

D6.6 Roadmap for collaboration with other projects/networks

116019 - RESCEU

REspiratory Syncytial virus
Consortium in EUrope

WP6 – Project management and
outreach to stakeholders

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Table of contents

| | |
|--|----|
| Document History | 3 |
| Document description | 3 |
| Definitions | 4 |
| Publishable Summary..... | 5 |
| 1. Introduction..... | 6 |
| 2. Methodological framework..... | 7 |
| 2.1. Identification..... | 7 |
| 2.2. Assessment..... | 8 |
| 2.3. Prioritisation | 8 |
| 2.4. Implementation..... | 9 |
| 2.5. Monitoring | 9 |
| 3. Potential levels of synergy | 10 |
| 4. Sources for the identification of relevant projects and networks | 11 |
| 5. Projects, networks and initiatives for collaboration..... | 11 |
| 6. Affiliated Partners | 21 |
| 7. Initiated contacts and established collaborations..... | 24 |
| 7.1. ReSViNET..... | 24 |
| 7.2. CIRN & IMPACT RSV Study Group | 25 |
| 7.3. ISARIC..... | 25 |
| 7.4. ECDC | 25 |
| 7.5. EMA | 26 |
| 7.6. GHSN..... | 26 |
| 7.8. BMGF | 27 |
| 7.7. WHO..... | 27 |
| 8. Conclusion | 28 |
| ANNEXES | 30 |
| ANNEX I – Affiliated Partner Agreement | 30 |
| ANNEX II – Template of Memorandum of Understanding by and between the IMI RESCEU Consortium and external initiative | 32 |
| ANNEX III - Advisory Agreement Contract Template..... | 36 |

Document History

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Document description

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| Deliverable description | This deliverable is intended to provide a roadmap of synergies with other projects/networks for future implementation. It also provides details on collaborations that were established during the first year by RESCEU. |
| Keywords | Roadmap, networks, synergies, collaboration, fast-track, initiatives, sustainability |

Definitions

Participants of the RESCEU Consortium are referred to herein according to the following codes:

- **UEDIN.** University of Edinburgh (United Kingdom)
- **UA.** Universiteit Antwerpen (Belgium)
- **UMCU.** University Medical Centre Utrecht (Netherlands)
- **UOXF.** The Chancellor, Masters and Scholars of the University of Oxford (United Kingdom)
- **SYNAPSE.** Synapse Research Management Partners S.L. (Spain)
- **Imperial.** Imperial College of Science, Technology and Medicine (United Kingdom)
- **SERGAS.** Servicio Galego de Saúde (Spain)
- **TUCH.** Varsinais-Suomen sairaanhoitopiirin kuntayhtymä (Finland)
- **RIVM.** Rijksinstituut voor Volksgezondheid en Milieu - National Institute for Public Health and the Environment (Netherlands)
- **SSI.** Statens Serum Institut (Denmark)
- **UMCG.** Academisch Ziekenhuis Groningen (Netherlands)
- **PENTA.** Fondazione PENTA for the treatment and care of children with HIV-ONLUS (Italy)
- **AZ.** Astrazeneca AB (Sweden)
- **Pfizer.** Pfizer Limited (United Kingdom)
- **GSK Bio.** GlaxoSmithKline Biologicals S.A. (Belgium)
- **SP.** Sanofi Pasteur (France)
- **JPNV.** Janssen Pharmaceutica, N.V (Belgium)
- **Novavax.** Novavax Inc. (United States of America)

- **Grant Agreement.** The agreement signed between the beneficiaries and the IMI JU for the undertaking of the RESCEU project (116019).
- **Project.** The sum of all activities carried out in the framework of the Grant Agreement.
- **Work plan.** Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
- **Consortium.** The RESCEU Consortium, comprising the above-mentioned legal entities.
- **Consortium Agreement.** Agreement concluded amongst RESCEU participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
- **Affiliated Partner.** Institution/team interested and supporting RESCEU, but that does not need to become full partner and sign the Grant/Consortium Agreements.

Publishable Summary

The aim of this document is to provide a roadmap of synergies with other projects and networks to be implemented during the project. Also, it provides the methodological framework and sources for the identification of projects and networks for the building of synergies with RESCEU. A list of relevant initiatives identified so far is followed by the description of the most relevant collaborations established during the first 18 months of RESCEU. A specific section is dedicated to RESCEU's Affiliated Partners, who together with partners, represent privileged channels to connect to and engage with other institutions and initiatives.

1. Introduction

RESCEU has been designed since its beginning as a strongly collaborative project. Continuous engagement with a broad range of stakeholders, including national and international public health agencies, the pharmaceutical industry and regulators, is considered essential to ensure high impact and long-term sustainability. Different kinds of collaborations are envisaged for each of the WPs and throughout the life span of RESCEU.

WP6 *Project management and outreach to stakeholders* is particularly devoted to ensuring strategic communication and dissemination to all kinds of stakeholders in order to raise project awareness, to disseminate results and to promote community-building around the project. D6.6 in particular, as part of Task 6.6 *Project communication, community-building, sustainability, fundraising and outreach to key stakeholders*, aims to establish a roadmap of synergies with other projects and networks to serve as a basis for future implementation throughout the project life cycle and as an instrument for sustainability.

WP2 *Consolidation of health care systems data* has an important outreach component, as it aims to link with external surveillance databases and actors, thereby contributing to the establishment of meaningful collaborations with external parties and initiatives.

Deliverable 6.6 starts by presenting the methodological framework that will serve as a continuous reference for the development of collaborations. The different steps of identification, assessment, prioritisation, implementation and monitoring of initiatives and networks are assessed and described in detail.

This is followed by a focus on the identification process and specifically on the sources that are taken as reference for consultation on projects and networks for potential synergies and collaborations.

A list of initiatives considered particularly suitable for the building of synergies with RESCEU, as well as for the sharing of good practices and facilitating sustainability, is then presented. In some cases the collaboration with RESCEU has already started at some level, while in others this is foreseen to happen further in time. The project and networks presented are both European and non-European, and most are carried out at an international, and sometime supranational (e.g. collaboration with the World Health Organisation) stage.

A specific section is dedicated to the Affiliated Partners, with a description of their status in the project and their contribution.

The last section focuses on concrete examples of collaboration initiated during the first year and a half of RESCEU, which is based on information gathered from all the WPs. This section describes the progress achieved and provides more details on the existing linkages between RESCEU partners and the projects and networks described.

2. Methodological framework

The process leading to the identification of synergies and collaboration entails a series of steps that need to be taken into consideration and continuously re-addressed. Most of the synergies identified in RESCEU, both potential and partially implemented, can be defined as **fast-tracked collaborations**, since they have been identified already in the proposal phase. These refer to collaboration with projects, networks, and other initiatives that are considered relevant for the RESCEU scope and to be within reach because RESCEU partners and Affiliated Partners are already involved, and/or collaborations are already implicitly or explicitly happening.

The process leading to the establishment of fast-tracked collaborations entails five essential steps, that together constitute the methodological framework of reference. The figure below illustrates the workflow for establishing collaborations, highlighting each phase and their interrelation.

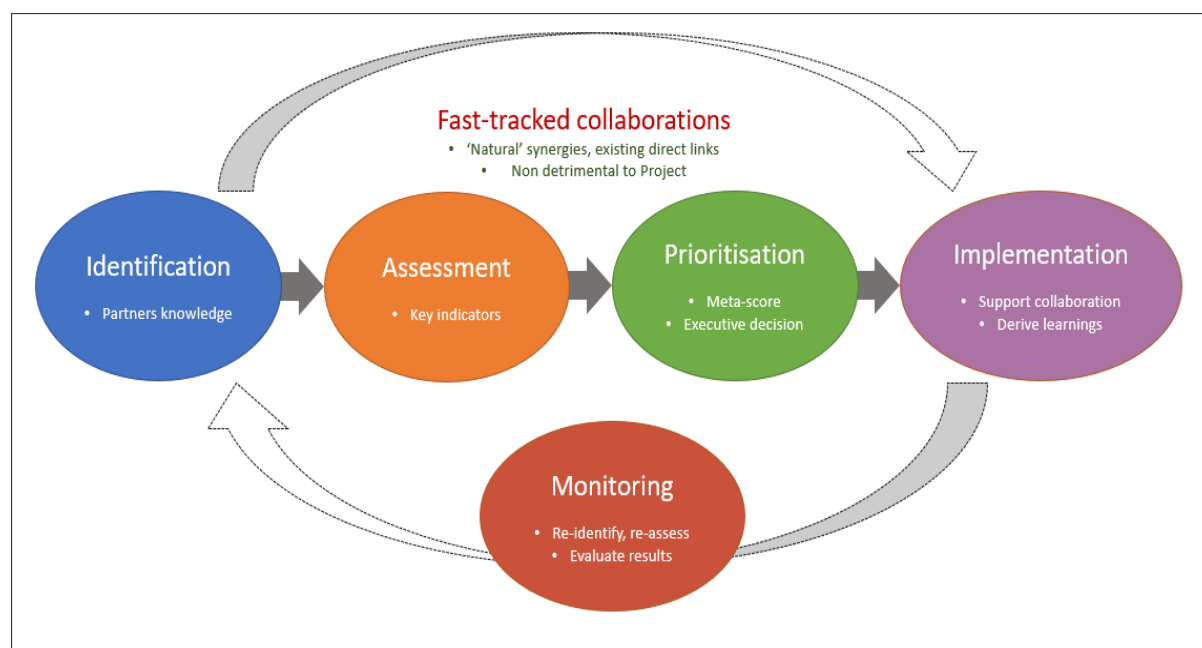


Figure 1: Workflow for the establishment of collaborations

D6.6, as outcome of the identification and assessment phases, also aims to provide an overview of the projects and networks identified. The whole process, including the prioritisation, implementation and monitoring phases, is described in detail below.

