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#Canada21

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

SPIKEVAX™ - Moderna COVID-19 Vaccine

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DIA

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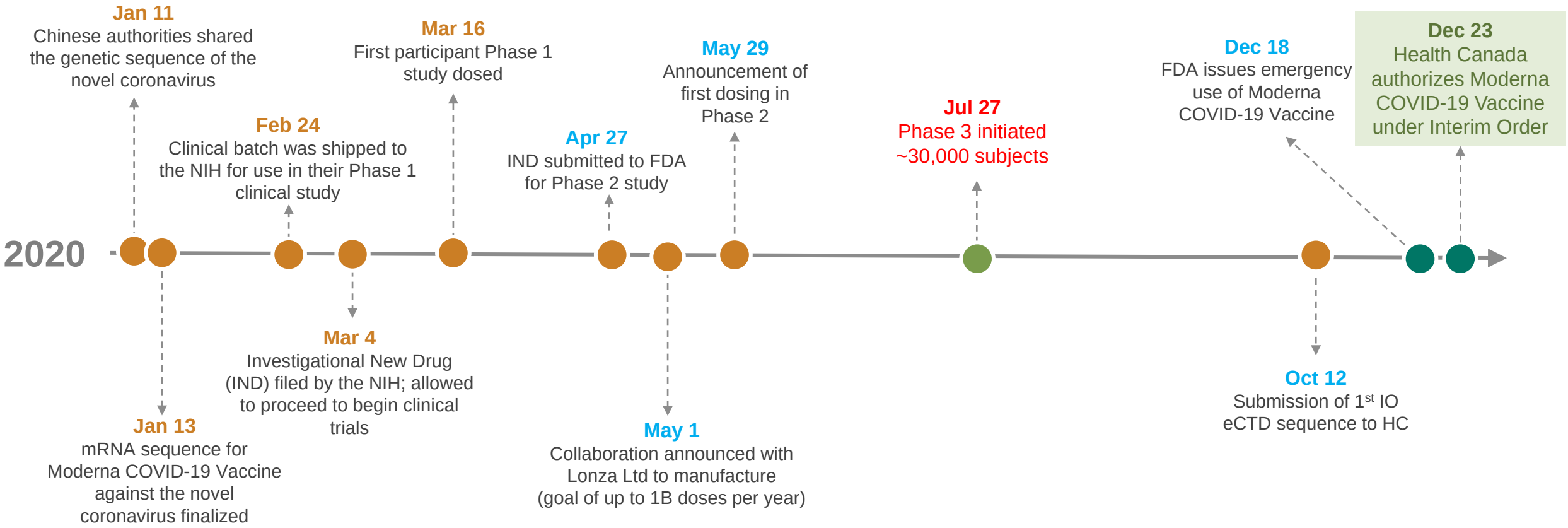
Moderna COVID-19 Vaccine: From Sequence Identification to First Authorizations

Moderna COVID-19 Vaccine Timeline



BARDA, Biomedical Advanced Research and Development Authority; CoV, coronavirus; COVID-19, coronavirus disease 2019; EUA, Emergency Use Authorization; FDA, US Food and Drug Administration; IND, Investigational New Drug; NEJM, New England Journal of Medicine; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Baden LR, et al. *N Engl J Med.* 2020. DOI: 10.1056/NEJMoa2035389.

Moderna COVID-19 Vaccine:
Activity Under the Interim Order (IO)

From Submission Under IO to Notice of Compliance (NOC)

115+	eCTD sequences
7	Updates to the Product Monograph
3	Health Product Risk Communications (HPRC)
17	Scheduled teleconferences with Health Canada
1	Submission of NDS-CV
+++	Touch-base with BRDD Project Manager

= **Volume of regulatory activity typical of an innovative drug over 2-3 years**

Compressed into <10 months

This regulatory activity was possible due to:

- Rapid implementation and adoption of Interim measures
  - Applied to CTAs, new therapies, the NDS-CV framework, etc.
- Deployment of novel regulatory approaches
- High degree of transparency and active communication
  - Including evenings, weekends & holidays!

