INFORMATION SESSION FOR CTR STAKEHOLDERS

3 th February 10h-12h

Joint action on support to coordinated and expedited assessment of clinical trials for COVID-19 therapeutics

CT Cure

EU4H-2021-JA-01

Background

Therapeutics continue to play a critical role in the response to the COVID-19 pandemic .
They help to save lives, speed up recovery time and help to avoid or reduce periods of hospitalisation. However, joint efforts are still needed to ensure access to safe and effective therapeutics. The EU Strategy on COVID-19 therapeutics highlighted that robust clinical trials are an essential source of evidence for the authorisation of innovative COVID-19 medicines and there is a need for speeding up and coordinating their authorisation.
Speeding up is a real necessity in the context of the current health crisis.
It has been two years since we were confronted with a worldwide health crisis caused by SARS-CoV-2 and unfortunately Europe is still going through a fourth devastating wave as you can see on the website https://www.ecdc.europa.eu/en. There is an urgent need

for therapeutic solutions to be tested and brought to the market as soon as possible.
It is also in this context that we would like this JA to start as early as February 2022 .

This joint action will implement the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supports innovation regarding such products .

This Joint action will focus on providing a harmonized and accelerated assessment of multi-national clinical trials with COVID 19 therapeutics using the Clinical Trial Information System (CTIS). The work process enabling this, will be continuously optimized by experiences gained from NCAs and Ethics Committees as well as from the sponsors (commercial and non-commercial).
The liaison with the Emergency task Force at EMA (according to the proposal for a regulation on a reinforced role for the EMA in crisis preparedness and management for medicinal products and medical devices COM/2020/725) will be foreseen in view of motivating sponsors to seek for previous scientific advice as well as for participating to the Horizon scan in detecting pro-actively promising therapeutic candidates.

This project will also foresee the strengthening of the expertise within the European medicines regulatory network (EMRN) by exchanging and optimising good practices and allowing less experienced Member States to participate so that citizens/patients within the EU territory can be reached in an optimal way during the pandemic.

Program :

10-10.15 h : Introduction of the Joint Action EU4 Health CT Cure : Expedited assessment of COVID 19 therapeutics :
CTR , COVID 19 Therapeutics , EU 4 health Joint action
SYLVAIN GIRAUD, European Commission Directorate-General for Health and Food Safety, Unit B4 Medical Products, Head of Unit

Implementation of the EU4Health, JA from HaDEA perspective
Giuseppe Simone , European Health and Digital Executive Agency (HaDEA), Project Adviser

10.15h-10.30 h : Highlights of the project EU4 Health CT Cure : Team members , Structure , Deliverables .
Greet Musch (Federal Agency for Medicinal and Health Products , General Director Pre-authorisation)

10.30h-11h : Best Practice Guide for expedited assessment of multi-national COVID 19 therapeutic trials
Ann Marie Janson Lang (Swedish Medicines Product Agency , Co-Chair CTFG)

11h-11.45h : Questions and Answers

11.45h-12h : Wrap up and close of the meeting
Edit Szepessy (European Commission DG Health and Food safety, Pharmaceuticals , Policy officer)
Georgios Symeonidis (European Commission DG Health and Food safety, Pharmaceuticals , Policy officer)