Clarity and Openness in Reporting: E3-based

News Summary

June 2026

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The recording of the CORE Reference Webinar "ICH M11: An Integrated and Forward-Looking CeSHarP Perspective", held on 17 June 2026 and presented by Marcie Roche, is available here. The presentation deck will be made available through the new CORE Reference website, which is currently under development and expected to launch in mid-July 2026. Watch this space.

MEDICINES AND VACCINES

ICH

1. ICH released ICH Guideline for Good Clinical Practice E6(R3) Annex 2, Adopted on 3 June 2026. This Annex should be read in conjunction with the Principles and Annex 1. Access guidance here. Download Annex 2 document here.

2. CIOMS has released Version 10 (15 June 26) of an updated Glossary of ICH Terms and Definitions, providing a single reference source for terminology used across ICH guidelines and Q&A documents.

CTR and CTIS

1. The latest Clinical Trial Highlights can be found here, including recent CTIS improvements, update on access to the CTIS training environment and CTIS modernisation.

2. There will be a DIA run CTIS Sponsor User Training Programme held on 19-22 October 2026. This in-depth, hands-on training course offers practical exercises within the CTIS training environment, live demonstrations by expert trainers, and on-demand content. You will gain the skills needed to access the system, manage users, and oversee a clinical trial from initiation through to the submission of results. You can register here (this is not a free programme).

3. The presentations from the CTIS Information Day held on 17 June 2026 are now available and include CTIS Progress: Sponsor's perspective/CRO perspective/Non-commercial sponsor perspective along with a FAST-EU update and COMBINE Project 1 'All-in-one' Coordinated Assessment Pilot Update.

EU Regulatory

The Evidence Base has published a blog post on EMA's adoption of a concept paper proposing the development of a reflection paper on the use of external controls in regulatory decision-making.

European Health Data Space (EHDS) News

How are AI and big data shaping the future of medicines regulation? Prof Dr Karl Christian Broich (BfArM) and Dr Peter Arlett (EMA) discuss the impact of AI, real-world data, and the European Health Data Space on regulatory science and what it means for public health: 10-minute video.

UK and MHRA News

1. MHRA has updated 'Clinical trials for medicines: modifying a clinical trial approval'. There is an updated decision tree for determining the correct category for a modification to reflect that sponsors must begin by determining whether the modification is substantial.

2. The latest edition of HRA Latest published by the NHS HRA can be found here with a strategic focus on innovation and system improvement as well as an emphasis on public involvement and collaboration.

3. FDA-MHRA collaboration - see FDA subsection for details.

FDA Guidance and News

1. FDA has issued draft guidance to assist manufacturers, applicants, and other stakeholders in developing human gene therapy (GT) products incorporating ex-vivo and in vivo genome editing (GE) of human somatic cells (GE products). Specifically, this guidance reflects FDA's current thinking on the type of prior knowledge (i.e., public and platform knowledge) that may be scientifically appropriate to leverage to advance product development. Access the draft guidance here.

2. Opinion Paper from J Soc Clin Data Management: Are You Ready for Elsa? What the FDA's Generative AI Inspection Tool Means for Clinical Data Teams. Includes useful cross-functional information.

3. FDA published final guidance detailing the statutory and regulatory requirements for postapproval abbreviated new drug applications (ANDAs). Access the guidance document here.

4. NLM has announced it will be phasing out the Classic PRS system now it has completed the modernisation of the Protocol Registration and Results System (PRS) and the public website, ClinicalTrials.gov. For the latest updates to the Modernized PRS and the timeline for retiring the Classic PRS, see here.

5. The latest ClinicalTrials.gov release notes are now available, including What's New and Improvements made: Updated content for How to Search for Clinical Studies, How to Read a Study Record, and How to Search for Studies with Results

6. FDA published final guidance titled M15 General Principles for Model-Informed Drug Development in June 2026. The guidance provides general recommendations for the planning, model evaluation, and documentation of evidence derived from model-informed drug development (MIDD).

7. On 15 June 2026, FDA Press Release 'FDA and MHRA Establish Reciprocal Staff-Sharing Initiative'. This is expected to deepen the FDA-MHRA relationship and accelerate initiatives. MHRA announcement here.

8. 22 Jun 2026 announcement: FDA Actions to Accelerate and Modernize Clinical Drug Development to accelerate and modernize clinical research across the full continuum of drug development, from the pre-Investigational New Drug (IND) phase to late-stage pivotal trials. The agency is eliminating unnecessary regulatory burden, clarifying phase-appropriate requirements and building partnerships with government, academic medical centers and the private sector. Phase 1 Investigational New Drug (IND) Navigator here.

9. The FDA draft guidance "Master Protocols for Drug and Biological Product Development | FDA" provides recommendations for designing, analyzing, and submitting clinical trials conducted under master protocols, including umbrella and platform trials, to support regulatory review. Comments can be submitted on the draft guidance before the close date of 24 August 2026.

10. FDA published a draft guidance 'Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials'. The guidance contains recommendations for the use of quantitative systems pharmacology modeling to inform first-in-human dose selection, supporting FDA's strategy to reduce the reliance on animal studies. Submit comments by 24 July 2026.

