



Master Plan 2018-2021

ciber-bbn

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1. Introduction

1. Introduction



1. Introduction

During the last years CIBER-BBN has been driven by the 2014-2017 Strategic Plan which came to an end in 2017. At that moment it was necessary to define the new objectives and design a new roadmap for the next 4-year period.

The following pages describe the results of an in-depth analysis of CIBER-BBN situation at some point in 2017 and the outcomes of several working sessions held out by the CIBER-BBN Steering Committee along the year 2017.

The purpose of this strategic document is to know the departure situation and to define a series of actions and measures allowing CIBER-BBN to achieve its goals in terms of transference, translation and scientific excellence.

CIBER-BBN is wide and complex community. In order to listen to all voices of this group of people an important element in this reflection has been the conduction of a survey, which has been distributed to all researchers involved in CIBER-BBN (Heads of Group, researchers from institutions and CIBER staff). The outcomes of this survey have been taken into consideration in the definition of the measures to be implemented in the following years.

It is the aim of CIBER-BBN Scientific Direction to make the most of our resources and to contribute to the position of the whole CIBER consortium in the high level of scientific excellence.

Ten years after its creation, CIBER is today, with 11 thematic areas, the most important Spanish entity devoted to biomedical research, gathering nearly 430 research groups and 6.500 researchers.

I would like to take this opportunity to thank all CIBER-BBN members for their constant effort and commitment with science.

Ramón Martínez Máñez Scientific Director of the CIBER-BBN

2. Methodology for the development of the Master Plan

The development of CIBER-BBN Master Plan includes the following activities:

- To lead a DIAGNOSIS of the current situation evaluating the fulfilment of the management, scientific and translation objectives recommended at the previous stage.
- To perform an internal REFLECTION PROCESS in the Steering Committee's framework in order to define the main guidelines in terms of human resources, funding, research programme, transfer and translation, organisation and management.
- To develop a MASTER PLAN containing the main strategic areas, the specific measures

Master Plan's metholology



and the monitoring indicators of the centre for the next four years.

Thirty-four individual interviews to stakeholders have been carried out including the Steering Committee, Scientific Advisory Board, Medical Advisory Board, principal investigators of the main research areas, programme managers, CIBER BBN spin-off managers, hired researchers and other leading Research Institutions' management.

Besides, six strategic meetings have been hold with the Steering Committee to discuss the main strategic lines of the Master Plan.

People interviewed in the framework of this Master Plan are:

- Ramón Martínez, Scientific Director;
- José Becerra, Deputy Scientific Director;
- Jordi Aguiló, Bioengineering and Medical Imaging coordinator;
- Julio San Román, Biomaterials and Advanced Therapies coordinator;
- María Pilar Marco, Nanomedicine coordinator;
- Jaume Veciana, ICTS / Platforms coordinator;
- Simó Schwartz, Industrial Transfer coordinator;
- Ramón Mangues, Clinical Translation Coordinator;
- Jesús Santamaría, Strategic Plan coordinator;

- Manuel Sánchez, Managing Director;
- Begoña Pérez, Scientific Director Assistant;
- Jesús Izco, Platform programme manager;
- Theodora Tsapikouni, Bioengineering and Medical Imaging programme manager;
- Aída Castellanos, Biomaterials and Advanced Therapies programme manager;
- Johanna Katharina Scheper, Nanomedicine programme manager;
- Nerea Argarate, Nanomedicine programme manager;
- Fernando Santos, Industrial Transfer programme manager;
- Begoña Castro, Scientific Director of Histocell;
- Alberto A. Gabizón, PhD Professor and Chairman, Shaare Zedek Oncology Institute Hebrew University-School of Medicine Jerusalem;
- Joan Bigorra, Head of Innovation, Hospital Clínico de Barcelona;
- Pilar Calvo, Chief of Pharmaceutical Development in PHARMAMAR;
- Anna Lluch, Head of Hematology and Oncology Department, Hospital Clínico Universitario de Valencia;
- Joaquín Arenas, Scientific Director of Instituto de Investigación del Hospital 12 de Octubre;
- Jesús Jiménez, Scientific Director of CIC bioGUNE;

- Manuel Doblaré, principal investigator, Universidad de Zaragoza (former Scientific Director of the CIBER-BBN);
- Pablo Laguna, principal investigator, Universidad de Zaragoza (former Scientific Director of the CIBER-BBN);
- Xavier Trepat, principal investigator, Instituto de Bioingeniería de Cataluña, IBEC;
- Santiago Grijalvo, CIBER-BBN hired researcher;
- Gema Martínez, CIBER-BBN hired researcher;
- Isabel García, CIBER-BBN hired researcher.
- Santiago Sala, Nanomol Technologies Founder;
- Pedro Moreo, EBERS Founder;

Members of the Scientific Advisory Board and Medical Advisory Board are:

Bioengineering and Medical Imaging:

- Niilo Saranummi (VTT Technical Research Centre of Finland);
- Leif Sörnmo, Biomedical Engineering Department (University of Lund, Sweden)

Biomaterials and Advanced Therapies:

- Matthias Epple, Centre for Medical Biotechnology (Univesität Duisburg-Essen, Germany)
- Abhay Pandit, Centre for Research in Medical Devices (National University of Ireland)

 Begoña Castro, Scientific Director of Histocell

Nanomedicine:

- Patrick Boisseau, Business Development in Nanomedicine at CEA-Leti, Chair of the Executive Board of European Technology Platform on Nanomedicine, France;
- Wolfgang Parak, Philipps Universität Marburg, Germany;
- Alberto A. Gabizón, PhD Professor and Chairman, Shaare Zedek Oncology Institute Hebrew University-School of Medicine Jerusalem;

Horizontal:

- Joan Bigorra, Head of Innovation, Hospital Clínico de Barcelona;
- Pilar Calvo, Chief of pharmaceutical development in PHARMAMAR;
- Arcadi García, Arrhythmia Head of Unit of the Cardiology Department at Hospital Universitario Virgen de la Arrixaca;
- Enrique Gómez, Specialist in the Area of Traumatology and Orthopedics at Hospital Universitario La Paz;
- Mª José Martí, Neurology Department at Hospital Clínico de Barcelona;
- José M. Ruíz, Specialist in the Area of Ophthalmology of the Complejo Universitario Hospitalario de Albacete;
- Josep Tabernero, Onco-hematology coordinator at Hospital Vall ď Hebrón

2. Executive summary

2. Executive summary

1. Introduction

Twelve years ago, the Carlos III Health Institute (ISCIII) conceived a network of biomedical research centres (CIBER), structured as a public consortium dedicated to promote excellence in biomedicine and health science research.

CIBER-BBN is one of the thematic areas of the consortium, specialised in bioengineering, biomaterials and nanomedicine. Throughout these years, CIBER-BBN has focused its efforts and resources on building a solid base of effective collaboration among its research groups.

Achieving effective collaboration has been the CIBER greatest challenge during these first years as the research groups were scattered throughout the country and on numerous occasions their research came from very varied disciplines.

According to a recent CIBER-BBN community survey, researchers consider that being part of the centre has meant a relevant improvement in their professional career due to the multidisciplinary network achieved.

This important objective has been reached as CIBER has allocated many resources and programmes to strengthen collaboration among the groups.

It is time to pose another great challenge for CIBER-BBN: focus on the valorisation process to get a higher number of collaborative projects with great potential for transfer. After analysing the cost-benefit assessment of all the activities developed in the centre, CIBER-BBN strategic plan includes a human and economic resources restructuring proposal to achieve greater alignment with this new objective.

Consequently, the strategic plan has focused on redirecting internal resources creating strategic programs and its related internal calls and restructuring the management team according to this new configuration.

Additionally, other goals have been considered such as opening collaboration borders to other CIBER areas, creating an objective and transparent policy to regulate group continuation in CIBER-BBN, implementing new measures aimed at motivating young research talent or promoting CIBER-BBN visibility.





(*) Extramural projects signed in collaboration with two or more CIBER groups Source: Information provided by CIBER-BBN Management

First steps of the Master Plan: 1.b. Analysing CIBER-BBN research lines

CIBER-BBN has taken advantage of its multidisciplinary groups classified in three research disciplines

Medical image's capture and processing optimisation (TAC, NMR, PET, DTI). Biomedical signals' capture and processing improvement (ECG, EEG, EMG, Respiration, etc.). Morphological and functional modelling of tissues and organs. Pre-operative and intra-operative planning as well as creation of virtual surgery programs. Intelligent Devices and Systems: Creation of systems to monitor and control patients (sensoring, controlling and robotic systems). Software applications to improve systems for patient diagnosis. E-health and M-health Systems. Gene therapy and cell therapy: Stem and progenitor cells. Cellular reprogramming. The development of non-viral vectors for gene therapy. Tissue engineering: Biomaterials for scaffolds. Signalling biomolecules.

- Cellular and molecular functionalisation of biomaterials.
- Mechanobiology and microfluidics.
- Decellularisation and recellularisation of organs and tissues.
- Generation of organoids from stem cells: Towards artificial organs.

• Prostheses and implants:

Multimodal Diagnostics:

- Modelling and biomechanics.
- System of treatment and surface functionalisation.
- Custom prosthesis. 3D Printing.

• Nanodiagnosis:

- Detecting specific biomarkers of disease through nanotechnolgies.
- Evaluation and validation of new biomarkers of disease.
- The development of new contrast agents.

• Therapeutic Nanosystems:

- Study and development of new agents (enzymes, proteins, nucleic acids...) and nanostructures with therapeutic properties.
- The development of nanosystems to improve pharmacokinetics and pharmacotherapy of therapeutic agent.

Nanobiotechnology:

- Study of biocompatibility and toxicity of therapeutic nanosystems and nanodevices.
- Biological processes research (physiology, cell adhesion or communication, cell biophysics and epigenetic) and development of techniques for their study.
- Theranostic systems development.

Source: CIBER-BBN 2016 annual report

BIOFNGINFERING

NANOMEDICINE

First steps of the Master Plan: 1.c. Identifying CIBER-BBN technology platforms.

CIBER-BBN has provided platforms and tools so as to boost collaborative research

- B. Biomaterials and Nanomaterials
- U9. Synthesis of Nanoparticles Unit

C. Tissue, Biomaterial and Surface Characterization

U13. Tissue & Scaffold Characterization Unit

- E. High Performance Computing
- U27. High Performance Computing
- B. Biomaterials and Nanomaterials
- U10. Drug Formulation



B. Biomaterials and Nanomaterials

U11. Pharmaceutical Lab

C. Tissue, Biomaterial and Surface Characterization

- U14. Cell Therapy
- U16. Surface Characterization and Calorimetry Unit
- U19. Clinical tests lab

D. Bioimaging

- U21. Experimental operating rooms
- U22. Animal housing
- U23. Assisted Reproduction
- U24. Medical imaging

Source: NANBIOSIS website

NANBIOSIS Units and their location



A. Biomolecules Production

- U1. Protein Production Platform (PPP)
- U2. Custom Antibody Service (CAbS)
- U3. Synthesis of Peptides Unit

B. Biomaterials and Nanomaterials

- U4. Biodeposition and Biodetection Unit
- U5. Rapid Prototyping Unit
- U6. Biomaterial Processing and
- Nanostructuring Unit
- U7. Nanotechnology Unit
- U8. Micro Nano Technology Unit

C. Tissue, Biomaterial and Surface Characterization

U12. Nanostructured liquid characterization unit U18. Nanotoxicology Unit

D. Bioimaging

U20. In Vivo Experimental Platform U25. NMR: Biomedical Applications I

D. Bioimaging U26. NMR: Biomedical Applications II

C. Tissue, Biomaterial and Surface Characterization

U15. Functional Characterization of Magnetic NPs Unit U17. Confocal Microscopy Service First steps of the Master Plan: 2. Assessing the evaluation made by ISCIII Carlos III Health Institute assessment of CIBER-BBN achievements, 2015

STRENGHTS

- Relevant scientific results.
- High international collaboration.
- Promotion of transfer actions (generation of license agreements, patents and spin-offs).
- Strategic Plan implemented and proper follow-up actions.
- Singular Scientific and Technological Infrastructures label (ICTS).
- Positive assessment of transfer contracts (FERRER).
- Development of FOCUSDET technology (software for epilepsy).
- Training and mobility actions carried out.
- Promotion and use of lab notebooks.
- High international visibility.

