

PROTOCOL

Review Infosheet



What is protocol reviewing at EATG?

On an ad hoc basis, EATG is contacted by a variety of stakeholders (mainly pharmaceutical companies) to conduct reviews of documents and protocols.

Types of document for review:

- Clinical protocols
- Patient leaflets
- Guidelines
- Other scientific materials

What kind of roles are possible?

Observer reviewer

Members who have no or little experience as reviewers are invited to participate as observers. Observers are not asked to provide feedback and won't receive compensation, but will have the opportunity to learn from the process.

Active reviewer

Active reviewers are split in to 2 pools: experts (those who have conducted more than 5 reviews) and supported (those who have conducted less than 5 reviews).

Coordinator

The review coordinator is selected from the expert review pool and communicates with pharmaceutical companies and coordinates the review process inside the group.

Desired member profile

- Clear understanding of HIV (or Viral Hepatitis, other related coinfections R&D science and recent pipeline)
- Understanding of inclusion criteria and recruitment processes for CT
- Expertise in reviewing protocols for CT
- Fluency in English

Remuneration

Selected reviewers and coordinators who complete their tasks will be remunerated by EATG.

Training Opportunities

For protocol review pool members, EATG can provide training and cover certificate costs of online EUPATI modules, such as:

INTRODUCTION TO MEDICINES DEVELOPMENT

- Process of medicine discovery and development
- Role of patients and PO in medicine development
- Concepts of evidence-based medicine and outcome research

CLINICAL DEVELOPMENT

- Clinical trial and trial management
- Trial participants' rights and obligations
- Ethics
- Statistics
- Documentation and management
- Interpretation and dissemination of results