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www.vaccelerate.eu

VACCELERATE

European Corona Vaccine Trial Accelerator Platform

9 June 2022

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101037867

Conflicts of interest

› Dr. Jon Salmanton-García

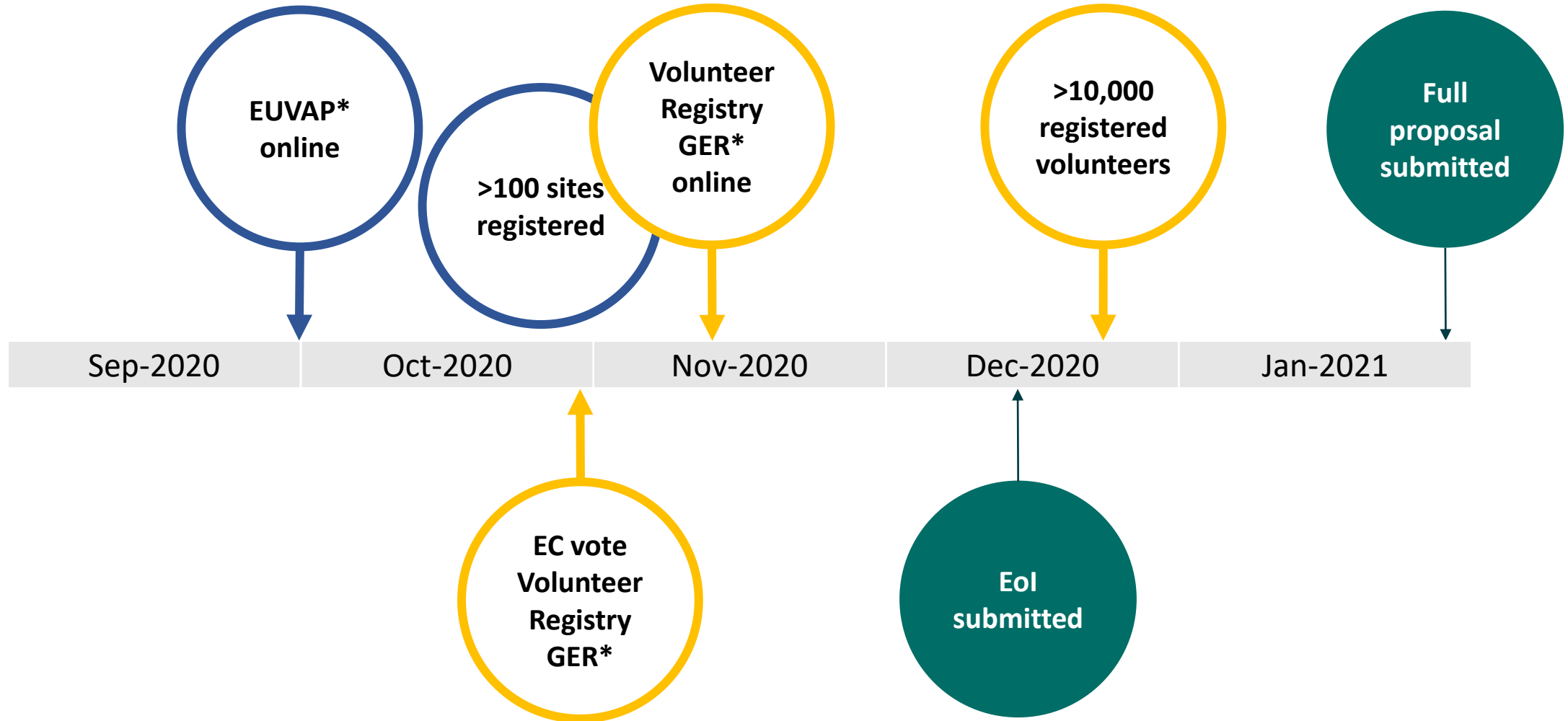
Speaker honoraria: Gilead Sciences and Pfizer

