Tackling multimorbidity at scale: Understanding disease clusters, determinants & biological pathways

Questions and Answers

1. Call Remit and General Questions

1.1 Are chronic infections or diseases with infectious triggers within the scope of the call?

Yes, we welcome broad spectrum of applications including research looking into multimorbidities which may include chronic infections or conditions triggered by infectious agents. These are within the scope of this call.

1.2 Does the work supported through this call have to be conducted in a UK population or can the research pertain to an overseas population be considered?

While we ask the PI to be based in the UK, the initiative is not restricted to the UK resources. It may be appropriate to involve international participants in collaborations where they could add significant value to the proposal e.g. unique expertise or infrastructure required to achieve the objectives of the study. The work done in other populations – based both in low- and middle-income settings and in high-income countries - will be eligible as long as it benefits better understanding of multimorbidity, can be generalised and would have relevance to the diverse UK population, and could be aligned with the UK-based data resources. Applicants are advised that there is an expectation that all data generated by the projects supported through this initiative will be made discoverable and available through the health data infrastructure currently developed by HDR UK. The panel will be assessing the strength of the applicants' plans to contribute to this work, and this will be one of the key assessment criteria.

1.3 Do I have to include a biopsychosocial approach in my research if it's just looking at biological mechanisms?

The biopsychosocial approach does not exclude projects that take a biomedical perspective, where this is appropriate and justified in terms of the research questions. However, thought and acknowledgement should be given to how the wider

psychological, social and environmental factors influence and interact with biological pathways.

1.4 Can the Collaborative funding be used to fund primary research?

Given the aims of this funding call we are expecting most Research Collaboratives to be carrying out secondary data analysis. However, where justified and clearly supporting the overall research aims, primary research could be funded. It would need to be achievable within the duration of the award.

1.5 My research doesn't directly address health inequalities, am I eligible for funding?

We expect all applicants to consider health inequalities in their proposed research. However, it is not a requirement for all funded projects to directly address health inequalities, but applicants should briefly outline how it was considered and why this was not possible in their research design.

1.6 Is there going to be another multimorbidity call either for Consolidator grants or for outlines of Collaborative awards under this SPF initiative?

No, this is a 'one off' call and though there may be other funding opportunities in this field in the future, they are likely to have different focus and/or be realised through different funding schemes. Prospective applicants are advised, however, that multimorbidity remains one of the 'opportunity areas' for the MRC Population and Systems Medicine Board, which welcomes Research and Programme grant applications in this field through its regular rounds of researcher-led funding calls.

1.7 Will we be able to apply for a Research Collaborative award later if we did not submit an outline proposal or a Consolidator grant application?

No, this is a staged competition and to be able to submit a full Research Collaborative proposal, applicants should either have received a Consolidator grant or have a successful outline application.

1.8 When are we expected to submit a full Research Collaborative application after receiving a Consolidator grant?

Applicants who received a Consolidator grant will be invited to submit their full Research Collaborative proposal in 6 months, by the end of the Consolidator grant tenure. Details of the application process will be communicated to the applicants separately shortly after the receipt of their awards but an outline timeline is included in the call text.

1.9 We are planning to work with an overseas collaborator/resource. Can we cost in a meeting overseas in our Consolidator grant application to work on preliminary proof-of-principle analyses and writing for the full grant application? Can you provide more detail on the level of engagement events that you deem permissible under the Consolidator grants?

While Consolidator grants may be used to support networking or engagement activity, this funding is mainly intended to cover relevant research expenses. Therefore, when requesting travel and associated costs, applicants are advised to justify the choice of location and the length of the proposed meetings. The benefits of holding such activities should be made clear in the proposal.

1.10 Are animal costs and funding for animal experiments permitted under this call?

Yes, these are allowed costs if animal experiments are part of the proposal.

2. Applicants and partners

2.1 Is there a minimum core set of inter-disciplinary researchers that you expect to see in a Collaboration?

There is no minimum core set of inter-disciplinary researchers that we expect to see in a Collaborative; the expertise should be relevant and sufficient to answer the research questions set out in the proposal. The funding panel will be looking for evidence that the proposal takes a truly inter-disciplinary/team science approach rather than developing workstreams where a mix of researchers work in silos on individual questions. Applicants should bear in mind that this programme seeks to tackle Multimorbidity at Scale, and as such we expect to see a broad representation of inter-disciplinary researchers if proposals are to achieve the progression required to move this field forward.

