EMA Workshop on generating clinical evidence for treatment and prevention options for Long-COVID/Post-acute sequelae condition (PASC)

PCWP/HCPWP Meeting 14th – 15th November 2023

Presented by Stephanie Buchholz on 14 November 2023
National Expert on Secondment, Health Threats and Vaccines Strategy (AF-HTV)
EMA-Workshop on generating clinical evidence for treatment and prevention options for Long-COVID/Post-acute sequelae condition (PASC)

Date: Friday 17th of November 2023
Time: 13:00-18:00, CET Amsterdam time
Location: Virtual only, WebEx meeting
Live broadcasting
Propose/Objective of the Workshop

- To bring together the expertise of clinicians, academic, regulatory and pharmaceutical communities and patients’ groups to address and discuss:
  - The complexity of the pathophysiological mechanisms and clinical syndromes associated with Long-COVID/Post-acute sequelae condition (PASC) that impacts the evaluation of possible therapeutic or preventive strategies in clinical trials.
  - The challenges of conducting clinical trials for novel/repurposed treatment and prevention approaches for Long-COVID with respect to the appropriate therapeutic endpoints, trial designs and patient populations to be included in clinical trials.
  - The regulatory concerns that are raised by the complexity of the conditions and pertain to trial design issues for both prevention and therapeutic strategies, especially the measures to assess efficacy in clinical trials.

→ Technical Workshop on challenges in clinical study design and potential outcome measures to assess efficacy for the multiple clinical syndromes of Long-COVID
Workshop Agenda – Session 1

Welcome remarks
Sandra Gallina (European Commission, DG Sante)

Session 1: Physiopathology and epidemiology of Long-COVID/Post-acute sequelae of SARS-CoV-2 infection (PASC)

Chairs: Christine Dehn (Patients’ representative, Deutsche Herzstiftung)
        Catherine Cohet (EMA)

Update on epidemiological data on characteristics, burden of disease, and risk factors for Long-COVID

Speaker: Lourdes Mateu Prunonosa (Hospital Universitari Germans Trias i Pujol, Badalona, Barcelona, Spain)

- Latest data on the elaboration of a working definition for Long-COVID/PASC, risk factors, main clinical aspects, long-term consequences and differences with other post-acute infection syndromes.
Workshop Agenda – Session 1 continued

*Update on the physiopathological mechanisms of Long-COVID*

- The complexity of pathological mechanisms and clinical syndromes associated, with an additional focus on possible therapeutic or prevention strategies

*The role of viral/antigen persistence and links to possible therapeutic strategies*

**Speaker:** Giulia Marchetti (University of Milan, Italy)

- Recent evidence of pathophysiological mechanism and the role of viral/antigen persistence, viral reactivation of other viruses, potential sanctuary sites and therapeutics evaluated in ongoing clinical trials

*The role of immunological mechanisms and links to possible therapeutic strategies*

**Speaker:** Daniel Altmann (Imperial College London, UK)

- Recent evidence on immunological mechanisms resulting in immune dysregulation, pathophysiological mechanism resulting in mitochondrial dysfunction, fibrosis, ME/CFS, hyperthrombolytic events, ongoing clinical trials and potential treatment options
Workshop Agenda – Session 2

Session 2: Clinical study design for prevention and treatment of Long-COVID/PASC

Chairs: Bruno Sepodes (INFARMED, Portugal Co-Chair ETF, Vice-chair CHMP)
Eugenia Di Meco (EMA)

Update on recent developments and ongoing trials for treatment and prevention of Long-COVID

• The NIH RECOVER Initiative – Strategic approach to the development of a clinical trials portfolio for Long-COVID
  
  Speaker: Laurie Gutmann (Indiana University School of Medicine, US. Co-chair RECOVER Clinical Trials Steering Committee)

• Case example of key considerations and trial design features: Viral persistence and reactivation, and immune dysregulation clinical trial (RECOVER-VITAL)
  
  Speaker: Lindsey Robert Baden (Vice President of Clinical Research, Brigham and Women’s Hospital, Co-Principal Investigator, RECOVER Initiative Clinical Trial)
Workshop Agenda – Session 2 continued

- **Regulatory challenges concerning the appropriate clinical study design for treatment and prevention options for Long-COVID**
  
  **Speaker:** Stephanie Buchholz (EMA)
  
  - Regulatory concerns due to the complexity of the clinical conditions pertaining the appropriate trial design, patient populations, therapeutic endpoints and outcome measures.

- **Joint industry presentation on challenges of designing and conducting clinical trials for treatment and prevention**
  
  **Speaker:** Amanda Radola (Pfizer, industry representative)
  
  - Challenges concerning the terminology/definitions, symptoms, clinical trial design: endpoints & population and the potential use of real-world data to complement clinical trial data
Workshop Agenda – Session 3

Session 3. Discussion

Moderator: Marco Cavaleri (EMA)

- Panel with representatives of involved stakeholders (patients, academics and clinicians, industry, regulators)
  
  Chantal Britt (Long-COVID Europe, patient representative)
  Daniele Dona (University of Padova, PENTA)
  Evelina Taconelli (University of Verona, ORCHESTRA)
  Eldrin F. Lewis (Co-chair of the RECOVER Clinical Trials Steering Committee, Chief Cardiovascular Medicine, Stanford University)
  Lindsey Robert Baden (Vice President of Clinical Research, Brigham and Women’s Hospital, Co-Principal Investigator, RECOVER Initiative Clinical Trial)
  Amanda Radola (Pfizer, industry representative)
  John Farley (Center for Drugs Evaluation and Research, FDA)
  Ewa Balkowiech-Iskra (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Warsaw, Poland, Member of Emergency Task Force - ETF)
  Ann-Marie Janson Lang (Swedish MPA, Member of the Clinical trials coordination group - CTCG)

- Open discussion with the whole audience
Potential outcome

- To **identify** the major challenges on the clinical study design for novel or repurposed prevention and treatment options of Long-COVID/PASC.

- To **better understand** and **potentially resolved** the methodology issues of conducting such studies.

- To **identify potential outcome measures** for the **various conditions** that could allow **reliable assessment of efficacy** in clinical trials.

- To **facilitate** and **expedite future designing** of **clinical studies** for prevention and treatment options for Long-COVID/PASC with the knowledge gather in this workshop.
Further information

• Event homepage:

Workshop on generating clinical evidence for treatment and prevention options for long-COVID and post-acute sequelae condition (PASC) | European Medicines Agency (europa.eu).

• Active involvement in the discussion or further information, please send an email to:

CTworkshop@ema.europa.eu

• Broadcast link:

EMA's Vimeo channel 2
Any questions?

Further information

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