Pan-European Backbone Accelerating Phase 2 & 3 Vaccine Trials



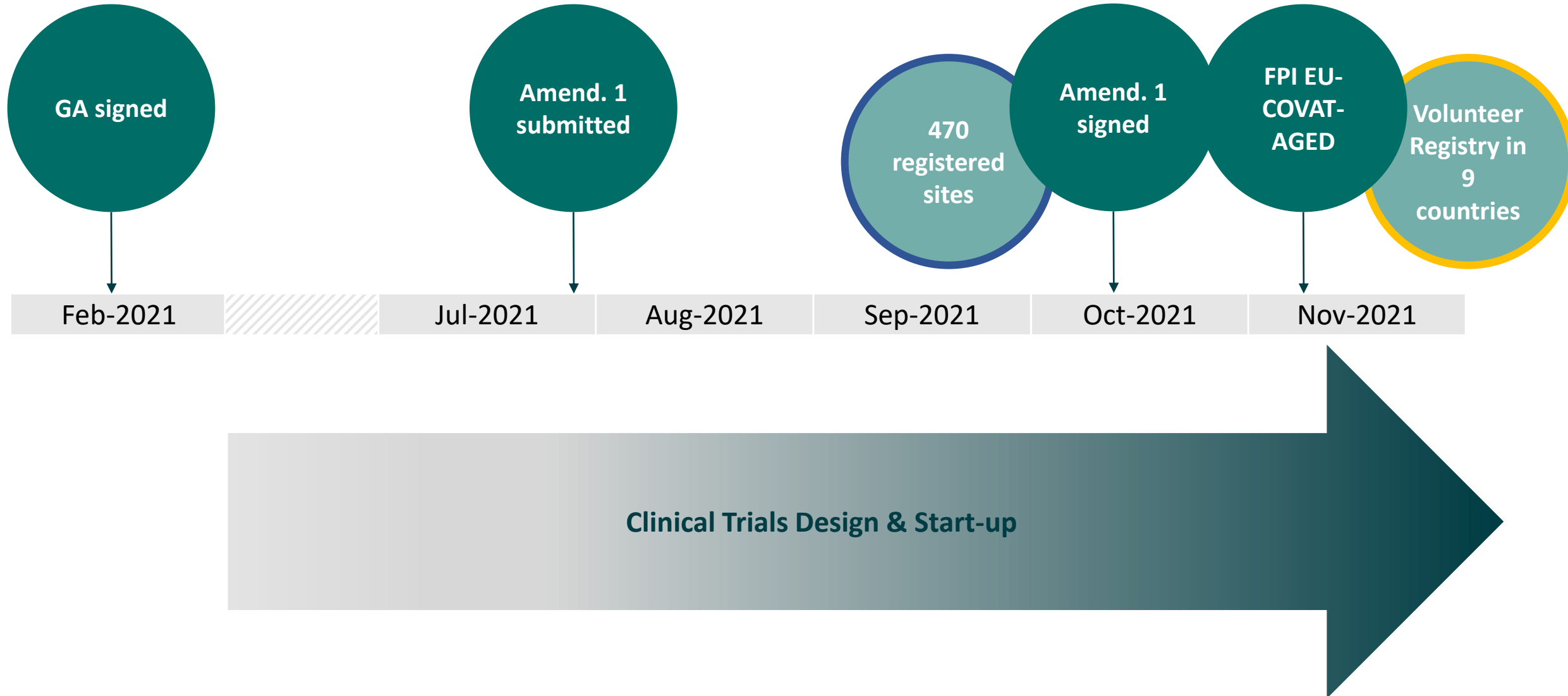
- › Largest clinical research network for COVID-19 vaccine trials
- › 29 partners, 18 EU Member States, 5 EU-associated countries
- › Initial funding: 12 M€
 - Top-up funding for three clinical trials: 14.5 M€
- › Part of EC pandemic preparedness

