



SYNCHROGENIX

Navigating the Evolving Regulations for Health Canada

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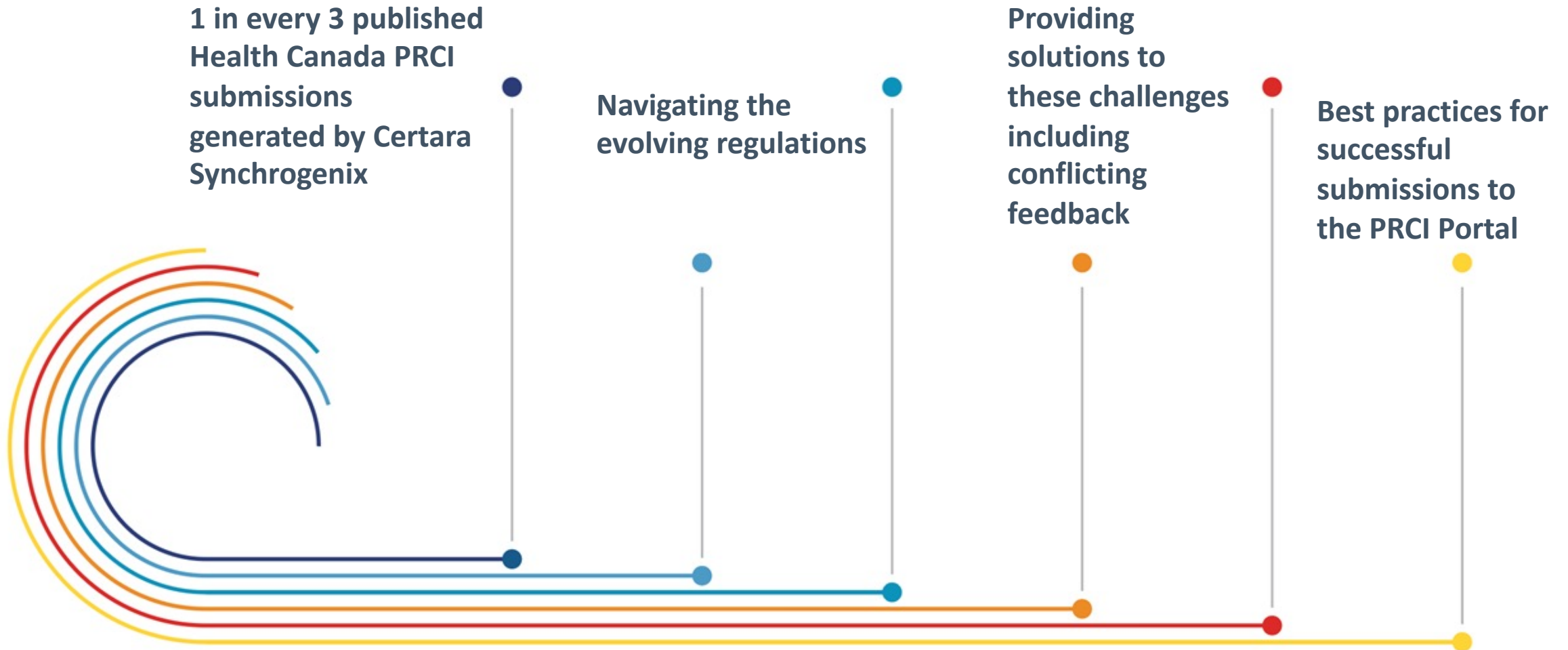
Introductions

Gina Bennett – Senior Redaction Specialist

- 3 years Transparency and Disclosure experience
- Certara Synchrogenix



Experience & Objectives



Examples reviewed



IRB Committee Company Names and Addresses

Challenge:

IRB names and addresses should be retained as they are not linked to any specific individual

Proposed Solution:

Individual's name, titles and department were redacted when in conjunction with committee name

Foreign Language

Challenge:

Submission document pages presented in non-English text

- Health Canada asked for non-English (French – national language) content in documents to be retained.

Proposed Solution:

- Utilize a native speaker/translation company to provide translation services to redact personal information from non-English text. (We utilized a native French speaking colleague.)



Hola
Bonjour
Nbote
Konnichiwa

Dossier With Old Documents

Challenge:

Submission with studies run >20 years ago

- Many documents did not follow ICH formatting
- Pages were scanned
- Extremely large submission

Proposed Solution:

- Sponsor requested extension from Health Canada
- Rolling review and submission of documents to Health Canada
- Global team provided round the clock support to meet the timeline

Medical History and Concomitant Medications



Challenge:

Health Canada rejects fully redacted information surrounding a patient's medical history and concomitant medications in conjunction with a participant ID

- Conflicting opinions among reviewers
 - Sponsor received feedback that only certain medical history terms were acceptable for redaction
 - Sponsor developed redaction approach to accommodate this feedback which was accepted. However, in a future submission another reviewer contradicted this guidance.
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- **Proposed solution:**
 - Sponsor gave justification that these terms were accepted in previous submissions and were therefore applied to comply with previous guidance

Challenge:

Health Canada requests all AE/SAEs to be retained for participants

Proposed Solution:

Scenario 1: Sponsor had very low study population numbers and rare disease variables causing a greater risk of re-identification of the participant should the AE/SAEs be unmasked.

