GrupoSur

CLINICAL RESEARCH

Department of Clinical Research of the Insituto Medico Platense 51 Ave. N° 315 La Plata
info.gruposurinvestigacion@gmail.com | Phone number221 3144563

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Who **we are**

Grupo Sur is an organization dedicated to generating knowledge to improve people's quality of life through clinical trials focused on the development of new methods for prevention, diagnosis and treatment. It is supported by a team of committed and qualified professionals, and continuous education is its fundamental tool. It develops its activities at the **Instituto Medico Platense.**

Our **History**

Our team has been developing local, national and international Clinical Research protocols for over 25 years. Over the years we have conducted both intervention and observational studies of great contribution to scientific advances. Throughout our career we have positioned ourselves as the largest recruiters in Argentina and Latin America in different studies. The quality of our work has been validated by external quality audits by sponsors and inspections by the Argentine regulatory agency, the National Administration of Drugs, Foods and Medical Devices (ANMAT by its Spanish acronym). We also have ongoing monitoring, evaluation and oversight by the Clinical Research Ethics Committee (CEDIMP by its Spanish acronym), accredited by the Central Ethics Committee (CEC) of the Province of Buenos Aires, Argentina.
Since 2022, together with the College of Physicians, District I, La Plata, we've started a training program in Clinical Research for medical professionals.

Clinical trial: It is a scientific investigation aimed at better understanding the functioning of a medication, vaccine or diagnostic technique to determine if it is effective and safe for humans.

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Our **Team**

Grupo Sur is composed of an interdisciplinary team with extensive experience in conducting clinical research protocols, which receives ongoing training and updates.

María Fernanda Alzogaray

Physician. Clinical Medicine Specialist.

Medical Director

Principal Investigator

Analía Mykietiuk

Doctor of Medical Science. Infectious Disease Specialist

Scientific Director

Principal Investigator

Agustín Romandetta

Physician. Doctor of Medical Science (in progress).

Head of Research

Sub-Investigator

Esteban C. Nannini

Physician Specialised in Infectious Disease.
Fellowship en HIV/AIDS at the Univ. of Texas, Houston.

Director of the Academic and Scientific Department

María Victoria Vulcano

Physician. Pediatrics and Neonatology Specialist

Medical Coordinator

Sub-Investigator

Bettina Cooke

Physician. Infectious Disease Specialist.

Infectious Disease Department

Sub Investigator

Sebastián Scala

Physician. Infectious Disease Specialist.

Infectious Disease Department

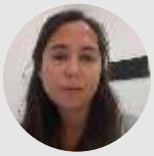
Sub Investigator

María Daniela Tonin

Physician. Infectious Disease Specialist.

Infectious Disease Department

Sub Investigator



María Belén Alcorta

Physician. Clinical Medicine Specialist.

Clinical Medicine Department

Sub Investigator

Alberto Rubén Cremona

Physician. Specialist in Infectious Disease, Clinical Medicine, Intensive Care and Infectious Diseases

Medical Staff

Fabiana Marmissolle

Physician. Consultant Oncology Specialist.

Oncology Department

Principal Investigator

Amparo Ivone Ritou

Physician. Pneumonology Specialist.

Pneumonology Department

Principal Investigator

Viviana Mastri

Physician. Pediatric Medicine and Pediatric Rheumatology Specialist.

Pediatrics Department

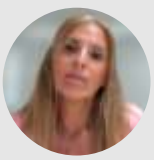
Principal Investigator

María Elena Bruzzone

Physician. Internal Medicine and Nephrology Specialist.

Nephrology Department

Sub-Investigator



María Marta Greco

Physician. Consultant Infectious Disease Specialist.

HIV and STD Department

Sub-Investigator

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Work Areas

To carry out the aforementioned tasks, Grupo Sur has a stable team of 35 people who work in interrelated areas to respond to the demands required at each stage of the clinical trials.

- **Regulatory and start-up area**
  It maintains the flow of information with the Ethics Committee, the provincial and national Regulatory Entities, and the sponsor, responding to their requirements and observations. It also ensures that the necessary supplies for the development of the protocol are available in sufficient quantity and viability for use.

- **Recruitment area**
  Its objective is to identify and invite individuals who could potentially enroll as volunteers in any of the protocols being conducted. We have 6 members and work with specialized Community Management companies that use tools such as special databases, social media, websites, WhatsApp and Google to carry out the aforementioned task. It is important to note that all materials used for dissemination and recruitment are approved in advance by the Ethics Committee to ensure they are clear and respect privacy.

