Request for Proposals (RFP) Program Overview

The Novo Nordisk Inc. Investigator Sponsored Studies (ISS) program is dedicated to building on our 100-year heritage of putting patients first. That's why we support independent scientific investigations that improve patient outcomes and add knowledge to our therapeutic areas of interest. The Novo Nordisk Inc. ISS program includes Request for Proposals (RFP), which are publicly posted, specific to areas of interest, address unmet research needs/evidence gaps, and have set timelines for submission and review.

Note that this is a competitive process. Submission of an application in response to this RFP does not constitute agreement by Novo Nordisk to support your study. Submitted RFP applications will be reviewed by the Novo Nordisk teams on both the US (NNI) and Global level.

Program Eligibility

Geographic Region	Unites States
Applicant Eligibility	Eligibility includes: • Health Care Professional • An institution or organization • A company (which is not a pharmaceutical company)

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Program Overview

RFP Issue Date	**October 2024**
RFP Therapeutic Area	Liver Health
RFP Study Focus	Observational Studies
Unmet Need/ Areas of Interest	This RFP will support observational research in the therapeutic area of Liver Health. Specifically, Novo Nordisk has interest in supporting independent scientific investigations that focus on Steatotic Liver Disease including Alcohol related liver disease (ALD) with or without Metabolic dysfunction and alcohol-associated steatotic liver disease (MetALD), as well as Metabolic dysfunction associated steatotic liver disease (MASLD)." **<u>Areas of interest:</u>** 1. Validation of single or combination ICD codes to identify patients with ALD 2. Validation of screening for ALD +/- MetALD utilizing Non-invasive tests (NITs) including but not limited to: • Imaging based biomarkers • Blood, urine, and other tissue biomarkers • Use of AI/ML to identify patients with MetALD or ALD 3. ALD +/- MetALD related to: • Clinical and humanistic burden • Real world incidence and prevalence • Risk factors that directly or indirectly impact prevalence • Risk factors/comorbidities for disease progression and the magnitude of risk they introduce • Risk stratification of patients for key surrogate and/or clinical outcomes through use of precision medicine and genomics 4. Among patients with MASH, impact of alcohol use on disease progression including but not limited to: • Fibrosis progression • Hepatic decompensation • Liver and all-cause related mortality

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	Areas not in scope: • NITs in MASLD • Studies and those that require drug supply • Studies that overlap with completed, ongoing or planned research
Award Funding Considerations	• Study duration in response to this RFP should be ≤ 12 months. • The allotted support for this RFP is up to $200,000 USD. • The final monetary value supported for this RFP, will be dependent on completion of a Fair Market Value (Analysis) on the budget.
Key Dates	• RFP issue date: October 2024 • Full application due date: January 3rd, 2025 • Anticipated award notification date: February 2025

How to Apply & Submission Requirements

How to Apply	• Applications should be submitted through **www.novonordiskiss.com** • First time users will need to register for an account. • Refer to our Quick Reference Guide for instructions on how to navigate the portal and submit your application. • If you experience technical difficulties with the portal, please call + 1 718-576-1406 or email the system administrator at support@steeprock.com. **Submission Requirements include:** • A well-written protocol and detailed line-item budget utilizing the NNI protocol and line-item budget templates. All budgets will be subject to FMV analysis. **Please reference RFP 002 on the protocol title page.** • Investigator Curriculum Vitae • Conflict of interest form (signed and dated) For more information on how to access the protocol and line-item budget templates, refer to our Quick Reference Guide.
Review Process	• Submitted RFP applications will be reviewed by the Novo Nordisk teams on both the US (NNI) and Global level. The teams are comprised of representatives from Medical, Clinical & Regulatory Affairs, Clinical Data Science & Evidence, and other functions as appropriate. • Applicants will be notified of decisions via email.
Important Reminders	• This is a competitive process. Submission of a protocol and budget in response to this RFP does not constitute agreement by Novo Nordisk to support your study. Novo Nordisk may not have any influence over the content or development of your proposal or budget and is unable to provide input that may shape or influence the content of the RFP

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	submission. All questions related to this RFP must be solely directed to the contact listed below.
Contact Information for Questions	• Please email NNI_ISS@novonordisk.com