GA4GH::CRDSA Strategic Partnership

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1. Overview

This document outlines the rationale and implementation of a Strategic Partnership between the Global Alliance for Genomics and Health (GA4GH) and the Clinical Research Data Sharing Alliance (CRDSA). This partnership formalises the collaboration between the two organisations to support responsible data sharing and align efforts in advancing standards for clinical research and genomic data interoperability.

CRDSA brings together key stakeholders in clinical research to improve **data sharing and interoperability through the development of standards and the advancement of regulatory policies.** For this agreement, clinical research data refers to the secondary use of individual patient data (IPD) from clinical trials and real-world data (RWD) sources. GA4GH provides global technical standards and policy frameworks to facilitate genomic data sharing. This **Strategic Partnership** will allow both organisations to leverage their respective strengths to advance data sharing across research and clinical domains.

2. Mission

Through this partnership, **GA4GH and CRDSA** will work collaboratively to expand **interoperability, responsible data sharing, and alignment of genomic and clinical research data standards**.

- GA4GH will provide **technical standards, policy frameworks, and ecosystem expertise** related to genomic data sharing to enhance and expand CRDSA initiatives.
- CRDSA will bring **clinical research data expertise and industry engagement** to ensure GA4GH standards align with clinical research needs.

3. Strategic Partnership Objectives

- **Alignment of Data Sharing Policies**: Ensure that CRDSA's clinical research data sharing frameworks align with and, as applicable, incorporate GA4GH's genomic and health data sharing policies.
- **Standardisation of Data Models**: Collaborate on developing and implementing GA4GH technical standards within CRDSA's data-sharing ecosystem.

- **Interoperability Between Clinical Research and Genomic Data**: Improve cross-domain data integration to advance precision medicine.
- **Regulatory and Compliance Harmonisation**: Address ethical, legal, and regulatory challenges related to clinical trial data sharing and genomic data interoperability.
- **Community Engagement**: Promote joint participation in Work Streams, strategic initiatives, and shared outreach activities.

4. Scientific Need

The integration of clinical trial data and genomic data is essential for advancing personalised medicine, biomarker discovery, and translational research. However, data fragmentation, regulatory challenges, and lack of common standards hinder progress.

This partnership will address these challenges by:

- **Enhancing data discoverability, access, and reuse** through shared frameworks.
- **Ensuring responsible data sharing** while complying with **global privacy regulations**.
- **Bridging the gap** between clinical research organisations and genomic research initiatives.

5. Operational Need

CRDSA and GA4GH recognise the need for structured collaboration to:

- **Promote the adoption of GA4GH standards** across CRDSA member organisations.
- **Develop a shared roadmap** for joint activities, including Work Stream participation, interoperability pilots, and community engagement.
- **Leverage CRDSA's expertise in clinical research data governance** to inform GA4GH policy development.
- **Engage stakeholders** across industry, academia, and regulatory agencies to drive adoption of standards.

6. Roles and Responsibilities

GA4GH's Responsibilities:

- Provide **technical expertise and frameworks** for data interoperability.
- Facilitate **Work Stream engagement** for CRDSA representatives.
- Align **GA4GH standards with clinical research needs**.
- Promote joint activities through GA4GH's **community engagement channels**.

CRDSA's Responsibilities:

- Advocate for **GA4GH standards adoption** within clinical research data-sharing initiatives.
- Provide **subject matter expertise** on clinical trial data sharing, data protection/privacy, and regulatory compliance.
- Support **pilot projects** implementing GA4GH standards in CRDSA-related initiatives.
- Encourage CRDSA members to engage with **GA4GH activities**.

7. Governance and Coordination

- **Work Stream Participation**: CRDSA representatives will participate in relevant GA4GH Work Streams.
- **Annual Strategic Meetings**: CRDSA and GA4GH will regularly convene to review progress, address challenges, and set future directions.
- **Ad hoc initiatives**: development of joint, time-limited projects to deliver on specific requirements, e.g. data protection and privacy.
- **Membership and Voting**:
    - CRDSA will have **one voting seat** on the GA4GH Product Steering Committee.
    - GA4GH will have **one voting seat** on CRDSA's Steering Committee.

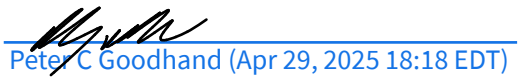
8. Amendments and Termination

This non-binding agreement is intended to be **flexible and evolving**. It may be amended by mutual written consent of both parties. Either party may terminate this agreement with **90 days' written notice**.

9. Signatories

This agreement is entered into by the authorised representatives of both organisations:

For GA4GH:


Peter C Goodhand (Apr 29, 2025 18:18 EDT)

Name: Peter Goodhand
Title: Chief Executive Officer
Date: 29/04/25

For CRDSA:

Aaron Mann

Name: Aaron Mann
Title: Chief Executive Officer
Date: 05/05/25