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Anna Millán Álvarez

Foreword by the CEO

Research and investigation at the service of the country's biomedical ecosystem Over the course of the last year, we have continued to make progress in our mission to grow and deliver innovative knowledge that will transform into a future full of hope for many patients in Catalonia in the years ahead. This is the driving force behind our presentation of the 2023 Research Report, which summarises all the work related to research and investigation that we have carried out over the past year.

We have embarked on a new phase, guided by the road map outlined in the new Strategic Plan (2024-2027), which places us in a new context: the consolidation of our scientific journey and the assumption of a research leadership position rooted in our historical role as the Catalan public entity responsible for the collection, processing, storage, and supply of all substances of human origin (SoHO) in Catalonia.

It is precisely for this reason that the Blood and Tissue Bank is the body appointed by the Government of Catalonia to promote the Advanced and Emerging Therapies Programme in Catalonia. This key leadership role aims to forge national alliances to make these new generation medications, derived from genes, cells and tissues, a reality accessible to as many patients as possible. Advanced therapies offer hope and new healing opportunities for patients who previously had none. And this is our deepest motivation: to be an active part of this commitment, which has been our raison d'être since the beginning.

We possess a wealth of experience that becomes more apparent each year in our published research reports; due to our continuous research activity, the increasing number of publications, the trials and projects conducted with research teams from around the world, and the international collaborations that define our daily work. We are a research institution that has steadily gained visibility, presence, and recognition in a number of fields over the past few years.

We are also, as a long-standing benchmark centre, a service platform for all scientific teams and research centres within the country's biomedical research ecosystem. We have specialised facilities, including clean rooms and cryopreservation spaces, along with accredited professionals, to support research teams and enable the development and scaling up of these new therapies, driving the leap to larger-scale production.

However, none of this would be possible without the dedicated team of people that make up the Blood and Tissue Bank. Their perseverance and excellence have brought us to where we are today, and I can confidently say that our achievements and leadership are thanks to each and every professional in our outstanding team. If we continue to work in this way, we will grow our projects and get to where we want: that is, to the patients who need us.

Anna Millán Álvarez





Joaquim Delgadillo Duarte Scientific Director

Foreword by the Scientific Director

A new strategic plan to establish ourselves as leaders in research and innovation in advanced therapies and substances of human origin.

I am delighted to present the BST Research and Education Report for the year 2023.

In the previous report, I mentioned that we were closing a cycle of more than six years associated with the implementation of the previous Strategic Research Plan (2017-2020). During these almost seven years, the Research Support Office has assisted in the submission of 186 applications for external funding calls, requesting a total of $\[\in \]$ 35,527,637. This has resulted in a significant annual increase in competitive funding acquisition and in the number of projects with a Principal Investigator from the Blood and Tissue Bank. Additionally, with the aim of facilitating the launch of new research projects, six internal funding calls have been made, totalling $\[\in \]$ 2,668,948.

The implementation of this Plan has led to the consolidation of the core platforms of the BST: the Biobank, the genomics platform, the cellular platform, and the advanced therapy medicinal products manufacturing platform. As a result of all this effort in research and innovation, 14 new products and services have been added to the BST catalogue.

During this 2023, through a participatory and consensus-driven process, we have also worked on defining the new Strategic Research Plan for 2024-2027. This plan aims not only to consolidate and enhance existing research lines but also to ambitiously launch new lines focused primarily on advanced therapies.

It only remains for me to thank all the people at the BST who have given, are giving, and will continue to give their best to advance research and innovation in new services, products, and therapies that improve the health and well-being of our community.

Joaquim Delgadillo Duarte

2023 highlights

• The Congenital Coagulopathies Laboratory – Genomics Platform has secured competitive funding through the award of a project in the 2023 R&D&I Projects in Health call from ISCIII: PI23/01672, dedicated to investigating the unresolved molecular aetiology of hereditary bleeding disorders using advanced molecular tools and data integration systems.

They have been awarded two prizes from the Victoria Eugenia Royal Foundation:

The Duchess of Soria Prize for International Research on Congenital Coagulopathies 2023 for "Unravelling the genetic mechanisms underlying severe haemophilia A. Comprehensive analysis of large deletions in the F8 gene".

The Clinical Medicine Research Project prize for "Exploring the unresolved molecular basis of haemophilia through the application of third-generation long-read sequencing (TGS)".

- BST-Analytics 2023: the automation of the weekly call for blood donors at the 12 permanent centres of the BST network was presented at the ISBT Congress with the Harold Gunson Fellowship. This presentation has sparked the interest of several international organisations, notably the Blood Byte Circle division (BBC) of the European Blood Alliance. BBC is a recent initiative under the EBA's Innovation and New Products Working Group aimed at assessing the current use of Artificial Intelligence to manage Blood and Tissue establishments across Europe.
- Molecular microbiology and microbiota: the article "Characterization of Seminal Microbiome of Infertile Idiopathic Patients Using Third-Generation Sequencing Platform" has been published in the INTERNATIONAL JOURNAL OF MOLECULAR SCIENCES (2023 Apr 26; 24(9): 7867. doi: 10.3390/ijms24097867).

We participated as speakers in the workshop "Planetary Protection Requirements for Future Exploration Missions: Assessing Metagenomic Methods For Their Inclusion In ESA Standards" by the European Space Agency, establishing the foundations for preventing biological contamination in space exploration using molecular biology methods.

Creation of the Microbiology Laboratory, equipped with the necessary technology and trained personnel to conduct sterility microbiological controls, microbial load assessments, and environmental microbiological monitoring. These tests are aimed at ensuring the safety and quality of BST products and supporting research. Currently, it conducts controls for blood components, milk, cell therapy, tissues, and advanced therapies. This addition enhances the areas of expertise within the laboratories of the Blood and Tissue Bank.

The Tissue Bank has achieved the following:

Granting of Techological Development in Health for the development of randomised pilot trial for Transvaginal human acellular dermal matrix and sacrospinous fixation for anterior and apical prolapse treatment in patients with hiatal ballooning or levator ani injury. This multicentre project is led by Hospital Mutua de Terrassa.

Fran Vidal



Anna Vilarrodona



Launch of the VASCRAFT project in close collaboration between Germans Tries i Pujol Institute, BST and Chemical Institute of Sarrià to develop new human decellularized and re-endothelialized tissue-engineered graft for coronary artery bypass grafting.

The EGALiTE project has successfully achieved all the intermediate goals and is preparing the final outcomes to be sustainable. Engagement with scientific associations and the development of IT platforms guarantee a successful pilot stage during early 2024 and ensure the continuity of EGALiTE's mission thereafter.

Receipt of the award for the best oral presentation for the work titled "Development of a preservation method at 33°C for fresh osteochondral allografts" at the 31st Annual Congress of the European Association of Tissue and Cell Banks (EATCB).

Presentation of the 20-year experience of cardiovascular banking at the Barcelona Tissue Bank [CELL TISSUE BANK. 2024 Mar;25(1):11-26.].

• The Cell Therapy Service has developed an in-house bone marrow collection kit.

The in-house kit manufactured by the Blood and Tissue Bank was validated and published in the journal *Vox Sanguinis*.

The Cord blood and Specialised Haemotherapy group has started a clinical trial this year on cord blood red blood cell (RBC) transfusion in very preterm infants. This is the first clinical trial in Spain on this approach and demonstrates our commitment to advancing medical knowledge to contribute to improving outcomes of this vulnerable patient population. Preterm infants often face challenges related to anaemia and other blood-related issues, so exploring innovative transfusion approaches could have a positive impact.

To obtain RBCs for transfusion and platelets for regenerative medicine products, an international study on multicomponent cord blood fractionation was proposed, coordinated by the BST Cord Blood Specialized Therapy Group (Samarkanova D, Codinach M, Montemurro T, Mykhailova L, Tancredi G, Gallerano P, Mallis P, Michalopoulos E, Wynn L, Calvo J, Pello OM, Gontica I, Rebulla P, Querol S; MultiCord12 Study Group (Appendix 1). Multi-component cord blood banking: a proof-of-concept international exercise. BLOOD TRANSFUS 2023 Nov 3;21(6):526-537. doi: 10.2450/BloodTransfus.492. PMID: 37146297; PMCID: PMC10645353.)

iPS Derived Advanced Therapies group has obtained a Public-private collaboration projects grant (Spanish Investigation Agengy) for the project *EPIFIN*: *Engineering induced pluripotent stem cells for a novel immunotherapy of fungal infections*. This study aims to develop a CAR therapy from iPSC cells to fight incurable fungal infections. It is a 3 year project in collaboration with CSIC (Madrid) and University of Wützburg (Germany).

Sergi Querol



Banc desang iteixits

Banc de Sang i Teixits

The Banc de Sang i Teixits (Blood and Tissue Bank, BST) is a public company of the Ministry Catalan Department of Health whose mission it is to guarantee the supply blood of sufficient quality for all citizens of Catalonia. The BST manages and administers the donation, transfusion, and analysis of blood and blood plasma. It also acts as a centre for obtaining and processing tissues and umbilical cords and develops other lines of action as a centre specialising in immunobiology, molecular analysis, cell therapy and regenerative medicine.

- It constitutes the backbone of the haemotherapeutic system in Catalonia.
- The BST's activity extends to all public and private centres in Catalonia and other areas of Spain, providing personal service to both donors and customers.
- Its aim is to function as a first-class centre for management, innovation and research in haemotherapy and tissues.

The BST participates in its own research projects and works in collaboration with all the Catalan Health Institute centres, many of the centres in the Public Hospital Network and Catalan universities. In addition, it works to promote strategic alliances with centres, researchers and industry.

1.1.

Governing Bodies

The Banc de Sang i Teixits' governing bodies are the Board of Directors and its committees.

1.1.1. Board of **Directors**

Chair

Andreu Mas-Colell

Vice Chair

Ignasi Carrasco Miserachs

Josep Inglés Lodos

Members

Núria Montserrat Pulido Irene Garcia Cadenas Laia Arnal Arasa Marc Soler Fàbregas Marta Chandre Jofré Judit Vall Castelló Antoni Castells Garangou Joan Comella Carnicé

1.2.

Executive and Management Bodies

1.2.1. Executive Committee

CEO

Anna Millán Álvarez

Director of Human Resources

Imma Garcia Pursals

Director of Communication and Marketing

Pilar Córdoba Tejero

Corporate Director and Head of Information Technologies

Antoni Masi Roig

Healthcare DirectorJoan Ramon Grífols Ronda

Strategy and Innovation Director:

Núria Gavaldà Batalla

Strategic Planning and Advanced Therapies Director

Joaquim Delgadillo Duarte



1.3.

Advisory Bodies

1.3.1. Internal Scientific Committee

The Internal Scientific Committee is the advisory body in charge of ensuring that all tasks in the organisation involving the promotion and development of RDI are carried out.

The tasks performed by this committee include:

- Reviewing RDI policy and ensuring that it be disseminated and adopted.
- Coordinating the deployment of the Strategic Research Plan (SRP) and evaluating its degree of success.
- Ensuring that the annual RDI objectives are met.
- Overseeing activities associated with the technology observatory (surveillance, foresight, analysis, etc.).
- · Periodically reviewing scientific production, economic aspects and research staff.
- As the unit responsible for the programmes, participating in research activities and evaluating projects' progress (anticipating deviations and problems).
- Reviewing the systematics of the process for continuous improvement.

