Outcome of EBF Survey on Multi-center Trials

Presenter: Bernd Matthes
(on behalf of EBF TT-12)

5th EBF Open Symposium
14-16 November 2012
Hisperia Towers, Barcelona

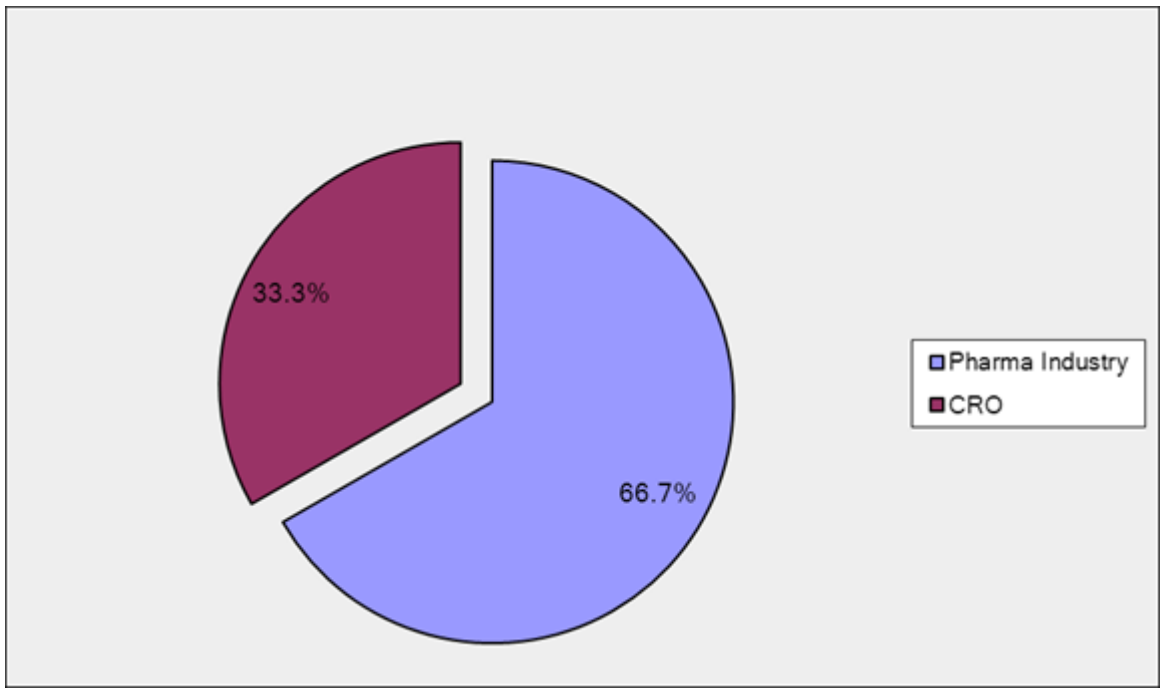
Introduction

- 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

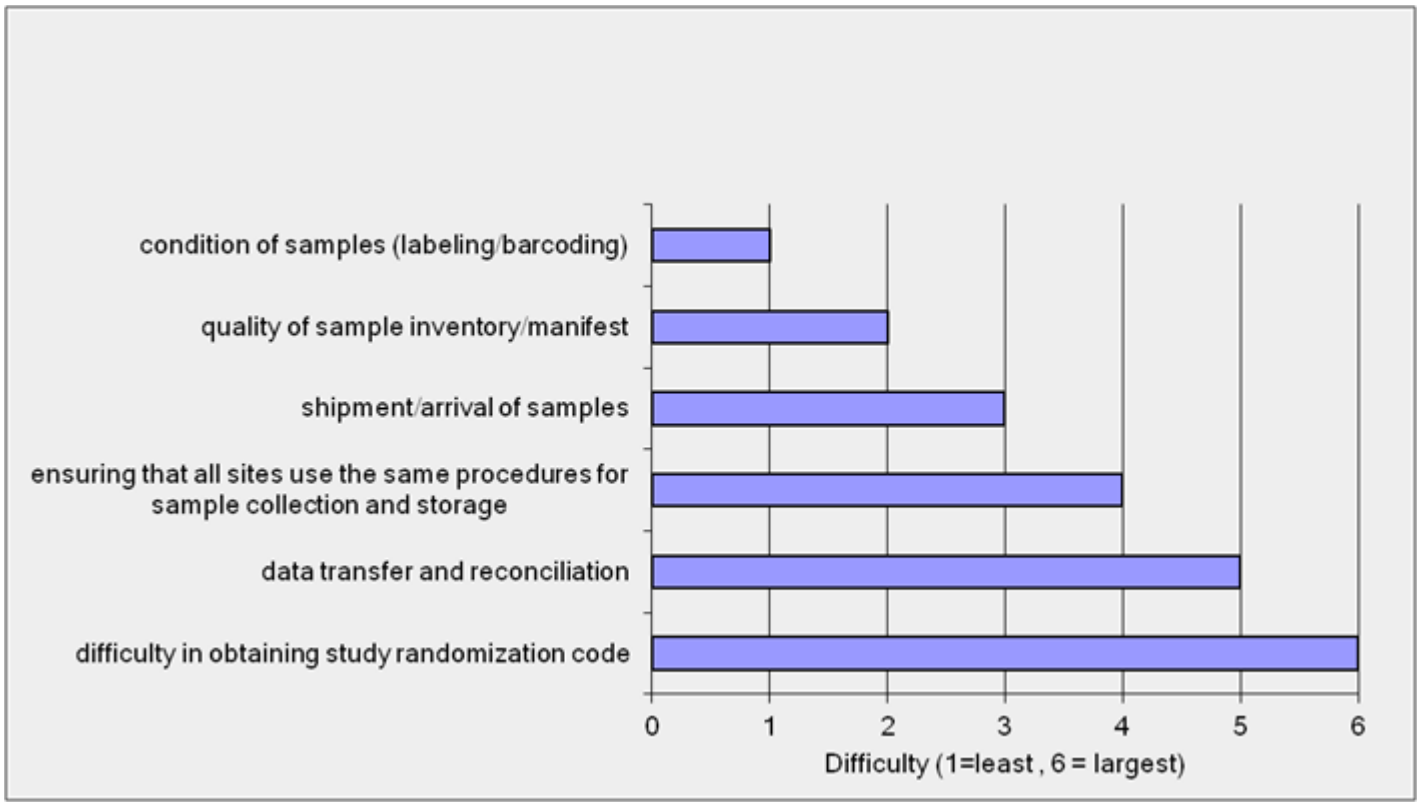
Sample Chaos

Q1. Which industry branch do you represent ?

