Healey Center
Sean M. Healey & AMG Center for ALS at Mass General

# HEALEY ALS Platform Trial Publication Policy

## Approvals & Revision History

**Healey Center for ALS at Massachusetts General Hospital (MGH)**

This Publication Policy has been reviewed and approved by:

DocuSigned by Merit Cudkowicz, MD, MSc
Merit Cudkowicz, MD, MSc
I approve this document
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Merit Cudkowicz, MD, MSc.
Study Principal Investigator and IND Holder

| Name & Title | Signature | Date |
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| Sabrina Paganoni, MD, PhD<br>Study co-Investigator | DocuSigned by Sabrina Paganoni, MD, PhD<br>Sabrina Paganoni, MD, PhD<br>I approve this document<br>07/07/2020 \| 6:17:45 PM PDT<br>58705BF61CB842A887521BEB826294FA | |
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**Revision History**

| VERSION / DATE | DESCRIPTION OF CHANGE(S) |
|---|---|
| Version 1.0 June 30, 2020 | Original |

## PURPOSE:

To describe the HEALEY ALS Platform Trial publication policy that applies to all public and scientific communication (including manuscripts, abstracts and accompanying posters, presentations, and public website postings) for reporting results from any HEALEY ALS Platform Trial related activity. This includes primary and secondary publications. The policy also applies to any trial-related publications that arise pertinent to trial design and operations.

## POLICY:

Timely publication of results from HEALEY ALS Platform Trial is central to the mission of the Center.

HEALEY ALS Platform Trial publications include manuscripts, abstracts and accompanying posters, presentations, and public website postings that report any results including baseline characteristics, clinical and laboratory findings and conclusions of individual regimens as well as those that address overall trial design and operations. Each regimen is expected to result in at least one peer-reviewed manuscript and most should include presentations of study results at national and international meetings.

The HEALEY ALS Platform Trial Executive Committee (Executive Committee) is charged with reviewing all proposed publications to ensure they comply with HEALEY ALS Platform Trial

requirements for authorship, acknowledgements and data sharing in accordance with the HEALEY ALS Platform Trial Publication and Data Sharing Policies The overarching purpose of HEALEY ALS Platform Trial publications are collaboration and inclusiveness. The publication terms from the Master Clinical Trial Agreement (MCTA) with sites and the Clinical Research Services Agreements (CRSA) with industry partners are found in Appendix I to the publication policy.

All Study Publications shall be submitted to the Executive Committee for review by the HEALEY ALS Platform Trial Executive Committee at least forty-five (45) days prior to the submission of the Study Publication. The Healey Center shall advise the authors within forty-five (45) days of receiving any Study Publication if the Study Publication: (i) contains or discloses any potentially patentable inventions ("Patentable Material"), or (ii) contains any Healey Center or Company Confidential Information. The authors will delete any Patentable Material or Confidential Information.

Each regimen company that is contracted to work with the Healey Center on the HEALEY ALS Platform trial is entitled to review Study Publications on their regimen solely for the purposes of reviewing for use of Company's name, for identifying Company's Confidential Information, which shall be removed from the publication upon Company's request; and to identify any patentable Inventions; and to provide any other comments Company desires to provide, provided that MGH and the HEALEY ALS Platform Trial Executive Committee shall have no obligation to address any such additional comments beyond considering them in good faith. The review period for publications shall be thirty (30) days. If during the Review Period, the regimen company notifies the Executive Committee in writing that: (i) it desires patent applications to be filed on any inventions disclosed or contained in the Publication, the Publication Committee will ensure, to the extent possible, that the Publication is deferred for a period not to exceed thirty (30) days, to permit regimen company to file any desired patent applications; and (ii) the Publication contains regimen company's Confidential Information and requests the Trial Executive Committee in writing to delete such Confidential Information (other than Data or results), the Executive Committee agrees to delete such Confidential Information (other than Study Data or results) only to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Study results. Any Company may request that their name be included or omitted in a Study Publication in accordance with acceptable standards and publication policies.

i.) Authorship: Authorship for manuscripts will reflect investigators who have made substantial intellectual contributions to the research and its report, per published guidelines: http://www.icmje.org/index.html#authorship. For each regimen-specific primary manuscript, a writing team and a list of authors will be generated based on intellectual contributions. Authors should be listed in the following order: primary author(s) (generally the regimen lead investigator or the regimen co-lead investigator), primary biostatistician(s), Regimen Steering Committee members, coordinating centers and key staff, Site PIs or their designates (in descending order based on number of participants randomized per site) as appropriate, industry representatives as applicable, and Master Protocol PIs. If the regimen lead investigator is not the primary author, then designation as senior author may be appropriate. Any professional medical writing support should be disclosed.

ii.) Acknowledgements: All publications (manuscripts, abstracts and/or presentations) should include an acknowledgement of the Healey Center for ALS at Mass General and appropriate grant citations as follows:
*" This investigation was supported by The Sean M. Healey and AMG Center for ALS and partially supported by Tackle ALS, The ALS Association, ALS Finding A Cure, ALS One and…." (insert other supporters, including industry partners if applicable – consult MGH Study Administrator). We acknowledge the altruism of the participants and their families and contributions of the HEALEY ALS Platform Trial research and support staff at each of the participating sites for their contributions to this study."*

In addition, the publication should include the ClinicalTrial.gov identifier, known as the NCT Number (NCT04297683)

iii.) Arbitration: If conflicts exist regarding HEALEY ALS Platform Trial publications, written summaries of the conflict submitted by those involved will be reviewed by the Executive Committee. Any investigator who wishes to opt out of any automatic authorship listing may do so in writing to the HEALEY ALS Platform Trial Executive Committee.

