

Sample logistics: problems and solutions in multi-center clinical trials

Outcome of survey

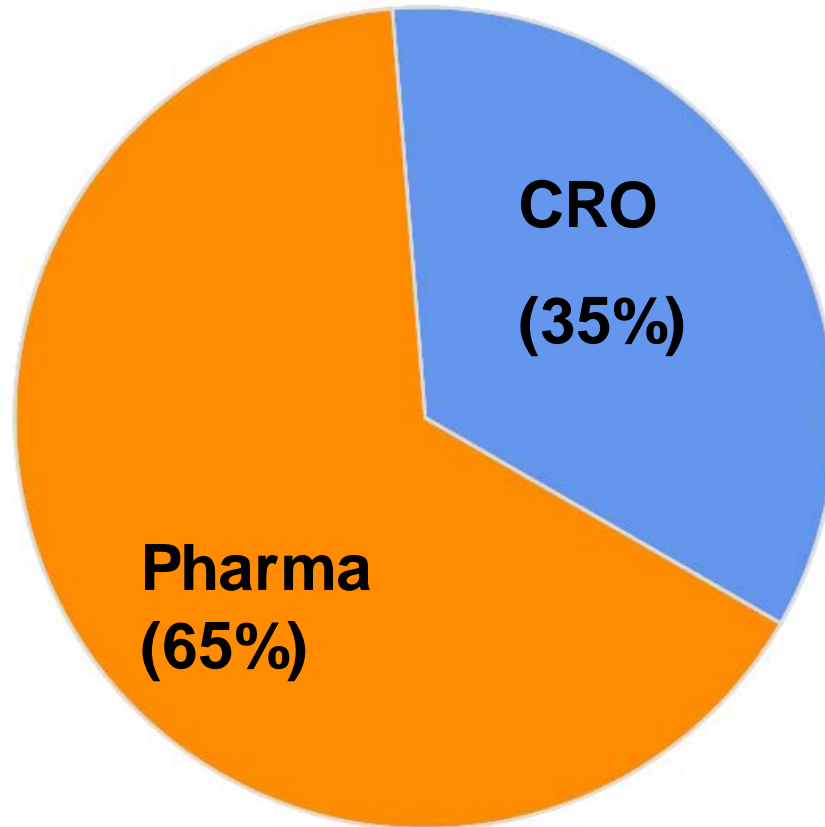
José W. Groenboom-Nieuwenhuijzen
on behalf of TT-12

6th EBF Open Symposium
20-22 November 2013
Hesperia Towers, Barcelona

Introduction

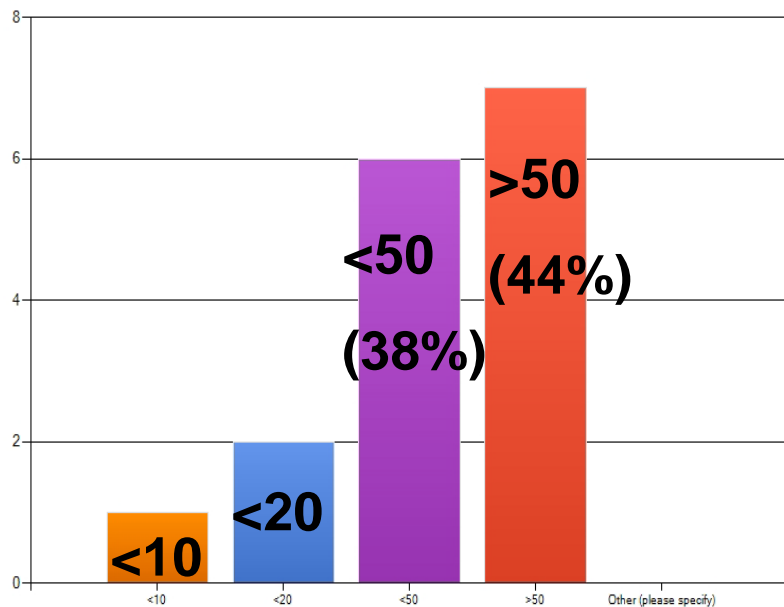
- General level of interest
- EBF strategy meeting in March 2013
 - Placebo samples
 - Back-up samples
 - Lab manual
- Tried to engage clinical colleagues: subset of survey
- # of responders: 29 of 53 EBF members (including 4 incomplete)

Which industry branch do you represent?

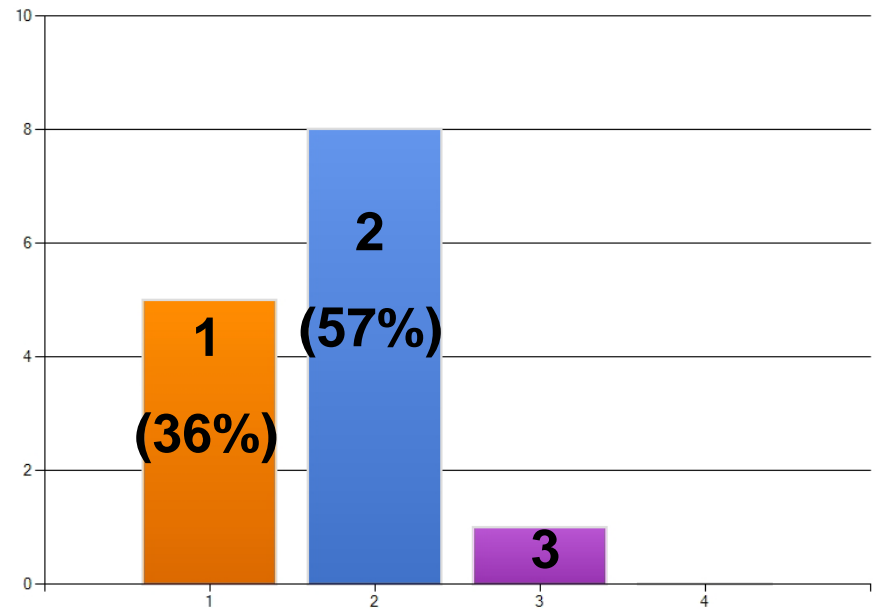


Questions to pharma companies

- How many clinical sites do you typically work with in a Phase III trial?

