What's New in Clinical Development Practices & Regulations Quarter 3 – 2018

BREXIT

UK Government has issued a Report to Clarify the Position on Brexit & Clinical Trial Legislation

For clinical drug development, the report underlines the government's commitment to ensuring that the UK maintains strong and effective links with the European Medicines Agency (EMA).

Despite the optimism, however, it acknowledges the lack of direct control over all the elements involved in meeting this objective. The EMA has also identified gaps in industry preparedness for Brexit.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/710125/government-response-to-health-select-committee-report-2017-to-2019.pdf

http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2018/07/WC500251843.pdf

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/08/news_detail_002999.jsp&mid=WC0b01ac058004d5c1

Updated Industry Guidance on Preparing for Brexit

The EMA and the European Commission have updated their guidance to help pharmaceutical companies prepare for the UK's withdrawal from the EU. An updated questions and answers (Q&A) document related to Brexit and medicinal products within the framework of the centralised procedure was issued on 19 June 2018.

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500228739.pdf

UK Industry Responds to Government's Brexit White Paper

The Association of the British Pharmaceutical Industry and the BioIndustry Association have released a joint statement in response to a government White Paper on the UK's future relationship with the EU

http://www.abpi.org.uk/media-centre/news/2018/july/pharmaceutical-industry-reaction-to-brexit-white-paper/

EMA 100th Management Board Meeting Focuses on Brexit

Brexit and the associated business continuity planning continue to be the key priorities for the EMA. Such continuity planning will help the EMA to maintain, as far as possible, its core activities in relation to the evaluation, maintenance and supervision of medicines.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/06/news_detail_002972.jsp&mid=WC0b01ac058004d5c1

ACCESS TO MEDICINES

EMA's PRIME Scheme – 2 Years on

In March 2016 the EMA launched the PRIME priority medicines scheme, to increase support for the development of medicines targeting an unmet medical need. The voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so that these medicines can reach patients earlier.

Two years on, the EMA has issued an overview report.

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/05/WC500248828.pdf

EU Paediatric Regulation

The EU Paediatric Regulation aims to improve the health of children in Europe, by facilitating the development of and access to medicines for patients aged 0–17 years.

10 years after the implementation of the Regulation, significant challenges remain in developing medicines for diseases that only affect children or that manifest themselves differently in adults and children.

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/05/WC500249617.pdf

DATA & DATA SHARING

Digital Transformation of Health and Care to Boost Data Sharing in EU

The European Commission (EC) has set out measures to enable EU citizens to safely access and share health data.

The EC's 'Communication on Enabling the Digital Transformation of Health and Care in the Digital Single Market' describes how pooling data across Europe will boost research and encourage the development of personalised medicine. It also explains how digitally enabled patient-centred care models can be developed.

https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering

4 National Regulators Advance Work-Sharing Practices

The New Chemical Entities (NCE) Working Group (Australia, Canada, Singapore and Switzerland) focuses on:

- Developing opportunities through greater alignment of regulatory approaches and technical requirements
- More efficient use of resources via information sharing
- Establishing an effective network among similar regulatory authorities

http://www.tga.gov.au/acss-nce-work-sharing-pilot

US – Data of Real World Routine Clinical Practice

The FDA has highlighted the importance of developing new tools to help it access and use data from all sources, including post-marketing routine medical care.

https://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm531556.htm

NEW UK, EMA AND FDA DOCUMENTS

- New Version of UK-wide Model Non-Commercial Agreement (mNCA) is Published
    - *https://www.hra.nhs.uk/about-us/news-updates/new-version-uk-wide-model-non-commercial-agreement-mnca-published/*
- EMA Draft Guidance on Sponsor Responsibilities for Investigational Medicinal Products (IMP) Release and Shipping
    - *http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/05/WC500249275.pdf*
- US Department of Health and Human Services Delays the General Compliance Date for the Revised Common Rule, to January 2019
    - *https://www.federalregister.gov/documents/2018/06/19/2018-13187/federal-policy-for-the-protection-of-human-subjects-six-month-delay-of-the-general-compliance-date*
- New FDA Guidance on Institutional Review Boards (IRB) Written Procedures
    - *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM512761.pdf*
- New US Legislation Provides Increased Access to Experimental Drugs
    - *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm609258.htm*
- FDA Issues Draft Guidance on Including Adolescents in Adult Oncology Trials
    - *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609513.pdf*
- New FDA Guidance on Incorporating Patient's Voice in Regulatory Decision Making
    - *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm610442.pdf*
- FDA Finalises Guidance on Using Electronic Health Records Data in Clinical Trials
    - *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf*
- FDA's Centre for Biologics Evaluation and Research (CBER), 6 New Draft Documents for Novel Human Gene Therapies
    - *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/default.htm*

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

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