



# VACCELERATE - EUROPEAN CORONA VACCINE TRIAL ACCELERATOR PLATFORM

28 January 2021 - 27 January 2024

Coordinated by: KLINIKUM DER UNIVERSITAET ZU KOELN

<https://vaccelerate.eu/about-us/>



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# VACCELERATE Background and Objectives



Set up in **January 2021** with the **main goal** of being a *single-entry point for any vaccine stakeholder*: developers, sites and volunteers. It is 3-year project that will run until January 2024.



**29 partners** in 18 EU-member states and 5 countries - co-financed by EU Horizon 2020 research programme

VACCELERATE has as its core objective to be a platform that can help *accelerate corona vaccine trials in Europe* and the following are the specific objectives of the platform:

## OBJECTIVES:

### 1. PLATFORM BUILDING

Central platform serving as single entry-point for European stakeholders in vaccine development

### 2. CAPACITY MAPPING

VACCELERATE Site Network - a continuously updated database of ready-to-engage vaccine trial sites in Europe.

### 3. CAPACITY BUILDING

providing educational measures to train and prepare clinical trial sites and laboratories.

### 4. VOLUNTEER REGISTRY

Registry for individuals volunteering to participate in phase 2 & 3 COVID-19 vaccine clinical trials

### 5. LABORATORY ACCESS

Access to laboratory sites in Europe; developing shared data infrastructure.

### 6. SOLUTIONS FOR VACCINE DEVELOPMENT

Providing solutions for characteristic vaccine development issues during pandemics (gaps in knowledge, harmonised data, protocols and assays)

### 7. PHASE 2 AND 3 CLINICAL TRIALS

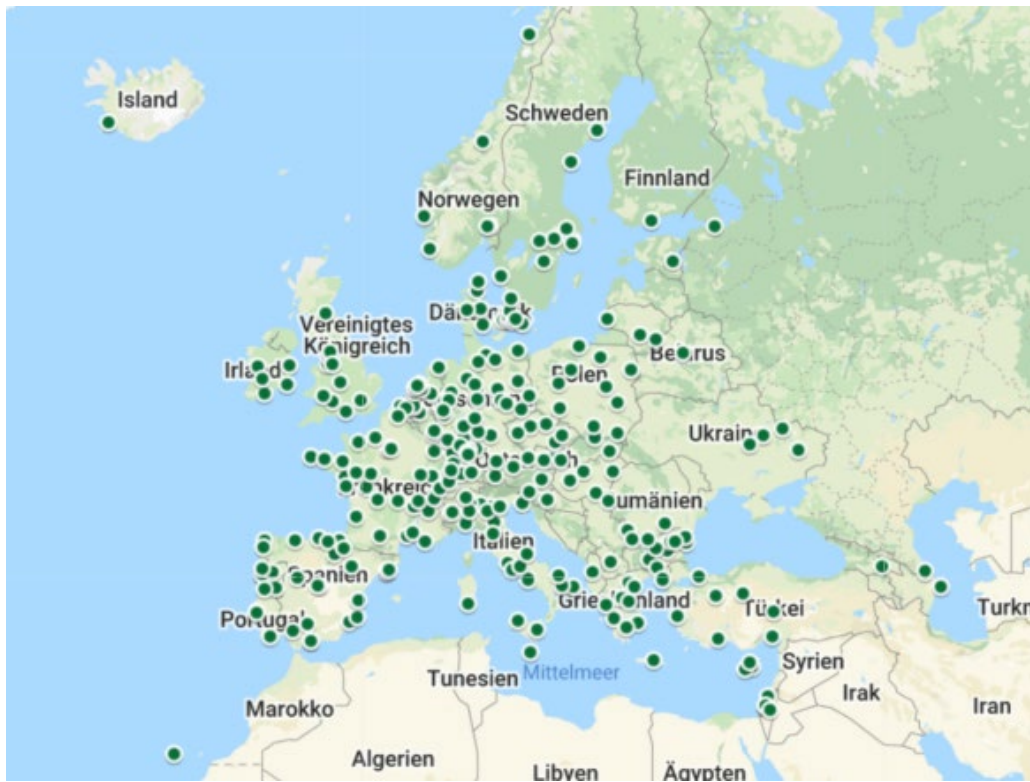
- **EU-COVAT-1 AGED:** A Multinational, Phase 2, Randomised, Adaptive Protocol to Evaluate Immunogenicity and Reactogenicity of Different COVID-19 Vaccines Administration in Older Adults ( $\geq 75$ ) Already Vaccinated Against SARS-CoV-2
- **EU-COVAT-2 BOOSTAVAC:** An International Multicentre, Phase 2, Randomised, Adaptive Protocol to Determine the Need for, Optimal Timing of and Immunogenicity of Administering a 4th Homologous mRNA Vaccination Dose against SARS-CoV-2 in the General Population (18+ years) Already Vaccinated with the BNT162b2 Vaccine
- **EU-COVPT-1 COVACC:** A Phase 2, Comparative Randomised Trial to Evaluate the Impact of Reduced COVID-19 mRNA Vaccination Regimen on Immunological Responses and Reactogenicity in Paediatric Subjects with Prior SARS-CoV-2 Immunity



