Regulatory Round-up

June 2025

Also available on our new online news hub at

https://ct.catapult.org.uk/news-hub

United Kingdom

Medicines and Healthcare Products Regulatory Agency (MHRA)

Medicines: clinical trials hub

As part of the preparations for the UK Clinical Trial Regulation, the MHRA and Health Research Authority (HRA) have published draft guidance documents covering several practical aspects of clinical trial approval, maintenance and reporting as well as close-out. The new guidances can be found here (MHRA) and here (HRA).

These guidances accompany the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the Clinical Trials Regulations"), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. The amendments come into effect on 28th April 2026. Until this date, these guidances are in draft and should only be used to support sponsors in preparing for the implementation of the new regulations. Prior to 28th April 2026 the guidances which are to be followed can be found here.

The updates to the clinical trials regulations will comply with the updated conditions and principles in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice.

Clinical trial sponsors should act to prepare for the upcoming changes. This can involve proactively reviewing the draft guidances to identify gaps in their current procedures for trial design, data handling, and reporting. Sponsors can also begin the training of personnel and the updating of internal systems to align with the new requirements. Furthermore, it will be prudent to revise submission strategies for applications and reports. Finally, early engagement with regulators and contingency planning are essential to clarify any ambiguities and minimise disruptions during this transition period.

The deadline for feedback on the new draft guidances is 30th July 2025.

Electronic Common Technical Document (eCTD) submissions update

On 17th June 2025, the MHRA published a guidance providing an update on eCTD submissions. Since April 2024, the MHRA has been using Lorenz DocuBridge for eCTD management in product license submissions as part of the modernisation of the MHRA's Legacy Systems. This change is one of the initial tools launched in the RegulatoryConnect programme. To improve the quality of submissions, the MHRA has introduced a stricter validation criteria for eCTD specifications. Please find further

information here. RegulatoryConnect is a new service from MHRA that provides the capability to track applications and view live authorisation details.The service will continue to evolve over time to provide further functionality. The video recording of the RegulatoryConnect May webinar is now available here.

First major overhaul of medical device regulation comes into force across Great Britain

On 16th June 2025, a new Post-Market Surveillance (PMS) regulation took effect across Great Britain, requiring medical device manufacturers to proactively monitor the safety and performance of their products once on the market. The reform applies to all UKCA- and CE-marked devices placed on the GB market.The regulations will ensure all manufacturers have an effective system in place to monitor devices once they are in use, collect comprehensive safety data, report serious incidents, and take swifter action when issues arise. The new reporting requirements will help the MHRA and industry spot patterns and intervene earlier to protect patients.

Key changes introduced by the new PMS device regulation include:

- Enhanced collection of real-world data: manufacturers must take a harmonised approach to gather and assess data on how their devices perform in everyday use, improving the ability to detect safety and performance issues.
- Expanded scope for incident reporting: serious incidents relating to side effects are now reportable, providing a more comprehensive picture of device performance.
- Shorter timelines for reporting serious incidents: serious incidents must be reported to the MHRA more quickly, allowing for faster regulatory action to protect patients.
- Trend reporting and summary reporting: new data analysis reporting options will support earlier detection of trends without overburdening manufacturers or the regulator.
- Clearer duties for risk mitigation and communication: manufacturers face stronger requirements to assess and manage risks, and to notify users promptly when safety issues arise.

Please find further information here.

UK MHRA leads safe use of artificial intelligence (AI) in healthcare as first country in new global network

On 24th June 2025 the UK became the first country in the world to join a new global network of health regulators focused on the safe, effective use of AI in healthcare. The move puts the MHRA at the centre of global efforts to get trusted AI tools safely into clinics faster – supporting earlier diagnosis, cutting NHS waiting times, and backing growth in the UK's health tech sector. Please find further information here. The MHRA will draw on its leading work in the UK to help shape the network from the ground up. That includes AI Airlock, a global leading example of a regulatory sandbox for AI medical devices – which lets companies test new tools with the regulator before wider NHS roll-out. On 23rd June 2025, the MHRA opened the second round of applications to test cutting-edge AI medical technologies following a successful pilot phase. The

MHRA pioneering AI Airlock programme will expand access to a first-of-its-kind regulatory testing ground where companies can work directly with regulators to safely test new AI-powered medical devices and explore how to bring them to patients faster, through streamlined regulations. Please find further information here.

