



# DIA Canadian Annual Meeting

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#Canada21



# Canada's Approach to COVID-19 Vaccine Strategies Development and Approval

Health Canada's COVID-19 Pandemic Vaccine Experience

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## EXPEDITED REGULATORY REVIEW



- **7** Interim Orders (temporary regulations) to manage shortages and expedite review, importation and sale of COVID-19 medical devices, treatment and drugs

### AUTHORIZING

- **5** Vaccines
- **7** treatments
- **650** medical devices
- **4,500** new hand sanitizer products and **270** new disinfectants

# Expediting Reviews: Agile Regulatory Measures for Vaccine Trials

- ▶ Implemented Interim Orders (IO) to facilitate clinical trials and to support access to COVID-19 vaccines
- ▶ Clinical Trials:
  - Over 50 pre-CTA consultation meetings
  - Decreased review target to 14 days
  - Authorized 18 clinical trials for vaccines
- ▶ Interim Order flexibilities included:
  - Use of terms and conditions
  - Broadened criteria for qualified investigators
  - Decentralized trials, remote informed consent



# Expediting Reviews: Agile Regulatory Measures for Vaccine Authorizations

- ▶ For market authorization of vaccines, [IO flexibilities](#) include:
  - Rolling submissions – data filed as it becomes available
  - Flexible data requirements
  - The use of terms and conditions on an authorization to require ongoing evidence submission
  - Prepositioning
- These flexibilities have been [introduced](#) under the *Food and Drug Regulations* (FDR) to continue to support access to safe, effective, and high quality COVID-19 drugs and vaccines following IO expiry
- Vaccines authorized under the IO are now transitioning to authorization under the FDR for continuity





# Expediting Reviews: Outreach, Readiness and Collaboration

## Outreach and Engagement

- Provided regulatory and scientific [advice](#) to vaccine sponsors for clinical trials & submissions
- Developed a dedicated website for the [health product industry](#) to provide regulatory guidance and updates
- Developed COVID-19 Vaccines and Treatments web [portal](#) for transparency
- Responded to media, provided press briefings and [communicated](#) with Canadians on regulatory activities

