INVEST IN ITALY

ITA ITALIAN TRADE AGENCY

Ministero degli Affari Esteri e della Cooperazione Internazionale

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BIO International Convention 2024

June 3-6, 2024 · San Diego Convention Center – San Diego, CA

Precision and Molecular Medicine Excellence Hub

for advanced healthcare and therapeutics

Cluster lombardo scienze della vita

Cluster lombardo scienze della vita

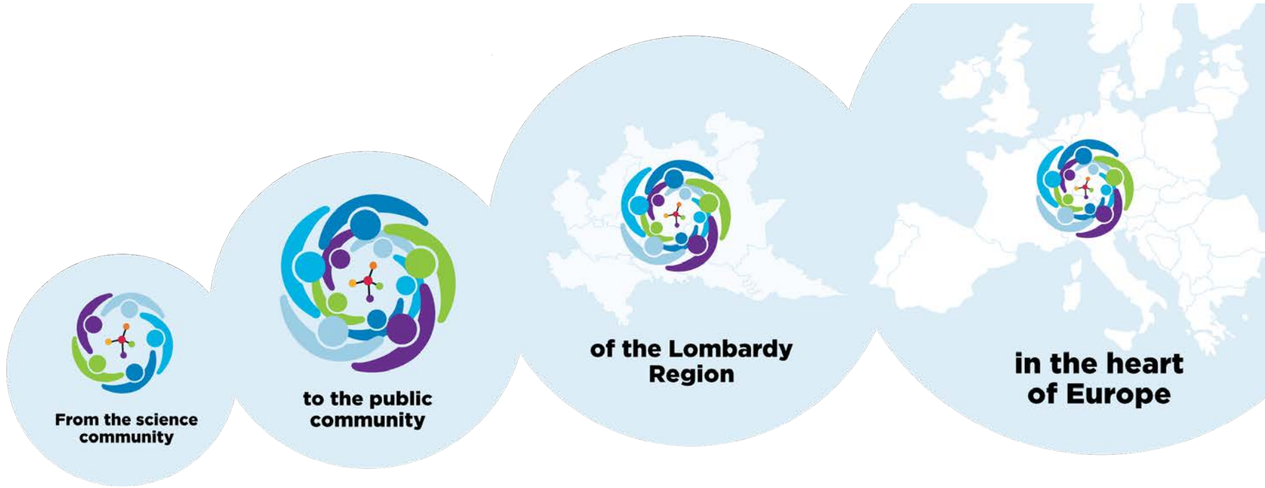
DESCRIPTION Cluster Lombardo scienze della vita is the community dedicated to life science in the Lombardy Region. As a non-profit association, it brings together all public and private entities - research, industry and clinics - active in every sector of the life science space. It embodies +100 member organizations and connects a network of +800 Life Science companies in the Lombardy Region.

Field of activity and technology

Creation of a virtuous ecosystem

Cluster lombardo scienze della vita works to foster connections and synergies, also at the international level, to generate innovation in the life science sector and to improve the lives of all citizens.
The main scopes of action are:

- **Research and open innovation** → The Cluster encourages the development of R&I skills in the Lombardy ecosystem, to promote Lombardy as a hub of excellence for research and innovation, by fostering technology transfer process and collaboration between business and research;
- **Networking & community sharing** → The Cluster facilitates the exchange of knowledge and know-how on R&I, strengthening the development of the life science community in Lombardy, in connection with Italian and European partners;
- **Visibility and representation** → The Cluster increases the visibility of the Lombardy value chain, both in the national and international scene. It daily contacts with Regional and National Governments, also in defining strategic trends at regional, national and EU level.



Precision and Molecular Medicine Excellence Hub

for advanced healthcare and therapeutics

DESCRIPTION The project aims at presenting to BIO the Precision and Molecular medicine supply chain, showcasing projects and initiatives, from both the public and private sectors, that stand as examples of excellence in this field in Lombardy.

In this regard, cutting-edge projects and collaboration opportunities with some of the largest centers of basic, translational and applied research, as well as business entities open to partnerships and joint ventures, are presented.

This ecosystem will be receptive to the possibility to engage with other entities at BIO and to contribute to the arrangement of internal and external meetings during the event, fostering connections and collaboration opportunities between the United States and Italy, with a focus on Lombardy, thanks to the collaboration with local partners such as Assolombarda, Milano&Partners, Invest in Lombardy.

Proposer *Cluster lombardo scienze della vita*

Requested investment *Defined for each of the following projects developed by Cluster members*

Precision and Molecular Medicine Excellence Hub

for advanced healthcare and therapeutics

Cluster lombardo scienze della vita

PROJECT MEMBERS

AdvicePharma
BIOREP
CENTRODIAGNOSTICOITALIANO CDI LIFE FROM INSIDE
CNAO Centro Nazionale di Adroterapia Oncologica
Dompé
Fondazione IRCCS Istituto Nazionale dei Tumori
Sistema Socio Sanitario Regione Lombardia
HUMANITAS RESEARCH HOSPITAL
IEO Istituto Europeo di Oncologia
INGM ISTITUTO NAZIONALE GENETICA MOLECOLARE "Romeo ed Enrica Invernizzi"
I.R.C.C.S. Ospedale San Raffaele Gruppo San Donato
UNIVERSITÀ DEGLI STUDI DI MILANO
UNIVERSITÀ DEGLI STUDI DI MILANO BICOCCA

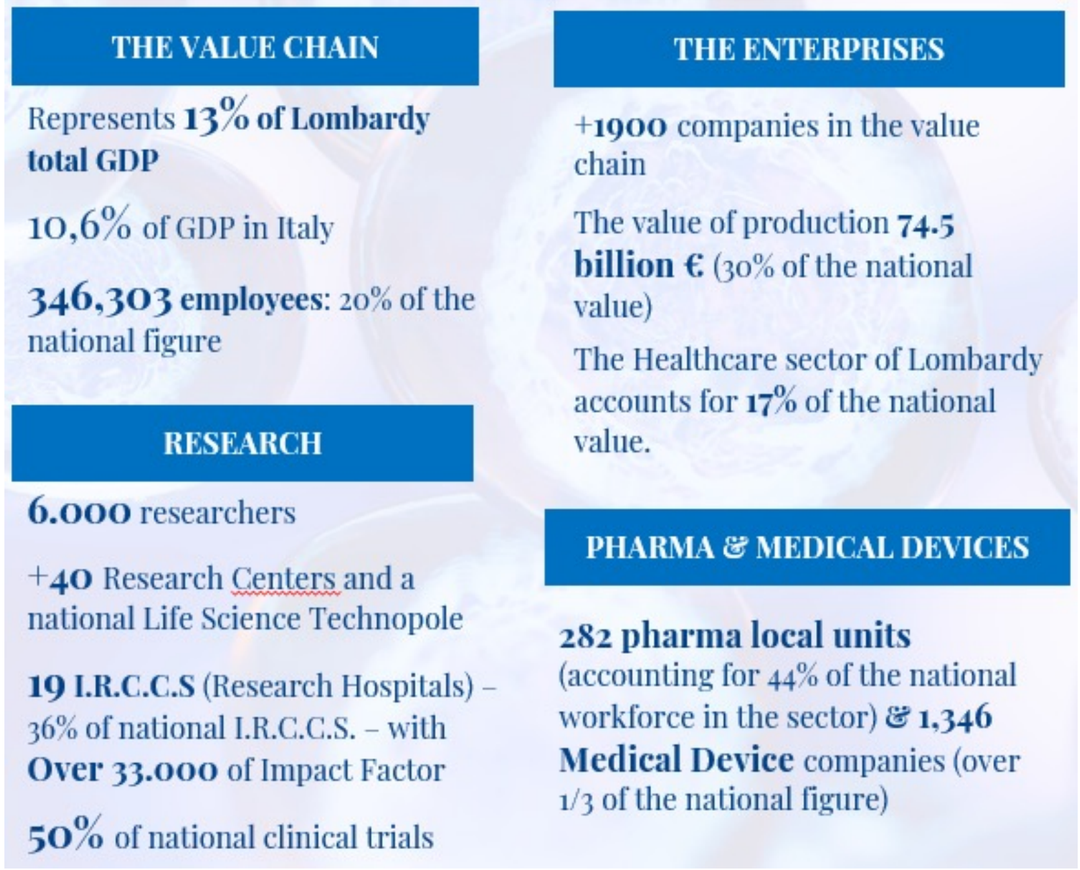
Mapping Areas of Excellence

Lombardy Life Sciences ecosystem generates over 13% of the regional GDP, representing over 1/3 of the national industry value. In this territory a large number of private and public organizations cooperate together fostering research, innovation and advanced healthcare. From precision to molecular medicine, many organizations are currently working for advancing therapeutics, diagnostics, and care.

