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EFFECTIVE

First Strategic Workshop – “Paving the way to effective clustering towards exploitation & dissemination of FoF project results”

SESSION-1: Business Trends and Market Prospects

Medtech ‘Made in Italy’: the Industrial Experience of Mirandola District

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Democenter Foundation

Democenter Foundation was born to:

- Manage Research and Development Projects in which Univesity, Research Centers, Laboratories and Business partners are involved together.
- Promote **Technology Transfer and Innovation among local Business.**
- Support the **Birth and Development of brand new Business projects,** focusing on hi-tech Start-up as well as university Spin-off

What do we do?

- Promote, manage and perform R&D projects
- Offer services including Business incubation and acceleration for hi-tech Start-up
- Support international networking creation for R&D projects

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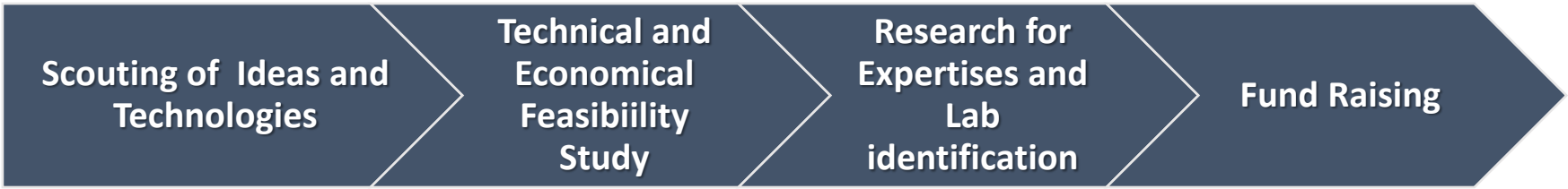
How do we work?



Our Business Partners:

- **Ferrari**
- **Maserati**
- **Lamborghini**
- **Landi Renzo**
- **CNH**
- **HPE**
- **Walvoil**
- **Electric 80**
- **B.Braun**
- **Gambro**
- **Medica**
- **Fresenius**
- **Bellco**
- **LiuJo**
- **Acantho – Hera**
- **Doxee**