## SUBMISSION PROCEDURE:

i.) Primary Manuscripts: The primary manuscript is written by regimen writing group, led by the primary author(s) (generally the regimen lead investigator and the regimen co-lead investigator), and describes results and analysis of the primary and key secondary aims of the study (i.e., analyses addressed in the formal study Statistical Analysis Plan {SAP}). Within 6 months of the close of regimen double-blind study, primary data will be presented to the regimen lead investigator, regimen co-lead investigator, industry partners and Master Protocol PIs. After that meeting, the primary author(s) (generally the regimen lead investigator and the regimen co-lead investigator) and the writing group and will begin manuscript development in accordance with the primary and secondary analyses specified in the SAP. The protocol statistician(s) will be the primary contact for any writing group, unless another statistician is assigned to support a specific writing group.

a) Authorship must be agreed upon by the writing group of each regimen, and approved by the Executive Committee.
b) A manuscript reporting the primary study results should be submitted by the primary author(s) to the Executive Committee in a timely manner from the date the primary author(s) are provided with primary data as specified in the SAP. The manuscript should be submitted along with the HEALEY ALS Platform Trial Publication Submission Form (Appendix II).
c) The Executive Committee will also provide manuscripts to participating companies to review identifying company Confidential Information, which may be removed from the publication upon the company's request, and the Data Safety Monitoring Board (DSMB) to review publication of the primary analysis for each regimen, prior to their distribution to any journal.

ii.) Additional Manuscripts: Additional manuscripts are those arising from other secondary or exploratory analyses of data by members of the regimen writing group, analysis of released study data by other investigators, and methodological papers. These may include baseline data, exploratory analysis, trial methods and operations.

a) Manuscripts based on the Master Protocol will also be written and led by the Master Protocol PI and Co-PI with input from Berry Consultants and MGH Biostatisticians and the Platform Trial Design Committee.
b) To ensure the integrity of meaningfulness of the platform trial model, publication of any Study Regimen Placebo Data shall be delayed until the HEALEY ALS Platform Trial Executive Committee grants explicit permission to publish it. Additional manuscripts that utilize final study data may be proposed by the regimen lead and co-lead investigators, site PIs or other investigators involved with the regimen design and execution. These additional manuscripts may be considered after the primary manuscript has been accepted for publication in a peer-reviewed journal.
c) Each manuscript proposal must be submitted to the Executive Committee for review and approval and must be accompanied by a written statement of manuscript and authorship approval from the regimen lead investigator. Manuscripts reporting on the data collected from an individual study site by Site PIs must be submitted to the Executive Committee for review at least 45 days prior to submission.
d) Authorship on invited reviews and book chapters should be determined by the invitee. Each invited paper must be submitted to the Executive Committee for review and approval and must be accompanied by a written statement of manuscript and authorship approval from the regimen lead investigator.

iii.) Abstracts for Oral/Poster Presentation: Abstracts, posters, and oral presentations are those prepared for presentations at professional meetings that will utilize data from HEALEY ALS Platform Trial and/or from data relating to the trial methods and operations.

a) Draft abstracts shall be submitted to the Executive Committee by the lead author at least fourteen (14) days prior to submission. Authors of abstracts are to ensure that the appropriate acknowledgments are included, and all co-authors have had an opportunity to review the abstract prior to submission.

iv.) Online Material/Press Releases: This policy governs materials related only to the report of any results including baseline characteristics, clinical and laboratory findings and conclusions of individual regimens as well as those that address overall trial design and operations. Other online materials/press releases should be submitted directly to the HEALEY ALS Platform Trial PI and Co-PI and administrative team for review.

a) Draft online material and press releases shall be submitted to the Executive Committee at least fourteen (14) days prior to submission.

## EXECUTIVE COMMITTEE REVIEW PROCEDURES:

i.) Review and Approval of Manuscripts:

All primary and secondary manuscripts will be sent to the Executive Committee whose members are to review the manuscript and return comments to the primary author(s). The Executive Committee Chair will summarize comments, including approval/ disapproval decisions and send them to the primary author(s) within 45 working days of original receipt of the manuscript. It is the responsibility of the Executive Committee to ensure appropriate authorship and acknowledgements are included in primary and exploratory papers, as well as confirmation of approval of the regimen lead investigator for invited articles or reviews.

Once co-authorship has been finalized, a final or near final draft will be circulated to ensure that all co-authors have had the opportunity to review and comment on the paper prior to submission. All site PIs who enrolled at least one participant will have an opportunity to make comments and provide the appropriate documentation for journal submission (e.g. conflict of interest, etc.). Site PIs will be allowed 14 days to complete these tasks to remain listed as co-authors.

The final draft of the manuscript is to be submitted to the journal by the corresponding author. Once submitted, a copy should be sent to the Executive Committee Chair (s) and all co-authors.

ii.) Review and Approval of Abstracts, Presentations or Public Releases:

Abstracts, presentations and public releases will be reviewed by the Executive Committee within 14 working days of receipt, and comments/approval will be provided within 14 working days of receipt.

iii.) Progress Tracking and Corrective Action:

The Executive Committee will track progress of all manuscripts and abstracts. The Executive Committee will follow manuscript progress and appropriate Conflict of Interest disclosure, and is authorized to recommend that a new writing group and primary author is chosen, if undue delays or concerns become apparent.