Call 3: New clinical and clinical-epidemiological studies (incl. platform trial) on infectious diseases

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Context of the call

The NUM is in the process of setting up a generic clinical study network and various specialist clinical study networks.[1] These receive a base funding for building up and maintaining their basic functionalities. This base funding initially is substantial, but will decrease over time and, therefore, needs to partially be replaced by performance-based funding from participation in clinical studies.

In the future, the NUM intends to spend a relevant part of its budget on funding potentially practice-changing clinical and clinical-epidemiological studies, including platform trials. These studies will be tied to the NUM study network and its respective specialist clinical study networks.

By the end of the current NUM funding period (June 30th, 2025), the NUM will have a specialist network on infectious diseases. This call focuses on clinical studies on infectious diseases, including a platform trial, planned within the already existing specialist network on infectious diseases.

As part of its routine activities, the specialist network on infectious diseases will generate prescreening-information. This information can be used to draw timely conclusions on the prevalence of infections that require hospitalization in German university hospitals (with and without pathogen validation). The resulting data will not be analyzed within the clinical study/specialist network, but be provided to the Surveillance, Monitoring and Rapid Reaction Platform that will be created as a result of the PREPARED project for further analyses. While this latter platform deals with population-based monitoring and surveillance, the clinical study/specialist network aims for answering study-specific questions in the field of individual medicine (diagnostics, therapy). Therefore, all matters falling within the scope of the Surveillance, Monitoring and Rapid Reaction Platform are not within the scope of this call.

When developing project ideas, the suitability criteria for NUM projects in the document **guiding criteria (annex 1)** should be used for guidance. These criteria

[1] For a detailed description of the status quo see the new NUM call number 2 and the **annex 2** "Synopse NUM Studiennetzwerk mit integriertem Fachnetzwerk Infektionsmedizin". In addition to this synopsis, there will be an online info session on 08.07.2024 from 11:30 to 13:00 o´clock, which will provide more in-depth information on the study network and the opportunity for questions.

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are meant to help identify projects that are particularly well suited to be implemented within the NUM framework.

Objectives of the call

This call is aimed at identifying clinical studies, clinical-epidemiological studies or platform trials in the field of infectious diseases that

- strengthen the NUM study network and the specialist network infectious diseases,
- strengthen the NUM´s ability to conduct clinical studies/trials as part of a rapid response to public health crises, i.e. a pandemic,
- are potentially practice-changing, with a high impact on patients,
- can potentially achieve a high international visibility.

The NUM does not fund basic research, early phase clinical trials, the development of tests, medical devices or drugs.

Specific requirements for the proposal

The proposal needs to lay out one or more specific prospective clinical studies/trials to be conducted by or in close cooperation with the specialist network on infectious diseases. Studies that are solely based on clinical routine data are not eligible under this call.

The respective research questions need to be based on evidence-based planning (i.e. with regard to the relevance of the research question).

The proposal needs to lay out the criteria that were used for selecting the chosen study/trial project(s) that has/have taken precedence over other research project ideas that were also discussed in the process. Such criteria could be the degree of evidence-based planning, patient relevance, scientific relevance or community support. Also, it should be specifically laid out why the chosen research project(s) are particularly well suited to contribute to the above-mentioned objectives.

If according to the criteria mentioned in the previous paragraph studies/trials are equally suitable, studies/trials with interdisciplinary leadership should be prioritized.

- The proposal needs to include one platform trial. If possible, this platform trial should build on the platform trial that has been established in NUM as part of the second funding period (NAPKON-TIP RAPID), i.e. by opening up at least one new arm. (Within the NAPKON-TIP sub-project (https://napkon.de/napkon-tip/) and the associated NAPKON-TIP RAPID sub-project, structures for conducting adaptive platform trials are being developed and established on the basis of an initial use case. As part of the call described here, it is possible to

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add a third arm to the existing post-Covid platform trial.)

At least 10 NUM sites must participate in each study/trial. Ideally, all sites of the specialist network on infectious diseases should participate. Other sites can participate if

- the requirements of the study network and the specialist network are met and
- their participation is essential for successfully conducting the study/trial, i.e. because of their track record in relevant studies/trials (i.e. NUM platform trial), a particular expertise or a particular patient population.

