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EMA, Health Canada and FDA: Three agencies tackle Data Sharing. Synergies and Differences

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ABSTRACT

The European Medicine Agency (EMA) and then Health Canada have respectively launched separate data transparency policies around sharing of Clinical Study Reports (CSRs) and Individual Patient Data (IPD). The 2 regulators are providing additional guidance to help with implementation of their policies and have each formed stakeholders' groups during 2017.

These 2 stakeholder's groups include a variety of professionals and representatives across Life Sciences and focus on topics around data anonymisation, risk of re-identification and data utility while Health Canada's Reference Group also addresses scope and processes related matters.

This presentation will elaborate on the approaches, goals and achievements of these 2 stakeholders' groups and reflect on the EMA and Health Canada data sharing processes and requirements and where they overlap and differ from each other. In addition, the recent initiative and pilots from FDA will be discussed. The author will also reflect on his experience participating in both stakeholders' groups and lessons learned that could benefit other industry committees and working groups.

INTRODUCTION

This paper intends to provide an exhaustive summary of data transparency efforts from EMA, Health Canada and FDA, how each agency engaged with stakeholders and how their initiatives differ.

The Data Transparency landscape has greatly changed since the first talks initiated at the EMA in 2012 and nowadays where a number of companies provide access to data on request to researchers, EMA Policy 0070 has been active for 2 years and a number of agencies are discussing similar initiatives. The current regulatory landscape focuses on sharing of Clinical Study Reports (CSRs) and discussions around sharing of Individual Patients Data are postponed at a later time with no firm commitments on timelines.

While sponsors are trying to adapt their processes, form teams and keep up to date with regulations and policies, it appears that the different agencies are taking slight or very different directions when it comes to requirements that apply to same documents. Sponsors are trying to understand both similarities and differences in order to in the near future be able to provide anonymized documents that are compliant with the different requirements while using their resources wisely.

This paper explores similarities and differences in terminology, processes and anonymization requirements that could be useful to highlight in order to both help regulators align where feasible and warn sponsors for competing requirements, especially when considering risk of re-identification where same documents would be available in different anonymization formats.

AGENCIES ENGAGING WITH STAKEHOLDERS

All 3 agencies are engaging in different ways with stakeholders, including Academia, Patients Organizations, Pharmaceutical Companies, Data Anonymization SMEs, Software Vendors, Standards Organizations, etc. through:

- Public consultations
- Stakeholders consultation
- Dedicated working groups or
- Pilots with industry

EMA PUBLIC AND STAKEHOLDERS GROUPS CONSULTATION & EXTERNAL GUIDANCE

EMA started their initiative on developing a clinical data publication policy with a workshop on 22. November 2012. Following the event, the Agency issued a call for nominations to join advisory groups to inform the policy on five topics and form 5 Clinical Trial Advisory Groups (CTAG): Protecting Patient Confidentiality, Clinical Trial Data Formats, Rules of Engagement, Good Analysis Practice and Legal Aspects. Each of the 5 Clinical Trial Advisory Groups issued an "Advice" document [00].

The Clinical Trial Advisory Groups included 318 individuals with 97 from Industry, 65 from Academia, 23 representing Healthcare professionals and 19 representing Patients' organizations.

In June 2013, EMA released a draft policy on publication and access to clinical data for a 3-month public consultation [0]. The initial draft policy was covering both what we know as Phase 1 (CSR) and Phase (IPD) and EMA received over 1000 comments. Following this, the EMA hold a number of meetings (internal and with stakeholders) in 2014, which led to Policy 0070 of 2. October 2014 with effective date of 1. January 2015 focusing on disclosure of CSRs (Phase 1) and informed about the stepwise implementation of the policy [000].

