MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD

Instituto de Salud Carlos III

ciber-bbn

Centro Investigación Biomédica en Red

Bioingeniería, Biomateriales y Nanomedicina

ACTION PLAN AND BUDGET 2015

November 2014

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1. INTRODUCTION

The CIBER-BBN was founded in December 2006, and was one of the first seven CIBERs (Networking Biomedical Research Centers) created by the Spanish Ministry of Health and Consumer Affairs of the Spanish Government, within the CIBER initiative, managed by the Instituto de Salud Carlos III, which is currently part of the Ministry of Science and Innovation. Initially a total of 32 groups from all over Spain joined the CIBER-BBN, and this number increased to 49 after the second selection call which took place in the year 2007. An additional group joined CIBER-BBN in 2008. In addition, three clinical associated groups have been incorporated since 2010. After the internal evaluation process carried out in 2010, two groups (one of them an associated group) were discontinued. Fourth other groups have discontinued at the end of 2011 (1), 2013 (1) and 2014 (2), as a result of the strategy plus scientific evaluation. Since January 2015 we are 44 groups (two of them associated). All the groups were selected by different international panels according to their scientific excellence and their compliance with the profile and priorities of the CIBER.

CIBER-BBN is an initiative with long-term projection in three areas with large development potential: Bioengineering, Biomaterials and Nanomedicine. The present document briefly presents the action plan and budget for 2015.

During 2013 the CIBER-BBN Steering Committee did a reflection process to define the strategy of the centre for the next four years. As a result of this reflection a Strategic Plan for the period 2014-2017 was elaborated and approved by the *Consejo Rector* at the end of 2013.

Mission and vision of CIBER-BBN are defined as:

- **Mission**: "To perform a research of excellence aimed at industrial transfer and clinical translation through the development of the scientific areas of bioengineering, biomaterials and nanomedicine."

- **Vision**: "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."

CIBER-BBN's structural objectives have been defined as:

1. To maintain the excellent scientific and technological quality level achieved over these years.

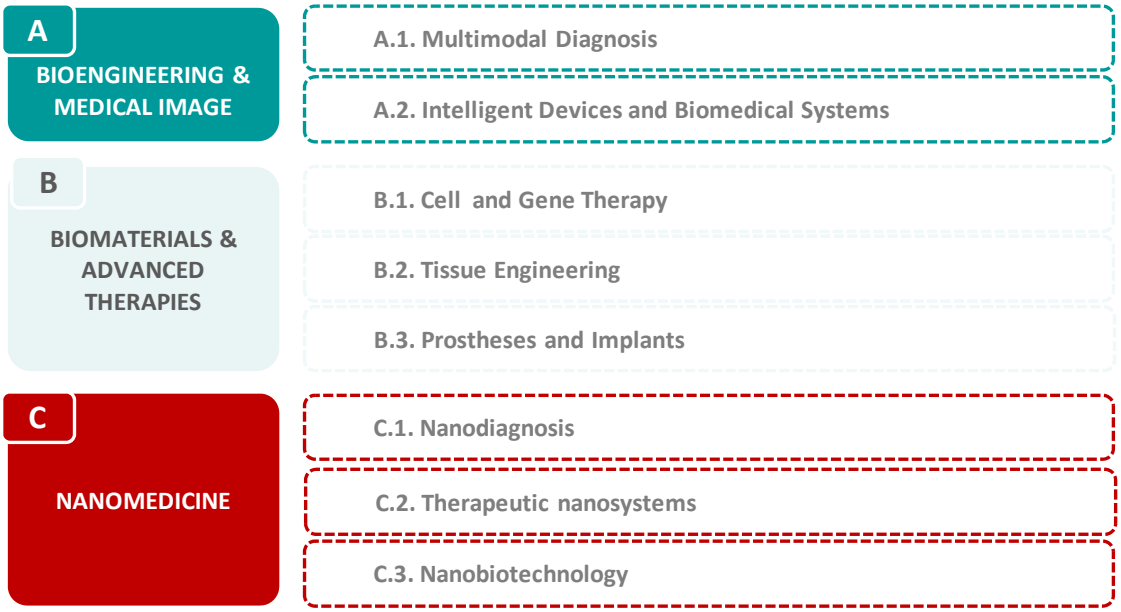
2. To promote collaboration between CIBER-BBN's research groups, strengthening stable alliances mixing basic and applied research and allowing the creation of multidisciplinary teams.