COSTRUIAMO INSIEME IL FUTURO

TECNOPOLO MODENA

SCIENCE & TECHNOLOGY PARK FOR MEDICINE

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Areas of Interest

Advanced Mechanics
Robotics

Elettronics

Automation

Motoristica

New Materials

Design

Sensoristics

Biomed & Biotech

Medical Devices

Drug Discovery

Sensoristics

E-Health

Nanotechnologies

New Materials

ICT

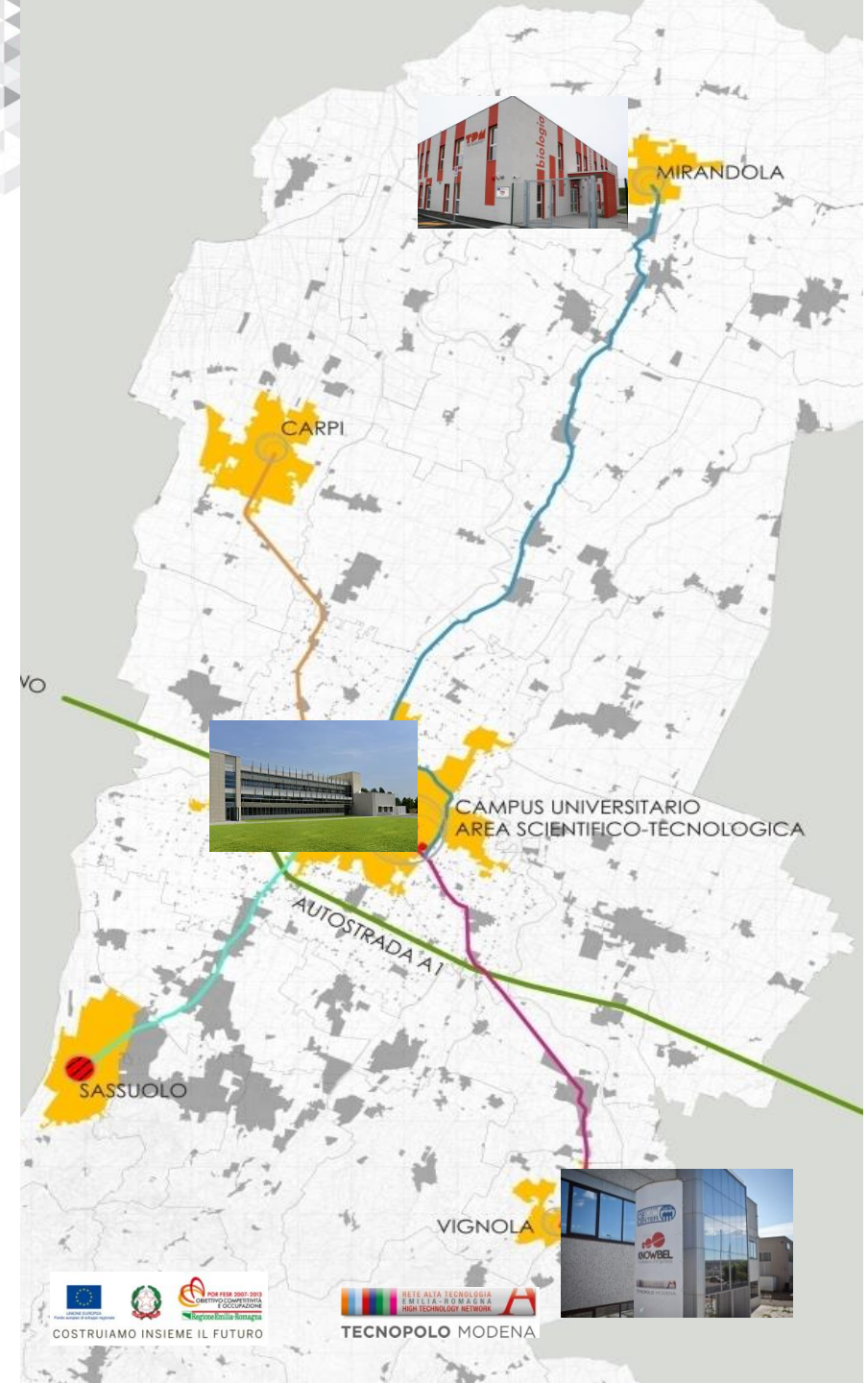
Info-security

Artificial Vision

I-Health

Database

Big Data



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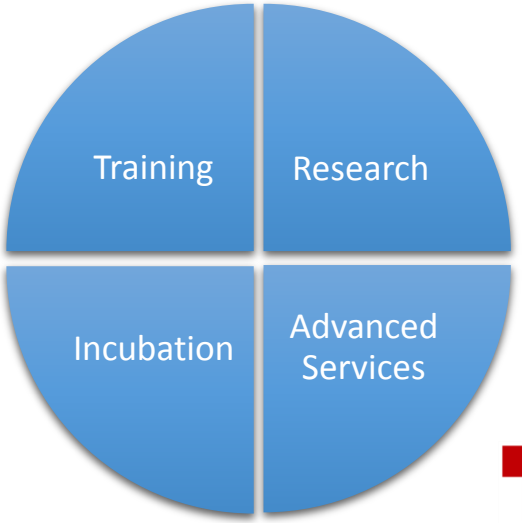
The Technopole: a new model of integration between University and local District.

A networking structure that connects Knowledge areas (University campus) and technology transfer terminals, located in the district and focused on local productive specializations.



