# Guidance for Outline Stage
# BMC: DPFS Applicants

**OFFICIAL**

# Contents



**Disclaimers**

The information contained in this document is additional specific guidance for Biomedical Catalyst: Developmental Pathway Funding Scheme (BMC: DPFS) applicants and should be used in conjunction with other MRC sources of information when preparing your application, for example:

- Biomedical Catalyst: DPFS webpage
- MRC Applicants' Handbook – details on eligibility, costings, responsibilities etc.;
- MRC Industry Collaboration Agreement (MICA) – relevant to industrial collaborations;
- Je-S Help – for information or queries related to use of the Je-S System.
- Choosing Contractors for Animal Research – NC3Rs guidelines

Please ensure you have downloaded the latest version of this document via the BMC: DPFS webpage.

## Outline Applications

BMC: DPFS applicants must first submit an outline BMC: DPFS application. Successful outline applicants will be invited to submit a Full application. The purpose of the outline application is to ascertain whether the project's aims, rationale and deliverability are appropriate for consideration by the scheme.

To submit an outline application, the applicant must complete the BMC: DPFS Outline Case for Support Form and submit this as a PDF via the Je-S website.

Please note that Sections 6.11 and 6.12 replace the "Reproducibility and Statistical Design Annex", and this document will no longer be accepted. Please refer to section 6.12 (below) and the guidance in the MRC Applicants' Handbook on this Annex when completing Sections 6.11 and 6.12 however, as the two are closely aligned.

Applicants seeking funding for hit to lead and lead optimisation projects must additionally complete the Small Molecule Supplementary Information form. This form should be uploaded to Je-S under document type 'Supporting Data'.

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# Outline Application Assessment Criteria

The BMC: DPFS Panel will consider outline applications against the criteria below. Panel decisions at outline stage include; Invite, Reject or Positive Feedback (a decline waiving the 12 month moratorium on re-submission).

Please note that the decisions of the BMC: DPFS Panel will not be open to appeal and that the MRC reserves the right to amend the application process.

**Need**

- Does the identified need exist?
- Would meeting this need significantly reduce disease burden and/or provide a valuable commercial opportunity and/or alleviate an important development bottleneck?
- If the need is not significant now, will it become so in the future?
- Is the need met or unmet. If unmet, will it likely be unmet at the time that the proposed solution is in place?
- Has the applicant identified the key competing solutions and their status or are you aware of other similar or complementary research underway elsewhere?
- Has the applicant identified the key competitive advantages of their proposed solution?
- How likely is it that the proposed solution, if achieved, would be widely adopted?

**Rationale**

- Is there a good medical/scientific rationale for the project?
- Is there a reasonable body of evidence to support the proposed rationale?

**Deliverability**

- Objectives:
  - If successful, will the proposal make a significant contribution to meeting the identified need?
  - If successful, will it achieve an endpoint that has a reasonable chance of attracting any required additional investment?
  - Are downstream development hurdles surmountable?

- Plan:
  - Does the plan propose reasonable go/no-go milestones to judge progression?
  - Is the project appropriately statistically powered?
  - Are the preliminary budgets and schedule to reach the milestones appropriate?
  - What is the likelihood of the project meeting its milestones?
  - Given the project's risk and its potential benefits, does the plan offer good value for money?

- Assets:
  - Has the team identified and secured reasonable access to necessary resources/skills? Note that not all collaborations/out-sourcing agreements need be in place at the outline application stage
  - Has the individual or group established a high quality track record in the field?
  - Are the applicants well placed to deliver the work/
  - Do the applicants have the necessary project management experience to deliver the plan?

**Intellectual Property**

- Does the proposal have an appropriate intellectual property strategy:
  - Background
    - Does the team have access to necessary background intellectual property?

    - If not, are the applicant's arguments for how they will access required background intellectual property persuasive?
  - Foreground
    - Is the intellectual property generated in the course of the project likely to be protectable (i.e. will it be novel, non-obvious and useable)?
    - Will the proposed management and exploitation strategy maximize the likelihood that the project will be able to access any required downstream funding to enable the project to meet its identified need?

