

Reliance in clinical trial review: International examples and approaches



Introduction

This document is intended to support regulators, policymakers, and other stakeholders involved in clinical trial oversight by providing practical examples of how reliance approaches are applied across different regions and regulatory settings. It complements a [position paper published by IFPMA on key principles for effective reliance in clinical trial reviews](#).

As described in the [World Health Organization Good Reliance Practices](#), reliance may take different forms and be applied to varying degrees. The examples in this document cover a range of implementation models across Europe, Latin America, Africa, the Middle East, and Asia-Pacific, as well as examples of regional collaboration and work-sharing arrangements, including mechanisms that are informal in nature as well as those guided by legislation. They are not intended to compare or assess regulatory systems, but rather to highlight the diversity of approaches that contribute to more efficient and coordinated clinical trial oversight globally.

Reliance approaches implemented by regulatory authorities



Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom



Regulatory framework: United Kingdom clinical trial authorization processes, including the Notification Scheme: [Clinical trials for medicines: apply for authorisation in the UK - GOV.UK¹](#).

Scope: Certain clinical trial applications, including Phase III trials already approved in the United States of America (USA) or the European Union (EU).

Application of reliance: MHRA may rely on assessments from recognized regulatory authorities to streamline clinical trial application evaluation for multinational studies. The Notification Scheme enables a risk-proportionate process with a 14-day review timeline (rather than 30 days), provided the same protocol and Investigator's Brochure (IB) versions are submitted (and for EU approvals, the same Investigational Medicinal Product (IMP) dossier version). For trials approved in the USA only, the IMP dossier submitted to the MHRA must document the same IMP manufacturing process.

Swissmedic, Switzerland



Regulatory framework: Swissmedic clinical trial assessment practices: [Clinical Trial Application Dossier guidance²](#).

Scope: Multinational clinical trial applications, with a particular focus on the assessment of quality related documentation.

Application of reliance: Swissmedic may selectively rely on decisions and/or assessment reports from EU National Competent Authorities or other recognized regulatory authorities, particularly in the evaluation of drug quality aspects, to support its scientific review of clinical trial applications for multinational trials.

This section presents examples of reliance approaches implemented by individual regulatory authorities across different regions and regulatory contexts.

Türkiye İlaç ve Tıbbi Cihaz Kurumu (TİTCK), Türkiye



Regulatory Framework: The TITCK [Guideline on Reliance Practices in Clinical Trial Applications \(KAD KLVZ 24\)³](#), first effective 1 September 2022, is the formal regulatory guidance establishing the procedures and principles for applying reliance in the evaluation of clinical trial applications under the national Clinical Trials Regulation.

Scope: The guidance allows TİTCK to take into account decisions, assessment reports, and inspection outcomes issued by other regulatory authorities or international organizations operating under comparable regulatory standards in the review of clinical trial applications.

Application of reliance: Reliance is applied operationally across key areas such as Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) inspections, as well as investigational product assessments. This enables TİTCK to leverage regulatory work conducted by other authorities, while retaining full authority to request additional information and to perform an independent final evaluation and decision.

Agência Nacional de Vigilância Sanitária (ANVISA), Brazil



Regulatory framework: Resolution RDC No. 945/2024 - New regulatory framework for clinical trials with medicines; [Normative Instructions \(NI\) No. 338/2024](#)⁴, as amended by [NI No. 345/2025](#)⁵.

Scope: Medical Product Clinical Development Dossiers (DDCM), Specific Clinical Trial Dossier (DEEC), substantial modifications to investigational products, and substantial amendments to the clinical trial protocols.

Application of reliance: The framework establishes guidelines and procedures for clinical trials conducted wholly or partially in Brazil for marketing authorization purposes. It introduces optimized regulatory pathways and a structured reliance framework, allowing ANVISA to use assessments performed by Equivalent Foreign Regulatory Authorities (EFRAs) as part of its decision-making process. The implementing Normative Instructions define the criteria for adopting reliance-, risk-, and complexity-based assessments and specify the list of accepted EFRAs, which includes US FDA, EMA, MHRA, Swissmedic, Pharmaceuticals and Medical Devices Agency (PMDA), and Health Canada. The framework aligns Brazil's clinical trial oversight with WHO Good Regulatory Practices and ICH Good Clinical Practice (GCP) standards.

Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), Mexico



Regulatory framework: [COFEPRIS Agreement](#)⁶ published on 24 March 2025.

