REGULATORY ROUNDUP

MedTech Leading Voice
Regulatory Roundup

Martin King

19. January 2026

MedTech Leading Voice
Regulatory Roundup

Created with the aid of Microsoft CoPilot & OpenAI ChatGPT

SUMMARY

Scope & Coverage

- Global regulatory intelligence spanning **medical devices, IVDs, pharmaceuticals, ATMPs, AI/Software, clinical trials, standards and HTA** across EU, UK, US, Canada, Asia, Africa, and Middle East.

Key Strategic Signals

- **EU MDR/IVDR governance** delivering stronger safety oversight but operating at capacity limits; **innovation and SME impact remain negative**, with device availability risks.
- **Emerging Health Technologies (2025)** signals significant **oncology, ATMP, and high-risk device pipeline** entering **EU Joint Clinical Assessment from 2026**.
- **Expert Panel & CECP activity increasing**, particularly for **Class III implantables**, reinforcing expectations for **robust clinical evidence**.
- **AI governance converging globally**: risk-based validation, lifecycle oversight, transparency, and human oversight now explicit regulatory expectations for **AI-enabled drugs and devices**.
- **Clinical development tightening**: new **PAOD guideline**, reinforced **GCP E6(R3)** informed consent expectations, and growing use of **Bayesian methods** (FDA).
- **Post-authorisation burden rising**: revised **EMA variations procedures**, lifecycle management, and pharmacovigilance alignment with **ICH E2D(R1)**.
- **Clinical trial regulation evolving**: UK **Clinical Trials Regulations (Apr 2026)**, **IMP+Device** pathway clarified; **insurance enforcement tightened** (SAHPRA).
- **Standards landscape expanding rapidly** (IEC/ISO/IDMP, AI, software, radiology, biobanking), increasing **compliance and evidence expectations**.
- **National actions**: Malaysia regulates **aesthetic/cosmetic devices**; Egypt strengthens **veterinary BE requirements**; China advances **BCI device standards**.
- **Patient voice strengthened** in England, highlighting **usability, equity, and information gaps** influencing future device assessment and design.

Overall Impact

- Regulators are **raising evidence, lifecycle, and digital governance expectations** while attempting to preserve innovation. **Early engagement, robust clinical strategies, AI governance, and standards readiness** are now critical to maintain market access and timelines.

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📌 Egyptian Drug Authority
- Guidance: Bioequivalence Studies for Generic Veterinary Medicinal Products

📌 European Commission
- Report: Study on Regulatory Governance and Innovation in the field of Medical Devices
- Report: Report on Emerging Health Technologies - 2025

📌 European Medicines Agency
- Expert Panel: Support for Breakthrough Medical Devices
- Guidance: Guiding principles of good AI practice in drug development
- Guidance: (CECP) Opinions Issued for Medical Devices Awaiting Conformity Assessment
- Guidance: Post-authorisation procedural advice for users of the centralised procedure
- Guidance: Clinical investigation of medicinal products for the treatment of PAOD

📌 European Directorate for the Quality of Medicines & HealthCare
- Report: Certification Monthly Report – End of December 2025 (EDQM).

📌 International Electrotechnical Commission
- Standard: IEC Update: 1. - 31. December 2025

📌 Health Canada
- Consultation: Draft ICH Documents for Consultation
- Guidance: (ICH) - Guidelines Implemented by Health Canada

📌 Health Sciences Authority (HSA), Singapore
- Guidance: miv-checklist-for-class-2-ctgtp

📌 ISO (International Organization for Standardization)
- Standards: ISO Update 1. December 2025 to 1. January 2026

📌 International Council for Harmonisation
- Guidance: Information Paper Regarding Alignment with ICH E2D(R1) Guideline
- Guidance: Mapping R1 versus R2 - ICH M4Q(R2) Mapping Document
- Guidance: Interpretation and Application of ICH E6(R3): Good Clinical Practice - Module 4

📌 Medical Device Authority Malaysia
- Press Release: Regulation of aesthetic and cosmetic medical devices

📌 Department of Health and Social Care
- Report: Patient views on medical devices prescribed to them outside of hospital in England

📌 Medicines and Healthcare products Regulatory Agency
- Guidance: Medicines: clinical trials hub
- Guidance: IMP+Device Review Investigational Medicinal Product + Investigational Device

📌 NMPA-National Medical Products Administration
- Standards: Establishment of Two Recommended Medical Device Industry Standards

📌 South African Health Products Regulatory Authority
- Guidance; Clinical Trial Insurance for New Clinical Trial Applications

📌 Swissmedic
- Forms: Swissmedic Forms for January 2026

📌 USA Food & Drug Administration FDA
- Guidance:Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products
- Guidance: Guiding principles of good AI practice in drug development

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GUIDANCE

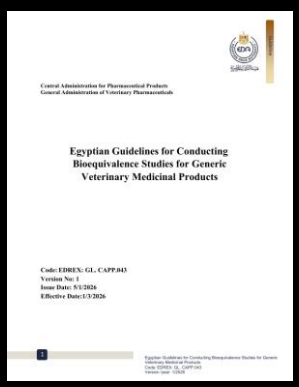
هيئة الدواء المصرية

EDA EGYPTIAN DRUG AUTHORITY

📌 Bioequivalence Studies for Generic Veterinary Medicinal Products

Provides **regulatory guidance** on the **design, conduct, and evaluation** of **bioequivalence (BE) studies** for **generic veterinary medicinal products**

- **Authority:** Issued by the **Central Administration for Pharmaceutical Products – Egyptian Drug Authority**
- **Scope:** Applies to **systemically acting pharmaceutical forms** and **in vitro dissolution studies**
- **Core principle:** Two products are **bioequivalent** when the **rate and extent of absorption** of the active ingredient(s) are equivalent
- **Study hierarchy (preferred order): Blood level studies → Pharmacologic end-point studies → Clinical end-point studies**
- **Reference product:** Must be the **authorized pioneer product** (or first approved generic if pioneer unavailable)
- **Waivers: In vivo BE studies may be waived** for specific dosage forms (e.g. **IV solutions, oral solutions, topical local products, inhalant anesthetics**) when criteria are met
- **Species requirements:** BE studies generally required in **each target species**, with justified **extrapolation** allowed to minor species
- **Dose selection:** Typically conducted at the **highest approved dose**, with guidance for **linear and non-linear pharmacokinetics**
- **Study designs:** Detailed requirements for **cross-over**, **parallel**, and **alternative designs**, including **washout periods**
- **Acceptance criteria:** Standard **80–125%** range for **AUC and Cmax**, with **narrower limits** for **NTI drugs** and justified **wider limits** for **highly variable drugs**
- **Dissolution studies:** Defines **sampling requirements**, **similarity testing (f_2)**, and criteria for **very rapid dissolution**
- **BCS-based biowaivers:** Allows **Class I and limited Class III** biowaivers with **species-specific considerations**
- **Outcome:** Ensures **quality, safety, and therapeutic equivalence** of generic veterinary medicines before approval


Central Administration for Pharmaceutical Products
General Administration of Veterinary Pharmaceuticals

Egyptian Guidelines for Conducting Bioequivalence Studies for Generic Veterinary Medicinal Products

Code: EDREX: GL: CAPP.043
Version No: 1
Issue Date: 5/1/2026
Effective Date:1/3/2026

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European Commission

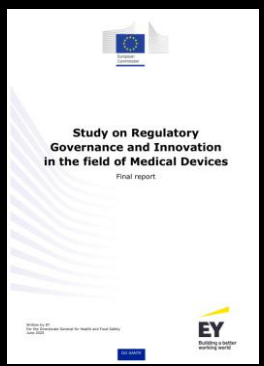
REPORT

📌 Study on Regulatory Governance and Innovation in the field of Medical Devices

Assesses how **EU MDR and IVDR governance** affects **patient safety**, **innovation**, and **market functioning**

Author & scope: EY for DG SANTE, covering **EU-27 + EEA**, with **global benchmarking**

- **Methodology: 277 sources**, **470 survey respondents**, **41 interviews**, **7 workshops**, **benchmarking (US, Japan, Korea, Singapore)**
- **Governance shift:** Move from **Directives to Regulations** improved **harmonisation**, but expanded **actor responsibilities**
- **Effectiveness:** Governance structures broadly **effective** in delivering outputs and safety objectives
- **Efficiency: Uneven and strained**, due to **resource constraints**, **complex coordination**, and **slow delivery**
- **European Commission:** Strong on **guidance and coordination**, weaker on **timeliness**, **EUDAMED rollout**, and **standards**
- **National Competent Authorities:** Key to implementation but face **capacity limits** and **inconsistent interpretations**
- **Notified Bodies:** Oversight strengthened, but **limited capacity**, **long timelines**, and **cost transparency issues**
- **Coordination bodies (MDCG):** Improved collaboration, but **slow decision-making** and **high administrative burden**
- **EUDAMED: Delays materially reduce transparency, predictability, and efficiency**
- **Innovation impact: Negative overall**, particularly for **SMEs**, due to **higher costs** and **longer certification**
- **Competitiveness:** Firms increasingly seek **first market access outside the EU**
- **Patient safety: Stronger clinical evidence and post-market surveillance** expected to deliver **long-term benefits**
- **Short-term risks: Device availability constraints** and **potential shortages**
- **Perceptions: Mixed stakeholder views**, with **widespread scepticism** on innovation support
- **Conclusion:** System is **not failing**, but **operating at its limits**



