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CENTER FOR COMPARATIVE MEDICINE

Tools to support Research and development with experience and quality

UNL CONICET ICIVET LITORAL

FCV UNL • FACULTAD DE CIENCIAS VETERINARIAS

ABOUT THE CENTER FOR COMPARATIVE MEDICINE

1997-2020, over 20 years providing high complexity technological support for biomedical research

MISSION

To support institutions and companies that require laboratory animals of high genetic and sanitary quality and/or the performance of high complexity bioassays following international ethics and welfare standards.

VISION

To constitute a center of national reference for the performance of complex bioassays that allow generation of knowledge in order to improve health and welfare of humans and animals.

VALUES

- Ethic in the use and care of animals through the respect of ethics and welfare standards.
- Ethic and commitment to the job.
- Commitment to society and environment.
- Quality and professionalism in performance of all activities.
- Team work.

The general objective of the Center for Comparative Medicine (CMC), at the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral (Esperanza, Santa Fe, Argentina), is to do research with laboratory animals following international standards of ethics and quality regarding their use and care.

The CMC was established in August 1997 by teachers and researchers interested in the care and use of laboratory animals, primarily for research in veterinary science, medicine and biology. The CMC currently boasts with a total area of approximately 520 m2, including areas for production of different laboratory animals, biological testing, quality management and administrative offices. In addition, there are 300 m2 of high complexity laboratories associated with the Center. Since March 2013, the CMC has become part of the Instituto de Ciencias Veterinarias del Litoral (Institute of Veterinary Sciences of Litoral; ICiVet-Litoral), an Institute that belongs to the Scientific and Technical Research Council of Argentina (CONICET) and Universidad Nacional del Litoral. Since 2016 to date, the CMC is the first and only center integrated to an institution of the Scientific and Technological System in the country that combines the certifications and qualifications corresponding to SENASA, ANMAT, ISO 9001 and GLP-OECD. The CMC has been a member of the National Bioterial System (NBS) of the Ministry of Science, Technology and Productive Innovation since 2014.

In 2019, the CMC received the National Quality Award by the National Direction of Processes, Quality and Efficiency of Management from the Government Secretary of Modernization.

Activities at the CMC are focused on improving animal and human health, through the provision of laboratory animals and the development of experimental models and high complexity biological assays required for improving products and biomedical procedures.

The team includes Veterinarians, Biologists, Biochemists, and graduates in Biodiversity and Biotechnology, as well as technicians specialized in the care of laboratory animals. The team thus covers different areas of the biomedical sciences such as pathology, microbiology, parasitology, pharmacology, toxicology, cell culture, immunology, imaging, fine chemistry, biochemistry, ethics and molecular biology, among others.

Laboratory animals are for medical science researchers, what a drawing panel is for an architect, or a chemical reagent for a chemist. Moreover, laboratory animals of high quality are required for pharmacological and toxicological tests as well as for everything related to microbiology and physiology. More importantly, it is essential to respect national and international standards on Ethics in Experimentation and Animal Welfare while using them. The work carried out at the CMC complies with the principles of international guidelines for research involving laboratory animals.

QUALITY MANAGEMENT

All records of the quality management system are available for on-site audit.

The CMC has implemented a Quality Management System certified according to the IRAM-ISO 9001 standards and declared by the Argentine Accreditation Organization (OAA) to be in accordance with the requirements for Good Laboratory Practices (GLP) of the Organization for Economic Co-operation and Development (OECD) to conduct non-clinical studies. In particular, some areas of competence are toxicity and mutagenicity assays of pharmaceutical products, industrial chemical reagents and agrochemicals, and toxicokinetic and pharmacokinetic assays of pharmaceutical products.

The Quality Management System, which is the result of the quality policy defined by the Board of Directors of the CMC, includes the organizational structure, functions, activities, resources, staff training and necessary documentation to ensure that the services provided meet the expectations of customers in addition to legal and regulatory requirements related to the activity.

The functioning of the organization following a Quality Management System provides control and forecast when providing laboratory animals and carrying out services entrusted by third parties, thus lowering risks of disruptions during their performance and thus leading to an increase in the productivity of the organization and in the fidelity of our customers. In addition, the CMC has very strict and specific procedures to ensure the confidentiality of the relationship with customers.

The CMC also has a quality measurement and monitoring system that allows the continuous improvement of procedures to detect and thoroughly analyze possible problematic aspects and thus implement the necessary actions to correct the causes of problems, in order to prevent them from reappearing. The organizational process includes periodic internal audits to each of the areas that encompass the CMC. In addition, clients and certification authorities make permanent audits to different processes within the CMC, actions that have led to many improvements in these processes.

