Clarity and Openness in Reporting: E3-based

News Summary

July 2025

Follow The CORE Reference Project on LinkedIn

As a follower of the 'CORE Reference Project' you will receive notifications of our postings including the monthly News Summaries and other resources to support your self-led CPD. To access the links in the News Summary, view in full screen and then either select 'accessibility mode', or download the News Summary PDF and then access.

The June 2025 issue of EMWA Journal MEW (Volume 34 (2) Communicating With the Public) features the Regulatory Public Disclosure section written and compiled by Sam Hamilton together with the CORE Reference Team. Our section provides updates for regulatory medical writers with an interest in regulatory public disclosure and can be downloaded from here.

MEDICINES AND VACCINES

CTR and CTIS

1. The redesigned Clinical Trials Information System (CTIS) training materials for sponsor users was published on the EMA website on 9 July 2025, superseding the existing training modules for sponsors. A Bitesize talk delivered on 9 July 2025 entitled: Redesign of the CTIS training material for sponsor users can be viewed here.

2. The European Medicines Agency (EMA) published Version 6.0 of the Sponsor Handbook on 9 July 2025. According to the history and summary of changes, “Version 5.0 was updated to Version 6.0 in order to fully integrate the content of the former CTIS training modules that were used by sponsors when operating on CTIS”.

3. The July issue of Clinical Trial Highlights includes the latest news on clinical trials from the European Medicines Regulatory Network (EMRN), including news on the joint Accelerating Clinical Trials in the EU (ACT EU) initiative and on the CTIS, including Frequently asked questions related to Clinical trials submitted under the EU CTR.

EU Regulatory

1. In July 25, EMA made a report available on a pilot conducted between Oct 21 and Dec 24 which provided tailored scientific advice to not-for-profit organisations and academics on repurposing authorised medicines for new indications. The report contains findings and recommendations to address opportunities and challenges identified during the pilot. The Commission's expert group on Safe and Timely Access to Medicines for Patients (STAMP) proposed the framework.

2. EMA have concluded their pilot project supporting the repurposing of authorised medicines for new therapeutic uses. Full report here. The pilot served as a test for a proposed European Commission framework to support not-for-profit organisations and academia in medicine repurposing.

UK and MHRA News

1. GOV.UK has clarified how to apply for authorisation in the UK prior to the amendments that come into force from 28 April 2026 and how to apply for a clinical trial from 28 April 2026.

2. UK's HRA publishes the 'Clinical Trials Update' which includes the latest news on the upcoming changes to the UK's clinical trials legislation. In the latest version: new guidance to accompany the updated clinical trials regulations which come into force in April 2026 and an update on the Inclusion and Diversity Plan pilot. Sign up and read here.

3. The NHS HRA has produced new guidance to help prepare researchers and sponsors for updated clinical trials regulations coming into effect in April 2026.
The new guidance covers definitions and terminology; PV; clinical trials approvals process; simplified arrangements for consent; RECs; and research transparency. Share your feedback here.

FDA Guidance and News

1. FDA has reported that it is to screen all imports with a previous exemption for low-value shipments now revoked. See the report in news item from Reuters.

2. The latest release notes for the Modernised PRS were released on 16 July 2025. This release includes added functionality to create customised Baseline Characteristics as well as enabling recording of Arms/Groups and Outcome Measures.

3. FDA is hosting a hybrid in-person/virtual public workshop on interchangeable biosimilar products on 19 Sep 2025 titled: "Future Needs for the Development of Interchangeable Products."

4. FDA's CDER's Center for Clinical Trial Innovation (C3TI) has published a white paper on selective safety data collection (SSDC). SSDC is the planned reduction in the collection of certain types of data in a clinical investigation for drugs with a well-characterised safety profile. The white paper describes the International Council for Harmonization's E19 final guidance of Dec 2022, A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-approval Approval or Post-approval Approval Clinical Trials, which FDA and other regulatory agencies have implemented.

EMA Guidance and News

1. EMA and HMA have decided to extend the duration of the Clinical study data pilot. This pilot involves voluntarily submitting patient-level clinical study data as part of a centralised authorisation procedure application. Expressions of interest will continue to be accepted until further notice. For

more information about the pilot, see here.

