Newsletter

December 2017 – Envisioned Clinical Research Horizons

The Wind of Change in Europe

Europe is vibrating. 2016 has brought, beyond others, the following changes:

- New Eudravigilance (EV) system (live since 22 November 2017)
- Announcement of EMA's relocation to Amsterdam (the Netherlands) to be completed on 30 March 2019
- Mutual recognition of FDA and EMA (GMP) inspectorates (effective since 1 November 2017)
- Adopted ICH E6(R2) guideline (effective since 14 June 2017)
- Ongoing transition to the Clinical Trials Regulation EU No. 536/2014

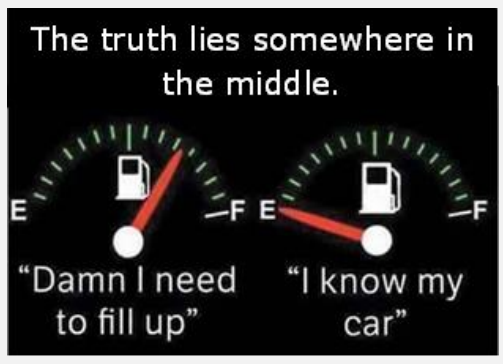
The PPH plus team will continue supporting its customers with seeing new drug development horizons in 2018. Thus, our Project Leadership, Medical and Consultancy Services are committed to turn our customers' vision into reality, through enlightening clinical trial regulatory adaptation and supreme operability.

PPH plus Serves up Safe Clinical Trials

"Learn from yesterday, live for today, hope for tomorrow." — Albert Einstein

PPH plus paves the way for tomorrow. Innovation drives new product development, opens new market opportunities and boosts biopharma growth. Thus, the risk-based Quality Management System (QMS) lifted clinical trial team spirits by giving them a confidence boost.

Let PPH plus show you where the truth lies.



Do you face hesitating planning concerning risk prevention according to risk criticality? The PPH plus Project Leaders will help you to identify and evaluate risk criticality properly. Our customers gain mastery over risk prioritization avoiding inappropriate, either overstated or deficient, risk management activities. The PPH plus Risk-based Monitoring (RBM) repository, including tools as the RACT plus, offers easy solutions for risk assessment and control.

Let our experts create tailored Risk Management Plans (RMP) as well as a Clinical Monitoring Plans (CMP) to ensure your clinical trial engine will not run out of fuel.

New Rules for Advanced Therapy Medicinal Products

The EMA has released new Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products (ATMPs). These guidelines harmonize GMP requirements in the EU with the specific characteristics of ATMPs (medicines for human use that are based on genes or cells), fostering a risk-based approach to manufacture and testing of such products. ATMP manufacturers must comply with these guidelines no later than 22 March 2018.

These guidelines derived from the joint action plan launched by the Directorate General for Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA) in October 2017 to foster the development of ATMPs.

***Note About Brexit:** The EMA has just released additional procedural (24 November 2017) and regulatory (1 December 2017) guidance for pharmaceutical companies to prepare for the UK's withdrawal from the EU.

How can we help you?

Awarded to PPH plus 05/2016

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