COVID-19 BOTTOM-UP FOCUS AREAS 1 AND 2
Subjects: COVID-19, bottom-up call focus areas (FA)1 and 2 –full proposal phase

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Call for proposals: COVID-19 Bottom-up FA 1 and 2

Disclaimer
Please note: This document is a translation of the Dutch version of this document. In case of any differences or other inconsistencies between the Dutch text and the English translation, the Dutch text is legally binding and prevails.

AIM CALL FOR PROPOSALS – FULL PROPOSAL PHASE
On behalf of the Ministry of Health, Welfare and Sport (VWS) and together with the Dutch Research Council (NWO), ZonMw via the programme COVID-19 invites researchers to submit proposals for research addressing the effects of the measures against the coronavirus pandemic.¹

The programme has three key objectives:
- Contributions to controlling the coronavirus pandemic and preventing or reducing the negative effects of the measures taken against it. For example: helping people who have become ill, supporting vulnerable people in society who are affected by the measures, and describing the effect of redeploying care on other care needs;
- Generating new knowledge about the control of epidemics and pandemics; generating knowledge about diagnostics, treatment and prevention of COVID-19 and related diseases as well as the recovery from these. Knowledge also needs to be generated about logistics and supply lines for the materials and equipment required, data collection/analysis, modelling and technical possibilities to follow and predict the development of the pandemic;
- Generating knowledge about the (global) societal dynamics during and after this and comparable far-reaching health crises and the measures taken against these. This societal dynamic is not limited to within the Netherlands. Worldwide, the consequences of measures taken against the spread of the virus will be greater than the consequences of the actual virus.

These objectives have been summarised in three focus areas in the programme: Predictive diagnostics and treatment, Care and prevention and Societal dynamics. Collaboration between researchers, disciplines and relevant stakeholders is the starting point for efficiently obtaining these insights and realising a satisfactory preparation for a future pandemic.

This call for proposals is aimed at focus areas 1. Predictive diagnostics and treatment and 2. Care and prevention. Research within this funding call requires an interdisciplinary approach: besides medical- and care-related research, sustainable solutions can only be achieved in collaboration with the engineering, physical, natural and social sciences and the humanities. For example, smart (key) technologies and artificial intelligence can contribute to the focus areas of the programme.

Focus area 1. Predictive diagnostics and treatment
The aim of this focus area is to provide knowledge for the (further) development of (predictive) diagnostics for the prevention and individualised treatment of COVID-19-related symptoms in the early, acute and recovery phases. It concerns research into new or existing therapies and their working mechanisms and obtaining insight into, amongst other things, the microbiome, immunity, predictive parameters and individualised treatment.
The focus area has four themes:
1. Treatment
2. Diagnostics of infection
3. Risk analysis and prognostics
4. Virus, immunity, immune response and pathogenesis. Within this theme, contributions to animal-free innovations can also be made.
The themes are further elaborated in Annex 1 and Annex 1a of this call for proposals.

Focus area 2: Care and prevention
The aim is to make urgent research within three themes directly possible and to initiate this:
1. Organisation of care and prevention
2. Care and prevention for vulnerable citizens
3. Transmission and epidemiology

Various types of research are possible: evaluation trajectories, action research, effect studies, facilitation pathways, efficacy research in the event of postponing treatment/care avoidance, organisation of care issues, development of epidemiological models and inventories. The emphasis must be on obtaining insights and lessons learned that contribute to an improved, substantiated approach towards the current pandemic and to the safeguarding of these improved approaches and processes in the care system of the future. The themes are further elaborated in Annex 2 of this call for proposals.

Who can apply
If your project idea received a positive advice for elaboration in the bottom-up round focus areas 1 and 2 of the COVID-19 programme, then you can submit a full proposal. For this you should make use of ProjectNet. If you decide to submit a full proposal, despite a negative advice, then you should inform ZonMw about this in advance by email. You can do this until 10 June 2020 (12:00 hours CEST) at the latest.

Research organisations and other entities registered in the Netherlands, such as UMCs, non-academic hospitals, universities, universities of applied sciences, “practoraten” (knowledge platforms in vocational (mbo) education), care organisations, research institutes, consultancy bureaus, umbrella organisations, professional organisations and patient organisations can submit a full proposal.

A knowledge-chain-wide approach and collaboration between disciplines and with relevant stakeholders must be the starting point. This also includes patients and/or target group representation. This may be deviated from if motivated reasons are given.

To safeguard the research results for the future and increase their chances of being applied outside of the original research consortium, the full proposals will be assessed for the composition of the collaboration. The collaboration can include, for example, researchers, policymakers, professional practitioners, patients, end-users and educational institutions. In particular, the collaboration between (care) researchers in the area of people, environment and public-private partnership, national or international collaboration and collaboration from different research fields or between different educational levels (vocational education (mbo), higher vocational education (hbo) and university education (wo)) facilitates broader implementation. Please explain the added value of the collaboration in your pre-proposal.

To be eligible for funding, organisations that realise both a statutory duty as well as economic activities (in the context of the EU state support law) should state that they are carrying out the funded activities in the context of their statutory task (and so not as an economic activity).

Which amount can be applied for
For focus area 1. Predictive diagnostics and treatment, a maximum of €8.5 million is available (€2 million of this is allocated for clinical drug studies and €1.5 million for animal-free innovations). For focus area 2. Care and prevention, a maximum of €6.5 million is available.

Per project, a maximum of €0.5 million is available. The budget should be realistic and well motivated. Co-funding is possible and desirable for certain types of project.

Different frameworks can apply per focus area; for these, please see the annexes per focus area.

The intended maximum duration of the project is 24 months. In certain cases, this can be deviated from, but a thorough motivation should be provided for that.