The Quality Management System of the CMC is reflected on the following documents:
Quality manual
Standard operative procedures (SOPs)
Instructional charts
Analytical techniques
Organization charts
Records

ACKNOWLEDGEMENTS, ACCREDITATIONS AND CERTIFICATIONS

ANMAT

In 2007, the CMC adopted compliance of «Good laboratory practices» (GLP), which has been verified by the National Institute of Medicines (INAME) of the National Administration of Drugs, Food and Medical Technology (ANMAT, Argentina), certifying compliance with ANMAT decree 6344/96, which refers to the «Regulation for Bioterium from laboratories that elaborate medicinal specialties and/or perform analysis for third parties».

IRAM - ISO 9001:2015

In 2014, the CMC has certified its Quality Management System according to the IRAM-ISO 9001 standard, under the registration number 9000-0006005, whose scope is «Production of rats, mice and rabbits of accepted strains, and design, performance and control of bioassays, commissioned by academic and scientific institutions and private companies».

NATIONAL SYSTEM FOR ANIMAL FACILITIES CENTERS

Since 2014, the CMC has been a member (ID 841) of the National System for Animal Facilities Centers (SNB) of the Ministry of Science, Technology and Productive Innovation.

NATIONAL QUALITY AWARD

In 2019, the CMC received the National Quality Award by the National Direction of Processes, Quality and Efficiency of Management, of the Government Secretary of Modernization.

SENASA

Since 2008, the CMC is part of the National Network of Assay and Diagnosis Laboratories, from the National Service of Animal Sanitation and Food Quality (N° LR0139, SENASA, Argentina), which authorizes the supply of laboratory animals and performance of bioassays, according to Resolution N° 736/06. In addition, the CMC has certified to be in compliance with Resolution N° 617/2002, which refers to «Requirements, conditions and procedures for the technical qualification of laboratories holding animal production, maintenance and experimentation facilities».

GOOD LABORATORY PRACTICES (GLP)

The CMC has been declared by the Argentine Accreditation Organization (OAA) to be in accordance with Good Laboratory Practices (GLP-OECD) for conducting preclinical studies. In particular, the areas of expertise include toxicity, mutagenicity, toxicokinetic, pharmacokinetic and preclinical safety assessments of biotech, pharmaceutical, chemical and agrochemical products. Conformity Record with GLP-018E.

ACKNOWLEDGEMENT BY THE SANTA FE PROVINCE SENATE CHAMBER

In 2019, the Senate Chamber of Santa Fe acknowledged the CMC for its contributions in health improvement through the development of experimental models and highly complex bioassays, which are required for the improvement of pharmaceutical products and biomedical procedures.

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Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

Premio Nacional a la Calidad

Cámara de Senadores de la Provincia de Santa Fe

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GESTION DE LA CALIDAD
RI-9000-0006005
Producción de ratas, ratones y conejos de laboratorio de cepas reconocidad y el diseño, ajecución y control de ensayos biológicos destinados a instituciones científicas, académicas y empresas.

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CERTIFIED MANAGEMENT SYSTEM

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BPL-OCDE
Cumplimiento de Buenas Prácticas de Laboratorio

Sistemas Nacionales Bioterios

OUR OBJECTIVE

The overall goal of the CMC is to provide an integrated approach to research with laboratory animals and alternative methods, following strict quality standards.

OVERALL AIMS

- To produce high quality laboratory animals in sufficient numbers. To design and execute biomedical assays, ensuring high quality, to meet the requirements of different costumers.
- To ensure respect for national and international standards on the care and use of animals for experimentation and other scientific purposes.

SPECIFIC AIMS

- To encourage the development of basic and applied research on the use of animal models.
- To contribute to the generation of knowledge in order to improve health and wellfare of humans and animals.
- To provide excellence technological support services.
- To constitute a regional reference center and spread knowledge that highlights the importance of the use of experimental models in the study of biomedical sciences.
- To contribute to the integral formation of professionals in Veterinary Sciences.
- To provide infrastructure and support for research and training of human resources within the scope of the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral and researchers from other public and private institutions that require it.

ETHICS AND WELFARE

The use of animals in research, teaching, and biological testing, is only acceptable if it effectively contributes to a better understanding of biological principles and if it can not be replaced with alternative methods.

