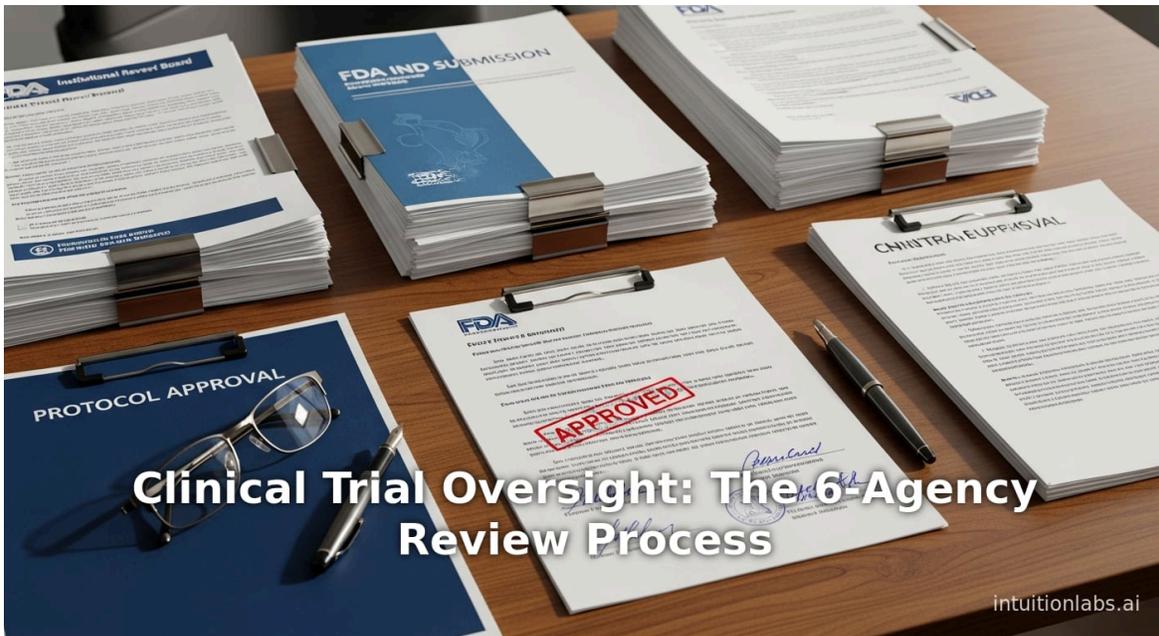


# Clinical Trial Oversight: The 6-Agency Review Process

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## Executive Summary

Clinical trials are governed by a complex **regulatory landscape** that spans multiple layers of oversight. A single trial protocol typically must pass through numerous review bodies – from **local ethics committees** to national regulators to international guidance bodies – before patient enrollment can begin. In practice, investigators often describe this as a “regulatory relay race,” with the trial “baton” shuttled sequentially through **at least half a dozen agencies or committees**. Each agency has distinct mandates – such as protecting human subjects, ensuring data integrity, and confirming legal compliance – and their reviews can be both *duplicative* and *time-consuming*. For example, a recent Lancet Global Health review confirms that “sequential submission to ethics committees and regulatory agencies within and across countries results in unwarranted delays” in starting trials (<sup>[1]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)). These inefficiencies have real-world consequences: one EU-funded multicenter trial reported a **median 784 days** (~26 months) to initiate a site due to protracted contract negotiations and approvals (<sup>[2]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)), and delays in regulatory approvals have been linked to lower enrollment rates and wasted research resources.

This report provides an in-depth examination of the regulatory pathway a typical clinical trial must navigate. We trace the historical origins of human research protections (from the Nuremberg Code to the Belmont Report and modern Good Clinical Practice) and outline the current framework of **international and national regulations**. We detail the roles of key agencies (e.g. institutional review boards, FDA/EMA, data safety monitoring boards, etc.) and explain how their interactions can resemble a cumbersome relay. Drawing on data from published studies and official sources, we quantify the timelines at each step: for instance, FDA law mandates a **30-day review** of an IND submission (<sup>[3]</sup> [www.law.cornell.edu](http://www.law.cornell.edu)), and recent empirical studies report **median IRB approval times** on the order of 6-7 months (<sup>[4]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) (<sup>[5]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). We include **markdown tables** that summarize the functions of each oversight body and typical review durations.

We also present multiple case studies and perspectives. A multicenter stroke trial in Europe encountered major legislative and contractual delays (<sup>[2]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)), whereas two rapid-response COVID-19 trials activated sites in just 12–15 days by deploying an emergency regulatory approach (<sup>[6]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)). Stakeholder viewpoints – from investigators lamenting red tape to regulators emphasizing public safety – are discussed. Finally, we consider reforms and future directions for streamlining the process: for example, the NIH’s single-IRB mandate for U.S. multisite trials, the EU’s centralized clinical trials portal, and international initiatives (ICH, WHO) aiming for harmonization. The report concludes that while robust oversight is essential for participant protection, the current “six-agency relay race” often impedes timely research. **Streamlining measures** – such as parallel reviews, mutual recognition agreements, and risk-based oversight – are critical to shortening the relay and delivering innovations to patients more efficiently.

