Consortia for biomedical cohort research into ME/CFS

Please note:

- The available grant budget for this funding round has been increased. The total available grant budget for this funding round is €11.600.000,-.

Consortia for biomedical cohort research into ME/CFS

Subjects: ME/CFS, research consortia, long-term, cohort research, patient participation

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Contents

1 Aim call for proposals

The aim of this call for proposals is the creation of research consortia that carry out long-term research into the multisystem disease myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). Within these consortia, transdisciplinary research will be carried out via various substudies into the cause, diagnosis and/or treatment of ME/CFS.

The reason for this call for proposals is an advisory report from the Health Council of the Netherlands published in 2018, which stated that scientific research is urgently needed to acquire more knowledge about ME/CFS. The advisory report states that Dutch science does too little research into ME/CFS. Furthermore, commercial parties are also not interested in research into ME/CFS. The Health Council of the Netherlands therefore considers it very important and that ZonMw establishes a substantial and long-term research programme into ME/CFS. This call for proposals is the first call published as part of this programme.

Within this call, funding can be requested for both the setting up of the consortium and the realisation of the substudies that the consortium will carry out during the next four years. The data and biological materials that will be collected in the studies must come together in a Dutch ME/CFS patient register and biobank.

1.1 Description research programme ME/CFS

The research programme ME/CFS stimulates the (further) development, use, safeguarding and utilisation of knowledge about the severe chronic illness ME/CFS. ZonMw facilitates this through funding research into the causes, diagnosis and treatment of ME/CFS and actively disseminating the research results in accordance with the principles of Open Science. The ultimate aim of the programme is to improve the health, quality of life and social position of ME/CFS patients.

With the research programme ME/CFS, ZonMw is realising the ZonMw research agenda ME/CFS published in 2020. The ZonMw research programme ME/CFS has a budget of € 28.5 million and a duration of 10 years. It consists of the programme lines 'Biomedical research' and 'Improving practice'. These programme lines are further described in the programme text[1]. This call is part of the programme line 'Biomedical Research'.

An important aspect of the programme is the building up of a Dutch ME/CFS patient registration and biobank, which will be fed by individual studies in the programme. Also, there will be a lot of attention within the programme for how the data from the different projects will be unequivocally and uniformly brought together in this patient registration and biobank. The data and the (information about) biological materials will be made findable, accessible, interoperable, and reusable in accordance with the FAIR principles. For the projects funded in this call, ZonMw will develop compulsory activities to standardise the collection of data and materials as much as possible to ensure the optimal exchange of data and information (interoperability).

1.2 Content of this call for proposals

In this round, two types of proposals must be submitted that will be considered separately but within the same call:

1. A proposal for a consortium;
   AND ALSO
2. At least 1 proposal for a substudy.

1.2.1 Consortium proposals

In this call, a consortium is understood to mean a sustainable collaboration between different institutions and organisations. In this funding round, consortium proposals will only be considered where a collaboration is entered into for a period of (at least) 8 years. By aiming for such consortia, ZonMw encourages transdisciplinary collaboration in the area of ME/CFS. Because only in the context

[1] At this moment, the programme text is only available in Dutch. Please keep an eye on the programme page; an English version of the programme text will be published here shortly.

of a broader collaboration can research into ME/CFS have an impact and genuinely improve the situation of ME/CFS patients.

The following types of collaboration must be represented in the consortium:
- **Collaboration between research disciplines:** This concerns disciplines that could be involved in ME/CFS research, such as immunology, microbiology, neurology, cell biology, (epi-)genetics, system biology, bioinformatics and cardiology.
- **International collaboration:** Dutch research should connect with research lines into ME/CFS that have been developed in other countries.
- **Collaboration between professional groups:** Such as researchers, professionals providing treatment, policymakers and education. They must jointly make use of the knowledge that the research programme produces and also draw up follow-up questions for new research into ME/CFS.
- **Collaboration with patients:** Patients must be involved in all consortia and substudies that receive financing in this funding round, including the agreements about participation in the patient registration and biobank.

