NADP Research & Development Agenda

Accelerating research and development of new antibiotics and alternatives in the Netherlands

nadp

netherlands antibiotic development platform

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1 Background

The discovery of penicillin in 1928 marked the beginning of the age of antibiotics, a revolution in healthcare that has been the cornerstone in decreasing the morbidity and mortality of major bacterial infectious diseases in humans and animals. The availability of antibiotics has played a pivotal role in reducing the impact of major bacterial infectious diseases, such as pneumonia and tuberculosis. However, from the moment that antibiotics were used commonly to treat infectious diseases, bacteria have developed resistance to them. Accelerated by the overuse of antibiotics in the 20th century, multiple drug-resistant (MDR) bacteria have emerged in all parts of the world.
Well-known examples include pathogens of the so-called 'ESKAPE' class, namely vancomycin-resistant Enterococcus (VRE), methicillin-resistant *Staphylococcus aureus* (MRSA) and multi-drug resistant (MDR) *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and *Escherichia coli*; as well as among others *Clostridium difficile* and MDR and extremely drug resistant (XDR) tuberculosis (TB). Infections with these pathogens pose an enormous threat to human health and lead to massive costs for health care.

An important aspect of the global problem on AMR is the lack of new drugs that can replace the increasingly ineffective set of antibiotics currently available. Worldwide, the pipeline for new antibiotics is limited because of scientific, regulatory and economic barriers. In response to this, multiple governmental and non-governmental organisation (NGO)-supported initiatives have been implemented at international and national level as an important step to boost the antibiotic research and development (R&D) pipeline.[1] These initiatives include European Union/European Federation of Pharmaceutical Industries and Associations (EU/EFPIA)-supported Innovative Medicines Initiative (IMI)[2], Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)[3], Global Antibiotic Research & Development Partnership (GARDP)[4], and the German-led G7/G20 Global AMR R&D Hub, in line with the national and EU strategies on AMR, the WHO Global Action Plan on AMR, and the UN general Assembly resolution in 2016.

Antibiotic resistance is one of the most urgent and severe threats to global public health and economy

In the Netherlands, this led to the establishment of the Netherlands Antibiotic Development Platform (NADP), bringing together Dutch academic institutions, medical centers, and private organisations working on R&D of antibiotics and alternative therapies spanning the entire spectrum from basic research to clinical Phase IV studies. An initiative that was taken by the Ministry of Public Health, Welfare and Sports together with already existing collaborative networks of public and/or private organisations (see Appendix I) active in antimicrobial research and drug development in the Netherlands. The NADP aims to collaborate with aforementioned international initiatives and stimulate the collaboration of Dutch researchers with these initiatives.

1 Renwick MJ, Simpkin V, Mossialos E. Targeting innovation in antibiotic drug discovery and development: The need for a One Health – One Europe – One World Framework. Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2016. (Health Policy Series, No. 45.)
2 https://www.imi.europa.eu/
3 http://www.carb-x.org/
4 https://www.gardp.org/

2 Netherlands Antibiotic Development Platform

The Netherlands Antibiotic Development Platform (NADP)[5] facilitates the collaboration between public and private organisations active in the Life Sciences Health sector with the goal to **fill and accelerate the R&D pipeline of new antibiotics and alternative therapies for use in human and animal health care (Figure 1).**

To achieve this goal the NADP actively supports:

- Lead finding and development via NADP support vouchers;
- Identification and initiation of public-private R&D collaborations via alliance management;
- Networking between (inter)national public and private organisations active in antimicrobial R&D.

In pursuit of its overall goal, NADP adopts a common **Research & Development Agenda (RDA)** that defines the long-term focus areas of NADP guiding its efforts and support in the Netherlands. The RDA distinguishes and reflects on the current antibiotic and alternatives research infrastructure of the Life Sciences Health sector in the Netherlands.

