What's New in Clinical Development Practices & Regulations

Quarter 1 – 2023

REGULATIONS

Clinical Trial Regulation (CTR) (EU) 536/2014

On 31 January 2023, the 1-year transition period came to an end and the Clinical Trials Information System (CTIS) is now the single-entry point for sponsors and regulators for the submission and assessment of all new clinical trials.

The European Medicines Agency (EMA) has highlighted the benefits of the CTR: *Regulatory harmonisation of clinical trials in the EU* The results of a 2022 survey of the key issues of the CTR implementation from the sponsors point of view can be seen here: *implementation_ct-regulation536-2014_consultation_en.pdf (europa.eu)*

Guidance is available, including Quick Guide for Sponsors: *mp_ctr-536-2014_guide_en.pdf (europa.eu)* CTIS Sponsor Handbook: *CTIS_Sponsor_Handbook_2022_v.3.01_(europa.eu)* EU CTR Q&A: *EudraCT FAQ_for internal use only (europa.eu)*

Good Manufacturing Practice (GMP)

The European Commission (EC) has determined that active substances manufactured in Canada and intended for human medicines placed on the EU market, are manufactured in an EU-equivalent regulatory system, including rules for GMP. Canada will therefore join the list of third countries recognised so far - Australia, Brazil, Israel, Japan, South Korea, Switzerland and the United States. *Improving the quality of medicines (europa.eu)*

Medical Device Regulations (MDR)

The EU MDR was adopted in 2017 and states that medical devices can be placed on the EU market under CE certifications issued in accordance with Directive 93/42/EEC (MDD) or 90/385/EEC (AIMDD) until 26th May 2024. The EC has proposed an extension to the transition period in order to prevent medical device shortages. *Implementation of the Medical Devices Regulation (europa.eu)*

ICH Guidelines and Guidance

EMA Q&A Guidance on GCP as discussed and agreed by the GCP Inspectors Working Group. *Q&A: Good clinical practice (GCP) | European Medicines Agency (europa.eu)*

Updated Glossary of ICH Terms and Definitions: *Glossary of ICH terms and definitions - CIOMS*

ICH M10 'Bioanalytical Method Validation and Study Sample Analysis' effective from January 2023: *ICH M10 on bioanalytical method validation - Scientific guideline | (europa.eu)*

ICH E19 'Safety Data Collection' has been adopted by the FDA**:** *E19 A Selective Approach to Safety Data Collection (fda.gov)*

ICH Q13 'Continuous Manufacturing of Drug Substances and Drug Products' reaches Step 5: *ICH guideline Q13 - Scientific guideline | European Medicines Agency (europa.eu)*

ICH Q9(R1) 'Quality Risk Management' Guideline reaches Step 4
ICH_Q9(R1)_Guideline_Step4_2023_0126_0.pdf

ICH E2(B)(R3) 'Pharmacovigilance' Q&A and Guideline reaches Step 4: *ICH E2B (R3) Electronic transmission of individual case safety reports (ICSRs) - (europa.eu)* and *E2B (R3) Step 5 Questions and Answers: s (europa.eu)*

GXP INITIATIVES

EMA - Quality Innovation Expert Group (QIG)

The EMA has announced a new group (QIG) who will support innovative approaches to the development, manufacture and quality control of medicines for the benefit of patients in the EU. *Quality Innovation Group | European Medicines Agency (europa.eu)*

European Forum for Good Clinical Practice (EFGCP) – eConsent Initiative

eConsent refers to the use of digital components to support and improve the overall clinical trial consent process. The eConsent initiative is a non-profit multi-stakeholder scheme involving pharmaceutical companies, vendors, academia, patients, sites, ethics committees and health authorities. *EFGCP - European Forum for Good Clinical Practice*

Heads of Medicines Agency (HMA), EC & EMA – EU Decentralised Clinical Trials (DCTs) Recommendation Paper

The recommendations aim to facilitate the conduct of DCTs while safeguarding the rights and well-being of trial participants, as well as the robustness and reliability of the data collected. *mp_decentralised-elements_clinical-trials_rec_en.pdf (europa.eu)*

EFGCP & European Federation of Pharmaceutical Industries and Associations – EU Cross-border Trials Initiative (EU-X-CT)

A multi-stakeholder consortium has been set up, comprising patient organisations, academics, research networks and the pharmaceutical industry. The aim is to develop recommendations which will enable cross-border access to clinical trials for EU patients. *EFGCP - European Forum for Good Clinical Practice*

REAL WORLD EVIDENCE (RWE) & REAL WORLD DATA (RWD)

Darwin EU – First Group of Data Partners Selected

As detailed in Q2 2022 Newsletter, the EMA has established a network of RWD sources across the EU with the aim of providing the EMA and EU Competent Authorities with valid and trustworthy RWE. The EMA has now selected eight partners, from the public and private sectors, all of whom have access to real world healthcare data. *DARWIN EU® welcomes first data partners | European Medicines Agency (europa.eu)*

Guidance 'Consideration for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products'

This draft guidance for industry has been issued for public consultation by the FDA. Comments are due by 02 May 2023: *Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products (fda.gov)*

FDA Consults on Medical Device User Fees

In January, the FDA announced it is seeking stakeholder comments on how it should use user fee funding for engaging with external organisations, other than the National Evaluation System for Health Technology, to support pre-marketing RWE. *FDA Seeks Public Comment: Advancing Real-World Data and Real-World Evidence with User Fee Funding (MDUFA V) | FDA*

FDA GUIDELINES

New Proposed Rule on 'Investigational New Drug Application Annual reporting' – The FDA Proposes Expanding the Requirements for IND Annual Reports**:** *2022-26731.pdf (govinfo.gov)*

Final Guidance 'Format and Content of a Risk Evaluation and Mitigation Strategy (REMS) Document' and **'REMS Document Technical Conformance Guide'**

January 2023: *Guidance for Industry: Format and Content of a REMS Document (fda.gov)* and *REMS Document Technical Conformance Guide (fda.gov)*

Draft Guidance 'Content of Human Factors Information in Medical Device Marketing Submission'
Issued for public consultation (ends 09 March 2023): *Content of Human Factors Information in Medical Device Marketing Submissions - Draft Guidance for Industry and Food and Drug Administration Staff (fda.gov)*

Draft Guidance 'Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products'
February 2023: *Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products (fda.gov)*

Draft Guidance 'Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products'
January 2023: *Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format (fda.gov)*

Draft Guidance 'Circumstances that Constitutes Delaying, Denying, Limiting or Refusing a Drug or Device Inspection'
December 2022: *Draft Guidance for Industry (fda.gov)*

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

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