

aHUS Registry Manuscript Authorship Criteria Process

**Alexion Pharmaceuticals, Inc.
Protocol Number M11-001 (aHUS Registry)**

**AN OBSERVATIONAL, NON-INTERVENTIONAL,
MULTI-CENTER, MULTI-NATIONAL STUDY OF PATIENTS WITH ATYPICAL HEMOLYTIC
UREMIC SYNDROME (AHUS)**

**Version: FINAL 1.0
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Purpose

The Scientific Advisory Board (SAB) is a collaborative scientific board and advocacy group for the aHUS Registry (Alexion Pharmaceuticals Protocol number M11-001). Its role is to review and provide feedback on clinical assessments and patient outcomes collected in the aHUS Registry, to raise awareness and communicate the value of the Registry, to ensure suggested topics for analysis are in line with existing medical evidence needs, to confirm analysis methodologies are scientifically sound and relevant to the treating community, and to provide important perspectives to support analysis of data and interpret the study's findings.

The M11-001: aHUS Registry Manuscript Authorship Criteria process (see also flow chart in Appendix A) is being defined to provide all SAB members, National Coordinators (NCs), and participating physicians a clear understanding of authorship criteria to ensure that – in line with international guidelines such as International Committee of Medical Journal Editors (ICMJE) and Good Publications Practices (GPP3)¹ - all Registry participants who meet the eligibility criteria have the opportunity to author manuscripts using aHUS Registry data as well as the process by which authors/contributors are included.

This process refers only to Alexion-sponsored manuscripts. Manuscripts and publications prepared using the aHUS Registry database but not utilizing Alexion resources (eg, biostatistics, programming, data management, or medical writing/editorial support) are not bound by this process but should adhere to the ICMJE and GPP3 guidelines.

As a courtesy, the SAB should be informed of data to be published on aHUS Registry data for review prior to submission for journals or congresses.

Manuscript Champion and Working Group Formation

- Once a manuscript topic has been agreed to by the SAB, based upon resource prioritization, whether the topic comes from internal discussion or a Concept Sheet received from an investigator (initiator of the project), the SAB Chair/Co-Chair will send an email to all SAB and NC members to assess interest in participation unless the initiator of the project declines additional support. The email communication should outline expected work load and estimated commitment to ensure transparency and to give those interested an idea of project expectations and deliverables.
- Before agreeing to participate;
 - Members should consider their time, expertise, and eligibility according to ICMJE
 - Members should share topic, expectations, and deliverables with appropriate local participating Registry physicians, and colleagues with expertise not represented in the participating Registry physician cohort; other working group members to consider: patient advocates or patients
 - Members should email SAB Chair/Co-Chair positive responses and potential working group members with contact information

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- SAB Chair/Co-Chair will work with initiator of the project, if from Concept Sheet submission, to choose or appoint an appropriate manuscript champion and working group members (≤ 10) from the interested SAB and NC members, participating Registry physicians, and individuals in medical community with specialized expertise that may not be represented in the participating Registry physician cohort.
- Consensus on working group members between initiator of the project and SAB Chair/Co-Chair should be confirmed before other members are invited to participate in the working group.
- All SAB members will acknowledge the manuscript champion and working group membership
- Manuscript champion facilitates discussions, planning, and timelines for manuscript completion
- Working group members are responsible for developing the manuscript and assigning authors order according to ICMJE guidelines
 - Working groups define and agree on roles, accountability and reporting progress to SAB at each meeting
 - Each working group will have a SAB member or NC as champion; this does not grant them first author status
 - The number of SAB and Alexion authors should be limited
 - For those experts not meeting ICMJE authorship criteria, their contribution can be noted in the acknowledgement section of the manuscript

General Authorship Criteria

- All authors working on manuscripts must meet accepted authorship criteria, namely those described by the International Committee of Medical Journal Editors (www.ICMJE.org).
- The following criteria are required for authorship:
 - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the manuscript
 - Additional criteria will be applied:
 - Number of patients enrolled. Enrollment of subjects alone does not qualify an investigator for authorship. Those who are initially considered on this basis must meet all ICMJE criteria
 - Quality of the data collected
 - Level of contribution to analysis plan
 - Level of contribution of interpretation and analysis of the data
 - Ability to commit to meeting the logistics and timelines associated with manuscript development. In the case of congress presentations, the presenting author will commit to being available to discuss the content of the presentation at the time(s) allotted by the congress. Drafting the work or revising it critically for important intellectual content
 - Final approval of the version to be published

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- Agreement to be accountable for all aspects of the manuscript in ensuring that questions related to the accuracy or integrity of any part of the manuscript are appropriately investigated and resolved

Authorship Assigned to a Group

If authorship is attributed to a group:

- All members of the group who are named as authors should fully meet the above criteria for authorship, according to ICJME (GPP3)¹
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. The group should jointly make decisions about authors before submitting the manuscript for publication; these decisions must be documented by the manuscript champion

Contributors Listed in Acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help or general support. Authors should declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. If such assistance was available, the authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article. Financial and material support should also be acknowledged and must be disclosed in the paper.¹

Author Sequence

Authors should decide how this will be determined at the initiation of the manuscript, including the designation of the lead, senior/last and corresponding authors, who may or may not be the same person. Final order, however, should be based on authors' actual roles and contributions in the development of the manuscript and, therefore, cannot be agreed upon until this is complete. (e.g., final draft).¹

Addition or Removal of Author

In certain circumstances during the development of a manuscript, it may be necessary to add or remove an author (e.g., if an author fails to provide substantial contribution or approve the final version of the manuscript). In such cases, all authors should agree to the change.¹

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Alexion Authors

Sponsor-employed scientists and clinicians are often qualified to participate as authors of company-sponsored research manuscripts and should have that opportunity. The criteria used to determine authorship should be applied equally to company employees, contractors, and others. The following activities are considered significant contributions meriting authorship.

- A. Protocol development
- B. Statistical Analysis Planning, data analysis and interpretation.
- C. Critical/essential study operations and monitoring

Attribution

In the disclosures section of the manuscript, authors should specify their contribution to the manuscript.²

Exclusions

Authorships will not be for the purpose of influencing purchasing, prescribing, or reimbursement decisions, or to reward past practices.

Acquisition of funding, collection of data, or general supervision of the research group, does not justify authorship.

Additional authorship exclusions include guest authorships (based solely on the expectation that inclusion of a particular individual will improve probability of manuscript acceptance), honorary authorships (indirect or minor affiliation with the study), or ghost authorships (undisclosed authors).

Authors are not to be compensated for any activities associated with manuscript development; such activities include, but are not limited to, data acquisition or interpretation, collection of references, author meetings, in addition to the formal drafting of manuscripts.

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References

1. Battisti W. et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Intern Med* 2015; 163:461-464
2. Council of Science Editors. White Paper on Publications Ethics. Updated March 30, 2012 Located at: http://www.councilscienceeditors.org/wp-content/uploads/entire_whitepaper.pdf

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Appendix A

