

# 2022 CAPRA Symposium

## *Public Release of Clinical Information*

CAPRA  
ACPR



Canadian  
Association of  
Professionals  
in Regulatory  
Affairs

Association  
canadienne des  
professionnels en  
réglementation



Since March 2019, Health Canada has provided public access to more than 200 therapeutic products, totaling over 4 million pages of clinical data. Amendments to Canada's Food and Drug Regulations in 2019 have enabled Health Canada to make clinical safety and efficacy information publicly available through proactive and on request disclosure.

The CAPRA Symposium Committee will host a virtual interactive session highlighting Health Canada's Public Release of Clinical Information (PRCI) initiative. Health Canada will provide an update on Health Canada's release process, including requests made through the portal, and an overview of the timelines. Health Canada will also outline recent disclosure of COVID-19 product information and international harmonization activities with the EMA.

This Symposium will also share Industry experiences and provide attendees with an opportunity to raise questions with all speakers on this topic.

This event will be of interest to:

- Regulatory Affairs professionals from medical devices, pharmaceuticals and biologics
- Clinical Research and Contract Research Organizations
- Clinical Data Management and Pharmacovigilance
- Research and Development

Please share the news of this event within your organization.

***CAPRA Virtual Symposium  
Via Microsoft Teams  
March 7, 2022***

<b>Agenda – March 7, 2022</b>	
<b>8:30 – 8:50</b>	<b>Logging into Virtual Session</b>
<b>8:50 – 9:00</b>	<b>Welcoming Remarks</b>
<b>9:00 – 10:00</b>	<p><b>Health Canada's Public Release of Clinical Information: A 2022 Overview of the Publication and Guidance</b></p> <p><b><u>Health Canada Speaker:</u></b>  <b>Etienne Thomas, M.Sc.</b>  Acting Team Lead, Information Science and Openness Division  Health Products and Food Branch  Health Canada</p>
<b>10:00 – 10:40</b>	<p><b>Understanding PRCI Public Disclosure: Risks and Delivery Landscape</b></p> <p><b><u>Speakers:</u></b>  <b>Lorella Garofalo</b>  Head of Regulatory Affairs at Pfizer Canada ULC.</p> <p><b>Lora Killian</b>  Clinical Trial Transparency and Disclosure Lead, Pfizer Inc.</p>
<b>10:40 – 10:50</b>	<b>Break</b>
<b>10:50 – 11:30</b>	<p><b>The Regulatory Landscape: Navigating the PIM for Health Canada Disclosure Submissions &amp; an Overview of Automated Redaction needs for EU CTR 536/2014</b></p> <p><b><u>Speaker:</u></b>  <b>Elliot Zimmerman</b>  CEO of Real Life Sciences</p>
<b>11:30 – 12:10</b>	<p><b>Industry Challenges and Opportunities with PRCI – AstraZeneca’s Perspectives and Experiences</b></p> <p><b><u>Speakers:</u></b>  <b>Julie Holtzople</b>  Senior Director of Clinical Transparency &amp; Data Sharing, AstraZeneca Global</p> <p><b>Tharany Ganesh</b>  Head of Regulatory Affairs, Patient Safety and Quality Assurance, AstraZeneca Canada</p>
<b>12:10 – 12:40</b>	<p><b>Panel Discussion and Q&amp;A:</b>  All Speakers to address questions or provide clarifications</p>
<b>12:40 – 12:45</b>	<b>Closing Remarks</b>

## Premium Event Sponsorship

# AmerisourceBergen

Innomar Strategies

<https://www.innomar-strategies.com/>

### **Disclaimer**

CAPRA reserves the right to make amendments to the conference (including but not limited to the identity of speakers, topics, locations, the timing of speakers) without notice to you. If the conference is canceled for any reason whatsoever, such reason not within the control of CAPRA, CAPRA shall not be liable for any cost or loss otherwise incurred.