Lombardy hosts 19 Research Hospitals (the so called I.R.C.C.S.), representing a total of **36% of the national I.R.C.C.S. in Italy**, with an **aggregate impact factor of over 33.000**. Results of such a strength include, amongst many, the achievement of having **over 6 certified centers for the development and administration of CAR-T therapy** and, through our region's research and application capabilities, constant **achievements of pioneering in the realm of advanced therapies.**

Consolidating our **strategic centrality** in the field of healthcare and medical R&D, Lombardy has the first National Center for basic Life Sciences research (Human Technopole) as well as 4 universities which are part of the National Center for the development of gene therapy and drugs with RNA technology, thus **making us a strategic center for foreign investors wishing to enter the Italian market.**

Value of Lombardy Life Sciences



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Exscalate: Advancing Pharmacogenomics Through AI and High Performance Computing

Dompé

Dompè contact person:
Andrea Beccari
VP Drug Discovery Escalate
andrea.beccari@dompe.com

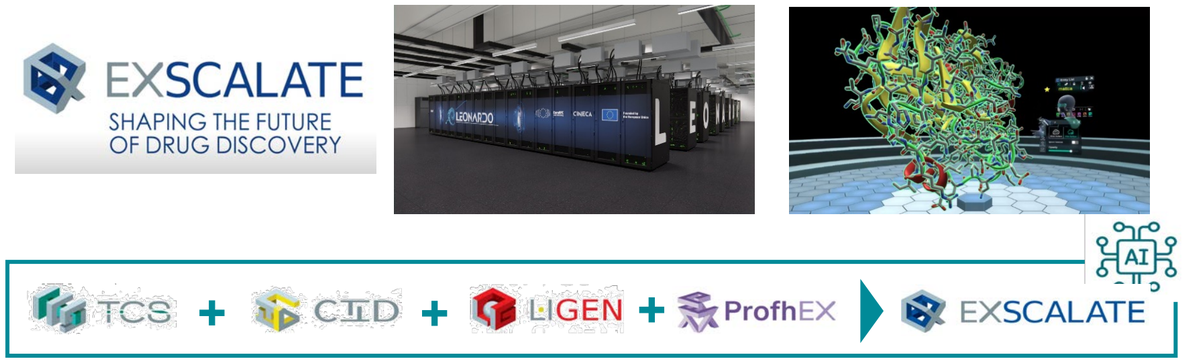
Exscalate: Advancing Pharmacogenomics

DESCRIPTION & Field of activity and technology

- **EXSCALATE** is a drug discovery platform stemmed from Dompé farmaceutici experience in the design of allosteric modulators for complex biological targets (https://exscalate.com/). A powerful computational AI and HPC-based tool, empowered by strategic partnerships with Leonardo (CINECA) supercomputer to develop innovative and proprietary AI algorithms (*structure-based virtual screening, docking simulations, poly-pharmacology predictions*).
- Impactful PoCs achieved and **breakthrough findings** discovered in a contest of open innovation in collaboration with Institutions (e.g. EU Commission) and Biopharma companies.
- Huge potential to **address unmet needs in precision medicine.**

Development stage: Advanced

Capital raised: Funded by Dompé Farmaceutici S.p.A.

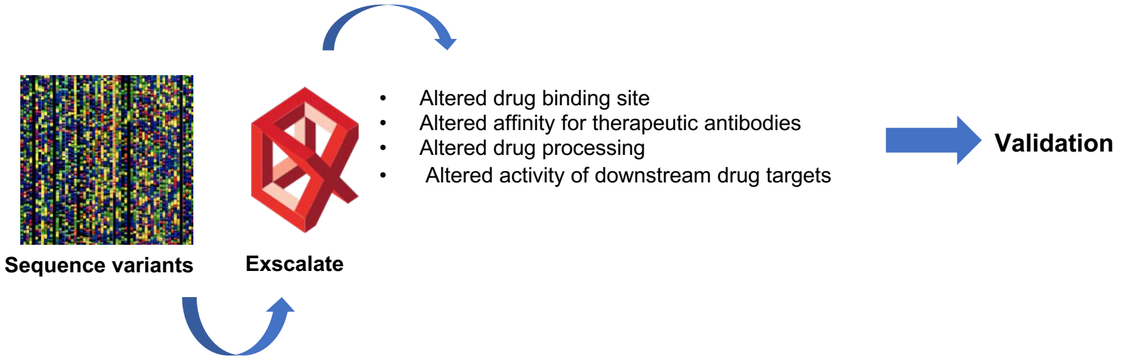


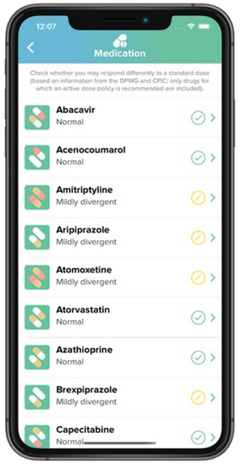
Proposer *Dompé Farmaceutici S.p.A.*

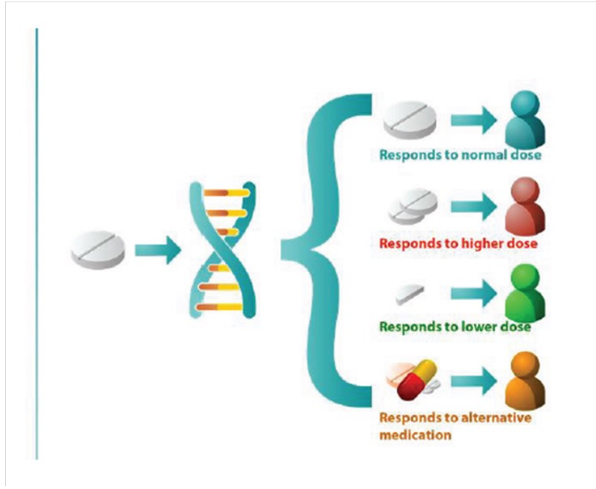
Exscalate: Advancing Pharmacogenomics

BUSINESS PROPOSAL

- The Exscalate approach allows to predict drug efficacy on mutations in several fields, including oncology. If a genetic mutation makes a drug inactive, **the Exscalate Suite allows to identify new molecules** effective on the mutated protein.
- **Strenghts:** Exscalate traces a **polypharmacological profile** of adverse events and significant liabilities. The Suite creates a heatmap to highlight the regions exposed to greatest vulnerability, by providing a list of the drugs taken by the patient.
- **Key advantages**: **1)** Improve predictive pharmacogenomics for the patient and doctor; **2)** Integrate structural information to explain and predict the effects of gene variants; **3)** Achieve and launch a new product for patients within 2 years of the project starting.







Requested investment *€ 500,000 – 1,000,000*

Target investor *Institutions or private companies focused on technological tool development for personalized medicine*

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Molecular tumor board portal

Fondazione IRCCS Istituto Nazionale dei Tumori

Sistema Socio Sanitario

Regione Lombardia

Fondazione IRCCS Istituto Nazionale dei Tumori

DESCRIPTION

Thanks to the efforts of its 2,175 people –of whom over 650 are devoted to research– and to its 27 Laboratories, Fondazione IRCCS Istituto Nazionale dei Tumori is a Comprehensive Cancer Center approved by OECI, a center of excellence for pre-clinical, translational, clinical-public health and organizational-management research activities. INT is a national and international reference center for both high-incidence and rare and pediatric cancers. The strong attention to technological innovation –which allows cutting-edge diagnostic and therapeutic services, capable of ensuring increasingly accurate and early diagnoses and personalized treatments– is one of the factors that helps the Institute playing a prestigious role in today's healthcare landscape, by being the foremost oncology center in Lombardy and in Italy, the leading pediatric oncology center in Italy (and among the first in Europe), as well as the only Italian cancer center to be authorized for liver transplantation.

Molecular tumor board portal

DESCRIPTION

The Molecular tumor board portal is an academic clinical decision support system developed under the umbrella of Cancer Core Europe, that creates a unified legal, scientific and technological platform to share and harness next-generation sequencing data, by collecting, organizing and analyzing the results of genomic analyses of tumors from patients. The adoption of an expert-agreed process to systematically link tumor molecular profiles with clinical actions promotes consistent decision-making and structured data capture across the connected centers.

The MTBP at INT was formalized in February 2020 and it consists of a core team composed of twelve professionals from various disciplines, particularly pathologists, molecular biologists, bioinformaticians, oncologists, geneticists, and pharmacists.

It is led by Professors Giacarlo Pruneri and Filippo De Braud and coordinated by Dr. Andrea Vingiani, a medical manager in the Department of Pathological Anatomy and Laboratory Medicine at INT.

