What's New in Clinical Development Practices & Regulations

Quarter 2 – 2021

COVID-19 & GUIDANCE DURING PANDEMIC

Europe:

European Medicines Agency (EMA) Implements Temporary Streamline Measures: *Additional measures to allow experts to focus on COVID-19 activities | European Medicines Agency (europa.eu)*

Monitoring of Safety, Efficacy and Impact of COVID-19 vaccines in European Union (EU) and European Economic Area (EEA): *EMA and ECDC join forces for enhanced post-marketing monitoring of COVID-19 vaccines in Europe | European Medicines Agency (europa.eu)*

European Commission (EC) Strategy to Support Development and Availability of COVID-19 Therapeutics: *EU Therapeutics Strategy (europa.eu)*

USA:

Food and Drug Administration (FDA) Issues Regulatory Guideline on Generics During the Pandemic: *Develpment of Abbreviated New Drug Applications During the COVID-19 Pandemic - Questions and Answers (fda.gov)*

Guidance on Master Protocols for COVID-19 Trials: *COVID -19 Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention (fda.gov)*

REGULATIONS AND GUIDANCE

Clinical Trial Regulation (CTR)

On 21 April 2021, EMA's Management Board confirmed that the Clinical Trial Information System (CTIS) is fully functional and meets all the specifications, as determined by an independent audit.

The EC will consider if the conditions set by the Regulation are met and, once confirmed, will publish a notice in the Official Journal of the EU. Six months after this notice, the Regulation will start to apply and the CTIS will go live, the expected date is 31 January 2022: *Clinical Trials Information System reaches major milestone towards go-live and application of the Clinical Trial Regulation | European Medicines Agency (europa.eu)*

EMA provides online CTIS training: *Clinical Trials Information System (CTIS): training programme | European Medicines Agency (europa.eu)* and maintains a Q&A document: *Clinical Trials Regulation Questions & Answers Version 2.3 - ECA Academy (gmp-compliance.org)*

Irish regulators have initiated the National Collaboration Project to prepare for the implementation of the CTR in Ireland: *guide-to-clinical-trials-regulation-national-collaboration-project.pdf (hpra.ie)*

Guideline for Medicinal Products Containing Genetically Modified Cells

Guideline on Genetically Modified revised final - clean - adopted (europa.eu)

New EU Recommendation on Archiving

21_02_24_Archiving_Position_Paper_version_A.pdf (eucrof.eu)

MHRA Issues New Guideline for Biosimilars

Guidance on the licensing of biosimilar products - GOV.UK (www.gov.uk)

Medical Device

The EC has released updates to ensure stakeholders are prepared for the transition to:

- Medical Device Regulation (MDR)
- EU In Vitro Diagnostic Regulation (IVDR)

Overview | Public Health (europa.eu)
mdcg_2021-4_en.pdf (europa.eu)

The FDA released the results of a recent analysis that illustrates the wide range of Real World Evidence it has used in making regulatory decisions related to medical devices: *Leveraging Real World Evidence in Regulatory Submissions of Medical Devices | FDA*

FDA - Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Guidance for Industry

Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Guidance for Industry | FDA

PATIENT FOCUSED DRUG DEVELOPMENT

Updates to ICH Guidelines

ICH E6(R3) and E8(R1) Guidelines are being developed. These will include patients' involvement in the development of clinical trial design and identification of critical to quality factors and associated risk management.

ICH has released draft updates - E6(R3): *ICH_E6-R3_GCP-Principles_Draft_2021_0419.pdf*
E8(R1) *E8-R1_EWG_Draft_Guideline.pdf (ich.org)*

EMA Publishes Comments on ICH Paper on Patient-Focused Drug Development

Overview of comments received on 'ICH reflection paper on proposed ICH guideline work to advance patient focused drug development' (EMA/CHMP/ICH/415588/2020) (europa.eu)

MHRA – Proposed Patient and Public Involvement Strategy

There are 5 strategic objectives - Patient and public involvement; Responsiveness; Internal culture; Measuring outcomes and Partnership
Proposed Patient and Public Involvement Strategy 2020-25 - GOV.UK (www.gov.uk)

New NICE Guidance Supports Shared Decision Making

National Institute for Health and Care Excellence (NICE) defines shared decision making as the collaborative process involving an individual and their healthcare professional working together to reach a joint decision regarding their care.
Shared decision making | NICE guidelines | NICE guidance | Our programmes | What we do | About | NICE

TRANSPARENCY & DATA INTEGRITY

ICMRA and WHO Statement on Transparency and Data Integrity

The International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organisation (WHO) have released a joint statement.

The COVID-19 pandemic has highlighted the importance of making data available to support those involved in developing vaccines and therapeutics, as well as regulators, health authorities and healthcare professionals. Transparency also improves public confidence in vaccines and medicines.

Joint Statement on transparency and data integrity - International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO) | International Coalition of Medicines Regulatory Authorities (ICMRA)

Failure to Submit Results to ClinicalTrials.gov

The FDA has issued its first Notice of Noncompliance to a pharmaceutical company for failing to submit the required summary results information to ClinicalTrials.gov.

FDA Takes Action For Failure to Submit Required Clinical Trial Results Information to ClinicalTrials.Gov | FDA

MISCELLANEOUS

EMA's Individual Case Safety Report (ICSR) Implementation Guide

From 30 June 2022, ISO ICSR format as set out in Article 26(2)(a) of the Commission Implementing Regulation (EU) No 520/2012, and the modalities on how to implement and apply the ISO ICSR standard as defined in ICH E2B(R3) shall become mandatory in relation to reporting obligations to EudraVigilance.

The aim of the guide is to help sponsors prepare for the changes and the revised guide includes:

- References to E2B(R3)
- New guidance on the use of the European Directorate for the Quality of Medicines & HealthCare terms for routes of administration and dosage forms
- Updates on the EudraVigilance registration process
- Updates related to the Clinical Trial Regulation (EU) No. 536/2014.

EU Individual Case Safety Report (ICSR)1 Implementation Guide (europa.eu)

Public Consultation on Revising Legislation on Medicines for Children and Rare Diseases

This consultation was launched by the EC and remains open until the end of July 2021: *Medicines for children & rare diseases – updated rules (europa.eu)*

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

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