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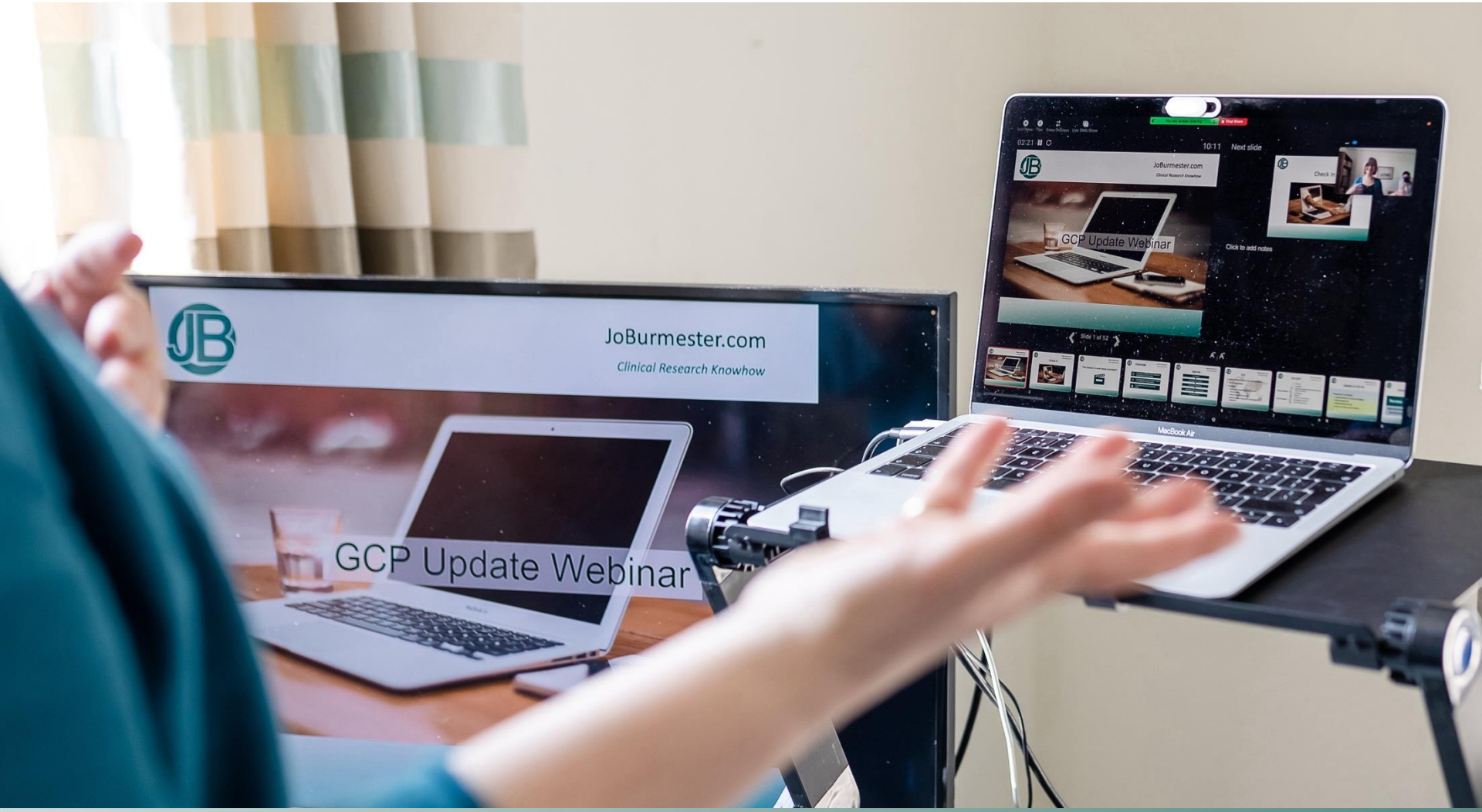
Clinical Research Knowhow



