
GENNOVA
Transforming
Healthcare
WWW.GENNOVA.BIO

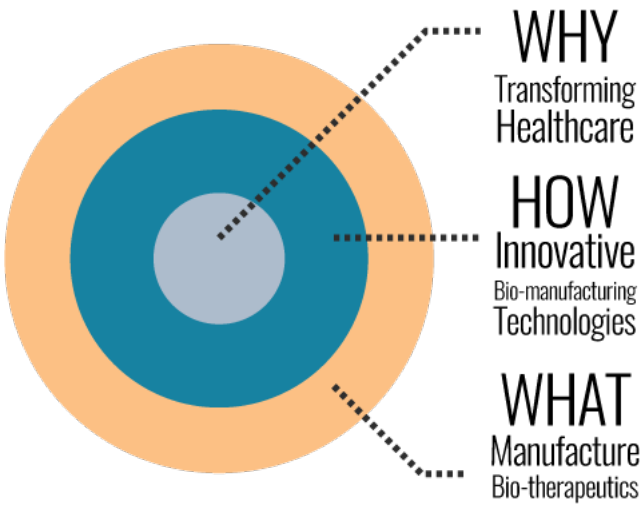

GENNOVA VALUES
HAPPY PLACE TO SERVE
We take pride in being purposeful and spreading happiness
INDIVIDUAL AND TEAM EXCELLENCE
Enabling limitless possibilities for self and team by leveraging strengths
FOCUS
Clarity with discipline of execution
INNOVATION AT ALL LEVELS
We challenge status quo in everything 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

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

Gennova 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.

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

Today, Gennova can proudly say that its technological innovation in healthcare has made a difference to hundreds of thousands of human lives. In subsequent years, Gennova would like to positively impact hundreds of millions of lives across the globe and, in the process, be one of the top 10 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**.

To date, Gennova has commercialized seven products; **5 biosimilars, one generic, and one pioneering – 'first in the world' product**. 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.

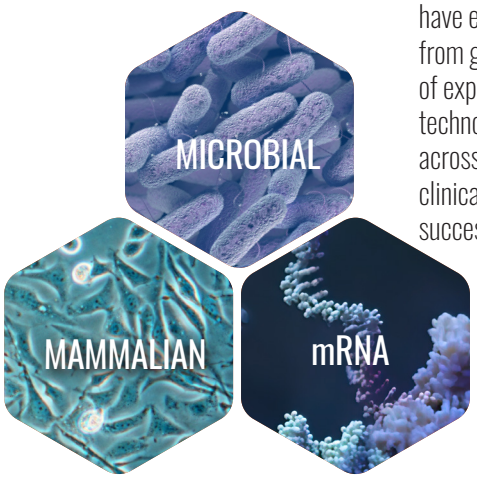
Innovation is central to Gennova's continued success. This innovation comes from both its internal attributes, capabilities, external collaborations and synergistic partnerships.

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

Gennova's Process Development Laboratory (PDL) fills in the huge gap in the availability of resources (instruments, equipment 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.

