Multidisciplinary Workshop

Towards A Better Future for Pharmacovigilance in Clinical Trials

8th February 2010

EORTC Headquarters, Brussels

Organised by EORTC and ECRIN

EORTC
European Organisation for Research and Treatment of Cancer
AISBL International Non-Profit Association under Belgian law IVZW

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

on behalf of the "Roadmap Initiative for Clinical Research in Europe"

Excellence in science
EBMT
European Group for Blood and Marrow Transplantation

EF GCP

CLINT: facilitating international prospective clinical trials in stem cell transplantation

ICREL

ELN European LeukemiaNet

Workshop Rationale

Currently, Directive 2001/20/EC on clinical trials requires that each suspected unexpected serious adverse reaction (SUSAR) has to be reported to the EMEA, to the competent authorities, to the relevant ethics committee(s) of countries participating in the study by the deadlines set by the Directive as well as to all investigators.

Due to the transposition of the Directive at the national level, the process (medium, language, etc.) for SUSARs notification as well as the parties to be addressed varies from one country to another. This becomes particularly complex when clinical trials are international or even intercontinental.

The current reporting requirements represent a significant and counterproductive amount of work for the sponsors, the competent authorities, ethics committees and investigators. They create a huge administrative burden adds no value to the information created in a clinical trial and has not been shown to improve patient safety.

This workshop will explore the experience of the clinical research stakeholders with respect to pharmacovigilance management in clinical trials and, examine proposals for a more appropriate pharmacovigilance reporting process in Europe. The ultimate goal is to produce ground for recommendations, acceptable for all stakeholders, which will be discussed and released during the final Stakeholder Conference in Brussels on 17th March 2010. The recommendations will be submitted to the European Commission requesting initiation of the necessary legal steps to create an efficient pharmacovigilance process for clinical trials in Europe.

Programme Committee

Delphine Bertram	Hospices Civils de Lyon, France
Gonzalo Calvo	Hospital Clínic de Barcelona, Spain
Jacques Demote	INSERM, ECRIN, France
Nathalie Dubois	European Organisation for Research and Treatment of Cancer (EORTC), Belgium.
Jocelyne Flament	European Organisation for Research and Treatment of Cancer (EORTC), Belgium.
Ingrid Klingmann	EFGCP, Pharmaplex, Belgium.
Stéphane Lejeune	European Organisation for Research and Treatment of Cancer (EORTC),Belgium.

Workshop Language

The language of the Workshop will be English. No translation will be provided.

Venue

EORTC Headquarters, 83 avenue E. Mounier, 1200 Brussels, Belgium.
More information: **www.eortc.be/about/map.htm**

Preliminary Programme

EORTC Headquarters, 83 avenue E. Mounier, 1200 Brussels, Belgium.

8h45	**Welcome and Introduction.** (F Meunier, EORTC)
9h00	**Session I: Current status of the safety reporting process for clinical trials in Europe** Co-chair: Brian Davis, MHRA & Ingrid Klingmann, EFGCP
9h00	The EMEA perspective. Gilles Touraille, EMEA
9h20	Experience of a Competent Authority. Karin Hedenmalm, MPA-SE
9h40	Experience of an academic sponsor. Nathalie Dubois, EORTC
10h00	Experience of an industry sponsor. (to be appointed)
10h20	**Coffee break**
10h40	Clinical site perspective: pharmacovigilance experience from the ward (to be appointed)
11h00	Patient perspective: what matters to the patient? David Haerry, EATG
11h20	Experience of an Ethics Committee. Xavier Carné, Hosp. Clinic Barcelona
11h40	Open Forum Discussion: Could we agree on a list of deficiencies in the current safety reporting process?
12h30	**Lunch**
13h30	**Session II: Proposals for a more appropriate safety reporting process in clinical trials**. Co-chair: Gonzalo Calvo, Hosp. Clinic Barcelona & Jacques Demotes, ECRIN
13h30	Competent authorities perspective: proposal by the CTFG. Chantal Bélorgey, AFSSAPS
13h50	Ethics committee perspective. Johannes Pleiner, Vienna Medical School
14h10	Academic sponsor perspective: proposal by ECRIN. Delphine Bertram, CHU Lyon
14h30	Pharmaceutical industry perspective: proposal by Industry Association.
14h50	Clinical Research Organisation perspective: proposal by ACRO.
15h10	**Coffee break**
15h30	Summary of the propositions. Jacques Demotes, ECRIN
15h50	Open Forum Discussion: Which safety reporting system would be the most appropriate in Europe?
16h50	**Next steps.** Ingrid Klingmann, EFGCP
17h00	**End of the workshop**