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# Clinical Trial Reform in the United Kingdom


June 2025

# Clinical Trial Reform in the United Kingdom

The disruptive energy coming out of the White House has also activated UK regulators as they think about how to reform their clinical trail system. And while the topic flies under the radar compared to attention-grabbing issues like price setting and tariffs, streamlining the clinical stage can have a profound impact on company's bottom line and a region's industrial ecosystem.

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# ClinicalTrials.gov Or ISRCTN: Getting Transparency Right For UK Trials

**Vibha Sharma**

21 May 2025

**Executive Summary**

**ISRCTN's systems are being redesigned to facilitate compliance with upcoming requirements in the UK's clinical trials legislation.**

Latest data on the registration status of UK trials shows that the majority of sponsors choose to register their studies on the US-based ClinicalTrials.gov registry, rather than ISRCTN – the UK government's preferred registry.

The findings are contained in the latest annual report that the UK's Health Research Authority publishes on the registration status of UK trials. The report, published last month, covered data on all trials that received a favorable opinion from a research ethics committee in 2023.

Sponsors' continued preference for ClinicalTrials.gov over ISRCTN reflects a trend that was also observed in the previous year, even though the UK registry is said to offer several advantages to sponsors over the US platform.

While the use of either the US or the UK registry at present ensures compliance with the UK's transparency requirements, the situation may change in 2026 when the UK's new clinical trial regulations come into force, ushering in specific timelines for disclosing clinical trial results.

# ClinicalTrials.gov Or ISRCTN: Getting Transparency Right For UK Trials

### Key Takeaways

- Despite the ISRCTN being the UK government's preferred clinical trials registry, 72% of UK trials that drew a favorable opinion from a research ethics committee in 2023 were registered on the US-based ClinicalTrials.gov, continuing a trend from previous years.
- Early data from 2024 and 2025 shows growing sponsor interest in the ISRCTN, driven by a UK-focused strategy and integration with national systems.
- With new UK clinical trial regulations coming into force in 2026, the ISRCTN is being enhanced to help sponsors meet stricter results disclosure timelines.

The ISRCTN is currently being updated to help sponsors comply with the new clinical trials law,Andrew Freeman, board chair of the ISRCTN, told the Pink Sheet. "Our priority for 2025 is to develop the results posting form" as required by the new UK regulations and also the World Health Organization, he said.

Freeman said efforts were underway to ensure that a greater proportion of UK studies are registered on the ISRCTN over the next two to five years via its UK-focused strategy. In addition, a project is set to begin in early 2026 that will make UK studies registered on other registries available on ISRCTN, creating a one-stop shop.

## HRA Report

The HRA's annual report showed that the "most popular" registry used for clinical trials that received a favorable REC opinion in 2023 was ClinicalTrials.gov. In all, 72% of trials were registered onClinicalTrials.gov, 25% on ISRCTN, and 2% on both platforms. When the report was published, 1% of trials were still in the process of being registered.

This was similar to the trend in 2022, when 66% of trials were registered on ClinicalTrials.gov, 32% on ISRCTN, and 55% on other registries recognized by the World Health Organization, such as EudraCT, the EU clinical trials register. The total was over 100% as some studies were included on more than one registry in 2022.

The HRA's annual report noted that no UK trials were registered in EudraCT 2023, as listing a trial on the EU registry was no longer considered a registration by the UK authorities, which lost access to the EudraCT database following Brexit and the UK's departure from the EU.

The HRA told the Pink Sheet it expects all UK studies to be registered on a WHO-recognized public register, which includes ISRCTN and ClinicalTrials.gov. Both registries feed into "Be Part of Research," an online service run by the UK's National Institute for Health and Care Research (NIHR) and helps members of the public understand what research is, what it might mean to take part, and shows what research is underway across the UK.

## Changing Trends? More Sponsors Favoring ISRCTN

While trial registration data for 2024 and 2025 is still being processed, Freeman said there were early indications of changing trends in response to a "UK-focused strategy" agreed by the ISRCTN board in 2023.

