The SAGITTARIUS project, for a personalised colon cancer therapy

The SAGITTARIUS project, supported by the European Union's Horizon Europe programme, will use the liquid biopsy, an **innovative precision medicine approach**, with the aim to provide patients undergoing surgery for locoregional colon cancer (high-risk stage II and operable stage III) with a therapy that is more targeted at the molecular characteristics of their disease. In this way, the results obtained by SAGITTARIUS could help to improve the effectiveness of treatments for this type of cancer, together with the quality of life of patients and health costs compared to today.

The SAGITTARIUS project is coordinated and sponsored by the **Institute of Molecular Oncology - IFOM** (Italy), in collaboration with the **AIRC Foundation for Cancer Research** (Italy), the **Hospital del Mar Research Institute** in Barcelona (Spain), the **Bocconi University** (Italy), the **Digestive Cancers Europe** (Belgium), **SporeData OU** (Estonia), the **Vall d'Hebron Institute of Oncology - VHIO** (Spain) and the **Berlin Charité University Hospital - Universitätsmedizin** (Germany).

Using liquid biopsy to assess the presence or absence of micrometastases after surgery, the study aims to evaluate whether analyzing the characteristics of the tumours of colon cancer patients may help **personalise the management and therapy of patients** with high-risk stage II colon cancer and operable stage III colon cancer. The clinical trial will personalize treatments **on two fronts: on the one hand, avoiding chemotherapy in those who may not need it, and on the other by replacing chemotherapy with other biological and immunological treatments based on the molecular characteristics of the tumour**.

The first challenge of the SAGITTARIUS clinical trial is to **recruit 900 patients while meeting rigorous medical criteria and the schedule** which is needed to complete the tests for each patient's treatment assignment. Patients should enter the study within 2-3 weeks after surgery, which is only possible through close collaboration and coordination between surgeons and pathologists and medical oncologists in participating centres.

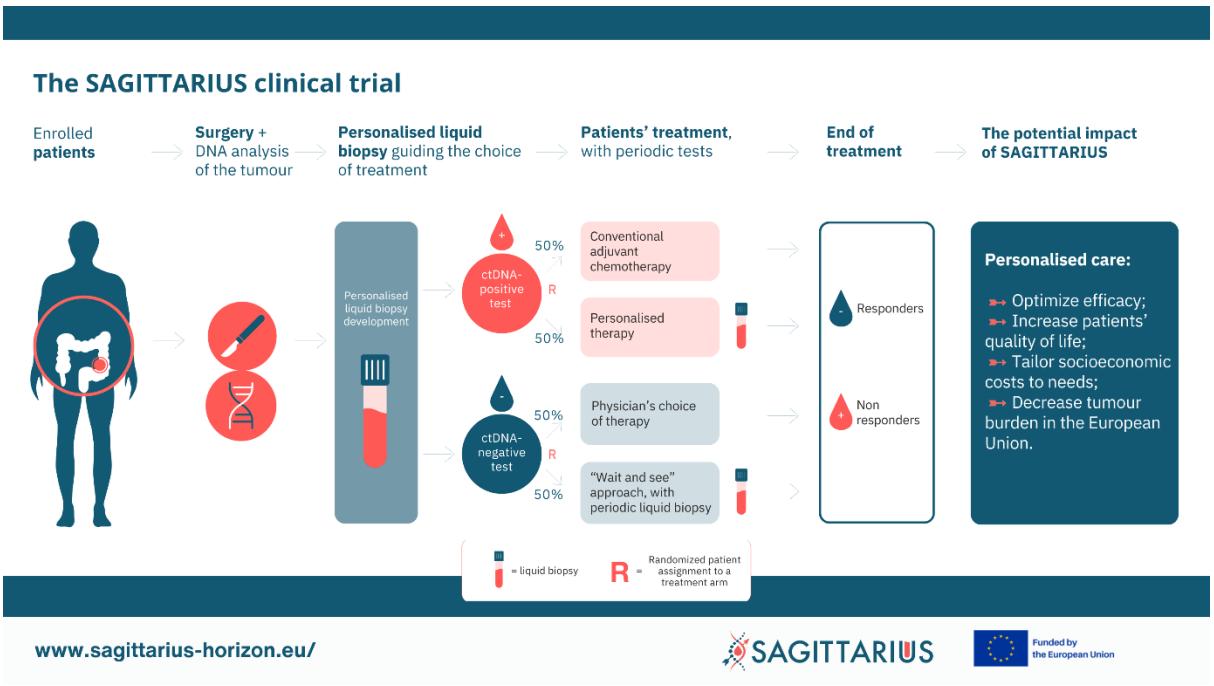
How will the clinical trial be conducted?

