THE HEATHER CUTLER FOUNDATION

Pancreatic Cancer Policy Research Program

Modernizing the Framework for Clinical Trials

Feedback on Draft Guidance Documents

Cover Letter and Annexes A, B, and C — April 2026

Cover Letter

April 2026

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Biologic and Radiopharmaceutical Drugs Directorate: brdd-cppic_brdd-cppci@hc-sc.gc.ca
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Re: Modernizing the framework for clinical trials — Guidance consultation comments

Dear Consultation Team,

The Heather Cutler Foundation is a Canadian registered charity dedicated to improving outcomes for people affected by pancreatic cancer. Our work focuses on policy research, patient advocacy, and equitable access to cancer care, with particular attention to communities in Atlantic Canada.

We are submitting feedback on the three draft guidance documents published alongside Health Canada's proposed Clinical Trials Regulations (opened December 20, 2025). We participate in this consultation as a patient safety and advocacy organization, one of the stakeholder groups Health Canada has specifically invited to contribute.

This document contains our cover letter and three annexes. Each annex addresses one guidance document and is addressed to the corresponding directorate as instructed in the consultation guidelines. Our comments draw on publicly available federal and provincial data

and Health Canada's own published regulatory guidance. We do not claim accredited or peer-reviewed research status.

Our principal asks across the three guidance documents are:

- Annex A (Clinical Trial Applications): Publish oncology-specific worked examples for the Category B1/B2 distinction, and clarify eligibility criteria for smaller Atlantic Canadian institutions to participate in the national approved REB list.
- Annex B (SGBA+ Action Plan): Explicitly include rural and remote geographic status as a demographic variable in the SGBA+ framework, particularly for diseases like pancreatic cancer that disproportionately affect older rural populations.
- Annex C (GUI-0100): Commit to a defined maximum review timeline for Category C oncology trial authorization, and clarify how protocol amendments are handled under whole-trial authorization for adaptive trial designs.

We thank Health Canada for the opportunity to contribute and for the extended consultation deadline of April 19, 2026.

Respectfully submitted,

The Heather Cutler Foundation
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Annex A — Draft Guidance on Clinical Trial Applications for Sponsors

CC Directorate	Pharmaceutical Drugs Directorate | bpsip-bpspiconsultation@hc-sc.gc.ca

This annex provides the Heather Cutler Foundation's feedback on the draft guidance document for clinical trial sponsors on clinical trial applications, as updated under the proposed Clinical Trials Regulations framework.

Clarity on Oncology Trial Categorization (B1 vs. B2)

The draft guidance describes the risk-based category framework but does not provide oncology-specific examples to support institutional interpretation of the B1/B2 boundary. For pancreatic cancer trials, this distinction has real practical consequences.

A trial combining two approved chemotherapy agents in a new dosing sequence — for example, components of established regimens like FOLFIRINOX or gemcitabine/nab-paclitaxel tested in a modified schedule — may have a reasonable evidentiary foundation under B1. However, without examples in the guidance, institutions and REBs will apply inconsistent interpretations, creating delays at the site approval stage even if federal timelines improve.

Is the guidance clear and easy to understand? Largely yes for well-resourced sponsors with dedicated regulatory affairs staff. Less so for smaller academic institutions and community hospitals in Atlantic Canada that may lack in-house regulatory expertise. A plain-language summary or decision-tree checklist for categorization would meaningfully support compliance at these sites.

Does it provide enough detail to support compliance? Not yet for oncology combination trials. The following additions would help:

- Disease-specific worked examples, particularly for oncology regimens using approved drugs in new sequences or patient populations;
- A clear definition of what constitutes "established practice" for B1 purposes — whether this refers to published clinical guidelines, regulatory precedent, or professional standards bodies;
- Guidance on how institutions should document their categorization rationale, so that REB and site review processes are consistent across Canada.

Are there resources that would help your organization implement the guidance? Yes. A categorization checklist or worked-example supplement, particularly one that includes oncology scenarios, would be valuable for smaller academic sites. A short FAQ document would support patient advocacy organizations that advise sponsors or participate in trial design.

Atlantic Institution Eligibility for the National Approved REB List

The draft guidance does not address eligibility criteria for the national approved REB list in detail. For Atlantic Canada, this is a significant gap. The current requirement for separate institutional REB processes at each site creates a meaningful barrier to participation in national and international pancreatic cancer trials — particularly for smaller centres serving rural and remote populations.

Atlantic cancer research institutions include QEII Health Sciences Centre (NS), Saint John Regional Hospital (NB), Eastern Health / Dr. H. Bliss Murphy Cancer Centre (NL), and the Queen Elizabeth Hospital (PEI). These centres serve smaller patient populations but face the same multi-site administrative burden as large academic centres.

How will the proposed approach impact your organization? Positively, if Atlantic institutions can access the national REB list. To make this work equitably, the finalized guidance should:

- Publish explicit eligibility criteria for REBs applying to the national list, including any minimum volume, staffing, or accreditation thresholds;
- Clarify whether institutional REBs at smaller regional sites qualify, or whether only centralized or joint REBs are eligible;
- Acknowledge that supporting Atlantic Canadian REBs to achieve national list status is consistent with Health Canada's stated goal of improving access to innovative therapies for all people in Canada, and consider whether bridging support is available for institutions serving rural and remote populations.

