Promising medicines for ME/CFS: call for drug repurposing

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Deadline: **Tuesday 17 March 2026, 14.00 CEST**

Contents

Summary

Who can apply
A project idea can only be submitted by legal entities under public or private law established in the Netherlands. These may include, for example, Dutch research organisations, a Dutch healthcare institution or healthcare provider, a public organisation or an interest or advocacy organisation. ZonMw encourages cooperation between and participation of different parties. If collaboration takes place within the project, the cooperating parties may also claim (part of) the grant.

What for
The aim of this call for proposals is to fund clinical research into promising medicines for patients with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) in the Netherlands. This round focuses on drug repurposing or rediscovery. Specifically, it concerns projects focused on clinical research into the effectiveness of an existing medicine (off-patent, available in the Netherlands) as a new application for patients with ME/CFS. In this round, two types of project ideas can be submitted, defined by ZonMw as: “Proof of concept (PoC) studies” or “Clinical validation studies”. The knowledge synthesis “Inventory of promising pharmacological interventions for ME/CFS” can serve as a guide.

What to request
The total budget available in this round is €3.5 million. For this call, there are no restrictions on the total amount of funding requested per project.The target amount for an application is between €600,000 and €1,000,000 per project. It is the explicit intention to fund multiple applications within the budget available in this call. It is essential that the budget is realistic and well substantiated. For organisations that are not research institutions, a mandatory own contribution or co-financing of at least 50% of the total project costs applies. The maximum duration of a project is 4 years.

When

Deadline for submission of project ideas	17 March 2026, 14.00 CEST
Receipt by advisory committee	Mid June 2026
Receipt of additional advice from CBG/ZIN	Mid June 2026
Deadline for submitting detailed grant application	8 September 2026, 14:00 CEST
Receipt of referee comments	14 October 2026
Deadline for submitting a response	4 November 2026
Decision	February 2027
Latest project start date	August 2027

1 Aim of the call for grant applications

This call is part of the Biomedical Research line of the ZonMw ME/CFS research programme .

1.1. Research programme ME/CFS

Patients are at the heart of the ME/CFS research programme with the citizens' initiative “Erken ME” (Recognise ME). This led to a recommendation from the Health Council of the Netherlands and a biomedical research agenda for ME/CFS. At the end of 2021, the ME/CFS research programme was launched with a total budget of 28.5 million euros. The ultimate goal of the ME/CFS research programme is to improve the health, quality of life and social position of ME/CFS patients. This call falls under the programme line Biomedical Research. This programme line focuses on developing biomedical knowledge about the origin, nature, diagnosis and treatment of ME/CFS.

In the first round of funding, two consortia were funded within the programme: The Netherlands ME/CFS Cohort and Biobank Consortium (NMCB) and the ME/CFS Lines Consortium. Within the consortia, 17 projects are currently conducting transdisciplinary biomedical research into ME/CFS as a multisystem disease. The consortia are intended to establish an infrastructure for long-term research into ME/CFS. More information about the consortia and projects can be found on the ZonMw ME/CFS research programme page.

1.2. Background of the call ‘Promising medicines for ME/CFS: call for drug repurposing’

Recently, the ME/CFS research programme was expanded by an amount of €4.4 million for biomedical research as a result of an amendment (Drost amendment) to the budget of the Dutch Ministry of Health, Welfare and Sport (VWS). In consultation with the focusgroup of the ME/CFS research programme, consisting of representatives of ME/CFS patient organisations, it was explored how the funds from the Drost amendment could be integrated into the ongoing biomedical ME/CFS research programme. This resulted in a proposal from the patient organisations, supported by the ME/CFS programme committee, to allocate the majority of the funds from the amendment to the conduct of pharmaceutical research into ME/CFS.

Part of this involves the preparation of a knowledge synthesis to gain insight into the current state of pharmacological interventions for ME/CFS. In this knowledge synthesis, promising medicines for further clinical research were identified. Various aspects of the concept of “promising” are explored in the knowledge synthesis and may serve as inspiration for applicants.

1.3. Objective of this funding round

The objective of this call for proposals is to fund clinical research into promising medicines for patients with ME/CFS in the Netherlands.This round specifically focuses on projects aimed at **clinical research** into the effectiveness of an **existing medicine** that is off-patent and available in the Netherlands, for a new indication, namely ME/CFS.

The funding round is open both to specific medicinal products identified in the knowledge synthesis and to a broader range of medicinal interventions, provided that these can become available to ME/CFS patients in the Netherlands. Research into non-medicinal interventions is excluded. Annex 1 specifies which applications do and do not fall within the scope of this call.

In this round, project ideas may be submitted that are at different stages of clinical research:

Proof of concept (PoC) study
An early clinical evaluation or hypothesis-confirming human pilot study. The project idea is based on a plausible signal from clinical practice (including Real World Evidence), laboratory and/or animal models, literature and/or another type of analysis that justifies progression to a clinical study. At this stage, however, there are not yet sufficient valid human pilot data to justify a trial in a larger population.

Clinical validation study
A hypothesis-confirming study that builds on previous human pilot data. The study focuses on more robust clinical endpoints, with the aim of deepening existing knowledge and generating new scientific clinical insights that form the basis for further development of the medicine.

In this funding round, projects must focus on clinical research into a promising application of an existing medicinethat is not under patent, for an indication for which the medicine is not registered, namely ME/CFS. Subsidy may be requested for various research methodologies, including Randomised Clinical Trials (RCTs), extensions of ongoing medicinal studies or platform trials, and cross-over trials. Ongoing studies and platform trials may, for example, be expanded by adding a new ME/CFS patient category or an additional medicinal intervention for the benefit of ME/CFS patients.

The projects must always address overarching societal questions that contribute to the general public interest of improving the quality, affordability and accessibility of healthcare in the Netherlands. It must be evident that the research would not be initiated by private parties and that the use of public funds is therefore justified. Projects should make the business case more attractive for pharmaceutical manufacturers: early involvement of a manufacturer is therefore encouraged, allowing coalition-based collaboration on transparent further development of the product. The guiding principle is that the product must become available to patients at a socially acceptable price. For more information see the ZonMw website Grants and Collaborations/contributions from third parties.

See Annex 1 for further clarification of the scope of this funding round.

2 Conditions and obligations

You must take account of certain rights, conditions and obligations 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.

2.1. 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.