Animal experimentation is one of the fundamental pieces in biomedicine, regarding research projects, diagnostic tests and controls for pharmacological products. On its 11th Inter-American Meeting of 1980, the Pan American Health Organization (PAHO) expressed that: «countries which have achieved a breakthrough in the control of human and animal diseases are those that have established entities dedicated to a better development of the Science of Laboratory Animals».

The use of animals in research, teaching, and biological testing, is only acceptable if it effectively contributes to a better understanding ofbiological principles and if it can not be replaced with alternative methods.

Animals should be used only when the researcher has already unsuccessfully sought for an acceptable alternative. The continuous exchange of knowledge, literature review, and adherence to the principles of «Three Rs» of Russell-Burch (Replacement, Reduction, and Refinement) are other necessary conditions. Researchers who use animals should use the most humanitarian methods available, make that the number used is the smallest possible, and use the appropriate species for valid results.

The work carried out at the CMC comply with the principles of international guidelines for use and care of laboratory animals, as well as ethical guidelines for bioassays.

In addition, the FCV has an Advisory Committee of Ethics and Safety (CAES), which was created to ensure that the activities that involve the use of animals, carried out at the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral, are conducted humanely and following international standards of ethics and biosafety. All protocols and standard operating procedures held at the CMC are assessed and approved by this Committee.

FACILITIES OF THE CMC

There is an area of productive biological trials with cages and facilities for the management of large animals during clinical assays.

The CMC has 520 m2 of covered space, integrating those areas destined to the production of different animal species, biological testing, quality management and several outbuildings for administration, maintenance and storage rooms. All the rooms, including those for both production and biological testing, have automated controls of temperature, illumination and air renewal with high efficiency filtering systems.

The production area has four rooms for breeding and stock, as well as changing rooms, laundries, preparation of materials and an independent storage room.

The area of biological testing has rooms for the maintenance of different species, boxes for the housing of large animals, a separate room for isolation and quarantine, and laboratories for general procedures and initial processing of samples.

There is also an administrative area, with a meeting room with a video conference system, an archive room with a system of fire protection, and research and development offices.

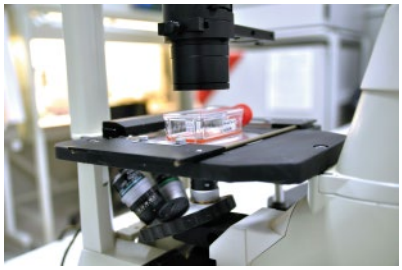
The facilities have a security system that allows the permanent remote monitoring of all the areas of the CMC by using high resolution cameras, as well as the equipment and environments control through specific sensors placed on each of them that ensure immediate response in case of any kind of emergency.

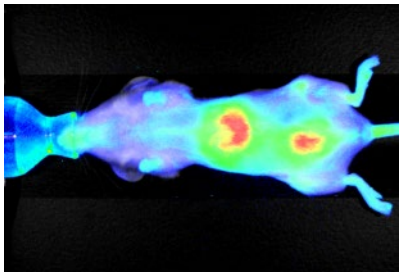
The building is integrated into the Faculty of Veterinary Sciences of the Universidad Nacional del Litoral and the ICIVET-Litoral (UNL-CONICET), in direct relation to its highly complex laboratories. This allows a comprehensive approach to complex experimental protocols.

These fully installed laboratories include:
Area of *in vitro* assay
Laboratory of applied cellular and molecular biology
Laboratory of clinical trials
Laboratory of pharmacology and toxicology
Laboratory of food analysis
Laboratory of image analysis
Laboratory of microbiology
Laboratory of parasitology
Laboratory of histology and pathological anatomy
Radiology and diagnostic imaging facilities
Operating room of high complexity

EQUIPMENT

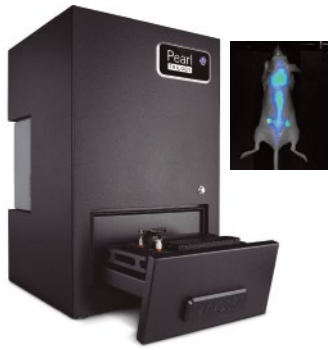
GENERAL





Air conditioning system with high efficiency filtering.
Individually ventilated cages (IVC systems).
Animal transfer stations with protection class II.
Biological safety hoods.
Emergency power system.
Autoclave sterilizer.
Automatic monitoring of environmental conditions system.
Digital portable ultrasound scanner, model Chison 8300 vet.
Emptying system of beds with high security.
Ultrafreezers.
High performance computer servers.
Integral system for building safety.
Automatic infusion pumps and anesthesia monitoring system.

