BIOMEDICINE IN NAVARRA

Industry and academia collaborate in each step from the bench to the bedside to jointly consolidate the Biomedical sector in Navarra.

DISCOVER ITS KEY PLAYERS AND THEIR CORE CAPABILITIES.

This catalog has been supported by the ShareBiotech project (2009-1/27) in the frame of INTERREG IVB Atlantic Area.

Biomedicine in Navarra

Biomedical Cluster in Navarra

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Biomedical Cluster in Navarra

Overview


Pamplona

The region of Navarra

The region of Navarra, the "Comunidad Foral de Navarra", is located in the north of Spain, at the western foot of the Pyrenees, where it shares a 163 kilometer stretch of the frontier with France. The population of Navarra, 642.051 inhabitants (National Statistics Institute- INE, 2011), represents 1.36% of the Spanish population and covers an area of 10,421 km^2.

The Region: Navarra is currently one of the most innovative regions in Europe and it is a leader in promoting R&D

Navarra is a strong industrial region that is the home to some major companies in the sectors of Renewable Energies, BioTech, Automotion & Food Processing, and it hosts over 120 multinational companies. Indeed, Navarra is a worldwide leader in technological development and production in the Renewable Energies sector, and today 79,58% of the electricity consumed in Navarra comes from renewable sources. In addition, the region boasts one of the most productive car manufacturing plants in the world and a vegetable food industry which is renowned for his high quality.

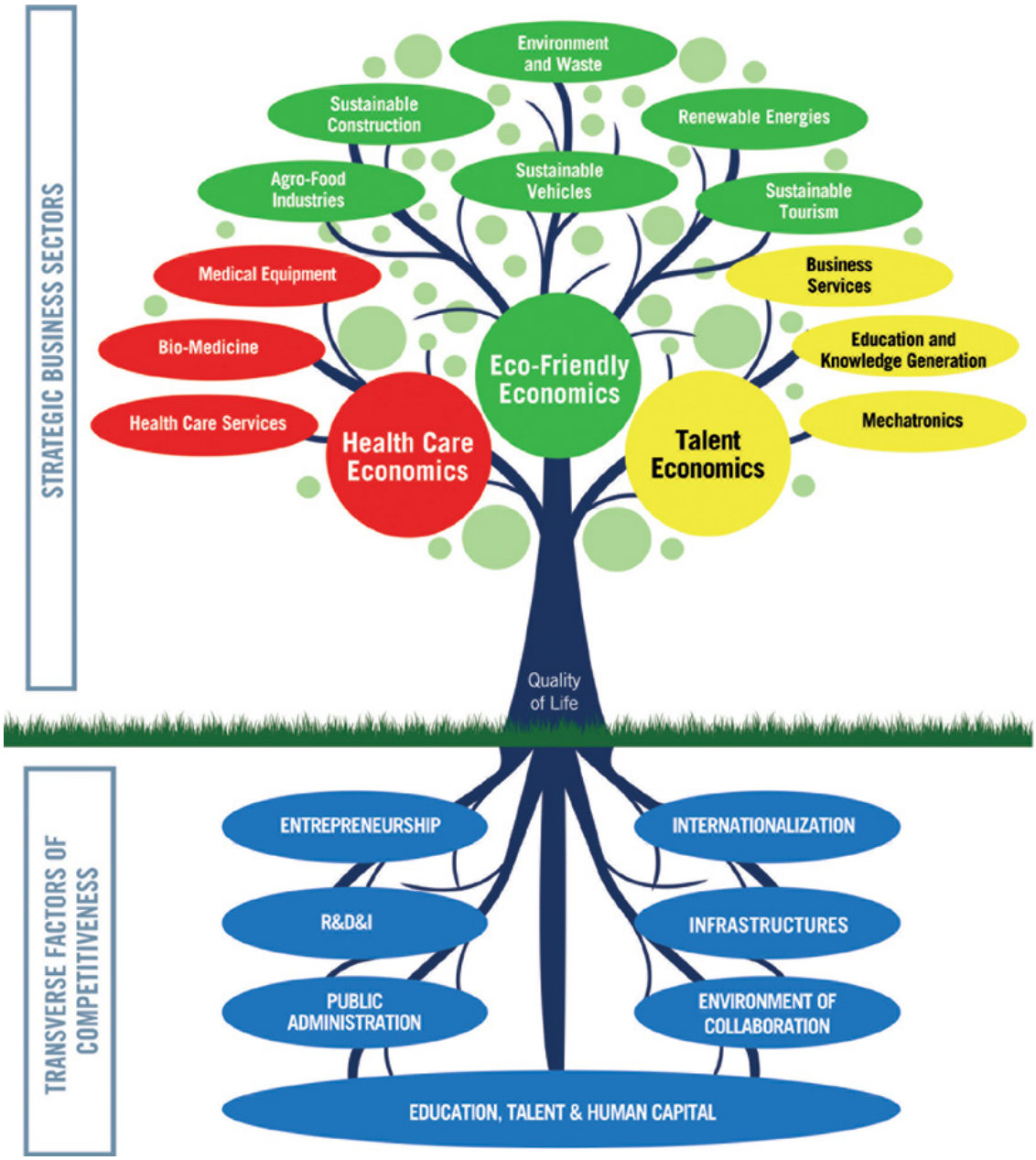
Among the most important assets in Navarra is its well-balanced productive structure, its excellent geographical position and degree of internationalization, as well as its good infrastructure.
Navarra is one of the Spanish regions with the best national indicators in terms of social welfare, access to services and quality of life. With a Gini index of 28 and an OCDE human development index (HDI) of 0.97, Navarra is one of the regions with the highest quality of life worldwide.

Through optimal and stable economic development, Navarra with a Gross Domestic Product (GDP) of 18,726 M€ (INE 2011) representing 1.8% of Spain's GDP, belongs to the group of Spanish regions that register the best economic indicators. In terms of GDP per capita, Navarra lies in 37nd position in the list of 271 European regions, with a GDP per capita of 30,500 euros.

Navarra is currently one of the most innovative regions in Europe and it is a leader in promoting R&D, with its growing investment in R&D supported especially by the private sector. The region had a R&D expenditure to GDP ratio of 2.05% in 2011, the best of all the regions in Spain, with the private sector representing 69% of the total R&D expenditure.

Navarra is also the home to important research and higher education centers (Public University of Navarra, University of Navarra, Spanish Open University) and to 17 Research Centers. In terms of qualified personnel in technological and innovative disciplines, the region ranks 19th in Europe and it is renowned for its range in terms of higher education. Moreover, 39,7% of the population between 25 and 64 years of age has passed through higher education in Navarra, which is reflected in the availability of highly qualified professionals in the region.

The regional administration is proud of its high level of self-government, which enables it to adapt its policies to the specific development strategies of the region. Moreover, Navarra´s government promotes a flexible and close relationship with the businesses located in the region.



Priority areas

MODERNA contains the challenges that the economy of Navarra faces, and defines the strategy and major action lines towards 2030 in the areas of Green Economics, Health Economics and Talent Economics. To this end, the plan lists up to 458 actions to be executed in the different strategic sectors and transverse factors reinforcing the competitiveness of our economy.

The plan lists up to 458 actions to be executed in the different strategic sectors and transverse factors reinforcing the competitiveness of our economy. All these actions are avhieved throught a bottom-up model managed by the MODERNA Foundation. It is a system of regional Open Innovation that ensures the incorporation of the best ideas to our economy at the right pace.

Smart Specialization Strategy

MODEL OF ECONOMIC MODERNA DEVELOPMENT FOR NAVARRE

The MODERNA Plan (Model of Economic Development for Navarra) is a medium and long-term strategic plan that fosters change in the Economic Development Model of Navarra, moving towards a knowledge-based economy that focuses on people. The plan was promoted by the main political, education, business and social institutions.

MODERNA aims to take advantage of Navarra's full potential for development and is a driver for future economic change. Citizen participation and Institutional consensus are key to the preparation and development of MODERNA.

OBJECTIVES OF MODERNA

MODERNA contains the challenges that the economy of Navarra faces, and defines the strategy and major action lines towards 2030 in the areas of Green Economics, Health Economics and Talent Economics.

MODERNA proposes 3 Objectives for the Future of Navarra:

> Prosperity: To position Navarra amongst the 20 leading. European regions in GDP per capita and with a fair distribution of wealth.
> Quality of life: To position Navarra amongst the 10 leading European regions in the Human Development Index (HDI).
> Sustainability: To position Navarra amongst the 20 leading European regions in sustainability.

AREA	INDICATOR	STARTING POINT	OBJECTIVE 2015	OBJECTIVE 2020	OBJECTIVE 2030
EDUCATION	PISA Points	502	510	525	550
	% of Population aged 18 with a B2 level of English	7%	30%	50%	90%
	% of Honours Graduates and Pre-university students	36%	40%	45%	55%
INNOVATION	% Investment in R+D+I	1,92%	2,20%	3,00%	4,00%
	Total No. of Patents	172	285	410	844
	Innovation index and position in Europe	0,48 and 76	0,51 and 60	0,60 and 50	0,70 and 35
INTERNATIONALIZATION	Exports (M€)	5.450	6.500	8.000	10.000
	No. of exporting companies	711	1.000	1.300	2.000
	No. of multinational companies	133	150	175	200
EMPLOYMENT AND COMPANY	No. employees	284.000	298.000	331.000	365.000
	Production per worker (€)	61.000	68.000	73.000	85.000
	% of companies with over 50 workers	1,30%	1,60%	2,00%	2,50%
	No. of new companies/year	943	1.100	1.250	1.600
PROSPERITY AND SOCIAL COHESION	Position in GDP/Capita	32	30	25	20
	GDP per Capita in Purchasing Power Parity (PPP) (€)	30.614	34.000	37.000	43.000
	Distribution of wealth	28	27	26	23
	Quality of life (HDI)	0,9720	0,9725	0,9790	0,9870
	Environmental sustainability	2.132	1.900	1.650	1.450


cima

The Biomedical sector

Highlights

Navarra is emerging as one of the most dynamic Biomedical clusters in Spain and offers exciting opportunities for investment and partnership in this sector, particularly since:

> It boasts innovation infrastructure that is among the best in Spain.
> CIMA is the largest private Biomedical research Center in Spain and it attracts more than 400 researchers from over 20 countries, representing an annual investment of over 20 million euros.
> Navarra´s Biomedical cluster is home to some of the most attractive Spanish Biomedical companies, such as Digna Biotech, the company with the largest product development pipeline in Spain or 3P Biopharmaceuticals, the first CMO in Spain, as well as CINFA, the leader in generic medicine sales in Spain.
> There are five products that have been discovered at institutions in Navarra already at different stages of clinical development. Moreover in the last two years, 10 clinical trials with Advanced Therapies - Cell Therapy have been conducted.
> Investment is handled by a highly skilled and talented regional people.
> Thanks to their tightly coordinated and networked activity, the biomedical companies and institutions of Navarra can develop a biomedical product through all the necessary stages, from its discovery to its commercialization.

Biomedical scientific research in Navarra has a long-standing tradition that has been developed around the University of Navarra and the Schools of Medicine, Sciences and Pharmacy. There are over 1,000 professionals working in this sector, the number of employees having doubled over the past 10 years at a rate of 4.8% per year. Moreover, over 60 patents have been awarded during this period.

The Biomedical cluster was initially created around the Center for Applied Medical Research (CIMA), in which most of the biomedical R&D carried out at the University of Navarra is undertaken, and a group of companies emerging from this initiative. This cluster has expanded in recent years, as more recently developed new business initiatives have emerged.

Accordingly, Navarra´s Biomedical cluster now comprises over 20 private firms and Research Centers, many of which have established partnerships with government agencies, universities, teaching hospitals and technical colleges. The high quality scientific research carried out in the universities, in affiliated teaching hospitals and mainly in CIMA has laid the foundations for the success of the majority of the companies in the cluster.
Apart from these regional initiatives, Navarra has developed a wide range of collaborations with other Spanish and international entities, such that new projects have been developed in the region, as well as new companies that have commenced their activities in Navarra.

Biomedical research in Navarra

In Navarra, groundbreaking research is carried out at numerous Centers of Excellence. The region is home to two prestigious universities with a long-standing academic tradition, a renowned public and private healthcare network strongly linked to the universities as well as relevant agents that promote applied research, such as the Center for Applied Medical Research (CIMA) and the Institute for AgroBiotechnology (IdAB).

The biomedical research activity in Navarra continues to grow with the construction of new R&D infrastructures, like NAVARRABIOMED, a initiative of the regional Health Department to promote and complement the currently available Biomedical research offer in Navarra. In addition, there is considerable research activity in newly emergent fields such as the Nanobiomedical R&D activity carried out at L´Urederra and FideNa, both centers for Nanotechnological research, which complement and expand the possibilities in biomedical research in the region.

In addition, Navarra is home to a strong health service sector, centered around a group of committed collaborative institutions which are active in this area, as well as public entities and companies from the financial sector. These organisations all pull together to optimize the development potential of the sector.