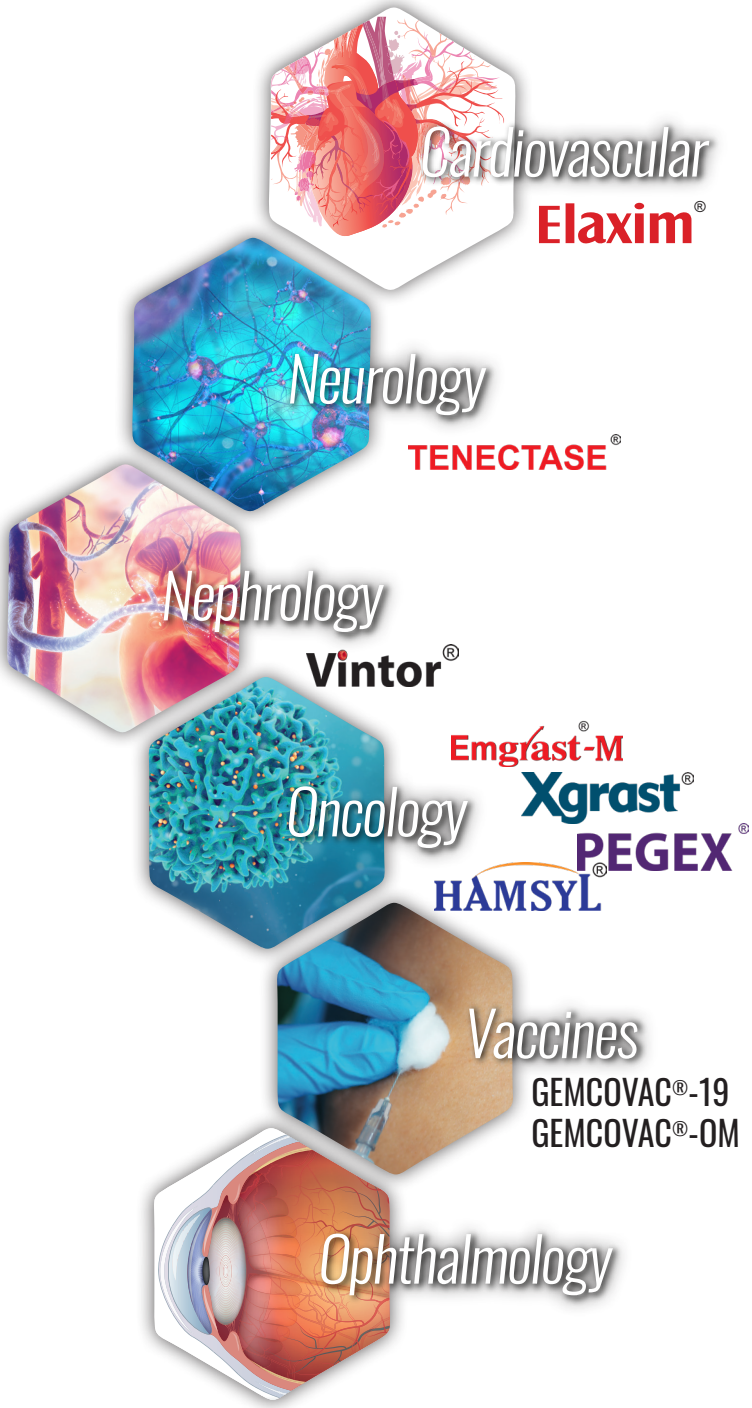
Under the **National Biopharma Mission,** an initiative of Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology, Govt. of India, Gennova is creating a shared PDL facility to enable ease of bench to bed side transition from taking 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 — **'Gennova 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.

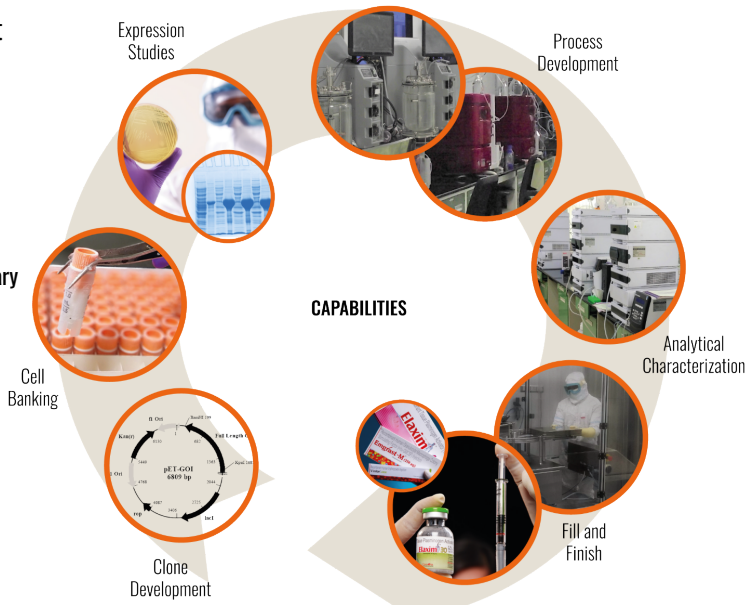
The current PDL unit has molecular biology, upstream process development, downstream process development, analytical development and formulation development laboratories for making research and clinical grade for phase-I biologics for therapeutic and vaccine purpose. Gennova has proven expertise in three platforms which includes **mammalian, microbial and mRNA platform technology**. Gennova 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. Gennova 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 purpose with the capability of designing and execution of processes from gene to protein to market.

