MCRN / arc Paediatric Rheumatology Clinical Studies Group

Remit and Terms of Reference

Overview
The MCRN/arc Paediatric Rheumatology CSG, formed in a partnership between the MCRN and arc, will support and develop a comprehensive portfolio of clinical studies directed towards and including clinical trials in all areas of paediatric rheumatology across the UK. It will advise the MCRN and arc in defining research priorities in paediatric rheumatology for their support and adoption.

Full details and important background information are available:
- MCRN/arc Rheumatology Clinical Studies Group
  (http://ctuprod.liv.ac.uk/mcrnweb/images/stories/csg/mcrn-arc%20rheumatology%20csg.pdf)
- MCRN Clinical Studies Groups – Remit Document
  (http://ctuprod.liv.ac.uk/mcrnweb/images/stories/csg/mcrn%20csg%20remit%20document.pdf)
- arc Clinical Trials Update
  (http://www.arc-research.org.uk/ClinicalTrialsUpdate.dot)

Responsibilities
The CSG will bring together the expertise and enthusiasm necessary to establish an authoritative voice in the paediatric rheumatology research community directed towards clinical trials and related studies.

The CSG will have two main responsibilities:
1. Reactive and Proactive - To support and develop a portfolio of clinical studies directed towards and including clinical trials in all areas of paediatric rheumatology across the UK
2. Advisory - To advise the MCRN and arc in defining research priorities in paediatric rheumatology for their support and subsequent adoption to run through the MCRN

The Remit of the CSG and its Members is to:
- be responsible for developing and overseeing a comprehensive portfolio / strategy for clinical trials and related studies covering the spectrum of major disease areas in paediatric rheumatology
- propose and support the development of protocols for trials and related studies. These protocols where relevant will include the design of pilot and feasibility studies to provide proof of concept for definitive studies in terms of recruitment, data collection etc.. The CSG will proactively advertise submissions of protocols needed to satisfy these goals, to be done in collaboration with the CSG
- review trial and related study protocols proposed by others (including industry proposals), to advise the MCRN and arc how they may fit into the CSG portfolio / strategy and how the protocol could be assisted in its development
- provide robust scientific evaluation, expert advice and support to investigators
- ensure consumer involvement in all activities
- work in close collaboration with other MCRN CSGs and arc CSGs
- consider research “add-ons” to established protocols (e.g. pharmacogenetics and qualitative studies)
- provide regular reports to the MCRN and arc of its work and recommendations
- support the development of partnerships with other research funders (e.g. NIHR, MRC, Welcome, other AMRC funders..) and industry in developing a comprehensive research programme in paediatric rheumatology
- uphold the highest standards of Research Governance and Good Clinical Practice (GCP) throughout its portfolio according to ICH-GCP guidelines, EU Directives on Clinical Trials and GCP, and UK law
CSG members with specific or general expertise may be asked to evaluate proposed trials from the pharmaceutical industry via the commercial trials adoption process under development with UKCRN. Evaluation will include relevance to the NHS and the important unmet needs of child health, statistical validity (at the level of an experienced clinical trialist) and feasibility. These evaluations will need to be undertaken as a matter of priority.

**Operation**
The CSG will be supported by the MCRN Coordinating Centre (MCRNCC) in partnership with arc. The CSG Administrator will oversee the organisation and administration of the CSG. The CSG Administrator is based at the MCRNCC and will attend and is responsible for arranging all CSG meetings and related working groups, circulating agendas and papers and taking minutes of the meetings. The CSG Administrator will be responsible for close administrative liaison with arc CSG Administrator (see http://ctuprod.liv.ac.uk/mcrnweb/images/stories/csg/mcrn%20csg%20remit%20document.pdf Appendix 1iii).

**Meetings of CSG**
- **CSG Meetings** - The CSG will hold a minimum of 2 meetings per year along with a minimum of 4 regular teleconferences / videoconferences. Teleconferences / videoconferences may also be called on an adhoc basis as required for specific areas by the requirements of the CSG’s developing research agenda.
- **CSG Email Discussion Forum** – This will aim to facilitate communication and progress of specific projects / areas concerning the CSG’s Remit.