IMPROVEMENT AREAS

- High technology transfer level but not enough for CIBER-BBN potential.
- Little connection of some groups with clinical professionals, lack of clinical trials of CIBER technologies.
- Publications in technological journals.
- Few European projects.
- Lack of royalty income.

MAIN GUIDELINES

- Increase the interrelation between basic and applied research groups.
- Create initiatives to improve technology transfer and translation.
- Analyse published results to detect if they are potentially protectable.
- Offer training courses to researchers in the entire innovation value chain (idea valorisation protection strategy - product development - business model construction – transfer strategy).
- Promote the achievement of international projects.

Source: CIBER-BBN evaluation report 2015, Carlos III Health Institute

First steps of the Master Plan: 3. Gathering the views of the CIBER-BBN community

Result of the survey formulated to the CIBER-BBN community

Most of CIBER-BBN researchers consider that being part of the centre has meant a **RELEVANT IMPROVEMENT IN THEIR PROFESSIONAL CAREER.** The PERFORMANCE OF NANBIOSIS platform 9 out of 10 researchers consider the is perceived as medium-high by 71% of degree of COLLABORATION between the CIBER-BBN community. CIBER-BBN groups is medium-high. The main LIMITATIONS found by researchers According to the researchers' point of are focused on the requirement of view, only 3 out of 10 have achieved a publishing according to their host TRL SCORE HIGHER THAN 4 in their institutions and on the complex technology with the highest degree of transfer. bureaucracy processes entailed. 83% of CIBER-BBN researchers consider 7 out of 10 researchers consider CIBER their collaboration with CLINICAL EVALUATION CRITERIA are fair and proper. GROUPS is medium-high. According to the CIBER-BBN community, SATISFACTION with CIBER-BBN HIRED HIRED RESEARCHERS do not apply for RESEARCHERS is high or very high in 81% of national or international projects as they the cases. do not lead an independent research line.

Source: Based on the information obtained in the surveys

First steps of the Master Plan: 4. Summing conclusions up into a SWOT matrix SWOT matrix

- SYNERGIES and scientific complementarity.
- Research groups of **EXCELLENCE**.
- **POSITIVE IMPACT** of CIBER benefits perceived by principal investigators.
- High level of international COLLABORATION.
- Facility to attract COMPETITIVE FUNDING.
- ICTS label: great technological/equipment base.
- Recurrent PUBLIC FUNDING.
- AUTONOMY for resources allocation.
 Groups receive FUNDS according to
- Groups receive FUNDS according to their ASSESSMENT.

- **RESULTS** must be more focused on translation
- Little connection of some groups with CLINICAL professionals.
- Excessive BUREAUCRACY and loss of agility of CIBER administration.
- Scope for improvement in BUSINESS DEVELOPMENT area.
- Possibility to improve CIBER-BBN strategic ALLIANCES and INTERNATIONAL VISIBILITY.
- Inability to **RECRUIT** new staff.
 - Unclear RESEARCH CAREER of hired staff.



- SYNERGIES due to CIBER's merger.
- Creation of NEW ALLIANCES.
- Ability to modify FUNDS DISTRIBUTION.
- SOLID CONNECTIONS between research groups.
- Weak BUSINESS NETWORK in some research areas.
- SCIENTIFIC POSITIONING of the groups in emerging research areas.
- Expanding the INTERNATIONAL IMPACT of CIBER-BBN.
- Spanish companies have little money to invest in R&D.
- LOSS of leadership in innovation and translation.
- AGILITY of management support structures.
- Loss of HUMAN CAPITAL.
- Loss of projects with companies due to **BUREAUCRACY**.
- Decrease of BASELINE FUNDING.
- Increasingly higher COMPETITION, low visibility.

Source: Based on the information obtained from the interviews conducted along the process

Master Plan definition: Major scientific challenges identified Major challenges for CIBER-BBN research areas

BIOENGINEERING AND MEDICAL IMAGING

<u>-</u>

Multimodal diagnosis

- Development of INTEGRATED SOFTWARE SOLUTIONS for biomedical image processing.
- MULTIMODAL ANALYSIS of cardiac, neural and respiratory signals for better disease and therapy insight.
- SYNTHESIS OF NOVEL CONTRAST AGENTS for better image acquisition.
- IMAGE GUIDED diagnosis and therapy for cardiac and brain diseases.
- Design of PREDICTION MODELS for relapse in mental diseases (depression).
- REALISTIC MODELS for multifunctional organ simulation.
- DYNAMIC 3D TISSUE MODELING based on real time video data for personalized support decision systems and virtual surgery utilities.

Intelligent Devices and Biomedical Systems

- Development of M-HEALTH TOOLS for follow-up and control of adherence-to-the-treatment for patients with non-communicable diseases (obesity, diabetes, dementia, depression).
- Design of SENSORING MICRO AND NANOSYSTEMS .
- Development of MICROFLUIDIC CO-CULTURE PLATFORMS based on organ-on-a-chip bioreactors for barrier function assessment and drug testing.

BIOMATERIALS AND ADVANCED THERAPIES

Cell and Gene Therapy

- IDENTIFICATION AND INTEGRATION of stem cells on tissues.
- FUNCTIONAL INTEGRATION of stem cells and effects on cell therapy.
- STEM CELL SECRETOME production and applications.
- REPROGRAMING cells and IPS for advanced therapies.

Source: Information provided by CIBER-BBN Management

Major challenges for CIBER-BBN research areas (cont.)

- GENE THERAPY: technologies and new trends.
- IMMUNOTHERAPY: methodologies and new approaches
- Bioprocessing and scaling of STEM CELL PRODUCTION.
- GENE EDITING technologies

Tissue Engineering

- DESIGN AND DEVELOPMENT OF SCAFFOLDS, growth factors and controlled release systems for Tissue Engineering
- INTEGRATION, BIODEGRADATION and VASCULARIZATION of scaffolds-cells systems
- Improving CELL PROLIFERATION, culturing methodologies and bioreactors
- Efficient METHODOLOGIES FOR DECELLULARIZATION /RECELLULARIZATION processes and organoids isolation.
- Other methods for DEVELOPING ARTIFICIAL ORGANS
- DYNAMIC INTERACTIONS of cells and tissues
- Development of STANDARDIZED PROTOCOLS for preclinical validation.

Prostheses and Implants

- Implementing SIMULATION TOOLS, IMAGE AND SIGNAL TREATMENTS AND MODELING biological systems.
- Develop of fabrication technologies by RAPID PROTOTYPING AND MICROFLUIDICS.
- INTEGRATION OF MICRO-DEVICES in implants and scaffolds
- SURFACE FUNCTIONALIZATION of implants and scaffolds.
- BIOPRINTING: new approaches for 3D methodologies and processes.
- Achieving integrated micro-devices for TELEMATIC MONITORING AND CONTROL of implanted prosthesis.
- Implementing models in-silico for the **PREDICTION OF THE BEHAVIOUR** of the implants.

Source: Information provided by CIBER-BBN Management

Major challenges for CIBER-BBN research areas (cont.)

NANOMEDICINE

Vitro Diagnosis

- Development of novel SENSING METHODS OF BIOMOLECULEs including point-of-care, lab-on-a-chip and multiplexed devices.
- Clinical VALIDATION of disease BIOMARKERS.
- Nanoparticle-based **DIAGNOSTIC TESTS**.
- TARGETED MOLECULE-based imaging technologies.
- ORGAN-ON-A-CHIP DEVICES for testing of new nanosystems in pre-clinical stage and to replace animal models.

Nanotherapy

- Programmable release by **REMOTE ACTIVATION AND DRUG FREE THERAPIES** (hyperthermia, untrasounds, etc)
- Novel strategies combining therapeutic effects and imaging (THERANOSTICS)
- Improving the INTERACTION AND UP-TAKE OF THERAPEUTIC AGENTS through biological barriers (cellular membrane, blood-brain barrier, etc).
- Novel strategies for drug and nanoparticle DELIVERY BASED ON CELLS and cellular vehicles (e.g. exosomes) as Trojan Horse carriers.
- Nanotherapy with NATURAL BIOMOLECULES (proteins, enzymes, growth factors, etc).
- Development of STANDARDISED PROTOCOLS for preclinical validation of new nanotherapies.

Nanosafety

• Nanosafety studies for PRECLINICAL AND CLINICAL STUDIES.

Source: Information provided by CIBER-BBN Management

Master plan definition: Five concrete lines of action proposed

modification

4

Lines of action and measures

Restructuring CIBER-BBN strategic programmes International Research and New Support to the initiatives collaboration New programme to Platform valorisation tasks of direction, and projects transfer technology: goprogramme programme administration and programme programme broadening to other to-market programme strengthening launches human resources configuration **CIBER** areas Redefining management team competences and organisational structure Management team Management team Team functions organisational and coordination structures Key indicators design for redefinition for achieving functional structure definition and follow up higher specialisation

Adapting CIBER-BBN internal calls

Intramural call redefinition

New call to boost young talent: early stage intramural call creation

Maintenance of the calls for collaboration with implementation clinical entities

implementation

Valorisation call

Enhancement of technology transfer call

Defining a general policy to regulate CIBER-BBN research group continuity

Current research group evaluation system adaptation

Configuration of objective and transparent criteria for PI substitution process

Other initiatives: young talent boosting, Medical Advisory Board renewal and website updating

Young talent incentives launch Medical Advisory Board (MAB) renewal

Reinforcement of the projection of CIBER through its website

3. CIBER-BBN at a glance

3. CIBER-BBN at a glance

1. CIBER: The creation of centres for biomedical network research.

CIBER-BBN (Biomedical Research Networking Centre in Bioengineering, Biomaterials and Nanomedicine) is one of the eleven thematic areas of CIBER, a public research consortium of excellence that arose on the initiative of the Carlos III Health Institute (ISCIII), as part of the National Health System and the Science and Technology System.

The CIBER mission is to perform a research of excellence focused on industrial transfer and clinical translation through the development of the scientific areas of bioengineering, biomaterials and nanomedicine.

CIBER-BBN aims to become a centre of reference in research and innovation both at a national and international level achieving a leading position in technological advances and their transfer to clinical practice.

Therefore, its structural objectives are aligned with an improvement in scientific excellence but, above all, with the translation of the research results:

- TO MAINTAIN THE EXCELLENT LEVEL OF SCIENTIFIC-TECHNOLOGICAL quality achieved over these years.
- 2. TO PROMOTE COLLABORATION BETWEEN CIBER-BBN research groups, strengthening



Source: CIBER website

stable alliances combining basic and applied research that allows the creation of multidisciplinary teams.

- **3.** TO BOOST TRANSLATION by establishing the required channels so the CIBER-BBN research is able to induce an improvement of patient health.
- 4. To FACILITATE THE TRANSFER OF CIBER-BBN'S RESULTS through patents, joint papers, creation of new technology-based companies, offering research services and consultancy about technology, research and innovation.