Scope: Initial authorization of Phase III clinical trials for medicinal products, biologicals, and biotechnological products (protocol amendments excluded).

Application of reliance: COFEPRIS may rely on prior authorizations issued by recognized reference authorities (EMA, FDA, MHRA, Health Canada), subject to predefined criteria and study design limitations. Eligible studies include Phase III, non-adaptive clinical trials, designs that are not part of master protocols and do not include pre-planned design changes, as well as studies in specific therapeutic areas (e.g. oncology, cardiology, endocrinology, and neurology) or addressing diseases with high epidemiological impact in Mexico (e.g. diabetes, hypertension, and certain cancers). COFEPRIS establishes a maximum review period of 45 calendar days to issue a decision.

Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), Argentina



Regulatory framework: Provision No. 4008/2017⁷, amending the national Good Clinical Practice framework (Provision No. 6677/2010).

Scope: Clinical pharmacology studies where the protocol has been approved and is under implementation in:

- Countries listed in Annex I of Decree No. 150/92
- Countries considered by ANMAT to have regulatory convergence with its standards
- Countries recognized by PAHO/WHO as National Regulatory Authorities (NRAs) of Reference.

Application of reliance: The framework introduces an expedited assessment pathway for eligible studies. Timelines for technical evaluation are reduced from 60 to 45 working days, with an additional 10 working days for the administrative decision. This pathway applies where prior approval and ongoing implementation in recognized jurisdictions can be demonstrated, allowing ANMAT to take into account prior scientific and regulatory evaluations conducted by trusted foreign authorities, while retaining full responsibility for the final decision.

Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA), Ecuador



Regulatory framework: Agreement No. 00069-2024⁸ establishing the regulation for the oversight of clinical trials with medicines and processed natural products for human use.

Scope: Clinical trial oversight, including studies conducted in Ecuador or involving participation of Ecuador, where consideration may be given to evaluations conducted by high-surveillance health authorities.

Application of reliance: The framework introduces elements of reliance within the clinical trial review process, allowing ARCSA to consider guidelines or assessment reports from recognized high-surveillance authorities for clinical trials in which Ecuador is participating.

National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria



Regulatory framework: Guideline for registration and related activities of drugs, vaccines, and in-vitro diagnostics using the reliance procedures⁹ (Doc. Ref. No: DR&R-GDL-035-00; effective 10 September 2024).

Scope: Clinical trial applications and progression to later phase clinical development, including progression to Phase III studies.

Application of reliance: Clinical trial applications submitted to NAFDAC must comply with national regulatory requirements and be identical to those approved by a recognized reference authority. NAFDAC may rely on:

- Prior approvals or assessments by reference authorities
- Evaluations conducted under WHO collaborative procedures and prequalification
- Assessments by ICH member regulatory authorities
- Outcomes of AVAREF-facilitated joint reviews.

This supports an abridged, locally focused review that considers population and practice-specific factors.

Early-phase (Phase I/II) data generated under stringent regulatory oversight may support progression to Phase III trials in Nigeria. Where uncertainties remain, targeted bridging studies may be requested.

Saudi Food and Drug Authority (SFDA), Saudi Arabia



Regulatory framework: National clinical trial regulatory framework aligned with GCP and international standards - [Regulations and Requirements for Conducting Clinical Trials on Drugs](#)¹⁰ (updated 2025, with further revisions underway).

Scope: Clinical trials involving products previously approved by Stringent Regulatory Authorities (SRAs), including studies eligible under the bridging principle and reliance pathway.

Application of reliance: While an independent national review is maintained, abridged, or verification pathways may be applied for eligible clinical trial applications where prior approval by an SRA exists. The approach is intended to facilitate the conduct of clinical trials and support more efficient regulatory review.

Egyptian Drug Authority (EDA), Egypt



Regulatory framework: Egyptian Clinical Trials Law No. 214/2020 and its executive regulations, implemented through the [Guideline for Good Regulatory Oversight of Clinical Trials by the Egyptian Drug Authority \(2026\)](#)¹¹, established and updated to align with the ICH E6(R3).

Scope: Interventional clinical trials involving investigational medicinal products, including pharmaceutical, biological, and innovative products, herbal products, as well as medical devices and other interventions conducted in Egypt involving human participants.