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Combined Treatment for Primary Central Nervous System Lymphoma

I.R.C.C.S. Ospedale San Raffaele

Gruppo San Donato

Combined Treatment for Primary Central Nervous System Lymphoma

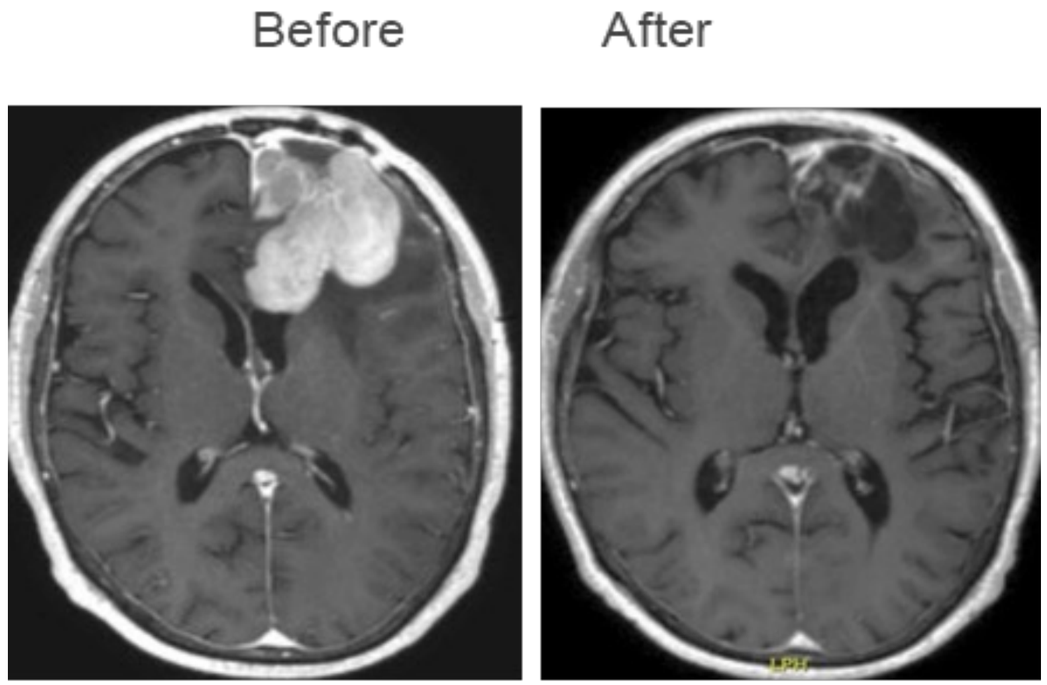
DESCRIPTION

Primary diffuse large B-cell lymphoma of the central nervous system (PCNSL) is a rare and highly aggressive neoplasm. Treatment of PCNSL consists of combinations of a few drugs able to penetrate the CNS tissues, which must be delivered at high dose, requiring hospitalization, with a consequent higher risk of toxicity. R-CHOP is the standard treatment of diffuse large B-cell lymphomas diagnosed in other organs, resulting in high cure rates. However, R-CHOP drugs exhibit a low capability to cross the BBTB, which results in an insignificant therapeutic effect on PCNSL.

Field of activity and technology
NGR-TNF consists of human TNF fused to the CNGRCG (NGR), a peptide ligand of a CD13 isoform overexpressed in tumor vasculature.
Clinical grade NGR-TNF has been produced and used in 18 clinical studies involving >1000 patients with different indications. However, the molecular heterogeneity of NGR-TNF was considered a major obstacle for lot-to-lot consistency.

Development stage - the first asset (NGR-TNF) has succesfully completed a phase II clinical trial in PCNSL. The second asset (sNGR-TNF) is in the discovery phase.

Capital raised - The program has been succesfully funded through various forms of financing and grants, all awarded to OSR's researchers.

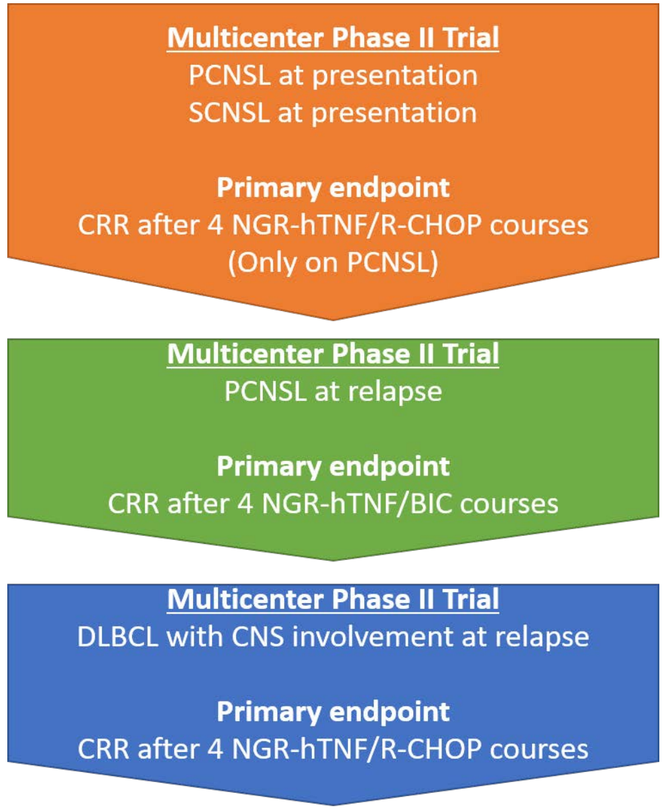


Proposer *Ospedale San Raffaele, Milan, Italy*

Combined Treatment for Primary Central Nervous System Lymphoma

BUSINESS PROPOSAL

S-NGR-TNF is a novel drug with long patent protection ahead, but already de-risked by preclinical and clinical safety and efficacy data of its closely-related old version (NGR-TNF).
Outstanding clinical results have already been obtained with NGR-TNF in a difficult and highly unmet medical need, such as relapsing/refractory PCNSL.
The peculiar combination of expertise in drug development and patient management at the San Raffaele Institute may allow rapid translation of the new drug to the clinic.
Notably, in the INGRID trial, 28 patients with relapsed/refractory PCNSL were enrolled in less than two years.
The proposed approach has potential application (permeabilization of the BBB) in other primary and secondary tumors of the CNS.
San Raffaele is seeking an industrial partner or investor to pursue rapid preclinical and clinical development of the two forms of NGR-TNF combination with R-CHOP for PCNSL as first-line treatment, and associated with other chemotherapy regimens as salvage treatment, and, eventually, in other primary and secondary CNS tumors.



Requested investment *We are looking to further fund the clinical validation and expand the treatment to other indications; we estimate € 12,000,000-15,000,000 to reach the market.*

Target investor *VC focused on early stage developments*

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Humanitas Research Hospital

HUMANITAS

Universal Peptide Vaccine

DESCRIPTION

A **novel immunotherapeutic strategy** based on immunogenic peptides released by cancer cells and used as a **tumor-type specific vaccine**, with focus on **Melanoma** and **Sarcoma**. This solution addresses the need for an improving cancer-targeted immunotherapy approach suitable for clinical application across a broad patient population and exhibiting at the same time reduced adverse side effects, without inducing autoimmunity reactions.

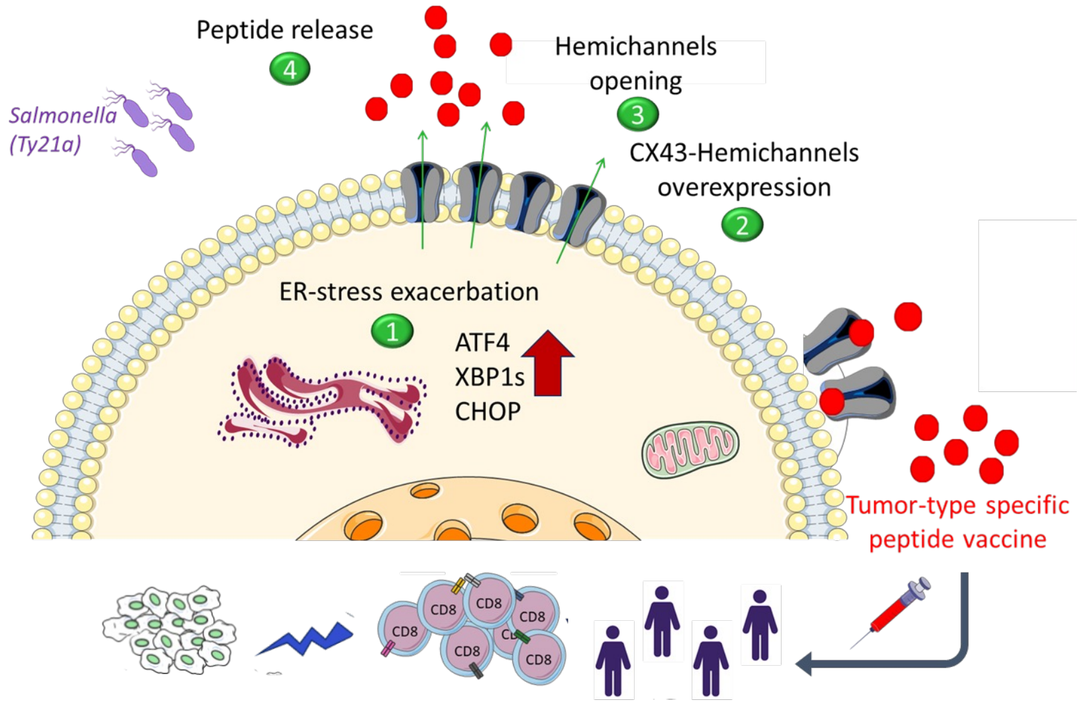
This strategy for Melanoma patient is based on a combination of an anti-PD-1 inhibitor and a vaccination with the identified Melanoma specific peptides. The **IP position and strategy** include the “Tumor-associated peptides and uses thereof” patent family (Publication n°: WO2022008634).