## Introduction and Background

The regulation of clinical research is born of historical abuses and ethical imperatives. In the wake of Nazi atrocities during World War II, the 1947 **Nuremberg Code** established the first formal rules for human experimentation (<sup>[7]</sup> [www.hhs.gov](http://www.hhs.gov)). These principles – voluntary consent, benefit outweighing harm, and transparency – were later echoed in the World Medical Association’s **Declaration of Helsinki** (1964) and the U.S. **National Research Act of 1974**. The 1978 Belmont Report distilled these ideas into the familiar bioethical principles of respect for persons, beneficence, and justice (<sup>[8]</sup> [www.hhs.gov](http://www.hhs.gov)). By the 1980s, the U.S. Department of Health and Human Services (HHS) codified these protections in regulations (45 CFR 46), leading in 1991 to a single “Common Rule” that unified human subjects protections across **15 federal agencies** (<sup>[9]</sup> [www.hhs.gov](http://www.hhs.gov)). Today, research involving human participants typically must comply with a patchwork of laws and guidelines –

from local laws and institutional policies to international guidelines like **ICH Good Clinical Practice** and **WHO guidance** – all designed to safeguard participant welfare and research integrity.

As a result of this evolution, virtually every modern trial must pass through **multiple layers of review**. In the United States, a new drug trial requires approval by an Institutional Review Board (IRB) to assess ethical and human-subject protections (per 45 CFR 46 and 21 CFR 56). An **Investigational New Drug (IND)** application must be submitted to the Food and Drug Administration (FDA), which by law cannot allow human dosing until 30 calendar days after receipt (unless a clinical hold is placed) (<sup>[3]</sup> [www.law.cornell.edu](http://www.law.cornell.edu)). If the sponsor is federally funded (e.g. NIH), the protocol may also undergo an internal scientific review and NIH program approval. Specialized committees – such as a **Data and Safety Monitoring Board (DSMB)** or biosafety committee – may further review the protocol. Finally, the trial must navigate institutional contracting offices, government funding audits, and registrations (e.g. [ClinicalTrials.gov](http://ClinicalTrials.gov)).

Internationally, each country has its own regulatory gatekeepers. In the European Union, for example, the 2022 EU Clinical Trials Regulation (CTR) now mandates a single European portal submission, yet still requires national evaluations by each member state and ethics committee. In the U.K., trials must clear the Health Research Authority's ethical review (through REC), plus the Medicines and Healthcare products Regulatory Agency (MHRA) for investigational therapies. Across other jurisdictions, analogous processes exist (e.g. Health Canada's Clinical Trials Application, Japan's PMDA review). Even beyond government, many academic medical centers have multiple internal committees (e.g. Scientific Review Committees, Conflict of Interest panels, Radiation Safety boards) that inspect research proposals in parallel or series.

In sum, the **current landscape** is one of depth but also redundancy. Investigators often remark that a trial must pass through a “healthcare octagon of bureaucracy” before it begins (<sup>[10]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). The phrase “Regulatory Relay Race” encapsulates how the trial protocol is effectively *handed off* from one body to another, each demanding review. While intended to protect participants and ensure quality, this siloed system has spawned delays and inefficiencies: as one recent study observes, “Lack of funding, increasing complexity of regulations, excessive monitoring... and complex... trial procedures... are important obstacles” (<sup>[10]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). By quantifying these delays and examining case examples, this report aims to shed light on *how* six (or more) agencies can sequentially review a single trial, the impacts thereof, and possible paths to reform.

## International and National Regulatory Frameworks

Before analyzing the “relay race” in detail, it is useful to outline the **principal agencies** and regulations that govern clinical trials. These can be grouped into international guidelines and national regulatory authorities.

### International Harmonization and Guidelines

Clinical trials are influenced by global standards and coalitions. The **International Council for Harmonisation (ICH)** has published the Good Clinical Practice (GCP) E6 guidelines, which specify responsibilities of Sponsors, Investigators, and Ethics Committees in trials (<sup>[11]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)). Although ICH guidelines are not laws, they underpin many national regulations and form the basis for mutual recognition. The **World Health Organization (WHO)** has also issued guidelines and resolution-driven initiatives emphasizing ethical and efficient trial conduct. For example, in 2022 the World Health Assembly adopted a resolution (WHA75.8) on strengthening clinical trials, and WHO released guidance advocating “ethical standards, regulatory considerations, and patient-centered research” to make trials more efficient and inclusive worldwide

([www.who.int](http://www.who.int)). Such international frameworks encourage *harmonization* – for example, promoting single ethical reviews in multi-country studies and standardizing informed consent processes to reduce duplication (<sup>[11]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)) ([www.who.int](http://www.who.int)). However, a truly unified global system remains elusive; as one Lancet Global Health review notes, longstanding inefficiencies stem from “absence of a harmonised, universal approach to the review, approval, and initiation of international clinical trials” (<sup>[12]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)).

