DISCHARGE Dissemination Policy: Draft 1.2, June 1, 2015

The main impact of the DISCHARGE trial will be transmitted by the number and the quality of its publications. Among these will be journal publications of systematic reviews and outcomes of the pragmatic trial and presentations at scientific conferences. The DISCHARGE Dissemination Policies aim to give guidelines about use of the DISCHARGE data, establish principles of authorship and encourage productive publication in addition to adhering to the ICMJE guidelines for authorship.

Objectives

- To lay down rules and procedures for dissemination to ensure accurateness, quality, objectiveness, and integrity.
- To oversee and encourage scientific dissemination in a timely and well-ordered manner to the scientific community and public.
- To ensure the participation of all investigators/researchers, including the ones with a junior position.
- To prepare documents for the Coordinator, the Steering Committee, and the General Assembly,
- To ensure internal and external access to recommendations, publications and presentations

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General Background:
The Dissemination Committee (DC) was chosen by the general assembly at the kick-off meeting. Dissemination will be the major output of the project. Therefore, all partners are involved. The DC is elected to lay down rules (including authorship), review the manuscripts, present them to the General Assembly and Steering Committee, and to make them public. It is crucial that the dissemination process takes into account the characteristics of the stakeholders that will be targeted. In this sense, the consortium will tailor the interventions according to these characteristics and the available evidence on successful dissemination strategies. The consortium will follow the rules of previously performed analysis and expertise of its members. Journals and platforms for presentations shall be found in both areas, cardiology and radiology. In addition, for the secondary outcomes the respective journals/platforms shall be identified. For Health Technology Assessment (HTA), the strategies for diffusion and dissemination for HTA shall serve as guidance (http://www.sergas.es/docs/Avalia-t/diffusion-Strategies.pdf). The DC reports regularly to the Coordinator and the Steering Committee. The DC is regulated by the Steering Committee and the Dissemination Office will function as a contact point for all partners who would like to submit suggestions.

Note:
Since this document is work in progress, possible revisions can be suggested to the DC through the DISCHARGE Dissemination Office by all members of the consortium. This may, for example, occur in case a circumstance arises that has not been considered before. The update needs to be approved by the DC.

1. Authorship

1.1 Method Paper of PRCT
The Method Paper is *based* on the proposal submitted by the Coordinator to the European Commission and which was finally selected for funding after a two-step review process. It will also use information from the study protocol (WHO/SPIRIT) and the scientific progress made in the preparation process for the PRCT (e.g. 10-steps guide to cardiac CT). It serves the purpose to give guidance, inform the stakeholders, and to meet the expectations of the European Commission that publications will be the main output of the DISCHARGE project.

1.1.1 Charité in the role of the Coordinator can list the Coordinator, the overall coordinating principal investigator for CT (Robert Haase) and the study's overall coordinating principal investigator for ICA (Michael Laule, In addition, Charité can list the following authors, if not already included, who have substantially contributed to writing the proposal and the study protocol. These are: Georg Schuetz, Robert Haase, and Adriane Napp. Charité shall be first and last author of the method paper.

1.1.2 The clinical sites and work package leaders (both with a maximum of two involved scientists), who gave input to the study protocol and respective documents will be listed in the order of their partner number for the clinical sites in order of the work package number for the work package leaders. The clinical sites name the two principal investigators for CT and ICA. The lead statistician and his co-worker will be second to last author.

1.2 Main Results Paper of PRCT
1.2.1 The site with the highest recruitment number will be allowed the first authorship in the main results paper. The first author will be responsible for drafting the manuscript.

1.2.2 Order and number of other authors
The order of authors from clinical sites depends on the number of patients. For this calculation, a patient only counts if the following criteria are met: successfully randomised, underwent CT/ICA, complete first and last follow-up is present, all data is entered in the eCRF.

The top 5 clinical sites who have met these standards will be awarded by being allowed to list more authors according to their ranking:
- Positions 1-3: 5 authors
- Position 4: 4 authors
- Position 5: 3 authors

In case that clinical sites present with the same number of patients, secondary criteria will be applied to decide on the authorship order, especially concerning the reward of the first/last author. These criteria are:
1. MACE follow-up
2. Full CT and ICA data
3. Full clinical physical data/vital signs
4. Full follow-up results
5. Final QOL follow-up
6. Final cost effectiveness

In case of minor missing information that is not within the control of the clinical site and cannot be retrieved despite all shown efforts (other than MACE, MICE, e.g. a question in the Quality of Life questionnaire that the patient cannot answer), the patient may still count for the clinical sites total patient number upon decision of the DC.