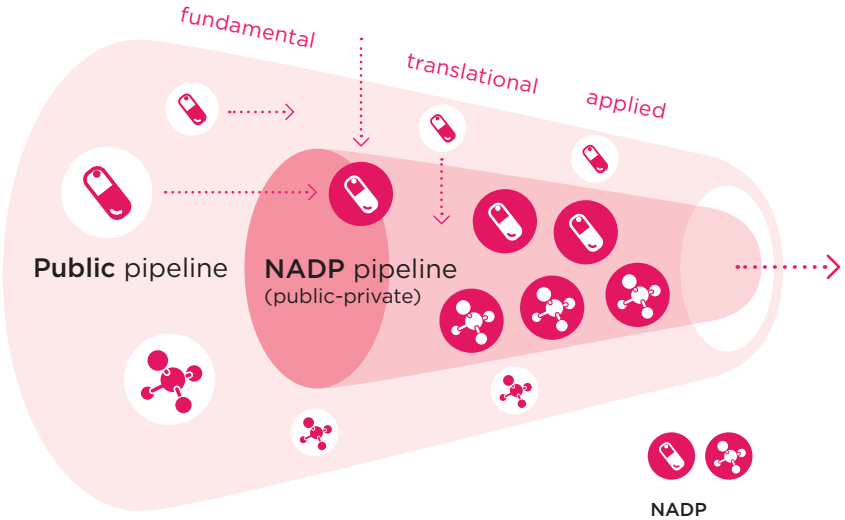

Figure 1 — Research and development of NADP spans from translational and preclinical research leading to applied and clinical studies.

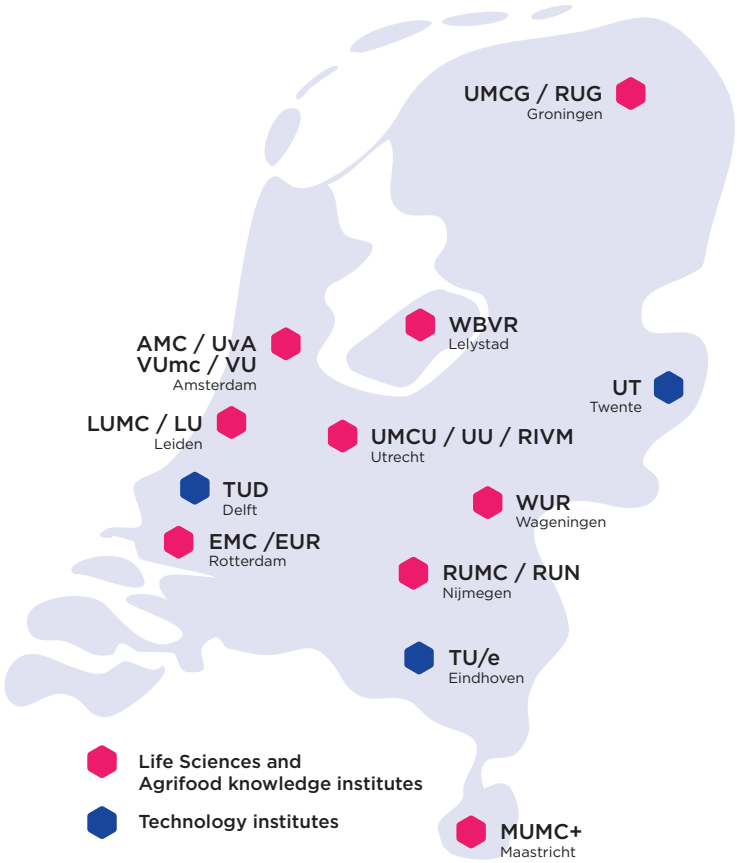

Figure 2 — Universities, university medical centers, and technological universities active in R&D of antimicrobial solutions in the Netherlands. Abbreviations: Academic Medical Center Amsterdam (AMC), Erasmus Medical Center (EMC), Erasmus University Rotterdam (EUR), Leiden University (LU), Leiden University Medical Center (LUMC), Radboud University Nijmegen (RU), Radboud University Medical Center (RUMC), Technical University Delft (TUD), Technical University Eindhoven (TU/e), University Groningen (RUG), University Medical Center Groningen (UMCG), University Medical Center Maastricht (MUMC+), University Medical Center Utrecht (UMCU), University Twente (UT), University of Amsterdam (UvA), Utrecht University (UU), VU University Amsterdam (VU), VU University Medical Center (VUmc), Wageningen University & Research (WUR), Wageningen Bioveterinary Research (WBVR).

