Copenhagen Economics

FROM REGULATORY SUBMISSION TO CLINICAL TRIAL SITE ACTIVATION

A comparative analysis of clinical trial authorisation processes and site initiation timelines in the EU, US and China

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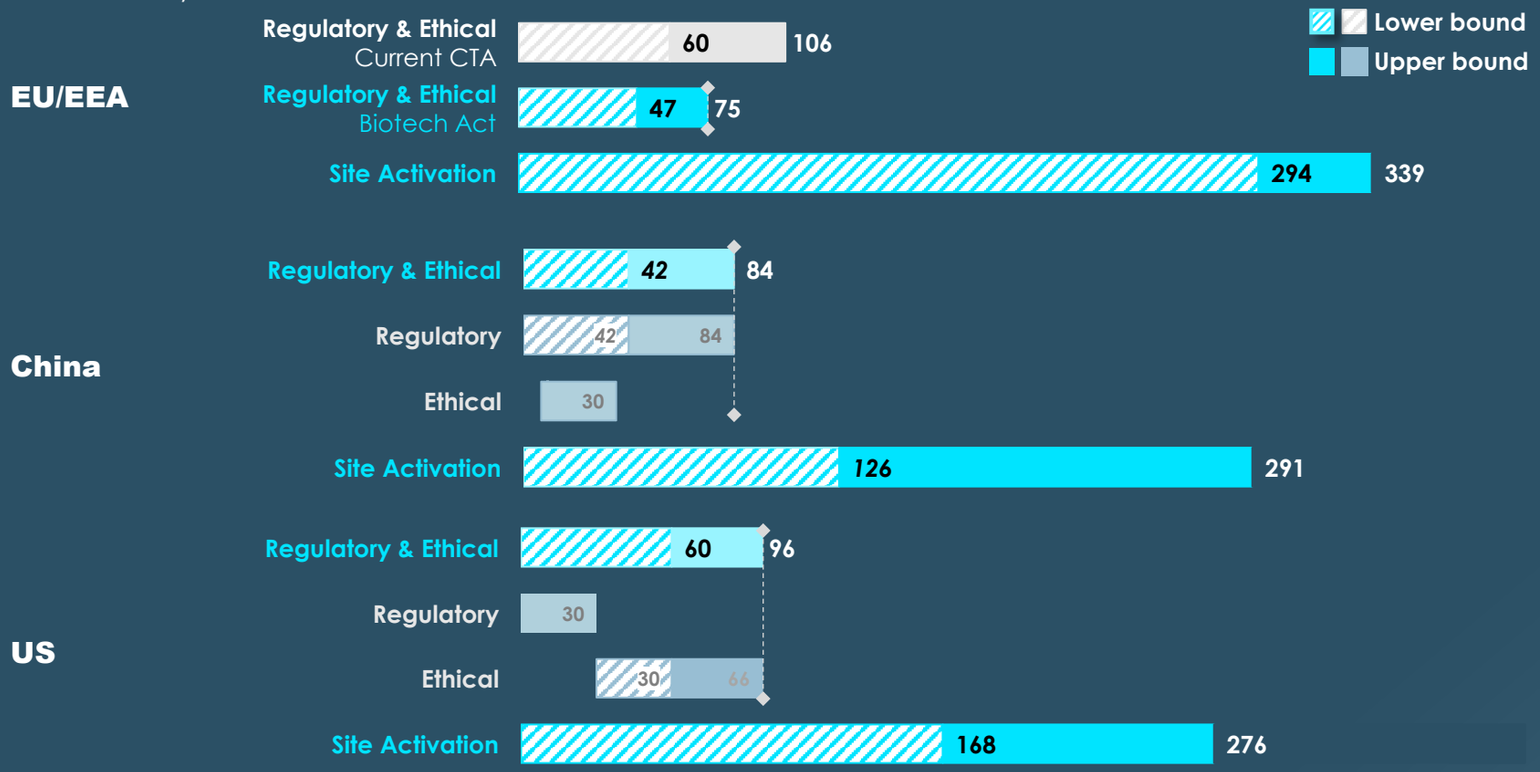
Summary figure: Timelines for regulatory review, ethical review and site activation
Calendar days



Notes: Regulatory and ethical review timelines reflect statutory timelines, except for ethical review in the US, where no statutory timelines are set at the federal level. The US estimates reflect actual timelines reported by Krafcik et al. (2017) and validated through expert interviews. For the EU/EEA regulatory and ethical review are conducted in one regulatory procedure. For China, the 42-day regulatory review period refers to the fast-track pathway, while the 30-day ethical review period refers to the time to obtain an ethics opinion. China's 162-day site activation estimate refers to activation of the first site under the fast-track pathway. Regulatory review timelines for the US and China refer to initial IND submissions; both countries allow multiple trials under an existing authorisation. Site activation estimates are based on different sources and definitions, so comparisons between the EU/EEA, US, and China are indicative. For further details, see the report.

Source: Copenhagen Economics, based on the anlaysis of regulatory frameworks, Krafcik et al. (2017), EFPIA (2024), and CDE report (2025), validated in expert interviews.

The proposed Biotech Act would bring EU/EEA authorisation timelines closer to those in the US and China.

However, activating clinical trial sites would remain slower in the EU/EEA, making this a separate priority.

As the US and China pursue further reforms, the EU/EEA must continue to shorten clinical trial timelines to remain competitive in attracting clinical trials.

The Biotech Act would make EU/EEA clinical trial authorisation timelines more competitive, but site activation timelines would remain slower

Summary of findings

The proposed Biotech Act aims to accelerate and streamline clinical trial authorisation (CTA) in the EU/EEA. The reforms seek to shorten statutory review timelines, better integrate ethical review into the authorisation process, and reduce administrative burdens.[1] A key question is whether these changes would make EU CTA timelines competitive with those in other major regions.

Comparing CTA timelines internationally is not straightforward because regulatory and ethical review procedures differ across regions. In the EU/EEA, regulatory and ethical assessments form part of a coordinated authorisation process, while in the US and China they follow separate, independent procedures. Comparing statutory regulatory review timelines alone would therefore not capture the full time required to obtain the two key approvals needed to start a clinical trial.