Field of activity and technology

Tumor-specific peptide vaccine with focus on Melanoma and Sarcoma.

Development stage

The vaccine formulation for **Melanoma** has been validated (in vitro and in vivo). The vaccine formulation protocol for **Sarcoma** is undergoing optimization and novel sarcoma peptides are to be identified.



Proposer

Humanitas Research Hospital; Prof.ssa Maria Rescigno (Vice Rector for Research, Deputy Scientific Director and Leader of the Immunology Program)

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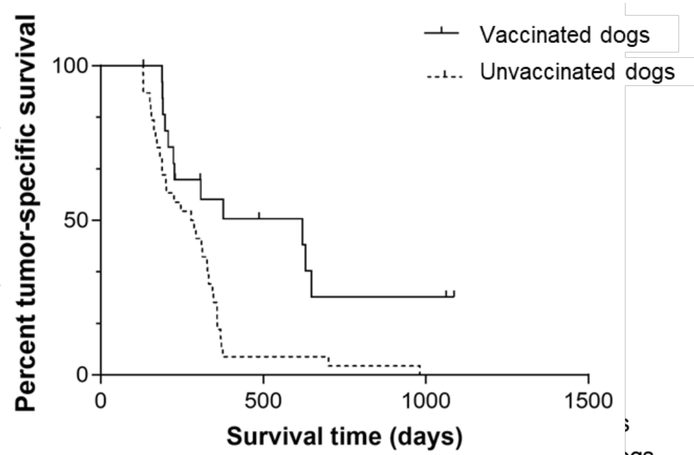
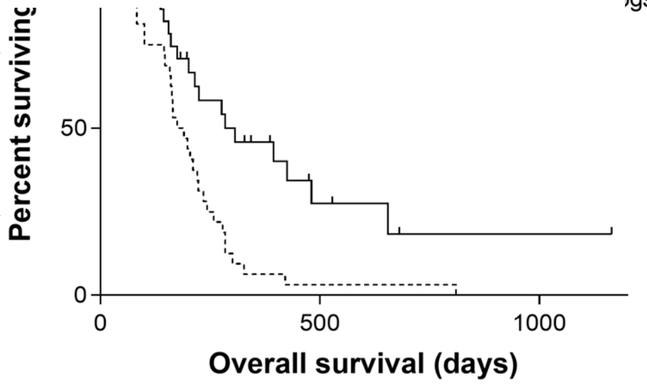
Overall survival in dog patients with **Osteosarcoma**



Overall survival in dog patients with **Emangiosarcoma**



Requested investment € 1,000,000 – 3.000,000

Target investor Seed investor in the Life Science sector interested in spin-out opportunity

CHI3L1 a new cancer immune checkpoint

DESCRIPTION

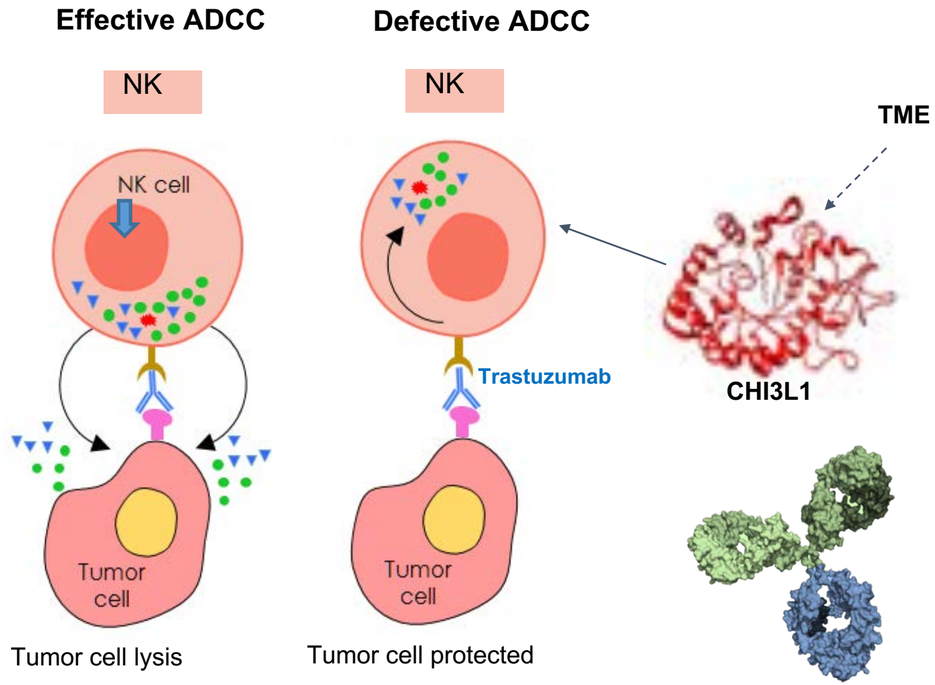
Chitinase 3 like-1 protein (CHI3L1) is a new immune checkpoint molecule involved in the mechanism of tumor resistance. The project developed a monoclonal neutralizing human antibody directed against CHI3L1, a mediator of immunotherapy resistance that inhibits healthy cell cytotoxicity by interfering with the polarization of lytic granules to the immune synapse. CHI3L1 neutralization potentiates the efficacy of anti-PD-1 therapy in the 4T1 TNBC model and CHI3L1 blockade potentiate CAR-T cells. The project refers to the patent family «CHI3L1 inhibitors and uses thereof»(publication n° WO2021013884).

Field of activity and technology

Strong potential in cancer immunotherapy, both as single agent and in combination with immune checkpoint blockade, ADCC-inducing biologicals, CAR-T and adoptive T cell therapy..

Development stage

Preclinical validation



Proposer

Humanitas Research Hospital; Prof.ssa Maria Rescigno (Vice Rector for Research, Deputy Scientific Director and Leader of the Immunology Program)

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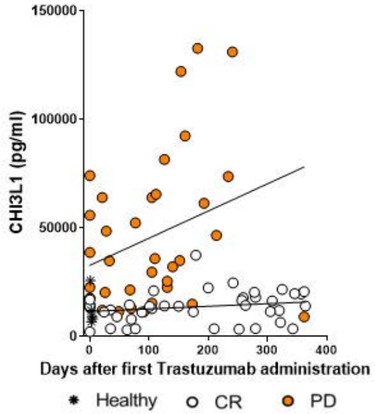
Field of activity and technology

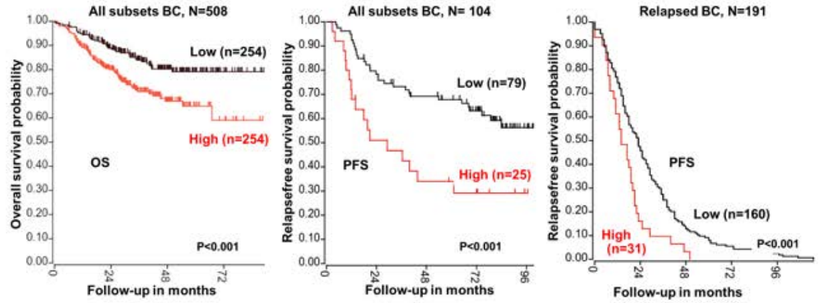
Strong potential in cancer immunotherapy, both as single agent and in combination with immune checkpoint blockade, ADCC-inducing biologicals, CAR-T and adoptive T cell therapy..

Development stage - Preclinical validation

CHI3L1 levels are elevated in sera of Her2+ patients that do not respond to Trastuzumab



CHI3L1 correlates with worst prognosis in multiple cohorts of BC



Requested investment *€ 500,000 – 1,500,000*

Target investor *Seed investor in the Life Science sector interested in in-licensing/spin-out opportunity*

CRUSTY: Clustering Unsupervised Methods For High Dimensional Cytometry Data

DESCRIPTION

Crusty Webtool provides an automatic identification of populations in multidimensional flow cytometry data. The software includes state-of-the-art bioinformatics methods and interactive visualization to improve the interpretation of data and reduce time of analysis. It provides a user-friendly platform to simplify complex flow cytometry data analysis with state-of-the-art analysis solution which would otherwise require complex bioinformatics skills. Crusty has advanced algorithms to efficiently analyze data, delivering fast and reliable results within minutes. Crusty algorithms thoroughly examine each individual event, ensuring comprehensive and reproducible outcomes and allow confident data-driven decisions. Crusty offers an intuitive and user-friendly software, facilitating the analysis of extensive data sets and enabling informed decision-making.

