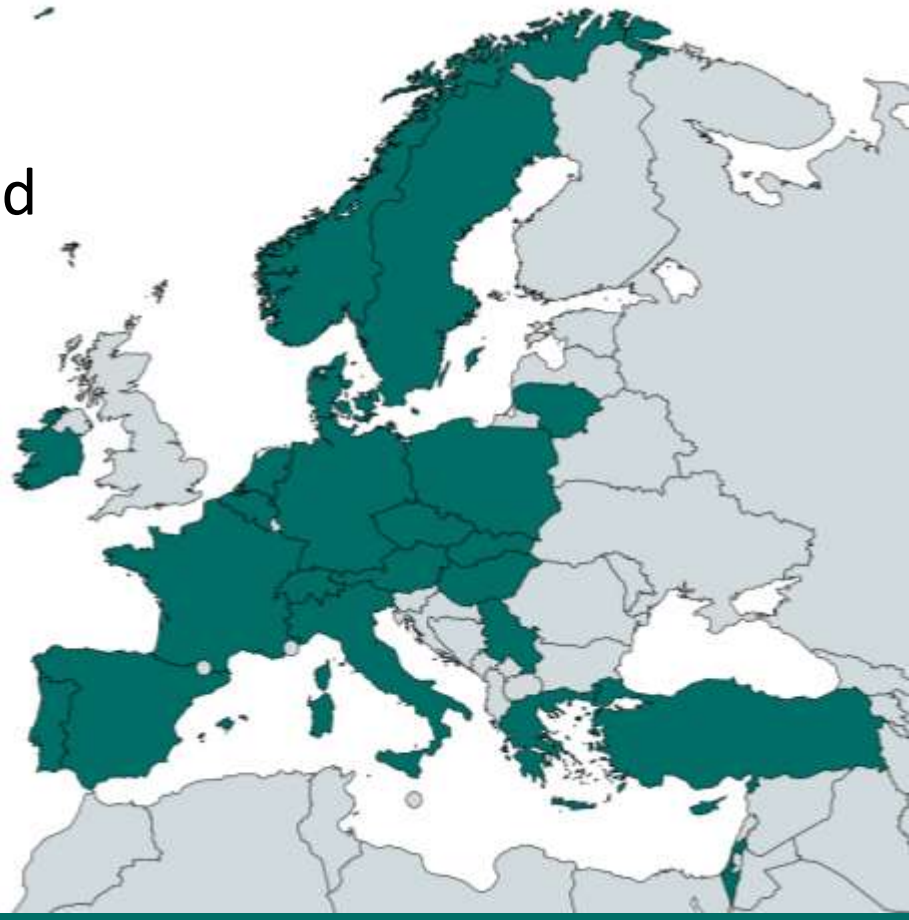
VACCELERATE

European Corona Vaccine Trial Accelerator Platform

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

Pan-European Backbone Accelerating Phase 2 & 3 Vaccine Trials

- Largest clinical research network for COVID-19 and other vaccine trials
- 31 partners, 18 EU Member States, 5 EU-associated countries
- Part of European Commission's pandemic preparedness



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

Two Years of VACCELERATE

>75.000
Volunteers invited to trials & surveys

11
trials/surveys provided with volunteers

30
Vaccine developer & CRO consultations

15
Accepted publications

24
Coordination Board meetings

16 TCB Vx
&
8 TCB Joint meetings

10
Project Management Office meetings

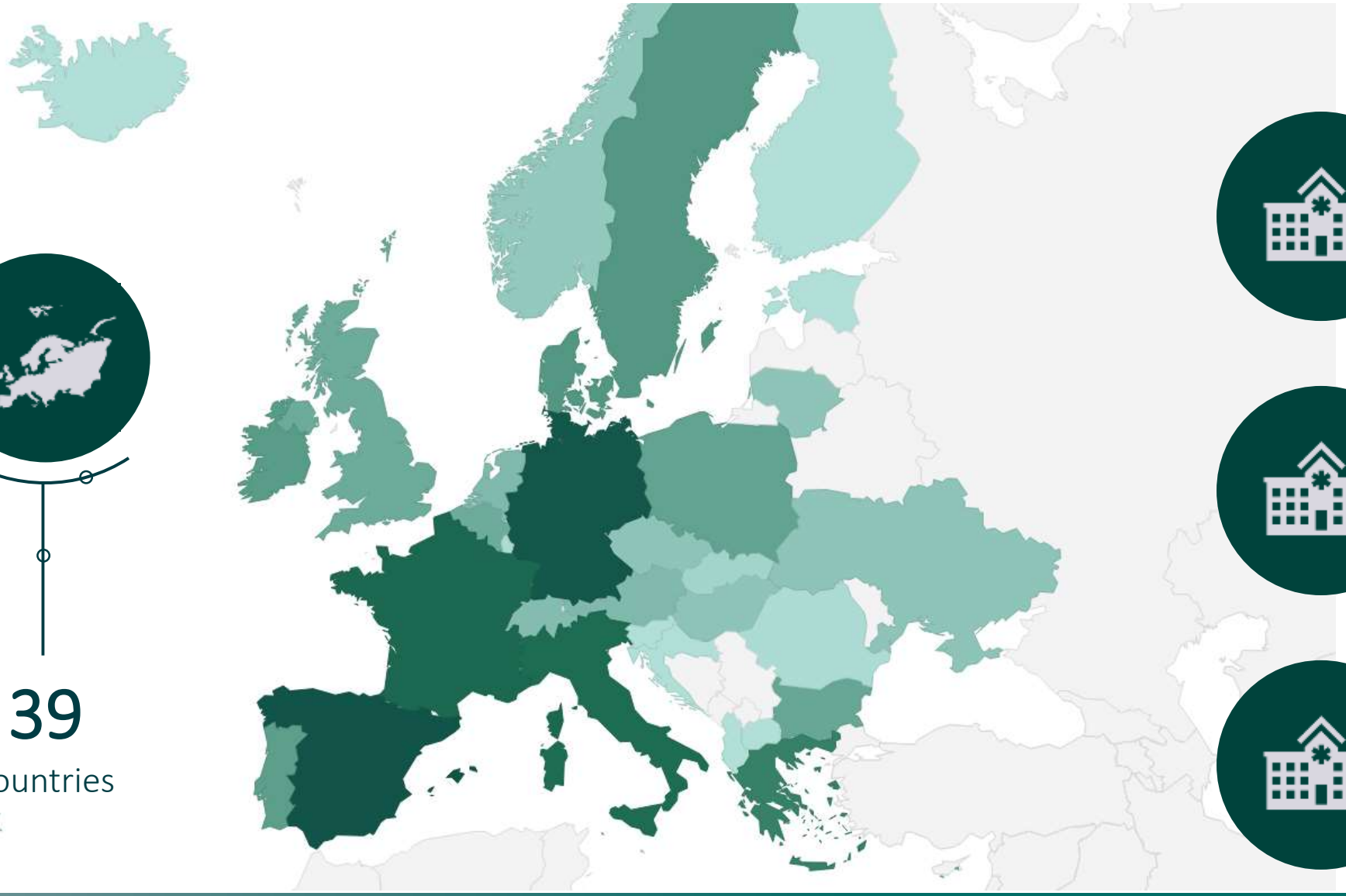
22
Feasibility requests and surveys to sites in Site Network

