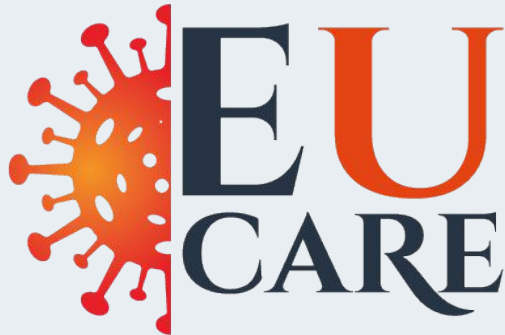


Tuesday 20 June
Session two:

Who owns data?

The value of patient cohorts
and databases



Francesca Incardona
EuCARE Project coordinator
CEO at EuResist Network

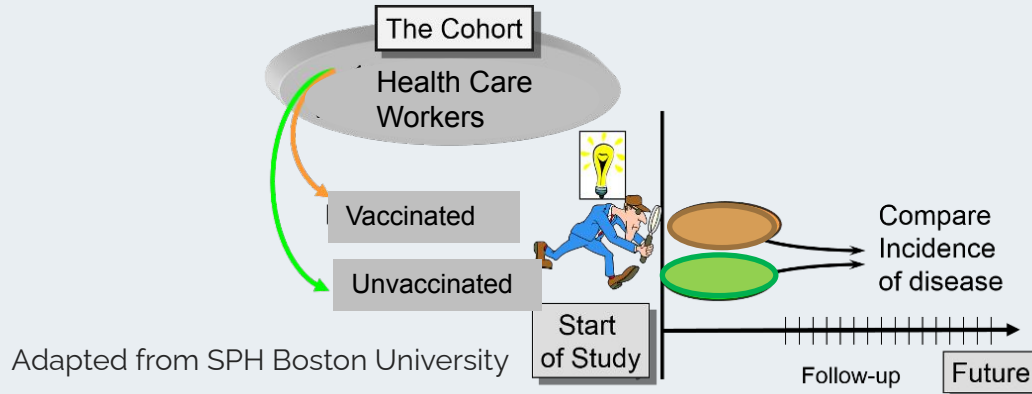


Funded by the
European Union

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.

Population descriptors – Baseline values – (Event) – Follow-up values

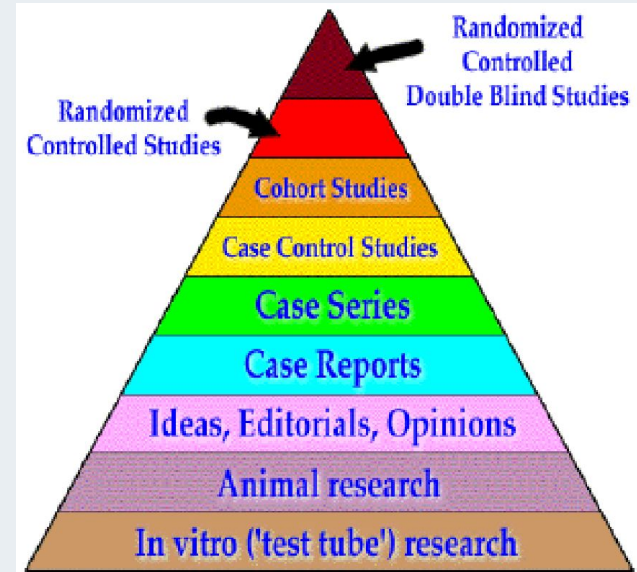


The role of cohorts in evidence based medicine

The classical pyramid of the hierarchy of strength of evidence concerning efficacy of therapeutic interventions.

Cohort studies are in the second position after the randomised controlled trials (RCTs).