TPM
SCIENCE & TECHNOLOGY PARK FOR MEDICINE

Scientific and Technological Park: Mirandola Technopole

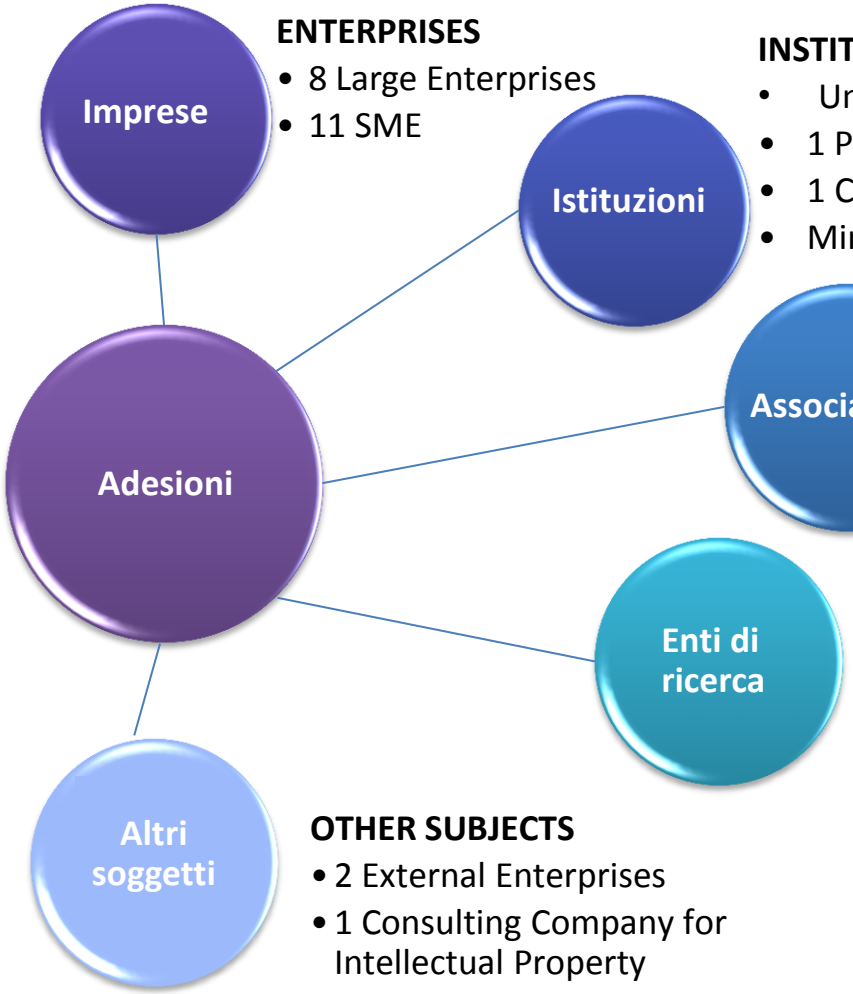
Scientific and Technological Park

- Advanced education institute and Master programme
- Incubator
- **Mirandola Technopole (TPM)**

  Industrial applied research

  Scientific and Technical services

Laboratories at Modena Technopole: Example of Territorial Involvment



ENTERPRISES
- 8 Large Enterprises
- 11 SME

INSTITUTIONS
- Union of Area Nord Municipalities
- 1 Province
- 1 CCIAA
- Mirandola Savings Bank Foundation

ASSOCIATIONS
- 3 Trade Associations
- 1 Sector Association
- 1 Research Foundation

RESEARCH CENTERS
- LTTA – Ferrara Technopole
- INTERMECH
- MISTER
- SOFTECH
- 1 department of Milan Polytechnic
- 1 Hospital Department
- 1 Hospital
- 6 Foreign Universities
- 1 Foreign Technolocical Transfer Center
- 2 Foreign Research Centers

OTHER SUBJECTS
- 2 External Enterprises
- 1 Consulting Company for Intellectual Property

Laboratories at Modena Technopole

Mirandola Branch:

-**TOP** : **Toxicology and Proteomics**

-**MAB** : **Applied Microscopy and Cellular Biology**

- MS² : **Materials, Sensors and Systems**

TOP – Toxicology and Proteomics

TOP Applied Researches:

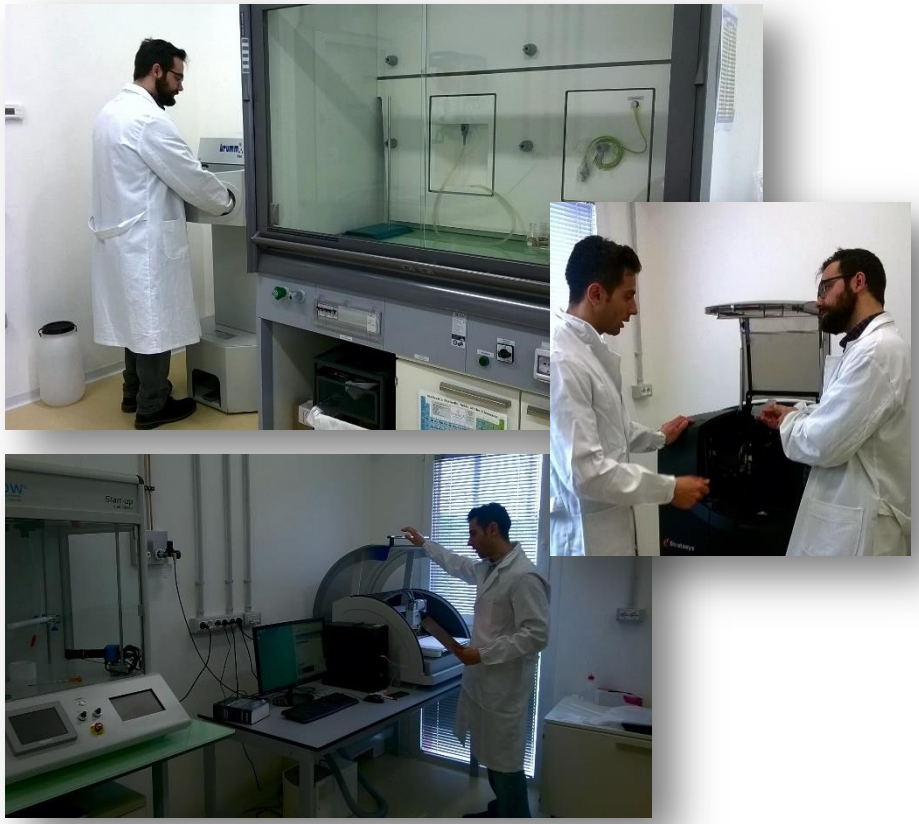
- Bio-compatibility and toxicology, metabolic activation with advanced methodologies in addition to sector regulations.
- Preparation and presentation of scientific papers to place and compare materials or devices already available on the market or from recent introduction.
- Partecipation to financed projects for applied research and product's development.

