



Biomedicine in Sardinia: State of the Art and Potentiality

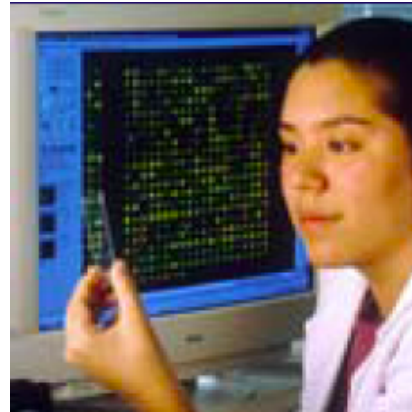
Giovanni Biggio
University of Cagliari

The context paradigm

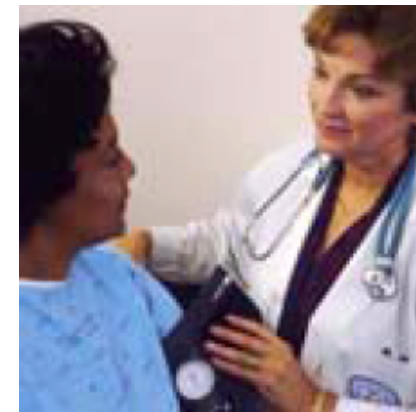
The Future Paradigm: The 4 P's
Transform Medicine from Curative to Preemptive