Experience in taking from Gene to Market

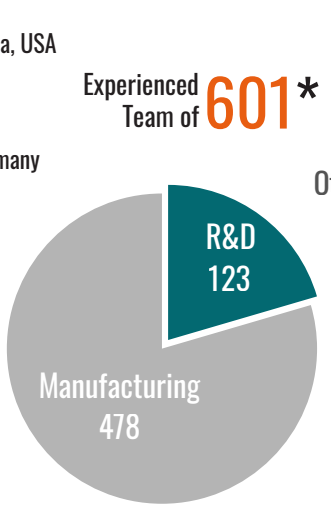
- Intellectual property
- R & D Capabilities - Innovation across
  - Bio-manufacturing processes
    - Upstream & Downstream processing
    - AI based systems
  - Cell & Molecular Biology
  - Antibody Discovery - Phage display library
- Manufacturing
  - Bulk and Drug Products
- Fill & Finish
  - Vial/PFS, Liquid/Lyophilized
- Quality Systems
  - Method development & Validation
  - Training
- Clinical Trials
- Regulatory Affairs
- Marketing



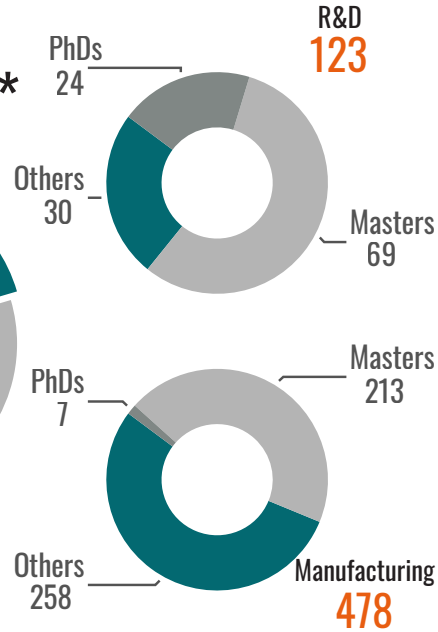
We have a team of experienced and capable scientists with advanced degrees from world renowned institutes and technocrats who have developed capabilities across scientific, manufacturing, regulatory, clinical and business arenas that have made it successful in the Indian market. The experience and capabilities 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

