DIA Canadian Annual Meeting

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#Canada21

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

Overview of COMIRNATY/*Pfizer-BioNTech COVID-19* Vaccine

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Addressing the Global Crisis

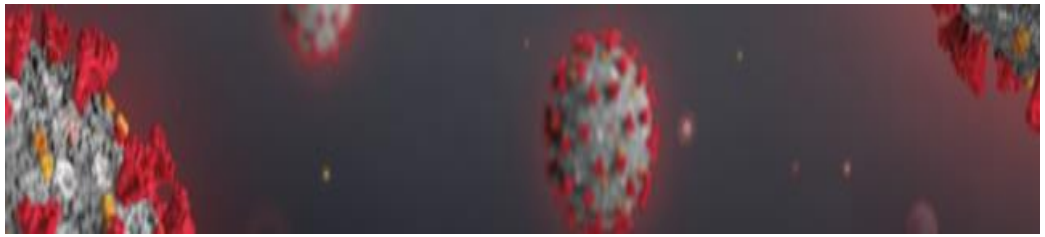
Global pandemic required expedited implementation of interim measures and innovative/novel approaches

- Health Canada and Industry mobilized to mitigate impact of COVID-19
  - Interim measures for management of clinical trials
  - Securing supplies of drugs used to manage symptoms of COVID-19
    - Exceptional importation of “designated drugs”
    - Critical Drug Supplies
  - Increased and dedicated manufacturing capabilities

- Deployment of Innovative Regulatory Strategies to Expedite Review of COVID-19 drugs, including vaccines
  - *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*

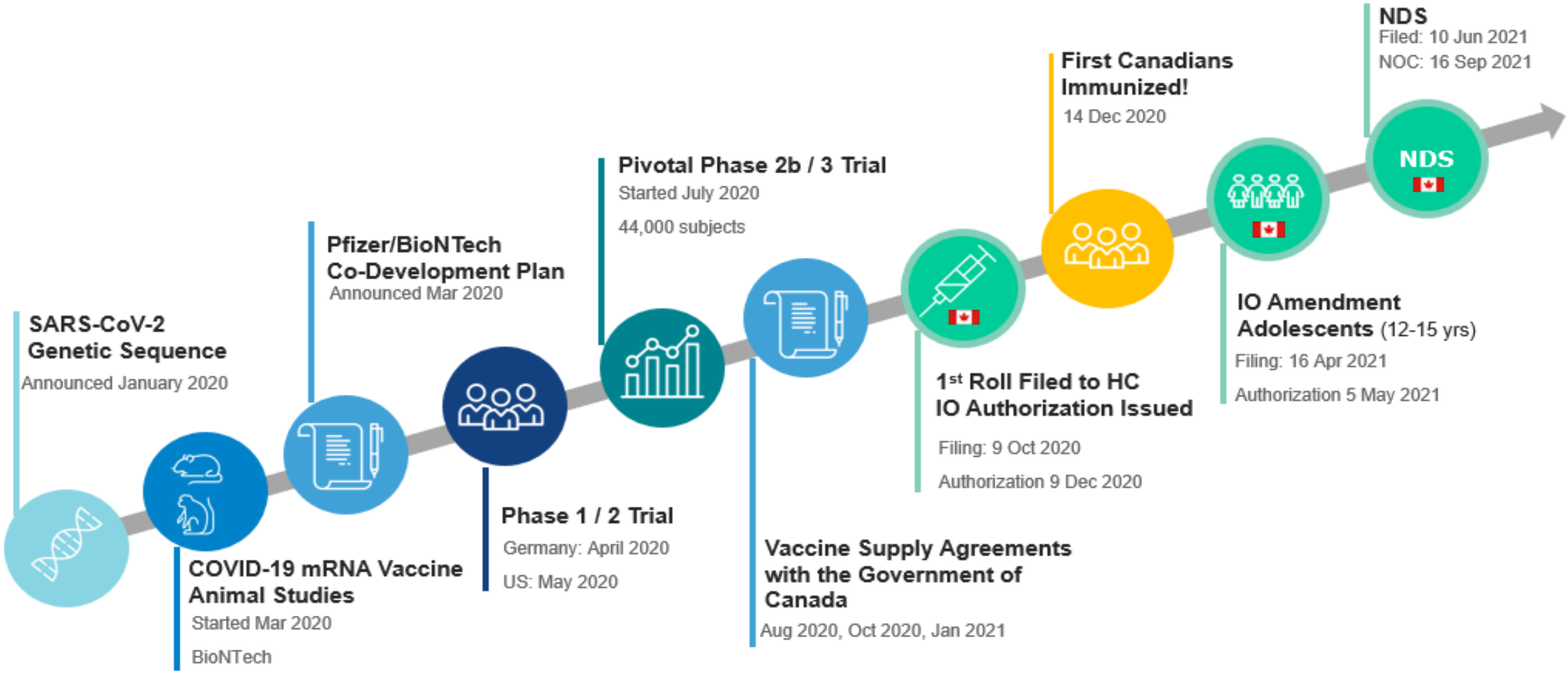
Interim Order & Path to COVID-19 Vaccine Authorization