**Meeting of CSG-related Topic-Specific Groups**
- **CSG-related Topic-Specific Groups (TSGs)** – Topic-specific groups will be established as required for the task of taking ahead development of projects (and subsequently disbanded in a timely manner).
- Although these Groups may naturally gather under disease-specific groupings for study / trial development, across-disease groups based on themes of intervention / disease may equally be formed where this facilitates fulfilling the remit of the CSG.
- **Disease specific TSGs** may include: juvenile idiopathic arthritis; juvenile-onset SLE; juvenile dermatomyositis; childhood scleroderma; childhood vasculitis; chronic musculoskeletal pain syndromes, bone metabolism, etc.
- **Where appropriate**, the TSGs will interlink with established research networks / groups in order to facilitate and not duplicate processes (while remaining inclusive of all potential stakeholders).
- **The TSGs** will be coordinated through the CSG and will be supported and attended by relevant members of the CSG. They will include any relevant stakeholder committed to the aims of the CSG, and may be led by non-CSG member investigators.

**Funding of CSG Meetings**
- The CSG will funds travel costs (second class rail or equivalent) for CSG meetings (members or their deputies) and TSG meetings for those confirming attendance five working days before the meeting. It will not fund accommodation. Accommodation is available free of charge at the MCRN Coordinating Centre in Liverpool, and the MRC Clinical Trials Unit, London.
- The CSG will fund teleconferences of the main CSG and TSGs with the prior authorisation of the CSG Chair or Administrator.

**Membership**
The membership will reflect, as reasonably as possible, the various agencies involved in the development and implementation of high quality protocols of clinical studies directed towards and including clinical trials in paediatric rheumatology across the UK. Where single representation of a given stakeholder is in place, deputies can be appointed to represent.

As a minimum, the CSGs will be made up of multi-professional representation and include:
- **Medical representative** (approximately 6), reflecting:
  - A balance between experienced members (clinical and academic) with a strong track record in clinical trials and less experienced, but equally committed, members showing the potential to become leaders in the research community.
As wide a geographical representation as possible
At least one representative of the devolved nations
- Clinical Nurse Specialist representative
- Allied Health Professional representative
- Basic Science Investigator representative
- Chair of the BSPAR Research Sub-committee - To ensure closest collaboration with and awareness regarding the full spectrum of paediatric rheumatology taking place in the UK

Advisory Members
A number of members can be appointed on a regular or an adhoc basis depending on the needs of the CSG and related topic-specific subgroups. Travel / teleconference costs associated with their participation must be agreed beforehand by the CSG Administrator.
- UK PRINTO link – To facilitate communication and collaboration (as appropriate) with PRINTO
- Pharmacy & Formulations – The MCRN Formulations Fellow will attend all CSG meetings and teleconferences and provide an advisory role on issues relating to paediatric formulations, pharmacy involvement, and provide a direct link with the expertise and advise of the MCRN Pharmacy & Pharmacology CSG
- Statistician / Clinical Trials Support Unit – This will be provided by both the MCRN CTU and arc-funded senior researcher (Caroline Doré) in Clinical Trials based at the MRC Clinical Trials Unit
- External expertise - Experts will be sought, including international experts, in a particular field to address specific issues/research questions
- Health economist – A health economist will be sought to advise on related opportunities arising from the CSG portfolio / strategy and study design

Non-voting members
Other representation on the CSG may include:
- Pharmaceutical industry representation – In association with the Medical Director of ABPI, a nominated representative of the pharmaceutical industry will be appointed on a rotational basis to advise the CSG on industry-related issues about portfolio / strategy and study design. They will represent and feedback to those ABPI members identified through the ABPI Medical Director as having a specific interest in the work of the CSG
- Funding body representatives - Relevant charitable bodies, identified with the advice of arc and the MCRN, will be in receipt of all meeting papers and be invited to attend relevant meetings as non-voting members (cost of attendance supported by their relevant charitable body)
- MCRN / arc representatives – MCRN and arc representation will be sought to optimise integration with the expertise, resources, and infrastructure of the relevant bodies. MCRN will be represented in the first place by the MCRN CSG Administrator

Consumer Representation
The CSG will involve consumers (children, young people or parents) in all aspects of its work.
- Consumer representatives will be appointed in consultation and collaboration with the MCRN Consumer Liaison Officer (CLO) based at the MCRNCC who will offer advice and support to the CSG and consumers to enable meaningful engagement.