But ongoing cohorts can be the basis also for RCTs



Green and Byar, 1984

Da A. Vestri "Metodologia della ricerca delle evidenze scientifiche"

Cohorts are invaluable source of information especially in case of a pandemic

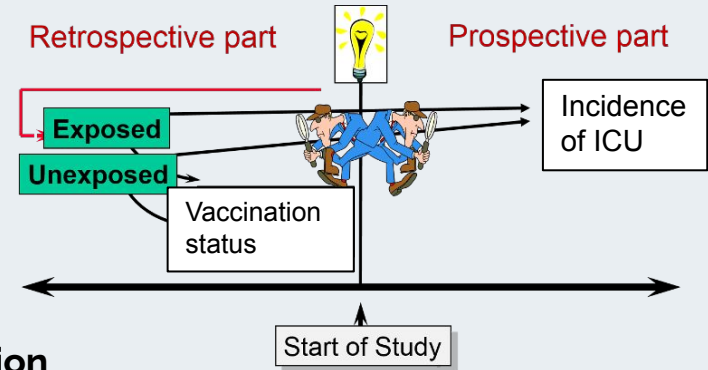
Throughout the Covid 19 pandemic, cohort studies have demonstrated their extraordinary value in supporting public health research by contributing new evidence on disease, social dynamics, vaccination, and long-term sequelae.

With the support of European Commission funding and research plans, several cohort projects have been funded and several new cohorts have been founded.

Different cohorts have been linked, to increase heterogeneity and comparability of data across countries and studies: the Cohorts Coordination Board (CCB).

Why?

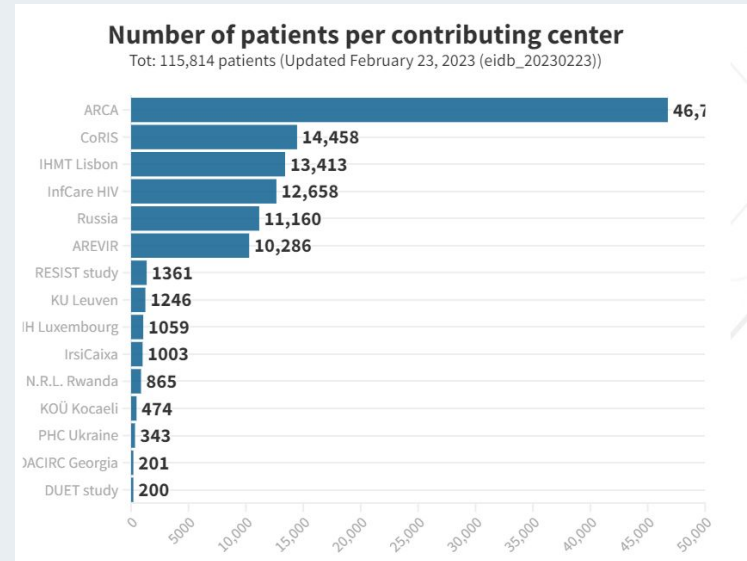
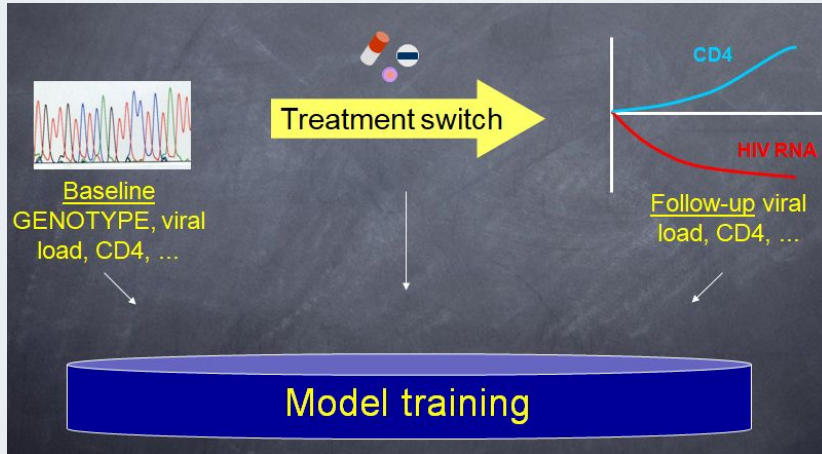
- Agile prospective studies
 - interim analysis always possible
- **Retrospective** and **retrospective/prospective** studies:
 - **the possibility to use already collected information**
- Mimic RCTs on **retrospective** datasets
- Facilitate the set-up of prospective RCTs



CAVEATS: real randomisation is missing! – Relevant information in the past may be missing

The EuResist cohort

The EuResist Integrated Database (EIDB) collects longitudinal information of PLWH since 1998.