This strategy is expected to lead to a greater proportion of UK studies being registered on the ISRCTN over a two-to-five-year time horizon, and "we are seeing evidence of that already," said Freeman. "If we directly compare Q1 of 2023 and Q1 of 2025, we have seen an 11% increase in registered studies, so more people are choosing to opt for ISRCTN now than they were two years ago," he said.

Freeman also pointed to an ongoing initiative, under which sponsors of clinical trials of investigational medicinal products (CTIMPs) and combined medicine and device studies in the UK have their trial information automatically passed on to the ISRCTN via the UK's revamped clinical trials application portal, the Integrated Research Application System (IRAS). This reduces the burden on sponsors by eliminating the need to manually register their studies elsewhere.

"In 2023, this automated process was still brand new and awareness of it amongst potential trial registrants was much lower, so fewer researchers were opting for this approach," Freeman noted.

Despite the push to make the ISRCTN the preferred registry, Freeman explained that it would not be possible to shift all UK studies to this platform. "Many industry-sponsored studies conducted with a centre in the UK are required to be posted on ClinicalTrials.gov as they come under US regulations (for example where they are conducted under a US Investigational New Drug application)," he noted.

"We would not expect these studies to be also registered on ISRCTN as this would be duplication and difficult to manage for sponsors," he clarified.

## Addressing The UK's Fragmented Trial Registration Landscape

From the sponsor's perspective, the choice of a trial registry is important for complying with local transparency regulations, while from the perspective of health authorities, it plays a key role in ensuring national oversight, data sovereignty and public accountability in clinical research.

A fragmented disclosure landscape can hinder the ability to track, compare and analyze clinical research activity at a national level, reduce transparency for patients and the public, and complicate regulatory oversight and policy development.

To address the fragmentation, Freeman said that the ISRCTN's registry board has agreed on a project under which all UK studies that are registered on registries abroad would be made available on ISRCTN. "The project to import UK studies from other registries is planned to start in early 2026," he said.

It will "create a one-stop-shop for anyone to find information about studies conducted in the UK and importantly, provides great opportunities to showcase the world leading clinical research taking place in the UK."

## Advantages Of ISRCTN And New UK Transparency Rules

The ISRCTN is expected to play a greater role in supporting transparency when the new UK clinical trials legislation comes into effect next year.

"For posting results for clinical trials of medicinal products under the new regulation, studies submitted in a timely fashion to ClinicalTrials.gov may not meet the required timelines for public disclosure – unlike the situation when submitting these studies to ISRCTN where our processes will be geared to helping sponsors meet the UK timelines," Freeman said.

He said the ISRCTN's results reporting system was currently being designed to comply with this legislation and the WHO's new requirements for results posting, to make compliance as easy as possible.

# ClinicalTrials.gov Or ISRCTN: Getting Transparency Right For UK Trials

Freeman also pointed to several advantages that the ISRCTN offers over ClinicalTrials.gov that sponsors can consider when deciding on a study register. He said that ISRCTN allows:

- Easier posting of trial results by enabling information to be directly uploaded, whereas inClinicalTrials.gov, the information has to be populated into an online form.
- Posting of plain language summaries for both trial protocols and trial results, while this is not possible with ClinicalTrials.gov. While plain language summaries of the trial protocol "can be really beneficial for encouraging the public to sign up for studies," the plain language summaries of trial results can be provided to participants and others and are an important aspect of patient engagement, said Freeman.
- Enhanced transparency for funders and sponsors through a first-of-its-kind dashboard that shows how many studies are complying with key transparency requirements.

## Barriers To ISRCTN's Adoption

"Despite being integrated with the HRA systems and offering UK-focused features," the ISRCTN has had limited uptake, noted Benedict Evans, disclosure regulations research manager at Citeline, the publisher of the Pink Sheet. Evans attributed this to potential misconceptions about the UK registry's global recognition.

As for the continued preference for ClinicalTrials.gov, Evans said this was due to its broader global visibility, no registration fees, and alignment with the requirements of the US Food and Drug Administration and International Committee of Medical Journal Editors.