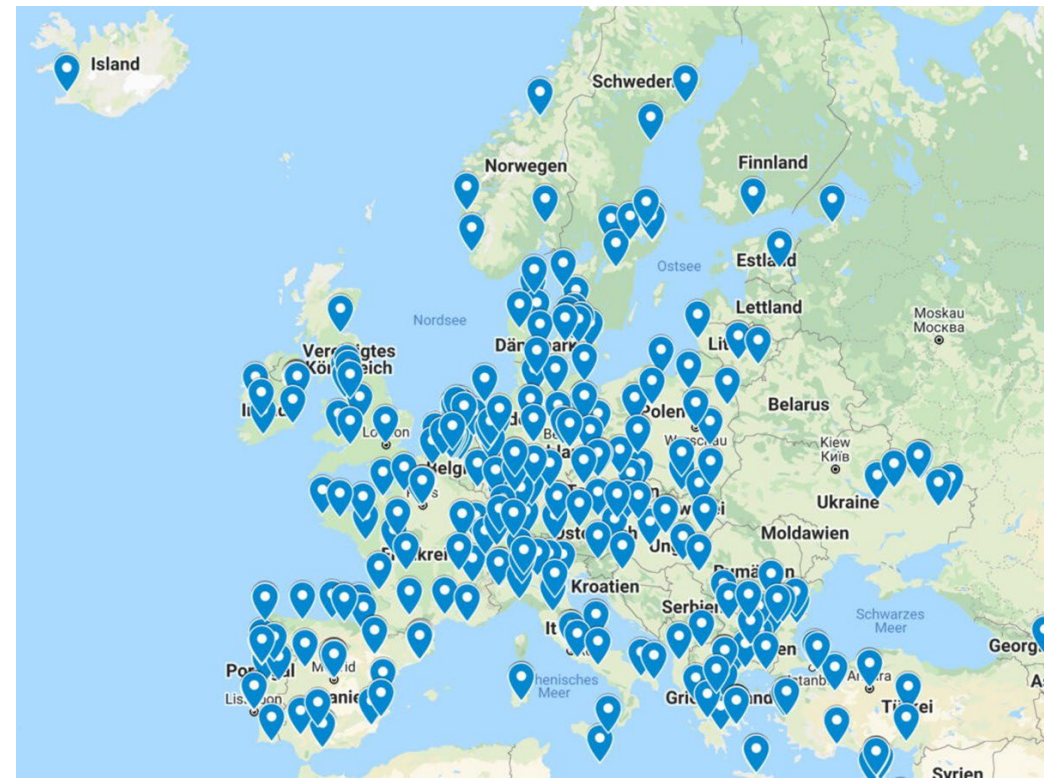
# VACCELERATE Site Network <https://vaccelerate.eu/site-network/>

The VACCELERATE Site Network is a platform for clinical trial sites interested in conducting vaccine studies. Clinical trial sites register with the network database by answering a short site questionnaire. Any clinical trial site can register. The VACCELERATE Site Network is managed at the Clinical Trial Infrastructure of the German Center for Infection Research (DZIF) at the University of Cologne.

484 Clinical Trial Sites in 39 Countries and growing.



Site Network laboratories



# Task 7.2 Identification of unanswered public health priority questions for future COVID-19 vaccine trials

Implemented 3 surveys

- May 2021
- November 2021
- March 2022

[3 more to go!]

