## ANDALUSIAN INITIATIVE FOR ADVANCED THERAPIES

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Around the year 2003, Andalusia, placed the first stone of a future project in research and advanced therapies. It started by passing a pioneer law that regulates the research with human preembryos no viable from in vitro fertilization in the region. This small step, for some, had a major significance for the region and Spain. Andalusia became one of the few leading region in this research field. However the plan was not centered in cell therapies but was designed with a broader spectrum. Andalusia decided to create and organize a program in advanced therapies that drive the region in the research areas towards the future.

To do so, the Andalusian Government created three research programs; Cell Therapy and Regenerative Medicine, Clinical Genetics & Genomic Medicine and Nanomedicine. Each of the programs is based and supported in a recently created centre; CABIMER (Cell therapy and regenerative medicine-Seville), GENYO (Genomics and Oncological Research-Granada) and BIONAND (Nanomedicine & Biotechnology-Malaga). Furthermore the Andalusian Government envisages the future as a mixture of collaboration among these three areas.

Moreover several biomedical research institutes are being born linked to the relevant University Hospitals, favoring the combination of basic and clinical research as well as the transfer of the research results to the everyday clinical practice within the health system. We already have two research institutes linked to university hospital centers –the Institute of Biomedicine of Seville (IBIS) and the Maimonides Institute for Biomedical Research in Cordoba (IMIBIC). And two more research Institutes are planned to be built for the next years.

The coordination and promotion of the future collaborative research among the all main centres and peripheral laboratories working in those topics required a major structure that hosts all the tools for the engine of future innovation. That structure in Andalusia was created and named the Andalusian Initiative for Advanced Therapies. The Initiative's structure and key action lines are based on the fundamentals of the R&D and innovation process, that is to say, knowledge generation, knowledge diffusion and technology transfer, and knowledge translation into clinical applications. To enforce this value-creating chain, more and stronger links amongst academia, research organisations, healthcare providers and biotech SMEs have been established.

The Initiative is not only a management structure but is also focused in the translation of knowledge between the basic and clinical research. To promote both ends of that chain, the initiative has generated a network of Biobanks that are primordial for basic research and has built a network of GMP facilities that are required for the transfer from basic science to applied clinical trials.

At the moment this effort has already granted our first results. The initiative counts with a full in running centre, CABIMER; five networks of Biobanks (cord blood, DNA, embryonic stem cells, tumours and tissues), one accredited GMP (seven more in process), five cell therapy clinical trials and the full backup of the whole Andalusian Health system.

In the other hand for the near future the initiative is managing the opening of GENYO and BIONAND; a new network of Biobanks, the validation of the rest of the GMP facilities and the authorisation of another three clinical trials.

The best description of the generated research infrastructures until the moment is drawn in the following diagram:



The Initiative is not only generating new structures is also generating supportive economical aid by having competitive grants available for new and established research groups working in Advanced Therapies.

In relation with the human resources area, the Initiative has also designed recruitment, training and return programs; reaching important agreements with international competitive centers and structures as is the case of the NIH and Michigan State University. The initiative is still working to broaden the agreements with other international structures. Finally the Initiative is giving a full training course directed to all the positions needed within the advanced therapies projects.

In the nanomedice area specifically, the Initiative has created BIONAND. BIONAND is a centred based in Malaga promoted by the Ministry of Health, the Ministry of Innovation, Science and Industry and the University of Malaga that will host around 150 scientists in a newly built centre of  $6,500 \text{ m}^2$ . The promoters are investing more than 12 millions  $\in$  in the building and the needed infrastructure. The centre will host multidisciplinary professionals (clinicians, molecular biologist, chemist, pharmacist, bioinformatics, physicists and bioengineers) working in the following research lines:

- <u>Diagnostic Devices</u>: will be focused on the identification of new diagnostic nanodevices using molecular and cellular tools.
- <u>Targeted Drug Delivery</u>: This area will be focus on new processes of reaching the targeted organ or tissue for a selective delivery.
- <u>Tissue Engineering and Regenerative Medicine</u>: For cell therapies to be effective, they need the adequate vehicles or scaffolds. This area will be focus in the more engineering aspect of the advanced therapies.

As a step forward for nanomedicine in Andalusia, this meeting will be held in Malaga the following year.