VACCELERATE Timeline



* Kick-started through DZIF and BMBF01KX2040

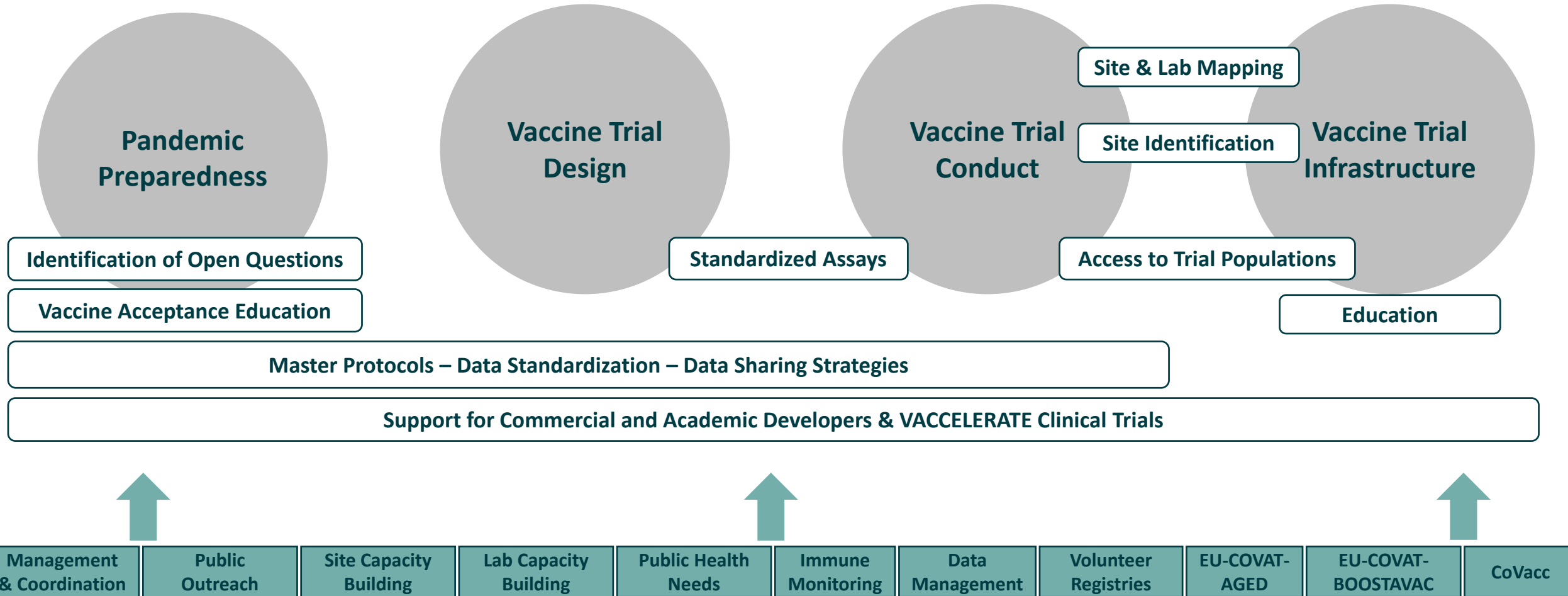
VACCELERATE Timeline



VACCELERATE Objectives

- › Platform building
- › Capacity mapping
- › Capacity building
- › Volunteer registries
- › Laboratory access & assay standardization
- › Solutions for vaccine development issues
- › Development & conduct of academically driven phase 2 & 3 vaccine trials

