INVITATION

Harmonization of RSV trials from design to performance

RSV High-Level Expert meeting organised by ReSViNET

2-3 March 2016
The Netherlands

info@resvinet.org | www.resvinet.org |

HIGH-LEVEL EXPERT MEETING

COMBINING EXPERTISE AND LEADERSHIP TO DECREASE THE GLOBAL BURDEN OF RSV INFECTION

ReSViNET
RESPIRATORY SYNCYTIAL VIRUS NETWORK

RSV (Respiratory Syncytial Virus) infection is the second most important cause of death during infancy, especially in developing countries. RSV infection has also been linked to an increased risk in the development of chronic airway disease in later life. Therefore, research on RSV is crucial.

ABOUT US

In order to improve research on RSV, the ReSViNET (**R**espiratory **S**yncytial **V**irus Network) network has been established. In this network, expertise and leadership are combined in order to decrease the global burden of RSV. It is our goal to improve knowledge of RSV epidemiology and to develop safe and effective therapeutic and preventive interventions.

EXPERT MEETING 2016

The goal of this meeting is to bring together the collective wisdom regarding RSV trials from stakeholders (e.g. regulators, pharmaceutical industry and scientists) and interaction between these stakeholders and all parties to learn more about the topic and how to best apply this information in future trials.

DATE

2-3 March 2016

LOCATION

Woudschoten Hotel & Conference Centre
Woudenbergseweg 54
3707 HX Zeist, The Netherlands

REGISTRATION

Only on invitation. For more information please contact ReSViNET network manager.

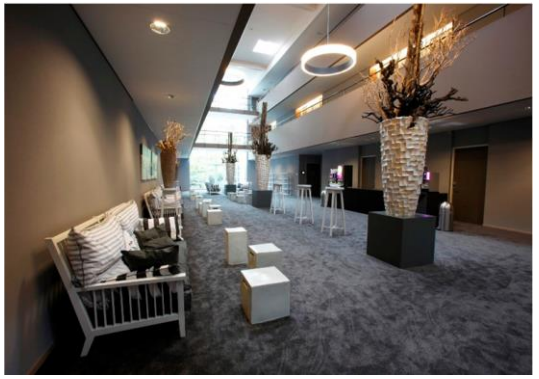
RESEARCH

We are open to collaborate in any RSV related research activity varying from advice to the necessary multidisciplinary engagements and clinical networks eventually necessary to develop the project.

We are very interested to collaborate in designing and performing clinical trials on RSV therapeutics that are aimed at decreasing the RSV burden/decreasing disease severity and saving young lives especially in developing countries.








PROGRAM DAY 1

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8:30-9:00	*Welcome and badge pick-up*
Session I	**The burden of RSV and how to tackle it**
9:00-9:15	**Chairman introduction, identifying gaps, aims of session** (Nikos Papadopoulos)
9:15-09:45	**Revised RSV burden estimates** (Harish Nair, The University of Edinburgh)
09:45-10:15	**Development status of different therapeutics, vaccines plus antivirals and resistance** (Octavio Ramilo, Nationwide Children's Hospital)
10:15-10:45	**Broad discussion/ Stakeholders perspective***
	Break
Session II	**Regulatory considerations in initiating Paediatric clinical trials for RSV vaccines and antivirals**
11:00-11:15	**Chairman introduction, identifying gaps, aims of session** (Louis Bont)
11:15-11:45	**Overview of Paediatric development plans evaluated by PDCO: regulatory considerations for initiating paediatric trials** (Irmgard Eichler, EMA)
11:45-12:15	**Regulatory aspects related to development of antivirals and vaccines for RSV** (Eric Pelfrene, EMA)
12:15-12:45	**Broad discussion/ Stakeholders perspective***
	Lunch
Session III	**Measuring Safety**
14:00-14:15	**Chairman introduction, identifying gaps, aims of session** (Renato Stein)
14:15-14:45	**Assessing the impact of anti-RSV interventions: Clinical endpoints and Biomarkers** (Asun Mejias, Nationwide Children's Hospital)
14:45-15:15	**Vaccines: how to look for toxicity (fetal toxicity, viral and maternal antibody interference)** (Fernando Polack, VanderBilt University Medical Centre)
15:15-15:45	**Broad discussion/ Stakeholders perspective***
	Drinks
18:00	**Aperitif & Dinner with Guest speaker Bas Lansdorp, CEO and co-founder of Mars One**