22
National Coordinator meetings

38
Project Updates to European Commission

5
Ethics & Scientific Advisory Board meetings

VACCELERATE Site Network



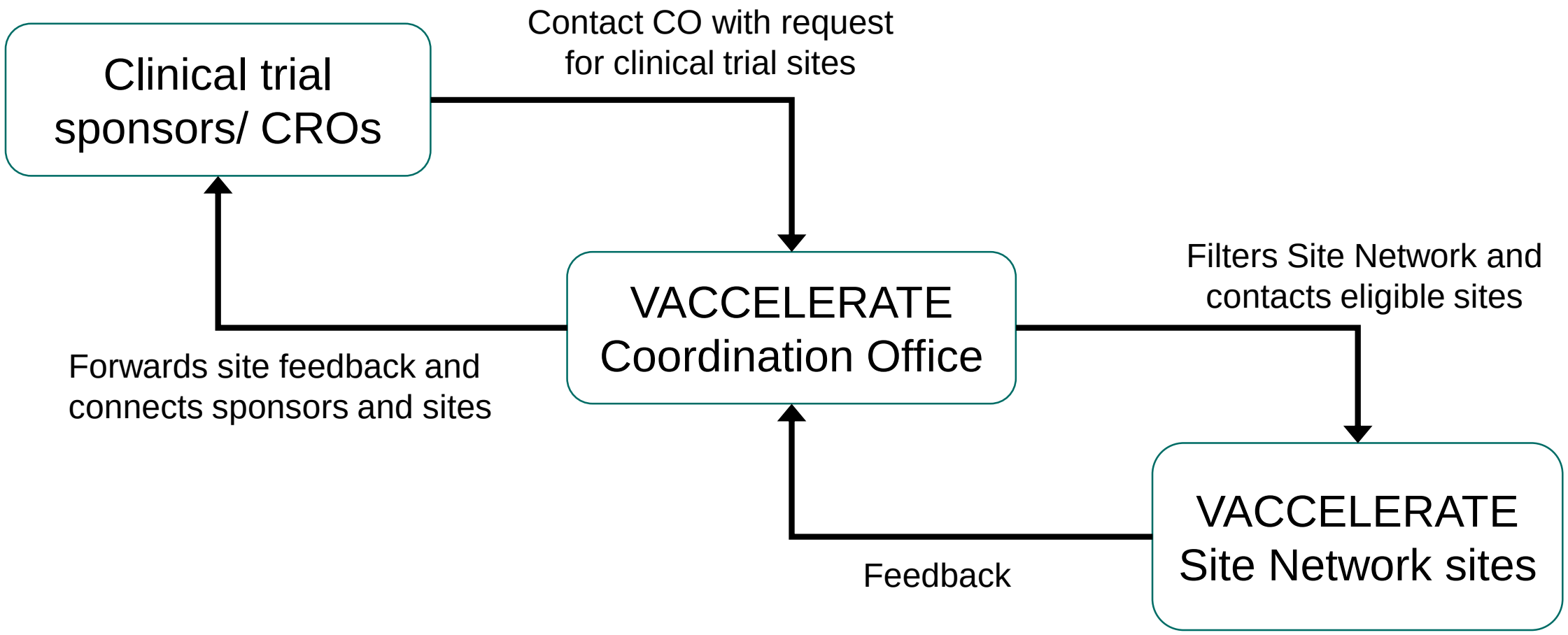
39
countries

490
overall sites

231
pediatric sites

396
adult sites

VACCELERATE Site Network



Site Network – Requests for Study Interest/Participation

Date	Study Content	Sponsor	Pathogen of interest	Country
28.10.2020	Protein-based subunit vaccine Phase 2/3 study – interested in sites Spain, Belgium	Clover Biopharma	SARS-CoV-2	China
05.02.2021	Phase 3 trial efficacy & safety of C21 COVID-19 therapy - Sites in Poland	PRA Health Science	SARS-CoV-2	US
17.02.2021	2 PIP trials - Safety & immunogenicity of CVnCOV vaccine candidate – Sites in EU	PRA Health Science	SARS-CoV-2	US
24.02.2021	V118 – Influenza vaccine – Pre-feasibility in Europe	IQVIA	Orthomyxoviridae	US
04.03.2021	S268019-vaccine efficacy trial phase 3 – Pre-feasibility to European sites	Shionogi / IQVIA	SARS-CoV-2	Japan
09.03.2021	BAYER Study - Site Pre-feasibility	Bayer	SARS-CoV-2	Germany
01.10.2021	Pre-fusion spike protein phase 3 -Pre-feasibility to sites	Medigen	SARS-CoV-2	Taiwan
06.07.2021	Protein-based COVID-19 vaccine – Pre-feasibility to sites	Beijing Health Guard Biotechnology	SARS-CoV-2	Germany
08.07.2021	C-19 vaccine safety study in immunocompromised patients – Pre-feasibility to sites	IQVIA	SARS-CoV-2	US
05.08.2021	VACCELERATE EU-COVAT-1_AGED – Site feasibility, Site Selection Process	University Hospital Cologne	SARS-CoV-2	Germany
06.08.2021	VACCELERATE EU-COVAT-2_BOOSTAVAC – Site feasibility, Site Selection Process	University College Dublin	SARS-CoV-2	Ireland
07.08.2021	VACCELERATE EU-COVPT-1_CoVacc – Site feasibility, Site Selection Process	University Medical Centre Utrecht	SARS-CoV-2	Netherlands
04.04.2022	RSV vaccine - Pre-feasibility to sites	Parexel / Moderna	RSV	Germany / US
04.05.2022	mRNA influenza vaccine - Pre-feasibility to sites	Parexel / Moderna	Orthomyxoviridae	Germany / US
25.05.2022	Monkeypox - Capacity mapping all sites	VACCELERATE	Monkeypox virus	Europe
02.06.2022	Monkeypox – Ongoing/planned trials Europe via NCs	VACCELERATE	Monkeypox virus	Europe
02.06.2022	Monkeypox – Ongoing/planned trials in Germany – pre-feasibility to sites	VACCELERATE	Monkeypox virus	Germany
07.07.2022	Monkeypox in children and adult women – Case study to sites	VACCELERATE	Monkeypox virus	Europe

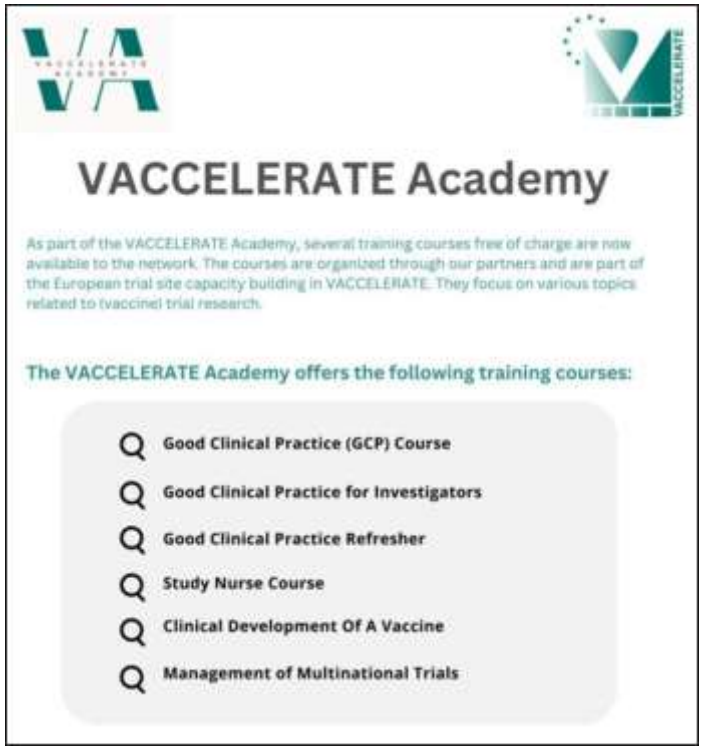
18 different requests towards sites in Site Network

Communication/Consultation with >29 external stakeholders/vaccine developers

Site Network – Capacity Building

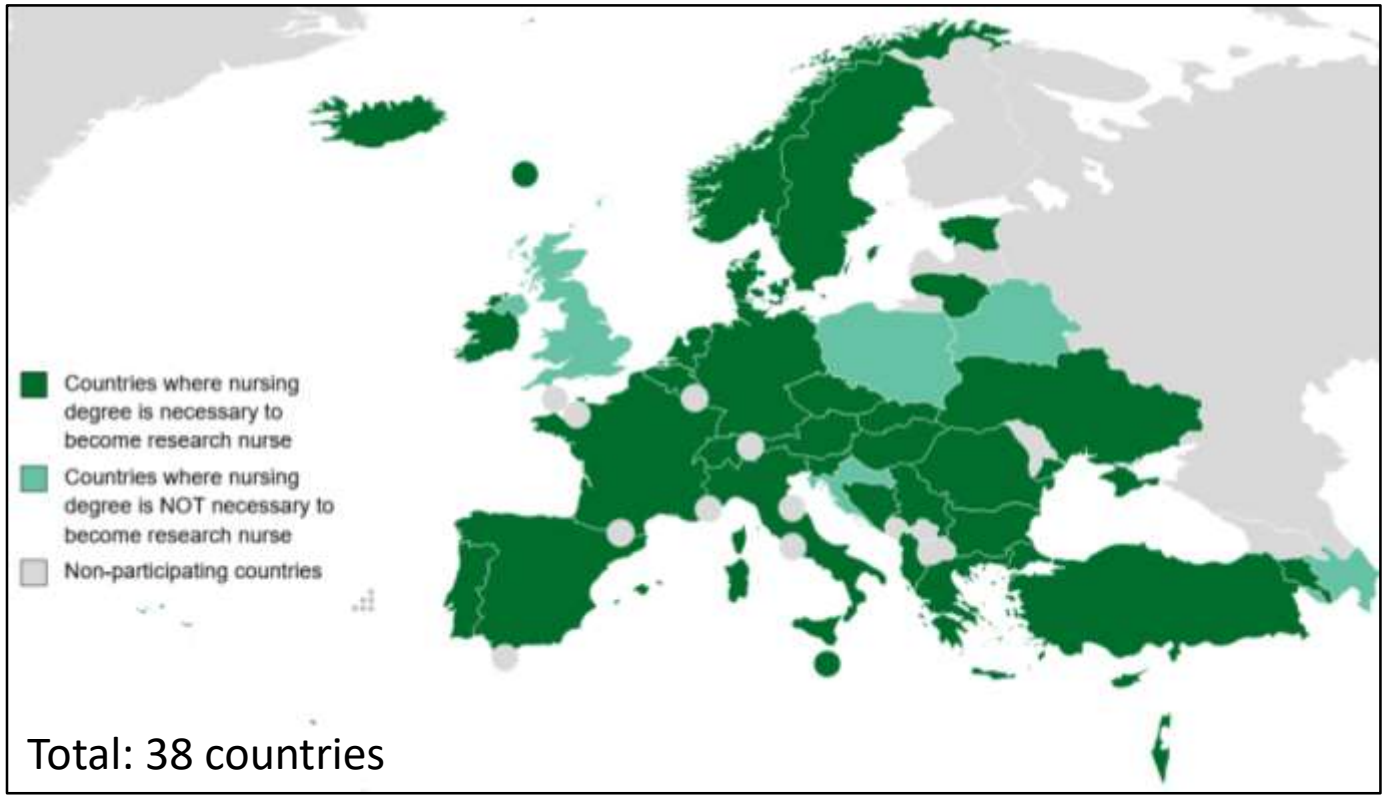
Objective: Trained & qualified site network across Europe

- 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 VACCELERATE Site Network members
  - Training requirements specified per site and study team role
  - Site qualification



How to Become a Research Nurse in Europe?

