Vaccines Europe pipeline review 2025

Innovating for tomorrow, today

Vaccines Europe

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Foreword

In a time of rapid scientific progress and mounting global health challenges, **immunisation** has become more than a tool for disease prevention, **it's a strategic asset for public health security, societal resilience, and long-term economic sustainability**. As the world faces the dual pressures of emerging health threats and demographic change, the role of immunisation is central to safeguarding well-being and maintaining economic stability.

Europe has long been at the forefront of vaccine innovation. However, recent trends point to a worrying decline in its global R&D presence. Between 2018 and 2023, the proportion of global immunisation clinical trials conducted in the European region fell from 17% to just 8% [(1)]. This signals an urgent need for the EU to enhance the attractiveness of its vaccine ecosystem by committing to adequate and predictable investment, expanding research infrastructure, supporting a highly skilled workforce, and improving evidence generation and procurement frameworks [(2)].

With a new "Choose Europe for Life Sciences" strategy [(3)], Europe is making strides to become the most attractive place in the world for life sciences by 2030. This is a unique moment for Europe to assert global leadership in advanced immunisation technologies to protect diverse at-risk populations, from newborns and pregnant women to older adults. With EU-level coordination and support, innovation can thrive where it's sometimes slowing elsewhere, positioning Europe to drive progress in areas like RSV (respiratory syncytial virus) and HPV (human papillomavirus) prevention.

The vaccine industry continues to evolve in response to a changing health landscape, with cutting-edge science driving the development of next-generation immunisation solutions. The current pipeline demonstrates a strong commitment to protecting populations from a broad range of infectious diseases, including those with pandemic potential, travel-related threats, and antimicrobial-resistant pathogens. These innovations are not only essential for immediate preparedness, they are foundational to maintaining the EU's strategic autonomy, competitiveness, and leadership in global health.

At the heart of this vision lies **life-course immunisation**, which is a holistic approach that promotes vaccination from infancy through older age. Ensuring protection at every stage of life helps reduce disease burden, enhances quality of life, preserves healthcare system efficiency, and sustains workforce productivity. In an ageing Europe, life-course immunisation is both a public health imperative and an economic necessity.

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Executive Director,
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"As the world faces the dual pressures of emerging health threats and demographic change, the role of immunisation is central to safeguarding well-being and maintaining economic stability."

Vaccination also plays a critical role in the fight against **antimicrobial resistance (AMR)**. By reducing infections and limiting unnecessary antibiotic use, vaccines target the drivers of AMR at their source. According to the WHO, immunisation has the potential to avert up to 515,000 AMR-related deaths and save $30 billion in hospital costs annually [4]. This makes vaccines a vital tool in AMR national action plans and One Health strategies.

To remain competitive, Europe must reinforce its innovation capacity through a stronger, more coordinated regulatory and access environment. **Streamlined and harmonised processes across EU Member States** (from clinical development and authorisation to Health Technology Assessment (HTA) and procurement) will accelerate access to new vaccines and improve health equity across the region. Regulatory convergence, transparency, and predictable pathways are essential to driving innovation and ensuring timely uptake.

This review underscores the urgency of a **collaborative, multi-stakeholder approach** that brings together industry, policymakers, academia, healthcare professionals, and civil society. Vaccine manufacturers are committed to delivering a healthier future for all, but success depends on sustained political will, robust partnerships, and an enabling policy framework that supports innovation, access, and life-course protection.

By prioritising **investment in vaccine R&D, adopting life-course immunisation, and fostering regulatory excellence**, Europe can not only secure the health of its citizens but also uphold its position as a global leader in vaccination and life-science innovation.

Introduction

Over the last century, **immunisation has played a transformative role in advancing global health, stability, and development**. Its impact is evident not only in the reduction of disease and prevention of long-term health complications, but also in the reshaping of societies through improved health, economic resilience, and social cohesion. By protecting health and enabling the smooth functioning of critical systems like education, employment, and healthcare, vaccines are a foundational pillar of social stability.

Immunisation efforts over the past 50 years have saved an estimated 154 million lives, including 101 million infants, thanks to programmes targeting 14 infectious diseases. That's the equivalent of **six lives saved every minute**. Vaccination accounts for 40% of the worldwide improvement in infant survival over last 50 years. Diseases such as measles, diphtheria, pertussis, polio, tetanus, and *Haemophilus influenza* type b (Hib), which once killed or disabled millions of children annually, are now preventable through routine immunisation. **The measles vaccine alone accounts for 60% of those lives saved**, highlighting its outsized impact on child survival [(5)].

While the historic achievements of vaccination are undeniable, recent advances demonstrate that its impact continues to grow. The HPV vaccine, with over a decade of real-world evidence, has proven its effectiveness with reductions of more than 80% in cervical cancer risk when administered in early adolescence [(6)]. Combined with improvements in screening, it offers the tangible possibility of eliminating HPV-related cancers, meaning that future generations could live in a world free of these diseases. More recently, the first paediatric RSV immunisation solutions approved for broad population use have shown a remarkable return on investment, with a significant drop in hospitalisations, saving babies' lives, sparing parents the trauma of severe illness, and easing pressure on healthcare systems [(7)].

Vaccines are essential to global health security, which extends well beyond the established childhood immunisation programmes. The demographic landscape is undergoing a historic transformation. For the first time, the number of people aged 65 and older surpasses those under the age of five. By 2030, nearly 1 billion individuals will fall within this older age bracket. This trend has profound implications for public health systems, social services, and sustainable development. During the COVID-19 pandemic, the rapid development and deployment of vaccines saved millions of lives and helped prevent the collapse of health systems. The global COVID-19 response demonstrated the feasibility of adult immunisation at scale. By the end of 2023, over 13.6 billion doses had been administered, with global coverage reaching 89% of healthcare workers and 84% of older adults [(8)] [(9)]. However, this momentum has not carried over to other adult vaccines. While childhood immunisation has delivered immense public health gains, **adult immunisation remains significantly underutilised**. For instance, pneumococcal pneumonia is still a major cause of hospitalisations and mortality among older individuals (despite being vaccine-preventable), underlining the need to strengthen adult immunisation.

Beyond its immediate benefits, immunisation also has a demonstrated preventative effect on non-communicable diseases (NCDs) which remain the leading cause of death and disability across Europe, accounting for 1.8 million avoidable deaths each year. 1 in 5 men and 1 in 10 women dying before age 70 from NCD-related conditions such as cardiovascular diseases (CVDs), cancers, chronic respiratory diseases, and diabetes [(10)].

Acute infections, particularly **respiratory infections**, are increasingly recognised as important, yet preventable, **triggers of cardiovascular events**. For example, laboratory-confirmed influenza has been associated with a sixfold increase in the risk of acute myocardial infarction following infection [11]. Globally, an estimated 4% of ischaemic heart disease deaths among adults aged 50 and over are attributable to influenza [12]. Immunisation against respiratory infections has been shown to reduce the incidence of major adverse cardiovascular events, particularly among older adults and those with pre-existing conditions [13]. Increasing the uptake of routine adult immunisation presents a major opportunity to prevent cardiovascular disease and reduce the global burden of heart attacks and stroke.

Infections are also responsible for at least a sixth of all cancer cases worldwide [14]. Currently, immunisation has the potential to prevent around 10% of all infection-attributable cancer cases (e.g., human papillomavirus (HPV), hepatitis B virus (HBV). As a public health intervention, prevention through immunisation represents the most cost-effective and sustainable strategy for long-term cancer control [15].

Growing evidence suggests that immunisation may also help prevent or reduce the risk of certain neurological and autoimmune diseases. Shingles (herpes zoster) vaccination has been associated with a 20% relative reduced risk of developing dementia [16] and recent research linking Epstein-Barr virus (EBV) infection to the development of multiple sclerosis (MS) suggests EBV immunisation may be an effective prevention strategy [17].

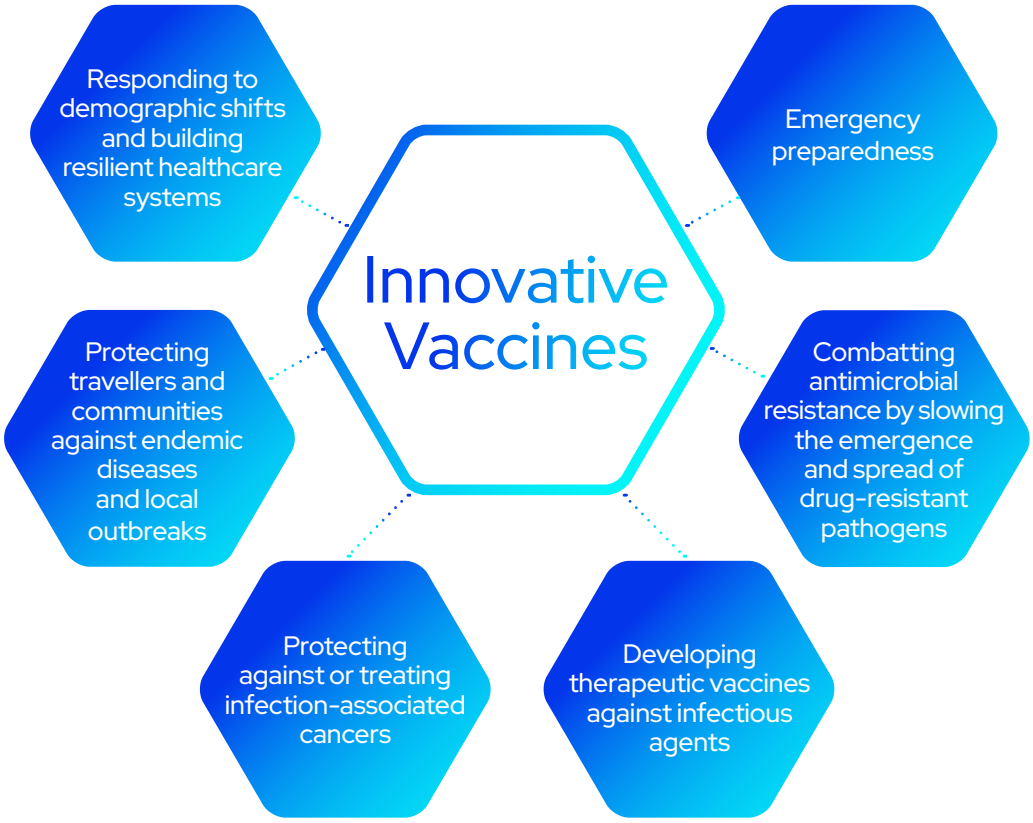
Climate change contributes to changing disease patterns, increasing the incidence and spread of infectious diseases that vaccines can prevent. This is especially relevant for vector-borne illnesses (such as malaria, dengue, Zika, chikungunya, West Nile disease) and waterborne diseases (like cholera), which expand in range and severity with shifting climate patterns [18]. By 2050, an additional 500 million people may be at risk of exposure to vector-borne diseases [19].