Assessment criteria
Selection committees per focus area will assess the relevance, quality and budget of all full proposals. The applicable relevance, general and quality criteria are stated below.

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2Economic activities entail offering a product or service in the market. Organisations that realise economic activities are considered to be a business with regard to these activities in the sense of EU law on state support.
For the weighing of relevance and quality, we refer you to the annexes per focus area (Annex 1 and Annex 2).

The committee is responsible for a balanced spread of grants across the different themes within the focus area. This could mean that a high-scoring full proposal is not awarded funding for a theme where several pre-proposals are submitted in favour of a lower scoring full proposal from a different theme.

In the case of full proposals with equal scores for relevance and quality, the ideas will be further ranked on the basis of geographical allocation of the proposed projects within the Netherlands.

**Relevance criteria**

**Call-specific criteria**

1. This programme intends to have an impact on the progress of this pandemic and the consequences of this for the Dutch population and society. You should therefore make it clear what the impact of applying the results from your project will be and when the application of the results will be effective in relation to this pandemic.
2. The proposal must make it clear that the Netherlands has a unique position to do this research. In other words, this is research for which the Netherlands can provide added value to what is already being done internationally.
3. The research is not already taking place elsewhere. For all subjects, the added value compared to research funded already or research awarded funding elsewhere must be convincingly stated.
4. The proposal should make it clear that public funding is indicated/necessary.
5. Safeguarding: it must be possible to use the developed structure/intervention/knowledge again in the future.
6. Scalability: the developed structure/intervention/knowledge must be applicable at both a regional and national level.
7. Collaboration: a knowledge-chain-wide approach and collaboration between disciplines and with relevant stakeholders is the starting point for the proposal. This also includes patients and/or target group representation. This may be deviated from if motivated reasons are given.
8. Added value: the contribution of the project for the discipline(s) concerned, stakeholders and target groups must be clearly described in relevant terms and must be demonstrable. Possible examples of this are health gain, reduced suffering, improved accessibility and processes.
9. Society and economy: the effect of the project on the societal and economic issues that the COVID-19 pandemic elicits, must be made clear.
10. **Please note:** For grant applications where the applicants have stated that they want to be considered for the earmarked MKMD budget for Animal-Free Innovations, additional relevance criteria apply (see Annex 1a). Please also see the for these grant applications modified and compulsory application form (in Dutch).

**General ZonMw criteria**

Where applicable, you should also devote attention to the following aspects:

- **Diversity**
  
  ZonMw and NWO consider attention for the diversity of people in research to be important. The pandemic has different consequences for men and women and for different age groups. There are strong indications that this has both biological and sociocultural causes. In addition, the consequences are different for different socioeconomic or cultural groups due to differences in lifestyle, positions, roles and tasks in society (see, for example, this Lancet article). In all projects – if relevant – attention will be requested for the diversity of target groups. This means that in the design, realisation, analysis and reporting of results, applicants must make a distinction between men and women and other relevant subgroups on the basis of diversity. ZonMw requests applicants to provide a clear description of how they will deal with the diversity of people in various

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3For more information on how to make your application more sex and gender sensitive, we invite you to take note of the general resources provided on these websites: https://genderedinnovations.stanford.edu/methods/health.html, http://www.cihr-irsc.gc.ca/e/32019.html. The CIHR-Institute of Gender and Health have also developed a specific guide for researchers why sex and gender need to be considered in COVID-19 research: https://cihr-irsc.gc.ca/e/51939.html
phases of the research. If diversity is not relevant for the proposed research, then the reasons for this must be motivated. At www.zonmw.nl/faqgender(only available in Dutch) more information is provided and resources can be found about how sex and gender can be properly integrated in research.

- **Application of ICT and e-Health**
  ZonMw has a broad view on the use of ICT in care. We understand this to be the use of e-Health applications, domotics, robotics, but also the storage of data with the help of ICT. We have formulated points of attention for ICT applications and ICT standards in research.

- **Education**
  Knowledge is mainly applicable and applied in education if it has been realised in an interaction between research, education and professional practice. How do you give shape and content to the interaction between education, research, professional practice and policy? Which results is your project or research expected to provide for professionals in the field of prevention, welfare and health?

- **The participation of patients and/or end-users**
  ZonMw strives to involve stakeholders in the project, including the final target group that, or end-user who, has “experience-based expertise”. In concrete terms, we understand the term “involve” to mean consulting with, obtaining advice from, or collaborating with stakeholders and/or allowing them to (co-)decide in the projects. How do these stakeholders already play a role during the project or research?

More information about relevant criteria can be found at https://www.zonmw.nl/en/news-and-funding/funding/relevance-criteria/

**Quality criteria**

- **Objective and problem or mission**
  Proposals will be assessed for clarity, scope and overlap with research that is already taking place or has already been funded. The objective is formulated in a SMART (specific, measurable, acceptable, realistic and time-limited) manner. State in concrete terms what the intended outcomes are and for whom these are intended.

- **Action plan**
  The action plan follows on from the objective. It provides a description of the methods and analyses chosen, including the theoretical and/or empirical motivation. A power calculation should be added, if applicable.

- **Feasibility**
  A competent research group is available that can start the project within several weeks after granting and the project must be feasible in the current pandemic situation. It must be likely that the aim of the proposal will be achieved within the time set with the available expertise, human resources, facilities and resources. A recruitment strategy must be described if the inclusion of patients/participants. You should also provide a timetable for this.

- **Project group**
  In the project group, relevant disciplines and intended target groups are represented.

  **Please note:** For grant applications where the applicants have stated that they want to be considered for the earmarked MKMD budget for Animal-Free Innovations, a slightly modified format and formulation for the quality and relevance criteria applies. For this, please see the modified and compulsory application form (in Dutch).

