

## Second call for biomedical research on ME/CFS

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Deadline: **24<sup>th</sup> of June, 14.00 CEST**

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## 1. Summary

### Who can apply

A project idea (and subsequent the detailed grant application) can be submitted by a main applicant situated in the Netherlands and connected to a Dutch research organization under the EU state aid laws, a Dutch healthcare facility or healthcare provider, a public organization or an advocacy organization. In the detailed grant application collaboration needs to be formed with at least one of the two consortia funded by the research program ME/CFS, the NMCB consortium and the ME/CFS Lines consortium. Furthermore, ZonMw stimulates collaboration between other parties. Especially collaboration with experts by experience and international researchers is important. Collaborative parties can make a claim on (a part of the) funding.

### Aim

The goal of this call is to fund biomedical projects that affiliate with at least one of the two established consortia. Within the projects, transdisciplinary research will be done investigating the cause, diagnose and/or treatment for the multisystem disease ME/CFS.

### Budget

The available budget for this call is €2.500.000,-. Each project applies for a grant with a maximum of €500.000,- with a maximum duration of 4 year. The project has to start within 6 months after awarding the grant.

### Deadlines

The following table shows a timeline of the procedure of the 'Second call for biomedical research on ME/CFS'. The procedure is explained in more detail in [section 4.1](#).

<b>Deadline for submitting project ideas</b>	Thursday 24 <sup>th</sup> of September 2024 at 14.00 CET
Assessment by advisory committee	November 2024
<b>Deadline for submitting detailed grant application</b>	Thursday 30 <sup>th</sup> of January 2025 at 14.00 CET
Referees' comments received	21 <sup>st</sup> of March 2025
<b>Deadline for submitting a response to referees' comments</b>	7 <sup>th</sup> of April 2025 at 14.00 CET
Decision	July 2025
Latest start date	6 months after awarding the grant

## 2. Aim of the call for grant applications

This call is part of the [research program ME/CFS](#) and the program line biomedical research.

### Rationale

Patients are at the base of the research program ME/CFS. The [citizen initiative](#) 'Erken ME' submitted a petition in 2013 with more than 56.000 signatures to the Dutch House of Representatives. The citizen initiative called for more biomedical research into ME/CFS. The Dutch House of Representatives requested the Health Council of the Netherlands to investigate the [state of scientific knowledge concerning ME/CFS](#). Subsequently, the Ministry for Healthcare and Sport requested ZonMw to develop [a biomedical research agenda](#) which was finished by the end of 2020. At the end of 2021, this led to the start of the 10 year ZonMw research program for biomedical research into ME/CFS.

The rationale for the research program is the lack of knowledge on the cause, diagnose and treatment of ME/CFS and the need, as expressed by the Dutch Health Council, for the Netherlands to catch up with the field of biomedical knowledge and scientific research. Dutch (healthcare) professionals and scientist have very limited biomedical understanding of the knowledge internationally available on ME/CFS. Therefore, the Health Council of the Netherlands advised to invest in research on ME/CFS by means of a long-term and substantial research program.

## Research program ME/CFS

The mission of the research program ME/CFS is to improve the health, quality of life and societal position of ME/CFS patients. By subsidising ME/CFS research the program aims to achieve three objectives:

1. Generation of biomedical knowledge about the development of ME/CFS, the diagnosis of ME/CFS and the treatment of ME/CFS;
2. Stimulating the implementation of knowledge in practice;
3. Developing a sustainable and dynamic ME/CFS knowledge infrastructure with the aim of improving the collaboration between knowledge institutes, patients and every day practice.

The program is composed of a program line 'Biomedical research' and a program line 'Improving practice'. This call for proposals is part of the program line 'Biomedical research' and focusses on the development of biomedical knowledge into the cause, diagnosis and treatment of ME/CFS.

Within the program line 'Biomedical research' 2 consortia have been funded in the first funding round of the research program, called the Netherlands ME/CFS Cohort- and Biobank consortium (NMCB) and the ME/CFS Lines consortium. Within the consortia, 10 projects are being executed within different disciplines, conducting transdisciplinary biomedical research into ME/CFS as a multisystem disease. The consortia are designed to compose an infrastructure for long-term research on ME/CFS. More information about the consortia and the current projects can be found at [section 5.6](#).

