

Seminar:

**FONDATION
BROCHER**



Data privacy, data property and data sharing: an interdisciplinary dialogue for post-pandemic transnational research

Fondation Brocher, Hermance
18-21 June 2023



Funded by the
European Union

Monday 19 June
Session one:

Setting the scene:

Emerging issues in transnational biomedical research: the example of the EuCARE Project

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EuCARE Project coordinator
CEO at EuResist Network

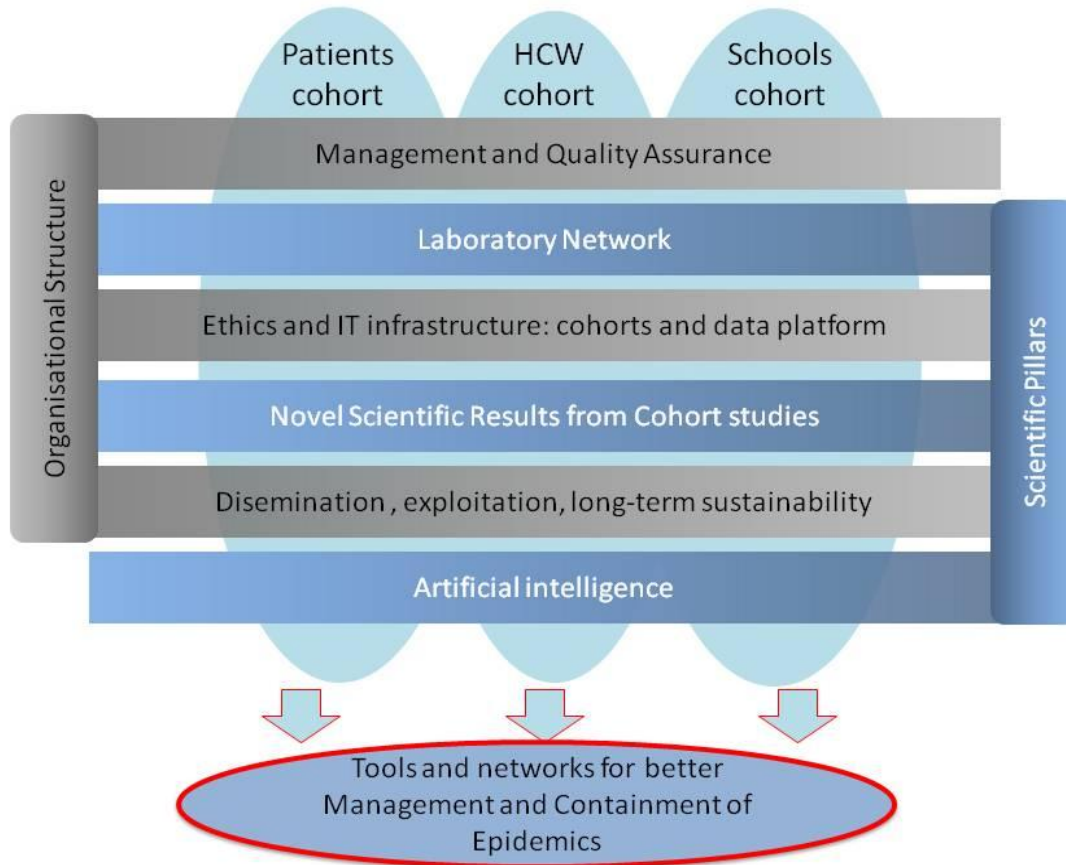


EuCARE stands for: **E**uropean **C**ohorts of Patients and Schools to **A**dvance **R**esponse to **E**pidemics

