

INVEST IN LAZIO

INVEST IN LIFE SCIENCES

BIO DIGITAL 2021 - USA



REGIONE
LAZIO

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WELCOME TO LAZIO

REGION OF ROME, HEART OF EUROPE AND CENTER OF THE MEDITERRANEAN AREA

- Lazio boasts a geopolitical position of global importance: in the heart of Europe and at the center of the Mediterranean region, a crossroad towards the Middle East and South-East Asia
- Rome is Italy's number one destination in Italy for international tourists and one of the most visited city in the world (with over 20 million tourists per year)



UP to 2 hours flight UP to 3 hours flight UP to 4 hours flight

LOGISTICS & MOBILITY

THANKS TO ITS VERY CENTRAL LOCATION, ITS INFRASTRUCTURES AND SERVICES, THE REGION IS ITSELF A STRATEGIC LOGISTICAL PLATFORM IN ITALY, IN THE MEDITERRANEAN, AND IN EUROPE



2 International Airports: **Fiumicino** and **Ciampino**, with over 50 million passengers and 363,000 national and international flights per year. Fiumicino Leonardo Da Vinci Airport is the first stopover in Italy and the first European airport for the satisfaction of travelers.



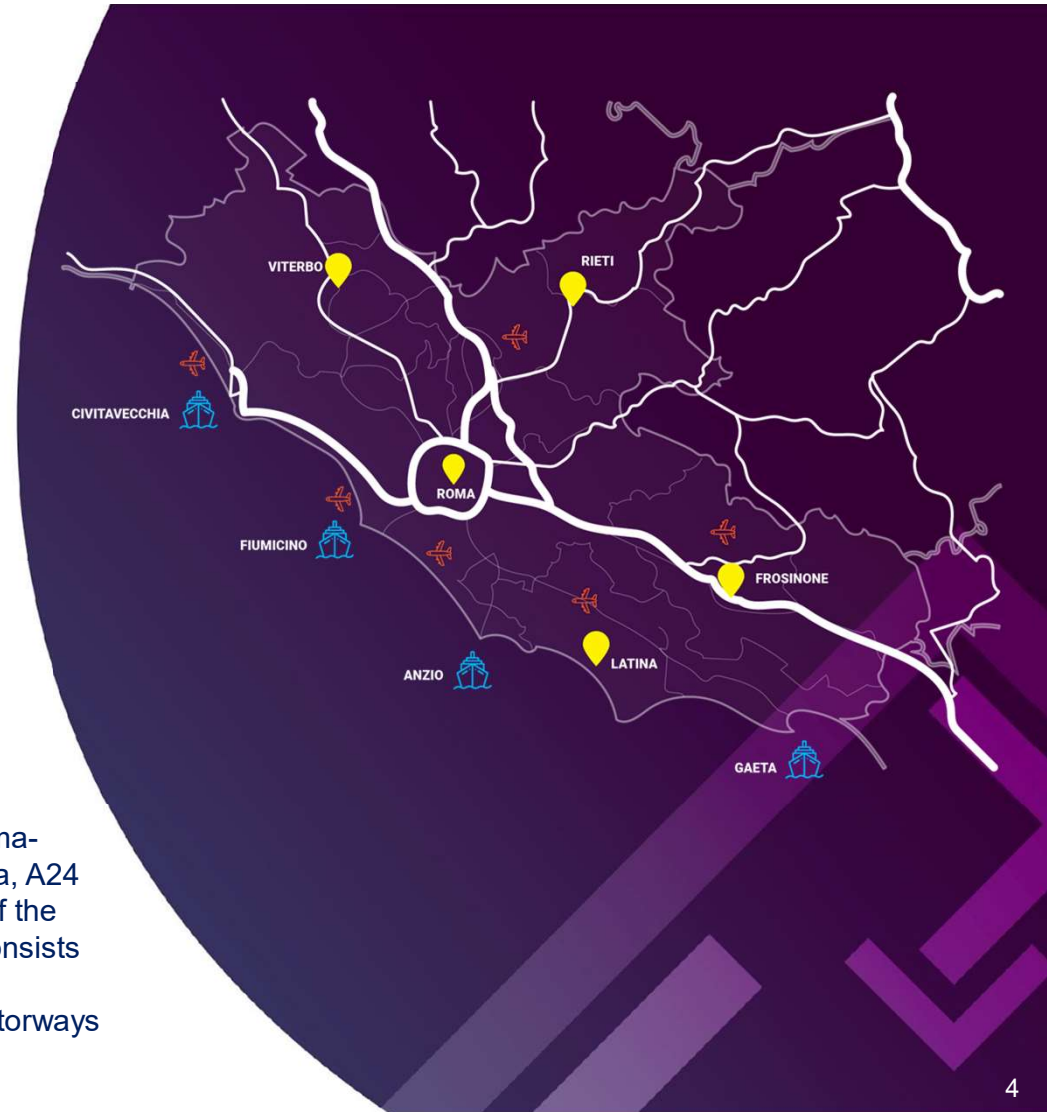
Civitavecchia Port is the major Italian touristic port, the 2nd in Europe and 7th in the world for number of passengers (3 million per year). Freight traffic is taking on increasingly an important role, boasting a movement of 10 million tons of goods a year.



2 main railway stations: **Termini** and **Tiburtina** which guarantee high speed rail connections with all major Italian and European cities. Lazio is part of the Trans-European Networks - Transport (TEN-T).



Main Highways: A1 Milano-Roma-Napoli, A12 Roma-Civitavecchia, A24 Roma-L'Aquila. The extension of the road network in Lazio Region consists of approximately 10 thousand kilometres, of which 473 are motorways and 553 national roads.



