ECHO for Clinical Research Professionals (CRP) – Session Summary of (i) Key presentation and (ii) Problem discussion from session held on 27 February 2026

(i) KEY PRESENTATION:

How to Get the Most Out of Your Regulatory Writer & Save Time, Money & Grief
Lorraine Graves and Dr. Michael Weaver

The presentation was on maximizing the value of regulatory writers in clinical research to save time, money, and effort. Key points covered when and why you might use regulatory writers, core principles, documents produced, best practices, costs, and the role of AI.

The role of regulatory writers

- Regulatory writers specialize in formatting research into documents meeting requirements for Health Canada, FDA, and European agencies.
- They bring advanced degrees, clinical experience, and knowledge of agency priorities.
- Anyone can learn the skill; start with mentorship from seniors before going independent.

Key principles in working with regulatory writers

- Involve writers early in planning and budgeting.
- Agencies prioritize honesty, simplicity, consistency—not elegant style; avoid phrases like "approaching statistical significance" and report failures transparently.
- First dishonesty destroys credibility.
- Circulate written procedures; respect deadlines (consider academic schedules); designate one contact.
- Respond promptly to writer; decide final versions and stop revising; use templates flexibly.
- Set realistic deadlines—delays cost ~$1M/day via patent clock. List busy periods upfront.
- Submit info once only. Lead with findings/weaknesses; keep data regulator-friendly; avoid marketing spin.

Documents produced by regulatory writers

Regulatory writers produce essential documents that ensure compliance with agencies like Health Canada, FDA, and European bodies. They transform raw research into structured formats prioritized for transparency and regulatory review e.g. they produce Standard Operating Procedures (SOPs), protocols (with team input), clinical study reports, pediatric investigation plans, responses to ethics/regulatory bodies, New Drug Applications (NDAs) and Clinical Trial Applications (CTAs) to Health Canada.

Version control is important

- Use SharePoint (affordable, needs setup) or Viva Vault (expensive, for pharma).
- One person checks out at a time; writer controls access; no emailing versions outside system.

Costs and Hiring

- $200-300 CAD/hour for experienced; freelancers common, CROs add 50% markup.
- Avoid cheap non-English-first-language writers (leads to rework); hire juniors under mentors; request references.

Pre-clinical-trial-application (CTA) and Communication

- Health Canada requires pre-CTA meetings, where regulatory writers know exact agency needs.
- Open communication is essential; writers aren't statisticians or mind readers, so limit QC reviewers

AI in Regulatory Writing

- Useful for literature reviews/summaries but needs human judgment; garbage in/out; biases in data. For example, skin tones, where AI models trained on unrepresentative datasets (e.g., lighter skin) misdiagnose conditions in diverse populations; another example is fibroids; limited trial data skews AI predictions on treatment efficacy for uterine fibroids
- Won't replace writers due to critical thinking needs.

Capacity Building and Advice

- Canada lacks writers; train via AMWA, UChicago, ex-Humber College; network at conferences.
- Budget for patient advisors early with EDI; switch writers in long projects (5-10 years).

Q & A discussion related to these areas:

1. **Work scope of regulatory writers:**
   - Handles protocols (study designs with team input), clinical study reports (summarizing trial outcomes), pediatric investigation plans, ethics/FDA responses (clarifying reviewer concerns), and NDAs (full drug approval dossiers).

2. **Document Control Tools**
   - Recommends SharePoint for affordable, accessible version control (requires initial setup) or Viva Vault for enterprise pharma needs (higher cost but robust).
   - Ensures one person edits at a time, preventing version chaos.

3. **Pharma Budget Guidance**
   - Always consult the signing authority early for budget alignment.
   - Understand approval ceilings to avoid overruns on writer fees (~$200-300 CAD/hour).

4. **Finding Mentors**
   - Approach seniors respectfully for guidance before launching independent writing careers.
   - Build skills via AMWA training, UChicago courses, or networking at conferences.

(ii) PROBLEM DISCUSSION:

The problem presentation was on developing and negotiating study budgets. Specifically:

1. How to approach study implementation planning when study budgets are estimated based on the number of participants estimated to be enrolled on the study.
   Can the site ask the sponsor or negotiate an upfront advance payment to cover start-up costs study costs pending when enough participants are enrolled into the study?

2. What are the common clinical study budget tools and templates available in Canada?

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

Budget negotiation in clinical research poses challenges for Canadian sites, particularly when dealing with fixed costs and sponsor-driven payments. Research Ethics Board (REB) fees are non-negotiable, requiring upfront payment directly to the board, while coordinator startup and visit costs should be calculated by multiplying hourly rates by estimated hours, including all personnel involved. Budgets must be tailored to each study's department and specifics, with non-negotiable startup fees enforced to safeguard against unpaid preparatory work if studies halt early.