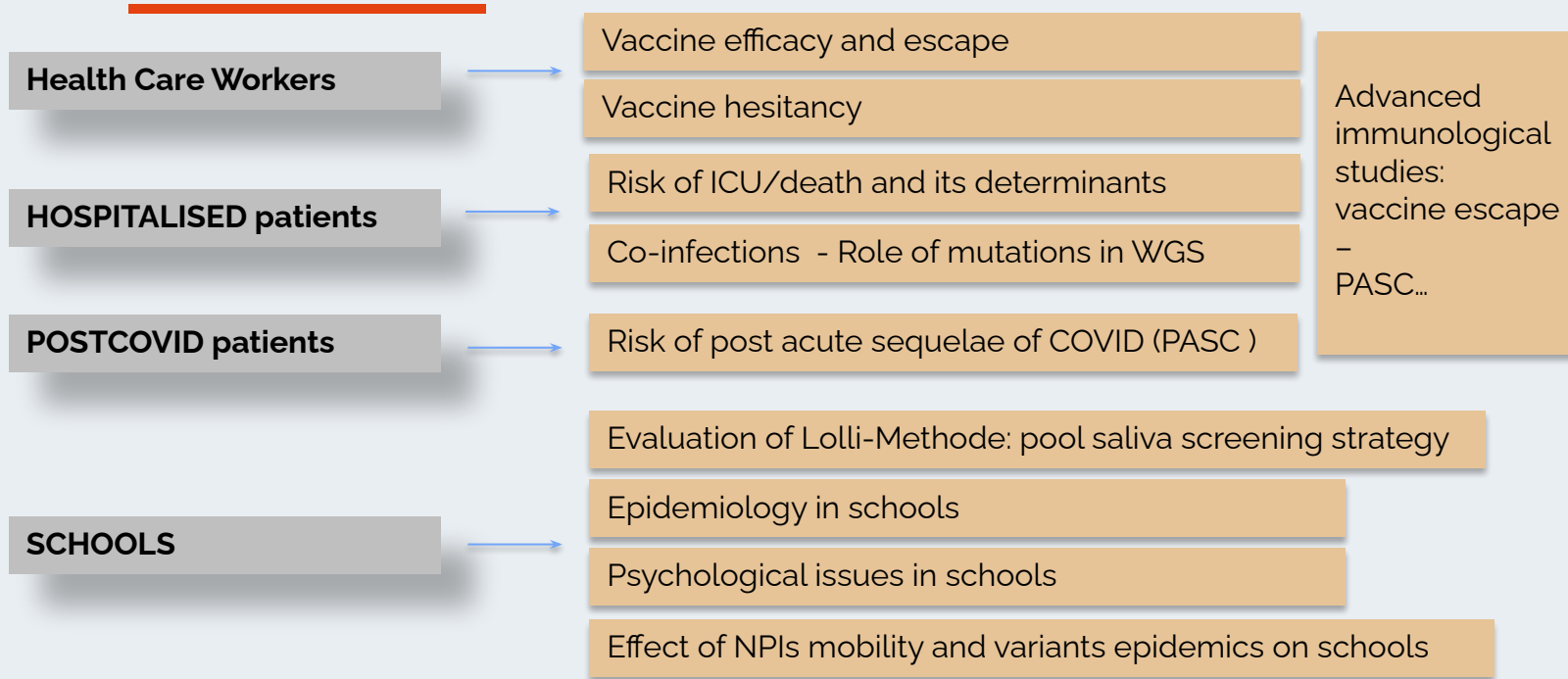


**An Horizon Europe project
with cohorts at its heart
coordinated by EuResist
Network:**

- Focus on SARS-COV-2 variants
- 19 partners + 9 subcontractors
- 5 continents
- 5 years
- Max funding: 9.995.920€



Four cohorts for multiple studies



Patients and HCWs cohorts



**Karolinska
Institutet**



Vilniaus universiteto ligoninė
SANTAROS KLINIKOS

Ospedale San Paolo
Polo Universitario

Sistema Socio Sanitario

Regione
Lombardia

ASST Santi Paolo e Carlo



Insieme neglistum



CENTRO HOSPITALAR DE
LISBOA OCIDENTAL. E.P.E.

