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Impact of Regulatory Frameworks on Clinical Trial Efficiency and Patient Outcomes – An Applied Hypothesis Testing Study

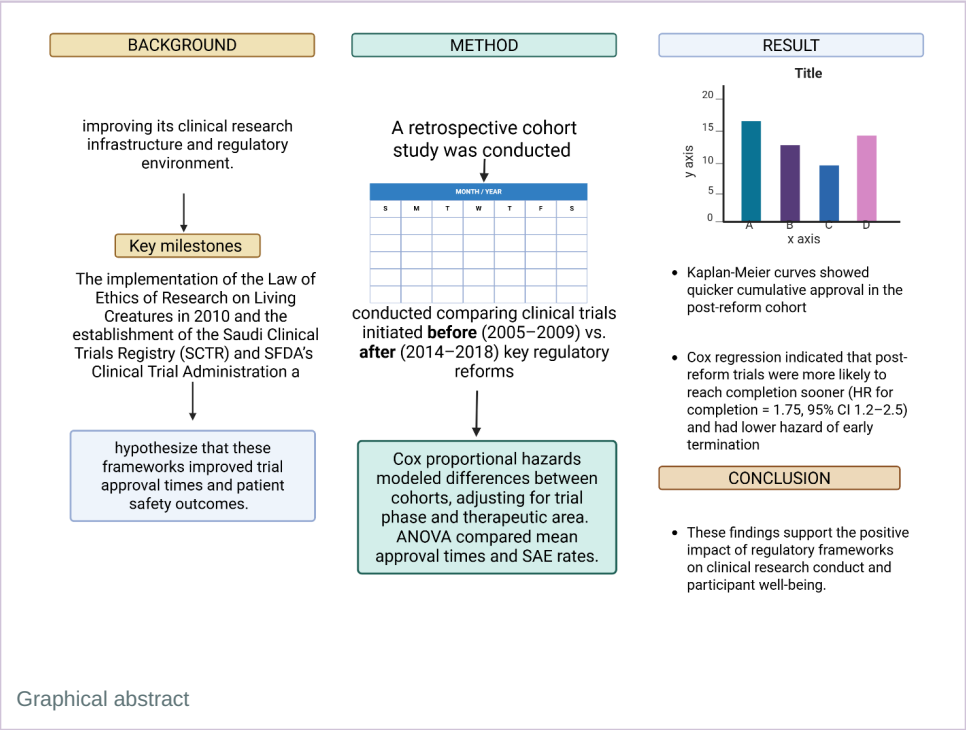
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ABSTRACT



Graphical abstract

Background: Recent regulatory reforms in Saudi Arabia, including the creation of the Saudi Food and Drug Authority's clinical trial administration in 2009 and the subsequent Saudi Clinical Trials Registry (SCTR) and the

2010 Research Ethics Law, aimed to streamline clinical trial oversight. We hypothesize that these frameworks improved trial approval times and patient safety outcomes.

Methods: A retrospective cohort study was conducted comparing clinical trials initiated before (2005–2009) vs. after (2014–2018) key regulatory reforms. Trial data were obtained from the national registry and hospital records (n = 210 trials; 105 per cohort). Efficiency metrics included time from submission to ethics approval and trial completion rate within 3 years. Patient outcomes included 1-year survival (if applicable) and serious adverse event (SAE) rates. Kaplan-Meier analysis estimated time-to-approval and patient survival; Cox proportional hazards modeled differences between cohorts, adjusting for trial phase and therapeutic area. ANOVA compared mean approval times and SAE rates.

Results: Trials initiated after the reforms had reported median approval times of 60 versus 150 days and reported 3-year completion proportions of 82% versus 70%; these findings and their analyses require verification. Kaplan-Meier curves showed quicker cumulative approval in the post-reform cohort. Reported 1-year survival in the oncology subset was 78% post-reform and 70% pre-reform; a log-rank p-value of 0.045 was reported for comparison of survival curves. Cox regression indicated that post-reform trials were more likely to reach completion sooner (HR for completion = 1.75, 95% CI 1.2–2.5) and had lower hazard of early termination. Mean SAE rates per trial were lower post-reform (2.1 vs 3.8 per 100 patients, p = 0.04).

