

18th EBF Open Symposium

**Tune in to Tomorrow
Science in High Definition**

GCP – Samples reconciliation

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Right message to the right people?

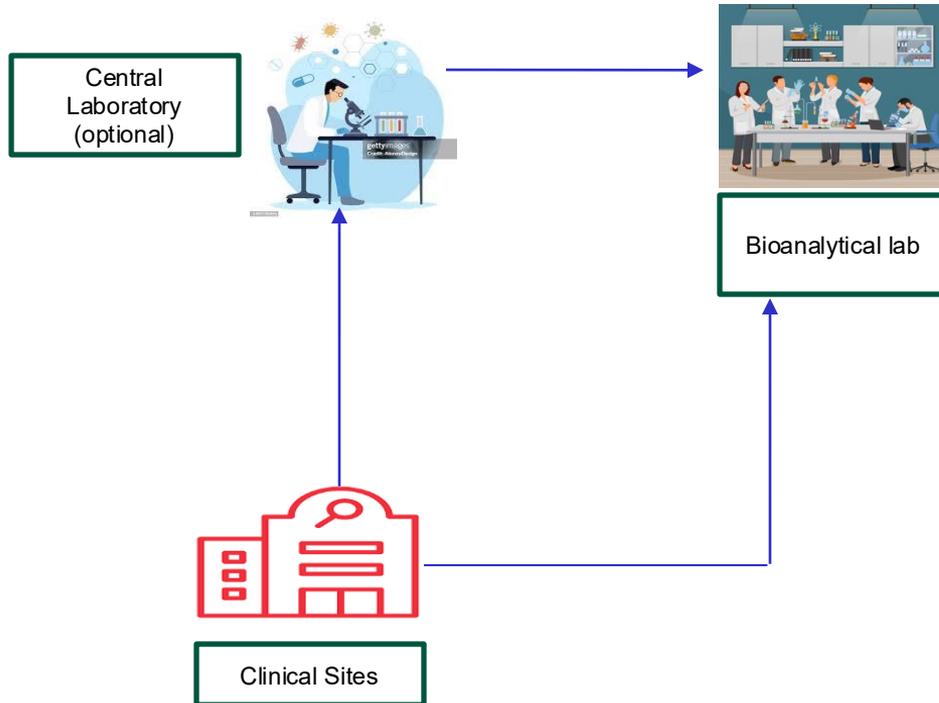
2025 – Samples reconciliation process:

- Samples reconciliation queries are not always directed to the information owner
- Samples reconciliation is usually performed after the samples have been received at the Bioanalytical lab
- Documentation for changes is not aligned.

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Act 1 - Proposed samples flow chart



Samples flow diagram with two scenarios:

Option 1:

- Samples sent from Clinical Site (s) to the Central Lab
- Then samples are sent from the Central Laboratory to the Bioanalytical sites.
- Samples to be “cleaned” before to be send to BioA. Samples which are not stored/processed as per required conditions in the Lab Manual should not shipped to BioA and put quarantine.

Option 2

- Samples are directly sent from the Clinical Sites to the Bioanalytical Laboratory

Documentation for samples shipment (both scenarios)

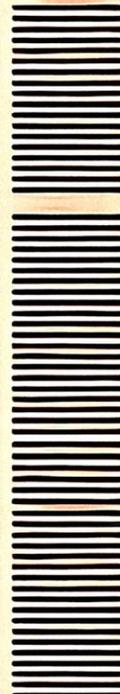
- Temperature records (from Central to BioA and from Clinical Sites to Central Lab) or information that the samples are shipped as per required conditions. This responsibility should be documented in advance.
- To have a shipper contact details in a dedicated form (e.g. Chain of Custody form)
- Sample manifest (electronically as well in advance to the shipment)

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Act 2 – Samples Manifest

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Item from SSM	Needed for BioA	Data ownership (provision of the data)	Comments
Study ID	Y	Central Lab/Clinical site/ (Definitely not BioA)	Protocol number
Analyte	Y	Central Lab/Clinical site (Definitely not BioA)	
Accession number	Y	Central lab (Definitely not BioA)	Sometimes with extensions (sampling at the same day)
Patient number	Y	Central Lab/Clinical site (Definitely not BioA)	
Visit description	Y	Central Lab/Clinical site (Definitely not BioA)	To be correlated with DTA. Generic kits (and labels) scenario to be considered
Barcode	Y	Central lab (Definitely not BioA)	To be linked to Accession number, if possible.



