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Towards an EBF recommendation of sustainable GCP compliance in the BA lab

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The journey to GCP in bioanalytical lab

The journey starts:

- Back in the early 1980s when animal testing laboratories modified their quality systems to incorporate GLP;
- In the early 2000s when GCP human analysis work was rapidly expanding and many GLP laboratories expanded their services to include these type of analysis;
- With the fact that GCP alone does not define laboratory analysis requirements and GLP focuses on animal testing and in 2012 EMA issued “Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples”

Specific implementation areas from the reflection paper

The EMA reflection paper has outlined some specific areas of GCP implementation:

- Handling unexpected results;
- Obtaining patient ICF status;
- Communication with other members of clinical trial team;
- Subject confidentiality protection;
- Blinded/unblinded sample analysis;

Handling unexpected results

Reflection paper statement:

“Consequently, prior to the initiation of laboratory work, lines of communication should be established with the sponsor, or their representative, and with the investigators, to ensure that any issues that may impact on patient/subject safety are reported without delay. These may include, but are not limited to, the reporting of **unexpected or out of range results** and significant deviations from the protocol or work instructions. It is always appropriate to consider the **need to expedite the reporting of results regardless of the nature of analysis or evaluation that is being conducted**. For example, **anomalous results or unexpected values associated with pharmacokinetic analysis** may indicate incorrect dosing or marked differences in a subject’s ability to metabolise an investigational medicinal product which may potentially have safety implications.”

Handling unexpected results – challenges on the road

- Could “unexpected or out of range results” be always defined?
- Should we consider expedited reporting regardless the nature of analysis? It is needed once the patient participation is completed?
- To whom to be reported “expedited” result?



Handling unexpected result – next steps in the journey

- Unexpected results should be defined in advance by Subject Matter Expert.
- Communication plan should be established and presented to bionanalytical laboratory
- Timelines for expedited reporting should be defined
- Nature of the analysis and phase of the study should be considered



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Obtaining patient ICF status

Reflection paper statement:

“There should be a mechanism to ensure that the laboratory is informed in a timely manner of **what actions to implement if consent is withdrawn**. While the responsibility for providing this information primarily resides with the sponsor, the laboratory should exercise due diligence. It is therefore recommended that these factors be considered and documented in the contractual agreement or other relevant documentation prior to the initiation of any analytical work .”

Why obtaining patient ICF status became a challenge?

- Bioanalytical lab is not familiar with the exact content of ICF and steps presented in case of consent withdraw i.e. how to proceed with the samples taken before the withdrawal?
- How to receive patient ICF status in case of actions needed from the lab – it is a mission possible?

Obtaining patient ICF status - next steps on the road

- Analysing all samples
- Moving to step for action taken on result reporting

The journey to GCP in bioanalytical lab continues

- Partnership between HA/Bioanalytical Community/QA
- Aligned expectation for all areas that should be part of GCP implementation.

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