POLICY

Publications

ID:	HCB-GM-COMM-171-1-POL	KMS Version:	**1**

1. PURPOSE

This Policy describes and explains how HOVON handles trials result publications.

2. SCOPE

This Policy applies to the HOVON Foundation.

3. TERMS & ABBREVIATIONS

Term / Abbreviation	Definition
DSMB	Data Safety Monitoring Board
HOVON DB	HOVON Executive Board
PI	Principal Investigator

4. REQUIRED & RELATED DOCUMENTS

Type	Document title
N/A	

5. POLICY

5.1 PUBLICATION POLICY FOR TRIALS SPONSORED BY HOVON

All publications of final and interim results of a trial will be written by the PI, the Co-investigators and the Trial Statistician on the basis of the statistical analyses performed by the Trial Statistician. A draft manuscript will be submitted for review to:

- All authors
- The Chair of the relevant HOVON Working Group
- An industry partner if so agreed in the contract between HOVON and company.

It is the duty of the PI and the Chair of the relevant Working Group to review the final manuscript of compliance with this Policy. After approval of all involved parties the manuscript will be sent to a peer reviewed scientific Journal.

5.2 FINAL PUBLICATION OF TRIAL RESULTS

Trial results will always be submitted for publication in a peer reviewed scientific Journal within 6 months after the final Study Report 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. In case of no publication of the final results of a trial, the PI should contact the HOVON DB.

5.3 INTERIM AND PARTIAL PUBLICATIONS

Only interim analyses as described in the Protocol of the study can be used for publication purpose, taken into account the precautions as stated below. Interim analyses should be not be extended for publication reasons only.

5.4 RANDOMIZED TRIALS

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. The primary endpoint analysis on which the study is powered should be protected in all cases.

5.5 NON-RANDOMIZED TRIALS

Interim publications, abstracts or presentations of the study may include demographic data, and prognostic factor analyses, results for secondary endpoints. In case partial results on the primary endpoint (or strongly related to the primary endpoint) be aware to protect the primary endpoint analysis, especially when the study is still accruing patients. Secondary endpoints may only be made publicly available if not directly related to the primary endpoint analysis, and if part of planned interim analyses as described in the protocol.

Investigators participating in the trial have a right to publish results from their own patients who participated in a study. The PI, 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.

5.6 SIDE STUDIES

Publications of side studies should always contain a reference to the HOVON studies from which data are used. The PI should be included in any publications using data from his/her study unless specifically discussed with the PI and Chair of the relevant HOVON Working Group.

5.7 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 and any other presentation materials will be designed using the HOVON logo. If the trial is conducted in partnership with a collaborator (e.g. Intergroup Trial), the abstract and presentation should represent the collaborator contribution and slides may show the collaborator logo in addition to the HOVON logo.

5.8 DATA SHARING STATEMENT

Please check the HOVON Data Sharing Policy for more information on a data sharing statement in publications.

5.9 AUTHORSHIP

Authors of the main manuscript include the PI, the Co-investigator(s) and Coordinating Investigator(s), the Local Investigators (by order of inclusion rate of 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 PI, the Co-investigator(s), Coordinating Investigator(s) and those persons who have made a significant contribution to the published results.

The PI 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 PI is urged to use the maximum number of authors allowed by the journal to the full extent.

DSMB members of a trial must not be mentioned as 'authors' in manuscripts concerning the respective trial. Members of the DSMB will be included in the acknowledgements.

Authorship arrangements:

1. The order of the contributors reported as 'authors' is as follows:
   a. PI
   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 subjects, none of them will be mentioned as author. E.g. 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 'HOVON Data Center trial team', no individual Trial Managers and/ or Central Data Managers will be mentioned.

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

6. REFERENCE

Reference title	Reference source
Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. (version December 2018)	http://www.icmje.org/recommendations

7. DOCUMENT HISTORY

Version	Date	Description of change
1	09OCT2020	Policy version 6 (until to date controlled via V-schijf) has been updated, transferred to the new Policy template and uploaded to KMS for the first time. Therefore the version number of this Policy automatically changed from version 6 (V-schijf controlled) to version 1 (KMS controlled).

8. APPENDIX

N/A