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Clinical Study

Oncology drug development in the UK: analysis of the past 25 years and focus on the 2026 reboot of the clinical trial regulatory framework

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OBJECTIVES: The aim of the article was to analyse the trends in oncology interventional clinical trials in the United Kingdom (UK) from 2000 to 2025, compare with major global regions, and to assess the potential impact of the New UK Clinical Trials Regulation (UK CTR) 2026 regulatory reform on the future competitiveness.
DESIGN: Retrospective observational analysis of interventional oncology trials registered on ClinicalTrials.gov with comparison across the UK, European Union (EU; comprising 27 member states), the United States, and the Republic of China (China).
MAIN OUTCOME MEASURES: Number of trials, phase distribution, funding source, and population-adjusted trial density across three time intervals (2000–2015, 2016–2020, 2021–2025).
RESULTS: The UK experienced growth in oncology trials until 2017, followed by declines associated with Brexit and the COVID-19 pandemic, and partial recovery thereafter. While the EU and USA maintained high absolute trial numbers, both showed declining population-adjusted research intensity over time. China demonstrated the fastest growth, with substantial increases in early phase trials and trial density.
CONCLUSIONS: Despite recent challenges, the UK retains strong infrastructure and expertise in oncology research; the 2026 regulatory reform may support the future attractiveness of the UK, particularly for early phase trials, although increasing global competition remains a significant issue.

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INTRODUCTION

The United Kingdom (UK) has long played an important role in the evolution of clinical research. In 1747, Dr. James Lind conducted what is widely recognised as the first controlled clinical trial, testing treatments for scurvy using a comparative design [1], helping lay early groundwork for evidence-based medicine. Two centuries later, the UK's position in clinical trial methodology was further advanced, when the Medical Research Council (MRC) conducted the first randomized controlled trial of streptomycin for pulmonary tuberculosis in 1946, introducing principles such as random allocation and blinded outcome assessment [2, 3].

This legacy has continued into the 21st century. During the COVID-19 pandemic, the UK illustrated regulatory responsiveness by becoming the first Western country to grant emergency regulatory authorisation for a COVID-19 vaccine [4, 5], with the first patient in the world to receive the Pfizer–BioNTech vaccine outside clinical trials [6]. The UK's capacity for science-driven innovation is being channelled into regulatory modernisation, as the UK enters the clinical trial regulatory reform in April 2026 [7]. In this article we aim to present the clinical trial activity in the UK from 2000 to 2025 and confront it with other geographical regions (especially in comparison with the United States of America (USA), the European Union (EU; 27 member states) and the Republic of

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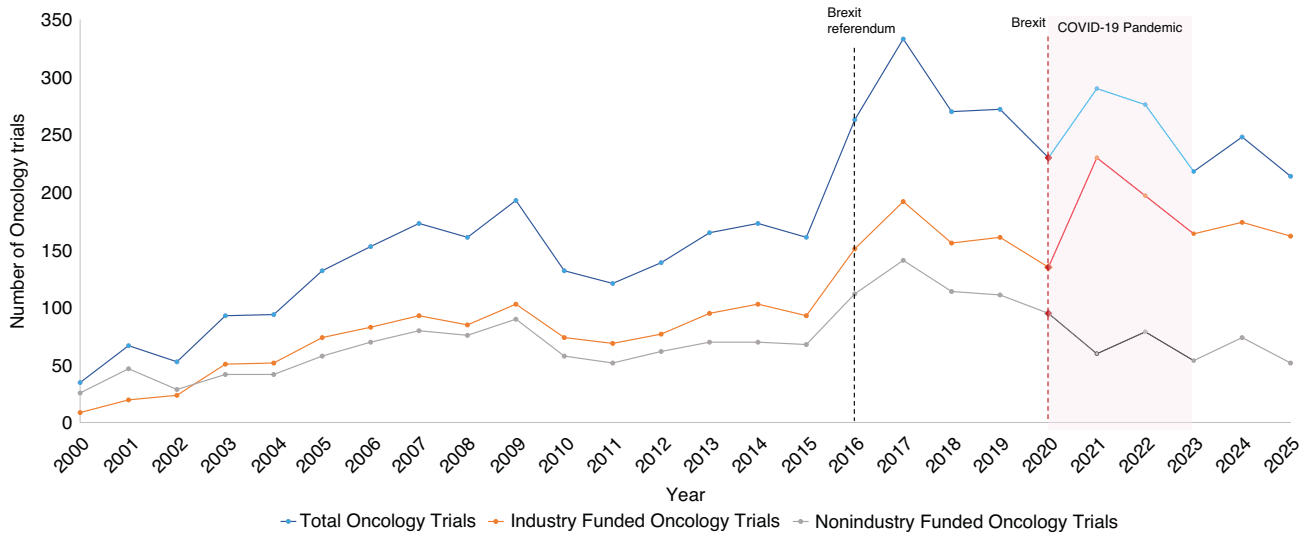

Fig. 1 Yearly initiation of UK oncology interventional trials (2000–2025), highlighting the timing of the Brexit referendum, Brexit and the COVID-19 pandemic. Data Source: ClinicalTrials.gov (search strategy described in Methods).

China (China)). Another goal of this study was to analyse the clinical research policy changes in the UK and compare it with other jurisdictions, including the USA and the EU. Moreover, we present the current advantages and disadvantages of conducting the global clinical trials in the UK in comparison to the USA and the EU. As this article presents the UK perspective, the regulatory environment in China was not discussed.

METHODOLOGY OF RESEARCH STRATEGY

To characterise oncology research activity across major global regions, we performed a structured search of ClinicalTrials.gov to identify cancer-related interventional studies that began between 1 January 2000 and 31 December 2025. This 25-year window was selected to allow examination of research trends across the first quarter of the 21st century. The search focused on studies conducted in the EU (defined as the 27 European Union member states where EU clinical trial legislation applied up to 2025), the UK, and China. As many oncology trials are conducted internationally and may include study sites across multiple regions, individual trials that met location criteria for more than one geography were included in each applicable regional dataset, allowing regional research activity to be captured comprehensively.