Vaccines can also play a crucial role in **addressing the root causes of antimicrobial resistance (AMR)**. A WHO report shows that increased vaccine use could decrease global antibiotic demand by 22% annually, thereby reducing the development of antimicrobial resistance. Existing vaccines could prevent up to 106,000 AMR-associated deaths per year [4].

Looking ahead, routine immunisation infrastructure is central to preparing for **future pandemics**, controlling AMR, mitigating NCDs, and preventing outbreaks of re-emerging diseases. Overall, an estimated 51.5 million deaths are expected to be averted due to vaccinations administered between the years 2021 and 2030 [20]. To achieve this, a **shift toward life-course immunisation is essential**. This approach recognises that protection should not end in childhood but must extend through adolescence, adulthood, and into older age. To stay ahead of emerging threats, governments must prioritise long-term investment in vaccine innovation and manufacturing. Crucially, national and EU-level immunisation frameworks should no longer view vaccination as an emergency intervention. Instead, it must be institutionalised as a permanent, proactive component of health systems to ensure continuity of protection, reduce disease burden, and strengthen resilience in both routine and crisis settings.

Tackling global health challenges demands both innovation and coordinated action across sectors.

This report highlights several priority areas where advances in vaccine development have the potential to deliver transformative impact:



Advancing innovation in vaccine technologies is key to addressing a diversity of pathogens and broadening the range of available immunisation tools, allowing healthcare professionals to tailor prevention strategies to the specific needs of different populations, communities and settings.

What's in this report?

The pipeline review of Vaccines Europe member companies [21] – first launched in 2022 [22] – represents a major advance in tracking the evolution of vaccine innovation. Now in its fourth edition, the report provides updated data collected by end of August 2025 among Vaccines Europe's 16 member companies (Abbott, AstraZeneca, Bilthoven Biologicals, CSL Seqirus, CureVac, GSK, HIPRA, Johnson&Johnson, Moderna, MSD, Novavax, Pfizer, Sanofi, Takeda, Valneva, Vaxcyte). It offers insights into recent breakthroughs in vaccine development and how these innovations are helping to address both current and emerging health challenges.

Changes in the Vaccines Europe membership since the inception of the project can impact the data collected and comparison to previous editions of the pipeline review. The analysis focuses on publicly available information of infectious disease vaccines and prophylactic monoclonal antibodies (mAb) in clinical development (Phase 1 to 3) classified according to specific criteria, with preclinical development being excluded. The pipeline review does not include vaccines or mAbs against non-infectious targets (e.g., cancer cells). 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 specific clinical trials, or expected timelines for regulatory submission).

Vaccines Europe is committed to enhancing the analysis with each annual publication. The following changes have been implemented in the 2025 edition to incorporate feedback from the European Commission (EC), the European Medicines Agency (EMA), National Immunisation Technical Advisory Groups (NITAGs), academia, industry and other stakeholders: new analysis on strain valency; new analysis on delivery routes; changed approach for calculation of attrition and registration rates now representing the average attrition and registration rates by year (2022-2025).

This report aims to highlight the essential role of innovation in strengthening the vaccine ecosystem. It underscores the ongoing commitment of vaccine developers to addressing preventable public health threats, saving lives, and supporting the resilience of health systems and economies. Organised around key healthcare and policy priorities, the report presents illustrative vaccine candidates under each thematic area. The report presents some redundance across sections as certain candidates fit under multiple categories. The structured approach is intended to support **horizon scanning** by EU Member States and foster early dialogue between developers and health authorities on critical issues such as vaccine **value assessment, immunisation financing**, and **national preparedness.**

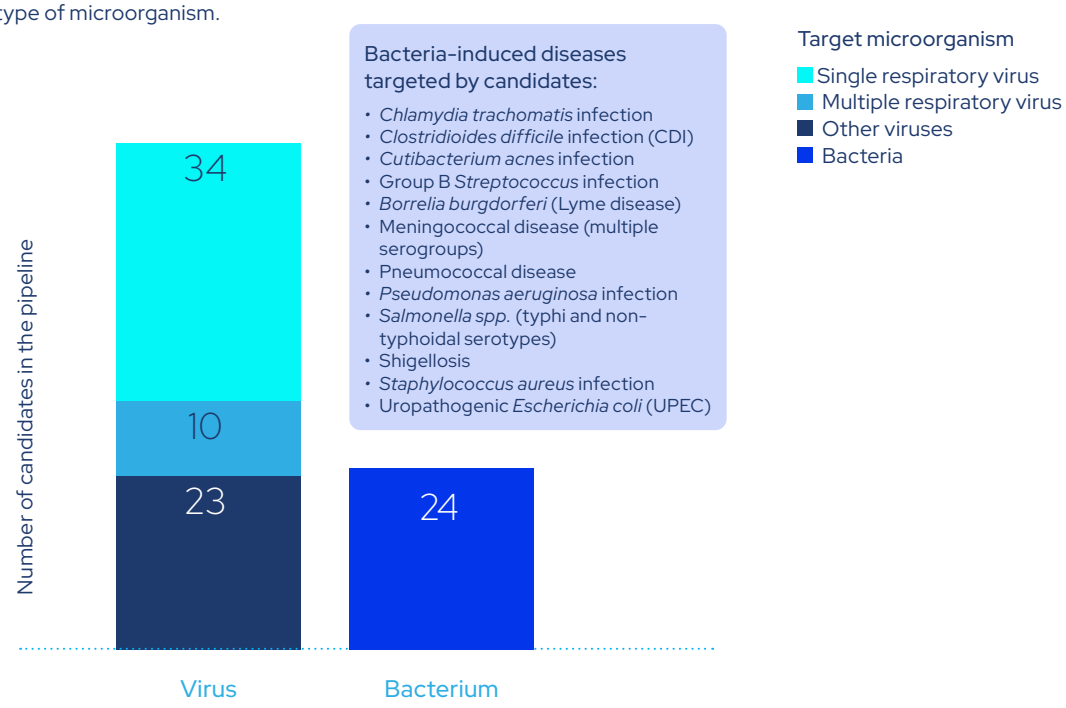
For an overview of the challenges that could potentially be addressed by these vaccine candidates, labels have been added next to each candidate, according to the following legend:

- AMR Antimicrobial resistance
- CC Climate change
- RI Routine immunisation
- ThV Therapeutic vaccines
- NI New indication (Diseases for which there was no vaccine on the market by the end of August 2025)
- CR Vaccines against infection-associated cancers
- STI Sexually-transmitted infections
- TrV Travel vaccines
- Z00 Zoonoses and pandemic preparedness

As of the end of August 2025, a total of 91 candidates were in development, comprising 86 prophylactic and 2 therapeutic vaccines (targeting infectious agents) and 3 prophylactic monoclonal antibodies (mAb). While most candidates are aimed at combating viral infections, a substantial portion focus on bacterial pathogens. To date, there are no pipeline candidates within Vaccines Europe member companies targeting fungal or protozoan pathogens.

Figure 1.

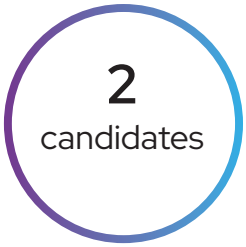
Number of candidates in the pipeline targeting a specific type of microorganism.



The most frequent targets for candidates were seasonal influenza (13 candidates), followed by pandemic influenza (8 candidates), pneumococcal disease (8 candidates), COVID-19 (SARS-CoV-2) (7 candidates) and respiratory syncytial virus (RSV) (6 candidates). On top of these, several candidates are designed to target combination of these viruses (6 candidates against COVID-19 + seasonal influenza, 2 candidates against RSV and human metapneumovirus (hMPV), 1 candidate against RSV + hMPV + human parainfluenza type 3 (PIV3), and 1 candidate against seasonal influenza + RSV). The full overview of the candidates of Vaccines Europe member companies can be consulted in *Figure 2*.

Figure 2.
Number of candidates per pathogen or disease

Acne
Chlamydia trachomatis infection
Dengue fever
Group B *Streptococcus* infection
Herpes simplex virus
Human papillomavirus (HPV)
Influenza (seasonal) + RSV
Measles, mumps, rubella/varicella
Mpox
Nipah virus
Pseudomonas aeruginosa infection
Rabies
RSV and human metapneumovirus (hMPV) and human parainfluenza type 3 (PIV3)
Shigellosis *(Shigella spp.)*
Staphylococcus aureus infection
Uropathogenic *Escherichia coli* (UPEC)
Yellow fever



Clostridioides difficile infection (CDI)
Cytomegalovirus (CMV)
Human immunodeficiency virus (HIV)
Meningococcal disease
Norovirus
RSV and human metapneumovirus (hMPV) and human parainfluenza type 3 (PIV3)
Salmonella spp.
Zika

Epstein-Barr virus infection (EBV)
Lyme disease

Varicella-zoster virus (VZV), varicella/shingles

COVID-19 and influenza
Respiratory syncytial virus (RSV)

COVID-19

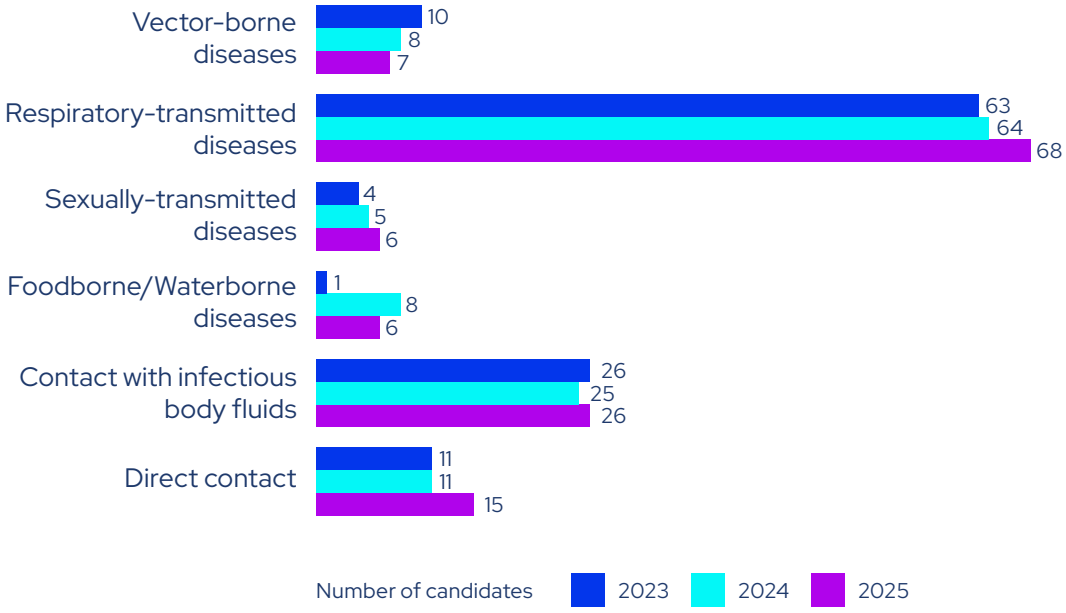
Influenza (pandemic)
Pneumococcal disease

Influenza (seasonal)

The *Figure 3* illustrates the number of candidates under development across three years (2023, 2024, and 2025) grouped by how the target diseases are transmitted. These are known as transmission routes, which help categorise infectious diseases based on how they spread from person to person, animals, or the environment. The chart shows changes in focus and diversification of vaccine research efforts over time.

