

Minutes – MCRN/arc Paediatric Rheumatology Clinical Studies Group Teleconference

Monday 5th October 2009

Present - Michael Beresford (MB), Nick Bishop (NB), Paul Brogan (PB), Helen Foster (HF), Laura Pilkington (LP), Utpal Shah (US), Athimalaipet Ramanan (AR), Madeline Rooney (MR), Wendy Thomson (WT), Katharine Venter (KV), Lucy Wedderburn (LW), Joanna Worsfold (JW)
 Apologies – Eileen Baildam (EB), Sharon Douglas (SD), Sue Maillard (SM), Pat Woo (PW)

Item	Subject	Briefing	Action Required
1	Welcome & Introduction	<ul style="list-style-type: none"> • <u>Welcome</u>: MB opened the meeting and welcomed everyone in attendance. • <u>Introductions</u>: MB introduced NB to the CSG. NB will be involved in all CSG activities and work with MR in the bone health TSG. All CSG members gave a brief introduction and welcome to NB • <u>Apologies</u>: These were noted – see above. 	None.
2	Review of Minutes from Last Meeting and Matters Arising	<ul style="list-style-type: none"> • <u>Review of the Minutes from the Last Meeting</u> The minutes from the last meeting (written by MB) were reviewed by the group and were accepted as an accurate record of the discussions that took place. • <u>Matters arising</u> <ul style="list-style-type: none"> - <u>JIA/Uveitis Trial</u> - The study team have submitted a full application to the HTA/arc Commissioning Board. It is anticipated that the funding outcome will be announced late November. - <u>JIA TSG Survey</u> – HF will present a report on the progress of the survey at the face-to-face meeting in November. - <u>Extended Biologics</u> – The MCRN have adopted this study subject to clarification on a couple of minor points. - <u>JDM Cohort Study</u> – This study has not yet been submitted to the MCRN Study Adoption Committee. An application is in the pipeline. MB written letter of support - <u>MYPAN</u> – This study was discussed at the last teleconference. The CSG agreed that it was in line with the strategy and were keen to support the development of the protocol. - <u>Validation of Paediatric Vasculitis Scores</u> – This study was previously reviewed by the CSG but it was felt that further work was needed. It has been provisionally submitted for other funding and will not be submitted for the November 09 ARC submission deadline. - <u>Roche (CHERISH Trial) – Tocilizumab in Poly JIA</u> – This study is moving forward. The CSG have encouraged the addition of other sites through the MCRN Industry Team. Of those sites previously selected by Roche: Bristol have got full MREC and R&D approval and Liverpool have got R&D approval. No update was given for London. It was noted that the UK is the first country out of the 20+ countries taking part in the trial to be up and running. - <u>Novartis (Phase II Trial in Systemic JIA) – Canakinumab in SoJIA</u> – Three related but distinct protocols covering the natural history of SoJIA have been forwarded to the MCRN and MB. The MCRN Industry Team are working with Novartis to try and identify sites (UK recruitment target = 8 UK sites; 18 patients). The MCRN are waiting for Novartis to submit more paperwork before raising it formally with the CSG. In principle, it was noted that the CSG are very supportive of this trial. - <u>Golimumab JIA Trial</u> – There were no further details to report since the last teleconference (September 09). - <u>Kingfisher Healthcare</u> – The CSG agreed in principle to support a trial of the agent being put forward (oral, non-biologic, for SoJIA). Specific points of note suggested included: <ul style="list-style-type: none"> • The CSG would like to be in a position to comment and advise on the development of the final protocol, in view of the expertise we offer • Clarification of the timescale envisaged • Whether the company had considered its use in sub-type of JIA other than just systemic-onset 	<p>MB to keep CSG posted on funding outcome</p> <p>HF to present the results from the survey at the face-to-face meeting in November</p> <p>PW, EB and AR to keep CSG posted;</p> <p>3 members of the JIA TSG to help in reviewing the 3 protocols on behalf of the CSG, along with MB; PW will be UK CI for this trial</p> <p>MB to keep the group informed about any new details relating to the Golimumab Trial</p> <p>MB to feedback the CSG's comments regarding the Kingfisher Healthcare Trial to the MCRN Industry Team [Actioned]</p>

