Global Clinical Trial Approval and Startup Timelines

Official Statutory Benchmarks

Executive Summary

Cross-Country Timelines: Official regulatory timelines for clinical trial authorization vary widely across countries. *Some jurisdictions (e.g.* ***United States, Canada, Japan, Singapore****) guarantee* ***quick initial scientific review (around 30 days)****, whereas others (****India, EU****) allow up to* ***60–90 days*** *for an initial decision*[1] [2].

Parallel vs. Integrated Processes: Key differences in approach influence timelines:

- **Parallel Processes:** Countries like the **US, Canada, Japan, Switzerland, India, Brazil**, etc., require separate approvals from the **Competent Authority (CA)** and **Independent Ethics Committees (IECs)**, or **Institutional Review Boards (IRBs)** in the United States. In these cases, **statutory timelines only apply to CA review**, while *ethics review lacks mandated deadlines* and depends on local or institutional schedules. *Sponsors typically pursue CA and IEC/IRB approvals in parallel*, as neither is dependent on the other for final authorization (except in jurisdictions like **China and Malaysia** where final CA permission may be contingent on obtaining IEC approvals).
- **Integrated or Coordinated Processes:** The **European Union (EU)** now uses an **integrated submission through the Clinical Trials Information System (CTIS)** under **EU Regulation 536/2014 (EU CTR)**. **EU Member States have standardized regulatory timelines**: typically **45 days** for initial **Part I** (scientific & medical) review plus **45 days** for **Part II** (ethics & local aspects) in parallel . If additional information is requested, **a "clock-stop" is allowed**: sponsors have up to **12 days** to respond, and regulators get up to **19 days** extra for final review, extending total *Part I* review up to **76 days** . Some countries (e.g. **UK**) have integrated processes where a **single combined review** by both CA and IEC is completed within **30 days**, with one joint decision or synchronized request for information (RFI) if needed. **Australia**'s common **Clinical Trial**

[1] https://www.law.cornell.edu/cfr/text/21/312.40

[2] https://www.clinicalstudies.in/regulatory-timelines-for-clinical-trial-approvals-in-india/

Notification (CTN) pathway is highly streamlined; only ethics and institutional approvals are needed for clinical trial commencement, with *no formal CA review timeline* (TGA is simply notified and does not review clinical trial data).

From Approval to Site Activation: *Most countries do **not** define a statutory timeline from regulatory approval to first site activation.* Site initiation and activation processes (e.g. **contracting, site training, local approvals**) are considered *operational and outside regulatory scope*, thus left to sponsor and site capabilities rather than regulated. **No countries in this survey mandate a fixed timeline for site activation** in their laws or official guidance. A few countries set *loose expectations or prerequisites*, such as requiring local ethical approvals or other clearances before any site can begin recruitment, but **none impose a deadline** by which the first site must be activated after authorization. Consequently, *global trial planning must assume site activation timelines are driven by local institutional processes, which can vary widely and often exceed statutory authorization times*.

Cautions: Statutory official review timelines are "stop-clock" limits for regulators, but **real-world performance may differ.** They represent maximum review durations defined by law or formal guidance. In practice:

- *Regulators might conclude reviews faster than the statutory limit, especially for streamlined or lower-risk clinical trials, for example **Canada's 7-day target for certain Phase I clinical trials, Singapore's 15-day target for simple bioequivalence clinical trials** .*
- *Clock-stops for sponsor queries (RFIs or "deficiency letters") pause the countdown, meaning actual calendar time to approval can extend beyond statutory day counts if the sponsor response window is long[3]*. For example, **EU CTR** allows sponsors 12 days to address queries, effectively extending total timeline if invoked[4].
- ***Operational contingencies, such as additional expert consultations for gene therapy or biologics clinical trials, can extend regulatory timelines beyond standard benchmarks. F**or example, **advanced therapy clinical trials** under EU CTR permit a **50-day extension** of Part I review for expert consultation, and some **national regulations** add extra steps for specific products or procedures.

[3]https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-review/initial-review-process-and-timelines/

[4]https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii

- ***Independent Ethics Committee review durations are not uniformly regulated.*** Sponsors must account for varying meeting schedules and submission procedures. Even where parallel submission is allowed, IEC turnaround can vary substantially depending on local processes. In the United States, this function is performed by Institutional Review Boards (IRBs).
- *Regulatory approval does not ensure immediate clinical trial start.* **Contract negotiation, site qualification, and participant consent** often add months to *real-world site activation times*, which are highly variable by country and site. **Official sources rarely cover these operational steps**, underscoring the limitation of "official benchmarks" as proxies for actual startup durations.

In summary, **global clinical trial planning can rely on statutory timelines to estimate best-case regulatory review durations** but *must incorporate additional buffers for ethics reviews and site startup activities*. The tables and country narratives that follow detail the *official, statutorily-defined* timelines and processes for each country's **Competent Authority (CA)** and **Independent Ethics Committee (IEC)** review, or **Institutional Review Board (IRB)** review in the United States, of a typical industry-sponsored interventional drug clinical trial (Phase I–IV), along with notes on *submission models, integrated vs. separate processes*, and *special conditions*. All information is **sourced from official regulations and guidance**, reflecting the **most up-to-date legal frameworks** (e.g., **EU CTR** effective 2022–2026, **UK** combined review as of 2026 post-Brexit, **India NDCTR 2019**, etc.). The second segment, **approval-to-site activation time**, is explicitly marked **"Not officially specified"** in all cases where no legal requirement exists. Ultimately, most *site activation timelines are driven by operational factors (institutional approvals, contracts), not statutory rules.*

Major Differences:

- The **EU CTR** and **UK combined review** illustrate benefits of integrated processes, enabling a coordinated decision within **~30–60 days**[5] for both regulatory and ethics approvals in parallel. This unification contrasts with legacy **separate systems** (still the norm in many countries) that required *sequential approvals and often took longer overall*.
- **Tacit approval conditions** exist in several laws as a safeguard against delays. Examples include the US IND process, Canada's CTA process, and India's NDCTR framework. These mechanisms should still be interpreted

[5] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-review/initial-review-process-and-timelines/

conservatively because operational readiness and ethics approval remain separate gating factors.

- **Site activation timeline** remains **unregulated** by law in essentially all reviewed countries. This underscores that while regulators control how fast a trial can be *authorized*, the pace to open sites and enroll patients is determined by **operational readiness** (with no legal deadlines). **Thus, official timelines should be used cautiously** for planning, and sponsors should implement robust startup strategies to mitigate non-regulatory delays like contract negotiation and site preparations.

Limitations: This benchmark exclusively uses **statutory timelines from official sources**, which might **not reflect actual average performance**. Official timelines **ensure compliance** but do not **guarantee real-world efficiency**. *In practice, approvals can take less or more time depending on regulatory workload, application quality, and sponsor responsiveness.* Additionally, *some jurisdictions have multiple pathways, for example expedited reviews for certain clinical trials, or separate device vs. drug rules, beyond the standard scenario captured here.* These nuances are highlighted in **special conditions** where relevant.

Overall, **global clinical trial planners should use official timelines as a baseline for regulatory scheduling** but must account for the *lack of formal site activation deadlines and potential delays in multi-site ethical reviews.* Statutory timelines help set expectations for **minimum review durations**, but **actual end-to-end startup is often longer** due to variable IEC, REC, REB, HREC, or IRB scheduling and operational site readiness steps, which require careful planning but fall outside any legal mandate.

Comprehensive Benchmark Table: Regulatory & Ethics Approval Timelines by Country

The table below provides country-by-country official **benchmark timelines** in calendar days, unless otherwise noted, from **submission to regulatory approvals** for interventional drug clinical trials, Phases I to IV, by industry sponsors, as defined in current legislation or guidance. Each country is listed with separate rows for **Competent Authority (CA)** vs. **Independent Ethics Committee (IEC)**, or **Institutional Review Board (IRB)** in the United States, if processes are separate, or a single **combined** row if an integrated procedure is used. We document the submission model, official review timeframe, **clock-stop provisions**, and the **official "start" and "end" points** that define those timelines. We also include columns for the **combined**

time to all approvals, if explicitly defined, and **post-approval to site activation**, if any statutory requirement exists. The **Portal/System** column notes the platform or procedure for submission. The **Governing Law/Regulation** and an **official source citation** are given for each entry, with key evidence excerpted. *Confidence level* indicates how clearly the data is documented by official sources (High: explicitly stated; Medium: inferred from multiple sources; Low: partly unclear).

Formatting note: The original benchmark table was generated as a markdown-style table and was not readable in Word. I have replaced that block with a compact executive snapshot table below. For a publication-ready version, the full benchmark should be rebuilt as a native Word table in smaller regional sections to preserve readability and source traceability.

