Session 1

- What are the governance challenges from these biomedical developments?
- Do our governance systems account for the opportunity risk of doing nothing?
- What governance models are emerging or are employed in OECD member countries to address these challenges?
- What are the goals of these new governance models?
- What governance models in these various fields, deliver more effective innovation (for example by establishing new organisational structures, streamlining regulatory review, more efficient communication etc)?

Whole genome-sequencing and genetic testing
The key challenges for governance

- What are the range of issues that require urgent consideration as full-genome sequencing moves towards reality?
- How should health services be preparing for the onset of whole genome-sequencing as a clinical tool?
- What are the wider ethical, societal and regulatory issues related to the more extensive use and storage of personal genomic information.
- Does our health professional workforce have the necessary knowledge and skills to capitalise upon the benefits of next generation whole genome sequencing technologies?

Session 2

- What are the main instruments to streamline governance of biomedical innovation?
- What are the major challenges beyond the stratification of patient groups and the fact, that new therapeutic strategies do not necessarily confirm with the established licensing and review pathways?
- How do we create a more effective and efficient clinical research enterprise?
- How can governments ensure better policy coordination and coherence and the necessary feedback across the whole innovation cycle?
- What forms of organisational/institutional responses are necessary and emerging?

Session 3

- How are governments combining the need to promote and sustain innovation with value to society?
- What models of risk-sharing are emerging?
- Are the emerging models limited to biomedical developments?
- How do current risk sharing agreements strengthen or complement other government policies aimed at increasing the efficiency of health innovation and at the same time, of health care systems?
- Do systems for sharing risk between the public/private sectors adequately match the uncertainties? If not what could be done?

Session 4

- What participatory regulatory models are emerging today to deal with the potential complexity, uncertainty and ambiguity of new technological developments?
- What incentives are necessary to facilitate the informal process of sharing scientific and technical information between applicants and regulators?
- How can experience be widely shared, good and bad practice identified and dialogue furthered?
- How are these models changing the traditional roles of regulators as well as of the regulated*?*

Addressing societal issues
Engaging the public in an early debate

- What are the opportunities and challenges in engaging the public in an early and transparent public debate?
- How and at what stages do the various stakeholders need to be engaged?
- What can we learn from these different fields?
- Are there new issues arising with nano-medicine and synthetic biology?

Session 5

- What governance model, deliver more effective innovation (for example by establishing new organisational structures, streamlining regulatory review, more efficient communication etc?
- How can regulators achieve “adaptive flexibility” in rule-making for a more efficient health innovation? What risk-sharing model, are emerging?
- What are the effects of increased engagement of stakeholders, including new forms of participatory regulation?
- How to achieve greater international convergence between regulatory regimes?
- How can the OECD Working Party on Biotechnology assist governments with these issues?