

Global Research and Innovation Forum

Building the world's resilience against future outbreaks and pandemics

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# **SPECIAL CONSIDERATIONS FOR CLINICAL EVALUATION OF COVID-19 MONOCLONAL ANTIBODIES: LESSONS BEYOND COVID**



**World Health  
Organization**

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**Pharmacist**  
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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**



**World Health  
Organization**



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Clinical Evaluation

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Special Populations

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Beyond COVID

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# CLINICAL EVALUATION



# CONSIDERATIONS

## Indication

Pre/Post-exposure prophylaxis  
Treatment

## Comparator

Anti-SARS-CoV-2 mAb  
Placebo

## Endpoints

Efficacy  
Safety  
Exploratory

## Viral Variants

Resistance

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# 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

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# LOOKING FORWARD



# INNOVATIONS AND LESSONS LEARNED

## Route of administration

Parenteral

Intranasal, Inhaled

## Target

Viral Variants

Conserved regions

## "Second Generation"

Platform technology

Immunobridging

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# BEYOND COVID



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# THANK YOU



# World Health Organization