2.2 Can I have a co-investigator based outside the UK?

Yes, see answer to Question 1.2.

2.3 Can social scientists lead an award?

Yes, social scientists can lead an award. The lead PI should have expertise to lead the consortium to answer the questions set out in their proposal and there is no reason why that shouldn't be someone with a social science background.

2.4 Our partnership is still forming. Can we engage with more Co-investigators/Project Partners during the tenure of our Consolidator grant to include them in our full Research Collaborative application?

We recognise that those applying for a Consolidator grant may still be developing their partnerships and would require additional time to form the membership of the proposed Research Collaborative. Therefore, the configuration of the research partnership may differ at the Consolidator and full Research Collaborative application stages.

Those applying with an outline of the Research Collaborative proposal would be expected to have their partnership plans already developed.

2.5 Can we include a charity or a patient representative in our application as a project partner and request funds to support the activities/work they will be carrying out?

*Yes, applicants are advised that participating charities and patient representatives should be listed as named **project partners**. Unlike with other MRC applications, project partners will be allowed to receive funds to support their involvement and engagement in the research project. Project partners do not need to be based at an eligible research organisation (RO) or have a verified Je-S account.*

All funded projects must have patient, public involvement and engagement (PPIE). Even if a charity or patient representative is not included as a project partner, all PPIE activity must be appropriately compensated and costed for in the application.

2.6 Can we have an industry partner as part of our Collaborative?

*Yes, industry partners can be part of the proposed Research Collaborative, in which case they should be listed as a **project partner**. Applicants are advised that industry partners are not expected to request funding to participate in the Research collaborative, and applicants must follow the guidance relating to the MRC Industry Collaboration Agreement (MICA).*

*Please note the role of a **subcontractor** is distinct from a **project partner**. 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).*

2.7 We are applying for a Consolidator grant and have an industry partner. Do we need to complete a MICA form?

We do not require completed MICA documents at the Consolidator grant or the Research Collaborative outline stage but will be requesting those at the time of the full Research Collaborative application. As public funders we are responsible to ensure that the research funding arrangements comply with the State Aid regulations. Therefore, applicants planning to include industry as partners are advised to contact the Head Office to clarify the industry involvement and to receive further advise and guidance.

2.8 Can I submit multiple proposals or be a co-I on several applications?

We are not expecting each investigator to lead more than one proposal, but given the collaborative nature of the scheme, an individual researcher may be a principal investigator (PI) on one and a Co-I on another proposal or appear as a co-investigator (Co-I) on several applications. Applicants are advised that the Panel will be assessing the level of engagement/commitment of all Co-Is on the proposal.

2.9 Would funders expect Research Collaboratives to obtain additional/matched funding or in-kind contribution from other sources?

This is not a prerequisite of getting the award. Leveraging additional funding is, however, welcome, as well as are strong sustainability plans to allow the Collaborative to maintain its research beyond the tenure of the award.

2.10 If Consolidator grant holders realise that there is an opportunity to partner up with each other for the Collaborative application, would that be possible?

Yes, this will be possible and will be encouraged where there are benefits and to avoid duplication of work. We would ask the PIs to contact MRC ahead of submitting a joint full Collaborative application.

2.11 The call specification mentions a dedicated, named Data Manager / Officer. We are combining data from different sources and so have several data managers. Does this mean that we still need to select one person for this role?

It is important that the senior data manager expertise is present in the proposed Research Collaborative. However, it is up to the applicants to decide on the best way it is represented in the partnership. Applicants are advised to describe what in their view is the best way to arrange data management given their specific set-up.

3. Data Approaches

3.1 How can I make data generated by my project discoverable and available through the health data infrastructure being developed by HDR UK?