Composition

Cristina Castells Sala Ruth Coll Bonet Joaquim Delgadillo Duarte Raquel Gil Muro Joan Ramon Grífols Ronda Alejandro Madrigal Núria Nogués Gálvez Sergi Querol Giner Sílvia Sauleda Oliveras Elisabet Tahull Navarro Francisco Vidal Perez Joaquim Vives Armengol

reviewing R&D&I coordinating Strategic Research Plan ensuring annual R&D&I Overseeing activities associated technology watch reviews scientific production evaluating projects progress continuous improvement

1.3.2. External Scientific Committee

The tasks to be performed by this committee include the following:

- Annually evaluating the RDI activity carried out at the BST.
- Giving opinions and making suggestions on the adequacy and follow-up of the SRP.
- Making recommendations on research lines and programmes (promoting, auditing, redirecting, etc.).
- Giving guidance on how to increase external resources for research and on possible alliances to be established.
- Acting as an external technology observatory.

Composition

Prof. Alejandro Madrigal, MD, PhD (president).

Scientific Director of the Anthony Nolan Research Institute, London (UK)

Prof. Catherine Bollard, MD, MBChB

Director of the Center for Cancer and Immunology Research at the Children's National Research Institute, Washington DC (USA)

Prof. Antony Atala, MD

Director of the Wake Forest Institute for Regenerative Medicine, North Carolina (USA)

Prof. Masja de Haas, MD, PhD

Senior researcher at the Dept of Clinical Transfusion Research, Sanquin, and at the Dept. of Immunohaematology and Blood Transfusion, Leiden University Medical Centre (LUMC), Leiden (Netherlands)

Annually evaluating
R&D&I in the BST
opinions suggestions
adequacy follow-up
recommendations
programmes research
promoting auditing redirecting
guidance external
resources for research
external technology observatory

1.4.

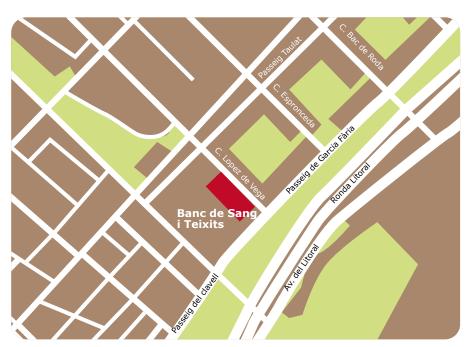
Location

Pg. del Taulat 106

The corporate headquarters of the BST is located at the corner of Passeig Taulat and Carrer de Lope de Vega, in the 22@ technology district of Barcelona. It is from this headquarters that the various lines of activity and many of the organisation's professionals are centralised. The BST also has offices in the main hospitals in Catalonia.



800 professionals



1.5.

Summary of research activity

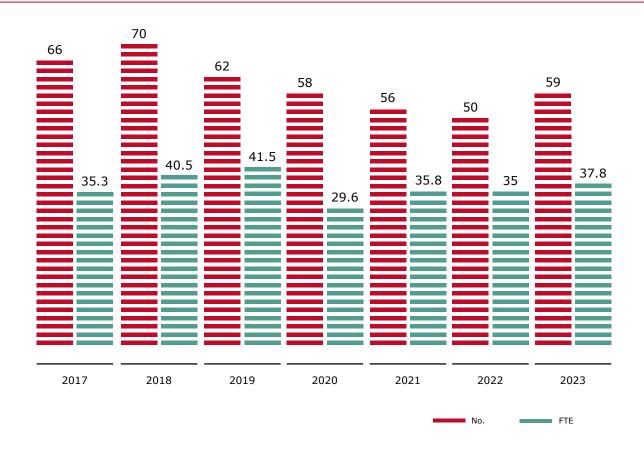
1.5.1. Research and technical staff

Research and technical staff 2023

	No.	FTE	No. of men	FTE of men	No. of women	FTE of women
Principal investigators	7	4.0	3	1.7	4	2.3
Senior researchers	26	16.8	7	4.3	19	12.5
Researchers	15	9.2	6	3.0	9	6.2
Support staff	11	7.8	0	0.0	11	7.8
TOTAL	59	37.8	16	9.0	43	28.8

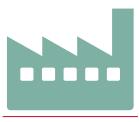
^{*} FTE: full-time employees

Research staff since 2017



1.5.2. Economic data

Research funding 2023



39,363,04€

Agreements with industry



Own funds*

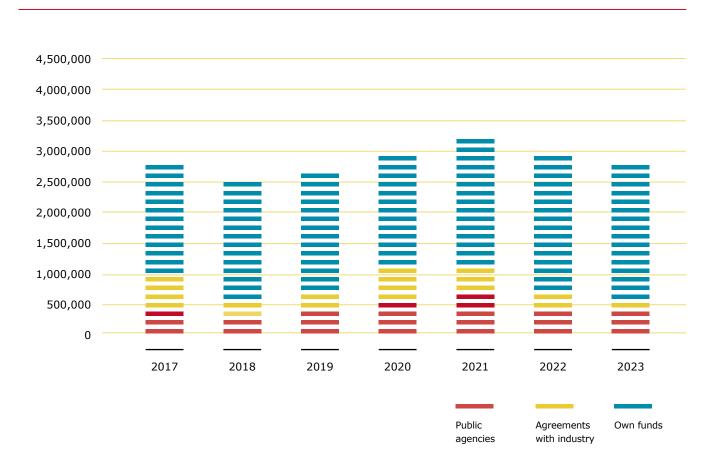
* Includes expenses for full-time or part-time staff and internal research funding

Total 2,874,297,70€



Public agencies

Research projects



The Strategic RDI Plan 2017-2020 set up five research programmes

R&D&I 2017-2020

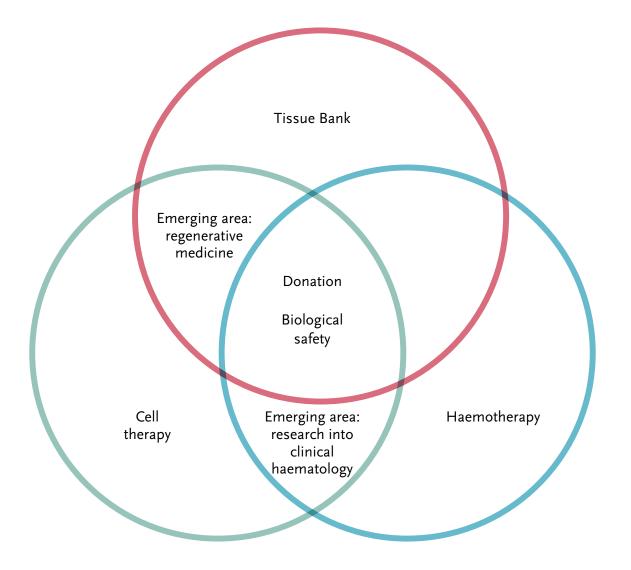
5 Research Programmes

Three core programmes:

- Haemotherapy: immunohematology, transfusion, molecular diagnosis, process development
- **Tissue bank:** development of products and processes of the tissue bank, regenerative medicine
- Cell therapy: transplant immunobiology/immunotherapy, regenerative medicine

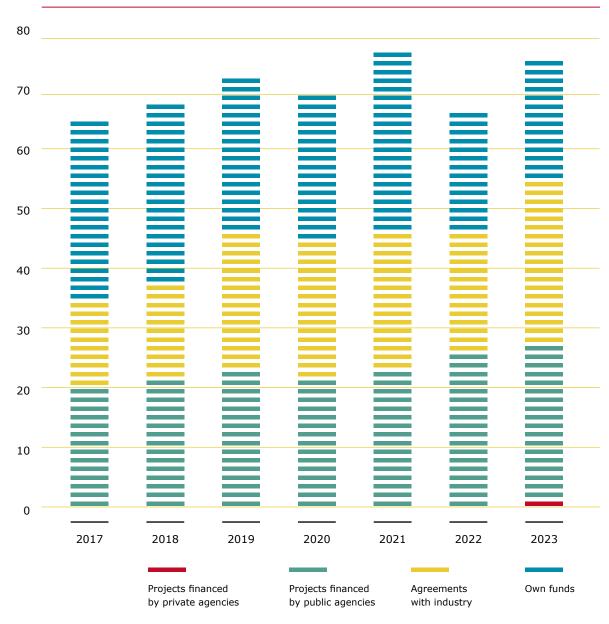
Two transversal programmes:

- Biological safety: emerging pathogens, epidemiological studies, harmonisation between products
- **Donation of blood, cells and tissues:** study of donation behaviours, donation ethics, donation promotion, protection, well-being and comfort of the donor

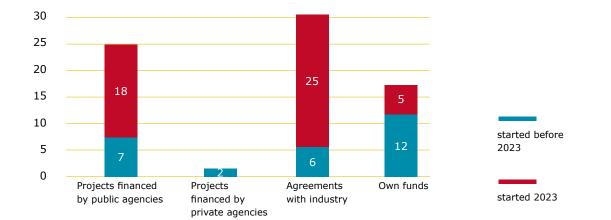


1.5.4. Research projects









Active projects during 2023

	BST PRINCIPAL INVESTIGATOR	COLLABORATION
PUBLIC AGENCIES		
Carlos III Institute of Health	5	7
European Commission	2	
IDIBAPS		1
Ludwig Maximilians Munich University		1
Spanish Investigation Agency	4	2
Vall d'Hebron Institute of Oncology		2
PRIVATE AGENCIES		
"La Caixa" Foundation	1	
Sant Joan de Déu Research Found.		1
AGREEMENTS WITH INDUSTRY		
Achilles Therapeutics Limited		1
Adaptimmune Therapeutics PLC.		3
Allogene Therapeutics		1
Allovir Inc.		1
ALX Oncology Inc.		3
Atara Biotherapeutics Inc.		2
Autolus Limited		2
BioNTech Manufacturing GmbH		2
Celgene Corporation		1
Cellnex Telecom S.A.	1	
Gilead Sciences Inc.		1
Johnson & Johnson Innovative Medicine		2
Kite Sciences Inc.		3
Igenomix		1
Instituto Grifols S.A.	1	
Iovance Biotherapeutics, Inc.		1
Medac GmbH		1
Miltenyi Biomedicine GmbH		2
Novartis Pharma AG		1
T-knife GmbH		1
OWN FUNDS	18	
OTAL		75

1.5.5. Doctoral theses

Theses

These were the theses read by BST researchers

PHD STUDENT	THESIS TITLE	DIRECTORS
Meritxell Llorens Revull	Studies of viral and host biomarkers in hepatitis C virus infected patients	Marta Bes Maijó, Josep Quer Sivila, Celia Perales Viejo
Jesus Fernandez Sojo	Peripheral blood hematopoietic progenitors: product characteristics impacting recipient and processing quality controls	Sergi Querol Giner, Joan Cid Vidal
Laura Medina Marrero	Proposal for a new consensus administration of Plerixafor, to reduce the percentage of failures of hematopoietic progenitors mobilization	Sergi Querol Giner

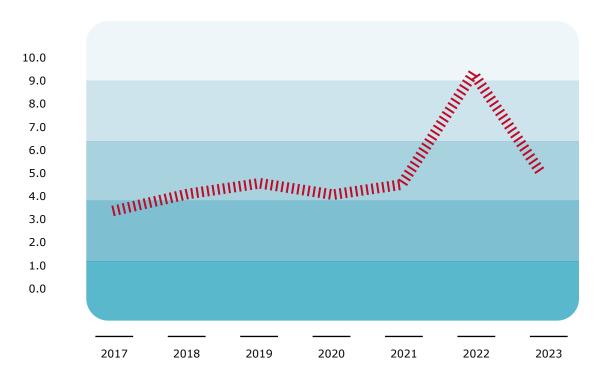
1.5.6. Publications

There were 47 publications by BST researchers in scientific journals in 2023, with an impact factor of 215. The average impact factor was 4.5. A 31% of the articles were published in first quartile journals.

