SUPPLEMENTARY APPPENDIX

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A. Interview guide for clinical trial investigators

Clinical trials are important for developing new drugs and providing the best medical care. However, about 4 in every 10 clinical trials are not published or only published after a long delay.[1] In this study, I am interested in trying to better understand this phenomenon, in part by talking to trial investigators about their experiences and views related to trials and trial reporting.

1. Introductory questions
    a. Could you tell me about the types of trials that you do? (e.g., research areas, phase of trials, single or multi-site trials, funding source)
    b. How much of your work involves conducting clinical trials? If this is only part of your work, how does it fit into your other work? (e.g., clinical practice, teaching, administration)
    c. Could you describe your typical role and responsibilities when conducting a clinical drug trial? (e.g., Principal Investigator/ co-investigator, trial design, recruiting patients, administering treatment, collecting data, reporting findings, grant-writing, liaising with sponsor)
    d. Optional, time-permitting: When you are conducting a trial, who would you typically have occasion to interact with during the course of a trial, from the planning to implementation and reporting? (e.g., co-investigators, clinical research coordinator, clinical research associate or monitor from contract research organization, project manager from contract research organization, patients)
2. Specific clinical drug trial
    a. Could I ask you to think about an example of a trial you were involved with as an investigator, which concluded prior to the last 12 months?
    b. Could you describe the trial?
        - Purpose of the trial (e.g., research question, drug, health condition, importance)
        - Generally how was it designed? (e.g., multi-site or single site, phase of trial, study population, intervention and control group, randomization, blinding, duration)
        - How was the trial funded? (e.g., industry, non-industry grant, unfunded)
    c. Experience of the trial
        - How did this trial come about?
        - Could you talk about your role and responsibilities in this trial?
        - How would you describe the experience of conducting this trial? (design, recruitment, treating patients, collecting data, interactions with others, etc.)
        - What were some things that went well in this trial? What were some challenges in this trial? (e.g., recruitment, treatment, analysis, reporting)
        - Was the trial completed? If so, when did the trial conclude (i.e., year and month)? (Could I ask what the main findings were?) If not, could you describe the factors that led to stopping the trial?
    d. Have the results of this trial been disseminated to the scientific community? If so, in what ways? (e.g., conference presentations, peer-reviewed publications, trial registry) Was the trial registered in clinicaltrials.gov or another registry?

- If the results have been reported in a registry or peer-reviewed journal: Could you talk about the events leading to the publication of the trial findings? (e.g., steps involved, any barriers or challenges) How long after trial completion were results reported?
- If the results have not been reported in a registry or peer-reviewed journal (more than 1 year following completion of the trial): It is relatively common that results from a trial are not published. Could you talk about events leading to the trial findings not being reported in this particular case? (For example, in comparison to trials you have been involved with that were published, what differed in this trial?)

3. Experience in other clinical drug trials
   a. If the trial discussed above was not published
      - Was your experience in the trial you just described typical or different from other trials you have been involved with, particularly with respect to delays or challenges in reporting the trial results? Could you provide an example? (purpose, design, role, experience, recruitment, treatment, analysis, results, reporting, interactions with others)
   b. If the trial discussed above was published
      - Could I ask whether you have participated as an investigator in trials for which the findings were not published in either a registry or peer-reviewed journal (1 or 2 years after trial completion)?
      - It is relatively common that results from a trial are not published. If we consider a trial you participated in that was not published, could you talk about events leading to the trial findings not being reported? (For example, in comparison to the trial you described above, what differed in this trial?)
      - Was your experience in the trial you just described typical or different from other trials you have been involved with, particularly with respect to delays or challenges in reporting the trial results? Could you provide an example?
   c. In your experience as a trialist, have you encountered (or could you talk more about) barriers to reporting the trial's findings? If so, could you describe those? (e.g., difficulties with co-investigators, constraints in clinical trial agreements or informal influences from a sponsor)
   d. Optional, time-permitting: Are you aware of instances in which colleagues have conducted trials and the results have not been reported? Could you describe an example? Could you talk about events leading to the results not being published? Are you aware of (or could you talk more about) barriers to reporting trial results that have been experienced by colleagues? (Could you give an example?)

e. Possible follow-up questions, if applicable:
    - How was the decision made on whether to publish?
    - Was the sponsor able to influence the decision to publish? If so, how did this occur? (clinical trial agreement, control of data, funding dependency)
    - In your experience of multi-site trials, is a given site allowed access to data from other sites? Does this differ between industry and investigator-initiated trials?
    - Could you talk more about an investigator's incentive to publish positive vs. negative findings?

