Newsletter

September 2017 – GCP Inspection Harvest

Advanced PPH plus Knowledge Center – All About RBM

With the new Knowledge Center section "All About RBM", PPH plus offers its customers a 360-degree view of what a risk-based quality management system (QMS) entails. Clinical operations teams will find essential guidance, with links to the most relevant practical tools, initiatives, and risk-based monitoring (RBM) implementation reviews such as the published results of the PUEKS and ADAMON projects.

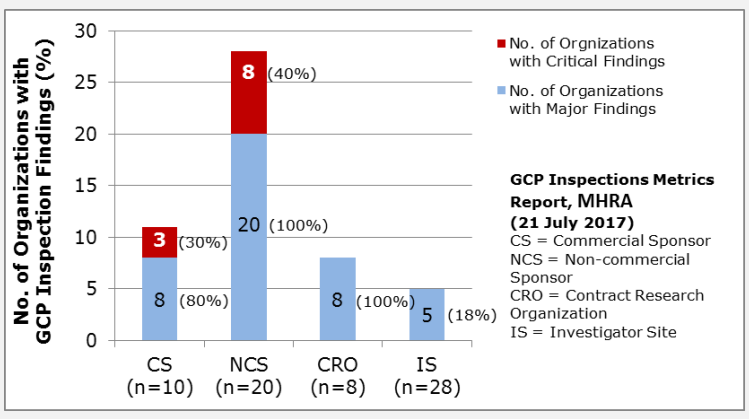
For late adopters, the ADAMON project provides now evidence that RBM reduces 50 % of onsite monitoring resources while being as effective as traditional monitoring in precluding major or critical GCP audit findings. The below-mentioned GCP IWG and MHRA inspection (critical and major) findings indicate that current QMS are not effective enough in safeguarding patient safety and data integrity.

GCP IWG & MHRA Annual Reports – Inspections Conducted in 2016

The GCP Inspectors Working Group (EMA) has published the "Annual Report of the Good Clinical Practice Inspectors Working Group 2016" on 18 August 2017.

A total of 495 main findings (66 critical and 429 major findings) were analyzed for 85 reported inspections. Some of the still present critical findings were relevant information missing in the Clinical Study Report (CSR), inconsistencies between source data and CSR data, insufficient design of the study protocol, CRF unsuited for accurate data collection, inadequate SAE documentation and SAE reporting and violation of inclusion criteria.

About a month earlier, the Medicines and Healthcare Products Regulatory Agency (MHRA, United Kingdom) published the "GCP Inspections Metrics Report" (21 July 2017) for the period 1 April 2015 to 31 March 2016.



The MHRA report denotes that all critical findings are related to sponsors' neglected responsibilities and systematic issues such as the lack of evidence of EDC testing, inclusion of ineligible subjects, TMF not meeting regulatory requirements and completely missing TMFs and CRFs. This ratifies the importance of a risk-based QMS that holds personnel and projects to the organization's rules as well as to the applicable legislation.

Happily, investigator sites have better performance statistics than sponsors and CROs with no critical findings and a reduction from 50 % (11 out of 22 sites, inspections reported in 2016) to 18 % of sites (5 out of 28, see figure) with reported major findings compared to the previous year.

EMA Facilitates Submission of Post-approval Data

The European Medicines Agency (EMA) facilitates with a new form the submission of data generated to satisfy post-authorization measures (PAMs) for centrally authorized products. The new form will help marketing authorization holders (MAHs) to provide required additional data on safety, efficacy and quality of authorized medicines. The use of the new form is mandatory from 1 September 2017.

EMA on First in Human (Revised Guideline)

The EMA has adopted the revised "Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products". The guideline aims to address issues related to the designing of studies in a clinical development program. It describes strategies to mitigate and manage risks for trial participants specifically concerning the calculation of the starting and maximum dose to be used in humans, through dose escalation approaches and rules. Guidance is also provided on adverse event handling, study stopping criteria, and regular review of emerging data.

How can we help you?

2016 | 2017 INNOVATIVE THROUGH RESEARCH
Awarded by the Stifterverband
PPH2594FRA

Awarded to PPH plus 05/2016

CONTACT

Dr. María Proupín-Pérez, PMP

Senior Project Leader

maria.proupin-perez@pph-plus.com

Phone +49 (0)69 587 00 35 24

Dr. Matthias Fehlinger, PMP

Senior Project Leader

matthias.fehlinger@pph-plus.com

Phone +49 (0)69 587 00 35 30

PPH plus on

Google Maps

Follow us

PPH plus GmbH & Co. KG

Altenhöferallee 3

60438 Frankfurt am Main

Germany

www.pph-plus.com