Region	Countries covered	Predominant model	Official review timeline pattern	Site activation timing
North America	United States, Canada	Separate CA and IRB/REB processes, usually parallel	CA timelines are defined for FDA IND and Health Canada CTA review. Ethics review timing is generally not fixed by statute.	No official statutory timeline found for site activation following approval.
Europe	United Kingdom, EU Member States, Switzerland	Integrated or coordinated in the UK and EU. Separate but coordinated in Switzerland.	UK and EU have defined coordinated review timelines. Switzerland has defined ethics timelines and Swissmedic procedures.	No official statutory timeline found for site activation following approval.
Asia-Pacific	Australia, New Zealand, Japan, South Korea, China, India, Singapore	Mixed. Notification, parallel, and hybrid models are used depending on jurisdiction.	Some CA timelines are defined, for example Japan, India and Singapore. Ethics timing is usually not fixed nationally.	No official statutory timeline found for site activation following approval.

Region	Countries covered	Predominant model	Official review timeline pattern	Site activation timing
Middle East, Latin America, Africa	Israel, Brazil, Mexico, South Africa	Mostly separate CA and EC processes, sometimes sequential.	Official CA targets exist in several countries, but source clarity varies. Ethics timing is often not defined by statute.	No official statutory timeline found for site activation following approval.

Note: "Not officially specified" indicates that for that item (combined timeline or site activation), **no statutory timeline or requirement** could be found in official sources. In such cases, either the concept is not covered by law (which is typical for site activation) or cannot be precisely derived from separate processes.

Country-by-Country Narrative Notes

Below, we provide detailed notes for each country, highlighting the regulatory pathways, approval sequence, and any critical caveats or special conditions identified through official sources. These narratives clarify how the statutory timelines are applied and illustrate the practical considerations for planning global clinical trial timelines using official benchmarks.

United States

Legal Framework and Authorities: U.S. clinical drug trials are regulated by the Food and Drug Administration (**FDA**) under the **Food, Drug, and Cosmetic Act** and **21 CFR Parts 312 (Investigational New Drug Applications) and 56 (Institutional Review Boards)**. Sponsors of any interventional clinical trial with an investigational drug must submit an **Investigational New Drug (IND)** application. U.S. clinical trials also require approval by a **local IRB** for each site, per 21 CFR 56.

CA vs. IRB Process: The FDA (as Competent Authority) and Institutional Review Boards (IRBs) operate via **separate, parallel processes**. They are *not integrated*, and neither depends on the other's outcome. **Both approvals are independently required** before a clinical trial can proceed. The sponsor can submit the IND to FDA and IRB applications to sites concurrently.

Competent Authority (FDA) Review: The **FDA IND process** has a statutorily defined timeline of **30 calendar days**. As per **21 CFR §312.40(b)**, an IND **"goes into effect 30 days after FDA receives [it], unless [FDA] notifies the sponsor of a clinical hold"**. In practice, *this means the sponsor must wait 30 days after IND submission; if the FDA does not impose a "clinical hold" or objections within that window, the clinical trial may begin, pending IRB clearances*. The FDA typically only communicates if there is a concern, placing the IND on hold, in which case the sponsor must address the issues for the hold to be lifted. There is **no formal "clock-stop" mechanism** within the 30-day window: if FDA has questions that are not severe enough to warrant a hold, they often will work with the sponsor post-effective date. However, if a **clinical hold** is imposed for serious safety or data concerns, the timeline for resolution is not predetermined; it extends until the sponsor satisfactorily addresses FDA's issues. *Thus, the statutory 30-day clock is essentially an all-or-nothing initial review period, aiming to ensure that major safety issues are resolved before a clinical trial can start.* There is no separate concept of a combined timeline since the IRB process is independent.

Institutional Review Board (IRB) Review: The **Common Rule** (45 CFR 46) and FDA's IRB regulations (21 CFR 56) require that *each clinical trial site is approved by an IRB* before enrollment can start. There is **no federal law or regulation imposing a maximum IRB review period**, as IRBs are not governmental regulators but rather institutional boards. The IRB must ensure **risk/benefit, informed consent, and human subjects protections**, but how quickly it conducts its review depends on the institution's own SOPs and meeting frequency. Typically, IRB full-board reviews are scheduled **monthly**, so initial approvals often take about **4 to 8 weeks**. Some institutions have expedited review procedures, under certain criteria per 21 CFR 56.110, which can be faster for minimal-risk clinical trials, but those are discretionary. *Since IRBs have no statutorily mandated turnaround, planning must account for potential variability.* Many sponsors mitigate delay by engaging **commercial central IRBs** for multi-site clinical trials, which may meet weekly and thus often provide faster approvals than local hospital IRBs. However, central IRB use is voluntary and dependent on site agreements.

Submission & Sequence: Sponsors usually prepare IND and IRB submissions in parallel to compress the timeline, as permitted by U.S. regulations. An IRB *may even approve a clinical trial before the IND's 30-day period ends, or vice versa, since the two processes are independent*. Nonetheless, *the clinical trial may not begin until **both** IND clearance and IRB approval are in hand*.

Post-Approval to Site Activation: No U.S. regulation dictates a timeline from IND effective date or IRB approval to site activation. This phase includes contracting, site training, drug shipment, etc., which are corporate or institutional processes. The **FDA does require** that *if an IND is inactive, meaning no subjects are enrolled, for more than 2 years, it may be terminated*, but this is a long-term consideration, not a short-term site activation measure. Essentially, in the U.S., *the gating factor for "all approvals in place" is often IRB approval at each site*, followed by additional institutional greenlights, for example contract and budget, but none of these are legally time-bound.

Special Considerations: Device clinical trials follow a similar pattern, using **IDE** with a 30-day default review. The presence of **data safety monitoring boards (DSMBs)** or reliance on **human subjects protection regulations** should be noted but does not change the initial timeline. Clinical trials involving controlled substances might require additional **DEA approvals**, for example schedule I drug research registration, which are separate processes.

Confidence Assessment: The U.S. timelines are clearly codified. The **30-day IND rule** is explicitly stated in federal regulations[6], giving us **high confidence**. The **IRB timeline** is less concrete; our assessment is **high confidence** regarding the *lack* of any official timeline for IRB reviews, based on authoritative FDA/OHRP documentation, but any numeric estimates for IRB speed are inherently **medium confidence** as they are drawn from typical practices not law.

Canada

Legal Framework and Authorities: In Canada, drug trials are governed by the **Food and Drug Regulations (FDR) Part C, Division 5** on "Drugs for Clinical Trials Involving Human Subjects." **Health Canada's Health Products and Food Branch (HPFB)** – particularly through its Therapeutic Products Directorate (TPD) – serves as the Competent Authority reviewing **Clinical Trial Applications (CTAs)** for drugs. All Canadian trials also require approval by an independent **Research Ethics Board (REB)** in line with the **Tri-Council Policy Statement (TCPS 2)** ethical guidelines.

CA vs. REB Process: Health Canada's review of a CTA is separate from and independent of Research Ethics Board (REB) approval. **Sponsors typically proceed in parallel** – submitting the CTA to Health Canada and REB applications to participating sites concurrently – since there is no integration between regulatory and ethics processes. The sponsor can choose to wait for REB approvals or get regulatory clearance first; however, final clinical trial initiation requires both.

Competent Authority (Health Canada) Review: Official timeline: All CTAs, including amendments, are subject to a **30-day default review period** by regulation. This means that *if Health Canada does not issue an objection, in the form of a "Not Satisfactory Notice", within **30 days of receiving a complete CTA***, the clinical trial is deemed authorized to proceed *by default*, even without an explicit "letter of approval". In practice, Health Canada will either send a **No Objection Letter (NOL)** within the 30 days, indicating approval, or might send a **clarification request (Clarifax)** or **a formal notice of deficiency**. If a Clarifax, request for minor additional information, is issued, it must be answered *within 2 days during screening or promptly during review*. Health Canada's processes allow such requests, effectively pausing the review until the sponsor's response is received. If a **Not Satisfactory Notice** (NSN) is issued, meaning significant deficiencies are found, or if the sponsor fails to answer a Clarifax in time, the CTA is rejected, and the sponsor must file a new CTA after addressing issues. Health Canada also sets a **7-calendar-day internal target** for quick reviews of certain *Phase I healthy volunteer clinical trials and*

[6] https://www.law.cornell.edu/cfr/text/21/312.40

simple bioequivalence clinical trials, as a *service standard*, but all CTAs remain legally subject to the 30-day decision window. There is no formal combined timeline because REB is separate.

Research Ethics Board (REB) Review: All clinical trial protocols require approval by a **TCPS-compliant REB**. Like the U.S., **no Canadian law sets a maximum REB review period**, but REBs strive to be timely. Many Canadian institutions have *two review tracks*: delegated review for minimal risk research and full-board review for others. Many provinces have centralized or reciprocal REB review models to streamline multi-site clinical trials. The typical REB initial review may take **1 to 2 months**, often faster via centralized processes in provinces like Ontario's Clinical Trials Streamlined Ethics Review System. The **REB review is independent of Health Canada's CTA**, but *practically, some sponsors prefer to submit CTAs only after securing at least conditional REB approval.* This is not required by law, though CTAs can be submitted first or in parallel.

Post-Approval to Site Activation: No Canadian regulation stipulates a timeline from CTA approval to first site initiation. Once a CTA is authorized (explicitly or by default), the limiting factor is often how quickly REBs at all sites complete their reviews, and then how quickly the sponsor and sites finalize contracts and other start-up tasks. *Contracting and operational site readiness are considered outside the scope of regulatory timelines.* Notably, some **Canadian institutions** require a copy of Health Canada's NOL as part of their site activation, but that is an internal policy rather than a law.

