

# **TT-12 Clinical Multi Center Trials Workshop: Survey Results, CDISC, Generic Data Transfer Agreement**

Members: José Groenboom-Nieuwenhuijzen,  
Richard Abbott, Carolyn Mailer, Melloney Dröge,  
Bernd Matthes, Rebecca Sleigh, Carina Ekstrom,  
René Megens, Tom Verhaeghe

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# Workshop 14.10-15.30

- 14.10-14.15 Welcome, introductions
- 14.15-14.40 Outcome surveys
  - One sent to bioanalysts
  - One sent to clinical data managers
- 14.40-15.00 Martina Wein
- 15.00 Agree on a way forward including perhaps :
  - some topic headings for a generic DTA
  - basic outline of a generic data template

# EBF TT-12 : Brief Review

- Previously worked on a Generic Lab Manual
  - Ideas and survey presented in BCN in 2013
  - Initial Lab Manual drafted by small subteam
  - Follow up workshop in Brussels in Feb 2014
    - o With input from clinical as well as bioanalysis
  - Draft Lab Manual refined and finalised June 2014
  - Publication on Bioanalysis zone and in Clinical Investigations (planned)
  - <http://www.bioanalysis-zone.com/2015/10/30/development-of-a-generic-laboratory-manual-for-biological-sample-logistics-in-clinical-pharmacokinetic-studies/>
- New topic : Generic Data Transfer Agreement

# Bioanalysis and Clinical Data Management

- These groups have different functions and follow different procedures
- Often they do not really understand each other
- They have different interests :
  - BA : interested in the quality of the data
  - CDM : interested in the format of the data
- CDISC : an important CDM language typically not used and understood by bioanalysts

# Generic Data Transfer Agreement

- Why needed?
- Some of the issues we encounter on a daily basis:
  - Data Reconciliation
  - Lacking (business) Relationships between Central Labs and Clinical sites
  - Variation in data formats, number and types of standard fields
  - Filename of data file
  - Number and types of data transfer
  - CDISC : a regulatory data formatting convention
  - Data Transfer Agreement template

# Survey for bioanalysts

- 39 responders: 29 from Pharma, 10 from CRO
- Companies: TNO Triskelion, Johnson & Johnson (Janssen Pharmaceutica), A&M Labor (2x), LEO, ABL, BAYER (3x), Grünenthal GmbH, Pierre Fabre, Ferring, AstraZeneca, F.Hoffmann-La Roche (2x), Almirall, Abbott, GSK, Novartis, Merck Serono, Charles River, Astellas, Nuvisan GmbH, Actelion, ABS Laboratories Ltd, Orion Pharma, PRA Health Sciences, Swiss BioQuant, Covance, MedImmune, Celerion and one unknown.

# Survey for datamanagers

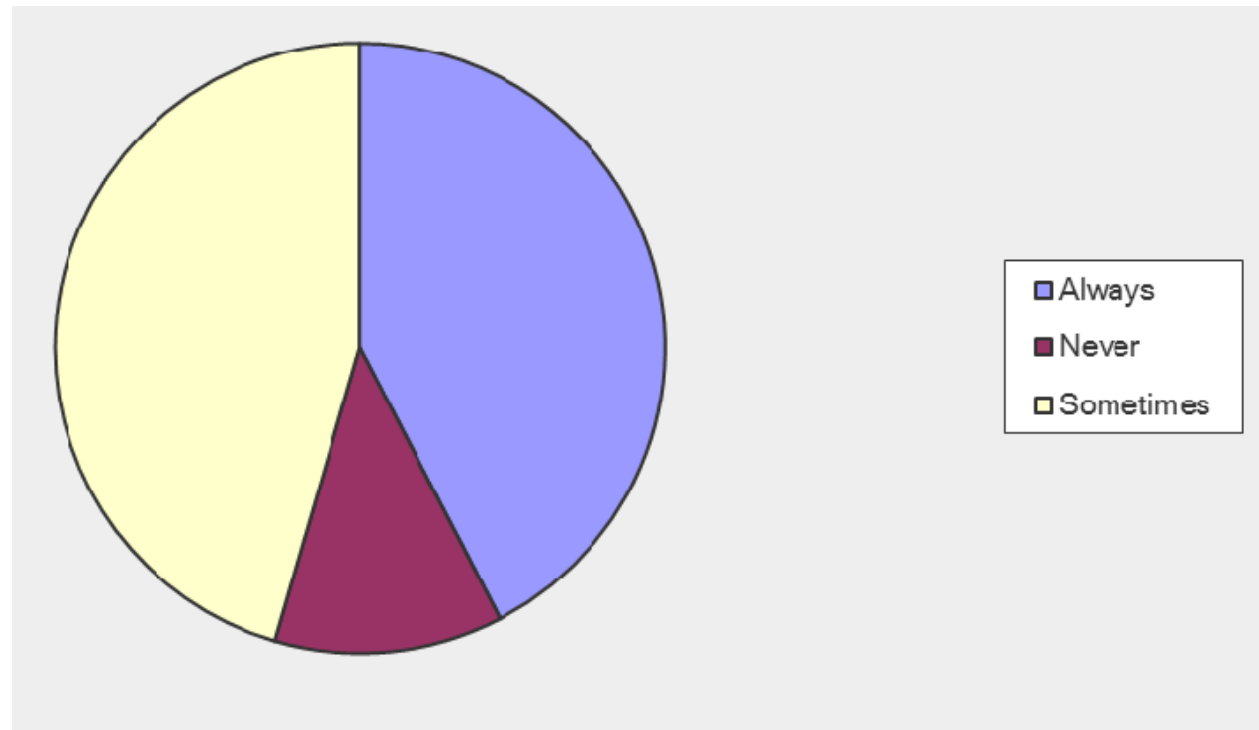
- 21 responders: 11 from Pharma, 10 from CRO