LAZIO AT A GLANCE

Lazio is the 2nd Italian Region for Gross Domestic Product (GDP) with **198 Bn euros**, contributing to **11,2% of Italian national GDP** (2018). It is one of the **most important R&D systems in Italy**.

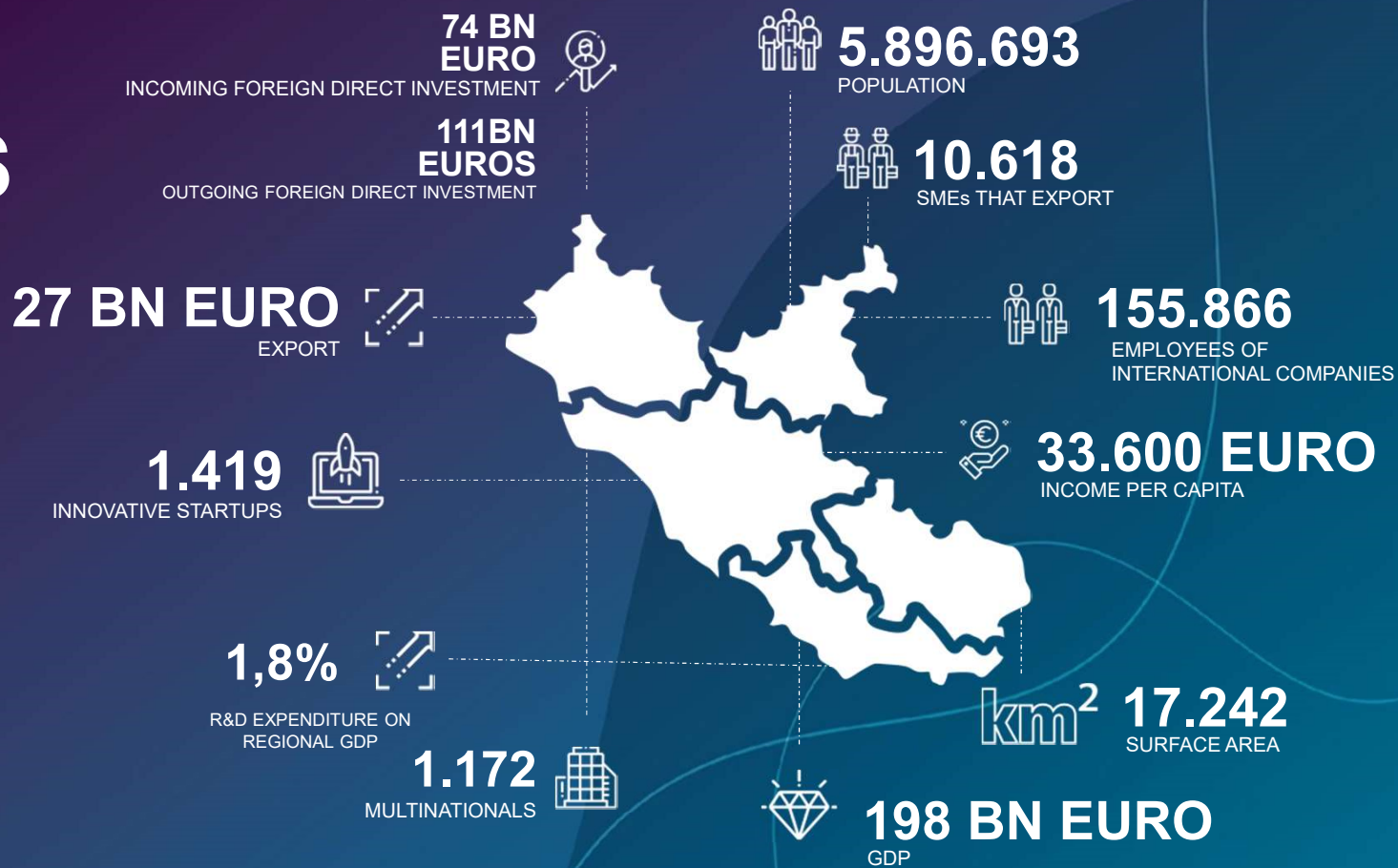
GDP per capita is equal to **€ 33.600**, above the Italian and the EU average. **Lazio is the sixth Italian Region** in terms of GDP per capita.

Lazio is the **location of important industrial and multinational groups with their own R&D centres**, and the Italian Region with the highest level of specialization in manufacturing and in high-tech knowledge intensive sectors.

Lazio's **share of exports in global leading sectors** is twice the national average (in percentage terms 72% vs 32%).



LAZIO KEY INDICATORS



ALL ROADS LEAD TO ROME

THE STRATEGIC ROLE OF ROME FOR THE ATTRACTIVENESS OF THE LAZIO REGION



TOURISM

Rome, with over **20** million **tourists a year**, is the most visited city in Italy and one of the most visited in the world.



VATICAN STATE

Rome is home to the Vatican State, with its own 85 diplomatic representations of the main countries, residence of the Pope and home to the Basilica of St. Peter, the Vatican Museums and the Sistine Chapel.



DIPLOMACY

Rome hosts 209 diplomatic missions (embassies, consulates, permanent missions and other diplomatic representations) according to Global Diplomacy Index 2019.



ROME AS A STRATEGIC HUB

2 International airports: Fiumicino and Ciampino. Fiumicino Airport is connected to Rome by the direct train "Leonardo Express". Travelling time: only 32 minutes, trains run every 15 min.



3 major railway stations: Termini, Tiburtina and Ostiense.
Head office of the important logistics center: CAR - the ROME AGRI-FOOD CENTRE (agroalimroma.it).