The **WHO** and **International Coalition for Harmonization (ICH)** also outline the roles of various bodies. Typically, **Regulatory Authorities** (e.g. HHS/FDA, EMA, MHRA, PMDA) are legally empowered to authorize trials (e.g. by approving INDs or Clinical Trial Applications), while **Ethics Committees/IRBs** ensure participant protection. The Lancet review highlights that it was national and regional regulators *and* IRBs (or RECs) who actually approve trials in practice (<sup>[13]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)). Amid calls for reform, initiatives such as joint/parallel reviews and reliance arrangements (e.g. African Vaccine Regulatory Forum’s shared reviews (<sup>[14]</sup> [www.sciencedirect.com](http://www.sciencedirect.com))) are recommended to integrated oversight across borders.

## United States Regulatory Bodies

In the U.S., multiple federal agencies intersect with clinical trials. The principal ones include:

- **Food and Drug Administration (FDA)**: Regulates drugs, biologics, and devices. For new drugs, sponsors file an IND; for devices, an Investigational Device Exemption (IDE). By law, FDA must review an IND within 30 days, after which the trial may proceed unless FDA issues a clinical hold (<sup>[3]</sup> [www.law.cornell.edu](http://www.law.cornell.edu)). FDA also inspects trial sites for compliance with regulations (21 CFR Parts 50, 56, 312, etc).
- **Office for Human Research Protections (OHRP)**: Under HHS, OHRP oversees IRBs. While it does not “approve” individual protocols, OHRP enforces the **Common Rule (45 CFR 46)** for HHS-funded research and maintains the Federalwide Assurance (FWA) process for IRBs. Over 20 agencies follow the Common Rule, meaning an IRB’s approval must meet OHRP standards (<sup>[9]</sup> [www.hhs.gov](http://www.hhs.gov)).
- **National Institutes of Health (NIH)**: As the largest research funder, NIH has internal scientific review and oversight. For funded grants with human subjects research, NIH requires adherence to its own policies (e.g. single IRB mandate for multi-site studies, grant progress monitoring). The NIH also oversees extramural STDs (Science, Technology, and Data Safety Boards) and ensures compliance via audits.
- **Other Federal Agencies**: Numerous U.S. departments fund human research (CDC, DoD, DOE, etc). Many have adopted similar regulations. For example, in 1991 fourteen agencies joined the HHS regulations (forming the Common Rule) (<sup>[9]</sup> [www.hhs.gov](http://www.hhs.gov)). Additional agencies like the EPA or Dept of Agriculture incorporate the policy into their funded research.
- **Ethics Committees/IRBs**: Institutions (hospitals, universities) establish IRBs (or independent IRBs) to review protocols. Each site, or a central IRB under an assurance, must approve a trial before enrollment. IRBs apply both the Common Rule and (if FDA-regulated) FDA regulations (21 CFR 50/56). Research indicates IRB review times vary widely; a recent survey found that IRBs often face increasing workloads and delays (<sup>[10]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) (<sup>[15]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- **Data and Safety Monitoring Boards (DSMBs)**: For many clinical trials (especially phase 3 or high-risk), an independent DSMB is established to monitor patient safety and data integrity midway. While not a “regulatory agency,” DSMBs have the power to stop or modify trials, effectively acting as an oversight body during conduct.
- **Institutional Oversight Committees**: Beyond IRBs, large institutions may have additional review requirements. For example, protocols involving recombinant DNA might need Institutional Biosafety Committee (IBC) approval, or investigations involving NASA personnel may need NASA HRPO review. If funded by NSF, their OSP conducts compliance checks. These bodies add layers to the approval process.

Collectively, a U.S. trial might be reviewed by *six or more* entities. For example, an NIH-funded multi-site drug trial could require: (1) internal scientific committee sign-off by the PI’s institution, (2) an IRB at each site (or a single IRB under NIH policy), (3) OHRP registration and oversight, (4) the NIH program official, (5) FDA IND

authorization, and (6) a DSMB setup. Each step involves separate submissions, correspondence, and often iterative changes.

## European and Other Regions' Regulators

Outside the U.S., similar but distinct systems operate:

- **European Union:** The 2022 EU Clinical Trials Regulation (EU No. 536/2014) established a single EU portal and database (the Clinical Trials Information System) for multinational trials. Sponsors submit one application covering all EU Member States; however, each state's authority still conducts the review (albeit coordinated), typically with a **60-day** (plus possible extensions) combined timeline (<sup>[16]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)). A trial requires both a favorable ethics opinion and regulatory approval in each country. Post-Brexit, the **UK** requires its own system: a UK Sponsor or NIHR evaluation, separate Research Ethics Committee (via the Health Research Authority), and MHRA approval. Other countries have their agencies (e.g. Swissmedic, PMDA in Japan, CFDA in China) with varying rules. Harmonization is incomplete – for example, definitions of “minimal risk” or consent nuances differ, making simultaneous submission cumbersome for global studies.
- **International Multi-agency Oversight:** In global health research (e.g. trials in low- and middle-income countries), sponsors often coordinate with multiple national drug authorities plus ethics review boards. Organizations like the **African Vaccine Regulatory Forum (AVAREF)** have pioneered joint reviews across countries, and similar reliance models exist (e.g. WHO prequalification linking with national approvals). Nevertheless, a lack of alignment can stall trials: slow review in any one country can delay the entire study.
- **Country-Specific Bodies:** Other countries may have unique requirements. For example, India's Central Drugs Standard Control Organisation (CDSCO) historically required approvals from its Drugs Controller General, plus Institutional Ethics Committees, plus an additional governmental science body for international trials. Differences like these illustrate why a “six agency” review is not unusual, especially in large multi-country trials.

## Institutional and Other Non-Governmental Review

Within host institutions (e.g., hospitals and universities), several committees may review a proposed trial in parallel or sequence:

- **Departmental and Scientific Review:** Many academic centers have a Research Committee or department-specific review to ensure scientific merit, resource availability, and alignment with institutional goals before a protocol is submitted to IRB.
- **Budget and Contract Offices:** Institutions negotiate clinical trial agreements with sponsors. While technically administrative, these offices ensure financial and legal terms are covered – often a time-intensive step.
- **Privacy and Billing Boards:** Under HIPAA, some studies require a Privacy Board review if an IRB is not available, although usually the IRB covers HIPAA issues. Additionally, hospital billing compliance officers may review to distinguish research procedures from clinical care.
- **External Monitoring and Accreditation:** For some trials, external audits (e.g., by sponsors or CROs) and accreditation by bodies like AAHRPP (Association for the Accreditation of Human Research Protection Programs) provide additional oversight layers, albeit more as quality assurance than “approval.”

Each additional committee, whether governmental or institutional, can add weeks to the start-up process. While not all are counted as formal “regulatory agencies,” they function effectively as checkpoints. Altogether, it is not unusual for a single trial to amass **half a dozen or more separate review processes**, each analogous to passing a baton to the next runner in a relay.

# The Regulatory Relay Race: Step-by-Step Trail of a Clinical Trial

To understand the term “Regulatory Relay Race,” consider a prototypical clinical trial’s journey from conception to launch. We outline below **key steps and agencies** involved. (The sequence may vary by country and trial type, but the pattern of multiple sequential approvals is common.)

**1. Protocol Development and Sponsor Approval.** The race begins with the sponsor (a pharmaceutical/biotech company or academic research group) drafting a detailed protocol. Internally, the sponsor’s scientific review board (or funding committee, if an NIH grant) scrutinizes the protocol for scientific validity and feasibility. A budget and project plan are prepared. This internal review is often not public, but any comments lead to protocol revisions before external submission.

**2. Institutional Review Board / Ethics Committee Submission.** Next, the finalized protocol is submitted to an **Institutional Review Board (IRB)** or Ethics Committee. In the U.S., this is typically the IRB of the site where research will occur, unless a single IRB (sIRB) model is used. In Europe and elsewhere, comparable ethics committees (RECs) provide similar review. The IRB examines the trial for ethical soundness and participant protections, informed consent language, and risk/benefit balance. Each participating site’s IRB must generally approve the trial before that site can begin enrolling.

- **Timeframe:** IRB review times vary. One study found for an exception-from-consent trauma trial that **median IRB approval took 216 days** after the preparatory “kickoff” (<sup>[4]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Another survey of 55 US IRBs reported substantial variability in “time necessary for an IRB to approve a study,” with high workloads and biomedical (drug) submissions taking longer (<sup>[17]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Delays of several months are not uncommon (<sup>[15]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)) (<sup>[4]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)).
- **Parallel Reviews:** Some institutions concurrently run other reviews at this stage. For example, if the trial involves genetic engineering, an Institutional Biosafety Committee may review in parallel with the IRB. Other specialized panels (radiation safety, conflict of interest) may also provide input.

**3. Regulatory Agency Submission (e.g. FDA IND/IDE or Equivalent).** After IRB clearance (or sometimes concurrently), the sponsor files a clinical trial application with the national drug regulator. In the U.S., this is the **Investigational New Drug (IND)** application to FDA (21 CFR 312). In Europe, a **Clinical Trial Application (CTA)** is submitted to the competent authority of each member state. Canada has the Clinical Trial Application (CTA) to Health Canada, Japan has the CTR submission to PMDA, etc.

- **FDA Example:** Upon receiving an IND, FDA has 30 days to review (<sup>[3]</sup> [www.law.cornell.edu](http://www.law.cornell.edu)). In many cases, the review is non-substantive (the trial “goes effective” after 30 days unless FDA raises issues). However, FDA may place a **clinical hold** if safety concerns arise, which stops the trial. FDA may also conduct a substantive review (e.g. for high-risk products), issuing comments that must be addressed before trials proceed.
- **Timeframe:** Besides the mandatory 30 days, review may stretch longer if questions arise. For multinational trials, sponsors often submit INDs alongside other CTAs. The European CTA process (under EU 536/2014) aims for a final decision in ~60 days (with a 31-day potential extension), but real timelines can be longer due to queries or national requirements.