## Funding round 'Second call for biomedical research for ME/CFS'

The aim of this call is to fund new projects for transdisciplinary research into the cause, diagnosis and/or treatment of ME/CFS within the established consortia. Within this call for proposals projects can apply for funding when involved in at least one of the two consortia funded within the research program ME/CFS. Projects eligible for funding must conduct biomedical, clinical or epidemiological research into the cause, diagnosis and/or treatment of ME/CFS.

The projects must follow the research lines as described in the [program text ME/CFS](#). Please note, there can be no overlap with the studies from the first round of grants. However, new projects can build on previously funded research and replication research is also a possibility.

## 3 Conditions and obligations

Specific rights, conditions and obligations must be taken into account when applying for a ZonMw grant. The rights, conditions and obligations of a grant applicant are based upon the [Dutch General Administrative Law Act \(Awb\)](#). Article 4.2 of the Awb contains specific provisions applying to ZonMw grants. [General Terms and Conditions Governing Grants of ZonMw](#) also apply.

### 3.1 Conditions

The project idea and (subsequently) the detailed grant application must conform to the following conditions to be taken into consideration. For the detailed grant application some additional practical conditions apply. These conditions will be stated in the call text for the detailed grant application.

#### 3.1.1. Who is eligible for a grant?

##### Main applicant

A main applicant is a legal entity under public or private law and is located in the Netherlands. A project idea or detailed grant application can be submitted by a main applicant connected to a Dutch research organisation according to the EU state aid legislation<sup>1</sup>, a Dutch healthcare facility or healthcare provider<sup>2</sup>, a public organisation or an advocacy organisation.

The main applicant submits the application and is the main contact person for ZonMw. The main applicant is responsible for all correspondence with ZonMw, the financing of cooperative partners and financial accountability.

##### Collaborative partners

<sup>1</sup> Framework for state aid for research and development and innovation (R&D&I Framework) (2014/C 198/01), Section 15(ee).

<sup>2</sup> Definition of healthcare facility: article 5, paragraph 1, [law for the admission of healthcare institutions](#)

All awarded projects are expected to be part of the existing research infrastructure that is being constituted by the research program ME/CFS. Therefore, projects must join at least one of the two consortia. The main applicant of the project will receive the grant and will coordinate the alignment of the project with the consortium leader(s) regarding scientific coherency, sharing of data and material and the implementation of research results. A project can also collaborate with both consortia. The collaboration with the consortia has to be formed during the composition of the detailed grant application (the second phase).

Besides the collaboration with the consortia, other parties can be involved in the project. Amongst others, the following parties may act as a collaborative partner:

1. Dutch research organisations within the meaning of EU state support law<sup>3</sup>;
2. Dutch healthcare institutions<sup>4</sup>;
3. Private sector treatment clinics for ME/CFS located in the Netherlands;
4. Dutch advocacy organisations that realise advocacy activities for this project amongst which patient organizations;
5. Dutch educational institutions that realise educational activities for this project;
6. International collaborative partners in research, education, healthcare and/or policy;
7. Possible other (international) collaborative partners.

A collaborative partner can make a claim on (a part of) the funding. If applicable, the collaborative partner will receive funding from the main applicant. This must be made clear in the detailed grant application. It is important that unlawful state aid is avoided. More information on state aid is written in paragraph 3.1.2. More information on collaboration within projects and the required administration is written in paragraph 3.1.3.

Within this call for proposals, a collaborative partner may participate in more than one project on the merit of his/her expertise.

### 3.1.2. Avoiding State aid

No grants will be awarded by ZonMw if this would or could constitute unlawful state aid<sup>5</sup>. Therefore, the following state aid measure applies to this funding round:

#### Exemption Decision for Services of General Economic Interest (SGEI)

If ZonMw will consider a part of the proposed project activities as Services of General Economic Interest (SGEI), then this will mean that there are specific conditions for funding and rules for budgets. More information about the SGEI Exemption Decision can be found in [Annex 1 – State aid – SGEI](#), as well as the requirements that have to be met under the SGEI Exemption Decision.

More information about state aid is written on the ZonMw web page [State aid exemption decrees](#).

### 3.1.3. Third-party collaboration and contributions

ZonMw encourages the participation of different partners in collaborative projects. Such projects will, however, not receive a grant if the agreements would or could lead to the provision of unlawful state aid or if ZonMw's [General Terms and Conditions](#) or the conditions of the call for grant applications cannot be met.

