

Post-pandemic: Strategies to advance your journey in vaccine development

Novotech
Dec 3

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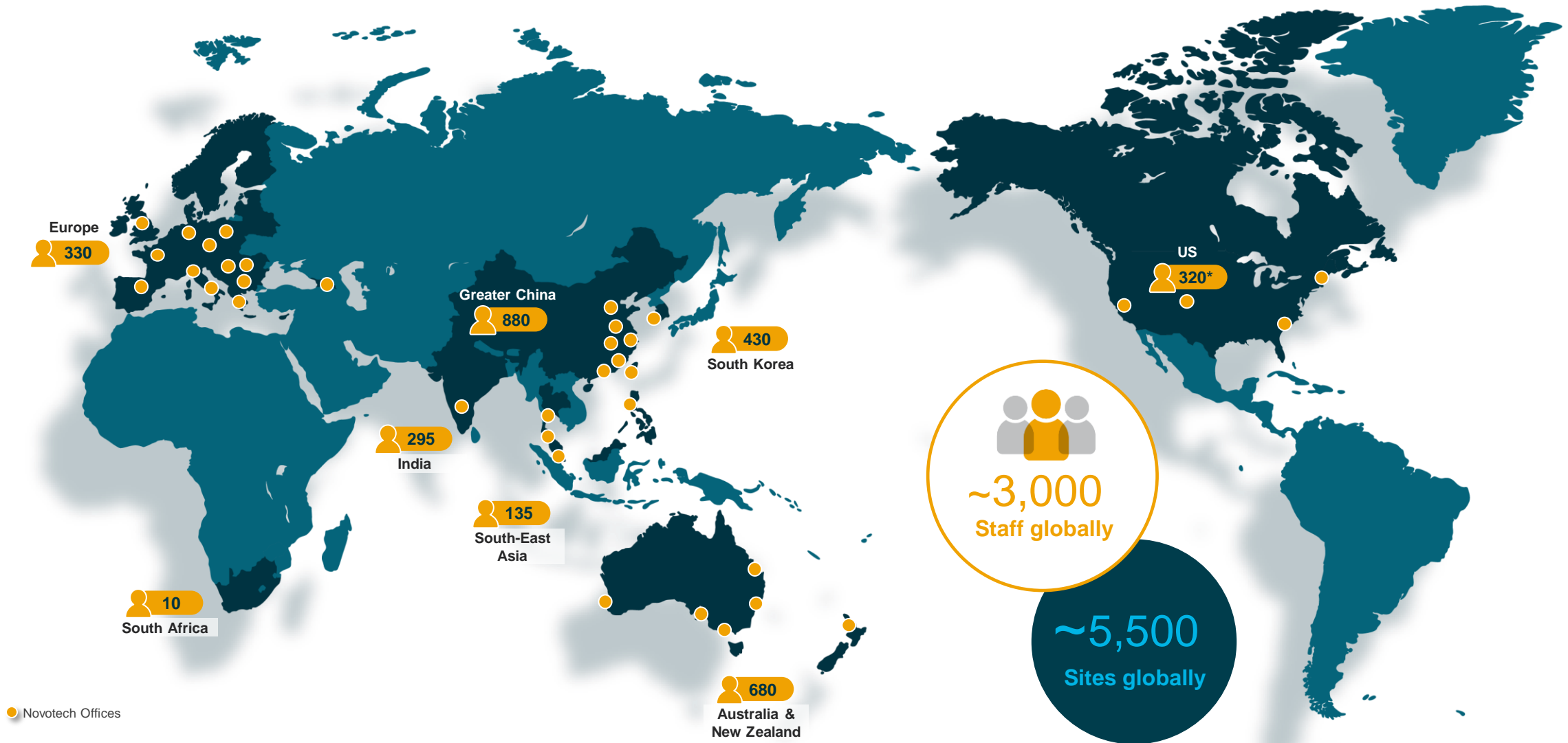
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A Brief Introduction to Novotech

Leading CRO with Local Relationships and Global Execution Capabilities

Partnering with sites, PIs and regulatory authorities to provide best in-country solutions



*Includes contractors

Tailored services to be your clinical development partner

Ability to adapt to Biotech needs to build and accelerate global clinical development strategies



Development Partner

- Development partner approach
- Experienced drug developers and regulatory strategists
- Global agency experience and expertise
- Medically and scientifically driven
- Robust feasibility and site intelligence for accelerated operational execution



Sophisticated Operational Infrastructure

- Robust, global project management, ISO accredited processes
- Local clinical teams – supported by global infrastructure
- Global biometrics, medical monitoring and pharmacovigilance
- Internal quality assurance
- Bioanalytical and central laboratory



