

European experts to discuss the new EU-funded clinical trial SAGITTARIUS, towards a precision medicine approach for colon cancer care

Locoregional colon cancer: investigating a precision medicine approach based on liquid biopsy and tumor genomics with the new EU-funded clinical trial SAGITTARIUS

13th May 2024 – Hospital del Mar Research Institute, Barcelona, Spain

15th May 2024 – Grande Ospedale Metropolitano Niguarda, Milan, Italy

Physicians, scientists, health economics researchers, data and communication experts from the Horizon Europe project SAGITTARIUS joined oncology specialists and members of an EU-wide community of cancer centres in Barcelona and Milan to **present the SAGITTARIUS clinical study**, a new EU-funded clinical trial leveraging the power of tumor genomics and liquid biopsy to guide the **post-surgical care of patients with locoregional colon cancer**.

Hosted by **Niguarda Cancer Center and Fondazione Oncologia Niguarda in Milan** and by **Hospital del Mar Research Institute in Barcelona**, the Spanish-Italian twin events discussed the clinical scenario in which the SAGITTARIUS study will take place, its design and more in-depth technical aspects of this innovative trial.

One of the twelve pragmatic clinical trials funded by the Horizon Europe Program under the EU Mission on Cancer, SAGITTARIUS is the first phase-III randomised clinical study in Europe **testing an individualized, tumor-informed liquid biopsy approach to optimize treatment in locoregional colon cancer**.

The SAGITTARIUS trial involves a **network of 26 EU clinical centres** and plan to recruit around 700-900 patients in **Spain, Germany, and Italy**, under the expert guide of **Clara Montagut**, from the **Hospital del Mar Research Institute (HMRIB)**, as a study chair. **Elena Élez** from **Vall d'Hebron Institute of Oncology (VHIO)**, **Sebastian Stintzing** from **Charité - Universitätsmedizin Berlin**, and **Andrea Sartore-Bianchi** from **Grande Ospedale Metropolitano Niguarda** will be the study co-chairs, respectively for Spain, Germany and Italy, along with **Salvatore Siena** (Niguarda Cancer Center and University of Milan) as **principal investigator** of the coordinating centre in Italy.

How can SAGITTARIUS make the difference?

Every year, **350.000 Europeans are diagnosed with colon cancer** and more than 150.000 die of it. The 5-year survival rate of this cancer in Europe ranges from 40% to 60%, with national differences. Local disease (stage I and stage II low-risk colon cancer) is mostly manageable with surgery alone. In contrast, loco-regional disease (high-risk stage II and stage III colon cancer) requires more. People with this type of colon cancer are recommended to have both surgery, to remove the tumor, and post-surgery chemotherapy (called adjuvant chemotherapy), to eliminate any residual cancer cell. Approximately **one-third of patients with loco-regional colon cancer**, in fact, are at **risk of recurrence after surgery** due to the presence of a **residual microscopic disease** which is **currently undetectable** by the available radiological techniques. Although not everyone benefits from the treatment, adjuvant chemotherapy is prescribed post-surgery to almost all patients since there is not an adequate instrument to distinguish who is at risk of having a minimal residual disease and who is not.

Liquid biopsy is a new innovative assay for detecting circulating tumor DNA (ctDNA) in the blood. This minimally invasive analysis has been recently shown to **identify cases with micrometastatic molecular disease** not yet diagnosable by imaging techniques.

“**SAGITTARIUS will capture the individual tumor genetic characteristics to generate a personalized liquid biopsy test** for detecting ctDNA in patients’ blood, identifying who has micrometastases and suggesting the most appropriate treatment, tailored on the specific molecular features of a patient’s tumor. With liquid biopsy we will also follow therapy response in order to **dynamically personalize the treatment**, with the aim to improve both the clinical outcome and the quality of life of each patient” explained **Silvia Marsoni** from IFOM, SAGITTARIUS project coordinator and clinical study sponsor.

“We know that ctDNA, detected through liquid biopsy, is a powerful tool to assess the risk for these patients, but we need to better know how to treat them after surgery” shared **Elena Élez**, principal investigator for SAGITTARIUS at VHIO.

“In patients with micrometastatic disease, **we will investigate which of two strategies, the conventional chemotherapy or a personalized therapy** designed according to the results of the liquid biopsy analysis, is **the most effective treatment option**. While in patients with no evidence in the blood of micrometastatic disease we will test if a wait-and-see approach based on the **active surveillance** of patients by means of several repeated liquid biopsies, is better than a pharmacological treatment. **Our aim**, in fact, is to **reduce unnecessary toxicity and improve patients’ quality of life**” said the clinical study leader **Clara Montagut**.