Figure 3.

Number of candidates in development by disease transmission route. Pathogens spreading through multiple routes have been counted under each section.

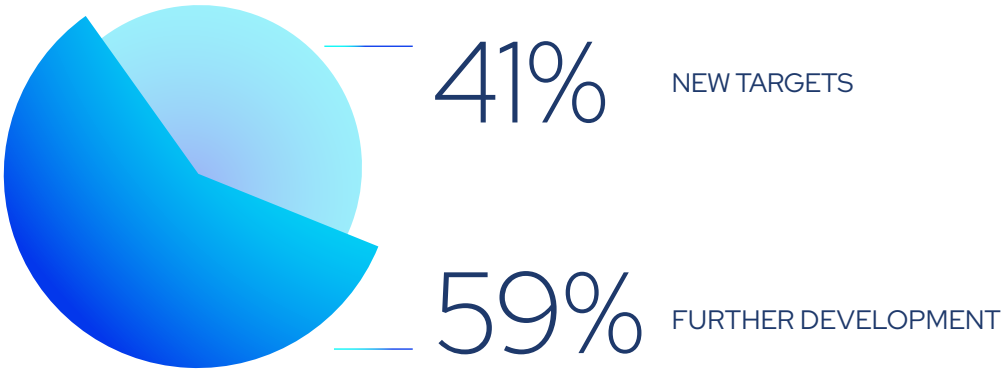


All stages of clinical development are well represented in the pipelines of Vaccines Europe members. At the end of August 2025, there were 17 candidates in Phase III clinical trials, 42 candidates in Phase II, 26 candidates in Phase I and 6 under regulatory review. A summary of candidates organised by 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 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 4

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



41% of the candidates in our members' pipelines aim to address diseases, combinations of diseases, or infectious syndromes, for which no vaccine or prophylactic mAb has been registered until now:

- Acne *(Cutibacterium acnes)*
- Lyme disease (*Borrelia burgdorferi*)
- *Chlamydia trachomatis* infection
- *Clostridioides difficile* infection (CDI)
- COVID-19 + seasonal influenza
- Cytomegalovirus (CMV) infection
- Epstein-Barr virus infection (EBV)
- Group B *Streptococcus* infection
- Herpes simplex virus infection
- Human immunodeficiency virus (HIV) infection
- Influenza (seasonal) + respiratory syncytial virus (RSV)
- Nipah virus
- Norovirus
- *Pseudomonas aeruginosa* infection
- Respiratory syncytial virus (RSV) + other respiratory infections (including human metapneumovirus – hMPV and human parainfluenza type 3 - PIV3)
- *Salmonella spp.* infection
- Shigellosis *(Shigella spp.)*
- *Staphylococcus aureus* infection
- Uropathogenic *Escherichia coli* (UPEC)
- Zika virus disease

[1]Note: Therapeutic candidates were classified as "new targets" if only a preventive vaccine is licensed. The "new targets" category applies for combination candidates for which a vaccine is licensed for individual pathogens, but not in combination (e.g., COVID-19 + seasonal influenza).

In the table below you can find description of candidates which are part of the Vaccines Europe members pipeline and can't be categorised under other sections of the document. Please note that some of the pipeline candidates can appear under multiple sections of the document.

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
CYTOMEGALOVIRUS (CMV) [23] [24] [25] [26] • 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: 2	Adults: (2)	Phase II: (1) Phase III: (1)	Protein subunit: (1) mRNA: (1)
NOROVIRUS [27], [28] • 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: o Approximately 685 million cases annually o Around 200 million cases among children under 5 years old, leading to an estimated 50,000 child deaths every year. PIPELINE CANDIDATES: 2	Adults + Older Adults: (2)	Phase II: (1) Phase III: (1)	mRNA: (2)

NI RI

Immunisation innovation is not limited to the development of entirely new vaccines or mAbs, but also includes improving existing interventions that have served the public for years, or developing new strategies to tackle diseases more effectively.

59% of candidates aim to address the disease areas for which there are already existing licensed products by:

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

Although all authorised products are proven to be safe and effective, members of Vaccines Europe remain committed to enhancing understanding of their benefits and risks through ongoing post-authorisation lifecycle development. Phase IV trials are not captured in this review.

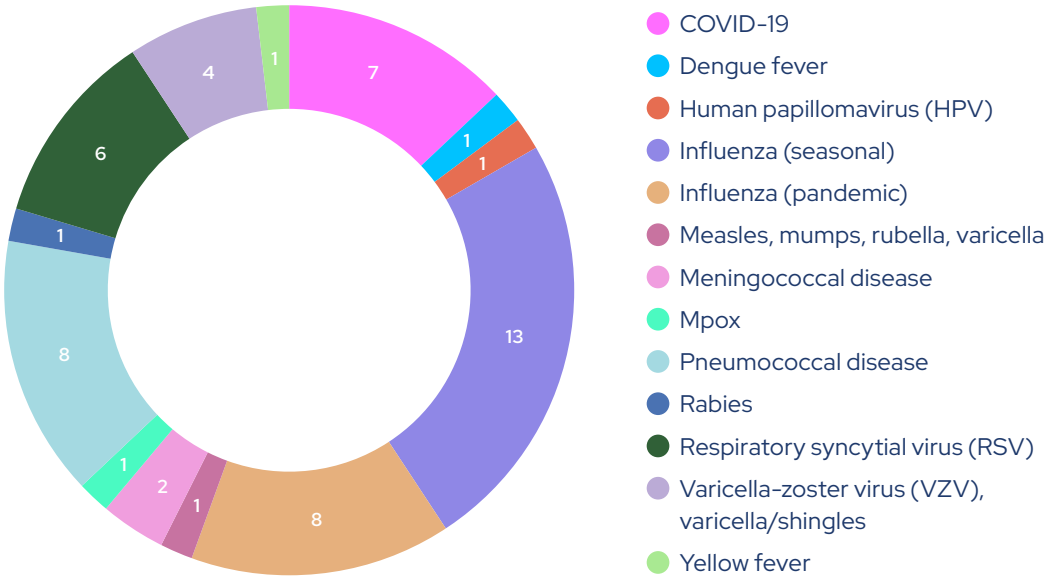


Figure 5.
Candidates for diseases for which there is already at least one registered vaccine or prophylactic mAb.

A constantly evolving research environment

The immunisation R&D landscape remains highly dynamic, evolving continuously to counter infectious diseases across diverse global regions. On average, vaccine development takes **10 to 15 years**, owing to the complexity of phases from discovery through approval [29]. Costs have been estimated to fall between $0.5 billion and over $8 billion depending on failure rates and indirect costs [30].

Clinical trials comprise a significant part of the development of new vaccines. These rigorous studies aim to assess the efficacy and safety of candidates, typically in large, healthy populations. The performance and safety of the candidates is constantly assessed, across each clinical trial stage and beyond licensure. 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 ensures only safe and effective vaccines 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 clinical trial volunteer group, especially for long-term follow-up studies to assess duration of protection;
- Managing regulatory and logistical complexities in multi-site or multinational trials;
- Resource constraints: funding, research infrastructure, trained personnel;
- Adapting to evolving epidemiology, 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 candidates for clinical trials,** relying on preclinical models which do not always predict human response;
- **Designing candidates and optimising formulations to provide protection across a diverse population** with variability in immune responses;
- **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;
- **Ensuring a continuous cold chain from production to administration,** especially in areas with limited resources and/or very high temperatures.

Despite these multifaceted challenges, the global vaccine research environment continues to evolve by adapting to scientific advancements, shifting public health priorities, and the urgent need for rapid response to emerging infectious threats. This adaptability remains essential for delivering safe, effective, and accessible vaccines to populations worldwide.

6 of the candidates reported in the 2024 pipeline review were granted Marketing Authorisation before the end of August 2025. During the same period, 13 candidates progressed to the next development stage, while 17 development programmes have been discontinued. 26 new candidates have been included in the pipelines of VE member companies.

Further change in the number of candidates compared to the previous year is explained by two factors: the exclusion of one company with 6 candidates following changes in Vaccines Europe membership, and the merging of 8 candidates into 4 programmes as they advanced to the next development stage, due to a change in the clinical trial population.

Between 2022 and 2025, the average annual attrition rate was approximately 17% and the average annual registration rate was approximately 9% underscoring the balance between challenges and successes in vaccine development during this period. The attrition rate represents the percentage of candidates discontinued relative to the pipeline of the previous year, while the registration rate indicates the percentage of candidates that received approval relative to the pipeline during the same timeframe.

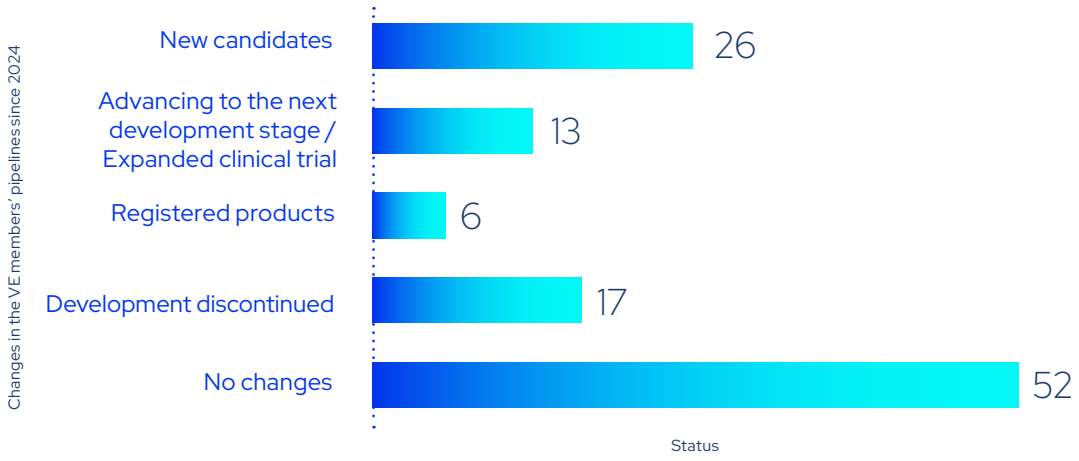


Figure 6a.

Updates in the pipelines of VE member companies since August 2024*.

*Changes in the Vaccines Europe membership since August 2024 impacts the total number of pipeline candidates in 2025 review.

Figure 6b.
Updates in the pipelines of VE member companies between August 2024 and August 2025.

