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

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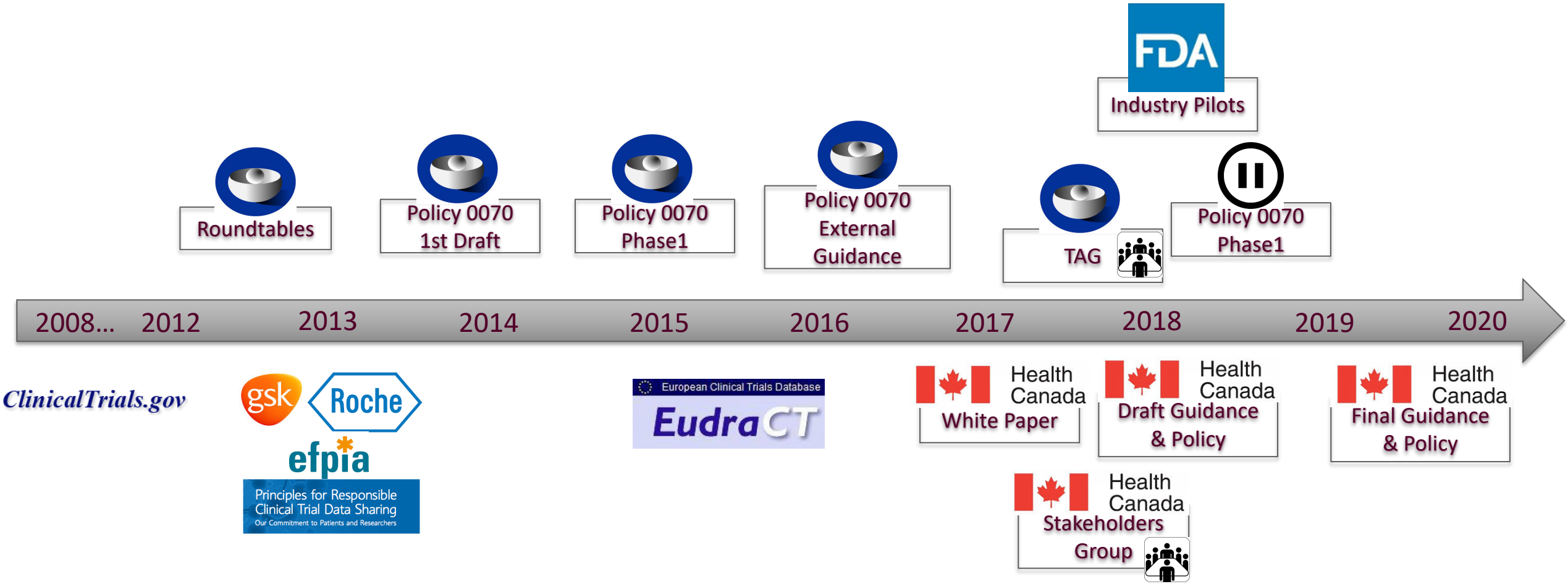
Agenda

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

Brief Overview



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Engaging Stakeholders

Item	EMA	Health Canada	FDA
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 to be planned with sponsors
Working Groups	EMA Technical Anonymisation Group	Health Canada Reference Group	FDA participates in the PhUSE Data Transparency Working Group
Working Groups Application	Public call for applications CV & Declaration of Interest (DoI) required	Individual call for applications Application Letter & DoI required	NA
Working Groups 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

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Processes

Item	EMA Policy 0070	Health Canada ~~(Draft)~~	FDA (Pilot)
Effective Date	1. January 2015	1. April 2019	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 ***Sponsors conduct anonymization*** *unless a certified EMA Policy 0070 document is available.* ***Documents are made public.***	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 ouctome**	**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** through a certification application	Not discussed
Review Process (Anonymization of PPD)	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**

