



portFOLIO of SERVICES

[Basic and Preclinical Development]

[Clinical Trials]

[Clinical - Scale Manufacturing and Development]

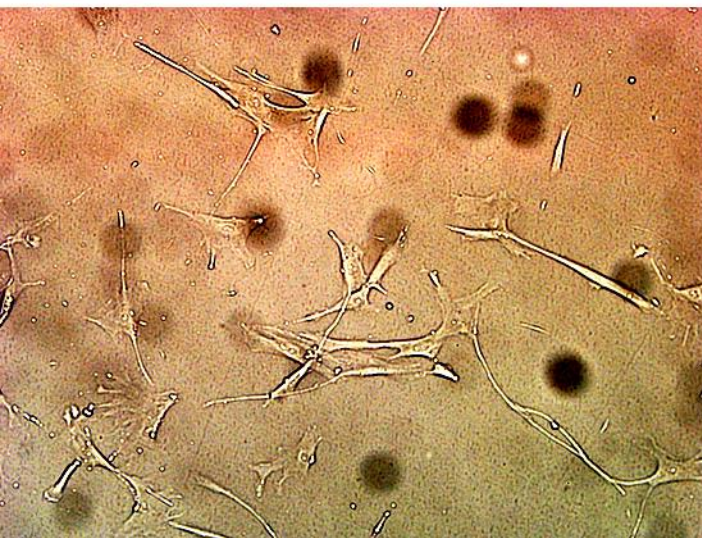
[Consultancy and Training]



Junta de Andalucía

Consejería de Salud y Familias

Fundación Progreso y Salud



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WHO WE ARE

The Andalusian Network for the design and Translation of Advanced Therapies (Progress and Health Foundation) was created under the terms of the Resolution of 9th April 2019 of the General Secretariat of Research, Development and Innovation of the Andalusian Ministry of Health and Families with a view to fostering the design and translation of advanced therapies in the Andalusian Region. The strategic commitment related to the development of this network for Advanced Therapies in Andalusia, was based on the certainty that this century's Medicine will be marked by the advance in research focusing on three main areas entailing new approaches in the prevention, diagnosis and treatment of many diseases in humans. The advances referred to are specifically those taking place in the field of **Cell Therapy and Regenerative Medicine, Clinical Genetics and Genomic Medicine and Nanomedicine**.

➤ **We are part of the Andalusian Public Healthcare System** which offers complete health services to about 8.5 million people and comprises, among other infrastructures, 47 hospitals, around 1,500 primary care centres, several research centres and institutes, a network of 10 GMP facilities to manufacture gene and cell-based therapies, a genomic and bioinformatics platform and a Biobank storing more than 750,000 samples from patients and normal controls- including hiPS and hES cells lines.

➤ **As we also form part of the strategy of the Regional Ministry of Economy, Innovation, Science and Employment**, we work closely with some of its entities such as the Agency for Innovation and Development of Andalusia (IDEA), the Andalusian Public Foundation EMPRENDE and the Andalusian Agency of Knowledge. We also collaborate with the Andalusian Corporation for Technology.

Being part of such a multidisciplinary system **allows us to interface between academia (hospitals, universities and other research institutions) and industry (biotechnological and pharmaceutical companies)** to facilitate translational research and knowledge and technology transfer together with the Andalusian Public Healthcare System's Transfer of Technology Office.

WHAT WE SEEK

We promote advanced therapy research because we are convinced of its potential in the ongoing search for new therapies for diseases where there is still no effective treatment or where improvements can be made in the quality of life of patients suffering from these diseases.

In this regard, **we try to collaborate with all institutions involved in this field.** Our hallmark is the search for synergies among the academic world, research institutions, health centres, patients' associations, biotechnological SMEs and the pharmaceutical industry. In this search, **we have no geographic bounds**, collaborating with numerous international institutions such as California Institute for Regenerative Medicine and different international universities.



We seek
collaboration with all
institutions involved in
the Advanced Therapy
field



WHAT WE OFFER

In connection with various partner institutions and with the cooperation of Patients' Associations, the Andalusian Network for the design and translation of Advanced Therapies provides wide-ranging **support to translational research** and provides opportunities for a unique **collaboration with the business sector**.

Thanks to the fact that our Coordination Unit consists of a highly specialized team in the advanced therapy field, we act **as sponsor for over 20 clinical trials** in different cell therapy and tissue engineering products and, furthermore, we are also taking the first steps in the gene therapy field. We assist in giving **regulatory and scientific advice** from the preclinical to the clinical phase of research. This specialized knowledge allows us to offer, among other **training programmes**, an International Master's programme in manufacturing of advanced therapy medicinal products, unique in Europe, organized together with the University of Granada.