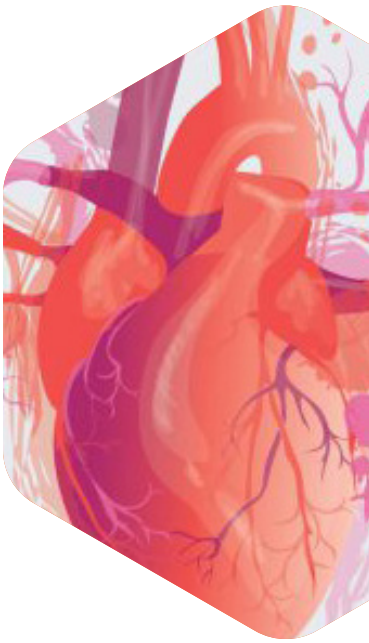


Experienced Team of 601*



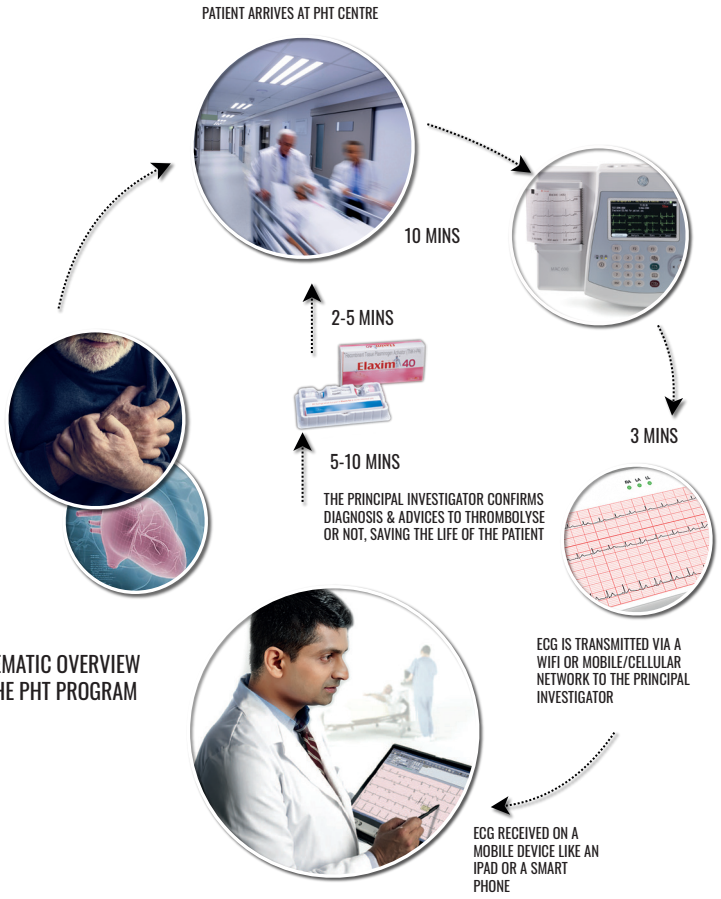
* Information updated till October 31st 2023

Gennova Biopharmaceuticals Ltd. 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) patient 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.

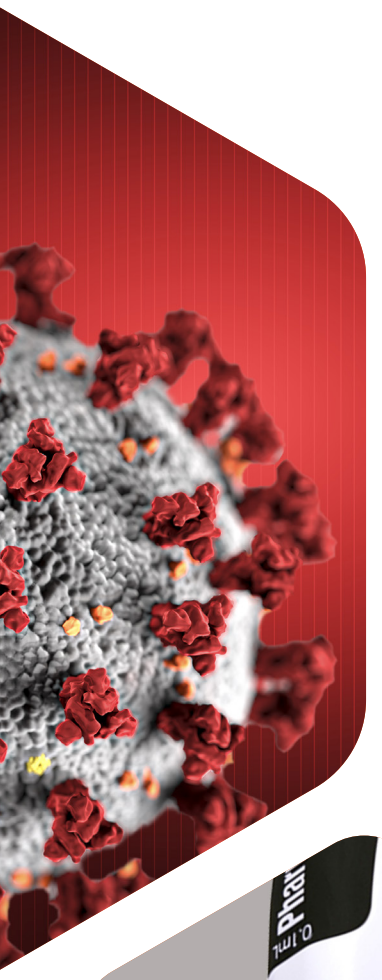
To address this extremely challenging scenario, Gennova and GE conducted the pilot PHT program in association with leading cardiologist from Hyderabad, connecting to nine primary care facilities without primary percutaneous coronary intervention (PCI) capabilities, that are remotely located and do not 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 minute of the heart attack – long before arriving at the emergency room or CATH lab.



SCHEMATIC OVERVIEW OF THE PHT PROGRAM

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.

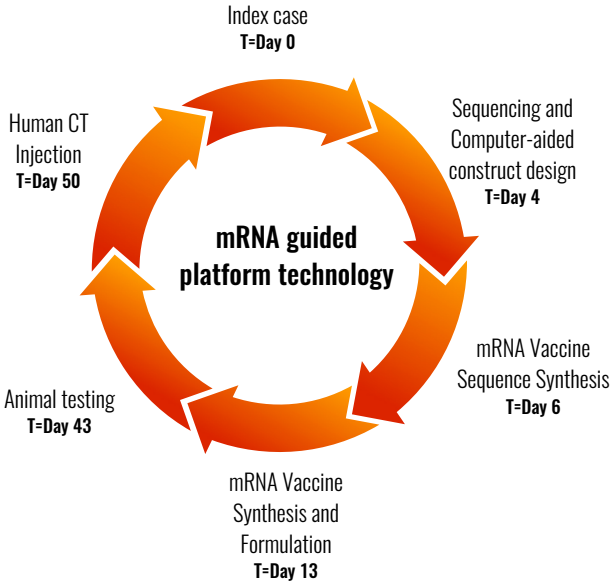
Gennova has developed two mRNA-based vaccines against COVID-19, GEMCOVAC®-19 & GEMCOVAC®-OM, which use self-amplifying mRNA adsorbed to Cationic Lipid Nano Emulsion (CLNE). Both vaccines have been approved by Central Drugs Standard Control Organisation for Restricted Use in Emergency Situation. They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



