AURELYN AI CLINICAL
REGULATORY INTELLIGENCE

The Global Clinical Trial Standards Atlas

A structured reference to the regulations, ethics frameworks, data standards, electronic-submission formats and live data APIs that govern interventional and non-interventional research — mapped across 22 jurisdictions and the complete clinical trial lifecycle.

22	14	14	10	9
JURISDICTIONS	ICH GUIDELINES	DATA STANDARDS	LIVE APIS	LIFECYCLE PHASES

VERSION v2.1 EFFECTIVE January 1, 2026 FACTS VERIFIED June 2026

Illustrative regulatory reference compiled in good faith — not legal, regulatory or investment advice.
Confirm all requirements against the primary sources and competent authorities cited herein.

HOW TO USE THIS ATLAS

Reference Guide & Contents

This document is the print companion to the interactive Global Clinical Trial Standards Atlas. It consolidates the competent authorities, governing legislation, trial-application pathways, electronic-submission formats, harmonised data standards, the full study lifecycle and the public data APIs that underpin clinical research across 22 jurisdictions. Each country profile is self-contained; the cross-cutting sections (ICH, ethics frameworks, data standards, eCTD, lifecycle and APIs) apply globally. All date-sensitive facts were web-verified in June 2026.

SECTION	CONTENTS
By Jurisdiction	12 country / regional regulatory profiles — authority, legislation, pathway, eCTD, registry
ICH & Global Frameworks	14 ICH guidelines (Q/S/E/M) + 8 ethics & quality frameworks
Data Standards	14 CDISC, dictionary, exchange & master-data standards across the data stack
eCTD & Submissions	CTD module structure + the v3.2.2 → v4.0 regional transition
Trial Lifecycle	9 phases from concept & nonclinical through post-market surveillance
Interventional vs Non-Interventional	Three study archetypes and their governing rules
APIs & Data Sources	10 public registries and regulatory APIs with verified endpoints
Glossary	25 core acronyms

Legend — version status reflects the global CTD transition: **v3.2.2** is the current mandatory eCTD baseline in most regions; **v4.0** is the HL7-based next generation, with Japan (PMDA) the earliest mandate (1 Apr 2026).

COUNTRY & REGIONAL PROFILES

By Jurisdiction

Each profile gives the competent authority, governing legislation, trial-application pathway and timelines, eCTD Module 1 status, national registry and transparency rules.

United States

NORTH AMERICA

U.S. Food and Drug Administration (CDER / CBER / CDRH) (FDA)

GCP	ICH E6(R3) — FDA adopted 9 Sep 2025 (non-binding guidance); 21 CFR GCP regulations remain binding
Legislation	21 CFR Part 312 — Investigational New Drug (IND) application · 21 CFR Part 11 — Electronic records & electronic signatures · 21 CFR Part 50 — Protection of human subjects / informed consent · 21 CFR Part 56 — Institutional Review Boards (IRB) · 21 CFR Part 54 — Financial disclosure by investigators · 21 CFR Part 312.32 — IND safety reporting · 21 CFR Part 812 — Investigational Device Exemption (IDE) · FD&C Act; FDAAA §801 (registration & results)
Trial Application	**IND** — Investigational New Drug application submitted to FDA before first-in-human; commercial INDs via eCTD. *(30-day safety review; trial may proceed unless FDA places a clinical hold.)*
eCTD	Module 1: FDA Module 1 (US Regional) — Forms 1571/1572/3674; comparatively simple regional structure · Version: eCTD v3.2.2 mandatory for NDA/BLA/ANDA/commercial IND; eCTD v4.0 accepted (voluntary) by CDER/CBER since 16 Sep 2024 · Required
Registry	ClinicalTrials.gov — https://clinicaltrials.gov
Transparency	Registration within 21 days of first enrollment; results within 12 months of primary completion (FDAAA 801 / Final Rule 42 CFR 11).
Distinctive	Diversity Action Plans (FDORA 2022) · Real-World Evidence Program (21st Century Cures) · Decentralized trials guidance (2024) · Project Optimus / Project Orbis (oncology)
Primary sources	FDA — Clinical Trials · FDA — eCTD

European Union / EEA

EUROPE

European Medicines Agency + National Competent Authorities + Ethics Committees (EMA + NCAs)

GCP	ICH E6(R3) Principles + Annex 1 — in effect in EU since 23 Jul 2025; Annex 2 (non-traditional interventional) expected 2026
Legislation	Regulation (EU) No 536/2014 — Clinical Trials Regulation (CTR); fully in force, single portal · Directive 2001/20/EC — repealed by CTR on 31 Jan 2022 · Regulation (EU) 2017/745 (MDR) & 2017/746 (IVDR) — device & IVD studies · GDPR (EU) 2016/679 — personal data processing · EU AI Act (Reg. 2024/1689) — phased; AI systems in trials · EudraLex Volume 10 — clinical trials guidance · Reg. (EC) 1901/2006 — Paediatric Regulation
Trial Application	**CTA via CTIS** — Single Clinical Trial Application to up to 30 EU/EEA states through the Clinical Trials Information System (CTIS); Part I (scientific) + Part II (national). *(Validation → ~45 days Part I assessment; combined assessment with RFI clock-stops; single decision per Member State.)*
eCTD	Module 1: EU Module 1 (M1 EU spec) — country-specific elements; cover letter, application form, PI/SmPC, PIL · Version: eCTD v3.2.2 standard for MAAs; EMA began optional eCTD v4.0 for centralised MAAs from 22 Dec 2025, mandate ~2028 · Required
Registry	CTIS public portal (euclinicaltrials.eu) — https://euclinicaltrials.eu
Transparency	CTIS is a public, transparency-by-default register; trial information & results summaries published per CTR Annex with deferral rules. CTIS designated a WHO ICTRP primary registry.
Distinctive	Single EU submission via CTIS · Transparency-by-default publication · ACT EU initiative · SmPC/QRD labelling consistency
Primary sources	EMA — Clinical Trials Regulation · EC — CTR 536/2014

United Kingdom

EUROPE

Medicines & Healthcare products Regulatory Agency + HRA / REC (MHRA)