For the other clinical sites that are not in the Top 5 ranking and the work package leaders:
The two principal investigators for CT and ICA of all clinical sites will be listed according the patient numbers. The work package leaders will be listed in the order of the method paper (section 1.1.2)

The lead statistician will be the second to last author. The Coordinator (Marc Dewey) shall be last author of the results paper and can list all seven authors mentioned under 1.1 in the order stated for clinical sites in this section.

1.3 Papers of Work Packages and Special Topics (secondary outcomes)
The order of authorship for the publications related to the topics of the work packages will be based on the contribution to the secondary outcomes list drafted in January 2015 before the start of the PRCT. The clinical sites will be listed according to their patient number and input to the topic. The lead statistician will be the second to last author. The first and last authors shall be determined by the investigators who have suggested and demonstrated their contribution on the topic. A secondary outcomes list shall be provided by the Coordinator to the principal investigators and work package leaders for suggestions. The first suggestions will need to be made by 21 January 2015 to enable a possible inclusion in the eCRF and will be presented to the DC for approval. Further suggestions can be made throughout the project by PIs and work package leaders by contacting the Dissemination Office. This list will be integrated into the dissemination policies. The lead statistician and his co-workers as well as work package leaders will be listed in relation to their specific contribution.

The papers related to the secondary outcomes of the PRCT will be published after the main results paper.

1.4 Authorships of the External Advisory Board (EAB), Data Safety Monitoring Board (DSMB) and Clinical Events Committee (CEC)
The EAB, DSMB, and CEC may be listed as authors depending on their contribution.

1.5 Informing Stakeholders

All clinical sites and work package leaders are obliged to inform the general public and stakeholders (e.g. patient organisations) about DISCHARGE. This is part of the Description of Work in the European Commission Grant Agreement (EC-GA 603226). Joint public statements (e.g., press releases) will be forwarded by the Coordinator for approval by the DC. Other individual public statements/articles/advertisement activities (e.g. institution's homepage, posters) need approval from the Coordinator only. For efficiency and since informing stakeholders is already part of the EC-GA, approval of the DC is not necessary in these cases. However, if the DC does not find certain activities or contents of the information given to stakeholders appropriate for DISCHARGE, it can stop or revoke the approval of the Coordinator. Not being appropriate means: False contents, contents that do not support the progress of the project, questionable platform for the information (e.g., facebook), too early or too late information (e.g., still confidential information, advertisement for recruitment after the recruitment phase).

2. Efficient and Effective Dissemination

2.1 DISCHARGE shall be registered at www.clinicaltrials.gov before the start of the PRCT.
2.2 Peer-reviewed international and broad medical journals will be the major target for the publications. Radiology and cardiology journals are also appropriate targets according to the specific outcomes analysed in the papers. National and other journals shall be approached as well.
ICMJE guidelines for authorship shall be followed, also containing a defined trial report template2.4 Journals or set of journals that publish trials by their funding agency and related libraries, including open access (e.g., http://www.journalslibrary.nihr.ac.uk/), shall be identified for maximising dissemination.
2.5. Access of third parties to raw data shall be discussed upon their requests (e.g., agencies) or suggestions by the DC or Coordinator.

3. Responsibilities and Decision Making of the DC

3.1 The DC shall be the decision making body concerning all aspects of the publications. The DC's responsibilities towards the Steering Committee are stated below.

3.2 The Dissemination Committee notifies the consortium members within14 days of a planned submission for publication/presentation (see procedure details in Section 4). Approval of the Steering Committee is not necessary. This is only the case when the following issues arise for which the Steering Committee needs to be notified immediately: The Steering Committee can only revoke authorships in case of a) the suggested author did not contribute or is missing, b) major incompliance of a partner, c) a partner has withdrawn from the DISCHARGE project, d) or possible upcoming issues approved by the Steering Committee.

3.3 The DC can give advice to the authors for all planned publications, which should be incorporated at the discretion of the authors. The DC also gives advice for the planning of the manuscript and enables the coordination and timelines for the suggested or planned publications. These activities will coordinated by the Dissemination Office and the Coordinator (Marc Dewey). Authors assigned to certain publications, who significantly delay the publication drafting unnecessarily by more than 6 months, can be relieved from this responsibility by the DC and the author contributing to the second greatest extent to this project can be assigned to the role of the first author.

