VACCELERATE Qs & As

Consortium Qs & WP1 – Project Management & Network Coordination

Q: What kind of trials do you run?

A: We run phase 2 and phase 3 vaccine trials, with hundreds to thousands of participants with an initial focus on the COVID-19 pandemic, and for the future expansion to any forthcoming European epidemic/pandemic.

We aim primarily at specific trials closing knowledge gaps rapidly especially in populations underrepresented in current vaccine trials (children, pregnant or breast-feeding women, individuals with comorbidities, immunosuppression, or allergies).

Q: Why do we need more clinical trials when we already have 3 approved vaccines?

A: More technologies should be tested and operational in case of new virus variants in addition to improving vaccine handling & distribution and trials in underrepresented populations.

Q: How are Member States involved?

A: In order to grow the existing site network within VACCELERATE-EUVAP, National Coordinators of each Member State are the key. They have been selected by their peers based on their clinical trial expertise, representation, and responsiveness. National Coordinators are the VACCELERATE Member State ambassadors and will encourage the enrolment of additional sites in their respective countries and will identify pre-existing national networks of clinical trial sites that should be offered to align with VACCELERATE.

Q: How does VACCELERATE interact with authorities, e. g. EMA, ECDC, or WHO, and sponsors of clinical trials?

A: VACCELERATE will bring together stakeholders, including public health authorities, vaccine developers, clinical trial sites and laboratories, and existing study networks across Europe into one VACCELERATE network. Through EUVAP, VACCELERATE has already matched sponsors and clinical sites in several countries for ongoing phase 2 & 3 COVID-19 vaccine clinical trials. Once VACCELERATE is operational as *the* European single entry-point for vaccine developers, many further collaborations are expected to follow. These will focus on COVID-19 for now but will expand to vaccines against other diseases in the future.

WP2 – Communication & General Public Outreach

Q: How will VACCELERATE ensure all vulnerable groups are included in clinical trials & also to overcome vaccine hesitancy?

VACCELERATE will develop targeted information packages which will be available in all European languages. These are adapted to the intended population i.e. cartoon videos for children. Vaccine hesitancy will be addressed through systematic reviews of available information and specific and clear information material to dispel myths about vaccines and clinical trials.

WP3 – Clinical Trial Site Capacity Building

Q: What is the added value of a European clinical trials network?

A: A permanent vaccine trials network across Europe ensures an adequately prepared infrastructure to rapidly initiate vaccine studies across different vaccine types, as well as age- and patient-groups. The network is of critical value for the conduct of such randomized controlled trials (RCTs) on vaccine efficacy, safety and tolerability within a relevant timeframe to guide evidence-based vaccine development.

Q: Explain how the decisions / prioritisation is done

A: When a vaccine developer seeks clinical trial sites for a new clinical trial, the VACCELERATE team is contacted to identify sites that match the required selection criteria such as study phase, geographical area, enrolment capacity, trial experience, etc. The VACCELERATE team notifies matching sites about the study which have previously provided their profile through EUVAP. In the future, this will be routed through the respective National Coordinators, to maintain an overview at country level.

WP4 – Laboratory Site Capacity Building

Q: What is the added value of a European laboratory network?

A: A fully operational laboratory network is essential to support the clinical studies. In Europe, such a network has been built in more than 40 countries, with support from the European Commission. Labs will be trained study-specifically to achieve standardised and harmonised sampling and to deploy next-generation diagnostic methods.

A: How will VACCELERATE monitor new variants?

Q: Exhaustive etiologic diagnosis will be performed on the samples collected from patients included in the vaccination trials. Subsequently, we will perform targeted and whole genome sequencing providing information about evolution of the virus, enable identification of potential virulence markers, and emergence of markers of resistance to vaccination. Sequencing data will feed into the European COVID-19 Data Platform.

WP5 – Public Health Needs

Q: What public health needs does VACCELERATE address?