Cutting-Edge Technology

- Veeva single suite of clinical systems
- Accredited EDC builders in Medidata, Viedoc and Veeva
- Decentralized clinical trials infrastructure and technology
- Partnerships that provide:
 - Access to prescribing data and EMRs for patient identification
 - Access to NGS screening data for precision medicine studies

Scientific, regulatory, medical and operational expertise in advanced and novel therapies

Pre-clinical → *clinical* → *marketing authorization*



Immuno-oncology

144 Trials

- Checkpoint Inhibitors
- Monoclonal Antibodies
- Bi/trispecific Antibodies
- Antibody Drug Conjugates
- Cell Therapies
- Cancer Vaccines
- Oncolytic Virus



Vaccines

114 Trials

- mRNA
- Plasmid DNA
- Conjugate Vaccines
- Subunit Vaccines
- Recombinant Vector
- Live Attenuated Vaccines



Cell & Gene

72 Trials

- CAR-T
 - Allogeneic, Autologous
 - T Cell Receptor (TCR)
 - Stem Cell Therapy
 - NK Cell Therapy
-
- In vivo gene therapies
 - Ex vivo gene therapies
 - Oncolytic viruses



RNA

52 Trials

- mRNA
- Antisense RNAi



Microbiome

12 Trials

- Gram Positive Bacteria
- Gram Negative Bacteria
- GMO Bacteria


Trend of vaccine development





Strong growth of clinical trials with prophylactic and therapeutic vaccines

There are approximately **1,000 trials** in ongoing and planning stage.

- ➔ **Prophylactic vaccine:**
Prevention of infectious disease
- ➔ **Therapeutic vaccine:**
Treat existing diseases like cancers and other chronic diseases

 The number of trials for **prophylactic vaccines** shows a robust **54.9% CAGR**

 **Therapeutic vaccine** trials have also grown significantly with a **21.2% CAGR**

 **Prophylactic vaccines** dominate the landscape, constituting **72%** of total clinical trials

 **Therapeutic vaccines** account for the remaining **28%**

Figure 1: Growth trends of vaccine trials (2019-2024)

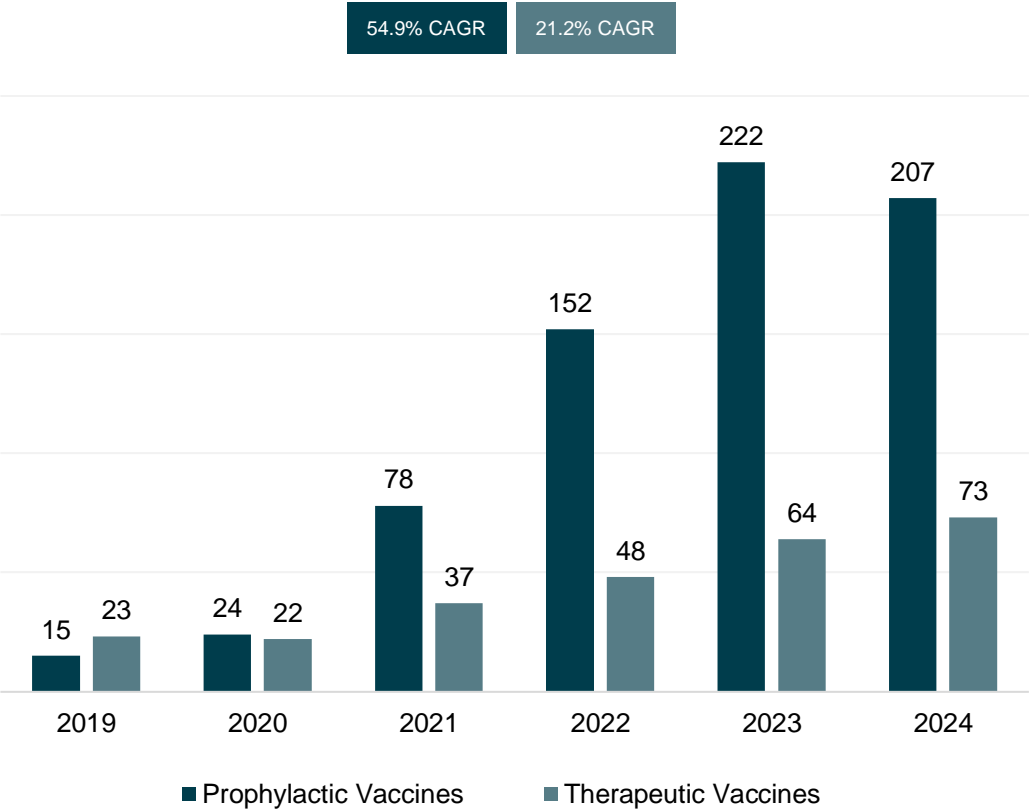
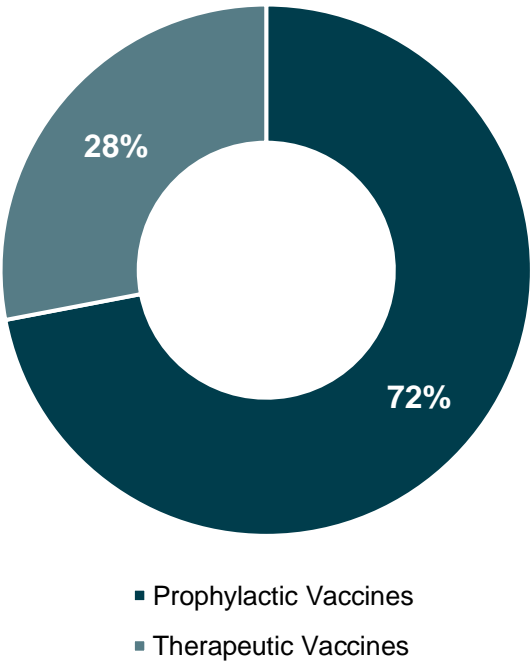