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European Commission

REPORT

📌 Report on Emerging Health Technologies – 2025

Supports **EU Health Technology Assessment (HTA)** planning by identifying **emerging health technologies** likely to fall under **Joint Clinical Assessment (JCA)** in **2026**

- **Legal basis:** Prepared under **Article 22 of Regulation (EU) 2021/2282**, fulfilling transparency obligations under **Article 30(3)(m)**
- **Scope:** Covers **medicinal products** and **medical devices**; **IVDs excluded** due to data limitations
- **Medicinal products focus:**
- Likely **new active substances** for **cancer treatment**
- Potential **Advanced Therapy Medicinal Products (ATMPs)** across indications
- **Regulatory designations highlighted: PRIME**, **orphan designation** (EMA/FDA) to flag special regulatory pathways
- **Data sources:** Horizon scanning from **EMA** and **International Horizon Scanning Initiative (IHSI)** only
- **Methodology:** Uses **anonymised, aggregated, non-confidential data** and **MedDRA terminology**
- **Uncertainty acknowledged:** High attrition in medicine development (up to **~40% failure rates**), timelines remain uncertain
- **Oncology products: 61 medicinal products** identified as potentially JCA-eligible in 2026
- **6 PRIME**, **21 orphan**, **9 potential ATMPs**
- **ATMPs overall: 25 ATMPs** identified
- **8 PRIME**, **17 orphan**, **9 oncology-related**
- **Medical devices: 15 devices** with recent EMA scientific advice may be JCA-eligible from 2026
- **Future outlook:** Plans to explore **manufacturer association data** via the **HTA Stakeholder Network**

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EXPERT PANEL

📌 Expert Panel Support for Breakthrough Medical Devices

EU expert panels provide **scientific and technical support** to notified bodies and manufacturers on innovative medical devices, especially those with **major clinical impact or unmet needs**.

Purpose:

- Help ensure **safety, performance and regulatory compliance** of breakthrough devices.
- Facilitate **timely availability** of high-impact technologies for patients.

Core Features:

- Expert panels give **opinions or advice** on device assessments that notified bodies must consider before granting a **CE mark**.
- Panels play a role in **designation and evaluation** of "breakthrough devices" under recent EU guidance (e.g., MDCG 2025-9).

Who's involved:

- Panels are **multidisciplinary** and composed of clinical, scientific and technical experts appointed by the European Commission.
- EMA provides **administrative, scientific and technical support** to the panels.

Criteria for "breakthrough" designation:

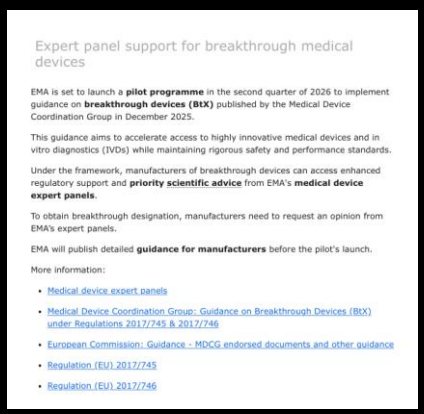
- Highly **innovative technology** with **significant clinical benefits** over alternatives.
- Targets **serious, life-threatening, or irreversible conditions**, or fulfills an **unmet clinical need**.

Benefits for manufacturers:

- **Early scientific advice** on clinical development and evidence plans.
- **Priority or rolling reviews** of regulatory submissions for qualifying devices.

Regulatory context:

- Builds on the European **Medical Devices Regulation (MDR) & In Vitro Diagnostic Regulation (IVDR)**.
- Linked with broader efforts to streamline innovation pathways while maintaining safety standards.



Expert panel support for breakthrough medical devices

EMA is set to launch a **pilot programme** in the second quarter of 2026 to implement guidance on **breakthrough devices (BtX)** published by the Medical Device Coordination Group in December 2025.

This guidance aims to accelerate access to highly innovative medical devices and in vitro diagnostics (IVDs) while maintaining rigorous safety and performance standards.

Under the framework, manufacturers of breakthrough devices can access enhanced regulatory support and **priority scientific advice** from EMA's **medical device expert panels**.

To obtain breakthrough designation, manufacturers need to request an opinion from EMA's expert panels.

EMA will publish detailed **guidance for manufacturers** before the pilot's launch.

More information:

- Medical device expert panels
- Medical Device Coordination Group: Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746
- European Commission: Guidance - MDCG endorsed documents and other guidance
- Regulation (EU) 2017/745
- Regulation (EU) 2017/746

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GUIDANCE

📌 Guiding principles of good AI practice in drug development

Establishes **10 guiding principles** for the **responsible use of AI** across the **drug product life cycle** (nonclinical, clinical, post-marketing, manufacturing).

These principles equally apply to **AI-enabled medical devices and software as a medical device (SaMD)**, where AI directly influences **diagnosis, treatment decisions, device performance, and patient safety** across the **entire device life cycle**, requiring the same **risk-based validation, transparency, and ongoing monitoring**.

1. **Human-centric design:** AI systems should align with **ethical values** and **human oversight**.
2. **Risk-based approach:** Validation, mitigation, and oversight are **proportionate to model risk** and **context of use**.
3. **Standards adherence:** Compliance with **legal**, **ethical**, **technical**, **scientific**, **cybersecurity**, and **GxP** standards is required
4. **Clear context of use:** AI roles, scope, and intended application must be **well defined**.
5. **Multidisciplinary expertise:** Integration of **AI specialists** and **domain experts** throughout the **technology life cycle**.
6. **Data governance & documentation:** Ensures **data provenance**, **traceability**, **verifiability**, **privacy**, and **protection of sensitive data**.
7. **Model design & development:** Follows **best practices** in engineering, using **fit-for-use data** with attention to **interpretability**, **explainability**, and **robustness**.
8. **Risk-based performance assessment:** Evaluates the **complete system**, including **human-AI interaction**, with appropriate metrics and testing.
9. **Life cycle management:** Continuous **monitoring**, **quality management**, and **periodic re-evaluation** to address issues like **data drift**.
10. **Clear, essential information:** Uses **plain language** to communicate **performance**, **limitations**, **data**, and **updates** to users and patients.

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GUIDANCE

📌 List of Clinical Evaluation Consultation Procedure (CECP) Opinions Issued for Medical Devices Awaiting Finalisation of Conformity Assessment

Aimed at improving **transparency** by publishing a list of **CECP opinions** issued by **EMA Expert Panels** for medical devices undergoing **conformity assessment**.

- **Publication status:** Opinions will be **published only after** the relevant **Notified Body (NB)** finalises the conformity assessment.
- **Timeframe covered: 5 December 2023 – 12 January 2026**.
- **Scope:** Predominantly **Class III implantable medical devices**, with **one Class IIb active device** intended to administer or remove medicinal products.
- **Medical areas represented:**
  Orthopaedics, **traumatology**, **rehabilitation**, **rheumatology**, **circulatory system**, **general & plastic surgery**, **dentistry**, **urology**, **nephrology**, **ophthalmology**, **obstetrics & gynaecology**, **respiratory & intensive care**.
- **Risk profile:** The majority of devices are **high-risk (Class III)**, reflecting the need for **expert clinical scrutiny**.
- **Reasons for opinion:** Opinions issued under **Criterion 1** and **Criterion 2** (no Criterion 3 cases listed).
- **Trend observed:** Increasing volume of CECP opinions across **2024–2025**, especially in **orthopaedics** and **circulatory system** devices.
- **Key identifiers included:** Each entry lists **date of opinion**, **CECP dossier number**, **EMDN level 3 code**, **risk class/type**, **medical area**, and **criterion applied**.
- **Abbreviations clarified:** CECP, EMDN, MD, and NB are defined to support **regulatory clarity**.

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13 January 2026

To enhance the transparency on the work of the Expert Panels, the list below shows the CECP opinions issued by the Expert Panels for medical devices undergoing conformity assessment. These CECP opinions will be published once the conformity assessment for the listed medical devices is finalised by the NB, and the list updated accordingly.