In 2015 EMA consulted stakeholders extensively, as well as the European Ombudsman and the European Data Protection Supervisor, which led to the development and finalization of the External guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use [1]. EMA provided the guidance for review to a number of organizations part of their stakeholder group. Stakeholder organizations (Scientific Journals, Pharmaceuticals, SMEs, Academics, Standards Organizations, Patients Groups, etc.) were invited to come to the EMA' offices or attend remotely and provide their comments directly in 2 separate meetings. Following these 2 meetings, EMA released the first version of the guidance on 2. March 2016. EMA continues to engage industry organizations from the stakeholder's group on regular teleconferences where challenges on implementing Policy 0070 and need for clarifications are discussed. The guidance is updated on a regular basis as outlined in Table 1 where updates related to scope clarifications are highlighted.

Table 1 - EMA Policy 0070 External Guidance Updates

version	Date	Scope Clarifications
1.0	02MAR16	• New Document
1.1	21DEC16	• *Additional information concerning EMA's position on clinical reports that are submitted as part of /or cross-referred to within a regulatory application in the context of policy 0070 has been added.* • *Practical guidance for the individual patient data (IPD) out of scope sections has been included.* • *In cases where an applicant/MAH (the Transferor) transfers a MA to another company (the Transferee), the Transferee becomes responsible for the transferred product and accepts all prior agreements under policy 0070 between the Transferor and the EMA.*
1.2	12APR17	• *Clarification has been provided on which clinical reports should be submitted for publication.* • *Clarification that individual patient data listings contained in CSR section 14.3.4 "Abnormal Laboratory Value Listing" can be considered out of scope of phase 1 of Policy 0070.*
1.3	22SEP17	• *Clarification has been provided on which clinical reports should be submitted for publication with regards to extension or modification of indications in the paediatric population:* • *Inclusion of revised wording regarding the submission of duplicate marketing authorisations and inclusion of a cover letter template to be used upon the submission of the final redacted document package of duplicate applications* • *Clarification added on the definition of listings out of scope of Phase 1 of Policy 0070*

version	Date	Scope Clarifications
		• *Clarification on the instructions on how to process information considered to be out of scope of phase 1 of Policy 0070*
1.4	*TBA*	*Should be published in October – To be Updated prior to Conference*

EMA POLICY 0070 FIRST RESULTS

After a year, the PhUSE Data Transparency Working Group analyzed the Policy 0070 submissions up to date [11] and assessed for each submission (57 at the time), the anonymization methods used, how companies justified data utility, etc. Figure 1 displays results of anonymization methods vs anonymization techniques in general and for narratives only and demonstrate that Policy 0070 External Guidance requirements are challenging to be met. In particular, a majority of companies were using qualitative methods in connection with redaction.

