



Programme co-funded
by the European Union



Project Future Medicine

Cross-border Cooperation Programme 2007-2013 IPA ADRIATICO 2007-2013

Priorità 1 – IPA Adriatic, Cross-border Cooperation Programme 2007-2013

Measure 1.3 - Economic, Social and Institutional Cooperation

Lead Beneficiary Abruzzo Region

Partnership

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	Fondation "Emanuele e Anna De Gennaro"
	Municipality of San Valentino in Abruzzo Citeriore
	University Hospital Of Bari, department of Obstetrics and Gynaecology, Unit of Pathophysiology of Human Reproduction and Gametes Cryopreservation
CROATIA	UNIVERSITY HOSPITAL RIJEKA, Department of Obstetrics and Gynecology, Unit for Human Reproduction
SERBIA	Institute for Gynecology and Obstetrics, Clinical center of Serbia
BOSNIA-HERZEGOVINA	University Clinical Centre in Sarajevo, Obstetrics and gynaecology hospital
ALBANIA	University Hospital for Obstetrics & Gynecology "Koco Gliozheni"
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SLOVENIA	University Medical Center Maribor

Objectives

The FUTURE MEDICINE project is in fact the synthesis and further development of two projects that have already received EU-funding under the INTERREG IIIA Programme, Futuro Donna and Adriatic Telemed, whose objectives included the acknowledgement by health operators of the patient's right to self-determination, putting emphasis on health as a collective good, and making medical care more humane. All this was achieved through constant training of different teams of doctors specialized in the field concerned, which involved holding very frequent meetings as well as clinical meetings at some of Italy's best professional centers. The actions foreseen will be implemented in the same areas covered by the two previous projects, namely: Region Abruzzo (L'Aquila), Region Puglia (Bari) as well as four territories in the Balkan Region: Croatia (Rijeka), Bosnia Herzegovina (Sarajevo), Albania (Tirana), Serbia (Belgrade). This will make it possible to take advantage of the participants' professional skills. The project is structured in such a way that the knowhow gained so far and the cultural and scientific knowledge acquired by participants in the previous projects mentioned above will not be lost. This remarkable deal of knowledge will be fully put to use and expose its value when the Centers are set up. The Excellence Centers to be established under this project will comply with all EU requirements applying to facilities, equipment and staff used in the provision of medically assisted reproduction services. Medically assisted reproduction techniques include both first level and third level techniques. The potential offered by such techniques also allows for work in the field of stem cells, with a view to developing treatment capabilities in the area of so-called Regenerative Medicine. This activity will necessarily make use of cell breeding methods typically used at MAR centers so as to use solely adult somatic cells instead of embryonic cells. In addition to human tissue transplants, new cell therapy procedures have been developed that are now commonly used in clinical practice and which are based on the selection and/or expansion of adult somatic or stem cells. The latter procedures and the field of medicine that studies them are referred to as "Cell Therapies" and "Regenerative Medicine", respectively. The project appears to be a challenge for the future in those places where such centers of clinical and scientific interest are still non-existent - indeed it aims to become the FIRST MODEL FOR 1ST LEVEL REGENERATIVE MEDICINE INTEGRATED CENTERS. Its positive repercussions on the area concerned will arguably be of great value; the human and financial resources involved will help develop a pro-life culture and ensure the successful implementation of the programme; in addition, the human resources concerned will be able to make full use of and upgrade their skills, which in turn will help them to consistently provide high quality services. This development will result in positive economic repercussions on the populations concerned in the areas covered by the project, starting from improvements in their health condition, which in turn will lead to improved work performances. Strengthening of cooperation results from the emergence of a new action approach, which not only acknowledges the plurality of development

actors, but also affects mutual relations among them by situating the latter within a new framework with a view to building “a common house”. This involves:

- opening Excellence Centers both for couple infertility diagnosis and treatment and for regenerative medicine;
- establishing a clinical and scientific network for the study and treatment of couple infertility-related diseases;
- devising joint behavioural protocols in the diagnosis and treatment of infertile couples
- setting up a scientific and training network with a view to opening various 1st Level Regenerative Medicine Centers; The project aims to set up excellence centers for both the study and treatment of couples' infertility and first-level adult somatic stem cells centers. The project specifically consists of:

- the establishment of a telematic information network for the study and treatment of diseases causing couples' infertility, which can be diagnosed and treated by means of medical and instrumental techniques
- training the staff involved in the study and preparation of behavioural protocols for the diagnosis and treatment of couples' infertility
- the establishment of centers for medical information networking
- planning the organization and running of courses, seminars, and advanced meetings intended to constantly upgrade the knowhow of the groups involved;
- the opening of first level centers for the study of the molecular mechanisms regulating self-renewal of adult somatic stem cells
- breeding and application of adult somatic stem cells which will later on be suitable for differentiation and clinical use in the treatment of various diseases
- designing experimental protocols for genic treatment of genetic diseases for clinical use in the field of Regenerative Medicine
- networking all centers with a single general center for cell extension and production (GMP)
- completion and synthesis of the two previous projects “Futuro Donna” and Adriatic Telemed” implemented under the Interreg IIIA Programme, which were funded by the European Union and involved the same partners. All such objectives are in line with the goals pursued by the Operational Programme, more exactly those covered by measure