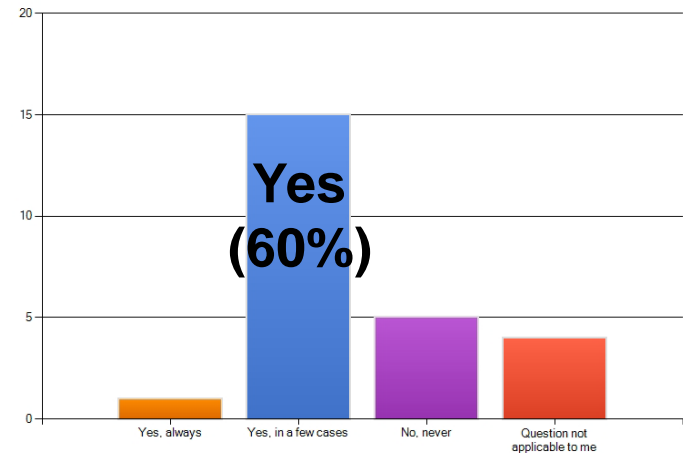


- How many central labs do you typically work with?

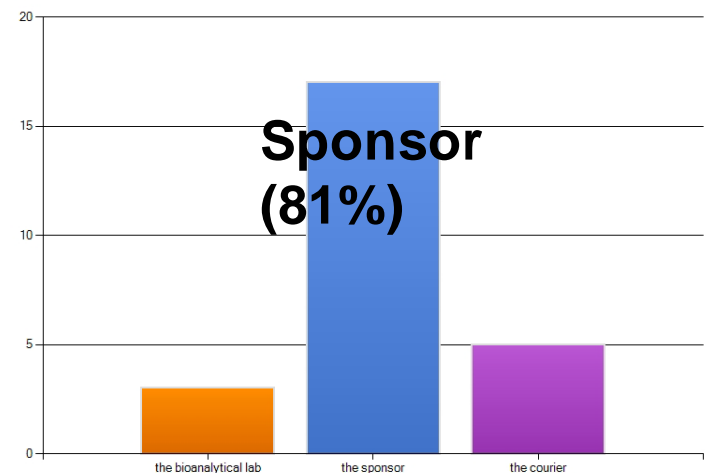


Temperature loggers

- Does your company use active temperature monitoring of sample shipments, for instance using temperature loggers?
(*Yes, always; Yes, in a few cases; No, never; Question n.a.*)
(**voting opportunity**)

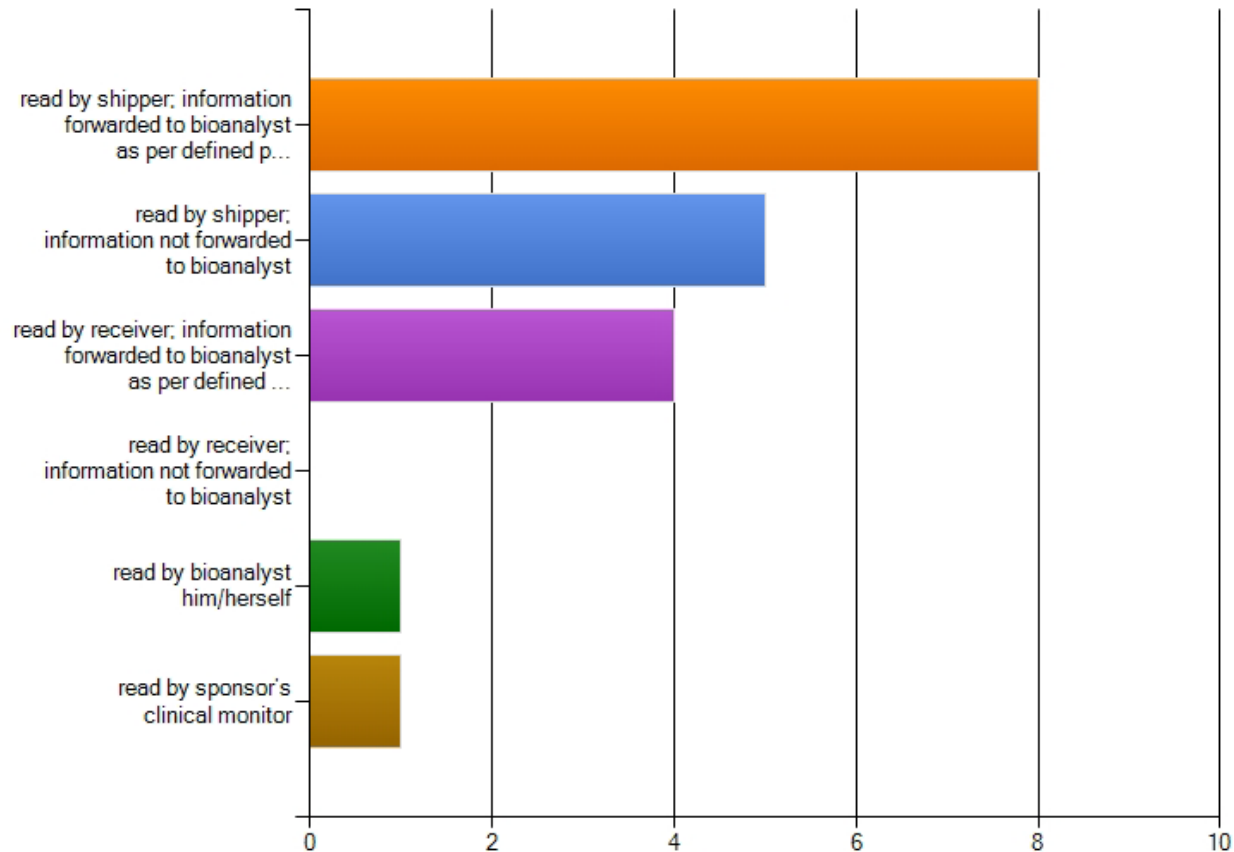


- In your opinion who is responsible for the shipment of samples, including these temperature loggers?
(*BA lab, Sponsor, courier*)