Allowing expedited regulatory pathway for COVID-19 vaccine development without compromising safety & efficacy



- Implementation of rolling submission concept
- Expedited review timelines
- Regulatory Flexibilities
- Expedited product availability: Importation and pre-positioning
- No cost recovery
- Flexibilities re. GMP requirements
- Authorization with Terms & Conditions
- Conversion to NOC

Pfizer-BioNTech Vaccine: Early Development to NOC



Rolling Submissions & Real-Time Updates

A First: Unprecedented Regulatory Approach for Canada

- Allows expedited filing & review
  - Submission Plan
- Working in real-time: filing as data becomes available
  - Parallel filings Globally
  - Multiple concurrent clarifaxes/requests
  - Support from all functional experts (Non-clinical, Clinical, CMC, Safety)
  - Open communication and *ad hoc* meetings with Health Canada

Putting it in perspective - from IO filing to now:

- ✓ 200 sequences and counting…
- ✓ 11 PM updates
- ✓ 28 HC Meetings
- ✓ 3 Health Product Risk Communications
- ✓ Multiple educational materials
- ✓ Numerous ad hoc calls & e-mails

Expedited Product Availability

Vaccine available immediately after authorization

- Requires multiple parallel & concurrent work

Points of Use

Worldwide Product Allocation

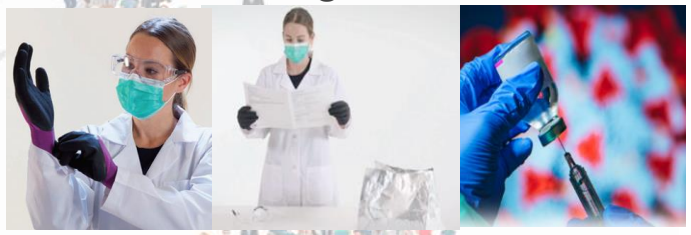
Contractual agreement with Government of Canada

Quality Assurance

Translation Service

Medical Information

Trainings & Website



Customer Service

Manufacturing & Supply Chain

Communications & Media

Overall Experience

We are all in this together!

Exemplary Cooperation & Resilience - “No Corners Cut”

- Working in real-time during a Global pandemic requires:
  - Accelerated filing of numerous components as they become available
  - Rapid responses to multiple concurrent requests
  - Flexibility regarding Regulatory requirements and administrative components
  - Open line of communication with Health Canada at all times (including evenings & weekends)
  - International alignment and collaboration
  - Terms and Conditions supports risk-based approach
  - Transparency

Important Lessons Learned

During a Global Pandemic plan for the unexpected!

- Multiple urgent demands on many fronts
  - Numerous concurrent requests with tight response timelines (same-day, 1 or 2 days)
  - Fully dedicated resources required with back-ups to manage high demands & long hours (nights & weekends)
  - Impact on Global resources
- Shipping & storage complexities
- Multiple and expedited translation needs
- Authorization vs Real-world use
  - Implementation not always aligned with clinical trials/authorized label recommendations
- Management of internal and external communications
  - High media attention
- Authorization is not the end
  - High level of activity post-authorization
  - Management of Terms and Conditions
  - Conversion to NOC not just an administrative step

Looking into the Future

Huge strides taken during the pandemic should serve as a base for continued evolution of our Regulatory Framework

- Build on Regulatory Innovation
- Implementation of Rolling Submissions
- International Cooperation Between Regulators is Key
  - Work-sharing models beyond ACCESS
    - Data & insight sharing
    - Streamlining of Regulatory requirements and Canadian-specific requirements
- Risk-Based Regulatory Decisions
  - Prioritization and fit-for-purpose regulatory strategies
- Expand focus of Advanced Therapeutic Products
- Implement Agile Regulations