Figure 2: % Share of vaccine types in clinical trials



Source: GlobalData October 2024

Asia-Pacific is leading the trial activities in both prophylactic and therapeutic vaccines

- Asia-Pacific leads with the highest number of trials, particularly for prophylactic vaccines, indicating strong regional involvement and capabilities.
- North America and Europe follow, with 168 and 115 prophylactic vaccine trials, respectively.
- In **therapeutic** vaccine, North America shows the highest involvement, followed by Asia-Pacific and Europe.



Prophylactic vaccine:

Leaders:
Asia-Pacific & North America



Therapeutic vaccine:

Leaders:
North America & Asia-Pacific

Figure 3: # Vaccine trials by regions

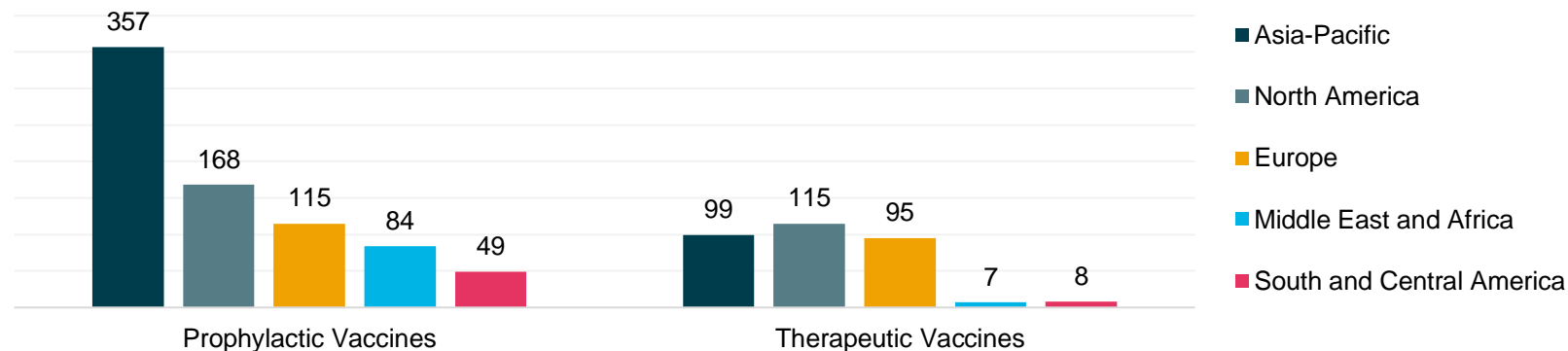


Figure 4: Prophylactic vaccine trials % share by regions

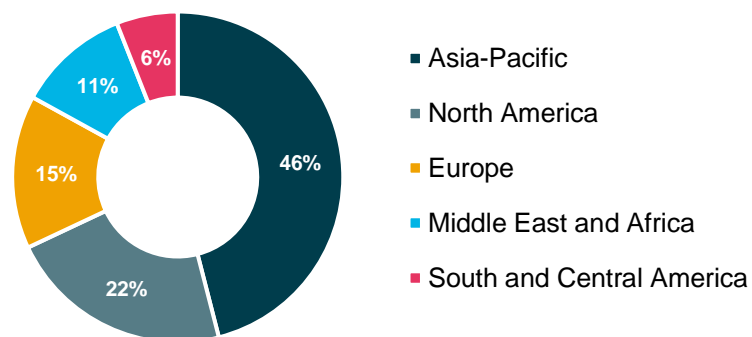
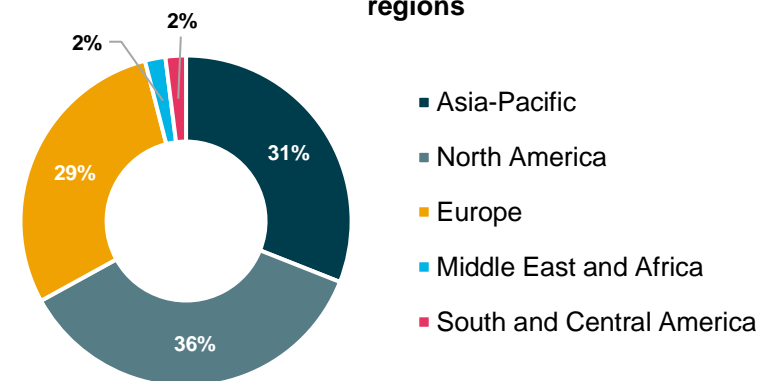