We provide a like-for-like comparison of regulatory and ethical approval procedures and timelines in the EU/EEA under the Biotech Act, the US, and China, from regulatory submission to site activation. We reconstruct the regulatory and ethical approval procedures through desk research and validate our findings with experts experienced in conducting clinical trials. This allows us to account for procedural differences and ensure a consistent comparison of timelines.

The proposed Biotech Act would make EU/EEA review timelines competitive with those in the US and China

The Biotech Act proposes to shorten the CTA timeline for multinational clinical trials from 106 days to 75 days, with decisions possible in 47 days where no additional questions are raised, see Figure 1. Emerging evidence from the FAST-EU pilot suggests that a timeline of 75 days is achievable.[2]

The proposed 75-day timeline would place the EU/EEA within the range of regulatory and ethical approval timelines in the US and China. In China, combined approval takes between 42 and 84 days, depending on whether the trial follows the fast-track or standard regulatory review procedure. In the US, it takes between 60 and 96 days to complete both reviews, depending on whether all participating sites can rely on a single institutional review board (IRB) or whether some require local IRB review.

However, the EU/EEA would remain slower than the US and China in activating clinical trial sites

Even under the proposed Biotech Act, the time from regulatory submission to site activation would remain longer in the EU/EEA than in the US and China, see Figure 2. We estimate that this process would take 294 to 339 days in the EU/EEA under the Biotech Act, compared with 168 to 276 days in the US and 126 (fast track) to 291 days in China.

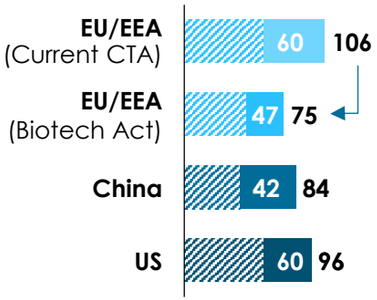
Improving the EU/EEA's competitiveness in timelines to site activation remains a separate challenge

The Biotech Act primarily targets the CTA process, which is only one part of the broader process leading to site activation. Before a site can begin recruiting participants, other steps, including contracting and operational preparations, must also be completed. These steps are not directly addressed in the Biotech Act proposal. Improving CTA timelines alone would therefore not resolve the EU/EEA's slower site activation.

Our comparison reflects the current regulatory frameworks and clinical trial authorisation timelines in the US and China. It does not fully account for upcoming reforms and initiatives, such as the US TrialBlazer initiative[3] and China's 15th Five-Year Plan for the pharmaceutical industry, which calls for optimising drug review and approval mechanisms.[4] These developments may affect future timelines from regulatory approval to site activation and should therefore be considered when interpreting the EU/EEA's relative competitiveness.

Figure 1. Time from regulatory submission to ethical and regulatory approval

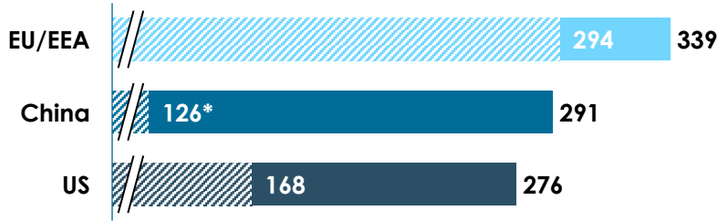
Number of calendar days, min and max



Notes: China: 42 days refers to the fast-track review period. US: Figures refer to the initial IND submission. See pages 14 to 15 for details.
Source: Copenhagen Economics.

Figure 2. Time from regulatory submission to site activation

Number of calendar days, lower and upper bound (indicative)



Note: China's 126 days refer to regulatory submission to trial initiation (first informed consent) under the fast-track pathway. For the EU/EEA and US, the lower and upper bounds reflect site activation timelines for infectious diseases and oncology, respectively. The estimates are not directly comparable. See pages 14 to 15 for details.
Source: Copenhagen Economics.

(1) European Commission (2025), the European Biotech Act proposal. / (2) AGES (2026). / (3) U.S. Department of Health and Human Services (2026). / (4) Ministry of Industry and Information Technology (2026).

The EU/EEA benefits from integrated review, but new initiatives in the US and China could affect relative site activation times

Summary of findings

The comparison of procedures in the EU/EEA, US, and China reveals two additional key findings:

The EU/EEA benefits from an integrated regulatory and ethical review

In China, regulatory and ethical reviews can proceed in parallel but remain separate, while in the US, ethical review generally follows the regulatory review period, see Table 1. While China also has a statutory 30-day deadline for ethics committees to issue an opinion, US review timelines vary by IRB, with no uniform statutory deadline. The timeline comparison reflects these differences, with shorter overall approval times possible in the EU/EEA and China than in the US.

Broader authorisations in the US and China can shorten timelines for subsequent trials compared with the EU/EEA

Unlike the EU/EEA, where each trial requires a separate authorisation, the US and China allow multiple trials to be conducted under an existing authorisation, subject to applicable conditions. This reduces the need for repeated full regulatory submissions and may allow subsequent trials to start sooner, as protocol amendments are generally less time-consuming than obtaining a new authorisation.

The proposed Biotech Act seeks to reduce this administrative burden through a product-specific dossier that would allow sponsors to reuse information across trials. However, each trial would still require separate authorisation.

Table 1. Comparison of regulatory and ethical procedures

	EU/EEA – Current CTA	EU/EEA – Biotech Act	US	China
Regulatory review				
Review model	Coordinated assessment by Member States: EU CTA	Coordinated assessment by Member States: EU CTA with strengthened RMS led review	Centralised IND review by the FDA	Centralised IND review by NMPA/CDE
Statutory review timeline	60 to 106 days	47 to 75 days	30 days	84 days
Accelerated procedures	No	No	No	Yes, fast-track, 42 days
Authorisation scope	Trial-specific	Trial-specific with an optional reusable product-specific core dossier	Product-specific IND covering multiple trials	Product- and indication-specific IND covering multiple trials
Requests for information	Yes, fixed response deadline	Yes, fixed response deadline	Yes, no fixed response deadline	Yes, 5-day deadline for clarifications, no routine clock-stop
Scientific advice	Yes, EMA and national authorities	Yes, EMA, national authorities and CTCG via ACT EU (permanent from January 2027)	Yes, FDA	Yes, NMPA/CDE
Ethical review	***In parallel***	***In parallel***	***Sequential***	***In parallel***
Review model	Integrated into EU CTA assessment	Integrated into EU CTA assessment	Single or multiple IRBs, depending on the trial	Single or multiple ECs, depending on the trial
Statutory timeline	60 to 106 days	47 to 75 days	No uniform timelines	30 days
Authorisation scope	Trial-specific approval	Trial-specific approval	Trial-specific approval	Trial-specific approval

Note: Number of days reflects calendar days.
Source: Copenhagen Economics, based on publicly available documents. Detailed references on the following pages.

