

Perspectivas

en Derecho y Genoma Humano

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Inter-University Chair BBVA Foundation-Provincial Government of Biscay in Law and the Human Genome. University of Deusto, University of the Basque Country

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Editorial

The *International Cancer Genome Consortium* (ICGC) (<http://www.icgc.org/>) is a non-profit organisation. Its mission is to foster and coordinate a great number of research projects, all of which share a common objective: studying the genetic changes caused by some of the oncological diseases with a major social and clinical impact on the world's population. By doing so, the organisa-

tion aims to contribute to a better understanding and treatment of these diseases. The countries that make up the consortium are Germany, Australia, Canada, China, Spain, France, India, Japan, the United Kingdom and the United States. Specifically, the chronic lymphatic leukaemia genome project is being developed in Spain, coordinated by Prof. Elías Campo, Head of the Haematopa-

thology Unit at the Hospital Clínic de Barcelona. The Consortium's international structure includes a group that specialises in analysis and consultancy regarding the legal and ethical aspects of the projects. The group is led by Professor Bartha Knoppers. The Inter University Chair of Law and the Human Genome is part of this international group and a member of the Spanish project.

Opinion

Informed consent special characteristics for xenotransplantation

I. Introduction

Xenotransplantation (hereafter XT), is a procedure that involves the transplantation or transfusion of live cells, tissues or organs from animals or body fluids, cells, tissues or human organs that have been in contact *ex vivo* with cells, tissues or animal organisms into a human recipient. This procedure is currently being presented as a possible solution to the problem of the selective lack of organs available for transplant. However, it poses a significant number of questions that must be resolved before it can be applied clinically.

It is impossible to avoid confronting the scientific-technical and ethical barriers that arise about this topic with the aim to optimise its possible benefits and minimise the risks involved as much as possible. The ethical considerations include certain questions that are specific to XT and others that apply to any experimental therapy. Our interest will focus on these questions and among them we will particularly focus on those affecting the patient and public health, given that these considerations include the difficulties arisen when it comes to informed consent. We will not refer to those considerations concerning the use and well-being of the donor animals, as this would exceed the established remit.

II. Some Ethical Questions Involved

XT poses a series of problems and ethical questions that require a wide and open public debate, both from a technical-scientific perspective and from an ethical-legal point of view.

1. *Scientific-Technical Issues*

The major problems arising at a practical level become the greatest difficulties posed by XT, from a scientific-technical perspective. Firstly, the immunological reaction of the recipient organism is turning out to be a major obstacle. This reaction cannot be considered to have been overcome. The scepticism shown by some regarding the possibility of achieving benefits in the short term through the use of this technique, is therefore not surprising. However, many of the staunch defenders of the technique continue to be convinced that XT will begin to bear fruit, as knowledge from specific research and about complementary techniques used in the research increases. In fact, the extraordinary progress that has been achieved in recent years in the development of these other inquiries has revived the optimism of many. Considerable advances have been made at the level of transgenesis from donor animals for their better assimilation by the patient and in relation to the development of knowledge regarding immunosupres-

sion. Furthermore, in relation to grafting, both the adaptation of the graft to the receptor organism and the adequate continuation of its functions in the receptor organism are still insufficiently reliable for the animal experimentation period to be considered to be over yet. However, the latest results achieved seem to cast doubt on the lack of confidence that some have in XT and give more weight to the need to continue investing funds for its development. Nevertheless, it is necessary to be very aware of the current state of knowledge regarding other possible alternatives for resolving the deficiency in the supply of allogenic grafts, such as the possible development of implant material based on stem cells or bioartificial organs.

2. *Risks for the Patient and for Public Health*

From this perspective the main question is the potential risk of the transmission of infectious agents from the donor animal to the patient, to other people around the patient (for example, family members) and others who would be responsible for the treatment, follow-up and subsequent monitoring of the patient and his/her progress. The potential spread of infectious diseases would in this way be transformed into a public health matter. This leads us to ask ourselves whether it is ethically acceptable that it is only the patient who is asked to consent to a therapy which, in general, could put other people

around him/her, and even society as a whole, at risk and to ask ourselves under what conditions consent has to be obtained from these other people.