CIBER-BBN is a singular thematic area due to its groups' multidisciplinary background and composition in order to tackle research in different pathologies. Nevertheless, the other ten thematic areas of CIBER are focused on specific clinic pathologies:

- CIBERES: Respiratory Diseases
- CIBEREHD: Hepatic and Digestive Diseases
- CIBERER: Rare Diseases
- CIBERESP: Epidemiology and Public Health
- CIBEROBN: Physiopathology of Obesity and Nutrition
- CIBERSAM: Mental Health
- CIBERDEM: Diabetes and Associated Metabolic Diseases
- CIBERFES: Fragility and Healthy Ageing
- CIBERONC: Oncology
- CIBERCV: Cardiovascular Diseases



2. CIBER-BBN: the success of collaboration between different institutions.

Forty-six research groups of excellence are integrated in CIBER-BBN structure, two of which are associated. These scientific groups

belong to twenty two different institutions distributed throughout the country.

These CIBER-BBN host institutions embrace very different centres as they include universities, hospitals and other technology or research entities.



Source: CIBER-BBN 2016 annual report

3. A solid governance model.

CIBER-BBN is an independent research centre in terms of scientific management, although it is constituted as a thematic area within CIBER.

The highest CIBER decision-making body is the Governing Body, which is formed by three representatives of the Carlos III Health Institute (ISCIII) and by an institutional representative of every host institution. It is chaired by the Director of the ISCIII and it meets every six months.

The Permanent Commission is a delegated committee formed by ISCIII's representatives and eight members of the Governing Body, who are renewed every six months. The Permanent Commission meets more frequently to decide those questions that can not wait to be approved by the Governing Body.

On the other hand, scientific decisions are made by the Scientific Director, advised by the Steering Committee and the Scientific and Medical Advisory Board.



Source: CIBER-BBN 2016 annual report

Governing bodies of CIBER-BBN					
Governing Body	 The Governing Body meets twice a year and it is the highest decision-making body. The Governing Body consists of three representatives of the ISCIII and one institutional representative of each of the centres in the consortium. It is presided over by the Director of the ISCIII and meets every six months. This Governing Body is the same for all the thematical areas. 				
Permanent Commission	 The Permanent Commission is an executive committee formed of the ISCII and eight members of the Governing Body, who can be renewed annually. The Permanent Commission meets with greater celerity to take those decisions which can not wait to be approved because of their nature. The operation and the purposes of the governing, support and advisory bodies are established in the statutes of the CIBER. 				
Scientific Advisory Board	 The Scientific Advisory Board is intended to advise the Management on research areas and is formed by active renowned scientists. 				
Medical Advisory Board	 The MAB is a non-statutory body, whose purpose is to advise the Management on issues related to the interactions of CIBER-BBN's Research programme with clinical practice. It is composed by prestigious active doctors in medical specialities relevant to CIBER-BBN research areas. Specifically, in the context of the development of this strategic plan, the participation of the Medical Advisory Board as 'coordinator by medical speciality' has been specified in order to both facilitate the connection with clinical professionals and determine if the projects supported by CIBER-BBN funds are focused on solving relevant health problems. 				
Steering Committee	 The Steering Committee is the body responsible for defining CIBER-BBN's scientific strategy and for implementing the scientific initiatives. Members of the Steering Committee need to be reassigned every four years. It is presided by CIBER-BBN's Scientific Director and integrated by: Scientific Director Deputy director Managing director Head of Industrial Transfer Area and Translational Research Programme coordinator. Platform Programme coordinator and Training Programme coordinator. Coordinators of the different research programmes 				

Source: CIBER-BBN 2016 annual report

The Steering Committee is led by the Scientific Director and integrates each CIBER-BBN programme coordinator as well as CIBER Managing Director.

CIBER BBN basic and functional units are the research groups.

A management structure of eight business developers supports CIBER-BBN researchers in different duties; such as looking for opportunities, advising in technology transfer processes or promoting different research collaborations.

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Principal investigator	Group name	Institution
AGUILÓ LLOBET, Jordi	Biomonitoring Group of the National Microelectronic Centre	Autonomous University of Barcelona, UAB
ALBERICIO PALOMERA, Fernando	Nanoparticle and Peptide Chemical Group	University of Barcelona, UB
ARÚS CARALTÓ, Carlos	Research Group in Biomedical Applications of Nuclear Magnetic Resonance	Autonomous University of Barcelona, UAB
BECERRA RATIA, José	Tissue Bioengineering and Regeneration Laboratory	University of Málaga, UMA
BELLÓN CANEIRO, Juan Manuel	Translational Research Group in Biomaterials and Tissue Engineering	University of Alcalá, UAH
CALONGE CANO, Margarita	Institute of Applied Ophthalmo-Biology (IOBA)	University of Valladolid, UVA
CORCOY PLA, Rosa	Research Institute of the Hospital de la Santa Creu i Sant Pau	Sant Pau Biomedical Research Institute, FIRHSCSP
ENGEL LÓPEZ, Elisabet	Research group in Biomaterials, Biomechanics and Tissue Engineering	Institute for Bioengineering of Catalonia, IBEC
ERITJA CASADELLA, Ramón	Nucleic Acid Chemistry Group, Institute of Advanced Chemistry of Catalonia	Spanish National Research Council, CSIC
FERNÁNDEZ JOVER, Eduardo	Neuroprothesis and Neuro-engineering Research Group	University Miguel Hernández of Elche, UMH
GÓMEZ RAMÍREZ, Rafael	Dendrimer Group for Biomedical Applications	University of Alcalá, UAH
GÓMEZ RIBELLES, José Luis	Biomaterials and Tissue Engineering Centre	Technical University of Valencia, UPV

CIBER-BBN research groups

Source: CIBER-BBN website

CIBER-BBN research groups				
Group name	Institution			
Research Group on Microbial Adhesion	University of Extremadura, UEX			
Nanoprobes and nanoswitches	Institute for Bioengineering of Catalonia, IBEC			
Bioengineering and Telemedicine Group	Polytechnical University of Madrid, UPM			
Biomedical Systems and Signals Research Group	Institute for Bioengineering of Catalonia, IBEC			
Communication Technologies Group, Aragon Institute of Engineering Research	University of Zaragoza, UZ			
Nanobiosensors and Bioanalytical Applications Group	Spanish National Research Council, CSIC			
Bionanoplasmonics Laboratory	CIC biomaGUNE			
Photonics Engineering Group	University of Cantabria, UC			
Oncogenesis and Antitumor Drug Group	Sant Pau Biomedical Research Institute, FIRHSCSP			
Applied Molecular Receptor Group, Advanced Chemistry Institute of Catalonia	Spanish National Research Council, CSIC			
Group of Structural Mechanics and Materials modelling	University of Zaragoza, UZ			
Nanotechnology and Apoptosis Group	Spanish National Research Council, CSIC			
Applied Molecular Chemistry Group	Technical University of Valencia, UPV			
Biomedical Imaging Group	University of Barcelona, UB			
Micro and Nano technologies, Biomaterials and Cells Research Group	University of the Basque Country, UP-EHU			
Health Technology Group	Biomechanic Institute of Valencia, IBV			
Centre of Regenerative Medicine in Barcelona	Centre of Regenerative Medicine in Barcelona, CMRB			
	Group nameResearch Group on Microbial AdhesionNanoprobes and nanoswitchesBioengineering and Telemedicine GroupBiomedical Systems and Signals Research GroupCommunication Technologies Group, AragonInstitute of Engineering ResearchNanobiosensors and Bioanalytical ApplicationsGroupBionanoplasmonics LaboratoryPhotonics Engineering GroupOncogenesis and Antitumor Drug GroupApplied Molecular Receptor Group, AdvancedChemistry Institute of CataloniaGroup of Structural Mechanics and MaterialsmodellingNanotechnology and Apoptosis GroupBiomedical Imaging GroupMicro and Nano technologies, Biomaterials andCells Research GroupHealth Technology Group			

Source: CIBER-BBN website

Principal investigator	Group name	Institution
RITORT FARRAN, Félix	Small System and Biomolecule Physics Group	University of Barcelona, UB
RODRÍGUEZ ABREU, Carlos	Colloidal and Interface Chemistry Group, Advanced Chemistry Institute of Catalonia	Spanish National Research Council, CSIC
RODRÍGUEZ CABELLO, José Carlos	BIOFORGE Group	University of Valladolid, UVA
RUBIO VIDAL, Nuria	Cell Therapy Research Group	Spanish National Research Council, CSIC
RUÍZ ROMERO, Cristina	Institute of Biomedical Research of A Coruña	Galicia's Health Service
SAMITIER MARTÍ, Josep	Nanomedicine Group	Institute for Bioengineering of Catalonia, IBEC
SAN ROMÁN BARRIO, Julio	Polymeric Biomaterials Group, Institute of Polymer Science and Technology	Spanish National Research Council, CSIC
SANTAMARÍA RAMIRO, lesús	Nanostructured Particle and Surface Group, Nanoscience Institute of Aragon	University of Zaragoza, UZ
SANTOS LLEÓ, Andrés	Biomedical Imaging Technology Group	Polytechnical University of Madrid, UPM
SCHWARTZ NAVARRO, Simó	Drug Delivery and Targeting Group, CIBBIM- Nanomedicine	Vall d'Hebron University Hospital
TREPAT GUIXER, Xavier	Integrative cell and tissue dynamics	Institute for Bioengineering of Catalonia, IBEC
VALLET-REGI, María	Research Group in Advanced Bioceramics	Complutense University of Madrid, UCM
VECIANA MIRÓ, Jaume	Molecular Nanoscience and Organic Materials Group, Materials Science Institute of Barcelona	Spanish National Research Council, CSIC
/ILABOA DÍAZ, Nuria	Research Group in Bone Physiopathology and Biomaterials	Madrid Health System
/ILLAVERDE CORRALES, Antonio	Applied Microbiology Research Group, Biotechnology and Biomedicine Institute	Autonomous University of Barcelona, UAB
MUÑOZ FERNÁNDEZ, María Ángeles	Molecular Immunobiology Laboratory	Madrid Health System
	Cellular and Respiratory Biomechanics Group	University of Barcelona, UB

Source: CIBER-BBN website

The Steering Committee is currently formed by:

- Scientific Director: Ramón Martínez-Máñez
- Deputy Scientific Director: José Becerra
- Coordinators of the different research programmes:
 - Bioengineering and Biomedical Imaging: Jordi Aguiló
 - -Nanomedicine: Pilar Marco
 - -Biomaterials and Advanced Therapies:

Julio San Román

- Platforms / ICTS Director: Jaume Veciana
- Industrial Transfer coordinator: Simó Schwartz
- Clinical Translation coordinator: Ramón Mangues
- Training coordinator: Raimon Jané
- Strategic Plan coordinator: Jesús Santamaría
- CIBER Managing Director: Manuel Sánchez



Source: CIBER-BBN 2016 annual report

CIBER-BBN structure

4. Cross-sectional research lines to address multiple pathologies.

The CIBER-BBN research programme is based on three main lines of research that are multidisciplinary and complementary, which favour the creation of synergies, interconnection and, therefore, collaboration between the different groups.

A. Area of bioengineering and medical imaging

- A.1. Multimodal diagnosis

diagnosis is Imaging increasingly complemented by other types of diagnosis based on different biophysical elements such as: the combined use of different imaging techniques (CAT, MRI, PET, DTI, etc.), the prior treatment of the image (atlas, advanced segmenting and detection systems. morphological co-registering, etc.), very different types of signals (ECG, EEG, EMG, Respiration, etc.), as well as morphological and functional models derived from tissue and organ modelling. The combination of these components allows a more efficient, complete and rigorous diagnosis.

The objective of this line is therefore related to the combined analysis of all this information, promoting improvements in diagnosis systems, elaborating tools for aiding in making clinical decisions and encouraging pre- and inter-operatory planning systems, as well as simulation and control tools in virtual surgery.

This line is in turn complemented with others, such as Nanodiagnosis and Prostheses and Implants lines, in which similar or complementary techniques are used.

