

GM6: International efforts and opportunities in Genomic Medicine

Why this topic?

- Genomic medicine is global
- Genome 'hubs': US, India, China, Japan, Korea, Canada
- Explore synergies, redundancies, collaborative opportunities
- Opportunities to advance the genome sciences as a global agenda and to impact global health

Some GM Activities Across the Globe

- Genome Canada - 2012 Large Scale Applied Research Projects in Genomics and Personalized Health
- Europe Science Foundation - Personalized Medicine and the European Citizen
- UK Human Genomics Strategy Group - Genomic Technology in Health Care
- The Israel National Inst for Health Policy Research - Personalized Medicine The Future is Here (But are we ready for it)?
- WEF - Global Agenda Council and Precision and Personalized Medicine

Other efforts in genomic medicine

- Kazakhstan – Center for Life Sciences and Genomic and Personalized Medicine Institute
- Qatar/Cornell Weill
- Singapore – Duke NUS
- Japan
- Scotland
- Australia
- Estonia
- Others....

Genome Canada and CIHR

- Genome Canada: To harness the transformative power of genomics to deliver benefits to Canadians
- “Genomics and Personalized Health” RFA
 - to support projects that will demonstrate how genomics-based research can contribute to a more evidence-based approach to health and improving the cost-effectiveness of the health-care system.
- \$67.5 million available
 - \$40 million through Genome Canada
 - \$22.5 million through CIHR
 - \$5 million from the Cancer Stem Cell Consortium
- At least 50% of funding through co-funding
- 10-12 projects funded in 2013

The Israel National Institute for Health Research Policy

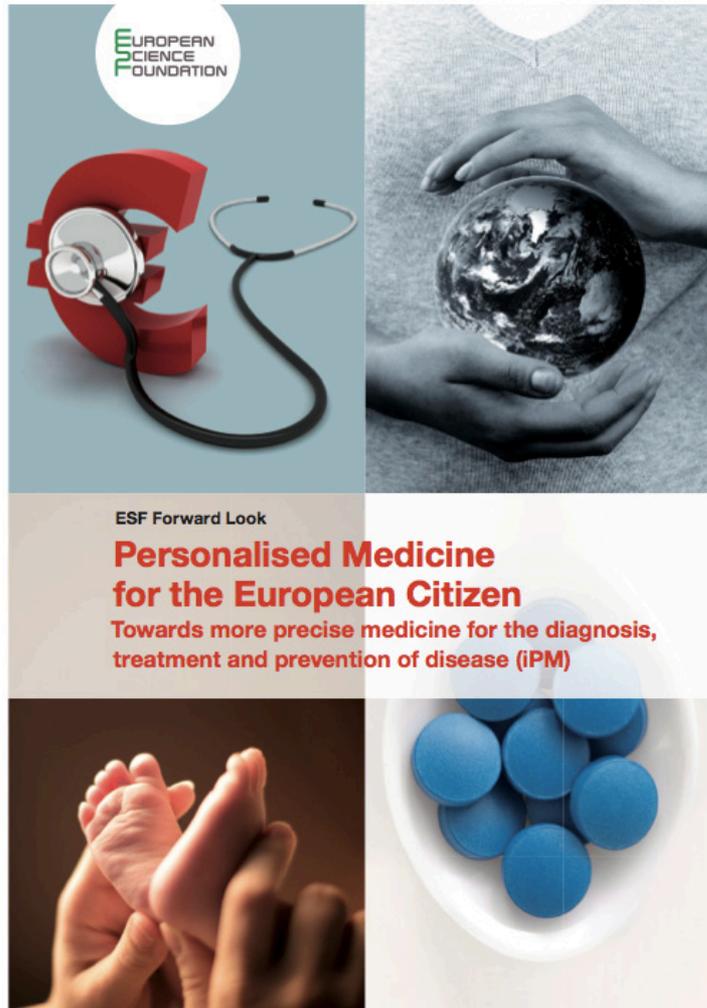
- International workshop Sept 2012
 - Assessment of personalized medicine technologies: PM vs CER
 - PM and Health Economics
 - Bioethical and Legal Aspects of PM
 - Barriers in Implementing Personalized Medicine
- Output recommendations
 - Address the knowledge gap in health professionals
 - Data sharing and national data bank
 - Encourage collaborations
 - Ministry of Health to define priorities
 - Take advantage of Israeli health service structure (full coverage for all) and populations to promote proof of concept studies and evaluate outcomes

