EDITORIAL

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Dear Reader,

The whole gamut of data industry has now either completed or working to be compliant with the latest EU data protection act called General Data Protect Regulation (GDPR) that has come into force since May 25, 2018. And this has significantly affected the Pharma world specifically the clinical trial segment that is particularly sensitive in this aspect. Only a small fraction of Pharma industry is currently ready for GDPR.

Though brought into force to strengthen and standardize protection of personal data across the EU and for other country's data being "processed" within the EU, it still has global implication forcing entire data industry e.g. social media giants e.g. Facebook, Twitter to revamp their privacy policies to be up to date with the Regulation.

Within GDPR, Clinical data is labeled as 'Special' data category - it aims to give more emphasis and rights to individuals about how their data is to be used and sets out clearer responsibilities and obligations on healthcare professionals and companies using such data. One of the most significant changes made in this regulation is to make the withdrawal of consent as easy as to give it.

From trial providers perspective the new act is not just for the participants, but also for their employees, customers, and subcontractors. As per the GDPR Act, there is provision for a role called the 'Data Protection Officer' responsible to act as the interface between organizations and the company and would be involved if there are any data breaches.

With significant penalties for non-compliance, let alone the cost and impact on trial progress, it is essential to identify trusted partners to ensure clinical trials are executed to the latest regulatory standards and the highest quality.

It now forces the researchers to be more aware of data handling and processing while carrying out their analysis. Overall, it can be predicted that at the wake of recent concerns about data breaches, the introduction of stronger guideline will improve the data handling process, and will not only impact EU but globally overall for Pharma sector and the drug research sphere.

Happy Reading!

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