Interim Order – Highlights & Best Practices

Experience with Moderna COVID-19 Vaccine

1. Rolling submissions / real-time submission & review of data
   - High degree of transparency
   - All updates filed as Amendments to the IO
2. Condensed regulatory timelines across all activities
   - Clarifax responses
   - DEL / GMP updates
   - Material development / translation
   - Public Release of Clinical Information (PRCI) process
3. Significant CMC activity
   - Supply & scale up for global demand
4. IO-specific labelling criteria
   - Internationally aligned labels; not country-specific
   - Allowed for streamlined global review & supply chain flexibility
5. HC-implemented online resources
   - Vaccines for COVID-19
   - Reported side effects following COVID-19 vaccination in Canada
6. Support from External Partners
   - Innomar Strategies agreement with GoC to support distribution of COVID-19 vaccines across Canada
   - FedEx Express Canada

Case Study 1: US Supply of COVID-19 Vaccine Moderna

Experience with IO Amendment

International

- Independent supply chains.
- Active manufacturing scale-up to supply 600 million to 1 billion doses per year.

Lonza (Switzerland) Pharma & Biotech → ROVI (Spain)

United States

moderna + Lonza (US) Pharma & Biotech → Catalent

- On May 17, 2021, the Biden administration announces that the US will begin export
- At the time, all supply of Moderna vaccine to Canada has been from International supply chain

Regulatory Considerations

1. New sites require CMC Amendment to IO for HC review + addition to DEL
2. US-specific inner & outer labelling (carton & vial); technical & time limitations make relabeling non-viable

Case Study 1: US Supply of COVID-19 Vaccine Moderna

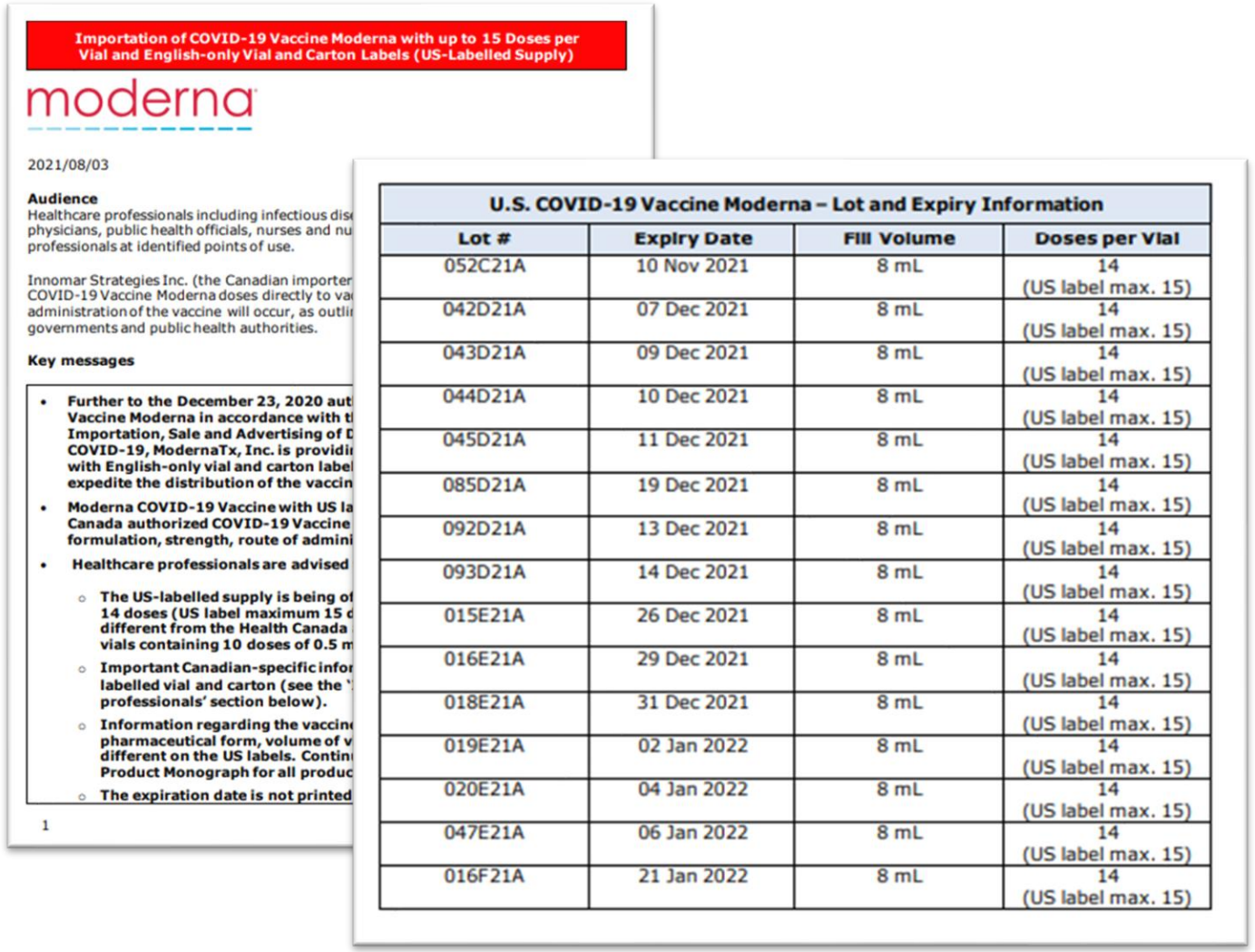
Clear priority: Increase availability of vaccine in Canada