Life Sciences Health sector in the Netherlands

The Netherlands is home to a vibrant, concentrated Life Sciences Health cluster with more than 2200 life science and medtech companies and research organisations, all within a 120-mile radius.[6] As such it is the most geographically concentrated region in the world when it comes to creating economic and social value in Life Sciences and Health. The excellent medical research infrastructure is strongly focused on translational research in different medical fields including infection and immunology of animal and man. Worldwide, the Netherlands ranks 6th and 8th in life sciences and health citations and patents, respectively.[6]

Within the Netherlands, 10 universities, 8 university medical centers and 3 technological universities are active in R&D of antimicrobial solutions (Figure 2). In nationwide public-private R&D programmes these research organisations cooperate in different niches such as identification and lead optimisation of new antibiotics and alternative therapies (NACTAR programme), bacterial vaccine technology development (Bac Vactory programme), and point-of-care diagnostics (ZonMW antimicrobial resistance programme). In addition, active participation of many of these institutes is seen in European-funded R&D programmes.
In particular, a prominent role is being played by the Netherlands in the IMI-funded programme NewDrugs4BadBugs, in which amongst others a European clinical infrastructure for anti-infectives efficacy testing is being established (COMBACTE project). Also a number of H2020 programmes are running focused on antibiotic development and production (SynPeptide; Rafts4Biotech).

5 https://nadp.nl/
6 https://www.health-holland.com/public/downloads/hh-toolkit/health-holland-factsheet-eng-.pdf

3 NADP focus areas in research and development

The aim of the research within the RDA is **to deliver and accelerate the development of new bioactive compounds and alternatives to antibiotics aimed at curing infectious diseases caused by antibiotic-resistant bacteria.** Genome sequencing and the resulting discovery of numerous previously unseen biosynthetic gene clusters and the advent of innovative engineering tools, such as CRISPR-Cas9 and large-scale gene and protein synthesis, have revolutionised the life sciences. Also it is becoming increasingly clear that host immune mechanisms are involved in the curative response to antibiotic treatment in case of chronic bacterial infections. Together, these technological and scientific advances have opened new opportunities to search for novel antibiotics and alternative therapies to treat bacterial infections in both humans and animals.

Reflective of the expertise and research excellence in the Netherlands, three focus areas are identified within the NADP that aim to decrease our dependence on last resort antibiotics:

1. **New antibiotic molecules**
2. **New alternative therapeutics**
3. **Clinical infrastructure**

The focus areas enable NADP in its support of collaborations between public and private organisations aimed at finding and accelerating the development of new antibiotics and alternative therapies. This RDA presents the current strategic focus of NADP activities, but it also recognises that R&D is a dynamic process and new centers and expertise will develop.

Figure 3 — NADP focus areas in research and development.

New antibiotic molecules

There is a need to identify and introduce novel antibiotics that can by-pass the current resistance mechanisms, to alleviate our dependency on the few antibiotics of last resort that are currently available. Antibiotic resistance is dependent on the chemical class and the mechanism of action of the antibiotic, thus new antibiotics must preferably affect novel targets and/or have sufficient structural novelty. Ideally, an antibiotic has multiple targets that are essential to the target cell, possibly including non-protein-based targets. In both cases there is a significantly lower chance of the occurrence of resistance.

The overall objective of focus area 'New antibiotic molecules' is to identify and optimise novel antibiotics against Gram-positive and Gram-negative pathogenic bacteria, based on novel, preferentially multiple, or non-protein based targets.