2.1. Identification

During this first phase, relevant projects and initiatives are detected and basic information about them is gathered. The primary sources for this information are typically the knowledge of partners, searches in databases, and spontaneous requests for collaboration received. For each one of the initiatives a

contact person within the RESCEU WPs is identified as responsible for driving the collaboration, with the support of WP6 if needed. The outcome of the Identification step includes basic information on the project, followed by a pre-assessment of the partner who suggested the potential initiative (e.g. areas of potential interests overlap, specific results, etc.). As previously mentioned, some of the projects and initiatives can be labelled as ‘fast-track’ – these are initiatives with which collaboration has been naturally established due to common intervening actors, obvious non-detrimental benefit, etc. Fast-track projects usually go directly to the Implementation step. For most of these projects, key contacts within RESCEU have been already identified (typically, the leader and key partners of the most relevant WP, or common partners with the external initiative in question).

2.2. Assessment

The information gathered during the identification phase is then assessed against qualitative/quantitative indicators, such as:

- technical relevance: results of interest, relevant technologies, WPs most affected, etc.
- estimated impact on project: benefit for the project, e.g. increased visibility, access to data, saving in time/costs, adding value, etc.
- feasibility: technical requirements, timelines alignment, approvals needed, etc.
- resources: needed to implement collaboration (human, infrastructural, expertise, financial, etc.)
- IPR: rights attached to results of interest, and ownership if known
- terms: terms for collaboration to happen (e.g. exchange of data, licensing, etc.)
- legal form: preferred legal instrument for formalisation of collaboration (MoU, Affiliated Partner agreement, etc.)

Not all information is known or gathered at this stage, but this step should aim to compile the crucial information needed for prioritisation and for establishing synergies.

Completion of this assessment may require initial interactions with the external projects/initiatives.

2.3. Prioritisation

Depending on the project's policy, needs and preferences, projects/initiatives are ranked according to one or more indicators. Projects may also be classified according to different criteria in this step, which essentially is about exploiting the information collected in the assessment phase to select which projects go forward to implementation, and when. This may require some form of executive decision (typically at the Steering Committee level at the proposal of the Project Management Office or a WP Leader).

2.4. Implementation

This step entails the enabling of the collaboration, which can include a wide range of actions depending on the needs and factors influencing the collaboration, the issues raised, etc. These can be as diverse as, e.g. helping negotiate and sign MoU/agreements/contracts, instigating and formalising changes in the work plan with the additional tasks needed (via new task forces if relevant), supporting the WP leaders and partners in effectively technically establishing the collaboration, addressing Intellectual Property rights (IPR), etc. It does not mean to carry out the work agreed as part of the collaboration per se but clarifying and facilitating it instead. It typically would also include the progressive creation of a 'toolbox' (templates, financial sheets, communication materials, summary of IPR conditions applicable to the own project, etc.) to aid in the establishment of the collaboration. In RESCEU significant effort has been devoted to signing agreements with the Affiliated Partners and advisors in order to formalise the collaboration framework (more than 50 agreements have been signed since the beginning of the project).

WP6 has the core role of supporting the WP leaders, as well as the Steering Committee and Project Management Office, in their efforts to materialise synergistic action. For this purpose, WP6 has devised the strategy outlined in this document and works with the appropriate RESCEU work package liaisons and external projects in their support. WP6 is generally responsible for helping assess the relevance of identified projects and the feasibility of any interaction, identifying key partners and project liaisons, and supporting the WP leaders in establishing contacts and implementing synergies.

2.5. Monitoring

This phase entails the continuing follow-up of collaborations, including re-identification (e.g. for projects or results closely related to those already identified, or for fine-tuning preliminary identification), reassessment and re-prioritisation, as needed. This step would also ideally include evaluation of the collaborations effectively implemented, in terms of impact on the own project at least.

3. Potential levels of synergy

Based on the project structure of RESCEU, synergies can be built at various levels:

- **Strategic alignment:** High-level interactions can offer a framework for collaboration, in which projects are mutually and regularly followed up, overlaps are detected, incentives for collaboration are created and joint programming is enabled. This can happen through joint meetings or mutual invitations and may also affect the strategic direction of external projects.
- **Outcome utilisation:** Deliverables and results from other projects/initiatives can be shared, re-used, leveraged or exchanged to accelerate progress and to promote program effectiveness. This would typically happens at the WP or task level.
- **Joint work:** Ideally, collaborations would reach a stage at which joint actual work is possible, for mutual benefit, towards the creation of knowledge and results that exceed the original work plan. This happens typically in the most effective manner through the creation of joint, cross-project task forces. Stretch goals through collaboration can multiply the impact of projects and create long-term relationships, providing an unparalleled thrust to the respective teams.

These three levels at which collaboration and synergies can happen are depicted in Figure 2. Typically, **strategic alignment** results in recommendations for **outcome utilisation**; this in turn can easily be the basis for a deeper mutual knowledge, help detect common gaps, and therefore trigger **joint work** plans.

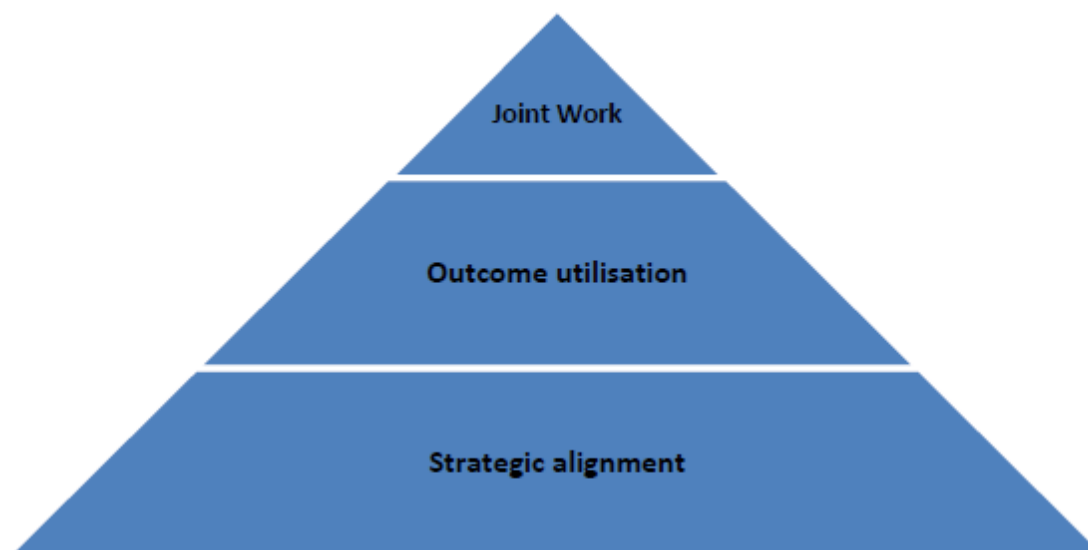


Figure 2: Levels of synergy and collaboration

4. Sources for the identification of relevant projects and networks

WP6 is mainly in charge of the identification of initiatives suitable for collaboration with RESCEU. A preliminary list of relevant projects and networks was provided in the DoA as part of the section dedicated to the Impact, Communication and Dissemination Activities. The projects and initiatives are considered at the same time targets for dissemination activities and for potential synergies. Many initiatives have been identified through RESCEU partners and Affiliated Partners (see section 6. Affiliated Partners) and in some cases the collaboration has been already established. This list has been expanded during project implementation based on suggestions received from Consortium members, who have extensive international network. The project is also monitoring any new initiatives in RSV and connected fields (in IMI, Europe and beyond).

The next section will provide the list of projects, networks and other initiatives that have been identified as potentially synergetic for RESCEU. For some of them, collaboration has already started at a certain level (see also section 7. *Initiated contacts and established collaborations*).