MAB – Applied Microscopy and Cellular Biology

MAB Applied Research:

- Bio-compatibility analysis between bio-material e biological matrices *in vitro* and *in vivo.*
- Analysis of medical devices' effectiveness, using methodologies based on direct contact with biological cells and tissues, especially stem cells or specific tissues.
- Development and safety test of new products and processes, data analysis, reports and papers editing.

MS2 - Materials, Sensors and Systems



MS² Applied Researches:

- Feasibility study for optical, elettronic, chemical systems, measuring chains and signal conditioning.
- Specifications editing.
- Sensors and innovative micro-systems development.
- Definition and analysis of dependability, avaibility and maintainability' targets.
- R&D of measuring systems and sensors on specification for practical use.
- Architectural definition of *mission critical* and *life critical* systems, systems' safety management and dependabilty.

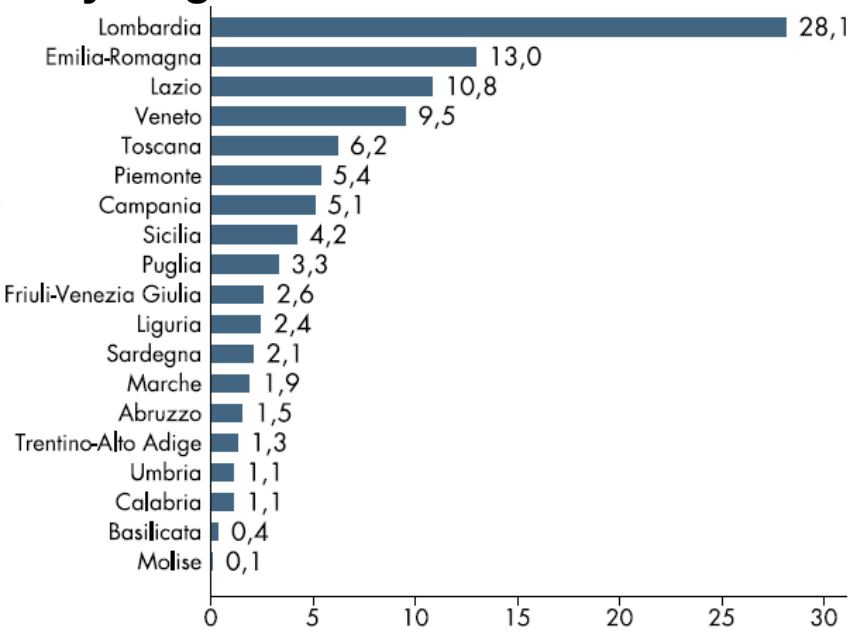
Facts & Figures
Italian Biomedical Sector

Sector Enterprises: Quantities, Employees and Turnover

Comparto	Imprese		Dipendenti		Fatturato (mil. euro)		
	N	%	N	%	%	Media	Mediana
Attrezzature tecniche	219	7,2	3.934	7,3	5,4	4,5	1,8
Biomedicale	1.337	44,2	22.375	41,6	43,7	5,9	1,2
Biomedicale strumentale	747	24,7	9.117	16,9	15,0	3,6	1,0
Borderline	104	3,4	2.968	5,5	5,5	9,6	2,3
Diagnostica in vitro	243	8,0	6.406	11,9	16,0	12,1	1,5
Elettromedicale diagnostico	179	5,9	3.808	7,1	8,1	8,3	1,7
Servizi e software	164	5,4	4.610	8,6	5,3	5,8	0,5
n.d.	32	1,1	614	1,1	1,0	5,5	2,4
Totale	3.025	100,0	53.832	100,0	100,0	6,0	1,2

