

Brussels, 12 November 2009

Subject: Invitation to the workshop “Towards A Better Future for Pharmacovigilance in Clinical Trials”
Brussels, 8th February 2010.

Dear Sir/ Madam,

We are pleased to inform you that the workshop “Towards A Better Future for Pharmacovigilance in Clinical Trials” will be taking place on 8th February 2010 at the EORTC Headquarters in Brussels. Please find attached the preliminary programme.

This event will be organised jointly by the European Organisation for Research and Treatment of Cancer (EORTC) and the European Clinical Research Infrastructures Network (ECRIN) on behalf of the Roadmap Initiative for Clinical Research in Europe. Please find detailed information on this initiative in the attached document.

This workshop will explore the experience of the clinical research stakeholders with respect to pharmacovigilance management in clinical trials. Due to the transposition of the Clinical Trial Directive at the national level, the process for suspected unexpected serious adverse reactions (SUSAR) notification to the concerned parties varies from one country to another. Reporting requirement represents a significant and counterproductive amount of work for the sponsors, the competent authorities and ethics committees without proved added value for the patient.

The workshop will examine proposals for a more appropriate pharmacovigilance reporting in Europe. The ultimate goal is to produce ground for recommendations which will be discussed during the final Stakeholder Conference in Brussels on the 17th March 2010 in advance of the review of the Clinical Trial Directive planned by the EU.

We would very much like to invite you to participate to the workshop.

There is no entrance fee. Coffee and lunch will be provided. The presentations will be in English. No translation will be provided. For instructions on how to arrive to the EORTC, please consult <http://www.eortc.be/about/map.htm> .

Since the number of seats is limited, please confirm your participation at your earliest convenience before the 7th December 2009 (Contact person: Stéphane Lejeune, Tel: +32 2 774 10 75, stephane.lejeune@eortc.be). You will be provided with a confirmation email.

Looking forward receiving your answer,

The Programme Committee,

D Bertram

G Calvo

J Demote

N Dubois

J Flament

I Klingmann

S Lejeune