1.2.2. Substudy proposals

The substudies will be realised in the consortium awarded funding and, in terms of content, follow the research lines described as having high potential in the ZonMw research agenda ME/CFS. More particularly, this concerns:

Fundamental research
- Research into (chronic) immune activation (for example, following viral infections and host-microbe interaction such as via the intestinal microbiome), metabolism in immune cells and neurological abnormalities.
- Brain imaging research into disruptions in the functioning of the brain.
- Research into cellular energy metabolism linked to cell function and cell damage.

Epidemiological research
- Research aimed at the aetiology of ME/CFS, such as an (epi)genetic basis of ME/CFS, the influence of environmental factors and research into infectious causes.
- Prognostic studies and longitudinal research into the disease progression of ME/CFS.
- Research aimed at a better description of ME/CFS, so that a better diagnosis can be made, subgroups and comorbidities can be established and similarities/differences with other diseases can be identified.

Clinical research

Once there exists more insight into the biomedical cause or biological mechanisms of ME/CFS, more targeted and innovative therapies can be developed. For outcomes in the shorter term, a start can already be made with:
- The testing of (existing) treatments that alleviate important symptoms.
- The testing of therapies known for other diseases, such as comorbid disorders that frequently occur with ME/CFS.
- Itemising and testing ME/CFS treatments that are used abroad.
- Research aimed at a better diagnosis, for example physiological testing/exertion tests, biomarkers, serology and genomics.

2 Call-specific conditions

The General Terms and Conditions Governing Grants of ZonMw apply to this call for proposals. In addition, the following call-specific conditions apply:

2.1 Patient participation

In its projects, ZonMw strives to involve stakeholders, including the final target group or end user who has the ‘experiential expertise’. By ‘involve’ we mean that stakeholders are consulted with, advice is obtained from them, collaboration with them takes place and/or an equal right is accorded to them to participate in the (joint) project decision-making process. For proposals in this funding round, it must

be clear how ME/CFS patients and their representatives participate in the consortium and all of its substudies: in which phases and how, with the roles clearly described and defined. Applicants must state how they will take the functional limitations of the patients into account. The budget of the grant proposal will also be tested for this point.

The ZonMw website (only available in Dutch) contains tips for involving patients in research. The kick-starter for patient participation from the Participatiekompas ('Participation Compass', only available in Dutch) offers practical tips for researchers as well.

2.2 ME/CFS cohorts

This funding round will only consider proposals for cohort studies. These cohorts must contribute to the uniform registration of a group of Dutch ME/CFS patients and the biological materials taken from them in a national ME/CFS patient register and biobank. The infrastructure of the cohorts will be funded within this round. Both cross-sectional and longitudinal studies are funded, and the research questions for the cohorts can differ from each other.

Researchers who apply for funding in this round must be prepared to connect their (sub)study with other studies that take place in the programme and to collaborate with researchers from other consortia to make this happen. The aim of this approach is to achieve uniformity with respect to the diagnostic protocols, assessment of patients for inclusion and the collection of data and biological materials. Connection with other Dutch and foreign registrations and biobanks is also desirable. This applies, in particular, to registrations and biobanks for possibly related disorders, such as PASC ('longCOVID'), Q fever fatigue syndrome and Lyme disease. Finally, researchers must be willing to participate in agreements that will be made for a national cohort infrastructure, similar to the infrastructure that is currently being shaped in the context of the Roadmap for Large-Scale Research Infrastructure 2021 (only available in Dutch).

Within the programme, the aim is to realise a standardisation of the data collection so as to facilitate the interoperability between cohorts and datasets from the projects. For the reusability of datasets and biological materials, the FAIR principles must be applied. ZonMw shall encourage the practice of making data FAIR ('FAIRification) in this programme by working together with the consortia to produce FAIR metadata schedules specifically for the ME/CFS research domain. ZonMw will organise several workshops for this. Participation in these is mandatory for the researchers involved. You should ensure the participation of a data steward in both the project and the workshops. In addition, a data steward must be available to help create the metadata for the description of the projects' datasets and biological materials.