3. To boost translation establishing the necessary channels so CIBER-BBN's research is able to induce an improvement of patient's health.

4. To facilitate the transfer of CIBER-BBN's results through patents, joint papers, creation of new technology-based companies, the offering of research services and consultancy about technology, research or innovation.

2. ACTION PLAN 2015: INTRAMURAL RESEARCH PROGRAM

The Master Plan 2014-2017 includes eight strategic lines which take into account the research priorities in our field at national and international level and also the experience of the CIBER-BBN member groups.



A more detailed view of the scientific contents of each strategic line is shown below:

	Lines of research
A.1	Multimodal diagnosis
A.1.1	Medical image's capture and processing optimization (IAC, NMR, PET, DTI)
A.1.2	Biomedical signals' capture and processing improvement (ECG, ELG)
A.1.3	Morphological and functional modelling of tissues and organs
A.1.4	Pre-operative and intra-operative planning as well as creation of virtual surgery programs
A.2	Intelligent Devices and Biomedical Systems
A.2.1	Creation of systems to monitor patients (sensoring and controlled systems)
A.2.2	Software applications to improve systems for patient diagnosis
A.2.3	E-health and M-health Systems

A BIOENGINEERING AND MEDICAL IMAGING

	Lines of research
A.1	**Multimodal diagnosis**
A.1.1	Medical image's capture and processing optimization (TAC, NMR, PET, DTI)
A.1.2	Biomedical signals' capture and processing improvement (ECG, EEG)
A.1.3	Morphological and functional modelling of tissues and organs
A.1.4	Pre-operative and intra-operative planning as well as creation of virtual surgery programs
A.2	**Intelligent Devices and Biomedical Systems**
A.2.1	Creation of systems to monitor patients (sensoring and controlled systems)
A.2.2	Software applications to improve systems for patient diagnosis
A.2.3.	E-health and M-health Systems

B BIOMATERIALS AND ADVANCED THERAPIES

	Lines of research
B.1	**Cell and Gene Therapy**
B.1.1	Stem and progenitor cells. Cellular reprogramming.
B.1.2	Development of non-viral vectors for gene therapy.
B.2	**Tissue Engineering**
B.2.1	Biomaterials for *scaffolds*.
B.2.2	Signaling biomolecules.
B.2.3	Cellular and molecular functionalisation of biomaterials.
B.2.4	Biomechanics and Microfluidics.
B.2.5	Decellularisation and recellularisation of organs and tissues
B.2.6	Generation of organoids from stem cells : Towards artificial organs.
B.3	**Prostheses and Implants**
B.3.1	Modelling
B.3.2	System of treatment and surface functionalisation
B.3.3	Custom prosthesis. 3D Printing

C NANOMEDICINE

	Lines of research
C.1	**Nanodiagnosis**
C.1.1	Development of biosensor devices based on micro / nanotechnologies to detect specific biomarkers of disease
C.1.2	Evaluation and validation of new biomarkers of disease through new strategies and devices based on micro / nanotechnologies
C.1.3	Development of new contrast agents
C.2	**Therapeutic Nanosystems**
C.2.1	Study and development of new agents (enzymes, proteins, nucleic acids...)and nanostructures with therapeutic properties
C.2.2	Development of nanosystems to improve pharmacokinetics and pharmacotherapy of therapeutic agents
C.3	**NanoBiotechnology**
C.3.1	Study of biocompatibility and toxicity of therapeutic nanosystems and nanodevices.
C.3.2	Biological processes research (physiology, cell adhesion or communication, cell biophysics and epigenetic) and development of techniques for their study.
C.3.3	Theranostic systems development

The purpose of the intramural research program is to support projects leading to control key technologies, to be aware of and increase knowledge on emerging technologies and to maintain support for basic technologies. In summary, the overall objective of the program is to lead CIBER-BBN towards a higher level of technology transfer.