› Survey in Site Network & among National Coordinators



Total: 38 countries

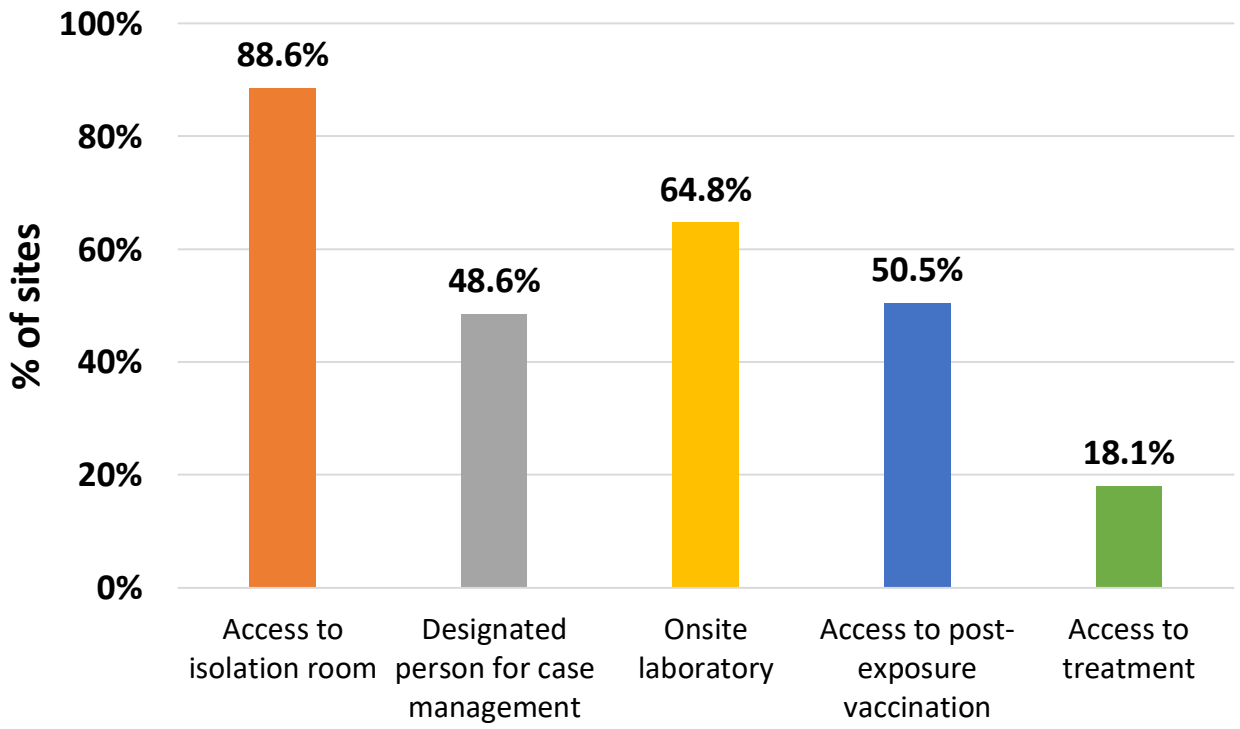
- Nursing degree necessary in 33 (87%) countries
- GCP course necessary in 24 (63%) countries
- Dedicated courses for research nurse education
  - Available in 18 (47%) countries
  - 29 (76%) countries considered them necessary
- Baseline educational background varies widely in Europe
- Education would benefit from dedicated research nurse course
  - VACCELERATE *Study Nurse Course* online from March 2023 (WP5)

GCP, good clinical practice

Manuscript in preparation

VACCELERATE - Mpox Diagnostic Capacity in Europe

- **Knowledge gap on diagnostic & clinical management capacity for mpox in Europe**
- VACCELERATE Site Network as registry of health-care sites

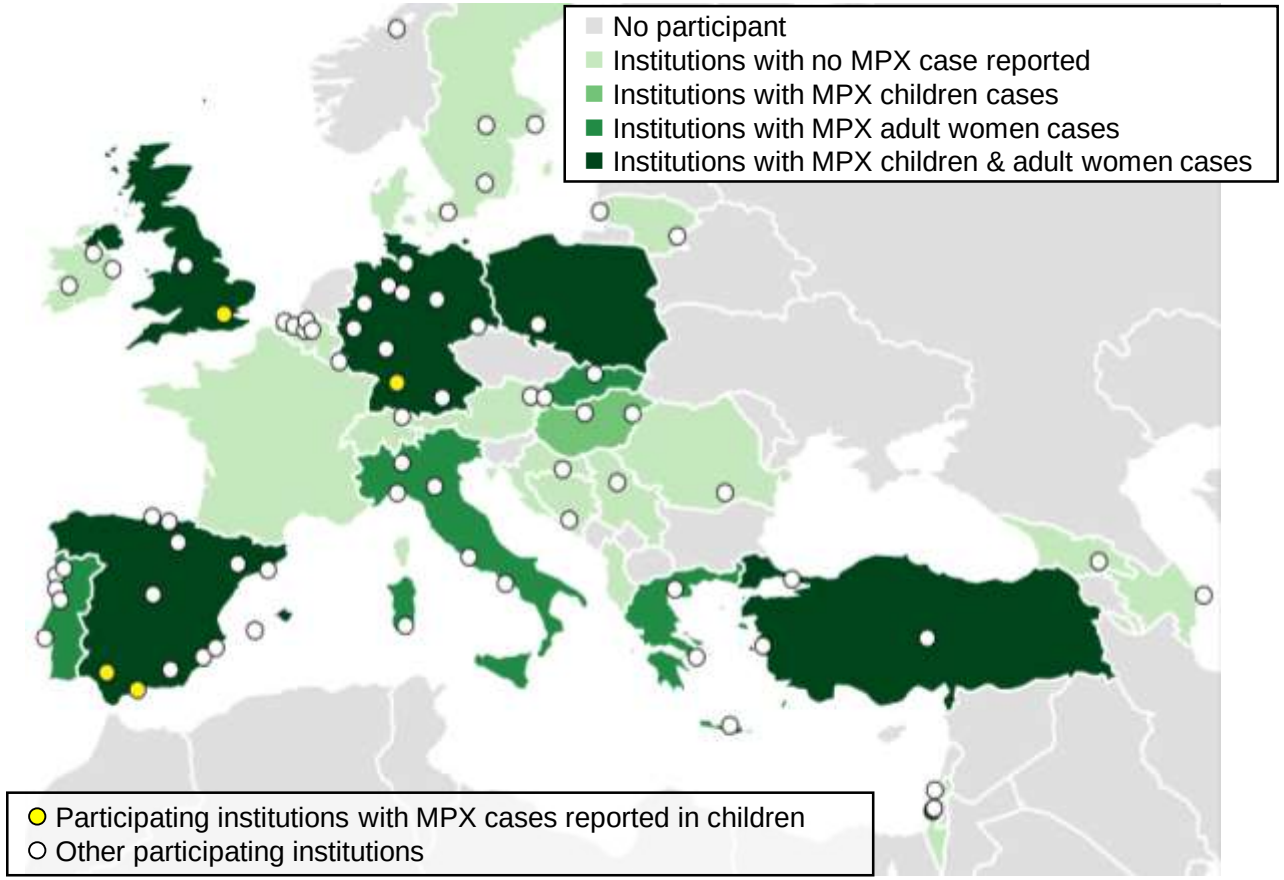


105 institutions in 36 countries

PMID: 36049256

VACCELERATE - Mpox in Children and Adult Women

- **Knowledge gap on number of evaluated & infected children & women with mpox in Europe**
- VACCELERATE Site Network as registry of health-care sites



- 88 participating institutions in 27 countries
- Most **children** *evaluated*: Belgium (n=47) & United Kingdom (n=20)
- BUT Spain (1.00) & Germany (0.33) highest ratios of *confirmed* cases
- Most **women** *evaluated*: Spain (n=226) & Belgium (n=60)
- BUT Spain (0.08) & Portugal (0.06) highest ratios of *confirmed* cases

