What's New in Clinical Development Practices & Regulations Quarter 1 – 2024

GLOBAL GUIDELINES AND FORUMS

World Medical Association (WMA) Declaration Documents

The 'Declaration of Helsinki' was originally adopted in 1964 and was most recently amended in October 2013. It is now being revised and this eighth revision will include a wide range of updates to reflect how the research environment has changed since 2013. This 2024 revision has been available for public consultation. The workgroup intends to recommend a final updated draft to be considered by the Council and the General Assembly in Helsinki, Finland in October 2024. *Declaration of Helsinki – WMA – The World Medical Association*

The 'Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks' was issued by the WMA in October 2016. It complements the Declaration of Helsinki and includes 12 ethical principles relating to health databases and biobanks. *WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks – WMA – The World Medical Association*

International Council for Harmonisation (ICH)

ICH E2D(R1) 'Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports' is available for public consultation. *ICH_E2D(R1)_Step3_Draft Guideline_2024_0205.pdf*

The 'Glossary of ICH Terms and Definitions' has been updated and version 5 was issued on 07 February 2024. *Glossary of ICH terms and definitions - CIOMS*

World Health Organisation (WHO) – Global Clinical Trial Forum

This Forum took place in November 2023, and delegates with a diverse range of experiences discussed how to strengthen worldwide clinical research in terms of functionality and sustainability. The outcome of the discussions identified seven key areas. *First WHO Global Clinical Trials Forum*

EU GUIDELINES AND Q&A DOCUMENTS

EU Clinical Trial Regulation (CTR) and Clinical Trials Information System (CTIS)

An update to the Q&A document (to version 6.7) was published on 21 December 2023 and includes frequently asked questions on implementing the CTR. *regulation5362014_qa_en_0.pdf (europa.eu)*

On 31 January 2024, the EMA published a reminder to Sponsors that all clinical trials in the EU must be transitioned to CTIS by 31 January 2025. *Clinical trials' transition to new EU system*. The Best Practice Guide *2023_11_CTCG_Best_Practice_Guide_for_sponsors.pdf (hma.eu)* and Cover Letter Template *2023_11_CTCG_Annex_cover_letter_template_ (live.com)* for Sponsors transitioning multi-national clinical trials to the CTR and CTIS have been updated.

A User Guide for macro, small and medium sized enterprises, published by the European Medicines Agency (EMA) include sections on CTR and CTIS. The latest version was published in November 2023 *user-guide-micro-small-and-medium-sized-enterprises_en.pdf (europa.eu)*

EMA – Revised Guidance on Distribution of Investigator's Brochures (IBs)

In January 2024, Q&A number 19, Section B 'GCP Matters' relating to the timely distribution of IBs, was updated. *Q&A: Good clinical practice (GCP) | European Medicines Agency (europa.eu)*

EMA – New Q&As on Centrally Authorised Products Marketed in Northern Ireland

The European Commission (EC) and UK Government reached an agreement for centrally authorised medicinal products intended to be placed on the market in Northern Ireland (Regulation (EU) 2023/1182). This Regulation entered into force on 21 June 2023 and will apply from 01 January 2025.

The EMA has published a Q&A document to provide practical guidance on the rules both before and after application of Regulation (EU) 2023/1182. *questions-and-answers-stakeholders-implications-regulation-eu-1182-2023-centrally-authorised-medicinal-products-human-use_en.pdf (europa.eu)*

EMA - Paediatric Submissions

In January 2024, the EMA published revisions to two of their documents:

- *guidance-paediatric-submissions_en.pdf (europa.eu)*
- *policy-determination-conditions-paediatric-investigation-plan-pip-waiver-scope-pip-waiver_en.pdf (europa.eu)*

In addition, the Q&As section on the EMA website has been updated. *Paediatric investigation plans: submitting documents | European Medicines Agency (europa.eu)*

Artificial Intelligence (AI) Workplan 2023-2028

This workplan, which was published on 18 December 2023 by the EMA and the Heads of Medicines Agencies (HMAs) details a strategy for maximising the benefits of AI whilst managing the risks. *multi-annual-artificial-intelligence-workplan-2023-2028-hma-ema-joint-big-data-steering-group_en.pdf (europa.eu)*

UK GUIDELINES AND INITIATIVES

International Recognition Procedure (IRP)

The IRP is a new procedure for medicines licensing applications and was developed following the UK's departure from the EU.