- A.2. Intelligent Devices and Biomedical Systems

The introduction of more portable and efficient medical devices, affording a greater deal of autonomy from the clinical specialist (incorporating а certain degree of intelligence), significantly increases life quality. These devices include remote monitoring systems for high-risk patients, in coniunction with automatic telecommunication systems, automated drug delivery systems, even in a closed loop, controllably adaptable implants, among many other examples.

This implantation entails a greater independence of the patients which in turn reduces the burden on healthcare personnel. Additionally, research results coming from this line offer more thorough and continuous control of the patients, since the evolution of their health condition is tracked and different variables can be simultaneously monitored.

In these years a new line has emerged within this research area and it is related to e-health systems, which is a term used for healthcare supported by electronic processes and communication as well as m-health, which is supported by mobile phones and other portable devices. CIBER-BBN has included this line to its current Research programme since research of several groups point to this area.



B. Area of Biomaterials and advanced therapies

- B.1. Cell and Gene Therapy

Gene therapy and cell therapy are overlapping fields of biomedical research with the goals of repairing the direct cause of genetic diseases in the DNA or cellular population, respectively.

These powerful strategies are also being focused on modulating specific genes and cell subpopulations in acquired diseases in order to re-establish the normal balance. In many diseases, gene and cell therapy are combined in the development of promising therapies.

In addition, these two fields have helped provide reagents, concepts, and techniques that are elucidating the finer points of gene regulation, stem cell lineage, cell-cell interactions, feedback loops, amplification loops, regenerative capacity, and remodelling.

Specifically, Gene therapy is defined as a set of strategies that modify the expression of an individual's genes or that correct abnormal genes. Each strategy involves the administration of a specific DNA (or RNA).

Within this framework, CIBER-BBN research groups are focused on finding an appropriate use of this novel strategy to deliver new and improved therapies.

Viral gene transfer is relatively efficient but there are concerns relating to the use of viral vectors in humans. Conversely, non-viral vectors appear safe but inefficient. Therefore, the development of an efficient non-viral vector remains a highly desirable goal and has been recently adopted as part of CIBER-BBN's Research programme.

On the other hand, Cell therapy is defined as the administration of live whole cells or maturation of a specific cell population in a patient for the treatment of a disease.

This research line involves (1) technologies used in cell therapy, including direct cell injection systems; bioreactors and in vitro pre-differentiation; combined drug-cell systems; controlled release systems; noninvasive follow-up and in vivo monitoring systems; (2) analysis of cell biophysical properties (cell channels, membrane and cytoskeleton mechanics, etc.), and its response to biophysical stimuli (cellular mechanotransduction, adaptation and plasticity) and (3) modelling the behaviour of the individual cell and of cell populations, down to the organization of tissues and organs.

This line of research has a huge development potential due to the enormous current and future interest of Regenerative Medicine.

- B.2. Tissue Engineering

A paradigm shift is taking place in orthopaedic and reconstructive surgery from using medical devices and tissue grafts to a tissue engineering approach that uses biodegradable scaffolds combined with cells or biological molecules to repair and/or regenerate tissues. CIBER-BBN studies scaffold-based tissue engineering which includes the development of new materials for scaffolds; the design and use of bioreactors for cell culture; the analysis of the processes involved and the effect of different tissue regeneration stimuli on scaffolds, both in vitro and in vivo; the functionalisation of the scaffold surface; or non-invasive follow-up and in vitro and in vivo monitoring systems, among many others.

Two new concepts have been added as they are leading research lines in this field: (1) Decellularisation and recellularisation of organs and tissues and (2) generation of organoids from stem cells.

(1) A promising tissue-engineering / regenerative-medicine approach for functional organ replacement has emerged in

recent years. Decellularisation of donor organs such as heart, liver, and lung can provide a natural three-dimensional biologic scaffold material that can be seeded with selected cell populations. Preliminary studies in animal models have provided encouraging results for the proof of concept. Some of CIBER-BBN research groups are focused on studying it as significant challenges for threedimensional organ engineering approach still remain.

(2) However, the severe shortage of donor organs is an obstacle for using these techniques. Toward that direction, the generation of transplantable organs using stem cells is a desirable approach for organ replacement and some CIBER-BBN basic and clinical scientists have great interest in it.



The main line of CIBER-BBN analysis will be a combination of stem cells and tissue engineering since both are consolidated and outstanding research lines.

- B.3. Prostheses and Implants

The global objective of this line is to move forward in a new generation of patientspecific prostheses and implants, with greater control over their behaviour and over the evolution of the organ after implantation.

Therefore, this line includes all those elements contributing to the improvement of implant design and features such as: advanced modelling, considering the implantorgan interaction (osseointegration, tissue adaptation, influence of drugs, etc.); systems for supporting surgical decisions; surface mechanization and functionalisation systems; local and controlled drug release systems operating from the surface of the implant; biomaterials for implantation; intelligent prostheses (active monitoring and control), etc.

C. Area of Nanomedicine

Nanomedicine aims to develop tools to diagnose, prevent and treat diseases at an early stage by applying concepts of nanotechnology into clinical research.

Lines of research included in this area can be grouped into nanodiagnosis, therapeutic nanosystems and nanosafety.

- C.1. Nanodiagnosis

Nanodiagnosis consists of developing systems and image analysis techniques both in vivo

and in vitro for the early detection of disease.

One of the detection systems developed to date is based on diagnosis with nanoparticles (semiconductor, or magnetic metal) such as quantum dots that are used as cell labelling, identification of tumors or diseased areas.

Another line of action within this field is the diagnosis with nanobiosensors. These integrated nanoscale devices for a biological receptor (proteins, DNA, cells) are prepared to specifically detect a substance and a transducer or sensor, capable of measuring biomolecular recognition reaction and translate it into a measurable signal.

The use of these techniques would allow diagnosis with a more solid biological base and more reliable results, which would translate into greater precision in the diagnosis of different pathologies.

- C.2. Therapeutic nanosystems

This line will concentrate on the development of new pharmacological therapies based on the intelligent design of guided nanoconjugates.

The therapeutic nanosystems research line contemplates both the development of pharmacological release systems optimized to traverse the blood-brain barrier, and the specific release of enzymes, proteins or gene inhibition strategies by means of siRNA.

The pharmacological reformulation of drugs, already existing in clinical practice, is not a priority, neither a technological development if it is not associated to a relevant clinical need. The line must assure that toxicological and therapeutic activity data are obtained in all the newly designed nanoconjugates. The basic objective is to obtain suitable proofs of concept.

The development of therapeutic nanoconjugates and of local and controlled release systems for these nanoconjugates, would allow guiding the treatment to the area of action, in the attempt to achieve perfect control of the therapy, thereby preventing the action of the drug or therapeutic particle in areas that might entail a potential risk for the patient.

This research line includes the study of biocompatibility and toxicity of therapeutic nanosystems and nanodevices, the development of theranostic systems and the analysis of biological processes, such as physiology, cell adhesion or communication, cell biophysics or epigenetic considering the development of different techniques for their study.

- C.3. Nanosafety

Toxicology and safety assessment is an integral part of any new medical technology. The aim of nanosafety research in this context is to enable safer design of nanomedicines.

Achieving safer design of nanomedicines requires an understanding of material's intrinsic properties along with an understanding of the behaviour of these materials in living systems.

Dose metrics, biokinetics (which is the movement and distribution of nanomaterials in the body) as well as the urgent need for validated means of extrapolating acute in vitro results for prediction of in vivo chronic effects are some of the nanotoxicologic concepts of relevance for safety assessment.

With the huge and broad onslaught of new nanomaterials, traditional studies addressing one material at a time are no longer adequate. Moreover, alternative approaches that pave the way to the reduction or refinement of traditional animal testing of chemicals or nanomaterials are needed. In the Nanomedicine field, with an increasing number of sophisticated nanomaterials being produced, it is required to demonstrate an acceptable risk-benefit profile. Hence, safety assessment is an integral part of any development of new nanomedicines or nanotechnologies.





Pathologies addressed through collaborative research models.

These three areas of research are not independent from each other as many of them converge in a common objective based on the diagnosis or treatment of a specific pathology.

CIBER-BBN fosters the creation of collaborative research lines between groups through the intramural projects.

Each intramural project involves two or more CIBER-BBN research groups and is focused on a concrete clinical specialty.

On the following page, there is a diagram which represents, in a simplified way, the number of groups and pathologies addressed in the last call for intramural projects (2016-2018).

Oncology is the medical speciality in which more groups are developing their collaborative research to provide solutions for breast cancer, brain tumours, colorectal cancer or thyroid tumours.

A large number of intramural projects are focused on the musculoskeletal system and try to provide solutions from both biomaterials and nanomedicine research lines.

Other medical pathologies addressed are neurological and mental disorders, rare diseases, diabetes, infectious diseases and other problems affecting the respiratory, cardiovascular, renal or ophthalmology systems.


Research lines and medi	cal pathologies addres	sed in the intramural call (2	016-2018)
	BIOENGINEERING AND MEDICAL IMAGING	BIOMATERIALS AND ADVANCED THERAPIES	NANOMEDICINE
ONCOLOGY	<u>\$</u>	<u>(</u>	<u>4</u>
MUSCULOSKELETAL		<u>6</u>	<u>4</u>
NEUROLOGICAL AND MENTAL DISORDERS	<u>\$</u>	<u>\$</u>	<u>4</u>
INFECTIOUS DISEASES		<u>5</u>	<u>\$</u>
CARDIOVASCULAR DISEASES	<u>\$</u>	<u>5</u>	
OPHTALMOLOGY DISEASES	<u>\$</u>	<u>6</u>	<u>6</u>
RENAL DISEASES	<u>\$</u>	<u>6</u>	
CICATRIZATION ULCERS		<u>5</u>	<u>4</u>
DIABETES AND ENDOCRINES	4		
RARE DISEASES			<u>6</u>
RESPIRATORY DISEASES	<u>\$</u>		
		Key: 🔥 6 or more groups 🔥	3-5 groups 🛃 Less than 3 groups

Research lines and medical pathologies addressed in the intramural call (2016-2018)

5. Integrated platforms: a collection of highlevel scientific infrastructures to provide research services.

In order to achieve the CIBER-BBN objectives regarding the increase of its groups' research capabilities through the sharing of resources, a Programme for Platforms Equipment was implemented during its early days.

Two calls for grants were tendered (2007 and 2008) in order to allow the groups to purchase equipment, providing priority to those applications that considered the equipment proposed for common and shared use with other CIBER-BBN's members, that is, those who were part of this open platform of services.

Additionally, applications limited to equipment for the exclusive use of the candidate groups, were dismissed.

Thus, clusters or units of technical and scientific equipment were established based on the use of existing facilities, or of those still in the acquisition process, that could complement or be complemented by those provided by CIBER-BBN, and destined to offer high-level technological resources to CIBER-BBN research groups and external groups, under specific conditions.

The equipment supplied by CIBER-BBN is owned by the consortium and is inventoried as such. To this end, 20 Establishment Agreements have been drafted and signed between CIBER-BBN and the host institutions where each unit has been placed.

During 2009, regarding the information collected by the corresponding Monitoring committee created, CIBER-BBN's Steering

committee implemented a process to evaluate the activity performed and the standpoint of each unit. As a result, the units were reorganised into five complementary platforms with clearly defined goals and purposes.

NANBIOSIS is one of the twenty-nine ICTS (Singular Scientific Technological Infrastructures) recognized by the Spanish Council for Science Policy, Technology and Innovation (MINECO). This ICTS is integrated by the CIBER-BBN and the Jesus Usón Minimally Invasive Surgery Centre (JUMISC).

NANBIOSIS integrates twenty-seven complementary units coordinated under one single contact point system and encompasses the phases from biomolecules, biomaterials and nanoconjugates production, to preclinical validation through physiochemical and toxicological characterization, biological characterization and in silico modelling and experimentation.

