Regulatory & Pharma News Update September 2018

REGULATORY NEWS

Update on EU portal and database development within the Implementation Clinical Trial Regulation EU No. 536/2014

The new Regulation harmonises the assessment and supervision processes for clinical trials throughout the European Union (EU), via an EU portal and database which will be set up by the European Medicines Agency (EMA) in collaboration with the Member States and the European Commission. The portal will be the single entry point for submitting clinical trial information in the EU, which will be stored in the database.
The following update was published by EMA: 'In October 2018, the EMA Management Board heard that the development of the auditable release of the portal and database is complete. The release is now in an intensive phase of pre-testing before formal user acceptance testing can start in early 2019. Taking into account the rate of progress with testing and bug fixing, and the EMA's relocation to Amsterdam, the audit field work will take place after March 2019. Dependent on successful completion of the audit and review by the Management Board around the end of 2019, the system could be ready to go live towards the end of 2020.'

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

Efforts are Amplified to Ensure Medicine Supply Post Brexit

Results of the EMA's survey with the marketing authorisation holders demonstrated that 108 medicines (88 human and 20 veterinary) to be at risk of supply shortages once the United Kingdom (UK) leaves the EU on 29 March 2019. EMA contacted the marketing authorisation holders of these 108 medicines between July and September and reassurance on the planning was received for a significant proportion of these medicines. As a result, in September 2018, EMA has revised the number of centrally authorised medicines of which there are concerns of Brexit-related supply disruptions from 108 to 39. For each of the 39 remaining products (25 human medicines and 14 veterinary medicines), EMA is analysing how to minimise supply disruptions and any resulting impact on public and animal health. The EMA plan to work directly with the marketing authorisation holders for these products to address the outstanding issues on an ongoing basis.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/09/news_detail_003030.jsp&mid=WC0b01ac058004d5c1

https://www.ema.europa.eu/documents/report/report-ema-industry-survey-brexit-preparedness_en.pdf

EMA Management Board's highlights of October 2018 meeting

On 5th October 2018, EMA publishes a summary of highlights on EMA's activities in the first half of 2018, which were announced to the EMA Management Board during a meeting in London on 4th October 2018. The summary includes, among others, some updates on different topics: the first two CAR-T cell medicines presenting new approach in treatment of the cancer which were recommended by EMA for approval in the EU; a six-fold increase in the number of transfers of marketing authorisation applications in the first half of 2018 compared to 2017, increase in the number of new initial evaluation applications for human medicines received in the first half of 2018 and the updates on the quality and status of the ongoing development of the EU clinical trial portal and database and the EMA's ongoing preparations for the withdrawal of the UK from the EU.

https://www.ema.europa.eu/documents/press-release/ema-management-board-highlights-october-2018-meeting_en.pdf

https://www.ema.europa.eu/en/news/ema-management-board-highlights-october-2018-meeting

MHRA to Consult on EU Exit No-deal Legislative Proposals

On 4th October 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) has launched a consultation on how its legislation and regulatory processes would have to be modified in the event of the UK not securing a deal with the EU after the UK's exit, with no Implementation Period.

https://www.gov.uk/government/news/mhra-to-consult-on-eu-exit-no-deal-legislative-proposals

Adverse Drug Reactions Reporting Scheme Now More Accessible to Healthcare Professionals

A new software functionality, provided by risk management software supplier Ulysses, allows healthcare providers' clinical systems to integrate with the Yellow Card system for direct reporting, which makes easier adverse reaction or medication error reporting from hospitals and trusts. Nottinghamshire Healthcare NHS Foundation Trust are the first to pilot this new integrated reporting across nearly 200 of their healthcare sites. It is anticipated that the new software and improved accessibility will increase reporting of adverse drug reactions (ADRs).

The publication highlights that the increased ADR reporting enables the MHRA to carry out one of its core functions of monitoring the safe use of medicines in the UK and is used alongside other safety information to identify possible drug safety issues promptly and protect public health.

https://www.gov.uk/government/news/drug-reaction-reporting-scheme-now-more-accessible-to-healthcare-professionals

HRA Published a Joined Statement with the MHRA on Seeking and Documenting Consent Using Electronic Methods

The joined NHS Health Research Authority (HRA) and MHRA statement which was supported and endorsed by the UK health departments in Northern Ireland, Scotland and Wales was published on 24th September 2018. The statement sets out the legal and ethical requirements for seeking and documenting consent using electronic methods (eConsent). As outlined in the statement, 'electronic methods for seeking informed consent' and 'eConsent' refer to the use of any electronic media (such as text, graphics, audio, video, podcasts or websites) to express information related to the study and to seek and/or document informed consent via an electronic device such as a smartphone, tablet or computer. The document is primarily focused on clinical trials of investigational medical products (CTIMPs). Also, it describes general principles of the consent process, as well as different types of the electronic signatures, outlines the legal requirements for seeking consent in CTIMPs, and demonstrates specific consent scenarios.

https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

https://www.hra.nhs.uk/documents/1588/hra-mhra-econsent-statement-sept-18.pdf

Part-2 of the 'Sponsor Oversight' Topic was Published by the MHRA Inspectorate

On 25th September 2018, the MHRA Inspectorate published their second part of the 'Sponsor Oversight' post. In the first part the different mechanisms of Sponsor oversight were outlined, but in the 'Part-2' MHRA demonstrated two case studies from inspections where major and critical findings have been identified at commercial and non-commercial organizations in regard to 'Organisation's Oversight of Clinical Trials of IMP'.

