

Terms of Reference

Aims, Structure and Role of the UK MND Clinical Studies Group

1. Background

The UK MND CSG was originally one of the Dementias & Neurodegenerative Diseases Research Network (DeNDRoN) Clinical Studies Groups (CSGs). During the transition of the research networks carried out during 2014/2015 DeNDRoN was integrated into Division 4 and there is no longer infrastructure or financial support for Clinical Studies Groups within the networks. It was deemed vital that the group continued to support the profile of the MND research portfolio and therefore a successful bid was developed to support the co-ordinator post via the MND Association and linked to the Yorkshire & Humber Clinical Research Network.

The process for the leadership and membership of this group has been established to promote transparency, encourage participation and ensure that the group is well equipped to undertake its role. The UK MND CSG represents a central component of the framework for MND research in the UK, providing the primary, but not sole, route through which portfolio studies will be monitored and supported and through which new ideas for clinical trials are developed.

2. Aim and Objectives

The Group should aim to bring together the expertise and enthusiasm necessary to establish them as an authoritative voice in the Clinical Research Network community. The Group has the following objectives:

- Be responsible for developing and overseeing the MND portfolio of studies;
- Identify gaps in MND research and agree on priority areas;
- Propose and develop new trials and other well-designed studies, and submit applications for approval;
- Consider studies proposed by others and advise the CRN Division 4 portfolio team where required;
- Consider international studies for inclusion in the portfolio;
- Receive inputs from UKCRN, LCRN and Research Funders;
- Provide MND advice to the CRN CC and Division 4 portfolio team, as required;
- Undergo peer review of their overall portfolio 3-yearly;
- Act as an expert panel for novice MND researchers and new PI's
- Ensure patient and carer involvement in activities.
- Seek opportunities to become involved in initiatives in other related disease areas (e.g. FTD)

The UK MND CSG historically developed to integrate the remit and principles of a portfolio management group and will continue to be responsible for delivering under the following remit and activities:

2.1 Remit

1. Oversee the delivery of portfolio studies on time, to predefined targets;
2. Recommend ways to improve the feasibility (“do-ability”) of portfolio studies
3. Advise on growing capacity to deliver portfolio studies
4. Provide written support and input to the Division 4 portfolio team, both for commercial trials and non-commercial trials which are not automatically eligible for the portfolio
5. Provide oversight of the portfolio (for example, to prevent duplication of effort within the topic and trials competing for insufficient patients)
6. Assess the appropriateness of NIHR infrastructure and working arrangements to support the portfolio of studies

2.2 Key Activities

1. Monitor study performance and have a complete overview of the disease portfolio and how it relates to other Division 4 topic portfolio activity
2. Liaise with Chief Investigators regarding study performance
3. Develop and implement study facilitation policies
4. Make recommendations to LCRNs on the allocation of network resources to support study delivery
5. Provide early advice on whether a potential study (both commercial and non-commercial) will be supported by the clinical community and will be feasible within the NHS (e.g. available resources such as MRI, acceptability of the control regimen, compatibility with UK clinical practice)
6. Provide advice to the NIHR Division 4 portfolio team on all topic aspects of the Portfolio
7. Make recommendations/provide reports to the CRN Co-ordinating centre and LCRNs regarding the development of new ways of working to integrate patient care and research in the NHS to support portfolio studies

The CSG will be mindful of the limited resource available to conduct studies with the patient population and within the network infrastructure and will identify priority studies. When there are multiple contending studies the CSG will undertake a prioritisation review.

3. Structure

The group is no-longer accountable to the CRN (but will report any issues to the CCRN) and thus the overall responsibility for the activity and performance of the UK MND CSG Group and any developments rests with the individual group.