Application of reliance: The framework provides multiple submission pathways for clinical trial applications, including a dedicated reliance pathway with shorter timelines as part of the clinical trial authorization process. Under this pathway, the EDA may take into account assessments conducted by trusted reference regulatory authorities selected according to published selection criteria when evaluating clinical trial applications. The EDA may revert to standard review pathways where necessary (e.g. in cases of safety, efficacy, or quality concerns).

Philippines Food and Drug Administration (FDA), Philippines



Regulatory framework: [FDA Circular No.2023-004 || Guidelines on Regulatory Reliance on the Conduct of Clinical Trials - Food and Drug Administration](#)¹².

Scope: All phases of multiregional clinical trials for investigational drug products addressing public health emergencies, rare diseases, and emerging or reemerging infectious diseases, intended for eventual product registration and marketing.

Application of reliance: Reliance may be applied across the approval, conduct, monitoring, and inspection of eligible clinical trials through an abridged regulatory pathway.

Regulatory decisions may be wholly or partially based on prior approvals by an identified Reference Drug Regulatory Authority (RDRA), provided that:

- The investigational product addresses priority public health needs
- All aspects of the clinical trial application, including protocol and investigational product information, are identical to those approved by the RDRA, subject to permissible local adaptations (e.g. informed consent materials)
- The trial or investigational product has not been rejected, withdrawn, suspended, or deferred by any RDRA.

Taiwan Food and Drug Administration (TFDA), Chinese Taipei



Regulatory framework: [Guidance for Clinical Trial Application of Pharmaceutical Products](#)¹³.

Scope: Multiregional clinical trials (MRCTs) and specified domestic clinical trials.

Application of reliance: TFDA applies two reliance-based review mechanisms depending on the study type and eligibility criteria:

- An abbreviated review for MRCT protocols conducted in any of the A10 countries and Taiwan, excluding clinical trials involving regenerative medicinal products, with a review timeline of 15 calendar days.
- A simplified (fast-track) review for eligible clinical trial protocols already approved by recognized authorities, including certain domestic trials approved as non-Investigational New Drug (IND) foreign studies or MRCTs involving regenerative medicinal products that are not first in human and use products previously approved for domestic clinical trials and manufactured using the same approved process. The simplified review pathway applies a 30-day review timeline, compared with standard review timelines of approximately 45 to 120 days, depending on study complexity.

Food and Drug Administration, Thailand (Thai FDA)



Regulatory framework: Clinical trial authorization framework, as outlined in [Thai FDA Notification for Clinical Trial Authorisation](#)¹⁴ and [Thai FDA Public Manual - Clinical Trial Authorisation](#)¹⁵ (in Thai).

Scope: Clinical trial applications where reference may be made to evaluation outcomes from recognized drug regulatory authorities, including US FDA, EMA (for products approved via the centralised procedure), PMDA (for cases that have undergone consultation), Swissmedic, Health Canada, MHRA, and Therapeutic Goods Administration (for approvals under the clinical trial authorization scheme).

Application of reliance: Within the clinical trial authorization process, reliance is applied as a supportive mechanism, enabling the consideration of evaluation outcomes from recognized authorities in the assessment of applications. The approach aligns with WHO Good Reliance Practices and supports more efficient review, while the Thai FDA retains full responsibility for its regulatory decisions.

Coordinated assessment under regional framework



This section presents examples of coordinated and collaborative assessment approaches, where regulatory authorities undertake joint or work sharing assessments. While distinct from reliance models, these approaches also contribute to reducing duplication and supporting efficient and aligned clinical trial oversight.

European Union

Regulatory framework:

The EU operates a unique work-sharing and coordinated assessment model under the [Clinical Trials Regulation \(EU\) No 536/2014](#)¹⁶.

Scope: Clinical trial applications for trials conducted in more than one EU Member State.

Application of the approach:

Clinical trial sponsors submit a single clinical trial application through the EU-wide Clinical Trials Information System (CTIS), which acts as the sole entry point for all Member States concerned. A designated Reporting Member State leads the Part I scientific assessment, the outcome of which is shared with all other concerned Member States. Part II assessments, covering ethical and national-specific aspects, are conducted separately by each Member State but within harmonized timelines.

AVAREF (African Vaccine Regulatory Forum)

Regulatory framework:

WHO facilitated collaborative procedures for joint regulatory and ethics review of clinical trial applications - [Clinical Trials Assessment Tools](#)¹⁷.

Scope: Clinical trial applications across multiple African countries.

Application of the approach:

NRAs and ethics committees jointly review a common clinical trial application, using shared procedures, tools, and coordinated timelines.

