ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 23 May 2025

(i) KEY PRESENTATION

REDCap – getting started and beyond – by Chris Battiston, REDCap Administrator / Research Data Analyst, Research Operations, The Center for Health Research Information Systems, Women's College Hospital (slides attached).

REDCap is a secure web platform for building and managing online databases and surveys. The platform requires no installation and offers streamlined processes for rapid project creation and data collection.

When starting a REDCap project, it's recommended to begin with pen and paper planning, followed by standardizing variable names and coded values.

Thorough testing, comprehensive documentation, and regular backups are essential practices. Protected Health Information (PHI) must be properly flagged as identifiers.

The platform's online designer serves as the primary tool for form building. Various field types are available, including text boxes, radio buttons, and checkboxes. A standardized coding system is recommended, using sequential numbers (1,2,3) for standard options and the presenter recommended 666 for "other" responses. Branching logic functionality allows for complex form design, enabling conditional question display based on previous responses.

REDCap includes features like automated data export to Excel and statistical packages, a built-in project calendar, scheduling modules, and advanced capabilities such as file uploading and calculated fields.

A comprehensive 350-page user guide, written by the Chris Battiston, is available for reference, covering everything from basics to advanced features like randomized surveys. See number 2, in the RESOURCES LIST.

When using a system such as REDCap, it is advisable to review your institution's policies and consult with the IT team responsible for managing and implementing the local REDCap instance.

(ii) PROBLEM DISCUSSION

Brief Description of the Situation/Scenario:

A community member presented a problem concerning specificity in clinical trial documentation, particularly regarding adverse event (AE) reporting. The core issue revolves around how specific protocols and essential documents need to be to ensure consistent site-level practices while maintaining flexibility.

The specific example involves the definition of adverse events in their trial. Their protocol aligns with GCP definition, describing AEs as "any untoward medical occurrence in a patient administered a pharmaceutical product."

The question arose when a site inquired about the timing of AE collection. While common practice suggests collecting AEs from the time of consent signature, their protocol's definition links AEs to investigational product administration. This created uncertainty about whether they need to amend the protocol to explicitly state AE collection starts at consent, or if they can enforce this as a best practice without protocol modification.

Discussion of the Problem:

The discussion following the problem presentation involved several key points about protocol specificity. A member shared experience with Manual of Procedures (MOP) documents that provided detailed specifications beyond protocol requirements. They noted that MOPs typically receive REB approval and can complement protocols without conflicts. Regarding adverse event timing, they mentioned that some protocols explicitly define AE collection from first dose rather than consent, with baseline conditions recorded as medical history. This practice was acknowledged as acceptable if approved by Health Canada and REB.

Another community member, speaking from a frontline perspective, emphasized that more specificity in protocols is highly appreciated as it helps prevent queries after the fact. They specifically mentioned that clear protocol specifications help avoid situations where staff might incorrectly assume AE collection timing, such as starting from treatment rather than consent, leading to subsequent data queries.

Being specific about protocol is particularly important for multicentre studies where sponsor coordinators may not always be present on-site. A hub member recommended including as much detail as possible in the protocol, especially for regulated or investigator-initiated studies.

A community member discussed the importance of site selection processes in multi-site studies, emphasizing that sponsors should review each site's SOPs during feasibility assessment to ensure alignment with protocol requirements. They also highlighted recent developments with GCP R3, noting that sponsors now need to explicitly define critical-to-quality factors in their studies. According to them, Health Canada inspectors will defer to these sponsor-defined critical factors when conducting inspections under GCP R3 framework. This approach gives sponsors more control in determining and documenting what aspects are most crucial for their specific studies.

Regarding the Manual of Operations (MOP), a hub member suggested that it could be as comprehensive as necessary or work in conjunction with protocol references. This flexibility allows for additional details to be provided outside the main protocol document when needed.
UHN is proposing the use of study management plans specifically for investigator-initiated studies. These plans are intended to provide comprehensive support from the initiation of the study, potentially offering another avenue for including important study details and procedures.

Members also discussed using secondary documents like eCRF completion guidelines to provide additional specificity without overburdening the protocol. However, for critical elements like AE timeline definition, the consensus suggested including these directly in the protocol rather than secondary documents. The conversation concluded with the problem submitter confirming that their protocol amendment would include the AE timing specification.

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RESOURCES

1. Slides from REDCap didactic presentation by Chris Battiston, 23 May 2025.

2. Chris Battiston's REDCap User's Guide, December 2024: womensacademics.ca/wp-content/uploads/2025/01/WCH-REDCap-v14.8-User-Guide-30Dec2024.pdf

3. Chris showed us a Dummy Case Report form: https://tinyurl.com/4mfk4ep7

4. Chris shared the webpage that outlines his area of work at Women's College Hospital (WCH) – WCH REDCap Support Services: WCH REDCap Support Services - Academics at Women's College Hospital

5. A Hub member shared the REDCap website: Resources – REDCap, note videos within this website: Videos – REDCap are particularly useful.

6. An ECHO Community member shared this video that explains how to export data from REDCap for analysis: https://www.youtube.com/watch?v=7f72uIrZ0r8

7. A Hub member shared this website on *Exploring the Critical to Quality (CTQ) Factors*: Exploring the Critical to Quality (CTQ) Factors - CTTI