Date of opinion	CECP dossier number	MD type – EMDN level 3	Risk class/type	Medical area	Reason for opinion (criterion 1, 2, 3)
05/12/2023	EMA/EX/0000137387	P0802	class III implantable	Nephrology, urology	Criterion 1
13/05/2024	EMA/EX/0000171363	P0912	class III implantable	Orthopaedics, traumatology, rehabilitation, rheumatology	Criterion 2
21/06/2024	EMA/EX/0000175268	P9002	class III implantable	General and plastic surgery, dentistry	Criterion 2
09/11/2024	EMA/EX/0000228672	P0901	class III implantable	Orthopaedics, traumatology, rehabilitation, rheumatology	Criterion 1
12/11/2024	EMA/EX/0000226097	C0104	class III implantable	Circulatory system	Criterion 1
13/12/2024	EMA/EX/0000232552	P0704	class III implantable	Circulatory system	Criterion 1
03/01/2025	EMA/EX/0000227217	P9002	class III implantable	General and plastic surgery, dentistry	Criterion 1

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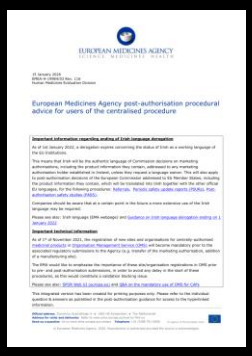
GUIDANCE

📌 Post-authorisation procedural advice for users of the centralised procedure

Provides comprehensive **procedural guidance** for **post-authorisation activities** for **centrally authorised medicinal products (CAPs)** in the EU.

- **Scope:** Addresses **variations**, **extensions**, **renewals**, **transfers**, **safety reporting**, **risk management**, and **marketing status obligations** applicable after marketing authorisation.
- **Variation Types:** Details requirements for **Type IA/IAIN**, **Type IB**, **Type II**, **grouping**, and **worksharing**, including **classification**, **submission timing**, **documentation**, and **fees**.
- **Annual Update for Type IA:** Introduces **Type IA annual updates** with defined **9–12 month windows**, transition rules, and **exceptions** aligned with the **revised Variations Guidelines (2025)** effective **15 January 2026**.
- **Procedural Oversight:** Explains roles of **EMA**, **Rapporteurs**, **PRAC**, **CHMP**, and timelines for **assessment**, **opinions**, and **implementation**.
- **Safety & Efficacy:** Covers **PSURs**, **PASS**, **PAES**, **post-authorisation measures (PAMs)**, and **risk management plans (RMPs)** with submission formats and enforcement.
- **Product Information:** Specifies when **SmPC**, **labelling**, and **package leaflets** must be updated, including **linguistic review** and **EU language requirements** (noting **Irish language** implications).
- **Administrative Changes:** Includes guidance on **invented name changes**, **pharmacovigilance system summaries**, **Article 61(3) notifications**, and **Article 46 paediatric submissions**.
- **Lifecycle Events:** Details **renewals**, **annual reassessments**, **conditional MA renewals**, **marketing withdrawals**, and **sunset clause monitoring**.
- **Operational Tools:** Emphasises **pre-submission meetings**, **OMS/SPOR registration**, **eCTD/eAF use**, and **validation completeness** to avoid delays.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European Medicines Agency post-authorisation procedural advice for users of the centralised procedure

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GUIDANCE

📌 Guideline on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease of the lower extremities

Provides regulatory guidance for **clinical development** of medicinal products for **atherosclerosis-related lower extremity arterial disease (LEAD/PAOD)**, including **Advanced Therapy Medicinal Products (ATMPs)**.

- **Status & Timing: Adopted 1 Dec 2025**; **effective 30 June 2026**; replaces **CPMP/EWP/714/98 rev 1**.
- **Scope:** Covers **symptomatic treatment** and **prevention of disease progression / ischemic events**; excludes **acute ischemia** and **inflammatory/immunologic vasculopathies**.
- **Patient Classification:** Recommends modern staging using **Fontaine/Rutherford**, **CLTI**, **WIfI**, and **GLASS**, including **angiosome concepts** for anatomical characterization.
- **Development Strategy:** Disease-stage–specific approach; clear definition of **study population**, **estimand of interest**, and **clinically meaningful endpoints**.
- **Efficacy Endpoints (Symptomatic):**
  - **Walking capacity** (treadmill **ICD/ACD** or **6MWD**; methods not interchangeable).
  - **Pain relief** (standardised scales).
  - **Complete ulcer healing** (total epithelialisation only).
  - **Interventions** (revascularisation, minor/major amputations).
- **Prevention Endpoints: Major amputation**, **cardiovascular morbidity**, and **mortality**—often as **pre-specified composite endpoints**; stage-dependent component selection.
- **Study Design:** Randomised, **double-blind**, controlled trials; **run-in phases** for stability; adequate **treatment duration** (≥6 months symptomatic; ≥12 months prevention).
- **Statistics & Estimands:** Confirmatory hypotheses (superiority/non-inferiority); careful handling of **intercurrent events** (e.g., revascularisation, treatment changes) with **ICH E9(R1)** alignment.
- **Confounders:** Exercise training, smoking cessation, placebo effects, comorbidities (esp. **diabetes type 1 vs 2**) must be controlled or stratified.
- **Safety Focus:** Blood pressure/heart rate, **pro-arrhythmic/pro-anginal effects**, **rebound/withdrawal**, and **no negative impact on mortality/CV morbidity**.
- **Special Populations:** Emphasis on **elderly** representativeness; **paediatric** development considered case-by-case with extrapolation principles.
- **ATMP-Specific Guidance:** Long follow-up, regenerative **mechanism-of-action support**, imaging-based evidence, stratification by **diabetes/smoking**, and enhanced **risk management**.

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REPORT

📌 Certification Monthly Report – End of December 2025 (EDQM)

Certificates of Suitability (CEPs):

- **Dec 2025 = 46**
- **Revisions approved Dec 2025 = 106,** with **74 approvals without CEP revision**.

suspended, expired and withdrawn CEPs:

- **Withdrawn by holder: 98 in Dec**.
- **Withdrawn by EDQM: 26 in Dec**.
- **Cases suspended by EDQM: 19 in Dec**.
- **Cases Expired: 10**

Time for treatment mean timelines for chemical CEP applications:

- **New dossiers** remained consistently **ahead of deadlines**, typically **–4.2 days.**
- **Revisions on time: (0 days).**

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

Certification of Substances Department

CERTIFICATION MONTHLY REPORT
End of December 2025

Certificates of Suitability

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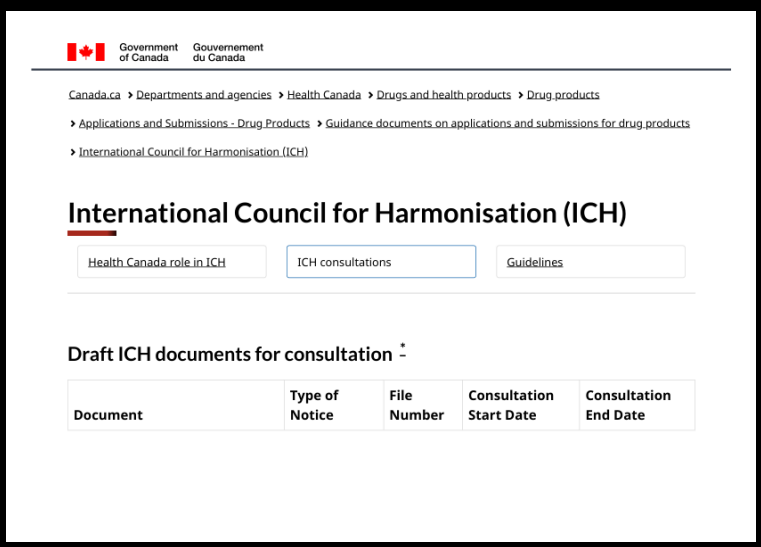
Health Canada

CONSULTATION

📌 Draft ICH Documents for Consultation

Notice of **current and recent consultations** on **draft ICH guidelines** coordinated by **Health Canada**

- **Scope:** Applies to **drug products** and **regulatory guidance** under the **International Council for Harmonisation (ICH)**
  - **Draft Guideline ICH E22 (Step 2): General Considerations for Patient Preference Studies**
    - **Consultation period:** January 12, 2026 – April 12, 2026
  - **Draft Guideline ICH Q3E (Step 2): Impurities – Extractables and Leachables**
    - **Consultation period:** October 17, 2025 – January 14, 2026
  - **Draft Guideline ICH E20 (Step 2): Adaptive Clinical Trials**
    - **Consultation period:** June 27, 2025 – November 28, 2025
- **Language note: Draft guidelines** are available **in English only**; **finalized ICH guidelines** may be translated into **French upon request**
- **Consultation process:**
  - Comments submitted to **Health Canada** are **forwarded to ICH as-is**
  - Submissions **do not represent Health Canada's views** unless stated separately
- **Submission guidance:**
  - Use the **ICH public consultation template**
  - Submit comments **by the listed deadlines** to allow review and transmission
  - **Contact: Health Canada – ICH Coordinator** via **ich@hc-sc.gc.ca**



