

## KEYNOTE



**Nicole Derksen**  
RESCEU Patient Advisory Board

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How is it possible so few people know about RSV when it is the most common cause of lower respiratory tract infections among young children and associated with more than 3 million hospital admissions every year? How can it be that RSV infection is the second cause of death in infants after malaria, and nobody knows about it?

When we started off as the RSV patient advisory board at UMCU in 2013, one of the first experiences we shared as parents of children who suffered from a severe RSV infection was the fact that we did not know about RSV and its potential health impact before it actually happened to us. We all felt very strongly that something needed to be done to raise public awareness about this very common virus. Therefore, creating awareness has been an important goal for us right from the start. We have developed some information materials and this RSV season we have experimented with a pilot campaign by distributing flyers and posters to nurseries and child healthcare centres in our communities/municipalities.

RESCEU offers us a unique opportunity to take RSV awareness to the next level by putting RSV on the map for decision makers and the general public throughout Europe. The RESCEU Patient Advisory Board (PAB) aims to play an important role here. The PAB will have representatives of all patient groups and from different European countries and we want it to become the heart of a pan European RSV patient network which has co-operative relationships with other patient organisations and relevant stakeholders on the local and (inter)national level. This network is an ideal platform not only to communicate project results to the general public, but also to run campaigns calling attention to RSV and its potential impact on children, families and society.

Clearly this is all easier said than done. We are only at the beginning of forming a European RSV patient organisation and from our modest campaigning activities so far, we have learned that we cannot do this alone. We need an integrated approach, supported by scientists, medical professionals and patients. With the multi-disciplinary and multi-stakeholder RESCEU team, conditions could not be better to develop more professional and more effective awareness campaigns which are aligned to local needs and circumstances. I look forward to a fruitful and mutually beneficial collaboration with the aim of ensuring communication between patients, scientists and medical professionals to guide research and learn from research results.

Let's use the RESCEU momentum to increase public awareness and thereby make a valuable contribution to decreasing the burden of RSV infection.

## The RESCEU Consortium is kicked off



**RESCEU Kick off meeting counted with the presence of one hundred participants**

After many months of intensive preparatory work following a competitive call process, the Respiratory Syncytial Virus Consortium in Europe (RESCEU) was launched in January 2017. The RESCEU project aims to develop robust evidence on RSV disease burden and economic impact; create a sustainable Europe-wide multidisciplinary, multi-stakeholder community from academia, public health, scientific societies, patient organisations, regulatory agencies and industry; and provide infrastructure to perform future pivotal trials for RSV vaccines and therapeutics. RESCEU represents a major research effort of 29 million euro, and receives funding from the Innovative Medicines Initiative 2 Joint Undertaking, supported by the European Commission and EFPIA.

The launch meeting was held in Sitges (Spain) and it was a memorable occasion to have about 100 participants from key stakeholder constituencies (RSV researchers ranging from epidemiologists and clinicians to more basic scientists; Public Health Agencies like ECDC, US CDC and WHO; esteemed members of our International Scientific Advisory Group, Patient Advisory Board and the Ethics Advisory Committee; agencies like EMA and PATH; funding agencies like BMGF and our IMI project officer) all participated wholeheartedly during the two-day meeting. The discussions were of very high quality and the enthusiasm was infectious. The Consortium is fully committed to sustain this positivity and make sure that we can achieve the objectives of RESCEU.

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## RESCEU presentation at the ECDC meeting

On February 7<sup>th</sup> 2017, several RESCEU Partners took part in a European consultation meeting on RSV surveillance led by European Centre for Disease Prevention and Control (ECDC) in Stockholm. The meeting was attended by epidemiologists, paediatricians, virologists and other RSV experts from many European countries. It aimed to explore the possibilities of a harmonized RSV surveillance by the European member states and consider available resources at national level and within the ECDC in developing such a system.

