Vaccines Europe pipeline review 2024

Innovating for tomorrow, today

Vaccines Europe

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Foreword

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"Vaccine manufacturers remain committed to playing their part in ensuring a healthier tomorrow for the entire population..."

In an era marked by unprecedented scientific advancements and increasing global health challenges, the importance of vaccines has never been more evident. As we navigate the complexities of a rapidly changing world, the role of immunisation extends beyond mere prevention, becoming a critical pillar for the global health security and economic stability.

Historically, Europe has been a leader in vaccine innovation. However, recent trends are concerning, with a drop in global immunisation clinical trials conducted in the European region from 17% in 2018 to 8% in 2023 (1). This decline signals the need for the EU to reinforce its commitment to fostering a vibrant environment for vaccine research, through sufficient levels of funding and investment as well as through appropriate infrastructure including a skilled workforce for vaccine R&D, manufacturing, evidence-based assessment and procurement practices (2).

The vaccine industry continues to evolve in response to the dynamic global health landscape, with innovation at its core. From pioneering new vaccine technologies to expanding the scope of immunisation strategies, the current pipeline reflects a commitment to saving as many lives as possible from dangerous infectious diseases. These advancements are not just about responding to immediate health threats but are also vital for sustaining the EU's long-term economic stability and competitiveness on the global stage.

Central to this vision is the concept of life-course immunisation. Protecting health at every stage of life, from infancy, through adulthood and into older age, populations can remain healthy, productive, and less susceptible to preventable diseases. Life-course immunisation is not only a public health priority but an economic necessity. By preventing disease across all age groups, we can reduce healthcare costs, maintain workforce productivity, and ensure a healthier, more resilient society. By reducing antimicrobial use and misuse, vaccination targets the root causes of antimicrobial resistance (AMR). Increasing the coverage of existing vaccines could prevent an additional 106,000 deaths linked to AMR annually, and developing new vaccines could save an additional 543,000 lives, according to a report by the World Health Organization (WHO)(3).

This review highlights the innovative approaches and collaborative efforts that are shaping the future of vaccination in Europe. It underscores the importance of remaining competitive through cutting-edge research and streamlined and harmonised regulatory and access processes across the EU and its Member States. By championing life-course immunisation and fostering an environment of innovation, we can ensure that Europe remains at the forefront of global health and economic prosperity.

Vaccine manufacturers remain committed to playing their part in ensuring a healthier tomorrow for the entire population, regardless of age or socio-economic status - but responding to these threats is complex and requires a concerted effort from all stakeholders.

Introduction

Vaccination has revolutionised public health over the last century, saving countless lives and preventing long-term health complications caused by a variety of pathogens. The benefits of vaccines go beyond individual protection, contributing to economic growth by reducing healthcare costs associated with preventable diseases and fostering social stability by ensuring children can attend school and adults can remain active in the workforce.

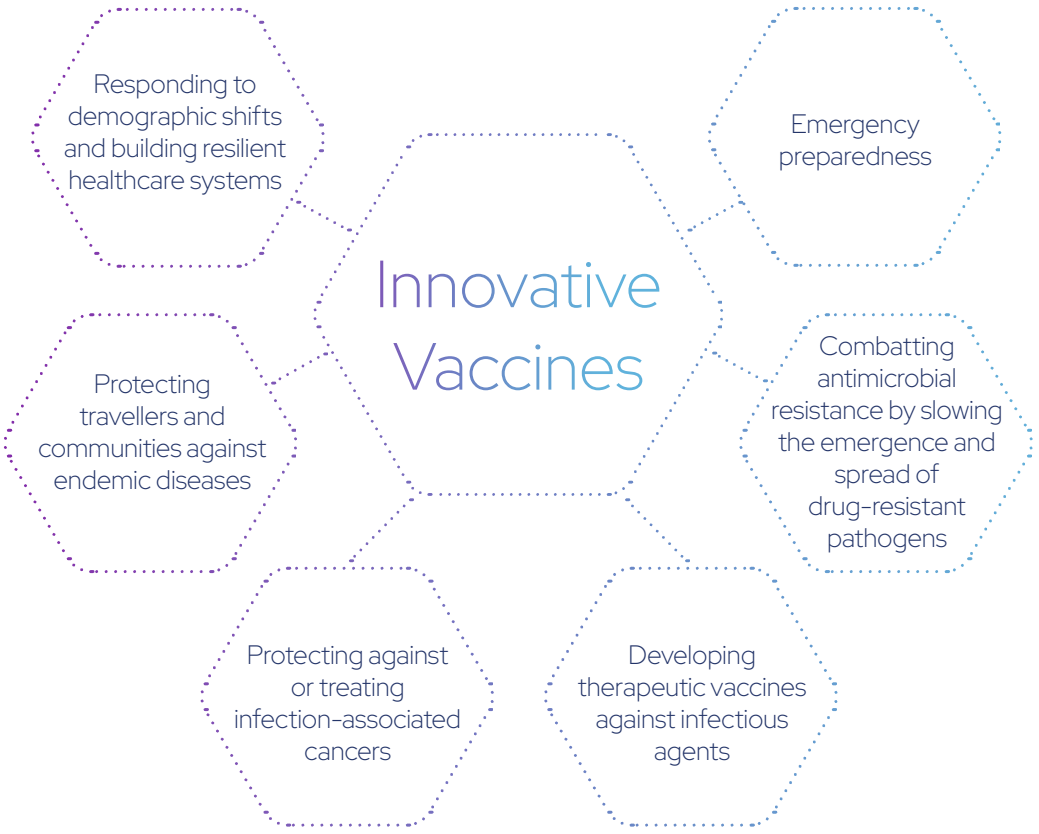
Over the last 50 years, immunisation efforts against 14 infectious diseases have saved over 154 million lives, with a significant proportion being infants. This highlights the crucial role immunisation plays ensuring children survive their early years and grow into healthy adults. The measles vaccine, in particular, has had a major impact in reducing infant mortality, accounting for 60% of the lives saved through immunisation. Smallpox, which was once a leading cause of death, has been entirely eradicated thanks to successful vaccination campaigns. Other diseases such as mumps, rubella, diphtheria, tetanus, and polio, once common and devastating childhood illnesses, are now largely controlled due to widespread vaccination efforts (4). In addition to these successes, vaccines play a crucial role in preventing sepsis by reducing the risk of infections that can lead to this life-threatening condition (5). In 2020 alone, sepsis accounted for 48.9 million cases and 11 million deaths globally, representing 20% of all deaths worldwide (6).

The impact of vaccination extends well beyond the established childhood immunisation programs, as highlighted by recent history.

The impact of vaccination extends well beyond the established childhood immunisation programs, as highlighted by recent history. COVID-19 vaccines have been pivotal in controlling the pandemic, reducing disease severity, preventing millions of deaths, and helping societies navigate the unprecedented challenges of the virus. It is estimated that COVID-19 vaccination has saved over 1.6 million lives among those aged 25 and older (7). Similarly, the Human papillomavirus (HPV) vaccine has proven to be a powerful tool in preventing cervical cancer and other HPV-related cancers in women and men, with the potential to avert more than 27,000 cases and 12,000 deaths annually (8). Vaccination has also been essential in combating antimicrobial resistance (AMR), contributing to the reduction of AMR and sepsis-related deaths in children under 5 by over 50% and 60%, respectively, between 1990 and 2021. However, the alarming rise in AMR-related deaths among adults over 70 highlights the urgent need for stronger adult vaccination programs to address this growing challenge (9).

Looking ahead, vaccination will continue to play a critical role in addressing the increasingly complex health challenges of our time. Climate change, antimicrobial resistance and the spread of zoonotic diseases are expected to drive the emergence of new pathogens, making it essential to invest in vaccine research and development. The concept of life-course immunisation emphasises the importance of maintaining vaccination throughout an individual's life, ensuring optimal protection at every age, notably in the context of an aging population. It is crucial for national and European immunisation strategies to reflect the importance of vaccination throughout one's entire lifespan and as a routine practice – not just in times of crisis.

Addressing global health challenges requires innovation and cross-sectoral collaboration. This report identifies several key areas where vaccine development holds immense promise:



Through innovation we can support the diversification of vaccine technologies, providing prescribers with options that enable them to meet more closely the varied needs of communities.

What's in this report?

The pipeline review of the Vaccines Europe member companies (10), launched in 2022 (11), marks a significant step forward in understanding the evolving landscape of vaccine innovation. Now in its third edition, the current report covers the period from August 2023 to August 2024, highlighting the latest developments within the vaccine industry and how these innovations are addressing existing and upcoming health threats.

There have been changes in the Vaccines Europe membership since the project was created, with two companies leaving and another one joining, slightly impacting the data compared to the previous editions of the pipeline review. The analysis focuses on publicly available information classified according to specific criteria, with preclinical development being excluded. The research trends are presented in an aggregated manner and therefore any direct references towards specific companies and their internal strategies are removed (such as vaccine candidate names, references to the clinical trials or expected timelines for regulatory submission).

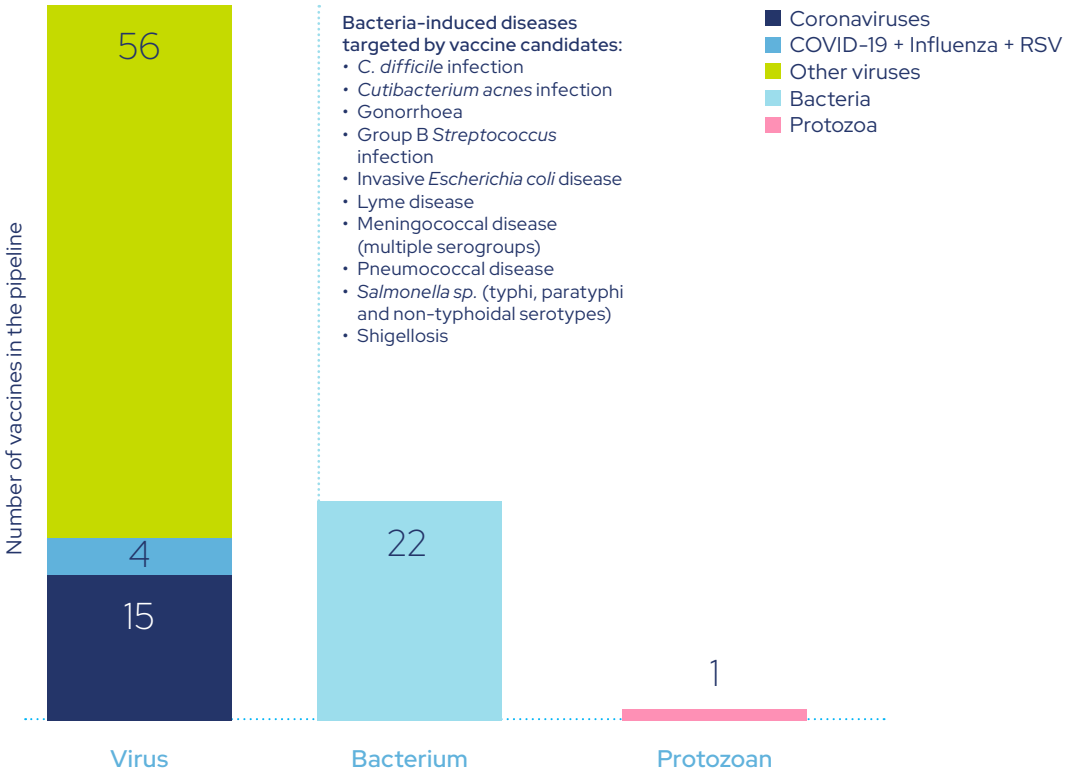
The primary goal of this report is to raise awareness of the critical role of innovation within the vaccine ecosystem. It showcases the commitment of vaccine manufacturers to mitigating preventable public health threats, saving lives, and contributing to healthcare and socio-economic resilience. **The document is structured around key healthcare and policy challenges, with examples of vaccine candidates provided under each section.** While some candidates could fit under multiple categories, the report's organisation facilitates horizon-scanning by EU Member States and serves as a basis for early dialogue between developers and health authorities on topics such as vaccine value assessment, immunisation financing, and country readiness.

