



## 2012 APEC Advanced Workshop of Good Review Practice on Medical Products

# Transparency and interaction - with the public and other stakeholders

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# Transparency: what, why, how

- Transparency and openness a growing priority of governments and public institutions; also an important issue for private sector
- Reflects increasing demands by the public to understandable information upon which they can make informed decisions
- Equally important in ensuring accountability and predictability and fundamental principles of participatory democracy– being able to participate and influence processes, policy and outcomes
- Definitions:
  - Openness: inviting, hearing, considering and sharing of information in conduct of one's business
  - Transparency: facilitating access to and understanding of information and processes used to conduct one's business



# The larger context

# Open Government Partnership



**Open Government Partnership (OGP)** was launched on September 20, 2011, as a multilateral initiative led by the US and Brazil.

Initiative aims to secure concrete commitments from governments to promote transparency, empower citizens, fight corruption, and harness new technologies to strengthen governance.

- Overseen by multi-stakeholder International Steering Committee comprised of government (8 original country members) and civil society representatives
- Canada one of 42 countries to have announced their intent to become OGP member countries in April 2012



# Principles

- **People have a right to seek information collected and held on their behalf**
- **Commit to pro-actively provide high value information (including raw data) in formats public can easily locate, understand and in formats that facilitate reuse.**
- **Commit to seek feedback from public to identify information of greatest value**
- **Implement highest standards of professional integrity**
- **Harness power of new technologies to promote information sharing, public participation and collaboration**
- **NB - Information sharing and collaboration is about behaviours not technology – complement, not substitute for clear, useful information**

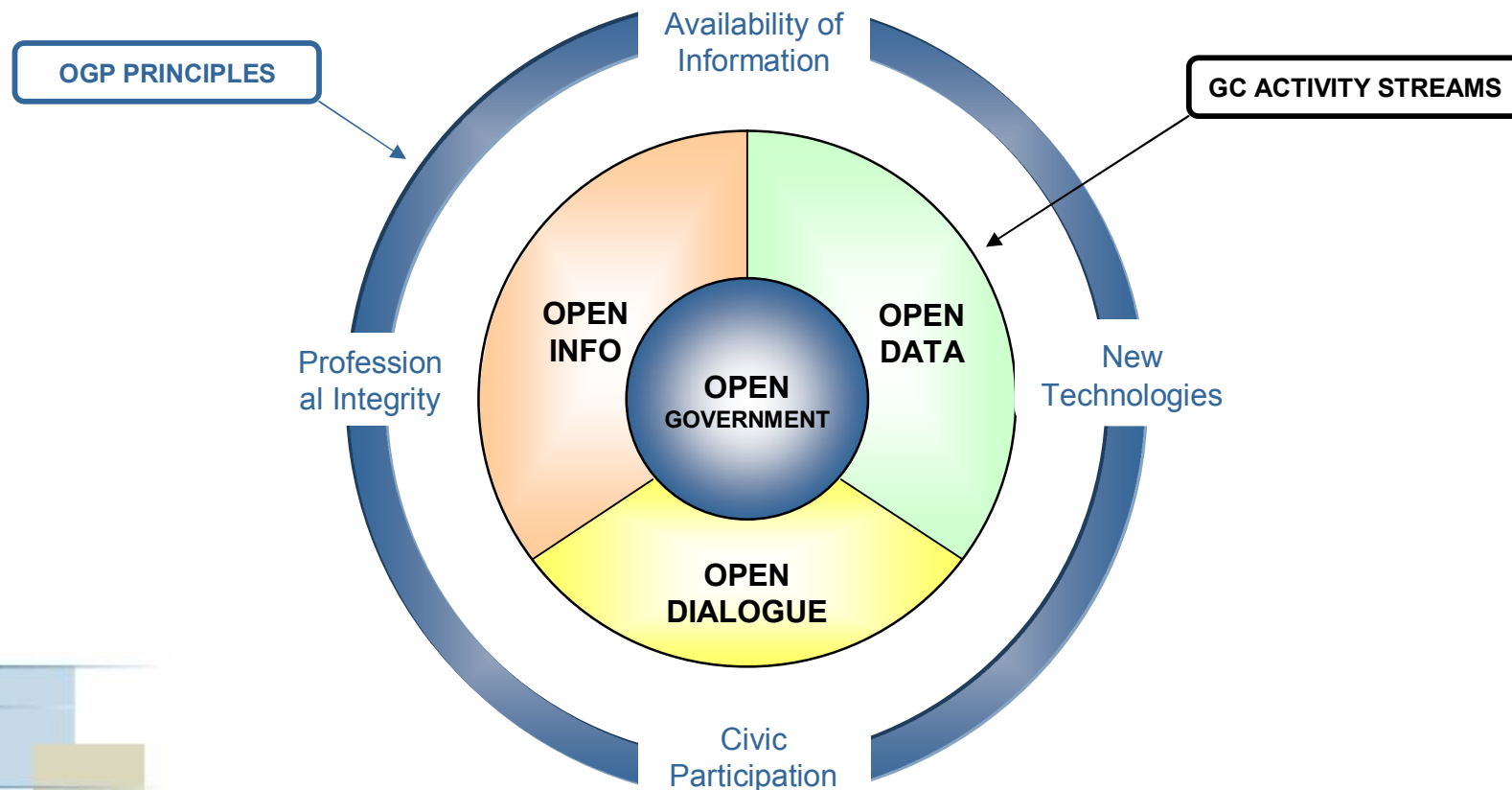


# Cultural Shift

- From permission-based culture to new service design and delivery model: citizen and business-centric services
- Understanding that we are simply custodians of information in our possession: public asset
- Should be available to public to view, use, analyze for their own personal or commercial purposes
- Created and gathered with use of tax dollars; public assumption that disclosure should prevail (commercial confidential and personal information excepted)
- Notions of ownership, control, and need-to-know change to information stewardship, need-to-share and sharing of information in a responsible manner

# Aligning the GC Open Government Initiative with the Open Government Partnership

- The four core OGP principles are consistent with Canada's current open government initiative with its focus on three streams of activity - open data, open information, open dialogue.





# Considerations within the regulatory context

- **Broad scope:**
  - Policies, laws, regulations, guidelines
  - Product and site related information (including tracking, product dbases, ACs)
  - Process related information
  - Appeal/dispute resolution mechanisms
  - Annual reports
  - FOI/ATI (NB – reactive approach)
- **Product life cycle**
  - Clinical trial registries -> public assessment reports/redacted review reports and risk communications





# Considerations

- **Is the information we produce understandable?**
  - Plain language
- **Is it used, and effective in achieving the desired outcome? How do we know?**
- **Is it readily accessible?**
  - Single window, searchable
- **Who is (are) the target audiences?**
- **What steps could we take that would add the greatest value for the investment?**
- **Need for clear principles and business rules**
- **Is there ever too much transparency?**



# GRevP implications

- **Concept of citizen and business-centric services  
→ Quality System approach**
- **Implementation of effective GRevPs should increase public confidence and trust**
- **In turn, demands for increased transparency influences the way we approach our work**



# Challenges

- Citizens particularly interested in matters related to their health; demands for increased transparency and involvement will only increase
- At same time, must strike a balance that allows for the protection of legitimate commercial interests, product development and innovation – is this balance shifting?
- Multiple clients, including internal, external stakeholders with different needs, and an emerging cliental of fellow regulatory authorities
- Increased transparency comes at a cost: not resource neutral; may also require legislative changes