GCP	UK GCP (ICH E6 basis); MHRA confirmed adoption of ICH E6(R3) Principles & Annex 1
Legislation	Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031, as amended) · New CT legislation 2024/2025 — major reform (combined review, proportionate, transparency mandate) · Human Medicines Regulations 2012 (SI 2012/1916) · Data Protection Act 2018 / UK GDPR · Windsor Framework — Northern Ireland under MHRA from 1 Jan 2025
Trial Application	**CTA (Combined Review)** — Single combined MHRA + Research Ethics Committee (REC) application via IRAS; post-Brexit UK operates independently of CTIS. *(Combined review ~30 days MHRA assessment alongside REC opinion; statutory clock with RFI.)*
eCTD	Module 1: UK Module 1 (UK regional eCTD spec, post-Brexit) · Version: eCTD v3.2.2; UK regional M1 specification maintained by MHRA · Required
Registry	ISRCTN registry — https://www.isrctn.com
Transparency	New regime introduces a legal duty to register trials and report results; HRA make-it-public policy.
Distinctive	Combined Review (MHRA+REC single application) · ILAP — Innovative Licensing & Access Pathway · 2024/25 CT reform legislation · International Recognition Procedure (IRP)
Primary sources	MHRA — Clinical trials for medicines · HRA

Switzerland

EUROPE

Swissmedic + Cantonal Ethics Committees (swissethics) (Swissmedic)

GCP	ICH E6(R3) Principles & Annex 1 in effect from 15 Aug 2025 (E6(R2) valid until that date)
Legislation	Human Research Act (HRA / HFG) · Clinical Trials Ordinance (ClinO / KlinV) · Therapeutic Products Act (TPA / HMG) · Ordinance on Clinical Trials with Medical Devices (ClinO-MD)
Trial Application	**Dual submission** — Parallel applications to Swissmedic (authorisation) and the responsible Cantonal Ethics Committee via the BASEC portal. *(EC ~30 days; Swissmedic ~30–60 days depending on category (A/B/C).)*
eCTD	Module 1: Swiss Module 1 (CH regional) · Version: eCTD v3.2.2; eCTD v4.0 voluntary 2024, mandatory target ~2028 · Required
Registry	SNCTP / Kofam portal — https://www.kofam.ch
Transparency	Mandatory registration in a WHO/ICMJE primary registry; SNCTP portal publishes trial summaries.
Distinctive	BASEC single ethics portal · ICH E6(R3) early adopter · Category A/B/C risk-based pathway
Primary sources	Swissmedic — Clinical trials

Japan

ASIA-PACIFIC

Pharmaceuticals & Medical Devices Agency + Ministry of Health, Labour & Welfare (PMDA / MHLW)

GCP	J-GCP (MHLW Ordinance) aligned to ICH E6; ICH E5 ethnic factors / bridging central to Japan strategy
Legislation	Pharmaceuticals & Medical Devices Act (PMD Act / former PAL) · J-GCP Ministerial Ordinance · Clinical Trials Act (Rinsho Kenkyu Ho) — investigator-initiated/specified trials · Act on Protection of Personal Information (APPI)
Trial Application	**CTN (Clinical Trial Notification)** — Chiken (□□) trials filed via CTN to PMDA; PMDA consultations heavily used pre-submission. *(CTN 30-day review before first dosing; PMDA scientific consultations scheduled separately.)*
eCTD	Module 1: JP Module 1 (Japan regional) · Version: eCTD v3.2.2; PMDA mandates eCTD v4.0 from 1 Apr 2026 (v3 accepted to 31 Mar 2026) · Required
Registry	jRCT (Japan Registry of Clinical Trials) — https://jrct.niph.go.jp
Transparency	Registration in jRCT (WHO primary registry); results posting required for specified/regulated trials.
Distinctive	eCTD v4.0 mandatory Apr 2026 (earliest globally) · ICH E5 bridging strategy · SAKIGAKE priority designation · PMDA consultation system
Primary sources	PMDA — Review of Drugs

China

ASIA-PACIFIC

National Medical Products Administration + Center for Drug Evaluation (NMPA / CDE)

GCP	China GCP (2020 revision) harmonised with ICH E6; China joined ICH in 2017
Legislation	Drug Administration Law (2019 revision) · Drug Registration Regulation (2020) · China GCP (NMPA/NHC Order, 2020) · Human Genetic Resources (HGR) Regulation · Personal Information Protection Law (PIPL)
Trial Application	**IND (CDE)** — Drug Clinical Trial Application to CDE; implied (default) approval if no objection in statutory window. HGR approval required for human genetic material. *(60 working-day default-approval mechanism (silence = approval) since 2018 reform.)*
eCTD	Module 1: China M1 (CDE eCTD specification, phased) · Version: eCTD adopted; CDE eCTD v1.0 specification, transitioning · Required
Registry	ChiCTR / CDE platform — https://www.chictr.org.cn
Transparency	Registration and results on the CDE drug clinical trial registration & information publicity platform.
Distinctive	60-day implied IND approval · HGR (genetic resources) approval gate · ICH member since 2017 · Priority review for innovative drugs
Primary sources	NMPA · CDE

Canada

NORTH AMERICA

Health Canada — Therapeutic Products Directorate / BGTD (Health Canada)

GCP	ICH E6(R3) — Health Canada implementation effective 1 Apr 2026
Legislation	Food and Drugs Act + Food and Drug Regulations, Division 5 (Drugs for Clinical Trials Involving Human Subjects) · Medical Devices Regulations (investigational testing) · TCPS 2 (Tri-Council Policy Statement) — ethics · PIPEDA — privacy
Trial Application	**CTA** — Clinical Trial Application to Health Canada; REB approval required; eCTD submission. *(30-day default review (no-objection letter / NOL).)*
eCTD	Module 1: CA Module 1 (Canadian regional) · Version: eCTD mandatory since 1 Jan 2018 for NDS/ANDS; eCTD v4.0 voluntary 2024, mandatory target ~2027 · Required
Registry	Health Canada CT Database + ClinicalTrials.gov — https://health-products.canada.ca/ctdb-bdec/
Transparency	Public Release of Clinical Information (PRCI) initiative; registration via WHO/ICMJE registry.
Distinctive	eCTD mandatory since 2018 · PRCI clinical data transparency · Agile licensing reform · ICH E6(R3) from Apr 2026
Primary sources	Health Canada — Clinical trials

Australia

ASIA-PACIFIC

Therapeutic Goods Administration + HRECs (TGA)