Field of activity and technology - Flow Cytometry software for academic institutions and pharmaceutical companies. Nature Communications article: https://www.nature.com/articles/s41467-023-40790-0

Development stage - Online https://crusty.humanitas.it, already in use by research institutes.

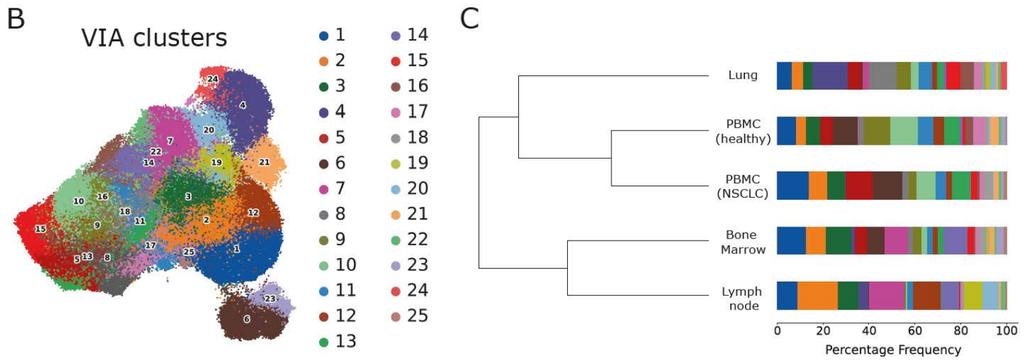
Proposer

Humanitas Research Hospital; Enrico Lugli (Head of the Flow Cytometry core facility and Leader of the Translational Immunology Lab at Humanitas Research Hospital)

CRUSTY: Clustering Unsupervised Methods For High Dimensional Cytometry Data

BUSINESS PROPOSAL

By the rapid identification of the most relevant biomarkers and/or cell populations in a complex dataset, Crusty will enable to improve the quality of care as Enhanced Diagnostic Accuracy, Monitoring Treatment Response, Novel Biomarker Discovery, and Personalized Treatment Strategies.



The next milestones to move forward and to optimize the project are:

- Enhancement of visualization tools and software platforms
- Incorporate Crusty with additional algorithms for data cleaning and normalization
- Validate the clinical utility of high-dimensional cytometry in different disease contexts
- Further development of automated workflows and streamlined data management solutions
- Extend application of Crusty to additional technologies, such as mass cytometry
- Adequate funding for research and software development

Requested investment *€ 500,000 – 1,000,000*

Target investor *Seed investor in the Life Science sector interested in in-licensing/spin-out opportunity*

DIAG-NOSE: Electronic nose for the non-invasive diagnosis of the prostate cancer

DESCRIPTION

Diag-nose is a diagnostic device for prostate cancer and for the early detection of its aggressiveness. It works with an in vitro method to analyze the urine specimen in a non-invasive way. Its diagnostic accuracy is of 90%, and also its sensitivity and specificity are much higher than the state of the art. it is easy to use, extrememly effective in the risk prediction and it can scalable to other tumors. The IP position and strategy include the “Methods to assess the risk of being affected by prostate cancer” patent family (publication n° WO2020178284).

Field of activity and technology

Non-invasive screening device for prostate cancer

Development stage

TRL 5

Capital raised

€ 60k prize for winning the Disruptive Innovation Award of the Switch2Product initiative, €200k non-dilutive fund by a Venture Builder

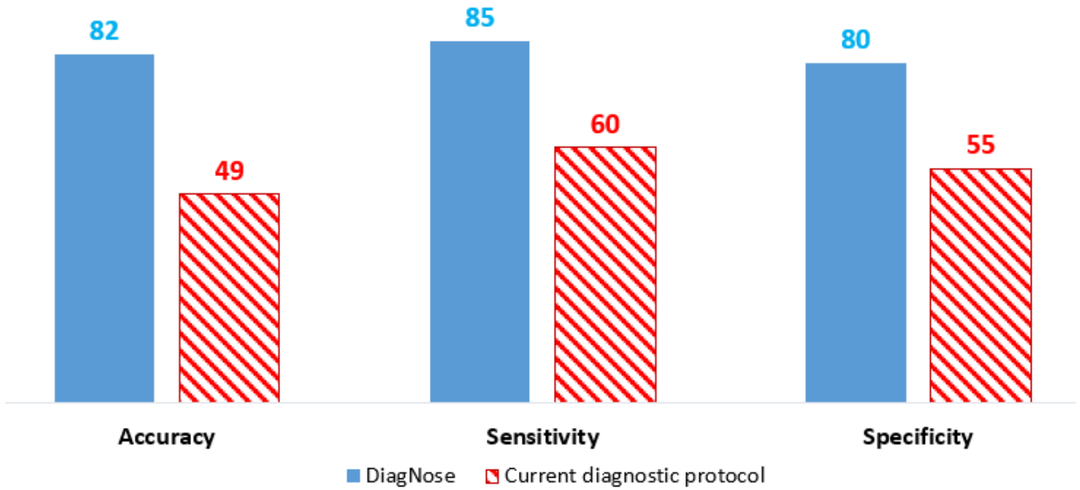
Proposer

Humanitas Research Hospital; Gianluigi Taverna (Head of Urology group at Humanitas Research Hospital), Fabio Grizzi (head of the Histology core facility at Humanitas Research Hospital)

DIAG-NOSE: Electronic nose for the non-invasive diagnosis of the prostate cancer

BUSINESS PROPOSAL

The current diagnostic procedure foresees PSA testing, as a first indicator, and then imaging (not definite) and prostate biopsies (really invasive). This device represents a disruptive innovative diagnostic tool that would revolutionize the prostate cancer practice and that could be adapted and applied to the early diagnosis of other types of cancer.



The next projected milestones are:

- Prototype final optimization and training
- Calibration transfer and Drift compensation
- Pre-industrialization
- Multicentric clinical study
- Certification

Requested investment € 1,000,000 – 2,000,000

Target investor Seed investor in the Life Science sector interested in spin-out opportunity

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Boron Neutron Capture Therapy (BNCT) & CNAO NEXT

CNAO

Centro Nazionale di Adroterapia Oncologica

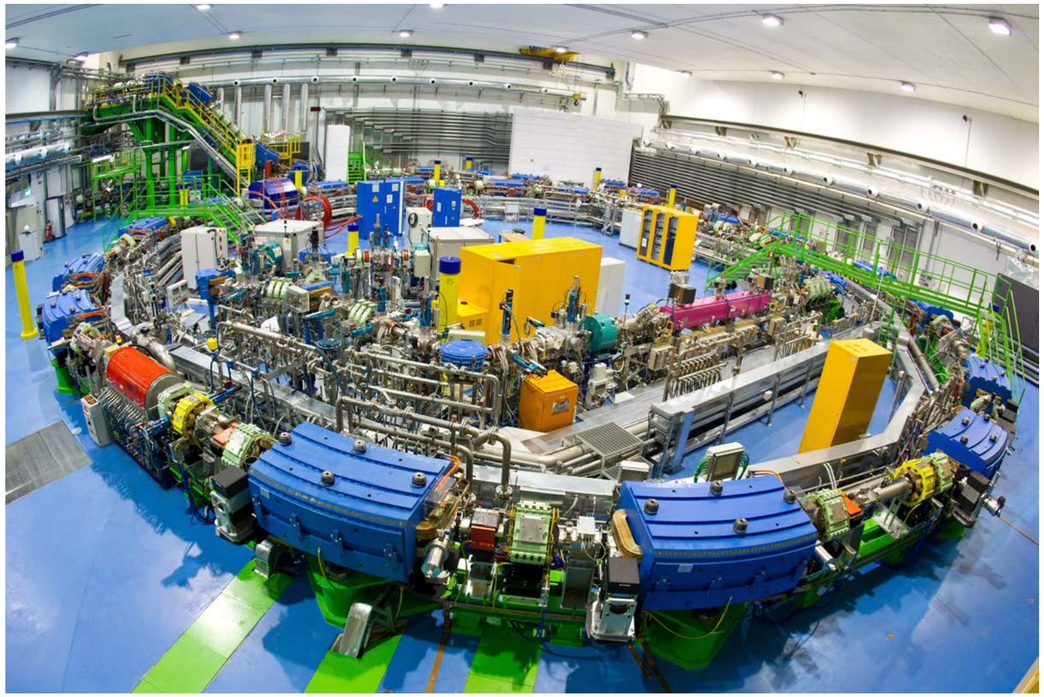
National centre for oncological hadrontherapy (CNAO)

DESCRIPTION CNAO represents the most advanced clinical and research centre in multi-particle therapy for the treatment of rare tumors and for the transnational research.

Field of activity and technology More than 5000 patients have been treated with carbon ions and protons, generated by the CNAO synchrotron, a CE labelled medical device, totally designed and realized in collaboration with CERN, GSI, TERA and INFN, involving more than 600 companies, among them 500 Italian.

