Big data & international harmonization efforts

UBC REB 2015 Retreat

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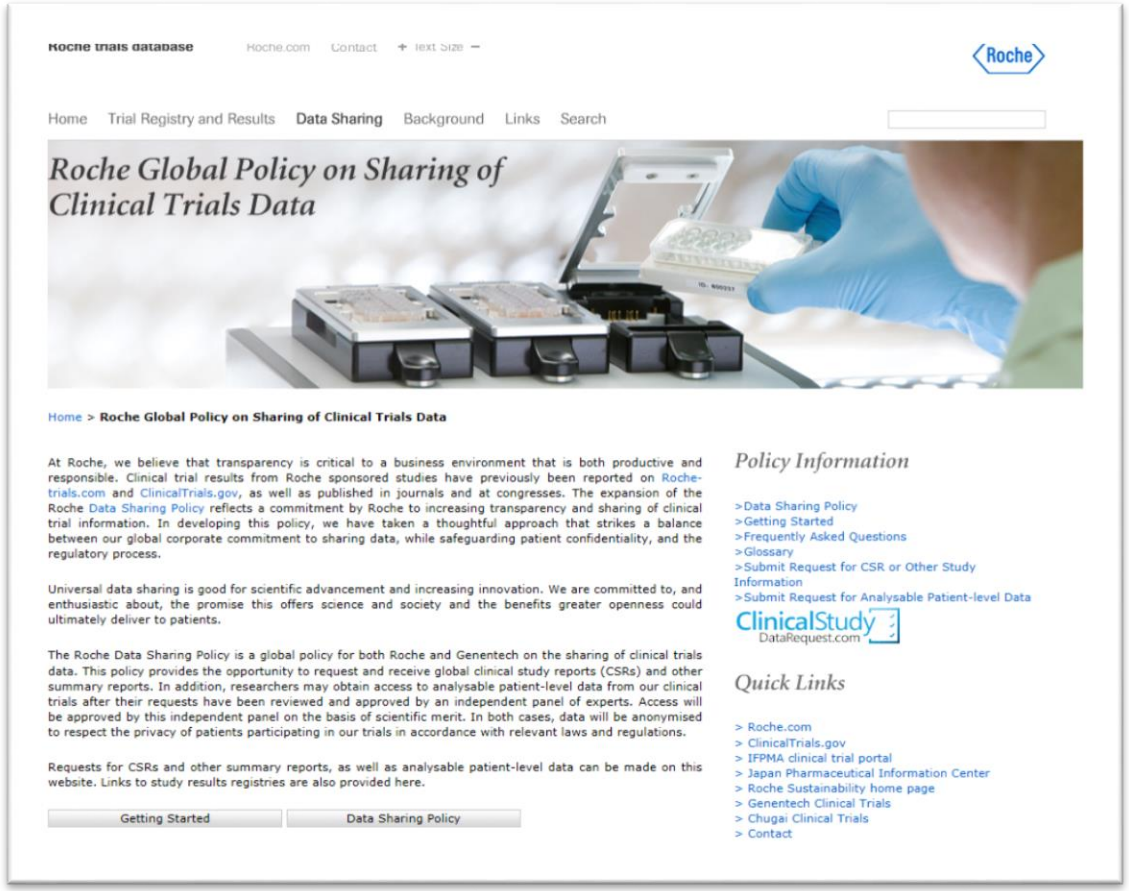
Big data & international harmonization efforts: The expectations



