

Great
Place
To
Work®

Certified

MAR 2024-MAR 2025

INDIA

™

GENNOVA

Transforming
Healthcare

WWW.GENNOVA.BIO

GENNOVA VALUES

HAPPY PLACE TO SERVE

We take pride in
being purposeful
and spreading
happiness

INDIVIDUAL AND TEAM EXCELLENCE

Enabling limitless
possibilities for self and
team by leveraging
strengths

FOCUS

Clarity with
discipline of
execution

INNOVATION AT ALL LEVELS

We challenge
status quo in
everything
we do

QUALITY AND SPEED OF DELIVERY

We are
patient-focused
and deliver what
we commit

TRUST AND RESPECT

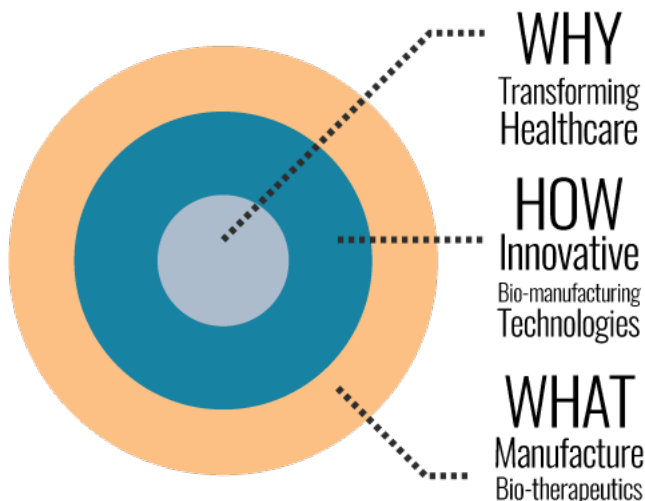
Being mindful
of thoughts
and actions

Genova Biopharmaceuticals Ltd., headquartered in Pune, India, is a leading biotechnology company dedicated to developing, producing, and commercializing biotherapeutics for life-threatening diseases across various indications.

Genova aspires to transform the healthcare of millions of people, primarily through technological solutions, employing AI-assisted innovation in bio-manufacturing, diagnosis, and treatment for a better outcome.

Genova believes that experience and success-driven approach will facilitate the present and future journey from product development to the clinic.

Today, Genova can proudly say that its technological innovation in healthcare has made a difference to hundreds of thousands of human lives. In subsequent years, Genova would like to positively impact hundreds of millions of lives across the globe and, in the process, be one of the top technology-driven companies in the world.



Gennova is transforming healthcare by creating efficient and effective solutions for manufacturing and successful commercialization. Bio-therapeutics across cardiovascular, neurology, nephrology, and oncology segments are developed by incorporating recombinant DNA technologies and innovative bio-manufacturing processes.

The company manufactures its recombinant products using **mRNA, microbial and mammalian-based platforms** and has developed deep expertise in **perfusion-based continuous manufacturing technologies**.

Till date, Gennova has commercialized nine products including **biosimilars, generics, and pioneering products in Stroke care and Cancer Care**. Gennova is credited to develop the **first thermostable mRNA vaccines** for COVID-19.

To boost the next-generation manufacturing technologies for bio-therapeutics production and the development of parallel innovating tools to reach patients, Gennova strives to improve and innovate continuously to respond effectively to healthcare challenges.

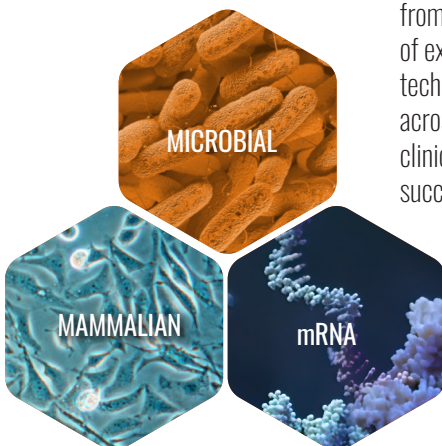
Innovation is central to Gennova's continued success. This innovation comes from both its internal attributes, capabilities, external collaborations, and synergistic partnerships.

The state-of-the-art facilities, R & D capabilities, and knowledgebase development have empowered Gennova to take a product from gene to market. Gennova has a team of experienced and capable scientists and technocrats who have developed capabilities across scientific, manufacturing, regulatory, clinical, and business arenas that have made it successful in the Indian market.

