efpia
European Federation of Pharmaceutical Industries and Associations

ENCePP Code of Conduct

Perspective from the Industry

Why the industry did not adhere so much to the CoC?

16th ENCePP Plenary Meeting – 21 November 2017

Current version of the Code of Conduct (14.07.2016)

5. General Provisions

By agreeing to follow the Code, investigators and study funders commit to adhere to the following general principles:

- The primary purpose of a study shall be to generate data of potential scientific or public health importance and not to promote the sale of a medicinal product;
- The design of the research shall not be aimed towards producing a pre-specified result;
- The results of a study shall always be published, preferably in a peer-reviewed journal, or made available for public scrutiny (e.g. via the EU PAS Register) within an acceptable time frame, regardless of the (positive or negative) results and the statistical significance; the EU PAS Register should be used as a repository for reports including those pending publication and those not published in a peer-reviewed journal in the ways specified in the protocol, and reference the final publication;
- Relevant information on the research process and results shall be made publicly available or on request as specified in this Code;

We all agree on these general provisions

Current version of the Code of Conduct (14.07.2016)

Main principles

- Scientific independence
- Transparency

Current version of the Code of Conduct (14.07.2016)

Main principles

- Scientific independence

Challenges in its concrete implementation within the context of industry-funded studies performed for regulatory purpose

- No possible ‚supervision' of the study conduct after protocol approval when the Sponsor is legally responsible of the study conduct
  - Accountability can not be passed on someone else
  - Need to ensure performance and deliverables (penalties)
- Epidemiology expertise available which can bring value to the study
- Focus on the independence regarding the study founder when there are also other potential conflicts of interest

6. Scientific Independence

For all studies, whether (partially) financed from external sources or not, the following principles of scientific independence apply in addition to the general provisions above:

- The highest level of scientific independence is desirable from agreeing the research contract through to protocol development, implementation of research, data analysis and publication of results;
- A contract shall be concluded between the (primary) lead investigator or the coordinating study entity and the study funder clearly defining the research assignment and addressing in sufficient detail critical areas of their interaction such as remuneration, protocol agreement, data analysis and publication of study results;
- Remuneration shall only be granted as specified in the research contract and shall not depend on the study results;
- The protocol must be designed to ensure scientifically valid and sound results are generated independently from any potential conflicting interest of the funder or the researcher (see Chapter 12).
- Once the protocol has been finalised, no person with a financial, commercial or personal interest in a particular outcome of the study shall take part in any study activity that could influence the results or interpretation thereof in any particular direction;
- The (primary) lead investigator has the unrestricted freedom of independent publication of the study results irrespective of data ownership (see Chapter 13);
- The study funder shall be entitled to comment on the results prior to submission of the publication. The (primary) lead investigator is free not to take the comments into account;

Current version of the Code of Conduct (14.07.2016)

Main principles

- Transparency

As currently stated in the CoC does not represent an issue

The following means of ensuring transparent research are required by the Code:

- Registration of the study in the EU PAS Register thereby making information on the study such as expected timelines publically available;
- The study entry in the EU PAS Register should be regularly updated to reflect and justify any changes during the study, such as protocol amendments, and to include an abstract/synopsis of the study results or links to all publications arising from the study on study completion;
- Agreement to make available on request relevant information including:
  - reports from independent reviewers,
  - a detailed description of how the raw data were transformed into the data set used for analysis as well as the data set for analysis and all scheduled interim and final study findings once the final study report is available (see chapter 13 and 15 as well as Annex 4 *Implementation Guidance for Sharing of ENCePP Study Data* for details),
  - for studies that are (partially) financed from external sources, the content of the research contract (actual financial figures may be redacted[8]),
  - for self-funded studies, a declaration on the use of own resources, making clear reference to the study and the (primary) lead investigator(s) and signed by (an) authorised representative(s) of the participating study entity/ies.
- State in advance and in publications the affiliations of the investigators and any conflicts of interest.

Revision of the Code of Conduct

Welcome by the Industry

- To get a more clear definition of scientific independence
- To ensure that the Industry can fulfill its legal obligations in following the CoC
- To allow some flexibility in the study team structure, as defined in the research contract
- To support better collaboration, and get an increased trust, between all involved stakeholders