EMA WORKSHOP
ON
CLINICAL TRIALS DURING EMERGENCIES

VACCELERATE

European Corona Vaccine Trial Accelerator Platform

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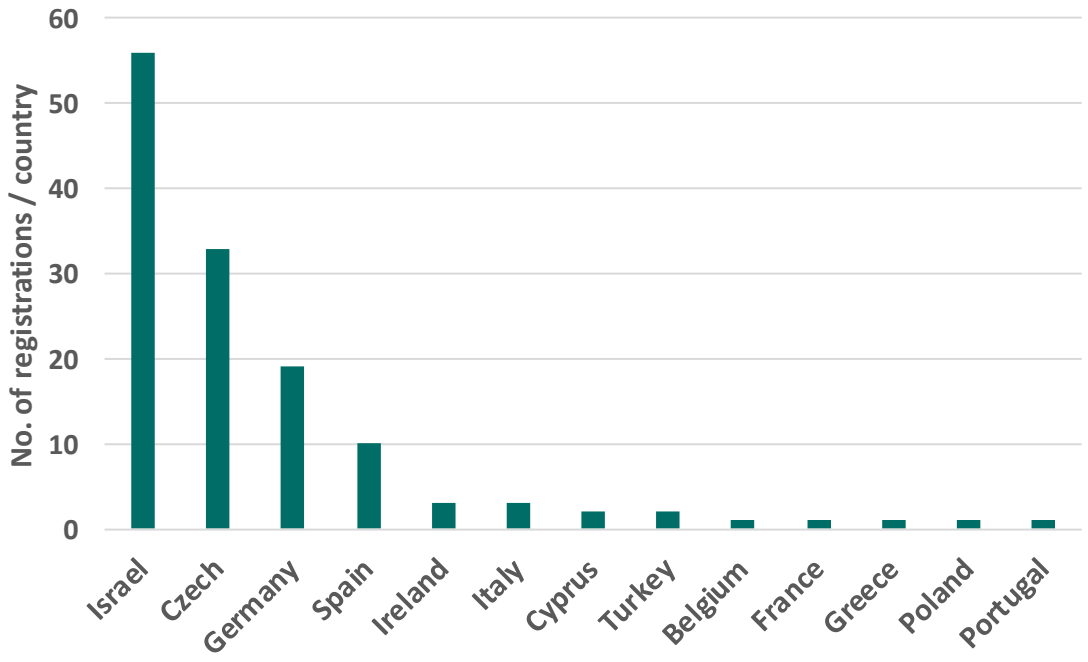
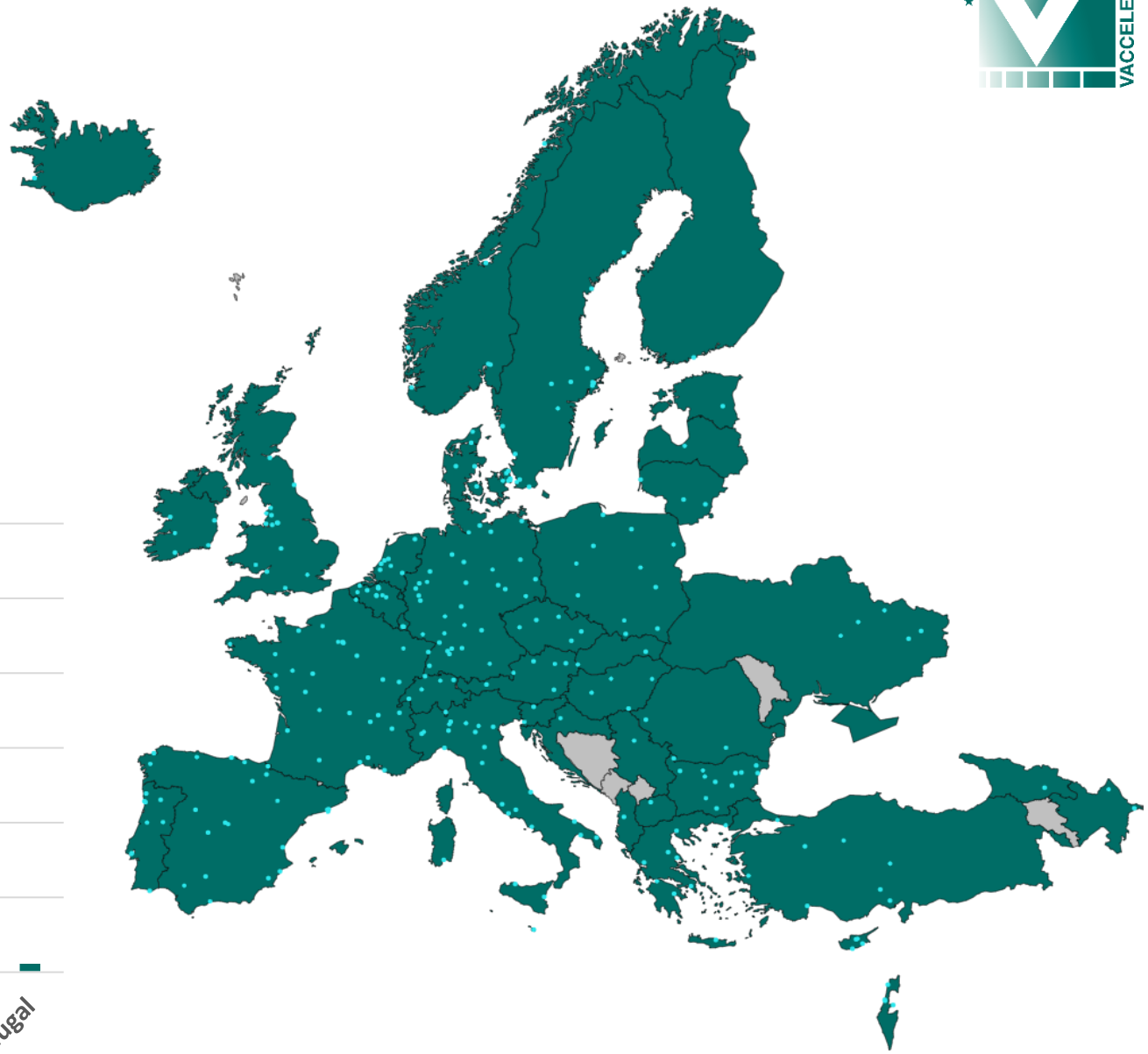
VACCELERATE Site Network