GCP	TGA-annotated ICH E6; integrated with the National Statement on Ethical Conduct in Human Research
Legislation	Therapeutic Goods Act 1989 + Therapeutic Goods Regulations 1990 · CTN (Clinical Trial Notification) & CTA (Clinical Trial Approval) schemes · National Statement on Ethical Conduct in Human Research (NHMRC) · Privacy Act 1988
Trial Application	**CTN / CTA** — Most trials use the CTN notification scheme (HREC-approved, TGA-notified); higher-risk via CTA approval pathway. *(CTN: notify TGA after HREC approval; no separate TGA review for CTN. CTA: TGA assessment.)*
eCTD	Module 1: AU regional eCTD M1 (used for marketing applications, not trial notification) · Version: eCTD v3.2.2 for marketing submissions; eCTD v4.0 voluntary · Not yet mandatory
Registry	ANZCTR — https://www.anzctr.org.au
Transparency	Prospective registration in ANZCTR (WHO primary registry) expected.
Distinctive	CTN notification scheme (fast start-up) · HREC-led ethics model · R&D tax incentive for trials · ANZCTR registry
Primary sources	TGA — Clinical trials

South Korea

ASIA-PACIFIC

Ministry of Food & Drug Safety (formerly KFDA) (MFDS)

GCP	KGCP harmonised with ICH E6; Korea is an ICH member
Legislation	Pharmaceutical Affairs Act · KGCP (MFDS Notification) · Bioethics & Safety Act · Personal Information Protection Act (PIPA)
Trial Application	**IND (MFDS)** — IND application to MFDS; IRB approval required. *(~30 working-day review.)*
eCTD	Module 1: KR Module 1 (Korean regional) · Version: eCTD adopted by MFDS; regional M1 spec · Required
Registry	CRIS (Clinical Research Information Service) — https://cris.nih.go.kr
Transparency	Registration in CRIS (WHO primary registry).
Distinctive	ICH member · CRIS primary registry · Global trial hub in Asia · MFDS GMP/GCP harmonisation
Primary sources	MFDS

India

ASIA-PACIFIC

Central Drugs Standard Control Organisation (DCGI) (CDSCO)

GCP	Indian GCP (CDSCO) + ICH E6; New Drugs & Clinical Trials Rules 2019
Legislation	New Drugs and Clinical Trials Rules, 2019 · Drugs and Cosmetics Act 1940 · Indian GCP Guidelines (CDSCO) · Digital Personal Data Protection Act 2023
Trial Application	**CT permission (DCGI)** — Application via SUGAM portal to CDSCO/DCGI; Ethics Committee registration with CDSCO required. *(NDCT Rules 2019: ~90 working days; deemed approval for certain applications if no decision in statutory time.)*
eCTD	Module 1: India regional (eCTD adopted via SUGAM) · Version: eCTD adopted; CDSCO eCTD specification · Required
Registry	CTRI (Clinical Trials Registry – India) — https://ctri.nic.in
Transparency	Prospective CTRI registration mandatory before first enrollment.
Distinctive	NDCT Rules 2019 modernisation · SUGAM e-portal · Deemed-approval timelines · Mandatory CTRI registration
Primary sources	CDSCO

Brazil

LATIN AMERICA

Agência Nacional de Vigilância Sanitária + CONEP/CEP (ANVISA)

GCP	ICH E6 basis; Brazil joined ICH (2016); Law 14.874/2024 modernised the national framework
Legislation	Law No. 14.874/2024 — National clinical research framework · ANVISA resolutions (DDCM / dossier; RDC series) · CNS Resolution 466/2012 & 510/2016 — ethics (CEP/CONEP) · LGPD (Lei Geral de Proteção de Dados)
Trial Application	**DDCM + CEP/CONEP** — Drug Clinical Development Dossier (DDCM) to ANVISA in parallel with ethics review (CEP/CONEP). *(Law 14.874/2024 sets statutory deadlines to cut historic delays.)*
eCTD	Module 1: BR regional · Version: eCTD adopted by ANVISA; regional specification · Required
Registry	ReBEC / Plataforma Brasil — https://ensaiosclinicos.gov.br
Transparency	Registration in ReBEC (WHO primary registry) / Plataforma Brasil.
Distinctive	Law 14.874/2024 reform (statutory timelines) · ICH member · CEP/CONEP dual ethics · ReBEC registry
Primary sources	ANVISA

Mexico

LATIN AMERICA

Federal Commission for Protection against Sanitary Risks (COFEPRIS) — Ministry of Health (SSA) (COFEPRIS)

GCP	ICH E6 GCP applied. Reliance agreement (DOF, effective 19 Jun 2025) lets COFEPRIS rely on prior FDA / EMA / MHRA / Health Canada authorizations to shorten review.
Legislation	General Health Law (Ley General de Salud) — health-research provisions · Regulation of the General Health Law on Health Research · NOM-012-SSA3-2012 — criteria for human research · Reliance criteria agreement for foreign protocol authorizations (2025) · Federal Law on Protection of Personal Data
Trial Application	**Protocol authorization via DIGIPRiS** — Research-protocol authorization (procedure COFEPRIS-04-010) filed through DIGIPRiS, the digital research & clinical-trials platform; Research, Ethics and Biosafety committee approvals required. *(~60 days (variable); reliance route is materially faster where a recognized foreign authority has already approved the protocol.)*
eCTD	Module 1: Mexico regional Module 1 (administrative, Spanish) · Version: eCTD / CTD accepted for protocol and registration dossiers · Required
Registry	National Registry of Clinical Trials (RNEC) / ClinicalTrials.gov — https://clinicaltrials.gov
Transparency	Registration expected in a recognized registry; protocol authorizations and amendments tracked via DIGIPRiS.
Distinctive	DIGIPRiS digital submission · Foreign-authority reliance route (2025) · CONBIOÉTICA-registered committees · Updated Bioethics Committee rules (2026)
Primary sources	COFEPRIS · DIGIPRiS

Argentina

LATIN AMERICA

Administración Nacional de Medicamentos, Alimentos y Tecnología Médica + jurisdictional ethics committees (ANMAT)