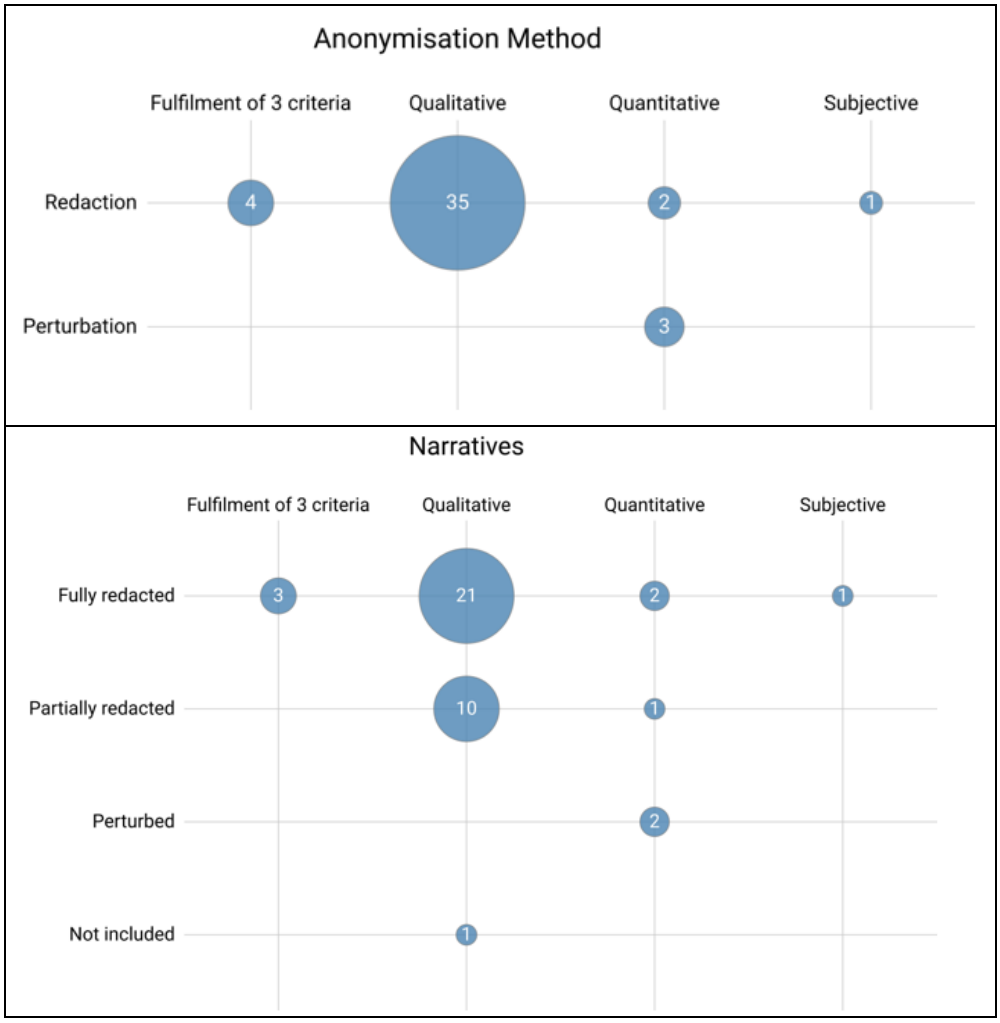

Figure 1 - Summary of Findings on first 57 Policy 0070 Submissions

The EMA has released a report over the same period *"Clinical Data Publication report oct16-oct17"* [111] where also more details on how CCI was assessed, accepted and rejected is shared. The conclusion over anonymization techniques are similar than the ones of the PhUSE Data Transparency Working Group. It became apparent that a need for further guidance beyond the scope of the Policy 0070 External Guidance is required to help sponsors meet Policy 0070 anonymization and data utility objectives.

EMA TECHNICAL ANONYMISATION GROUP

In addition and as a result of the first set of Policy 0070 submissions, the EMA decided to form a Technical Anonymization Group [2] with individuals representing different stakeholders and skillset and the following objective:

The European Medicines Agency (EMA) has established an expert group in data anonymisation known as the technical anonymisation group (TAG) to help further develop best practices for the anonymisation of clinical reports, in the context of the Agency's policy on the publication of clinical data.

The group includes members from academia, industry, patients and healthcare professionals with expertise in areas such as data protection, developing standards and guidance for anonymisation and re-analysis of clinical data. EMA established the group following a public call for applications launched in March 2017.

The group will consider experience to date with EMA's publication of clinical reports. In particular, it will assess:

- *patient re-identification and any privacy risks in the light of new technological developments;*
- *the scientific utility of the published clinical data as a function of the anonymisation methodology used;*
- *whether it is possible to successfully conduct a secondary analysis of the anonymised clinical data.*

The application process consisted of sending a CV and a Declaration of Interest. Among 45 applications received, the following 14 individuals were selected:

Table 2 - EMA TAG Members, affiliations and countries

Pharmaceuticals R&D / Data Sharing (2)	**Academia – Medical Science (3)**
Christine Fletcher (Amgen) - UK	Sarah Nevitt (University of Liverpool) - UK
Lukasz Kniola (Biogen) - UK	Frank Rockhold (Duke University) - USA
Pharmaceuticals / CRO Legal (3)	Kristian Svendsen (Hospital Pharmacy Tromsø) - Norway
Nicola Orlandi (Novartis) - Switzerland	**Software (2)**
Lee Parker (Biogen) - UK	Khaled El Emam (Privacy Analytics) - Canada
Uwe Fiedler (PAREXEL) - Germany	Cathal Gallagher (d-Wise) - UK
Patient Association (1)	**SME (2)**
Rafal Swierzewski (EPPOSI) - Belgium	Jean-Marc Ferran (Qualiance) - Denmark
Data Protection Agency (1)	Bradley Malin (Vanderbilt University) - USA
Guiseppe d'Acquisto (Italian DPA) - Italy	

In addition, a member of European Data Protection Supervisor (Dina Kampouraki) participates as an observer.

EMA TAG Members are contributing to 5 topics:

- Anonymisation Techniques
- Data Utility
- Legal Issues/GDPR
- New Technological developments
- Potential Attackers

Subteams are meeting remotely and members draft deliverables. One Face-to-Face meetings take place at the agency with all members. The TAG will develop additional guidance (e.g. Q&A) to further clarify certain aspects of the methodology described in the external guidance.

HEALTH CANADA'S DOCUMENTS FOR PUBLIC REVIEW

Health Canada launched their Data Transparency initiative in 2017 and provided the opportunity to review the following documents with each time a 75-day timeline:

Table 3 - Health Canada's Data Transparency Documents for Public Review

Document*	Release Date for Public Review	Purpose
White Paper [3]	10MAR2017	*"This document introduces Health Canada's initiative to publicly release clinical information concerning the safety and efficacy of drugs and safety and effectiveness of medical devices. It sets out the policy objectives, rationale and considerations for future regulations that would specify that certain clinical information contained in drug submissions or medical device applications would not be treated or cease to be confidential business information following a final regulatory decision and that would authorize the public release of that information."*
Regulation [4]	09DEC2017	*"The objective of this proposal is to provide public access to clinical information submitted to Health Canada in drug submissions for human use and medical device applications following a final regulatory decision…This proposal contains amendments to the Food and Drug Regulations and the Medical Devices Regulations. Proposed amendments to the Food and Drug Regulations would specify the kind of clinical information in drug submissions that would cease to be CBI following a final regulatory decision."*
Guidance [5]	10APR2018	*"This document is designed to help the public, industry, healthcare professionals and other stakeholders better understand the implementation of Health Canada's Public Release of Clinical Information initiative, including: the procedures to prepare information for release; the categories of information that continue to be subject to the definition of confidential business information (CBI) and that may be eligible for redaction; and how Health Canada will protect personal information."*

*: The White Paper was restricted for comments to Canadians or Canadian organizations (e.g. the affiliate of a given sponsor could send their comments) only while there was not such restriction on the 2 other documents.

Health Canada provided an anonymized summary [6] of the results of the consultation on the White Paper. Figure 2 represents the distribution of unique submissions from each stakeholder group (some submissions were submitted on behalf of multiple individuals or organizations).

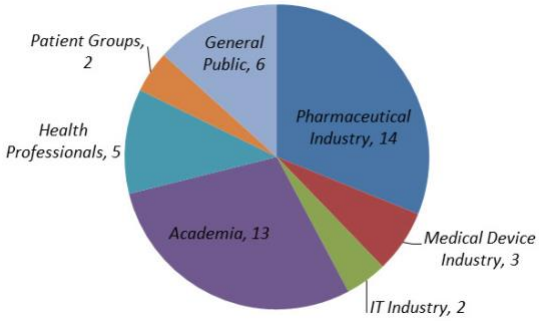

Figure 2 - Submissions in response to Health Canada's White Paper by stakeholder groups

As expected Pharmaceutical Industry and Academia are well represented.