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Anonymization Requirements

Item	EMA Policy 0070	Health Canada ~~(Draft)~~	FDA (Pilot)
Narratives in scope	Yes	Yes	**No**
Risk analysis	WP29 Opinion 3-Criteria Qualitative Quantitative	**Quantitative** ~~only~~ **Qualitative tolerated for an "intermediate period"**	"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, 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

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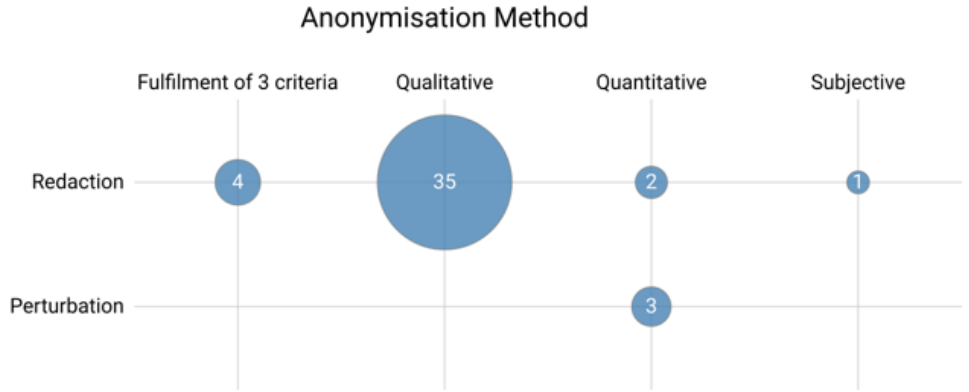
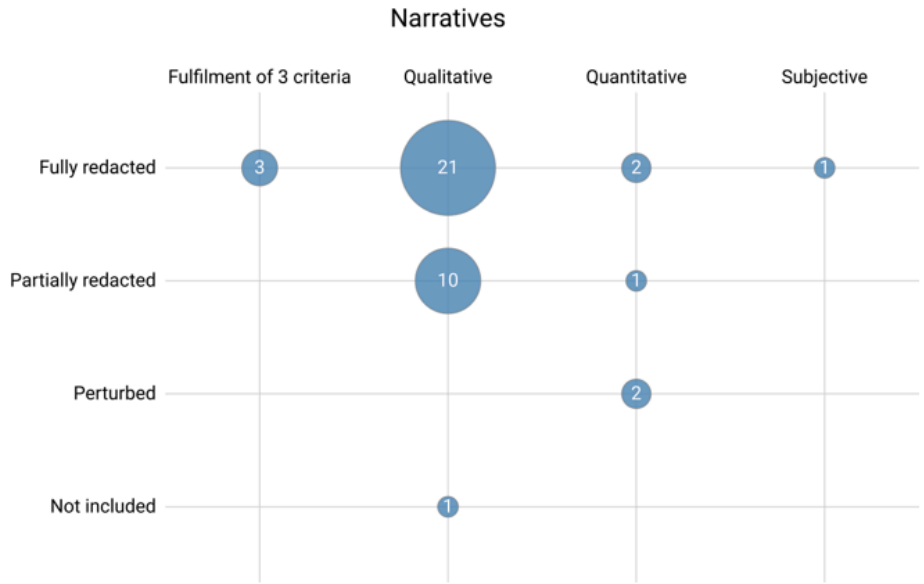
EMA Policy 0070, 2 years on…





- 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

Ref: Analysis of CSRs already published, PhUSE Review based on 47 submissions – Lukasz Kniola, November 2017