The first step is joining the UK Health Data Research Alliance. The Alliance is an independent coalition of health data custodians from some of the UK's leading health, care and research organisations. Alliance members have united to establish best practice for the ethical use of UK health data for research at scale. To join the Alliance, project teams can register at: https://ukhealthdata.org/join-the-alliance/

The UK Health Data Alliance is coordinated by Health Data Research UK and is open to any public sector organisation with responsibility for data custodianship, where they agree to work collaboratively to make data safely and securely accessible for research and innovation. This includes agreeing to the Alliance Principles of Participation (https://ukhealthdata.org/projects/promoting-participation-and-improving-access/), incorporating a commitment to:

1. *Encourage the availability and use of diverse health data that serves the public interest, while promoting privacy and data security*
2. *Make data Findable, Accessible, Interoperable and Reusable*
3. *Use a proportionate approach to the governance of data access based on the five "safes"*
4. *Maximise the benefits of data for research and innovation, through non-preferential access to data (i.e. data must be accessible by external researchers)*
5. *Establish mutually beneficial ways of working in partnership and working collaboratively to increase harmonisation and reduce the complexity of data sharing arrangements, to improve the efficiency of accessing data for trustworthy and ethical research and innovation*
6. *Work in partnership with existing, relevant health research infrastructure and contributing to a joined-up and UK-wide offer for researchers in all sectors.*

3.2 Will the UK Health Data Research Alliance take the responsibility of making our data available to the research community once we join it?

Joining the Alliance as a data custodian and benefiting from the Health Data Innovation Gateway comes with the expectation that the applicants can meet the requirements of the Alliance Principles of Participation (e.g. it is their responsibility to have an existing or planned mechanism for making their data safely accessible to external researchers). It is an important principle that HDR UK is not a data custodian working in partnership with those who are.

3.3 Can we join the UK Health Data Research Alliance, if we do not have a mechanism to make data safely and securely available to researchers outside of our project team?

If you do not have a mechanism for making data accessible by others (subject the applying the five safes) and do not intend to have such a mechanism then Alliance membership would not be appropriate.

Applicants who wish to become Alliance members will need to demonstrate that they have sufficient expertise to establish these functions (or the intention to work with a partner organisation to achieve this), either before or during the application, requesting suitable resources and staff time to enable this. Neither HDR UK nor the Alliance can take responsibility for the data management, curation, security, information governance or data access mechanisms of individual custodians. It may be possible to receive guidance and supporting services in this area from some Alliance members.

3.4 I would like to access data from a data custodian who is already a member of the UK Health Data Research Alliance. Will membership of the Alliance give me access to these data?

Alliance membership does not provide preferential or priority access to data. The Alliance establishes and shares best practice and works with data custodians to streamline data access for research and innovation. However, applicants wishing to access or link to data from existing Alliance members need to request data directly from the relevant data custodians, in line with current access and information governance mechanisms.

3.5 How will membership of the UK Health Data Alliance help to make my project data discoverable?

As a member of the Alliance, project data will be made discoverable through the Health Data Research Innovation Gateway: https://healthdatagateway.org/

The Gateway provides a common access point to discover and enquire about access to UK health datasets, held by members of the UK Health Data Research Alliance. You will be asked to provide detailed descriptions (metadata) of the project datasets to support discoverability (more information is available in the current metadata specification). The Innovation Gateway does not hold or store any patient or health data.

Applicants to the call wishing to join the Alliance and make their datasets discoverable through the Gateway, will need to ensure that they have sufficient capability to support the onboarding of dataset metadata to the Gateway (see the Alliance Metadata onboarding webinar for further details) as well as a defined process and sustainable approach to making their datasets safely and securely accessible to other researchers.

3.6 There is not enough space in the application to set out how we will meet the requirements of the UK Health Data Alliance Principles of Participation, where should I include this?

Applicants for Research Collaborative awards can use the separate Data Management Plan attachment (please use this template) to provide further detail of their approach to data management, particularly where they intended to participate in the UK Health Data Alliance, providing evidence that they have sufficient capabilities, to meet the requirements of the Alliance Principles of Participation (as set-out in the questions above).