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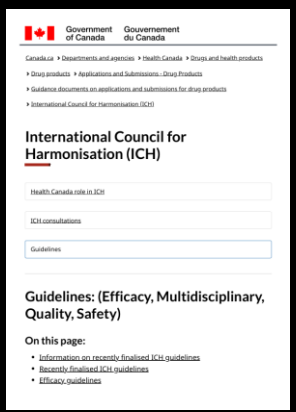
Health Canada

GUIDANCE

(ICH) – Guidelines Implemented by Health Canada

A Comprehensive listing of **ICH guidelines** that are **finalised, implemented, or in progress** under **Health Canada** across **Efficacy, Multidisciplinary, Quality, and Safety** domains

- **Regulatory status:** Guidelines are **endorsed by the ICH Assembly** and **implemented by Health Canada** in line with international harmonisation commitments
- **Precedence rule:** Where inconsistencies exist, **Health Canada–implemented ICH guidelines take precedence** over existing national guidance
- **Language note:** ICH website content is **English-only**; **French versions** of guidelines may be requested from Health Canada
- **Recently finalised / implemented guidelines (last 12 months):**
  - **M13A:** Bioequivalence for Immediate-Release Solid Oral Dosage Forms (**implemented Dec 27, 2025**)
  - **Q12:** Pharmaceutical Product Lifecycle Management (**interim implementation Jan 12, 2026**)
  - **Q14:** Analytical Procedure Development (**implemented Jan 12, 2026**)
  - **M14:** Real-World Data for Safety Assessment (**implemented Jan 12, 2026**)
  - **E2D(R1):** Post-Approval Safety Data Management (**implemented Jan 12, 2026**)
- **Efficacy guidelines:** Broad coverage of **clinical trials**, **safety reporting**, **biostatistics**, **pediatrics**, **geriatrics**, **genomics**, and **real-world evidence** (e.g., **E6(R3) Good Clinical Practice**, **E8(R1)**, **E9/R1**, **E11/E11A**, **E19**)
- **Multidisciplinary guidelines:** Include **CTD/eCTD**, **nonclinical safety studies**, **mutagenic impurities (M7)**, **drug interactions (M12)**, **bioequivalence (M13A)**, and **real-world data (M14)**
- **Quality guidelines:** Extensive framework covering **stability**, **impurities**, **analytical validation**, **pharmacopoeial harmonisation (Q4B annexes)**, **biotechnology products**, **GMP for APIs (Q7)**, **quality risk management (Q9)**, and **pharmaceutical quality systems (Q10)**
- **Safety guidelines:** Nonclinical requirements for **carcinogenicity**, **genotoxicity**, **toxicokinetics**, **reproductive toxicity**, **immunotoxicity**, **oncology products**, **gene therapy biodistribution**, and **photosafety** (e.g., **S1–S12**)
- **Stakeholder communication:** Questions and requests should be directed to **Health Canada – ICH Coordinator (ich@hc-sc.gc.ca)**


Government of Canada | Gouvernement du Canada

Canada.ca > Departments and agencies > Health Canada > Drugs and health products > Drug products > Applications and Submissions - Drug Products > Guidance documents on applications and submissions for drug products > International Council for Harmonisation (ICH)

International Council for Harmonisation (ICH)

Health Canada role in ICH

ICH consultations

Guidelines

Guidelines: (Efficacy, Multidisciplinary, Quality, Safety)

On this page:

- Information on recently finalised ICH guidelines
- Recently finalised ICH guidelines
- Efficacy guidelines

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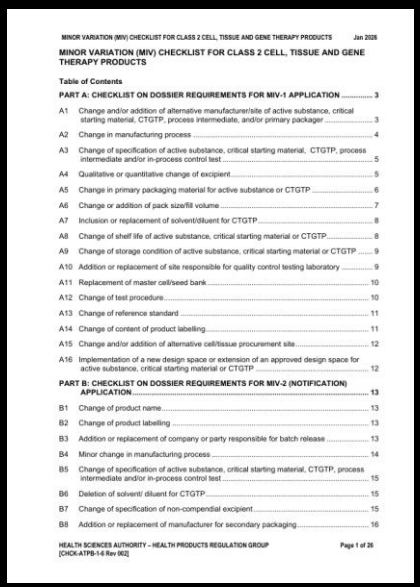
HSA Health Sciences Authority

GUIDANCE

📌 Minor Variation (MIV) Checklist for Class 2 Cell, Tissue and Gene Therapy Products

Defines **regulatory requirements** for **Minor Variations (MIV)** to **Class 2 CTGTPs** submitted to **HSA**

- **Status: Primary and binding regulatory document** used for **assessment and compliance**
- **Structure:** Organised into **three parts** covering **MIV-1**, **MIV-2 (Notification)**, and **MIV-2 (Do-and-Tell)**
- **Part A – MIV-1:** Covers **higher-impact changes** requiring **prior approval**, including **manufacturing sites**, **process changes**, **specification changes**, and **design space modifications**
- **Part B – MIV-2 (Notification):** Covers **lower-impact changes** requiring **notification**, such as **minor process changes**, **specification additions**, and **secondary packaging changes**
- **Part C – MIV-2 (Do-and-Tell):** Covers **administrative or low-risk changes** that can be **implemented before notification**
- **Decision logic:** Each change is assessed using **eligibility criteria (C)** and **documentary requirements (D)**
- **Scientific focus:** Emphasises **comparability**, **stability data**, **validation**, and **risk-based justification**
- **Consistency controls:** Prevents misuse of MIV pathways for **unexpected events**, **product defects**, or **unresolved CAPAs**
- **Outcome:** Ensures **product quality, safety, and efficacy** are maintained throughout the product lifecycle



MINOR VARIATION (MIV) CHECKLIST FOR CLASS 2 CELL, TISSUE AND GENE THERAPY PRODUCTS Jan 2026

MINOR VARIATION (MIV) CHECKLIST FOR CLASS 2 CELL, TISSUE AND GENE THERAPY PRODUCTS

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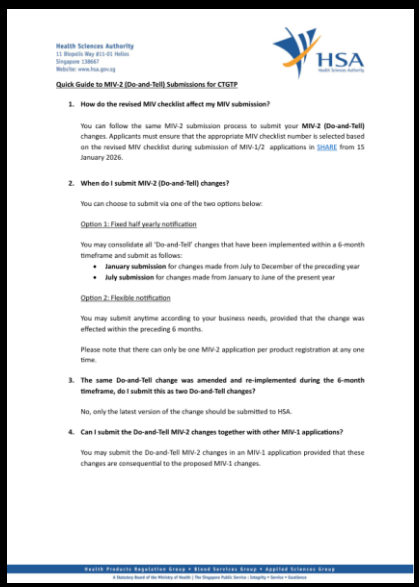

Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Website: www.hsa.gov.sg

Quick Guide to MIV-2 (Do-and-Tell) Submissions for CTGTP

1. **How do the revised MIV checklist affect my MIV submission?**

   You can follow the same MIV-2 submission process to submit your **MIV-2 (Do-and-Tell)** changes. Applicants must ensure that the appropriate MIV checklist number is selected based on the revised MIV checklist during submission of MIV-1/2 applications in SHARE from 15 January 2026.

2. **When do I submit MIV-2 (Do-and-Tell) changes?**

   You can choose to submit via one of the two options below:

   Option 1: Fixed half yearly notification

   You may consolidate all 'Do-and-Tell' changes that have been implemented within a 6-month timeframe and submit as follows:
   - **January submission** for changes made from July to December of the preceding year
   - **July submission** for changes made from January to June of the present year

   Option 2: Flexible notification

   You may submit anytime according to your business needs, provided that the change was effected within the preceding 6 months.

   Please note that there can only be one MIV-2 application per product registration at any one time.

3. **The same Do-and-Tell change was amended and re-implemented during the 6-month timeframe, do I submit this as two Do-and-Tell changes?**

   No, only the latest version of the change should be submitted to HSA.

4. **Can I submit the Do-and-Tell MIV-2 changes together with other MIV-1 applications?**

   You may submit the Do-and-Tell MIV-2 changes in an MIV-1 application provided that these changes are consequential to the proposed MIV-1 changes.

Health Products Regulation Group • Blood Services Group • Applied Sciences Group
A Statutory Board of the Ministry of Health | The Singapore Public Service | Integrity • Service • Excellence

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ICH harmonisation for better health

GUIDANCE

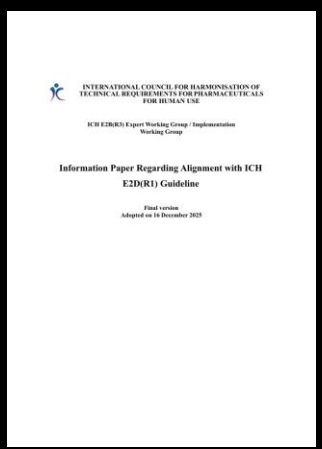
📌 Information Paper Regarding Alignment with ICH E2D(R1) Guideline

Explains how **ICH E2B(R3)** safety reporting specifications are **aligned with the revised ICH E2D(R1)** guideline on management of **solicited safety data**.