REGIONAL BRIEFS

Clinical trials face similar requirements across regions, but authorisation procedures and time to site activation differ

Regional briefs

Before a clinical trial can begin, sponsors must satisfy regulatory and ethical requirements and ensure that participating sites are operationally ready. These requirements serve broadly similar purposes across the EU/EEA, US, and China:

- **Regulatory review** assesses whether the scientific, safety, and quality information supports initiating the proposed clinical trial.
- **Ethical review** assesses whether participants' rights, safety and well-being are adequately protected, including through informed consent and appropriate safeguards.
- **Site activation** ensures that participating sites are ready to begin the trial, including through contract negotiations, staff training, and other operational preparations, see Box 1. The extent to which these activities overlap with regulatory and ethical review determines how quickly a site can be activated once the necessary approvals are obtained.

Beyond these core requirements, additional obligations may apply depending on the investigational product and trial characteristics. For example, trials may be subject to import requirements, rules governing genetically modified organisms or requirements concerning human genetic resources.

Similar requirements are implemented through different authorisation procedures

Although the underlying objectives are broadly comparable, the procedures for meeting these requirements differ across regions. Key differences include how regulatory and ethical reviews are organised and sequenced, whether statutory review deadlines apply and how regulatory authorisation is granted. In the EU/EEA, ethical and regulatory reviews are part of one clinical trial authorisation review, while in the US and China they are conducted separately. In addition, in the EU/EEA clinical trials require an explicit authorisation decision. In contrast, the US and China generally allow trials to proceed if the regulatory authority raises no objection within a defined period, provided that ethics committee approval and other applicable requirements have been obtained.

These procedural differences matter when comparing timelines. In particular, the sequencing of regulatory and ethical reviews can affect the time needed to obtain both clearances, while differences in site preparation can influence how quickly a trial begins after approval.

We apply a common framework to compare procedures and timelines across regions

To account for these differences, we examine the same key milestones across the EU/EEA, US and China: from regulatory submission to completion of regulatory and ethical review, and ultimately to site activation. We also consider the operational activities required to prepare trial sites, with particular attention to contractual arrangements.

For the EU/EEA, we focus on the EU/EEA CTA procedure and assess the proposed changes under the Biotech Act. We exclude national procedures that may apply to trials conducted in a single Member State, including the availibility of any accelerated pathways.

The analysis draws on desk research, validated through seven interviews with local experts.

In what follows, we present regional briefs describing the authorisation procedures, their sequencing, and timelines in the EU/EEA, the US, and China.

Box 1. Activities needed to make the site operationally ready

Site activation requires regulatory and ethical clearance alongside the following contractual and operational preparations:

- **Site contracts:** The site contract must be signed and the budget agreed. Contracts typically cover financial terms, data protection and data ownership. Negotiations can begin during regulatory and ethical review but may take considerable time, particularly where site-specific terms and conditions must be agreed.
- **Staff and systems:** Site staff must be trained, and the necessary systems and services, including central laboratories, must be available. Much of this preparation can take place during regulatory and ethical review, although some sites defer training until approval.
- **Investigational products and supplies:** The site must have the investigational product and the necessary supplies, including laboratory kits, available before relevant trial activities begin. Products can be manufactured and stored in advance, while shipment to sites may depend on the required approvals.

Source: Copenhagen Economics, based on expert interviews.

The EU/EEA combines regulatory and ethical review in one coordinated assessment

Regional brief – EU/EEA

The Biotech Act proposes a more coordinated CTA procedure

Clinical trials in the EU are authorised under the Clinical Trials Regulation ("**CTR**")[1], applicable since 31 January 2022. One Clinical Trial Authorisation procedure brings together regulatory and ethical review and is approval-based.

Reforms proposed under the Biotech Act[2] aim to amend the **CTR** to make EU clinical trial authorisation faster by proposing shorter statutory timelines and integrating more of the ethical review in the process. Sponsors would continue to submit a single application through the Clinical Trials Information System ("**CTIS**") for trials conducted in one or more EU/EEA Member States.

One Member State would coordinate the procedure, while each Member State remains responsible for matters within its national competence

The proposed Biotech Act would retain the CTR's coordinated assessment model for multinational trials, while preserving national decision-making by individual Member States.

For multinational trials, the sponsor proposes a Reporting Member State ("**RMS**"). The RMS leads the coordinated regulatory assessment and helps align the review across participating Member States.

The Member States Concerned ("**MSCs**"), meaning the additional countries in which the clinical trial will take place, remain responsible for national matters and ethical aspects within their competence, typically through their own ethics committees.

The procedure remains approval-based, but a positive decision may allow the trial to start subject to conditions, unless the Member State requires those conditions to be fulfilled before the trial begins.

Clinical trial authorisation procedure would follow five steps

The following steps and statutory timelines reflect the clinical trial authorisation procedure proposed under the Biotech Act, see next page for an illustration.

Step 1: Submission through CTIS. The sponsor submits the dossier through CTIS for all participating Member States. After submission, the assessment is split into two parts, each subject to a 47-day statutory timeline running from the date of submission.

Step 2: Selection of the RMS. The sponsor proposes an RMS. The suggested RMS must accept the role within 6 days or decline within 3 days.

Step 3: Validation of the application. Before the substantive assessment begins, the RMS has 7 days to review and validate Part I of the submitted dossier.[3]

Step 4: Assessment.

- **Part I: Coordinated regulatory and related ethical assessment**[4]. The RMS leads the coordinated regulatory assessment on behalf of all participating Member States. Its strengthened role is intended to reduce duplicate assessments and requests for information, creating a more consistent EU process. The RMS ethics committee reviews ethical aspects relevant to all Member States.
- **Part II: National and ethical assessment**. In parallel, each MSC assesses national/ethical aspects that fall within its competence. An MSC may also choose to rely on the RMS ethics committee for common elements of Part II.