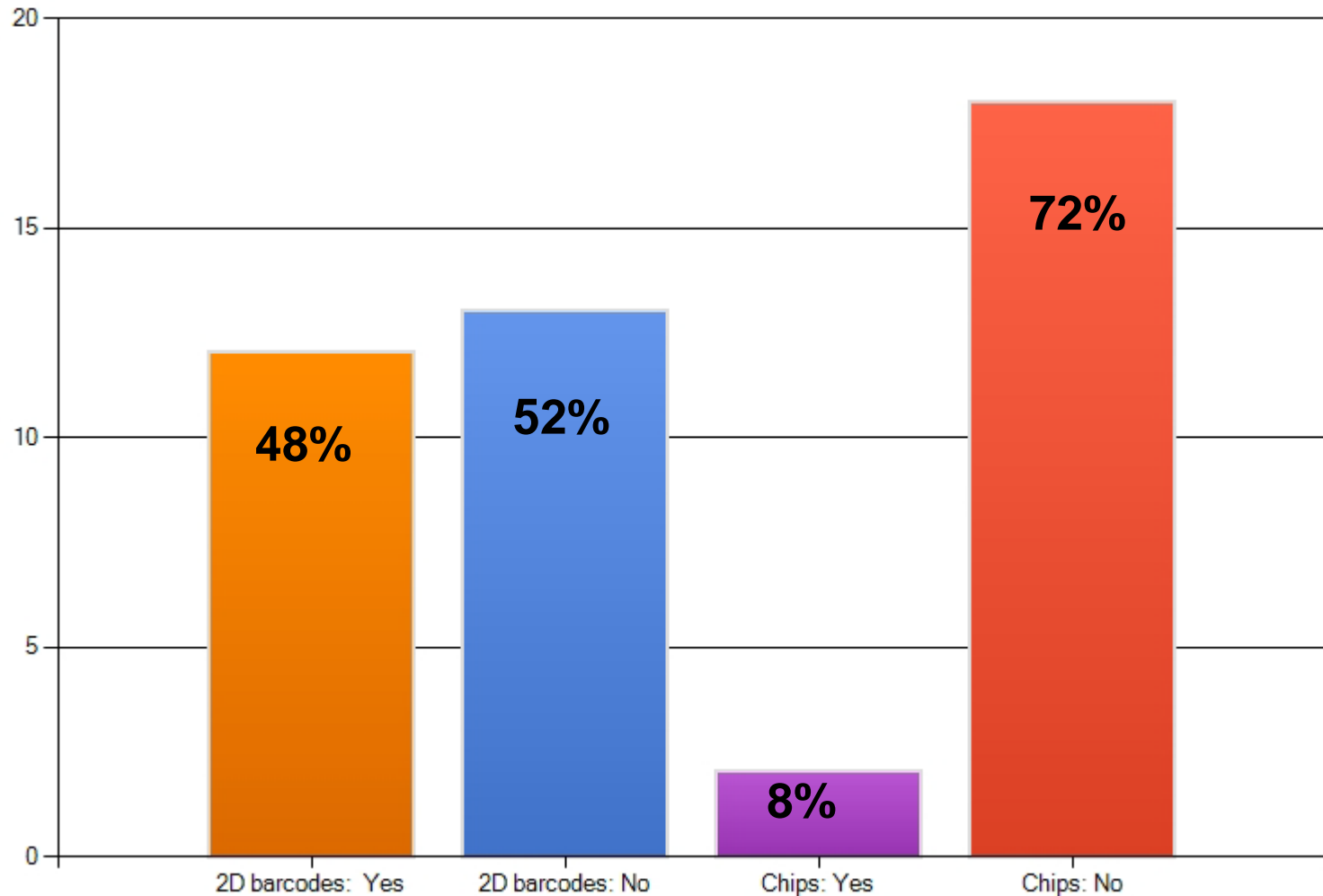


Temperature loggers

- If temperature loggers are used: who is reading the temperature information and how is it assured the bioanalyst gets the information?

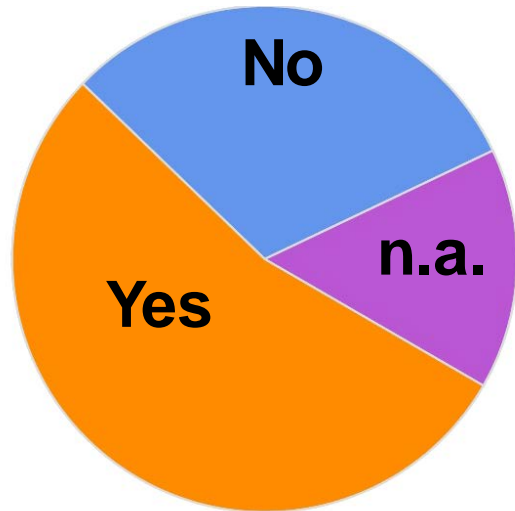


New technologies: 2D barcodes and chips



Back-up samples

➤ Do you take back-up samples?