Participating authorities exchange scientific questions, discuss findings collectively, and align evaluation steps as part of a single review process. Each authority subsequently issues its national decision, taking into account the jointly generated scientific assessment.

A recent pilot involving 16 countries has been conducted to test and prove the value of multi-country collaboration between NRAs and ethic committees. This approach reduces duplication, supports harmonization, and enhances regulatory efficiency and capacity across participating countries.

Association of Southeast Asian Nations (ASEAN) Joint Assessment Procedure

Regulatory framework:

[ASEAN Joint Assessment procedures for pharmaceutical products](#)¹⁸, from 2022.

Scope: Primarily established for marketing authorization, with elements of the collaborative assessment approach applied by participating ASEAN Member States (e.g. Thailand, Malaysia, Singapore, Indonesia, and Vietnam) in the context of MRCT, in accordance with national regulatory frameworks.

Application of the approach:

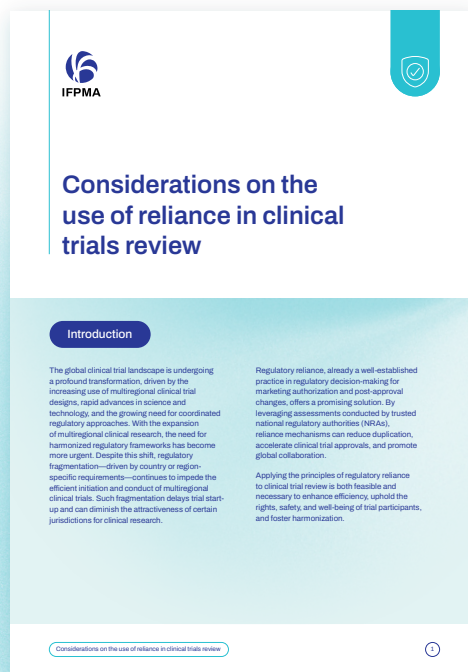
Participating NRAs conduct collaborative assessments through joint review activities and share assessment reports and scientific outcomes. Each authority retains responsibility for its national regulatory decision-making, while making use of the jointly generated assessment outputs to support coordinated, efficient, and consistent regulatory evaluations across participating countries.

Endnotes

1. Medicines and Healthcare products Regulatory Agency (MHRA), [Clinical trials for medicines: apply for authorisation in the UK - GOV.UK](#), revised 2026
2. Swissmedic, [Clinical Trial Application Dossier guidance](#), 2025
3. Türkiye İlaç ve Tıbbi Cihaz Kurumu (TİTCK), [Guideline on Reliance Practices in Clinical Trial Applications \(KAD KLVZ 24\)](#), revised 2025.
4. Agência Nacional de Vigilância Sanitária (ANVISA), [Normative Instructions \(NI\) No. 338/2024](#), 2024.
5. Agência Nacional de Vigilância Sanitária (ANVISA), [Normative Instruction No. 345/2025](#), 2025.
6. Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), [Agreement on Clinical Trial Reliance Procedures](#), 2025.
7. Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), [Provision No. 4008/2017 Amending the Good Clinical Practice Framework](#), 2017.
8. Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA), [Agreement No. 00069-2024 on the Oversight of Clinical Trials with Medicines and Processed Natural Products for Human Use](#), 2025.
9. National Agency for Food and Drug Administration and Control (NAFDAC), [Guideline for Registration and Related Activities of Drugs, Vaccines, and In Vitro Diagnostics Using the Reliance Procedure](#), 2025.
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11. Egyptian Drug Authority (EDA), [Guideline for Good Regulatory Oversight of Clinical Trials by the Egyptian Drug Authority](#), 2026.
12. Food and Drug Administration (Philippines FDA), [FDA Circular No. 2023-004: Guidelines on Regulatory Reliance on the Conduct of Clinical Trials](#), 2023.
13. Taiwan Food and Drug Administration (TFDA), [Guidance for Clinical Trial Application of Pharmaceutical Products](#), 2025.
14. Food and Drug Administration, Thailand (Thai FDA), [Notification for Clinical Trial Authorisation and Public Manual for Clinical Trial Authorisation](#), 2025.
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17. World Health Organization (WHO), [Clinical Trials Assessment Tools: African Vaccine Regulatory Forum \(AVAREF\)](#).
18. Association of Southeast Asian Nations (ASEAN), [ASEAN Joint Assessment Procedures for Pharmaceutical Products](#), 2022.



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