GCP	ICH E6(R3) formally adopted via ANMAT Disposition No. 7516/2025, which repeals the prior 6677/2010 regime and unifies GCP for registration studies.
Legislation	ANMAT Disposition No. 7516/2025 — GCP; adopts ICH E6(R3); repeals 6677/2010, 4008/17, 9929/19 · Resolution No. 1480/2011 (Ministry of Health) — clinical-research requirements · Law No. 26,529 — patients' rights & informed consent · Personal Data Protection Law No. 25,326
Trial Application	**ANMAT authorization** — Prior ANMAT authorization required for Phase I–III protocols (Phase IV in defined cases, e.g. placebo control), with jurisdictional ethics-committee approval. Documents in Spanish. *(~70 business days or less (accelerated from 160 days by Disp. 4008/17; framework modernized 2025).)*
eCTD	Module 1: Argentina regional Module 1 (Spanish) · Version: eCTD / CTD accepted · Required
Registry	ReNIS — National Registry of Health Research — https://www.argentina.gob.ar/salud
Transparency	Studies recorded in ReNIS; ANMAT publishes authorizations and inspection outcomes.
Distinctive	ICH E6(R3) adopted (Disp. 7516/2025) · Accelerated ~70-day review · ReNIS national registry · Jurisdictional ethics committees
Primary sources	ANMAT

Singapore

ASIA-PACIFIC

Health Sciences Authority — Health Products Regulation Group (HSA)

GCP	ICH E6(R3) Principles + Annex 1 implemented 1 Jan 2026.
Legislation	Health Products Act & Health Products (Clinical Trials) Regulations 2016 · Medicines Act & Medicines (Clinical Trials) Regulations · Human Biomedical Research Act (HBRA) · Personal Data Protection Act (PDPA)
Trial Application	**CTA / CTN / CTC via PRISM** — Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC) submitted through PRISM; IRB approval runs in parallel and is required before start. *(CTA ~30 working days; ~15 working days for certain Phase 1 BA/BE/food-effect studies; CTN is a notification route for lower-risk trials.)*
eCTD	Module 1: Singapore regional Module 1 · Version: CTD format; eCTD accepted for product registration · Required
Registry	WHO ICTRP / ICMJE-acceptable registry (e.g. ClinicalTrials.gov) — https://clinicaltrials.gov
Transparency	Registration in a WHO/ICMJE-acceptable registry required; HBRA governs human biomedical research oversight.
Distinctive	E6(R3) live 1 Jan 2026 · PRISM e-submission · HBRA research governance · Risk-tiered CTA/CTN/CTC routes
Primary sources	HSA — clinical trials · Apply CTA / CTN

Taiwan

ASIA-PACIFIC

Taiwan Food and Drug Administration + Center for Drug Evaluation (CDE) (TFDA)

GCP	ICH member (since 2018); national GCP regulations applied.
Legislation	Pharmaceutical Affairs Act · Regulations on Human Trials · Regulations for Good Clinical Practice · Personal Data Protection Act
Trial Application	**IND review** — Investigational New Drug review filed via the TFDA Online Application Platform; central IRB (c-IRB) + local IRBs run in parallel. TFDA does not approve until ethics approval is obtained. *(Standard IND ~45 calendar days; multinational CTN fast-track ~14 days (same protocol filed with FDA/EMA); First-in-Human simplified to ~30 business days.)*
eCTD	Module 1: Taiwan regional Module 1 · Version: eCTD accepted · Required
Registry	Taiwan Clinical Trial Registry / ClinicalTrials.gov — https://clinicaltrials.gov
Transparency	Trial registration required; case-review status published on the TFDA portal.
Distinctive	~45-day IND / ~14-day fast-track · Central IRB (c-IRB) system · Oncology-heavy pipeline · Online application platform
Primary sources	TFDA · CDE Taiwan

Thailand

ASIA-PACIFIC

Thai Food and Drug Administration (Ministry of Public Health) + recognized ECs (ECMOPH / CREC) (Thai FDA)

GCP	ICH-GCP applied (with local amendments).
Legislation	Drug Act B.E. 2510 (and amendments) · Clinical sample-production & drug-import orders for research · Ethics committee registration procedures · Personal Data Protection Act B.E. 2562 (2019)
Trial Application	**Drug import licence / sample-production permission** — Thai FDA approval of the research drug import licence (or sample-production permission) is tied to EC approval by a Thai FDA-recognized ethics committee; submitted after or in parallel with EC review. *(EC + FDA review typically takes several months; a local bridging study may be requested if Thai patients are not represented.)*
eCTD	Module 1: ASEAN CTD (ACTD) / regional Module 1 · Version: ACTD; eCTD accepted · Required
Registry	Thai Clinical Trials Registry (TCTR) — https://www.thaiclinicaltrials.org
Transparency	Registration in the Thai Clinical Trials Registry (TCTR) required before start.
Distinctive	Thai FDA under MOPH · TCTR registration · CREC / ECMOPH central ethics · Possible local bridging data
Primary sources	Thai FDA · ClinRegs — Thailand

Malaysia

ASIA-PACIFIC

National Pharmaceutical Regulatory Agency + Drug Control Authority (DCA) (NPRA)

GCP	Malaysian GCP (ICH-GCP basis), strictly enforced via NPRA inspections.
Legislation	Control of Drugs and Cosmetics Regulations 1984 · Malaysian Guideline for Application of CTIL / CTX (8.1 ed., effective 30 Apr 2025) · Personal Data Protection Act 2010
Trial Application	**CTIL / CTX** — Clinical Trial Import Licence (CTIL) for an imported IP or Clinical Trials Exemption (CTX) for a local IP, submitted to the DCA in parallel with MREC/IEC review; NMRR registration required. First-in-Human accepted since Apr 2025. *(DCA review in parallel with ethics; CTIL/CTX is not issued before IEC/IRB approval is submitted.)*
eCTD	Module 1: ASEAN CTD (ACTD) / regional Module 1 · Version: ACTD; eCTD accepted · Required
Registry	National Medical Research Register (NMRR) — https://www.nmrr.gov.my
Transparency	NMRR registration required; NPRA publishes an interactive GCP/BE/ethics inspection dashboard.
Distinctive	CTIL/CTX dual route · NMRR registration · FIH accepted (2025) · SUSAR via CIOMS + DSUR to NPRA
Primary sources	NPRA — clinical trials

New Zealand

ASIA-PACIFIC

Medsafe (NZ Medicines & Medical Devices Safety Authority, Ministry of Health) + SCOTT + HDEC (Medsafe)