4. Addressing the issue of unpublished trials
    a. In your view, how important is it to address the issue that many trials are not published, or not published within 1 or 2 years of trial completion?
        - Could you explain why you think that?
        - Do you feel there is a responsibility to the trial participant to ensure that trials are published?
    b. What do you think would help ensure that trial results are published? (e.g., resources, policies, education)
        - For example, in the unpublished trials that you or your colleagues have participated in, can you think of something that might have helped ensure that a trial was reported?
        - Based on your experience, do you have any advice for clinical investigators for navigating challenges or barriers to reporting trial results?
    c. Similarly, what role would you envision for others to help ensure that clinical trials are reported:
        - Research ethics boards?
        - Administrators at universities or other research institutions?
        - Health Canada?
    d. As academic or career incentives may be related to delays in publication or whether results are reported, do you think anything could be done to change incentives?

5. Additional comments
    a. Is there something we have not talked about that would help me to understand the experience of conducting a clinical trial?
    b. Similarly, is there something we have not talked about that would contribute to understanding of the phenomenon of unpublished trials?

Short-answer questions (Based on background questions from survey by Rochon et al 2011.)[2]

6. Could you describe your primary appointment?
   a. University or academic teaching hospital
   b. Non-academic community-based hospital
   c. Other (e.g., private practice, cancer centre, pharmaceutical)
7. How many years experience do you have in conducting clinical trials?
   a. <=5 years
   b. >5 years
8. What types of funding have the trials you have conducted had?
   a. Non-industry trials only
   b. Industry trials only
   c. Both industry and non-industry trials
9. What is the most senior role you have had in a clinical trial?
   a. Principal investigator for the entire trial
   b. Principal investigator for site
   c. Other
10. Have you conducted the following types of trials?
    a. Only single site trials
    b. Only multiple site trials
    c. Both single and multiple site trials

B. Interview guide for research administrators

Clinical trials are important for developing new drugs and providing the best medical care. However, about 4 in every 10 clinical trials are not published or only published after a long delay.[1] In this study, I am interested in trying to better understand this phenomenon, in part by talking to trial investigators and research administrators about their experiences and views related to trials and trial reporting.

What follows include questions for (1) administrators involved in oversight of clinical research, and (2) administrators involved with oversight, review or negotiation of clinical trial agreements or other agreements with industry sponsors. Questions specific primarily to one of these groups are denoted A1 or A2, respectively.

1. Introductory questions
    a. Could you describe your experience with
        - A1: Administration of research including clinical trials? (Do you also have experience conducting clinical trials? If so, could you describe your experience conducting clinical trials?)
        - A2: Review, drafting or negotiation of clinical trial agreements with industry funders?
    b. What is your current role and responsibilities with respect to involvement in
        - A1: Administration of research including clinical trials?
        - A2: Clinical trial agreements (CTAs) with industry funders? What types of clinical trial agreements are you involved with? (e.g., CTAs for industry-sponsored trials, CTAs for investigator-initiated trials with industry funding)
2. Research institution policies on dissemination of trial research (A1)
    a. In your view, does your research institution have a role in ensuring that the results of trials conducted at your institution or affiliated institutions are published? How do you see your institution's role in that?
    b. Does your research institution have a policy to require trial registration? Does policy also require reporting of findings in a trial registry or in a peer-reviewed journal? If so, is reporting required to occur within a particular timeframe?
    c. Does your research institution monitor the proportion of clinical trials conducted at your institution that are published in a timely way or do other monitoring of trial reporting?
    d. Does your research institution have other types of policies to try to ensure that trials conducted at your institution or affiliated institutions are published?
    e. Has your research institution considered introducing such policies or additional policies? Could you elaborate on the types of policies considered?
3. Clinical trial agreements (A2)
    a. Review of agreements
        - Does your research institution require that clinical trial agreements between researchers and funders of clinical trials be reviewed by the institution? Are you aware of whether there are sometimes publication agreements with industry funders separate from clinical trial agreements? If so, would your institution also review the publication agreements?