1.3 which aims to establish and strengthen both new and existing cooperation networks in the field of social, employment and health policies. The measure also intends to facilitate the exchange of experiences and the transfer of skills and competencies in the social, health and employment sectors. The beneficiaries of this action are professionals and researchers who have already participated in EU-funded programmes, which will allow their institutions (Hospitals and Universities) at a later stage to take measures aiming to improve health services, improve the cost-benefit ratio as well as to increase the percentage of medical successes. The geographical area covered by the project comprises the Adriatic Region in its entirety as public institutions from both Italy and the

Eastern Adriatic Countries are involved. The high degree of specialization and the complex organizational requirements which today's society demands as well as the countless advances in the field of biotechnology all require constantly improved professional skills, close intersectoral cooperation, and greater knowledge exchange between research centers and researchers in order to identify the best treatments and to be able to follow medical and administrative developments as effectively and efficiently as possible. It is strictly in line with the guidelines set by Measure 1.3 of the Operational Programme in that:

- a direct and immediate communication network will be set up among the centers involved which will serve as the first immediate relationship channel between the actors concerned;
- the activity carried out in the center will be the early stage of a scientific and training activity coordination process among the different Adriatic regions, which, while differing in professional training, culture and history, are nevertheless uniform in the formulation of human-specific diseases;
- it will optimize the use of already existing health and social infrastructures given the fact that the applicants involved have participated in EU-funded projects implemented under INTERREG IIIA (namely "Futuro Donna" and "Adriatic Telemed"), thus resulting in greater cohesion, and widening the scope of the scientific and training activity carried out by the already established association of professionals, who want to further develop theoretical and scientific methodology which they have already used by drawing on the experience exchange and training activities which began under the aforesaid projects;
- it will establish a number of integrated networks of health services between the centers intended to make telematic and satellite inter-communication possible;
- it will give greater prominence to the Eastern Adriatic Countries and improving their international image and reputation from both a technical and professional point of view by supporting geographic and professional mobility of the specialized staff involved, thereby strengthening the cross border integration of the labour markets concerned;
- it will spread knowledge and pave the way for the extension of this service to the different areas across the Adriatic region, which will result in the integration of health policies, with service distribution being harmonized as a result, something that will in turn help the development of the geographic areas concerned;
- it will establish regenerative medicine centers by adapting suitable facilities to adult somatic stem cells preparation and multiplication.

The objectives of the project are fully in line with the goals pursued by the Operational Programme; indeed, the project pursues the goal of coordinating and improving cooperation actions intended to qualify human resources and to support up skilling initiatives. The project is fully consistent with the priorities of the Programme since it

allows to develop and strengthen the specialized medicine centers, setting them apart from the competition by offering highly innovative services. The project will set up an important cross border network for specialized medical care in the area of couples' infertility and for the initiation of lab activity focusing on adult somatic stem cells, which will support the development internationalization of medical care services. The idea for this project arose from needs which are strongly felt in both the European Union and the area covered by the project. From this perspective the project aims to provide solutions with a big international impact, which will subsequently make it possible to design highly innovative services. Regenerative Medicine is the future of medicine, and this is something which the governments of the Eastern Adriatic Countries and the Italian Adriatic Regions are aware of. The project aims to promote internationally the skills of the centers concerned thru research projects in the field of the Regenerative Medicine and at the same time to identify new treatment methods intended to improve the health service (for instance by using the project's technologies to allow earlier discharge of patients), which will obviously reduce health costs. The goals of the project are consistent with the following factors set forth by the Lisbon Strategy: 1) preparing the transition to a knowledge-based economy and society by better policies for the information society and R&D, also by creating a European space for research and innovation which will enable Europe to provide attractive opportunities for its best researchers as well as making it possible to coordinate at a higher level research activities taking place at the national level; 2) modernizing the European social model by investing in people and by building up an active welfare state: this point is closely related to the policies aiming to train, up skill and retrain human resources. The European Council held in Lisbon has also called on member states to make promotion of inclusion an integral part of their policies in the health sector, among other fields. The coherence of the project with the Goteborg Strategy is ensured by the implementation of actions which help situate the social component of development within one of the four priority sectors identified by the Council: public health service. The goals of the projects are consistent with the priorities set by the most relevant Programmes and Documents in the field of EU health policies: "Second Programme of Community Action in the Field of Health"; the Report by the European Observatory on Health Systems and Policies "Financing health care in the European Union. Challenges and policy responses"; "e-Health: improving health and healthcare through the use of information and communications technologies"; "EU's Research Framework Programme"; the October 23rd 2007 issue of the EU Commission's White Book entitled "Together for Health: A Strategic Approach for the EU 2008-2013", which defines a new EU strategy in the health sector which aims to strengthen, within a single strategic framework, EU cooperation in domains in which member states can only act on an individual basis, and also to ensure better understanding of health at the European level as well as worldwide and to pay more attention to health in policy-making as a whole. The goals of the project match the following policy guiding principles of the horizontal issue of the Programme "Promotion of sustainable development": Promotion

