ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 26 September 2025

(i) KEY PRESENTATION: Data and document essentials in clinical research management, by Polina Sutyrina *(Slide deck attached, including monthly newsletter from CCRU).*

The presentation covered the function of key roles in clinical research studies including the sponsor, principal investigator, site study teams with frontline &patient-facing roles and back-end data regulatory roles, service providers, and research ethics boards.

Data in clinical research include: source data i.e. information in original medical records, including clinical findings and observations necessary to reconstruct and evaluate trials; clinical research data i.e. protocol-specific data collected per research protocols, used to evaluate safety and efficacy of interventions, and must always match source data; and clinical research data which gets transcribed onto case report forms and includes patient questionnaire data like Patient Reported Outcomes and Clinical Outcome Assessments.

Documents in clinical research include: regulatory binders which are required for regulated trials and serve as centralized repositories for essential documents that relate to studies themselves rather than participant-specific documents. Three types of binders exist: sponsor trial master files, site trial master files maintained by sponsors, and investigator site files maintained at clinical trial sites. Essential documents demonstrate compliance with regulatory requirements, Good Clinical Practice, and trial protocols while providing clear written records for evaluation.

Three quick wins were highlighted from a recent analysis of data errors in quality audit reviews (see slide on next page):

1. Pay attention to paper documents (especially blank spaces) since 95% of findings were on paper sources.
2. Document all correspondence, especially regulatory essential documents and discussions with sponsors and ethics boards.
3. Use comprehensive tracking practices (i.e. tracking dates and submissions in excel) since 40% of findings related to missed or delayed essential documents, and tracking systems help identify missing trainings, signatures, and current protocol versions.

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Quick Wins

Pay attention to paper

- 95% of patient source document findings were on paper source
- 50% of these findings were due to presence of blank spaces

Don't forget to document

- 95% of insufficient/inappropriately filed correspondence was related to regulatory essential documents (not patients)

Try to track

- 40% of findings were related to missed, delayed, deficient essential documents
- Most of these findings can be mitigated by comprehensive tracking practices

(ii) PROBLEM DISCUSSION: How can we effectively manage expectations for treatment with research participants in a hospital-research setting?

At a Canadian hospital, there is an Aging Lab which works closely with the Falls Prevention Clinic, mostly with older adults, many whom experience cognitive, physical limitations and experience life-changing falls. Participants often understandably expect certain outcomes, ie. Improving their mobility, strength, cognition. The reality of any research is that we cannot guarantee any outcome and although sometimes these things improve, often they don't.

In this trial specifically, they were comparing effects of Health Coaching vs. Health Education on physical activity levels and mobility in older adults with limited mobility. The wording "Health Coaching" comes with certain connotations, and so does "Health Education." Aside from making sure that participants fully read the consent form, how does the research team reconcile their expectations?

Suggestions from the community included:

- Having an open discussion with the patient at the beginning of the consent process to define expectations. Include caretakers or family/friend companions of the older-adult group. “They are more accepting if the bar is set at the beginning.” Also make it clear that the intervention “might not work” and is experimental at this stage.
- At follow-up visits, highlight little wins and make clear that we hope for the best outcome but that little wins are still wins, and that the outcome may also not be beneficial to them. Apply emotional intelligence when relating to the participants.
- Include risks and benefits in the recruitment poster.
- Use interim results to confirm significant benefit or no benefit of intervention, so the participants are not shocked at the end.
- Introduce a brief evaluation (questionnaire, interview, a short writeup) of the participant’s expectations to track how their perspectives may evolve. Comparing the recruitment point with the last day helps participants reflect on their expectations but also clinicians and researchers, about where the study/program may be falling short.
- The current poster “free health coaching” may create unrealistic expectations. Modify wording to be more objective and stress that there are no guaranteed benefits.
- The importance of emotional intelligence when connecting with participants' fears and hopes, providing assurance that contributing data helps future innovations regardless of personal outcomes.

- Periodic reinforcement through follow-up and ongoing consent, documenting continued reminders about the risks and that there are no guaranteed results.
- Clarifying if participants are not understanding potential outcomes versus being disappointed in actual outcomes.
- Hub members emphasized that the reason for the patients' disappointment will impact how you address it. If it's a lack of understanding that the intervention might not directly benefit them then addressing the recruitment materials and consent discussion makes the most sense. If it's more that the patients understand it might not work, but they're still disappointed in their own outcomes you might look at providing more support or further referrals at the end of the study.
- Additionally, hub members agreed with community members that GCP often focused on the 'back-end' administrative stuff but at the end of the day the human interaction and empathy component may be just as important from a patient trust and satisfaction perspective. Making sure there is a trusting relationship during consent is important. We understand that patient participants may be disappointed by the results of a clinical research study, but we have to ensure they are informed, not surprised.