A working paper outlining several options for setting up RSV surveillance in EU/EEA countries was discussed. A SWOT (Strength, Weaknesses, Opportunities, Threats) analysis was performed by the participants to discuss several options for RSV surveillance. A revised paper will be presented to the ECDC Advisory Forum in May 2017 (which will also decide whether RSV should be designated as an official health priority in Europe). One of the conclusions of the analysis was that a minimum dataset should be identified that can be provided by most of the countries. To start this process, it was suggested by a representative from the Statens Serum Institut (SSI), Denmark, to conduct an inventory across European countries on the current surveillance activities and surveillance sources on RSV. This initiative was agreed upon and planned as a joint effort by RESCEU Partners from SSI, Denmark and the National Institute for Public Health and the Environment (RIVM), Netherlands, together with ECDC. RESCEU partners from the University of Edinburgh, UK also assisted WHO Geneva in designing a global RSV surveillance pilot to be conducted in 14 countries globally (2 of which are in Europe). Plans for this were also briefly presented at this meeting.

Overall, this was a very successful meeting for RESCEU as Work Package 2 activities on RSV surveillance were significantly advanced, relationships with ECDC were strengthened and links with other surveillance systems (e.g. in USA and Canada) were established.

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### 3rd ReSViNET High-Level Expert Meeting

The 3<sup>rd</sup> ReSViNET High-Level Expert Meeting titled: "RSV - The Next Steps" took place at the Park Hotel on March 8<sup>th</sup>-10<sup>th</sup> 2017 in Amsterdam, The Netherlands. This meeting is held annually and is devoted exclusively to RSV infection prevention and treatment. The 2017 ReSViNET High-Level Expert Meeting focused on the scientific developments and demands in RSV field and aimed to bring together the scientific data and expertise whilst connecting different stakeholders involved in RSV research e.g. scientists, physicians, pharmaceutical companies, regulators and representatives from FDA, PATH, WHO, NIH and BMGF. The organisers endeavour was to stimulate discussions regarding the opportunities for future international collaboration and achievements in the field. The most renowned RSV experts and scientists presented during the plenary sessions to update the attendees and discuss the following topics: Infant mortality by RSV, viral bacterial interactions, RSV related bronchiolitis and asthma, RSV in older adults and prematurely born infants and human challenge studies. The meeting concluded with an interactive round table session, where the different models regarding clinical endpoints in the trials were discussed.

## The birth cohort study (10.000 infants) is submitted to the IRB in the Netherlands (UMCU)

The RESCEU Kick-Off meeting in Sitges has created a wave of enthusiasm and determination to make a good start in the clinical studies that will be performed all across Europe. For the prospective cohort studies, the first step is to design the various study documents and prepare for Ethical Committee (IRB) submission. Together with the sites involved in the clinical studies we managed to already finalize these documents for the infant birth cohort study. In summary, the infant birth cohort study will be performed in Great-Britain, Finland, Spain and the Netherlands and will consist of 10.000 term born infants included at five sites. We are proud to announce the birth cohort study is submitted to the Ethical Committee (IRB) in the University Medical Center Utrecht, the Netherlands and is currently awaiting approval. IRB Submission at the other sites will soon follow and together we are still on track to start including the first patients this summer!

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### Upcoming major RSV/respiratory meetings

- **ESPID 2017**

The 35th Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) will be held in Madrid, Spain, from May 23<sup>rd</sup>-27<sup>th</sup> and will cover different topics in the entire field of paediatric infection-related diseases. The symposium will bring together a large number of internationally renowned experts to potential networking for both already established research networks as well as research newcomers.

Info: [www.espid2017.kenes.com](http://www.espid2017.kenes.com)

- **ERS International Congress 2017**

The European Respiratory Society 2017 (ERS) covers the topics of Medical, Health Care, Respiratory, Respiratory Medicine, Respiratory Care and Respiratory System and much more. The next annual ERS will be held in Milan, Italy, from September 9<sup>th</sup>-13<sup>th</sup>. More than 26000 attendees are expected to visit the ERS meeting this year.

Info: [www.erscongress.org](http://www.erscongress.org)

- **International Neonatal and Maternal Immunization Symposia (INMIS)**

The 4th International Neonatal and Maternal Immunization Symposia (INMIS) will take place in Brussels, Belgium, from September 10<sup>th</sup>-12<sup>nd</sup> 2017 and will bring together scientists, clinicians and public health experts from all continents. The symposium will provide up to date information on key areas and latest progress on the basic science underpinning maternal and neonatal immunization, as well as the most recent data from large vaccine trials and vaccines under

development. The implementation of maternal and neonatal immunization worldwide will be debated.