Measures to Achieve Objectives



VACCELERATE Work Packages

The VACCELERATE Coordination Board



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WP4
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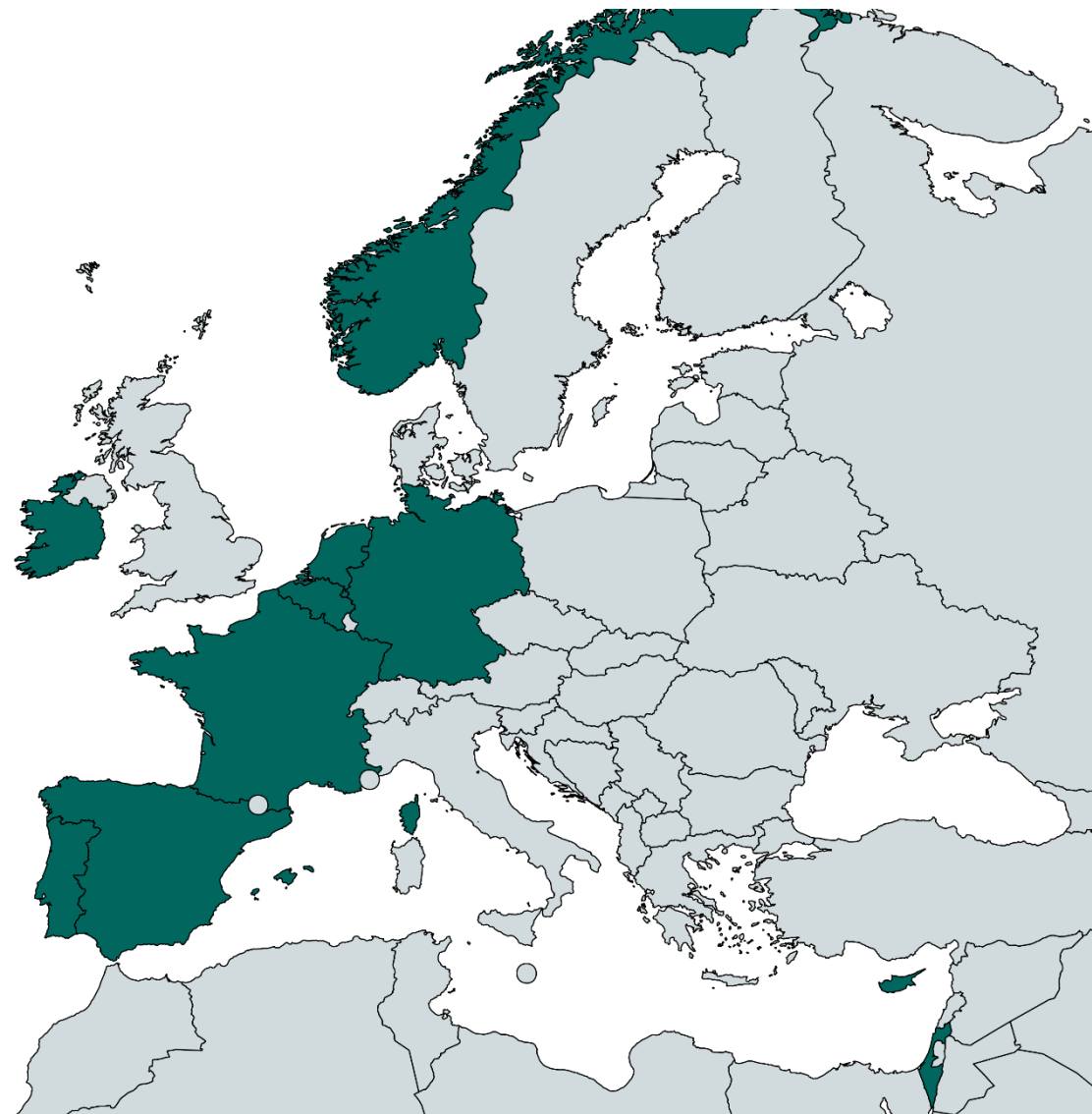
