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VACCELERATE Volunteer Registry: A European study participant database to facilitate clinical trial enrolment

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ABSTRACT

Introduction: The coronavirus disease 2019 (COVID-19) pandemic has evidenced the key role of vaccine design, obtention, production and administration to successfully fight against infectious diseases and to provide efficient remedies for the citizens. Although clinical trials were rapidly established during this pandemic, identifying suitable study subjects can be challenging. For this reason, the University Hospital Cologne established a volunteer registry for participation in clinical trials first in Germany, which has now been incorporated into the European VACCELERATE clinical trials network and grew to a European Volunteer Registry. As such, VACCELERATE's Volunteer Registry aims to become a common entry point for potential volunteers in future clinical trials in Europe.

Methods: Interested volunteers who would like to register for clinical trials in the VACCELERATE Volunteer Registry can access the registration questionnaire via http://www.vaccelerate.eu/volunteer-registry. Potential volunteers are requested to provide their current country and area of residence, contact information, including first and last name and e-mail address, age, gender, comorbidities, previous SARS-CoV-2 infection and vaccination status, and maximum distance willing to travel to a clinical trial site. The registry is open to both adults and children, complying with national legal consent requirements.

Results: As of May 2022, the questionnaire is available in 12 countries and 14 languages. Up to date, more than 36,000 volunteers have registered, mainly from Germany. Within the first year since its establishment, the VACCELERATE Volunteer Registry has matched more than 15,000 volunteers to clinical trials. The VACCELERATE Volunteer Registry will be launched in further European countries in the coming months.

Conclusions: The VACCELERATE Volunteer Registry is an active single-entry point for European residents interested in COVID-19 clinical trials participation in 12 countries (i.e., Austria, Cyprus, Germany, Greece, Ireland, Lithuania, Norway, Portugal, Spain, Sweden and Turkey). To date, more than 15,000 registered individuals have been connected to clinical trials in Germany alone. The registry is currently in the implementation phase in 5 additional countries (i.e., Belgium, Czech Republic, Hungary, Israel and the Netherlands).

1. Introduction

The first patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) associated pneumonia were described in Wuhan, central China, in December 2019. [1] After an exponential global expansion, coronavirus disease 2019 (COVID-19) was declared a pandemic 3 months later. [2] The SARS-CoV-2/COVID-19 pandemic has showcased the urgent need for ready-to-use public health tools to adequately face emerging epidemics and pandemics. [3–5] COVID-19 is the perfect example of the enormous impact of emerging global health threats caused by behavioural and climatic changes on our societies. [6].

The European vaccine development landscape is widely scattered, as well as difficult to access and to navigate. [7–10] Therefore, Europe was less attractive for vaccine developers than other regions in the world. [11–14] However, during recent years, advances have been made in order to implement European platforms for therapeutic clinical trials. [15–17] Moreover, the COVID-19 pandemic highlighted the need to bring all European residents closer to phase 2 and phase 3 COVID-19 clinical trials, for example through volunteer registries, [18,19] including healthy volunteers, patients with comorbidities, minorities and/or underrepresented populations. An easily accessible registry of well-characterised potential study volunteers can be a key tool for the early identification of suitable subjects in any phase 2 and phase 3 vaccine clinical trial.

The main goal of the VACCELERATE [20] Volunteer Registry is the implementation of an Europe-wide, dynamic, harmonised and sustainable single-entry volunteer registry for phase 2 and phase 3 clinical trials. While the focus is currently on COVID-19, the registry can be expanded to other indications for vaccine testing and adapted for future health emergencies under the mandate of the EU Health Emergency Preparedness and Response Authority (HERA) Incubator initiative. [21].

2. Overview of the VACCELERATE Volunteer Registry

The VACCELERATE Volunteer Registry (https://www.vaccelerate.eu/volunteer-registry) collects information on basic demographic details (first and last name, e-mail, gender, year of birth, area of residence and country), willingness to travel to a clinical trials site, COVID-19 infection prior to registration, vaccination status (number of doses, time of administration and manufacturer), as well as underlying conditions (adapted for adult and paediatric populations) (Table 1). Volunteers have to consent to data processing, storage and validation prior to submitting their personal data, in accordance with article 13 of the EU General Data Protection Regulation (GDPR). [22] In the case of minors, additional consent by the respective legal guardian(s) is requested, according to the respective national version with regards to local and national regulations. Online registration does not automatically mean participation in a clinical trial. Obtaining informed consent for clinical trial participation falls under the obligation of the respective clinical trial sponsor and/or its representative. Registration in the Volunteer Registry can be withdrawn at any time and without explanation, followed by deletion of the submitted data set. Once volunteers agree to the terms and conditions, their personal data are saved and incorporated into the database.