The nature of their involvement will vary according to different areas of CSG’s portfolio and development. To these ends, it will include:
- Establishment of a database of consumers, from whom representation can be invited on a topic-specific or generic basis to advise the work of the CSG or its associated working-groups
- A shadow consumer panel of young people or parents to report their views to the CSG with specially designed exercises for focus groups in order to capture their views
- A database of charitable bodies, including at times a consortium of agencies, representing consumer issues

MCRNCC will fund travel costs, child care costs and other out-of-pocket expenses for consumers who attend CSG meetings.

Appointment of Membership
Membership of CSGs will be appointed through an open, transparent and competitive process (see Appendix B).

**Membership Terms of Reference of CSG**

- Membership will be for three years with the possibility of an extension for further two years duration.
- After three years, the CSG Chair will write to the Member asking if they would like to continue on the CSG.
- Where several Members are due to resign from the CSG at the same time, this will take place in a phased manner to ensure the continuity and expertise on the CSG is maintained throughout.
- Decisions on extension of membership duration will be made by the CSG Chair in agreement with the MCRN Operational Group and **arc**, following an application in which the overriding consideration will be the needs of the CSG and its work.
- At the end of a term of membership a one-year period must elapse before members can reapply for a further term in the same role. Exceptions to this, should they arise, will be reviewed on a case-by-case basis.
- If a Member fails to attend two CSG Meetings in succession, or participate on a regular basis in the work of the CSG, the CSG Administrator will send a letter to the Member asking of their intention to continue working on the CSG.
- If a Member fails to attend three CSG Meetings in succession or participate in the work of the CSG, it will be understood that they have voluntarily withdrawn their Membership of the CSG and the CSG Administrator will inform the 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 CSG Chair or CSG Administrator.
- The effectiveness and composition of the CSG will be considered as part of the yearly review of its portfolio.

**Accountability**

The CSG will be accountable to the MCRN Board, chaired by the Director of the MCRN, and the **arc** Clinical Trials Research Group, chaired by the Medical Director of the **arc**. These will manage the performance of the CSG, the appointment of the Chair and oversee the appointment of new members and the development of new groups.
Appendix A
MCRN / arc Paediatric Rheumatology CSG - Job Description for Scientific Membership

1. DUTIES
Members are expected to:
- attend all meetings and teleconferences of the CSG whenever possible
- participate actively and respond in a timely fashion to CSG Email Discussion Forum
- actively support the CSG achieving its Roles and Remit
- contribute actively to the development of the CSG’s portfolio of research by:
  a. actively engaging with studies and trials within the CSG’s portfolio (e.g. through entering patients, offering information and advice to collaborators, presenting findings as appropriate);
  b. identifying existing high quality studies that could be supported / adopted by the CSG;
  c. generating ideas for new trial protocols and related studies
  d. taking a lead in one (or more) specific area of the CSG’s portfolio of development
  e. contributing to the development of high quality applications through robust scientific evaluation and expert advice for trial ideas and protocols submitted to the CSG in order to support investigators
  f. contributing to the CSG’s annual report and review of the portfolio
  g. contributing to the consultation exercises undertaken by the CSG by providing expert advice to the CSG Chair and through the CSG to the MCRN and arc, funders, MCRN commercial trials adoption process, and the wider clinical paediatric community, for work related to the CSG’s portfolio
  h. upholding the highest standards of Research Governance and Good Clinical Practice

