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

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https://doi.org/10.1016/j.vaccine.2022.05.022
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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 under-represented 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** | Legal representative's first name  
Volunteer's first name  
Volunteer's last name  
E-Mail  
Year of birth  
Gender (female, male, diverse) |
| **2. Distance willing to travel to study site** | COPD, chronic obstructive pulmonary diseases; COVID-19, coronavirus diseases 2019; HIV, human immunodeficiency virus. |
| (≤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** | Congenital heart defect  
**Cardiovascular diseases**  
High blood pressure  
Coronary heart disease or history of heart attack  
Heart failure |
| **Lung / Liver / Kidney diseases** | 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** | Overweight  
Congenital metabolic disorder  
Cystic fibrosis |
| Diabetes mellitus | |
| **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**  
History of stroke  
Pregnancy and breastfeeding (Expected date of delivery and end of breastfeeding [month and year]) |
| **CHILDREN** | Failure to thrive  
Chromosomal anomalies (e.g., trisomy 21)  
Other illness (please specify)  
No pre-existing illness |

COPD, chronic obstructive pulmonary diseases; COVID-19, coronavirus diseases 2019; HIV, human immunodeficiency virus.
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 VACCELERATE 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).
| Country Language | AT | BE* | CY | CZ* | DE | ES | GR | HU* | IE | IL* | IT | LT | NL* | NO | PT | SV | TR |
|------------------|----|-----|----|-----|----|----|----|-----|----|-----|----|----|-----|----|----|----|----|
| Arabic           |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Czech*           |    |     |    |     |    |    |    | x   |    |     |    |    |     |    |    |    |    |
| Dutch*           | x  |     |    |     |    |    |    | x   |    |     |    |    |     |    |    |    |    |
| English          | x  | x   | x  | x   | x  | x  | x  | x   | x  | x   | x  | x  | x   | x  | x  | x  | x  |
| German           |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Greek            |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Hebrew*          |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Hungarian*       |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Irish Gaelic     |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Italian          |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Lithuanian       |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Norwegian, Bokmål|    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Polish           |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Portuguese       |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Russian*         |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Spanish          |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Swedish          |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |
| Turkish          |    |     |    |     |    |    |    |     |    |     |    |    |     |    |    |    |    |

* 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.
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]
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 population.

| Country   | Children (n = 3,976) | Adults (n = 32,717) | Total (n = 36,693) |
|-----------|----------------------|---------------------|--------------------|
|           | n                    | %                   | n                  | %                   |
| 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  | Adults  | Total     |
|-----------|---------|-----------|
| 0–4       | 896     | 896       | 22.5 |
| 5–11      | 1654    | 1654      | 41.6 |
| 12–17     | 1426    | 1426      | 35.9 |
| Adults    |         |           |       |
| 18–29     | 0       | 0         | 0.0  |
| 30–39     | 0       | 0         | 0.0  |
| 40–49     | 0       | 0         | 0.0  |
| 50–59     | 0       | 0         | 0.0  |
| 60–69     | 0       | 0         | 0.0  |
| 70–79     | 0       | 0         | 0.0  |
| 80–89     | 0       | 0         | 0.0  |
| ≥ 90      | 0       | 0         | 0.0  |
| Gender    |         |           |       |
| Female    | 1876    | 17,111    | 51.7 |
| Male      | 2090    | 15,512    | 48.0 |
| Divere    | 10      | 94        | 0.3  |
| Previous COVID-19 infection | 69 | 1578 | 4.5 |
| Number of COVID-19 doses |     |           |       |
| None reported | 3888 | 26,649 | 83.2 |
| At least 1 | 18       | 1253       | 3.8  |
| At least 2 | 60       | 3056       | 9.3  |
| At least 3 | 10       | 1686       | 5.2  |
| At least 4 | 0        | 73         | 0.2  |
| Underlying conditions |     |           |       |
| Cardiovascular diseases | 2       | 4291       | 13.1 |
| Overweight | 8        | 3348       | 10.2 |
| Lung diseases | 165    | 2748       | 8.4  |
| Diabetes mellitus | 17      | 913        | 2.8  |
| Acquired immunodeficiencies | 5     | 622        | 1.9  |
| HIV       | 0       | 271        | 0.8  |
| Cancer (active previous last 2 years) | 5       | 358        | 1.1  |
| Liver diseases | 0       | 196        | 0.6  |
| Chronic hepatitis B or C | 0       | 68         | 0.2  |
| Renal diseases | 20     | 193        | 0.6  |
| Epilepsy  | 32      | 172        | 0.5  |
| Mental illness | 61     | 1723       | 5.3  |
| Gastrointestinal illnesses | 9      | 273        | 0.8  |
| Musculoskeletal system illnesses | 9    | 318        | 1.0  |
| Other diseases | 555   | 8024       | 24.5 |
| Current or expected breastfeeding | 0     | 1265       | 3.9  |
| Pregnancy | 0       | 385        | 1.2  |
| History of stroke | 0     | 178        | 0.5  |
| Chromosomal anomalies (e.g., trisomy 21) | 30     | 0          | 0.0  |
| Failure to thrive | 14    | 0          | 0.0  |
| Underlying rheumatological disease | 14     | 0          | 0.0  |
| Congenital immunodeficiencies | 8      | 0          | 0.0  |
| Congenital metabolic disorder | 6      | 0          | 0.0  |
| Cystic fibrosis | 4      | 0          | 0.0  |
| Hypoxic brain damage | 4      | 0          | 0.0  |
| Other diseases | 475    | 6581       | 20.1 |
| No pre-existing disease | 3141   | 18,551     | 56.7 |

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

Funding statement

The German Volunteer Registry receives funding from the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF) specifically grant BMBF01KX2040. The VACCELERATE Volunteer Registry, i.e., registries outside Germany, has received funding from the European Union's Horizon 2020 research and innovation programme (grant agreement No 101037867).

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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