The Biotech Act also strengthens requests for information, capping them at 28 days (down from 31).

Step 5: Decision
Based on the outcomes of the Part I and Part II assessments, each MSC issues a single decision within 5 days of the Part I assessment outcome or completion of the Part II assessment, whichever is later, authorising, conditionally authorising or refusing the trial.

The RMS conclusion on Part I generally applies across MSCs, although an MSC may depart from it on limited specified grounds. The final decision also reflects the MSC's Part II assessment of national and ethical matters.

The proposed Biotech Act would introduce an optional product-specific core dossier

Under the proposed Biotech Act, clinical trial authorisation remains trial-specific. Sponsors submit an application for each clinical trial through CTIS, covering all participating Member States. However, the proposal introduces an optional investigational medicinal product core dossier, allowing product-specific information to be reused across multiple trial applications. This reduces duplication while retaining a separate authorisation process for each trial.[5]

(1) Regulation (EU) No 536/2014, the Clinical Trials Regulation ("CTR"). / (2) European Commission (2025), the European Biotech Act Proposal. / (3) In case there are issues with the application, the sponsor has 7-days to respond, followed by a 7-day confirmation period. / (4) Part I includes ethical review of common aspects of the application dossier; Member State-specific ethical matters remain subject to Part II assessment. / (5) see footnote (2).

The EU/EEA combines regulatory and ethical review in one coordinated assessment

Regional brief – EU/EEA

Sequencing and observed timelines

The proposed Biotech Act would shorten clinical trial authorisation timelines from up to 106 days to 75 days, or as few as 47 days if no additional information is requested, see Figure 3.

Expert interviews suggest that the 47-day timeline is unlikely to reflect routine practice. Sponsors typically receive two to three RFIs, and although the Biotech Act would streamline and consolidate RFIs, experts expect them to remain common. Early FAST-EU pilot results also suggest that 75 days is achievable. The first three procedures met or came close to the 70-day target.[1] These findings remain preliminary, and a more comprehensive report is still expected.

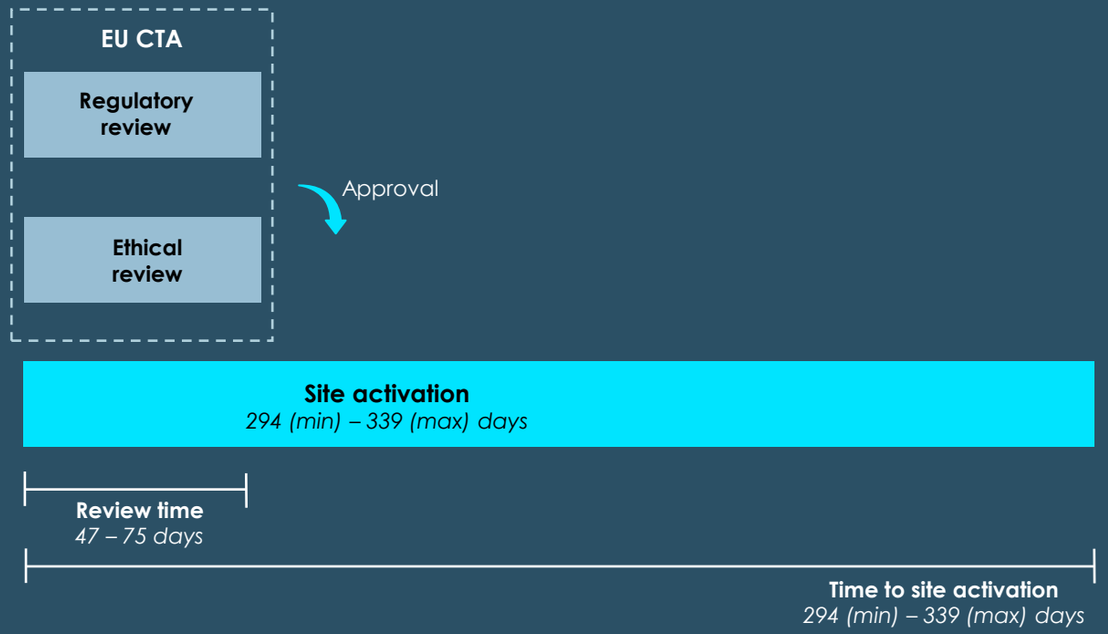
Site preparation can largely run in parallel with clinical trial authorisation, but the extent of overlap varies considerably across sites and countries. Activities such as contract negotiations, staff training and documentation can be completed before approval, enabling rapid activation.[2] In contrast, sites that begin these activities only after approval may create additional delays.

Status of the framework

Published on 16 December 2025, the Biotech Act proposal remains under negotiation.

Alongside the Biotech Act, ACT EU[3], launched in January 2022, addresses wider barriers to trial initiation, such as contractual agreements between sponsors and sites,[4] and pre-submission advice.[5] These measures may further reduce administrative delays and shorten the time to trial initiation.

Figure 3. Sequencing and timelines, EU/EEA



(1) AGES (2026). / (2) During the interviews, an expert gave an example of a Polish site that was activated just two hours after the EU CTA approval. Expert interviews (October 2026). / (3) ACT EU, see link. / (4) EMA (2026a). / (5) From January 2027, its pre-submission advice, piloted since 2024, will become permanent and give sponsors consolidated feedback from the Member States concerned before they submit a clinical trial application, see EMA (2026b) and ACT EU (2026).

In the US, regulatory and ethical review are conducted separately and typically take place sequentially

Regional brief – United States

In the US, regulatory and ethical reviews are conducted in two independent procedures

The clinical trial authorisation involves two independent review processes of the same clinical trial protocol:

- Regulatory review by the Food and Drug Administration ("**FDA**") through an Investigational New Drug ("**IND**") application.[1]
- Ethical review by an Institutional Review Board ("**IRB**").

The two reviews are independent and may proceed in parallel. In practice, the IRB submission usually follows the FDA's feedback. A trial can only begin once both clearances have been obtained.