From 01 January 2024, developers of new medicines can submit applications via the Medicines and Healthcare products Regulatory Agency's (MHRA's) IRP. *MHRA's new International Recognition Procedure (IRP) goes live from 1 January 2024 - GOV.UK (www.gov.uk)*

Clinical Trials Best Practice Guide 2024

The National Health Service (NHS) and industry representatives have developed a new guideline 'Clinical trials best practice guide 2024' *Clinical trials best practice guide 2024 (abpi.org.uk)*

The guide focuses on four parts:

- Establishing a study's feasibility
- Confirming a site's capability and capacity
- Escalating blockers to study set up and delivery
- Establishing strategic communication between sites and sponsors

Medical Devices

On 09 January 2024, the MHRA published brief details of new regulations for medical devices in the UK. *Roadmap_towards_the_future_regulatory_framework_for_medical_devices__Jan_24.pdf (publishing.service.gov.uk)*

At the beginning of February, the MHRA announced two new UK Approved Bodies to certify medical devices. *MHRA announces two new UK Approved Bodies to certify medical devices - GOV.UK (www.gov.uk)*

TRANSPARENCY

EMA Updates Q&As CTIS Transparency Rules

On 31 January 2024, the EMA published an updated version of the Q&A document on the protection of commercial confidential information and personal data while using CTIS (current version 1.4). *ACT EU_Q&A on protection of Commercially Confidential Information and Personal Data*

CTIS does not allow information about UK trials conducted as part of a multinational trial. The Health Research Authority (HRA) has provided clarification of other public registries to be used to register the UK part of multinational trials. *HRA Now - clarification of HRA policy on registration of CTIMPs taking place in the UK and EU (govdelivery.com)*

UK Transparency and Information Sharing

The MHRA has developed a process to share operational information with health system partners across the UK. The updated guidance was published 02 January 2024: *Operational Information Sharing Guidance - GOV.UK (www.gov.uk)*

Transparency is one of the key priorities set out in the HRA 2022-25 Strategy. *HRA_Strategy_2022-25.pdf*

US Database of Worldwide Clinical Trials - ClinicalTrials.gov

The Clinical Trials Transformation Initiative (CTTI) has investigated factors and barriers to registration and summary results reporting. Their findings and suggestions for improvements have been published in a recent report: *CTTI_SuggestedPractices_ClinicalTrials-gov_FINAL.pdf (ctti-clinicaltrials.org)*

In addition, the Commissioner of the FDA has described the importance of ClinicalTrials.gov in clinical trial transparency and FDA oversight. *The Importance of Clinical Trial Transparency and FDA Oversight | FDA*.

GOOD MANUFACTURING PRACTICE (GMP)

EU

The EMA Q&A document – "EU GMP Guide Annexes … Annex 1, Question 2" has been updated: *Guidance on good manufacturing practice and good distribution practice: Questions and answers | European Medicines Agency (europa.eu)*

The EMA and Food and Drug Administration (FDA) have generated a joint Q&A document on 'Quality and GMP Aspects of PRIME/Breakthrough Therapy Applications' *FDA-EMA-joint-QA.pdf*

UK

The MHRA has extended the validity period for GMP and Good Distribution Practice (GDP) certificates. *GMP & GDP Certificates: Validity Period Extended - MHRA Inspectorate (blog.gov.uk)*

POST PANDEMIC

Lessons Learnt for Inspection Activities

On 24 January 2024, the EMA published a document 'Guidance on remote GCP inspections during public health threats, political conflict, natural disasters, or other major disruptions' (document is dated 30 November 2023). *guidance-remote-gcp-inspections-during-public-health-threats-political-conflicts-natural-disasters-or-other-major-disruptions_en.pdf (europa.eu)*

On 26 January 2024, the FDA issued a draft guidance 'Conducting Remote Regulatory Assessments [RRAs] – Questions and Answers' *FDA-Remote Regulatory Assessments- Revised Draft Guidance-Jan2024.pdf*

EMA – Publication of Data

On 26 January 2024, the EMA confirmed it has resumed clinical data publication for all medicines, not just medicines relating to Covid-19 treatments. *Clinical data publication | European Medicines Agency (europa.eu)*

FDA - Return to Face-to-Face (FTF) Meetings

The FDA has provided an update on In-Person FTF Formal meetings. A FTF meeting between the FDA and industry is defined as either in-person meeting and virtual (camera on) meetings. *Update on In-Person Face-to-Face Formal Meetings with FDA | FDA*

FDA GUIDANCE DOCUMENTS

Final FDA Guidance Documents:

- December 2023: Real-World Data: Assessing Registries to support Regulatory Decision-Making for Drug and Biological Product Development *54619456fnl 12-19-23.pdf (fda.gov)*
- December 2023: Rare Diseases: Considerations for the Development of Drugs and Biological Products *30212783fnl_Rare Disease.pdf (fda.gov)*
- December 2023: Data Standards for Drug and Biological Product Submissions Containing Real-World Data *55614023-data-standards-for-drug-and-Biological-product-submissions.pdf (fda.gov)*
- December 2023: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations *55626970fnl.pdf (fda.gov)*
- January 2024: Human Gene Therapy Products Incorporating Human Genome Editing *Human-Gene-Therapy-Incorporating-Human-Genome-Editing_UPDATED_Jan-2024.pdf (fda.gov)*

Draft FDA Guidance Documents:

- January 2024: Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products *45585115dftrv1.pdf (fda.gov)*

Thank you for taking the time to read this Industry Update from S-cubed

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