When a clinical trial becomes ready to enrol, potential study participants are identified and filtered according to the trial's key enrolment criteria. Herewith, potentially eligible candidates are briefly informed about the clinical trial, including contact details of the trial site closest to their area of residence, via e-mail. Interested volunteers will autonomously and independently decide whether they wish to contact the trial site to learn more about the clinical trial and if they wish to participate (Fig. 1).

(1) Potential participants may register via an online questionnaire available at https://www.vaccelerate.eu/volunteer-registry and data are stored. (2) Entities managing or performing clinical

Table 1
VACCELERATE Volunteer Registry - Survey Categories Captured.

ADULTS	CHILDREN
1. Personal data	
Volunteer's first name	Legal representative's first name
Volunteer's last name	Legal representative's last name
E-Mail	
Year of birth	
Gender (female, male, diverse)	
2. Distance willing to travel to study site (≤10 km, ≤25 km, ≤50 km, ≤100 km, >100 km)	
3. COVID-19 infection (Not infected, infected + month/year of diagnosis)	
4. Vaccination status ([un-]vaccinated [vaccine brand, number of doses and administration month and year])	
5. Pre-existing illnesses	
Cardiovascular diseases	
High blood pressure	Congenital heart defect
Coronary heart disease or history of heart attack	
Heart failure	
Lung / Liver / Kidney diseases	
Chronic hepatitis B or C	
	Asthma
	Polycystic kidney disease
	Renal malformation, double kidney
Asthma, COPD, chronic bronchitis or emphysema	
Chronic non-infectious liver disease, including liver cirrhosis	
Chronic kidney disease, including renal insufficiency	
Metabolic diseases	
Diabetes mellitus	
	Overweight
	Congenital metabolic disorder
	Cystic fibrosis
20 kg or more overweight	
Diseases with impairment of the immune system	
HIV	
Cancer currently being treated or having been treated in the last 2 years	
	Congenital immunodeficiencies
	Underlying rheumatological disease
Other pre-existing conditions	
Epilepsy	
Serious chronic illness of the stomach or intestine	
Serious disease of the musculoskeletal system	
Mental illness	
	Hypoxic brain damage
ADULTS	**CHILDREN**
	Failure to thrive
	Chromosomal anomalies (e.g., trisomy 21)
History of stroke	
Pregnancy and breastfeeding (Expected date of delivery and end of breastfeeding [month and year])	
Other illness (please specify)	
No pre-existing illness	

COPD, chronic obstructive pulmonary diseases; COVID-19, coronavirus diseases 2019; HIV, human immunodeficiency virus.

