Uveitis National Clinical Study Group Clinical Studies Study Proposal Form

This Study Proposal Form operates as a framework to facilitate CSG interactions, capturing information in relation to the proposed study to aid the clinical study group consider:

(i) the priority in relation to the James Lind priorities
(ii) issues of methodology and design

Preliminary approaches to CSGs, with partially completed forms or alternative outline presentation or verbal discussion are encouraged. CSGs guide regarding next steps and potential for future work up. Reference should be made to the Types of Study document for guidance.

At the early stages, investigators are encouraged to fill in what they can to enable initial dialogue. Its completion can then be an iterative, cumulative process in collaboration with the CSG and as the study becomes more defined over time.

The Uveitis CSG support development and submission of applications to all funders.

Date : _____

Proposal title (expand any abbreviations) : _____

_____

1) Investigator details (to whom all correspondence will be addressed)

Title and name:
e-mail:
Position held:
Department:
Organisation:
Official address including postcode:
Telephone numbers:

2) Co-investigator details

Title and name:	Organisation:	e-mail:

3) Research proposal

Purpose and type of study? *(max 200 words)*
Purpose of the study Type of study *- Definitive question assessment (trial or observational study) / Pilot study / Feasibility study / Outcome measure development study*
Research Question(s) *(max 200 words)*
Context and background *(max 600 words)*
• *Explain why the proposal is novel* • *Explain the potential impact of the study's finding in the immediate and longer time frame both in terms of the research community, NHS and internationally* • *Describe any relevant research by potential applicants and other researchers in the field (completed and in progress) leading to this proposal*

4) Proposal history

Is this, or a related application, currently or about to be submitted to a funder?	*YES / NO (delete as appropriate)* *If YES, provide details of which funder and date when a decision is expected*
Has this, or a related application, previously been submitted to a funder?	*YES / NO (delete as appropriate)* *If YES, provide details of which funder, the date of submission and date funder decision was notified and summarise the feedback received at the bottom of this form*

5) Study development and feasibility

Methodology and statistical development
Summarise the input (to date or planned) with a Clinical Trial Unit, the Research Design Service or other methodology group - what has been the nature of the discussions to date and with whom OR What is the expected interaction

Proposed Clinical Trial Unit to be involved
If NONE, outline the reasons for non-involvement
For full a study, summarise the pilot and feasibility work completed

6) Proposed application dates, duration and value

Proposed duration (months):	*If known, outline expectations for overall grant duration encompassing set up, conduct and analysis*
Anticipated grant start date:	*If known, outline expectations for grant start date*
Anticipated recruitment start date:	*If known, outline expectations for recruitment start date*
Planned application submission date:	*Which Arthritis Research UK or other funder deadline is this project aimed at?*
Estimated grant value sought:	**£**

7) Study description

Please provide information in relation to the following elements of the proposed study ***(max three pages)***
1. **Study tools / intervention / technology / instrument**
2. **Design of trial or study** *(interventional or observational and design characteristics)*
3. **Licencing status of the drug in relation to the research question, licensed or unlicensed indication for the drug?**
4. **Control or comparator treatment**
5. **Recruitment population and setting** *(the target population from which subjects intend to be recruited and the setting (a) in which they will be approached with respect to participation and (b) where delivery of the study intervention will take place)*
6. **Primary outcome measures and other key outcome measures e.g health economics** *(details for outcome measures should include justification of the use of outcome measures where a legitimate choice exists between alternatives. Please see THE COMET Initiative website at www.comet-initiative.org.)*
7. **Sample size anticipated** (*may be approximate and as such should include a substantiation of the estimated effect size and power as available)*

8. Recruitment feasibility *("enrollability", presentation of activity that is needed to assess the potential for study take up or is already available from other experience; to include patient perspective as well as strategic (within the wider UK clinical research network), scientific and operational perspectives)*
9. Team expertise
10. Further explanation

8) Lay Summary

Please provide a summary of the background, question and study proposal in lay terms *(max 300 words – please add extra sheet if insufficient space)*