2. The EMA Annual Report 2024 is now available. This report highlights the key achievements and key figures in 2024.

3. In early 2025, ACT EU conducted a survey to assess the clinical trials training needs of academia and micro, small and medium-sized enterprises (SMEs). The feedback from around 400 stakeholders has been analysed and published in a report outlining key training needs, and identifying potential gaps as well as challenges and suggesting ways to address them.

4. ACT EU hosted a multi-stakeholder workshop on the revised ICH E6(R3) guideline on 19–20 February 2025. The full workshop report was published online on 21 July 2025. The report summarises the key messages, panel discussions, and stakeholder perspectives shared during the event.

5. The revised guideline for Good Clinical Practice (GCP) ICH E6(R3) principles and Annex 1 is applicable in the European Union as of 23 July 2025. The update aims to:

- apply GCP principles to the increasingly diverse trial types and data sources supporting regulatory and healthcare related decision-making on medicines;
- provide flexibility to facilitate the use of technological innovations in clinical trials.

6. On 24 July 2025, EMA published an updated version of the Guidelines on good pharmacovigilance practices (GVP) Introductory cover note. The cover note is updated to reflect the new Guideline on good pharmacovigilance practices (GVP) Addendum II to Module VI (published 22 July 2025) on masking of personal data in individual case safety reports submitted to EudraVigilance.

Real-World Data

1. 3rd Annual EMA RWE Report (Feb 2024–2025): 59 studies conducted, a 47.5% increase vs. last year; DARWIN EU now includes 30 data partners across 16 countries, representing 180 million patients. Some of the strategic recommendations: Expand international collaborations; use RWE earlier in regulatory and HTA dialogues, not just post-approval; embrace AI and federated analytics to optimise speed, reproducibility, and patient-centred insights.

2. An article by Fink et al and published in Regulatory Focus July 2025, highlights the similarities and differences in the acceptance of real-world evidence (RWE) as clinical data for medical devices in the US and the EU. Access the article here. See more details in the Devices section below.

3. An EFPIA position paper on randomised pragmatic trials to generate high-quality real-world evidence for regulatory decisions has been published and can be accessed here.

Transparency and Disclosure Resources and News

1. Lancet paper 'Reporting summary results in clinical trial registries: updated guidance from WHO' describes 2025 guidance issued by the World Health Organisation stating that all interventional trials must make their protocols and results public on trial registries within a year of trial completion. Transparimed summary article is here.

2. Registration is open for the online PHUSE Data Transparency Autumn Event 2025. The free event will take place from 16–18 September 2025. Presentations will be delivered over 3 days from 10:00-12:30 (EDT) / 15:00-17:30 (BST) / 16:00-18.30 (CEST). Register in advance here; access agenda here.

3. On 10 July 2025, US FDA published >200 Complete Response Letters (CRLs) issued in response to applications submitted to the FDA for approval of drugs or biological products between 2020 and 2024, which is a significant step to modernize and increase transparency. This initial batch is now accessible to the public at openFDA.

4. In the June 2025 issue of EMWA Journal MEW, K Edwards has published an article entitled: "Considerations for the use of artificial intelligence in the creation of lay summaries of clinical trial results." The full article can be downloaded here.

5. A recent podcast entitled: "Being Transparent About Clinical Trial Transparency" features Lisa Chamberlain James and Julie Holtzople and can be freely accessed on YouTube here.

6. PHUSE invites you to be part of the Data Transparency Working Group's newest project: 'PHUSE Stakeholder Review of UK MHRA Clinical Trials Regulation Guidance'. Get involved in reviewing the MHRA's new clinical trials regulation guidance ahead of its implementation in April 2026. This is a unique opportunity to directly influence guidance. Apply by 19 August and find out more.

7. In June 2025, the UK Policy Framework for Health and Social Care Research outlined four key areas of responsibility for research transparency. The guidance clarifies what you need to do to be transparent in each of the 4 key areas of: registering your research; reporting results; informing participants; and sharing study data and tissue.

GDPR and Data transfer Ex-EU

1. The European Parliamentary Research Service (EPRS) released a Briefing document "Revisiting the GDPR: Lessons from the United Kingdom experience", including a section on Artificial Intelligence "Facilitating the development and deployment of AI".