Through innovation-driven bio-manufacturing, Gennova became the first biotechnology company in India to launch the biosimilar of the third-generation thrombolytic protein, **tenecteplase**, addressing the unmet need in cardiovascular diseases. Carrying on with its innovation to transform healthcare, Gennova launched **TENECTASE®**, a pioneering work, where first time globally, a third-generation thrombolytic was approved for the indication of **Acute Ischemic Stroke (AIS)**.

This innovation was recognized by the Department of Biotechnology (DBT), Govt. of India for the '**Biotech product, process development and commercialization award 2019**'. Additionally, this '**Make in India**' product has found its way in the list of drugs for emergency care for stroke management in the guideline - '**Prevention and Management of Stroke**,' issued by the **Ministry of Health and Family Welfare, Govt. of India**.

Gennova's innovation around high cell density fermentation and genetic manipulations for its microbial products have successfully culminated in the development and commercialization of filgrastim and its long-lasting pegylated version PEG-filgrastim. Continuing its efforts on innovative pegylation processes, Gennova was the first Indian company to develop generic pegaspargase, **HAMSYL®**, and launch it in 2014 for use in **Acute Lymphoblastic Leukemia (ALL)**, an orphan indication at the request of the Tata Memorial Hospital, Mumbai, India.



Our Production Platforms

Genova's Process Development Laboratory (PDL) fills in the huge gap in the availability of resources (instruments, equipments, and manpower) through its Product Development Program (PDP) using diverse production platform (Microbial/Mammalian) that can develop the processes right from cell banking to cGMP pilot manufacturing, validating all methods (in-process, analytical etc.) and processes making it suitable for required technology transfer of manufacturing for clinical studies.

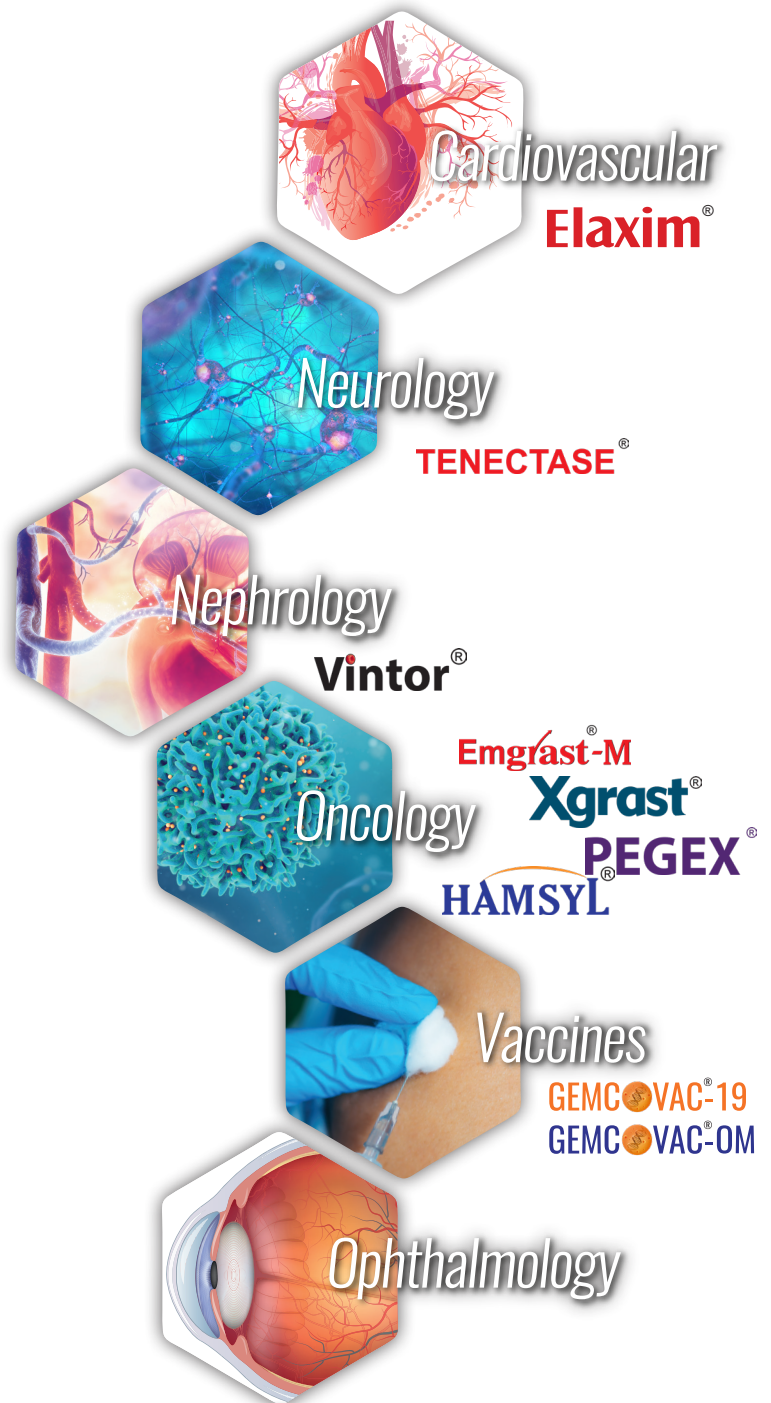
Under the **National Biopharma Mission**, an initiative of Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology, Govt. of India, Genova is creating a shared PDL facility to enable ease of bench to bed side transition from taking a product at the proof-of-concept stage to Phase III CT material production and assist in preparing regulatory documentations for submission.

