ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

27 March 2023

To: James O'Shaughnessy
Co-Founder and Senior Partner, Newmarket Strategy Ltd
Niddry Lodge, 51 Holland Street
London W8 7JB

Cc: Clare Hedwat, Senior Strategy Advisor, Office for Life Sciences
Emily Hirsz, Senior Team Leader, Genomics, Office for Life Sciences
Claire Beaton, Statistics and Data Lead, Office for Life Sciences
Rosie Fox, Genomics Policy Adviser, Office for Life Sciences

Dear Lord O'Shaughnessy,

Thank you for the opportunity to provide input into the Independent Review of Commercial Clinical Trials.

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. ACRO member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-human studies through post-approval, pharmacovigilance and health data research. ACRO member companies manage or otherwise support a majority of all biopharmaceutical-sponsored clinical investigations worldwide. The member companies of ACRO advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.

ACRO member companies have extensive experience conducting trials in the UK and regularly engage with leadership across the system (MHRA, HRA, DHSC, NIHR, and DIT) to advance UK clinical trials. In 2018, at our Clinical Research Roundtable meeting with you and NIHR leadership, held at St. Bartholomew's hospital, we highlighted three key areas which would support the attractiveness of the UK for clinical research:[1] optimizing study set-up and start time; increasing participation in clinical research; and demonstrating government commitment to clinical research. We believe these key areas continue to be critical and would like to highlight these in this submission.

I. Optimizing study set-up and start time

The timelines to initiate new trials in the UK need to be predictable and competitive with timelines in other countries. ACRO members have raised concerns about delays in responses from and approvals by the MHRA. We strongly support the commitment to implement a timeline for MHRA completion of an application review within a maximum 30 calendar days in general, with a maximum 10 calendar days for a decision to be granted once the regulator has received responses to any Request for Further Information, as described in the newly published Government response to consultation on legislative proposals for clinical trials[2]. However, the reasons for existing delays in the MHRA need to be addressed urgently. ACRO would welcome

[1] ACRO UK Policy Proposals, November 2018, https://www.acrohealth.org/wp-content/uploads/2018/11/ACRO-UK-Policy-Proposals-2018-11.pdf
[2] Government response to consultation on legislative proposals for clinical trials, March 2023 https://www.gov.uk/government/consultations/consultation-on-proposals-for-legislative-changes-for-clinical-trials/outcome/government-response-to-consultation-on-legislative-proposals-for-clinical-trials

the opportunity to provide ongoing feedback on the impact of the MHRA delays and to provide input, as appropriate, to help resolve any issues.

In our previous correspondence, we raised the potential for central contracting to improve the competitiveness of the UK for clinical trials. We appreciate the progress that has been made but acknowledge that central contracting is not yet fully embedded. We welcome the commitment made within the UK Clinical Research Recovery, Resilience and Growth (RRG) program to take forward plans to identify additional ways to simplify and streamline requirements (including costing and contracting)[2]. In order to press forward on this work, to the extent to which the government can require the use of central contracting on the part of research sites and NHS trusts, ACRO member companies can commit to using central contracting as standard when working in the UK.

II. Increasing participation in clinical research

One of ACRO's initiatives has been to advance decentralized clinical trials (DCTs) through ACRO member companies' thought leadership and innovation on DCTs. A dedicated ACRO DCT committee, initiated after a discussion with MHRA in 2019, has overseen the development of the ACRO DCT toolkit (available on ACRO's website[3]), and we appreciate the input from MHRA in regular, ongoing meetings between MHRA and ACRO in 2019, 2020, 2021, 2022 – and a scheduled upcoming meeting in April of 2023. ACRO would welcome further adoption of DCTs in the UK in order to increase participation in clinical research, and we are committed to continuing to provide thought leadership in partnership with MHRA, FDA and the EMA.

III. Demonstrating government commitment to clinical research

ACRO welcomes the ongoing cross-system approach to implementation of the UK vision for clinical research delivery through the Recovery, Resilience and Growth (RRG) Program. ACRO has representation on the RRG advisory board and participation in this board provides valuable insight into the challenges being faced in relation to conducting NIHR-supported trials within the NHS; it has also been very helpful to understand where commercial research sits within the wider research community and to understand the connection between ability to deliver research and the general constraints within the NHS (e.g., facilities, staffing, infrastructure, technology).

We note that, until recently, much of the emphasis has been on the delivery of academic/charity sector trials with significantly less attention to, and understanding of, commercial clinical trials. This includes a potential lack of consideration about how the conduct of industry-sponsored research at UK sites may provide additional support for clinical care services and fit into the global development of an investigational product. To date, focus has been on NIHR-supported trials only, so it is unclear how non-NIHR-supported trials fit into the overall research picture within the NHS.

We believe there may also be an incomplete understanding of the pivotal role CROs and clinical technology companies play in drug development and the frontline expertise they can contribute to the resolution of current challenges. ACRO would be happy to facilitate a meeting between the RRG and operational, regulatory and quality teams from ACRO member companies in order to help increase this understanding with a view to finding solutions for commercial clinical trials in the UK.

[3] The ACRO DCT Toolkit can be found at https://www.acrohealth.org/dct/

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We look forward to seeing the outcome of the review and ongoing engagement, and ACRO staff are available to support and assist this initiative on commercial clinical research.

Respectfully submitted,

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