As described in paragraph 3.1.1. collaboration with one of the two consortia is required and must be formalized during the detailed application phase. The collaboration with these consortia is twofold. On one hand the consortium/consortia are part of the collaboration as co-applicant. On the other hand, all awarded projects must join at least one consortium and are obliged to actively contribute to the development of the research infrastructure. This includes the availability and accessibility of data/biomaterial, transdisciplinary collaboration with researchers and experts by experience within the consortium, distribution and implementation of results and alignment of communication activities. In addition, collaboration with international (research) organisations is encouraged by ZonMw.

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<sup>3</sup> Framework for State aid for research and development and innovation (2014/C 198/01), article 15 under ee).

<sup>4</sup> Definition of health care facility: article 5, paragraph 1, [law for the admission of healthcare institutions](#)

<sup>5</sup> Section 107 of the Treaty on the Functioning of the EU (TFEU).

Regarding implementation, ZonMw encourages projects to pay attention to the connection of the project with relevant societal parties such as healthcare insurers, health and safety services, social security administrators, educational institutions, patients and/or policymakers. From the start of the project idea phase the project needs to work in collaboration as much as possible. The engagement of patients/experts by experience in the project group is mandatory.

Collaboration and sponsorship must be described in the project idea but need to be finalised before presenting the detailed grant application.

In the detailed grant application and budget the following must be made clear:

- Which parties are participating. Describe how each party will be actively contributing to the project; these should in any case be parties who appear in the budget as a party intending to claim a portion of the grant. Also include parties that will be making an active contribution as partners in the collaborative project for their own account and at their own risk.
- With which party or parties a sponsorship agreement will be concluded and what their donation in kind or monetary contribution will be.
- Which parties will be hired, or, if this is not yet known, which activities are forecast as being performed by third parties, plus the related costs that will be incurred (including VAT). For more information and the conditions of hire/terms of contract, see the [ZonMw web page](#).

### **Letters of Commitment**

Because ZonMw requires assurance that a project party or sponsor will be legally bound to provide the agreed amounts, each project party or sponsor must provide a Letter of Commitment, which is to be submitted together with the detailed grant application. Please use the template letter which can be found on the ZonMw web page [Grants and collaborations/contributions from third parties](#). During the detailed grant application phase a Letter of Commitment from at least one of the consortia must be added to the application. If a project is affiliated with both consortia, a Letter of Commitment from each consortium must be added to the application.

### **Collaboration and sponsorship agreement**

More information about the various types of collaboration and contributions (sponsoring/assignment) with sample agreements can be found on the ZonMw web page [Grants and collaborations/contributions from third parties](#) as an aid to drafting the relevant agreement; the accompanying explanation contains the conditions the agreement must meet. The conditions specified on this web page and in the explanation form an integral part of this call for grant applications. Where ZonMw requests draft collaboration and/or sponsorship agreements, it awards the grant on the condition that the agreements are found to be acceptable. Collaboration and sponsorship agreements must be provided for after approval of the funding.

All awarded projects must document the collaboration with the consortia in writing in the form of a collaboration agreement. This can be done by adding an addendum to the already existing collaboration agreement as compiled by the consortia. The project will become part of the consortium and will hold the same position as the other projects within the consortium funded in the first funding round of the ME/CFS research program.

#### **3.1.4. What is the amount of the grant I can apply for?**

The total available grant budget for this funding round is € 2.500.000,-. In this call for grant applications a maximum of € 500.000,- can be requested for a maximum project duration of 4 years.

When submitting the project idea, an indication of the costs for the project are requested. For the detailed applications, it is mandatory to submit a precise calculation of the costs. There are several requirements for this budget. More information about the standard requirements can be found on the [website of ZonMw](#).

Other requirements regarding the budget:

- In the detailed grant application, 10% of the budget must be reserved for communication and implementation. This must be clearly stated in the budget. Communication and implementation activities can (partially) be executed by the consortium. For this purpose, the consortium can claim a part of the funding for the project.

- Reserve an certain amount of funding for the participation of ME/CFS patients and include this in the budget.

The total amount applied for in the detailed application cannot deviate more than 15% of the funding requested in the project idea.