HEALTH EXCELLENCES



32 HOSPITAL



4 UNIVERSITY POLYCLINICS

8 IRCCS, i.e. **HOSPITALS OF EXCELLENCE** that pursue **research purposes**, mainly clinical and translational, in the biomedical field and in the organization and management of health services. Among them, the **INMI SPALLANZANI HOSPITAL** and the **IFO HOSPITAL**.

SISTEMA SANITARIO REGIONALE

IRCCS
ISTITUTI FISIOTERAPICI
OSPITALIERI

EBRI EUROPEAN BRAIN RESEARCH INSTITUTE

IRBM IRBM - "PIERO ANGELETTI" MOLECULAR BIOLOGY RESEARCH INSTITUTE



CENTRES OF EXCELLENCE IN THE FIELDS OF ONCOLOGY, NEUROSCIENCE, GENETIC THERAPY AND STEM CELLS

INTERNATIONAL ORGANISATIONS HEADQUARTERS BASED IN ROME



FOOD AND AGRICULTURAL ORGANISATION



INTERNATIONAL FUND FOR AGRICULTURAL DEVELOPMENT



WORLD FOOD PROGRAMME



INTERNATIONAL GENETIC RESOURCES INSTITUTE



INTERNATIONAL CENTRE FOR THE STUDY OF THE PRESERVATION AND RESTORATION OF CULTURAL HERITAGE

WHY CHOOSE TO INVEST IN LAZIO

GROWTH POTENTIAL

- Strong growth of exports in technological niches of excellence
- Presence of large companies, even multinationals, capable of stimulating SMEs' growth through innovative demand
- Significant growth, in quantity and quality, of incubators, accelerators and other organizations and initiatives to support startups

TERRITORIAL ATTRACTIVENESS

- Geopolitical position of global relevance
- High international attractiveness of the metropolitan area of Rome
- Presence of important industrial and multinational groups with their own R&D centers
- High number of public and private research infrastructures
- Strong presence of international organizations (i.e. FAO)
- High concentration of graduates in technical-scientific subjects and qualified researchers


THE REGIONAL KNOWLEDGE SYSTEM

LAZIO IS A TERRITORY RICH IN **HUMAN CAPITAL** AND IT IS AMONG THE FIRST ITALIAN REGIONS FOR NUMBER OF **RESEARCHERS**, **UNIVERSITIES** AND PUBLIC AND PRIVATE **RESEARCH INSTITUTIONS**. LAZIO IS ALSO ONE OF THE MOST SIGNIFICANT **RESEARCH CENTRE** IN EUROPE

8,000 
Professors and Researchers
in the Universities

6,000 
Other researchers

19 
Universities
• **6 Public**
• **7 Private**
• **6 Distance Learning Universities**









44,587 
Graduates
• **20.422 Female**
• **15.969 Male**

82,000 
Scholarships

25,905 
College freshmen

ACADEMIC HUMAN CAPITAL

GRADUATES (2019) AND STUDENTS (2019/2020)
IN **LIFE SCIENCES**-RELATED DISCIPLINES

UNIVERSITY COURSES	GRADUATES	STUDENTS
 PHARMACY AND INDUSTRIAL PHARMACY	364	4,060
 BIOTECH AND BIOTECH TRADES	410	2,103
 BIOLOGY	931	4,522
 BIOMEDICAL ENGINEERING	183	655
 MEDICINE AND DENTISTRY	1,503	11,312
 HEALTHCARE ASSISTANCE	3,532	13,856
 NUTRITION AND HEALTH SCIENCE	389	2,220
 CHEMISTRY AND CHEMISTRY TRADES	511	2,662



7,823

**GRADUATES IN LIFE SCIENCES -
RELATED DISCIPLINES**

41,390

**STUDENTS IN LIFE SCIENCES -
RELATED DISCIPLINES**

Source: MIUR (Ministry of Education University and Research)

SECTOR OF EXCELLENCE

LIFE SCIENCES

LAZIO PHARMACEUTICAL INDUSTRY IS AT THE TOP IN ITALY AND EUROPE FOR PRODUCTION EFFICIENCY

Lazio is the **2nd Italian hub** and one of the most important in Europe for the life sciences industry, with **RELEVANT** international players and highly innovative local SMEs **LINKED** with the **NATIONAL** public research network.



LAZIO HEALTH TECHNOLOGICAL CLUSTER (DTB) was established in 2008 and is one of the founding members of the Italian National Technological Cluster of Life Sciences **ALISEI**.

MAIN SPECIALIZATIONS

- Pharmaceutical innovative drugs
- New vaccines (one of the most effective anti-Ebola vaccines is from Lazio) and biomedical production
- Pre-clinical development of inhibitors for the treatment of solid cancers
- E-Health
- Medical devices.



9 BN €

ANNUAL TURNOVER



11.5 BN €

EXPORTS



+300

COMPANIES



22,000

EMPLOYEES



+10,000

RESEARCHERS



26

SPECIALIZED
RESEARCH CENTRES



8

UNIVERSITIES WITH
BIOMEDICINE DEPARTMENTS

SECTOR OF EXCELLENCE

A FOCUS ON BIOTECH

LAZIO IS THE SECOND REGION IN TERMS OF NUMBER OF BIOTECH COMPANIES AND TURNOVER IN ITALY. OVER THE LAST FIVE YEARS, LAZIO HAS RECORDED AN INCREASE IN ITS SHARE FROM 17% TO 21% IN TERMS OF INVESTMENTS IN BIOTECH

Over the last years, **BIOTECHNOLOGY** has expanded to include new and diverse sciences, such as GENOMICS, RECOMBINANT GENE techniques, applied IMMUNOLOGY, and development of PHARMACEUTICAL therapies and DIAGNOSTIC TESTS. It includes also the commitment to health to create **vaccines, such as that against Covid-19.**

THE BIOTECHNOLOGY INDUSTRY IN ITALY:

- a growing and research-intensive sector
- the growth trend continues for all the main indicators
- biotech is characterized as one of the main national science-based sectors
- biotechnologies are an innovative lever for the bioeconomy and sustainable economic development



63

BIOTECH COMPANIES
(ABOUT 10% OF THE
NATIONAL TOTAL)

26%



CONTRIBUTION TO
BIOTECH
TURNOVER



2.7 BN €

BIOTECH TURNOVER



1,975

BIOTECH
EMPLOYEES

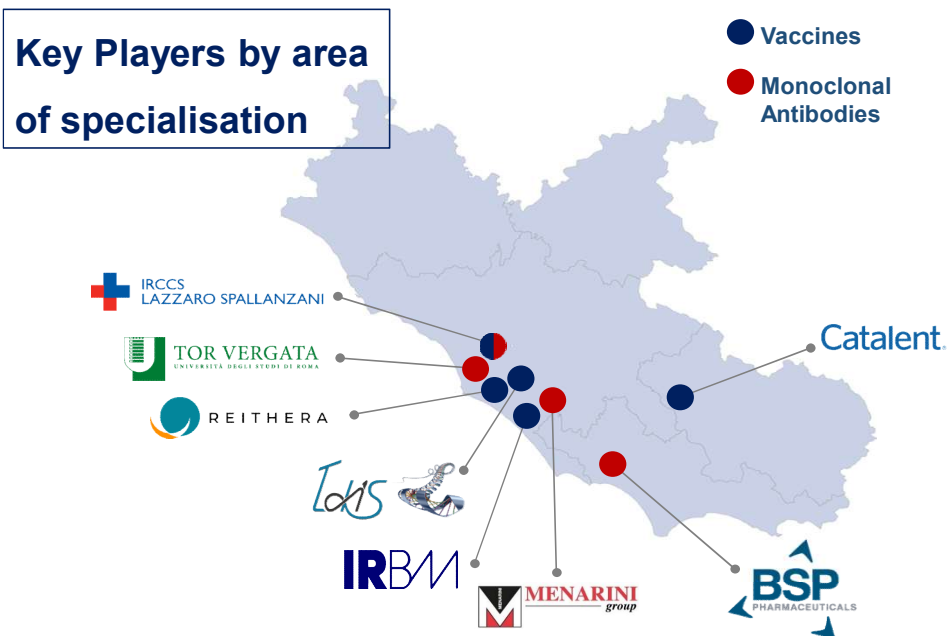


2,075

BIOTECH
RESEARCHERS

AT THE FOREFRONT OF THE COVID-19 RESPONSE

IN THE LAZIO REGION, WE FIND AN EXTREMELY HIGH CONCENTRATION OF NATIONAL AND INTERNATIONAL PLAYERS THAT HAVE IMPLEMENTED A SET OF INITIATIVES TO LEAD THE COVID-19 RESPONSE:



The **INMI Spallanzani Hospital** is an **international excellence** in terms of **clinical research**. In February 2020, it was among the first research institutes to **isolate the DNA sequence of the coronavirus**. Nowadays, the Spallanzani Institute is one of the **leading international centres in the COVID-19 response** – currently supporting the development of the Italian COVID-19 vaccines and monoclonal antibodies

COVID-19 VACCINES IN LAZIO



Biopharmaceutical company based in Castel Romano (Rome).

Reithera is developing and testing a **COVID-19 vaccine** (GRAd-COV2). In January 2021, the company signed the **Development Contract with Invitalia** to support an industrial and research investment of € 81 mln.

In March 2021 Reithera started the **Phase 2 of the clinical trials** along with the INMI Spallanzani Hospital (Rome).



IRBM of Pomezia (Rome) contributed to the development of the **AstraZeneca and University of Oxford COVID-19 vaccine** as a research partner.

Catalent, the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, consumer health products, **is taking care of the bottling of the AstraZeneca's as well as Johnson & Johnson's COVID-19 vaccines** in its production site in Anagni.

The Anagni **Catalent** plant **currently produces 1.5 mln dosis of AstraZeneca vaccine per day**



Takis Biotech is a **biotechnology company** based in **Rome**, with over 10 years of experience in drug discovery.

In partnership with Rottapharm Biotech, Takis is developing the second Italian COVID-19 vaccine (Covid-eVax).

In March 2021, the company **started the Phase 1 of the clinical trials.**



REGIONE
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COVID-19 MONOCLONAL ANTIBODIES IN LAZIO



Founded in 2006, **BSP Pharmaceuticals** is based in **Latina**, **60 km from Rome**.

Since the end of 2020, BSP Pharmaceuticals has been producing monoclonal antibodies created by the US-company **Eli Lilly's** and approved **AIFA – the Italian Drug Agency**.

In 2021, it is expected that the pharma company will also **supply the Italian market with Lilly's antibodies**.



Tor Vergata Universities Laboratories have been studying **monoclonal antibodies** for months, biological products capable of preventing the virus from entering host cells and preventing their replication.

The Lazio Region has chosen to focus on the **new technique** developed in Tor Vergata, which uses **synthetic antibodies, potentially able to adapt to virus mutations**.

In October 2020, **Lazio Region and Tor Vergata Universities** have signed a **MoU** to support with 2 million euros "research and experimentation for the development of a drug capable of treating Covid-19 patients in as short as possible". Project partners are INMI Spallanzani Hospital (Rome) and Toronto (Canada).



Partnering with **Tuscany Life Sciences Foundation** on the **MabCo19 project**, which aims at developing producing monoclonal antibodies against the COVID-19.

Menarini's **biotech plant in Pomezia** (Rome) started the production of the new drug, which consists of a mixture of **monoclonal antibodies that neutralise the SARS-CoV-2 spike protein**.



