Guidance for Outline Stage DPFS Applicants

Contents

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

- DPFS Webpage
- MRC Guidance for Applicants – details on eligibility, costings, responsibilities etc.;
- MRC Industry Collaboration Framework (ICF) – relevant to industrial collaborations;
- Je-S Helpdesk – for information or queries related to use of the Je-S System.
- Choosing Contractors for Animal Research – NC3Rs guidelines
- MRC Guidance on Research Involving Animals
- Sex in experimental design – new guidance as of September 2022

Please ensure you have downloaded the latest version of this document via the DPFS Webpage.

Outline Applications

DPFS applicants must first submit an outline 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 DPFS scheme.

To submit an outline application, the applicant must complete the DPFS Outline Case for Support Form, available from the "How to Apply" tab of the DPFS Webpage, and submit this as a PDF via the Je-S website.

Please note that Section 6.10 displaces the "Reproducibility and Statistical Design Annex", and this document **will not be accepted**. Please refer to the guidance given for these questions below, and the guidance on the "Reproducibility and Statistical Design Annex" given in Sections 2.2.3.5 and 4.3 of the MRC Guidance for Applicants when completing these sections, as the topics covered are closely aligned.

Note that applicants seeking funding for hit to lead, lead optimisation and/or candidate selection **must** complete the Small Molecule Supplementary Information form (available under the "Additional Info" tab of the DPFS Webpage) in addition to the Case for Support form. You may also email the DPFS Office (DPFSandDCS@mrc.ukri.org) to obtain a copy of this form. This form should be uploaded to Je-S under document type "Supporting Data".

A checklist of the compulsory and optional attachments that should be included in the application is provided at the end of this document.

Outline Application Assessment Criteria

The DPFS Panel will consider outline applications against the criteria below. Panel decisions at outline stage are to; Invite a full proposal or Reject the proposal (Decline). Should your outline proposal be Declined, you **cannot** re-submit the same or a similar application to the DPFS scheme within 12 months of the original application deadline.

In exceptional circumstances, the Panel may give Positive Feedback, whereby the proposal is declined, but the 12-month moratorium on a re-submission is waived.

Please note that the decisions of the 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 risks and its potential benefits, does the plan offer good value for money?
  - Are the proposed study design and methodology appropriate to address the research questions?

- 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 DPFS Outline Case for Support Form

The 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., Translation Research Office (TRO)), and failure to do so may prejudice your application. A contact at your Institution's TTO, or equivalent, is **required** to submit a letter of support indicating the role they have played in developing the application. This letter should be converted into a PDF and submitted under document type 'Letter of Support' as part of the Je-S submission.

In terms of the TTO's role:

- 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 (max 150 characters) [same as Je-S Project Title]

Please provide a concise title for your proposal. This title should be the same as the project title of your Je-S submission. If your application is in collaboration with an industrial partner, the title should be prefixed with "**ICF:**" (for example: "ICF: Development of a series of small molecule androgen receptor antagonists for use in prostate cancer").

1.2   Technical Summary (max 2000 characters) [same as Je-S 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 in 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 [same as in Je-S submission]

Please enter the proposed project start date. This date should be the same as the proposed start date in your Je-S submission.

You **do not need** to enter the other figures (proposed duration of award, project fEC, estimated MRC contribution and project partner contribution) here. These are calculated from duration and cost inputs you are required to enter in **Section 8** later in the form.

Section 2: Investigator Details

Please refer to Section 1.3 of the MRC Guidance for Applicants 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 research staff member, from the same Research Organisation as the Principal Investigator or a Co-Investigator, who has substantially contributed to the formulation and development of the proposal but who is not yet eligible to be listed as a Co-Investigator (for example, because they do not have a contract of employment with any of the participating ROs for the duration of the grant prior to application).

A Letter of Support for a Researcher Co-Investigator is **optional, but highly recommended** at the DPFS outline application stage. The Principal Investigator should use this letter to highlight the support for the Researcher Co-Investigator(s) to further their career and personal development throughout the duration of the project.

Please also refer to Section 1.3.3 of the MRC Guidance for Applicants and the MRC 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). Please also refer to Section 1.3.4 of the MRC Guidance for Applicants, and ensure details are given in the Je-S proposal form.

Each project partner must also provide a letter of support (please refer to Section 2.2.6 of the MRC Guidance for Applicants).

