

## REQUEST FOR APPLICATIONS

**Opportunity Title:** Health Research Priorities:  
Late-Stage Preclinical Development Studies

**Code:** SNIH-RO-HRP-RG32-2506

**FUNDING YEAR(s):** FYs 2025-2026

**OPEN LETTER OF INTENT SUBMISSION:** 01 July 2025

2025

Research Office

Saudi National Institute of Health

## Synopsis

### General information

		Note
<b>Funding Organization</b>	Saudi NIH	
<b>Administration Information</b>	Research Office	
<b>Application Type</b>	Ready to Initiate or Ongoing Late-stage Preclinical Development Studies	
<b>Funding Mechanism</b>	Technology Transfer Grant	Mechanism Code: RG32
<b>Opportunity Title</b>	Health Research Priorities: Late-stage Preclinical Development Studies	Opportunity ID: SNIH-RO-HRP-RG32-2506
<b>Opportunity Announcement</b>	01-07-2025	
<b>Open Letter of Intent Submission</b>	01-07-2025	
<b>Open Application Submission</b>	Within 1-2 months of LOI submission	
<b>Opportunity Expiration</b>	30-06-2026	Applications may be submitted at any time prior to the opportunity expiration date; however, applications will be processed quarterly.
<b>Targeted Priority Fields</b>	All fields under Saudi NIH Health Research Priorities	

### Eligibility

<b>Eligible Applicants</b>	<ul style="list-style-type: none"> <li>The applicant must be affiliated with a Saudi organization, including academic institutions, research organizations, hospitals.</li> <li>Affiliation with a Saudi business is permitted only if a collaboration with a local research organization has already been established.</li> <li>The applicant must hold a doctorate degree or an equivalent qualification in a relevant field.</li> <li>The applicant must have publication history and a minimum of four years of experience in the proposed research area.</li> <li>Both Saudi citizens and non-Saudi residents are eligible to apply.</li> </ul>
<b>Additional Eligibility Requirements</b>	<ul style="list-style-type: none"> <li>The applicant must serve as the Principal Investigator (PI) for the proposed research project.</li> <li>The PI must not be leading any other currently active project funded by Saudi NIH.</li> <li>The PI's organization must have an Authorized Organization Representative.</li> <li>Each PI is permitted to submit only one research proposal under this funding opportunity.</li> </ul>

	<ul style="list-style-type: none"> <li>• A Co-Investigator may participate in up to five active Saudi NIH-funded research projects across all grants.</li> <li>• Collaboration with organizations/entities (including non-governmental, national, or international organizations) is allowed, subject to terms and conditions.</li> <li>• Proposed studies must be compliant with SFDA preclinical studies requirements.</li> </ul>
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#### Additional information

<b>Description and Scope</b>	<p>Saudi National Institute of Health (Saudi NIH) invites research applications under its Health Research Priorities Strategic Plan in alignment with Vision 2030 and national research and development priorities.</p> <p>This opportunity is designed to accelerate the late-stage preclinical development of candidate therapeutic and preventative agents—including drugs, biologics, gene therapies, medical devices, and vaccines that address diseases with significant public health relevance in the Kingdom within the fields specified in the <a href="#">Saudi NIH Health Research Priorities</a>. Researchers awarded under this funding opportunity will play a pivotal role in advancing the national health research agenda.</p>
<b>Clinical Trial Allowability</b>	Clinical Trial Not Allowed: Applications that propose clinical trial(s) are not accepted.
<b>Eligible Types of Studies</b>	Ready to initiate or ongoing preclinical studies that investigate novel pharmacologic therapies, vaccines and intervention modalities across the health research priority fields identified by Saudi NIH.
<b>Maximum Duration</b>	Up to 36 months, subject to extension.
<b>Maximum Budget</b>	Based on case-by-case negotiation.
<b>Contact Information</b>	GRANTS@SNIH.GOV.SA

## **Executive Summary**

The Saudi National Institute of Health (Saudi NIH) invites applications under the Health Research Priorities: Late-stage Preclinical Development Studies opportunity to support investigator-initiated preclinical studies addressing national health priorities. This opportunity aims to accelerate the late-stage preclinical development of candidate therapeutic agents, including drugs, biologics, gene therapies, medical devices, and vaccines that address diseases with significant public health relevance in the Kingdom within the fields specified in the Saudi NIH Health Research Priorities.

Studies must align with the research priority fields identified by the Saudi NIH and demonstrate strong scientific merit, feasibility, and potential for health impact. The funding mechanism supports both new and ongoing studies that are ready to initiate or expand. Researchers applying for this opportunity must thoroughly read this funding opportunity announcement and ensure to follow the application guidelines and eligibility criteria. Eligible applicants must be based in the Kingdom of Saudi Arabia and capable of conducting late-stage preclinical studies in accordance with ethical and operational standards.