It should be pointed out that the aforementioned priority areas include the multidisciplinary nature of current research. They will most certainly include methodological and disciplinary aspects from several of the basic strategic lines and will therefore be interdisciplinary by definition. Some priority areas are closer to the final application, either in the healthcare system or in the industrial sector, whereas others include more basic aspects of research which on the one hand try to continue generating long-term knowledge and, on the other, pose greater and therefore riskier challenges. We are therefore attempting to maintain and strengthen the dual nature required for an institution like ours: a research center of excellence and a short-term effect on generating wealth and improving the health of the population as a whole.

A total of 49 intramural research projects have been active during 2014 in the three research programs. These 49 were approved and started their development by the early months of 2014 and are planned to be running for the period 2014-2015. These projects have recently present their evolution during our Annual Conference held in November 2014 in Girona so both Scientific Advisory Board and to the Medical Advisory Board, together with the general public could provide feedback on their evolution.

CIBER-BBN funding for these projects for the period 2014-2015 was allocated in terms of group evaluation from previous years.

In addition to these standard intramural projects a new modality, Transfer program projects, was issued starting in January 2014. They are a new modality of

projects to fund the transfer of already mature research results to industry. They are collaborative projects with at least two CIBER-BBN groups in collaboration with one or more industrial companies. These projects count with direct funding coming from CIBER-BBN and from the company ("50% explicit contribution each").

Four projects were approved under this modality, and after one cancellation, the other three have been starting its first steps during 2104. The companies BRUKER (Alemania), SYLENTIS (grupo ZELTIA) y PRAXIS are the ones that have team up with us to develop this program, together with FERRER which already in involved in a transfer project with CIBER-BBN since 2012.

This intramural (both regular and transfer projects) call was asses in this occasion by ANEP (*Agencia Nacional de Evaluación y Prospectiva*), by National and International experts. Proposals werw assessed by ANEP in terms of alignment with CIBER-BBN priorities, scientific relevance, scientific opportunity and quality, multidisciplinarity, degree of collaboration among groups, clinical impact and potential transference to industry.

In addition to these intramural projects, the research groups are involved, through their home institutions or through CIBER-BBN, in competitive research projects related to the research topics described in the CIBER-BBN Strategic Plan. CIBER-BBN takes part in projects funded by private entities (v.g. La Marató TV3), and public organizations, at National and International level, such as Plan Nacional de I+D (Innpacto initiative, FIS), FP7, H2020 or ERA-NETs. There are also funds for hiring Human Resources (such as grants in Ramón y Cajal or Miguel Servet programs, or grants for technician staff).

As for scientific results, it is expected that in 2015 the quantitative numbers of research production (publications, patents, …) tends to stabilizations after several years of growing, being now the goal to increase even further the level of quality of the production, with special emphasis in those related to transference and translation.

3. ACTION PLAN 2015: HORIZONTAL PROGRAMS

The three Horizontal Programs are: 1. Equipment Platforms, 2. Technology Transfer, Translational Research and Dissemination and 3. Training and Capacities.

