



Universiteit Antwerpen
| Faculteit Geneeskunde en
Gezondheidswetenschappen

Perspective for the future: Vaccinopolis and biopreparedness initiative

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Biopreparedness ... historically

- The terrorist use of diseases as bioweapons has been one of the major security concerns in recent years
 - Anthrax letter attacks in the USA in 2001
 - = uncertain threat of intentional outbreaks of diseases
- Constantly changing very real threat from diseases, epidemics, and pandemics
 - H1N1 influenza pandemic, SARS, H5N1 bird influenza, SARS-CoV2, ...

The need for speed

- If the world had developed a COVID-19 vaccine **within 100 days**, the first injections might have been given in **April 2020**, when there were just **2.3 million cases** of COVID-19 rather than on the **8th of December**, when **more than 68 million people** had already been infected with COVID-19

Biopreparedness – key elements from re-active mode to pro-active mode!

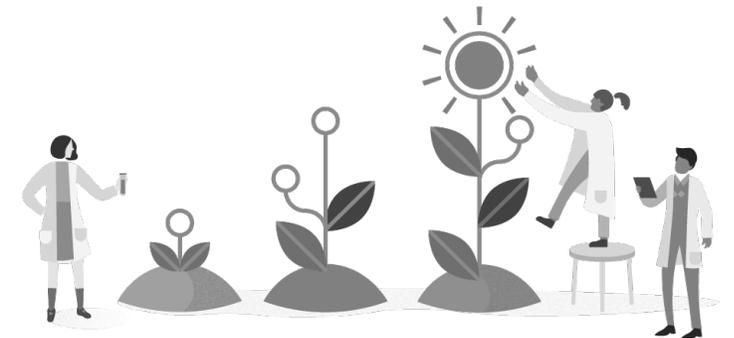
- **Regulatory**
- **Platform technologies (e.g. create a library of prototyp vaccines)**
- **Process innovations**
 - Availability of data (epi, vaccine, strain, ...)
 - Data sharing
- **Excellence in execution**
- **National and international collaboration**
 - Peace time studies and activities
 - Vaccine schedules, co-administration, alternative administration, ... (availability of approved vaccines!!)
 - Community engagement, re-create trust in science
- **What would you regret if you don't operate now?**
 - Speed/scale/access

Bio-preparedness vision
aligns with
global objectives to improve our collective response to epidemics

Mission = help humanity in the fight against infectious diseases

> **Vaccinopolis**: local bio-preparedness by accelerating the vaccine development & testing process

> **EU-Vaccelerate**: will strengthen the capacity within Europe and improve collaboration cross-national





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VACCELERATE



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- VACCELERATE is a European project, a Horizon 2020 program, aimed at **accelerating vaccine development**.
STARTED: February 2021
END: February 2024
- VACCELERATE is a clinical research network for the coordination & conduct of COVID-19 vaccine trials.
- Network of academic institutions from all over Europe, led by the University of Cologne, Germany

Includes:

- 29 national partners in 18 EU-member states
- 5 non-EU countries, associated to the EU Horizon 2020 research programme

<https://vaccelerate.eu/>



VACCELERATE objectives



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1. Platform building
2. Capacity mapping and building (EUVAP)
3. Volunteer registry
4. Laboratory access
5. Solutions for vaccine development
6. Phase 2 and 3 clinical trials

<https://vaccelerate.eu/>



Extra Work Packages

Master protocol trial platform:

A multinational Phase 2, Randomised, Evaluator-Blinded, Adaptive Master Protocol to Evaluate the Impact of Different COVID-19 Vaccine Booster Strategies in Adults Already Vaccinated Against SARS-CoV-2

WP	Description	WP Leader
11	Evaluation of Immunogenicity of <u>Third mRNA-based Vaccination Dose</u> against COVID-19 in <u>Elderly Persons</u>	UHC, Köln, (GE)
12	Evaluation of Requirement and Optimal <u>Timing of Third mRNA Vaccination Dose</u> against COVID-19 in Adults	NUID UCD, Dublin, (IRL)
13	Evaluation of Immunogenicity and Reactogenicity of reduced COVID-19 mRNA vaccination regimen in <u>children</u> (12-13 YOA)	UMCU, Utrecht, (NL)