EUROPE

European Directorate for the Quality of Medicines (EDQM)

All-digital 12th Edition marks a new era for the European Pharmacopoeia

EDQM has announced the launch of the 12th Edition of the European Pharmacopoeia (Ph. Eur.). This edition is now available on a redesigned, user-friendly platform enabling users to stay connected with a new 365-day licence. Please find further information here. A webinar will be held on 3rd July 2025 to reveal the latest updates and enhancements.

EDQM removes rabbit pyrogen test monograph

The rabbit pyrogen test (RPT) has been the traditional method used for pyrogen detection, ensuring the safety of parenteral medicines. This test relies on the use of rabbit, a practice consuming a large number of rabbits worldwide. In an effort to encourage medicine developers to move away from the RPT, the European Pharmacopoeia Commission adopted 57 revised texts from which the RPT has been deleted, together with a new general chapter on *pyrogenicity (5.1.13).* As a result, the use of the RPT will no longer be required in any text of the Ph. Eur. and it will be the responsibility of medicine developers to select a suitable *in vitro* test (e.g. the monocyte-activation test) to test the pyrogenicity of their product, based on a risk assessment as described in the new general chapter which is effective from 1st July 2025. A list of these texts can be found here.

30th General European Official Medicines Control Laboratories Network (GEON) Annual Meeting– Highlights

The 30th Annual Meeting of GEON took place in Oslo, Norway, from 19 to 23 May 2025. Over 250 participants representing 61 official medicines control laboratories (OMCLs) from 41 countries participated. The five-day meeting was hosted by the Norwegian Medical Products Agency and co-organised with the European Directorate for the Quality of Medicines & HealthCare (EDQM).The event featured nine different sessions, each focusing on various critical topics. The General Session covered interactions between OMCLs and key stakeholders such as Good Manufacturing Practice (GMP) inspectors, quality defect managers and quality assessors. Another focus was the concept of encouraging the development of specialised centres to help address testing needs across the network, with examples including the testing of gene therapy products, medical devices and radiopharmaceuticals. Please find further information here.

European Medicines Agency (EMA)

New stem cell therapy to treat patients with blood cancers

EMA has recommended granting a conditional marketing authorisation for Zemcelpro (dorocubicel) to treat adults with haematological malignancies (blood cell cancers). Zemcelpro can be used in patients requiring an allogeneic haematopoietic stem cell transplantation (allo-HSCT, transplantation of stems cell from a donor) following myeloablative conditioning (chemotherapy and/or radiotherapy) for whom no other type of suitable donor cells is available. Zemcelpro is a allogeneic stem cell therapy derived from umbilical cord blood. The two active substances of Zemcelpro are dorocubicel (CD34+ cells expanded ex-vivo) and non-expanded CD34- cells are stem cells from umbilical cord blood. By increasing the number of cells, Zemcelpro makes the stem cells from a small cord blood unit more effective. Please find further information here.

European Platform for Regulatory Science Research

The European Platform for Regulatory Science Research facilitates collaboration between academic researchers, not-for-profit researchers, regulators, and other relevant stakeholders. The platform's aim is to advance research for new regulatory tools, methodologies and approaches that medicine developers and regulators use throughout a medicine's lifecycle to support their regulatory decisions.

EMA and the Heads of Medicines Agency launched the platform in March 2025 in line with the European medicines agencies network strategy to 2028. EMA invites researchers and regulators to express their interest in participating in the platform and its meetings. Researchers from academic, public and not-for-profit institutions, as well as regulators, can participate in the platform. Please find further information including how to submit expression of interest here.