5. Projects, networks and initiatives for collaboration

Projects, networks and other initiatives that have been identified for collaboration with RESCEU are reported below. A preliminary list was provided in the DoA and has been expanded throughout the first year of the project. For each of the initiatives, the following information was extracted:

- Name/Acronym
- Full title
- Description (main goal and funding entity)
- Location
- Website
- RESCEU Partners providing Linkage

This list is intended to provide a first reference and can be expanded in the future with an assessment of the specific relevance of the initiative for RESCEU through surveys to WP Leaders and other relevant partners and AP's contacts. Different level of synergies will be assessed during the next 4 years of the project.

| Name/Acronym | Full Title | Description | Location | Website | Partners providing Linkage |
|---------------------|---|--|----------|--|----------------------------|
| ADVANCE | Accelerated development of vaccine benefit-risk collaboration in Europe | Intimately linked IMI project on benefit-risk assessment of vaccines. | Europe | www.advance-vaccines.eu | SYNAPSE, SSI, RIVM |
| ARPEC/GARPEC | Antibiotic Resistance and Prescribing in European Children | EU FP7 project which aimed to develop and implement a novel method of surveillance of antimicrobial prescription and resistance in children attending hospitals and primary care across Europe. | Europe | n/a | PENTA, UA |
| BMGF | Bill & Melinda Gates Foundation | Private foundation founded by Bill and Melinda Gates in 2000. One of the main goals of the Foundation is to enhance healthcare globally and reduce extreme poverty. Specifically, the Foundation is supporting different actions and programmes for the development of an RSV vaccine and a global RSV surveillance system (with WHO). | US | www.gatesfoundation.org | UEDIN |

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|-----------------|--|--|--------|--|------------------|
| CIRN | Canada Immunization Research Network | National network of key vaccine researchers who develop and test methodologies related to the evaluation of vaccines as they pertain to safety, immunogenicity and effectiveness, and program implementation and evaluation. | Canada | www.cirnetwork.ca | UEDIN |
| COMBACTE | Combatting Bacterial Resistance in Europe | IMI-funded project which battles antimicrobial resistance by speeding up the development of new antibiotics. | Europe | www.combacte.com | UA |
| ECDC | European Centre for Disease Prevention and Control | EU agency aiming at strengthening Europe's defences against infectious diseases. ECDC works in three key strategic areas: it provides evidence for effective and efficient decision-making, it strengthens public health systems, and it supports the response to public health threats. | Europe | www.ecdc.europa.eu | UEDIN, SSI, RIVM |

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|------------------------|---|--|--------|--|----------------|
| EMA | European Medicines Agency | The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU), located in London. It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. | Europe | www.ema.europa.eu | PENTA |
| EMIF | European Medical Information Framework | IMI-funded project aiming to develop common technical and governance solutions and improve access and use of health data. | Europe | www.emif.eu | PENTA, SYNAPSE |
| EU-ADR Alliance | Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge | Research consortium carrying out observational studies. The EU-ADR Alliance's main goal is running studies and answering drug safety questions with the use of extracted data from multiple European privately and publicly owned Electronic Healthcare Records (HER) databases. | Europe | www.eu-adr-alliance.com | PENTA, SYNAPSE |

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|-----------------------|--|--|--------|--|----------------|
| EUCLIDS | Childhood-life threatening infectious disease study | EU FP7 project aiming to understand the genetic basis underlying susceptibility and outcome to the major childhood infections including meningitis, septicaemia, bone and joint infections due to meningococcus, pneumococcus, staphylococcus aureus, Group A streptococcus and salmonella. | Europe | www.euclids-project.eu | SERGAS |
| EUROHOPE | European Health Care Outcomes, Performance and Efficiency project. | EU FP7 project to evaluate the performance of European health care systems in terms of outcomes, quality, use of resources and costs. | Europe | www.eurohope.info | UEDIN |
| Farr Institute | The Farr Institute for Health Informatics Research | The Farr Institute is a UK-wide research collaboration involving 21 academic institutions and health partners in England, Scotland and Wales. Publicly funded by a consortium of ten organisations led by the Medical Research Council, the Institute is committed to delivering high-quality, cutting-edge research using 'big data' to advance the health and care of patients and the public. | UK | www.farrinstitute.org | UEDIN and UOXF |

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|------------------------|--|---|-----------|--|-------|
| GIHSN | Global Influenza Hospital Surveillance Network | Platform able to generate strong epidemiological and medical evidence on the burden of severe influenza and the public health impact of influenza vaccines. The GIHSN was initiated by Sanofi Pasteur in 2011 to fill the gap in epidemiology and public health knowledge. The GIHSN gathers several sites affiliated with national health authorities. | Worldwide | www.gihsn.org | SP |
| GRACE | Genomics to combat Resistance against Antibiotics in Community-acquired LRTI | EU FP6 project aiming to integrate and coordinate the activities of physicians and scientists from many institutions in 14 European countries to combat antibiotic resistance in community-acquired lower respiratory tract infections. | Europe | www.grace-lrti.org | UA |
| GRIP | Global Research in Paediatrics – Network of Excellence | EU FP7 project, which aims to stimulate and facilitate the development and safe use of medicines in children. | | www.grip-network.org | PENTA |
| INDEPTH Network | INDEPTH Network | Network of >50 surveillance systems sites in 20 LMIC with mortality data. INDEPTH membership is currently composed of 42 member health research centres that observe through 49 HDSS field sites the life events of over three million, eight hundred people in 19 LMICs in Africa, Asia and Oceania. | Worldwide | www.indepth-network.org | UEDIN |

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|-------------------------|--|--|-----------|--|---------------|
| ISARIC | International Severe Acute Respiratory and Emerging Infection Consortium | ISARIC is a global initiative aiming to ensure that clinical researchers have the open access protocols and data-sharing processes needed to facilitate a rapid response to emerging diseases that may turn into epidemics or pandemics. | Europe | www.isaric.tghn.org | |
| MCEE | Maternal and Child Epidemiology Estimates | Project funded by Gates Foundation with the overall goal of ensuring that high-quality and timely data are utilized in the assessment of global and national priorities in maternal, neonatal and child health and in planning and evaluation of health intervention programs. | Worldwide | www.jhsph.edu/research/centers-and-institutes/institute-for-international-programs/current-projects/maternal-child-epidemiology-estimation/ | UEDIN |
| PENTA-ID network | PENTA Infectious Diseases network | EU (FP7 and IMI) and pharma funded International ID network conducting world class clinical studies, training programmes and infrastructure development initiatives in the area of paediatric infectious disease. | Worldwide | www.penta-id.org | PENTA, SERGAS |
| PERCH project | Pneumonia Etiology Research for Child Health | Bill and Melinda Gates Foundation funded and multi-country project and case-control study to determine the etiology of and risk factors for severe and very severe pneumonia in children 1-59 months of age. | Worldwide | n/a | UEDIN |

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|----------------|--|---|--------|--|----------------------|
| PERFORM | PErsonalised Risk assessment in Febrile illness to Optimise Real-life Management | EU FP7 project with the aim of developing a comprehensive management plan for febrile patients, capable of being implemented across different health-care systems in Europe, linking sophisticated new genomic and proteomic approaches to clinical phenotyping. | Europe | www.perform2020.eu | SERGAS |
| PoC-ID | Platform for ultra-sensitive Pont-of-Care diagnostics for Infectious Diseases | H2020 funded EU Platform for ultra-sensitive Point-of-Care diagnostics for Infectious Diseases focused on RSV infection. The project addresses the increasing demand for rapid and sensitive point-of-care diagnostics to reduce healthcare costs and increase the quality of life with a focus on infectious diseases, one of the world's leading causes of morbidity and death. | Europe | www.poc-id.eu | SERGAS |
| PREPARE | Platform for European Preparedness Against (Re)-emerging Epidemics | EU FP7 funded network for harmonised large-scale clinical research studies on infectious diseases, prepared to rapidly respond to any severe ID outbreak, providing real-time evidence for clinical management of patients and for informing public health responses. | Europe | www.prepare-europe.eu | SERGAS, UA, IMPERIAL |

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|-------------------|--|--|-----------|--|---------------------------|
| ReSViNet, | Respiratory Syncytial Virus Network | ReSViNET is a global network of experts in the field of Respiratory Syncytial Virus (RSV) infections, established in 2014 in Utrecht. | Europe | www.resvinet.org | UMCU, UEDIN, TUCH, SERGAS |
| RSV GEN | RSV Global Epidemiology Network | Global network of >70 sites contributing RSV disease burden data. | Worldwide | n/a | UEDIN, UMCU |
| RSV GOLD | RSV Global Online Mortality Database | Online accessible database containing information on individual RSV-related mortality cases. Health care providers and researchers from all over the world are encouraged to share cases of children dying from RSV infection. | Worldwide | www.hetwkz.nl/en/Research/Research-themes/RSV-Gold | UMCU, UEDIN |
| VENICE III | Vaccine European New Integrated Collaboration Effort | ECDC funded project started in December 2013 with the aim of collecting, sharing and disseminating information on national immunization programmes through a network of professionals and providing information useful to build up methodologies and provide guidance for improving the overall performance of the immunisation systems in the EU/EEA Member States. | Europe | www.venice.cineca.org | UEDIN |

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|---------------------------------------|---|---|-----------|--|-------|
| WHO Global Influenza Programme | World Health Organization Influenza Programme | <p>Programme providing WHO MS with strategic guidance, technical support and coordination activities to support their health systems against seasonal, zoonotic and pandemic influenza threats to population and individuals. The programme, with support from Bill and Melinda Gates Foundation, is piloting RSV surveillance strategy based on the Global Influenza Surveillance and Response System (GISRS) in 14 countries in order to develop an evidence-base for informing RSV vaccination policy.</p> | Worldwide | www.who.int/influenza/rsv/en/ | UEDIN |
|---------------------------------------|---|---|-----------|--|-------|

6. Affiliated Partners

One of the fundamental founding principles of RESCEU is to generate a critical mass of research capacity spanning all relevant stakeholders, in order to maximise the project's impact and create a long-lasting, far-reaching community effort in the field. In order to achieve this goal, RESCEU was designed from the outset as an inclusive structure that encourages active participation of all members and in which their diverse perspectives have appropriate exposure and consideration. At the same time, the Consortium needs to be manageable in order to not endanger the ambitious, pragmatic scientific goals of the project.