A first round of workshops will be held in the autumn of 2022: after awarding, but before the start of the data collection within the projects. As preparation for these workshops, researchers of projects awarded funding must draw up a draft data management plan in collaboration with a data expert. Please allow for the opportunities and requirements with respect to FAIR data and data management in the planning and budget for your project.

2.3 Knowledge dissemination

The consortium partners must contribute to the intended outcomes of the research programme ME/CFS by providing usable knowledge products that can be applied at the regional, national and international levels in healthcare practice, research and education. Where relevant, a regional implementation focus will be applied in the consortia so that healthcare organisations, policymakers and patient organisations can participate in the implementation of the knowledge products to improve the health and societal position of ME/CFS patients. New findings and knowledge from the research lines fundamental research, epidemiological research and clinical research will be disseminated and communicated with specific communication strategies that are appropriate to the target group. For this, collaboration will take place with relevant parties in research, education, policy, industry and healthcare practice.

2.4 Who can apply for funding?

Main applicant
The main applicant submits the proposal on behalf of the consortium and is the point of contact for ZonMw. The main applicant receives the grant and is, on behalf of the consortium, responsible for the scientific coherency, results, funding of the collaboration partners as well as the financial accountability. The main applicant is a legal entity under public or private law and is located in the Netherlands.

Collaborative partners
A collaborative partner in the consortium can be eligible for a part of the funding and receives this via the main applicant. Amongst others, the following parties may act as a collaborative partner:
1. Dutch research organisations within the meaning of EU state support law[2];
2. Dutch healthcare institutions;
3. Private sector treatment clinics for ME/CFS located in the Netherlands;
4. Dutch advocacy organisations that realise advocacy activities for this project;
5. Dutch educational institutions that realise educational activities for this project;
6. Possible other collaborative partners who add a clear value to the project that is convincingly described in the proposal.

Within this call for proposals, a collaborative partner may participate in more than one consortium on the merit of his/her expertise. If a collaborative partner is involved in more than one proposal, then this must be clearly stated in the proposal.

2.5 State aid

No grants will be awarded by ZonMw if this would or could constitute unlawful state aid[3]. Therefore, the following state aid measure applies to this grant round:

2.5.1 Exemption Decision for Services of General Economic Interest (SGEI)
For the purposes of this call for applications, ZonMw will consider proposed project activities to be performed by the consortium within the project as Services of General Economic Interest (SGEI). This means that there are specific conditions for funding and rules for budgets. You can find out more about the SGEI Exemption Decision in **Fout! Verwijzingsbron niet gevonden.**, as well as the requirements that have to be met under the SGEI Exemption Decision.

You can find more information about state aid on the ZonMw webpage Vrijstellingverordeningen staatssteun (only available in Dutch).

2.6 Collaboration with and contribution from third parties

In the context of this programme, ZonMw encourages collaboration with international (research) organisations. With a view to implementation, specific attention should also be paid to connections with relevant parties from society, such as health insurers, occupational health services, social security agencies, educational institutions, patients and/or policymakers.

From the proposal and budget it must be clear:
- Which parties are part of the collaboration. For each party, describe how it actively contributes to the project; these must, in all cases, be the parties stated in the budget as a party which wants to be eligible for a part of the funding. Parties who, at their own risk and cost, make an active contribution are also part of the collaboration.
- With which party or parties shall a sponsor agreement be entered into and what the in cash or in-kind contribution is.
- Which parties, if any, will be contracted. If this is not yet known, it should be listed which activities will probably be carried out by third parties and against which costs (including Dutch VAT).

[2] Framework for State aid for research and development and innovation (2014/C 198/01), article 15 under ee).
[3] Article 107 of the Treaty on the Functioning of the EU.