# USE AND PREPARATION OF DATA TRANSFER AGREEMENTS



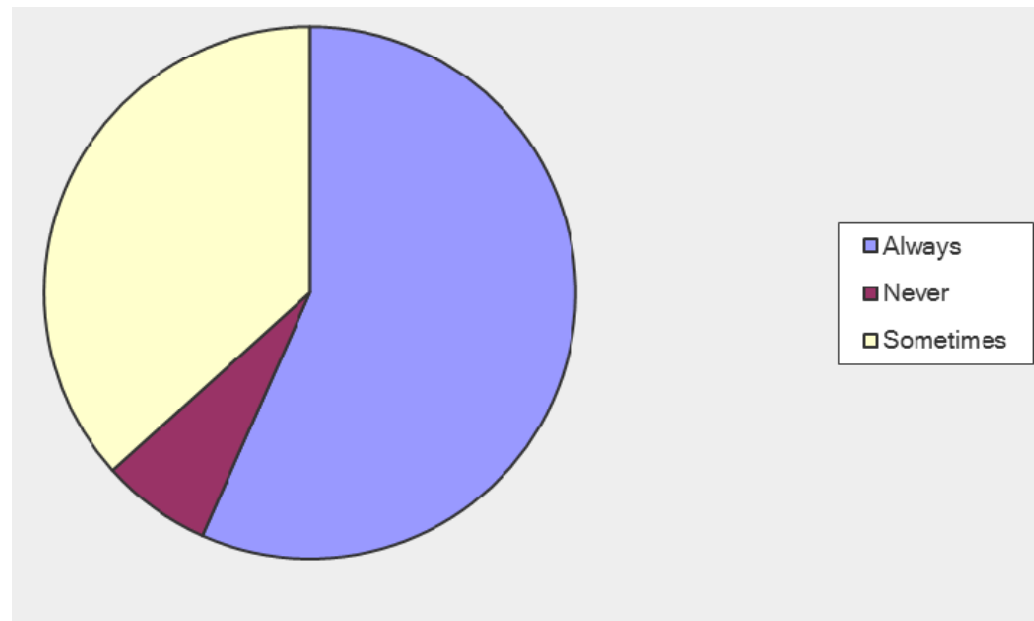
# Bioanalysts: Are you provided with a document describing the data transfer before trial start?

Always 14  
Never 4  
Sometimes 15  
Skipped 6



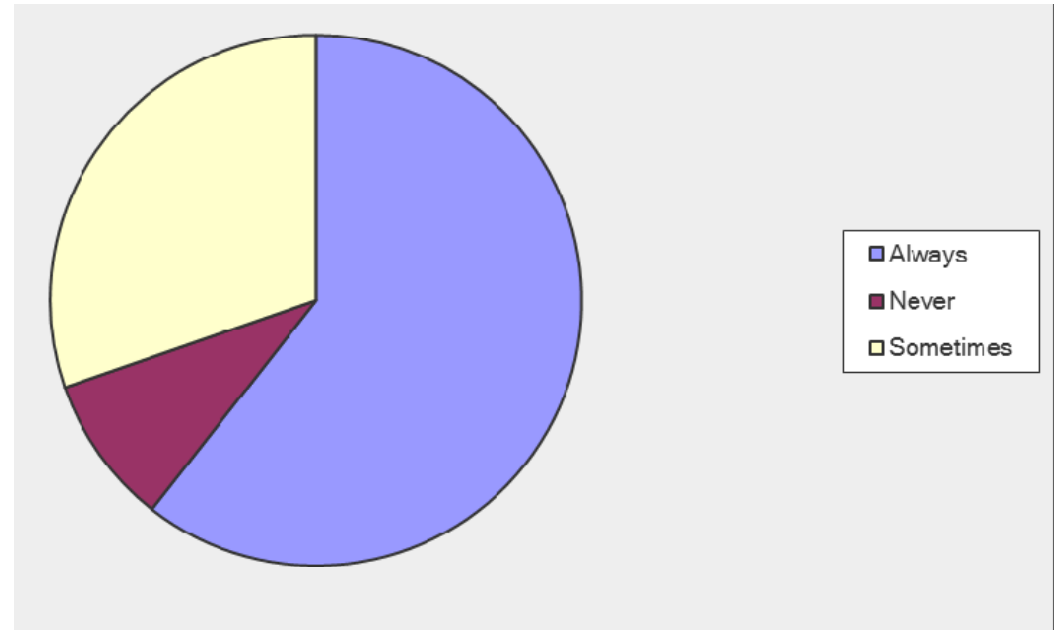
# Bioanalysts: Do you use a formal data transfer agreement?

Always 17  
Never 2  
Sometimes 11  
Skipped 9



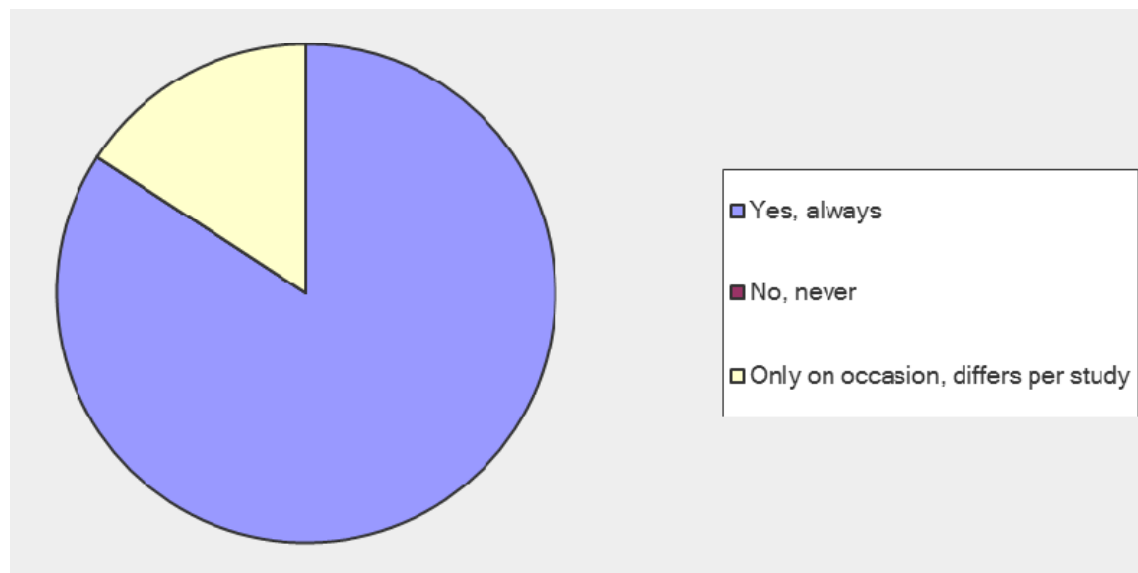
# Bioanalysts: Are you given the opportunity to give input to this document?