The solution for this trade-off, inspired by the successful experience acquired in the currently ongoing IMI project ADVANCE (devoted to creating a framework for rapid benefit-risk assessment of vaccines), is the Affiliated Partner (AP) role. APs are institutions/teams interested and supporting the project, but that do not need at this stage to become full partners and sign the Grant/Consortium Agreements.

This allows the project's constituency to expand beyond the core consortium partners and to leverage third parties' expertise, knowledge and connections with other relevant worldwide initiatives for the benefit of the project. All APs identified at the beginning of RESCEU have signed a letter of support, and agreed to basic engagement mechanisms. Most APs have long-standing scientific relationships with core partners. AP represents a privileged channel for establishing contacts with other institutions and initiatives.

RESCEU has entered into a signed Agreement with individual Affiliated Partners so as to confer them with rights to results they contribute to generate and access rights.

The list of current RECEU APs is provided in the table below; given the structure and approach of RESCEU, this list is expected to grow throughout the project's life span:

| Academic (Inner Circle) | Public Health Institutions (Inner Circle) |
|---|---|
| Barcelona Institute for Global Health (ES) | National Institute for Health and Welfare (FI) |
| Queen's University Belfast (UK) | Norwegian Institute of Public Health (NO) |
| Emma Children's Hospital, Academic Medical Centre (NL) | Public Health Institute Slovenia (SL) |
| Erasmus Medical Centre (NL) | National Centre For Epidemiology Department of Respiratory Viruses (HU) |
| Institut Pasteur (FR) | Center for Health Policies and Services (RO) |
| London School of Hygiene & Tropical Medicine (UK) | Netherland Institute for Health Services Research (NL) |
| Ospedale Bambino Gesù di Roma (IT) | Public Health Institution of Galicia (ES) |
| Royal Manchester Children's Hospital (UK) | Patient Societies (Inner Circle) |
| U. Valencia/Global Influenza Hospital Surveillance Network (ES) | chairman ReSViNET Patient Advisory Board (UK) |
| Université de Versailles Saint-Quentin (FR) | Clinical Societies (Inner Circle) |
| University of Cambridge (UK) | RCGP Research & Surveillance Centre (UK) |
| University of Groningen (NL) | Royal College of Physicians of Edinburgh (UK) |
| University of Leuven (BE) | World Association of Perinatal Medicine (WAPM) (INT) |
| University of Lille (FR) | Academic Institutions (Outer Circle) |
| University of Lisbon (PT) | Nationwide Children's Hospital in Columbus (USA) |
| University of Liverpool (UK) | Fundación INFANT (ARG) |
| University of Perugia (IT) | Pontifícia Universidade Católica do Rio Grande do Sul (BRA) |
| University of Surrey (UK) | Public Health Institutions (Outer Circle) |
| Utrecht University (NL) | Canada Immunization Research Network (CAN) |
| University Children's Hospital Sant Joan de Deu (ES) | PATH - Center for Vaccine Innovation and Access (USA) |
| Medical Faculty of the Martin-Luther University Halle-Wittenberg (DE) | |

During the first year of RESCEU, some Aps have committed resources to the implementation of RESCEU tasks and contributed to the delivery of some of the RESCEU deliverables.

For example, collaborations have been established with Martin-Luther University Halle-Wittenberg for the implementation of certain WP1 tasks, while the Norwegian Institute of Public Health (NIPH), the Netherland Institute for Health Services Research (NIVEL), the National Institute for Health and Welfare (THL) and the University of Lisbon collaborated with WP2 and the University of Lille (ULille), the London School of Hygiene & Tropical Medicine (LSHTM), the University of Cambridge (UCam), the Center for Health Policies and Services (CHPS) contributed to WP3.

The interrelation between different RESCEU stakeholders, including APs and some of the initiatives identified and previously listed, is shown in the diagram below:

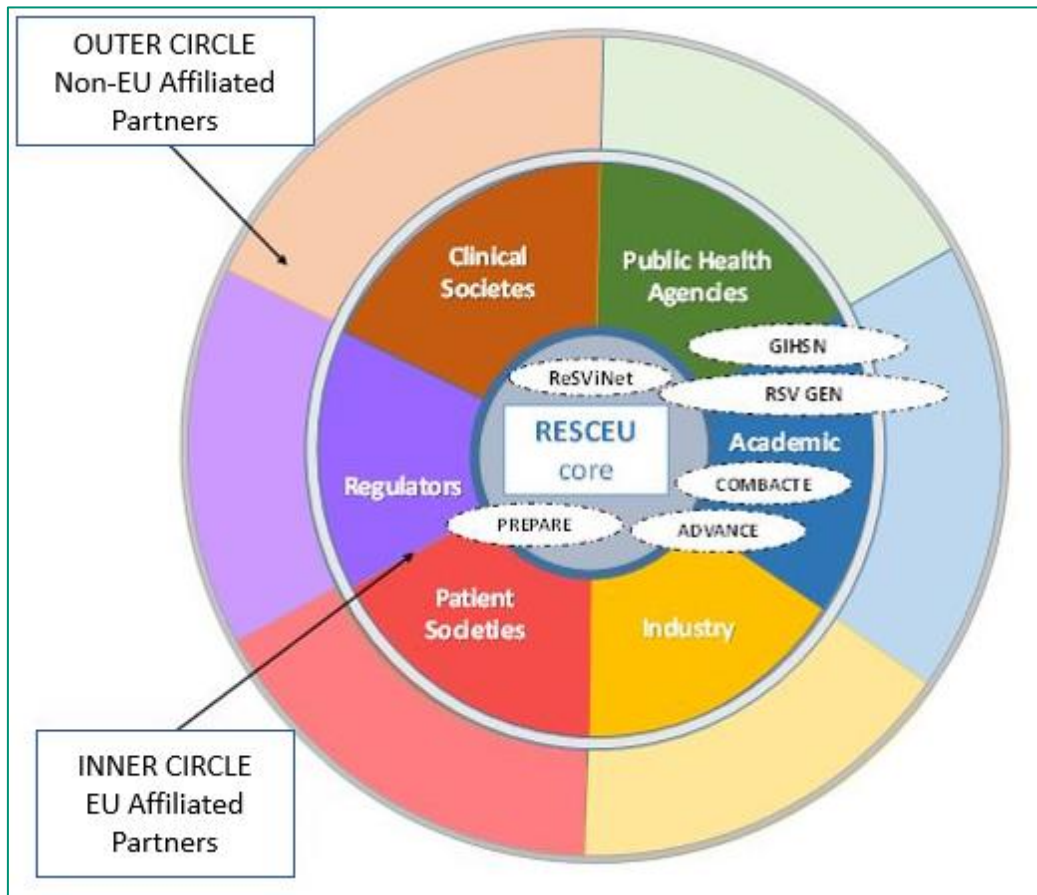


Figure 3: Schematic diagram of various stakeholders in RESCEU and their relationship in consortium structure

The **RESCEU core** is formed by the RESCEU Consortium involving Partners who are leaders in RSV research across Europe from academia, public health and industry. This is complemented by Affiliated Partners, who can be divided into two groups. The first group is a broader pan-European network of academic institutions, national public health agencies, clinical societies and patient networks who are expected to participate in regular meetings, contribute intellectually and play an important role in disseminating the results (**Inner Circle**). The Affiliated Partners who established collaborations within specific WPs and actively participate in the work of carrying out specific tasks and developing deliverables (along the scheme of a joint work synergy), are considered part of this Inner Circle. The second group of stakeholders outside Europe is expected to meet less frequently to share relevant data, promote consensus on case definitions and analytic approaches, facilitate international research collaborations and assist with wider dissemination (**Outer Circle**).