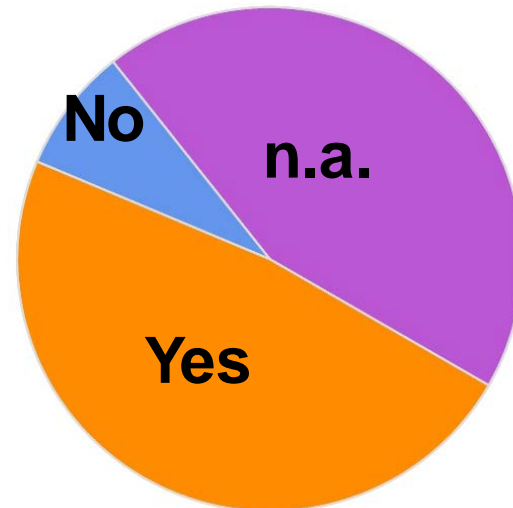


➤ Do you ship the back-up and primary samples to the bioanalytical lab in separate shipments?

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➤ Do you store them in separate freezers?
(voting opportunity)

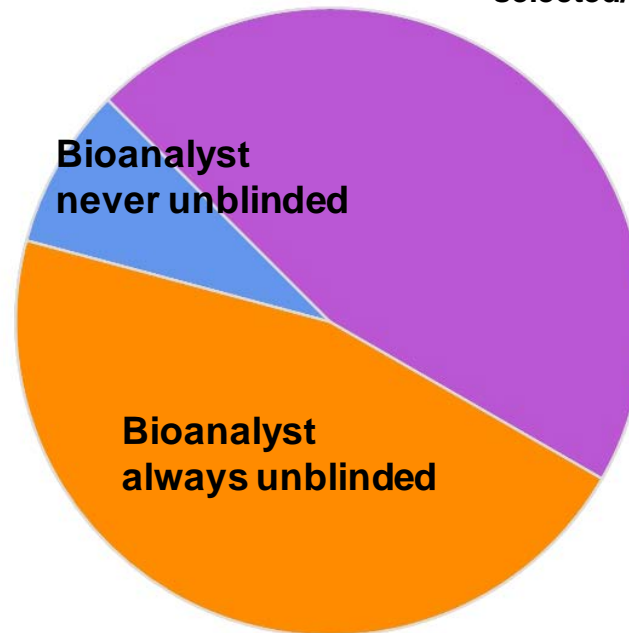


Placebo samples (I)

- Do you send placebo samples to the bioanalytical lab?
- Do you have a policy unblinding the bioanalyst?

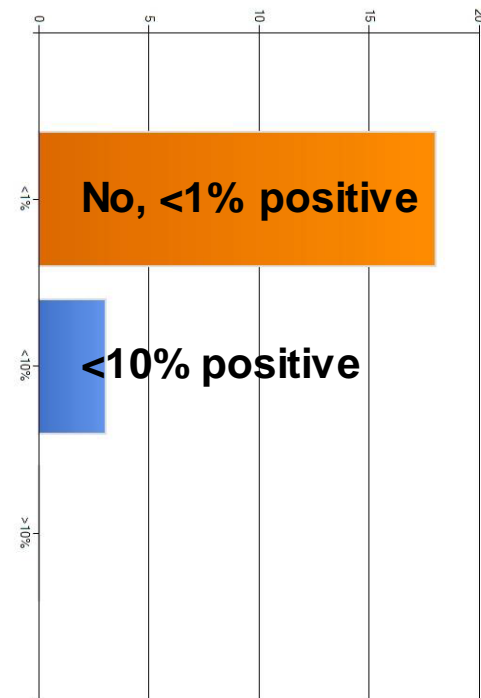
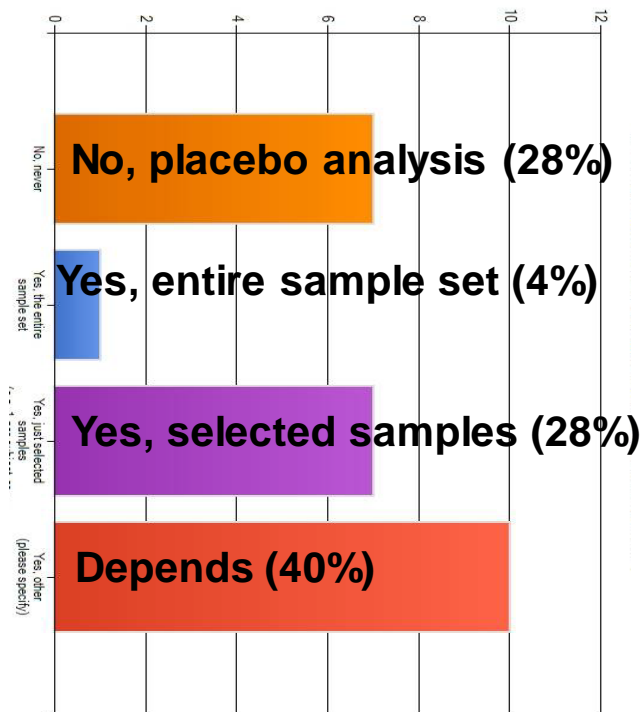
Other

- Depends on trial, Sponsor (4)
- Typ. Ph I blinded /(Ph II/III) unblinded
- blinded = barcode samples
- unblinded preferred as default, except BE/ when placebo must be selected/ only management



Placebo samples (II)

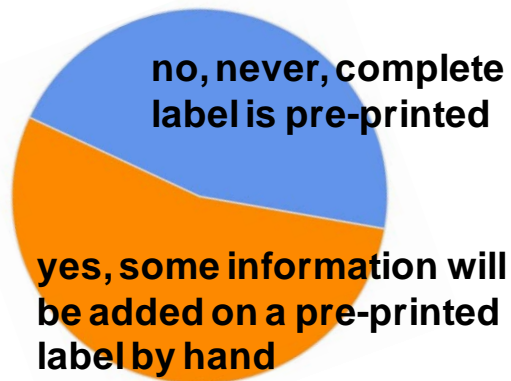
- Do you actually analyse placebo samples and if so, to which extent?
 - No, Yes (entire set or selection), depends on sponsor/trial/protocol/type of analyte)
- (...) Any positive placebo results?