Freeman, however, does not believe the ISRCTN's £250 ($335) registration fee poses a barrier to its use. He said there were costs for any registry and the funding needs to come from registration fees and/or other funding channels.

"In the US, ClinicalTrials.gov is funded by the US government and has a remit for registration of studies to meet US regulations – whether it will always be possible to register studies outside US regulations on this register for free is not something we can comment on," he said.

# HRA To Revisit Simplified Consent Provisions Under New UK Clinical Trials Law

**Vibha Sharma**

15 Apr 2025

**Executive Summary**

**Study sponsors looking for guidance on how the simplified informed consent provisions will be implemented under the new UK clinical trials legislation will have to wait longer. The Health Research Authority is looking at what safeguards are needed to address the "range of concerns" stakeholders had regarding its initial proposal.**

The Health Research Authority has gone back to the drawing board to determine how best to roll out a key element in the new UK clinical trials law, relating to simplifying the process of seeking and recording informed consent in lower-risk clinical trials.

The new clinical trials legislation is set to take full effect on 10 April 2026, following a 12-month implementation period that began on 11 April 2025, a day after the Medicines for Human Use(Clinical Trials) (Amendment) Regulations 2024 were signed into law. The changes represent the most significant overhaul of UK clinical trial regulations in 20 years.

In a copy of a draft guideline that once finalized will support the implementation of the new law and which the HRA shared online on 11 April, the authority noted that its initial proposal for the simplified consent arrangements had drawn negative feedback from stakeholders.

# HRA To Revisit Simplified Consent Provisions Under New UK Clinical Trials Law

### Key Takeaways

- The Health Research Authority is reconsidering its approach to implementing simplified informed consent provisions for lower-risk clinical trials under the new UK clinical trials legislation after stakeholders raised concerns.
- Stakeholders were worried about the HRA's proposal to allow doctors to record consent, in place of participants signing the consent form themselves.
- The new clinical trials legislation will take full effect on 10 April 2026, and the HRA is working in partnership with medicines regulator, the MHRA, to develop complementary guidelines to support the implementation of the new law.

The HRA, which is responsible for overseeing research ethics committees in the UK, had last year suggested that the new legal provision for simplifying the consent process for lower-risk trials could be implemented by allowing doctors to record consent in a participant's medical records, rather tha by requiring the trial participants to fill out and sign the consent form themselves.

The HRA had launched a survey in November 2024 to gather feedback on the suitability of its proposed simplified approach for low-risk trials. Such trials involve authorized medicines that pose minimal burden and risk for participants.

The survey drew nearly 1,000 responses, with 55% of the respondents saying they would not support a doctor recording their consent to participate in a lower risk clinical trial in their medical record, and that they would prefer to sign a consent form themselves.

The HRA said the respondents raised a "range of concerns" about the safeguards that would have to be put in place to allow the proposed simplified approach. "We will build on this feedback and work with stakeholders to explore what safeguards we should put into future statutory guidance," the authority said in the draft guideline.

Until it finalizes guidance on how the simplified consent provision should be implemented, the HRA is asking trial sponsors to continue using its existing guidance on applying a proportionate approach to the process of seeking consent. "This guidance is in line with the provisions contained in the new legislation to reduce burden and increase flexibility whilst safeguarding participants," it noted.

### Draft Guideline

The HRA's draft guideline deals with number of aspects relating to the implementation the UK clinical trials legislation.

The authority said it was seeking feedback on the document to "ensure the final guidance is clear and easy to understand" on what stakeholders need to do. Comments on the draft guideline are being accepted until 23 April.

The guideline explains what will change in terms of processes, legal requirements and expectations to help researchers and sponsors prepare for when the regulations come into force in April next year. It deals with:

- New or updated definitions and terminology relating to clinical trials. For example, the term "trial site" is replaced with "trial location," and it refers to a hospital, health center, surgery or other establishment, or facility or premises at or from which a clinical trial, or any part of such a trial, is conducted.

- Transparency requirements covering trial registration, publishing of summary results,

and sharing of summary results in lay language with participants. It also explains provisions for deferrals and waivers from these requirements.