### 3.2.5. Practical conditions

Please take the following points into account when writing the application:

- Compose the application in English.
- The application for the project idea may include one optional annex with figures and tables. This annex is part of the assessment. Other annexes will not be taken into consideration during the assessment.

## 3.2 Obligations

Obligations apply when the funding is granted. For the obligations, ZonMw uses the [General Terms and Conditions Governing Grants of ZonMw](#). Additionally, obligations are applicable for [Open Access](#) and the [ten principles of Socially Responsible Licensing](#).

## 4 Assessment criteria

### 4.1 Assessment procedure

This funding round consists of 2 phases: a project idea phase and a detailed application phase.

#### Project idea

A project idea contains a short description of the project. During the assessment focus will lie on the relevance criteria. This includes also the relevance for the program, in other words: does the application fit within the objective and framework conditions of the funding round and the program? In addition, at this stage, the program committee broadly reviews the project ideas for quality. The committee selects the project ideas that fit best with the objective of the call and that are most promising. These project ideas receive a positive advice to further elaborate the idea into a detailed application. Paragraph 4.2 and 4.3 contain the relevance and quality criteria applicable to the project idea.

#### Detailed grant application

The detailed grant application is a comprehensive and detailed description of the project. When submitting the detailed grant application, a detailed budget needs to be provided. The assessment procedure for the detailed grant application phase consists of a written review of scientific and experiential reviewers. After the reviewers' assessment, the applicants can submit a written rebuttal. This is followed by a final assessment of the application by the program committee. The scientific reviewers assess the scientific quality of the application. The reviewers who are experts by experience assess the added value and feasibility of the study for the patient and the way in which the input of experts by experience is secured in the project. Prioritization of the applications by the program committee regarding quality and relevance is based on the detailed grant application, the reports of the reviewers and the rebuttal. The program committee gives a final advice to ZonMw on the relevance, quality and budget of all applications. [Annex 2](#) contains the relevance and quality criteria which are applicable for the detailed grant application.

If desired, the program committee may opt for an interview meeting with the main applicant during the detailed application phase as part of the assessment procedure. An audio recording will be made of the interview, which will be deleted at the end of the assessment procedure.

The deadline for application of a project idea is **September 24<sup>th</sup> 2024 at 2 pm**. The deadline for submitting the detailed application is **January 30<sup>th</sup> 2025 at 2 pm**.

For the procedures on how to assess grant applications, please refer to the infographic '[applying for a grant in 10 steps](#)' and the [procedure brochure for applicants](#) (available in Dutch only).



## 4.2 Relevance criteria

### 4.2.1 Relevance criteria for project idea

For the project idea, the following relevance criteria apply.

#### Contribution to program objectives

The project idea must fit within the program objectives of the research program ME/CFS (please see: [program text](#)). The final objective of the program is to improve the health, the quality of life and the societal position of patients with ME/CFS and the subject of the project idea must fit within the framework (of the program text) of the research program 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 result from or are related to disorders other than ME/CFS (i.e. post-COVID) can only be researched in relation to ME/CFS.

#### Collaboration

When submitting the project idea, the collaboration with the consortium does not yet need to be defined. However, the project must be in line with one or both of the consortia regarding research direction, method, data collection and the dissemination and implementation of results. The project idea should contain an outline description on these points.

Furthermore, collaboration with other parties is strongly encouraged. For the project idea, the concerned parties do not have to be determined yet. However, the project idea must contain a description which type of collaborations are pursued and an outline description on how these collaborations will be designed.

The following forms of collaboration are important:

- Collaboration between research disciplines involved in ME/CFS research, such as immunology, microbiology, neurology, cell biology, (epi-)genetics, systems biology, bioinformatics and cardiology;
- International collaboration, because Dutch research should connect with research lines into ME/CFS that have been developed in other countries;
- Collaboration between professional groups, such as researchers, clinicians, policymakers and education professionals.
- Collaboration with experts by experience with regard to the field of ME/CFS (see also the paragraph 'participation of patients/experts by experience')

#### Participation of patients/experts by experience

Collaboration with patients/experts by experience is mandatory. In the project idea it must be described how stakeholders, end target groups or end users who are [experts by experience](#), are actively involved in the different phases of the project. Involvement means consulting, seeking advice, cooperating and/or allowing stakeholders to (co-)decide when drawing up the project idea and the dissemination of results. The [ZonMw website](#) (only available in Dutch) contains suggestions for involving patients in research. The kick-starter for patient participation from the [Participatiekompas](#) ('Participation Compass', only available in Dutch) offers practical insights for researchers as well. [Paragraph 5.7](#) contains the contact information of patient organisations that can be approached for the involvement of patients in the research.