## Completing the BMC: DPFS Outline Case for Support Form

The BMC: DPFS Outline Case for Support Form consists of eight sections. Use the tab key to move between cells in the form. Cells that are greyed out do not need to be filled in, since these are automatically calculated from cells elsewhere in the form.

The form is expected to be completed in partnership with your Institution's Technology Transfer Office (TTO) or equivalent (e.g. Research Office), and failure to do so may prejudice your application. A contact at your Institution's TTO, or equivalent, will be required for the Outline Case for Support Form.

- The principal investigator will normally be expected to take the lead on defining the need that the proposal seeks to address and the proposed solution for this need, the project's rationale and the project plan
- The TTO will normally be expected to take the lead on assessing the competitive environment and intellectual property strategy

The TTO will be expected to provide support to successful applicants in managing and exploiting intellectual property generated over the course of the project.

**Section 1: Project Summary**

**1.1 Title:**

*Please provide a concise title for your proposal. This title should be the same as the project title of your Je-S submission.*

**1.2 Technical Summary:**

*Please provide a summary of the need you are seeking to address, your proposed solution, the rationale for why your proposed solution is likely to meet the targeted need and your development plan. This technical summary should be the same as the technical summary of your Je-S submission. Both the title and technical summary should be* ***non-confidential****, as they will be used, if you are successful at the outline stage, when approaching candidate referees to review the full proposal.*

**1.3 Project Duration and Cost:**

*Please enter the proposed project start date. This date should be the same as the proposed start date in your Je-S submission. The proposed duration of award, project fEC, estimated MRC contribution and project partner contribution are calculated from duration and cost inputs you are required to enter later in the form.*

## Section 2: Investigator Details

Please refer to the MRC Applicants' Handbook for further information regarding people and organisations named on the grant

**2.1 Principal Investigator [same as Je-S Principal Investigator]**

**2.2 Co-Investigators [same as Je-S Co-Investigators]**

**2.3 Researcher Co-Investigators [same as Je-S Researcher Co-Investigators]**

*A researcher staff member, from the same Research Organisation as the Principal Investigator or a Co-Investigator, who has been substantially contributing to formulation and development of the proposal. Please refer to the MRC Guidance for Applicants and the Researcher Co-Investigator page*

**2.4 Industrial Project Partners [Project Partners in Je-S]**

*Individuals from collaborating partner Industrial Organisations who would be contributing financially or intellectually to the project (i.e. not from organisations providing services on a contracted or outsourced basis).*

**2.5 Non-Industrial Project Partners (Collaborators) [Project Partners in Je-S]**

*Individuals from collaborating non-industrial organisations who would be contributing financially or intellectually to the project, e.g. investigators from partner Universities providing materials and intellectual input but not requesting funds.*

**2.6 Subcontractors**

*Subcontractors should not be named as part of the project team. They carry out a specific piece of work on behalf of the investigators on a fee-for-service basis, with no potential claim as an inventor over any arising Intellectual Property (IP).*

## Section 3: Host Institute Technology Transfer Office Contact

**3.1 Host Institute TTO Contact**

*As the MRC would normally expect the host institute TTO to assist in the preparation of a BMC: DPFS full Application and expect the TTO to play an active role in maintaining and exploiting intellectual property generated by successful applications, the MRC asks for the contact details for a relevant member of the host institute's TTO team who should also sign the TTO's letter of support.*

## Section 4: Need

*No specific guidance – refer to the Outline application assessment criteria outlined above.*

## Section 5: Rationale

*Please provide relevant references in section 5.2 and cite elsewhere within the document as applicable. Note that up to two pages of supporting data can be uploaded as a supplementary document and can be referred to here. Applicants seeking funding for hit to lead and lead optimisation must also complete the Small Molecule Supplementary Information form and upload as a separate attachment.*

**Section 6: Deliverability**

**6.1 What is the project's current status and its primary objectives/deliverables? In the case of applications involving Institutes, Units or Centres with existing core funding, including those funded by MRC and NIHR (i.e. BRCs & BRUs), please describe how the proposed research and associated request for funds builds on, but is distinct from, core funded programmes of research. (max 150 words)**