Activity:

- Pre-submission teleconference with HC
- Amendment to IO submitted
- Use of existing HPRC framework
  - Multiple updates to HPRC, similar to Product Monograph management

Outcome:

- HPRC enabled communication of key labelling information in parallel with vaccine inner/outer labelling



Importation of COVID-19 Vaccine Moderna with up to 15 Doses per Vial and English-only Vial and Carton Labels (US-Labelled Supply)

moderna

2021/08/03

Audience
Healthcare professionals including infectious dis
physicians, public health officials, nurses and nu
professionals at identified points of use.

Innomar Strategies Inc. (the Canadian importer
COVID-19 Vaccine Moderna doses directly to va
administration of the vaccine will occur, as outli
governments and public health authorities.

Key messages

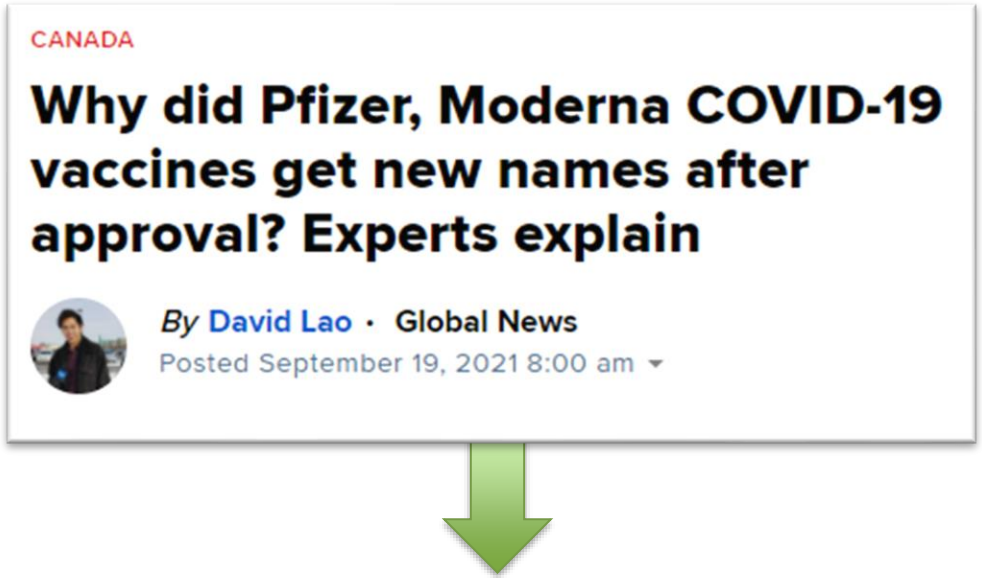
- **Further to the December 23, 2020 aut**
  Vaccine Moderna in accordance with t
  Importation, Sale and Advertising of D
  COVID-19, ModernaTx, Inc. is providi
  with English-only vial and carton label
  expedite the distribution of the vaccin
- **Moderna COVID-19 Vaccine with US la**
  Canada authorized COVID-19 Vaccine
  formulation, strength, route of admini
- **Healthcare professionals are advised**
  - **The US-labelled supply is being of**
    14 doses (US label maximum 15 d
    different from the Health Canada
    vials containing 10 doses of 0.5 m
  - **Important Canadian-specific infor**
    labelled vial and carton (see the '
    professionals' section below).
  - **Information regarding the vaccin**
    pharmaceutical form, volume of v
    different on the US labels. Contin
    Product Monograph for all produc
  - **The expiration date is not printed**

