



QUALIANCE

SA01

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

EU Connect 2018, Frankfurt

5. November 2018

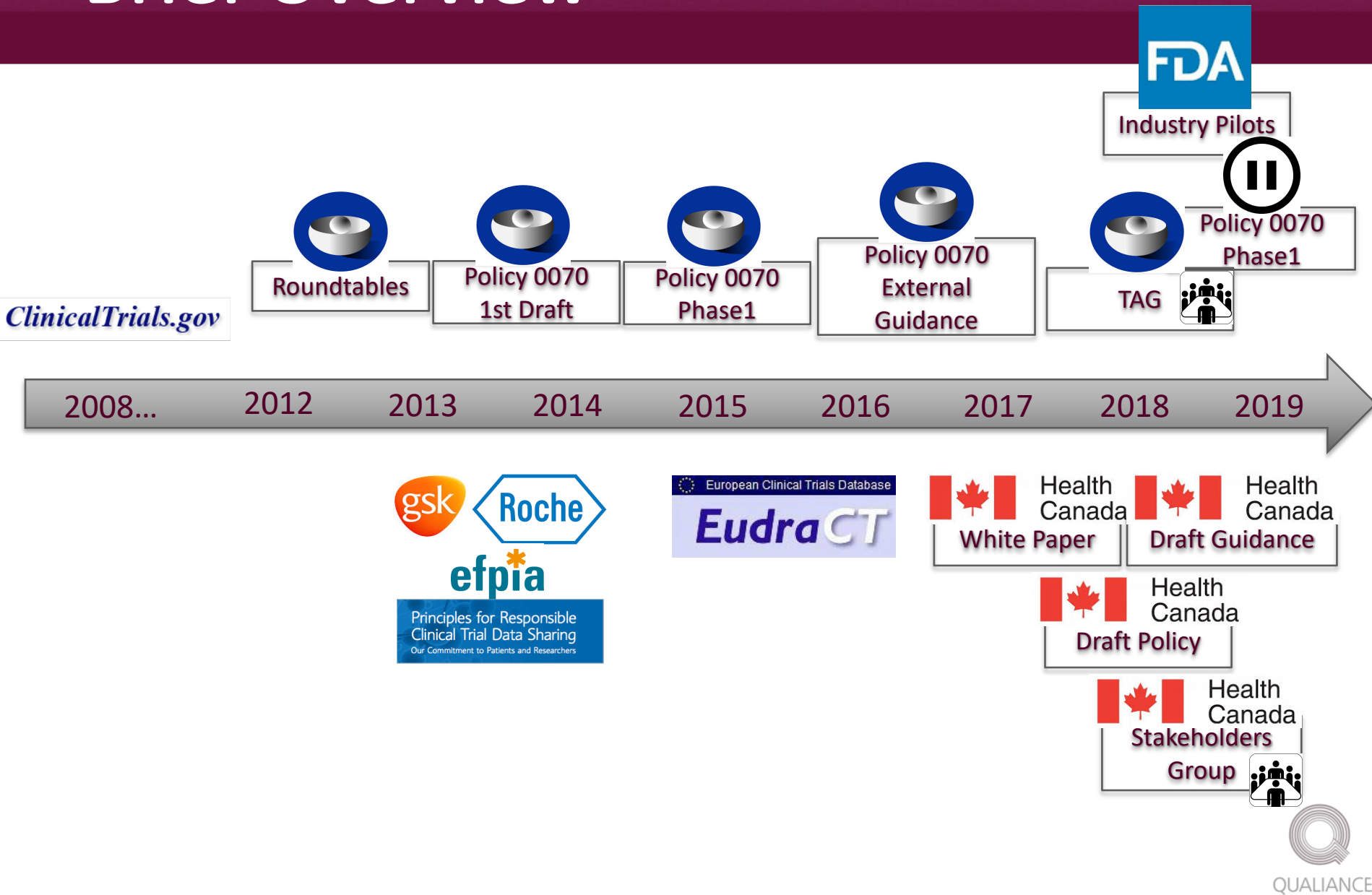
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Agenda

- **Brief Overview**
- **Comparisons of the 3 Initiatives**
 - Engaging Stakeholders
 - Processes
 - Anonymization Requirements
- **In Practice**
 - EMA Policy, 2 years on
 - Health Canada Draft Process
 - Focus on FDA approach
 - Recognition Process?
- **Conclusions**

