EBF

16th Open Symposium

Science Winning the Race

GCP

Tsvetelina Ivanova, on behalf of the EBF

15-17 November 2023, Barcelona

On the start

ICF communication flow - internal formation lap

ICF drafted (MW Scientific Operations)

Protocol (MW Scientific Operations)

Analytical Plan drafted (BioA)

ClinOps/Outsourcing Manager – review the documents and ensure that the fate of the samples (analysis used and retention period) are aligned between the two documents and the study protocol. They need also to provide the study protocol to BioA team

ICF communication flow - internal formation lap

Site 1, Country 1

Information about ICF withdrawal

Information about ICF version to be used

Site 2, Country 2

ClinOps (Sponsor/CRO)

Outsourcing Manager

Information about
- ICF withdrawal and instructions how to handle the data

BioA Lab

Or…ICF communication flow - internal formation lap

Site 1, Country 1

Information about ICF withdrawal

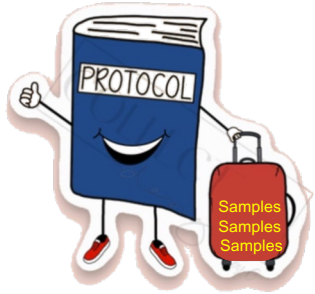
Information about ICF version to be used

Site 2, Country 2

ClinOps (Sponsor/CRO)

Outsourcing Manager

Information about
- ICF withdrawal and instructions how to handle the data



BioA Lab

Or…they deal with it and when the samples arrive in BA, the BA lab is not involved on ICF. The fact that samples arrive in BA = ICF is OK
And during of post analsys withdrawal is handles again in ClinOps

Full speed to the community

A short survey was sent to the EBF core community aiming to:

- Recalibrate internal discussions
- understand the community challenges better

THE SURVEY

Definitions to be considered:
"Clinical Operations" – Clinical site management team

Question 1: I am
- → CRO
- → Pharma

Question 2: For samples analysis from GCP studies do you have documented responsibilities for information alignment with regards to the samples fate between Analytical plan, protocol and ICF:
- → Yes, please specify where:
  - → Internal policy/procedure
  - → Analytical Plan/Communication plan/Analytical Communication Plan
  - → Other, please specify:
- → No

Question 3: Who has the responsibility for information alignment with regards to the samples fate between Analytical plan, protocol and ICF:
- → Clinical Operations
- → Clinical Outsourcing Manager
- → The responsible BA scientist
- → Other, please specify:

Question 4: Who has the responsibility to provide BioA team with information about ICF withdrawal and instructions how to handle the data:
- → Clinical Operations
- → Clinical Outsourcing Manager
- → The responsible BA scientist
- → Other, please specify:

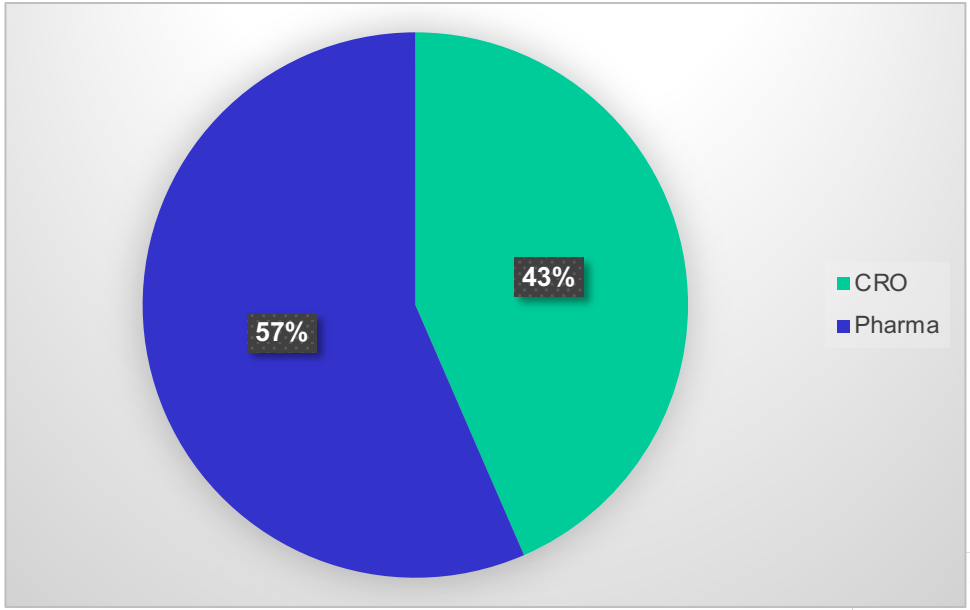
Question 5: Is the responsibility to provide BioA team with information about ICF withdrawal and instructions on how to handle the data documented?
- → Yes, please specify where:
  - → Analytical Plan/Communication plan/Analytical Communication Plan
  - → Policy/procedure
  - → Other, please specify:
- → No

