CRG and CNAG are part of a global alliance to share and interpret personal genomic data

- *The first steps to create this alliance were made by over 70 leading health care, research, and disease advocacy organizations in order to enable secure sharing of genomic and clinical data.*

- *3 of the partners are Spanish: the Centre for Genomic Regulation (CRG), the Centro Nacional de Análisis Genómico (CNAG) and the Spanish National Cancer Research Centre (CNIO).*

- *The alliance aims to develop agreed standards to facilitate the interpretation of genomic data from users all over the world with the necessary biomedicine base, which requires a great amount of effort that any party alone can develop.*

Over 70 leading health care, research, and disease advocacy organizations that involve colleagues all across the world have taken the first steps to form an international alliance dedicated to enabling secure sharing of genomic and clinical data. Among these institutions, there are 3 Spanish centers: the Centre for Genomic Regulation (CRG), the Centro Nacional de Análisis Genómico (CNAG) and the Spanish National Cancer Research Centre (CNIO).

The cost of genome sequencing has fallen one-million fold, and more and more people are choosing to make their genetic and clinical data available for research, clinical, and personal use. However, interpreting these data requires an evidence base for biomedicine that is larger than any one party alone can develop, and that adheres to the highest standards of ethics and privacy. These organizations recognize that the public interest will be best served if we work together to develop and promulgate standards (both technical and regulatory) that make it possible to share and interpret this wealth of information in a manner that is both effective and responsible.

BACKGROUND

Technological advances have led to large-scale collection of data on genome sequencing and clinical outcomes, with great promise for medicine. In late January 2013, 50 colleagues from eight countries met to discuss the current challenges and opportunities in genomic research and medicine, and how these groups could work together to foster medical progress. They concluded that the greatest need was a common framework of international standards designed to enable and oversee how genomic and clinical data are shared in an effective, responsible, and interpretable manner. They envisioned a trusted and authoritative international partnership, intended to include leading healthcare providers, research institutions, disease advocacy groups, life science and information technology companies, and others, to facilitate this.

This alliance is now in the beginning stages of formation. Following the circulation of a White Paper, over 70 organizations from Africa, Asia, Australia, Europe, and North and South America, have joined together to form a non-profit global alliance that will work to develop this common framework, enabling learning from data while protecting participant autonomy and privacy.

THE COMMITMENT

Each organization has signed a non-binding Letter of Intent, pledging to work together to create a not-for-profit, inclusive, public-private, international, non-governmental organization (modeled on the World Wide Web Consortium, W3C) that will develop this common framework. They have committed to furthering innovation by supporting the creation of open technology standards to support the development of interoperable information technology platforms that will embody these principles and accelerate progress in biomedicine.

The aim is that ultimately data will be stored in platforms built using the interoperable standards. Whether participants and organizations put all or some data into these or other platforms will be their own decision, but the common vision for the platforms is not that they will be a shared repository for data; rather, the platforms will enable sharing and learning regardless of where data are stored.

In signing the Letter of Intent, the organizations have committed to the global alliance having the following core principles:

- Respect – for the data sharing and privacy preferences of participants
- Transparency – of governance and operations
- Accountability – to best practices in technology, ethics, and public outreach
- Inclusivity – partnering and building trust among stakeholders
- Collaboration – sharing data and information to advance human health
- Innovation – developing an ecosystem that accelerates progress
- Agility – acting swiftly to benefit those suffering with disease

Member organizations recognize that when discussions occur about sharing large amounts of data, important questions about ethics and privacy naturally arise. Accordingly, members have committed to work together to establish a framework so that participants will have the right to share genomic and clinical information to advance human health as broadly or narrowly as they are comfortable with, including not at all.

A list of organizations that have signed the Letter of Intent is attached below.

NEXT STEPS

Thus far, the Letter of Intent has been signed by healthcare providers, disease advocacy organizations, research funders, and biomedical research institutions—all dedicated to improving human health. Now, they are inviting other organizations – for-profit as well as not-for-profit – to join in forming the alliance, building on many ongoing efforts around the world to address these opportunities and challenges. There is much work ahead, but they are confident that, working together as partners, they will respond to important challenges and enable future advances that would be impossible working alone.

STATEMENTS FROM PARTNERS AND STAKEHOLDERS:

“The ability to collect and analyze large amounts of genomic and clinical data presents a tremendous opportunity to learn about the underlying causes of cancer, inherited and infectious diseases, and responses to drugs,” said David Altshuler, Deputy Director of the Broad Institute of Harvard and MIT. “However, we will only

realize this opportunity if we can establish effective and ethically responsible approaches to share data. We believe that by working together, and by committing to the principle that each individual has the right to decide whether and how broadly to share their personal health information, we can accelerate progress in life sciences and medicine."

"Now that sequencing a genome is becoming cheaper everyday, one single institution can't cope with the vast information coming from both the personal genomic data that users make available for research and from the fast pace biomedical findings are happening", says Luis Serrano, Director of the Centre for Genomic Regulation (CRG), in Barcelona, Spain. "Being part of this pool of expert centers is an invaluable step forward for Spanish research institutions. It is just a first step and we have a lot of work ahead to do".