Challenges for the future in Biomedicine in Navarra

Based on MODERNA Plan, Biomedicine is included in Health Economics and the Challenge in Biomedicine for the Future is set as:

"For many years now, Navarra has shown an outstanding level of scientific research and development in the area of biomedicine and, today, although the biomedical sector is still small, it is well established and well recognised. Factors such as the existence of excellent research entities, a powerful healthcare service sector and a group of committed institutions around the sector (public entities and financial community), comprise the basic foundations for growth. Navarra must change from being a small, although sophisticated, group of entities that are capable of participating in the entire drug development process, to become a quantitatively important economic sector in the region and become a qualitative benchmark at an international level, bearing in mind the fact that this is an international and global sector."

Financial support for Investment

At present, the overall investment in the Biomedical sector in Navarra is above 300 M€. Out of these investments, about two thirds come from private investors and one third from governmental grants. There are numerous grants available for R&D projects, provided by National and Regional technology support programs, that include both non dilutive grants and low interest loans.

Private investors have played a key role in consolidating the sector, accounting for over 64% of the overall investment in R&D within Navarra, an amount that is twice as much the average of private investment in Biomedical research in Spain.

Indeed, the region is currently home to some of the most relevant Spanish investors in Biotechnology, such as SODENA that has become a key element in the consolidation of this sector, with a direct investment in most of the biomedical companies currently operating in the region.

In addition, the MODERNA Foundation gives access to the finance instruments of MODERNA:

- Entrepreneur MODERNA grant: 35 per year
- BEI-MODERNA credit line: 250 M€ from the European Investment Bank for the advantaged financing of "MODERNA Businesses" with SODENA
- MODERNA bank guarantee for business financing: Public complement for funding projects (30% - 60%) with SODENA
- MODERNA co-investment found: Mechanisms of co-investment involving public and private investors.
- MODERNA Investors forum: 4 forums per year.

Finally, other private investors, such as venture capital firms like Clave Mayor and other financial institutions, like Caja Rural de Navarra, play a major role through their participation in the majority of the entrepreneurial initiatives in the region.

In addition to private investment, public financial support, both at a national and regional level, has been instrumental in providing funding, representing 30% of the overall investment. For example, since the implementation of Navarra´s III Technological Plan (2008-2011), the Government of Navarra has supported 39 Biotechnological R&D projects, representing 33.5% of the overall budget applied for.

Workforce and educational Institutions

Around 1,000 people are employed in the life science sector in Navarra and most of them are active in the area of R&D. Indeed, the scientists and technicians in Navarra receive outstanding training.

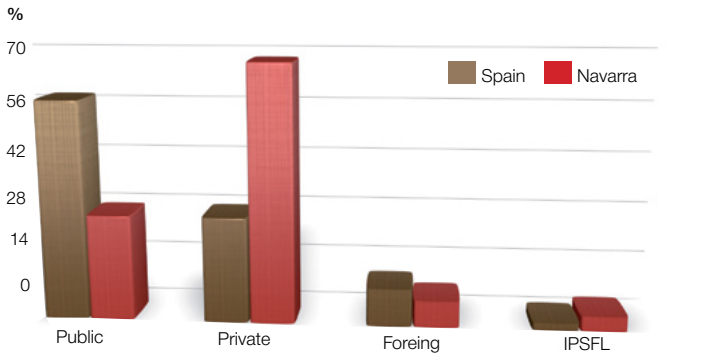
Navarra's Biomedical cluster is supported by programs and initiatives that are offered through a network of educational institutions. The University of Navarra is internationally recognized for its excellent educational quality, as well as its advanced research facilities and outstanding achievements in the Biomedical field.

The University of Navarra has three Schools which are active in the area of Biomedicine: the Schools of Medicine, Pharmacy and Sciences, with a diverse and highly specialized range of Degree, Doctoral and Master Programs in this area. At this institution, the Master's Program in the Research, Development and Innovation of New Drugs was recognized as the best Master's Program offered in Spain in this field.

Moreover, in Navarra there are a wide range of highly skilled Associate Degrees/Senior Technician training courses that are related to Biomedicine, ensuring that specialized training is available to the professionals working in this sector at all levels.

All in all, Navarra guarantees a steady supply of highly qualified professionals that are ready to work in the field of Biomedicine at all levels. Moreover, the scientific and business opportunities, together with Navarra's renowned quality of life, attract researchers from all over Spain and beyond.

Percentage funding to finance R&D expenditure in Biotechnology in Spain and Navarra (Navarra's Statistics Institute-2007)



Products, services and technologies

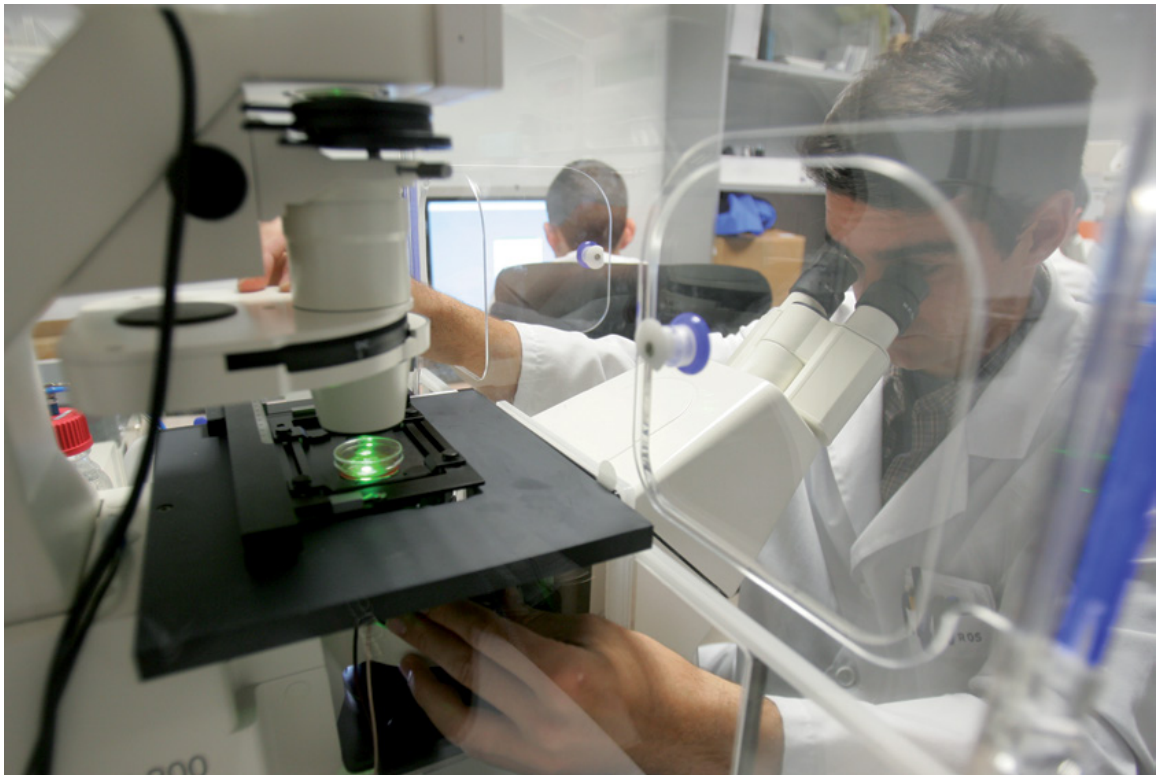
The diversity within the Biomedical cluster in Navarra is continuously expanding. Currently, the biopharmaceutical research focuses on Oncological, Neurological, Cardiovascular, Gastrointestinal, Ophthalmological and Dermatological diseases, with special strength in biologicals, such as recombinant proteins and gene and cell therapies, drug delivery technologies, nanoparticle and pharmaceutical development.

The biopharmaceutical firms are working with more than 50 therapeutic and diagnostic products in different stages of development. Some of the more advanced products include a product in Phase III of development for the treatment of Sclerodermia, skin cancer and actinic keratosis, a Phase II product to treat Hepatitis C or a Phase I product for use in liver transplants and resection. All of these products are currently being developed by Digna Biotech.

In addition, CINFA is the leading generics company in Spain and it offers a wide range of prescription and OTC products in a variety of therapeutic areas.
Along with product development companies, the cluster also hosts a number of companies offering support services that include, but are not limited to, protein production, pharmaceutical development and production, pharmacokinetics and pharmacodynamics modeling, dosage formulation, drug delivery and quality control and regulatory assessment.

Navarra's Biomedical cluster is supported by top private and public research and innovation infrastructure. These facilities are the result of strategic region-wide partnerships formed to encourage industry growth (for further information, please see the Biotechnological core facilities section).

Some infrastructures include Genomic and Proteomic platforms, clinical trial sites for Phase I clinical studies,



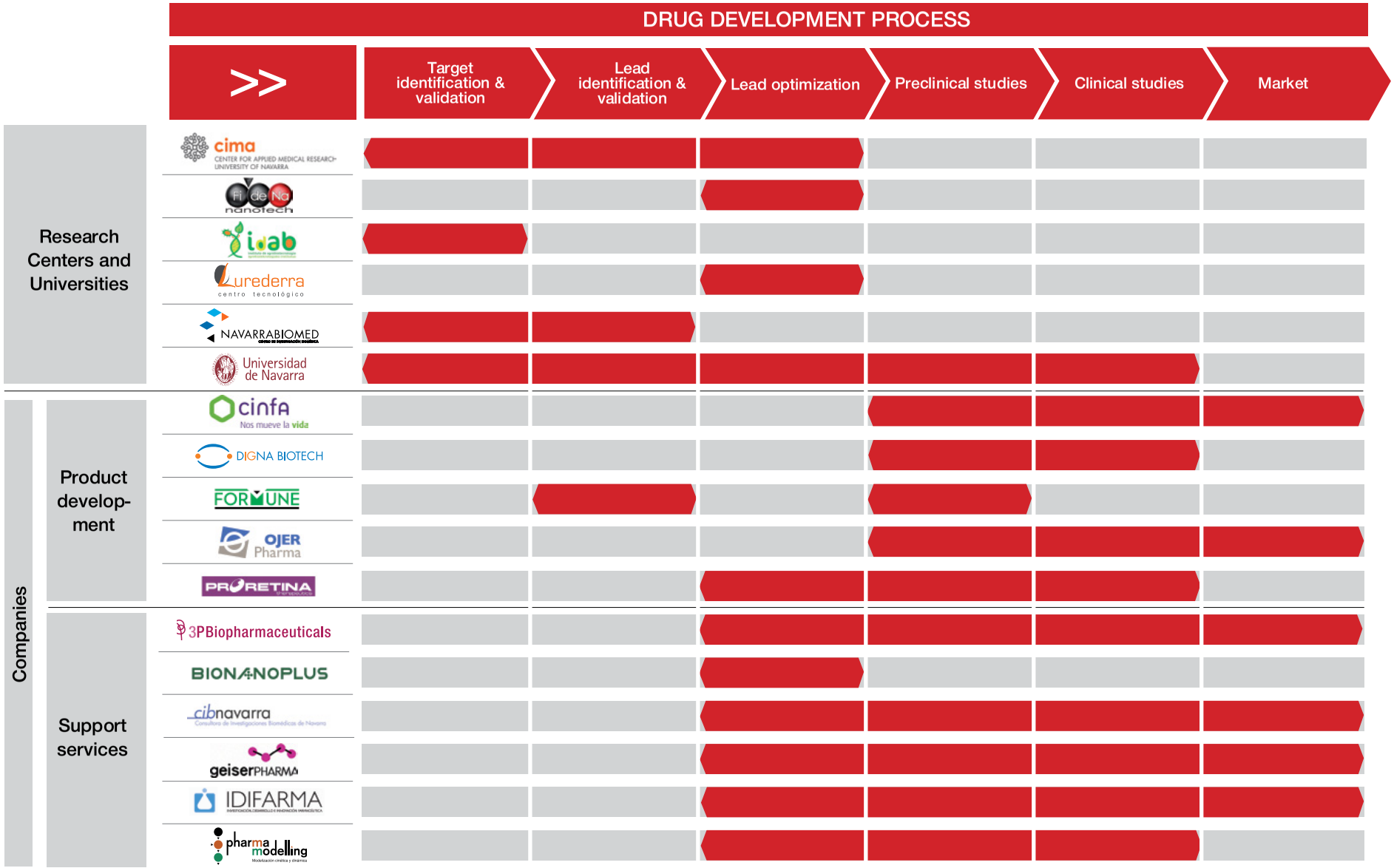
state-of-the-art Medical Imaging technologies that range from Magnetic Resonance Imaging (MRI) to Positron Emission Tomography (PET), biobanks with different tissue and DNA samples or animal facilities to provide access for preclinical testing.

Furthermore, Navarra´s Innovation Park provides an environment where technology-based companies can set up, grow and perform all kinds of R&D activities. The Park has all the basic elements of an innovation agency (technological centers and companies, access to universities, incubator space, etc), as well as first class infrastructure.