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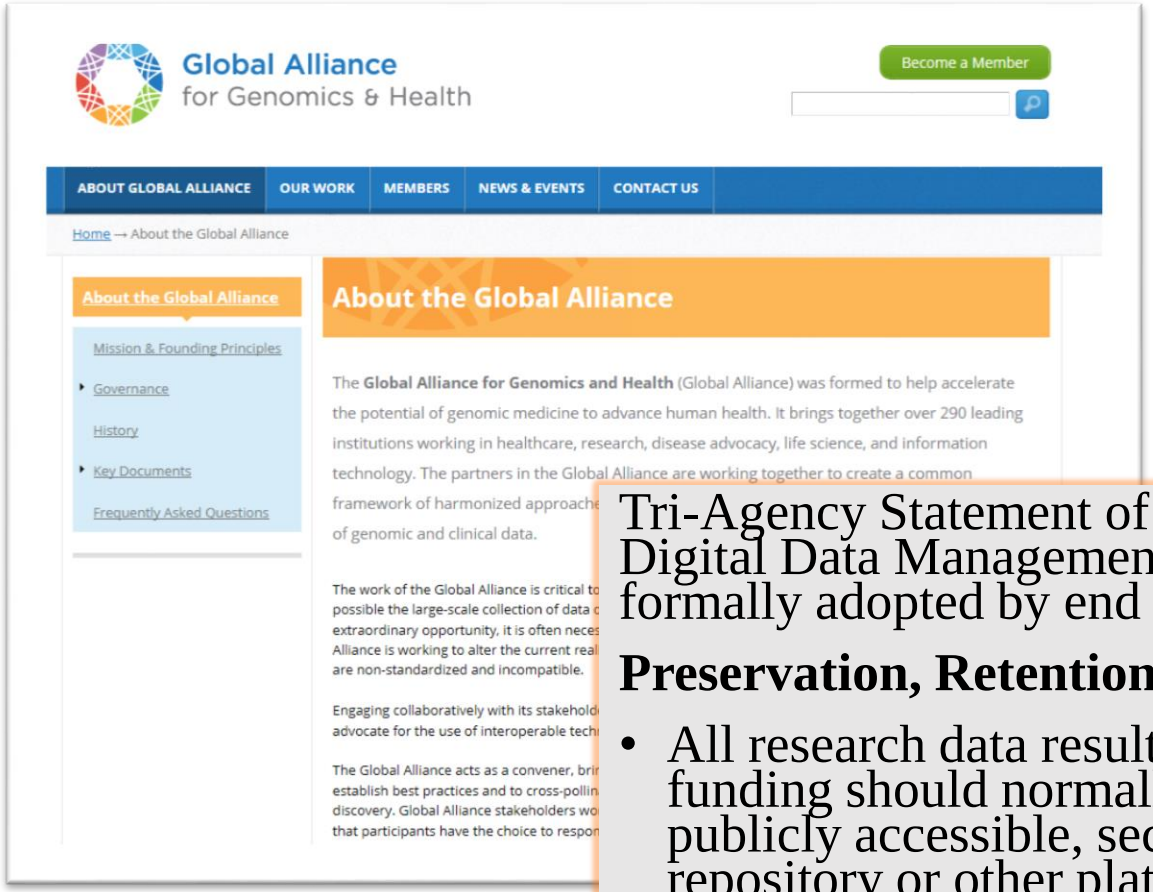