- The process for approving clinical trials via the combined process for regulatory and ethical reviews, as well as post-approval changes.
- Provisions relating to research ethics committees (REC), including their constitution and quorum for full REC meetings.
- Safety reporting requirements for clinical trials of investigational medicinal products.

While the HRA's guideline focuses on aspects relating to research ethics and transparency, the UK medicines regulator, the MHRA, is also preparing supporting guidelines to support the implementation of the new trial legislation. Both agencies said they had collaborated throughout the process to ensure that both pieces of guidance are consistent and clear.

# UK Mandates Unmodified Standardized Contracts To Speed Clinical Trial Set-Up

**Vibha Sharma**

30 Apr 2025

**Executive Summary**

**The policy expectation that the model clinical trial agreements are used without modification is in line requests from industry and the NHS/HSC.**

As part of ongoing efforts to help streamline and reform clinical research set-up in the UK, the Health Research Authority (HRA) has made changes to how certain "model agreement" templates should be used for running commercially-sponsored clinical trials in National Health Service/Health and Social Care (HSC) organizations.

Companies are being asked to use the newly-developed model commercial chief investigator agreement (mCCIA), and two existing model confidential disclosure agreements (model CDA template (mCDA) and the model master CDA template (mMCDA)) "without modifications across the UK" as of 28 April.

"It is now a policy expectation in England, Wales, Scotland and Northern Ireland that these model agreements are used without modification," the HRA explained.

The policy change is in response to the work being done under the cross-sector UK Clinical Research Delivery (UKCRD) program that is responsible for, among other things, developing

# UK Mandates Unmodified Standardized Contracts To Speed Clinical Trial Set-Up

**Key Takeaways**

- The UK is taking steps to streamline the process of setting up commercially-sponsored clinical trials in National Health Service/Health and Social Care organizations.
- From 28 April, it is a policy expectation that the newly-developed model commercial chief investigator agreement (mCCIA) and the existing model confidential disclosure agreements (mCDA and mMCDA) are used without modification.
- Their unmodified use will help streamline the process of contracting, freeing resource and speeding up the overall study set-up process.

and mandating an efficient and streamlined single UK standardized commercial contracting process to reduce unnecessary negotiation.

"Our expectation that they are used without modification is in keeping with requests from industry and the NHS," said Alastair Nicholson, HRA's head of co-ordination and standardization.

Their unmodified use will help streamline the process of contracting, freeing resources and speeding up the overall study set-up process. "It will also ensure that the contracts in use across health and social care research are equitable and robust," Nicholson told the Pink Sheet.

The changes are driven by the government's ambitious goal to slash clinical trial set-up times, aiming to bring the average down to 150 days by March 2026, compared to over 250 days as per data collected in 2022.

"Government is undertaking a programme of work to deliver on this ambition. The use of model contracts without modification at local NHS sites is an important step towards reducing unnecessary and duplicative contract negotiation," noted Janet Valentine, executive director of innovation and research policy at the Association of the British Pharmaceutical Industry.

"This advance is welcome and should contribute to faster trial set-up times," Valentine told the Pink Sheet.

## Chief Investigator Agreement

The mCCIA is new template for use between commercial sponsors and NHS/HSC organizations whose substantive or honorary employee will act, in their NHS/HSC capacity, as chief investigator (CI) for a commercial contract clinical trial of an investigational medicinal product (CTIMP).

The HRA had consulted on a draft version of the mCCIA in November 2024. Based on stakeholder feedback, it has updated the final template by standardizing certain areas of the agreement, addressing concerns raised by stakeholders and making the agreement easier to understand and use.

The authority said it was working on a contract research organization (CRO) version of this agreement, following a demand for it from stakeholders. "Until then, if sponsors and CROs prefer to use an agreement to include the CRO as a party to the agreement, they should use the mCCIA as the template and modify it accordingly," it said.

The HRA is also considering developing chief investigator agreement templates for other study types. It is also working on updating the model commercial site agreements, which are expected to be published in May.