👉 **Our area of expertise ranges from** the preparation of the preclinical evidence to justify the start of a clinical trial through the adaptation of the manufacturing process to comply with GMP regulation, the clinical trial design and monitoring, to the finding of strategic associates. We have proven experience providing consultancy services in the development and manufacture of advanced therapy medicinal products.

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A unique Master's
programme in
Manufacturing of
ATMPs



ANDALUSIAN NETWORK FOR THE DESIGN AND TRANSLATION OF ADVANCED THERAPIES' PORTFOLIO OF SERVICES

1. Basic and Preclinical Development

- Analysis of research lines
- Support in the design of the experimentation
- Search for scientific advice from the pertinent Regulatory Agencies
- Preparation and updating of documentation

2. Clinical Trials

- Design and planning of clinical trials
- Clinical trial start- ups
- Support throughout the development of clinical trials
- Surveillance of the medicinal product safety
- Data processing of clinical trials

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3. Manufacturing and Clinical - Scale Development

- Centralisation of many quality control services
- Product development and manufacturing

4. Consultancy and Training

- Strategic and regulatory compliance
- Strategic product development and partnership
- Training and staffing



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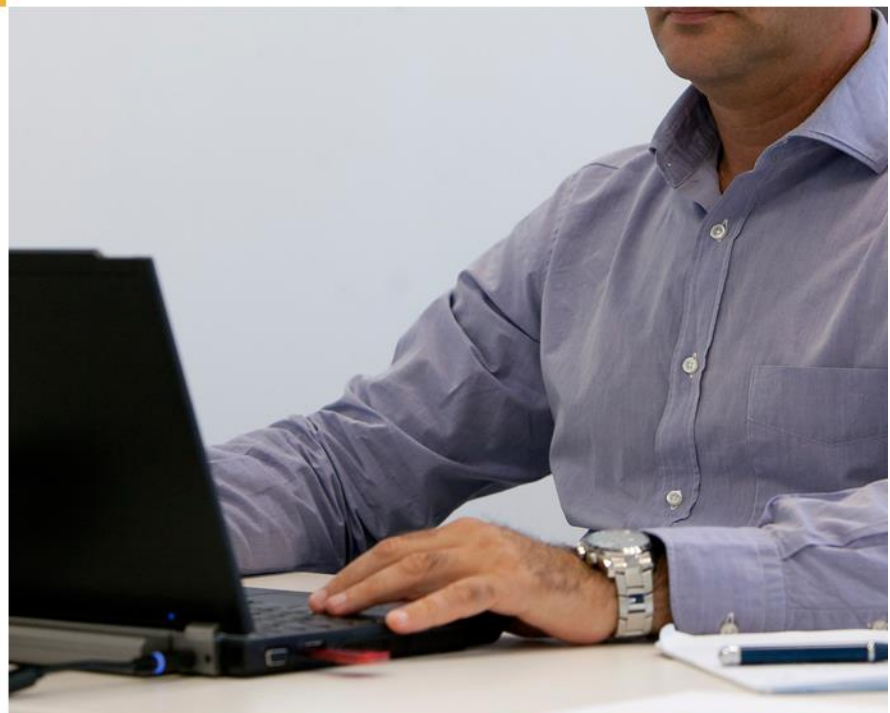
1. Basic and Preclinical Development



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1. BASIC AND PRECLINICAL DEVELOPMENT

The coordination unit of the Andalusian Network for the design and translation of Advanced Therapies comprises a multidisciplinary group of professionals who are able to focus their combined experience on the development of advanced therapy medicinal products, giving strategic and regulatory support to the different projects in research and development.

👉 As Coordination Unit, **we analyse research lines in this type of products**, defining their translational potential, assessing their grade of adaptation to the existing regulation as well as giving support in the design of the experimentation which completes the data required by the Regulatory Agencies to authorize the clinic study.

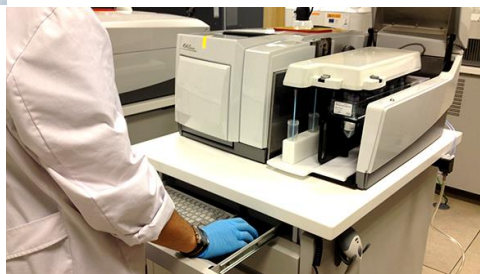
👉 **We seek scientific advice on behalf of the researcher** from the pertinent Regulatory Agencies (AEMPS, EMA) as well as preparing and updating all the documentation required by those agencies in the different phases of medicinal product development.