Always 20  
Never 3  
Sometimes 10  
Skipped 6



# Data managers: Do you use data transfer agreements/documents (either own template or sponsor template) ?

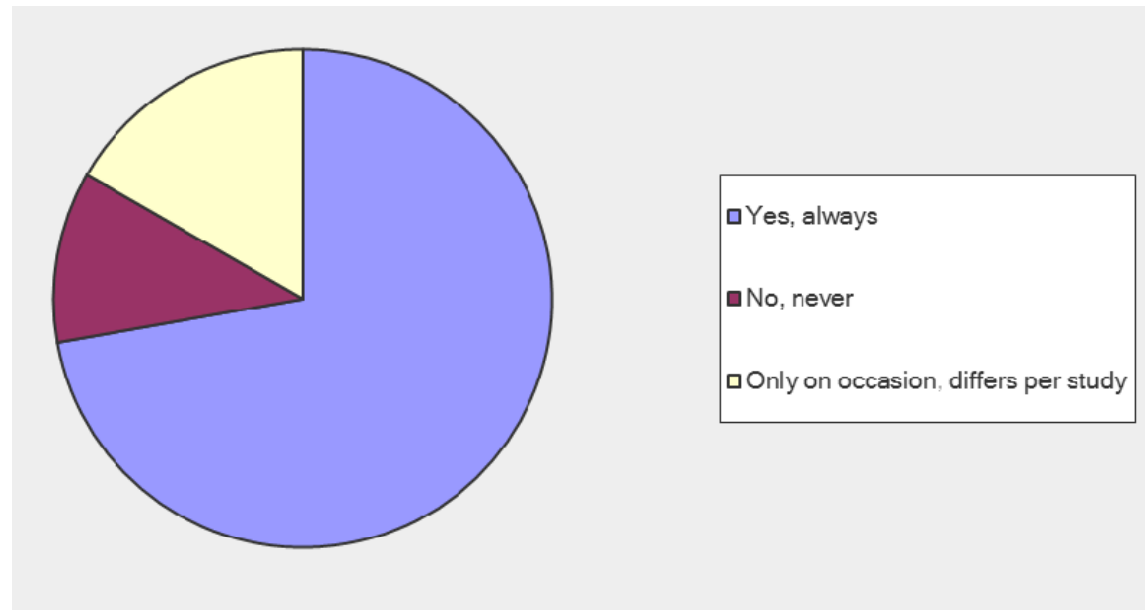
Yes, always 16  
No, never 0  
Only on occasion 3



84% of the data managers responded that they prepare the data transfer agreement.

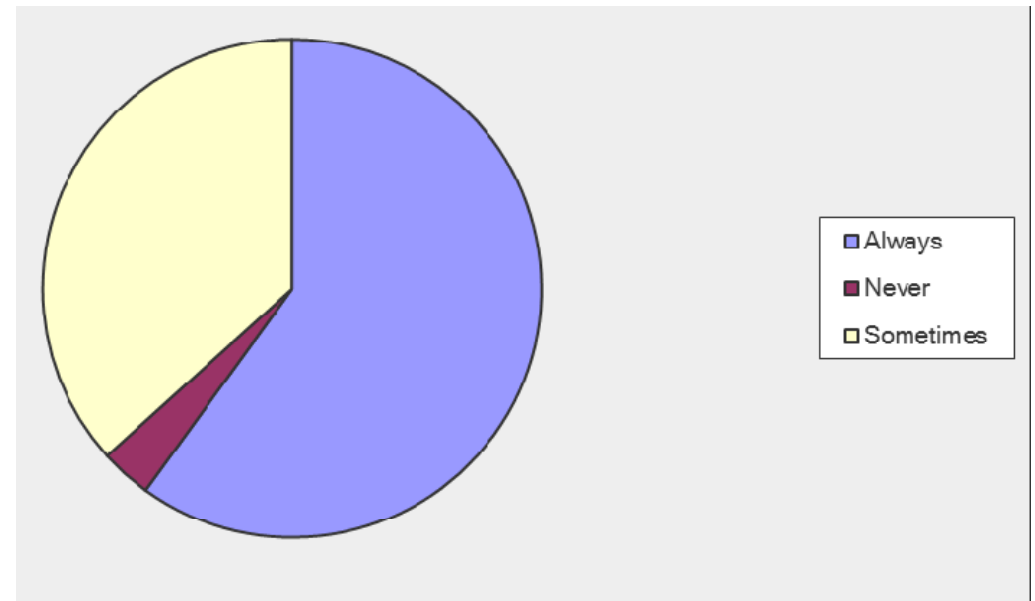
# Data managers: Do you as the data manager allow bioanalysts to give input to or review the data transfer agreement/document?

Always 13  
Never 2  
Sometimes 3



# Bioanalysts: In case of changes to the data transfer agreement/document during analysis, are you made aware of these changes?

Always 18  
Never 1  
Sometimes 11  
Skipped 9



# USE AND PREPARATION OF DATA TRANSFER AGREEMENTS - SUMMARY

Bioanalysts	yes		Data managers	yes
Provided with specs in time?	36%		Use specs?	84%
Transfer agreement in place?	44%		Let review?	72%
Input possible?	51%			
Made aware of changes?	46%			

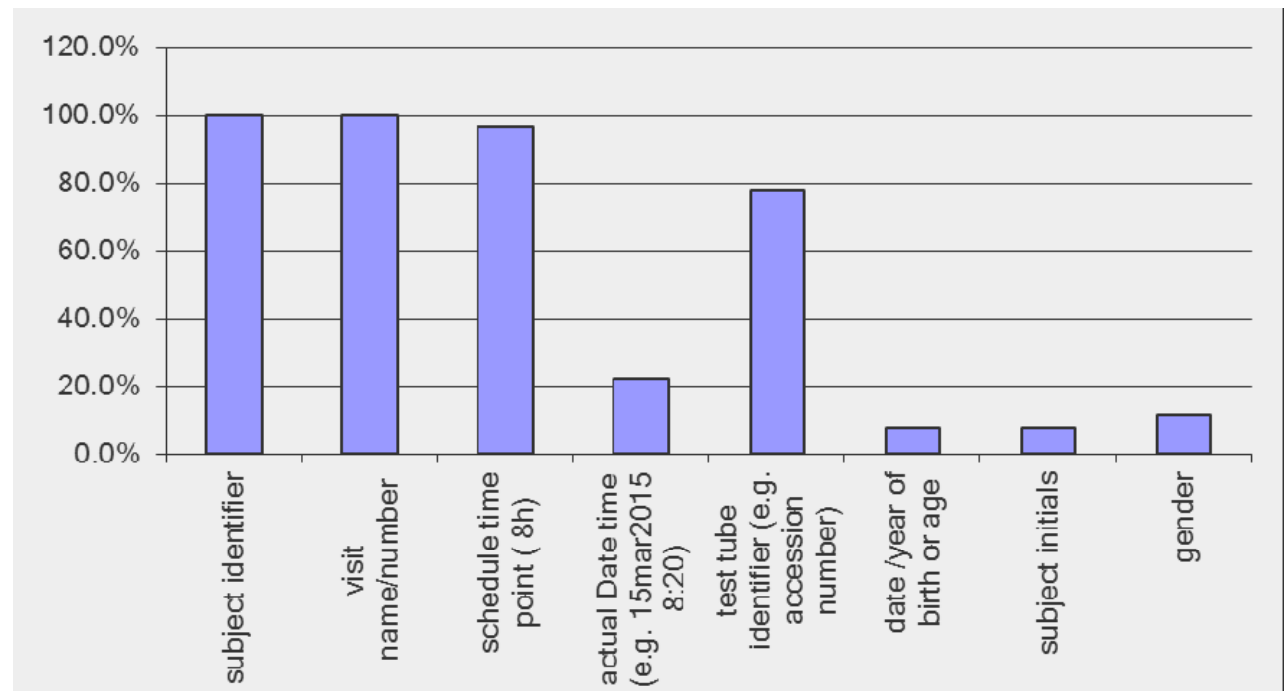
# WHAT ARE WE REPORTING?