Navarra's Biomedical cluster is also working in establishing international scientific and financial partnerships to help fulfill the potential commercial benefits available from the cutting-edge R&D and the pioneering intellectual property generated at the region's world-class research institutions.

Map of the Biomedical sector

Thanks to a tight networked activity, the Biomedical industrial and academia institutions in Navarra collaborate in each phase in the development of pharmaceutical products, from the bench to the bedside.



Biomedical cluster

description

BITA - Proyecto Biomedicina CIMA S.L.

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Contact Person
Antonio Martín (CEO)

General description
BITA, the trade name of "Proyecto de Biomedicina CIMA S.L.", is the owner entity for all the patents generated from the research carried out at the Center for Applied Medical Research (CIMA) in Pamplona. BITA is a biotechnology firm whose purpose is to adequately protect the intellectual property generated at CIMA and to exploit them through license agreements with other firms and companies in the field of the biotechnology.
From the very moment of its inception, the company commenced with some patents contributed by one of its founder-members, the University of Navarra. Since then, there has been a notable increase in the number of findings protected, thanks to the efficiency and productivity of the research carried out at CIMA.
DIGNA Biotech, a firm that also belongs to the CIMA-DIGNA Project, is a unit that acts as a preferential licensee of the patents from BITA.
BITA came into being as the consequence of a joint venture between the University of Navarra, owner of CIMA, and a group of 15 financial backers. These included some of the most important companies in Spain, as well as some of the most representative regional entities from Navarra, such as the Regional Government of Navarra (through its arm for business development, SODENA), the University of Navarra, and the savings banks, Caja Navarra (today La Caixa) and Caja Rural de Navarra. BITA embraces some of the largest national corporations from different sectors of the national economy, such as, BBVA, El Corte Inglés, Fuertes I Más D S.L-Grupo Fuertes (El Pozo), Loyalty Square S.L. which represents Omega Capital, Masaveu de Investigaciones y Desarrollo S.L., Pontegadea Biotecnológica S.L. and Ungría Patentes y Marcas.

Priority areas
Oncology, Neurosciences, Cardiovascular diseases, Gene Therapy and Hepatology.

Products, services and/or technologies
The company owns over 50 patents related to therapeutic and diagnostic approaches in Oncology, Neurosciences, Cardiovascular diseases, Gene Therapy and Hepatology.

Achievements and future prospects
BITA has achieved joint ownership and patent management agreements with organizations from all over the world, such as the University of Navarra (Spain), Universidad Pública de Navarra (UPNA), the University of Barcelona (Spain), University of Alabama (USA), University of California (USA), University of Minnesota (USA), University of Washington (USA), Pasteur Institute (France), Inserm Transfert(France). Centro Superior de Investigaciones Científicas (CSIC), and Borstel Research Center (Germany), among others.
Moreover, BITA has signed license agreements with several companies, such as DIGNA Biotech (Spain), 3P Biopharmaceuticals (Spain) and UniQure (The Netherlands).

Product development

Laboratorios CINFA S.A.

> Therapeutics

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Contact Person

Julio Maset
(Director of Innovation)

General description

With over 40 years' experience, CINFA offers one of the most complete formularies on the market with over 270 products and 800 presentations. The company's capital stock is 100% Spanish and the drug manufacturing process is managed from start to finish at our head offices in Navarra, from the development of the drug to its marketing through distributors and pharmacies.

All this makes CINFA the leading pharmaceutical company in terms of volume of sales through retail pharmacies in Spain. The company has modern laboratories and two industrial sites equipped with the very latest technology, where more than 85 million product units are manufactured every year under the most rigorous standards of quality control.

The company began its activity in 1969, when a group of pharmacists led by Ezequiel Lorca created CINFA. Since then, the company has grown significantly and currently, more than 900 people work at Cinfa.

CINFA is present in over 50 countries worldwide, mainly in French-speaking Africa and Latin America. CINFA also distributes and markets generic medicines in Portugal through an agreement with the pharmaceutical company Faes Farma, and it has a marketing subsidiary in Algeria.

Priority areas

All therapeutic areas.

Products, services and/or technologies

CINFA's work is focused on five product ranges: generic medicines in all therapeutic areas; OTC medicines that do not require prescription; a full range of orthopaedic products; a dermo-cosmetic product line with treatments for the care of all skin types; and and a new nutraceutical range.

CINFA's commitment to R&D can be seen in its team of 53 professionals, its development contracts with 60 universities, national and foreign research centers, and the EUR 56,6 million investment in the last five years. This figure will rise to more than EUR 115 million between 2012 and 2016.

Amongst CINFA's R&D projects, the company continues to focus on the development of highly specialized generic drugs, especially for the areas of oncology and transplant.

Main infrastructures

CINFA has two industrial plants for the manufacture of its own products, both located in Navarra. The first has an area of 17,000 m^2 and manufactures most of CINFA's production. The second was constructed on a plot of 48,000 m^2 and it consists of a building for the storage, management and dispatch of orders, a laboratory equipped with cutting-edge technology and an oral-solids manufacturing plant to produce highly specialized generic drugs.

Achievements and future prospects

Apart from being the leading in Spain, pharmaceutical company in terms of the volume of sales through retail pharmacies, CINFA is a leading company in its several business strategies. Regarding the generic drug market, CINFA is the leading Spanish company with a 24.62% market share. Currently, one in four generic drugs in Spanish homes is sold by CINFA and the company has sold over 500 million units since 1998.

CINFA is ranked first among the Spanish pharmaceutical companies in the OTC sector. In the Orthopedics market, the Farmalastic brand is the leader in pharmacies with a market share exceeding 45%.

All in all, CINFA keeps on researching and focusing on new business lines to meet the needs of society in different areas of healthcare.

Product development

Support Services

Digna Biotech, S.L.

> Product development (Therapeutics and Diagnostics)

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Contact Person

Jesús Hernández (CEO)

Product development

General description

Digna Biotech is a biotechnology company created as a spin-off of the Centre for Applied Medical Research (CIMA) of the University of Navarra in Pamplona. With 25 employees, Digna Biotech is dedicated to the development of innovative therapies for unmet medical needs in strong collaboration with CIMA and other entities at the University of Navarra (CIFA, Clinical Universidad de Navarra and several Schools of the University of Navarra). DIGNA conducts preclinical studies and clinical trials with the final objective of adding value to the products in order to obtain license agreements with pharmaceutical companies that could complete the development of the products and reach the market. From its conception, the company possesses an extensive series of products and technologies which have been licensed from CIMA.

Priority areas

Oncology, Neurosciences, Hepatology, Cardiovascular diseases, Dermatology, Ophthalmology.

Products, services and/or technologies

The company possesses more than 30 patents, covering therapeutic and diagnostic products as well as methods of use:

Therapeutic products in development:

- Phase III: P144. Dermatology (Scleroderma, skin cancer, actinic keratosis).
- Phase II: IFN. Hepatology (Hepatitis C).
- Phase I and Phase II: CT-1. Hepatology (Liver Transplant and Resection) and Nephrology (Kidney Transplant).
- Phase I: Vector AAV-PBGD. Hepathology (Acute Intermittent Porphiria). In co-development with uniQure.
- Preclinical:
  - P144: Ophtalmology (Chorneal Haze and Dry Eye).
  - P17: Fibrosis (Lung Fibrosis in Systemic Sclerosis) and Ophthalmology (Age-related Macular Degeneration).
  - MTA: Immunology (Multiple sclerosis)
  - MMP10: Hematology (Thrombosis, Stroke).
  - Inh-MMP10: Hematology (Bleeding treatment).

Diagnostic products:

- Preliminar validation:
  - Osteosarcoma markers: Oncology (Osteosarcoma).
  - DNA mutation detection test.
- R&D:
  - MTA Prognostic treatment markers for Multiple sclerosis.
  - Metabolomic prognostic markers for Multiple sclerosis.

Achievements and future prospects

Digna has developed 4 new biological (NBE) or chemical (NCE) entities into clinical trials and it is currently in conversations with several companies to license out those products. The strong pipeline of the company anticipates the succession of current products with those from the the pipeline once the first products are licensed.

Digna has signed agreements with Spanish and International companies (Biotechnol, uniQure, Genentech) as well as spin-out new companies (Hepacyl, Formune) around products from the pipeline with a common focus in a particular therapeutic area.

ForMune S.L.

> Therapeutics and Diagnostics

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Contact Person

Thomas Zürcher (CEO/ Director general)

General description

ForMune has been created in October 2012 as a spin-off from DIGNA biotech and is dedicated to the development of therapeutic vaccines for the treatment of chronic infections and cancer. The company owns a proprietary, novel platform technology based on recombinant proteins incorporating an endogenous ligand for TLR4 fused to disease specific antigens and aims to progress its first vaccine candidate to clinical studies.

Created by SODENA, Caja Navarra and Inveready, together with the biotechnology company, Digna Biotech, as a technology partner, aims ForMune to out-license and/or co-develop products with industrial partners once effectiveness in humans has been demonstrated.

Priority areas

Therapeutic vaccine R&D based on EDA-platform technology.

Products, services and/or technologies

The development of new therapeutic vaccines is essential for the treatment of chronic infections and tumours. Adjuvant EDA (Extra Domain A of Fibronectin) activates dentritic cells (DC) through TLR-4 and the EDA-antigen fusion technology ensures the simultaneous antigen targeting to DCs, expression of co-stimulatory signals and DC maturation. EDA-antigens have shown improved anti-viral or anti-tumoural T cell responses and excellent vaccine efficacy in animal models. The company's R&D activities can count on the strategic support of DIGNA biotech and the close alliance with the group of Dr. Juan Jose Lasarte at the CIMA who discovered and developed the EDA technology.

ForMune has selected EDA-HPV as its first development candidate for the cure of cervical cancer, the second most prevalent cancer in women and will focus in the next 2 years on the preclinical development of EDA-HPV and discovery efforts to progress a second vaccine to candidate selection.

Achievements and future prospects

EDA-antigen vaccines generate strong immune response based on TLR-4 specific cell targeting, DC stimulating /maturation and CTL activation and EDA-HPV has demonstrated excellent efficacy eliminating large tumors in a relevant animal model.

ForMune has secured patent protection for the EDA-technology platform and its lead product and has obtained financing to advance its first candidate vaccine to safety and efficacy testing in humans.

Product development

Laboratorios Ojer Pharma, S.L.

> Therapeutics

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Contact Person

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(Managing Partner)

General description

Ojer Pharma is a pharmaceutical company, a University of Navarra spin-off, founded in 2005 under the Centre for Research in Applied Pharmacobiology (CIFA) and the Scientific and Technological Institute of Navarra (ICT).

The laboratory has two major founders: the University of Navarra Foundation (FUNA) and the promoter, Mr. Carlos González Ojer. Additionally, there are the following shareholders: SODENA (Sociedad de Desarrollo de Navarra), two venture capital funds "Ronda Vida" and "Real de Vellón" managed by Clave Mayor and Caja de Ahorros de Navarra.

In collaboration with the University of Barcelona (SDM- UB), has developed an innovative technology (bioadhesive gels) that allows guiding more effectively and safely a range of topical molecules (both lipophilic and hydrophilic) for the treatment of dermatological diseases.

Over the last 5 years the company has developed clinical and non-clinical studies. According to the results, the bioadhesive gel remains at the site of action for a period of 6 to 8 hours acting as a sustained release matrix. This technology facilitates compliance treatment by the patient.

This technology generates a bioadhesive film on the skin that makes unnecessary the use of dressing pads and its transparency facilitates the patient treatment compliance.

Due its innovative features, the technology can be applied to a range of topical molecules so the company is looking for partners interested in the co-development of projects based on such technology.

Priority areas

Dermatology.

Products, services and/or technologies

Ojer Pharma is focused on the dermatological area and its portfolio comprises innovative products both medical device as Rx medicine and OTC medicine. These products are indicated in the treatment of skin infections, ulcers and skin protection.

Main infrastructures

Ojer Pharma has incorporated a business management tool that arose as a result of the tho-rough investigation of current organizational models of R&D. The R&D Management Unit (referred to as "UGIDI" according to its Spanish abbreviation) is an unparalleled system to manage research, development and implementation activities, in compliance with a number of rules (UNE 16600X) that conform with European regulations to guarantee both the quality and success of R&D activities.

We maintain collaboration agreements with spanish universities and research centers that allow us to develop innovative pharmaceutical forms.

Achievements and future prospects

Ojer Pharma recently obtained the the MODERNA Certificate besides having EIBT Brand (Technology Based Business) through the National Association of Spanish BICs (ANCES). Ojer Pharma has also been awarded SME status by the European Medicines Agency.

Product development

ProRetina Therapeutics S.L.

> Therapeutics

info@proretina.com
www.proretina.com

General description

ProRetina is a spin-off from the Center for Biological Research (CIB-CSIC) that is developing the results in neuroprotection obtained by the Laboratory of Development, Cell Differentiation and Degeneration at this intitution.
The company develops drugs for the treatment of ophthalmological diseases, specifically retinal dystrophies and degenerations.
The main investors of the company are Caixa Capital Risc, Clave Mayor, Inveready Seed Capital, SODENA and the founding partners.