For an overview of the challenges that could potentially be addressed by these vaccine candidates, labels have been added next to each candidate, according to the following legend:

AMR	Antimicrobial resistance
CR	Infection-associated cancer vaccines
CC	Climate change
NI	New indication (Diseases for which there was no vaccine on the market by the end of August 2024)
RI	Routine immunisation (including vaccines that could potentially be administered routinely in the future)
STI	Sexually-transmitted infections
ThV	Therapeutic vaccine
TrV	Travel vaccine
ZOO	Zoonoses and pandemic preparedness

Figure 1

Number of vaccines in the pipeline targeting a specific type of microorganism.

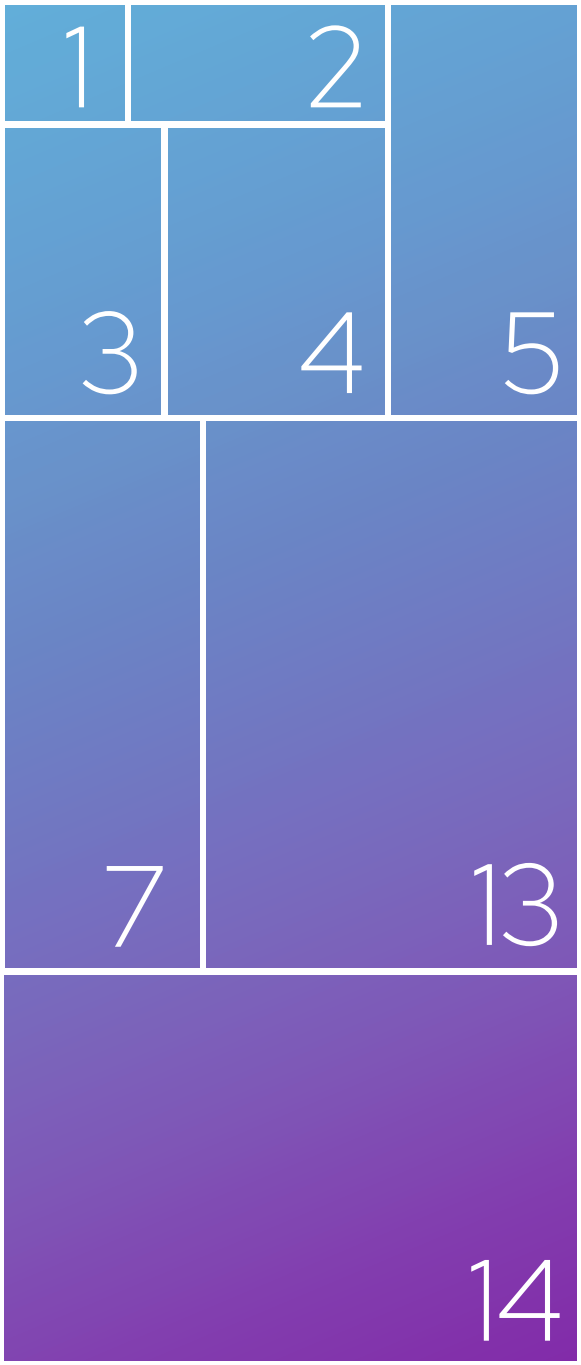


By the end of August 2024, there were 98 vaccine candidates in the pipeline, of which 93 were prophylactic vaccines and 5 were therapeutic vaccines (targeting infectious agents). Most of the vaccine candidates target infectious diseases caused by viruses, but there are also a significant number targeting bacteria-induced infections. There is also 1 vaccine candidate against *Plasmodium*, the parasite causing malaria.

The most frequent targets for vaccine candidates were COVID-19 (SARS-CoV-2) (15 candidates, including in combination with other coronaviruses), followed by seasonal influenza (13 candidates), Respiratory syncytial virus (RSV) (7 candidates) and pneumococcal disease (5 candidates). On top of these, several vaccine candidates are designed to target combination of these viruses (3 candidates against COVID-19 + seasonal influenza, 1 candidate against COVID-19 + seasonal influenza + RSV, and 2 candidates against seasonal influenza + RSV). The full overview of the vaccine candidates of Vaccines Europe member companies can be consulted in *Figure 2*.

Figure 2

Number of vaccine candidates addressing a disease area.



1 vaccine candidate

Acne
COVID-19 + Influenza+ RSV
COVID-19 and other coronaviruses
Dengue fever
Glioblastoma (via CMV)*
Gonorrhoea
Group B *Streptococcus* infection
Human papillomavirus (HPV)
Invasive *E. coli* disease
Malaria
Measles, mumps, rubella, varicella
Mpox
Nipah virus
Rabies
RSV and other infections
Shingles
Yellow fever

2 vaccine candidates

C. difficile infection
Epstein-Barr virus (EBV) infection
Hepatitis B*
Herpes simplex virus*
Human Immunodeficiency virus (HIV)
Human metapneumovirus and RSV (hMPV/RSV)
Influenza + RSV
Norovirus
Salmonella sp.
Shigellosis
Varicella
Zika

3 vaccine candidates

COVID-19 and Influenza
Cytomegalovirus (CMV)
Lyme disease

4 vaccine candidates

Meningococcal disease

5 vaccine candidates

Influenza (pandemic)
Pneumococcal disease

7 vaccine candidates

Respiratory syncytial virus (RSV)

13 vaccine candidates

Influenza (seasonal)

14 vaccine candidates

COVID-19 (different strains)

*Therapeutic vaccine

All stages of clinical development are well represented in the pipelines of Vaccines Europe members. At the end of August 2024, there were 21 vaccine candidates in Phase III of the clinical trials and 4 under regulatory review. A summary of the vaccines organised by their status of development can be consulted in Annex I. For this analysis, the highest global development status has been considered, meaning:

- Candidates in Phase I/II clinical trials, have been counted as Phase II;
- Candidates being under review by any Regulatory Authority have been counted as under 'Regulatory Review', even if the status in Europe might be at an earlier stage;
- Products that have received marketing authorisation in any region in the world are no longer part of the VE pipeline review.

Figure 3
Percentage of vaccines targeting diseases for which there is no registered vaccine ('New targets') vs those further developing existing products ('Further development')[1].

42% OF THE VACCINE CANDIDATES ADDRESS DISEASES FOR WHICH NO VACCINE HAS BEEN REGISTERED

58% OF THE VACCINE CANDIDATES AIM TO FURTHER DEVELOP EXISTING VACCINES OR FIND A NEW APPROACH TO ADDRESS A DISEASE

42% of the vaccine candidates in our members' pipelines aim to address diseases, combination of diseases, or an infectious syndrome, for which no vaccine has been registered until now:

- Acne (*Cutibacterium acnes*)
- *Borrelia burgdorferi* (Lyme disease)
- *Clostridioides difficile (C. difficile)* infection
- COVID-19 + seasonal influenza
- COVID-19 + seasonal influenza + Respiratory syncytial virus (RSV)
- Cytomegalovirus infection
- Epstein-Barr virus (EBV) infection
- Glioblastoma (via Cytomegalovirus)
- Gonorrhoea
- Group B *Streptococcus* infection
- Hepatitis B – therapeutic use
- Herpes simplex virus infection
- Human Immunodeficiency virus (HIV) infection
- Influenza (seasonal) + Respiratory syncytial virus
- Invasive *Escherichia coli* disease
- Nipah virus
- Norovirus
- Respiratory syncytial virus (RSV) + other respiratory infections (including human metapneumovirus - hMPV)
- *Salmonella spp.* infection
- *Shigella spp.* (Shigellosis)
- Zika virus disease

[1]Note: for therapeutic candidates for which there is a preventative vaccine licensed, the answer was marked 'no'. The answer has also been marked 'no' for candidates for which a vaccine is licensed for individual pathogens, but not in combination (e.g., COVID-19 + seasonal influenza).

DISEASE	POPULATION	STATUS	PLATFORM
ACNE *(CUTIBACTERIUM ACNES)* [12], [13], [14] • *Cutibacterium acnes* is a bacterium that is a normal inhabitant of human skin. While it's typically harmless, it plays a significant role in the development of acne vulgaris. • Acne is a chronic inflammatory skin disease and 8th most common medical condition globally. • Estimated to affect 9.4% of the global population. • Approximately 231.2 million prevalent cases globally. PIPELINE CANDIDATES: 1*	 Paediatric + Adults (1)	 Phase I (1)	 mRNA (1)
CYTOMEGALOVIRUS (CMV) [15], [16], [17], [18] Cytomegalovirus (CMV) is a common virus for people of all ages, affecting the eyes, lungs, liver, oesophagus, stomach, and intestines of people with weakened immune systems. • ~60% of adults in developed countries and more than 90% in developing countries infected. • Babies born with congenital CMV infection could lose their hearing and may suffer other developmental disabilities. • In the US, nearly one in three children infected by age five. • Currently, no vaccine available to prevent congenital cytomegalovirus (CMV). PIPELINE CANDIDATES: 3	 Adults (3)	 Phase I (1) Phase II (1) Phase III (1)	 Protein subunit (1) mRNA (1) Virus-like particle (1)
HUMAN IMMUNODEFICIENCY VIRUS (HIV) [19] • Major global public health issue, having claimed 42.3 million lives so far. • Attacks the body's immune system, weakening a person's immunity against opportunistic infections (tuberculosis, fungal infections, severe bacterial infections, and some cancers). • 39.9 million people living with HIV at the end of 2023. 630,000 deaths in 2023. • No cure for HIV infection but a manageable chronic health condition. PIPELINE CANDIDATES: 2	 Adults (2)	 Phase I (2)	 mRNA (2)

NOROVIRUS [20], [21]
• Highly contagious infection that can cause vomiting, diarrhoea, and stomach pain, resulting in fluid loss.
• As immunity may only last a few months and is strain-specific, and given their genetic variability, infection can happen several times in a lifetime and affects individuals of all ages.
• Leading cause of acute gastroenteritis outbreaks:
  • Approximately 685 million cases annually
  • Around 200 million cases are seen among children under 5 years old, leading to an estimated 50,000 child deaths every year.
PIPELINE CANDIDATES: 2
	
	Adults + Older Adults (2)
		
		Phase I (1)
		Phase II (1)
			
			mRNA (2)

*Therapeutic vaccine

NI ThV RI

The vaccine research environment is very dynamic, continuously evolving to tackle emerging infectious diseases that affect people across different regions. Vaccine development is complex, usually taking 10-15 years (22), with costs varying between $0.5 billion and over $8 billion USD (23), (24).

58% of vaccine candidates aim to address the disease areas for which there are already existing vaccines by:

- Improving formulations to increase the convenience for healthcare professionals and patients
- Expanding a vaccine's use to a new population
- Including more target strains in a vaccine
- Developing combination vaccines, which could decrease the number of injections and better fit with national vaccination schedules
- Using a new approach to address a disease (e.g., using a different technology, targeting a different part of the antigen)

While all authorised vaccines are safe and effective, Vaccines Europe members are continuously working to improve the knowledge of vaccines' benefits/risks as part of their post authorisation lifecycle development.

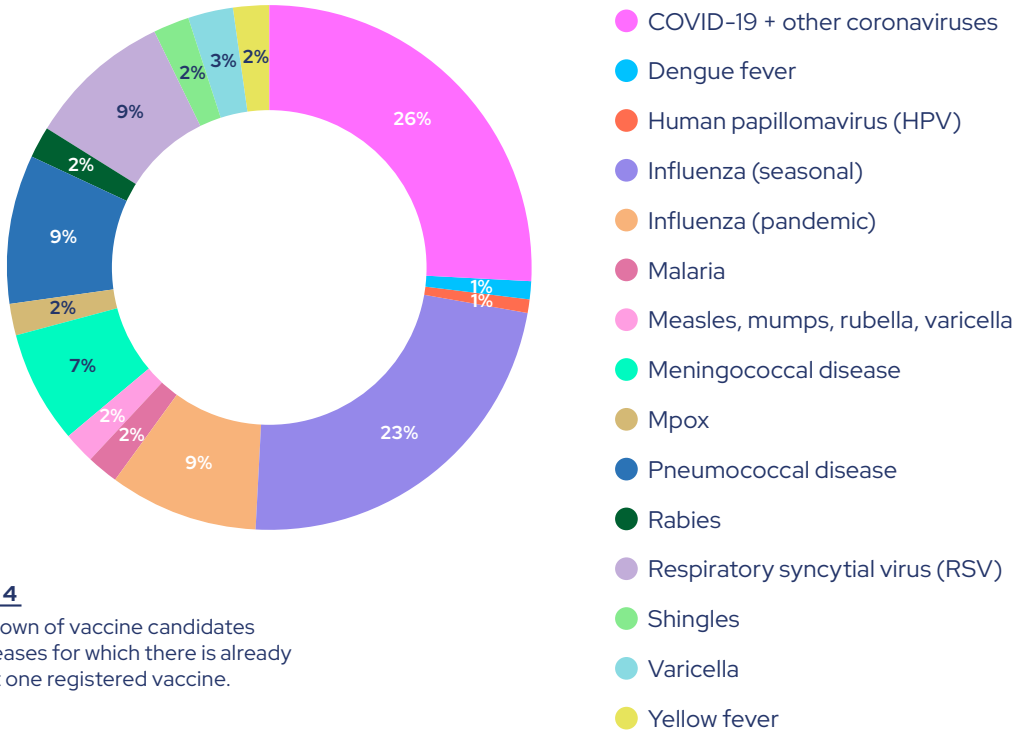


Figure 4
Breakdown of vaccine candidates for diseases for which there is already at least one registered vaccine.