Public-private partnership
Collaboration between public and private parties can contribute to (accelerated) research results, improved transmission within the knowledge cycle and increased impact of the research. ZonMw therefore values the involvement of private parties in the consortium, but does not make this mandatory. However, the consortium must have made clear efforts to involve relevant private parties in the development of the proposal and the subsequent realisation of this. If public-private partnership is not (yet) possible, then the reason why should be explained in the proposal.

Letter of Commitment
As ZonMw wants to be certain that collaborative parties/co-funders of the project have legally committed themselves to the pledged amount, a Letter of Commitment from each collaborative party/sponsor is mandatory with the submission of the proposal. For this, please make use of the template on the ZonMw web page Grants and Collaboration/contributions from third parties (only available in Dutch).

Consortium and sponsor agreement
If ZonMw requests a draft collaboration and/or sponsor agreement(s), then it will issue the grant on the condition that it accepts these agreement(s).

On the ZonMw web page Grants and Collaboration/contributions from third parties (only available in Dutch) you will find more information about the different types of collaboration and contributions (sponsoring/commission) together with model agreements as a resource for drawing up the agreement concerned. On the same page, you will also find the accompanying explanation with the conditions that this agreement must satisfy. The conditions stated on this webpage and in the explanation are an integral part of this call for proposals.

2.7 Which amount can you apply for?

2.7.1 Budget allocation within the funding round

- The total available grant budget for this funding round is ~~€10,000,000~~ €11.600.000,-. The aim is to use this to fund 2 to 4 consortia including the subprojects.
- The budget for each proposal should be realistically and thoroughly motivated. In the budget, the applicant should make it clear which partners will perform which activities for which budget.
- For the substudy proposals, a reference amount of €500,000 per substudy applies. This reference amount gives an estimate of the maximum amount that may be requested for substudies with a duration of 4 years. For very cost-intensive studies, for example due to the equipment used, this amount may be higher as long as this is well-motivated.
- In a later phase of the research programme ME/CFS budget can be requested for new and additional studies within the consortium.

2.7.2 Consortia activities eligible for funding

In the budget for consortium proposals, costs should be included for:

- **The infrastructure of the consortium**
  For proposals, a budget category for consortium management must be reserved that is no more than 5% of the total budget applied for from ZonMw (consortium and also substudies). For this budget category, the budget applied for can consist of personnel, material and/or realisation costs during a period of 8 years. Amongst other things, consortium management is understood to mean the optimal development of the organisation structure of the consortium, supporting the consortium and the main applicant, monitoring the coherency, progress and uniformity of the programme, and the alignment between the subprojects within the consortium. This task may also be performed by external parties and, in that case, should be listed in the budget under ‘other costs’ as contracting ‘name third party’. In the budget, room must also be reserved for remuneration of the participation of ME/CFS patients and other stakeholders.

- **The design of ME/CFS cohorts**
  The infrastructure of the research cohort described in the proposal including costs for data and/or biological materials storage, data infrastructure, the use of data services, data stewardship and other experts during a period of at most 8 years. During the first year, a data steward must be

available on a full-time basis to supervise the data management in the consortium. For this, ZonMw calculates a reference amount of 5% of the entire project budget (consortium and also substudies). When you draw up this budget, please involve a data steward/expert from your institute who is informed about the approach in this funding round. ZonMw also advises you to involve a biobank expert, who can be someone within your institute but also someone within the theme 'Biobanks and Collections', part of Health-RI.

– **Internationalisation**
Within this round, funding can be requested for making and expanding contact with foreign institutes where research into ME/CFS seems to offer perspectives and, moreover, is of a relevant size. Possible examples are the ME/CFS research centres in the United States, Canada, Australia, Norway, Sweden, Germany and the United Kingdom. You should reserve specific budget for obtaining foreign expertise by means of a short- or long-term exchange of researchers, and/or other possible forms of internationalisation. The reasons for the exchange of researchers should be well-argued. It must be described how the knowledge and experience acquired will benefit Dutch ME/CFS research.