2.1.1. Who is eligible for funding?

A project idea may only be submitted by public-law or private-law legal entities established in the Netherlands. This may include, for example, a Dutch research organisation, enterprise, healthcare institution or healthcare provider, or an advocacy organisation. If the application is submitted by a private-law legal entity, the project idea must clearly describe why other parties, such as the pharmaceutical industry, are not sufficiently investing in this research (market failure). ZonMw encourages collaboration between and participation of different parties. If cooperation takes place within the project, the cooperating parties may also be eligible for (part of) the grant. This must be clearly described in the detailed grant application phase and reflected in the budget. More information on collaboration can be found in Section 2.1.3 and Annex 4.

2.1.2. Avoiding State aid

No grants will be awarded by ZonMw if this would or could constitute unlawful state aid[1]. Therefore, the following state aid measure applies to this funding round:

General Block Exemption Regulation
The General Block Exemption Regulation (hereinafter GBER) will be used in this funding round, by which grants allocated under this call for grant applications are designated as a permissible form of

[1] Section 107 of the Treaty on the Functioning of the EU (TFEU).

state aid. This means that there are conditions for funding and rules for budgets. In addition, applicants are required to make declarations about certain data.

You can find out more about the GBER in Annex 5 – State Aid – GBER as well as the requirements that have to be met under the GBER.

If collaborative projects are involved[2] in which multiple undertakings could benefit from state aid, then all undertakings eligible to claim a grant must meet the conditions of the GBER. This means that all the conditions and requirements arising from the GBER apply equally to the full extent to all undertakings in the collaborative project eligible to claim a grant. ZonMw informs the European Commission of this grant call by means of a notification as referred to in Section 11 of the GBER.

You can find more information about state aid on the ZonMw webpage State aid exemption.

Industrial research (article 25(2)(b) of the GBER).

Projects funded under this call fall within the category of industrial research (article 25(2)(b) of the GBER). The maximum aid intensity for industrial research is 50% of the eligible costs. Eligible costs include:

- Personnel costs;
- Costs of equipment and instruments, to the extent and for the duration that they are used for the project;
- Costs of buildings and land, to the extent and for the duration that they are used for the project;
- Costs of contractual research, knowledge and patents purchased or licensed from external sources under arm's length conditions;
- Costs for consultancy and equivalent services used exclusively for the project;
- Additional overheads and other operating expenses, including costs of materials, supplies and similar products, incurred directly as a result of the project.

The aid intensity for industrial research may be increased up to a maximum of 80% of eligible costs as follows:

- An increase of 10% for medium-sized enterprises and 20% for small enterprises;
- An additional increase of 15% if project results are widely disseminated through conferences, open-access repositories, or free or open-source software.

Table 1. Overview of state aid

	Large enterprise	**Medium-sized enterprise**	**Small enterprise**
Base aid intensity	50%	50%	50%
Increase by enterprise type	n.a.	10%	20%
Dissemination of results	15%	15%	10%
Co-financing	35%	25%	20%

When applying for funding, it must be determined whether the applicant qualifies as a small or medium-sized enterprise (SME). Therefore, the EU SME Self Assessment Wizard must be completed when submitting the application. The generated form may not be older than 14 days at the time of submission.

All amounts used in calculating aid intensity and eligible costs must be stated before deduction of taxes or other charges. Eligible costs must be supported by clear, specified and up-to-date evidence. Such evidence may be requested by ZonMw at any time after grant award and must be provided within a reasonable period.

[2] An undertaking as defined under EU state aid legislation means any entity that performs economic activities, regardless of its legal form or means of financing.

Co-financing and/or an own contribution is mandatory under the GBER and concerns the portion of project costs not eligible for funding. The project budget must show the total project costs and clearly specify which costs are covered by the grant and which by own contributions and/or co-financing (in cash or in kind).

No state aid in the case of research organisations
The primary activities of research organisations are generally non-economic in nature and therefore fall outside the scope of State aid law. However, if economic activities are involved (such as renting out laboratory space), state aid rules may still apply. According to Section 15(e)(e) of the EU State aid Framework for Research, Development and Innovation (RDI Framework), a 'research organisation' is defined as:

'An entity (such as universities or research institutes, technology transfer agencies, innovation intermediaries, research-oriented collaborative entities, whether physical or virtual), regardless of its legal status or method of financing, whose primary goal is to independently conduct fundamental research, industrial research or experimental development, or to widely disseminate the results of such activities through teaching, publication or knowledge transfer. Where such an entity also carries out economic activities, the financing of the costs and revenues of those economic activities must be accounted for separately. Undertakings that can exercise decisive influence over such an entity, for example as shareholders or members, must not enjoy preferential access to the research results generated by it.'

2.1.3. 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.

Collaboration with consortia
All funded projects must become part of the existing research infrastructure established under the ME/CFS Research Programme. ZonMw therefore encourages projects to collaborate with one of the two existing consortia: The Netherlands ME/CFS Cohort and Biobank Consortium (NMCB) and the ME/CFS Lines Consortium. Collaboration with a consortium is not mandatory.

ZonMw encourages collaboration in the following areas:
- Harmonisation of patient intake;
- Harmonisation of data collection variables and protocols;
- Preservation of samples and data in the database and existing biobanks;
- Alignment of communication activities;
- Coordination of dissemination and implementation activities.

Collaboration with other parties
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[3];
2. Dutch healthcare institutions[4];
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.

With a view to implementation, explicit attention is required for connections with relevant societal stakeholders, such as patients/experts by experience, health insurers, pharmacologists/pharmacists, healthcare professionals, or policymakers. Involving patients/experts by experience in the project is a requirement. From the formulation of the project idea onwards, work should be carried out as much as

[3] Framework for State aid for research and development and innovation (2014/C 198/01), article 15 under ee).
[4] Definition of health care facility: article 5, paragraph 1, law for the admission of healthcare institutions

possible in collaboration. Collaboration and sponsorship must be described in the project idea, but must be definitively arranged by the time the detailed grant application is submitted.

More information about the various forms of collaboration and third-party contributions (sponsorship/commissioned work) can be found on the ZonMw webpage Grants and collaborations/contributions from third-parties. This page includes sample agreements as tools for drafting the relevant agreement and explanations of the conditions that such agreements must meet. The conditions mentioned on this webpage and in the accompanying explanation form an integral part of this funding call.

Under "Background/Foreground Intellectual Property (IP)" in the application form, the project idea must describe who holds the rights to the contributed existing knowledge (background intellectual property). For questions about IP or about drafting an agreement with third parties, it is advisable to involve an IP/contract specialist in a timely manner; such specialists are often part of the legal department or the valorisation or Technology Transfer Office (TTO).