A constantly evolving research environment

The vaccine research environment is very dynamic, continuously evolving to tackle emerging infectious diseases that affect people across different regions. Vaccine development is complex, usually taking 10-15 years (20), with costs varying between $0.5 billion and over $8 billion USD (21), (22).

Clinical trials comprise a significant part of the development of new vaccines. These rigorous studies aim to assess the efficacy and safety of vaccine candidates in healthy populations. The performance and safety of the candidates is constantly assessed, across each clinical trial stage. While some candidates will progress to the next development step, others will be discontinued for various reasons, such as suboptimal immune response or safety concerns. This thorough and robust analysis will ensure only safe and effective vaccines will reach the population. However, clinical trial results are not the only factors influencing vaccine development. There are many other challenges that research-based companies encounter at this stage, such as:

- Recruiting and retaining a diverse and representative participant group, especially for long-term follow-up studies to assess duration of protection;
- Managing logistical complexities in multi-site trials;
- Resource constraints: funding, research infrastructure, trained personnel;
- Adapting to emerging pathogens and new strains.

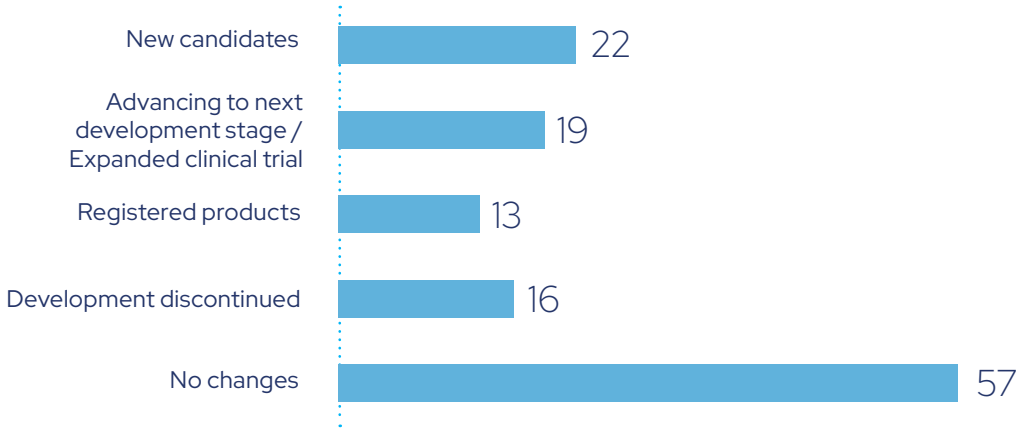
Beyond clinical trials, vaccine manufacturers must also overcome other hurdles to bring successful candidates to market, such as:

- **Bridging gaps in scientific knowledge and investment in epitope and antigen discovery:** fully understanding the structure of specific pathogens, how they replicate and spread as well as pathogen-host interactions is critical to selecting the appropriate antigen and developing effective candidates;
- **Evidence-based selection of vaccine candidates for clinical trials;**
- **Designing candidates that provide protection across a diverse population** with variability in immune responses, and optimisation of vaccine formulations;
- **Ensuring a continuous cold chain from production to administration**, especially in areas with limited resources and/or very high temperatures;
- **Securing funding beyond preclinical and clinical development, to ensure manufacturing scale up and wide distribution of the product**. This includes ensuring Good Manufacturing Practices (GMP) compliant manufacturing, necessary to meet regulatory standards and guarantee product safety and quality at a large scale.

Despite these challenges, the vaccine research ecosystem is constantly developing and adjusting to match the needs of populations.

13 of the vaccine candidates reported in the 2023 pipeline review were granted Marketing Authorisation before the end of August 2024. During the same period, 19 candidates progressed to the next development stage, while 16 development programmes have been discontinued. 22 new candidates have been included in the pipelines of VE member companies.

Figure 5A
Updates in the pipelines of VE member companies since August 2023.



Between 2022 and 2024, the attrition rate was approximately 20% and the registration rate was approximately 17%, underscoring the balance between challenges and successes in vaccine development during this period. The attrition rate represents the percentage of vaccines discontinued relative to the total pipeline over these years, while the registration rate indicates the percentage of vaccines that received approval relative to the overall pipeline during the same timeframe.

Figure 5B
Updates in the pipelines of VE member companies between August 2023 and August 2024.

NUMBER OF CANDIDATES	CHANGE COMPARED TO THE 2023 VACCINES EUROPE PIPELINE REVIEW	INDICATIONS
13	**Marketing Authorisation granted**	Chikungunya virus infection, COVID-19, Malaria, Meningococcal disease (ABCWY, ACWY serogroups), Pandemic influenza, Pneumococcal disease, Respiratory syncytial virus (RSV) disease.
19	**Advancing to next development stage or expanded clinical trials**	*C. difficile* infection, COVID-19, COVID-19 + seasonal influenza, COVID-19 + seasonal influenza + RSV, Cytomegalovirus infection, Epstein-Barr virus infection, Dengue fever, Herpes simplex virus infection, Lyme disease, Meningococcal disease (ABCWY serogroups), Norovirus,Pandemic influenza, RSV disease, Non-typhoidal *Salmonella*, Zika virus infection.
22	**New candidates**	Acne, COVID-19 infection, Mpox, Pandemic influenza, Pneumococcal disease, RSV disease, RSV + other infections (including hMPV), Seasonal influenza, Shigellosis.
16	**Development discontinued**	*C. difficile* infection, COVID-19, COVID-19 + RSV disease, *K. pneumoniae* infection, Meningococcal B disease, Rabies, RSV disease, Seasonal influenza.

Cross-sectorial collaborations and partnerships play a critical role in vaccine development. These either provide funding for promising candidates to enable progress through costly development stages, or leverage knowledge and other resources from various stakeholders to enhance scientific understanding and accelerate the development process. Vaccines Europe members are partnering with a wide range of private and public stakeholders to advance vaccine candidates. Examples include but are not limited to: Bill and Melinda Gates Foundation, universities, National Institutes of Health (NIH), the US Biomedical Advanced Research and Development Authority (BARDA), the National Institute of Allergy and Infectious Diseases (NIAID), the International AIDS Vaccine Initiative, Government of Canada and the Coalition for Epidemic Preparedness Innovations (CEPI).

Protecting the health of our society through lifecourse immunisation

The vaccines that are currently in the pipeline cover different types of populations across the lifespan. However, 81 of them are tested in adults (18-60 years old, including maternal immunisation) and older adults (over 60 years old), reflecting the challenges ahead and the need for a paradigm shift towards a life-course approach to vaccination.

Figure 6a
The number of vaccine candidates tested in each type of population.[2]

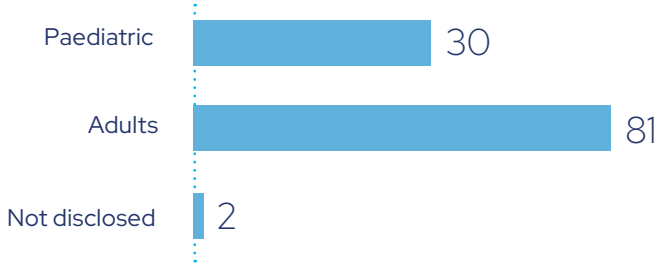
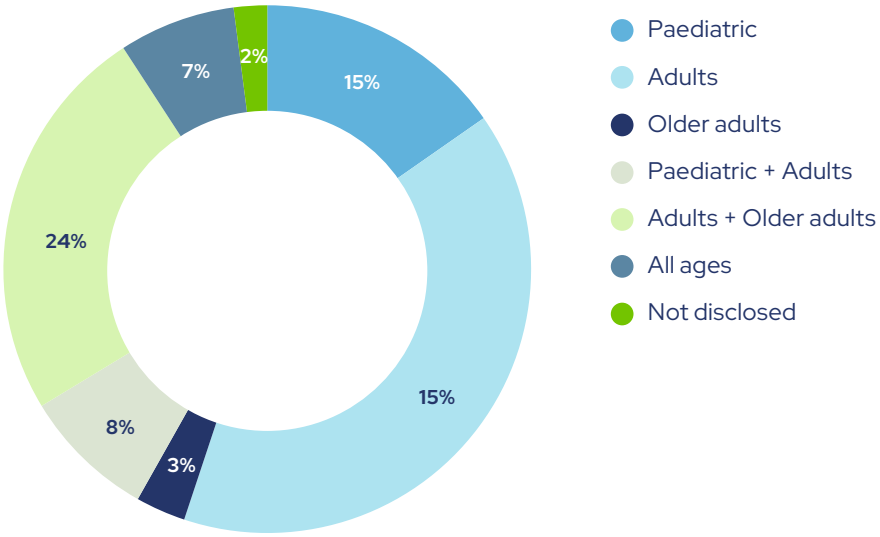


Figure 6b
The number of vaccine candidates tested in each type of population.



[2] Some of the candidates are tested in multiple populations and therefore have been counted multiple times.

Routine vaccines across the lifespan

The life-course approach to vaccination means protecting people at all stages of life. This includes key groups such as infants, children, adolescents, adults, older adults, pregnant individuals, people with comorbidities, and immunocompromised individuals.

Childhood vaccination is one of the greatest medical achievements of the 20th century. **While paediatric immunisation schedules are well-established across Europe, adult vaccination products are less developed, and vaccination coverage rates remain low in this group**. This is particularly important considering the current demographic trends. At the beginning of 2023, the median age in the EU reached 44.5 years, with the aging trend expected to persist (25). Globally, the population aged 60 and over is projected to rise from 1 billion in 2020 to 2.1 billion by 2050 (26).

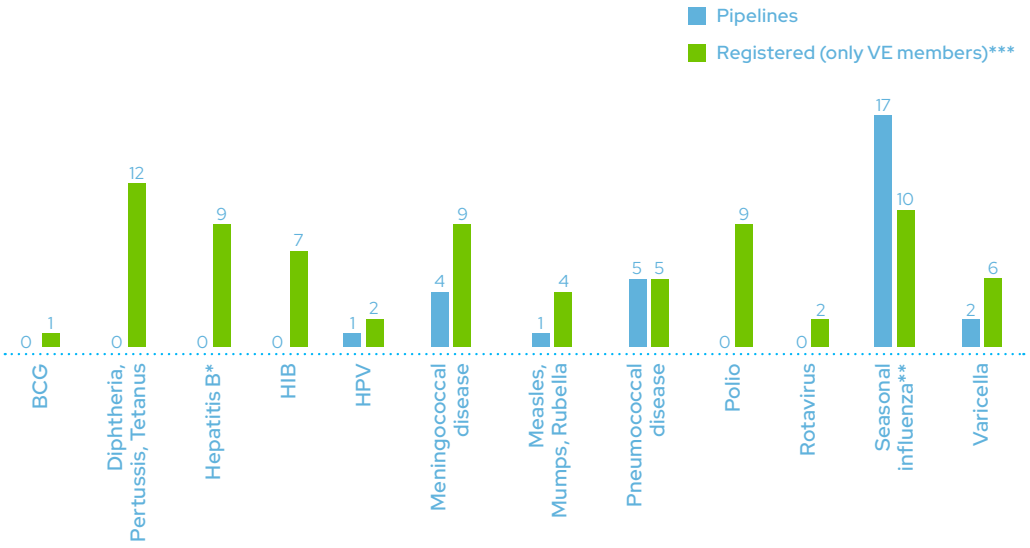
As people age, their immune systems weaken, increasing their susceptibility to infectious diseases. Adult immunisation, including for specific populations such as pregnant individuals or people with chronic health conditions, is essential to protect populations against current and future vaccine-preventable diseases, but also to drive socio-economic prosperity and equity and help mitigate potential public health crises. In fact, a recent report has shown that adult immunisation returns 19 times its initial investment to the society and economy (27). Extending the benefits of vaccination from childhood alone to the entire lifespan aligns with the growing emphasis on prevention within healthcare systems. To achieve this goal, better policies and funding allocation are needed to ensure adequate coverage rates for adults (28).

