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

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The submitted proposal is under ongoing evaluation to be funded under the EU4Health programme

European Commission

EU4Health - CT Cure

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Background

- Urgent need for therapeutic solutions in response to COVID-19 pandemic
- Robust clinical trials are essential sources of evidence for marketing authorisations of COVID-19 therapeutics
- Need for speeding up assessment and clinical trial authorisation without compromising the quality of the scientific and ethical review
- EU4Health Joint Action CT-Cure focuses on accelerated and harmonised assessment of multinational clinical trial applications

Scope of CT-Cure 1/2

- **Multinational trial applications investigating the efficacy and safety of novel COVID-19 therapeutics submitted to the Clinical Trials Information System (CTIS) under the Regulation (EU) No 536/2014 (here called the Clinical Trials Regulation, CTR)**

- **Novel COVID-19 therapeutics are defined as:**

  i) investigational medicinal products (IMPs) without marketing authorisation

  ii) IMPs with marketing authorisation for a different indication than COVID-19-related indications

  iii) COVID-19 therapeutics with a marketing authorisation used with a new posology or in novel populations, e.g. in children

Scope of CT-Cure 2/2

- Initial Best Practice Guide already developed and agreed among participating Member States to enable efficient start of the project
- Work procedures will be adapted following experience by MSs (NCAs and Ethics Committees) and sponsors (commercial and non- commercial) at regular basis
- Sponsors are encouraged to file excellent and complete applications, preferably by seeking previously central or (simultaneous procedures organised by EU-IN, EU Innovation Offices) national scientific advice
- Sponsors are strongly recommended to inform the proposed Reporting Member State and all Member States Concerned receiving the application at least two weeks in advance of the submission

General state of play 1/2

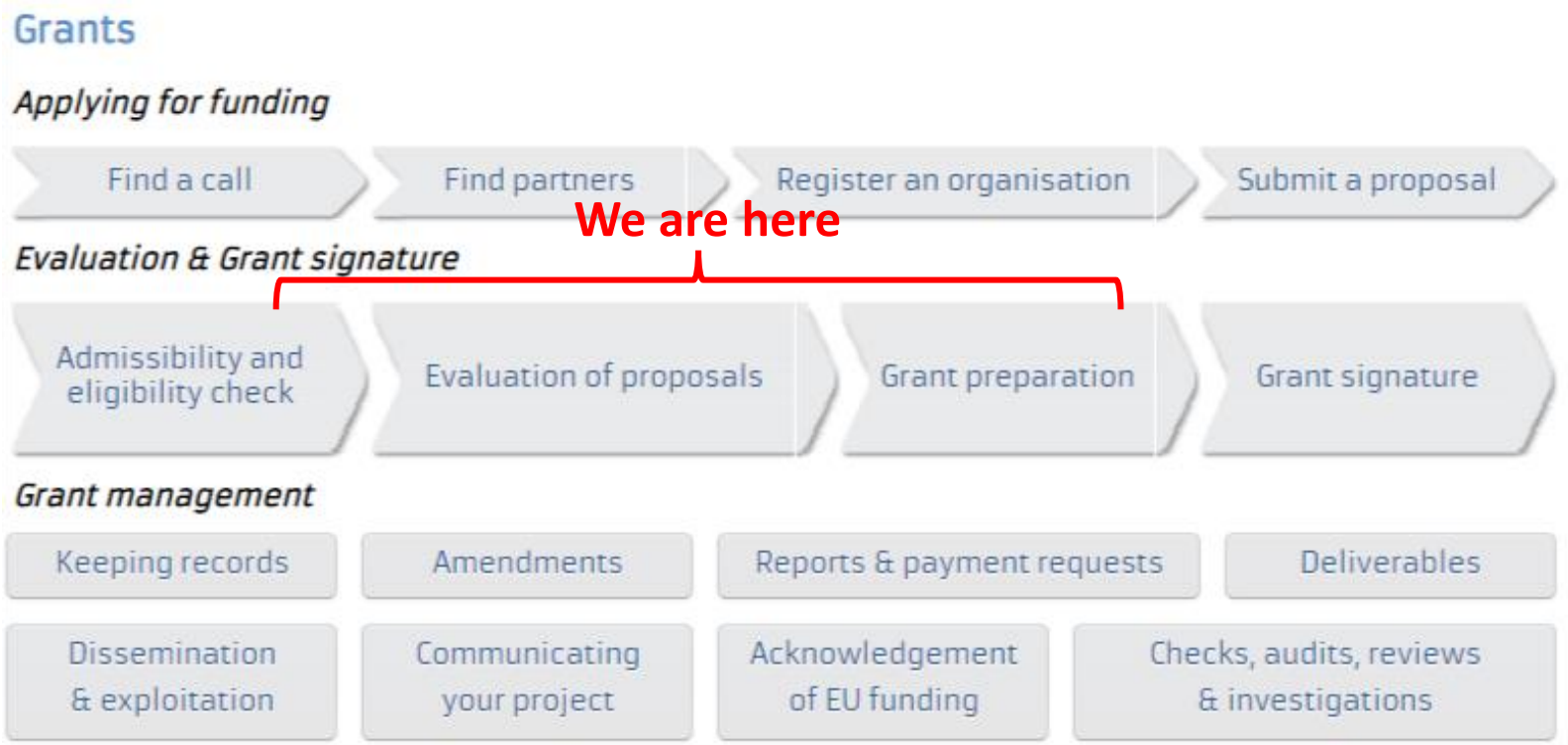
15 Member States have confirmed their participation

