ERAvsCORONA Action plan - *Ad hoc* working group of MS: Clinical trials sub-group

Meeting minutes 6 May 2020

Introduction – State of play (by EC)

- Clarification on role of CT sub-group, which is focused on operational issues; the CT sub-group does not have decisional power. Depending on the scope, decisions are made on the following level:
  - Operational issues: the R&I DGs, receiving the information via the Ad hoc WG of the MS (set up by the R&I DG's for the purpose of the COVID-19 response)
  - Budgetary issues: Programme Committee
  - Political issues: Research working party, for decision by the Council
- Next meeting of R&I DG's planned for 14 May, where the different sub-groups will report on progress made.
- Successful pledge event on 4 May yielded more than 7 billion EUR.

Terms of Reference on clinical trial (CT) sub-group

- The temporary nature of the CT sub-group was confirmed, i.e. in line with the COVID-19 pandemic response.
- The advisory role of the CT sub-group was emphasised. Further clarification on the relationship between the CT sub-group and the Ad hoc WG of the MS would be helpful. It was agreed to share the ToR of the latter with the CT sub-group members.
- Several MS expressed their concern on the multiplication of sub- and other groups, with the risk of dispersing coordination efforts; in particular, the added value of the scientific steering committee was questioned. It was suggested that the role of such an advisory group could be ensured by the adaptation of the profile of the members of the CT sub-group.
- At the same time, MS agreed on the importance of strong collaboration in order to streamline efforts and ensure robust results from large-scale and multi-centre trials throughout Europe. Harmonisation of protocols and data collection is key, and all MS should have the opportunity to participate in such trials.
- The representatives of the Clinical Trials Facilitation Group (CTFG) of the Heads of Medicine Agencies (HMA) emphasised the efforts made in this regard in the past years, supporting the harmonisation of clinical trial assessments and through the voluntary harmonisation procedure. The use of a single sponsor for large-scale trials greatly facilitates a harmonised approach across the multiple sites involved.

- The importance of an integrated approach, where the clinical trial coordination works with the regulatory authorities and the ethics experts from early on in the trial, was also emphasised.
- ECRIN clarified their intent to facilitate combining different national initiatives, through a "market place" approach that supports the exchange between different trial initiatives at an early stage. For this market place fully to fit the purpose, information on any planned trial as soon as funding is secured, is needed.

Action points

The following action points were identified. Progress will be reported at the next meeting of the sub-group.

- Update ToR with comments received;
- Share the ToR of the Ad hoc WG of the MS;
- The Commission will develop a concrete proposal on how to move forward, for the CT sub-group to be able to meet its goals;
- ECRIN will develop a short explanatory note on how the "CT market place" approach could work.