



Clarity and Openness in Reporting: E3-based

News Summary

September 2026

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NEW SEARCHABLE CORE REFERENCE WEBSITE

The CORE REFERENCE team are delighted to announce the launch of the [new CORE Reference website](#), with the ability to search our monthly News Summaries as a valuable new feature. All News Summaries will be posted on the website as well as on our LinkedIn page and those issued from January 2025 onwards can be searched using key words or phrases.

How to find and use the NEW search function: On the main page of the CORE Reference [website](#), use the 'Navigate CORE Reference' pane on the right-hand side of the landing page. Click on '[News Summaries](#)' where you will find the NEW search function. Search monthly summaries from January 2025 onwards using one of the listed search terms or phrase to identify relevant news summaries.

By accessing the News Summaries on the website, and searching by topic you will be able to more efficiently target specific CPD needs.

An archive of pre-2025 News Summaries can be accessed on the same page.

The CORE Reference team would like to extend a huge thanks to EMWA for supporting the creation of this new site.

Celebrating 10 Years of the CORE Reference Project with AMWA

The CORE Reference team are delighted to share our [open-access article from the AMWA Journal](#), which reflects on the first decade of the CORE Reference Project. The article was originally published in the EMWA Journal earlier this year, and to contextualise the original article for readers of the AMWA Journal it now includes a preface by Sam Hamilton, Chair of the CORE Reference team.

MEDICINES AND VACCINES

ICH

The ICH M11 Expert Working Group has published training materials to support implementation of the ICH M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP) template and technical specification. Available on the ICH Training Page, [the materials can support stakeholders involved in clinical trial protocol development and review](#).

CTR and CTIS

1. The following White Paper has been published by the PHUSE Working Group: Data Transparency: [Protecting Commercially Confidential Information \(CCI\) While Complying with the European Union Clinical Trials Regulation 536/2014](#). The White Paper aims to provide clinical study sponsors with practical guidance and strategies for identifying, managing, and protecting CCI in clinical study documentation submitted to CTIS under the EU CTR.
2. Clinical Trials Highlights [issue 36 - September 2026](#) confirmed work is ongoing to prepare for the go-live of a new safety module for the submission and management of Annual Safety Reports (ASRs) in CTIS. Users will be informed of the date of the go-live in due course. After the go-live, a two-month transition period will follow. A bitesize talk on the ASRs from 23 July 2026 can be accessed [here](#).
3. Next CTIS Walk-in clinic 7 October 2026. Details are [here](#).
4. The list of public holidays for 2027, as recorded in CTIS for each EU Member State, is now available on the EMA website: [European Union Member State Public Holidays Recorded in CTIS](#).

EU Regulatory

New monthly document from EU Commission (Press Corner): "[Entry into force or application of EU legislation: key milestones | 1 September – 15 October 2026](#)". Locate it from the [Press Corner page](#), by searching for "Entry into force or application of EU legislation" in the keywords below the Top Stories.

European Health Data Space (EHDS) News

European Health Data Space opened draft technical requirements for HealthData@EU act for public consultation. This Implementing Decision sets out the technical and functional framework for the HealthData@EU infrastructure, which will enable secure and interoperable cross-border access to electronic health data for secondary use. It also sets out the specifications of the IT tool for enforcement transparency, facilitating cooperation and information exchange between health data access bodies on enforcement measures. Feedback period was 01 September 2026 - 29 September 2026 and was provided [here](#). Commission adoption is planned for fourth quarter 2026.

UK and MHRA News

1. The most recent '[HRA Latest](#)' includes information about guidance that can help researchers to use health information to identify people to invite to take part in research in a way they can trust as well as the HRA's response to the MHRA's consultation on a proposed regulatory framework for rare disease therapies.
2. On 22 September 2026 MHRA updated their Guidance document entitled "[Clinical trials for medicines: Good clinical practice inspections](#)." Information relating to good clinical practice (GCP) inspections. The update includes "Updated wording on submission of inspection dossiers and the introduction of a specific dossier for organisations providing computerised systems in support of clinical trials."

FDA Guidance and News

1. [FDA Tightens Expectations for Biosimilar Promotion: Guidance, Warnings, and Policy Proposals](#): this DIA article explores the FDA's December 2025 Q&A Guidance for Industry, providing insight into regulatory expectations for the communication of reference and biosimilar product information in promotional labeling and advertising.
2. On 27 August 2026, NIH released its [Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants](#) for public comment. Comments on the Draft Policy will be accepted until 26 October 2026, and must be submitted through this [comment form](#).
3. FDA Draft Guidance Sep 2026: [Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling](#). [Submit comments](#) by 01 Dec 2026. This guidance provides recommendations to sponsors and applicants who plan to conduct studies to assess the influence of hepatic impairment on the pharmacokinetics (PK) and, where appropriate, the pharmacodynamics (PD) of a drug, including therapeutic biological products.
4. FDA has [announced the launch of an expedited IND pilot](#), and has begun accepting applications. According to the announcement "The FDA will accept applications to participate in the pilot until 30 October 2026."

EMA Guidance and News

The EMA has published a new page on [women's health](#) including details of the various initiatives launched by the EMA to better embed women's health considerations in medicines development and regulation. The page also includes a section on the representation of women in clinical trials.

Transparency and Disclosure Resources and News

Bioforum is holding a free webinar "Clinical Trial Report Writing Under New Regulatory Requirements: Navigating EUCTR, ICH M11, EMA Policy 0070, and Beyond" on 08 October 2026, 3pm CET/9am EST. The session will cover how these

frameworks connect and interact. Topics include structural changes in CSRs, anonymisation, machine-readable content, layperson summaries, workflow considerations, gap analysis, and tools that can support compliance across global submissions. Register [here](#).

