



What's New in Clinical Development Practices and Regulations

November 2011

WORLD

Medical Device Regulators Move to Increase Harmonisation

Representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and United States, as well as the World Health Organization (WHO), met in Ottawa to address the establishment and operation of a new organisation, the International Medical Device Regulators' Forum (IMDRF).

This Forum will accelerate international medical device regulatory harmonisation. The IMDRF will meet bi-annually, with the inaugural meeting taking place in Singapore from 28 February to 01 March 2012 under the leadership of Australia. As part of these bi-annual meetings stakeholders will have an opportunity to learn of the work of the Forum, provide input on emerging issues and suggest potential new work items.

<http://www.tga.gov.au/about/international-imdrf-111105.htm>

International Conference on Harmonisation (ICH) to Revise Pre-clinical Genotoxicity Testing Guidelines

The ICH Steering Committee (SC) and its working groups met in Seville, Spain from 05 - 10 November 2011.

Following an extended consultation period, the SC approved a revised ICH S2(R1) Guideline for genotoxicity testing and data interpretation for medicines intended for human use. This revised Guideline reflects state of the art options for genotoxicity testing and is expected to improve risk assessment of human medicines.

The Quality Implementation Working Group (IWG) completed three documents on points to consider on 'Process validation/Process verification', 'Role of Modelling in Quality by Design' and 'Design Space'.

<http://www.ich.org/ichnews/press-releases/view/article/ich-steering-committee-seville-spain-9-10-november-2011-1.html>

UK

Health Research Authority to be Established 01 December 2011

Secondary legislation to establish a Health Research Authority (HRA) for England was placed before the UK Parliament in September. This legislation has successfully completed its formal consideration period, and has come into force.

An inaugural meeting of its Board will take place on 01 December and further information about the organisation will be published in due course. It is widely expected that the organisation will include the existing structure and activities of the National Research Ethics Service (NRES).

<http://www.nres.npsa.nhs.uk/news-and-publications/news/health-research-authority-to-be-established/>

USA

The Food and Drug Administration (FDA) Reports Faster Approvals of New Medicines in 2011

Over the past 12 months, the FDA approved 35 new medicines. This is among the highest number of approvals in the past decade, surpassed only by 2009 (37).

In a report, the FDA provides details of how it used expedited approval authorities, flexibility in clinical trial requirements and resources collected under the Prescription Drug User Fee Act (PDUFA) to boost the number of innovative drug approvals to 35 for the fiscal year (FY) ending 30 Sep 2011.

The report shows faster approval times in the USA when compared to the FDA's counterparts around the globe. Twenty-four of the 35 approvals occurred in the USA before any other country in the world and also before the European Union.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm278383.htm>

THE NETHERLANDS

The Dutch Regulators CCMO will Simplify Applications for Multi-centre Studies in The Netherlands

In an attempt to diminish the often needlessly long start-up times for multi-centre trials in the Netherlands, a new 'Guidance for De-centralised Applications' has been drafted. The Guidance is due to be implemented 01 Jan 2012.

Key elements of the Guidance are:

- Local feasibility declarations will be obtained from Hospital Board of Directors - local Ethical Committees (EC) will be abandoned
- The head of department at the investigational site will now be responsible for issuing a Research Statement which will be forwarded to the central EC
- Stricter timelines will apply for the central EC

<http://www.ccmo-online.nl/main.asp?pid=25&sid=49&ssid=230> (text in Dutch)

INDIA

India Publishes Draft Guidelines on Compensation for Research Related Injury

The Indian Society for Clinical Research (ISCR) and Forum for Ethics Committees in India (FERCI) have prepared draft guidelines addressing issues related to compensation for research-related injury.

The Indian law for clinical trials specify the need for provision of compensation of participants for research-related injuries.

The guidelines apply to all clinical research, whether sponsored by the pharmaceutical or medical device industry, government or academia or individual investigators, but do not apply to post-marketing surveillance and ancillary care.

Comments on the guideline are invited no later than 31 December 2011.

<http://icmr.nic.in/icmrnews/Compensation%20Guidelines%20for%20Website.pdf>

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

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