Regulatory Round-up

January 2026

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United Kingdom

Medicines and Healthcare products Regulatory Agency (MHRA)

Patients to benefit sooner as UK boosts clinical trials attractiveness with faster assessments and agile regulation

The MHRA is setting up the latest reforms for 2026 which demonstrate a strong national commitment to accelerating clinical research and improving patient access to innovative treatments. According to the MHRA, clinical trial activity rose significantly in 2025, including a 9% increase in applications and notable growth in early phase and first inhuman studies. The upcoming regulatory changes—such as a new fast track notification route for lower risk trials and a dedicated 14-day assessment pathway for Phase I studies—are designed to reduce delays, streamline trial setup, and reinforce the UK's position as a globally competitive environment for cutting edge research. These measures aim to ensure patients benefit sooner from emerging therapies while maintaining the highest safety and regulatory standards. Please find further information here.

EUROPE

European Directorate for the Quality of Medicines (EDQM)

EDQM: new general chapter 'Quality of Data' available

The EDQM has introduced a new general chapter, *5.38 "Quality of Data"*, within European Pharmacopoeia (Ph. Eur.) Issue 12.3, published in January 2026. This chapter establishes a comprehensive framework for assuring the quality of data—particularly digital data—throughout its entire lifecycle. It outlines foundational concepts of data governance, including accuracy, bias, completeness, reproducibility, and traceability, and highlights the importance of robust data management processes such as Extract–Transform–Load (ETL). The chapter also stresses the essential role of subject-matter experts in ensuring that data is fit for purpose, especially when used in automated and data-driven decision-making systems. By complementing existing Ph. Eur. chapters on chemometrics, process analytical technology, and experimental design, this new standard supports the ongoing digital transformation of pharmaceutical quality control and strengthens confidence in the reliability of data used to assess medicinal product quality. This new chapter is scheduled to come into force in July 2026. Please find further information here.

European Medicines Agency (EMA)

Questions and answers on the use of Product Lifecycle Management (PLCM) document - scientific guideline

The PLCM document is one of the lifecycle management tools introduced in the revised Variations Regulation (Article 6a – Additional Regulatory Tools) and in the updated Annex of the Variations Guidelines (chapters Q.I.e and Q.II.g – Additional Regulatory Tools).

Its purpose is to support global harmonisation of post-approval CMC changes. Although the PLCM document is not required for effective lifecycle management of medicinal products authorised in the EU, it is acknowledged that a globally harmonised tool can provide advantages for applicants when managing lifecycle activities across multiple regions.

Detailed guidance on the scientific and technical content of the PLCM document is provided in ICH Q12, Lifecycle Management (chapter 5). Please find the Q&A on the PLCM document -scientific guideline here.

Head of Medicines Agency (HMA)

FAST-EU pilot: official sponsor guidance published by Clinical Trials Coordination Group (CTCG)

FASTEU Sponsor Guidance (v1.0), published on 21 January 2026, provides essential instructions for sponsors participating in the new FASTEU pilot initiative. This EU wide programme introduces a coordinated fast track assessment pathway for multinational clinical trials, aiming to shorten evaluation timelines, increase regulatory predictability, and improve the overall efficiency of clinical trial authorisation processes across Member States. The guidance—now available via the CTCG—supports the launch of the FASTEU pilot on 30 January 2026, forming a key component of the EU's broader strategy to strengthen clinical research infrastructure and enhance Europe's competitiveness in innovative trial development. The guidance sets out expectations for sponsor eligibility, procedural steps, documentation requirements, and submission processes via the CTIS portal, enabling sponsors to prepare high quality, timely applications for inclusion in the pilot.

USA

Food and Drug Administration (FDA)

FDA increases flexibility on requirements for cell and gene therapies to advance innovation

The FDA has announced a new, flexible framework for CMC requirements tailored to the unique demands of cell and gene therapies (CGTs). Over the past decade, CBER has approved nearly 50 CGTs, many aimed at life-threatening or rare diseases. To address the complexity and individualised nature of these treatments, FDA

Commissioner Marty Makary emphasised that **"**regulatory flexibility must be tailored for cell and gene therapies", calling the changes "common-sense reforms" to encourage innovation.