Annex B — Draft Guidance on SGBA+ Demographics Action Plan

CC Directorate	**Biologic and Radiopharmaceutical Drugs Directorate** | brdd-cppic_brdd-cppci@hc-sc.gc.ca

This annex provides the Heather Cutler Foundation's feedback on the new draft guidance document for clinical trial sponsors on Sex and Gender-Based Analysis Plus (SGBA+) and the demographics action plan in clinical trial applications.

General Support for the SGBA+ Approach

The Heather Cutler Foundation welcomes the introduction of SGBA+ requirements for clinical trial applications. Requiring sponsors to plan for demographic analysis at the application stage is a meaningful step toward producing evidence that reflects the full population of people in Canada who may benefit from new therapies.

Pancreatic Cancer and the Case for Geographic Stratification

Pancreatic cancer incidence, treatment response, and outcomes vary across sex, age, Indigenous identity, and geographic context. Trial designs that do not stratify for these variables produce evidence that may not generalize to the communities most in need of new therapies — including older adults in rural Atlantic Canadian communities and Indigenous peoples whose cancer care access faces compounding structural barriers.

Is the guidance clear and easy to understand? Yes for larger sponsors with equity and diversity expertise. We recommend Health Canada publish a plain-language FAQ or summary specifically for smaller academic sponsors and patient advocacy organizations.

Does it provide enough detail to support compliance? The guidance addresses sex, gender, race, ethnicity, age, and disability. However, it does not explicitly name rural and remote geographic status as a demographic variable requiring action plan consideration. For pancreatic cancer, this is a material gap:

- Pancreatic cancer disproportionately affects older adults, many of whom live in rural and remote communities, particularly in Atlantic Canada;
- Geographic barriers — distance to trial sites, limited transportation, and lower rates of specialist access — directly affect whether rural patients can enrol in and complete clinical trials;
- Without geographic stratification in trial design, enrolment data will systematically under-represent rural populations, and evidence generated will not reflect their treatment needs.

Are there areas that should be clarified? Yes. The guidance should clarify:

- Whether sponsors are required to report on demographic enrolment mid-trial, or only at the application and completion stages. A mid-trial reporting requirement would allow course correction if certain populations are under-enroling;
- How the SGBA+ action plan interacts with existing Indigenous data sovereignty frameworks, including OCAP® principles, for trials that include or seek to include First Nations, Métis, or Inuit participants.

Are there resources that would help? Yes. A plain-language implementation guide with worked examples for different disease contexts — including rare cancers and geographically dispersed patient populations — would be valuable for sponsors and advocacy organizations alike.

Annex C — Draft Guidance on Proposed New Clinical Trials Regulations (GUI-0100)

CC Directorate	**Medical Devices and Clinical Compliance Directorate** | GUI100Consultation@hc-sc.gc.ca

This annex provides the Heather Cutler Foundation's feedback on the updated draft guidance document on the proposed new Clinical Trials Regulations (GUI-0100).

Category C Authorization Timelines

The proposed GUI-0100 guidance describes the authorization scheme for Categories A, B, and C, including the removal of the Day-31 automatic start for Category C trials. The Heather Cutler Foundation raises concern about this change in the absence of a committed Health Canada review timeline.

For diseases with short survival windows — pancreatic cancer carries a median survival of six to twelve months from diagnosis — regulatory uncertainty at the trial authorization stage is not an administrative inconvenience. It directly affects whether patients have the opportunity to enrol. Under the current framework, sponsors could rely on the Day-31 default to begin planning site activation. The proposed change to explicit authorization is appropriate in principle, but creates meaningful risk if Health Canada's review timelines are not specified.

Is the guidance clear and easy to understand? The authorization process is described clearly. However, the guidance does not commit to a maximum review timeline for Category C applications, which is a significant gap for sponsors and sites planning trials in high-mortality disease areas.

Does it provide enough detail to support compliance? Not yet for Category C. The finalized guidance should:

- Commit to a defined maximum review timeline for Category C drug trial authorizations;
- Establish an expedited authorization pathway for rare or high-mortality cancers, consistent with the spirit of Priority Review already applied at the drug approval stage;
- Clarify how sponsors will be notified of the expected authorization timeline at the point of submission, so that site and REB planning can proceed with reasonable certainty.

Protocol Amendments Under Whole-Trial Authorization

The shift from product-level authorization to whole-trial authorization is conceptually sound and the Heather Cutler Foundation supports it. However, the guidance should clarify how significant protocol amendments are handled — specifically:

- Whether amendments that modify primary endpoints, patient eligibility criteria, or treatment protocols require re-authorization and, if so, within what timeline;

- How adaptive trial designs — increasingly common in oncology and directly relevant to pancreatic cancer research — are handled under the whole-trial authorization model, given that pre-specified adaptations may substantially change a trial's conduct after initial authorization.

Are there areas that should be clarified? Yes. A worked example illustrating how a typical Phase II/III adaptive oncology trial would be authorized, amended, and re-authorized under the new framework would be very useful for sponsors and academic sites.

Partial Trial Suspension

The proposed ability to suspend a trial in part rather than requiring full suspension is a practical improvement and the Heather Cutler Foundation supports it. For multi-site pancreatic cancer trials, a site-specific safety issue should not result in the removal of access from patients at all other participating sites. The guidance should clearly describe the notification process, reinstatement criteria, and any timeline commitments that apply to partial suspension decisions.