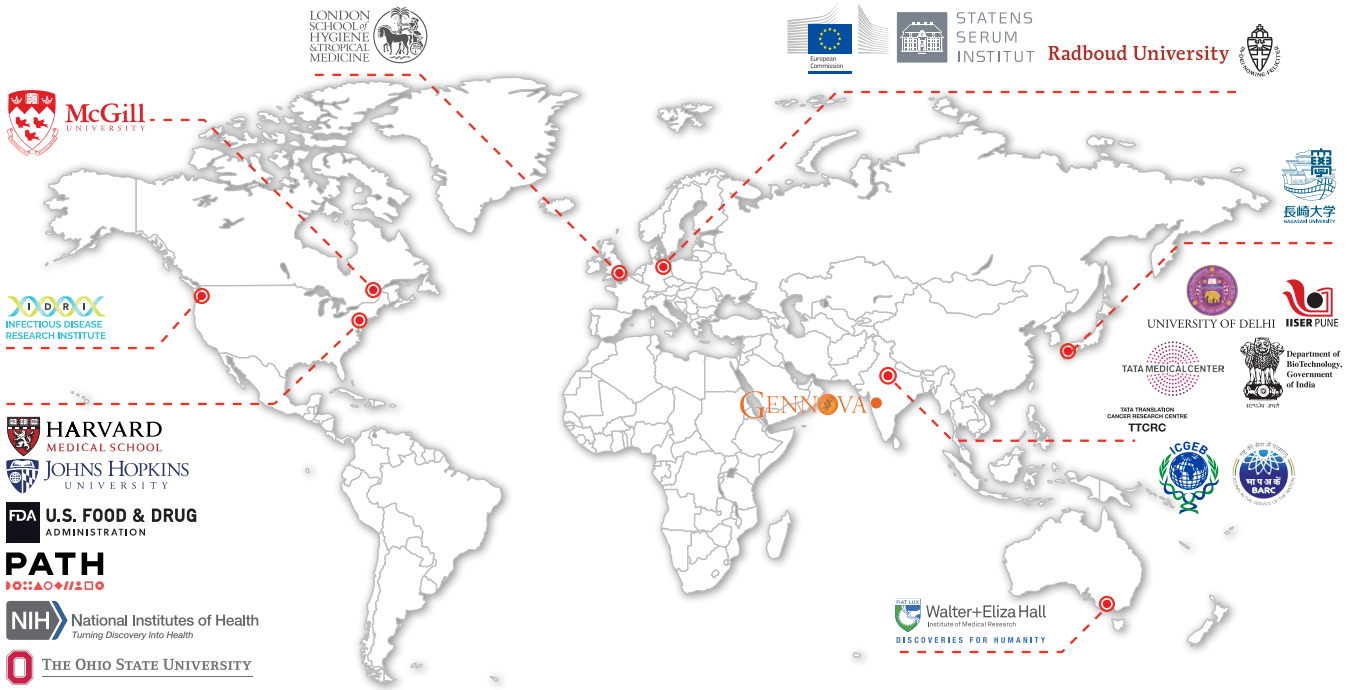
GEMCOVAC®-OM is approved as a single dose booster specifically targeting the Omicron strain. GEMCOVAC® vaccines overcome the limitations associated with the currently approved mRNA vaccines. They are stable at **2-8 °C** and can be considered superior in terms of deployability in India and other developing 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.