Brief Overview



Engaging Stakeholders

Item	EMA	Health Canada	FDA
Consultation on:	Policy & Guidance through Stakeholders Review	Policy & Guidance through Public Review	Planned “ <i>public feedback through a Federal Register notice and docket for public comments</i> ” following the conduct of the pilots
Pilot	None	None	9 pilots to be 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

Processes

Item	EMA	Health Canada	FDA
Effective Date	1. January 2015	Not effective yet	Not effective yet
Retrospective access to past CSR	Not in scope Possibility through Policy 0043. Sponsors conduct the redactions. Documents are sent to requester.	In scope, based on prioritization system <i>Sponsors conduct anonymization unless a certified EMA Policy 0070 document is available.</i> <i>Documents are made public.</i>	Not in scope Possibility through FOIA request FDA conduct the redactions Documents are sent to requester.
Studies in Scope	All studies part of a Central Application regardless of submission outcome	Step-wise approach over 4 years including Medical Devices studies from year 3 regardless of submission outcome	Only Phase III pivotal studies CSRs following approval of an NDA
Recognition Process with other Agencies	None has been communicated so far	Yes with EMA if compliant with Health Canada's requirements through a certification application	Not discussed
Review Process	Using Annotated Documents and Anonymisation Report. Opinion is provided.	Same as EMA but HC validates de-identification of patient information and keeps decisions on what is publicly released.	None but Sponsor can notify FDA of special-attention item in CSRs

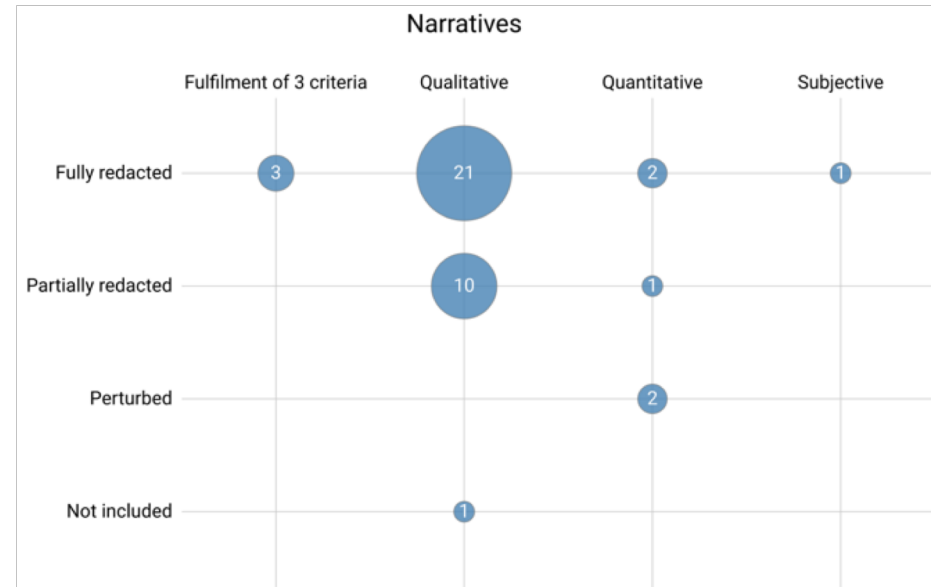
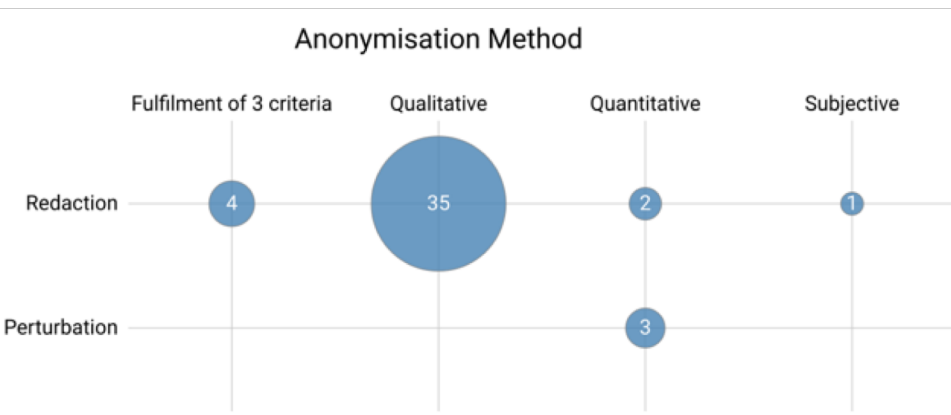