7. Initiated contacts and established collaborations

Projects, networks and initiatives where there was immediate apparent relevance and further assessment was not needed before engaging in interactions (especially those where partners of RESCEU were already involved in and benefits were obvious), were prioritized for “fast-track” implementation of synergistic interaction.

The list below provides details on the interactions between RESCEU and external initiatives that have been established so far. These collaborations range from simple email communication or teleconferences to active participation in meetings and joint activities. As mentioned, in many cases cooperation is being facilitated through the linkage of a RESCEU partner or a partner’s organisation key contact.

7.1. ReSViNET

The Respiratory Syncytial Virus Network is a global network of experts in the field of RSV with the following main objectives:

- To combine the knowledge and capacity required to enhance development of novel RSV therapeutics.
- 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 and introduction of prevention and treatment strategies for better care for patients with RSV infection.
- To bring together information related to RSV infection 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.

The collaboration with RESCEU started very early in the project and has proved to be successful on different fronts. Shared goals, resources and the presence of key contacts who are fully involved in both initiatives, are the key success factors.

Academics from RESCEU are part of ReSViNET Executive Committee, in particular Prof. Louis Bont, who is the Academic leader for WP4 in RESCEU and chairman of ReSViNET, while board members of ReSViNET includes the RESCEU coordinator, Prof. Harish Nair (UEDIN), some of RESCEU Principal Investigators, and members of the project Scientific Advisory Boards.

RESCEU representatives participated to the ReSViNET RSV Vaccines for the World 2017, in Malaga, where preliminary results from sections of the systematic review for WP5 were presented.

WP6 is collaborating with ReSViNET on the Paper of the Month initiative. Every month two teams of researchers (at UEDIN and UMCU), select a recent publication on RSV considered particularly relevant and/or ground breaking. The team, led by Prof. Harish Nair, University of Edinburgh, focuses on the assessment of clinical epidemiology papers, while the team led by Prof. Louis Bont, University

Medical Centre Utrecht, is in charge of the selection of basic science papers. Both teams provide a lay summary of the articles, that is posted both on the ReSViNET as well the RESCEU websites. Before posting, the authors of the selected papers are contacted and informed of the initiative. The statement “in collaboration with ReSViNET” has been included as a subheading on the RESCEU website, and vice versa as regards to ReSViNET. This joint effort is positive for both projects, as it allows the selection of two publications per month instead of only one, each one focusing on different, but complementary, aspects of RSV research. Furthermore, the combined online publication and dedicated space on each website provides an additional channel for dissemination and promotion for both projects.

Currently, 11 publications have been selected and shared. The Paper of the Month’s section for RESCEU can be found in the Publications section, while a preview is also visible on the homepage. Each issue includes Vancouver style reference information, a title, a summary and a link to the full article online (when this is available), often to PubMed.

All Papers of the Month in a given quarter are highlighted in the quarterly RESCEU Newsletter through a dedicated space in order to keep all partners and subscribers updated on the monthly selection.

This collaboration will foster cooperation on multiple fronts and will continue in the future.

7.2. CIRN & IMPACT RSV Study Group

As part of Task 2.3 *International linkages to promote interaction/synergy*, and specifically as part of the activities aiming at forming links with other major international efforts to quantify healthcare consequences of RSV disease, WP2 has made initial contact with the CIRN and IMPACT research group. This has been both by teleconferences and through face to face meetings at conferences. This has included reaching general agreement on future efforts to share best practices and develop common case definitions/core datasets.

7.3. ISARIC

On April 2017, RESCEU became a member of ISARIC, the International Severe Acute Respiratory and Emerging Infection Consortium. ISARIC is a global initiative aiming to ensure that clinical researchers have the open access protocols and data-sharing processes needed to facilitate a rapid response to emerging diseases that may turn into epidemics or pandemics.

7.4. ECDC

The collaboration with the European Centre for Disease prevention and Control during the first year of RESCEU was particularly successful.

It was established by WP2, and in particular as part of Task 2.2. *National/large scale surveillance systems in Europe*. This task has the major goal of mapping and improving European collaboration in the field of RSV Surveillance. ECDC was identified as a crucial partner to achieve this goal, as this organisation, together with WHO, is coordinating surveillance of infectious disease on a European level.

Two developments have been beneficial for collaboration with ECDC:

- ECDC has agreed to be member of the International Scientific Advisory Group (ISAG) of RESCEU;
- ECDC has adopted RSV surveillance in their official strategy as a key activity.

As a collaboration between ECDC, SSI and RIVM, a survey has been initiated to assess the current state of national surveillance systems among all EU/EEA Member States. The publication of the results of this survey will be beneficial to the RESCEU project, as they can provide an important starting point to map the possibilities for enhancing the surveillance of RSV and demonstrate how harmonization of surveillance strategy at a (regional) European level would be most promising and beneficial.

A representative from ECDC, Dr. Pasi Penttinen, has been invited and will attend the RESCEU General Assembly Meeting that will take place in Oxford on June 21-22 this year. He also accepted to hold a keynote speech which will focus on *Surveillance of respiratory viruses at EU level. Perspective from ECDC.*

7.5. EMA

Since its very beginning, RESCEU was aware of the importance of establishing an early and continuous dialogue with regulatory bodies to ensure a lasting impact to the project. In the specific case of RESCEU, interaction with regulators is crucial to identify the most critical regulatory issues and bottlenecks for the development of medicinal products intended for the treatment and prophylaxis of RSV infection.

As a first step, a request for an EMA ITF meeting was submitted to the EMA in November 2017, after the topics for discussion were identified by partners and all relevant documents were provided to the EMA. The request was accepted and the briefing meeting was held on March 16th at the EMA premises. Eight representatives from all the WPs were identified to attend the face-to-face meeting, while others could follow the meeting through teleconference. The discussion helped identify future steps to be taken by RESCEU, such as the Scientific Advice procedure. As a first follow up of this meeting, RESCEU representatives from WP2 have been invited to present RESCEU and explain its relevance to the EMA during a Vaccine Working Party meeting taking place on June 8, 2018.

More details on the interaction with the EMA can be found in D6.7 *Report on the Meeting with European Medicines Agency.*

7.6. GIHSN

WP2, as part of Task 2.3 *International linkages to promote interaction/synergy*, has been in communication with and attended the annual meeting of the Global Influenza Hospital Surveillance Network (GIHSN) and discussed with them how this could develop RSV activities in the coming years.

7.8. BMGF

As part of its Global Health strategy for significantly reducing child mortality, the Bill and Melinda Gates Foundation is actively engaged in research on RSV vaccines and the development of a RSV Surveillance Global Strategy.

The RESCEU Consortium established an early linkage with the Foundation, thanks to the connection provided by Prof. Harish Nair, RESCEU Coordinator and member of the Scientific Advisory Committee (SAC) for the RSV mortality studies in Pakistan and Zambia funded by the Foundation.

RESCEU is in regular contact with the Foundation, and Dr. Niteen Wairagkar, BMGF's Global Initiative Lead for Influenza and RSV, Pneumonia, Global Health, accepted to participate to the RESCEU General Assembly Meeting in June 2018.

7.7. WHO

The RESCEU Consortium is aware of the importance of involving supranational organisations as a means to leverage the impact of RESCEU and ensure sustainability of its results in the long term. Along these lines, the Consortium has been particularly keen, since the beginning of the project, to involve the World Health Organisation as a fundamental actor on RSV research and surveillance on the world stage.

The main point of contact between WHO and RESCEU is provided by Prof. Harish Nair, University of Edinburgh, who is on one side coordinator of the project and, on the other side, a member of two WHO Advisory Groups, one on RSV Surveillance (as Chair) and another on RSV vaccines.

WHO was initially envisaged as Affiliated Partner for RESCEU. As previously described, Affiliated Partners are institutions and organisations who have not signed the Grant Agreement, but that are participating to different extents to the activities of the project. At the moment, RESCEU and the WHO are in the process of exploring forms of collaboration over the next 4 years of the project, and WHO is considering the possibility of becoming a full partner.

In the meanwhile, the collaboration is continuing on a more informal level and has already brought some results. For example, as a follow up of the WHO RSV Surveillance Meeting hold on December 2017, WP1 was able to reach about 10 investigators in Latin America and Africa, for collecting unpublished data, and shared data collection template with them. These links have revealed crucial to collect unpublished data from outside the EU and tangibly advance on the WP1 research, in particular as part of Task 1.1 *RSV disease burden in the elderly* and Task 1.2 on *Burden of all-cause acute lower respiratory infections in the elderly, have mostly benefited from this approach*. In this case the link with WHO was facilitated through the establishment of connections and forms of cooperation with non-EU investigators that could have proved harder to establish otherwise.

As part of WP2, Task 2.3 *International linkages to promote interaction/synergy* has among its main goals to coordinate with WHO as it develops global plans for RSV surveillance, building on the excellent existing working relationship with WHO outlined. During the first year of RESCEU, WP2 worked with WHO to design and start to implement an RSV surveillance project in 14 countries around the world. The collaboration with WHO was also strengthened through the participation of WP2 PIs in several WHO meetings on RSV.