- Solution: Sponsor came to agreement with Health Canada to keep AE/SAEs redacted with the justification that revealing them would increase the risk of re-identification due to the very low study population numbers.
- Scenario 2: Sponsor had rare disease submission with <100 participants in each study.

Solution: Sponsor conceded with Health Canada feedback to retain AE/SAEs and lab values while fully redacting medical history and concomitant medications in full case narratives.

Study Site & Site IDs

Challenge:



- Site IDs should not be redacted. Site names and addresses should not be considered personal information including names of the countries where the clinical study is/was conducted.

Proposed Solution:

- Study site names and addresses were only redacted in studies with a population size of <100 participants where exact geographical location of the study combined with the small population size posed a high risk to patient re-identification.
- Health Canada has allowed redaction of site IDs when presented in conjunction with the participant ID.

Qualitative vs Quantitative Approach

Challenge:

- A quantitative approach offers more precision than a qualitative approach since it is based on empirical measurement and calculation. The suggestion that a qualitative approach being deemed as the safest is misleading as a quantitative approach could be used as well. (PRCI reviewer)
- Sponsor has no datasets for a quantitative approach

Proposed Solution:

- While it's known that Health Canada PRCI has a preference of a quantitative approach for anonymization, the sponsor has chosen a qualitative approach. With a careful risk assessment of direct and quasi-identifiers, the sponsor has taken every measure possible to establish the risk threshold as “low.”
- Accepted sponsor response: “The qualitative approach is considered the most reliable and efficient approach available to the sponsor at the time.”



Challenge:

- Health Canada proposed that the sponsor consider and/or discuss why alternatives to full redaction had not been used. Alternatives might include partial redaction of the day while retaining the month and year.
- **Proposed Solution:**
- Supported sponsor with rare disease submission providing the following justification that was accepted by Health Canada: We strongly believe that unmasking of any part of the date, (eg, the year retained in a birth date) will lead to higher risk of re-identification. The risk of re-identification is especially valid when such data (ie, year of birth) is analyzed in conjunction with other available demographic information in the document (eg, race, age, birth, ethnicities in a specific study)
- For submissions that do not have low population or rare disease variables, Health Canada has accepted redacting month and day of medical event and retaining the year.

Proposed Redaction Control Sheet

Challenge:

- Confidential Business Information (CBI) must not include fully redacted pages of text. The percentages/number values of accepted CBI may be redacted. Tables must not be fully redacted, but only select words or values within the tables. (PRCI reviewer)

Proposed Solution:

- Sponsors advised to be extremely detailed with justifications for these proposed privacy redactions
- All out of scope sections (e.g., Appendix 16.2 Patient Data Listings) and foreign language pages are also requested to be included with the qualifying exception indicated as “N/A” to indicate need for Health Canada review.

Best Practices for
a Successful
Health Canada
PRCI Submission





Best Practices

- Know the Health Canada scoping requirements for the submission documents.
- Attend the Process Initiation Meeting (PIM).
 - Each PRCI submission avails this opportunity for the sponsor to discuss the scope of the submission (e.g., interim analyses) as well as discussions regarding redaction of CBI or personal information (medical history & concomitant medications, medical event dates, AE/SAEs, etc.)
 - Sponsors receive a valuable email contact for questions encountered during the preparation process of the PRCI submission.
 - Questions answered by Health Canada regarding the proposed anonymization approach (quantitative or qualitative)

An abstract network diagram on the left side of the slide. It features a complex web of nodes (circles) in black, grey, yellow, and red, connected by thin black lines. A series of blue curved lines sweep across the diagram from the top left towards the bottom right, creating a sense of flow or direction.

Best Practices

- Keep in frequent contact with Health Canada concerning timelines or change in approach.
- Having a well-thought-out transparency strategy in place before a regulatory decision will ultimately save time and money and help to avoid the stress of meeting timelines.
- Team members representing clinical, regulatory, and legal departments to review and submit documents constitute a solid transparency team.



Best Practices

- A decision should be made as early as possible as to whether your company has the infrastructure to successfully complete the transparency requirements in-house or whether a partnership with a vendor is the best solution.
- Decide early on the best anonymization approach for your submission documents.
- Although Health Canada is currently accepting a qualitative approach with redaction, the future is strongly in favor of anonymization rather than redaction due to the amount of data utility that is lost.



Recent Feedback...

- Sponsors are starting to have joint meetings with both the EMA and Health Canada present to ensure alignment on the approach for their submissions.

Have Questions?

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