Development Strategy News

1. Nature Reviews Drug Discovery article 21 Sep 2026, Arlett et al: [Two trials or not two trials? That should not be the question](#). In this article, experts set out EMA's position: rather than setting a requirement for a specific number of trials when evaluating a medicine, we should focus on understanding the evidence available, the disease, the patient population, existing knowledge and remaining uncertainties (note: behind a paywall).
2. A LinkedIn post by Bhawna Basin and Giulia Angelini entitled “ICH M11 in practice: a new era of structured protocol authoring for medical writers” can be accessed [here](#).
3. The evolving landscape of drug targets by Halip et al, Nat Rev Drug Discov (2026). <https://doi.org/10.1038/s41573-026-01530-3> (note: behind a paywall).
4. Wilkinson et al, 2026 published a tool to assess the trustworthiness of randomized controlled trials in the BMJ entitled [‘INSPECT-SR tool for assessing trustworthiness of randomised controlled trials’](#). The publication describes the development of INSPECT-SR and presents the tool and an associated guidance document as well as an editable template.
5. An online article by Amie Harp entitled [‘ICH M11 Is Final, Not Mandatory: What a Machine-Readable Protocol Changes for Clinical Systems’](#) explores the status of ICH M11 across regulatory authorities as of Sept 2026.

Artificial Intelligence/Machine Learning

1. As AI continues to expand in the pharmaceutical industry, the following white paper explains the regulatory climate, challenges, and solutions for moving from traditional to generative AI in drug safety: Demanding More from AI Governance in Drug Safety. The white paper can be downloaded [here](#).
2. Regulatory Perspectives article 11 Sep 26: [FDA’s AI Expansion: Opportunities, Risks, and What Companies Should Expect](#).
3. The UK MHRA and National Commission into the Regulation of AI in Healthcare published “National Commission into the Regulation of AI in Healthcare” on 10 Sept 2026. Access the guidance document [here](#).
4. New WHO report calls for stronger ethics oversight of AI-related health research. Read the WHO news report [here](#). Access the report [here](#).
5. HMA / EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations to be held online 12- 13 November 2026. Registration and details

[here](#). The online workshop aims to:

- Showcase state-of-the-art AI and data applications across the medicines' lifecycle
- Discuss the evolving EU regulatory landscape for data and AI
- Hear from stakeholders on data foundations, governance, quality, and interoperability across the Network
- Strengthen stakeholder collaboration to accelerate the adoption of trustworthy AI
- Input to the NDSG workplan in alignment with the Network Strategy to 2028

6. EMA has published open access article entitled: “[Regulatory Research Priorities for AI Use in the Medicine Lifecycle: A European Perspective with Global Relevance](#).” The publication summarises the outcomes of a multi-stakeholder survey investigating regulatory research priorities for AI across the medicines lifecycle.

News from US: Possible Impact on Clinical Trial Ecosystem

1. FDA Voices 02 Sep 2026: [Good Clinical Practices Are Not Optional: The FDA's Commitment to Human Subject Protections and Gold Standard Science in an Era of Global Clinical Research](#). Outlines agency concerns with foreign clinical trials.
2. BMJ article 07 Sep 2026: [Trump's bid for political oversight of research grants is blocked by Congress](#)
3. FDA Voices 15 Sep 2026 article: [An America First Approach to Medical Innovation](#).
4. BMJ Feature article 17 Sep 2026: [Trump's “dismantling” of NIH research continues apace](#).
5. BMJ News 22 Sep 26: Trump: “[Split vaccines into five doses to reduce autism](#)”—the US president's latest unevicenced claim.

MEDICAL DEVICES

This subsection 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.

FDA

1. FDA CDRH has launched a new [Medical Device Regulatory Reliance Portal](#), bringing together information on FDA review processes, decision-making, post-market surveillance, and other publicly available resources intended to support regulators considering reliance-based approaches. The portal is a useful resource for regulators and regulatory affairs professionals involved in international market access and regulatory reliance programmes.

2. FDA has released a draft guidance document entitled: “[Electronic Submission Template for Premarket Approval Applications \(PMA\)](#).” It introduces submitters to the current publicly available resources and associated content developed to support electronic submissions of PMAs and certain PMA supplements to FDA.

Asia

1. China NMPA has released new GMP inspection guidelines for medical devices: [Devices](#) (original source in Mandarin). This newly announced framework immediately requires sponsors and manufacturers to prepare for modernised inspection standards regarding quality control, safety, and the integrity of clinical evaluation data. A brief summary in English by a third party is available [here](#).

2. Singapore HSA announced expanded regulatory reliance collaborations to reduce duplicative reviews during the 30th [International Medical Device Regulators Forum](#) (IMDRF) held in Singapore (Sept 14–16). The HSA also advanced 4 practical deliverables on reliance, artificial intelligence, cybersecurity, and regulatory convergence.

3. On 14 September 2026, South Korea’s MFDS issued a formal [legislative pre-notice regarding partial amendments to the Enforcement Rule of the Medical Devices Act](#) (original source in Korean). Key provisions include expanding clinical trial participation to institutions beyond traditional designated trial centers, implementing a "one-stop" review process for Class II medical devices, and establishing formal procedures for advance classification reviews and emergency device supply planning. Additionally, the amendment bans AI-driven advertisements claiming expert endorsements and introduces regulatory fee exemptions for medical devices designed for visually and hearing-impaired user. Brief summary in English by a third party available [here](#).