- **Status: Final version adopted 16 December 2025**; applies pending formal incorporation into the **E2B(R3) Implementation Guide and Q&A**.
- **Key Impact:** Requires clarification and updates to two **E2B(R3) data elements**:
  - **C.1.3 – Type of Report:** Confirms that **value "2 = Report from study"** must be used **not only for studies**, but also for **all other solicited sources** (as defined in **E2D(R1)**).
  - **C.5.4 – Study Type Where Reaction(s)/Event(s) Were Observed:** Updated to reflect **origin of solicited reports**, enabling clearer differentiation and analysis of safety data sources.
- **New C.5.4 Values Introduced:**
  - **4 = Patient Support Program**
  - **5 = Market Research Program**
  - **6 = Organised Data Collection System with source data from a digital platform** (e.g. social listening not under MAH responsibility).
- **Clarification Rules:**
  - Digital platform data linked to a **Patient Support Program** must use **value 4**, not 6.
  - Value **6** applies only when none of values **1–5** are appropriate.
- **Transition Approach:**
  - **Prospective use only**; previously submitted **ICSRs do not need resubmission**.
  - **Follow-up or amendment reports** must use the **new values**, where applicable.

  Legacy Programs: Certain **one-way service programs** no longer qualify as PSPs under **E2D(R1)**; follow-up ICSRs should revert to **C.1.3 = Spontaneous** and leave **C.5.4 empty**, with narrative clarification.
- **Regional Implementation:** Timelines depend on **regional regulators**; until implemented locally, reporters should use **"3 = Other studies"** as an interim value.

ICH E2B(R3) Implementation Guide Package here


INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH E2B(R3) Expert Working Group / Implementation Working Group

Information Paper Regarding Alignment with ICH E2D(R1) Guideline

Final version
Adopted on 16 December 2025

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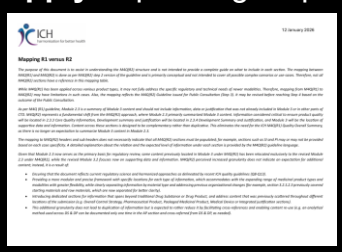
GUIDANCE

📌 Mapping R1 versus R2 - ICH M4Q(R2) Mapping Document

Provides a **conceptual mapping** between **ICH M4Q(R1)** and **M4Q(R2)** to help users understand the **restructured CTD Quality (Module 2.3 and 3.2)** under **M4Q(R2)**.

- **Status:** Dated **12 January 2026**; based on **M4Q(R2) Step 2 / Step 3 (public consultation)** and may change before **Step 4 adoption**.
- **Key Paradigm Shift: Module 2.3** is no longer a **Quality Overall Summary (QOS)** of Module 3. Instead, it becomes the **primary basis for regulatory review**, with clearly separated roles:
  - **2.3.3 Core Quality Information** – critical quality information for decision-making
  - **2.3.4 Development Summary and Justification** – development rationale and justification
  - **3.2 Body of Data** – detailed **supporting data only**
- **Elimination of QOS:** The traditional **M4Q(R1) QOS is removed**; duplication between Modules 2 and 3 is intentionally avoided.
- **Complementary Content Model:** Information across **2.3.3, 2.3.4, and 3.2** is designed to be **complementary, not repetitive**, enabling clearer review and content re-use.
- **Granularity Without Added Burden:** Increased section granularity does **not imply additional data requirements**; it reflects:
  - Alignment with **modern ICH quality guidelines (Q8–Q13)**
  - Support for **new modalities and product types**
  - Clearer separation of **materials, processes, and controls**
- **Relocation of Content:** Some information previously in **Module 3 (R1)** is now located **exclusively in Module 2.3 (R2)**, reinforcing 2.3 as the review anchor.
- **Cross-Referencing Principle:** Encourages **single-source documentation** with cross-references (e.g. analytical methods documented once and referenced across DS/DP).
- **New Dedicated Sections:** Introduces structured locations for topics previously scattered, such as **Overall Control Strategy**, **Integrated Justifications**, **Pharmaceutical Product**, **Packaged Medicinal Product**, and **Medical Device components**.
- **Regional Information:** The standalone **Regional Information section is removed**; regional requirements should be integrated into relevant sections using **regional keywords**.
- **Limitations:** Mapping is **illustrative**, not exhaustive; some **M4Q(R2) sections may not apply** depending on product type and development context.



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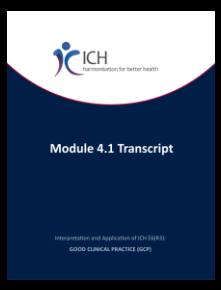
ICH harmonisation for better health

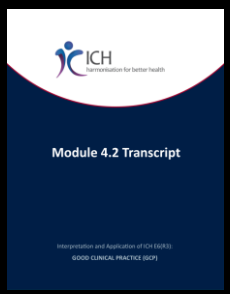
GUIDANCE

📌 Interpretation and Application of ICH E6(R3): Good Clinical Practice – Module

Training transcripts and video for **ICH E6(R3) Module 4.1 and 4.2**, focusing on **informed consent** as a core ethical requirement of **Good Clinical Practice (GCP)**. Reinforces **E6(R3) Principle 2** – informed consent must be **freely given**, **voluntary**, and based on adequate understanding of **benefits, risks, and burdens**.

- **Sponsor Responsibilities:** Development of **clear, concise, participant-focused consent materials**, with input from **patients and other interested parties**, and updates when new information emerges.
- **IRB/IEC Oversight:** Review and approval of **consent materials**, **consent process**, **re-consent**, **assent for minors**, and **participant compensation** to avoid coercion.
- **Investigator Responsibilities:**
  - Ensure **IRB/IEC approval** before consent is obtained
  - Use **plain, understandable language**
  - Allow adequate time for questions and decision-making
  - Avoid **undue influence or coercion**
- **Consent Formats:** Allows **paper or electronic consent**, including **remote consent**, provided identity verification and regulatory requirements are met and IRB/IEC approval is obtained.
- **Impartial Witness:** Required when participants cannot read the consent language; must be **independent of trial conduct**.
- **Vulnerable Populations:** Introduces **additional safeguards** for vulnerable participants, including **minors** (consent by representative + age-appropriate assent) and **emergency situations** where prior consent is not feasible.
- **Emergency Research:** Permits enrolment without prior consent only with **IRB/IEC-approved procedures** and requires **consent as soon as possible** afterward.
- **New / Modified Consent Elements (E6[R3]):**
  - Risks to **partners, embryos, foetuses, or nursing infants**, where applicable
  - **Follow-up procedures** after withdrawal or discontinuation
  - **Data handling** after withdrawal
  - **Trial registration** in public databases
  - Availability of **trial results and individual treatment information**, if desired
- **Re-consent:** Required when **new information** emerges that may affect a participant's willingness to continue; revised materials must receive **prior IRB/IEC approval**.





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STANDARD

IEC Update: 1. - 31. December 2025

Medical electrical equipment & radiology

- IEC 60601-2-64:2025 - Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment
- IEC 60601-2-64:2025 RLV - Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment (Redline version)
- IEC 61267:2025 - Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics
- IEC 80601-2-89:2025 - Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

Medical device software & treatment planning

- IEC 62083:2025 - Medical device software - Requirements for the safety of radiotherapy treatment planning systems

IVD & laboratory equipment

- IEC 61326-2-7:2025 - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-7: Particular requirements for devices with Ethernet-APL interfaces

Biotech, genomics & bioinformatics

- ISO/IEC 19583-27:2025 - Information technology - Concepts and usage of metadata - Part 27: Mapping between metamodel for computable data registration and bioinformatics analyses by high-throughput sequencing (HTS)

Medical IT, AI & digital health

- ISO/IEC 23093-2:2025 - Information technology - Internet of media things - Part 2: Discovery and communication application programming interface (API)
- ISO/IEC 27566-1:2025 - Information security, cybersecurity and privacy protection - Age assurance systems - Part 1: Framework

Foundational materials & components (medical relevance)

- IEC 60216-1:2025 - Electrical insulating materials - Thermal endurance properties - Part 1: Ageing procedures and evaluation of test results
- IEC 60216-1:2025 CMV - Electrical insulating materials - Thermal endurance properties - Part 1: Ageing procedures and evaluation of test results (Commented version)

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STANDARD

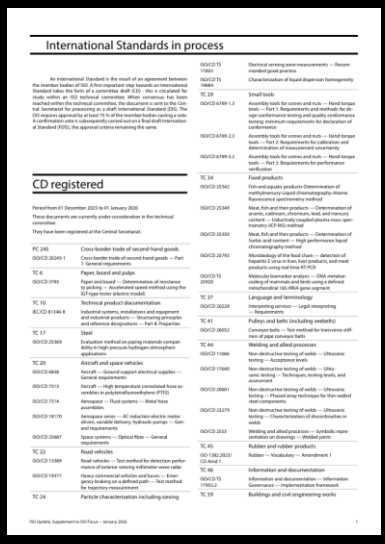
📌 ISO Update 1. December 2025 to 1. January 2026

