Call 4: Setting up new registries in the NUM

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Context of the call

Medical registries generally are defined as systematic anonymized or pseudonymized collections of data from clinical routine for a specific disease/group of patients. For the purpose of this call, the term „registry“ is defined more broadly. For example, registries in the sense of this call can also draw from data sources other than clinical routine data (i.e. self-reported patient data or data on treatment capacity).

Currently, two registries (AKTIN and NAREG as part of NATON) are part of the NUM research (data) infrastructures. Also, with NUM-DIZ the NUM is working in close collaboration with the MII on making clinical routine data from university hospitals available for medical research across the whole spectrum of diseases/patient groups. This opens up the potential to feed medical registries directly with data from the NUM-DIZ in the future. And finally, with NUKLEUS the NUM has a strong platform to support EDC-based documentation of clinical routine data including biosamples and images across all medical treatment settings, inside and outside of university hospitals. In the foreseeable future, NUKLEUS will also be able to link data gathered within NUM with NUM-external data, i.e. from health insurance funds or cancer registries.

This call is aimed at identifying new registries that should be established specifically in the NUM (as opposed to other contexts) on NUM (data) infrastructures, in order to enrich and take advantage of the NUM ecosystem. Any such registry must directly support patient-oriented and potentially practice-changing research and/or public health (crises) management.

In the future, the NUM will strive to establish as many registries as possible that utilize NUM (data) infrastructures, thereby being fully compatible with the NUM clinical research data space and enriching this data space with additional data. However, NUM funds are limited. Therefore, the NUM will support setting up these registries, but cannot engage in long-term funding of their operating costs. Consequently, any registry proposed in response to this call needs to demonstrate that – after the initial setup period – it is able to cover its operating costs from NUM-external sources.

When developing project ideas, the suitability criteria for NUM projects in the document guiding criteria 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.

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Objectives of the call

This call is aimed at identifying registries that

- enrich the NUM clinical data space with additional patient data and/or
- support patient-oriented and potentially practice-changing research and/or
- support public health (crises) management and/or
- strengthen the NUM´s ability to conduct clinical studies/trials and/or
- can potentially achieve a high international visibility.

Specific requirements for the proposal

The proposal needs to describe one or more registries to be set up on the NUM research (data) infrastructures.

Each registry needs to address clearly defined research questions and/or purposes. The respective research questions need to be based on evidence-based planning (i.e. with regard to the relevance of the research questions).

The proposal needs to lay out the criteria that were used for selecting the chosen registries that have taken precedence over other registry 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 registries are particularly well suited to contribute to the above mentioned objectives.

If according to the criteria mentioned in the previous paragraph registries are equally suitable, registries that include non-university hospital sites and settings (including outpatient sector etc.) and/or have an interdisciplinary leadership should take precedence over registries that are limited to the university hospital setting and/or to a particular discipline.

At least 25 NUM sites must participate in each registry. Ideally, all NUM sites should participate.

Patient organizations covering the diseases or disease groups in question must be involved. Existing registries that can be built upon should be taken into account. However, double funding must be ruled out in the proposal.

The proposal needs to lay out why the respective registries are particularly well suited to be conducted within the context of the NUM (see suitability criteria, **annex 1**).

All registries applied for under this call must be set up using the existing NUM (data) infrastructures and provide the necessary letters of support.

If necessary for implementing a particular registry, measures to expand these

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infrastructures (with the exception of the NUM data integration centers (DIC), see below) can be included into the proposal with the consent of the respective NUM infrastructures.

All registries must adhere to the FAIR principles and follow the respective NUM standards and principles (i.e. with regard to use & access) as far as possible. However, data sovereignty should remain with the research community that is scientifically responsible for the registry.

This call is limited to proposals for setting up registries. Therefore, only the initial setup costs can be funded under this call. Long-term operating costs cannot be funded. The proposal must therefore include a section on the long-term and sustainable financing of the registries after the end of NUM funding.
Should a prolongation of funding become necessary, e.g. to bridge the gap until long-term funding from an external source is available, further funding can potentially be made available following this funding period, provided that the registry was set up 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.
Costs for data capture/documentation of individual patient data or other data items are not eligible for funding.

If setting up a registry requires access to data from DIC that is either part of the MII core data set or any dataset of an MII-funded use case, then the DIC cannot receive any funding for the provision of this data within the project. If other data are needed, then the necessary development and implementation costs can be funded as part of a reference implementation that includes at most 5 DIC. This reference implementation must be scalable to be rolled out across all DIC subsequently.

The definition of an overarching governance for the various registries that are part of this proposal is not necessary. Instead, each registry should have its own steering committee. For close alignment of all activities, the respective steering committee needs to link with the governance of the respective NUM (data) infrastructures that it utilizes. However, if there are potential synergies and/or interdependencies among the registries that are part of the proposal, this should be adequately reflected in the proposal and in the governance.

If PIs with leadership roles in infrastructure platforms that are relevant to this call are pitching for registries under this call, conflicts of interest need to be ruled out. In particular, support by the respective infrastructure platform for implementing the registry 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 registry.

For each registry, the proposal should encompass clearly distinctive work packages and show their interdependencies.

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Duration

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

As mentioned above: Should a prolongation of funding become necessary, e.g. to bridge the gap until long-term funding from an external source is available, further funding can potentially be made available following this funding period, provided that the registry was set up 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 overhead, is envisaged:
2025: 1.250.000 €
2026: 2.500.000 €
2027: 1.250.000 €

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.

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

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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 registry: two spokespersons with two substitutes, each from different 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.

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