The selection of the individual partner sites needs to be based on clear and transparent criteria.

The proposal needs to lay out why all studies/trials are particularly suited to be conducted within the context of the NUM (guiding criteria see **annex 1**).

All studies/trials need to be conducted using the NUM infrastructure for clinical studies/trials, including data management and biosampling.

In order to support performance-based funding and incentivize patient recruitment and data capture, funding via case fees should be planned wherever possible.

The definition of an overarching governance for the various studies/trials that are part of this proposal is not necessary. Instead, each study/trial should have its own steering committee. The respective steering committee needs to link with the governance of the NUM study platform, the specialist network infectious diseases and all affected other NUM infrastructures for close alignment of all activities.

Overlap in the leadership of the various studies/trials should be avoided in order to provide as much opportunity as possible for different research groups to participate.

If PIs with leadership roles in infrastructure platforms, the NUM study network or the specialist network that are relevant to this call are pitching for studies/trials under this call, conflicts of interest need to be ruled out. In particular, support by the respective infrastructure platform for implementing the study/trial may not be made dependent on said PIs being included in the proposal. Inclusion in the proposal should be solely dependent on the scientific contribution of the individual PI to the specific research project.

Duration

The overall proposal should be planned from July 1st, 2025 until the end of 2027.

Should an extension of the study/trial become necessary or provide added scientific value, e.g. for performing follow-ups, further funding can potentially be made available

following this funding period, provided that the study was carried out successfully and on time. Should this become an issue, then the NUM will decide on this at the appropriate time, based on available budgets and the prioritization of the NUM´s overall needs and goals.

Budget framework

The following indicative budget, including a 20 percent flat-rate project allowance, is envisaged:
2025: 1.500.000 €
2026: 4.500.000 €
2027: 4.500.000 €

The proposal cannot exceed the above mentioned budget ceiling.~~Depending on the total volume requested in the proposal, d~~ Downward deviations ~~upwards or downwards~~from the above mentioned budget, are possible during the approval process. The basis for the decision is the result of the external evaluation and the available budget in the overall context of all NUM funding measures.

General requirements for content of the proposal

As long as this does not contradict the specific requirements above, the content of the proposal must fulfil the following general requirements that are applicable for all NUM projects:

- Only multi-site, collaborative projects involving and/or benefiting as many NUM partner sites as possible can be funded
- Clearly defined objectives/outcomes and added value, including a definition of indicators against which these can be tested
- Builds on or complements existing NUM infrastructures as far as possible - avoids creating parallel structures.
- Clearly defined interface of the governance/steering of the project with the governance/steering of the pre-existing NUM infrastructures that are addressed within the project(s)
- Reflection on the current evidence situation and the international context, in particular international best practice
- When collecting data, international standards should be used and the data needs to be made accessible within the NUM

Insofar as infrastructures are to be developed in the project that are to be operated in the NUM on a permanent basis, these must fulfil the following requirements:

- Potentially usable by all NUM partners and, if applicable, external third parties.
- Detailed participatory governance concept for the operation of the infrastructure, synchronized with pre-existing NUM governance

- Clearly defined technical and procedural interfaces with pre-existing NUM infrastructures
- Ensuring continuous and permanent availability
- Precise specification of the use cases and types of research that can be supported by this infrastructure
- Clearly described functionalities or services of the respective infrastructure, including key performance indicators
- Avoidance of a "vendor lock-in", e.g. through the definition of obligations for the transfer of data in the event of a change of provider; this is applicable for both academic and industry providers
- Avoidance of single points of failure
- Scalability
- Implementation of standards
- If necessary, ensuring the reusability of research data

Formal requirements for the proposal

- For each clinical study/trial: two spokespersons with two substitutes, each from different Academic Medical Centres (AMCs), with gender parity
- Submission of the proposal in English
- Use of the template provided by the NUM
- Structured into clearly defined, preferably non-overlapping work packages, for each of which a sub-budget is specified. A distinction should be made between cross-sectional work packages (e.g. central project management) and topic-specific work packages. Topic-specific work packages should be tailored in such a way that they have as little dependency on each other as possible and can therefore stand on their own. Interdependencies between work packages should be described in the application.