Question 6: What are the main challenges to obtain information about ICF withdrawal and instructions on how to handle the data?
- → Stakeholders not aware about their responsibilities with this regard
- → Timelines are not respected.
- → Lack of defined process
- → Other, please specify:

Participants

23 companies responded to the survey:

- 10 CRO
- 13 Pharma



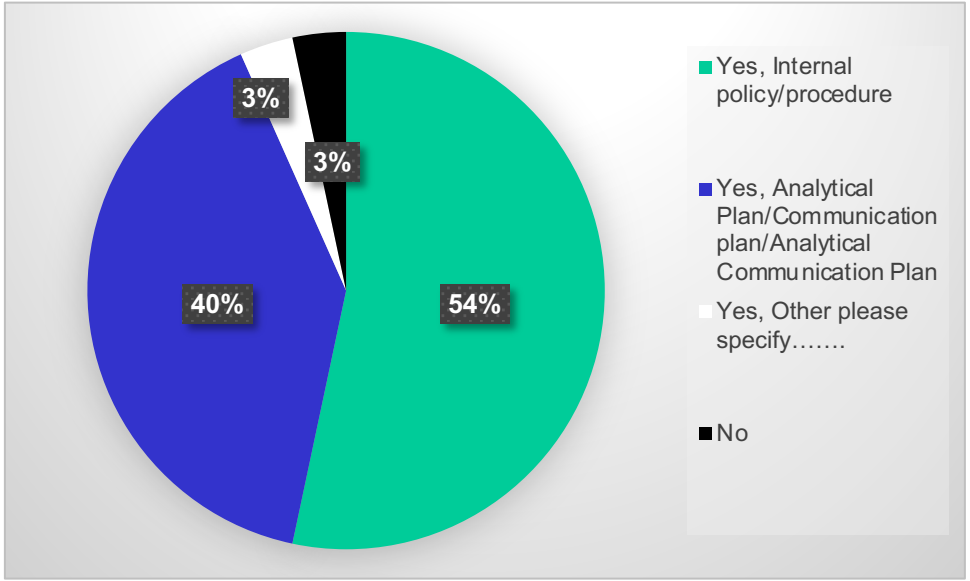
On the road – corner 2

Q2 For samples analysis from GCP studies do you have documented responsibilities for information alignment with regards to the samples fate between Analytical plan, protocol and ICF?

- Yes, please specify where:
  - ✓ Internal policy/procedure
  - ✓ Analytical Plan/Communication plan/Analytical Communication Pla
  - ✓ Other, please specify
- No

Others:

- additional documentation for the fate of samples



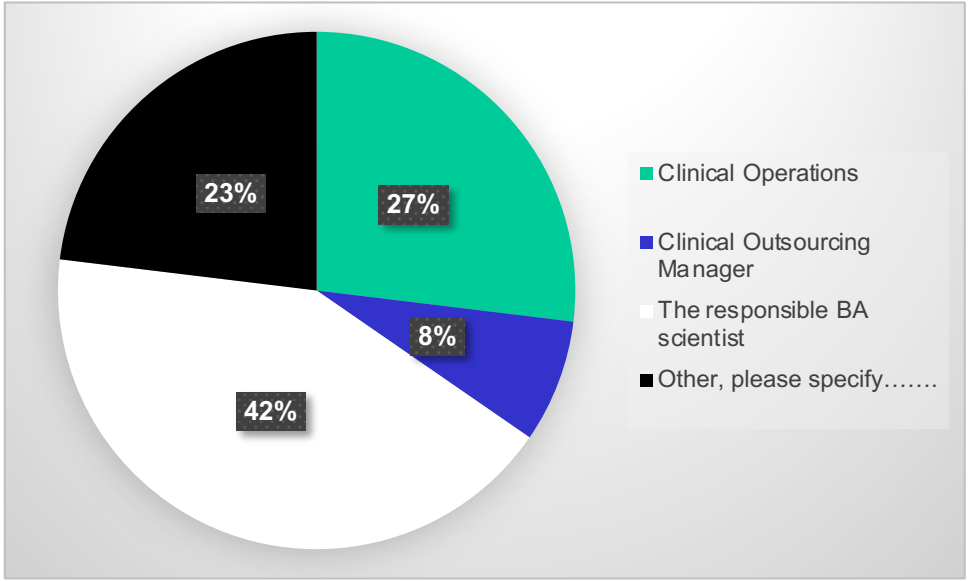
On the road – corner 3

Q3 Who has the responsibility for information alignment with regards to the samples fate between Analytical plan, protocol and ICF?

