

Minutes – MCRN/arc Paediatric Rheumatology Clinical Studies Group Teleconference

1st December 2008

Present: Michael Beresford – MB (Chair), Sharon Douglas – SD, Laura Pilkington – LP, Athimalaipet Ramanan – AR, Madeline Rooney – MR, Wendy Thomson – WT, Pat Woo – PW, Joanna Worsfold – JW, Utpal Shah – US and Katharine Venter - KV.

Apologies: Eileen Baildam, Paul Brogan, Helen Foster and Lucy Wedderburn

Item	Subject	Briefing	Action Required
1	Welcome & Introduction	<ul style="list-style-type: none"> • MB opened the meeting and welcomed all in attendance. • Apologies were noted from Eileen Baildam, Paul Brogan, Helen Foster and Lucy Wedderburn 	None
2	Review of minutes from the last teleconference	<ul style="list-style-type: none"> • It was noted that some members had not been able to open the minutes from the previous meeting. Therefore it was agreed that approval would be done via email. • <u>ERANET PRIOMEDCHILD Conference</u> <ul style="list-style-type: none"> - The conference took place on 6th and 7th November 2008 at the Wellcome Collection Centre in London - SD/KV attended the conference on both days; Their presentation was very well received and highlighted the importance of consumer involvement in research - MB thanked SD/KV for representing the MCRN consumer representatives/MCRN/arc Paediatric Rheumatology CSG - <u>JDM Vasculopathy</u> - The TSG proposal has been submitted successfully; MB thanked PB/LW for all of their work 	<p>LP to re-circulate the minutes via email</p> <p>Members to review the minutes and to send any comments to LP before the next meeting</p> <p>LW/PB to up date the group with any developments</p>
3	Extended Biologics	<ul style="list-style-type: none"> • The proposal has been developed through an open and inclusive process • It has been very well received and has been submitted to the arc **(1/12/2008)** • The proposal has gone in as a CSG/JIA-TSG study proposal • Kimme Hyrich has been named as the Principal Investigator along with all active members of the JIA TSG; Tauny Southwood was approached and included among co-applicants • The steering group for the study will include TSG members and 1 consumer representative • If awarded, the study anticipates to have a major impact for children with JIA • It is hoped that, in the future, other Rheumatological diseases will be included • MB thanked all CSG and TSG members who have been involved in the proposal 	Other TSGs (e.g. Lupus/JDM) to consider options for collecting biologic data for other rheumatic diseases including participation in the Extended Biologics Study (avoiding duplication) SD/KV/JW to consider possible consumer representation on the steering group (& inform MB)
4	Adalumimab Trial – Update	<ul style="list-style-type: none"> • AR gave an update • The application will not take place for the 1st Dec submission deadline; problems have been multiple: <ul style="list-style-type: none"> - Abbott withdrew their initial offer of providing the drug; there has been no word from the company since - Work on the protocol has been difficult in view of methodological difficulties with trial design, sample size and primary outcome • MB / AR worked extremely hard in trying to achieve success with this application • The HTA are reviewing a study proposal for ‘Infliximab in Uveitis’ a couple of months ago • MB / AR contacted the HTA; this call is still high on the HTA agenda for “anti-TNFs in JIA-related uveitis; It has gone through first round of prioritisation; the next stage is January 2009 • AR will continue to facilitate development of the trial protocol and related issues including costings with a view to submission to a possible future HTA call or future arc timelines • Tony Nunn (TN) has been acting on behalf of the CSG in contact with Abbott including Global Abbott in Chicago. They have not directly responded to TN’s request for discussion to date • Adalumimab trial = still high on everyone’s priority list • MB thanked everyone who has been involved with this proposal 	<p>AR to continue to work with the JIA-uveitis TSG and MCRN CTU in developing the trial protocol and costings to be ready for future submission (e.g. to the HTA or arc)</p> <p>MB to update Alan Silman [AS will discuss with HTA on behalf of CSG scenario of major treatment costs (e.g. biologics trials) in HTA-supported trial)</p> <p>AR/MB to provide an update at the next meeting</p>
5	Industry Trials	<ul style="list-style-type: none"> • <u>New IL1 antagonist CAZ trial (Novartis)</u> 	MB to contact Novartis through the