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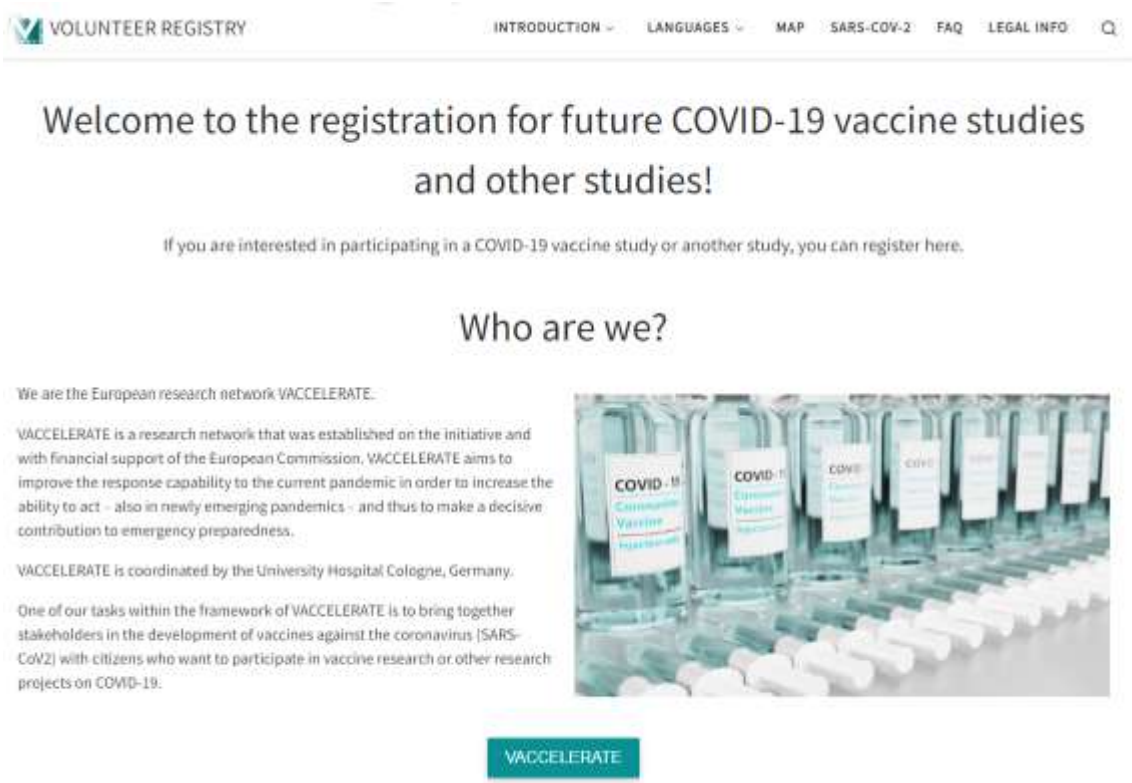
Volunteer Registry – Website

https://vaccelerate.eu/volunteer-registry

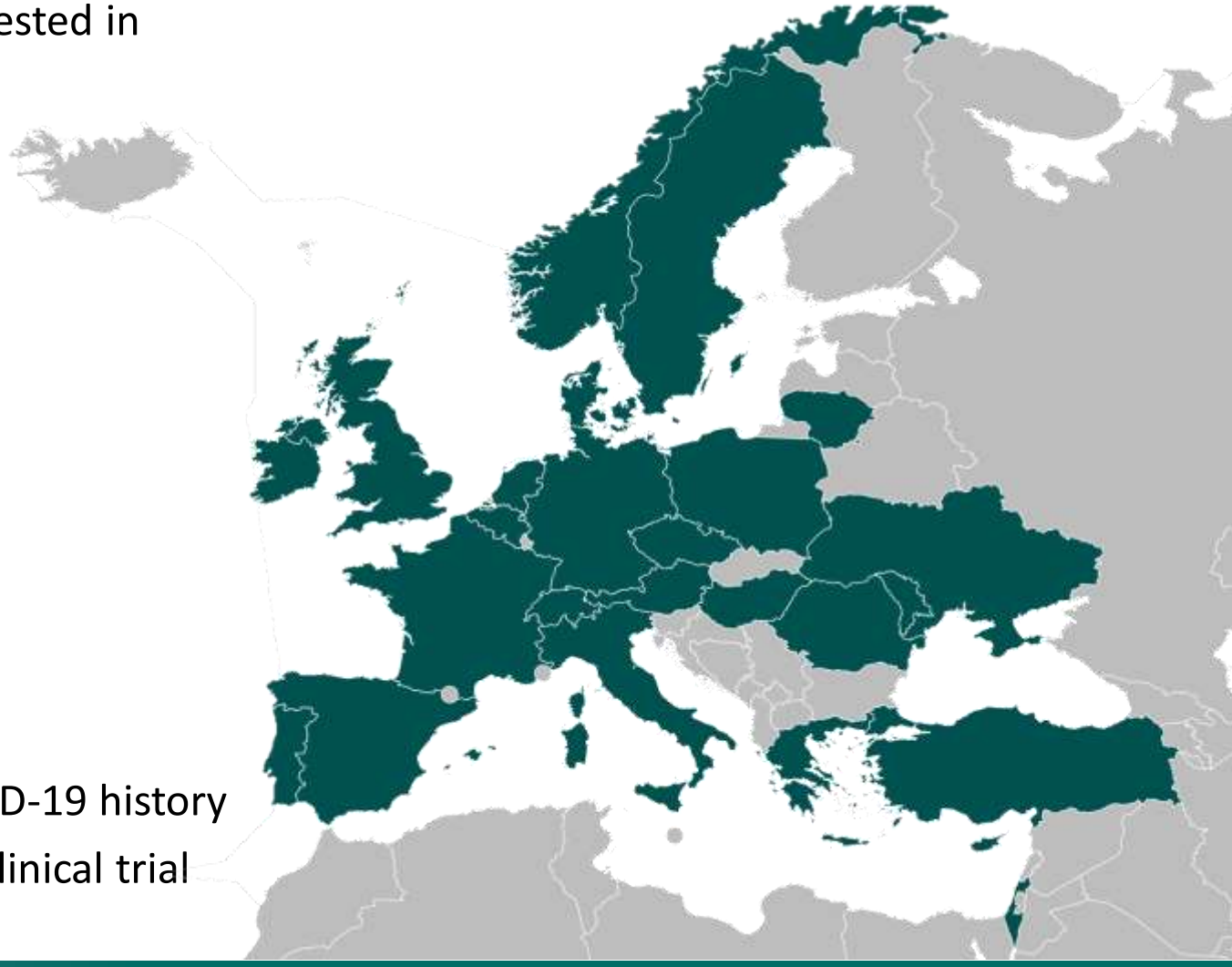


VACCELERATE Volunteer Registry – What is it?

- Single-entry point for European residents interested in clinical trial participation in 22 countries

- Speeds up the volunteer recruitment process

- Participants provide
  - First and last name
  - E-mail address
  - Age
  - Gender
  - Pre-existing comorbidities
  - Vaccination status for SARS-CoV-2 + COVID-19 history
  - Maximum distance willing to travel to a clinical trial site, if needed

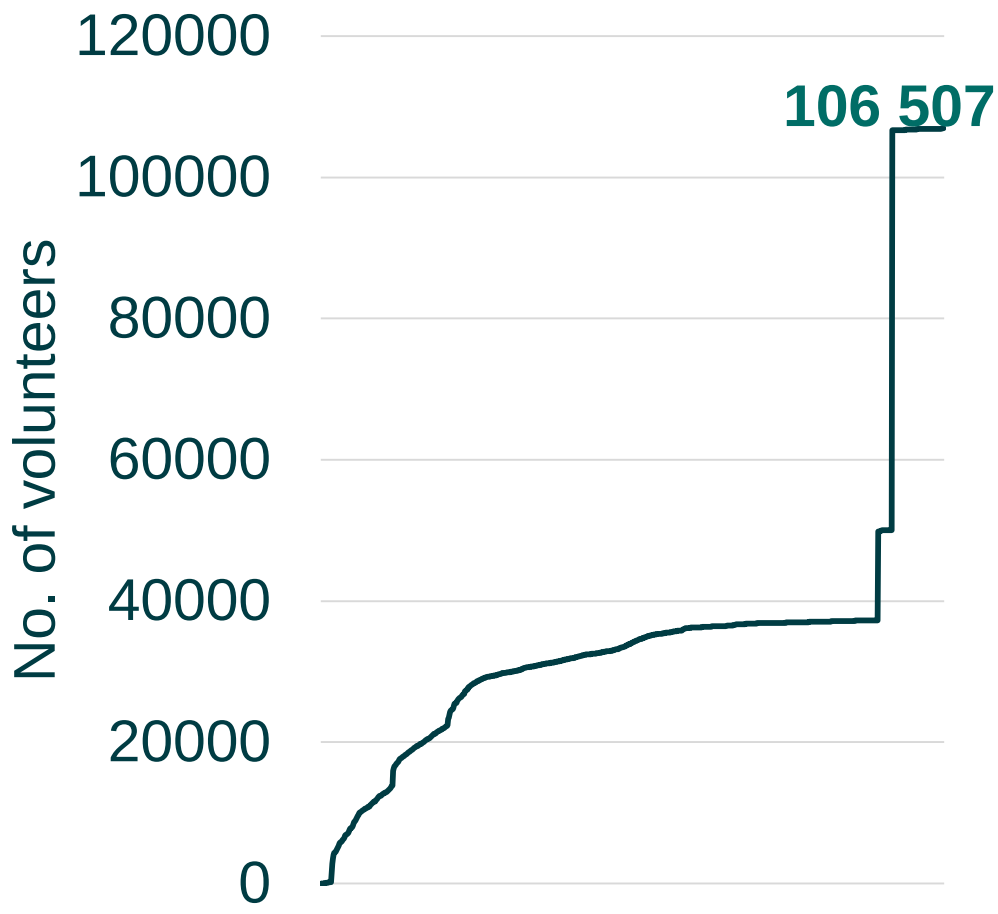


VACCELERATE Volunteer Registry – How to register?

