What's New in Clinical Development Practices & Regulations Quarter 1 – 2019

BREXIT

Guidance for Industry on No-Deal Brexit

The European Medicines Agency (EMA) and the European Commission are providing guidance to help pharmaceutical companies responsible for both human and veterinary medicines prepare for the UK withdrawal from the EU.

This aims to ensure that companies are ready to take the necessary steps to enable undisrupted supply of their medicines in the EU for the benefit of patients, based on the assumption that the UK will become a third country as of 30 March 2019.

https://ec.europa.eu/info/sites/info/files/medicinal_products_for_human_and_veterinary_use-qa_en.pdf

UK – FAST TRACK ACCESS TO GROUND-BREAKING MEDICINES

New Voluntary Scheme for Branded Medicines Pricing and Access

The aim of this new scheme, which came into effect on 01 January 2019 and replaces the Pharmaceutical Pricing Regulation Scheme, is to:

- Allow medicines to reach patients up to 6 months earlier than present.
- Save millions, by placing a 2% cap on the growth in sales of branded medicines to the National Health Service (NHS) with pharmaceutical companies repaying the NHS for spending above that limit.

http://www.abpi.org.uk/media-centre/news/2018/november/faster-access-to-groundbreaking-medicines-as-major-milestones-reached-in-deal-with-pharmaceutical-industry/

REAL WORLD DATA & REAL WORLD EVIDENCE

US - Real-World Data (RWD) and Real-World Evidence (RWE) in Clinical Drug Development

RWD and RWE is used by:

- The Food and Drug Administration (FDA) to monitor post marketing safety and adverse events.
- The healthcare community to develop guidelines and support tools for use in clinical practice.
- Industry to support clinical trial designs and observational studies aimed at generating new innovative treatment approaches.

https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RealWorldEvidence/UCM627769.pdf

POLICIES, CONSULTATIONS & GUIDELINES

Guidance on Drug Development for Rare Diseases

Currently, the FDA and the EMA offer incentives to biopharmaceutical companies that aim to develop new orphan drugs.

Ethical and regulatory standards for clinical trials of rare diseases are the same as for other trials, but the regulatory agencies are now trying to provide the flexibility needed to facilitate more efficient and successful orphan drug development programmes.

https://ec.europa.eu/health/sites/health/files/files/orphanmp/doc/2019_cons_guideline_appdes_en.pdf

New Rules for Certain Medical Devices

The EMA are publishing a series of guidance documents to help applicants prepare for obligations stemming from the new EU regulations on medical devices.

https://www.ema.europa.eu/en/news/first-guidance-new-rules-certain-medical-devices

EMA Revises Guidance on the Implementation of Policy 0070

In November 2018, the EMA issued revision 4 of the guidance on its clinical data publication policy (Policy 0070). It clarifies the requirements to withdraw an application if it has been/will be resubmitted.

The EMA has temporarily suspended the publication of clinical data until further notice, following the implementation of the third phase of its business continuity plan prior to its move to The Netherlands.

https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication/support-industry/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data

EMA Launches Consultation on Regulatory Science 2025

The EMA has issued its draft 'Regulatory Science to 2025' strategy for a 6-month public consultation.

The draft strategy outlines EMA's plans for advancing engagement with regulatory science over the next 5–10 years.

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

Updated Guidance on Reference Safety Information (RSI)

One of the most common grounds for non-acceptance of clinical trial applications is the lack of acceptable RSI in the Investigator's Brochure or Summary of Product Characteristics. The Clinical Trial Facilitation Group (CTFG) has developed recommendations relating to RSI.

http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2017_11_CTFG_Question_and_Answer_on_Reference_Safety_Information_2017.pdf

Advances in New Scientific Framework for Oncology Drug Development

The FDA has issued new guidance on selecting suitable endpoints for oncology clinical trials and includes new resources, references and examples of prior regulatory approvals. It clarifies how oncology endpoints can support traditional or accelerated approval.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071590.pdf

GENERIC DRUGS

New ICH Reflection Paper

Historically, most of ICH's efforts have been directed towards harmonising activities for novel drugs. ICH has however now issued a short Reflection Paper outlining an approach to enhancing the guidelines in order to support harmonisation of scientific and technical standards for generic drugs.

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Reflection_Papers/ICH_ReflectionPaper_GenericDrugs_Final_2019_0130.pdf

US and Australian Agencies Focus on Patient Access to Generic Drugs

The current regulatory framework for generic drugs places unnecessarily high burden on organisations seeking marketing authorisations. Generic drugs may however increase competition and moderate the price of prescription medicines, leading to better medicines access for a broader population of patients.

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM631401.pdf

https://www.tga.gov.au/consultation/consultation-reforms-generic-medicine-market-authorisation-process

GCP, GMP AND GPVP INSPECTIONS

The Medicines and Healthcare products Regulatory Agency (MHRA) Inspectorate Blog

The MHRA has used two case studies from inspections where critical and major findings were identified to highlight the importance of Sponsor oversight in the conduct of clinical trials.

https://mhrainspectorate.blog.gov.uk/2018/09/25/sponsor-oversight-part-2/

Inspections – EU and US Mutual Recognition

In recent months, Belgium, Denmark, Finland, Latvia, Estonia Poland and Slovenia have been added to the mutual recognition agreement between the US and EU, confirming that these countries perform Good Manufacturing Practice (GMP) inspections at a level equivalent to that in the USA.

Switzerland's regulatory agency has begun to input information on Swiss GMP inspections into the EU's EudraGMDP database as part of a mutual recognition agreement. Paper GMP certificates issued by EU or Swiss authorities may now be substituted with a downloadable EudraGMDP file.

https://www.ema.europa.eu/en/news/five-additional-countries-benefit-eu-us-mutual-recognition-agreement-inspections

https://www.ema.europa.eu/en/news/eu-switzerland-improve-information-sharing-good-manufacturing-practice-through-use-eudragmdp

UK – Expectations of MHRA GPvP Inspections

An informal presentation of the planning, conduct, reporting and follow-up of pharmacovigilance inspections in the EU is available on MHRA's website.

https://www.gov.uk/guidance/good-pharmacovigilance-practice-gpvp

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

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