Role Centre for the Evaluation of Vaccination



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WP	Description	Update
3	Project Management & Network Coordination	National coordinator for Belgium for 17 Belgian sites
4	Communication & General Public Outreach	<ul style="list-style-type: none">- Cochrane review on factors impacting recruitment to pandemic/epidemic vaccine trials- Survey of attractants and deterrents of vaccine trials + vaccine hesitancy report- Evaluation of educational packs to improve participation in vaccine trials
5	Clinical trial Site Capacity Building	<ul style="list-style-type: none">- SOP's for vaccine trials- Digital training courses for site personnel- EUVAP registrations: adult sites and pediatric sites- Site selection for VACCELERATE vaccine trials
6	Laboratory Site Capacity Building	Group of Herman Goossens <ul style="list-style-type: none">- Lab manual for VACCELERATE trials- Logistics of samples





Role Centre for the Evaluation of Vaccination

WP	Description	Update
7	Public Health Needs	<ul style="list-style-type: none">- Protocols for trials- Living mapping of COVID-19 trials- What questions should be answered by future trials?- Webinars- Belgian IMCOVAS Study – supported by KCE
8	Immune Monitoring	<ul style="list-style-type: none">- Discussion on assays used in VACCELERATE trials- Logistics samples
9	Data management, Standards and sharing	/
10	Volunteer Registry	<ul style="list-style-type: none">- Volunteer registry for Belgium- Promotion of registry- Measure impact on participation in vaccine trials
11-12	Vaccine trials	<ul style="list-style-type: none">- Investigator meeting and staff training- Input on site selection



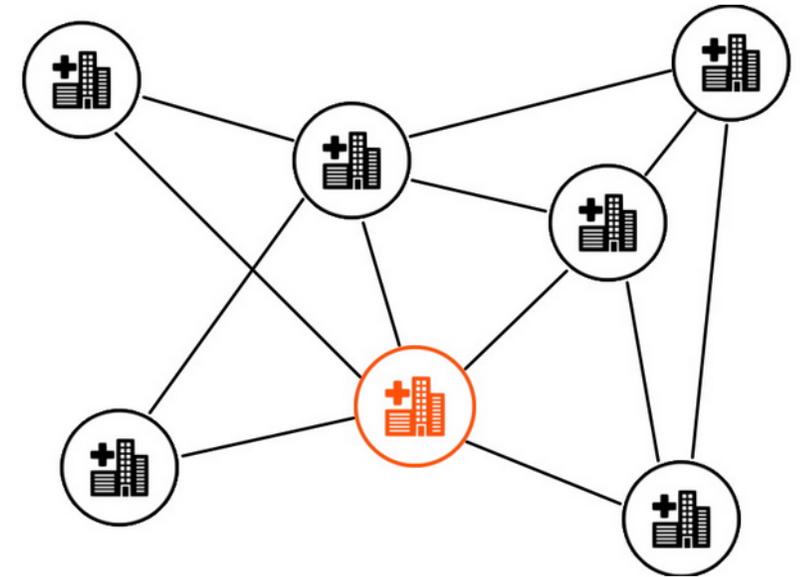


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European Vaccine Trial Accelerator Platform

- Database with different clinical trial sites from all over Europe, who are interested in conducting COVID-19 vaccine trials
- Allows EU-wide mapping on vaccine trial sites
- matchmaker between interested sites and sponsors
- Sites answer a short feasibility questionnaire, that determines their level of experience in vaccine trials

Aim = accelerate clinical development of COVID-19 vaccines for all populations and risk groups