More information about these criteria can be found in the procedure booklet (in Dutch) and on our [website](#).

**CONDITIONS**

**Open Science**

ZonMw and NWO pursue a policy to encourage Open Science. They have signed the international statement to make research results and data public as fast as possible in the fight against COVID-19. Furthermore, research results, research data and measurement and analysis methods that are
produced within this programme should be shared in line with the [Joint statement on sharing research data and findings relevant to the novel coronavirus (nCoV) outbreak](https://www.zonmw.nl).

**FAIR data**

The web page [Open Science in COVID-19 research](https://open.science/p/COVID-19) provides an explanation about what can be done in projects to make data reusable and FAIR. Several options are possible. The starting point is that applicants together with a data steward (or other data expert) determine what is most appropriate within the project. We advise you to involve your data steward/expert at an early stage in your proposal. ZonMw will organise webinars for data stewards/experts to inform them about the approach of FAIR data management and COVID-19 research. They can register for this via covid19@zonmw.nl

ZonMw has eight instructions for Open Science and FAIR data. Four of the eight apply to the full proposal. Applicants can answer these by means of a form that must be submitted together with the full proposal. Your grant application is only admissible if you have fully completed the form. After granting, ZonMw will contact successful applicants to make further agreements about the application of COVID-19 specific FAIR data standards and the like.

No data management plan needs to be supplied during the full proposal phase. That is only required after granting, but before the start of the research project.

**Open Access publishing**

Within this funding call, ZonMw requires researchers to make all publications emerging from scientific research that is partly or entirely funded by ZonMw immediately available (without embargo) in Open Access form with an open licence.

In this manner, we will share all new knowledge that can contribute to the improvement of public health with respect to COVID-19 as quickly as possible.

You can include the costs for full golden open access publications in the project budget (up to a maximum amount of €5000, specify with “Open Access”) in so far as this is permitted on the basis of European and other legislation. The Open Access journal platform should be registered in the [Directory of Open Access Journals](https://doaj.org). You should mail ZonMw a proof of payment (Article Processing Charges) via openscience@zonmw.nl. Immediate Open Access publication via other routes is also permitted but ZonMw does not make any funding available for this. For questions and more information please contact the Open Access team via openscience@zonmw.nl.

**State aid regulation**

For this call for proposals, no funding will be granted if that leads or can lead to the provision of unlawful state support. This means that ZonMw will assess the submission against the relevant prevailing laws and legislation.

ZonMw reserves the right, in view of the unusual circumstances under which this call for proposals is being published, to modify the conditions of the call text while the call is open. Any changes will be published via the usual channels and all applicants who have already submitted a proposal will be informed about these changes. Additions and changes submitted before the close of the submission period will count towards the assessment of the proposal. You should take into account possible changes to the exemption decision Services of General Economic Interest, General Block Exemption Regulation or the Amendment to the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak from the European Commission and the requirements and consequences associated with these. That could even mean that for certain applications you will need to realise a cash or in-kind contribution of 20%.

If licensing will be part of the project, the most recent requirements have been included from the agreements emerging from the trajectory concerning [Socially Responsible Licensing](https://www.zonmw.nl). Thereby due consideration should be given to the aim of this commission which is aimed at facilitating a rapid and broad application of the results in the Netherlands.

For further information, please see Annex 4.
Consortium and/or sponsor agreement
If there are several project partners, then a final draft of the consortium agreement (approved by all project partners but not yet signed) is required after your project proposal has received a grant. ZonMw will assess and approve the agreements made for compliance with the relevant European law concerning state support and the ZonMw General Terms and Conditions Governing Grants. In this consortium agreement, you should at least specify all items as described under the legal aspects for collaboration on the ZonMw website and in the General Terms and Conditions Governing Grants of ZonMw. A skeleton agreement that you can use for this can be found here as well. We advise you to use this skeleton agreement to speed up the assessment of your agreement.

Sponsoring from a third party is permitted under the condition that there is a thorough sponsor agreement in which the role, involvement, possible licence agreements, intellectual property (IP) regulations pertaining to foreground and background knowledge, and financial obligations of the co-funding partner(s) are described.

ZonMw retains the right to revoke the granting decision if the consortium agreement and/or sponsor agreement (proof of co-funding) have not been realised or are not acceptable under the European law for state support and/or the General Terms and Conditions Governing Grants of ZonMw.

If you have any questions about this, then please contact your IP, contract and/or legal adviser from the valorisation department of your organisation or the technology transfer office (TTO). ZonMw advises you to involve your IP, contract or legal specialist in your proposal as early as possible.

See annex 4 for more information.
PROCEDURE & TIMETABLE

When you write the full proposal, please bear in mind the following points:

- By **10 June** at the latest you should submit the definite list of project group members via covid19@zonmw.nl. For this you should use the Excel template sent with the email about the positive advice.
- Write your full proposal briefly and concisely in Dutch or English. The guideline is approximately 8 pages of text (A maximum 8 pages A4 for the proposal, including references and excluding the front page with general information - font type Arial 10 pts).
- The **General Terms and Conditions Governing Grants of ZonMw apply**. On the conditions and funding page of the ZonMw website information about the medical research ethics committees (MERC) / Central Animal Testing Committee (Dutch acronym CCD), Code for Transparency in Animal Testing and the Code Biosecurity can be found.
- In the full proposal, you are required to submit a detailed budget together with a justification of the budget as an annex.
  - Make it clear which organisations will realise which activities for which amount. You should preferably state work packages.
  - Costs incurred before granting of the budget can only be remunerated from 1 March 2020 onwards and only if a clear motivation is given.
  - The grant budget requested from ZonMw may be no more than 15% higher than the amount requested in the project idea, and with this the maximum amount that can be applied for is still €500,000.
  - Reserve at least 5% of your project budget for communication and implementation. Include this amount in your budget.
  - With respect to costs for Open Access publications; see section about Open Access above.
  - In the budget, include the (estimated) costs for data stewardship and - if applicable - the use of data services and extra infrastructure during the project. For this you should involve a data steward/expert from your institute who is informed about the approach in this funding call. If it is not possible to estimate the costs, then enter 5% of your project budget for this.
  - If applicable, you should submit quotations for products and services to be purchased in order to substantiate the budget.
  - In case of co-funding, you should submit a letter of commitment, preferably as an annex to your application, yet no later than 29 June 2020 in an email to covid19@zonmw.nl, stating the focus area and project number. For more information please see Annex 4.
  - If your full proposal has previously been submitted elsewhere as a proposal, then you can add the previous proposal and (if it was rejected) the possible comments from referees as an annex.

