

Publication Guidelines

Approved by the Steering Committee of the Hereditary TTP Registry on 6th of May 2019.

Version 1.0 (06.05.2019)

Content

1. Goals	2
2. Scope of the Guidelines and types of publications	2
3. Rights and ownership of data	2
4. Authorship	2
5. Required acknowledgement	3
6. Analysis Plan	3
7. Assessment of analysis plans, articles/manuscripts & congress abstracts	4
8. Time-lines for submission and review	5
9. Decision and approval	5
10. Expiration and number of analysis plans	5
11. Archives	5
12. Communication and organization	6
13. Chair and Committee members	6

Annex I Analysis Plan Form

Annex II Review Form

Annex III Flow-charts of review and decision processes of the Steering Committee

Abbreviations

AP	Analysis Plan
hTTP	Hereditary Thrombotic thrombocytopenic purpura
SC	Steering Committee
RF	Review Form
TC	Telephone Conference
hTTP	hereditary Thrombotic thrombocytopenic purpura
WAME	World Association of Medical Editors

1. Goals

- To coordinate the publications produced by investigators during and after (up to 10 years) the project life of the Hereditary TTP (hTTP) Registry study
- To encourage high quality publications produced in a timely fashion
- To encourage broad participation by hTTP Registry members, collaborators and affiliated investigators

2. Scope of the Guidelines and types of publications

The guidelines in this policy cover scientific articles/manuscripts, letters to the editor, meeting proceedings and congress abstracts that use data collected as part of the hTTP Registry. In addition, the guidelines cover publications from ancillary studies (defined as so-called sub-projects that involve the collection and analysis of new data and biological samples, other than defined in the hTTP Registry proposal; e.g. new data and/or samples directly obtained from enrolled patients). This policy remains in force and the Steering Committee (SC) of the hTTP-Registry assuming the function of the publication committee will remain active during a period of 10 years after the end of the hTTP Registry study.

3. Rights and ownership of data

The rights on the information entered into the hTTP Registry database do not change with their entry. The responsible local study site that enters the patient and family member information into the database can use their data freely for analysis and publication with the condition to acknowledge the Registry in their publication (see paragraph 5). The hTTP Registry can assist the site by exporting their data and providing these in excel format.

Publication of results from data of multiple sites from the Registry is governed by the current publication guideline and approval by the SC.

4. Authorship

Authors should participate in performing the study, analysing data and/or writing of the article in accordance with the policy statement about authors by the World Association of Medical Editors (WAME; <http://wame.org/authorship>). The first author will first make a list of authors with the senior author and at least one SC member, who serves as hTTP Registry “supporter” (see under 6). The first, senior author and supporter are responsible for the overall validity and quality of the manuscript. To encourage co-author participation, the first author should invite all co-authors to comment on the analysis plan (AP, see under paragraph 6) at a stage when co-authors may still

contribute to methods of analysis and to the writing of the manuscript. The SC has the right to assign additional co-authors to any paper resulting from the hTTP Registry, based on their contributions to the study and following WAME rules.

In view of the above:

- All articles/manuscripts and abstracts resulting from the Hereditary TTP Registry must include those members of the SC who are actively participating in the respective study as co-author.
- All site investigators contributing with data to the study will be listed as collaborators in a supplement of the manuscript, or will be listed as authors/collaborators in the manuscript and indexed in Pubmed (depending on the options the journal provides).
- Study sites that contribute with data from several confirmed patients should be considered for an authorship

The SC may decide to restrict the application of these rules in exceptional cases, if necessary to avoid exclusion of researchers, who have made substantial contributions.

5. Required acknowledgement

All articles, abstracts, and presentations (oral and poster) using data from the hTTP Registry database or ancillary studies based on the Registry should acknowledge the Registry as far as applicable and reasonably justified. The acknowledgement should include: “Hereditary TTP Registry (www.ttpregistry.net)”.

6. Analysis Plan

All investigators planning scientific projects or publications (including abstracts, oral or poster presentations) using data from the hTTP Registry or ancillary studies must submit the project topic using an Analysis Plan (AP, Annex I) to the SC (via the Registry Manager) for approval. Investigators not being a Steering Committee member themselves should have one of the SC members as an active “supporter” of their AP.

Each AP should be designed to result in a single manuscript. When, in the course of performing the study, data analysis, writing a manuscript or after peer review of a submitted manuscript, it becomes apparent that an AP will result in multiple manuscripts, additional APs should be submitted to the SC for each additional manuscript.

