ASTERIX Collaboration model with third parties

Introduction

ASTERIX is a novel FP7 project focusing on the development of more efficient and effective research designs to study new drugs and treatments for rare diseases. The overall aim is to stimulate the search for treatments for these devastating and largely ignored diseases.

This document describes the model of ASTERIX to collaborate with third parties not involved as partner in the project.

Scope of collaboration

ASTERIX is open for collaboration with third parties, like pharmaceutical companies, if that will support the primary research goals of ASTERIX. Typically, collaboration will be considered if

(1) it will enhance the potential for implementation of results, or

(2) it will improve the quality of results, e.g. by making these more acceptable or generalizable to a wider field of application.

ASTERIX will ensure that the involvement of any third party will not affect the rights and obligations of any partner under the ASTERIX consortium agreement and is not in conflict with the FP7 contract agreements.

The research aims and questions as well as the expected results of the collaboration should be clearly described and the collaboration should *not* serve commercial nor political interests.

Conflict of interest

The collaboration between ASTERIX and the third party should avoid any conflicts of interest. It will specifically exclude a collaboration that can be judged as direct service or advice to a third party. Collaboration will in that sense always be pre-competitive.

Researchers and Advisory Board members of ASTERIX are involved in regulation of drugs (such as member of a Working party of EMA). As such collaboration with only one commercial company cannot take place, because this would cause conflicts of interest. Companies are welcome to share data and knowledge, and in return ASTERIX will report on new developments in methodology, but NOT exclusively to one company: information should be open to everybody, with no preferential position for specific third parties.

Lastly, companies collaborating cannot derive any rights from the interaction with Asterix, nor can any of the recommendations on clinical trial methodology to be made by the Asterix project be interpreted as regulatory advice or opinion on any specific new drug.

Procedure

1. After a request for collaboration with a third party through any of the consortium partners the Executive Board (EB) will be informed.

2. The scope of the potential collaboration should be determined. In particular the research aims and questions, the timeframe of the collaboration, the expected results as well as the benefits and risks for both ASTERIX and the third party should be described.

3. The written proposal will be brought to the EB for consideration.

4. If the EB is in favour of the proposal, it will discuss the potential collaboration with the Advisory Board (AB) to ensure that other stakeholders are in agreement with the proposal.

5. Depending on the nature of the third party and the type of collaboration, the EB may judge it relevant to ask the Ethics Advisory Board (EAB) also for advice.

6. If the EB unanimously agrees in favour, after AB and EAB (if indicated) recommendation, the EB and the third party will document and sign the collaboration agreement.

7. Thereafter the collaboration will be published on the ASTERIX website.

8. The results of the collaboration will be publicly available on our website.

9. The EB will monitor the collaboration and will discuss its progress in the EB meetings. If needed the EB will take appropriate actions.