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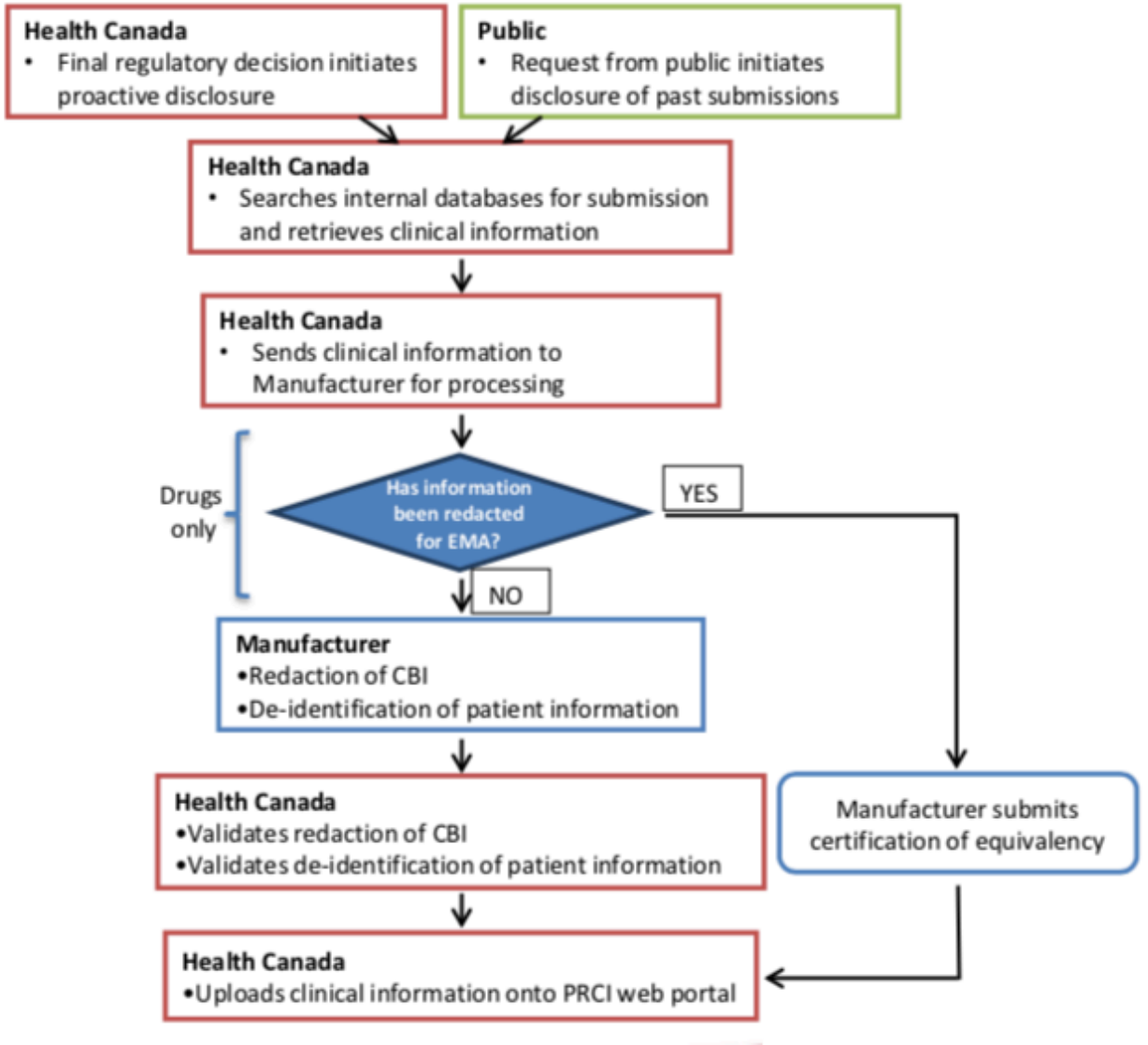
Health Canada Process