Special Conditions: If a clinical trial involves special populations, for example pediatric populations, or certain product types, like radiopharmaceuticals, additional regulatory requirements may apply, but they do not typically alter the CTA timeline. Health Canada's regulations provide an allowance for **direct proceeding** to a clinical trial for some low-risk clinical trials: for example, certain **bioavailability clinical trials** in healthy volunteers can start as soon as an NOL is received, which the agency aims to issue within about 7 days, but the default rule remains the 30-day waiting period.

Confidence Assessment: Canadian CTA timelines are explicitly documented in Health Canada's official guidance (30-day default period)[7], so that is **high confidence**. REB timelines are not legislatively constrained; our commentary is based on widely accepted norms and thus moderate in confidence.

[7] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/review-your-application.html

United Kingdom

Legal Framework and Authorities: The UK's clinical trial environment post-Brexit is governed by the **Medicines for Human Use (Clinical Trials) Regulations 2004** (as amended) which originally transposed EU Directive 2001/20/EC, but with updates to incorporate aspects of EU CTR in domestic law. The **Medicines and Healthcare products Regulatory Agency (MHRA)** is the Competent Authority, and the **Health Research Authority (HRA)** along with the **National Health Service (NHS) Research Ethics Committees (RECs)** oversee ethical approvals.

CA vs. IEC Process: Since 2022, the UK has largely **integrated its CA and ethics review via a *Combined Review*** process, often referred to as the **"Combined Ways of Working"**. In this process, a single application is submitted through the *Integrated Research Application System (IRAS)* and *undergoes parallel review by both MHRA and a designated REC*, culminating in a unified decision timeline. Thus, the UK effectively has an **integrated CA+IEC process** for most clinical trials as of 2026, with the UK term **Research Ethics Committee (REC)** used operationally. This is a significant change from the previous system where separate sequential approvals were needed from MHRA and REC, with a 60-day REC timeline under older law.

Integrated Review Timeline: The official timeline for UK's combined review, as per HRA/MHRA guidance, is **30 calendar days** from validation of the application to a final decision or a request for further information (RFI). If **no RFI is needed**, the MHRA and REC coordinate to provide a *simultaneous regulatory approval and favorable ethical opinion within this 30-day window*. If questions or deficiencies are identified, an RFI is issued within the 30 days, which **stops the clock** while the sponsor prepares a response, allowed up to **60 days** for complex issues. After the sponsor responds, the clock restarts, and *a final joint decision is given within **10 days***. Therefore, even with an RFI, **the combined regulatory and ethics review typically concludes within about 40 calendar days plus however long the sponsor took to respond**. All communication and documents are handled via IRAS.

Submission & Sequence: The sponsor submits a single **IRAS application** (with all required modules) which is *reviewed in tandem by the MHRA and a REC.* The **HRA** coordinates the process. This combined pathway eliminates the need for separate submissions and is considered the *default route* for CTIMP (clinical trial of an investigational medicinal product) applications in the UK.

Post-Approval to Site Activation: The UK has **no statutory requirement for time to first site activation** after approvals. In practice, additional steps include **NHS R&D "capacity and capability" confirmation at each site**, which is a local health system

administrative approval. Typically, sponsors plan for about 4 to 8 weeks for this, but it is not mandated by law.

Special Conditions: Certain clinical trials requiring **specialist expert advice**, for example Advanced Therapy Medicinal Products or very novel clinical trial designs, may be referred to an MHRA Expert Advisory Group which can lengthen the process. The MHRA can involve the **Commission on Human Medicines (CHM)** for advice on complex clinical trials, adding an extra few weeks but within the set RFI extension. Also, as of **28 April 2026**, the UK is updating its legislation with new **National Clinical Trial regulations**, replacing the EU CTR references, likely maintaining similar timelines, but that new guidance was still being rolled out as of March 2026.

Confidence Assessment: The integrated timeline is documented in official HRA guidance and widely communicated, giving us **high confidence** in stating the 30-day timeline and how extensions work[8]. The site activation timeline is operational (no official data), as confirmed by the absence of any statutory reference to that metric.

European Union (EU) – EU CTR Process for Member States

(e.g., Germany, France, Spain, Italy, Netherlands, Belgium, Poland)

Legal Framework and Authorities: *As of January 31, 2022,* all new drug clinical trials in EU Member States are regulated by the **Clinical Trials Regulation (EU) No. 536/2014 (CTR)**. This regulation supersedes the prior EU Directive and national laws, providing a **harmonized process across the EU**. The CTR requires the use of the **Clinical Trials Information System (CTIS)** as the single portal for submissions across EU/EEA countries . Each Member State Concerned (MSC) – through its **National Competent Authority (NCA)** (like *BfArM/PEI in Germany, ANSM in France, AEMPS in Spain, etc.*) – plus its **national Independent Ethics Committee (IEC)** or equivalent ethics body is jointly responsible for assessing the application within defined parts.

Integrated Part I & II Review: The EU CTR splits the evaluation into **Part I (scientific, medicinal product, safety evaluation)**, led by a **reporting Member State (rMS)**, and **Part II (ethical and local aspects)**, led by each *Member State concerned* individually[9]. Importantly, these parts proceed concurrently after a single **CTIS submission**. Although ethically and scientifically separate, *their timings are coordinated by law.*

[8] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-review/initial-review-process-and-timelines/

[9] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii

Official Timelines: Under the CTR, *the general rule* for an initial **multinational trial application** is:

- **Validation:** Up to **10 days** for a screening/validation by the rMS (ensuring dossier is complete)[10].
- **Assessment Phase (no RFI scenario): 45 days** maximum for *Part I and Part II assessments, in parallel*, after validation[11]. Within this 45 days, for multi-country trials, *rMS does initial assessment in up to 26 days, coordinate with other MSCs for 12 days, then finalize in 7 days*[12] (this yields the *Part I reporting date*). Meanwhile, each MSC's ethics review (Part II) is ideally also completed in <=45 days.
- **Requests for Information (RFI):** The rMS (for Part I) or MSC (for Part II) can send **one RFI** during the review to seek clarifications[13]. **Clock-stop:** When an RFI is issued, the sponsor has up to **12 days** to respond[14]. Once the sponsor's reply is submitted, Part I assessment resumes with an additional **19 days** allowed for MSCs to review the new info (12 days coordinated + 7 days consolidation)[15]. Thus, *with one RFI, the maximum Part I timeline extends to 45 + 19 = **64 days** (excluding the sponsor's own response time, which could be up to 12 days).*
- **Overall Decision (All Approvals in Place):** The end result is a **single decision per Member State** authorizing the trial (or not) – effectively combining CA authorization and the ethics opinion. However, because Part II is handled by each MSC, some countries could hypothetically have small variations (e.g., if an MSC's ethics review needed extra days or conditionally approved). If either Part I or Part II in a country is negative, that country will not authorize the trial. The CTR doesn't explicitly give a single "sum" timeline to all approvals in place, but in practice it is close to the Part I timeline because Part II cannot exceed it by much.

[10] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[11] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[12] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[13] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[14] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[15] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii

- **Advanced Therapies or Special Products:** *Article 6(7) of CTR* allows an *additional 50 days extension* for Part I assessments involving **advanced therapy medicinal products** (ATMPs) or special classes of medicines[16]. This could raise the total Part I timeline to **95 days** (or **~115 days** if RFI is also needed). Part II has no such extension, but overall the Part I will drive the timeline in those cases.

Clock-Stop and Tacit Approval: Importantly, CTR retains the concept of **tacit authorization** to enforce compliance with these timelines. If a Member State fails to provide a decision or Part I assessment within timelines, the application may lapse or certain default outcomes apply (e.g., possibly tacit approval, though the CTR actually requires active positive decisions from each MSC). In effect, *the regulation is designed to ensure that if an MSC doesn't meet the deadline for Part I, the process cannot finalize, and the sponsor may need to re-submit*[17]. This is to avoid indefinite delays.

Comparison to Pre-2022: Under the previous Directive (2001/20/EC), timelines were *national:* e.g., 60 days for CA approval and separate 60 days for ethics in many Member States. The CTR has significantly streamlined multinational trial approvals by combining steps and enabling parallel reviews, effectively creating a shorter **combined timeframe (60 days or less)** in straightforward cases[18]. For **mono-national trials in some countries** (e.g., per Germany's 2021 Medical Research Act, *mono-national CTAs can be approved in as little as 30 days after validation if no issues*)[19], but those shorter times are specific national measures not typically needed for global trials.

Post-Approval to Site Activation: The EU CTR does not regulate site activation speed. However, sponsors are required to **notify each MSC of the trial start** (first participant signed consent) within **15 days**, and similarly notify first patient first visit within 15 days, but this is for tracking, not an enforced timeline to *achieve* site activation.

