Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Letter to the Editor

Accelerating clinical trial implementation in the context of the COVID-19 pandemic: author's response

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To the Editors,

The DisCoVeRy and EU-SolidAct EU RESPONSE group appreciates the thorough feedback from the European Commission [1] to our commentary entitled "Accelerating clinical trial implementation in the context of the COVID-19 pandemic: challenges, lessons learned and recommendations from DisCoVeRy and the EU SolidAct" [2].

We acknowledge the substantial European Commission support to EU funded multinational trials, the fact that they recognize the importance of rapid and sustainable funding mechanisms, and the ongoing efforts to facilitate implementation despite the hurdles (regulatory, legal and financial) we have described. The support to our proposal of developing a harmonized European site contract template is particularly appreciated, as such a template will remove major legal hurdles in the rapid expansion of multinational trials.

The new clinical trials regulation 536/2014 (CTR) which will be operative from 31 January 2022 will hopefully also be a major step forwards, with joint evaluation from competent authorities and ethical committees within defined and monitored time frames. It is vital that the implementation of the new clinical trials regulation works as planned, including the possibility of a specific status with shorter timelines for approval of multi-country COVID-19 trials. We welcome the expedited scientific advice from the European Medicines Agency (EMA), as well as the possibility for pre-submission communication with the regulatory authorities to ensure high quality applications.

We also suggest that the European Commission plans and performs a solid evaluation during and after the initial implementation of the new clinical trials regulation to explore how it works in practice and how it impacts current timelines. We will be happy to contribute to such an evaluation, and to engage in future discussions regarding our common goal of facilitating more expedite clinical trial implementation in Europe.

Author contributions

M. Trøseid, A. Diallo wrote the original draft of the reply, which was reviewed and edited by M. Hites, J-A. Røttingen and Y. Yazdanpanah. All authors contributed to refinement of and approved this manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Transparency declaration

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the submitted work; acting as a treasurer for the Belgian Society of Clinical Microbiology and Infectious Diseases, outside the submitted work. All other authors declare no competing interests.

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