The list below documents the key stakeholders which the group will link with to support the MND portfolio:

- Motor Neurone Disease Association
- UK Clinical Research Network Co-ordinating Centre
- Local Clinical Research Networks (LCRNs)
- LCRN Research Delivery Managers for Division 4
- MND care centre Directors and Co-ordinators
- Allied health care professionals working within MND
- The wider MND community

The MND CSG meet monthly via teleconference and have an annual face to face meeting to discuss strategic planning. Sub groups and working parties are established between these meetings to take forward new projects and ideas that the group has.

3.1 Strategic Priorities

On an annual basis strategic priorities are developed by the group to facilitate development of new research ideas and ensure that the gaps in clinical care and scientific research are highlighted amongst the group and where feasible writing groups are set up to develop these areas.

3.2 Scorecards, targets and recruitment

As part of the Portfolio Management group responsibilities scorecards, targets and recruitment data of MND portfolio studies is reviewed on a monthly basis assessing the recruitment of studies to date and estimating whether they are on target to achieve full recruitment by the proposed end date of the study. Key members of the group indicate if recruitment figures are accurate and any interventional actions required will be planned at the meeting should concerns about targets being achieved be highlighted – these will be documented in the minutes of the UK MND CSG meetings.

3.3 Reporting

Minutes of each meeting are recorded, along with actions which are allocated to the relevant individuals. These are then reviewed by group members for accuracy and records are maintained for future reference and circulation.

Activity of the group is fed back to other MND researchers within the UK who have indicated an interest in updates. Minutes circulated to the MND interest group are amended to ensure any confidential discussions are secure.

The CCRN National Lead for Neurodegenerative disorders will receive the monthly minutes from the UK MND CSG.

4. Group Chair and Membership

The group has a Chair and Vice chair to ensure continual leadership of the groups objectives.

A summary of main duties and qualities of expected of the Group Chair is provided in Appendix 1.

Chairmanship and membership of the UK MND CSG is unpaid. However, following discussion with individuals trusts work relating to the Group may be regarded as National Work for the purposes of the consultant contract and job planning.

Membership to the group is sought from throughout the United Kingdom and applications to join the group are reviewed by the Chair and Deputy Chair. Membership is in an individual capacity, and attendance of deputies for specific meetings should reflect exceptional circumstances and be by prior arrangement with the Group Chair.

Membership of the UK MND CSG has been composed to reflect, as reasonably as possible, the various agencies involved in the development and implementation of high quality protocols involved in MND research. The group includes clinical (see Appendix 2 for duties), scientific (see Appendix 3 for duties), funding bodies, patient and carer and multi-professional members and is drawn from a wide geographical area to ensure that each research network has representation.

The UK MND CSG seeks to involve patients and carers in all aspects of its work and has a patient and a carer representative on the group (see Appendix 4 for duties).

There is a balance between experienced members with a strong track record in clinical studies and less experienced, but equally committed, members showing the potential to become leaders in the research community. Links with Local Clinical Research Networks are encouraged.

The number of members is decided by the group chair. An updated list of all Members is maintained and available on request. The group aims to replace any members who leave the group and put out a call for applicants to fill the post.

The group has a co-ordinator who has responsibility for assisting the group in achieving its aims and objectives and working groups and projects that derive from its members.

4.1 Appointment of Members

Members will be appointed through an open process. This can be as a result of an advertisement or a nomination process. Vacancies will be routinely advertised through the ABN and MNDA communication routes (e.g. websites) and professional bodies.

Nominations may be made through the following channels:

- the Group's chair, in liaison with other Group members if necessary,
- individuals wishing to self-nominate
- or nominations from other group members

People will be invited to submit an application and CV. These will then be reviewed by:

- 1) the Chair of the Group,
- 2) and Deputy Chair

The panel will review applications (CV) and recommend the appointment of new members.

Notification of appointment will be by letter from the UK MND CSG Chair.

4.2 Co-opted/Invited Members

Where appropriate, and as advised by the group, individuals with the relevant experience can be invited to address specific issues/research ideas to benefit the development or outcome of a project. These individuals will not be considered as full members in this capacity.