UK Human Genomics Strategy Group

January 2012

- A strategic vision for how the healthcare system in the UK can benefit from the mainstream adoption of genomic technology
- Successful translation of laboratory and academic research into quality-assured care pathways
- Developing a “service delivery infrastructure” that will enable equitable and affordable access to high quality genomic and genetic testing services
- Establishing the bioinformatics platform needed to underpin genomic and genetic testing and facilitate ongoing research
- Training the NHS and public health workforce of today and tomorrow
- Developing the policy agenda for the use of genomic data, and developing appropriate safeguards and processes to protect individuals
- Raise public awareness of genomic technology and how it can be used to benefit the care of patients across the NHS

European Science Foundation





The World Economic Forum

- Global Agenda Committee on Personalized and Precision Health – 2012
 - USA, India, Germany, Switzerland, UK, Singapore

Early concepts: NEJM 2011

- More incentives for innovation
- New disease classification systems that incorporate emerging molecular data
- More streamlined clinical trial regulation frameworks
- Effective data interpretation and clinical decision support (CDS)
- Stimulation of consumer interest and active participation
- A rational approach to Health Authority regulatory oversight of Precision Medicine

Personalized and Precision Health: Focus Areas for Consideration

Addressing the Economic Burden of Disease with PPH

- Personalized approaches also improve outcomes and reduce mortality and disability
- Output: Whitepaper publication on value proposition of personalized health approaches in various world economies

Personalized and Precision Health: Focus Areas for Consideration

Accelerating the Science and Practice of Data Sharing for PPH

- Lay groundwork for creation of true global “data commons” for sharing to accelerate discovery, validation, and translation of PPM technologies
- Facilitate our collective ability to harness ‘big data’ from disparate EMRs, molecular and imaging data repositories
- Output: Landscape and gap analysis project on data sharing with a knowledge partner

Personalized and Precision Health: Focus Areas for Consideration

Best practices in regulatory and reimbursement strategies for implementation of PPH

- Regulatory and reimbursement policy alignment among regions to assure international dialogue and transparency for sponsors
- Bring together academic, industry, regulatory, patient, 3rd party payor communities to create model standard guidance and/or make other recommendations for addressing common barriers
- Output: Workshop proceedings/white paper