Fonte: elaborazioni CSA su dati PRI 2012

Biomedical Enterprises divided by Region



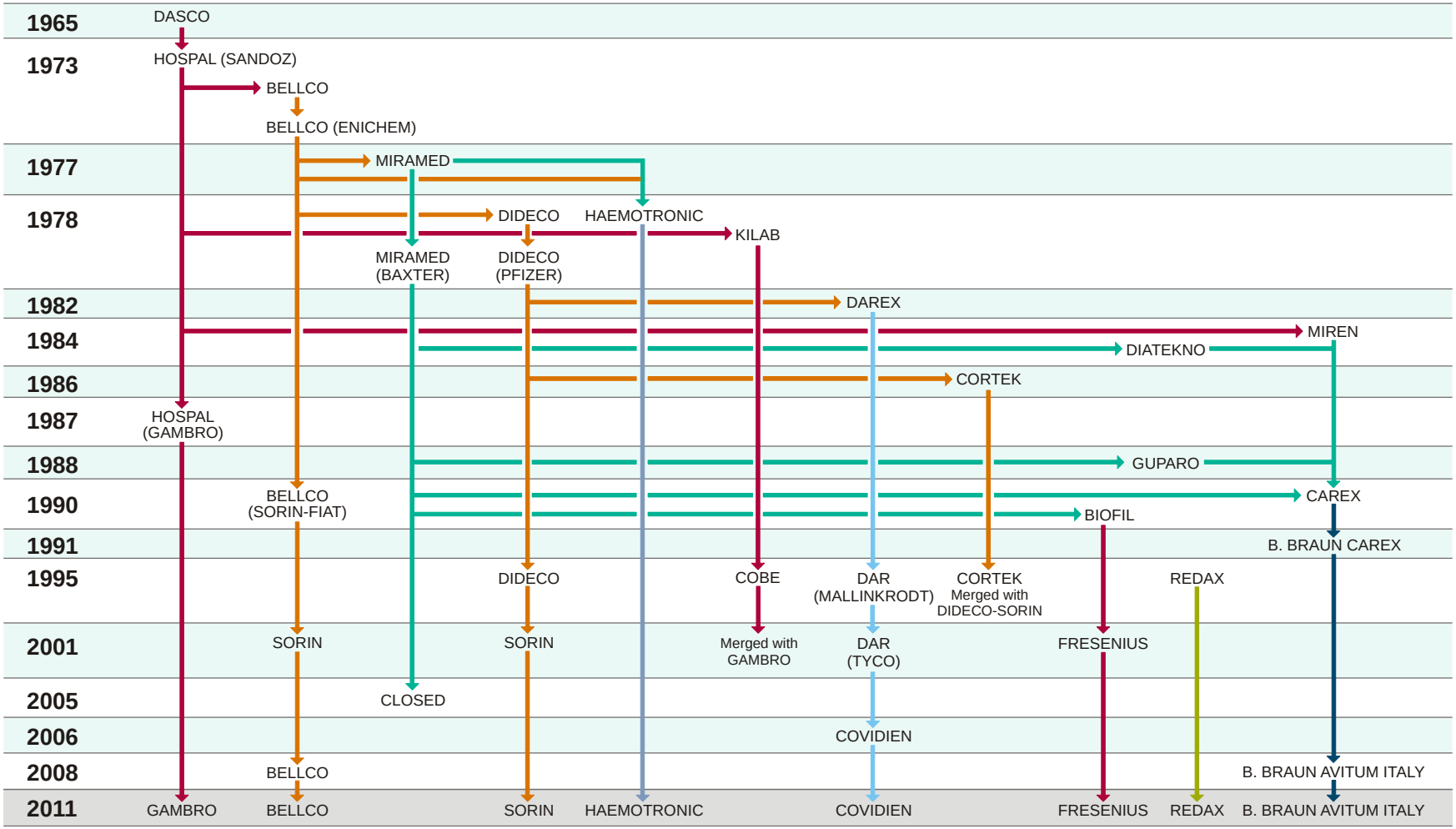
Fonte: elaborazioni CSA su dati PRI 2012

Mirandola District: an European Excellence

- Mirandola Biomedical District is a Compound of Companies specifically focused on the production of Medical Devices

- The beginning of the industrial hystory started in the late 60s, the district hugely developed in the 80s and 90s. Positive economical trend and competence concentration attracted several multinational and global companies that invested in the area mailny through acquisition (but also "de novo").

Biomedical District History



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Different Medical Therapeutical Fields in the District

DIFFERENT MEDICAL THERAPEUTICAL FIELDS IN THE DISTRICT

Mirandola Biomedical District is a **Compound of Companies** specifically focused on the development and production of **medical devices** in form of active and non active

- *Apheresis and Plasmapheresis*
- *Haemodyalisis*
- *Heart surgery*
- *Anesthesia*
- *Gynecology*
- *Infusion, Transfusion, Autotransfusion*
- *Continuous Renal Replacement Therapies*
- *Enteral and Parenteral Nutrition*

Facts & Figures
Area Nord = Mirandola Biomedical District

	N	%
Area Nord	3.189	90,0%
Carpi	185	5,2%
Modena	168	4,7%
Totale	3.542	100,0%

Tab.3 - FTE in biomedical field - Distribution per area, 2009 data

Data source: Production, research and innovation in medical devices field in Emilia-Romagna region, Mirandola District , April 2012

INCREASE IN 2013
> 4.000

INCREASE IN 2013
> 900.000.000 €

	€	%
Area Nord	750.206.695	90,1%
Carpi	40.516.304	4,9%
Modena	41.923.141	5,0%
Totale	832.646.140	100,0%

Tab.4 Turnover of the district – province of Modena, Distribution per area, 2009 data

