



What's New in Clinical Development Practices and Regulations

April 2011

EUROPE

The European Medicines Agency (EMA) Publishes 2012-2013 Paediatric Investigation Plan (PIP) Submission Deadlines

The EMA has published its 2012 and 2013 submission deadlines for PIP applications, applications for waivers and answers to Request for Modification Plan of the application.

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/03/WC500075566.pdf

European Union Drug Regulating Authorities Clinical Trials (EudraCT) New Version 8.0.1

The new version of EudraCT was launched in Mar 2011. Version 8.0.1 includes an updated Clinical Trial Application Form.

For the UK:

- Integrated Research Application System (IRAS) is currently being updated. Whilst this system update is in progress, IRAS will continue to be available for the completion of EudraCT forms and users should continue to use IRAS to prepare applications for submission to the MHRA Medicines as normal.
- MHRA will continue to accept the MHRA Medicines (EudraCT) form in the version 7 format, which is currently in IRAS, until at least 11 April 2011.
- Applicants should note that while IRAS is being updated the function that allows the EudraCT XML file to be imported into IRAS will only work for import of version 7 EudraCT forms. EudraCT version 8 forms cannot be imported into IRAS at this time.

<https://eudract.ema.europa.eu/>

<https://www.myresearchproject.org.uk/Signin.aspx>

European Commission (EC) to Update Pharma Pricing and Transparency Directive

The EC is launching a public consultation to possibly revise the transparency rules for member states' decisions on pricing and reimbursement of medicines, which have not been updated since 1989.

All interested parties have until 25 May to comment on the review of Council Directive 89/105/EEC, commonly known as the transparency directive.

http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/index_en.htm

The Medicines and Healthcare Products Regulatory Agency (MHRA) Introduces E-learning on Pharmacovigilance for Clinical Practitioners

The MHRA has introduced a new learning package on pharmacovigilance for clinical practitioners. This self-directed learning resource covers:

- How information on adverse effects of medicines is produced
- How to seek up to date and authoritative information on the risk of individual medicines
- How to fill out a Yellow Card and contribute to improving our knowledge about possible harms

The module concludes with exercises and a reading list for those wanting to learn more. Doctors, nurses, and pharmacists all stand to benefit from the pharmacovigilance module.

<http://www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/pharmacovigilancelearningmodule/index.htm>

MHRA Reporting Adverse Incidents and Disseminating Medical Device Alerts

The MHRA has published guidance on reporting adverse incidents with medical devices.

<http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON111565>

MHRA Provides Guidance on Supply of Herbal Medicines

At the beginning of the year, the MHRA published a section which outlines the required routes by which herbal medicines can be legally supplied in the UK.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/PlacingaherbalmedicineontheUKmarket/index.htm>

Merges, Closures and Research Ethics Committee's (REC) Change of Name

A number of NHS RECs have changed their names effective 01 April 2011. Please see below for guidance.

<http://www.nres.npsa.nhs.uk/applications/booking-and-submitting-your-application/find-your-local-rec/mergers-closures-and-rec-name-changes/>

The Association of the British Pharmaceutical Industry (ABPI) Joint Statement Supporting Changes to the Code of Practice

In an unprecedented joint statement the 17 signatories pledge their support for two key changes to the ABPI Code of Practice published last month.

- The industry will no longer provide branded promotional aids, such as pens, pads and mugs to health professionals. This will take effect from 01 May 2011. Some companies have already made this change and others may do so ahead of this date.
- From 2012, companies will be required to collect and declare on an annual basis aggregate total amounts paid to health professionals and others for certain services such as speaker fees and participation in advisory boards. Similarly companies will be required to declare sponsorship for attendance at meetings organised by third

parties. The first declaration of payments will be in 2013 for payments made in 2012. The Code does not require individual health professionals to be named but does require the total number of health professionals involved to be declared and the total number of meeting attendances sponsored.

<http://www.abpi.org.uk/our-work/library/guidelines/Pages/code-2011.aspx>

<http://www.abpi.org.uk/our-work/library/industry/Pages/joint-statement.aspx>

The National Institute for Health Research (NIHR) Coordinating System for Gaining NHS Permission (CSP) Operating Guidelines Version 4.2 is Released

Version 4.2 of the NIHR CSP Operating Guidelines has now been published, along with a summary of the main changes:

- Revised Amendments Process
- Arrangements for Studies involving Devolved Administration
- Revised R&D Form Process
- Clarification of the principles of Participant Identification Centres
- Requirement for documents to be sent as a full application package
- Details of metrics in place from 01 April 2011, including the requirement for a valid application package

http://www.crnc.nihr.ac.uk/about_us/processes/csp

USA

Food and Drug Administration (FDA) Publishes Guidance on Post-Marketing Studies and Clinical Trials

The guidance provides information about the requirement for post-marketing studies and clinical trials under section 505 (0)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C 355(0)) added by section 901 of the FDAAA (Food and Drug Administration Amendments Act of 2007). It gives guidance on the types of studies which may be required and the responsibility of the New Drug Application (NDA) holder with regards to these studies.

This legislation allows the FDA to require additional post-marketing research as a condition of a NDA approval.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf>

FDA Issues Final Guidance on Exception from Informed Consent Requirements for Emergency Research

This guidance, which finalises a 2006 draft document, is intended to assist Institutional Review Boards, clinical investigators and sponsors in the development, conduct and oversight of investigations to determine the safety and effectiveness of FDA regulated products in emergency settings when an exception from the informed consent requirements is requested under 21 CFR 50.24.

Emergency investigations involve human subjects who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory),

and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent. The research must have the prospect of direct benefit to the patient and must involve an investigational product that, to be effective, must be administered before informed consent from the subject or the subject's legally authorised representative can be obtained and in which there is no reasonable way to identify prospectively individuals likely to become eligible for participation.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf>

FDA Extends Deadline for IND Safety Reporting Requirements

In September 2010, the FDA published a draft guidance on safety reporting for IND and Bioavailability and Bioequivalence Studies. The FDA has now issued a statement to say that the original implementation deadline of 28 Mar 2011 has effectively been extended to 28 Sep 2011. This extension was granted due to concerns about the significant internal process changes required in order to meet these new requirements.

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm248650.htm>

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

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