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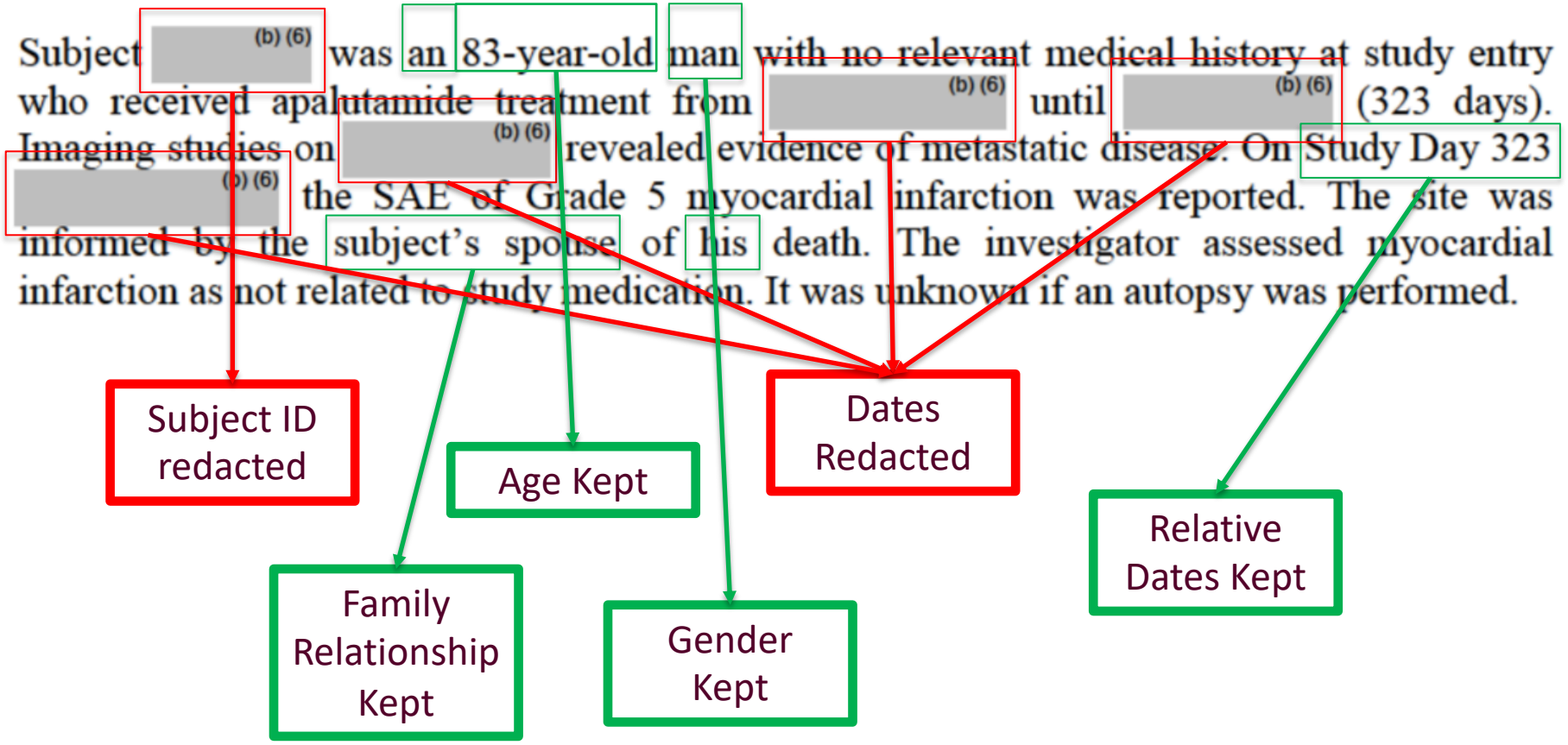
Focus on FDA Approach

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



Ref: "Drug Approval Package: ERLEADA" posted on FDA website, page 102, section 7.2.3.1 Deaths