3.4 The DC should attempt to make all decisions in a fair balanced and unanimous manner. The DC shall not deliberate and decide validly unless SEVEN of its 13 members are present or represented (quorum) or having given their vote in writing. Each one of the present or represented members or members who give their vote in writing shall have one vote, and

decisions shall be made with an absolute majority of (>50%) where abstentions do not count and the difference of one single vote can enable decisions (e.g., with 13 members: 5 votes “yes”, 4 votes “no” and 4 abstentions result in “yes”). Members who do not give their vote are counted as abstentions. If however, in an email, or other communication, it was announced how the abstention will be counted towards the decision making, this specific communication supersedes the previous. In case of an equality of votes, measures will be taken to come to a consensus. In case, one or more members are not in the DC anymore and decisions have to be made before the Steering Committee meets, the DC can still decide with the above 50% rule. The Steering Committee will temporarily approve the new DC members and during the annual meeting these new members shall be confirmed by the general assembly. In case of conflicts within the DC, efforts should be undertaken to overcome them. If no consensus results, the Steering Committee is empowered to make the respective decision to solve disputes. The chairs of the DC informs the Steering Committee immediately through the Dissemination Office for all the above described cases. The Coordinator and the project management office can also inform the Steering Committee and request decisions.

4. Procedures for Abstract, Papers, and Presentations

- The review process can be in writing (e.g. email with WORD Document with comments and tracked changes). In addition, the DC will meet regularly (phone conference).
- The first author is responsible for the communication process to the Coordinator and DC.
- The contribution of each author according to the ICMJE guidelines needs to be presented to the DC for approval of authorship.
- The DC reviews final manuscript drafts within four weeks after receipt.
- New secondary study proposals that are suggested to be added to the secondary outcomes list, should be reviewed within 12 weeks. The Dissemination Office will provide a template for proposals.
- Approved topics for the secondary outcomes publications will be listed on the DISCHARGE homepage in the members’ area
- Journals shall be suggested by the first, last and co-authors and the DC and will be decided by the authors, the DC, and the Coordinator to enable a swift process.
- All authors, co-authors shall respect the publication policies of the respective journal (e.g. approval of manuscript by all authors and declaration of conflicts of interest) and those of the ICMJE and that of COPE.
- Abstracts that will be presented at a congress need to be submitted with their related final manuscript for journal publication to the DC at least 2 weeks before the submission deadline of the planned congress. This will ensure consistency of oral and written presentations of the DISCHARGE consortium. The abstract as well as the participation in the congress require approval from the DC.
- In case the publication/abstract are submitted by the authors without approval from the DC; the DC can revoke them. This is the same for presentations and related materials.
- All submissions shall be made to journals immediately after approval by the DC.
- In case of major changes requested by the journals or congresses, the authors are obliged to re-submit their revision for approval to the DC.
- The first author needs to provide an electronic re-print/ copy of the published article or the abstract/presentation for publication on the DISCHARGE website (full text only in the Members’ Area) and provide a link on the open part of the website to the DISCHARGE Dissemination Office.
- A list of all possible locations (e.g., congresses) to present the research shall be kept and agreed upon together with the secondary outcomes list in a tabular format. The Dissemination Office will present the suggestions and the related decision making process to the authors, including the DC.

5. Intellectual Property Rights

The Intellectual Property Rights (IPR) in DISCHARGE are closely linked to Dissemination, since publications and recommendations for guidelines constitute the major output of the project. Thus, the DC is also responsible for IPR and is regulated by the Steering Committee in case of issues beyond the normal scope. Further details about IPR can be found in the Consortium Agreement version 2.

6. DISCHARGE Pilot study quality ranking

Study performance	Points
End of the study until last official deadline (1rst December), regular reports about status of the study	2
Delay of the study due to objective reasons, regular reports about status of the study	1
Delay of the pilot study due to unclear reasons, no responses to e-mails	0
Study clarity	
All pilot study data filled correctly	2
Pilot study data filled with minor mistakes*	1
Pilot study data filled with major mistakes, or missing patient data**	0
Test patients	
Data of test patients sent on time (1rst December), performed and reconstructed according 10-steps protocol	2
Data of test patients sent delayed, performed and reconstructed with minor deviations to 10-steps protocol***	1
Data of test patients absent or major deviations to 10 steps protocol****	0

* Examples: mistakes in cardiac noninvasive tests results filling (except for CT)

** Examples: corrupted excel sheet due to ignored recommendations of data input, incorrect file saving format; incorrect angina classification according patient symptoms; mistakes in CT or ICA results filling (for example discrepancy between CT or ICA result and segmental stenosis grading); missing values (except due to missing source data)

*** Examples: borders of the scan area <1 cm or >3 cm to coronary arteries; not all reconstructions performed; scan FOV>20 cm

**** Examples: pure contrast in ascending aorta; scan parameters selected not according heart rate; missing or non-diagnostic segments

The sum of these three criteria will reflect the quality of Pilot study.
The ranks of the Pilot study could be:
I rank: 5-6 points
II rank: 2-4 points
III rank: 0-1 points