Info: [www.inmis.org](http://www.inmis.org)

- **4<sup>th</sup> ReSViNET meeting**

The 4<sup>th</sup> ReSViNET meeting is titled “Vaccines for the World” and will be held on November 29<sup>th</sup>-December 1<sup>st</sup> 2017 in Malaga, Spain. For more information regarding ReSViNET and the High-Level Expert meetings please visit the website [www.resvinet.org](http://www.resvinet.org) or contact Louis Bont (Chairman ReSViNET, [L.bont@umcutrecht.nl](mailto:L.bont@umcutrecht.nl)) and Leyla Kragten-Tabatabaie (Network Manager ReSViNET, [Leyla.kragten@juliusclinical.com](mailto:Leyla.kragten@juliusclinical.com)).

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## List of recent RSV papers

### Apr 2017

Openshaw PJM, Chiu C, Culley FJ, Johansson C. **Protective and Harmful Immunity to RSV Infection.** Annual Review of Immunology; Vol. 35.

### Mar 2017

Reeves RM, Hardelid P, Gilbert R, Warburton F, Ellis J, Pebody RG. **Estimating the burden of respiratory syncytial virus (RSV) on respiratory hospital admissions in children less than five years of age in England, 2007-2012.** Influenza Other Respir Viruses.;11(2):122-129.

Farrag MA, Amer HM, Öhlschläger P, Hamad ME, Almajhdi FN. **Novel Recombinant DNA Vaccine Candidates for Human Respiratory Syncytial Virus: Preclinical Evaluation of Immunogenicity and Protection Efficiency.** Hum Vaccin Immunother.;8:0.

### Feb 2017

Resch B, Egger B, Kurath-Koller S, Urlesberger B. **Respiratory syncytial virus hospitalizations in infants of 28 weeks gestational age and less in the palivizumab era.** Int J Infect Dis.;57:50-53.

Lynch JP, Al Amin Sikder Md, Curren BF, Werder RhB, Simpson J, Ó Cuív P, Dennis PG, Everard ML, Phipps S. **The Influence of the Microbiome on Early-Life Severe Viral Lower Respiratory Infections and Asthma—Food for Thought?** Front. Immunol.; in press.

Jounai N, Yoshioka M, Tozuka M, Inoue K, Oka T, Miyaji K, Ishida K, Kawai N, Ikematsu H, Kawakami C, Shimizu H, Mori M, Ishii KJ, Takeshita F. **Age-Specific Profiles of Antibody Responses against Respiratory Syncytial Virus Infection.** EBioMedicine.;16:124-135.

Almogly G, Stone L, Bernevig BA, Wolf DG, Dorozko M, Moses AE, Nir-Paz R. **Analysis of Influenza and RSV dynamics in the community using a 'Local Transmission Zone' approach.** Sci Rep.; 9;7:42012.

### Jan 2017

Heikkinen T, Ojala E, Waris M. **Clinical and Socioeconomic Burden of Respiratory Syncytial Virus Infection in Children.** J Infect Dis.;215(1):17-23.

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Geoghegan S, Erviti A, Caballero MT, Vallone F, Zanone SM, Losada JV, Bianchi A, Acosta PL, Talarico LB, Ferretti A, Grimaldi LA, Sancilio A, Dueñas K, Sastre G, Rodriguez A, Ferrero F, Barboza E, Gago GF, Nocito C, Flamenco E, Perez AR, Rebec B, Ferolla FM, Libster R, Karron RA, Bergel E, Polack FP. **Mortality due to Respiratory Syncytial Virus. Burden and Risk Factors.** Am J Respir Crit Care Med.;195(1):96-103.

**Dec 2016**

Caserta MT, Qiu X, Tesini B, Wang L, Murphy A, Corbett A, Falsey AR, Holden-Wiltse J, Walsh EE. **Development of a Global Respiratory Severity Score (GRSS) for Respiratory Syncytial Virus Infection in Infants.** J Infect Dis.; jiw624.

Blake SM, Tanaka D, Bendz LM, Staebler S, Brandon D. **Evaluation of the Financial and Health Burden of Infants at Risk for Respiratory Syncytial Virus.** Adv Neonatal Care; in press.

**Nov 2016**

**Global RSV surveillance.** Wkly Epidemiol Rec. 4;91(44):523-524.

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For more information, visit us at [www.resc-eu.org](http://www.resc-eu.org)  
Sign up for RESCEU-Newsletter at [nfebrer@synapse-managers.com](mailto:nfebrer@synapse-managers.com). Next issue in June.

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