Stratified Medicine Initiative - call for proposals for disease-focussed partnerships to stratify for patient benefit

Applicant Questions and Answers

Eligibility

1. **Who is eligible to apply?**
   The Principal Investigator must be a UK-based researcher at an eligible institution (although Co-Investigators on the application can be international), or at an overseas establishment supported by the MRC.

2. **Is my UK institution eligible?**
   Eligible organisations fall into three categories:
   - UK higher education institutions (HEIs)
   - Research Council Units and Institutes
   - Independent research organisations (IROs)
   Please see [eligibility for research council funding](#) on the RCUK website for further details.

3. **Is there a limit to the number of applications I can submit?**
   Individuals may be the Principal Investigator on only one application, but may act as a Co-Investigator on any number of applications. However, please note that the assessment will consider the level of engagement of Principle Investigators and Co-Investigators with the research and their capacity to meet these requirements.

4. **Can MRC units and institutes apply under this call?**
   Yes. However any award to a MRC unit/institute would be made on the basis of 100 per cent directly incurred costs only and would not include indirect or estates costs. University Units (former MRC Units) will be awarded at the standard fEC rate under all cost headings (see guidance for applicants [3.2 costing of applications involving MRC units and institutes](#) and [3.3 university units](#)).

5. **Can I submit research which has previously been submitted to an MRC Research Board or Panel and was not funded?**
   Applications previously declined by the MRC or another Research Council will not be considered by the MRC within 12 months (from the date of submission to the original Research Council, as either an outline or full application) unless substantially revised.

6. **If my application doesn’t fit the call remit, what options do I have?**
   If your application does not fit the remit of this call, but is within the broader sphere of MRC interest, then you may apply via other normal funding mechanisms. Please see [Funding](#) on our website for more information.

Disease focus

7. **What diseases are included?**
   All diseases will be considered but applicants must make a clear and compelling case that the disease is stratifiable based on response to existing therapy or by risk, diagnosis and/or prognosis, that it is likely to contribute important understanding of disease, that there is sufficient critical mass to develop a large consortium and that it would be of interest to industry.

8. **I am already part of an MRC disease-focussed consortium; can I apply within the same disease area?**
   You may submit an outline application within the same disease area but the new application must be markedly different from the aims of the established consortium and with a compelling justification to do so.

9. **What will happen if more than one application is received in any particular disease?**
   The MRC will expect researchers to take a collaborative approach in developing these consortia. MRC may consider short listing two outlines in the same disease area if there is marked difference in
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10. There are no current therapies on which to base stratification in my disease area, can I apply? Yes, for this round diseases where there are no existing therapies will be considered. However, there should be compelling evidence of the potential to distinguish clinically important subgroups by means other than response to treatment, such as rate of progression of disease.

Official Development Assistance (ODA)

11. What is ODA? ODA is an international definition owned by the Organisation for Economic Co-Operation and Development (OECD) and is not only a RCUK or UK government term.

The OECD’s Development Assistance Committee (DAC) defines ODA as ‘flows to countries and territories’ which are on the DAC’s list of ODA recipients, provided by official agencies to promote the economic development and welfare of counties on the list. It is expected that funding streams eligible for allocation from the UK’s ODA budget should demonstrate how they aim to reduce poverty and increase sustainable development is required. ODA is highly relevant to the UN’s Sustainable Development Goals (SDGs), to which 17 goals have been described as part of the 2030 Agenda for Sustainable Development, including zero hunger and good health and well-being.

12. How do I meet the ODA criteria for the call? Generic guidance cannot be provided; you will need to demonstrate that the primary purpose of your project is the economic development and welfare of the LMICs. To achieve this, you should consider the following aspects when preparing your application:

- Your proposed research should investigate a specific problem or seek a specific outcome which will impact on the economic development and welfare of LMICs in the immediate or longer-term
- You should articulate a clear and specific case for the benefit and relevance of the proposed research to the LMICs
- Consider the pathway to realising the development impact (even if outside the timeframe of the project)

13. Which countries are eligible for partnering with? The OECD Development Assistance Committee’s List of ODA recipients (available at www.oecd.org/dac/stats/daclist) defines the sets of countries whose health needs (individual or collective) are relevant to this fund. All of the countries on the DAC list are eligible to be partnered with.