There are currently 30 vaccine candidates for routine immunisation (29) in our members' pipelines, against seasonal influenza, varicella, Human Papillomavirus (HPV), measles, mumps, rubella, varicella (MMRV combination vaccine), and pneumococcal and meningococcal diseases.

Some of them are tested in both paediatric and adult populations. Routine immunisation refers to vaccinations recommended for defined eligible individuals at national or subnational level. In our analysis of routine immunisation, diseases relevant for the European region have been selected.

Figure 7

Vaccines in VE members' pipelines for routine immunisation.



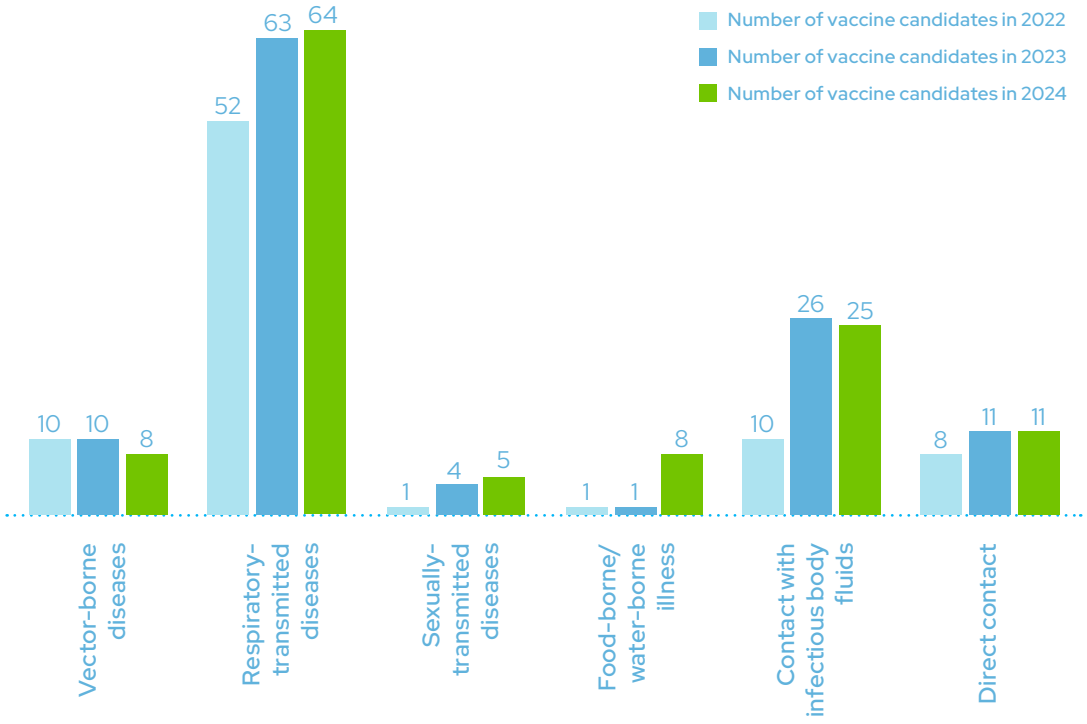
*There are two vaccine candidates against Hepatitis B in the pipeline, however they are intended for therapeutic use and therefore have not been included in this figure.

** The 17 influenza candidates include combinations with SARS-CoV-2 and/or RSV

*** Some of the vaccines might be registered only outside Europe at the moment of writing this document.

Figure 8

Number of vaccines in development by disease transmission route.



The comparison with 2022 data is approximate as in 2022 the pathogens spreading through multiple routes have been counted separately, while in 2023 and 2024 there are counted multiple times, under each section.

Respiratory-transmitted infections

Respiratory infections, a major drive of sick leave, hospitalisation and death (30), are a key challenge in the adult population. For example, seasonal influenza is responsible each year for up to 50 million symptomatic cases in the European Union/European Economic Area (EU/EEA), and 15,000–70,000 European citizens die of complications associated with influenza. The annual economic and healthcare burden of influenza is substantial, despite the usually short duration of illness (31). It is estimated that yearly seasonal influenza vaccination can save between €248 million and €332 million in healthcare costs in Europe by avoiding hospitalisations and visits to general practitioners (32), (33).

Another example is RSV which causes an average of 213,000 annual hospitalisations in children under five years and 158,000 annual hospitalisations in adults in the EU, Norway and the United Kingdom (34). A recent study conducted in Belgium using a static, cohort-based decision-tree model predicts that an RSV vaccine with a three-year duration of protection administered in adults over 60 years old would prevent 154,728 symptomatic acute respiratory infection cases, 3,688 hospitalisations, and 502 deaths over three years compared to no vaccination. Additionally, it would save approximately €36 million in direct medical costs in Belgium (35).

COVID-19 or pneumococcal disease further illustrate the widespread impact of respiratory infections, affecting disproportionately vulnerable populations, such as the elderly or those with pre-existing conditions. For instance, it is estimated that persons aged 60 years and older accounted for over 80% of all COVID-19 fatalities (36). On the other side, infections with *Streptococcus pneumoniae* are more frequent in children and in elderly, with a particular risk of death in 10-20% of the seniors infected (37).

64 of the vaccine candidates in our members' pipelines target respiratory-transmitted infections (aerosols and droplets), including coronaviruses, influenza, meningococcal disease, measles, Mpox, pneumococcal disease, rubella, RSV and varicella-zoster virus *(Figure 8)*.

Sexually-transmitted infections (STIs)

Despite global efforts to curb the spread of STIs, recent data published by WHO revels alarming trends. Infections such as syphilis, gonorrhoea, chlamydia and trichomoniasis continue to rise, leading to severe health complications and contributing to a substantial burden of disease worldwide. Syphilis alone saw a significant increase, reaching 8 million cases globally among adults aged 15-49 in 2022. STIs may also be a driver of AMR as suggested by the increased reporting of drug-resistant strains of gonorrhoea (38).

At the European level, the situation is similarly alarming. In March 2024, ECDC raised concerns over the rising trend of STIs in the EU/EEA. The data published highlighted a sharp increase in infections in 2022 compared to the previous year, with gonorrhoea cases rising by 48%, syphilis by 34%, and chlamydia by 16% (39).

Other prevalent STIs include Human Papillomavirus (HPV) and Human Immunodeficiency virus (HIV). HPV is a significant concern as it can lead to several cancers, including cervical cancer, which is one of the most common cancers affecting women globally. In the EU alone, HPV causes about 87,000 cancers cases of which approximately 33,000 cases of cervical cancer resulting in 15,000 deaths annually (40), (41). On the other hand, HIV is a virus that compromises the immune system, potentially leading to severe illness and death if not treated. The final stage of HIV infection, known as Acquired Immune Deficiency Syndrome (AIDS), occurs when the immune system is critically weakened, making the body susceptible to various opportunistic diseases (42). Although the number of new HIV infections decreased from 1.5 million in 2020 to 1.3 million in 2022, HIV-related deaths remain significant. In 2022, there were 630,000 deaths attributed to HIV, with 13% of these occurring in children under the age of 15 (38)

5 of the vaccine candidates in our members' pipelines target sexually-transmitted infections, including gonorrhoea, HPV, Mpox and HSV-2 *(Figure 8)*.

Maternal immunisation

Vaccination has already contributed massively to reducing infant morbidity and mortality worldwide, but more still can be done by using maternal immunisation. Vaccination during pregnancy induces antibodies which are then transmitted to the foetus trough the placenta during pregnancy, or after birth in breast milk, providing protection against infections in the first few months of life. Our members' pipelines contain vaccine candidates for maternal immunisation against group B *Streptococcus* infections.

	POPULATION	STATUS	PLATFORM
GROUP B *STREPTOCOCCUS* INFECTION (GBS) [43] • GBS bacteria can cause many types of infections, such as bacteraemia and sepsis, bone and joint infections, meningitis, pneumonia, skin and soft-tissue infections. • GBS disease can cause long-term problems, such as deafness and developmental disabilities in babies. • 2 to 3 in every 50 babies (4% to 6%) who develop GBS disease die. • On average, about 1 in 20 non-pregnant adults with serious GBS infections dies. • Currently, no licensed vaccine for the prevention of GBS. • Pipeline candidates: 1 PIPELINE CANDIDATES: 1	Adults* (1)	Phase II (1)	Glycoconjugate vaccine (1)
MENINGOCOCCAL DISEASE [44], [45], [46] • Caused by various serogroups of *Neisseria meningitidis* which is one of the most common causes of bacterial meningitis in the world and the only bacterium capable of generating large epidemics of meningitis. • At least 12 serogroups of meningococcus have been characterised; five serogroups cause most of the cases worldwide (A, B, C, W, Y). • In 2012, 1,149 confirmed cases of invasive meningococcal disease (IMD), including 110 deaths, reported in 30 EU/EEA countries. • Often a rapid progression of the disease, with an 8-20% case-fatality ratio, the highest being for serogroups C and W. This may result in death within one or two days after onset of symptoms. PIPELINE CANDIDATES: 4**	Paediatric: (1) Paediatric + Adults: (3)	Phase II: (2) Phase III: (1) Regulatory review: (1)	Glycoconjugate vaccine: (1) Multiple platforms: (3)
MEASLES, MUMPS, RUBELLA, VARICELLA [47], [48], [49], [50] • **Measles:** highly contagious viral disease that can lead to severe complications and death. Vaccination averted 57 million deaths between 2000 and 2022, but in 2022 approximately 136,000 deaths were caused by measles globally, mostly in children under the age of 5. • **Mumps:** contagious viral disease characterised by swelling of the salivary glands. In 2022, 2,593 mumps cases were reported in the EU/EEA. • **Rubella:** leading vaccine-preventable cause of birth defects, accounting for an estimated 100,000 infants born with congenital rubella syndrome (CRS) each year worldwide. In 2022, there were an estimated 17,865 cases of rubella in 78 countries. PIPELINE CANDIDATES: 1	Paediatric (1)	Phase II (1)	Live-attenuated virus (1)

NI TrV RI AMR

	POPULATION	STATUS	PLATFORM
RESPIRATORY SYNCYTIAL VIRUS (RSV) [51], [52] • RSV is a globally prevalent cause of lower respiratory tract infection in all age groups, but most at risk are children under six months old, people over 65 and those with weakened immune systems or pre-existing health conditions. • Annually, the virus is responsible for the hospitalisation of around 213,000 children under five with some requiring intensive care, and approximately 158,000 adults. PIPELINE CANDIDATES: 7 (RSV) 3 (RSV + OTHER INFECTIONS, INCLUDING HMPV) 2 (SEASONAL INFLUENZA + RSV) 1 (COVID-19 + INFLUENZA + RSV)	Paediatric: (5) Adults: (3) Adults + Older Adults: (3) Older Adults: (2)	Phase I: (4) Phase II: (4) Phase III: (5)	Live attenuated virus: (1) mRNA: (6) Monoclonal antibody: (1) Protein subunit: (3) Virus-like particle: (1) N/A: (1)
SEASONAL INFLUENZA [53] • Influenza virus types A and B are both common causes of acute respiratory illnesses. • Severe morbidity and mortality more common among elderly people and in specific high-risk groups. • There are around 1 billion cases of seasonal influenza annually, causing 290,000 to 650,000 respiratory deaths every year. • Influenza viruses undergo frequent changes in their surface antigens, with new influenza outbreaks occurring every year. PIPELINE CANDIDATES: 13 (SEASONAL INFLUENZA) 2 (SEASONAL INFLUENZA + RSV) 3 (SEASONAL INFLUENZA + COVID-19) 1 (SEASONAL INFLUENZA + COVID-19 + RSV)	Paediatric: (1) Adults: (7) Adults + Older Adults: (11)	Phase I: (4) Phase II: (9) Phase III: (6)	Protein nanoparticles: (2) mRNA: (14) Whole-inactivated virus: (2) N/A: (1)
VARICELLA-ZOSTER VIRUS (VZV) [54], [55] • Varicella (chickenpox) is an acute, highly contagious disease caused by varicella-zoster virus (VZV). Following infection, most often in early childhood, the virus remains latent in neural ganglia and can be reactivated later in life to cause shingles. • Varicella is more severe in adults than in children and can be fatal especially in neonates and in immunocompromised individuals. • In the USA, around 4 million annual varicella cases reported with 100-150 deaths and more than 10,000 hospitalisations before the introduction of routine varicella vaccination. PIPELINE CANDIDATES: 2 (VARICELLA) 1 (SHINGLES)	Paediatric: (1) Adults: (1) Adults + Older Adults: (1)	Phase I (1) Phase II (2)	Live-attenuated virus (1) mRNA (2)

*Maternal immunisation

**3 vaccine candidates against Meningococcal A, B, C, W, Y disease, 1 vaccine candidate against Meningococcal A, C, W, Y disease.