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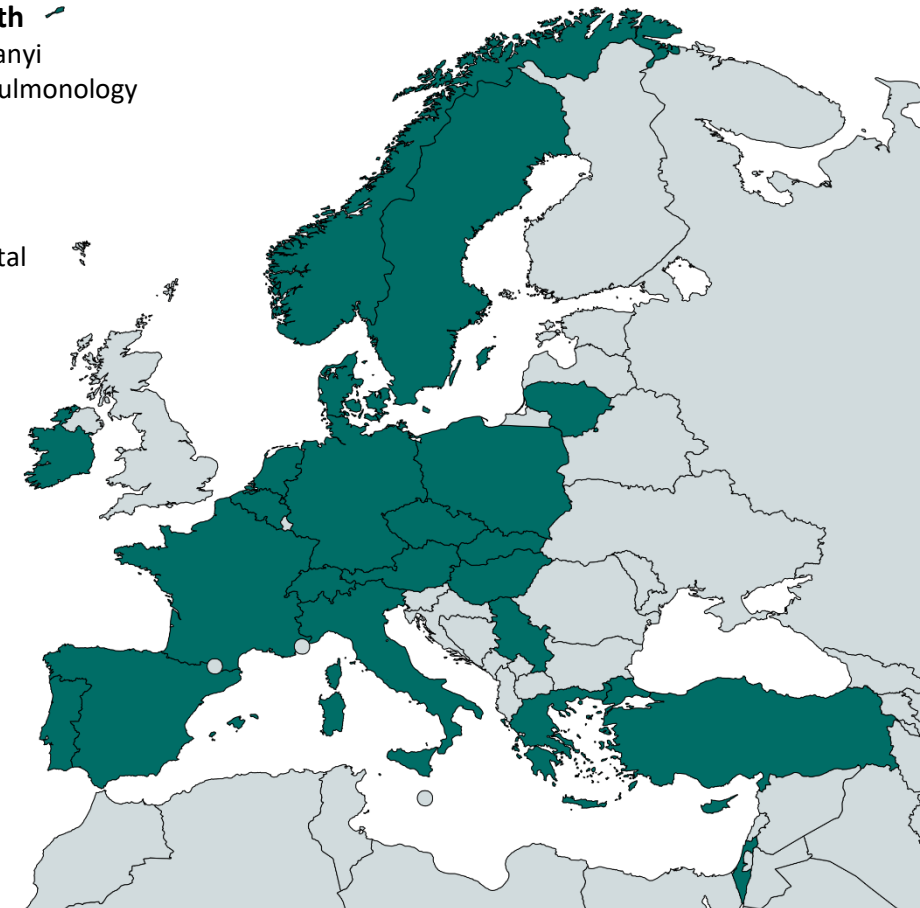
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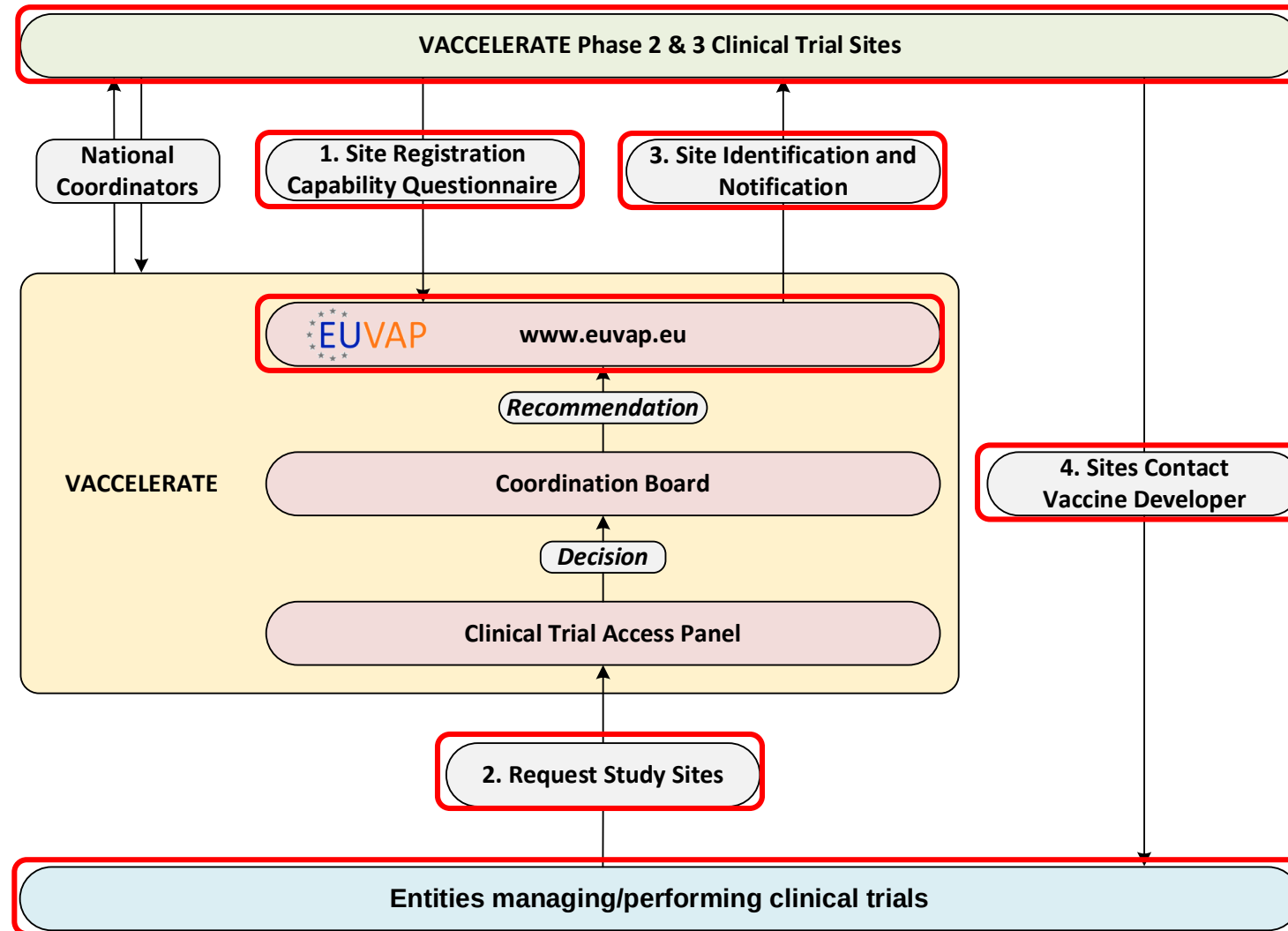
Capacity Mapping

