



How Quality Biobanking Starts During a Clinical Trial

Caoimhe Vallely-Gilroy
Head of Clinical Trial Biosample Management and Informed
Consent

Porto, February 2019



MERCK

Session overview

1

The function of Clinical Trial Biosample Management at Merck

2

How clinical trial design and operations can lead to high quality biosamples

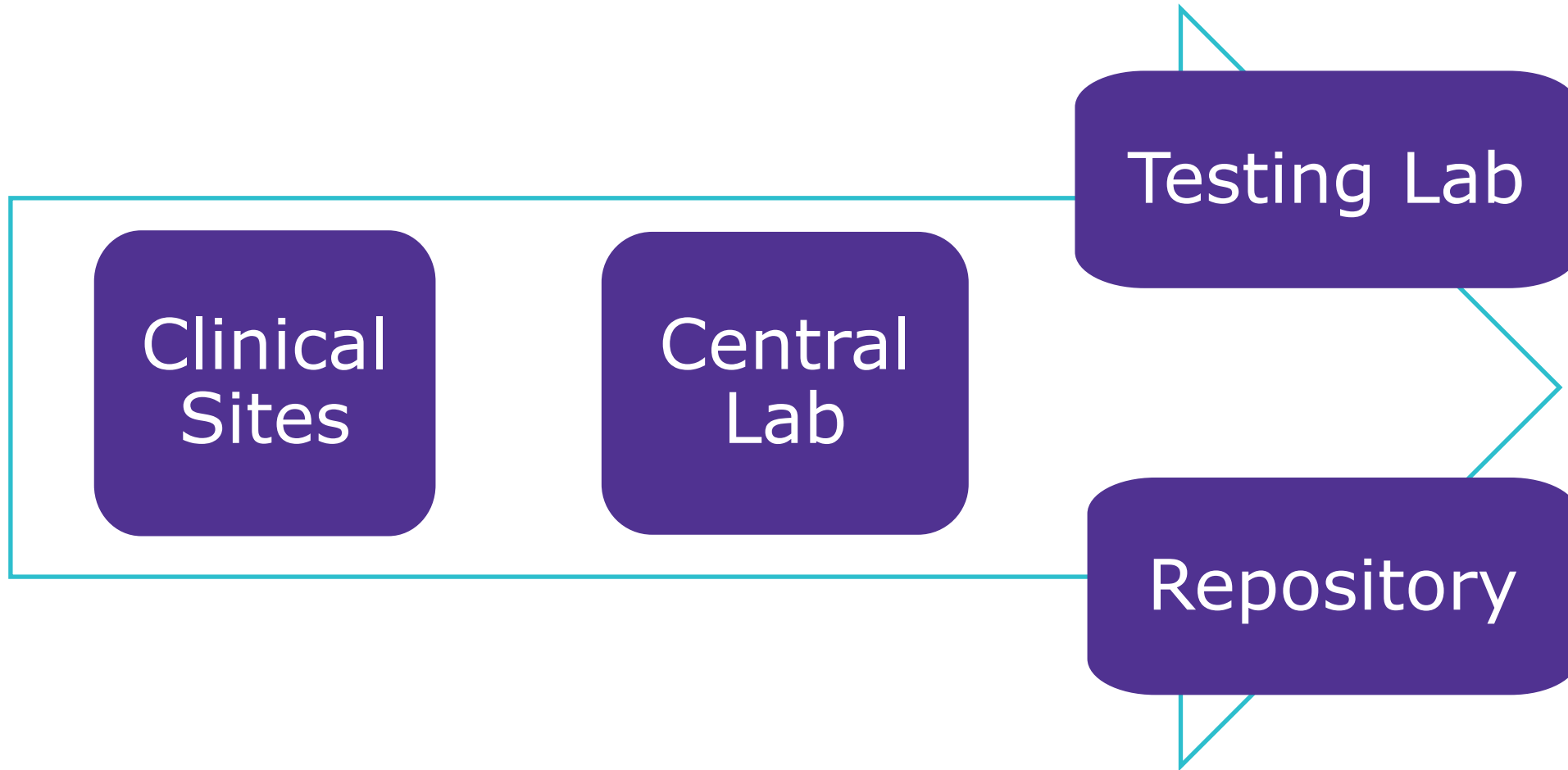
3

Opportunities for improvement

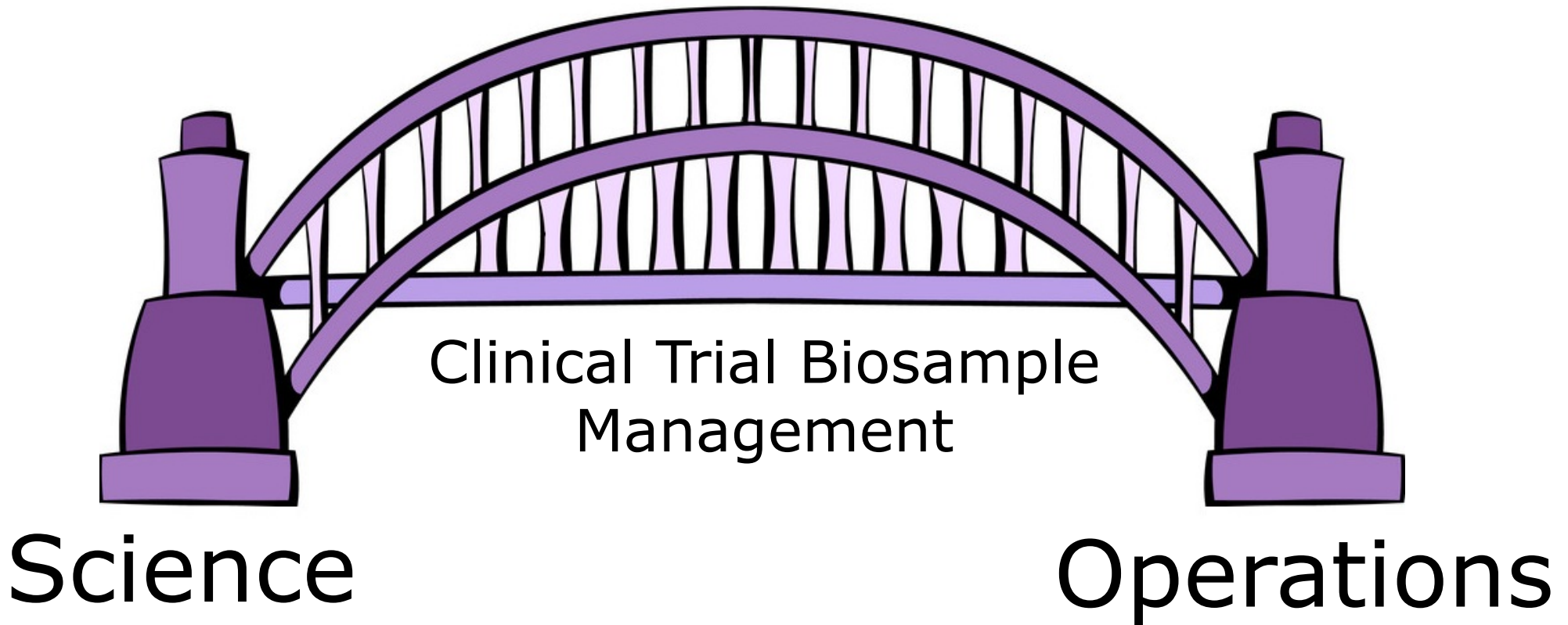
4

Key Messages

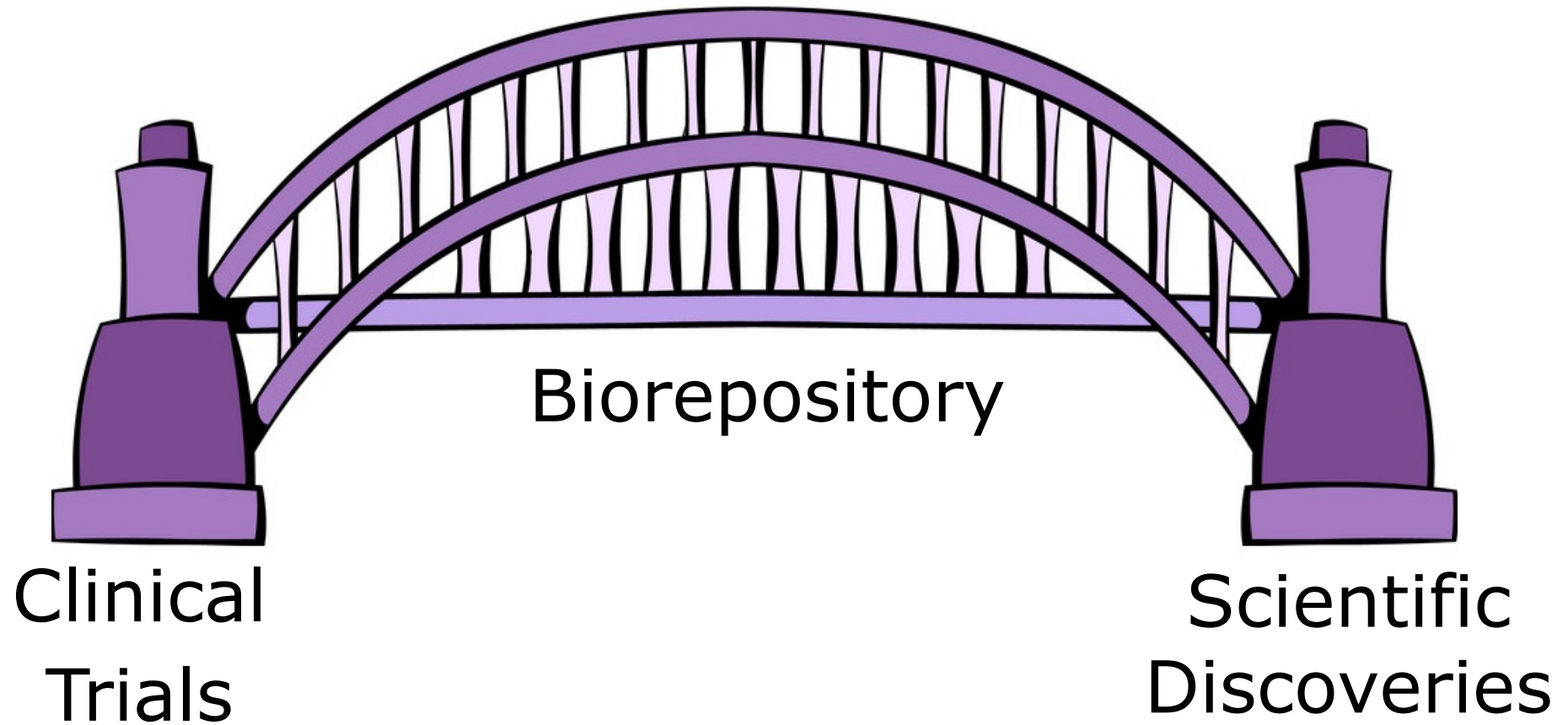
The function of Clinical Trial Biosample Management at Merck



The function of Clinical Trial Biosample Management at Merck



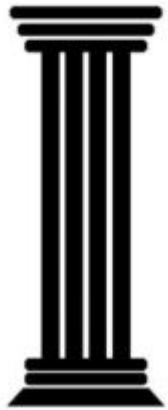
The function of Clinical Trial Biosample Management at Merck



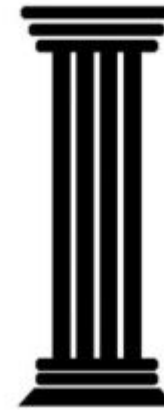
How Clinical Trial Design and Operations can lead to high quality biosamples

