Global Research and Innovation Forum

Building the world's resilience against future outbreaks and pandemics

SPECIAL CONSIDERATIONS FOR CLINICAL EVALUATION OF COVID-19 MONOCLONAL ANTIBODIES:

LESSONS BEYOND COVID



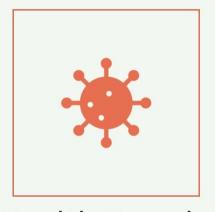
JÉRÉMIE LACROIX ABOUT ME



Pharmacist
Doctor of Pharmacy



Health Canada Special Access Program

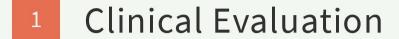


Health Canada
Clinical Evaluation
Division: COVID-19

GUIDELINES ON THE NONCLINICAL AND CLINICAL EVALUATION OF MONOCLONAL ANTIBODIES AND RELATED PRODUCTS INTENDED FOR THE PREVENTION OR TREATMENT OF INFECTIOUS DISEASES: ADDENDUM ON COVID-19/SARS-COV-2







- Special Populations
- Looking Forward
- 4 Beyond COVID



CLINICAL EVALUATION



MADE WITH

CONSIDERATIONS

Indication

Pre/Post-exposure prophylaxis

Treatment

Comparator

Anti-SARS-CoV-2 mAb

Placebo

Endpoints

Efficacy

Safety

Exploratory

Viral Variants

Resistance

SPECIAL POPULATIONS





POPULATIONS

Pregnancy

Delayed access
Altered PK/PD

Immunocompromised

Unlikely to mount an adequate immune response to vaccination

Elderly

Immunosenescence

Pediatric

No licensed mAbs in children under 12 years of age

Comorbidities

Severity Complications

LOCKING FORWARD



INNOVATIONS AND LESSONS LEARNED

Route of administration

Parenteral

Intranasal, Inhaled

Target

Viral Variants

Conserved regions

"Second Generation"

Platform technology

Immunobridging

BEYOND COVID



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THANK YOU