#### Added value and feasibility for ME/CFS patients

In the project idea the applicant substantiates the importance of the subject: what is the eventual relevance and/or added value of the research for people with ME/CFS? Besides that, during the assessment, attention will be paid to the feasibility of the plan of action and the additional burden for the patients resulting from participation in the project. From the project idea it should be made clear how the capacity of the patient is taken into account and if patients are reimbursed for their participation.

#### Animal models

Regarding the transition to laboratory animal-free research, ZonMw encourages researchers to use or develop alternatives for animal testing. In case animal testing is proposed in the application, the program committee will be vigilant on the substantiation about the use of animal testing. What is the relation between the used animal model and the research question? What is the methodological and

statistical substantiation of the tests? Are alternatives available for the animal test, for example by using computational models?

### Implementation and impact

Projects funded by ZonMw must have impact. New knowledge and expertise must be used in practice, policy, education and/or further research. On our website we explain what impact is, how we work to achieve and demonstrate it and what we expect from project managers. More information about implementation can be found on the ZonMw web page [Implementation](#). The project idea should contain a short description of the strategy regarding the dissemination and implementation of results.

#### 4.2.2 Relevance criteria for detailed grant application

For the detailed grant application, additional criteria apply. The relevance criteria for the detailed grant application are written in [annex 2.1](#).

## 4.3 Quality criteria

### 4.3.1 Quality criteria for project idea

For the project idea the following quality criteria apply.

#### Objective and research question/mission statement

The project idea must match the objectives of the research program ME/CFS (see [program text](#)). The objective and research question should be described clearly resulting in a concrete and verifiable question that can be objectively assessed. The project idea should demonstrate the added value of the project in relation to available knowledge or current practice. The proposal may not be a duplication of previous or current research projects in the Netherlands or abroad but can build upon earlier projects or join in with ongoing projects in the Netherlands or abroad. Alignment of the project with promising international directions of research is stimulated. Within this call for proposals, replication research is also possible.

#### Action plan

The project idea should contain an outline of the action plan: what is the setup of the research, which methods are used, with methods of analysis are applied and which results are expected. The approach must be adequate for the objective and research question. In the case of research on human subjects, the project idea must provide a substantiated description of the study population and the inclusion criteria used, based on relevant literature for the specific research question. In the project idea, the research population must be clearly defined. 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 [program text](#)).

#### Project group or person

The project idea should contain a short description on 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. If necessary, this expertise should be sourced from abroad.

#### 4.3.2. Quality criteria for detailed grant application

For the detailed grant application, additional criteria apply. The quality criteria for the detailed grant application are written in [annex 2.2](#).

## 4.4 Prioritisation

Relative weighting of relevance and quality takes place according to the following prioritisation matrix:

Relevance / Quality	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

To be eligible for funding, the proposal should be assessed as very relevant or relevant. The quality of the proposal should be assessed as very good or good to be eligible for funding. A project with the score (very) relevant and sufficient is in principle not eligible for honouring unless there is budget left and the quality of the proposal is significantly improved. An X in the prioritisation matrix indicates that the application is not eligible for funding.

If after applying the prioritisation matrix the number of eligible applications exceeds the available budget, the committee will deploy the following additional grounds of evaluation (in random order). Focus on these grounds in the application is a plus.

- **International collaboration**  
Internationally, various research lines focussing on ME/CFS have been developed. Dutch research can pick up on this. Good collaboration with international researchers or other experts with knowledge and experience in the field of ME/CFS is very desirable. If applicable, the project application should contain a clear description on how the collaboration with international experts in the field of ME/CFS is being realised.
- **Target group**  
Overall, the program aims to focus on research on young people and adolescents with ME/CFS and severely ill patients. If applicable, the way in which attention is paid to young patients and adolescents with ME/CFS and/or seriously ill patients should be clearly described.
- **Diversity**  
Within the general policy priorities of ZonMw, a lot of attention is paid to [diversity](#) within research proposals. Therefore, if applicable, attention should be paid to different characteristics such as sex (taking into account the fact that most of the ME/CFS patients are female), age, socioeconomic status, educational level, and cultural background. Attention for the diversity of people with ME/CFS is a plus within this call for proposals.