A broad set of oncology-related terms was applied in the Condition or Disease field, including oncology, malignancy, metastatic, tumour, carcinoma, haematologic malignancy, and solid tumour. The term ‘cancer’ and ‘sarcoma’ was also added under ‘Other Terms’ to capture studies indexed under alternate headings. Location filters ensured that only trials with at least one study site in any EU country, the UK, or China were included. We restricted the search to interventional studies and retained all participant age groups, children, adults, and older adults, to avoid excluding paediatric or geriatric oncology research. All clinical trial phases were included, from phase 1 through phase 4, as well as studies where phase was classified as ‘Not Applicable’, which could encompass device-based or procedural interventions relevant to cancer care. No limitations were placed on study sponsorship, allowing inclusion of trials funded by industry, NIH, other US federal agencies, and all other funders. Population-adjusted clinical trial density was calculated using publicly available annual population estimates, with the average population for each time interval (2000–2015, 2016–2020, and 2021–2025) defined as the arithmetic mean of yearly values within the interval. Trial density was expressed as the number of oncology trials per million population, calculated by dividing the total number of trials by the average population for each region and period, and multiplying by one million. Multinational trials were counted for each region in which at least one study site was located, reflecting regional research participation intensity rather than exclusive trial ownership.

This combination of disease terms, geographic filters, study-type restrictions, broad age eligibility, and inclusive phase and funding criteria yielded a comprehensive dataset of oncology trials conducted across the EU, the UK, the USA and China.

RESULTS AND DATA ANALYSIS

The first fifteen years of this century presented an almost steady increase in the number of cancer clinical trials being conducted in the UK (Fig. 1). All trial counts reported in this section are derived from an author-conducted structured search of ClinicalTrials.gov, performed in March 2026, using the predefined oncology-related condition terms, geographic filters, and study-type criteria described in the Methods section. A drop seen in 2008 affected both commercial and non-commercial studies. After the highest number of initiated clinical trials observed in 2017 (333 studies), a subsequent decrease till 2020 (230 studies) was observed in both commercial and non-commercial studies in the UK [8, 9]. A recovery trend in overall number of clinical trials is visible from 2020. Based on sponsor classifications in ClinicalTrials.gov, this increase was primarily driven by growth in the number of commercial studies (Fig. 1), as a decreasing trend was observed in non-commercial trials. Another drop in the number of clinical trials was observed after 2021, declining from 290 studies in 2021 to 218 studies in 2023, affecting both commercial and non-commercial studies. Again, from 2023 an increase in the number of trials can be observed; however, by the end of 2025 (214 studies), the total number of trials did not reach the highest value observed in 2017 (333 studies). This increase was largely directed due to growth in the number of non-commercial trials; the number of commercial trials after 2023 remained relatively stable.

Across the three time intervals (2000–2015, 2016–2020, and 2021–2025), marked regional differences were observed in oncology trials volume, developmental phase focus (1–4), funding patterns, and population-adjusted research intensity (Table 1). The EU consistently contributed the highest absolute number of trials across all periods (21,777, 12,521, and 12,840, respectively),

Table 1. Distribution of oncology interventional clinical trials across the UK, the EU, China, and the USA by time interval (2000–2015, 2016–2020, and 2021–2025).

		Time interval		
		2000–2015	**2016–2020**	**2021–2025**
UK	Total number of oncology trials	2523	1368	1247
	Phase 1	370	224	205
	Phase 2	978	495	381
	Phase 3	873	396	436
	Phase 4	54	15	18
	Industry funded	1621	900	927
	Non-industry funded	902	468	319
	Average population (millions)	61.7	66.2	68.5
	Oncology trials per million population	40.9	20.6	18.2
EU	Total number of oncology trials	21,777	12,521	12,840
	Phase 1	1731	1454	1318
	Phase 2	7935	4275	3653
	Phase 3	9402	4588	4995
	Phase 4	739	195	212
	Industry funded	14,613	8294	8522
	Non-industry funder	7163	4227	4318
	Average population (millions)	437.8	446.0	448.4
	Oncology trials per million population	49.7	28.1	28.6
China	Total number of oncology trials	2251	4397	8908
	Phase 1	169	801	1867
	Phase 2	809	1756	4081
	Phase 3	711	837	1214
	Phase 4	167	130	171
	Industry funded	632	1407	2937
	Non-industry funded	1619	2989	5969
	Average population (millions)	1321.2	1401.1	1412.0
	Oncology trials per million population	1.7	3.1	6.3
USA	Total number of oncology trials	20,589	9563	9577
	Phase 1	5464	2608	2444
	Phase 2	10,089	3861	3553
	Phase 3	2230	814	857
	Phase 4	634	135	127
	Industry funder	5896	3034	3309
	Non-industry funder	14,693	6529	6268
	Average population (millions)	302.3	328.3	338.0
	Oncology trials per million population	68.1	29.1	28.3

Data are derived from a structured search of ClinicalTrials.gov for interventional oncology trials. Time intervals represent trial start dates grouped as 2000–2015, 2016–2020, and 2021–2025. The EU refers to the European Union comprising 27 member states. Trials were counted for each region in which at least one study site was located; multinational trials may therefore be included in more than one regional total. Population figures represent the average population for each region and time interval, calculated as the arithmetic mean of annual population estimates. Phase totals may not equal overall totals due to trials registered as 'Not Applicable' phase. Trial density is expressed as the number of oncology trials per million population. Industry and non-industry funded classifications are based on sponsor information reported in ClinicalTrials.gov.

followed by the USA (20,589, 9563, and 9577), the UK (2523, 1368, and 1247, respectively). China was characterised by the lowest number of trials registered in clinicaltrials.gov at the beginning of the century, but demonstrated the most pronounced growth over time (2251, 4397, and 8908, respectively). In the UK and EU, phase 2 and phase 3 studies accounted for the majority of trials across all intervals, indicating a sustained emphasis on mid- to late-stage development. The USA showed a disproportionately high contribution of phase 1 and phase 2 trials throughout, reflecting strong early-stage research activity. In contrast, China exhibited substantial expansion in early-phase research over time, with phase 1 and phase 2 trials increasing sharply in the most recent interval.