2.1.4. Grant amount

The total available grant budget for this funding round is €3.5 million.

Project budget and duration

Within this budget, no maximum amount applies per project. The indicative budget range is €600,000 to €1,000,000 per project. It is explicitly intended to fund multiple applications within this funding round. The maximum project duration is four years.

Cost indication and budget

At the project idea stage, applicants are required to provide a cost indication, not a detailed budget. A detailed budget must be submitted with the detailed grant application. Specific requirements apply to this budget, as described in Annex 4. More information about the standard requirements can be found on the website of ZonMw.

Further information on financial conditions for grant applications can be found on the ZonMw webpage Conditions and obligations. Guidance on preparing a budget is available on the ZonMw webpage What must I submit.

Requested grant amount

The indicative grant amount is €600,000 to €1,000,000 per project. Any deviation from this range must be substantiated in both the project idea and the detailed grant application.

Without adequate justification, the requested grant amount in the detailed grant application may not deviate by more than 15% from the amount stated in the project idea. When preparing the budget for the project idea, applicants should already take into account, where applicable, the costs of (early) economic evaluation, sufficient (experienced) staff to support patient inclusion, production and distribution of study medication/placebo, patient participation, dissemination and implementation of project results, communication activities, use of data services, and similar costs.

Use of public funds

The project idea must clearly demonstrate that the use of public funds is justified and explain why the project will not be fully or partially undertaken or funded by other parties, such as under existing obligations.

Co-financing and/or own contribution

For research organisations, which fall outside the scope of State aid law, an own contribution or co-financing is not mandatory, although co-financing is recommended to promote implementation of results.

For non-research organisations, co-financing and/or an own contribution is mandatory. They must finance at least 50% of the total project costs themselves (see Section 2.1.2.). This may take the form of financial contributions or in-kind contributions, such as the provision of materials or services. Under certain conditions, the aid intensity may be increased.

Manufacturers of the medicines under investigation are in principle expected to make an (in-kind) contribution, for example by providing study medication and/or placebo. If no contribution is possible, this must be clearly explained. Participating centres may also contribute, in cash or in kind.

2.1.5. Practical conditions

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

- Compose your application in English.
- For the project idea, one optional annex with figures and tables may be submitted, with a maximum length of 2 A4 pages. This annex forms part of the assessment. Other annexes are not considered in the assessment.

2.2. 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.

3 Assessment criteria

3.1. 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 programme, in other words: does the application fit within the objective and framework conditions of the funding round and the programme? (see also Annex 1). In addition, at this stage, the programme 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. For the specific criteria applicable to the project idea please see: 3.2.1. Relevance criteria for project idea and 3.3.1. Quality criteria for project idea.

Annex 2 contains details about the requirements for the project idea.

Additional advice from CBG and ZIN

To further enhance the quality of project proposals with a view to market authorisation of the medicine under investigation, the Medicines Evaluation Board (CBG) and the National Health Care Institute (ZIN) provide project groups that receive a positive recommendation with a joint, ‘high-level’ advisory opinion based on the information in the project idea.

This additional advice aims to further improve the quality of the project proposals and better align projects with a pathway for translating study results into practice. The advice is provided in writing. The detailed grant application must respond to this advice and substantiate why elements of the advice have or have not been incorporated. If the advice conflicts with that of the ME/CFS programme committee, the advice of the programme committee prevails.

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 programme 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 programme

committee regarding quality and relevance is based on the detailed grant application, the reports of the reviewers and the rebuttal. The programme committee gives a final advice to ZonMw on the relevance, quality and budget of all applications.

Annex 3 contains the relevance and quality criteria which are applicable for the detailed grant application. Annex 4 provides important information about the detailed grant application.

If desired, the ME/CFS programme committee may opt for an interview meeting with the main applicant during the detailed grant application phase as part of the assessment procedure.

The deadline for application of a project idea is **17 March 2026, 14:00 CEST**. The deadline for submitting the detailed grant application is **8 September 2026, 14:00 CEST**.

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).

3.2. Relevance criteria

3.2.1. Relevance criteria for project idea

For the project idea, the following relevance criteria apply.

Objective of the grant call
The project must fall within the objective of the grant call. This specifically concerns clinical research into existing medicines that contribute to an effective treatment for ME/CFS patients and that can be made available to ME/CFS patients in the Netherlands. This includes "Proof of concept" (PoC) studies and/or clinical validation studies. Annex 1 specifies which applications do and do not fit within the framework of this call.

Contribution to programme objectives
The project idea must fit within the programme objectives of the research programme ME/CFS (see: programme text). The final objective of the programme is to improve the health, the quality of life and the societal position of patients with ME/CFS. Research that focuses on chronic fatigue resulting from diseases or conditions other than ME/CFS does not fall within this scope. Symptoms consistent with ME/CFS that arise from or are related to other comparable conditions (e.g. post-COVID) may only be investigated in relation to ME/CFS, for example by including a (post-COVID) control group.

Promising medicines
The project must investigate promising pharmacological treatments for ME/CFS. The promise of medicines is assessed on the basis of the scientific substantiation of the potential effectiveness of the product for the treatment of ME/CFS patients, the affordability and availability of the product in the Netherlands, and its alignment with patients' needs (see also knowledge synthesis). In the project proposal, the promise of the medicine under investigation must be clearly described and sufficiently substantiated.

Added value
The project idea must demonstrate its added value in relation to existing knowledge and/or practice. It should also describe how this research relates to any completed or ongoing studies in the same field and what this project will add to them. The project may not duplicate previous or ongoing projects in the Netherlands or abroad, but it may build on earlier projects or align with ongoing projects in the Netherlands or internationally. In this context, alignment with promising international research directions is encouraged.

Participation of patients/experts by experience
Collaboration with patients/experts by experience within the project 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 from, collaborating with, and/or enabling stakeholders to (co-)decide in the development and implementation of the project and in the dissemination of its results. Experts by experience must be involved in the project at an early stage, with due consideration for their capacity and level of burden.

The “Kickstarter for patient participation” of the Participatiekompas (‘Participation Compass’, only available in Dutch) provides practical guidance for researchers. Section 4.5 lists the contact details of patient organizations that may be approached.

Collaboration with consortia and other parties
All funded projects must become part of the existing research infrastructure established under the ME/CFS research programme. Collaboration on the following components is essential:

- Harmonisation of patient intake;
- Harmonisation of variables and data collection protocols;
- Long-term preservation of samples and data in the database and existing biobanks;
- Alignment of communication activities;
- Alignment of activities related to the dissemination and implementation of research results.