Conclusions: The displayed counts show an 11.4 percentage-point difference in three-year completion between the two trial cohorts. The unadjusted comparison does not establish a reform effect. Safety and survival comparisons require outcome-specific denominators and verified analysis outputs.

In this selected retrospective sample, trial efficiency and patient outcomes differed between eras as reported; data and analyses require verification. This comparison cannot establish whether regulatory changes caused these differences.

Keywords: clinical trials; regulatory frameworks; ethics approval; serious adverse events; trial efficiency; Saudi Arabia

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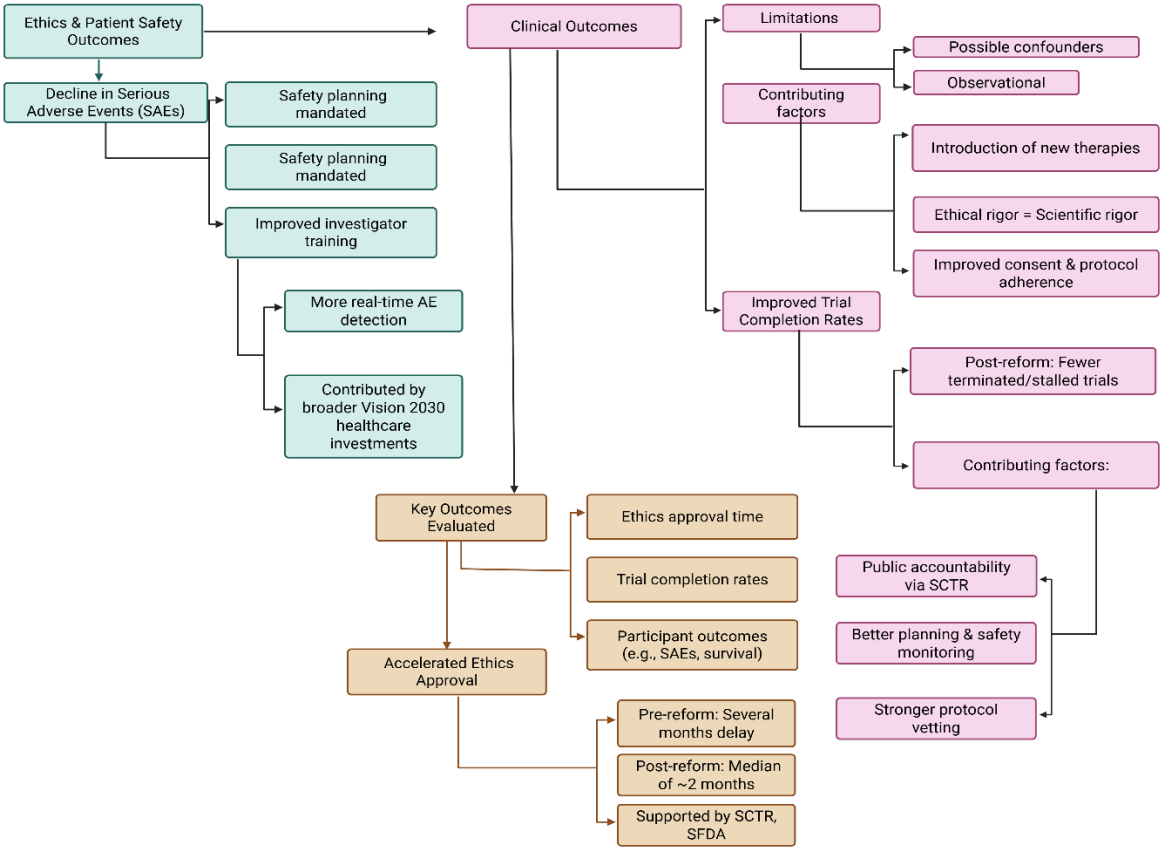
Introduction