Figure 5: Therapeutic vaccine trials % share by regions



Source: GlobalData October 2024

Leveraging Philippines for Phase 1 and 2/3 typhoid Conjugate Vaccine development

Phase 1

Typhoid Conjugate Vaccine

Comparative, single dose, clinical phase 1 study to assess the safety and tolerability of typhoid conjugate vaccine in healthy adults

- Start: **Apr 2019**
- Participants: **Adult**
- Site: Vaccine specialised institution
- PI: Specialist in Infectious Disease
- Enrolled 75 healthy volunteers in <2 weeks
- Participant retention at **100%**

Phase 2/3

Typhoid Conjugate Vaccine

Multi-centre, observer-blinded, randomized, Non-inferiority and Safety study of typhoid conjugate vaccine compared to Typar – TCV ® in healthy 6 months – 45 years aged participants

- Start: **Mar 2020**
- Participants: **infants, paediatrics, adults**
- Enrolled 444 healthy volunteers in 10 weeks
- Site: Two institutions with vaccine facility
- PI: Specialist in Infectious Disease
- Participant retention at **98.8%**
- Challenge: Covid-19 pandemic and flu season and increased government efforts on Polio & MMR vaccination of paediatric age group, targeted timelines were achieved.



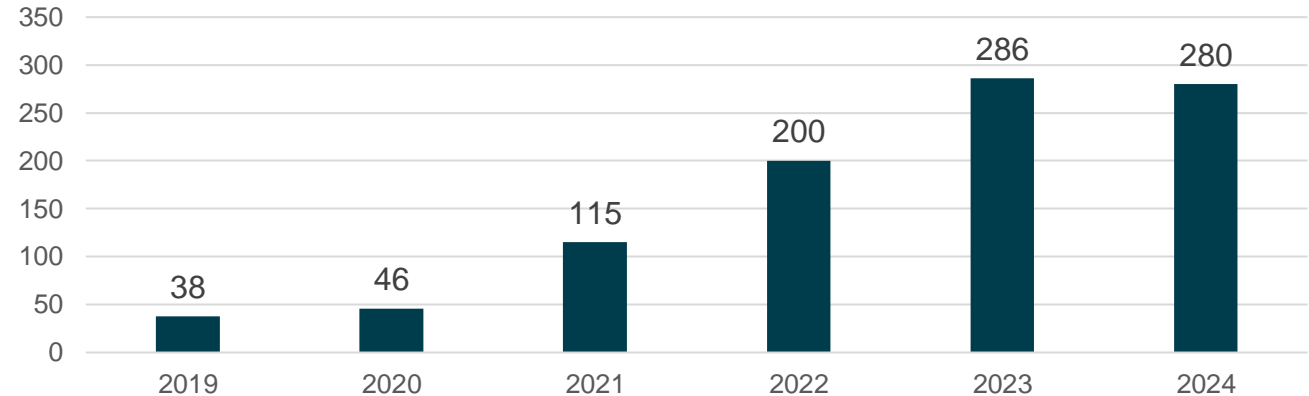
COVID-19 pandemic and beyond

Vaccine trials has been growing significantly since COVID-19 outbreak and remain at high level post pandemic