When a site acts as the sponsor, budgets separate fixed costs like personnel, ethics, pharmacy, and infrastructure from variable ones such as startup and per-patient reimbursements, emphasizing global equity in multi-site trials. As a participating site, costs reflect real coordinator time for recruitment, in-house pharmacy fees, and indirect institutional expenses, all raised upfront with sponsors.

Realistic enrollment estimates are crucial since per-patient or per-visit payments can be low without sufficient recruits. Pharmaceutical offers are often negotiable, especially in US-Canada multi-centers where Canadian sites may initially receive less; adding flat monthly administrative fees covers regulatory tasks, queries, and mid-study requests beyond patient-facing work.

Strong sites capable of recruiting 10+ patients can negotiate per-patient payments from $3K up to $11-17K in sponsor-driven studies by detailing tasks like scans, consenting, and samples to establish a baseline lump sum—approach pharma aggressively as they have resources, unlike limited-fund PI-initiated studies.

Standard budget templates include non-negotiable items like higher startup fees for pharma sponsors (invoiced on signing), REB/pharmacy/lab fees, annual renewals, early termination provisions, closeout administrative fees, and archiving costs even for electronic materials. Asking pharma contacts about signing authorities and approval ceilings helps align budget asks appropriately.

RESOURCES shared at the meeting:

- CANTRAIN: Online courses and resources on study budgeting via their LMS; register at https://wecantrain.ca/
- American Medical Writers Association (AMWA): Has chapters for regulatory writer training and capacity building.
- University of Chicago: Regulatory writing courses.
- Humber College, Toronto: Has programs on regulatory affairs and writing.
- Budget Templates: Heidy Morales, a Faculty Member shared two resources: (**Attached**: Basic Budget Template and Sample Budget with OH).