You do not have to work with specific partners from the DAC list however you do need to demonstrate how your research proposal will deliver primary benefits to Lower and Middle Income Counties (LMICs) in the long-term, and how you will deliver this pathway to impact.

14. What is the DAC list? Counties on the DAC list are divided among income groups according to their gross national income per capita, calculated using the World Bank Atlas method. Among the groups include ‘Least Developed’ ‘Low Income’, ‘Lower middle income’ and ‘Upper middle income’.

15. Are middle income countries eligible to be partnered with? What if my partner country is taken off the DAC list? Yes, middle income countries are eligible for partnering – if the country is named on the DAC list your application will be eligible for ODA. If a country is taken off the list before the end of your project, the project will continue through to completion but will be ineligible for any future ODA awards.

16. Can my research also benefit the UK?
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Yes, we expect that the research will also benefit the UK, in terms of the wider impacts such as new scientific knowledge, publications and training etc, however, LMICs should be the primary beneficiaries.

Consortium development

17. Who should be involved in a consortium?
This should ultimately be determined by the scientific direction but consortia should be multidisciplinary, must build on existing clinical research infrastructure and must have industrial partners.

18. Do I have to attend the applicants workshop if I’m accepted for full submission?
The workshop is not mandatory, but we would suggest that you attend. The objective of the workshop is to assist applicants in developing high quality applications by providing them with:

- The aims of the Stratified Medicine Initiative
- An overview of the requirements of the full application
- An introduction to the process of consortium governance, planning and management
- An overview of consortium reporting between applicants and the MRC
- The views of a consortium awardee and an Expert Review Panel member on what makes a good consortium and applicants; and
- An opportunity for applicants to raise questions with the MRC stratified medicine team

19. Will the MRC provide support for developing the consortia?
MRC will provide up to £15K for consortia development activities (e.g. workshops, meetings) but will not provide assistance for organising or running such initiatives.

Funding

20. How much funding is available under this call?
The MRC has allocated £15 million for this call. There will be an option for MRC to leverage additional funding from potential funding partners such as Cancer Research UK, Arthritis Research UK and British Heart Foundation.

21. What do the MRC envisage funding?
The funding is to establish multi-disciplinary research platforms. It is not intended to fund typical 3 or 5 yr project grants but to be larger scale, multi-partner endeavours. Naturally, there must be a strong patient focus that will draw in clinical expertise, clinical data handling and possibly methodology development. However, it is expected that this will link to strong mechanistic research to determine the biological basis underpinning stratification and identify new diagnostic biomarkers and potential new targets.

22. What is the expected duration of the grants under this call?
Depending on the nature of the research it is expected that grants would be between 4-5 years.

23. Are applications under this call value limited?
No. Awards under this call will not be limited. However applications are expected to be appropriately costed and all resources requested adequately justified.

24. Will the application attract full economic costs (FEC)?
Yes, the application will need to be submitted on a FEC basis.

25. Can awards be pruned?
Yes, the MRC will retain the option to prune awards in line with developing the consortium and feedback received from the expert panels. However, it is still important that applications are appropriately costed and represent clear value for money.

26. When will the awards be announced?
Awards will be announced following the review panel in November 2017.
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Preparing an application

27. How do I apply?
All applications must be submitted using the Research Councils’ Joint electronic Submission (Je-S) System (https://je-s.rcuk.ac.uk). Applicants should refer to the general guidance for applicants (on Je-S Help), the Call Guidance and MRC standard terms and conditions.

28. Is there an outline stage?
Yes. All applicants must submit an Outline application via Je-S.

29. When is the deadline for submission of the outline and full proposals?
Outline applications must be submitted to the MRC no later than 4pm on 1st December 2016. Full applications must be submitted to the MRC no later than 4pm on the 22nd June 2017. Please note that clicking ‘submit document’ on your proposal form in Je-S initially submits the proposal to your host organisation’s administration, not to MRC. Therefore, please allow sufficient for your organisation’s submission process between submitting your proposal to them and the call closing date.