– **Valorisation, application impact**
Deploying activities at the consortium level in the area of knowledge transfer and the broad dissemination of the research results. This also concerns the implementation of the results from subprojects and the mutual connections between the subprojects. An impact plan must be drawn up for the entire duration of the consortium. In the budget, you should reserve at least 5% of the total budget requested (consortium and also substudies) for the realisation of this impact plan.

2.7.3 Substudy activities eligible for funding

The substudies realised via the cohorts have an intended duration of maximum 4 years. An exception applies to longitudinal research for which funding can also be requested in this round and which may have a maximum duration of 8 years.

For the purpose of the substudies, funding can be requested for new (and existing) personnel and material facilities for independent research and development projects within the focus area of the consortium. The different cost categories must be justified taking into account the following points:

– In each substudy, budget must be reserved for remuneration of the participation of ME/CFS patients.
– Please reserve an amount for 'out of the box' ideas that will be further developed during the course of the project. No (minimum) amount has been determined for this. You should include this amount in the budget template under the tab 'out of the box'.
– If you publish according to the full golden Open Access route, then you may include costs for Open Access publications in the project budget. These costs can be included up to a maximum amount of €5000. In the budget, you should include 'Open Access' as a separate budget line. For more information about this please see Section 3.1. Open Access and the ZonMw webpage Open Access.

2.8 Open Access

Publications that emerge from (scientific research) that is entirely or partially funded by ZonMw must be made available in Open Access form (in accordance with the ZonMw Open Access policy). ZonMw accepts different Open Access routes. Besides articles, ZonMw also encourages making other types of (scientific) publications available in Open Access form (such as monographs, books, conference proceedings and grey literature), but also research data and knowledge products from practice-oriented research (such as models, protocols, prototypes, digital tools and demonstrations). We refer you to our website for more information about the ZonMw Open Access policy, the full conditions and possibilities.

3 Assessment criteria

The programme committee will assess the relevance and quality of the proposals submitted based on the relevance and quality criteria stated below.

3.1 Relevance criteria

- **Contribution to the programme objectives**
  The projects must fit within the programme objectives of the research programme ME/CFS (please see: programme text). The final objective of the programme is to improve the health of patients with ME/CFS. Research that is limited to chronic fatigue or research that is aimed at chronic fatigue as a consequence of diseases or disorders other than ME/CFS does not fall within the scope of this call. Forms of fatigue that do not result from ME/CFS can only be investigated within this call for proposals in so far as this takes place in relation to ME/CFS. The proposal must do justice to the diversity of people with the disease ME/CFS and the differentiation of their clinical picture. The programme as a whole also wants to focus on research aimed at young people or severely ill patients. In the assessment, special attention for these groups is an advantage.
- **Collaboration**
  Collaboration as described in Section 1.2.1 is an important relevance criterion that proposals will be assessed against. The form that this collaboration takes will be weighed in the case of the consortia as well as the substudies.
- **Participation of patients and/or end users**
  An important relevance criterion that the proposals will be assessed against is the nature and degree of collaboration with (representatives of) ME/CFS patients in consortia and all substudies, as described in Section 2.1.
- **Ratio costs/benefits**
  What is the balance between effort, input, deployment of resources and (expected) outcomes and yield? During the assessment of proposals that concern gravely ill (for example bedridden) patients, extra attention needs to be accorded to the additional burden these patients will have to bear as a consequence of participating in the research. Proposals will be assessed for whether the expected benefits of the research sufficiently weigh up against possibly lasting, negative health effects due to participating in the project.
- **Added value**
  The project has added value compared to existing knowledge and/or practice. The added value is explained and it is described how this research relates to potentially completed or other current studies in the same area.
- **Valorisation, application impact**
  For knowledge utilisation and valorisation a clear and well-considered strategy and phased plan has been described in an impact plan. In the impact plan, the possibilities for knowledge utilisation by third parties are described: both outside the research community (in society, industry, government) and in other research disciplines and in the next phase in the knowledge chain. The impact plan describes strategies for 1. implementation activities and dissemination, 2. communication, 3. safeguarding in education, 4. valorisation and (market-oriented) knowledge transfer. Also, a knowledge manager will be appointed who will monitor the progress of the impact plan for each consortium.
- **Diversity**
  From the perspective of its general policy priorities, ZonMw explicitly includes diversity in the assessment of project proposals. This concerns diversity in gender (differences according to sex), culture (cultural differences and prevention and care for citizens of different ethnicities) and age (extra attention for young people and the elderly). In the proposal, the applicant sufficiently describes how and why the aspects stated receive no attention, if that is the case. In the quality assessment, it will be examined whether these factors have been adequately elaborated upon in the project plan.
- **Animal models**
  In the context of the transition to animal-free research, ZonMw encourages researchers to develop and/or apply alternatives for animal experiments. The programme committee will therefore pay extra attention to the justification for such experiments in case the use of experimental animals is proposed in a project proposal. What is the relationship between the animal model chosen and the research question? What is the methodological and statistical rationale for the experiments? Are there no alternatives for the animal experiment, for example in the sense of computational models?

