Newsletter

February 2018 – EMA's Medicines Highlights

Choose the Seeds for the ClinOps Garden

"When the flower blooms, the bees come uninvited." – Ramakrishna

Apart from unmatched Project & Medical Leadership Services, comprising overall Clinical Study Management activities through novel risk-based quality management services, PPH plus owns decades of experience in strategic overarching program management in clinical development.

PPH plus medical consultancy experts provide strategic medical/scientific and general drug development input into high-priority development programs and clinical studies. Let PPH plus guide you on how to get flowers instead of weed.

EMA's Human Medicines Highlights

The European Medicines Agency (EMA) has released the Medicines Highlights for 2017 (see EMA's press release). The EMA issued a favorable opinion on the authorization of 92 new medicines, 35 of which consist of new active substances. Remarkably, 2 advanced therapy medicinal products (ATMPs) and 19 orphan medicines obtained a positive opinion on marketing authorization as well as 4 new medicines for children.

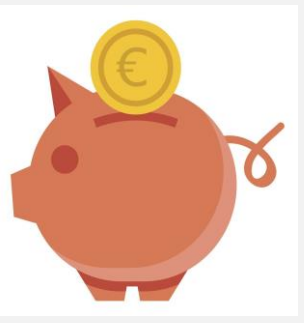
EMA's Substance and Product Management Services (SMS & PMS)

The EMA announced four domains of master data, Substance, Product, Organization and Referential (SPOR) data, in pharmaceutical regulatory processes. In order to support EU-wide regulatory activities, the EMA offers Referentials Management Service (RMS) and Organizations Management Service (OMS) (launched in June 2017), as well as the recently announced Substance Management Service (SMS) and Product Management Service (PMS). Once the PMS and SMS are ready, pharmaceutical companies must start preparing to update to a new data-submission format (the eXtended EudraVigilance Product Report Message, XEVPRM format), compatible with ISO IDMP (see EMA's introduction). EMA is currently developing the EU IDMP implementation guide for the submission of data on substances and products.

EMA's Survey on Pharma Preparedness for Brexit

The EMA has launched a survey to evaluate companies' Brexit preparedness plans and identify medicines supply issues that may impact public or animal health (see EMA's press release). Invited participants are marketing authorization holders of centrally authorized medicines that are located in the United Kingdom (UK), or who have quality control, batch release, and/or import manufacturing sites or a qualified person for pharmacovigilance (QPPV) or pharmacovigilance system master file (PSMF) in the UK. The deadline for completion of the questionnaire is 9 Feb 2018. A summary of the survey results will be published on the EMA website.

EMA's Budget for 2018 – What's the Figure?



The EMA has released the annual budget for the agency's activities (figures as adopted by the Management Board on 14 Dec 2017) with a comparative assessment against the previous two years. The EMA's Budget for 2018, 337,761,000 EUR, denotes a 10.71 % increase on refunds and a 13.7 % increase on expenditure if compared to the year 2016 (305,098,698 EUR and 297,012,706 EUR respectively).

*Meet PPH plus at Forthcoming Conferences:

- 4th EUCROF Conference, Vienna, Austria, 26-27 Feb 2018 (see EUCROF announcement)
- 34th Annual DGPharMed Conference, Berlin, Germany, 22-23 Mar 2018 (see DGPharMed announcement)
- 13th PPH plus Annual Interdisciplinary Drug Development Expert Workshop, 20 Apr 2018, Frankfurt am Main, Germany

How can we help you?

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