Revision 3
Timeline so far

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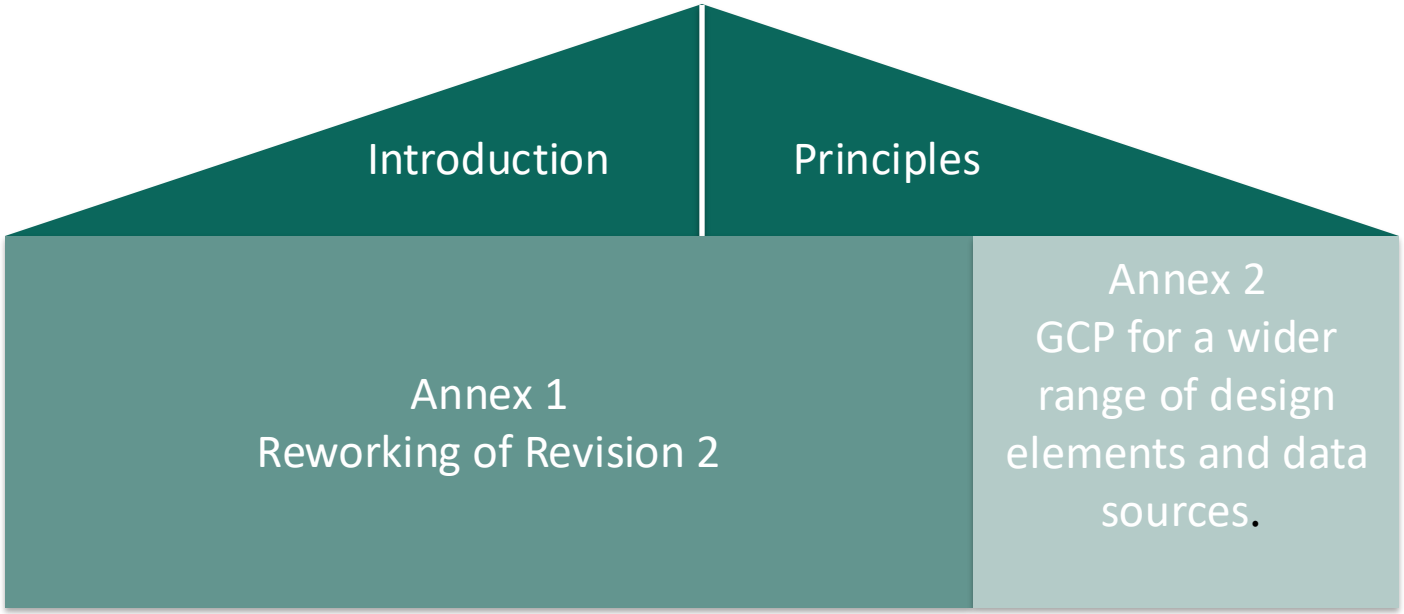
Clinical Research Knowhow

2020	Stakeholder engagement
2021	Draft Principles Published
May-Nov23	Draft of Annex 1 and Public Consultation
January 2025	Prinicples and Annex 1 finalised
October 2024	Annex 2 draft published
February 2025	Public Consultation on Annex 2

Summary - purposes of main changes

- New structure
- Increased clarity on scope
- Facilitation of innovation
- Feasibility and practicality – QbD, CtQF and Risk Proportionality
- Transparency
- Improved informed consent