BE , CZ , DE , EL , ES , FR , HU , HR , LT , LV , NL , SE , SI , PT , RO

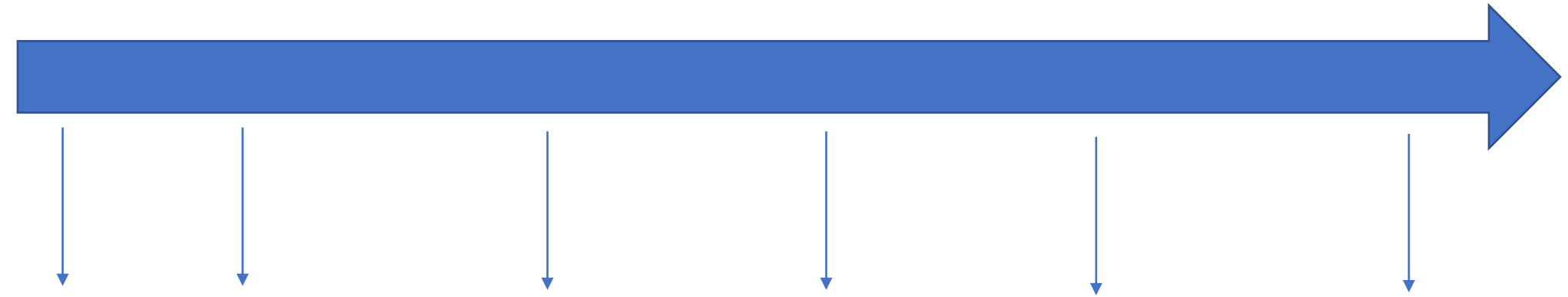
Also, Member States outside these participating ones, have expressed interest in joining the expedited assessment

General state of play 2/2

- Joint action will start at 1st February 2022 (retroactivity accepted by Hadea)
- First applications expected Mid-February 2022