The **Research and Development (R & D) facility** – '**Genova Vaccine Formulation Centre and Research Laboratory**' is recognized by the **Department of Scientific and Industrial Research (DSIR)** with a work space of over **78,000 sq. ft.**

The R & D facility was established with the following primary objectives:

- Recombinant cell line development for protein therapeutics and antigens as vaccine candidates;
- Process development for protein therapeutics and antigens as vaccine candidates;
- Product characterization and analytical method development;
- Formulation development.

The current PDL unit has molecular biology, upstream process development, downstream process development, analytical development and formulation development laboratories for making research and clinical grade for phase-I biologics for therapeutic and vaccine purpose. Genova has proven expertise in three platforms which includes **mammalian, microbial and mRNA platform technology**. Genova has the capability of designing and execution of processes from gene to finish products. Our formulation facility can produce GMP grade material for clinical trials up to phase-I. Genova as a company focuses on optimizing processes that will eventually result in healthcare transformation.



The research and development facility has molecular biology, upstream process development, downstream process development, analytical development, and formulation development laboratories for making clinical-grade biologics for therapeutic purposes, with the capability of designing and executing processes from 'gene to protein to market'.



Gennova has a team of experienced and capable scientists with advanced degrees from world-renowned institutes and technocrats who have developed capabilities across scientific, manufacturing, regulatory, clinical, and business arenas, that have made it successful in the Indian market. The experience and capabilities will facilitate the expansion of business in the global market for our current and pipeline products.

Leadership Team brings in GLOBAL experience from

- National Institutes of Health (NIH), USA
- The Wharton School of the University of Pennsylvania, USA
- Cornell University, USA
- Johns Hopkins University (JHU), USA
- University of Chicago, USA
- European Molecular Biology Laboratory (EMBL), Germany
- Max Planck Institute for Biochemistry, Germany
- Indian Institutes of Technology (IIT)
- Indian Institute of Management
 - University of Delhi, India
 - Central Drug Research Institute (CDRI), India
 - National Chemical Laboratory (NCL), India
 - Institute of Chartered Accountants of India
 - University of Liverpool
 - University of California Irvine
 - University of Iowa
 - All India Institute of Medical Sciences (AIIMS)
 - Indian Institute of Management (IIM), Ahmedabad

