Newsletter

May 2015 – PPH plus Expert Workshop – Part I of II

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The Optimal Clinical Study Protocol & Management

After the vibrant X Interdisciplinary Drug Development Expert Workshop on "Successful drug development under cost constraints and complex regulations" (8 May 2015, Frankfurt am Main), PPH plus provides a summary of the expert assessment of protocols and risk-based study management outcomes.

The Ideal Protocol by Dr. Klausmann

Dr. med. Gerhard Klausmann, internist and clinical investigator, Aschaffenburg, provided professional advice to the attendees on how to improve study protocols. To gain investigator commitment, ensure study patient and site protocol adherence, and optimize resource utilization, Dr. Klausmann advises the following:

- Avoid amendments by a proactive adjustment of the protocol to the study needs prior to the start, so that patient trust and consent are not impacted by preventable changes
- Commit first - request later, do not expect pre-screened patients during a feasibility survey prior to a commitment with the clinical investigator
- Schedule patient-friendly visits and flexible time windows to facilitate patient engagement and retention with due observance of rational factors such as study personnel and patient vacations
- Provide simple working materials for patients instead of complex study medication arrangements or over-complicated diaries
- Eliminate duplication of data entries in different documents by designing a unique form for each relevant data set (e.g., merging site and subject drug accountability in a single document)
- Offer reasonable investigator fees according to the work package assigned to clinical sites

A rationalized protocol together with the sponsor's and CRO's support guarantees the optimal conduct of the clinical study by reassured investigators. As a result, inspectors are welcome!

Full presentation available here.

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Risk-based Study Management – Clinical Trial Dos and Don'ts

Dr. Beat Widler, Managing Partner, Widler & Schiemann, Zug (Switzerland), highlighted in his presentation reasons why clinical studies went wrong and measures to get them right.

Clinical study management don't dos:

- Abuse of investigational sites as a cheap resource for completion of sponsor tasks
- Cause additional (unpaid) tasks to investigational sites, e.g., implementation of protocol amendments
- Neglect support to investigational sites and thinking that centralized monitoring can replace on-site monitoring visits
- Make quality seem unimportant

Clinical study management dos:

- Deliver a lean and realistic study protocol, which was validated with facts and not opinions
- Conduct a feasibility study substantiated with real data by the relevant investigational sites
- Provide timely feedback to the investigator in order to drive compliance
- Put emphasis on the quality management process rather than wasting time and resources over details that have no impact on patients' safety, integrity and rights, and data integrity. For instance, source data verification (SDV) should be understood and used as a tool rather than the primary quality control (QC) instrument
- Focus study management on key protocol parameters and deliverables

Full presentation available here.