FDA conducts a single federal regulatory review

Human clinical testing of an investigational drug requires the sponsor to submit an IND application to the FDA, which conducts a single federal review to assess the scientific and safety basis for the study. The FDA's IND review covers three core components: preclinical animal pharmacology/toxicology data, chemistry, manufacturing and controls ("**CMC**") information, and the clinical protocol together with investigator qualifications.

The FDA process is **objection-based**. Following submission, the FDA has 30 calendar days to review the IND. The trial may proceed once this period expires unless the FDA places the study on clinical hold.

The regulatory review follows three steps:

Step 1: Pre-submission engagement (*optional*). Sponsors may request an INTERACT meeting (scheduled within 75 days of the request) or a Pre-IND consultation (scheduled within 60 days of the request). These meetings give clinical trial sponsors an opportunity to obtain early regulatory and scientific feedback from the relevant FDA review division on the studies, data, and development plans needed to support IND submission.

According to expert interviews, these meetings are useful when a sponsor enters a new area or departs from precedent. Publicly available evidence on their effectiveness remains limited.

Step 2: IND submission. The sponsor files the IND with preclinical pharmacology/toxicology data, CMC information, and the clinical protocol.

Step 3: Review. The FDA has 30 calendar days from receipt of the IND to review the application. The trial may proceed after this period, or earlier if the FDA explicitly allows it. However, the FDA may place the trial on clinical hold due to concerns such as unreasonable risks or unqualified investigators. According to expert interviews, the FDA typically uses the full review period, and questions do not stop or extend the review clock. If the FDA imposes a clinical hold, the sponsor must resolve the concerns before the trial can proceed.[2] The FDA may also provide non-hold comments, which do not delay trial initiation.

Ethical review is decentralised and conducted independently from regulatory review

Separately from FDA review, each clinical trial requires IRB approval before it starts. IRB review is decentralised and has no centralised statutory review timelines, with timing varying according to the review model, committee schedules, and workload.[3,4]

Sites may rely on a central IRB or undergo review by their local institutional IRB. According to expert interviews, between 30 and 40 per cent of sites in a clinical trial typically use a central IRB.

- **Central IRB review:** Participating sites rely on the review of a commercial or independent central IRB under a reliance agreement, rather than conducting a separate full review themselves.[5] Examples include Advarra[6] and WCG[7]. The sponsor submits the core protocol to the central body, while individual sites provide site-specific documentation. According to expert interviews, the central review typically takes 14 to 24 calendar days (2 to 4 weeks).
- **Local IRB review:** Sites submit the protocol to their own institutional IRB. Academic, cancer and children's hospitals typically conduct their own review. The actual timelines depend on committee schedules, which may involve monthly meetings. Approval can take between 28 and 42 calendar days, although timelines can extend to around 90 days. Some institutions also require an agreed budget and contract before initiating IRB review.

A trial may begin once the FDA's 30-day review period has elapsed without a clinical hold and IRB approval has been obtained. Subsequent trials under the same IND generally do not require a new 30-day waiting period but must obtain IRB approval before initiation.[8]

IND covers multiple clinical trials involving the same investigational drug

In the US, regulatory authorisation is organised around an IND application rather than individual trials. A single IND can cover multiple clinical trials involving the same investigational drug, including different development phases and potentially different indications. Sponsors can add new trials through protocol amendments to the existing IND, without necessarily submitting a new application.

(1) IND application, submitted under 21 CFR Part 312. / (2) Holds are uncommon when issues are addressed in a pre-IND meeting, and the FDA moves quickly to resolve them, so a hold can sometimes be lifted within weeks. The FDA can also issue a partial hold, allowing the trial to start with restrictions, such as limited enrolment. Expert interviews (2026). / (3) FDA (2025). / (4) 21 CFR 56.103(a) and 21 CFR 312.66. / (5) 45 CFR 46.114. / (6) Advarra website. / (7) WCG website. / (8) Once underway, trials remain subject to ongoing IRB oversight and FDA reporting requirements, including annual IND reports (21 CFR 56.109(f) and 21 CFR 312.33).

In the US, regulatory and ethical review are conducted separately and typically take place sequentially

Regional brief – United States

Sequencing and observed timelines

IRB review is independent of, and may proceed in parallel with, the FDA's IND review. However, according to experts interviewed, sponsors and sites usually wait for the FDA's feedback before submitting to the IRB so that any protocol changes the FDA requests are reviewed only once,[1] see Figure 4. Parallel review happens only at selected sites, at the sponsor's and site's risk.[2]

According to expert interviews, sites open on average about 140 days after FDA clearance in infectious diseases, but 215 to 230 days in oncology and rare diseases. This is in line with the site activation timelines reported in EFPIA (2024).

As in the EU/EEA region, site preparation activities can proceed in parallel with regulatory and ethical review.