ANALYTICAL EQUIPMENT



Cellular and molecular biology equipment (real time thermocyclers, digital microscopes, etc.) for diagnosis and health monitoring.
Near infrared (NIR) spectrophotometer, Shimadzu Prestige.
Clinical chemistry autoanalyzer, Metrolab 2300 plus.
Hematology autoanalyzer, Mindray BC-2800Vet.
Cellular and tissue culture laboratory fully equipped for in vitro assays.
Acoustic Focusing Flow Cytometer, Attune NxT.
Full UV/visible spectrum microplate readers, SPECTROStar Nano and CLARIOStar BMG LABTECH.

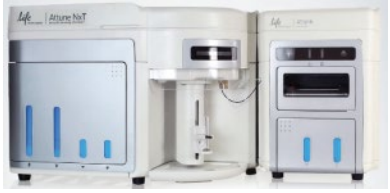
R FLUORESCENCE AND BIOLUMINESCENCE IMAGING SYSTEM PEARL TRILOGY

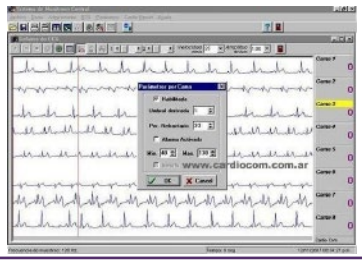
An image capturing system for small animals allows the precise detection of small and deep targets.

Its direct applications include: receptor marking, biodistribution assays, vascular and lymphatic network visualization, structural imaging and bioluminescence.

MASS SPECTROMETRY

A LC-MS/MS system, consisting of a Shimadzu UFLC XR liquid chromatograph and a triple quadrupole mass spectrometer with linear ion trap AB Sciex Q-Trap 3200, allows the identification and quantification of molecules within different matrices with very high specificity and sensitivity.





FLOW CYTOMETRY

An acoustic focusing flow cytometer ATTUNE NXT allows detecting the presence of molecules and materials of interest by immunofluorescence techniques, fluorescent sensors or fusion to fluorescent proteins, both in fixed particles and in living cells, which makes it possible to address, among others, the study of cellular dynamic processes and identifying cell populations in specific models.

HISTOPATHOLOGICAL STUDIES

A histopathology laboratory, which integrates veterinary pathologists with extensive training in the area, along with the advanced technology that includes microtomes and automatic microscopes equipped with digital imaging systems and a panel of more than 300 antibodies, enables the efficient resolution of findings through immunohistochemical techniques.

COLOR DOPPLER ULTRASOUND SCANNER

A doppler ultrasound scanner Mindray Z6Vet, with high frequency linear and microconvex transducers, allows obtaining high resolution images that facilitate correct data collection in different studies. It is useful in the exploration of organs and structures in lab animals, including abdominal, small parts, cardiovascular and ophtalmological studies. In addition, since it has a doppler ultrasound system, it allows to evaluate the speed, direction and spectral frequency, as well as the indices of resistance and pulsatility, of the blood flow. These benefits are essential during the assessment of tumor development and response to treatments in *in vivo* models applied to oncology, among many other benefits.

HEMATOLOGY AUTOANALYZER

An automatic analyzer Mindray BC-2800 Vet allows to perform all the analytical stages of hematology following GLP and being monitored by the Quality Management Area of the CMC. This equipment has validated routines for different species and allows the automatic and small volume analysis of 19 hematological biomarkers in different toxicology and safety tests.

DIGITAL ELECTROCARDIOGRAPH

A Cardiocom Digital CC12Der device allows to respond to international standards that require the evaluation of cardiotoxicity in preclinical trials of new medicines intended for use in humans. It works with seven simultaneous leads, manual and automatic scanning, and a specific software for laboratory animals that automates the analysis of the different segments of the electrocardiogram.

ANIMALS

The CMC has its own production of genetically certified mice, rats and rabbits and has registered its own international laboratory code (Cmedc) at the Institute for Laboratory Animal Research (The National Academies of Sciences, Engineering, and Medicine, USA). In addition, it has areas available for the maintenance of other species often used in biological trials such as poultry, pigs and cattle, and it is considered to add a specific area to develop models of immunosuppressed animals

1. RATS

Wistar/Cmedc strain: Strain of own production, currently stabilized with inbreeding superior to F30.