Predictive



Personalized



Preemptive

Participatory

The context paradigm

Prediction of individual risk for various diseases

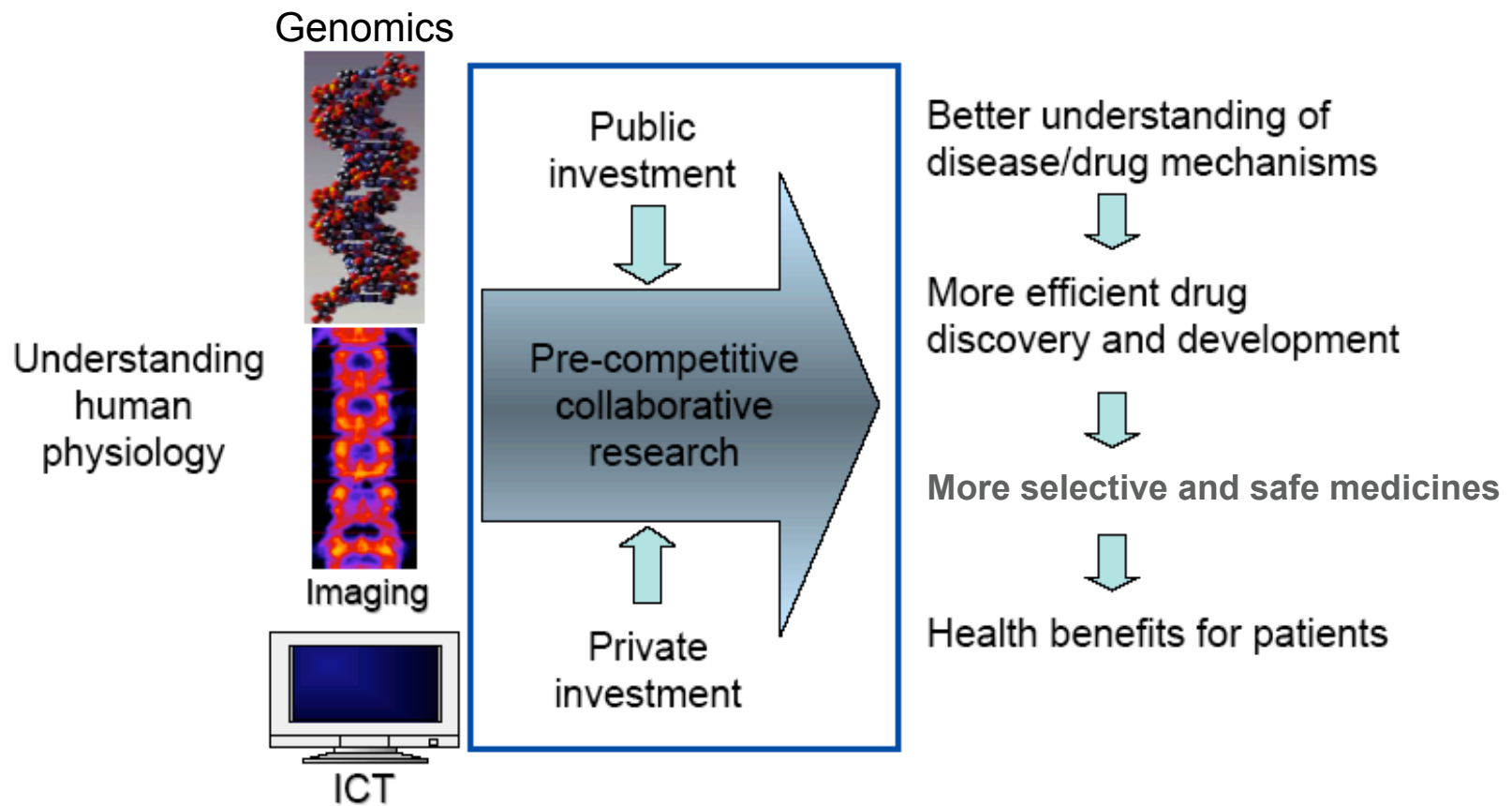
Personalized treatments

Preemption of clinical disease through early detection

Participation in health maintenance

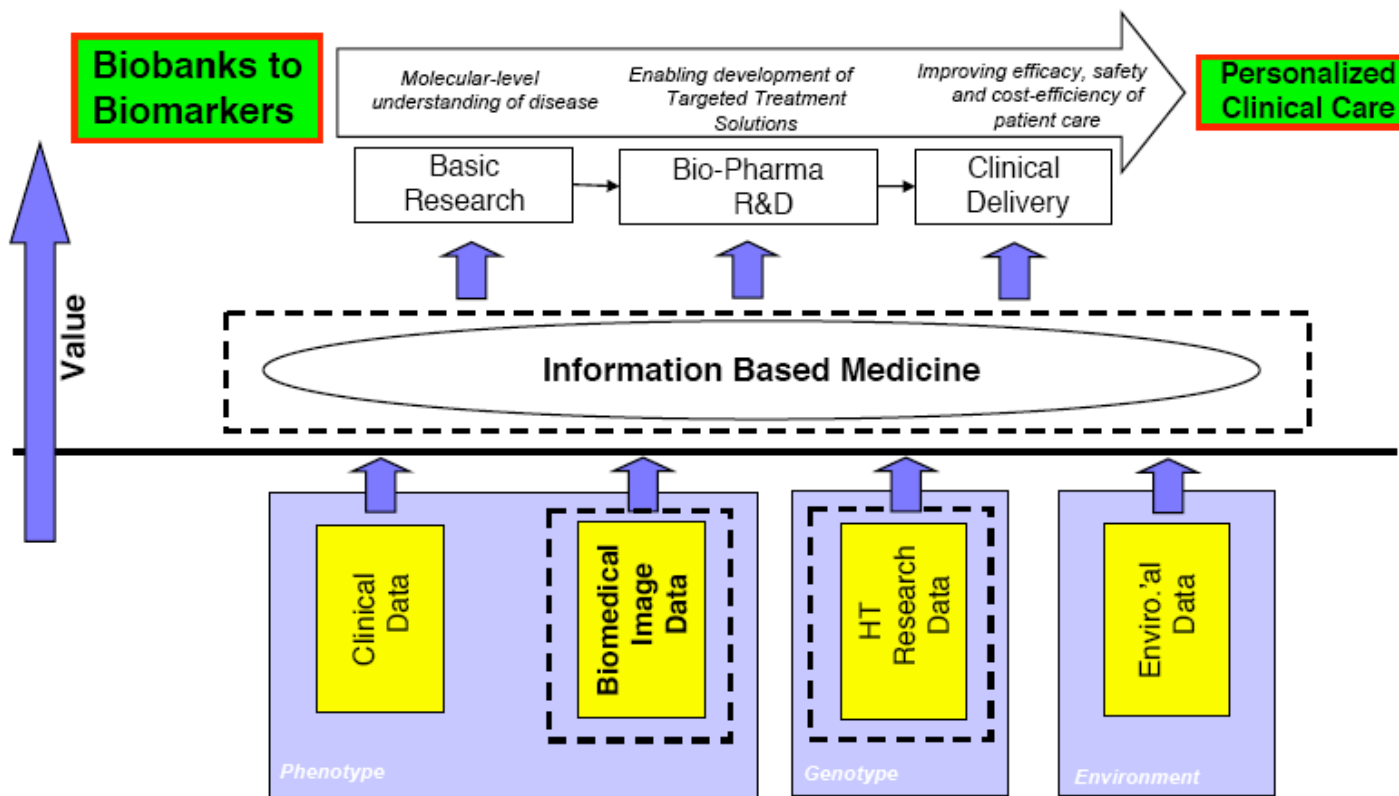
Vision

The advances of science and technology gives new significant opportunities



Information Based Medicine

Clinical Data must be integrated with Imaging, Genotypic, and Environmental Data



Fields of Excellence

ICT - BIOINFORMATICS

Hardware
Software
Communications

GENETICS

Genomics
Bioinformatics
Proteomics

BIOMEDICINE IN SARDINIA

PHARMACOLOGY

Neuropharmacology
Drug Delivery
Device-based drug Therapy
Pharmaceuticals
Diagnostics research