30. My organisation is not registered to use the Je-S system.
Please contact the J-eS helpdesk as soon as possible with details of your organisation and the grant scheme you wish to apply for.

31. Do all investigators need to be registered on Je-S?
Yes. For any submission through the UK Research Council online submission system which is used by the MRC, ALL named investigators (Principal Investigators and all Co-Investigators) must be registered users. Easy instructions to register are available here. For help with using Je-S please contact the Je-S helpdesk:

   Email: JeSHelp@rcuk.ac.uk
   Phone: +44 (0)1793 444164
   Je-S website: https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Login.aspx

32. Can I create my own case for support document as I would for a normal research grant?
No, outline applications must use the Strat Med Outline Case for Support Form template.

33. Can I include annexes in my application?
Yes, applicants should include letters of support from industry collaborators with their outline applications. No other annexes will be accepted.

34. Will I need to complete a MICA form?
All applicants invited to submit a full proposal will need to complete a MICA form as there will be an expectation that the full applications will be collaborative proposals with industry partners. MICA forms will not be required for the outline stage. Please refer to the additional guidance for submitting MICA proposals which can be found here.

35. What happens if my application is received after the deadline?
Any proposals received after the deadline will not be eligible for this call and will be declined.

Assessment

36. How are proposals assessed?
At the Outline stage, applications will be reviewed by an Expert Review Panel comprising UK, international and industry experts. There will be two possible outcomes of this review stage:

Outline proposal successful – applicants will be invited to develop a full proposal to be submitted 22nd June 2017
Outline proposal unsuccessful – applicants will not be allowed to submit a full proposal
At the Full proposal stage, applications will be sent out for international peer review and assessed by the same expert Panel supplemented with subject specific experts if necessary. **Applicants will be invited to MRC for an interview with this Panel before funding decisions are made.** The expert panel will make the final funding decisions.

**37. Will the applicant be given the opportunity to respond to the panel?**
Applicants will be able to respond to reviewers comments following submission of a full proposal. Applicants however, will not be allowed to respond to the Panel. The Panel's decision is final.

**Ethics and governance**

**38. Do I need full ethics permission and regulatory approvals for any human studies in the proposal? If so, when should I apply for this?**
The MRC does not require ethics permissions and regulatory approvals to be in place when you submit an outline application. 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 your 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.

**39. Who has liability and indemnity responsibilities for any clinical studies?**
Liability and indemnity responsibilities will follow those outlined in the Lambert Model Agreements for Pre-clinical Studies and the model Industry Collaborative Research Agreement (miCRA) for Clinical Studies. Briefly, it is expected that the responsibilities for the conduct of the study will lie with the Sponsor of the research.

**Communications**

**40. How will you let me know if my application has been successful?**
The Principal Investigator will be notified of the decision on outlines and also full applications by email communication.

**41. Will you publish a list of the awards that are made?**
Yes, MRC intend to publish a list of the short-listed outline applications to raise awareness to the broader industry and academic communities of potential collaborative opportunities.

Following the final funding decisions a list of awards will be made available on the MRC website (the list will be inclusive of name, title of grant, host institution and value awarded).

**Other**

**42. If my query is not addressed in the various guidelines, answered by the FAQ’s, or I have a scientific query regarding my application, who do I contact?**
For scientific queries please contact Dr Rosie Fryer at [rosemary.fryer@headoffice.mrc.ac.uk](mailto:rosemary.fryer@headoffice.mrc.ac.uk)

For queries regarding preparation and submission of your application, in the first instance please refer to all documentation relating to the scheme, particularly the Guidance Notes and Je-S Help which will guide you through the standard processes for preparing a proposal and costing your proposals. If you still have a query, contact the Je-S helpdesk:

Je-S Helpdesk: Monday – Friday 9.00am – 5.00pm
Telephone: +44 (0) 1793 44 4164
Email: [JeSHelp@rcuk.ac.uk](mailto:JeSHelp@rcuk.ac.uk)
Web: [https://je-s.rcuk.ac.uk](https://je-s.rcuk.ac.uk)