👉 **The development of an advanced therapy medicinal product** implies the establishment of strict systems of quality throughout all the research phases. In this regard, we give support in the generation of quality assurance systems to those laboratories wanting to implement Good Laboratory Practice guidelines into their procedures

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A multidisciplinary
group of professionals focusing
their expertise on the
development of ATMPs





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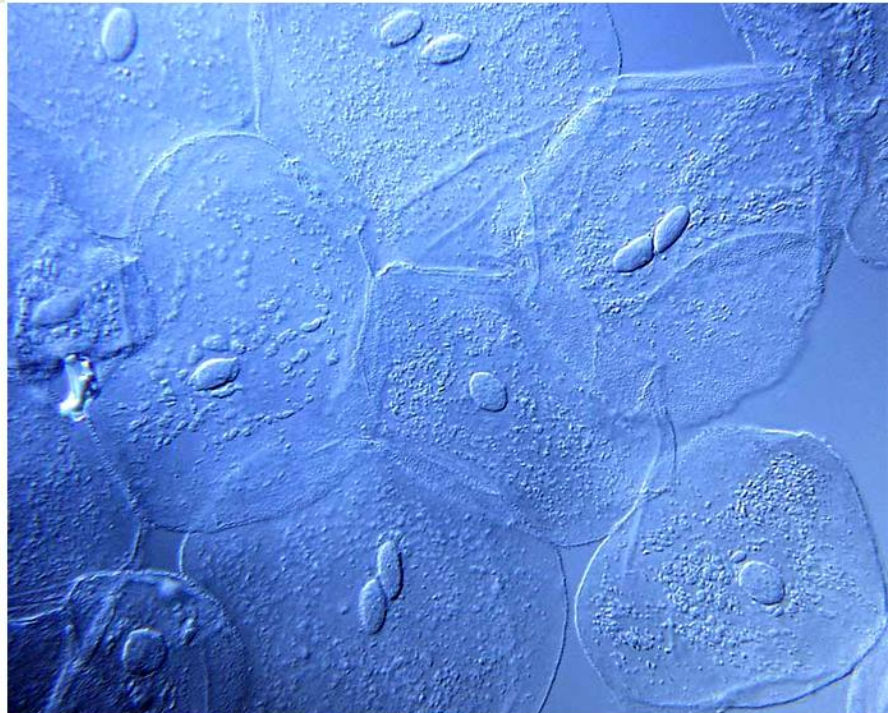
2. Clinical Trials



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2. CLINICAL TRIALS

With the patients' benefit as our main concern, the Coordination Unit of the Andalusian Network for the design and translation of Advanced Therapies sponsors clinical trials which might bring about new evidence in important areas of healthcare as well as improve the quality of life of patients and their families. Thanks to the collaboration and commitment of our researchers we can claim that we are leaders in the field of Advanced Therapy clinical research in Spain.

At present, the Coordination Unit of the Andalusian Network for the design and translation of Advanced Therapies **manages 24 clinical trials** with advanced therapy medicinal products in which several hundred of patients have participated. These trials are being developed in various centres belonging to the Andalusian Public Health System as well as to other Regional Communities. Over 10 products in different therapeutic areas are being trialled.

DESIGN AND PLANNING OF CLINICAL TRIALS

The professionals of the coordination unit of the Andalusian Network have undergone specialised training in research methodology and have gained broad experience in the area of clinical research. This allows us to offer methodological support in preparation of clinical trial protocols as well as other essential documents related to a clinical trial (Investigator's brochure, Patient Information sheet - Informed consent form, the investigational medicinal product dossier, etc.). As we are part of the Andalusian Public Health System, we work very closely with its clinicians specialized in specific therapeutic areas of interest. This allows us to assess and select centres in accordance with the needs of the different clinical trials.

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CLINICAL TRIAL START-UPS

Our expertise in clinical trial management enables us to offer **services covering every aspect involved in the implementation of a clinical trial**, i.e., from the preparation of the pertinent documentation to request authorisation and the management of contracts with participating centres through to the point at which clinical trial authorisation is obtained from the Spanish Agency of Medicines and Medicinal Devices.

SUPPORT THROUGHOUT THE DEVELOPMENT OF CLINICAL TRIALS

The Coordination Unit of the Andalusian Network for the design and translation of Advanced Therapies has highly qualified professionals to carry out the **management of clinical trials** according to the requirements set out in existing regulation giving support to the research teams throughout the development of the clinical trial. This includes the monitoring of the trial, the processing of possible amendments or modifications of clinical protocols or the authorisation of possible compassionate uses of advanced therapies medicinal products.

