GROUPE REVISE – GROUPE DE REFLEXION SUR LA VIGILANCE ET LA SECURITE DES ESSAIS
THE ACADEMIC CLINICAL TRIAL SAFETY WORKING GROUP

Fédération Hospitalière de France – Coordination des Promoteurs Institutionnels – Comité National de Coordination de la Recherche.

COMMENTS ON THE PUBLIC CONSULTATION DOCUMENT
DRAFT DETAILED GUIDANCE ON THE COLLECTION, VERIFICATION AND PRESENTATION OF ADVERSE REACTION REPORTS ARISING FROM CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE ('CT-3')

I. INTRODUCTION

The French academic clinical trials safety working group (REVISE: groupe de REflexion sur la VIgilance et la Sécurité des Essais) was created in 2007 on behalf of the French Hospital Federation (FHF) and of the French Academic Sponsor Coordination (CPI) to face the implementation of the EU Clinical Trials Directive (2001/20/EC) among non-commercial sponsors. REVISE gathers more than 80% of the French University Hospitals' safety clinical trials departments and the majority of French non-commercial sponsors. This French academic working group includes over 40 stakeholders.

II. COMMENTS

Preamble : this new detailed guidance appears to be very practical and to leave less room for interpretation. However, a short reminder on the responsibilities of both the sponsor and investigator should be added (done in the ENTR/CT 3) at the beginning of this guidance.

2. REPORTING OF SERIOUS ADVERSE EVENTS BY THE INVESTIGATOR

POINT 16 : a clear definition of the important medical event is welcome.

POINT 19 third Line : BY THE INVESTIGATOR should be added in the following sentence to be clear and without ambiguousness: "therefore, the immediate report should be made BY THE INVESTIGATOR within a very short period …..".

4. REPORTING OF SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTIONS BY THE SPONSOR

POINT 28 : References on the NIMP guidance should be added [Guidance on Investigational Medicinal Products (IMPs) and other medicinal products used in Clinical Trials - To be included in The rules governing medicinal products in the European Union - Volume 10 Clinical Trials - Notice to Applicants - Chapter V Additional Information] + [Definition of Investigational Medicinal Products (IMPs) - Definition of Non Investigational Medicinal Products (NIMPs) - To be included in The rules governing medicinal products in the European Union - Volume 10 Clinical Trials - Notice to Applicants - Chapter V Additional Information - Questions and Answers].

POINT 35 : it should be clearly expressed that the investigator has to report SUSAR without time limit even after the termination of the clinical trial if a causal relationship is suspected between the event and the IMP.

POINT 36 : it is not clearly stated here that the sponsor has to assess seriousness too.

POINT 40 : it is not clearly stated here that the sponsor has to assess causality too.

POINT 44 : the expectedness is normally done by the sponsor.

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POINT 46 : the term **ONLY** should be added at the beginning of the first sentence just to be unequivocal [*for non commercial sponsors that have agreement with pharmaceutical industries, for supplying IMP for example, a SUSAR is often reported 2 times in EVCTM (by the non commercial sponsor and by the pharmaceutical industry)].*

POINT 57 : the sponsor verifies whether the anticipated therapeutic and public health benefits continue to justify the risks → a sentence should be added on the responsibilities of the sponsor when the benefits do not justify the risks as it is mentioned on **POINT 96**.

POINT 66 : If the follow-up information is received after the 15 days reporting timeline, information should be reported as a follow-up report within 15 days → this delay is also applicable for fatal or life-threatening cases ? Moreover, this point seems to be confusing with **POINT 88**.

POINT 83 : For EVCTM it is stated that the data in free-text fields should be entered in English and **POINT 107** mentioned that some translations can be used. → All the cases reported to EVCTM should be in English.

POINT 89 : Definitively yes but the article 7 of the CT directive is far from being applied for all the Member States

POINT 98 : References on the NIMP guidance should be added [Guidance on Investigational Medicinal Products (IMPs) and other medicinal products used in Clinical Trials - To be included in The rules governing medicinal products in the European Union - Volume 10 Clinical Trials - Notice to Applicants - Chapter V Additional Information] + [Definition of Investigational Medicinal Products (IMPs) - Definition of Non Investigational Medicinal Products (NIMPs) - To be included in The rules governing medicinal products in the European Union - Volume 10 Clinical Trials - Notice to Applicants - Chapter V Additional Information - Questions and Answers].