NI TrV RI AMR

Travel vaccines

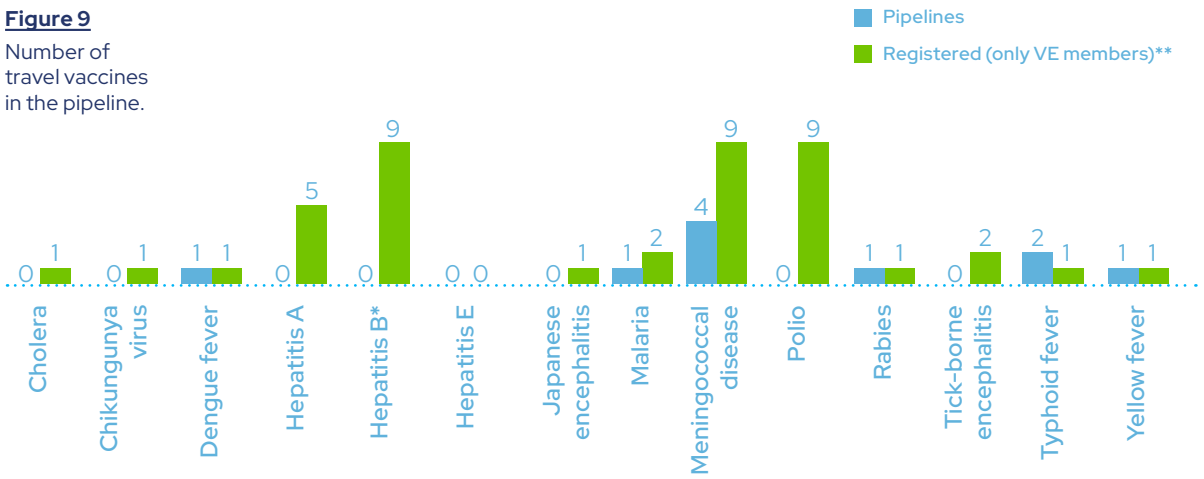
In today's interconnected world, international travel and migration are more common than ever before, increasing the risk of spreading infectious diseases. It is estimated that between 42% and 79% of travellers to low- and middle-income countries become ill with a travel-associated disease. While most of these health issues are mild, there are significant cases when the help of a healthcare professional is requested (56). An analysis evaluating the travel-related infections present in Europe over a 20-year period revealed that the most frequently diagnosed diseases are influenza and malaria, with infections caused by arboviruses being on an upward trend (e.g., Dengue, Chikungunya, Zika, yellow fever, West-Nile fever) (57).

The impact of these diseases extends beyond individual health, placing a strain on public health systems and contributing to economic burdens through treatment costs and productivity losses. Therefore, travel vaccines play a crucial role in safeguarding the health of international travellers. These vaccines are specifically recommended based on the traveller's destination and are designed to protect against severe diseases prevalent in that specific region. Vaccination is instrumental in preventing the importation of diseases that can otherwise spread globally. Essential vaccines for travellers include, but are not limited to cholera, chikungunya virus, dengue fever, hepatitis A, B, and E, Japanese encephalitis, malaria, meningococcal disease, polio, rabies, tick-borne encephalitis, typhoid fever, and yellow fever (58), (59).

Travel vaccine candidates against dengue fever, malaria, meningococcal disease, rabies, typhoid fever and yellow fever are currently in development in the pipelines of Vaccines Europe members.

Figure 9

Number of travel vaccines in the pipeline.



*There are two vaccine candidates against Hepatitis B in the pipeline, however they are intended for therapeutic use and therefore have not been included in this figure.

** Some of the vaccines might be registered only outside Europe at the moment of writing this document.

	POPULATION	STATUS	PLATFORM
DENGUE FEVER [60], [61] • Mosquito-borne viral disease affecting humans worldwide. • Half of the world's population now at risk of dengue with an estimated 100–400 million infections occurring each year. • Approximately 20,000-25,000 deaths mainly in children. PIPELINE CANDIDATES: 1	Paediatric + Adults + Older Adults: (1)	Phase II (1)	Live-attenuated virus (1)
YELLOW FEVER [62], [63], [64] • Acute viral haemorrhagic disease transmitted by infected mosquitoes. • As of 2023, 34 countries in Africa and 13 countries in Central and South America are endemic for yellow fever. • 200,000 cases and 30,000 deaths each year, with 90% occurring in Africa. • 30% to 60% of infected persons who develop severe disease die. PIPELINE CANDIDATES: 1	Paediatric + Adults + Older adults: (1)	Phase II: (1)	Live-attentuated virus (1)

Zoo TrV RI AMR CC

Antimicrobial resistance

Antimicrobial resistance (AMR) is rapidly emerging as one of the most severe global health threats, with drug-resistant infections resulting in longer hospital stays and higher medical costs, as well as increased mortality. In 2019, approximately 4.95 million deaths worldwide were associated with bacterial AMR, with 1.27 million deaths directly attributable to bacterial resistance (65). In the EU/EEA region, the health burden of infections due to AMR is comparable to that of influenza, tuberculosis and HIV/AIDS combined (66). If current trends continue, it is projected that the number could rise to 10 million deaths per year globally by 2050 (67). The economic implications are equally important, with healthcare costs generated by AMR potentially ranging from $300 billion to over $1 trillion annually by 2050. Furthermore, AMR could push an additional 28.3 million people into extreme poverty by 2050, exacerbating economic challenges, particularly in low- and middle-income countries (LMICs) (68).

In response, the World Health Organization (WHO), along with other international and national bodies, has intensified efforts to combat AMR in a sustainable and equitable manner (69), proposing an integrated One Health framework that considers the contributive value of various solutions, including vaccines (70). Vaccines target the root causes of AMR, being effective before bacteria start to multiply and before different tissues and organs are affected, decreasing the likelihood of resistant mutations spreading. Vaccination is largely credited for the 50% reduction of AMR deaths in children under 5 observed between 1990 and 2021 in sharp contrast to the 80% increase in people 70 and over (9).

According to a recent report published by the WHO, vaccines could reduce antibiotic use by 22% and save up to US$ 30 billion in hospital costs. Increasing the coverage of existing vaccines could prevent an additional 106,000 deaths linked to AMR annually, and developing new vaccines could save an additional 543,000 lives, highlighting the urgent need for both a better use of existing vaccines and the development of new ones (3). Recognising the essential role of vaccines alongside antimicrobials, diagnostics, and other infection prevention and control measures is vital in the broader effort to address AMR effectively.

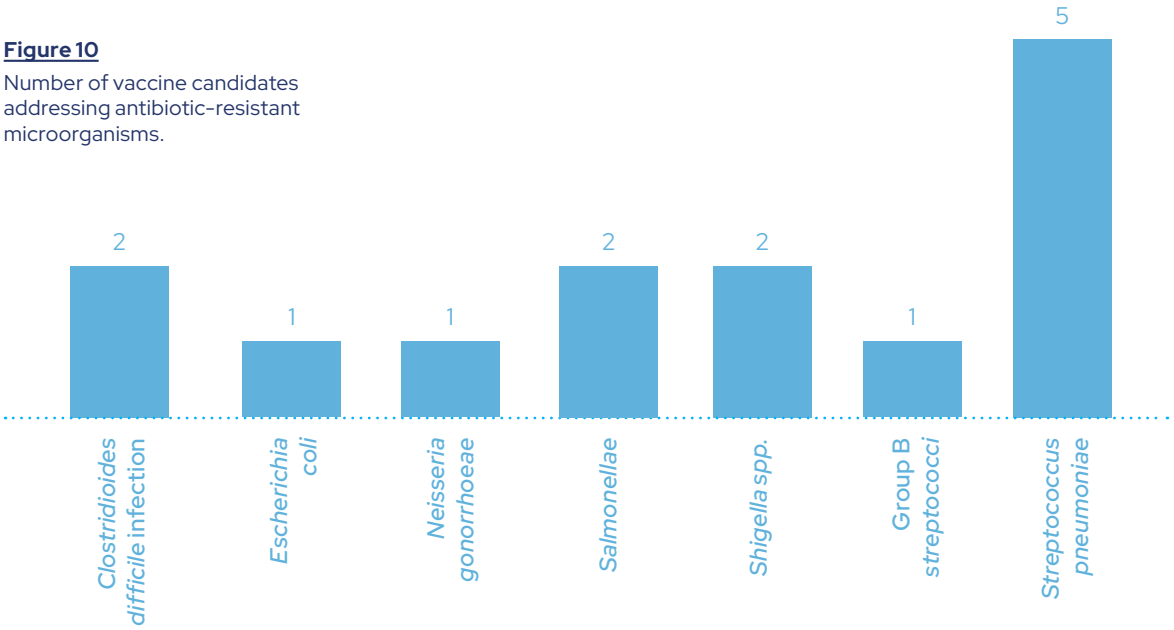
Developing vaccines that address resistant pathogens is an extremely challenging task. However, Vaccines Europe members are playing their part in addressing AMR, in line with the strategy developed by WHO as a technical annex to the Immunisation Agenda 2030 (70). Strengthening surveillance systems to address data gaps and developing regulatory guidance and health technology assessment frameworks would be of tremendous help in accelerating the development, availability, and use of these products (71).

Vaccines that prevent viral infections also play an important role in decreasing the overuse and misuse of antibiotics, either by reducing erroneous prescriptions that encourage the inappropriate treatment of viral diseases with antibiotics, or by preventing secondary bacterial superinfections (72). There is increasing evidence in this direction for vaccination against rotavirus, influenza, varicella and dengue (73), (74), (75), (76) and similar trends are expected for COVID-19 and RSV. For example, a recent study showed that administering an RSV vaccine to pregnant mothers would reduce antimicrobial prescribing for their infants by 12.9% over the first three months of life (77). When it comes to COVID-19, a recent study highlights that COVID-19 vaccination significantly reduces outpatient antibiotic prescribing among older adults, with the most pronounced decrease for antibiotics used for respiratory infections. This reduction was especially marked after the third vaccine dose and during periods of high SARS-CoV-2 circulation (78).

There are currently 14 vaccine candidates in our members' pipelines that are targeting antibiotic-resistant bacteria on the new WHO's Bacterial Priority Pathogens list (79). Additionally, their pipelines contain 47 candidates against COVID-19, dengue, seasonal influenza, RSV and varicella/shingles.

Figure 10

Number of vaccine candidates addressing antibiotic-resistant microorganisms.