		<p>(e.g. polyarticular course)? This would extend the scope and patients eligible, and on initial consideration, the mechanism of action may extend to other forms of JIA rather than just SoJIA. Has the company considered this or any data in support of this?</p> <ul style="list-style-type: none"> As previously mentioned, key issues of formulation would be important to be considered in the light of its paediatric use The CSG would strongly advocate the inclusion of development a parallel "Biobank" for investigator-led study of the immunopathogenesis of JIA, in keeping with its translational research priority in rare auto-inflammatory diseases 	
3	HTA Prioritisation	<p>MB listed the different panels that the submitted proposals are considered under by the HTA. These are as follows:</p> <ul style="list-style-type: none"> Pharmaceutical panel; Diagnostic technologies and screening tools; Disease prevention; Intervention Procedure (including surgery); PCT (including psychology and community programmes); External and/or physical therapies. MB informed the group about a recent teleconference he had with the HTA about the CSG's submitted priorities. There were three priorities that 'fitted' into the scheme: 1) Steroid induction regimen for JIA 2) RCT of mycophenolate mofetil versus methotrexate in childhood localized scleroderma 3) Musculoskeletal ultrasound in the diagnosis and treatment of JIA. There were two priorities that 'didn't fit': 1) Methotrexate in paediatric rheumatology: Development and assessment of oral formulations more palatable and less painful subcutaneous / needle free technologies (it was felt that this would be covered by other RfPB programme grants) 2) Validity and cost effectiveness of eye screening performed by non-ophthalmologists (e.g. opticians, optometrists) with guidelines for referral to ophthalmology for screening of JIA-related Uveitis. There were two priorities which the HTA said 'no' to as the intervention was not clearly defined or established: 1) Diagnostic algorithm and educational strategy to enable fast-track, early referral pathways for JIA 2) Role of psychological assessments in addressing issues of non-compliance in paediatric rheumatic disease; these could be re-considered if the established model of intervention was being validated It was noted that the HTA are happy for the CSG to revisit those submitted priorities and any areas that haven't yet been submitted (e.g. bone health). MB encouraged further work in both of these areas. Those key areas not submitted at this time were not done so simply for reasons of time, not lack of importance, and CSG members were encouraged to continue to help in this process 	<p>All - reconsider submitted proposals and any additional proposals, especially in field of Bone Health</p> <p>MW, NB and MB to have off-line TC to discuss the Bone Health priorities and potential submissions for both the HTA priorities and ARC funding</p>
4	ARC CSG Chairs' Update	<p>MB needs to prepare a report on the activities of the CSG over the last 12 months for the ARC. Subject headings for the report were discussed and it was agreed that the following sections should be included: 1) Successful Grants (including the post for the Vasculopathy of JDM; Extended Biologics; JIA/Uveitis Trial; POPs funding extension) 2) Publications to promote the work of the CSG 3) Industry Trials 3) Inclusivity (i.e. consumer representation) 4) Developments with the Bone Health TSG and links with BPABG 5) HTA Applications (including those submitted and accepted) 6) A list of those studies that the CSG have commented on (EOI) 7) BioBank. It was noted that MB has reviewed 25 studies to date. Seven of these studies have been commercially funded trials. Several members expressed concerns for MB's workload and volunteered to assist him where possible.</p>	<p>MB/LP to draft a report and circulate to the CSG for comment before the end of the month</p> <p>MB to distribute to CSG members through the respective TSGs protocols of relevance or interest for comment and feedback, to assist MB where possible</p>
5	CSG Topic Specific Groups	<p>A brief update of activity was given: <u>JDM (LW)</u> – The JDM Cohort Study will be submitted for MCRN adoption over the coming months. This will allow the study to be opened up to new centres. A survey to assess what people are doing clinically will be sent out to all centres currently enrolled in the study and eventually to all new centres. The TSG are planning to hold their next teleconference in 2-3 months time. NB asked about studies of</p>	<p>All - Actively reflect on the projects that could be considered for November deadline</p> <p>All to have available detailed update</p>