<https://www.euvap.eu/>

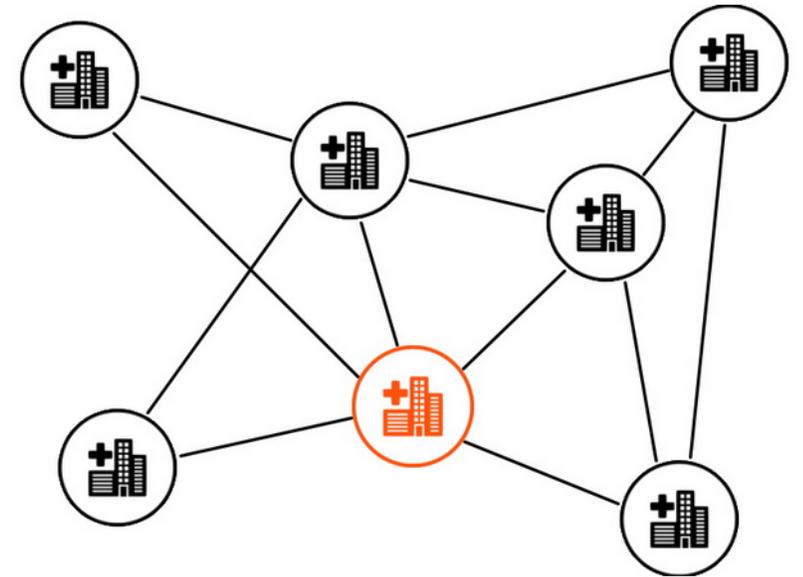




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European Vaccine Trial Accelerator Platform

- 474 clinical trial sites located in EU
- 17 Belgian sites



<https://www.euvap.eu/>





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Volunteer registry Belgium



Introduction Legal information SARS-CoV-2 FAQ Map Language

Welcome to the registration for upcoming vaccination studies!

If you are interested in participating in an upcoming vaccination study...

[REGISTER HERE](#)

Tetanus
Diphtherie
Pertussis
Covid-19



Volunteer registry Belgium

1. Goal

- To help people interested in vaccine studies and organizers of COVID-19 vaccine studies to get in touch more quickly.
- Identifying eligible volunteers for phase 2 & 3 COVID-19 vaccine trials
- **Create an EU-wide, harmonized and sustainable volunteer registry** (future extension to any upcoming European pandemic/epidemic)

2. Advantages

- Capacity to mobilize and recruit a large number of participants into vaccine studies in a short period of time.
- Provides access to volunteers with/without co-morbidities and specific subgroups that are underrepresented in current vaccine studies





Volunteer registry Belgium

3. Who can register?

- Anyone who is interested in participating in a COVID-19 vaccine study.
- all ages, with and without pre-existing conditions, with and without previously experienced COVID19 infection...

!! Registration in the database is entirely voluntary and volunteers may withdraw their consent to registration in the database at any time without giving reasons and without any disadvantages.



Volunteer registry Belgium

4. Working mechanism

- a) **The registry collects limited personal information (age, gender,...)**
 - ✓ This information reflects the core inclusion/exclusion criteria of contemporary phase 2 and 3 COVID-19 vaccine trials.

- b) **Data will be used to contact participants and inform them about available vaccine studies**
 - ✓ Potential study participants receive an email with the basic information about the study and contact information about the investigators at the vaccine trial site

- c) **Potential participants need to actively contact the PI/study center if they wish to participate in the suggested vaccine trial**

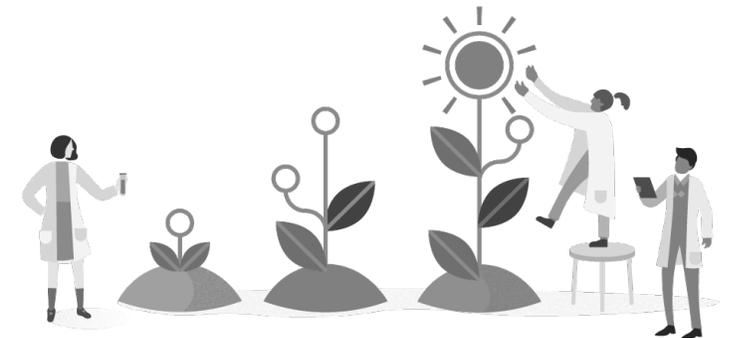
- d) **The study site will take further steps to include the volunteer in their specific vaccine trial**

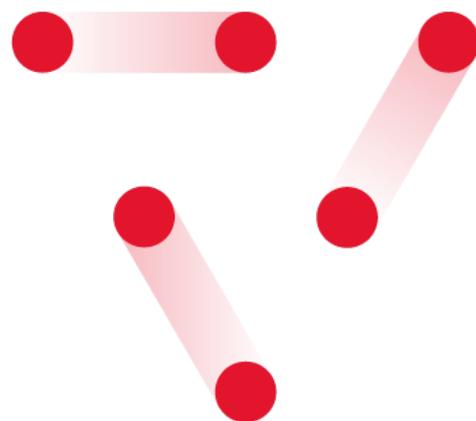
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Vaccinopolis



