ACCELERATED ACCESS COLLABORATIVE (AAC) BOARD

Meeting date: 21 June 2023

Paper Title: Independent review into clinical trials in the UK

Agenda item: 5

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Paper type: For discussion

AAC Priority Area:

Research	☒	Building innovation capacity	☐
Demand signalling and horizon scanning	☐	Innovator support	☐
Uptake of proven innovation	☐	Cross-cutting (Health Inequalities, Net Zero, Life Sciences Vision)	☐
Other (statutory, governance)	☐		

Ask of the AAC Board:

To note the review and government response and to identify/ agree any specific actions for the AAC (and individual partner organisations) to take forward.

Executive summary:

In February 2023, the government commissioned an independent review to consider how to resolve key challenges in conducting commercial clinical trials in the UK and transform the UK commercial clinical trial environment. The review report and recommendations, alongside the government response, were published on 25 May 2023 and are available here.

The review sets out 27 recommendations, including both priority actions to progress in 2023 and longer-term ambitions for UK commercial clinical trials. A short summary, including the recommendations and government response is appended to this report.

Background

1. In February 2023 the Office for Life Sciences (OLS) announced that Lord James O'Shaughnessy had been appointed to conduct an independent review into the UK commercial clinical trials landscape. At the time of the announcement, it was recognised that the outcomes of the review were likely to have impacts on, and be of interest to, the AAC Board and associated partners.

2. At the AAC Board meeting in March 2023, the Board was briefly updated on the independent review process and anticipated reporting timescales. The

AAC Board agreed to receive the outcomes and recommendations of the independent review into clinical trials in the UK (once published) and consider any specific implications for the AAC.

3. The review report and recommendations, alongside the government response, were published on 25 May 2023 – details of which are available using the following link: Commercial clinical trials in the UK: the Lord O'Shaughnessy review - GOV.UK (www.gov.uk)

Considerations

4. The review sets out 27 recommendations, including both priority actions to progress in 2023 and longer-term ambitions for UK commercial clinical trials. A short summary, including the recommendations and government response is attached at Annex A.

5. The Chair of the review, Lord James O'Shaughnessy, will attend the meeting to present the review and help the Board consider any AAC specific implications.

Board members are asked to:

6. Note the review and government response and to identify/ agree any specific actions for the AAC (and individual partner organisations) to take forward.

Annex A

Commercial clinical trials in the UK: the Lord O'Shaughnessy review

Lord O'Shaughnessy's review was commissioned to offer recommendations on how commercial clinical trials can help the life sciences sector unlock health, growth and investment opportunities in the UK. Extensive engagement with industry, medical research charities, academia, the NHS, regulators and other partners in clinical research, highlighted a high degree of consensus about both the areas of success and where action is needed to further competitiveness. The review builds on the pre-existing work of delivery partners to tackle the challenges in clinical trials, including in attracting commercial trials. The 27 recommendations of the review are set out in Appendix 1.

The review focuses on 8 problem statements

1. Clinical trial set-up and approval processes in the UK are slow and bureaucratic, especially compared to other countries.
2. There is a lack of transparency and data about commercial clinical trials activity in the UK.
3. There is a lack of accountability at every level for underperformance in clinical trials.
4. Research is not systematically prioritised by or within the NHS.
5. Doctors, nurses and NHS organisations lack incentives to take part in research, especially when it is commercially funded.
6. Conversations about research are absent from many interactions between clinicians and patients. The topic has a low profile with the public, especially among disadvantaged or marginalised groups.
7. We are failing to take advantage of the NHS's considerable data assets.
8. Primary care is a negligible provider of clinical trial activity, despite the opportunities it provides for delivering population-scale trials, and there is too much reliance on hospital settings for the delivery of trials.

Government Response
Through the Government response, £121million over three years has been provided to take immediate action on five headline commitments, with reporting on progress to be made to the Life Sciences Council. A full implementation update on this progress will be published in Autumn. The five headline commitments are to:

1. Substantially reduce the time taken for approval of commercial clinical trials, with the goal of reaching a 60-day turnaround time for all approvals – backed by £3m DHSC funding over 3 years, in conjunction with the £10m to the MHRA announced at the Spring Budget.
2. Deliver a comprehensive and mandatory national approach to contracting – backed by an additional £15.75m over 3 years provided by the NIHR.
3. Provide 'real-time' data on commercial clinical activity in the UK – backed by £81m over 3 years provided by the NIHR.
4. Establish a common approach to contacting patients about research – backed by up to £1m through the NIHR Policy Research Programme.
5. Establish CTANs – backed by £20m HMG funding over 2 years.

The Government also accepts in principle the foundational actions set out by the review. The UK Clinical Research Recovery, Resilience and Growth Programme will develop SMART objectives for commercial clinical research and report these regularly to the Life Sciences Council.