There is therefore a clear need to tackle the most serious problems and the main consequences for the patient and/or for public health before proceeding to the clinical phase. Indeed, in the first phases of its application to human beings it will be essential to observe the necessary steps established by the regulations on clinical trials. In order to proceed with the clinical phase, it is a prior requirement that XT has achieved the necessary guarantees, i.e., the clinical stage is only started once the scientific data provided by the preclinical phase can be corroborated. This must ensure that its introduction as a clinical treatment provides more advantages than disadvantages at all levels. Such regulations will attempt to ensure, amongst other aspects, the patient's safety, avoiding any risk of the objectification of the patient, and respecting his or her free and individual decision, in such a way that the patient's informed consent (IC) must be obtained in all cases. However, certain difficulties regarding this matter will now be discussed.

3. *The Specific Features of Informed Consent in XT*

There are various questions related to criteria that must be taken into account when developing an adequate IC process regarding the potential risk of XT for society. Although the risk of the process is normally only taken by the patient, it must be born in mind that in the case of XT risk is also taken by the people close to the patient, the health professionals and society in general. Consequently, within the general aspects covered by the IC documents other specific aspects will have to be included for gene graft recipients. Therefore, given the particular features of XT, the information provided will have to go beyond the generally accepted patterns of the doctor-patient relationship. Therefore, the information that is conveyed to the patient must, first of all, be adapted to the patient's situation and provide the patient with a clear understanding of: his/her condition; the benefits and risks of the operation itself, specifically rejection and the development of an illness derived from the donor animal; the existing alternatives, and the need to inform the patient about the operation itself and its risks to those people around the patient. In addition, the information must cover other aspects related to the possible limitations or conditioning factors in the patient's subsequent life, both immediately after the operation and in the medium and long term, including especially those factors that may affect the patient's private life.

Various recommendations about the different elements, that would have to be included in the IC procedures, can be foreseen. Amongst these, the following are particularly significant: a) the potential risk of infections from non-human agents, whether known or not; b) the potential risk of transmis-

sion of unknown infectious xenogenic agents; c) the potential risk of transmission of infectious xenogenic agents (and, if applicable, the possible development of the illness); d) the recipient must be informed about the responsibility that he or she would have to inform his or her relatives and people around him or her about the possibility of transmitting agents; e) the potential need for isolation procedures, and any other unavoidable, specialised, precautionary measure to minimise the acquisition or transmission of infections; f) the potential need to follow specific precautions to avoid contact with animals of the same species from which the gene graft was obtained; g) the importance of complying with a medical monitoring system throughout the recipient's whole life, as well as the need to have available the store of tissues and/or samples of bodily fluids for public health purposes; h) the importance of carrying out an autopsy after the death of the recipient; i) long term access by the relevant health authorities to the recipient's medical history; j) as a provisional precautionary measure, recipients of gene grafts and particular people around them would have to give up, for an indefinite period of time, donating blood, ova, sperm, etc.

Some of the difficulties shown by this IC procedure concern whether it would be possible to expect the current or future people around the recipient to accept having to follow a monitoring system if it were considered necessary. Notifying the people in contact with the recipient of the potential risk of infection from the recipient could violate the principal of confidentiality and other human rights of the recipient. It would therefore be necessary to plan specific measures in relation to the particular reasons for breaking the duty of secrecy in these cases. In addition, it would be necessary to determine the requirements that would have to be observed by the centres in which the xenogenic material was extracted and/or the centres in which the XT was carried out. Furthermore, it would be necessary to establish the qualifications that the professional staff would have to have in each XT phase, as well as how to regulate specific aspects of this therapy, such as patient follow-up, obtaining, using and storing samples, etc. It would be necessary to establish to what extent it is possible to extend the requirements already established in the current legislation on this issue to XT. In addition, we have seen that the potential recipient of a gene graft could be obliged to observe certain measures or behaviour aimed at reducing or avoiding any possibility of contagion. These measures would affect the recipient's fundamental rights to a greater or lesser extent. These could range from the requirement to have only protected sexual relations to the imposition of restrictions on the recipient's movements, such as the imposition of a quarantine or subjection to rigorous post-operational monitoring by the medical staff. In both cases, as has already been indicated, the patient must be informed about the possibility that these restrictions could result from and be covered by his consent, as in these situations it is not only a matter of respecting the free, indi-

vidual decision of the patient, but also of balancing individual autonomy against collective public health interests which, as has been seen, can be of greater priority. Once any of these measures were adopted by the corresponding health authority, the patient would no longer be able to oppose them. Then the revocability of consent, recognised as a basic principle in the Helsinki Declaration, would be more than doubtful once the operation had been carried out. In addition, if an individual accepted all the limitations given for XT to be carried out, consideration would have to be given to the measures that would have to be adopted to force the recipient to comply with these limitations if he or she were not to follow them voluntarily.