Health Informatics / Pharma IT (IDMP)

- ISO/TR 14872:2025 - Health informatics - Identification of medicinal products - Core principles for maintenance of identifiers and terms
  Describes core principles for maintaining identifiers and terminology used for Identification of Medicinal Products (IDMP).
- ISO/TR 18728:2025 - Health informatics - Global medicinal product and ingredient and batch registration as part of identification of medicinal products (IDMP) Addresses concepts for global registration of medicinal products/ingredients/batches within an IDMP context.
- ISO 27799:2025 - Health informatics - Information security controls in health based on ISO/IEC 27002
  Applies ISO/IEC 27002-based security controls to health information environments. Healthcare organization management

Biotech

- ISO 20070:2025 - Biotechnology - Biobanking - Requirements for primary containers for storing biological materials in biobanks
  Specifies requirements for primary containers used to store biological materials in biobanks.
- ISO 20309:2025 - Biotechnology - Biobanking - Requirements for deep-sea biological material
  Defines requirements related to biobanking of deep-sea biological material.


International Standards in process

CD registered

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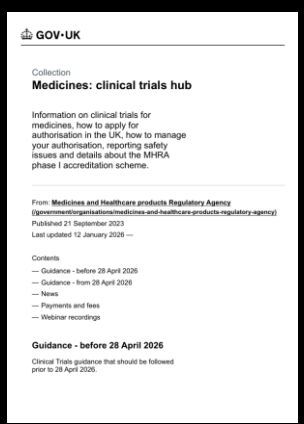
Medicines & Healthcare products Regulatory Agency

GUIDANCE

📌 Medicines: clinical trials hub

MHRA has refreshed the Medicines: clinical trials hub and linked guidance to help sponsors prepare for the new UK Clinical Trials Regulations coming into force on **28 April 2026**.

- Clarified **transitional arrangements**, explaining how trials submitted **before vs after 28 April 2026** are treated under the **old and new regulatory frameworks**
- Updated guidance on **applying for clinical trial approval in the UK**, including **eligibility**, **documentation**, and **authorisation routes**
- Revised processes for **modifying a clinical trial approval**, helping sponsors determine how and when changes must be submitted
- Updated definition and handling of **notifiable trials**, confirming continued use of the **combined review pathway**
- Strengthened requirements for **labelling** of investigational medicinal products to support **traceability** and **participant safety**
- Refreshed expectations for **collection, verification, and reporting of safety events**, reinforcing pharmacovigilance responsibilities
- Updated guidance on **archiving and retention of clinical trial records**, including **minimum retention periods** and sponsor responsibilities
- Clarified requirements for **clinical trials that include an in vitro diagnostic device (IVD)**, including additional information needed at submission
- Published UK-specific annotations to **International Council for Harmonisation ICH E6(R3)**, supporting adoption of **modernised Good Clinical Practice**
- Confirmed alignment between the **Declaration of Helsinki** and UK Clinical Trials Regulations, including how to manage and document any conflicts
- Updated **enforcement provisions**, outlining MHRA powers, inspection outcomes, and escalation measures
- Expanded access to **expert advice** to support sponsors with complex or novel trial designs
- Highlighted **common issues identified during clinical trial applications**, helping sponsors reduce delays and avoid validation failures
- Included updated **borderline products** guidance to help determine whether a product is regulated as a **medicine** before entering the clinical trial pathway


GOV.UK

Collection

Medicines: clinical trials hub

Information on clinical trials for medicines, how to apply for authorisation in the UK, how to manage your authorisation, reporting safety issues and details about the MHRA phase I accreditation scheme.

From: Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)
Published 21 September 2023
Last updated 12 January 2026 —

Contents
— Guidance - before 28 April 2026
— Guidance - from 28 April 2026
— News
— Payments and fees
— Webinar recordings

Guidance - before 28 April 2026

Clinical Trials guidance that should be followed prior to 28 April 2026.

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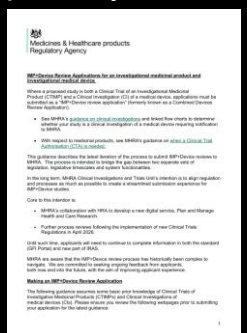
Medicines & Healthcare products Regulatory Agency

GUIDANCE

📌 IMP+Device Review Applications for an Investigational Medicinal Product and Investigational Medical Device

IMP+Device review applications are required when a study is both a **CTIMP** (Clinical Trial of an Investigational Medicinal Product) and a **clinical investigation of a medical device**. Applications must be submitted through an **IMP+Device review pathway** (formerly **Combined Devices Review**).

- The process is designed to **bridge separate legislative frameworks**, timelines, and IT systems for medicines and devices.
- Applicants must currently submit information in **both standard IRAS (GFI Portal)** and the **new part of IRAS**.
- **Device application must be submitted first** via standard IRAS.
- **MHRA Devices validation** occurs before review timelines begin; incomplete submissions delay the process.
- Once validated, MHRA Devices confirm **Day 0 (start)**, **Day 14 (CTIMP submission window)**, and **Day 60 (end)**.
- **CTIMP application** must be submitted **on or after Day 14** to align review periods.
- **MHRA Devices review period:** up to **45 days** to issue RFIs (Requests for Information).
- Multiple **RFIs** may be issued, each with a defined response deadline.
- No new RFIs are issued after **Day 45**, but responses may still be required.
- **Final Devices Decision Letter** is issued by **Day 60**.
- **MHRA Clinical Trials review period: 30 days** from CTIMP submission.
- If a **Grounds for Non-Acceptance (GNA)** is issued, applicants have **≥14 days** to respond.
- MHRA Clinical Trials assess responses within a **minimum of 16 days**.
- **Final MHRA outcome** (Devices + Clinical Trials + ethics decision) is usually communicated within **60 days**, subject to extensions.
- The MHRA aims to **streamline and align processes** through collaboration with **HRA**.
- A new digital service, **Plan and Manage Health and Care Research**, supports this goal.
- Further process changes are expected following **new Clinical Trials Regulations in April 2026**.
- Annex A provides a **visual process flowchart** of the IMP+Device submission and review pathway.


Medicines & Healthcare products Regulatory Agency

IMP+Device Review Applications for an investigational medicinal product and investigational medical device

Where a proposed study is both a Clinical Trial of an Investigational Medicinal Product (CTIMP) and a Clinical Investigation (CI) of a medical device, applications must be submitted as a "IMP+Device review application" (formerly known as a Combined Devices Review Application).

- See MHRA's guidance on clinical investigations and linked flow charts to determine whether your study is a clinical investigation of a medical device requiring notification to MHRA.
- With respect to medicinal products, see MHRA's guidance on when a Clinical Trial Authorisation (CTA) is needed.

This guidance describes the latest iteration of the process to submit IMP+Device reviews to MHRA. The process is intended to bridge the gap between two separate sets of legislation, legislative timescales and system functionalities.

In the long term, MHRA Clinical Investigations and Trials Unit's intention is to align regulation and processes as much as possible to create a streamlined submission experience for IMP+Device studies.

Core to this intention is:

- MHRA's collaboration with HRA to develop a new digital service, Plan and Manage Health and Care Research.
- Further process reviews following the implementation of new Clinical Trials Regulations in April 2026.

Until such time, applicants will need to continue to complete information in both the standard (GFI Portal) and new part of IRAS.

MHRA are aware that the IMP+Device review process has historically been complex to navigate. We are committed to seeking ongoing feedback from applicants, both now and into the future, with the aim of improving applicant experience.

Making an IMP+Device Review Application

The following guidance assumes some basic prior knowledge of Clinical Trials of Investigative Medicinal Products (CTIMPs) and Clinical Investigations of medical devices (CIs). Please ensure you review the following webpages prior to submitting your application for the latest guidance:

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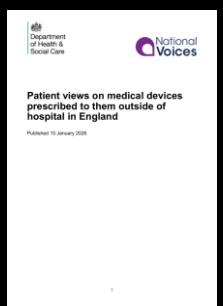
Department of Health & Social Care

REPORT

📌 Patient views on medical devices prescribed to them outside of hospital in England

Research commissioned by **Department of Health and Social Care (DHSC)** to understand **patient experiences** of **~60,000 medical devices** prescribed under **Part IX of the NHS Drug Tariff**.

