Regulatory Round-up

June 2026

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United Kingdom

Medicines and Healthcare Products Regulatory Agency (MHRA)

Liaison programme set to reinforce close collaboration between MHRA and Food and Drug Administration (FDA)

The MHRA and the FDA have announced a new liaison programme to strengthen their long-standing regulatory partnership and enhance collaboration. The initiative introduces dedicated, reciprocal liaison officer roles within each organisation. These roles are designed to improve day-to-day cooperation, facilitate scientific exchange, and enable faster, more coordinated responses to emerging regulatory challenges.

The programme focuses on key areas such as innovative medicines, medical devices, and emerging technologies including artificial intelligence (AI). By improving communication and sharing regulatory expertise, both agencies aim to respond more rapidly to scientific advancements and support the development of safe and effective products for patients in both countries. While the collaboration will promote closer alignment, both MHRA and FDA will continue to make independent regulatory decisions, ensuring that national responsibilities and standards are maintained. Please find further information here.

Pioneering AI health innovations regulatory sandbox launched

The MHRA in partnership with NHS England (London) and the London Health Innovation Networks, has launched a regulatory sandbox to accelerate the safe adoption of AI-enabled healthcare technologies.

The initiative, known as London Region I, provides a secure, real-world testing environment where AI medical devices can be deployed in clinical settings while generating robust evidence on safety and effectiveness. This approach aims to enable earlier patient access to innovative technologies without compromising safety standards.

The sandbox brings together regulators, healthcare providers, and technology developers in a controlled environment to support collaboration and innovation. Up to 10 AI medical device manufacturers will participate in the initial phase, working alongside NHS organisations across London under MHRA oversight. By supporting

outcomes-based, real-world evaluation, the programme is designed to create clearer and more predictable pathways for wider adoption of AI technologies across the NHS. It will also contribute to improving patient outcomes, expanding access to care, and reducing health inequalities. The MHRA's AI Airlock second phase ran between April 2025 and May 2026. This report contains a comprehensive overview of the methodology for establishing the regulatory sandbox, the seven case studies and the lessons learned from the independent programme evaluation. It also summarises the key technical and regulatory insights and recommendations for changes to the regulatory and support framework for AI as a medical device.

EUROPE

European Medicines Agency (EMA)

Committee for Advanced Therapies (CAT) rules of procedure

On 10th June 2026, the EMA's CAT issued an official regulatory-procedural guideline, titled *"Committee for Advanced Therapies (CAT) Rules of Procedure"*. The document establishes the governance, structure, and operational framework of the CAT. It is grounded in the EU regulatory framework, particularly Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products ATMPs and Regulation (EC) No 726/2004, as well as Directive 2001/83/EC, ensuring alignment with the broader legal basis for medicinal product regulation in Europe.

The document details the composition and functioning of the Committee, including representation from EU Member States, EEA-EFTA countries, the European Commission, clinicians, and patient representatives, ensuring a multidisciplinary approach. It also defines the roles and responsibilities of the Chair, Vice-Chair, rapporteurs, and the EMA Secretariat, alongside procedures for appointments, voting, and conflict-of-interest management.

Furthermore, it outlines the procedures governing the CAT's scientific and regulatory activities, including the preparation and adoption of draft opinions, certification of quality and nonclinical data, classification of ATMPs, and coordination with other EMA committees such as the CHMP (Committee for Medicinal Products for Human Use). Provisions for meetings, written procedures, expert involvement, and stakeholder interactions are also included.

USA

Food and Drug Administration (FDA)

Leveraging prior knowledge in the development of human gene therapy products incorporating genome editing

The FDA has issued a draft guidance to provide recommendations for incorporating existing scientific knowledge into the development of genome editing gene therapy products. It is intended to assist manufacturers, applicants, and other stakeholders in improving development efficiency while maintaining product quality, safety, and effectiveness. The document emphasises the potential to utilise prior knowledge, including both publicly available scientific information and platform-based knowledge derived from similar technologies or manufacturing processes, to reduce redundant data generation and accelerate regulatory review timelines. Key areas where prior knowledge may be leveraged include chemistry, manufacturing, and controls (CMC), nonclinical studies, and clinical data, with the aim of streamlining submissions and facilitating faster patient access to innovative therapies, particularly for serious or rare diseases. The deadline for comments is 1st September 2026.

FDA actions to accelerate and modernise early and late-stage clinical development

The FDA has announced a set of actions to accelerate and modernise clinical development across both early and late stages, from the Investigational New Drug (IND) phase through pivotal trials. These actions are part of the broader Health and Human Services initiative "Operation TrialBlazer," aimed at improving efficiency, reducing unnecessary regulatory burden, and strengthening the U.S. position in biomedical innovation.

