Short Topic for Discussion

Masking of open label studies

Anja von Heydebreck, Merck Healthcare KGaA

4th EFSPI Workshop on Regulatory Statistics
September 24, 2019

Background

Not all clinical studies are blinded (especially in oncology). While for the purpose of monitoring, study sponsors or their delegates may need some form of access to the data of an ongoing study, unblinded data access by staff involved in the conduct of the study is prone to introduce bias and affect the integrity of the study.

- Especially in the days of digitalisation access to patient information gets easier, and staff from different functions is technically able to run own analyses.

ICH E9:

In single-blind or open-label trials … steps taken to minimise **bias** by other means. For example, the sponsor should have adequate standard operating procedures to ensure that access to the treatment code is appropriately restricted during the process of cleaning the database prior to its release for analysis.

Potential preventive actions

Limit Data Access by

1. **Removing treatment information?**

   Note that treatment information can be hidden in many variables, e.g. due to different dosing schedules per treatment arm.

2. **Outsourcing monitoring to an independent group?**

3. **Removing outcome information?**

   E.g. in a study with survival as primary endpoint, could block access to survival data for the sponsor.

Other

4. **Training /Raise awareness?**

5.

6.

Questions for Discussion

- Which measures to prevent access to study information that might affect the integrity of an ongoing clinical study are
  - considered adequate by regulators?
  - considered practical and effective by study sponsors?
- Specific considerations for randomised vs single-arm studies?