Areas of excellence in the Netherlands comprise

Drug discovery — From the dawn of the antibiotic era to present day, excellence in microbiology has underscored the Dutch contribution to antibiotics research and development. From historic contributions by van Leeuwenhoek, Beyerinck, and Kluyver to current dedicated microbiology centers focussing on identification of new antibiotics via isolation of novel molecules from actinomycetes (van Wezel (LU, NIOO-KNAW)), the largest fungal collection in the world (Westerdijk Fungal Biodiversity Institute), and a large collection of Bacilli with high antimicrobial potential (Kuipers (RUG)). Innovative biotechnology approaches are thereby developed to enable and/or enhance the production of antibiotics and derivatives (van Wezel (LU), Kuipers (RUG)). Furthermore, an internationally renowned research base in bacterial membrane biogenesis including bacterial protein transport is available and being exploited for the discovery of novel antibiotics (Driessen (RUG), Bitter (VU), Tommassen (UU)). The past decade has also witnessed the continued merging of the fields of biology and chemistry - chemical biology - as related to the pursuit of new antibiotics. Aside from providing new tools for the discovery of novel antibiotics, such as the design of activity-based probes to selectively isolate antibiotics (Overkleeft and van der Stelt (LU), (RUG)), chemical biology approaches can also be applied to understanding the mechanisms of action of novel antibiotics and the mechanisms by which pathogenic bacteria develop antibiotic resistance (UU, RUG, UMCG). The focus in chemical biology lies in characterisation and adaptation of antimicrobial compounds (Martin, van Wezel (LU), Kuipers, Minaard (RUG)). Furthermore, strong bioinformatics expertise exists, and the antiSMASH algorithm developed by Medema (WUR) is the most used software for the identification and analysis of biosynthetic gene clusters worldwide. Microbial ecology is an important new field in drug discovery, that harnesses natural signals and eliciting conditions to activate biosynthetic gene clusters that are inactive under routine screening conditions (van Wezel (LU), Raaijmakers (NIOO-KNAW)). Variants of naturally occurring antibiotics are engineered via molecular genetics approaches (Kuipers (RUG)). Elucidating antibiotic mechanisms of action and identification of un(der)exploited targets. Application of activity-based probes (VU, UvA, LU). Important supporting technologies include organs-on-a-chip in which the Netherlands have a leading position (Clevers (Hubrecht-KNAW), Hankemeier (LU) and Mummery (LUMC)).

Drug design — The Dutch chemical community is extremely strong and has a reputation for delivering world-class innovation as evidenced by a recent Nobel Prize. Synthetic chemistry (Rutjes (KUN), Martin (LU), Feringa (RUG), Breukink (UU)) and innovative concepts (i.e. light-activated antibiotic molecules; Feringa (RUG)) aid in the design of novel structures and libraries and are reflective of excellence in their application to antibiotics. Moreover, synthetic biology approaches have generated large libraries of novel antimicrobial peptides tested by novel high-throughput screening methods, yielding new drug candidates (Kuipers, RUG).

New alternative therapeutics

A complementary strategy to the development of new antibiotics is the development of alternative modalities, that can either eliminate bacteria without selecting for novel resistance traits, or that modulate the immune response of the host during (or before) infection. Such strategies should be based on mechanisms of action not yet used by existing antibiotics or whose delivery mechanisms are not (or at least less) susceptible to evolutionary resistance pressure, or on better understanding of the innate and humoral immune response to bacterial infections caused by species creating current and future treatment problems because of AMR.

The overall objective of focus area 'New alternative therapeutics' is to develop strategies that are targeted towards establishing and/or boosting host immunity as well as reduction of pathogen burden by means of therapies other than broad-spectrum antibiotics.

Areas of excellence in the Netherlands comprise

Host-directed therapy — The use of preventive vaccination to boost host immune responses to clear or to accelerate clearance of the bacterial infection is a potent strategy. Research in vaccine technology and vaccine design dates back to 1950 when the Netherlands introduced the National Immunization Program. It has led to strong research communities in infection biology, microbiology, and innate and adaptive immunology. Particularly the understanding and design of immunomodulatory and anti-inflammatory therapy are a primary strength in the Netherlands (van der Poll (AMC), Rooijakkers (UMCU), van Strijp (UMCU), Haagsman (UU)). Moreover, the ground-breaking concept of trained immunity foreseen to aid in the design of future vaccine strategies was established by Dutch researchers (Netea (RUMC)). To tackle intracellular infections novel vaccination strategies (mostly in tuberculosis) and host-directed therapy (HDT) are being pioneered in the Netherlands. The latter attempts to reprogramme the host immune system by pharmacological and chemical-genetic manipulation. Importantly, HDT-driven manipulation of host signalling pathways may be effective also against drug-resistant bacteria and help to restore host control of infection in metabolically

