

## DPFS assessment criteria

### Outline applications

The outline project plan should include up to 4 milestones, depending on project complexity. The criteria used to assess the project at each milestone should be chosen so that they address reasons for progressing or discontinuing the project, ensuring that the plan progresses along the critical developmental path.

The criteria by which the outline applications will be assessed are:

- Clinical/medical need: Is the need significant and does the proposal have an advantage over competing solutions?
- Rationale: What is the strength of the rationale and supporting evidence for why the proposed solution will meet the targeted need?
- Deliverability: Is the proposed development plan realistic? Will it answer the question or address the need identified? Does it offer good value for money? Does the team have access to the necessary assets and expertise to deliver the planned work?
- Intellectual Property: Is there an appropriate intellectual property strategy in place to facilitate potential downstream exploitation (funding, partnering, commercialisation, etc)? Note that projects that will not generate patentable materials but that will nevertheless be able to provide health benefits are accepted on an equal basis by the DPFS scheme.

Further guidance is provided in the guidance for outline stage applicants. Successful outline applicants will be invited to submit a full application using a full case for support form which will be provided directly by the MRC.

### Full applications

The purpose of the full application is to assess in greater depth the need being targeted and the proposal's rationale, and to establish whether there is a robust development plan in place to deliver the project goals.

As for the outline, the full application should be completed in partnership with the lead academic research organisation's institution's Technology Transfer Office (TTO), or equivalent, and additional external experts as required. Failure to do so may prejudice the application.

The criteria by which the full applications will be assessed are:

- The significance of the need the proposal is seeking to address and competitive advantage.
- Potential impact of the research
- The quality of the proposal's rationale and approach
- Robustness of the design, methodology and analysis plans to address the research questions
- The feasibility and appropriateness of the project plan: Project start points; Project objectives; Costs, tasks, deliverables, and schedule; Value for money, Adequacy of the risk management plan

- Appropriateness of the project management plan: Project management group membership and experience, Assignment of responsibility within the project team, Key performance indicators (for example, time, cost), Suitability of the exploitation strategy
- For clinical studies, the ability of the team to design and deliver a methodologically robust study will be a key assessment criterion.
- Applications must demonstrate a strong understanding of the regulatory environment and the requirements for good clinical practice and research governance.
- Ethical issues must be addressed appropriately.

The decisions of the panel will not be open to appeal and that the MRC reserves the right to amend the application process.

## Oversight

To ensure effective delivery of the proposal's objectives, successful proposals will be required to establish an appropriate project management group and reporting system.

During the period of support, the project management group will be required to submit Project Milestone and End Reports to the MRC. If a milestone is at risk of not being met, the project management group may submit a request for change, proposing a resolution to the issues they face. Project Milestone Reports, End Reports and requests for change are reviewed by the MRC. Projects which fail to meet milestones may be terminated.

Selected studies may be deemed to require additional oversight by the MRC. For a small proportion of awards, on a case-by-case basis, the MRC will establish an oversight group to monitor progress against milestones.

## Intellectual Property

The generation of intellectual property is not an essential requirement for this scheme; projects that will not generate patentable materials but that will nevertheless be capable of providing health benefits are accepted on an equal basis.

Intellectual property generated in the course of a project will be owned by the generating organisation(s), which will have the right to manage and exploit this intellectual property. The costs of managing, protecting and exploiting the intellectual property are borne by the generating institution(s) and are not eligible costs for MRC support.

The MRC wishes to assure itself that host institutions are able to manage and exploit effectively the intellectual property generated from MRC-funded research. This is particularly important in the case of the DPFS scheme, as projects will likely require further development in order to meet their ultimate clinical aims.

The project management group will be asked to submit, as part of their Project Milestone and End Reports, details of the intellectual property generated during the course of the project and of the management and exploitation of this intellectual property. The MRC will also require the Principal Investigator to submit an annual follow up report on downstream outcomes of intellectual property for up to three years after the project end date.

## How to apply and timings

Outline applications must be submitted via the Je-S system using the outline case for support form in conjunction with the guidance for applicants.

Please bear in mind that all proposals have to be submitted via your research organisation's administrative department. Please ensure sufficient time to complete their parts of the proposal before the MRC deadline dates. Standard MRC terms and conditions apply to this scheme.

Application deadlines are usually in March, July and November for consideration by the Panels at meetings in May/June, September/October and January/February respectively.

Your proposal must be submitted through the MRC Je-S system by 4pm on the relevant deadline date.

## Ethics and governance

The MRC does not require ethics permissions and regulatory approvals to be in place when an application is submitted. However, given that research requiring the use of human tissue/organs may raise various ethical and regulatory issues, applicants will be required to demonstrate that they have adequately considered these matters. Early discussions with regulatory bodies may be required to ensure that all requirements can be met in a timely manner. Once an application is successful, it is the responsibility of the host institution to ensure that the appropriate ethics approval(s) has been obtained and that no research requiring such approval is initiated before it has been granted. Please read the MRC terms and conditions for further details.

## Additional guidance

Applicants should review the MRC Applicants' Handbook and Guidance for Outline Stage Applications or guidance for Full Stage applications as appropriate.

Applicants proposing a clinical study are referred to the following literature on experimental medicine methodology and governance in developing their research plans:

- [Royal Statistical Society's Working Party on Statistical Issues in First-in-Man Studies](#)
- [EM Toolkit](#)
- [EMA guidance on high risk, first-in-man clinical trials](#)

For questions regarding the Je-S application process, please contact the Je-S Helpdesk:

Email: [JeSHelp@rcuk.ac.uk](mailto:JeSHelp@rcuk.ac.uk)

Telephone: +44 (0) 1793 44 4164 (lines open 9-5, Monday-Friday)

Website: <https://je-s.rcuk.ac.uk>

## Hints and tips

General:

Evidence and/or rationale for the proposed study/target/intervention will generally be required. It is strongly advised that as much preliminary data be included as is possible. 2 pages of supplementary data can be uploaded at outline and 5 pages of supplementary data at full stage. Project milestones should be specific, quantifiable and measurable. Costings should be realistic and appropriate.

Work plans and timescales should be realistic, factoring deliverability of the proposed work and taking into consideration any subsequent developmental or clinical work.

Preclinical projects:

For projects developing a novel therapeutic, it is advised that a target product profile (TPP) be included. It is strongly suggested that for small molecule drug discovery projects, (lead) chemical structures and DMPK/ADMET data should be provided where available. Work plans should factor in requirements for progression to clinic.

Clinical projects:

There should be sufficient clinical need to justify the proposed trial. Trial design should be appropriate and be informed by relevant expertise. Powering calculations/information on powering should be included for all proposed clinical studies. Inclusion/exclusion criteria should be specified and recruitment plans realistic. Endpoints should be relevant, appropriate and measurable.

Outline assessment criteria:

Need: What is the need the proposal aims to help address. Is the need significant and does the proposal have a competitive advantage over competing solutions?

Rationale: What is the rationale and supporting evidence for why the proposed solution will meet the targeted need? Is the rationale and level of qualification reasonable?

Deliverability: Is the proposed development plan realistic? Does it offer good value-for-money? Does the team have access to the necessary assets to deliver the plan?

Intellectual Property: Is there an appropriate intellectual property strategy in place to optimise the chances of downstream funding/partnering?