A representative from WHO, Dr. Siddhivinayak Hirve, has been invited and will attend the RESCEU

General Assembly Meeting that will take place in Oxford on June 21-22 this year. Dr. Hirve will also update the Consortium on the WHO RSV pilot.

8. Conclusion

Liaisons between RESCEU partners and stakeholders from external initiatives have followed various tracks to initiate collaboration. A limited number of potential synergies have been formalised thus far, such is the case of ECDC becoming an ISAG member through the signature of an Advisory Agreement with RESCEU. Main factors potentially affecting synergy creation include:

- Timing/schedule: schedules of external initiative may not coincide with needs of RESCEU.
- Prioritisation of own work and deliverables for either party: synergies are not foreseen.
- Legal/IPR: documentation of terms of use.

Previous experiences have proved that where knowledge and/or output from external initiatives are already the public domain synergies occur mostly at the level of outcome utilization for which formalization is not necessarily needed. Such publicly accessible information is an important and sustainable element for synergy creation with past initiatives, but also for current synergies where possibilities for joint work may be limited due to the factors listed above. Another form way for facilitating collaboration is the signature of a MoU, which has been considered as a possible agreement in RESCEU and for which a specific template was developed (see Annex II), WP6 contributions occur at the level of identifying potential relevant external initiatives, identifying relevant output, maintaining the awareness on the external environment and supporting the WPs in the assessment of formalizing those initiatives. Direct interaction between the relevant WP members with identified stakeholders of external initiatives is however the most efficient to initiate and explore potential synergies. This stresses the importance of consortium members with a large network within the research domain. These members play a key role in a “synergy” creation.

The establishment of new collaborations and identification of potential synergies, which has just started, will continue in the next years of RESCEU.,

To support the objectives of the scientific WPs (namely WP2), the Consortium is envisaging the collaboration in the organisation of a series of relevant events on RSV with a high networking potential. In particular, the collaboration with ECDC on the organisation of two European RSV surveillance meetings to report data, share good practices, promote engagement with clinical societies and encourage and support extension of RSV surveillance across Europe.

Also, building on the successful influenza model, RESCEU plans to hold a high-level RSV Science Policy Forum including sessions with European national immunisation technical advisory groups (NITAGs), national regulatory agencies and policy makers. This would represent a European Summit to give an overview of scientific advances in the RSV field; present RESCEU cost-effectiveness data; draw attention to key issues and relevant data for EMA and national medical regulation agencies; and develop a roadmap for an RSV action in Europe. A session will be organised at the Annual

Health Forum in Gastein (a high-level policy meeting including Members of EU parliament and governments (<http://www.ehfg.org/home.html>)) and presentations at the EUPHA conferences (<https://www.eupha.org/who-we-are>).

During the next year, WP2, as part of Task 2.3 *International linkages to promote interaction/synergy*, plans to develop international relationships further and start work towards promoting the development of a global data sharing platform.

Synergies will be also established for dissemination purposes, for example as part of Task 2.5 *Dissemination of findings to raise awareness of RSV healthcare burden*, which is expected to start later in the project. The aim of this task is to raise awareness about RSV healthcare burden among policy makers, healthcare workers and the general public across Europe, through coordination with WP6 and exploitation of different dissemination channels. To prepare the way to the activities envisaged within this task, a draft list of relevant stakeholders has been developed, followed by the identification and understanding of the types of information that should be targeted to different audiences to address the needs of policy makers, healthcare workers and the general public.

ANNEXES

ANNEX I – Affiliated Partner Agreement

Appendix 7: Affiliated Partner Agreement

This **Affiliated Partner Agreement** (this "Agreement") is made and entered into as of the [insert date] (the "Effective Date"), by and between:

[X] Consortium Members holding the Mandate;

And

_____ (ORGANISATION), represented by _____ (NAME), the RESCEU Affiliated Partner.

Whereas, _____ (ORGANISATION), agrees to become Affiliated Partner of the RESCEU Project (REspiratory Syncytial virus Consortium in EUrope), an IMI2 JU funded Project with reference number 116019.

Affiliated Partners are legal entities which have not signed the RESCEU Grant Agreement or the RESCEU Consortium Agreement, but support and can participate in the RESCEU Project Work Packages and as members of the RESCEU Forum.

The RESCEU Forum (RF) is a body of the RESCEU governance structure, comprising all Beneficiaries in the Project, plus Affiliated Partners . The RF will be a forum for discussion, dissemination and scientific community-building within the project. The RF will consist of the project partners (Beneficiaries) and the Affiliated Partners and may be convened by electronic means or face-to-face with the purpose of stimulating discussion and promoting dialogue on scientific issues. The RF will not have decision-making powers.

By agreeing to become a RESCEU Affiliated Partner, _____ (ORGANISATION) accepts the following rights and obligations:

- 1) Receiving updated information on RESCEU activities and outcomes.
- 2) Receiving invitations to attend meetings of the RESCEU Forum (travel expenses would be covered by the Project funding following the RESCEU reimbursement and costs policy.
- 3) Being invited to participate in specific tasks of the Project work packages, under conditions to be agreed on a case-by-case basis. If necessary, travel expenses associated with participation in those tasks will be also covered by the project funding following the RESCEU reimbursement and costs policy.
- 4) In a case where participation in specific project activities in point 3) triggers the generation of specific project results, the same Intellectual Property Rights regime agreed for project beneficiaries in the RESCEU Consortium Agreement will be extended to Affiliated Partners (see Annex I – Core text of the RESCEU Consortium Agreement, Clauses 6-8).

5) Keeping confidential all information related to RESCEU unless explicitly authorized to divulge such information by the RESCEU project Steering Committee. The conditions of Clause 10 of the RESCEU Consortium Agreement will be applicable to Affiliated Partners (see Annex I – Core text of the RESCEU Consortium Agreement, Clause 10).

6) Respecting the RESCEU governance model established in the Consortium Agreement (see Annex I – Core text of the RESCEU Consortium Agreement, Clause 11), especially regarding the decision making processes.

Signatures,

Name:

Name:

Function:

Function:

Place: _____

Place: _____

Date: _____

Date: _____

ANNEX I: CORE TEXT OF THE RESCEU CONSORTIUM AGREEMENT

ANNEX II – Template of Memorandum of Understanding by and between the IMI RESCEU Consortium and external initiative

| | |
|---|----------------------------|
| RESCEU Consortium Agreement | Execution version_18112016 |
| <p>Appendix 11: Memorandum of Understanding under Mandate pursuant to Clause 10.5.1.5</p> <p>MEMORANDUM OF UNDERSTANDING BY AND BETWEEN THE IMI RESCEU CONSORTIUM AND EXTERNAL INITIATIVE</p> <p>This Memorandum of Understanding ("MOU") between the IMI RESPIRATORY SYNCYTIAL VIRUS CONSORTIUM IN EUROPE (RESCEU) and the [External Initiative] (hereafter termed "the Parties") expresses the willingness of the two parties to collaborate by establishing an overarching framework to facilitate interaction and exchange of information between the Parties.</p> <p>This MOU is not a legally binding document. Separate appropriate formal agreements may be executed as required for any activities that result from this collaboration, including establishing confidentiality agreements between the relevant members of both consortia prior to the exchange of Confidential Information.</p> <p><u>I. Background</u></p> <p>RESCEU and [External Initiative] are both funded by the Innovative Medicines Initiative (if this is the case), a pan-European public and private sector collaboration between large and small biopharmaceutical and healthcare companies, regulators, academia and patients. In the spirit of collaborative working across relevant IMI-funded Projects, the RESCEU and [External Initiative] consortia have proposed to establish a relationship to cooperate in a range of areas identified in Annex I.</p> <p>The goal of RESCEU is to xxx</p> <p>The goal of [External Initiative] is to [goal external initiative].</p> <p><u>II. Purpose</u></p> <p>The purpose of this MOU is:</p> <ul style="list-style-type: none"> - To establish the overarching framework for collaboration between the Parties, and - To facilitate and develop existing synergies between the Parties in relevant activities, in accordance with policies and procedures for each Party and of the Projects. <p><u>III. Substance of Agreement</u></p> <p>The areas on which the Parties agree to collaborate could include but are not limited to the following activities:</p> <ol style="list-style-type: none"> 1. To maintain effective communication between the Parties to identify areas of mutual research interest; 2. To foster exploratory discussions amongst scientists in the Parties' projects in order to identify areas of shared scientific interest and scientific gaps that are inhibiting progress by the Parties; 3. To explore the sharing of knowledge and data that advance the mutual interest of the parties in accordance with policies and procedures for each Party; | |

RESCEU Consortium Agreement

Execution version_18112016

4. To publish and disseminate the results of collaborations (the "Results") in accordance with the policies of each Party and their consortia/working teams.

