Newsletter

May 2017 – XII PPH plus Expert Workshop – Part I of II

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Regulatory Clinical Trial Framework & European Patients' Academy

After the exciting XII Interdisciplinary Drug Development Expert Workshop on "Successful drug development under cost constraints and complex regulations" (Frankfurt Biotech Innovation Center - FIZ, Frankfurt am Main, 5 May 2017), PPH plus is pleased to offer a summary of the expert assessment of the changes to the German clinical trials regulatory framework and novel European patients' academy.

EU Regulation No. 536/2014 - Is the Previous AMG Already History?

Dr. med. Peter Klöpel, Director Consulting Services at PPH plus, Frankfurt am Main, Germany, provided an expert review of the recent changes to the German medicines law (4. Arzneimittelgesetz - Änderungsgesetz, AMG-ÄndG, 23 December 2016) derived from the new EU Clinical Trials Regulation No. 536/2014.

- The 4th AMG amending law entered into force on 24 December 2016 (e.g., Ethics Committees must professionalize and register with the BfArM)
- Significant parts of the 4th AMG amending law will come into force only after the European Commission's (EC) communication on the functioning of the EU portal (e.g., single clinical trial application through the EU portal)
- Even after the official activation of the EU portal, transitional AMG regulations with long-term effects must be observed
- The previous AMG (valid before 24 December 2016) and the German ordinance on Good Clinical Practice (GCP-Verordnung) are by no means already history (e.g., they remain effective for clinical trials with blood and tissue samples until 23 December 2024)

Full presentation (in German language) available here.

EUPATI Project – The European Patients' Academy

Dr. med. Brigitte Franke-Bray, Consultant, Specialist in Pharmaceutical Medicine FMH (Foederatio Medicorum Helveticorum), Muttenz, Switzerland, presented the European Patients' Academy (EUPATI).

- EUPATI, the European Patients' Academy on Therapeutic Innovation, is a project developed within the Innovative Medicines Initiative (IMI), a public-private partnership between the EU Commission and EFPIA, led by the European Patients' Forum (EPF)
- EUPATI focuses on education and training of patients in order to increase their capacity and capability to understand and contribute to the research and development (R & D) of medicines. It does not educate about disease-specific therapies
- EUPATI provides education and information on three levels: Patient experts in a special English training course, the online toolbox and the online library in 7 priority languages with additional languages to be added in 2017
- EUPATI also coordinates a network of national platforms for patient advocates in order to generate public interest for the research and development of medicines
- The EMA framework for the interaction of patients and consumers provides on its website internal training possibilities and also recommends external training options such as EUPATI
- Guidance on patient involvement in clinical R & D as well as "best practice procedures" have been developed and can be found on the website www.eupati.eu

Full presentation (in German language) available here.