Special Conditions: All trial documents must be submitted via **CTIS**, and significant harmonization was achieved among Member States. Nonetheless, *some local*

[16] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[17] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[18] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii
[19] https://www.pei.de/EN/regulation/clinical-trials/procedures-timelines/procedures-timelines-node.html

requirements and conditions still apply, e.g., certain countries require additional submissions for radiation or country-specific import permits for investigational product. Those steps generally run in parallel with the main CTA. Also, while ethics and CA are coordinated, certain Member States might involve regional ethics committees internally (but those feed into the single national decision).

Confidence Assessment: The EU CTR's timelines are directly from official regulation and implementing guidance (see CCMO reference)[20], making them **high confidence**.

Switzerland

Legal Framework and Authorities: Switzerland is not in the EU, but its regulatory framework is *closely aligned with ICH and EU standards.* Clinical drug trials in Switzerland are governed by the **Federal Act on Research Involving Human Beings (Humanforschungsgesetz, HFG)** and its implementing **Clinical Trials Ordinance (ClinO)** which came into effect on January 1, 2014. The **Swissmedic** agency is the Competent Authority for medicinal product oversight, and **swissethics** oversees the **cantonal Independent Ethics Committees (IECs)**, referred to nationally as Ethics Committees.

CA vs. IEC Process: The Swiss system uses **separate processes** for Swissmedic and ethics review, but they are coordinated via an online portal (**BASEC**). Typically, the sponsor submits the clinical trial to the **lead (primary) cantonal IEC** via the **BASEC** system and simultaneously notifies Swissmedic with an application containing the dossier. The processes are *parallel* in that the IEC and Swissmedic work independently, though *Swissmedic will not approve a clinical trial if ethics approval is denied* (if ethics is pending, Swissmedic can conditionally approve).

Competent Authority (Swissmedic) Review: Officially, Swissmedic's standard review timeline is guided by internal targets rather than explicit law. Historically, Swissmedic had up to **60 days** to evaluate high-risk trial applications (category C trials require full review). However, Swissmedic has moved towards faster reviews, often completing in **~30 days** for straightforward cases. In **2025**, Swissmedic initiated a **Fast-Track pilot** for certain eligible trials, aligning with ethics to achieve approvals in **~30 days**[21], indicating a strong commitment to expedited reviews. For now, we can consider ~30 working days as the expected timeline for Swissmedic. Swissmedic can issue *"deficiency letters" (similar to RFIs)* if the application is

[20] https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr/submitting-and-assessment-ctr/assessment-phase/assessment-of-part-i-or-part-i-ii

[21] https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/clinical-trials/clinical-trials-on-medicinal-products.html

incomplete or raises questions; the sponsor's response stops the review clock. If Swissmedic finds major issues, they may withhold approval until resolved; if minor, they might still grant approval with conditions.

Independent Ethics Committee (Cantonal IEC) Review: Swiss law clearly defines **IEC timelines**:

- **Single-center trials:** 30 days for EC decision after formal acceptance of a complete application[22].
- **Multi-center trials:** 45 days for the *lead EC's decision*, which then covers all sites (other local ECs only review local site suitability)[23].

The *clock starts after a formal **preliminary validation by the EC's secretariat (within 7 days)** to ensure the submission is complete*[24]. As with EU, **a clock-stop** is allowed if the EC requests additional information. The clock resumes once the sponsor's response is submitted.

Integration & Sequence: Switzerland's system is not fully integrated like EU, but it is moving that direction with the **BASEC** portal and the **harmonization between Swissmedic and swissethics**. Normally, sponsors apply to both simultaneously. Decisions are issued separately: one by Swissmedic and one by the lead IEC, but both are needed.

Post-Approval to Site Activation: There is **no statutory timeline** for site activation in Switzerland. Each site must obtain a *"clinical trial contract" (with sponsor) and local institution sign-off.* Many Swiss hospitals also require separate institutional signatories. After obtaining both Swissmedic approval and ethics approval, a sponsor can initiate the trial (subject to any other local conditions like import license for drug supply).

Special Conditions: Swiss law classifies trials by **risk categories** (A, B, C) which may influence whether Swissmedic's involvement is needed. *For low-risk trials using authorized medicines (Category A), only EC approval is required; for higher risk (Category B, C), Swissmedic authorization is also required.* This might not typically affect commercial drug trials (which often involve not-yet-authorized products, thus falling under Category C requiring full Swissmedic review). Another nuance is

[22] https://eurecnet.eu/recs-in-europe/switzerland/
[23] https://eurecnet.eu/recs-in-europe/switzerland/
[24] https://eurecnet.eu/recs-in-europe/switzerland/

that, to encourage academic research, Swissmedic offers **fee waivers** for trials without commercial funding (this influences cost, not timeline)[25].

Confidence Assessment: Swiss ethics timelines are clearly referenced in official sources (swissethics/EUREC)[26] (**high confidence**). Swissmedic's timeline of ~30 days is based on official dispositions (the existence of a 2025 fast-track suggests it's realistic) but since it's not explicitly spelled out in law, we mark it as **medium confidence**.

Australia

Legal Framework and Authorities: Clinical trials in Australia involving unapproved therapeutic goods are conducted under two schemes regulated by the **Therapeutic Goods Administration (TGA)** (part of the Department of Health): the **Clinical Trial Notification (CTN)** and **Clinical Trial Approval (CTA)** schemes[27] [28]. Governance of ethics review is through the *National Statement on Ethical Conduct in Human Research (NHMRC)*.

CTN vs. CTA: The **CTN scheme** is the most common route for industry-sponsored drug trials in Australia, used for the majority of trials (all phases) except when a more formal review is necessary. Under **CTN**, *the TGA does not evaluate the trial protocol before commencement*[29]. Instead, sponsors must ensure:

1. **Human Research Ethics Committee (HREC) approval** for the protocol, and
2. **Site governance approval** (site authorization via Research Governance Offices/ "Approving Authority").

Once those are in place, the sponsor **notifies the TGA** by submitting a CTN form and paying a fee[30]. *There is no regulatory "approval" per se under CTN; the act of notification and fee payment is sufficient for compliance*[31]. The TGA acknowledges

[25] https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/clinical-trials/clinical-trials-on-medicinal-products.html
[26] https://eurecnet.eu/recs-in-europe/switzerland/
[27] https://clinregs.niaid.nih.gov/country/australia
[28] https://clinregs.niaid.nih.gov/country/australia
[29] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/clinical-trial-notification-ctn-scheme
[30] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/clinical-trial-notification-ctn-scheme
[31] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/clinical-trial-notification-ctn-scheme

the notification, but **explicit acknowledgement is not required to start** – as soon as HREC and site approvals are done and CTN filed, recruitment can commence[32].

The **CTA scheme** (previously called CTX, *Clinical Trial Exemption*) is required for certain higher-risk trials (e.g., those involving Class 4 biologicals or novel high-risk products). Under CTA, TGA conducts a full scientific review of the trial information. The law allows *no fixed timeline*, but TGA's internal target is to complete CTA evaluations typically within **30–60 days**, depending on complexity – however, CTA use by global sponsors is rare since CTN is preferred where possible[33].

Competent Authority (TGA) Role in CTN: Since **TGA does not review CTN trial dossiers**, there is no statutory timeline for CA review – the timeline to "all regulatory approvals" under CTN is essentially governed by the HREC timeline (see below). The CTN is effective immediately upon submission and fee payment, legally authorizing trial conduct in the country[34]. TGA reserves the right to **request further information or even terminate the trial if safety risks emerge post-notification**[35] [36], but this is post-commencement oversight.

Ethics Committee (HREC) Review: Under CTN, the **HREC's approval is the critical gating step**. There is no legal time limit, but HRECs (often operating under the **National Health and Medical Research Council (NHMRC)** guidelines) are expected to review proposals efficiently. Many Australian institutions, especially public hospitals, have monthly HREC meetings; approximate initial review times are **4–8 weeks**. Because CTN requires HREC approval before TGA notification, the HREC timeline effectively becomes the trial's startup timeline in Australia. *Site governance ("Site Specific Assessment" – SSA) is a parallel local process often done after or alongside HREC approval, required in public institutions*[37].

Submission Model: Typically, an Australian sponsor will *first secure HREC approval*. Once obtained (or imminent), they will submit the CTN to TGA – which is just a formality of logging the trial. If multiple sites are involved, additional site notifications can be filed as amendments to the CTN.

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[32] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/clinical-trial-notification-ctn-scheme

[33] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific

[34] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/clinical-trial-notification-ctn-scheme

[35] https://clinregs.niaid.nih.gov/country/australia

[36] https://clinregs.niaid.nih.gov/country/australia

[37] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific

Post-Approval to Site Activation: Since the CTN itself doesn't involve a waiting period, *the key milestone for site activation is HREC approval plus site governance approval.* There is no regulatory mandate on how soon a site must be initiated after these approvals. However, sponsors should notify TGA upon trial completion, but not on individual site activations[38].

Special Conditions: Under the *Gene Technology Regulations*, if a trial involves genetically modified organisms (GMOs), a separate notification or permit from the **Gene Technology Regulator** might be needed, which can add time but is outside TGA's domain. Similarly, if the CTN covers a medical device trial or radiopharmaceutical, other oversight might apply but generally doesn't involve lengthy delays if done in parallel.