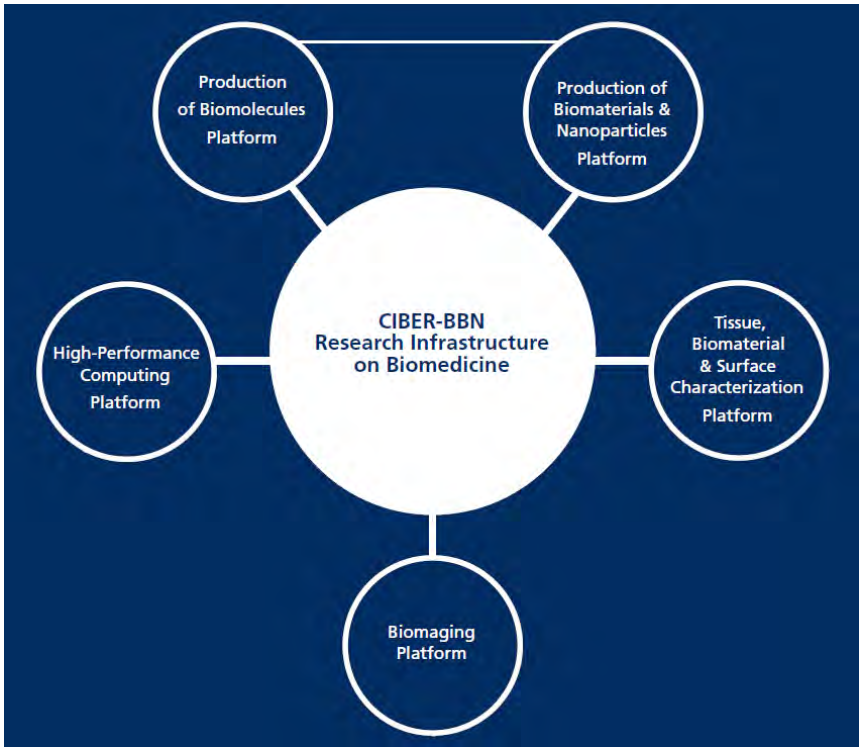
3.1 EQUIPMENT PLATFORMS PROGRAM

During 2015, the yearly based follow up of all the units concerning the activities performed during 2014 will be carried out.

Bilateral meetings between CIBER-BBN and institutions where platforms are located will be held during the first months of the year.

One more year, looking for external funding will be a priority during 2015, both from public and private sources. The presentation of the program in International bodies and partnering events will be therefore carried out. We will also continue the process of presenting the program to national companies, private research foundations and public research organizations.

In October 2014, a positive resolution from MINECO related to our application for the recognition of our infrastructure (together with the infrastructure of Centro de Cirugía Mínimamente Invasiva Jesús Usón) as ICTS (Infraestructura Científico-Técnica Singular), was received. This is considered a mayor point for the infrastructure and for the CIBER, and the necessary procedures to deploy the infrastructure will be implemented during 2015 in order to accomplish the requirements of the ICTS status.



Assignation of resources to all platforms units for the next year (2016) will be done in 2015 as a function of the results obtained in the evaluation of all units activity during 2014. This mechanism to assign resources was designed in 2012 and has already been implemented in 2013.

A new strategic action to enhance the use of the equipment platforms was launched with success in 2012, and will be maintained also during 2015. This initiative aims at developing collaborative projects with companies. These projects need to involve the participation of at least one unit of the CIBER-BBN research infrastructure.

Standardization of procedures and normalization processes will continue being a priority for the program. In this context, an aspect to be highlighted is the support to those units which are interested in obtaining accreditation for quality standards by official agencies. CIBER-BBN considers that this is a key action so as to be able to offer a highly qualified research services.

Associated Platforms will be internally promoted and disseminated within the CIBER-BBN groups in order to encourage a better knowledge of their services. New complementary platforms or initiatives will be contacted in order to establish ways of collaboration.

Due to limitations for hiring research and technical staff, only a small amount of new contracts will be allowed to CIBER-BBN during 2015. Therefore, necessities in the groups will need to be prioritized.