III. Final Considerations

As it has been stated, XT's ultimate goal is to save human lives in the future, but it must be made clear that the risks involved for public health in general have not yet been quantified. This does not prevent the appropriate measures required from being adopted. The most important problems and the dangerous consequences for the patient and/or for public health will have to be resolved before proceeding to the clinical phase. In relation to this, a series of basic measures will have to be adopted before taking this step. Amongst others the following can be mentioned: In the event that therapy takes place, the preclinical phase will have to provide the necessary data to justify it. The strict regulations regarding the acceptance of this must be observed. The competent authority, the research ethics committees, health professionals and other governmental bodies will have a key role in guaranteeing the appropriateness of the respective methodological, ethical and legal aspects of XT and their adequacy for ensuring compliance with the respective preventative measures that must be adopted. The therapy will have to be carried out with approval and supervision at an institutional level to ensure the ethical conduct of the research subject. This approval and supervision will also have to be carried out at this level to ensure the well being of the donor animals.

The XT potential for solving the scarcity of organs for allotransplants and for curing illnesses currently not treated because of this, makes it advisable to continue with the work in the pre-clinical phase and, when it is appropriate, in the clinical phase. However, the possible risks that this procedure imposes on society require an effort by the legal community to ensure the safety of these clinical experiments in both the short and long term and to provide for any use of animals in medical experiments when they are first used on patients. It is proposed that there is international coordination with the aim of adopting effective measures for these purposes.

María Jorqui Azofra

Latest Chair News

Criminal Law, Science, Technology and Technological Innovation Seminar (II)

On 3 and 4 March 2009 at the Sarriko Campus of the University of the Basque Country/EHU the «Seminar: Criminal Law, Science, Technology and Technological Innovation (II)» took place. Led by Prof. Dr. Carlos María Romeo Casabona and coordinated by Prof. Dr. Fernando Sánchez Lázaro, the seminar was divided into four sessions comprising the following topics: «Criminal law and the principle of proportionality. Examples of acceptable behaviour», «On the concept of allowed risk and other problems of imputation», «The commission of crime in relation to ICT and new forms of prevention» and, finally, «Criminal law in the information society».

The following speakers took part in the seminar: Professor Doctor Santiago Mir Puig (University of Barcelona), Ángel Torío López (University of Valladolid), Sandro F. Abralde (University of Belgrano, Argentina), Esteban Sola Reche (University of La Laguna), Andreas Hoyer (University of Kiel, Germany), Asier Urruela Mora (University of Zaragoza), Fernando Sánchez Lázaro (University of La Laguna) and, finally Raúl Cueto Peruyero (Scientific Investigations Unit of the Ministry of the Interior, Madrid). They led the following lectures and discussions respectively: «The principle of proportionality and state intervention», «The concept of an offence, *lex artis* and technical standards», «The principle of trust: the current debate on its legal/criminal nature and its possible applications», «Objective (non)imputation», «Permitted risk and technological development», «Telematic monitoring and criminal law», «Possibilities and limits of the framework of a state under the rule of law», «Social panic and criminal law» and «New technologies and security: new tools for the prevention of crime». Finally, the plenary session was chaired by Emilio José Armaza Armaza, Pre-PHD Researcher of the University of the Basque Country.

The seminar took place within the framework of Research Project no. SEJ2005-07489, «Criminal law and new technologies: on the attempts to adapt criminal law to social and technological development», financed by the Ministry of Education and Science.