After having circulated the AP to co-authors for feedback by the first author, the AP can be submitted to the SC for evaluation. Any significant change in the proposed AP, including new first or senior authors, or changes in key measurements, primary outcome or statistical approach requires a formal amendment to the AP and re-review by the SC. The first author is responsible for submitting an amended analysis plan.

7. Assessment of analysis plans, articles/manuscripts & congress abstracts

The detailed procedure for obtaining approval of AP's:

- a. Analysis Plans must be sent to the hTTP Registry Manager, who will attribute it to a member of the SC. The appointed SC member will act as reviewer and will complete the review form (Annex II). All SC members agree to accept to perform the short written reviews. The reviewer will evaluate any overlap with existing and ongoing proposals and will make a recommendation to the SC regarding approval, revision or rejection. Assessment criteria include originality, objectives, methodological validity, and feasibility. Then, the SC will vote (see 8) and may add further suggestions (e.g. to suggest additional co-authors).
- b. The reviewer's feedback and decision will be sent to the first author by e-mail + cc all SC members. The first author may be requested to revise and resubmit the plan. Subsequently, the revised AP along with the response to the review will be evaluated by all members of the SC for approval.
- c. After approval by the SC, APs will be posted on the workspace reserved for the SC on the restricted website of the hTTP Registry database.
- d. Any SC member not listed as co-author, but wishing to join the writing group should contact the first author/senior author. The first author provides the SC with updates regarding members of the writing group.

Rules for articles/manuscripts are as follows:

- e. Articles/manuscripts must have a SC-approved AP before they are submitted to the SC for review.
- f. Articles/manuscripts must be sent for feedback to all co-authors prior to submission to the SC. It is the first author's responsibility to manage this step.
- g. In case of articles/manuscripts, the same procedure is applied as for AP's described above under a, b, and c.

Rules for abstracts are as follows:

- h. Abstracts are to be sent to the Registry Manager, and will be forwarded to all SC members for review. After feedback from the SC is implemented, abstracts will be posted on the restricted website of the hTTP Registry database.

8. Time-lines for submission and review

In order to ensure proper review of APs, articles/manuscripts and abstracts, the following timeline should be followed for submitting items for review to the SC (see also Annex III):

Submission by the Author

- a. Analysis plans and articles/manuscripts must be submitted a minimum of **25 calendar days** prior to the intended submission to a journal.
- b. Abstracts must be submitted a minimum of **10 calendar days** prior to an abstract submission deadline.

Review by the SC members

- a. In case of APs and articles/manuscripts, reviewers of the SC will have **14 calendar days** to perform the review, and send the comments to the Manager.
- b. For review of abstracts, SC members are given **7 calendar days** for feedback.

9. Decision and approval

Decisions on APs and articles/manuscripts require a majority vote of the SC. The majority of votes (1 per SC member) will be based on votes sent in the required time:

- **7 calendar days** after receipt of the request to vote in case of APs and manuscripts (see also Annex III).

The Chair decides in case of no consensus and equal number of votes.

10. Expiration and number of Analysis Plans

APs remain valid for 12 months from the date of approval by the SC. If the SC has not received a draft of a manuscript within 12 months or good reasons for delays, the plan might be considered expired and first authorship may be reassigned or claimed by other investigators, unless extenuating circumstances.

11. Archives

An electronic archive of all approved APs and publications will be maintained on the restricted website of the Hereditary TTP Registry database, in the workspace reserved for Publications.

Electronic copies of the final version of all articles and abstracts, as well as electronic copies of the published publications are to be sent to the Manager of the Hereditary TTP Registry.

12. Communication and Organisation

Submissions are to be sent to the Manager of the hereditary TTP Registry, who will coordinate the distribution of the submissions to the members of the SC, and the further process. Communication with and between the SC members will take place through email (e.g. sending in submissions, to announce a new submission or a voting). If needed, a TC will be organized.

13. Chair and Committee members

The members of the Steering Committee assume the function of the Publication Committee. One member of the SC is appointed as Chair.

Annex I

Analysis Plan

Analysis Plan (AP)

Instructions: please complete the entire form (3-5 pages max.) and send it by email to the Manager of the hereditary TTP Registry for review by the Steering Committee (SC).