EMA Guidance and News

1. In June 2026, the EC published Version 2.0 of the 'Informed consent and patient recruitment procedure template' under EudraLex Volume 10. The 5-page template is recommended for use now, with full implementation from 01 Sep 2026 for new Part II submissions under the EU CTR. The template was developed by the MedEthicsEU group (consisting of representatives of MRECs from the EU Member States) and endorsed by the Clinical Trials Coordination and Advisory Group (CTAG).

2. The European Commission (EC), Heads of Medicines Agencies (HMA), and European Medicines Agency (EMA) have published the first quarterly report (Jan–Mar 2026) tracking progress toward the EU's 2030 clinical trial targets under the ACT EU initiative. Initiatives like ACT EU and FAST-EU aim to accelerate authorisations, improve transparency, and track performance through quarterly reporting, supporting the EU's ambition to remain a leading location for clinical trials.

Real-World Data

1. FDA updated several of its webpages related to real-world evidence (RWE), including a page that lists examples of RWE being used in regulatory decision-making at the agency's three medical product centers in the premarket and postmarket settings. These can be accessed here.

2. The Center for Devices and Radiological Health (CDRH) published a webpage to promote the use of RWE, including through guidance, training, and a National Evaluation System for health Technology (NEST). Details can be accessed here.

3. EMA has published a 4th progress report (based on studies EMA conducted using real-world data between February 2025 and February 2026) on the use of real-world evidence (RWE) in medicines regulation. The report summarises the progress in integrating real-world evidence in regulatory decision-making. It contains a list of research topics and a portfolio of use cases. The full report can be accessed here. An infosheet reporting cumulative experience gained from September 2021 to February 2026, including the challenges and opportunities of providing real-world evidence to support EU regulatory decision making can be accessed here.

GDPR and Data transfer Ex-EU

1. The GDPR enforcementtracker.com site has relaunched. As before, it shares free public data including 3000+ GDPR enforcement actions across the EU/EEA and the UK - in an improved site with new features including the analytics tool.

2. This 13 Jun 26 TranspariMED article titled 'European health groups demand action on missing clinical trial results' describes how a coalition of 20 health groups from across Europe wrote to EMA calling for urgent action on weak compliance with the EU's new CTR reporting law.

3. The PHUSE Data Transparency Autumn Event 15–17 September 2026 10:00-12:30 (EDT) / 15:00-17:30 (BST) / 16:00-18:30 (CEST) agenda includes: Day One - Regulatory Compliance & Protecting Sensitive Information; Day Two - Global Transparency & Evolving Data Use Regulations; and Day Three - Innovation, Patient-Centred Transparency & Operational Excellence.

4. Health Research article 12 June 2026: the French Data Protection Authority (CNIL) updates its Reference Methodologies (MRs) to reflect current practices and raise compliance standards.

Artificial Intellligence/Machine Learning

1. An article by Beth Stackpole, MIT entitled "Agentic AI, explained" can be accessed here.

2. An article by Bilgin et al., entitled "Agreement between large language models, human reviewers, and authors in evaluating STROBE checklists for observational studies in rheumatology" can be accessed here.

3. EMA's HMA 12 May 2026: '2025 AI Observatory Report' is available. It offers a system-wide view of ongoing initiatives and the use of AI. It reveals emerging trends and helps the European Medicines Regulatory Network (EMRN) to anticipate future needs so that the network can lead on the use of AI in medicines regulation. See Annex 7.2.3 'Clinical Development and Clinical Trials' for applications of AI discussed with Applicants.

4. In DIA Global's session spotlight on 16 June 26, panelists explored how AI and the Unified Study Definitions Model (USDM) can help streamline protocol development and support more patient-centric clinical trials. Expect recordings to appear soon; visit this page for a full agenda.

5. On 10 June 26, the EC published the final Code of Practice on marking and labelling of AI-generated content. The Code is voluntary and sets out practical steps to help providers and deployers of generative AI systems meet the AI Act transparency obligations that will apply from 02 August 26. Press Release here.

6. A blog article by David Elder entitled "Use Of AI In FDA Inspection Activities: Strategies For Effective Preparation" can be accessed here.

7. On 05 June 2026, Japan's PMDA revised its core guidance for Software as a Medical Device (SaMD), adding rigorous validation benchmarks for adaptive AI/ML logic in clinical settings. On 08 June 2026, PMDA established a cross-office Project team for Consideration of Guiding Principles for AI Utilisation to draft overarching guiding principles for appropriate use of AI.

8. Nature Article 24 June 26 by Moritz AK et al titled 'Disparate privacy risks from medical AI'. This new study raises a serious warning: the standard ways we evaluate AI privacy risks may dramatically underestimate how exposed individual patients really are. The researchers found that as AI models get larger, more patients may become highly vulnerable to attacks that can reveal whether their data was used in training.