Sample labels

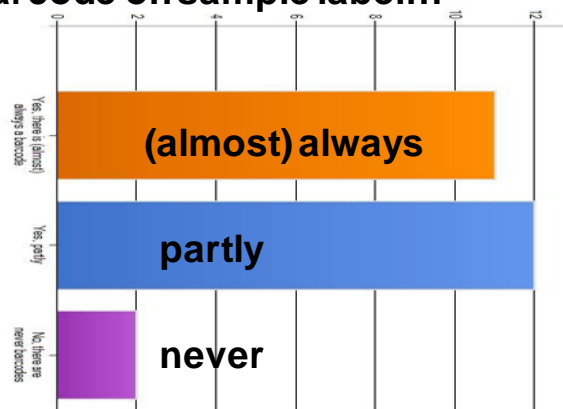
- are your labels ever (partly) handwritten?
- do you receive bioanalytical samples with a barcode on the label?
- do you routinely actually use barcodes?

Handwritten labels...

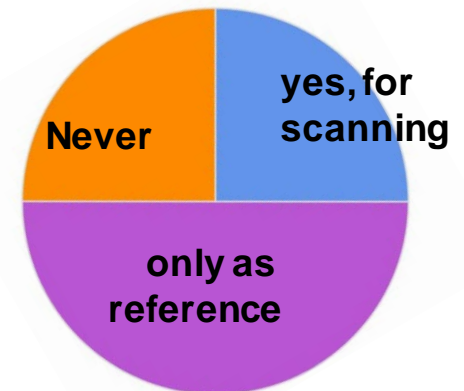


And: zero answers to:
mostly/entirely handwritten

Barcode on sample label...

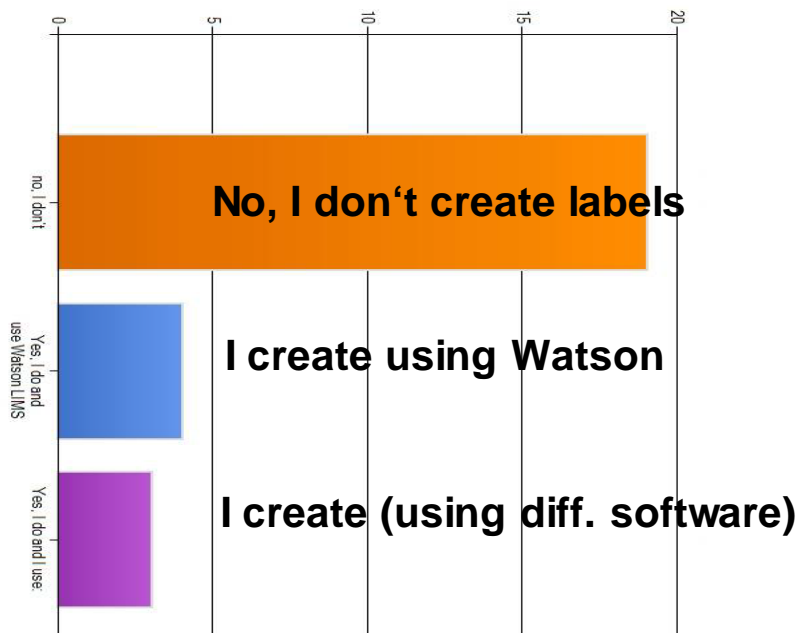


Barcodes actually used...



Sample label and tube

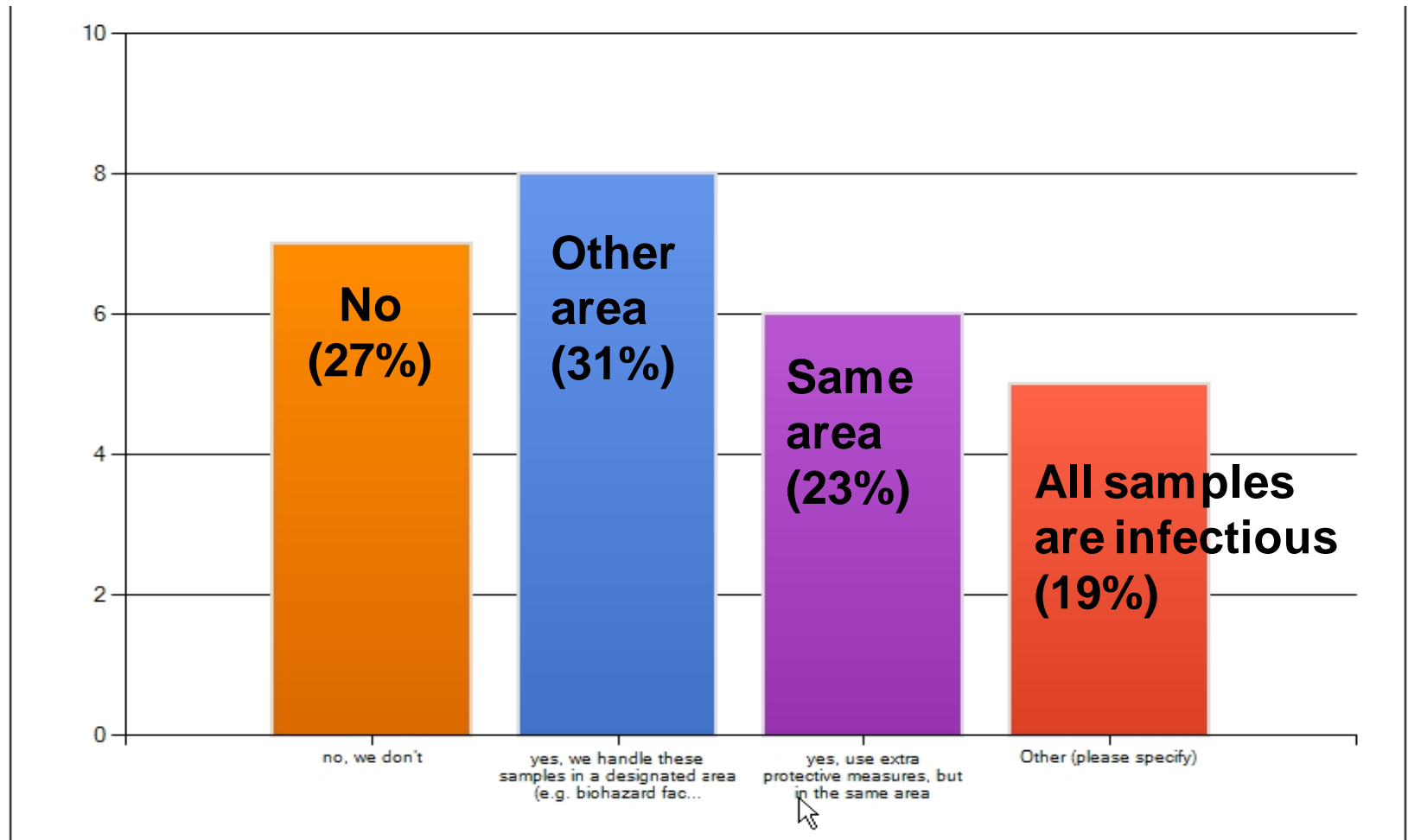
- Do you create labels yourself, and if yes, what software do you use?
- Would you be prepared to standarize on an 'industry' standard sample label e.g. a generic EBF agreed sample label)?
- Would you be prepared to standarize on 'industry' standard sample tube?