4. Filling in application form

4.1 How should I fill in financial part of the Je-S application?

Applicants submitting an outline of the Research Collaborative *proposal are advised that they are expected to provide an estimate of the proposed Research Collaborative award resource request within the 'Case for Support' template. They are* ***not*** *required to detail any costs within the Je-S proposal form. Full costing information will be required at the full proposal stage. The outline application should be submitted as* ***'Zero'*** *cost through Je-S to MRC.*

Consolidator grant applicants *are requested to provide an estimate of their future Research Collaborative application resource request in the relevant section of the 'Case for Support' template and to detail the expenses ,expected during the 6-month consolidator stage period in the Je-S form. We understand that for the evolving partnerships it may be difficult to accurately allocate all associated costs of their Consolidator grant and, therefore, will only require a high-level breakdown of the proposed expenses. Applicants are advised that directly incurred (DI) costs* ***are*** *allowed to be vired between other DI fund headings and Exceptions, as per standard MRC rules. Should a Consolidator grant holder require further adjustment of the spend within their award budgets, they are advised to contact the Head Office.*

4.2 I am applying with an outline of the Research Collaborative, but the Je-S system does not allow me to have a 'zero' cost proposal when I include a Researcher Co-investigator (RCo-I) on my application?

This is a known issue. Applicants are advised to add any proposed RCo-I staff in their Research Collaborative outline proposal as a Co-Investigator (Co-I) in the Je-S form at this stage. Please make a note of that in your Proposal Cover Letter letting the Panel know if any Co-I will be a RCo-I in the full proposal.

4.3 I see there is a Data Management Plan attachment on Je-S, do I need to submit one?

This attachment is optional and aims to provide an opportunity for groups with more mature data approaches to describe their data strategies in more detail.

4.4 I am submitting an outline for the Research Collaborative award proposal, but the Je-S does not allow me to enter the duration of the project over 6 months?

Because the same Je-S form is being used for both Consolidator applications and Research Collaborative outlines, applicants submitting outline proposals should detail the duration of their suggested Research Collaboratives in the 'Case for Support' template, and in the Project Details section of the Je-S form put the project duration as 6 months.

4.5 Our proposal has many project partners and collaborations do we need to provide all letters of support?

We ask applicants to limit the length of each Letter of Support to 1 side of A4 and submit only letters from the key project partners.

4.6 Can I get help to work out whether I have excess treatment costs associated with my proposal?

Treatment Costs are the care costs that would continue to be incurred if the patient care service in question continued to be provided following the end of the research study. The difference between the Treatment Costs and the costs of the existing standard treatment is referred to as the Excess Treatment Cost (ETC). Guidance from the Department of Health and Social Care for the Attribution of Costs for Research and Development (AcoRD) sets out the principles for determining who pays for the different costs. Researchers are required to complete one of the Schedule of Events Cost Attribution Template (SoECAT) forms which help calculate an average per patient ETC value for the study. The NIHR Clinical Research Network provides AcoRD specialists to support researchers, their teams and sponsors in completing this. For more information about AcoRD support, visit our study support service.

4.7 Do we need to submit CVs and publications of the researchers named on the application?

Please provide CVs of the Principal Investigator and Co-investigators on your proposal. CVs should be a maximum of two sides of A4 and should cover:

- *Employment history:*
  - *A description of your current post and the source(s) of funding for this post (including dates)*

- *List and description of previous posts (including dates)*
- *Educational qualifications (including dates)*

- *Please also state whether you are:*
  - *Clinically qualified*
  - *Clinically active*

The CV should only include information relevant to the application. Please accompany. Each CV should be accompanied by a list of relevant and recent publications of the applicant as a separate attachment. Publication list should be a maximum of one side of A4.

For more details see MRC Guidance for Applicants sections 2.2.1 and 2.2.2.

CVs of other individual research staff named on the application and PPI representatives included as project partners (see Question 2.5) will be required when submitting a full Research Collaborative application. Please note that applicants who are patients, service users or carers will not be obliged to complete a standard CV but will be required to provide a summary of any knowledge, skills and experience relevant to their role in the application. This will be detailed further in the guidelines for submission of a full Research Collaborative application.

4.8 Je-S form allows to attach a Data Management Plan. Do we need to submit one?

The Data Management Plan is not required. However, if the applicants feel that the space provided in section 5 of the Case for Support template is not sufficient in their particular case, they may use the attachment to provide further details, for example, describing how they intend to participate in Health Dara Research Alliance (please see also Question 3.6). Data Management Plan template can be downloaded here: https://mrc.ukri.org/documents/doc/data-management-plan-template. Additional information about data sharing can be found on this page: https://mrc.ukri.org/research/policies-and-guidance-for-researchers/data-sharing/.

