

Study outline form

To initiate a new BEACON study you will need to form a study group with a lead and a study design group. These will generally form the design, analysis and writing group for manuscripts. Once the concept has been finalised please complete a BEACON study outline form as below to be completed and posted on the BEACON website. Studies listed will then appear on the 'Current projects page' with links to your study outline form and a link to the the study lead to request more info, along with case report forms and other details (eg data transfer arrangements)

The study outline form contains the following details

Full Title: [Should be descriptive to describe study]

Acronym: [Include an acronym to make communication easier]

Proposer name:

Proposer position: [eg Consultant Ophthalmologist]

Proposer location: [eg Sunderland Eye Infirmary]

Proposer email:

Other members of study design group:

What you are studying: [e.g. Macular hole after vitrectomy for VMT]

What is your primary research question: [e.g. What are the visual results of surgery on this type of MH?]

[Remember if you want to also perform a risk factor analysis you would need a control group and you would have to add extra details regarding this]

Background and importance: [~5-6 sentences]

Case definition: [has to be very specific, clear and unequivocal and only relying on conventionally routinely collected data, (unless funding is available to allow prospective additional data collection - note this will require ethical approval and Trust R&D approval as well). *It is the responsibility of the study lead to ensure the correct ethical and trust specific regulatory guidelines are followed.* Consider adding inclusion and exclusion criteria to make it as clear as possible exactly what case you wish to collect]

Likely incidence: [Ideally should be less than 10 cases max per annum per surgeon if prospective. It should also be noted that depending on rarity case collections should be on conditions where more than 10 cases at the very least can be collected. Common conditions would be less suitable unless a very short study period is used]

Prospective/Retrospective data collection?: [could be both]

If Retrospective:

Eligible study period: [eg beginning Jan 2015- end Dec 2019]

Target completion for end of data collection: [typically 1-year from start of case collection]

If Prospective:

Case collection period: [eg from Jan 2022 to end Dec 2022]

Follow up duration: [if applicable eg 6-months]

Primary outcome measure: [What is the most important outcome measure you want to study]

Secondary Outcome measures:

Pre-planned analysis outline: [to help you collect the data you need]

Data collection form(s): [These should be preformatted and members who want to participate will contact the study lead to request one. These are to be designed by researchers themselves using BOSU principles of conciseness, only collecting data required and avoiding any data that could identify the patient outside of the immediate care team. They can however take the form of either easily completed 'case report forms' for each patient seen, or an excel (or other database) for recording data. Remember to unequivocally define each data item to be included- this is much easier done in advance. It is envisaged that the majority of projects will use retrospectively collected data. Each study will require a study number system eg site identifier and number eg SUN001. If your study is prospective a baseline and follow up questionnaire/database will be needed. If you are including controls this form may need to be different again. As a general rule there should be ~3 controls per case.

Remember it is very worthwhile/vital piloting your CRFs with colleagues before they are posted on the web site to assist in refining them.]

Images required: [must be fully anonymised and non-identifiable, with study numbers only. It is up to the study team to organise all aspects of this including data security issues, consent etc]