



# Policy Plan Stichting ReSViNET

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# 1. Introduction and Background

## Introduction

The Stichting ReSViNET (translated as ReSViNET Foundation) is the leading international non-profit organization committed to reducing the global burden of Respiratory Syncytial Virus (RSV) infection. RSV Acute Lower Respiratory Infection (ALRI) is one of the most significant global health challenges, not only in infants, but also in older adults. RSV remains among one of the leading causes of hospitalization and mortality of young infants. It affects 33.1 million children under age five worldwide. Yet, there remains no vaccine and limited therapeutic options for treatment.

The ReSViNET Foundation is the first official Respiratory Syncytial Virus (RSV) Foundation. It aims to foster global collaboration among researchers, health sector professionals, governmental and international statutory bodies, non-profit organizations and the wider civil society. By fostering global collaboration, we can coordinate actions and initiatives, raise awareness about RSV infection and tackle the challenge of RSV infection prevention and treatment.

## Background

Prior to 2018 the ReSViNET Network was initially founded in Utrecht, the Netherlands on January 14th, 2014 on initiative of dr. Louis Bont. The founding board consisted of nine European investigators, various RSV experts, and Julius Clinical, an Academic Research Organization. The Network functioned as a fully independent research Network. In 2015 and 2016, in order to have a global reach the Network expanded and invited an additional seven investigators from other continents.

The nominated investigators and Julius Clinical were the main stakeholders of the ReSViNET Network bringing together the necessary and complementary components, e.g. RSV expertise, patients and operational quality to achieve the shared objectives, mission and vision of the Foundation.

After 4 years of building and shaping the network and months of preparation, the ReSViNET Foundation was officially founded on March 19th, 2018. Since then, the ReSViNET Foundation was accredited and registered as a not-for-profit entity under Dutch law. As a Foundation, ReSViNET is now a financially and otherwise independent regulated entity which represents a major milestone for the entire ReSViNET project.

## 2. Mission and Objectives

The ReSViNET Foundation has set several objectives for the short and long term.

The Foundation seeks to achieve its goal by undertaking the following:

1. Combatting and reducing the prevalence of the Human Respiratory Syncytial Virus (hereafter referred to as: RS virus);
2. Stimulating and supporting (quality) research on the RS virus;
3. Promoting awareness and increasing knowledge of the RS virus;
4. Developing and improving effective medicines and treatments to combat the RS virus;
5. Striving towards other related goals formulated by the Scientific Advisory Board referred to below;
6. Performing any further actions pertaining n to the above in the broadest sense or that may be conducive thereto.

### **The statutory objectives of *Stichting ReSViNET* are:**

- To support performance of high quality research, to improve knowledge of RSV epidemiology, and to develop safe and effective therapeutic and preventive interventions (Mission).
- To connect global expertise and leadership in order to decrease the global burden of RSV infection (Vision).
- To combine knowledge and capacity required to enhance RSV therapeutics development.
- To advocate and create awareness for the RSV disease.
- To stimulate and perform cutting-edge research, with a focus on randomized clinical trials.
- To advocate appropriate allocation of resources for RSV-related research
- To introduce prevention and treatment strategies for better care for patients with RSV infection.
- To bring together information related to RSV infection and disseminate to all stakeholders.
- To act as a focal point for effective partnerships with stakeholders with the ultimate aim of reducing global child morbidity and mortality.

*Source:* The Articles of Foundation establishment document (2018)

The Foundation strives to fulfil its purpose by executing the following:

1. Organizing conferences and meetings about and for scientists;
2. Raising funds by receiving remuneration for bringing parties together to agree on further RS virus research and initiatives;
3. Gathering information on the RS virus and making it available to researchers and stakeholders;
4. Initiating and supporting research and offering scientific guidance during the set-up and execution of research and studies.

The Foundation shall be non-profit making and the Foundation's resources will come from:

1. The financial contributions of participants attendance at conferences and meetings;
2. Funds received on statutory grounds;
3. Donations, inheritances, legacies;
4. Return on capital;
5. Contributions and subsidies;
6. Capital amounts made available by the government or other bodies and amounts made available in operating costs;
7. All other assets and income.