# Bioanalysts: What metadata are you typically requested to report along with the concentration data, multiple options possible:

- Subject identifier
- Visit name/number
- Scheduled time point
- Actual Date/Time

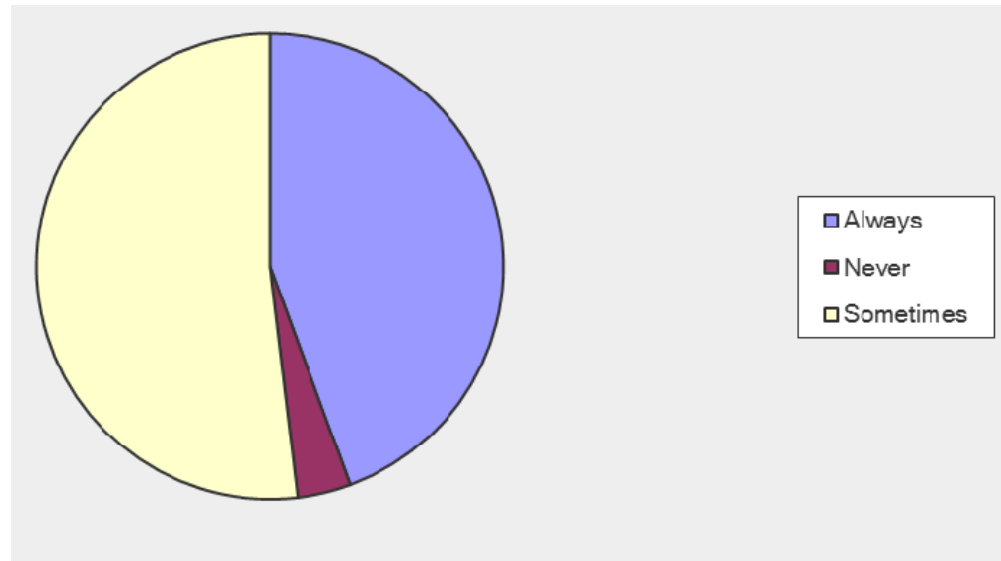
**Similar answers received from data managers**



# RECONCILIATION

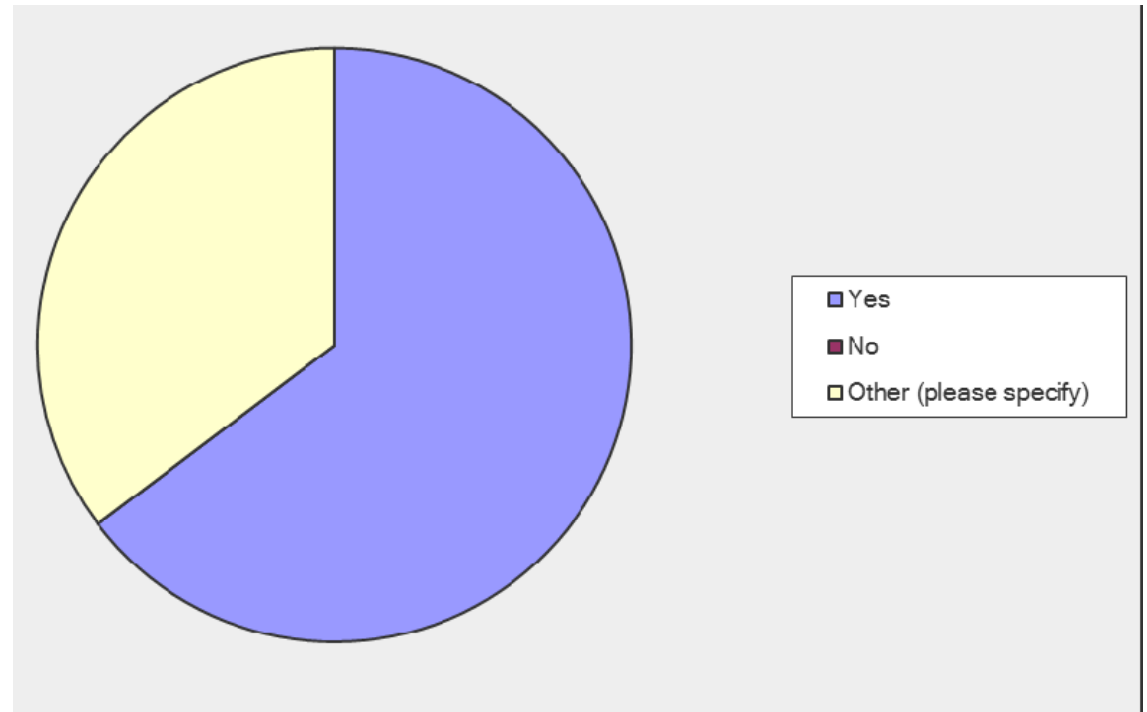
Bioanalysts: Are you requested to provide dummy transfers to check for accuracy of the metadata (data reconciliation) or formats of the files before reporting the final concentrations?