9. On 16 July 2026 at 16.00 UK time, Khaled El Emam will present a webinar entitled "Can You Use This Data for AI? the New Rules of Anonymization, Risk and Responsible Data Sharing". The session will discuss the technologies that are available to responsibly use data for AI model training and inference. Register here.

News from Asia Regulators

1. The United Arab Emirates (UAE) established a new federal authority for AI and data on 15 June 26. Under one regulator there is one mandate, with AI policy, data governance, and digital government all reporting directly to Cabinet. Morgan Lewis Lawflash here.

2. On 15 May 2026, China's NMPA released the "Administrative Measures for Drug Trial Data Exclusivity (No. 47 [2026])", effective 15 May 2026. An accompanying Q&A on the Measures was also released (pages in Mandarin). Data exclusivity applies to qualified domestic and foreign-developed chemical drugs and biologics upon being granted marketing authorisation. During the data exclusivity period, protected data from the MAH may not be re-used for applications for improved new drugs, generic chemical drugs, or biosimilars by other applicants without the consent of the MAH. A third-party description of the Measures here (note the different translated terminology used).

3. On 08 June 2026, China's NMPA announced a revised version of the Good Clinical Practice (GCP) (page in Mandarin), to officially take effect on 01 September 2026. Two documents were released in the announcement: (1) GCP for Drug Clinical Trials (2026 Revision), and (2) Q&A Document on GCP for Drug Clinical Trials (2026 Revision).

4. On 12 June 2026, China's CDE released the translated ICH M11 and related guidance documents, and requested public comments within a month.

5. South Korea's MFDS launched the 240-day approval reform, effective 01 June 2026, reducing the review periods for new drugs, biosimilars, and advanced medical devices to 240 days. To support the new target, the MFDS introduced a comprehensive submission checklist, and at least two formal pre-NDA meetings with applicants can be arranged before the submission. Read this news release for more.

6. On 22 May 2026, Japan's PMDA launched two new websites: Designation/Early Access and Overview of Orphan Drug Designation, providing global sponsors comprehensive information of early-access study expectations in Japan.

News from US: Possible Impact on Clinical Trial Ecosystem

1. MedPage Today Special Report 05 June 2026: Video: Police Tussle With Diabetes Experts at ADA Meeting—Researchers told they could no longer attend the annual scientific sessions. Read ADA's 07 June official statement here.

2. BMJ Opinion piece 10 Jun 26: Trump administration has its sights set on destroying international research collaborations.

3. BMJ News article 11 Jun 26: Vaccination: RFK Jr cited autism link studies are retracted as Trump doubles down on recommendation changes.

MEDICAL DEVICES

This section covers transparency in relation to medical devices, and the emerging intersection of the regulatory medical devices and the regulatory drugs spaces. Devices information or regulations that impact the reporting of device studies are also covered. Combination products, including pharmaceutical and medical device components, may need to be reported under pharmaceutical legislation, depending on what the product is, and how regulatory authorities in different global regions assess combination products. Contextualisation is provided, where possible, to help readers navigate the information.

General Updates and News

1. The presentation and recording from the EMA information session entitled “Breakthrough medical devices: information session” held on 24 Apr 2026 are available from here.

2. Public consultation on a new standard for digital mental health technologies (DMHTs) that qualify as software as a medical device (SaMD) has taken place. The MHRA sponsored the BSI to develop this standard, which provides recommendations for designing and conducting clinical studies to generate evidence for DMHTs. The consultation was open until Monday 29 June 2026. Access the BSI consultation notice here.

EU Combine Initiative

The next phase of the COMBINE Pilot is open for expressions of interest. This initiative offers a unique opportunity to benefit from coordinated assessment through the Clinical Trials Information System (CTIS) of combined study applications across clinical trial and medical device regulatory frameworks.

Phase 2 marks a major step forward, with a significantly expanded scope. It now includes studies involving in vitro diagnostics (IVDs), medical devices (MDs) and trials with advanced therapy medicinal products (ATMPs), all within standard CTR timelines and supporting separate sponsor setups.

The first procedures are expected to begin in September 2026. Find out more via the official COMBINE Pilot webpage.

US FDA

The FDA's Center for Devices and Radiological Health (CDRH) has developed a series of patient engagement courses about medical devices and the important role of patient advisors throughout the medical device life cycle. The courses are intended for patients, caregivers, patient organizations, industry, and health care stakeholders who are interested in learning how to more effectively engage with the FDA and Medical Device Developers. Details of courses here.

UK MHRA

The MHRA AI Airlock programme has published a programme report with key learnings from Phase 2 alongside a suite of simulation workshop summary reports from multi-stakeholder engagements. The MHRA’s AI Airlock second phase ran between April 2025 and May 2026. The report can be downloaded from here. The MHRA AI Airlock regulatory sandbox was established to create a safe, structured environment for MHRA to work directly with AI medical device developers to understand how current regulation performs in practice, and where there is opportunity to change.

South Korea

South Korea’s MFDS amended the Medical Device Act on 30 December 2026, to take effect on 01 July 2026, and the “Regulation on the Permission, Notification, Review of Medical Devices” on 28 April 2026. More info can be read in this third-party blog.