

Launch of the REVERT project clinical study: research and innovation to support colorectal cancer patients

The REVERT (taRgeted thErapy for adVanced colorEctal canceR paTients) project, financed by the European Horizon 2020 Programme and led by the San Raffaele Research Center of Rome, has recently **launched the start-up of its clinical study**. This important step of the project is coordinated by the University Hospital 'Tor Vergata' of Rome and focuses on testing and validating a predictive model in the oncology setting- supported by Artificial Intelligence - in order to improve clinical practice and management of healthcare services for cancer patients.

University Hospital 'Tor Vergata', indeed, will coordinate the European clinical Centers involved in the clinical trial, which aims at validating the clinical decision support system based on algorithms for predicting treatment response in metastatic colorectal cancer patients.

According to the European Cancer Information System of the European Commission, "Colorectal cancer is the third most diagnosed cancer in men (after prostate and lung cancers) and the second one in women (after breast cancer). It is the second cause of cancer death in men (after lung cancer) and the third one in women (after breast and lung cancers). Colon cancer and rectal cancer are often grouped together because they have many features in common. It is estimated that, in EU-27 countries in 2020, colorectal cancer accounted for 12.7% of all new cancer diagnoses and 12.4% of all deaths due to cancer. That made it the second most frequently occurring cancer (after breast cancer) and the second cause of cancer death (after lung cancer)".

"The project stems from the experience carried out at the San Raffaele Research Center in Rome, where an interinstitutional and multidisciplinary biobank database was created back in 2006 for the application of Artificial Intelligence methodologies aimed at the development of predictive medicine protocols," explains Prof. Fiorella Guadagni, REVERT project Coordinator, Head of the BioBIM® Biobank and associated database at San Raffaele Research Center and Full Professor of Clinical Biochemistry and Clinical Molecular Biology at the San Raffaele Open University of Rome. "The goal", she says, "is to build an innovative Artificial Intelligence-based decision support system using the experience and real-world data of several general hospitals operating in the EU healthcare system for an innovative combinatorial therapy model, based on a personalized medicine approach, which identifies the most effective therapeutic intervention for each individual colorectal cancer patient".

Through this innovative model, based on Artificial Intelligence, the aim of the study is to personalize the therapeutic treatment of patients with unresectable metastatic colorectal cancer by identifying the most effective intervention for each patient.

"The clinical study will test the predictive efficacy of Artificial Intelligence on a case-by-case basis from a 'personalized' perspective", explains Prof. Mario Roselli, Director of the Medical Oncology Unit at the University Hospital Tor Vergata and Full Professor at the same University. "The predictive algorithm", he continues, "has been previously 'trained' through retrospective evaluation of the clinical profiles of patients already treated at the Oncology Units participating in the project and who, based on their response to treatment, has been defined as 'responder' or 'non-responder'. This algorithm, applied to new patients enrolled in the clinical study, will allow the investigators to be supported in choosing the best therapeutic option. Finally," Prof. Roselli concludes, "although the REVERT trial is specifically aimed at metastatic colorectal disease, its results are expected to have a positive impact on other types of cancer."

Among the European partners, beyond the San Raffaele *Research Center* (REVERT project Coordinator) and the University Hospital 'Tor Vergata', the REVERT project involves 7 Medical Oncology Units from 3 different European countries that will be in charge for patient enrollment: the University of Rome 'Tor Vergata' (clinical coordinating Center), the Careggi University Hospital of Florence and the University Hospital of





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Palermo "P. Giaccone" (Italy); the Regional Institute of Oncology of Iasi and the Clusterul Regional Inovativ de Imagistica Moleculara Structurala (both in Romania); the Servicio Murciano De Salud (Spain).

Non-clinical partners participating in the project include: ProMIS – Programma Mattone Internazionale Salute (Italy), responsible for dissemination and communication of the project results, Malmo Universitet (Sweden), Umea Universitet (Sweden), Genxpro GMBH (Germany), Bundesanstalt Fuermaterialforschung Und-Pruefung (Germany), Biovariance GMBH (Germany), Fundacion Universitaria San Antonio (Spain), Luxembourg Institute of Health (Luxembourg) and Olomedia (Italy).

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