NUMBER OF CANDIDATES	CHANGE COMPARED TO THE 2024 VACCINES EUROPE PIPELINE REVIEW	INDICATIONS
6	Marketing Authorisation granted	• COVID-19 • Meningococcal disease (ABCWY, ACWY serogroups) • Respiratory syncytial virus (RSV) disease
13	Advancing to next development stage or expanded clinical trials	• Acne (*Cutibacterium acnes*)* • COVID-19 • COVID-19 + seasonal influenza • Dengue fever • Group B *Streptococcus* infection • Mpox • Norovirus • Pneumococcal disease • Respiratory syncytial virus (RSV) • Varicella-zoster virus (VZV), varicella/shingles • Yellow fever
26	New candidates	• *Chlamydia trachomatis* infection • *Clostridioides difficile* infection (CDI) • COVID-19 • COVID-19 + seasonal influenza • Epstein-Barr virus infection (EBV) • Human papillomavirus (HPV) • Influenza (pandemic) • Influenza (seasonal) • Pneumococcal disease • *Pseudomonas aeruginosa* infection • Respiratory syncytial virus (RSV) • RSV and human metapneumovirus and human parainfluenza type 3 (RSV/hMPV/PIV3) • *Salmonella spp.* infection (typhi and non-typhoidal serotypes) • *Staphylococcus aureus* infection • Uropathogenic *Escherichia coli* (UPEC) • Varicella-zoster virus (VZV), varicella/shingles
17	Development discontinued	• *Clostridioides difficile* infection (CDI) • COVID-19 • COVID-19 + seasonal influenza • Gonorrhoea • Hepatitis B* • Herpes simplex virus* • Human papillomavirus (HPV) • Influenza (seasonal) • Influenza (seasonal) + RSV • Invasive *E. coli* disease • Malaria • Pneumococcal disease • RSV and human metapneumovirus (RSV/hMPV) • *Salmonella spp.* infection (typhi and paratyphoid A serotypes) • Shigellosis (*Shigella spp.*)

*Therapeutic vaccine

Cross-sector collaborations and partnerships are essential to advancing vaccine development. They provide critical funding to help promising candidates progress through costly stages and facilitate the sharing of expertise and resources across sectors to strengthen scientific knowledge and accelerate innovation. Members of Vaccines Europe actively engage with a diverse range of public and private stakeholders to support vaccine research. Key partners include the EU Health Emergency Preparedness and Response Authority (HERA), the Bill & Melinda Gates Foundation, academic institutions, the National Institutes of Health (NIH), the US Biomedical Advanced Research and Development Authority (BARDA), the National Institute of Allergy and Infectious Diseases (NIAID), IAVI (formerly the International AIDS Vaccine Initiative), the Government of Canada, and the Coalition for Epidemic Preparedness Innovations (CEPI).

Immunisation technologies

Immunisation, once reliant on a limited set of technologies, has significantly evolved to incorporate scientific and technological advancements. Today, a broad spectrum of vaccine platforms exists, enabling protection against a wider range of pathogens and infectious diseases and allowing for more targeted approaches tailored to different population needs. This diversity supports flexible immunisation strategies that consider factors such as age, underlying health conditions, cultural beliefs, geographic location, and socio-economic status, helping to improve vaccine acceptance and accessibility. Crucially, the **availability of multiple vaccine technologies boosts global preparedness and response capabilities**, increasing the likelihood of rapid and successful vaccine development in the face of emerging health threats.

Currently, a lot of effort is focused on further developing the mRNA technology, but other technologies, both novel and established, are also well-represented (*Figure 7*) and equally important. Emerging approaches such as Generalised 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*.

Adjuvants, present in many of the vaccine candidates, mainly aim 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. 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 7.
Number of candidates in development by technology.

Immunisation technology	Total number of candidates	Adjuvanted candidates**
Live-attenuated vaccines	5	0
Whole-inactivated vaccines	4	3
Protein subunit	12	10
• Protein nanoparticles	3	2
Toxoid vaccines	1	1
Virus-like Particles (VLP)*	1	1
Glycoconjugate vaccines	9	2
Generalised modules for membrane antigens (GMMA)	1	0
Multiple Antigen Presenting Systems (MAPS)	1	0
RNA	48	1
Monoclonal antibodies (mAbs) for preventative use	3	0
Multiple platforms	3	0

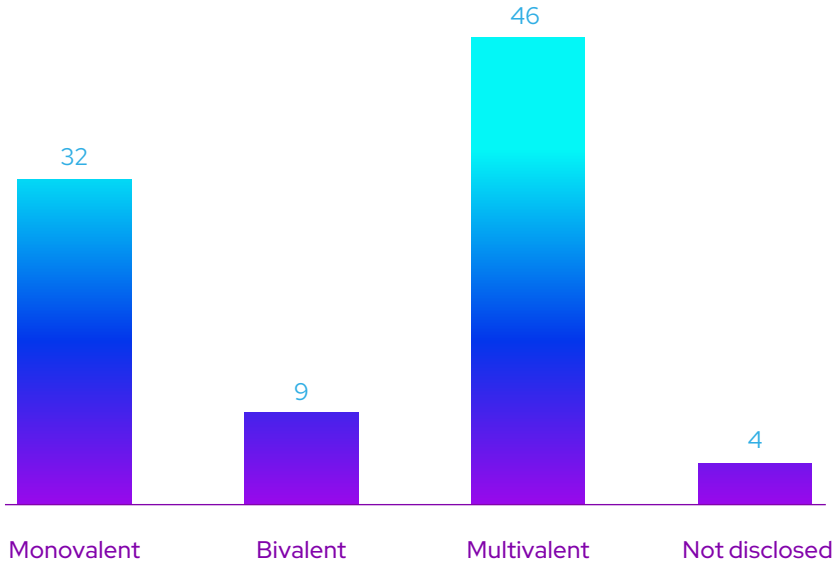
* including enveloped VLP (eVLP)
** for some candidates the information is not disclosed

Combination vaccines, which have been used for years in routine immunisation (e.g., MMR for measles, mumps, and rubella, and DTP for diphtheria, tetanus, and pertussis) remain a significant area for innovation. Combination vaccines contain antigens that protect against multiple diseases in a single injection, helping to reduce the number of shots a person needs, which streamlines vaccination schedules and has the potential to improve uptake and access. Several new combination vaccines are currently under development, mainly for respiratory infections (e.g., SARS-CoV-2, influenza, RSV, human metapneumovirus). Syndromic approaches to vaccine development, targeting multiple pathogens that cause similar clinical syndromes such as respiratory infections, can enhance efficiency in disease prevention, simplify implementation, and support integrated public health responses.

Additionally, for the first time, candidates in the pipeline review were analysed according to their **strain valency**. This aspect is particularly significant for pathogens that mutate frequently, such as influenza or COVID-19. Immunisation can be either monovalent or multivalent. In contrast to combination vaccines, multivalent vaccines target multiple strains or serotypes of the same disease-causing organism within one vaccine, broadening protection against variants of that specific pathogen. For example, the DTP vaccine is a combination vaccine protecting against diphtheria, tetanus, and pertussis, while the HPV vaccine is multivalent, offering protection against several strains of the human papillomavirus. Multivalent vaccines, which include higher numbers of strains, are vital to ensuring that immunisation strategies remain effective as pathogens evolve or as different strains circulate across regions and seasons. While multivalent vaccines offer broader coverage, their development is accompanied by increased scientific and regulatory complexity. Valency is, therefore, a key consideration in vaccine design, with the selection of appropriate antigens depending largely on the specific disease being targeted.

Figure 8

Number of mono-, bi- and multivalent candidates in development.

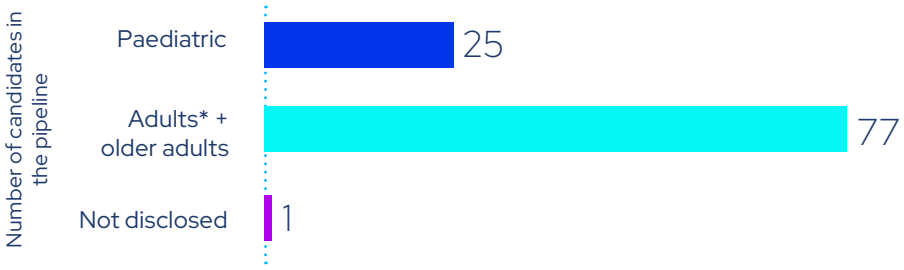


Protecting the health of our society through lifecourse immunisation

The candidates that are currently in the pipeline cover different types of populations across the lifespan. However, 77 out of total of 91 candidates 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 immunisation.

Figure 9a.

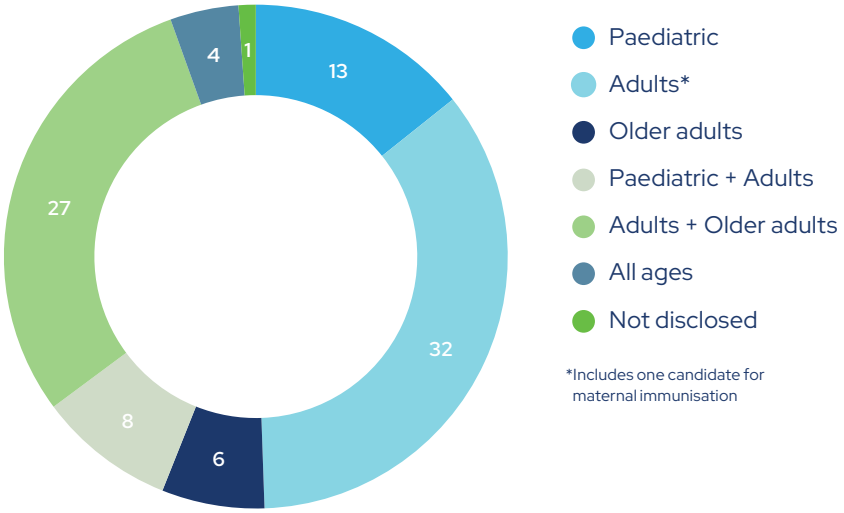
The number of candidates tested in each type of population.[2]



*Includes one candidate for maternal immunisation

Figure 9b.

The number of candidates tested in each type of population.



*Includes one candidate for maternal immunisation

Vaccines can be administered through several delivery routes, each chosen based on the type of vaccine, the immune response required, target population, and logistical considerations. Below are the main **delivery routes** of the candidates:[3]

- Intramuscular (IM) injection – 85 candidates
- Subcutaneous (SC) injection – 4 candidates
- Intravenous (IV) injection/infusion – 3 candidates
- Intranasal (IN) administration – 1 candidate

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

Routine immunisation 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 immunisation is one of the greatest medical achievements of the 20th century. **While paediatric immunisation schedules are well-established across Europe, adult immunisation products are less developed, and immunisation 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 ageing trend expected to persist [31]. Globally, the population aged 60 and over is projected to rise from 1 billion in 2020 to 2.1 billion by 2050 [32].