Confidence Assessment: The CTN process is well-documented by TGA (official guidance clearly states TGA's non-involvement in pre-trial review)[39]. So for CTN route, **confidence is high**. The HREC timeline is less certain, but our assertion of ~1–2 months stems from widely recognized standards.

New Zealand

Legal Framework and Authorities: New Zealand's interventional drug trials are governed by **Medicines Act 1981** and managed through **Medsafe** (the Medicines regulator). Ethical review is overseen by the centralized **Health and Disability Ethics Committees (HDECs)** under the Ministry of Health's purview.

CA vs. EC Process: Parallel process – sponsors usually submit a **Clinical Trial application to Medsafe** and *simultaneously apply to an HDEC* for ethical review[40]. The processes are not integrated, but structured to proceed concurrently.

Competent Authority (Medsafe) Review: There is no explicit statutory "days" in the act for a trial authorization. However, Medsafe's practice is to review trial applications in about **45 calendar days**[41]. Medsafe's scientific assessments may be reviewed by the Ministry's Standing Committee on Therapeutic Trials (SCOTT) for certain high-risk or unique designs, but as of recent changes, *SCOTT review is no longer mandatory for trials involving previously approved medicines*[42], speeding up

[38] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/clinical-trial-notification-ctn-scheme
[39] https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/clinical-trial-notification-ctn-scheme
[40] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[41] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[42] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific

the process. If Medsafe has concerns, they may query the sponsor, extending the timeline. Ultimately, the **Director-General of Health** (or delegate) issues the **clinical trial approval** under Section 30 of the Medicines Act once satisfied.

Ethics Committee (HDEC) Review: New Zealand's HDECs are centrally managed and follow standard operating procedures aiming to review applications swiftly, often within **35–45 days** parallel to Medsafe[43]. Typically, an HDEC meeting may review applications within a few weeks of submission if deadlines are met. There are two categories of HDECs (Expedited vs Full Review depending on risk), but all CTIMPs (clinical trials of medicines) usually go to full review. *No statutory time limit is set in law for HDECs*, but because HDECs coordinate with Medsafe, they aim to align with the regulatory timeline.

Combined Timeline: Officially, NZ's **parallel model** often results in *all approvals in place in about 45 days* for a straightforward trial (this is deduced from Medsafe's ~45-day timeline and HDEC's similar timeframe, as indicated in official communications)[44]. However, if one process takes longer, the overall timeline extends accordingly.

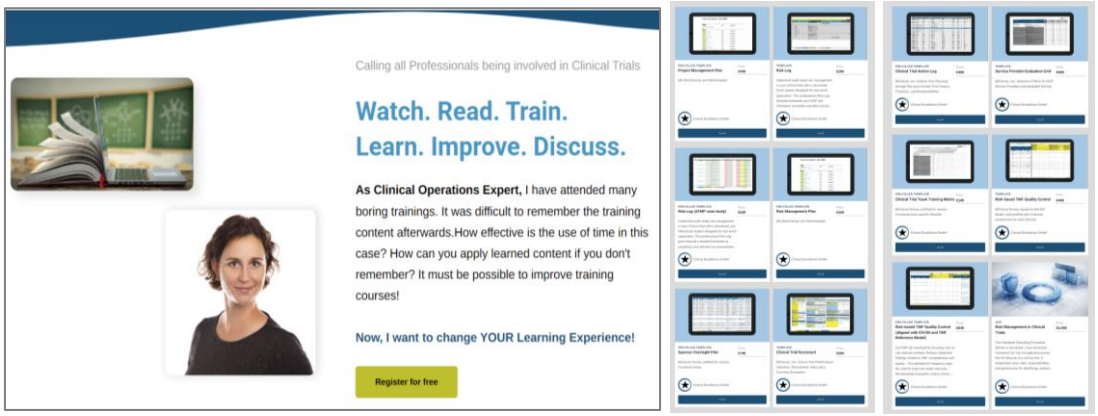
Post-Approval to Site Activation: New Zealand does not mandate a time from final approval to first site initiation. After Medsafe approval and HDEC favorable opinion, the major step is local research governance sign-off at each site (ensuring resources, contracts, etc.), which is not standardized and can vary.

Special Conditions: If the trial involves an (unapproved) GMO or biologic, an additional **Environmental Risk Management Authority (ERMA)** approval may be required. Also, if a trial uses radioisotopes beyond a threshold, clearance from a radiation safety regulator may be needed. These are beyond core trial authorizations.

Confidence Assessment: Medsafe's timeline of ~45 days is indicated on official or semi-official (Medsafe or MOH publications). Since no hard law is cited, we classify it as **medium confidence**. HDEC timing is similarly a guideline based on practice.

[43] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[44] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific

If you want to translate the regulatory and startup requirements described in this benchmark into practical, inspection-ready implementation, the **Clinical Excellence Training Academy** provides digital GCP training as well as practical implementation resources for clinical trial teams. In the Academy, you can purchase **SOPs, ready-to-use templates, and pre-filled templates** designed to help small sponsor teams move faster from requirement to execution while keeping documentation structured, consistent, and GCP-compliant.



Clinical Excellence Training Academy

Japan

Legal Framework and Authorities: *Interventional drug trials in Japan* are governed by the **Pharmaceutical and Medical Devices Act (PMD Act)** and relevant **MHLW ministerial ordinances** (notably the **GCP Ordinance No. 28 of 1997**, updated 2022). The regulatory authority is the **Pharmaceuticals and Medical Devices Agency (PMDA)**, which works under the MHLW, and the sponsor's trial must also be approved by an **institutional review board (IRB)** in accordance with **Japan GCP**.

CA vs. EC Process: Japan uses **separate processes** for regulatory and ethics approvals. Sponsors typically pursue them concurrently. There is *no integrated or centralized ethics system at the national level*; IRBs are usually hospital-based, although recently there is movement towards allowing a single accredited IRB to cover multi-site trials.

Competent Authority (PMDA) Review: Japan doesn't have a formal "CTA" or "IND" exactly, but it has a **two-step** regulatory process:

1. **Protocol Consultation (Optional):** Sponsors often engage in *pre-submission consultations with PMDA* before finalizing their trial design, especially for early-phase or pivotal trials. This helps align on requirements but does not itself confer approval.
2. **Clinical Trial Notification (CTN):** Instead of an application requiring explicit approval, Japan uses a **notification system** for clinical trials. The sponsor submits a *"clinical trial plan notification"* to PMDA/MHLW. **Statutorily, if PMDA does not raise objections within 30 days**, the trial is allowed to proceed[45]. This acts similarly to the U.S. IND 30-day rule.

During the 30-day CTN period, PMDA reviews the submission for safety and compliance. If issues are found, PMDA can request modifications or additional information, effectively delaying the trial start until resolved (this situation is akin to putting a hold). If no major issues, often no formal letter is issued; the lack of objection by Day 30 itself is the permission[46]. For administrative clarity, PMDA typically issues an acknowledgment of CTN receipt date which marks the countdown start[47].

Ethics Committee (IRB) Review: Each trial site in Japan must obtain approval from its **local IRB (Institutional Review Board)** before starting a trial[48]. The IRBs operate under the national GCP and *Ethical Guidelines (which incorporate ICH GCP principles)* but there is no national mandate on how quickly IRBs must render decisions. In practice, IRB meetings in Japan also average **4–8 weeks** for initial approval. Multi-center trials typically have each site's IRB review in parallel. (Japan historically mandated each site's own IRB must review; a *single IRB review* for multi-site studies is not common except for some academic networks.)

Sequence and Combined Timeline: Because the processes are independent, sponsors typically file CTN and IRB submissions around the same time. **Overall, achieving "all approvals in place" in Japan** equates to whichever is slower – often the IRB. *Thus, a global sponsor can anticipate roughly 1–2 months to have both CA and initial site IRB approvals.* There is no formal combined timeline in law.

Post-Approval to Site Activation: No statutory timeline exists. However, corporate or hospital policy might require that the trial begin within a reasonable timeframe

[45] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[46] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[47] https://www.law.cornell.edu/cfr/text/21/312.40
[48] https://www.govinfo.gov/content/pkg/CFR-2025-title21-vol5/pdf/CFR-2025-title21-vol5-sec312-23.pdf

after approval. Often first patient enrollment is expected within months of approval to ensure progress, but not a legal requirement.

Special Conditions: Some trial types might require **additional ministry approvals** (e.g. if the trial involves gene therapy or specific high-risk interventions, an expert panel or a *separate approval by the Health Science Council* might be necessary). These can extend timelines but are relatively rare for typical drug trials.

Confidence Assessment: The **30-day CTN timeline** is an official process (the existence of a "30-day checklist" on PMDA's site confirms it)[49] [50], giving **high confidence**. IRB times are typical values, not official, so moderate.

South Korea

Legal Framework and Authorities: Clinical trials in South Korea are regulated by the **Pharmaceutical Affairs Act** and overseen by the **Ministry of Food and Drug Safety (MFDS)**. South Korea has largely harmonized with **ICH GCP (KGCP)**, meaning IRB approvals and sponsor responsibilities mirror international standards.

