EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK - TRANSNATIONAL WORKING GROUPS

ECRIN-TWG

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Work package 6: **Transnational working group on standard operating procedures**

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1 Background

In the first part of the project the Working Group 6 on Standard Operating Procedures proposed a frame for the development of the ECRIN SOPs for multinational studies and a list of SOPs to be developed in order to facilitate the conduct of multinational studies (see Deliverable 15).

The general framework and the delineation between the different categories of research were given by the survey on regulatory requirements that was performed by the working group 2 "regulatory affairs and interaction with competent authorities".
According to the results of this survey, seven categories of research were considered that required the development of guidelines and procedures:

- clinical trials on medicinal products
- clinical trials on medical devices
- other therapeutic clinical trials (radiotherapy, surgery, transplantation, transfusion, physical therapy, psychotherapy)
- diagnostic studies
- nutrition studies
- other clinical research (physiology, pathophysiology, psychology, biobanks, complementary and alternative medicine)
- epidemiology

The first focus of the network was the development of tools for clinical trials on medicinal products with the objective to further develop tools for the other categories when needed.

2 Achievements and next steps

The first set of SOPs was developed through cooperation between the working group on quality assurance and the working groups on ethics, regulation, vigilance, and monitoring (see deliverables 16/18/19/20/21) in order to provide information on how to:
Develop an informed consent
Interact with ethics committees
Interact with competent authorities
Obtain EudracT number
Archive ECRIN studies
Monitor ECRIN studies
Report adverse events
Perform logistics of IMP
Manage blood and tissues samples

After completion of a draft version of this first set of SOPs, some questions were still under discussion within the Network and working groups and in particular:

- the format of the SOPs
Lots of information from the different countries were collected and included in the SOPs. For the SOPs on interaction with ethics committees and with competent authorities, all the practical information were removed from the SOP and one instruction per country issued.
This approach can be used for the other SOPs leading to shorten the SOP with only the description of WHO DOES WHAT according to the definition of a standard operating procedure, and to write guidance documents referring to the content, as repository of knowledge and know-how, and subject to more frequent changes.

- the task delegation and the type of activity of ECRIN
The nature of the quality assurance system is highly dependent on the **type of activity of ECRIN**. Different models can be proposed to describe the ECRIN activities:

- Full services model: contract with sponsor, and ECRIN staff involved in all the steps of provision of services
- Delegation model: services through a task delegation contract with sponsors on the one side, and with the national networks on the other side, taking advantage of existing resources in the national networks
- Consulting and information
- Matchmaker : facilitating contacts

Depending on the model used or proposed, the quality management strategies may differ.
The services that will be provided can be centralised (data management, etc..), or distributed (monitoring, interaction with EC and CAs, etc..). Sharing of responsibilities will be achieved through a task delegation contract with the sponsor, and framework agreements with the national counterparts of ECRIN. In this case also the requirements regarding quality management may be different according to the type of service.

For all these reasons the set of standard operating procedures developed was considered as a final draft version, and before releasing the SOPs, ECRIN should address the following:

- Discuss the content of the SOP and the need to develop guidance document or instructions to keep the SOP as focussed as possible on "Who does what"
- List the SOPs existing at the national level (centres and networks) in the various countries and start defining target requirements for the bottom-up development national SOPs systems
- define a strategy for the development of national SOPs systems
    - use of a common template ?

  - use of skeleton procedures with addition of country specific content?
  - implementation of a national SOP system with local adaptations?
  - or free development of SOPs at the centres based on the requirement defined by ECRIN ?
- the language issue: national SOPs should be written in national language, therefore not understandable by foreign staff. This means that a certain amount of country-specific data should be present in the ECRIN.

This will be the first activity of the WP 8 (quality assurance unit and working groups on ethics, regulation, adverse event reporting, monitoring) of the ECRIN PPI project.