ECHO for Clinical Research Professionals (CRP) – Session Summary of (i) Key presentation and (ii) Problem discussion from session held on 23 Jan 2026

(i) KEY PRESENTATION:

Clinical Research Sponsorship: Key Considerations & Best Practices by Heidy Morales, Research Quality Associate, University Health Network *(Slide deck attached).*

The presentation covered sponsor responsibilities, ICH E6 R3 modernization, and Health Canada alignment in the context of investigator-initiated trials and institutional practices, with the following key points:

- The presentation noted that the sponsor is the entity (institution, company, or individual investigator) that "owns" the study from a regulatory standpoint, and while specific tasks can be delegated, overall accountability cannot be delegated. The sponsor remains responsible for ensuring the trial is designed, conducted, recorded, and reported in accordance with Good Clinical Practice (GCP), even when vendors or service providers are used.
- The ICH E6 R3 modernizes GCP by shifting expectations from pure process compliance to thoughtful planning and risk-based quality management, including quality by design, risk-based monitoring, appropriate documentation, and robust audit trails. There are heightened expectations for oversight of service providers and third-party vendors (for example, CROs), with clearer requirements to define, manage, and document delegated activities and oversight.
- In investigator-initiated trials, the sponsor-investigator carries dual responsibilities and must meet the same regulatory obligations as any external sponsor; there is no "light" or reduced version of sponsorship. Institutional support was highlighted as critical, and the presentation underscored that unclear delegation of roles and responsibilities increases compliance risk, especially around regulatory submissions and safety reporting.
- Common compliance gaps come from underestimating operational responsibilities, particularly around submitting CTAs or equivalent device submissions and ensuring robust safety reporting systems. These areas are frequent themes in regulatory inspections for investigator-initiated trials, where sponsors may not fully appreciate their regulatory role and obligations.
- Health Canada's evolving framework aligns with ICH E6 R3, requiring CTAs for most interventional drug and biologic trials (except certain Phase 4 studies), and expecting adherence to GCP principles even in CTA-exempt trials. The presentation also highlighted requirements such as long-term record retention (for example, 15 years) and a risk-based approach to trial planning, conduct, and oversight.
- The presentation emphasized several best practices for strong sponsorship: defining critical-to-quality factors early, identifying risks to scientific validity and participant safety, implementing traceable decision-making, and engaging regulatory expertise early in protocol development. Clear documentation of roles, oversight, and system validation was presented as essential to demonstrating compliance with R3 and Health Canada expectations.

The Q & A that followed related to the following areas:

Pre-CTA consultations

- A member commented that they fully agreed with engaging Health Canada in pre-CTA interactions and found pre-CTA engagement very useful. This aligned with guidance that sponsors may request pre-CTA consultations when needed to clarify regulatory expectations.

Differing interpretations of R3 (REDCap / e-signatures)

- A member asked how to resolve differences in interpretation of ICH E6 R3 requirements between a sponsor-investigator and a REDCap administrator, including disagreements about the need for e-signature functionality on certain forms and how to mitigate such "butting of heads." The underlying concern was whose opinion would prevail when interpretations conflict at the project level.

- The speaker responded that this is a relatively new and evolving scenario under R3, but underlined that regulations clearly require validated systems, appropriate audit trails, and flexible use of e-signatures where relevant. Responsibilities and expectations should be clearly defined in institutional SOPs or project manuals, including requirements for system validation and documentation practices.

- A member then asked whether teams must follow the REDCap administrator's project-level SOPs or whether the PI/sponsor could create their own SOPs. The speaker indicated that this should be determined at the institutional level, distinguishing what is prescribed centrally versus where flexibility is allowed. As an example, the presentation referred to large institutions where some units maintain internal SOPs, while central quality or regulatory teams provide adaptable templates and consultative support rather than prescriptive control.

Confidentiality agreements and seeking advice

- A member raised confidentiality agreements, highlighting that while some NDAs can be problematic in other contexts, NDAs in drug research are important, beneficial, and should be kept clear and simple. They contrasted this with other industries to underscore why confidentiality is more critical in drug development.

- The same member strongly encouraged seeking advice when starting new research projects, suggesting making a list of multiple people with relevant experience and approaching them for guidance over, for example, a coffee. They emphasized pre-planning what to disclose to protect ideas, and noted that advice is highly valuable even if not all suggestions are ultimately followed, while also helping to build professional relationships.

Documentation expectations

- A member wrote in the chat that clear documentation is critical and recommended teams behave as if an audit could occur "next week." They stressed that everyone involved in the study (PI, fellows, coordinators, nurses, and anyone interacting with participants or source documents) must document activities and corrections thoroughly.

- The same member later elaborated that documentation must be treated as an ongoing, real-time process rather than something to reconstruct when an audit is announced. They provided an example emphasizing the importance of ensuring contract signatory sections are fully signed and dated at the time, noting that otherwise teams may later have to search through emails or correspondence to confirm when agreements were executed. They reiterated that meticulous, up-to-date documentation is very important for trial conduct and inspection readiness.