By having all this potential, being able to develop a therapeutic agent and to arrive to its preclinical validation under the umbrella of NANBIOSIS, its Spanish leading research groups in bioengineering, biomaterials and nanomedicine have a great opportunity to open paths of collaboration with industry in order to develop their products, using the potential of every unit involved.

Additionally, this centralised model allows participation in competitive calls and international initiatives as a single partner and a single well-organized infrastructure.

Through research and training, NANBIOSIS infrastructure has been growing and adding a large number of research groups that form a

critical mass which consolidates biomedicine as a strategic area with high scientific and innovative potential for our country.

The five platforms that constitute NANBIOSIS are the following and they can be observed in the diagram included below:

- Biomolecules Production (three units)
- Biomaterials and Nanomaterials Production (eight units)
- Preclinical validation: Tissue, Biomaterials and Surfaces Characterization (eight units)



Source: NANBIOSIS website

- Preclinical validation: Bioimaging (seven units)
- High Performance Computing (one unit)

Specifically, the services that these platforms are able to provide, are the following:

A. Biomolecules Production

Supplies biological molecules needed to develop research projects framed in the strategic lines of Tissue Engineering,

Intelligent Devices, Implants, and specially Therapeutic Nanoconjugates and Biosensors by providing customized design and production services for applications such as:

- Functionalisation of nanosystems.
- Functionalisation of implants and prosthesis.
- Tissue regenerative processes.
- Surfaces functionalisation.

B. Biomaterials and Nanomaterials Production

Supplies 2D and 3D materials and constructs for the correct development of research projects dealing with the strategic lines of Tissue Engineering, Implants and with the Area of Nanomedicine. Some of the possible applications are:

- Functionalisation of biosensors and devices by biodeposition.
- Surface treatment to improve the integration of implants and prosthesis.
- Creation of 3D matrixes made of polymers, ceramics or composites; elaboration of scaffolds and prototypes for experimental

assays, and functionalisation of scaffolds with stem cells.

- Production and characterization of pure active pharmaceutical ingredients with nanoscale size, vesicular systems, nanosuspensions or composites of a biopolymer with an active ingredient.
- Synthesis of functionalized nanoparticles and surfaces.
- Preparation at lab-scale of molecular materials with controlled micro-, nano- and supramolecular structure.
- Growing of materials on surfaces to improve the bio-electronic interphases to enhance the signals biomonitoring.

C. Preclinical validation: Tissue, Biomaterials and Surfaces Characterization

Provides services for characterization of biological tissues, biomaterials and nanosystems that may be produced in the Platform of Biomaterials and Nanomaterials Production or in any other internal or external laboratory. The services are focused on:

- Characterization of the structural, physicochemical and functional behaviour of 2D and 3D scaffolds.
- Characterization of the histological and mechanical behaviour of biological tissues.
- Compositional, surface and colloidal characterization of materials and biological fluids.
- In vitro and ex vivo real time study of cells and tissue behaviour in presence of

potential therapeutic agents and identification and localization of therapeutic targets.

- Intramolecular interactions characterization and control of functional properties of materials.
- Characterization and control of the process of internalization of therapeutic agents in cells.

D. Preclinical validation: Bioimaging

Provides support in the preclinical development of new therapeutic compounds by validating new therapeutic targets and/or nanotherapies by using optical image techniques and NMR.

Some of the functions of this platform are:

• Analysis of fagocytic behavior and interactions of cells in presence of magnetic nanoparticled therapeutic agents.

- Spectroscopies for in vivo applications and for applications in biofluids, tissues and biomaterials.
- In vivo Validation, visualization and quantification of new therapeutic agents of the induced tissue regeneration and of the cellular and genetic activities dealing with pathologies in real time.
- Validation of new therapeutic targets.

E. High Performance Computing

Provides technical support for research projects in the line of Multimode Diagnostic by allowing the remote access for applications dealing with advanced analysis of biomedical images and signals along with the integration of multiphysical and multiscale calculation models for in silico experiments.

The location of the NANBIOSIS units is summarized on the next page.



NANBIOSIS units and their location

B. Biomaterials and Nanomaterials

U9. Synthesis of Nanoparticles Unit

C. Tissue, Biomaterial and Surface Characterization

U13. Tissue & Scaffold Characterization Unit

E. High Performance Computing

U27. High Performance Computing

B. Biomaterials and Nanomaterials





B. Biomaterials and Nanomaterials

U11. Pharmaceutical Lab

C. Tissue, Biomaterial and Surface Characterization

- U14. Cell Therapy
- U16. Surface Characterization and Calorimetry Unit
- U19. Clinical tests lab

D. Bioimaging

- U21. Experimental operating rooms
- U22. Animal housing
- U23. Assisted Reproduction
- U24. Medical imaging

Source: NANBIOSIS website

NANBIOSIS Units



A. Biomolecules Production

- U1. Protein Production Platform (PPP)
- U2. Custom Antibody Service (CAbS)
- U3. Synthesis of Peptides Unit

B. Biomaterials and Nanomaterials

- U4. Biodeposition and Biodetection Unit
- U5. Rapid Prototyping Unit
- U6. Biomaterial Processing and
- Nanostructuring Unit
- U7. Nanotechnology Unit
- U8. Micro Nano Technology Unit

C. Tissue, Biomaterial and Surface Characterization

U12. Nanostructured liquid characterization unit U18. Nanotoxicology Unit

D. Bioimaging

U20. In Vivo Experimental Platform U25. NMR: Biomedical Applications I

D. Bioimaging U26. NMR: Biomedical Applications II

C. Tissue, Biomaterial and Surface Characterization

U15. Functional Characterization of Magnetic NPs Unit U17. Confocal Microscopy Service

4. Analysis of the CIBER-BBN current situation

4. Analysis of the CIBER-BBN current situation

The analysis and diagnosis phase has been approached from several perspectives:

- An analysis of the quantitative information of each initiative carried out by CIBER-BBN in the last four years to establish a costbenefit assessment (2012-2016).
- A study of the evaluation report carried out by the Carlos III Health Institute (2015).
- An assessment of the results of the survey developed in the framework of this strategic plan for the CIBER-BBN community (2017).
- The SWOT analysis obtained through the interviews carried out both to stakeholders and to different research and management CIBER-BBN profiles (2017).

Perspectives considered through the analysis and diagnosis phase:



2. Assessment of CIBER-BBN's former initiatives

The analysis of CIBER-BBN's key performance indicators has focused on the valuation of the cost of the resources allocated for the development of an activity or programme and the impact, achievements or results achieved.

The results of this cost - benefit assessment of former initiatives has been analysed by the Steering Committee as part of the strategic reflection process carried out.

This process has been essential for the Steering Committee to globally visualize the areas in which CIBER-BBN is focusing its efforts. One of the main consequences of this analysis has been the redefinition of the centre's programmes and activities.

Scientific production and technology transfer results are shown below as well as fund raising and human resources achievements.



(*) Extramural projects signed in collaboration with 2 or more CIBER groups Source: Information provided by CIBER-BBN Management





2. Carlos III Health Institute assessment of CIBER-BBN achievements

At the end of 2015, the Carlos III Health Institute commissioned an external evaluation of the main results obtained in the previous four years (2011 - 2014) by the different research areas composing CIBER. This review pursued two objectives:

- Evaluate the results of each research area according to its scientific achievements and social value obtained.
- Identify improvement areas concerning global management and research programmes.

The evaluation focuses on four specific issues considered essential to any research centre or

structure:

- Produce relevant results for the scientific and clinical community but also for society.
- Train the next generation of research leaders.
- Increase global cooperation and achieve international visibility.
- Carry out activities whose results consolidate viability and sustainability of clinical attainments.

One of the main conclusions of the Evaluation Committee points to CIBER-BBN's solid foundations in terms of organisation, strategy and management. The Evaluation Committee appraises CIBER-BBN's clear leadership and

Carlos III Health Institute assessment of CIBER-BBN achievements, 2015

STRENGHTS

- Relevant scientific results
- High international collaboration
- Promotion of transfer actions (generation of license agreements, patents and spin-offs)
- Strategic Plan implemented and proper follow-up actions
- Singular Scientific and Technological Infrastructures (ICTS) label
- Positive assessment of transfer contracts (FERRER)
- Development of FOCUSDET technology (software for epilepsy)
- Training and mobility actions carried out
- Promotion and use of lab notebooks
- High international visibility

IMPROVEMENT AREAS

- High technology transfer level but not enough for CIBER-BBN potential.
- Little connection of some groups with clinical professionals, lack of clinical trials of CIBER technologies.
- Publications in technological journals
- Few European projects
- Lack of royalties

Source: CIBER-BBN evaluation report 2015, Carlos III Health Institute

scientific capacities for research and innovation.

The Committee considers that CIBER-BBN initiatives are aligned with the strategic objectives and views fauvorably that the Steering Committee periodically analyses potential risks or deviations and designs corrective actions.

The main weaknesses identified by ISCIII broadly coincide with those defined in CIBER-BBN's former Strategic Plan Management. ISCIII main guidelines are the following:

- Evaluation of published results to detect the existence of potentially protected results.
- Creation of business advisory boards or strengthen the Scientific Committee with

business members.

- Improvement of the collaboration between basic and clinical research groups (increasing the participation of clinical groups, generating more collaborative projects, designing initiatives that include a phase of clinical validation, etc.) as well as creating mechanisms to enhance the translation of results.
- Offering training courses to researchers in the entire innovation value chain (idea valorisation - protection strategy - product development - business model construction – transfer strategy).
- Encouraging the achievement of international projects and the protection of results.

Carlos III Health Institute assessment of CIBER-BBN achievements, 2015

TOTAL SCORE	68/100
Scientific and clinical output	13/30
Value for society	18/25
Training offer for young researchers	15/15
International visibility and cooperation	9/15
Viability and sustainability of clinical attainments	13/15

MAIN GUIDELINES

- Increase the interrelation between basic and applied research groups.
- Create initiatives to improve technology transfer and translation.
- Analyse published results to detect if they are potentially protectable.
- Offer training courses to researchers in the entire innovation value chain (idea valorisation - protection strategy - product development - business model construction – transfer strategy).
- Promote the achievement of international projects.

Source: CIBER-BBN evaluation report 2015, Carlos III Health Institute

4. CIBER-BBN strategic plan: an opportunity to gather the point of view of CIBER-BBN's community.

The CIBER-BBN community was invited to complete an online survey about key issues for the centre.

The survey was totally anonymous and voluntary. The population sample included forty-seven principal investigators, one hundred and one CIBER-BBN hired researchers,

Methodological bases of the survey

three hundred and eleven associated researchers and eight programme managers (a total of four hundred and sixty-seven requests). The survey was structured in four large blocks including:

- Respondent profile: research area, years of seniority, etc.
- Level of satisfaction: specifying how satisfied or dissatisfied the respondent is with the centre. Special emphasis on



Source: Based on the information obtained in the surveys

pointing out the weaknesses found in current performance.

- Level of technology transfer and collaboration: this is based on the perception of respondents about the level of technology transfer reached and the degree of collaboration between CIBER groups.
- Vision on certain topics associated to human resources area and international visibility.

The engagement rate reached 41% of the community as a whole. This percentage increases to 68% if associated researchers are not considered.

Therefore, these results obtained are robust with a statistical confidence level of 99%. The main conclusions of the survey are shown below:

- Most of CIBER-BBN researchers consider that being part of the centre has meant a relevant improvement in their professional career.
- 9 out of 10 researchers consider the degree of collaboration between CIBER-BBN groups is medium-high.
- The performance of NANBIOSIS platform is perceived as medium-high by 71% of the CIBER-BBN community.
- According to the researchers' point of view, only 3 out of 10 have achieved a TRL score higher than 4 in their technology with the highest degree of transfer.

