ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 28 February 2025

(i) KEY PRESENTATION

Health assessment in clinical trials by Julie Gundry, RN, MSc(A), Advanced Practice Nurse Educator, Cancer Clinical Research Unit, Princess Margaret Cancer Centre (slides attached)

Key points from the presentation:

- We need to incorporate the protocol-required assessments as well as the clinical assessments into the full trial patient assessment. Both are important and it is easy to get skewed to one assessment and thus have less focus on the other.
- Pay attention to the footnotes of protocol assessments as they can have a lot of important information e.g. giving you important context or extra follow-up that needs to be done.
- Make sure that you are looking at the schedule for the correct arm, for studies with multiple arms or cohorts because this will mean there are multiple versions of the protocol.
- Be aware if there are any optional consents associated with the study e.g. patients may be asked to consent to provide extra optional blood samples at certain visits or to do extra quality-of-life questionnaires. We want to make sure we are not giving those extra optional assessments to patients if they have not consented to these.
- Be aware of rules for schedule changes. If, for example, the patient is not able to continue with the treatment or, for some reason, are now not eligible or not well enough to particpiate, then understand if we will be delaying this cycle or skipping the cycle entirely. Check with sponsor or monitor.
- Be prepared for these considerations that will generally apply to most situations:
    - Review adverse events.
    - Note baseline symptoms.
    - Do a thorough head-to-toe assessment of the patient, and make sure to do a thorough assessment every time they come in for study visits – it's good for the patient but also important for regulatory approval of new treatments.
    - Ask focused questions about the patient's diagnosis and it will be tailored to their condition e.g. if a patient has colorectal cancer, you would ask about changes in nausea, vomitting, diarrhoea, how are they eating, what do they weigh?
    - Make sure you are caring for the whole patient.
    - Use open-ended questions to allow the patient to direct the conversation, being careful that it does not come across as 'just small talk' e.g. be specific rather than asking "how are you doing today?"
    - Ask the patient to come prepared for their visit e.g. bring a list of your comments, note when you started taking medications, etc.
    - Have a study checklist that you put in front of the chart, so that we can check off everything that needs to happen at the next visit.
    - Review any lab or imaging or other reports required by the study so that we can use those results.
- If something arises that is completely unrelated to the study, facilitate referrals e.g. to social work or financial management.

(ii) PROBLEM DISCUSSION

Problem Presented on **Archiving by Mannie Fan PhD**, Clinical Research Manager, ALSRD Research Program, University of British Columbia (UBC), Department of Medicine (Neurology), Vancouver Coastal Health Research Institute (VCHRI)

Problem statement:

I would like to know how electronic records are to be archived, and how records containing personally-identifying information should be handled post-trial.

- For source data containing participant personally identifying information that will be retained and archived after study closure, do the personal identifiers get redacted prior to archival? If so, what determines when this should or can happen?
- What are regulatory-compliant best practices for retention and archival of paper and electronic source records (i.e. patient medical records) that contain participant personally identifying information?
- What are the recommendations and best practices for digital archival of electronic records post-study closure?

The decision to retain positive patient identifiers in clinical trial data, rather than redacting all participant information, is driven by several key factors:

Compliance with Regulations

Health Canada's Division 5 regulations require that clinical trial records be retained for a specified period (currently 15 years) to ensure the integrity and reliability of the data. This includes maintaining identifiable information to verify the existence and accuracy of patient data during audits or future analyses.

Verification and Audits

Positive patient identifiers are crucial for verifying the authenticity of clinical trial data. During audits or inspections, regulatory bodies need to confirm that the data corresponds to actual participants. This helps prevent fraud and ensures that the trial results are based on real, verifiable data

Patient Safety and Data Integrity

Accurate patient identification is essential for maintaining the integrity of clinical trial data. It ensures that each participant's data is correctly linked to their medical records, which is vital for tracking adverse events, follow-up studies, and long-term outcomes. Inaccurate or missing identifiers can lead to data gaps, inefficiencies, and potential risks to patient safety.

Legal and Ethical Considerations

From a legal and ethical standpoint, maintaining identifiable information ensures that participants' rights are protected. It allows for proper consent management and ensures that participants can be contacted if necessary, for example, in case of new findings or safety concerns.

While redacting all patient information might seem like a straightforward way to protect privacy, it would compromise the ability to verify, audit, and analyze clinical trial data effectively. Therefore, retaining positive patient identifiers is a balanced approach that complies with regulatory requirements, ensures data integrity, and supports future research while safeguarding patient privacy through secure storage and handling practices.

References

- Guidance Document: Part C, Division 5 of the Food and Drug ... - Canada
- Policy on collection and retention of records related to health product ...
- Notice: Period reduced for keeping clinical trial records for ... - Canada

Additional discussion points:

- It is important to collect only necessary data in your protocol to meet endpoints for statistical analysis, and maintain proper record retention in Canada.

- Many community members use off-site storage companies and there are agreements in place to protect and safeguard the records.

- A community member shared that a Health Canada inspection did not like redacted documents as they need to verify who the participants were.

- Standard operating procedures (SOPs) and institutional policies are in place to outline the steps to allow auditors and monitors access to the date. Refer to your internal policies and SOPs when storing electronic documents.

- A member reminded us of the regulatory basis for keeping intact some level of identifiability: Health Canada Guidelines (see Resources), section 5.12: *The sponsor shall record, handle and store all information in respect of a clinical trial in a way that allows its complete and accurate reporting as well as its interpretation and verification.*

- It is important to maintain identifiable information while minimizing personal data collection, but clearly there is a need for risk control measures such as establishing proper agreements with third-party service providers, and ensuring patient informed consent forms clearly communicate how personal health information will be handled and who will have access to it.

- When redaction of a copy is necessary to send outside of the institution, there are a few ways to accomplish this. Redacting documents using Adobe PDF tools was discussed, with a crucial sanitization step (a technical step in the software) to prevent the ability to reverse the redaction of sensitive information. Another method discussed was to make a copy, and use the black wax china marker to de-identify the personal health information (PHI), noting that using a pen redaction method may still show the information.

- Encryption using password-protection was discussed, with a caution about using Adobe's encryption feature- it invalidates DocuSign signatures.

RESOURCES

Health Canada. (n.d.). *Guidance for clinical trials for drugs and natural health products*. Government of Canada. Retrieved from https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html

Lapworth, T., & Cook, D. (2022). *Clinical assessment: Survival guide* (2nd ed.). Routledge.