Commercially funded trials predominated in the UK and EU across all periods, while non-industry sponsorship accounted for the most trials in China and the USA, with increasing industry participation over time in both regions. Table 1 summarises population-adjusted oncology trial activity, expressed as trials per

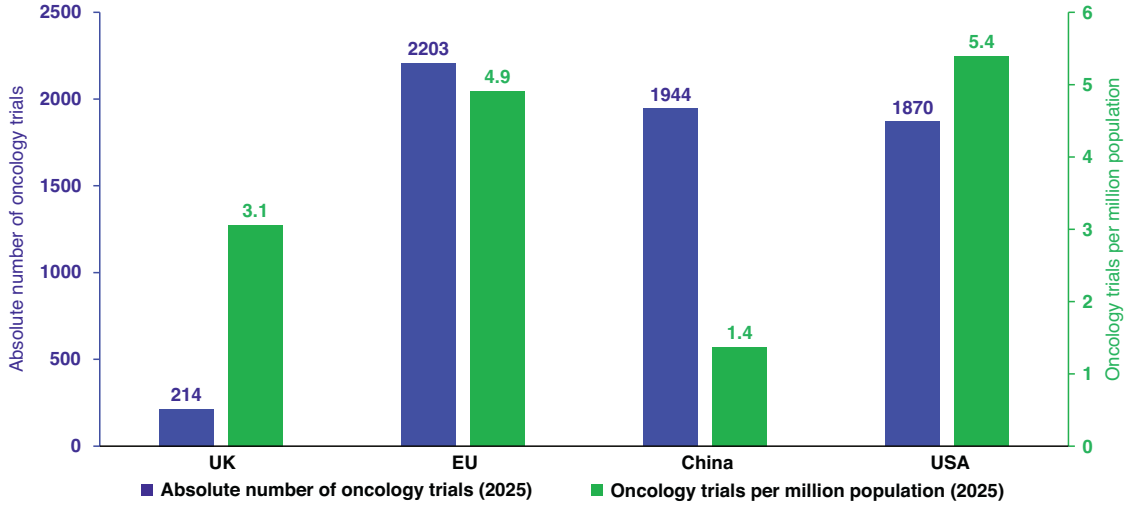

Fig. 2 Oncology trial activity across major geographic regions in 2025. Absolute trial counts (blue bars, left y-axis) and population-adjusted trial intensity (trials per million population; green bars, right y-axis).

million population, across aggregated time intervals of unequal duration; results are therefore described descriptively rather than as directly comparable annual rates. In the 2000–2015 period, trial activity per million population was highest in the USA (68.1 trials per million population) and the EU (49.7), followed by the UK (40.9), whereas China showed very low trial density (1.7). A similar geographic pattern was observed in 2016–2020, with trial density again highest in the USA (29.1) and the EU (28.1), and lower levels in the UK (20.6) and China (3.1). In the most recent interval (2021–2025), population-adjusted trial intensity continued to vary across regions, remaining highest in the EU (28.6) and the USA (28.3), followed by the UK (18.2), while China remained lower at 6.3 trials per million population.

Figure 2 presents a single-year snapshot of oncology trial activity in 2025, showing both absolute trial numbers and population-adjusted trial density across regions. In terms of absolute activity, the EU (2203 trials), China (1944), and the USA (1870) each conducted substantially more oncology trials than the UK (214). When assessed using trial density, however, the relative pattern differed. The USA recorded the highest trial density (5.4 trials per million population), followed by the EU (4.9), while the UK showed a moderate level of trial density (3.1). Despite its high absolute trial volume, China had the lowest trial density (1.4 trials per million population), illustrating the divergence between overall trial volume and population-adjusted research activity across regions.

DISCUSSION

The first fifteen years of this century presented an increase in the number of cancer clinical trials being conducted in the UK (Fig. 1), although a temporary drop was seen in 2008. This decrease has been attributed in part to the global financial crisis and affected both commercial and non-commercial studies; this issue has been discussed by other authors [10]. Later, during the years 2011–2017 a significant increase was seen in the number of clinical trials initiated in the UK. This trend was consistent with the UK being a competitive location for clinical trials and was, among others, a result of sustained investment in the UK research infrastructure [11].

Later, the decrease in trials number was observed during 2017–2020 period. This period overlapped with the time following the Brexit referendum. and preceding the UK's formal exit from the EU [8]. Regulatory changes, a reduction in application numbers, and observed longer approval timelines (with a median of 247 days from regulatory submission to first patient dosing in 2020) [9], together with potential constraints in resource allocation, may have contributed, among other factors, to the observed decline in the number of clinical trials conducted in the UK during this period [8]. Other reasons might involve attitudinal barriers to the UK as a clinical trials hub by commercial and non-commercial players. Although the real regulatory barriers were set up only in 2020, the anticipated impacts of Brexit may have contributed to reduced selection of the UK as a trial location by the clinical trials entities [12]. Additionally, there were difficulties with setting up the supply chains due to location outside the EU, and necessity of obtaining separate marketing authorisations, leading to a decline in the number of initiated clinical trials during years 2017–2020 [13]. A recovery trend in overall number of clinical trials is visible from 2020 till 2021. This increase was achieved mainly due to growth in the number of commercial studies (Fig. 1), as in non-commercial trials a decreasing trend was observed. The partial recovery observed after 2020 may reflect increased engagement by commercial sponsors alongside broader stabilisation of the UK clinical research environment [10].