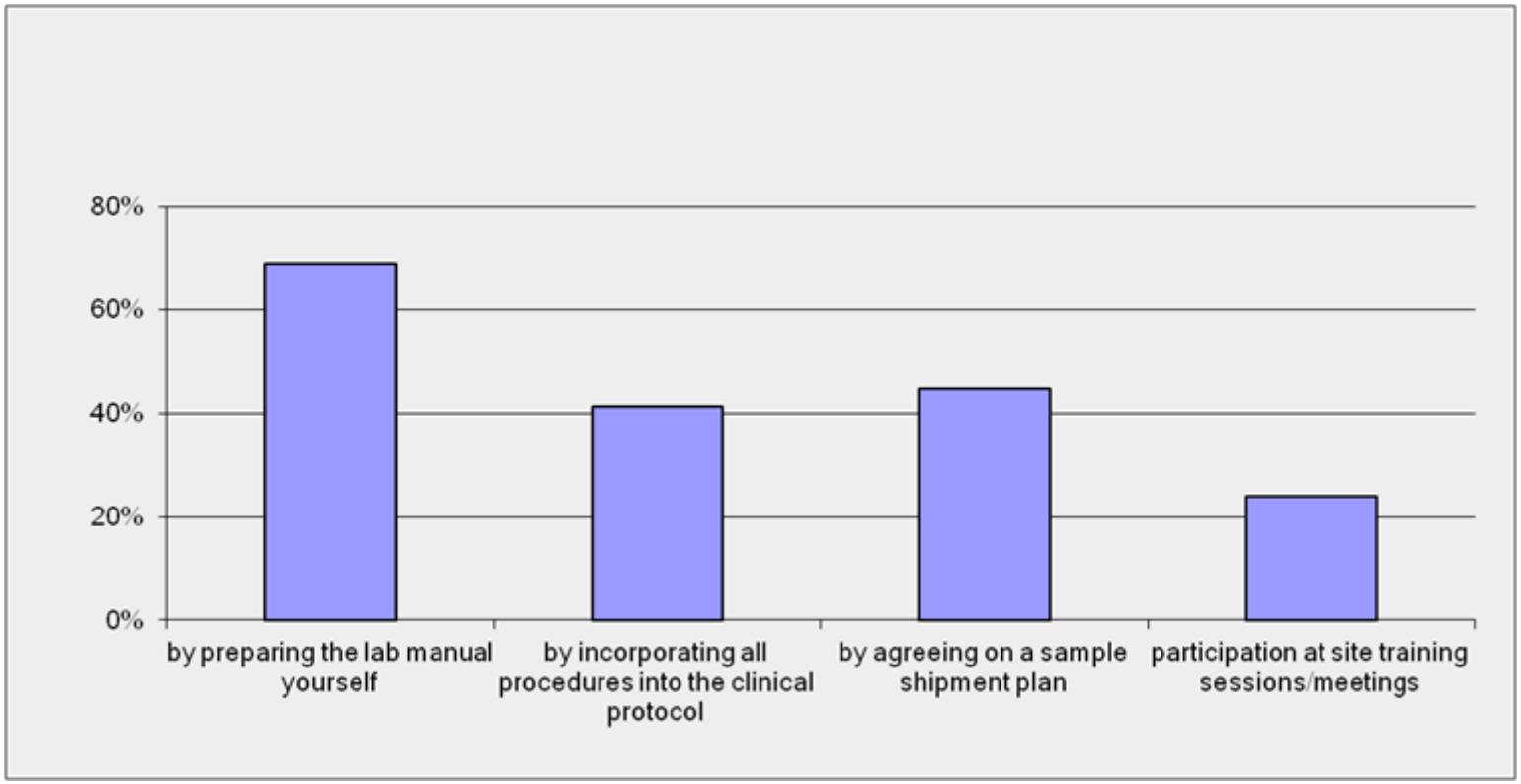
- Pharma Industry or CRO



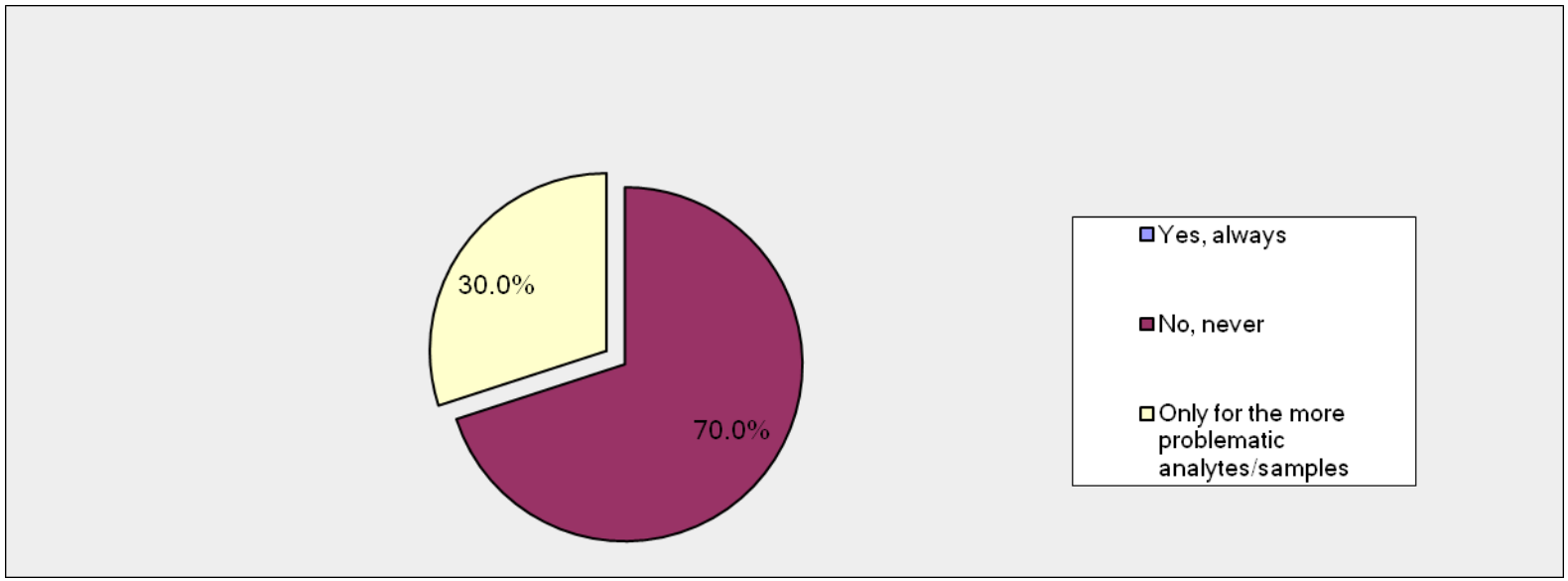
Q2: Please rank the areas where you experience the largest difficulties