VACCELERATE Volunteer Registry – Usage

- Clinical trials
  - Dementia
  - Influenza
  - SARS-CoV-2
  - *Streptococcus pneumoniae*

- Epidemiological studies/Citizen science
  - SARS-CoV-2 point-prevalence
  - Poliovirus vaccination coverage
  - Adenovirus, influenza A + B, respiratory syncytial virus, SARS-CoV-2 incidence



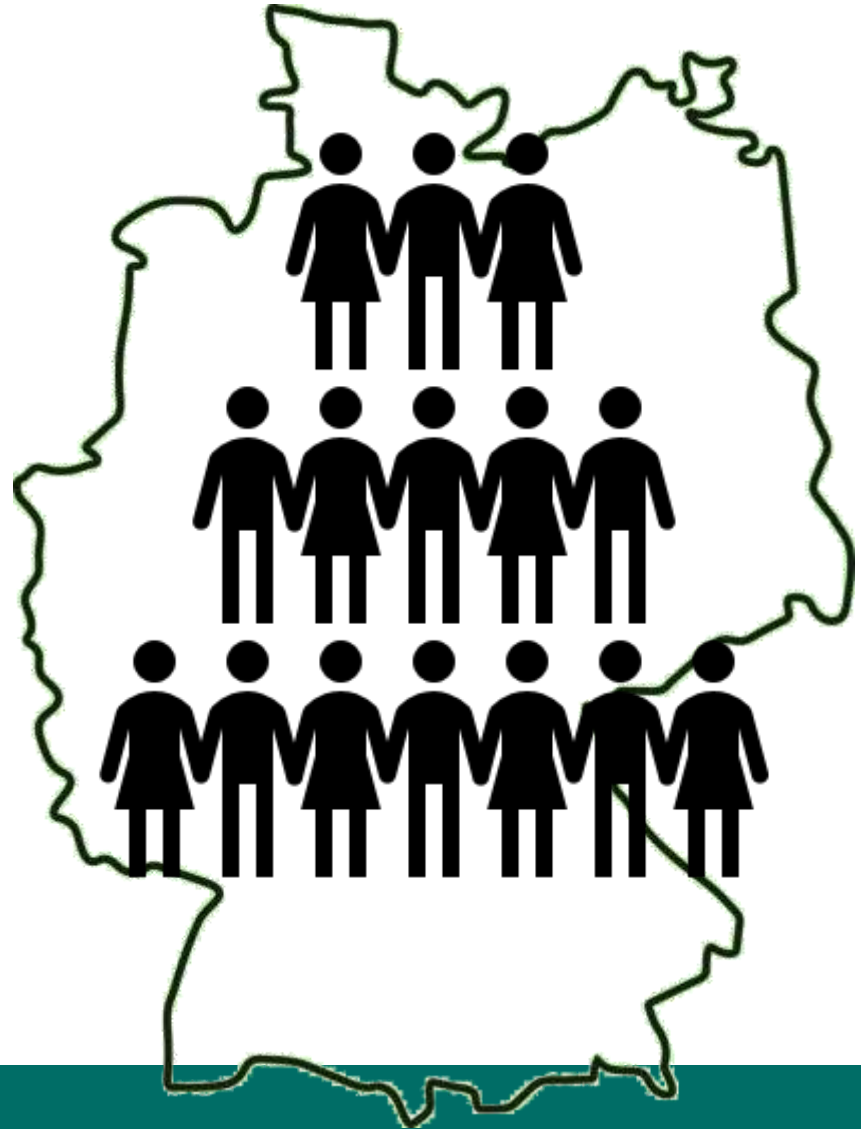
VACCELERATE Volunteer Registry – SARS-CoV-2 point-prevalence

- **Hypothesis:** There is a discrepancy between officially reported SARS-CoV-2 infection and real-life prevalence

  - Only PCR tests registered in official statistics
  - Underreporting due to shortage of PCR testing capacities
  - Underreporting due to funding cuts for SARS-CoV-2 rapid antigen tests

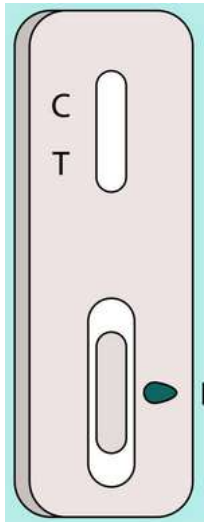
VACCELERATE Volunteer Registry – SARS-CoV-2 point-prevalence