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Item from SSM	Needed for BioA	Data ownership (provision of the data)	Comments
Visit	Y	Central Lab/Clinical site (Definitely not BioA)	
Actual day	Y	Central Lab/Clinical site (Definitely not BioA)	Only for stability purposes, but not reconciliation purposes.
Actual time	Y	Central Lab/Clinical site (Definitely not BioA)	Not for reconciliation purposes.
Aliquot	Y	Central Lab/Clinical site (Definitely not BioA)	Aliquot from a site (to be clarified)
Condition (storage at the central lab and site)	Y	Central Lab/Clinical site (Definitely not BioA)	To be clarified in the samples manifest, what type of storage conditions should be listed here.



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Item from SSM	Needed for BioA	Data ownership (provision of the data)	Comments
Sample type	Y/N	Central Lab/Clinical site (Definitely not BioA)	Could be skipped only if analyte information is presented.
Box ID	Y/N	Central Lab/Clinical site (Definitely not BioA)	“ Yes” only for larger shipment and/or fast TAT
Box Position	Y/N	Central Lab/Clinical site (Definitely not BioA)	“ Yes” only for larger shipment and/or fast TAT



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Item from SSM	Needed for BioA	Data ownership (provision of the data)	Comments
Subject ID	Y/N	Central Lab/Clinical site (Definitely not BioA)	If it not the same to "Patient number". Otherwise, to be skipped
Day	Y/N	Central Lab/Clinical site (Definitely not BioA)	If relevant for study design (if visit description is not enough to differentiate the timepoint).
Cycle	Y/N	Central Lab/Clinical site (Definitely not BioA)	If relevant for study design
Status	Y/N	Central Lab/Clinical site (Definitely not BioA)	If used, there should be harmonization between the site and the lab how to complete this field (e.g. hemolysis evolution). Could not be used in cases hemolysis and lipemia not an issues for the analysis



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Item from SSM	Needed for BioA	Data ownership (provision of the data)	Comments
Period	Y/N	Central Lab/Clinical site (Definitely not BioA)	If relevant for study design (if visit description is not enough to differentiate the timepoint).
Step	Y/N	Central Lab/Clinical site (Definitely not BioA)	If relevant for study design (if visit description is not enough to differentiate the timepoint)
Cohort	Y/N	Central Lab/Clinical site (Definitely not BioA)	If relevant for study design (if visit description is not enough to differentiate the timepoint)
Nominal time	Y/N	Central Lab/Clinical site (Definitely not BioA)	If relevant for study design (if visit description is not enough to differentiate the timepoint)



Act 3 – Achieving clear picture (part 1)

- To define who is samples “owner” i.e. to introduce Biosamples responsible person as **a role (not necessary as a separate position)**
- Biosamples responsible person/”samples owner” responsibilities:
 - Liaison between Central Lab/DM/Clinical Site/BioA
 - Provide documentation in case of change in labelling (Note To file or Change Request/ Tracker of changes). This documentation to trigger an update in the samples manifest.
 - Support during samples reconciliation during samples receipt at BioA
 - Samples management plan preparation