Anonymization Requirements

Item	EMA	Health Canada	FDA
Narratives in scope	Yes	Yes	No
Risk analysis	WP29 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 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: Unique Patient Identifiers Dates Clinical Trial Site Geographic Location Demographics Relative dates (study days) are retained
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

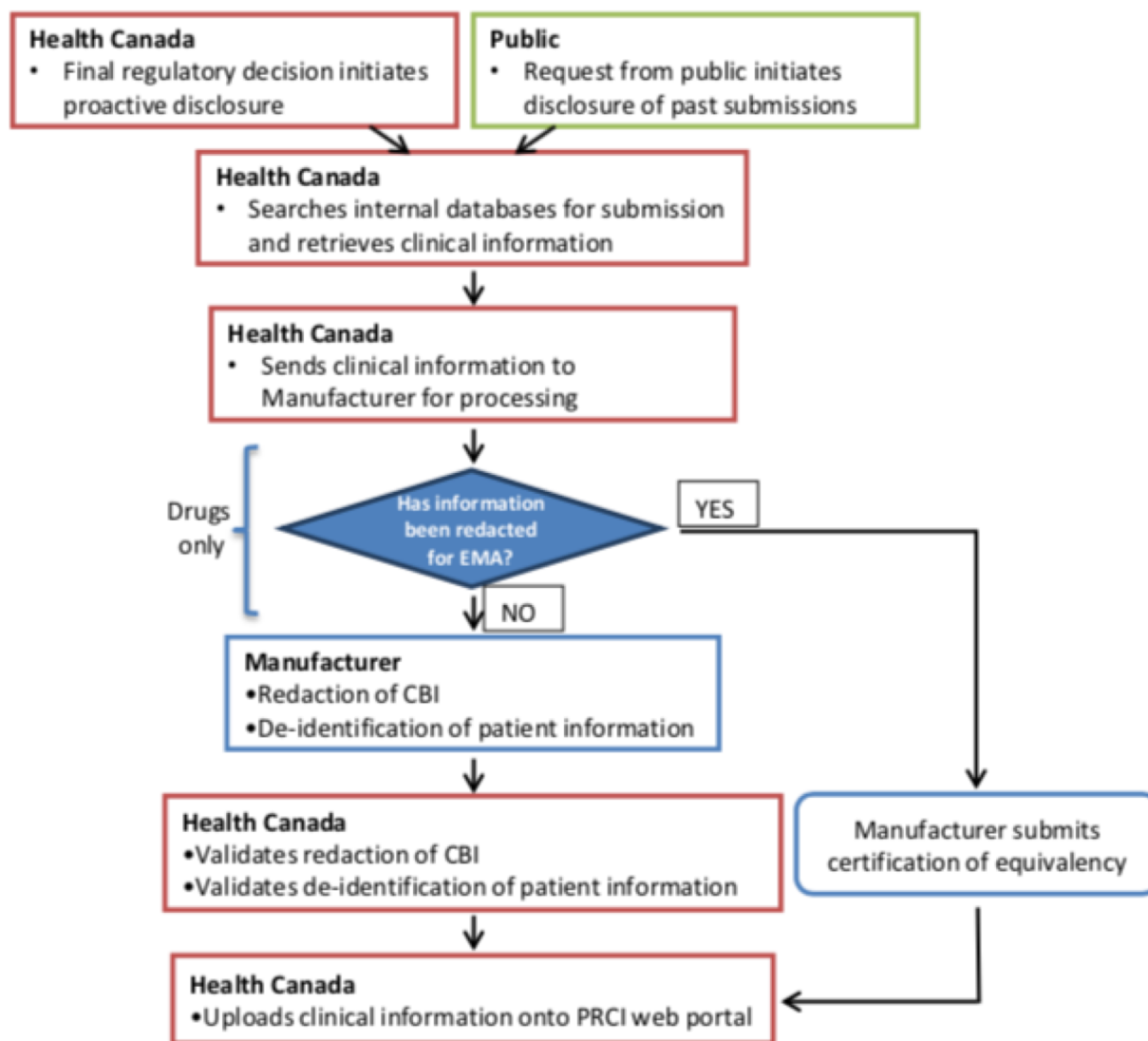


EMA Policy 0070, 2 years on...



