

Big data & international harmonization efforts

UBC REB 2015 Retreat


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Big data & international harmonization efforts: The expectations

**Global Alliance**
for Genomics & Health

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About the Global Alliance

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About the Global Alliance

The **Global Alliance for Genomics and Health** (Global Alliance) was formed to help accelerate the potential of genomic medicine to advance human health. It brings together over 290 leading institutions working in healthcare, research, disease advocacy, life science, and information technology. The partners in the Global Alliance are working together to create a common framework of harmonized approaches to enable the responsible, voluntary, and secure sharing of genomic and clinical data.

The work of the Global Alliance is critical to realizing the potential of recent technological advances that make possible the large-scale collection of data on genome sequencing and clinical outcomes. To seize this extraordinary opportunity, it is often necessary to ask questions that span individual datasets. The Global Alliance is working to alter the current reality where data are kept and studied in silos, and tools and methods are non-standardized and incompatible.

Engaging collaboratively with its stakeholders, the Global Alliance works to establish, broadly disseminate, and advocate for the use of interoperable technical standards for managing and sharing genomic and clinical data.

The Global Alliance acts as a convener, bringing together global stakeholders across sectors to share and establish best practices and to cross-pollinate ideas and learning, fostering a culture of innovation and discovery. Global Alliance stakeholders work together to promote the highest standards for ethics, ensuring that participants have the choice to responsibly and securely share their genomic and clinical data to advance

Roche trials databaseRoche.comContact+ Text Size -

Roche

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Roche Global Policy on Sharing of Clinical Trials Data



Home > Roche Global Policy on Sharing of Clinical Trials Data

At Roche, we believe that transparency is critical to a business environment that is both productive and responsible. Clinical trial results from Roche sponsored studies have previously been reported on [Roche-trials.com](#) and [ClinicalTrials.gov](#), as well as published in journals and at congresses. The expansion of the Roche [Data Sharing Policy](#) reflects a commitment by Roche to increasing transparency and sharing of clinical trial information. In developing this policy, we have taken a thoughtful approach that strikes a balance between our global corporate commitment to sharing data, while safeguarding patient confidentiality, and the regulatory process.

Universal data sharing is good for scientific advancement and increasing innovation. We are committed to, and enthusiastic about, the promise this offers science and society and the benefits greater openness could ultimately deliver to patients.

The Roche Data Sharing Policy is a global policy for both Roche and Genentech on the sharing of clinical trials data. This policy provides the opportunity to request and receive global clinical study reports (CSRs) and other summary reports. In addition, researchers may obtain access to analysable patient-level data from our clinical trials after their requests have been reviewed and approved by an independent panel of experts. Access will be approved by this independent panel on the basis of scientific merit. In both cases, data will be anonymised to respect the privacy of patients participating in our trials in accordance with relevant laws and regulations.

Requests for CSRs and other summary reports, as well as analysable patient-level data can be made on this website. Links to study results registries are also provided here.