Another drop in the number in the UK of newly initiated oncology trials was observed since 2021, affecting both commercial and non-commercial studies, caused by the COVID-19 pandemic (Fig. 1) [14]. Factors that may have contributed to the decreased clinical trials activity during this period included resource re-allocation to acute clinical care and to COVID-19-related studies, lower recruitment rates and the necessity of prolonging recruitment of already opened trials, operational and logistical challenges, including (but not limited to) reduced access to oncology patients, and site staff absence due to COVID-19 [15]. Elective procedures integral to clinical trials were delayed, due to reduced clinical and surgical capacity. Implementation of mitigating measures focused on additional engagement with site trials teams, online data collection, and trial protocol changes (including online visits) [14]. Moreover, the COVID-19 pandemic underscored a need for flexible, decentralized oncology trial designs to sustain operations during future global health crises [16, 17]. While temporary disruptions were observed across all trial phases in the UK, later phase studies were the first to hold recruitment during the acute crisis (due to equipoise with control arms representing standard care) [8]. The solutions implemented after COVID-19 pandemic, along with post pandemic normalization, supported the increase in the numbers of commercial clinical trials (recovery trend from 2023), however still the number of trials did not reach the peak reported in 2017 (Fig. 1). This finding is supported by

data showing the decrease in the number of patients recruited to UK commercially funded clinical trials since 2021 till 2024/25 [18]. Significant UK investment in the clinical research infrastructure, especially the UK Clinical Research Network (UK CRN), transitioning into the Research Delivery Network (RDN) in October 2024 [19] may have contributed to the recovery trend after 2020 and 2023 [19]. The main goal of RDN network is to provide the infrastructure necessary to conduct non-commercial clinical research within the National Health Service (NHS). Transitioning from CRN into RDN aimed to improve efficiency and reduce bureaucracy, ensuring better access to contemporary therapies [20]. RDN (previously CRN) has been also providing funding of clinical research, it contributed significantly to the financing of clinical research during the 2000–2025 period [21, 22].

The increasing proportion of commercially funded trials observed in the UK after 2020 (Table 1) aligns with the efforts to position the UK as a competitive destination for commercial research. In contrast, the reduction in non-industry-funded trial numbers may reflect capacity constraints within the NHS and academic sector, particularly following the COVID-19 pandemic. Importantly, this shift may not necessarily indicate reduced academic engagement but rather highlights a changing funding balance in which commercially sponsored trials may be more resilient to systemic shocks and resource competition. Evidence from the COVID-19 period suggests that trial conduct and recovery differed by sponsor type. A comparative analysis of oncology trials reported variation in the pace of recovery between industry- and publicly-sponsored studies [23], while larger cross-disciplinary evaluations indicated that trial infrastructure and sponsorship characteristics influenced trial activity during periods of disruption, with patterns that appeared to favour commercial studies [24].

The interval-based analysis in Table 1 and the 2025 snapshot in Fig. 2 show that global differences in oncology trial activity are shaped not only by absolute trial volume but also by population-adjusted trial density [25]. As larger countries and regions inherently accumulate higher numbers of trials owing to population size, patient availability, and scale effects interpretation based on raw trial counts alone can be misleading [26]. Population-adjusted trial density therefore provides a more unbiased measure of research intensity, capturing how effectively regions translate demographic capacity into clinical research activity [27]. Within this context, the UK consistently demonstrates a level of trial density that is intermediate between the highest-intensity regions (the USA and EU) and emerging large-scale research environments such as China, indicating a sustained ability to deliver oncology trials at scale relative to population size. Considered alongside absolute trial numbers, this combined perspective highlights the UK's continued relevance as a competitive potential and research-active trial environment despite its smaller population base [25, 27].

The substantial increase in oncology trial activity observed in China over time appears to be driven by a distinct set of structural factors. This growth may be associated with several factors including the regulatory reform in China in 2015 (China Food and Drug Administration (CFDA) reform), now the National Medical Products Administration (NMPA) [28], large patients' pool, lower trials costs as well as substantial increase in non-commercial investment. Oncology clinical trial activity in China has historically been characterised by a strong contribution from publicly and academically funded research, particularly through investigator-initiated studies conducted within major academic centres and national research networks [29, 30].

The methodological approach used in this analysis, whereby multinational oncology trials were counted in each region in which at least one study site was located, provides a pragmatic estimate of regional research activity rather than exclusive trial ownership. This approach is consistent with the contemporary oncology drug development, increasingly multinational in design, and allows assessment of each region's ability to attract and host clinical research infrastructure. Differences observed between regions should be interpreted as reflecting comparative research participation intensity rather than mutually exclusive trial volumes. The analysis across the three time intervals demonstrate that, despite a reduction in absolute trial numbers after 2017, the UK has maintained a relatively stable distribution of trials across development phases, with a predominance of phase 2 and phase 3 studies (Table 1). This pattern may reflect the UK's sustained engagement in oncology development. The modest decline observed in phase 1 trials number during 2020–2025 period may reflect increased global competition for early-phase studies rather than necessarily indicating a loss of domestic early-phase capability. Similar dynamics have been observed across EU countries, where changes in phase I trial activity have reflected global competition and sponsor site-selection decisions rather than definitive reductions in domestic early-phase capability [13].

ONCOLOGY - EARLY-PHASE (I, II) TRIALS VERSUS LATER PHASE TRIALS (III, IV)

Oncology trials are distinct from those in other therapeutic areas due to the fast-evolving nature of cancer biology, the increasing use of biomarker-driven stratification, and a high unmet clinical need that often justifies accelerated regulatory pathways [31, 32]. Early phase oncology trials are particularly complex, frequently involving first-in-human use of novel agents in patients (rather than healthy volunteers) who have advanced, life-limiting disease, sophisticated pharmacodynamic and biomarker endpoints, and adaptive protocol designs that evolve in real time as safety and efficacy signals emerge [33, 34]. In contrast, late phase oncology trials are typically large, multicentre, and more often international in scope, requiring rapid site activation, harmonised operational protocols across jurisdictions, and long-term follow-up to capture survival and other delayed efficacy endpoints [35]. These various scientific and logistical demands make early and late phases oncology trials especially sensitive to regulatory delays and systemic inefficiencies, including complex ethics approvals, delays in investigational medicinal product (IMP) logistics, and inconsistencies in site activation timelines. This underlines the need for a streamlined and transparent trial environment with interoperable processes and data systems across jurisdictions.