CLINICAL RESEARCH AND TRIALS

Preclinical development
Clinical development

ICT

Sardinia has been a global forerunner in this field:

➤ CRS4,
Center for Advanced Studies, Research and
Development

➤ Polaris, Science and Technology Park of Sardinia

ICT is one of its main areas of specialisation, has fostered over the years the creation of new high-tech companies and the enhancement of specialised resources

- Pole of Excellence for Bioinformatic Technology
- ICT Farm
- Technology platforms: ICTs, Bioinformatics, Digital Television (DTV)

➤ In the next 5 years (2009-2013) a special attention and interest will be given to increase the involvement of ICTs in the Biomedicine Research



GENETICS

Genetic isolates Sardinia displays particular genetic characteristics arising from its geographical isolation and low immigration rate. Isolated communities are precious “tools” for research, for discovering and better defining the genetic factors predisposing to common and multifactor diseases.

INSTITUTE OF POPULATION GENETICS (CNR Sassari)

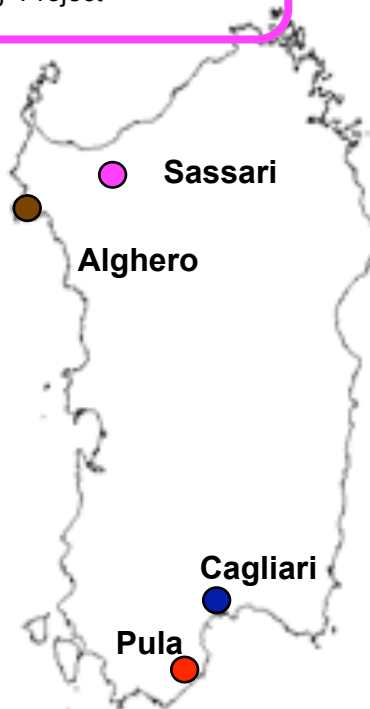
Ogliastra Genotyping Project

UNIVERSITY OF SASSARI (Sassari)

Microbiology Genetics and Biodiversity

PORTO CONTE RICERCHE (Alghero)

Proteomic Biotechnology and agrofood



INSTITUTE OF NEUROGENETICS & NEUROPHARMACOLOGY (CNR Cagliari)

Population Genetics - PROGENIA CONSORTIUM - NIH

POLARIS (Pula)

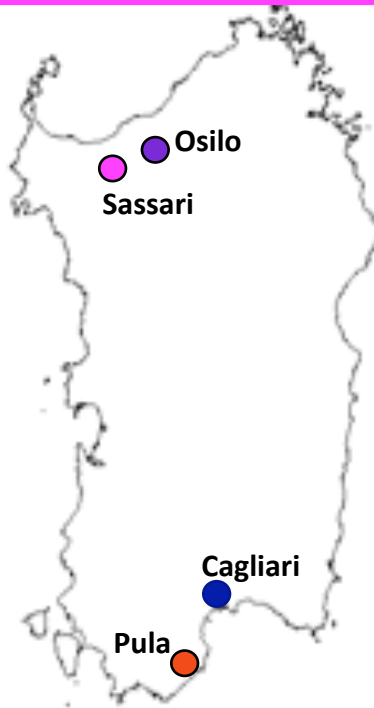
Genotyping , Gene Expression
Profiling and Bioinformatics

PHARMACOLOGY

**RESEARCH CENTERS FOR THE DEVELOPMENT OF
BIOTECHNOLOGY RESEARCH AND FOR THE STUDY OF
BIODIVERSITY IN SARDINIA AND MEDITERRANEAN AREA
(University of Sassari)**

**INBB-Osilo
NATIONAL INSTITUTE OF
BIOSTRUCTURES AND
BIOSYSTEMS**

**BIOTECH AT THE TECHNOLOGY
POLARIS PARK
(Pula)**



**CENTER OF EXCELLENCE FOR THE
NEUROBIOLOGY OF DEPENDENCE AND
MENTAL DISEASES
(University of Cagliari)**

**CNR - INSTITUTE OF NEUROSCIENCE
(Cagliari)**

**Interdisciplinary Center for the development of Biotechnology research
and for the study of Biodiversity in Sardinia and Mediterranean Area
(University of Sassari)**