In particular, Pharmaceutical Industry's comments were encouraging Health Canada to align as much as possible with Policy 0070 requirements while also highlighting current challenges with Policy 0070 to take in consideration as these conversations with EMA are also progressing. Among other comments, Health Professionals raised *"concerns with respect to risks of delay in implementation and proper resourcing of this initiative."* and Academia insisted that *"consultation on the scope of the redactions and time allowed for industry should be well defined in order not to prolong the process."*. A complete summary is available at [6].

The final regulation and guidance should be published at the end of the year 2018 as announced at DIA in London in September 2018.

Main points:

- Health Canada approves anonymization approach

- Only Quantitative approach is mentioned for risk analysis
- Recognition process with EMA Policy 0070 documents is possible through a certification
- Four Reference Populations are listed to consider in modeling the risk and compute the residual risk

HEALTH CANADA'S STAKEHOLDERS GROUP FOR PUBLIC RELEASE OF CLINICAL DATA

Following the public review of their White Paper, Health Canada contacted stakeholders to apply to their Stakeholders Group:

In follow up to our public consultation, HPFB will engage with experts and stakeholders on implementation of public release of clinical information. To support this process HPFB intends to establish a roster of experts who are available to provide advice, specific to the Canadian context, in the following areas:

- *Clinical trial reporting, medical writing*
- *Regulatory affairs & CTD structure*
- *Health data science and statistics*
- *Data protection and privacy law*
- *Anonymization and de-identification methods*
- *Open data and end-user experience*

An application letter and a DoI were requested to apply. The following 15 members were selected:

Table 3 - Health Canada Stakeholders Group's Members, affiliations and countries

Pharmaceuticals Regulatory Affairs (4)	**Academia - Law & Policy (2)**
Arshia Ghani (Pfizer) - Canada	Matthew Herder (Health Law Institute, Dalhousie University) – Canada
Noel Geaves (Medtronic) - Canada	Joel Lexchin (School of Health Policy & Management, York University) - Canada
Sarah Marshall (NAPRA) – Canada	**Academia – Medical Science (2)**
Sandra Wainwright (Merck) - Canada	Nav Persaud (Family & Community Medicine, University of Toronto) - Canada
Sally Prawdzik (J&J) - Canada	Angela Spelsberg (Comprehensive Cancer Center Transparency International) - Germany
Pharmaceuticals R&D / Data Sharing (2)	**Software (1)**
Milan Shah (J&J) - USA	Hazel Nicholls (Privacy Analytics) - Canada
Teresa Armstrong (Eli Lilly) - USA	**Standards Organization (1)**
Professional Organization (2)	Jean-Marc Ferran (PhUSE) - Denmark
Barry Power (Canadian Pharmacists Association) - Canada	
Bradley Mitchelmore (Canadian Agency for Drugs and Technologies in Health) - Canada	

The Stakeholders Group met at the pace of one 2-hour teleconference per month where documents drafted by Health Canada's officers were sent in advance and discussed during each call. The themes were:

- KO Meeting and review of overall draft process (October 2017)
- Overview of operations and key implementation issues (November 2017)
- Protection of personal information (January 2018)
- Process to specify clinical information, safeguards against commercial use (February 2018)
- Public release options and health system impacts (April 2018)

Health Canada officers recorded and circulated meeting minutes among the Stakeholders Group and different opinions were reflected by affiliation type (e.g. Representative from Academia, Representative from Professional Organization) rather than in name.

Health Canada officers used the comments and feedback from the Stakeholders Group to further elaborate the Draft Guidance in some aspects. The Draft Guidance was discussed with the Stakeholder Group after its publication.

FDA DATA TRANSPARENCY INITIATIVE AND PILOTS WITH SPONSORS

FDA has launched their Clinical Data Summary Pilot Program [7] in January 2018. FDA has extensive experience in redacting clinical documents through FOIA requests they are routinely processing since 1996.