The applicant must submit the compulsory annex(es):

- Application form
- Budget
- Explanation of the budget
- Response to comments in email with positive advice.
- FAIR data form

For further information please see “Annex 3 Explanation of full proposal submission” at the end of this call text.

In addition, you may submit annexes to provide clarification. However, you still need to enter all the details in ProjectNet, and your full proposal must still be clear and complete also without the optional annexes.

**Assessment procedure**

For the information about the procedures for assessing proposals, we refer you to the information on our website and in the procedure brochure applicants (only available in Dutch). You should also read the section about assessment criteria.

Due to the high urgency of the subject, this programme will work with adjustments to the standard ZonMw procedures. This is because ZonMw, in view of the preamble of the General Terms and
Conditions Governing Grants of ZonMw, can deviate from the granting conditions if there are compelling reasons to do so. The deviations will be made known in this call text. Furthermore, individual deviations from the General Terms and Conditions Governing Grants of ZonMw can also be described in the granting decision. In doing so, the safeguarding of due diligence, the Code for Dealing with Personal Interests and the prevailing legislation will nevertheless remain paramount. By submitting, the applicant agrees with the modified procedures described in the call.

1. This call was opened for pre-proposals with a clear thematic demarcation (for this, see annexes 1 and 2).
2. From the pre-proposal submitted, the selection committees selected the proposals with the highest chance of being awarded funding, based on the criteria formulated in advance, and have issued an advice as to whether the researchers can elaborate their idea into a full proposal.
3. ZonMw translated this advice into a positive advice for the selected applicants to elaborate the pre-proposal and a negative advice for all other applicants. A negative advice has not been motivated in the guidance letter (with the exception of negative recommendations from the sub-subject Animal-Free Innovations; these are motivated).
4. ZonMw retains the right to ask applicants with similar pre-proposals, which in the opinion of the selection committee aim to realise the same objective, to jointly submit a full proposal.
5. In the case of a positive advice, the applicant can submit a full proposal, based on this call.
6. The process of involving referees will be replaced by the COVID-19 committee members making an initial assessment of all full proposals. Questions arising from this assessment will be submitted with a very short lead time for written or verbal rebuttal to the applicants.
7. During the committee meeting, the full proposal will be assessed for relevance, feasibility and quality, with due consideration to the rebuttal. If the budget available for the focus area is not sufficient to award funding to all eligible proposals, then the committee will produce a ranking proposal based on the criteria formulated in advance.
8. The committee will advise the ZonMw board about the full proposals to be awarded funding.
9. The ZonMw Board will take the granting decision.

Timetable

<table>
<thead>
<tr>
<th>Event</th>
<th>Date/Time</th>
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<tbody>
<tr>
<td>Pass on names of project group members to <a href="mailto:covid19@zonmw.nl">covid19@zonmw.nl</a></td>
<td>10 June</td>
</tr>
<tr>
<td>Deadline submission full proposal</td>
<td>15 June, 14:00 hours</td>
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<tr>
<td>Receipt comments from referees</td>
<td>22 June</td>
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<tr>
<td>Deadline submission rebuttal</td>
<td>24 June 12:00 hours</td>
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<tr>
<td>Decision</td>
<td>Mid-July 2020</td>
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<tr>
<td>Latest starting date</td>
<td>3 weeks after decision</td>
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More information:
Please keep an eye on the regularly updated page about research into COVID-19 on the ZonMw website.

SUBMISSION

Submission (via ProjectNet)
Full proposals can only be submitted via the online submission system of ZonMw (ProjectNet) and in accordance with the guidelines. Please use the application form for your application and add the form as a PDF file as an annex in ProjectNet.

TIPS
- If you have not previously worked with ProjectNet, then you first need to register as a “New user”. See the manual for instructions about making an account.
- For further information, please see the explanations in ProjectNet and Annex 3 of this document.
Before you upload your final application as a PDF file, we advise you to check this for irregularities. During the conversion of a Word document to a PDF file, figures and/or some punctuation marks and symbols are not always converted properly.

**Statement of consent submission full proposal**

Immediately after the digital submission of the full proposal, you will be referred to the form “Statement of approval submission of application”. Even if you have already submitted this with the project idea, you must submit this again. Digital signatures are accepted. You are kindly requested to enter the following details on this:
- the name,
- Dutch Chamber of Commerce number,
- signature of the responsible administrative body,
- signature of the main applicant

This completed statement of approval should be mailed within 1 week after submitting the application form to covid19@zonmw.nl, stating the submission number that you were allocated.

**Substantive questions**

For substantive questions please contact: covid19@zonmw.nl or +31 70 515 03 13. State the focus area and theme. We will then answer your question via email or we will phone you. In the mail, state which telephone number you can be reached on and when you would like us to phone you back.