- Clinical Operations
- Clinical Outsourcing Manager
- The responsible BA scientist
- Other, please specify:

Others:

- Client/Sponsor
- BA Outsourcing Manager
- PM/PI



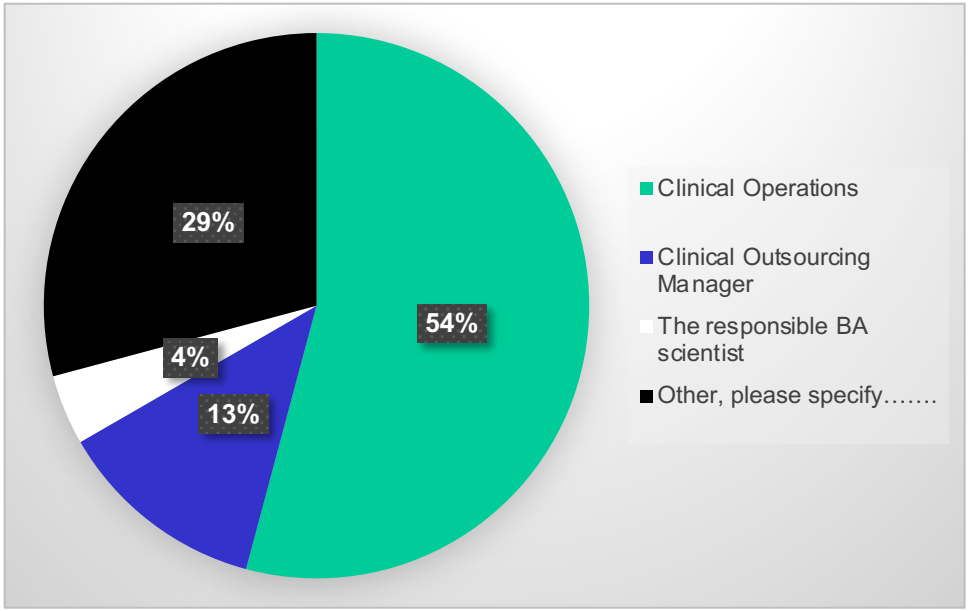
On the road – corner 4

Q4 Who has the responsibility to provide BioA team with information about ICF withdrawal and instructions how to handle the data?

- Clinical Operations
- Clinical Outsourcing Manager
- The responsible BA scientist
- Other, please specify

Others:

- Client/Sponsor
- BA Operations Manager
- No need to be specified



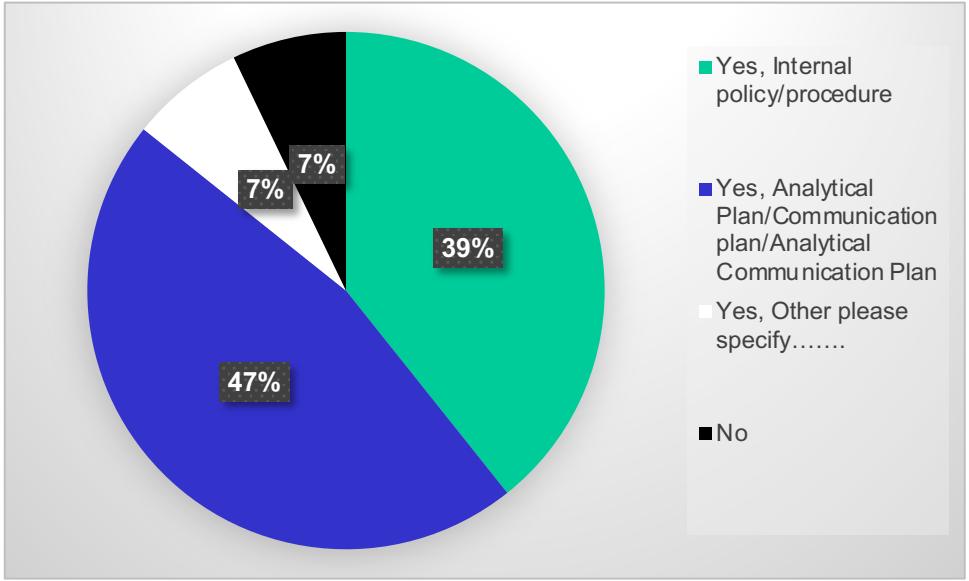
On the road – corner 5

Q5 Is the responsibility to provide BioA team with information about ICF withdrawal and instructions on how to handle the data documented?

