

Technical Project Summary- SDI

Project title

PHARMIGA: An infrastructure to accelerate IgA-based therapeutic development

Acronym (optional)

PHARMIGA

Project leader + organisation

Prof. Roos Masereeuw, Utrecht University

File number:

10920012510005

Key words

Novel IgA-based therapeutics; Mass spectrometry; IgA production, characterization and function; Advanced in vitro models; AI & MS epitope characterization

Domain 4D Map ([link](#))

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| ☒ A. Basic Science & Target Identification | ☐ F. Regulatory review |
| ☒ B. Target Pharmacology | ☐ G. Post-marketing |
| ☒ C. Lead Identification | ☐ H. Medical Landscape |
| ☒ D. Lead Optimization | ☐ I. Commercial Manufacturing & Distribution |
| ☐ E. Clinical Research & Development | |

Theme investmentagenda (if applicable)*Investeringsagenda SDI 2025 ([link](#))*

- ☐ 2025. "Molecular Diagnostics and Imaging"
- ☒ 2025. "Early Discovery Infrastructure"
- ☐ 2025. "Small scale (shared) manufacturing facilities, "Bioprocessing and fermentation" and "Sustainable manufacturing"

Aims and objectives

PHARMIGA project will establish an openly accessible, high-performance infrastructure for the discovery, production, engineering, and structural and functional validation of IgA-based monoclonal antibodies. The key objective is to overcome technological barriers, de-risk IgA therapeutic development, and accelerate clinical translation by providing advanced tools and expertise to academic and industrial users.

User group and application

The infrastructure is designed for biotech companies, pharmaceutical firms, CROs, and academic groups active in antibody research and development. It provides modular access to technologies for IgA engineering, glycoengineering, production, characterization, functional testing, and delivery. Users can access these services for innovation projects spanning early discovery, preclinical validation, and down-stream translational research. Access will be granted via innovation projects, initially with early adopters, but ultimately also by external users from university hospitals and big pharma.

Impact

PHARMIGA is based on the key idea that IgA-based therapeutics could be more effective in mucosal immunity and oncology, areas where current IgG-based mAbs has limited efficacy. PHARMIGA addresses a critical gap in therapeutic antibody development of IgA based modalities. By uniting technologies and expertise, PHARMIGA will reduce risks, time-to-market, lower R&D costs, and increase the reliability of IgA production and functionality. This broadens and accelerates

pharmaceutical innovation, creates opportunities for new product pipelines, and enhances the competitiveness of the Dutch biotech ecosystem.

Technical description of the shared infrastructure

The PHARMIGA infrastructure integrates multiple highly complementary service platforms into a coherent organization. These platforms include: State of the Art Mass spectrometry facilities with advanced hybrid fragmentation for IgA glycosylation analysis and AI-supported de novo sequencing combined with IgA repertoire profiling. IgA engineering and production capable of upscaling recombinant and/or glycoengineered IgA in different molecular (circulatory and secretory) formats, overcoming current challenges in production and stability. Predictive in vitro models, including organ-on-chip and immune-microbiome co-cultures, for human relevant efficacy and safety testing, reducing reliance on animal models. Formulation and delivery platforms supporting mucosal IgA delivery, nanoparticle formulations, and RNA-based approaches to overcome IgA's short half-life and targeted administration challenges. PHARMIGA will provide end-to-end capabilities for IgA mAb discovery, functional testing, process development, and translational readiness. It is designed for both stand-alone service modules and complete workflow integration, enabling tailored solutions for diverse user needs.

Project group and collaborating partners

The project is executed by a consortium of leading experts in the field of IgA biology and therapeutics, namely Roos Masereeuw (UU, main applicant & lead of in vitro models), Albert Heck (UU, lead of mass spectrometry, UU), Gestur Vidarsson (Sanquin, lead of IgA engineering), Jeanette Leusen (UMCU, lead IgA engineering), Enrico Mastrobattista (UU, lead of formulation & delivery). Their entire groups and research infrastructure will support PHARMIGA. This entails expertise in IgA biology, IgA glycosylation and engineering, and mucosal immunology and IgA delivery. PHARMIGA is strongly supported, as evidenced by a dozen Letter of Support, of large biopharma companies (e.g. Genmab) as well as start-up companies, and by instrument developers (e.g. Bruker, ThermoFisher). Several early adopter demonstrator projects are already under construction, including those with researchers embedded in Dutch academic hospitals (e.g. LUMC, Radboud) UU financial and legal experts will assist with business development, financial & legal affairs.

Innovation and Distinctiveness

IgA-based modalities are unexplored treasures in antibody development with strong potential in cancer, auto-immune diseases as well as infections. PHARMIGA will boost the successful development of IgA based biotherapeutics, with a unique integrated open-access infrastructure. Unlike existing small & fragmented resources, it combines IgA production, engineering, structural characterization, AI-based modelling, in vitro functional models, and delivery technologies into an integrated platform, enabling an efficient and scalable translational pipeline for the development of IgA therapeutics.

Alignment PharmaNL programme (optional)

The project aligns with PharmaNL's Human Capital Growth program by training researchers and industry professionals to explore next-generation therapeutic modalities, building national expertise in IgA, and increasing the number of people receiving awareness about the potential of IgA. Within the project, education will be provided, and training on site will be offered to all users of the infrastructure.