VACCELERATE

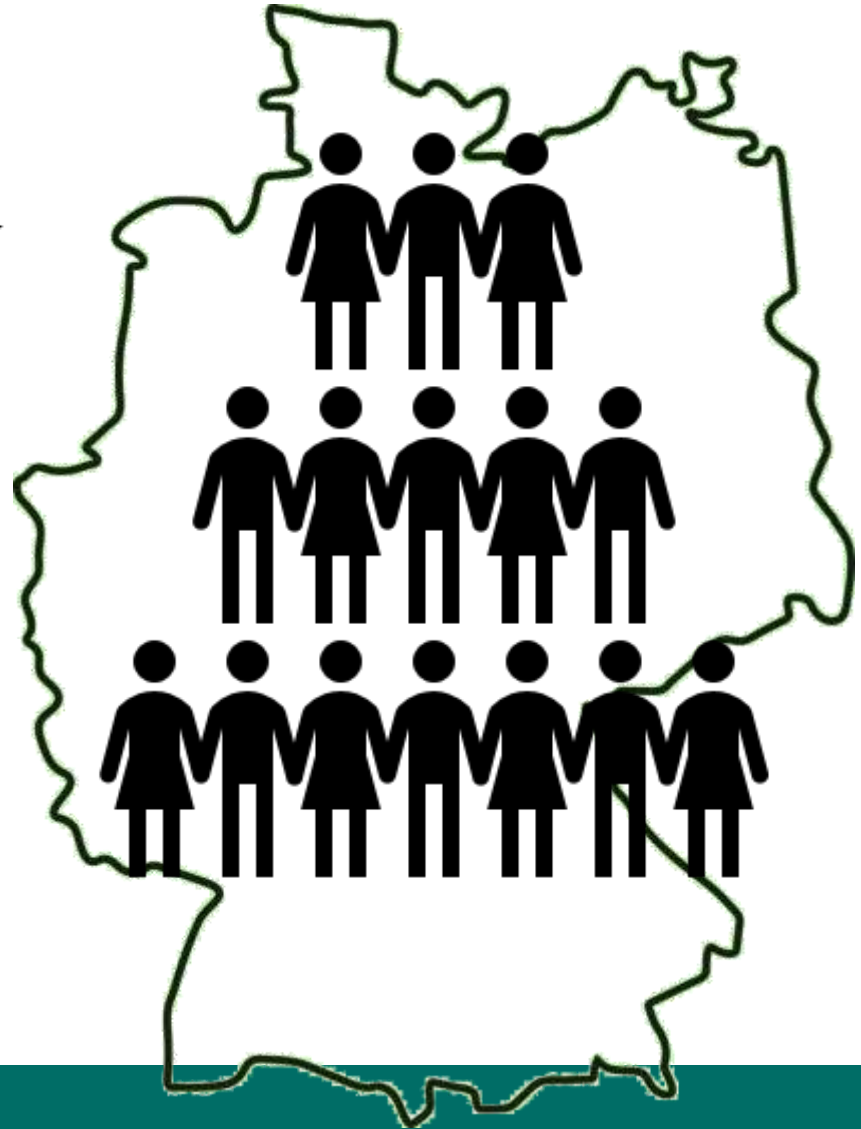


VACCELERATE Volunteer Registry – SARS-CoV-2 point-prevalence

VACCELERATE



x500

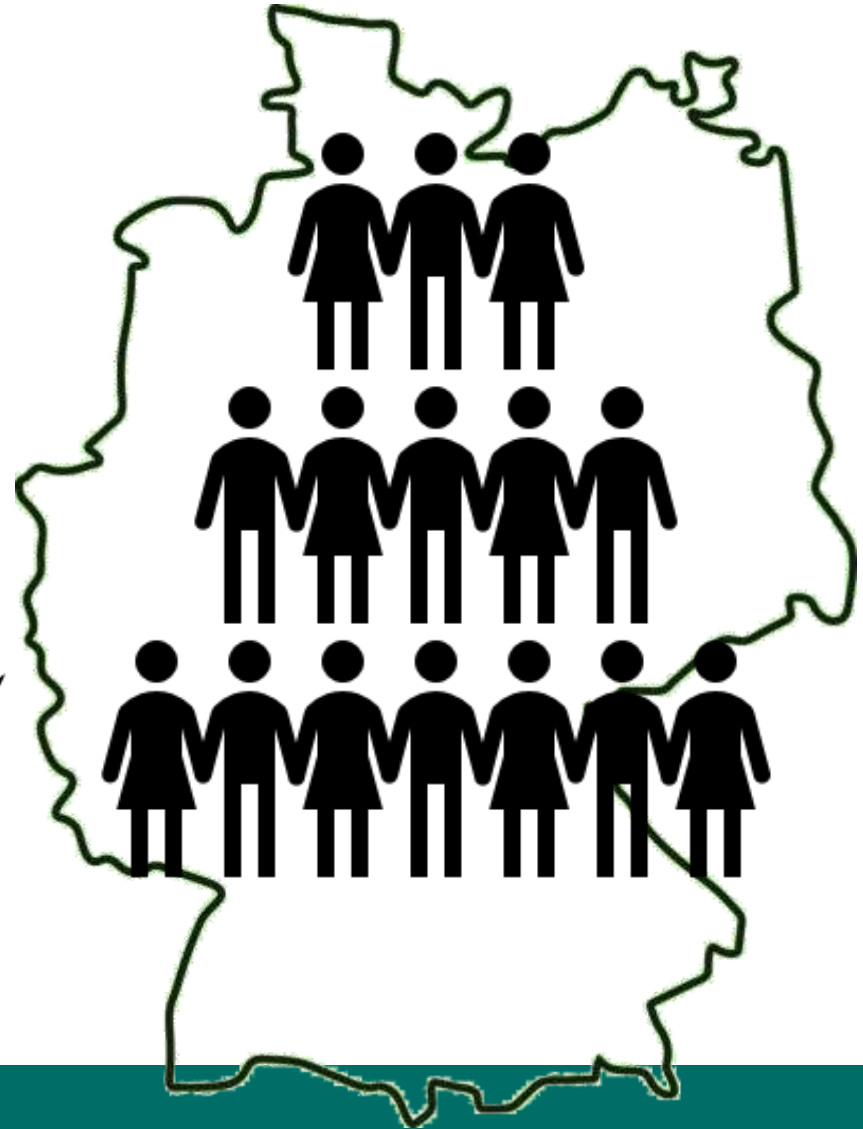


VACCELERATE Volunteer Registry – SARS-CoV-2 point-prevalence

VACCELERATE

Neg.
x412

Pos.
x7



VACCELERATE Volunteer Registry – SARS-CoV-2 point-prevalence

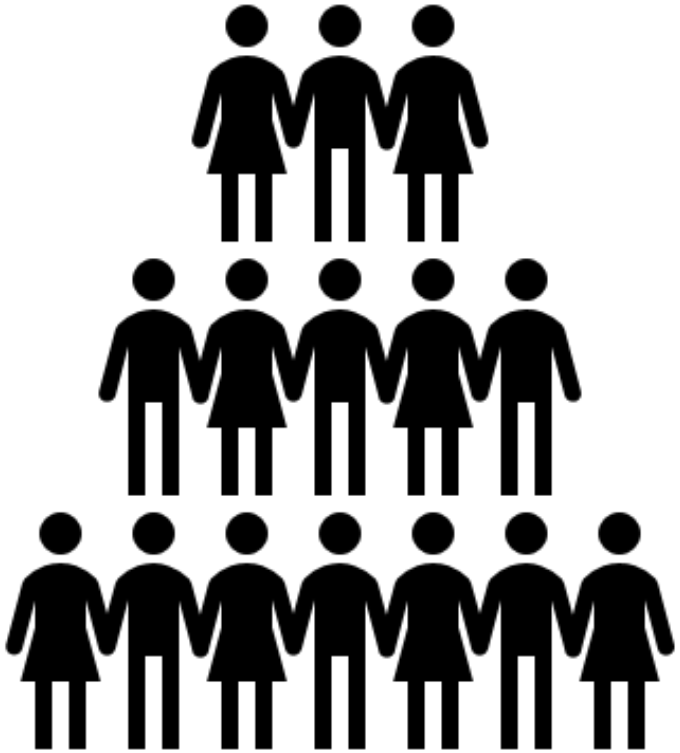
- 7/419 (1.67%) tested positive
- 2.39-fold higher prevalence compared to official reports
- Actual SARS-CoV-2 prevalence could be higher than what surveillance systems were detecting
- Pandemic surveillance and testing strategies needed to be adapted

VACCELERATE Volunteer Registry – Poliovirus vaccination coverage

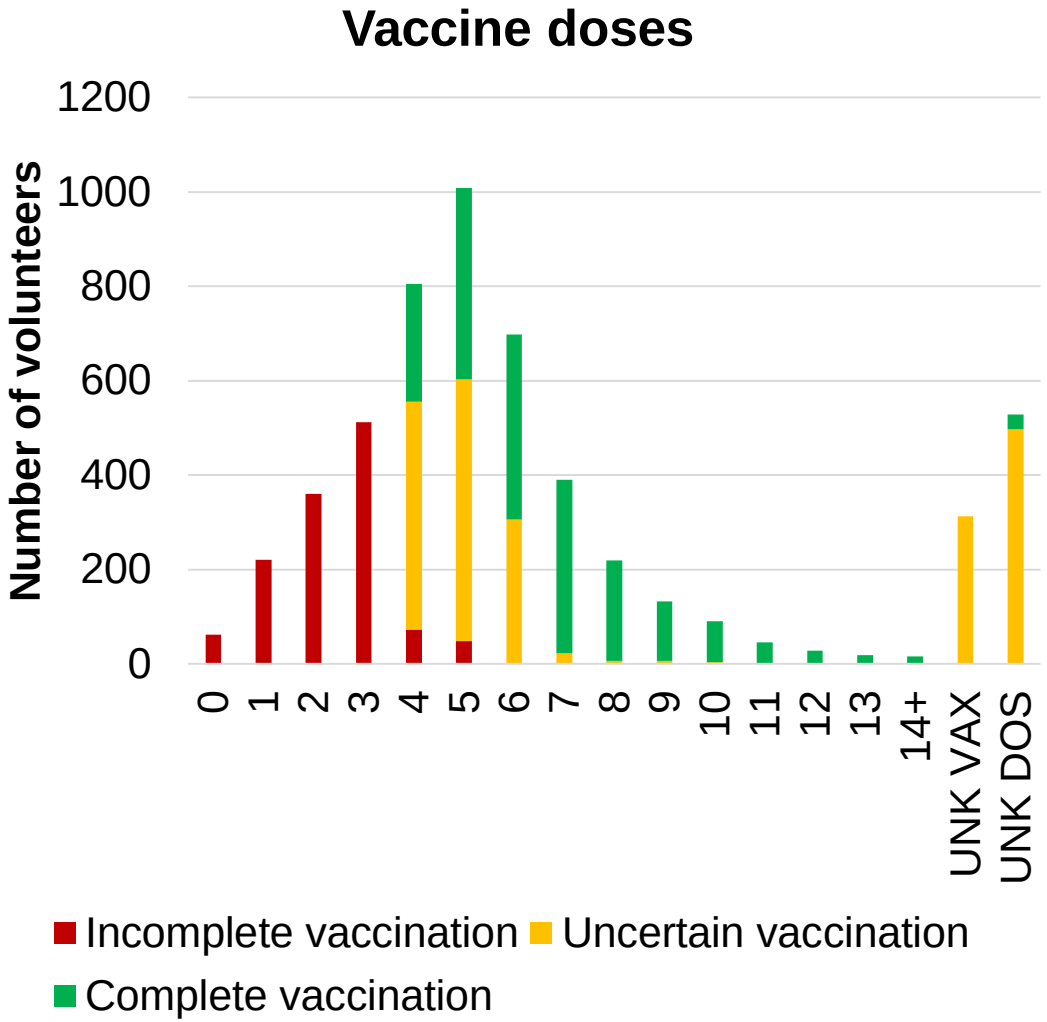
- **Hypothesis:** Is there an adequate poliovirus vaccination coverage in non-endemic countries?
- Poliovirus cases in unvaccinated patient from Jerusalem (IL) and New York (US)
- Poliovirus found in sewage water in London (GB) and New York (US)
- How is the situation in Germany?

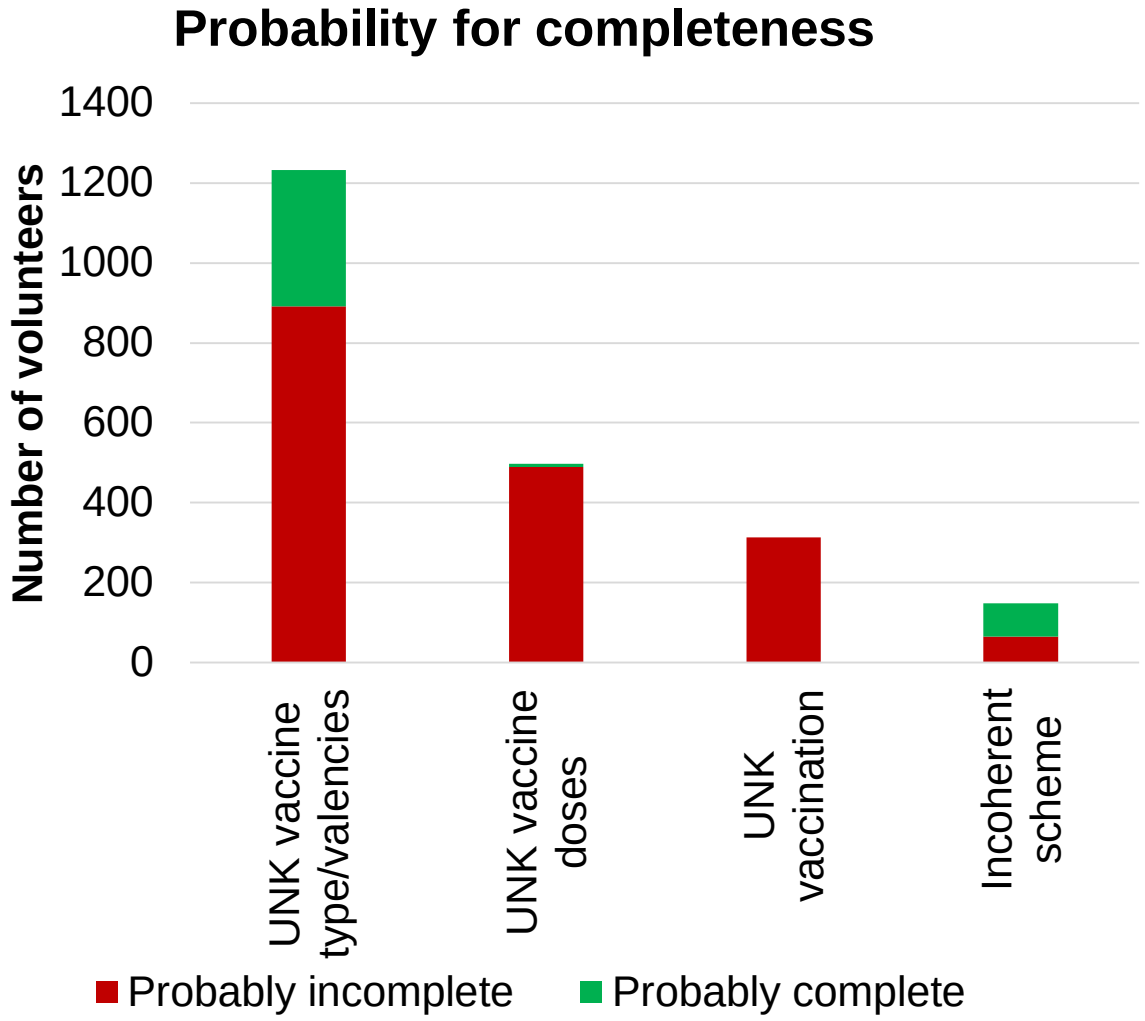
VACCELERATE Volunteer Registry – Poliovirus vaccination coverage

