The Andalusian Initiative for Advanced Therapies

Natividad Cuende and José L Zugaza at the Andalusian Initiative for Advanced Therapies discuss an organisational model to facilitate new therapeutic opportunities

Andalusia is located in the south of Spain, and with 8,300,000 inhabitants, it is the most populated region of the country. In 1981, it was established as an autonomous region, taking on the responsibilities for its population's health. The Regional Ministry of Health of the Andalusian Government currently manages all public health resources, and has a public healthcare system with universal coverage.

This region aspires to become a leader in offering the latest therapeutic opportunities to its citizens, and the Regional Government, in line with the wishes of the Andalusian people, is committed to promoting research on advanced therapy and its translation into clinical settings.

Recent Achievements

From a legislative point of view, Andalusia was one of the first regions in the world to pass a law authorising investigations using embryonic stem cells, as well as to allow techniques such as cell reprogramming, including somatic nuclear transfer with therapeutic aims only. Additionally, in 2005, the Regional Government approved a decree that regulates preimplantation genetic diagnosis that is offered for free in the Andalusian public health system as well as the selection of a human leukocyte antigen (HLA) identical sibling for therapeutic purposes.

In recent years, several research groups from Andalusia have been recognised for their contributions in this area by participating in national and international networks. Besides that, the Regional Government, through its Ministries of Health and Innovation, Science and Industry, has invested in this biomedical field, and has developed, specifically but not exclusively, three research programmes related to advanced therapies: the cell therapy and regenerative medicine programme, the clinical genetics and genomic medicine programme and the nanomedicine programme. The Regional Government supports these programmes through the Andalusian Initiative for Advanced Therapies, sponsoring research projects, implementing training programmes, recruiting research groups, creating a network of research facilities and establishing collaborations with some biotechnological and pharmaceutical companies.

This investment has resulted in agreements between the Regional Ministries of Health and Innovation, Science and Industry with different Andalusian universities and, in some cases, with the CSIC (the Spanish Research Council), the Health Institute Carlos III (belonging to the Spanish Ministry of Science and Innovation) or pharmaceutical companies, to build specific research centres for the three programmes (see Figure 1):

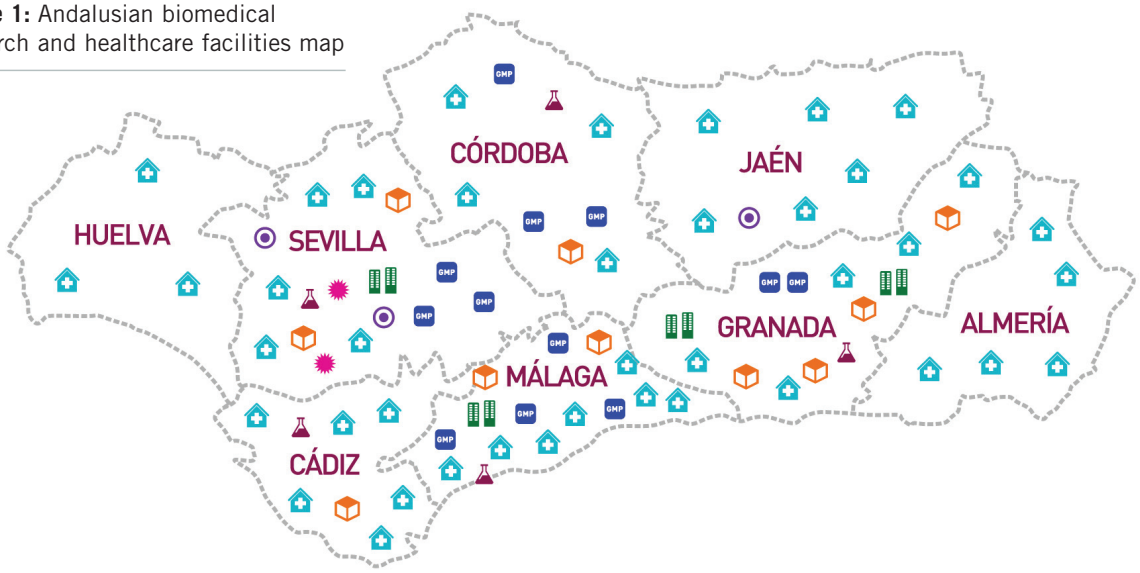
- The programme for cell therapy and regenerative medicine: CABIMER (Andalusian Centre for Molecular Biology and Regenerative Medicine) in Seville
- The programme for clinical genetics and genomic medicine: GENYO (Pfizer – University of Granada – Andalusian Government Centre for Genomics and Oncological Research) in Granada
- The programme for nanomedicine: BIONAND (Andalusian Centre for Nanomedicine and Biotechnology) in Malaga

Other research centres have been created, including the research centre in innovative medicines: MEDINA (Andalusian Government-MSD-University of Granada) and several health research institutes linked to the Andalusian University Hospitals, such as IBIS (Biomedical Research Institute) in Seville and IMIBIC (Maimónides Institute for Biomedical Research) in Cordoba, among others. Recently, the Regional Government has announced the creation of the Andalusian Cellular Reprogramming Laboratory and the investment of €27 million for a high-throughput sequencing platform within the Medical Genome Project to characterise directly a large number of genetic diseases.