## 5 Submitting your application

### 5.1 Submission through Mijn ZonMw

Project ideas and grant applications can only be submitted by the main applicant in ZonMw's online submission system ([Mijn ZonMw](#)). The closing date for submitting a project idea is **24<sup>th</sup> of September 2024, at 14.00 CET**.

The complete timeframe for this call for proposals can be found [here](#).

### 5.2 Guidelines for use 'Mijn ZonMw'

If the main applicant of the project has no previous experience with Mijn ZonMw, it is necessary to register as 'New user'. More information can be found via [Mijn ZonMw manual](#).

We advise you to print out a Word version of your application (via Mijn ZonMw) and carefully review it for errors before you submit it digitally. This is especially important if you have created your application in Word and then copied it to Mijn ZonMw, as some characters (such as quotes) may not be converted correctly. You can correct this yourself in Mijn ZonMw.

### 5.3 Statement of agreement for submission of detailed grant application

For the detailed application the '[Statement of agreement for submission of detailed grant application](#)' must be signed by the individual with administrative responsibility and the main applicant. The signed declaration can be added to the application in Mijn ZonMw or sent to ZonMw by email to [mecvs@zonmw.nl](mailto:mecvs@zonmw.nl). The declaration must have been received no later than one week after submission of the application. For the submission of the project idea this statement is not necessary.

## 5.4 Content-related questions

For questions regarding the contents of the application, please contact one of the program managers: Minne Prüst, via telephone number 070 349 5198 or Linda Gerth, via telephone number 070 349 5230. Or contact us via e-mail [mecvs@zonmw.nl](mailto:mecvs@zonmw.nl).

## 5.5 Technical questions

If you have any technical questions about using ZonMw's online application system, please contact the Service Desk from Monday to Friday between 8.00 and 17.00 (+31 070 349 51 78, [servicedesk@zonmw.nl](mailto:servicedesk@zonmw.nl)). Please include your telephone number in your email so that we can call you back if necessary.

## 5.6 Information consortia

The ME/CFS research program provides funding for two consortia, the NMCB consortium and the ME/CFS lines consortium.

### NMCB

The Netherlands ME/CFS Cohort and Biobank (NMCB) consortium is a broad national collaboration between academic medical centres, knowledge institutes (universities, RIVM, KNAW) and patient organisations. The consortium focusses on biomedical research on ME/CFS but also other Post Acute Infectious Syndromes (PAIS: post-COVID, Lyme, Q-fever). The consortium manages a patient cohort and biobank with a rich collection of biomaterials, medical data, questionnaires and physical and cognitive tests. The biomaterials and data are internationally harmonised but leave space for additions later on made by individual studies. In total, 1600 patients and 450 healthy controls will be recruited, matched based on demographics, topographics and infectious background. Patients will undergo a medical screening on the case criteria for ME/CFS. A home visit program is conducted to enable severely ill patients to participate. Furthermore, the cohort functions a patient registry for additional studies, including studies researching treatment.

### ME/CFS Lines

In the ME/CFS Lines consortium several national and international research partners work on biomedical research on ME/CFS. For this research data and biomaterials are used that have been collected in the Lifelines population cohort since 2006, in which 167.000 people participate. Using questionnaires and diagnostic research, ME/CFS patients within Lifelines are identified. Biomaterials are used to map the genetics, microbiome, antibody repertoire, proteome and metabolome of ME/CFS patients and matched controls. The focus is on a multi-omics approach, for which also biomaterials are available collected before the onset of ME/CFS. With this data researchers within the consortium will search for new mechanisms explaining the onset of ME/CFS in search of a better diagnosis and treatment.

More information about the consortia can be found on the project pages of the website of ZonMw (NMCB and ME/CFS Lines) and on the website of the consortia (NMCB and ME/CFS Lines). For more information, the consortium leaders can be contacted via e-mail:

- NMCB consortium, consortium leader Jos Bosch, [nmcb@amsterdamumc.nl](mailto:nmcb@amsterdamumc.nl)
- ME/CFS Lines consortium, consortium leader Judith Rosmalen, [mecfslines@umcg.nl](mailto:mecfslines@umcg.nl)

Note: For the project idea it is not yet necessary to establish the collaboration with a consortium. For the detailed application this collaboration must be determined.