First, each patient's tumour tissue will be analysed to identify the tumour's "molecular signature". This will be used to personalize the liquid biopsy test for each patient, thus determining whether or not a micrometastatic disease is present.

If the test detects micrometastasis, patients will be randomly assigned to two groups: either the group receiving standard adjuvant chemotherapy or the group treated with customized therapies such as molecular target drugs or immunotherapy, based on the molecular characteristics of the tumour.

If micrometastases are absent, patients, potentially already treated by surgery, will be randomly divided into a group treated with mild therapies chosen by the doctor or the group with a "wait and see" approach, that is the patient's monitoring for 2 years after surgery without further treatment.

In any case, SAGITTARIUS experts will carry out periodic tests, adjusting treatments as necessary.



The SAGITTARIUS clinical network

The participating oncology centres include:

For Italy:

- Ospedale Niguarda (Milan), Salvatore Siena e Andrea Sartore-Bianchi;
- Istituto Clinico Humanitas (Rozzano), Armando Santoro;
- Istituto Europeo di Oncologia (Milan), Maria Giulia Zampino;
- Fondazione Poliambulanza (Brescia), Michela Libertini;
- Azienda Unità Sanitaria Locale della Romagna (Ravenna), Stefano Tamberi;
- Ospedale Maggiore di Novara (Novara), Alessandra Gennari;
- Istituto di Candiolo (Candiolo), Elisabetta Fenocchio;
- Policlinico Universitario Gemelli (Rome), Lisa Salvatore;
- Azienda Ospedaliera Universitaria San Martino (Genova), Maria Stefania Sciallero;
- Azienda Ospedaliera Universitaria di Parma (Parma), Francesca Negri;
- Ospedale Santa Maria della Misericordia (Perugia), Mario Mandalà;
- Azienda Sanitaria Locale di Biella (Biella), Francesco Leone.

For Spain:

- Hospital del Mar (Barcelona), Clara Montagut;
- Hospital Vall d'Hebrón (Barcelona), Elena Élez;
- Hospital Sant Pau Barcelona (Barcelona), David Páez;
- Instituto Catalán de Oncologia (Barcelona), Cristina Santos;
- Hospital 12 de Octubre (Madrid), Cristina Graválos;
- Hospital Clinico Universitario San Carlos (Madrid), Javier Sastre;
- INCLIVA Instituto de Investigación Sanitaria (València), Noelia Tarazona;
- Hospital General Universitario de València (València), Maria José Safont;
- Hospital Universitario Marqués de Valdecilla (Santander, Cantabria), Carlos López;
- Hospital Universitario Reina Sofía (Córdoba), Enrique Aranda;
- Hospital Clínico Universitario de Santiago (Santiago de Compostela), Juan Ruiz;
- Hospital Universitario Miguel Servet (Zaragoza), Vicente Alonso;
- Complejo Hospitalario de Navarra (Navarra), Ruth Vera.

For Germany:

- Charité - Universitätsmedizin Berlin (Berlino), Sebastian Stintzing e Loredana Vecchione.

Clinical study coordinator centres

Ospedale Niguarda Cancer Center · Sistema Socio Sanitario Regione Lombardia · Oncologia Niguarda · Hospital del Mar Research Institute Barcelona · Charité Universitätsmedizin Berlin

SAGITTARIUS consortium

IFOM · cogentech · AIRC · Hospital del Mar Research Institute Barcelona · Università Bocconi Milano · Digestive Cancers Europe · Spore Data · VHIO · Charité Universitätsmedizin Berlin

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