Under this initiative:

- Looser quality controls may be allowed during later-stage clinical trials, and minor manufacturing changes between Phase I and Phase II can proceed if supported by appropriate comparability data.
- Post-approval manufacturing specifications can be adjusted for Biologics License Applications, with criteria revised based on real-world product consistency.
- Process Performance Qualification requirements may be waived or customised — including batch-by-batch validation — where sufficient process understanding exists.

Please find further information here.

Guiding principles of good AI practice in drug development

The FDA, in collaboration with the EMA, has established ten guiding principles to support the responsible, safe, and effective use of artificial intelligence (AI) across the drug development lifecycle. These principles emphasise:

- a humancentric and risk-based approach,
- adherence to ethical, legal, scientific, and regulatory standards,
- strong data governance to ensure the reliability and traceability of AI-generated evidence.

They further highlight the importance of multidisciplinary expertise, transparent context of use, robust model development practices, and lifecycle management to safeguard patient safety, strengthen regulatory confidence, and promote innovation in drug and biologics development.

Minimal residual disease and complete response in multiple myeloma: use as endpoints to support accelerated approval

The FDA has issued a draft guidance titled *"Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval"*, outlining how minimal residual disease (MRD) and complete response (CR) may be used as primary endpoints in clinical trials for multiple myeloma therapies seeking accelerated approval. The guidance provides recommendations on clinical trial design, statistical considerations, and assay validation, emphasising the use of highly sensitive MRD assessment methods such as flow cytometry or sequencing. MRD negativity—assessed in patients who have achieved a complete response—is recognised as a surrogate endpoint reasonably likely to predict clinical benefit, reflecting deeper treatment responses than traditional measures. While MRD or CR can support accelerated approval, confirmatory trials demonstrating long-term benefit through endpoints such as progression free survival or overall survival will still be required.

Use of Bayesian methodology in clinical trials of drug and biological products

The FDA has issued a draft guidance titled *"Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products"* which provides recommendations for sponsors on the appropriate use of Bayesian statistical methods in clinical trials intended to support investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), and supplemental applications. The guidance outlines how Bayesian approaches may inform interim analyses, adaptive design features, dose selection decisions, and—importantly—may be used to support primary inference for establishing the safety and effectiveness of drugs and biological products when properly justified. It emphasises careful prior specification, transparency in modelling, and evaluation of operating characteristics to ensure regulatory reliability.

INTERNATIONAL

International Conference on Harmonisation (ICH)

Presentation and training materials now available for draft guideline on patient preference studies

Following the November 2025 endorsement and publication of the ICH E22 draft guideline on general considerations for patient preference studies, the E22 Expert Working Group has released an informational presentation and accompanying training materials. The E22 draft guideline outlines general principles, describes different types of patient preference studies, and provides recommendations and practical considerations for their design and conduct.

Please find further information as well as access to the presentation and training materials here.

Updated technical documents issued by ICH Expert Working Groups for three guidelines

According to the latest ICH announcement, three Expert Working Groups have released updated supporting materials for their respective guidelines. These updates include a revised document package, a mapping document, and new training resources linked to three technical guidelines: E2B(R3) – Individual Case Safety Report Specification, M4Q(R2) – The Common Technical Document, and E6(R3) – Good Clinical Practice. Please find further information here.

Public consultations

26 November – 28th January 2026

European Medicines Agency (EMA)

	Title	Consultation Period	Category
1.	*Guideline on quality aspects of phage therapy medicinal products*	*End date: 30 Apr 2026*	*Draft guidance*
2.	*Guideline on non-inferiority and equivalence comparisons in clinical trials*	*End date: 31 May 2026*	*Draft guidance*

British Pharmacopoeia (BP)

	Title	Consultation Period	Category
1.	*Determination of Vector Genome Identity, Integrity and Encapsidated DNA Impurities*	*End date: 27 March 2026*	*Draft guidance*
2.	*Capsid Protein Characterisation*	*End date: 27 March 2026*	*Draft guidance*

Food and Drug Administration (FDA)

	Title	Consultation Period	Category
1.	*Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval Guidance for Industry*	*End date: 23 March 2026*	*Draft guidance*
2.	*Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products Draft Guidance for Industry*	*End date: 13 March 2026*	*Draft guidance*