**Technical questions**

For technical questions about the use of the online submission system of ZonMw (ProjectNet) you can contact the service desk: Monday to Friday from 08.00 to 17.00 hours CET: +31 70 349 5178, projectnet@zonmw.nl. In the email, please state your telephone number so that we can call you back if necessary. See also www.zonmw.nl/faqcovid (Dutch version; English version will follow)

**Downloads and links:**

Before you complete the forms, please see Annex 3.
- Grant rules
- Procedurebrochure applicants (only available in Dutch) See also the information on our website: https://www.zonmw.nl/en/news-and-funding/funding/procedure/
- The application form
- Budget
- FAIR data form

**Annexes call for proposals**

- Annex 1 Themes and criteria predictive diagnostics and treatment
- Annex 1a More Knowledge with Fewer Animals
- Annex 2 Themes and criteria Care and prevention
- Annex 3 Explanation of full proposal submission
- Annex 4 Legal aspects of collaboration
Annex 1. Predictive diagnostics and treatment

The aim of this focus area is to provide knowledge for the (further) development of (predictive) diagnostics for the prevention and individualised treatment of COVID-19-related symptoms in the early, acute and recovery phases. It concerns research that is urgently needed into new or existing therapies and their modes of action, and on obtaining insight into, amongst other things, the microbiome, immunity, predictive parameters and individualised treatment.

You should clearly state that there is currently no other research aimed at the same problem. Furthermore, you should make it clear what your proposal adds to current initiatives and studies.

Budget focus area 1
Which amount can be applied for
Please see the section on page 2 of this call.
The intended maximum duration of the project is 24 months. This can be deviated from if a good motivation is provided.

Description themes and criteria
Line 1 of the COVID-19 Programme focuses on predictive diagnostics and treatment. The development of a new vaccine will not be eligible within the programme. Research into the reuse of existing vaccines is, however, appropriate.
In this focus area, a separate budget has been allocated for animal-free innovations, see Annex 1a.

This focus area contains the following overarching themes:

1. Treatment

Research in this theme must contribute to at least one of the following objectives:
- Optimising the (prophylactic) treatment of patients in the early or acute phase in hospitals, nursing homes and primary care.
- Optimising care at intensive care (IC) departments for both patients and professionals, reducing post-IC issues.

The following requirements apply to clinical studies:
The following types of investigator-initiated studies are eligible for funding:

A. RCT (phase 3 type study) with insufficient financial coverage for the complete realisation, urgent additional research questions, increasing the number of participating centres and/or expanding the patient population. For such studies, a mode of action and proof-of-concept data are already known and substantiated. For type A studies, a condition is that the study makes use of the REMAP-CAP platform. The contact person for this is Dr Lennie Derde, email address: l.p.g.derde@umcutrecht.nl. Read more information about this platform. As a result of this, the central coordination of COVID-19 treatment trials will be safeguarded, which also includes central MERC approval, data collection, harmonisation of data and protocols, data analysis, alignment with international initiatives and optimum inclusion allocation of patients. Independent phase 3 clinical studies will not be funded in this trajectory. An exception to this can be made if the study has already started, with a clear substantiation, and it is clear how the data will be shared. A total of €2 million has been reserved for this type of study.

B. Small-scale proof-of-concept studies (phase 1 or 2a type) for new treatment options. For type B studies, a drug for which a mode of action has already been described will be investigated in a limited group of COVID-19 patients so that sufficient indications can be obtained of a positive treatment effect, with enough starting points and preparation for a later randomised evaluation of clinical efficacy. For the programme elements in which a licence is needed, the most recent requirements have been included from the agreements emerging from the trajectory concerning Socially Responsible Licensing.
2. **Diagnostics of infection**

Research in this theme must contribute to at least one of the following objectives:
- Insights in the correlation between diagnostic tests and clinical protection for the purpose of surveillance and obtaining insight into the degree of group immunity;
- Development of strategies with respect to the proper use of diagnostic tests.

This concerns fully developed tests that are deployed for test characteristics in practice and clinically relevant outcomes.

Not appropriate: development and validation of diagnostic tests.

3. **Risk analysis and prognostics**

Research in this theme must contribute to at least one of the following objectives:
- Urgently needed and practically applicable knowledge that is necessary to support the medical action perspective;
- Making urgently needed and practically applicable knowledge available that is required to support choices in policy and practice concerning restrictive measures.

This theme focuses on answering urgent research questions at both the patient and population levels. Answering these questions requires data from case histories and physical examinations, questionnaires, observational studies and clinical research as well as material from biobanks and imaging data. Artificial intelligence (machine learning) will play an important role in developing new predictive diagnostics and prognostics. That requires access to high-quality observational data. For this, the requirements concerning FAIR data will be emphatically tested as described in Section 6 of the call text.

4. **Virus, immunity, immune response and pathogenesis**

Research in this theme must contribute to at least one of the following objectives:
- Making knowledge and models available of the pathophysiology and pathogenesis of the virus in interaction with the human body for the various populations (gender, age, et cetera), which during the pandemic is vitally important for supporting the medical action perspective and/or policy formulation, for example in relation to restrictive measures;
- Making knowledge and models available about the underlying mechanisms of the disease progression and, in doing so, providing possible intervention points for treatment and predictive diagnostics (for example, biomarkers, virus interference);
- Development of animal-free innovations to support the treatment of predictive diagnostics (for this aspect separate budget is available with specific criteria (see Annex 1a)).

**Ranking of research proposals**

The final ranking of the proposals (with respect to quality and relevance) takes place with the help of the matrix below. In the matrix, relevance carries a heavier weighting than quality. However, only proposals with a quality of good or higher are eligible for funding.