As individuals grow older, their immune defenses naturally decline, making them more vulnerable to infections [33]. Adult immunisation, including vaccines targeted at specific groups like pregnant people or those with chronic medical conditions, is vital not only for individual protection against vaccine-preventable diseases, but also for promoting **socioeconomic wellbeing**, addressing equity concerns, and averting broader public health emergencies. A landmark analysis demonstrates that adult immunisation programmes can deliver up to **19 times the societal return on investment**, when wider economic and social benefits are accounted for [34].

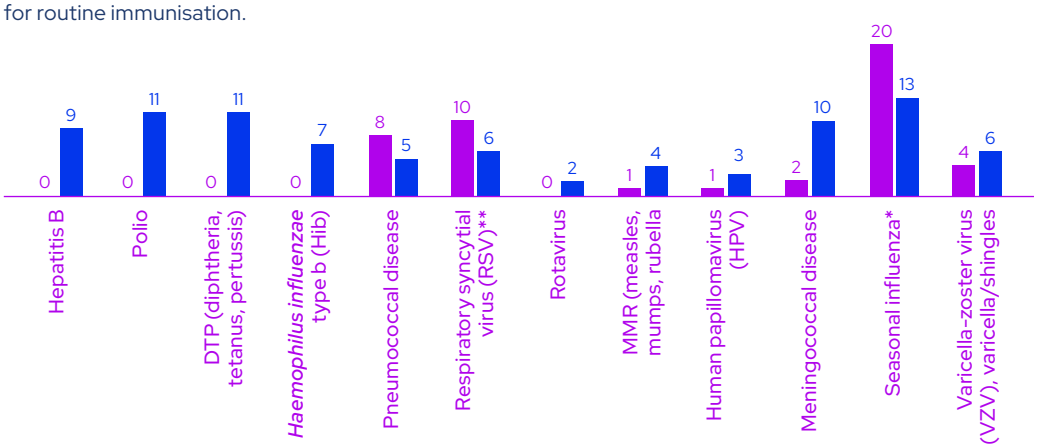
Expanding immunisation strategies beyond childhood to encompass the entire life-course aligns with the increasing shift toward preventative healthcare. To realise this vision, comprehensive **policy frameworks** and **sustainable funding models** are required to boost adult vaccine coverage, ensuring access throughout the lifespan and closing critical gaps in prevention delivery [35].

There are currently 46 vaccine candidates for routine immunisation [36] in our members' pipelines, against seasonal influenza, respiratory syncytial virus (RSV), varicella-zoster virus, 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. Although dengue is part of routine immunisation in endemic countries and in endemic regions of some non-endemic countries (e.g. parts of France), it was not included in this year's analysis. The noticeable increase in the total number of candidates in routine immunisation, compared with the previous editions, is explained by the inclusion of RSV candidates in this year's pipeline review.

Figure 10.

Candidates in VE members' pipelines for routine immunisation.



* The 20 influenza candidates include combinations with SARS-CoV-2 and/or RSV.
** The 10 RSV candidates include combinations with seasonal influenza, human metapneumovirus and parainfluenza.
*** Some of the vaccines might be registered only outside Europe at the moment of writing this document.

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
HUMAN PAPILLOMAVIRUS (HPV) [37], [38], [39] • 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. • Besides cervical cancer, HPV causes 12%–63% of oropharyngeal cancers, 36%–40% of penile cancers, 40%–64% of vaginal cancers, 40%–51% of vulvar cancers, anal cancer and genital warts. PIPELINE CANDIDATES: 1	Adults: (1)	Phase I: (1)	Virus-like particle: (1)
MENINGOCOCCAL DISEASE [40], [41], [42] • 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: 2	Paediatric + Adults: (2)	Phase II: (2)	Multiple platforms: (2)

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DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
MEASLES, MUMPS, RUBELLA, VARICELLA [43], [44], [45], [46] • **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)
RESPIRATORY SYNCYTIAL VIRUS (RSV) [47], [48] • 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: 6 (RSV), 2 (RSV + HMPV) 1 (RSV + HMPV + PIV3), 1 (SEASONAL INFLUENZA + RSV)	Paediatric: (4) Adults: (2) Adults + Older Adults: (3) Older Adults: (1)	Phase I: (5) Phase II: (2) Phase III: (1) Regulatory review: (2)	Live attenuated virus: (1) mRNA: (7) Protein subunit: (2)
SEASONAL INFLUENZA [49] • 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), 6 (SEASONAL INFLUENZA + COVID-19) 1 (SEASONAL INFLUENZA + RSV)	Adults: (5) Adults + Older Adults: (11) Older Adults: (4)	Phase I: (6) Phase II: (7) Phase III: (6) Regulatory review: (1)	Protein nanoparticles: (2) Protein subunit: (4) mRNA: (13) Whole-inactivated virus: (1)
STREPTOCOCCUS PNEUMONIAE [50], [51] • *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: 8	Paediatric: (3) Paediatric + Adults: (2) Paediatric + Adults + Older Adults: (1) Adults + Older Adults: (1) Not disclosed: (1)	Phase I: (2) Phase II: (5) Phase III: (1)	Glycoconjugate vaccine: (7) Multiple Antigen Presenting System (MAPS): (1)
VARICELLA-ZOSTER VIRUS (VZV), varicella/shingles [52], [53] • 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: 4	Paediatric: (1) Adults + Older Adults: (2) Older Adults: (1)	Phase I: (1) Phase II: (2) Phase III: (1)	Live-attenuated virus: (1) mRNA: (3)

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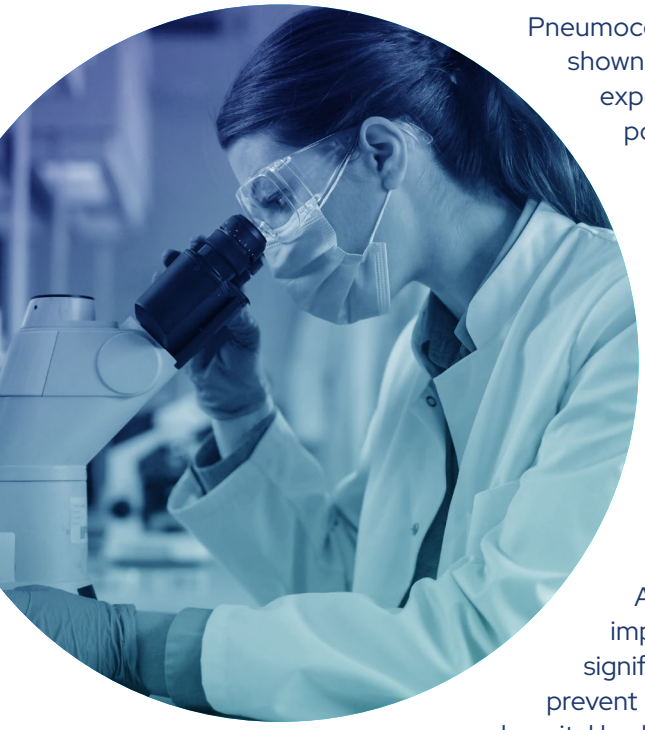
Respiratory infections

Respiratory infections, such as influenza, COVID-19, respiratory syncytial virus (RSV), and pneumococcal disease, represent some of the most common and costly illnesses globally. Despite declines since the COVID-19 peaks, **respiratory infections activity remains elevated** compared to pre-pandemic norms and seasonal patterns continue to shift. In Europe, respiratory infections impose a substantial economic and healthcare burden. On average, they impact employees' productivity by more than one working week each year, leading to estimated productivity costs per worker of €983 per year [54].



Pneumococcal, RSV, influenza, and COVID-19 vaccines are shown to reduce morbidity, mortality, and healthcare expenditure in adults, especially in older and chronically ill populations. Seasonal influenza vaccination alone is estimated to save European healthcare systems between €248 million and €332 million annually by reducing the number of medical consultations and hospital admissions [34]. A recent study in France showed that expanding influenza vaccination to at-risk individuals aged 50 and older could prevent over 918,000 cases of influenza, avoid 332,000 general practitioner visits, reduce hospital admissions by more than 16,000, and save over 6,300 lives. These benefits translate to cost savings of approximately €163 million through avoided medical treatment and reduced work absenteeism [55].

A recent study in the UK shows that over time, the health impact of adult respiratory immunisation accumulates significantly. In year 1, the UK programs are estimated to prevent over 40,000 hospitalisations and free up substantial hospital bed-day capacity. When assessed over 5 years, this number grows nearly fourfold, preventing over 159,000 hospitalisations [56].

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 [57]. 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 [58]. Among adults, immunisation was associated with approximately **50% reduction in pneumonia-related mortality** [59]. Protecting against respiratory infections through immunisation has been linked to a decreased likelihood of serious cardiovascular complications, with the greatest benefits observed in older populations and those with underlying medical conditions [60].

68 of the vaccine candidates in our members' pipelines (approx. 75%) target respiratory-transmitted infections (aerosols and droplets), including coronaviruses, influenza, meningococcal disease, measles, mpox, pneumococcal disease, rubella, RSV and varicella-zoster virus (*Figure 3*).

Sexually-transmitted infections (STIs)

Sexually-transmitted infections (STIs) are among the most common communicable diseases and affect the health and lives of people worldwide. More than 30 pathogens can be transmitted sexually, and individuals may have multiple infections at the same time. Despite global efforts to curb the spread of STIs, their global burden remains substantial. Infections such as syphilis, gonorrhoea, chlamydia and trichomoniasis continue to rise with over 1 million of new cases per day in adults aged 15-49 [61].

In February 2025, ECDC released its latest Annual Epidemiological Reports on STIs, revealing continued increases across EU/EEA. In 2023, nearly 100,000 confirmed cases of gonorrhoea were reported, showing a 31% increase compared to 2022. Syphilis cases also continue to rise. In 2023, 41,051 confirmed cases were reported, representing a 13% increase compared to 2022. Despite a slowdown in the increase of chlamydia notifications in 2023, it remains the most frequently reported bacterial STIs in Europe. In 2023, more than 230,000 cases were reported, representing an increase of 13% since 2014. STIs may also be a driver of AMR as suggested by the increased reporting of drug-resistant strains of gonorrhoea [62].

Other prevalent STIs include human papillomavirus (HPV) and human immunodeficiency virus (HIV). HPV is a significant concern as it can lead to several cancers in both men and women, including cervical cancer, which is one of the most common cancers affecting women globally. In the EU alone, HPV causes approximately 33,000 cases of cervical cancer resulting in 15,000 deaths annually [63]. While HPV immunisation is widely implemented, coverage remains low in most countries, just one-quarter of girls receive the first dose globally [64]. Besides cervical cancer, HPV is also a significant cause of oropharyngeal, penile, anal, vaginal and vulvar cancers, as well as genital warts. 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 [65]. Although the number of new HIV infections decreased during the last 20 years, HIV-related deaths remain significant. In Europe, an estimated 160,000 people acquired HIV in 2024, and 51,000 deaths were attributed to HIV-related causes in 2024, which is an increase of 37% from 2010 [66].