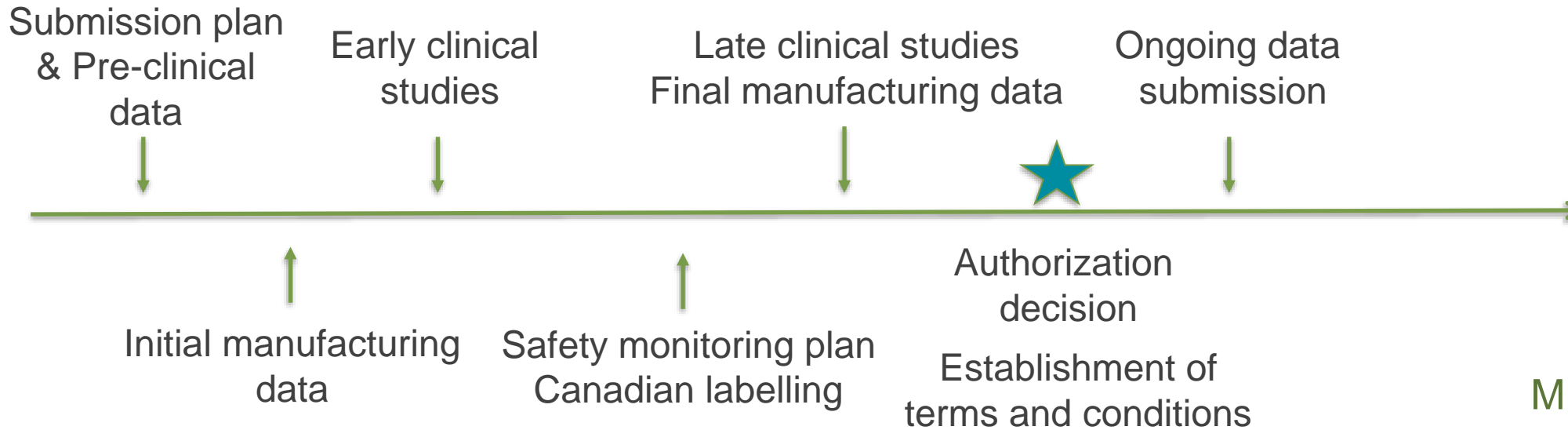
## Operational Readiness

- Created COVID-19 Regulatory [Response Team](#) as a focal point for COVID-19 regulatory activities
- Adapted existing review framework including SOPs and templates
- Formed [dedicated review teams](#) focussing on vaccine submissions and post-market surveillance
- Collaborated with PHAC including to enhance mechanisms to [share information](#) from regulatory and public health surveillance activities, to identify and assess safety signals

## International Collaboration

- Worked with [international partners](#) both pre and post authorization on a coordinated and aligned approach, including joint statements and guidance
- Leveraged international partnerships at multi-national fora and bilaterally to share information and to raise collective level of awareness of evidence-based approaches
- Conducted [parallel reviews](#) and information sharing to maximize the use of global expertise

# What does a Rolling Submission Look Like?



Several months to receive complete data from manufacturer

Authorization based on integrated evidence of safety, quality, and efficacy

- Are we confident that the product is safe, effective, and of acceptable quality?
- Are any known risks mitigated to the extent possible?
- Are potential risks going to be adequately characterized?
- Does the product labelling accurately reflect what we know?

Multiple review teams, average of ~2000 hours spent per vaccine over the course of several weeks/months



# Supporting Vaccine Confidence: Transparency

- When a vaccine submission is received, it is added to the online [list](#) of submissions under review
- When a decision is made to approve a new vaccine, HPFB publishes a number of key documents, including:
  - The Canadian Product Monograph (prescribing information)
  - The Regulatory Decision Summary – overview of review decision
  - Any necessary communications to healthcare professionals
- A few weeks later, more detailed information is made available to Canadians, including:
  - A detailed description of the data used to make the authorization decision
  - Clinical study information, including summaries and the detailed study reports that were contained in the drug submission

<https://covid-vaccine.canada.ca/>

# Post-market Activities in Place for COVID-19 Vaccines

## Standard requirements on manufacturers

- Risk management plans
- Adverse event reporting – all serious domestic adverse events, all serious, unexpected foreign reports

## Enhanced surveillance and communication by HPFB

- Ongoing assessment of any reported adverse events
- Manufacturers required to provide monthly safety analyses
- Close collaboration with PHAC and PTs to assess and take action on any emerging safety signals (e.g., communicating information on risks, revising conditions of use or population to be vaccinated, other risk mitigation measures)
- Frequent exchange of information bilaterally and multilaterally with international partners to detect and discuss any emerging safety concerns and risk mitigation measures.
- Additional transparency for Canadians, in collaboration with PHAC, to provide regular updates and risk communications on adverse events and emerging safety information

# Lessons Learned

## ▶ What worked well

- Interim Orders and their flexibility
- Dedicated teams
- Sponsor engagement and responsiveness
- Engagement with PHAC and PSPC
- Transparency and risk communications
- International engagement
- Safe and effective vaccines

## ▶ Considerations for next time

- Availability of emergency pathways
- Rigour around rolling reviews
- Foreign Decisions pathway not utilized
- Worksharing with international partners
- Labelling and Risk Management Plans
- Health Canada vs public health communications
- Transition to FDR
- Biomanufacturing in Canada

# Where do we go from here?

- ▶ Apply lessons learned to regulatory innovation agenda
- ▶ Agile [Phase I](#)
  - Terms and Conditions
  - Rolling Reviews
  - Mandatory Risk Management Plans
  - Renewal of Division 4



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