IV. Operation of the collaboration

Each Project will appoint a contact person to lead the interactions described in this MOU. Regular meetings will be held, where additional Project members can be invited to attend depending on the items to be discussed.

V. Dissemination and publications

V.I. Confidential Information

Shall Confidential Information be concerned, the Parties shall have a duty to protect such Confidential Information, other confidential and/or sensitive information which is (a) disclosed by a Party in writing and marked as confidential (or with other similar designation) at the time of disclosure; and/or (b) disclosed by a Party in any other manner and identified as confidential at the time of disclosure.

The Party having access to such Confidential Information shall use the Confidential Information only for the purpose of activities within the limit of the MOU.

The Party having access to such Confidential Information shall limit disclosure of Confidential Information within its own organisation to its partners, members having a need to know and shall not disclose Confidential Information to any Third Party (whether an individual, corporation, or other entity) without the prior written consent of disclosing Party.

V.II. Implications of information exchange

This MOU shall not be construed as creating, conveying, transferring, granting or conferring upon the any of the Parties any rights, license or authority in or to the information exchanged, except the limited right to use Confidential Information specified in this MOU. Furthermore and specifically, no license or conveyance of any intellectual property rights is granted or implied by this MOU.

Neither Party has an obligation under this MOU to purchase any service, goods, or intangibles from the other Party. Furthermore, both Parties acknowledge and agree that the exchange of information under this MOU shall not commit or bind either Party to any present or future contractual relationship, nor shall the exchange of information be construed as an inducement to act or not to act in any given manner.

Neither Party shall be liable to the other in any manner whatsoever for any decisions, obligations, costs or expenses incurred, changes in business practices, plans, organisation, products, services, or otherwise, based on either Party's decision to rely on any information exchanged under this MOU.

V.III. Communication

RESCEU Consortium Agreement

Execution version_18112016

Should the Parties decide to publish and/or disseminate the Results of collaborations in accordance with the policies of each Party and their consortia/working teams, the Parties will work together to identify potential scientific and technical publications based on the collaboration between the Parties. Authorship credit for any publication shall be guided by the usual practices of academic scientific publications (i.e. ICMJE recommendations), provided that all publication authors shall have made substantial contributions to the conception and design of the Results described in the publication, the acquisition of the applicable data, and/or the analysis and interpretation of the applicable data.

VI. Resource Obligations

This MOU describes in general terms the basis upon which the Parties intend to collaborate. It does not create binding, enforceable obligations against any Party. All activities undertaken pursuant to the MOU are subject to the approval of the involved consortia members and/or the relevant Project committees that oversee the specific Projects and also subject to the availability of personnel and resources. Separate agreements may be implemented as needed.

This MOU does not affect the ability of the Parties to enter into other agreements or arrangements.

VII. Communications and Liaisons

For RESCEU:

Project Leader

Name:
Address:
Tel:
Email:

Coordinator

Name:
Address:
Tel:
Email:

For EXTERNAL INITIATIVE:

Name:
Address:
Tel:
Email:

VIII. Period of Agreement

This MOU becomes effective upon the date of the last Party to sign ("effective date") and will continue until the termination date of [External Initiative], which is set at [date]. This MOU may be modified by mutual written consent or terminated by either Party upon a 30-day advanced written notice to the other Party.

RESCEU Consortium Agreement Execution version_18112016

SIGNATURES OF PARTIES:

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR RESCEU

Name _____ Date _____
Position

APPROVED AND ACCEPTED FOR [EXTERNAL INITIATIVE]

Name _____ Date _____
Position

ANNEX III - Advisory Agreement Contract Template

| | |
|--|---|
| RESCEU Consortium Agreement | Execution version_18112016 |
| Appendix 10: Contracts under Mandate: Advisory Agreement | |
| Advisory Agreement | |
| Between | <i>[X]</i> Consortium Members as listed in Appendix 1 - hereinafter jointly referred to as "Consortium" - |
| And | <i>[Name and private address of consultant]</i> - hereinafter referred to as "Advisor" - |
| WHEREAS, | |
| (A) | The Consortium has been formed under the Innovative Medicines Initiative 2 ("IMI") for the purpose of establishing the Project called " <i>[title of IMI Consortium]</i> " (IMI Grant Agreement No. <i>[...]</i>) (the "Action"). It consists of the participants listed in <u>Exhibit 1</u> hereto (collectively the "Participants"), including <i>[name of authorized company or institution]</i> acting as the "Coordinator" and <i>[name of authorized company or institution]</i> acting as the "Project Leader". The Participants are parties to an IMI Consortium Agreement for <i>[title of IMI Consortium]</i> effective as of <i>[...]</i> (the "Consortium Agreement"). |
| (B) | in the Consortium Agreement, a <i>[insert name of committee]</i> is established to <i>[insert short description of the role of the committee]</i> . |
| (C) | Advisor, who is employed by <i>[name and address of employer]</i> , has extensive experience, scientific and/or industrial prominence and leadership in the field of <i>[field of expertise]</i> relating to the Action. |
| (D) | The Consortium is interested to have the Advisor to be part of the <i>[insert name of committee]</i> . |
| (E) | Each Participant has authorized the Project Leader and the Coordinator to execute this Advisory Agreement on its behalf. |
| <i>[Alternative in case of "on the spot/one time consultancy":</i> | |
| (A) | <i>Advisor, who is employed by [name and address of employer], has extensive experience, scientific and/or industrial prominence and leadership in the field of [field of expertise] relating to the Action.</i> |
| (B) | <i>The Consortium is interested to have the advice of the Advisor be brought into the Action.</i> |
| (C) | <i>Each Participant has authorized the Project Leader and the Coordinator to execute this Advisory Agreement on its behalf.]</i> |

RESCEU Consortium Agreement

Execution version_18112016

Therefore, it is agreed as follows:

1. SUBJECT MATTER OF THE AGREEMENT

- 1.1 Advisor shall provide consultative and advisory services to the Consortium according to the terms and conditions of the Consortium Agreement and this Agreement as set forth below (hereinafter referred to as the "Services"):

[In case Advisor is to be a member of a committee:

The Advisor agrees to be a member of the [insert name of committee] in accordance with the Consortium Agreement.]

The Advisor shall [insert precise description of services, e.g., providing expert interpretation, analysis and opinion on scientific data/information, Project management, attending meetings etc., including preparation and timelines tasks, e.g.: "be available for [time needed] and shall, on request by [committee to be inserted], provide and/or approve reports or meeting minutes as agreed upon.]

Further details of the Services will be agreed between the parties, and recorded in writing.

- 1.2 *[Insert for healthcare professionals, otherwise delete]* For the term of this Agreement Advisor agrees to declare in an appropriate way that he/she is an advisor to the Consortium whenever he/she writes or speaks in public about a topic that is the subject matter of this Agreement or any other issue relating to the Action.

2. COMPENSATION

- 2.1 The parties agree that the Advisor shall not be compensated for the performance of the Services.
- 2.2 *[Insert Participant who reimburses below costs]* will, in compliance with the applicable laws, regulations and codices, offer to pay for reasonable travel expenses and hospitality, such as flights (economy class airfare), train travel, accommodation (up to 4-star rating), work related meals and transportation. In addition, Advisor shall be reimbursed by *[insert Participant who reimburses costs]* for other reasonable travel expenses actually incurred by Advisor in connection with providing the Services, subject to the receipt of invoices or receipts. Costs for meals and drinks are not considered as travel expenses.
- 2.3 Any payments will be made by *[insert Participant who reimburses costs]* within 90 Days to an account nominated by the Advisor previously in writing upon receipt of a correct invoice (i) complying with applicable legal and tax requirements and (ii) containing the original receipts. Further details will be agreed between the parties. Advisor acknowledges and agrees that the amounts paid will be reported to the members of the Consortium as well as the country to which the amount is paid.
- 2.4 Advisor shall be responsible for all other taxes payable on account of payments made hereunder.

