PART III

Shared Development Infrastructure | Round 2025

PharmaNL

Investment Agenda

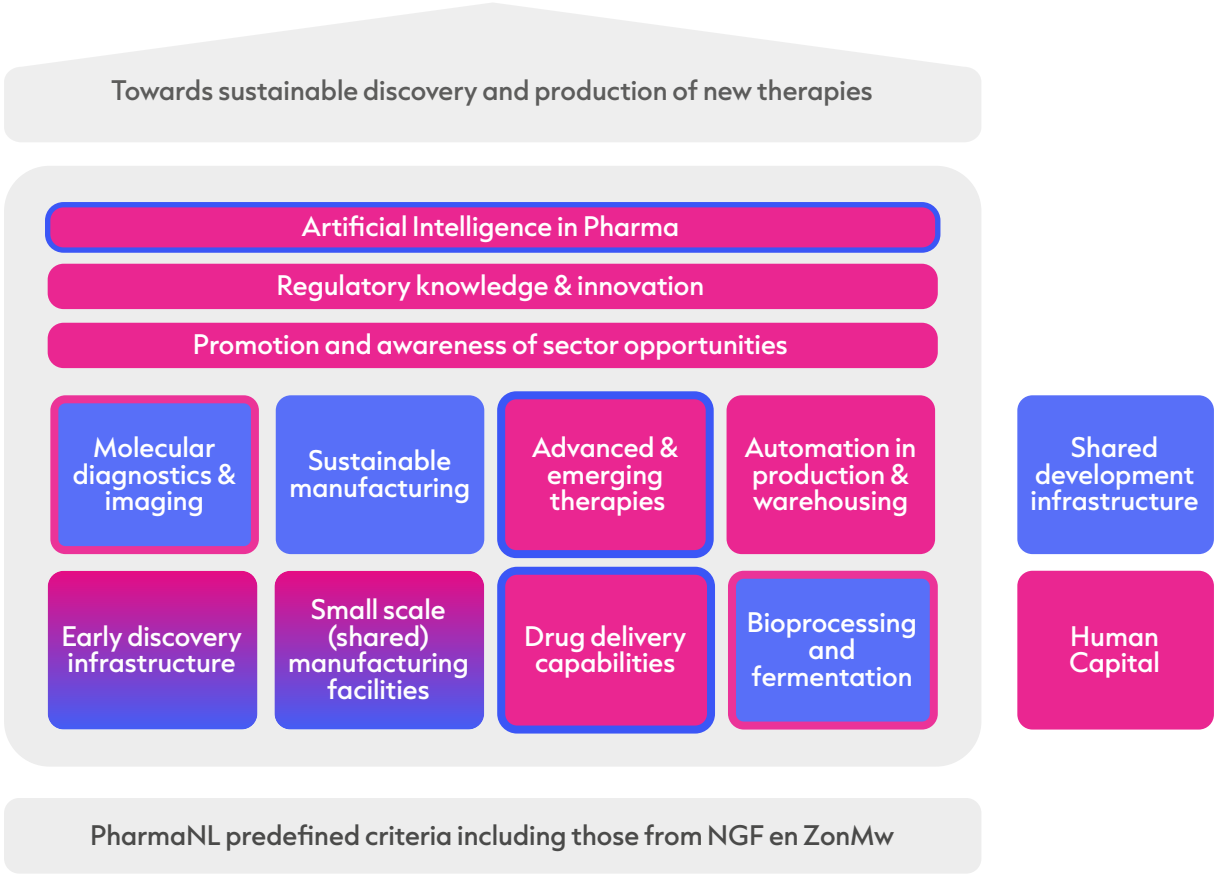
PharmaNL

This document is an integral part of the PharmaNL investment agenda as presented on August 22, 2024. Following the publication of the investment agenda for Program Line 2: Human Capital, this document focuses solely on Program Line 1: Shared Development Infrastructure. The background, process, and methodology used to develop this agenda can be found in the previously published document:

www.pharmanl.org/nieuws/pharmanl-presenteert-investeringsagenda

Themes

Based on the GAP analysis conducted by PharmaNL, the subsequent PharmaNL Expert Meeting, and consultations with the Ministry of Health, Welfare and Sport (VWS), the following SDI-specific themes have been identified. Where applicable, the evaluation of the first SDI program funding round has also been considered.



Thematic Prioritization by PharmaNL for the 2024/2025 Rounds

In blue are the topics for the SDI program line, in pink those for the Human Capital program line. Themes that are primarily Human Capital with a small Infrastructure component are shown as pink blocks with blue borders (e.g., drug delivery capabilities). Conversely, themes that are primarily Infrastructure with a small Human Capital component are blue with pink borders (e.g., bioprocessing and fermentation). Topics of equal importance to both lines are depicted half blue, half pink.