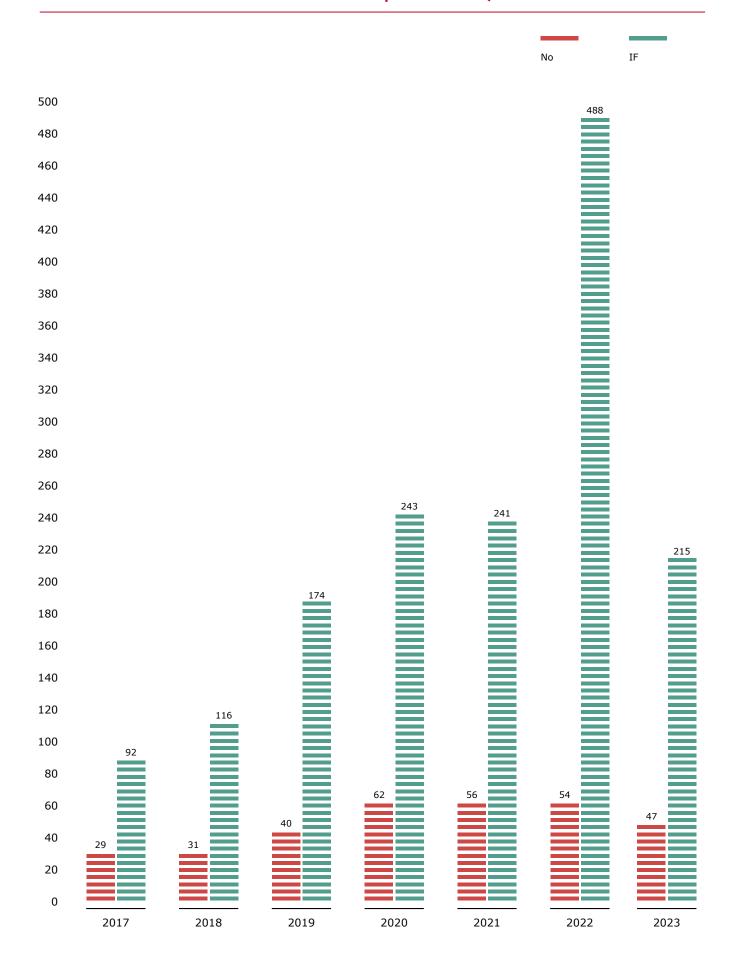
The 2022 *Journal Citation Reports* (JCR) were used to calculate the 2023 impact factor. Original articles, reviews, and editorials were included in the calculation.

Evolution of the BST's scientific production

Medium Impact Factor



BST scientific output since 2017

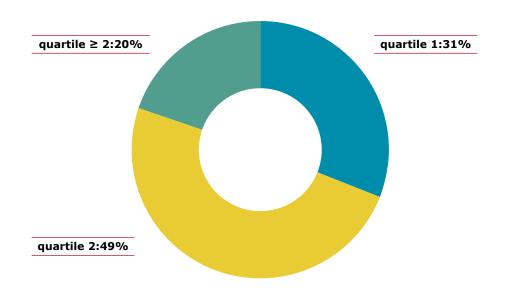


1.5.6. Publications

Classification of publications



2023 BST publications by quartiles



1.5.7.
Patents and protection of industrial and intellectual property

The BST has one patent granted in the United States, and two granted by the European Patent Office and validated in several European countries.

1.6.

Innovation

The Congenital Coagulopathies Laboratory – Genomics Platform

Whole exome sequencing: the implementation of this technique has allowed us to apply the diagnosis of hereditary connective tissue disorders, hereditary haemorrhagic telangiectasia and other vasculopathies, congenital platelet disorders, Noonan syndrome and other RASopathies, as well as congenital disorders of glycosylation in clinical practice.

Quality control in CAR-T immunotherapy: we participated in the quality control of an autologous T cell immunotherapy product (CAR-T) through the application of molecular studies during the production process. We have developed molecular validation techniques for the sequencing of plasmids, the viral vector, the determination of the number of copies integrated into the therapeutic gene and the envelope, the identity of the producing cells, and the residual DNA.

Digital PCR (dPCR): we have implemented digital PCR in various molecular studies to achieve precise detection and quantification of nucleic acids.

Detection of Cutibacterium acnes: we have developed and applied molecular biology techniques to detect Cutibacterium acnes in umbilical cord blood units intended for transfusion to extremely premature infants.

BST-Analytics initiative: this multidisciplinary data science and innovation unit of the Blood and Tissue Bank has been established to optimise donor recruitment processes, promote donation, and distribute blood products in Catalonia. Currently, we are working on a mobile collection management system to improve efficiency in donor recruitment.

The Tissue Bank has:

Developed and validated a new preservation method for fresh osteochondral allografts to extend expiry time, aiming to optimise tissue allocation and reach more patients.

Validated the human decellularized valve procedure in a controlled microenvironment.

Designed and developed a safe and effective full-thickness acellular dermal graft using the EuroGTPII Methodologies. [THERAPEUTICS AND CLINICAL RISK MANAGEMENT 2023:19 567–578].

Developed a full-thickness acellular dermal graft for human skin, which has been used in a first case for rotator cuff patch augmentation [TRANSPL IMMUNOL 2023 Jun:78:101825].

Presented a comparative in vitro study on the predisposing factors of hamstring grafts to infection in R-ACL surgery, in collaboration with H. del Mar, Universitat Autònoma of Barcelona, and Charité-Universitätsmedizin Berlin [PATHOGENS. 2023 May 25;12(6):761].

Used decellularized nerve grafts for repairing severe peripheral nerve injuries in sheep, in collaboration with Universitat Autònoma of Barcelona [NEUROSURGERY. 2023 Dec 1;93(6):1296-1304].

Enhanced the safety of cornea preservation by incorporating an antifungal agent into the media composition.

1.6. Innovation

The Immunohaematology Laboratory

Development of a novel high-throughput NGS method for simultaneous HPA and HLA genotyping of platelet apheresis donors.

The Immunohaematology Laboratory, in collaboration with the Histocompatibility Lab and the Genomic Platform has developed and validated a new tool for the extensive HPA and HLA Class I typing of platelet apheresis donors.

The results of this work were presented at the ISBT Congress 2023 in Gothenburg.

The Transfusion Safety Laboratory has:

Pre-commercial validation of a new molecular biology reagent for the joint detection of West Nile Virus, Dengue, Zika and Chikungunya arboviruses. The evaluation carried out in the Transfusion Safety Laboratory contributed to obtaining the CE marking for the screening of blood, tissue and cell donations.

Evaluation of a commercial ELISA method for pseudo-neutralisation to ensure the neutralising potential of anti-Spike antibodies against SARS-CoV-2 in convalescent COVID plasma.

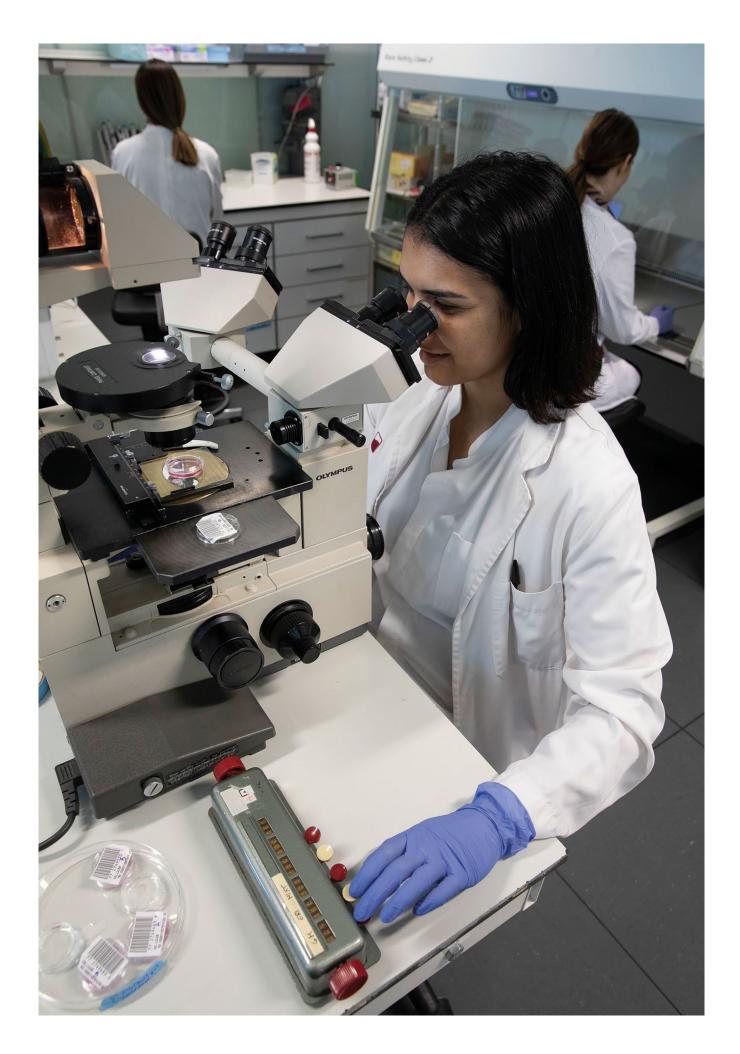
The Cell Therapy Service

Creation of the GMP bioreactor platform for 3D manufacturing of mesenchymal cells derived from umbilical cord.

Manufacturing of tumour infiltrating lymphocytes (TIL) therapy to treat patients with metastatic, refractory-epithelial cancer (NEXTGEN-TIL clinical trial).

Development of a molecular testing and genomic integrity characterisation algorithm for iPSC based in WES and RNAseq in collaboration with the Group of Congenital Coagulopathies at BST and the Genomics Platform at BST (Dr Fran Vidal and Dr Irene Corrales). Manuscript in preparation.

BK Virus renal transplant. 2023-2025: Scale-up and validation of the expansion protocol of IFN- γ + T lymphocytes against BK virus under GMP conditions as a potential therapeutic option for patients who have undergone renal transplant and are suffering for BK virus infection.



BS The research activity



BST research activity

2.1. Haemotherapy programme

Research in the haemotherapy programme aims to foster knowledge about the practice of transfusion medicine and related technologies.

Researchers in this programme are currently studying the basic biology and clinical implications of a wide range of problems regarding transfusions, immune responses to transfused blood, and underlying mechanisms, as well as practices related to the processing, storage and safety of blood.

The programme also focuses on research and development of diagnostic and decision-making techniques and processes that make transfusions safer, more effective and more efficient.

This programme not only has the support of its core members but also the simultaneous involvement of the area's principal laboratories and territorial centres.