	POPULATION	STATUS	PLATFORM
CLOSTRIDIOIDES DIFFICILE (80), (81) • Nearly 124,000 healthcare-associated C. *difficile* infections (CDIs) annually in acute care hospitals in the EU/EEA. • 1 in 11 people over age 65 diagnosed with a healthcare-associated CDI dies within one month. • Currently no licensed vaccine for the prevention of CDI. PIPELINE CANDIDATES: 2	Paediatric + Adults + Older Adults: (1) Older Adults: (1)	Phase II: (1) Phase III: (1)	Toxoid vaccine: (2)
INVASIVE *ESCHERICHIA COLI* DISEASE (82), (83), (84), (85), (86) • Leading cause of global deaths and adult sepsis from bacterial infections and the second most common cause of neonatal meningitis. • Over 60% of infections show resistance to at least one antibiotic class. • Accounts for 70-95% of community-onset urinary tract infections (UTIs) and approximately 50% of nosocomial UTIs. • The incidence is three times higher in older adults compared to the general adult population. PIPELINE CANDIDATES: 1	Older Adults: (1)	Phase III: (1)	Glycoconjugate vaccine: (1)

NI RI AMR

	POPULATION	STATUS	PLATFORM
GONORRHOEA [87], [88] • Preventable and curable sexually-transmitted infection caused by the bacterium *Neisseria gonorrhoea*. • In 2020 there were an estimated 82.4 million new infections among adults globally. • In the EU/EEA region, there were over 70,000 cases of gonorrhoea in 2022. • Increasing antimicrobial resistance to antibiotics have been observed in *N. gonorrhoea*. PIPELINE CANDIDATES: 1	Paediatric + Adults: (1)	Phase II: (1)	Generalised Modules for Membrane Antigens: (1)
SHIGELLOSIS [89], [90], [91] • Gastrointestinal infection caused by one of four species of *Shigella*. • 450,000 infections in the United States each year and an estimated $93 million in direct medical costs. Of these, 77,000 infections are antibiotic resistant. • Over 2,100 confirmed shigellosis cases in 2021 in the EU/EEA. PIPELINE CANDIDATES: 2	Paediatric: (1) Adults: (1)	Phase II: (2)	Generalised Modules for Membrane Antigens: (1) Glycoconjugate vaccine: (1)
STREPTOCOCCUS PNEUMONIAE [92], [93] • *Streptococcus pneumoniae* (*S. pneumoniae*) is the leading cause of community-acquired pneumonia. • Incidence of community-acquired pneumonia caused by *S. pneumoniae* is 1 in 1,000 adults per year. • 1 million children die of pneumococcal disease every year. • Pneumococcal resistance to antimicrobials is a serious and rapidly increasing problem worldwide. PIPELINE CANDIDATES: 5	Paediatric: (2) Adults: (1) Paediatric + Adults + Older Adults: (1) N/A: (1)	Phase I: (1) Phase II: (4)	Glycoconjugate vaccine: (3) Multiple Antigen Presenting System (MAPS): (2)

NI STI RI AMR

Infection-related therapeutic vaccines

Therapeutic vaccination is a field still in its infancy compared to preventive vaccines. There is no established regulatory and access environment pathway for therapeutic vaccines. They work by utilising a patient's own immune system to fight or control an existing infection or infection-related disease, rather than immunising for prevention of a future disease. The aim of therapeutic vaccination is therefore to boost or redirect the immune response and help to control or clear the disease caused by an infection.

	POPULATION	STATUS	PLATFORM
HEPATITIS B [94] • Viral infection that attacks the liver and can cause both acute and chronic disease. • 254 million people living with chronic hepatitis B infection in 2022, with 1.2 million new infections each year. • Estimated 1.1 million deaths in 2012, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer). PIPELINE CANDIDATES: 2*	Adults: (2)	Phase II: (2)	Multiple platforms: (1) Virus-like particle: (1)
HERPES SIMPLEX VIRUS (HSV) [95], [96] • 2 types of HSV: HSV-1 and HSV-2. They can cause oral herpes HSV-1), genital herpes (HSV-1 and HSV-2) and eye infection leading to blinding complications (HSV-1 and HSV-2). • 3.7 billion people under age 50 (67%) with HSV-1 infection globally. • 491 million people aged 15-49 (13%) worldwide with HSV-2 infection. • Like Varicella Zoster virus, latent HSV infection can re-activate and lead to recurrent outbreaks of symptoms. PIPELINE CANDIDATES: 2*	Adults: (2)	Phase II: (2)	Protein subunit: (1) mRNA: (1)

*Therapeutic vaccine

NI STI CR ThV

Infection-associated cancer vaccines

Two main approaches are considered:

- Prophylactic: refers to the prevention of infection-related cancers, such as liver cancer that could be a consequence of the hepatitis B infection, those related to infection with HPV (Human Papillomavirus) or EBV (Epstein-Barr virus).
- Curative: induce tumour regression, eradicate minimal residual disease, establish lasting antitumour memory and avoid non-specific or adverse reactions (97).

This review only includes vaccines targeting infectious agents.

	POPULATION	STATUS	PLATFORM
EPSTEIN-BARR VIRUS (EBV) (98), (99) • The first human tumour virus discovered, being strongly involved in the aetiology of multiple lymphoid and epithelial cancers. • EBV is also the primary cause of infectious mononucleosis. • Over 200,000 new EBV-associated cases of cancer and 150,000 deaths worldwide annually. • Up to 70% of adolescents and young adults in developed countries suffer from infectious mononucleosis caused by EBV. • Currently no vaccines or treatments against EBV infection. PIPELINE CANDIDATES: 2	Paediatric + Adults: (1) Adults: (1)	Phase II: (2)	mRNA: (2)
GLIOBLASTOMA (CMV-MEDIATED) (100), (101) • Fast-growing and aggressive brain tumour that can result in death in six months or less, if untreated. • Incidence of 3.21 per 100,000 population. • GBM presents unique treatment challenges due to the localisation of tumours in the brain. • Approximately 40% survival in the first year post-diagnosis and 17% in the second year. • Cytomegalovirus (CMV) plays a crucial role in the pathogenesis and treatment of glioblastoma, but among glioma patients with confirmed CMV infection, a low pathological positive rate was associated with better prognosis and longer survival. PIPELINE CANDIDATES: 1*	Adults + Older Adults: (1)	Phase II: (1)	Virus-like particle: (1)
HUMAN PAPILLOMAVIRUS (HPV) (102), (103) • Group of viruses that can cause cervical cancer, which is the fourth most common type of cancer in women aged 15–44 years. • Each year, there are around 33,000 cases of cervical cancer in the EU, and 15,000 deaths. • At global level, there were approximately 660,000 new cases and 350,000 deaths in 2022. About 94% of the new deaths in 2022 occurred in low- and middle-income countries. PIPELINE CANDIDATES: 1	Paediatric + Adults: (1)	Phase II: (1)	Protein subunit: (1)

*Therapeutic vaccine

NI ThV RI CR STI

Climate change

2023 is recognised as the warmest year on record, the average global temperatures exceeding pre-industrial levels by 1.5°C. Europe, as the fastest-warming continent, is witnessing unprecedented changes in its climate. Extreme heatwaves, once rare, are now frequent, while shifts in precipitation patterns have led to severe downpours, catastrophic floods, and, in contrast, worsening droughts, especially in southern Europe. These climate shifts impact severely food and water security, energy supplies, and public health (104).

The intersection of climate change and infectious diseases is a growing area of concern for global health, with the warming climate altering the distribution, transmission, and severity of various infectious diseases. Approximately 58% of infectious diseases are believed to be aggravated by global warming and extreme weather due to increased spread of disease vectors like mosquitoes and changes in the lifecycles of pathogens (105).

a) New habitats for vector-borne diseases

Global warming and altered precipitation patterns enable the creation of new habitats for disease vectors such as mosquitoes, ticks, and other insects in regions where they were previously unable to survive. These vectors are responsible for transmitting some of the world's most dangerous diseases, such as West Nile fever, Zika, dengue fever, chikungunya, malaria and yellow fever. These diseases cause more than 700,000 deaths each year, accounting for over 17% of all infectious diseases (106).

For example:

- As of July 2024, Europe has observed a seasonal rise in locally acquired West Nile virus and cases are expected to increase due to favourable weather conditions (107).
- Projections indicate a rise in the environmental conditions in temperate zones suitable for *Aedes albopictus* and *Aedes aegypti*, the vectors carrying dengue, chikungunya, Zika and yellow fever. This led to a considerable increase of locally acquired dengue cases after 2022, compared to the period 2010-2021 (108).

b) Contaminated water and food sources

It is estimated that more than 3.4 million people die annually due to water-borne and sanitation-related diseases, such as cholera, rotavirus, typhoid fever (*Salmonella sp.*) and dysentery (*Shigella sp.*, *E. coli*). The contamination of water supplies with these pathogens is expected to increase as a consequence of climate change, due to high temperatures, flooding, droughts and storms (106).

Every year, approximately 600 million people become sick worldwide due to contaminated food. Heavy rains, flooding and high temperatures increase the spread of pathogens into watersheds and croplands and will accelerate their replication cycles, increasing the risk of food contamination with pathogens such as *Salmonella* and *Campylobacter* (106).

c) Disruption of natural habitats

As climate change disrupts natural habitats, wildlife is forced into closer proximity to human populations, increasing the risk of disease spillover. This has been observed with diseases such as Ebola or malaria, which have been linked to deforestation and changes in land use (109), (110).

d) Changes in human behaviour

Climate change can also impact human behaviour. Extreme weather, such as heatwaves and heavy rainfall, can drive people to cluster together indoors more often, making it easier for infectious diseases to spread. In addition, as humans adapt to changes in temperature, our immune systems can be weakened, making us more vulnerable to respiratory diseases like influenza.

e) Migration

Climate change is a significant drive of human migration, with a considerable amount of people forced to leave their homes due to deteriorating environmental conditions, such as rising sea levels and extreme weather. The World Bank estimates that climate change could force 216 million people to migrate within their own countries by 2050 (111), due to the impact on their livelihoods and loss of liveability in highly exposed locations. The displaced populations are often vulnerable to infectious diseases due to overcrowding, limited access to healthcare and poor living conditions. The movement of large groups could also facilitate the spread of infectious diseases across borders.

The pipelines of Vaccines Europe members include vaccine candidates against dengue fever, malaria, typhoidal and non-typhoidal *Salmonella*, *Shigella sp.*, yellow fever and Zika.

	POPULATION	STATUS	PLATFORM
MALARIA [112] • Life-threatening disease caused by *Plasmodium* parasites that are transmitted to people through the bites of infected female mosquitoes. • Left untreated, malaria can progress to severe illness and death within a period of 24 hours. • In 2022, 249 million cases of malaria worldwide and 608,000 deaths. • In 2022, 94% of malaria cases and 95% of malaria deaths occurred in the WHO African Region. Children under five accounted for about 80% of all malaria deaths in the Region. PIPELINE CANDIDATES: 1	 Adults: (1)	 Phase II: (1)	 Protein subunit: (1)

SALMONELLA [113], [114], [115]
• Categorised as typhoidal and non-typhoidal serotypes.
• Increasing resistance to various types of antibiotics.
• **Typhoidal:** cause typhoid and para-typhoid fever, resulting in approximately 9 million cases and 110,000 deaths every year.
• **Non-typhoidal:**
  • 1 of 4 key global causes of diarrhoeal diseases; most cases of salmonellosis are mild; but sometimes they can be life-threatening.
  • In Europe the second most common food-borne zoonosis in 2022, with 65, 208 confirmed human cases.
PIPELINE CANDIDATES:
1 (TYPHOIDAL AND PARATYPHOIDAL *SALMONELLA*)
1 (INVASIVE NON-TYPHOIDAL *SALMONELLA*)
	
	Adults: (2)
		
		Phase I: (1)
		Phase II:(1)
			
			Glycoconjugate vaccine: (1)
			Generalized Modules for Membrane Antigens: (1)

ZIKA [116], [117], [118] • Disease caused by a virus transmitted primarily by infected mosquitoes. • Over 707,000 Zika virus disease cases reported in the Americas in 2015-2016. • Infection during pregnancy is associated with complications such as preterm birth and miscarriage or can cause infants to be born with microcephaly and other congenital malformations. • An increased risk of neurologic complications is associated with Zika virus infection in adults and children. • Currently no licensed vaccines or treatments or Zika. PIPELINE CANDIDATES: 2	 Adults: (2)	 Phase I: (1) Phase II:(1)	 mRNA: (1) Whole-inactivated virus: (1)

Zoo TrV RI AMR CC NI

Zoonoses and pandemic preparedness

Zoonotic diseases, transmitted from animals to humans, account for around 60% of infectious diseases affecting humans. They result in approximately 2.7 million deaths and 2.5 billion illnesses each year, with significant implications for livestock production and food security (119). For instance, the recent COVID-19 pandemic, believed to have originated from zoonotic transmission, has highlighted the profound impact of such diseases on global health systems and economies.