THE NEW UK CLINICAL TRIALS REGULATION IMPLICATIONS AND OTHER INITIATIVES

Since leaving the EU on 31 January 2020, the UK legal regulations have been based upon the EU Clinical Trials Directive (2001/20/EC) (the EU CTD) [36]. To improve the submission process, Medicines and Healthcare Products Regulatory Agency (MHRA) has implemented a new national portal for electronic clinical trial submissions, initiated on 1 January 2022 (Integrated Research Application System, "IRAS") [37]. The update included a combined review (regulatory and ethics), available for new Clinical Trials of Investigational Medicinal Products (CTIMPs). The Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 called also new UK Clinical Trials Regulation (UK CTR) is becoming effective on 28 April 2026, with the details presented in Tables 2 and 3.

The UK has decided to work towards a 150-day target from submission of regulatory documents to first patient recruited (from about 250 days in 2022) [38]. Such acceleration of regulatory approvals may unintendedly cause competition between commercial (Commercial Research Delivery Centres, CRDC) and primarily non-commercial sites (RDN), affecting non-commercial work, such implication warrants monitoring (Table 4). Data published by MHRA show acceleration in the average initial

Table 2. Key regulatory features in the UK, EU, and USA in 2026

	The UK after 28 Apr 2026	The EU	The USA
Applicable law	Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024 (the new UK CTR) [86]	EU CTR; Regulation EU No 536/2014 (the EU CTR) [36]	Investigational New Drug (IND) Application Federal Register collected in the Code Of Federal Regulations (CFR) [87]
Submission process	Electronically	Electronically [56]	Electronically or in paper; commercial INDs - electronically; research INDs – electronically or in paper
Transparency	Registration of trials in a WHO compliant registry; necessity to publish a summary of results within 1 year of completion; a summary of results provided to participants in lay format	Removal of deferral mechanism from June 2024 [88]; requirement to publish the trial results within 1 year of study completion; results should be provided to all study participants [88]	The USA regulation is FDAAA [89] registration on ClinicalTrials.gov and reporting the results in the same database [90]

IND Investigational New Drug, *FDAAA* Food and Drug Administration Amendments Act, *CTIS* Clinical Trials Information System.

clinical trial assessment timelines till 29 days in recent reporting cycles [39, 40]. However, MHRA approvals can take longer than 30 days in reality, due to the fact the new "notifiable trial' features are not applicable to unlicensed drugs. The new "notifiable trial" category involves trials which have no significant safety concerns with any of the investigational medicinal products, namely all IMPs are authorised for use in the UK, and all IMPs are used according to that authorisation. If IMPs are administered outside of the licensed indication, that use should be established practice and supported by sufficient published evidence and/or guidelines and all IMPs are unmodified [41]. These trials do not require assessment by the MHRA; however, they still require full review by the EC. The risk-proportionate approach may be advantageous for low risk studies [42], but it should be noted that majority of oncology trials do not fall into this category.

Recent efforts by the UK government and regulatory bodies, such as accelerated trial approval timelines [43], health database investments of up to £600 million [44] may support a shift towards long-term competitiveness of the UK trials industry. Table 4 summarises the authors suggestions to restore the UK as a competitive location for clinical trials internationally.

Recent initiatives led by the MHRA are aimed at reducing administrative burdens, accelerating trial approvals, and improving cross-border supply-chain efficiency [39, 45]. These include the Medicines for Human Use (Clinical Trials) Regulations, which introduce a more risk-proportionate and streamlined regulatory framework for clinical trials; the Department of Health and Social Care's Transforming the UK Clinical Research System programme, which focuses on improving study set-up times, delivery performance, and coordination across the NHS; the Medium Term Planning Framework, which aims to enhance predictability and capacity planning for clinical research delivery; and the Life Sciences Sector Plan and 10-Year Health Plan for England [46], which outline longer-term government commitments to investment, workforce development, and regulatory competitiveness in the life-sciences sector. In addition, the 2025 Spending Review included a commitment to establish a Health Data Research Service, intended to improve secure access to high-quality health data for research. Ongoing government investment in life-sciences infrastructure has further supported the modernisation of the research environment [47], consistent with recommendations identified in the Lord O'Shaughnessy review [38]. Sponsor interest may be supported by the launch of the £15.5 billion Life Sciences Investment Package in June 2023 [48]. International collaboration is supported by renewed participation in Horizon EU and reinforced by nearly £500 million in competitive EU grants [49]. All of these initiatives have potential to support improvements in the recruitment to clinical trials in the UK [50, 51].

NEW UK CLINICAL TRIALS REGULATION IMPACT ON EARLY AND LATE PHASE STUDIES

Large multicentre global Phase trials require rapid and efficient patient recruitment across multiple sites and countries, while primarily focusing on confirmatory efficacy and safety assessments [52]. While the UK offers accelerated approval timelines [51], the phase 3 trials benefits may be diluted by set up timelines in other countries. Smaller phase 1 and 2 trials, on the other hand, often operate with a limited number of sites within a limited geographical area. For these trials and their sponsors, the UK's streamlined approval processes and investments in early phase infrastructure, such as the Clinical Research Facilities (CRFs), UK Experimental Cancer Medicine Centres (ECMCs) and the RDN, may enhance its competitiveness as a clinical trial site [53] (Table 5).

Regarding IMP logistics, the UK will continue to recognise qualified person (QP) certification from approved EU/EEA countries. Sponsors must prepare for additional procedures when exporting IMPs from the UK to the EU [54]. For small companies operating solely in the UK, this may simplify logistics for phase 1 and 2 trials.

Drug safety reporting will require parallel submissions to both MHRA and EudraVigilance for trials spanning the UK and EU. While this increases workload for phase 3 trials, phase 1 and 2 studies conducted solely in the UK may not face additional burdens [55].

Adaptive and cost-effective trial designs are encouraged under the new UK CTR. Following COVID-19 pandemic, unique Complex Innovative Design (CID) trials recommendations were published; their implementation can be particularly useful in enhancing oncology trial delivery [43, 56, 57]. In summary, the new UK CTR may offer substantial benefits for phase 1 and 2 trials, particularly for small biotech companies.