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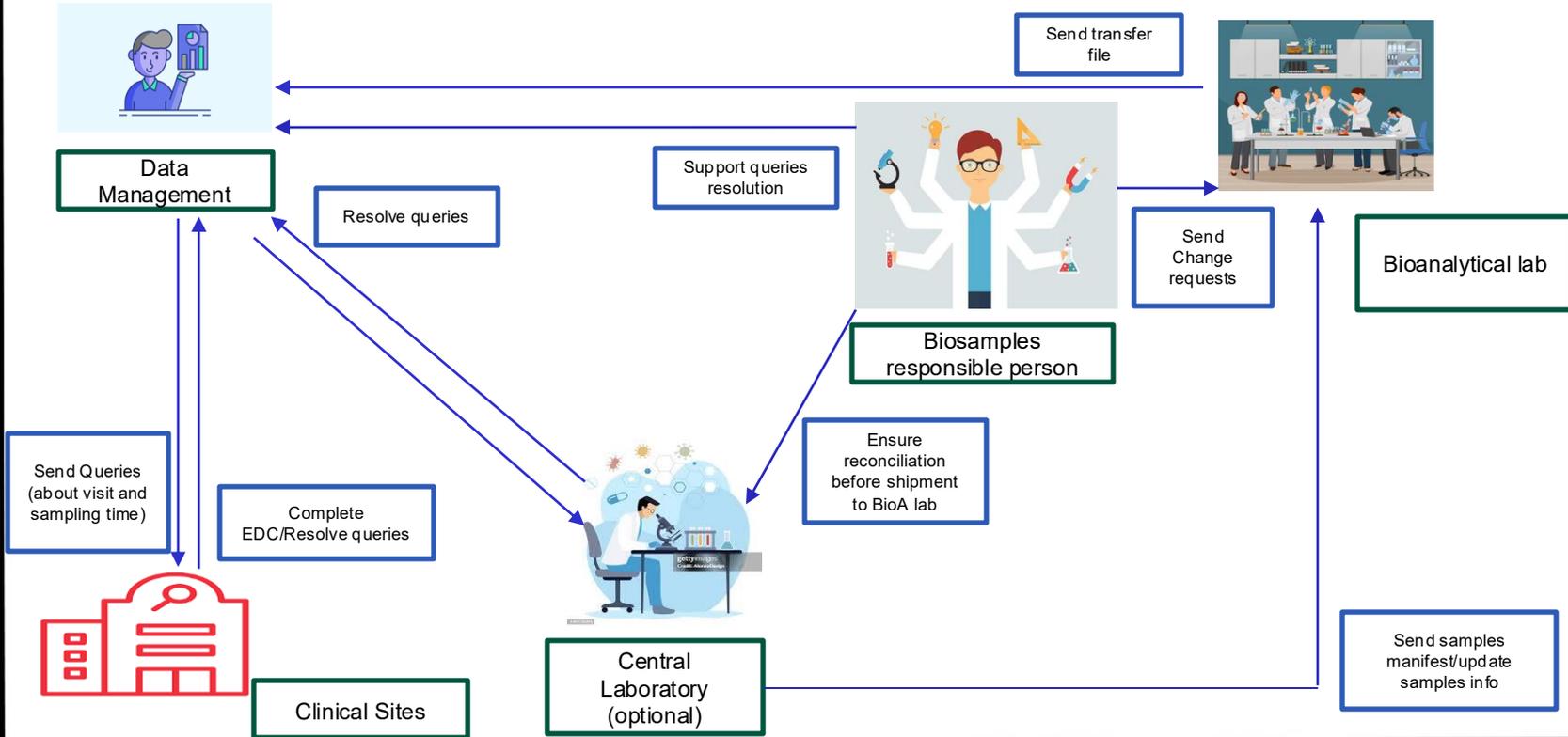


Act 3 – Achieving clear picture (part 2)

