

# EORTC 1409-GITCG CLIMB: An EORTC-ESSO Prospective Colorectal Liver Metastasis Database with an Integrated Quality Assurance Program

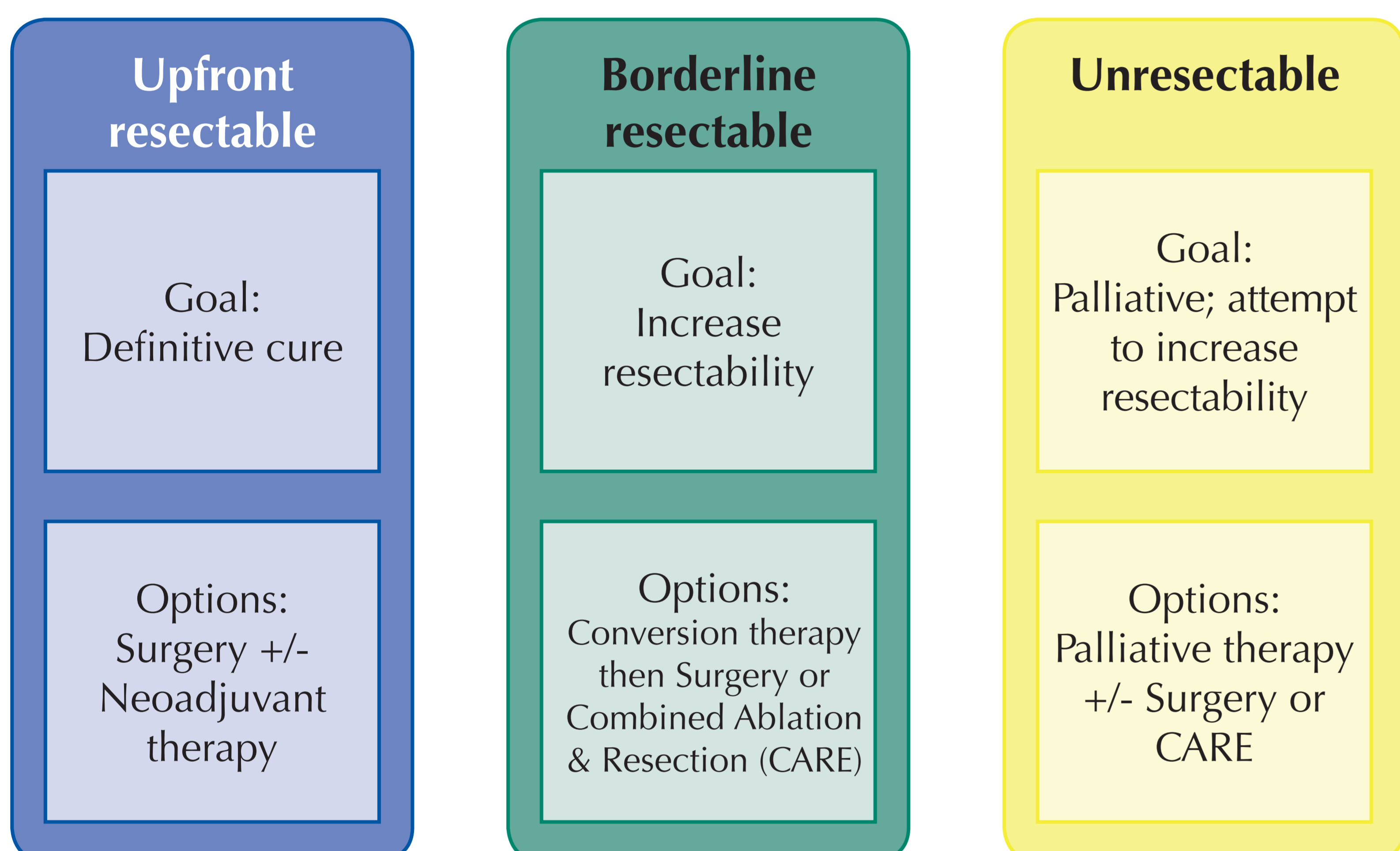
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## CONCEPT OVERVIEW

- The definition of resectability of colorectal liver metastasis (CRLM) has broadened because of better systemic therapy and diagnostic modalities.
- Different surgical techniques are now possible depending on:
  - Future remnant liver volume
  - Possibility to achieve R0 resection
- However, prospective and high quality data are lacking to determine the impact on survival of these techniques.