4.3 Confidentiality

Proposals, protocols, associated papers and progress reports submitted to the UK MND CSG are forwarded 'in confidence' to members for consideration. Under no other circumstances should these documents and possible outcomes be discussed outside the meeting without prior written permission from the Chair.

Applications involving industrial partners may contain confidential and commercially sensitive information. Panel members must hold such information in strict confidence and not make use of the information other than for the purposes of the meeting.

All documentation provided for the purpose of the meeting should be disposed of in confidential waste.

UK MND Clinical Studies Group – Chairmanship

1. DUTIES

The Chair will directly or by delegation:

- Oversee the activities of the Group
- Contribute to studies developed or adopted by the Group
- Monitor the progress of the Group
- Liaise with other National and International studies organisations
- Propose membership of the Group
- Report any issues to the CCRN National Lead for Neurodegenerative disorders Bi-annually
- Provide advice to the CRN CC or LCRNs, attending meetings as needed
- Promote good clinical research practice.

2. QUALITIES

The candidate must have highly developed leadership skills, be an excellent communicator and skilful team player. Specifically, the post holder needs to be able to demonstrate the following experience and competencies:

- Clinician with academic excellence in the research strand
- Previous experience of chairing research meetings effectively
- Evidence of an ability to provide leadership to a research group
- Be prepared to take action and implement decisions
- Previous track record of collaborative research in the research strand.

3. RELATIONSHIPS

- Will report into Theme E via the CCRN National Lead for Neurodegenerative disorders.
- Secretariat support will be provided by the UK MND CSG Co-ordinator.
- The term of appointment will be 3 years in the first instance.

4. REMUNERATION

There is no formal remuneration for the post of Chairman of a UK MND Clinical Studies Group.

UK MND Clinical Studies Group - Clinical Member

Role summary

Clinical members provide local leadership to the network in their disease area. They are responsible for overseeing the development and delivery of a balanced portfolio of studies; supporting the active management of the network; and ensuring the needs of industry are met in their disease area. They support the development of new ways of working and of the local workforce to increase the integration of health research and patient care, and to improve the speed, quality and integration of clinical research in trusts across the network. They encourage local clinicians to participate in NIHR portfolio studies, and provide clinical research leadership in their disease area.

1. Active management of the network

- Support the development of new ways of working that will increase the integration of health research and patient care, and improve the quality, speed and co-ordination of clinical research in MND.
- Ensure that the service support requirements for the disease portfolio are fully understood and that each trust in the network is receiving the appropriate service support for its participation in portfolio studies, from the appropriate NIHR funding stream.

2. Development and delivery of a balanced portfolio

- Participate fully as a member of the Clinical Studies Group, representing the requirements of their region and contributing to the running of the group as a whole.
- Provide clinical leadership to identify and ensure high quality delivery of the MND portfolio of clinical trials and other well-designed studies in MND within the UK, to which NHS patients within the CRN will be recruited.
- Build upon existing clinical research activity and clinical strengths within the UK.
- With other members of the CSG, to be responsible for the overall recruitment to, and data quality of, clinical trial research in the CRN, ensuring that appropriate governance processes are in place and all clinical trial activity is supported by appropriate guidelines and protocols and complies with established quality standards.
- Work with and support CRN member organisations in order to maximise their involvement in NIHR Clinical Research Network Portfolio studies, so as to make available high-quality clinical research to NHS patients in all sectors and all geographical areas of the CRN.
- To provide clinical leadership in the development of new research proposals within the CRN by liaising with existing research groups in the LCRN and establishing other groups as appropriate.

- To liaise with other Clinical Studies Groups and Special Interest Groups to promote integrated development of clinical studies throughout the CRN and respective LCRN.
- Keep abreast of local, national and international developments in clinical research studies and of the inclusion of new studies in the NIHR Clinical Research Network Portfolio and inform and guide the LCRN accordingly.

3. Meeting the needs of industry

- Work with the group Chair and local commercial PIs to understand industry's needs and pipeline.
- Work with local trusts to develop and implement strategies to increase their capacity to deliver commercial research.
- Support the delivery of commercial trials in the LCRN.