GCP applicability to non-CTA studies

- A member asked for elaboration on Health Canada's expectations for GCP applicability to non-CTA studies, particularly in smaller institutions with many non-CTA interventional trials. They observed that ICH E6 R3 explicitly scopes its applicability to trials intended to support regulatory submissions, which appears narrower than ICH E6 R2, and asked what has been heard from Health Canada on this point.

- The speaker responded that Health Canada is still updating its guidance and regulations and is currently running an open consultation to align practice with ICH E6 R3. The presentation noted that Health Canada is drafting more explicit regulations and expects teams to continue applying GCP principles in non-CTA studies (for example, some Phase 4 studies), and that authorities may request evidence from such trials demonstrating oversight and management consistent with GCP. The key message was that teams should always be able to provide a narrative showing they considered and applied GCP principles from start to finish, even when a CTA is not required, while recognizing that current guidance remains in draft form.

Planning an investigator-led interventional trial and pre-CTA interactions

- A member described planning their first investigator-led interventional trial, noting prior experience mostly with observational and industry-sponsored trials, and expressed concern about knowing what to ask in a pre-CTA meeting and not wanting to waste Health Canada's time. They outlined a plan to obtain internal institutional review (regulatory/QA plus protocol review for grants) once a draft protocol and consent are prepared, then approach Health Canada.

- The speaker affirmed that starting with internal institutional supports is a good approach and suggested finding a colleague who has already gone through a CTA and pre-CTA interaction to serve as a peer resource. Clarification was expressed that formal pre-CTA meetings with Health Canada are generally used for very complex studies (for example, involving both a CTA and a device), and suggested that, in many cases, emailing the appropriate Health Canada directorate with specific questions is a more efficient first step, as those mailboxes are actively monitored and responses are typically timely. It was noted that Health Canada can indicate, based on those questions, whether a meeting format would be more appropriate, thereby avoiding unnecessary workload for both the team and the regulator.

(ii) PROBLEM DISCUSSION:

The problem presentation outlined challenges from high staff turnover in a small research team managing multiple active trials, risking quality maintenance, protocol adherence, and audit readiness without adequate onboarding or documentation.

In the example presented, high staff turnover has left a small team overburdened with active trials. This situation heightens difficulties in maintaining trial quality, ensuring timely patient visits, and bridging operational gaps during transitions. Budget constraints limit hiring, exacerbating the crisis while emphasizing the need for sustainable strategies like SOPs, prioritization, and cross-coverage.

ECHO members discussed the problem, and focused on the following areas:

CRO and Internship

- A member clarified budget as a partial issue, then suggested hiring a CRO to offload workload if funding allows or can be secured. They also recommended research internships from colleges for trained day-to-day support, offering to share specific program names.

Prioritization and Crisis Management

- A member shared their experience managing 20+ studies with one coordinator during a three-month staffing gap, prioritizing patient visits to avoid protocol deviations or SAEs. They advised clear stakeholder communication on delays (e.g., 1-2 weeks for amendments), deferring non-essentials like monitor visits, and continuous SOP/email documentation for transitions.

- The same member cautioned against short-term interns due to onboarding costs, favoring permanent hires, and reassured that experienced managers can double output during crises.

SOPs and Volunteers

- A member strongly endorsed SOPs as essential for audit protection, demonstrating proactive gap management. They discussed research volunteers for free data entry/management support post-onboarding, and stressed caring for remaining staff to prevent burnout cascades through recognition.

Study Suspension and Training

- A member relayed regulatory writer advice: consider full study suspension with early Health Canada negotiation if unmanageable; CROs offer quality despite cost as they're SOP-trained; mandate paid SOP learning as job-core like safety training. They noted manager loss's impact and offered networking help for hires.

Training Resources

- A hub team member shared about their standardized onboarding resources: a consolidated document/checklist merging institutional/unit/training requirements, modifiable for needs, with contact shared for access.

Shared Calendar and Universal Backup Systems

- A member described self-managing seven studies from scratch without SOPs via a shared calendar for all patient activities/follow-ups, enabling visibility during leaves. They promoted universal backups, weekly planning (Thurs/Fri check-ins), and encouraged the problem presenter as a capable crisis manager who will succeed and earn supervisor appreciation!

Resources shared by the community included:

N2 Canada's SOP resources: https://n2canada.ca/study-operations-data-management/

N2 Canada's Job board: https://www.linkedin.com/posts/n2-canada_clinicalresearch-researchethics-workforcedevelopment-activity-7420480451846397952-5cmS?utm_source=share&utm_medium=member_desktop&rcm=ACoAAArprDkBSG0dmRWIG2obBtqnHJR_nd2p3KU

White Paper: "The Hidden Crisis in Clinical Research"
https://www.flipsnack.com/85A8DA5569B/white-paper-crp-workforce/full-view.html

Seneca CDM Course (CRP109) 7-week Clinical Research Data Management course taught by member, Chris Battiston
https://www.senecapolytechnic.ca/ce/classes/CRP109.html

Seneca Clinical Research Diploma
https://www.senecapolytechnic.ca/ce/community/health-care/clinical-research.html#Curriculum