SURVEILLANCE OF THE MEDICINAL PRODUCT SAFETY

We have a sound knowledge of the regulatory requirements in matters of **surveillance of the safety of the medicinal product in research as well as in pharmacovigilance**.

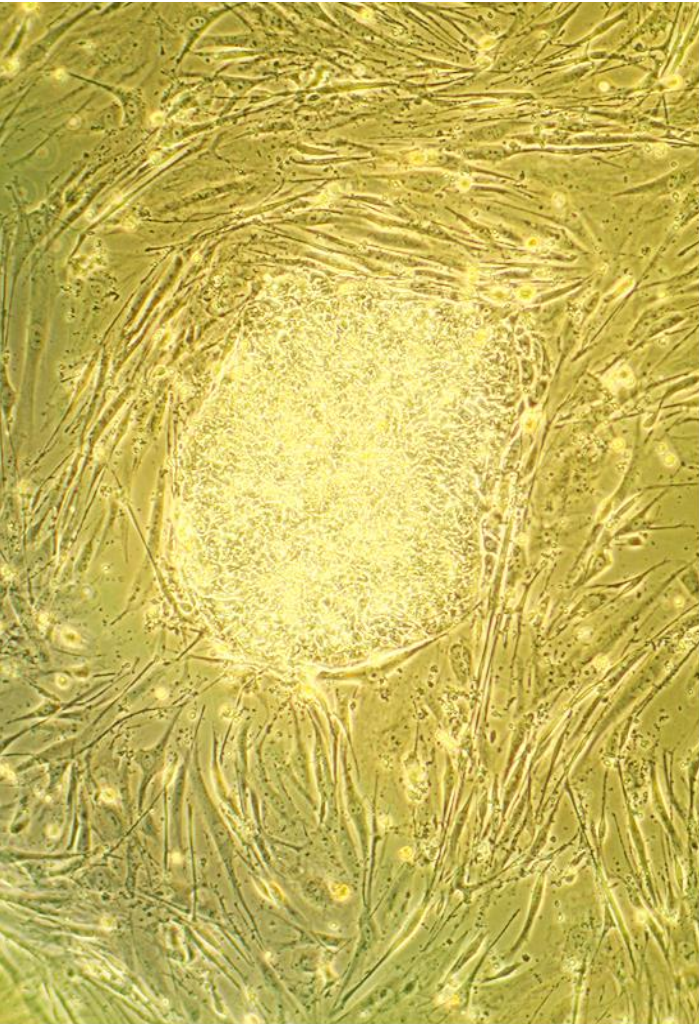
In addition, the collaboration agreement between the Andalusian Pharmacovigilance Centre and the Andalusian Network for the design and translation of Advanced Therapies should not be overlooked as provides us with an added value.

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DATA PROCESSING OF CLINICAL TRIALS

Finally, the **data collection and processing of clinical trials** are as important as the initial stages in their development. This stage must be well planned from the outset to ensure the maximum efficiency of the research. A detailed Data Processing Plan together with a thorough Plan of Queries and accurate monitoring throughout the whole clinical trial will guarantee the reliability of the clinical trial results.

The Coordination Unit has the experience required to give **support to researchers** in these significant aspects.



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3. Manufacturing and Clinical - Scale Development



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3. MANUFACTURING AND CLINICAL - SCALE DEVELOPMENT

The network of GMP laboratories coordinated by the Coordination Unit of the Andalusian Network for the design and translation of Advanced Therapies represents the most important network of public GMP laboratories in Spain. They are mostly located on hospital complexes allowing keeping all clinical aspects under one roof and enhancing profitability as a result of economies of scale.

CENTRALISATION OF MANY QUALITY CONTROL SERVICES

The experience gained by the coordination unit of the Andalusian Network for the design and translation of Advanced Therapies as a consequence of its participation in the development of more than ten medicinal products in research has led to the centralisation of many quality control services at the reference laboratory at the Virgen de las Nieves University Hospital (Granada). This move has also led to greater efficiency.

The above-mentioned laboratory, which belongs to the Andalusian Public Health System, has been authorised by the Spanish Agency of Medicines and Medicinal Devices to manufacture advanced therapies medicinal products as well as to act as reference centre to carry out required quality controls in the manufacture of this type of products.

The quality control trials for which our reference laboratory is authorized are the following: sterility and control of microorganisms in cell products, endotoxin analysis, mycoplasma identification, phenotype analysis by flow cytometry, viability analysis, cytogenetic analysis, analysis of the presence of adventitious viruses and finger printing among others. All these trials are on guaranteeing the quality of the manufactured medicinal products in research. Therefore, our laboratory is equipped with the full range of resources needed to carry out these various analyses.