perturbed cells. Promising compounds and host target molecules for HDT against MDR-TB and Salmonella have been identified by research groups in the Netherlands working in the field of chemical immunology (Ovaa (LU), Neefjes (LUMC), Ottenhoff (LUMC)). The Netherlands have also pioneered in developing microbiomes for host protection, and in particular to treat infections with Clostridium difficile, using faecal transplants (Kuijper (LUMC)), whereby a faecal transplant bank has been set up (Dutch Donor Feces Bank, LUMC).

Microbe-directed therapy — Antimicrobial host-derived peptides can kill bacteria rapidly. They function as first line of defence in animals and humans. In addition to antimicrobial activity they also have the ability to stimulate the host's immune system and in this way indirectly disable microorganisms. Research groups in the Netherlands are leading experts in the field of unravelling the working mechanisms of antimicrobial host-derived peptides (Nibbering (LUMC), Kuipers (RUG), Haagsman (UU), Zaat (AMC)).
In addition, an excellent infrastructure in peptide and protein chemistry and synthesis is available (Drijfhout (LU), Heck (UU), Gros (UU)). Another antimicrobial strategy based on the power of the host's immune system is to combat resistant bacteria via antibody-based therapies. The so-called therapeutic vaccines based on human monoclonal antibodies allow specific targeting of certain bacteria without affecting the host microbiome and thus reducing the risk for antibiotic resistance development. Furthermore, antibodies act immediately and require only basic immune functions that are often retained even in immunocompromised patients. With world-leading academic (Rooijakkers (UU), Parren (LUMC)) and industrial (van de Winkel (Genmab)) experts in antibody discovery, antibody biology research, and antibody engineering the Netherlands is at the forefront of this fast-moving field. Finally, development of bacteriophage technologies and research into the clinical benefits of phage therapy show potential as renewed solutions for antimicrobial therapy (Bonten (UMCU), Brouns (TUD), Struijs (EMC)).

Clinical infrastructure

A major challenge in the antibiotics pipeline is how to bring developed antibiotics and alternative therapeutics into the clinic. The pathway of resistance investigation and from hit to lead is a long one. The time needed for clinical evaluation of promising antibacterial compounds (from phase 1 to phase 3 trials) is generally between 5 and 10 years.

The Netherlands includes state-of-the-art 'Clinical Infrastructure' that aims to support the clinical development of antibiotics and alternatives and to improve the efficiency of these difficult (and thus expensive) trials.

Areas of excellence in the Netherlands comprise

Clinical trials infrastructure — the European Federation of Pharmaceutical Industrial Associations and IMI have created the New Drugs for Bad Bugs programme. An important goal is to create a high-quality clinical and laboratory trial network in Europe to optimise clinical trials with new antimicrobial agents. With a managing entity and coordinator in the Netherlands, the Dutch are leading the development of this clinical trial network COMBACTE (Bonten (UMCU)).

Infection models — The Netherlands is home to a number of groups developing cutting edge (predictive) methods for how well a given compound might behave as a drug. Such technologies have the power to greatly benefit antibiotics and alternatives research by accelerating the process by which early stage lead compounds become clinical candidates. Importantly, such models also have the potential to reduce the need for animal testing in preclinical evaluation of large numbers of candidate compounds. Particularly exciting technologies being developed and applied in the Netherlands today include organs-on-a-chip (Clevers (KNAW-Hubrecht), Hankemeier (LU), Mummery (LUMC)), and zebrafish and other infection models (Spaink & Meijer (LU), Bitter (VUmc)).