GCP	ICH E6 GCP applied.
Legislation	Medicines Act 1981 (section 30) · Medicines Regulations 1984 · Health & Disability Ethics Committees (HDEC) standards
Trial Application	**SCOTT / Medsafe + HDEC (parallel)** — Application submitted to a Health & Disability Ethics Committee (HDEC) and Medsafe simultaneously; the Standing Committee on Therapeutic Trials (SCOTT) advises the Director-General of Health. *(~45 days via the parallel pathway; SCOTT review not required for trials using a previously-approved medicine.)*
eCTD	Module 1: NZ regional Module 1 · Version: eCTD / CTD accepted · Required
Registry	ANZCTR (Australian New Zealand Clinical Trials Registry) — https://www.anzctr.org.au
Transparency	Registration in ANZCTR (a WHO ICTRP primary registry).
Distinctive	Parallel HDEC + Medsafe · ANZCTR registry · ACC no-fault injury context · Strong early-phase ecosystem
Primary sources	Medsafe — clinical trials · HDEC

Israel

MIDDLE EAST

Israel Ministry of Health – Pharmaceutical Division + institutional Helsinki Committees (MOH)

GCP	ICH E6 GCP applied.
Legislation	Public Health Regulations (Medical Experiments on Humans) 1980 · MoH Procedure / Guideline 14 (NOHAL 14) · MoH Procedure EX-012 — import/release of investigational products
Trial Application	**MOH authorization + Helsinki Committee** — Dual-scrutiny mechanism: the institution's Helsinki Committee and the MOH. The Higher Helsinki Committee reviews genetic, fertilisation and other defined special-category trials. *(Variable (~60 days typical); for some trials on registered preparations institutional director approval may suffice.)*
eCTD	Module 1: Israel regional Module 1 · Version: CTD / eCTD accepted · Required
Registry	MOH clinical-trials registry / ClinicalTrials.gov — https://clinicaltrials.gov
Transparency	Registration in the MOH registry and an international registry; results reporting per ICMJE norms.
Distinctive	Helsinki Committee + MOH dual review · Higher Helsinki Committee for genetics · Fast site activation · Strong investigator base
Primary sources	Israel MOH

Saudi Arabia

MIDDLE EAST

Saudi Food and Drug Authority – Clinical Trials Department + National Committee of Bioethics (NCBE) (SFDA)

GCP	ICH GCP and ICH E2A safety reporting applied.
Legislation	Regulations & Requirements for Conducting Clinical Trials on Drugs (SFDA, updated Feb 2025) · Research Ethics Code on Living Creatures (Royal Decree M/59) · Implementing regulations of the Living-Creatures ethics law
Trial Application	**SFDA Clinical Trial Authorization** — SFDA reviews the scientific data (protocol, ICF, IB, IRB/EC approval) by trial phase; EC approval is required before start. Trials of products already registered in Saudi Arabia may proceed on a notification basis. *(Variable; priority handling for pandemics, national emergencies and unmet-need indications. SUSAR 7 days (fatal/life-threatening) / 15 days.)*
eCTD	Module 1: Saudi regional Module 1 · Version: eCTD for drug registration · Required
Registry	Saudi Clinical Trials Registry (SCTR) / ClinicalTrials.gov — https://clinicaltrials.gov
Transparency	Registration in the Saudi Clinical Trials Registry (SCTR) and an international registry.
Distinctive	SCTR national registry · NCBE bioethics oversight · ICH E2A safety reporting · Priority review for unmet need
Primary sources	SFDA — clinical-trial regulation

South Africa

AFRICA

South African Health Products Regulatory Authority – Clinical Trials Unit (SAHPRA)

GCP	ICH E6 GCP and the SA GCP Guidelines applied.
Legislation	Medicines & Related Substances Act 101 of 1965 (section 21 — unregistered medicines) · National Health Act 61 of 2003 (research ethics) · Protection of Personal Information Act (POPIA)
Trial Application	**Clinical Trial Application (CTA)** — SAHPRA Clinical Trials Committee authorization plus approval by an ethics committee registered with the National Health Research Ethics Council (NHREC). Imports of unregistered medicine use a section-21 authorization. *(~2–3 months; provisional approval ~4 weeks and final ~6 weeks after the committee meeting; Requests for Information pause the clock.)*
eCTD	Module 1: South Africa regional Module 1 · Version: eCTD per the modernized Sept 2025 dossier standards · Required
Registry	South African National Clinical Trials Register (SANCTR) — https://sanctr.samrc.ac.za
Transparency	Registration in the SANCTR; SAHPRA publishes committee meeting and submission dates.
Distinctive	SAHPRA Clinical Trials Committee · NHREC-registered ethics · Proof of insurance (2025) · eCTD modernization (2025)
Primary sources	SAHPRA — clinical trials

WHO (Global)

GLOBAL / MULTILATERAL

World Health Organization (WHO)

GCP	WHO Guidance for best practices for clinical trials (2024); WHO/ICTRP registry standards
Legislation	WHO Guidance for best practices for clinical trials (2024) · WHO ICTRP — Trial Registration Data Set & registry standards · Declaration of Helsinki (WMA) — ethical principles · CIOMS International Ethical Guidelines
Trial Application	**—** — WHO sets normative standards and aggregates data from primary registries worldwide; it is not a national approval authority. *(N/A — normative & registry-network role.)*
eCTD	Module 1: N/A · Version: N/A · Not yet mandatory
Registry	WHO ICTRP Search Portal — https://trialsearch.who.int
Transparency	ICTRP aggregates trials from primary registries (ClinicalTrials.gov, CTIS, ISRCTN, jRCT, ChiCTR, CTRI, ANZCTR, ReBEC, CRIS, …); WHO joint statement on results reporting.
Distinctive	ICTRP global trial aggregation · Trial Registration Data Set (24+ items) · Best-practice guidance 2024 · Declaration of Helsinki & CIOMS ethics
Primary sources	WHO ICTRP

HARMONISATION

ICH & Global Frameworks

The International Council for Harmonisation guidelines (Quality, Safety, Efficacy, Multidisciplinary) and the ethics and quality frameworks that sit alongside them.