2. EFPIA reports that it has submitted GDPR Code of Conduct on Clinical Trials and Pharmacovigilance to the Belgian Data Protection Authority for formal assessment. According to the news release: "The EFPIA GDPR Code of Conduct aims to provide a consistent interpretation of key GDPR provisions as they apply to pharmacovigilance and clinical research, aiming to enhance legal certainty and reduce administrative burden across the EU."

EMA Policy 0070 in Practice

EMA have published Revision 4 of Q&As on the External Guidance on the Implementation of the EMA Policy 0070, dated 2 July 2025. The document addresses key questions on the Clinical Data Publication (CDP) process and provides a compilation of, and references to, relevant guidance, recommendations and supportive documentation to facilitate the submission of documents in the context of CDP.

Development Strategy News

1. In the Lancet Group, World Health Organization have highlighted countries and organisations around the world driving progress in strengthening clinical trials. One of the examples is the ACT EU Trial Map. The map expands patient access to innovative research across the EU and is available on the Clinical Trials Information System website.

2. British Pharmaceutical Society paper 'Sentinel dosing: A Proposed Algorithm To Guide Decision making on which cohorts in early phase clinical pharmacology trials should use this approach' One

aim of this paper is to support sentinel dosing frameworks in trials because 'Sentinel dosing is an approach described in EMA guidelines; however, the guidance does not provide detail on which cohorts or dose levels sentinel dosing applies'. The CORE Reference Team thanks News Summary reader, Ellen Van Bavel for forwarding this.

3. The European Commission published their Life Sciences Strategy on 02 July 2025. 'Choose Europe for life sciences: A strategy to position the EU as the world's most attractive place for life sciences by 2030' is helpful to understand the direction of clinical research planned for within Europe.

4. On 07 July 2025, EMA published a Q&A document that outlines EMA's proof-of-concept pilot for submitting structured individual patient data in selected marketing authorisation and post-authorisation applications.

5. A broad group of organisations (including academic and industry sponsors, investigators, and professional societies) have published a report setting out actions to be taken to support clinical trials in the EU. Challenges include difficulties in recruiting patients, regulatory complexity, high administrative burden and financial challenges. The link to the report and further comment can be accessed here.

6. EFPIA are hosting a virtual webinar entitled "Decentralised clinical trials: Turning experience into established practice" on 4 Sep 2025 (10-11 CEST). Details can be found here and you can register for the event here.

7. EMA held a workshop on the use of Bayesian statistics in clinical development on 17 June 2025. The agenda and presentations from the day can be accessed here.

8. An AMWA blog published 17 July 2025 entitled: Clinical Protocol Writing: 4 Proven Tips to Help You Succeed as a Medical Writer can be accessed here.

9. In 2016, the World Medical Association adopted the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. It's time to revise the Declaration of Taipei. If you are interested in following this revision process, you are invited to sign up for related news here.

10. AMWA Blog article: 'Clinical Protocol Writing: 4 Proven Tips to Help You Succeed as a Medical Writer'.

11. This BMJ Evidence Based Medicine paper 'Understanding synthetic data: artificial datasets for real-world evidence' gives a good overview of synthetic data, and explains the difference between synthetic data and deidentified data.

Artificial Intelligence/Machine Learning

1. The MRCT Center of Brigham and Women's Hospital and Harvard, in collaboration with WCG Clinical have published resources to address ethical and regulatory challenges during the IRB review of clinical research protocols involving AI. The Framework for Review of Clinical Research Involving AI is available to download together with an accompanying webinar presentation.

2. The European Commission has published the General Purpose AI Code of Practice. The 'Transparency' and 'Copyright chapters address all providers of general-purpose AI models; the 'Safety and Security' chapter is relevant only to a limited number of providers of the most advanced models. Press release here. The Code is designed to help industry comply with the AI Act's rules on general-purpose AI, which will enter into application on 2 August 2025.

3. The first AI Observatory report by EMA and HMA summarises the experience gained in AI across the EU medicines regulatory network in 2024. The report includes a high-level horizon scanning to identify gaps, challenges and opportunities for integrating AI in medicines regulation. Follow this page to keep up with further publications.

4. A newsreport from CNN has stated that FDA's artificial intelligence model used in drug approvals is "making up studies". This type of incident is known as "AI "hallucinating," or misrepresented research."