"Achieving a system for secure sharing of genomic and clinical data will hugely accelerate findings that will benefit patients. It should be kept in mind that all of us at some point in our lives are patients," says Ivo Gut, Director of the Centro Nacional de Análisis Genómico (CNAG), in Barcelona, Spain. "Sharing will benefit us all."

"As we form this alliance, we feel a great sense of urgency," said Brad Margus, founder and Volunteer President of A-T Children's Project, a non-profit organization that aims to find life improving therapies and a cure for A-T, a rare genetic disease that attacks children. "Patients and families want and deserve better approaches to treatment, and it is a responsibility to organize ourselves to maximize progress. At the same time, in our haste to make progress, we must make sure to respect the various opinions that exist, and to respect the autonomy of each individual to decide how he or she participates."

"In recent years, many groups around the world have recognized the need for improved approaches to bring together genomic and clinical data, and some have made progress addressing this," said Michael Stratton, Director of the Wellcome Trust Sanger Institute, a leading genome research institute in Hinxton, UK. "But in coming together, and studying the challenges, we recognized that something was missing: an international body that spanned diseases and institutions, committed to furthering progress in an innovative and responsible fashion."

"We are facing a crossroads regarding how we learn from and protect people's genomic and clinical data—and there is the exciting chance to do this correctly from the beginning," said Sharon Terry, President of the Genetic Alliance, a non-profit health advocacy organization committed to transforming health through genetics and including 1,200 disease-specific advocacy organizations. "We have come together to serve the public interest, to maximize learning, and to respect the autonomy, privacy, and security choices of participants. Our announcement today serves as an open invitation to the world health community to join us as part of an effort that hopefully will spur medical progress across the globe."

"At present, it is generally not possible to predict which changes in DNA sequence lead to clinical consequences. Only by comparing each personal genome sequence to a large repository of other such data can robust patterns and relationships be identified," said Tom Hudson, Chairman of the Executive Committee of the International Cancer Genome Consortium, and President of the Ontario Institute for Cancer Research in Canada. "The stakes are high, because if we get it right we can create new opportunities to define diagnostic categories, streamline clinical trials, and match patients to therapy. We want to make sure this is done in a global manner, and with the highest standards for ethics and privacy."

“The progress in biomedicine made possible by widespread sequencing of the human genome and integration with clinical information will raise important questions about ethics, patient consent, technology, and regulation,” said Bartha Knoppers, Chair of the Board of P3G, an international consortium of population biobanks, and Director of the Centre of Genomics and Policy at McGill University. “In forming this international partnership that brings together ethics, privacy, medicine, research, and technology under one tent, we aim to confront those questions from the most informed position.”

“In order to speed progress from research discoveries to improved patient care we must work together – not only within our own counties, but across national and geographic boundaries,” said Fabien Calvo, Director of Research Programs at INCa, the French National Cancer Institute. “Doing so requires that we define shared approaches from the outset, rather than trying to do so after the fact.”

"The H3ABioNet (Bioinformatics network for H3Africa) project aims to provide bioinformatics capabilities so that genomics can benefit people and societies across Africa,” said Nicky Mulder of the University of Cape Town in South Africa. "By working internationally as part of a global alliance, we can rapidly bring cutting-edge capabilities to bear on problems relevant to the local setting. The technical challenges we will be facing with genomics data generated in Africa will be addressed by this alliance."

“Medicine is in the midst of a revolution, and as we enter the era of precision medicine and widespread genome sequencing, we are at a crossroad,” said Betsy Nabel, MD, President of the Brigham and Women’s Hospital in Boston, and a former Director of the National Heart Lung and Blood Institute at NIH. "If we continue to work in silos, each lacking the critical mass of data and methods needed to make progress and care for patients we will miss this tremendous opportunity to improve human health and save lives. The physicians and scientists of Brigham and Women's Hospital believe that, through the work of the Global Alliance, we will have access to the data we need to realize the promise of genomic medicine.”

"Understanding the role of genome sequence in disease will require a technological infrastructure adequate to analyze millions of genomes with associated clinical information," said David Haussler, Director of the Center for Biomolecular Science & Engineering at the University of California at Santa Cruz and an investigator of the Howard Hughes Medical Institute. "If we design it up front for interoperability, and to include the mechanisms needed to manage privacy and consent, we will accelerate progress immeasurably."

"Cancer is one of the earliest and most compelling areas of medicine in which genomics is providing benefit to patients," said Charles Sawyers, Chair of the Program in Human Oncology and Pathogenesis at Memorial Sloan-Kettering Cancer Center and President of the American Association for Cancer Research. "Our ability to provide accurate information to patients, and to learn why some people respond to therapy and others do not, requires the international approach and shared standards that the alliance aims to create."

More information:

CNAG: Anna Borrell - 93 402 0580 – amborrell@pcb.ub.cat
CRG: Glòria Lligadas – 93 3160153 – gloria.lligadas@crg.eu