Awards will be subject to case-by-case negotiation based on project scope and justification. The duration of projects is up to 36 months, with the possibility of extension upon review. Applications are accepted on a rolling basis for FYs 2025-2026 and are processed quarterly.

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## **Background**

### **Saudi National Institute of Health**

Saudi National Institute of Health (Saudi NIH) focuses on implementing a strategy based directly on prioritizing translational research and clinical trials to meet public health needs while working to identify and mitigate challenges that hinder the development of effective and high-quality research, strengthening coordination and scientific collaboration, and improving the impact of the research and innovation system in the health sector. Therefore, one of the ways through which Saudi NIH aims to achieve its goals is to create funding opportunities for promising clinical and translational health research.

### **Research Office**

The Saudi NIH Research Office is responsible for overseeing the design, implementation, and evaluation of Saudi NIH's funding programs and opportunities. It manages the full grant lifecycle, including announcing funding opportunities, processing applications, overseeing peer-review processes, contracting, and monitoring funded research projects. Additionally, the Research Office establishes administrative, technical, and financial policies for Saudi NIH-funded research projects, ensuring alignment with both the needs of researchers and regulatory frameworks within the Kingdom and internationally.

## **Opportunity Description and Scope**

### **Description**

Preclinical studies are foundational components of health research that provide critical evidence on the safety, mechanism of action, and potential efficacy of medical interventions before they are tested in humans. These studies generate essential data that guide the development of new drugs, vaccines, and medical devices, helping researchers and regulators assess feasibility and risk. The Saudi NIH plays a critical role in supporting and advancing preclinical studies in the Kingdom.

This opportunity contributes to advancing translational research by promoting the translation of scientific discoveries from the bench to the bedside, and enhancing national research capabilities.

Eligible types of studies include ready-to-initiate or ongoing preclinical studies that investigate novel pharmacologic therapies, medical devices, vaccines, and intervention modalities across the health research priority fields identified by the Saudi NIH.

## Scope

This opportunity is designed to accelerate the late-stage preclinical development of candidate therapeutic agents, including drugs, biologics, gene therapies, and vaccines that address diseases with significant public health relevance in the Kingdom within the fields specified in the [Saudi NIH Health Research Priorities](#).

The Saudi NIH seeks to support high-potential therapeutic innovations by providing funding for critical late-stage preclinical development activities. These include IND-enabling studies, safety pharmacology, and other regulatory-aligned requirements necessary for clinical trial initiation.

Applicants must demonstrate alignment with the pre-specified priority fields in their research applications. However, applications addressing other areas may be considered if a strong and well-justified rationale is provided. Applications should address scientifically sound and unanswered research questions with potential for significant clinical or public health impact.

## Eligibility

### Minimum Eligibility Requirements:

- The applicant must be affiliated with a Saudi organization, including academic institutions, research organizations, hospitals.
- Affiliation with a Saudi business is permitted only if a collaboration with a local research organization has already been established.
- The applicant must hold a doctorate degree or an equivalent qualification in a relevant field.
- The applicant must have publication history and a minimum of four years of experience in the proposed research area.
- Both Saudi citizens and non-Saudi residents are eligible to apply.

### Additional Requirements:

- The applicant must serve as the Principal Investigator (PI) for the proposed research project.
- The PI must not be leading any other currently active project funded by Saudi NIH.
- Each PI is permitted to submit only one research proposal under this funding opportunity.
- A Co-Investigator may participate in up to five active Saudi NIH-funded research projects across all grants.
- Collaboration with organizations/entities (including non-governmental, national, or international organizations) is allowed, subject to terms and conditions (See [Funding Allocation](#)).
- Proposed studies must be compliant with SFDA preclinical studies requirements.

## Funding Allocation

Awardees will receive the funding amount according to their signed contract. The Saudi NIH has the authority to determine the allocation of funding in accordance with its policies and regulations. The budget is subject to case-by-case negotiation, with a maximum proposed project period of 36 months (extendable upon review).

Conditions for collaboration apply in accordance with [Saudi NIH policies and regulations](#).

## Allowable Costs and Budget Guidelines

Detailed allowable costs and budget guidelines are available in the [Saudi NIH Policies and Regulations](#).

## Review Process and Timeline

Table 1: Saudi NIH proposal review process.

