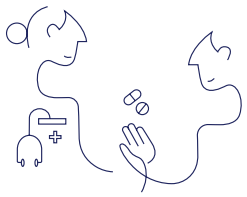
Novo Nordisk Inc. (NNI) Investigator Sponsored Studies (ISS) Program

Quick Reference Guide

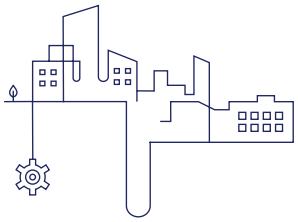
What is the NNI ISS Program?

The NNI ISS Program is dedicated to building on our 100-year heritage of putting patients first. That's why we support independent scientific and clinical investigations that improve patient outcomes and add knowledge to our products and/or therapeutic areas of interest. The NNI ISS Program aims to support high-quality independent research that addresses data gaps/unmet needs and potential areas of innovation.

Who can apply?



An individual
(e.g., healthcare professional)



An institution or organization

A company (which is not
a pharmaceutical company)

Studies we support

1. Clinical	Interventional drug research that processes data derived from humans or human specimens.
2. Observational	Research measured according to standard of care, without any attempt to change or intervene. Data can be obtained through primary data collection, secondary use of data (e.g., claims data, medical chart review, electronic healthcare records, meta-analyses, etc.), or a combination of both.

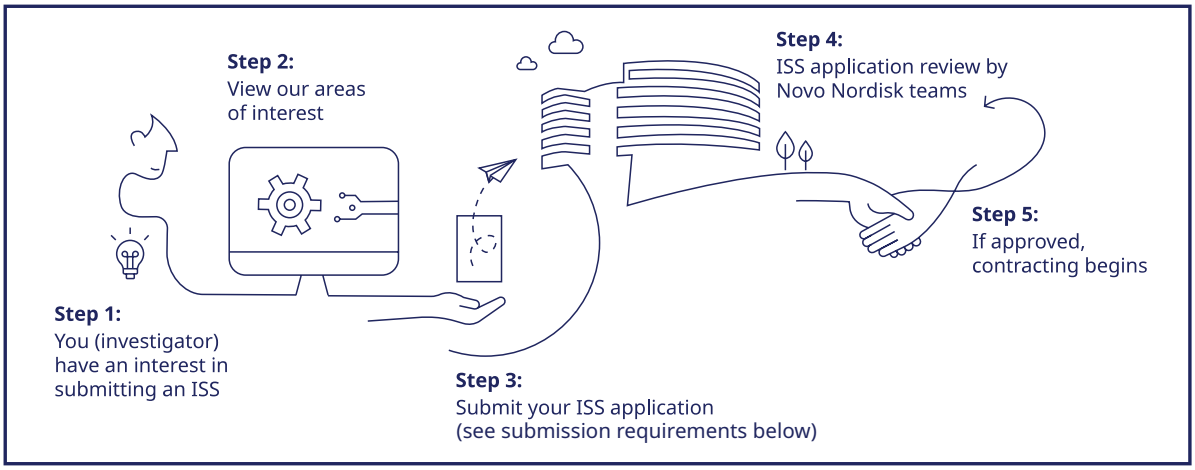
Provided support

Drug only

Funding only
(e.g., observational studies)

Drug and funding

Submission overview



Key areas of interest

Diabetes | Obesity | Liver Health | Neurologic Health | Cardiovascular Disease | Rare Diseases

How to apply online

- Register at the ISS Portal to create an account username and password (new users only).
- Refer to our ISS Portal Quick Reference Guide for detailed instructions on how to navigate the portal.

Submission requirements

Submission of a full protocol, line-item budget, and all other supporting documentation is required (see protocol requirements and Sponsor-Investigator's responsibilities below). ISS applications will be reviewed by the Novo Nordisk teams on both the local (NNI) and Global levels.* For instructions on how to access our protocol and line-item budget templates, refer to our ISS Portal Quick Reference Guide.

Protocol requirements

Section of protocol	Page limits
• Protocol Summary	30 lines of text
• Protocol Background and Specific Aims	1 page
• Protocol Significance	2 pages
Protocol research strategy	**No page limit**
• Protocol Study Design and Study Population	No page limit
• Protocol Research Methods	No page limit
• Statistical Considerations	No page limit
• Protocol Ethics	No page limit
• Protocol Study Drug and Materials	No page limit
• Protocol Adverse Events	No page limit
• Protocol Premature Study Termination	No page limit
• Protocol Publication Plan	No page limit
• Protocol References	No page limit

Submission deadlines

There are two submission deadlines per year. Please visit our NNI ISS website for more information.

*Please note that an ISS application can be rejected at any stage within the review process, and the time to study drug distribution for an ISS is approximately 5 (five) months from execution of the ISS contract.

Responsibilities of Sponsor-Investigators

The NNI ISS Program is committed to supporting high-quality independent research endeavors. NNI requires proper documentation from their Sponsor-Investigators throughout the life cycle of an ISS.

Documentation at time of submission

- A well-written protocol and detailed line-item budget utilizing the NNI protocol and line-item budget templates. All submitted line-item budgets will be subject to Fair Market Value (FMV) analysis.
- Active medical license (e.g., if requesting study drug).
- Signed and dated Conflict of Interest form.
- Signed and dated (within the last year) Curriculum Vitae.

Timely submission and responses

- Adherence to the yearly submission deadlines.
- Timely responses for updates/clarifications to the Novo Nordisk teams.

Documentation for study drug

- Final approved protocol.
- Executed ISS contract.
- Institutional review board/ethics committee (IRB/EC) review and approval.
- Investigational new drug (IND) application review and approval, as applicable.

Study execution and maintenance expectations

- Registration on the FDA's ClinicalTrials.gov site no later than 21 days after the study is opened for enrollment. NNI should not be listed as the sponsor or collaborator.
- Quarterly study status updates (e.g., enrollment, protocol changes, IRB's continuing review and approval).
- IRB/EC reportable deviations, adverse events, progress on planned analysis, and reports of results.
- Submission of all public communications (e.g., abstracts, manuscripts, social media posts, news articles, etc.) 60 days ahead of Sponsor-Investigators' own deadline for review by NNI. NNI should not be listed as the sponsor or collaborator.

Study closure expectations documentation

- Final written report of study results.
- Completed drug reconciliation form.

Publications

- Demonstrated attempt to publish study results in a peer-reviewed journal.
- Ongoing submission of any public communications (e.g., abstracts, manuscripts, social media posts, news articles, etc.) 60 days ahead of Sponsor-Investigators' own deadline for review by NNI. NNI should not be listed as the sponsor or collaborator.