Always 12  
Never 1  
Sometimes 14

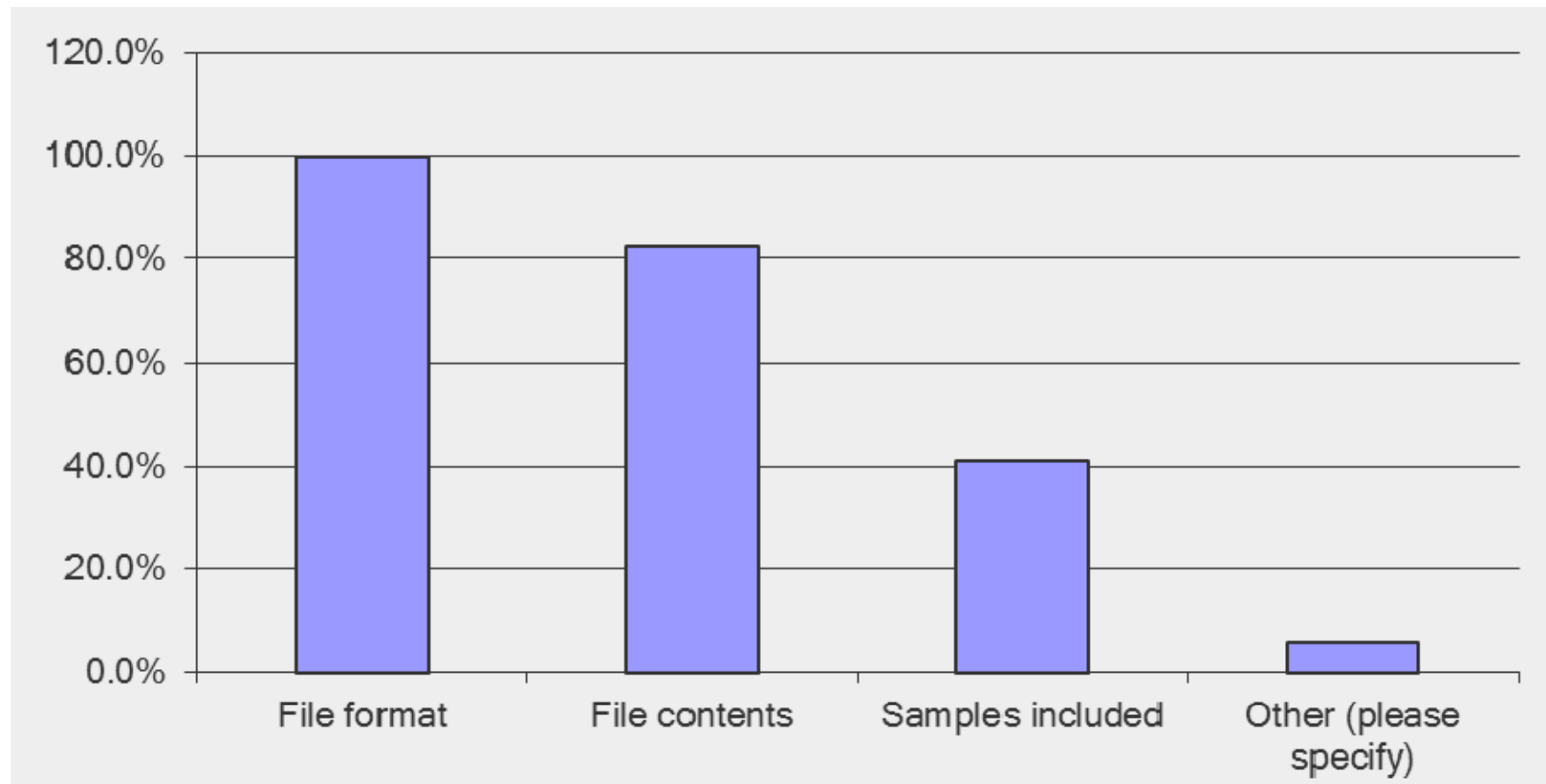


# Data Managers: Do you request a test transfer containing dummy data?

Yes 11  
No 0  
Skipped 2  
Other 6 (depends on Study, timelines etc)

