



MCRN / arc Paediatric Rheumatology Clinical Studies Group Meeting 8th July 2008, UBHT Education Centre, Bristol

Present: Michael Beresford (Chair), Eileen Baildam, Paul Brogan, Sharon Douglas, Jane Dunnage, Helen Foster, Laura Pilkington, Jenny Preston, Athimalaipet Ramanan, Madeline Rooney, Moin Saleem (9.25am), Wendy Thomson, Katharine Venter, Lucy Wedderburn, Patricia Woo, Joanna Worsfold.

Apologies: Utpal Shah

Welcome and Introductions

MB opened the meeting and welcomed all in attendance. MB introduced the consumer representatives (Katharine Venter, Joanna Worsfold, Sharon Douglas {and Jane Dunnage, representing the JSLE TSG – observer}) to the CSG.

Minutes from the teleconference on 02/06/08

The minutes were approved by the CSG as being an accurate record of the meeting held on 2nd June 2008.

Consumer Roles on the CSG

- The consumer representatives gave a very positive account of the Consumer Induction Day (13th June 2008). The CSG all agreed consumer representatives should be actively involved in all aspects of the work of the TSGs / CSG.
- The CSG discussed the types of models that could be developed to integrate consumer involvement both directly and indirectly with work of the CSG. MB indicated the lupus / JDM groups as existing models of consumer participation which could be developed in other TSGs, or others. Examples of consumer input could include: commenting on patient information leaflets, advice and linking with steering committee lay reps, commenting on public websites (CSG and other), BSPAR Research portfolio, strategy development of CSG, participation / facilitation of consumer groups
- JP – MCRN would like to develop a virtual consumer group, which would be available via the NIHR portal to be able to canvass consumer opinion for relevant activities. JP currently in discussions with the NIHR and agreed to keep the group up to date will all activity.
- MB agreed to inform BSPAR of these initiatives involving the consumer representatives – Actioned at BSPAR Research Day

Action: Consumer Reps – to consider ways of participation in activities of CSG, and present to CSG in due course

Development of CSG's Portfolio

ARC Timetable: MB informed the CSG that the arc expect that by 1st Dec '08 for one / two full study applications (fully worked up including MCRN/CTU input and supported by the CSG) to be submitted for funding. The CSG is required to submit a comprehensive report outlining its key strategic priorities by the same time. Each TSG gave an update of its main activity and key focus points for development to strategy:

Uveitis and JIA

- AR – TSG meeting on June 20th at the Bristol Eye Hospital to discuss future research initiatives in children with Uveitis and JIA. The meeting was well attended; general ideas as well as two trial design proposals were discussed.
- AR informed the group that the following trial design was agreed: A multi-centre, two-part, 1-year Phase 3 study with Part I consisting of a 12-week randomized, double blind, placebo-controlled, parallel group, 2-arm study to evaluate the efficacy and safety of Adalimumab in patients with active Uveitis in association with JIA refractory to subcutaneous MTX therapy; with Part II a 40-week single-arm open-label extension to examine chronic safety and efficacy.

*RESULT: The CSG agreed to give full support of taking this proposal forward for funding to the **arc**. PW to provide CSG advisory role to AR*

ACTION: MB – to negotiate with MCRN CTU and Caroline Dore for support for this trial development; AR to arrange with visit to MCRN CTU for their input along with Industry Team, Formulations LRN, etc.. AR to keep the CSG updated

JIA TSG

HF - informed CSG not had face-to-face meeting of this TSG to date but teleconference discussions have taken place. The main focus of discussion has been on the status of the current biologics registry and how best to take this forward. HF noted that Data Files have expressed an interest in being involved/support the future development of studies associated with a core “registry” dataset. Possibilities of linking with the adult registry were also discussed.