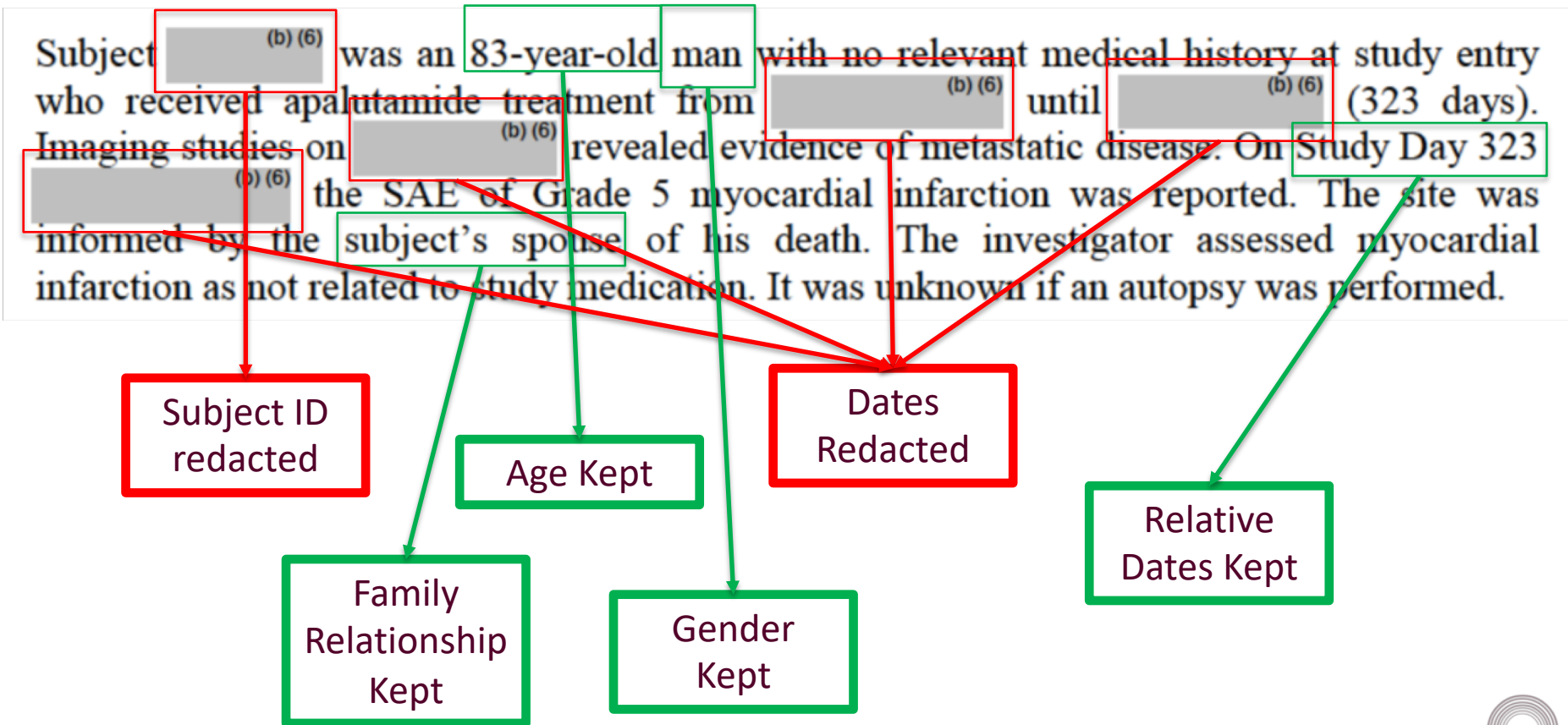
- 100+ Submission Packages published
- Sponsors still using in majoring qualitative approach coupled with redaction
- External Guidance updated 3 times, mainly for scope clarifications
- Due to Business Continuity Plan in connection with Brexit, Policy 0070 is posed since August 2018