Director

Núria Nogués Gálvez

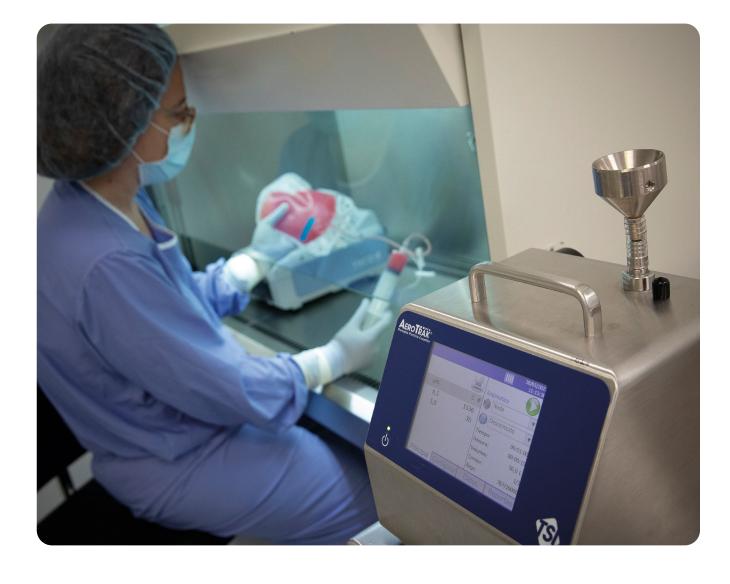
Support Staff

Natàlia Comes Fernandez Noemí Gonzalez Leon Carina Lera Asensio Lorena Ramírez Orihuela

Researchers

Perla Bandini Nina Borràs Agustí Laia Closa Gil Irene Corrales Insa Iris Garcia Martinez Cecilia Gonzalez Santesteban

Jordi Gual Obrador María José Herrero Mata Carlos Hobeich Naya Sergio Huertas Torres Laura Martín Fernández Laia Miquel Serra Francisco Vidal Pérez



Projects with a PI or CO-PI from the BST

Research projects

Principal investigator: Núria Nogués Gálvez

Lab-grown red cells for the transfusion management of vaso-occlusive crisis in sickle cell patients Funding organisation: "La Caixa" Foundation File: HR23-00367 Duration: 2023 – 2026

Principal investigator: Núria Nogués Gálvez

LAB-REDCELL: Lab-grown red cells from immortalized erythroid cell lines as an alternative source of red cells with rare phenotypes for diagnostic and therapeutic applications Funding organisation:

Spanish Investigation Agency File: PID2022-1418490B-I00

Duration: 2023 – 2027

Principal investigator: Francisco Vidal Perez

RELECOV 2.0 Consolidation of WGS and RT-PCR activities for SARS-CoV-2 in Spain towards sustainable use and integration of enhanced infrastructure and processes in the RELECOV network Funding organisation:
European Commission
File: 101113109

File: 101113109 Duration: 2023 – 2025

Principal investigator: Ma José Herrero Mata

Advancing in the implementation of Third Generation Sequencing technology within the field of Immunogenetics and deployment in other areas of the BST

Funding organisation: BST File: I.2021.029
Duration: 2023 – 2026

Principal investigator: Laia Miguel Serra

Generation of a panel of immortalised erythroid progenitor cell lines from selected blood donors as a sustainable source of cultured red cells Funding organisation: BST

File: I.2021.028 Duration: 2021 - 2024

Principal investigator: Laia Miguel Serra

Lab-grown red cells from immortalized erythroid precursor cell lines as an alternative source of red cells with infrequent or rare phenotypes

Funding organisation: BST File: I.2023.024

File: I.2023.024 Duration: 2023 – 2026

Principal investigator: Iris Garcia Martínez

Development of a functional model of the flow of the Blood and Tissue Bank stock based on artificial intelligence to optimize the planning of donation campaigns and the distribution of hemocomponents Funding organisation: BST

File: I.2023.026 Duration: 2023 – 2026

Principal investigator: Nina Borràs Agustí

Resolving the genetic basis of complex diagnostic inherited bleeding disorders through the application of advanced molecular tools Funding organisation: BST File: I.2023.030

Duration: 2023 – 2026

Principal investigator: Antoni Masi Roig

Study of the life cycle of the blood and plasma donor: segmentation into stages, their transitions and design of targeted communication actions

Funding organisation: BST File: I.2023.032 Duration: 2023 – 2025

Principal investigator: Vanessa Pleguezuelos Hernández

Obtaining sterilized donated breast milk applying the emerging technology of ultrahigh pressure homogenization (LMD-UHPH)

Funding organisation: BST File: I.2023.033

Duration: 2023 - 2025

Collaboration projects

Principal investigator: Anna Bigas Salvans (IMIM), Núria Nogués Gálvez (BST)

HEMO-GAS: Recreating the embryonic niche for hematopoietic stem cell production and derivatives in human gastruloids Funding organisation: Spanish Investigation Agency

File: PLEC2021-007518 Duration: 2021 - 2024

Principal investigator: Marc Oliva Bernal (Hospital Universitari de Bellvitge), Isabel Gonzalez Medina (BST)

A phase II study of
ALX148 in combination
with pembrolizumab in
patients with advanced head
and neck squamous cell
carcinoma (ASPEN-03)
Funding organisation:
ALX Oncology Inc.

File: 2020-004093- 21 Duration: 2021 - 2023

Principal investigator: Marc Oliva Bernal (Hospital Universitari de Bellvitge), Isabel Gonzalez Medina (BST)

A phase II study of ALX148 in combination with pembrolizumab and chemotherapy in patients with advanced head and neck squamous cell carcinoma (ASPEN-04) Funding organisation: ALX Oncology Inc.

File: 2020-004662-19 Duration: 2021 - 2023

Principal investigator: Cristina Santos Vivas (Hospital Universitari de Bellvitge), Isabel Gonzalez Medina (BST)

A phase II study of A Phase 2, Randomized, Open-Label Study Evaluating the Safetyand Efficacy of Magrolimab in Combination With Bevacizumaband FOLFIRI Versus Bevacizumab and FOLFIRI in Previously Treated Advanced Inoperable Metastatic Colorectal Cancer Funding organisation: Gilead Sciences, Inc.

File: 2022-500177-13 Duration: 2023 - 2024

Principal investigator: Cinta Hierro Carbó (Hospital Germans Trias i Pujol), Águeda Ancochea (BST)

A phase 2/3 study of ALX148 in patients with advanced HER2overexpressing gastric/ gastroesophageal junction adenocarcinoma (ASPEN-06) Funding organisation:

Alx Oncology, Inc. File: 2021-001008-14 Duration: 2023 - 2024

Publications

Bandini P, Borràs N, Berrueco R, Gassiot S, Martin-Fernandez L, Sarrate E, Comes N, Ramírez L, Hobeich C, Vidal F, Corrales I. Gaining Insights into Inherited Bleeding Disorders of Complex Etiology in Pediatric Patients: Whole-Exome Sequencing as First-Line Inve stigation Tool. THROMB HAEMOST. 2023 Dec 29. doi: 10.1055/s-0043-1778070. Epub ahead of print.

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de la Morena-Barrio B, Palomo Á, Padilla J, Martín-Fernández L, Rojo-Carrillo JJ, Cifuentes R, Bravo-Pérez C, Garrido-Rodríguez P, Miñano A, Rubio AM, Pagán J, Llamas M, Vicente V, Vidal F, Lozano ML, Corral J, de la Morena-Barrio ME. Impact of genetic structural variants in factor XI deficiency: identification, accurate characterization, and inferred mechanism by long-read sequencing. J THROMB HAEMOST 2023 Mar 20:S1538-7836(23)00239-8. doi: 10.1016/j. itha.2023.03.009. PMID: 36940803.

Garcia-Segura S, Del Rey J, Closa L, Garcia-Martínez I, Hobeich C, Castel AB, Vidal F, Benet J, Oliver-Bonet M. Characterization of Seminal Microbiome of Infertile Idiopathic Patients Using Third-Generation Sequencing Platform. INT J MOL SCI. 2023 Apr 26;24(9):7867. doi: 10.3390/ijms24097867. PMID: 37175573; PMCID: PMC10178615. IF 5.6. Q1

IF 10.4. Q1.

Pardos-Gea J, Martin-Fernandez L, Closa L, Ferrero A, Marzo C, Rubio-Rivas M, Mitjavila F, González-Porras JR, Bastida JM, Mateo J, Carrasco M, Bernardo Á, Astigarraga I, Aguinaco R, Corrales I, Garcia-Martínez I, Vidal F. Key Genes of the Immune System and Predisposition to Acquired Hemophilia A: Evidence from a Spanish Cohort of 49 Patients Using Next-Generation Sequencing. INT J MOL SCI. 2023 Nov 15;24(22):16372. doi: 10.3390/ ijms242216372. PMID: 38003562; PMCID: PMC10671092. IF 5.6. Q1.

Pujol-Moix N, Muñiz-**Díaz E**, Español I, Mojal S, Soler A, Souto JC. Pseudothrombocytopenia, beyond a laboratory phenomenon: study of 192 cases. ANN HEMATOL 2023 Mar 31. doi: 10.1007/s00277-023-05192-8. PMID: 37002444. IF 3.5. Q2.

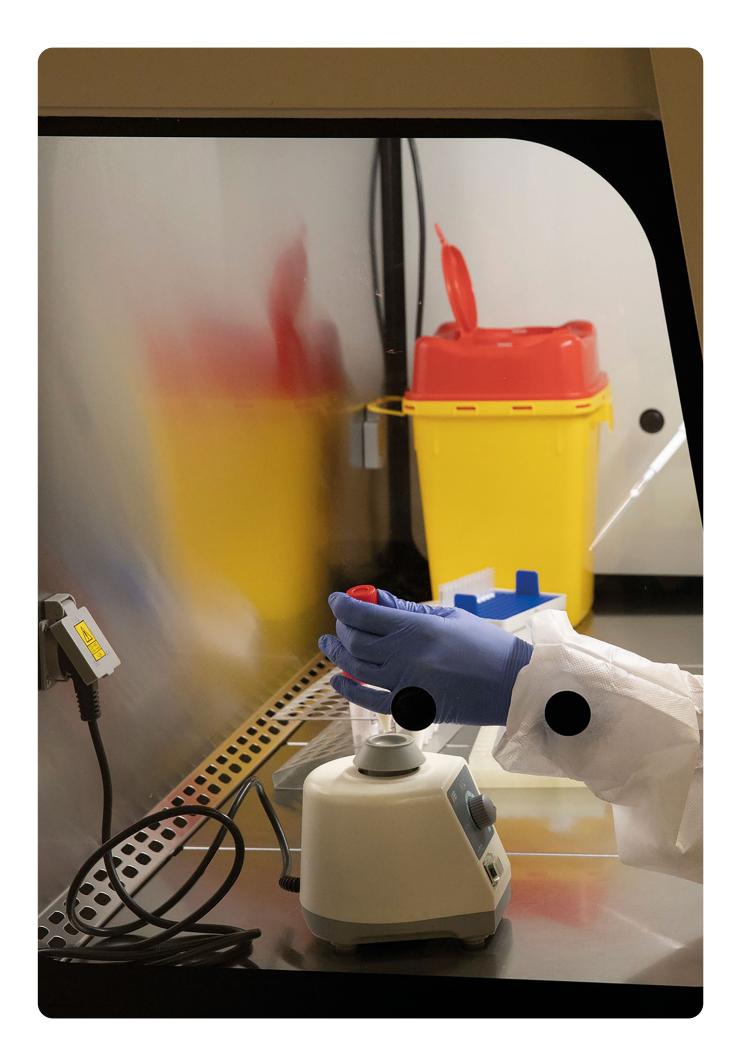
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Romera Martínez I, Bueno Cabrera JL, Domingo-Morera JM, López Aguilar JC, Villegas Da Ros C, García Erce JA, Sáez Serrano I, Flores Ballester E, Maglio LA, Arbona Castaño C, Sola Lapeña C, Guerra Domínguez L, Berberana Fernández M, Madrigal Sánchez ME, Rubio Batllés M, Pérez-Olmeda M, Ramos-Martínez A, Velasco-Iglesias A, Avendaño-Solá C, Duarte RF. Pathogen reduction with methylene blue does not have an impact on the clinical effectiveness of COVID-19 convalescent plasma. VOX SANG 2023 Feb 3. doi: 10.1111/vox.13406. PMID: 36734378. IF 2.7. Q3.