Powered by UAntwerp

Vaccinopolis



Building on the experience of Poliopolis



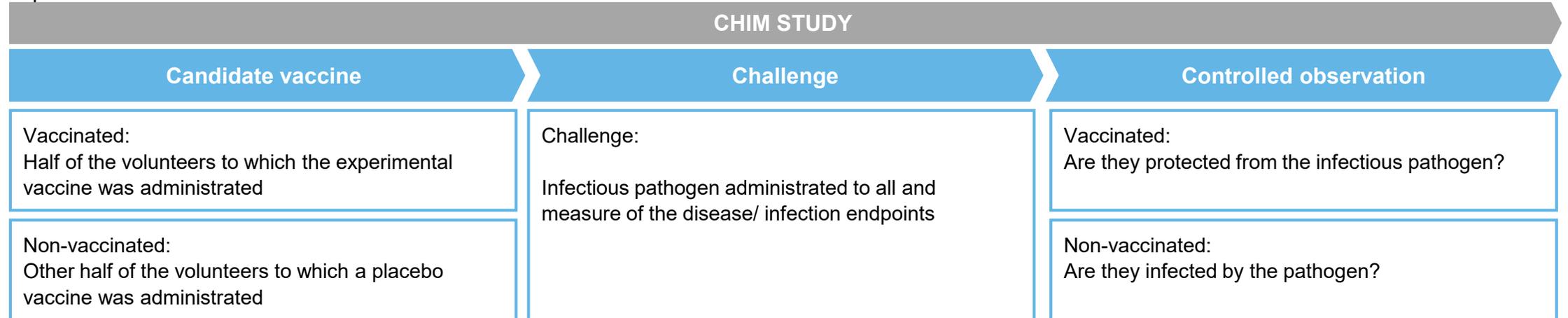
- Van Damme P*, De Coster I*, Bandyopadhyay A, Revets H et al, The safety and immunogenicity of two novel live attenuated, monovalent (serotype 2) oral poliovirus vaccines in healthy adults: a double-blind, single-centre phase 1 study, www.thelancet.com Published online June 4, 2019 [http://dx.doi.org/10.1016/S0140-6736\(19\)31279-6](http://dx.doi.org/10.1016/S0140-6736(19)31279-6)
- Van Damme P*, De Coster I*, Bandyopadhyay A, Suykens L et al, Poliopolis: pushing boundaries of scientific innovations for disease eradication, <https://www.futuremedicine.com/doi/10.2217/fmb-2019-0196>.
- De Coster I*, Leroux-Roels I*, Bandyopadhyay A, Gast C et al, Safety and immunogenicity of two novel type 2 oral poliovirus vaccine candidates compared with a monovalent type 2 oral poliovirus vaccine in healthy adults: two clinical trials, www.theLancet.com Published online December 9, 2020 [https://doi.org/10.1016/S0140-6736\(20\)32541-1](https://doi.org/10.1016/S0140-6736(20)32541-1)

Important role for Controlled Human Infection Model (CHIM) studies in the evaluation of the efficacy of new vaccine candidates

Controlled Human Infection Model (CHIM) studies involve **deliberate exposure** of human volunteers to an **infectious agent** in a regulated environment.

As such, they make it possible to monitor specific elements of immune responses and make a bridge to clinical significance. The volunteers are carefully selected participants that are typically young, healthy and dispose from a normal immune system.

These studies are often conducted in the context of vaccine development, with participants exposed to a pathogen after being immunized with an experimental vaccine:

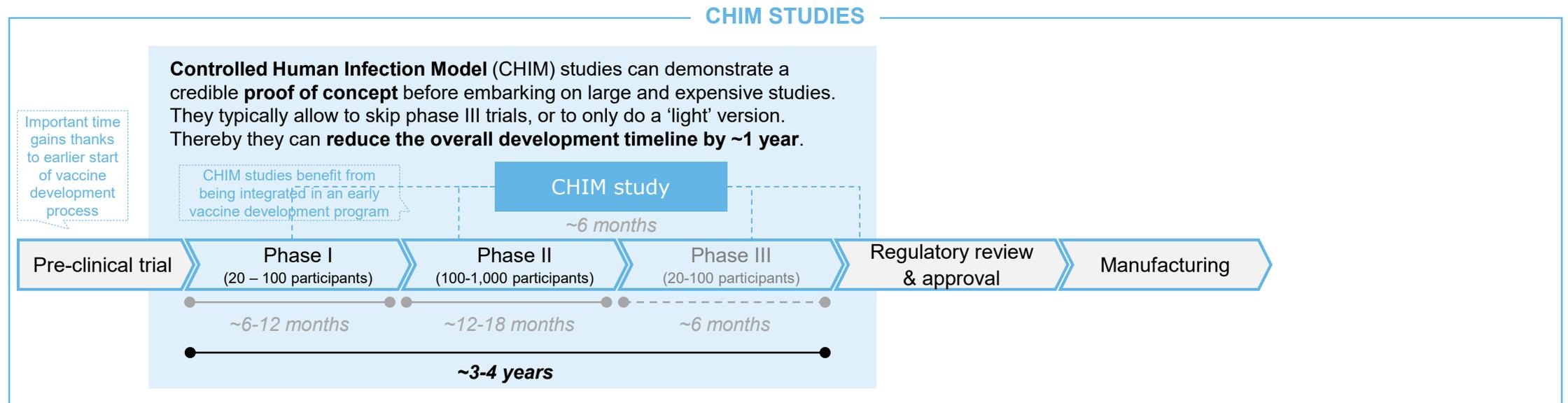
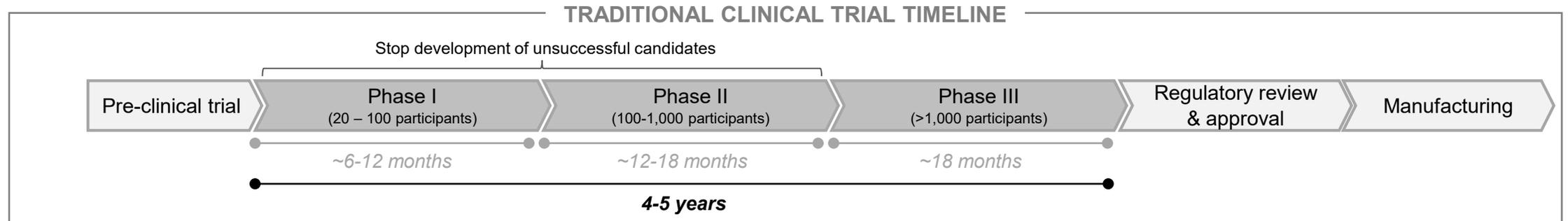