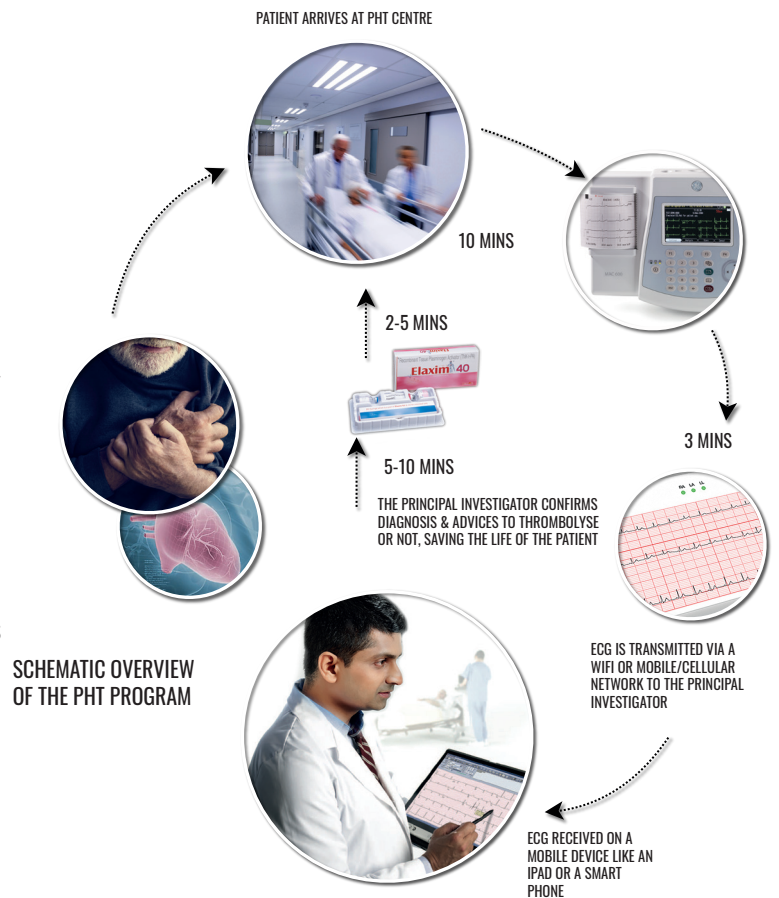


Gennova has implemented a Pre-Hospital Thrombolysis (PHT) program across India. The impetus and driving force for the innovative PHT program comes from two important issues pertinent to India. The first is that the availability and implementation of a US standard 911-type emergency system is extremely limited as is the number of CATH labs (catheterization laboratory) for a country with such a large population.

In other words, there is a limited opportunity for AMI (acute myocardial infarction) patients to receive emergency care at their residence and it is unlikely that there is a nearby CATH lab for emergency primary catheterization. The second is that given the issues with inaccessible emergency transport and extreme traffic density, it is no surprise that the median symptom-to-door time was 300 minutes for Indian patients with ST-segment elevation myocardial infarctions (STEMI), well beyond the prescribed “Golden Hour” for reperfusion treatment. Lack of evidence-based care has also been cited as a major reason for high mortality rates from CVD in India.

To address this extremely challenging scenario, Gennova and GE conducted the pilot PHT program in association with a leading cardiologist from Hyderabad, connecting to nine primary care facilities without primary percutaneous coronary intervention (PCI) capabilities, that are remotely located and do not have access to either a cardiologist or a CATH lab or both. This pilot program utilized a portable electrocardiogram (ECG) device, which generated an electronically transmitted report for a cardiologist at the CATH lab located in Hyderabad. The cardiologist opines on the cardiogram and instructs the general practitioner at the primary care facilities to thrombolyse with Elaxim®, if required. This in turn allows the patient who may be suffering from a life-threatening STEMI event to be diagnosed and treated with Elaxim® within the critical 90 minutes of the heart attack – long before arriving at the emergency room or CATH lab.

207 patients presenting with STEMI were diagnosed and treated with an average time from initial diagnosis (ECG) to Elaxim® treatment of less than 25 minutes. Development plans are already underway for the Phase II program to expand the PHT program to 500 centers pan India.



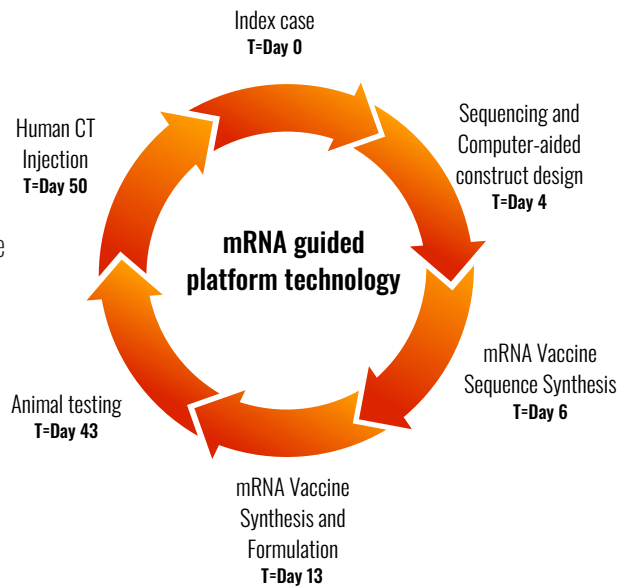
Genova has developed two mRNA-based vaccines against COVID-19, GEMCOVAC®-19 & GEMCOVAC®-OM, which use self-amplifying mRNA adsorbed to Cationic Lipid Nano Emulsion (CLNE). Both vaccines have been approved by Central Drugs Standard Control Organisation for Restricted Use in Emergency Situation. They are India's first mRNA vaccines and the world's first thermostable mRNA vaccines against COVID-19.