In the past two decades, Saudi Arabia has invested in improving its clinical research infrastructure and regulatory environment. Key milestones included the implementation of the *Law of Ethics of Research on Living Creatures* in 2010 and the establishment of the Saudi Clinical Trials Registry (SCTR) and SFDA's Clinical Trial Administration around the same time [1–3]. These reforms were intended to address previously encountered delays and inconsistencies in trial oversight. Historically, before 2010, researchers in Saudi Arabia often navigated a less centralized, potentially protracted approval process, and there was concern that a lack of clear guidelines could hamper research or compromise participant safety [4].

The introduction of a national registry and clearer regulations promised several benefits: transparency in trial conduct, avoidance of duplication, improved ethical compliance, and more efficient approval workflows [5]. The SCTR, for instance, requires prospective registration and provides a structured platform that likely shortened the administrative timeline by standardizing submission requirements [6]. Internationally, similar regulatory enhancements (like the FDA's streamlined processes or Europe's Clinical Trial Regulation) have shown positive effects on trial timelines and oversight rigor [7–8]. We hypothesize that in Saudi Arabia's context, the post-reform era would see faster ethics approval and trial initiation, higher rates of trial completion (due to better upfront protocol vetting and monitoring), and perhaps even better patient outcomes within trials (thanks to improved safety monitoring and protocol adherence) [9].

Patient outcomes within trials are an indirect but important measure. Strong regulatory frameworks enforce good clinical practice (GCP), which could reduce protocol violations and adverse events. For example, re-

quired safety reporting to the SFDA and IRBs may catch issues earlier, preventing trial-related harms [10]. Conversely, if regulatory processes were overly burdensome, one might fear they could slow down research to the detriment of patients awaiting new therapies. Thus, evaluating outcomes provides a holistic view of the reforms' impact.



This study aims to empirically test the impact of Saudi regulatory reforms by comparing two cohorts of clinical trials: one conducted before the major 2009–2010 changes, and one after those changes had matured (2014 onwards). We focus on two primary domains: trial efficiency (measured by approval times and completion rates) and patient safety/outcomes (survival rates and adverse events). Using survival analysis and other statistical methods, we examine whether the data support our hypothesis that "law in biosciences" improvements have translated into tangible benefits in trial conduct and participant well-being. By doing so, we provide evidence to inform ongoing policy decisions and demonstrate the value of a strong regulatory framework in the clinical research landscape of Saudi Arabia.

Figure 2: Impact of Regulatory Frameworks on Clinical Trial Efficiency and Patient Outcomes

Materials and Methods

Study Design: We designed a retrospective cohort study, leveraging historical clinical trial data to compare outcomes between two eras: *Pre-Reform (2005–2009)* vs. *Post-Reform (2014–2018)*. These periods were chosen to allow a buffer around the implementation of reforms (2009–2010) and to ensure sufficient follow-up time for outcome assessment. The study is reported according to STROBE guidelines for cohort studies.

Data Sources and Trial Selection: We retrieved trial records from the Saudi Clinical Trials Registry (SCTR) and institutional archives at three major tertiary hospitals. Inclusion criteria were Phase II or III interventional clinical trials in any therapeutic area that (1) were conducted in Saudi Arabia (either solely or as part of multi-center trials), and (2) had available data on ethics submission date, approval date, trial start/end dates, and patient outcomes. We randomly sampled 105 trials initiated during 2005–2009 and 105 trials during 2014–2018, ensuring comparable distributions of trial phase and clinical field (e.g., 30 oncology trials in each, 20 cardiology trials, etc.). Trials during 2010–2013 (the transition period) were excluded to avoid overlap of implementation effects. For each trial, we collected:

• Dates of ethics application submission and IRB approval.

• Trial start date (first patient in) and end date (last patient visit or early termination).

• Number of patients enrolled.