Development stage CNAO in the next years will become the unique Centre in the world, providing treatments with carbon ions, protons (with a dedicated synchrotron and a rotating gantry with a large irradiation field), Boron Neutron Capture Therapy (BNCT) and new ion species (Oxygen, Helium, Lithium),offering personalized treatments for rare and difficult tumors.

Discover CNAO with an amazing virtual tour:
https://virtualtour.fondazionecnao.it/en/
CNAO is located in the North of Italy, in Pavia.



Boron Neutron Capture Therapy (BNCT)

BUSINESS PROPOSAL

In November 2020, TAE Life Sciences (TLS), from California, USA, and CNAO signed an agreement to create at CNAO a new facility equipped with a dedicated tandem accelerator to perform BNCT treatments.
This collaboration aims to create, within the clinical & research environment of CNAO, the optimal conditions to pursue the goal of treating metastatic patients with this innovative modality. This technique integrates the principles of infusion of a drug, with the potential of accumulating in cancer cells, with the cornerstone of radiation therapy (the capability of targeting tumor volume on a spatial basis).
A New Generation of Biologically Targeted Radiation Therapy: combining targeted boron-10 drugs and low-energy neutrons in a novel way to find and treat cancers at the cellular level.

A glance to the future at:
https://virtualtour.fondazionecnao.it/en/il-progetto-di-espansione/

Requested investment *Disclosed privately*

Target investor *Pharma companies for development of boron-carrying drugs. Industrial companies for realization of high technology medical devices. Clinical and research institutes interested in Multi-Particle Therapy applications.*

CNAO NEXT

BUSINESS PROPOSAL

elevating Particle Therapy Excellence, offering you unparalleled expertise, from cutting edge facility design to comprehensive personnel training, all within the realm of the latest and most advanced technologies. A team envisaged to work alongside you in order to build your NEW particle therapy in your site.

CNAO NEXT proposal is likely to be very convenient for your facility in terms of costs, time plan and adaptability to present and future requirements. It allows inclusions of local expertise that will be needed in future clinical and research development.

CNAO NEXT will guarantee the BEST model to face non-standard endeavor to build a multi-particle facility, including protons, carbon ions, other ions and BNCT treatments, that has the must of being at the cutting edge of technology, clinics and research for the next decades.

CNAO NEXT profits of many years of CNAO experience in partnerships with international companies and research institutes.

Requested investment *Disclosed privately*

Target investor *Pharma companies for development of boron-carrying drugs. Industrial companies for realization of high technology medical devices. Clinical and research institutes interested in Multi-Particle Therapy applications.*

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BIO International Convention 2024

June 3-6, 2024 · San Diego Convention Center – San Diego, CA

Proton Therapy & the new Proton Center

IEO Istituto Europeo di Oncologia

Istituto Europeo di Oncologia

DESCRIPTION

The IEO (European Institute of Oncology) is one of the world's most prestigious hospitals and the fastest growing comprehensive cancer centre in Europe. IEO integrates the various areas related to the fight against cancer such as prevention, diagnosis, treatment, training and education, basic and translational research.

Field of activity and technology

IEO specializes in the fields of molecular medicine and research and precision medicine application and research, with over 15.000 admissions and a new proton therapy center that can host up to 800 new patients a year.

Development stage

IEO has announced their new upcoming proton center, which will make them a hub for oncological treatment of inoperable or complicated tumor cases. This, paired with their already strong profile in molecular and precisison therapy medicine research as well as their high level of capacity for patient admissions and their high level of innovation will make them a strong player in medical care and research worldwide.

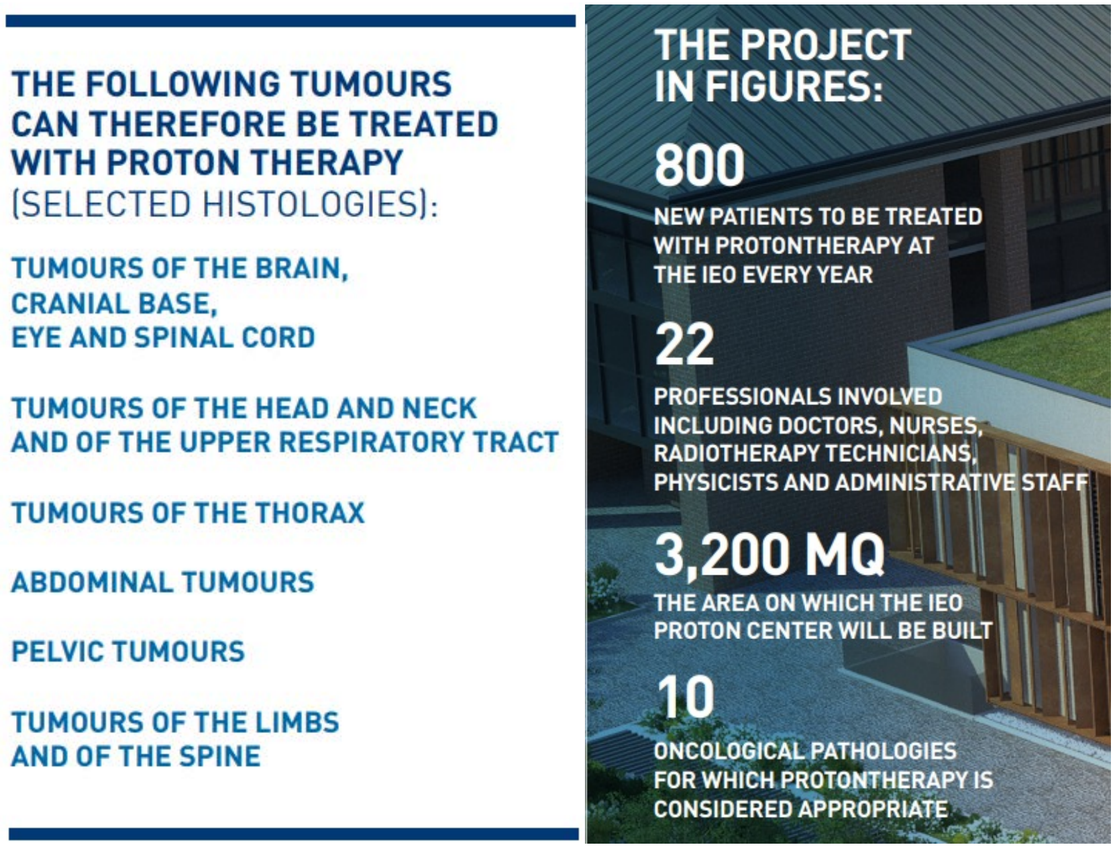
Proton Therapy & the new Proton Center

BUSINESS PROPOSAL

Proton therapy offers high precision radiotherapy, with protons - heavier particles with greater energy than photons used in conventional therapy - target tumors effectively and with high precision while sparing nearby organs from tissue damage. It complements, rather than replaces, conventional radiotherapy, enhancing therapeutic outcomes. Italy potentially has **7,000 eligible cancer patients annually for proton therapy**, according to Essential Levels of Assistance guidelines.

APPLICATION

- Tumours in particularly difficult or delicate locations such as, for example, tumours located near vital organs, in areas particularly sensitive to radiation toxicity or tumours with complex geometries such as those of the head and neck area.
- Very small tumours: the precision of the treatment allows the tumour cells alone to be targeted, without affecting the surrounding healthy tissue's.
- Radiation-resistant or recurring previously treated tumours: the release of energy from the proton beams used causes a greater number of breaks in the chemical bonds present between the cells, making it possible to obtain results even in tumours resistant to traditional therapy.



Requested investment *Disclosed privately*

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International Full Service Bio-Digital CRO

BIOREP 8TH ANNIVERSARY / AdvicePharma

International Full Service Bio-Digital CRO

DESCRIPTION

360°BioSample Trials Management & DTx
BioRep S.r.l. and its acquired company Advice Pharma Group S.r.l., SAPIO Group companies, work in synergy on the international market for clinical and research trials complete management, from study development, enrollment management, monitoring and data analysis, to the complete biological samples management, logistics, laboratory analysis and centralized cryopreservation in its biobank located within the scientific park of the San Raffaele Hospital in Milan.
Special attention is paid to the development and marketing of certified digital therapies.