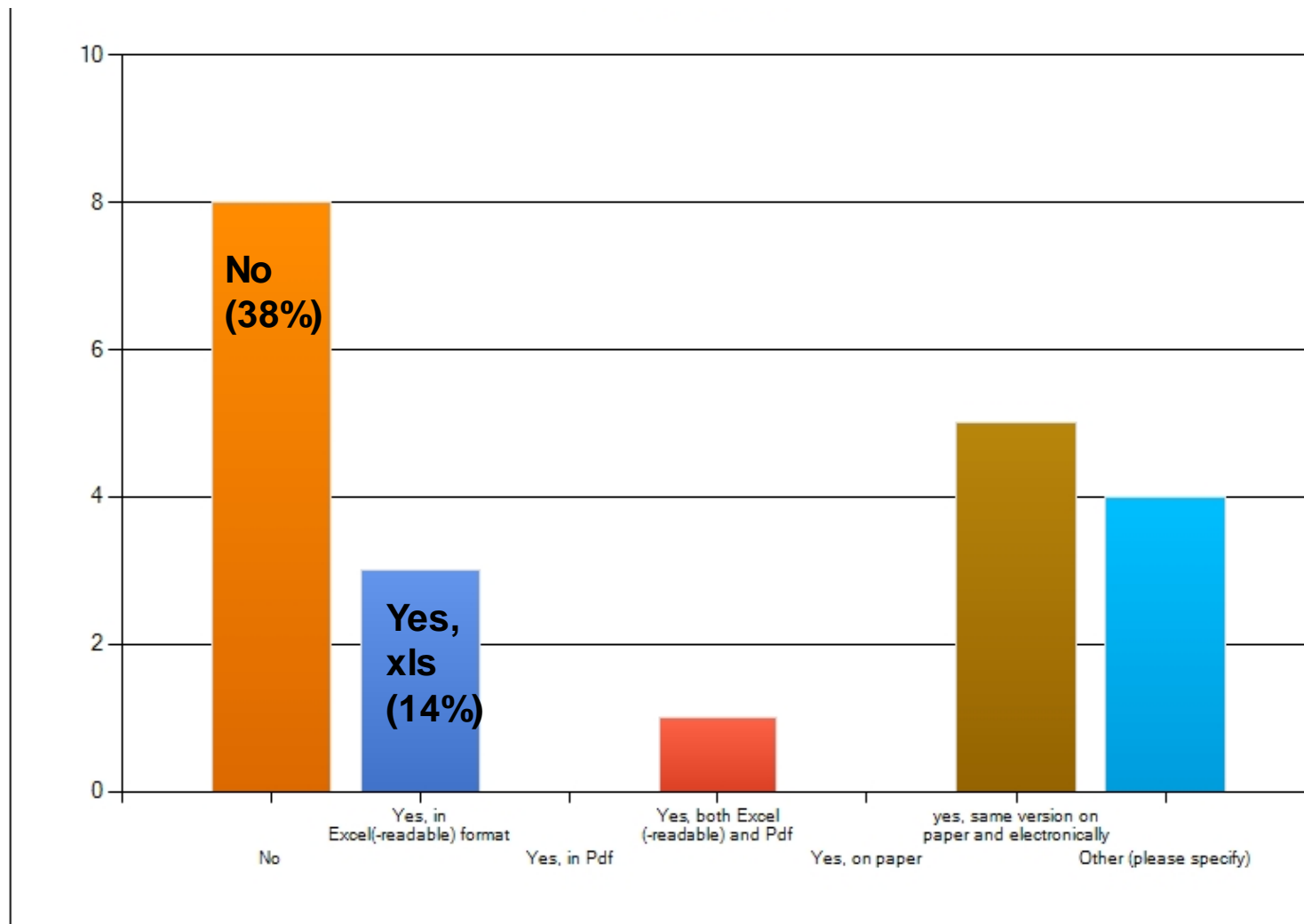
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Handling infectious samples