In addition to research centres, Andalusia has a network of biobanks for tumours, DNA, umbilical cord blood (the third largest bank in the world in terms of stored samples of umbilical cord units for allogeneic transplant) and stem cells (the central node of the National Cell Lines Bank). The Regional Ministry of Health has also built a network of public GMP laboratories to produce cell-based medicinal products. Last year, the Regional Ministry of Health, in collaboration with the Spanish Ministry of Health and Social Policy, developed a pioneer programme in Europe aimed at training professionals to manufacture medicinal products for advanced therapies.

Other achievements to consider are the establishment of new embryonic stem cell lines, as well as the remarkable increase in the number of clinical trials in cell therapy currently in progress in the region (see Figure 2, page 84).

Figure 1: Andalusian biomedical research and healthcare facilities map



SPECIALISED RESEARCH CENTRES

CABIMER Andalusian Centre for Molecular Biology and Regenerative Medicine (Sevilla)
GENYO Pfizer-Universidad de Granada-Junta de Andalucía Centre for Genomics and Oncological Research (Granada)
BIONAND Andalusian Centre for Nanomedicine and Biotechnology (Málaga)
MEDINA Research Centre in Innovative Medicines (Granada)

NETWORK RESEARCH CENTRES

Structures to promote the investigation:
CEAS Excellence Centre in Research about Olive Oil and Health (Jaén)
CAIT Andalusian Research Centre in Nicotine Poisoning (Sevilla)
Andalusian Research Center in Physical Activity, Health and Sport (Sevilla)

HEALTH RESEARCH INSTITUTES

Research centres linked to university hospitals to promote translational research:
IMIBIC Maimonides Institute for Biomedical Research (Córdoba)
IBIS Biomedical Research Institute (Sevilla)
CÁDIZ Biomedical Research Institute
MÁLAGA Biomedical Research Institute
GRANADA Biomedical Research Institute

BIOBANKS

Research tools for cooperative research:
BLOOD CORD BANK (Málaga)
DNA BANK (network centre, Granada is the central node)
STEM CELL BANK (Granada)
TISSUES (Málaga, Cádiz, Sevilla, Córdoba y Granada)
TUMOURS BANK (network centre, Granada is the central node)
BIOLOGICAL FLUIDS OF HUMAN NEUROGICAL DISEASES (Sevilla)

HEALTHCARE CENTRES

Providing healthcare and developing research:
41 Hospitals · **1459** Primary Care Centres

GMP FACILITIES

Fitted in compliance with European Good Manufacturing Practice:
4 (Málaga) · **3** (Sevilla) · **3** (Córdoba) · **2** (Granada)

SPECIALIZED LABORATORIES

MGP Medical Genome Project (Sevilla)
Andalusian Cellular Reprogramming Laboratory (Sevilla)

On the other hand, the Regional Ministry of Innovation, Science and Industry has also developed a set of financial and support tools, such as grants for research projects of excellence and an incentive programme for the promotion of innovation and business devlopment. This programme includes direct non-repayable and repayable incentives, interest rate subsidies, participatory loans and investment in share capital. These tools are contributing to R&D and innovation in this research field and promoting the creation of companies.

These scientific contributions and health activities have occurred in a context in which Andalusian society has supported them and in which different institutions have expressed their engagement to boost these therapies. As a result of this combined effort conducted over the last few years, today we find that Andalusia is fast becoming one of the most active regions in advanced therapies.

The Andalusian Initiative for Advanced Therapies

The recent progress of research in advanced therapies (cell and gene therapies and tissue engineering) has given rise to new hope in the treatment and diagnosis of many illnesses for which there is currently no cure. Translational research in the fields of cell therapy and regenerative medicine, clinical genetic and genomic medicine and nanomedicine seems to have a key

Figure 2: Current non-commercial clinical trials with cell therapies in Andalusia

CLINICAL TRIALS IN ADVANCED THERAPIES 2010	Authorisations pending	Start-up phase	Recruitment phase	Follow-up phase
Cardiology				
Dilated myocardiopathy			1	
Myocardial infarction				1
Chronic ischemic cardiopathy	1			
Neurology				
Multiple sclerosis			1	
Stroke			1	
Immunology				
Graft versus host disease		1		
Peripheral vascular diseases				
Chronic critical isquemia in lower limbs in diabetic patients			2	1
Chronic critical isquemia in lower limbs in non-diabetic patients	2			
Digestive				
Hepatic regeneration	1			