- 39 countries
- 489 registered sites
  - Adult and Paediatric
  - Capacity building
  - 1st Study Nurse Course world-wide





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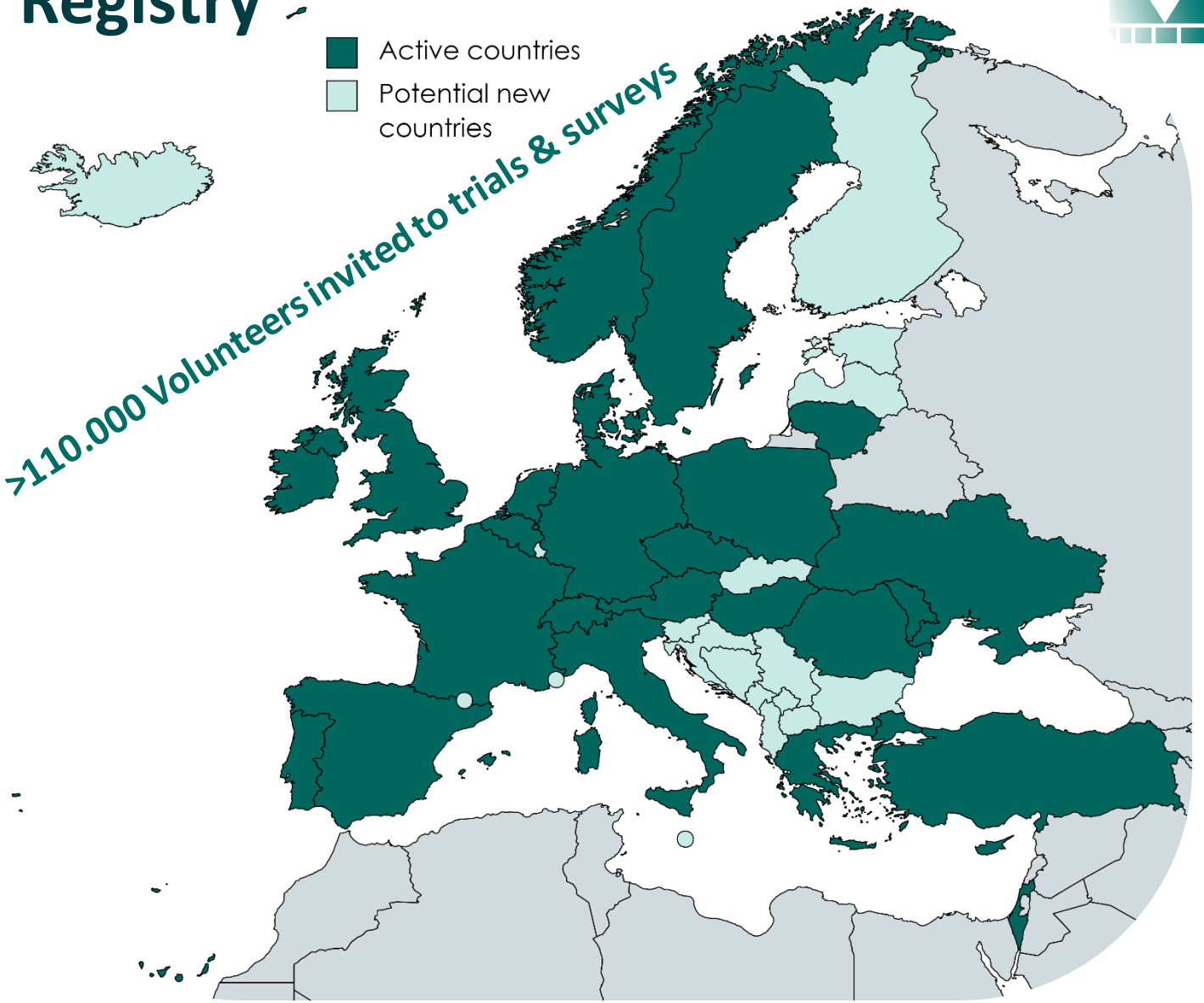
VACCELERATE Volunteer Registry

