

SIOPE Clinical Trials Working Groups

Background:

SIOPE is currently working on the setup of *the clinical trials support desk* in order to facilitate future paediatric oncology trials. Therefore we are currently launching a call for experts in the field who would like to participate and share their expertise with others via one of the different **Clinical Trials Working-Groups** that have been setup with each their specific clinical trial topic: Protocol Guidelines, Regulation and Ethics.

Topics and tasks of three SIOPE Clinical Trials (CT) Working Groups

1. **Protocol Guidelines Working groups (1WG)**
 - Standardisation of protocol templates for Phase II and III trials
 - Creation standard template for data collection and CRF design including the following requirements:
 - Defining the minimum and maximum required data
 - Advising on toxicity data collection (Pan European definitions on SAE and SUSARs)
 - Creating the end of treatment summary forms
 - Standardising (procedures) for long term follow up beyond the trial

2. **CT Regulation Working groups (2WG)**
 - Balance of clinical trials versus the best practice guidelines
 - Pan-European clinical trial sponsorship
 - Pharmacovigilance and safety
 - Monitoring and audit requirements in clinical academic trials
 - Trans-european harmonisation and implementation of expedited reporting of SAEs and SUSARS
 - Role of Data Monitoring Committees
 - Pan European harmonisation of sponsor duties in academic trials
 - Declaration of IMP's
 - Creation of CTA (Clinical Trials Application process)
 - Risk based requirements for insurance in clinical trials
 - Central European registration and information on clinical trials open to public
 - Recommendation to standardise documents such as the structure of trials master file (TMF)

3. **CT Ethics Working groups (3WG)**
 - Review key ethical differences for paediatrics across Europe
 - Age of competency
 - Need for parental consent
 - Attitude to phase I trials
 - Guidance towards harmonisation for the composition and working procedures of administrative authorities
 - Ethical review standards and procedures for EU member states
 - Educational programmes for officers and
 - Setup key items for patient information and consent forms
 - Including consent for access to tissues for research
 - Consent for future contact for long term follow up
 - Work on the national regulation on tissues storage and use in research
 - Consent to share tissues outside of countries and the EU
 - Permission to share with potential commercial benefits of the pharma
 - Generic consent for future research

Your feedback is needed !!!

Please fill in the following page and answer the questions if you are interested to work with SIOPE:



Questionnaire

Name:

Contact address / Hospital:

Email address:

Position:

I am willing to support building a Clinical Trial's Facilitation Group within SIOPE: Yes - No

I am willing to actively contribute to this work with SIOPE Yes - No

I am engaged with the following trial group (s):

I am /have been chairing a trial: Yes - No

I previously had an active role in creating a new trial: Yes - No

I have developed documents for trial management: Yes - No

Which type of documents (examples) ?

I would like to be part of the following Working Groups (please select): Yes - No

1 WG 2 WG 3 WG

I do have a special interest in the following topics:

I am able to contribute preexisting documents for the New SIOPE CTM platform: Yes - No

I am ready to transmit electronic information Yes - No

I am ready to actively participate in working meeting in Brussels Yes - No

I am interested to take a lead (chair /co chair position) in one of the Working Groups Yes - No

I accept to join 2 to 3 working meeting to create this common platform Yes - No

End of January Middle March End of April

I suggest the following key person to be contacted to become part of this group Yes - No

Please keep me informed and invited Yes - No

Comments /Suggestions:

Thank you very much for this information