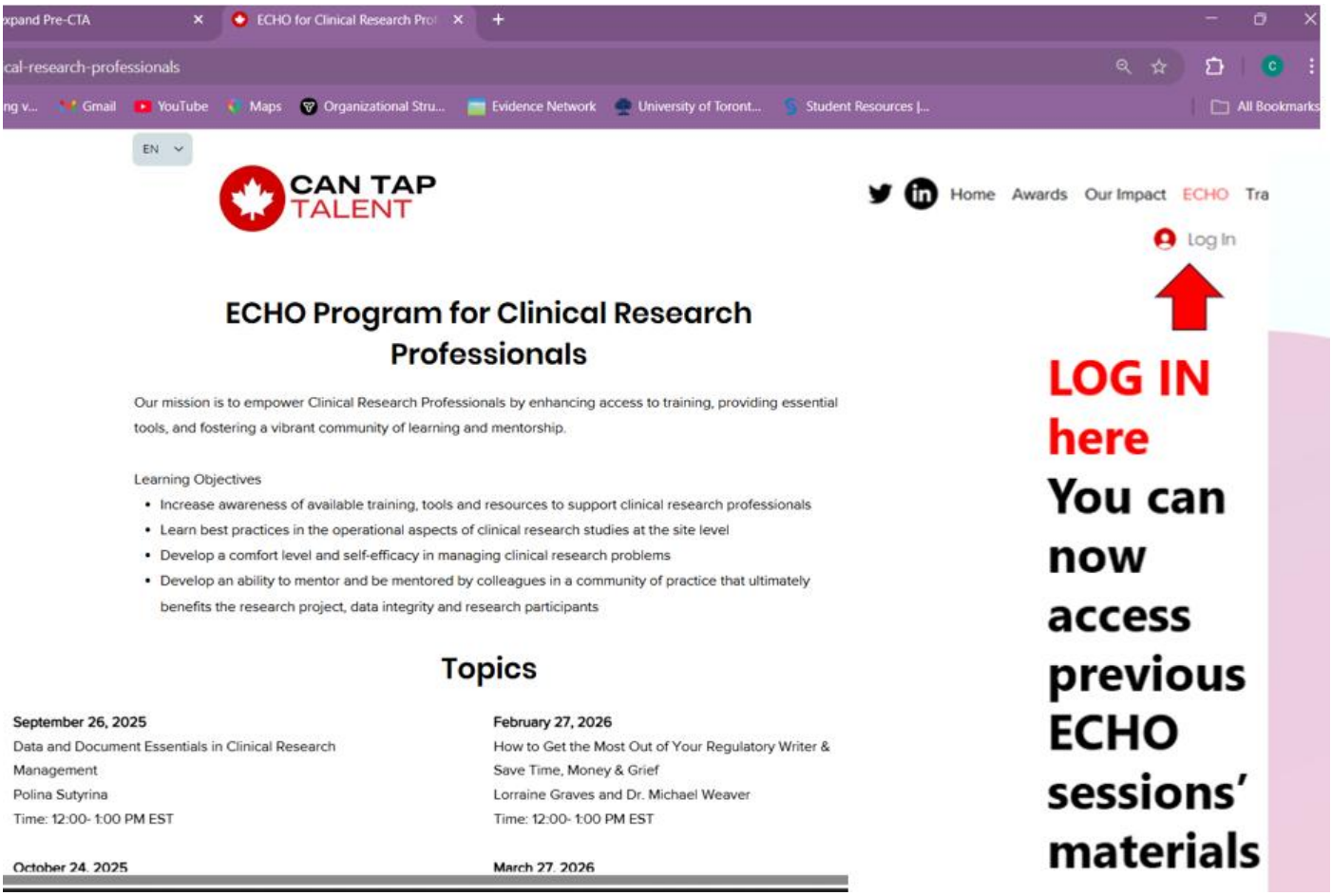
NEW

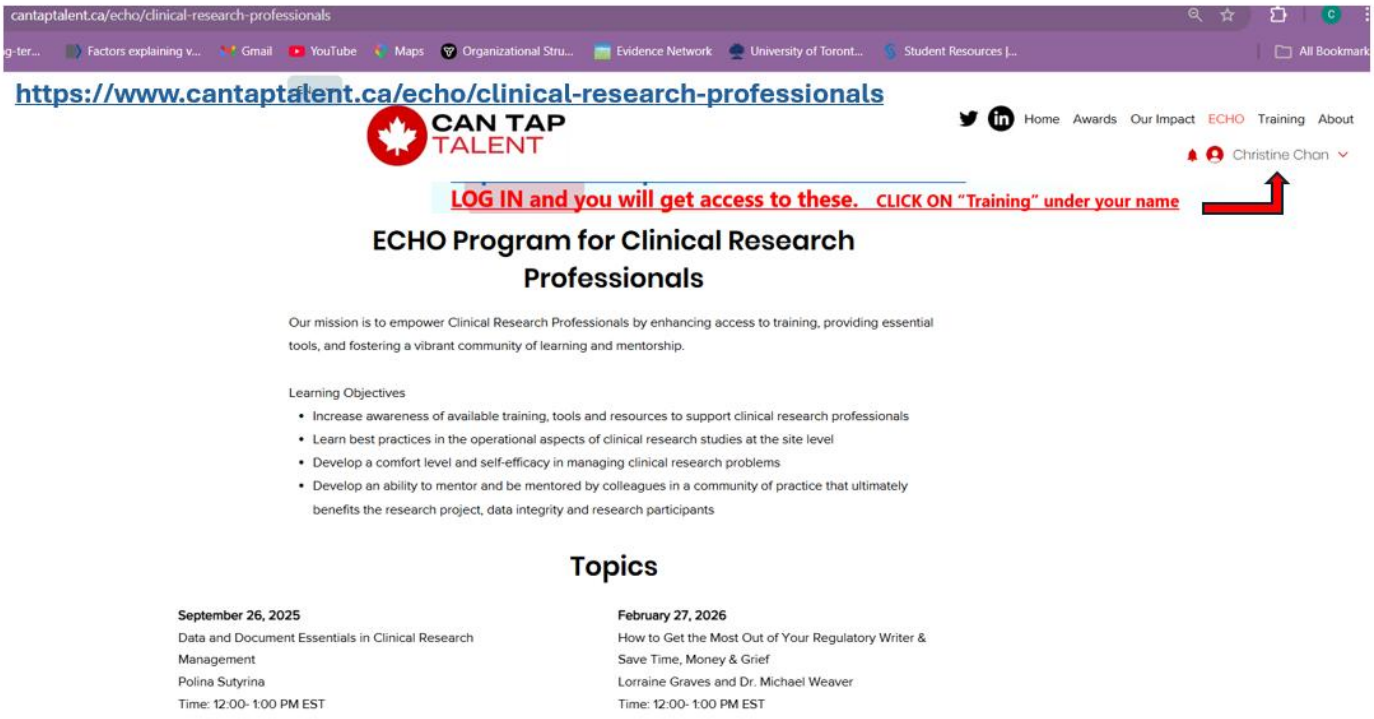
A repository of resources from previous ECHO sessions is now available on our website:

Go to https://www.cantaptalent.ca/echo/clinical-research-professionals

And click on LOG IN to register for the first time, then re-enter the website, and click “TRAINING” under your name, to see the resources.

See screenshots below and on the following page.





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