Introduction

Monitoring in clinical trials is essential to protect the rights and well-being of human subjects and to ensure complete and accurate data and protocol compliance. Good Clinical Practice (GCP) implemented by EC and national regulations has specified the purpose, responsibilities and procedures of clinical trial monitoring. The sponsor should determine the appropriate extent and form of monitoring. There is a general need for on-site monitoring, however, in exceptional circumstances, central monitoring in conjunction with procedures may be sufficient. Extensive on-site-monitoring is routinely used in drug approval trials. Due to economic constraints and varying risk profiles adapted monitoring procedures are discussed for investigator initiated trials (IITs). In several EC-countries specific monitoring strategies for IITs have been developed (e.g. France, UK). The great benefit of IITs to the patients concerned has been widely recognized. EC-Guidance for specific modalities of non-commercial trials, such as monitoring, is under preparation. Researchers, planning and performing IITs need specific advice on how to implement GCP-compliant monitoring in their clinical trials.

This international workshop focuses on the issue of monitoring in IITs. The meetings brings together experts/professionals from regulatory bodies, pharmaceutical industry and clinical research to explore the viewpoints of the different stakeholders and to assess regulatory compliance, practicability and effectiveness of specific monitoring strategies for IITs. The workshop is organized by the Coordination Centre for Clinical Trials in Düsseldorf/Germany together with the Coordination Centres for Clinical Trials in Cologne, Leipzig and the Competence Network Malignant Lymohoma and cooperation with the European Clinical Research Infrastructures Network (ECRIN). Financial and organisationall support is given by the German Telematic Platform (TMF e.V.) as part of the approved project “GCP-compliant monitoring in IITs”.

We would like to invite you to join our workshop. Registration is free, however, written registration is necessary. Participation will be limited to 25 persons.

C. Ohmann

Program

10:00 – 10:10
Welcome

10:10 – 12:10
Framework conditions for monitoring and perspectives of regulatory bodies and pharmaceutical industry
Chair: F. Sweeney (European Medicines Agency, London, UK),
P.H. Bertoye (Agence français de sécurite sanitaire des produites de sante, Saint Denis cedex, France)

10:10 – 10:40
EU regulations for monitoring in clinical trials: GCP, EU-Directives and guidance – an update
(B. Davis, Medicine and Health Care Products Regulatory Agency, London, UK)

10:40 – 11:10
New perspectives in monitoring of industry managed trials
(B. O`Neill, Roche Products Ltd., Basel, Switzerland)

11:10 – 11:30
Implications for monitoring from inspections of investigator initiated trials – the Swedish experience
(G. Danielsson, Medical Products Agency, Sweden)

11:30 – 11:50
Implications for monitoring – the German experience of the higher federal competent authority
(G. Schwarz, German Federal Institute for Drugs and Medicine Devices, Bonn, Germany)

11:50 – 12:10
Overview on data quality in clinical trials
(C. Ohmann, Coordination Centre for Clinical Trials, Düsseldorf Germany)

12:10 – 13:00
Lunch

Program

13:00 – 15:05
Monitoring in investigator trials: strategies and projects:
Chair: C. Ohmann (Coordination Centre for Clinical Trials, Düsseldorf, Germany)
J. Demotes (European Clinical Research Infrastructures Network, Bordeaux, France)

13:00 – 13:25
Data quality in investigator initiated trials: experience from from EORTC
(D. Lacombe, European Organization for Research and Treatment of Cancer, Brüssel, Belgium)

13:25 – 13:50
A risk-based approach to monitoring: the AP-HP experience
(O. Chassany, Assistance Publique - Hôspitaux de Paris, Paris, France)

13:50 – 14:15
A risk-based approach to monitoring: the MRC/DH joint project
(S. Meredith, Medical Research Council, London, UK)

14:15 – 14:40
Adaption of monitoring procedures to patient`s risk: OPTIMON a randomised controlled trial of two monitoring strategies in French/CTUs
(G. Chene, V. Journot, INSERM Unité 593, Bordeaux, France)

14:40 – 15:05
The German approach: GCP-conform monitoring in IITs
(O. Brosteanu, Coordination Centre for Clinical Trials, Leipzig, Germany)
(B. Pfistner, German Hodgkin Study Group, Köln, Germany)

15:05 – 15:30
Coffee-Break

15:30 – 16:45
Round table discussion (all participants)

16:45 – 17:00
Summary and conclusions
(C. Ohmann, Düsseldorf, Germany)

Speakers/Chairmen

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Location

Hotel National is close to the main railway station. Please leave the railway station exit "south"/"Süd" and cross the street). There are railways/metro from Frankfurt airport to Frankfurt railway station (10-15 minutes).

Alternative monitoring procedures in investigator initiated trials

Program

- International Workshop -

Monday, 3.4.2006,
10:00 – 17:00

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Scientific organisation:

- Coordination Centre for Clinical Trials, Düsseldorf, Germany
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- European Clinical Research Infrastructures Network (ECRIN)

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