- For university administrators: If an investigator affiliated with the university is involved in a clinical trial with industry funding, would the CTA typically be reviewed by your office? Are there cases where the CTA would only be reviewed by a hospital affiliated with the university?

b. For CTAs for clinical trials of pharmaceutical drugs, who would the parties to the agreement typically be? For example, would the industry partner typically be a drug company or a contract research organization? (Are independent academic research organizations sometimes involved?)

c. Does your research institution allow clauses in clinical trial agreements with industry relating to clinical trials in which:
   - The funder can decide on whether trial results are published? If so, how common would that be in CTAs for industry-sponsored trials (or in investigator-initiated trials that have industry funding?
   - The funder can delay publication of trials results? If so, what types of delays are permitted in terms of duration and rationale? (e.g., delays of 6 months to seek patent protection for a drug)

d. Ownership of data and access to data
   - Does your research institution allow clauses in clinical trial agreements with industry in which the funder would have ownership of the data? How common would it be for the industry funder to own the data in industry-sponsored clinical trials? Does this differ in investigator-initiated trials that have industry funding, as compared to industry-sponsored trials?
   - If so, in the context of a multi-site trial, how common would it be for the clinical trial agreement with industry to specify that investigators have access to data collected from all sites of the trial? Again, does this differ in investigator-initiated trials that have industry funding, as compared to industry-sponsored trials? In CTAs for multi-site trials, how is the issue of access to data from all sites by investigators typically addressed, if at all?(e.g., who has access, process for accessing data from all sites)
   - Are you aware of contracts which specify that an academic research organization would be part of the study organization in an industry-sponsored study and must have an identical copy of the study database? (to allow shared data access and validation of analyses conducted by the sponsor)

e. Protection of the right to publish trial results
   - Do some clinical trial agreements require publication of trial results in a peer-reviewed journal or trial registry? (in investigator-initiated trials with industry funding, in industry-sponsored trials)
   - Does your institution require language to be included in clinical trial agreements with industry that would protect the investigator's right to publish clinical trial results? What type of language is required?
   - If language <u>is required</u> that would protect the investigator's right to publish: In the context of a multi-site trial, would the investigator's right to publish trial results apply only to data from the local site or would it include the right to publish results based on all of the data collected in the trial? Would this apply to industry trials or only investigator-initiated trials with industry funding?

- Does your institution require language to be included in clinical trial agreements with industry to set out timelines for publication? If so, what would need to be specified?

f. Do you feel that clinical trial agreements (or other agreements such as publication agreements) between your research institution and industry provide sufficient protection of the right to publish clinical trial results? Or do you feel this could be strengthened?

g. Are you aware of difficulties or challenges in negotiating clinical trial agreements with industry? Could you describe some of the challenges?

h. Publication agreements. If publication agreements are reviewed, what issues are typically addressed in the publication agreement and how do these compare with CTAs?

i. Some investigators have expressed that industry funders can sometimes influence the decision to publish clinical trial findings. Do you have thoughts on how clinical trial agreements may help create the context for that to occur?

4. Experience or examples related to dissemination of research (A1)

   a. It is relatively common that results from clinical trials are not published. Could I ask if you have become aware of cases of unpublished trials at your research institution during your time as an administrator? If so, could you describe an example?

   b. In your view, how does the case you have described relate more generally to policies or practices at your research institution with respect to dissemination of trial research? Would you say the case you described reflects a pattern?

   c. Are you aware of cases where investigators from your research institution have had difficulties with industry funders in relation to publishing of trial findings? Could you describe a case? Again, how would you relate this case to policies or practices at your research institution with respect to dissemination of trial research?