ÁVolunteer monitoring and medical care area

Its task is to identify and monitor any medical events that occur to each volunteer (whether related to the clinical trial or not). This highly relevant information will determine whether a product under research is considered safe and, if it's proved to be effective, whether it can be marketed. To meet the objectives, this team, consisting of 4 physiciansand 4 advanced medical students, operates a 24-hour hotline managed by a medical professional, available every day of the year to receive calls and provide relevant instructions. If necessary, the volunteer is summoned to the center for a medical evaluation conducted by a member of the research team. Additionally, this area includes web platforms and mobile apps for the volunteer to use, allowing the participant to reach out to the research team for any medical inquiries or other types of questions.

Data entry area

The data entry team consists of 4 advanced medical students in the role of Data Entry, who input the participant's clinical history into web platforms known as 'Case Report Forms' (CRFs). The purpose of these forms is to standardise the data collection and processing methods across all centers worldwide conducting the clinical trial.

Additionally, in its daily activities, this area uses Microsoft Office and Google Workspace, and if there's a need to conduct statistical tests for academic studies they are carried out using the IBM Statistical Package for the Social Sciences (commonly known as SPSS).

Laboratory area

Led by 2 extraction professionals and advanced students in Biochemistry, this area conducts the collection and processing of the required samples according to each protocol (blood, urine, swabs, etc.).

Typically, these samples are not analyzed on-site; they are sent to 'central' laboratories, in accordance with international standards, to unify the analysis of samples collected from all research centers involved in the clinical trial.

To fulfill these functions, this area requires state-of-the-art equipment, including conventional and refrigerated centrifuges, refrigerators, freezers at -20° C and -70° C, and computer systems designed to track shipments.

Pharmacy area

The sponsor (pharmaceutical laboratory conducting the study and holding the patent for the molecule) provides the research product (medication/vaccine/test), and the center is responsible for storage, preparation (if required), and administration, ensuring the traceability at each stage and the maintenance of the appropriate room or refrigeratedtemperature. To this end, Grupo Sur employs 3 professionals qualified for the management of pharmaceutical products in clinical trials and has a restricted-access area equipped with a cabinet that's exclusive for medications that need room temperature storage and a refrigerator for those requiring temperatures between 2ºC and 8ºC. Both compartments feature digital thermometers that record temperature continuously, and this data can be transferred via USB to a computer. In turn, in the event of temperature excursions, these devices send an email alert to notify of the situation, allowing for timely actions to be taken to maintain the viability of the research drugs. All our equipment is connected to a generator set to ensure the viability of the research product.

Administration and management area

Our team comprises three Economics professionals dedicated to managing the company's accounting and finances. We also have the support of an external accounting service.

Education and training area

We consider the training of our professionals and the medical community at large to be a fundamental tool, which is why we offer two training modalities:

Clinical Research Training Course: annual course endorsed by the College of Physicians of the Province of Buenos Aires, with theoretical content and a blended virtual/in-person format.

Clinical Research Fellowship: intended for physicians seeking to train in this discipline, with practical-theoretical content and an annual duration.

Additionally, we serve as the venue for the Master's program in Clinical Research at UNLP (Universidad Nacional de La Plata), hosting students for their practical training. In terms of scientific publications, we have a medical coordinator with experience in writing articles for renowned medical journals, who guides and promotes the publication of Grupo Sur's lines of research, focusing on local epidemiological issues. These lines of research have led to several publications that helped in health decision-making at a national level, and this should also be considered a valuable contribution.

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Conducted **Studies** (last 10 years)