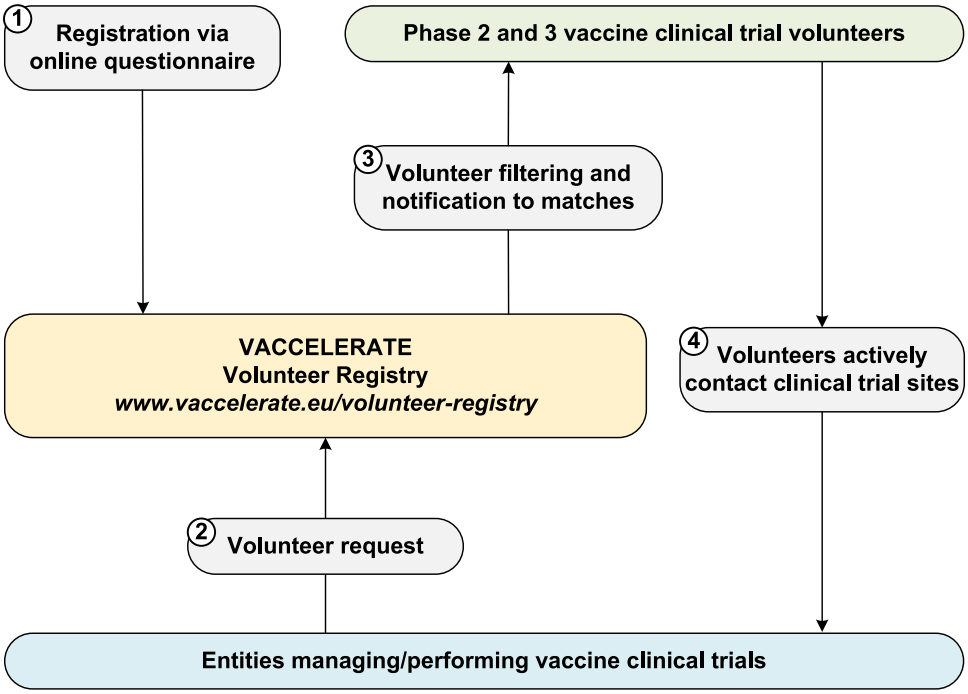

Fig. 1. Volunteer Registry Management.

trials might contact VACCELERATE Volunteer Registry with a participant request. (3) Potential participants are identified and filtered according to the trial's key enrolment criteria, and briefly informed about the clinical trial, including contact details of the trial site closest to their area of residence, via e-mail. (4) Interested volunteers can independently decide whether they contact the trial site to learn more about the clinical trial and if they wish to participate.

In order to determine the need for country-based registries, VACCELERATE National Coordinators (NC) provide information on existing (COVID-19) clinical trial registries in their countries. NCs are the main point of contact for member states reaching out to VACCELERATE, including translations and implementation of consortium activities in their respective countries.

Connecting the VACCELERATE Volunteer Registry with other established national registries is encouraged, for example through linking to these registries on the VACCELERATE website and sharing support requests from clinical trials sponsors. The VACCELERATE Volunteer Registry and established, independent national registries do not share any collected personal data. National versions of the VACCELERATE Volunteer Registry are established as needed upon request of the respective NC, and adjustments are made in terms of required languages (Table 2) and minor/adult cut-offs. While the VACCELERATE Volunteer Registry guarantees compliance with European legislation and requirements, NC may adapt their respective national version with regards to local and national regulations, with a particular focus on data protection and in coordination with local ethics committees.

2.1. Ethics and data protection

The VACCELERATE Volunteer Registry was approved by the Ethics Committee of the Medical Faculty of the University of Cologne (Cologne, Germany) (Study number 20–1536). If required, the corresponding local ethics committee of each participating country may also approve the VACCELERATE Volunteer Registry. Personal data are collected in accordance with article 13 of the EU General Data Protection Regulation (GDPR), [22] with no data transfer either within or outside the EU and no data are shared to any third party.

