ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

6 November 2018

Lord O'Shaughnessy
Parliamentary Under Secretary of State for Health (Lords)
Department of Health and Social Care
39 Victoria Street
London
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Dear Lord O'Shaughnessy,

On behalf of the Association of Clinical Research Organizations (ACRO), thank you for joining the leaders of St. Bartholomew's Hospital, along with senior executives from IQVIA and other ACRO member companies for a Clinical Research Roundtable on 24 October 2018. Meeting participants were greatly encouraged by your commitment to positioning the UK as a preferred location for clinical research. We appreciate the invitation to make specific policy recommendations to achieve that outcome.

ACRO member companies operate around the world in a global research enterprise. Our members work with biopharmaceutical research sponsors who continually search for the most attractive regulatory and business environments, enabling ACRO's unique insight into the globally competitive nature of clinical trial placement.

With its expertise in biomedical science, highly skilled workforce and an integrated healthcare system with unparalleled data resources, the UK should be highly competitive in attracting clinical research. Several specific regulatory, funding and business factors, however, put the UK at a disadvantage in relation to other countries. The EU exit has opened a "window" for creative and innovative thinking about improving the attractiveness of the UK for clinical research. **The following six proposed policy changes address current challenges, with solutions that position the country for future successes that can be shared by all stakeholders.**

OPTIMIZING STUDY SET-UP AND START TIME:
Clinical research is hampered by inefficiencies in the procedures to initiate new trials in the UK

1. Centralized Ethics Review
Problem:
There are currently more than 80 NHS Research Ethics Committees across the UK. As a result, the ethics review process is variable, inconsistent and takes too long.

Recommendation:
The government should undertake a review of the current Ethics Committee system to address the urgent need for standardization, professionalization and centralization of ethics review in the UK. A new, centralized National Ethics Team should operate with:

Expertise – Adequate resources to rapidly draw upon relevant skills.
Consistency – Review proposed projects on a predictable, continuous basis.
Speed – Accomplish a thorough and meaningful ethical review within a short and consistent time, such as 15 calendar days. ACRO notes that the current MHRA/HRA Combined Ways of Working pilot is improving ethics committee review times in participating committees, but even in this process there is a certain amount of "dead time" that could be removed if ethical review operated on a professional, full-time basis.

This new approach will improve study start-up time and make UK clinical research more efficient and predictable for all stakeholders.

2. Centralized Contracting

Problem:

Wildly varying contracting procedures and timelines create significant delays in study start-up and put UK clinical research at a disadvantage.

Recommendation:

Similarly to a Centralized Ethics Review mechanism, the development of a centralized Contract Negotiation Team would cost studies against site/institution-managed cost data and patient pathway templates, and accomplish contract negotiations within a short and consistent time (timing developed with input from the NIHR and NHS). Centralizing and standardizing these efforts would make the UK a more competitive location for clinical research.

INCREASING PARTICIPATION IN CLINICAL RESEARCH:

Finding and enrolling patients to participate in clinical trials is more difficult than it needs to be, as is accessing patient data for research purposes

3. The Right to Write

Problem:

In the current system of patient recruitment, a site cannot cast its net wide enough. This results in slow enrolment; the need to initiate too many sites; increased variability caused by too many sites; and the inability of patients to participate because they do not fall within the small catchment area of a site.

Recommendation:

Utilizing NHS patient records, UK doctors/clinical investigators should be able to contact patients not directly under their care to offer the opportunity to participate in an appropriate clinical trial. This would be done following ethical approval of appropriate outreach. Despite the interest expressed by patients in being informed of appropriate trials, this so-called "Right to Write" does not exist currently in the UK; instead there are unnecessary bureaucratic delays and patient access to clinical trials is significantly hampered. In addition, virtual trials have the potential to increase the investigator site catchment area, and this will require new ways of contacting eligible patients.

It is critical to understand public perceptions and concerns around privacy, data protection and engagement. ACRO recommends that a trusted third party (e.g., the Wellcome Trust) conduct a survey of patient attitudes on this topic and build an evidence base that can be used for effective implementation of a Right to Write policy. This effort is also an opportunity to collaborate with NHS as they develop a mobile device application to engage with patients.