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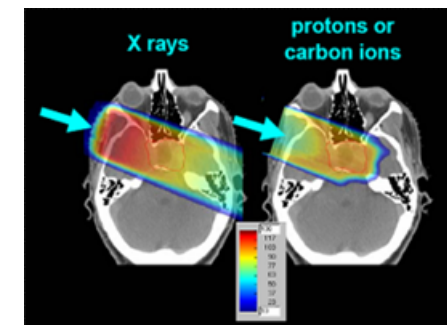
BEST PRACTICE

TOP IMPLART – ONCOLOGICAL THERAPY WITH PROTONS

PARTICLE ACCELERATORS AND MEDICAL APPLICATIONS LABORATORY



ITALIAN NATIONAL AGENCY FOR NEW TECHNOLOGIES,
ENERGY AND SUSTAINABLE ECONOMIC DEVELOPMENT



The accelerator group of the ENEA Frascati Research Centre is part of the FSN-TECFIS-APAM Laboratory, which develops particle accelerators for medical, industrial and research applications.

The aim of **TOP-IMPLART PROJECT**, developed by the **ENEA FRASCATI RESEARCH CENTER** (about 20 km from Rome), **ISS - Italian National Institute of Health** and **IFO - Regina Elena National Cancer Institute of Rome**, is to develop a **PROTON THERAPY CENTER** based on a sequence of linear accelerators and designed with three treatment rooms: one with a 150 MeV beam for superficial tumors and two with a 230 MeV beam for deep tumors.

The energy of 150 MeV (corresponding to a penetration in tissue of about 15 cm) is a milestone in design being useful for the proton therapy treatment of almost 50% of tumors based on their position and depth (including ocular melanoma, head-neck tumors, pediatric tumors, and more superficial tumors).

The program was funded by the Lazio Region. The activities have started in 2013 and the deadline of the agreement is currently February 2022.

<http://www.frascati.enea.it/accelerators/Sito/index.htm>

Castel Romano Technology Park TECNOPOLO SpA



BUSINESS ENVIRONMENT

THE CASTEL ROMANO TECHNOLOGY PARK IS ONE THE **MAIN ITALIAN CENTERS FOR APPLIED RESEARCH AND A FIRST-CLASS LOCATION FOR BUSINESS**, IT IS CONNECTED TO THE MOST QUALIFIED NATIONAL AND INTERNATIONAL PARTNERS FOCUSED ON **HEALTH AND LIFE SCIENCES**. IT IS **PART OF TECNOPOLO S.P.A.**, A PUBLIC COMPANY CREATED IN 1995 WITH THE AIM TO PROMOTE AND IMPROVE THE LOCATION AND DEVELOPMENT OF HIGH-TECH AND INNOVATIVE INITIATIVES

- PRESENCE OF KEY PLAYERS OF THE LIFE SCIENCES INDUSTRY
- INNOVATIVE INFRASTRUCTURES AND SERVICES
- STRONG LINKS WITH UNIVERSITIES AND RESEARCH
- MAIN AREAS OF EXPERTISE: ADVANCED MANUFACTURING, LIFE SCIENCES, NEW MATERIALS, GREEN ECONOMY



52

HECTARES



400

PEOPLE INVOLVED

COMPANIES AND RESEARCH CENTER

- NOUSCOM S.R.L.
- ALLEVAMENTI PLAISANT S.R.L.
- REITHERA S.R.L.
- TAKIS S.R.L.
- TESTING POINT 5 S.R.L.
- I.S.P.R.A. - ISTITUTO SUPERIORE PER LA PROTEZIONE E LA RICERCA AMBIENTALE

C.H.I.CO – Cluster of Health Innovation and Community

www.clusterchico.eu

C.H.I.CO IS THE FIRST **HEALTH CLUSTER** CREATED IN THE LAZIO REGION. IT IS MADE UP OF 150 PRIVATE AND PUBLIC ENTITIES (COMPANIES, UNIVERSITIES, RESEARCH CENTRES AND HOSPITALS) WITH THE AIM TO DEVELOP **INNOVATIVE PROJECTS IN THE FIELD OF HEALTH AND WELLNESS**.

MAIN ACTIVITIES

- It supports the development of projects and partnerships thanks to its dynamic ecosystem
- It contributes to direct national strategies on the subject of Life Sciences
- It promotes synergy between **INDUSTRY** and **RESEARCH**
- It develops partnerships in the field of technology transfer and industrial cooperation
- It promotes the technological innovation of the production system, promoting the creation of start-ups and spin-offs
- **CHICO SINERGY**: matchmaking and networking tool - for the exclusive use of members - to promote and enhance innovative projects <http://www.clusterchico-synergy.eu/>
- **LIFESEEDER**: first equity crowdfunding platform dedicated to all those who wish to invest in Life Sciences <http://www.lifeseeder.com>

 **7 BN €**

REVENUES FROM THE NETWORK

 **1,500**

PEOPLE INVOLVED

 **150**

PARTNERS

BUSINESS ENVIRONMENT



PARTNER C.H.I.CO



BUSINESS ENVIRONMENT

BUSINESS ENVIRONMENT

BIG INTERNATIONAL PLAYERS



BUSINESS ENVIRONMENT

R&D Network



Agenzia nazionale per le nuove tecnologie,
l'energia e lo sviluppo economico sostenibile