GEMCOVAC®-OM is approved as a single dose booster specifically targeting the Omicron strain. GEMCOVAC® vaccines overcome the limitations associated with the currently approved mRNA vaccines. They are stable at 2-8 °C and can be considered superior in terms of deployability in India and other developing nations (especially LMICs) compared to other approved mRNA vaccines. In GEMCOVAC® vaccines, the mRNA is **adsorbed on the surface** of the nano-lipid emulsion (as opposed to it being entrapped in other mRNA vaccines using NLPs), thereby **easing manufacturability** and minimizing losses.

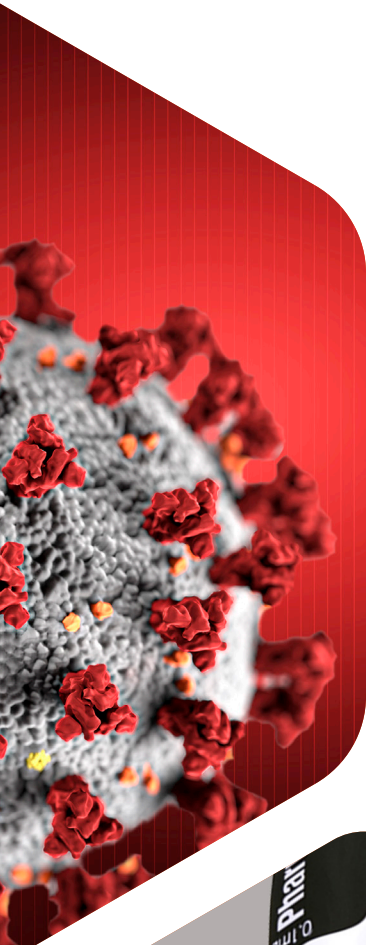
This also makes the **process scalable** and **amenable for technology transfer**-a must for the democratization of the mRNA-based technology to eliminate the inequitable vaccine distribution globally.

mRNA-based vaccines are the ideal choice because of their rapid developmental and production timeline. mRNA vaccines are considered safe as mRNA is **non-infectious**,