*RESULT: The CSG were supportive of a wider remit of the biologics registry (all biologics, all diseases in which used); extremely important for the CSG’s agenda; may or may not be a specific project to take to the **arc** for funding in November deadline.*

*ACTIONS: MB – to discuss with MCRN and arc re their support for this type of project; CSG to support and apply through the JIA TSG to **arc** for funding to conduct qualitative / survey of relevant parties including the BSPAR membership regarding the design, feasibility and requirements of conducting a prospective cohort study(ies) of children on biologics; HF to take forward with EB and WT; HF to give update and open discussions with all at BSPAR Research Day re priorities for JIA TSG*

Bone Health TSG - POP Study

MR - work underway to recruit new centres to POPS. MR reported probable will need to go back to the **arc** for additional funding. MB informed the CSG this is likely to come through the CSG; MB updated that 3 research groups had approached the CSG re bone health studies - to engage with MR to discuss prioritising research topics in bone health.

RESULT: The CSG supportive of success of POPS Trial; bone health key area of interest and prioritisation

ACTION: MR - To consider re-costing POPS using the current UKCRN costing template. MB to contact bone health research leads and circulate a list of proposed dates for a bone health TSG meeting. LP to facilitate this process.

Auto Inflammatory Diseases TSG

PW - A database, based on a European model, to study clinical and genetic aspects of auto-inflammatory diseases in the UK was being developed by Philip Hawkins and Michael McDermott, in collaboration with the Royal Free

*RESULT: The CSG agreed that this project would not be ready for the December deadline but could be considered for funding in the next round of calls from the **arc** in 2009 and form part of portfolio.*

ACTION: PW - To update CSG with details of database for comment in due course

Vasculitis

PB – initial progress with the MYCYC Trial (MCRN adopted); due to arrange teleconference of interested parties; has established links with EUVAS; other clinical trials to be considered include Childhood PAN; Key strength is determining biomarkers in childhood vasculitis. With this in mind, proposal to explore developing this in context of JDM (see below JDM TSG)

JDM TSG

LW - Agreement by the JDRC to form the basis of the TSG, opening meeting up to all interested parties; Agreed plan to change the existing Registry to “Cohort and Biomarker Study” in order to seek UK CRN adoption – with support of CSG; Teleconference booked for the 7th August – circulated via the BSPAR mailing with support of the CSG; PRINTO JDM trial has COREC approval – proposal to circulate questionnaire for feasibility to other centres: agreed to do this as part of CSG “feasibility” questionnaires, with LP support.

Proposal to develop “Vascular health in JDM” (as basis of developing this theme in other CSG disease areas) as a priority area for the TSG; this could take place as part of an initial pilot / feasibility study using members of the current registry cohort, looking at established biomarkers from systemic vasculitis.

RESULT: The CSG agreed that this was an excellent early project and were supportive of taking this proposal forward (also as a model of collaboration between TSGs). A 6 month multi-centre pilot study in Biomarkers of Vasculopathy in JDM – under £30k leading into a more comprehensive study

*ACTIONS: LW to proceed with feasibility for PRINTO JDM; to update teleconference; PB to write outline and submit to the **arc** for CSG development funding. MB to discuss with **arc** about this; PB and LW to up date CSG with progress.*

Scleroderma TSG

EB – Systemic sclerosis – development of links with European collaborations; localised scleroderma – key area that can be developed within the UK, including biomarkers, skin scores, as basis of intervention (e.g. MTX, MMF, etc.); to take ahead network of interested parties to form TSG; not for initial wave of funding to **arc** but could be key area for support for second phase

ACTION: EB – to take forward with view to next phase of funding opportunities. Subject: Looking at localised scleroderma in children.