6 of the vaccine candidates in our members' pipelines target sexually-transmitted infections, including chlamydia, HSV, HIV, HPV and mpox (*Figure 3*).

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
CHLAMYDIA TRACHOMATIS INFECTION [67], [68] • Responsible for the greatest number of STIs and the majority of infection-related blindness worldwide. • In 2020 there were an estimated 128.5 million new chlamydia infections among adults (15–49 years old) globally. • Chlamydia infection can cause long-term complications in women including pelvic inflammatory disease (PID) and salpingitis, conditions that can lead to infertility and extra-uterine pregnancies. • Chlamydia is a preventable and curable STI. PIPELINE CANDIDATES: 1	Adults: (1)	Phase I: (1)	mRNA: (1)
HERPES SIMPLEX VIRUS (HSV) [69], [70] • 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: 1*	Adults: (1)	Phase II: (1)	mRNA: (1)
HUMAN IMMUNODEFICIENCY VIRUS (HIV) [71] • 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)
HUMAN PAPILLOMAVIRUS (HPV) [37], [38], [39] • 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. • Besides cervical cancer, HPV causes 12%–63% of oropharyngeal cancers, 36%–40% of penile cancers, 40%–64% of vaginal cancers, 40%–51% of vulvar cancers, anal cancer and genital warts. PIPELINE CANDIDATES: 1	Adults: (1)	Phase I: (1)	Virus-like particle: (1)
MPOX [72], [73], [74] • 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 II: (1)	mRNA: (1)

*Therapeutic vaccine

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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 through the placenta or after birth in breast milk, providing protection against infections in the first few months of life. Our members' pipelines contain one vaccine candidate for maternal immunisation against group *B Streptococcus* infections.

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
***GROUP B STREPTOCOCCUS* INFECTION (GBS)** [75] • 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	Adults*: (1)	Phase III: 1	Glycoconjugate vaccine: (1)

AMR NI RI

*Maternal immunisation

Travel vaccines

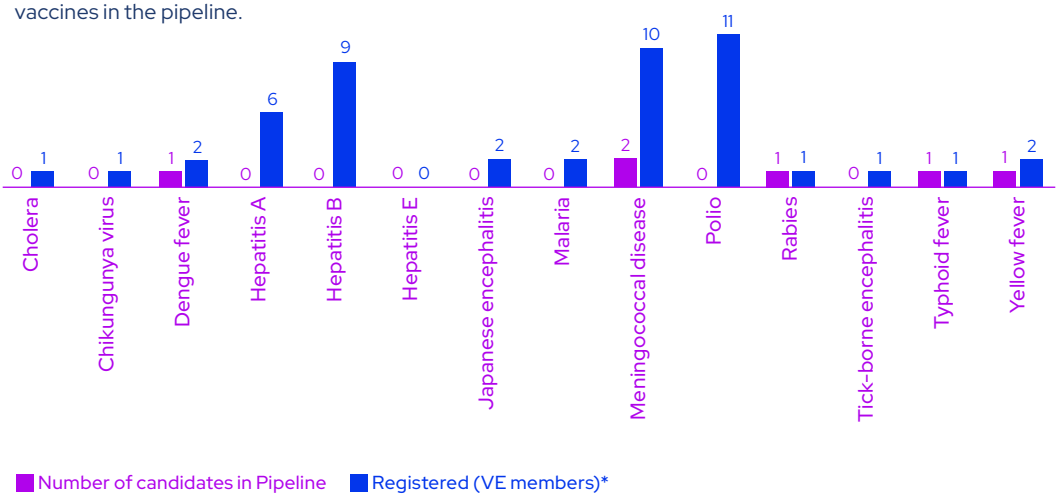
In today's interconnected world, international travel and migration are more common than ever before, increasing the risk of spreading infectious diseases. It is estimated that between 42% and 79% of travellers to low- and middle-income countries become ill with a travel-associated disease. While most of these health issues are mild, there are significant cases when the help of a healthcare professional is requested [76]. 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) [77].

These diseases have consequences that reach beyond personal health, putting pressure on public health systems and generating significant economic costs due to medical treatment and lost productivity. As a result, travel vaccines are essential for protecting the health of international travellers. They are recommended according to the traveller's destination and are tailored to guard against serious illnesses common in those regions. Moreover, immunisation plays a key role in preventing the cross-border spread of infectious diseases, helping to contain potential global outbreaks. 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 [78] [79]. Some vaccines commonly referred to today as "travel vaccines" have become part of routine immunisation in certain tropical territories of EU countries.

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

Figure 11.

Number of travel vaccines in the pipeline.



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

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
DENGUE FEVER [80], [81] • 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. • Four autochthonous cases have been reported in two EU/EEA countries in 2025. More than 200 autochthonous dengue cases have been reported in Europe in 2024. PIPELINE CANDIDATES: 1	Paediatric + Adults: (1)	Phase III: (1)	Live-attenuated virus: (1)
MENINGOCOCCAL DISEASE [40], [41], [42] • 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: 2	Paediatric + Adults: (2)	Phase II: (2)	Multiple platforms: (2)
RABIES [82], [83], [84] • 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 locally-acquired human rabies infections were reported between 2020 – 2023. PIPELINE CANDIDATES: 1	Paediatric + Adults + Older Adults: (1)	Phase III: (1)	Whole-inactivated virus: (1)
YELLOW FEVER [85], [86], [87] • 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	Adults: (1)	Phase III: (1)	Live-attenuated virus: (1)

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Therapeutic infectious disease vaccines

Therapeutic vaccination is a field still in its infancy compared to preventative vaccines. There is no established regulatory and access environment pathway for therapeutic vaccines. They work by training a patient's immune system to fight or control an existing infection or infection-related disease, rather than immunising for the 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.

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
ACNE (*Cutibacterium acnes*) [88], [89], [90] • *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*	Adults + Older Adults: (1)	Phase I: (1)	mRNA: (1)
HERPES SIMPLEX VIRUS (HSV) [69], [70] • 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: 1*	Adults: (1)	Phase II: (1)	mRNA: (1)

*Therapeutic vaccine

NI STI ThV

Vaccines against infection-associated cancers

Vaccine technology is increasingly being leveraged to unlock novel approaches to cancer prevention and treatment by training the immune system to recognise and attack cancer cells directly. These approaches are out of scope for this review which focuses on vaccines targeting infectious agents which can lead to cancers.

In 2018, infectious diseases were estimated to be responsible for 2.2 million cancer cases globally, representing at least one sixth of all cancer cases worldwide [91]. In the EU/EEA, hepatitis B is responsible for around 15,000 deaths annually, with mortality from liver cancer caused by the virus continuing to rise [92]. The inclusion of the hepatitis B (HepB) vaccine in routine immunisation programmes marked a pivotal milestone in the global effort to combat liver cancer. Today, human papillomavirus (HPV) vaccines present a similar opportunity, their broad uptake has the potential to dramatically reduce the burden of cervical cancer [93]. As a public health intervention, prevention through immunisation represents the most cost-effective and sustainable strategy for long-term cancer control [15].

Vaccines aiming to prevent infection-associated cancers, can act both by preventing (prophylactic) the infection such as HPV and EBV, or treating (therapeutic) the infection. The current edition of the pipeline review includes the following prophylactic vaccines against infection-associated cancers:

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
EPSTEIN-BARR VIRUS (EBV) [94], [95] • 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: 3	Paediatric + Adults: (1) Adults: (2)	Phase I: (1) Phase II: (2)	Protein nanoparticles: (1) mRNA: (2)
HUMAN PAPILLOMAVIRUS (HPV) [37], [38], [39] • 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. • Besides cervical cancer, HPV causes 12%–63% of oropharyngeal cancers, 36%–40% of penile cancers, 40%–64% of vaginal cancers, 40%–51% of vulvar cancers, anal cancer and genital warts. PIPELINE CANDIDATES: 1	Adults: (1)	Phase I: (1)	Virus-like particle: (1)

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Addressing global health threats

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. Although annual deaths from AMR increased by about 8% between 1990 and 2021, the study done by Global Research on Antimicrobial Resistance (GRAM) Project predicts a rise of almost 70% in the decades thereafter, with annual deaths rising from 1.14 million in 2021 to 1.91 million in 2050. A detailed forecast predicts that without further policy interventions global deaths would reach 39 million between 2025 and 2050—the equivalent of three deaths per minute [96]. 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) [97].

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 [98], proposing an integrated One Health framework that considers the contributive value of various solutions, including vaccines [99]. Most recently, a WHO Resolution on AMR, proposed for agreement at the 77th World Health Assembly in May 2024, references the need for research and development for vaccines, diagnostics and treatments. Despite this, vaccines continue to be undervalued as a tool to tackle AMR [100].

Bacterial vaccines address the root causes of AMR by preventing both drug-susceptible and drug-resistant infections, reducing the need for antibiotics, and thereby slowing the development of resistance in target pathogens and bystanders. Vaccinated people will have fewer infections and thus will also be protected against potential complications from secondary infections that may trigger the use of antimicrobials or require admission to hospital.

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 aged 70 and above [101]. According to a recent report published by the WHO, vaccines could prevent up to 515,00 deaths, saving up to US$ 30 billion in hospital costs, and averting the use of 2.5 billion antibiotic doses. The report highlights the urgent need for both a better use of existing vaccines and the development of new ones [4]. 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.

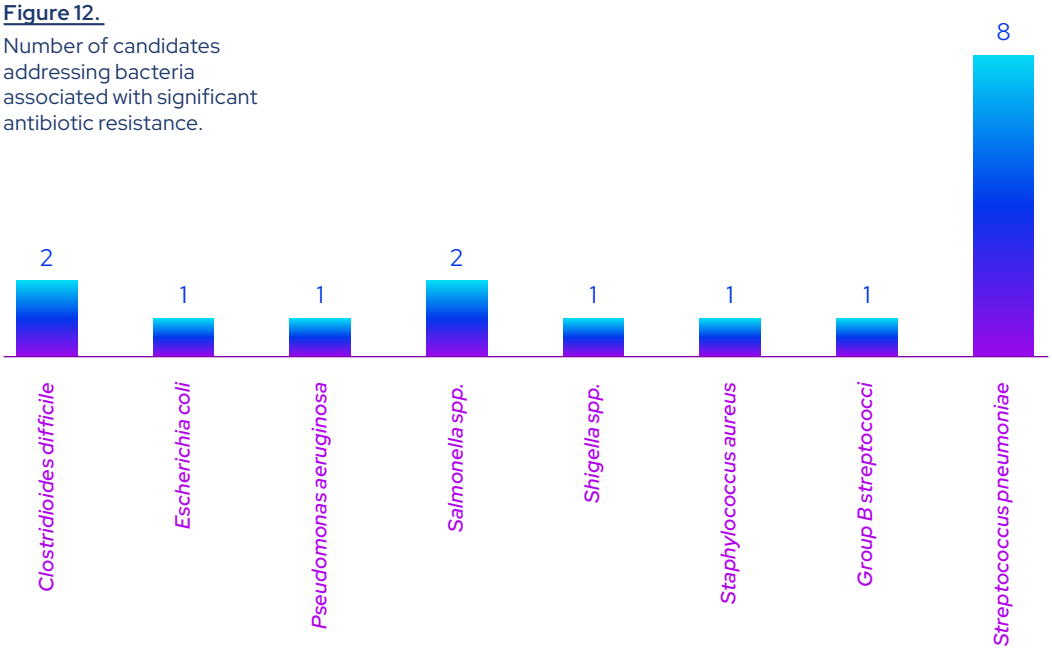
Developing vaccines that address resistant pathogens is an extremely challenging task. However, Vaccines Europe members are playing their part in addressing AMR, in line with the strategy developed by WHO as a technical annex to the Immunisation Agenda 2030 [102]. Strengthening surveillance systems to address data gaps and developing regulatory guidance and heath technology assessment frameworks would be of tremendous help in accelerating the development, availability, and use of these products [103].