5. Academic or career incentives (A1)

   Some trial investigators I have spoken to have expressed the view that there is a stronger incentive to publish trials with positive findings as compared to negative trials. For example, positive trials might be more likely to lead to additional grant funding, and there is a perception among some investigators that positive trials are easier to publish in prestigious journals, which could help their careers.

   a. In your view, is it possible that trial investigators at your research institution have a stronger incentive to publish positive trials as compared to negative trials?

   b. Do you think that it would be worthwhile to try to change incentives in a way which might encourage full reporting of trials? If so, how might this be done?

6. Addressing the issue of unpublished trials
    a. A1: In your view, how important is it to address the issue that many trials are not published, or not published within 1 or 2 years of trial completion?
        - Could you explain why you think that?
        - Do you feel there is a responsibility to the trial participant to ensure that trials are published?
    b. A1/A2: Are there policies or actions your research institution, or other research institutions, could take to better address the need for trial findings to be disseminated? Could you elaborate on those?
    c. A1/A2: Are there policies or actions that could be taken by others to help ensure that clinical trials are reported, such as:
        - Research ethics boards?
        - Health Canada?
    d. A1/A2: Are there policies at your research institution that it might be useful for me to review to understand issues relating to trial reporting and/or clinical trial agreements?
7. Additional comments (A1/A2)

    Is there something we have not talked about that would contribute to understanding of policy issues regarding trial reporting?

Short-answer questions (A1/A2) (Based on background questions from survey by Rochon et al 2011.)[2]

8. Could you describe your primary appointment?
    a. University or academic teaching hospital
    b. Non-academic community-based hospital
    c. Other (e.g., private practice, cancer centre, pharmaceutical)

9. How many years experience do you have either in administration at a research institution that conducts clinical trials?
    a. <=5 years
    b. >5 years

C. Interview guide for clinical research ethics board members

Clinical trials are important for developing new drugs and providing the best medical care. However, about 4 in every 10 clinical trials are not published or only published after a long delay.[1] In this study, I am interested in trying to better understand this phenomenon, in part by talking to members of research ethics boards about experiences and relevant policies.

1. Introductory questions
    a. Could I ask you how long you have been involved with ethics review of clinical trials?
    b. Could you describe your current role in ethics review of clinical trials? Has your role changed over time, since you became involved?
    c. Do you also have experience conducting clinical trials? If so, could you describe your experience conducting clinical trials?
2. Review of clinical trials and clinical trial reporting
    a. Could I ask you to describe the typical process for review of a clinical trial, from your point of view as an REB member (for example, in relation to a clinical drug trial that has come before the REB)? (documents, key questions, discussion, time required)
    b. Does the REB have a policy to require registration of clinical trials prior to enrolment of patients? If so, does the REB require that the trial be registered as a condition of ethics approval?
    c. Does the REB require that trial results are reported in a trial registry or in a peer-reviewed journal? If so, is reporting required to occur within a particular timeframe?
    d. Does the REB track whether each trial has been registered and whether results have been reported in a registry or peer-reviewed journal? If so, are you aware of whether the REB monitors the proportion of trials that have been registered and/or have reported results in registries or peer-reviewed journals?
    e. Are the past practices of investigators in terms of clinical trial registration or reporting considered at the time of ethics review for a clinical trial?
3. Protocols, contracts and other agreements with funders
    a. Responsibility for review
        - Does the REB review not only protocols but also contracts and other agreements between clinical trial investigators and funders?
        - Or is review of contracts and other agreements delegated to others at your research institution? If so, who has responsibility for reviewing these?
        - If responsibilities are divided, are the agreements reviewed for consistency periodically?
    b. Does the REB/ your research institution allow clauses in protocols, or clinical trial agreements with industry funders, in which:
        - The funder can decide on whether trial results are published?
        - The funder would have ownership of the data and may not give permission to site investigators to access all of the data collected in the trial?