THE UK'S PUBLIC INFRASTRUCTURE IN CLINICAL TRIALS

The UK trials infrastructure is supported by significant investment of public finds through the National Institute for Health and Care Research (NIHR), which amongst other benefits helps to foster collaboration between investigators based in hospitals and in general practice. The RDN and CRDCs from April 2025 are now central to commercial trial delivery across the UK. These structures enhance site identification and recruitment capabilities for both early and late phase trials, supporting faster trial startup, workforce training, and real time site performance monitoring across the UK. In 2023/24, NIHR-facilitated commercial studies recruited over 37,000 participants, with continued funding planned confirmed for 2026 [58]. Despite additional regulatory steps in other jurisdictions for multi-country phase 3 trials, the UK may remain a strategic choice due to its infrastructure and regulatory reforms.

Table 3. Key differences and changes in conducting studies in the UK in different time periods since the start of this century.

	Pre-Brexit era (before 2020)	Brexit (2020) to 27 April 2026	After 28 April 2026
Applicable law	EU Clinical Trials Directive (2001/20/EC) the EU CTD [91]	EU Clinical Trials Directive (2001/20/EC) EU CTD [7]	The New UK CTR [12]
Initial submissions for E&R	Separate submissions for E&R; the CESP and, from 31 Jan 2022, onward, the CTIS	IRAS implemented from 1 Jan 2022; combined review available for new CTIMPs applications, single E&R application and decision	Combined review, application for E&R approval at the same time
Costs of submission to E&R	Duplicating costs due to separate submissions to E&R	Duplicating costs due to separate submissions to E&R	Cost savings due to efficiency but not fees reduction; single submission to E&R
Time from study application till FPI	Median time from application till FPI - 186 days [12]	From application till FPI longer than 250 days [12]	Accelerated approvals aim to reduce the time to FPI from 250 to 150 days [92] current implementation status available [93]
Submission procedure for high and low risk trials	Same procedure for high risk and low risk trials	Simplified approval procedure for low risk phase 3 and 4 studies (combined review available for new CTIMPs from 1 Jan 2022)	"Notifiable trial" introduction - a trial using IMPs of no safety concerns, to be approved within 14 days
Process of applying for clinical trial approval/ modification/ end of a trial	Electronically/ in paper; before implementation of the EU CTR on 31 Jan 2023 applications submitted separately to each member state's E&R	Electronically, centralized procedure via MHRA gateway and combined review for new CTIMPs from 1 Jan 2022	Electronically - the notice given within the 30 days via MHRA gateway, combined review
Transparency requirements	Information on clinical trials not always transparent across the EU member states; limited transparency	Registration and reporting of trial results in public databases	Registration of clinical trials in a WHO-recognised public registry; publishing results in 1 year of the trial end; information about the study results provided to study participants
GCP compliance	Full adherence to GCP based on EU legislation	Compliance with ICH-GCP or proportionate approach; low risk CTIMPs follow only the principles of ICH-GCP, not full ICH-GCP [94]	Adherence to principal GCP requirements; for global studies, full GCP adherence required
Drug safety reporting for studies conducted in the UK and the EU	EU channel (EudraVigilance gateway)	Parallel reporting through the EudraVigilance gateway and the UK MHRA gateway	Parallel reporting through the EudraVigilance gateway and the UK MHRA gateway [95]
IMP manufacturing, assembly and logistics between UK and EU	UK as EU member, no additional procedures	For IMPs imported to UK assurance if IMPs are certified by a QP; For export of IMPs from UK to the EU, an importer, batch releaser and new QP declaration needed	Additionally, requirement that non-investigational medicinal products are manufactured in accordance with GMP and meet labelling and safety requirements
Applicable law of data protection	The EU's GDPR for clinical trials [96]	The UK-GDPR, the UK-DPAct, and the G-GDPR [97]. No adaptation required after Brexit, regardless of if studies are UK or EU-based	UK-GDPR [98] - extension of minimum retention period for TMF and study records from 5 years to 25 years

E&R Ethics and Regulatory, *IRAS* Integrated Research Application System, *CTIMPs* Clinical Trials of Investigational Medicinal Products, *CESP* Common EU Submission Portal, *CTIS* Clinical Trials Information System, *IMPs* investigational medicinal products, *RA* regulatory approval, *FPI* first patient in, *TMF* clinical trial master files, *SAE* serious adverse event, *SAR* serious adverse reaction, *MHRA* Medicines & Healthcare products Regulatory Agency, *GMP* good manufacturing practice, *EC* EU Commission, *GDPR* the EU's General Data Protection Regulation

INTERNATIONAL COMPETITION AND OPPORTUNITIES

The global clinical trials landscape has expanded over recent decades, with changes in trial sponsorship patterns and research activity [59]. More recently, this landscape has continued to evolve, with regions like China [60], the EU and the USA enhancing regulatory efficiency and research investment. The EU's harmonised Clinical Trials Regulation and the USA's historically robust public funding have contributed to their positions in oncology research [27]. There is an increasing competitiveness within EU countries to attract industry clinical trials. Spain has shown a particularly strong performance over the past decade with investment in clinical trials rising at an average annual rate of 5.7% [61]. Spain is frequently cited informally as an example of the EU country perceived by sponsors to perform well in rapid study set-up and recruitment; however, this manuscript refers to Spain illustratively rather than as a formal quantitative comparator, as systematic cross-country benchmarking was beyond the scope of this analysis. Germany is also taking steps to attract more investment in clinical trials by providing incentives for commercial terms for new medicines if at least 5% of all global clinical trial participants are enrolled at German sites [49].

Growth in global clinical trial activity over the past two decades has been driven by increasing trial complexity, rising per-trial costs, and the expanding role of biologic and precision-medicine approaches. Over the same period, the regional distribution of clinical research has shifted, with the United States maintaining a central role in clinical development, China demonstrating rapid growth in trial activity, and the EU experiencing a relative decline

Table 4. Recommendations to restore the UK clinical research competitiveness.