Interactive summary

<https://bit.ly/3DrwQEI>



## Summary of report on unanswered COVID-19 vaccines and vaccination priority questions for future trials



Implemented by CHIP/RegionH  
Contact email:  
[vaccelerate.rigshospitalet@regionh.dk](mailto:vaccelerate.rigshospitalet@regionh.dk)

### Responses by professional background



# Interlinks with Task 7.1 *Living mapping, living evidence synthesis, and living monitoring of COVID-19 vaccine trials*

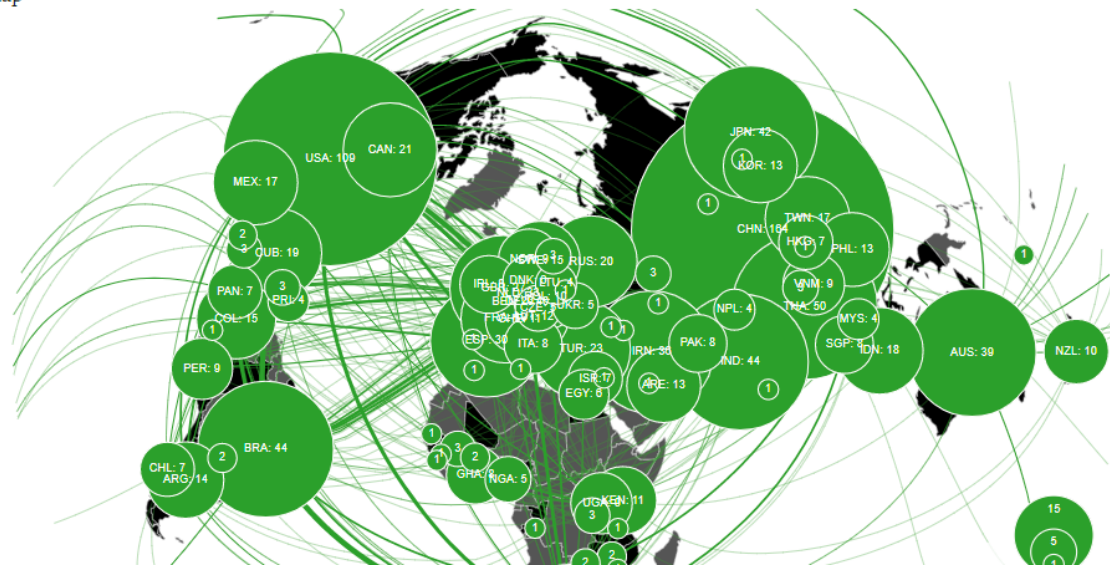
## COVID-19 living NMA initiative <https://covid-nma.com/vaccines/mapping/>

As of September 08, 2022 the Covid-19 - living NMA initiative collected 655 RCTs and 302 non-randomised studies of vaccines from the ICTRP. 365 of these trials are recruiting patients.

### ▼ User Guide 🖱️

- To see how to explore the mapping, check our [tutorial](#).
- Make your browser window as **wide** as possible for a 2-column display.
- Click on the **map** or any of the **graphs** to create filters on the data.
- All the **filters** are applied jointly, refining your selection.
- Click **Reset all** to remove the filters.
- Click on the **arrows** to open or close any section.
- For any questions or remarks, *please contact us*.

### ▼ Map



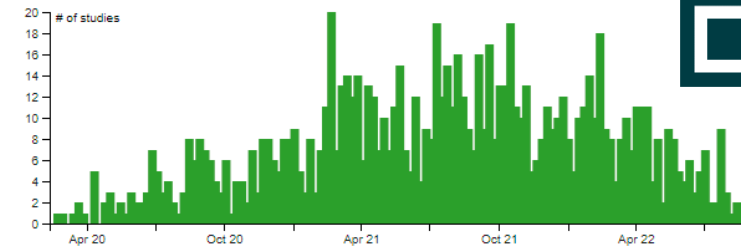
### Filters

All trials selected (957) | Reset all

Search...

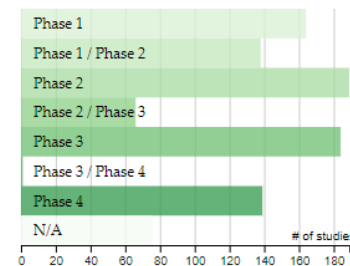
Ex: RNA. Adenovirus, Oxford...

