2019

Impact of GDPR on Clinical trials

EU GDPR AND CLINICAL TRIALS

SHILPA DESAI

SARJEN SYSTEMS PVT. LTD. | Ahmedabad, India

Sarjen Systems
Business Solutions with Technology Edge

Understanding GDPR

Amongst the latest changes that were introduced by EU was GDPR, one of the most significant, and it enforced the security of personal data and personal identifiable data to the highest applicable for EU citizens.

To that effect that there are severe fines with respect to even smallest of non-compliances. And, thus, it has reshaped the way organisations process the data – collect, use, protect and secure data privacy, empowering EU citizens for decisions of use of their personal data.

Consent and Use of personal data define the privacy of the data, which is pertinent to maintaining stringent controls to adhere to GDPR guideline.

Understanding Clinical trials

The World Health Organization (WHO) definition for a clinical trial:

'Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.' And, 'Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.'

* https://www.who.int/topics/clinical_trials/en/

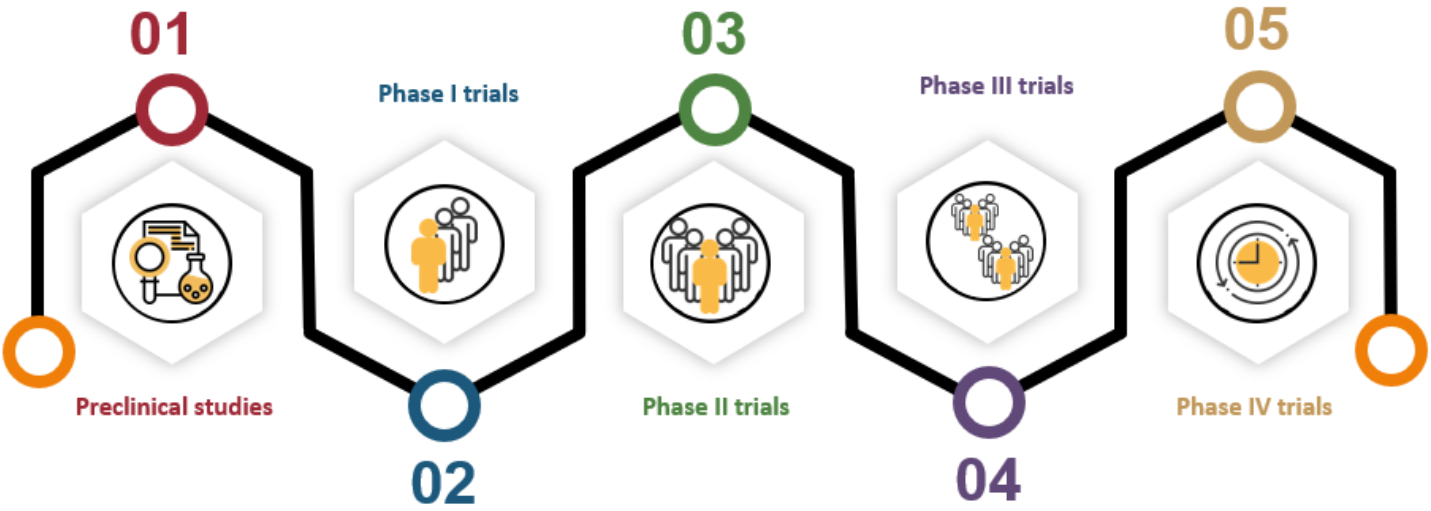
And, as per US FDA,

'Clinical trials are voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using existing treatments.'

Clinical trials are often conducted in four phases:

1. Phase I trials

Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.



2. Phase II trials

   The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

3. Phase III trials

   The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

4. Phase IV trials

   Post-marketing studies, which are conducted after a treatment is approved for use by the regulatory agency, provide additional information including the treatment or drug's risks, benefits, and best use.

* https://www.fda.gov/ForPatients/ClinicalTrials/Types/ucm20041762.htm

GDPR and Clinical trials

Use of electronic systems; be it process automation or use of big data, are a norm nowadays in GcP environment and it has facilitated the collection and use of personal data in different BA-BE and Clinical trials.

Use of certain personal data is necessary for scientific research purposes. Owing to this, the data collected across different studies would be used for this scientific research purposes. But firstly, even before the data is collected, the Consent and the content of the consent and explaining of the intent of whatever data is going to be collected in each cycle becomes very important.