More information about relevance criteria can be found on the ZonMw webpage Relevance criteria.

3.2 Quality criteria

- **Objective and research question or remit**
  The objective is clear and tangibly formulated and results in a concrete research question that can be objectively assessed. Further, the scope of the question or remit is important: what is the importance of the subject, is there adequate theoretical substantiation, which knowledge and experience are already available and what will the project add to this? Finally, a proposal may not be a duplication of a previous or current project in the Netherlands or abroad, but must be aligned with these. Replication research is, however, possible within this call for proposals.
  Action plan
  1. The action plan is thoroughly substantiated; theoretically and/or empirically.
  2. The action plan is clear and satisfactory for the question or remit concerned.
  3. In the action plan, a step-by-step description of the activities is given. Please state how these steps lead to solving the question and achieving the objective you have formulated.
  4. For each step, you describe which stakeholders you will collaborate with and what this collaboration will look like. In doing so, you should also state how consideration will be given to, for example, the burden placed on ME/CFS patients and how their participation will be remunerated.
  5. The methods and analyses chosen are of optimal scientific and statistical quality and are described in a manner that can be assessed. It is explained why these methods and analyses, in particular, are appropriate for the research questions.
  6. The action plan describes and substantiates the dissemination, implementation and safeguarding of the expected research outcomes, including planned activities that contribute to the dissemination, implementation and safeguarding of these outcomes. Sustainable funding, ownership, maintenance and further development, necessary infrastructure, conditions for implementation and connection with the existing infrastructure should be considered in this plan.
  7. A timetable and budget are also part of the action plan.
- **Description target group**
  In the case of research on human subjects, projects must provide a substantiated description of the study population based on literature appropriate to the specific research question. This description will be assessed for how well it matches the research question but also for how this relates to the advantages and disadvantages of the various criteria with which ME/CFS is often defined (as described in Section 2.2.2 of the programme text).
- **Feasibility**
  For each type of project, it must be made apparent that the applicant will be able to answer or realise the intended question or remit with the available expertise, people and facilities in the planned time. The project description includes attention for facilitating and limiting factors. Here, particular attention should be paid to feasibility in terms of inclusion. ME/CFS patients are not always known to care providers and can be difficult to reach. Also, the nature and severity of their symptoms can hinder their participation in research. Due consideration should be given to this in the study designs.
- **Project group or person**
  Describe how the composition of the consortium and individual research groups contributes to the quality of the studies. In the context of patient selection and devising a realistic study design, the involvement of clinical experience and expertise in the area of ME/CFS is highly desirable. The description of the quality of people and groups can concern the research outcomes of collaborative groups and people (publications, reports, guidelines, protocols and interventions), their experience (grants obtained, participation and (inter)national networks, education) and the impact of their products. In addition to this, the elaboration of the proposal should include the principles of the new 'Recognition and Rewarding', as stated in the Position Paper (only available in Dutch) 'Room for everyone's talent'.

More information about these criteria can be found in the procedure brochure.

