Clinical Research Professionals ECHO

Welcome &

Housekeeping

Agenda

12:00 PM: Welcome & Introduction

12:15 PM: Announcements/Introduction to Project ECHO

12:30 PM: Didactic

12:35 PM: Problem/Question Presentation

12:55 PM: Discussion, Questions, and Recommendations

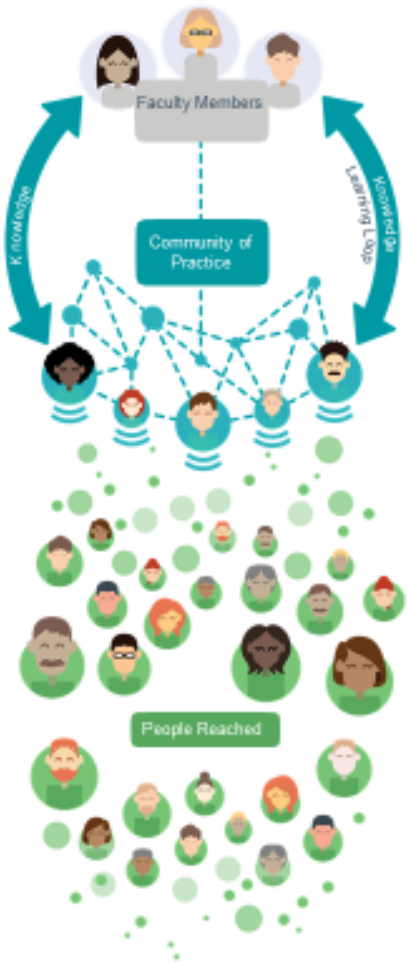
1:00 PM: Final Closing Announcements

ECHO Etiquette

- We kindly request all the participants to remain on mute unless speaking. Please introduce yourselves on chat using the following template; (Name, Organization, Role)
- Please keep your videos on whenever possible.
- Please use respectful and appropriate language.
- Please use the chat function or the raise hand feature for any questions.

Project ECHO®

The ECHO Model™



Moving Knowledge, Not People

Project ECHO (Extension for Community Healthcare Outcomes) is a movement to demonopolize knowledge and amplify the capacity to provide best practice care for underserved people all over the world. The ECHO model is committed to addressing the needs of the most vulnerable populations by equipping communities with the right knowledge, at the right place, at the right time.

Four Principles of the ECHO Model

- Use Technology to leverage scarce resources
- Share "best practices" to reduce disparities
- Apply case-based learning to master complexity
- Evaluate and monitor outcomes

Benefits of Becoming a Part of the ECHO community

- Access Communities
- Reduce Disparities
- Promote Consistency
- Rapid Dissemination
- Increase Professional Knowledge
- Isolation Decrease

Are you part of CAN-TAP-TALENT ECHOs? For more information visit us at: **cantaptalent.ca**

Facing Issues with Zoom? Contact Us!

Email: Prasanth.pillai@uhn.ca

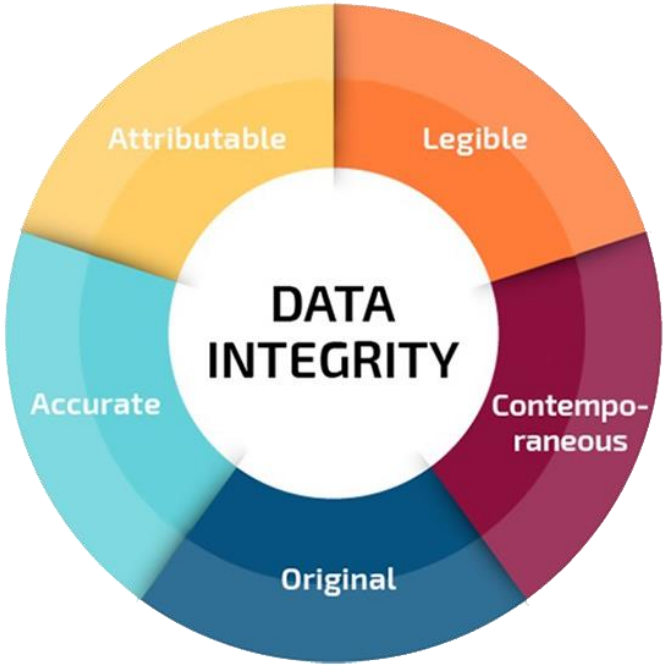
Zoom Private Chat: Prasanth Pillai, CRP ECHO COORDINATOR