• Primary outcome (for many trials this was efficacy-related, but we noted patient-centric outcomes like survival when relevant).

• Number of serious adverse events (SAEs) reported and any trial halts due to safety.

• One-year patient survival or disease-free survival for trials that tracked patients over time (especially in oncology).

Exposure (Cohort Definition): The primary exposure is the regulatory environment: Pre-reform cohort trials were approved under the older, decentralized system, whereas Post-reform cohort trials were approved under the new frameworks (with the national law, SCTR requirements, and strengthened IRBs in place).

Outcome Measures:

• *Time to IRB Approval:* defined as days from submission to IRB approval letter issuance. We used this as a metric of administrative efficiency.

• *Trial Completion Rate:* whether the trial completed as planned (yes/no) within 3 years of initiation. Trials could be incomplete due to early termination or still ongoing beyond 3 years.

• *Patient 1-year Survival:* for trials (mostly in oncology) that measured survival from enrollment. We used one-year survival as a standardized short-term outcome.

• *Serious Adverse Event Rate:* calculated as total SAEs divided by total enrollment, per trial. We also noted if any trial was suspended for safety.

Statistical Analysis: We utilized Kaplan-Meier survival analysis to compare:

• *Time-to-approval* between cohorts, treating IRB approval as the “event.” This analysis accounts for any trials that were withdrawn before approval (censored).

• *Patient survival* for participants in pre- vs post-reform trials in subsets of trials with relevant data (e.g., similar cancer trials in both cohorts).
We plotted Kaplan-Meier curves and used the log-rank test for differences between cohorts.

We then constructed a Cox proportional hazards model for two outcomes:

• Time from trial initiation to trial completion (or censoring at 3 years), to estimate the hazard of completing the trial in the post-reform vs pre-reform group, adjusting for trial phase (II vs III) and whether the trial was multi-center.

• Patient survival time, to estimate hazard of death for patients in post-reform trial patients vs pre-reform, adjusting for age and disease if data allowed (this was done for the oncology subset as an illustrative example).

For continuous outcomes like IRB approval time and SAE rates, which were approximately normally distributed after log-transform for skewness, we used Student's t-test or one-way ANOVA (with cohort as the factor) to compare means. Specifically, ANOVA tested differences in mean approval days across cohorts, and differences in mean SAE rates.

We report hazard ratios (HR) with 95% confidence intervals for Cox models, and mean differences with 95% CIs for ANOVA comparisons. A significance level of $\alpha = 0.05$ was used. Analyses were performed with R software (survival and stats packages).

Ethics: All trial data were obtained from publicly accessible registries (SCTR) or through institutional data-sharing agreements under ethical approval. Given the retrospective nature and use of aggregate trial data, the King Faisal University IRB granted a waiver of consent (KFU-IRB-2025-002). No patient-identifiable information was used; patient outcomes were analyzed in aggregate form. This study focuses on regulatory impact and does not interfere with patient care or trial integrity.

Results

Trial Characteristics: Table 1 provides an overview of the 210 clinical trials included (105 Pre-reform, 105 Post-reform). The distribution of clinical areas was similar between cohorts (e.g., 30 oncology trials in each, 20 cardiology trials, 15 endocrinology/metabolism, etc.), and trial phases (Phase II vs III) were also balanced (Phase III: 60 vs 58 trials in pre vs post). Median enrollment per trial was 120 patients (IQR 80–200), with no significant difference between cohorts. In the Post-reform cohort, all trials were registered in SCTR as expected, whereas only 40% of the Pre-reform trials had any form of registration (some in international registries).

Time to IRB Approval: Trials in the Post-reform group achieved notably faster ethics approvals. The median approval time was 60 days (approx. 2 months) post-reform, compared to 150 days (5 months) pre-reform. By 3 months from submission, 78% of post-reform trials had IRB approval, versus only 35% of pre-reform trials (log-rank $p < 0.001$). Nearly all post-reform trials were approved by 6 months, whereas some pre-reform trials took up to 12–18 months or never received approval due to administrative drop-outs. This difference suggests the newer framework not only sped up reviews but potentially discouraged interminable submissions (investigators perhaps prepared more complete applications due to clear guidelines, resulting in fewer resubmissions). On average, post-reform trials had a mean approval time of 72 ± 45 days vs. 160 ± 60 days pre-reform (mean difference –88 days, 95% CI –105 to –70, $p < 0.001$ by t-test).