### ▼ Registration date by week

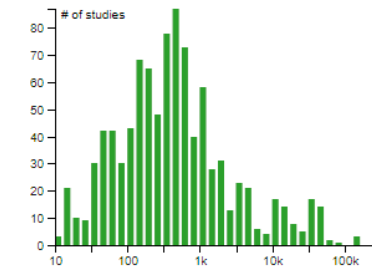


To filter by Registration dates, click and drag to create a range.

### ▼ Phase



### ▼ Sample size



### ▼ Recruitment status

- Not recruiting (398 studies) ⓘ
- Recruiting (365 studies) ⓘ

### ▼ Publication status

- Not published (792 studies)
- Published (165 studies) ⓘ



# List of identified public health priority questions for future COVID-19 vaccine trials and COVID-NMA mapping search results



VOTES	PUBLIC HEALTH PRIORITY QUESTIONS FOR FUTURE COVID-19 VACCINE TRIALS	IDENTIFIED CLINICAL TRIALS
26	*How can immunisation schedule (booster timing and number) and technologies (vaccine dose and type) be optimised to ensure maximum protection (incl. immunocompromised groups)?	<b>Filter:</b> 'Booster' – 185 trials identified (incl. immunosuppressed patients – 11) 'Vaccine schedule' – 131 trials identified (incl. immunosuppressed patients – 4)
19	*How long does immunity (humoral-cellular) last after vaccination with current vaccines?	Search option: <b>Free text search:</b> "Cellular immunity" – 8 and "Humoral immunity" – 7
18	Are currently available vaccines effective against SARS-CoV-2 variants in the short- and long-term and is there a need to develop new vaccine to protect against the VOCs?	<b>Filter:</b> 'VOC' (alpha, beta, gamma, delta) – 26 'VOC' (omicron) – 14
17	Can novel vaccines achieve non-inferiority efficacy and safety by non-parenteral route (e.g., nasal vaccines) and possibly with only one dose?	Search option: <b>Free text search</b> 'intranasal' or synonyms. <b>2 trials found.</b> This search will miss a lot of relevant trial as the route information is collected manually in our database and not presented
17	Developing vaccines which are protective against a broad range of coronaviruses (e.g., pansarbecovirus vaccine)	Filter not available (search not successful)
16	What are the long-term adverse side effects of vaccination in terms of vaccine-related or vaccine-induced diseases (autoimmune, oncologic, fertility etc.)?	Filter not available (search not successful)
8	What is the best measure of protective immunity after vaccination at the individual level and when after vaccination should it be taken?	Search option: <b>Free text search</b> for 'protective' and synonyms. <b>8 trials to screen.</b>
7	What are the long-term safety considerations of vaccination in children?	Search option: Free text search for 'long-term safety' and synonyms combined with 'Under 18 y. o. filter'. No results found.
5	What is the vaccine efficacy and are there other immunological correlates of protection than antibodies in various immunocompromised groups?	Search option: Free text search for 'immunological correlates' and synonyms combined with immunosuppression status filter.
5	Are current vaccines and vaccine strategies effective in preventing SARS-CoV-2 transmission?	Search option: Free text search for 'transmission' and synonyms. No results found, but a surveillance on this type of search could be relevant.
4	How can immunisation schedule (booster timing and number) be optimised for the paediatric population to ensure maximum protection?	<b>Filter:</b> 'Booster' & 'Under 18 y. o. filter' – 19 trials identified (incl. immunosuppressed patients – 3) 'Vaccine schedule' & 'Under 18 y. o. filter' – 13 trials identified (incl. immunosuppressed patients – 0)
4	What are the individual or sub-population genetic or metabolic differences in response to vaccines (Precision medicine approach to COVID-19 vaccination)	Filter not available (search not successful)
3	What is the efficacy and the specific immune response to the vaccine in children, (incl. immunocompromised pediatric population)?	<b>Filter:</b> 'Under 18 y. o. filter' – 107 trials identified (incl. immunosuppressed patients – 7)
1	Vaccination strategy be in pregnant women?	<b>Filter:</b> 'Pregnant women' – 8 trials identified
1	Integration of new type of COVID-19 vaccines (e.g. Nuvaxovid) in EU vaccination programs	<b>Filter:</b> 'Type of vaccine: Protein subunit' & 'Heterologous regimen' – 38 trials identified

<sup>[1]</sup> Search conducted using COVID-NMA mapping website <https://covid-nma.com/vaccines/mapping> (accessed on 14th of January 2022).