VACCELERATE



VACCELERATE Volunteer Registry – Poliovirus vaccination coverage

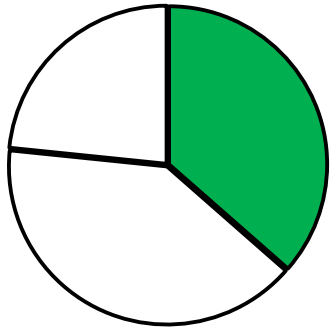




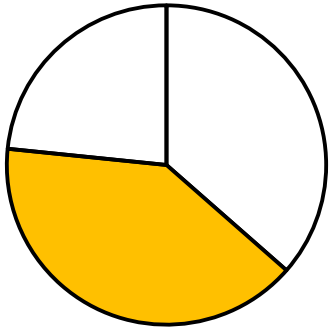
VACCELERATE Volunteer Registry – Poliovirus vaccination coverage

› Minimum of 4 doses necessary to be fully vaccinated
  - *Differences by type of vaccine possible*

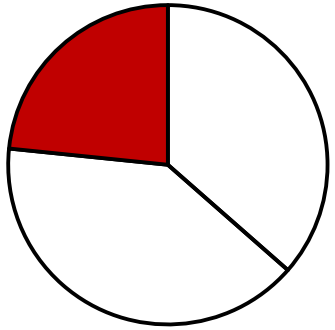
Fully vaccinated
36.4%



Uncertain vaccination
40.2%



Incomplete vaccination
23.4%



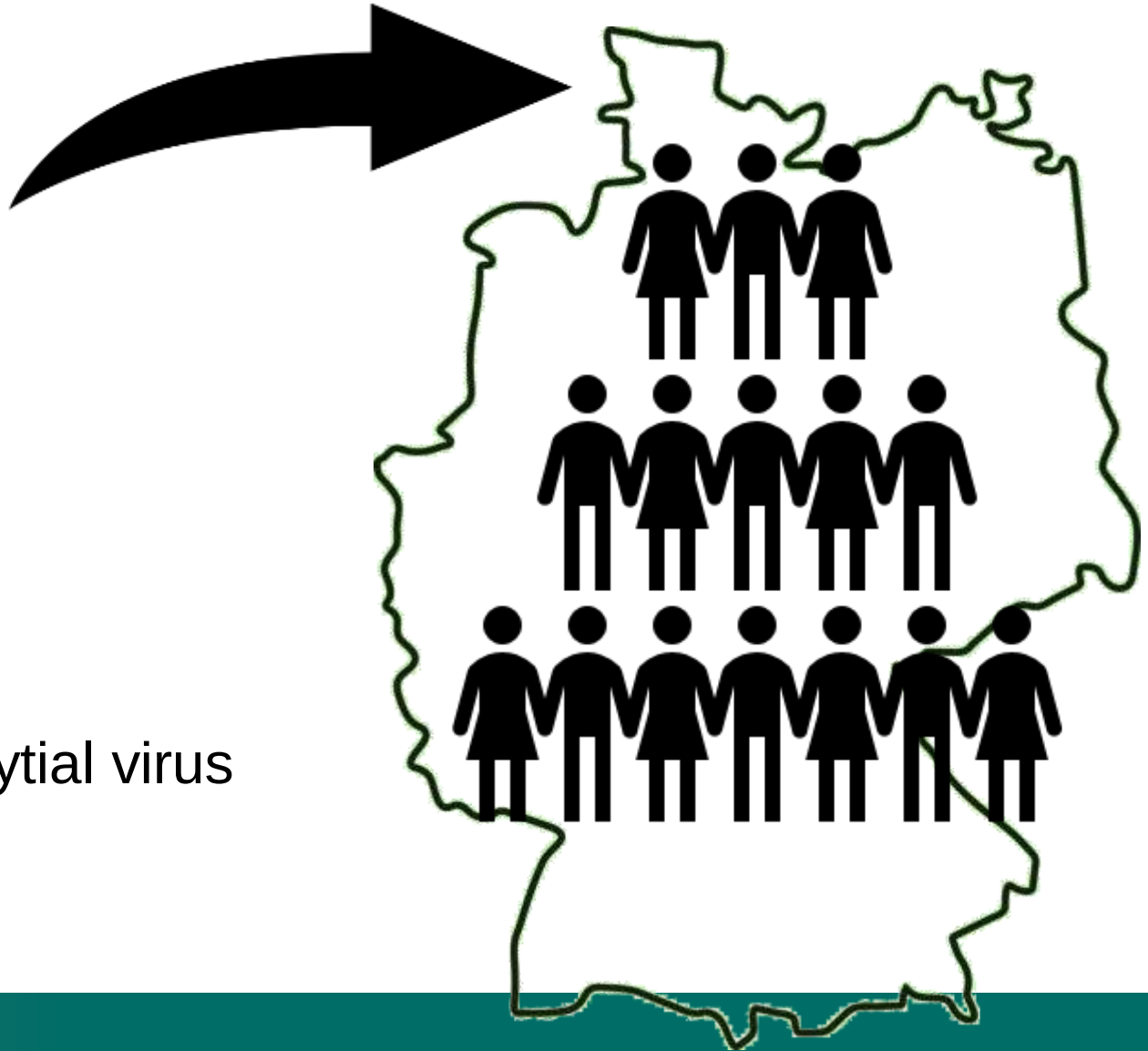
› Poliovirus vaccination status difficult to assess due to
  - Absent or incomplete records on previously administered doses

VACCELERATE Volunteer Registry – Multipathogen Antigen Test Kit (MAK-5)

