline for all countries to follow.

The GDPR will apply to organizations all over the world, not just those located in the EU, including those in the drug development industry. Companies will be confronted with a tremendous amount of changes, much more than what is was currently required under the DPD. Like the DPD, the GDPR governs the processing of any information that identifies or could be used to identify a natural person. Common examples of personal data under the DPD include names, addresses, social security numbers, dates of birth, and bank account details.

In addition to that – and almost anything else you can think of that relates to a person's identification – the GDPR now also covers location information, genetic data, and IP-addresses. A broader definition means the GDPR will have a further reach than the DPD.

Another significant change in scope brought by the GDPR is included in the tightening of “transparency” regulations. Transparency is a core principle to data privacy protection practices.

It requires that organizations ensure that those individuals whom they are collecting information from understand in very clear terms how their data is used and protected, what it is used for and where it might be transferred to. Transparency ensures that the organization properly obtains an individual’s consent prior to collecting any data. Consequently, these new transparency regulations will require a complete reevaluation of businesses’ transparency practices.

Under the GDPR individuals’ rights are expanded. Currently, the DPD includes the individual rights of access, rectification, erasure, objection, and the right not to be subject to automated processing decisions. The GPDR enumerates all of these rights, expands on almost all of them, and introduces new ones. The only right that is largely unchanged with the GPDR is the individual right of rectification, which allows individuals to correct, update, and amend the data an organization processes about that individual.



The right to access under the GDPR is expanded. It allows individuals the ability to confirm whether or not an organization is processing that individual’s data, and if so, what types of data is processed. Individuals must now also be provided with more information in connection with a data access request, such as the data retention period, and the right to complain to a data protection authority.

The right to erasure is also expanded. Under the GPDR, individuals can request their data be erased when such data is no longer needed for its original purpose, when an individual withdraws their consent, and when erasure is necessary for compliance with EU or Member State law.

Stay aware of your rights and make sure you follow the law 😊