MALARIA VACCINE | TUBERCULOSIS VACCINE | LEISHMANIA VACCINE | COVID-19 VACCINES | mRNA VACCINES | FLU VACCINES | VACCINE ADJUVANTS | CANCER THERAPEUTICS | THERAPEUTIC PROTEINS | PEGYLATED BIOLOGICS

Gennova's socio-economic responsibility has propelled it to set up the Global Health Initiative program, under which Gennova has established itself as a preferred research and cGMP manufacturing partner in the area of vaccines.

GLOBAL GRANTS

CEPI

Department of BioTechnology, Government of India

बाइरैक इग्नाइट इनोवेट इंक्यूबेट

birac Ignite Innovate Incubate

Horizon 2020 Programme

SEVENTH FRAMEWORK PROGRAMME

BILL & MELINDA GATES foundation

GHIT Fund

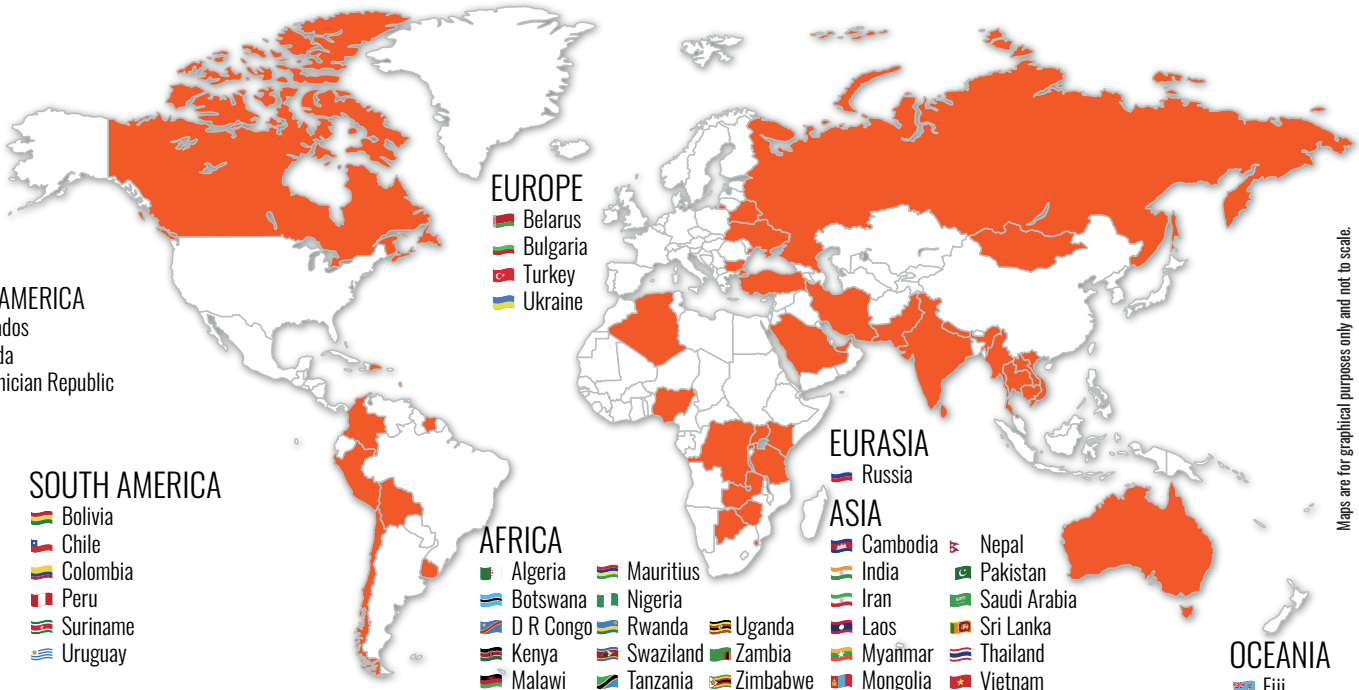
Global Health Innovative Technology Fund