All these services are carried out in accordance with the standards set out in the European Union guidelines for good manufacturing practice and European Pharmacopoeia, and are performed by highly qualified experts.

PRODUCT DEVELOPMENT AND MANUFACTURING

Our network of GMP laboratories has vast experience in the manufacturing of advanced therapy medicinal products ranging from cell therapy products, tissue engineering products to gene therapy for the use of the society at large.

The variety of GMP laboratories available allows for the **development of various kinds of products**. The logistics of the distribution of the various medicinal products in research for patient use are facilitated by the fact that many GMP laboratories are located on hospital sites. Otherwise a simple authorised distribution system is in place to serve those hospitals which might become involved in the treatment of patients.

We have **highly educated professionals with extensive experience** in the advanced therapy area. Consequently, we can facilitate, to a large extent, the **development of the advanced therapy medicinal product of interest**.



The most important network of public GMP laboratories in Spain





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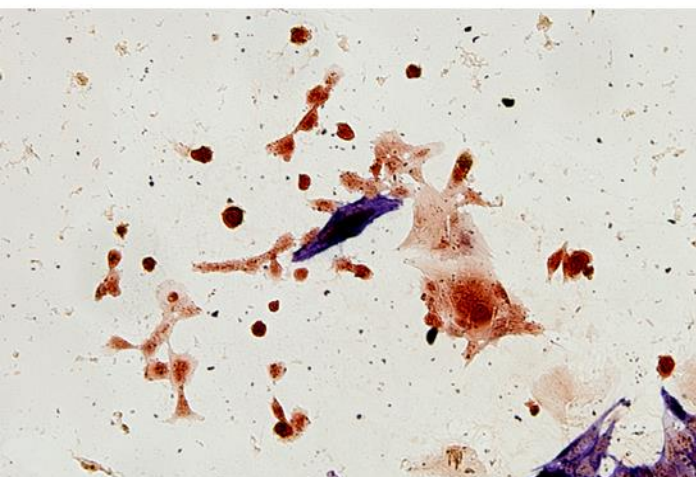
4. Consultancy and Training



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4. CONSULTANCY AND TRAINING

Our professionals make their expertise and experience available in the service of diverse projects and collaborative agreements, with the aim of guaranteeing the success of all phases involved in the various research and development programmes (preclinical, manufacturing, clinical, etc) being carried out by the Coordination Unit of the Andalusian Network.

STRATEGIC AND REGULATORY COMPLIANCE

The approval of a therapeutic candidate as a medicinal product implies the strict observance of a wide range of regulations and guidelines. In the case of certain products this will require high levels of precision.

We have a sound background in the **implementation of quality systems** and procedures guaranteeing the accomplishment of current guidelines: GMP, GPC, etc.

Each advanced therapy product will comprise some specific peculiarities and we, therefore, tailor our advice in every individual case.

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STRATEGIC PRODUCT DEVELOPMENT & PARTNERSHIP

We participate and/or collaborate with the main scientific, corporate and technological networks in the advanced therapy field. Consequently, we are in contact with most of the international and national opinion leaders in this area. Thanks to this network of contacts and our expertise, we are able to establish **strategic collaborations** and also to bring projects with a direct patient focus, to a successful conclusion by increasing operational efficacy, improving the predictability of efforts in research and in development, managing indirect and manufacturing costs and complementing our knowledge with external expertise.

TRAINING AND STAFFING

The reality of healthcare today requires ongoing and updated training of all those professionals involved in the development of medicinal products: doctors, researchers, manufacturing managers and any other supporting personnel.

As a result, we have built an **e-learning platform** to organise training activities, both official training programmes and tailor-made programmes for institutions and companies.

By means of this platform, all activities, components and **procedures involved in an e-learning system** can be managed. Among others, the following:

- Integral management of the faculty and participants in the training activity.
- Content design.
- Development of online tracking tools for the training process.

We also offer specialised training in advanced therapies:

- **Master Degree in Manufacturing of Advanced Therapy Medicinal Products.** University-specific degree of the University of Granada:
www.atmp-masterinmanufacturing.com
- Course on **“Guidelines of Good Clinical Practice”** (only available in Spanish)
- GMP, GCP, GVP y GDP.



CONTACT

ADDRESS

Andalusian Network for the design and translation of Advanced Therapies

(Fundación Progreso y Salud)

Avenida de Américo Vespucio nº 15 Edificio S-2

41092 Seville (Spain)

E-MAIL

terapias.avanzadas@juntadeandalucia.es

TELEPHONE + 34 955 04 83 66

WEBSITE

www.juntadeandalucia.es/terapiasavanzadas



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