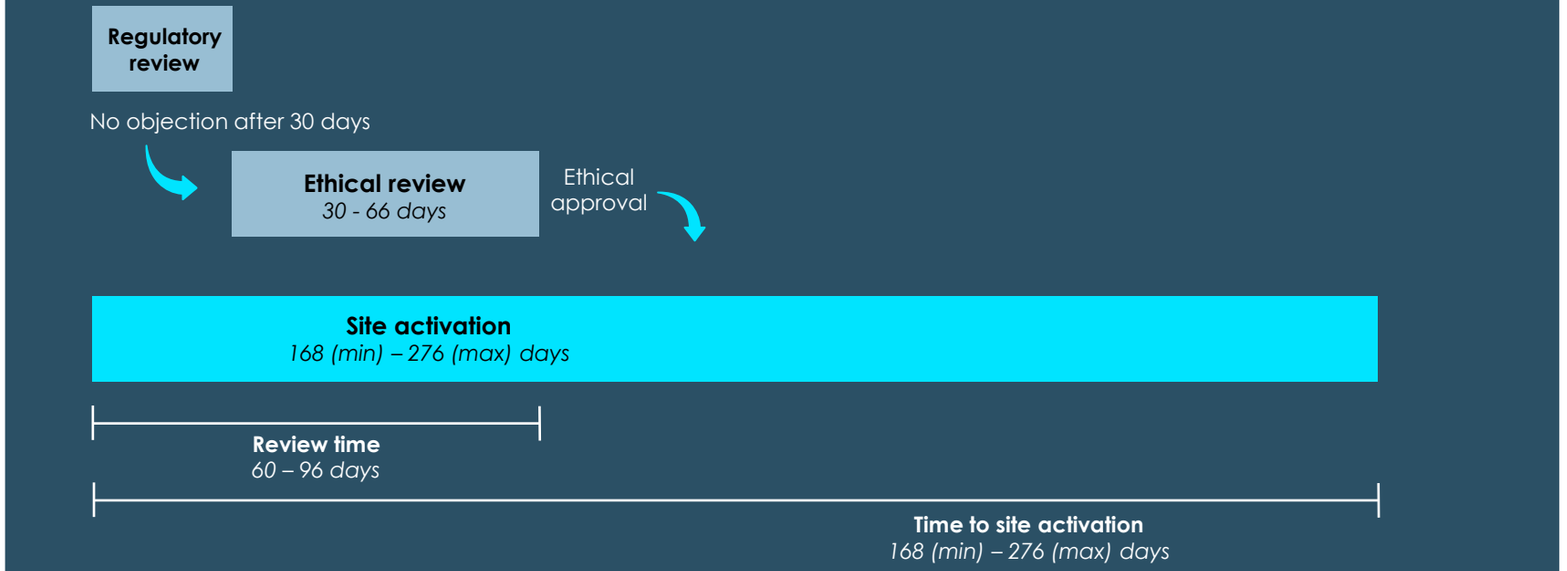
Status of the framework

The IND framework has been stable for decades.[3,4]

Recent FDA initiatives have focused on streamlining pre-IND engagement, such as INTERACT meetings.[5]

In September 2026, the FDA launched an **Expedited IND Pilot Program** under Operation TrialBlazer[6] to accelerate the initiation of first-in-human clinical trials. Under the pilot, sponsors work with qualified research institutions, and the FDA reviews parts of the IND on a rolling basis before formal submission, so issues can be resolved earlier, reducing the risk of clinical holds. The pilot also tests whether IRB review and site contracting can run in parallel with IND preparation. The statutory 30-day IND review remains. The FDA expects to select 8 to 10 sponsor–institution pairs, with applications closing on 30 October 2026.[7,8]

Figure 4. Sequencing and timelines, US



Note: A full regulatory review is done only for the initial "IND" submission.
Source: Copenhagen Economics, based on EFPIA (2024) and Krafcik et al. (2017).

(1) Expert interviews (October 2026). / (2) Insight from expert interviews. / (3) Neuman et al. (2018). / (4) FDA (1987). / (5) 21 CFR Part 312; FDA (2026a). / (6) (3) U.S. Department of Health and Human Services (2026). (7) FDA (2026b). / (8) FDA (2026c).

China's regulatory and ethical review follows separate, parallel pathways with clearly defined statutory deadlines

Regional brief – China

In China, regulatory and ethical review follow separate, parallel pathways

Clinical trial authorisation in China involves two distinct review tracks:

- **Regulatory review** by the National Medical Products Administration ("**NMPA**"), conducted through its Centre for Drug Evaluation ("**CDE**").
- **Ethical review** by an institutional ethics committee.

The two reviews are separate and may proceed in parallel

Ethics committee approval may be obtained independently of the NMPA/CDE's[1] review, but both reviews must be completed before the trial can begin.

For multinational and foreign-sponsored trials, additional requirements may also apply under China's Human Genetic Resources (**"HGR"**) framework.[2]

NMPA/CDE conducts a single, national regulatory review

Clinical trials in China are authorised by the NMPA, through its CDE, under the Provisions for Drug Registration. Sponsors submit a drug clinical trial application using the Common Technical Document ("**CTD**") format.

China operates an objection-based system. If the CDE does not reject the application or request clarification within 60 working days of clinical trial application acceptance, the trial is automatically deemed approved, without an explicit approval letter.

In 2025, the NMPA introduced a further fast-track procedure[3] that reduces the review period to 30 working days for eligible Category I innovative drugs. These include certain priority products, paediatric and rare disease programmes, and selected multi-region clinical development programmes. If additional review is required, the CDE notifies the applicant within 20 days, and the application reverts to the standard review timeline.

Trials must begin within three years from the IND approval, or within 12 weeks under the IND fast-track procedure. Trial initiation is measured by the first participant signing informed consent. According to expert interviews, sponsors are likely to pursue expedited review only when they can realistically complete site preparation and initiate the trial within the shorter deadline.

The regulatory review follows three main steps:

Step 1: CTA submission. The sponsor submits the CTA dossier to the CDE, including the non-clinical data, quality documentation, and clinical trial protocol required for review.

Step 2: Validation. The CDE checks the CTA dossier at a preliminary review. Applications are accepted within 5 working days of submission.[4]

Step 3: CDE technical review. The CDE organises a technical review, which may include an expert review, of the trial's safety, efficacy, and quality management. If no rejection or request for clarification is issued, the trial is automatically approved.

During the 60-working-day review, the CDE may request clarifications, generally requiring a response within five days. Unlike the EU, China has no routine RFI clock-stop mechanism for initial clinical trial applications. If substantial new data are needed, sponsors may have to withdraw and resubmit the application.

Ethical review is separate and institution-based

Separately, the relevant ethics committee reviews the protocol and must issue an opinion within 30 calendar days of accepting the application.[5] This is a deadline for issuing an opinion, not a guarantee of approval. There is no automatic approval if the committee misses the deadline.

Ethical review can start once the CDE has accepted the application for regulatory review. In most cases, the sponsor initiates it with the CDE's acceptance letter. The institutional ethics committee typically conducts the review.[6,7,8] For **multi-site trials**, two procedures are used:

- **Mutual recognition**: The lead site conducts the ethical review, and the other sites recognise its opinion, avoiding duplicate assessment. They may still review site-specific requirements before confirming their participation.
- **Independent review:** Sites that do not recognise the lead site's ethics opinion conduct their own review through their own ethics committee

Regulatory approval covers multiple clinical trials for the same product–indication combination

In China, regulatory authorisation is generally organised around an investigational drug and its intended indication. Once the NMPA/CDE has authorised the initial application, sponsors can conduct subsequent trial phases within the authorised scope by submitting additional protocols and supporting information, subject to ethics approval. According to expert interviews, sponsors may nevertheless opt to submit a separate application for each trial to ensure clarity on documentation requirements and avoid regulatory uncertainty.[9]

(1) Provisions for Drug Registration (2020); Drug Administration Law of the People's Republic of China (2019). / (2) Ministry of Science and Technology of the People's Republic of China (2023). / (3) NMPA (2025). / (4) State Administration for Market Regulation (2020). / (5) National Health Commission et al. (2023); NMPA et al. (2026). / (6) Expert interviews (October 2026). / (7) National Health Commission of the People's Republic of China et al. (2023). / (8) National Institute of Allergy and Infectious Diseases (2026). / (9) Expert interviews (October 2026).