Sebastian Stintzing, principal investigator for SAGITTARIUS at Charité - Universitätsmedizin Berlin, also underlined that “By now, we have no precision oncology in

adjuvant treatment, but this trial really has the potential to optimize treatment for patients in the early setting of adjuvant colorectal cancer”.

The clinical network of the SAGITTARIUS trial

SAGITTARIUS approach to the post-surgical care of patients with operable locoregional colon cancer will be experimentally tested across the EU in three different countries: Italy, Germany and Spain. The participating Cancer Centers include:

for Italy:

- Grande Ospedale Metropolitano Niguarda (Milan), Salvatore Siena and 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), Patrizia Racca
- Policlinico Universitario Gemelli (Roma), 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 Oncología (Barcelona), Cristina Santos
- Hospital 12 de Octubre (Madrid), Cristina Graválos
- Hospital Clínico 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 (Berlin), Sebastian Stintzing and Loredana Vecchione

“Thanks to a recent study conducted by our research groups, PEGASUS, using liquid biopsy we have identified some characteristics that allow us to distinguish the patients who benefit most from precautionary post-surgical chemotherapy for colon cancer. Based on this knowledge, the SAGITTARIUS study aims to determine whether precautionary therapies with molecular or immunological targets are better than the standard therapies currently used. **We have good indications** that the results will be positive, but it is only the SAGITTARIUS study, a phase III study of postsurgical precautionary therapy, that will be able to confirm this. Having such **important and qualified centers** all dedicated to the same study will allow us to offer the study results to the scientific and colon cancer patient communities in a timely and efficient manner” declared **Salvatore Siena** from Grande Ospedale Metropolitano Niguarda.

In the frame of the Horizon Europe project SAGITTARIUS

The SAGITTARIUS trial is the centerpiece of the newly started, homonymous project funded by the European Union under the Horizon Europe program, which will measure the potential of the SAGITTARIUS clinical approach considering multiple aspects, which include also the cost-effectiveness of using liquid biopsy to decide the post-surgical care for patients with either high-risk stage II or stage III colon cancer and its impact on the patient’s quality of life, health and sense of wellbeing.

Moreover, thanks to a dedicated omics subproject, SAGITTARIUS will shed new light on the ability of cancer cells to spread and evolve.

The SAGITTARIUS project includes partners and affiliated entities from 5 different European countries, Italy, Belgium, Estonia, Spain, and Germany:

- **IFOM – the AIRC Institute of Molecular Oncology**, led by Silvia Marsoni, which manages the SAGITTARIUS project and its clinical trial;
- **Cogentech** (Milan, Italy), IFOM affiliated partner. In the person of Marco A. Pierotti, the company takes care of the tumor genetic profiling analyses;
- The **AIRC Foundation for Cancer Research** (Milan, Italy), with the coordination of Cristina Zorzoli, is involved in stakeholder engagement and communication, dissemination and exploitation of project results;
- **Hospital del Mar Research Institute** (HMRIB), from Barcelona (Spain), is led by Clara Montagut. It takes care of clinical trial execution and leads the Spanish clinical centres participating in the project;

- The **Centre for Research on Health and Social Care Management (CERGAS)** from **Bocconi University** (Milan, Italy), with the coordination of Aleksandra Torbica and Carlo Baldassarre Federici, is in charge of the health economics aspects of the trial;
- **Digestive Cancers Europe (DiCE)**, from Brussels (Belgium), with the coordination of Zorana Maravic and Marianna Vitaloni. Together with AIRC, DiCE manages stakeholder engagement, communication, and dissemination of SAGITTARIUS results, and is in charge of assessing the impact of the SAGITTARIUS approach on patients' quality of life;
- **SporeData OU**, from Tallinn (Estonia), led by Ricardo Pietrobon, takes care of the integrative analysis of project data;
- **Vall d'Hebron Institute of Oncology (VHIO)**, from Barcelona (Spain). Led by Elena Élez, VHIO takes care of clinical trial execution and is involved in the cost-effectiveness analyses;
- **Charité - Universitätsmedizin Berlin** (Germany), guided by Sebastian Stintzing, takes care of the clinical trial execution and coordinates the clinical study in Germany.

For more information

On <https://sagittarius-horizon.eu/> you can download:

- both short-version and long-version of this press release;
- SAGITTARIUS logos;
- useful factsheets on the SAGITTARIUS project and liquid biopsy;
- information about SAGITTARIUS partners and coordinating clinical centres and their logos;
- useful infographics.

Key news will also be shared on SAGITTARIUS site, newsletter and social media profiles: [LinkedIn](#), [Facebook](#), [X](#), [Instagram](#), [YouTube](#).

To set up interviews with SAGITTARIUS leaders, please contact SAGITTARIUS Communication and Media Relations Managers at info@sagittarius-horizon.eu.

Clinical study coordinator centres



SAGITTARIUS consortium





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