Getting StartedData Sharing Policy

Policy Information

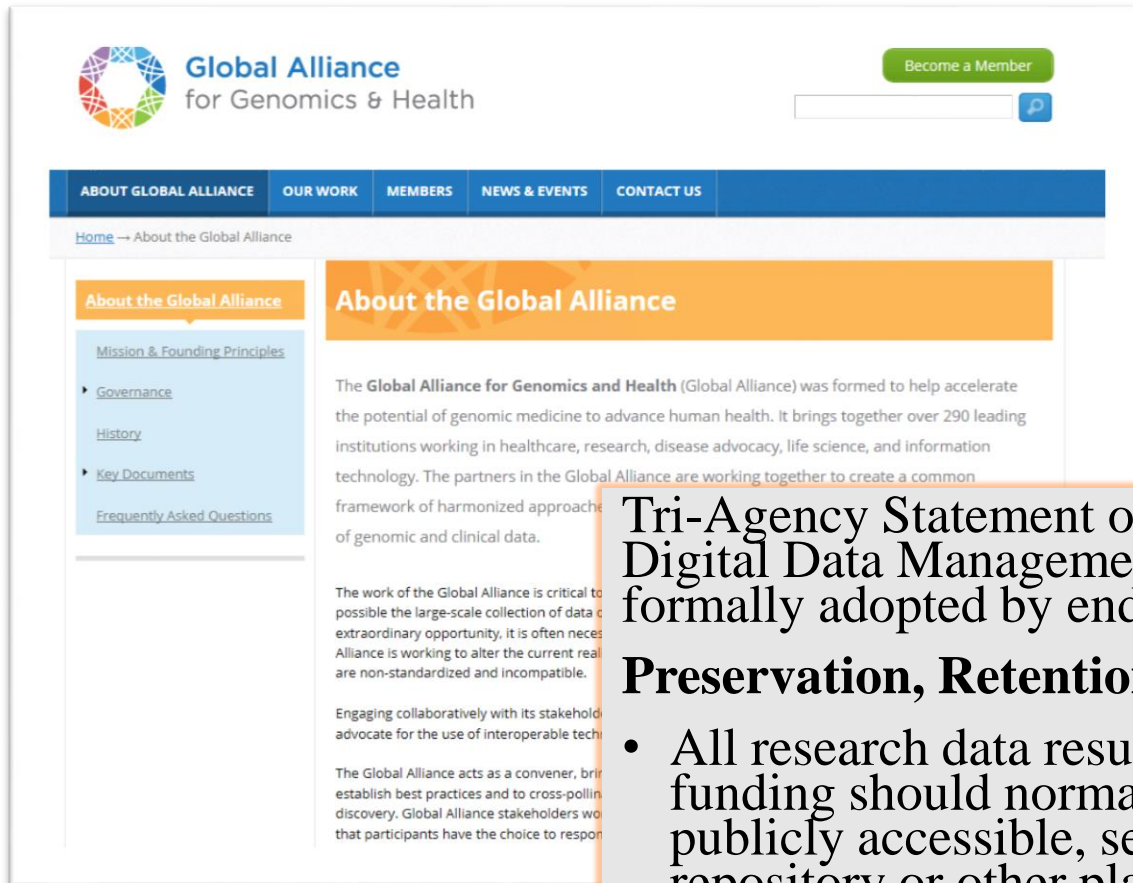
- > [Data Sharing Policy](#)
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Quick Links

- > [Roche.com](#)
- > [ClinicalTrials.gov](#)
- > [IFPMA clinical trial portal](#)
- > [Japan Pharmaceutical Information Center](#)
- > [Roche Sustainability home page](#)
- > [Genentech Clinical Trials](#)
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Big data & international harmonization efforts: The expectations



The screenshot shows the homepage of the Global Alliance for Genomics & Health. The header includes the logo, the text "Global Alliance for Genomics & Health", a "Become a Member" button, and a search bar. A navigation menu contains links for "ABOUT GLOBAL ALLIANCE", "OUR WORK", "MEMBERS", "NEWS & EVENTS", and "CONTACT US". Below the menu, a sidebar on the left lists "About the Global Alliance" with sub-links for "Mission & Founding Principles", "Governance", "History", "Key Documents", and "Frequently Asked Questions". The main content area, titled "About the Global Alliance", contains text about the organization's mission and the importance of data harmonization.

About the Global Alliance

The **Global Alliance for Genomics and Health** (Global Alliance) was formed to help accelerate the potential of genomic medicine to advance human health. It brings together over 290 leading institutions working in healthcare, research, disease advocacy, life science, and information technology. The partners in the Global Alliance are working together to create a common framework of harmonized approaches to the management and sharing of genomic and clinical data.

The work of the Global Alliance is critical to making possible the large-scale collection of data that offers an extraordinary opportunity. It is often necessary to alter the current reality where data are non-standardized and incompatible.