Moreno-Vílchez C, Muniesa C, González-Barca E, García-Muñoz N, Ortega-Sánchez S, Servitje O. Efficacy and safety of offline extracorporeal photopheresis in cutaneous T-cell lymphomas: A retrospective study. PHOTODERMATOL PHOTOIMMUNOL PHOTOMED. 2023 Jul 19. doi: 10.1111/phpp.12901. Epub ahead of print. PMID: 37465951. IF 2.6. Q2.

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2.2. Cell therapy programme

The aim is for cell therapy at the BST to be a platform for knowledge and cell production for the Catalan healthcare system in order to provide the appropriate response to the needs of patients and the doctors who treat them.

The BST wants to facilitate the introduction of new advanced therapies in the health system, making the BST clean rooms available to research clinicians who need to perform concept tests.

Moreover, the BST is also interested in scaling products and taking on the challenge of bioreactor production in the development of clinical trials jointly with the Spanish Agency of Medicines and Medical Devices (AEMPS) and other entities.

Along with the above, the cell and advanced therapy service research focusses on the development of new products and services in the areas of immunotherapy and regenerative medicine.

Director

Sergi Querol Giner

Support staff

Kenia Rodriguez Gonzalez

Researchers

Belén Álvarez Palomo Raquel Cabrera Perez Margarita Codinach Creus Ruth Coll Bonet Emma Enrich Rande Rubén Escribá Piera Alba Lopez Fernandez Ruth Mora Buch Sara Morini Jara Palomero Gorrindo Luciano Rodríguez Gómez Francesc Rudilla Salvador Dinara Samarkanova Maria Tomas Marin Joaquim Vives Armengol



Research projects

Projects with a PI or CO-PI from the BST

Principal investigator: Sergi Querol Giner

OSCAR-iNK: Off-the-Shelf iPSC-derived next generation CAR-NK cells for solid tumor allogenic immunotherapy Funding organisation: Spanish Investigation Agency

File: CPP2021-008350 Duration: 2022 - 2025

Principal investigator: Joaquim Vives Armengol

Translation of an allogenic tissue engineering product with mesenchymal stem cells from Wharton's jelly for the treatment of osteonecrosis in paediatric oncology patients
Funding organisation: Carlos

III Institute of Health File: PI19/01788 Duration: 2020 – 2024

Principal investigator: Ana Belén Álvarez Palomo

Universal cord blood iPSC-derived CAR-NK cells for an 'off-the-shelf' immunotherapy for cancer (UNiKAR)

Funding organisation: BST File: I.2021.027 Duration: 2021 – 2024

Principal investigator: Sergi Querol Giner

Cellular immunological response to SARS-CoV-2. Decisions on the immunisation of T-cells and their use in potential therapy Funding organisation: Cellnex Telecom, S.A.

File: I.2020.038

Duration: 2020 – 2023

Principal investigator: Sergi Querol Giner

Clinical evaluation of umbilical cord blood red blood cells for transfusion in extremely premature infants Funding organisation: Carlos III Institute of Health File: PI22/00290

Duration: 2023 – 2025

Principal investigator: Joaquim Vives Armengol

Translation of an allogeneic tissue-engineered product for the treatment of focal articular cartilage lesions Funding organisation: Carlos III Institute of Health

File: PI22/01906 Duration: 2023 - 2025

Principal investigator: Ana Belen Álvarez Palomo

UNIKAR: Universal cord blood iPSC-derived CAR-NK cells for an 'off-the-shelf' immunotherapy for cancer Funding organisation: Carlos III Institute of Health

File: PI21/00796 Duration: 2022 - 2024

Principal investigator: Francesc Rudilla Salvador

Application of T cell receptor sequencing in the development, optimization and characterization of antiviral cellular products. Funding organisation: BST File: I.2023.025

Duration: 2023 - 2026

Principal investigator: Joaquim Vives Armengol

Fibrin Sealant Grifols as scaffold in advanced therapies. 3D printing scaffolds for advanced trauma applications. In vivo study Funding organisation: Instituto Grifols, SA

File: I.2016.035 Duration: 2017 - 2024

Principal investigator: Joaquim Vives Armengol

Design and validation of a platform for the production of mesenchymal cells derived from pluripotent cells with genetic characteristics of therapeutic interest and their scaling up in a bioreactor for clinical use Funding organisation: BST

File: I.2023.027 Duration: 2023 - 2026

Principal investigator: Ana Belén Álvarez Palomo

EPIFIN: Engineering induced Pluripotent stem cells for a novel Immunotherapy of Fungal Infections Funding organisation: Spanish Investigation Agency

File: CPP2022-009594 Duration: 2023 – 2026

Principal investigator: Ruth Coll Bonet

Phase I/II, randomised, double-blind, parallel, 2-arm, placebo-controlled clinical trial to evaluate the safety and efficacy of intrathecal administration of Wharton's jelly mesenchymal stem cells in the treatment of chronic traumatic incomplete cervical spinal cord injury Funding organisation: BST File: 2021-000346-18

File: 2021-000346-18 Duration: 2021 - 2023

Collaboration projects

Principal investigator: José María Moraleda Jiménez (Instituto Murciano de Investigación Biosanitaria Virgen de la Arrixaca), Joaquim Vives Armengol (BST)

RICORS TERAV. Technology and therapeutic developments: innovation, transfer to the health system and education Funding organisation:
Carlos III Institute of Health

File: RD21/0017/0022 Duration: 2022 -2024

Principal investigator: Nerea Maiz Elizaran (Hospital Universitari Vall d'Hebron), Margarida Codinach Creus (BST)

Tissue engineering for the improvement of the surgical technique for the fetoscopic repair of spinal neural tube defects in sheep foetuses Funding organisation:
Carlos III Institute of Health File: PI20/00421

Duration: 2021 – 2023

Principal investigator: Elena Garralda Cabanas (Hospital Universitari Vall d'Hebron), Sergi Querol Giner (BST)

Next-generation TIL therapy targeting neoantigens for immune checkpoint blockade-resistant tumours Funding organisation:
Carlos III Institute of Health

File: ICI/20/00076 Duration: 2021 – 2024

Principal investigator: Antoni Bayés Genís (Hospital Germans Trias i Pujol), Joaquim Vives Armengol (BST)

Modulation of inflammation by extracellular vesicles in STEMI-derived cardiogenic shock: EV4MI Trial Funding organisation: Carlos III Institute of Health File: ICI20/00135

Duration: 2021 - 2024

Principal investigator: Joan Vidal Samsó (Guttmann Institute), Ruth Coll Bonet (BST)

A safety, randomized, double-blind, two therapeutic doses and placebo-controlled clinical trial for the treatment of incomplete cervical spinal cord injury with multiple intrathecally infusions of Wharton jelly mesenchymal stromal cells

Funding organisation: Carlos III Institute of Health File: PI19/01680 Duration: 2020 – 2024

Principal investigator: Jorge Alemany Herrera (One Chain Immunotherapeutics), Sergi Querol Giner (BST)

Development of a dual CD1a/CCR9-directed CAR-T therapy for the treatment of R/R T-cell Acute Lymphoblastic Leukemia Funding organisation: Spanish Investigation Agency

File: CPP2022-009759 Duration: 2023 - 2026

Principal investigator: Guillermo Orti Pascual (Hospital Universitari Vall d'Hebron), Sergi Querol Giner (BST)

Phase I-Ib clinical trial of safety and immunobiology of the Prophylactic Infusion of $\gamma\delta$ Lymphocytes and NK Cells from an HLA identical donor post Allo-HSCT with T depletion

Funding organisation: Carlos III Institute of Health File: PI22/00710 Duration: 2023 – 2025

Principal investigator: Gloria Iacoboni (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as SubInvestigators; BST-STC as Cell Processing

A phase 2 multi-centre Study evaluating the efficacy of KTE-X19 in subjects with relapsed/ refractory mantle cell lymphoma

Funding organisation: Kite Pharma, Inc File: 2015-005008-27 Duration: 2021 - 2023

Principal investigator: David Valcárcel Ferreiras (Hospital Universitari Vall d'Hebron), Sergi Querol Giner (BST)

Efficacy and Safety of Autologous, Mobilized, Unexpanded CD133+ Cells to Treat Patients With Asherman's Syndrome: A Prospective, Multicenter, Phase I/II Clinical Trial Funding organisation: Igenomix

File: 2016-003975-23 Duration: 2018 - 2023

Collaboration projects

Principal investigator: Ana Oaknin (Hospital **Universitari Vall** d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators**

A Phase 2, Multicenter Study to Evaluate the Efficacy and Safety Using Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Recurrent, Metastatic, or Persistent Cervical Carcinoma Funding organisation: **Iovance Therapeutics**

File: 2016-003447-11 Duration: 2022 - 2024

Principal investigator: Gloria Iacoboni (Hospital **Universitari Vall** d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators; BST-STC** as Cell Processing

A single arm, open-label, multi-centre, phase I/II study evaluating the safety and clinical activity of auto4, a car t cell treatment targeting TRBC1, in patients with relapsed or refractory TRBC1 positive selected T cell non-Hodgkin Lymphoma Funding organisation: Autolus Ltd

File: 2017-001965-26 Duration: 2020 - 2023

Principal investigator -**Pediatrics: Constantino** Sabado (Hospital Universitari Vall d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators; BST-STC** as Cell Processing

Multicenter, Open-Label, Phase 3 Study of Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Subjects with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease after Failure of Rituximab or Rituximab and Chemotherapy (ALLELE Study)

Funding organisation: Atara Biotherapeutics File: 2017-002949-30 Duration: 2020 - 2024

Principal investigator: Susana Rives Sola (Hospital Sant Joan de Déu), Enric Garcia Rey (BST)

A phase Ib/II, multi-centre, open-label, single-arm, multi-cohort study to evaluate the safety and efficacy of JCAR017 in paediatric patients with acute B-cell lymphoblastic leukaemia and relapsed/ refractory B-cell non-Hodgkin's lymphoma Funding organisation: Celgene Corporation

File: 2018-001246-34 Duration: 2018 - 2024

Principal investigator: Pere Barba (Hospital **Universitari Vall** d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators; BST-STC** as Cell Processing

Phase I, open-label, multicentre, dose escalation study of YTB323 in adult patients with CLL/SLL and DLBCL

Funding organisation: Novartis Pharma AG File: 2018-004336-30

Duration: 2021 - 2024

Principal investigator: **Claudia Valverde Morales** (Hospital Universitari

BST participation: **BST-HVH** as Sub-**Investigators; BST-STC** as Cell Processing

Vall d'Hebron)

A phase 2 single-arm, open-label clinical trial of ADP-A2M4 SPEAR™ T-cells in subjects with advanced synovial sarcoma or myxoid/ round cell liposarcoma Funding organisation: Adaptimmune Therapeutics PI C

File: 2019-000589-39 Duration: 2020 - 2024

Principal investigator: Pere Barba Suñol (Hospital Universitari Vall d'Hebron), Sergi **Querol Giner (BST)**