16 Workshop on Law and the Human Genome

The Inter University department of Law and the Human Genome held 16 Workshops on Law and the Human Genome, led by Prof. Dr. Carlos María Romeo Casabona and coordinated by Dr. María Jorqui Azofra. The workshops were inaugurated and presented by Iñaki Goirizelaia Ordorika, Rector of the University of the Basque Country and Carlos María Romeo Casabona, Head of the Department, after which Juan Ignacio Pérez Iglesias, Professor of Physiology at the

University of the Basque Country, gave the inaugural paper, entitled «Anti-scientific attitudes, open society and regulations». In addition, Dr. Carlos María Romeo Casabona, member of ERAB and member of the Spanish Bioethics Committee, described the new research challenges in Europe, highlighting the important role that the Advisory Council for the European Research Area plays in shaping and establishing this Research Area.

The lectures were grouped into three sessions, which dealt with highly current themes of significant importance. The first session dealt with «Genetic Analysis» and the speakers were Dr. Carmen Ayuso (Head of the Genetic Service and Assistant Director of Research of the Jiménez Díaz Foundation, and member of the Spanish Bioethics Committee), Dr. Itziar Alkorta (Head Professor in Civil Law and Vice Rector for Teaching Quality and Innovation at the University of the Basque Country) and Dr. Amedeo Santosuosso (University of Pavia). The second session was about «New Technologies»; and Miriam Baeta (University of Zaragoza), Prof. Dr. Markus Düwell (Professor of Moral Philosophy and Director of the Ethics Institute at the University of Utrecht), Prof. Dr. María Casado (Director of the Observatory of Bioethics and Law, Head of the UNESCO Department of Bioethics at the University of Barcelona and member of the Spanish Bioethics Committee), and Prof. Dr. Andrés Moya (Director of the Cavanilles Institute of Biodiversity and Evolutionary Biology, University of Valencia) were the participants. The speakers in the final session, on the «Internationalisation of Genetics», were Dr. Iñigo De Miguel Beriain (researcher in the Inter University Department of Law and the Human Genome), Joan Lluís Vives Corrons (Head of the Erythropathology Unit at the Hospital Clinic i Provincial (University of Barcelona) and Coordinator of ENERCA (European Network for Rare and Congenital Anaemias) and Dr. Pilar Nicolás Jiménez (Researcher in the Inter University Department of Law and the Human Genome).

At the end of each session a discussion was held with the speakers, each of them chaired by Prof. Dr. Inmaculada Herbosa (Professor of Civil Law of the University of Deusto), Dr. María Jorqui Azofra (researcher in the Department of Law and the Human Genome) and Prof. Dr. Antonio Casado da Rocha («Ramón y Cajal» researcher, Faculty of Philosophy, University of the Basque Country)

LATINBANKS Project

On 20 and 21 March the third LATINBANKS Project research members meeting, coordinated by the department along with the University of Lünenburg, was held in the Law Faculty at the University of Buenos Aires (Argentina). As in

the previous meeting, it started with a *session prior to the meeting itself and it was attended by members and open to the general public*. It was followed by the *internal meeting for project members*.

The *open session*, held on March 20th morning, was entitled «Seminar: Biological Samples and Biobanks for Medical Research. Current situation and future challenges (II)». The seminar, chaired by Prof. Salvador Darío Bergel, was presented by Prof. Dr. Tulio Ortíz, Vice Dean of the UBA Law Faculty, and chaired by Professor Dr. M^{ra} Fátima Freire de Sá and Lorena Donoso Abarca. The lectures were given by Professor Dr. Pilar Nicolás Jiménez, Carlos Valerio, Jürgen Simon, Ana del Pozo, Lilita Bisiniano, Adriana Carballa and Sergio Miguel, who discussed the following topics, respectively: «International Legal Framework», «Donor consent in the use of biological samples in medical research», «Exploiting and distributing the financial benefits», «The situation at collecting and handling biological samples in Argentina», «Biobanks in Argentina: Technical Aspects», «Biobanks in Argentina: Legal aspects» and finally, «Biobanks regulation in the National Administration of Laboratories and Health Institutes in Argentina».

The *project members' internal meeting* was opened by Prof. Dr. Jürgen Simon and chaired by Prof. Dr. Pilar Nicolás Jiménez. The following took part: Professor Drs. Salvador Darío Bergel (Argentina), Carlos Valerio (Costa Rica), Lorena Donoso Abarca (Chile), Fátima Freire de Sá (Brazil), Emilssen González de Cancino (Colombia), Ingrid Brena Sesma (Mexico), Myriam Blumberg-Mokri (France), Pilar Nicolás Jiménez (Spain), Jürgen Simon (Germany), Rainer Paslack (Germany), Jürgen Robiński (Germany), Sonia Fidalgo (Portugal) and Emilio José Armaza Armaza (Spain). The session was the vehicle to set the basis for the work to be done in the coming months in connection, firstly, with the final adjustments to the national reports and, secondly, with the template letter of consent and the guidelines that will be attached to the monograph. Finally it was agreed to hold the fourth meeting on 17 and 18 July in Hannover (Germany).