3. Registry progress and outlook

3.1. Participation

As of May 2022, the VACCELERATE Volunteer Registry is available in 12 countries and 13 languages (Arabic, English, German, Greek, Irish Gaelic, Italian, Lithuanian, Norwegian (Bokmål), Polish, Portuguese, Spanish, Swedish and Turkish). More than 36,000 volunteers from 12 European countries have registered in the VACCELERATE Volunteer Registry (Fig. 2). Among these, 35,443 volunteers (95.81%) have registered from Germany (the first registry, activated at the end of 2020, Fig. 3), 725 (2.0%) from Ireland, 155 (0.4%) from Cyprus, 130 (0.4%) from Austria, 74 (0.2%) from Greece, 50 (0.1%) from Spain, 41 (0.1%) from Sweden, 25 (0.1%) from Portugal, 22 (0.1%) from Norway, 14 (0.04%) from Turkey and 7 each (0.02%) from Italy and Lithuania, respectively. A total of 18,987 (51.3%) registered individuals identified as female, 17,602 (48.0%) as male, and 104 (0.3%) reported other gender identities. Volunteers were born between 1925 and 2022 (overall median age 38 years, adults (n = 32,717) 40 years old, children (n = 3,976) 9 years old). Most of the patients reported no underlying conditions prior to their inclusion in the registry (overall 58.7%, adults 56.7%, children 79.0%). Among the volunteers reporting pre-existing illnesses, cardiovascular diseases (n = 4,293, 11.6%), overweight (n = 3,356, 9.1%, lung diseases (n = 2,913, 7.9%), diabetes mellitus (n = 930, 2.5%), and acquired immunodeficiencies (n = 627, 1.7%) were the most commonly reported ones (Table 3). In less than one year from its launch, the Volunteer Registry was contacted more than 10 times to support identification of participants for clinical trials, with more than 15,000 volunteers matched to clinical trials in Germany alone. The VACCELERATE Volunteer Registry will be launched in further countries and languages during the coming months (Table 2, Fig. 2).

