SIOP EUROPE STATEMENT ON THE PROPOSED INTRODUCTION OF AN ‘END OF TRIAL CLINICAL STUDY REPORT’ IN THE EU CLINICAL TRIALS REGULATION

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SIOP Europe, the European Society for Paediatric Oncology (SIOPE), representing the paediatric and adolescent oncology clinical research community across Europe, welcomes the proposal to increase the transparency of clinical trials carried out in the EU. The European Commission, in its proposal for an EU Clinical Trials Regulation (COM (2012) 369 final) to revise the EU Clinical Trials Directive (2001/20/EC), has encouraged the disclosure of clinical trials through the publication of a “summary of trial results” within a year of the end of the trial.

Since the Commission tabled its proposal, the debate on the EU Clinical Trials Regulation (CTR) particularly in the European Parliament has shifted around disclosure and transparency issues and on whether, how and when the results of the clinical trials should be disclosed.

The European Parliament is currently considering an amendment, for an end-of-trial Clinical Study Report in accordance with the guidelines provided by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) on the structure and content of clinical study reports (ICH E3). However, we consider that the ICH E3 guidelines, which were created in 1995, are outdated in the context of current trials and the stipulations outlined in the EU Clinical Trials Directive legislation (introduced in 2001). Moreover it is not a relevant format for all trials. See attached the joint statement on this issue by the Birmingham Centre for Clinical Trials at the University of Birmingham, which is strongly endorsed by SIOPE.

The SIOPE community supports the need for transparency of clinical trial results but only after appropriate public consultation.

- It is important to underline that any regulatory or governance requirements that codify these principles should be drafted with great care and consulted on widely to prevent any unintended adverse consequences.

- Currently, all clinical study data for a new drug are submitted and assessed by the regulator, the European Medicines Agency.

- **Eudra CT is currently not efficient.** Efforts were made in 2004 to enhance transparency through the introduction of the Eudra CT, an online database of all clinical trials. Registration of clinical trials on Eudra CT is compulsory, in order to acquire a Eudra CT trial number for regulatory and ethical approval. However, one of the major shortcomings of this website is that it is not accessible to the public and still has reserved access for competent authorities only. SIOPE encourages greater open access efforts to this...
platform for all stakeholders and a more efficient tool that can increase transparency in Europe.

- **We support the disclosure of trial summaries, as proposed in the draft legislation.** But criteria for what a summary should contain in a reasonable format should be detailed, but not based upon the ICH E3 guidelines, which, as per the attachment, are completely outdated. Trial summaries, unless with a very clear definition of what they should contain, will vary in form and are vulnerable to bias. It may be useful for a new annex to be created setting out what should be contained in such a summary. Raw data should not be included in the summary.

- **SIOPE believes that the protection of the patient and patient data are essential.** Given the sensitive nature of the data from the perspective of the trial participant, it is not appropriate to make all trial data publicly available online. Data recipients should be identified and access should be controlled, although if this is the case it is not at all clear currently who can monitor the safeguarding of this access. Complete access to data could have detrimental consequences for patients and private information related to their health. Patients with rare diseases like childhood cancer are under threat from their data being unprotected, even if the data is anonymised. For those that had a life-threatening disease like cancer during their youth, this is particularly sensitive as they try to live a normal life once cured. As 80% of patients with paediatric cancer survive, protecting patients’ personal data is extremely important.

- **Clinical trial data summaries and/or reports should not contain any line listings or raw data** (personal data of trial participants) which apart from privacy issues are not being made available in a usable nor easily interpretable format and do not meet the true principles of transparency.

- **Increased transparency should not increase unnecessary administrative bureaucracy associated with clinical trials.** This would undermine the European Commission’s efforts to support the academic community in undertaking clinical trials in Europe, a key objective of the proposed EU CTR.

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BACKGROUND INFORMATION ON SIOP EUROPE

**SIOP Europe, the European Society for Paediatric Oncology**

SIOP Europe is a specialised network of health professionals working in the field of childhood cancers in Europe. It is the only multidisciplinary, pan-European organisation dedicated to paediatric oncology and it exists to address the main challenges in childhood cancer such as promoting and supporting collaborative clinical trials within Europe, furthering education and training for health professionals, increasing awareness on and around childhood cancers and improving information exchange and dissemination across borders.

Established in 1998 with an office based in Brussels since 2007, SIOP Europe is the continental branch of SIOP (the International Society of Paediatric Oncology), a Founding Member of the European CanCer Organisation (ECCO), and a member of Eurordis – Rare Diseases Europe, the European Forum for Good Clinical Practice (EFGCP) and Rare Cancers Europe. Representing multinational clinical trials groups and national childhood organisations, SIOP Europe develops novel strategies for cancer awareness, cancer diagnosis, and cancer treatment focused on children.

Aware that a highly dedicated multidisciplinary approach to treatment as well as investing in high-quality clinical research can greatly increase survival rates, SIOP Europe actively encourages greater coordination of clinical trials activity in Europe, as well as supporting education and exchanges between all professionals working in the field of paediatric oncology. SIOP Europe additionally maintains strong links with national patient organisations ensuring a strong patient perspective is maintained, as well as keenly promoting information dissemination of the latest development in cancer research and EU policy. Moreover, SIOP Europe leads on the dissemination of the EU-funded Network of Excellence, ENCCA – the European Network for Cancer research in Children and Adolescents.

For more information on SIOP Europe, please visit our website, [www.siope.eu](http://www.siope.eu) or contact Edel Fitzgerald at edel.fitzgerald@siope.eu.

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