Ongoing trials and ICH GCP R2 and how about Regulation 536/2014 (Serious Breaches and Inspection reports)

7th Conference on Clinical Trials in the Nordic Countries 2019

Philip Lange Møller

19 November 2019

ICH GCP E6 (R1)

- ICH GCP E6 was adopted in 1996 and has since been implemented in European legislation (EU Directives and national regulations).
- ICH GCP is not directly implemented into the regulation in the USA.
  - However, FDA recognise ICH GCP

- ICH GCP E6 (R1) gave sponsors flexibility to implement innovative approaches – but has been misinterpreted and implemented in ways that impede innovation.
  - For example; Monitoring of 100 % of everything loosing focus on what might be more important.

ICH GCP E6 (R2)

- The objective of the addendum to the R1 was to facilitate the understanding of quality management.
- ICH E6(R1) has therefore been amended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and reliability of trial results.

- Adopted by CHMP 15 December 2016
- Came into force 14 June 2017

The Addendum (R2)

- The addendum supplements ICH E6(R1) with additional text.
- The addendum introduced monitoring plan and the concept of quality management using a risk based approach.
- No further changes, just more words and explanations.

- No transition period – in force from day one.

Regulation 536/2014 – Serious breach

Article 52:

1. The sponsor shall notify the Member States concerned about a serious breach of this Regulation or of the version of the protocol applicable at the time of the breach through the EU portal without undue delay but not later than **seven days** of becoming aware of that breach.
2. For the purposes of this Article, a 'serious breach' means a breach likely to affect to a significant degree the safety and rights of **a** subject or the reliability and robustness of the data generated in the clinical trial."

When does the clock start

- Day 0 of the 7 calendar days start when the sponsor (or CROs, contractors, co-development partners, etc.) become aware of the breach.
- If the sponsor receives information that provides reasonable grounds to believe that a serious breach has occurred, it is expected that the sponsor reports the breach first within 7 calendar days, investigate and take action simultaneously or after notification.
- The investigator should also have a process in place to identify and notify the sponsor of the occurrence of a serious breach.

The portal and inspection reports

- Inspection reports will be published in the portal.

The portal and access

- Remember to review the access and privileges in the portal.
- The portal is web based = you have access from …..

- What happens after an employee leaves the sponsor:
  - Is it OK an former employee have access for a week, month half year?
  - What if the former employee was angry with the sponsor?

Philip Lange Møller
plm@dadlnet.dk
+45 2094 7016