

Minutes – MCRN/arc Paediatric Rheumatology Clinical Studies Group Teleconference

6th May 2008

Present: Michael Beresford (Chair); US – Utpal Shah; LP – Laura Pilkington

Via teleconference: PB – Paul Brogan; LW – Lucy Wedderburn; HF – Helen Foster; MR - Madeline Rooney; PW – Patricia Woo

Apologies: Eileen Baildam; Jennifer Blakeburn; Jennifer Preston; Athimalaipet Ramanan; Wendy Thomson

Item	Subject	Briefing	Action Required
1	Welcome & Intro	MB opened the meeting and welcomed all in attendance.	None
2	Update on April's teleconference	<ul style="list-style-type: none"> • JDM – JDRG, on 14th April, agreed to act as basis for JDM TSG with an open session for TSG related issues; approach to CSG to help with adoption by MCRN, change of name etc. • Formulations - Scoping exercise regarding MTX and related issues sent to BSPAR. • Auto-inflam – Pat to provide an update in due course • Tocilizumab - Now has MHRA approval but there still appears to be plans for only one centre. MB written to Roche for clarification. • Consumer Rep - Call through BSPAR; EB kindly agreed to be on interview committee. MB asked members if anyone could attend the training day for consumers, to represent the CSG, on 13th June in London (even for short time) 	<p>LW to take forward</p> <p>US to keep CSG informed Pat to update</p> <p>MB is waiting to hear back from Roche</p> <p>MB: BSPAR reminder LP – seek CSG rep for consumer training day</p>
3	ARC timetable and funding	<p>Briefing: ARC Timescale and Funding:</p> <ul style="list-style-type: none"> • <i>Initial wave of funding through its Clinical Trials Initiative directed towards CSG key priorities. Full proposals (or pilot) November 2008. ARC Clinical Studies Sub-Committee will give methodological/feasibility assessment and meet bi-annually and virtually as needed.</i> • <i>CSGs to submit one or two flagship studies/trials while finalising its overall strategic approach by the end of 2008. Subsequent applications will need to fit into the (evolving) strategy. These proposals must be achievable and realistic to demonstrate success of CSG and ARC. Pilot studies also acceptable.</i> • <i>These “fast track submissions” cannot have the PI as the Chair of the CSG (they can be co-applicants, subsequently will also be able to be PIs). The study will need to be signed off by the CSG outlining CSG support / involvement with the core application submitted by the PI and its relevant applicants. New ARC form being produced.</i> • <i>A brief summary from an international advisor, independent international advice to the ARC as to whether the study is of relevance and importance. The CSG and ARC are free to ignore this, but it gives some independent support to both the ARC and CSG that's its studies/strategy is robust.</i> • <i>Development of the protocol must include involvement of the MCRN/CLRN and the CTU (from as early as possible).</i> • <i>There is funding up to the value of £30,000 for any pilot/feasibility studies, which the CSG deems strategically important in the development of more definitive applications.</i> <p>Discussion</p> <ul style="list-style-type: none"> • PB: are any of the TSGs likely to be in this position by the autumn? • Will be variable across TSGs but focus of discussions between now and July meeting • £30K limited but CSG members and their TSGs to consider how may be used to get larger project off the ground 	<p>CSG members each to consider these items and feedback Jun / July mtgs</p>
4	JIA TSG	<p>Briefing: Biologics</p> <ul style="list-style-type: none"> • <i>CSG already identified Biologics and collection of relevant data (and related studies) from across diseases both pre and post marketing as a key strategic area to develop. So far this has been incorporated primarily into discussions related to the JIA-TSG's activities.</i> • <i>Proposal for the CSG to call a “CSG Biologics-related meeting” asap; hosted by the CSG and its JIA-TSG either in</i> 	<p>MB informed Convenor BSPAR this</p>

