What's New in Clinical Development Practices & Regulations Quarter 4 – 2020

COVID-19 GUIDANCE

Europe and World:

Aiming to prevent future outbreaks - National Institutes of Health (NIH) establishes Centres for Research in Emerging Infectious Diseases: *https://www.nih.gov/news-events/news-releases/nih-establishes-centers-research-emerging-infectious-diseases*

International Regulators and WHO join forces: *https://www.ema.europa.eu/en/news/international-regulators-who-join-forces-address-covid-19-challenges*

Clinical Trials Transformation Initiative (CTTI) 8 Best Practices for conducting clinical trials during the pandemic: *https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/best_practices_for_conducting_trials_during_covid_final_002.pdf*

EU - Best practice guidance for managing clinical trials during the pandemic: *https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf*

Methodological aspects of ongoing clinical trials: *https://www.ema.europa.eu/en/documents/scientific-guideline/points-consider-implications-coronavirus-disease-covid-19-methodological-aspects-ongoing-clinical_en-0.pdf*

EMA organises a public stakeholder meeting on 11 Dec 2020 on COVID-19 vaccines: *https://www.ema.europa.eu/en/events/public-stakeholder-meeting-development-authorisation-safe-effective-covid-19-vaccines-eu*

UK:

UK - Best practice guidance for managing clinical trials during the pandemic: *https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19*

Health Research Authority (HRA) - lessons learnt from ethics review of COVID-19 research: *https://www.hra.nhs.uk/about-us/news-updates/learning-lessons-ethics-review-covid-19-research/*

Fast track ethics review pilot scheme: *https://www.hra.nhs.uk/about-us/news-updates/fast-track-ethics-review-pilot-opens-january/*

USA:

US - Best Practice guidance on the conduct of managing clinical trials during the pandemic: *https://www.fda.gov/media/136238/download*

Reporting of all Adverse Events relating to regenerative medicine products: *https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/reporting-adverse-events-related-stem-cells-exosomes-or-other-products-marketed-regenerative*

BREXIT

BREXIT Guidance Documents (for the end of the Transition Period, 31 Dec 2020)

EMA Guidance for Companies: *https://www.ema.europa.eu/en/about-us/brexit-uk-withdrawal-eu/brexit-related-guidance-companies*

MHRA Guidance for industry and organisations: *https://www.gov.uk/government/collections/mhra-post-transition-period-information*

Register onto the MHRA Submission Portal as soon as possible (for initial applications, substantial amendments, end of trial notifications and Development Safety Update Reports (DSURs)): *https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021*

Importing Investigational Medicinal Products (IMPs) into Great Britain from approved countries: *https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries-from-1-january-2021*

Guidance on Pharmacovigilance Procedures: *https://www.gov.uk/government/publications/guidance-on-pharmacovigilance-procedures-in-the-event-from-1-january-2021/updated-guidance-on-pharmacovigilance-procedures*

MHRA Joins the Access Consortium

The Australia, Canada, Singapore and Switzerland (ACSS) Consortium of regulators will become the Access Consortium when the MHRA joins on 01 January 2021. The combined population of participating countries will then be approximately 145 million.

The countries in the consortium work together to reduce regulatory duplication in order to give patients timely access to high quality, safe and effective therapeutics.

https://www.gov.uk/government/news/uk-medicines-regulator-joins-up-with-australia-canada-singapore-and-switzerland-regulators

REGULATIONS AND GUIDANCE

EU Clinical Trial Regulation (CTR)

The CTR becomes applicable 6 months after the EC confirms the full functionality of the Clinical Trial Information System (CTIS) following an independent audit. The CTIS will be the single entry point for submitting clinical trial information in the EU, and information stored in the CTIS will be made publicly available subject to transparency rules.