<table>
<thead>
<tr>
<th>Quality</th>
<th>Relevance</th>
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<th>Relevant</th>
<th>Low relevance</th>
</tr>
</thead>
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</tr>
<tr>
<td>Moderate</td>
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</tr>
<tr>
<td>Unsatisfactory</td>
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</tr>
</tbody>
</table>
Annex 1a. More Knowledge with Fewer Animals

Programme More Knowledge with Fewer Animals (Dutch acronym MKMD) and COVID-19
The programme MKMD aims to develop new innovation in animal-free testing and to encourage the use of existing animal-free innovations. In the area of safety and risk assessments, MKMD also contributes to new methods or models. The ultimate aim is more relevant health(care) research for humans.

By contributing to the COVID-19 funding programme, MKMD wants to encourage the development of animal-free innovations with impact in this research area because, amongst other things, it is often difficult to translate the results from animal models to humans. In the area of theme 4 Virus, immunity, immune response and pathogenesis, we see opportunities to make a contribution to the development of the new or wider application of existing animal-free innovations. Through encouraging animal-free innovations within theme 4, we intend to boost the development of better translatable and more relevant models for humans.

The Dutch Society for the Replacement of Animal Testing (Dutch: Stichting Proefdiervrij) is co-funder of this animal-free testing module within this call for proposals and is making €500,000 available for this.

General boundary conditions for this earmarked budget

- The project is aimed at developing or applying animal-free testing methods and/or models for COVID-19 research;
- The project also satisfies the conditions stated and criteria described above in theme 4 Virus, immunity, immune response and pathogenesis;
- The impact of the project on the use of animal models will be substantiated. The application explicitly states which impact will be achieved with the technique/model and/or service;
- The innovative methodologies are based on human body material (tissues, cell lines or human data);
- The use of laboratory animals, other animals or animal material is not permitted. Although it is not compulsory, use should preferably not be made of foetal bovine serum (FBS) or foetal calf serum (FCS);
- Collaboration between relevant stakeholders: Public-private partnerships (PPPs) are recommended but are not obliged. In the case of projects with equal ranking in the selection procedure, preference will be given to a PPP;
- The involvement of legislative bodies is recommended, if applicable.
- Use the modified application form (in Dutch) to submit a full proposal.

If a project is awarded funding, then ZonMw requires the project leaders to cooperate with several visits from employees (and possibly donors) from the Dutch Society for the Replacement of Animal Testing for communication purposes. The Dutch Society for the Replacement of Animal Testing will directly contact the grant recipient concerning publicity in the public domain.

Ranking of research proposals
Same as for focus area 1. Please see Annex 1.

For questions about this element, please contact the programme team via: MKMD@zonmw.nl.
Website: https://www.zonmw.nl/mkmd (English).
Annex 2. Care and prevention

The focus area Care and prevention concerns the following themes:

1. Organisation of care and prevention
2. Care and prevention for vulnerable citizens
3. Transmission and epidemiology

The aim is to make urgent research within three themes directly possible and to initiate this. Various types of research are possible: evaluation pathways, action research, effect studies, facilitation pathways, efficacy research in the case of postponement of treatment/avoidance of care, organisation of care issues, development of epidemiological models, and inventories.

The emphasis must be on obtaining insights and lessons learned that contribute to an improved, substantiated approach towards the current pandemic and to the safeguarding of these improved approaches and processes in the care system of the future.

Collaboration between researchers, disciplines and relevant stakeholders is the starting point for efficiently obtaining these insights and realising a satisfactory preparation for a future pandemic.

THEMES
Activities for which funding can be requested must fit within the themes stated below:

I. Organisation of care and prevention
COVID-19 has an impact on the entire care system: it touches upon the entire care pathway from healthy citizen to patient and vice versa. All sectors in healthcare experience the effects of this: citizens/patients as well as care providers and the actual organisations. This theme therefore focuses on all these sectors. So not just (acute or postponed) hospital care, but also prevention, disabled care, home care, paramedical care, youth (health) care, elderly care, nursing home care, GP care, mental healthcare or palliative care. Where possible, the knowledge-chain-wide approach is desirable. How can these sectors learn from each other, align with each other better and collaborate better during and after the crisis situation? At the same time, certain developments require a specific, sector-specific approach.

The subjects that proposals can be submitted for are:

- **National and regional collaboration:**
  Positive learning effects of existing and initiated collaborations during the crisis situation. Insights into who, or what, ensures coherency and the conditions both within the acute and non-acute care chains and between both chains.

- **Remote care and prevention:**
  Further development and evaluation of e-Health for quality, effectiveness, risks and applicability: integration of telemonitoring (including self-monitoring) in remote prevention, treatment and supervision (in the various forms of care) for both the citizen/patient and the care professional.

- **Care for care professionals:**
  Further development of instruments to support personnel both professionally and psychosocially, during and after the national health crises. In addition, insights into the effect of modified working methods to prevent infection for personnel and organisation.

- **Effects of pandemic and measures:**
  Provide insight into (in)direct effects of the pandemic and measures on care and prevention. Possible directions are effects and size of postponed care, care avoiders, appropriate care and care that has been postponed or modified due to the redeployment of care or preventative measures. It is also aimed at issues such as quality of life versus quality of care and the relationship between informal and formal care.

- **Aftercare for coronavirus patients and their family:**
  Support of coronavirus patients and their family after recovery, but also towards the palliative phase and bereavement care.

II. Care and prevention for vulnerable citizens
Vulnerable citizens are citizens with limited health skills or physical or psychological conditions. They are affected more than others by the COVID-19 pandemic and the consequences of the measures taken.
It could concern mental consequences as well as risks in the vulnerable home situation, both in the short and longer term. Consequences that could be investigated are: no visiting arrangements in nursing homes (including arrangements for people in the palliative phase), changes in the care or support at mental health care institutions, youth (health) care, institutions for people with a physical and/or mental disability, for elderly people living at home, and the increased risk for people with lung conditions or young people who are growing up in poverty or an unsafe home situation. Loss of necessary care from the medical crèche, special education, day activities centre, home care and outpatient support.