A. Strategic recommendations for sustained recovery	
Regulation	Continue simplifying and modernising combined review based on comments from the system users. Introducing clear regulatory guidance for sponsors and investigators based on received inquires [40, 99].
Infrastructure	Dedicated ring-fenced funding for oncology trial units in underrepresented regions. Establishing national minimum standards for digital interoperability between NHS Trusts to facilitate multicentre recruitment [100].
Workforce	Creation of a nationally funded Clinical Research Career Track for research nurses and coordinators, incentivised academic–clinical hybrid positions; creating protected research time embedded within consultant contracts [101, 102].
Global collaboration	Promote international partnerships to encourage multi-country trials in the UK, showing advantages of the UK as a competitive research destination [64, 103].
Incentives	Strengthen incentives for commercial and non-commercial sponsors to initiate trials in the UK, including supportive contracting, trial startup processes, and predictable timelines [104].
Monitoring	Create a national framework for transparent reporting of research metrics (e.g., approval times, site activation, delivery performance). Use data-driven insights to address bottlenecks; monitoring if acceleration of regulatory approvals causes delays for studies conducted in non-commercial settings [39, 82].

CTIMP Clinical Trial of Investigational Medicinal Product, *MHRA* Medicines and Healthcare products Regulatory Agency, *NIHR* National Institute for Health and Care Research, *NHS* National Health Service, *UKRI* UK Research and Innovation.

Table 5. The UK organisations conduct clinical trials glossary.

Organisation	Full name	Role
NIHR	National Institute for Health and Care Research	UK government's primary funder of clinical and applied health research; supports translational science and trial infrastructure
ECMCs	Experimental Cancer Medicine Centres	UK-wide network supporting early phase (I/II) oncology trials and translational research
CR UK	Cancer Research UK	Major independent cancer research charity funding discovery, translational, and clinical research
CRFs	Clinical Research Facilities	NHS-based units delivering early phase and experimental medicine studies
RDN	Research Delivery Network	NIHR network (est. 2024) providing infrastructure and operational support for clinical trial delivery across the NHS
MHRA	Medicines and Healthcare products Regulatory Agency	UK regulator overseeing clinical trials, medicines, and medical devices
UKCRN	UK Clinical Research Network	Former NIHR network supporting research delivery; replaced by RDN in 2024
NCRI	National Cancer Research Institute	UK partnership (2001–2023) coordinating cancer research strategy and collaboration
MRC	Medical Research Council	UKRI council funding biomedical and clinical research
NHS	National Health Service	UK public healthcare system providing clinical infrastructure and patient access for trials
CRDCs	Commercial Research Delivery Centres	NIHR-supported centres accelerating setup and delivery of industry-sponsored trials
ATTCs	Advanced Therapy Treatment Centres	Centres supporting development and delivery of advanced therapies (e.g., cell and gene therapies)
UKVN	UK Vaccine Network	Government-led network coordinating vaccine research and funding priorities
CGT	Cell and Gene Therapy Catapult	Innovation centre supporting development and commercialisation of cell and gene therapies
UK Vaccine Innovation Pathway	UK Vaccine Innovation Pathway	Framework accelerating vaccine development, evaluation, and deployment

in its global share. These changes have occurred alongside a rapid increase in the overall number of clinical trials worldwide and an escalation in development costs between 2000 and 2025, reflecting the evolving scientific, regulatory, and operational demands of drug development [25].

While the number of initiated trials did not reach the peak values from 2017 till 2025 and the number of patients recruited has continued to fall [62], it seems that, the UK needs to leverage more the scientific expertise, regulatory reforms and the healthcare infrastructure to remain competitive [43, 63].

As an opportunity, the NHS together with RDN, works alongside the UK's world-class academic infrastructure to deliver clinical trials incorporating translational research. In 2023, the MHRA introduced an international recognition framework, allowing reliance on approvals from trusted regulators like the Food and Drug Administration (FDA) and The EU Medicines Agency (EMA) [64]. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 streamlined the combined review process and established statutory timelines, reducing regulatory delays in the UK [7] (Tables 2 and 3). These efforts should contribute to

rebuilding the academic research base and expanding early phase trials [49]. A further possibility for the UK lies in differentiating from the EU and the USA clinical trials legislation, capitalising on its flexibility to convene diverse international participants, adjusting the study designs and direction of global clinical trial initiatives. All these activities may contribute to an increase in the number of early and late clinical trials and patient recruitment in the near future [12, 49, 65, 66].

Finally, the context of cancer drug development is evolving. There is a renewed interest in cancer vaccines that build on advances in vaccine technology that emerged during COVID-19 pandemic [67] and the increased number of advanced therapy medicinal products (ATMPs), innovative medicines utilising genes [68], cells [69] and tissues [70].

UK SYSTEM SUPPORT FOR ADVANCED THERAPEUTIC MEDICINAL PRODUCTS

ATMP trials pose distinct scientific, regulatory, and operational challenges, but also represent a significant potential opportunity for innovation in oncology. Key challenges include manufacturing complexity and scale-out constraints, particularly for autologous therapies; supply-chain and cold-chain logistics requiring tight coordination between manufacturing sites and clinical centres; interpatient variability inherent to cell-based products; and high per-patient production costs, which can affect commercial scalability and sponsor decision-making. In addition, ATMP development is associated with heightened regulatory and chemistry, manufacturing, and controls (CMC) requirements, justifying robust quality systems and early regulatory engagement [71]. At the same time, continued advances in manufacturing platforms, regulatory science, and clinical trial infrastructure offer opportunities to address these barriers and support broader integration of ATMPs into clinical development.

Over the past decade, UK infrastructure and regulatory initiatives have enabled steady progress in cellular and gene therapy. The achievements included integration of CAR-T and gene therapies into commissioned NHS care, or the introduction of support for ATMPs early phase clinical trials [72]. Strategic frameworks such as the Innovative Licensing and Access Pathway (ILAP) expedited MHRA review processes [73]. The government funding for networks like the RDN [74] and for the four Advanced Therapy Treatment Centres (ATTCs) [75] have streamlined approvals and trial delivery across the country. The Cell and Gene Therapy Catapult partnerships enhanced commercialisation of advanced therapies and accelerated trial start [76]. These systems may collectively reinforce the UK's position in competitive clinical research.