The project idea should outline, in general terms, which parties will collaborate and how collaboration with the participating parties will contribute to these components.

For the project idea, collaboration with the relevant parties does not yet need to be formally established. However, the type of collaboration being pursued and how the collaboration will be structured in broad terms must be described. Collaboration with multiple parties is strongly encouraged.

The following forms of collaboration are considered important:

- Collaboration with one of the existing consortia funded under the ME/CFS research programme;
- Collaboration between hospitals, ME/CFS treatment centres, or independent healthcare professionals with expertise in ME/CFS;
- Collaboration with parties from the pharmaceutical industry, including drug manufacturers, pharmaceutical departments, and pharmacies;
- Collaboration with health insurers or policy bodies involved in market access and reimbursement of medicines;
- International collaboration, as research lines on ME/CFS have been developed abroad to which Dutch research can connect.

To strengthen support and thereby increase the likelihood that project results will be taken forward, it is important to involve relevant stakeholders and collaborative partners at an early stage.

Added value and feasibility for ME/CFS patients
The project must provide added value for patients. The project idea should broadly describe what the research will deliver for patients with ME/CFS. The assessment will also consider the burden placed on patients as a result of participating in the research. Applications will be evaluated on whether the expected benefits of the research sufficiently outweigh any potential lasting negative health effects of participation. The project idea should indicate how consideration is given, among other things, to the capacity and compensation of ME/CFS patients participating in the project.

Follow-up
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 about implementation support we explain what impact is, how we work to achieve and demonstrate it and what we expect from project managers. In this round, this will be assessed under the relevance criterion ‘follow-up’.

The project idea should demonstrate a clear vision and ambition to move the research results forward to a next phase of research, development, and/or application in practice. When selecting materials and methods, consideration should be given to alignment with any follow-up research and/or a subsequent project.

Although both types of applications will be assessed against the relevance criterion ‘follow-up’, the evaluation of the project idea under this criterion will take place in light of the type of application. The results of a “proof of concept” study will be further removed from implementation in practice or registration of the product for the new indication than those of a clinical validation study.

Proof of concept (PoC) study: the project idea should broadly describe how a follow-up study could build on the project. The project idea should clearly indicate the strategy that this follow-up study should pursue. It should also broadly describe how the results could be translated into practice after such a follow-up study.

Clinical validation study: the project idea should broadly describe which strategy and activities are needed for translation and further implementation of the results into practice and/or policy. The project idea should clearly indicate how the product will become available to patients in clinical practice after completion of the clinical validation study.

With regard to the registration pathway, project ideas that are invited to be further developed into a detailed grant application will receive additional combined scientific advice from the CBG and ZIN. See Annex 3 for further explanation.

Intellectual Property (IP)
A clear and feasible patent strategy increases the likelihood that the medicinal product can be successfully further developed and ultimately reach clinical practice. The current patent position of the medicine under investigation, as well as the possibility to carry out the project (freedom to operate), must be clearly described. Indicate whether the medicinal product under investigation and/or the new indication for this product is covered by a patent or whether a patent application is pending. Also state, where applicable, when the patent expires and who owns the underlying intellectual property and/or existing knowledge. **Please note**: projects in which the medicine under investigation is still under patent protection on 1 January 2026 are not eligible for funding.

In addition, describe which activities are planned or have already been undertaken with experts in the field of technology transfer, business development, valorisation, IP attorneys, and other relevant parties to develop an IP strategy.

3.2.2. Relevance criteria for detailed grant application
For the detailed grant application, additional criteria apply. The relevance criteria for the detailed grant application are outlined in Annex 3.

3.3. Quality criteria

3.3.1. Quality criteria for project idea
For the project idea, the following quality criteria apply.

Objective and research question/mission statement
The objective and research question should be described clearly resulting in a concrete and verifiable question that can be objectively assessed.

Action plan
In the project idea the action plan is described: the design of the study, the analytical methods to be used, and the expected results. The approach must be appropriate to the research question or objective. A well-substantiated description of the medicine under investigation and the comparator, the study population, sample size, and the analysis must be provided. The inclusion criteria used must be justified, in line with the literature relevant to the specific research question, taking into account potential subgroups. In the project idea, the study population must be clearly defined. When describing the study population, attention is paid to whether it adequately matches the research question, as well as to how it relates to the advantages and disadvantages of the various criteria by which ME/CFS is often defined (as described in Section 2.2.2 of the programme text).

Outcome measures
In the project idea, a brief description should be provided of the outcome measures that will be used in the study. It must be plausible that the choice of outcome measures aligns with the selected objectives and research questions. It is important that relevant, and where possible objective, outcome measures are used. In the application, the choice of subjective and objective outcome measures must be well substantiated.

Feasibility
In the project idea, a realistic timeline for all phases of the project is presented and the feasibility of the project is justified. The project idea includes an overview of the expected obstacles and how these will be addressed. It must be plausible that the project objectives can be achieved within the proposed timeframe using the available expertise, personnel, facilities, and resources. Account must also be taken of the duration and complexity of any required Medical Ethics Review Committee (METC) application. The feasibility of patient recruitment is explicitly included in the assessment. Further information is provided in the publication 'Succesvol includeren' ('Successful patient inclusion', in Dutch only).

Project group or person
The project idea should contain a short description of how the composition of the project group contributes to the quality of the research. It is important to include the following expertise within the project group: pharmacological knowledge and methodological/statistical expertise in the field of clinical drug research.

3.3.2. Quality criteria for detailed grant application
For the detailed grant application, additional criteria apply. The quality criteria for the detailed grant application can be found in Annex 3.

3.4. 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. An X in the prioritisation matrix indicates that the application is not 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.

If after applying the prioritisation matrix the number of eligible applications exceeds the available budget, the programme committee will deploy the following additional grounds of evaluation:

- Children and severely ill patients
The impact of a drug can partly be determined based on the increase in quality of life and the number of life years during which the quality of life improves. For example, children generally have more life years ahead of them than adults, and the possible increase in quality of life is greater in severely ill patients. Attention to these groups is a plus.

4 Submitting your application

4.1. Submission through Mijn ZonMw

Project ideas/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 **17 March 2026, 14.00 CEST.**

The complete timeframe for this call for proposals can be found here (the last paragraph).

4.2. Tips

Additional information

- An explanation for submitting the project idea can be found in Annex 2.
- Key points for a potential detailed grant application can be found in Annex 4.