**4. Additional U.S. Oversight (if applicable).** In NIH-funded or Official Government trials, there may be additional approvals:

- **NIH Scientific / Compliance Review:** If funded by NIH, the Study Section oversees science at funding stage, and Program Officers review progress. Depending on the institute, specific policies (e.g. data sharing plans) must be approved.
- **Public Health & HRP Registrations:** The protocol must be registered (e.g. [ClinicalTrials.gov](https://clinicaltrials.gov)). If the research involves certain pathogens or technologies, approvals from CDC/HICPAC or NIH Office of Science Policy may be needed.

- Funding Release:** For government grants, even after peer review, releases of funds require grant management steps (which can involve programmatic and compliance checks).

These steps can add weeks to months *after* IRB/FDA approval before actual funds and drug supplies are in hand.

**5. Site Contracting and Institutional Agreements.** Meanwhile, if a trial is multicenter, contracts and budgets between the sponsor and each site must be negotiated. This is a major bottleneck. In the PRECIOUS stroke trial (Europe), solving one site contract took a **median 194 days** <sup>[18]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov/)). Contract offices, legal reviews, and institutional sign-offs (Finance, Office of Sponsored Programs) typically occur in parallel with regulatory reviews but can also delay final site activation.

**6. Data and Safety Monitoring Board (DSMB) Setup.** Prior to first patient enrollment, a DSMB (or independent data monitoring committee) is constituted. The DSMB Charter, membership, and monitoring plan are approved by institutional leadership and sometimes by funders. While DSMB review is ongoing as the trial runs, the initial setup is another checkpoint before "Go."

**7. Final Approvals and Trial Start.** Once all previous steps are cleared – IRB(s), regulatory body, funding, contracts, DSMB – the trial is technically ready to start enrollment. In practice, there may be a final launch meeting or briefings for site staff.

Altogether, this sequence shows why clinical trials can require authorization from multiple agencies: each baton pass represents a separate **set of regulations and standards**. Figure 1 (Table 2 below) summarizes common steps and the agencies involved.

**Table 1: Agencies/Committees Involved in Clinical Trial Review**

Agency/Body	Jurisdiction/Sector	Primary Role in Review	Typical Authority/Reference
Institutional Review Board (IRB)/Ethics Committee (REC)	Local research institution (academic/hospital); international ethics	Ethical review of protocol, informed consent, subject safety	45 CFR 46 (Common Rule); 21 CFR 56; Declaration of Helsinki
U.S. Food and Drug Administration (FDA) / National Drug Regulator (e.g. EMA, MHRA)	Federal government (drug/biologics regulatory authority)	Assess safety of investigational product and trial design; grant permission (IND/CTA) for study to proceed	21 CFR Part 312 (IND); EU CTR (Reg 536/2014)
Office for Human Research Protections (OHRP)	U.S. HHS agency (federal oversight)	Oversees compliance with ethical regulations across institutions; registers IRBs (FWA)	45 CFR 46 (Common Rule)
National Institutes of Health (NIH) (or analogous funding body)	Federal agency (grant sponsor)	Scientific review of protocol, compliance with funding policies (e.g. single IRB, data sharing); release of funds	NIH Policy; 2 CFR 200 (grants)
Data and Safety Monitoring Board (DSMB)	Independent expert panel (trial-level oversight)	Ongoing safety monitoring; authority to pause/stop trial for safety/efficacy reasons	Data Monitoring Plans; NIH/NIH-DM standards
Institutional Biosafety Committee (IBC)	Local (if genetic engineering/biotech)	Review of recombinant DNA or biologic safety procedures	NIH Guidelines for Recombinant DNA
Institutional Administrative (Contract/Budget Office, R&D Office)	Local institution	Negotiate study budget and contractual terms; grant institutional approval to proceed	Institutional policy; federal grant regulations (OMB)

**Table 2: Typical Regulatory Review Steps and Timelines (Example)**

Step / Review Body	Purpose	Approximate Timeline (Oit from literature)	Example Reference(s)
Sponsor Scientific Review	Assess scientific merit before submission	Internal, variable	–
Institutional IRB/REC Approval	Ethics, consent form, risk/benefit	<b>1–3+ months</b> (median ~6–7 mo reported)	[61*L398-L401], [23*L88-L97]
FDA IND Review (US)	Regulatory review of drug safety in protocol	<b>30 days</b> mandatory review; can extend if hold	[32*L21-L25]
CTA Approval (EU)	Regulatory navigation in EU member states	~60 days (with 31-day extension); can be longer	[26*L93-L99] (implied)
Site Contract/Budget Finalization	Legal/ financial agreement with sponsor	<b>6–12+ months</b> (e.g. 194 days median)	[17*L44-L51] (contract time)
DSMB Charter Approval	Establish data safety monitoring plan	Several weeks	–
Study Launch (post all approvals)	Final checks, site training, first patient in	N/A – culmination of above steps	–

Note: Times depend on country, trial complexity, and resources. For example, during the COVID-19 pandemic, exceptional measures allowed accelerated reviews: one U.S. coordinating center activated sites in **12–15 days** ([6] [www.sciencedirect.com](http://www.sciencedirect.com)), far faster than typical.