This document focuses exclusively on the Shared Development Infrastructure Program Line and therefore addresses only the blue-colored or blue-bordered topics.

The fully elaborated Investment Agenda for the Human Capital Growth Program Line (2024 round) has already been published and can be found here: **www.pharmanl.org/nieuws/pharmanl-presenteert-investeringsagenda/**

2025 SDI Funding Round

A total budget of approximately €24 million will be available in the 2025 open funding round for the Shared Development Infrastructure program line. This allows for funding of approximately 5–10 projects, with a maximum PharmaNL contribution of €5,000,000 per project.

Budget Allocation and Theme Prioritization

Theme	2025 Budget	Notes	Additional Conditions
Molecular diagnostics & imaging	€6,000,000		+ bonus scoring for AI
Early discovery infrastructure	€6,000,000		+ bonus scoring for AI
Small scale (shared) manufacturing facilities	€12,000,000	These three themes are clustered due to their production focus	+ bonus scoring for Advanced & Emerging Therapies** + bonus scoring for Drug Delivery Capabilities + bonus scoring for AI
Bioprocessing* and fermentation	—	Included in the above cluster	
Sustainable manufacturing	—	Included in the above cluster	
AI in Pharma	Not applicable	Integrated as an additional requirement in the above themes. Separate budget may be available in a future round.	
Advanced & emerging therapies**	Not applicable	Integrated as an additional requirement in the above themes. Separate budget may be available in a future round.	
Drug delivery capabilities	Not applicable	Integrated as an additional requirement in the above themes. Separate budget may be available in a future round.	
Cross-thematic projects	Not applicable	—	

* In this investment agenda, *"Bioprocessing"* is defined as the use of intact, living cells, or their components, to generate or process pharmaceutically active ingredients.

** Radiopharmaceuticals, bacteriophages, cell & gene therapy, nanomedicines, and advanced vaccines are explicitly included under *"Advanced & Emerging Therapies"*.

Overall Objective of Program Line 1 – Shared Development Infrastructure

To develop a shared infrastructure for the development, scaling-up, and manufacturing of innovative medicines in the Netherlands, with the aim of establishing a state-of-the-future shared development infrastructure for use by pharmaceutical start-ups, scale-ups, and academic research groups.

Through investments within the themes defined in this 2025 agenda, PharmaNL aims to ensure that:

1. Essential and innovative infrastructures become more accessible and sustainably available to innovators from academia, SMEs, and the wider private sector.
2. Providers of infrastructure have the opportunity to upgrade and innovate existing infrastructure to enhance its quality.
3. Proposal budgets include activities for training personnel to operate PharmaNL-funded infrastructure.

General Conditions

Only project proposals that contribute to the overarching goal of **Program Line 1 – Shared Development Infrastructure** are eligible for funding. That is, they must help "Develop a shared infrastructure for the development, scaling-up, and manufacturing of innovative medicines in the Netherlands."

Proposals seeking investments in facilities that are already sufficiently available in the Dutch R&D landscape, have already been funded in the first SDI call, or can be realized without PharmaNL funding, are not eligible.

Thematic Descriptions

Further elaboration of the themes and any additional conditions per theme are as follows.

Molecular Diagnostics and Imaging

To accelerate the development and application of molecular diagnostics and imaging in the development of new medicines, PharmaNL offers investments in shared R&D infrastructure. These investments aim to provide access to advanced facilities and expertise for both researchers and companies.

PharmaNL focuses on enabling key capabilities in molecular diagnostics and imaging to support new therapeutic interventions, including but not limited to:

- Advanced optical tracing technologies (e.g., MRI, PET, high-resolution microscopy)
- Molecular analysis facilities for biomarker identification and validation (e.g., next-gen sequencing, qPCR, multiplex assays)
- AI- and machine learning-supported imaging and data analysis facilities
- Access to integrated platforms for multimodal in-vitro imaging and diagnostics in support of therapeutic development

By making these infrastructures available, PharmaNL supports the development of new diagnostic methods and imaging techniques that have the potential to significantly improve the precision and effectiveness of pharmaceutical interventions. Ultimately, this will help pave the way for further personalized medicine, and potentially improve the overall quality of care and treatment outcomes

Applications that incorporate AI innovation within this theme will be eligible for bonus scoring.

Projects focused on patient treatment or frequent use in everyday clinical practice are outside the scope of this theme.