in clinical multi-center trials



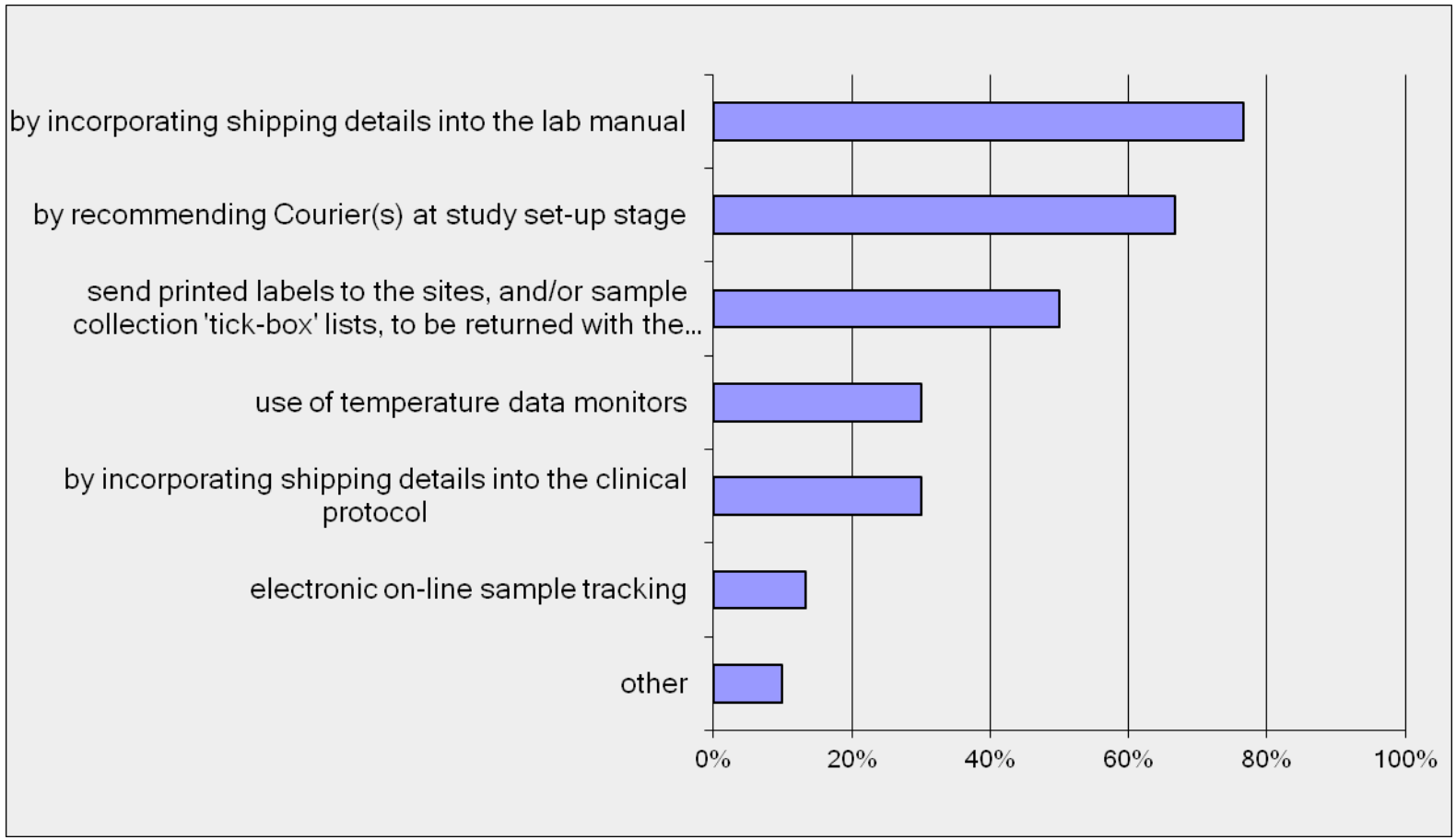
Q3: How do you ensure that all sites use the same procedures for sample collection and storage?