		<p>calcinosis in JDM as an area of overlap between TSGs; LW to discuss further</p> <p><u>Vasculitis (PB)</u> – This TSG exists as a virtual group. Activities to date include: running a clinical trial based at GOSH and participating in a programme of work with European colleagues. It was noted that the TSG is hoping to get MYPAN online over the next 24 months.</p> <p><u>JIA / Uveitis (AR)</u> – Update already given – see subject 2 and 3. To inform BSPAR members of CSG role with MCRN in relation to Industry trials</p> <p><u>JSLE (MB)</u> – There is lots going on but nothing specific to report on at the moment. MB will give a detailed update at the face-to-face meeting in November.</p> <p><u>Bone Health (MR)</u> – MR was delighted that NB has been appointed as a full member of the CSG and will work with her in the TSG. Other points noted: 1) POPs has been extended 2) The AVN Study – Simon Thomas plans to submit a full proposal for the November deadline. He has got a CTU on board and has met with his local MCRN. There is an investigators meeting on 21st October. At this meeting they will consider including a placebo.</p>	<p>information of the respective TSGs for the face-to-face meeting</p> <p>HF to draft letter and MB to send to BSPAR</p> <p>MB, MR and NB to meet over the next 10 days to discuss TSG priorities/potential applications</p>
6	International JIA Consortium	<p>Consortium Lead: Rae Yeung (based in Toronto, Canada)</p> <p>Phase I: Formation of the research consortium through invitation to attend an initial meeting (UK representatives include: LW (Steering Committee); MB, WT and MR (appointed independently following competitive application); Phase II: Development of a research proposal, identification of funding partners, feasibility and pilot data; Phase III: Submission of a research proposal; Goals: 1) Standardised clinical data collection, validation and archiving 2) Standardized biologic sample collection, processing, transport and repository 3) Knowledge transfer and exchange and training infrastructure 4) imaging and pathology cores 5) Manpower and expertise from individual operating grants and team grants. It was noted that there was incredible buy in and enthusiasm from each country represented at the phase I meeting. The UK seems to be at the heart of the whole process. The CSG/MCRN and other research networks are a great strength for this initiative.</p>	<p>LW and others to keep CSG informed of progress and developments in a timely manner</p>
7	Consumer Matters	<ul style="list-style-type: none"> JW (Consumer Steering Committee) informed the group about the re-launch of the Liverpool based Young Persons Group and the launch of two new groups in West Midlands and Trent. These groups will be able to help researchers with their protocols. Time at the face-to-face for discussion of the role of consumers on the CSG, and discussion regarding perceptions and experiences of consumers in clinical trials / related studies will also be given. 	<p>JW to write a short paragraph about the recent consumer steering group meeting/recent progress made</p> <p>LP to put ‘consumer matters’ on the agenda for Nov meeting</p>
8	Non-Medicines	<p>MB has been tasked to develop a draft document with the Chair of the Paediatrics (Non-Medicines) Specialty Group about how CSGs and the Non-Medicines Specialty Group can work together. To be discussed at the MCRN Board meeting 26th November '09. MB asked members to email any comments/concerns to him after the meeting. MB/LP update at face-to-face. NB underlined the delicate potential relationship between local and national strategic priorities and importance of getting the balance right at both the national and local level; MB pointed out that CSG to date has not had non-medicines role.</p>	<p>All members to send comments to LP / MB on this matter as soon as possible</p> <p>MB/LP will update at the face-to-face meeting</p>
9	Agenda items for next time	<p>Due to lack of time, the following items were postponed to next time:</p> <ul style="list-style-type: none"> Scottish MCN update 	<p>LP to put ‘Scottish MCN Update’ on the agenda for next teleconference</p>
10	Teleconference time	<p>All those on the call felt that the meeting start time should revert back to 4.30pm. This has worked well for the last 18 months.</p>	<p>Meeting to revert to 4.30pm start (4.30-5.45pm approx)</p>
11	Date of Next Teleconference	<p>The next teleconference will take place on Monday 2nd November between 4.30pm and 5.45pm (approx). This will be a shorter teleconference due to the face-to-face meeting on 23rd – 24th November. **Please note that the December teleconference will be CANCELLED**</p>	<p>Members to email any ideas for agenda items to MB/LP</p>