AUDITING COMPUTER SYSTEMS

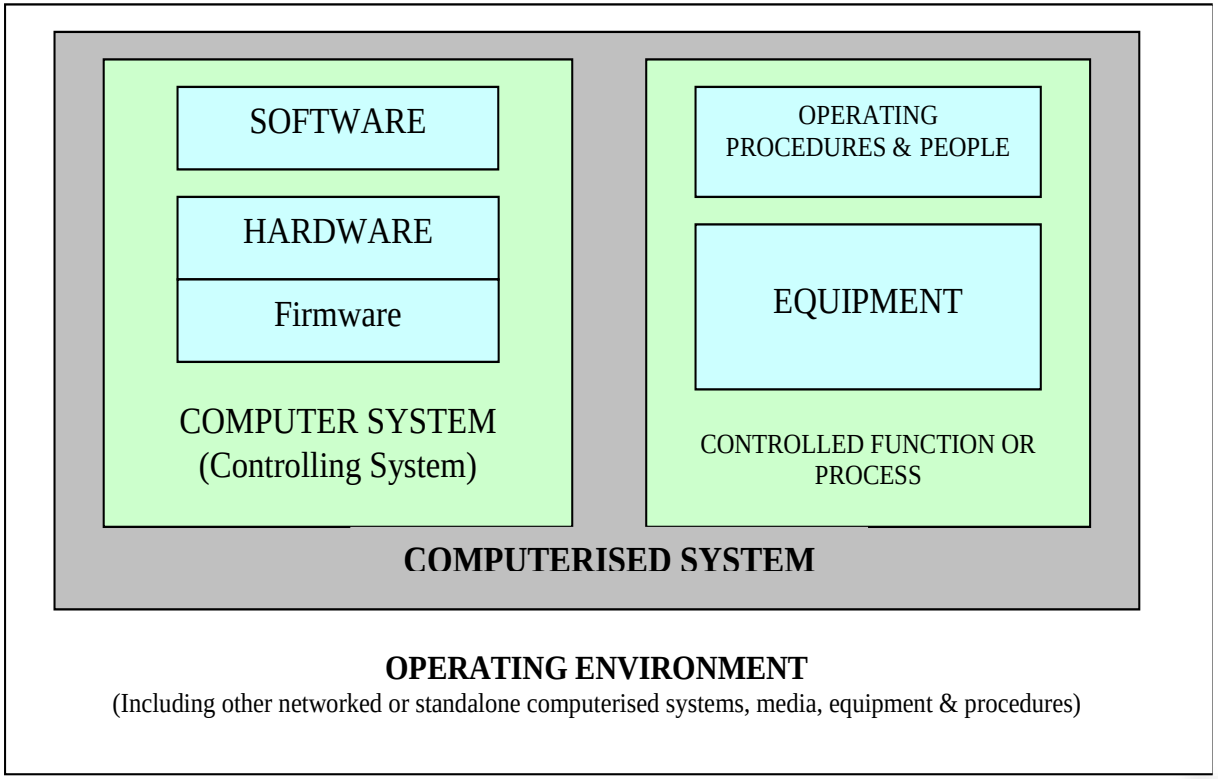
Auditing computer systems – Overview of what to consider

- What is a computerised system?
- What are the relevant standards?
- Areas to audit

AUDITING COMPUTER SYSTEMS

What is a computerised system?

- A computerised system includes:



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What are the relevant standards?

- **Statutory Instrument 2004/1031 (as amended)**
  - **Regulation 31A (4)**
    - The essential documents relating to a clinical trial are those which…enable both the conduct of the clinical trial and the quality of the data produced to be evaluated
  - **Schedule 1, Part 2 (9)**
    - All clinical information shall be recorded, handled and stored in a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remain protected.

What are the relevant standards? (2)

- **EMA Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012), Section 6.16**

  - All computerised systems used for the capture, processing, manipulation, reporting and storage of data should be developed, validated and maintained in ways which ensure the validity, integrity and security of the data

  - Prior to use, all computerised systems should be subject to an appropriate level of validation. The primary aim of any validation process will be to demonstrate that the computerised system is fit for its intended purpose and can produce reliable and reproducible data.