Study	Description
Merck MK-3415 A	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Adaptive Design Study of the Efficacy, Safety, and Tolerability of a Single Infusion of MK-3415 (Human Monoclonal Antibody to Clostridium difficile toxin A), MK-6072 (Human Monoclonal Antibody to Clostridium difficile toxin B), and MK-3415A (Human Monoclonal Antibodies to Clostridium difficile toxin A and toxin B) in Patients Receiving Antibiotic Therapy for Clostridium difficile Infection / 2013
IRC 003	A Randomized Double-Blind Phase 2 Study Comparing the Eficacy, Safety, and Tolerability of Combination Antivirals (Amantadine, Ribavirin, Oseltamivir) versus Oseltamivir for the Treatment of Influenza in Adults at Risk for Complications / 2014
Nv20234	A double-blind, randomized, stratified, multi-center trial evaluating conventional and double dose oseltamivir in the treatment of immunocompromised patients with influenza / 2014
CE01-301	A Randomized, Double-Blind, Multi-Center Study to Evaluate the Efficacy and Safety of Intravenous to Oral Solithromycin (CEM-101) Compared to Intravenous to Oral Moxifloxacin in the Treatment of Adult Patients with Community-Acquired Bacterial Pneumonia / 2014
AC 061 A 302	A multi-center, randomized, double-blind study to compare the efficacy and safety of cadazolid versus vancomycin in subjects with Clostridium difficile-associated diarrhea (CDAD) / 2014
FLU002 Plus New	An International Observational Study to Characterize Adults With Influenza or Other Targeted Respiratory Viruses / 2014-2015
FLU003	An International Observational Study to Characterize Adults Who Are Hospitalized With Influenza or Other Targeted Respiratory Viruses 2014-2015
T705Aus317	A Phase 3, Randomized, Double Blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Favipiravir in Adult Subjects with Uncomplicated Influenza
Revive-2	A Phase 3, Randomized, Double-Blind, Multicenter Study To Evaluate the Safety and Efficacy of Intravenous Iclaprim versus Vancomycin for Treatment of Acute Bacterial Skin and Skin Structure Infections Suspected or Confirmed To Be Due to Gram-Positive Pathogens (REVIVE-2 Study)
NAB-BC-3781-3101	A Phase 3, Randomized, Double-Blind, Double-Dummy Study to Compare the Efficacy and Safety of Lefamulin (BC 3781) Versus Moxifloxacin (With or Without Adjunctive Linezolid) in Adults With Community-Acquired Bacterial Pneumonia/ 2016
MK-7655A-014	A Phase III, Randomized, Double-Blind, Active Comparator-Controlled Clinical Trial to Study the Safety, Tolerability, and Efficacy of Imipenem/Cilastatin/Relebactam (MK-7655A) Versus Piperacillin/Tazobactam in Subjects With Hospital-Acquired Bacterial Pneumonia or Ventilator-Associated Bacterial Pneumonia / 2016-2019

Study	Description
FLU-IVIG	Anti-Influenza Hyperimmune Intravenous Immunoglobulin Clinical Outcome Study (INSIGHT 006: FLU-IVIG) / 2017-2018
NAB-BC-3781-3102	A Phase 3, Randomized, Double-Blind, Double-Dummy Study to Compare the Efficacy and Safety of Lefamulin (BC 3781) Versus Moxifloxacin (With or Without Adjunctive Linezolid) in Adults With Community-Acquired Bacterial Pneumonia / 2017
NOPRODRSV0006	Study of adults hospitalized with ARI during the influenza/RSV 2017-1019
64041575RSV2003	A Phase 2b, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Antiviral Activity, Clinical Outcomes, Safety, Tolerability, and Pharmacokinetics of Orally Administered ALS-008176 Regimens in Adult Subjects Hospitalized with Respiratory Syncytial Virus
Theravance 0112	A Phase 3 Multicenter, Randomized, Open-label, Clinical Trial of Telavancin Versus Standard Intravenous Therapy in the Treatment of Subjects with Staphylococcus aureus Bacteremia Including infective endocarditis / 2017
ML-3341-306	A phase 3, multicenter, randomized, double-blind, comparator-controlled study to evaluate the safety and efficacy of intravenous to oral Delafloxacin in adult subjects with community-acquired Bacterial Pneumonia / 2017 - 2018
63623872FLZ3001	A Study to Evaluate the Efficacy and Safety of Pimodivir in Combination With the Standard-of-Care Treatment in Adolescent, Adult, and Elderly Hospitalized Participants With Influenza A Infection / 2018 -2020
63623872FLZ3002	A Phase 3 Randomized, Double-blind, Placebo-controlled, Multi-center Study to Evaluate the Efficacy and Safety of Pimodivir in Combination With the Standard-of-care Treatment in Adolescent, Adult, and Elderly Non-hospitalized Subjects With Influenza A Infection who Are at Risk of Developing Complications / 2018-2020
Ri-CoDIFy 1 S MT19969/C004	A Phase 3, randomized, double-blind, active controlled study to compare the efficacy and safety of ridinilazole (200 mg, bid) for 10 days with vancomycin (125 mg, qid) for 10 days in the treatment of Clostridium difficile infection (CDI) / 2020
ENSEMBLE VAC31518COV3001	A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older / 2020 -2024
CT-INM005-01	Phase 2/3, adaptive, randomized, controlled, double-blind study to study the pharmacokinetics, efficacy and safety of hyperimmune equine serum (INM005) in adult patients with confirmed moderate-severe SARS-CoV2 disease. 2020
CS-CTP-AD5NCOV-III	A global multicenter, randomized, double-blind, placebo -controlled, adaptive designed phase III clinical trial to evaluate the efficacy, safety and immunogenicity of Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) in adults 18 years old and above / 2020-2022
(ACTIV-1 IM	Immune Modulators for Treating COVID-19 /2021-2022
C3671013	A phase 3 study to evaluate the efficacy, immunogenicity, and Safety of respiratory syncytial virus (RSV) prefusion f subunit Vaccine in adults / 2022-2024
ARVAC - F2/3 – 002	Phase 2/3 study to evaluate the safety, tolerability and immunogenicity of a recombinant protein vaccine against SARS-CoV-2 (ARVAC Cecilia Grierson), in a population of adult volunteers previously vaccinated against the SARS-CoV-2 virus
TILIA_D9185C00001	A Phase III, Multicentre, Randomised, Double-blind, Parallel-group, Placebo-controlled Study to Evaluate the Efficacy and Safety of Tozorakimab (MEDI3506) in Patients Hospitalised for Viral Lung Infection Requiring Supplemental Oxygen (TILIA). 2022 - ongoing