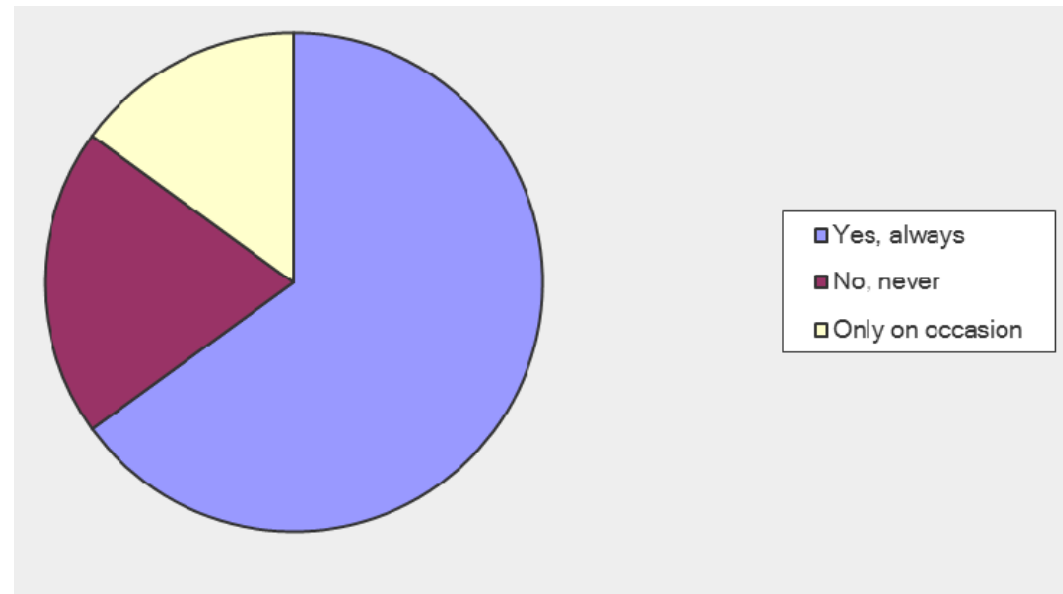


# Data Managers: What are you checking in the test transfer containing dummy data? (multiple answers possible)

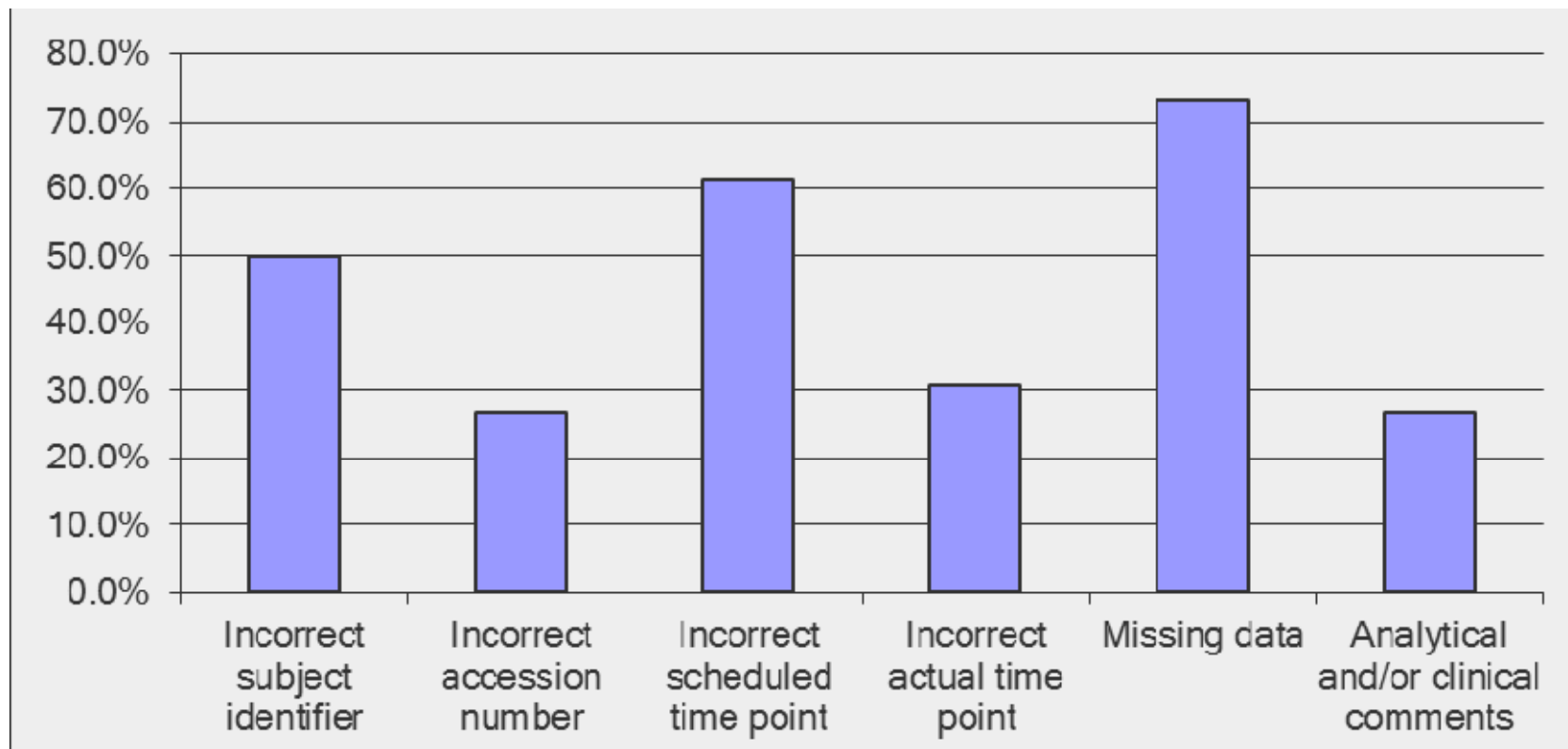


# Data Managers: Do you perform or have experience with reconciliation of bioanalytical data during a study?

Always 13  
Never 4  
Sometimes 3

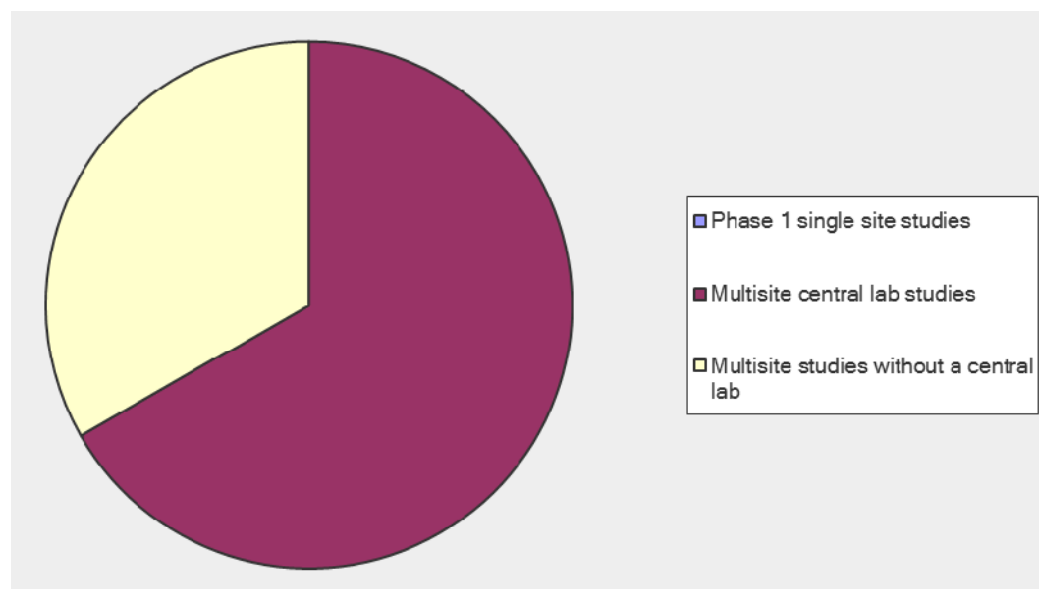


# Bioanalysts: What are the most common issues encountered during data reconciliation? Please choose the three most common issues



# Bioanalysts: Do you observe a clear link between the number of issues in data reconciliation and the study type?

- Yes (63%) versus No (37%)
- In case of Yes, most issues are with multi-center clinical trials with central lab (67%) or without central lab (33%)

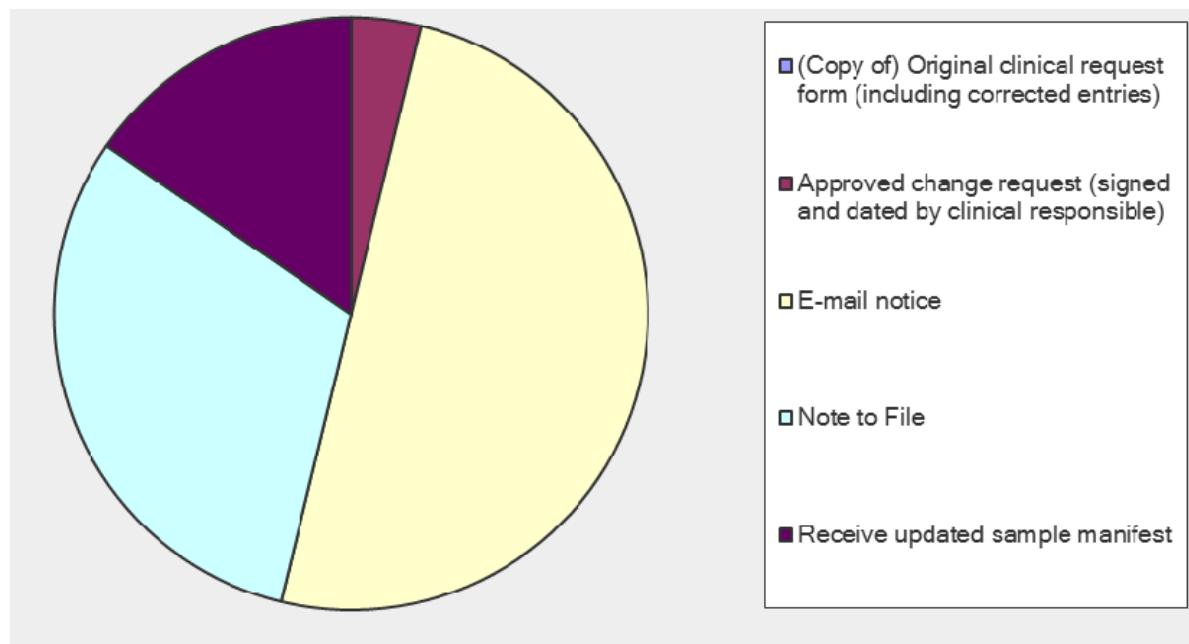




# CHANGES TO DATA

# Bioanalysts: How do you document any requested changes to the data?

Corrected CRF 0  
Approved change request 1  
E-mail notice 13  
Note to File 8  
Updated sample manifest 4  
Other 1 (depends)