Agenzia
Spaziale
Italiana



National Institute for
Astrophysics



National Institute of
Geophysics and
Volcanology



Italian Institute for
Environmental Protection



Consiglio Nazionale delle Ricerche



Istituto Nazionale
di Alta Matematica



ISTITUTO NAZIONALE
DI GEOFISICA E VULCANOLOGIA



Istituto Nazionale di Fisica Nucleare



Bambino Gesù
FONDAZIONE



Consiglio per la ricerca in agricoltura
e l'analisi dell'economia agraria



International Center for Relativistic Astrophysics



MUSEO
STORICO DELLA FISICA
E
CENTRO
STUDI E RICERCHE
ENRICO FERMI



SANTA LUCIA
NEUROSCIENZE
E RIABILITAZIONE



REGIONE
LAZIO

LAZIO BUSINESS OPPORTUNITIES

BIO DIGITAL 2021

TAKIS COVID- eVax: a vaccine against COVID-19 based on DNA Electroporation

REITHERA GRAd-COV2 vaccine against Covid-19 Pandemic

TAKIS: COVID- eVax

A vaccine against COVID-19 based on DNA Electroporation

DESCRIPTION

COVID-eVax is a vaccine against COVID-19 based on a DNA plasmid encoding a portion of the Spike protein (called RBD), present on SARS-CoV-2 surface and key for viral infectivity. COVID-eVax is a “precision medicine vaccine” approach designed to induce a strong immune response while minimizing potential undesired effects.

Field of activity and technology

Biotechnology/genetic Vaccines

Development stage

Phase 1-2 Clinical trial

Capital raised

NA - In partnership with Rottapharm Biotech

Proposer

Takis srl, Red Biotech

Area of activity

Genetic Vaccines, Epidemic Preparedness



TAKIS BUSINESS PROPOSAL

COVID-eVax was **validated in pre-clinical settings** with support of the National Institute for Infectious Diseases (INMI) Spallanzani in Italy and Ulm University in Germany, confirming that the animals' sera were able to block the infectivity of the virus in vitro on cells and protect animals from SARS-CoV2 infection. **The vaccine can protect from viral variants as well.**

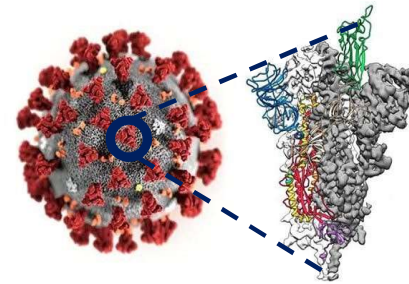
The first-patient-in for the Phase I part of the protocol was vaccinated on March 1st 2021. Data enabling the start of the Phase II part of the study are foreseen for August 2021. Phase III enabling data are foreseen to be available by the fall of 2021.

Next milestones are:

- Late stage clinical trial (Phase III) (3Q21)
- Large-scale GMP manufacturing (1Q22)
- Scale-up plant/manufacturing for EGT gun disposable and new electric pulse generator (4Q21)
- EMA (or other) authorization and commercial approval (1Q22)

Requested investment **150 M€**

Target investor **Corporate Venture Capital or Big Pharma**



ReiThera: GRAd-COV2 Vaccine

against Covid 19 Pandemic

DESCRIPTION: ReiThera is a biotech company dedicated to the development, GMP manufacturing and clinical translation of genetic vaccines and medicinal products for advanced therapies. The company has a long-standing expertise in the development of scalable processes for viral vector manufacturing, supported by a cGMP facility inclusive of filling suite and quality control laboratories.

ReiThera has recently developed a candidate vaccine against SARS-CoV-2 (GRAd-COV2) based on a novel and proprietary replication-defective simian (gorilla) adenoviral vector called GRAd encoding the full-length coronavirus spike protein. The vaccine was tested into a phase I clinical trial involving 90 Healthy Volunteers including Adult and Elderly. In the study the vaccine has demonstrated to be safe and well tolerated in all the dosage tested.

In this context, REI has strongly invested in its CDMO organization by expanding the existing GMP area and by acquiring state-of-the-art technologies including stirred-tank bioreactors supporting a working volume at the scale of 200L, 1000L and 2000L. Based on the productivity of the GRAd-COV2 vector and the scale of the manufacturing process (3000L), a monthly production of various million doses of vaccine will be possible.

ReiThera's vaccine is currently under investigation in a phase II, double blinded, placebo controlled clinical trial. In the trial, the Healthy Volunteers will be treated with a single or double dose of the vaccine. Interim analysis is planned in mid-May

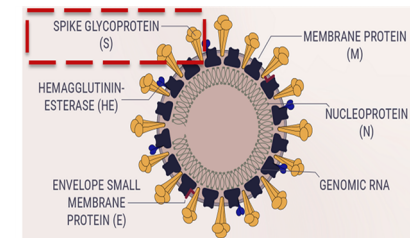
Phase III trial is planned to start in mid June in order to the vaccine ready for CMA submission in Autumn 2021

Proposer

ReiThera - Claudio Panzarella, Head of Business Development

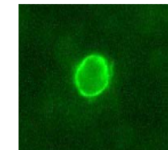
Area of activity

Vaccine against Covid 19 virus



✓ The vaccine antigen is the **prefusion stabilized full length Spike protein*** (K986P, V987P)

✓ Upon infection of cells with GRAd-COV2 the Spike protein is correctly displayed on the cell membrane



mAbαS2-staining

*Palllesen J et al. PNAS 2017

REITHERA BUSINESS PROPOSAL

ReiThera's vaccine is in the late registration and the current results support a safe and efficacious profile.

ReiThera is looking for a strategic support for completing the product registration and then the for market consolidation.