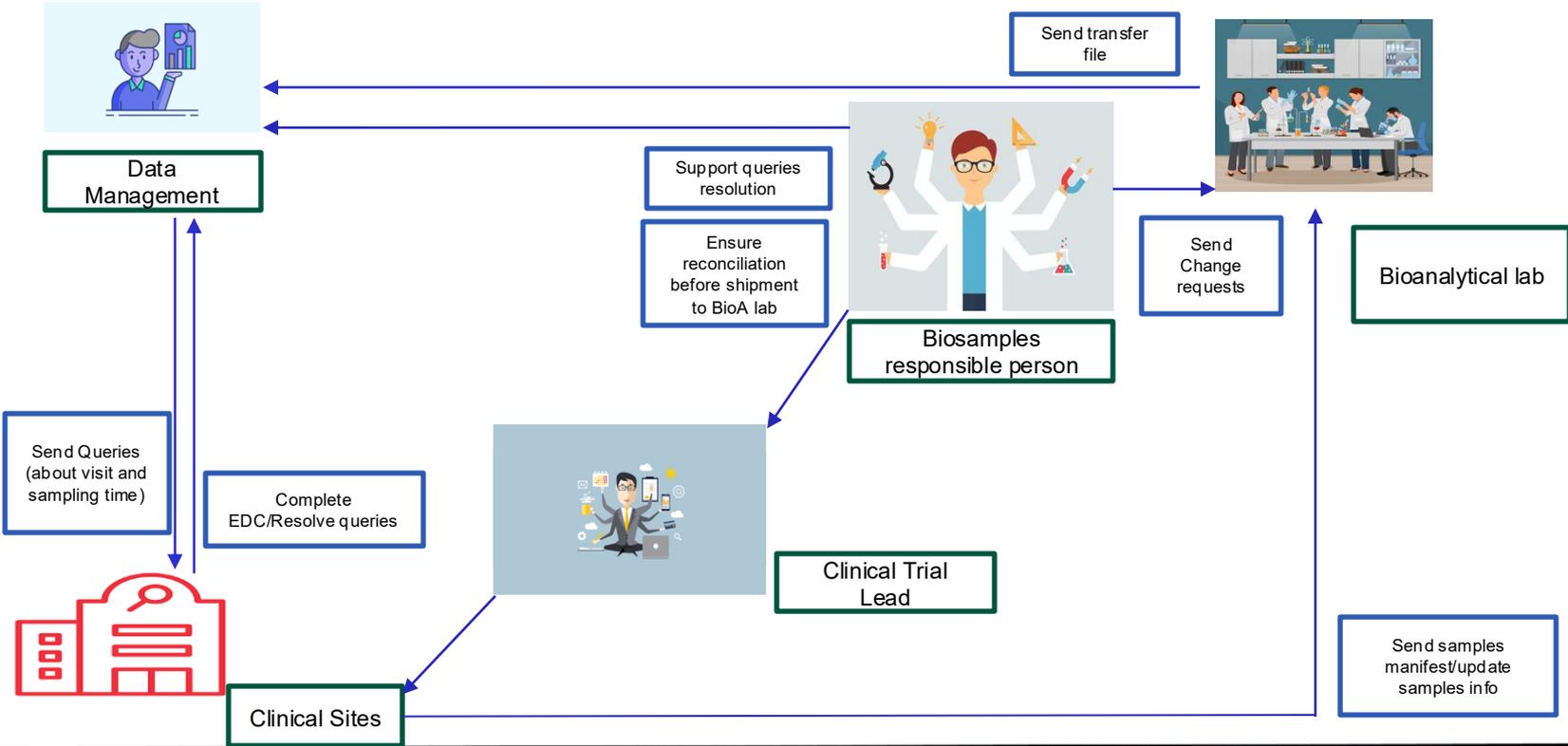
- Preliminary reconciliation to be introduced before samples to be received at BioA.
- To have communication plan with all contact details and describe the reconciliation process.
- Engagement of all stakeholder (Central, DM and Stat) in the beginning of the study.
- To identify the samples in a same manner preferably with “barcode” by central and special lab
- BioA Lab responsibility is to connect to the barcode/label to results and not owning the metadata received
- Note to File to keep the changes in the contact list (e.g. Project Manager)



Act 4 – picture in high resolution (part 1)



Act 4 – picture in high resolution (part 2)



Acknowledgement

- EBF Samples Reconciliation Team
- EBF Community

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