All applications with one or more industrial partners should review the Industry Collaboration Framework guidance to decide if the proposal should be submitted under this Framework. Please also refer to Pages 12-13 of this document.

Applicants may consult with industry advisors during the delivery of the project. If these industry advisors do not provide financial or substantive intellectual contributions to the project, and they claim no rights to arising IP, then you may not need to complete an ICF form. Please discuss such arrangements with your Programme Manager prior to the submission of your application.

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). Please also refer to Section 1.3.4 of the MRC Guidance for Applicants, and ensure details are given in the Je-S proposal form.

Each project partner must also provide a letter of support (please refer to Section 2.2.6 of the MRC Guidance for Applicants).

2.6 Subcontractors

Subcontractors should **not** be named as part of the project team in Sections 2.2 – 2.5. 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). High-level details of any subcontracting arrangements should be provided in Section 6.11 of the Case for Support; further information on these will be sought if the proposal is invited to Full stage. For further guidance on subcontractors, please refer to Section 3.2.2.3 of the MRC Guidance for Applicants.

Dual Roles: An organisation or individual may act as **both** a Project Partner and Subcontractor on a DPFS project. A dual role may be appropriate or required, for example, when an organisation or individual is contributing to the project *in-kind*, but has also been tendered to deliver other work on the project covered via a subcontract. A dual role **must be fully justified**, and you **must** be able to demonstrate that it remains compliant with standard guidance for both Project Partners and Subcontractors (e.g. the work will be subject to the procurement rules of the host Research Organisation, offer value for money, and its inclusion be required for the project's success).

Where a dual role is being proposed, you are strongly encouraged to get in touch with your Programme Manager to discuss these arrangements prior to submitting the application. You may also wish to submit a Cover Letter (of up to 2 pages) to outline the arrangements and confirm compliance with the MRC guidance.

Full guidance on dual roles may be found in Section 3.2.2.3 of the MRC Guidance for Applicants.

Section 3: Host Institute Technology Transfer Office Contact

3.1 Host Institute Technology Transfer Office (TTO) Contact

As the MRC would normally expect the host institute TTO to assist in the preparation of a DPFS proposal 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

The significance of the clinical/medical need for your proposed solution is a key assessment criterion for DPFS. You should describe, and quantify where possible, the users and market for your proposed solution, and demonstrate awareness of the competitive landscape including existing products or solutions in development that could also address the stated need.

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.

For **Section 4.3**, please compile a list here of all major competing solutions, and their progress (if known). (e.g. Competing Solution 1, Company/Organisation, project status (i.e. preclinical, in clinical development, already marketed). Be sure to fully justify in Section 4.4 why your proposed solution is advantageous – e.g., is it significantly different, or further along the translational pathway.

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Section 5: Rationale

Please provide up to 10 relevant references in **Section 5.2** and cite these elsewhere within the document as applicable. Please also note that **up to two pages of supporting data** *must* be uploaded as a supplementary document; this is **now mandatory for DPFS applications**. Applicants seeking funding for hit to lead, lead optimisation and/or candidate selection must also complete the Small Molecule Supplementary Information form (available under the "Additional Info" tab of the DPFS Webpage), and upload this as a separate attachment.

Section 6: Deliverability

In completing Section 6, please also refer to the outline application assessment criteria outlined above.

6.1   What is the current status of the project? (max 100 words)

No specific guidance.

6.2   Please list the project's primary objectives (max 150 words)

No specific guidance.

6.3   Please list the project's specific intended deliverables (max 100 words)

No specific guidance.

6.4   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)

In addition to answering this question, if your application involves staff from an MRC Unit or partnership institute, you should submit a letter of support from the Unit/Institute Director as part of your application. Please refer to Section 3.9 of the MRC Guidance for Applicants for information on the MRC's expectations and requirements.

If this section does not apply to you, please write "Not Applicable".

6.5   Please give details of previous/concurrent awards relevant to the project, stating the funder, time awarded, grant period, grant title and £s awarded, alongside a short summary of how each supported the current application. If you currently hold any funding concurrent to this project, please give details of any overlap and how this work will support your application (max 500 words)

Please acknowledge any previous or current funding (MRC or otherwise) related to the proposal, and describe progress-to-date on delivery of this research. If the proposal is a follow on to work previously funded by the MRC (e.g. through one of the Research Boards or Confidence in Concept/Impact Acceleration Account funding), it would be advantageous to detail these in answering this question.