Type of study proposal

(Check one or two of the answers below)

Full manuscript

Yes No

Abstract

Yes No

Title

--

Proposed Writing Group

(Indicate potential investigators/authors for this study)

First author:			
Senior author:			
Hereditary TTP Registry supporter*:			
Data handling/ Statistical analysis:			
Provisional list of co-authors/investigators:			
Source of funding (if any):			
Ethical committee approval (if needed):			
Has the AP been circulated to all co-authors for feedback?			
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

* Steering Committee member(s)

Background

(Explain briefly why this study is innovative with respect to prior studies done in this field)

--

Study Hypotheses/Specific aims

(List the study hypotheses and specific aims of this study)

--

Methods

(Describe the methods you plan to use to address the study hypothesis/questions, in particular, if you need specific variables from the Registry database to accomplish your goals)

Study population with inclusion/exclusion criteria you intend to include

Baseline variables needed *(If applicable, please be as specific as possible)*

Primary and secondary outcome variables needed *(If applicable, please be as specific as possible)*

Planned analyses *(Provide a brief description of the statistical analysis plan)*

Project Timeline *(Indicate the presumed date when the study will be completed)*

References

Annex II

Review Form

Review Form

a. Title submission:

b. Type of submission: Analysis Plan Manuscript

c. Review due: (14 calendar days after receipt by reviewer)

d. Name of reviewer:

f. Date of review:

g. Potential overlap with previous Analysis Plans?

Yes Please specify _____
No _____

h. Feasibility with actual data available within the Hereditary TTP Registry?

Yes _____
No Please specify _____

i. Recommendation:

I. Approve
 II. Recommend revision and resubmission
 III. Do not approve

Comments (to always fill in if options II or III)

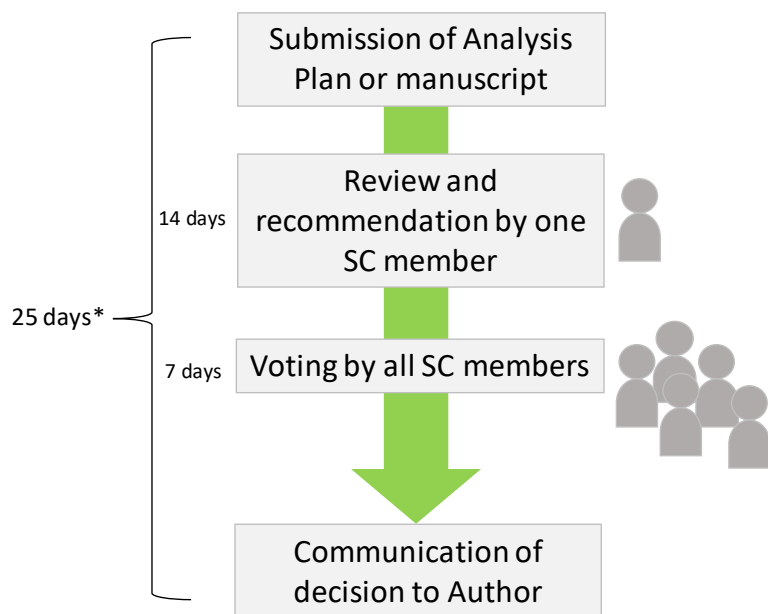
Additional co-authors to suggest + short justification:

Please EMAIL your completed form to the manager of the Hereditary TTP Registry

Thank you!

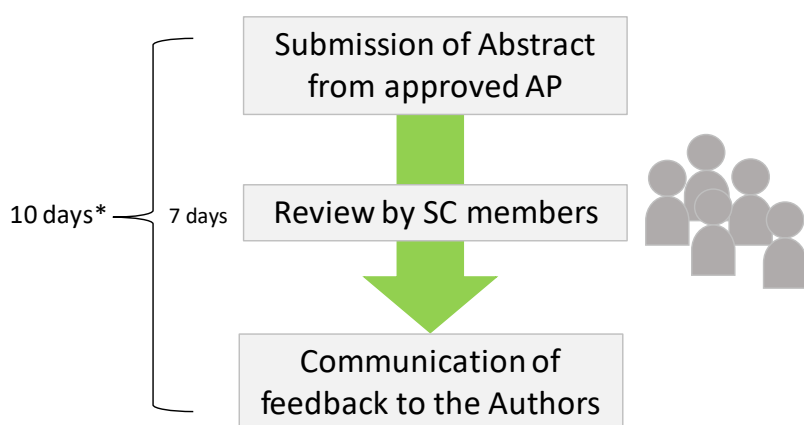
Annex III Flow-charts of review and decision processes of the Steering Committee

Submission, review and decision of Analysis Plan's & Manuscripts from approved APs



** 4 days for coordination reserved; days refer to calendar days*

Submission, review and decision of Abstracts with approved APs



** 3 days for coordination reserved; days refer to calendar days*