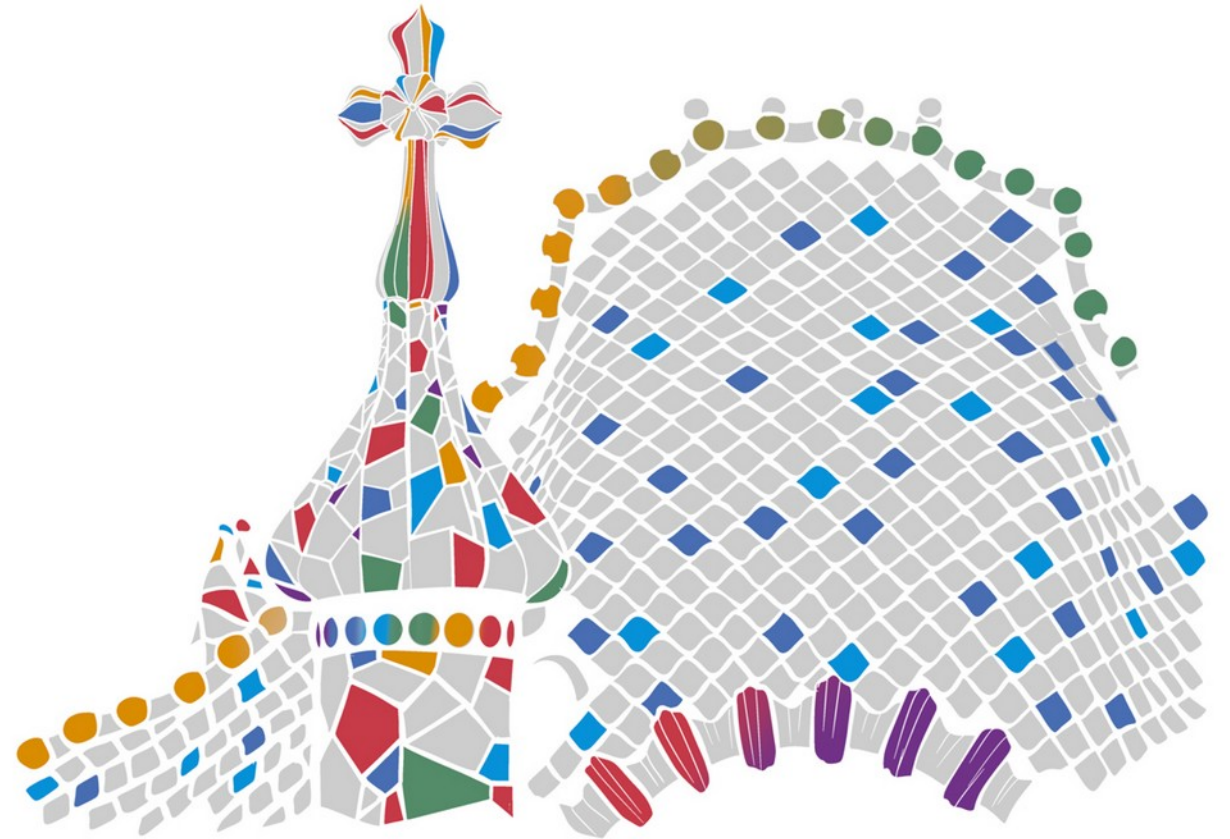




**DIGESTIVE CANCERS**  
EUROPE

8<sup>TH</sup> ANNUAL MASTERCLASS  
29 JUNE – 01 JULY 2023  
BARCELONA



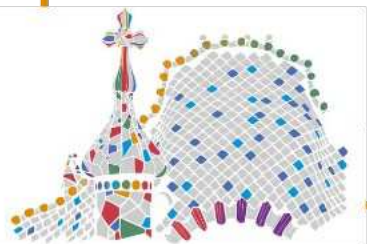
# Patient Co-Creation in Clinical Trials

Marianna Vitaloni  
Digestive Cancers Europe

# Patient Co-Creation

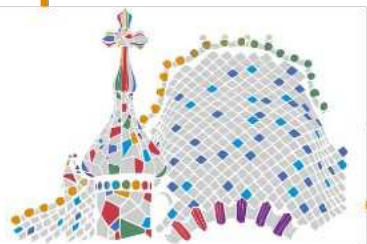
- Patient co-creation is an approach that values patient engagement in the design, development, and delivery of solutions for patient use.
- This model focuses on building trust between patients and providers by engaging with patients throughout all stages of the development process.

