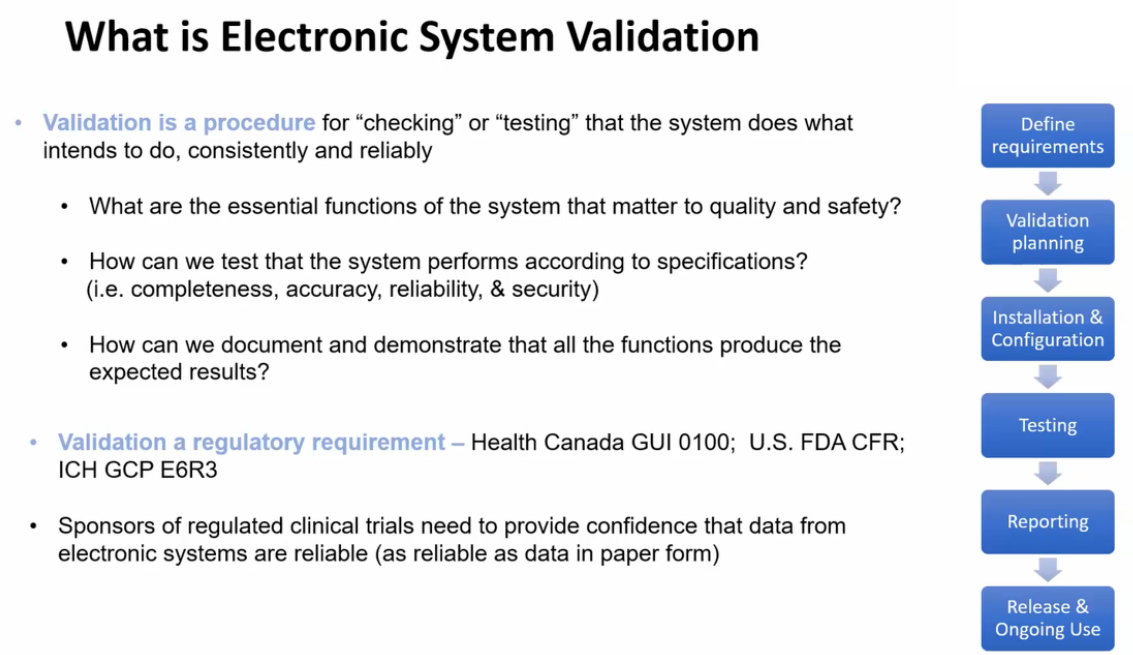
ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 24 April 2025

(i) KEY PRESENTATION: Electronic System Validation in Clinical Research by Michael Voth *(Slide deck attached).*

This presentation was a high-level introduction to electronic (computerized) system validation for regulated clinical research, explaining that any system in the data "pipeline" – for example, Electronic Data Capture (EDC), Clinical Trial Management System (CTMS), e-consent, trial master file, Patient-reported outcome (PRO) tools - should be shown to be fit for purpose, reliable, and protective of data integrity and confidentiality.



Why validation matters

Computerized systems are now embedded throughout the research data pipeline, from electronic data capture and wearable devices to clinical trial management systems, e-consent platforms, electronic trial master file systems, and patient-reported outcome tools.

Because these systems collect, store, transform, and archive data that underpin final analyses and regulatory submissions, they must be shown to be "fit for purpose," accurate, and protective of participant information.

Electronic medical records were highlighted as a partial exception: they are usually controlled by hospitals under their own standards and are generally not validated by research sponsors, although they contribute source data.

Regulatory expectations

The speaker emphasized that electronic system validation is a regulatory requirement for Health Canada- and FDA-regulated trials, anchored in Health Canada Guide 100, ICH GCP, and U.S. FDA regulations such as 21 CFR Part 11. Sponsors are expected to demonstrate that electronic

systems are at least as reliable as paper-based processes and to provide evidence of validation during inspections. An ECHO participant's example and the speaker's own inspection experience showed that inspectors may request validation documentation not only for primary data capture systems but also, in some cases, for CTMS implementations used in regulated studies.

Core elements of the validation process

Validation was described as a structured, documented procedure to show that a system consistently does what it is intended to do, without introducing errors or security failures.

Key elements include: a requirements or design specification describing system functions; a risk-based validation plan and test plan; installation and configuration in the real operating environment (including access controls); execution of test cases based on critical functions (e.g. formulas, workflows, role-based access); and a validation report summarizing activities and confirming that the system performs as intended.

The speaker stressed that validation is not a one-time event: changes or upgrades should trigger a risk-based assessment of whether re-validation is needed.