## Data Analysis and Evidence of Delays

Quantitative data from published studies underscore the long timelines associated with multi-agency trial review. Key findings include:

- IRB Review Delays:** In a survey of U.S. IRBs, respondents noted increasing “burden of review board requirements” over the years ([19] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) ([15] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). A Boston Trauma team reported that *even using a single central IRB*, median time to approval was **216 days** ([4] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). Another study of a multicenter trial (EFIC waiver study) found median IRB/starter approval nearly 7 months, with only ~10% of sites approved within 5 months ([20] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) ([4] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). The variability is high: IRBs serving high volume or complex biomedical trials tend to be slower ([17] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) ([15] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- Contract Negotiation:** The PRECIOUS stroke trial (EU, 80 sites) reported that the **clinical trial agreement** with each site took a median **194 days** to finalize ([18] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)), longer than any other step. This legal review is not a regulatory “agency” per se, but it demonstrates an often overlooked delay in the startup.
- Multi-Site Coordination:** Delays grow with more sites. Concurrent IRB submissions can theoretically occur in parallel, but often sponsors wait for an initial “green light” (like an IND) before pushing all site IRBs. In large trials, lack of a central IRB historically meant each hospital’s board reviewed separately, multiplying delays ([19] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- Regulatory Approval Times:** On the regulator side, the legally mandated 30-day FDA IND review is usually a fixed wait, but FDA can extend this (clinical hold) if issues arise. In practice, safety or data queries can add weeks or months. Under the EU’s old system (prior to 536/2014), trial authorization often took several months per country; the new CTR aims to reduce this, but real-world data is still emerging ([1] [www.sciencedirect.com](http://www.sciencedirect.com)).
- Trial Activation:** Combining all factors, one analysis found **site initiation** took a median **784 days** (~26 months) from first regulatory submission to first patient enrolled in a European stroke trial ([2] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). Approximately half of that time was spent on contracting. Notably, longer initiation times correlated with poorer accrual: sites that later recruited fewer patients tended to take longer to start ([2] [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).

- **Pandemic-Outbreak Exception:** By contrast, COVID-19 trials showcased accelerated processes. In the convalescent plasma trial mentioned earlier, four oversight agencies (likely IRB, FDA, funding body, and hospital R&D) reviewed 26 sites in parallel, enabling most sites to activate within **12–15 days** (<sup>[6]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)). This required extraordinary coordination and relaxation of standard procedures, highlighting how timeline compression is possible in urgent settings.

These data, drawn from contemporary reports, quantify the delays at each “handoff.” For example, Table 2 above approximates these intervals, and Table 1 lists the agencies. Together, they illustrate that before a patient can be treated on protocol, many months (or even years) may pass, depending on trial scope.

## Case Studies and Examples

To illustrate the regulatory relay race in action, we highlight several real-world examples:

### A. PRECIOUS Stroke Trial (EU, Phase III, 2021)

The PRECIOUS trial (PREvention of Complications in Stroke) was an EU-funded, multi-nation Phase III trial across 9 countries (over 80 sites) in Europe (<sup>[21]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)) (<sup>[22]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). Investigators tracked the time required for each preparatory milestone. They found:

- **Median time to first site activation:** 784 days (~2.1 years) from initial regulatory submission (<sup>[2]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- **Biggest bottleneck:** Contract negotiations – median **194 days** to finalize a clinical trial agreement with a site (<sup>[18]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- **IRB/Ethics Delays:** Not explicitly separated, but “ethical, regulatory, and legal approvals” were each major factors.
- **Impact on recruitment:** Every extra day of delay correlated with slower enrollment (sites that took longer to activate recruited fewer patients in the first 6 months) (<sup>[2]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).

The authors concluded that excessive bureaucracy was impeding trial progress. They recommended proportionality (match contract/legal complexity to trial risk), to avoid gumming up low-risk academic trials (<sup>[23]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)). This study highlights how *multiple* agencies (national regulators, local ethics, legal departments) combined to delay startup on the scale of years.