Today's Topic:

Source Documentation in Clinical Research

Objectives

1. Review Source Data, Source Documents and Good Documentation Management
2. Review Case Report Forms (CRFs), Electronic Data Captures (EDCs) and Good Data Management



Definitions

Source

Source Data: All information in original records (and certified copies) of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

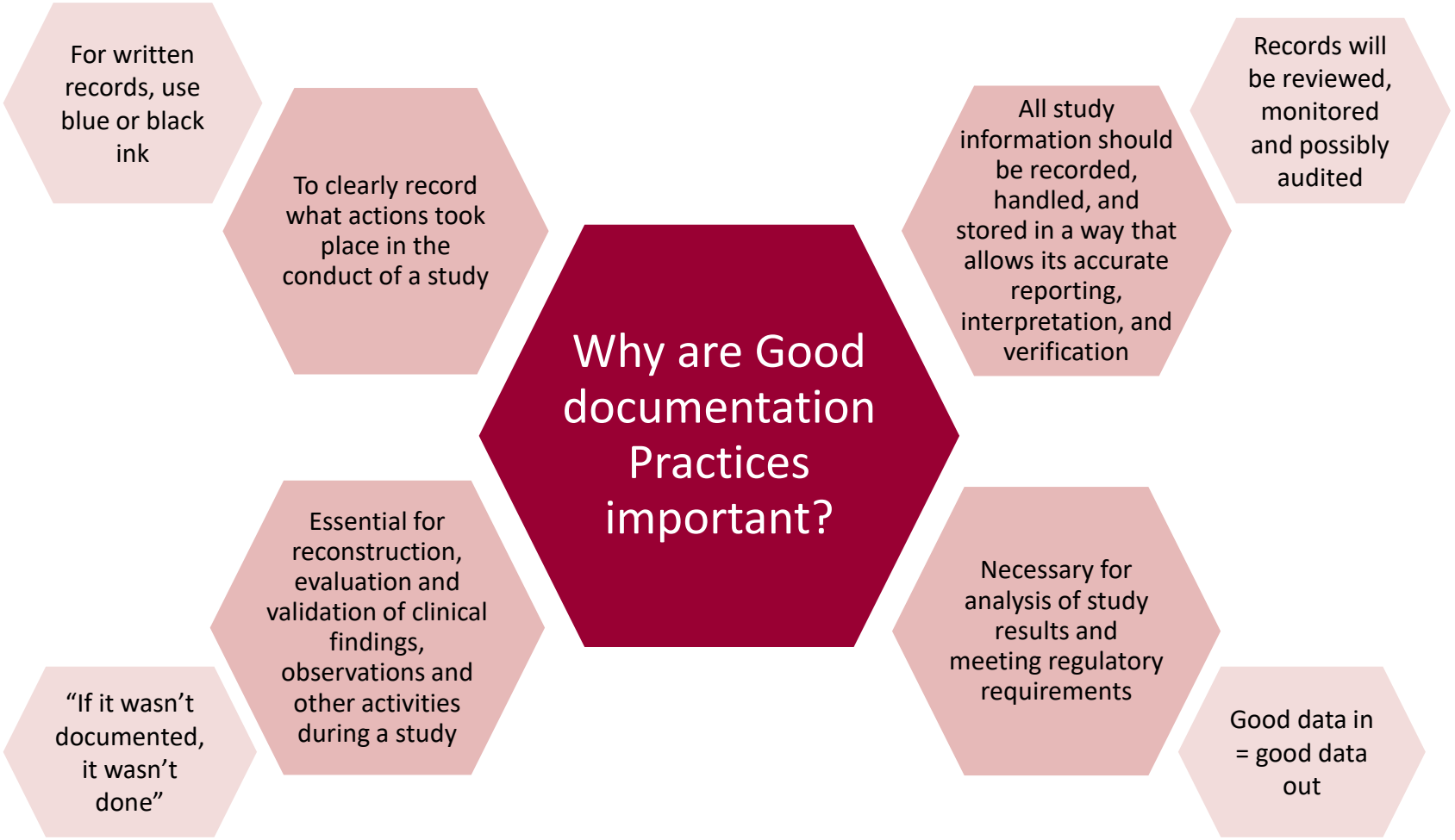
Source documents: Original documents, data and records which contain the source data.