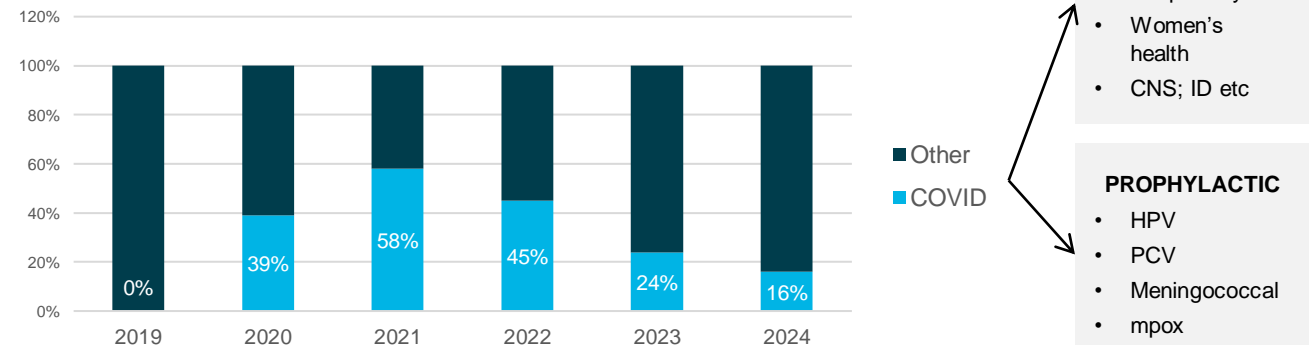


- World's first phase 1 COVID-19 vaccine trial initiated in Mar2020 and shifted the vaccine landscape in COVID-19 trials globally. In 2021, every 10 vaccine trials, ~6 were for COVID vaccine.
- Vaccine trials have reached a record-high in 2023 at 286.
- COVID-19 vaccine trials increased up to 58% during 2020-2022 and reducing in 2023 to 2024.
- Attention to COVID-19 has been reducing but it did not reduce the vaccine trials to pre-pandemic level.
- Emerging approaches like challenge and platform trials are accelerating vaccine development, particularly for rapidly emerging infectious diseases like COVID-19.

Trend of vaccine trials (2019-2024)



Breakdown of COVID and other trials (2019-2024)



Contract research organization’s robust strategic planning helps achieve rapid subject enrollment for a global vaccine Phase III clinical trial program

Background

Biopharma dedicated to accelerating vaccine R&D for global health based in Seoul, South Korea



Enrollment Challenge in 2020 - Numerous ongoing COVID vaccine trials and limited naive subjects, presented a significant enrollment challenge.



Award Rationale Client engaged Novotech because of company’s extensive experience managing global vaccine studies in various regions and to help them take advantage of the rapid subject enrollment across the globe.

The Global Solution Strategy:

Expertise in conducting Feasibility Assessment

- Conducted assessments in multiple regions
- Explored regulatory environment, vaccination landscape
- Sites’ experience and strategies on rapid enrollment of healthy volunteers for vaccine trials.



Collaborative Approach

- Novotech closely collaborated with sites
- Ensured logistics, manpower, and proactive scheduling through community networks.

Large Participant Recruitment from SEA

Philippines	40%	} 75%
Thailand	20%	
Vietnam	15%	
Other regions (New Zealand, Ukraine)	25%	

Achievements:

- The global first SIV was done on 21 Oct 2021
- The global first subject was enrolled on 22 Oct 2021.
- All subject first vaccination was started on 25 Oct 2021 and completed on 14 Jan 2022
- With in 59 working days, more than 3,300 subjects covered.

- Rapid Enrollment Success
- Regulatory approvals obtained efficiently.
- Sites initiated enrollment swiftly, achieving enrollment goals.

Feedback

- Commendable effort during the pandemic despite the limitations faced by the teams
- Appreciation to the teams highlighting dedication, commitment, and resilience
- Adaptability and professionalism acknowledged
- Setting an example for the organization
- Honored to be part of the collaboration

Asia-Pacific is leading participant recruitment landscape



Asia-Pacific excels in faster and more efficient recruitment for prophylactic vaccine



Prophylactic vaccine usually takes shorter recruitment timeline than Therapeutic vaccine.



Therapeutic trials involve more complex protocols, more intensive monitoring, and competition with other trials and Asia-Pacific is enrolling more participants per site per month.

Which part of APAC is suitable for vaccine trials?

Figure 19: Prophylactic vaccine trials (2021-2024 YTD) – Enrolment period (months)

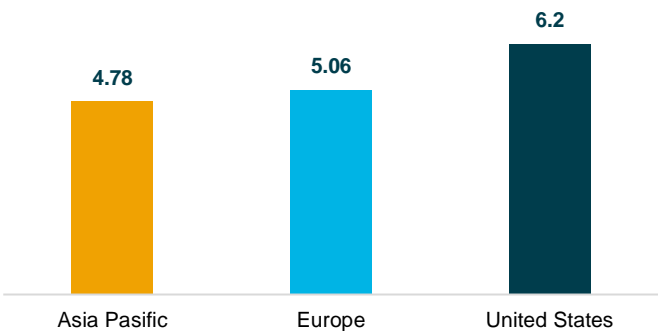


Figure 20: Prophylactic vaccine trials (Subjects/Site/Month)