AREA NORD

Facts & Figures
Italian Commercial Flows

Table 33 - Evolution of the Italian Foreign Trade Flows in 2013

TABELLA 33 – EVOLUZIONE DEI FLUSSI DI COMMERCIO ESTERO ITALIANO NEL 2013

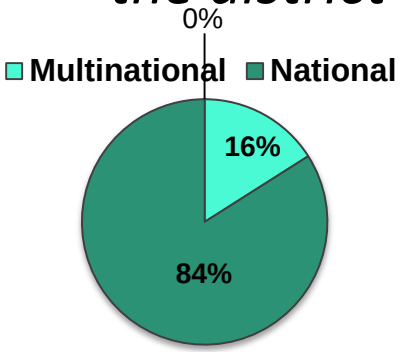
Comparto	Export		Import		Saldo (mil. euro)	
	Mil. euro	Var. %	Mil. euro	Var. %	2012	2013
Attrezzature tecniche	2.506,4	*1,1*	1.005,2	*5,0*	1.522,2	1.501,3
Biomedicale	875,6	*3,6*	2.601,8	*6,7*	-1.594,3	-1.726,2
Biomedicale strumentale	1.398,2	*7,6*	1.713,3	*1,2*	-393,0	-315,1
Elettromedicale diagnostico	474,4	*-7,1*	518,0	*-13,0*	-85,2	-43,7
Diagnostica in vitro	674,0	*6,3*	1.015,7	*-2,7*	-409,9	-341,7
Totale	5.928,6	*2,8*	6.854,0	*1,9*	-960,2	-925,4

Fonte: elaborazioni CER su dati ISTAT

Data source: Production, research and innovation in medical devices field in Italy, 2014 report

Types of Biomedical Companies in Mirandola

Number of MD companies in the district



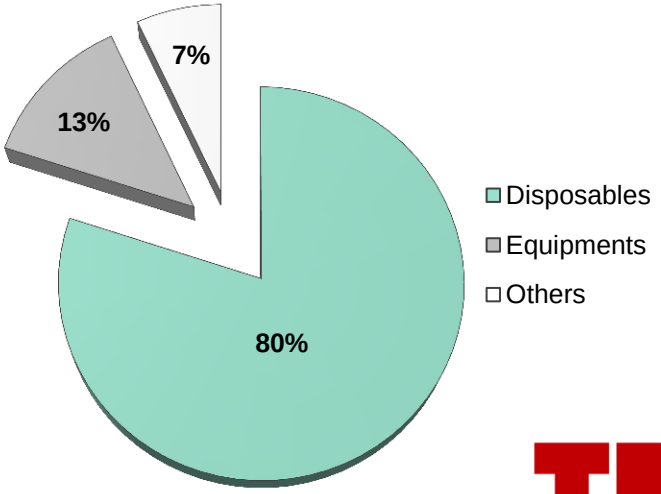
	N	%
Area Nord	62	67,4%
Carpi	7	7,6%
Modena	23	25,0%
Totale	92	100,0%

Table Companies of the District – Province of Modena. Distribution per area, 2009 data

Specialization

Production of **DISPOSABLE devices** (80%)

Production of biomedical **EQUIPMENT** (13%)

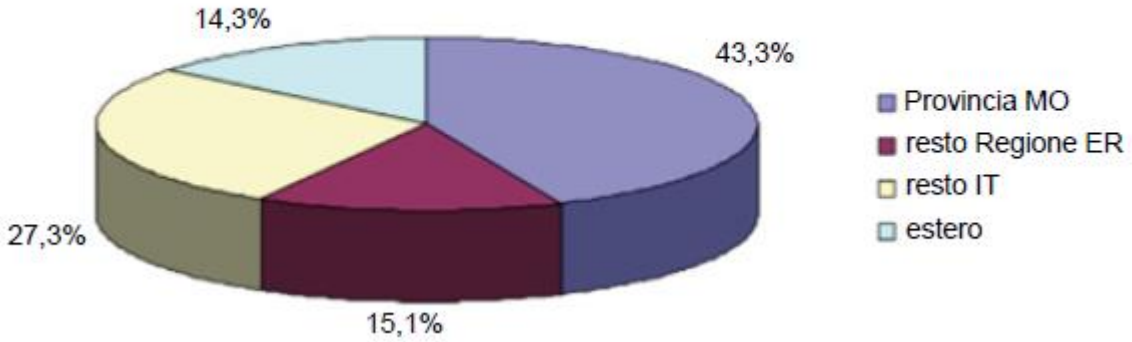


Facts & Figures
Operative Relations of the District

2010 Study of the supply arrangements and R&D activity among Enterprises within the District

Graph 6.: Supply arrangemets, analysed by Democenter-Sipe, 2010

GRAFICO 6. DELLA FORNITURA, INDAGINE DI DEMOCENTER-SIPE, 2010.