### B. COVID-19 Convalescent Plasma Trials (USA, 2020)

In the early COVID-19 crisis, the Mayo Clinic’s leadership attempted to rapidly test therapies. One example involved two outpatient randomized trials of COVID-19 convalescent plasma (<sup>[24]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)). Here several agencies and processes were streamlined:

- **Coordinating Center:** A central team managed submissions to four oversight bodies (likely: central IRB, FDA for an IND, clinical research governance, and funder review) for 26 sites and two protocols (<sup>[6]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)).
- **Informed Consent Forms (ICFs):** Emergency conditions required quick translation and approvals for English/Spanish forms. Over 68 protocol amendments and consent changes were handled within a two-month start-up cycle (<sup>[6]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)).
- **Outcome:** Sites were ready to enroll in just **12–15 days** on average (exceedingly fast). Even with normal processes, median activation is often months; here rapid “parallel” coordination achieved in a few weeks (<sup>[6]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)).

[www.sciencedirect.com](http://www.sciencedirect.com)).

- **Lesson:** Under crisis SOPs, agencies can collaborate and cede authority. The coordinating center recommended adopting “emergency interagency standard operating procedures” and guidelines to cede reviews in multicenter settings (<sup>[6]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)) (<sup>[25]</sup> [www.sciencedirect.com](http://www.sciencedirect.com)).

This case illustrates the agility possible when regulators share the baton simultaneously (parallel processes) rather than in strict sequence. It also underscores patient-centered practices (rapid community announcements, returning results to participants) that were tied to the expedited approach.

## C. Exception from Informed Consent (EFIC) Trauma Trial (USA, 2024)

The Southern Surgeons network analyzed start-up for a high-risk trial where consent was waived (EFIC trial in trauma). Key findings:

- Despite using a **single IRB** for all sites, the median approval time was **216 days** (7+ months) (<sup>[4]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- Other approvals (e.g. hospital/local IRBs, although cIRB was used) also added time.
- The first site to complete all regulatory steps took nearly 5 months, and 32% of sites took *6 months or more* just to get initial approvals (<sup>[20]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- Experienced sites and new sites both required similar time, debunking any expectation that repeated experience would greatly shorten approval time (<sup>[4]</sup> [pmc.ncbi.nlm.nih.gov](http://pmc.ncbi.nlm.nih.gov)).
- This case shows that even with central IRB models, coordinating among 60+ institutions, each with their own contracts, ancillary reviews, and hospital forms, remains slow.

## D. Hypothetical Multi-Country Vaccine Trial

Consider a Phase II vaccine trial conducted simultaneously in the U.S., U.K., and Uganda. It might require:

- U.S. IRB, FDA IND, NIH funding approval;
- U.K. REC (HRA) and MHRA approval;
- Uganda national ethics committee and NDA submission;
- Data monitoring boards;
- And local hospital research committees in each country.

Each of these is a separate “agency” check. If all were done strictly sequentially, delays could easily accumulate to 1-2 years before first enrollment. Joint review initiatives (like using the U.S. FDA’s Project Orbis or WHO pre-review) are potential solutions, but in practice the trial team often has to juggle six parallel submission processes.

These examples – one real EU trial, one fast-tracked U.S. outbreak trial, and one domestic IRB-heavy trial – demonstrate the spectrum of regulatory timelines and the interplay of multiple agencies. In each case, multiple separate bodies assessed the trial in series or parallel, with significant influence on how quickly patients could be enrolled.

## Perspectives of Stakeholders

The “regulatory relay race” elicits different reactions from various stakeholders in clinical research:

- Investigators (Researchers):** Many researchers voice frustration at the bureaucratic burden. Delays mean lost time for potentially life-saving therapies, wasted grant funds, and high administrative cost. As one ethics journal noted, IRB inefficiency “deters or impedes the speed of research,” potentially causing sites to drop out of multicenter trials (<sup>[26]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). Academic investigators often cite IRB and contract negotiations as top barriers. However, they also acknowledge that oversight is key to credibility and avoiding past abuses.
- Sponsors (Industry):** Pharma companies operate under tight timelines and budget. Every regulator’s “stopwatch” adds expenses. Regulatory affairs professionals often lobby for parallel submissions and mutual recognition to expedite trials. They emphasize that predictability of review timelines (rather than length) is crucial for planning. Industry also argues that too many review boards (e.g. multiple IRBs) create duplicative work.
- Institutional Review Boards:** IRB members and administrators defend their role as protecting participants, not just hindering research. They point out that each unique protocol or population may require distinct ethical considerations. IRBs also note resource constraints: growing caseloads without proportional funding. The 2018 Common Rule update (with a focus on harmonization and eliminating redundancies) was partly in response to IRB complaints of overwork and conflicting requirements (<sup>[19]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)).
- Regulators:** Agencies like the FDA or EMA see themselves as safeguarding public health. They emphasize that scrutiny in trial design and conduct prevents harmful products reaching patients. From their perspective, separate reviews (e.g. by FDA vs IRB) have different aims: one checks science, one checks ethics. Nonetheless, agencies also participate in streamlining efforts (e.g. FDA’s 21st Century Cures Act provisions for expedited pathways, or DIA’s open regulatory science dialogues).
- Ethicists and Patients:** Some ethicists lament that procedural inefficiency can itself be unethical, as it delays beneficial research. Patient advocacy groups often urge faster access to trials, especially in life-threatening diseases. They generally support robust ethics but question the value of redundant review (e.g. multiple IRBs covering the same protocol). The patient perspective often gets less direct voice in regulatory discussions, though initiatives like returning results to participants (as seen in the COVID trial above) reflect a shift toward patient-centered practices.
- Policy Makers and Public Health Officials:** Government entities see clinical trials through the lens of societal benefit. They support oversight for safety, but also recognize the need for research agility, especially in emergencies. Bodies like WHO and national governments frequently commission reviews of the trials ecosystem (e.g. after COVID commissions) and propose reforms (some of which are noted below).

