aHUS Registry

National Coordinator Charter

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: 2.0
Date: 22 March 2017

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1 Objectives

National Coordinators are physicians appointed via an agreement with the aHUS Registry (Alexion Pharmaceuticals Protocol number M11-001) Sponsor (Alexion) to function as advocates of the aHUS Registry in their country. The goal is to have a National Coordinator represent each country that is participating in the aHUS Registry. National Coordinators will participate in the definition of the Registry organization in their Country. Further, the National Coordinators will support Alexion's scientific communications related to the aHUS Registry in the National Coordinator's country; provide opinions on the results of the Registry and consultation to other physicians as appropriate.

2 Members

The aHUS Registry National Coordinator members will include those listed below.

2.1 National Coordinators

Name	Country
Donata Cresseri	Italy
Hans Dieperink	Denmark
Galina Generalova	Russia
Patricia Hirt-Minkowski	Switzerland
Nicole Isbel	Australia
Natalya Lvovna Kozlovskaya	Russia
Danny Landau	Israel
Anne-Laure Lapeyraque	Canada
Chantal Loirat	France
Christoph Mache	Austria
Leena Martola	Finland
Annick Massart	Belgium
Eric Rondeau	France
Lisa Sartz	Sweden
Franz Schaefer	Germany
Andrew Siedlecki	United States
Nadezda Simankova	Czech Republic
Nicholas Webb	United Kingdom

3 Roles and Responsibilities

National Coordinators will be responsible for performing the following services associated with the aHUS Registry at their best efforts.

- Help to define the Registry organization in the Country
- Support site participation and data quality for their Country
- Serve as a local resource for medical or scientific requests from physicians in the country
- Encourage Registry support and advocacy

- Country specific data analyses and publications
- Participation in local meetings where any communication on the aHUS Registry shall be addressed

The anticipated commitment of each National Coordinator will be four (4) years, when another appropriate alternative is available.

4 Meetings

National Coordinators will meet on a regular basis, anticipated to be approximately once per year.

Meetings will focus on the current status, progress, and expansion of the Registry, best practices from the country perspective, and publications.

Each meeting will be followed by written minutes sent to all National Coordinators within 2 weeks after the meeting.

5 Data Access and Publication Rules

5.1 Data Access

Access to the aHUS Registry database will be based on the following guidelines:

- Scientific Advisory Board (SAB) has access to the global database and will be involved in review of requests from physicians for analyses of global dataset, via Concept Sheets.
- National Coordinators (NC) have immediate access to their country data through the database and can receive data, upon request. Additionally, they may request global data from the SAB.
- Individual participating physicians can access their own data at any time. They can request access to national data through the NC or global data through the SAB.
- As a courtesy, the SAB should be informed of all data requests; data requests from individual participating physicians will also be shared with National Coordinators.
- Data will be returned to individual investigators on cessation of the Registry.

Alexion Pharmaceuticals is responsible for:

- Managing and maintaining the study database
- Generating and distributing standard reports upon request as follows:
  - Individual sites have immediate access to their own site level data and general information on global registry/country/region, upon request
  - National Coordinators will receive Standard Country Reports, upon request
- Responding to *ad hoc* requests for data via Concept Sheets following consultations with the SAB
- Generating and submitting annual updates to relevant regulatory authorities

- Safety Reporting – regular reporting and signal detection analyses
- Responding to *ad hoc* requests from regulatory agencies (FDA, EMEA, Australia, Japan, etc.)

5.2 Publications

5.2.1 National/Local Publications

National Coordinators may publish in professional journals an analysis of data from own patients and aggregated data from patients from sites in responsible country that contributed to the aHUS Registry.

National Coordinators independently analyzing their country data without Alexion registry operational support may develop a publication without SAB approval. However, if Alexion registry operational resources are required to conduct analysis and/or develop publication materials, then a request should be made to the SAB for prioritization against other requests and projects.

National Coordinators should engage other investigators contributing to their national cohort of registry patients prior to presenting their national data (oral, abstract, or written presentation). Specifically, investigators from other centers should be invited to provide input and serve as co-authors based on interest, expertise, and the number of patients contributed to the registry. All national site principal investigators should be invited to review abstracts and manuscripts prior to submission.

5.2.2 Global Registry Publications

The SAB, in conjunction with Alexion Pharmaceuticals, will define a plan for regular publications based on analysis of global registry data, including the contents of such publications. Publications include manuscripts submitted to peer-reviewed journals, along with abstracts submitted to scientific conferences and subsequent conference poster/presentational materials. For each publication, the SAB and Alexion Pharmaceuticals will work together to develop working groups who will have the primary responsibility for actively taking part in guiding data analyses, interpretation of data analyses, and for the publication writing. Membership of working groups will consist of aHUS experts, SAB members, National Coordinators, et al. as defined in the M11-001: aHUS Registry Authorship Criteria Process document.

6 Consulting Agreement

National Coordinators agree to provide consulting services via participation in the aHUS Registry National Coordinator membership; services shall be performed at such times as they will not interfere/be in conflict with your obligations to any institution(s) with which you are affiliated.

National Coordinators further agree that any tangible property provided to physicians in connection with the aHUS Registry, including all data, reports, or other information generated under the aHUS Registry (and any inventions or other results of such data, reports, or other information) shall be and remain the exclusive property of Alexion Pharmaceuticals.

6.1 Honoraria

It is expected that National Coordinators' involvement will require a maximum of 40 hours in the first twelve (12) months and a maximum of 24 hours in each following year. Honoraria will not be paid for time related to publication development.

Financial conditions will be specified in an agreement executed with each National Coordinator and Alexion.

7 Operating Principles

National Coordinators agree to serve as an independent contractor (to Alexion Pharmaceuticals); nothing in this Charter shall be construed in any manner as an obligation or inducement for National Coordinators to recommend that patients utilize Alexion Pharmaceuticals' products or those of any organizations affiliated with Alexion Pharmaceuticals.

8 Confidentiality and Nondisclosure

National Coordinators agree that all non-public information (disclosed by Alexion Pharmaceuticals or becoming known to you as a result of serving as a National Coordinator) is confidential and shall not be disclosed.