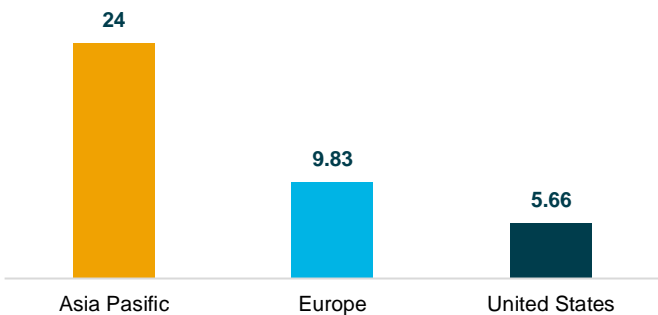


Figure 22: Therapeutic vaccine trials (2019-2024 YTD) – Enrolment period (months)

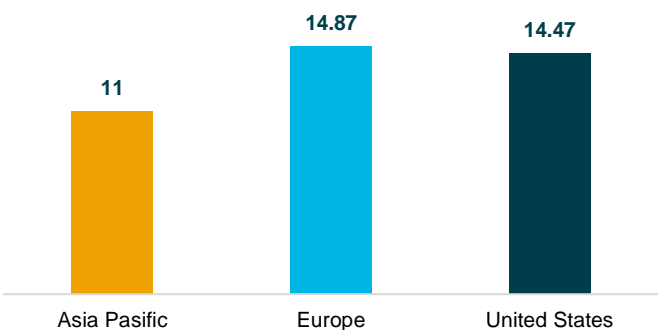
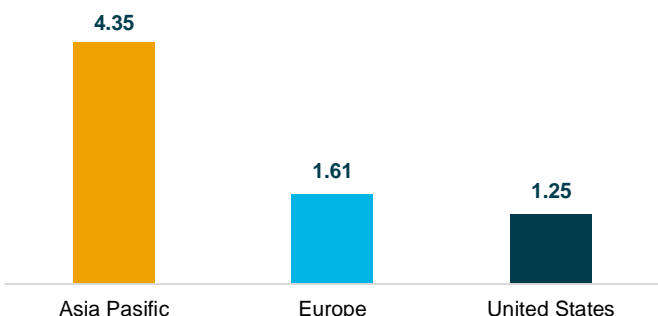


Figure 21: Therapeutic vaccine trials (Subjects/Site/Month)



Source: GlobalData October 2024

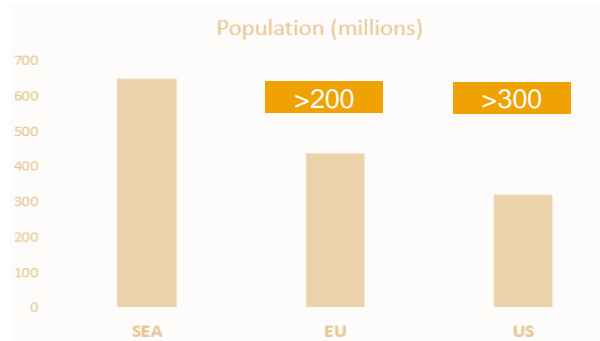
Novotech's Southeast Asia: A destination for vaccine trials



Southeast Asia is a perfect match for vaccine trials

Large vaccine naïve population & cost effectiveness

- >670 millions in ASEAN
 - Growth rate: 1-1.3% per year
 - Wide ethnic groups
- Lower immunisation rate from later introduction of vaccine
- WHO immunization agenda 2030 support
- Given lower cost, thousands of subject means millions of cost difference/saved



High prevalence of emerging communicable diseases

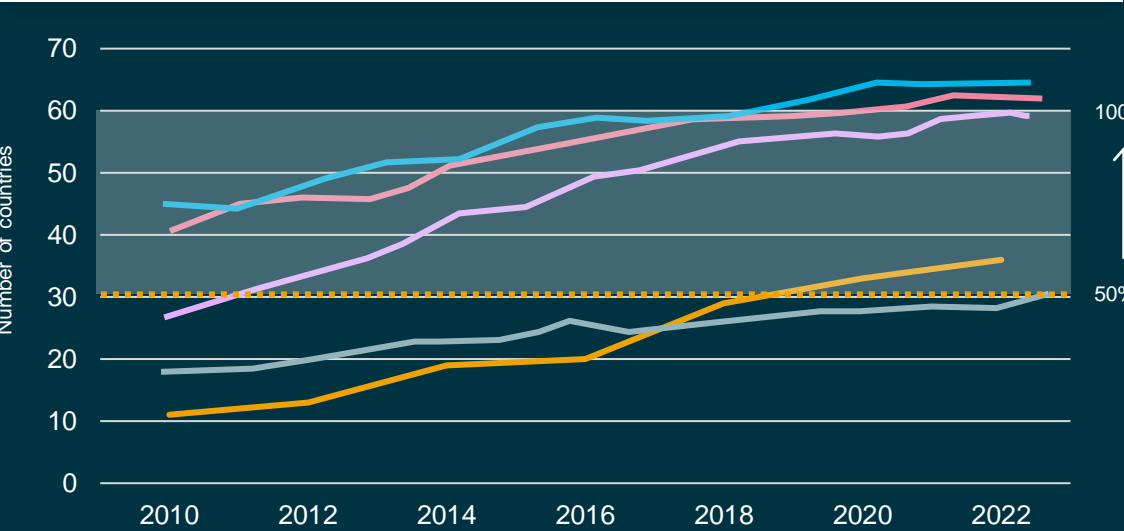
- Tuberculosis: 25% of global cases
- Malaria: 2nd highest globally
- HIV: 3rd largest epidemic globally
- Dengue: >500k to 1m yearly cases
- Chikungunya (CHIKV) & Zika: Africa, Asia & Americas prevalent
- **Globally common respiratory infections** e.g. flu, respiratory syncytial virus (RSV), Pneumococcal infections