2. QUALITIES
Members should be enthusiastic, energetic, a skilful team player and committed to collaborative research. They should have a strong track record of active participation in research, experience and expertise in areas relevant to fulfilling the roles and remit of the CSG, and a strong commitment and advocate to the goals and vision of the CSG.
Desirable criteria for members include:
- experience of collaborative clinical trials activity in a leadership capacity;
- success in trial accrual into local and national studies;
- evidence of publications and/or presentations nationally/internationally;
- links with paediatric research networks;
- an enthusiasm and commitment to developing research into medicines for children
- highly developed leadership skills, excellent communicator, skilful team player
Members should be prepared to maintain commercial confidentiality when working with the pharmaceutical industry and to declare conflicts of interest.

3. RELATIONSHIPS
Members will be responsible to the MCRN Board and arc Clinical Trials Research Group through the CSG Chair. Administrative support will be provided by the MCRN CSG Administrator.

4. REMUNERATION
Work relating to the groups is regarded as national work for the purposes of the consultant contract and job planning. This is a voluntary, non-remunerated position. Reasonable travel expenses (second class fares) will be reimbursed in accordance with the MCRN/arc Rheumatology CSG – Remit & Terms of Reference policy.
Appendix B
Recruitment of MCRN/arc Paediatric Rheumatology CSG Members
The process for recruitment of new Members to the CSG will be open, transparent and competitive.
The positions will be made available to all members of the paediatric clinical research community. Adverts will be placed on such outlets to reach a wide coverage of the relevant audience as defined in Appendix C.

Process for Recruitment of CSG Membership:
- Vacancy advertised via approved communication routes (appendix C)
- Applicants requested to send CV and detailed statement outlining their suitability for role as Member to the CSG Administrator
- The CSG elects a ‘Selection Group’ of at least 3 members who are independent of all applicants (to avoid conflict of interests) to select the most suitable candidate.
- (The initial Selection Group at the start of the CSG will be made up of the CSG Chair, senior MCRN representative and a senior arc representative)
- Following closing date for applications, all CVs posted on relevant CSG Email Discussion Forum for review by selection group (within a firm timescale)
- Selection group recommend an appointment.
- Chair produces report to justify the group’s choice of member, to be sent to MCRN Executive and Medical Director of arc.
- Appointment ratified by MCRN Executive / Medical Director of arc.
- Successful applicant informed via letter from CSG Chair.
For Membership Terms of Reference - see main document

Recruitment of MCRN/arc CSG Chair
The process for recruitment of new Members to the CSG will be open, transparent and competitive.
The position will be made available to all members of the paediatric clinical research community. Adverts will be placed on such outlets to reach a wide coverage of the relevant audience as defined in Appendix C.

Process for Recruitment of CSG Chair:
- Vacancy advertised via approved national communication routes (Appendix C)
- Applicant(s) requested to send CV and 1000 word statement outlining suitability for role to the CSG Administrator
- Appointment will be following competitive interview with an interview panel including the Director of the MCRN and medical Director of arc (or appropriate representatives)
- Successful applicant informed via letter from MCRN Director / arc Medical Director
Term of office for MCRN CSG Chair: initially 3 years, extendable to 6 years following agreement of Director of MCRN / Medical Director arc

Appeals Process:
Should there be an appeal raised during the selection process the MCRN Executive reserves the right to review all applications.
Appendix C

Advertisement of Vacancies for CSG Members

Recruitment of Scientific Members:
Vacancies for Chairs should be advertised on:
- MCRN website
- arc website
- UKCRN website
- BSPAR mailing list and website

All advertisements will include details of the MCRN and arc website, from which the CSG Document can be accessed for further information.

In addition to the above standard advertising outlets, there are specific contacts that can be used when advertising for specific allied professionals to join the CSGs:

Clinical Nurse Specialist / Allied Health Professional Representative:
The following possible routes for advertising vacancies have been identified:
- BSPAR Clinical Nurse Specialist Group
- BSPAR Allied Health Professionals Group
- Royal College of Nursing (RCN) Research and Development Coordinating Centre
- RCN Research Society