

UoM/MRC

Confidence in Concept

Advice for early translational
studies

Dr Sam Butterworth
UoM CiC Academic Lead

1. Title of proposal.
2. Name of PI and Co-Investigators, Division, Faculty, Organisation.
3. Project duration, proposed start date and overall cost (at 100% of the directly incurred costs). NB. All projects must start by 6th Jan 2020 at the very latest.
4. What is the unmet health, clinical or product development need you are seeking to address? Please include a description and size of the target patient population. (Max 100 words)
5. What is your proposed solution to meeting this need? (Max 100 words)
6. What are the competing solutions (direct or indirect) and their developmental status, and what is the competitive advantage of your proposed solution? (Max 100 words)
7. What is the rationale and supporting evidence for why your proposed solution will meet the targeted need? (Max 100 words)
8. If successful, how soon would the proposed innovation reach a) patient care or other clinical setting and b) commercial market or other means of distribution? Please explain what additional studies or development work will be required to achieve these endpoints? (Max 100 words)
9. Explain what the specific hurdle/bottleneck is that you need to overcome by carrying out the proposed CiC study, before a proposal for follow-on funding could be submitted. (Max 100 words).
10. How will the project achieve its objectives? Summarise the project workplan including key progression milestones and the timeline (one being the project end). For each milestone, please set out the success criteria that will be used to ascertain whether the milestone has been met. (Max 100 words)
11. If access to data, tissue, software etc. is required, has access been agreed? If not, how and when will these be obtained?
12. Does your study require NHS ethics & governance approvals? If yes, when will these be obtained?
13. Will the project generate intellectual property (IP) that will be shared with or owned by an external party (e.g. external project partner)? YES/NO: If yes, briefly describe the steps to be taken to manage this IP.
14. Brief plan for follow on studies, potential industry collaboration and further funding, including targeted funding schemes and deadlines.
15. Describe how your study will contribute to one or more of the CiC8 strategic priority areas (please see Appendix 1).
16. Explain how you obtained clinician input on the medical aspects (e.g. unmet medical need) of your CiC proposal.

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Project description

5. What is your proposed solution to meeting this need?

7. What is the rationale and supporting evidence for why your proposed solution will meet the targeted need?

10. How will the project achieve its objectives? Summarise the project workplan including key progression milestones and the timeline (one being the project end). For each milestone, please set out the success criteria that will be used to ascertain whether the milestone has been met.

Line of sight

4. What is the unmet health, clinical or product development need you are seeking to address? Please include a description and size of the target patient population.

6. What are the competing solutions (direct or indirect) and their developmental status, and what is the competitive advantage of your proposed solution?

8. If successful, how soon would the proposed innovation reach a) patient care or other clinical setting and b) commercial market or other means of distribution? Please explain what additional studies or development work will be required to achieve these endpoints?

You may want to consider the Target Product Profile for your end solution to help define this – this will be required at full application stage

IP and follow on funding

13. Will the project generate intellectual property (IP) that will be shared with or owned by an external party (e.g. external project partner)? YES/NO: If yes, briefly describe the steps to be taken to manage this IP.

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DPFS projects need to be free from barriers to further translation

If project requires access to external IP there must be FTO

If project develops IP that benefits a commercial partner this would need to be at least 50% cash funded at DPFS stage

Purpose of the award

9. Explain what the specific hurdle/bottleneck is that you need to overcome by carrying out the proposed CiC study, before a proposal for follow-on funding could be submitted.

CiC is not intended to fund full projects, but rather address key hurdles that are critical to address prior to obtaining more significant translational funding...

If the project has so many unknowns that the CiC objectives can only address a small aspect of this, it may be too early?

If the objectives do not address risk (i.e. could be reasonably included as the first stage of a larger application), it may not be suitable?

If the objectives do not address a/the critical risk in the project, it may not be suitable?

...however these are subjective points – please discuss with us.

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