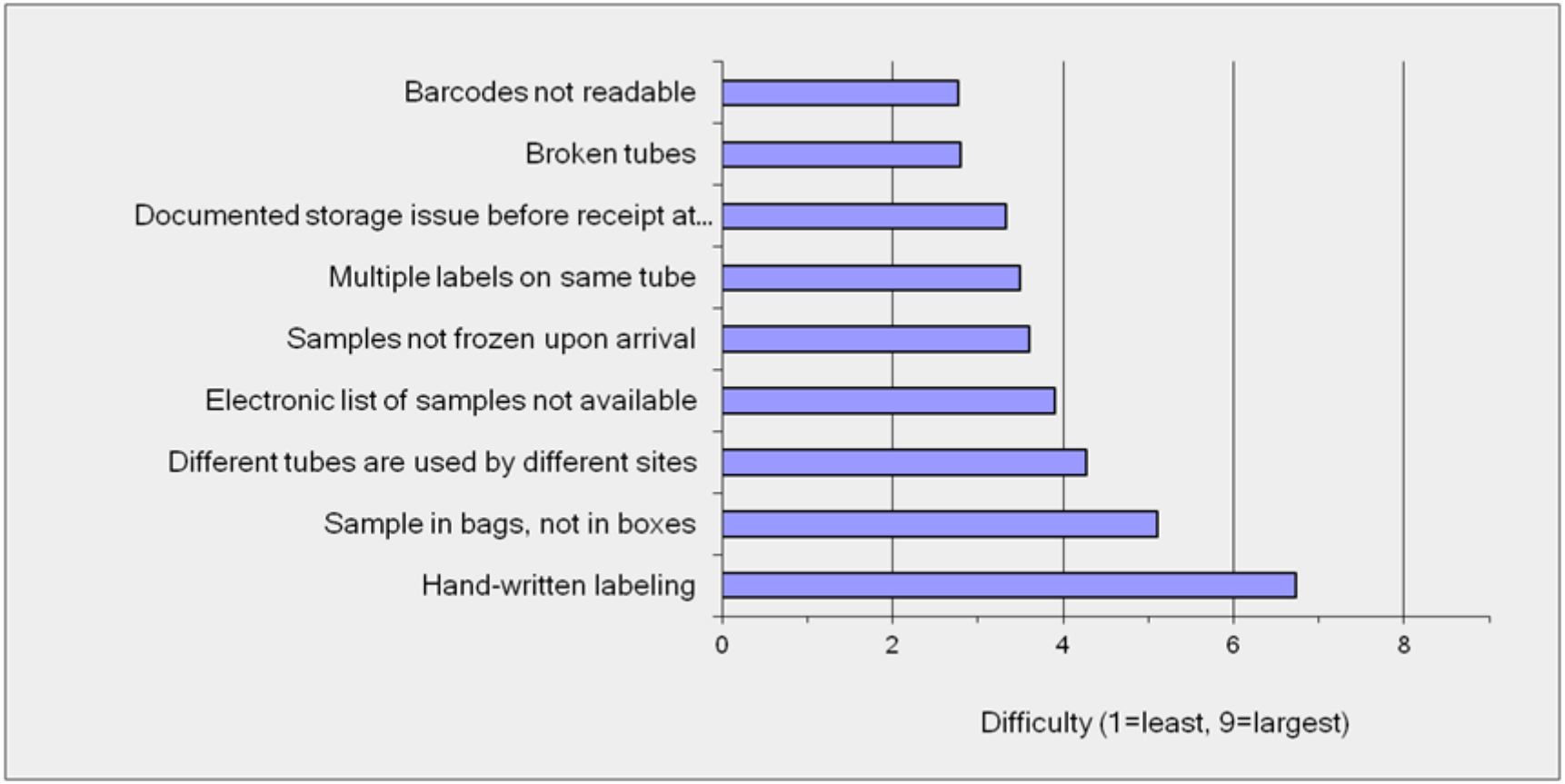
Q4. Do you monitor on-site - by "monitoring" we mean actually 'verifying' or 'checking' whether collection, processing and storing is conducted in the way it was instructed ?