- The funder can delay publication of trials results? If so, what types of delays are permitted in terms of duration and rationale? (e.g., delays of 6 months to seek patent protection for a drug)

c. Protection of the right to publish trial results
   - Does the REB/ your research institution require language to be included in protocols or clinical trial agreements with industry that would protect the investigator's right to publish clinical trial results? What type of language is required?
   - If language <u>is required</u> that would protect the investigator's right to publish: In the context of a multi-site trial, would the investigator's right to publish trial results apply only to data from the local site or would it include the right to publish results based on all of the data collected in the trial? Would this apply to industry trials or only investigator-initiated trials with industry funding?
   - Does the REB/ your research institution require language to be included in protocols or clinical trial agreements with industry to set out timelines for publication? If so, what would need to be specified?

d. Do you feel that protocols, or clinical trial agreements between your research institution and industry, provide sufficient protection of the right to publish clinical trial results? Or do you feel this could be strengthened?

4. Experience related to dissemination of research
   a. It is relatively common that results from clinical trials are not published. Could I ask whether, in your experience as an REB member, you have become aware of clinical trials that have not be published? If so, could you describe an example?
   b. In your view, how does the case you have described relate more generally to policies or practices at the REB/ your research institution with respect to dissemination of trial research? Would you say the case you described reflects a pattern?
   c. Potential influence of industry funders
      - Are you aware of cases where investigators from your research institution have had difficulties with industry funders in relation to publishing of trial findings? Could you describe a case? Again, how would you relate this case to policies or practices at the REB/ your research institution with respect to dissemination of trial research?
      - In your experience in ethics review, have you seen protocols or clinical trial agreements for industry-funded trials that may constrain full reporting of clinical trial results? If so, could you describe an example? Could this still occur or would current policy or practices likely prevent this?
      - In your experience, have observed other barriers to publications due to influence of industry funders? If so, could you describe an example? Could this still occur or would current policy or practices likely prevent this?

5. Addressing the issue of unpublished trials
   a. In your view, how important is it to address the issue that many trials are not published, or not published within 1 or 2 years of trial completion?
      - Could you explain why you think that?
      - Do you feel there is a responsibility to the trial participant to ensure that trials are published?

- Do you think this relates to informed consent or other aspects of research ethics?

b. How do you view the role of REBs, if any, in addressing the issue of unpublished trials? Are there other policies or actions that could be taken on this issue? What barriers to such policies or actions exist, or what could facilitate these?
c. Are there policies or actions that could be taken by others to help ensure that clinical trials are reported, such as:
    - Others at research institutions?
    - Health Canada?
d. Is there something we have not talked about that would help contribute to understanding why many trials are not published or the role of the REB in addressing this?

Short-answer questions

How many years experience do you have as a member of an REB?

a. 1 to 2 years
b. 3 to 5 years
c. >5 years

D. Interview guide for clinical trial participants

1. Involvement and expectations
    a. How did you come to be involved in the trial? (e.g., sought trial to participate in, invited by physician, saw advertisement; change in health condition)
    b. How did you understand the purpose of the trial? (e.g., drug, health condition, research question, outcomes, efficacy, safety and efficacy for regulatory approval, postmarket safety)
    c. How would you describe what motivated you to enroll in the trial?
        - How important did you feel it was to get access to the treatment?
        - How important did you feel it was that it might help future patients?
        - How important were other factors in your decision to enroll in the trial? (e.g., having your health monitored closely, having a good relationship with your physician)
    d. Do you recall how you felt about enrolling in the trial? What were your expectations of the trial?
    e. What did you understand about how the trial was designed? (e.g., controlled or not, placebo or comparison drug, randomization, blinding, duration of treatment, study population) What did you understand to be the potential benefits or risks of participation?
    f. How was information about the purpose, design and benefits or risks of participation in the trial communicated to you?
2. Activities in the trial
    a. When did your participation in the trial begin and end?
    b. What did participating in the trial involve? (e.g., taking medication, clinic visits or medical tests)
    c. Did you receive the trial medication from your regular physician? Who did you interact with as part of the trial? (e.g., clinical research coordinator, regular physician, other physician or nurses)
    d. What did participating require of you, in comparison to your prior therapy or routine? (e.g., travel to clinic, investment of time)
3. Experience of trial
    a. How would you describe the experience of participating in the trial? (e.g., what was it like to participate in the trial, what did you think of the experience at the time, how did it feel to participate in the trial)
    b. Did you feel you benefited from participating in the trial? In what ways? (e.g., health benefits, satisfaction)
    c. Did you feel you experienced any adverse effects from the treatment or participation in the trial? How would you describe these effects? (e.g., health effects, stress)
    d. Did you complete the treatment in the trial? If not, what led to withdrawal from the trial?
    e. Are you aware of whether the trial has concluded? Do you know when it was (or was expected to be) concluded?