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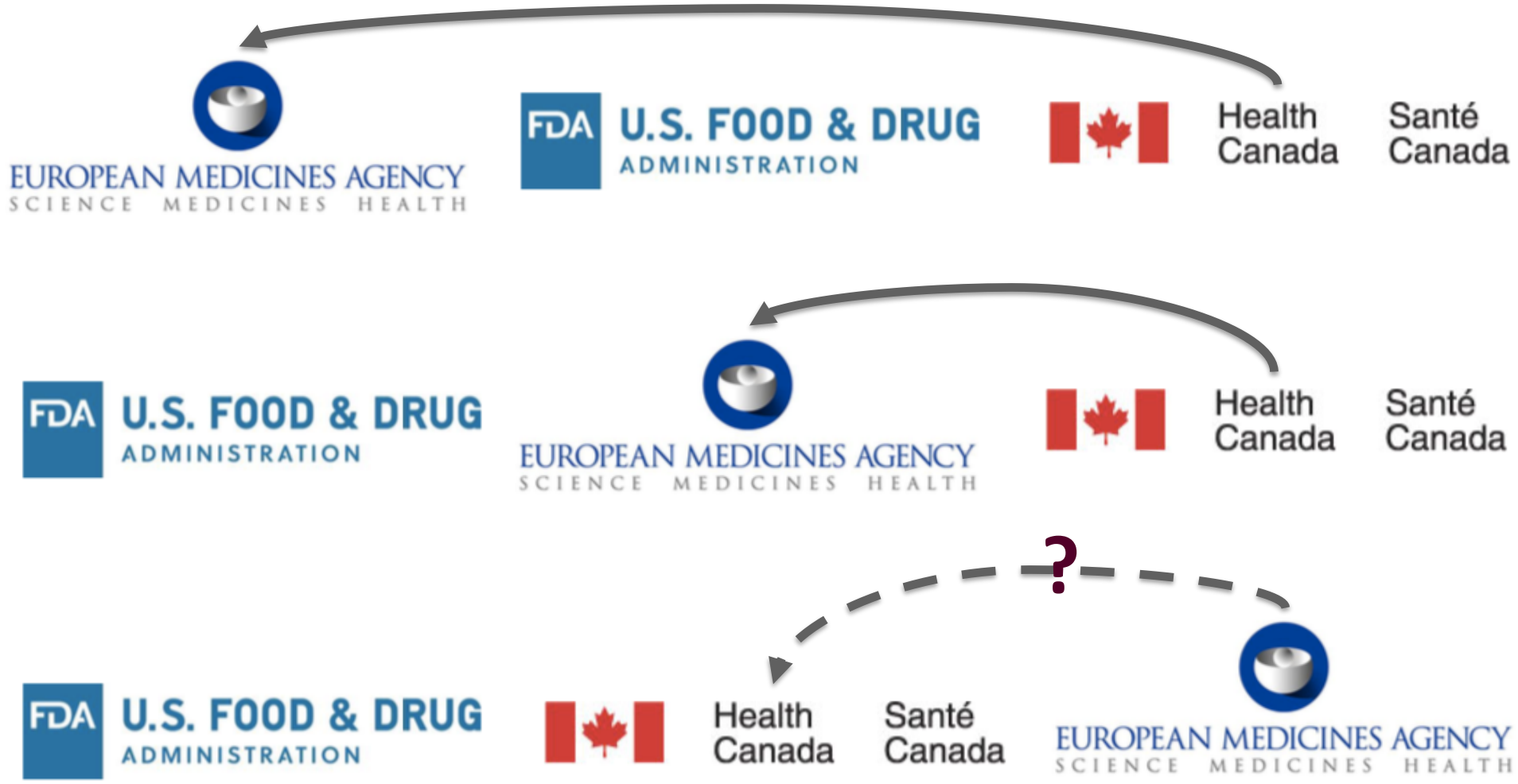
Recognition Process?



Who is the Data Controller? Sponsor or Agency?

- **EMA** provides opinions and comments…
- **Health Canada** plans to validate de-identification of Personal Protected Information…
- **FDA** conducts the redactions and Sponsors can notify FDA of special-attention items in CSRs…

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 accepeted by all 3 agencies as anonymized dates
- The question of **Joint Controllership** 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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