# UK Mandates Unmodified Standardized Contracts To Speed Clinical Trial Set-Up

### Confidential Disclosure Agreements

Model confidential disclosure agreements (also called non-disclosure agreements or NDAs) are often used in commercial contract research to govern the sharing of confidential information from the commercial sponsor to the prospective participating NHS or HSC organizations prior to the site agreement.

The study specific mCDA, the mMCDA and their associated guidance were developed in April 2024 to help make the early sharing of information, for feasibility and site set-up purposes, clearer, more consistent, and efficient.

The policy expectation regarding their unmodified use did not apply before, but it does now. From 28 April 2025, the four UK governments expect that sponsors of commercial contract research wishing to enter into a CDA with a prospective NHS or HSC research site, will do so using an unmodified mCDA or mMCDA only.

# UK MHRA's Clinical Trial Lead On Combined Reviews, The Notification Scheme & Increasing Diversity

**Eliza Slawther**
20 May 2025

**Executive Summary**

**In light of the UK's MHRA announcing a major overhaul of its clinical trial legislation, the agency's deputy director for clinical investigations and trials, Andrea Manfrin, tells the Pink Sheet what sponsors can expect from the new regulation.**

The UK is overhauling its clinical trial framework in a bid to attract research by being "more risk-proportionate and streamlined," which will include the introduction of a 'combined review' and a new notification scheme, the MHRA's deputy director for clinical investigations and trials Andrea Manfrin has said.

"The new clinical trials framework represents the biggest overhaul of the UK regulations in over 20 years," Manfrin told the Pink Sheet, explaining that the agency hoped to cut duplication and "unnecessary delays," in addition to improving transparency.

The UK's new clinical trials legislation is set to take full effect on 10 April 2026, following a year-long implementation period. Some of the changes announced so far include plans to simplify the process of seeking informed consent in lower-risk trials, a push to increase diversity in trial participants and a combined review system that lets researchers apply for ethics and regulatory approval in one go.

# UK MHRA's Clinical Trial Lead On Combined Reviews, The Notification Scheme & Increasing Diversity

### Key Takeaways

- The MHRA's deputy director for clinical investigations and trials Andrea Manfrin explains what sponsors can expect from the new clinical trial legislation, which were signed into law last month and will apply next year.
- The framework will see the MHRA's notification scheme, under which certain lower-risk trial approvals will occur within 14 days, embedded into law and expanded.
- The MHRA is working with industry on many issues related to clinical trials and has launched a consultation on the use of real-world data in external control arms.
- The agency is also planning to launch its Clinical Trial Lifecycle Package later this year after working with industry to "crystalize the project's structure," Manfrin said.

"The reforms will see our notification scheme embedded into law," Manfrin said, adding that this process "aims to streamline application assessments and integrate a risk-proportionate approach into new working practices."

He said that the use of the new notification scheme has already reduced the time it takes for the MHRA to process new applications by more than 50% for those that meet the eligibility criteria, listed on the agency's website.

The notification scheme is for clinical trial authorization (CTA) applications for Phase IV and certain Phase III clinical trials deemed to be of lower risk. Applications processed under this scheme can benefit from a 14-day approval, much shorter than the 30-day statutory timeline, if inclusion criteria are met.

"The new clinical trials regulations will expand the notification scheme even further, allowing the clinical trials unit to support new initiatives, such as life sciences innovation and upstream advice," Manfrin said.

A pilot of the notification scheme is set to begin in autumn, which will "allow the MHRA and sponsors to start testing the introduction of one extremely important element of the new regulations in a controlled way, allowing all stakeholders willing to take advantage of this opportunity to road-test this novel approach," he said.

Meanwhile the combined review process, which involved the MHRA working with the Health Research Authority, is already seeing approvals take place in 40 days, 20 days quicker than the 60-day timeline, according to Manfrin.

He said that sponsors can expect implementation guidance from the MHRA and HRA, which is responsible for overseeing research ethics committees in the UK, in the coming months.

This will include guidance on "everything from submitting and modifying trials to ending them," Manfrin explained, adding that the MHRA also wants to support companies looking to set up a trial in the UK under the new regulations.