PROGRAM DAY 2

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Session IV	**RSV in Older Adults**
9:00-9:15	**Chairman introduction, identifying gaps, aims of session** (Octavio Ramilo)
9:15-09:45	**RSV vaccine in development: assessing the potential cost-effectiveness in high risk adult populations** (Koen Pouwels, Public Health England)
09:45-10:15	**RSV infection in older adults : lessons learned from Influenza** (TBD)
10:15-10:30	**Broad discussion/ Stakeholders perspective***
	Break
Session V	**Development of RSV Vaccines for Use in Pregnancy**
11:00-11:15	**Chairman introduction, identifying gaps, aims of session** (Terho Heikkinen)
11:15-11:45	**Clinical endpoints in trials of RSV vaccines in pregnant women: study design issues, assessment of safety and effectiveness** (Marta Nunes, University of Witwatersrand)
11:45-12:15	**Lessons learned from non-RSV maternal immunization - safety, immunogenicity and effectiveness** (Hester de Melker, RIVM)
12:15-12:30	**Broad discussion/ Stakeholders perspective***
	Lunch
Session VI	**Interactive Break-out Session**
13:45-14:00	**Introduction of specific questions by group chairman**
14:00-14:45	**Group Discussion**
14:45-15:30	**Plenary reporting on the conclusions of the discussions during break-out session**
15:30-16:00	**Interactive multidisciplinary discussion on conclusions**
	Closing remarks followed by drinks

*Each session ends with a broad discussion with presenters, Scientific representatives , Pharmaceutical industry and regulators

YOUR HOSTS

LOUIS BONT
UNIVERSITY MEDICAL CENTER UTRECHT, UTRECHT, THE NETHERLANDS

ASUNCION MEJIAS
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VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE, UNITED STATES

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WOMEN'S AND CHILDREN'S HEALTH DEPARTMENT, UNIT OF RESPIRATORY MEDICINE AND ALLERGY, PADOVA, ITALY

RENATO T STEIN
PEDIATRIC PULMONARY UNIT, PONTIFICIA UNIVERIDADE CATÓLICA RS, PORTO ALEGRE, BRAZIL

NIKOLAOS G. PAPADOPOULOS
MANCHESTER CHILDREN'S HOSPITAL, UNITED KINGDOM
2ND PEDIATRIC CLINIC, UNIVERSITY OF ATHENS, GREECE

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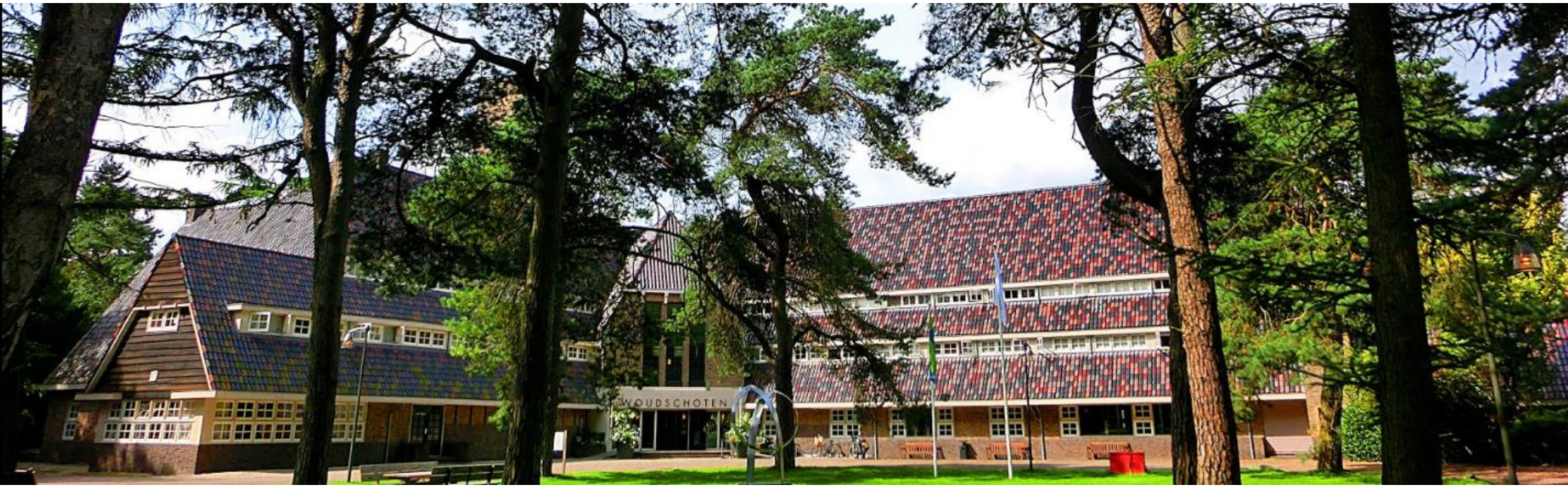

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JULIUS CLINICAL

Wilhelmina Kinderziekenhuis

RESVINET IS AN INITIATIVE OF JULIUS CLINICAL AND UNIVERSITY MEDICAL CENTER UTRECHT, THE NETHERLANDS