Cohorts for retrospective studies

EuResist cohort

Using real world data to assess the impact of drug resistance on clinical outcome and to

predict response to treatment, also by AI models

It has been the basis for 118 scientific papers since 2008



KI cohort in EuCARE

Linked hospital registries.

Data from more than 24000 patients, largely collected before project start

Invaluable information for the project studies

Data reuse – the power of cohorts

- **The lawfulness of data use and reuse in many countries is based on the Informed consent, in others on the public interest or scientific research (R. 50, 52, 53, Art. 6.1.e, Art.9.1.j)**
- The informed consent should be specific: how much specific?
- The objectives of the research should be compatible: how much compatible?

The School Study posed unique challenges

EuCARE- SCHOOLS:

Objective: **To support the school mission in pandemics time, based on real world data**

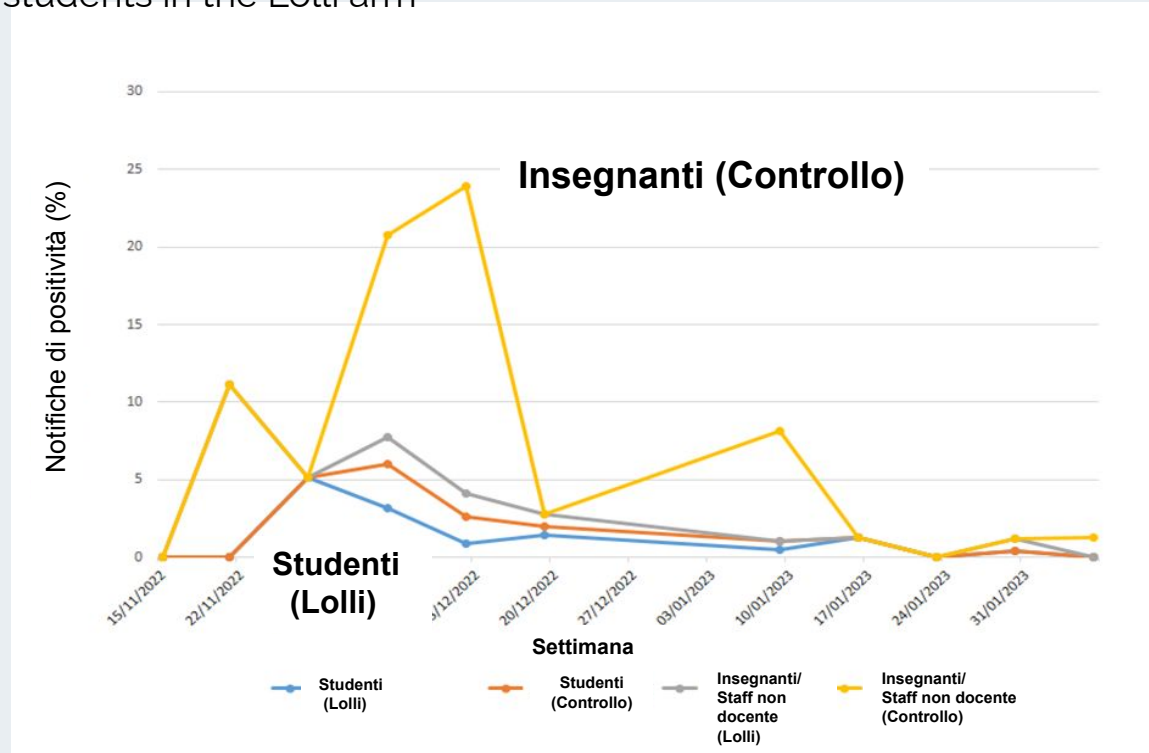
1 interventional randomised trial and 1 observational study:

- To compare regular screening with pooled saliva tests (Lolli-Methode) with SoC
- To determine the prevalence of SARS-COV-2 in schools with new variants, frequencies and size of clusters and attack rates in schools, comparing among different waves.
- To compare the effectiveness of different preventive measures and quarantine protocols
- **To investigate potential psychological problems in students and teachers related to different containment measures, including school closure.**
- **To evaluate learning loss associated with psychological status, socio-economic and environmental variables**



