



# **Canada's Shared Vision for Collaborative Healthcare Innovation** Agile Regulations and Patient Engagement Will Help Lead Growth

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**D**elivered to more than 110 attendees who came from various public and private sectors, the topics of the *DIA Canadian Annual Meeting 2019* keynote address were both timely and relevant, even in the election transition period that Canadians are currently in.

In Budget 2017, the Government announced a new vision for Canada to become a global leader in innovation. Sector-specific roadmaps were developed to help support this innovation and the opportunities that innovation presents for growth. Jennifer Chan (Merck Canada, Inc.) shared her experiences from participating in the strategic Health and Biosciences Table, including identifying barriers to not only healthcare sector growth but also barriers to the vision of what Canada could become. One of the proposed solutions was to design Agile Regulations.

Health Canada's Chief Regulatory Officer David Lee reported on the results of horizon scanning done by his team. The drivers and insights they uncovered led them to legislative solutions, including Agile Regulations.

Health Canada defined and explained Agile Regulations and two key areas of regulatory modernization focus in their [July 2019 discussion paper](#): Using a risk-based approach for regulating clinical trials; and creating a flexible approach for authorizing complex and novel health products.

### Key Regulatory Takeaways

- Ambitious goals have been set for Health and Biosciences Sector.
- Alignment and collaboration through consultations fosters innovation.
- Callout from industry to revisit the strategy to ensure identified barriers (including pricing regulation by the Patented Medicines Prices Review Board) are addressed.

The theme of collaboration continued through presentations and panel discussion surrounding the importance of patient input throughout the drug's lifecycle because they are the ones who bring "lived expertise," as Dawn Richards (Canadian Arthritis Patient Alliance) explained. Health Canada and FDA presented their work to evolve the "science" of patient involvement and the importance of finding the right balance. Both agencies are confident that, through ongoing consultations and iterative approaches, they are heading in the right direction.

### Key Patient Engagement Takeaways

- Important to understand what outcomes are meaningful to patients.
- There is value in incorporating patient voice throughout drug development and lifecycle.
- Patients becoming part of the process is being recognized by ICH; E8 guidance is undergoing review with patient input.