3.2 INDUSTRIAL TRANSFER, TRANSLATIONAL RESEARCH AND DISSEMINATION PROGRAM

INDUSTRIAL TRANSFER

The Technology Transfer Office in CIBER-BBN is receiving economical support from Ministry of Economy and Competitiveness for carrying out transference activities. This support is in the framework of INNCIDE initiative, which supports strategic transference plans for a four-year period. This strategic plan in CIBER-BBN is being implemented since mid-2011 until mid-2015.

This plan includes, among others, these activities:

- Support to researchers in protection and transference procedures.
- Identification of research results that should be protected.
- Patentability studies and patents application.
- Prospective studies and technological surveillance.
- Dissemination of CIBER-BBN technological offer and research services.
- Participation in congresses, technological fairs and partnering events.
- Organization of thematic CIBER-BBN – Industry workshops.
- Support to the creation of spin off.

Thus, priority will be given to the promotion of our technological offer (research projects, patents and services) in national and international events, industry workshops, thematic meetings, fairs and congresses, ..

The prospective work of our projects will continue, with the objective of identifying aspects with potential in terms of technology transfer to industry. Identified results will be protected, mainly through patents.

We will continue to organize CIBER-BBN / Industry meetings. We expect to organize a couple of forums in 2015, in topics which still have to be defined, but which could be related with neurology, infections disease, or others.

TRANSLATIONAL RESEARCH

The promotion of the interaction with the clinical environment will be prioritized. New workshops with the aim of establishing cooperation with medical researchers and favoring the translation of our research to the patients will be organized. We expect to organize Clinical Workshops through 2014 in topics to be defined, one of which could most probably be aimed at neurology in conjunction with the technological forum. The format of such workshops will consist in a brief presentation of the technological capabilities of CIBER-BBN groups in a certain medical theme and an open debate. This debate should give us the inputs of the real problems the doctors have in real clinical practice so as we can provide them with the suitable tools. After the debate session, brief meetings between

researchers and physicians (partnering procedure) will be organized. These brief meetings can lead to further collaboration, as is the case in the Industrial Workshops that have already been organized by CIBER-BBN. Also, the design will be made so to favor internationalization, and formation of consortiums for H2020 proposals.

During 2014 a second edition of the initiative launched with CIBER on Respiratory Diseases and SEPAR (Spanish Society of Pneumology and Thoracic Surgery) has been launched, and a first edition with the IIS IMIBIC has also put in place. A similar initiative has been launched in 2013 with Fundación ECO (Fundación para la Excelencia y Calidad en Oncología). Other similar initiatives with clinical partners will be initiated in 2015, perhaps with some Instituto de Investigación Sanitaria. The objective is to promote collaborative research projects with groups of different institutions which need to be aligned with the scientific priorities of each institution and need to be focused in solving a clinical problem. This initiative will continue and consolidate during 2015 and following years.

During 2015, CIBER-BBN will be open to admitting applications from clinical research groups to join the consortium under the role of "adhered member".

As the main objective of the translational research program is to bring closer CIBER-BBN research to patients and clinical practice, a series of presentations of CIBER-BBN scientific program and research capabilities will be done in Spanish Hospitals and Health Research Institutes.

DISSEMINATION

Dissemination of CIBER-BBN activities will be carried out in close collaboration with the communication responsibles in the administrative office in Madrid.

We expect to celebrate the CIBER-BBN 9th Annual Conference at the end of 2015, in a location to be defined. The format of the Annual Conference could remain based on presentation of research projects grouped by pathologies, with emphasis in intramural project reviews.

Corporate documents, such as Annual Report, general brochure, infrastructure brochure … should be conveniently updated.

Appearance of CIBER-BBN in specialized and general media will be pursued by releasing press notes with relevant information.

New issues of our Newsletter will be edited and distributed to a large audience, comprising not only CIBER members, but also institutions, hospitals, research centres, companies and entities related to the field of biomedical research.

3.3 TRAINING AND CAPACITIES PROGRAM

The activities making up the training Program during the previous year will continue to take place with some changes and new initiatives will be integrated in the Program. The Capacities Subprogram has the main goal of strengthening multidisciplinary research and new complementary methodologies in our groups.