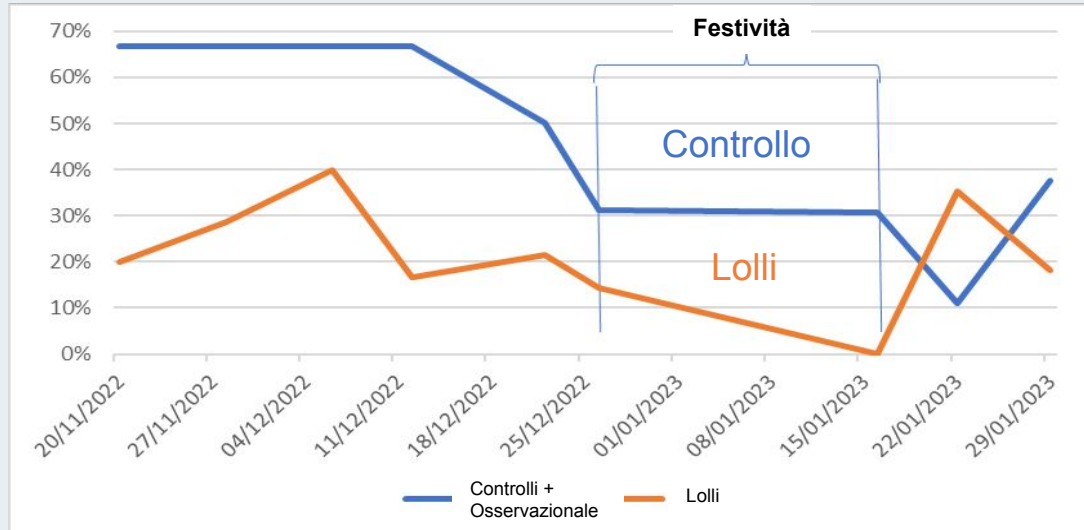
Positive cases per kind of participants

The highest positivity rates are among teachers in the control arm (without Lolli) while the lowest are among the students in the Lolli arm



Syntoms and prevention measures

Syntoms rates are significantly lower in the Lolli arm:
47% among controls vs 23% in the Lolli arm ($p=0.009$).



No differences among the two arms in terms of use of prevention measures, except for the use of ventilation and windows opening, lower in the Lolli arm ($p=0.01$ and $p=0.02$).



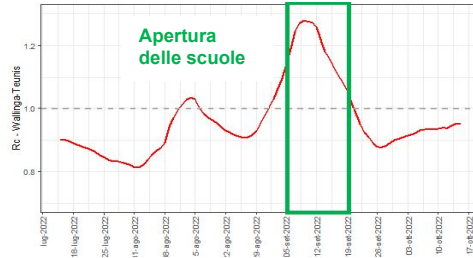
R, by age in relation to schools opening 2022

Young people (5-19)

Adults (20-79)

ITALIA

5 settembre - 19 settembre 2022

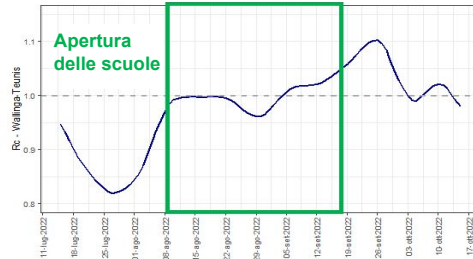


5 settembre - 19 settembre 2022

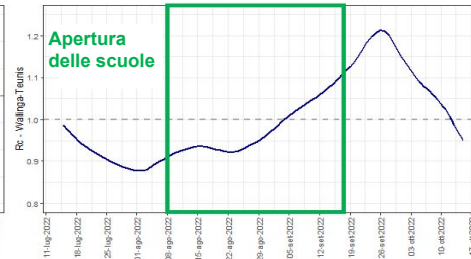


GERMANIA

8 agosto - 16 settembre 2022



8 agosto - 16 settembre 2022

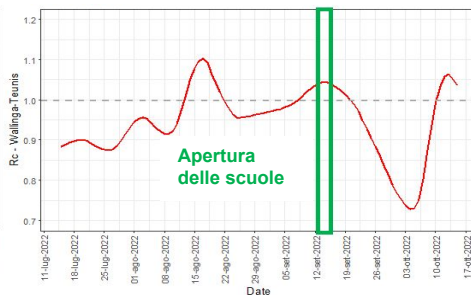


PORTOGALLO

13-16 settembre 2022



13-16 settembre 2022







The periods of schools opening are indicated with the green rectangle

F. Bellerba, 2023







Primary schools (n=36)