A: VACCELERATE will

- continuously monitor COVID-19 trial quality and results to improve future trials.
- answer gaps in public health knowledge on COVID-19 vaccines and vaccination in general.
- will give us information for future vaccine trials.
- will work on answering vaccination questions related to ethnicity and gender issues, as well as for other populations such as paediatric, pregnant, breast feeding, and patients with specific comorbidities, immunosuppression, or allergies.
- will aim to close other gaps, such as the utility of COVID-19 vaccine combinations, the length of immunity or the influence of certain virus mutations on vaccine efficacy.

Q: What are the groups where clinical trials are needed most?

A: Children, immunosuppressed patients, chronic diseases, the extremes of age, pregnant or breast-feeding women.

WP6 – Immune Monitoring

Q: What are the added values of immune monitoring in VACCELERATE?

A1: Standardisation of neutralising antibody assays: Phase 3 clinical trials have shown the efficacy of several candidates. However, at present the protective immunological correlates (biomarker) are not precisely determined. Neutralising antibodies appear to be good candidates but the lack of standardisation for this assay makes it difficult to compare one assay to another. This standardisation will be one of the objectives of VACCELERATE, thus allowing comparison between different vaccines and also in the study of the response against the different variants.

A2: Standardisation of the T-cell response: The human immune response consists of two distinct elements, namely an antibody response and a cellular (or T-cell) immune response. Remarkably, both immune responses appear important to elicit a strong and lasting protection against the virus. However, the T-cell response is much less analysed at present, although it could be one of the important elements to be stimulated with future vaccine candidates. This is because the parts of the virus that stimulate the T-cell response are different from those that induce antibody responses, and therefore variants are unlikely to have the same impact on the antibody and the T-cell response. The T-cell response is therefore a key element in understanding, together with the antibody response, to determine the clinical response to the variants. The standardisation of this assay and its comparison from one clinical trial to another seems indispensable, and could pave the way for a more intelligent use of vaccines and combination of different vaccines in the future.

A3: Standardisation of the mucosal immune response: This response is currently poorly studied even though it is the key element allowing to analyse the protection not only against the disease (end point of phase 3 clinical trials) but also against the infection and therefore against transmission. The analysis of the mucosal immune response and its standardisation are therefore essential elements in defining effective vaccine strategies at the collective level.

A4: Harmonisation with global initiatives: There are currently a large number of clinical trials ongoing around the world. Each of these have their own unique properties and many use slightly different methods for analysing the immune responses. Developing a standardised and validated set of immune monitoring assays for COVID-19 vaccine trials in VACCELERATE can put Europe in a strong position for global standardisation and collaboration in this area.

WP7 – Data Management, Standards & Sharing

Q: How will the network make the best possible use of the clinical trial data?

A: VACCELERATE will offer services promoting harmonised data collection and management, both in terms of content (clinical outcomes) and of data standards, making data from multiple trials interoperable and available for secondary analyses. It will also promote data sharing solutions compliant with the European regulations, hosted by the EU COVID-19 Data Portal.

WP8 – Volunteer Registries

Q: What is the added value of the volunteer registry in VACCELERATE?

A: The three main pillars of the VACCELERATE EU consortium are SPEED- TRANSPARENCY-INCLUSIVENESS.

The overall objective is the design and implementation of an EU-wide, dynamic, harmonised, and sustainable volunteer registry for phase 2 & 3 vaccine clinical trials with an initial focus on the COVID-19 pandemic, and for the future expansion to any forthcoming European epidemic/pandemic. The registry can be used to facilitate access to populations underrepresented in current vaccine trials. Not all European countries have implemented such an infrastructure, so the consortium will strive to expand volunteer registries, from healthy individuals to patients in specific sub-groups. Thus, added values of VACCELERATE for vaccine developers lie in the specific expertise needed for vaccine trials, combined with access to volunteers with or without co-morbidities, in- and out-patient settings, and the capacity to enrol a high number of participants in a short period of time.