Call 2: Two additional specialist networks for clinical studies, including new clinical and/or clinical-epidemiological studies, beyond infectious diseases

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Context of the call

The NUM is in the process of setting up a generic clinical study network. In each participating site this network will provide general support services (feasibility tools, standardized contracts, tooling for drafting consents etc.) to facilitate the implementation of multi-center clinical studies. These infrastructures will be available for the whole range of clinical studies across all medical disciplines.

The generic study network will eventually support and be complemented by various specialist clinical study networks. These specialist networks are comprised by clinicians and clinical staff in the respective research fields, who are responsible for drafting and implementing study protocols and recruiting patients within the respective specialist area.

The generic study network as well as the specialist networks 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 be partially 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.

So far, one specialist network has been initiated in the field of infectious medicine as a pilot project, with an envisioned start on January 1st, 2025. The specialist area of the first network is due to the fact that the NUM was originally created as a response to the COVID-19 pandemic. Therefore, since 2020 it has already established clinical and clinical-epidemiological research resources and networks in the field of infectious medicine. The specialist network for infectious medicine builds on these pre-existing structures.

In NUM 3.0, the NUM intends to extend its infrastructure and research activities beyond COVID-19 and infectious diseases. Therefore, the NUM intends to fund two more specialist clinical study networks that are further complementing the generic study network infrastructure. The first new specialist network will be funded beginning 1st of July 2025. The second new specialist network will be funded beginning 1st of

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January 2027. The limitation to two new specialist networks is due to NUM budget restraints. The NUM intends to onboard additional specialist networks as soon as additional funding becomes available.

As part of its pitch, the first of the two new specialist networks, that is supposed to start July 1st, 2025, is expected to propose at least one clinical study to be funded under this call for the period from July 1st, 2025, until December 31st, 2027.

The second new specialist network that starts January 1st, 2027, is not eligible for funding of corresponding studies under this call. The NUM intends to start another call in early 2026 to provide the opportunity for this second specialist network to apply for funding of clinical or clinical-epidemiological studies that start January 1st, 2027. This future call will also be open for the other specialist networks (infectious medicine network and the first new network under this call) for new funding beyond 2027.

The current setup and requirements of the generic study network as well as the specialist network on infectious medicine are not subject to this call. New specialist networks have to fit into the established structures and requirements of the generic network. For a detailed description of the status quo see **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, in which the generic clinical study network (incl. the planned collaboration with the specialist networks) will be presented in more detail and there will be room for asking questions. All parties interested in this call are strongly encouraged to use these sources of information and develop a thorough understanding of the study network, its prerequisites and goals before participating in the further discussions.

When developing project ideas, the suitability criteria for NUM projects in the document **guiding criteria (annex 1)** should be used for guidance. These criteria are meant to help identify projects that are particularly well suited to be implemented within the NUM framework.

Objectives of the call

New specialist networks need to contribute to the overall objectives of the NUM study network as much as possible within the given governance model. This call is aimed at identifying those specialist areas that are best suited to be added to the existing study network.

For the specialist network that will start in 2025 the call also aims to identify clinical studies, clinical-epidemiological studies or platform trials that

- strengthen the NUM study network and its specialist networks,
- strengthen the NUM´s ability to conduct clinical studies/trials as part of a rapid response to public health crises, i.e. a pandemic,

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- 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.

