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UK Aims To Quadruple Patient Recruitment To Industry Clinical Trials By 2027

by Vibha Sharma

The UK government has set aside dedicated funds to deliver ambitious changes that would make it quicker and easier for companies to trial more of their products in the National Health Service.

The UK government has *conveyed* its seriousness about reversing the evident decline in commercial clinical trial activity in the country by promising "decisive action" on all 27 recommendations from an independent review on this topic.

A budget of £121m ($150m) has been set aside over three years to deliver five key commitments on a priority basis that will make approving and setting up trials quicker, make it easier for people to find trials and to contact patients who could benefit from ground-breaking treatments, and create exemplars for delivering trials in key areas, such as cancer and infectious disease, to improve the delivery of all trials.

The need for these and other changes was identified by former health minister Lord James O'Shaughnessy in his report *published* on 26 May after he reviewed the state of commercial clinical trials in the UK.

Key Takeaways

- Acting swiftly on recommendations from an independent review into how to improve the current state of commercial clinical trials in the UK, the government has pledged five new funding commitments totalling £121m.
- The changes will reduce the time taken to approve and set up commercial trials, make it easier for people to find trials and to contact potential participants, and create exemplars for delivering trials in key areas, such as cancer and infectious

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After extensive engagement with pharmaceutical companies, academic institutions, and patient groups, O'Shaughnessy concluded that "we can do so much better than we currently are" and made 27 recommendations focused around eight critical themes, which ranged from slow and bureaucratic clinical trial set-up and approval processes to the UK's over-reliance on hospitals for delivering trials.

The government published its response to the review on the same day and, as an immediate first step, made five headline commitments to improve the speed of commercial trials in the UK. An update on the implementation of these commitments will be published in the autumn along with details of how the government intends to respond to the remaining recommendations.

disease.

- The government will offer an implementation update on these commitments in autumn 2023 and also respond to the remaining recommendations in the O'Shaughnessy review.
- Stakeholders have welcomed the government's response and are keeping a close eye on how these reforms will be delivered in practice.

The clinical trial reforms guided by the O'Shaughnessy review form part of the government's £650m "Life Sci for Growth" package to bolster the life sciences sector. Under this initiative, money is also being made available to boost scientific innovation in preparation for future health emergencies, increase the capacity of the UK's biological data bank, and incentivize pension schemes to invest in the most promising science and tech firms. (Also see "*UK In Major Move To Boost Commercial Clinical Trials & Improve Life Sciences Environment*" - Pink Sheet, 26 May, 2023.)

'Refreshingly Clear'

The O'Shaughnessy review was ordered earlier this year following an outcry from the UK pharma industry association and critical comments from the CEOs of two big pharma companies, AstraZeneca and GSK, about the country's worsening research climate. (Also see "*UK Launches Inquiry Into Its Clinical Trials Problems After Pharma Outcry*" - Pink Sheet, 22 Feb, 2023.)

Oliver Buckley-Mellor of the Association of the British Pharmaceutical Industry (ABPI) said the O'Shaughnessy review was "refreshingly clear" in its ambitions, with all recommendations being focused on the sole target of quadrupling patient recruitment to industry trials by 2027.

"By my estimates, the UK would need to go from recruiting 28,000 people a year to just over 100,000 within 4 years to meet this target," noted Buckley-Mellor, who is research policy manager at the ABPI.

Given that patient recruitment to industry trials has fallen by 44% since 2017, Buckley-Mellor said realizing this ambition "will be tricky, but it's well worth it," as increasing the UK's share of global recruitment would generate additional income for the National Health Service. (Also see "*Industry Calls For Urgent Action As UK Drops In Global Ranking For Clinical Trials*" - Pink Sheet, 20 Oct, 2022.)

The government is presently focusing on five key priorities to deliver this goal and has committed the following sums to do so:

- £3m to the Health Research Authority (which oversees research ethics committees) to support ongoing work to speed up the approval of commercial trials, with the goal of approving all clinical trials within 60 days. This is on top of £10m recently announced for the UK medicines regulator, the MHRA, to develop an agile approval process for cutting-edge medicines. The MHRA has already established a "task and finish" group with industry trade associations to reduce the backlog of delayed applications and has committed to making regulatory decisions within statutory timeframes, working towards all new fully compliant clinical trial applications being received from 1 September 2023.

- £81m to improve the transparency and accessibility of clinical trial data by providing "real-time" information on commercial clinical activity in the UK. This is expected to make it easier for patients and the public to participate in trials and also to improve the ability of organizations with oversight for research to keep studies on track and intervene quickly if problems occur. This initiative will build on the existing "Be Part of Research" platform, an online service designed to help the public to participate in research.

- £20m to establish two or three Clinical Trial Acceleration Networks (CTANs), which will bring together several existing mechanisms to create a joined-up approach to clinical trials across the country, focusing on accelerating priority areas of research and delivering best practice.

- £15.75m to implement national contracting processes for commercial clinical trials to address delays in the set-up of studies taking place across multiple NHS organizations. This work will be led by NHS England and will result in an enhanced service being delivered from October 2023.

- Up to £1m to establish a common approach to contacting patients about research. This will involve, among other things, identifying whether legislation is needed to establish clinical research as part of direct care.

All Eyes On How Reforms Are Delivered

The government's response to the O'Shaughnessy review has been welcomed by all players active

in the UK clinical trial space, who are now interested in seeing how these reforms will be delivered in practice and at what pace.

With its "Life Sci for Growth" package, the ABPI said the government had moved closer to realizing its life sciences vision, but the delivery of these proposals and addressing acute commercial challenges remained the key to success.

The UKRD, a representative body for research in the NHS, said it was "eager to explore" how some of the new investment could be deployed to benefit delivery in the NHS by supporting the clinical trials workforce and securing and building the clinical trial capability that the NHS needs for its patients.

Medical charities like Asthma + Lung UK are particularly interested in recommendations to promote research to the public. The Association of Medical Research Charities said the proposal to update legislation to make clinical research part of direct care was "potentially an exciting way to ensure all patients can benefit from the opportunities of taking part in clinical trials."

Till Bruckner, founder of advocacy group TranspariMED, said proposal to set up a national clinical trial "directory" to provide continuously updated information on the studies being conducted in the country could be extremely useful for many stakeholders.

He noted, however, that "this government has a history of making bold announcements about improving clinical trials and then failing to deliver." Here Bruckner was referring to the government's earlier "Make It Public" strategy under which all trials were to be automatically registered by the HRA. (Also see "*UK To Up Transparency By 'Auto Registering' Trials*" - Pink Sheet, 20 Oct, 2021.)

"Currently 8% of UK clinical trials are still not being pre-registered because the government has so far failed to deliver on that simple pledge," Bruckner said, adding that "providing monthly updates on the recruitment figures for each and every UK clinical trial would be far more challenging – and far more expensive – to implement."