5. Assessment process

5.1 How will our application be reviewed?

At this stage, all Consolidator grant applications and outlines of the Research Collaborative award will be reviewed by members of the Expert Review Panel and discussed at the funding Panel meeting in March/April 2020 (date TBC). The criteria for success are included in the call text.

Full Research collaborative applications will be reviewed by external peer-reviewers prior to the Panel assessment.

5.2 What feedback will we receive on our application, and will there be a rebuttal stage?

Consolidator grant applications and outlines of the Research Collaborative award will receive feedback from the Panel following the funding Panel meeting. There will be no rebuttal at this stage.

5.3 Can I challenge Panel's decision?

No, the Panel's decision in final, and there is no mechanism for appeal.

5.4 Are all the criteria listed in section 6 all essential?

All the success criteria are desirable and will be used by the Expert Review Panel to assess the applications. The more criteria applicants address, the greater the likelihood of success.

5.5 Are the success criteria the same for the Consolidator grants and the Research Collaborative Awards?

The success criteria are the same for the Consolidator grants and the Research Collaborative Awards. However, the Expert Review Panel will be aware that the Consolidator grants are a step towards the Collaborative Award and as such will take into account that applications seek to move towards a state of readiness but will not yet have achieved it.

5.6 My research is basic science so do I need to include PPI? Does PPI need to be costed?

All applications will need to include PPI, and this will be considered in the assessment of applications. All PPI will need to be appropriately funded and costed. Guidelines on suitable funding for PPI can be found on the INVOLVE website.

5.7 Is sustainability beyond the lifetime of the award mandatory?

Sustainability beyond the lifetime of the Research Collaboration Awards is one of the success criteria against which proposals will be assessed. It is not mandatory, but the Expert Panel will look for evidence of this in high quality proposals.

5.8 Is it a requirement of this funding to make the data available open access upon project completion?

Applicants are advised that there is an expectation that all data generated by the projects supported through this initiative will be made discoverable and available through the health data infrastructure currently developed by HDR UK (see Section 3 'Data Approaches' of this document). The panel will be assessing the strength of the

applicants' plans to contribute to this work, and this will be one of the key assessment criteria. However, if applicants are unable to comply with making the data generated available this should be outlined and justified.

5.9 Expectation of pathway to health and/or social care impact and patient benefit?

High quality proposals should consider the trajectory towards benefiting the health *and wellbeing of* patients *and users of the NHS and social care services as part of the long-term impact aims of their proposal*. *These should be realistic to make a convincing case. We appreciate that some projects will be further away from direct patient benefit but are still an important step in the pathway.*

5.10 What research outputs do the funders expect within the six month duration of the Consolidator grant?

The specific outputs of each Consolidator grant would vary depending on the needs of the proposed Collaborative and the gaps identified by each group. Consolidator grants are expected to provide the applicants sufficient time and some additional financial resource to develop and prepare a full Research Collaborative Application. Some groups may feel they need to gather additional pilot data, others may wish to check the feasibility of their approach, develop new methodology, test their initial hypothesis or to support work stemming from a newly established collaboration. So, there is no 'one size fits all' answer to this question, but having a well-defined package of work that can be completed within six months might help the applicants to demonstrate that the ambition of the Collaborative has good chances to succeed.

6. Starting and managing your award

6.1 When can/should we start our Consolidator grant?

Consolidator grants have a fixed start date (01/05/2021) and duration of the tenure to ensure all applicants have equal amount of time to develop their approaches and mature plans before submitting their full Research Collaborative applications at the end of the 6 month period.

6.2 When can we start our Research Collaborative Award?

Research Collaborative awards will start in two waves. Wave 1 Collaboratives are expected to be able to start no later than October/November 2020, subject to confirmed dates of the funding Panel meeting, and Wave 2 Collaboratives – in early 2021.

6.3 We have not used all our funds, can we extend the duration of the Consolidator grant beyond 6 months?

No, the duration of the Consolidator grants is fixed and cannot be extended.