Case Report Forms (CRFs)

Case Report Forms: A printed or electronic document designed to record all the protocol-required information to be reported to the sponsor on each trial subject/participant.

ALCOA-C Checklist

Good Documentation Practice (GDP)



GDP: ALCOA-C Principles in Action

Data Accuracy

- Recorded accurately
- Cross-checked for errors or inconsistences
- Non-intentionally misleading (prevents fraudulent entries, editable entries)

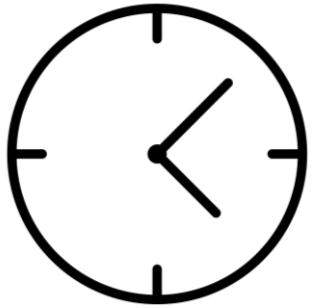
Data Integrity/Validation

- Genuinely true data
- Validated and supported/witnessed
- Relevant to the reporting requirement
- Not changeable after original record-keeping entry (extensively track changed)

Reporting/Record-Keeping Timelines

- Information is recorded contemporaneously
- Real-time record keeping including date stamps (typically automated on EMRs)
- Prevents errors from memory-uses and prevents editing of original data

Late Entry Timelines

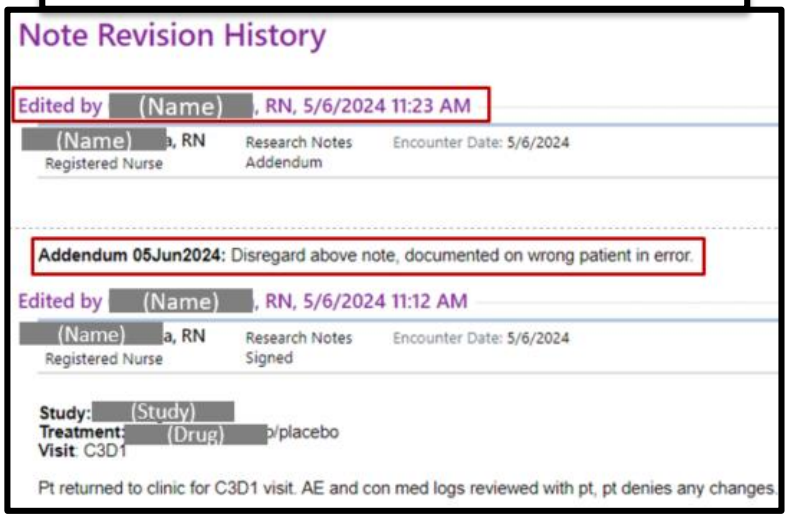


- Any documentation of a visit >24hrs is considered late. For proper GDP, use the following steps:
  1. Title the note as "*Late Entry*"
  2. Add the entry with the *date of the event* as well as the *date of the entry documentation*.
  3. Add an addenda to the next blank spot in the note to *indicate what was missed and why*

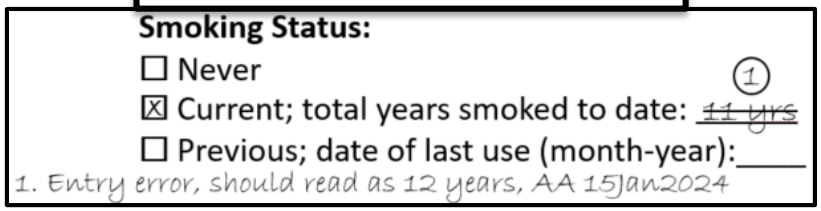
Source Document Corrections

DOs	DON'Ts
• Make corrections **attributable** (either via signing + dating or by using your individual electronic medical record login • Explain the **rationale** for your corrections • The person who wrote the original entry should be the **same person** making the correction • For electronic systems, ensure systems are **validated with an audit trail** that cannot be tampered with	• **Do not obstruct** the original entry to a point where it is not legible (e.g. white-out, scribbling out, overlay stickers, etc.) • **Do not alter** and entry **or disguise** an addition • **Do not use pencil** as it can be easily erased

