EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA workshop on primary efficacy endpoints for antivirals and monoclonal antibodies intended to treat COVID-19 and Influenza

05-06 June 2025, 13:00 -17:00 CEST

Virtual workshop

The aim of this workshop is to bring together academic, regulatory, industry and healthcare professionals to:

- Discuss aspects on similarities and major challenges experienced with the clinical study design in antiviral treatment trials for COVID-19 and Influenza
- Discuss and identify feasible and clinically relevant primary efficacy endpoints that can generate robust data to allow the approval of new antiviral and monoclonal antibodies for the treatment of COVID-19 and Influenza.
- Discuss aspects on pandemic preparedness, including clinical study designs, the importance of pre-approved protocol for clinical trials that can be implemented during a pandemic and considerations on the evidence that is needed to support public health recommendations and stockpiling of antivirals and monoclonal antibodies for pandemic preparedness purposes.

EMA Workshop on primary efficacy endpoints for antivirals and monoclonal antibodies intended to treat COVID-19 and Influenza

Chaired by Marco Cavaleri (EMA, Chair of Emergency Task Force - ETF)

Organising committee: *Nathalie Morgensztejn (ANSM, France)*
Filip Josephson (MPA, Sweden)
Ewa Balkowiec-Iskra (Office for registration of medicinal products, medical devices and biocidal products, Poland)
Marco Cavaleri (EMA, The Netherlands)
Ecaterina Golea (EMA, The Netherlands) and
Stephanie Buchholz (EMA, The Netherlands)

Day 1: 5 June 2025

12:30 Joining and technical checks

13:00 Welcome and opening remarks (10 min)

Welcome remarks, housekeeping and objectives **10'**
Marco Cavaleri (EMA, The Netherlands)

13:10 Session 1: Epidemiology and clinical presentation of disease due to SARS-CoV-2 and Influenza (25 min)

Chairs: *Ewa Balkowiec-Iskra (Office for registration of medicinal products, medical devices and biocidal products, Poland)*

Similarities and differences between SARS-CoV-2 and Influenza – Course of disease from incubation to symptom onset, disease progression and secondary complications **15'**
Speaker: Lennie Derde (UMC Utrecht, The Netherlands)

Burden of disease – COVID-19 and Influenza **10'**
Speaker: Edoardo Colzani (ECDC, Sweden)

Questions and answers **5'**

13:40 Session 2: Clinical study design challenges (115 Min)

Chair: Mike Ison (NIH/NIAD, USA)

What are clinically relevant study endpoints for COVID-19 and Influenza?

Regulatory perspective **15'**
Speaker: Stephanie Buchholz (EMA, The Netherlands)

Clinician perspective **15'**

Speaker: Leon Peto (University of Oxford, UK)

Industry perspective **30'**

Speakers: Richa Chandra (Novartis, USA)
Simon Portsmouth (Shionogi, Japan)

14:40 Coffee break (10 min)

14:50 Session 2: continued

Considerations for immunocompromised patients ***15'***

Speaker: Michael Boeckh (Fred Hutchinson Cancer Center, USA)

Antiviral development landscape for COVID-19 and influenza **10'**

Speaker: James F. Demarest (INTREPID Alliance)

Antivirals for pre- or post-exposure prophylaxis of Influenza **10'**

Speaker: Arnold Monto (University of Michigan School of Public Health, USA)

Antivirals for pre- or post-exposure prophylaxis of COVID-19 **10'**

Speaker: Cameron Wolfe (Duke University School of Medicine, USA)

Clinical evidence for viral load as surrogate endpoint for antivirals for COVID-19 **10'**

Speaker: Michael Hughes (Harvard TH Chan School of Public Health, USA)

Clinical evidence for viral load as surrogate endpoint for antivirals for Influenza **15'**

Speaker: Frederick Hayden (University of Virginia School of Medicine, USA)

16:00 Discussion (60 min)

Moderator: Marco Cavaleri (EMA, The Netherlands)

Panel discussion **25'**

Peter Horby (Oxford University, UK)

Jens Lundgren (University of Copenhagen, Denmark)

Maya Hites (Hôpital Universitaire de Bruxelles, Université Libre de Bruxelles, Belgium)

Stije Leopold (University of Oxford, UK)
Barbara Rath (Vaccine Safety Initiative, Germany)
Mike Ison (NIH/NIAD, USA)
Richa Chandra (Novartis, USA)

Open discussion with the audience **35'**

17:00 Closing remarks (5 min)

Wrap up **5'**
Marco Cavaleri (EMA, The Netherlands)

Day 2: 6 June 2025

13:00 Welcome and outline of the day (5 min)

Welcome remarks, housekeeping and objectives **5'**
Marco Cavaleri (EMA, The Netherlands)

13:05 Session 3: Specific considerations for mAbs for COVID-19 and Influenza (90 min)

Chair: Jan Müller-Berghaus (PEI, Germany)

Challenges in evidence generation for COVID-19 mAbs

Regulatory perspective **15'**
Speaker: Filip Josephson (MPA, Sweden)

Clinician perspective **10'**
Speaker: Peter Horby (University of Oxford, UK)

Industry perspective **15'**
Speakers: Ian Hirsch and Taylor Cohen (Astra Zeneca)

Challenges in evidence generation for Influenza mAbs

Clinician perspective **15'**
Speaker: James Crowe (Vanderbilt University Medical Center, Nashville, USA)

Industry perspective **15'**
Speaker: Jintanat Ananworanich (Leyden Labs, The Netherlands)

Convalescent plasma for treatment of respiratory viruses **15'**
Speaker: Daniele Focosi (Azienda Ospedaliero-Universitaria Pisa, Italy)

14:30 Session 3: Discussion (30 min)

Moderator: Filip Josephson (MPA, Sweden)

Open discussion with the audience **30'**

15:00 Coffee break (10 min)

15:10 Session 4: Pandemic preparedness (65 min)

Chairs: *Yazdan Yazdanpanah (Hôpital Bichat-Claude Bernard, France)*

Marco Cavaleri (EMA, The Netherlands)

Importance of pre-approved protocols for clinical trials during a pandemic to support pandemic preparedness **10'**

Speaker: *Inge Christoffer Olsen (Oslo University Hospital, Norway)*

Potential clinical study designs for clinical trials intended to be conducted in case of an outbreak **15'**

Speaker: *Yazdan Yazdanpanah (Hôpital Bichat-Claude Bernard, France)*

Challenges associated with the pre-approval of clinical study protocols for pandemic preparedness

Regulatory perspective **10'**

Speaker: *Nele Steens (FAMPH, Belgium)*

Clinician perspective **10'**

Speaker: *Karine Lacombe (Sorbonne Université, France)*

Industry perspective **10'**

Speaker: *Yoshihiko Murata (Gilead, USA)*

16:05 Session 4: Discussion (30 min)

Moderator: *Marco Cavaleri (EMA, The Netherlands)*

Panel discussion on the evidence needed to support public health recommendations and stockpiling of antivirals for pandemic preparedness **40'**

Evelina Tacconelli (University of Verona, Italy)

Jose Ramon Arribas Lopez (Autonomous University of Madrid, Spain)

Inge Christoffer Olsen (Oslo University Hospital, Norway)

Yazdan Yazdanpanah (Hôpital Bichat-Claude Bernard, France)

Dr Janet V Diaz (Safe Scalable Care Unit, WHO Health Emergencies Programme, Switzerland)

Emmanuel André (KU Leuven, Belgium)

16:45 Closing remarks (5 min)

Wrap up **5'**

Marco Cavaleri (EMA, The Netherlands)