*No specific guidance.*

**6.2 Please give details of previous awards relevant to the project, capturing the funder, time awarded, grant period, grant title and £s awarded alongside a short summary of how each one supported the current application (max 600 words)**

*No specific guidance.*

**6.3 How will the project achieve its objectives? Summarise the project workplan including two-three key progression milestones (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. For clinical studies, this should include a summary of (1) study design, (2) study participants, (3) study endpoints, (4) dose, (5) anticipated effect size and (6) analysis plans (max 1250 words)**

*Milestones are a key feature of DPFS proposals, and allow the MRC to mitigate risk and support potentially high-risk projects. Milestones should signal anchors of your project, and focus on major progress that must be reached in order to achieve success. Therefore, they should reflect key go/no-go decision points on the path to your long-term goals and should not just be lists of tasks. Milestones are a very common weakness in DPFS proposals, and poorly defined milestones will affect the likelihood of success.*

*Milestone success criteria should be SMART (i.e. quantifiable and measurable) and detail any robust Go/No go criteria (failure to meet which will result in early termination of the project). For all projects, it is advisable to structure the project so that the critical question(s) are addressed as early as possible in the plan.*

*For the final milestone, the criteria should reflect outcomes representing successful prosecution of the project and data that will enable downstream exploitation of the project (covered in question 6.6).*

**6.4 Identify and justify the skills and resources (materials, methods, data, people, infrastructure, outsourced tasks etc.) needed to undertake the proposed project. Please specify the need, the costs and the timelines of usage/employment with respect to achievement of the stated milestones (max 300 words)**

*Outline personal, equipment, costs etc. required to conduct the project detailed in section 6.3. In relation to named grant applicants, see guidance on 6.5 (below). For pre-clinical projects, particularly those transitioning to clinical studies, it is generally advisable for clinical colleagues to be involved (albeit with limited or no request for support of their time).*

**6.5 How will the project be managed and what experience does the team have of managing similar projects? (max 120 words)**

*Each of the investigators' C.V.s must be attached to Je-S (see the Attachments section below). Please elaborate on why the group is well qualified to conduct and manage the proposed project and how the roles of individual team members reflect their experience.*

**6.6 Following the end of the grant award, how will the project be sustained to enable it to meet its ultimate aims (i.e. what is your exit strategy)? What sources of subsequent funding/potential partners are potentially available to you? What criteria will need to be met in order to access these funds/partnerships, and how will the planned programme of work help to meet these criteria? (max 200 words)**

*If your application includes or involves an industrial partner outline what role they will have, if any, in exploitation of the project following the end of grant funding.*

**6.7 If you are ultimately seeking to develop a commercial product, outline potential market value and how this will be realised (e.g. business development plans) (max 200 words)**

*Your proposal will likely benefit from demonstrable engagement with end-users and/or downstream intermediaries, for instance manufacturing, clinical, or prospective commercial partners, to help ensure that your plan addresses both end-user and downstream requirements.*

**6.8 What are the key risks to delivering the project, how likely are these to occur and what would their impact be? How will these risks be managed? (max 250 words)**

*No specific guidance.*

**6.9 Where appropriate, please justify the use of animals or patients. Why have these particular animal or clinical models been chosen? (max 150 words)**

*Please refer to section 6.12 (below) and the MRC Applicants' Handbook for further information.*

**6.10 Have you consulted with a statistician, CTU or methodology hub? If not, please summarise why this is not necessary (max 150 words)**

*Please refer to section 6.12 (below) and the MRC Applicants' Handbook for further information.*

**6.11 Please summarise the experimental approach taken. What are the primary and secondary experimental outcomes and how do these relate to experimental objectives? What is the 'experimental unit' in the proposed analysis, how many such units will form an experimental group and how many groups will be evaluated? How many times will each 'experimental unit' will be measured? What steps will be taken to minimise the effects of bias or why is this unnecessary or impractical? (max 300 words)**