Large vaccine naïve population

Southeast Asia have lower immunisation from later vaccine introduction compared to many high & middle income countries

Introduction of HPV, PCV, Rotavirus, meningococcal, polio vaccines over time

High income countries: Total 62



Number of Countries – HPV (Human Papilloma Virus) vaccine, High income, Yes

Number of Countries – IPV (Inactivated polio vaccine) 2nd dose, High income, Yes

Number of Countries – Meningococcal meningitis vaccines (all strains), High income, Yes

Number of Countries – PCV (Pneumococcal conjugate vaccines), High income, Yes

Number of Countries – Rotavirus vaccine, High income, Yes

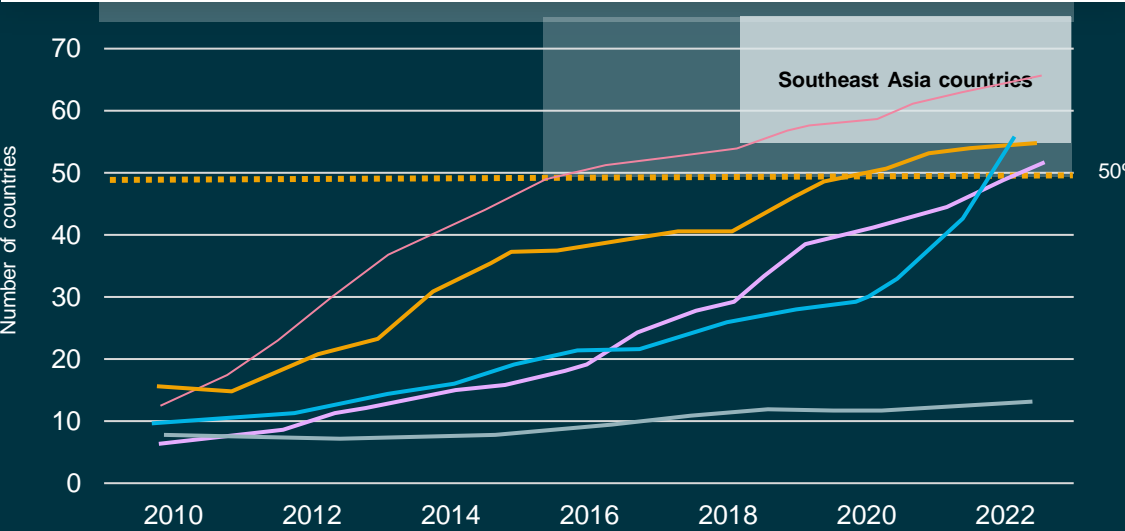
Source: WHO Immunization Data portal - All Data

Source: WDI - The World by Income and Region

Source: WHO Immunization Data portal

World Health Organization, WHO, 2024, All rights reserved

Middle income countries: Total 103



Number of Countries – HPV (Human Papilloma Virus) vaccines, Middle income, Yes

Number of Countries – IPV (Inactivated polio vaccine) 2nd dose, High income, Yes

Number of Countries – Meningococcal meningitis vaccines (all strains), High income, Yes

Number of Countries – PCV (Pneumococcal conjugate vaccines), High income, Yes

Number of Countries – Rotavirus vaccine, High income, Yes

Singapore and Brunei are part of high income countries according to World Bank

Source: WHO Immunization Data portal

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Southeast Asia is a perfect match for vaccine trials

Sophisticated vaccine specialised sites, experienced KOL and infrastructure

- >30 sites capable or specialised in vaccine research:
 - Infectious & non-infectious
 - Pediatrics, adults and elderly
- Large dedicated research support teams: averaged 20+ site staff assigned including investigators, study nurse, coordinators, pharmacists etc
- Experienced KOLs in clinical trials from collaboration with global pharmas & biotechs – trial oversight; regulatory support; expedited execution etc
- Government continuous support in clinical trials – Shortening timelines, increasing site capabilities, subject access to trials and boosting quality oversight