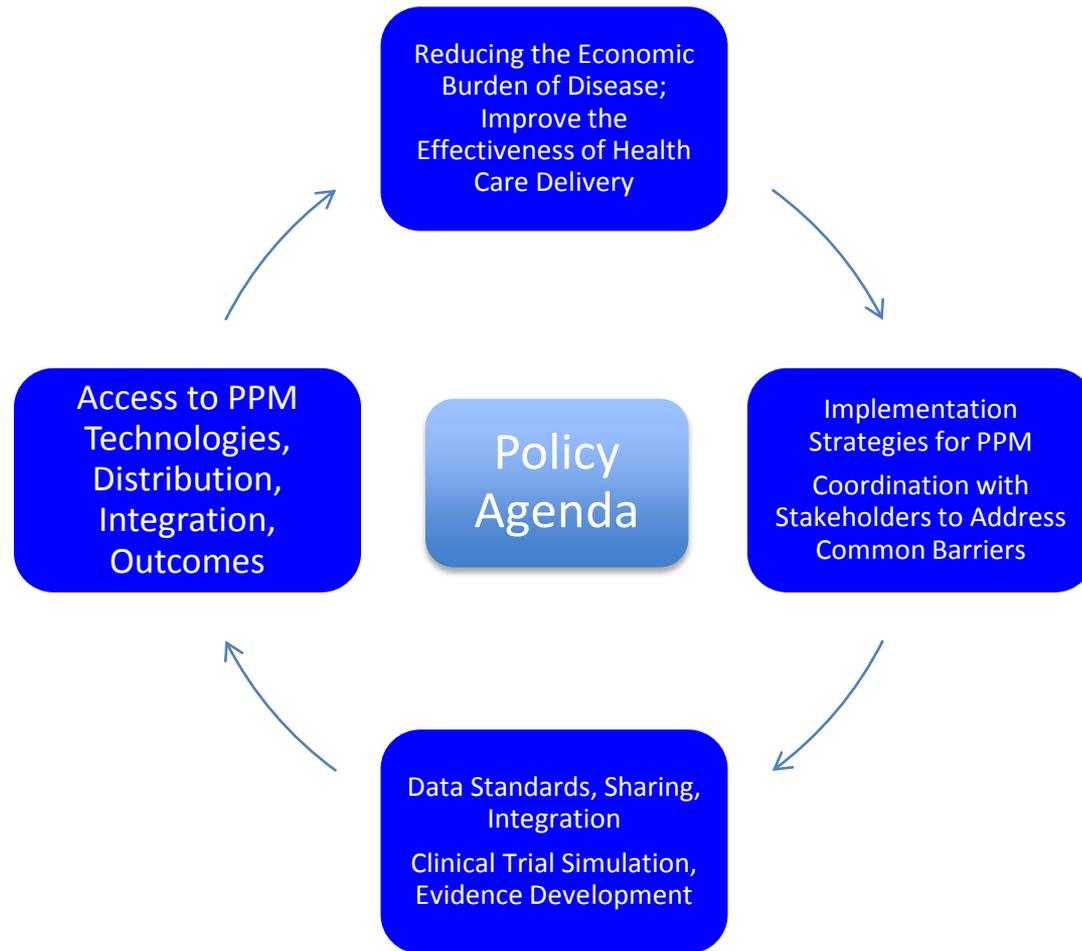
Questions & Direction

- Should we convene an international meeting/workshop in GM?
- Why would we ?
 - Identity common barriers, synergies and redundancy
 - Development of standards for data capture and outcome measures
 - International pilot projects – focused on common issues in the translation of genomics to health care
 - Public private partnerships
 - Economic analyses
 - Identify common policy agenda
 - Systems where it might be easier to get results (city state, single payer)
 - Develop an international organization with funding
 - International guidelines
 - International educational initiatives
- Who: Gov't program leaders and scientists from
 - Canada, UK, ESF, Israel, Japan, H3Africa, Australia, Singapore ???
 - Diligence and refinement needed
- Where: Washington DC

- Pros
 - Leverage the global intellectual community
 - Leverage global resources
 - Ongoing activities together may be more powerful
 - Opportunity to unify themes and strategies

- Cons
 - More complex to organize
 - Unique issues for various populations, cultures and governments

Conceptual Framework for PPM GAC



WEF Idea: Implementation Strategies

Key issues

- Regulatory harmonization among regions to assure international dialogue and transparency for sponsors
- Bring together academic, industry, regulatory, patient, 3rd party payor communities to create model standard guidance and/or make other recommendations for addressing common barriers
- Broaden perspectives on personalized medicine and how fits into the whole practice of medicine

Potential activities

- As a council develop the “ideal” policies that would enable the implementation of PPH
- Work with a specific geography (e.g., UAE, Singapore) to create demonstration projects and implement the policies in order to create the case for broader adoption

WEF Idea: Accelerating the Science Through Data Sharing

Key issues

- Assemble/centralize data sharing policies, frameworks, governance principles and nomenclature standards to advance interoperability
- Promote precompetitive sharing of data, analytical and interpretive tools and software
- Where are standards and methodologies needed and how can these be disseminated?
- Many pharma companies are opening their clinical trials to leverage data
- All stakeholders will benefit: payers, patients, academia, regulators, pharma, providers, diagnostics companies

Potential activities

- Develop a new standards-based data sharing project (Implementing the WEF Global Health Data Charter)
- Could range from data standards to interoperability to data commons
- Create Public Private Partnerships around certain disease areas
- Integration of digital health strategies

WEF Idea: Define the Value Proposition

Key issues

- Personalized approaches to treatment can reduce waste of resources through elimination of unnecessary interventions (e.g., imaging in disseminated cancer), rapid treatment of deadly diseases (e.g., febrile illness), and better targeting of therapies in chronic disease (e.g., biomarker profiling of tumors)
- Personalized approaches also improve outcomes and reduce mortality and disability

Potential activities

- Whitepaper publication on value contribution of personalized health approaches
- Make the economic case for data sharing and regulatory harmonization
- Address the issue of rational pricing in this space

Public dialogue
Education
Regulatory frameworks
Testing and reimbursement models
Infrastructure planning
Stakeholder participation
Collection of reference data
Proof of principle
Data standardisation
Biomarker validation

Phase 1

Responsible governance frameworks
Apply metrics
Harmonisation of procedures
Patient-centred partnerships
Interaction networks
(molecular and environmental)
Infrastructure testing
Data integration
Data sharing
Dynamic monitoring

Phase 2

In silico models
Remote sensing
E-learning and adaptable interfaces
Real-time monitoring
Systematic data collection

Phase 3