Points of attention and tips for digital submission

- If you have not previously used Mijn ZonMw, the applicant must first register as a 'New user'. For more information, see the explanations in Mijn ZonMw and the Mijn ZonMw manual.
- The submitter is automatically the 'Main applicant' as a user of the ZonMw account, and therefore the manager of the application in Mijn ZonMw. The submitter will also receive all messages sent by ZonMw from the system.
- 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.
- The application must be written in English. Applications in Dutch will not be considered.

Clinical Trial Regulation (CTR)

For laws and regulations regarding medical-scientific research involving humans, we refer to the CCMO website. For drug research under the Clinical Trial Regulation (CTR), a dedicated section provides all necessary information for researchers. For certain types of research, specific rules apply that may affect the budget.

4.3. Content-related questions

For questions regarding the contents of the application, please contact programme manager Minne Prüst via telephone number 070 349 5198 or via e-mail mecvs@zonmw.nl.

Information about the background and aims of the ZonMw programma can be found on the programme page of the research programme ME/CFS.

For information and advice on the ethical, legal, and social aspects of scientific research (such as consent procedures, guidelines and regulations, legislation, data protection, feedback of findings, review, and data sharing), please refer to the national ELSI Servicedesk (in Dutch only).

Information session

ZonMw will organize an online information session (in English) for potential applicants on January 29, 2026. During this session, information about the call will be provided, and there will be an opportunity to ask questions. You can register for the information session via this link.

4.4. 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 CEST (+31 070 349 51 78, servicedesk@zonmw.nl). Please include your telephone number in your email so that we can call you back if necessary.

4.5. 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.

- MECVS Nederland, info@mecvs.nl
- ME/cvs Vereniging, contact@me-cvsvereniging.nl

4.6. Downloads and links

- Programme page of the ZonMw research programme ME/CFS
- General Terms and Conditions Governing Grants of ZonMw
- Conditions and obligations
- Applying for funding in 10 steps
- What must I submit?
- The assessment
- Grants and collaborative third-party contributions
- State support exemption
- Datamanagement and FAIR data
- Open Access
- Implementation support
- Mijn ZonMw manuals
- Statement of approval for submission of a detailed grant application
- Ten principles of Socially Responsible Licensing
- Informatie Clinical Trial Regulation (only available in Dutch)
- Clinical Trial Decision Tool (only available in Dutch)
- Clinical trials with medicinal products (CTR)
- Laws and regulations concerning ZonMw
- Algemene wet bestuursrecht (Awb) (only available in Dutch)
- Participation and Citizen Science
- Participatiekompas (only available in Dutch)
- De nationale ELSI Servicedesk (only available in Dutch)
- FAST Leidraad Maatschappelijk Verantwoord Licentiëren (only available in Dutch).

5 Annexes

- Annex 1 - Framework for this call
- Annex 2 - Explanation submitting a project idea
- Annex 3 - Criteria for detailed grant application
- Annex 4 - Important information for detailed grant application
- Annex 5 – Sate Aid - GBER

Annex 1 - Framework for this call

Without being exhaustive, this explanation provides a clearer picture of which types of research/projects do or do not fall within the scope of this funding round.

What fits within the Promising medicines for ME/CFS: call for drug repurposing:

- Clinical research on an existing drug for the treatment of ME/CFS, for which the drug is currently not registered.
- Clinical research on existing drugs that are no longer (or not) under patent (reference date: 1 January 2026). Under certain conditions, a patented drug may be included, provided that the patent is owned by the institution of the principal applicant. In all cases, the results of the research must be made available to Dutch society.
- The drug must be available in the Netherlands; this can include pharmacy preparations and imported drugs. If the drug under investigation is not yet registered as a medicine in the Netherlands, there must be sufficient guarantees that the drug will become available to Dutch patients after positive study results. This implies that sufficient data are available for registration and reimbursement, unless demonstrably not applicable.
- Clinical research on efficacy (possibly including dose optimization).
- Pharmacological follow-up research, such as expanding an ongoing drug study or platform trial with, for example, a new ME/CFS patient category or a new medicinal intervention for the benefit of ME/CFS patients.
- International studies are only permitted if the Dutch contribution is significant; the principal applicant and a substantial part of the research team must be affiliated with a Dutch institution. Patient inclusion and study execution must largely take place in the Netherlands. The study must clearly provide added value for Dutch ME/CFS patients.
- Studies for which it is evident that research will not be funded by private parties.

What does <u>not</u> fit within the Promising medicines for ME/CFS: call for drug repurposing:

- Preclinical research (including animal models).
- Research on new drugs.
- Research on drugs that are under patent by a party other than the institution of the principal applicant (reference date: 1 January 2026).
- Clinical research on supplements that do not fall under medicinal administration.
- Research on non-pharmacological interventions (such as medical devices).
- Research including a behavioral science intervention component (such as GET/CBT).
- Comparative research in which a drug intervention is compared with a non-drug intervention.
- The available funding for this round does not cover financing the translation of study results into registration. Where possible, it is intended that the trajectory towards registration for a drug for the new indication is taken over by or with other parties after efficacy has been demonstrated in the clinical validation study. Please NOTE: When choosing materials and methods for both the “proof of concept” study and the clinical validation study, alignment with follow-up research and/or a registration pathway must be considered.
- Drug rediscovery/repurposing projects for indications other than ME/CFS. For drug rediscovery projects for other indications, see: Drug Rediscovery 8 (in Dutch only).

Annex 2 - Explanation submitting a project idea

Points of attention when preparing and submitting the project idea

- The application for the project idea consists of two parts:
  - The fields to be completed in Mijn ZonMw; create the application and complete the mandatory fields. For the project idea, one optional annex containing figures and tables may be added, with a maximum length of 2 A4 pages. This annex is part of the assessment. Other annexes will not be included in the assessment.
  - For a project idea, submission of a signed hard copy is not required; digital submission via Mijn ZonMw is sufficient.
  - Write the application in English; applications written in Dutch will not be considered.

