Outcome of EBF Survey on Multi-center Trials

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(on behalf of EBF TT-12)

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Introduction

- Topic team formed after EBF Strategy Meeting in March 2012
- Members felt that there are recurrent issues connected to clinical trial management which impact on the bioanalysis
- None of these issues involve ‘rocket science’ but nevertheless they deserve close attention
- An EBF survey was drafted and the results will be presented here
- 60% response rate from the EBF members
- Key case examples will be presented later in the session by Carolyn Mailer
Q1. Which industry branch do you represent?

- Pharma Industry or CRO
Q2: Please rank the areas where you experience the largest difficulties in clinical multi-center trials.

- Condition of samples (labeling/barcoding)
- Quality of sample inventory/manifest
- Shipment/arrival of samples
- Ensuring that all sites use the same procedures for sample collection and storage
- Data transfer and reconciliation
- Difficulty in obtaining study randomization code

Difficulty (1=least, 6=largest)
Q3: How do you ensure that all sites use the same procedures for sample collection and storage?
Q4. Do you monitor on-site - by "monitoring" we mean actually 'verifying' or 'checking' whether collection, processing and storing is conducted in the way it was instructed?
Q5: How do you ensure the integrity of sample shipments/arrivals? (multiple answers possible)

- by incorporating shipping details into the lab manual
- by recommending Courier(s) at study set-up stage
- send printed labels to the sites, and/or sample collection ‘tick-box’ lists, to be returned with the...
- use of temperature data monitors
- by incorporating shipping details into the clinical protocol
- electronic on-line sample tracking
- other
Q6: Please rank the areas where you experience the largest difficulties with regard to sample condition upon arrival

- Barcodes not readable
- Broken tubes
- Documented storage issue before receipt at...
- Multiple labels on same tube
- Samples not frozen upon arrival
- Electronic list of samples not available
- Different tubes are used by different sites
- Sample in bags, not in boxes
- Hand-written labeling

Difficulty (1=least, 9=largest)
Q7: What is the largest problem with regard to data transfer?
Q8: In your organization, which group is responsible for the sample shipment?
Q9: Which parties are involved in drafting the lab manual?
Q10: Do you have difficulty to obtain the final study protocol (and amendments, where applicable)?
Q11: Do you experience more or less issues with sample collection, processing and storage in a single centre trial as compared to a multi-center clinical trial?
Q12: Are the issues with sample collection, processing and storage in a single centre trial of the same kind as compared to a multi-center clinical trial?

Yes, same kind of issues
No, other kind of issues
Q13: General comments-Summary

- Sometimes difficult for CROs to get involved at all, or at an early stage.
- (Proactive) communication between all parties is essential
- Preference to use a uniform tube with a single label, with barcode, that is resistant to freezing/thawing
- Less difficult data management and earlier involvement.
Conclusions

- Nobody in TT-12 was surprised by the survey results
- Nevertheless, these issues keep recurring
- Suggestions:
  - Pay attention to protocol detail and ensure you have the opportunity to contribute
  - Assume nothing
  - Communicate with your project team, clinical and data management colleagues and ensure they understand the bioanalytical issues
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