Faculties involved:

Agrarian
Pharmacy
Medicine
Veterinary
Biology

Goals

- Study of biodiversity in plants and micro-organisms existing in Sardinia related to their ability of expressing a specific quality in the following areas: biomedical-veterinary phytopathologic, food farming, environment and biotech;
- Development of new technologies in order to identify encoding genes of resistance to biotic and environmental stress, for sustainable agricultural systems, or responsible for genetic predisposition to liver cancer;
- Set up of data base of genetic resources in agro-environment field, of micro-organism isolated in Sardinia, of serum and cell;

Research activities are well-integrated with the following educational facilities: Master, PhD courses, Specialisation schools, partnership University – enterprises, relationship with operative structures, cooperation with national and international agencies

Center of Excellence for the Neurobiology of Dependence

University of Cagliari



❖ **Established since 31.01.01 by MIUR (Ministero dell'Università e della Ricerca Scientifica e Tecnologica)**

❖ **Granted**

by MIUR

1.826,192 Euro

by University of Cagliari

456.458 Euro

Center of Excellence for the Neurobiology of Dependence

University of Cagliari



**Department of
Experimental
Biology**

**Department of
Neuroscience**

**Department of
Toxicology**

**CNR, Unit of
Neuropsychopharmacology**

FASE 1 srl

Fase 1 s.r.l. is a company fully owned by the Regional Administration of Sardinia
Position FASE1 among the first initiatives in Italy for the development of new drugs

Its corporate goal is to develop - through clinical research :

- new drugs



- new indications for existing diagnostic tests and drugs



- Pre- and post-patenting selection of new diagnostic and treatment agents, optimisation and preparation for industrial development.
- Clinical development of medicinal drugs and new therapeutic formulations and applications
- Development of procedures and services supporting diagnosis, prognosis and treatment
- Assistance in the development, production and marketing of biotechnology and pharmaceutical products

ORGANIZATION

DEVELOPMENT LINE

- General coordinator
- Project manager
- Technical-scientific expert
- Technical-economic expert
- Staff manager
- Administration assistant
- Secretariat assistant



CLINICAL TRIAL LINE

- Director
- Principal investigator
- Co-investigators
- Quality control expert
- Head nurse
- Nurses
- Pharmacist



SCIENTIFIC AND STEERING COMMITTEE

GIOVANNI BIGGIO

University of Cagliari,
President SSC

ANTONIO CAO

Director of the Institute of Neurogenetics and Neuropharmacology of the National
Research Council (CNR), Cagliari

ENRICO GARACI

President of the National Institute Health (ISS)

GIANFRANCO GENSINI

Dean of the Medical School - University of Florence

GUIDO RASI

General Director of the Italian Drug Regulatory Agency (AIFA)

LUCA PANI

Director of Research at the Institute for Biomedical Technologies (Milan) of CNR

CARLO TOMINO

Director of Clinical Trials Unit at the Italian Drug Regulatory Agency (AIFA)

GOALS

Towards Pharma Companies:

Top-rate services for phase 1 and 2 trials in terms of quality and productivity

Towards trial participants (healthy volunteers and patients):

guarantee competency, respect, courtesy and kindness

For the inhabitants of Sardinia:

- To create local expertise in the field of clinical research and drug production.
- Professional development in the biomedical field



Origgio, 24 settembre 2009

Oggetto: Analisi di fattibilità Progetto di collaborazione Fase I in indicazioni emato-oncologiche

Egregio Dr. Marcheschi,

con la presente, considerato l'esito positivo dell'incontro in data 21 settembre 2009, e il significativo numero di molecole in fase iniziale di sviluppo clinico da parte di Novartis Oncology, desideriamo confermare il nostro interesse ad effettuare un'analisi di fattibilità per il seguente progetto:

Implementazione di collaborazione tra Fase 1 srl- Cagliari, l'Ospedale Businco – ASL 8 Cagliari, e Novartis Farma S.p.A. – Business Unit Oncologia, finalizzato all'implementazione di protocolli di Fase I aventi ad oggetto prodotti in fase iniziale di sviluppo appartenenti alla pipeline Novartis Oncology.