SERIES	CODE	TITLE	SUMMARY
Efficacy	**E6(R3)**	Good Clinical Practice	The cornerstone GCP standard. Final version adopted 6 Jan 2025: overarching Principles + Annex 1 (interventional trials); Annex 2 (non-traditional interventional / decentralised, pragmatic) expected 2026. Emphasises quality-by-design, risk-based oversight, data governance, fit-for-purpose technology and a media-neutral approach.
Efficacy	**E8(R1)**	General Considerations for Clinical Studies	Foundational study-design standard. Introduces 'quality by design', critical-to-quality factors and proportionate, risk-based thinking that E6(R3) builds upon.
Efficacy	**E9 / E9(R1)**	Statistical Principles + Estimands	Statistical principles for clinical trials. The R1 addendum formalises the estimands framework and sensitivity analysis for handling intercurrent events.
Efficacy	**E3**	Clinical Study Report (CSR)	Defines the structure and content of the integrated clinical study report — the authoritative narrative source for downstream regulatory documents.
Efficacy	**E2A–E2F**	Pharmacovigilance / Safety Reporting	E2A (expedited reporting / SUSARs), E2B(R3) (electronic ICSR transmission), E2D (post-approval), E2F (Development Safety Update Report / DSUR).
Efficacy	**E5(R1)**	Ethnic Factors	Acceptability of foreign clinical data; bridging-study strategy — central to Japan and broader multi-regional development.
Efficacy	**E17**	Multi-Regional Clinical Trials (MRCT)	General principles for planning and designing MRCTs to support simultaneous global development and submission.
Efficacy	**E18 / E19**	Genomic Sampling / Safety Data Collection	E18 genomic sampling & data management; E19 optimisation of safety data collection (selective, fit-for-purpose collection).
Multidisciplinary	**M4**	Common Technical Document (CTD)	The harmonised dossier structure (Modules 1–5) underpinning all marketing applications; the conceptual basis of the eCTD.
Multidisciplinary	**M2**	Electronic Standards (eCTD)	Electronic specifications for the CTD — the eCTD message and backbone enabling electronic submission and lifecycle management.
Multidisciplinary	**M11**	Clinical electronic Structured Harmonised Protocol	Harmonised, structured clinical protocol template and technical specification (CeSHarP) to standardise protocol content across regions.
Multidisciplinary	**MedDRA**	Medical Dictionary for Regulatory Activities	Standardised medical terminology for coding adverse events, indications and medical history across the regulatory lifecycle.
Safety	**S-series**	Nonclinical Safety	Preclinical safety standards (e.g., S7 safety pharmacology, S9 oncology nonclinical) that gate first-in-human and inform IND/CTA dossiers.
Quality	**Q-series**	Quality / CMC	Q8 (pharmaceutical development), Q9 (quality risk management), Q10 (pharmaceutical quality system) — feed CTD Module 3 and IMP quality.

ETHICS & QUALITY FRAMEWORKS

Foundational & Cross-Cutting Frameworks

FRAMEWORK	SUMMARY
Declaration of Helsinki (WMA)	The foundational ethical statement of principles for medical research involving human subjects (latest revision 2024). Underpins informed consent, risk–benefit and independent ethics review worldwide.
CIOMS International Ethical Guidelines	Council for International Organizations of Medical Sciences guidance operationalising Helsinki for health-related research, including in low-resource settings.
Belmont Report (US)	Respect for persons, beneficence and justice — the ethical bedrock of US human-subjects protection (45 CFR 46 / Common Rule).
ALCOA+ (Data Integrity)	Attributable, Legible, Contemporaneous, Original, Accurate — plus Complete, Consistent, Enduring, Available. The data-integrity standard enforced across GxP inspections.
GAMP 5 (2nd ed.)	ISPE Good Automated Manufacturing Practice — risk-based, computerised-system validation for GxP software, incl. a critical-thinking and Agile-aware approach.
21 CFR Part 11 / EU Annex 11	Electronic records & signatures (US) and computerised systems (EU GMP) — the regulatory basis for validated e-systems, audit trails and e-signatures.
GVP (EU Good Pharmacovigilance Practices)	Modules governing post-authorisation safety, signal management and Risk Management Plans (RMP) — bridges trials to real-world safety.
GPP (Good Pharmacoepidemiology Practices) / ENCePP	Methodological and ethical standards for non-interventional / observational and real-world evidence studies.

DATA INTEROPERABILITY

Data Standards

The collection-to-submission data stack — CDISC (CDASH→SDTM→ADaM), nonclinical SEND, metadata, controlled terminologies and the modern exchange standards (FHIR, IDMP).

ORG	STANDARD	TITLE	LAYER	SUMMARY
CDISC	**CDASH**	Clinical Data Acquisition Standards Harmonization	Collection	Standardises CRF/eCRF data collection fields at source, ensuring traceability from collection through to submission datasets.
CDISC	**SDTM**	Study Data Tabulation Model	Tabulation	The FDA/PMDA-required structure for organising collected trial data into standard domains (DM, AE, LB, EX, VS, ...) for regulatory submission.
CDISC	**ADaM**	Analysis Data Model	Analysis	Analysis-ready datasets derived from SDTM, supporting traceable, reproducible statistical analyses behind TLFs and the CSR.
CDISC	**SEND**	Standard for Exchange of Nonclinical Data	Nonclinical	SDTM-aligned standard for nonclinical (toxicology) study data — required by FDA for IND/NDA nonclinical packages.
CDISC	**Define-XML**	Dataset Metadata / Data Definition	Metadata	Machine-readable metadata (data definition) document that accompanies SDTM/ADaM/SEND submissions; required by FDA & PMDA.
CDISC	**Controlled Terminology**	CDISC CT (NCI EVS)	Terminology	Standardised codelists maintained with NCI Enterprise Vocabulary Services, versioned quarterly, underpinning SDTM/ADaM consistency.
CDISC	**TAUGs / 360i**	Therapeutic Area User Guides / CDISC 360i	Cross-cutting	Disease-area implementations and the metadata-driven, end-to-end automation vision linking protocol concepts to analysis.
MedDRA MSSO	**MedDRA**	Medical Dictionary for Regulatory Activities	Terminology	Hierarchical medical terminology (SOC→HLGT→HLT→PT→LLT) for AE, indication and history coding; versioned twice yearly.
WHO / UMC	**WHODrug**	WHODrug Global	Terminology	Reference dictionary for coding concomitant and prior medications; required for many submissions.
Regenstrief	**LOINC**	Logical Observation Identifiers Names & Codes	Terminology	Universal codes for laboratory and clinical observations — increasingly used to standardise lab data exchange.
SNOMED Int'l	**SNOMED CT**	Systematized Nomenclature of Medicine	Terminology	Comprehensive clinical terminology used in EHR-sourced and real-world data pipelines feeding trials.
HL7	**FHIR**	Fast Healthcare Interoperability Resources	Exchange	Modern API-based health-data exchange standard; the bridge for EHR-to-EDC, decentralised data and real-world data ingestion (see Vulcan FHIR-to-CDISC).
ISO	**IDMP**	Identification of Medicinal Products	Master data	ISO 11615/11616/11238/11239/11240 suite for standardised medicinal-product identification (SPOR/substance data in EU).
ICH	**E2B(R3)**	Electronic ICSR (ICH E2B/R3 + ISO ICSR)	Safety exchange	Electronic transmission standard for Individual Case Safety Reports to pharmacovigilance databases (e.g., EudraVigilance, FAERS).

