UK CLINICAL RESEARCH DELIVERY

A cross-sector programme

October 2025 Update

This monthly update summarises recent news, announcements, guidance, and updates on progress made to propel the aims of the UK Clinical Research Delivery (UKCRD) programme of work.

As such, this update provides examples of how organisations individually and collaboratively are achieving the collective goal of making the UK a world leader in clinical trials.

This month's update has a focus on the 150 days set-up target.

150 days study set-up target

The Study Set-Up Plan update: Progress and next steps **webinar** was held to provide an update on the completed **Study Set-Up Plan** and focus on the necessary next steps to achieve the Government's target of reducing clinical trial set-up time to 150 days or less by March 2026.

Read more about this in the latest **Policy Statement**.

The NIHR is focusing on stages 2 and 3 of the 150 day target, set out in the **Policy Statement**. The NIHR's role is to support delivery organisations and sponsors to open studies within 60 days and recruit first participants within 30 days. There are a number of NIHR workstreams to support the 150 day metric, they are:

Data completeness - Assisting delivery organisations to complete their data accurately in a timely manner, and ensuring that set-up data is presented in a satisfactory format to interpret.

Site-level offer - NIHR Regional Research Delivery Networks (RRDNs) will be working with delivery organisations in each region to plan and test offers to alleviate set-up pressure.

Study level offer - The **NIHR Industry Hub** has been set up to strengthen collaboration between the NHS and industry to enable faster study set-up, contracting, and recruitment, ensuring efficient and consistent commercial trial delivery across the UK.

Additionally:
Health Research Authority (HRA) overview of work to streamline and reform study set-up

Medicines and Healthcare products Regulatory Agency (MHRA) announced that **UK clinical trial approval times are twice as fast** following major reforms backed by new digital platforms.

Trust Level Set-Up Report

One of the deliverables of the **Study Set-Up Plan**, a UKCRD programme of work aimed at streamlining and reforming the set-up and delivery of clinical trials, is to provide an additional monthly snapshot of site-level commercial study set-up performance. The aim of this report is to take initial steps in improving the granularity of study set-up activity to support closer to real time monitoring of system performance.

You can find the latest report here: **Trust Level Set-Up Report.**

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UK Clinical Research Delivery Performance Indicators Report

The latest monthly **UK Clinical Research Delivery Performance Indicators Report** incorporates a collection of system-wide UK metrics that monitor progress towards developing a faster, more efficient and more innovative clinical research delivery system.

The indicators were developed in collaboration with the NHS, industry and medical research charities. Using data collected by the NIHR and the Medicines and Healthcare products Regulatory Agency (MHRA), the monthly report is produced by the DHSC on behalf of the UK clinical research system.**The report provides transparent updates on progress towards our goals over time.**

Below is a snapshot of the full UK Clinical Research Delivery Performance Indicators Report. **Click here to read the full report.**

UK Performance Indicator		Target	Delivery	Trend	Baseline [2]	September 2025
All [3]	Proportion of studies receiving a combined review decision within 60 days	99%	Maintain target	➖	100%	98%
C [4]	Proportion of studies open to recruitment within 60 days of HRA approval letter or equivalent process used by the Devolved Administrations	90%	November 2024	🔴	39%	8%[5]
C	Proportion of studies recruiting first participant within 30 days of sites opening to recruitment	90%	November 2024	🔴	25%	14%[5]
C	Proportion of NHS trusts in England that accept the NCVR process for late-phase studies	100%	December 2023	✅	79%	100%
All	Proportion of open studies on track, delivering to time and target	80%	June 2023	✅	80%	83%[6]
All	Recruitment to studies is maintained compared to the pre-pandemic baseline (61,000)[7, 8]	70,000 or more per month[9]	Ongoing	✅	70,000	82,268[9]
C	Recruitment to all commercial studies to be monitored in support of the ambition to double and double again from the pre-pandemic baseline of 3,200[7, 8]	Reported per month[9]	Ongoing	🔴	3,200	3,615[9]

[2] Some measures are new and therefore the baseline was established in different months.
[3] All indicates a measure that applies to all studies.
[4] 'C' indicates that it applies to commercial contract studies only.
[5] There is a latency or lag between activity and data being recorded in the central system. This means that the data for these indicators for most recent months is often incomplete and low. The data are updated retrospectively, taking six months or more for the datasets to be fully consolidated.
[6] Based on recruitment in England and England target.
[7] Average per month in England only from 2015 to 2020.
[8] Data on trial phase to be provided subsequent to implementation of digital infrastructure.
[9] Rolling average across the previous 12 months.

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News and Announcements

The following updates are from our dedicated partners from across the sector.

- The MHRA has added a summary of the key amendments for each set of regulation guidance for clinical trials to be implemented from April 2026 in their **Clinical Trials hub**.
- The HRA has published **final guidance** that sets out what will change in terms of processes, legal requirements, and expectations for clinical trials involving medicines when the updated clinical trial regulations come into force in April 2026. HRA have also updated the **UK study-wide governance review criteria on information governance**, the criteria are now easier to find, read, understand, use and navigate.
- HRA and MHRA are publishing a series of updates offering practical advice on actions that sponsors and researchers can take now to prepare for the new clinical trial regulations. The latest articles explore the **transparency to ensure trust in research** and **safety reporting processes in clinical trials**.
- The Association of the British Pharmaceutical Industry (ABPI) published the Pharmaceutical industry investment competitiveness framework report - **Creating the conditions for investment and growth**.
- The ECMC Network have developed and piloted an adapted costing approach for Early Phase (EP) and Advanced Therapy Medicinal Products (ATMP) oncology trials, designed to reflect the unique complexities of these studies. An updated **report** outlining the project and pilot findings has been published.
- HRA have shared **guidance for NHS organisations about the model Master Confidential Disclosure Agreement (mMCDA)**, this work is supporting a more efficient and streamlined single UK standardised commercial contracting process. The next big piece of work in this area is the 'site selected agreement' which you will hear referred to as 'location selected agreement'. This reflects the upcoming change to terminology in the updated Clinical Trials Regulations.
- Work is underway to develop a new **NIHR national funding model** to distribute RDN funding across England. The funding model will allocate 20% of delivery funding aligned towards achieving a reduction in study set-up times and improving study delivery.
- NIHR held a webinar on driving research delivery with data - How to supercharge your feasibility, site identification and site selection, watch the recording **here**.
- Over 650,000 people have now signed up to **Be Part of Research**. Since July, the registry has been back on the **homepage of the NHS App** - increasing visibility and making it even easier for people to register.
- Read NIHR's Life Sciences Industry Director Dr Maria Koufali's latest blog on **Transforming commercial research delivery: NIHR's pivotal role** detailing how the NIHR and Vaccine Innovation Programme (VIP) are speeding up trial delivery, simplifying the system, and making the UK the partner of choice for the life sciences industry.
- The UK VIP held a **webinar** on their trailblazing programme of work which has created a new blueprint for clinical trial delivery at pace and scale.

If you would like to submit an update to this monthly publication, please email **UKCRDprogramme@dhsc.gov.uk**.

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