

## SOP 10: Study Report and Publication

### Study Report

It is the responsibility of the sponsor of a clinical study that the results of that study are being analyzed and reported. Preferably, an integrated study report should be prepared that complies with the ICH guideline E3: Structure and Contents of a Study Report. The discussion and medical conclusions of the study report have to be based on the analyses of the data as presented in the statistical section of the report or in a separate Statistical Report (see 'SOP 09: Statistical Design and Analysis'). The report must discuss the quality assurance measures used (see 'SOP 11: Quality Assurance') and the implications of the results for the further development of the investigational drug(s) and for the disease-related treatment options.

The manuscript for publication must be prepared on the basis of the study report.

### Responsibility for Publication

The Coordinating Investigator (CI) is responsible for the publication of the study results, according to the bylaws (XIV).

In particular, it is his/her job to select the authors for a publication, to determine the order of authors, to designate an author to prepare the draft, and to choose the journal to which the manuscript shall be submitted. In case of disagreement, he/she should try to find a consensus but finally the results determined in the bylaws have to be followed.

### Authorship for Publications

Every publication (abstracts as well as full papers) must include a statement to the effect that the study was performed by CESAR. In addition, all investigators and the sponsor should be acknowledged in the appropriate location of a full paper.

All publications on clinical studies that were conducted under the auspices of CESAR have to comply with the statutes of CESAR. In brief, the following rules will apply:

In these publications the name CESAR has to be mentioned in capital letters in the title and/or under the authorship. Results deriving from collaborative internal work of CESAR has first to be published as CESAR publication as long as this has not been otherwise agreed upon, e.g. with the sponsor.

No such information may be provided outside of CESAR without written acceptance by the president of CESAR, the vice-president of CESAR, or the chairperson(s) of the working group, the CI, and the sponsor unless otherwise agreed upon in writing. Each of these individuals/parties has to have a period of 30 days to react. Thereafter, in case of lack of response, the application is approved.

The CI has to consider the following individuals as authors for a publication:

The CI and the investigators who have contributed significantly to the study by entering evaluable patients. In case of phase I studies the CI will be the first author only under the condition that his patient allocation to the study was equivalent to the mean contribution of all study participants. Individuals who have performed and evaluated pharmacokinetic investigations have to be considered equivalently. In addition to these, the chairperson(s) of the respective working group, the biostatistician, the data manager and last but not least the president or vice-president of CESAR will be considered as coauthors.

Authorship for phase II and phase III studies comprises the CI as first author under the condition that his patient allocation to the study was equivalent to the mean contribution of all study participants. In addition, coauthorship will be guaranteed to investigators of those 5 institutions with the main contribution – in order of their patient recruitment – and double coauthorship to investigators of institutions entering  $\geq 20\%$  of all patients of a study.

Further persons to be mentioned as coauthors are the same as detailed above for phase I procedure.

The sponsor will be coauthor only upon separate agreement.

Persons who have additionally contributed to the results of a study, not indicated in detail above will be mentioned under 'Acknowledgement'.

In addition to these, other individuals who have made substantial contributions to the study may be chosen as coauthors. An investigator who has been excluded from the study for any of the reasons specified in 'SOP 06: Selecting the Participating Centers and Activation of a Trial' will not be listed as coauthor.

### **Time Schedule**

Completion of the study report in the shortest possible time should be attempted to ensure that decisions on further studies can be based on valid analyses and conclusions on preceding studies. Usually, the signed study report should be available within 2 months after receipt of the statistical report or the respective report section of the integrated report. A longer period may be acceptable under certain circumstances, for example, if completion of test drug or metabolite assays are time-limiting for the completion of pharmacokinetic analyses.

A first manuscript draft for publication is to be written not later than 3 months after receipt of the statistical report. In case the CI does not respect these time lines, the chairperson(s) of the leading working group will determine an alternative principal author. The coauthors (including the sponsor's representative) must submit their written approval of the manuscript or request for modification(s) to the principal author within 4 weeks after receipt of the draft. In case they do not respond, their tacit agreement is assumed.

### **Publication of Data from an Ongoing Study**

As stipulated above, the policy is that any publication is written on the basis of a formal report that has passed appropriate quality control procedures. For this reason, interim results may only be published if these are backed up by an interim analysis that has been performed or approved by the data center of CESAR. As a rule, abstracts written before an official report has been prepared should only present the study design, the current status of patient accrual and the expected dates of closure of patient accrual and presentation of the final report. No interim results on a primary endpoint should be published from an ongoing study.

### **Publication of Data from Single Institutions**

An investigator who wishes to separately present the data that his/her institution has contributed to a study of CESAR may do so only after a joint publication of the results by the study group is available. Nevertheless, also for doing so, a written acceptance by the president of CESAR and the vice-president of CESAR must be given.

In case of persisting refusal of the acceptance of several publications by the president(s) of CESAR, the general assembly may be approached by the applicants for a final decision.

### **Press Release and Information to the Public**

Information about study results at the request of the press or the public may only be given by the CI after consultation of the sponsor and the chairperson(s) of the working group or the president(s) of CESAR.