4. Reporting of trial results

   Clinical trials are important for developing new drugs and providing the best medical care. However, about 4 in every 10 clinical trials are not published or only published after a long delay.[1] When clinical drug trials remain unpublished, they are unavailable to the larger wider scientific community. This makes it harder for researchers, doctors and others to understand which drugs are safe and effective.

   a. If the trial has concluded:
      - Were you informed about the results of the trial? If so, how did this occur? How did you feel about being informed about trial findings (or about not being informed)?
      - Are you aware of whether results of the trial have been published?
        - If aware, how did you become aware of this? How do you feel about the fact the results were published / were not published?
        - If not aware, how do you think you would feel if the results of the trial were not published?

   b. If the trial has not concluded:
      - How do you think you would feel if the results of the trial were not published?

   c. Importance of reporting and of participants being informed of results:
      - Given your experience as a trial participant, how would you describe the importance of whether trial results are published? Could you explain why you think that?
      - How would you describe the importance of trial participants being informed of the results of the trial they participated in? If you feel this to be important, what do you think would be a good way to communicate the findings to participants? (e.g., summary in lay language or information shared by physician)

   d. Additional comments:
      - Is there something we have not talked about that you think I should know to understand your experience of the trial?
      - Similarly, is there something we have not discussed that you think I should know to understand your views on the publication of trial results?

Short answer questions

5. Could I ask you to tell me your age? (<30 years, 30-39, 40-49, 50-64, >=65)
6. Could I ask you the highest level of education that you have completed? (<= grade 8, high school, community college, university, graduate school)

E. Additional detail on study methods

Consistent with grounded theory, our research involved comparative analysis of the accounts of interview participants, attention to actions and processes, and systematic analysis of data to develop conceptual understanding.[3] As these analytic strategies are helpful for elucidating social processes,[3 4] this approach was well-suited to analyzing the complex process of clinical trial reporting.

We aimed to include participants from different provinces to capture variation in experiences related to differences in policy and practice across institutions and provinces in Canada. The analysis presented in this paper was informed by interviews with all participants but draws most directly on interviews with those involved in the conduct, administration or ethical review of clinical trials.

The research team for this study included members with expertise in clinical trials, medicine, pharmacoepidemiology, pharmaceutical policy and regulation, qualitative methods, and sociology. No prior relationship existed between the researchers and interview participants. Reporting of this study followed the Standards for Reporting Qualitative Research (SRQR).[5]

Recruitment

Recruitment of past trial participants involved newspaper advertising, requesting cooperation from clinical research coordinators and research centres to seek consent for us to contact individuals who had participated in clinical trials at their centres, and following up by email or telephone with individuals who expressed interest or agreed to be contacted. We identified other types of prospective participants in ClinicalTrials.gov,[6] the Canadian Clinical Trials Asset Map database,[7] and the websites of research institutions and ethics boards, and invited participation through an email with an accompanying cover letter, follow-up emails, and snowball sampling. We offered a $50 honorarium to trial participants and trial investigators for their participation.

Data collection and analysis

The research primarily involved one-on-one interviews, with the exception of an interview involving both a trial investigator and a clinical research coordinator. Interviews were held in person or by telephone. Following the constant comparative method of grounded theory, a key strategy throughout the coding process involved comparing incidents described by interview participants to other incidents which were similarly coded.[38]

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