TRACE: Treatment of chemorefractory viral infections after allogeneic stem cell transplantation with multispecific T cells against CMV, EBV, and AdV: a phase III, prospective, multicenter clinical trial Funding organisation: Ludwing Maximilians Munich University

File: 2018-000853-29 Duration: 2021 -2023

Principal investigator: Pere Barba (Hospital Universitari Vall d'Hebron) **BST** participation: BST-**HVH** as Sub-Investigators; **BST-STC** as Cell **Processing**

An open-label, multi-centre, phase Ib/II study evaluating the safety and efficacy of AUTO1, a CAR T-cell treatment targeting CD19, in adult patients with relapsed or refractory B-cell acute lymphoblastic leukaemia. Funding organisation: Autolus Therapeutics Ltd File: 2019-001937-16

Duration: 2021 - 2023

Principal investigator: Eva Muñoz (Hospital **Universitari Vall** d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators; BST-STC** as Cell Processing

An open-label, phase I study of NEO-PTC-01 in patients with advanced or metastatic melanoma Funding organisation:

Biontech

File: 2019-003908-13 Duration: 2021 - 2024

Principal investigator: Elena Garralda (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing

A phase 1 dose escalation study to assess safety and efficacy of ADP-A2M4CD8 as monotherapy or in combination with nivolumab in HLA-A2+ subjects with MAGE-A4 positive tumors Funding organisation:
Adaptimmune Therapeutics PLC

File: 2019-001965-34 Duration: 2022 – 2024

Principal investigator: María Solá (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as SubInvestigators; BST-STC as Cell Processing

A Randomised, Open-label, Multicentre, Phase 3 Trial of First-line Treatment with Mesenchymal Stromal Cells MC0518 Versus Best Available Therapy in Adult and Adolescent Subjects with Steroid-refractory Acute Graft-versus-host Disease After Allogeneic Haematopoietic Stem Cell Transplantation (IDUNN Trial) Funding organisation:

File: 2019-001462-15 Duration: 2021 - 2024

Principal investigator: Elena Garralda (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing; BST-FTA as Manufacturing Plant

A Phase I study to assess the safety and tolerability of ex vivo next-generation neoantigen-selected Tumorinfiltrating Lymphocyte (TIL) therapy in advanced epithelial tumors and immune checkpoint blockade (ICB) resistant solid tumors. Funding organisation: Vall d'Hebron Institute of Oncology

File: 2020-005778-90 Duration: 2020 - 2024

Principal investigator: Elena Garralda (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing

A phase Ib study with a safety lead-in cohort and expansion phase, of the safety, tolerability, biological effect, and efficacy of allogenic natural killer cells in combination with trastuzumab and pertuzumab in adult patients with refractory metastatic Her2 positive breast cancer Funding organisation: Vall d'Hebron Institute of Oncology

File: 2020-004543-84 Duration: 2023 - 2024

Principal investigator - Adults: Pere Barba (Hospital Universitari Vall d'Hebron) Principal investigator Pediatrics: Pere Soler (Hospital Universitari Vall d'Hebron) BST participation: BSTHVH as Sub-Investigators; BST-STC as Cell Processing

An open-label, single-arm, multicohort, phase II study to assess the efficacy and safety of tabelecleucel in subjects with Epstein-Barr virus-associated diseases Funding organisation: Atara Biotherapeutics, Inc. File: 2020-000177-25

Duration: 2021 – 2024

Principal investigator: Elena Elez (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing

A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection Funding organisation:

Funding organisation: Biontech

File: 2020-000451-12 Duration: 2021 – 2024

Collaboration projects

Principal investigator: Cristina Saura (Hospital **Universitari Vall d'Hebron) BST** participation: **BST-HVH** as Sub-**Investigators; BST-**STC as Cell Processing

Treatment of advanced or metastatic triple-negative breast cancer with adoptive therapy of PD1+ tumorinfiltrating lymphocytes Funding organisation: Clínic Foundation for Biomedical Research

File: 2020-003638-19 Duration: 2022 - 2024

Principal investigator: Gloria Iacoboni (Hospital Universitari Vall d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators; BST-STC** as Cell Processing

A pivotal Phase II randomised, multi-centre, open-label study to evaluate the efficacy and safety of MB-CART2019.1 compared to standard of care therapy in participants with relapsed/refractory diffuse large B-cell lymphoma, who are not eligible for high-dose chemotherapy and autologous stem cell transplantation Funding organisation: Miltenyi Biomedicine GmbH

File: 2020-003908-14 Duration: 2022 - 2024

Principal investigator: Juan Martín Liberal (Catalan Institute of Oncology), Isabel González Medina (BST)

Prospective collection of donor tissue and blood or leukapheresis product from patients with solid tumours to enable development of methods for the manufacturing of clonal neoantigen T-cell products Funding organisation: **Achilles Therapeutics** Limited

File: I.2021.019 Duration: 2021 - 2023

Principal investigator: Pere Barba (Hospital Universitari Vall d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators**; **BST-STC** as Cell Processing

A Phase 3 Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of Axicabtagene Ciloleucel Versus Standard of Care Therapy in Subjects with Relapsed/Refractory Follicular Lymphoma Funding organisation: Kite Pharma, Inc

File: 2021-003260-28 Duration: 2023 - 2024

Principal investigator: Cecilia Carpio (Hospital Universitari Vall d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators**; **BST-STC** as Cell Processing

A Phase 3 Randomized Study Comparing Bortezomib, Lenalidomide and Dexamethasone (VRd) followed by Ciltacabtagene Autoleucel, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA versus Bortezomib, Lenalidomide, and Dexamethasone (VRd) followed by Lenalidomide and Dexamethasone (Rd) Therapy in Participants with Newly Diagnosed Multiple Myeloma for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy Funding organisation: Johnson & Johnson Innovative Medicine

File: 2021-001242-35 Duration: 2021 - 2024

Principal investigator: Elena Garralda (Hospital Universitari Vall d'Hebron) **BST** participation: **BST-HVH** as Sub-**Investigators; BST-STC** as Cell Processing

A phase 1/2, first-in-Human, open-label, accelerated titration, two-part clinical trial of TK-8001 (TCR1367transduced autologous CD8+ T cells) in subjects with HLA-A*02:01 genotype and advanced-stage, MAGE-A1+ solid tumors in non-curable state that have received a minimum of two lines of approved systemic therapy

Funding organisation: T-KNIFE GMBH File: 2021-004158-49 Duration: 2022 - 2023

Collaboration projects

Principal investigator: Cristina Diaz de Heredia (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing

Phase 3, Randomized,
Double-Blind, PlaceboControlled Trial, with
Cross-Over, of Posoleucel
(ALVR105) for the
Treatment of Adenovirus
Infection in Pediatric and
Adult Participants Receiving
Standard of Care Following
Allogeneic Hematopoietic
Cell Transplantation
Funding organisation:
AlloVir

File: 2021-003450-22 Duration: 2022 - 2023 Principal investigator: Ana Oaknin (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing

Phase 2, open-label, randomized, non-comparative clinical trial of ADP-A2M4CD8 monotherapy and in combination with Nivolumab in subjects with recurrent ovarian cancers Funding organisation:

Adaptimmune Therapeutics

File: 2022-003176-16 Duration: 2023 - 2024

Principal investigator: Pere Barba (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as SubInvestigators; BST-STC as Cell Processing

A Single-Arm, Open-Label, Phase 1/2 Study
Evaluating the Safety,
Efficacy, and Cellular
Kinetics/Pharmacodynamics
of ALLO-501A, an Anti-CD19 Allogeneic CAR T Cell
Therapy, and ALLO-647,
an Anti-CD52 Monoclonal
Antibody, in Subjects with
Relapsed/Refractory Large B
Cell Lymphoma (LBCL).
Funding organisation:
Allogene Therapeutics Inc.

File: 2022-501927-25 Duration: 2023 - 2024

Principal investigator: Cristina Diaz de Heredia (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing

Phase 2 study of the infusion of differentiated autologous T-cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-CD19 specificity (A3B1) conjugated with the co-stimulatory regions 4-1BB and CD3z (ARI-0001 cells) in children and adolescents aged 0-18 years with CD19+ acute lymphoblastic leukaemia resistant or refractory to treatment Funding organisation: Fundació Privada per a la

Recerca i la docència Sant Joan de Déu File: 2022-001101-52

Duration: 2023 - 2024

Principal investigator: Gloria Iacoboni (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as Sub-Investigators; BST-STC as Cell Processing

An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene Ciloleucel versus Standard of Care Therapy as First-Line Therapy in Subjects with High-Risk Large B-Cell Lymphoma

Funding organisation: Kite Pharma, Inc

File: 2022-000649-33 Duration: 2023 - 2024

Principal investigator: Josefina Cortés (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as SubInvestigators; BST-STC as Cell Processing

An open-label, multicenter, phase ½ study to assess safety, efficacy and cellular kinetics of YTB323 in participants with severe, refractory systemic lupus erythematosus (srSLE) Funding organisation: Novartis

File: 2022-001796-14 Duration: 2023 - 2024

Principal investigator: Pere Barba (Hospital Universitari Vall d'Hebron) BST participation: BST-HVH as SubInvestigators; BST-STC as Cell Processing

A randomized, open-label, multi-center phase III trial comparing tisagenlecleucel to standard of care in adult participants with relapsed or refractory follicular lymphoma Funding organisation: Johnson & Johnson Innovative Medicine

Innovative Medicine File: 2023-503452-27-00 Duration: 2023 – 2024

Publications

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2.3. Tissue Bank programme

The Tissue Bank programme is dedicated on translational research, as well as the development, optimisation and innovation of procedures and techniques aimed at improving the effectiveness, quality and safety of human cells and tissues, for therapeutic or biosubstitutive purposes.

Researchers also play a coordinating role in projects, assessing their feasibility and, when possible, securing resources for their development through competitive public grants (Spain and the European Community), as well as from private entities, foundations and industry partners.

Our research programme promotes self-sustainability and fosters innovation through collaboration with the business sector, working in coordination with leading translational research clinical groups in the national and international context.



Translational research is a tool for continuous improvement, with a focus on addressing therapeutic needs using effective and appropriate approaches and procedures.

The strategy of our RDI program strengthens the various research lines identified as strategic for the organization, while keeping key factors in mind, such as our primary focus on patient care. Furthermore, adherence to ethical and regulatory standards, a commitment to quality and excellence, and a focus on sustainability are essential pillars throughout the process.