### Information meeting

To facilitate connecting with the consortia, ZonMw organizes an online information meeting for potential applicants on the 24<sup>th</sup> of June 2024. This way the applicants get a better understanding of the activities of the consortia. During this information meeting both consortium leaders will be present.

## 5.7 Contact information patient organisations ME/CFS

The following patient organisations can be contacted to involve experts by experience in the project and ME/CFS patients who are willing to participate in research.

- ME/cvs Vereniging, [contact@me-cvsvereniging.nl](mailto:contact@me-cvsvereniging.nl)
- Steungroep ME en Arbeidsongeschiktheid, [info@steungroep.nl](mailto:info@steungroep.nl)
- MECVS Nederland, [info@mecvs.nl](mailto:info@mecvs.nl)

## 5.8 Downloads and links

On the ZonMw website more information can be found regarding:

- [General Terms and Conditions Governing Grants of ZonMw](#)
- [Applying for funding in 10 steps](#)
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## 6. Annexes

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## Annex 1 – State aid – SGEI

If an undertaking applies for a grant in this funding round, ZonMw will provide the grant under the SGEI Exemption Decision<sup>6</sup>, provided a number of conditions have been met. You can find these conditions below.

ZonMw has designated the activities referred to under the heading 'aim of the call for grant applications' as economic activities of general interest. Before allocating the grant, ZonMw will, by means of a decision, charge the grant recipient or recipients of the activities described above with the administration of a Service of General Economic Interest (SGEI).

The SGEI consists of implementing (a part of) the activities described in the project proposal. The grant recipient(s) are obligated on the grounds of Article 5(2) of the SGEI Exemption Decision to list revenue and expenditure associated with activities in the service of general economic interest separately from revenue and expenditure for other activities that do not fall within the SGEI.

Project funding will not exceed the maximum duration of the project. In line with the SGEI Exemption Decision, the maximum duration of a project is 10 years.

The grant amount applied for may not exceed the net cost of the planned project activities. The parameters for calculating the compensation for each project are included in the [budget documents](#) of ZonMw. The calculation methods included in the submitted budget are in accordance with Article 4 of the SGEI Exemption Decision.

ZonMw will recover any proven overcompensation on the basis of Article 6(2) of the SGEI Exemption Decision. If the project duration exceeds 3 years, ZonMw will perform an interim check to establish whether there has been any overcompensation.

If there is a consortium and at the time of application, it is still unclear which parties are participating in the consortium, it is possible to add these parties to the consortium at a later stage. If a new party is added to the consortium, please notify ZonMw of this in writing. The new party will only be included in the consortium if ZonMw has approved this. All parties must individually meet all the conditions of the SGEI Exemption Decision.

If the project activities are shown not to have been carried out, or not to have been carried out in full, or if the obligations attached to the grant have not been fulfilled, ZonMw may set the grant at a lower amount and recover all or part of any advance payments made.

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<sup>6</sup> Commission Decision of 20 December 2011 on the application of Article 106(2) of the TFEU on state aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, 2012/21/EU, OJ EU 2012 L7/3.

## Annex 2 – Criteria for the detailed grant application

### 2.1 Relevance criteria

#### Contribution to program objectives

The detailed grant application must fit within the program objectives of the research program ME/CFS (please see: [program text](#)). The final objective of the program is to improve the health, the quality of life and the societal position of patients with ME/CFS. The subject of the detailed grant application must fit within the framework (of the program text) of the research program ME/CFS. 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 result from or are related to disorders other than ME/CFS (i.e. post-COVID) can only be researched in relation to ME/CFS.

#### Collaboration

The project should be affiliated to at least one of the two existing consortia funded by the research program ME/CFS. The detailed application should clearly describe the way in which cooperation with the consortia will be designed. For example, the method of (FAIR) data collection should be coordinated with the consortium. Also, the dissemination and implementation of the results arising from the project should be coordinated with the consortium to improve knowledge exchange, transfer and implementation.

Furthermore, the collaboration with different parties is strongly encouraged. The following forms of collaboration are important and need to be described convincingly if present in the proposal.