Field of activity and technology

Service Provider

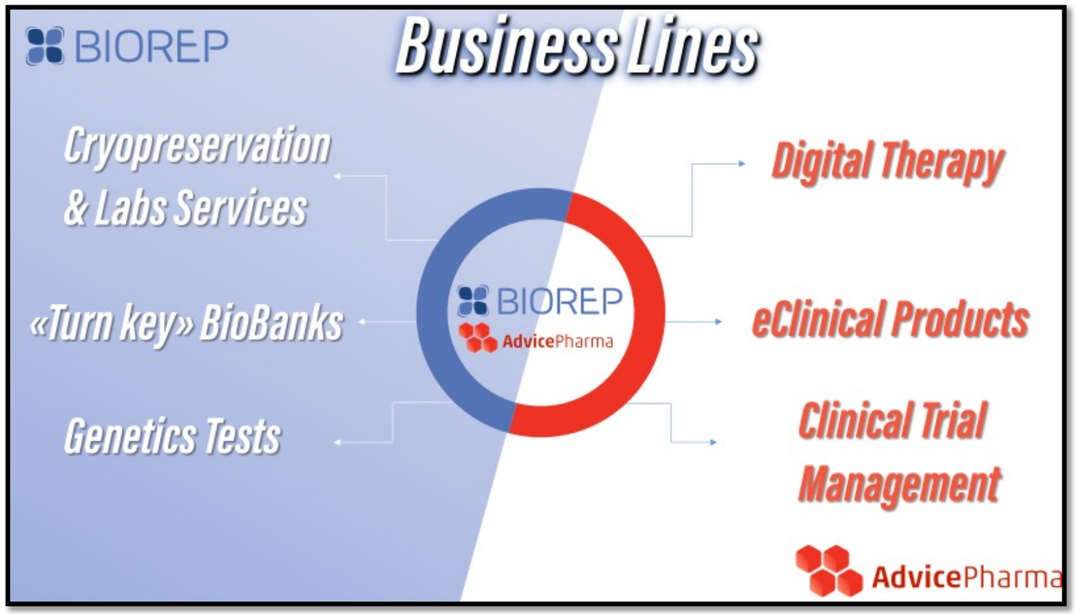
Proposer *BioRep S.r.l. & Advice Pharma Group S.r.l.*

International Full Service Bio-Digital CRO

BUSINESS PROPOSAL

Thanks to their several years of knowhow BioRep and Advice Pharma propose themselves on the market with three specific operating sectors able to synergize with each other and offer a complete, integrated and standardized model to their customers:

- Cryopreservation & Lab Services
- “Turnkey” Biobanks
- Genetic tests
- Clinical Study Management
- Clinical Research Software
- Development and manufacturing of Digital Therapies DTx (ISO 13465 certified**).**



Target investor *No-profit Foundations, Institutions, Pharma & Biotech companies, Researchers*

Requested investment *Disclosed privately*

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BIO International Convention 2024

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Competence Center on RNA Drug Pharmacology

UNIVERSITÀ DEGLI STUDI DI MILANO

Competence Center on RNA Drug Pharmacology

DESCRIPTION

Given the emerging nature of the field of nucleic acid (NA) therapeutics, our understanding of the methodologies required for studying their pharmacokinetics (PK), pharmacodynamics (PD), and toxicology remains limited. The Center build upon the long-term expertise in Biotechnology and Pharmacology of the University of Milan to develop the necessary tools to evaluate the biodistribution, metabolism, and activity of NA-based drugs at both desired targets and unintended sites of action. Additionally, considering their known immunogenicity and potential for off-target effects, new pathways are explored for appropriate immune-toxicological evaluations.

Field of activity and technology: Nucleic acid-drugs development and regulatory issues

Development stage TRL4-TRL8

Capital raised 20 million

Finanziato dall'Unione europea NextGenerationEU

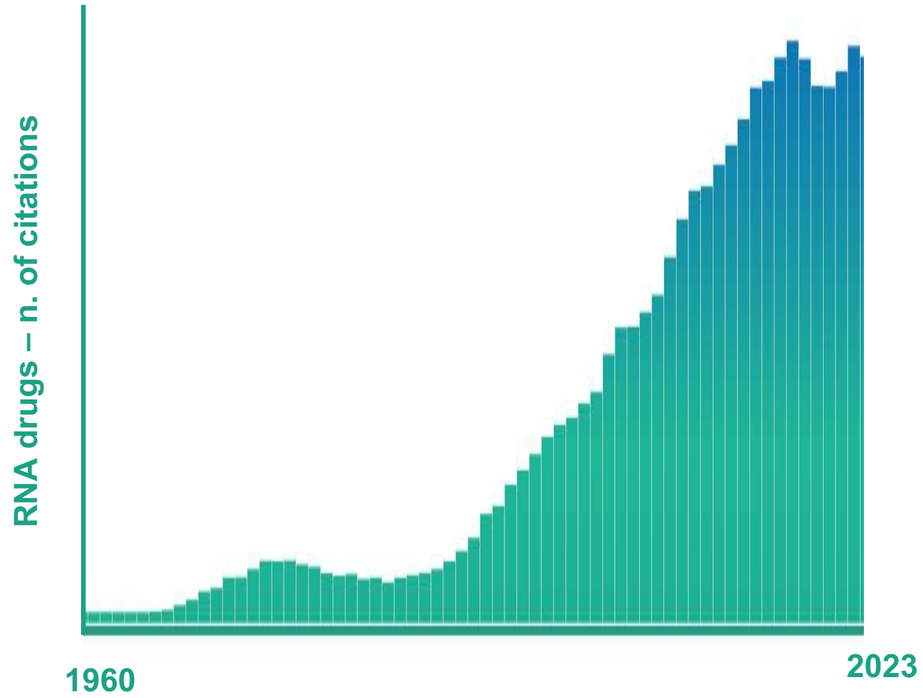
Proposer *University of Milan*

Competence Center on RNA Drug Pharmacology

BUSINESS PROPOSAL

The center adapts existing technologies and develops new ones to expedite the RNA drug development process. The most effective and robust technologies are certified for regulatory use and provided as services to the pharmaceutical industry through spin-offs generated from the process.

- The RNA drug market is at the beginning of an exponential development.
- Regulatory-recognized methodologies for RNA drug development are currently limited.
- There is a strong demand for new technologies to accelerate the market entry of RNA drugs.
- Concentrating expertise for the development of new technologies in a single Center is an innovative model in the field with few equals worldwide.



Requested investment *€ 3,000,000*

Target investor *Venture capital*

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IMPACT MEDICINE: Combined digital imaging and pathology for new diagnosis and therapy trajectories

UNIVERSITÀ DEGLI STUDI DI MILANO BICOCCA

IMPACT MEDICINE: Combined digital imaging and pathology for new diagnosis and therapy trajectories

DESCRIPTION

The **IMPACT MEDICINE** Excellence project addressed research on the application of cutting-edge technologies linked to digital pathology and molecular imaging to the study of chronic pathologies (of the liver, lungs, heart, bone marrow, brain), orphans of effective drugs, with severe prognosis and high impact on patient quality of life and healthcare spending. In continuity with **PREMIA (Precision Medicine)** Excellence project, is modeled following the idea to move from the concept of disease to "disease trajectories", in which only a technologically complex approach, based on new generation platforms, can refine the level of understanding. This complexity must be integrated at a clinical-pathological level to obtain usable knowledge.

Field of activity and technology

- Digital medicine applied to precision medicine
- Advanced informatics and technological platform: Digital Pathology, In vivo Imaging; Biostatistic and Bioinformatics; Proteo-genomic, advanced imaging, radiochemistry and molecular pathology platforms; A certified animal model development enclosure with BSL2 safety level;

Development stage - The programme (2023-2027) is articulated both in the purchase of digital medicine infrastructure including the implementation of international networks for the recruitment of case studies and in the implementation of new profiles among professor, research associates and technical-administrative staff (12 units). Starting meeting was held on 2nd February 2024

Capital raised - The project is financed by the Ministry of Education, Universities and Research (MIUR) for 9,050,590 EU

Proposer *University of Milano-Bicocca School of Medicine and Surgery*

IMPACT MEDICINE: Combined digital imaging and pathology for new diagnosis and therapy trajectories

BUSINESS PROPOSAL

The Department of Medicine of University Milan Bicocca was financed by the Italian Minister of University within the “Fund for the financing of university departments of excellence - Law no. 232 of 11/12/2016” for the second Departmental Excellence Project “Combined digital imaging and pathology for new diagnosis and therapy trajectories (IMPACT MEDICINE).

The project will be focused on 5 clinical pillars (lung, liver, bone marrow, heart, brain) and four actions (digital pathology, diagnostic imaging and radiomics, bioinformatics and biostatistics and animal models of diseases) with final the final goal to apply digital imaging and artificial intelligence to identify biomarkers applicable in the clinical real world.

On the basis of the emerging interest in using digitalization for the diagnosis of chronic diseases and for molecular imaging in the personalization of therapies, the project will be conducted in tight collaboration with companies.

A particular commitment will be made to ensure that the products of the project have real impacts on the health needs of society (third mission). The computational data, obtained by enhancing digitalization processes and managed Open & FAIR, will be analyzed with artificial intelligence algorithms for the development of decision-making supports complementary to human judgment in the diagnostic-predictive evaluation of diseases..

Combined digital imaging and pathology for new diagnosis and therapy trajectories

Biomedical areas of University of Milan-Bicocca has a strong interdisciplinary vocation in all three main development sectors: clinical care, translational research and higher education. Precision medicine was the central theme of the previous Department of Excellence project of the Department of Medicine and Surgery. The excellent results of PREMIA have allowed the consolidation of researches areas that will be further strengthen through the creation of a Digital Medicine Center. The project will allow to invest in digital pathology and molecular imaging both in terms of professional skills and technologies to increase the translational productivity of research, the culture of "data curation" and the international networking.