Stage	Description
Letter of Intent Submission	<ul style="list-style-type: none"><li>Applicants will submit their Letter of intent (LOI) through the <a href="#">Saudi NIH Application Platform</a>.</li><li>The Research Office (RO) will evaluate the LOIs and provide initial approval for those selected to proceed with a research proposal.</li></ul>
Proposal Submission	<ul style="list-style-type: none"><li>Applicants who have received approval for their LOI will be eligible to submit a research proposal.</li></ul>
Prescreening	<ul style="list-style-type: none"><li>Saudi NIH will begin prescreening applications as soon as they are submitted.</li><li>Applications are screened for eligibility, originality, completion, and compliance with Saudi NIH Grants Policy.</li></ul>
Technical Review	<ul style="list-style-type: none"><li>Saudi NIH will conduct a technical review of applications that have passed the prescreening stage.</li><li>Applications will be reviewed to ascertain that all requirements have been fulfilled.</li></ul>
Scientific Review	<ul style="list-style-type: none"><li>A scientific review committee will assess applications and nominate them for funding based on scientific merit.</li></ul>
Ethical Review	<ul style="list-style-type: none"><li>The Saudi NIH will review all submitted documents and approvals, including Institutional Review Board approval, to ensure they are in accordance with the National Committee of Bioethics' requirements.</li></ul>
Notice of Award	<ul style="list-style-type: none"><li>The final approval is made by the Chief Executive Officer (CEO) of Saudi NIH.</li><li>Saudi NIH will communicate with the applicants to inform them that they have been nominated to receive the award.</li></ul>



Contracting	<ul style="list-style-type: none"> <li>Following the receipt of the notice of award, the awardees and their affiliated organization's Authorized Organizational Representative are required to sign the contract and submit all required documentation to facilitate the disbursement of the award.</li> </ul>
Project Start	<ul style="list-style-type: none"> <li>Projects may commence after receiving the Project Execution Notice from Saudi NIH.</li> </ul>
Reporting and Monitoring	<ul style="list-style-type: none"> <li>After receiving the Notice of Award, awardees are required to agree to undergo monitoring by Saudi NIH for the duration of the research project.</li> <li>Systems will be in place for monitoring all activities involving human subjects.</li> <li>Saudi NIH has the right to conduct periodic visits to the awardee's organization's research site(s) to conduct evaluations.</li> <li>Awardees will be required to submit periodic reports throughout the duration of the project, and a final report at the end of the project according to deadlines determined in the signed project contract.</li> </ul>
Award Close-out	<ul style="list-style-type: none"> <li>Saudi NIH will end the award period after ensuring that agreed-upon milestones have been reached.</li> <li>The awardee must present all the necessary documentation for the scientific review committee and the Ethics and Compliance Department to issue approvals for award close-out.</li> <li>The results of the research project are subject to disclosure according to Saudi NIH Grants Policy.</li> </ul>

## Timeline and Important Dates

Applications will be processed through funding cycles, each with its own important dates (See Table 2: Opportunity Timeline and Important Dates).

Table 2: Opportunity Timeline and Important Dates

	LOI Submission period	Request for full application
Cycle 1	1 July, 2025 - 30 September, 2025	Within 1-2 months of LOI submission
Cycle 2	1 October, 2025 - 31 December, 2025	
Cycle 3	1 January, 2026 - 31 March, 2026	
Cycle 4	1 April, 2026 - 30 June, 2026	

## Evaluation Criteria

Applications will be evaluated based on the following criteria:

- Relevance to the priority research fields defined by Saudi NIH

- Scientific and technical merit
- The integrity of the work
- Significance of the problem
- Approach to addressing the problem
- The soundness of the rationale.
- The realistic estimation of outcomes
- Risk management criteria
- Alignment with Saudi NIH strategy and the National Vision 2030

## **Expected Research Outcomes**

- Demonstrated readiness for a first-in-human (Phase I) clinical trial
- Approval of Investigational New Drug (IND) application if applicable
- Awards
- Publications in scientific journals and scientific meetings (i.e. research papers, scientific reports, abstracts, scientific lectures, etc.)

## **Reporting and Monitoring**

Saudi NIH will monitor awarded projects. The monitoring process includes the submission of periodic progress reports by awardees and may involve periodic site visits. A final report will be required upon completion of the project.

## **Other Information**

### **How to Apply**

Researchers interested in applying must register on the [Saudi NIH Application Platform](#) to submit their application, then apply through the following link: [Start an application](#).

Saudi NIH will only accept applications submitted through its application platform. Please take advantage of the submission manual tool provided to you [here](#) to guide you through the registration and submission processes.

### **Confidentiality**

All information submitted by applicants is confidential. In accordance with Saudi NIH Grants Policy, all application reviewers must adhere to the confidentiality guidelines set forth by Saudi NIH.

## **Sub-Grants**

Sub-grants to collaborating organizations are permitted within this opportunity only to local organizations. Additional conditions for collaboration apply in accordance with [Saudi NIH policies and regulations](#).

## **Related Required Documents**

All required documents should be uploaded to the online application form.

Please note that these requirements may differ based on the nature of the proposed study. Upon passing the prescreening stage, the Saudi NIH will communicate with the applicant to specify the required documents based on their application. Generally, applicants may be required to submit the following documents after passing the prescreening stage.

End of Request for Applications