The EMA management board has confirmed that the CTIS audit began in November 2020.

https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation

Revision of Good Clinical Practice guideline (ICH E6(R3))

On the 03 June 2020, a virtual half-day workshop was held, aimed at gathering the views of European patients, healthcare professionals and clinical researchers on clinical trials and applying GCP.

https://www.ema.europa.eu/en/documents/report/meeting-report-ich-e6r3-good-clinical-practice-workshop-pcwp-hcpwp-3-june-2020_en-0.pdf

Paediatric and Orphan Drug Regulatory Framework

The EC has published its evaluation of the paediatric and orphan drug regulations.

https://ec.europa.eu/health/human-use/paediatric-medicines/evaluation_en

TRIAL MANAGEMENT

Filing of e-mail communication in the Trial Master File: *https://tmfrefmodel.com/wp-content/uploads/TMF-RM-Deliverable-eMail-Communications-Guidance-v1-2020-07-31.pdf*

EMA clarifies guidance on Data Monitoring Committees:
https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-data-monitoring-committees-issues_en.pdf

New online platform for requesting EMA scientific advice:
https://www.ema.europa.eu/en/news/new-online-platform-scientific-advice

REAL WORLD EVIDENCE (RWE) & BIG DATA

MHRA Consults on Trials Generating RWE to Support Regulatory Decisions

The consultation period for this new draft guidance ends soon and is the first in a planned series of documents that will address issues related to the use of RWE to support regulatory submissions.

https://www.gov.uk/government/consultations/mhra-draft-guidance-on-randomised-controlled-trials-generating-real-world-evidence-to-support-regulatory-decisions/consultation-document-

Global Collaboration on COVID-19 RWE

On 13 October 2020, medicines regulators from around the world took part in a workshop to discuss their experiences of using RWE to facilitate regulatory decision making on COVID-19 treatments and vaccines.

http://www.icmra.info/drupal/covid-19/13october2020/summary

EMA Releases Plans on the Use of Big Data for Public Health

Big data are extremely large, rapidly accumulating datasets captured from for example electronic health records. It can complement the evidence from clinical trials and fill knowledge gaps on a medicine, and help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems.

The Big Data Steering Group (set up by the EMA and the Heads of Medicines Agencies) has published its workplan for 2020–2021.

https://www.ema.europa.eu/en/news/making-best-use-big-data-public-health-publication-big-data-steering-group-workplan-2020-21

REGISTRATION AND TRANSPARENCY

EMA Implements Extra Transparency for COVID-19 Vaccines and Therapeutics

During the pandemic, the EMA is implementing exceptional measures to maximise the transparency of its regulatory activities on treatments and vaccines for COVID-19 that are approved or under evaluation.

https://www.ema.europa.eu/en/news/extra-transparency-measures-covid-19-vaccines-therapeutics

UK's HRA Launch 'Make it Public' Strategy

When applying for HRA approval, applicants currently have to describe their dissemination plans, including whether they plan to inform participants about the study findings.

In the future, the HRA will ask applicants:

- How and when will study results be shared with participants
- To submit a lay summary of the study results as part of the final report (which the HRA will publish on its website).

HRA will produce new guidance on how to inform participants about study findings, including research involving adults without capacity, emergency research and research in which participants are likely to die from their existing illness.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/make-it-public-transparency-and-openness-health-and-social-care-research/

FDA and ClinicalTrials.gov Penalties

US legislation allows the FDA to seek financial penalties from developers of drugs, biological products and devices who fail to submit clinical trial registration and/or results to the ClinicalTrials.gov database, or who submit false or misleading information.

The FDA has issued a guidance document on the ClinicalTrials.gov penalties.

https://www.fda.gov/media/113361/download

Publication of Clinical Trial Results – Danish Regulators

A 2019 survey found that only 24% of non-commercial sponsors in Denmark fulfil their obligation to publish the results of clinical trials of medicines.

Legislation in Denmark allows the public prosecutor to impose fines or up to 4 months' imprisonment on sponsors who fail to publish their clinical trial results in a timely manner. The agency intends to use this legal power in the future.

https://laegemiddelstyrelsen.dk/en/news/2020/danish-medicines-agency-takes-tougher-action-to-ensure-the-publication-of-clinical-trial-results/

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

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