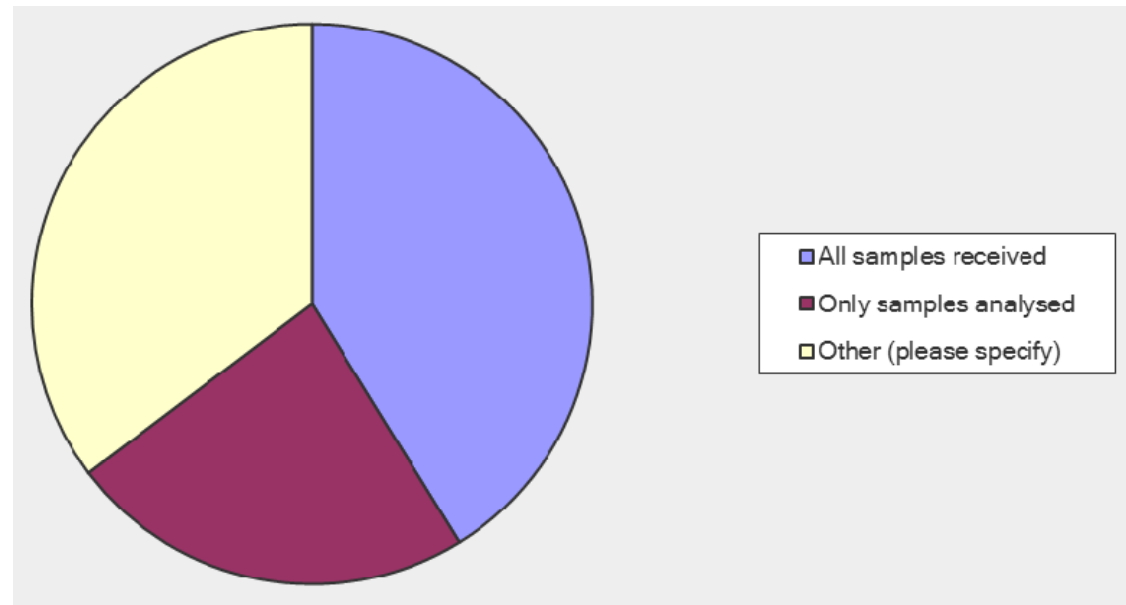
# GENERIC DATA TRANSFER AGREEMENT

# Bioanalysts: What would be the minimal criteria for a generic DTA?

- Timelines
- Who should receive the data
- How to transfer the data
- File format
- Column headers
- Contents of the columns
- Which samples should be reported
- Any abbreviations to be used
- Blinded/Unblinded
- Sign off Vendor and receiver

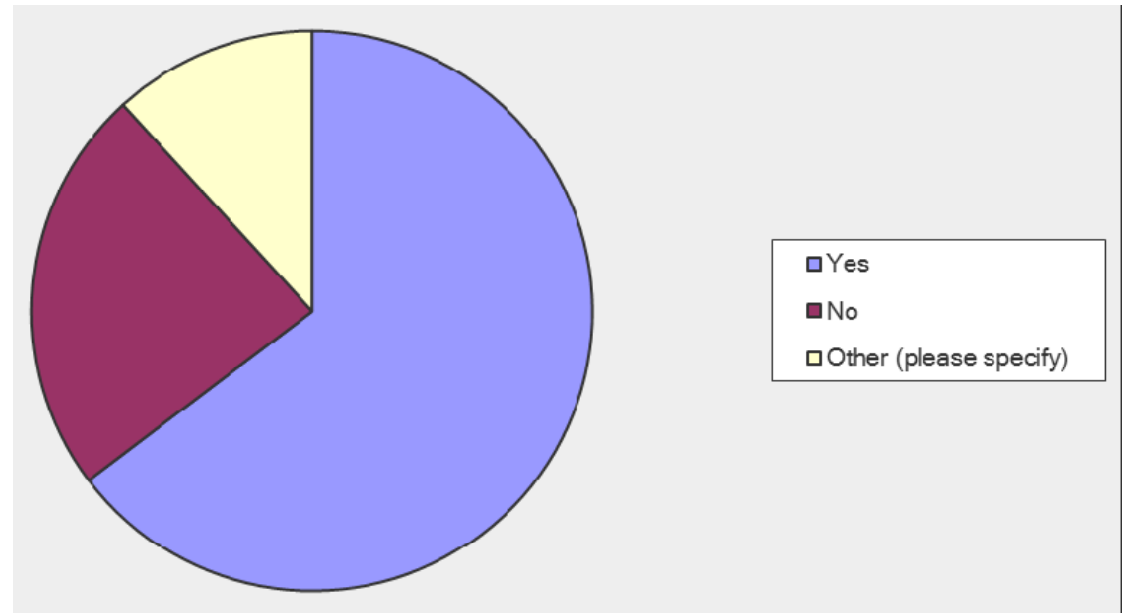
# Data Managers: Do you clearly state what samples should be reported in the DTA/document?

All samples received 7  
Only samples analyzed 4  
Other 6 (depends on study (design))



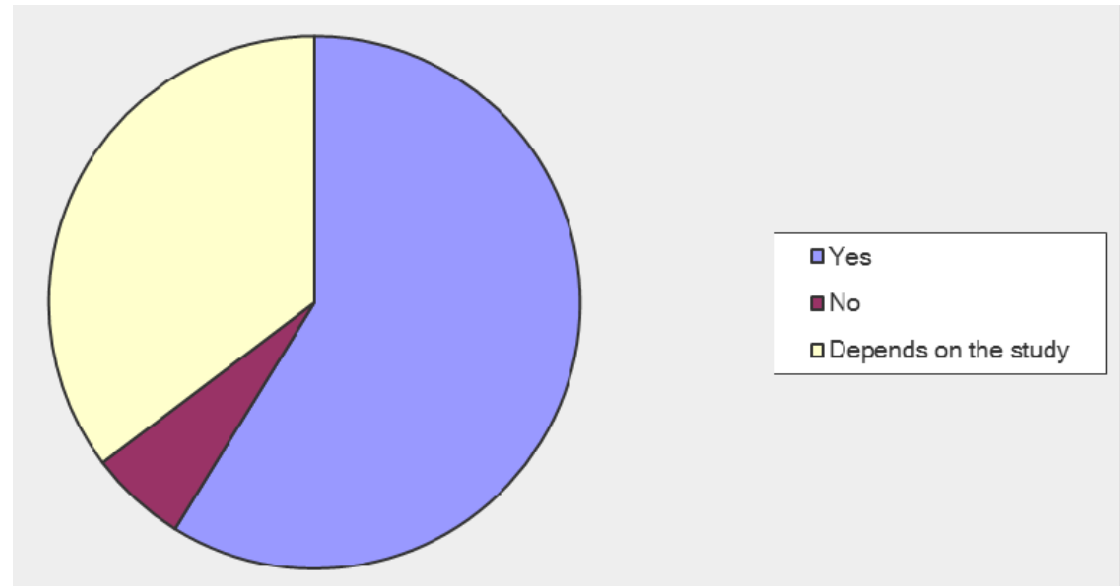
# Data Managers: Are the number and types of transfers clearly stated in the DTA/document e.g. QC or QA, reconciliation, blinded, unblinded?