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 [104]. There is increasing evidence in this direction for vaccination against rotavirus, influenza, varicella and dengue [105] [106] [107] [108] 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 [109]. 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 [110].

There are currently 17 vaccine candidates in our members' pipelines targeting 8 bacteria associated with significant antibiotic resistance, 7 of which are on the WHO 2024 Bacterial Priority Pathogens list [111]. Additionally, the pipelines contain 41 candidates against COVID-19, dengue, seasonal influenza, RSV and varicella/shingles, all viral infections which can lead to antibiotic use or misuse.

Figure 12.

Number of candidates addressing bacteria associated with significant antibiotic resistance.



DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
CLOSTRIDIOIDES DIFFICILE INFECTION _(CDI)_ [112], [113] • 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	Adults: (2)	Phase I: (1) Phase II: (1)	Toxoid vaccine: (1) Monoclonal antibody: (1)
UROPATHOGENIC _ESCHERICHIA COLI_ (UPEC) [114], [115] • Leading cause of urinary tract infections globally, with potential to progress to urosepsis and invasive disease. • UPEC is responsible for 70–95% of community-onset urinary tract infections (UTIs) and about 50% of nosocomial (hospital) UTIs. • UPEC frequently carry multidrug resistance including extended-spectrum β-lactamase (ESBL) and carbapenem-resistance. For instance, ESBL prevalence in UPEC hospital isolates can exceed 80%, with carbapenem resistance reaching 34% in hospital settings. PIPELINE CANDIDATES: 1	Adults: (1)	Phase II: (1)	Protein subunit: (1)
PSEUDOMONAS AERUGINOSA INFECTION [116], [117] • Leading opportunistic pathogen in healthcare settings, causing a range of infections including pneumonia, bloodstream infections, UTIs, and wound or burn-site infections especially in immunocompromised or critically ill patients. • *P. aeruginosa* ranks among the top contributors to AMR-related mortality, accounting for hundreds of thousands of deaths. • Antimicrobial resistance rates of the pathogen show marked regional variation, with Europe reporting higher levels compared to other parts of the world. PIPELINE CANDIDATES: 1	Paediatric + Adults + Older Adults: (1)	Phase II: (1)	Monoclonal antibody: (1)

SALMONELLA spp. [118], [119], [120]
• 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 FOR TYPHOIDAL AND NON-TYPHOIDAL *SALMONELLA*
1 INVASIVE NON-TYPHOIDAL *SALMONELLA*
	Paediatric + Adults: (2)	Phase II: (2)	Multiple platforms: 1
			Generalised Modules for Membrane Antigens: (1)

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DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
SHIGELLOSIS [121], [122], [123] • 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: 1	Paediatric: (1)	Phase II: (1)	Glycoconjugate vaccine: (1)
STAPHYLOCOCCUS AUREUS INFECTION [124], [125] • *S. aureus* asymptomatically colonises about 21–30% of people. • It remains a leading cause of both superficial and invasive infections, including pneumonia, bacteraemia, endocarditis, osteomyelitis, toxic shock syndrome, and sepsis. • In 2019, Methicillin-resistant *S. aureus* (MRSA) was linked to approximately 100,000 deaths globally due to AMR, and attributable MRSA deaths have more than doubled since 1990, reaching around 130,000 by 2021. PIPELINE CANDIDATES: 1	Adults: (1)	Phase II: (1)	Monoclonal antibody: (1)
GROUP B *STREPTOCOCCUS* INFECTION (GBS) [75] • 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	Adults*: (1)	Phase III: (1)	Glycoconjugate vaccine: (1)
STREPTOCOCCUS PNEUMONIAE [50], [51] • *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: 8	Paediatric: (3) Paediatric + Adults: (2) Paediatric + Adults + Older Adults: (1) Adults + Older Adults: (1) Not disclosed: (1)	Phase I: (2) Phase II: (5) Phase III: (1)	Glycoconjugate vaccine: (7) Multiple Antigen Presenting System (MAPS): (1)

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*Maternal immunisation

Climate change

2024 was recognised as the warmest year on record [126]. **Europe continues to warm** about twice as quickly as the global average, which creates unprecedented changes in its climate [127]. 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 [128]. These climate shifts impact severely food and water security, energy supplies, and public health.

Climate change, with associated high temperatures and irregular rainfall, **has multifaceted impacts on the transmission of infectious diseases**, leading to changes in pathogen development, vector distribution, and human behaviour, with increases in some infectious diseases [129]. 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 [130].

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 [131].

For example:

- Recent studies show up to 5-fold increase in West Nile virus risk for 2040-2060 in Europe, compared to 2000-2020. The proportion of disease-reported European land areas could increase from 15% to 23-30%, putting 161 to 244 million people at risk [132].
- 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. For every 1 °C rise in temperature, dengue risk increases by about 13% due to faster mosquito life cycles and virus replication [133]. Dengue is spreading to new areas, including the European region. In 2024, 308 cases were reported to WHO from three European countries (France, Italy and Spain) and an additional 1291 cases and four deaths were recorded in the French overseas territories [80].
- Chikungunya is another vector-borne disease with a projected increase in prevalence in the coming years because of climate change. Since the beginning of 2025 and as of July 2025, two countries in Europe have reported cases of chikungunya virus disease [134].

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 spp.*) and dysentery (*Shigella spp., 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 [131].

Every year, more than 23 million people fall ill from eating contaminated food in European region, resulting in 5000 deaths and more than 400 000 disability-adjusted life years [135]. 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* [131].

c) Disruption of wildlife 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 [136] [137].

d) Changes in human behaviour

Climate change can also influence human behaviour in ways that increase disease transmission. During extreme weather events, such as heatwaves or intense rainfall, people are more likely to gather indoors, creating conditions that facilitate the spread of infectious diseases. Furthermore, as people adjust to shifting temperatures, their immune responses may become compromised, heightening susceptibility to respiratory illnesses 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 [138], 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, typhoidal and non-typhoidal *Salmonella, Shigella spp.*, yellow fever and Zika.

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
DENGUE FEVER [80], [81] • 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. • Four autochthonous cases have been reported in two EU/EEA countries in 2025. More than 200 autochthonous dengue cases have been reported in Europe in 2024. PIPELINE CANDIDATES: 1	 Paediatric + Adults: (1)	 Phase III: (1)	 Live-attenuated virus: (1)

SALMONELLA spp. [118], [119], [120]
• 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 FOR TYPHOIDAL AND NON-TYPHOIDAL *SALMONELLA*
1 INVASIVE NON-TYPHOIDAL *SALMONELLA*
	
	Paediatric + Adults: (2)
		
		Phase II: (2)
			
			Multiple platforms: (1)
			Generalised Modules for Membrane Antigens: (1)

SHIGELLOSIS [121], [122], [123] • 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: 1	 Paediatric: (1)	 Phase II: (1)	 Glycoconjugate vaccine: (1)
YELLOW FEVER [85], [86], [87] • 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	 Adults: (1)	 Phase III: (1)	 Live-attenuated virus: (1)
ZIKA [139], [140], [141] • 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 for Zika. PIPELINE CANDIDATES: 2	 Adults: (2)	 Phase I: (1) Phase II: (1)	 mRNA: (1) Whole-inactivated virus: (1)

AMR NI RI CC TrV ZOO

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 [142]. For instance, the 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. According to the latest WHO data, over 25,000 laboratory-confirmed cases have been recorded globally in 2025, already exceeding the total of cases reported in 2024 [143] [144]. 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) [145] and the WHO to declare it a Public Health Emergency of International Concern (PHEIC) [146].

Beyond COVID-19 and mpox, the continued circulation of other viruses with zoonotic potential in both farmed and wild animals serves as a persistent warning that another pandemic could emerge at any time. While implementing strong measures to predict and prepare for zoonotic disease outbreaks is crucial, preventing their emergence is just as essential.

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) [147].

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, rabies, Nipah virus disease, salmonellosis and yellow fever.

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
CORONAVIRUSES [148], [149], [150] • 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: 7 (CORONAVIRUSES) 6 (SEASONAL INFLUENZA + COVID-19)	Paediatric: (2) Adults: (4) Older Adults: (2) Adults + Older Adults: (4) Paediatric + Adults + Older Adults: (1)	Phase I: (4) Phase II: (3) Phase III: (2) Regulatory review: (4)	Protein nanoparticles: (1) Protein subunit: (3) mRNA: (9)
DENGUE FEVER [80], [81] • 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. • Four autochthonous cases have been reported in two EU/EEA countries in 2025. More than 200 autochthonous dengue cases have been reported in Europe in 2024. PIPELINE CANDIDATES: 1	Paediatric + Adults: (1)	Phase III: (1)	Live-attenuated virus: (1)
LYME DISEASE [151], [152] • 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: (1) Adults: (2)	Phase II: (2) Phase III: (1)	Protein subunit: (1) mRNA: (2)
MPOX [72], [73], [74] • 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 II: (1)	mRNA: (1)

AMR NI RI STI CC TrV ZOO

DISEASE/PATHOGEN	POPULATION	STATUS	TECHNOLOGY
NIPAH VIRUS INFECTION [153], [154] • 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 [155], [156]
• Global outbreak associated with the emergence of a new influenza A virus to which most of the population does not have immunity and 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: 8
	Adults: (1)
	Adults + Older Adults: (7)
		Phase I: (3)
		Phase II: (5)
			Protein subunit: (2)
			mRNA: (5)
			Whole-inactivated virus: (1)

RABIES [82], [83], [84] • 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 locally-acquired human rabies infections were reported between 2020 – 2023, 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)

AMR NI RI TrV ZOO

Conclusion

This report highlights the pivotal role vaccines innovation play in addressing emerging and persistent health threats. The experience of COVID-19 has accelerated innovation, particularly in the development of combination vaccines that offer protection against multiple respiratory illnesses such as seasonal influenza and respiratory syncytial virus (RSV). These advancements reflect a proactive approach to evolving viral risks and underline the importance of integrated immunisation strategies. **Notable progress has been made in RSV vaccine development**, with several candidates either receiving regulatory approval or advancing into late-stage clinical trials, offering new tools to protect vulnerable populations.