Priority areas

Ophthalmology.

Products, services and/or technologies

One of their target projects is the preclinical and clinical development of a neuroprotective factor for the treatment of retinitis pigmentosa.
The company is also working on a gene therapy approach to treat retinitis pigmentosa.
In December 2008, the FDA and the Committee for Orphan Medicinal Products of the EMA adopted the designation of Orphan Drug for Proretina´s neuroprotective factor.

Achievements and future prospects

ProRetina has taken a product from academia to the preclinical stage of development in a very short time, completing the manufacturing of the active ingredient and formulation in less than one year. The company has also obtained orphan drug designation and secured patent protection for its leading product.

Product development

3P Biopharmaceuticals S.L.

> Contract Manufacturing Organization - CMO

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Contact Person

Dámaso Molero (CEO)

General description

3P Biopharmaceuticals is a GMP certified CMO (Contract Manufacturing Organization) specialized in the development and manufacture of biologics and cell therapy products, from proof of concept to commercial phase.

3P is a biotechnological company with the capacity and resources to produce biologics of the highest standard and quality, such as that demanded by the EMA for third party use. 3P aims to become a leading CMO in the European biotechnology sector, capable of successfully participating in the development of projects and in manufacturing processes within key international markets, thereby contributing to the enhanced health and well-being of our society. 3P Biopharmaceuticals has the support of key regional government agencies, financial institutions, and pharmaceutical and biotechnological companies.

Priority areas

3P´s target clients are Biopharmaceutical and Biotech companies actively developing biopharmaceuticals and/or diagnostic procedures, Multinationals requiring additional and flexible processing capacity with a quality system comparable to their own “Quality Standards”, Research Centers and international companies from countries outside the EU that require official approval for their products from the EMA in Europe and the FDA in the USA.

Products, services and/or technologies

Manufacture of biologics:

> Proteins: Recombinant proteins, native proteins, monoclonal antibodies, fusion proteins, Vaccines and Biosimilars.
> Other biological molecules: Peptides, Lipids, Carbohydrates and Complex molecules.

Advanced therapy products:

> Advanced Therapy Medicinal Products: Cell therapy products and Tissue engineered products.
> Intermediate products: Cell culture media and Biomaterials (scaffolds or membranes).

3P Biopharmaceuticals offers the following services to its clients:

> Generation of protein expression systems.
> Development and validation of analytical methods.
> Generation and characterization of MCB and WCB.
> Cell bank storage.
> Development of stability studies.
> Release of raw materials, drug substances and drug products.
> GMP and Regulatory consulting assessment.
> Fill & finishing.

Main infrastructures

> A production plant of 4,600 m where the capacity for development and production can be increased according to the needs of the client and/or the market.
> Equipment and processes adapted to GMP specifications.
> State of the art equipment:
  > Prokaryotic Area: fermentors 10L, 100L, up to 1,000 L.
  > Eukaryotic Area: bioreactors 50L, 200L, up to 2X200L (disposable).
  > R&D Area for full process development.
  > QC and QA Area.

Achievements and future prospects

Due to its new production capacity, over 2,000 liters, and its new “Fill and Finishing” line, 3P will increase its production capacity to produce up to commercial phases, as well as to develop and produce biosimilar products.

Support services

Bionanoplus S.L.

> Drug Delivery Technologies

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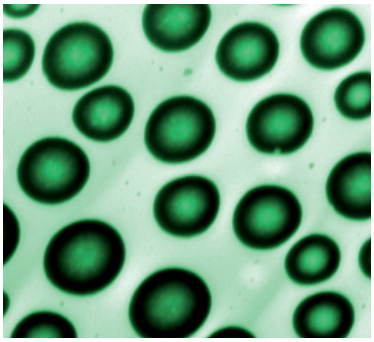
Contact Person

Hesham Salman (Founder and CSO)



Support services

General description

Bionanoplus was founded in 2010 thanks to its founder efforts that was able to raise funds from venture capital firms such as StartUp Capital Navarra and Inveready Technology Investment Group.

The company provides real solutions based on nanotechnology to overcome delivery problems in various types of industries such as: pharmaceutical (mucosal drug delivery, vaccination and immunotherapy), cosmetic, food, and agrochemical, always aiming to offer high quality and applicable innovative products.

Bionanoplus has developed different technology platforms based on polymeric nanoparticulate systems that allow tackling delivery, processing, and efficacy issues of therapeutic and non-therapeutic molecules with cheap, easy to scale-up proprietary technologies that fit market needs and regulatory requirements.

Bionanoplus' team has more than 10 years of experience in nanotechnology and drug delivery fields with high capabilities in Intellectual Property Management and technology innovation.

Priority areas

> Pharmacy (Oral and ocular drug delivery vaccination and immunotherapy).
> Veterinary vaccines (Microbial infection).
> Cosmetics and personal care.
> Agro-food.

Products, services and/or technologies

Bionanoplus has developed different technology platforms called *Adaptive Polymeric Platforms* (APPs) which permit the development of nanotech products with simple and easy innovative processes. These APPs are based on the company patents:

> I) Cationic Micro E Technology: Technology based on the *in situ* formation of self-assembled cationic bioadhesive microemulsions after oral administration, thus enhancing the oral bioavailability of mainly class III drugs.
> II) NANO-GES Technology: Technology based on mucoadhesive poly-anhydride nanoparticulate platform that allows the buccal and dental delivery of anti-microbial agents or sublingual vaccination.
> III) SANP Technology: Technology based on the *in situ* formation of self-assembled polymeric matrix nanoparticulate systems composed of vegetal food grade proteins which are suitable for the oral administration of Nutraceuticals and omega-3 oils.

Based on these technologies, Bionanoplus has developed its own products for:

> Oral delivery of anti-neoplasic drugs.
> IV delivery of peptides.
> Treatment of Alopecia.
> Buccal delivery of antimicrobials.
> Vaginal delivery of hormones.
> Sublingual or mucosal vaccines.

Our service is aimed to develop real and easy solutions to our clients based on R&D tasks including:

> Development, optimization, characterization and scale-up of polymeric nano and microparticles to increase therapeutic efficacy of bioactive molecules.
> Analysis and efficacy evaluation in appropriate animal models.

Achievements and future prospects

All of the surveys highlighted the growth forecasting, market needs and commercialization challenges for nanotechnology companies.

High processing costs, problems in the scalability of R&D towards prototypes, industrial production and the basic research orientation of the field and concerns about health and safety issues (especially public perceptions of these issues) have emerged as key challenges.

Bionanoplus is completely aware of these challenges and thus an adaptive flexible and hybrid operating model has been selected to solve many problems related to growth forecasting, and market needs. Since 2010, Bionanoplus owns three patents and four products that are currently under outlicensing process.

CibNavarra-Consultora de Investigaciones Biomédicas de Navarra

> Quality control and regulatory consultancy

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Contact Person

Idoya Calvo
(CEO and Senior Consultant)

General description

CibNavarra is a consultancy agency specialized in pharmaceutical R&D and other healthcare related products.
CibNavarra is a personal iniciative of Idoya Calvo, CEO and Senior Consultant of the company, from her 20 years experience as professor and director of the quality assurance unit in the University of Navarra, and as an expert of the EMA.
CibNavarra has 4 employees and collaborates in the evaluation of the most recent products approved by the EMA.

Priority areas

The company has two focus areas:

> Optimization of resources for Biotech and non-Biotech products and processes requiring special development.
> Development of integrated management systems combining different systems to manage Quality Control that are applied on a case by case basis, according to the UNE166000 standard (R&D and innovation management).

CibNavarra´s target clients are biopharmaceutical companies with R&D activity related to drug development and that of other health products (cosmetics, medical devices, novel foods, etc...). Their customers include: Digna Biotech, 3P Biopharmaceuticals, Progenika and Lactest, among others.

Products, services and/or technologies

The company's main services are focused on strategic project development and registration of new products, quality assessment, training, incorporation of new technologies in project management, vendor evaluation, evaluation of records, evaluation of the CTD of new products and pre-official audits.
CibNavarra carries out its own R&D activity in relation to the development of management systems supported by ICT applications and its objective is to achieve an informatics tool to optimize management resources through specific indicators, prioritizing projects and taking appropriate decisions based on objective data from the organization under study.

Achievements and future prospects

CibNavarra aims to become the reference supplier to define regulatory strategy and quality control for biopharmaceutical R&D, as well as providing an integrated software application to manage R&D for medicines and other health products, with specific indicators that serve to rank projects and prioritize business decisions.

Support services

GeiserPharma S.L.

> Pharmaceutical Development

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www.geiserpharma.com

Contact Person

Carlos Yañez (Scientific Director)
David Zubeldía (CEO)

General description

Geiser Pharma offers its worldwide partners the possibility to carry out Pharmaceutical development activities from the initial selection of alternatives to the final registration, including the licensing and supply of the final product (Pharmaceutical Development, Clinical Studies, Regulatory and Licensing). The main goal is to focus its portfolio and services on selected products that have additional value and involve the application of advanced technologies, including niche products. Geiser Pharma uses its know-how and experience in the selection and design of these products. Geiser Pharma complements R&D activities with a well experienced team in business development and commercial strategies in regulated markets.

Priority areas

Non standard pharmaceutical dosage forms.

Products, services and/or technologies

The company offers the following services:

> Business Intelligence - market analysis and opportunity selection.
> Pharmaceutical Development - DMF evaluation, IP analysis and legal strategies, API analysis, Pre-formulation and formulation, Scale-up and Implementation, Pilot Batches, Manufacturing Process Validation, Stability studies, Expert report.
> Clinical studies - CRO selection, Clinical study protocol, Clinical Experts report, Bibliography.
> Regulatory affairs - Regulatory affairs strategies, Dossier compilation and submission, Regulatory support.
> Business Development: Customer selection, Commercial agreements in EU, Networking for Commercial activities.

The company also offers a wide range of non-standard different dosage forms such as:

> Microeffervescent technology direct to mouth.
> Hard lozenges.
> Liquids and tablets.
> Injectables.
> Oral dispersible technologies.
> Effervescents.
> Soft gel capsules.
> Lyophilized.
> Semisolids.

Achievements and future prospects

Currently the company is running up to 30 added valued and niche projects for its two business lines, contract research and out licensing. Geiser Pharma focuses both these lines on the European Market, but in the near future it plans to enter the US, and it is evaluating new business lines to be implemented by the company.

Support services

Product development

IDIFARMA, Investigación, Desarrollo e Innovación farmacéutica S.L.

> Pharmaceutical Contract Development Organization

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www.idifarma.com

Contact Person

Luis Oquiñena (CEO)

Support services

General description

IDIFARMA is a leading Contract Development Organization and Specialty CMO for the pharmaceutical and biotechnology industries, carrying out all experimental, documental and advisory activities that a new or generic drug may require to obtain the Marketing Authorization, and being a suitable industrial manufacturer for oral solid projects.

IDIFARMA has a proven track record and a reputation for high quality and compliance with deadlines. There are four key elements in any pharmaceutical development carried out by IDIFARMA for any of its 100+ clients: Confidentiality, compliance with regulatory requirements, industrialization-transferability and knowledge of the patent landscape for each project.

IDIFARMA, with over 11 years in the market, has an experienced staff of 75 people, most of them with university degrees, and offers a "one-stop-shop" service for any pharmaceutical development: drug formulation, development and validation of analytical methods, quality control and batch release in the EU, GMP manufacturing, ICH stability studies, clinical trial logistics management and regulatory support.

IDIFARMA is an authorized pharmaceutical laboratory and it counts with Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP) certifications.

Priority areas

High potency: IDIFARMA has expertise in the development of highly potent pharmaceutical products in different dosage forms (oral, injectable, etc).

Specialty CMO: IDIFARMA is authorized as a GMP manufacturer of investigational/clinical batches and human use/industrial batches. Its state-of-the-art facility features a purpose-built high containment plant for the manufacturing of GMP-compliant batches in oral solid dosage forms, for both conventional and high potency drugs (cytotoxic, hormonal...), as well as placebo.

Spray Drying technologies: In its ongoing effort to find appropriate technological solutions to address existing formulation challenges, IDIFARMA has recently installed top-level Spray Drying equipment. With this equipment, IDIFARMA provides their clients a comprehensive solution to solubility, stability and bioavailability problems from formulation to scale-up production applying the latest micro and nanoencapsulation technologies.

Products, services and/or technologies

Based in Navarra (Spain), and with an increasingly international reach, IDIFARMA provides a full range of services to turn an active substance into a pharmaceutical product ready to be approved by Regulatory Agencies: formulation and analytical development, technology transfer, quality control and batch release, stability studies, clinical trial and industrial GMP manufacturing (including high potency products), clinical trial supply (packaging and labeling), regulatory support, optimization of manufacturing processes, etc.