Data source: Production, research and innovation in medical devices field in Emilia Romagna Region, Mirandola District

The Importance of Innovation: Where Companies Look to

Regional Innovation Strategy

HEALTHCARE INDUSTRY

- «Custom-made» Healthcare
- Independent and Active Life
- Innovation in Industrial Processes and Healthcare
- Wellness

Source: S3 Emilia-Romagna Region. Technological Priorities

Regional Technological trends for Biomedical Field

Regenerative Medicine

- Cellular Therapies
- Biomaterials
- Combined Devices

Source: S3 Emilia-Romagna Region. Technological Priorities

Regional Technological trends for Biomedical Field

Biomaterials for Medical and Diagnostic Applications

Biomaterials for Medical Applications

R&D on polymers and smart materials that can respond to external stimulus like temperature, pH, radiations, electrical field, …

Biomaterials for regenerative medicine and tissue engineering

Controlled-release systems for medicines and innovative systems for medicine transportation

Biomaterials for Diagnostic Applications

Micro/nano-structured or functionalised biomaterials to integrate into medical devices

Source: S3 Emilia-Romagna Region. Technological Priorities

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Regional Technological Trends for Biomedical Field

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New Therapeutic Applications for Biomedical Devices

Areas of action:

- Blood Purification
- Oxygenation
- Intensive care
- Liquid Infusion
- Bio-engineering
- Regenerative Medicine

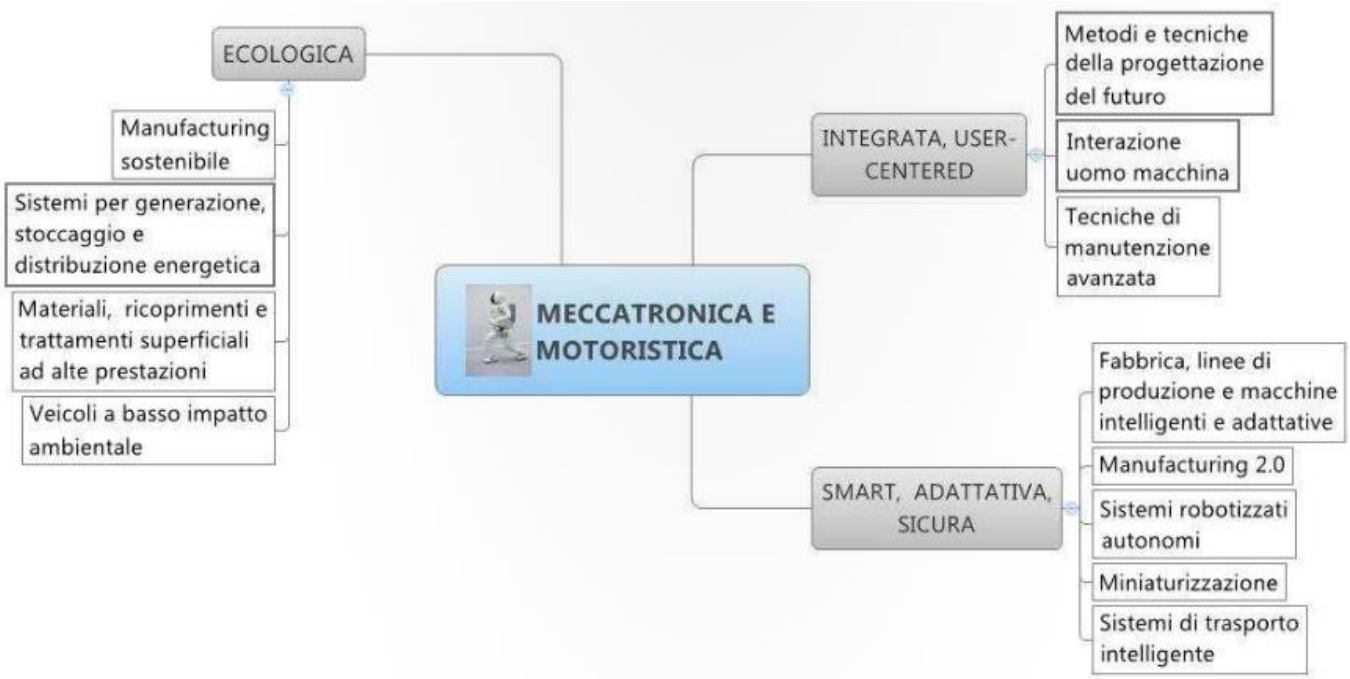
Source: S3 Emilia-Romagna Region. Technological Priorities

The Importance of Innovation: Where Companies Look to

Regional Innovation Strategy

MECHATRONICS AND ENGINE TECHNOLOGY

- Ecological
- Integrated and user-centered
- Smart, safe and adaptive



Source: S3 Emilia-Romagna Region. Technological Priorities

Regional Technological Trends for Biomedical Field

Miniaturisation

Areas of action:

- Flexible micro-systems based on polymers
- Flexible micro-systems based on materiali biocompatible e biodegradable materials
- Devices based on nano-structured materials

Source: S3 Emilia-Romagna Region. Technological Priorities

Regional Technological Trends for Biomedical Field

Materials, Coatings and High-performance Surface Treatments

Areas of action:

- Micro/nano-functionalisation
- Smart materials

Source: S3 Emilia-Romagna Region. Technological Priorities

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The Importance of Innovation: Where Companies Look to

Ri-Medical

After the analysis of:

- Global Trends of Technology Market for Healthcare Industry
- Biomedical Field
- Regional Partecipation to Cluster Project
- Project TPM (Mirandola Technopole)

ASTER believes that the creation of a joint project, between the expertises of regenerative medicine and the biomedical district, is of strategic importance.