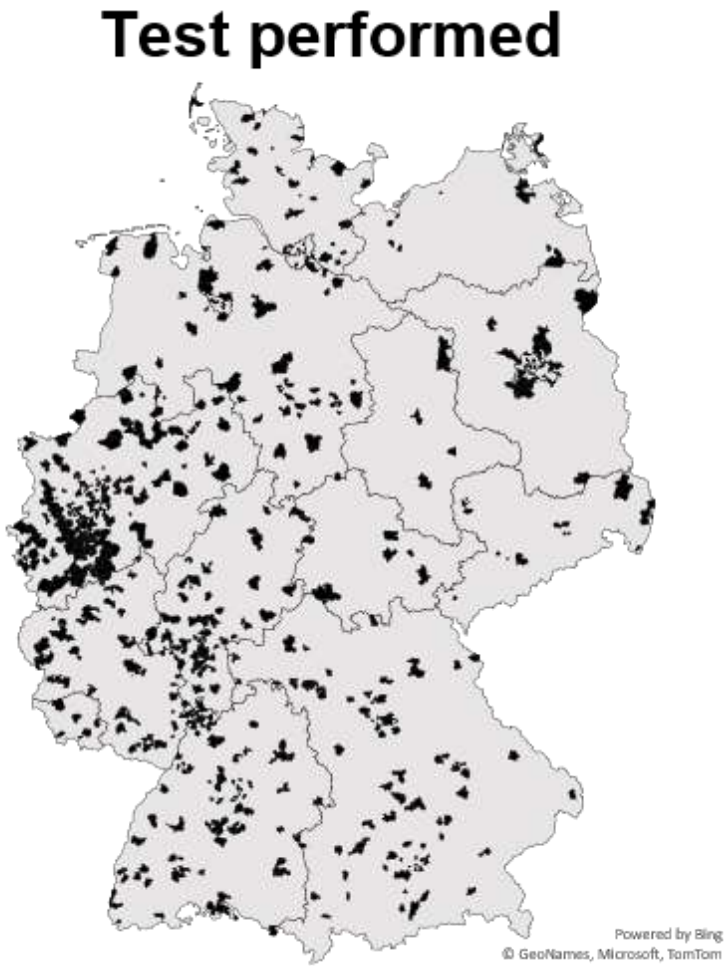
VACCELERATE

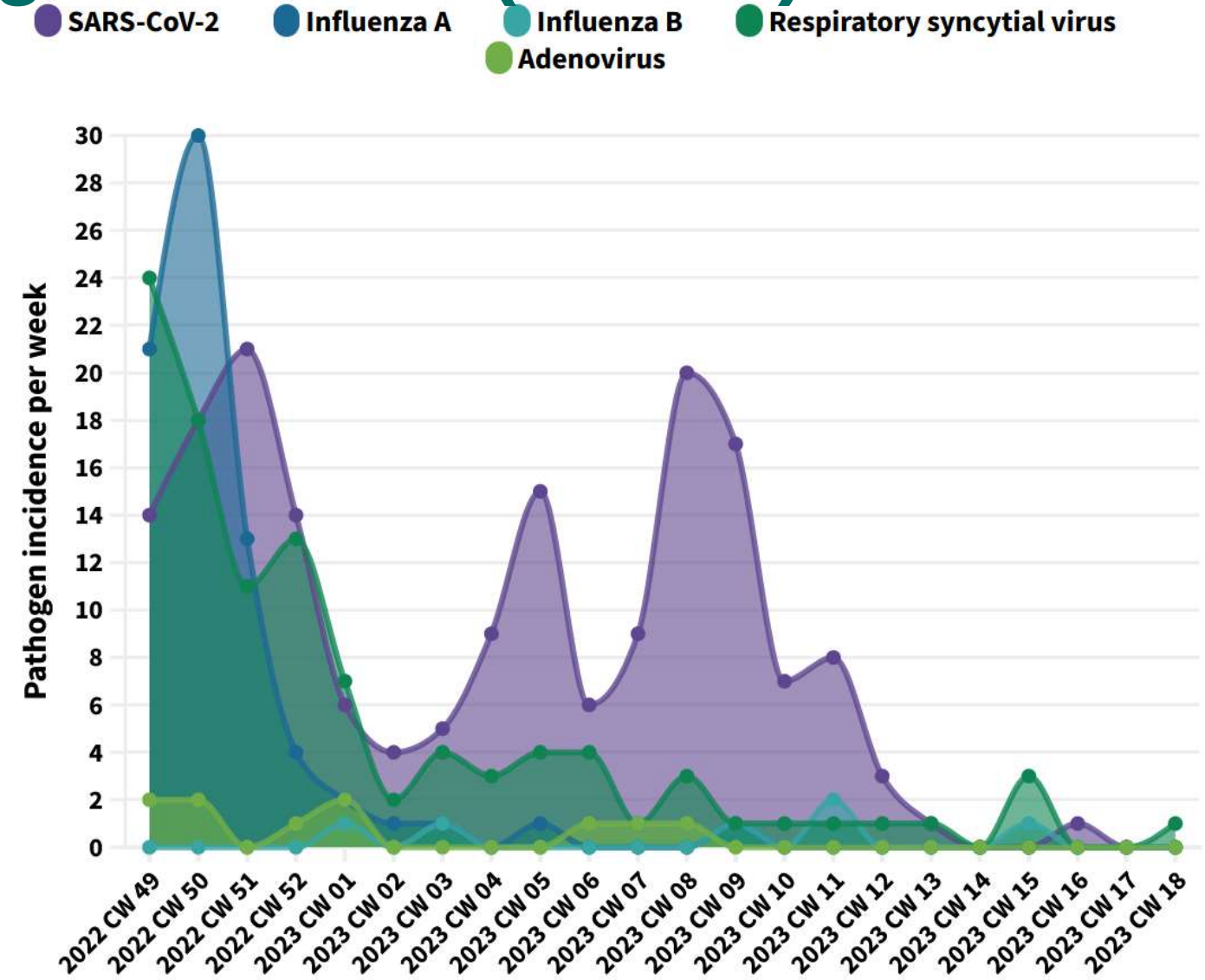
x2000

1. Adenovirus
2. Influenza A
3. Influenza B
4. Respiratory syncytial virus
5. SARS-CoV-2



VACCELERATE Volunteer Registry – Multipathogen Antigen Test Kit (MAK-5)





VACCELERATE Volunteer Registry – Multipathogen Antigen Test Kit (MAK-5)

- In the past, “Influenza-like illness“ was a valid endpoint
- Today, “ILI endpoint“, and detects disease BEFORE any medical attention
- Opportunity to study acute respiratory infection with more detail
  - More respiratory syncytial virus than official records

Volunteer Registry – Study Contributions since Oct 2020

Date	Topic/Study	Pathogen	Sponsor	Site	Country
22.12.2020	mRNA	SARS-CoV-2	CureVac	Tübingen	Germany
22.12.2020	mRNA	SARS-CoV-2	CureVac	Cologne	Germany
08.01.2021	mRNA	SARS-CoV-2	CureVac	Tübingen	Germany
21.07.2021	MVA-SARS-ST Phase 1 study	SARS-CoV-2	UKE, Hamburg	Hamburg	Germany
30.09.2021	VACCELERATE AGED, 3rd vaccination	SARS-CoV-2	UHC, Cologne	Cologne	Germany
13.12.2021	VACCELERATE AGED, 3rd vaccination	SARS-CoV-2	UHC, Cologne	Frankfurt	Germany
13.12.2021	MVA	SARS-CoV-2	UKE, Hamburg	Cologne	Germany
21.02.2022	VACCELERATE BOOSTAVAC, 4th vaccination	SARS-CoV-2	UCD, Ireland	UC Dublin	Ireland
24.06.2022	VACCELERATE AGED, 4th vaccination	SARS-CoV-2	UHC, Cologne	Cologne	Germany
26.06.2022	Point-prevalence	SARS-CoV-2	UHC, Cologne	Cologne	Germany
27.06.2022	V116-003	Streptococcus pneumoniae	MSD	Cologne	Germany
30.06.2022	VACCELERATE AGED, 4th vaccination	SARS-CoV-2	UHC, Cologne	Cologne	Germany
18.07.2022	Dementia prevention	NA	CECAD, UHC	Cologne	Germany
26.07.2022	V116-003	Streptococcus pneumoniae	MSD	Cologne	Germany
03.08.2022	VACCELERATE BOOSTAVAC, 4th vaccination	SARS-CoV-2	UCD, Ireland	Cologne	Germany
16.08.2022	MVA	SARS-CoV-2	UKE, Hamburg	Cologne	Germany
30.08.2022	V116-003	Streptococcus pneumoniae	MSD	Cologne	Germany
05.10.2022	VACCELERATE AGED, 4th vaccination	SARS-CoV-2	UHC, Cologne	Dublin	Ireland
28.10.2022	Vaccination status	Enterovirus poliovirus	UHC, Cologne	Cologne	Germany
23.11.2022	Point-prevalence	SARS-CoV-2, influenza A/B, RSV, Adeno	UHC, Cologne	Cologne	Germany
23.11.2022	V116-010	Streptococcus pneumoniae	MSD	Munich	Germany
23.11.2022	V116-010	Streptococcus pneumoniae	MSD	Cologne	Germany

14 different trials/surveys supported with ~75,000 Volunteer-to-Study Matches

Continuing next page→

Volunteer Registry – Study Contributions since Oct 2020

Date	Topic/Study	Pathogen	Sponsor	Site	Country
05.12.2022	mRNA/Influenza	SARS-CoV-2 / Influenza	Moderna	Cologne	Germany
14.12.2022	mRNA/Influenza	SARS-CoV-2 / Influenza	Moderna	Berlin	Germany
14.12.2022	mRNA/Influenza	SARS-CoV-2 / Influenza	Moderna	Hamburg	Germany
14.12.2022	mRNA/Influenza	SARS-CoV-2 / Influenza	Moderna	Dresden	Germany
14.12.2022	mRNA/Influenza	SARS-CoV-2 / Influenza	Moderna	Hannover	Germany
14.12.2022	mRNA/Influenza	SARS-CoV-2 / Influenza	Moderna	Karlsruhe	Germany
14.12.2022	mRNA/Influenza	SARS-CoV-2 / Influenza	Moderna	Schwerin	Germany
06.01.2023	VACCELERATE BOOSTAVAC, booster vaccination	SARS-CoV-2	UCD, Ireland	Dublin	Ireland
27.01.2023	VACCELERATE BOOSTAVAC, booster vaccination	SARS-CoV-2	UCD, Ireland	Dublin	Ireland

14 different trials/surveys supported with ~75,000 Volunteer-to-Study Matches

VACCELERATE Trials

- AGED – Best booster 75+, H2H-RCT

  - MS policy changes → 4 protocol AMDs
  - Contracting: 6-country avg 5 months

- BOOSTAVAC – Best booster strategy 18+

  - Recruitment ongoing
  - MS policy changes → 3 protocol AMDs
  - Contracting: 6-country avg 7 months

- CoVACC – Best vaccination strategy 5-11 yrs

  - Recruitment ongoing
  - MS policy (changes) → 4 protocol AMDs
  - Contracting: 5-country avg 7 months

PMID: 36209129

VACCELERATE Volunteer Registry – Remarks

- Useful for both clinical trials and epidemiological studies
- Reference in Europe for study sponsor and clinical trial site units to speed up volunteer recruitment process
- Expansion expected

Thank you!