Our experienced technical staff has developed almost 100 generic and innovator drugs for our clients, in different dosage forms (oral solids and liquids, injectable, topical use, etc). We are specialized in the development of high potency drugs (cytotoxics, cytostatics, hormonals,...) and we have the capacity to work with many different technologies: film coating, spray drying, modified release, etc.

Main infrastructures

Recently built in 2008, our 2.800 m^2 laboratory is divided in 3 main areas: Formulation laboratory, Analytical & Quality Control Laboratory (including stability chambers and a microbiology laboratory) and GMP manufacturing area (clinical and industrial GMP batches manufacturing and clinical trials labeling/packaging activities).

Achievements and future prospects

IDIFARMA specializes in the development of complex products, such as: high potency products (oncologicals and hormonals), low solubility products, sustained release products, innovative pharmaceutical forms (transdermal patches, microtablets,...) and formulations containing peptides.

The internationalization of the company is the challenge for the future. IDIFARMA is a well established company in the Spanish market and has been steadily growing in important European markets (Germany, Netherlands, Switzerland, Denmark, Hungary, etc), with over 100 clients ranging from small start-ups to Big Pharma.

pharma modelling
Modelización cinética y dinámica

Pharmamodelling S.L.

> Drug discovery

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Contact Person

Onintza Sayar (CEO)

Support services

General description

Pharmamodelling S.L. is a pharmaceutical consulting company specialized in clinical trials. Pharmamodelling S.L. gives support to the pharmaceutical companies involved in drug development. It improves the results using new modelling techniques that save time and money along drug development.

The company is owned by the entrepreneur Onintza Sayar and SODENA, although the company has also support of financial institutions.

Pharmamodelling S.L. is expert in data analyzing using pharmacokinetic/pharmacodynamic modelling. This method helps to identify and validate therapeutic targets. It allows analyzing biomarkers, as proof of mechanisms along drug development. It is also possible to perform allometric scaling, as well as to extrapolate from specific populations, this method assess proof of concept, and bioequivalence studies along drug development.

Priority areas

Although Pharmacokinetic/pharmacodynamic (PK/PD) modelling is not a new science, in recent years it has advanced significantly through the development of Monte-Carlo based simulation programs that can be used to design and simulate clinical trials. This approach is a powerful extension of classical PK/PD modelling as it integrates an established PK/PD model with estimates of variability.

Products, services and/or technologies

The main services offered by Pharmamodelling are:

> **Population pharmacokinetic and pharmacodynamic modelling.** Thanks to drug modelling it is possible to plan and design clinical trials, it is possible to define correctly patient populations, as well as to optimize the number of data and parameters to be measured as it helps to reduce variability. Basically, it allows focusing the project in the really precise variables.

> **Add value in the design and development of clinical trials.** The advice in pre clinical trial design helps to reduce sampling times, as well as the number of animals, and it helps to identify significant covariates to bear in mind. In clinical trials, population modelling gives advice to adjust sample size and sampling times, to identify covariates and key points to take care along drug development. Population modelling serves to identify promising and non promising drugs trying to eliminate the lasts as soon as possible, providing as a result an efficient design in the trial to optimize the resources during research, and eliminate early projects that will not become and economic feasible product.

> **Biostatistics analysis,** gives answer to hypothesis, organization of the research system as well as organization of the general and sampling design, it gives answer to the quality of information and the presentation of results. All of these allow agile and trustworthy information.

> **Bioequivalence studies.**

Achievements and future prospects

In 2006, the Pharmamodelling project received an EIBT award from the Government of Navarra in recognition of its role as a Technology Based Innovative Enterprise. Moreover, the Pharmamodelling project won a “Best Business idea from PhD” Ideactiva award in 2007. Pharmamodelling S.L. began its activities in 2010 and it was finalist of Young Innovative Company and Entrepreneur XXI, both national prizes in 2011.

Pharmamodelling is currently entering the International market as it has developed medium size partners in Mexico. Pharmamodelling has signed already several agreements with medium size national companies for the outsourcing services.

cima
CENTER FOR APPLIED MEDICAL RESEARCH
UNIVERSITY OF NAVARRA

Centro de Investigación Médica Aplicada (CIMA)

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Contact Person

Jesús Hernández (COO)

Research center

General description

The Center for Applied Medical Research (CIMA) of the University of Navarra was inaugurated in 2004 as a result of fifty years' experience in the School of Medicine and the University Clinic of Navarra, as well as the Schools of Science and Pharmacy and the Center for Research in Applied Pharmacobiology. It also has a close relationship with the Schools of Engineering and Nursing. The main purpose of the center is to carry out high-quality scientific work in the service of humankind, combating diseases that cause great suffering and for which no cure has yet been discovered.

Around 350 professionals from 25 countries work in CIMA in cooperation with other international centers to bring pure research closer to its clinical application. The biotechnology company Digna Biotech is in charge of developing the patents of CIMA's discovery in order to obtain new products for diagnosis and treatment.

Priority areas

The interdisciplinary work carried out by physicians, biologists, biochemists, pharmacists, engineers, laboratory technicians and other professionals is organized into four priority research divisions:

Products, services and/or technologies

> **Gene Therapy and Hepatology:** 1. Study of the mechanisms of liver diseases; 2. Investigation on viral hepatitis, liver cirrhosis and liver cancer; 3. Identification of novel hepatoprotective therapies; 4. Development of gene therapy for the treatment of liver diseases.

> **Cardiovascular Sciences:** 1. Unravelling the mechanisms through which hypertension damages the myocardium and the arterial wall, unravelling mechanisms leading to thrombosis in atherosclerosis; 2. Developing circulating biomarkers for early detection of injuries caused by such mechanisms; 3. Identifying new therapeutic targets of such mechanisms to design more effective treatments of heart failure and cerebral and cardiac ischemic events.

> **Neurosciences Division:** 1. Study the basis of neuronal death in the brains of Alzheimer's patients, the involved cellular mechanisms and the origin of memory loss; 2. Discovery of methods for early diagnosis in mild cognitive disorder, which may lead to more effective treatments; 3. Explore new therapeutic approaches in Parkinson's disease to promote neuronal regeneration and differentiation; 4. Employing neuromodulating techniques, such as deep brain stimulation, to modify abnormal activity in the circuits of the basal ganglia.

> **Oncology:** 1. Improving diagnosis and predicting the response to treatment for prostate, breast and colon cancer; 2. Looking for new therapies which attack specific molecular targets to fight these tumors. 3. Finding in lung cancer, how tumors develop until they invade other organs; 4. Exploring new treatments to correct genetic disorders in leukemia and lymphoma and producing new therapies for clinical trials; 5. Isolation of stem cells from adult tissues, and their use in different debilitating and incurable illnesses.

As backup for the work in all 4 research divisions there are 2 core facilities: Proteomics, Genomics and Bioinformatics and Imaging; and 3 support services: Biological Sample Bank, Instrumental techniques and Small molecule discovery platform.

Achievements and future prospects

CIMA takes part in all the competitive research programs on a regional, national and international level. It is recognized by the Ministry of Economy and Competitiveness as a Center of Technology and takes part in one of the groups in the first program of Strategic National Consortiums in Technical Research (CENIT). It also belongs to the Thematic Networks of Cooperative Research of the Carlos III Institute of Health. CIMA is experienced in 7th EU Framework Programme, and participates in 20 FP7 projects: 9 collaborative projects, one of them coordinated by CIMA, 7 Marie Curie grants (mobility of research personnel), 3 ERANET grants and one European Research Council Starting Grant which started on 2012 (1.5 million). Also, CIMA receives financial support from private american societies such as Leukemia Research Foundation and the Alzheimer Association.

The center has produced 55 patents from the four main Research Areas, 33 of which involved with Gene Therapy techniques. CIMA works in close collaboration with the University Clinic of Navarra, with whom it has developed more than 20 clinical trials.

FideNa (Fundación I+D en Nanotecnología)

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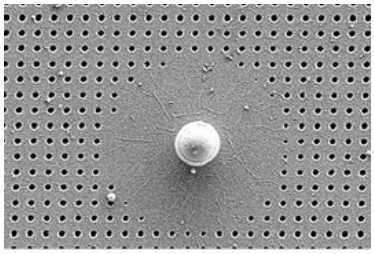
Ernesto Bravo (CEO)



Research center

General description

FideNa (Foundation for R&D in Nanotechnology) is a research center working since 2007 with the goal of fostering the use of nanotechnology by the industry in Navarra. Navarra is a strong industrial region of Spain home to some major players in Renewable Energies, Biotech, Automotive & Food Processing.

One target of FideNa is to develop technology that can be transferred to industry. In order to do this, FideNa is located on the campus of the university of Navarra (UPNA) and carries its own R+D+i lines, some of them in collaboration. FideNa has a team of 17 people (growing), with several years of experience in nanotechnology & tech transfer.

FideNa is organized in three main areas: nanofab, nanobio, nanomat. These areas allow the centre to provide services to the four most relevant sectors in Navarrian economy: automotive, agri-food industry, energy and biomedicine.

Particularly nanobio is an area where FideNa works intensively, and has developed the following expertise & applications:

> **[expertise]** development of nanobiohybrid systems, of biomolecules & nanoparticles (NPs) or nanostructured surfaces. Optical sensors based on Localized Surface Plasmon Resonance (LSPR). Functionalized nanoparticles as nanobio probes & nanobio carriers.
> **[applications]** LSPR biosensors using NPs or nanostructured surfaces for detection of analytes & biomarkers. Nanobio probes for signal amplification (enhanced ELISA, LSPR) & nanobio carriers for smart delivery.

Products, services and/or technologies

FideNa carries out external R+D projects for companies; participates as a partner in consortiums; provides technology consultancy & training; and pursues its own R+D lines.

Particularly in nanobio FideNa has a multidisciplinary team (Molecular Biologists, Chemists & Engineers) with experience in:

> Biomolecule handling (DNA, antibodies or other proteins).
> Immunoassay & biosensor performance.
> Fabrication of nanostructured surfaces on large areas & NPs of different materials in controlled shapes and sizes.
> Biofunctionalization of surfaces & NPs with biomolecules for application in sensors, drug delivery, therapy, bio-catalysis...
> Optical simulation of biofunctionalized systems.

Achievements and future prospects

FideNa is already participating in several projects in nanobio, funded by the Regional Government of Navarra and from the Spanish Ministry of Science and Innovation. It has also gained funding from the program EuroTransBio from the EU, and has presented several projects to the FP7 calls of 2013 both as partner and as coordinator. FideNa collaborates with some of the major players of biomedicine in Navarra: Universities, IdAB, IDIFARMA, 3P Biopharmaceuticals...

FideNa works to become the reference entity in nanobio in Navarra within the next years, contributing to the development of niche opportunities in drug delivery, diagnosis, sensing, medical imaging... and always in collaboration with the rest of the agents active in the field of biomedicine in Navarra.

Instituto de Agrobiotecnología - IdAB

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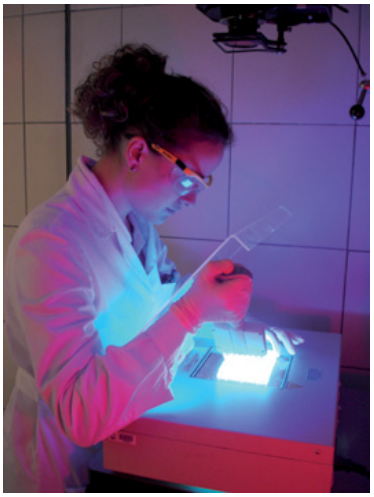
Contact Person

Iñigo Lasa (CEO)



Research center

General description

Founded in July 1999, the AgroBiotechnology Institute (IdAB) is a joint Center belonging to the Public University of Navarra (UPNA), the Spanish Higher Scientific Research Council (CSIC) and the Government of Navarra.
With over 70 employees, the main health-related research carried out in the Center involves the use of molecular biology to understand relevant disease mechanisms and to develop tools related to: diagnosis, prophylaxis, immune response and biochemical processes of infectious diseases; the development of plants as biofactories of health-related substances; and plant, microorganisms' and animal metabolism, physiology and genetics with different implications in health.

Priority areas

The Center focuses its Agrobiotechnological efforts in two main lines of work: Biotechnology in Animal and Plant Health, and Plant Biotechnology. In each of these areas there are 3 research groups focusing on Microbial Biofilms, Animal Health and Microbial Bioinsecticides in the former and on Carbohydrate Metabolism, Plants as Biofactories and Agrobiology and Plant Physiology in the latter case.

Products, services and/or technologies

The Center focuses on Agrobiotechnological research areas of biomedical interest through the efforts of the following research groups active in health related areas:

> **Microbial biofilms:** The work of this research group is centered on the impact of biofilms in the development of chronic infections in live tissue (mastitis, otitis, pneumonia, urinary infections, osteomyelitis) or problems related to medical implants, among others. The research focuses on the mechanisms employed by bacteria to form and maintain these multicellular communities; the influence of biofilm lifestyle on the infectious process associated to bacteria and resistance to anti-microbials; the identification and characterization of the molecular and biochemical mechanisms involved in the formation of Biofilms of pathogenic bacteria and vaccine development against biofilm bacteria. The main microorganisms studied so far are *Salmonella* and *Staphylococcus*.