- The main limitations found by researchers are focused on the requirement of publishing according to their host institutions and on the complex bureaucracy processes entailed.
- 83% of CIBER-BBN researchers consider their collaboration with clinical groups is medium-high.
- According to the CIBER-BBN community, hired researchers do not apply for national or international projects as they do not lead an independent research line.
- Satisfaction with CIBER-BBN hired researchers is high or very high in 81% of the cases.
- 7 out of 10 researchers consider CIBER evaluation criteria are fair and proper.

Some of the most relevant questions and results of the survey developed are shown on the following pages.





Summary table: Results obtained in the survey (collaboration network)

Source: Based on the information obtained in the surveys



Source: Based on the information obtained in the surveys



Summary table: Results obtained in the survey (clinical translation)

Source: Based on the information obtained in the surveys



Source: Based on the information obtained in the surveys



Summary table: Results obtained in the survey (CIBER-BBN research group tenure)



5. Main conclusions expressed through the **SWOT matrix**

The starting point is an initial SWOT analysis developed with the information obtained through the thirty-four interviews conducted. This SWOT matrix is discussed with the Steering Committee in order to prioritize the more relevant issues for the centre.

SWOT

areas

CIBER-BBN

- SYNERGIES and scientific complementarity
- Research groups of EXCELLENCE
- POSITIVE IMPACT of CIBER benefits perceived by principal investigators
- High level of international COLLABORATION
- Facility to attract COMPETITIVE FUNDING
- ICTS label: great technological/equipment base
- Recurrent PUBLIC FUNDING
- AUTONOMY for resources allocation
- Groups receive FUNDS according to their ASSESSMENT

• SYNERGIES due to CIBER's merger Creation of NEW ALLIANCES

emerging research areas

Ability to modify FUNDS DISTRIBUTION

• SOLID CONNECTIONS between research groups

Weak BUSINESS NETWORK in some research

SCIENTIFIC POSITIONING of the groups in

• Expanding the INTERNATIONAL IMPACT of

- **RESULTS** must be more focused on translation
- Little connection of some groups with CLINICAL professionals.
- Excessive BUREAUCRACY and loss of agility of CIBER administration.
- Scope for improvement in BUSINESS **DEVELOPMENT** area.
- Possibility to improve CIBER-BBN strategic ALLIANCES and INTERNATIONAL VISIBILITY
- Inability to RECRUIT new staff

- Spanish companies have little money to invest in R&D
 - LOSS of leadership in innovation and translation
- AGILITY of management support structures
- Loss of HUMAN CAPITAL
- Loss of projects with companies due to BUREAUCRACY
- Decrease of BASELINE FUNDING
- Increasingly higher COMPETITION, low visibility
- Source: Based on the information obtained from the interviews conducted along the process





Strengths



Transfer and translational research programme

- SYNERGIES and scientific complementarity: CIBER-BBN is the perfect framework for collaboration between basic and clinical researchers and between researchers with different scientific profiles and disciplines.
- Research groups of EXCELLENCE: Group selection was made through competitive calls based on their scientific excellence.
- POSITIVE IMPACT of the centre for its groups: In general, incorporation to CIBER-BBN has meant an improvement in scientific production, technology transfer and translation indicators (access to other groups, funding, staff, equipment).
- High level of international **COLLABORATION:** Generally groups have a good connection with other international groups of excellence.
- Facility to attract COMPETITIVE FUNDING: groups are very active in applying for Spanish and European projects.
- ICTS label, great technological and equipment base: A great technological investment has been made so as to be used by CIBER groups. The fact of having achieved the Singular Scientific Technological Infrastructures label facilitates the funding obtaining and improves the visibility of the centre.



Human resources and economicfinancial programme

- **CIBER-BBN BENEFITS perceived by principal** investigators: The fact of being part of CIBER-BBN has been valued as highly positive by most principal investigators and hired researchers.
- APPROPIATE internal ADMINISTRATION structure: There is a proper vertical communication of the Steering Committee decisions. Besides, there is a management team for each programme.
- Possibility to use incorporation or **MOBILITY programmes**: CIBER-BBN offers these programmes to their researchers to enhance their exchanges and favour the integration of young talent.
- Recurrent PUBLIC FUNDING: There is an annual baseline budget that allows medium term strategies and a stable environment to be established.
- CIBER has autonomy for the ALLOCATION of resources: Funds raised annually by CIBER-BBN can be distributed depending on programmes and projects, by groups or in a combined way as decided by the Steering Committee.
- Groups receive FUNDS according to their **ASSESSMENT:** It is valued positively that part of the funding is distributed according to the assessment of group evaluations.

Source: Based on the information obtained from the interviews conducted along the process

Weaknesses



Transfer and translational research programme

- Little connection of some groups with CLINICAL professionals: Not every CIBER-BBN group has incorporated clinical staff (role of clinical scientists, etc.) or are working closely with hospital groups.
- INTRAMURAL projects without specific funding: Collaboration through projects is considered positive although they should be more specific, properly funded and with a fixed length.
- Scope for improvement in BUSINESS DEVELOPMENT area. Industry demands full documentation to perform an analysis from the business point of view (scientific dossier, but also a business plan, regulatory aspects, etc.). Industry also demands researchers being more active introducing their results and new achievements.
- SCIENCE PUSH versus market pull: The research programme is oriented by scientific areas rather than by product or pathology. Research groups have made great efforts in the last four years to focus on pathologies but there is still a lot of work to be done.
- Few RESULT-ORIENTED projects, not attractive for companies: In order to be considered interesting for the company, a project must reach the PPOC phase,

although not many projects actually do.

- Too many formalities and BUREAUCRACY in the relationship CIBER-host institutions: Periods to arrange transfer or coordination agreements are too long.
- Lack of BUSINESS DEVELOPMENT associated to some research areas in Spain. In Spain, a strong business network, with which CIBER-BBN groups can create alliances, has not yet been developed for some research areas, especially those associated to bioengineering and medical imaging.
- Business FORUM with national focus: Despite the fact that the business network corresponding to some research areas is broadly international, forums are more focused on national companies.
- Economical return of the PLATFORMS: At present CIBER-BBN continues investing in platforms and their marketing and promotion (almost €250k / year) having no economic return for them as benefits go to host institutions.

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Human resources and economicfinancial programme

 DEPENDENCE on ISCIII and other institutions: this dependence reduces freedom in making certain decisions.

Weaknesses

- Scarce WORKING LOBBY mechanisms: ISCIII has to consider CIBER-BBN singularity when evaluating and supporting certain initiatives, etc.
- There is no agreed view of the **RESPONSIBILITIES of the Medical Advisory** Board: It is not clearly perceived if the role of the Medical Advisory Board is to lobby at national level, to evaluate projects from a clinical perspective or to generate knowledge at clinical level (participation in forums). There is a general feeling of little connection and underuse.
- · Operational steering committee but with little TIME FOR REFLECTION: Meeting spaces are used to solve problems quickly but hardly to think about certain strategic aspects of the organization.
- · Inability to RECRUIT new staff: Since the recruiting is linked to public job regulation.
- RESEARCH CAREER of the strengthening programme is not clear enough: The necessity to assess the definition of a new research career for CIBER-BBN's hired staff, an evaluation of their objectives, customized training, etc.
- UNDERUSE of **CIBER-BBN** mobility programmes: Intragroup stays add up to just sixteen since their implementation.

- OVERHEADS system is not always properly explained: Some host institutions do not have a clear system to refund overheads when it comes to projects awarded by CIBER-BBN.



Communication and visibility programme

- Opportunity to improve CIBER-BBN VISIBILITY towards ISCIII: A closer approach and greater presence in ISCIII is needed to transmit some aspects that are critical for CIBER-BBN as its evaluation criteria.
- Little CIBER-BBN INTERNATIONAL visibility: Despite many groups collaborating with other groups of excellence in the international arena, CIBER-BBN is not considered as a renowned centre beyond national level.
- Scope for improvement in CIBER-BBN strategic ALLIANCES: Some agreements were reached with prestigious institutions that should be used to launch global strategies for collaboration.
- CIBER-BBN CORPORATE IMAGE is not visualised: In order to contribute to the creation of brand image, it is necessary to consider some corporate issues such as signing, card, mail, image in stands, etc.



Opportunities

Transfer and translational research programme

- SYNERGIES after CIBER merger: It is easier for CIBER-BBN groups to establish new scientific collaborations with groups who belong to other research areas of CIBER. Multidisciplinary groups are able to apply a call under the same legal entity.
- Creation of new ALLIANCES: this is an untapped field where initial steps are being taken. This can be translated into opportunities to collaborate with groups of international excellence and to improve visibility.
- Ability to modify FUNDS DISTRIBUTION: The Steering Committee has absolute power to change the distribution of funds between programmes (funding by group or project, competitive or baseline funding, specific funding for value enhancement, etc.).
- **CONNECTION between groups**: After these years of collaboration, the connection between groups will be able to provide valuable results.
- Weak BUSINESS NETWORK in some research areas: this provides scope for the generation of spin off or the creation of strong strategic alliances with industrial partners.

Human resources and economicfinancial programme

- Integration of TALENT: It is possible to incorporate new research groups of excellence through recurrent calls aimed at reinforcing the scientific programme.
- CIBER as an EXAMPLE in its scientific fields: Its scientific positioning is a competitive advantage for the attraction of future funding in an environment of fewer calls.



Communication and visibility programme

 Expanding the INTERNATIONAL IMPACT of CIBER-BBN: A larger dissemination of CIBER-BBN, with an international perspective, will attract new collaborating companies or groups.



Threats



Transfer and translational research programme

- Spanish companies have little money to invest in R&D: Funding reserved by companies for R&D projects is being cut back in Spain and Europe which complicates partnerships with CIBER-BBN. Between 2012 and 2015 there has been a 36% decrease.
- Loss of leadership in innovation and translation: When CIBER was launched, it was a new way of biomedical research management In Spain. Therefore, CIBER-BBN took international models of excellence and collaboration as reference. CIBER was configured with the right structures at that precise moment. However, ten years have passed and it is necessary to evaluate them in order to adapt them to the current situation. This way, its leadership will be maintained and it will not be seen as an ordinary biomedical research centre.
- CIBER merger: The loss of agility and accessibility of administrative tasks because of the merger may lead to a decrease in the use of CIBER services by researchers, especially regarding public calls submission.
- Loss of projects with companies due to BUREAUCRACY: Celerity in the arrangement of agreements is necessary.

Human resources and economicfinancial programme

- Loss of HUMAN CAPITAL: If wages remain uncompetitive and hired staff are not encouraged in other ways, a drain of talent could occur.
- Loss of BASELINE FUNDING: In the current situation there is a risk of losing part of the baseline funding received by CIBER-BBN (12% of the baseline funding has been lost between 2012 and 2015).
- COMPETITIVE funding decrease: Calls are increasingly scarce and include a smaller budget, so if CIBER-BBN is not competitive, it will lose the opportunity to raise funds.
- AGILITY of management support structures: Both the Steering Committee and Scientific Director combine their management tasks with their teaching and research activity in their host institutions.



Communication and visibility programme

• Increasingly higher COMPETITION: There are highly competitive centres in biomedicine all over the world.

 Definition of CIBER-BBN objectives and strategies

5. Definition of CIBER-BBN objectives and strategies

1. Introduction

This section will point out CIBER-BBN objectives and strategies both for management and research.

2. Scientific strategy

CIBER-BBN scientific strategy uses the Research programme as an instrument to set out the main research lines to be developed by the groups, the medical specialities to be focused on and major scientific challenges to be undertaken in the different research areas.

2.1. The CIBER-BBN Research programme and major challenges of CIBER-BBN research areas: Scientific goals.

CIBER-BBN has developed its research programme through a 'bottom up' strategy since 2006, providing a structured scientific programme with clear research lines.

