

**Journal of Population Therapeutics
and Clinical Pharmacology**

INCORPORATING FETAL ALCOHOL RESEARCH

**Journal de la thérapie des populations
et de la pharmacologie clinique**

Available at: www.jptcp.com

CANADA'S PROGRESS TOWARD AN ORPHAN DRUG FRAMEWORK: 2014

**Montreal
February 2013**

**Ottawa
May 2013**

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The following papers have been brought together in a mini-symposium describing the challenges facing Canadian patients, academic institutions, clinicians, and regulators in the development of an improved process for clinical investigation of orphan drugs. Commitment to creation of a national orphan drug framework was announced by the federal Minister of Health on October 3, 2012, triggering an active discussion that continued throughout 2013. A process of early engagement with key stakeholders included two meetings bringing together researchers, clinicians, regulators, interested organizations, and patient/family representatives. These took place in Montreal in February 2013 with a focus on rare genetic disorders and in Ottawa in May 2013 with a focus on oncology.

The papers presented here did not originate from those meetings but the content reflects an active discussion that took place and is intended to provide a starting point for further refinement of Canada's proposed orphan drug framework.

We are grateful to the Journal of Population Therapeutics and Clinical Pharmacology for providing a venue for publication of this collection reflecting current thoughts in an important and rapidly evolving area of therapeutics.

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