Industrial Trends of the Italian Medtech: Research Projects

Cyber Doctor: full artis automation system

RESEARCH THEME: Hardware/software platform for the automated tests of medical devices (especially dialysis)

COMPANIES:

- Gambro Dasco spa (MO)
- Egicon srl (MO)
- Data River srl (MO)
- Pirazzoli Consulting sas (MO)
- Damitec srl (MO)

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Industrial Trends of the Italian Medtech: Research Projects

Cyber Doctor: Artis Monitor Full Automation System

PROJECT ABSTRACT :

One of the main **critical points in the lifecycle of dialysis therapy monitors consists in the testing process during prototypes validation and the finished products trial**. Effectively, the machine strenght and reliability during the dialysis treatment need to be ensured through accurate operating tests , which involve significant investments in terms of time and resources from the manufacturer. The project is intended to conduct a feasibility study to develop an istrument for Artis Monitor testing activity: **an hardware/software paltform that allows to conduct all the required tests, running automatic and repeated dialysis cycles**. The purpose of the system is to maximise tests automation during prototype validation phases in order to minimise operator intervention and significantly reduce test timing . Such a system will also increase test standardisation and severity, ensuring better results quality.

The criteria that will be followed during the platform architecture engineering are:

- Lower impact on the monitor assembly and on software production for testing phase execution;
- Use of the Production software for the automatic cycle implementation ;
- Time reduction for tests conducted by an operator;
- Technical specifications of the hardware/ software platform architecture will be detected after the project conclusion.

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Industrial Trends of the Italian Medtech: Research Projects

Pressens - Pressure measurement system for disposable medical devices through a force sensor

RESEARCH THEME: Pressure measurement system in disposable medical systems (air free, low priming, without cross contamination) using force sensors in direct contact with specific disposable systems.

COMPANIES:

- Bellco srl (MO)
- Egicon srl (MO)
- Medifly srl (MO)
- SA.GE srl (MO)
- Goldoni Vainer - Dondi Franco e c. snc (MO)

bellco

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Industrial Trends of the Italian Medtech: Research Projects

Pressens – Pressure measurement system for disposable medical devices through a force sensor

Extracorporeal circulation systems are complex circuits characterised by several pipelines and disposable devices within which different biological and non-biological fluids are flowing. For the extracorporeal therapies proper conduct, these systems complement a number of pressure sensors to note adverse events variations (like occlusioni per presenza di trombi, distacco di cateteri…) that could compromise the treatment safety.

Project "**PRESSENS** –PREssure measurement system for disposable medical devices through a force SENSor " provides for the development of a prototype for a new sensor able to detect fluids pressure in an extracorporeal system without using a pressure sensor.

Developed by a joint research team, the new sensor is based on a force sensor, without including a direct contact with the fluid and interposed air between the detection system and the fluid itself. The aim of the project is to find an high value added and low production costs technical solution, in line with the disposable devices costs in which it will be integrated.

The project implementation will grant a close cooperation between companies fitted with specific technological know-how, in order to cover all the operative fields needed to product a prototype, which will be validated in vito at the conclusion of the project.

Research Critical Points/ TT

- Cross sectoral skills required to develop equipments and disposables (ICT, materials manufacturing, chemistry, …)

- Several corporations' headquarters are located abroad, not in the district: this fact holds back the development of research projects in Mirandola.

- New products require specific regulatory analisys (medical devices vs pharma), CE marking…

- In the District are active many SMEs which in their everyday practice have difficulties to introduce innovative products / processes / services.

- The market is characterised by specific issues depending on final purchasers (hospitals) which operate through tenders.

Examples of Awareness Raising
European Conference
AGEING WEALTH

The Conference focused on the specific topic of the EU Health Programme: **the need to "ageing well" at home, supporting the elderly through technologies and services which are economically auto-sustainable**. To this purpose, several experts in the field who previously joined important and strategic projects have been invited to join the Conference. As the development of such a market promotes a more sustainable economic system also for the economy of the European countries (due to the ageing of the population), the Conference addressed a dedicated focus on chronic diseases management and on health system sustainability. The event also contributed to increase the discussion on ICT technologies and home automation and represented an opportunity to disclose best practices, exchange opinions and propose solutions about regulatory aspects related to the adoption of tele-medicine solutions in the healthcare system.

Examples of Awareness Raising
European Conference
AGEING WEALTH

<u>260 Total Participants</u>:

219 Participants on October 16th and **152 participants** on October 17th (**111 participants joined the Conferenced both days)**

Regarding participants provenance, they represented all the actors of the value chain, and in details they belonged to Public or Private Bodies (134), Industry (118), Associations (6), Start-ups (2)