Industry related to antibiotic and alternative therapies research and development

Within the Netherlands, the industrial expertise required in the complex process of bringing an initial discovery of an antibiotic hit, through lead and candidate drug development, towards phase I and II clinical trials is available. A complete pipeline of contract research organisations covering essential steps in this process provide hit-to-lead and lead-to-candidate screening assay services (i.e. cytotoxicity), ADME/DMPK (absorption, distribution, metabolism, and excretion/ drug metabolism and pharmacokinetics) modelling, chemical synthesis and medicinal chemistry, and in vivo rodent model testing. Examples are Pivot Park screening Center and Syncom, both partner in the European Lead Factory programme of IMI, Mercachem and Triskelion.

With respect to biotechs developing new antibiotics and alternative therapies, the Netherlands is home to a growing number of small start-ups as well as Europe's largest biotech Genmab developing antibody-based technologies which can be applied in a variety of indications, including bacterial infections. Also based in the Netherlands is Micreos that develops endolysin- and phage technology enabling targeted killing of pathogenic bacteria, for which the company was chosen as having one of Europe's ten most impactful innovations in 2017. Most major human pharma companies (Merck Sharp & Dohme (MSD), GlaxoSmithKline, Pfizer, Johnson & Johnson, Novartis, etc.) as well as veterinary pharma companies (Zoetis, Boehringer Ingelheim, and MSD Animal Health) have strong alliances to Dutch scientists and invest in collaborative antibiotic and alternative therapies programmes. In total, 15 companies participate and invest in the nationwide NACTAR programme that aims to bring new antibiotics and alternative therapies into pre-clinical development between 2018-2023.

Appendix I
NADP Partners

The NADP partners are the Centre for Antimicrobial Research (CARES), the Centre for Sustainable Antimicrobials (CeSAM), Immuno Valley, and the Netherlands Centre for One Health (NCOH).

Centre for Antimicrobial Research

Centre for Antimicrobial Research (CARES)[7] in Leiden is a Dutch research initiative for antimicrobials research, focusing on the development of novel antibiotics and antimicrobials. The CARES programme aims at delivering novel lead compounds to refill the antibiotic pipelines. An aim in itself is to build a strong collaborative network consisting of universities, university medical centres and companies. Some 15 groups are united within CARES, from both Leiden University and LUMC, with strong focus on actinomycete and fungal microbiology, chemical biology, bioorganic synthesis and design of activity-based probes, host-pathogen interactions, drug development, infectious diseases and immunology. Major pathogens that are targeted include *Mycobacterium tuberculosis, Clostridium difficile* and *Pseudomonas aeruginosa*. In 2017 a new profile area on antibiotics was funded by the faculty of sciences (LU), with 6 PhD students working between leading groups in antibiotic research in chemistry, biology and drug research. Furthermore, Leiden has the largest bioscience park of the Netherlands, which offers a strong platform for public-private partnerships.
CARES believes it is vital that the public and private sector jointly take up responsibility to develop new antibiotics and to ensure a continuous supply of novel candidate drugs into clinical trials. CARES focuses on the development of novel compounds and the translational science to bring these new antibiotics to the clinic.

CONTACT PERSON – **Prof. Gilles van Wezel**

Centre for Sustainable Antimicrobials

The Centre for Sustainable Antimicrobials (CeSAM)[8] in Groningen comprises creative fundamental research, including advanced facilities for high-throughput (animal) testing and adequate patient-screening. CeSAM's goal lies in interdisciplinary basic and translational research to develop novel antibiotics and therapeutic ('theragnostic') concepts to fight resistant bacterial strains, simultaneously allowing sustainable prevention of resistance development and spreading.
The scientific challenge is to develop novel intelligent and sustainable antimicrobials to combat resistant pathogens, which will be pursued throughout the production pipeline to complete phase I clinical trials.
More than 20 chemistry, biology and pharmacy groups are active in the field of antibiotic design, (bio)synthesis, resistance and pharmaceutical characterisation, collaborating in various programmes, e.g. ALERT (EU-Cofund with 18 PhD students) and Pronkjewail (EU-Cofund, 17 PhD students)

7 https://www.universiteitleiden.nl/cares/
8 http://cesam-nnl.com/

both highly focused on antimicrobial development and AMR. The clinical challenge is to develop innovative solutions for personalised on-demand theragnostic strategies based on existing and novel antibiotics to optimise treatment and to prevent both health care-associated infections due to antimicrobial resistance and spreading of resistant strains.

