Newsletter

March 2018 – Doing the Right Things Right in Bioresearch

2016 | 2017 INNOVATIVE THROUGH RESEARCH
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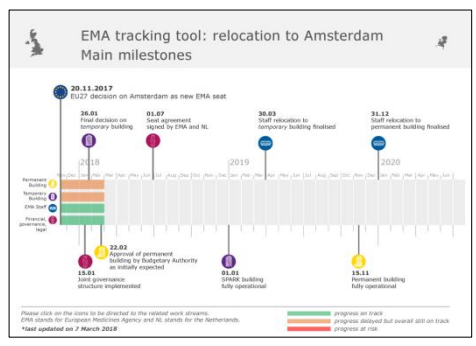
FY 2017 Inspection Metrics Issued by the U.S. FDA's Office of Scientific Investigations (OSI) & Office of Study Integrity and Surveillance (OSIS)

The updated GCP BIMO (Bioresearch Monitoring) metrics derive from inspections at 512 clinical investigator and 73 sponsor/CRO sites (585 GCP inspections in total, more than ever before per year in the last decade). Four hundred-nine (70 %) of GCP inspections took place domestically, the remaining 176 (30 %) outside the U.S. The largest proportion of international clinical investigator inspections occurred in Western Europe (31 %), very closely followed by Eastern Europe. The 2017 final outcome classification of international clinical investigator inspections favorably compares to the overall outcome (No Action Indicated: 76 vs. 70 %, Voluntary Action Indicated: 24 vs. 28 %, and Official Action Indicated: 0 vs. 2 %). The limited number of BIMO Warning Letters and the fact that no Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) letter was issued point towards continuing improvement of clinical trial standards. Despite huge challenges through the ever increasing complexity of clinical study conduct and related inspections, involved parties work hard to do the right things right for the ultimate sake of patients.

New Tracking Tool for EMA's Relocation to Amsterdam



In line with best-practice project management planning the European Medicines Agency (EMA) has released a tracking tool for the relocation from the United Kingdom to the Netherlands (see EMA's press release). In view of its important role to safeguard public and animal health in the European Union (EU), EMA is committed to giving stakeholders and the public full visibility of the relocation project. The tracking tool will allow all interested parties to follow the progress made. It will be updated monthly.

Doing the Right Things Right in Pharmaceutical Medicine Demands Continuing Professional Development – Berlin is Calling

Continuing Professional Development (CPD) is the ongoing process of acquiring and updating work-related knowledge and skills throughout professional life. Whatever the annual target of training hours in your working environment is, a valuable platform for getting updated on pharmaceutical medicine matters at large are the conferences and workshops offered by the not-for-profit scientific societies in pharmaceutical medicine at national levels. Latest views from regulators, clinical trial practitioners, biopharma regulatory affairs specialists, clinical research scientists and representatives of other involved disciplines are being exchanged at affordable cost in a neutral environment. The next of such opportunity is just a week ahead. Join the German pharmaceutical medicine and clinical research community for the

34th Annual DGPharMed Conference "Medicines and Device Development: Clever and Smart!"
Berlin, 22-23 March 2018

Please double-check the program and complete your last-minute registration at the DGPharMed website. You will benefit from knowledge gain and collegial networking conquering company, authorities and discipline silos, and thereby increasing the likelihood of doing the right things right.

How can we help you?