- **Not a  exercise to make sure the project proposal looks better**



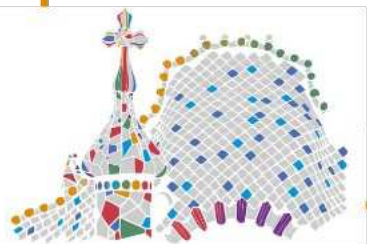
# Why is it important?

- Creates **better outcomes**.
- Encourages **open dialogue and collaboration** between all parties, allowing for the sharing of ideas, experiences, and perspectives that can help inform decisions.
- Allows for **feedback from patients** to be incorporated into the design, planning, and delivery of healthcare services.
- Helps to gain a better understanding of **how to improve services**. This information can be used to inform decisions about how to create **more effective and tailored care solutions for patients**



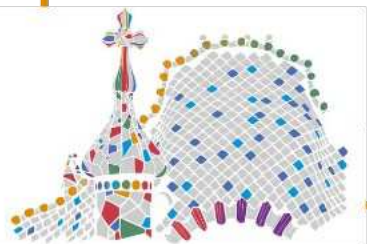
# Benefits of Patient Co-Creation

- Allows healthcare organisations to access **valuable patient insights** and incorporate them into their decision-making process.
- **Tailor services to meet individual needs.**
- **Strengthen communication** programs and improve communication strategies.
- Provide more **effective and personalised services** to patients.
- **Build trust** with the community by including the patient voice.



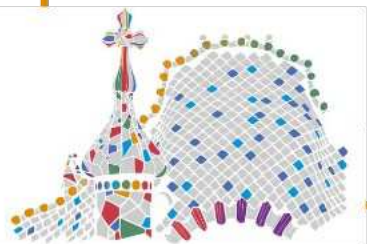
# Barriers...

- Traditional **paternalistic and hierarchical organization of medicine**, with an emphasis on physician autonomy. The hierarchical nature of healthcare settings can create an imbalance of power in meetings, placing patients and patient advocates at a disadvantage.
- Complexity in process and low patient **health literacy**
- **Conflicts of interest**



# DiCE strategies

- Focus Groups
- Surveys
- Patient Advisory Committee
- Patient Advisory Board
- One-to-one interviews
- Feedback on documents
- Dissemination of the results



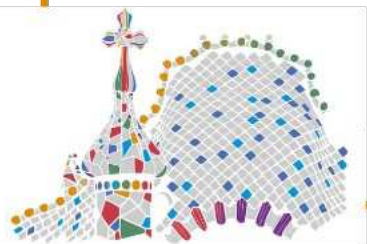
# Sagittarius Clinical Trial

*8 Partners from 5 countries.*

*Coordinated by IFOM in Milan*

*5 years project*

- Aim to optimize the clinical management of **locoregional stage II high-risk/stage III colon cancer**.
- **Pragmatic Clinical Trial** in three countries (Spain, Italy and Germany)
- Will deploy a **ctDNA assay** to detect the absence, presence, or persistence of **micro-metastatic residual disease (MMRD)** in individual patients.
- The diagnosis of MMRD will guide and **personalize therapeutic interventions**.
- Stakeholders engagement, Communication, dissemination, and exploitation.