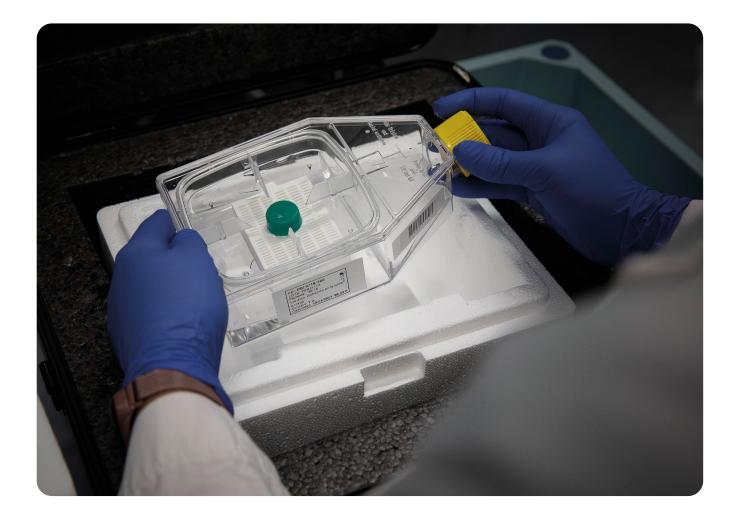
Director

Cristina Castells Sala

Researchers

Elba Agustí Robira Ana Rita Baptista Piteira Raquel Bermudo Gascón Ana Bofill Ródenas Oscar Fariñas Barbera Laura López Puerto Eva Maria Martínez Conesa Nausica Otero Areitio Maria Luisa Pérez Rodríguez Natzaret Pujagut Mercader

José Ignacio Rodríguez Martínez Laia Ruiz Ponsell Andrés Savío López Jaime Tabera Fernandez Carlos Torrico León Anna Vilarrodona Serrat



Research projects

Projects with a Pl or CO-Pl from the BST

Principal investigator: Cristina Castells Sala

VASCRAFT: New human decellularized and reendothelialized tissueengineered VASCular gRAFT for coronary artery bypass araftina Funding organisation:

Spanish Investigation Agency

File: CPP2021-008438 Duration: 2022 - 2025

Principal investigator: Raquel Bermudo Gascón

Technological development and implementation of a computer system for digitising grafts and donorrecipient correlation for use in tissue banks

Funding organisation: BST File: I.2021.026 Duration: 2021 - 2024

Principal investigator: Anna Vilarrodona Serrat

EGALITE: European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments Funding organisation: European Commission

File: 101056852 Duration: 2022 - 2024

Principal investigator: Oscar Fariñas Barbera and Pablo Gelber (Hospital de la Santa Creu i Sant Pau)

Fresh preservation of osteochondral allografts at

Funding organisation: Carlos III Institute of Health

File: PI18/01771 Duration: 2019 - 2023

Principal investigator: Anna Vilarrodona Serrat

Reduction of post-infarction lesion by bioimplants with reparative capabilities: biomimetic hydrogels and extracellular vesicles for cardiac regenerative medicine

Funding organisation: BST File: I.2019.039 Duration: 2020 - 2023

Principal investigator: Oscar Fariñas Barbera

Development of SoHo bioinks for 3D bioprinting of an osteochondral graft prototype Funding organisation: BST

File: I.2023.031 Duration: 2023 - 2026

Principal investigator: Laia Ruiz Ponsell

Development of a large caliber decellularized nerve production protocol for clinical use in peripheral nerve regeneration Funding organisation: BST

File: I.2023.028 Duration: 2023 - 2026

Publications

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2.4. Biological safety programme

The Transfusion Safety Laboratory (LST in the Spanish acronym) aims to improve knowledge on pathophysiological, epidemiological and detection aspects of infectious agents that affect the safety of blood, cells, tissues and breast milk.

In this respect, we should highlight the activity carried out to improve knowledge of the presence of pathogens from other countries among the BST's reference population in Catalonia.

Studies in this direction are aimed at planning and establishing strategies to ensure the safety of blood products on the basis of a correct selection of blood donors and the use of diagnostic tests. It should be borne in mind that the BST is the only centre that distributes blood products in Catalonia and its direct responsibility is to maintain and promote research along these lines.

The LST comprises the Healthcare Unit and the R&D Unit for transmissible agents. The R&D activity of the LST has two main lines:

- A. Viral hepatitis (HBV, HCV and HEV) and HIV coinfection
- **B.** Epidemiological research and development of new tools for the detection of emerging infectious agents (Chagas disease, HTLV-I/II, Chikungunya virus, malaria, XMRV, ZIKA)

Director

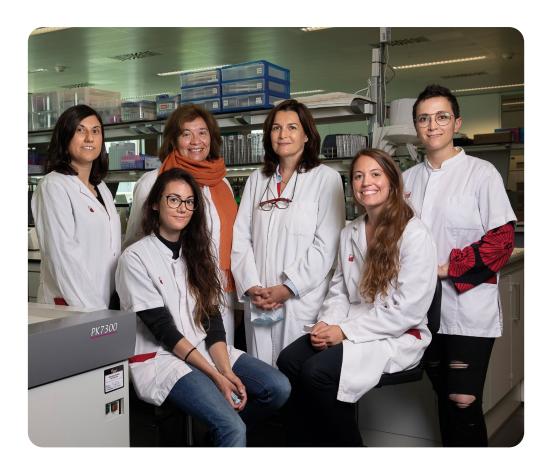
Sílvia Sauleda Oliveras

Researchers

Marta Bes Maijó Meritxell Llorens Revull Maria Piron

Support staff

Angeles Rico Blázquez Esther Vicente Encina



Research projects

Projects with a PI or CO-PI from the BST

Principal investigator: Maria Piron

Development of real-time PCR protocols (ZIKA, Dengue, Chikungunya, HTLV-I, HTLV-II, etc.) as supplementary screening or analysis tools for emerging infectious pathogens and a field study of emerging pathogens in high-risk travellers and immigrant donors Funding organisation: BST

File: I.2016.037 Duration: 2009 - 2023

Principal investigator: Marta Bes Maijó

Prevalence of HIV preexposure prophylaxis and hepatitis A virus antibodies as surrogate markers of undisclosed high-risk sexual practices among blood donors in Catalonia Funding organisation: BST

File: I.2019.031 Duration: 2020 - 2023

Principal investigator: Sílvia Sauleda Oliveras

Naturally- and vaccineinduced humoral immune response to SARS-CoV-2: A holistic approach from the Blood Bank

Funding organisation: BST

File: I.2021.029 Duration: 2021 - 2024

Collaboration projects

Principal investigator: Juan Ignacio Esteban Mur (Hospital Universitari Vall d'Hebron), Sílvia Sauleda Oliveras (BST)

Dynamic changes in HCVspecific immune response during and after DAAs treatment to unravel new approaches to prophylactic vaccine development Funding organisation: Carlos

III Institute of Health File: PI19/00533 Duration: 2020 - 2023



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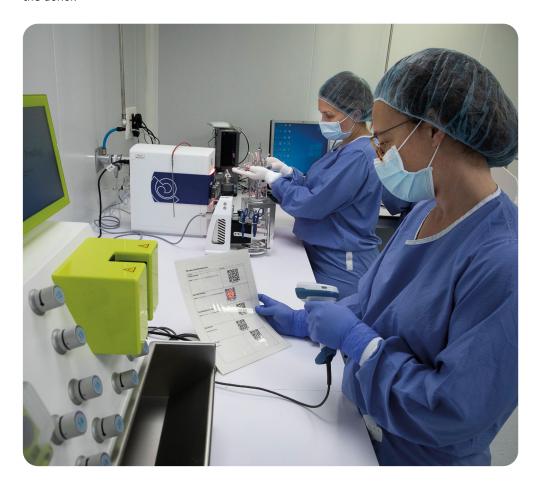
2.5.

Blood, cell and tissue donation programme

This is a newly created programme in the SRP 2017-20.

It aims, among other things, to develop projects for the improvement of our knowledge of donors' behaviour and their affective and decision-making mechanisms in order to better adapt donations to therapeutic needs, while preserving the well-being and ethical and social values of donors.

The research focuses on a series of priorities, one of which is the study of ethical principles, promotion, donation behaviours and, above all, the protection, well-being and comfort of the donor.



3.

Core platforms

The central or core platforms are shared research resources that provide access to BST researchers and institutions with links to instruments, technologies and services, as well as expert consultations and collaborations.

The BST has fostered the consolidation of these platforms through the laboratories of the healthcare divisions, taking advantage of their technological capabilities and opening up their own research resources to general use.

3.1. Genomics platform

The Genomics Platform of the Banc de Sang i Teixits (BST) supports the adaptation of molecular diagnostic protocols to next generation sequencing (NGS) technology, as well as its application to different research and innovation projects. The extensive experience in the development of NGS applications is complemented by a solid support structure in equipment. Currently, the platform has two MiSeq and one Illumina NextSeq 500 equipment, which allow great scalability to address protocols ranging from the identification of point variants in one or a few genes to whole exome sequencing or transcriptome study. It also has Oxford Nanopore's MinION and PromthION P2 third-generation sequencing (TGS) platforms, which enable ultra-long reads and are being implemented in different areas of interest to the BST. In addition to sequencing technology, the Platform has a specific molecular biology instrumentation infrastructure within the laboratory area (nucleic acid extractors, automatic dispensers, traditional SeqStudio genetic analyzers, Thermalcyclers, Real-Time PCR, Luminex technology, Nanodrop, Qubit, etc.) that allows automation for the processing of large sample volumes simultaneously. It also has bioinformatics tools and specific analysis programs for the interpretation of the results, as well as data management systems to store the large volume of information generated by these technologies in an agile and secure manner. The functions of the platform consist in the management and optimization of the use of NGS and TGS technology. Moreover, the platform provides technical support to researchers who want to use these genomic techniques in the design and development of projects, in the execution and analysis of data. In this sense, it is essential to support the projects from the initial stages to determine the most suitable strategy that allows the achievement of the objectives.

Director

Irene Corrales Insa

Researchers

Nina Borràs Agustí Natàlia Comes Fernandez Carlos Hobeich Naya Francisco Vidal Pérez



3.2. Cell laboratory

Its functions include maintenance and provision of the necessary equipment to researchers working with cell cultures and characterisation (mainly with cytometry, microscopy and metabolism analysis), as well as the basic training needed for their correct use.

Moreover, the experience of the platform's professionals is used to support and offer added value to the research and assistance activities of BST researchers, including technical support in the design and execution of projects, data management and analysis.

In summary, the functions of the platform include: user training, organisation of the equipment use, supervision, maintenance and calibration/verification of the devices, the development and updating of standard working procedures, and support for users in the design and execution of tests with cells and technological surveillance, among others.

Director

Margarida Codinach Creus

Researchers

Francisco Javier Algar Gutierrez Begoña Amill Camps Mireia Lloret Sanchez Fatima Shettiyar Brun Sara López Molina Nicole Somarribia Hernández Laura Galvez Saleta Isabel Tarragó Canela Ruth Forner Gómez Margarita Blanco Garcia Gemma Aran Canals Silvia Torrents Zapata



3.3. Clinical development

The clinical development platform supports BST teams and their collaborators in the development of clinical trials conducted with the products their research generates as well as promoted by their public and private collaborators. It is also a channel of communication with regulatory agencies.

It is headed by

Ruth Coll Bonet

3.4. The Biobank

The BST Biobank provides the scientific community with the necessary biological material, in optimal conditions, to contribute to its research of excellence while guaranteeing the rights of donors.

It began its activity on 17 September 2010, with provisional authorisation, and obtained definitive administrative authorization on 12 April 2013.

It currently has a cross-cutting structure that manages the transfers of biological samples (blood components, plasma, serum, progenitors, tissues, etc.) between the BST's different departments and the researchers who request them.

The Biobank's scientific committee has 5 members:

Silvia Sauleda. Anna Vilarrodona Sergi Querol

Head of the Transfusion Head of the Tissue Bank Head of the Cell Therapy Safety Laboratory (LST) Service

Francisco Vidal

Aurora Navarro

Notify project coordinator

Coagulopathies
Laboratory

Scientific management of the Biobank is led by Joaquim Delgadillo Duarte, Scientific Director at the BST, and Pilar Monleón Martinez, coordinator, handles all the administrative processes related to sample transfer.

The BST supply area and its different territorial centres are responsible for the supply of samples to all BST services and departments.

