

International Advisory Committee on Clinical Trials in MS Committee Charter

Mission

The mission of the International Advisory Committee on Clinical Trials in Multiple Sclerosis (“the Committee”) is to provide perspective and guidance to the multiple sclerosis (MS) scientific and clinical community related to planning and implementation of clinical trials of MS therapies and allied topics.

The Committee has been in existence for over 30 years, initiated and supported by the US National Multiple Sclerosis Society (NMSS) and since 2009 sponsored and supported jointly by the Society and the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). Over the years, the Committee has evolved from a primarily North-American based group of experts in MS clinical trials design and implementation to a Committee fully represented by North American and European members, with participation by others for special Committee projects.

Authority

The Committee and its activities are organized under the auspices of and are supported by the NMSS and ECTRIMS (“the Sponsors”), under provisions of a **Memorandum of Understanding** between the sponsoring organizations.

The Memorandum recognizes that joint sponsorship serves to strengthen the development of independent international consensus efforts without redundancy of effort and helps to ensure a productive future. However, neither organization is in any way prohibited from pursuing MS clinical trials-related activities independent from the Committee. The Memorandum further articulates the specific roles and responsibilities for each

organization in terms of Committee membership, review and approval of major projects, and financing of the Committee's ongoing activities and of specific projects.

In general the financial costs associated with committee activities are borne by the sponsors. However in special circumstances other funding sources may be sought with the agreement of the sponsoring organizations.

The Sponsors jointly hold any intellectual property emerging from deliberations of the Committee.

Specific Responsibilities

The Committee conceives of and prioritizes timely clinical trials-related projects to be undertaken as a whole, in task forces or panel groups, or as larger Committee-sponsored activities. Projects may be pursued in consensus-building international conferences and workshops, held on an as-needed basis, and through other mechanisms as needed. Outcomes of projects are prepared for publication in high-impact relevant scientific journals for wider distribution to the MS community. (See <http://www.ectrims.eu/international-advisory-committee-clinical-trials-ms/>) for recent projects and links to publications)

Members

The Committee shall be composed of no fewer than 20 members, generally academic or clinical practice-based individuals chosen for their expertise in clinical, imaging, statistical, and trials design issues related to MS therapeutics. Approximately half of members will be from North America and half from Europe, reflecting the jurisdictions of the sponsoring organizations, although other geographic representation may be included. Members serve independently of their home institutions. The Sponsors designate two members each as organizational representatives, who serve and speak on behalf of the organizations they represent and consult with their organizations as needed.

A consultant Committee Administrator provides both practical and intellectual support to organize the Committee's day-to-day activities, manage its budget and other administrative details, and help with planning and organization of large-scale projects and consensus meetings. The Administrator serves in his/her position under the terms of separate contractual terms with the Committee Sponsors.

A Committee Chair is identified by consensus among the Committee Sponsors and Committee Administrator, usually from among members who have served for one or more terms as a Committee member. The Chair will be an individual with international recognition and demonstrated record of leadership in clinical trials in MS. The Chair serves for a three-year term and may be reappointed for a second three-year term.

Committee membership terms are generally for three years with reappointment for an additional three-year term possible. Membership appointments are made based consensus among the Committee Administrator, Committee Chair, and Sponsors' organizational representatives to the Committee, who review and recommend appropriate candidates for rotation, appointment or reappointment.

For Committee decisions requiring a vote, each Committee member holds one vote; for decisions on Committee projects unrelated to specific project financing, a majority vote controls. In the event of a tie vote, the Chair would cast a tie-breaking vote. In the event that a decision by the Committee or by the Committee's organizational representatives needs to be solicited by email, a response within 2 working weeks is expected.

Meetings

Administrative and planning meetings of the Committee are held twice annually at the American Academy of Neurology andECTRIMS congresses, and, if needed, at other times/venues. The Committee Chair and Administrator set meeting days/times and agendas in consultation with the Sponsors organizational representatives. Topics and

agendas for such meetings, together with relevant materials, will be presented for approval in advance to the NMSS and ECTRIMS organizational representatives to the Committee. Documents related to Committee meetings will be sent to Committee members at least 10 days in advance of a scheduled meeting. Minutes for all meetings are drafted by the Administrator and reviewed and edited by the Chair, and other relevant meeting participants. Minutes are distributed as a “meeting summary” within 30 days of each meeting.

The Committee also convenes at workshops and consensus conferences held to pursue specific topics relevant to clinical trials-related projects in MS. Topics for planned conferences and workshops are discussed and decided upon by the Committee as a whole. There will be a date finding process with all parties involved before setting a final date for each workshop and consensus conference. NMSS and ECTRIMS organizational representatives will be given the opportunity to provide input on conference/workshop co-chairs and on the organization of such events including review of a draft program, in advance of finalizing plans. Once set, such conferences and workshops will be the responsibility of the Committee Chair, Administrator and conference/workshop co-chairs who have relevant content expertise chosen from among the Committee members and/or more broadly in the MS clinical and research community.

Outcomes of such conferences are prepared as one or more manuscripts by the project organizing team for submission to high-profile relevant scientific/clinical journals, in as expeditious a manner as possible. The sponsors will be consulted regarding publication plans for proceedings arising from any meetings of the Committee. Manuscripts resulting from conferences/workshops or other Committee activities will be provided to the sponsor representatives for review prior to submission.

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