- **Delivery partner: National Voices**, representing health and social care charities across England.
- **Aim:** Identify **device features patients value most** to inform **future categorisation and assessment** of medical devices and strengthen the **patient voice** in decision-making.
- **Methods: Mixed-methods** approach including **679 survey responses** and **66 interviews/focus groups** (Nov 2024–Mar 2025).
- **Scope:** Feedback across **7 device categories**, including **wound care**, **stoma and urological products**, **respiratory devices**, **diabetes and glucose monitoring**, and **oral/eye/ear/nasal care**.
- **Key cross-cutting theme 1:** Devices should help people **live full lives**, not restrict daily activities, relationships, or independence.
- **Key cross-cutting theme 2: Comfort, appearance, and fit** significantly affect **confidence, dignity, and mental wellbeing**.
- **Key cross-cutting theme 3: One size does not fit all**—patients value **choice** and **customisation**.
- **Key cross-cutting theme 4:** Devices often fail to meet the needs of **diverse users**, including people with **different skin tones**, **limited dexterity**, or **sensory impairments**.
- **Key cross-cutting theme 5: Accessible, high-quality information** is essential for **informed choice** and safe use.
- **Findings (wound & skin care):** Patients value **absorbency**, **skin protection**, **ease of use**, and **hypoallergenic materials**; poor adhesion and allergies cause harm.
- **Findings (stoma & urological care): Leak prevention**, **skin-friendly adhesives**, **discretion**, and **durability** are critical; leaks have major **quality-of-life impacts**.
- **Information gaps:** Many patients were **unaware of alternatives**, experienced **poor consultation**, or received **inaccessible formats**.
- **Equity issues:** Under-representation of some groups and **digital exclusion** limit who can engage with device choices.
- **Outcome:** Report sets out **recommendations** for **DHSC**, **manufacturers**, and **local decision-makers** to improve **patient-centred prescribing** and device design.



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PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

PRESS RELEASE

📌 Malaysia gazettes Medical Device Order 2026 to regulate aesthetic and cosmetic medical devices

- **Authority:** Issued by **Medical Device Authority (MDA)** Malaysia
- **Date & place: Cyberjaya, 9 Januari 2026**
- **Regulatory action: Perintah Peranti Perubatan (Peranti Perubatan yang Ditetapkan) 2026** has been **gazetted** and will **enter into force on 1 June 2026**
- **Objective:** Strengthen **regulatory control and oversight** of medical devices used in **aesthetic and cosmetic medical treatments**
- **Public protection:** Ensures **patient safety, quality, and user protection** in aesthetic and beauty-related medical procedures
- **Devices covered:** Includes **laser devices**, **High-Intensity Focused Ultrasound (HIFU)**, **liposuction devices**, and **related technologies**
- **Regulatory requirements:**
- Devices will be subject to **medical device regulatory controls**
- Operators must demonstrate **government-recognised qualifications and competency**
- Ensures **suitability and safety** for public use
- **Benefits to the public:**
- Reduces risk from **unsafe or non-compliant devices**
- Increases **confidence, safety, and accountability** in aesthetic treatments
- **Policy alignment:** Reflects government commitment to **public health protection**, **ethical industry growth**, and **legal compliance**
- **Technology governance:** Supports **responsible adoption of medical technology** without compromising safety
- **Implementation approach:** MDA will **collaborate with practitioners, industry players, and the public** to ensure smooth enforcement before June 2026
- **Issuing office: Bahagian Komunikasi Korporat, MDA**


Siaran Media
PRESS RELEASE

Penarikan Perintah Peranti Perubatan (Peranti Perubatan yang Ditetapkan) 2026

Cyberjaya, 9 Januari 2026

MedTech Leading Voice
Regulatory Roundup

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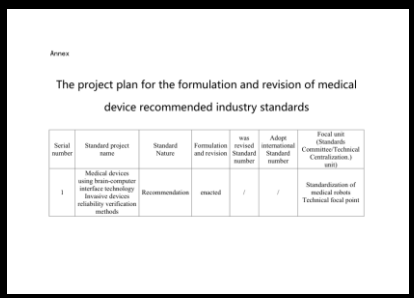
国家药品监督管理局
National Medical Products Administration

STANDARDS

📌 Establishment of Two Recommended Medical Device Industry Standards for Brain-computer interface (BCI) medical devices

Establish two recommended (non-mandatory) medical device industry standards for Brain-computer interface (BCI) medical devices

- **Document Type: Annex / project plan** supporting an **official SFDA announcement**
- **Standard Category: Recommended medical device industry standards**
- **Technology Focus: Brain-computer interface (BCI) medical devices**
- **Regulatory Status: Formulation plans approved and publicly announced**
- **Standard 1: Reliability verification methods** for **medical devices and invasive devices using BCI technology**
- **Standard 1 Nature: Recommendation enacted** (not mandatory)
- **Standard 1 Scope: Safety, performance, and reliability validation** of **invasive BCI devices**
- **Standard 2: Paradigm design and application specifications** for **motor function reconstruction** using BCI
- **Standard 2 Nature: Recommendation enacted**
- **Standard 2 Scope: Design and application guidance** for **functional rehabilitation use cases**
- **Formulation Stage: New standards**, not revisions of existing ones
- **International Alignment: No adopted international standards** listed
- **Technical Focal Unit: Standardization of medical robots - Technical focal point**
- **Governance Process:** Includes **public consultation**, **expert review**, and **formal publicity**
- **Strategic Significance:** Strengthens **standardization, safety assurance, and clinical readiness** of **neurotechnology-based medical devices**
- **Feedback Contact: mdct@nmpa.gov.cn**



Annex

The project plan for the formulation and revision of medical device recommended industry standards

Serial number	Standard project name	Standard Nature	Formulation and revision	was revised Standard number	Adopt international Standard number	Focal unit (Standards Committee/Technical Centralization.) unit)
1	Medical devices using brain-computer interface technology Invasive devices reliability verification methods	Recommendation	enacted	/	/	Standardization of medical robots Technical focal point

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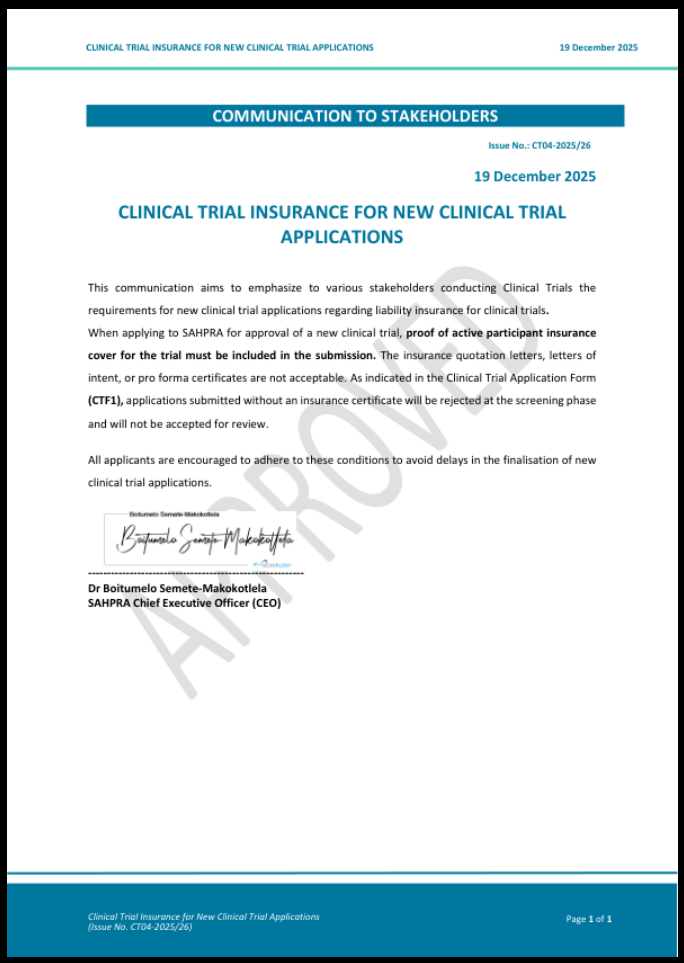
SAHPRA
South African Health Products Regulatory Authority

GUIDANCE

📌 Clinical Trial Insurance for New Clinical Trial Applications

SAHPRA reinforces **mandatory insurance requirements** for **new clinical trial applications**.

- **Authority: SAHPRA** requires **proof of active participant insurance cover** at submission.
- **Unacceptable documents: Insurance quotations**, **letters of intent**, and **pro forma certificates** are **not accepted**.
- **Screening outcome:** Applications **without an insurance certificate** will be **rejected at screening** and **not reviewed**.
- **Reference form:** Requirement explicitly stated in **Clinical Trial Application Form (CTF1)**.
- **Impact:** Non-compliance will cause **delays** in **finalisation** of applications.
- **Signatory: Dr Boitumelo Semete-Makokotlela**, **SAHPRA CEO**



CLINICAL TRIAL INSURANCE FOR NEW CLINICAL TRIAL APPLICATIONS 19 December 2025

COMMUNICATION TO STAKEHOLDERS

Issue No.: CT04-2025/26

19 December 2025

CLINICAL TRIAL INSURANCE FOR NEW CLINICAL TRIAL APPLICATIONS

This communication aims to emphasize to various stakeholders conducting Clinical Trials the requirements for new clinical trial applications regarding liability insurance for clinical trials.