Consent

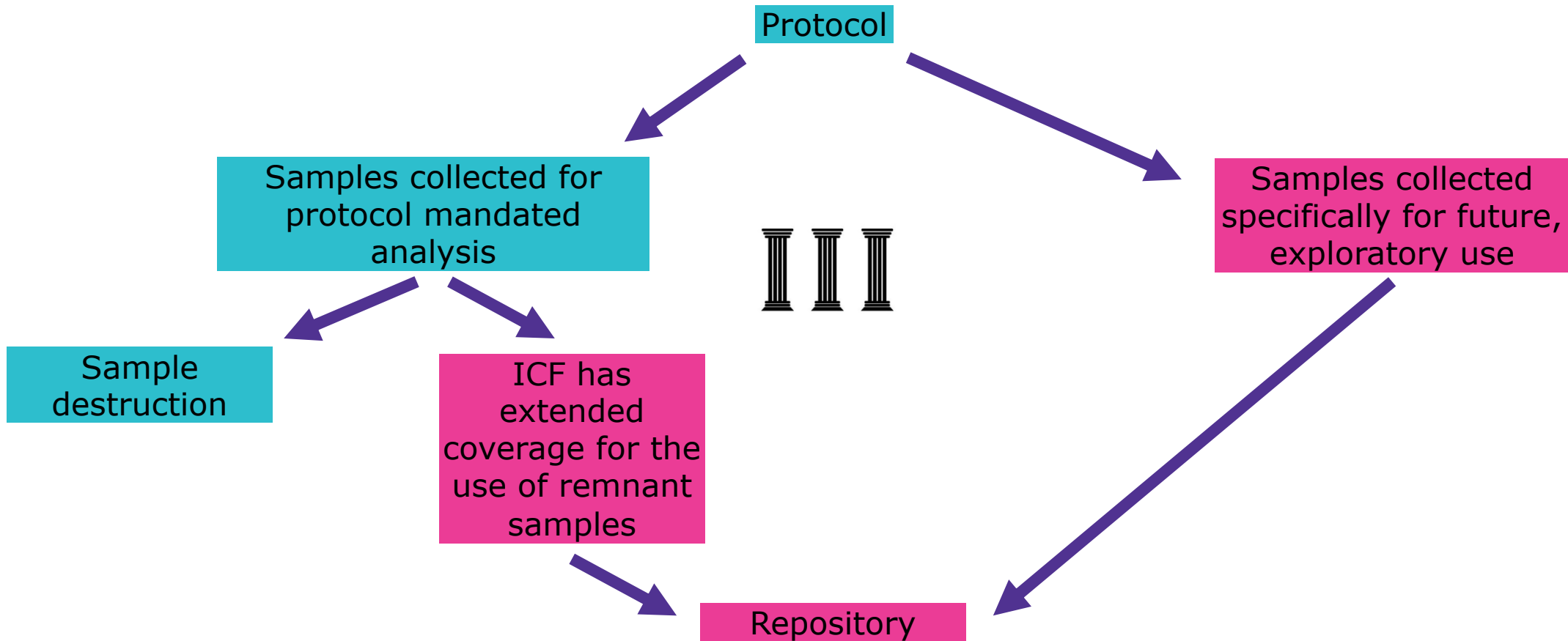
Sample
Quality



Associated
Data



How Clinical Trial Design and Operations can lead to high quality biosamples



Opportunities for improvement



Internal education and communication




Robust biosample management policy



Education of clinical sites

Key Messages

Biobanking is an extension of a clinical trial, not an inconvenience The value of a clinical trial does not end after CSR completion



Operational challenges and solutions for Translating Clinical Trial Samples into Biobank Assets