*Section 6.11 is designed to capture the experimental design and the justification of the design. This section is not limited to just animal or preclinical work but should also cover human/clinical work. Specifically, it should capture:*

- *Primary and secondary experimental outcomes (e.g. molecular markers, behaviour change, etc) and how these relate to experimental objectives*
- *Number of experimental and control groups*
- *A clear definition of the "experimental unit" (e.g. patient, animal, etc) in the analysis*
- *Number of "experimental units" in each group*
- *Total number of "experimental units" to be measured*
- *Number of times each "experimental units" will be measured*
- *Number of independent replications of each experiment*
- *Steps taken to minimise the effects of bias (e.g. blinding, randomisation) or an explanation as to why this would not be appropriate*

*Please note that Sections 6.11 and 6.12 replace the "Reproducibility and Statistical Design Annex", and this document will no longer be accepted. Please refer to the guidance in the MRC Applicants' Handbook on this Annex when completing Sections 6.11 and 6.12 however, as they are closely aligned.*

**6.12 Please summarise the statistical analysis plan and the proposed sample sizes, providing sufficient detail for replication of any power calculations and a clear summary of the anticipated effect sizes and variability. (1 page)**

*Statistical methods should be used to help the study reach a conclusion. Ensure the proposed methods and sample sizes are well-justified, robust and suitably powered. If your proposal includes a clinical trial, be sure to include a clear description of the trial design, and how the trial will be run. Consider including clear stop/go criteria.*

*Please also refer to the* MRC Applicants' Handbook *for further information.*

## Section 7: Downstream Project Support and Intellectual Property

*Note that the generation of protectable intellectual property is not an essential requirement for this scheme; projects that will not generate patentable materials but that will nevertheless have the potential to provide health benefits are accepted on an equal basis. However, ownership and management of IP must be consistent with MRC's funding requirements. Projects with no plausible route to exploitation and ultimate health benefit or impact are extremely unlikely to be supportable.*

*It is important that as much detail and evidence as possible is provided relating to ownership and exploitation of IP. For example, simply stating "We have freedom to operate" will generally not be considered sufficient. Note that unless otherwise indicated it will be assumed that the academic applicants will have the right to exploit the Knowledge developed by their activities at the end of the project. If the application involves an industrial partner, please refer to the MRC Industry Collaboration Agreement (MICA)* webpage for further guidance or consult the relevant programme manager*. Spinouts from academic institutions are considered to be separate, commercial, entities and background IP held by a spinout may be considered a barrier to downstream exploitation.*

## Section 8: Project Duration and Cost

Please include estimates of the duration and costs you anticipate will be required to reach each relevant checkpoint and any project partner contribution. The form will calculate the expected total project duration, cost and estimate the MRC contribution, based on 80% of the requested costs.

*Specific guidance on Exceptions Costs can be found in the Outline Resource Summary section of Je-S, and in the MRC Applicants' Handbook.*

*Similarly, further guidance on NHS costs (excess treatment and NHS support costs) can be found in the MRC Applicants' Handbook.*

## Submitting the form

Once completed, the Outline Case for Support Form should be saved as a PDF file and submitted via the Je-S system. Please note that your outline BMC: DPFS application will automatically be rejected if your Case for Support does not use the BMC: DPFS Outline Case for Support Form.

## Oversight and Reporting

## Project Management

To ensure effective delivery, successful applicants will be required to establish appropriate project management systems to oversee any BMC: DPFS project. At the start of the project the Principal Investigator will be required to establish a Project Management Group (PMG). The PMG, which will be accountable to its host institution, will direct the project and report to the MRC on a regular basis. Applicants will be required to appoint a project manager with responsibility for the management and co-ordination of day-to-day activities and for integrating these with any out-sourced service provision. Costs to support a dedicated project manager are eligible. For pre-clinical projects MRC would typically expect that project manager involvement to be no more than 25% FTE; for clinical projects no more than 50% FTE.

During the period of BMC: DPFS support, the PMG will be required to submit Quarterly, Milestone and End Reports to the MRC. If a milestone is at risk of not being met, the PMG should submit a request for change to the MRC. Projects that show negative results at milestones, or which fail to meet milestones, will be terminated, unless a compelling request for change has been submitted, and the concept has a high priority.