The PRIVILEGED project

On 22, 23 and 24 June 2009 the meeting of the European «Privileged» Project was held in the Department of the History of Medicine and Ethics in the University of Vilna, Lithuania. The meeting discussed how and up to what point the regulation on the protection of genetic data can be consistent with, or sufficient for, the protection of privacy. The meeting also debated the different proposals for doctoral articles that have been prepared on the subject matter covered by groups integrated into the project.

Department Publications

Revista de Derecho y Genoma Humano/ Law and the Human Genome Review. Issue 30. *Obama's Remarks at the National Academy of Sciences*, The White House; *El discreto horror de la clonación (The discrete horror of cloning)* (Guibourg); *Prenatal Diagnosis and the Trouble with Eugenics* (Landeweerd); *Clonación: reflexiones necesarias sobre lo imaginario (Cloning: necessary reflections on the imaginary)* (Minahim); *Actitudes anticientíficas en la sociedad abierta (Anti-*

scientific attitudes in open society) (Pérez Iglesias); *Comentario a propósito del proyecto de ley que modifica la ley de prevención de defectos congénitos en Argentina (On the Bill modifying the Prevention of Congenital Defects Law in Argentina)* (Siverino Bavio); *El régimen jurídico de la conservación de datos de salud sobre identificadores obtenidos a partir del análisis de ADN, a la luz de la Sentencia del tribunal Europeo de Derechos Humanos (The legal system for the preservation*

of health data about identifiers obtained through DNA analysis, in the light of the decision of the European Human Rights Tribunal (Gran Sala), 4 December 2008 (Asunto S. and Marper C. United Kingdom) (Reverón Palenzuela); *El Derecho de familia, testigo de las nuevas pruebas de paternidad prenatal (Family Law: evidence from the new prenatal paternity tests)* (Rodríguez López; Marfil Gómez; González Poveda); *Key principles about genetic testing and insurance* (Bale).

The activities of the Department members

Carlos María Romeo Casabona: *Work or research groups:* bimonthly meetings of the European Research Area Board, Brussels; chair of the 2nd meeting of the Group of Specialists on Predictivity, Genetic Testing and Insurance, Council of Europe, Strasbourg; High Level Representatives Conference on Ethics of Biomedical Research in Countries with Emerging or Developing Economies, Council of Europe, Madrid; 36th meeting of the European Committee on Bioethics (CDBI), Council of Europe, Strasbourg; European projects: Poseidon, Enerca and ICGC. *Publications:* «On the structure of fraud», Pub. Ubijus, Mexico D.F., 2009. *Speaker at congresses and seminars:* II International Workshops of the UNESCO Department of Bioethics, University of Barcelona, (lecture: «Cultural diversity and pluralism in the Universal Declaration on Bioethics and Human Rights»); II Annual Conference of the Biomedical Research Technological Platforms: Innovative Medicines and Nanomedicine, NANOMED-Spain, Madrid; Seminar of the Spanish Data Protection Agency, Madrid, («The protection of health data in biomedical research»); Congress on the criminal responsibility of doctors and health personnel in exercising their profession, University of Granada («Genetics and Criminal Law»); VI World Bioethics Congress, SIBI, («New perspectives on consent: advanced biomedical research»), Gijón; 51st Congress of the Spanish Geriatric and Gerontology Society («The law on medical research: ethical evaluation»), Bilbao; 10th European Symposium Eurocat, Bilbao («Ethical and legal factors in prenatal diagnosis and genetic counseling in Europe»); European TISSEU Project, Université Paris II («Biobanking»: three lectures). *Postgraduate courses:* Carlos III University, Madrid («Protection of DNA data and archives»). Other courses: «Biometry: between safety and fundamental rights»). *Evaluating commissions:* Jürgen Robiński, doctoral thesis board («Die Auswirkungen von Gewebegesetz und Gendiagnostikgesetz auf die biomedizinische Forschung. Biobanken, Körpermaterialien und Gendoping»); Director: Prof. J. Simon, Leuphana University (Lüneburg, Germany); member of the Catalina Peña doctoral thesis board («Genetic Manipulation *sensu lato* and Criminal Law: reflections on some dogmatic assumptions»); Director: Prof. S. Mir, University of