> **Animal-human health:** The work of this research group is centered on applying novel immunological and molecular biology techniques to understand host-pathogen interactions and on to develop vaccines and diagnostic tools for livestock and zoonotic infections caused by bacteria and viruses. Immunological issues are addressed at the molecular, cellular and individual levels. Genetic analysis is performed at the microorganism and host levels. The knowledge generated on the genetic, biochemical and antigenic characterization of the microorganism can be applied to the fields of pathogenesis, molecular epidemiology, prophylaxis and diagnosis of the corresponding infections. The main microorganisms stu died so far are Salmonella, Brucella, Haemophylus, lentivirus (Maedi Visna) and mastitis pathogens.

> **Plants as biofactories:** The work of this research group is centered on the production of transgenic plants as biofactories of substances of biopharmaceutical and therapeutic interest (compounds and vaccines). Gene expression in chloroplasts is the technology used in some of these areas, and specific transgenic plants are generated where necessary (generally through chloroplast transformation). Distinct ilsolation and purification techniques are applied to obtain the different substances and novel vaccines.

> **Carbohydrate metabolism:** The work of this research group is centered on the study of glycogen and starch metabolism in plants and microorganisms. Plants producing high levels of starch are being generated with different industrial applications (biopharmaceutical, food, cosmetics, bio fuel, etc.). Novel technical approaches in metabolic engineering and metabolomics are employed by this team.

Achievements and future prospects

The research carried out and the technological advances achieved at the IdAB lead to publications in internationally recognized journals, patents of applied and practical interest, technology transfer to industry, student training on Masters, Technology and Doctoral programmes, and the development of new enterprises (including spin-offs). The personnel presently belonging to the Center have produced/commercialized 24 patents in the last 10 years (up to 2012).

L'Urederra

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Contact Person

Claudio Fernández (CEO)

General description

L'Urederra is a non-profit, private Technological Center that mainly applies its knowledge of technical research to innovation in the area of new materials, with special emphasis on nanotechnology, polymer processing, biotechnology and advanced environments, with the aim of transforming this knowledge into industrial value.

L'Urederra has 52 employees and it was created in June 1999 by the association of seve-ral public authorities, financial organisations, R&D organisations and companies in diverse productive fields. The organisation is a Spanish CIT (Center of Innovation and Technology) recognised by the Spanish Ministry of Science. In its short lifetime, the center has become very active in European research and it has participated in key areas of a large number of projects.

Priority areas

Materials technology related to biomedicine is the main area of activity at L'Urederra, focusing on the following fields:

- **Production and modification of nanoparticles:** This field not only involves the manufacturing of simple and complex nano-oxides of a small size and high purity, but also the physical-chemical treatment of nanoparticles for their subsequent use in dispersions and polymeric materials. These nanoparticles can be used in many sectors, like biomedicine.
- **Non-metallic materials:** This field is centerd on advanced materials, including multicomponent systems with controlled response and sensorised intelligent materials that may form part of special delivery systems in biomedicine.
- **Fine chemistry:** These activities are based on the synthesis of special organic fun ctional chemicals that are of interest to the pharmaceutical industry, such as organic and inorganic coupling agents, or intermediate precursors for complex reactions and sophisticated polymers.

Products, services and/or technologies

On the one hand, L'Urederra cooperates with companies and other agents providing standard services, such as support for the optimisation of industrial lines or production problems, and to rapidly resolve specific needs.

On the other hand, L'Urederra develops its own technological activities that are generally protected by patents. In the biomedical area, a patent titled "Hyperbranched polymers based on cyclodextrine and poly(amidoamine) for the controlled release of insoluble medicines" has been applied for. This invention relates to controlled release systems for drugs, and in particular it involves the use of hydrophilic polymers, poly(amidoamines) (PAA), that can complex with highly hydrophobic drugs and dissolve in water vehicles. In particular, this is being applied to antitumoral drugs, although other drug types are under study, such as antivirals, so that they can also be administered by injection.

In this sector, L'Urederra also participates in a project titled "Multifunctional nanoparticles for detection and treatment of biofilms" (MNP-Biofilms), the main objective of which is the development of a new vector based on nanosphere-encapsulated magnetic nanoparticles to detect and treat bacterial biofilms produced by microorganisms, mainly Staphylococcus Aureus (S Aureus). The most important task carried out by our center in this project is the production of the magnetic nanoparticles, carried out at the nanoparticle production plant. This is the only installation of its type in Europe, with a continuous production capability in the range of 1Kg/h, producing small nanoparticles, between 7 and 25 nanometres, of very high purity and with very little agglomeration. This plant is currently being expanded a production capacity of 5kg/h, by far the largest in the world.

Achievements and future prospects

In terms of achievements in the biomedical area, our center has a wealth of experience in the development of several types of materials and in the preparation of nanoparticle dispersions. The materials dealt with include nanoparticles, principally oxides that can be prepared as simple, complex or doped, nanocomposites or advanced polymers for different applications.

Research center

NAVARRABIOMED

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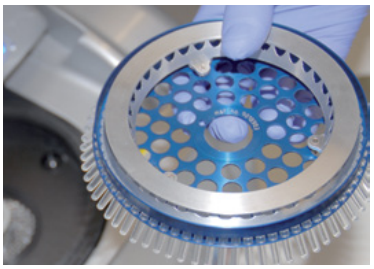
Contact Person

Jose Mª Roig Aldasoro (CEO)



General description

Navarrabiomed is a non-profit, public research centre in Navarra Region. It was created and originally named "Navarra Biomedical Research Centre" (CIB) in 1997, to provide technical assistance to the scientific community within Navarra Public Health Service-Osasunbidea.

In October 2012, CIB is integrated into the structure of the Miguel Servet Foundation with a brand new name "NAVARRABIOMED" and would maintain its full functionality.

The aim of the centre, in the framework of the aims and objectives as stated in the Health Strategy by the Health Department, is to boost biomedical research within Navarra Public Health Services and (Government of Navarra).

Research undertaken by the centre is mainly translational and its priorities areas are Onco-hematology and Neurosciences. The centre has 4 technological core facilites: Proteomics, Flow Cytometry, Genomics, biobanks. There are also a number of support services to facilitate research: Methodology, Clinical Trials and R&D&i Project Management Unit.

Priority areas

Though the main priority areas are Onco-hematology and Neurosciences, there are other important research areas such as Mental Health, Epidemiology, Primary & Public Health.

Achievements and future prospects

Navarrabiomed is the scientific platform to provide services to health professionals within the public health sector who are willing to investigate.

The activity at the centre contributes to the development of translational research, and its results are implemented in public hospitals. This is translated into improved health services for the benefit of patients. In addition to this, Navarrabiomed helps in meeting the technological needs of the biomedical sector by offering its services to private sector and therefore; complementing existing technologies and contributing to the economic development of Navarra through research and development activities.

Navarrabiomed understands the importance of having quality assurance systems in place. We have successfully achieved the implementation of ISO-9001:2008 in Clinical Trials, Biobanks and R&D&I Projects Unit.

Navarrabiomed is working towards expanding the implementation of the standard progressively to all its services.

In addition to this, the centre will have GMP rooms available for researchers.

Research center

Universidad de Navarra

> University

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Research Management Service
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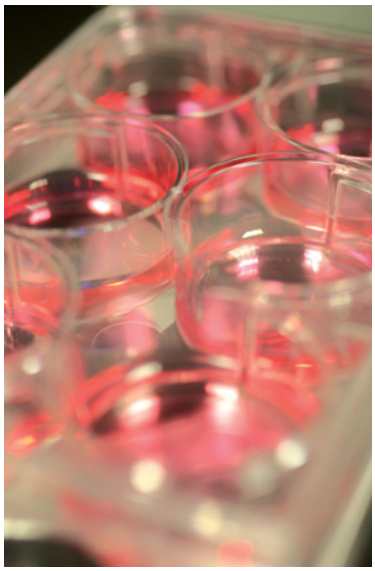
Contact Person

Fernando de la Puente (Director R&D)



University

General description

University of Navarra (UNAV) is a private university, offering a prestigious research in the field of Biomedicine, through the faculties of Medicine, Pharmacy and Science.

UNAV seeks to differentiate itself throught a distinct knowledge that comes from an interdisciplinary research. This knowledge is oriented to society. The fostering of the culture of entrepreneurship and a formation oriented to society provide the key piece to the system for generating innovation and providing value to the productive infrastructure. At its teaching and research centers, global talent is generated and attracted. All of this will contribute to improving the quality of life, culture and environmental consciousness of the society.

Priority areas

Main areas of research include: Preclinical Drug Development Studies (from idea to clinical studies); Pharmaceutical Technology Unit including Mucosal drug/antigen delivery and Nanotherapy and biomaterials; and Genetics Unit.

Products, services and/or technologies

1. Preclinical Drug Development Studies:

> Drug Formulation Unit:
  > Design and formulation studies.
  > Chemical reactivity and forced degradation studies.
  > Process development optimization.
  > Excipient compatibility studies.
  > Preliminary process identification.
  > Commercial formulation development
> Analytical and Bionalytical Unit: covered by GLP standard.
  > Development and validation methods.
  > Sample analysis for clinical and non-clinical studies.
  > Chromatographic Analysis:
  > ICH Stability Studies.
> Toxicology Unit: studies under GLP standards using different dose regimens, model species (from rodents to non-human primates) and routes of administration (parenteral, enteral, topical, subcutaneous, oral, ocular,...).
  > General Toxicology: single dose toxicity studies, repeated dose toxicity studies and Immunotoxicology studies.
  > Specific Toxicology: Local Tolerance (topical, intramuscular, subcutaneous), Skin and eye irritation/corrosion, Mutagenicity and Genotoxicity.
  > Pharmacokinetics and Toxicokinetics Studies.
  > Expertise in Animal Development Model.
  > Efficacy Studies: in vitro and in vivo models.
> Pharmacokinetic and Pharmamodynamic-Modelling Unit:
  > Physiological and mechanistic models to correlate drug dosage with pharmacological responses.
  > Prediction of clinical response to drugs in the different development stages.

2. Pharmaceutical Technology Unit:

> Mucosal drug/antigen delivery:
  > Vehicles for oral drug administration of poorly soluble and permeable drugs.
  > New adjuvants for vaccines and immune therapy through the mucosa.
> Nanotherapy and biomaterials:
  > Improvement of controlled release systems for polymeric and lipidic micro and nanoparticles.
  > Development of non-toxic, biocompatible and biodegradable biomaterials.

3. Genetics Unit:

> Genetic research on different types of Leukemia: search for new chromosomal rearrangements and evaluation of diagnostic and prognostic implications.
> Genetics in cellular mechanisms.
> Bioinformatic analysis of genes involved in chromosomal translocations in cancer.

Achievements and future prospects

Since its inception in 1952, the University of Navarra has consolidated its activity around the diagnosis and treatment of major diseases. It´s continuous commitment to life sciences and biomedicine is reflected in the creation of a series of new research infrastructures. One of the cornerstones of UNAV is the Horizon 2015 Project. Through this project, UNAV has already established the Center for Neglected Diseases and (until 2015) we will see the emergence of new Research Centers: Center for Nutrigenomic Research and the Center for Bioengineering, in the coming years.

They will operate in close cooperation with the University of Navarra, the University Clinic and the Center for Applied Medical Research (CIMA).

Clínica Universidad de Navarra

Clínica Universidad de Navarra (CUN)

> Healthcare center

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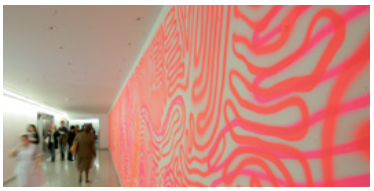
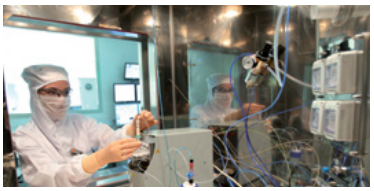
Contact Person

Gabriel Canel (Director R&D)





Healthcare center

General description

The University Clinic of Navarra is a private healthcare center owned by the Universidad de Navarra. This association is one of the most relevant characteristics of the Clinica, since it fully complements the excellent clinical practices and patient attention with elements of research and teaching.

The Clinica has over 2.000 employees and it aims to remain at the forefront of scientific innovations/progress in order to offer a leading, innovative and integral medical service. The Clinica is also committed to ongoing training and teaching at all levels, from undergraduate training where it works very closely with the School of Medicine at the University of Navarra, to many specialized training programmes.