The threat posed by zoonotic diseases is underscored by emerging pathogens with potential to cause widespread outbreaks. A notable example is Mpox (previously monkeypox), which, historically transmitted from animals to humans, has now shown increased human-to-human transmission, particularly through close physical contact. Since January 2022, over 99,000 cases of Mpox have been reported globally, with 208 deaths, marking a significant rise compared to historical patterns (120), (121). This escalation prompted the Africa CDC (Africa Centres for Disease Control and Prevention) to declare the ongoing Mpox outbreak across the continent a Public Health Emergency of Continental Security (PHECS) (122) and the WHO to declare it a Public Health Emergency of International Concern (PHEIC) (123).

In addition to COVID-19 and Mpox, other viruses carrying zoonotic infection potential circulating in farmed and wild animals, are a constant reminder that another pandemic could be around the corner. While it is important to implement robust measures to predict and prepare for the outbreak of zoonotic infectious diseases, it is equally important to prevent their emergence.

The recent events have highlighted the importance of focusing on the interconnectivity between the health of human communities, animals, and the environment, requiring strong interdisciplinary collaboration. A One Health approach is essential for the future of animal and public health, as highlighted in a joint report published by ECDC (European Centre for Disease Prevention and Control), EFSA (European Food Safety Authority), EMA (European Medicines Agency), and OECD (Organisation for Economic Co-operation and Development) (124).

The increasing global incidence of zoonotic diseases calls for a concerted effort to develop and implement new strategies and technologies for disease prevention and management, ensuring preparedness for future outbreaks and safeguarding public health.

Vaccines Europe members are addressing the challenge of zoonotic diseases by researching vaccines against coronaviruses, dengue fever, pandemic influenza, Lyme disease, malaria, rabies, Nipah virus disease, salmonellosis and yellow fever.

	POPULATION	STATUS	PLATFORM
CORONAVIRUSES [125], [126], [127] • Most coronaviruses infect animals (i.e., birds and mammals - bats and pangolins), which act as reservoirs and intermediate hosts, but can sometimes change host and infect humans. • There are currently seven coronaviruses known to infect humans, four of them causing mild-to-moderate disease and three of them cause more severe and possibly even fatal disease (SARS-CoV, MERS-CoV, SARS-CoV-2) • MERS-CoV: from 2012 to August 2024, over 2,600 confirmed cases, with a death rate of 36%. • SARS-CoV2 (COVID-19): over 775 million confirmed cases, with over 7 million deaths. PIPELINE CANDIDATES: 15 (CORONAVIRUSES) 3 (SEASONAL INFLUENZA + COVID-19) 1 (SEASONAL INFLUENZA + COVID-19 + RSV)	Paediatric: (3) Adults: (6) Adults + Older Adults: (7) Paediatric + Adults + Older Adults: (3)	Phase I: (5) Phase II: (5) Phase III: (6) Regulatory review: (3)	Monoclonal antibody: (1) Protein nanoparticles: (1) Protein subunit: (2) mRNA: (12) Virus-like particle: (3)
LYME DISEASE [128], [129] • Caused by the bacterium *Borrelia burgdorferi* and transmitted to humans by the bite of infected ticks. • Around 476,000 cases diagnosed and treated per year in the USA, and over 200,000 cases per year in Western Europe. • If left untreated, infection can spread to joints, the heart, and the nervous system. • Currently no vaccine available. PIPELINE CANDIDATES: 3	Paediatric + Adults: (2) Adults: (1)	Phase I: (2) Phase III: (1)	Protein subunit: (1) mRNA: (2)
MPOX [120], [121], [130] • Infectious disease caused by the Mpox virus that can cause a painful rash, enlarged lymph nodes and fever. • Historically the disease is transmitted from animals to humans, however in the last years human-to-human transmission has been observed leading to global outbreaks. • Between January 2022 and August 2024, over 99,000 cases of Mpox have been reported globally, with 208 deaths. PIPELINE CANDIDATES: 1	Adults: (1)	Phase I: (1)	mRNA: (1)

NI AMR RI Zoo STI

	POPULATION	STATUS	PLATFORM
NIPAH VIRUS INFECTION [131], [132] • Estimated fatality rate 40% to 75%. • 639 human cases of Nipah virus infection reported from Bangladesh, India, Singapore, Philippines and Malaysia, with a mortality rate of about 59% until 2018. • Fruit bats are the wildlife reservoir of Nipah virus. • Currently no treatment or vaccine available against Nipah virus. PIPELINE CANDIDATES: 1	Adults: (1)	Phase I: (1)	mRNA: (1)

PANDEMIC INFLUENZA [133], [134]
• Global outbreak that appears when a new flu A virus emerges to which most of the population does not have immunity and is spreading from individual to individual in an efficient and sustained way.
• Previous influenza pandemics caused a significant number of deaths, not only among those at risk of complications, but also in healthy individuals:
  • 1918: around 50 million deaths.
  • 1957 and 1968: around 2 million deaths
  • 2009 H1N1: over 500,000 deaths
PIPELINE CANDIDATES: 5
	Adults: (2)
	Adults + Older Adults: (3)
		Phase I: (3)
		Phase II: (2)
			mRNA: (4)
			Whole-inactivated virus: (1)

RABIES [135], [136], [137] • Viral disease that causes around 59,000 deaths every year globally. • Dogs are the main source of human rabies deaths, contributing up to 99% of all rabies transmissions to humans. • Estimated global cost of US$ 8.6 billion per year. • In the EU/EEA, no human rabies infections were reported between 2020–2022, however travel-associated infections and infections in animals occurred occasionally. PIPELINE CANDIDATES: 1	Paediatric + Adults + Older Adults: (1)	Phase III: (1)	Whole-inactivated virus: (1)

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Vaccine technologies

Traditionally limited to a few technologies only, vaccinology has evolved over the years to overcome limitations and reflect technological advancements. A diverse array of vaccine technologies has been developed and perfected over time, allowing for broader protection against a wide range of infectious diseases. This variety also enables tailored vaccination strategies for specific populations, potentially increasing vaccine acceptance. Flexible vaccination options address unique needs shaped by factors such as age, health status, beliefs, geographical location and socio-economic status. A wide portfolio of vaccine technologies also ensures uninterrupted access to essential vaccines by distributing manufacturing and supply risks across multiple products, taking into account regional differences in infrastructure, resources, and healthcare systems. Last but not least, the availability of multiple vaccine technologies enhances preparedness and response capabilities for both current and emerging health threats, increasing the chances of successful vaccine development and enabling rapid adaptation to new pathogens.

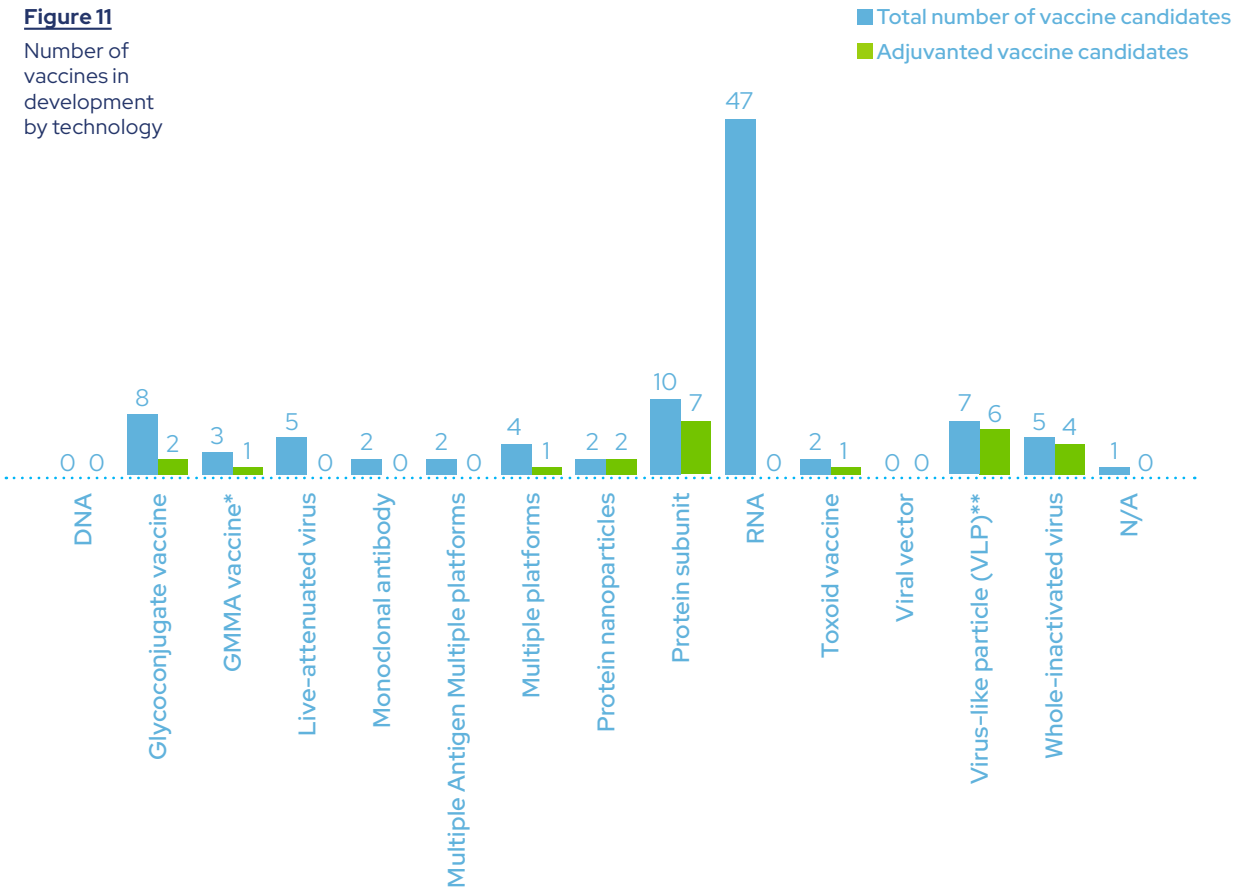
Currently, the mRNA technology dominates the pipeline of VE member companies, but other technologies are also well-represented and equally important. Emerging approaches such as Generalized Modules for Membrane Antigens (GMMA vaccines), antigen-presenting systems, and monoclonal antibodies for preventative use are gaining traction. An overview of these technologies is present in Annex III.

Combination vaccines, which have been used for years in routine immunisation (e.g., MMR for measles, mumps, and rubella, and DTaP for diphtheria, tetanus, and acellular pertussis), remain a valuable tool. They reduce the number of injections needed to protect against multiple diseases and help streamline vaccination schedules. Several new combination vaccines are currently under development, mainly for respiratory infections (e.g., such as SARS-CoV-2, influenza, RSV, human metapneumovirus).

Adjuvants are present in many of the vaccine candidates, their main aim being to enhance the body's immune response to vaccine antigens. A wide range of adjuvants are used by Vaccines Europe members in their candidate products, from well-known ones to innovative adjuvants developed by each company. Examples of adjuvants used in their pipelines are alum (aluminium salts, usually phosphate or hydroxide), AS01, AS03, E6020, MF58, Matrix-M and GM-CSF. The composition of these adjuvants varies and consists of different natural or synthetic substances, such as oils, lipids found on the outer membrane of bacteria, salts, surfactants, saponins, liposomes and proteins.

Figure 11

Number of vaccines in development by technology



*Generalized Modules for Membrane Antigens

**including enveloped VLP (eVLP)

Conclusion

This report underscores the transformative power of vaccines in addressing evolving health threats. COVID-19 continues to drive innovation, with a noticeable shift toward combination vaccines that integrate protection against multiple respiratory infections, including seasonal influenza and RSV. This development reflects a strategic response to evolving viral threats and the need for integrated solutions. RSV vaccines in particular have made significant progress, with several candidates either receiving marketing authorisation or nearing late-stage development.