Another change introduced by the agency is the applied evidence-based regulatory science (AEBRS), which Manfrin said "aims to introduce a system based on peer-reviewed papers that support regulatory activities, inform policy and practice, and shape the future of research."

### Industry Engagement

The new framework will not include a systemic mechanism for companies to provide feedback to the MHRA, but the agency will "continue to engage regularly with key stakeholders," he stated.

"Stakeholder feedback is really important, which is why some of our key guidance has already been out for consultation," he said, adding that this included the MHRA's diversity and inclusion guidance,developed in conjunction with the HRA.

The agency has also launched a six-week consultation on the use of real-world data in external control arms of clinical trials. The consultation opened on 20 May, which the agency noted is the international clinical trials recognition day.

"We will also be keeping a close eye on the clinical trials landscape, including the split between commercial and non-commercial trials, and how our reforms – particularly the notification scheme – is supporting that," Manfrin said in relation to the MHRA's monitoring of how the reforms are impacting its clinical trial ecosystem.

Meanwhile, the agency plans to start the Clinical Trial Lifecycle Package (CTLP), which will offer sponsors enhanced support across the entire lifecycle of the trial, from Phases I to III and IV, towards the end of this year.

The agency will be organizing a workshop with stakeholders to "crystallize the project's structure" ahead of its launch, Manfrin explained.

The CTLP was announced in May 2024, but it has yet to begin. The package will see sponsors offered scientific advice in parallel to running their trial to help expedite the trial process.

## Tackling Challenges

Manfrin said that there are "always going to be challenges" when undertaking such significant reform, and that the MHRA was looking to address these in partnership with stakeholders using an evidence-based approach.

"One challenge, for example, has been setting the criteria for the notification scheme and making sure that this criteria is clear to sponsors," he said.

"Ways in which we have addressed this challenge include involving key stakeholders from industry and academia in the review of the criteria and developing the pilot testing scheme," Manfrin added,noting that the agency had "also kept the criteria for the notification of trials under close review, and have made changes to it when there has been evidence to support the need for this."

"Furthermore, our analysis of the 4,616 clinical trials initial submissions published in April 2025 informed the development of the notification criteria for the new clinical trials regulations," he said.

The MHRA analysis of all clinical trials submitted in the UK between 2019 and 2023 found that the country excels in cancer research but lags behind in other areas, such as heart disease and cell and gene therapies.

## Improving Diversity

Another area that the MHRA is focused on improving is diversity in clinical trials, which Manfrin described as a "priority" for the agency.

The MHRA trial analysis also revealed a notable imbalance in the proportion of male-only trials (6.1%) vs female-only trials (3.7%). Pregnant and breastfeeding women are especially under represented,featuring in just 1.1% and 0.6% of trials respectively.

"This paper is an example of AEBRS system mentioned earlier – it offers an important baseline for policy makers and other stakeholders," Manfrin said.

"We also support the future uptake of preclinical evidence using computer model simulations to enable safer participation of under represented groups, including pregnant and breastfeeding women, including through the UK Centre of Excellence on In-Silico Regulatory Science and Innovation," he added.

The UK Center of Excellence on In-Silico Regulatory Science and Innovation, led by the University of Manchester, is aimed at shaping a national strategy for the adoption of in-silico trials.

"We're working closely with sponsors, researchers, ethics committees and global regulators to promote trial designs that better reflect the populations who will ultimately use these medicines," he said.

# UK Promises To 'Turbocharge' Clinical Trials As US Tariff Threat Remains

**Andrew McConaghie**
08 Apr 2025

**Executive Summary**

**Faced with Trump's hostile tariff moves, the UK aims to speed up clinical trial start times to support its pharma sector and invest £600m in a new health data research service.**

British prime minister Sir Keir Starmer announced new measures to bolster the UK's pharma sector on 7 April, as the country moves fast to minimize the potential damage to its homegrown industries, including pharma, from US President Donald Trump's tariffs.

Starmer unveiled plans for a single National Health Service database for medical research and an ambitious goal to slash clinical trial start-up times in the UK by 100 days within a year.