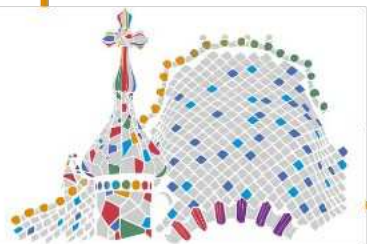


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# Sagittarius: the role of DiCE

## Patients Engagement

- Selection of the most suitable PRO to be used during the clinical trial by means of a patient focus group
- Feedback on the information sheet and consent form
- Feedback on the study protocol
- Infographic to explain the trial
- Educational materials for patients participating in the clinical trial
- Educational toolkit on ctDNA analysis and its impact on personalized treatment





# GUIDE.MRD

*22 Partners from 13 countries.*

*Coordinated by University of Hamburg*

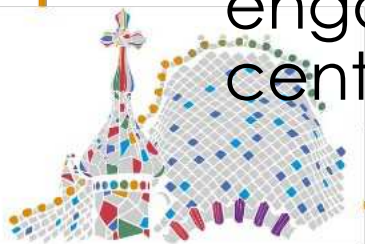
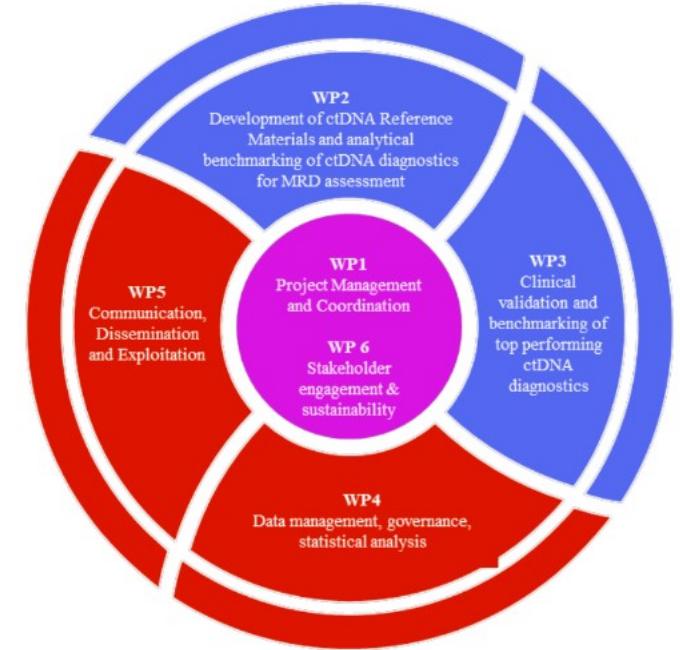
*5 years project*

A people centered precision oncology project designed to improve the utility and clinical implementation of ctDNA as biomarker of MRD to predict clinical response and choice of multi-modal therapy for patients with solid tumour malignancies.

- To **benchmark available circulating tumor DNA (ctDNA) assays** for sensitivity, specificity, and predictive value in the **adjuvant setting**, where minimal residual disease (MRD) is indicative of disease progression.
- To **clinically validate the top ranking ctDNA assays prospectively** in patients diagnosed with non-small cell lung cancer (NSCLC), colorectal carcinoma (CRC) and pancreatic ductal adenocarcinoma (PDAC) and **produce a patient-centric roadmap for the clinical implementation of ctDNA diagnostics.**
- To **determine the utility of ctDNA assays as prospective decision tools** of clinical response and choice of multi-modal therapy including novel combination therapies.

# GUIDE.MRD the role of DiCE

- Set up a **Patient Advisory Board**, representing, EU patient organizations, people with cancer and caregivers across lung, colorectal and pancreatic cancers, with DiCE and LuCE, to understand patients' needs and experiences along the care pathway, and particularly post-surgery and prior to relapse.
- **Engagement of the Patient Advisory Board** individual organizations, individuals and caregivers across the entire process of research & development to ensure patient engagement in project research and outcomes are patient-centered.



# Conclusion

- In DiCE we believe in the power of Patient Co-Creation
- Part of our mission is to make Patient Co-Creation a reality in every CT
- Strengthening relationships with Institutions and Researchers believing in the importance of Patient Co-Creation
- Working on overcoming barriers
- Not playing the tick box game



# Thank you!



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