3.3 Ranking

Ranking of the proposals (for relevance and quality) will take place with the help of the matrix below. In the matrix, quality has a heavier weighting than relevance. However, to be eligible for funding, the

proposal should be assessed as ‘very relevant’ or ‘relevant’ in accordance with the relevance criteria in this call. An X in the ranking matrix indicates that the proposal is not eligible to be awarded funding.

Quality/Relevance	Very relevant	Relevant	Not relevant
Very good	1	2	X
Good	3	4	X
Satisfactory	5	6	X
Moderate	X	X	X
Unsatisfactory	X	X	X

4 Procedure & Timetable

4.1 Key considerations

In writing your proposal, please bear in mind the following points:

- Before you start writing, you should read the programme text Research programme ME/CFS and the research agenda ME/CFS so that you can thoroughly integrate the frameworks of the programme in your proposal.
- In this round, two types of proposals must be submitted that are entered separately in the online submission system of ZonMw (‘Mijn ZonMw’):
  1. A proposal for the consortium in which the following elements are described: A. the collaboration within the consortium, B. the design of the ME/CFS cohort, C. internationalisation, D. valorisation, application and impact, E. short description of the substudies (max. ¼ A4 per substudy);

  AND ALSO
  2. At least 1 proposal for a substudy. Clearly state which consortium proposal this substudy belongs to.
- Please write your proposal in English, as foreign referees will assess your proposal.
- On the ZonMw webpage conditions and funding you can read which conditions your proposal must satisfy.
- If your proposal has previously been submitted elsewhere as a proposal, then you are requested to submit the previous proposal and (if it was rejected) any possible comments from referees as an annex. This does not mean that you do not have to fully complete the application via ‘Mijn ZonMw’. Neither does it mean that your proposal does not need to be complete and clear without the optional annexes.
- An interview can be part of the selection procedure for your proposal. A sound recording of the interview will be made. After the assessment procedure, the sound recording will be destroyed.
- The main applicant must submit the following **mandatory annex/annexes**:
  1. For a consortium proposal a Letter of Commitment from the partner concerned must be provided for each collaboration described in the proposal.
  2. For both the consortium proposal and the proposal for the substudy/substudies a budget should be added.
  3. A maximum of 2 pages of A4 in supporting figures and tables (not mandatory).

4.2 Assessment procedure

For information about the procedures for the assessment of proposals we refer you to the infographic ‘applying for funding in 10 steps’ (only available in Dutch) and to the summary of the assessment procedure.

4.3 Timetable

Deadline submission full proposal	21-4-2022 at 14:00 hours
Receipt referees’ comments	2-6-2022
Deadline submission rebuttal	23-6-2022 at 14:00 hours
Decision	28-2-2023

Mandatory course days data management	Dates to be determined
Latest possible start date	31-8-2023

More information
Please visit the ZonMw programme page (at this moment only available in Dutch); this is regularly updated.

5 Submission

5.1 Submission (via 'Mijn ZonMw')

Applicants can only submit proposals via the online submission system of ZonMw ('Mijn ZonMw') and in accordance with its guidelines. The deadline for the submission of full proposals is 21 April 2022 at 14:00 hours.

5.2 Tips

- ZonMw has switched to a different online submission system. If you have not previously worked with 'Mijn ZonMw', then you should first register as a 'New user'.
- For more information, please see the 'Mijn ZonMw' Manual.

Before you digitally submit your proposal, we advise you to print out a Word version of it (via 'Mijn ZonMw') and to check this for any errors. Especially if you initially wrote your proposal in Word and then copied it to 'Mijn ZonMw', it could be the case that some symbols (such as quotation marks) have not been properly converted. You can subsequently correct this yourself in 'Mijn ZonMw'.

5.3 Statement of approval submission full proposal

The 'Statement of approval submission full proposal' should be signed by an authorised signatory at the institution concerned and by the main applicant. The signed statement can be added to the proposal in 'Mijn ZonMw' or sent by email to Ms Patricia Gomes at ZonMw (mecvs@zonmw.nl). The statement should be received no later than one week after the proposal has been submitted.