The quality and productivity of the recent work will be a factor in assessing the likely quality of future work (e.g. for applications involving a clinical trial, the track record of the applicant(s) in registering and publishing previous trials will be considered before making further awards).

It will be important to differentiate the objectives of any existing funding from those of the DPFS application, and to clarify that no element of the work proposed is being funded from another source.

6.6   How will the project achieve its objectives? Summarise the project workplan, including at least two key progression milestones (one being the project end). For each Milestone,

please set out the success criteria that will be used, and detail robust Go / No-Go criteria (max 1250 words)

Milestones are a key feature of DPFS proposals that allow the MRC to mitigate risk and support potentially high-risk projects. Milestones should gate progression of your project and focus on major progress points that must be reached in order to achieve success. They should therefore reflect key Go / No-Go decision points on the path to your long-term goals, and should not be represented by a list of tasks.

A DPFS project will typically have between 2-4 Milestones. Poorly defined Milestones are a common weakness in DPFS proposals and can impact the likelihood of success.

Milestone success criteria should be SMART (specific, measurable, achievable, relevant, timely), 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 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 (when applicable), (5) anticipated effect size / accuracy measures and (6) analysis plans

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 7.1).

6.7   Where applicable, please justify the use of animals or patients. Why have these particular animal models or clinical populations been chosen? (max 250 words)

If the proposed research involves animals, please detail the rationale for the use of animals and the choice of species, strain and any disease models being used. Please also include information about the severity of the planned procedures.

Unless there is a strong justification for not doing so, MRC now requires both sexes to be used in the experimental design of grant applications involving animals, and human and animal tissues and cells. Please ensure you have included clear information about the sex of the animals, tissues and cells you plan to use. You may also provide further details on your design in Section 6.10 (below). For full guidance, please refer to the MRC's webpage on [sex in experimental design](#).

Please also refer to [Section 4 of the MRC Guidance for Applicants](#) for further information and guidance on the use of animals in research.

6.8   For clinical studies, please outline the recruitment and retention strategy (max 200 words)

Please describe your strategies for the recruitment and retention of participants. Please outline how these will help achieve / guide the target recruitment rate described in Section 6.10 below. If your proposal includes pilot studies, please describe them here, and expand upon how they will help guide the final trial design and expected numbers, etc.

6.9   Have you consulted with a statistician, CTU or methodology hub during the development of the application, and will you have access to statistical support during the project? If not, please summarise why this is not necessary (max 300 words)

Please refer to Section 6.10 (below) and [Section 4.3 of the MRC Guidance for Applicants](#) for further information. In general, it would be expected that professional statistical advice will be sought in putting this section together, and a relevant expert may be included as a co-applicant or project partner.

6.10 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. Consider potential sources of biases and describe strategies that will be adopted to minimise their effects (1 page)

In general, it would be expected that professional statistical advice will be sought in putting this section together, and a relevant expert may be included as a co-applicant or project partner. Please also refer to Sections 2.2.3.5 and 4.3 of the MRC Guidance for Applicants for further information, as much of the guidance designed for the reproducibility and statistical design annex is applicable to this section.

Please describe the planned experiments / study, including (but not limited to): primary and secondary outcome variables; how many groups will be evaluated; study design and statistical analyses planned; justification of the sample size, including, when applicable, how many experimental units (e.g. patient or patient group, animal or cage) per level are required, and the number of independent replications.

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, and that sample size calculations can be reproduced. 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. Ensure clear stop / go criteria are included.

Although we acknowledge that performing a formal power calculation may not be possible in some cases, a clear scientific justification of the sample size required to satisfactorily address the research question(s) is expected (e.g., to achieve a certain level of accuracy in parameter estimation).

You should consider potential sources of biases and describe strategies that will be adopted to minimise their effects.

In general, explanations based solely in terms of 'usual practice' will not be considered adequate. This section should be completed in full, regardless of whether the academic institution, contract research organisation or industrial partner will be conducting the work.

Applications that do not provide sufficient detail to convince the Panel that the proposed experiments will be carried out appropriately to produce robust and reproducible research will be rejected for funding on these grounds, and subject to the usual limits on resubmission.

Please ensure that any summary statistics are clearly described (e.g. mean / median, 95%CI / ±SE / ±SD etc.) and are easily reproducible. If you need to use a figure or table these can be included in the supporting data attachment and referenced in this section.