ELECTRONIC SUBMISSIONS

eCTD & the Common Technical Document

The CTD's five modules and the regional electronic-submission landscape. Modules 2–5 are harmonised; Module 1 is region-specific. Version status reflects the global v3.2.2 → v4.0 transition.

MODULE	NAME	SCOPE	DESCRIPTION
Module 1	Regional Administrative Information	Regional	Region-specific: cover letter, application forms, prescribing information / SmPC / PI, labelling, environmental assessments. NOT part of the harmonised CTD — differs by jurisdiction.
Module 2	CTD Summaries	Harmonised	Overviews & summaries: Quality Overall Summary (2.3), Nonclinical Overview/Summaries (2.4/2.6), Clinical Overview (2.5) and Clinical Summary (2.7). The most-read section by assessors.
Module 3	Quality (CMC)	Harmonised	Chemistry, manufacturing & controls — drug substance and drug product data. Maps to ICH Q-series.
Module 4	Nonclinical Study Reports	Harmonised	Pharmacology, pharmacokinetics and toxicology reports (with SEND datasets). Maps to ICH S-series.
Module 5	Clinical Study Reports	Harmonised	Clinical study reports (ICH E3), protocols, SAPs, case-report forms, and SDTM/ADaM datasets with Define-XML.

THE v3.2.2 → v4.0 TRANSITION

eCTD Version Status by Region

REGION	CURRENT STANDARD	eCTD v4.0 STATUS	NOTES
United States (FDA)	v3.2.2 (mandatory)	Voluntary since 16 Sep 2024	CDER/CBER; forward-compatibility & two-way comms in later phases
Japan (PMDA)	v3.2.2	Mandatory 1 Apr 2026	Earliest global v4.0 mandate; v3 accepted to 31 Mar 2026
EU (EMA)	v3.2.2 (mandatory)	Optional from 22 Dec 2025 (CAP MAAs)	Full mandate targeted ~2028
Canada (Health Canada)	v3.2.2 (mandatory since 2018)	Voluntary 2024	Mandatory target ~2027
Switzerland (Swissmedic)	v3.2.2	Voluntary 2024	Mandatory target ~2028
Australia (TGA)	v3.2.2	Voluntary	For marketing applications; trial notifications outside eCTD
United Kingdom (MHRA)	v3.2.2 (UK regional M1)	Under evaluation	Independent UK eCTD spec post-Brexit

END-TO-END

The Clinical Trial Lifecycle

Nine phases from concept and nonclinical work through submission, conduct, analysis and post-market surveillance — with the standards and core activities that govern each stage.

PHASE	GOVERNING STANDARDS	CORE ACTIVITIES
1 · Concept & Nonclinical	ICH S-series · ICH M3(R2) · SEND · GLP	Target validation, nonclinical pharmacology/tox, GLP studies, SEND datasets, and the nonclinical package that gates first-in-human.
2 · Protocol & Design	ICH E8(R1) · ICH E9(R1) estimands · ICH M11 protocol · ICH E6(R3) QbD	Quality-by-design, critical-to-quality factors, estimand definition, structured protocol (M11), statistical analysis plan, risk assessment.
3 · Regulatory & Ethics Application	IND/CTA · eCTD M1–5 · ICH M4 (CTD) · Local ethics law	IND/CTA/CTN dossier assembly, ethics/IRB/REC review, registry entry, IMP import permits. Gating approval before enrollment.
4 · Start-up & Activation	ICH E6(R3) Annex 1 · CTA contracts · ICF (21 CFR 50 / CTR) · Site qualification	Site selection/qualification, contracts & budgets, informed-consent finalisation, EDC/CTMS/eTMF build, investigator training.
5 · Conduct & Monitoring	ICH E6(R3) RBQM · ALCOA+ · 21 CFR 11 / Annex 11 · CDASH collection	Enrollment, risk-based quality management, central/remote monitoring, source data verification, data capture, deviation management.
6 · Safety & Pharmacovigilance	ICH E2A SUSARs · E2B(R3) ICSR · E2F DSUR · MedDRA · GVP	Expedited safety reporting (SUSARs), DSMB oversight, DSUR, signal detection, EudraVigilance/FAERS transmission.
7 · Data Management & Analysis	SDTM · ADaM · Define-XML · CDISC CT · ICH E9(R1)	Database lock, SDTM mapping, ADaM derivation, statistical analysis, TLF generation, traceability to source.
8 · Reporting & Submission	ICH E3 CSR · CTD M2/M5 · eCTD v3.2.2/v4.0 · Transparency rules	Clinical study report, CTD authoring, eCTD compilation, results posting (FDAAA / CTIS), marketing application (NDA/MAA).
9 · Post-Market & RWE	GVP · ICH E2D · RMP · RWE/RWD frameworks · GPP	Post-authorisation safety/efficacy studies (PASS/PAES), risk-management plans, real-world evidence, label maintenance.

STUDY ARCHETYPES

Interventional vs Non-Interventional

Three study archetypes whose regulatory obligations differ sharply — from full interventional trials to decentralised / pragmatic designs to observational real-world-evidence studies.

Interventional (Clinical Trial)

Definition	A study in which participants are prospectively assigned to an intervention per a protocol to evaluate effects on health outcomes. The assignment is not part of standard clinical practice.
Governance	ICH E6(R3) Principles + Annex 1 · IND/CTA/CTN authorisation · Full GCP, monitoring & safety reporting · CDISC SDTM/ADaM submission datasets · CTD/eCTD marketing pathway
Examples	Randomised controlled trials, adaptive & platform trials, basket/umbrella oncology trials, first-in-human.

Non-traditional Interventional

Definition	Interventional trials using decentralised, pragmatic or real-world elements (e.g., DCTs, point-of-care trials, registry-based RCTs). Addressed by the forthcoming ICH E6(R3) Annex 2.
Governance	ICH E6(R3) Annex 2 (expected 2026) · FDA/EMA decentralised-trial guidance · Fit-for-purpose technology & data governance · FHIR / EHR-sourced data
Examples	Decentralised trials, registry-based randomised trials, pragmatic point-of-care studies.