## CURRENT TREATMENT FOR COLORECTAL LIVER METASTASIS



## KEY QUESTIONS TO BE ANSWERED

1. Which surgical treatment strategy leads to best over-all survival?
2. Do multiple complex surgeries improve patient outcomes?
3. What is the impact of different treatment combinations to over-all survival?
4. Can we benchmark quality of liver metastasis surgery?
5. Can innovative research methodologies generate high quality data in surgical research?

## IMPACT OF CLIMB

- CLIMB will benchmark the quality liver metastasis surgery in Europe through high quality, real-life data about different treatment strategies with complex CRLM.
- This is the first project between EORTC and the European Society of Surgical Oncology (ESSO) that will initiate more prospective surgical clinical research within and beyond Europe

## OBJECTIVES

- To benchmark quality of liver metastasis surgery in Europe by documenting morbidity and mortality rates from different surgical strategies for unresectable, borderline resectable or initially unresectable CRLM
- To determine long-term outcomes of patients who undergo different treatment strategies (different combinations of systemic treatment vs. multiple surgeries)

## STUDY ENDPOINTS

- Rate of Post-operative complications graded according to the Clavien and Dindo Classification of Surgical complications at 30 and 90 days
  - \* Sample size: at least 100 post-operative patients must be registered in the study within 1 year
  - \* Duration of follow-up: until 2 years from initial registration
- Over-all survival, progression free survival and recurrence rate based on the different treatment strategies (chemo and surgery)
- Proposal for Quality parameters for complex liver metastasis surgery

## DESCRIPTION OF PATIENT POPULATION

- Histologically proven colorectal adenocarcinoma with liver metastasis.
- With unresectable, borderline or initially unresectable liver metastasis assessed by a multi-disciplinary tumor board (MDT) before surgery
- With a possibility to undergo a surgical procedure after systemic treatment
- Age > 18 years
- Absence of other active malignancy and other exclusion criteria
- Written informed consent according to ICH/GCP regulations

## TRIAL DESIGN AND INTEGRATED QA PROGRAM

- Prospective observational clinical research
  - Patients are registered only after MDT
  - MDT must include at least a liver surgeon, oncologist and radiologist
- Data to be collected include:
  - MDT evaluation and plan
  - Surgery, post-operative complications
  - Pathology evaluation and Follow-up
- Site monitoring will be performed for quality assurance

## 16 PARTICIPATING CENTERS FOR SPECIALIZED LIVER SURGERY

Country	Institution
Austria	Rudolf Foundation Salzburg University Hospital
Belgium	Ghent University Hospital
Denmark	Aarhus University Hospital
France	Institute Bergonié Centre Leon Berard
Germany	Universitaetsklinikum Carl Gustav Carus
Italy	Policlinico Universitario Gemeilli Istituto Europeo di Oncologica
Norway	Oslo University Hospital
Spain	Hospital Universitario de Fuenlabrada
Sweden	Danderyd / Karolinska University Hospital
Switzerland	Hôpitaux Universitaires de Genève
The Netherlands	The Netherlands Cancer Institute Leiden University Medical Center
United Kingdom	Aintree University Hospital

## STUDY STATUS

- CLIMB is now open in 6 centers and is actively recruiting patients.
- All sites are expected to be open by second semester of 2015.
- High quality MDT have been confirmed among the participating sites through initial site visits.

## CORRESPONDENCE

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