Objectives refer to *"making a CSR publicly available after a drug's approval will provide stakeholders with more information on the clinical evidence supporting a drug application and more transparency into the FDA's decision-making process."*. The press release does not refer to secondary analysis or more specific goals but only to a general data transparency principle related to the agency decision making process.

Main points:

- FDA is "doing the work" and redacts the documents. Sponsor is not consulted but "*If the sponsor is uncertain about whether we will redact certain types of information, the sponsor should ask us in advance"*
- Only redaction as an anonymization method is listed. In particular "*Demographic information, such as sex, age, and race, will generally **not** be redacted, except in very unusual circumstances"*
- Narratives are out of scope
- Only pivotal phase III studies are in scope

SUMMARY

The table below summarize how the 3 agencies have engaged with Stakeholders on their Data Transparency initiatives. All Agencies have actively participated in conferences and webinars to inform stakeholders and discuss comments and concerns. The table below describes formal engagement only.

Table 4 - Overview of differences and similarities between agencies on engaging Stakeholders

Item	EMA Policy 0070	Health Canada Public Release of Clinical Information	FDA Clinical Data Summary Pilot Program
Consultation on:	Policy & Guidance through Stakeholders Review	Policy & Guidance through Public Review	Planned *"public feedback through a Federal Register notice and docket for public comments"* following the conduct of the pilots
Pilot	None	None	9 pilots planned with sponsors
Working Groups	EMA TAG	Stakeholders Group	Not planned so far
Working Groups Application	Public call for applications CV & DoI required	Individual call for applications Application Letter & DoI required	NA
Working Group Mandate	Maximum 2 years renewable	6 months between October 2018 and April 2019	NA
Working Groups Deliverables	Q&A, Additional Guidance, Critical Review (TBA) developed by TAG members under EMA officers' supervisions	Participation in 5 Meetings to comment on 5 key topics that led to the development of the guidance by Health Canada officers.	NA

FDA is the only agency that has taken an approach involving Pilots that would help inform the final policy. These pilots are beyond just prototypes done in "under closed doors". One pilot done with J&J (Janssen Pharamceutica) has been published so far and redacted CSR is available in public access with no geographical restriction [8].

EMA and Health Canada approaches are similar in terms of involving stakeholders in reviewing policy and guidance and running Working Groups to further advise them. Their 2 Working Groups are different on 2 aspects:

- Timelines (2 years vs. 5 months) and Involvement (Drafting Deliverables vs. Commenting)
- Working Groups Members. Health Canada had many professionals coming from Regulatory bodies of Pharmaceutical companies while EMA had none and a more diverse representation also involving lawyers and R&D staff from pharmaceutical companies.

The 2nd difference on membership can be explained by the timing of the initiatives and the fact that EMA had already a guidance released and was running their initiatives while Health Canada was still scoping theirs and could also benefit from EMA's experience.

EMA also refer in their external guidance to a qualitative approach and use of redaction in an initial phase until sponsors gain more experience and can use quantitative approach and anonymization. There is no pilot as such but the guidance suggests that there is a period where sponsors can develop their skills and approach to fully meet Policy 0070 external guidance requirements. Health Canada Draft Guidance does not refer to such "grace period".

REQUIREMENTS COMPARISON

The 3 initiatives from the 3 agencies differ in terms of:

- Terminology
- Scope and Processes
- CSR Anonymization Requirements

TERMINOLOGY

When reviewing the different documents, one can notice subtle differences in terminology. Table summarizes differences on main terms.

