

Do's and Don'ts for PRCI submissions

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INTRODUCTION

Clinical Data sharing for transparency is a hot discussion topic since the Policy 0070 and Health Canada publishing requirements has been implemented. Pharmaceutical companies need to redact their clinical documents to support their submission for market authorization, but regulatory bodies are motivating sponsors to anonymize clinical documents to maintain the higher data utility.

This poster is discussing on our experience with PRCI submissions and suggestions for making the process of approval faster.

Redaction versus Anonymisation

- PRCI prefers anonymization over redaction
- Redaction only approach is acceptable for older studies but with prior discussion and approval from PRCI
- Redaction only approach will be considered as Deviation and shall be specified clearly in deviation section of anonymization report
- Transformation approach shall be used for subject information with direct and indirect identifiers
- Do not redact any information which is already publicly available. Sponsors shall have clear information on reports and protocols which are already available in public for particular project. It saves time for anonymization and review time from regulatory bodies

Confidential Business Information

- Vendor names shall not be redacted
- Batch or Lot number is not CBI
- Any references in scope for release and can not be redacted
- SAS code snippet does not meet qualifying exemption
- Questionnaire or surveys are in scope of release
- LOQ values shall be released to allow for analysis of clinical data
- Justification for CBI/CCI redactions shall be more logical and not only related to economic value to company. For example, if vendors name is redacted then it can be justified if there is any agreement between vendor and sponsor to not reveal vendor's name in public.
- Standardize the CBI redactions across the company for publishing purposes CT.gov, other registries, and publications.

Personal Information

Dates	Phuse suggested or random offset
IDs or Names	Recode or Pseudonymize. Study personnel details shall be redacted uniformly across the documents
Demographic Information	Anonymize based on quantitative risk assessment
Medical History/Conmeds	Retain information related to events in narratives as much as possible
Adverse Events	Only sensitive information shall be redacted with proper justification

Redaction Control Sheet

- Once submitted, number and order of rows in redaction control sheet shall not change
- Detailed justification column shall be updated for revised justification with Sentence starting with ORIGINAL for original justification and REVISED for updated justification
- Pages removed shall be mentioned in the redaction control sheet

Anonymization Report

- Anonymization report shall not include any details on CBI redactions
- Risk assessment approach justification approach shall be clearly justified
- There shall be no mention of vendor name, contracted for anonymization, in anonymization report
- Deviation section shall always be populated whenever there is qualitative approach used for any study within the project

Summary

Clinical Documents publishing is mandatory for any submissions to Health Canada. Hence, it is necessary to standardize the process of anonymization within organization ad across the industry. This will help in reducing the time, cost and efforts needed for this additional activity.