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

https://mhrainspectorate.blog.gov.uk/2018/07/26/sponsor-oversight-part-1/

NHS Health Research Authority Announces Implementation of the Updated Policy 'Governance Arrangements for Research Ethics Committees'

The HRA announced that the updated 'Governance Arrangements for Research Ethics Committees' policy document replaces the 2011 version. The revised version has been implemented on 17th September 2018 by the HRA and the UK health departments in Northern Ireland, Scotland and Wales. Updates have been made to references, organisations' names and branding, as well as legal, policy and operational developments. One policy change was to include research involving human DNA extracted from acellular material (previously did not require Research Ethics Committee review).

https://www.hra.nhs.uk/about-us/news-updates/new-governance-arrangements-research-ethics-committees/

https://www.hra.nhs.uk/about-us/news-updates/revised-governance-arrangements-research-ethics-committees-implemented/

EUPATI Publishes the Guidance for Patient Involvement in Ethical Review of Clinical Trials

European Patients' Academy on Therapeutic Innovation, EUPATI, released guidance on patient involvement in ethical review of clinical trials on 07th September 2018. The guidance covers patient involvement in ethical review of clinical trials. The EUPATI is a pan-European Innovative Medicines Initiative project of 33 organizations with partners from patient organizations, universities, not-for-profit organizations, and pharmaceutical companies. There are four separate guidance documents covering patient involvement in: Pharmaceutical industry-led medicines R&D; Ethics committees; Regulatory authorities; Health technology assessment (HTA). EUPATI has developed these guidance documents for all stakeholders aiming to interact with patients on medicines research and development (R&D). As stated in the publication, guidance may be deviated according to specific circumstances, national legislation, or the unique needs of each interaction.

https://www.frontiersin.org/articles/10.3389/fmed.2018.00251/full

PHARMA NEWS

Recardio Halts UK Heart Trial on Brexit Uncertainty

According to a report by BBC News online published on 3rd October 2018, California-based medical research firm Recardio was due to try the drug dutogliptin on patients in Clydebank, Leeds and Exeter, however it has suspended all UK activities due to uncertainty about how new medicines will be approved after Brexit. The publication states Recardio is worried that the research data collected in the UK sites might not be acceptable to the EMA after Brexit. Work appears to be continuing on dutogliptin trials in various EU countries including Austria, Belgium and Hungary.

https://www.bbc.co.uk/news/uk-scotland-scotland-politics-45727317

FDA: King Bio Issues Voluntary Nationwide Recall of All Aqueous-Based Products for Human and Animal Use Due to Possible Microbial Contamination

On 27th August 2018, King Bio voluntarily recalled all aqueous-based products due to possible water-purity issues (microbial contamination). As the publication states, these include all company brands (Dr. King's: Natural Medicine, Aquaflora, Natural Pet Pharmaceuticals, SafeCareRx, Natural Veterinary, and Safecare) in different forms such as liquids, oral sprays, nasal gels, creams, and lotions. Full recall list can be found at King Bio website. King Bio is notifying its distributors and customers by letter and

is arranging for return and/or replacement of all recalled products. Consumers, distributors and retailers that have product which is being recalled should discontinue use/distribution and contact King Bio to make arrangements to return product. These products were distributed nationwide to distributors and retail stores through 24th August 2018.

https://www.gov.uk/government/news/voluntary-recall-of-usa-manufactured-homeopathic-products-check-for-affected-products

https://www.fda.gov/Safety/Recalls/ucm618585.htm

https://www.drkings.com/en/message-from-dr-king/

Digital Pregnancy Tests Recalled Due to False Positive Results

Guangzhou Wondfo Biotech has announced in September 2018 that they are recalling one lot of faulty Clear & Simple Digital Pregnancy Tests following the tests producing a small number of false positive results. The manufacturer estimates more than 58,000 affected tests have been distributed in the UK. People are advised to check if they have any of the affected tests with lot numbers which are listed in the table available in the MHRA publication.

https://mhra.filecamp.com/public/file/3lur-nmtgssck

https://www.gov.uk/government/news/digital-pregnancy-tests-recalled-in-new-alert-amid-false-positive-results

Nobel Prize for Medicine Goes to Cancer Immune Therapy Pioneers

Professor James P Allison of the University of Texas, US and Professor Tasuku Honjo, of Kyoto University, Japan won the 2018 Nobel Prize for physiology or medicine for their discovery of cancer therapy by inhibition of negative immune regulation.

A known protein that functions as a brake on the immune system studied the potential of releasing the brake and thereby unleashing our immune cells to attack tumors was realised. Allison and Honjo showed how different strategies for inhibiting the brakes on the immune system can be used in the treatment of cancer. The treatment, often referred to as “immune checkpoint therapy”, has fundamentally changed the outcome for certain groups of patients with advanced cancer. A large number of checkpoint therapy trials are currently underway against most types of cancer, and new checkpoint proteins are being tested as targets.

https://www.bbc.co.uk/news/health-45704322

https://www.nobelprize.org/prizes/medicine/2018/press-release/