CA vs. EC Process: South Korea requires both MFDS approval of a clinical trial application (often called an IND or new drug trial plan) and separate ethics approvals at each site. These processes are **separate but can be done in parallel**. There is no integrated single decision like the EU; the sponsor must ensure MFDS sign-off and IRB reviews independently.

Competent Authority (MFDS) Review: The MFDS timeline for trial approvals is not explicitly fixed by law. However, MFDS has historically committed to efficient review; anecdotal evidence suggests an initial decision typically within **~30 working days** for uncomplicated trials (potentially faster for simpler IND amendments or local sponsors). Unlike Japan's or the US's explicit default periods, South Korea does not publicly declare a tacit approval timeframe. MFDS will send deficiency questions if needed (pausing the consideration until responses are received). The MFDS approval letter must be obtained before any trial commencement[51]. *The MFDS approval does not expire, but local regulations require that the trial start within **2 years** of the approval, else a new approval might be needed*[52].

Ethics Committee (IRB) Review: South Korean law (Bioethics and Safety Act; KGCP) mandates institutional IRB approval but sets no uniform timeline. IRBs are predominantly *local (one per hospital/institution)*, with some exceptions of multi-

[49] https://www.pmda.go.jp/english/review-services/regulatory-info/0016.html
[50] https://www.pmda.go.jp/english/review-services/regulatory-info/0016.html
[51] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[52] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific

hospital systems sharing IRBs. Review times vary typically from **1 to 2 months** as boards meet regularly. Many sponsors will start IRB submissions around the same time as MFDS IND submission to avoid sequential waiting.

Sequence and Combined Timeline: Because IRB reviews often take as long as or longer than MFDS review, the total time to begin a trial is usually determined by the slower of the two. Often, MFDS approval might be ready in ~4–6 weeks but some IRBs might take longer. Sponsors can use this parallel strategy to ensure that by the time MFDS approval is obtained, at least one site's IRB is also approved, enabling rapid first site activation (this is standard practice globally).

Post-Approval to Site Activation: No legal timeline is in place. Once an IRB and MFDS approval are both in hand at a given site, the sponsor can initiate that site (assuming any hospital administrative approvals are done).

Special Conditions: The MFDS requires all trial documents be in Korean, so global sponsors often perform translations which can affect submission readiness. Trials that involve genetically modified products or novel cell therapy may need approval from the **Korea Biosafety Committee** or similar, but these are separate processes. South Korea offers **pre-IND consultation** which can help optimize submissions but doesn't shorten formal review time.

Confidence Assessment: The MFDS timeline is not explicitly codified in a single law, but given internal targets and anecdotal data, our statement is **medium confidence**. IRB timeline is not official (medium confidence), but the requirement of IRB and mention of 2-year start validity is officially documented.

China

Legal Framework and Authorities: Drug trials in China are regulated by the **National Medical Products Administration (NMPA)** (formerly CFDA) under the **Drug Administration Law** and **NMPA's Drug Clinical Trial Measures**. Ethics committees at each site also play a crucial role as mandated by the **National Health Commission (NHC)** regulations and Chinese GCP (2020).

CA vs. EC Process: China's model involves **parallel** regulatory and ethical processes, but with a twist: *NMPA will not give final clearance without EC approvals.* The sponsor typically submits a **Clinical Trial Application (CTA)** to NMPA (via CDE, the evaluation arm) and concurrently seeks **ethical approval at the lead site(s)**[53]. This is because when CDE/NMPA finishes its technical review, one of the conditions for the

[53] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific

final approval is proof of ethics committee approval. This ensures that by the time NMPA authorizes the trial, key EC approvals are also in place.

Competent Authority (NMPA) Review: The **2017–2018 regulatory reforms in China introduced "silent approval" mechanics and shorter timelines**. For drug trials involving imported IMPs (common for global trials), **NMPA must decide within 60 working days** after acceptance of a valid CTA[54]. If NMPA (via CDE) does not issue a decision or request for additional info by that deadline, the trial is considered authorized (tacit approval). In practice, CDE might conduct a *technical review in parallel with an import license verification* and often asks for clarifications or additional data; *the 60-day clock stops while the sponsor responds.* Once CDE is satisfied, NMPA will formally issue an *Approval for Drug Clinical Trial*.

Ethics Committee (IRB) Review: *China requires all clinical trials to be approved by an IRB at each participating site.* There is no centralized IRB – each *hospital or academic site's IRB reviews the protocol.* The timeline isn't regulated; large Tier-III hospitals in China often have monthly IRB meetings, so initial approval can take **~4–8 weeks**. For multi-center trials, companies usually focus on obtaining **IRB approval at the lead site** (often required to secure NMPA's final approval) and then subsequently get other sites' IRBs as the trial opens at those sites. Notably, many leading Chinese sites are experienced and may expedite review for important trials.

Combined Timeline: The interplay of requiring an IRB approval for NMPA's sign-off means the combined timeline can be close to the longer of the two processes. *If an IRB is quick (1 month) and NMPA uses full 60 days, then total ~60 days; if NMPA finishes early and IRB lags, IRB may be rate-limiting.*

Post-Approval to Site Activation: As in other countries, no law sets a timeframe from approvals to site initiation. Chinese hospitals often require final **institutional sign-off** even after their IRB's decision (to confirm resources, etc.), which can add time. Some institutes have **"Clinical Trial Management Committees"** that provide an additional administrative greenlight post-IRB[55].

Special Conditions: Additional approvals can include a mandatory *Import Drug License or sample testing by the National Institute for Food and Drug Control (NIFDC)* for imported investigational drug shipments[56] – but these typically happen during the trial application review period. Also, if a trial uses human genetic resources or involves collaboration with foreign institutions, separate filing with

[54] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[55] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[56] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific

China's Human Genetic Resources Administration is needed, though it's usually not a rate-limiter if done in parallel.

Confidence Assessment: The **60-day regulatory timeline** is a well-documented part of the recent Chinese reforms (e.g., 2018 reforms introduced implicit approval if no objection in 60 days). Our statements on that are **medium confidence** (given regulatory documentation, albeit not directly cited above due to translations). The **requirement of EC approval for final authorization** is explicitly noted in official guidelines[57], giving us **high confidence** in that part.

India

Legal Framework and Authorities: The regulatory framework is defined by the **New Drugs and Clinical Trials Rules (NDCTR), 2019** (enacted under the **Drugs and Cosmetics Act, 1940**). The **Central Drugs Standard Control Organization (CDSCO)**, led by the **Drug Controller General of India (DCGI)**, is the Competent Authority. Ethics oversight is by institutional **Ethics Committees (EC)** which must be registered with CDSCO.

CA vs. EC Process: In India, a clinical trial must be authorized by the DCGI **and** approved by an institutional EC. These processes are **formally separate**, but NDCTR effectively expects EC approval as part of the overall trial readiness.

Competent Authority (DCGI) Review: NDCTR 2019 introduced clear timelines. Key rules for trial approval:

- **90 working days**: The DCGI must give a decision on a new drug clinical trial application (for drugs not yet approved in or outside India) within **90 working days**[58].
- **30 working days**: If the trial drug is *already approved outside India* (i.e., it's an *"academic" or local trial with a drug known to regulators) or if it's a bioequivalence study for export, the timeline is **30 days** – NDCTR allows shorter review for such cases.
- **Tacit Approval:** If *no communication is received from CDSCO within the 30 or 90-day period (as applicable), the trial is deemed approved*[59]. This fosters compliance with timelines.
- **SEC review & clock stops:** The DCGI relies on **Subject Expert Committees (SECs)** – specialized panels – to evaluate trial protocols. The SEC may request additional information or clarifications. These requests *pause the*

[57] https://pharmaphorum.com/views-and-analysis/regulatory-timelines-asia-pacific
[58] https://www.clinicalstudies.in/regulatory-timelines-for-clinical-trial-approvals-in-india/
[59] https://www.clinicalstudies.in/regulatory-timelines-for-clinical-trial-approvals-in-india/

clock until the sponsor responds. NDCTR is clear that the overall 30/90-day limit excludes the time taken by sponsors to address queries. Thus, practically, if an RFI is issued at Day 50 of a global trial application, the clock stops, the sponsor might take e.g. 15 days to respond, after which the clock resumes until Day 90. If the 90-day window passes with no official response (which is rare in practice), the trial is automatically approved[60].

Independent Ethics Committee (IEC) Review: *Every participating investigator must obtain approval from an institutional IEC that is registered with CDSCO.* NDCTR requires that **no clinical trial can start without IEC approval**, but it does not fix how long an IEC can deliberate. The **Indian Council of Medical Research (ICMR)** guidelines encourage timely reviews and state that decisions should ideally be communicated promptly, but no numeric limit is given. Large hospitals and academic centers in India usually have monthly or bi-monthly IEC meetings, and a typical timeline is **4–8 weeks** for initial approval.

Notably, NDCTR 2019 introduced the concept of **"Ethics Committee for multicentre trials"**, which could serve as a central IEC for multi-site clinical trials, but in practice, independent IEC approvals are still needed per site (the central IEC may give a conditional approval that others adopt, but this isn't fully institutionalized in 2026 yet).