### **3. Governance of the ReSViNET Foundation**

The Board of Directors represents the Foundation and is responsible for the management of the Foundation. Each director's duty towards the Foundation is to duly fulfil the task assigned to him or her. Board Members meet periodically to discuss and vote on the affairs of the organization. The Foundation's Board of Directors shall consist of at least two (2) directors, of which at least one board member must have demonstrable scientific knowledge of the RS Virus, hereafter referred to as the expert board member, and at least one other board member who is a director or employee of Julius Clinical Research B.V. (Chamber of Commerce number 30244124), or its successor in title, and who has been appointed as such by Julius Clinical Research B.V.

Board directors are appointed for an indefinite period. The appointment of a new expert board director must preferably be based on the recommendation of the current expert board director who proposes a successor.

None of the directors can position the assets of the Foundation as if it were his/her own assets as the Board of Directors consist of 3 members who are independent from each other and none of the members have the decisive vote.

All board directors are entitled to compensation for expenses incurred in the performance of their duties.

***As per 19 March 2018 the first Foundation Board of Directors consist of:***

Mr L.J. Bont, appointed as chair and expert board member

Louis Bont is a Paediatrician Infectiologist at the Wilhelmina Children's Hospital at the University Medical Center Utrecht, The Netherlands. He leads the Utrecht RSV Research Group, which covers the spectrum of translational medicine research in the RSV field. Basic research includes animal studies and the development of airway organoids, while more clinical studies encompass international cohort studies and multicentre drug trials. He has published more than 100 RSV-related papers in peer reviewed journals. Dr. Bont has a strong interest in education of young talented researchers. Louis Bont is the founding chairman of ReSViNET and has been a regular advisor of the World Health Organization (WHO) and the European Center of Disease Control (ECDC).

Mr A.J. Smink, appointed as treasurer/deputy chair,

Aize Smink has a degree in Biochemistry from the University of Groningen, the Netherlands. He has over 25 years of clinical development experience, including pharma, biotech and medical devices. His experience includes a wealth of clinical development projects executed around the globe. With a long successful track record in the CRO sector. Aize Smink was at Chiltern as a member of the executive board. He has joined Julius Clinical in December 2015 and has been following and supporting the developments within ReSViNET since then. He values true cooperation and a partnership approach with academic partners and site networks to achieve real innovative results.

Ms L. Kragten-Tabatabaie, appointed as secretary and manager of the foundation

Leyla Kragten-Tabatabaie has a background in Medical Biology and received her PhD in Metabolic diseases in children at the Wilhelmina Children's Hospital, University Medical Center in Utrecht, The Netherlands. Leyla Kragten-Tabatabaie has been involved from the beginning with the inception, shaping and managing of ReSViNET and has a central role in all ReSViNET activities including communications with ReSViNET (scientific) board, involvement in clinical trials and related educational activities and organizing scientific conferences and masterclasses. She has set up and is the former project leader for the RSV GOLD study, is involved in the ReSViNET activities for the RESCEU study and plays a crucial role in all ReSViNET RSV studies regarding patient advisory board activities, peer-to-peer education for the site study team and overall communication lines between the sponsor, project manager and Principal investigator ensuring clinical trials are smoothly and efficiently rolled-out in the network.

### Scientific Advisory Board

The Scientific Advisory Board is well established and the number of members is determined by the Board of Directors. The Scientific Advisory Board shall give solicited and unsolicited advice on the Foundation's scientific policy and the effect thereof. Joining the Scientific Advisory Board is only on invitation by the Board of Directors and only when supported by the majority of the members of the Scientific Advisory Board. Potential new board members must fit pre-determined criteria including shared interest in RSV, clinical research and the mission and vision of the Foundation.

As of March 19th, 2018, the Scientific Advisory Board consists of:

1. Prof. dr. Terho Heikkinen (Finland)
2. Prof. dr. Anne Greenough (UK)
3. Prof. dr. Harish Nair (UK)
4. Prof. dr. Paolo Manzoni (Italy)
5. Prof. dr. Eugenio Baraldi (Italy)
6. Prof. dr. Nikolas Papadopoulos (Greece)
7. Prof. dr. Federico Martinon-Torres (Spain)
8. Prof. dr. Renato Stein (Brazil)
9. Dr. Asuncion Mejias (US)
10. Prof. dr. Fernando Polack (Argentina)
11. Prof. dr. Octavio Ramilo (US)
12. Prof. dr. Ann Falsey (US)
13. Prof. dr. Peter Richmond (Australia)
14. Prof. dr. Rick Grobbee (The Netherlands)
15. Dr. Marta Nunes (South Africa)

The members of the Scientific Advisory Board do not receive any remuneration for their general activities and advice to the Foundation.