What are the relevant standards? (3)

- **ICH E6 (R1) Guideline for Good Clinical Practice**
  - **When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:**
  - **Ensure and document that the electronic data processing system(s) conforms to the sponsors established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation)**

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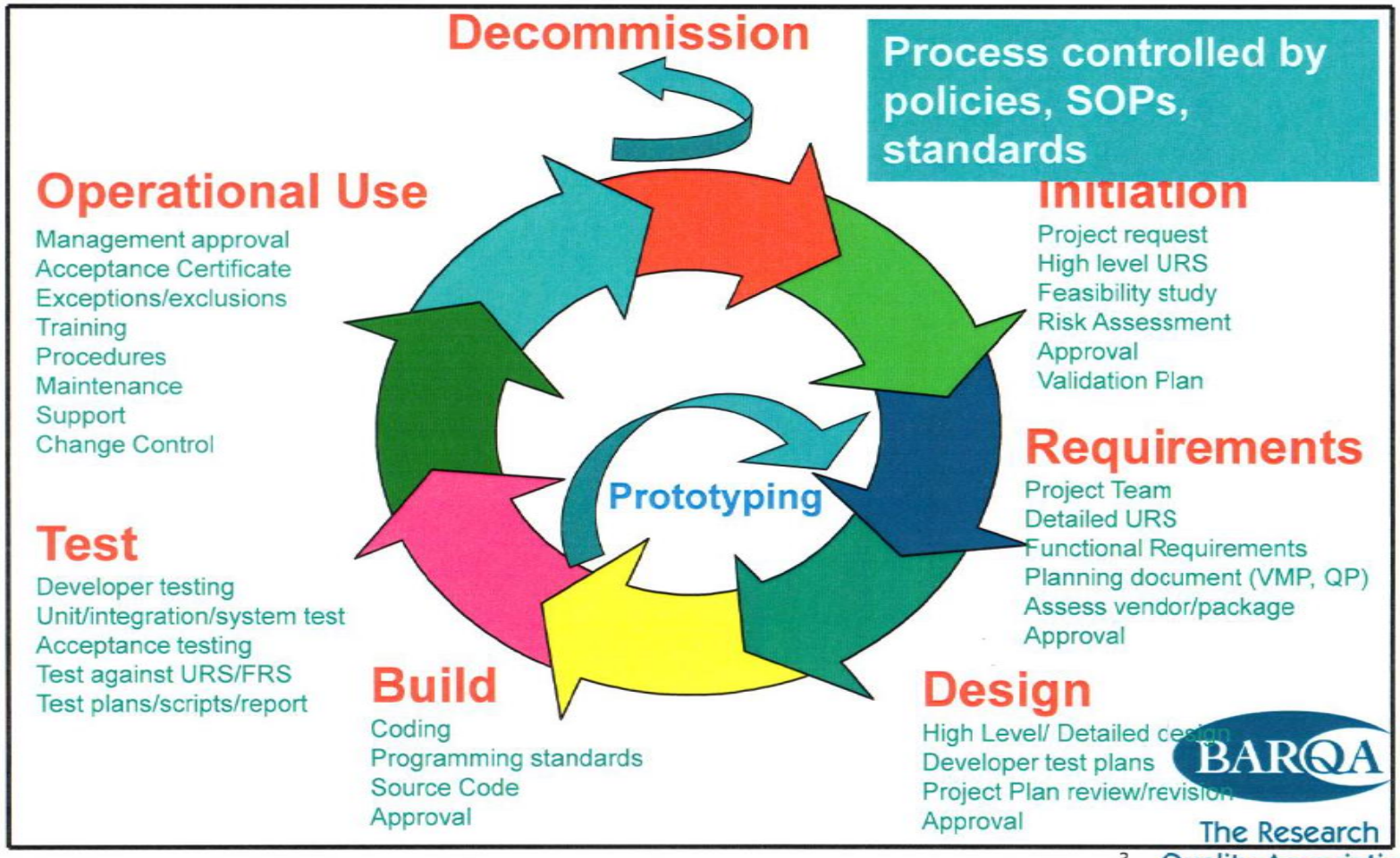
Computer System Lifecycle



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Areas to audit

- User Requirement Specification (URS)
- Validation
- Change Control
- Security
- Back Up/Disaster Recovery

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Areas to audit (2)

- System Monitoring
- SOPs
- Training
- Data Archiving
- End of Life Cycle Provisions
  - For both Previous & Current Systems

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References

- **Regulations**
  - EU Clinical Trial Directive 2001/20/EC
  - UK Clinical Trial Regulations: SI 2004/1031, as amended
  - 21 CFR Part 11 ‘Electronic Records; Electronic Signatures’

- **Guidance**
  - Good Clinical Practice Guide (MHRA)
  - EMA ‘Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples’
  - INS-GCP-3 Annex iii – ‘To procedure for conducting GCP inspections requested by the EMEA: Computer Systems’
  - ICH E6 (R1) Guideline ‘Guideline for Good Clinical Practice’
  - ICH Q9 Guideline ‘Quality Risk Management’
  - Good Automated Manufacturing Practice (GAMP) 5 ‘A Risk Based Approach to Compliant GxP Computerised Systems’
  - ECRIN Guidelines
  - Computerised System Validation (CSV): Risks, Requirements, Tests and Traceability (RQA Booklet)

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HAPPY COMPUTER SYSTEMS AUDITING!

Any Questions?