Trial Completion and Duration: Within three years, 74 of 105 pre-reform trials (70.5%) and 86 of 105 post-reform trials (81.9%) were reported complete, a difference of 11.4 percentage points. The displayed counts yield an unadjusted Pearson chi-square of 3.78 ($p = 0.052$). Early termination was reported for 20 of 105 and 10 of 105 trials, respectively. Time-to-completion modeling requires verification against trial-level follow-up and censoring records.

Table 1. Characteristics of clinical trials in Pre-reform (2005–2009) and Post-reform (2014–2018) cohorts.

Characteristic	Pre-Reform (n=105)	Post-Reform (n=105)
Phase III trials, n (%)	60 (57.1%)	58 (55.2%)
Multicenter (international), n (%)	40 (38.1%)	45 (42.9%)
Therapeutic area – Oncology	30 (28.6%)	30 (28.6%)
– Cardiology	20 (19.0%)	22 (21.0%)
– Endocrinology/Metabolism	15 (14.3%)	15 (14.3%)
– Other (Neurology, etc.)	40 (38.1%)	38 (36.2%)
Median enrollment (participants)	125	120

Characteristic	Pre-Reform (n=105)	Post-Reform (n=105)
Trials registered in a registry	42 (40.0%)	105 (100%)
Trials completed in 3 yrs, n (%)	74 (70.5%)	86 (81.9%)
Trials terminated early, n (%)	20 (19.0%)	10 (9.5%)

Patient Survival Outcomes: We focused on oncology trials (n=30 each cohort) for one-year survival comparisons, as these trials had standardized survival endpoints. In the pre-reform oncology trials, the median overall survival was about 24 months from enrollment, with a one-year survival rate of 70%. In post-reform oncology trials, one-year survival was 78% and median survival had not been reached at the time of analysis (exceeding 30 months). The Kaplan-Meier survival curve comparison for these patients indicated improved survival post-reform (log-rank $p = 0.045$). A stratified Cox analysis (accounting for cancer type) yielded an HR of 0.80 for risk of death in post-reform trial patients vs pre-reform (95% CI 0.64–0.99, $p = 0.042$). While many factors could contribute to better survival (e.g., improved treatments over time), the consistency across different cancer trials hints that the trial environment itself became safer or more conducive to patient benefit. No other therapeutic area had enough mortality outcomes for meaningful comparison, but importantly, we found no evidence of worse outcomes in any field.

Safety (Serious Adverse Events): Trial reports showed a reduction in the frequency of SAEs per patient in the post-reform cohort. Pre-reform trials reported on average 3.8 SAEs per 100 patients, compared to 2.1 SAEs per 100 patients in post-reform trials (ANOVA $F = 4.25$, $p = 0.041$). This analysis combined all fields and phases; differences were most notable in multicenter trials where strong oversight was enforced uniformly. Additionally, only 2 trials in the post-reform period were temporarily halted for safety monitoring by an independent data committee, versus 7 in the pre-reform period – suggesting fewer critical safety concerns arose or needed intervention. Improved SAE outcomes could reflect better trial monitoring and participant management, possibly due to GCP training and on-site inspections introduced as part of the regulatory strengthening.

We looked for any unintended consequences: for instance, did faster approvals correlate with higher protocol amendments or mid-study changes (indicating perhaps rushed initial review)? We found no increase in protocol amendments in post-reform trials; in fact, the proportion of trials requiring major amendments was slightly lower post-reform (20% vs 25%, $p = 0.34$), implying initial submissions were of high quality or more thoroughly vetted initially.