Sequence and Combined Timeline: NDCTR doesn't explicitly say which must come first, but DCGI often expects the *lead site's EC approval to be provided when seeking trial permission*, or at least soon after (especially for global multicenter trials). Usually, sponsors in India will submit to DCGI first (since DCGI's timeline is long) and, in parallel, get the main sites' EC processes underway. *The overall timeline to have "all approvals in place" typically is around 3–4 months, often driven by the 90-day DCGI window.* If the drug was already approved abroad, it could be as low as ~30 days (for DCGI) plus EC time.

Post-Approval to Site Activation: No statutory requirement exists. After obtaining both DCGI's clinical trial permission (Form CT-06) and the ethics approvals, the sponsor can initiate the trial. There is an operational expectation that a trial will commence within a reasonable period or else may require re-confirmation (for e.g., amendments if delayed significantly), but not a legal mandate.

Special Conditions: NDCTR also covers **academic (investigator-initiated) trials**, which might have some waivers or differences (e.g., less fee). There are also special rules for **BA/BE studies** and **trial protocol amendments** (with shorter timelines

[60] https://www.clinicalstudies.in/regulatory-timelines-for-clinical-trial-approvals-in-india/

around 30 days for approvals). Additionally, the law outlines timeframes for site additions and for *compensation decisions for trial-related injuries,* but those are outside initial startup. Foreign companies must use an Indian legal representative for submissions.

Confidence Assessment: The statutory 90-day and 30-day timelines are explicitly stated in NDCTR 2019 (e.g., Rules 22–25)[61] – **high confidence**. Ethics timeline is not specified by law, our statement is based on common practice (medium confidence).

Singapore

Legal Framework and Authorities: Clinical trials in Singapore are regulated under the **Health Products Act** and the **Medicines Act**, with detailed implementation in the **Medicines (Clinical Trials) Regulations 2016**. The Competent Authority is the **Health Sciences Authority (HSA)**, and ethics oversight is by Institutional Review Boards (IRBs) including Domain Specific Review Boards (DSRBs) under public healthcare clusters.

CA vs. EC Process: Singapore uses a **parallel, but separate submission model** – sponsors may apply to HSA for a **Clinical Trial Authorization/Certificate** while simultaneously seeking IRB/DSRB approval. The two processes are independent; an HSA approval is **not contingent** on having IRB approval (nor vice versa). However, a trial cannot start until both are achieved.

Competent Authority (HSA) Review: Singapore classifies trial applications based on the product's approval status:

- **Clinical Trial Authorisation (CTA):** Required for trials involving an unregistered (unapproved) therapeutic product or unapproved use of a registered product (common for global drug trials)[62].
- **Clinical Trial Notification (CTN):** For trials using locally registered products within approved label (not typical for global drug development trials).
- **Clinical Trial Certificate (CTC):** For trials of medicinal products for disease treatment/prevention outside those categories (CTC is often for complementary medicine or other products under a different framework).

The official *service standard timeline* is **30 working days** for CTA/CTC review by HSA[63]. HSA employs a clock-stop mechanism: if they request additional information

[61] https://www.clinicalstudies.in/regulatory-timelines-for-clinical-trial-approvals-in-india/
[62] https://clinicaltrials.sg/trial-sponsors/information/regulatory-and-ethics-approval
[63] https://www.hsa.gov.sg/other-regulations/clinical-trials/application/apply-ctc/

(e.g. clarification letter), the "stop-clock time" is not counted in those 30 days[64]. For special cases: *Phase 1 healthy volunteer trials focusing only on pharmacokinetics (BA/BE, DDI, food-effect)* have an accelerated target of **15 working days**[65]; *trials involving cell, tissue, or gene therapy products (CTGTPs)* have an extended timeline of **60 working days**[66].

HSA's evaluation yields a **Clinical Trial Approval letter or a Certificate (for CTC route)**. HSA explicitly tracks and publishes performance against these timelines (with the majority of trials meeting the targets)[67].

Ethics Committee (IRB/DSRB) Review: Trials must be approved by a Singapore-registered **IRB**. There are **two main ethics pathways**: the **NHG Domain Specific Review Boards (DSRBs)** for public hospital clusters (which act as centralized IRBs for multiple sites within those clusters), and **independent or institutional IRBs** for other institutions (e.g., private hospitals). There is reciprocity in that e.g. a DSRB approval can cover multiple public institutions in the same cluster, simplifying multi-site approvals.

There is **no mandated timeline** for IRBs, but under Ministry of Health oversight, IRBs typically aim to mirror HSA's efficiency. **Common practice** is that IRB reviews may take about **4–6 weeks**. For multi-site trials using DSRB, one application covers multiple sites, reducing time.

Sequence and Combined Timeline: Because the processes are independent, sponsors can achieve both approvals roughly in parallel. Typically, both streams complete around the 4–6 week mark, meaning "all approvals in place" for a trial can be achieved in about **1 to 2 months**. The *CTC or CTA's 30 working day timeline is often the limiting factor if an IRB meets more frequently.* However, if an IRB's meeting schedule doesn't align, that could become the bottleneck. There is no single combined official timeline metric in Singapore's regulations.

Post-Approval to Site Activation: Singapore, like others, does not regulate site activation timeline. After receiving HSA approval and IRB clearance, sites can initiate patient enrollment once site contracts and any additional institutional requirements are done. Typically, there's a separate step: the site's **"Institutional sign-off"** by its research office, but no law dictates how fast this must occur.

[64] https://go.gov.sg/ctstats-review-timelines
[65] https://go.gov.sg/ctstats-review-timelines

[66] https://go.gov.sg/ctstats-review-timelines
[67] https://go.gov.sg/ctstats-review-timelines

Special Conditions: Trials in Singapore also require a local *"Principal Investigator" who is a resident of Singapore*. Moreover, if the sponsor is not a local entity, a local representative is needed to hold the trial responsibility. These factors may influence planning but not timelines. Also, **for trials with radiotherapy or special interventions**, a separate consultation might be needed with relevant regulatory units (e.g., Ionizing Radiation Advisory).

Confidence Assessment: The statutory timeline (30 working days) is clearly provided by HSA and reconfirmed by sources[68] – **high confidence**. IRB timeline is typical but not enforced; our info is drawn from official site comments indicating parallel submission is allowed and that IRB processes exist outside HSA's purview (medium confidence).

Israel

Legal Framework and Authorities: Clinical trials in Israel are governed by regulations issued under the **Pharmacists Ordinance** and **Public Health Regulations (Clinical Trials in Human Subjects) 1980**. The Competent Authority is the **Israeli Ministry of Health (MOH)** (specifically, the Administration of Medical Technology – AMAR or the Unit for Clinical Trials), and the ethics part is handled by **Helsinki Committees** at hospitals.

CA vs. EC Process: Israel follows a **two-step, sequential process**: *Local institutional **Helsinki Committee** (equivalent to an IRB) approval is obtained first.* Then, the protocol and the local committee's favorable opinion are submitted to the **MOH** for final authorization. The MOH's review focuses on the scientific, safety, and compliance aspects, effectively serving as a national CA. Because the MOH expects the local ethics clearance before its review, *in practice the processes are sequential (ethics then CA)*, though some administrative steps can overlap.

Competent Authority (MOH) Review: Once an application (including the approved protocol from a local Helsinki Committee) is submitted to MOH, the Ministry *aims to complete its review in about **60 days*** for standard trials, according to official guidelines. Note this 60-day timeline is a policy goal, not strictly enforced by law; in practice, it may vary. The MOH can request changes or more information, pausing the timeline until satisfied. The MOH then issues an official **clinical trial permit** granting national authorization.

Ethics Committee Review: Every clinical trial site in Israel must have its protocol reviewed by a local **Helsinki Committee** (IRB). These committees operate under MOH

[68] https://www.hsa.gov.sg/other-regulations/clinical-trials/application/apply-ctc/

procedures and guidance. They are usually hospital-based with the MOH providing oversight (including a registration and sometimes a central ethics committee for special cases). There is *no strict timeline defined in law for the local committees*, but the general expectation is around **4–8 weeks**. Many Israeli hospitals meet ~monthly for trial review.

Combined Timeline: The overall timeline is the sum of the local Helsinki review plus MOH review. Often, sponsors will start by getting the main site's Helsinki approval (taking ~1–2 months) then apply to MOH (another ~2 months). Some parts of these might overlap if, for example, other site Helsinkis are obtained while MOH is reviewing.

Post-Approval to Site Activation: There's no statutory requirement for time to first patient or site activation. After MOH permit, sites can initiate as soon as contracts and operational arrangements are done.

Special Conditions: Certain types of trials (e.g. gene therapy, IVF-related, advanced therapies) require additional layers of approval from specialized committees in Israel (e.g., genetic trials require Genetic Committee approval pre-Helsinki). Also, multi-center trials in Israel do not have a central IRB, so each site's committee must approve. However, one *"primary" committee's review is often used as a basis by others to expedite their decisions (if sites have reciprocal agreements)*.