While the moves extend existing policies and were clearly devised before Trump's tariff blitz, they have been welcomed by the country's life science sector, which remains wary of potential US import levies.

The policy is two-pronged. The first measure is a £600m ($766m) investment from the government and the health not-for-profit foundation, the Wellcome Trust, to create a new Health Data Research Service. This is aimed at slashing red tape for medical research by creating a secure single access point to national-level NHS datasets.

# UK Promises To 'Turbocharge' Clinical Trials As US Tariff Threat Remains

**Key Takeaways**

- The pharma sector is the UK's second biggest exporter to the US behind the automotive industry.
- The new 150 day target for clinical trial set-ups is ambitious, though there are signs the country has already achieved major timesavings.

The second measure is to speed up clinical trial set-up times, bring the average down to 150 days byMarch 2026, the government citing data from 2022 when they averaged at over 250 days. The government aims to achieve this by cutting bureaucracy and standardizing contracts at a national rather than local level.

Pharmaceuticals is the second biggest export sector to the US from the UK (behind the automotive industry which now faces a 25% tariff) and was worth £7.2bn in the 12-month period up to Q3 2024. While pharmaceuticals are currently exempt from the new import levies, the UK and other European nations with major life science sectors are concerned that Trump will follow through on a threat made earlier this year to add medicines to the tariff list.

Speaking at a visit to the Jaguar Land Rover car plant in Solihull in the West Midlands, Starmer said: "The new era of global insecurity requires a government that steps up, not stands aside," and vowed to reshape the UK economy with targeted investment and industrial strategy.

"Life sciences, like our brilliant car industry, is a great British success story. The measures I am announcing today will turbo-charge medical research and deliver better patient care. I am determined to make Britain the best place in the world to invest in medical research."

The Health Data Research Service will be launched from the end of 2026 with the goal of speeding up medical research by simplifying access to datasets such as primary care, hospital and mortality data. The government said its creation follows on from its recent decision to abolish the arm's length body, NHS England, which it said had created unnecessary bureaucracy and silos in the NHS.

The new service, backed by £100m from Wellcome and up to £500m from the government, will give approved researchers a single secure route to health data where personally identifiable information has been removed.

The service will be housed at the Wellcome Genome Campus in Cambridgeshire, where Wellcome is building a range of new R&D lab and office spaces to expand the current campus's capacity for innovative genomics and biodata companies.

## What The New Trial Target Means – And Is It Feasible?

Recent years have seen concerns about the UK's declining share of global clinical trials, with total numbers of trials and trial participants having fallen steeply since 2017.

The UK Prime Minister's newly announced targets for trial set up are understood to measure the total time taken for trial applications to be granted regulatory approval and for the first participant consenting to take part in the UK.

The influential O'Shaughnessy review of 2023 found that UK set-up times had been getting longer since 2018, when the median time was 222 days. It pointed to the success of Australia and Spain in accelerating set-up times, which in 2020 were 182 and 197 days, respectively, compared with 247 in the UK.

# UK Promises To 'Turbocharge' Clinical Trials As US Tariff Threat Remains

Janet Valentine, executive director of innovation and research policy at the UK drug industry association, the ABPI, said that it welcomed the scale and ambition of the Prime Minister's announcement, and that the new measures "were the right things to do" in order to promote the country as a world leader in clinical research.

It remains unclear how difficult hitting the 150 day goal will be. In October 2023, the National Institute for Health and Care Research announced it had shaved off 100 days using a new streamlining process called the National Contract Value Review for trials run in the NHS. This resulted in the average start-up time being reduced by 36%, though this was from a much higher 305 days to 194 days. The abolition of NHS England could be another complicating factor, however, as this will see large-scale cutbacks to national and regional health service managers.

## Concerns About Profit Clawback Most Urgent

The most urgent matter facing the UK pharma sector is a review of its pricing agreement, the Voluntary Scheme for Branded Medicines Pricing, Access, and Growth (VPAG). This year, the rebate rate reached 22.9%, far higher than the predicted 15.3%. The move caused protest, leading some companies to call the country "uninvestable". The government has now agreed to bring a review of the scheme forward a few months to June, however its tight fiscal management policy means the sector is unlikely to gain major concessions.