Specialist networks eligible for funding

Specialist networks need to fulfill the following criteria in order to be eligible for NUM funding within this call:

- Each of the two new specialist networks should encompass at least 10 NUM sites.
- Each specialist network needs to be focused on a specific, clearly defined disease or disease area. Overlap between different specialist networks needs to be avoided as far as possible. If overlap exists, mechanisms to synchronize activities between the respective specialist networks need to be laid out in the proposal.
- The specialist network that is intended to start July 1st, 2025, needs to demonstrate the ability to conduct a multi-center clinical or clinical-epidemiological study in the period from July 1st, 2025, until December 31st, 2027. Therefore, this specialist network needs to present a strong concept for at least one such study under this call (specific requirements see below).
- The selection of the individual partner sites for the two new specialist networks needs to be based on clear and transparent criteria regarding their scientific and organizational suitability, in particular, if more sites than the envisaged 10 would like to join the specialist network. If sites are equally suitable, sites that are not already part of the specialist network for infectious medicine should take precedence. This serves the purpose of onboarding as many of the 36 NUM sites as possible by the end of 2029.
- The networks should have an established track record of collaboration in the field of clinical studies. Ideally, the network partners have already successfully implemented multi-center clinical or clinical-epidemiological studies in the past.
- The specialist areas that are covered by these networks must not have access to or cover disease areas of established clinical study networks and/or infrastructures that receive infrastructure funding from other federal sources, i.e. NCT, DZG. The NUM intends to focus on specialist areas that do not yet have a strong resource base for clinical or clinical-epidemiological studies. This excludes specialist areas like i.e. oncology.
- The specialist areas need to demonstrate a strong potential to significantly increase the number of practice-changing clinical studies with international significance in their field, thereby gaining international visibility.
- The networks need to demonstrate a clear commitment to adhere to the

requirements of the study network, deliver the necessary key performance indicators and implement the requested tools, SOPs and structures. For further information see **annex 3** “Selbstauskunft und Absichtserklärung der Universitätsklinik XXX zur Mitwirkung am Netzwerk Infektionsmedizin innerhalb des NUM Studiennetzwerks“ and the above mentioned sources of information. The new specialist networks can only apply for funding if the study network has confirmed (letter of support) that all network partners have committed to fulfilling all requirements.

Specific requirements for the first specialist network´s proposal of at least one clinical and/or clinical-epidemiological study

Besides addressing the above mentioned criteria for new specialist networks, the proposal of the network starting July 31st 2025 needs to lay out at least one specific prospective study/trial to be conducted by or in close cooperation with the specialist network. 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, clinical 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.

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

- the requirements of the study network and the respective 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, 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 (criteria see **annex 1**).

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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.

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 relevant specialist network 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.

The overall proposal needs to clearly differentiate between the specialist network and the clinical study/trial(s). It should encompass clearly distinctive work packages and show their interdependencies.

Duration

The overall proposal, which has to be drafted by both new specialist networks together, should be planned from July 1st, 2025 until the end of 2029. As mentioned above, the first new specialist network including the corresponding studies should start July 1st, 2025, the second January 1st, 2027.

The NUM intends to continue base funding for these specialist networks beyond 2029. However, this depends on political decisions about the NUM´s future that have not yet been made at the time this call was drafted.

Budget framework

The following indicative budget, including a 20 percent overhead, is envisaged:
2025: 1.750.000 €
2026: 5.000.000 €
2027: 6.050.000 €
2028: 3.950.000 €
2029: 3.350.000 €

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This overall budget falls into the following categories (reciprocal cover eligibility[1]):

Year	Budget for base funding of both specialist networks together	Additional budget clinical and/or clinical-epidemiological studies (1st specialist network)
2025	1.750.000	
2026	3.500.000	1.500.000
2027	4.550.000	1.500.000
2028	3.950.000	Neuer Call
2029	3.350.000	Neuer Call

As part of a further call for proposals in 2026, additional funding will be made available for the second specialist network as well as the other specialist networks to conduct clinical and/or clinical-epidemiological studies from 2027 on (see chapter “Context of the call” above).

Depending on the total volume requested in the proposal, deviations upwards or downwards 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.

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.

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

[1] Die Zahlen dienen der Orientierung, es besteht gegenseitige Deckungsfähigkeit.

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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 specialist network: two spokespersons with two substitutes, all from different AMCs, with gender parity
- Submission of the proposal in English
- Use of the template provided by the NUM
- Structured into clearly defined, 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.