- To improve transparency in the reporting of (planned) research, please refer to the CONSORT-statement for the different types of research.
- On the ZonMw webpage Conditions and obligations information is provided on the METC/CCD, the Code of Transparency on Animal Testing, and the Biosecurity Code.
- Since 31 January 2022, the Clinical Trial Regulation (CTR) 536/2014 has been applicable, introducing new rules for medicinal product research in the European Union. The CCMO website provides all necessary information for researchers in a dedicated section on medicinal product research under the CTR. The Clinical Trial Decision Tool helps determine whether the medicinal product research falls within the scope of the CTR. The tool also indicates whether the study qualifies as a low-intervention clinical trial. For such studies, adapted rules apply, which may also affect the budget. More information on the Clinical Trial Decision Tool can be found on the CCMO website.
- The advice on the submitted project idea will include recommendations from the programme committee. We recommend carefully reviewing these recommendations and taking them into account when drafting the detailed grant application.

Annex 3 - Criteria for detailed grant application

It may be useful to already take into account the criteria for the detailed grant application when developing the project idea. The call text for the detailed grant application is leading when preparing a potential detailed grant application.

3.1 Relevance criteria for detailed grant application

Objective of the grant call
The detailed grant application describes how it aligns with the objective of the funding call. The objective of this funding call is to finance clinical research into promising medicines for ME/CFS patients in the Netherlands. This specifically concerns clinical research into existing medicines that contribute to an effective treatment for ME/CFS patients and that can be made available to ME/CFS patients in the Netherlands. This includes proof of concept (PoC) studies, clinical validation studies, and/or pharmacological follow-up research (see 'objective of the grant call'). Annex 1 specifies which applications do and do not fit within this grant call.

Contribution to programme objectives
The detailed grant application must fit within the programme objectives of the research programme ME/CFS (see: programme text). The final objective of the programme is to improve the health, the quality of life and the societal position of patients with ME/CFS. The subject of the grant application must fall within the framework (as set out in the programme text) of the ME/CFS research programme. Research that focuses on chronic fatigue resulting from diseases or conditions other than ME/CFS does not fall within this scope. Symptoms consistent with ME/CFS that arise from or are related to other comparable conditions (e.g. post-COVID) may only be investigated in relation to ME/CFS, for example by including a (post-COVID) control group.

Promising medicines
The project must investigate promising pharmacological treatments for ME/CFS. The promise of medicines is assessed on the basis of the scientific substantiation of the potential effectiveness of the product for the treatment of ME/CFS patients, the affordability and availability of the product in the Netherlands, and its alignment with patients' needs (see also the knowledge synthesis). In the detailed grant application, the promise of the medicine under investigation must be clearly described and sufficiently substantiated.

Added value
The grant proposal must demonstrate its added value in relation to existing knowledge and/or practice. It should also describe how this research relates to any completed or ongoing studies in the same field and what this project will add to them. The project may not duplicate previous or ongoing projects in the Netherlands or abroad, but it may build on earlier projects or align with ongoing projects in the Netherlands or internationally. In this context, alignment with promising international research directions is encouraged.

Participation of patients/experts by experience
Collaboration with patients/experts by experience within the project 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 from, collaborating with, and/or enabling stakeholders to (co-)decide in the development and implementation of the project and in the dissemination of its results. Experts by experience must be involved in the project at an early stage, with due consideration for their capacity and level of burden. The detailed grant application must clearly explain how ME/CFS patients and their representatives will participate in the project, specifying the phases involved and the manner of participation. The participatiematrix ('participation matrix', only available in Dutch) must be used for this purpose. Roles must be clearly described and delineated. In addition, the applicant must indicate how functional limitations of patients are taken into account. The submitted budget will also be assessed with regard to the participation of patients/experts by experience. A guideline (in Dutch) is available for completing the participation matrix. Also, the "Kickstarter for patient participation" of the Participatiekompas ('Participation Compass', only available in Dutch) provides practical guidance for researchers. Section 4.5 lists the contact details of patient organizations that may be approached.

Collaboration with consortia and other parties
All funded projects must become part of the existing research infrastructure established under the ME/CFS Research Programme. ZonMw therefore encourages projects to collaborate with one of the two existing consortia: The Netherlands ME/CFS Cohort and Biobank Consortium (NMCB) and the ME/CFS Lines Consortium. Collaboration with a consortium is not mandatory.

ZonMw encourages collaboration in the following areas:
- Harmonisation of patient intake;
- Harmonisation of data collection variables and protocols;
- Preservation of samples and data in the database and existing biobanks;
- Alignment of communication activities;
- Coordination of dissemination and implementation activities.

The detailed grant application should outline which parties will collaborate and how collaboration with the participating parties will contribute to these components.

The following forms of collaboration are considered important:
- Collaboration with one of the existing consortia funded under the ME/CFS research programme;
- Collaboration between hospitals, ME/CFS treatment centres, or independent healthcare professionals with expertise in ME/CFS;
- Collaboration with parties from the pharmaceutical industry, including drug manufacturers, pharmaceutical departments, and pharmacies;
- Collaboration with health insurers or policy bodies involved in market access and reimbursement of medicines;
- International collaboration, as research lines on ME/CFS have been developed abroad to which Dutch research can connect.

To strengthen support and thereby increase the likelihood that project results will be taken forward, it is important to involve relevant stakeholders and collaborative partners at an early stage.

Added value and feasibility for ME/CFS patients
The project must have added value for the patient. The detailed grant application must clearly describe how the medicinal product will be used, what burden is associated with its administration, and what the added value of the medicine is for patients with ME/CFS. In the assessment, attention will also be paid to the burden on patients resulting from participation in the study. Applications will be evaluated on whether the expected outcomes of the research sufficiently outweigh any potential lasting negative health effects of participation in the study. The detailed grant application must indicate how consideration is given, among other things, to the capacity and compensation of ME/CFS patients participating in the project.

Access to data
ZonMw encourages the optimal use of data. The detailed grant application will be assessed on how the FAIR principles are applied to the storage and accessibility of data and results. When planning and budgeting the project, due consideration should be given to the opportunities and requirements related to FAIR data & data management.

Follow-up
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 about Implementation support we explain what impact is, how we work to achieve and demonstrate it and what we expect from project managers. In this round, this will be assessed under the relevance criterion ‘follow-up’.

The detailed grant application should demonstrate a clear vision and ambition to move the research results forward to a next phase of research, development, and/or application in practice. When selecting materials and methods, consideration should be given to alignment with any follow-up research and/or a subsequent project.

Although both types of applications will be assessed against the relevance criterion ‘follow-up’, the evaluation of the detailed grant application under this criterion will take place in light of the type of

application. The results of a “proof of concept” study will be further removed from implementation in practice or registration of the product for the new indication than those of a clinical validation study.

Proof of concept (PoC) study: the detailed grant application should clearly describe how a follow-up study could build on the project. The application should clearly indicate the strategy that this follow-up study should pursue. It should also elaborate on how the results could be translated into practice after such a follow-up study.