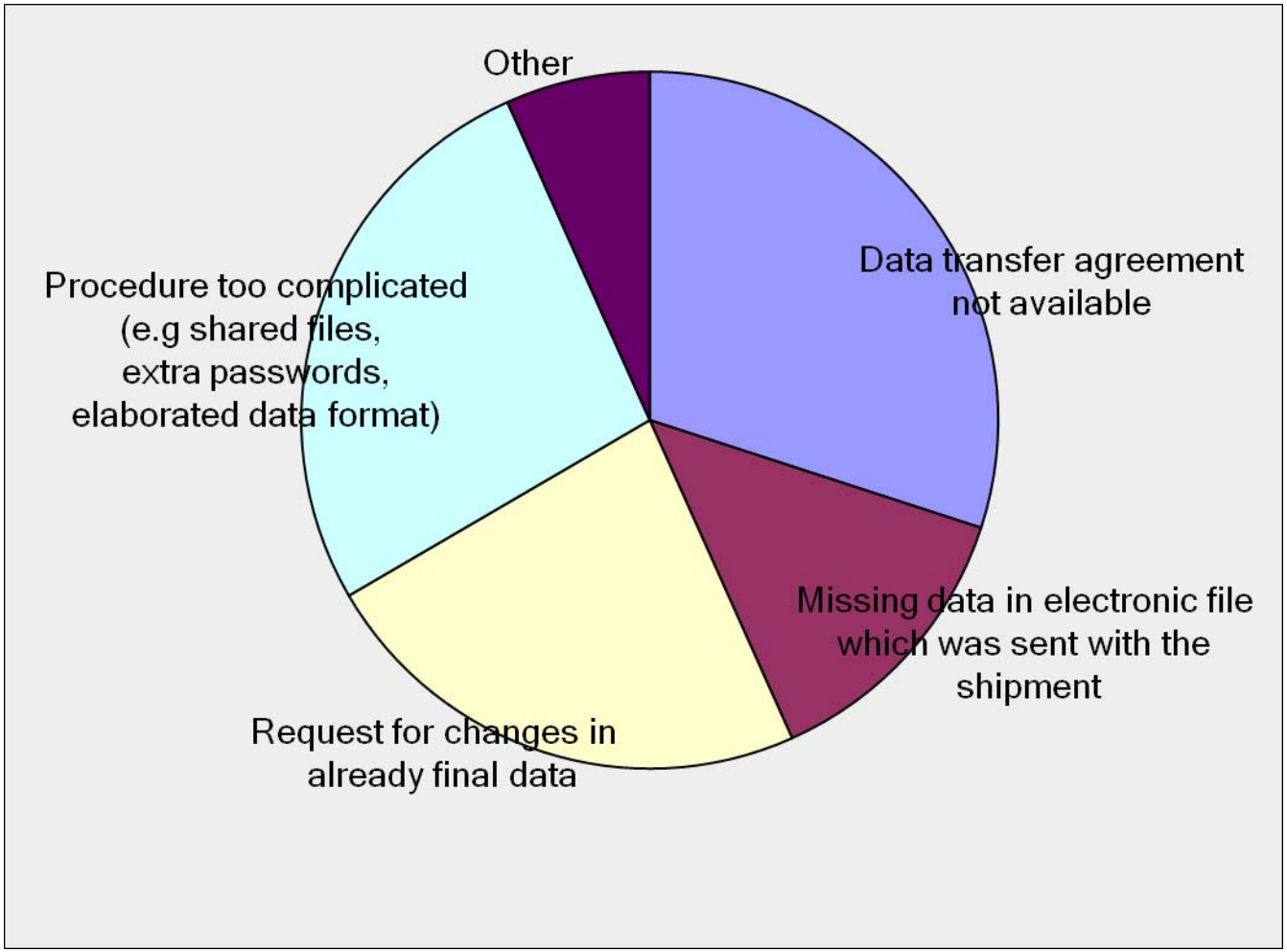
Q5: How do you ensure the integrity of sample shipments/arrivals? (multiple answers possible)



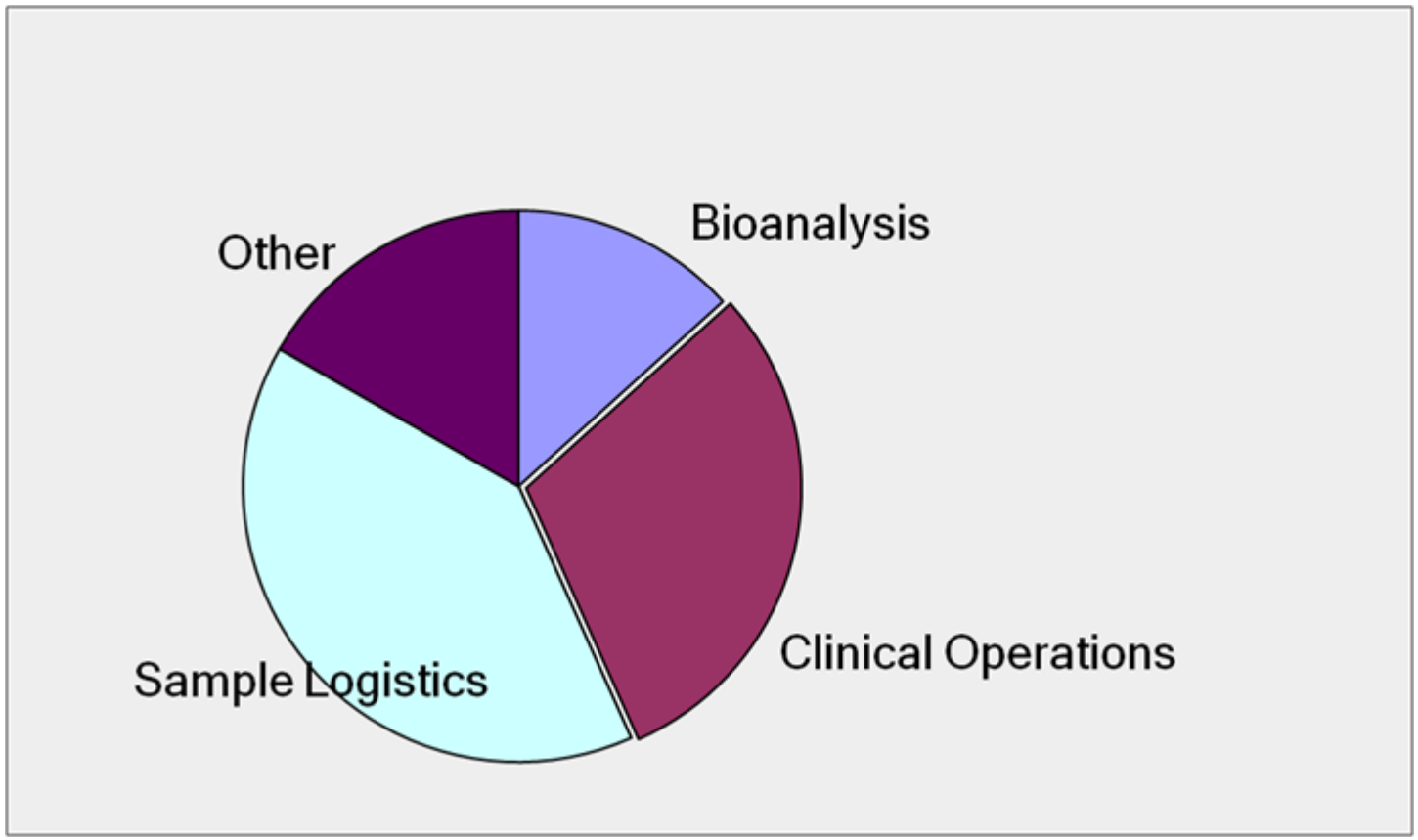
Q6: Please rank the areas where you experience the largest difficulties with regard to sample condition upon arrival