New Structure



Annex 1

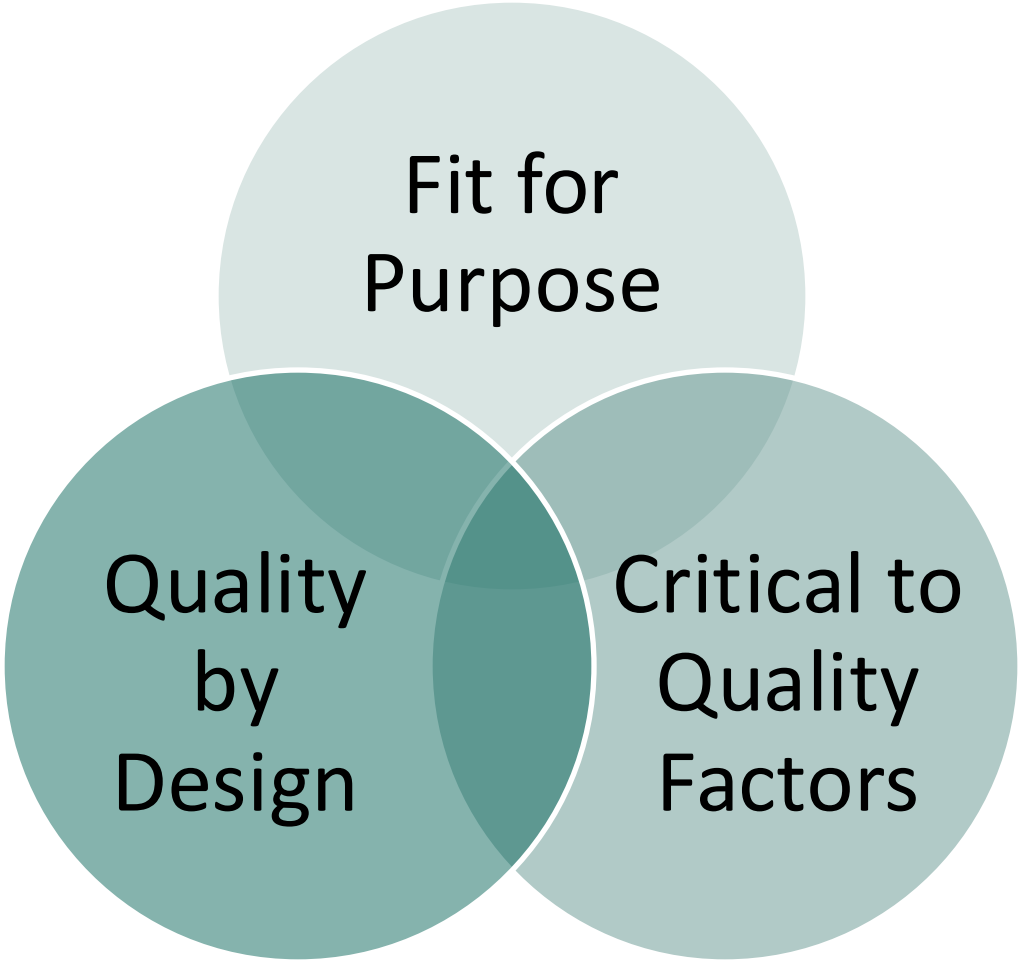
Reworking of Revision 2

- Responsibilities of IRB/IEC; Investigator; Sponsor
- Data Governance, investigator and sponsor
- Appendices:
  - IB
  - Protocol
  - Essential Records
- Glossary

Scope

"This guideline applies to interventional clinical trials of investigational products that are intended to be submitted to regulatory authorities. The Principles of GCP in this guideline may also be applicable to other interventional clinical trials of investigational products that are not intended to support marketing authorisation applications in accordance with local requirements."

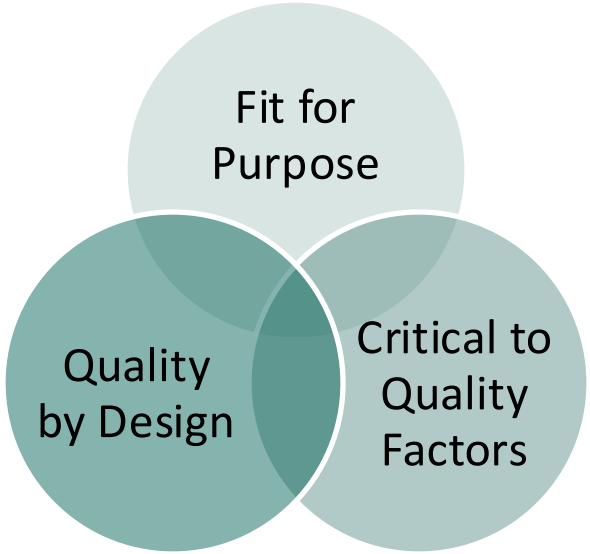
Underlying Philosophy



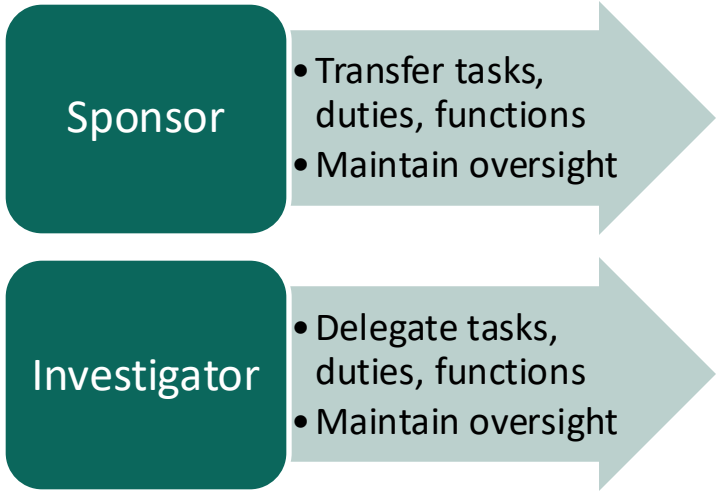
Principles - Changes

- 11 principles – much more detail!
- Biggest changes:

Principle 7



Principle 10

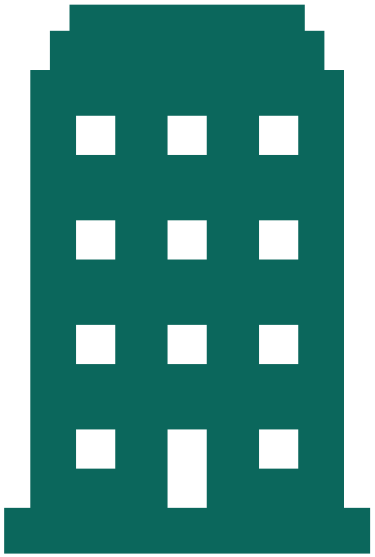


Annex 1

Responsibilities	Data Governance*	Appendices	Glossary*
• IRB/IEC • Sponsor* • Investigator*	• New section	• IB • Protocol • Essential Records*	

* Substantial changes in these sections

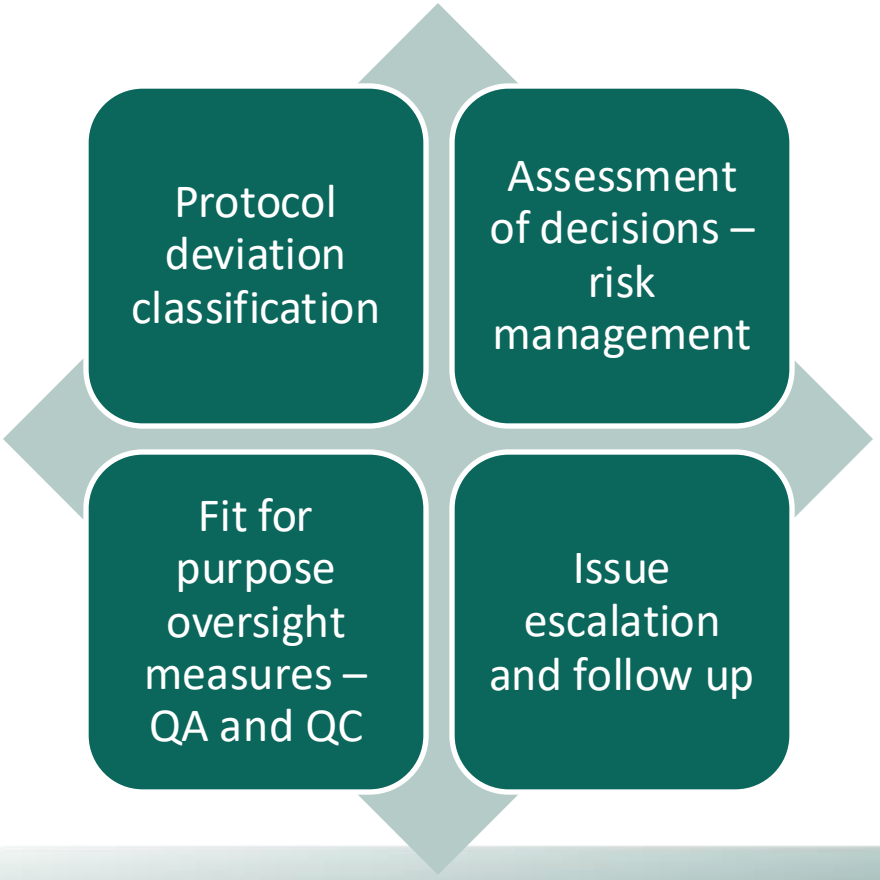
Sponsor Responsibilities



Agreements

- Sites and service providers – before initiating activities
- Updated when there are changes
- Responsibility of sponsor and investigator
- Service provider management