The "Initiation to Research" Grants, redefined in 2012 so as to cover grants not only to students who want to join a research group and initiate themselves in research career but also to graduated persons through a training contract. Due to the fact that new contracts are very strictly limited in number for public bodies, more senior research contracts will be prioritized. Then, these grants will be only allocated to students.

Mobility grants will be maintained, in both versions for mobility intra-CIBER and for mobility from CIBER-BBN researchers to external institutions and viceversa.

4. SUMMARY OF ACTIONS PLANNED IN STRATEGIC PLAN 2014-2017:

These are the new actions which are planned to continuously be developed in the next four-year period:

RESEARCH PROGRAMME AND TECHNOLOGY TRANSFER

1.To consolidate CIBER-BBN's research programme

- 1.1. Definition of scientific challenges for each research area.
- 1.2. Strengthening of determined research lines with new research groups (ISCIII Call).

2. To promote translational research and technology transfer in the field of biomedicine

- 2.1. Change of the intramural project's model:
  - Inclusion of a clinical group in the project specifying the level of collaboration.
  - Positive assessment of the project if it achieves the proof of concept.
  - Specification of the pathology involved in the project.
  - External evaluation (ANEP).
- 2.2. Establishment of a new figure for the main specialties: "Coordinator for pathology"
- 2.3. Creation of a call focused specifically on technology transfer and translation:
  - Industrial or business partner able to fund an amount equal or greater than CIBER is required.
  - At least two CIBER-BBN groups involved.
  - Projects with two-year-long approach.
  - External evaluation (ANEP).

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2.4. Implementation of CIBER-BBN's alliances with other CIBERs, Hospitals, Institutes for Health Research, Networks, etc.

2.5. Enhancement of CIBER-BBN's platforms through its accreditation as an ICTS.

3. To continue promoting scientific synergies and complementarity between groups

3.1. Maintenance of specific calls for collaboration.

3.2. Strengthening of scientific contact between groups (scientific conferences, Clinical-Academic and Industry - Academic forums).

3.3. Launch of specific calls for collaboration with other CIBERs' groups (particularly, CIBERES and new intra-CIBER's calls suggested by ISCIII after the merger).

HR AND ECONOMIC-FINANCIAL PROGRAMME

1. To enhance staff's professional development

1.1. Maintenance of the Strengthening Programme but including a specific evaluation of the staff every four years (for all hired researchers, not just for those assigned to the Strengthening Programme)

1.2. Enhancement of the competences associated to a "business developer" figure to be adopted by CIBER-BBN Programme Managers.

2. To strengthen the training of CIBER-BBN researchers and technicians (both hired and assigned)

2.1. Creation of a specific training programme in platforms for CIBER-BBN groups

2.2. Implementation of an online workshop programme.

3.To support the mobility of researchers within CIBER-BBN

3.1. Promotion of mobility programs intra and extra CIBER

4. To redefine competences of CIBER-BBN's Medical Advisory Board

4.1. Definition of new competences in order to achieve a greater connection between the Medical Advisory Board and the research groups

5. To establish funding programmes for research groups based on their assessments

5.1. Distribution of funds between the research groups according to :
-Annual evaluation.
-New call for projects based on technology transfer and translation
-Call for projects in the framework of the Clinical Partnership Programme.

COMMUNICATION AND VISIBILITY PROGRAMME

1. To position CIBER-BBN's image and scientific potential

1.1. Development of a bibliometric study of CIBER-BBN with SCIMAGO group.

1.2. Promote CIBER-BBN's corporate image.

1.3. Continuity of online communication mechanisms established, active presence on social networks and website.

2. To facilitate the interaction and knowledge between CIBER's groups

2.1. Maintenance of , Clinical-Academic and Industry - Academic forums with an international approach

2.2. Increase the frequency of research area's internal meetings as a complementary format for the annual meeting.