		<ul style="list-style-type: none"> - PRINTO led feasibility for UK centres (collaboration with PRINTO worked well) - 6 UK centres have expressed an interest • <u>Tocilizumab trial (Roche)</u> <ul style="list-style-type: none"> - Already MCRN adopted - Roche have only allocated 1 UK centre (just recruited first patient) but there has been interest from other centres (initially Birmingham and Liverpool included, also Bristol) - MB wrote to Roche recently to enquire re opening to other centres, and inform them that e.g. there were 3 patients at Alder Hey who would be eligible to take part in the study - Roche currently reviewing the number of centres and meeting arranged with MB to discuss opening other UK sites <p>Things to note:</p> <ul style="list-style-type: none"> - The Tocilizumab trial will impact on the recruitment of the CAZ trial, as the populations are similar but time scales such that recruitment to one will likely be over before second is set up; As a CSG we should look to recruit to both trials - Move forward with the Tocalizumab trial and MB to write to Novartis to inform them of the 6 UK centres that have expressed an interest to participate ion the trial 	<p>MCRN Industry Team to inform them of the 6 UK centres that are keen to participate in the trial [await reply from Novartis]</p> <p>MB to meet with Roche [successful meeting, outlining importance of MCRN and CSG in optimising recruitment; early engagement with CSG would aide Industry; also met with MCRN Industry Team; meetings with local PIs for B’ham, Liverpool and Bristol arranged]</p>
6	CSG strategy document	<ul style="list-style-type: none"> • <u>Timelines</u> <ul style="list-style-type: none"> - Need preliminary drat by 19th December 2009 - Submit by 31st December 2009 - Open consultation for comment - Need an international peer reviewer • <u>Comments during CSG teleconference on initial draft strategy document</u> <ul style="list-style-type: none"> - 1st draft = excellent - AR sent comments to MB - WT suggested 1) adding a section/paragraph describing BSPAR 2) making “treatment and treatment prediction response” an overarching theme - All members to send their comments to MB (with track changes) by 17th December, if possible. - MB keen for Jacqui Clinch (JC) to be involved in strategy document (pain and non-inflammatory = extremely important) and has already invited contribution 	<p>All members to send their comments to MB (with track changes) by 17th December</p> <p>MB to circulate pre-final draft for comment by 22nd Dec for comment / correction</p> <p>CSG members to recommend International Peer reviewer of Strategy</p> <p>MB re-written to JC inviting contribution</p>
7	Biology of JIA	<ul style="list-style-type: none"> • <u>International consortium to look into Biology and classification of JIA</u> <ul style="list-style-type: none"> - Seeking nominations from the UK; 3 clinicians to represent/participate on behalf of the UK Paediatric Rheumatology community/CSG. Chief Investigator: Rae Yeung (RY) - Circulate a call through BSPAR to gain expression of interest (CV and Statement of Interest) - If large numbers, CSG to consider short list based on skill mix needed (RY advised) and send with CV to RY - Otherwise to send list of applicants to RY to nominate based on international skill mix of consortium 	<p>MB to get more information of the consortium from RY/LW and circulate to the BSPAR members [letter sent 221208]</p> <p>Depending on expression of interest, CSG to clarify the nomination process</p>
8	Qualitative Survey	<ul style="list-style-type: none"> • HF and Carl May are going to undertake the web-based survey without applying for a small grant 	<p>HF to provide further feedback at the next meeting</p>
9	AOB	<ul style="list-style-type: none"> • There was no AOB reported 	<p>None</p>
10	Date of next meeting	<ul style="list-style-type: none"> • Face-to-face meeting (date to be confirmed) • Next teleconference will take place on Monday 5th January 2009; Apologies have been received from: Pat Woo and Utpal Shah 	<p>LP to re-circulate doodle link and to confirm date of next meeting</p>