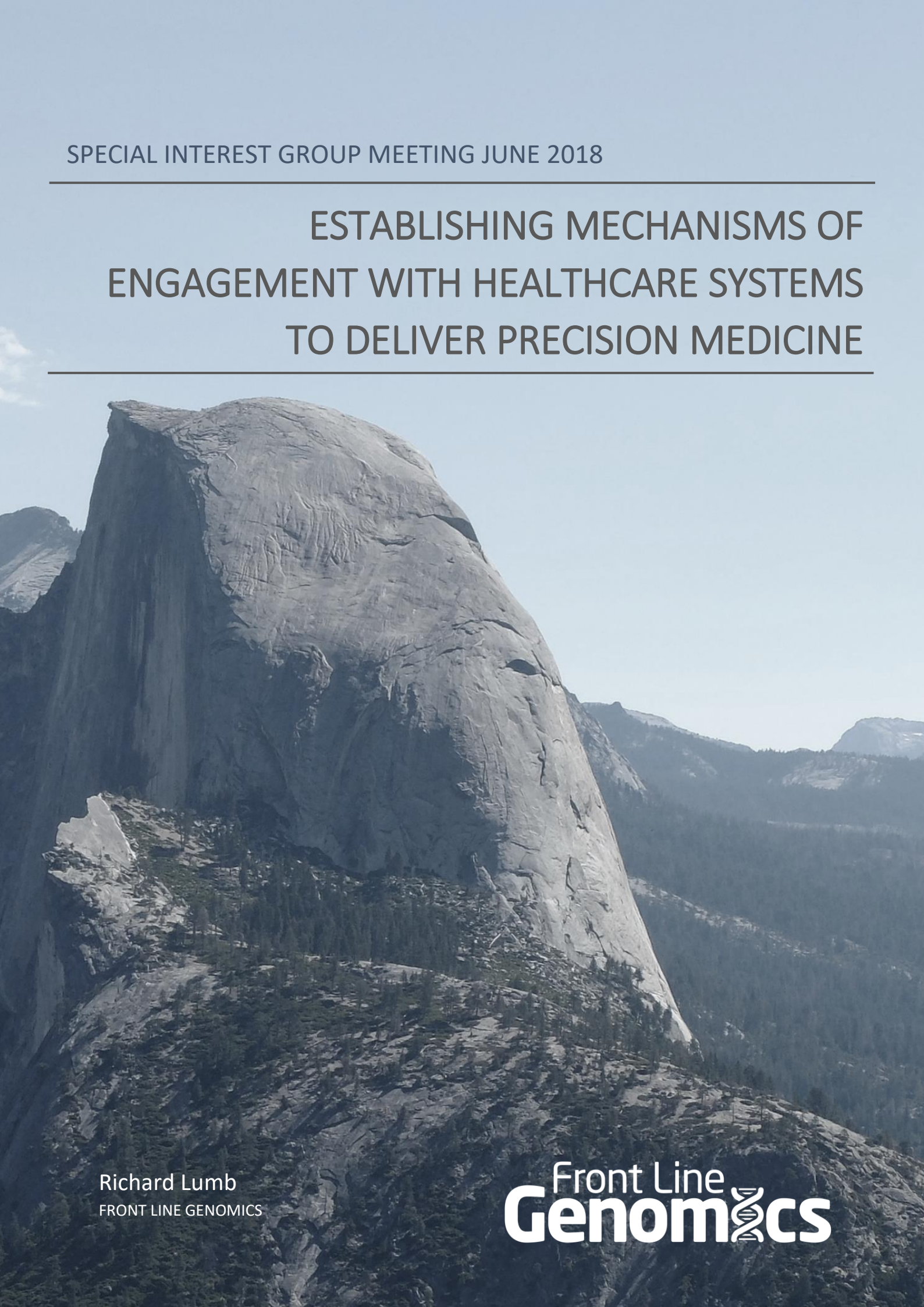
SPECIAL INTEREST GROUP MEETING JUNE 2018

ESTABLISHING MECHANISMS OF ENGAGEMENT WITH HEALTHCARE SYSTEMS TO DELIVER PRECISION MEDICINE



Richard Lumb
FRONT LINE GENOMICS

Front Line Genomics

Foreword

Healthcare systems are generating increasing amounts of genetic data enriched with linked phenotypic information as genomics becomes a more established part of clinical care. Amassing genomic data in healthcare silos creates an access barrier to rich information that both researchers and drug developers could mine to understand and treat disease.

To explore how such barriers may be overcome in future, experts in the field were brought together for a meeting under Chatham House Rules, in Boston on June 19th. In order to maintain a balanced perspective, the participants of the meeting were selected from a range of backgrounds, with many different specialties and focuses.

The purpose of this meeting was to identify current roadblocks to enabling the full potential of precision medicine to patients. Through peer-level discussion immediate priorities were to be identified with a clear focus on topics such as patient consent, privacy, the associated cultural attitudes, and collaborative opportunities that will help to harmonize work carried out across organization types. Following on from the meeting with the key barriers now recognized, progress towards a shared goal can be accelerated through conversations, collaboration, and collective thinking.

This report presents an accurate reflection of the discussions that took place at this meeting and does not constitute an official statement from any of the individual participants, their organizations, or Front Line Genomics.