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Molecular Genetics

INGM
ISTITUTO NAZIONALE GENETICA MOLECOLARE
"Romeo ed Enrica Invernizzi"

Molecular Genetics

DESCRIPTION

The National Institute of Molecular Genetics (INGM) “Romeo and Enrica Invernizzi” is a research institute with focus on molecular genetics and on other methods of detection and diagnosis. INGM research began in 2007 and still continues inside the campus of the historic Policlinico Hospital, located in the very centre of Milan, in the “Romeo and Enrica Invernizzi” building. The Foundation has achieved significant scientific results in understanding the mechanisms of regulation of gene expression and interactions between the immune system and tumor cells.

As of today, INGM stands as a center of excellence in biomedical research both at national and international level.

Proposer *National Institute Of Molecular Genetics*

Molecular Genetics

DESCRIPTION

The decodification of the human genome sequence more than a decade ago has opened the greatest gap between the accumulation of scientific information and the possibility of translating this into new therapies or diagnostics. Hence, the need for more “translational” research and for a greater capacity to network between research organizations. INGM aims at strengthening European biomedical research in these two key points.

INGM biomedical research is based on “state of the art” technological platforms with strong connections to clinical needs. The presence among the founders of INGM of IRCCS Ospedale Maggiore of Milan and its location within the University Hospital campus facilitates the establishment of more clinically oriented research programs. In Europe, INGM collaborates with international institutes on the base of common, equally shared research programs funded by EU agencies. In the entrepreneurial sector, INGM collaborates, on the basis of Intellectual Property sharing, with several biotech companies, so as to reinforce the translational link of technological innovation.

INGM is an advanced research center, which creates a well-defined niche of activities in the field of human “omics” research. Through a diversified research network of public and private collaborations, INGM develops research projects aimed at identifying new biomarkers and new therapeutic targets that could improve the secondary prevention of chronic diseases (infectious, autoimmune or neoplastic). With the continuous aging of the population, secondary prevention is becoming a key factor for more sustainable health programs of our societies.

Thus, INGM strives to translate new discoveries into new diagnostic and new therapies aimed at reducing morbidity and mortality caused by chronic diseases, with the big objectives of improving quality of life while making public health more sustainable.

Requested investment *Disclosed privately*

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Development of predictive digital system to optimize the treatment of brain borderline lesion like Meningioma in clinical practice

CENTRODIAGNOSTICOITALIANO

CDI

LIFE FROM INSIDE

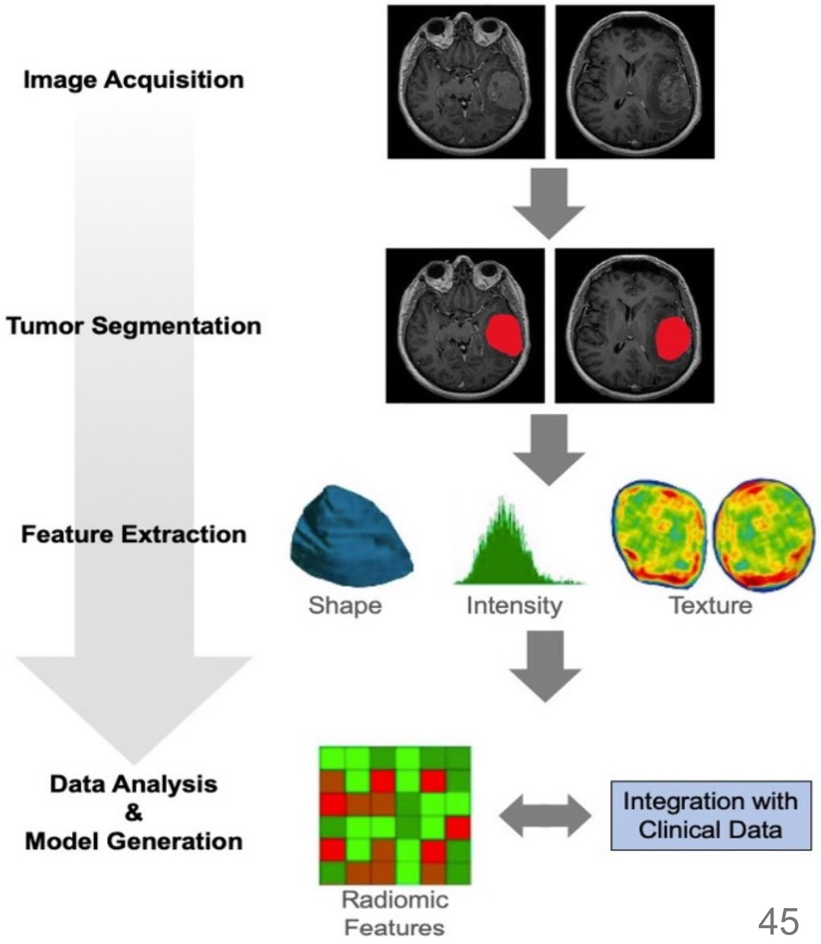
Development of predictive digital system to optimize the treatment of *brain borderline lesion* like Meningioma in clinical practice

DESCRIPTION*:*

Meningiomas, which are often benign tumors, affect a substantial portion of the population with a higher incidence in females (3:1 ratio). These tumors are usually discovered incidentally during MRI scans, and their management presents intricate challenges. Stratifying histotypes is vital for tailored therapies; however, current surgical decisions are primarily driven by the tumor's location and the patient's symptoms rather than its histological type. Artificial Intelligence (AI) has the potential to transform this paradigm. By analyzing MRI images, AI can predict the tumor's histotype prior to a biopsy, thereby refining therapy choices and enhancing patient outcomes. This research represents a progressive step towards the personalized treatment of meningiomas.

Field of activity and technology: Diagnostic Imaging, Radiomics, AI Predictive Analytics, MRI, Data Science.

Development stage:
Collectingt series from different clinical institutions in Milan and overall Lombardy

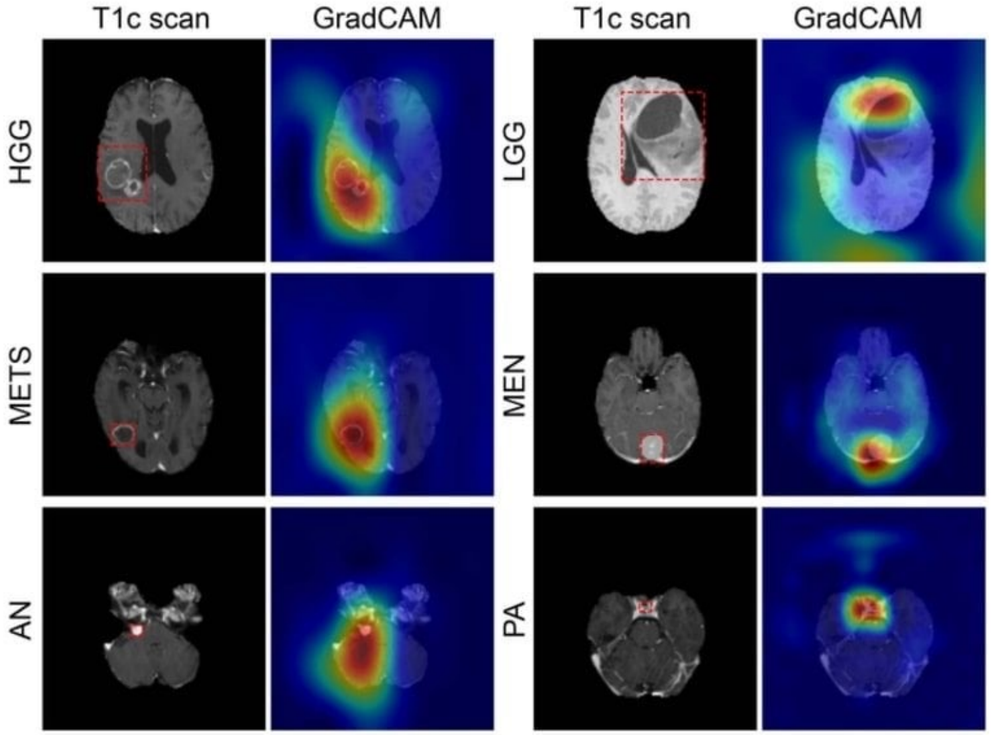


Proposer *Centro Diagnostico Italiano*

Development of predictive digital system to optimize the treatment of *brain borderline lesion* like Meningioma in clinical practice

BUSINESS PROPOSAL

This project aims to harness artificial intelligence to differentiate using AI the meningioma isotypes via pre-surgical MRI, tailoring treatment to each patient.
Key benefits include enhanced diagnostic accuracy, reduced surgical risks, and more targeted therapy that could potentially improve patient outcomes and lower healthcare costs.



Requested investment *500:000 USD*

Target investor *Surgical device companies, major in diagnostic technology, machinery and equipment, ai development companies*

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