- Yes, please specify where:
  - ✓ Internal policy/procedure
  - ✓ Analytical Plan/Communication plan/Analytical Communication Plan
  - ✓ Other, please specify
- No

Others:

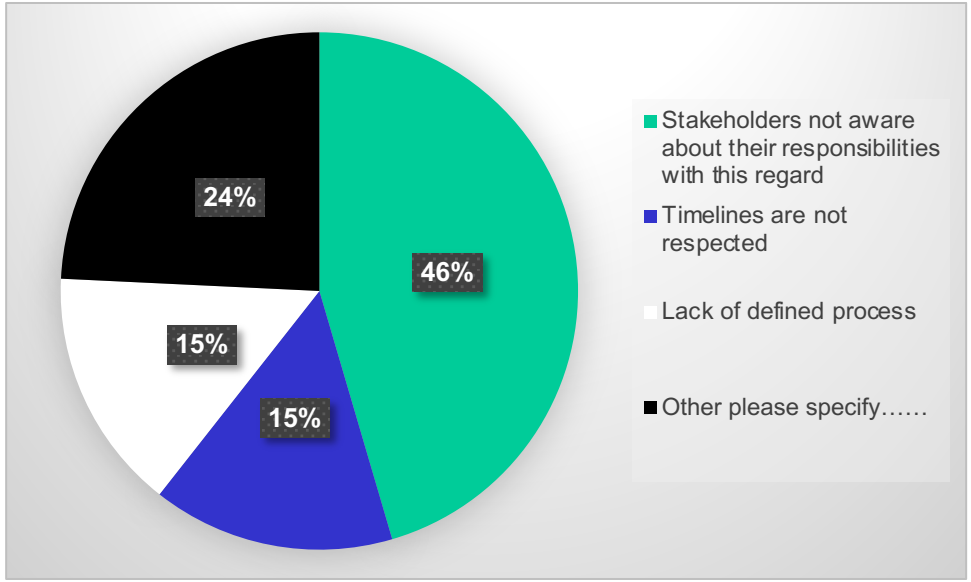
- ICF language
- Not need to be specified



On the road – corner 6

Q6 What are the main challenges to obtain information about ICF withdrawal and instructions on how to handle the data?

- Stakeholders not aware about their responsibilities with this regard
- Timelines are not respected.
- Lack of defined process
- Other, please specify



And some more details

Others:

- Information about samples affected by withdrawn informed consent not always clear, which samples need to be discarded, which could still be measured.
- Immediate discard of samples often not possible, samples still in shipment process, not sorted, not registered in a Lims, discard of single samples high workload
- Even stakeholders are sometimes not or too late informed about withdrawal
- Lack of defined process in regards of data already provided with ICF withdrawal

Need for a chicane – discussion with the audience

1. Should the Bioanalyst have the responsibility for information alignment with regards to the samples fate between Analytical plan, protocol and ICF?
   - If yes, Why?
   - If yes, How?
   - If no, who should be responsible?

2. The main challenge in obtaining information about ICF withdrawal and instructions on how to handle the data is the stakeholders' awareness. Is this applicable for your organization?
   - If yes, why?
   - If not, what is the successful approach?

3. Will a generic BA section for ICF have added value?

4. Do you have recent inspection observations related to sample analysis and ICF status?

New Circuit for discussion – unexpected results

Unexpected results definitions (PK)

- what should be the definition *(Measurable concentration in placebo arm)*

Unexpected results reporting (PK)

- who needs to be informed (high level)
- when should the results be reported
- how should the investigation be triggered
- who needs to be informed about the final outcome

On the final stretch of this race

Outcome from the GCP II team discussion about expedited results:

For PK BioA activities expedited results reporting is not required/anticipated.

Fast results reporting is different from the “expedited” reporting and it is anticipated for FIH studies.

Acknowledgements

EBF GCP II Team
EBF Community
EBF Steering Committee

Contact Information

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