- 2.5 **Advisor agrees that the Consortium (by stating Advisor's private information) may store, process and publish any payments made by the Consortium under this Agreement, if such disclosure is required by statutory or internal regulation or any binding Code of Conduct.**

3. CONFIDENTIALITY, ARCHIVING, DATA PROTECTION

- 3.1 Advisor undertakes to hold in strict confidence any information, in particular without limitation scientific, technical or commercial information relating to the business, products or research of the Consortium, which becomes known to Advisor during the course of this collaboration, together with any information regarding the Action and all Results (as defined in Clause 4 below) of the cooperation with the Consortium, to use such information and Results only for the purposes of this Agreement, and not to disclose such information or Results to any third party without a prior written consent of the Consortium. The foregoing restrictions on use and disclosure will not apply to any of such information which: (a) at the time of receipt by Advisor is available to the public; or (b) becomes public knowledge other than by an act or omission on the part of Advisor; or (c) which Advisor can demonstrate by reasonable proof was known to Advisor before the date of its disclosure to Advisor by the Consortium; or (d) is legally acquired by Advisor from a third party not bound to Consortium or any of its Participants by any express or implied obligation of secrecy, or (e) Advisor can demonstrate by reasonable proof was developed independently by him/her without reference to or use of the information.
- 3.2 Furthermore, Advisor may disclose such information to the extent that such disclosure is required to comply with law or an enforceable judicial order, provided, however, that Advisor shall give reasonable advance notice to the Consortium and on request, shall cooperate with the Consortium to seek a protective order or other appropriate remedy. The Advisor shall cooperate with the Consortium in seeking an appropriate relief or remedy and use his/her reasonable efforts to secure confidential treatment of any such information that will be disclosed.
- 3.3 Information shall not be deemed to be or have become public knowledge merely because any part of such Information is embodied in general disclosures or because individual features, components or combinations thereof are known or become known to the public.
- 3.4 Advisor agrees to duly preserve all information and documentation provided to Advisor and to ensure that no third parties gain access thereto. Any documentation provided must be returned to the Consortium at Consortium's request during the term of this Agreement, and shall be returned to the Consortium, without being asked, upon the termination of this Agreement.
- 3.5 This confidentiality and non-use obligation shall remain in effect for ten (10) years after the Consortium Agreement expires or is terminated. *[To be checked if this is in line with the Consortium Agreement]*
- 3.6 In the event the performance of Services or the preparation thereof requires Advisor to use or process any personal data, Advisor agrees to use such personal data only for the Services provided hereunder and in compliance with applicable data protection laws.

4. RIGHTS TO RESULTS

In case that results are generated by Advisor including intellectual property rights relating thereto (collectively "Results") Advisor shall promptly disclose any Results to the Project Leader and the Coordinator in writing. All rights, title and interest in any Results will be owned exclusively by the Participants in equal shares, and Advisor shall assign (or cause to be assigned) and does hereby assign fully to each of the Participants in equal shares all rights, title and interest in and to any Results, without payment of any additional compensation to Advisor. At a Participant's request and expense, Advisor shall also reasonably assist such Participant in obtaining, perfecting, or defending such Participant's rights, title, and interest in any Results, including, without limitation, the drafting, filing and prosecution of any patent applications. As between the Participants, such Results shall be deemed to be *allocate as suitable pursuant to Consortium Agreement terms, e.g. "Foreground"* and rights thereto shall be exploited and shared pursuant to the terms of the Consortium Agreement. With regard to any copyrights, Advisor consents to the right to reproduce, modify and use all copyrightable works designed or made by the Advisor by each of the Participants.

5. COMPLIANCE

- 5.1 The parties declare that this Agreement is in no way associated with any business or sales activities between the parties hereto and in particular Advisor is by no means obligated to prescribe, recommend or purchase any goods from the Consortium.
- 5.2 Advisor agrees to comply with all applicable laws and regulations in the performance of the Services pursuant to this Agreement.
- 5.3 Advisor represents and warrants that: (a) Advisor has received all necessary approvals in connection with entering into this Agreement and performing the Services to be provided hereunder; (b) compliance with the terms of this Agreement and performance of the Services do not and will not breach or conflict with (i) any other agreement or arrangement, to which Advisor is a party, or (ii) any statutory or internal regulations Advisor is subject to; (c) compliance with the terms of this Agreement and performance of the Services do not and will not breach any agreement to keep in confidence information acquired in confidence or in trust; and (d) during performance of the Services, Advisor will not disclose to Consortium, or induce Consortium to use, any information belonging to a third party.
- 5.4 Advisor further represents and warrants that he/she has fully informed the management of his/her medical agency/institution or other employer, or any other organizations or authorities, if necessary, about the execution and content of this Agreement and that he/she has obtained the necessary written approvals of such employer that are required for the performance of this Agreement. *[The medical agency/institution or other employer may confirm that it has no objections to Advisor entering into this Agreement, through an authorized Representative's signature at the place indicated below.]*
- 5.5 The Advisor represents that in performing the Services he/she is not and he/she will not use in any capacity the services of anyone debarred, disqualified, blacklisted or banned or under investigations or threat of investigations by any regulatory authority for debarment, disqualification, blacklisting or any similar regulatory action in any jurisdiction anywhere in the world. Furthermore, the Advisor represents and warrants that neither he/she, nor its employees, agents, representatives or permitted sub-contractors have been debarred, disqualified,

RESCEU Consortium Agreement

Execution version_18112016

blacklisted or banned by any regulatory authority, nor that they are currently to the best of his knowledge, the subject of such a debarment, disqualification, blacklisting or banning proceeding. During the term of this Advisory Agreement, the Advisor shall promptly notify the Project Leader should the Advisor, any of its employees, agents, representatives or permitted sub-contractors become subject of such debarment, disqualification, blacklisting or banning proceeding.

FOR US:

Advisor should notify if he/she is or becomes an employee of NIH and the Consortium would have the right to terminate this Agreement.

Advisor agrees to comply with all applicable federal, state and local laws and regulations in the performance of the Services pursuant to this Agreement, including, without limitation, laws related to fraud, abuse, privacy, discrimination, disabilities, samples, confidentiality, false claims and prohibition of kickbacks. Without limiting the generality of the foregoing, each party to this Agreement certifies that such party shall not violate the U.S. Anti-Kickback Statute (42 U.S.C § 1320a-7b (b)) with respect to the performance of this Agreement.

Without prejudice to the generality of section above, Advisor further agrees to comply with all applicable U.S. federal, state and local laws and regulations relating to the privacy of patient health information, including, but not limited to, the Standards for Individually Identifiable Health Information, 45 C.F.R. §§ 160 and 164 (the "HIPAA Privacy Regulation") promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. If Advisor deems it necessary in the performance of the Services under this Agreement to disclose to the Consortium the "Protected Health Information" (as such term is used in the HIPAA Privacy Regulation) of a patient, then, in advance of any such disclosure, Advisor shall obtain a written authorization executed by such patient for the use and disclosure of such Protected Health Information in accordance with the HIPAA Privacy Regulation.]

6. TERM

- 6.1 This Agreement comes into force upon signature by the parties and continues effective until all parties' obligations pursuant to Section 1 and 2 hereof have been fulfilled [or specific date].
- 6.2 The terms set forth in Sections 3, 4, 6.2 and 7.1 shall survive any termination or expiration of this Agreement.

7. MISCELLANEOUS

- 7.1 Advisor shall not use any name, logos or trade names or product trademarks owned by a member of the Consortium, IMI or the Consortium as such in any public announcement, press release or other public document without prior written consent of the Consortium and/or the member of the Consortium that owns the name, logos or trade names or product trademarks.
- 7.2 Advisor shall be deemed for all purposes to be an independent contractor. Advisor shall not have the authority to enter into agreements or make any representations on behalf of or otherwise bind the Consortium.

RESCEU Consortium Agreement

Execution version_18112016

- 7.3 This Agreement contains the entire agreement between the Advisor and the Consortium. Any amendments to this Agreement shall be made in writing. If any provision of this Agreement is or becomes invalid or unenforceable, this shall not affect the remaining provisions hereof. The parties shall in this case replace the invalid or unenforceable provision with a provision that is as close as possible to the economic effect of the invalid or unenforceable provision.
- 7.4 Each Participant is intended to be a third party beneficiary with the ability to enforce the terms of the Agreement in its own name and as if it was a party to this Agreement.
- 7.5 This Agreement shall be construed, controlled and interpreted by the laws of Belgium, regardless of its conflict of laws provisions. Exclusive place of jurisdiction shall be Brussels.

Remainder of this page intentionally left blank

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| <p>IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in <i>[insert number of necessary duplicates]</i> in their own name and, in case of Project Leader and the Coordinator, in addition in the name and on behalf of the Participants as their duly authorized Representatives.</p> <p><i>[name of authorized company or institution] [Advisor]</i> (Project Leader)</p> | |
| _____ Name: _____ Function: _____ Place: _____ Date: _____ | _____ Name: _____ Function: _____ Place: _____ Date: _____ |
| <p>(Coordinator)</p> _____ Name: _____ Function: _____ Place: _____ Date: _____ | |
| <p>Acknowledged and agreed <i>[Participant responsible for reimbursement of costs]</i></p> | |
| _____ Name: _____ Function: _____ Place: _____ Date: _____ | |
| <p>Approval of Employer: <i>[Insert name of employer]</i></p> <p>We have read the foregoing Advisory Agreement between the Consortium and <i>[Insert name of advisor]</i> and approve the content and the conclusion of such Agreement:</p> | |
| Name: _____ Place/Date: _____ Signature/Seal: _____ | |

RESCEU Consortium Agreement

Execution version_18112016

[Add further signature lines for further signatures on behalf of signing entity, if requested by such signing entity]

RESCEU Consortium Agreement

Execution version_18112016

EXHIBIT 1*[list names and addresses of Consortium Participants]*