Explicit, precise and unambiguous consent for collection of data becomes mandatory. Although, Consent was always a part of clinical research, but importance of it has strengthened, and organisations must ensure that the volunteers are suitably informed, and consent received with the details which clearly state the type of data collected, intent of the data collected, its use, their rights, etc. With the GDPR enforced, it would now cover not just the organisations but the employees, customers, contractors, subcontractors, etc. involved in entire clinical trials.

This would initiate a subtle but marked operational change conducting clinical trials with respect to the data and how it is managed in its life cycle – right from pseudonymization and anonymization of the data defined and distinguished from protocol design throughout the entire study life cycle; wherever required.

Under the very said, the data that is collected during a trial would give full rights to the CROs/organisations to use and the subjects would have limited to 'no' rights for the data given. The only way subject can prevent from additional data collection would be to leave the trial.

But on the other hand, GDPR also empowers individuals to be better informed to make informed decisions such that they are clearly aware of the type of data that would be collected, also about clearer responsibilities and obligations on data collectors and CROs/organisations for using the data.

And, thus, CROs/ organisations must identify the data that they collect and process, what it is processed for, where it is transferred to, who processes that collected data, associated risks, security measures maintained throughout – all in all, enhanced 360° privacy and security for the data. Also, data handlers to be trained and trained enough to understand the necessity of maintaining privacy and understanding the importance of GDPR.

Clear policies and training become mandatory part for organisations conducting clinical trials to ensure that they are aligned with the changes enforced through GDPR. And they are GDPR ready to avoid penalties for non-compliance let alone the fate of the clinical trials and its impact on overall operations to maintain latest regulatory standards to the highest quality.

In nutshell,

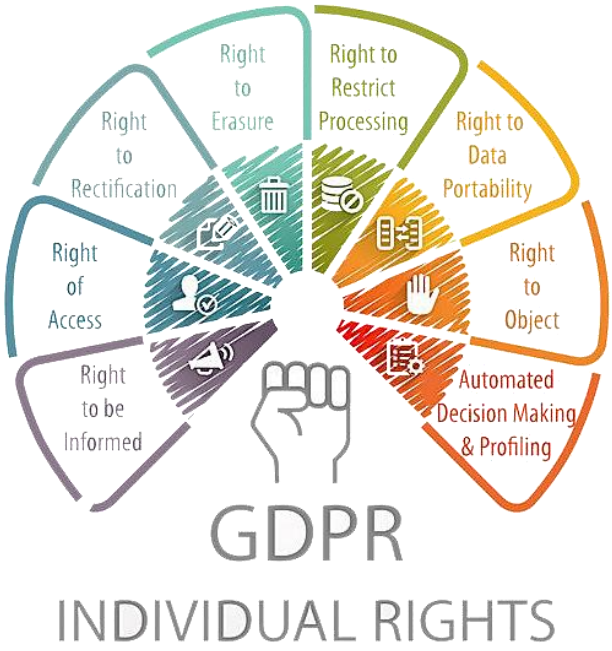
In a clinical trial;

Consent for details that would be collected, and communicating proper understanding of the details (data)…

- that would be collected as datasets that would be CDISC compliant
    - direct as biometric data
    - indirect as the vitals and results of different tests
    - interlinking of various data (combination of details accounting as personal identifier)
- that would be processed in the workflow as SDTM/ADaM
- that would be stored
- that would accessed for different reasons and rights to access at clinical trial site
- that some of the data can be rectified or deleted
- that there can be rights to object to use or process

Also,

- intent of use of that data
- privacy and security measures applied to that data
- measures taken against data breaches
- organisations could face serious consequences for failing to comply with the GDPR guideline



Contact us

1. Corporate Office:

6th floor, Arista,
Anandnagar Road,
Ahmedabad 380015
Tel.: +91-79.66214899

2. Mumbai:

11 Shantidharma, 2nd Floor
284 Mogul Lane,
Opp. Harishchandra Apt.,
Mahim, Mumbai 400016
Tel.: +91-22.24303318

3. UK:

Sage House,
319 Pinner Road,
North Harrow HA1 4HF
Tel.: +44-208.432.6393

4. USA:

1009 Slater Road,
Durham, NC 27703
Tel.: +1-847.307.5937

5. Online Presence

Web: www.sarjen.com
E-mail: sarjen@sarjen.com

6. Social media:

Sarjen Systems
Business Solutions with Technology Edge