2. MICE

BALB/c Cmedc strain: Strain derived from animals of the Jackson Laboratory (USA), currently with inbreeding superior to F20.

C57BL/6: Strain a strain derived from animals of the Jackson Laboratory (USA).

3. RABBITS

New Zealand Breed: Animals produced in our Center, coming from colonies acquired in the best ranches of the country, with genetic certification granted by the Sociedad Rural Argentina.

CMC

ONLY CENTER INTEGRATED TO AN INSTITUTION OF THE SCIENTIFIC - TECHNOLOGICAL SYSTEM IN THE COUNTRY THAT CONJUGATES THE CERTIFICATIONS AND APPROVALS CORRESPONDING TO SENASA, ANMAT, ISO 9001 AND GOOD LABORATORY PRACTICES (GLP-OECD).

NATIONAL QUALITY AWARD 2019.

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Premio Nacional a la Calidad

SERVICES AND OFFERS

High complexity biological trials following strict quality management systems

The main services provided include production and sale of animals, and the performance of tests with different complexity, including among others: the production of hyperimmune sera, specific protocols and research projects, complex multidisciplinary trials, surgeries, immunogenicity studies, *in vitro* tests, comprehensive preclinical evaluation of biopharmaceuticals, counseling on regulatory aspects.

The CMC also seeks to provide users with a place to carry out all the work within the facilities, assigning specific rooms to each test and thus avoiding the need to move the animals to areas that do not meet the corresponding standards or their manipulation by unqualified staff.

In recent years, the CMC has provided services to more than 40 research and development groups related to National Universities and Institutes from CONICET, and to more than 30 companies from the pharmaceutical and health sectors. These users come from different parts of the country and abroad, and have the necessary logistics for the transport of animals and samples.

Provision of animals for the development of research and teaching activities.
Advicing for the installation of Animal Facilities Centers and Test Areas.
Design and execution of biological trials according to national and international standards (SENASA, ANMAT, OPPT, OECD, FDA, EMA, EPA, ICH, Pharmacopoeias, etc.).
Planning and development of preclinical trials of high complexity according to national and international standards (ANMAT, FDA, EMA, ICH, ANVISA).
Planning and development of field clinical trials in farm animals, according to national and international standards (SENASA, VICH).
Biological evaluation of medical devices according to the ISO 10993 standard.
Development of specific experimental models of high complexity.
Quality control and biological activity control of drugs according to pharmacopoeias.

Safety tests.
Pyrogen test.
Acute, subacute and chronic toxicity tests.
Biocompatibility studies.
Tolerance and sensitization tests.
Studies of carcinogenesis, reproductive toxicology and teratogenicity.
Pharmacokinetic and toxicokinetic studies.
In vitro assays.
Preparation of polyclonal sera.
Molecular biology techniques.
Biochemical studies.
Pharmacological studies.
Toxicological studies.
Histopathological studies.
Immunologic studies.
Experimental surgeries.
Regulatory studies
Development of analytical methods
Residues and time of withdrawal studies for veterinary drugs

The CMC has a Quality Management System certified by ISO 9001 for the provision of animals, and the tests are performed in accordance with Good Laboratory Practices (GLP-OECD). This system includes the organizational structure, functions, activities, resources and documentation necessary to ensure that the services provided meet customers' expectations in addition to regulatory and legal requirements related to the activity. All records are available for on-site auditing.

MONITORING AND QUALITY CONTROL

Periodically, the microbiological monitoring of: supplies (bed, food andwater), animals from the production and stock colonies, is performed in order to evaluate different health aspects. It is also performed the chemical monitoring of bed, food and water to test for agrochemicals. In addition, microbiological and genetic monitoring is carried out in external laboratories of worldwide reference, in order to evaluate the presence of frequent pathogens in laboratory animals and the genetic quality of our animals. The controls performed include the specific pathogens and parasites listed in the corresponding reports that are recognized for causing disease or compromising health status. Opportunistic agents are also detected, however, some of them are tolerated on the basis of international guidelines. The production data of all species are under a system of good practices, with archived records that allow the traceability of all the animals used or sold.

RESEARCH AND TRANSFER

Research and transfer projects are carried out within the CMC, and they have allowed for the constant growth of the Center's operational capacities and the generation of knowledge in the field of comparative medicine. Several of these projects have been carried out in collaboration with companies from the pharmaceutical sector of the country and abroad.