GDP-Compliant Electronic Correction



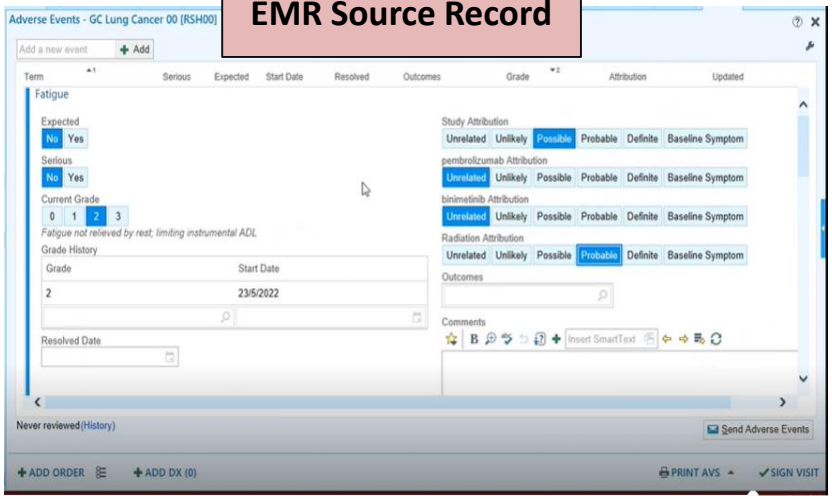
GDP-Compliant Paper Correction



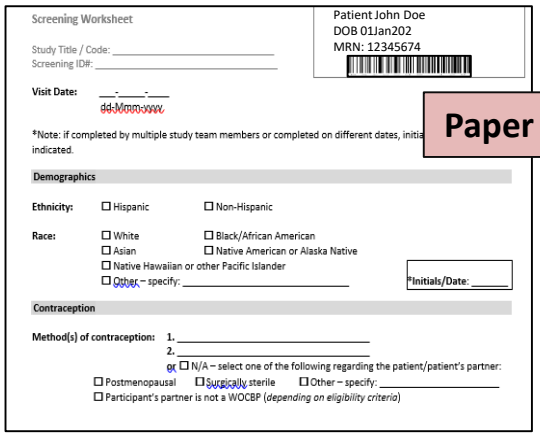
Source Versus CRFs

Source

EMR Source Record