Detto progetto di collaborazione avrà le caratteristiche di cui al documento allegato alla presente sub All. 1 e sarà disciplinato da apposite convenzioni tra gli enti interessati, nei quali andranno definiti i rispettivi ruoli e responsabilità nonché le specifiche tecniche, procedurali e normative da seguire per la corretta implementazione del progetto stesso, oltre agli aspetti economici. Si prevede che la stipula di dette convenzioni verrà finalizzata entro Gennaio 2010

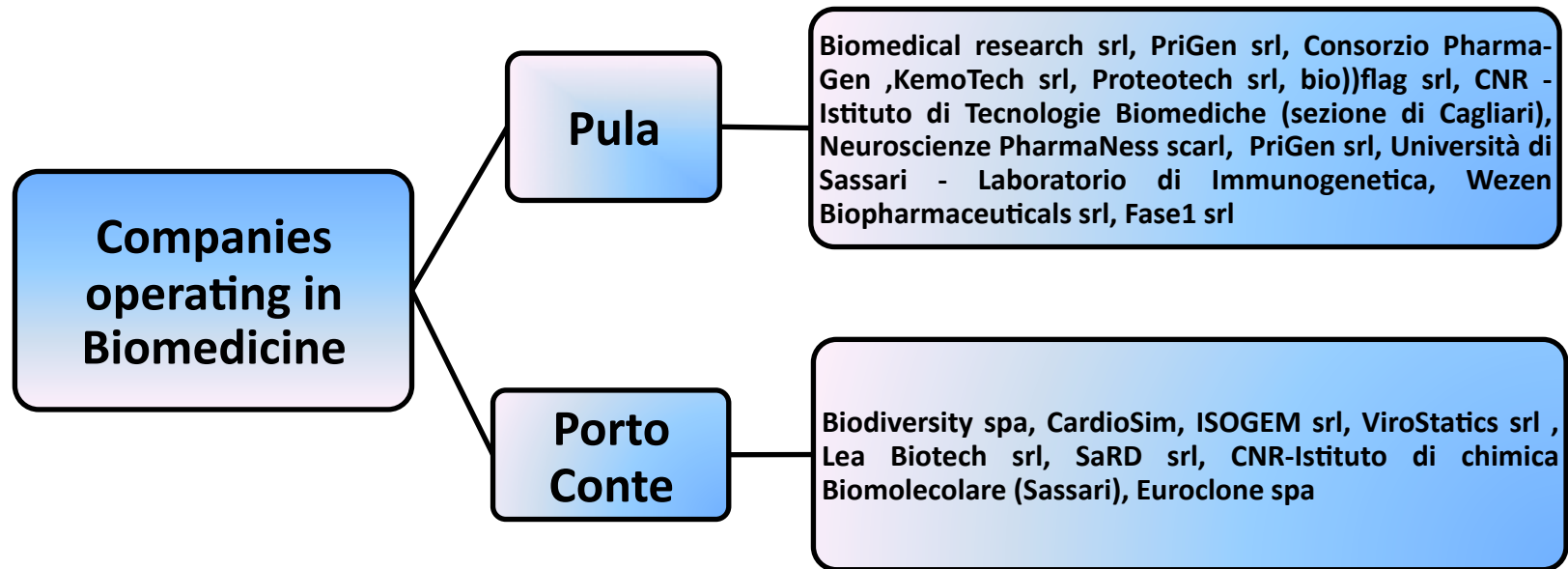
Auspicando in una proficua collaborazione, porgiamo cordiali saluti.

Novartis Farma S.p.A.


Dr. Gino Boano


Dr. Daniele Alberti

Biomedicine in Polaris



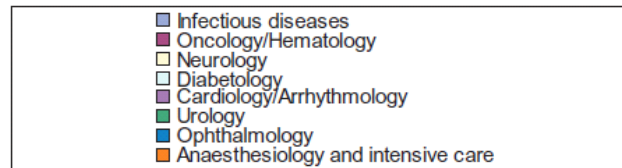
New venue of the FONDAZIONE SAN RAFFAELE in Sardinia