Among the projects that have been implemented until 2019 or that are currently being developed, the following stand out:

Project «Centro de Experimentaciones Biológicas y Bioterio (FCV-UNL): Adecuación a Normas Nacionales», financed in the framework of the Application for Registration Change of Scale, Course of Action for Technology Transfer 2006. Universidad Nacional del Litoral.

Project «Adopción de Buenas Prácticas de Laboratorio (BPL) en el Centro de Experimentaciones Biológicas y Bioterio (FCV-UNL): herramientas imprescindibles para el aseguramiento de la calidad», financed in the framework of the Application for Registration Change of Scale, Course of Action for Technology Transfer 2007. Universidad Nacional del Litoral.

Project «Validación de métodos alternativos en el Centro de Experimentaciones Biológicas y Bioterio (FCV-UNL): nuevas herramientas para la investigación aplicada al desarrollo», financed in the framework of the Application for Registration Change of Scale, Course of Action for Technology Transfer 2008. (Res CS 292/08). Universidad Nacional del Litoral.

Project «Certificación de Buenas Prácticas de Laboratorio (BPL) en el Centro de Experimentaciones Biológicas y Bioterio (FCV-UNL): herramientas imprescindibles para el aseguramiento de la calidad», financed in the framework of the Application for Registration Change of Scale, Course of Action for Technology Transfer 2009. Universidad Nacional del Litoral.

Project «Aplicación de los principios de Buenas Prácticas de Laboratorio (BPL) a los sistemas informáticos del Centro de Experimentaciones Biológicas y Bioterio (FCV-UNL)», financed in the framework of the Application for Registration Change of Scale, Course of Action for Technology Transfer 2009. Universidad Nacional del Litoral.

Project «Desarrollo de una plataforma analítica para estudios preclínicos bajo los lineamientos de las Buenas Prácticas de Laboratorio», financed in the ramework of the Application for Registration Change of Scale, Course of Actionfor Technology Transfer 2010. Universidad Nacional del Litoral.

Project «Plataforma tecnológica para el desarrollo y producción de nanotransportadores inteligentes para fármacos», financed by the Agency for Scientific and Technological Promotion, within the framework of the Application for Nanotechnology FS 2011, through the Argentine Sectoral Fund (FONARSEC).

Project «Generación de una plataforma tecnológica bajo Buenas Prácticas de Manufactura (BPM), para la industria farmacéutica dentro del Centro de Experimentaciones Biológicas y Bioterio», financed in the framework of the Application for Registration Change of Scale, Course of Action for Technology Transfer 2010. Universidad Nacional del Litoral.

Project «Desarrollo de métodos alternativos para la evaluación de nuevos materiales de uso biomédico en Medicina Humana y Veterinaria», financed in the framework of the application for Strengthening of the innovation capacities of the productive system of Santa Fe province 2010. State Secretary of Science, Technology and Innovation (SECTeI), Santa Fe.

Project «Desarrollo de una plataforma de producción de proteínas recombinantes de interés veterinario y sus aplicaciones», financed in the framework of Application for Registration Change of Scale, Course of Action for Technology Transfer 2012. Universidad Nacional del Litoral.

Project «Programa de Acreditación de Laboratorios en Ciencia y Tecnología», financed by the Agency for Scientific and Technological Promotion Res MINCyT 428/12.

Project «Centro de Medicina Comparada: Consolidación de una plataforma tecnológica de alta complejidad para el análisis de fármacos y productos biotecnológicos», financed by the Agency for Scientific and Technological Promotion, in the framework of the application FIN-SET 2015 by the Argentine Technological Fund (FONTAR).

Project «Desarrollo y validación de tecnologías analíticas de micrométodos bajo normas BPL para el estudio de biomarcadores en ensayos preclínicos de alta complejidad», financed in the framework of the application Orientated Research 2016. Ministry of Science, Technology and Productive Innovation. Santa Fe.

Project «Mantenimiento de las certificaciones de Calidad del Centro de Medicina Comparada ICiVet-UNL», financed in the framework of the application Pilot Scheme to Support Projects for the Development of Products and Processes in a Technological Basis. Course of Action for Technology Transfer 2018. Universidad Nacional del Litoral.

Project «Consolidación del Centro de Medicina Comparada del ICiVet-Litoral (UNL/CONICET): Mejora ante eventos críticos». Projects for the strengthening of the National Bioterium Program. Ministry of Science, Technology and Productive Innovation. 2018. Financing Fund for Activities of Promotion, Encouraging and Technological Management (CONICET).

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CENTRO DE MEDICINA COMPARADA

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CONICET