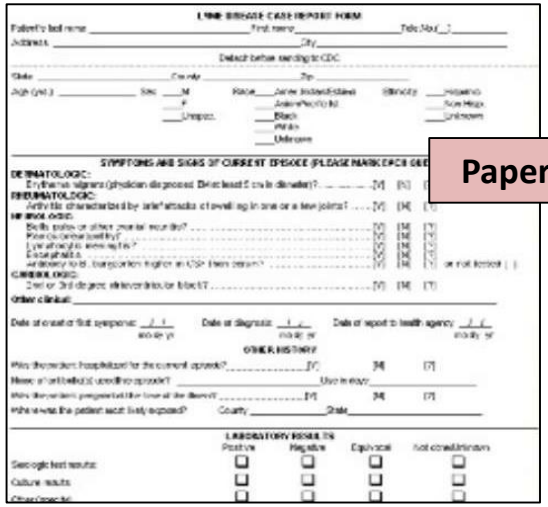
Paper Source Record



CRFs

e-CRF

Paper CRF



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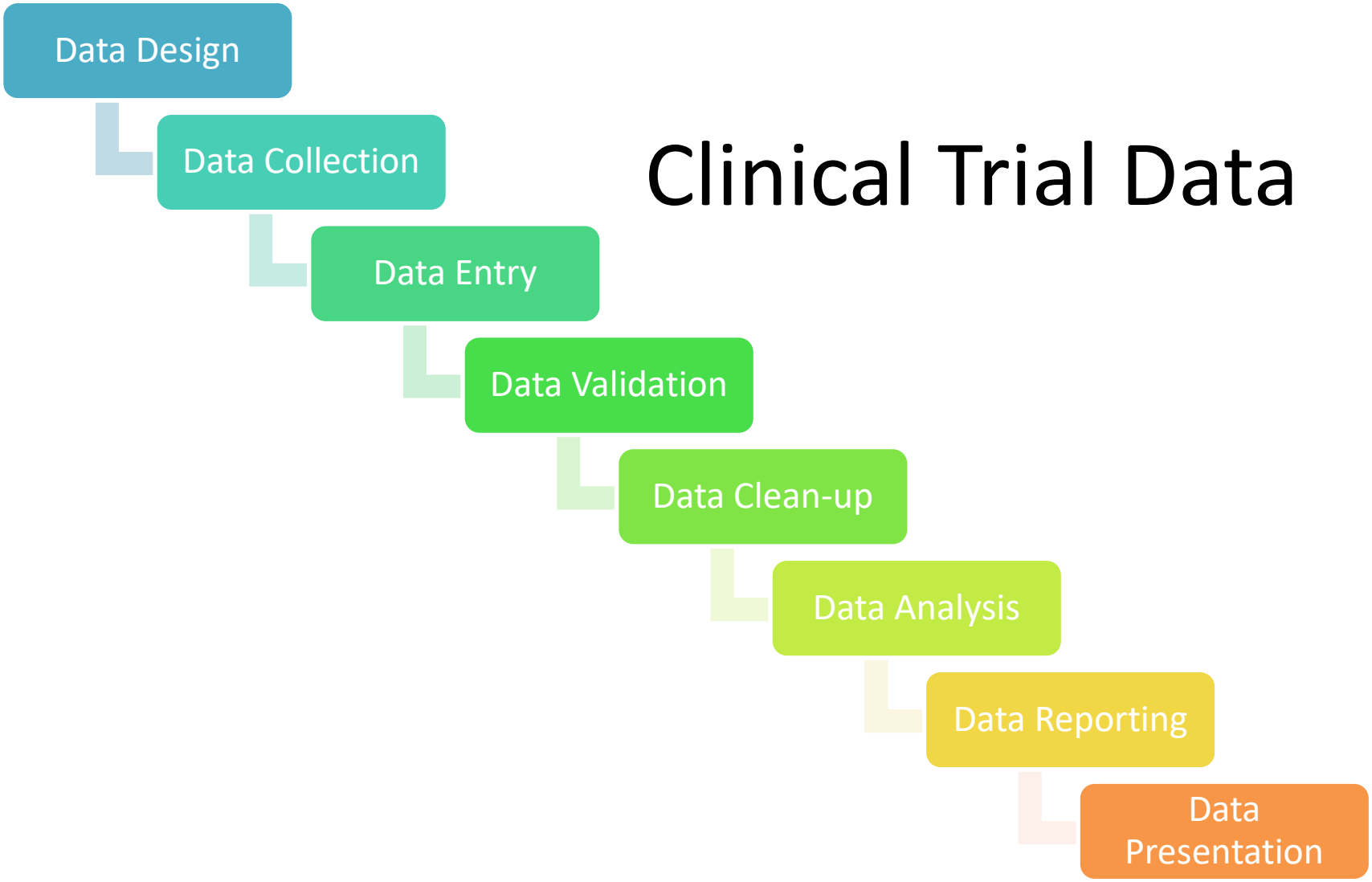
Clinical Trial Data