## **4. Activities and Projects**

The ReSViNET Foundation unites the necessary and complementary components, (e.g. RSV expertise, research leadership and knowledge, patients and operational quality) with the ultimate aim of reducing the global burden of child morbidity and mortality.

ReSViNET has built strong partnerships with many stakeholders, including the World Health Organization (WHO), the Bill and Melinda Gates Foundation (BMGF), PATH, the European Medicines Agency (EMA), the Food and Drug Administration (FDA) and the academic world and pharmaceutical companies.

ReSViNET has created a strong Patient Advisory Board (PAB) which has been active in the network, including participation in research.

ReSViNET has developed the mobile application ReSViNET Scale App for parents and professionals. Previously, scores to assess breathing problems were designed for health professionals only and now with the ReSViNET Scale App, parents are able to participate in documenting their children's symptoms.

ReSViNET engages in various activities, including publishing relevant papers, organizing educational activities and major bi-annual conferences, including “RSV Vaccines for the World” in 2017 in Malaga, Spain and the upcoming “RSVW2019” conference on November 12th-14th 2019 in Accra, Ghana.

ReSViNET is actively involved in research and was the nucleus of the IMI-funded project RESC-EU. The RSV GOLD project (funded by the Bill and Melinda Gates Foundation) has been strongly related to ReSViNET from the start (Scheltema, Lancet Infect Dis 2017).

## 5. Financial Responsibilities

### Financial Management

The Foundation Board of Directors is responsible for managing its financial(s). The Foundation keeps track of finances through accurate and complete financial administration. The financial administration is completed by the staff of Julius Clinical. Julius Clinical’s representative has direct contact with the treasurer and the secretary and reports to Foundation Board of Directors and when appropriate the audit committee.

The financial administration of the Foundation includes the nature and scope of:

1. Foundation income;
2. Expenditures in the context of objectives, activities and projects;
3. Any (running) costs incurred for managing of the Foundation;
4. Any expense allowances spent on board directors or third parties.

The Foundation Board of Directors will prepare and report the balance sheet and income statement of the Foundation within six months after the end of the financial year. Where necessary, the Foundation Board of Directors will engage an accountant to conduct an audit and/or consult concerning financial statements.

The Foundation will keep the financial administration clear and accessible and keep it available for at least seven years. The Foundation also uses general guidelines for its financial management (see financial manual).

### Financing the Foundation

#### Asset Management

The foundation generates its income for its activities in the following ways:

- Sponsorship contracts with different stakeholders for organizing conferences
- Conference fees from participants
- Initializing and supporting research in RSV
- Providing scientific Advice during the set-up and performance of studies and clinical research
- Providing Educational activities and training

The assets of the Foundation are managed by the treasurer of the board, in collaboration with the other board members, and where necessary supported by financial experts. The Scientific Advisory Board members of the Foundation are volunteers and receive no compensation for carrying out the activities on behalf of the Foundation. It is not allowed for one person or legal entity to manage the assets of the Foundation. The assets of the Foundation are strictly separated and are managed under the responsibility of the entire Board of Directors. The Foundation has no profit motive.

The Foundation does not own more capital reserve than is reasonably necessary for the continuity of the work performed for the purposes of the Foundation. The Foundation will always check whether the costs are in reasonable proportion to the goals of the Foundation.

The Foundation keeps the right to have an operating reserve for unexpected cash flow shortages, expense or losses. These might be caused by delayed payments, unexpected building repairs, or economic conditions. Reserves should be enough to cover at least 6-12 months' expenses. The Foundation also reserves the right to set aside (part) of the surpluses from conferences or other income as funding for the preparation costs of the next conference.

## **6. Dissolution and Liquidation**

If the board decides to dissolve the Foundation, or in other cases of dissolution, the funds remaining after the dissolution of the organization will be allocated to another tax-exempt entity, which must directly and exclusively use it for charitable or other public-benefit purposes. In these events the board members may not receive more than the paid-up capital and the value of the assets contributed by them from the entity.

The board and those involved in the ReSViNET Foundation make every effort to optimally support and achieve the objectives. We are available to provide additional information and further explanation if required.