www.euvap.eu

EUVAP – Added Value

- › Transnational capability questionnaire for clinical trial sites in Europe
- › Data collected
 - Contact details
 - Prior clinical trial experience
 - Infrastructure
 - Preferred parameters
- › Next steps: Promotion/dissemination Eastern Europe

Participation process



SME, small and medium-sized enterprise

Capacity Mapping

Brno (1)
Hradec Králové (1)
Olomouc
Plzeň (2)
Prague (3)

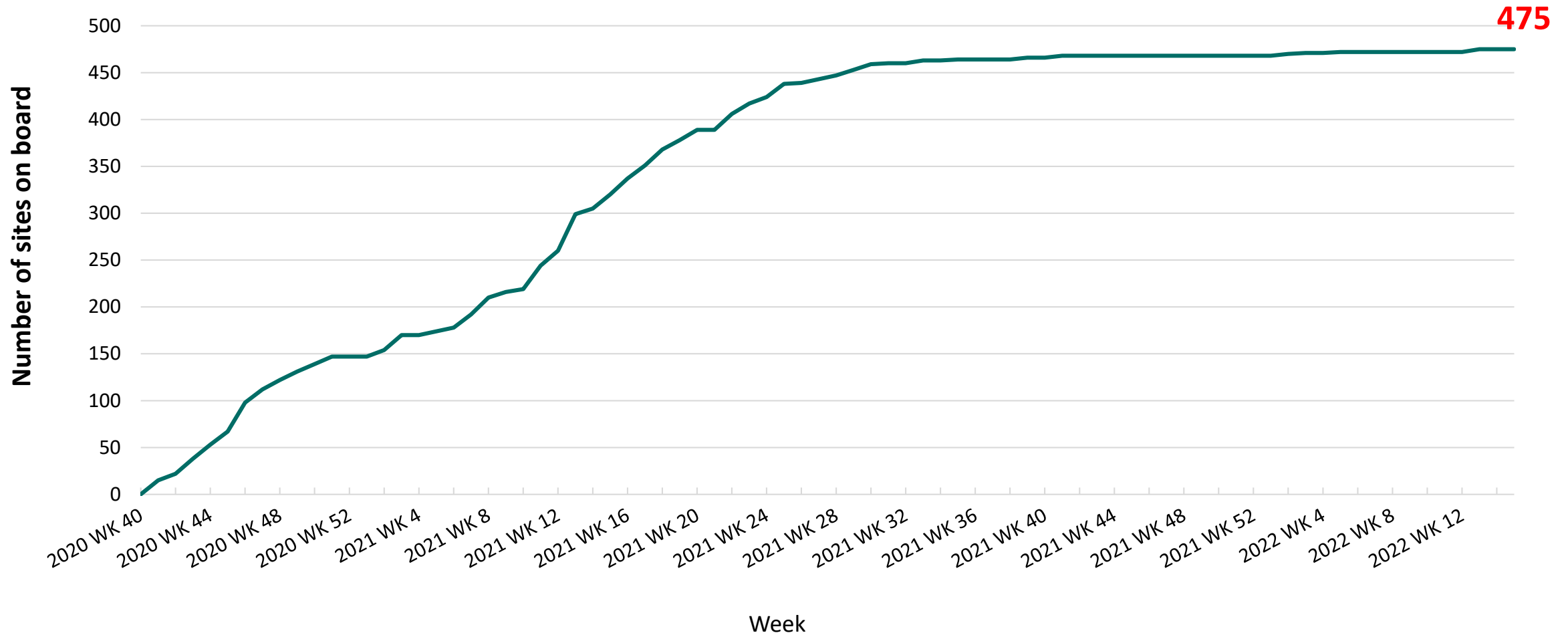
- › www.euvap.eu
- › 39 countries
- › 475 sites registered
 - 384 interested in adult trials
 - 230 interested in pediatric trials