CRF Requirements

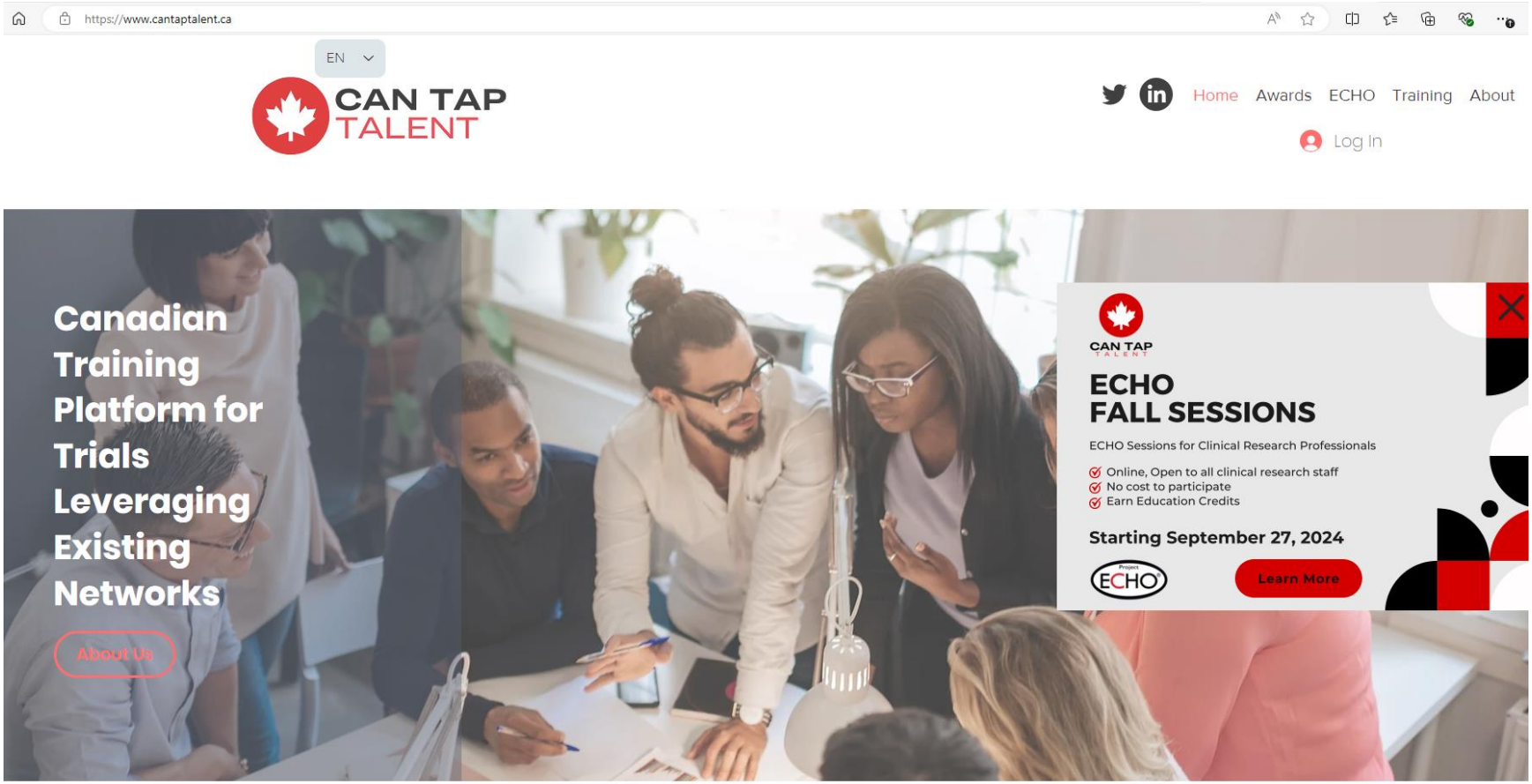
All CRF entries should comply with the following:

- Follow the ALCOA-C Principles
  - Accurate, Legible, Contemporaneous, Based on Original Source, Attributable, Complete
- Consistent with source
- Error corrections are attributable to the editor, dated and include and explanation for the change
- Include administrative information on each page as follows:
  - Study title/protocol information
  - Page numbering
  - Version dates
  - Study participant ID

Thank you!
Questions?