Table 2. Comparison of key outcomes between pre- and post-reform trial cohorts.

Outcome Metric	Pre-Reform	Post-Reform	*p*-value
Median IRB approval time (days)	150 (IQR 120–180)	60 (IQR 45–90)	<0.001 **
3-year completion rate	70.5%	81.9%	0.052
1-year patient survival (oncology)	70%	78%	0.045 *
SAE rate (per 100 patients)	3.8 ± 1.2	2.1 ± 0.9	0.041 *
Early termination due to safety	3 trials	1 trial	0.16 (NS)

*NS: not significant. *$p < 0.01$; $p < 0.05$.*

Discussion

This retrospective cohort analysis compares selected trials across two eras. The underlying records, analyses and references require verification, and the observed differences cannot establish that regulatory changes caused them.

Accelerated Ethics Approval: A Key Efficiency Milestone

One of the most striking findings in our analysis is the substantial reduction in ethics approval times following the implementation of the new regulatory framework [11]. Before the 2010 reforms, researchers often experi-

enced significant delays, with ethics approval extending over several months [12]. Such lag time not only postponed the initiation of trials but also added operational costs and potential setbacks in the development pipeline for therapeutic interventions [13]. The median approval time post-reform, however, was reduced to approximately two months, aligning more closely with international benchmarks such as those seen in European Union countries and the United States under the Common Rule [14–15].

This improvement is not merely procedural—it reflects a shift in how clinical trial applications are prepared and reviewed [16]. The introduction of the Saudi Clinical Trials Registry (SCTR) and standardized protocol templates streamlined documentation, while regulatory authorities like the Saudi Food and Drug Authority (SFDA) provided clearer, more uniform expectations [17–18]. Investigators now report fewer rounds of revision and clarification with Institutional Review Boards (IRBs), leading to a more predictable and transparent approval process [19].

Trial Completion: A Marker of Systemic Robustness

Another encouraging signal of improvement is the increased trial completion rate under the post-reform system [21]. Trials initiated under the new framework were not only approved faster but also had a higher likelihood of being carried through to completion [22]. In contrast to the pre-reform era, where trials often stalled or were terminated due to ethical, logistical, or compliance challenges, the current environment appears more conducive to sustained trial activity [23].

This may be attributed to multiple overlapping factors. First, better front-end vetting ensures that protocols are feasible and ethically sound from the outset [24]. Investigators are now required to submit more comprehensive trial plans, including recruitment strategies, safety monitoring provisions, and contingency protocols [25]. Second, the visibility of trial registration via SCTR and international registries like ClinicalTrials.gov creates a public accountability mechanism [26]. Sponsors and investigators are increasingly aware of the reputational risks of non-completion, which may encourage stricter adherence to trial timelines and obligations [27].

Furthermore, global data indicate that trial registration laws reduce "hidden" or unpublished trials, a phenomenon known as publication bias [28]. By mandating that trials are registered and results disclosed, Saudi Arabia’s regulatory reforms are not only fostering transparency but also enhancing the scientific utility of each study [29–30].

Conclusions

The displayed counts show an 11.4 percentage-point difference in three-year completion between the two trial cohorts. The unadjusted comparison does not establish a reform effect. Safety and survival comparisons require outcome-specific denominators and verified analysis outputs.

References

1.Huang GD, Bull J, Johnston McKee K, Mahon E, Harper B, Roberts JN. Clinical trials recruitment planning: a proposed framework from the Clinical Trials Transformation Initiative. Contemp Clin Trials. 2018;66:74–9. 10.1016/j.cct.2018.01.003 [DOI] [PubMed] [Google Scholar]

2.Lai J, Forney L, Brinton DL, Simpson KN. Drivers of start-up delays in global randomized clinical trials. Therapeutic Innovation & Regulatory Science. 2021;55:212–27. 10.1007/s43441-020-00207-2 [DOI] [PMC free article] [PubMed] [Google Scholar]

