# Call 1: Additions to and improvements of current NUM research (data) infrastructures

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## Context of the call

The NUM currently operates several research (data) infrastructures with different purposes:

- **AKTIN emergency department registry (AKTIN@NUM):**
  The AKTIN registry enables the daily collection and use of standardized routine medical data from emergency departments, independently of the respective hospital information system. It currently collects data from 39 AMCs and 32 non-AMCs. The registry supports quality assurance, public health surveillance (in collaboration with the Robert Koch-Institute (RKI)) and healthcare research. Researchers can apply to use the data and/or integrate their research ideas into the platform.

- **NUM Genomic Pathogen Surveillance and Translational Research (GenSurv):**
  This platform collects sequencing data and metadata on SARS-CoV-2 variants, e.g. to support the surveillance of newly emerging virus variants.

- **NUM Clinical Epidemiology and Study Platform (NUKLEUS):**
  NUKLEUS enables researchers to plan, conduct and analyze large-scale clinical and clinical-epidemiological studies nationwide. The platform offers support throughout the whole lifecycle of any study project, from methodological planning over data collection up to FAIR data sharing and reimbursement. This includes the structured and quality-assured collection and management of clinical and imaging data as well as the collection, processing and documentation of biosamples. NUKLEUS provides organized access (use and access committee) to high-quality data and biosamples to the scientific community and supports the secondary use of clinical study data. Record linkage with external data, such as health insurance data or data from cancer registries, is currently being developed.

- **Radiological Cooperative Network (RACOON):**
  RACOON is a medical imaging platform of all 36 AMC radiology departments that supports the creation of highly structured multi-centre imaging datasets. The platform enables clinical and clinical-epidemiological studies and the creation and use of innovative artificial intelligence (AI) applications on shared medical image data.



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- **NUM Routine Data Platform (NUM-RDP):**
  The aim of the NUM-RDP is to provide a generic platform for using and sharing comprehensive multi-centre datasets from clinical routine documentation, imaging and biosampling for secondary use. Data will eventually be made available from the 36 AMCs and additional sources like non-AMCs und outpatient doctors. The NUM-RDP draws its data from the local data integration centres (DIZ) at the respective AMC sites (see NUM-DIZ).

- **NUM Data Integration Centres (NUM-DIZ):**
  The aim of NUM-DIZ is to develop and maintain cooperation throughout Germany based on interoperability standards as well as common technological and organizational solutions, structures and processes that are implemented in the form of local DIZ at each site. NUM-DIZ forms the decentralized technical and organizational prerequisites for the multi-center use of clinical routine data across all NUM locations. The DIZ have been built up within the Medical Informatics Initiative (MII), another research project funded by the Federal Ministry of Education and Research that started in 2018. In order to exploit synergies between the MII and the NUM, the DIZ became part of the NUM research infrastructure starting 2023. NUM-DIZ still operates in close cooperation with MII.

- **National Autopsy Network (NATON 2.0):**
  NATON provides a service, expert, and development platform for networked autopsy-driven research. NATON includes a data platform with an autopsy registry that holds clinical data and biosample data from autopsies, as well as a methodology platform providing expertise in post-mortem examination and sample acquisition, handling and analysis. NATON brings together the expertise of the institutes of pathology, neuropathology and forensic medicine institutes in Germany. The central data platform for the network is the National Autopsy Registry (NAREG), which is an extension of the nationwide registry of COVID-19 autopsies (DeRegCOVID).

These research (data) infrastructures need to be continually improved and expanded to best serve the needs of clinical researchers. To this end, the NUM funds additional research projects for infrastructure development outside of the base funding of the NUM infrastructures. This serves the purpose to open up the participation in infrastructure development projects to the entire NUM community, not only to those who are already operating NUM infrastructures.
This call deals with the improvement and further development of the NUM infrastructures listed above, starting July 1st, 2025. However, funding of the NUM-RDP in the infrastructure line will be discontinued. With the exception of the RDP-dashboard, within this call all components of the RDP are up for a reassessment of their future role and necessity within the context of the functionalities of the other NUM infrastructures. This is one of the topics that are eligible for funding under this call (see below).

If applicable, the resulting infrastructure solutions should be aligned with the requirements of the European Health Data Space (EHDS) and help the NUM to pursue



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its strategic goal to provide a German data space for clinical research data as part of the overall German health data space.

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

This call serves the purpose to identify projects on various topics (see list in next chapter below) that improve and/or expand the current NUM research (data) infrastructures. Each of the proposed individual projects must pursue at least one of the following six objectives:

1. improve quality, scalability and efficiency
2. eliminate single points of failure and/or improve crisis resiliency
3. improve data security
4. improve usability for clinical researchers
5. make new data sources accessible for clinical researchers
6. promote the use of available data for new research projects and/or public health management

## Specific requirements for the proposal

The proposal resulting from this call must consist of several individual projects (work packages). Each of these individual projects (work packages) needs to address one of the topics listed below. There can only be one individual project (work package) per topic.

The establishment of an overarching steering committee across all work packages (individual projects) needs to be part of the proposal. Such a steering committee needs to be closely linked to the NUM Steering Group for Research Infrastructures (SG FIS).

Additionally, individual projects (work packages) may set up their own specialized steering committees if the overarching steering committee does not sufficiently address the specific needs of the individual project (work package). These decentralized steering committees must include representatives of the affected NUM research (data) infrastructure(s).

