What's New in Clinical Development Practices & Regulations

Quarter 3 – 2021

COVID-19 & GUIDANCE DURING PANDEMIC

Global:

Global Collaboration of Covid-19 Real World Evidence and Observational Studies: *ICMRA meeting: COVID-19 Real-World Evidence and Observational studies | International Coalition of Medicines Regulatory Authorities (ICMRA)*

Call to Include Cancer Patients in Covid-19 Vaccine Trials: *2021-ASCO-Friends-Vaccine-Trials-Position-Statement.pdf*

USA:

New Guidance from Food and Drug Administration (FDA) on re-opening Trial Sites and Retrospective Monitoring: *Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency (fda.gov)*

EU - New Danish Guidance on Decentralised Elements of Clinical Trials

In order to reduce the need for trial participants to visit sites, the Danish Regulators are the first to publish detailed guidance on how this may be achieved: *5A96356760ED408CBFA9F85784543B53.ashx (laegemiddelstyrelsen.dk)*

REGULATIONS AND GUIDANCE

EU Clinical Trial Regulation (CTR)

On the 31 January 2022, the CTR 536/2014 will be implemented (the publication of the notice occurred on 31 July 2021): *Clinical trials - Regulation EU No 536/2014 | Public Health (europa.eu)*

The CTR has a 3-year transition period. Member States will use the Clinical Trial Information System (CTIS) immediately after the system goes live. Until 31 January 2023 (1 year after the go-live date), applicants can choose to submit their application to start a clinical trial under either the current system (the Clinical Trials Directive) or the CTR. From 31 January 2023, submission under the CTR becomes mandatory, and by 31 January 2025 all ongoing trials approved under the Clinical Trials Directive will need to transition to the CTR and the CTIS. *Six-month countdown to go-live for the Clinical Trials Information System (CTIS) | European Medicines Agency (europa.eu)*

The European Medicines Agency (EMA) has published a CTIS Sponsor Handbook: *CTIS Sponsor Handbook 2021 (europa.eu)*

UK – Single Regulatory and Ethics Decision

In the UK, a combined review service will allow applicants to submit a single application that will undergo coordinated review from both the Medicines and Healthcare products Regulatory Agency (MHRA) and the UK Research Ethics Services. This change will happen on 31 January 2022, coinciding with the CTR go-live date: *Combined review to facilitate speedier set up for clinical research trials - GOV.UK (www.gov.uk)* and *Combined review - Health Research Authority (hra.nhs.uk)*

Voluntary Harmonisation Procedure (VHP)

The EU Clinical Trials Facilitation and Coordination Group (CTFG) has issued a deadline for VHP submissions. This includes any submission (initial, substantial amendment, second round) and there will be no exceptions. The deadline is midnight (CET) on 15 October 2021:
2021_07_CTFG_Conclusion_VHP_Deadlines_for_VHP_Submissions.pdf (hma.eu)

EMA and MHRA Guidance:

Computer System and Electronic Data: *Draft guideline on computerised systems and electronic data in clinical trials (europa.eu)*

Q&A relating to the implementation of Medical Devices and In Vitro Diagnostic Medical Devices Regulations: *Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746) (europa.eu)*

MHRA launches public consultation on the future of Medical Device Regulation: *MHRA launches public consultation on future of medical device regulation - GOV.UK (www.gov.uk)*

FDA Guidance:

Final Intended Use Regulation: *Federal Register :: Regulations Regarding "Intended Uses"*

Sponsor's Responsibility for Safety Reporting: *Guidance for Industry (fda.gov)*

Evaluating Cancer Drugs for Central Nervous System Metastases: *Evaluating Cancer Drugs in Patients with Central Nervous System Metastases (fda.gov)*

Patient Reported Outcomes (PROs) in Oncology Clinical Trials: *Core Patient-Reported Outcomes in Cancer Clinical Trials | FDA*

DATA PROTECTION

The European Commission (EC) Adopts Adequacy Decision for the UK

On 29 June 2021 the EC announced the approval of adequacy decisions for the UK. This means that data can safely flow to the UK from the EU and the European Economic Area (EEA) without further safeguards - Data transfers to the UK will be treated as within-EU transfers.
Commission adopts adequacy decisions for the UK (europa.eu)

UK Information Commissioner's Office's (ICO's) has issued a guidance relating to anonymisation and pseudonymisation: *anonymisation-intro-and-first-chapter.pdf (ico.org.uk)*

ICO's draft international data transfer agreement (IDTA) and guidance – this will replace the Standard Contractual Clauses (SCCs): *ICO consults on how organisations can continue to protect people's personal data when it's transferred outside of the UK | ICO*
Standard Contractual Clauses (SCC) | European Commission (europa.eu)

REGULATORY ALIGNMENT & PATIENT FOCUSED DRUG DEVELOPMENT

Regulatory Bodies' Strategic Plans

The Access Consortium (Australia, Canada, Singapore, Switzerland and the UK) 2021-2024:
Access_Strategic_Plan_2021-2024_Final__with_graphic_.pdf (publishing.service.gov.uk)

The Irish Health Products Regulatory Authority (HPRA) 2021-2025: *strategic-plan-2021-2025.pdf (hpra.ie)*

The Australian Therapeutic Goods Administration (TGA) 2021–2025: *TGA international engagement strategy 2021-2025 | Therapeutic Goods Administration (TGA)*

The MHRA 2021-2023: *The Medicines and Healthcare products Regulatory Agency Delivery Plan 2021-2023 - GOV.UK (www.gov.uk)*

Collaboration Between EMA and the European Network for Health Technology Assessment (EUnetHTA)

EMA and EUnetHTA have worked together since 2010. Together they have performed regulatory evaluations as well as Health Technology Assessments (HTAs) which have speeded up patients' access to innovative medicines.
Technical reporting - work plan 2017-2021 May 2021 (europa.eu)

ICH Assembly Reflection Paper

The updated version of the Patient Focused Drug Development reflection paper includes modifications based on public stakeholders comments. The paper presents opportunities for the development of new ICH guidelines to provide a globally harmonised approach which incorporates the patient's perspective.
ICH_ReflectionPaper_PFDD_FinalRevisedPostConsultation_2021_0602.pdf

FDA Using Clinical Outcome Assessments (COAs)

COAs provide information on a patient's health status (such as how a patient feels, functions or survives). The FDA uses COAs for regulatory decision making when evaluating medical devices. *Clinical Outcome Assessments (COAs) in Medical Device Decision Making | FDA*

PHARMACOVIGILANCE

MHRA GPvP Inspections Highlight need for Improved Risk Management

In order to ensure the safe use of medicines, Marketing Authorisation Holders (MAHs) need to adhere more effectively to risk management activities, including risk identification, risk assessment, and risk minimisation and prevention.
MHRA GPvP Inspection metrics 2019-20 (publishing.service.gov.uk)

EC Consultations

Targeted stakeholder consultation on the amendments to (EU) 520/2012 on pharmacovigilance activities: *Targeted stakeholder consultation on the amendments to Commission Implementing Regulation (EU) 520/2012 on pharmacovigilance activities | Public Health (europa.eu)*

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

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