Annette Amon-Hassenzahl
Clinical Trial Biosample Manager

Porto, February 2019



MERCK

Quality repository samples

Operational challenges



Sample management at sponsor and/or CRO



Sample management at site

Operational challenges – sponsor/CRO and site



Protocol



'Translation' into systems and documents

'Usability' of the protocol



Quality repository samples

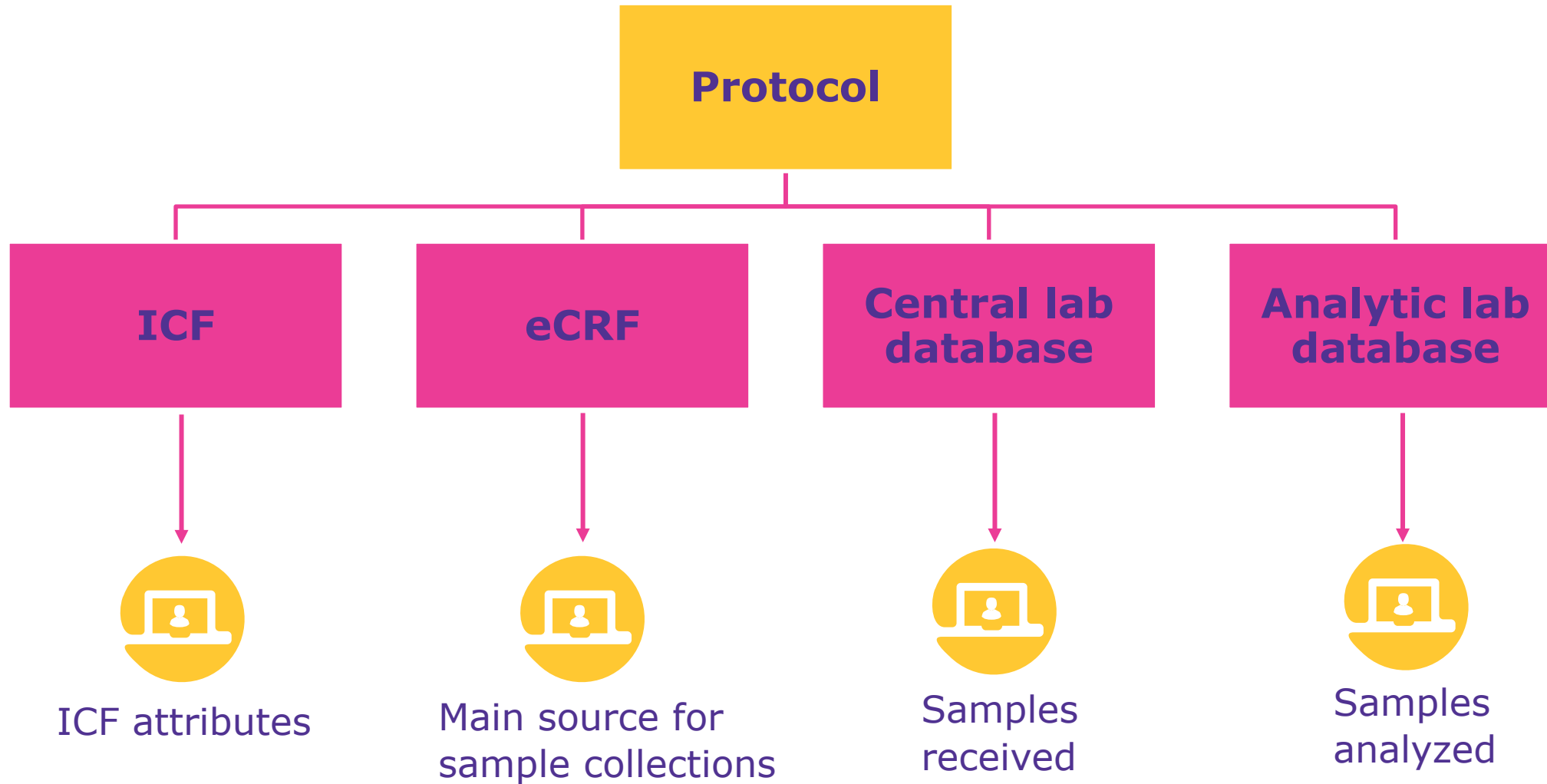


Operational challenges – sponsor/CRO and site

Solution

- Establishment of a dedicated group that is working cross-functionally
- Responsibility starts early
- Review of ALL study and sample related systems and documents
- Knowing what is going on throughout the whole study