hhu

Heinrich Heine
Universität
Düsseldorf

**Imperial College
London**



UFMG

UNIVERSIDADE FEDERAL
DE MINAS GERAIS



Istituto Nazionale per le Malattie Infettive
"IRCCS 'Lazzaro Spallanzani'"

Schools cohort



**UNIKLINIK
KÖLN**

euresist network



IEO
Istituto Europeo
di Oncologia



DESDE 1902
INSTITUTO DE HIGIENE E
MEDICINA TROPICAL
UNIVERSIDADE NOVA DE LISBOA



**UNIVERSITÀ
DEL SALENTO**



OBESSU

Organising Bureau of
European School Student Unions

Artificial intelligence

IBM

EBERHARD KARLS
UNIVERSITÄT
TÜBINGEN



Laboratory network

UNIVERSITÀ
DI SIENA 1240

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TOR VERGATA
UNIVERSITÀ DEGLI STUDI DI ROMA



Ethics & IT

euresist network

ROMA
TRE
UNIVERSITÀ DEGLI STUDI

EUI

I-PRO

euresist network



Status of project

Cohort studies ongoing

6 study protocols have been approved in 10 countries.
First results published or submitted

New collaborations

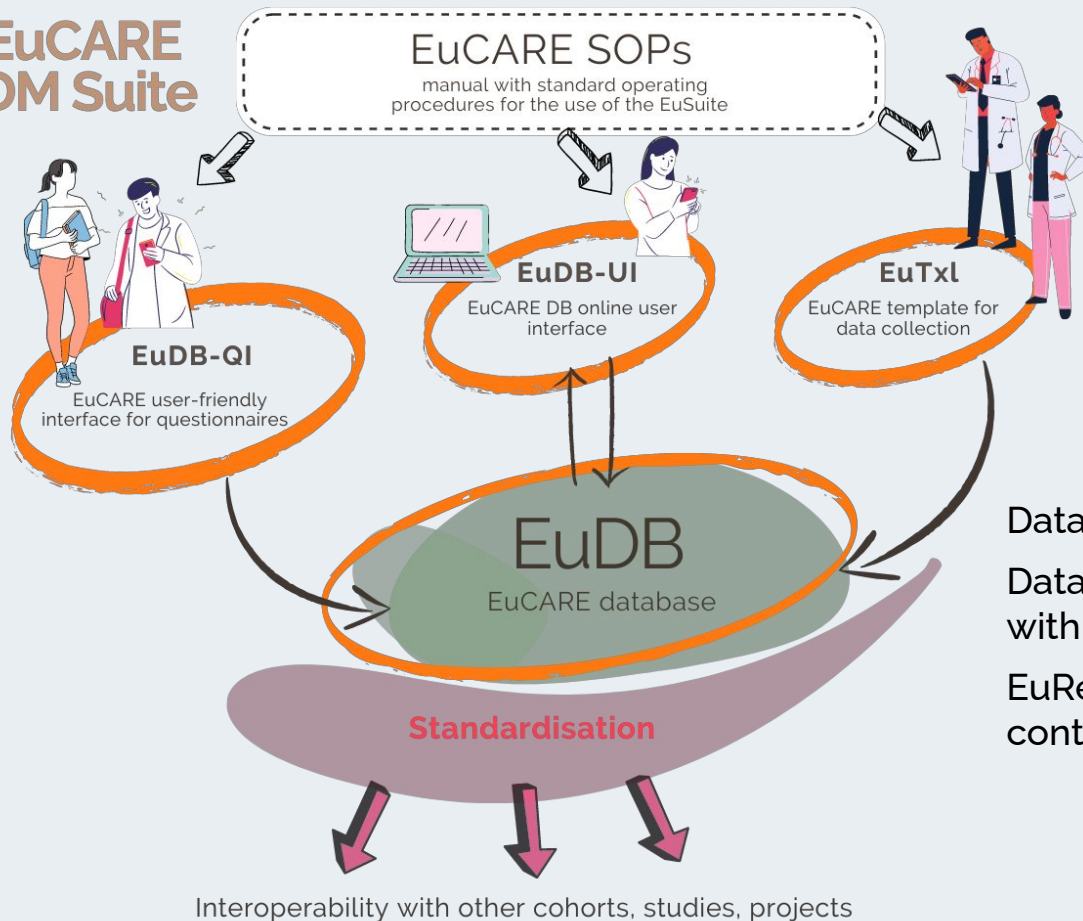
Beyond COVID, INVALSI,
Calamandrei Foundation,
University of Milan, Sapienza
University, PTP lab Milan,
CHLN Portugal, **CCB**