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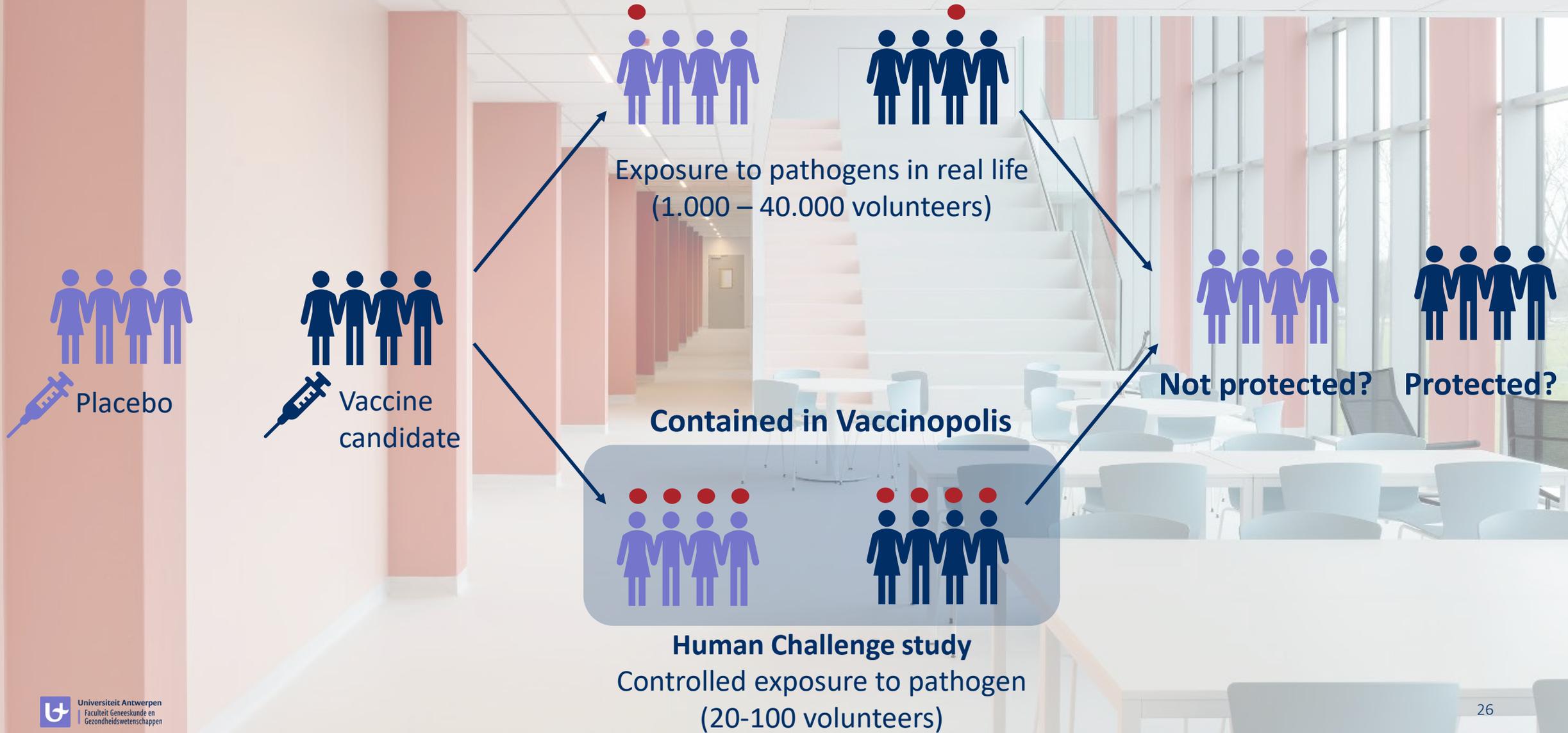
-down-select candidate vaccines or therapeutics before conduct of phase 3 trial: saves money and time

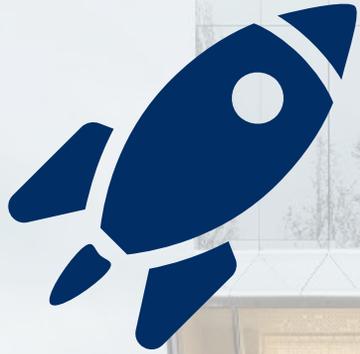
-assess new vaccines for old vaccine-preventable diseases (e.g. new pertussis vaccines)

CHIM studies allow faster selection of potential vaccine candidates and **accelerate vaccines' development timelines** by around twelve months



Human Challenge studies

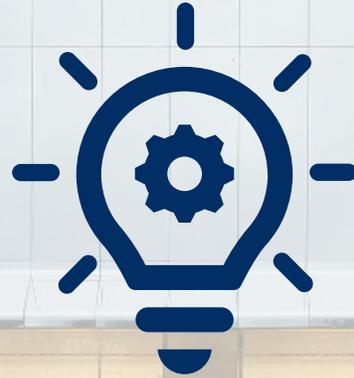




Mission

Accelerate the evaluation of vaccine candidates

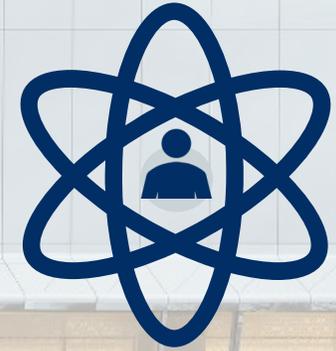
Participate in global efforts for better epidemic preparedness



Vision

Build a unique clinical infrastructure

Support a global network and internationalization



Values

Ensuring maximal participant safety and security

Flexibility to perform almost any vaccine trial

What is does Vaccinopolis offer?