Operational challenges – sponsor/CRO

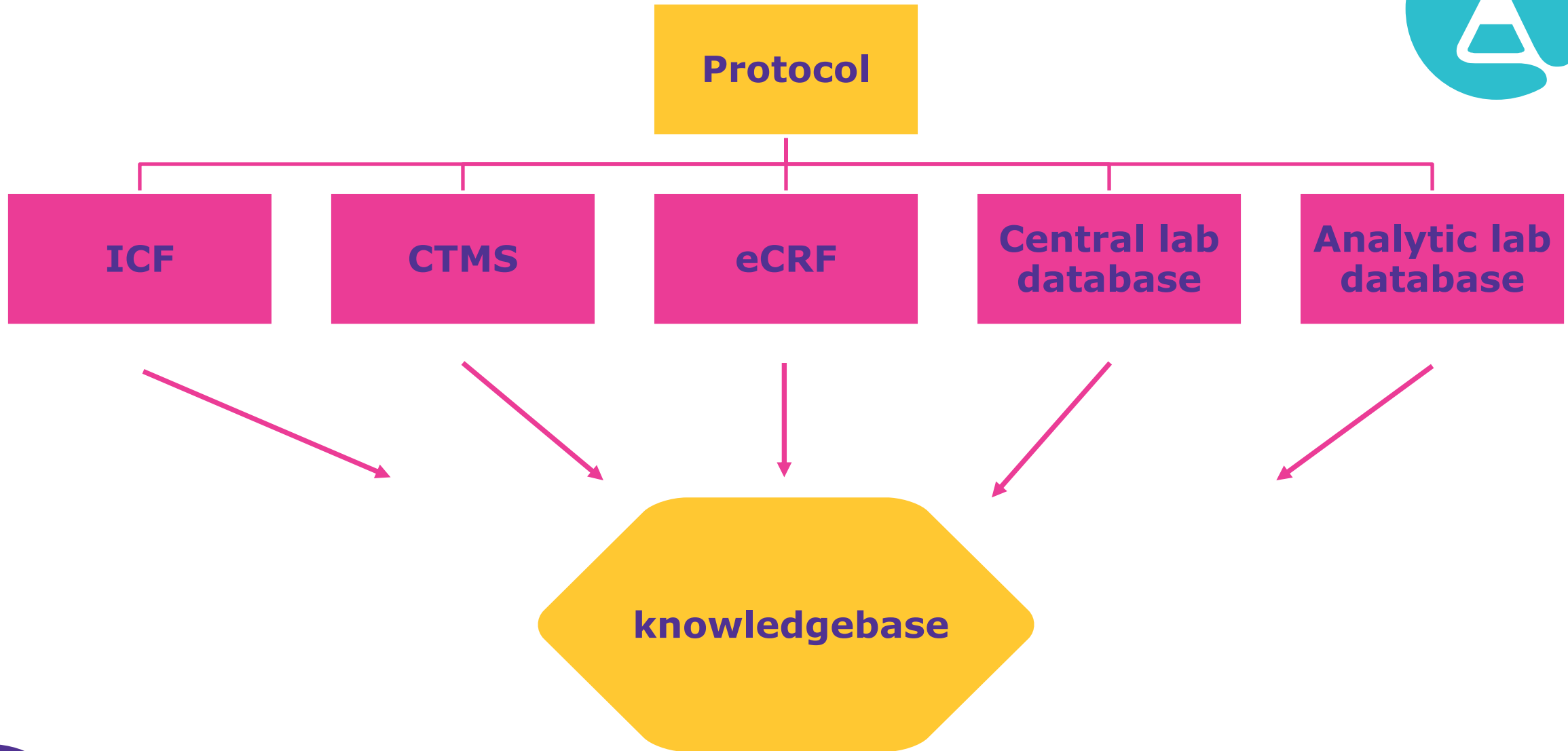


Operational challenges – sponsor/CRO

Solution

- Manual review of vendor reports
- Follow ups when information provided is not matching between the systems
- Combining several sources and merging reports
- Reconciliation, each is different
- Time-consuming and risk of errors due to manual processes