Attendees:

Michael Braxenthaler, Global Head, Strategic Initiatives, Roche

Carrie Blout, Senior Genetic Counsellor and Project Manager, Brigham and Women's Hospital and Harvard Medical School

Adem Albayrak, Product Lead, DFCI Informatics, Dana-Farber Cancer Institute

Vasu Rangadass, CEO, L7 Informatics

Shira Rockowitz, Genomics and Bioinformatics Lead Research Computing, Boston Children's Hospital

Matthew Lebo, Director, Bioinformatics, Brigham and Women's Hospital

Will Chen, Director of Computational and Systems Biology, Biogen

Vibhor Gupta, Director, Pangaea Group

Gaurav Kaushik, Associate Director, Data Products & Strategy, Foundation Medicine

Taunton Paine, Senior Policy Analyst, Clinical and Healthcare Research Policy Division, Office of Science Policy, National Institutes of Health (NIH)

Michael Hunter, SVP, Strategy, and General Manager, US Operations, PetaGene

Will Chen, VP Product Management and Business Development, Precision Medicine, Elsevier

David Thomas, Director of Cachexia Research and Therapeutic Development, The Broad Institute

Ingrid Holm, Associate Professor of Paediatrics, Harvard Medical School

David Koepsell, CEO & Partner, Encrypgen

Piotr Sliz, Chief Research Information Officer, Boston Children's Hospital

Jason Labonte, Head of Product, DataVant

Frances Shaw, Producer, Front Line Genomics

Richard Lumb, CEO and Founder, Front Line Genomics

Report Author: Frances Addison, Staff Writer, Front Line Genomics

Points of Discussion:

Communication

- **Institutional review boards are not harmonized** across different organizations and this has led to an imbalance of what work is being enabled. A part of this is due to a lack of clear communication between the scientists and the different institutional counsels, ultimately causing patient care to suffer.
  Harmonization of IRBs is already possible with multi-site studies because there are standard protocols in place. If similar protocols with an agreed-upon language could be implemented universally, research could be enabled more easily, and IRBs would be in a stronger position to judge work accurately.

- **Providing consent is too difficult and complicated for patients** and this is limiting their willingness to do so. To account for all the possible uses of their data, the forms necessary for patients to share their genomic information are very long and technical, and lack consistency across different clinical centers.
  There is also currently no practical way for patients to revoke consent at a later date, should they decide that they no longer want their data being made available. As new uses for genomic data are being continually developed, this can be an important issue for some patients and may dissuade them from sharing their data.

- **People need to feel empowered by their data.** There are many ways in which this is being achieved, such as through direct-to-consumer companies that leave the patient in control of their data or blockchain alternatives that make the data owner the broker. Enabling patients to be more directly involved in research could also be advantageous.
  Some of these solutions, particularly DTC testing and blockchain technology, have encountered problems as a result of their novelty, but these are likely to improve in the future.

- **Marginalized communities are not being heard.** This has lead to a lack of fair representation both within data sets and in groups of decision makers. Different communities will have different aspirations for genomics and precision medicine, and by excluding them from the conversation, their perspective is lost.
  More effort needs to be made across all research and healthcare to invite these communities to the conversation. This will allow their opinions to be heard, while also building trust between the public and researchers.

- **Human biology is very complex and our data architecture needs to reflect that.**
  Different groups are trying to build their own healthcare IT architecture, but this

creates a problem when different groups need to work together and find that their networks are not easily compatible. To enable efficient collaborations, there needs to be much stronger standardization of data architecture.

Organization

- Institutions rarely have their own dedicated data steward or officer, and this limits data functionality and security. Often the task falls to the head of the department, but they are often too busy to spend the necessary time to fill the role. Alternatively, an IRB might be involved, but they often don't have a clear understanding of the technology. For the technology to be fully realized, institutions need to start investing in the necessary staff to maintain their network and control the data available.

- Data has intrinsic value and this is going to prevent people from being willing to share their data freely. If researchers are spending time and money to obtain data, then they are going to want a value exchange if they choose to pass it on to other groups. Breaking down data silos will ultimately benefit everyone, but that will not necessarily constitute a fair exchange for an individual research group.

Cultural and Legal

- Problems with data sharing are primarily cultural, not technological in nature. There is still hesitation from participants when it comes to sharing data, which may be because of poor communication of how their data can be used and the benefits of sharing. At the same time, institutions might not wish to invest heavily in data sharing because of that hesitancy.
  In order for institutions to overcome these issues, the community at large needs to build a better culture around data sharing that encourages best practices.

- Concerns of data sharing impacting insurance payments are still a problem and are significantly limiting the number of people willing to consent to sharing their information. There needs to be greater standardization for how institutions handle data so that participants can be certain of how their data will be handled.
  At the same time, it may be beneficial to see implementation of stricter, more specific legal controls that prevent insurance companies from utilizing genomic data in this manner.

- Regulations are often misinterpreted because of a lack of clarity, specifically relating to whether or not they constitute legal restrictions, or merely guidelines. There is also a question of whether regulations are sufficient to prevent unethical or dangerous research and testing, as they were often developed before the advent of precision

medicine.

- It is difficult to change a culture quickly. The standard method of thinking for both patients and researchers is asking how data sharing or collaboration can help them, but this approach will ultimately harm precision medicine. The focus needs to move from ‘me’ to ‘us’, and this is going to be very hard to do. It will need the attention and dedication from individuals in all of the fields involved.