Technology Framework

ICH E6(R3) – Good Clinical Practice

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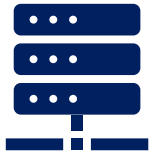
Introduction to Computerized Systems



What is a computerized system (CS)?

Digital systems, including hardware, software, and related documentation (such as user manuals), that are used to capture, generate, correct, retain, archive, access, or transfer information in digital format for clinical trial activities.

Why are computerized systems important in clinical trials?

Computerized systems play an important role in clinical trials. Examples include, but not limited to:

- Data integrity
- Participant safety
- Efficiency and compliance
- Risk management
- Real-time monitoring

How does ICH E6(R3) discuss computerized systems?

"Computerised systems used in clinical trials should be fit for purpose (e.g., through risk-based validation, if appropriate), and factors critical to their quality should be addressed in their design or adaptation for clinical trial purposes to ensure the integrity of relevant trial data" (Section II 9.3)

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- **What is it?** A PowerPoint slide deck that explains the **computerized Systems (CS) requirements** outlined in ICH E6(R3). It covers procedures for using CS, training, security, validation, periodic reviews, system failure, technical support, and user management. It also includes TransCelerate and ACRO's proposed definitions and details the roles and responsibilities of those involved in the process.
- **Who is it for?** This slide deck is intended for clinical research professionals, including study sponsors, contract research organizations (CROs), and other stakeholders involved in the implementation and management of computerized systems in clinical trials.
- **How to use it?** Use this slide deck to clarify the CS requirements of ICH E6(R3) and understand the roles and responsibilities of those involved. Click on the sections of interest to access detailed information about roles, responsibilities, definitions, and examples. The tool also points to other relevant ICH guidelines, providing a comprehensive resource for managing computerized systems in clinical research.

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Computerized System (CS) Elements

Click on each box to know more

Procedures for the Use of Computerized Systems

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- Is the business process associated with the use of the system clearly documented in a controlled document?
- Is there an access management process clearly described?
- Is a user manual required?
- Are change requests assessed for impact to the system?
- Does the system undergo periodic review?