News from US: Possible Impact on Clinical Trial Ecosystem

1. Former NEJM editors respond to RFK Jr. claim that medical journals are "corrupt." Access their response here.

2. US DHHS has cut some subscriptions to some Springer journals including Nature.

3. FDA News Release 10 July 2025 explaining publishing of decision letters or complete response letters (CRLs)

4. 100-day statement from FDA Commissioner.

5. The US National Institutes of Health (NIH) plans to disinvite dozens of scientists from advisory councils that make final decisions on grant applications. The dismissal will leave many NIH advisory councils understaffed and lacking the necessary expertise to review grant applications effectively. Read more here.

6. FDA Law Blog has published an article by CD Snow entitled "Federal Hiring Shake-Up (Again): What the Latest Executive Action and Supreme Court Decision Mean for Industry." The article includes reference to pharmaceuticals, medical devices, food safety, and the cosmetics industries.

7. The US Congressional Budget Office (CBO) has released a report examining the implications of a permanent cut to the National Institutes of Health (NIH) budget and extending drug review times at the FDA. The CBO report can be accessed here.

8. BMJ News article: 'RFK Jr bans thiomersal from influenza vaccines in "safety" move'.

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.

Medical Devices General Updates and News

1. The European Association of Medical devices Notified Bodies (TEAM -NB) released a position paper entitled "Software qualification under the IVDR" in June 2025. It is estimated that 80% of in vitro diagnostic medical devices (IVD MD), including several types of software used in in vitro diagnostics, are subjected to an assessment by a notified body before being placed on the market under Regulation (EU) 2017/746, which came into force in May 2022. This position paper is intended to provide clarification on the expectations of the Notified Bodies regarding qualification of software in the IVD MD field.

2. The similarities and differences in the acceptance of real-world evidence (RWE) as clinical data for medical devices in the US and the EU has been compared in a Regulatory Focus article by Fink et al. Key differences between the regulations in the US and the EU are explored and two case studies presented.

3. An on-demand webinar by Intertek entitled: "Expanding Medical Device Markets Beyond Canada and the US" can be accessed from here. Details of other medical devices webinars offered by Intertek can be found here.

4. The European Commission published a regulation that establishes a new expert panel on medical devices focused on pediatrics and rare diseases. The panel will provide scientific, technical, and clinical opinions to support the development of medical devices intended for small size patient populations, such as patients with a rare disease. An overview of all EMA Medical device expert panels can be found here (last updated 10 July 2025).

EUDAMED News

The launch of the EUDAMED database is **delayed again**. The official OJEU notice is now expected in September 2025.

Key dates:

- EUDAMED will be mandatory at the earliest from March 2026
- Transition for UDI/Device registration may end at the earliest in September 2026
- The Vigilance module will launch later.

The European Commission also plans to introduce new features for EUDAMED over the next two years.

US FDA

1. US FDA released draft guidance for Industry entitled "Unique Device Identifier Requirements for Combination Products" in June 2025. Comments can be submitted online until 24 Sep 2025.

2. US FDA issued the final guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions on 27 June 2025, superseding the final guidance issued on 27 September 2023. This guidance adds Section VII to address FDA's recommendations regarding section 524B of the FD&C Act for cyber devices.

UK MHRA

1. The MHRA plans to update its Medical Devices Regulations 2002 to align with the EU Common Specifications for high-risk in vitro diagnostic (IVD) devices.

2. An editorial in the BMJ entitled "Regulation of AI scribes in clinical practice" discusses the UK MHRA and NHS England guidance that now classifies AI scribes as "software as a medical device" thereby aligning the status of AI scribes in the UK with their status in the EU and the US.

Asia

1. Health Sciences Authority (HSA) Singapore released the latest GN-21-R6 Guidance on Change Notification for Registered Medical Devices in July 2025. Under the Health Products (Medical Devices) Regulations 2010, registrants are required to notify changes concerning registered medical devices to the authority. This guidance document is intended to aid registrants in determining whether a Change Notification has to be submitted for a medical device that is registered on the Singapore Medical Device Register (SMDR).

2. China NMPA issued the revised "Clinical Trial Exempt Catalog for In Vitro Diagnostic Reagents" on 24 June 2025 (complete list from the NMPA website in Mandarin). The catalog contains 445 IVDs which are exempted from clinical trials, including 27 Class III IVDs. Refer to this third-party webpage for more info in English.