Considering that:

- The global market is only minimally covered by the vaccines approved.
- Despite ReiThera's vaccine is still in phase II, any investment is de-risked since the registration (CMA) will be at short term (Autumn 2021)
- Competitor with similar vaccines have been already registered successfully
- Follow On vaccines based in the same technology platform are already under development (ie. Covid 19 variants)
- Easy manufacturing Technology Transfer and expansion based on disposable technology only

ReiThera's vaccine represents a valid opportunity for investment with a fast payback

Requested investment **50-100M€**

Target investor *A potential partner with an operational infrastructure in place would be welcome*

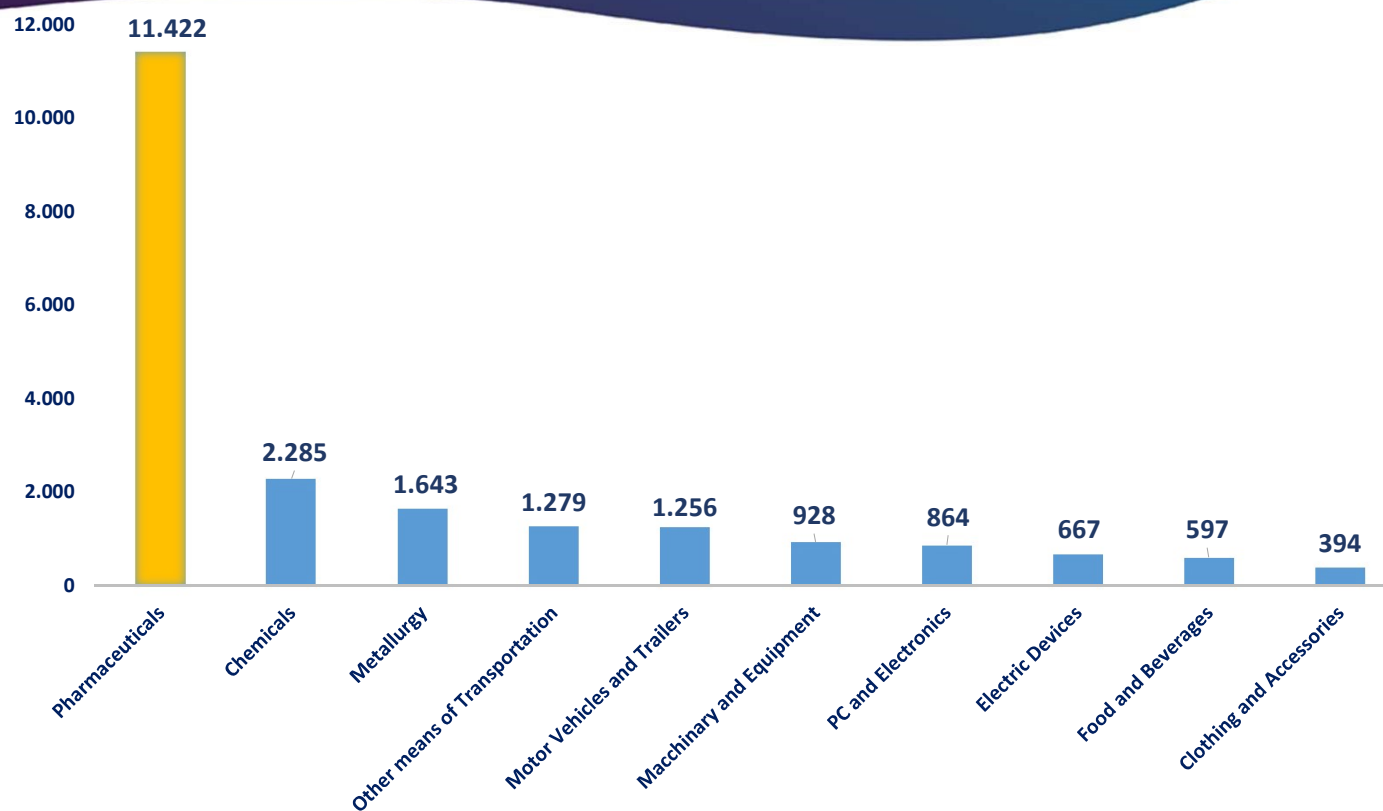


LAZIO EXPORT DATA 2020

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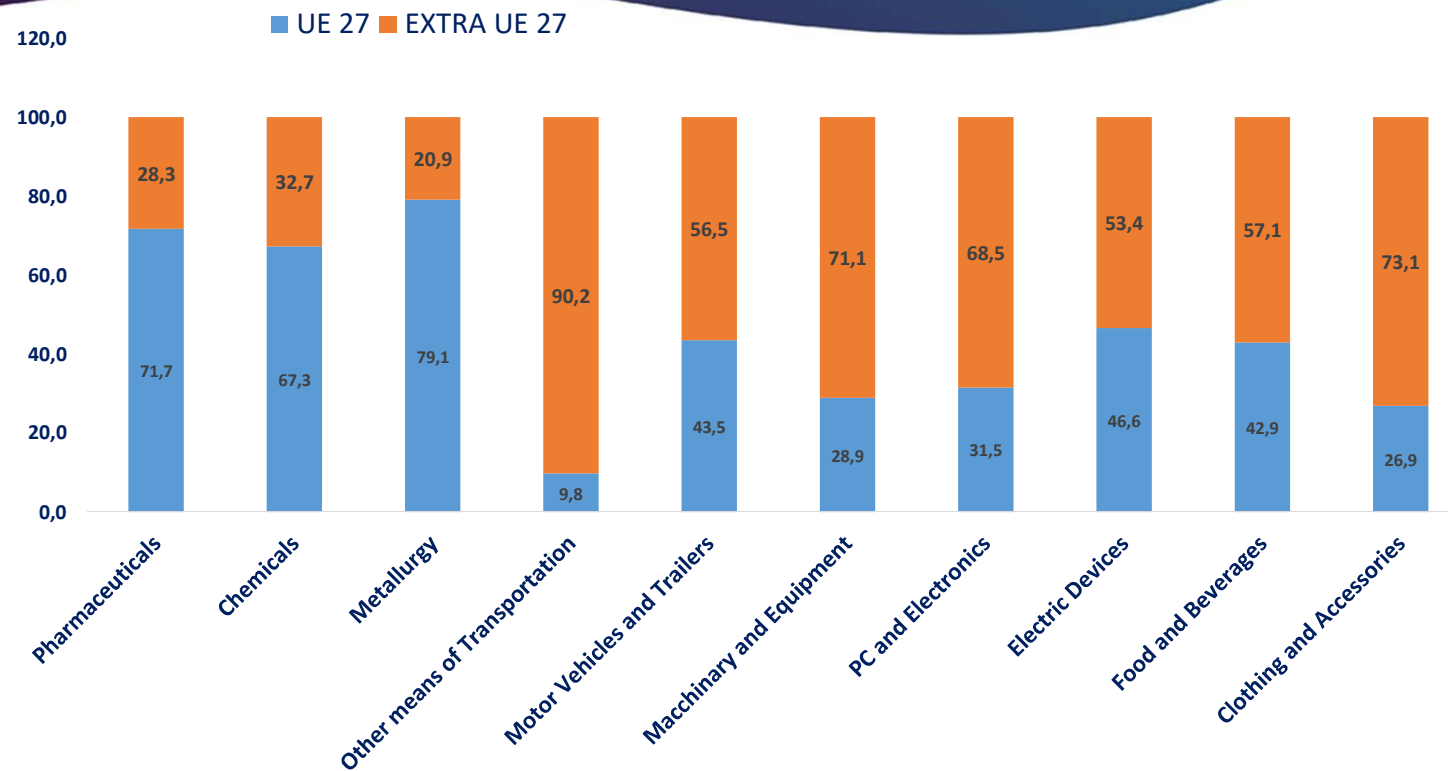
TOP 10 EXPORT GOODS OF LAZIO REGION

