

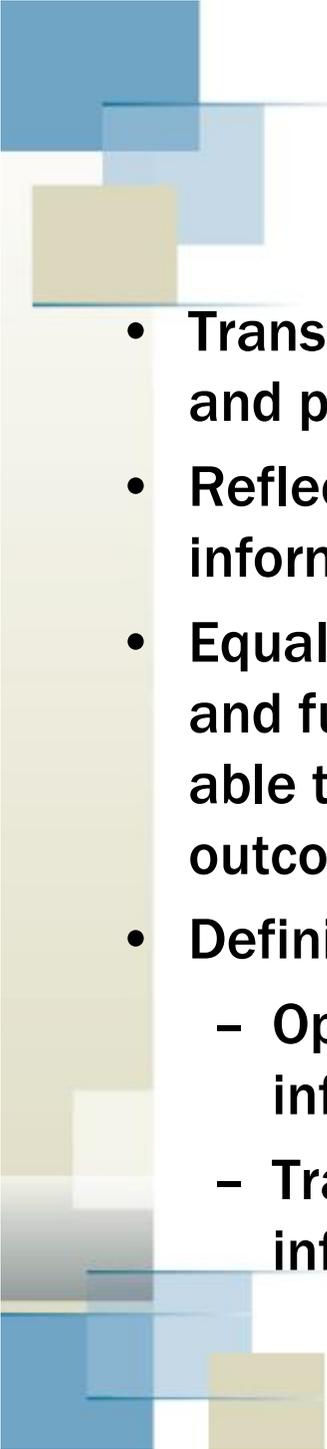


2012 APEC Advanced Workshop of Good Review Practice on Medical Products

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**

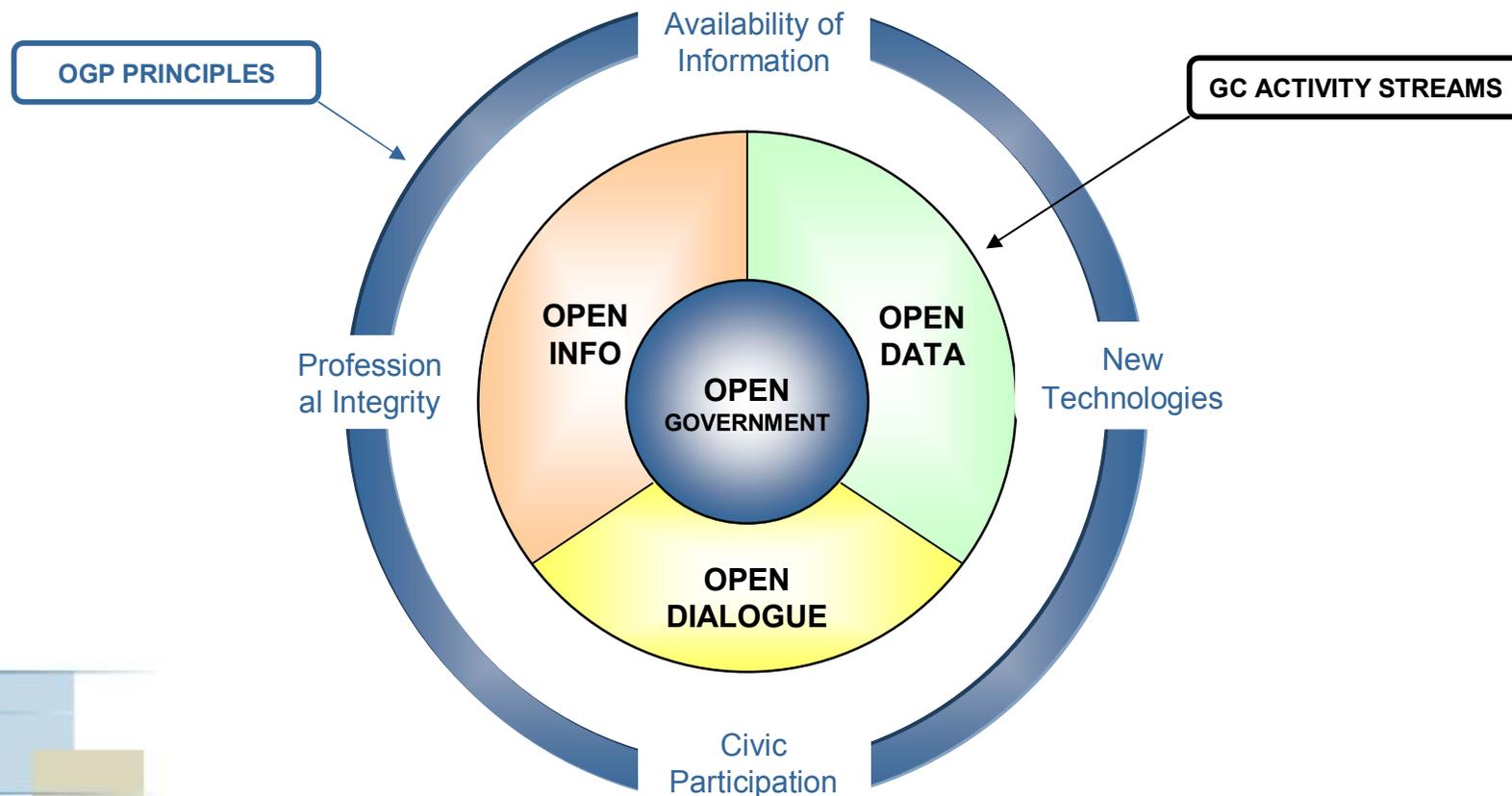


Cultural Shift

- 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**