In addition to viral vaccines, there have been promising developments in addressing bacterial infections. The presence of candidates against drug-resistant pathogens indicates a growing recognition of the importance of vaccination in tackling antimicrobial resistance. The rising prevalence of sexually-transmitted infections has also accelerated the development of vaccines aimed at addressing these urgent concerns, as evidenced by alarming trends in both global and European data.

Vaccines for travel-related and zoonotic diseases further illustrate the role of immunisation in managing global mobility and emerging threats. This ongoing work to enhance travel safety demonstrates a commitment to safeguarding public health across diverse settings.

Vaccines are essential in protecting public health, saving millions of lives annually, and supporting healthcare efficiency and socio-economic progress. Adopting a life-course approach to vaccination is crucial to ensure that everyone can benefit from these advantages. This approach ensures that vaccines are available and recommended across all life stages, addressing vaccine-preventable diseases and improving overall public health. The vaccine pipeline demonstrates manufacturers' commitment to developing vaccines for all age groups, reinforcing the importance of comprehensive immunisation strategies.

The diversification of vaccine technologies stands out as a significant achievement, offering tailored solutions for varied populations and ensuring a robust response to both current and future health threats. This variety not only enhances vaccine accessibility but also bolsters our ability to respond with agility to emerging pathogens.

Vaccines are very complex biological products, and it takes many years and resources to develop safe and effective vaccines. The pipeline review is a testimony of the commitment of vaccine manufacturers to deliver a diverse portfolio of vaccines that address many challenges of today and tomorrow, such as health emergencies, zoonoses and arboviruses, antimicrobial resistance, socio-economic and demographic changes, as well as the dangers posed by climate change. However, the successful transition of vaccines from the lab to the public requires a collaborative effort. Everyone has a role to play in ensuring that vaccines reach the people who need them: from discovery in academia, biotech or pharma, to clinical development; to the European Medicines Agency (EMA) and regulators who review and approve new vaccines; to the National Immunisation Technical Advisory Groups (NITAGs) and Health Technology Assessment (HTA) bodies that assess them; to the governments providing funding, infrastructure and campaigns to support immunisation programmes; to the healthcare providers who inform patients, answer questions and administer the vaccines.

To maintain its leadership in vaccine research, innovation, and manufacturing, Europe must enhance its attractiveness to vaccine manufacturers. This will ensure continued progress in addressing the evolving health needs of its population effectively.

We must prepare for tomorrow, today.

ANNEX I: Summary of vaccine candidates based on the stage of the clinical development

DISEASE	NUMBER OF VACCINE CANDIDATES	TRIAL POPULATION		
		PAEDIATRIC	ADULTS	OLDER ADULTS
PHASE I CLINICAL TRIALS[3]				
Acne	1	✔	✔	
Coronaviruses	5		✔	✔
Cytomegalovirus (CMV)	1		✔	
Human immunodeficiency virus (HIV)	2		✔	
Influenza (seasonal)	3		✔	✔
Influenza (pandemic)	3		✔	✔
Influenza + RSV	1		✔	
Mpox	1		✔	
Nipah virus	1		✔	
Norovirus	1		✔	✔
Pneumococcal disease	1	✔		
RSV +/- other infections	2	✔		✔
RSV + Human metapneumovirus (hMPV/RSV)	1	✔		
Salmonella sp.	1		✔	
Varicella	1		✔	
Zika	1		✔	
PHASE II CLINICAL TRIALS[3]				
Clostridioides difficile infection	1		N/A	
COVID-19	3	✔	✔	✔
COVID-19 + Influenza	1		✔	✔
COVID-19 + Influenza + RSV	1		✔	✔
Cytomegalovirus (CMV)	1		✔	
Dengue fever	1	✔	✔	✔
Epstein-Barr virus infection (EBV)	2	✔	✔	
Glioblastoma*	1		✔	✔
Gonorrhoea	1	✔	✔	
Group B *Streptococcus* infection**	1		✔	
Hepatitis B*	2		✔	
Herpes simplex virus* (HSV)	2		✔	
Human Papillomavirus (HPV)	1	✔	✔	
Influenza (seasonal)	6	✔	✔	✔
Influenza (pandemic)	2		✔	✔
Influenza + RSV	1		✔	✔
Lyme disease	2		✔	
Malaria	1		✔	
Measles, mumps, rubella, varicella	1	✔		
Meningococcal disease	2	✔	✔	

DISEASE	NUMBER OF VACCINE CANDIDATES	TRIAL POPULATION		
		PAEDIATRIC	ADULTS	OLDER ADULTS
PHASE II CLINICAL TRIALS (CONT)[3]				
Pneumococcal disease	4	✔	✔	✔
Respiratory syncytial virus (RSV)	1			✔
RSV + Human metapneumovirus (hMPV/RSV)	1		✔	✔
Salmonella sp.	1		✔	
Shigellosis	2	✔	✔	
Shingles	1		✔	✔
Varicella	1	✔		
Yellow fever	1	✔	✔	✔
Zika	1		✔	
PHASE III CLINICAL TRIALS				
Clostridioides difficile infection (CDI)	1		✔	✔
COVID-19	4	✔	✔	✔
COVID-19 + Influenza	2		✔	✔
Cytomegalovirus	1		✔	
Invasive *E. coli* disease	1			✔
Influenza (seasonal)	4		✔	✔
Lyme disease	1	✔	✔	
Meningococcal disease	1	✔		
Rabies	1	✔	✔	✔
Respiratory syncytial virus (RSV)	5	✔	✔	
UNDER REVIEW BY THE REGULATORY AUTHORITY				
COVID-19	3	✔	✔	✔
Meningococcal disease	1	✔	✔	

[3]Phase I/II clinical trials have been counted as Phase II in this document.
*Therapeutic vaccine **Vaccine dedicated to maternal immunisation

ANNEX II: Development of the pipelines of Vaccines Europe members companies between 2022 and 2024

DISEASE	NUMBER OF VACCINE CANDIDATES IN 2022	MARKETING AUTHORISATION GRANTED	DEVELOPMENT PROGRAMS DISCONTINUED	NUMBER OF VACCINE CANDIDATES IN 2024
VIRAL INFECTIONS				
Chikungunya virus	2	1	1	0
COVID-19 (different strains)	27	11	10	14
COVID-19 + Influenza	2	0	1	3
COVID-19 + RSV	0	0	1	0
COVID-19 + Influenza + RSV	0	0	0	1
COVID-19 and/or other coronaviruses	1	0	0	1
Cytomegalovirus (CMV)	4	0	1	3
Dengue fever	1	1	0	1
Ebola	2	1	1	0
Epstein-Barr virus infection (EBV)	1	0	0	2
Glioblastoma (via CMV)*	1	0	0	1
Hepatitis B*	2	0	0	2
Herpes simplex virus*	1	0	0	2
Human immunodeficiency virus (HIV)	3	0	1	2
Human Papillomavirus (HPV)	0	0	0	1
Human metapneumovirus and parainfluenza virus 3 (hMPV/PIV3)	1	0	1	0
Human metapneumovirus and RSV (hMPV/RSV)	0	0	0	2
Influenza (seasonal)	9	0	1	13
Influenza (pandemic)	0	3	0	5
Influenza + RSV	0	0	0	2
Measles, mumps, rubella, varicella	0	0	0	1
Mpox	0	0	0	1
Nipah virus	1	0	0	1
Norovirus	0	0	0	2
Rabies	2	0	1	1
Respiratory syncytial virus (RSV)	10	4	6	8
Varicella/Shingles	1	0	0	3
Yellow fever	1	0	0	1
Zika	3	0	0	2

DISEASE	NUMBER OF VACCINE CANDIDATES IN 2022	MARKETING AUTHORISATION GRANTED	DEVELOPMENT PROGRAMS DISCONTINUED	NUMBER OF VACCINE CANDIDATES IN 2024
BACTERIAL INFECTIONS				
Acne	0	0	0	1
Clostridioides difficile infection (CDI)	3	0	2	2
Gonorrhoea	0	0	0	1
Invasive *E. coli* disease	1	0	0	1
Group B *Streptococcus* infection	1	0	0	1
Klebsiella pneumoniae	1	0	1	0
Lyme disease	1	0	0	3
Meningococcal disease	6	2	1	4
Pneumococcal disease	4	2	1	5
Salmonella sp.	0	0	0	2
Shigellosis	1	0	1	2
Skin & soft-tissue Infections caused by S. *aureus*	1	0	1	0
PROTOZOAN INFECTIONS				
Malaria	2	1	0	1

*Therapeutic vaccine
The table only includes pipeline data between 2022 and 2024 and does not take into account any previously authorised vaccines.

ANNEX III: Description of vaccine technologies

Immunisation technology	Description
Live-attenuated vaccines	Vaccines containing pathogens that have been weakened, altered or selected to be less virulent. In this state, the pathogens mimic a natural infection but do not cause the actual disease or only induce a mild form of it. In general, live-attenuated vaccines are produced from viruses rather than bacteria due to their genetic characteristics (138).
Whole-inactivated vaccines	Vaccines produced by inactivating preparations of whole pathogens using heat, radiation or chemicals. The pathogen's capacity to replicate and cause the disease is therefore reduced, but the immune system can still recognise it (138).
Subunit vaccines	**Protein vaccines** Protein vaccines contain fragments of proteins naturally found in the pathogens rather than the entire pathogen. These proteins are recognised by the immune system that produces antibodies and immune cells to attack them (139). There are several types of protein vaccines: • **Purified antigenic proteins:** extracted and purified from the whole pathogen (138); • **Recombinant protein vaccines:** produced through genetic engineering in host cells (138); • **Protein nanoparticles:** the proteins are delivered through nano-sized carriers (140).
	Toxoid vaccines Toxoids are toxins secreted by bacteria, that have been inactivated using heat and/or chemicals. These toxoids are no longer pathogenic, by they can induce an immune response in the organism (138).
	Virus-like Particles (VLP) VLPs are large molecular structures made to resemble real viruses in their size, shape, and surface characteristics. These particles cannot replicate because they lack the viral genome, but they can elicit an immune response in the organism (138), (141).
	Polysaccharide vaccines Polysaccharides are substances that can be found in the protective capsules of several bacteria, aiding their survival during infection. Vaccines against these bacteria use purified capsular polysaccharides from the whole pathogens (138).
	Polysaccharide conjugate vaccines (Glycoconjugate vaccines) Polysaccharide conjugate vaccines combine polysaccharide of certain bacteria with a carrier protein. This combination has been shown to enhance antibody production and immune memory (138).
	Outer membrane vesicles (OMVs) OMVs are spherical particles that are naturally released from the outer membrane of Gram-negative bacteria. These vesicles contain various components from the bacteria, such as proteins, lipopolysaccharides and other molecules that can induce a robust immune response (142).

Immunisation technology	Description
Subunit vaccines	**Generalised modules for membrane antigens (GMMA)** GMMA are outer membrane vesicles (OMVs) produced by genetically modifying the bacteria to increase the yield of vesicle production, reduce toxicity (by altering or removing harmful components like certain lipopolysaccharides), and enhance the expression of specific antigens (142).
	Multiple Antigen Presenting Systems (MAPS) MAPS is a vaccine platform designed to present multiple antigens to the immune system simultaneously. This approach allows for the combination of various antigens from one or more pathogens in a single vaccine. By displaying multiple antigens, MAPS aims to generate a stronger and more comprehensive immune response compared to vaccines that target only one antigen (143).
Viral vector	Viral vector vaccines use a modified virus like adenovirus, influenza, or measles to carry genetic material that stimulates an immune response against specific pathogens. These vaccines can mimic natural infections without causing illness (144), (145).
Nucleic acid	**DNA** DNA vaccines use a small piece of circular DNA to instruct our cells to produce a protein from a pathogen. This protein then triggers the immune system to create a defence against the real pathogen (141).
	RNA RNA vaccines utilize a molecule called RNA (ribonucleic acid) to instruct our cells to make a protein that triggers an immune response. There are 3 types of RNA vaccines: • conventional mRNA • self-amplifying mRNA (SAM) • circular RNA (circRNA) (141).
Monoclonal antibodies (mAbs) for preventative use	Monoclonal antibodies (mAbs) for prophylactic use work by binding to the surface of a specific pathogen, thereby preventing it from entering human cells and replicating (146), (147).

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