San Raffaele Hospital

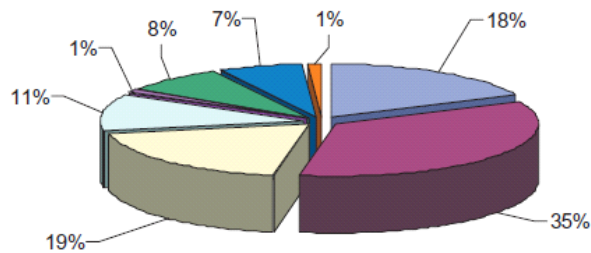


New venue of the FONDAZIONE SAN RAFFAELE in Sardinia

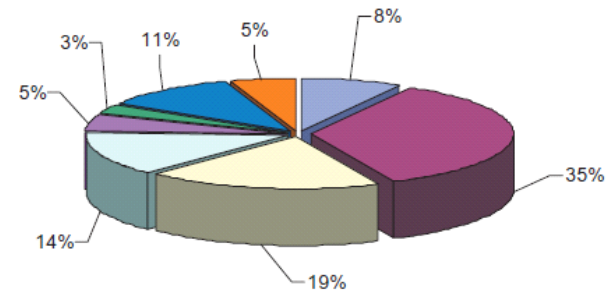
Clinical trials approved in 2008 by therapeutic area



Sponsored trials



No-profit trials



Biomedicine in Sardinia: State of the Art and Potentiality

University of Sassari (Sassari)

Microbiology Genetics and Biodiversity

Institute Of Population Genetics (CNR Sassari)

Ogliastra Genotyping Project

**Research Centers for the Development of
Biotechnology Research and For the Study of
Biodiversity in Sardinia and Mediterranean Area
(University of Sassari)**

Porto Conte Ricerche (Alghero)

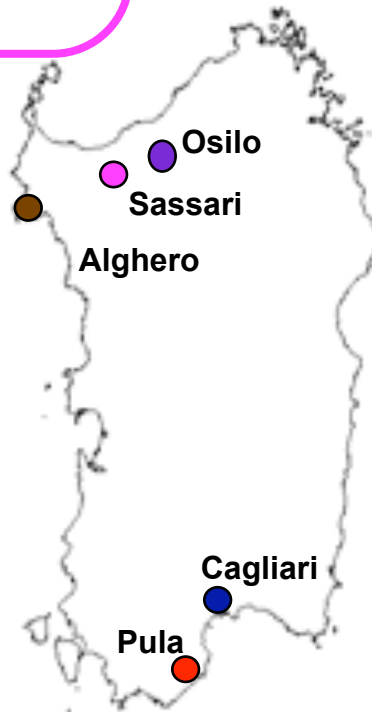
Proteomic Biotechnology and agrofood

Polaris (Pula)

Genotyping , Gene Expression
Profiling and Bioinformatics

**Biotech at the Technology
Polaris Park
(Pula)**

**ICT - CRS4
Polaris Park
(Pula)**



**INBB-Osilo
National Institute of
Biostructures and
Biosystems**

**Center of Excellence for the Neurobiology of
Dependence and Mental Diseases
(University of Cagliari)**

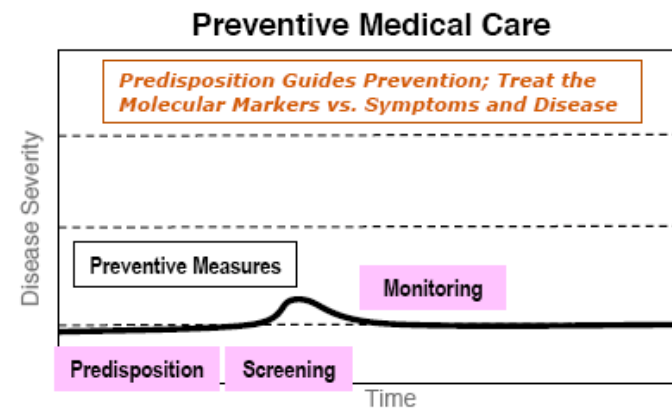
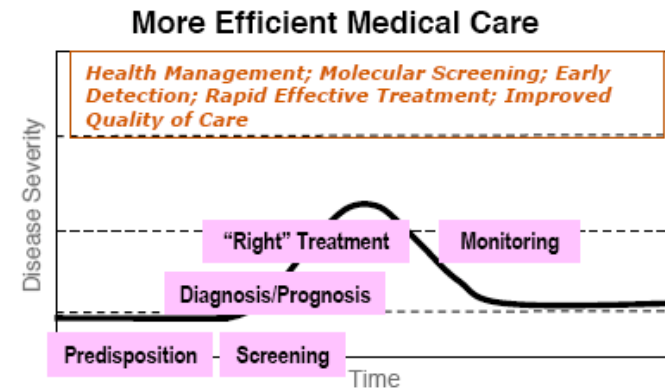
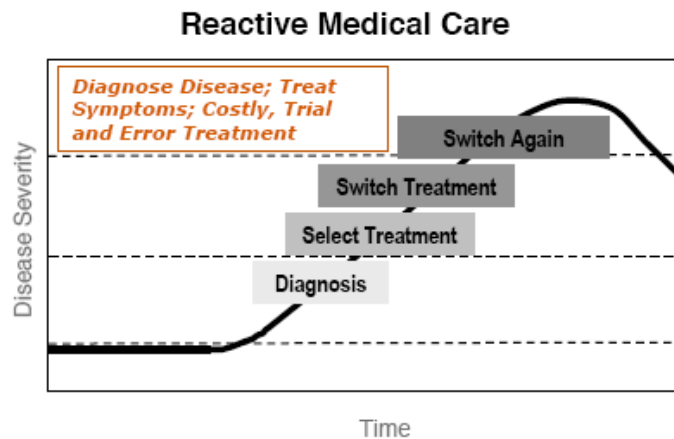
**CNR - Institute of Neuroscience
(Cagliari)**