Yes 11  
No 4  
Skipped 4  
Other 2 (described  
in other documents)



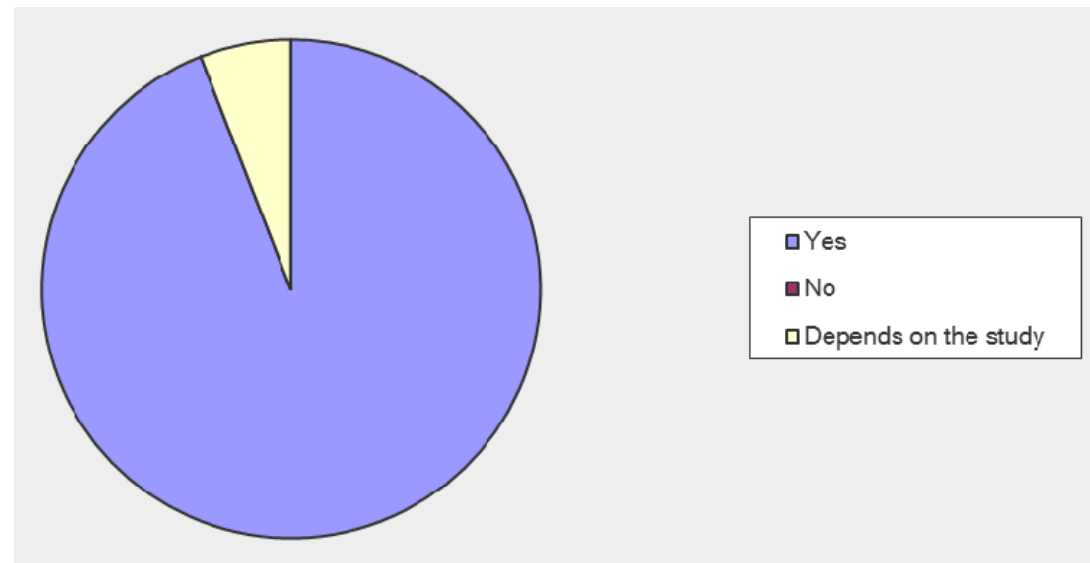
# Data Managers: Are data transfer timelines clearly stated in the DTA/document?

Yes 10  
No 1  
Depends on study 6  
Skipped 4



# Data Managers: Are the data file recipients clearly stated in the Data Transfer Agreement (DTA)/document?

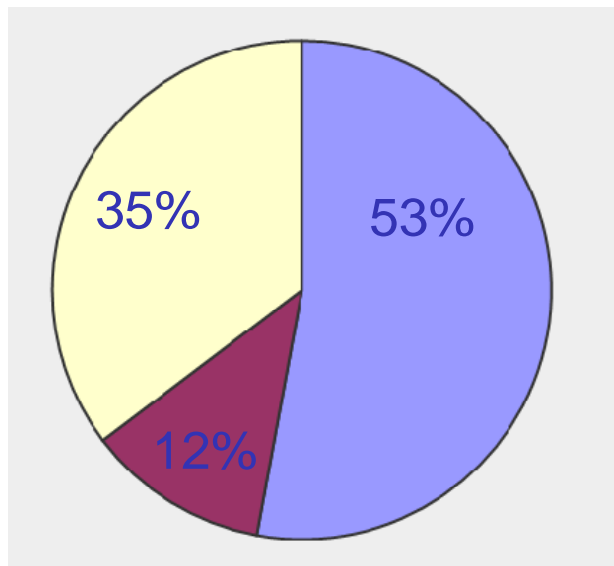
Yes 16  
No 0  
Depends on study 1  
Skipped 4



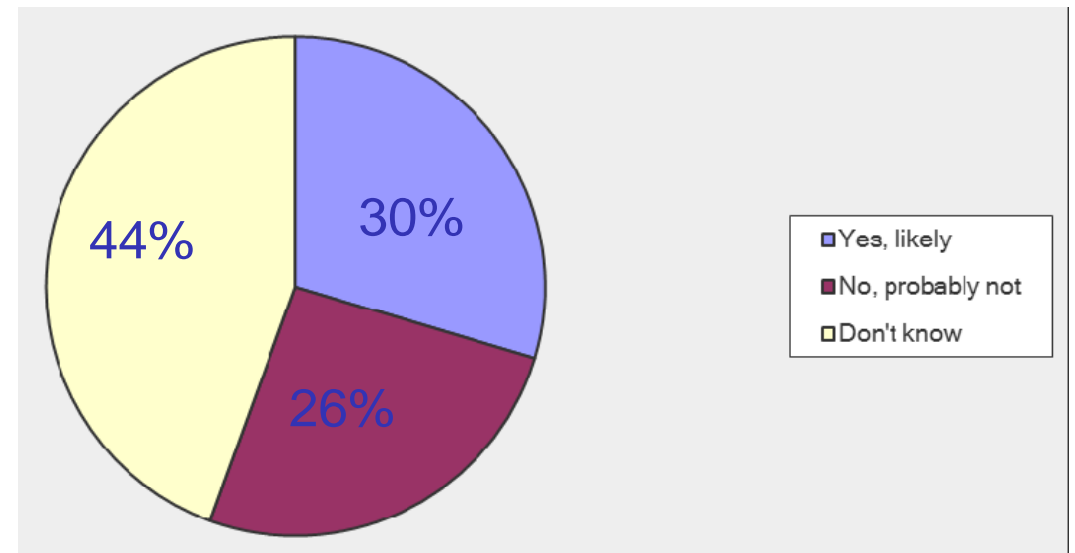


# Would your company implement a generic data transfer agreement/document?

Data managers



Bioanalysts



# Conclusions

- Many questions are answered with a clear 'yes' from only 1/3 to 2/3 of responders => currently no harmonized procedure in place at all
- (the most harmonized was: DMs use spec's and have a review process)
- Perspectives of BA's and DM's differ – overall, DM's picture seems to be more harmonized, BA's more critical/variable
- Only approx. 50% of bioanalysts have input to spec's, spec's in place, made aware of changes => *50% of data reported non-specified/incorrect!*

# Conclusions

- Information does not always end up at the bioanalyst
- Information does not always end up in time at the bioanalyst (e.g. before set up and definition of samples in database(s))
- Not all information required/desired by the bioanalyst is available in data transfer agreements
- Seems like a lot of study-dependent variables are present, whereas these could probably be standardized?
- Support from bioanalysts and data managers for a generic data transfer agreement

# Acknowledgements

- TT-12:
  - Bernd Matthes
  - Carine Ekstrom
  - Carolyn Mailer
  - Melloney Droge
  - Rebecca Sleigh
  - Rene Megens
  - Richard Abbott
  - Tom Verhaeghe
  - Philip Timmerman
- All participants in the two surveys!

# Discussion

- Are you prepared to use a generic data transfer agreement?
- What should it contain?
- What are the most common problems that you encounter on a daily basis regarding data transfer?
- ...