6.11 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 each stated milestone (max 500 words)

Outline the personnel, equipment, consumables etc. required to conduct the project detailed in Section 6.6. Resources could include, where appropriate: materials, methods, data, personnel, project management, infrastructure, equipment, outsourced tasks, therapeutics, models, assays, and/or access to facilities.

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).

6.12 How will the project be managed, and what experience does the team have of managing similar projects? (max 200 words)

Please describe why the group is well qualified to conduct and manage the proposed project, and how the roles of individual team members reflect their experience.

All named staff – including the Principal Investigator and all Co-Investigators and Researcher Co-Investigators – **must** provide a C.V. (up to 2 pages) and Publication List (up to 1 page) as part of the proposal (please refer to the Checklist of Attachments).

6.13 Please list the key risks to delivering the project, how likely these are to occur, and what their impact would be on the success and deliverability of the project? How will these risks be managed? What mitigation plans will be in place? (max 500 words)

List the key risks to the project and for each risk indicate the likelihood (e.g. unlikely, occasional, likely) and the consequence this could have on the project (e.g. minor, moderate, severe). Describe how the risk will be managed and any risk mitigation plans that are in place. Risks, Impact and Mitigations **may** instead be given in bullet point format (**NB:** bullet point lists may need to be copied and pasted into the Case for Support form). **Alternatively,** a **1-page** Risk Table may be uploaded as "Supporting Data", and the comment "*Please Refer to Risk Table*" written in the text box in the Case for Support (please refer to the Checklist of Attachments).

Section 7: Downstream Project Support and Intellectual Property

It is expected that this section should be completed in partnership with your Institution's Technology Transfer Office (TTO) (or equivalent), and failure to do so may prejudice your application. The host TTO should lead on the performance of prior art searches to identify documents relevant to freedom to operate (FTO), which should be listed in this section.

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.

If the application involves an industrial partner, please refer to the MRC Industry Collaboration Framework (ICF) webpage for further guidance or consult the relevant Programme Manager. Spin-outs 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.

When completing this section, please also refer to the Intellectual Property Management and Exploitation guidance given below.

7.1 What new IP or knowledge is the project expected to generate? (max 200 words)

You are encouraged to think broadly about the IP that will be developed during the project. In addition to patents and copyright, you may wish to consider: know-how, methods, materials, algorithms, designs, pre-clinical results, clinical trial data, software and trademarks.

The generation of protectable intellectual property is not an essential requirement for this scheme; projects that will not generate patentable materials, but that nevertheless have a feasible route to realisation of health benefits, are accepted on an equal basis.

7.2 How will project-generated IP be managed and exploited to support the project in meeting its targeted need? Detail the organisations / individuals who will own any arising IP and any live, pending or envisioned agreements governing ownership or exploitation of that IP (max 200 words)

Please detail the organisations / individuals who own / will own any project IP, and any live, pending or envisioned agreements governing ownership or exploitation of that IP.

Please list any arrangements you may have with third parties that might limit the freedom of exploitation of this IP by the academic applicants. These could be restrictions imposed by collaborators or sub-contractors, pipeline agreements, or restrictions imposed by the owner of the IP. Please describe any restrictions, and how these will affect your exploitation strategy.

7.3 Following the end of the grant award, how will the project be supported to enable it to meet its ultimate objectives (i.e., what is the route to market / patient benefit)? (max 200 words)

Outline the downstream planned route to market / patient benefit, taking into account the required skills and resources needed.

7.4 What sources of subsequent funding/partners are available to the project? 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)

Identify the sources of funding available and detail why these would be appropriate for the next stage of development. If licensing or commercial funding is anticipated, list potential partners and the data package that would be offered.

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

7.5 If you are ultimately seeking to develop a commercial product, please outline the 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.

7.6 Do the applicants have freedom to operate for this project, for future development work, and/or for clinical use? If access is required, what IP does the proposal need access to? (max 200 words)

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 not be considered sufficient. Please provide details to support any claims of Freedom to Operate (e.g. freedom to operate analysis, patent searches, details of ownership of the background IP by the Research Organisation). 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.

7.7 If access to background IP is required, please detail the institutions or individuals that hold the relevant background IP rights. If this background IP is held by a third party (or a non-academic applicant), has access been agreed? If not, why do you believe you will be able to access the required IP on reasonable terms? (max 200 words)

No specific guidance.