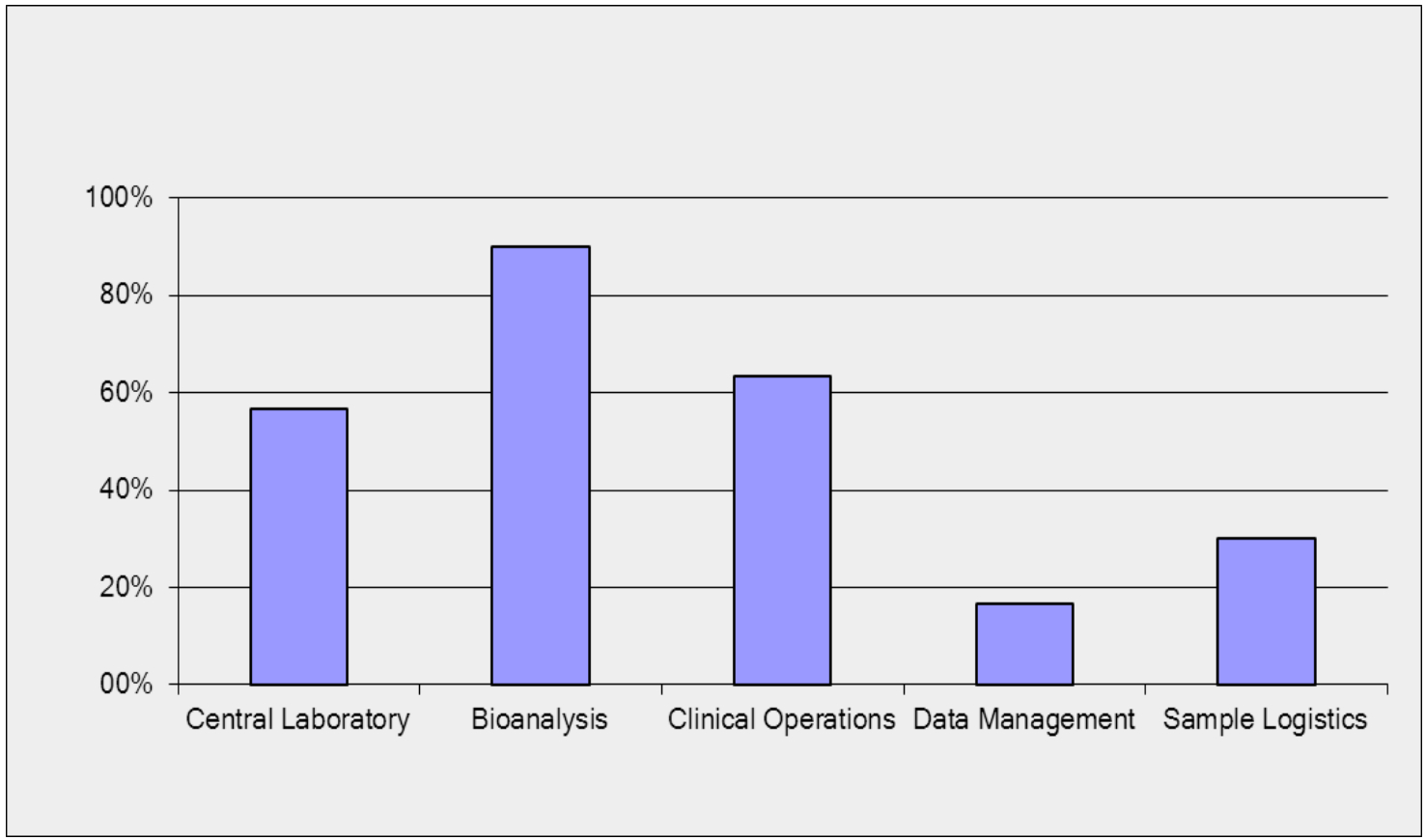
Q7: What is the largest problem with regard to data transfer?