Emails: jasmine.grant@uhn.ca + efa.pasieka@uhn.ca

Training Available



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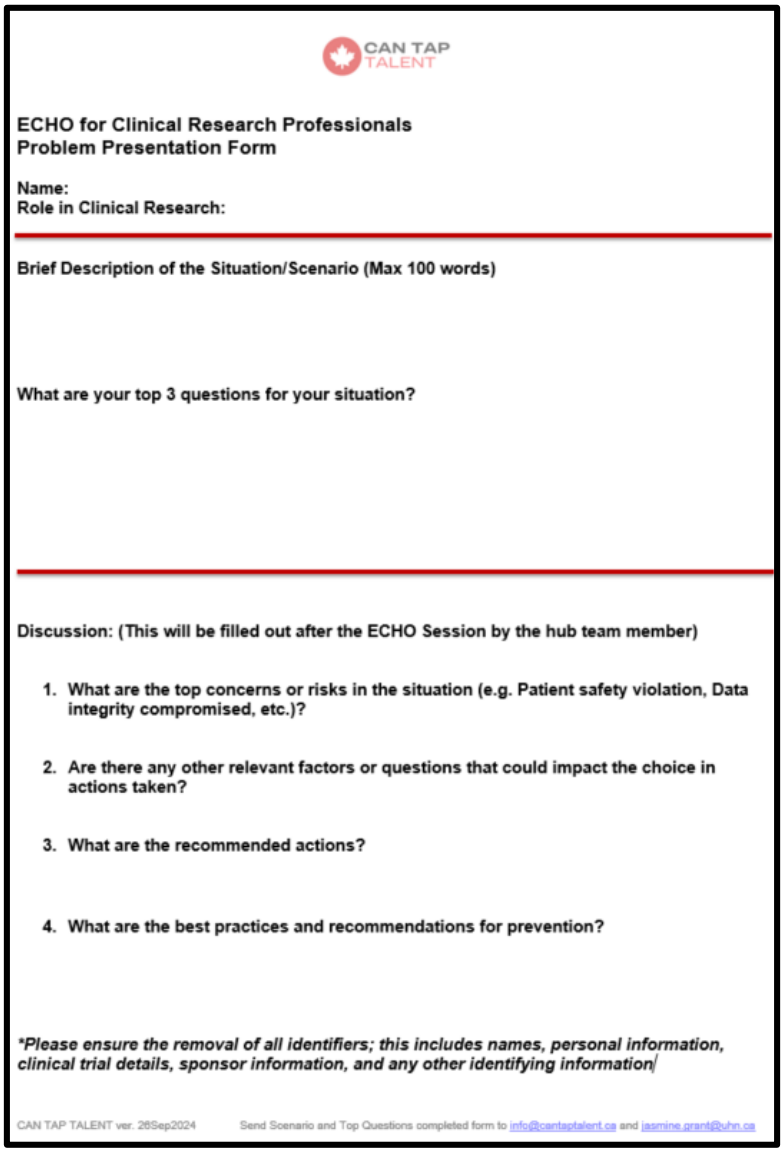
Case Report Examples

Active participation is encouraged

ECHO Case Reports



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ECHO for Clinical Research Professionals
Problem Presentation Form

Name:
Role in Clinical Research:

Brief Description of the Situation/Scenario (Max 100 words)

What are your top 3 questions for your situation?

Discussion: (This will be filled out after the ECHO Session by the hub team member)

1. **What are the top concerns or risks in the situation (e.g. Patient safety violation, Data integrity compromised, etc.)?**
2. **Are there any other relevant factors or questions that could impact the choice in actions taken?**
3. **What are the recommended actions?**
4. **What are the best practices and recommendations for prevention?**

Please ensure the removal of all identifiers; this includes names, personal information, clinical trial details, sponsor information, and any other identifying information

CAN TAP TALENT ver. 26Sep2024 Send Scenario and Top Questions completed form to info@cantaptalent.ca and jasmine.grant@uhn.ca

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Case Report Example 1

Brief Description of the Situation/Scenario

A patient had a history of tuberculosis from a positive skin test in the past. At a monitoring visit, the monitor issued a query asking for this item to be added to the baseline symptoms. The patient did not have active disease at the time and it was unclear how this should be documented.

What are your top 3 questions for your situation?

1. What defines a baseline symptom versus a medical history item?
2. Should we make the update in this case?
3. How should we clarify with the monitor in this case?

Case Report Example 2

Brief Description of the Situation/Scenario

A patient participant incorrectly spelled their name on the consent. The monitor brought this forward to the coordinator and asked for this to be corrected. The patient participant corrected their name however added the wrong date (not today's date – instead wrote the date of initial consent) beside their correction. The nurse at the time is no longer working in the department.

What are your top 3 questions for your situation?

1. How do we proceed with the correction from here?
2. Can we do any corrections since this happened 6 months ago and we cannot discuss it with the study nurse (as they have now left)?
3. Does the patient need to re-consent at this point?

Next ECHO:
October 25th at 12(EST)

Topic:
Managing Participant Safety & Risk in Clinical Trials

Connect with us! Info@cantaptalent.ca

Submit a case or propose a topic. All ideas welcome.