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Fondazione Parco Biomedico San Raffaele (PSB) and Centro di ricerca per la sperimentazione clinica (CRISC) sign collaboration for the creation of a pre-clinical to clinical trial platform in Lazio.

Fondazione Parco Biomedico San Raffaele and Centro di ricerca per la sperimentazione clinica (CRISC) have signed a collaboration for the creation of a pre-clinical to clinical trial platform in the Lazio (Italy) region to foster the development and validation of new diagnostics and therapeutics.

The Lazio Clinical translation platform will facilitate the development of clinical research in the Lazio Biomedical community by providing a co-ordinated approach to the investment and practice of clinical research. The project focuses on established academic and not-for-profit centres, providing a framework for the coordination of clinical research. Emphasis is placed on the promotion of clinical research in rare diseases, orphan treatments, and biotherapies from pre-clinical validation through to late stage clinical trials for proof of efficacy. This project will also be open to the international community including industry partners, particularly for biotechnology SMEs, combining Industrial expertise, know-how, and investment into a knowledge-based economy. The increase in biotech products being developed associated with the value created at pre-clinical, phase 1 and phase 2 clinical stages implies that an integrated platform matching these phases will have significant positive economic value for all participants.

The genome revolution has resulted in the identification of at least 3000 to 4000 potential genes for therapeutic targeting. In contrast the **100 top selling pharmaceutical drugs target only 43 genes**, which if extended to the top 200 selling drugs is only increased to 57. The prohibitive costs of the pharmaceutical development of one drug (ranging **from 850 million euros to 1.7 billion euros** when including marketing) has resulted in a significant number of diseases simply being untouched and unconsidered. Analysis reveals that despite the investments made by large pharma companies in drug development the number of new drugs developed by them reaching market has remained constant for 20 years, while the world clinical pipeline of biopharmaceuticals currently boasts more than 2500 compounds all in different phases of development and validation..

The platform will provide the region with an infrastructure and expertise that facilitates a harmonised implementation of Good Clinical Practice (GCP), according to Directive 2001/20/EC and Member State legislation, into clinical research centres and springboard the region onto the European and Global Biomedical map. In addition, the project will promote a stronger appreciation for legal considerations (including GCP regulations), informed consent, and ethical review among researchers and funders. This infrastructure and expertise will contribute to a broader based capacity for medicinal development and registration. Finally, the project also contributes to developing Italian and European-level capacities for participating in international research collaborations with other regions of the world, including North America, Eastern Europe, Latin America, Asia, and Africa, complementing existing European infrastructures including the European-Developing Countries Clinical Trials Programme (EDCTP), the European centre for clinical trials in rare diseases and the European clinical research infrastructure network (ECRIN).



The dramatic development and success of translational research, from bedside to bench and from bench to bedside, emphasises the central role of efficient clinical research infrastructures for European biomedical research and industry development in the field of biotechnology.

The current lack of coordination of clinical research at the European level often inhibits the ability of European expertise and resources from being brought to bear efficiently on multinational clinical studies aimed at rare diseases, orphan drugs, and biotherapies. Rare diseases affect less than 5 people in 10000, of which there are at least 5000 known, but are economically unviable for large industry to invest. This has led to recent concerted effort to research the mechanisms of these diseases, and the implementation of several European laws and directives aimed at facilitating this process, but is still lacking: this research has a strong impact on the quality of life as well as the morbidity and mortality of European citizens. Alternatively, European industries, and particularly SMEs involved in the development of new prophylactic, diagnostic and therapeutic tools based on biotechnology research, need a platform for clinical research. Further, the implementation of Directive 2001/20/EC brings with it new demands regarding GCP for academic and industry clinical research. This also includes the development of new understandings between regulatory authorities, researchers, funders, and ethics committees.

Centro di ricerca per la sperimentazione clinica (CRISC)

The Centre for Experimental Clinical Research (CRISC) located in the University of Rome ‘La Sapienza’ was founded on the 15th of December 2004 following rectoral decree. The aim is to generate a centre for clinical research in the University adhering to the Italian Law ‘decreto legislativo 211 del 24 giugno 2003 (an extrapolation of and in line with the European directive 2001/20/CE for the application of good clinical practice in clinical assessment of new compounds).

The centre also performs training and formation through a masters programme for clinical experimentation - in agreement with the Italian ministry of health, General directorate for medical evaluation and pharmaco-vigilance – to train active professionals in the field in the different aspects of the clinical experimentation.

To achieve these objectives, CRISC follows and develops the following aspects:

- Assistance in the acquisition of institutional or private funds to enable the clinical trials to be sponsored, with the aim to finance trials of high scientific relevance and therapeutic benefit.
- Partial or complete management of all activities linked to sponsored mono- or multicentric clinical trials
- Training at masters level (level 1 and 2) for those already qualified in medicine-surgery, biological sciences, biology, Pharmacy and chemistry
- Advanced informatic tools for following the implementation of clinical trials to assist trial execution

Fondazione Parco Biomedico San Raffaele (PSB)

Located approximately 15 km south of Rome in a natural reserve, the science park was created by the Banca di Roma, the Chamber of Commerce of Rome, and the Fondazione San Raffaele Monte Tabor in response to the recognised need to have a biomedical research centre in the Lazio region. Opened in 2002, the park is now home to 2 companies and 9 research groups from Universities and centres working in: Stem cells, Oncology, leukaemia and Immunology; Molecular cardiology; Skeletal regeneration; Cell therapy and tissue engineering; Muscular dystrophies; Biomedical quality control; Neurological Disorders



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and Diabetes. The infrastructure permits the development of concept to preclinical development based on the state-of-the-art facilities including a animal facility encompassing conventional and SPF small animals and a large animal surgery unit.