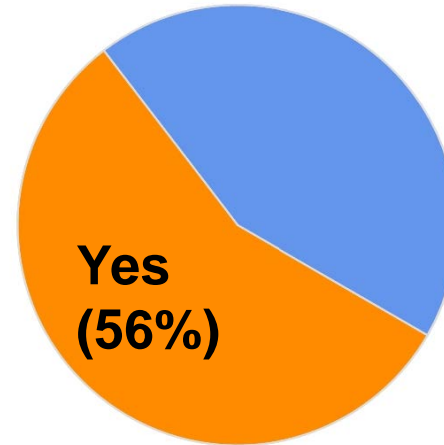
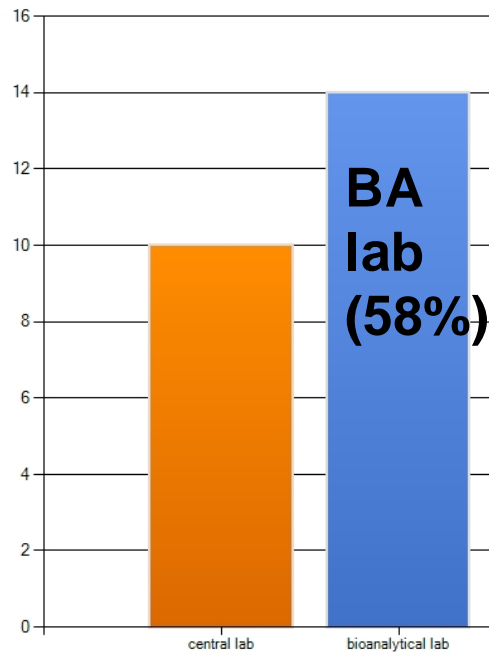


Shipment/sample manifest, which form?



Reconciliation

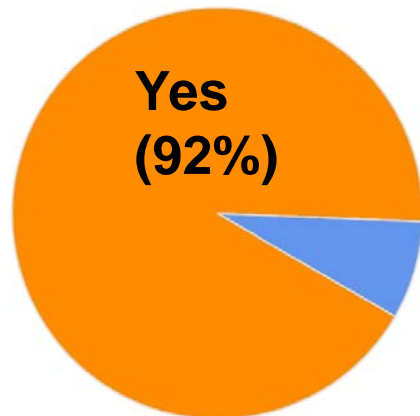
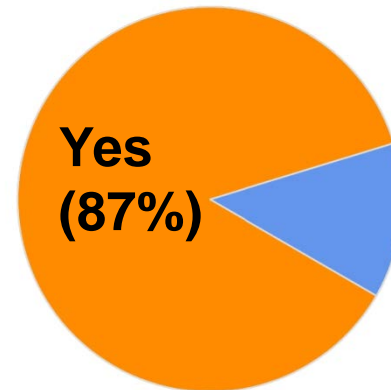
- Are sample labels checked against the manifest before shipped?
(voting opportunity)



- Where does reconciliation occur before analysis?

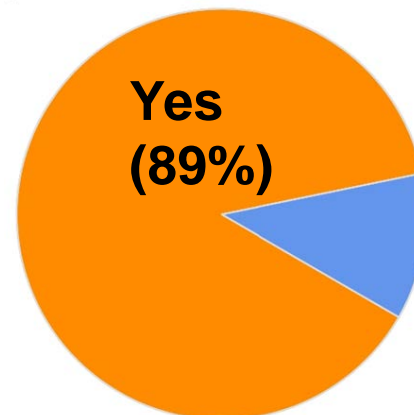
Lab Manuals

➤ Do you use a Lab Manual?