Data collection

IT infrastructure set-up.
Variables harmonised and
standardized.
Data collection and cleaning
ongoing

Dissemination

19 scientific papers published
Project appeared in several
newspapers, radio and TV
programmes
Seminars organised



Data are stored in Europe
Data are managed in accordance with GDPR by EuResist Network.
EuResist Network is joint data controller

Currently stored data in the EuDB

Study	Data	Samples*	Tot expected cohort size
Cellular immune response	150	150	200 samples
Vaccine escape	1 521	3 244	1 500
Risk of ICU/death	34 014	4405	32 317
Risk of PASC	995	807	2 750
Lolli-Methode	3 414	2 745 + 453	440 classes
Epidemiology in schools	2 199	-	-
Psychology in schools	495	-	-

* saliva/nasopharyngeal, PBMC or blood/serum samples linked with clinical info

EuCARE: a cohorts project

A **cohort** is a group of individuals who share some characteristics that define the entry and exit criteria and who are followed over time. Data about them are collected longitudinally to allow the study of some features related to the individuals' health status, use of drugs or devices and the correlations among such features.

The cohorts in EuCARE allow for several different types of studies:

- Interventional randomised controlled trial (SCHOOLS' study)
- Interventional non randomised clinical trials (POSTCOVID studies)
- Observational prospective studies (HCW and HOSPITALISED studies)
- Observational retrospective studies (HCW and HOSPITALISED studies)

We don't have pharmacological studies (we would not make use of the new CTIS)

Ethics and legal structure

- External Ethics Advisory Board (A. Mantelero, C. M. Cascione, P. Franc, L. Norén)
- Regulatory and Ethics manager (G. Resta)
- DPO (A. Bezenchek)
- Data Management Board
- Local Ethics Committees
- Local DPOs



- Grant Agreement among EU and beneficiaries
- Consortium Agreement among beneficiaries
- Subcontracting agreements
- Study protocols approvals



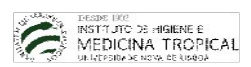
Main ethical and regulatory issues we faced .1

- **International cohorts**, fundamental to study a pandemic: Israel, UK, Kenya, Brazil, Mexico, Viet Nam □ **international data sharing:**
 - Completely anonymised data from UK and to IBM Israel
 - An issue even within Europe: the EU COVID-19 data portal
- **Differences** among the principles and rules adopted by the different ethics committees in the involved centres, even within Europe, even within the same country
 - The lawfulness of data use and reuse in many countries is based on the **Informed consent**, in others (e.g. Sweden) on the **public interest** or **scientific research (GDPR Recital 50, 52, 53, Art. 6.1.e, Art.9.1.j)**
- **Data sharing with WHO: international organisation.** The application of Art. 46 adequate guarantees would be a nightmare; Art.49.1.d – public interest)



Main ethical and regulatory issues we faced .2

- **Use of retrospective data**, the power of cohorts: **data reuse** □ validity of the consent?
- **Should the third countries comply with GDPR?**
- **Involvement of minors** - inter country differences, e.g. age of consent
- **Changing protocols** to adapt to changing pandemic



Thank you for your attention

And thanks to the whole EuCARE team!



Francesca Incardona - EuCARE Project, CEO EuResist

www.eucareresearch.eu