1

U.S. COVID-19 Vaccine Moderna – Lot and Expiry Information

Lot #	Expiry Date	Fill Volume	Doses per Vial
052C21A	10 Nov 2021	8 mL	14 (US label max. 15)
042D21A	07 Dec 2021	8 mL	14 (US label max. 15)
043D21A	09 Dec 2021	8 mL	14 (US label max. 15)
044D21A	10 Dec 2021	8 mL	14 (US label max. 15)
045D21A	11 Dec 2021	8 mL	14 (US label max. 15)
085D21A	19 Dec 2021	8 mL	14 (US label max. 15)
092D21A	13 Dec 2021	8 mL	14 (US label max. 15)
093D21A	14 Dec 2021	8 mL	14 (US label max. 15)
015E21A	26 Dec 2021	8 mL	14 (US label max. 15)
016E21A	29 Dec 2021	8 mL	14 (US label max. 15)
018E21A	31 Dec 2021	8 mL	14 (US label max. 15)
019E21A	02 Jan 2022	8 mL	14 (US label max. 15)
020E21A	04 Jan 2022	8 mL	14 (US label max. 15)
047E21A	06 Jan 2022	8 mL	14 (US label max. 15)
016F21A	21 Jan 2022	8 mL	14 (US label max. 15)

Case Study 2: News, Media & Press Releases



- Lack of understanding of regulatory framework & process has been highlighted during the pandemic
  - In the press and on social media
- Communication of all activity, even ‘standard’ activity, should be thoughtfully considered

Interim Order: Lessons Learned

Resourcing, resourcing, resourcing!

- Cross-functional engagement is paramount to manage multiple activities within/across HAs
- Significant demand on regulatory eCTD publishing

Enable flexibility of process

- As the pandemic evolves so does the regulatory activity, e.g. emerging VOCs, heterologous dosing, booster dosing
- Submission plan is important, revision is inevitable & communication is key

News & social media

- Increased visibility of regulatory activity; consider psychological well-being of your teams

Expanded regulatory stakeholders

- PHAC, NACI, CIC

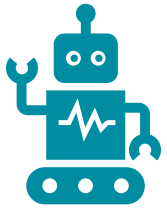
NOC is just one important step in the journey

- Employment of Terms & Conditions
- Significant post-market safety & efficacy collection ongoing

The Future of Regulatory Sciences

Regulatory Modernization

- Rolling submissions
- International cooperation between regulators
- Embracing real-world evidence: enhanced generation, review and incorporation of RWE
- Platform clinical development for mRNA technology



Use of Artificial Intelligence (AI) & Machine Learning

- Manpower was critical to success in a pandemic, but is not sustainable
- Tools to enable rapid review are also required
- Development of regulatory dossiers & management of global queries coordination
- HA use to enable review

Consideration of Social Media and Medical Misinformation

- Need to continue building trust

Consideration of pathways to enable direct-to-consumer (DTC) disease education & product information

- A global world requires global communication
- Consistent regional messaging just as important

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