

The announcement today, just days after the conclusion of the ASCO congress in Chicago

Oncology, the 'microenvironment' is the super challenge of diagnostics Genomic tests are now used to create 50% of drugs. Aiming for 100%, Diatech creates the first expert board for new guidelines

The tests refer to the diagnostic standards required by the Ministry of Health, medical associations (SIAPEC, AIOM, ESMO) and drug regulatory bodies (AIFA, EMA). Also on the way are kits for monitoring tumours over time and computer systems for simulating the effects of cancer therapies

Jesi, June 8th 2023 - Today, sequencing tumours means finding a genomic alteration in 50 per cent of cases. This is where many of the new drugs come from. The goal is to get to 100%. That is why knowing the genetic composition and molecular characteristics of the tumour will be increasingly important. The breakthrough will come from genomic research on the 'microenvironment', i.e. the inflammatory component that enables the tumour to evade the body's defence mechanisms. This can only happen through increasingly advanced tests, analysis instruments and data interpretation software. But above all through a process of 'democratising' access to tests, which is only possible by extending their use to all tumour types, and by equipping laboratories with reliable and easy-to-perform systems. Whether traditional biopsies or 'liquid' biopsies (a blood sample), tests today also serve to monitor the progress of the disease, identifying further genetic mutations on which to readjust treatments. With the aim of guaranteeing the maximum quality of these tests and related software, and to identify initial guidelines, one of Europe's leading companies, an Italian excellence, Diatech Pharmacogenomics, has decided to set up an internal board of seven experts, multidisciplinary in nature, who took office today just a few days before the end of the American oncology congress ASCO in Chicago. These are internationally renowned academics who have distinguished themselves in the fields of biology, genetics, oncology and bioinformatics: Stefano Pileri (chairman), director of research at the Division of Haematopathology at the IEO in Milan; Reinhard Buettner, professor and director of the Institute of Pathology at the hospitals of Bonn and Cologne; Giuseppe Curigliano, full professor of Medical Oncology at the University of Milan and director of the Clinical Division of Early Drug Development at the IEO in Milan, as well as a member of the Consiglio Superiore della Sanità; Riccardo Dalla-Favera, professor of pathology and cell biology and director of the Institute of Cancer Genetics at Columbia University in New York; Umberto Malapelle, associate professor and director of the Laboratory of Predictive Molecular Pathology at the Department of Public Health of the Federico II University in Naples and scientific secretary of the International Liquid Biopsy Society; Bertrand Nadel, laboratory director at the Centre d'Immunologie de Marseille-Luminy (CIML); Raul Rabadan, professor at the Department of Systems Biology at Columbia University and director of the Program for Mathematical Genomics.

“Over the last ten years, precision medicine has made enormous progress in terms of personalising treatment and reducing side effects,” explains **Prof. Curigliano**. 'This is thanks to the

study of genomics and immunomics, two different worlds that work in parallel in an area that goes from treatment, towards the future of prevention, with the study of mRNA vaccines tailored just like drugs. Today, for not all cancers there is the possibility of benefiting from targeted therapies against specific genomic alterations. This is why it is crucial to work together to widen access to tests for the genomic characterisation of tumours, in other words, to democratise access to precision medicine. If we sequence tumours, we have a 50 percent chance of finding a genomic alteration on which we can then build a personalised and more effective therapy pathway”.

“If sequencing techniques make it possible to identify gene alterations in tumour cells with diagnostic and therapeutic value,” **Prof. Pileri** continues, “a new scenario is opening up with regard to the accompanying inflammatory component (microenvironment). Indeed, it plays an equally important role in detecting tumour progression and response to therapy, its composition being influenced by the neoplastic elements themselves through a complex network of signals. In particular, the microenvironment enables the neoplasm to evade the body's defence mechanisms ('tolerogenic effect'). Not coincidentally, several of the new smart drugs such as immune checkpoint inhibitors act not only on the pathological elements, but also on the inflammatory population, contributing to its remodelling. Fine-tuned knowledge of the characteristics of the microenvironment can, among other things, predict the response or non-response to therapy, which is relevant when using high-cost drugs. This has led to the development of new molecular technologies specifically tailored to interrogate the microenvironment, whose defining power extends to the cell-cell relation”.

“Today, it is liquid biopsy that represents the future of gene diagnosis in solid tumour patients,” adds **Prof. Malapelle**. “Given the technological advances of recent years and the possibility of applying next-generation gene sequencing strategies to circulating free nucleic acids (cfDNA) extracted from biofluids of solid tumour patients, the ability to extract an important amount of dynamic information concerning the biological evolution of that specific tumour is now in our hands. In many cases, liquid biopsy allows us to complement the information we obtain from tissue characterisation of the same patients, and this will be the way forward in the coming years, ensuring, for instance, a better molecular assessment of the patient population to be eligible for treatment with molecularly targeted drugs”.

"Over the last five years, the progress made by technology in pathological anatomy, in the development of intelligent oncological drugs, in analysis instrumentation and data interpretation software, has been extraordinary, enabling us to develop increasingly high-performance solutions for treating cancer,' explains **Fabio Biondi**, President and founder of Diatech Pharmacogenetics. 'Hence the need and desire of Diatech to create a multidisciplinary scientific board represented by the leading experts in this field. The union of these talents will promote a discussion on advances in research and technology that will be able to generate the scientific guidelines to anticipate the future of molecular target therapy. The synergy between the world of science and the world of biotech, if successful, is able to anticipate the future needs of the patient and consequently produce increasingly sophisticated diagnostic solutions”.