Early Discovery Infrastructure

To accelerate Dutch therapeutic innovations through the discovery and early preclinical phases, PharmaNL supports investments in *"Early Discovery Infrastructure."* Access to this infrastructure will help researchers and businesses develop therapeutic solutions more effectively and efficiently.

PharmaNL targets the following types of infrastructure, among others:

- Advanced physico-chemical characterization (e.g., NMR, LC-HR-MSn, X-ray)
- Biological characterization and translational techniques (e.g., target engagement, organ-on-a-chip, ADME-Tox, in vitro/in vivo correlation studies)
- Medicinal chemistry support and expertise
- High-throughput and high-content screening, including automated robotic systems and advanced preclinical imaging

Applications integrating AI innovation will be eligible for bonus scoring.

Cluster: Small Scale (Shared) Manufacturing Facilities, Bioprocessing*, and Sustainable Manufacturing

These themes are clustered due to their strong production components. Investments should contribute to the sustainability and environmental footprint reduction of the pharmaceutical sector, supporting a future-proof industry and enabling Dutch innovations to better capitalize on their economic value.

Only projects with a clear sustainability component will be considered. Three general additional conditions apply:

- Bonus scoring for projects supporting Dutch *"Drug Delivery Capabilities"*
- Bonus scoring for projects incorporating AI innovation
- Bonus scoring for projects integrating *"Advanced & Emerging Therapies"*

Small Scale (Shared) Manufacturing Facilities

To strengthen the competitive position of the Dutch pharmaceutical sector and stimulate innovation in the manufacturing processes of (bio)pharmaceuticals, PharmaNL offers investments under the theme *"Small Scale (Shared) Manufacturing Facilities"*. By facilitating access to small-scale production facilities and/or innovative technologies in the small-scale manufacturing of (bio)pharmaceuticals, researchers and companies can develop new products and production methods more quickly and efficiently. This not only promotes innovation but also has the potential to accelerate the market readiness of new products.

PharmaNL focuses on unlocking access to essential production facilities and related expertise, including but not limited to:

- Flexible and modular production systems suitable for small-scale manufacturing
- *"Small-scale pilot production facilities"* used for process development and optimization to enable the transition to scaling up
- Automated and robotic production lines, including AI-driven process control and quality monitoring

Bioprocessing and Fermentation

To accelerate progress and application in *"Bioprocessing and fermentation,"* PharmaNL offers investments in shared R&D infrastructures within this theme. These investments are focused on "scale-up for manufacturing of small molecules and biologics" and "commercial manufacturing and distribution," as described in the Drug Discovery, Development, and Deployment (4D) map, see page 14 of part I of the investment agenda. The investments are intended to provide researchers and companies access to advanced facilities and expertise in "bioprocessing and fermentation."

PharmaNL focuses on unlocking opportunities within the theme "bioprocessing and fermentation." Examples of this include, but are not limited to:

- Advanced shared facilities for biopharmaceutical production, including microbial/cell culture optimization
- Scale-up and process intensification technologies to enhance efficiency and consistency
- Shared infrastructure for advanced production, purification, and isolation of proteins (e.g., target receptors, enzymes) or biopharmaceutical candidate products
- Integration of AI and machine learning for process monitoring and precision in bioprocessing

Sustainable Manufacturing

Investments within this theme must lead to the adoption of sustainable methods in the development and production of current and future pharmaceutical products. These methods can therefore have a significant impact on reducing the ecological footprint of the manufacturing process of current and future pharmaceutical products.

To accelerate the development and implementation of sustainable manufacturing methods within the R&D of (bio)pharmaceutical products, PharmaNL aims to invest in making existing R&D infrastructures more sustainable.

Investment plans may include the following, but are not limited to:

- Advanced bioprocessing facilities optimizing resource and energy use
- Technologies for green chemistry and sustainable synthesis processes, aimed at reducing waste and emissions, the use of solvents, and emissions in the production of pharmaceutical products. Continuous production platforms that reduce costs and ecological impact
- Innovative platforms for continuous manufacturing and process intensification that reduce production costs and ecological footprint, applicable to both biopharmaceutical and chemical products.
- Shared facilities for waste(water) treatment and recycling of chemical reagents to minimize the environmental impact of pharmaceutical production processes.
- Integration of digital tools, such as process optimization via AI and machine learning, to promote sustainability.

*** In this investment agenda, *"Bioprocessing"* is defined as the use of intact, living cells, or their components, to generate or process pharmaceutically relevant products.**

**** Radiopharmaceuticals, bacteriophages, cell & gene therapy, nanomedicines, and advanced vaccines are explicitly included under *"Advanced & Emerging Therapies."***

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