Beyond cellular therapies, the UK also maintains the status in vaccine research through initiatives like the UK Vaccine Network (UKVN), an expert advisory group bringing together industry, academia and relevant funding bodies to guide government investment in vaccine research [77]. The UK Vaccine Innovation Pathway has focused on translating learning from the COVID-19 pandemic into the delivery of cancer (and infectious disease) vaccine trials through fast-track innovative approaches. The NHS Cancer Vaccine Launch Pad (CVLP) platform, initially established with the pharmaceutical company BioNTech, supports accelerated access to messenger ribonucleic acid (mRNA) personalised cancer vaccine clinical trials through a "hub and spoke" with hospitals identifying potentially eligible patients who are then referred to centres running the trial.

LIMITATIONS

Despite the attempt to present the perspective of the first quarter of 21st century oncology clinical trial activity in the UK, this analysis has several limitations. We used publicly available databases, which could be incomplete or reporting to these databases could be delayed. The analysis did not capture trial quality or scale (e.g., sample size). In addition, population-adjusted trial density provides insight into regional engagement in clinical research; however, it reflects research participation rather than independent trial activity and should not be interpreted as an indicator of global leadership. Moreover, there was no comparative international benchmarking analysis and worldwide perspective. All these factors could be associated with the bias to the presented data.

RISKS ASSOCIATED WITH THE NEW CTR REGULATION

Despite all efforts performed so far, still the number of clinical trials and recruited patients in 2025 in the UK is decreasing. Restoring the positive trend is possible, but associated with the risks, including rapidly growing number of clinical trials in China. Although the majority of studies in China are publicly funded, there is a rapid growth also in commercial trials (Table 1); due to broad population, low costs and large potential market, this trend is likely to continue. Moreover, there is a significant non-commercial support for early phase clinical trials in the USA, which may result in strengthening the USA's leading position in early phase clinical research. Moreover, there is an opportunity to further leverage the new UK regulatory framework, as lack of communication to the sponsors and non-commercial players worldwide may result in further decrease in the clinical trials number in the UK. Additionally, operational delays in non-commercial studies in the UK as unintended consequence of competition with the commercial studies.

ENVIRONMENTAL SUSTAINABILITY IN CLINICAL TRIALS IN THE UK AS A COMPETITIVE ADVANTAGE

Environmental sustainability is recognised as a core component of high-quality oncology clinical research. Growing evidence for the carbon footprint of clinical trials highlighted the need for mitigation strategies, such as remote assessments and streamlined logistics to reduce the carbon emission [78]. In the UK, policy developments over the past few years have accelerated this shift, positioning greener trial design as an integral element of contemporary research practice. The NHS has committed to achieving net-zero carbon emissions, including those under its direct control by 2040 and those it can influence (e.g., supply chain) by 2045 [79]. This supports NHS and national climate goals, facilitating broader adoption of decentralized and hybrid trial elements, electronic consent, and reduced on-site visits [80].

SUMMARY

From 2000 to 2025, the UK clinical trials setting has evolved into a system that has adapted to global research demands. While transitional challenges emerged in the past decade, the UK has transformed towards a modernised, risk-proportionate, and globally applicable regulatory model [81]. Key reforms, such as the upcoming new UK CTR planned for 2026 are enabling faster trial approvals, increased regulatory predictability, and stronger industry engagement. Trial approval speed has improved, from 118.9 days in July 2023 [82] to 29 days in October 2025 [83, 84]. Clinical trials infrastructure supports both commercial and non-commercial studies. All these assets should contribute to growth of clinical trials number in the near future. However, there are some risks to be taken into account, including extensive non-commercial funding and government support for clinical trials abroad, or relying on NHS support in clinical trials when constraints on the delivery of routine clinical services are widely acknowledged [85].

DATA AVAILABILITY

The datasets generated during and analysed during the current study are available from the corresponding author on request.

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AUTHOR CONTRIBUTIONS

KSS, AM, PC-F contributed to study conception, designed the methodology, and drafted the manuscript; CT, JS, LV, RP, DM, MN, JB, GS, SD, SS; VB, CJ, KM, SC, FT, AW, GC, MG, DS, RA, SB, TRJE, interpreted the results, provided critical feedback on the manuscript, read and approved the final submission.

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COMPETING INTERESTS

PC-F, AM, LV, DM, MN, JB, SD, VB, CJ, SC, MG, and KSS are employees of Fortrea Inc. SPB is co-founder and Director of Prenostics Ltd. VB reports stock ownership interests in Fortrea Inc. TRJE has received travel expenses from Bristol-Myers Squibb, Merck Sharp & Dohme, Pierre Fabre, Eisai, Nucana, and Roche. His institution has received consulting fees and/or speaker fees/honoraria and/or research funding from Karus Therapeutics, Eisai, Bristol-Myers Squibb, Merck Sharp & Dohme, United Medical, Nucana, Roche/Genentech, Ascelia, AstraZeneca, Bicycle Therapeutics, Medivir, Seagen, CV6 Therapeutics, Ewopharma, iOnctura, Beigene, Basilea, Celgene, MiNA Therapeutics, Lilly, Merck Serono, Janssen, Johnson & Johnson, Verastem, Novartis, Iovance Biotherapeutics, Sanofi/Aventis, Clovis Oncology, Plexxikon, Sierra Pharma, GlaxoSmithKline, Halozyme, CytomX Therapeutics, Vertex, Athenex, Adaptimmune, Immunocore, Modulate Pharma, Berg, Starpharma, BiolineRx, UCB, Sapience Therapeutics, Astellas Pharma, Boehringer Ingelheim, Avacta Life Sciences, Nurix, Codiak BioSciences, T3 Pharmaceuticals, BioNTech, Moderna Therapeutics, Exelixis, Exscientia, Bayer, Amgen, Sotio, and Pfizer. His institution also received honoraria from Genmab for serving as Chair of the Independent Data Monitoring Committee for a phase 1 trial. He is also Editor-in-Chief of The British Journal of Cancer. KSS reports consulting fees from the EU Commission and stock and/or other ownership interests in Fortrea Inc. and Quantum Health Analytics (UK) Ltd, outside the submitted work. The other authors declare no competing interests.

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