Gennova's vaccine development initiative addresses four endemic diseases - malaria, tuberculosis, leishmaniasis, and flu. In this field, Gennova has national and international collaborations, e.g., **University of Delhi South Campus (UDSC), PATH Malaria Vaccine Initiative (MVI), European Commission (under FP7 and Horizon 2020), Infectious Disease Research Institute (IDRI), National Institutes of Health (NIH), Johns Hopkins University (JHU), The London School of Hygiene & Tropical Medicine (LSHTM) and The Walter and Eliza Hall Institute (WEHI).**

Gennova, in partnership with the **US-FDA, McGill University, Ohio State University, Nekken Institute of Tropical Medicine, NIH, and JHU**, has entered into a collaboration to develop and manufacture clinical-grade material of the genetically modified **live attenuated Leishmania vaccine candidate**, funded by the **Global Health Innovative Technology Funds (GHIT)**, Japan. The program represents two important milestones for Gennova: having a **collaborative vaccine program with the US-FDA** is a significant testimony to Gennova's capabilities and attributes and involves the formulation and manufacturing of a live attenuated vaccine to Gennova's other vaccine programs, which focuses on recombinant-based products.

Recently, **The Coalition for Epidemic Preparedness Innovations (CEPI)** is supporting Gennova to develop **novel RNA vaccine platform technologies** against emerging infectious diseases.

Gennova has presence in 42 countries in 6 continents



NORTH AMERICA
- Barbados
- Canada
- Dominician Republic

EUROPE
- Belarus
- Bulgaria
- Turkey
- Ukraine

SOUTH AMERICA
- Bolivia
- Chile
- Colombia
- Peru
- Suriname
- Uruguay

AFRICA
- Algeria
- Botswana
- D R Congo
- Kenya
- Malawi
- Mauritius
- Nigeria
- Rwanda
- Swaziland
- Tanzania
- Uganda
- Zambia
- Zimbabwe

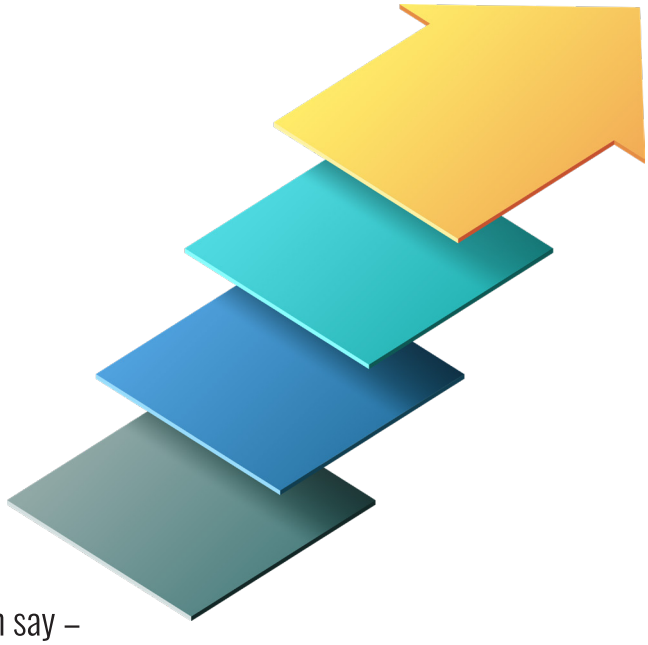
EURASIA
- Russia

ASIA
- Cambodia
- India
- Iran
- Laos
- Myanmar
- Mongolia
- Nepal
- Pakistan
- Saudi Arabia
- Sri Lanka
- Thailand
- Vietnam
- Singapore

OCEANIA
- Fiji
- Australia

Maps are for graphical purposes only and not to scale.

Being successful in the local market, we aspire to take our innovation across various technologies globally. We are defining the future by doing what we do best – AI-assisted innovation in bio-manufacturing, diagnosis, and treatment for a better outcome to transform the healthcare of millions of people.



10 years from now we want to say –
We have made a difference in **100,000,000s** of human lives

Today we can say –
In last 10 years, we have made a difference in **100,000s** of human lives

GENNOVA

GENNOVA BIOPHARMACEUTICALS LIMITED

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Pune – 411 057, Maharashtra, India.

Manufacturing Address:
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Pune – 411 057, Maharashtra, India.

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