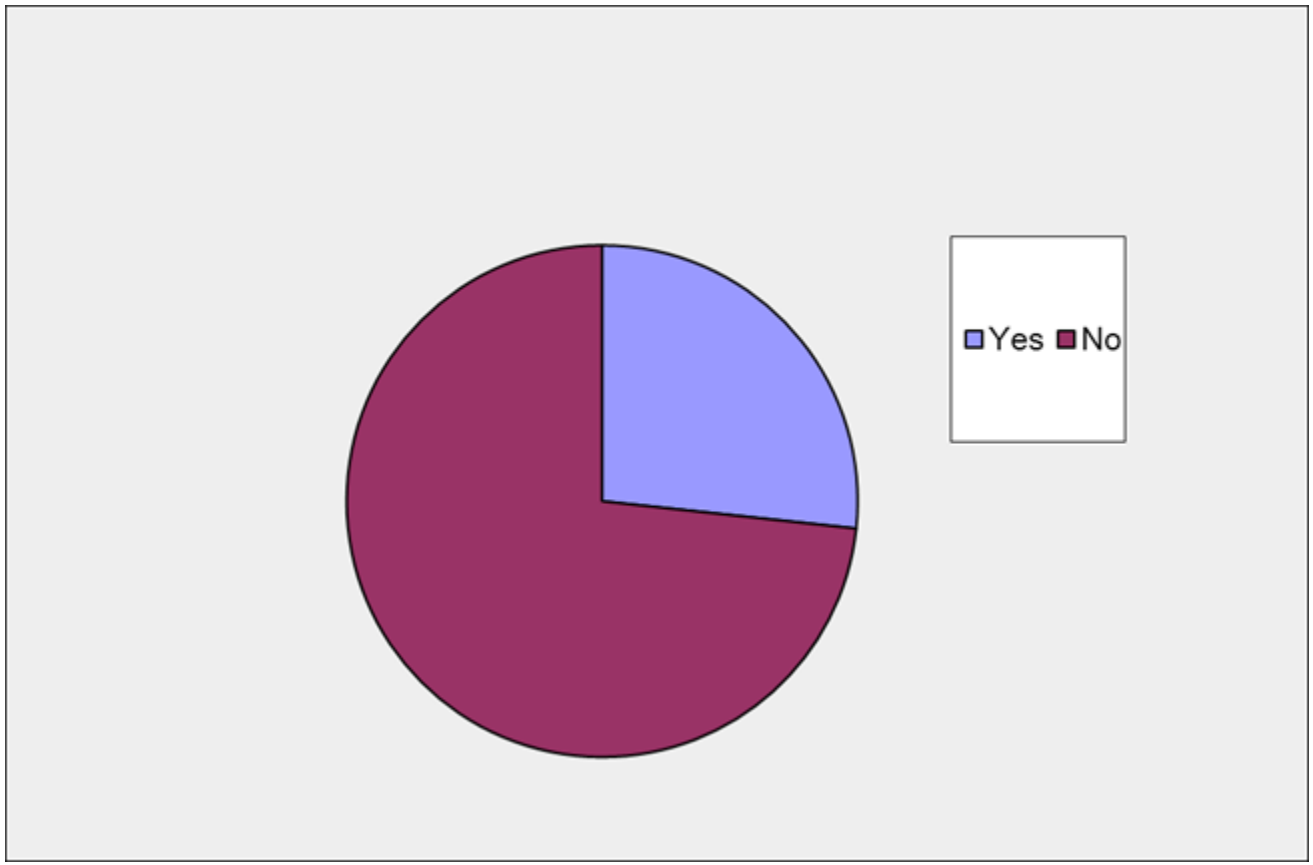
Q8: In your organization, which group is responsible for the sample shipment?



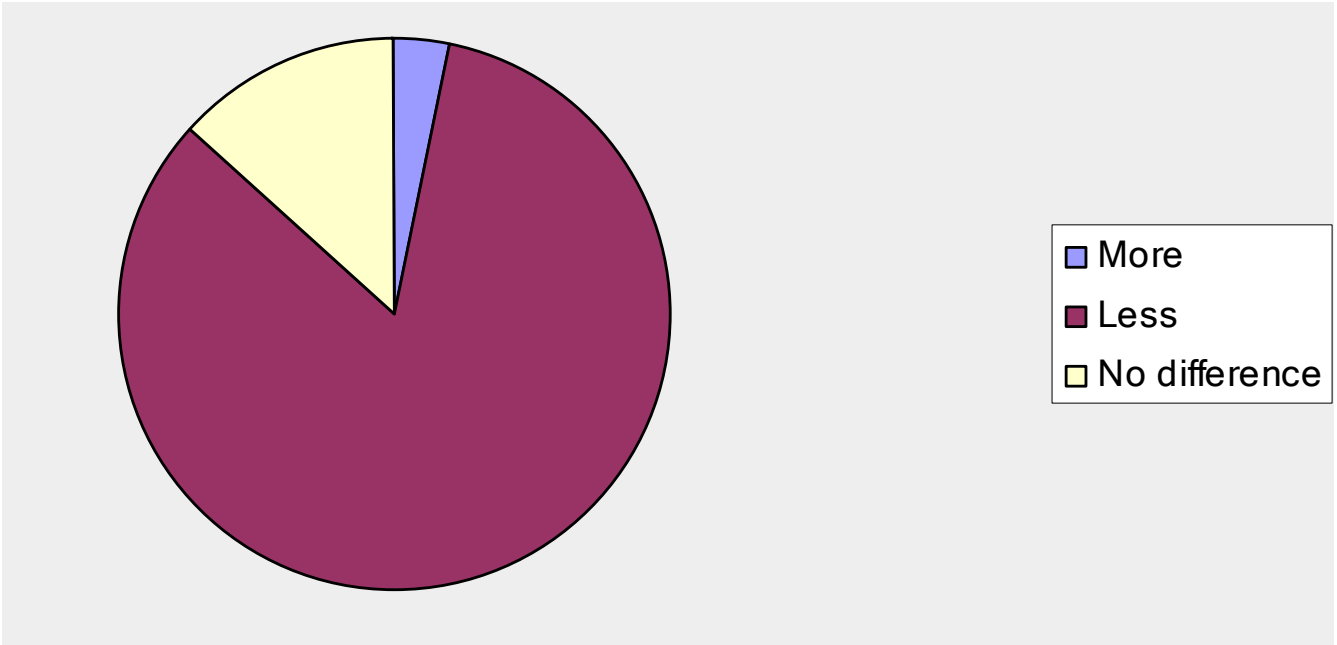
Q9: Which parties are involved in drafting the lab manual?



