MICYRN

COVID 19 and Clinical Research in Canada

COVID-19 Health Canada Perspective

- May 23, 2020 Canada's Minister of Health enacted the Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19:

- Introduces flexibilities in how Health Canada authorizes trials over their lifecycle.
- Facilitates a broader range of trials that may not otherwise have been authorized or allows the ability to further address uncertainties or mitigate risks.
- Reduces reporting requirements to lighten administrative burden on sponsors.

Health Canada Santé Canada

COVID-19 Health Canada Interim Order

- Reduces burden where safety profile is aligned with standard medical practice to facilitate studies involving the repurposing of existing marketed drugs. Aligns qualified investigator definition across drugs and medical devices.
- Supports greater decentralization of trials to multiple/remote sites as broader range of health care practitioners can conduct the trial.
- Broadens who can apply for medical devices trials.
- Allows for remote and non-written consent when appropriate to facilitate virtual trials and infection control in the context of COVID-19

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COVID-19 Health Canada Current State

- Minister of Health has approved a Ministerial Order that will temporarily extend the review time for clinical trial applications filed under the Food and Drug Regulations from 30 calendar days to 45 days. All COVID applications will continue to be reviewed in an expedited manner

- Changes are effective as of August 14, 2020 and will apply to all new and existing clinical trial applications. It will be in place for all complete applications received by Health Canada on or prior to November 16, 2020

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COVID-19 Environmental Scan- Current State

- Most research units:
  - In the ramp-up phase of clinical research
  - Allowing research visits within hospital that are either COVID related studies or patients already coming in for standard of care visits (essential visits only)
  - On average, 50-60% of studies are “turned on”
  - Research staff are encouraged to work from home when able
  - Addendum to ICFs required by some institutions outlining risks related to COVID
  - On-site patient visits require PPE and social distancing measures in place
  - Limited on-site monitoring visits, qualification visits etc.

COVID-19: Changes to Process, What's New

- Ethics Review
  - COVID studies prioritized
  - Ethics review meetings shift from in-person to virtual
  - Delegated review occurs in place of full board review for some low-risk studies
  - Intra-provincal ethics reviews are expedited
- Recruitment
  - Some institutions have allowed intermediary contact using the provincial health care system to access patient's with a positive COVID test (COVID studies only)

COVID-19: Changes to Process, What's New

- Consent
  - Verbal and e-consent now allowed at most institutions
- Study Visits
  - Virtual or remote visits increasing, use of secure zoom platforms and telehealth systems
  - Some institutions have allowed for home visits when necessary
- Study Drug/Pharmacy
  - Curb side pick-up
  - Delivery to pt's homes by courier with temperature monitoring

COVID-19: Changes to Process, What's New

- Monitoring
  - On-site monitoring visits halted
  - Batch certified copies of source documents scanned with redacted patient identifiers
  - Use of zoom meetings, with "over the shoulder" source verification
  - Remote access granted to EMR for monitors

Processes Expected to Stay in Place Post Pandemic

- Expeditated intra-provincial ethics reviews
- Virtual and electronic consent
- Telehealth and remote visits with patients (when able)