Novotech's expertise and well-established network

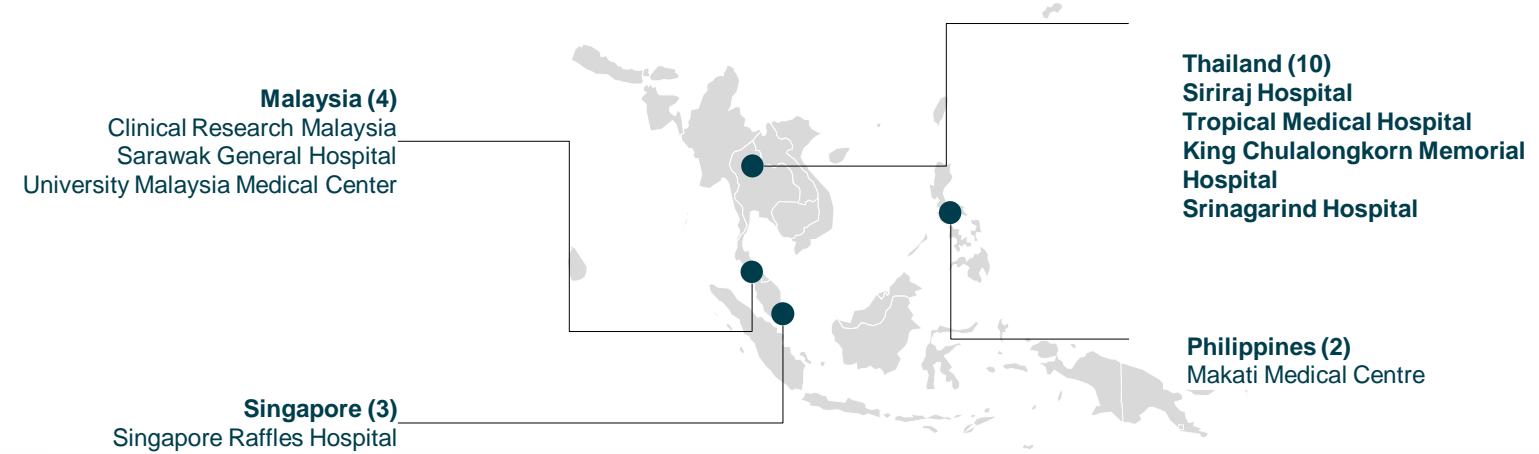
- Novotech vaccine dedicated teams: combination of Onsite and remote monitoring
 - Large batch of vaccine CRAs onsite for consecutive days to weeks
- RBQM strategies – proactive data quality oversight
- Novotech well-established with formalised partnership with key institutions:
 - Top-notch universities
 - Public & private institutions
 - Nationwide clinical research management organisations
 - Innovation parks

~20 partnership sites in Southeast Asia

Novotech has established site partnerships throughout SEA

Site partnerships in hard-to-enter markets

Sample of leading site partnerships across Southeast Asia⁽¹⁾



Novotech has

19

site partnerships in Southeast Asia⁽¹⁾

Novotech has worked with

~150

sites in Southeast Asia⁽²⁾

~1,200

Novotech partnership sites median number of beds



Key benefits to Novotech and customers

- ➔ Priority access to site **staff and premises**
- ➔ Priority for **new study feasibility assessments**, enabling **rapid responses** and **quicker decision making** and engagement with sponsors
- ➔ **Sponsor attraction** and competitive differentiator
- ➔ **Efficient protocol discussions** by removing the need to sign NDAs for each interaction
- ➔ Easily **integrate clinical input** into operating strategy; CRO can provide preferred access to innovative protocols
- ➔ Accelerated **contract execution**
- ➔ SMO function provides additional **local site support**

Source: BCG CDD Report, hospital websites. Note: 'SMO' refers to site management organisation. (1) Represents sites where a memorandum of understanding exists, dictating a preferred working partnership between a site and Novotech; (#) represents the number of site partnerships in each geography; Select sites listed; As at Jun-24. (2) As at Dec-23.

Key takeaway

- Strong growth of clinical trials in both prophylactic and therapeutic vaccines, in which Asia-Pacific has a leading position

- Southeast Asia has particular strengths for vaccine trials including:
 - large population with lower immunisation
 - strong medical needs and interest from sites and investigators
 - cost effective for trials requiring over thousands of participants

- Through these strengths, Novotech continues to play a pivotal role in advancing vaccine development in Southeast Asia, which contributes to global health initiatives with rapid delivery of vaccines to populations in need

Thank you