Non-Interventional (Observational)

Definition	Studies where the medicine is prescribed per normal practice and assignment is not dictated by a protocol; data arise from routine care. Often called observational, PASS/PAES, or real-world studies.
Governance	GVP Module VIII (PASS) · GPP / ENCePP Code of Conduct · STROBE reporting (epidemiology) · RWE/RWD regulatory frameworks (FDA, EMA, HMA-EMA DARWIN EU) · GDPR/HIPAA data protection
Examples	Prospective/retrospective cohort, case-control, registry studies, database (claims/EHR) studies, drug-utilisation studies.

PROGRAMMATIC ACCESS

APIs & Data Sources

Public registries and regulatory APIs for trial discovery, safety data and standards metadata — with verified base endpoints and example calls. Confirm current terms and rate limits with each provider.

ClinicalTrials.gov API v2

NLM / NIH (US)

Modern REST/OpenAPI 3.0 API for the US registry. Classic API retired Jun 2024; data refreshed daily. Query by condition, intervention, status, location.

Auth: **None (public)** Format: **JSON / CSV** Docs: https://clinicaltrials.gov/data-api/api

```
GET https://clinicaltrials.gov/api/v2/studies?query.cond=lung+cancer&filter.overallStatus=RECRUITING&pageSize=10&format=json
```

openFDA

FDA (US)

Elasticsearch-based access to FDA public data: drug adverse events (FAERS), labelling (SPL), NDC directory, enforcement/recalls, devices.

Auth: **Optional API key (higher rate limit)** Format: **JSON** Docs: https://open.fda.gov/apis/

```
GET https://api.fda.gov/drug/event.json?search=patient.drug.medicinalproduct:aspirin&limit=5
```

EU CTIS — public data

EMA (EU)

Clinical Trials Information System public site — the single EU/EEA portal under CTR 536/2014 and a WHO ICTRP primary registry. Public search of authorised trials & summaries; programmatic access via the portal's data endpoints.

Auth: **None (public portal)** Format: **Web / JSON endpoints** Docs: https://euclinicaltrials.eu

```
Browse / search authorised EU trials and decision documents via the public CTIS portal.
```

WHO ICTRP

WHO (Global)

International Clinical Trials Registry Platform — aggregates records from all primary registries (CTgov, CTIS, ISRCTN, jRCT, ChiCTR, CTRI, ANZCTR, ReBEC, CRIS, …). Weekly downloadable data set.

Auth: **None** Format: **Web search / data set** Docs: https://www.who.int/clinical-trials-registry-platform

```
Search the meta-register across all WHO primary registries from a single portal.
```

EU Clinical Trials Register (legacy)

EMA (EU)

Legacy EudraCT-based register — searchable for historical (pre-CTIS) trials but no longer updated with new submissions.

Auth: **None** Format: **Web** Docs: https://www.clinicaltrialsregister.eu

```
Historical EU trial look-up by EudraCT number / sponsor.
```

ISRCTN registry

BMC / UK

International primary registry (used heavily in the UK), feeding WHO ICTRP. Prospective registration of interventional & observational studies.

Auth: **None** Format: **Web / data** Docs: https://www.isrctn.com

```
Look up trials by ISRCTN identifier.
```

jRCT

NIPH (Japan)

Japan Registry of Clinical Trials — WHO primary registry for Japanese specified/regulated trials.

Auth: **None** Format: **Web** Docs: https://jrct.niph.go.jp

```
Search Japanese clinical & specified trials.
```

EudraVigilance / FAERS

EMA / FDA

Spontaneous adverse-reaction databases. EudraVigilance public dashboard (adrreports.eu) and the FDA FAERS public dashboard support pharmacovigilance signal review.

Auth: **Public dashboards** Format: **Web / data** Docs: https://www.adrreports.eu

```
Review suspected adverse-reaction reports by substance.
```

CDISC Library API

CDISC

Machine-readable source of CDISC standards metadata (SDTM, ADaM, CDASH, SEND, controlled terminology) for automation and conformance tooling.

Auth: **API key / membership** Format: **REST JSON / RDF** Docs: https://www.cdisc.org/cdisc-library

```
Retrieve SDTMIG domain & variable metadata programmatically.
```

RxNorm / UMLS

NLM (US)

Normalised drug nomenclature (RxNorm) and terminology services (UMLS) for medication coding and mapping across vocabularies.

Auth: **API key (UMLS)** Format: **REST JSON** Docs: https://rxnav.nlm.nih.gov

```
GET https://rxnav.nlm.nih.gov/REST/drugs.json?name=ibuprofen
```

REFERENCE

Glossary

Core acronyms used throughout this Atlas.

TERM	DEFINITION
ADaM	Analysis Data Model — CDISC analysis-ready datasets
ALCOA+	Attributable, Legible, Contemporaneous, Original, Accurate (+ Complete, Consistent, Enduring, Available)
CDASH	Clinical Data Acquisition Standards Harmonization
CDISC	Clinical Data Interchange Standards Consortium
CRF / eCRF	Case Report Form / electronic CRF
CSR	Clinical Study Report (ICH E3)
CTA	Clinical Trial Application / Agreement (context-dependent)
CTD / eCTD	Common Technical Document / electronic CTD
CTIS	Clinical Trials Information System (EU)
CTN	Clinical Trial Notification (Australia / Japan)
DCT	Decentralised Clinical Trial
DSUR	Development Safety Update Report (ICH E2F)
GCP	Good Clinical Practice (ICH E6)
IND	Investigational New Drug application (FDA)
IRB / REC / EC	Institutional Review Board / Research Ethics Committee / Ethics Committee
MedDRA	Medical Dictionary for Regulatory Activities
NDA / MAA	New Drug Application (FDA) / Marketing Authorisation Application (EU)
PASS / PAES	Post-Authorisation Safety / Efficacy Study
RBQM	Risk-Based Quality Management
RWE / RWD	Real-World Evidence / Real-World Data
SAP	Statistical Analysis Plan
SDTM	Study Data Tabulation Model
SEND	Standard for Exchange of Nonclinical Data
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF / eTMF	Trial Master File / electronic TMF

Disclaimer

This Atlas is provided for general informational and educational purposes as an illustrative regulatory reference. It does not constitute legal, regulatory, medical or investment advice, and it does not create any advisory relationship. Regulations, guidance and timelines change frequently and vary by product type and context; readers must verify all requirements against the primary sources and competent authorities cited herein before relying on them. Governing law: Commonwealth of Pennsylvania, USA.