5.4 Call-specific questions

For call-specific questions, please contact Ms. Simone van Montfort, mecvs@zonmw.nl, tel. 070 515 03 11.

5.5 Technical questions

For technical questions about the use of the online submission system of ZonMw, please contact the service desk: Monday to Friday from 08:00 to 17:00 hours, +31 70 349 5176, servicedesk@zonmw.nl. In your email, please state your telephone number so that we can contact you by phone if necessary.

5.6 Contact details patient organisations ME/CFS

Please contact the patient organisations listed below for the involvement of experiential experts in the intended consortium or substudy, as well as for ME/CFS patients who want to make their data and biological materials available, and/or want to participate in some studies:

- ME/cvs Vereniging, contact@me-cvsvereniging.nl
- Steungroep ME en Arbeidsongeschiktheid, info@steungroep.nl
- ME/CFS Stichting Nederland, info@mecvs.nl

5.7 Downloads and links

- General Terms and Conditions governing ZonMw grants
- Summary of the assessment procedure

- Conditions and funding
- Grants and collaboration/contributions from third parties (only available in Dutch)
- FAIR data and data management
- Open Access
- Ten principles of MVL (only available in Dutch)
- Strengthening impact
- Programme page research programme ME/CFS (at this moment only available in Dutch)

Annex 1 – State aid – SGEI

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When the consortium applies for funding within this funding round, then ZonMw will award the funding under the Services of General Economic Interest (SGEI) exemption regulation[4] as long as the conditions are satisfied.

ZonMw has designated the activities described under the heading “Aim call for proposals” as economic activities in the general interest. Prior to awarding the grant, ZonMw will charge the consortium for the implementation of the activities described above with the administration of a Service of General Economic Interest by means of a decision (‘DAEB’).

In the budget, it must be clear which parties in the project receive funding and which activities they realise for this. When you submit the proposal, you should add the name and address details of the businesses that receive funding within this project.

The SGEI will consist of realising the activities described in the project proposal. The grant payment made only be used for the activities that fall under the SGEI.
The consortium parties that receive financing within this funding round are, on the basis of article 5 (2) of the SGEI, required to separately itemise in their accounting the costs and benefits associated with the SGEI activities from the costs and benefits of activities that do not fall under the SGEI.

The funding of the project will not exceed the maximum duration of the project. In line with the SGEI exemption regulation, the maximum duration of the project will in any case be no longer than 10 years.

The amount of funding requested may not be more than the net costs of the foreseen project activities. The parameters for calculating the compensation for each project are included in the budget documents of ZonMw. The calculations included in the budget documents are in accordance with Article 4 of the SGEI exemption regulation.
Any overcompensation will be reclaimed by ZonMw on the basis of article 6 (2) of the SGEI exemption regulation.

If the duration of the project exceeds 3 years, then ZonMw will perform an interim audit to check whether overcompensation has occurred. ZonMw will reclaim the surplus if the audit reveals that the funding received by the applicants is higher than the net costs. This audit covers the entire duration of the project or from the moment of the last interim audit.

ZonMw can settle the grant for a lower amount and (partly) reclaim any advance payments made when it transpires that the project activities have not, or have not entirely, been carried out or that the obligations attached to the funding have not, or have not entirely, been satisfied

If there is a collaboration:
All parties are individually subject to and must satisfy all conditions of the SGEI exemption regulation. Therefore the project activities **can only start** after the collaboration agreement has been accepted by ZonMw and has been signed by all collaborative parties involved.

If, when the proposal is submitted, it is not yet clear which parties will participate in the partnership/consortium, then it is possible to add these parties to the consortium later. Please inform ZonMw in writing about the addition of a new party to the consortium. The new party will only become part of the consortium if ZonMw approves this addition.

[4] Commission Decision of 20 December 2011 on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380) (Text with EEA relevance) (2012/21/EU)