The subjects that proposals can be submitted for are:

- **Groups with a direct increased risk and vulnerability:**
  Providing insight into the direct negative effects of preventive measures and preventing or reducing negative effects of the measures among increased risk groups due to a condition or limitation or the severe progress of the COVID-19 disease and/or increased sensitivity for the effects of the measures against COVID-19.

- **Freedom-restricting measures in intramural and extramural settings:**
  Providing insights into dealing with the effect of freedom-restricting measures in terms of quality of life and quality of care for both the citizen/patient and the care professional. This concerns nursing home care, care for the handicapped, mental health care, psychiatry, secure institutions for young people and extramural palliative care. The danger of loneliness and lack of social interaction, also in the home situation, such as for elderly people and young adults.

- **Medium- and long-term effects:**
  Effects of the measures for young people and vulnerable families. Risk of an increase in social inequality and physical and psychosocial health.

- **Medical ethical issues:**
  Access to care for vulnerable groups in the case of capacity issues, allocation systematics and issues concerning personal protective equipment (such as facemasks) and measures.

### III. Transmission and epidemiology

Insights into epidemiology and transmission and the effect of the measures taken are needed to predict the progress of the COVID-19 pandemic and decisions about which measures to support. For this, further research is needed into transmission routes as well as studies into behaviour and to what extent different population groups adhere to the measures.

The subjects that proposals can be submitted for are:

- **Spread of the virus in the most affected areas or population groups:**
  How to facilitate infection-avoiding behaviour, how much transmission occurs from asymptomatic cases, estimating import from abroad, risk estimates for groups?

- **Feasibility, effect and efficacy of various measures:**
  Feasibility, effect and efficacy of public measures and specific, organisational measures in practice, including source and contact research into the progress of infections. Estimating the effects of measures on disease burden in terms of quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs). This also includes comparisons of the efficacy of measures between countries and regions.

- **Role of and prevention of underlying conditions on the COVID-19 pandemic:**
  Research into the role of underlying conditions on the COVID-19 pandemic, and also research into the potential gain due to primary prevention (healthy lifestyle) and effect on the progress of virus infections and pandemic.

- **Improvements in the following of measures and/or compliance:**
  How can adherence to measures and/or compliance be improved; with a view to the variation between groups due to limited possibilities to comply and the lack of easily accessible information.

### Ranking of research proposals

The final ranking of the proposals (with respect to quality and relevance) takes place with the help of the matrix below. In the matrix, relevance carries a heavier weighting than quality.
<table>
<thead>
<tr>
<th>Quality</th>
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Annex 3 Explanation of full proposal submission

Full proposal in general
The full proposal consists of several parts:
A. The fields to be completed in ProjectNet;
B. The completed application form (PDF), which is sent as an annex in ProjectNet.
C. The budget
D. Explanation of the budget
E. Response to comments in email about positive advice
F. FAIR data form

The full proposal (including annexes) should be written in Dutch. Applications in English are also permitted and will also be taken into consideration.

A. ProjectNet

You can further elaborate your proposal by logging in to https://projectnet.zonmw.nl. Your idea has already been converted into a grant proposal and is ready to be edited. In the overview of your applications you can find your grant application with status “Not submitted”. You can elaborate and submit this.

Project members
- In ProjectNet, you can enter a maximum of 10 project group members. In any case you are required to enter the following three project group members:
  - **Main applicant**: bears final responsibility for the proposal; during the application process this is the contact person for ZonMw.
  - **Project leader/official secretary**: is responsible for realising the project; during the realisation of the project this is the contact person for ZonMw.
  - **Official representative**: person who can represent the legal or statutory entity.

  NB: main applicant and project leader/official secretary can be the same person.
- For the composition of your project group, please bear in mind the right expertise needed for a successful realisation of your project.
- By 10 June at the latest you should submit the definite list of project group members via covid19@zonmw.nl. For this you should use the Excel template sent with the email about the positive advice. After 10 June, it is no longer permitted to make changes to the project group.

Summary
- In this field in ProjectNet you should preferably enter the summary in Dutch. Summaries in English are also accepted.
- Maximum 2000 characters.
- Make use of the following headings:
  - **RESEARCH QUESTION**
  - **URGENCY**
  - **HYPOTHESIS**
  - **ACTION PLAN/STRATEGY**

Budget
- Please complete the table.
- Please state any possible co-funding including the amount and the status of the co-funding pledge.

B. Application form

You can download the application form here. For More Knowledge with Fewer Animals please see the modified application form (in Dutch).

General instructions
- Please enter something in all text fields.
Call for proposals: COVID-19 Bottom-up FA 1 and 2

- Please make use of the headings stated in the application form.
- There is no limit on the number of characters and/or words per text box, but the total size of the application form is limited to a **maximum of eight (8) A4 pages** (including literature references and excluding the title page with "basic details").
- Substantive annexes can, if relevant, be uploaded separately in ProjectNet.
- It is also possible to add figures in the text boxes.
- You should use the font Arial (size: 10 points).
- We advise you to check your application for mistakes before you upload it as a PDF file. During the conversion from Word to PDF, figures and/or some characters and symbols may not be converted properly.

C. Budget
Please use the attached template.

D. Explanation of the budget
Please provide a convincing motivation of all items in the budget.

E. Response to comments in email about positive advice
In a separate annex, you should clearly state how you have addressed the instructions, recommendations and conditions from the committee in your full proposal. These were provided in the email with the positive advice. Copy each point from the email and subsequently state your response below these points.

