Session 1

- Health outcomes as main driver for health innovation
- Many challenges are not unique
- Randomized controlled trials *are not the be all and end all*- need to consider the alternatives
- Create conditions to show how we can apply the new knowledge at point of care
- Create conditions for early and ongoing dialogue and collaboration with all major players to achieve successful translation into clinical practice (innovative tech transfer platforms)

- High-throughput is here-whole genome sequencing is inevitable - it will have major implications-
- How to capture the knowledge (interpretation and use)
- We have a lot of unfinished business with the governance frameworks for genetic testing
- Sustainability of current business and regulatory models
- Need to learn from past experience -reactive regulation may not pay off
- Wild card: IP landscape

Session 2

- Globalization of clinical trials is inevitable and need to adapt regulatory processes- encourage and help it
- Regulatory science must evolve
- Need to find ways to share the burden of decision-making – resource and capacity constraints (and beyond...how about data sharing and oversight?)
- A networked regulator- consortia arrangements- work-sharing arrangements
- Map initiatives across the globe (APEC)

Session 3

- The cost of drug development has become outrageous-failures remain high
- Costs in Biomedicine to rise – Distributive Justice Debate needed – Resources in HC are limited
- Sustainability of the conditional coverage model - dealing with administrative burden and need for IT platforms-
- Enable effective gathering and tracking of information pre-post marketing (feedback loops)
- Type 1 and Type 2 error- inclining towards Type2 error
- Incorporate patients valuation in governance decisions, including regulatory processes
- Bring the user/patient back in dealing with the benefit-risk equation, especially in rare diseases/orphan drugs
- Calls for adaptive-regulatory flexibility
- We can create conditions for higher predictability
- Landscape mapping

Session 4

- Models are emerging to: advance regulatory science on a global scale and develop the foundations for common standards in evidence development and data sharing
- Success stories show that bringing main actors together at an early stage and new ways to share and manage knowledge are key (to predict and enable uptake)
- Reliability, transparency and adaptability required in governance
- Models needed to incorporate patient values and interests in appropriate stages of product development
- Working through knowledge clusters