Across perspectives, a common tension emerges: **safety vs speed**. Everyone agrees trials must be safe and ethical; the dispute is over whether the current regulatory “relay” is **excessively burdensome** relative to its benefits. The data and cases above clearly indicate opportunities to trim unnecessary delays without compromising participant protection.

## Discussion: Implications and Future Directions

The phenomena described have broad implications:

- Impact on Innovation and Public Health:** Extended trial start-up times can stifle innovation. As [<sup>23</sup>L88-L96] emphasizes, many patients (30 million Americans with unmet needs) are waiting for new therapies even as researchers wade through paperwork. Delays can also discourage research sites, diminishing trial participation. If half of trials fail to meet enrollment targets on time (<sup>[10]</sup> [pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)), society pays in slower new treatments and wasted resources.
- Regulatory Evolution:** Agencies are aware of these issues. Recent reforms aim to reduce the relay effect. For example, the **NIH Single IRB Policy** (effective 2018) mandates one IRB for multi-site U.S. studies, to cut duplicate IRB reviews. The revised U.S. Common Rule (2018) allows some categories of low-risk research to bypass annual continuing review. Internationally, the EU CTR and similar efforts are intended to reduce administrative steps for cross-border trials.

- **Harmonization and Reliance:** Global health experts advocate for “joint and parallel reviews” as in [26+L43-L48]. The European CTIS portal exemplifies centralized submission, though further harmonization (e.g. truly single ethics opinion for multi-country trial) is still aspirational. In emerging markets, reliance models (WRP reliance on reference authority’s review) are being piloted to avoid duplicative review in low-resource settings. The African Vaccine Regulatory Forum’s accelerated timelines (as short as 15 days in emergencies) show what is possible ([14] [www.sciencedirect.com](http://www.sciencedirect.com)).
- **Technology and Process Innovation:** Digital tools (e-consent, centralized databases, automated regulatory trackers) may shave days off administrative steps. Some propose real-time IRB meetings or “IRB Express” processes for minimal-risk protocols. The NIH CT.gov system mandates result reporting within a year of trial completion, ensuring some accountability for timeliness.
- **Ethical and Social Considerations:** Beyond efficiency, there is a push for transparency and inclusivity. Ensuring oversight is not only expedient but trusted is essential. Ongoing reforms include requiring that participants be offered the option to receive study results, and better inclusion of underrepresented populations. Importantly, streamlining does not mean cutting corners – balancing ethical rigor with reduced redundancy is the goal.
- **Preparedness for Emergencies:** The COVID experience has been instructive. Agencies stood up new working groups, prioritized certain protocols, and sometimes “ceded” authority to expedite studies ([25] [www.sciencedirect.com](http://www.sciencedirect.com)). A key future direction is embedding such flexibility into routine practice – e.g. clear criteria for when to allow parallel reviews or simplified processes for priority drugs (as partly enacted in FDA’s Emergency Use authority).

## Conclusion

The journey of a single clinical trial through the modern regulatory maze is long and intricate. On average, as this report has detailed, it often involves **six or more distinct agencies or committees** – from a local IRB to national drug regulators to funding and contract offices – each adding time and requirements. This “Regulatory Relay Race” has led to growing concern that research is slowed at the very time we need it to be nimble.

However, the stakes of participant safety and research integrity necessitate oversight. The challenge is to preserve essential protections while removing wasteful duplication. As Franklin E. [Kesselheim] and colleagues note in the Lancet, “streamlining and harmonising these review processes is crucial” for timely GLOBAL trials ([1] [www.sciencedirect.com](http://www.sciencedirect.com)). Emerging data and case studies show both the problem (years-long delays) and potential solutions (weeks-long activations). The future likely lies in balance: **risk-based oversight** that tailors requirements to each trial’s profile, combined with greater reliance on joint reviews and technology, to ensure that the regulatory baton can be passed more quickly – but safely – to the finish line.

In summary, understanding the regulatory relay race involves mapping out each checkpoint and quantifying its impact. This report has provided that map through historical context, detailed breakdowns, evidence, and examples. It has also pointed toward reforms (single IRBs, coordinated global systems, emergency SOPs) that could shorten the track. Ultimately, a more efficient relay not only speeds up medical progress, but also honors the ethical imperative to deliver innovations to patients without undue delay, all while keeping the research enterprise robust and trustworthy.

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