# VACCELERATE webinars & education

<https://vaccelerate.eu/webinars/>



- The VACCELERATE webinars are taking place once a month with a duration of approx. 1 hour. In the webinars different countries present their results on COVID-19 vaccine trials. The webinars are accredited by EACCME.



National Cohort Study of **E**ffectiveness **a**nd **S**afety  
of **SARS-CoV-2**/Covid-19 **v**accine**s** (ENFORCE)

Vaccelebrate Webinar  
14 June 2022

## Lessons from an international trial evaluating Vaccination Strategies for Recovered Inpatients with COVID-19 (VATICO)

### VATICO Protocol Team

**Eleftherios Mylonakis, M.D., Ph.D., FIDSA, FAAM**  
Charles C.J. Carpenter Professor of Infectious Disease  
Professor of Molecular Microbiology and Immunology,  
Chief, Infectious Diseases Division  
Assistant Dean for Outpatient Investigations  
Director, Center for Outpatient and Longitudinal Medical Research  
Director, COBRE Center for Antimicrobial Resistance and Therapeutic Discovery



1. Fourth dose COVID-19 Vaccination – Experiences from Israel & UK

**2. ENFORCE Study and VATICO Study with Joanne Reekie and Eleftherios Mylonakis**

3. Influence of age on the effectiveness and duration of protection of Vaxzevria and CoronaVac vaccines: A population-based study with Manoel Barral-Netto
4. What's the problem with SARS-CoV-2 variants? – Experiences from Denmark with Troels Lillebaek
5. COVID-19 Vaccine Cohort in Specific Populations (ANRS0001S COV-POPART) with Linda Wittkop
6. Effectiveness of vaccination against COVID-19, with Nick Andrews, Fredrik Kahn, Frederik Plesner Lyngse and Laith Jamal Abu-Raddad
7. COV-BOOST: Safety and immunogenicity of 7 COVID-19 vaccines as a 3rd dose (booster) following ChAdOx1 nCov-19 or BNT162b2 in the UK, with Prof. Saul N. Faust
8. Correlates of protection against symptomatic and asymptomatic SARS-CoV-2 infection With Prof. Merryn Voysey, University of Oxford, Oxford Vaccine Group, UK
9. Humoral Immune Response in Hemato-oncological Patients, with Prof. Matthias Preusser
10. Vaccine waning and booster protection across ages – data from Israel, with Yair Goldberg and Amit Huppert
11. HeVACC Study – Heterologous SARS-CoV-2 Vaccination with Prof. Dorothee von Laer
12. Com-COV Vaccine Trials, with Prof. Matthew Snape and Emma Pleded
13. Spanish Combivacs Study & VACCELERATE

# VACCELERATE is engaged in EU level Public Health and Vaccine Related Expert Networks



- › **National Immunisation Technical Advisory Groups (NITAG)**  
This EU/EEA collaboration is hosted and run by ECDC
- › **European Medicines Agency (EMA)**  
Meeting with Marco Cavaleri, Head of Health Threats and Vaccines Strategy
- › **Population Health Information Research Infrastructure (PHIRI)**  
PHIRI is a EU-co-financed project that has a Rapid Exchange Forum - infrastructure to support rapid exchange between actors from competent authorities, their advisors, researchers and stakeholders in the joint efforts to handle the COVID-19 pandemic.  
<https://www.phiri.eu>
- › **Trial Coordination Board (TCB) (new vaccine pillar)**  
gathers the main actors, playing a role in the successful implementation and development of the European COVID-19 adaptive platform trials (APT).  
<https://covid19trials.eu/en/tcb>



# The VACCELERATE: Long-term plans

- › Development of long-term infrastructure
- › Production of outputs that generate sustained public health value
- › Successful dissemination and communication
- › Maintaining engagement
- › Broadening of scope

## Project Progress Timeline

28 January 2021

27 January 2024