- Collaboration between research disciplines involved in ME/CFS research, such as immunology, microbiology, neurology, cell biology, (epi-)genetics, systems biology, bioinformatics and cardiology;
- International collaboration, because Dutch research should connect with research lines into ME/CFS that have been developed in other countries;
- Collaboration between professional groups, such as researchers, clinicians, policymakers and education professionals.
- Collaboration with experts by experience with regard to the field of ME/CFS (see also the paragraph 'participation of patients/experts by experience')

#### Participation of patients/experts by experience

Collaboration with patients/experts by experience is mandatory. In the detailed grant application it should be made clear how stakeholders, target groups and/or end users who are [experts by experience](#) are involved in the project. Involvement means that stakeholders are consulted, advice is obtained from them, collaboration with them takes place and/or an equal right is granted to participate in the (joint) project decision-making process. In the detailed application it should be made clear how ME/CFS patients and their representatives participate in the project: in which phases and in which way. Their roles should be clearly described and defined. The applicant should indicate how functional limitations of patients are taken into account. Also the budget of the detailed application will be assessed on this. The [ZonMw website](#) (only available in Dutch) contains suggestions for involving patients in research. The kick-starter for patient participation from the [Participatiekompas](#) ('Participation Compass', only available in Dutch) offers practical insights for researchers as well. [Paragraph 5.7](#) contains the contact information of patient organisations that can be approached for the involvement of patients in the research.

#### Added value and feasibility for ME/CFS patients

In the detailed grant application the applicant substantiates the importance of the subject: what is the eventual relevance and/or added value of the research for people with ME/CFS? Besides that, during the assessment, attention will be paid to the feasibility of the plan of action and the additional burden for the patients resulting from participation in the project. Proposals will be evaluated whether the revenue of the project outweighs the possibly permanent, negative health effects of participation in the project. In the application it should be made clear how the capacity of the patient is taken into account and if patients are reimbursed for their participation.

#### Access to data

ZonMw promotes the optimal use of data. In the detailed grant application, describe the use of existing data files or materials from the affiliated consortium or other (international) biobanks and patient registrations. If new data collection is necessary for the project, describe the necessity of this and the

way in which the project contributes to the consortium. Indicate how FAIR principles will be applied on future data/results. When planning the project and its budget, take into account the opportunities and requirements set out at [FAIR data & data management](#). If you do not intend to collect any data, please mention this in your grant application.

### **Animal models**

Regarding the transition to laboratory animal-free research, ZonMw encourages researchers to use or develop alternatives for animal testing. In case animal testing is proposed in the application, the program committee will be vigilant on the substantiation about the use of animal testing. What is the relation between the used animal model and the research question? What is the methodological and statistical substantiation of the tests? Are alternatives available for the animal test for example by using computational models?

### **Implementation and impact**

Projects funded by ZonMw must have impact. New knowledge and expertise must be used in practice, policy, education and/or further research. On our website we explain what impact is, how we work to achieve and demonstrate it and what we expect from project managers. You can find more information on the ZonMw web page [Implementation](#). In the detailed grant application a strategy should be described for 1. implementation activities and dissemination, 2. communication, 3. safeguarding in education, 4. valorisation and (market-oriented) knowledge transfer, 5. patient information.

More information about relevance criteria can be found on the [ZonMw webpage Relevance criteria](#).

## **2.2 Quality criteria**

### **Objective and research question/mission statement**

The detailed grant application must match with the objectives of the research program ME/CFS (see [program text](#)). The objective and research question should be described clearly resulting in a concrete and verifiable question that can be objectively assessed. The detailed grant application should demonstrate the added value of the project in relation to available knowledge or current practice. The added value must be clearly substantiated. Also needs to be described how the project relates to completed or current research projects in the same field and what the added value is of this project. The proposal may not be a duplication of previous or current research projects in the Netherlands or abroad. Alignment of the project with promising international directions of research are stimulated. Replication research is 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 formulated.
4. 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.
5. 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.
6. 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 relevant literature for the specific research question. The research population must be clearly defined. 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 [program text](#)).



**Feasibility**

In the application, 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**

The detailed grant application should contain a description on 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. If necessary, this expertise should be gattered abroad. 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 '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 on the [ZonMw webpage Assessment](#).