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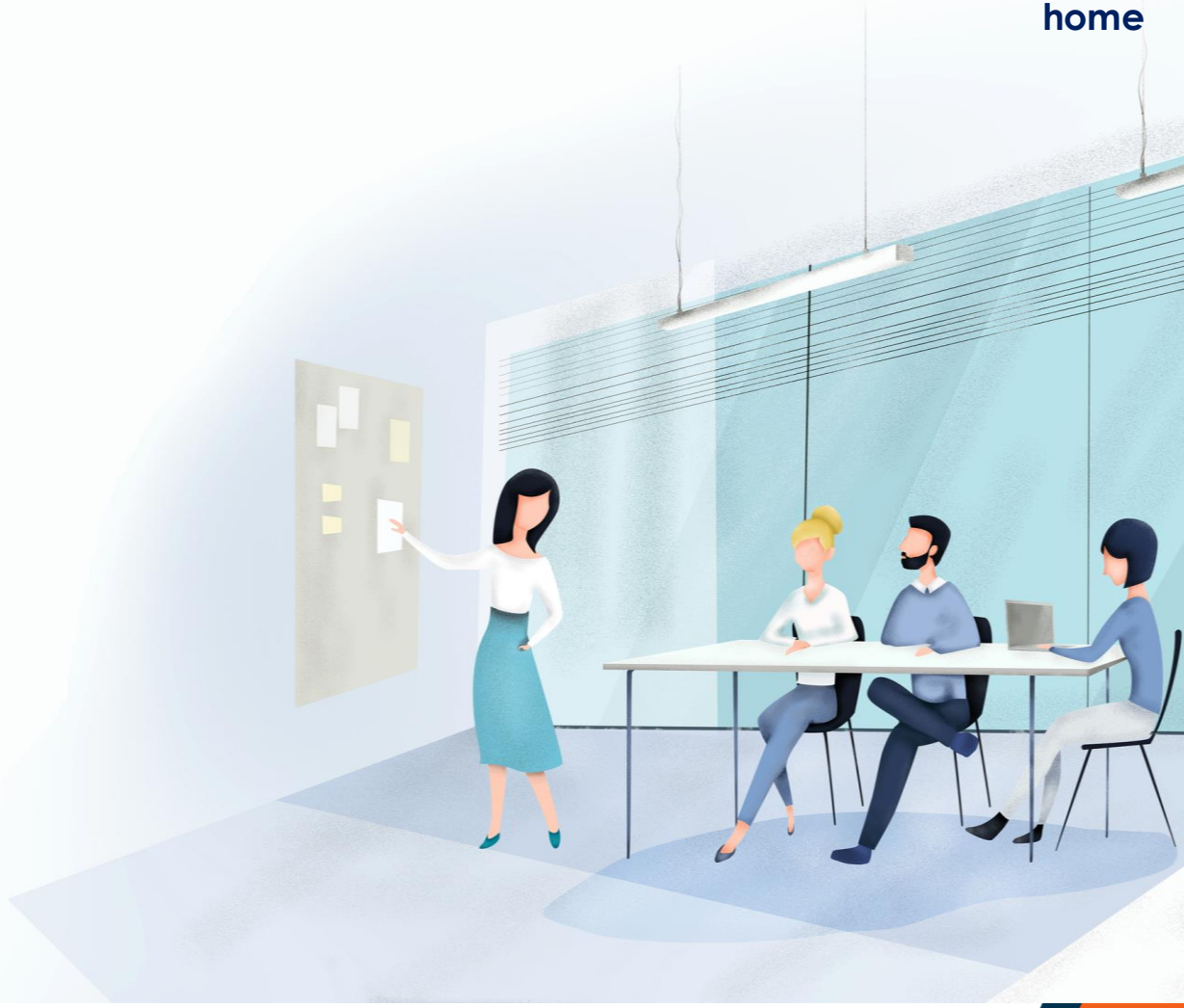
Training

- Are there documented procedures to ensure the appropriate use of computerized systems for essential activities related to data collection, handling and management?
- Are personnel performing these essential activities trained in the procedures for their use?
- For computer systems deployed in a given trial has the responsible party who deployed the system provided appropriate training in their use?
- Are there procedures in place for data handling in the system to maintain the trial blind (if applicable)?



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Security in Computerized Systems Has Several Facets

Controls to Confirm Attributability and Availability

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Security Management System

Is there a Standard Operating Procedure (SOP) for user access and security reviews?

What procedures are in place for revoking access? Are access permissions reviewed on a periodic interval?

What is the password policy and is it a current industry practice?

Is the system built with an inactivity logout?

Authentication

Is strong authentication, such as multi-factor authentication (MFA), enforced?

Are inactive accounts promptly disabled?

How are authorized users and their access privileges documented, maintained, and retained? This includes records of updates, roles, access rights, and timestamps for access privileges.

Data Transfers Security

Are the data transfer methods documented with system documentation?

Are interfaces validated and include error handling/ notifications?

Are email exchanges encrypted, along with attachments?

Are File Transfer Protocol (FTP) and file sharing tools included in security patching management and network controls?

Threat Management

Does the anti-malware policy or program include defined operating systems that require antivirus?

Do network Vulnerability Scans and penetration testing occur at defined intervals?

How is the platform monitored for security, any logs that get reviewed and detect unauthorized accesses?

Digital Health Technology

Do wearable devices have individual usernames and passwords?

Are the data transfer methods from wearable devices encrypted and notify of failures and prevent duplicate data?

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Computerized System Validation

Controls to ensure adequate and fit for purpose validation status of the systems used in a clinical study

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Risk-based Approach

Is risk assessment process conducted to identify potential risks associated with the computerized systems used in the study?

Has the criticality of the data collected in each system been assessed for the study (e.g., primary endpoint data versus non-critical data)?