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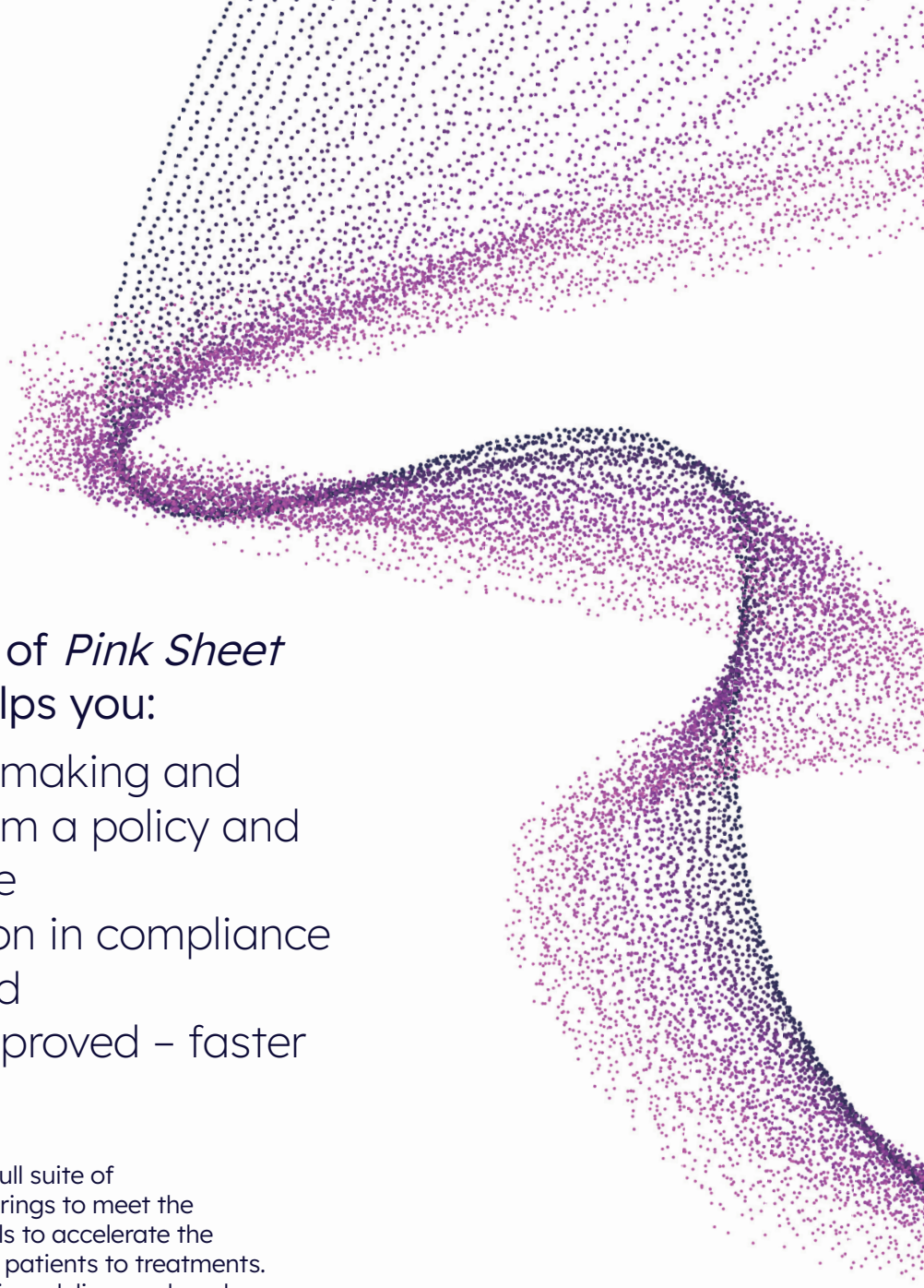

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