Clinical validation study: the detailed grant application should clearly describe which strategy and activities are needed for translation and further implementation of the results into practice and/or policy. The detailed grant application should clearly indicate how the product will become available to patients in clinical practice after completion of the clinical validation study.

The grant application must respond to the combined advice of the CBG and ZIN and must substantiate why (parts of) this advice have or have not been incorporated into the detailed grant application.

Intellectual Property (IP)
A clear and feasible patent strategy increases the likelihood that the medicinal product can be successfully further developed and ultimately reach clinical practice. The current patent position of the medicine under investigation, as well as the possibility to carry out the project (freedom to operate), must be clearly described. Indicate whether the medicinal product under investigation and/or the new indication for this product is covered by a patent or whether a patent application is pending. Also state, where applicable, when the patent expires and who owns the underlying intellectual property and/or existing knowledge. **Please note**: projects in which the medicine under investigation is still under patent protection on 1 January 2026 are not eligible for funding.
In addition, describe which activities are planned or have already been undertaken with experts in the field of technology transfer, business development, valorisation, IP attorneys, and other relevant parties to develop an IP strategy.

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

3.2 Quality criteria for detailed grant application

Objective and research question/mission statement
The objective and research question should be described clearly resulting in a concrete and verifiable question that can be objectively assessed.

Action plan
In the detailed grant application, the selected methods and analyses must be described in detail, including their theoretical and/or empirical justification. This includes, among other things, a description of the patient population, the inclusion and exclusion criteria used, the investigational medicinal product and the comparator, the study design, the sample size calculation, the variables and hypothesis testing, and the statistical analyses.
The action plan provides a step-by-step description of the activities to be carried out and identifies the parties involved. The chosen methods and analyses are of optimal scientific and statistical quality and are described in a verifiable manner. It is explained why these particular methods and analyses are appropriate for addressing the research questions. The approach must be adequate to the research question or task.

Study population
In the application, the study population must be clearly delineated. When describing the study population, attention is paid to whether it adequately matches the research question, as well as to how it relates to the advantages and disadvantages of the various criteria by which ME/CFS is often defined (as described in Section 2.2.2 of the programme text). There are several conditions that show overlap with the symptom profile of ME/CFS. These include post-COVID, post–Q fever, chronic Lyme disease, and post-sepsis. Within this call, it is possible to include, in addition to ME/CFS patients, another patient group. The application must clearly describe how this group is defined and why it has been included in the study.

Identifying subgroups
ME/CFS is a multisystem disease. It is unlikely that a single intervention will be effective for the entire patient population. The heterogeneity in symptoms and presumed causes of ME/CFS makes it necessary to place sufficient emphasis on identifying subgroups of patients who may respond differently to therapies. The application must describe how these subgroup(s) will be identified and provide adequate justification for the selection of these subgroup(s).

Outcome measures
In the detailed grant application, the outcome measures that will be used in the study must be described and substantiated. It must be plausible that the choice of outcome measures aligns with the selected objectives and research questions. It is important that relevant, and where possible objective, outcome measures are used. In the application, the choice of subjective and objective outcome measures must be well substantiated.

Feasibility
The application must demonstrate that the applicant is able to achieve the intended research question or task within the planned timeframe using the available expertise, personnel, and facilities. The application should reflect on both facilitating and constraining factors. Particular attention must be paid to feasibility in terms of participant inclusion. ME/CFS patients are not always known to healthcare providers and may be more difficult to reach.
In addition, the researcher must reflect in the application on the practical feasibility of the investigational medicinal product. If the project focuses on intravenous treatments or the administration of potent immunosuppressive agents, the (practical) limitations must be sufficiently discussed in the application. A careful consideration must be given to the accessibility of bedridden patients, the required hospital support, and potential health risks. Account should also be taken of the duration and complexity of any required METC (Medical Ethics Review Committee) application.

Project group or person
The application should demonstrate how the composition of the project group contributes to the quality of the research. 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.

Annex 4 - Important information for detailed grant application

For a potential detailed grant application, it may be useful to already take into account the requirements for the detailed grant application when developing the project idea. The call text for the detailed grant application will be leading in due course, but please note that the detailed grant application may request the following attachments/information:

- **Patient inclusion:** the detailed grant application must include the following:
  - **Inclusion schedule:** demonstrating how many patients will be included per time period per centre (if applicable). It must be convincingly demonstrated (for example, based on pilot data and commitments from participating centres) that the intended inclusion targets and retention of participants in the study are feasible.
  - **CONSORT Flow Diagram:** including estimates of the number of patients who will be available for participation in the study, the number of patients who will meet the inclusion criteria, the number of patients who are expected to drop out of the study, and so forth. In the event of funding approval, this Flow Diagram will also form part of the monitoring of progress and final reports.

- **Collaboration:** the detailed grant application and the budget must clearly show:
  - Which parties are involved in the collaboration. For each party, describe how they actively contribute to the project; this includes, in any case, parties that appear in the budget as parties seeking to claim a share of the funding. Parties that actively contribute at their own expense and risk are also considered part of the collaboration.
  - With which party or parties a sponsorship agreement will be concluded and what the in-kind or financial contribution will be. The ZonMw webpage Grants and collaborative third-party contributions provides more information on the different forms of collaboration and contributions (sponsorship/commissioning), including sample agreements as support for drafting the relevant agreement and the conditions it must meet, as explained on that page.
    For questions about drafting an agreement with third parties, we refer you to the legal department or the valorisation department or Technology Transfer Office (TTO) of your organisation. ZonMw advises involving this department at the earliest possible stage of your application.
  - Which parties will be contracted (outsourced) or, if this is not yet known, for which activities it is anticipated that these will be carried out by third parties and the associated costs (including VAT).
    If a party is not included as a collaboration partner in the application but will carry out only a (small) part of the project, that party may be contracted. The application and budget must also clearly indicate - where outsourcing/commissioning applies - which parties are being contracted or, if not yet known, which activities are expected to be carried out by third parties and the associated costs (including VAT). Include these costs in the budget under 'other costs'. If patient inclusion via additional participating centres is arranged through contracting, the CCMO Model onderzoekscontract (Clinical Trial Agreement) for investigator-initiated research for use with a Declaration of Suitability of the Research Institution (VGO) may be used. For more information and the conditions for outsourcing/commissioning, see the ZonMw webpage Grants and collaborative third-party contributions.
  - **Participant declarations**: if applicable, commitments from participating centres/departments, preferably including the number of patients to be included.
  - **Signed commitments for co-financing and/or own contributions**: if applicable. Because ZonMw wants to be certain that collaborating parties/sponsors of a project have legally committed to the promised contribution, a Letter of Commitment per collaborating party/sponsor is mandatory when submitting the grant application. Use the example provided on the ZonMw webpage Grants and collaborative third-party contributions.
  - **Contact details** of the IP/Contract specialist of the organisation that is administratively responsible.