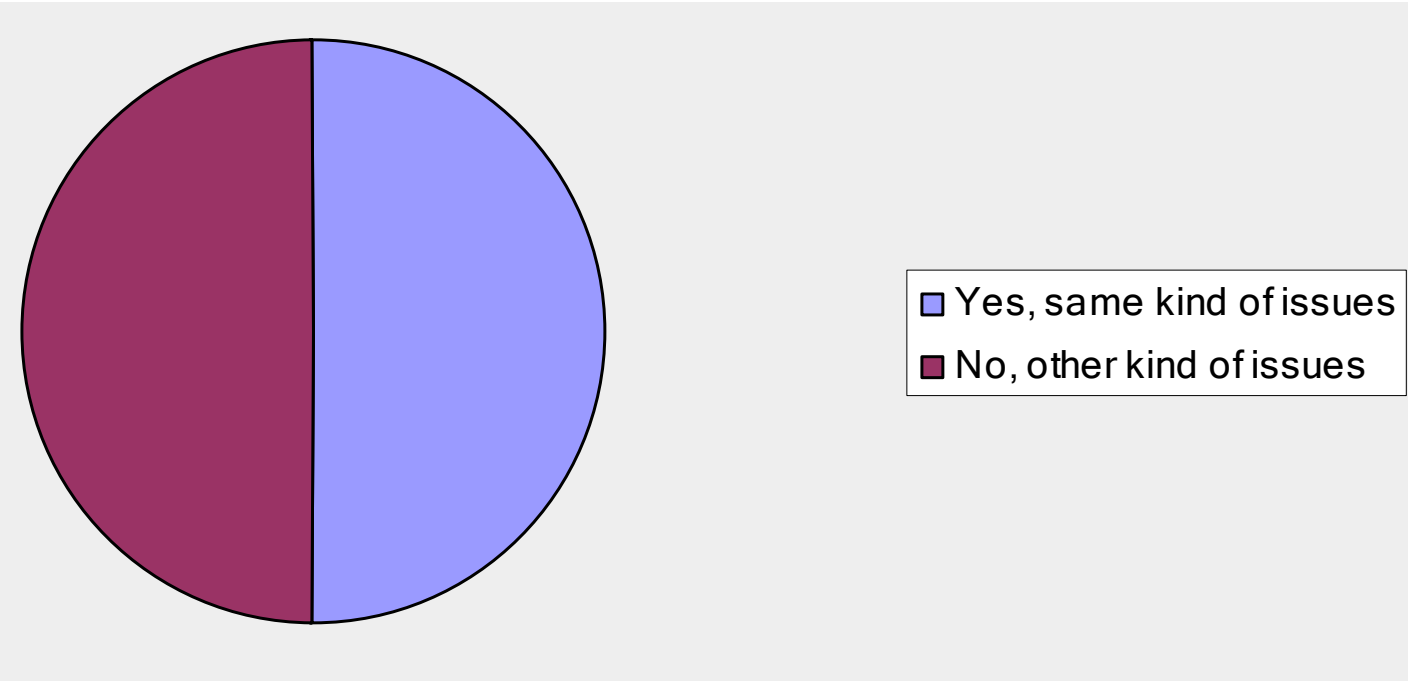
Q10: Do you have difficulty to obtain the final study protocol (and amendments, where applicable)?



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 ?



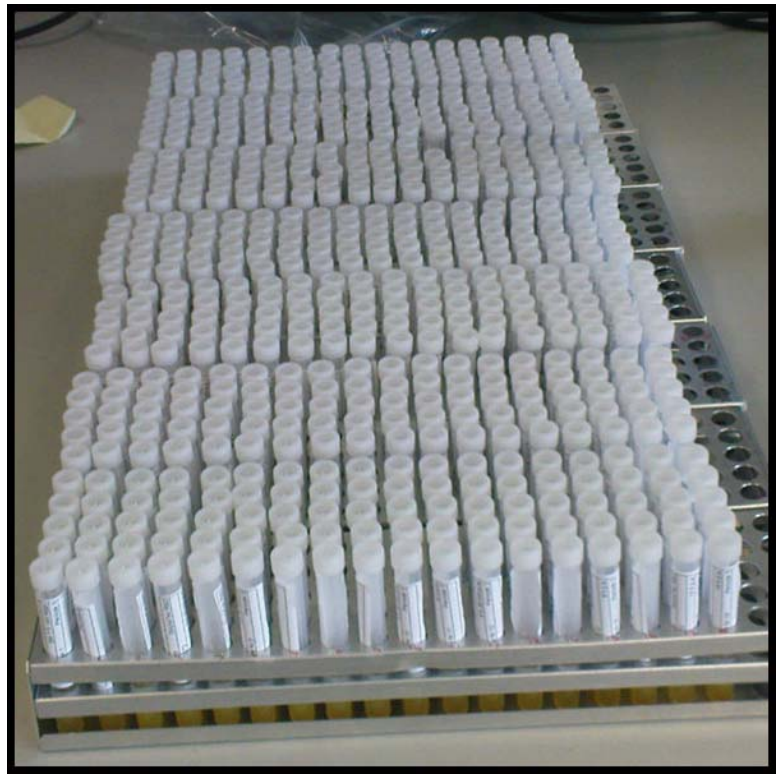
Q13: General comments-Summary

- 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

Sample Order



Acknowledgement

- EBF

- Team members :
  - Bernhard Beckerman — Bayer
  - Carolyn Mailer — Covance
  - José W. Groenboom-Nieuwenhuijzen — PRA
  - Benno Ingelse — Merck
  - Bernd Matthes — Celerion
  - Iris Vanwelkenhuysen — J and J
  - Marianne Scheel Fjording — Novo Nordisk
  - Rebecca Sleigh — Quotient
  - Rudi Segers — Eurofins
  - Silke Lüdtke — Boehringer
  - Richard Abbott — Shire
  - Jaap Wieling — QPS