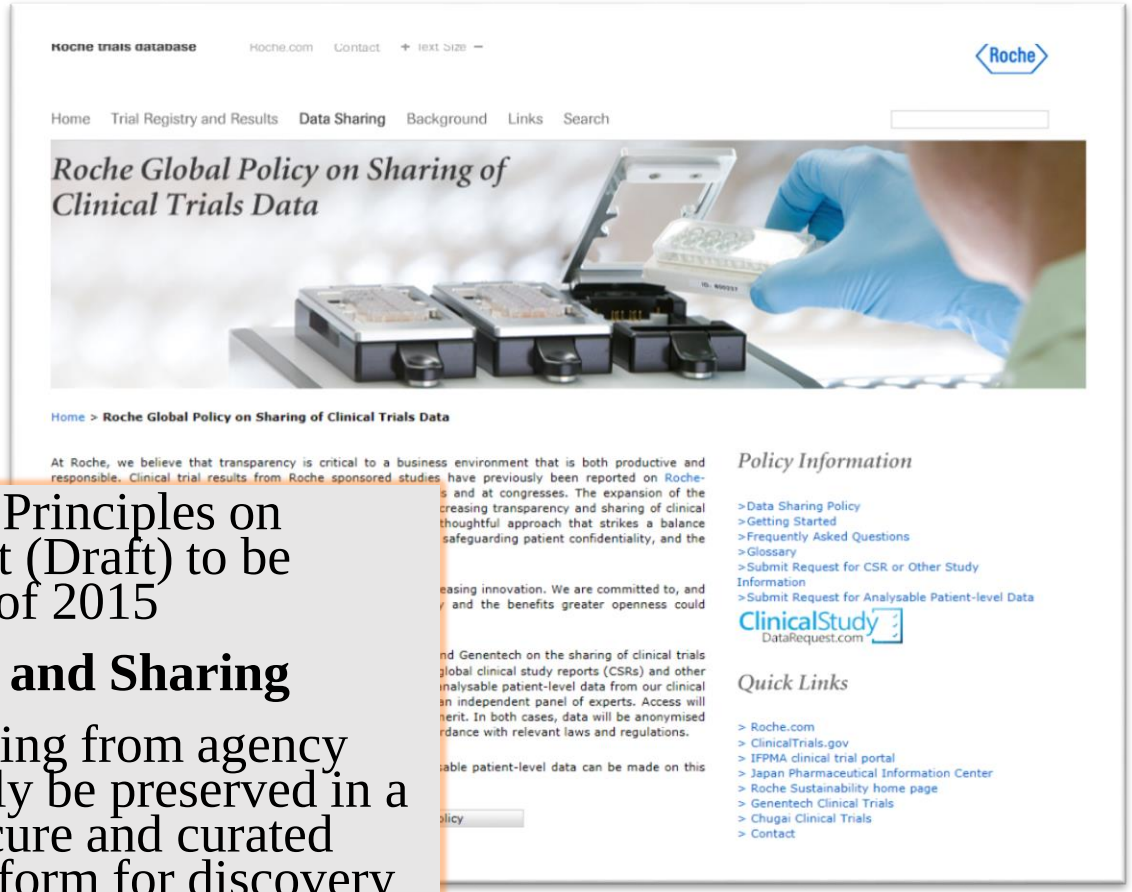

Tri-Agency Statement of Principles on Digital Data Management (Draft) to be formally adopted by end of 2015

Preservation, Retention and Sharing

- All research data resulting from agency funding should normally be preserved in a publicly accessible, secure and curated repository or other platform for discovery and reuse by others.

But…. *How to operationalize by REBs?*

We can all follow *TCPS2 (2014)* Article 5.5 criteria but are we doing it consistently?

- Uncertainty about legal implications
- How do we define de-identification and identifiable data?
- Who can be a data steward?

"Canada's governance of research ethics is fragmented, with significant differences across the provinces/territories. As well, laws on sharing data across provinces/ territories & between countries differ or are lacking, sometimes leading to confusion for researchers and REBs about whether, or on what basis, data can be shared."

"The risk of potential harm resulting from access to data is tangible but low. The level of risk can be further lowered through effective governance mechanisms."

Accessing Health and Health-Related Data in Canada **(2015) Key Findings (Council of Canadian Academies Expert panel)**
http://www.scienceadvice.ca/uploads/eng/assessments%20and%20publications%20and%20news%20releases/Health-data/HealthDataFullReportEn.pdf

Big data disconnect in practice

Table 3. Gap analysis results.

Procedural ethics theme	**Significant**	**Brief**	**Gap**
Data and tissues stored	88%	13%	0%
Accessibility	63%	19%	19%
Requirements for permission to access data and tissues	56%	31%	13%
Confidentiality	56%	31%	13%
Volume of data and tissues stored	56%	6%	38%
Data quality control	50%	19%	31%
Consent/assent guidelines	44%	38%	19%
Data management/ updating	38%	38%	25%
Requirements to store data and tissues	25%	38%	38%
Control to check if data/tissues are being submitted	6%	13%	81%
Disaster recovery	6%	13%	81%
Substantive ethics theme	**Significant**	**Brief**	**Gap**
Benefit sharing	44%	31%	25%
Commercial ties	25%	31%	44%
Special considerations for minors	13%	25%	63%
Incidental findings (IFs)	6%	6%	88%

Totals may not equal 100% due to rounding error.

*Longstaff, Khramova, Portales-Casamar, Illes. (2015). Sharing with More Caring: Coordinating and Improving the Ethical Governance of Data and Biomaterials Obtained from Children. PLOS One. 10(7): e0130527. doi:10.1371/journal.pone.0130527

Centering the human participant in REB review:
Consent relationship is intended to be a flexible process and participant specific

The reality with high risk clinical research

- Very little flexibility in how consent ought to be obtained
  - Fragile populations who are often very ill
  - No room for mistakes
  - Information is highly complex (study and risk information)
  - Extensive set of risks
  - What information can properly be omitted?
  - Who should make decisions to omit information?
  - Harmonized internationally and must meet rules/ guidelines from around the world
- One small but significant example –use of appendices (BC Cancer REB)

What to watch for ….*proposed changes to the US Common Rule (agreement to be governed ethically)*

- Issue 2: Reforms would require written consent for research use of biospecimens, even those that have been stripped of identifiers. Consent could be obtained using a standard, short form by which a person could provide open-ended consent for most research uses of a variety of biospecimens (such as all clinical specimens that might be collected at a particular hospital). This change would only apply to biospecimens collected after the effective date of the new rules.

- Issue 5: The regulations would be revised to provide greater specificity about how consent forms should be written and what information they should contain. The goal would be consent forms that are shorter, more readily understood, less confusing, that contain all of the key information, and that can serve as an excellent aid to help someone make a good decision about whether to participate in a study.

OHRP Webinar Series on the Common Rule NPRM

- **http://www.hhs.gov/ohrp/education/training/nprmwebinars.html**