Health Canada Draft Process

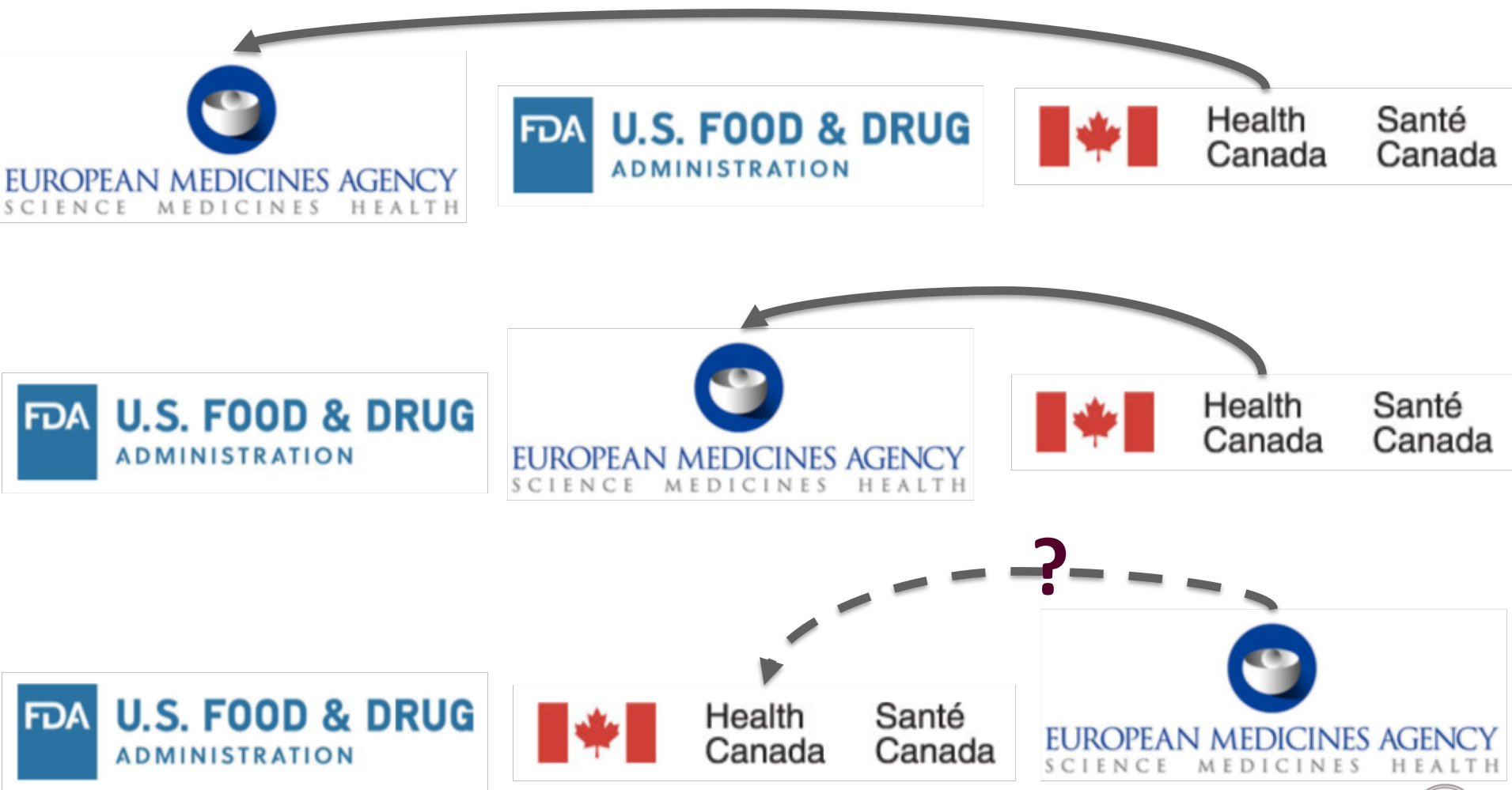


Focus on FDA Approach

- 1 Pilot Published so far, Janssen Pharmaceutica / ERLEADA
- Narratives out of scope, redaction only according to FOIA approach



Recognition Process?



Conclusions

- **EMA and Health Canada initiatives are very similar** while FDA's differ significantly in anonymization requirements and processes
 - Will FDA consider anonymized CSRs already published in other jurisdictions when conducting redaction on same documents? And vice-versa?
- **Use of Study Days in the CSRs** could minimize the anonymization effort and seems accepted by all 3 agencies as anonymized dates
- The question of **Joint Controllershship** should be clarified by all agencies as they review, validate or conduct anonymisation or redaction of documents
- **Three sources of same clinical documents** could be available in public domain. Which one will suit better the need of researchers?
- **Recognition processes** is only viable if there is an alignment of anonymization requirements

Thanks!

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