Beyond viruses, important strides are also being taken in combating **bacterial infections**, especially those caused by drug-resistant pathogens. The development of vaccines targeting these threats signals a growing recognition that immunisation is a crucial component in the global fight against **antimicrobial resistance (AMR)**. At the same time, the increasing burden of **sexually-transmitted infections (STIs)**, as highlighted by alarming global and European data, is driving the development of targeted vaccines to address these urgent public health concerns.

In our interconnected world, **vaccines for travel-related and zoonotic diseases** are critical to managing cross-border health risks and emerging pathogens. These efforts help ensure the safety of individuals on the move and reinforce **global health security and pandemic preparedness**.

Vaccines not only **save millions of lives annually**, but also strengthen healthcare systems and support **economic and societal resilience**. Embracing a **life-course approach to immunisation**, ensuring access and recommendations at every stage of life, is essential to fully realise these benefits and protect all age groups against vaccine-preventable diseases. The current Vaccines Europe members' pipeline reflects the industry's strong commitment to this approach, with **candidates targeting a wide range of diseases and demographics**. Equally important is the continued advancement of immunisation technologies, which enables more targeted, adaptable, and rapid responses to both current and emerging public health threats.

However, vaccines are complex products that require substantial time, investment, and expertise to develop. The strength of today's vaccine pipeline is a testament to the dedication of vaccine developers in tackling a wide range of challenges, from **pandemics and climate-sensitive diseases, to AMR and shifting demographics**.

While vaccines are powerful tools, it is **immunisation that saves lives**. The real impact comes when vaccines are delivered to people, protecting individuals and communities. In recent years, the emergence of diseases that were once under control, such as measles and pertussis, has highlighted the risks posed by declining immunisation coverage. This trend is being fuelled by rising misinformation and mistrust, underscoring the urgent need to strengthen public acceptance and confidence in immunisation. Therefore, delivering vaccines to the people who need them most requires a **collective effort**. Success depends on cooperation across the entire ecosystem – from researchers and developers to regulators like the European Medicines Agency (EMA), to advisory bodies such as National Immunisation Technical Advisory Groups (NITAGs), Health Technology Assessment (HTA) agencies and the European Centre for Disease Prevention and Control (ECDC), as well as governments, healthcare providers, and civil society. Each plays a critical role in ensuring vaccines are not only developed, but also approved, funded, trusted, and administered.

To maintain Europe's global leadership in vaccine innovation and production, it is essential to foster a **supportive environment for vaccine manufacturers**. This includes strong regulatory frameworks, stable funding, investment in infrastructure, and public awareness campaigns. With the right policies in place, Europe can continue to lead in addressing its population's evolving health needs and contribute meaningfully to global health resilience.

We must prepare for tomorrow, today.

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

DISEASE/PATHOGEN	NUMBER OF CANDIDATES	TRIAL POPULATION		
		PAEDIATRIC	ADULTS	OLDER ADULTS
PHASE I CLINICAL TRIALS[1]				
Chlamydia trachomatis infection	1		✓	
Clostridioides difficile infection (CDI)	1		✓	
COVID-19	2		✓	✓
COVID-19 + influenza	2		✓	✓
Epstein-Barr virus infection (EBV)	1		✓	
Human immunodeficiency virus (HIV)	2		✓	
Human papillomavirus (HPV)	1		✓	
Influenza (seasonal)	3		✓	✓
Influenza (pandemic)	3		✓	✓
Influenza + RSV	1		✓	✓
Nipah virus	1		✓	
Pneumococcal disease	2	✓		
Respiratory syncytial virus (RSV)	1	✓		
RSV + human metapneumovirus (RSV/hMPV)	2	✓	✓	✓
RSV + hMPV + human parainfluenza type 3 (RSV/hMPV/PIV3)	1			✓
Varicella-zoster virus (VZV), varicella/shingles	1		✓	✓
Zika	1		✓	
PHASE II CLINICAL TRIALS[1]				
Acne*	1		✓	✓
Clostridioides difficile infection (CDI)	*1*		✓	
COVID-19	*1*	✓	✓	✓
COVID-19 + influenza	*2*		✓	✓
Cytomegalovirus (CMV)	*1*		✓	
Epstein-Barr virus infection (EBV)	*2*	✓	✓	
Herpes simplex virus* (HSV)	*1*		✓	
Influenza (seasonal)	*5*		✓	✓
Influenza (pandemic)	*5*		✓	✓
Lyme disease	*2*		✓	
Measles, mumps, rubella, varicella	*1*	✓		
Meningococcal disease	*2*	✓	✓	
Mpox	*1*		✓	
Norovirus	*1*		✓	✓

PHASE II CLINICAL TRIALS CONT[1]				
Pneumococcal disease	*5*	✓	✓	✓
Pseudomonas aeruginosa infection	*1*	✓	✓	✓
Respiratory syncytial virus (RSV)	*2*	✓	✓	✓
Salmonella spp.	*2*	✓	✓	
Shigellosis *(Shigella spp.)*	*1*	✓		
Staphylococcus aureus infection	*1*		✓	
Uropathogenic *Escherichia coli* (UPEC)	*1*		✓	
Varicella-zoster virus (VZV), varicella/shingles	*2*		✓	✓
Zika	*1*		✓	
PHASE III CLINICAL TRIALS				
COVID-19	*1*	✓		
COVID-19 + influenza	*1*			✓
Cytomegalovirus (CMV)	*1*		✓	
Dengue fever	*1*	✓	✓	
Group B *Streptococcus* infection**	*1*		✓	
Influenza (seasonal)	*5*		✓	✓
Lyme disease	*1*	✓	✓	
Norovirus	*1*		✓	✓
Pneumococcal disease	*1*	✓	✓	✓
Rabies	*1*	✓	✓	✓
Respiratory syncytial virus (RSV)	*1*	✓		
Varicella-zoster virus (VZV), varicella/shingles	*1*	✓		
Yellow fever	*1*		✓	
UNDER REVIEW BY THE REGULATORY AUTHORITY				
COVID-19	*3*	✓	✓	
COVID-19 + influenza	*1*			✓
Respiratory syncytial virus (RSV)	*2*		✓	

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

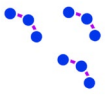
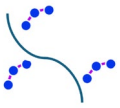
ANNEX II: Evolution of the pipelines of Vaccines Europe members companies between 2022 and 2025*

DISEASE/PATHOGEN	NUMBER OF CANDIDATES IN 2022	NUMBER OF CANDIDATES IN 2023	NUMBER OF CANDIDATES IN 2024	MARKETING AUTHORISATION GRANTED SINCE 2022	DEVELOPMENT PROGRAMS DISCONTINUED SINCE 2022	NUMBER OF CANDIDATES IN 2025
VIRAL INFECTIONS						
Chikungunya virus	2	1	0	1	1	0
COVID-19	27	17	14	13	13	7
COVID-19 + influenza	2	3	3	0	1	6
COVID-19 + RSV	0	1	0	0	1	0
COVID-19 + influenza + RSV	0	1	1	0	1	0
COVID-19 and/or other coronaviruses	1	1	1	0	0	0
Cytomegalovirus (CMV)	4	3	3	0	1	2
Dengue fever	1	1	1	1	0	1
Ebola	2	0	0	1	1	0
Epstein-Barr virus infection (EBV)	1	2	2	0	0	3
CMV-associated Glioblastoma**	1	1	1	0	0	0
Hepatitis B**	2	2	2	0	1	0
Herpes simplex virus**	1	2	2	0	1	1
Human immunodeficiency virus (HIV)	3	2	2	0	1	2
Human papillomavirus (HPV)	0	1	1	0	1	1
Human metapneumovirus and human parainfluenza virus type 3 (hMPV/PIV3)	1	0	0	0	1	0
Influenza (seasonal)	9	16	13	0	2	13
Influenza (pandemic)	0	1	5	3	0	8
Influenza + RSV	0	2	2	0	1	1
Measles, mumps, rubella, varicella	0	1	1	0	0	1
Mpox	0	0	1	0	0	1
Nipah virus	1	1	1	0	0	1
Norovirus	0	1	2	0	0	2
Rabies	2	2	1	0	1	1
Respiratory syncytial virus (RSV)	10	6	8	6	6	6
RSV + hMPV	0	1	2	0	0	2
RSV + hMPV + PIV3	0	0	0	0	0	1
Varicella-zoster virus (VZV), varicella/shingles	1	3	3	0	0	4
Yellow fever	1	1	1	0	0	1
Zika	3	3	2	0	0	2

DISEASE/PATHOGEN	NUMBER OF CANDIDATES IN 2022	NUMBER OF CANDIDATES IN 2023	NUMBER OF CANDIDATES IN 2024	MARKETING AUTHORISATION GRANTED SINCE 2022	DEVELOPMENT PROGRAMS DISCONTINUED SINCE 2022	NUMBER OF CANDIDATES IN 2025
BACTERIAL INFECTIONS						
Acne**	0	0	1	0	0	1
Chlamydia trachomatis infection	0	0	0	0	0	1
Clostridioides difficile infection (CDI)	3	4	2	0	3	2
Gonorrhoea	0	1	1	0	1	0
Invasive *E. coli* disease	1	1	1	0	1	0
Group B *Streptococcus* infection***	1	1	1	0	0	1
Klebsiella pneumoniae	1	1	0	0	1	0
Lyme disease	1	2	3	0	0	3
Meningococcal disease	6	7	4	4	1	2
Pneumococcal disease	4	5	5	2	2	8
Pseudomonas aeruginosa infection	0	0	0	0	0	1
Salmonella spp.	0	2	2	0	1	2
Shigellosis *(Shigella spp.)*	1	1	2	0	2	1
Staphylococcus aureus infection	1	0	0	0	1	1
Uropathogenic *Escherichia coli* (UPEC)	0	0	0	0	0	1
PROTOZOAL INFECTIONS						
Malaria	2	2	1	1	1	0

*The table only includes pipeline data between 2022 and 2025 and does not take into account any previously authorised vaccines.
** Therapeutic vaccine
*** Vaccine dedicated to maternal immunisation

ANNEX III: Description of immunisation 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 [157].
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 [157].
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 [158]. There are several types of protein vaccines: • ***Purified antigenic proteins:*** extracted and purified from the whole pathogen [157]; • ***Recombinant protein vaccines:*** produced through genetic engineering in host cells [157]; • ***Protein nanoparticles:*** the proteins are delivered through nano-sized carriers [159].
		**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 [157].
		**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 [157] [160].
		**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 [157].
		**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 [157].
		**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 [161].

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 [161].
		**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 [162].
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 [163] [164].
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 [160].
		**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) [160].
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 [165] [166].

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