and protection of fundamental rights; Solidarity within and between generations; Open and democratic society; Involvement of citizens; Involvement of business and social partners; Policy coherence and governance; Policy integration; Use best available knowledge; Precautionary principle. In addition, the goals comply with European and national policies on equal opportunities and non-discrimination at all stages of the Project while aiming to improve and make appropriate use of human resources as well as to promote, enhance and spread competitiveness-boosting research and innovation.

1) Direct online communication: human resources and professionals skills from the areas concerned will be used and promoted to implement the project, thus setting up a direct and immediate communication network for continued knowledge and information exchange (knowhow transfer). The reason for the choice of this methodology is the intention to implement a scientific, clinical and technical coordination (2) between the Adriatic regions, which differ widely in terms of professional training, culture and history but are nevertheless united by the formulation of human-specific diseases. 3 Benchmarking as an instrument for improving the performance of the MAP centers which form the scientific and clinical network established under previous projects, by comparing results against EU's clinical standards. 4 Internal evaluation. In order to monitor project implementation by the different actors involved procedures and activities are due to be standardized based on European quality systems. An ex-ante management manual will be thus drafted which will allow to identify within procedures the activities and implementation modes to be followed by each partner-executor while implementing its own actions. Procedures will be monitored at regular intervals along with the financial and physical implementation data related to each action of the project in order to be able to constantly follow project implementation and to make changes to the latter, if any, where these become necessary to ensure correct implementation of the project as well as to take account of the data thus collected and the periodical forecasts required under the Programme. 5 Dissemination. The partners will attend lectures, organize meetings and seminars, produce material for dissemination of the results achieved and will present the latter at the local, national and international level. The start of the clinical and scientific network using the most advanced techniques of telemedicine, distance teaching and distance consultation will make it possible to use the resources available to health facilities more efficiently, thereby allowing to reduce health spending. The spread of new technologies suitable for the study and treatment of couples' infertility, as well as the new frontiers of regenerative medicine, the field of medical science that will be the scientific and cultural revolution of the third millennium, will allow to save time and space, and distance learning will make it possible to use new tools. The project will create added value during its implementation and beyond. Due to the benefits expected in the areas where regenerative medicine and the treatment of couples' infertility will be applied as well as to the resulting revenues, the service provided will continue to be available and will be self-sustainable even after the project has been completed. The strength of the service provided will indeed be the wide territorial network set up in the IARs and EACs

as a result of this action (universities, hospital remedies, specialized physicians, paramedical staff involved). The project is also marked by highly innovative features and will bring the EACs gradually closer to IARs' standards, and will also lay the foundations for a new, steady development process which will prepare them to enter the global market. The project also helps establish close twinning relations between university hospital facilities in the EARs and IARs, something that will last well beyond the completion of the project and that will allow to lift the geographic and cultural barriers separating the different countries involved. The innovative elements introduced will have a visible impact on health policy planning, on gynaecological disease management methods, as well as on the study and clinical application of cell therapies or, better said, of regenerative medicine. The aforesaid internal evaluation procedures will be defined jointly in the beginning stage of project implementation within WP1 (technical management) in order to ensure that project results will meet high quality standards. A quality management manual will set procedures and frameworks for operational project activities, including internal communication specifications, document management procedures, archiving, etc. In addition, a Partnership Agreement will regulate relations among partners, including rights and duties, emergency procedures and conflict resolution. A Steering Committee will be appointed at the start of the project with the task of monitoring, directing and approving progress in the different project implementation stages. The Steering Committee will be composed of the project partners' representatives. The operational management of the project will consist of three primary components:

- 1) Technical management (administrative & financial), which:
 - a) ensures delivery of technical results in terms of quality and timing (the first activity will consist of setting a detailed workplan and of entrusting roles and responsibilities at the sub-task level);
 - b) develops procedures and frameworks for the functioning of project activities (set by the quality management manual), including internal communication specifications, procedure management-related documents);
 - c) facilitates uniform project implementation progress and solves operational problems if any;
 - d) notifies the project coordinator of potential risks and problems;
 - e) submits implementation progress reports;
 - f) manages cross border activities;
 - g) defines agreements by common consent;
 - h) checks and collects financial data of both a physical and procedural kind;
 - i) submits payment requests to pay the authorities;

- l) checks financial progress of the project;
 - m) helps update financial data in the workplan;
- 2) Scientific Management, which involves coordination of the strictly scientific activities to be implemented under the project;
- 3) Clinical Management focusing on the strictly clinical project activities with regard to both the Medically Assisted Reproduction Centers (MAR) and the First Level Stem Cells Laboratories (S.C.L).

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