Sponsor Oversight



Committees

- Purpose
- Access to data and blinding issues
- Expertise and processes

Data Governance

Large new section

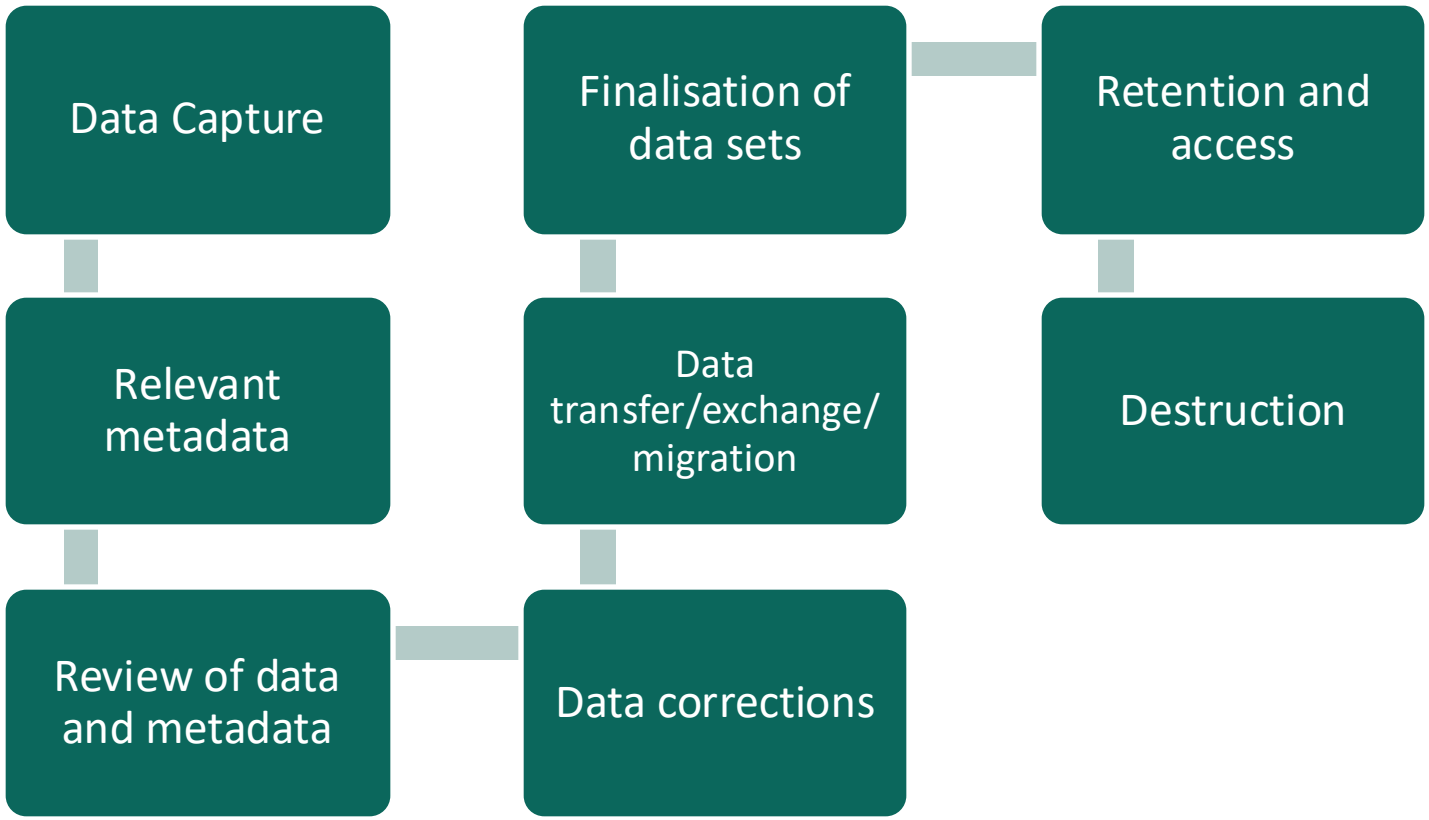
Responsibilities of sponsor and investigators

- Data integrity and traceability
- Data Security

Emphasis on protection of blinding

Data Lifecycle

Data Lifecycle



Summary of common themes

Flexibility and proportionality

- QbD
- CtQ

More reference to local requirements

- Ongoing review
- Doc retention
- Safety reporting

Control of data and records

Implementation Timelines Principles and Annex 1

EU – 23 July 2025

UK – Spring 2026 (at the same time as new UK Legislation)

US – Unknown at this time

Annex 2

Draft now available for consultation via Regulators

Focus on:

- Decentralised elements
- Pragmatic elements
- RWD

Areas covered in Annex 2

IRB/IEC	Investigator	Sponsor
• Consent and confidentiality	• Ethics • Consent • IMP management • PI oversight • Safety assessment and reporting	• Long List!

EMA Updates

- Clinical Trials Regulation fully applicable from January 2025
- CTIS guidance updated regularly
- Latest Inspection Metrics Report
  - Critical findings – highest number in Data Management and Monitoring.
  - Most common findings overall - Documentation (including Source Documentation), Training and Qualification, Investigational Site Protocol Compliance

FDA Updates

- Many changes at FDA
- Some guidance has been removed
- Some new guidances on DCTs, use of AI, Evaluation of Sex Differences, IRBs