The main actions introduced are:

1. **Early-stage development (IND phase)**

- **Expedited IND Pilot Program**
    - Collaboration between sponsors and research institutions
    - Use of a rolling IND submission process
- **Phase 1 IND Navigator**
    - Centralised guidance and resources to simplify regulatory navigation
- **Updated CMC requirements**
    - Focus on phase-appropriate data only
    - Avoid unnecessary over-submission
- **Phase 1 Contact Center**
    - Direct support channel for sponsors during early development

2. **Late-stage clinical development**

- Greater flexibility in evidentiary requirements
    - In some cases, one high-quality pivotal trial + confirmatory evidence may be sufficient for approval

Please find further information here.

Oncology pharmaceuticals: streamlined nonclinical safety studies for biologics and conjugated products

The FDA draft guidance *"Oncology Pharmaceuticals: Streamlined Nonclinical Safety Studies for Biologics and Conjugated Products"* is intended for sponsors and developers in the pharmaceutical and biotechnology industry who are responsible for designing and conducting nonclinical safety studies for oncology biologics and conjugated products. It may also support regulatory professionals and other stakeholders involved in nonclinical safety evaluation.

The guidance provides recommendations for a streamlined, science- and risk-based approach to general toxicology studies, highlighting that, in certain cases, traditional testing requirements can be reduced, modified, or replaced (e.g., fewer animal species or use of weight-of-evidence assessments) based on existing data, mechanistic understanding, and prior regulatory experience. These approaches are intended to improve development efficiency while maintaining adequate safety evaluation and minimising unnecessary animal use.

This guidance represents the FDA's current thinking but is non-binding, and alternative scientifically justified approaches may be used, provided they comply with applicable regulatory requirements. The deadline for comments is on 30th July 2026.

Protocols for drug and biological product development

The FDA draft guidance *"Master Protocols for Drug and Biological Product Development"* (June 2026) provides recommendations for the design, conduct, and analysis of clinical trials conducted under a master protocol, as well as for the preparation and submission of documentation to support regulatory review. It is intended for sponsors, investigators, and other stakeholders in the pharmaceutical and biotechnology industry involved in the development of drugs and biological products using innovative trial designs. The guidance focuses on the use of master protocols such as umbrella, basket, and platform trials to evaluate multiple therapies, indications, or patient populations within a single overarching trial structure, with the aim of improving development efficiency and flexibility.

The document outlines key considerations for trial design, statistical analysis, operational conduct, and regulatory interactions, supporting consistent

implementation of complex trial designs while maintaining scientific rigor and patient safety.

This guidance contains non-binding recommendations and represents the FDA's current thinking, allowing alternative approaches provided they meet applicable statutory and regulatory requirements. The deadline for comments is on 24th August 2026.

INTERNATIONAL

International Conference on Harmonisation (ICH)

Key Outcomes of Biannual ICH Assembly Meeting

The ICH held its biannual Assembly meeting on 2–3 June 2026 in Rio de Janeiro, Brazil, bringing together regulators and industry representatives to advance global pharmaceutical harmonisation.

Key outcomes included the approval of a new ICH Strategic Vision and progress toward a multi-year Strategic Roadmap to guide future guideline development and topic selection. The Assembly also adopted ICH E6 (R3) Annex 2 (Good Clinical Practice) at Step 4, marking its transition to implementation.

In addition, the Assembly reviewed ongoing progress across multiple guideline areas (quality, safety, efficacy, and multidisciplinary), reflecting continued advancement of harmonised technical standards. It also approved new Observers (Pakistan DRAP (Drug Regulatory Authority of Pakistan) and New Zealand Medsafe), further expanding ICH's global reach.

Finally, updates were provided on the ICH Technology Task Force, including plans for a digital collaboration platform to support more efficient guideline development and implementation worldwide. Please find further information here.

Public consultations

Medicines and Healthcare products Regulatory Agency (MHRA)

	Title	*Consultation Period*	Category
1.	*Draft rare disease therapies regulatory framework*	*End date: 30 July 2026*	*Open consultation*

Food and Drug Administration (FDA)

	Title	Consultation Period	Category
1.	*Draft Guidance: Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing*	*End date: 14 July 2026*	*Public consultation*
2.	*Master Protocols for Drug and Biological Product Development*	*End date: 24 August 2026*	*Draft guidance*
3.	*Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing*	*End date: 1 September 2026*	*Draft guidance*