

## **ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 24 January 2025**

### **(i) KEY PRESENTATION**

#### **Integrating Principles of Quality Management into Clinical Research by Monika Schmuck, Quality Assurance Associate, UHN (slides attached)**

The objective of the presentation was to understand quality in the context of clinical research; specifically to (a) understand key quality principles; and (b) how to implement them in clinical research.

Quality is important for regulatory (standards and guidelines) and institutional policy (departmental SOPs, protocols) reasons. It is also important because of its impact on outcomes – quality affects data integrity and the safety of study participants.

- (a) Key quality principles are as follows, and examples were given on how these can be demonstrated in studies.

### **Key Quality Principles**

- ▶ **Consistency:** Ensuring consistent procedures and protocols
- ▶ **Accuracy:** Importance of accurate data collection and reporting
- ▶ **Reliability:** Building reliable and reproducible results
- ▶ **Transparency:** Maintaining transparency in methodologies and reporting
- ▶ **Communication:** Effective communication among team members and stakeholders

- (b) Implementing quality principles

Risk management is a key part of this whereby we identify and mitigate risks in clinical research. A risk severity matrix was shown, which is a tool that helps us rank risks based on their severity and likelihood of occurrence. Understanding the likelihood and severity of a risk helps sites develop effective mitigation strategies (SOPs, training, early warning indicators) and processes to minimize its impact, catch a near-miss or identify an issue before it impacts many participants.

## Implementing Quality Principles

- ▶ **Risk Management:** Performing risk assessment to identify hazards and evaluation of risks associate with exposure to identified hazards
- ▶ Three fundamental questions:
  - ▶ What might go wrong?
  - ▶ What is the likelihood (probability) it will go wrong?
  - ▶ What are the consequences (severity)

Risk Rating = Likelihood x Severity

Consequence	Extreme	5	10	15	20	25
	Severe	4	8	12	16	20
	Substantial	3	6	9	12	15
	Moderate	2	4	6	8	10
	Slight	1	2	3	4	5
		Very unlikely	Not likely	Likely	Very Likely	Extremely likely
		Likelihood				

  

<span style="display: inline-block; width: 15px; height: 10px; background-color: red; border: 1px solid black;"></span> Very high risk
<span style="display: inline-block; width: 15px; height: 10px; background-color: orange; border: 1px solid black;"></span> High risk
<span style="display: inline-block; width: 15px; height: 10px; background-color: yellow; border: 1px solid black;"></span> Moderate risk
<span style="display: inline-block; width: 15px; height: 10px; background-color: lightgreen; border: 1px solid black;"></span> Low risk

Dallias, Helen & Rivers-Moore, N.A.. (2019). Environmental water temperature guidelines for perennial rivers in South Africa. Volume 2: A technical manual for setting water temperature targets..

On a day-to-day basis, it's important to develop and maintain Standard Operating Procedures (SOPs). An example was given whereby there are procedures but the process was not documented.

It's also important to have study tools and templates for data collection and checklists to ensure all assessments are performed. Ensure study tools are consistent with the protocol and good documentation practices.

Deviations from the protocol happen, and identifying and documenting protocol deviations (e.g. using a 'deviation log' is a key quality task and a best-practice to capture protocol deviations and to prepare a Corrective Action/Prevention Action plan. Ensure your site has an SOP on documenting and managing protocol deviations.

Clearly, ongoing training and education is important to ensure the quality principles are upheld and maintained.

## (ii) PROBLEM DISCUSSION

### Problem Presented by Mousumi Mahanta

There is often confusion about the proper storage practices of Personal Health Information (PHI), including what is permitted and what is not, and where electronic files should be stored. Key points that need further clarification include the rules around storage locations, security measures, and compliance requirements.

- How can PHI be stored effectively and anonymously?
- What are the guidelines for what is allowed and not allowed?
- Is it acceptable to store PHI on a drive or shared drive?
- What are the essential things to remember?

## Discussion:

A poll conducted during the ECHO session revealed that 68% of participants have experienced issues or had questions regarding the storage of Personal Health Information (PHI).

Some key points discussed included:

- Connect with your institutional IT department and discuss the following situation, including where it is safe to store electronic data at the institution. Review all policies and ensure your department are all consistently storing data, according to FDA Part 11, institutional policies, privacy laws and the governing regulations.
- A key consideration is where the data is stored. In this instance, REDCap data is hosted on the case presenter's University servers, but concerns arise when data is stored in less secure locations or other countries outside of Canada.
- If shared drives within an organization are secure, they may be considered acceptable storage options. Confirm with the institutional IT department.
- The way data is used also affects storage decisions. If data is frequently accessed and shared among team members, consider this when choosing electronic storage methods that are accessible by all team members and supported by the institutional IT department.
- Another consideration is how often individuals (e.g., monitors) will access the data onsite, whether from physical files or remotely.
- The size of the data file can also influence storage decisions.
- Password protection and encryption are essential for safeguarding research data, especially when dealing with sensitive information like PHI.
- The discussion also touched on original and redacted documents
- A reminder was made to ensure compliance with FDA 21 CFR Part 11, which is part of the US regulations and is also followed in Canada with US Sponsors, discusses electronic records and signatures.
- Implementing a source locator index was suggested as a helpful best practice.

The importance of consistency in storage practices was emphasized. Once a storage solution is decided upon, it's crucial to maintain consistency and document the process.

Additionally, separating study records from PHI documents is recommended. This allows for the development of storage practices with a higher level of protection for PHI, which is not necessary for general study records which do not have PHI.

The session also briefly touched on sharing, dissemination, and archiving of PHI, with the decision to focus on PHI archiving at the next ECHO session, scheduled for Friday, 28 February 2025.



## Resources:

Some resources related to PHI at UHN:

Storing and Accessing Personal Health Information (PHI), Corporate Confidential Information (CCI) – UHN Clinical Research Guidance (attached)

UHN Policy [Administrative: Privacy & Access policy 1.40.007](#)