Operational challenges – sponsor/CRO

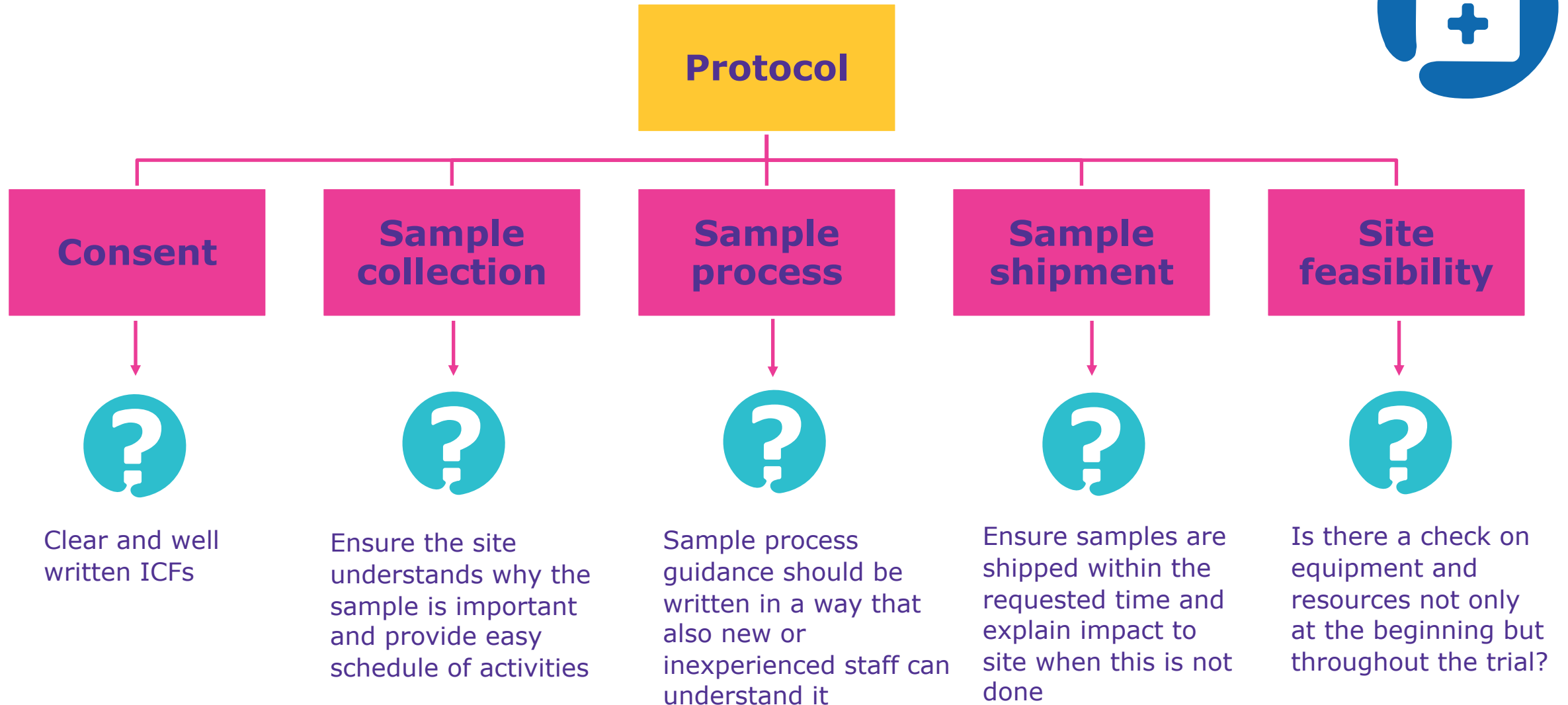


Operational challenges – sponsor/CRO

Solution

- Streamlines process by using an interface that is fed by all 'protocol-downstream-systems'
- ICFs – attributes broken down to patient level
- eCRF – clinical data, including the ICF attributes
- Central laboratory sample management, accessions
- Analytic laboratory, using parent-child IDs
- More compliant, faster, better audit trail, even more inspection ready

Operational challenges – site



Operational challenges - site

Solution

- Understanding of the patient's needs and burden
- Considering the site's feasibility
- Logical kit design and supporting documents
- Translation of the protocol into handy formats
- Contact in case of questions or/and concerns

**Quality repository samples
require pro-active and cross-
functional collaboration and
focus with the clinical team**