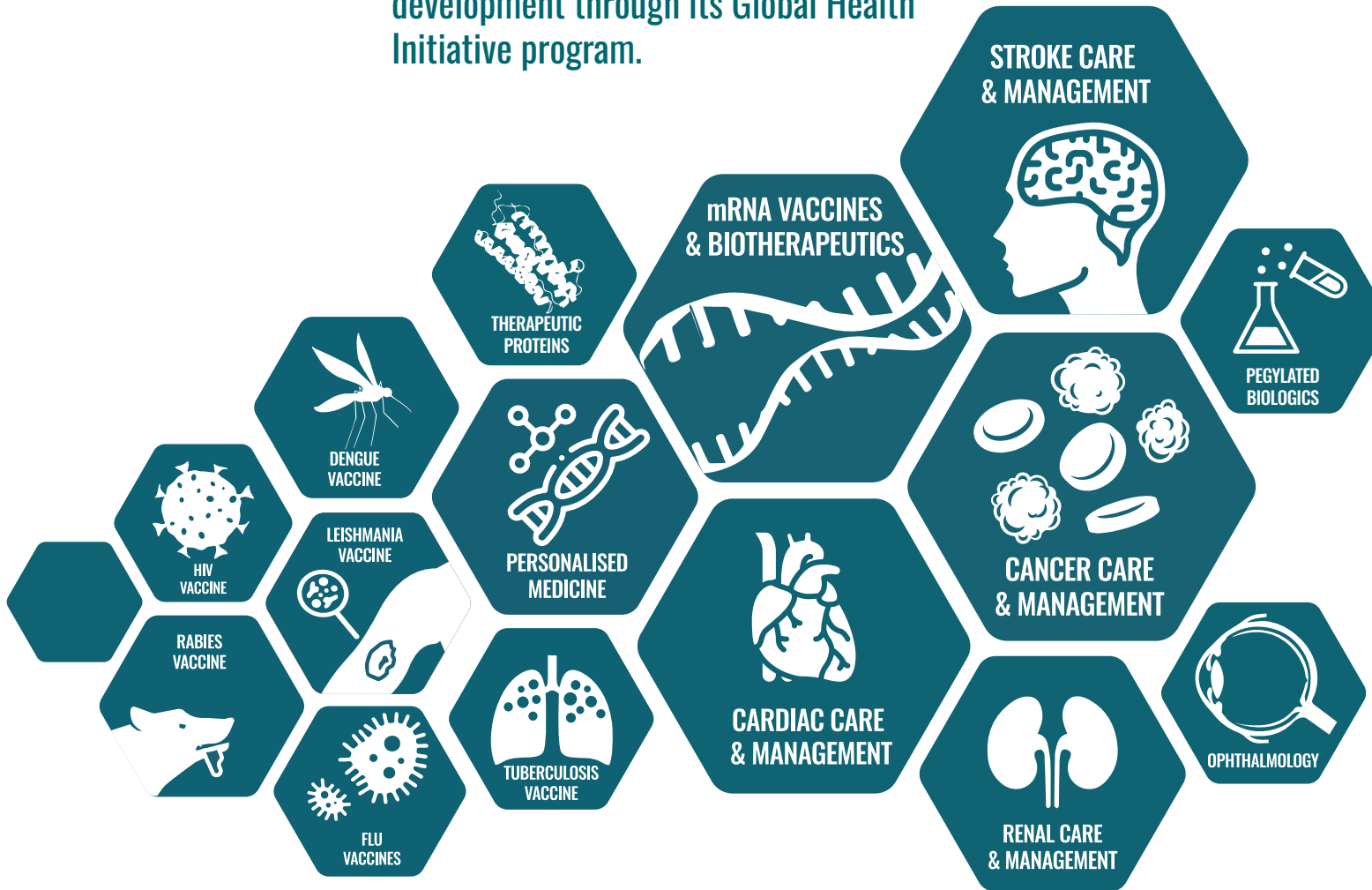
non-integrating in nature, and is degraded by standard cellular mechanisms. They are **highly efficacious** because of their inherent capability of being translated into proteins. Additionally, mRNA vaccines are fully synthetic and do not require a host for growth. Therefore, they can be quickly manufactured in a cost effective manner under cGMP conditions to ensure their "availability" and "accessibility" for mass vaccination on a sustainable basis.



In addition to the obvious application to infectious diseases, mRNA-based vaccines have the potential for multiple administrations in patients with low intrinsic immunity, thereby opening up bright prospects for developing novel therapeutics with the potential to treat or prevent diseases that are currently incurable. Creating such an unprecedented 'disease agnostic mRNA- based technology platform' empowers the world to be ready for future pandemics.



Genova Biopharmaceuticals, a leader in innovative biotherapeutics, has established itself as a preferred research and cGMP manufacturing partner in vaccine development through its Global Health Initiative program.