Registry active in 25 countries

- Austria
- Belgium
- Cyprus
- Czech Republic
- Denmark
- France
- Germany
- Greece
- Hungary
- Ireland
- Israel
- Italy
- Lithuania
- Moldovia
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- United Kingdom

Cooperating registries

- France
- Netherlands
- United Kingdom



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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

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VACC
Vaccine Pandemic Preparedness
Obstacles and Mitigation Strategy Report

Emergency Trial Funding

Obstacle 1b: No emergency funding for clinical trials, e.g., Mpox vaccine trials

Mitigation:

April-29	1st EU Mpox case
May	Diagnostic and therapeutic capacity mapping
June	eCRF defining a standard for the new disease
June	Linking European activities
July-02	eCRF Ethics approval
July-23	WHO declares public health emergency

Solution: Emergency funding to cover initial steps
7 days from 'Emergency declared' to 'Funds released'

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Delays in Vaccine Trial Funding

Obstacle 7e: Extensive Review Cycles for vaccine trial funding applications
Promise of retroactive eligibility no solution for employers and study sites

Mitigation: Working in parallel on GA-AMD, clinical trial protocols, and documents needed for trial execution without approved funding

Solution: Emergency funding with short approval times

Contracting

Obstacle 7f: Contracting of Clinical Trial Agreements (CTA) delayed by substantially differing views between MS

Mitigation: Maximized interface management for >90 contracts, of which ~50% were never concluded

Solution: CDAs and contracts with >200 potential trial sites for continuously enrolling VACCELERATE adaptive platform trial (VACC APT)

Obtainment of Investigational Medicinal Products (IMP)

Obstacle 2: Joint procurement did not consider clinical trials

Mitigation: Multiple discussions and negotiations at EU and MS levels >8 months until vaccines use okayed by single MS

Solution: Negotiations with vaccine developers need to consider continuously developing public health needs

Ethics and Regulatory Study Approval Paths

Obstacle 7a,c: Extensive Review Cycles – Ethics and RA/CA authorities
No fast-track approval despite emergency

Mitigation: Beyond VACCELERATE mandate

Solution: Establish expedite procedure for urgent public health scenarios
Revisit regulations and timelines for non-emergency scenarios, too

VACCELERATE Infrastructure Utilization

Obstacle 3: EU Calls bypass VACCELERATE

- e.g., HERA Incubator Call on SARS-CoV-2 vaccines
- Grant awarded to industry, no obligation to involve VACCELERATE

Mitigation: Multiple futile conversations with industry awardee

Solution: Do not bypass EC-funded consortia
Use VACCELERATE expertise when phrasing calls on clinical vaccine research to maximize value

COVID-19 Vaccination Schedule

Obstacle 4: No harmonized MS vaccination schedule, including COVID-19

Mitigation: Adapting VACCELERATE protocols, manuals, amendments to rapidly changing MS policies

Solution: Harmonize EU-wide vaccination schedule
Continuously enrolling VACC APT accommodating MS schedules randomizing vs new IMPs in different Disease Domains

Overarching Mitigation Strategy

VACC APT

Adaptive Platform Vaccine Trial for EU Pandemic Preparedness

Domains covered: Priority pandemic pathogens & Disease X