JSLE TSG

MB – UK JSLE Study Group open to all interested parties and has been exploring this agenda for some time; had considered RCT of steroid use in induction of initial / flare including methylprednisolone and weaning regimens; however for this, and also B-cell depletion trials, need stronger evidence base for biomarkers / disease activity scores in JSLE – particularly paediatric BILAG - this therefore is the priority for the next six months; therefore no trial to submit for this round of **arc** funding but possible biomarker project

ACTION: MB to keep CSG informed of plans

Biologics and related Studies

Update relating to the Biologics Registry Including MCRN Adoption

MB informed the group that he had a teleconference with the Deputy Director of the MCRN, Chair of the MCRN Study Adoption Committee and MCRN Industry Lead on 05/06/08 to discuss the various possibilities of MCRN adoption of a biologics-associated ‘registry’ and related studies. MB prepared a 4 page document for this meeting. MB informed the group that the meeting was very helpful although there are issues with

the registry in terms of the DOHs rules for adoption into the MCRN portfolio. MB informed the group that work will be done to try and tick the boxes that need to be ticked. The CSG's proposal will be discussed at forthcoming MCRN Exec meeting to see how to proceed

TREAT Trial

MB informed the CSG that only three feasibility questionnaires were returned, of which all three said that they strongly supported participation in North American trials but that partly for protocol details, partly for time scale, this trial was not one they would participate in; discussion of getting accurate returns from feasibility questionnaires – MB to also explore doing this through the MCRN LRNs

ACTION: MB informed the group that he would write a letter to CARRA and would clearly point out that for future feasibility questionnaires to involve the CSG from the beginning.

Update from the MCRN Coordinating Centre

Performance Monitoring and Annual Progress Report of CSGs

MB informed the group that the Department of Health is undertaking a 3 year progress review of the MCRN in early January 2009. An initial CSG Performance Report was made at the end of 2007. Performance measures include: Membership; Key Activities and Achievements; Study proposals and protocols reviewed; Future Plans and timelines. Key performance areas identified include: Response time by CSG when contacted by an investigator to review a study (within two months of receipt of this request); following a review the progress of a study should be logged; funding calls should feature as an agenda item for all meetings.

Appointment of Membership

MB informed the group that an advert for the position of Clinical Nurse Specialist and Allied Health Professional had been drafted. The group were happy with both adverts and agreed for them to be disseminated via: MCRN/UKCRN/arc web pages, BSPAR Community (to include BSPAR Clinical Nurse Specialist Group emailing list and BSPAR Allied Health Professional Group emailing list), LRNs, cLRNs and CSG members.

MB informed the group that as part of the recruitment process, at least three members from the CSG who are independent of all applicants would need to be selected to decide on the most suitable candidates. MB asked the group for volunteers and the following members agreed: Sharon Douglas and Madeline Rooney (NB. The deadline for both adverts is Friday 1st August 2008).

Update on ERA-NET PRIOMEDCHILD

MB informed the group that the first survey for this work package, where stakeholders were invited to suggest research topics within medicines for children, had finished and that all responses had been collated and fed into a Delphi Consensus Questionnaire. MB informed the group that the questionnaire asks participants to rate each research topic against a criteria and that rating will be done using a 1-9 Likert scale with 1 relating to strong disagreement, and 9 representing strong agreement. Consensus on an item will be said to have been reached if 75% or more of the responses rate an item in the range of 1-3 (disagreement) or 7-9 (agreement). MB informed the group that this questionnaire would be available to complete over the next couple of days and that it was very important that CSG members take the time to complete it.

Current Calls for Funding

LP informed the group that this agenda item will appear on all future meeting agendas (a measure that was agreed at the last Chairs/LRN Directors joint meeting). LP requested that CSG members keep her up to date with the names of professional bodies that offer funding to researchers so that she can be kept informed with the opportunities that are available.

ACTION: CSG members to LP informed of new funding opportunities.

Any Other Business

LP reminded the CSG to complete and return a copy of the MCRN conflicts of interest document to her, as soon as possible. Thanks to AR for organising the venue and meeting facilities

Date, Time and Location for Next Meeting

The next meeting of the CSG will be via teleconference on Monday 4th August 2008.

ACTION: LP will circulate a list of proposed dates for a face-face meeting in