Study	Description
EDP 938-104	A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of EDP-938 in Non hospitalized Adults with Acute Respiratory Syncytial Virus Infection who are at High Risk for Complications
DEBIO: 1450-BJI-205	Randomized Open-label Active-controlled Study to Assess the Safety, Tolerability and Efficacy of Afabicin IV/oral in the Treatment of Patients with Bone or Joint Infection due to Staphylococcus
DOMPE REP0321	Reparixin 1200 mg three times a day as add-on therapy to standard of care to limit disease progression in hospitalised adult patients with COVID-19 and other community-acquired pneumonia. A multinational, multicentre, randomised, double-blinded, placebo-controlled,parallel-group phase III trial. (REPAVID-22). 2023 – continúa
MICU MRXC-302	A Phase 3, Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of Contezolid Acefosamil and Contezolid Compared to Linezolid Administered Intravenously and Orally to Adults with Moderate or Severe Diabetic Foot Infections. 2023- Ongoing.
Bordetella	Frequency of Bordetella Pertussis infection in older adults who present cough in different cities of Argentina / 2022 - 2024
eVOLVE-Lung02	A Phase III, Two-Arm, Parallel, Randomized, Multi-Center, Open-Label, Global Study to Determine the Efficacy of Volrustomig (MEDI5752) Plus Chemotherapy Versus Pembrolizumab Plus Chemothe rapy for First-Line Treatment of Patients with Metastatic Non-Small Cell Lung Cancer (mNSCLC) (eVOLVE-Lung02) / 2024 - ongoing.
BaxDuo ARTIC D6972C00003	A Phase III, Randomised, Double -Blind, Active-controlled Study to Assess the Efficacy, Safety and Tolerability of Baxdrostat in Combination with Dapagliflozin Compared with Dapagliflozin Alone on Chronic Kidney Disease (CKD) Progression in Participants with CKD and High Blood Pressure/ 2024 - ongoing
INSIGHT 018/STRIVE	A multicenter, adaptive, randomized, controlled trial platform to evaluate safety and efficacy of strategies and treatments for hospitalized patients with respiratory infections. / 2024 - ongoing
AJAX D8210C00003	Phase 2a Study to Assess the Efficacy and Safety of AZD4604 in Adult Patients with Moderate-to-Severe Asthma Uncontrolled on Medium-High Dose ICS-LABA - AJAX Phase 2a Study to Assess the Efficacy and Safety of AZD4604 in Adult Patients with Moderate-to-Severe Asthma Uncontrolled on Medium-High Dose ICS-LABA - AJAX / 2024 - ongoing
INSIGHT 012 /OTAC	An International Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of Anti-Coronavirus Hyperimmune Intravenous Immunoglobulin for the Treatment of Adult Outpatients in Early Stages of COVID-19 / 2024 - ongoing
SPERO/SPR994-305:	A Phase 3, randomized, double-blind, double-dummy, multicenter, multinational study to assess the efficacy and safety of orally administered tebipenem pivoxil hydrobromide (TBP-PI-HBr) compared to intravenously administered imipenem- cilastatin in patients with complicated urinary tract infection (cUTI) or acute pyelonephritis (AP) / 2024 - ongoing