4. Remuneration

There is no formal remuneration for membership of the UK MND CSG.

UK MND Clinical Studies Group – Scientific Membership

1. DUTIES

Members are expected to attend all meetings of the Group and will contribute to the maintenance and further development of its portfolio of research by:

- actively engaging with studies within the Group's portfolio, for instance through entering patients, offering information and advice to collaborators, presenting findings as appropriate;
- identifying existing high quality studies that should be adopted onto the portfolio;
- generating ideas for new studies;
- contributing to the development of high quality applications to Funding Bodies through the review of trial ideas and protocols submitted to the Group;
- contributing to consultation exercises (e.g. NICE) undertaken by the Group as requested;
- contributing to the Group's annual report and peer-review of the portfolio;
- Providing expert advice to the Chair, research funders, and the wider LCRN community as required.

2. QUALITIES

Scientific members should have a track record of conducting research in MND.

Members should contribute actively to the work of the Group, and support studies within the Group portfolio. Membership may be terminated if a member fails to attend three consecutive meetings. Membership is in an individual capacity, and attendance of deputies for specific meetings should reflect exceptional circumstances and be by prior arrangement with the Group Chair.

The intention is to develop a portfolio that is well balanced and draws on local research network strengths to stimulate accruals. The composition of the Group should reflect this and members should, therefore, be able to demonstrate some of the following:

- experience of collaborative clinical studies activity in a leadership capacity;
- success in trial accrual into national studies;
- evidence of publications and/or presentations nationally/internationally;
- links with Local Clinical Research Networks;
- Enthusiasm and commitment to developing MND research.

3. RELATIONSHIPS

Members will be responsible to the Group Chair. Secretariat support will be provided by the UK MND CSG Co-ordinator.

4. REMUNERATION

There is no formal remuneration for membership of the UK MND CSG.

UK MND Clinical Studies Group – Lay Membership

1. ROLE

Clinical Studies Group lay members are expected to:

- Provide their perspective as a person affected by neurodegenerative diseases into the development, management and reporting of individual clinical studies.
- Offer advice on the development of active PPI.
- Assist with the prioritisation and development of the overall portfolio of clinical studies.
- Respect any requests for confidentiality, and declare any conflicts of interest if they arise.

2. DUTIES

Clinical Studies Group Members are expected to contribute to the activities of the Clinical Studies Group, its sub-Groups or associated working parties by:

- Actively engaging with trials within the Group's portfolio, for instance through offering information and advice to other patients on request, and participating in discussions of findings as appropriate.
- Generating ideas for new clinical studies/identifying priorities and research gaps.
- Contributing to the development of high quality applications to funders through the review of trial ideas and protocols submitted to the Group.
- Contributing to consultation exercises (e.g. NICE) undertaken by the Group as requested.
- Contributing to the Group's annual report.
- Providing advice to the Chair as required.
- Reading Clinical Studies Group paperwork.
- Attending Clinical Studies Group meetings.

3. RELATIONSHIPS

CSG Members will be responsible to the Group Chair.

4. REMUNERATION

There is no formal remuneration for membership of the UK MND CSG. Reasonable travel expenses to the annual face to face meeting and the costs of calling into the teleconferences will be reimbursed by the MNDA for PPI members, in accordance with their policies.

5. MENTORSHIP

A Mentor will be available to provide support to lay members on Clinical Studies Groups. The UK MND CSG co-ordinator will be available:

- To be contacted by telephone/email before and after each meeting.
- To welcome lay members to each meeting of the Group.
- To answer questions from lay members.

A buddy system with another member of the UK MND CSG will be set up for new Lay members who join the group to support their induction.

6. TRAINING & SUPPORT

Lay members of the CSG will be advised to link with the INVOLVE network and highlight any training needs to the group. New members will be linked into a buddy system with another member of the CSG to integrate them into the group activities.