Barcelona; member of the committee for a post in the Department of Criminal Law, University of the Basque Country; member of the commission for assessing the Area of Criminal Law, CEU-Cardenal Herrera University, Valencia. He has acted as assessor for diverse international, state and autonomous government agencies. *Appointments:* member of the Advisory Board «International Multilanguage Archive on the Law of Genetics, Intellectual Property Rights and Life Sciences», University of Pavia (Italy) and of the editorial board of the journal «Revista Aranzadi Doctrinal».

Aitziber Emaldi Cirión published the article «Los perfiles de ADN y la Administración de Justicia. La protección de datos en la cooperación policial y judicial» («DNA Profiles and the Administration of Justice: Data Protection in Police and Legal Cooperation»), Pub. Thomson Aranzadi - the Spanish Data Protection Agency, Madrid. She has given the following lectures: «Research and Stem Cell Therapy: Where is it Going?» Health Meetings Conferences, Faculty of Medicine, UPV; «Clinical research and data protection» 6th Forum on Health Data Protection, Pamplona; «The protection of human rights in the application of biology and medicine», International Congress on the Law and New Technologies, Bilbao; «Handling biological samples and data protection», Congress 360 on Oncology, A new vision, Madrid; «Fundamental rights affected during the judicial process», International Congress on the Law and New technologies, Bilbao; «Genetic analysis in the field of reproduction: genetic counselling», Oviedo. She is a tutor for the dissertation for the Masters in International Law, «The advanced directives».

Leire Escajedo San Epifanio attended the 18th European Food Law Conference, on Food Labelling & Health Claims, organised by EU Food Law, in Brussels. She gave a paper at the Training Workshop on Research on Functional Foods, organised by the Basque Country Clinical Research Ethics Committee, at Txagorritxu Hospital (Vitoria). Title of the paper: «Research on functional foods: the legal and political approach».

Pilar Nicolás Jiménez has given the following lectures: «The legal implications of research

with biological samples», in the *3rd Workshop on Clinical and Experimental Immunosuppression in Transplants*, organised by the UAM-ROCHE Transplant Department; «International legal and ethical principles applicable to human genetic research», at the 16 Workshop on Law and the Human Genome; «The rights of patients and research subjects related to the use of their personal details», at the workshop *The Pharmaceutical Industry in relation to the Data Protection Law and its regulation*, organised by the ESAME Foundation (School of Medicine); «Informed consent in Spain», at the *Informed Consent Forum*, organised by the Portuguese Health Regulatory Body, Lisbon.

Iñigo de Miguel Berian attended the conference «Beyond Pattison» held in London, as part of the REMEDIE research project, where he gave a presentation on the regulatory situation in Italy, Portugal and Spain regarding regenerative medicine. He gave the following lectures: «The recent regulation of genetic analysis in Portugal. A comparative study with Spanish legislation», as part of the 16 Workshop on the Human Genome, and «Is dignity a useless concept?», in the 3rd DILEMATA Applied Ethics Workshop, Madrid. He published the monograph «Bioethics and new biotechnologies in human health», published by SIBI and the Principality of Asturias General Council, as well as the text «Globalisation and Immigration: *multiculturalism and human rights*», published by UNED-Tirant lo Blanch.

María Jorqui Azofra. She took part in the 6th Bioethics World Congress held in Gijón and organised by the International Bioethics Society, giving the paper «The particular features of informed consent in xenotransplantation», and «An ethical-legal reflection on the donation and private use of umbilical cord blood» at the Law and New Technologies International Congress, Bilbao. She participated as coordinator and chair at the 16 Workshop on Law and the Human Genome, held in Bilbao.

Emilio José Armaza Armaza took part in the third meeting of LATINBANKS project research members held in Buenos Aires.

Inter University Department of Law and the Human Genome

Members:

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Dr. Leire Escajedo San Epifanio (Postgraduate Studies Coordinator)
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