Is a risk-based approach used for the evaluation of the revalidation needs of a system?

Process Documentation

Is there a Validation Plan in place that describes the validation needs for the system?

Are user requirements specifications (URS), functional requirements specifications (FRA) and design specifications documented?

If applicable, is there evidence that system validation has been successfully executed?

If a system is provided by a third-party vendor, have vendor qualification assessments been performed to evaluate vendor capabilities, quality assurance practices, and regulatory compliance?

Performance Controls

Are there oversight mechanisms in place to monitor computerized system performance and ensure ongoing compliance?

Are the responsibilities clearly defined for computerized system validation activities?

Integrity Controls

Are there controls in place to prevent unauthorized access, data manipulation, and loss of data integrity?

Does the system qualify for an audit trail review?

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Periodic Review

Controls to ensure that systems used in clinical trials remain compliant, functional, and reliable throughout their lifecycle

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- Has a risk-based approach been used to define the frequency of periodic reviews?
- Were there any changes in the system that impact its adherence to the regulatory requirements relevant to its use?
- Are the validation documents available and up-to-date?
- Have the user access controls and permissions reviewed to ensure that access privileges are appropriate and aligned with user roles and responsibilities?
- Is the user access adequately restricted to maintain data integrity and confidentiality?
- Is there any impact of the incidents and changes on system functionality, performance, and compliance?

Data Governance Controls for Technical Support

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- Are support staff adequately trained on GCP guidelines and relevant clinical trial systems?
- How is information about reported issues stored and managed, ensuring confidentiality and data integrity?
- What procedures are in place for escalating critical issues to higher levels for management review?
- Is there a process for analyzing customer support trends and identifying opportunities for improvement?
- How is user satisfaction measured and monitored in relation to technical support services?
- Are there periodic audits or checks to verify compliance with established support protocols?
- What communication channels are available for users to contact technical support?
- Is there appropriate management review in all functional areas for issues to be reported?

User Management

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Access Controls that:

- Is system access limited to authorized users
- Are changes attributable to an individual
- Are controls unduly burdensome

Documentation to support:

- Is there a system description that includes Roles and permissions available within the system
- Is there a process to add new users to the system
- Does the system have multi-factor authentication (MFA)
- What are the controls on passwords
- Are authorized users and access privileges documented, maintained and retained
- Is there a User account listing
- Is there a User account review process and records
- Is there a User account addition and deactivation process with associated records
- Are there procedures to assign user access rights based on user duties and roles and consistent with blinding requirements
- Are permissions based on User role
- Is there a User access log
- Is there an Audit trail that confirms who accessed the system and when

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System Failure Controls: Business Continuity and Disaster Recovery

Business Continuity:

Is there a business continuity Plan?

What communication protocols are established for internal and external communication in the event of an incident?

Are alternate locations or processes identified for business operations if the primary system becomes unavailable?

Are employees educated about the Business Continuity procedures through training and awareness programs?

Does the Continuity plan align with legal and regulatory compliance requirements?

Do contracts with suppliers identify the joint responsibilities for recovery? Does your company review the results of supplier Disaster Recovery results annually?

Disaster Recovery:

- Is there a disaster recovery plan in place?
- How frequently is the DR plan tested to ensure its effectiveness, and how is it routinely updated and maintained?
- What are the defined Recovery Time Objective (RTO) and Recovery Point Objective (RPO) timeframes for system and data recovery?
- What immediate actions are outlined in the Emergency Response Procedures during and after a disaster?
- How are data backups conducted, and what are the procedures for data restoration?
- What roles and responsibilities are assigned to employees during a disaster or disruption?
- Are employees educated about the Disaster Recovery procedures through training and awareness programs?
- What strategies are in place for maintaining essential relationships with suppliers and vendors during disruptions?
- Does the organization's insurance coverage adequately address potential risks and liabilities related to disasters?
- Who is responsible for managing and responding to incidents as part of the Incident Response Team?

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