Educating people about clinical research helps build trust and advances the concept that clinical research means better care. The Right to Write can help raise the profile of clinical research, catalyse recruitment and improve care for patients.

4. Modernizing Data Access Policies

Problem:

The world's richest health data ecosystem of de-identified patient data should be deployed robustly. However, there are impediments to both academic and commercial researchers having appropriate and timely access to these data – delaying UK study start-up and recruitment and hindering the use of "real-world evidence" to advance innovation.

Recommendation:
The government needs to set a clear and transparent policy and remove barriers to accessing and linking data sets for real-world evidence and recruitment purposes, with explicit direction to data custodians (e.g., NHS Digital, HDR UK) to collaborate with the private and public sectors to enable appropriate data access. The ESRC's Administrative Data Research Network (now the Administrative Data Research Partnership) was set up to explore social science research but generally excludes healthcare data. A similar model should be explored for healthcare data with NHS Digital in a similar partnership role to the one the ONS plays in the ADRP.

Patients recognize that the UK's wealth of data is an asset and that fairness requires the public see a benefit of the use of their data. Modernizing data access policies enables this vast resource to be used as a collective benefit that the public, government, academia and industry can be proud of.

DEMONSTRATING GOVERNMENT COMMITMENT TO CLINICAL RESEARCH:
Performance metrics and government investment are not currently optimized for the future

5. Prioritizing Clinical Research Within Trusts
Problem:
Currently, clinical care is given greater emphasis than clinical research, with clinical care viewed as distinct from clinical research. This outdated perspective fails to recognize the interconnectedness of clinical care and clinical research, thereby harming the competitiveness of the UK in clinical research.

Recommendation:
The government could facilitate meaningful improvement in the competitiveness of UK clinical research by taking several actions regarding the health care trusts:

- Clearly indicating to the trusts that both clinical care and clinical research are vitally important, and that clinical research activity will be used as one performance metric for assessing each trust.
- The government expects the trusts to make meaningful efforts to integrate "clinical care" and "clinical research," for example by presenting clinical trials as a care option, as appropriate.
- Encouraging the trusts to "pre-consent" individual patients about their willingness to be considered for appropriate clinical research projects upon intake to a trust facility.

Making clinical research a clear priority for the trusts will help increase public awareness and advance the UK's global competitiveness.

6. Supporting High-throughput Clinical Research Centres in NHS Trusts
Problem:
The absence of dedicated clinical research infrastructure to demonstrate, communicate, and showcase the UK's commitment to research.

Recommendation:
ACRO and other stakeholders have met recently with the leadership of the NIHR and from several of the NHS trusts to discuss the development of "high throughput clinical research centres." This would provide facilities dedicated to research (both commercial and academic), staffed with highly skilled personnel. The creation of such research centres within NHS trusts will require a modest investment in infrastructure. We urge the government to make this investment as we are confident that such high throughput centres will attract significant commercially-funded clinical trials research. Such centres will make the UK a more attractive location to do research and create a ripple effect of investment.

ACRO believes that the UK has an opportunity to rethink and energise clinical research. By evolving its policies around ethics review, contracting, patient engagement, data access and the prioritization of research, the UK can drive innovation, build trust and boost competitiveness. Our proposals outline changes that would advance the healthcare landscape in the UK.

Thank you for meeting with the stakeholders of ACRO and St. Bartholomew's Hospital on 24 October. We look forward to the opportunity to continue this dialogue and serve as an expert resource.

Yours sincerely,

Douglas Peddicord
Executive Director, ACRO

Karen Noonan
Vice President Global Regulatory Policy, ACRO

On Behalf of ACRO Members

About ACRO

ACRO represents the world's leading clinical research organizations. Our member companies provide a wide range of specialised services across the entire spectrum of development for new drugs, biologics and medical devices from discovery, pre-clinical, proof of concept and first-in-human studies through post-approval and pharmacovigilance research. With more than 13,000 employees engaged in research activities in the United Kingdom (and 57,000 in Europe and 130,000 around the world), ACRO members advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 7,000 clinical trials involving 1.3 million research participants in over 100 countries, including over 1,300 clinical trials conducted in the UK.