Section 8: Project Duration and Cost

To allow the Panel to evaluate the value for money, please indicate what the <u>entire</u> project cost will be. Please include <u>estimates</u> 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 and full economic cost.

Please add in the estimated MRC contribution, **which should match the figure listed on your Je-S submission**. This total will comprise 80% of the requested academic fEC, and account for any requested exceptions costs to be paid at 100%.

To ensure that all the automatic calculations pull correctly, please start from the first entry and use the "Tab" key to navigate between the 'cost' cells in Section 8 of the document. Alternatively, press F9 to update all fields.

8.1 If you have requested support for resources under Exceptions Costs, please describe the nature of these resources (max 200 words)

Certain costs in excess of £50,000 for sub-contracts with contract ROs (CROs) may be paid at 100 per cent. This is limited to activities that meet **all three** of the criteria outlined below:

- Are required to be undertaken to regulatory standards by a competent authority to allow clinical evaluation
- Do not involve creativity/intellectual input to the development of the entity by the CRO
- Require access to skills and resources not available in academia, where this can be robustly justified.

Examples of eligible activities include:

- Pre-clinical toxicology package carried out under Good Laboratory Practice (GLP)
- Synthesis/ manufacture of an entity carried out under Good Manufacturing Practice (GMP)

Applicants should consult with the relevant Programme Manager about the scientific justification of any exceptional costs ahead of submission.

Please also refer to Section 3.6 of the MRC Guidance for Applicants. Additional guidance on Exceptions Costs can be found in the Outline Resource Summary section of Je-S, and in Section 3.2.5 of the MRC Guidance for Applicants.

8.2 Please summarise any NHS costs (excess treatment and NHS support costs) that the project will require (max 150 words)

Applications may include research costs associated with NHS studies, if appropriate. Please summarise the expected activities and costs, alongside justification to why/how these are necessary for the research proposed.

If you are applying for research grants that require NHS support or HRA approval, you will need to submit a completed Schedule of Events Cost Attribution Template (SoECAT) at the full application stage. **This is not required at the outline stage.**

Please refer to Section 3.5 of the MRC Guidance for Applicants for further guidance on NHS costs.

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 DPFS application will automatically be rejected if your Case for Support does not use the DPFS Outline Case for Support Form.

Compiling the Gantt Chart

You will be required to provide a one-page Gantt chart of the proposed plan showing:

- Project tasks (these being short, achievable and measurable activities) with, where relevant, the party responsible for delivering the task and dependency relationships between tasks; and

- The progression milestones (including the project end goal), as detailed above. These should reflect the major specifically-timed decision points when a judgment will be made on whether or not to progress the project based on the achievement/non-attainment of specific measurable targets.

Once completed, the Gantt chart should be saved as a pdf file and submitted via the Je-S system under the document type "Gantt Chart". Please ensure the file is readable and displayed correctly across **one A4 page** before uploading.

Applications submitted under the Industry Collaboration Framework (ICF)

If the application involves an industrial partner, please refer to the MRC Industry Collaboration Framework (ICF) webpage for further guidance on whether the partnership falls under the ICF or consult the relevant Programme Manager.

Applicants can also use the ICF Decision Tree to check if they need to submit using the ICF.

ICF Applicants should:

- Prefix their project title with "**ICF:**" in the Je-S proposal and the Case for Support form
- Ensure the proposed collaboration meets the requirements set out in the ICF framework.
- Include a completed ICF Form (available to download here), attached as a PDF in the 'Attachments' section of Je-S (under document type 'MICA Form').
- Provide the name of their industrial partner's organisation, the name of their industry partner's contact and their industrial partner's contribution under the 'Project Partner' sections in Je-S and in the Case for Support.
- Provide a signed Letter of Support from the Project Partner (up to 2x A4 pages, and uploaded to Je-S as document type 'Project Partner Letter of Support'). A template containing all mandatory elements of this letter of support may be found here.
- Provide CVs and Lists of Publications for named Industrial Partner contacts (optional). Please refer to Section 2.2.1-2 of the MRC Guidance for Applicants for further information on CV and Publication List requirements (document type 'CV' and 'List of Publications' – no more than **2 x A4 pages** and **1 x A4 pages**, font Arial 11 point respectively).