Chapter 9 of Guideline on epidemiological data on blood transmissible infections revision

Applicants for Plasma Master File (PMF) certification are required to include the donor population epidemiological data on blood transmissible infections for each individual blood/plasma collection centre and blood establishment listed in the PMF application. Chapter 9 of "Guideline on epidemiological data on blood transmissible infection" lays out the requirement to collect epidemiological data on blood transmissible infections. Adequate selection of donors is one of the important measures for the safety of plasma derivatives together with the virus testing of donations and pools, and the virus reduction capacities of manufacturing steps. The purpose of collecting epidemiological data is to characterise the donor population with respect to infection risk, to allow detecting epidemiological changes over time, and to allow comparison of risks between donor populations. Revision to this guideline includes more detailed guidance for PMF holders on the calculation of Alert Limits, which impacts the information to be submitted in the dossier.

Outcome of public consultation on the Reflection Paper Use of real-world data in non-interventional studies to generate Real-World Evidence for regulatory purposes.

28 May – 27th June 2025

EMA conducted a public consultation on the revised reflection paper titled "Use of Real-World Data (RWD) in Non-Interventional Studies (NIS) to Generate Real-World Evidence (RWE)." This draft reflection paper was built on the discussions from the Multi-stakeholder workshop on real-world data (RWD) quality and Real-World Evidence (RWE) use organised by the EMA on 26th June 2023, and aims to provide guidance on the use of RWD in NIS to support regulatory decisions. Please find the summary report of comments received during the public consultation and next steps here.

USA

Food and Drug Administration (FDA)

FDA halts new clinical trials that export Americans' cells to foreign labs in hostile countries for genetic engineering

On 18th June 2025, the FDA announced an immediate review of new clinical trials that involve sending American citizens' living cells to China and countries considered by the US to be hostile, where the cells undergo genetic engineering and subsequent infusion back into U.S. patients – sometimes without their knowledge or consent. Please find further information here.

FDA to issue new Commissioner's National Priority vouchers to companies supporting U.S. national interests

FDA has announced its Commissioner's National Priority Voucher (CNPV) program to enhance the health interests of Americans. The new voucher may be redeemed by drug developers to participate in a novel priority program by the FDA that shortens its review time from approximately 10-12 months to 1-2 months following a sponsor's final drug application submission. The new CNPV process brings together experts from FDA offices for a team-based review instead of using the standard review system whereby a drug application is sent to numerous FDA offices. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a 1-day multidisciplinary style meeting. Please find further information here.

Public consultations

MHRA

	Title	Consultation Period	Category
1.	*Clinical trials for medicines: applying for approval in the UK*	*End date:30 July 2025*	*Draft Guideline*
2.	*Clinical trials for medicines: expert advice*	*End date:30 July 2025*	*Draft Guideline*

3.	*Clinical trials for medicines: collection, verification, & reporting of safety events*	*End date:30 July 2025*	*Draft Guideline*
4.	*Clinical trials for medicines: Labelling for medicinal products used in clinical trials*	*End date:30 July 2025*	*Draft Guideline*
5.	*Clinical trials for medicines: notifiable trials*	*End date:30 July 2025*	*Draft Guideline*
6.	*Clinical trials: Non-investigational medicinal products*	*End date: 30 July 2025*	*Draft Guidline*
7	*Clinical trials regulations: transitional arrangements*	*End date: 30 July 2025*	*Draft Guidline*
8.	*Clinical trials for medicines: modifying a clinical trial approval*	*End date: 30 July 2025*	*Draft Guidline*
9.	*Clinical trials for medicines: ending a clinical trial*	*End date: 30 July 2025*	*Draft Guidline*

European Medicines Agency (EMA)

	Title	**Consultation Period**	**Category**
1.	*QRD annotated template v11*	*End date: 31 August 2025*	*Public consultation*
2.	*GMP/GDP Inspectors Working Group (GMP/GDP IWG) Concept paper on the revision of Part IV Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products*	*End date: 8 July 2025*	*Public consultation*
3.	*Chapter 9 of Guideline on epidemiological data on blood 4 transmissible infections*	*End date:31 August 2025*	*Public consultation*

Food and Drug Administration (FDA)

	Title	Consultation Period	Category
1.	*Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again*	*End date: 14 July 2025*	*Public Consultation*

International Council for Harmonisation (ICH)

	Title	Consultation Period	Category
1.	*Stabiltiy testing of drug substances and drug products Q1* *Draft guidance*	*End date: 30 July 2025*	*Stakeholder Consultation*