The CIBER-BBN Steering Committee and principal investigators have defined the greatest scientific challenges of the research areas which are shown below and in the following pages.

Scientific goals: Major challenges for CIBER-BBN research areas



Scientific goals: Major challenges for CIBER-BBN research areas

	Intelligent Devices and Biomedical Systems
BIOENGINEERING AND MEDICAL IMAGING	 Development of M-HEALTH TOOLS for follow-up and control of adherence-to-the-treatment for patients with non-communicable diseases (obesity, diabetes, dementia, depression). Design of SENSORING MICRO AND NANOSYSTEMS . Development of MICROFLUIDIC CO-CULTURE PLATFORMS based on organ-on-a-chip bioreactors for barrier function assessment and drug testing.
	Cell and Gene Therapy
BIOMATERIALS AND ADVANCED THERAPIES	 IDENTIFICATION AND INTEGRATION of stem cells on tissues. FUNCTIONAL INTEGRATION of stem cells and effects on cell therapy. STEM CELL SECRETOME production and applications. REPROGRAMING cells and IPS for advanced therapies. GENE THERAPY: technologies and new trends. IMMUNOTHERAPY: methodologies and new approaches Bioprocessing and scaling of STEM CELL PRODUCTION. GENE EDITING technologies
	Tissue Engineering • DESIGN AND DEVELOPMENT OF SCAFFOLDS, growth factors and controlled release systems for Tissue Engineering





3. CIBER-BBN strategic objectives

From a global perspective, CIBER-BBN's mission is to transform public investment into collaborative research which is able to be translated to the patient.

After CIBER-BBN scientific excellence is consolidated, there is a need for strengthening the foundations of the area. It is necessary to reinforce industrial transfer and clinical translation processes.

This conclusion has been decisive for the Master Plan design as it has entirely directed its strategy. Available resources have to be aligned with the main goals by reconfiguring the current programmes and activities performed by the centre.

In this sense, lines of action suggested focus on: (1) reconfiguring the centre strategic programmes and, consequently, (2) redefining management team responsibilities so as to accommodate them to the new work dynamic. (3) CIBER-BBN own calls have also been adapted around the new structure.

In addition to those, Master Plan has (4) defined a general policy which regulates group continuation and it has proposed new measures aimed at (5) developing young talent, renewing Medical Advisory Board and updating the CIBER-BBN website.



Restructuring CIBER-BBN strategic programmes

Line of action context

1

When CIBER-BBN was established, in 2007, tools and structures were created with the main purpose of meeting the needs at that moment. These tools allow the area to create a solid collaboration network among its groups and they also allow consolidation of CIBER scientific excellence.

More than ten years since the foundation of CIBER-BBN have passed and these ambitious goals have already been achieved. Therefore, there is a need to redefine the tools used.

CIBER-BBN's programmes map

Renewed tools should focus on valorisation and transfer processes so as to achieve some projects with real potential to be translated in the mid term.

The suggested programme configuration can take advantage of current CIBER-BBN human and economic resources. It is also associated to some well defined and concrete strategic goals.

In this sense, four strategic programmes are designed. These programmes are aligned with the value chain and CIBER-BBN mission: "to transform public investment into collaborative



Restructuring CIBER-BBN strategic programmes (cont.)

research which is able to be translated to the patient.".

In addition to strategic programmes, there are two other support and cross-programmes.

The implementation of this new strategy will be supported by the management team.

1. International initiatives and projects programme configuration.

- Objective: to create a strategic frame which favours national and international CIBER-BBN visibility and its strengthening as a centre through economic and human resources collection.
- Tools: improvement of international visibility through working on projects collaboration with prestige international institutions; strengthening international presence; promotion of collaboration with international institutions and others.

2. Research and collaboration programme broadening to other CIBER areas.

- Objective: to promote research excellence through consortium group collaboration (CIBER-BBN, other CIBER areas and some other networks).
- Tools: intramural call, new early stage intramural call, collaboration projects with clinical institutions, organization of clinical forums and conferences.

3. New valorisation programme launches.

- Objective: to support researchers with the main purpose of increasing their technology transfer opportunities.
- Tools: economic resources through new valorisation calls.

4. New programme to transfer technology: goto-market programme.

- Objective: to favour market reach by either transferring the technology to a company or assigning it to a hospital or even creating a spin off.
- Tools: transfer projects call and CIBER patents support.



Restructuring CIBER-BBN strategic programmes (cont.)

5. Support to the tasks of direction and administration.

• **Objective:** to support the Director in an administrative way in order to coordinate and execute the new programme plan.

6. Platform programme strengthening.

- **Objective:** to boost CIBER-BBN research by providing a complementary service.
- Tools: ICTS, platform call.

Suggested programmes diagram

INTERNATIONAL INITIATIVES AND PROJECTS PROGRAMME	To create a strategic frame which favours CIBER VISIBILITY and its STRENGTHENING through economic and human resources collection in a global way (economic and human resources).
RESEARCH AND COLLABORATION PROGRAMME	To promote research excellence provided by COLLABORATION of consortium groups (CIBER-BBN, other CIBER areas and some other networks).
VALORISATION PROGRAMME	To support researchers with the main purpose of increasing their technology TRANSFER opportunities.
GO-TO-MARKET PROGRAMME	To favour MARKET reach by either transferring the technology to a company or assigning it to a hospital or even creating a spin off.
DIRECTION SUPPORT PROGRAMME	To support the Director in an administrative way in order to coordinate and execute the new programme plan allowing the structure to focus on ADDED VALUE TASKS .
PLATFORMS / ICTS PROGRAMME	To BOOST CIBER-BBN research by providing a complementary service

Redefining management team competences and organisational structure

Line of action context:

2

The team of programme managers is one of the driving forces of CIBER BBN and the springboard where groups find support for starting up their initiatives.

People who form the programme manager team have a high qualification profile and a proven professional management and research development. In this sense, many of them have professional experience in international research centres and they can speak many languages. Their primary functions are: (i) to focus on the active search opportunities and resources for projects, platforms and collaborative opportunities (focusing on calls for proposals, supporting the drawing up and following-up projects) and (ii) to manage and follow up on technology transfer process.

In order to achieve these objectives, the management team has been organised by groups and programmes:

 Four programme managers distributed in bioengineering, biomaterials and nanomedicine lines.



71

Redefining management team competences and organisational structure (cont.)

- One manager in platforms programme.
- One manager in transference programme.
- One Scientific Director Assistant.

2

As a result, the four scientific programme managers play the same role for different research groups.

In addition to that, each manager depends hierarchically and functionally on an area coordinator who belongs to the Steering Committee. There are informal coordinator meetings every fortnight promoted by the Scientific Director Assistant.

In order to take advantage of the available resources, it has been decided to redefine competences and original structures of the management team.

Taking all of this into account, four measures

have been proposed in order to boost the role of the CIBER-BBN management team.

1. Management team organisational and functional structure modification.

Nowadays, each manager depends on one programme coordinator which makes coordination and management less efficient.

It is suggested to have a structure design with a unique responsible person for all managers in order to:

- Achieve good use of management team abilities since the unique dependent model leads to better coordination among programme managers.
- Succeed at creating a team work environment and more agility in decision making or in conflict solving.


2. Team functions redefinition for achieving higher specialisation.

2

Nowadays, some managers are focused and structured by areas of knowledge bioengineering, biomaterials and nanomedicine's managers- whereas others are aligned with determined key processes such as technology transfer and platform managers.

Besides, functions aimed at obtaining more funds for the centre are blurred.

It is suggested to reorganize the management team according to the new strategy approved: international initiatives and projects programme, research and collaboration programme, valorisation programme, go-tomarket programme and platform programme.





Suggested tasks to be done by the programme manager on the projects support function (

The external project development support will be part of the manager functions. However, they will be restricted to some development stages as shown in the diagram below.

2

Objectives which are pursued by implementing this measure are the following:

- To have support in order to guarantee the success of each CIBER-BBN structural programmes.
- To allocate managers to each programme and to favour, at the same time, the coordination among them when it is necessary.



Management team functions and activities diagram

2

International initiatives and projects programme manager	Research and collaboration programme manager	Valorisation programme manager	Go-to-Market programme manager	
To work on CIBER INTERNATIONAL VISIBILITY and to come up with solutions for the competitive RESOURCES COLLECTION for the centre: • Supporting in INTERNATIONAL INSTITUTION contacts so as to promote centre visibility. • NEW RESOURCES SEARCHING and supporting in competitive projects appliances	To support groups on the intra- CIBER COLLABORATION RESEARCH and to search connections with other clinical groups with the purpose of increasing translation potential: • Supporting RESEARCH COLLABORATION among CIBER groups: organising meetings, forums or any collaborative action. • Organizing ANNUAL CIBER-BBN CONFERENCES • Supporting intramural and early stage calls • Supporting CIBER-BBN and clinical institution calls • Supporting the search for collaborative projects among CIBER groups	 To support researchers in order to increase their TECHNOLOGY TRANSFER opportunities. For more advanced technologies: Supporting elaboration of TECHNICAL VIABILITY PLAN, an ECONOMIC VIABILITY study and a TRANSFER PLAN. Supporting VALORISATION and TRANSFER calls Supporting the search for projects with companies and external valorisation calls (Mind the gap, etc.) SUPPORTING DEVELOPMENT of pa CIBER groups or between a CIBER groups or between a CIBER groups or between a companies of the part of the search of the part of the search of the part of the search of the part of the part of the search of the part of	group and a company as long as	
Administration manager • DIRE • Mana confe	CTION supporting aging initiation grants, aids for mob rrences)	there is CIBER technology involved ector so as to allow him to focus on m ility and helping in events organization o the platforms and to BOOST its use	nore added value tasks:	
manager PRON	Managing the platform PROMOTING platforms use by companies and research groups. Supervising and following up the marketing plan and analysing the results.			

3. Management team coordination structures definition and implementation.

2

Structuring managers by the new definition programmes, and consequently by processes, allows for better following up of CIBER-BBN objectives.

However, a flexible team that can quickly adapt to different volumes of work has to be generated.

As a tool of this necessary coordination, it is proposed to create a Management Committee on a periodic basis.

During the mentioned Committee the programme progress will be exposed either by questions or issues arisen during the daily work activity.

Objectives which are pursued by implementing this measure are the following:

- Better coordination and communication among managers.
- A strong team feeling.

4. Key indicators design for follow up.

Some indicators have been designed in order to have a correct follow up on new management team competences distribution. These indicators will be renewed every three years and they will be updated taking strategic objectives into account.

Objectives which are pursued by implementing this measure are the following:

- **To guide** managers in the key and strategic aspects at a precise point of time.
- **To know and evaluate** the management team development and the new programme structure.



Adapting CIBER-BBN internal calls

Line of action context:

After structuring the CIBER-BBN in programmes and reorganising the management team, it is necessary to consider how to direct the rest of internal resources to align them with programme objectives.

In this sense, an in-depth refection on the current calls and available budget needed to be done. For that, a historical cost-benefit analysis of the already existing initiatives was performed.

In the same way as programme restructuring, it was decided to direct available resources to actions which boost industrial transfer and translation and which help to improve the professional career of hired researchers.

1. Intramural call redefinition

Framed in the research and collaboration programme, this call tries to promote excellence and collaborative research.

- Objective: to encourage complete collaboration among CIBER-BBN research groups, not only groups from the area but also groups which belong to other thematical areas in the consortium. The main goal of this measure is to boost the existing synergies.
- Who it is addressed to: Principal Investigators (PIs) and associated members. At least two groups will have to

be involved and at least one of them will have to belong to CIBER-BBN.

 Monitoring and evaluation: since there will be open lines of collaboration, a resultsbased evaluation will be performed. In this sense, all publications, patents and funds collection will be considered.

2. New call to boost young talent: early stage intramural call creation

This call, which is also included in the research and collaboration programme, tries to empower hired researchers.