When applying to SAHPRA for approval of a new clinical trial, **proof of active participant insurance cover for the trial must be included in the submission.** The insurance quotation letters, letters of intent, or pro forma certificates are not acceptable. As indicated in the Clinical Trial Application Form **(CTF1),** applications submitted without an insurance certificate will be rejected at the screening phase and will not be accepted for review.

All applicants are encouraged to adhere to these conditions to avoid delays in the finalisation of new clinical trial applications.

Boitumelo Semete-Makokotlela

Dr Boitumelo Semete-Makokotlela
SAHPRA Chief Executive Officer (CEO)

Clinical Trial Insurance for New Clinical Trial Applications (Issue No. CT04-2025/26) Page 1 of 1

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📌 Swissmedic Forms for January 2026

- Up until 31 January 2026, variations and extensions for human medicinal products must be submitted using the existing form (valid until 31 January 2026) and, from 1 February, using the new form (valid from 1 February 2026).A Swissmedic form used to submit or update a PSUR/PBRER and related Risk Management Plan information for human medicines.
  ZL300_00_003e_FO Form Variations and extensions HAMvalid until 31 January 2026 and for the correction of applications received by Swissmedic until 31 January 2026
  ZL300_00_003e_FO Form Variations and extensions HAMvalid from 1 February 2026
- **I-321.AA.01-A02e Form Application Scientific GMDP Meeting**: This form is used to submit an official application to Swissmedic for holding a Scientific GMDP meeting, including all required details for review and scheduling.
  I-321.AA.01-A02e Form Application Scientific GMDP Meeting
- **I-321.AA.01-A09e Form Scientific GMDP Meeting Minute**: This form is used to document the official minutes, decisions, and outcomes of a Scientific GMDP meeting in compliance with Swissmedic requirements
  I-321.AA.01-A09e Form Scientific GMDP Meeting Minute
- The application form used to request an operating license for handling, storing, or working with controlled substances in accordance with regulatory requirements.
  BW102_50_004d_FO Gesuchsformular Betriebsbewilligung zum Umgang mit kontrollierten Substanzen

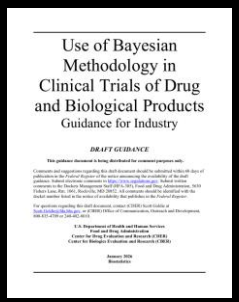
U.S. FOOD & DRUG ADMINISTRATION

GUIDANCE

📌 Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products

FDA Draft Guidance for Industry (nonbinding, not for implementation) on **Bayesian methods** in clinical trials for sponsors submitting **INDs, NDAs, BLAs, and supplements** for **drugs and biologics**

- **Primary focus:** Use of **Bayesian methodology to support primary inference** on **effectiveness and safety**
- **Core concept:** Combines **prior distributions** with trial data via **Bayes' theorem** to form **posterior distributions** for inference
- **Key applications discussed:**
  - Borrowing from **previous clinical trials**
  - Use of **external or nonconcurrent controls**
  - **Pediatric extrapolation**
  - Borrowing across **diseases, subtypes, or subgroups**
  - **Dose-finding trials**, especially in **oncology**
  - **Success criteria:** Typically based on **posterior probabilities** (e.g., Pr(effect > threshold) > c) rather than p-values
- **Two regulatory approaches:**
  - Bayesian analyses **calibrated to Type I error rate**
  - Bayesian analyses **not calibrated** but relying on prior credibility
- **Operating characteristics:** Emphasizes **simulation studies** to assess power, bias, error rates, and decision accuracy
- **Prior distributions:** Guidance on **noninformative**, **skeptical**, and **informative priors** with strong justification required for borrowing
- **Discounting methods:** Discusses **power priors, mixture priors, hierarchical models**, and **dynamic borrowing** to manage prior–data conflict
- **Prior influence:** Recommends quantifying impact using **effective sample size (ESS)** and related metrics
- **Sensitivity analyses:** Required to test robustness to **alternative priors and borrowing assumptions**
- **Estimands & missing data:** Must align across **external and prospective data sources** to ensure interpretability
- **Documentation expectations:** Detailed **protocols, SAPs, and simulation reports** are critical for FDA review


Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products
Guidance for Industry
DRAFT GUIDANCE

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Guiding principles of good AI practice in drug development

Establishes **10 guiding principles** for the **responsible use of AI** across the **drug product life cycle** (nonclinical, clinical, post-marketing, manufacturing).

These principles equally apply to **AI-enabled medical devices and software as a medical device (SaMD)**, where AI directly influences **diagnosis, treatment decisions, device performance, and patient safety** across the **entire device life cycle**, requiring the same **risk-based validation, transparency, and ongoing monitoring**.

1. **Human-centric design:** AI systems should align with **ethical values** and **human oversight**.
2. **Risk-based approach:** Validation, mitigation, and oversight are **proportionate to model risk** and **context of use**.
3. **Standards adherence:** Compliance with **legal**, **ethical**, **technical**, **scientific**, **cybersecurity**, and **GxP** standards is required
4. **Clear context of use:** AI roles, scope, and intended application must be **well defined**.
5. **Multidisciplinary expertise:** Integration of **AI specialists** and **domain experts** throughout the **technology life cycle**.
6. **Data governance & documentation:** Ensures **data provenance**, **traceability**, **verifiability**, **privacy**, and **protection of sensitive data**.
7. **Model design & development:** Follows **best practices** in engineering, using **fit-for-use data** with attention to **interpretability**, **explainability**, and **robustness**.
8. **Risk-based performance assessment:** Evaluates the **complete system**, including **human-AI interaction**, with appropriate metrics and testing.
9. **Life cycle management:** Continuous **monitoring**, **quality management**, and **periodic re-evaluation** to address issues like **data drift**.
10. **Clear, essential information:** Uses **plain language** to communicate **performance**, **limitations**, **data**, and **updates** to users and patients.


FDA U.S. FOOD & DRUG ADMINISTRATION EMA EUROPEAN MEDICINES AGENCY

Guiding Principles of Good AI Practice in Drug Development

January 2026

Artificial Intelligence (AI) has the potential to transform the way drugs (medicines)[1] are developed and evaluated, ultimately improving health care. In this context, AI refers to system-level technologies used to generate or analyze evidence across the drug product life cycle, including nonclinical, clinical, post-marketing, and manufacturing phases.

Drugs are authorized based on demonstrated quality, efficacy and safety, and when their benefits outweigh their risks. As new technologies emerge, including AI, it is essential that their use reinforces these requirements for the benefit and safety of patients.

The use of AI throughout the drug product life cycle has increased significantly in recent years. The complex and dynamic processes involved in developing, deploying, using, and maintaining AI technologies benefit from careful management throughout the drug product life cycle to ensure outputs are accurate and reliable. Among other innovations, AI technologies are anticipated to support a multi-faceted approach that promotes innovation, reduces time-to-market, strengthens regulatory excellence and pharmacovigilance, and decreases reliance on animal testing by improving the prediction of toxicity and efficacy in humans. This document outlines a common set of principles to inform, enhance, and promote the use of AI for generating evidence across all phases of the drug product life cycle.

These 10 guiding principles are intended to lay the foundation for developing good practice that addresses the unique nature of these technologies. They will also help cultivate future growth in this rapidly progressing field.

The 10 guiding principles identify areas where the international regulators, international standards organizations, and other collaborative bodies could work to advance good practice in drug development. Areas of collaboration include research, creating educational tools and resources, international harmonization, and consensus standards, which may help inform regulatory policies and regulatory guidelines in different jurisdictions, in line with applicable legal and regulatory frameworks.

As the use of AI in drug development evolves, so too must good practice and consensus standards. Strong partnerships with international public health partners will be crucial to empower stakeholders to advance responsible innovations in this area. Thus, this initial collaborative work can inform our broader international engagements.

1. Human-centric by design
The development and use of AI technologies align with ethical and human-centric values.

2. Risk-based approach
The development and use of AI technologies follow a risk-based approach with proportionate validation, risk mitigation, and oversight based on the context of use and determined model risk.

3. Adherence to standards
AI technologies adhere to relevant legal, ethical, technical, scientific, cybersecurity, and regulatory standards, including Good Practices (GxP).

4. Clear context of use
AI technologies have a well-defined context of use (role and scope for why it is being used).

[1] For the purpose of this document, the term "drug" is used to refer to drugs and biological products as defined in the United States of America, and medicinal products as defined in the European Union.

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REGULATORY ROUNDUP

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Martin King

Thank you 🙏 to Sean Smith and the team at MedTech Leading Voice
Thank you 🙏 **for your time and please share, like** 👍 and/or comment.

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