		<p><i>Liverpool at the MCRN Co-ordinating Centre or at the MRC (CSG can have meetings in London at MRC)</i></p> <ul style="list-style-type: none"> • <i>CSG remit to invite interested parties and ad-hoc advisors the CSG felt were key.</i> <p>Discussion</p> <ul style="list-style-type: none"> • Consensus to this plan, await feedback from BSPAR Exec re current application process for next phase of BNDR <p>Briefing: JIA strategic areas</p> <ul style="list-style-type: none"> • <i>Other areas include the use of ultrasound imaging in clinical trials and the development of biomarkers.</i> • <i>Biologics Registry are of initial priority; proposed that at the BSPAR Research Day, a part of the CSG update to focus interest and ideas on JIA and key areas for strategic development in this area.</i> • <i>All members of the CSG will be involved in the development of studies related to JIA. In order to support HF and WT in facilitating this process, it is proposed that EB joins them so there is a link group</i> <p>Discussion</p> <ul style="list-style-type: none"> • All agreed to these plans 	<p>plan and await feedback (attending mtg on 19th may)</p> <p>AR to confirm time in BSPAR Research Program for CSG JIA TSG to facilitate this part of session</p>
5	CARRA and the CSG	<p>Briefing: Principles</p> <ul style="list-style-type: none"> • <i>Carrol Wallace and Dan Lovell enthusiastic about CSG and the MCRN-supported UK Paediatric Rheumatology community collaborating in CARRA clinical trials. They need to understand potential contributing centres, types/amount of infrastructure support, trials/studies that such centres have already done and mechanisms for getting multi centre studies up and running as soon as possible.</i> • <i>Funding is a potential issue, as they have NIH funding and they would need to negotiate whether this can go internationally.</i> • <i>Initial proposal - TREAT trial. Funding for study visits and investigations as well as drug costs, but not start up fees as these have already been allocated. In the future, such costs could also be negotiated for UK centres.</i> • <i>Any shortfall for start up fees could be considered as a research priority in an application to the ARC. We would also negotiate with the CLRNs as to service support costs.</i> • <i>“Translational samples” related to the trial, most of which would be shipped to the US, almost all the associated laboratory tests should be done in one central place.</i> <p>Discussion</p> <ul style="list-style-type: none"> • General consensus important to take forward and develop links; MB to proceed in discussions with comment from CSG in this process • TREAT protocol summary: http://clinicaltrials.gov/ct2/show/record/NCT00443430?term=NCT00443430&rank <ul style="list-style-type: none"> ○ CSG members to consider and comment ○ Possible feasibility / survey across BSPAR for interest 	<p>MB to draft a response to CARRA and details of UK situation; CSG to comment</p> <p>CSG members to review the protocol/website and feedback to MB within three weeks (23/05/08)</p>
6	Bone Health	<p>Briefing:</p> <ul style="list-style-type: none"> • <i>3 full applications submitted via ARC to CSG related to Bone Health - key area of strength in research community</i> <ul style="list-style-type: none"> • <i>Alison McGregor, Imperial – What is the optimal exercise programme and level for bone accrual in children?</i> • <i>Simon Thomas, Bristol - Multicentre RCT bisphosphonates for AVN of femoral head</i> • <i>Nick Bishop, Sheffield - Functional development of MS system and skeletal fragility during childhood / adolescence</i> <p>Discussion</p> <ul style="list-style-type: none"> • Long discussion about role of CSG in assessing applications coming to the CSG (in these cases from out with TSG’s proactive role via ARC), particularly in relation to CSG role in peer review, conflict of interest, prioritisation, expertise in given area; • Need for clarification of roles and procedures in on going discussions and dialogue with the ARC 	<p>CSG members to email concerns / areas needing clarification to MB / CSG; MB written to CSG 070508 to try and clarify current understanding of roles and procedure; MB invited A Silman to join next call;</p>

		<ul style="list-style-type: none"> • Suggestion to invite Alan to attend next teleconference to clarify queries and answer questions • As ARC timescale unable to support now the 3 applications, MB to respond to each explaining this in relation to ARC website which clarifies change in ARC's funding approach for clinical trials and related studies • MB to invite them to be involved in a Bone-Health TSG which would help define priorities for bone health which could be done in partnership with ARC Bone Metabolism CSG to bring together interested parties? 	<p>MB to write to applicants; MB to discuss with David Reid;</p>
7	Uveitis and JIA	<p>Briefing</p> <ul style="list-style-type: none"> • <i>Meeting 20th June with interested parties including 5 centres (rheumatology & ophthalmology) led by AR to discuss detail protocol (adalimumab fixed dose vs placebo), design etc. and wider TSG issues. Bristol / Bath LRN and CTU support for trial development. Abbott interested in funding possibilities of investigator led trial</i> 	<p>AR to keep CSG informed MB approved support for TSG mtg</p>
11	AOB	<p>CSG membership</p> <ul style="list-style-type: none"> • Nurse and AHP representatives not present; to re-advertise • Discussion about psychology input as some interest expressed; as CSG already quite large, to consider for the time being on <i>ad hoc</i> basis and review; PW suggested Professor Stan Newman at UCL as possible contact 	<p>MB talking to nurses LP / MB to then advertise PW: to forward details</p>
	Next Meeting	<ul style="list-style-type: none"> • Next teleconference meeting: Monday 2nd June, 4.30pm • Next meeting of the CSG is to be held at the BSPAR meeting in Bristol on 8 July 2008, 9-10.30 • Face to face during PRES/BSPAR – agreed not possible due to many other commitments of CSG members during this meeting 	<p>LP: To arrange call and MCRN Mtg room LP to ensure same mtg room as BSPAR Research Day</p>