Variables	No Symptoms	Symptoms
	n (%)	n (%)
Psychological difficulties	32 (88.89%)	4 (11.11)
Emotional problems	34 (94.44)	2 (5.56)
Behavioural problems	29 (80.56)	7 (19.44)
Hyperactivity/attention deficit	34 (94.44)	2 (5.56)
Relational problems with peers	33 (91.67)	3 (8.33)
Prosocial behaviour	31 (86.11)	5 (13.89)

Variables				
Anxiety	-	-	-	-
Sadness	41.67%	58.34%	50%	-
Anger	52.78	47.23%	47.23%	-
Safety/Protection	58.33	-	69.44%	69.44%

Secondary schools (n=38)

Variables	No Symptoms	Symptoms
	n (%)	n (%)
Psychological difficulties	28 (73.68)	10 (26.32)
Emotional problems	24 (63.16)	14 (36.84)
Behavioural problems	29 (76.32)	9 (23.68)
Hyperactivity/attention deficit	32 (84.21)	6 (15.79)
Relational problems with peers	32 (84.21)	6 (15.79)
Prosocial behaviour	30 (78.95)	8 (21.05)

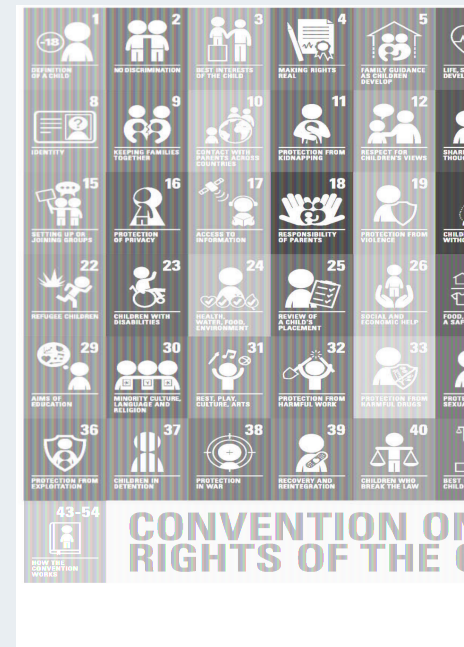
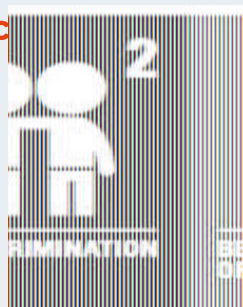
Variabili				
Anxiety	-	-	-	10.53%
Sadness	-	63.16%	71.05%	2.63%
Anger	-	42.11%	42.11%	7.89%
Safety/Protection	68.43%	60.52%	57.9%	86.84%

Madigan S, Racine N, Vaillancourt T, et al. Changes in Depression and Anxiety Among Children and Adolescents From Before to During the COVID-19 Pandemic: A Systematic Review and Meta-analysis. *JAMA Pediatr.* 2023;177(6):567–581.
doi:10.1001/jamapediatrics.2023.0846



Schools' closure was unethical

- Children are less infected and have a much less severe response
- Schools closure caused severe drawbacks to children
- Has been used to protect older adults without stopping the economy
- **Violates the third principle of the Convention on the Rights of the Children.**



There are no institutions to enforce the Convention (at least in Italy) and thus protecting the rights of the children

Thanks to S. Gandini, M. Bellerba, E. Tomezzoli and the
whole EuCARE and EuResist teams
and

Thank you for your attention!

Francesca Incardona

www.eucareresearch.eu