2020 – MLN €



GOODS DESTINATION

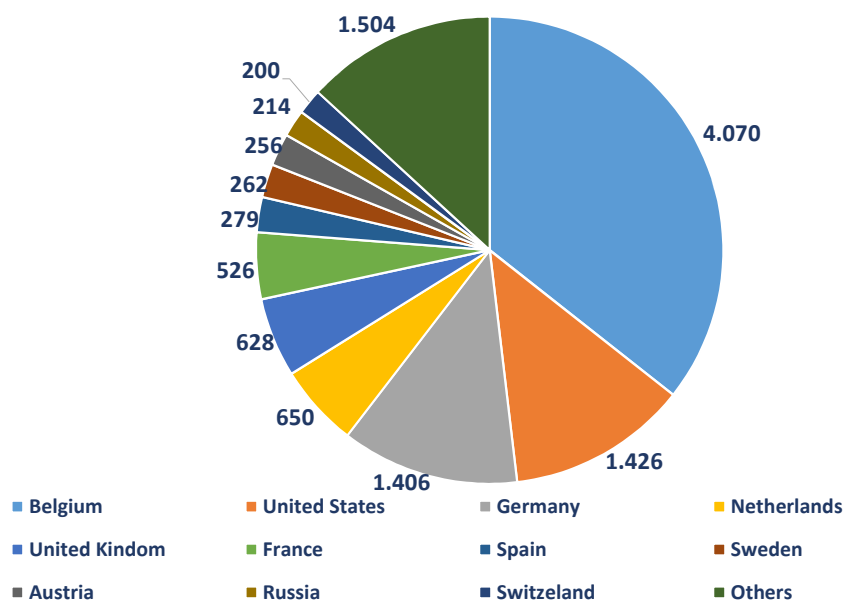
UE/EXTRA UE – LAZIO REGION % - 2020



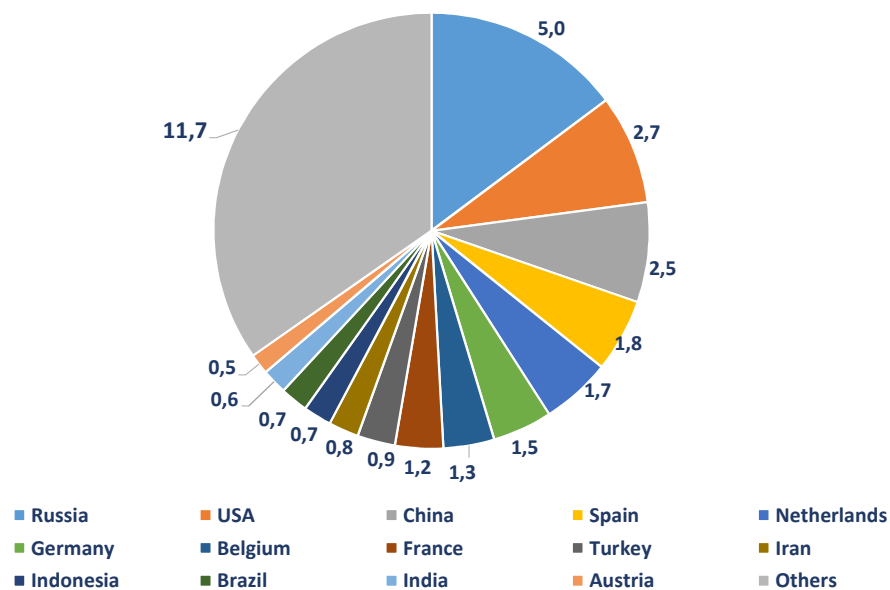
LAZIO REGION MAIN EXPORT PARTNERS FOR DRUGS & MEDICAL DEVICES

2020 - MLN €

Pharmaceutical Exports by Country



Medical Device Exports by Country



Contact us

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COMMUNITY OF INNOVATORS 

Life Sciences: <https://www.linkedin.com/groups/8846745/>

Updated to April 2021