**Institute of Neurogenetics & Neuropharmacology
(CNR Cagliari)**

Population Genetics - Progenia Consortium - NIH

The context paradigm

Personalized, Preventive and Predictive Medicine is holding great promise for a more efficient health management approach.



Center of Neurobiology of the Dependency (University of Cagliari)

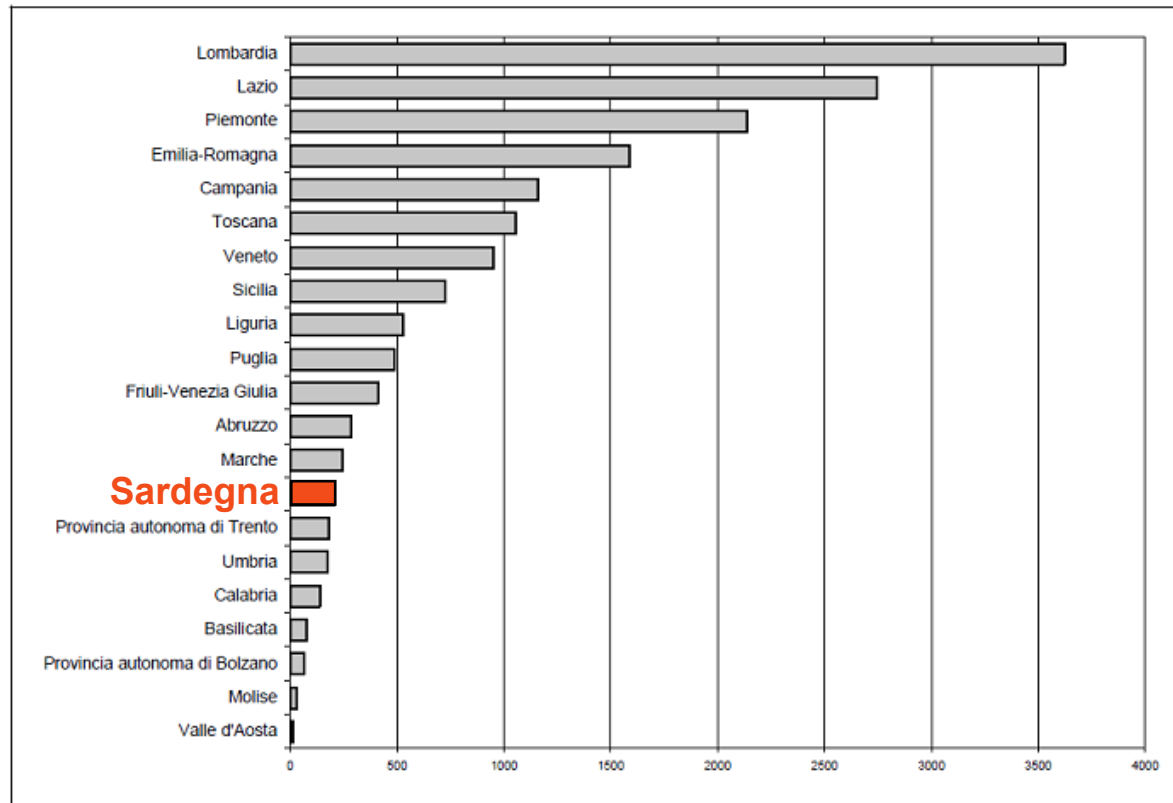
The Centre will bring together various areas of the field of basic Neurosciences and will enhance a synergic collaboration between highly qualified research groups