Priority areas

As a general hospital, the University Clinic of Navarra treats all prevalent diseases. However, the research carried out focuses strongly on oncology, cardiovascular diseases, neurological diseases, obesity and nutrition, in tight collaboration with the Schools of Medicine, Pharmacy and Sciences at the University of Navarra, as well as the Center for Applied Medical Research (CIMA). These close ties allow the Clínica to cover the whole process of therapeutic and diagnostic product development, from basic R&D to clinical practice.

Products, services and/or technologies

Over the course of the last four years (2008-2012) the Clínica participated in more than 250 clinical trials, collaborating with a large number of pharmaceutical companies. Almost half of these trials were in the fields of Medical Oncology (29.8%) and Hematology (18.3%), although despite this concentration, the trials covered a total of 27 different medical areas, including Cardiology, Neurology, Dermatology, among others.

In addition, the Clínica also conducts and promotes its own trials. Between 2008 and 2012, the entity carried out 27 clinical trials in the areas of Internal Medicine, Hematology, Oncology, Cardiovascular research and Neurology.

The Clínica engages in trials at all stages of development, ranging from pilot studies to phase IV. Of the more than 250 trials in which the Clínica has participated, Phase I represents 15.2%; Phase accounts for 38.4%; Phase III covers 41.1%, while 4% were conducted in Phase IV.

Approximately 2,700 individuals have participated in these trials over the last four years.

The clinical trials in the area of Oncology are particularly important, and as such, a specific unit with exclusively dedicated staff manages the nearly 60 Oncology related trials carried out, with the participation of over 400 patients.

Achievements and future prospects

As a university hospital the University Clinic of Navarra is dedicated to advancing current medical knowledge. Hence, it is actively involved in research projects at both the national and international level, and it participates in various thematic networks.

As a result, the University Clinic of Navarra often generates industrial property and the entity's Doctors frequently publish their scientific findings in high caliber international publications.

ARPA Abogados Consultores

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Contact Person

Fernando Armendáriz (Director of the Legal Consultancy Department)

General description

ARPA Abogados Consultores is a law firm that was set up in 1991 in Pamplona, by their foundational partners which have more than 25 years experience providing economic, taxation, and legal assistance within the business field.

Currently it counts on more than 55 specialized employees, qualified to provide direct, constant and efficient assistance.

Such commitment compels us to keep the highest quality at all times therefore we are always betting on improvement and formation of both our professionals and our processes and services which are our main pillars.

ARPA Abogados Consultores is a member of Eurojuris International, one of the most important Law-Firm Network worldwide.

This Network has offices in more than 40 countries, therefore, it has access to more than 7000 lawyers all around the world and this will guarantee legal coverage for clients, no matter where they are.

Priority areas

Practice areas:

> Trade & Corporate.
> Tax.
> Litigation.
> Labour.
> Economic.
> Administrative.
> Urban.
> New technologies.

Multidisciplinary teams:

> Pharma and Biotechnology .
> Venture Capital.
> Family Business.
> Holding Companies.
> Energy and Environment.
> Foundations.
> International Law.
> Corporate Compliance.
> Town consultancy.
> Sports Law.
> Agro-Food Sector.
> Enterprising.

Products, services and/or technologies

Design and starting up:

> Definition of the business model.
> Design of the Company´s plan.
> Writing and negotiation of the shareholders´ agreement.
> Creation of Companies.
> Advising of the Administration Board of the Company.
> Hiring of research personnel.
> Confidentiality agreement.
> Service agreement and collaborative frame agreements.
> Legal protection of knowledge.

Consolidation:

> Production contracts.
> Technology transfer agreements.
> Assignment, license and/or co-development agreements.
> Tax, legal and financial Due Diligence.
> Companies´ assessment.
> Entry of new investors.
> Specific Tax Advice.

Project monitoring:

> Commercial Exploitation agreement.
> Internationalization.
> Stock Market capitalization (SMC).
> Divestiture process.
> Mergers, acquisitions.

Tecnical assessement:

> Management of public aids.
> Regulatory Road-maps.
> Definition and review Ad-Hoc of Development Plans.
> Technical Due Diligence.
> Orphan Drug Designation (EMA-FDA).
> Design and/or review of Technical Documents (IMPD/IB/CTAs).
> Scientific Advice.
> Design and validation of registration Dossier (e-CTD).
> Application for registration process (Europe, USA, emerging markets).

Achievements and future prospects

ARPA Abogados Consultores has a broad experience in advising the different agents who work in the pharmaceutical and biotechnological sector (Private and Public Companies, Universities, Technology and Research Centers, Venture Capital Companies, Foundations,..) This experience makes the law firm be able to fully advise projects of Research, Development and Innovation in all the phases of his life cycle.

CENTRO EUROPEO DE EMPRESAS E INNOVACIÓN navarra

Centro Europeo de Empresas e Innovación de Navarra - CEIN S.L.

> Regional Government Agency

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Contact Person

María José Fernández Iraizoz
(Project Manager)

General description

CEIN, the Business Innovation Center in Navarra, is a regional business innovation agency that provides assistance to prospective entrepreneurs and SME's in order to promote economic development through the creation of enterprises and the promotion of innovation. With more than 70 employees, CEIN encourages entrepreneuship, helps start up projects to develop and support businesses grow and innovate. CEIN is a nonprofit organization depending on the Government of Navarra. CEIN's working methodology is constantly searching for innovative services and new business opportunities or economic development projects in collaboration with other European regions.

CEIN S.L is the result of the merger between CEIN S.A and ANAIN (Innovation Agency of Navarra), in October 2011.

Priority areas

> The creation and consolidation of innovative companies.
> Support to entrepreneurs with new ventures and innovative start ups.
> Business incubator services.
> Promotion of collaborative R&D projects and the participation in the international R&D space.
> Fostering collaboration and coordination among the triple helix entities: Science–Technology – Enterprise.
> Technological transfer and strategic watch.
> Awareness and communication of the benefits of innovation to the Navarra society.

Products, services and/or technologies

Its main support service areas are:

> Promotion of entrepreneurial values in society, specifically in schools, universities and other groups.
> New Business creation support: specific services for new ventures and technology based companies: agile entrepreneurship, entrepreneurs grants, business expert advice, training programs, networking, financial advice, coaching.
> Growth and consolidation of existing companies: Business incubator, training programs, cooperation, networking and mentoring services.
> Detection of new business opportunities for Navarra.
> Innovation promotion: events, training, workshops, publications.
> Navarra Factori: center of excellence in creativity and innovation with a broad range of activities to foster innovation and specially equipped to get it.
> Coordination of the "Technological Network for Navarra" (RETECNA).
> Management of the Navarra´s Innovation Park.
> Management of www.navarrainnova.com, Navarra's Innovation website.
> Participation in certain programmes, such as the EU-funded Euroinnova Navarra, Sharebiotech etc.
> Training programmes for innovative, effective and modern entrepreneurs and SME's.

Two specific services for the biomedical field are:

> **Entrepreneurial Support and preincubation**
The objective of this service is to build-up innovative projects, with suitable professional, scientific and technological support to launch those projects on the market. Inspired by the most successful European experiences in this field, the Navarra Technology based innovative Enterprise (EIBT) Program supported new EIBT projects for several years. (not active now)
> **Business Incubator**
The Business Center is based at CEIN's own premises on the Polígono Industrial Mocholí (Noáin) industrial estate, 7 kilometres from the city of Pamplona. The center covers an area of 4,186 m^2, divided into a total of thirtynine 35 and 55 m^2 offices/business premises, and 100 to 400 m^2 industrial buildings.

Achievements and future prospects

In accordance to the MODERNA Plan, the main target for the biomedical sector is to encourage its companies' growth and development. By providing services specially designed for these companies, CEIN will enhance the sector's potential growth and generate wealth and employment in Navarra.

Clave Mayor S.A.

> Venture capital

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Contact Person

Ricardo Pérez (Managing Director)

General description

Clave Mayor is a Venture Capital management company that was established in June 2002 through the activities of its founders for more than 10 years in "Mergers and Acquisitions". The company currently employs 16 professionals and its capital is entirely private. Clave Mayor has developed an extensive understanding of the Biomedical sector and it now has a strong reputation among those involved in this sector. Similarly, it has a good network to study any kind of investment proposal worldwide.

Priority areas

The financing of Health Sciences companies with a special interest in Biomedical, Medical Devices and Diagnostics.

Products, services and/or technologies

This venture capital company manages over 10 venture capital funds: Arista Viva, Tres a Partner, Agora Mayor, Punto Futuro, Ronda TIC, Ronda Innovación, Comval Emprende, Ronda Viva, Real de Vellón and Seguranza.
Indeed, Clavemayor has invested in several Spanish Biomedical companies: IDIFARMA, Vivotecnia, 3P Biopharmaceuticals, Ojer Pharma, Vivia Biotech, Clavesuan Desarrollos Biomédicos, Proretina Therapeutics, Gadea Pharmaceutical Group, Activery Biotech, Biotica Bioquimica Analitica, TCD Pharma, Hepacyl, Cytognos.
Ronda Vida is the fund that is specifically dedicated to the Health Science market. Clave Mayor manages a total investment of 25 M euros in this area of knowledge.

cajanavarra

Fondo Comunal de Caja Navarra

> Venture capital

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Contact Person

Javier Martínez
(Investment Director)

General description

Following the former "Plan de Inversiones Navarra" Caja Navarra has recently launched a new initiative called "Fondo Comunal" to manage the portfolio of companies in Navarra in which Caja Navarra holds stakes, and to promote its interest in new companies. The target is to promote the region entrepreneurship and development and to protect the quality employment.

Concerning the Biotech sector, Caja Navarra focuses in the development of the biotech cluster as a source of innovation, talent, investment attraction and qualified employment.

The business model of Caja Navarra is fundamentally based on taking minority stakes in unlisted companies settled in Navarra, catering for pre-agreed disinvestment mechanisms to facilitate the active turnover of investments.

Caja Navarra has a unique network to identify projects and analyses investment proposals. It exhaustively monitors the companies it holds stakes in and it has a proven track record since 2000. The strategy of Caja Navarra is to participate in business projects at all phases of development: from seed and start ups to matured profitable companies, usually with participative loans and equity investments as the most common financial instrument.

Priority areas

> Biomedical companies.
> New Technologies.
> Renewable energies.
> Other sectors and projects capable of creating employment.

Products, services and/or technologies

Caja Navarra through its "Fondo Comunal" initiative has a committed investment In 10 companies, 3 of which are in the biotechnological sector. The investment in biotechnology enters directly to the companies:

> Direct investment: 3P Biopharmaceuticals,
> Ojer Pharma and ForMune

Achievements and future prospects

Caja Navarra considers the medical Biotechnology sector a high priority in Navarra and works actively looking for new opportunities in this sector.

Fundación Moderna

> Economic Development Partnership

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Contact Person

Begoña Vicente (Project Manager)

General description

The **MODERNA Foundation** is a public-private non profit organization in charge of developing the regional economic development strategy (The MODERNA Plan) through a distributed leadership model. We launch collaborative actions and projects in a flexible and decentralised way through the **MODERNA Teams.**

> **We support the pilot projects** that test future solutions with a consensus model and results.
> **We form mixed teams** of professionals who make change possible in their own sectors and work environments.
> **We seek leaders** to promote the actions agreed in the Plan.

To achieve the goals, the Foundation applies a bottom-up model: all the good ideas to foster competitiveness are discussed in teams where all the relevant actors participate, and the projects are monitorized and connected by the MODERNA Foundation.

In 9 months, the Foundation has launched 90 projects of improvement of the economic conditions and 250 projects of SMEs.

Priority areas

MODERNA contains the challenges that the economy of Navarra faces, and defines the strategy and major action lines towards 2030 in the areas of **Green Economics, Health Economics and Talent Economics.** To this end, the plan lists up to 458 actions to be executed in the different strategic sectors and transverse factors reinforcing the competitiveness of our economy.

> Finance

The MODERNA Foundation gives access to the finance instruments of MODERNA:

> **Entrepreneur MODERNA grant:** 35 per year.
> **BEI-MODERNA credit line:** 250 M€ from the European Investment Bank for the advantaged financing of "MODERNA Businesses" with SODENA.
> **MODERNA co-investment found:** Mechanisms of co-investment involving public and private investors.
> **MODERNA Investors forum:** 4 forums per year.
> **MODERNA bank guarantee for business financing:** Public complement for funding projects (30% - 60%) with SODENA.