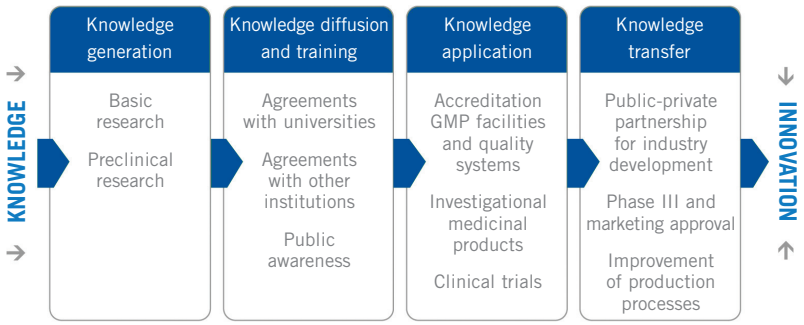
role in facing these research challenges. As a result, the Regional Government steered the Andalusian Initiative for Advanced Therapies in 2008, giving it high priority.

This Initiative is promoted by the Ministries of Health and Innovation, Science and Industry. Its mission consists of developing new therapies in order to improve the health of the population and to incorporate advanced therapies in Andalusia as a part of healthcare innovation and progress of our region. It seeks alliances between academies, research institutions, medical centres and patient organisations. To make this project successful, strong links must be established with biotech and pharmaceutical companies, and ways must be found that enable these companies to become strategic partners to develop this Initiative, in order to make the advanced therapies area one of the most dynamic elements of our business network and economy.

The overall objectives that the Andalusian Initiative for Advanced Therapies plans to develop are:

- To promote development and application in clinical practice of new therapies, mainly based on research results obtained from the three research programmes related to advanced therapies and carried out in Andalusia
- To provide equitable access to potential new treatments for the population
- To develop a business network that facilitates the development of therapies, promoting effective

Figure 3: From knowledge to innovation: areas that the Andalusian Initiative for Advanced Therapies encompasses



mechanisms for knowledge transfer and collaboration to business

- To promote synergy of the three research programmes in advanced therapies: the cell therapy and regenerative medicine programme, the clinical genetics and genomic medicine programme and the nanomedicine programme
- To facilitate partnerships between all the actors involved in R&D processes through open and transparent mechanisms that allow optimal use of resources and efforts spent on this project
- To concentrate efforts to promote translational research, providing the support tools for the production and application of medicinal products for advanced therapies, according to the requirements of regulatory agencies
- To facilitate the participation of leading scientists from all biomedical fields, clinical researchers, research managers, patient associations and the private sector
- To identify the necessary tools to meet the needs of all stakeholders involved in the Andalusian Initiative for Advanced Therapies

Current Activities

This Initiative, in accordance with its mission statement and objectives, is developing appropriate plans and tailoring resources, as well as encouraging synergies among the three research programmes related to advanced therapies and promoting clinical translation. The strategic plan for the period 2010 to 2015 has been established through the Initiative's steering committee, advisory board and seven working groups, with the participation of all the stakeholders: scientists, research managers, clinicians, members of the regional ministries of health and innovation, science and industry and representatives from Andalusian universities, ethics committees, patient associations, and biotechnological and pharmaceutical companies.

The activities that the Andalusian Initiative for Advanced Therapies is carrying out are part of the key stages in the process of research and innovation: generation, diffusion and application of new knowledge, and knowledge transfer (see Figure 3), with special emphasis on translating research results into new therapies. For this reason, the organisation is acting as the sponsor of non-commercial clinical trials with advanced therapies. At present, eight clinical trials are being carried out, and another four multi-centre clinical trials approved by ethics committees are awaiting approval by the Spanish Medicine Agency (see Figure 2).

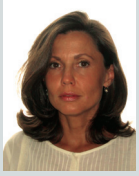
One important aspect of this project is the role and contribution of biotech and pharmaceutical companies to generate not only knowledge, but also to support major economic and social development in Andalusia. Consequently, the Andalusian Initiative for Advanced Therapies has signed several collaboration agreements with different companies and is interested in seeking other partnerships.

Conclusion

Over the last few years, Andalusia has made a tremendous effort to promote research, development and innovation in the biomedical field, particularly in the advanced therapies area, which includes: cell therapy and regenerative medicine, clinical genetics and genomic medicine and nanomedicine.

The aspirations of Andalusia are to occupy an important role in research, development and innovation in this biomedical area, making advanced therapies one of the drivers of scientific progress, health improvement, and social and economic development for the region.

About the authors



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