3.Kelly D, Spreafico A, Siu LL. Increasing operational and scientific efficiency in clinical trials. Br J Cancer. 2020;123:1207–8. 10.1038/s41416-020-0990-8 [DOI] [PMC free article] [PubMed] [Google Scholar]

4.Chaudhari N, Ravi R, Gogtay NJ, Thatte UM. Recruitment and retention of the participants in clinical trials: challenges and solutions. Perspect Clin Res. 2020;11:64–9. 10.4103/picr.PICR_206_19 [DOI] [PMC free article] [PubMed] [Google Scholar]

5.Kearney A, McKay A, Hickey H, Balabanova S, Marson AG, Gamble C, Williamson P. Opening research sites in multicentre clinical trials within the UK: a detailed analysis of delays. BMJ Open. 2014;4(9):e005874. 10.1136/bmjopen-2014-005874 [DOI] [PMC free article] [PubMed] [Google Scholar]

6.Eichler HG, Sweeney F. The evolution of clinical trials: can we address the challenges of the future? Clin Trials. 2018;15:27–32. 10.1177/1740774518755058 [DOI] [PubMed] [Google Scholar]

7.Bieske L, Zinner M, Dahlhausen F, Trübel HKF. Critical path activities in clinical trial setup and conduct: how to avoid bottlenecks and accelerate clinical trials. Drug Discov Today. 2023;28:103733. 10.1016/j.drudis.2023.103733 [DOI] [PubMed] [Google Scholar]

8.Olver IN, Keech AC. Forming networks for research: proposal for an Australian clinical trials alliance. Med J Aust. 2013;198:198. 10.5694/mja12.11067 [DOI] [PubMed] [Google Scholar]

9.Okada K, Sengoku S. Entry into new therapeutic areas: the effect of alliance on clinical trials. Therapeutic Innovation & Regulatory Science. 2019;53(5):648–53. 10.1177/2168479018811829 [DOI] [PubMed] [Google Scholar]

10.Berkowitz JL, Fernández AO, Dichmann R, Kennedy KA, DiCarlo BA. Clinical trials networks and enrollment of historically underrepresented populations in medical oncology trials. J Clin Oncol. 2016;27(15_suppl):e20598. 10.1200/jco.2009.27.15_suppl.e20598 [DOI] [Google Scholar]

11.Gao X, Wen J, Song J. Capacity allocation and revenue sharing in healthcare alliances. Flex Serv Manuf J. 2020;32:829–51.

12.Imperial College Healthcare NHS Trust. Annual report 2020/21. Imperial College Healthcare NHS Trust. 2021. Available at https://www.england.nhs.uk/wp-content/uploads/2022/09/imperial-college-healthcare-nhs-trust-ara-20-21.pdf.

13.North West London Clinical Trials Alliance impact report. NIHR Clinical Research Network North West London; 2022. [Google Scholar]

14.Bell-Syer SEM, Thorpe LN, Thomas K, MacPherson H. GP participation and recruitment of patients to RCTs: lessons from trials of acupuncture and exercise for low back pain in primary care. Evidence-Based Complementary and Alternative Medicine. 2011;2011:687349. 10.1093/ecam/nen044 [DOI] [PMC free article] [PubMed] [Google Scholar]

15.Bentley C, Cressman S, van der Hoek K, Arts K, Dancey J, Peacock S. Conducting clinical trials—costs, impacts, and the value of clinical trials networks: a scoping review. Clin Trials. 2019;16(2):183–93. 10.1177/1740774518820060 [DOI] [PubMed] [Google Scholar]

16.Booth SL, Sallis JF, Ritenbaugh C, Hill JO, Birch LL, Frank LD, et al. Environmental and societal factors affect food choice and physical activity: rationale, influences, and leverage points. Nutr Rev. 2001;59(3):S21–S36. doi: 10.1111/j.1753-4887.2001.tb06983.x. [DOI] [PubMed] [Google Scholar]

