

D5.1 “Virtual biobank” of archived samples and metadata established-online database of pre-existing samples and samples from WP4 established to promote sharing of archived samples

116019 - RESCEU

REspiratory Syncytial virus
Consortium in EUrope

**WP5 – Presumed risk factors
and biomarkers for RSV-
related severe disease and
related sequelae**

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Document History

Version	Date	Description
V0.1	20/05/2017	First Draft
V0.2	15/06/2017	Review by the Steering Committee
V0.3	23/06/2017	Final Version

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 – University Medical Center Groningen (Netherlands)
 - **PENTA.** Fondazione PENTA for the treatment and care of children with HIV-ONLUS (Italy)
 - **KEMRI.** Kenya Medical Research Institute (Kenya)
 - **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.
 - **COPD.** Chronic Obstructive Pulmonary Disease.
 - **RSV.** Respiratory Syncytial Virus.
 - **PBMC.** Peripheral Blood Mononuclear Cells.

Publishable Summary

We have collated four datasets of archived biological samples and associated metadata that investigators within the RESCEU consortium can apply for access to. The samples include those from healthy infants, infants with RSV infection and adults with COPD. The datasets will be available to review on the RESCEU Sharepoint. Details on who to contact to enquire about access to the samples and metadata are available in the dataset. In addition, a list of samples and metadata that will be collected in the four WP4 clinical studies has been established.

1. Introduction

To promote sharing of archived samples between collaborators within the RESCEU consortium we have collated a list of those samples and metadata that are already held by investigators within the RESCEU Consortium. This will allow other collaborators to be aware of samples and metadata that are potentially available for access.

The standard biobank policy applies whereby collaborators can apply to use samples and metadata but it is up to the guardian to:

- decide whether they should be released (not compulsory)
- check that the ethical approval allows for the planned usage.

We have also established a list of samples and metadata that will be collected in the four WP4 clinical studies.

2. Methods

We have established a database of pre-existing samples that RESCEU collaborators can apply for use of (see Results section). An online database of samples collected from the clinical studies in WP4 will be available within the RESCEU Sharepoint.

The clinical studies from which samples will be available are listed below (N=number of participants from which samples will be available):

- The infant active birth cohort study (N=1,000)
- The infant case-control study (N=630)
- The older adults study (N=1000)
- The adult COPD study (N=500)

3. Results

The archived samples and associated metadata available within the RESCEU consortium are listed in Table 5.1. To apply for access to these, contact the guardian of the samples and metadata shown in the table. It will be up to the guardian/their institution to decide whether access to the samples is permitted and whether the ethical approvals in place cover the planned analysis of the samples and/or metadata.

An overview of the samples and metadata that will be available from the four WP4 clinical studies are shown in Table 5.2. Further details of the sampling and metadata being collected are available in the document Deliverable D4.1.

If knowledge of further samples became available they could be added to the database.

Table 5.1: Archived samples and associated metadata available within the RESCEU consortium.

Site	Site contact	Population	Time frame of samples	Number of samples	Timing of samples			Type of samples						Metadata			
					Acute RSV infection	Convalescence	Other	Serum	Plasma	Transcriptomics (whole blood)	PBMC/Whole blood	Host DNA	Respiratory sample	Urine	Demographics	Healthcare use	Other results (e.g. haematology / biochemistry results, lung function tests)
SSI, Denmark	Thea Kølsen- Fischer (THF@ssi.dk)	Infants	1981-present	~80,000			X ¹					X			X	X	X ³
Kenya Medical Research Institute (KEMRI), Kenya	Charles Sande (charles.sande@paediatrics.ox.ac.uk)	Infants	2015-present	~1000	X	X		X		X	X	X	X		X	X	X
Imperial, UK	Ryan Thwaites (r.thwaites@imperial.ac.uk)	Infants	2015-present	42	X			X			X	X	X		X	X	X
Imperial, UK	Gavin Donaldson (gavin.donaldson@imperial.ac.uk)	Adults with COPD	2006-present	>2000			X ²	X	X	X	X	X	X	X	X	X	X

¹ Dried blood spots from soon after birth; ² Baseline and COPD exacerbation; ³ Linked to national database and any associated results

Table 5.2: An overview of the samples and metadata that will be available from the four WP4 clinical studies.

Study	Sample type								Metadata	
	Number of participants	Serum/Plasma	Transcriptomics (whole blood)	Whole blood/PBMC	Host DNA	Respiratory sample	Urine	Stool	Demographics	Healthcare use
Infant active cohort	1000	X	X	X	X	X	X	X	X	X
Infant case-control	630	X	X	X	X	X	X	X	X	X
Adult elderly	1000	X	X	X	X	X			X	X
Adult COPD	500	X	X	X	X	X	X		X	X

4. Discussion

Not applicable.

5. Conclusion and next steps

It is already possible for members of the RESCEU consortium to apply for use of the pre-existing samples and metadata. The samples and metadata collected from the four WP4 clinical studies will be available once the studies are underway (first study due to start July 2017). An online database will be set up within the RESCEU Sharepoint detailing the samples and metadata that have been collected from these studies. Access to those samples is as per the RESCEU grant agreement.