Table 2
VACCELERATE Volunteer Registry Country-Language Correlation.

Country Language	AT	*BE**	CY	*CZ**	DE	ES	GR	*HU**	IE	*IL**	IT	LT	*NL**	NO	PT	SV	TR
Arabic					x					x							
*Czech**				x													
*Dutch**		x											x				
English	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
*French**		x															
German	x				x						x						
Greek			x				x										
*Hebrew**										x							
*Hungarian**								x									
Irish Gaelic									x								
Italian					x						x						
Lithuanian												x					
Norwegian, Bokmål														x			
Polish					x												
Portuguese															x		
*Russian**										x							
Spanish						x											
Swedish																x	
Turkish			x		x												x

* Country or language to be activated.
AT, Austria; BE, Belgium; CY, Cyprus; CZ, Czechia; DE, Germany; ES, Spain; GR, Greece; HU, Hungary; IE, Ireland; IL, Israel; IT, Italy; LT, Lithuania; NL, Netherlands; NO, Norway; PT, Portugal; SV, Sweden; TR, Turkey.

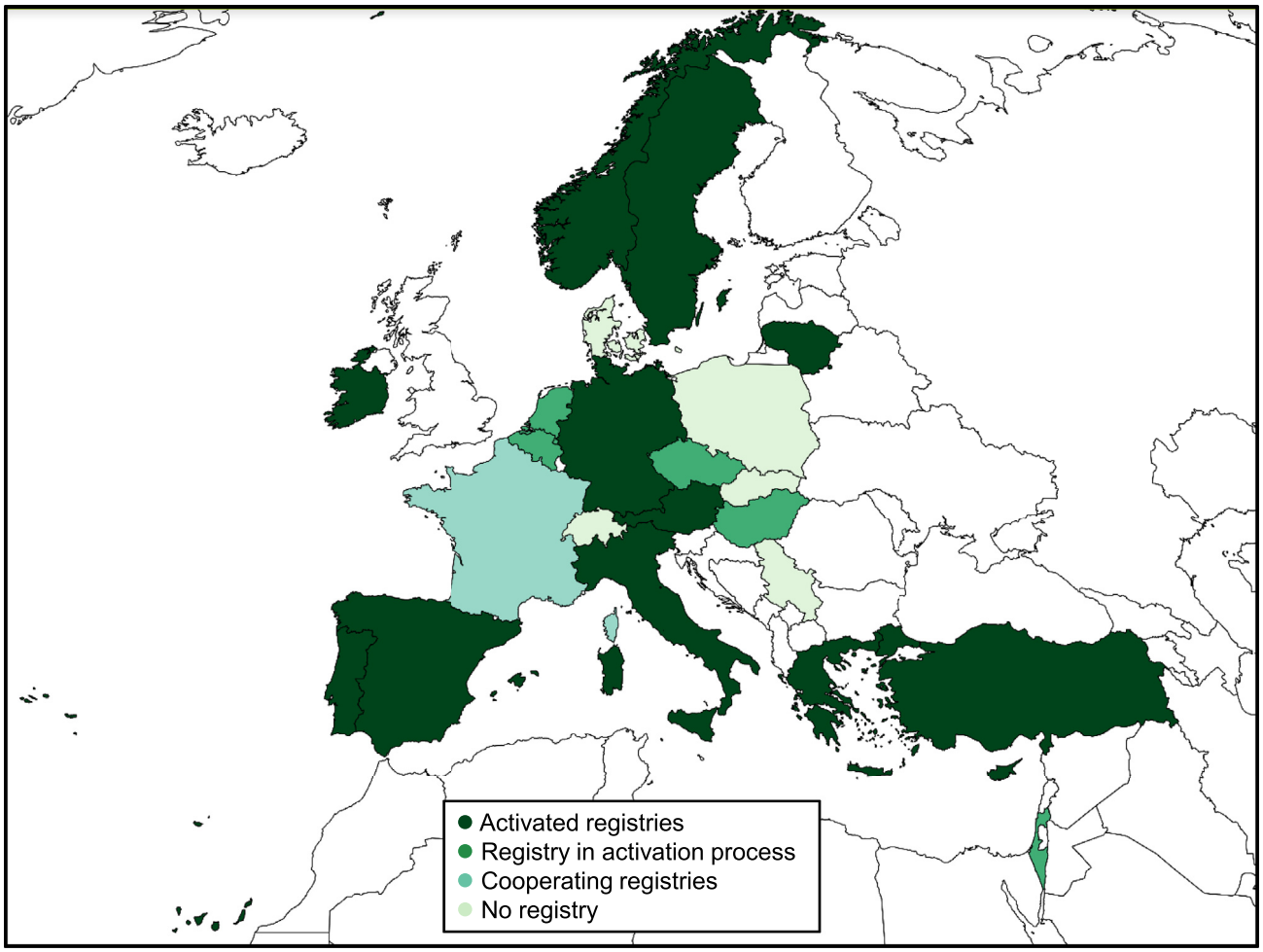

Fig. 2. Current Implementation of the VACCELERATE Volunteer Registry *Active registries: Austria, Cyprus, Germany, Greece, Ireland, Italy, Lithuania, Norway, Portugal, Spain, Sweden, and Turkey; Registries in activation process: Belgium, Czech Republic, Hungary, Israel, and the Netherlands; Cooperating registries: France; No registry: Denmark, Poland, Serbia, Slovakia, and Switzerland.*