The perspective of those researchers who are supposed to use the respective infrastructure platforms/solutions for their research should be included into the governance wherever possible.



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The following topics will be prioritized for funding, under the premise that the respective individual projects (work packages) are clearly aligned with above mentioned objectives of the call:

- Fostering the use of clinical routine data from the NUM-DIZ within prospective clinical and clinical epidemiological studies that are set up on the NUKLEUS platform (reference implementation, max. 5 participating sites)
- Fostering data exchange between the NUM imaging platform (RACOON) and the NUM-DIZ (reference implementation, max. 5 participating sites)
- Creating a one-stop-shop (i.e. portal) for clinical researchers who want to access NUM infrastructures and/or NUM data, which
    - allows for need-specific feasibility queries across all NUM research (data) infrastructures and data domains and
    - directs researchers through all the necessary steps for accessing NUM data, including harmonized use & access procedures wherever possible
- Extending the NUM data space, particularly with regard to
    - biosample data from routine pathology examinations
    - OMICS data: this should address the issue of how existing NUM capabilities (i.e. NUKLEUS LIMS, DIZ) can be connected to initiatives like genom.DE, GHGA and the "Modellvorhaben Genomsequenzierung nach § 64e SGB V"
    - NUM-external data, i.e. from health insurance funds or cancer registries, if not already funded in the NUKLEUS clinical study platform
    - data from telemedicine-based patient treatments
    - data from wearables, including consumer health data
- Strengthening the coherence and alignment of <u>all</u> central[1] (not local) components of <u>all</u> NUM infrastructures, potentially including the Central Research Repository of NUM-RDP and the other central RDP components (see introductory remarks above), by
    - specifying how these components will interface in the future, which use cases/types of research they will support respectively, which research communities and purposes they will cater to and which data they will process to what ends
    - including specific proposals for expanding, adapting or discarding the existing central components
    - implementing projects to strengthen the alignment of the central components across the various NUM platforms, wherever this creates synergies or provides additional functionalities
    - implementing projects to eliminate single points of failure and create redundant (backup) infrastructures to improve crisis resilience

[1] „central" in this sense means any component that processes and/or stores data from various NUM sites, even if the component is operated/hosted by only one NUM site



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- Harmonizing NUM activities (SOPs, logistics, quality standards, data standards etc.) across sites and across the various infrastructure platforms, primarily in the fields of biosampling and laboratory analyses
- Improving clinical routine documentation at the point of care, i.e. by standardizing documentation or providing adequate documentation tools (reference implementation, max. 5 participating sites); broad support of the affected clinical communities responsible for clinical documentation needs to be demonstrated
- Implementing innovative partnerships between academia and small and medium-sized enterprises (SME) in order to
    - solve issues of scalability within NUM infrastructures and/or
    - improve efficiency, quality, reliability or accountability of infrastructure provision.

  Such partnerships must not lead to a vendor lock-in and may not weaken the knowledge base and expertise of the NUM infrastructure community.

The overall proposal should encompass individual projects (work packages) that together address as many of these topics as possible.

Topics not listed above can be applied for as well. In the overall proposal, they have to be presented as a separate individual project (working package). However, in case of funding restrictions the topics listed above take precedence over unlisted ones.

For each individual project (work package), its benefits with regard to the objectives of the call (see above) need to be laid out clearly, ideally in the form of measurable key performance indicators. Gaps, limitations, weaknesses etc. of current NUM infrastructures, that will be addressed by the respective individual project (work package), need to be specified. Added value, additional functionalities etc. need to be described in detail. Also, each individual project (work package) needs to have a governance concept which integrates all affected NUM infrastructures (also see the remarks on governance above).

The NUM aims for increasing its capacity (human resource base) to develop and operate research (data) infrastructures. Therefore, wherever possible, the individual projects (work packages) should include researchers that do not already operate a NUM infrastructure component. If this is not possible, detailed reasons have to be given in the proposal.

Interdependencies between the various individual projects (work packages) need to be addressed in the proposal, including appropriate measures for managing these interdependencies.

All individual projects (work packages) need to reflect on relevant activities from other funding initiatives (NFDI, MII, DZG, BMBF, DFG etc.) and take into account solutions and results that could be adopted from these activities. This needs to be addressed in the proposal.



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If applicable, projects/solutions need to demonstrate how they contribute to the NUM´s strategic goal to provide a German data space for clinical research data as part of the overall German health data space.

## Duration

The overall proposal should be planned from July 1st, 2025 until the end of 2027. However, the individual projects can end earlier or start later if they do not need the entire two and a half years to achieve their goals.

## Budget framework

The following indicative budget, including a 20 percent overhead, is envisaged:
2025: 1.500.000 €
2026: 3.000.000 €
2027: 3.000.000 €

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)
- Establishment of a steering committee (with guest status for NUM Coordination Office) to monitor and coordinate the various individual projects;
- 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 network.



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Insofar as new infrastructures or infrastructure components 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:

- 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

- Overall consortium: Two spokespersons and two substitutes from different sites, with gender parity
- Each individual project (work package): Two spokespersons from different sites, with gender parity
- Submission of the application in English
- Use of the templates provided by the NUM
- Structured into clearly defined, non-overlapping work packages (representing the individual projects), 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 (individual projects). Topic-specific work packages (individual projects) 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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