Please note: A Heads of Terms is **no longer required** as part of a DPFS application. If your full application is awarded, funding will be conditional upon MRC receiving a copy of a fully signed, legally binding collaboration agreement between the partners (which must be consistent with information outlined in the ICF form) within three months of the issue of an award letter and in advance of a project starting.

Intellectual Property Management and Exploitation

Intellectual Property generated in the course of a 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 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.

Project Management

To ensure effective delivery, successful applicants will be required to establish appropriate project management systems to oversee any 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 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.

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 Je-S Helpdesk can be contacted on:

- Email: JeSHelp@je-s.ukri.org
- Phone: +44 (0) 1793 44 4164 *
- Staffed Monday to Thursday 8:30am – 5:00pm; Fridays 8:30am – 4:30 pm (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.

Contacts

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

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

Checklist of Attachments

Attachment (in PDF format)	Attachment type on Je-S	Page limit or formatting
Mandatory		
DPFS Outline Case for Support Form	Case for Support	DPFS Outline Case for Support Form
CV for • Principal Investigator • Co-Investigator(s) • Researcher Co-Investigator(s) • Any named research staff Please refer to Section 2.2.1 of the MRC Guidance for Applicants for further information on CV requirements.	C.V.	Up to 2 x A4 pages Font Arial, 11 point
Publication list for • Principal Investigator • Co-Investigator(s) • Researcher Co-Investigator(s) • Any named research staff Please refer to Section 2.2.2 of the MRC Guidance for Applicants for further information on publication list requirements.	List of Publications	1 x A4 page each Font Arial, 11 point
Gantt chart	Gantt Chart	1 x A4 page
Letter of Support from the Technology Transfer Office (or equivalent) The letter should be signed by the member of the TTO listed in Section 3, and should indicate the role they have played in developing the application and they will play in supporting the project on an ongoing basis.	Letter of Support	Up to 2 x A4 pages Font Arial, 11 point
Supporting figures and data tables	Supporting Data	Up to 2 x A4 pages
Mandatory if applicable		
Cover letter if the project is a resubmission This should detail the applicants' response to Panel comments on the prior submission of the project. 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.	Feedback Letter	Up to 5 x A4 pages Font Arial, 11 point
If the project involves any industrial partners, please ensure the following documents are appended: • *Optional:* CV(s) & Publications List(s) for named Industrial Partner contact(s) • A completed **ICF Form** • Project Partner Letter of Support	Respectively; • CV and List of Publications • MICA Form • Project Partner Letter of Support	

DPFS Outline Stage – Guidance

Small Molecule Supplementary Information form if the application is seeking funding for a hit to lead, lead optimisation and/or candidate selection project. This form can be downloaded via the 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.	Supporting Data	Small Molecule Supplementary Information form

Attachment (in PDF format)	**Attachment type on Je-S**	**Page limit or formatting**
Optional (but highly recommended)		
Letter(s) of Support from any key collaborator/partner, recruiting centre, Contract Research Organisation, regulatory body, or other relevant party to the application.	Letter of Support	Up to 2 x A4 pages each Font Arial, 11 point
Letter(s) of support if the project includes Researcher Co-Investigator(s) (RCo-I) The Principal Investigator should use this letter to highlight the support for the Researcher Co-Investigator(s) to further their career and personal development throughout the duration of the project. Please refer to Section 1.3.3 of the MRC Guidance for Applicants for further information on our expectations of support for Researcher Co-Investigators.	Letter of Support	Up to 2 x A4 pages each Font Arial, 11 point
A Risk Table if you wish to address question 6.13 in the Case for Support Form. Should you choose to use the table instead of responding in the form, you should write "Please Refer to Risk Table" in the Case for Support form.	Supporting Data	1 x A4 page
Not accepted at outline stage		

Anything not listed will be considered an ineligible attachment and will **not** be accepted (unless prior permission has been sought from your Programme Manager). These include, but are not limited, to:

- Heads of Terms
- Impact Statement
- Justification for Resources
- Patent Search Reports
- Quotations (for equipment, subcontracted work, etc.)
- SoECAT Form

Please refrain from including any links to external sites (such as Dropbox) within your application. If you wish for supplementary files or information not listed above to be included in the application, please get in touch with the DPFS Office (DPFSandDCS@mrc.ukri.org) to discuss this first.

Please 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.