- Objective: the main objective is that hired researchers can develop new skills and their own rewarding lines of research through collaboration with other CIBER-BBN groups. This way they will be able to create their own collaboration network.
- Who it is addressed to: PhD researchers hired by CIBER-BBN. There will have to be at least two CIBER-BBN groups involved.
- Monitoring and evaluation: projects will be evaluated by the Steering Committee members and a final results report should be done at the end of the project.

3. Maintenance of the calls for collaboration with clinical entities

Included in research and collaboration programme, collaboration projects with clinical

Adapting CIBER-BBN internal calls (cont.)

institutions remains as it is:

- Objective: to create and promote collaboration between CIBER-BBN groups and other thematic areas in the consortium, or other institutions of a medical nature. The main goal is to generate innovative technologies as a response clinical needs.
- Who it is addressed to: PIs, associated and hired researchers. Since it is a call offered jointly with another area or institution, it will be necessary to join at least a CIBER-BBN group with other research group from the institution or thematic area specified in the call.
- Monitoring and evaluation: evaluation will be performed by an internal committee which will value scientific quality. Besides, a Monitoring committee will evaluate project results and their applicability.

4. Valorisation call implementation

A new call is created: valorisation call. It is included in valorisation programme:

- Objective: to boost and to support technological development in those which have arisen from scientific collaborations created over the last ten years. They will need a proper transference orientation.
- Who it is addressed to: PIs, associated and hired researchers. It will be necessary to be either a research group which holds a CIBER

patent or two or more groups with technology arisen from an intramural collaboration with a minimum of TRL 3 (Technology Readiness Level).

 Monitoring and evaluation: the review of this call will be performed by an on-site panel of experts which will evaluate the potential of the project.

The afore mentioned panel will be composed of scientists, professionals with a medical background and representatives from the business field.

Subsequently, performed activities and achieved results will be evaluated.

5. Enhancement of technology transfer call

Included in go-to-market programme, and as a consequence of the good feedback received by the CIBER-BBN community, transfer calls remain as they are:

- Objective: to encourage transference of CIBER technological developments through favouring collaboration among thematic area groups and companies.
- Who it is addressed to: PIs, associated and hired researchers. At least one company will have to be included and, either a research group which holds a CIBER patent or two or more groups with technology arisen from an intramural collaboration.

The company will fund at least the 50% of

3

Adapting CIBER-BBN internal calls (cont.)

the project cost.

 Monitoring and evaluation: activities performed and achieved results will be evaluated.

In order to have a project granted, an on site

panel of experts will evaluate the appliances.

The afore mentioned panel will be composed of scientists, professionals with a medical background and representatives from the business field.



	C C		
	1 Intramural calls	2 Early stage intramural calls	3 Collaboration with clinical entities calls
No. groups	At least two groups	At least two groups	At least one CIBER-BBN group
Thematic areas	All CIBER thematic areas	CIBER-BBN	To be defined in the call
Characteristics	Multidisciplinary research / One pathology focus	Multidisciplinary research	Mandatory participation of one group belonging to the specified institution
Applicants	PIs / associated researchers	PhD researchers hired by CIBER-BBN	PIs / associated researchers / hired researchers
Funding	Groups direct funding	Groups direct funding	Seed funding: to be defined in the call
Duration	Annual renewing lines of collaboration of three or four years	Two years	To be defined in the call
Preliminary assessment	No preliminary assessment	Steering Committee	To be defined in the call
Appliance	Simple, but with a planning and objectives	Simple, but with a planning and objectives	To be defined in the call
Monitoring	Results: publications, patents and collected funds	Final results report	Final results report
No. collaborator groups	Not limited	Not limited	Not limited
No. projects per groups	Not limited	Each doctor can be PI of one project, but there is no limit to collaboration	One project per group

CIBER-BBN internal calls diagram

CIBER-BBN internal calls diagram

	4 Valorisation calls	5 Technology transfer calls
No. groups	At least one group which holds a CIBER patent, or two groups with an intramural technology with a minimum of TRL 3	At least one group which holds a CIBER patent, or two groups with an intramural technology with a minimum of TRL 3
Thematic areas	CIBER-BBN	CIBER-BBN
Characteristics	N/A	Mandatory one company included (at least 50% funded by the company) CIBER-company agreement sign.
Applicants	PIs / associated researchers / hired researchers	PIs / associated researchers / hired researchers
Funding	Depending on annual budget	Depending on annual budget (at least 50% funded by the company)
Duration	Depending on the project	Two years from the agreement signature
Preliminary assessment	An on-site panel of experts composed of scientists, clinical and business representatives	An on-site panel of experts composed of scientists, clinical and business representatives
Appliance	Plannification for TRL upgrading	Standard report
Monitoring	Performed activities and achieved results. Manager supporting	Performed activities and achieved results. Manager supporting
No. collaborator groups	Not limited	Not limited
No. projects per groups	Not limited	Not limited

Defining a general policy which regulates CIBER-BBN research group continuity

Line of action context:

4

Defining a general policy which regulates CIBER-BBN research groups continuity in the area aims:

- To provide a stable work context for research groups through clear, transparent and stable rules. These rules will not require any intervention or criteria by the Steering Committee for their implementation.
- To favour research groups rotation in order to facilitate the entrance of potential

Research groups exit criteria through evaluation system

excellence groups at a national level in CIBER-BBN research fields.

Measures defined in this scope focus on stabilising the current group evaluation system. They also focus on configuring some criteria which regulate the situation that occurs when a principal investigator of a CIBER-BBN's group disassociates himself from the consortium due to any reason (institution change, retirement. professional incompatibility, etc.).

1. Current research group evaluation system adaptation.

1. Current evaluation system by punctuation	 Up to 2017 evaluation, a group is disassociated from CIBER-BBN if it scores less than forty points in the evaluation during three consecutive years. It is suggested to slightly modify this premise so as to guarantee that evaluation can take into consideration a positive trend and not something done in a certain point in time: a group will be disassociated from CIBER-BBN if it scores less than forty points in three out of the last five years.
2. Additional and mandatory criteria for the current evaluation system	 Research groups must fulfill all three suggested criteria in the evaluation performed on an annual basis. These criteria are based on average data evaluated in the last three years. When a research group does not fulfill any of the following sections in two years (consecutive or not consecutive), it should leave CIBER-BBN: Either having AT LEAST ONE COLLABORATIVE PUBLICATION with any other CIBER group during the last three years, or at least ONE COLLABORATIVE PATENT with any other CIBER group. Having at least SIX PUBLICATIONS PLACED IN Q1 during the last three years. Having at least ONE PROJECT FUNDED BY COMPETITIVE RESOURCES during the last three years.

Defining a general policy which regulates CIBER-BBN research group continuity (cont.)

Current evaluation system performed annually by CIBER-BBN to its research groups has been positively valued by 68% of the survey respondents (PIs, associated and hired researchers).

4

Taking into account the positive valuation, it has been decided to keep the same punctuation system but to introduce some adjustments. These adjustments are made with two purposes: maintaining scientific excellence and maintaining collaboration levels taking advantage of the already existing synergies among research groups. These additional criteria were introduced to the PIs and they will be applicable from the evaluation performed in 2019 of 2018 data (check previous page diagram).

2. Configuration of objective and transparent criteria for PI substitution process.

76% of people who responded the launched survey would like to have clear and strict rules which regulate the situation when PI disassociate themselves from CIBER.

Due to this fact, throughout the Master Plan have been studied these rules, taking into

(1) Connection	with the group and (2) scientific and technologic excellence criteria
1. Connection with the research group	 COLLABORATIVE PRODUCTION EVALUATION with the group: Joint publications, patents, projects, clinical trials or spin-offs during the last five years. A minimum global percentage of collaboration is required (example: when the new IP to lead the group has been part of CIBER-BBN for five years, 50% of the obtained results have to be achieved together with the research group. Results understood as the summing up of publications, patents, trials, spin-offs.
2. Scientific and technologic excellence	 Accomplishment of similar criteria used in Severo Ochoa programme (NI > 1.5 & Q1 > 65%). All the publications related to the researcher in scientific data bases (Scopus and Web of Science) during the last five years will be considered. Although the Q1 publication rate is fixed at 65%, this will be reviewed every three years by the Steering Committee. Additionally, new excellence criteria of the candidate professional background will be reviewed: Having led a European project as a coordinator or a partner Having led two national projects (MINECO/FIS/Others) Having signed any agreement with any company with a minimum funding of €50,000 Having registered any patent which is at national stages, or having signed any agreement of technological use with royalties collection or having promoted a clinical trial.

Defining a general policy which regulates CIBER-BBN research group continuity (cont.)

account two main concepts: connection and excellence.

- In order to make sure a real connection • exists between the new principal investigator and the research group to be led, the level of collaboration between them will be reviewed. This level will be evaluated by considering the outcome produced jointly in the last five years. By outcome it is meant publications, patents, projects, clinical trials or spin-offs. A global minimum percentage will be mandatory for approving the new leadership.
- On the other hand, with the purpose of maintaining group scientific and technological excellence level after the new leadership, the following sections will be

reviewed:

- Having achieved, in the five years before taking leadership, a pre-specified criteria of scientific quality measured by Normalized Impact and the percentage of publications ranked in the first quartile.
- The fulfillment of other requirements which measure scientific and technological excellence such as participation in European or national projects as a group leader, having signed funding agreements with any company, any registered patent, a signed agreement of a technological operation which has obtained royalties or promotion of a clinical trial.



Other initiatives: young talent boosting, Medical Advisory Board renewal and website updating

Line of action context:

There are some other measures which are specially relevant although they have less impact on the organization. These measures focus on young talent development and on CIBER-BBN international repercussion.

- 1. Young talent incentives launch.
- Medical Advisory Board (MAB) renewal. It will include clinical representatives who are close to the research process, especially in bioengineering, biomaterials and nanomedicine fields.
- **3.** Reinforcement of the projection of CIBER through its website.

1. Young talent incentives

A period of time at annual CIBER-BBN conferences will be reserved for young researchers.

An annual awards ceremony will take place. These awards, with economical support will reward young researchers work (doctoral thesis, publications, projects, any transfer action done, etc.).

Objectives pursued by this measure are the following:

- To stimulate and recognise the talent and effort of young researchers at CIBER-BNN
- To favour network creation. This way young researchers will develop a teamwork feeling.



Other initiatives: young talent boosting, Medical Advisory Board renewal and website (cont.)

2. Medical Advisory Board (MAB) renewal

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A regular renewal of Medical Advisory Board is suggested. It is proposed to choose doctors who are examples to be followed in those pathologies which are more researched in CIBER-BBN. They should also have a knowledge of the basic research process.

These two requirements could be accomplished by choosing other thematic area team leaders. This will also have a positive impact as they know well the slightly different nature of the consortium.

Three objectives are pursued with the launch of this measure:

- To add value to Medical Advisory Board advice. This will be especially relevant in designing useful technology for clinical practice.
- To obtain information about patient priorities. This would focus CIBER-BBN research on real patient needs.
- To favour synergies detection between CIBER-BBN and other thematic areas; or RETIC networks.

3. Reinforcement of the projection of CIBER through its website

Current website includes a technological offer section. However, it could be have a better visualization experience.

Therefore, with the purpose of having a more attractive technological offer and creating expectation in the potential customer, some items are suggested:

- To update the available technologies interface so it shows their pipeline.
- To recognise available technologies by topic so as to create a simpler search process.
- To outline the existence of the technology offer through a link on the website home page.

There are three objectives which are pursued by implementing this measure:

- To give visibility to technologies of CIBER-BBN groups.
- To make the technology search easier.
- To stay informed about the maturity of the technology offered.



6. Appendix

6. Appendix



Source: Information provided by CIBER-BBN Management

cïber-bbn, 10 years of collaborative research