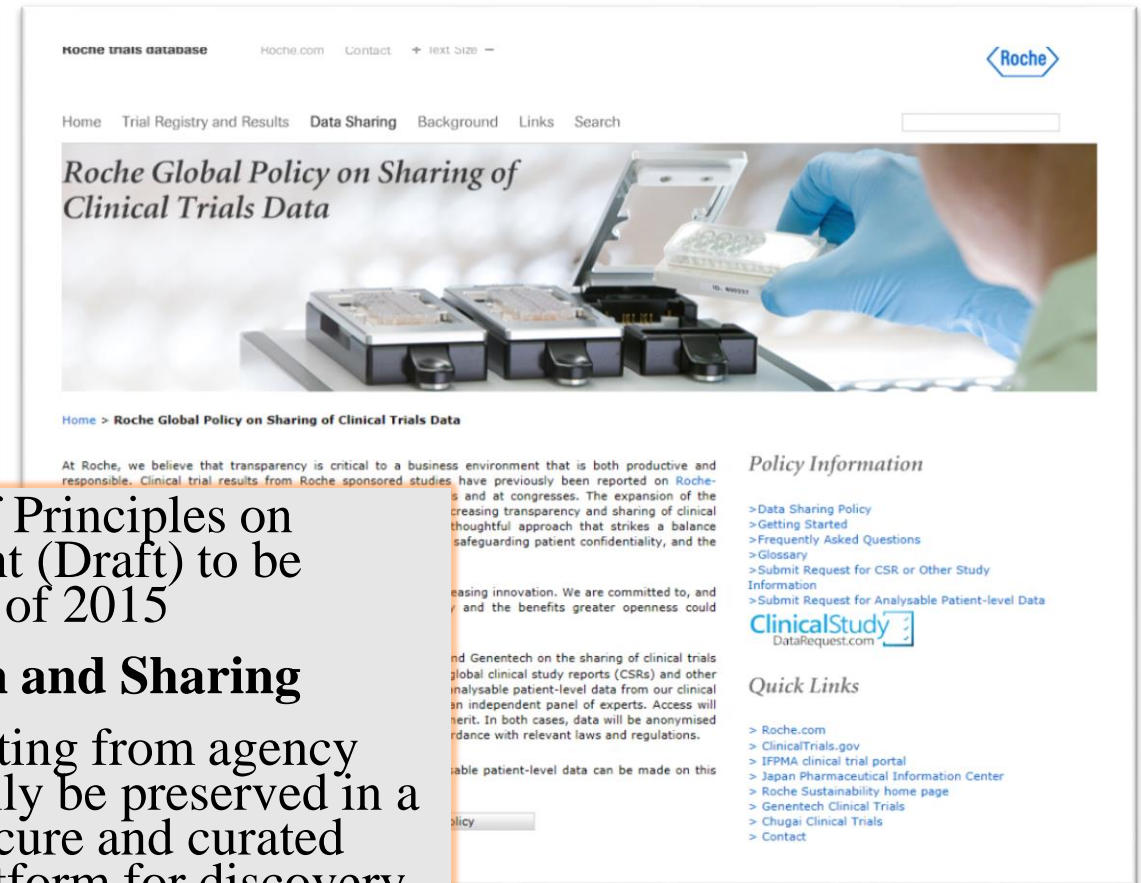
Engaging collaboratively with its stakeholders, the Alliance advocates for the use of interoperable technologies and standards.

The Global Alliance acts as a convener, bringing together stakeholders to establish best practices and to cross-pollinate ideas for discovery. Global Alliance stakeholders work to ensure that participants have the choice to respond to their needs.

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.



The screenshot shows the Roche Global Policy on Sharing of Clinical Trials Data website. The header includes the "Roche trials database" logo, links for "Roche.com", "Contact", and "Text Size", and the Roche logo. A navigation menu contains links for "Home", "Trial Registry and Results", "Data Sharing", "Background", "Links", and "Search". Below the menu, a large image shows a hand in a blue glove holding a small vial next to a multi-well plate. The main content area, titled "Roche Global Policy on Sharing of Clinical Trials Data", contains text about the importance of transparency and data sharing in clinical trials. A sidebar on the right lists "Policy Information" with links for "Data Sharing Policy", "Getting Started", "Frequently Asked Questions", "Glossary", "Submit Request for CSR or Other Study Information", and "Submit Request for Analysable Patient-level Data". Below this is a "ClinicalStudy DataRequest.com" logo and a "Quick Links" section with links for "Roche.com", "ClinicalTrials.gov", "IFPMA clinical trial portal", "Japan Pharmaceutical Information Center", "Roche Sustainability home page", "Genentech Clinical Trials", "Chugai Clinical Trials", and "Contact".

Roche Global Policy on Sharing of Clinical Trials Data

At Roche, we believe that transparency is critical to a business environment that is both productive and responsible. Clinical trial results from Roche sponsored studies have previously been reported on Roche websites and at congresses. The expansion of the transparency and sharing of clinical trial data is a thoughtful approach that strikes a balance between the need for transparency and the need for safeguarding patient confidentiality, and the need for increasing innovation. We are committed to, and the benefits greater openness could bring to the world of medicine.

Roche and Genentech on the sharing of clinical trial data. Roche will make available patient-level data from our clinical trials to an independent panel of experts. Access will be granted in both cases, data will be anonymised in accordance with relevant laws and regulations.

Available patient-level data can be made on this platform.

Policy Information

- > Data Sharing Policy
- > Getting Started
- > Frequently Asked Questions
- > Glossary
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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, Khranova, 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>