

Title:	Publications	
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<i>Author name</i>	<i>Signature</i>	<i>Date</i>
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<i>Approver name</i>	<i>Signature</i>	<i>Date</i>
J.J. Cornelissen		7-12-2017

Related information:

International committee of medical journal editors recommendations, "defining the role of authors and contributors"

Publication policy for trials sponsored by HOVON

Final publication of trial results

Trial results will always be submitted for publication in a peer reviewed scientific journal regardless of the outcome of the trial – unless the trial was terminated prematurely and did not yield sufficient data for a publication. Premature termination per se is no reason for not writing a manuscript.

The final publication of the trial results will be written by the Principal Investigator, the Co-investigators and the trial statistician on the basis of the statistical analysis performed by the trial statistician. A draft manuscript will be submitted for review to:

- ◆ All authors
- ◆ The chair of the relevant HOVON working group, who is entitled to share and discuss the manuscript with working group members. This discussion is to be regarded as confidential.
- ◆ An industry partner if so agreed in the contract between HOVON and company

After revision the final manuscript is submitted to the HOVON Manager for review of compliance with this policy. All diversions from this policy will be well documented and reported to the authors and chair of relevant working group. After approval of all involved parties the manuscript will be sent to a peer reviewed scientific journal.

Sharing trial results with patients

Once the main manuscript with the trial results has been published digitally or in writing, in a scientific journal, the Principal Investigator will write a summary of the trial results using language that can be understood by patients. The summary will be submitted (in Dutch) to the patient organization Hematon for publication.

The Principal Investigator will collaborate with Coordinating Investigators to publish a summary of the results for patients through appropriate channels in other participating countries, if possible.

Authorship

Authors of the main manuscript include the Principal Investigator, the Coinvestigator(s) and Coordinating investigator(s), the local investigators (by order of inclusion rate of evaluable patients) and the trial statistician. If a substantial part of the publication is based on centrally reviewed data (e.g. cytogenetics, pathology or imaging), the central reviewer will be included as author. Others who have made a significant contribution to the trial may also be included as author, or otherwise will be included in the acknowledgement.

Authors of correlative manuscripts (e.g. results of side studies) will include the Principal Investigator, the Co-investigator(s), Coordinating investigator(s) and those persons who have made a significant contribution to the published results.

The Principal Investigator should discuss and decide on the matter of authorship of the main manuscript prior to the start of the trial – with the exception of authors included on account of inclusion rate. The Principal Investigator is urged to use the maximum number of authors allowed by the journal to the full extent.

DSMB members of a trial may not be mentioned as 'authors' in manuscripts concerning the respective trial.

Authorship arrangements:

- 1 The order of the contributors reported as 'authors' is as follows:
 - a. Principal Investigator
 - b. Co-Investigator(s); in alphabetic order if more than 1
 - c. Coordinating Investigator(s); in alphabetic order if more than 1
 - d. Statistician(s); in alphabetic order if more than 1
 - e. Local Investigators
- 2 Local investigators are mentioned in order of inclusion of evaluable patients until the maximum number of authors of the respective journal is reached.
- 3 If multiple authors have include equal numbers of evaluable subjects, authors are mentioned in alphabetic order.
- 4 If the maximum number of authors is reached half way the selection of authors who have all included an equal number of evaluable subject, none of them will be mentioned as author. For example: 8 local investigators have included 10 evaluable subjects, however only 6 of them can be reported as author because of the maximum number of authors. In this case none of the investigators who have included 10 evaluable subjects will be mentioned, only the investigators who have included 11 or more evaluable subjects.
- 5 All investigators that have included evaluable subjects but are not mentioned as author and a 'writing group' is not supported by the respective journal, will be mentioned in the acknowledgements.
- 6 The HDC trial team must be thanked for their efforts in the acknowledgements. They will be referred to as the 'HDC trial team', no individual trial managers and/ or central data managers will be mentioned.

Interim and partial publications

Interim publications, abstracts or presentations of the study may include demographic data, overall results and prognostic factor analyses, results for secondary endpoints, but no comparisons between randomized treatment arms for the primary endpoint or secondary endpoints may be made publicly available before the recruitment is discontinued.

Investigators participating in the trial have a right to publish results from their own patients who participated in a study. The Principal Investigator, the Co-investigator(s) and the trial statistician must approve any such publication, abstract or presentation based on patients included in this study. This is applicable to any individual patient or any subgroup of the trial patients. Such a publication cannot include any comparisons between randomized treatment arms unless the final results of the trial have already been published.

Abstracts and presentations

Abstracts and presentations at public meetings will represent the trial as a project under HOVON affiliation. The abstract or presentation should not be represented under affiliation of the working group or a specific hospital.

Slides will be designed using the HOVON style template and any other presentation materials will show the HOVON logo.

If the trial is conducted in partnership with a co-sponsor (e.g. intergroup trial), the abstract and presentation should represent the co-sponsor contribution and slides may show the co-sponsor logo in addition to the HOVON logo.