Levels of validation and roles

The speaker outlined three possible levels of validation: design-level (by the software developer), implementation-level (when an organization installs or hosts the system), and study-level or user-level (when a study team configures forms, branching logic, or study-specific workflows).

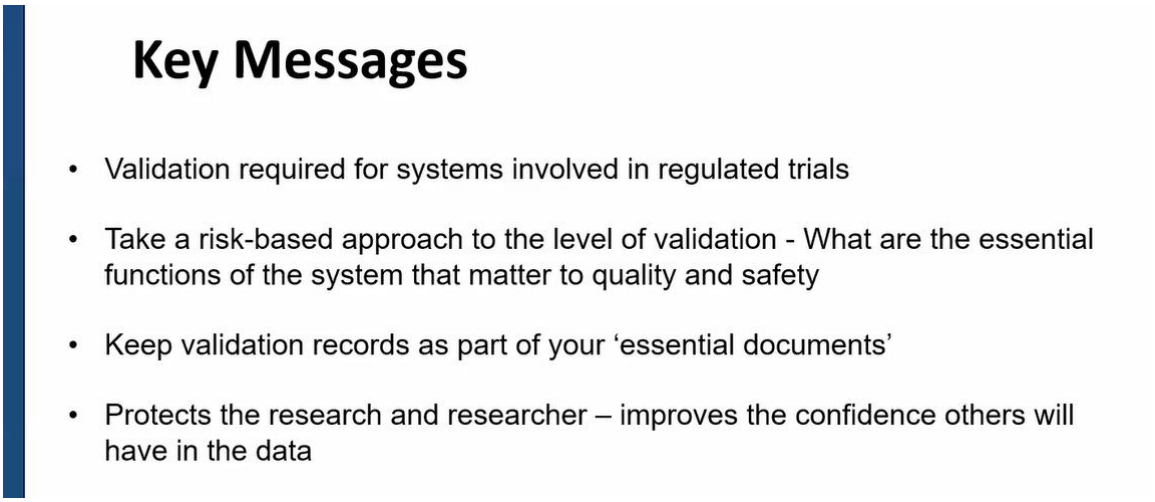
For cloud-hosted, externally managed tools, organizations may rely mainly on the vendor's design-level validation, whereas locally hosted tools like institutional REDCap instances typically require both implementation-level and study-level validation.

In the Q & A discussion that followed the presentation, ECHO participants described how, even in small teams, validation work can be organized through an inventory of key systems, impact ratings (low/medium/high), and collaboration between IT, quality, and study teams.

Inspection example and practical take-aways

The speaker described a Health Canada inspection where an academic sponsor was cited for not having a written validation plan or comprehensive validation report for an EDC system, despite having emails indicating that some tests had been performed. This example underlined that informal evidence is insufficient: regulators expect structured plans, documented test cases and results, and a formal validation report, kept with other essential trial documents.

The key message was to treat validation as part of overall system control (alongside SOPs, training, and access management) that protects the research, protects researchers, and builds confidence among regulators and other stakeholders that electronic data are secure, accurate, and reliable (as shown in the following slide).



(ii) PROBLEM DISCUSSION:

The problem or question presented was: "We are currently creating Power BI dashboard for clinical trials from the clinical trial management system. What metrics would you like to see in a dashboard from a Clinical Research Professional's perspective conducting the study?"

Metrics discussed by the problem presenter included recruitment data overall, accruals per month, and active studies, as well as ideas from the community:

- Study level and site level views.
- Recruitment vs plan / target.
- Recruitment projections.
- Distance participants traveled.
- Contracts and contract execution dates.
- Ethics submission and approval dates.
- Study startup timelines.
- Financial aspects such as startup costs and annual fees.

Design and usability considerations were also discussed:

- Avoid overly busy or complex dashboards.
- Tailor dashboards to user needs (role-specific views)
- Use dashboards to prompt desired behaviors (e.g. filling in EDI or patient engagement fields).
- The "right" dashboard content depends heavily on:
    - Audience (leadership vs research teams vs public).
    - Use case (operational vs strategic vs compliance).
    - Institutional priorities.

Resources shared in the ECHO session:

From Rebecca Xu:

3CTN Power BI reports: https://3ctn.ca/our-impact/3ctn-reports/ (using EDGE CTMS)

Next ECHO sessions:

Fri May 29, 2026, at 12 to 1pm ET- **Using AI to Support REDCap- A Judgment First Framework by Christopher Battiston**

Fri June 26, 2026, at 12 to 1pm ET- **How to Progress Your Study and Influence People by Julie Gundry**

Keep up-to-date with our ECHO:

Visit our home page often: https://www.cantaptalent.ca/echo/clinical-research-professionals and keep an eye out for the Post-ECHO survey that will be coming out in June/July 2026.