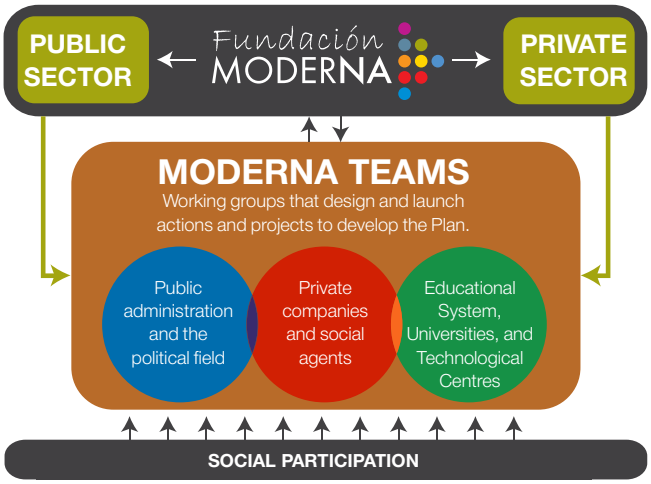
> Cluster Management

This service is aimed at fostering biomedicine cluster initiatives, synergies and collaboration leading to the identification and implementation of new collaborative projects in any area (infrastructures, knowledge, R&D, marketing, etc.). The main cluster management activities are:

> Support Services in order to enhance the competitiveness of regional companies.
> Dinamization of sectorial clusters in the areas of Health, Environment and Talent.
> Organization and management of thematic/sectorial panels.

Achievements and future prospects

The MODERNA Plan is a medium and long-term strategic plan that fosters change in the economic development model of Navarra, moving towards a knowledge-based economy that focuses on people.



Sociedad de Desarrollo de Navarra (SODENA)

> Venture capital

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Contact Person

CEO: Carlos Fernández Valdivielso

Biotech Investment Manager:
Mª Eugenia Lecumberri

General description

SODENA is the key investment instrument of the Government of Navarra for business development in the region, with more than 150 M€ committed in 65 different investments.

SODENA carries out its activities as a public limited company that actively and prominently participates in different phases of business projects which contribute to the balanced and sustainable development of Navarra.

Venture capital is the main financial instrument used in these projects, a constant feature since SODENA was constituted in 1984, usually taking the position of co-investor.

SODENA is composed of 19 employees and it leads business projects that private investors are not undertaking sufficiently but are considered strategic.

SODENA's activity is focused on:

> Generation of local projects.
> Attraction of investment for Navarra.
> Development of Navarra's companies abroad.

SODENA´s strategy is to participate in business projects in all phases of development, from seed/start ups to mature projects, and it considers the Biomedical/Biotechnological sector a high priority for the region of Navarra.

SODENA also offers support for the internationalisation of companies that wish to set up operations in other countries.

Priority areas

The strategic sectors where SODENA is going to focus its investment activities are:

> Biotechnology.
> Renewable Energy.
> Agrifood.
> ICTs.

Products, services and/or technologies

SODENA has committed 10 investments in the biotechnological sector. The biotechnology investment is both direct in the companies and indirect through investment funds.

> Investments in Biotechnological companies: CIMA-DIGNA Project, 3P Biopharmaceuticals, Idifarma, Ojer Pharma, ProRetina Therapeutics, Albyn Medical, Wasserlab, Formune.
> Investments in Funds: Ysios BioFund, Suan Farma Biotech, Inveready, Start Up Capital Navarra.

Achievements and future prospects

The companies where SODENA invests already generate around 600 positions and thanks to SODENA's continued investment since 1996, Navarra can boast that it has all the necessary means to carry out the full cycle of drug development.

SODENA's main strategy for the development of biotechnology is to invest in setting up and managing a portfolio of biotech companies devoted to the development of molecules that will serve as future human therapeutic drugs, as well as attack new companies or new offices of existing ones to settle down in the region (Big Pharmas, R&D Laboratories, Production Plants, ...).

Biotechnological core facilities

The Biomedical sector in Navarra is supported by excellent research and innovation facilities that can be made available to any interested Biopharmaceutical and Biotechnological company or research institution.

The main biomedical facilities and equipment available at the universities and research centers in Navarra are detailed below:

Universidad de Navarra

Universidad de Navarra
(University of Navarra)

- **Unit of Organic Chemistry:** this unit provides services associated with molecular modelling and design. The unit offers:
  - Analytical equipment, with infra-red technology, Magnetic Nuclear Resonance, spectrophotometers, Chromatographers, among others.
  - Molecular modelling equipment, with computing equipment´s and software (Almond 2.0.8, Amber 8.0; Autodock 3.0.5, among others).
- **Pharmaceutical technology Unit:** this unit offers services associated to pre-formulation design and study, and the selection of formulations. The unit is equipped with analytical equipment, such as spectrofluorometers, spectrophotometers, gas and liquid chromatography equipments (Ultraviolet, Electrochemistry, Fluorescence, Masses), among others.
- **Pilot Plant Production Unit:** this unit offers semi-industrial scale production through the use of disintegration/dissolution speed equipment, microscopes, as well as other laboratory equipment.
- **Analytical Unit:** The Analytical Area can offer a full method development and validation, technology transfer, and tailoring of methods for specific requirements.The unit isequipped withLC-MS (TOF; Ionic Tramp; QqQ); HPLC-UV; HPLC- Fluorescence; GC-MS;Capillary electrophoresis (CE) – DAD and Differential Scanning Calorimetry (DSC). Moreover, the Analytical Unit offers stability studies in controlled temperature and humidity conditions according to ICH guidelines (Controlled T/HR Climatic Chambers).

- **Animal facility:** housing a wide range of animal species including large animals, such as monkeys and groundhogs. Actually the animal facility has been reformed until a total of 2,425 m^2 of which 625 m^2 are composed of clean and mixed areas for rodents, together with 28 rooms for housing and/or working with rodents. The remaining 1,800 m^2 are dedicatedto large animals or farm animals (sheep, pigs, minuature pigs and hybrids, etc.), as well as an animal surgery facility.

NAVARRABIOMED

Domains of expertise and services offered
Pathological and molecular mechanisms definition and biomarker detection/identification in cancer and neurodegenerative diseases are the main activities of the Unit.

PROTEOMICS UNIT
The Unit offers global proteome analysis based on the following specific services:
> Consultancy on proteomic workflows.
> Experimental design.
> Different peptide fractionation methods.
> Protein identification by LC-MS/MS.

The Proteomics Unit participates actively in Accredited Training Technical Courses based on Clinical Proteomics recognized by the Spanish Laboratory Technicians Society (AETEL).
The proteomics lab takes part in the following projects:
> Proteomic expression profiles of different breast cancer subtypes.
> Molecular characterization of specific pharmacological resistance in colon cancer.
> High-throughput proteomic/peptidomic analysis of specific human brain subproteomes.

Contact:
Enrique Santamaría (esantamma@navarra.es).
Joaquín Fernández-Irigoyen (jfernani@navarra.es).

GENOMICS
Our experience is based on the analysis of molecular alterations and gene expression in cancer, related to survival and response to treatment, in tumour samples and in vitro cell lines.
> Genomics, Epigenetics and Bioinformatics.
> Pharmacogenetics.
> Epigenetic analysis .
> Sequencing and CGH-arrays: from January 2013.
> Pyrosequencing: from January 2013.
> Methylation arrays : from January 2013.
> Data analysis and functional clustering: from January 2013.

Contact:
David Guerrero, PhD. (dguerres@navarra.es).

BIOBANK
Navarra Public Health Service Biobank is a service platform, with the aim of improving the scientific knowledge in biomedical research providing high quality human samples and their associated data to the scientific community according to a precise ethical and legal setting that assures the donor rights.
It is part of the Spanish National Biobank Network, an initiative of the Carlos III Health Institute.
The Biobank facilities are able to provide human samples for the study of the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses – including, but not exclusive, cancer, neurodegenerative diseases or genetic disorders.
> Brain Bank: Nervous system tissue and cerebrospinal fluid of various neuropathological disorders and healthy donors.
> Tumour Bank: Tumour and normal tissue, serum and DNA of various kinds of malignancies and healthy donors.
> Other tissue and biological samples.

Contact:
Isabel Gil-Aldea, MD, PhD (isabel.gil.aldea@navarra.es).

L´Urederra

> A nanoparticle production plant capable of producing 1 kg/h of highly pure nanoparticles, mostly oxides (simple, complex or doped), phosphates and carbonates, of very small size and with very little agglomeration, suitable for use in biomedical applications.
> Nanoparticle production equipment with a capacity to produce 100 g/h of a wide variety of very small size nanopowders with a narrow distribution, and with the possibility of working under GMP conditions for their use in sectors such as the pharmaceutical or biomedical industry.

Centro de Investigación Médica Aplicada - CIMA

> **Proteomics, genomics and bioinformatics Core Facility.**
Provides biological information for researchers in order to identify diagnostic and therapeutic targets and determine the mechanisms by which drugs function.

> **Imaging Core Facility.**
Offers full service support to all CIMA laboratories in the areas of imaging and quantitative image analysis.

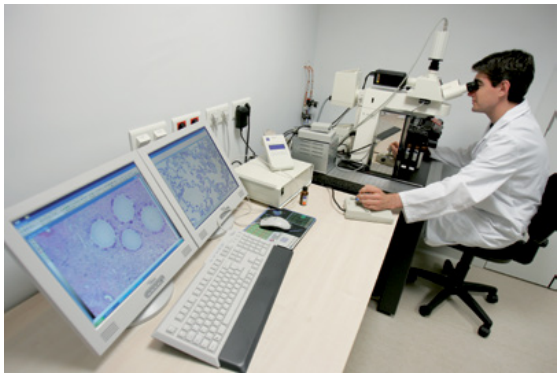
Support services:

As backup for the work in all 4 research divisions, there are 3 support services:

> **Biological Sample Bank:** this service, belonging to the University of Navarra, collects, stores and provides human biological samples for research. Furthermore it provides a service in histological techniques through the Morphology Core Facility.

> **Instrumental techniques:** Irradiator (inactivator of cell proliferation and experimental bone marrow transplant in mice), cytometry (identification and separation of cell populations marked with fluorochromes), microPET (positron emisión tomography for use with animals), sequencing (reading of DNA bases), Aptamer Unit and Biostadistic Unit.

> **Small molecule discovery platform:** this unit is focused on small molecule discovery as potential therapeutic agents. This is a transversal platform, involved in different therapeutic areas, working in a multidisciplinary environment where translational medicine plays an important role. Thus, our lines of research are mainly two: Chemical biology (chemical genomics and medicinal chemistry) and Drug discovery informatics.



FideNa

> Clean Room Class 10000.
> Lithography capability for large areas (up to 15 cm^2) that can be used for surface functionalization, to induce biomolecule self assembly and scaffolding, including an E-Beam Evaporator, Interference Lithography Equipment and Reactive Ion Etching.
> High Resolution Carl Zeiss FE-SEM Ultra Plus, with low voltage and charge compensation for biological samples. EDX.
> Analytical equipment with AFM, Spectro-Photometer, Zeta Sizer among other laboratory equipment.
> Optical Microscope.
> Laptop SEM.
> RIE.
> E-Beam Evaporator.
> UV Spectrophotometer.
> UV Spectrophotometer UV-VIS-NIR.
> FPLC.
> Electrophoresis.
> FTIR 4100 LE.
> Micro plates Reader.
> Metalizer.
> Profilometer.

Clínica Universidad de Navarra

Clínica Universidad de Navarra

> **Clinical Pharmacological Research Unit:** the unit is used for Phase I clinical trials and focuses on drug monitoring in the body. The laboratory has a capacity for up to 12 individuals, and it is managed under GLP and GCP conditions.
> **Pharmacy and Pilot Production Plant:** this service is comprised of a Mixture Unit and a Pilot Plant for the production of medicines.
> **Cell Therapy Laboratory:** this unit develops advanced therapeutic products with special emphasis on Hematopoietic ancestor program, idiotypic vaccines, adult stem cell therapy, tissue banks and cancer immunotherapy. All production fully complies with GMP standards.
> **Radiopharmacy Unit:** this unit employs PET technology for in vivo pharmacokinetic studies that are used in clinical trials, adhering to GMP standards.
> **Clinical Genetics Unit:** where genetic alterations related to medical diseases are studied, such as cancer, neurodegenerative disorders and cardiovascular diseases. A specific program was initially set up to detect genetic predisposition for breast and ovarian cancer, as well as a program for the early detection of hereditary colon cancer.
> **Experimental Surgery:** in compliance with all existing legislation, this facility provides practical training for future professionals and further services that support to the pre-clinical research conducted at the Clínica, as well as in other private or public entities.
> **3TESLAS - Radiomagnetic Resonance:** this state-of-the-art installation is used both for treatment and research, and it enables the Clínica to carry out advanced imaging studies, particularly in the area of neurology.

CEIN CENTRO EUROPEO DE EMPRESAS E INNOVACIÓN navarra

Business Incubator– Navarra's Innovation Park

> Space to accommodate start - up companies: there are offices/businesses premises of 35 and 55 m^2, and incubator spaces of 100 to 400 m^2, all available on a global site of 4,186 m^2. All the premises are equipped with their own water and electricity supplies, telephones, Internet access, heating, 24/7 security system, etc. meaning that as soon as a company moves in it can get down to work.
> Business development, strategic advice, support and mentoring services, as well as access to funding, business guidance and training programs tailored to the companies' needs.
> Networking events.

BIOMEDICINE IN NAVARRA

-SPAIN-

Gobierno de Navarra

ShareBiotech

MODELO DE DESARROLLO ECONÓMICO DE NAVARRA MODERNA

January 2013