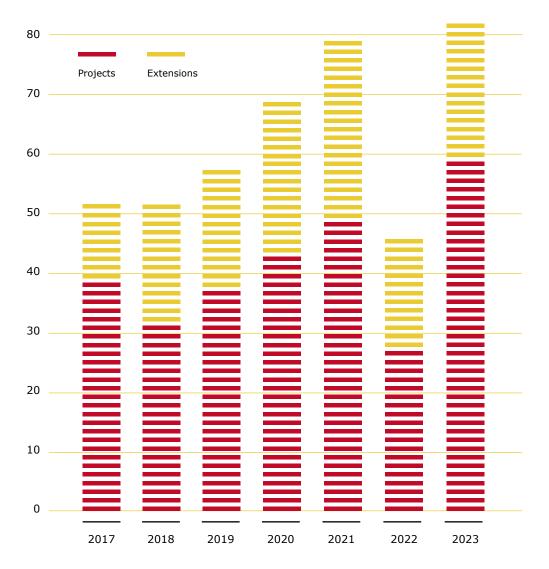
Pilar Monleon



Active projects

Fifty-nine new projects have been approved for sample assignment and another twenty-two projects have had approval extended.

Here is a list of the number of projects and extensions since 2017:





MoU

Agreements for the transfer of biological samples are regulated through memorandums of understanding (MoU) with research institutions, universities or companies in the health sector.

These come from the different BST services shown below, where the number of units delivered is also expressed.

The samples come from the different services of the BST

supplied

BLOOD COMPONENT PROCESSING LABORATORY	TRANSFUSION SAFETY LABORATORY	CELLULAR LABORATORY	HLA LABORATORY
2,550	89,825	2	71
CELL THERAPY SERVICE	BST TISSUE BANK	MILK BANK	TERRITORIAL CENTRES
429	135	10	1,969

Collaboration agreements

During 2023, twenty MTA's and four extensions of previous agreements have been signed with the following entities:

MTA's:

Vall Hebron Institut de Recerca, Institut de Recerca Biomèdica, Institut Nacional de Toxicologia i Ciències Forenses, Fundación para la Investigación Biomédica del Hospital Gregorio Marañón, Hospital Universitari de Zúric, Bioliquid, Integra TX, One Chain, Cell Easy, SAS, The Art of Discovery, SL, Orikine Bio, Antonio Puig, SA, Rejuversen Europe, SLU, Almirall, SA, University of Edinburg, IPBLM-CSIC de Granada, Emercell, Fundació Institut Germans Trias i Pujol, Fundació Privada Món Clínic, Institut de Bioenginyeria de Catalunya

Extensions:

Institut d'Investigació i Innovació Parc Taulí, Vall d'Hebron Institut d'Oncologia, Universitat de Barcelona, Fundació Institut Hospital del Mar d'Investigacions Mèdiques

ECONOMIC ACTIVITY

During 2023 the Biobank has invoiced 317.890.79 €



4.

Education at the BST

The mission of the BST education area is to promote and collaborate in the training of Health and Life Sciences students and professionals, particularly in the field of transfusion medicine and cell and tissue therapy.

It develops its own teaching and training services and acts as a reference centre for professionals in the sector at a national and international level.

It also manages the MoUs and coordinates and plans residents' training and the training stays of external and internal professionals, as well as handling student internships in the BST's different departments. It is also responsible for the induction all these professionals and students when they arrive at our main centre's facilities.

The education area engages in different activities, which can be seen in detail in the special 2023 report, aimed at different profile groups:

4.1.

Students from other institutions

4.1.1. Schools and centres

This 2023 we signed specific agreements with the following schools and vocational training centres:

- · Institut Escola del Treball
- · Jesuïtes del Clot
- Escola Santa Maria dels Apòstols
- · Escola Pia Nostra Senyora
- · Institut la Guineueta
- · Institut Roger de Lluria
- Institut les Vinyes
- · Institut Rambla Prim
- · Institut Castellarnau
- · Institut Joviat
- · Institut Eugeni d'Ors
- Institut Pedraforca
- · Centre d'Estudis Roca
- IFP
- · Escola Lexia
- · SOC
- · Escola Familiar Agrícola
- Camp Joliu
- · AF Centre d'Estudis
- · Escola Ramon i Cajal
- · CE Dolmen
- · Institut Lacetània
- Institut Alexandre Satorras and Col·legi Sagrada Família.

Twenty-eight students joined us at the BST headquarters, the specialities being:

Clinical and Biomedical Laboratory	
Pathological Anatomy	
Web application development (bioinformatics)	
Clinic Electromedicine	3
Health Documentation and Management	
Administrative Management	
Organization and management of warehouses	
Nursing Assistant Care	

Seventeen students joined the territorial centres, in the following specialities:

Clinical and Biomedical Laboratory	
Sales assistant, office or public service	1
Health Documentation and Management	

In addition, we welcomed 3 secondary school students.

4.1.2. Universities

Twelve degree students have been tutored at the headquarters—of which 3 have completed their final degree work—from the following universities:

- · Universitat Autonoma de Barcelona (UAB): Faculties of Biology (2) and Biotechnology (1)
- · Universitat Pompeu Fabra (UPF): Faculties of Biology (6) and Medicine (1)
- Universitat de Vic Universitat Central de Catalunya (UVic-UCC): Facultie of Biotechnology (1)
- · Universitat Blanquerna: Faculty of Pharmacy (1)

The departments involved in this practical training are:

Cellular Laboratory: 3Quality Department: 1Microbiology Laboratory: 5

· Immunohematology Laboratory: 2

· Breast Milk Bank: 1

And three master's students from:

- · UPF. Master Lab. Clinical Analyzes
- · UB-UAB. Advanced Immunology Master
- · CEU San Pablo. Master in Regenerative Medicine and Advanced Therapy

Where the departments involved are:

- · Microbiology Laboratory (1)
- · Cell and Advanced Therapy Service (2)

The practices of forty-nine nursing degree students from the following Universities have been tutored at the territorial centers:

- · University of Manresa
- · Escola Universitaria Gimbernat
- · EUI Terrassa
- UVIC
- · EUI Sant Pau and Blanquerna University

The students are distributed as follows:

BST-Badalona: 12
BST-Bellvitge: 9
BST-Sant Pau:7
BST-Tarragona: 2
BST-Terrassa: 8
BST-Girona: 2
BST-Vall d'Hebron: 9

4.2.

Medical residents

BST is the reference centre for the training of resident doctors (MIR) in the specialty of Hematology and Haemotherapy.

In 2023, the BST headquarters trained 21 medical residents in the speciality of Hematology and Haemotherapy; they came from hospitals in Catalonia, other autonomous communities (2) and other specialties (9).

The hospitals of origin of the MIRs in Catalonia are as follows:

Origin MIR Catalunya

Hospital del Mar	
Hospital Joan XXIII	
Hospital Arnau de Vilanova	2
Hospital Clínic	4
Hospital Josep Trueta	2
Hospital Sant Pau	3
Hospital Bellvitge	2
Mútua Terrassa	
Hospital GTiP	3
Hospital Vall d'Hebron	2

Residents rotate through the following departments:

 Immunohematology Laboratory

 Histocompatibility and Immunogenetics Laboratory

· Congenital Coagulopathies

· Cell Therapy Service

Cell Laboratory

 Blood Component Processing Laboratory

 Transfusion Safety Laboratory Quality and Communication Department

Biovigilance

Residents are evaluated both at the territorial centres and at the headquarters with the rotation evaluation report provided by the Subdirectorate General for Professional Management of the Ministry of Health, Consumer Affairs and Social Welfare.

This report assesses the degree of compliance with the rotation objectives and evaluates the skills acquired on a scale of 1 to 10.

Dr. Jesús Fernández is the coordinator and responsible for these evaluations.

Academic training

More and more BST professionals (there are now 25) carry out teaching activities in the various universities of Catalonia: Universitat de Barcelona, Universitat de Girona, Universitat Rovira i Virgili, Universitat de Barcelona, Universitat Internacional de Catalunya and Universitat Ramon Llull.

We would also like to give a special mention to all BST staff, whoever they may be, for their work in tutoring and accompanying all the students who are trained in our facilities.

4.3.1. Chair in transfusion medicine and cell and tissue therapy (cmt₃)

The Cmt3 has continued the same line of teaching activity:

· Breastfeeding and Human Milk Donation program with 23 students enrolled.

Coordinated by Carlos González and Luis Ruiz, Vanessa Plequezuelos and Marina Vilarmau, with the collaboration of the Universitat Autònoma de Barcelona and the Universitat de

· Fifth edition of the University Master's Degree in Transfusion Medicine and Cellular and Tissue Therapies, in which 24 students from all over enrolled.

Coordinated by Joaquim Vives Armengol (Universitat Autònoma de Barcelona) and Jaap Jan Zwaginga (Leiden Univesity Medical Center).

4.4.

Lifelong learning

During 2023, fourteen professionals from different backgrounds have had a training stay at the BST headquarters. To highlight: H.U. Alexandrovska (Bulgaria), FIMABIS (Málaga), DTI, Grifols Institute, Chulalongkorn University, U.N. Autonomous of Mexico, H. Italiano of Buenos Aires, and Kariadi Hospital (Indonesia).

The departments involved are the Cellular and Advanced Therapy Service, the Histocompatibility and Immunogenetics, Congenital Coagulopathies, Immunohematology Laboratories, the Tissue Bank and the Breast Milk Bank.

Coordinators

In charge of the on-line part



Carlos Gonzalez Pediatric Specialist

He is the founder and president of ACPAM (Catalan Association for Breastfeeding) since 1991. From this association, he has directed and imparted teaching in more than 100 courses on breastfeeding for health professionals.

Author of the books: My child does not eat, Kiss me a lot, A gift for life or growing together.



Marina Vilarmau

Pedagogue, specialist in Training Projects in the Area of Health Sciences.

Master's degree in clinical simulation methodology (UVic-UCC). Master's degree in sexual difference studies (UB). With more than 10 years dedicated to the design and direction of training projects in the area of health and education sciences.



Luis Ruiz Pediatric Specialist

Pediatrician. Trained in maternal and child health (MSc) University of London and Diploma in Senology at the University of Barcelona. Pediatrician in Primary Care at the CAP 17 de Setembre in El Prat de Llobregat and private consultation in Breastfeeding at the Quirón-Dexeus i Gavà Family Health Clinic. Former national coordinator of the IHAN and Emergency Pediatrician at the Children's Hospital of Barcelona.



Vanessa Pleguezuelos

Biologist specializing in Biosanitary

Head of the Human Milk Bank, Blood and Tissue Bank. Master's degree in scientific, medical and environmental communication. Master's degree in TAC training, Learning management and Innovation in Organizations. Certificate of Pedagogical Skills. Professor of breastfeeding courses at the Public Health Agency, the College of Nursing and the University of Barcelona.

5.

The BST Research and Education team

Apart from the people directly involved, a very large number of professionals from the different departments of the BST collaborate in the smooth running of research and education at our organisation. It is only fair to thank them for their contribution.

Specific mention should be made of the people who make up the Research and Education team:



BST Project Manager

Elisabet Tahull

Head of Clinical Development

Ruth Coll

Project manager Raquel Gil Educational programmes staff, Fundació Salut i Envelliment UAB (Health and Ageing Foundation UAB)

Marina Vilarmau

Coordinator for educational projects, UAB Remei Camps **Director, Fundació Salut i Envelliment UAB**Antoni Salvà

Administrative assistant, Fundació Salut i Envelliment UAB Helena Garrigós







Some of the projects carried out at the BST during 2023 were funded by the following institutions