Table 5 - Overview of differences in Terminology

EMA External Guidance	Health Canada Draft Guidance	FDA Clinical Data Summary Pilot Program
Anonymisation De-Identification	Anonymization De-identification	Redaction
Direct Identifers	Directly-identifying variable	Unique Patient Identifier
Quasi Identifiers	Indirectly-identifying variable	No equivalent term although such identifiers are discussed but not named as such
Protected Personal Data (PPD)	Personal Information	Personal Privacy Information
Data Utility	Analytical Value/Analytical Utility Data Utility	No equivalent term, concept not addressed
Risk of Re-identification Residual Risk	Risk of Re-identification Data Risk	NA
Commercially Confidential Information (CCI)	Confidential Business Information (CBI)	Confidential Commercial Information Trade secret

Certain differences are driven by design by the difference of approaches chosen (e.g. redaction for FDA vs. Anonymisation/De-Identification for EMA and Health Canada). It is not clear from the different documents whether other terms hold any differences in meaning (Commercially Confidential Information vs. Confidential Business Information vs Confidential Commercial Information, Data Utility vs. Analytical Value) and some alignment could contribute to provide clarity to the different stakeholders as the policies cover the same documents. Certain guidances also interchangeably refer to different terms for the same concepts (Anonymization/Anonymisation and De-Identificvation, Risk of Re-identification and Residual Risk/Data Risk) and efforts could be made in future versions to align intra- and inter-documents.

SCOPE & PROCESS

The 3 agencies differ in scope and processes.

Table 6 - Overview of differences in Scope & Processes

Item	EMA External Guidance	Health Canada Draft Guidance	FDA Clinical Data Summary Pilot Program
Effective Date	1. January 2015	Not effective yet	Not effective yet
Retrospective access to past CSR	Not in scope Possibility through Policy 0043	In scope, based on prioritization system using *metrics that identify products and information with high health system impact*	Not in scope Possibility through FOIA request
Studies in Scope	All studies part of Central Submissions regardless of submission outcome	Step-wise approach: Year 1: NDS-NAS + SNDS-c + Rx-switch Year 2: All NDS + SNDS-c + Rx-switch Year 3: All NDS, all SNDS & Class IV devices Year 4: All NDS, SNDS, ANDS, SANDS + Class III & IV devices Regardless of submission ouctome	Only Phase III pivotal studies CSRs following approval of a NDA
Timelines to submit anonymized documents to agency	<= 30 days pre-opinion and <= 10 days post-opinion	20 days after notification	Not discussed
Recognition Process with other Agencies	None	Yes with EMA if compliant with Health Canada's requirements through a certification application	Not discussed
Data Controller	Sponsor	Sponsor & Agency	Agency
Handling of CCI/CBI	5-rejection criteria	2 categories: Clinical information that was not used by the manufacturer in the submission Clinical information that describes tests, methods or assays used exclusively by the manufacturer	Handled by FDA but approach not described
IPD in scope	Planned in Phase 2	Could be in the future	Not in scope of present initiative

One of the most notable difference is on the Data Controller side. *It is not possible in the case of the FDA approach to "the sponsor will not have an opportunity to review our redactions before the CSR is posted. If the sponsor is uncertain about whether we will redact certain types of information, the sponsor should ask us in advance"*. In the case of Policy 0070, sponsor remain the Data Controller and define anonymization level while discuss comment and remark from EMA Policy 0070 team during the submission process. As per Health Canada Draft Guidance, anonymization level must be agreed with Agency upfront, meaning that the agency would share the Data Controller role.

CSR ANONYMIZATION REQUIREMENTS

Anonymization requirements are different starting as we could see above by the Data Controller.