Goals

- perform advanced research activities, in order to represent a national and international reference point for studies concerned with the neurobiology of dependence;
- promote integration of activities performed on a regional level
- provide for the valorization, development and technological transfer of results obtained in research projects
- in association with other public (CNR) and private institutions, it co-ordinates national and international research programmes in the field of Neurosciences;
- carry out high level post-degree courses (specializations and post-doctorate) and periodic training courses for researchers and technicians involved in the fields of pharmacology and neurosciences;
- create complex equipment centres in order to carry out more competitive projects

Regional investment in technological R&D



[1] "Il settore delle biotecnologie in Italia. Un quadro conoscitivo degli operatori e dei programmi di sostegno." 2006, IPI

Sardinia ranks 8th among Italian regions as to number of biotech

		% su ITALIA	% su Area
Nord - est	Emilia Romagna	5,30%	28,6%
	Friuli V.G.	4,97%	26,8%
	Trentino A.A.	0,99%	5,4%
	Veneto	7,28%	39,3%
Nord - est Totale		18,54%	100,0%
Nord - ovest	Liguria	1,32%	2,6%
	Lombardia	39,40%	76,3%
	Piemonte	10,93%	21,2%
Nord - ovest Totale		51,66%	100,00%
Totale NORD		70,20%	
Centro	Lazio	7,62%	44,2%
	Marche	1,68%	9,6%
	Toscana	7,28%	42,3%
	Umbria	0,66%	3,8%
Centro Totale		17,22%	100,00%
Sud e isole	Abruzzo	0,66%	5,3%
	Basilicata	0,66%	5,3%
	Calabria	0,66%	5,3%
	Campania	2,32%	18,4%
	Molise	0,33%	2,6%
	Puglia	1,99%	15,8%
	Sardegna	4,64%	36,8%
	Sicilia	1,32%	10,5%
Sud e isole Totale		12,58%	100,00%
Totale complessivo		100,00%	

Fonte: Elaborazioni IPI-DPP, 2006

[1] "Il settore delle biotecnologie in Italia. Un quadro conoscitivo degli operatori e dei programmi di sostegno." 2006, IPI

[2] Blossom Associati – Assobiotech report for 2007

Vision

Academic Research

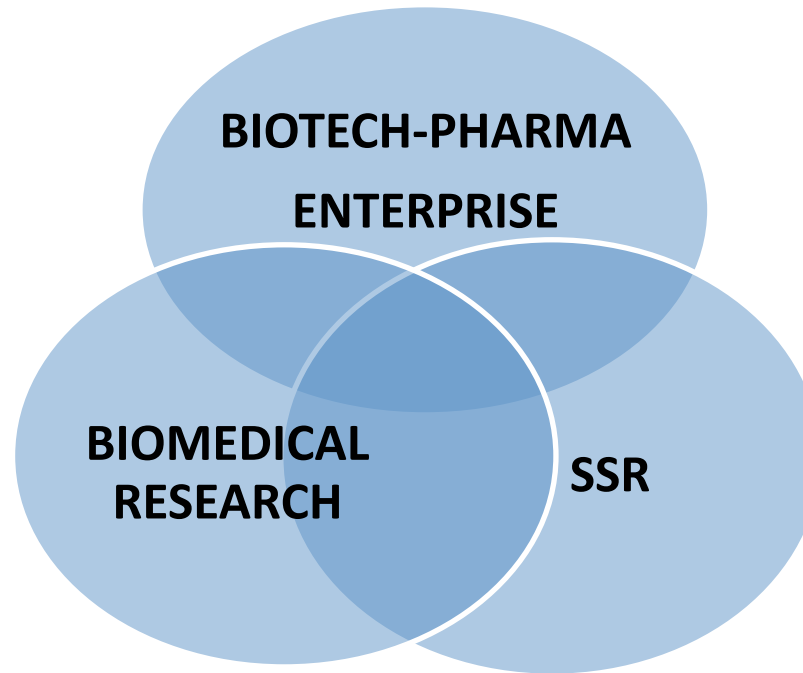
BioPharmaceutical Companies



National Health System

Regional Government

CLINICAL RESEARCH AND TRIALS



➤ **MAN SIMULATOR PLAN**

The group will develop new computing techniques and virtual models to hasten the research and development for new drugs. We will design and implement an informatics platform that will be the basis to build a software pipeline for the simulation of clinical trials of type FASE 1, to predict collateral effects and limit in the efficiency of drugs.

➤ **Fase1 srl**

IMPACTS

The expected impact in the local and national context will consist of:

- fostering competence in drug development and clinical trials
- pushing the regional health system towards an innovative position
- attract interest in Sardinia in terms of scientific, economic and entrepreneurial