Flexibility to perform almost **any vaccine trial**

First in human, human challenge, containment studies, genetically modified vaccine



In a **residential environment**

in which participants feel at ease



Compliance with GCP, GCLP legislation

managed with a stringent quality system



Facts & Figures

- ✓ Unique 6000m² clinical facility
- ✓ 30 beds quarantine unit (BSL-3 level)
- ✓ Ambulatory vaccine trial unit
- ✓ Fully equipped BSL-2 and BSL-3 labs
- ✓ < 500m from university hospital
- ✓ Located at University of Antwerp
- ✓ Strategic location in Belgium with easy connection to Antwerp and Brussels

The infrastructure at Vaccinopolis



30-bed quarantine facility – BSL2 / BSL3 adjustable

Quarantine unit employs leading infection control technologies, including controlled under-pressure, HEPA-filtering of exhaust air and airlock system, with individualized, compartments for volunteers



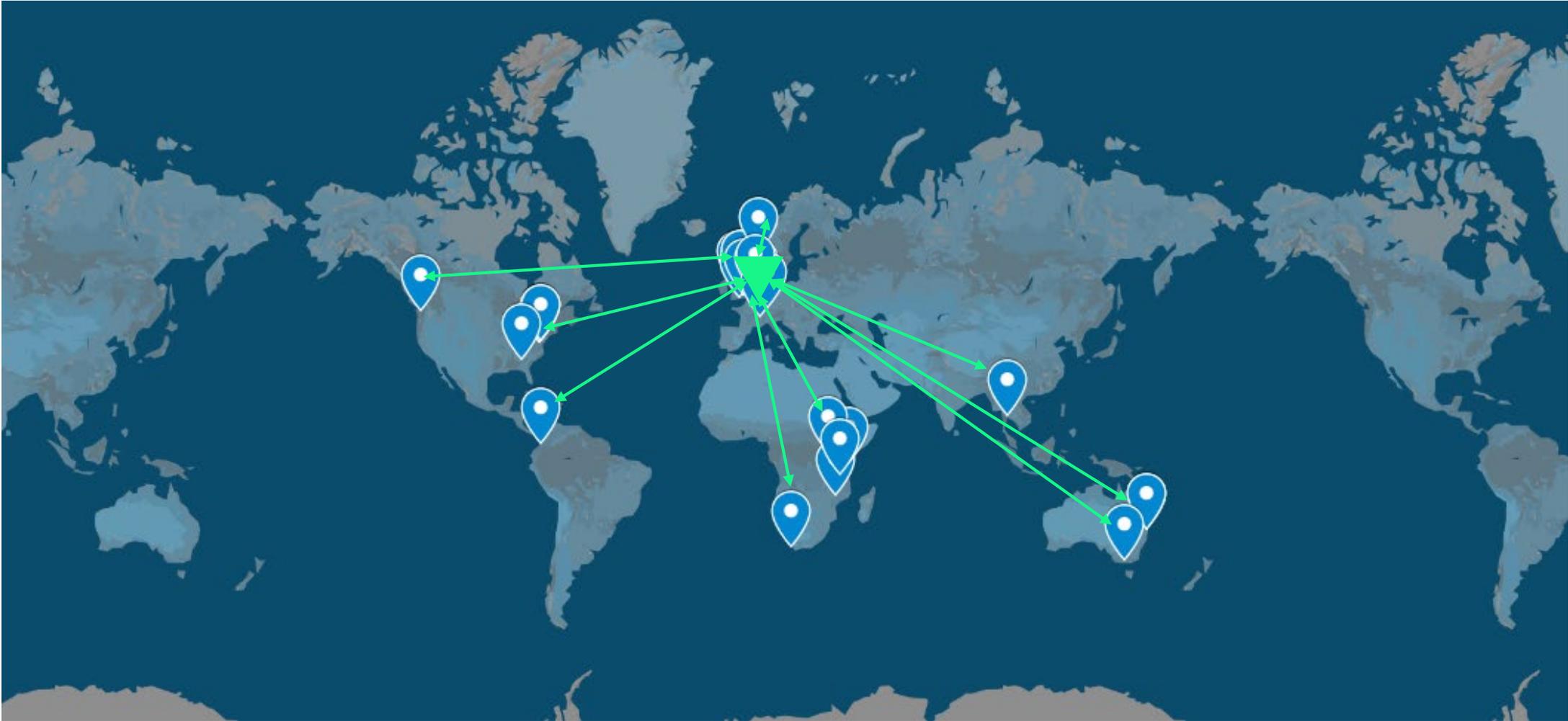
Dedicated QC laboratory

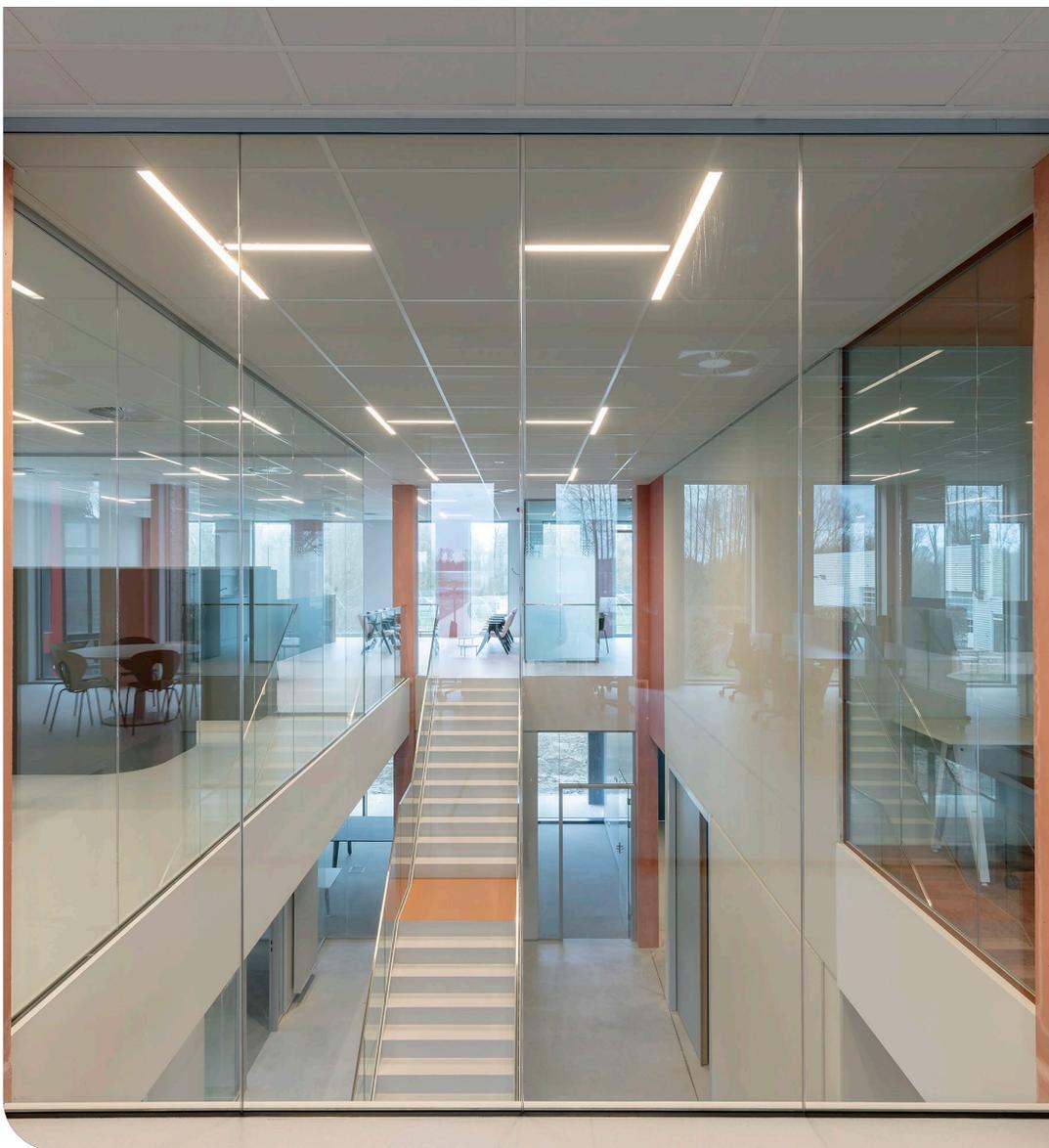
Biosafety level 1, 2 and 3 laboratories specifically equipped for handling of clinical materials and vaccine candidates according to the required containment level. Equipped with flow cabinets, dedicated workspace and workflows to handle specific (viral/bacterial/other) cultures



Planning, construction and qualification in just 14 months

Building up a network with other study centers & institutions





Vaccinopolis provides a unique and much needed infrastructure and system to efficiently evaluate novel therapeutics and vaccines. Because of its scale it should also considerably accelerate their development.

Peter Piot