GEFÖRDERT VOM



Bundesministerium
für Bildung
und Forschung

Increasing Number of VACCELERATE Sites



Progress

Objective: Trained & qualified site network across Europe

- › Development of VACCELERATE training curriculum
 - GCP-training
 - Vaccine trial course
 - Multinational trial course
 - Study Nurse course
- › Digitizing training content
- › VACCELERATE Online Academy
 - Website with online training courses available for EUVAP members
 - Training requirements specified per site and study team role
 - Site qualification

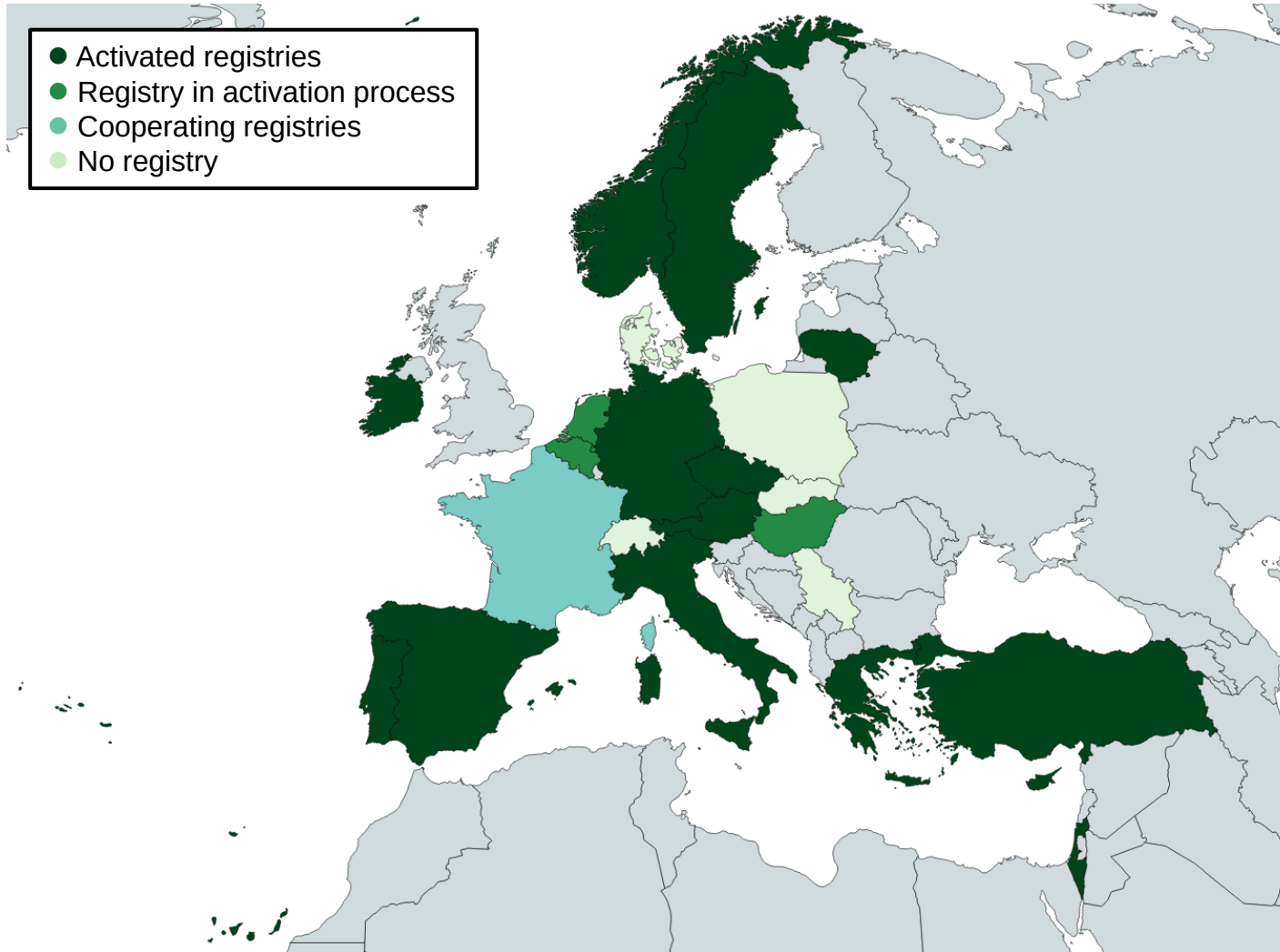
Volunteer Registries

www.vaccelerate.eu/volunteer-registry

Volunteer Registry – Added Value

- › The only transnational Volunteer Registry in Europe
- › Data collected
 - Demographics (adult/pediatrics)
 - Underlying condition(s)
 - Prior SARS-CoV-2 infection
 - COVID-19 vaccination status
- › Next steps: Promotion/dissemination including patient advocacy groups and underrepresented groups
- › Expected increase in registrations over the next 3 months