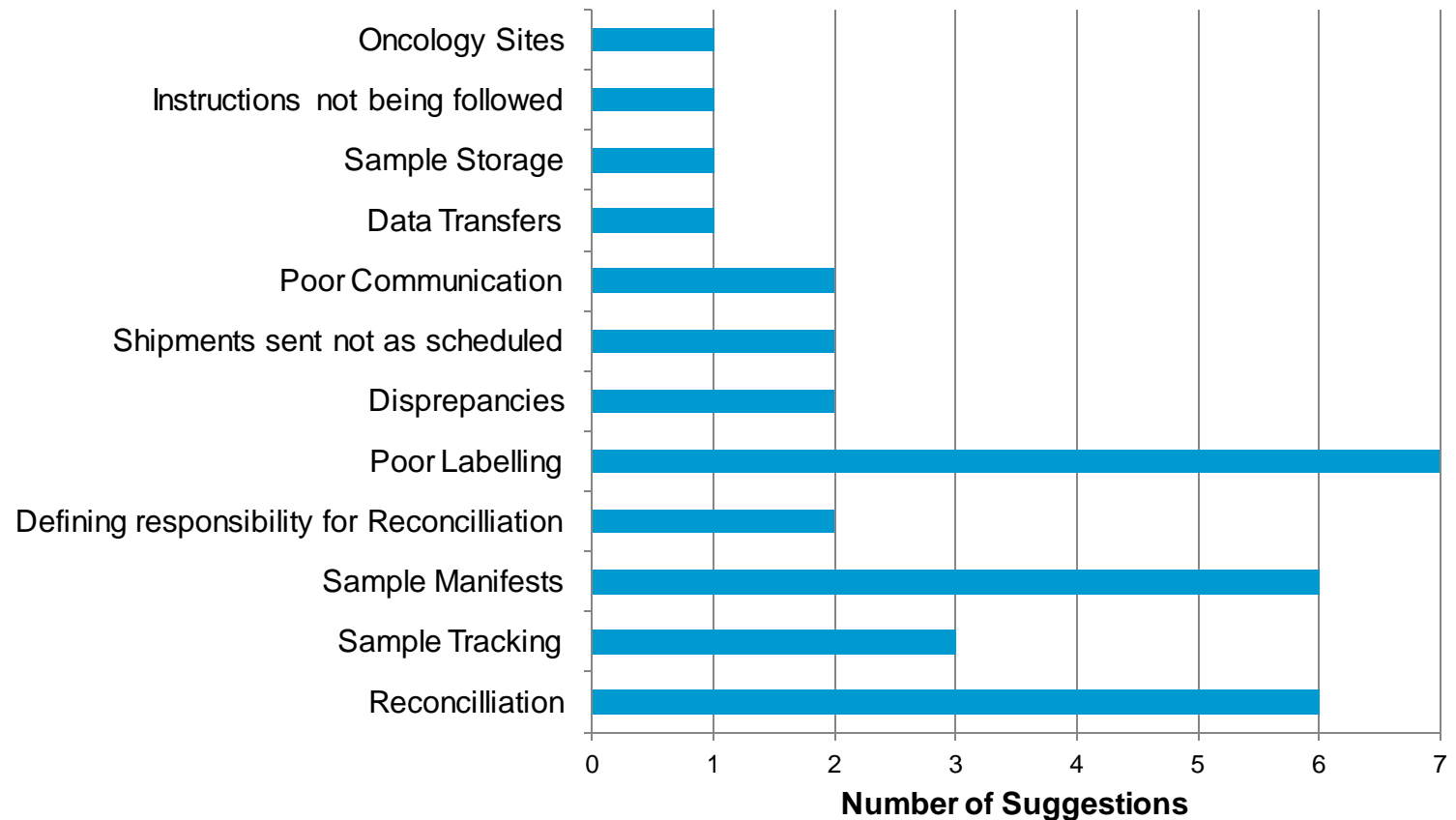


➤ Does the Bioanalytical Lab have input?

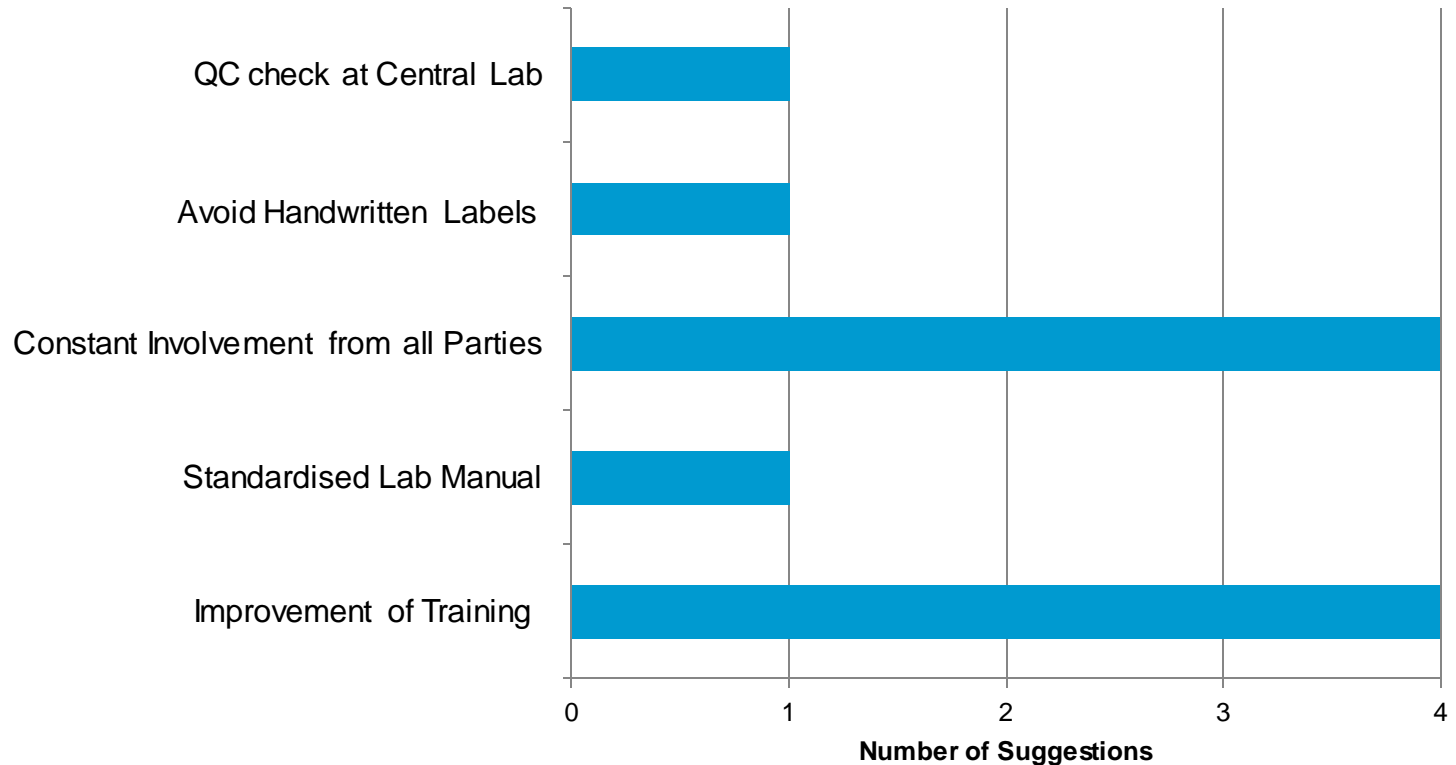
➤ Would you use an Industry Standard Lab Manual?



Which issue around sample management causes most problems?



What do you think should be done to improve the situation?



Concluding remarks

- Room for improvement (EBF community?):
 - Discuss how to handle temperature loggers
 - Barcoding (2D or not)
 - Consensus on back-up, placebo and infectious sample handling/shipping
- Start working on generic sample label, tube, lab manual (lab manual drafted already, more in next presentation)
- Start/continue using sample manifests in Excel
- Reconciliation of bioanalytical identifiers before shipment to lab
- Communicate!

Acknowledgements

- Topic Team 12 'Multi-center clinical trials'
 - Bernd Matthes
 - Rebecca Sleigh
 - Richard Abbott

- You!

Questions?