China's regulatory and ethical review follows separate, parallel pathways with clearly defined statutory deadlines

Regional brief – China

Human Genetic Resources (HGR) requirements may introduce an additional regulatory step for multinational clinical trials that are also carried out in China

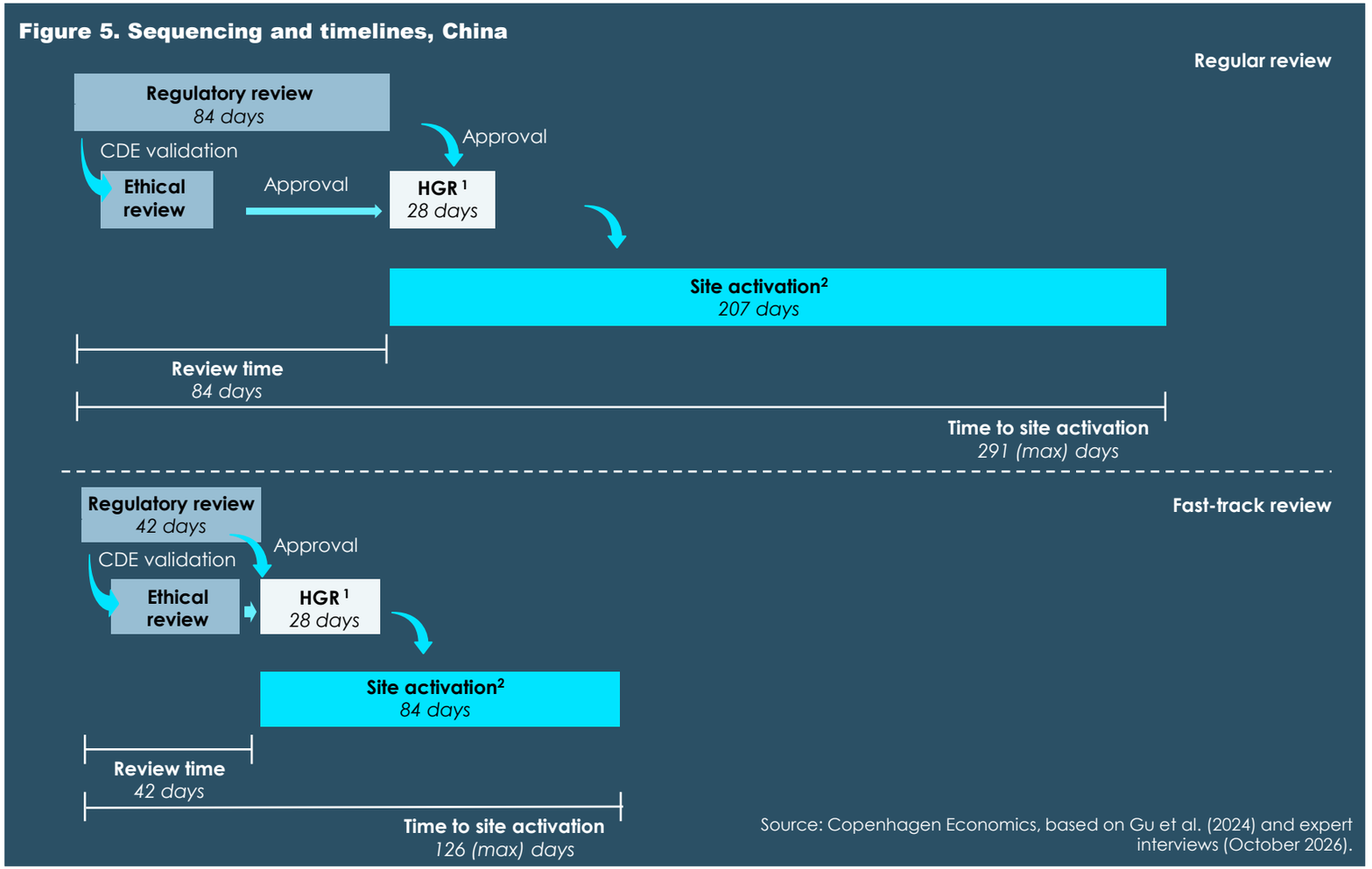
China separately regulates the collection, use, and export of human genetic material under its HGR framework,[1] administered by the National Health Commission ("**NHC**"). These requirements aim to protect Chinese human genetic resources, safeguard national interests, and ensure oversight of international research collaboration. Depending on the research activities, multinational trials involving Chinese human genetic resources may require HGR filing or prior approval. One application covers the whole trial. Preparation of HGR documentation can run in parallel with CTA and ethics review. However, certain HGR procedures require prior ethics approval and other supporting documentation, potentially affecting the timeline to trial initiation.

HGR rules can add a separate filing or approval step before a clinical trial starts. Sponsors can prepare the HGR application in parallel with the CTA and ethical review, but can file it only after CTA approval, the lead site's ethics approval and signed contracts with the lead site and laboratories, see Figure 5. Most trials use the filing route, available when samples stay in China, which takes about 7 days.[2] Trials that export samples need full approval: the NHC must decide within 28 days of accepting the application, extendable by 10 days, and approvals took 22 to 28 days on average in 2024.[3]

Status of the framework

Proposed 2026 amendments to the HGR framework would narrow the scope of regulated HGR data and introduce faster filing procedures for certain international collaborative trials not involving export of HGR information.

Figure 5. Sequencing and timelines, China



Source: Copenhagen Economics, based on Gu et al. (2024) and expert interviews (October 2026).

(1) Ministry of Science and Technology of the People's Republic of China (2023). / (2) Expert interviews (October 2026). See also CDE report (2025). / (3) Gu et al. (2024).