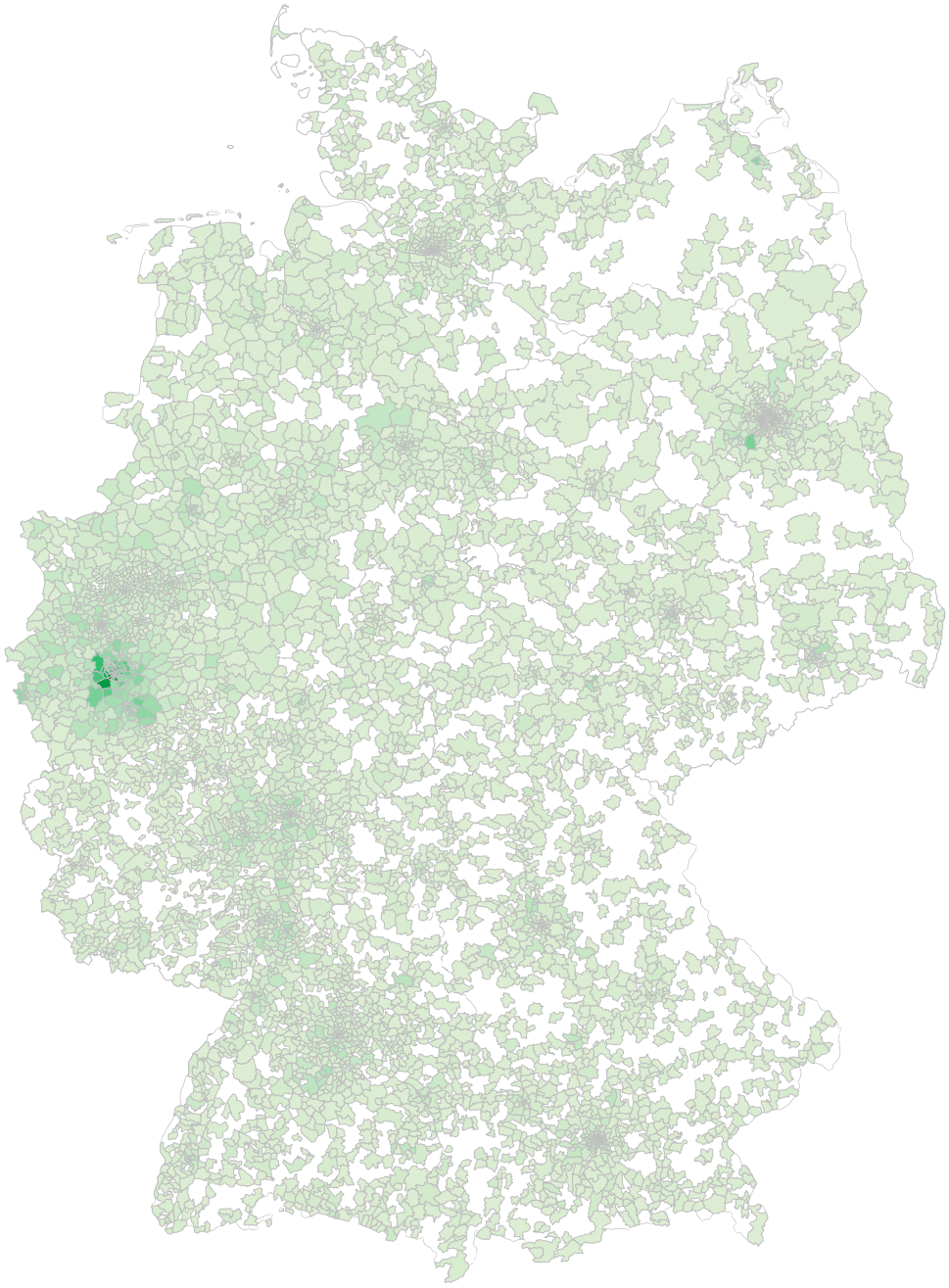

Fig. 3. Current Geographical Distribution of Volunteers in Germany *Heat map of the volunteer distribution in Germany. Coloured areas represent ZIP-code regions with at least one registered volunteer. The darker the area, the more registered volunteers there are. In grey areas, no volunteers are registered.*

3.2. Development of promotional and educational tools for volunteers in clinical trials

VACCELERATE is developing harmonised promotional materials for the Volunteer Registry that can be adapted according to country and language needs. Promotional and educational material targets various populations, such as children and the elderly as well as 'hard-to-reach (HTR)' populations that are largely underrepresented in clinical trials, like migrants or national minorities using languages different from the prevailing national language.

Promotional materials include brochures, content for social media and flyers. All materials will be freely available to the scientific community and industry, as well as to the general public via relevant traditional media (newspapers, radio stations, television channels), public health authorities, patient advocacy groups, scientific associations and societies, VACCELERATE social media channels (LinkedIn® and Twitter®), websites, and additional other stakeholder organisations both at a national (via NC) and pan-European level. NC will take the lead in advertising campaigns promoting national versions of the VACCELERATE Volunteer Registry, and with minor adaptations to match local requirements and needs. Lessons learned and best practice models of successful campaigns will be shared among NC.

Entities outside VACCELERATE were consulted to optimise promotional efforts. The European Patients' Academy on Therapeutic Innovation foundation (EUPATI) [23] was contacted to explore potential synergies, specifically with regards to patient engagement and promotion of the Volunteer Registry. Think Young, [24]

Table 3
Description of the VACCELERATE Volunteer Registry Participants.

