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ALERT

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Driving the UK's Life Sciences Vision: Government Responds to Proposed Clinical Trials Regulatory Framework

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On 21 March 2023, the UK Government or the "Government" published its response[1] to the reforms of the UK clinical trials legislation proposed by the Medicines and Healthcare products Regulatory Agency ("MHRA") and Health Research Authority ("HRA"). The response comes in the follow-up to a consultation on these reforms in the spring of 2022. The proposed reforms have been the subject of public consultation.

UK Government policy

- It is recognised by the UK Government that clinical trials constitute an important research and development process of safely bringing pioneering new treatments directly to patients and are a key step to health care innovation.
- The United Kingdom's position in the global clinical trial landscape has shifted as other countries recover their delivery performance post-pandemic, providing attractive alternatives in what is a highly competitive field.
- The UK Government is keen to capitalise on the post-Brexit opportunity to strengthen and improve the regulatory environment whilst minimising regulatory burdens on clinical trial sponsors.
- In line with the UK Government's Life Sciences Vision, the proposals themselves are geared towards securing the United Kingdom's status as an attractive place for multi-country clinical trials. The general trajectory of reducing administrative strain can be seen in the proposals and, in particular, in the agreed reforms of streamlining the regulatory process and safety reporting. Respondents, including UK trade bodies such as the Association of the British Pharmaceutical Industry ("ABPI"), were, staunch in their support for increased transparency for the clinical trial process.

The UK Government is in alignment on the following key points relating to the legislative reforms.

Streamlining the regulatory process

- The current regulatory landscape for clinical trials in the United Kingdom is complex. This can lead to delays and inefficiencies as well as confusion for trial sponsors and participants. To address these issues, the Government has proposed streamlining the regulatory process.
- The Government has agreed to simplifying the process for a decision on approval for a clinical trial by reducing the time frame for issuing the approval and thus allowing clinical trials to begin sooner. For example, there will be a maximum time frame for 30 days for an initial decision and a maximum time frame of 10 days for a final decision to be made. Respondents in the initial consultation were broadly on board, with 66.9% of them in favour of the proposal.
- The Government has also agreed with the 66.5% of respondents who wanted a combined MHRA and ethics final decision on a trial application to be made within a maximum period of 10 days following the receipt of a Request for Further Information ("RFI") response. The UK Government notes that this time frame has already been successfully piloted in the past.

[1] The UK Government's response to consultation on legislative proposals for clinical trials can be found at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1144407/Clinical_Trials_Final_government_response_to_consultation.pdf. Last accessed 22 March 2023.

Ensuring patient safety

- One of the key priorities for the UK Government in reforming the regulatory framework for clinical trials is to ensure the safety and well-being of trial participants whilst also "reducing the administrative burden". This has entailed cutting down the adverse event reporting obligations.
- For example, the Government will remove the requirement:
    - to report individual Serious Unexpected Suspected Adverse Reactions ("SUSARs") to all investigators and research ethics committees because there are other ways both investigators and RECs can receive this information. This is in spite of the fact that the plurality of respondents in the initial consultation (46.2%) disagreed with the removal of such an obligation; and
    - to report SUSARs to Research Ethics Committees whilst maintaining the need for safety reporting to the MHRA because the Agency has the statutory responsibility for safety monitoring of clinical trials. SUSARs will be reported in an aggregate manner to assess the causality of some serious adverse events instead of single occurrences.

Enhancing transparency

- Transparency was a major theme in the Government's responses. Respondents to the consultation were categorically in favour of improved transparency in the trial results. For example, respondents were almost entirely in agreement with implementing a requirement to register trials (96.7% of them agreed), and the Government has agreed to adopt this requirement. To this end, it will be required that trials be registered with a World Health Organization-compliant public register.
- Similarly, in line with the existing EU requirement, there will be a legislative requirement to publish a summary of trial results within 12 months of the trial's completion. Moreover, there is a requirement to offer trial findings in a suitable format with participants or otherwise explain why this is not possible. This proposal received overwhelming support from the respondents with over 90% of them in support.

What comes next?

- The Government is expected to introduce legislation carrying these reforms in May of 2023.
- The MHRA and HRA will develop guidance documents to implement this new legislation when passed by the UK legislature.
- The legislative proposal will serve as a basis for and align with other UK initiatives to guarantee the cohesiveness of the UK life sciences ecosystem with the objectives detailed within the Life Sciences Vision, specifically with regard to the Future of Clinical Research Delivery, to maximise the potential to accelerate implementing innovations that are of particular significance to patients and the National Health Service such as the following:
    - the Clinical Research Recovery, Resilience, and Growth ("RRG") Programme,
    - an independent review of clinical research presided over by Lord O'Shaughnessy, and
    - the scrutinisation of a pro-innovation regulation spearheaded by Sir Patrick Vallance, the UK Government's Chief Scientist.

This alert was authored by Lincoln Tsang and Azim Rahman, a trainee solicitor, in the European Life Sciences Practice.