Table 7 - Overview of differences in CSR Anonymization Requirements

Item	EMA External Guidance	Health Canada Draft Guidance	FDA Clinical Data Summary Pilot Program
Narratives in scope	Yes	Yes	No
Risk analysis	Working Party 29 Opinion 3-Criteria Qualitative Quantitative	Quantitative only	Qualitative based on FDA's approach for FOIA request
Anonymization Technique	Anonymization & Redaction	Anonymization	Redaction only based on FDA's approach for FOIA request. In particular, "*Demographic information, such as sex, age, and race, will generally **not** be redacted, except in very unusual circumstances"*
Guidance on Identification of Direct/Quasi Identifiers	Refer to PhUSE Standard [9] and discuss in particular quasi identifiers such as: • Dates • Geographic Location • Other Quasi-Identifiers (e.g. Demographics)	Indirectly-identifying variables are other identifying variables that fall within the definition of 'personal information' within Canada's Privacy Act. And refer to Demographics and medical history and SAE. ***Country should remain unmodified.***	Different type of identifiers discussed in Q&A page [7]: • Unique Patient Identifiers • Dates • Clinical Trial Site Geographic Location • Demographics
Guidance on Reference Population	No direct guidance but examples of plausible attacks to consider for risk modeling are listed	4 populations are provided for consideration: • Study Population • Similar Sponsor Trials Population • Similar Trials Population • General Geographic Population	NA
Risk Threshold	Default 0.09, possible to justify another one	Default 0.09, possible to justify another one	NA
Anonymisation Report	Yes	Yes, similar to EMA	NA
Guidance on Data Utility	No definition provided Must be justified in Anonymization report Refer to not altering interpretation of study results and ability to produce similar analysis results	No definition provided Must be justified in Anonymization report as to *state the efforts made to maximize the utility of the anonymized information*.	Not Addressed
Personal Data of Investigators and Sponsor staff	Only sponsor and coordinating investigator signatories of the CSR	Not Addressed	*Generally **not** redacted if the contract relationship is public*

While the EMA and Health Canada requirements are fairly similar, the FDA requirements are very different starting with the "redaction-only" anonymization technique and the fact that Demographics *will generally not be redacted*, which is impossible to enforce when using quantitative methods as advised by the 2 other agencies. It must also be noted that while EMA and Health Canada emphasize the importance of Data Utility (or Analytical value) and justifying how sponsors have optimized it, none really provide neither a definition nor tangible guidance on how to do so.

DISCUSSION

At the time this paper is written, EMA has announced to pause their Policy 0070 activities while Health Canada is targeting to release policy and guidance by end of 2018. Only one FDA pilot has been published. The conclusions below are extrapolative and may need to be adjusted or confirmed once agencies have progressed further their initiatives.

Sponsors will have to adjust to 3 policies and process documents in a way where they would have to consider what may be released at a later point by another agency in another jurisdiction. In particular the FDA plan to conduct the redaction without consulting the sponsors would mean that sponsors understand very well FDA's redaction approach and can take it in consideration when anonymizing documents for EMA or Health Canada.

The possibility that EMA documents are accepted for Health Canada submissions through a certification process is a good news for the industry and would help sponsors save resources should the 2 agencies keep their requirements rather close to each other.

When the different policies are all effective, it will be interesting to analyze which of the different sources will be used by the different data consumers [X] and which documents will hold the maximum data utility, in particular by the academic research community.

Since discussions around sharing IPD are postponed by all agencies, the main source for IPD remain through sponsors' own Data Sharing initiatives.

Health Canada refered to comments in Stakeholders' group meeting minutes in terms of affiliation. This reflects the truth of the interactions where indeed each stakeholders may have competing interests and is also important not only for transparency reasons, but to understand the background of the comments.

Other countries such as Japan or Ukraine are also working on similar initiatives. We can only hope for alignment in requirements with the other agencies and the systematic implementation of a "certification" mechanism like Health Canada is referring to in their Draft Guidance.

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RECOMMENDED READING
TBA

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Jean-Marc Ferran leads the PhUSE Data Transparency Working Group since 2014 and represented PhUSE at the EMA Stakeholders Group meetings that took place during the development of Policy 0070 External Guidance. Jean-Marc joined later on the EMA Technical Anoymisation Group in 2017 and was a member of the Health Canada Stakeholders Group for Public Release of Clinical Data.

Jean-Marc Ferran is also an Independent Consultant and supports d-Wise Technology as an SME with the development of their Data Anonymization products.

The opinions in this paper are my own.

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