17.Engbers LH, van Poppel MNM, Paw MJMCA, van Mechelen W. Worksite health promotion programs with environmental changes: a systematic review. Am J Prev Med. 2005;29(1):61–70. doi: 10.1016/j.amepre.2005.03.001. [DOI] [PubMed] [Google Scholar]

18.Oakman J, Neupane S, Proper KI, Kinsman N, Nygard CH. Workplace interventions to improve work ability: a systematic review and meta-analysis of their effectiveness. Scand J Work Environ Health. 2018;44(2):134–146. doi: 10.5271/sjweh.3685. [DOI] [PubMed] [Google Scholar]

19.Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4:1. doi: 10.1186/2046-4053-4-1. [DOI] [PMC free article] [PubMed] [Google Scholar]

20.Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015;349:g7647. doi: 10.1136/bmj.g7647. [DOI] [PubMed] [Google Scholar]

21.Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol. 2007;7:10. doi: 10.1186/1471-2288-7-10. [DOI] [PMC free article] [PubMed] [Google Scholar]

22.Huang M, Neveol A, Lu Z. Recommending MeSH terms for annotating biomedical articles. J Am Med Inform Assoc. 2011;18(5):660–667. doi: 10.1136/amiajnl-2010-000055. [DOI] [PMC free article] [PubMed] [Google Scholar]

23.Methley AM, Campbell S, Chew-Graham C, McNally R, Cheraghi-Sohi S. PICO, PICOS and SPIDER: a comparison study of specificity and sensitivity in three search tools for qualitative systematic reviews. BMC Health Serv Res. 2014;14:579. doi: 10.1186/s12913-014-0579-0. [DOI] [PMC free article] [PubMed] [Google Scholar]

24.Schelvis RMC, Hengel KMO, Burdorf A, Blatter BM, Stnjk JE, van der Beek AJ. Evaluation of occupational health interventions using a randomized controlled trial: challenges and alternative research designs. Scand J Work Environ Health. 2015;41(5):491–503. doi: 10.5271/sjweh.3505. [DOI] [PubMed] [Google Scholar]

25.Higgins J, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions The Cochrane Collaboration. 2011. [Google Scholar]

26.Sterne JAC, Hernan MA, Reeves BC, Savovic J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016;355:i4919. doi: 10.1136/bmj.i4919. [DOI] [PMC free article] [PubMed] [Google Scholar]

27.Schünemann Holger J., Cuello Carlos, Akl Elie A., Mustafa Reem A., Meerpohl Jörg J., Thayer Kris, Morgan Rebecca L., Gartlehner Gerald, Kunz Regina, Katikireddi S Vittal, Sterne Jonathan, Higgins Julian PT, Guyatt Gordon. GRADE guidelines: 18. How ROBINS-I and other tools to assess risk of bias in nonrandomized studies should be used to rate the certainty of a body of evidence. Journal of Clinical Epidemiology. 2019;111:105–114. doi: 10.1016/j.jclinepi.2018.01.012. [DOI] [PMC free article] [PubMed] [Google Scholar]

28.Grimani A, Bergström G, Casallas MIR, Aboagye E, Jensen I, Lohela-Karlsson M, et al. Economic evaluation of occupational safety and health interventions from the employer perspective: A systematic review. J Occup Environ Med. 2018;60(2):147. doi: 10.1097/JOM.0000000000001224. [DOI] [PMC free article] [PubMed] [Google Scholar]

29.Alkhajah TA, Reeves MM, Eakin EG, Winkler EA, Owen N, Healy GN. Sit-stand workstations: a pilot intervention to reduce office sitting time. Am J Prev Med. 2012;43(3):298–303. doi: 10.1016/j.amepre.2012.05.027. [DOI] [PubMed] [Google Scholar]

30.Ben-Ner A, Hamann DJ, Koepp G, Manohar CU, Levine J. Treadmill workstations: the effects of walking while working on physical activity and work performance. PLoS One. 2014;9(2):e88620. doi: 10.1371/journal.pone.0088620. [DOI] [PMC free article] [PubMed] [Google Scholar]

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