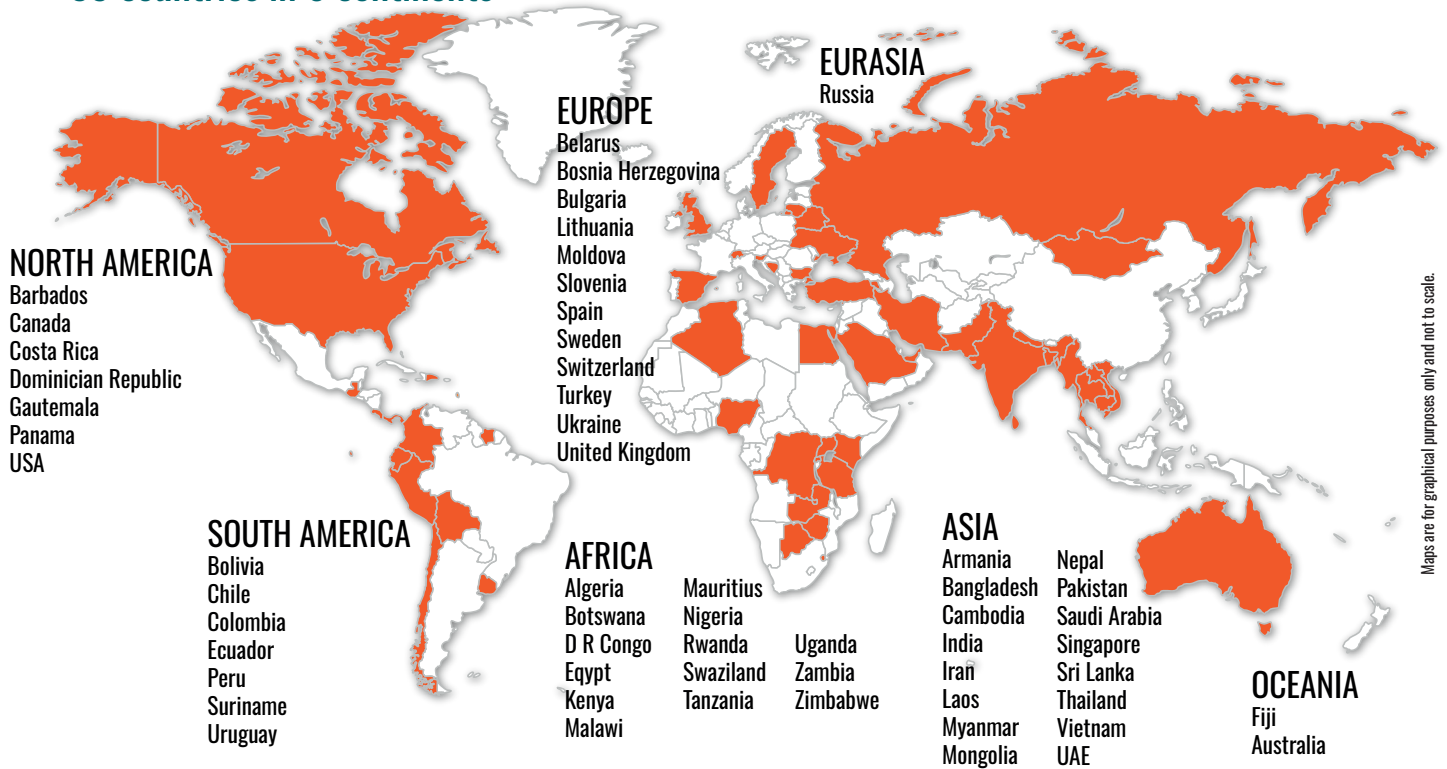


The company is addressing endemic diseases such as tuberculosis, malaria, and dengue, and enhancing vaccines for flu and rabies by leveraging its advanced mRNA-based platform. Additionally, Genova is developing a genetically modified live attenuated Leishmania vaccine, showcasing its expertise and commitment to tackling global health challenges.

These efforts have earned Genova international recognition, reflecting its dedication to transforming healthcare through advanced solutions. Through strategic collaborations and a strong emphasis on innovation, Genova is at the forefront of developing advanced solutions that address critical health challenges worldwide.



Genova has its footprints in 59 countries in 6 continents



Being successful in the local market, Genova aspires to take its innovation across various technologies globally. Genova is defining the future by doing what it does best – AI-assisted innovation in bio-manufacturing, advanced diagnosis, and treatment for better outcomes to transform the healthcare of millions of people.



10 years from now Genova wants to make an impact on **100,000,000s** of human lives

In the last 10 years, Genova has made a difference in over **100,000s** of human lives

GENNOVA

GENNOVA BIOPHARMACEUTICALS LIMITED

Registered Office:

P-1 & P-2, IT-BT Park, Phase-II, MIDC
Hinjawadi, Pune – 411 057, Maharashtra, India

R&D Address:

BTS – 2 Building, Chrysalis Enclave, Block – 2, Plot -2
TCG International Biotech Park, Phase II, MIDC, Hinjawadi
Pune – 411 057, Maharashtra, India

Manufacturing Address:

Block – 1, Plot P1 & P2, IT-BT Park, Phase II, MIDC, Hinjawadi
Pune – 411 057, Maharashtra, India

WWW.GENNOVA.BIO

FOLLOW US ON