Appendix 1

Lord O'Shaughnessy's Recommendations

	Recommendations
1	Develop and publish SMART (specific, measurable, achievable, relevant and time-bound) metrics for all the ambitions in the clinical research vision *Saving and Improving Lives: The Future of UK Clinical Research Delivery*, and subsequent implementation plans, with owners held to account for delivery by the Life Sciences Council.
2	The Medicines and Healthcare products Regulatory Agency (MHRA), Health Research Authority (HRA) and other system leaders should set up a rapid 'task and finish' group to produce a plan on reducing the regulatory burden of approving trials and removing delays in set-up, including with the goal of reaching a 60-day turnaround time for all approvals.
3	Additional funding should be provided by the UK government to the regulators, the MHRA and the HRA, to rebuild capacity and deliver reduced turnaround time for all approvals.
4	A comprehensive and mandatory national approach to costing and contracting should be developed and instigated, in partnership with industry.
5	The MHRA, the HRA, the NIHR and its equivalent organisations across the UK should collect, consolidate and publish national monthly returns on all the clinical trials activity that is happening in the NHS, and NHS bodies and commercial sponsors should publish numbers of patients in trials on a monthly basis.
6	Building on near real-time activity and performance generated according to the above recommendation, UK governments should create a UK phase 1 to 4 clinical trial directory – called 'clinicaltrials.gov.uk' – to create a single source of activity for patients, clinicians, researchers and potential trial sponsors.
7	DHSC, DSIT and the NHS should set stretching annual targets for increasing commercial trials in the 4 countries of the UK and carry out annual benchmarking exercises comparing performance against competitor countries. Central to this ambition should be the objective of doubling recruitment to commercial clinical trials within the next 2 years, with a further doubling by 2027.
8	A new UK-wide set of KPIs for clinical trials should be established covering all critical aspects of the approval and set-up of and recruitment to trials, an overall measure for UK performance in clinical trials, and outcome measures for the impact of commercial trials. These KPIs should apply to all bodies involved and be benchmarked against global exemplars.
9	In England, a new operating model for the NIHR CRN should be introduced to strengthen accountability and delivery.

	Recommendations
10	A statement should be made by the NHS leadership and ministers of the UK's intention for the health service to be the world's leading platform for health R&D, and annual R&D targets should be introduced for the NHS at every level.
11	The business development service in NIHR and its equivalent bodies should be set explicit performance targets to increase the number, kind and diversity of commercial trials.
12	Income generated by commercial sponsors should be explicitly directed to units and departments leading trials in NHS sites to provide direct financial incentives to take part in commercial trials.
13	The NHS should use the upcoming NHS Long Term Workforce Plan and UK Recovery, Resilience and Growth (RRG) Research Workforce Strategy to establish a Clinical Trials Career Path for training critical roles for research.
14	An ongoing public campaign should be conducted to promote research and to generate evidence on the most effective communication methods, in partnership with medical and research charities.
15	Full integration of NIHR Be Part of Research with the NHS App should be accelerated, with enhanced opportunities to take part in clinical trials added to the platform.
16	The government and the NHS should work with royal colleges and unions to integrate 'research conversations' into all NHS communications and clinical interactions.
17	Specific targets should be introduced for the new Research Delivery Network (RDN) co-ordinating centre and regional centres to expand research to multiple sites, and to increase diversity of patients recruited.
18	Agencies responsible for information governance within clinical trials should establish a common approach to contacting patients to take part in research within the current legislative framework.
19	All patients receiving genomic sequencing of any kind in the UK should be offered a standard consent for engaging in research.
20	A national participatory process should take place on patient consent to examine how to achieve greater data usage for research in a way that commands public trust. This should seek to establish a publicly supported position around the proactive contacting of patients to take part in trials that could form part of their care.
21	The NHS England Data for R&D Programme's NHS Research Secure Data Environment Network should be rolled out, including urgent publication of guidance for NHS bodies on engaging in research with industry.
22	Financial incentives should be introduced for GPs to take part in commercial trials.

	Recommendations
23	New primary care research networks should be introduced to increase the proportion of commercial trials taking place in primary care and ‘at home’ settings.
24	Regulators should produce guidance to support and promote innovative and decentralised trials.
25	The government and regulators should develop a strategy for the use of AI in clinical trial design and regulation.
26	A new ‘enhanced service’ option should be developed, through the proposed clinical trial acceleration networks (CTANs) to enable government and the NHS to develop an excellent process for every step of a trial for specific areas, both to further research in the selected fields and to prove the case and create an exemplar for improving the service for all trials in the future.
27	An action plan should be developed, to report by autumn 2023, outlining how the government and delivery partners will implement the recommendations of this review. The Life Sciences Council should provide objective accountability for the delivery of this action plan by the government and its agencies.