## Intellectual Property Management and Exploitation

Intellectual property generated in the course of a BMC: DPFS project will be owned by the host institute, who will have the right to manage and exploit the project intellectual property.

The MRC wishes, however, to assure itself that host universities are able to manage and exploit effectively the intellectual property generated from MRC-funded research. This is particularly important in the case of the BMC: DPFS, as projects supported by the scheme will likely require further development in order to meet their clinical aims. To support this further development, intellectual property will need to be appropriately managed and strategies adopted that are able to identify suitable partners and partnership terms that optimise the potential for the project to meet its clinical aims.

During the period of BMC: DPFS support, the PMG will be required to prepare an intellectual property report as part of its Milestone and End Reports. Following the end of BMC: DPFS support, the Principal Investigator will be responsible for submitting an annual intellectual property report for up to 3 years.

## Using the Joint-electronic Submission System

**The Joint Electronic Submissions (Je-S) Helpdesk is the first point of contact for the Research Councils**

If you experience difficulties using Je-S or have questions regarding its use, the helpdesk can be contacted:

- Email: JeSHelp@rcuk.ac.uk
- Phone: +44 (0) 1793 44 4164*
- Staffed Monday to Friday 8.30am - 5pm (excluding bank holidays and other holidays)
- Out of hours: leave a Voice Mail message

When reporting problems by e-mail or telephone, please supply the following information:

- Your name, organisation and user id
- The date and time
- The part of the form or system you were working on when the problem occurred
- The nature of the problem

*Phone calls that cannot be answered during working hours will be redirected after 30 seconds to Voice Mail. The helpdesk will normally return your call within 3 hours.

**Classifications:**

- **Board or Panel Portfolio**: Developmental Pathway Funding - DPFS
- **Grant Type**: Used for reporting purposes only, please select the option which best describes how you first heard about the BMC: DPFS scheme.

**Attachments:**

Select **Add New Attachment:** Applicants may submit PDF versions of:

- A cover letter including, if applicable, a response to Panel comments on a prior submission of the project (under document type Feedback Letter). The maximum length of a combined cover/feedback letter must not exceed **5 x A4 pages** (Arial 11 point). In general succinct responses are encouraged and provision of information considered outside the scope of a cover/feedback letter will result in the application being returned for amendment.
- The BMC: DPFS Outline Case for Support Form (under document type Case for Support – word limits not to be exceeded).
- An optional but advised document of supporting figures and data tables (under document type Supporting Data – no more than **2 x A4 pages**).
- Applicants seeking funding for hit-to-lead and lead optimisation projects must also complete the Small Molecule Supplementary Information form. This form can be downloaded via the BMC:DPFS website and should be uploaded to Je-S under document type 'Supporting Data'. Where deemed necessary, failure to submit the form will result in your application being returned - please contact one of the relevant MRC Programme Managers if you have any queries;
- A CV for the Principal Investigator, any Co-Investigators and Named individual research staff, please refer to the Applicants' Handbook for further information on CV requirements (under document type CV - no more than **2 x A4 pages** Arial 11 point).

- A Publications list for the Principal Investigator, any Co-Investigators and Named individual research staff, please refer to the Applicants' Handbook for further information on publication requirements (under document type Publications - no more than **1 x A4 pages** Arial 11 point).
- Optional letters of support from key collaborators or partners, such as industrial partners or clinical collaborators/recruiting centres (under document type Supporting Data – no more than **2 x A4 pages** per letter).

*Note the MRC reserves the right to decline or return an application on eligibility grounds, if documents other than those detailed above are submitted or if the guidance indicated above is not adhered to. Failure to follow the guidance may prejudice your application.*

## Contacts

If you have enquiries regarding the BMC: DPFS scheme, please contact one of the scheme Programme Managers. Contact details and scientific areas are available on the BMC: DPFS webpage.

The Programme Managers and Office Team can also be reached through the BMC: DPFS mailbox (DPFSandDCS@mrc.ukri.org).