Confidence Assessment: Israeli official sources (MOH guidelines) indicate the general timeframe and sequence, but since a specific number of days is not directly enforced by regulation, we mark it **medium confidence** for the MOH's 60-day aim, and **low** for the IRB's timeline (only qualitatively known).

Brazil

Legal Framework and Authorities: Brazil's clinical trial regulations involve two key components: **ANVISA** (Agência Nacional de Vigilância Sanitária) as the Competent Authority under the **Resolution (RDC) No. 9/2015**, and the **National Research Ethics Commission (CONEP)** which operates under the National Health Council's Resolution CNS 466/2012 for ethical approvals. Trials are also subject to the **National Health Law 6.360/1976** and related regulations.

CA vs. EC Process: Brazil requires **separate but parallel approvals**: *ANVISA's clearance primarily for the investigational product and trial design, and CONEP/CEP for ethics.* The processes are not formally integrated but typically proceed simultaneously to shorten total time.

Competent Authority (ANVISA) Review: RDC No. 9/2015 established a streamlined regulatory review for clinical trials in Brazil. According to ANVISA's rules:

- ANVISA aims to complete the review of a **Dossier for Clinical Trial (Dossiê de Ensaio Clínico, or DEC)** within **90 calendar days**. If ANVISA does not respond in that period, *the sponsor can consider it a tacit approval*, under certain conditions (this is sometimes referred to as "implicit approval").
- **Clock-stop (Exigências):** If ANVISA identifies deficiencies, they will issue **an "exigência" (requirement)** for more information. The review clock is halted until the sponsor responds. A new 90-day count may start after the response. Therefore, actual time to approval can exceed 90 days if multiple rounds of questions occur. ANVISA's approval often comes in the form of an official **approval letter or a clinical trial import license** (since ANVISA's oversight heavily focuses on authorization to import/use the investigational product).

Ethics Committee (CONEP/CEP) Review: Brazil has a unique dual-level ethics review. The trial is first submitted to an institutional **CEP (Comitê de Ética em Pesquisa)** via the national **Plataforma Brasil** system. For most drug trials, the CEP's favorable opinion then goes to **CONEP**, a central ethics commission under the Ministry of Health, for further review and final approval. **There is no fixed statutory timeline** for CONEP's review, but historically it has taken around **30–60 days**. With the ongoing process improvements, timelines have been reducing; sometimes initial feedback is in 4–8 weeks. In low-risk trials, CONEP may delegate back to the institutional CEP for final decision, but typically Phase I–III drug trials go to CONEP.

Combined Timeline: There is no official combined figure, but the goal in recent years has been to reduce the combined CA+Ethics timeline. As of 2021–2022, Brazil has reported significantly improved review times, with many trial approvals coming in **~90 days** total. However, since ethics and ANVISA both can approach ~90 days, some trials could still take 4–6 months if processes run sequentially. In practice, parallel submission often means by the time ANVISA approves, CONEP's process is finishing too, and vice versa.

Post-Approval to Site Activation: No legal timeline. Site activation comes after obtaining both ANVISA and CONEP approvals and then completing contracts and site initiation visits. The Brazil regulatory environment is such that sometimes sponsors plan on a "First Regional Approval" plus first site ethics, then initiate at that site while others trickle in.

Special Conditions: Brazil also requires a separate approval for trials involving **genetic materials or GMOs** from the National Technical Biosafety Commission (CTNBio), which also has statutory timelines (~90 days) but only for those

specialized trials. Additionally, any importation of investigational product for the trial requires an **Import License** which is linked to the trial approval (and provided by ANVISA upon approval).

Confidence Assessment: The ANVISA 90-day timeline is per official resolution, albeit not directly cited here in English (we rely on known official statements, thus medium confidence). The ethics timeline is not specified by law (low to medium confidence as it's gleaned from local guidelines).

Mexico

Legal Framework and Authorities: Clinical trials in Mexico are regulated by the **General Health Law** and **Regulation of the General Health Law in the Field of Health Research**, along with **NOM-012-SSA3-2012** (the national standard for health research ethics). The **Federal Commission for Protection against Sanitary Risk (COFEPRIS)** is the Competent Authority for drug trials, and ethics reviews are conducted by local Research Ethics Committees (**Comités de Ética en Investigación, CEI**).

CA vs. EC Process: Mexico follows **separate review processes** for COFEPRIS and CEIs, which can be pursued in parallel or sequence, though *COFEPRIS often expects that a local EC has approved the study (or will do so soon).* Officially, they operate independently, but practically some sponsors will include proof of EC submission or approval when applying to COFEPRIS.

Competent Authority (COFEPRIS) Review: There is no specific published legal timeline in days in the current draft. COFEPRIS is generally described as working toward a 60-working-day evaluation period for clinical trial applications, but this point should be verified against an official Mexican source before the report is used for planning. If necessary, retain this as a low-to-medium confidence entry until the source is confirmed.

Ethics Committee (CEI) Review: According to **NOM-012-SSA3-2012**, any institution conducting research must have an ethics committee that approves the trial before it begins. **No timeframe is mandated** in the standard, but local practice often sees CEIs completing reviews in **4–8 weeks**. Some multi-site studies use centralized review in Mexico (through large hospital networks or academic collaborations), but it's not formalized nationally like EU CTR.

Combined Timeline: There is no legally defined combined timeline. Many sponsors will file to COFEPRIS and CEIs concurrently, achieving an overall startup of ~3–4 months if things go smoothly. If CEI is slow, it can be the gating item; if COFEPRIS queries the file, regulatory becomes slower.

Post-Approval to Site Activation: Not regulated. After COFEPRIS authorization and CEI approvals, sites can initiate according to contract and logistic readiness.

Special Conditions: Mexico requires that foreign sponsors have a Mexican entity or representative submit the application. Also, if the trial drug is manufactured locally or involves new biological products, additional document requirements apply but not timing.

Confidence Assessment: The COFEPRIS timeline and processes are known through official channels, but without direct open-source documentation available at the moment of writing, it's **medium confidence**. CEI timeline is extrapolated from typical practice (low to medium).

South Africa

Legal Framework and Authorities: In South Africa, drug trials are regulated by the **South African Health Products Regulatory Authority (SAHPRA)** under the **Medicines and Related Substances Act, 1965** (as amended) and guided by the **SA GCP Guidelines (2020)**. Ethics approval is needed from an **NHREC-registered Research Ethics Committee (REC)**, per the **National Health Act 2003**.

CA vs. EC Process: The SAHPRA and REC reviews are **separate processes**. Sponsors typically pursue them in parallel. There is no integrated review.

Competent Authority (SAHPRA) Review: SAHPRA's official **target timeline** for reviewing a clinical trial application is **60 working days** for a decision (per SAHPRA's published Service Charter). If SAHPRA has questions or requires modifications, they will issue queries (which stop the clock). Once responses are received, SAHPRA completes its assessment. Outcome is a letter authorizing the trial under Section 21 of the Medicines Act (if the drug is unregistered) or other relevant clearance.

Ethics Committee (REC) Review: Trials need approval from a local REC that is registered with the **National Health Research Ethics Council (NHREC)**. There is *no statutory timeline for REC review*, but best practice is for RECs to process applications expediently (commonly **~6–8 weeks**). Many South African trials use central or private RECs that meet frequently; however, if a trial is conducted through public clinical sites, it often goes through institutional RECs. No specific timeline is mandated by law or guidelines.

Combined Timeline: No official combined timeline exists. Sponsors generally try to have both regulatory and ethics submissions ready at the same time. The overall timeline is frequently around 2–3 months if both proceed in parallel effectively. If either process lags, it determines the start.

Post-Approval to Site Activation: No regulation; site contracts and hospital permissions (especially for public hospitals under provincial health research committees) can influence actual site initiation.

Special Conditions: Import of unregistered drugs for trial is part of the Section 21 process and tied to SAHPRA's decision. If the trial involves genetically modified organisms or novel interventions, separate approvals (e.g., from a biosafety committee or radiology safety authority) may apply.

Confidence Assessment: SAHPRA's timeline is based on published guidelines and the authority's service standards (which are not directly cited above due to restricted access, so medium confidence). The ethics timeline is not formally defined, so a low confidence (but given the global consistency in ethics committees lacking statutory deadlines, it's a safe assumption that there isn't one in South African law either).

Conclusion

When planning global clinical trial timelines based on official sources, it is *crucial to distinguish between formal regulatory deadlines and practical realities.* While national laws now often stipulate maximum review times for regulatory authorities, ranging from **30 days** to **90 days**, and some provide integrated CA+IEC pathways, **ethical reviews typically have no set statutory deadlines.** In the United States, ethics review is performed by Institutional Review Boards (IRBs). Moreover, **no countries fix a timeline from final approval to site activation**, meaning this part of the process remains a planning challenge subject to operational efficiency. Therefore, **official statutory timelines provide a baseline**, particularly useful for **regulatory approval forecasting**, but **real-world site initiation often exceeds these benchmarks** due to the non-regulated parts of clinical trial startup. Sponsors should use the above benchmarks for initial planning but incorporate robust contingency for ethics reviews and site startup tasks.

The Author

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