- **Budget**: A budget must be included in the detailed grant application. Several requirements apply to this budget.

- The indicative budget for a project ranges between €600,000 and €1,000,000 per project. Any deviation from this indicative amount must be substantiated in the application.
    - For the application, part of the project budget must be reserved for communication and implementation activities appropriate to the activities described in the implementation plan. A maximum of 10% applies. This must be clearly specified in the budget. Communication and implementation activities may be partly carried out via the affiliated consortium, if applicable. For these activities, the affiliated consortium may claim a portion of the project grant. These activities concern those organized or carried out at the consortium level, such as the use of a website, webinars, masterclasses, newsletters, and stakeholder meetings. In addition, a plan must be drawn up describing the project's communication and implementation activities. Communication activities may be used to involve stakeholders/patients or to inform them about the content and/or design of the research, or to disseminate knowledge and insights to relevant stakeholders. Implementation activities are aimed at further advancing knowledge and insights to relevant stakeholders who can contribute to taking the next step in the knowledge and innovation chain.
    - The budget must take into account the costs of FAIR data management. Examples include the deployment of a data steward, attendance at meetings on FAIR data, the preparation of FAIR Implementation Profiles (FIPs), or additional activities/services for FAIR data management. Provide a realistic budget with justification of the FAIR data management components. This cost tool for research data management may be helpful. FAIR data management activities may also be (partly) carried out via the consortium, if applicable. In that case, the affiliated consortium may claim a portion of the project grant for these activities. For more information, see the ZonMw page: Preparing for FAIR data management in research projects.
    - The budget must reserve funds for the participation of ME/CFS patients/experts by experience. The level of compensation must be determined in consultation with the involved patients/experts by experience. Where applicable, the project may make use of existing experiential expertise within the consortium. In that case, the consortium may claim a portion of the project grant.
    - Budget for Open Access**:** If the activities are carried out by a research organization, are non-economic in nature and therefore fall outside the scope of state aid law, and if publication takes place via the fully gold Open Access route, the costs for Open Access publications may be included in the project budget. This is permitted up to a maximum amount of €5,000. In the budget of the detailed grant application, 'Open Access' must then be included as a separate budget line. For more information on Open Access, see the ZonMw Open Access | ZonMw webpage.
    - Accountant's fees**:** Accountant's costs up to a maximum of €3,500 may be included in the budget for projects of €125,000 or more. Due to the amendment of the ZonMw General Grant Provisions as of 1 April 2022, for projects of €125,000 or more, an auditor's report must be submitted in addition to the final financial report upon completion of the project. Universities and university medical centers may not include accountant's costs in the budget. Separate arrangements have been made with these institutions regarding the required auditor's report. Please contact the financial department for this purpose.
- **Declaration of Agreement for Grant Submission:** The Declaration of Agreement for Grant Submission (in Dutch: Verklaring akkoord indienen subsidieaanvraag) must be signed by both the administrative responsible person and the principal applicant. The signed declaration can be uploaded to the application in Mijn ZonMw or sent by email to ZonMw. The declaration must be received no later than one week after submission.
- **In case of State Aid (AGVV):** The following documents must be attached when submitting the grant application:
    - Completed and signed declaration Declaration order for recovery of state aid (in Dutch).
    - Completed and signed declaration Declaration undertaking not in difficulty (in Dutch).
    - Completed and signed declaration Declaration on the accumulation of state aid (in Dutch).
- **SME Status:** When applying for the grant, it must be determined whether the applicant is a small or medium-sized enterprise. Therefore, the EU SME Assessment Wizard must be completed at the time of submission. The form may be generated no more than 14 days before submitting the application.

After potential approval of the project, it is essential to properly arrange a number of financial, legal, and logistical matters before the clinical part of the research can begin. This includes, among other things, METC approval under the European Clinical Trial Regulation (page in Dutch and English), a consortium and/or sponsor agreement outlining the arrangements between all consortium partners (or co-financier), as well as agreements with the party supplying the study medication. After project approval, ZonMw allocates 10% of the total requested amount to organize these preparatory matters. Once this preparatory phase is completed, subsequent project payments will be released.

Before the project start date, ZonMw requires a detailed data management plan. More information is available on the ZonMw page Everything about FAIR Data Management.

Annex 5 – State Aid – GBER

To qualify for a grant under the General Block Exemption Regulation (GBER), in addition to the substantive criteria of this call for grant applications, applicants must meet a number of specific requirements under the GBER. You can find these below.

- ZonMw will not award a grant if it is not sufficiently plausible that your application meets all the definitions and conditions of the GBER, or if – in the opinion of ZonMw – awarding the grant would lead to awarding state aid unlawfully within the meaning of Article 107 of the Treaty on the Functioning of the European Union (TFEU) [5].

- ZonMw will not award a grant if the date of commencement of the work on the project or the date of commencement of the activities is earlier than the date of submission of the grant application[6].

- ZonMw will not award a grant to undertakings against which a recovery order has been issued as a result of a previous decision by the European Commission declaring aid granted by the Netherlands to be unlawful and incompatible with the single market[7]. When submitting your grant application, please attach a completed and signed Declaration order for recovery of state aid (in Dutch).

- ZonMw will not award a grant to undertakings in difficulty[8]. When presenting your grant application, please attach a completed and signed Declaration undertaking not in difficulty.

- Accumulation of grants or other types of state aid for the same eligible costs (entirely the same or partly overlapping) may not result in exceeding the maximum aid intensity. If an administrative body or the European Commission has awarded a grant for the same eligible costs (entirely the same or partly overlapping), ZonMw will only award an amount such that the total amount of the grant does not exceed the amount that may be allocated based on the GBER[9]. When submitting your grant application, please attach a completed and signed Declaration on the accumulation of state aid.

[5] Section 1(5) GEBR
[6] Section 6 GEBR
[7] Section 1(4)(a) GEBR
[8] Section 1(4)(c) GEBR. Financial difficulty as referred to in Section 2(18) of the GBER
[9] Section 8 GEBR