CONTACT PERSON – **Prof. Oscar Kuipers**

Immuno Valley

Immuno Valley[9] is specialised in matching business and science with the goal to build sustainable partnerships for the research and development of solutions to infectious diseases in humans and animals. In addition, Immuno Valley supports partnerships with specialised services that are designed to maximise collaboration and drive a project forward.
The Immuno Valley team is comprised of professionals with a relevant track record in science and business. The Immuno Valley network comprises multinational pharmaceutical companies, SMEs, academic hospitals, and knowledge institutes active in the field of human and animal health. In the field of infectious diseases, Immuno Valley has previously established the multistakeholder R&D programme on Alternatives to Antibiotics (ALTANT)[10] and also initiated and manages the Bacterial Vaccine Technology Center (Bac Vactory; 6 PhDs and 4 postdocs).[11]

CONTACT PERSON – **Liana Steeghs, PhD**

Netherlands Centre for One Health

The Netherlands Centre for One Health (NCOH)[12] brings together world-leading academic research institutes in the Netherlands active in various complementary fields of One Health together with other leading parties. Thereby, it forges an open innovation network to take joint responsibility for finding answers to global One Health challenges. The NCOH primarily aims for an integrated approach to tackle the global risk of infectious diseases by considering human, animal, wildlife, and ecosystem health. This virtual science-driven institution focuses its research and increase of knowledge along four major Strategic Research Themes related to infectious diseases: Tackling Antibiotic Resistance (NCOH-AMR), Emerging Infectious Diseases Preparedness (NCOH-EID), Smart and Healthy Farming (NCOH-SHF), and Healthy Wildlife and Ecosystems (NCOH-HWE).
The NADP is strategically and organisationally embedded within NCOH-AMR. The strategic theme NCOH-AMR aims to decrease the morbidity and mortality of antibiotic-resistant bacterial infections in humans through use-inspired, excellent, fundamental, translational, and applied One Health research on antimicrobial resistance. The NCOH-AMR, as other NCOH themes, is organised through so-called Solution Sets. Within NCOH-AMR, the NADP provides a platform for public-private partnerships in the Solution Sets “New Antibiotics” and “New Alternatives”.

CONTACT PERSON – **Prof. Marc Bonten**

9 http://www.immunovalley.nl/
10 http://www.immunovalley.nl/altant/
11 http://www.immunovalley.nl/bac-vactory/
12 https://ncoh.nl/

Appendix II
NADP Governance

The NADP is a virtual institution, governed by a joint Consortium Agreement with Utrecht University acting as the Coordinator (penvoerder). The NADP governance is defined by three bodies. The NADP Commissioners Board functions as a supervisory board and consists of appointed representatives of the Ministry of Health, Welfare and Sport (VWS), Ministry of Economic Affairs and Climate Policy, and one member on behalf of the relevant Dutch Topsectors (Life Sciences & Health, Agri&Food, Chemistry). The NADP Executive Board consists of appointed representatives of all four NADP Partners (NCOH, CARES, CeSAM, and Immuno Valley) and an independent Chairperson. The Boards are supported by a dedicated Support Office, consisting of the Secretary to the Board, a communication manager, an alliance manager and IP and TTO support.

NADP **Commissioners Board**

M. van Raaij, PhD
Ministry of Health, Welfare and Sport

O. Knap
Ministry of Economic Affairs and Climate Policy

Prof. N. van Meeteren
Dutch Topsectors

NADP **Executive Board**

Chair

C. de Joncheere
PharmD/MBA

Partner Representatives

Prof. M. Bonten
NCOH

Prof. O. Kuipers
CeSAM

L. Steeghs, PhD
Immuno Valley

Prof. G. van Wezel
CARES

NADP **Support Office**

Secretary to the Board
Communication Manager
Alliance Manager
IP and Technology Transfer support

Colophon

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