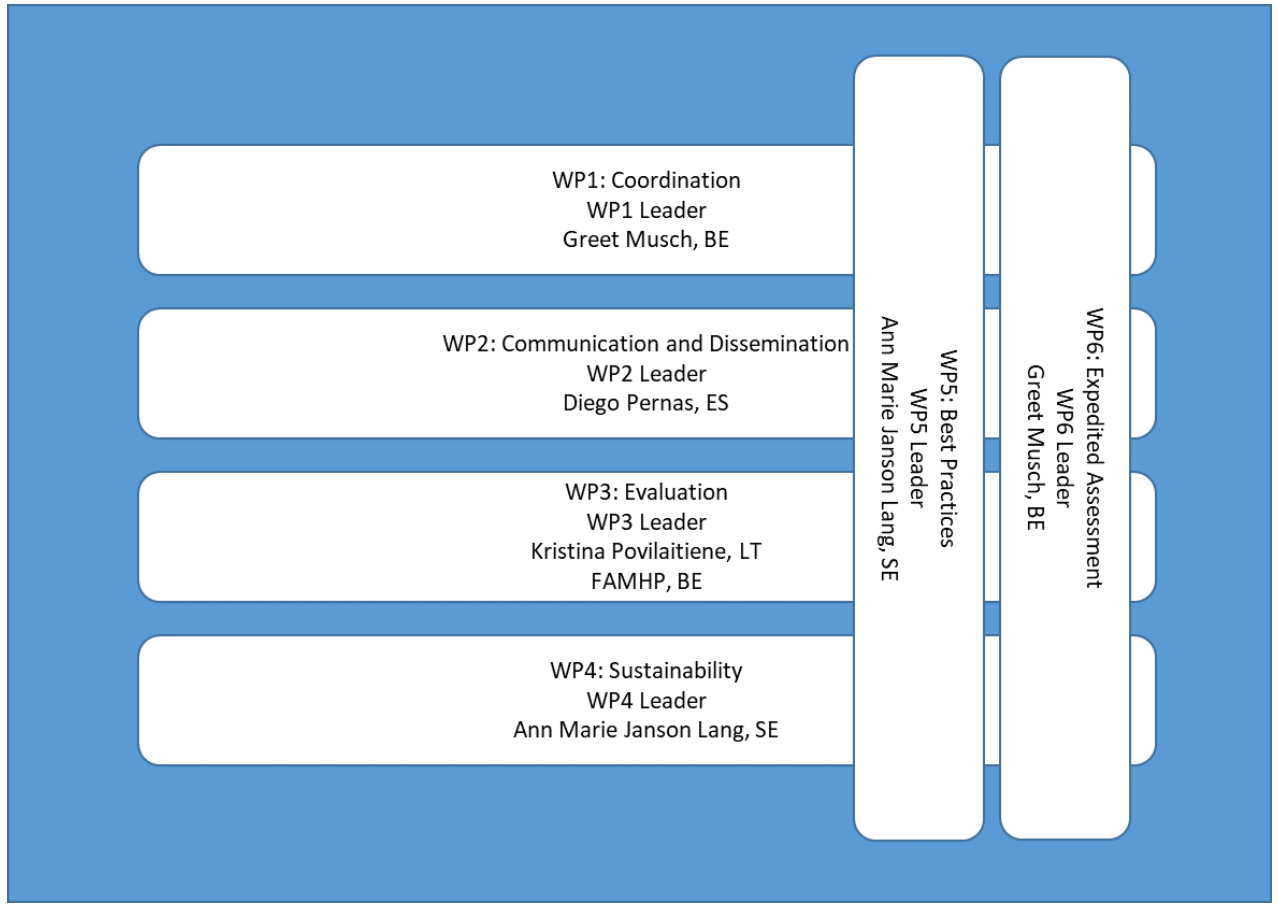
CT-Cure timeline



CT-Cure Team

- Ann Marie Janson Lang, SE, *Swedish Medical Products Agency:* ***Best Practice Guide and Sustainability***
- Diego Pernas, ES, *AEMPS*: ***Dissemination***
- Kristina Povilaitienė, LT, *SMCA*: ***Evaluation***

- Pascal Giloteau, Valerie Nys, Sandra De Boever and Greet Musch, BE, Federal Agency for Medicines and Health products: ***Coordination team***



Our first delivrable

- **Best practice for Member States participating in the joint action CT-CURE**

Vs 1.0 Dec 10 2021

Best Practice for Member States participating in the joint action CT-CURE as RMS or MSCs in multinational COVID-19 Therapeutic Trials

The following multinational trials investigating the efficacy and safety of novel COVID-19 therapeutics submitted to the Clinical Trials Information System (CTIS) under the Regulation (EU) 536/2014 (here called the Clinical Trial Regulation, CTR) are eligible for inclusion in the joint action CT-CURE under EU4Health.

Novel COVID-19 therapeutics are defined as i) investigational medicinal products (IMPs) without marketing authorisation, ii) IMPs with marketing authorisation for a different indication than COVID-19-related indications and iii) COVID-19 therapeutics with a marketing authorisation used with a new posology or in novel populations, e.g. in children.

Thank you for your attention

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