	Children (n = 3,976)		Adults (n = 32,717)		Total (n = 36,693)	
	n	%	n	%	n	%
Country						
Germany	3897	98.0	31,546	96.4	35,443	96.6
Ireland	62	1.6	663	2.0	725	2.0
Cyprus	2	0.1	153	0.5	155	0.4
Austria	8	0.2	122	0.4	130	0.4
Greece	1	0.0	73	0.2	74	0.2
Spain	1	0.0	49	0.1	50	0.1
Sweden	0	0.0	41	0.1	41	0.1
Portugal	4	0.1	21	0.1	25	0.1
Norway	0	0.0	22	0.1	22	0.1
Turkey	0	0.0	14	0.0	14	0.0
Italy	1	0.0	6	0.0	7	0.0
Lithuania	0	0.0	7	0.0	7	0.0
Age (years), median (IQR) [range]	9 (5–14), [0–17]		40 (30–53), [18–96]		38 (26–52), [0–96]	
Children						
0–4	896	22.5	0	0.0	896	22.5
5–11	1654	41.6	0	0.0	1654	41.6
12–17	1426	35.9	0	0.0	1426	35.9
Adults						
18–29	0	0.0	7565	23.1	7565	23.1
30–39	0	0.0	8195	25.0	8195	25.0
40–49	0	0.0	6261	19.1	6261	19.1
50–59	0	0.0	6385	19.5	6385	19.5
60–69	0	0.0	3191	9.8	3191	9.8
70–79	0	0.0	970	3.0	970	3.0
80–89	0	0.0	135	0.4	135	0.4
$\geq$ 90	0	0.0	15	0.0	15	0.0
Gender						
Female	1876	47.2	17,111	52.3	18,987	51.7
Male	2090	52.6	15,512	47.4	17,602	48.0
Diverse	10	0.3	94	0.3	104	0.3
Previous COVID-19 infection	69	1.7	1578	4.8	1647	4.5
Number of COVID-19 doses						
None reported	3888	97.8	26,649	81.5	30,537	83.2
At least 1	18	0.5	1253	3.8	1271	3.5
At least 2	60	1.5	3056	9.3	3116	8.5
At least 3	10	0.3	1686	5.2	1696	4.6
At least 4	0	0.0	73	0.2	73	0.2
Underlying conditions						
Cardiovascular diseases	2	0.1	4291	13.1		4293
Overweight	8	0.2	3348	10.2		3356
Lung diseases	165	4.1	2748	8.4		2913
Diabetes mellitus	17	0.4	913	2.8		930
Acquired immunodeficiencies	5	0.1	622	1.9		627
HIV	0	0.0	271	0.8		271
Cancer (active previous last 2 years)	5	0.1	358	1.1		363
Liver diseases	0	0.0	196	0.6		196
Chronic hepatitis B or C	0	0.0	68	0.2		68
Renal diseases	20	0.5	193	0.6		213
Epilepsy	32	0.8	172	0.5		204
Mental illness	61	1.5	1723	5.3		1784
Gastrointestinal illnesses	9	0.2	273	0.8		282
Musculoskeletal system illnesses	9	0.2	318	1.0		327
Other diseases	555	14.0	8024	24.5		8579
Current or expected breastfeeding	0	0.0	1265	3.9		1265
Pregnancy	0	0.0	385	1.2		385
History of stroke	0	0.0	178	0.5		178
Chromosomal anomalies (e.g., trisomy 21)	30	0.8	0	0.0		30
Failure to thrive	14	0.4	0	0.0		14
Underlying rheumatological disease	14	0.4	0	0.0		14
Congenital immunodeficiencies	8	0.2	0	0.0		8
Congenital metabolic disorder	6	0.2	0	0.0		6
Cystic fibrosis	4	0.1	0	0.0		4
Hypoxic brain damage	4	0.1	0	0.0		4
Other diseases	475	11.9	6581	20.1		7056
No pre-existing disease	3141	79.0	18,551	56.7	21,103	59.1

COVID-19, coronavirus disease 2019; HIV, human immunodeficiency virus; IQR, interquartile range.

a not-for-profit organisation (NFPO), was consulted with regards to a) approaches targeting adolescents and young adults, e.g. educational and informational material to minimise information gaps and increase knowledge and b) strategies to improve awareness of, provide access to, and improve quality of information on vaccination processes and participation in clinical trials for the general

public. Local entities were involved as needed to promote the VACCELERATE Volunteer Registry. [25] The European Patients Forum (EPF) was invited to share the perspective of EU patient advocacy groups and to discuss per-country requirements, challenges, and commonalities of participating in the Volunteer Registry. [26].

3.3. Volunteer Registry promotion among underserved/hard-to-reach groups

In order to overcome the traditional underrepresentation of underserved or HTR communities in clinical trials, such as subjects affected by various forms of immunosuppression both on an organic and iatrogenic basis, institutionalized elderly populations, pregnant women, or extreme age groups, understanding country-specific barriers must come first. Identifying the reasons for poor participation will aid to develop suitable methods and to increase access and engagement, while promoting the Volunteer Registry. The VACCELERATE Volunteer Registry group will investigate the access mechanisms of underserved/HTR groups to clinical trials participation, seeking out previous experiences by local authorities, NFPOs, and other relevant organisations.

4. Outlook

We aim for the VACCELERATE Volunteer Registry to become a powerful tool across Europe and act as a central hub for clinical trials, bringing together potential volunteers with entities managing and performing clinical trials, with the ultimate goal of fast-tracking the process of vaccine development and implementation at the pan-European level.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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