Volunteer Registry Progress



Total number of volunteers: 36,723

Activated registries

- Austria
- Cyprus
- Czech Republic
- Germany
- Greece
- Ireland
- Israel
- Italy
- Lithuania
- Portugal
- Norway
- Spain
- Sweden
- Turkey

Registries in activation process

- Belgium
- Hungary
- Netherlands

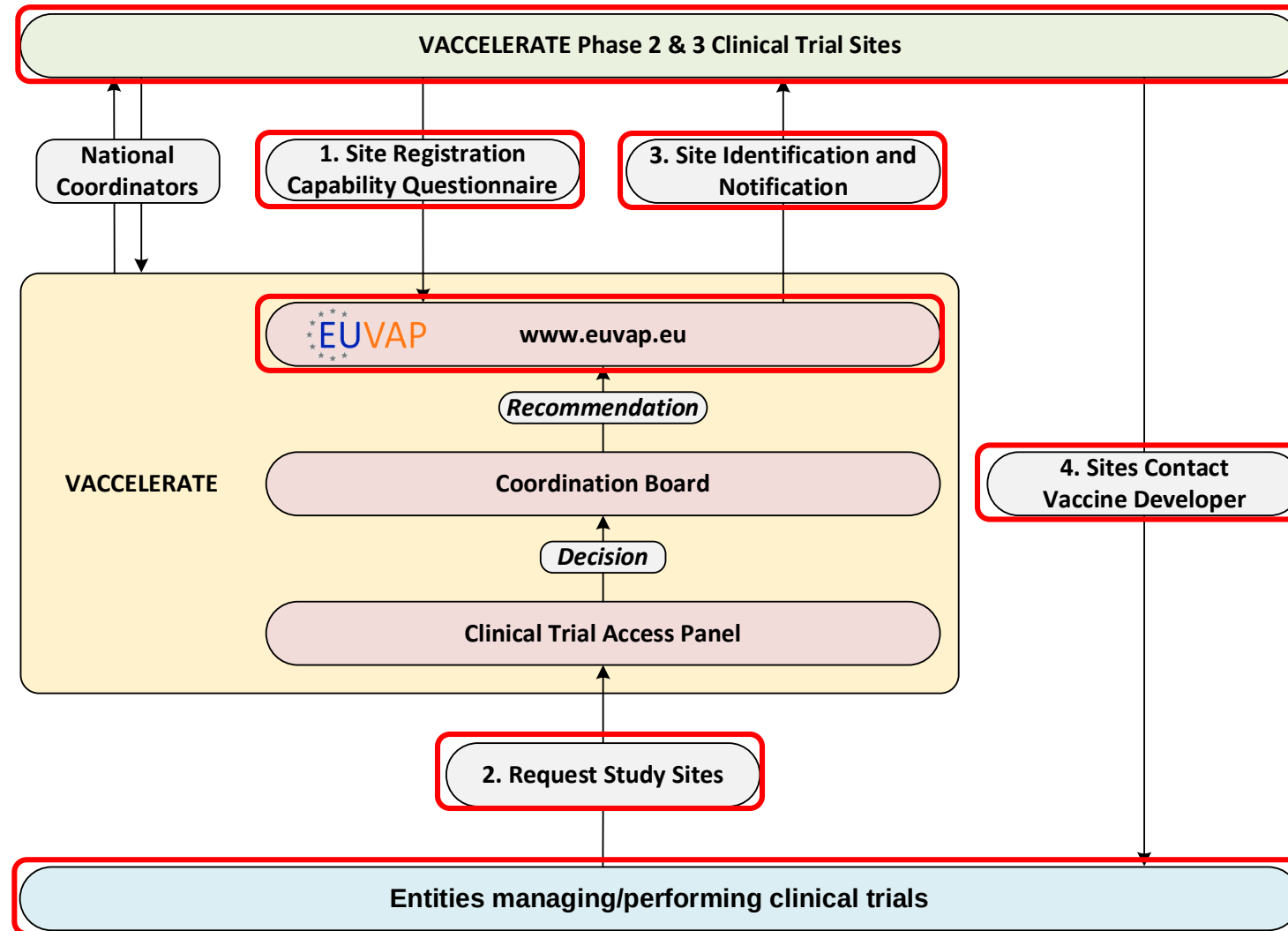
Cooperating registries

- France

No registry

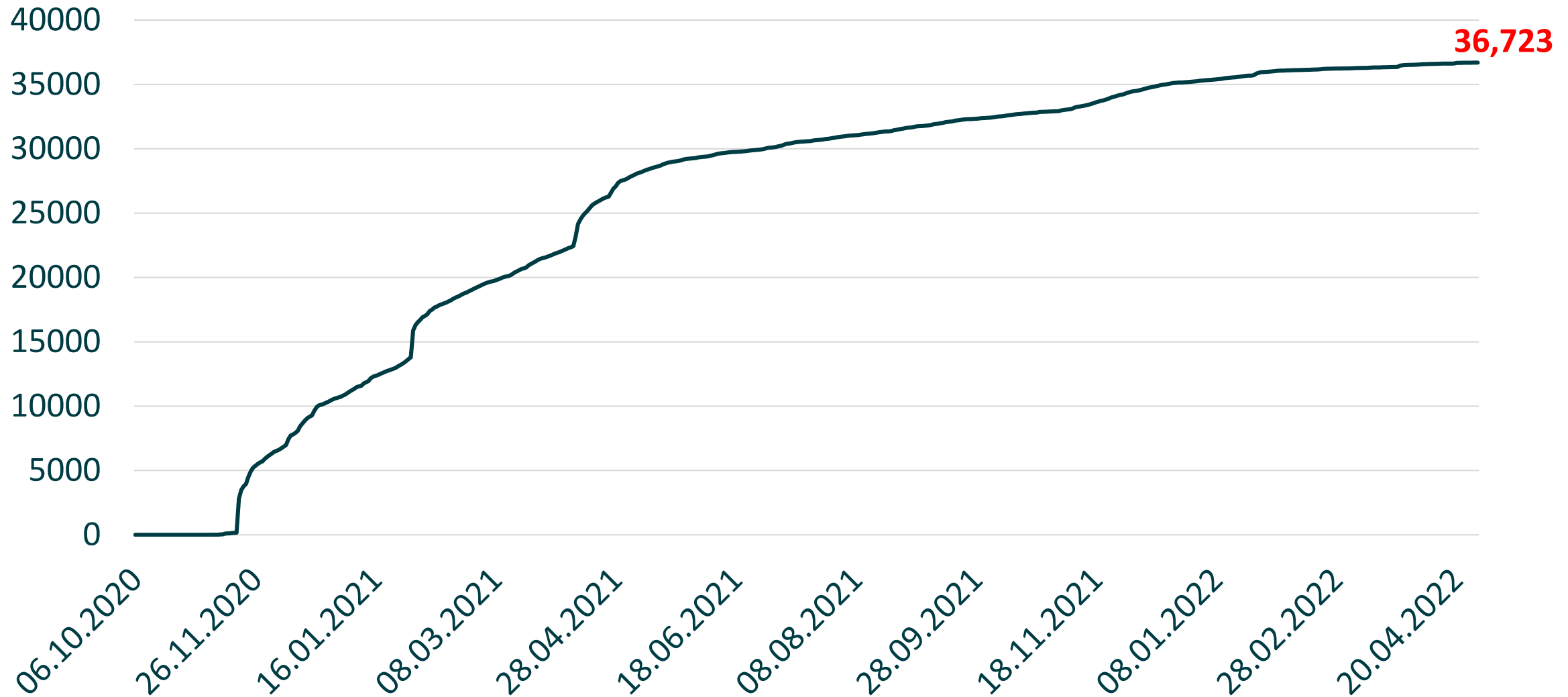
- Denmark
- Poland
- Serbia
- Slovakia
- Switzerland

Participation process



SME, small and medium-sized enterprise

VACCELERATE European Volunteer Registry Progress



The VACCELERATE Volunteer Registry: Next steps

› Registries capacity building

- Activation of the VACCELERATE Volunteer Registry in pending countries
- Inclusiveness in volunteer registration
- Transformation of the registry into a longitudinal cohort

› Increase awareness, clinical trial literacy and community engagement

- Promotion of campaign and dissemination of the VACCELERATE Toolkit
- Assessment of the promotional and educational strategies (with other WPs)
- Focus on underserved and hard to reach populations

› Gap analysis and recommendations

- Patient advocacy groups

VACCLERATE Clinical Trials

VACCELERATE Phase 2 Vaccine Trials

VACCELERATE Phase 2 Master Protocol for Adult Trials

A Multinational, Phase 2, Randomised, Adaptive Master Protocol to Evaluate the Impact of Different COVID-19 Vaccine Booster Strategies in Adults Already Vaccinated Against SARS-CoV-2 (EU-COVAT)

Sub-Protocols

EU-COVAT-1-AGED

Sponsor: University of Cologne

A Multinational, Phase 2, Randomised, Adaptive Protocol to Evaluate Immunogenicity and Reactogenicity of Different COVID-19 Vaccines Administration in Older Adults (≥ 75) Already Vaccinated Against SARS-CoV-2

Enrolling in Germany, expansion to other countries ongoing
FPI 08-Nov-2021

EU-COVAT-2-BOOSTAVAC

Sponsor: University College Dublin

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 fully vaccinated with the BNT162b2 vaccine

Enrolling in Ireland, expansion to other countries ongoing
FPI 09-Mar-2022

CoVacc

Sponsor: University Medical Center Utrecht

A Phase 2, Comparative Randomised Trial to Evaluate the impact of reduced COVID-19 mRNA vaccination regimens on immunological responses and reactogenicity in paediatric subjects with and without prior SARS-CoV-2 infection

Working on Protocol Amendment (V4.0)
FPI planned Apr-2022

In development

VACCELERATE Phase 2 Master Protocol for Pediatric Trials

VACCELERATE Coordination Office

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Mockrát děkuji

VACCELERATE Volunteer Registry

9 June 2022

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