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APPENDIX

Methodology for assessing timelines

Timelines are calculated from regulatory submission to completion of regulatory and ethical review, and ultimately to site activation. To ensure comparability across the EU/EEA, US, and China, we use regulatory submission as the common starting point and account for differences in the sequencing of activities. Estimates combine statutory review periods with observed or estimated site activation timelines.

Time to complete regulatory and ethical review

The overall review duration depends on whether regulatory and ethical reviews run in parallel or sequentially. Review is considered complete when both regulatory authorisation and ethics approval are in place. Parallel reviews are measured by the longer duration, while sequential reviews are calculated by adding their durations.

- **EU/EEA:** We apply the proposed Biotech Act timelines of 47 calendar days without RFIs and 75 calendar days with RFIs, covering the coordinated regulatory and ethical assessment, see Table A1.[1]
- **US:** Based on input from expert interviews, we assume that IRB review begins after the 30-day FDA review period, although the two reviews can overlap in practice. Adding mean IRB review times of 30 days for central IRBs and 66 days for local IRBs gives an estimated 60–96 calendar days.[2]
- **China:** Ethics review runs in parallel with regulatory review, with an ethics opinion issued within 30 calendar days.[3] The overall duration is therefore determined by the longer CTA review period: 60 working days under the standard pathway or 30 working days under the expedited pathway. Applying an approximate conversion factor of 7/5 gives 84 and 42 calendar days, respectively.

Table A1. Timing
Calendar days

	EU/EEA (Biotech Act)	US	China
Regulatory review	47 - 75 days[1]	30 days	42 days (fast-track) 84 days
Ethical review	47 - 75 days[1]	30 (central) – 66 (local)[2]	30 days
Time to complete regulatory and ethical review	**47 - 75 days[1]**	**60 - 96 days**	**42 (fast-track)** **84 days**
Time from regulatory approval to site activation	-	-	207[6]
Time from regulatory submission to site activation (lower – upper bound)	294 - 339 days[4,5]	168 - 276 days[4,5]	126 (fast track) – 291 days[6]

Source: Copenhagen Economics.

(1) European Biotech Act. / (2) Krafcik et al. (2017). / (3) The 30-day timeline refers to the issuance of an ethics opinion, which may not constitute final approval if further information or revisions are required. It should be considered a lower bound. / (4) EFPIA (2024). / (5) Range from the fewest number of days to the largest, between oncology, rare diseases and infectious diseases. / (6) CDE report (2025).

Methodology for assessing timelines

Time from regulatory submission to site activation

We estimate total initiation time by combining regulatory review durations with available site-activation timelines.

Site-activation timelines are measured differently across regions.

For **the EU/EEA and US**, the available data measures the period from the Site Initiation Visit (SIV) to the Site Activation Visit (SAV),[1] averaged across sites.[2] The reported site activation timelines cover two therapeutic areas: infectious diseases and oncology.

We use i**nfectious disease trials as the lower bound** and **oncology trials as the upper bound**, reflecting the observed differences in site initiation times. This is consistent with the greater operational complexity of oncology trials, which often require more specialised site capabilities and preparation.

Based on expert interviews,[3] we assume that the SIV-to-SAV period in the EU/EEA and US can overlap with regulatory review.

For **China**, the available data measure a different period. We use data from the CDE (2025) report, which measures the mean time from clinical trial approval to the signing of the first informed consent form in China.[5] The CDE uses this milestone to measure the time taken to initiate a trial. We use it as a proxy for first-site activation, recognising that it generally occurs later. Because the period starts at approval, we model a parallel scenario for China, and both scenarios are sequential.

We calculate the following scenarios:

- **Fast-track pathway (lower bound):** We combine an approximate 42-calendar-day regulatory review period with the 12-week requirement to initiate the trial, giving 126 days.
- **Standard pathway (higher bound):** We add the approximate 84-calendar-day regulatory review to the CDE's mean initiation time of 6.8 months (about 207 days), giving 291 days.

The resulting estimates should be interpreted as indicative scenarios rather than directly comparable measures of total time from regulatory submission to site activation.

(1) SIV to SAV measures the time from site initiation activities to confirmation that the site is ready to recruit participants. / (2) See page 33 in EFPIA (2024). / (3) Text (4) EFPIA (2024). / (5) CDE report (2025).

Expert interviews

Table A2. Expert interviews

	Date	Region	Expert profiles
1	September 2026	EU/EEA	• Study start-up expert responsible for clinical trial start-up activities in a large European country. • Study start-up expert overseeing clinical trial start-up activities across EMEA, with 15 years of experience in study start-up.
2	September 2026	EU/EEA	• Pharmaceutical industry professional with extensive experience in implementing the EU CTA and managing clinical trial submissions, including regulatory requirements and requests for information. • Clinical operations professional overseeing trial placement and delivery across Europe, with experience in study set-up, site activation, and analysis of approval and recruitment timelines.
3	September 2026	US	• Expert in US clinical trial start-up and ethical review, including hands-on experience with central and local IRB submissions and oversight of regulatory submission activities. • Expert in clinical trial regulatory pathways across the US and Europe, including regulatory and ethical approval requirements.
4	October 2026	US	• Expert in US clinical trial start-up and site activation, including FDA submissions, IRB pathways, contracting, and operational timelines. • Expert in global clinical trial operations, with experience comparing regulatory, ethics, and site activation processes across the US, Europe and China.
5	October 2026	US	• Senior regulatory expert with extensive experience in US regulatory processes and global regulatory strategy, including clinical trial requirements and FDA interactions.
6	October 2026	China	• Clinical development expert with practical expertise in clinical trial start-up in China, particularly ethics review, site activation and HGR requirements. • Regulatory expert specialising in China's clinical trial authorisation framework, including NMPA/CDE procedures, regulatory timelines and alternative authorisation pathways.
7	October 2026	China	• Senior clinical trial operations expert, currently leading multiple clinical trial functions in China, including study start-up, regulatory submissions, drug importation and CTA activities. • Clinical trial study start-up expert in China, with nine years of experience and current responsibility for managing study start-up activities and staff.

Note: We conducted interviews between 28 September and 12 October 2026 with experts from pharmaceutical companies. Names and affiliations are withheld.
Source: Copenhagen Economics, based on expert interviews.

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