F. FAIR data form
Please complete the form and upload this together with the other annexes in ProjectNet.
Annex 4. Legal aspects of collaboration

Criteria for company participation
If organisations participate in your proposal that cannot be regarded as organisations in the sense of the European state support law4 (‘non-research organisations’), then please bear in mind the following points:

• A letter of commitment should be submitted with the full proposal by all participating partners, in which the pledged contribution in kind and/or cash has been stated;
• The main applicant is responsible for ensuring good arrangements for the collaboration. The main applicant is required to involve the Knowledge Transfer Office (KTO) and legal department of his/her institution;
• During the realisation of this programme, ZonMw will ensure that the agreements with respect to the (project) results facilitate these results becoming available for Dutch healthcare as much as possible against a reasonable and affordable price.

For this call for proposals no funding will be granted if agreements between the collaborative partners (= parties involved in the research) lead or could lead to the provision of state support. If funding is awarded, then ZonMw retains the right to request a final draft version (approved by the parties but not yet signed) of the consortium agreement and to assess whether this is in accordance with the EU state support law, the ZonMw General Terms and Conditions Governing Grants and the specific granting conditions of the call for proposals concerned. If ZonMw does not accept the consortium agreement or if an underlying licence agreement limits the utilisation of the project results in a legal sense, then no grant will be awarded.

As an independent administrative body, ZonMw is required to make its own assessment with respect to the risk of providing illegal state support. Acceptance by ZonMw of the relevant agreements does not discharge the grant recipient from its own responsibility concerning the violation of the European state support law.

In the full proposal, you should describe under Background Intellectual Property (IP) who holds the rights to the existing knowledge contributed (background intellectual property). If a consortium partner that contributes existing knowledge (whether or not protected by an intellectual property right), only has a users right to this based on a licence agreement with a third party, then this consortium partner should demonstrate that the underlying licence agreement will not give rise to any legal limitations with respect to the use (publication, dissemination and utilisation) of the project results.

If the applicant hires third parties for or during the realisation of the project activities, then this will be viewed as the awarding of contracts. The applicant should then adhere to the applicable tendering rules. Please bear in mind that purchasing/tendering must take place under the same conditions as those under which the grant is awarded. The applicant must record this with the parties concerned in a (market standard) written agreement in which it is stipulated that the results will automatically be transferred to the applicant. Furthermore, this means that the applicant must provide clear details about the costs to be incurred (including Dutch VAT) in both the application and the budget.

Letter of Commitment
In the case co-funding, ZonMw requires a letter of commitment from each co-funding party when a full proposal is submitted. As ZonMw wants to know with certainty that co-funding parties of the project have legally obliged themselves to provide the pledged amounts for the co-funding, a letter of commitment from each co-funding party is compulsory with the submission of the full proposal. The letter of commitment must be printed on the stationary of the co-funding party concerned and be signed by a person authorised to do so. In principle, the letter of commitment may only contain one suspensory condition, namely that the pledge with respect to the co-funding only applies if ZonMw awards the grant application funding. Every other condition will be separately assessed by the ZonMw lawyer.

Consortium and/or sponsor agreement

44 Framework for State aid for research and development and innovation
The ZonMw General Terms and Conditions Governing Grants (article 11) states that: ‘The results of the project must be made available free of charge to the Dutch society at large or to other projects in the same field. Any products may be made available on the basis of the cost price. An exception to this rule may be made in the event that knowledge valorisation is the purpose of the programme or in the event that there has been a collaboration with commercial parties.’

If commercial parties are worked with in the project, then a consortium agreement should be concluded after the grant has been awarded. During the assessment of the consortium agreement, ZonMw will take into account the interests of the commercial parties and it will specifically assess the provisions with respect to the (valorisation of) the project results.

It must be apparent from the agreement that:

There is a genuine collaboration; collaboration between at least two independent parties to exchange knowledge or technology or to achieve a joint objective based on an allocation of tasks, in which the parties together determine the size of the collaborative project, contribute to the realisation of this, and share the project risk and results. Contract research and the carrying out of research services as equally solely a financial contribution without further participation in the research project, are not considered to be forms of collaboration;

(Main) applicants have the right to publish their own research results;

The knowledge that emerges from the collaboration must be made publicly accessible.

Furthermore, the collaboration agreement should contain agreements about intellectual property for the knowledge from the project and about the products that will be developed in the project. For projects with participation from commercial parties, these agreements about intellectual property should satisfy the following conditions:

- Insofar as results are generated, these will be the property of the person/entity that developed these.
- Results from a collaborative project to which no intellectual property rights can be granted may be disseminated.
- In the case of results from a collaborative project to which intellectual property rights could be granted, due consideration should be given to the purpose of this commission, which is aimed at facilitating a rapid and broad application of the results.

Assessment: the consortium agreement and other relevant agreements for the (project) results will be assessed by ZonMw for conformity with the stated requirements as part of the granting process. Acceptance of these agreements by ZonMw is one of the conditions for granting. Besides participating in a consortium, an organisation can also decide to contribute financially to a project without any further active participation. In this case, the organisation is seen as a sponsor. The sponsor often concludes a separate agreement with the main applicant/project leader, which states the conditions under which the sponsor provides a financial contribution to the project (the sponsor agreement).

On the ZonMw webpage Legal aspects of collaboration, you can find an exemplary agreement which can help with the drawing up of a consortium and/or sponsor agreement.

We kindly request you to contact the legal department, valorisation department or Knowledge Transfer Office (KTO) of your organisation at as early a stage as possible for assistance with drawing up the consortium and/or sponsor agreement.

Socially Responsible Licensing

For the programme elements in which a licence is needed, the most recent requirements have been included from the agreements emerging from the trajectory concerning Socially Responsible Licensing. With this, due consideration should be given to the purpose of this commission which is aimed at facilitating a rapid and broad application of the results in the Netherlands.