Etudes PRODIGE

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Journées GERCOR 20 Septembre 2019

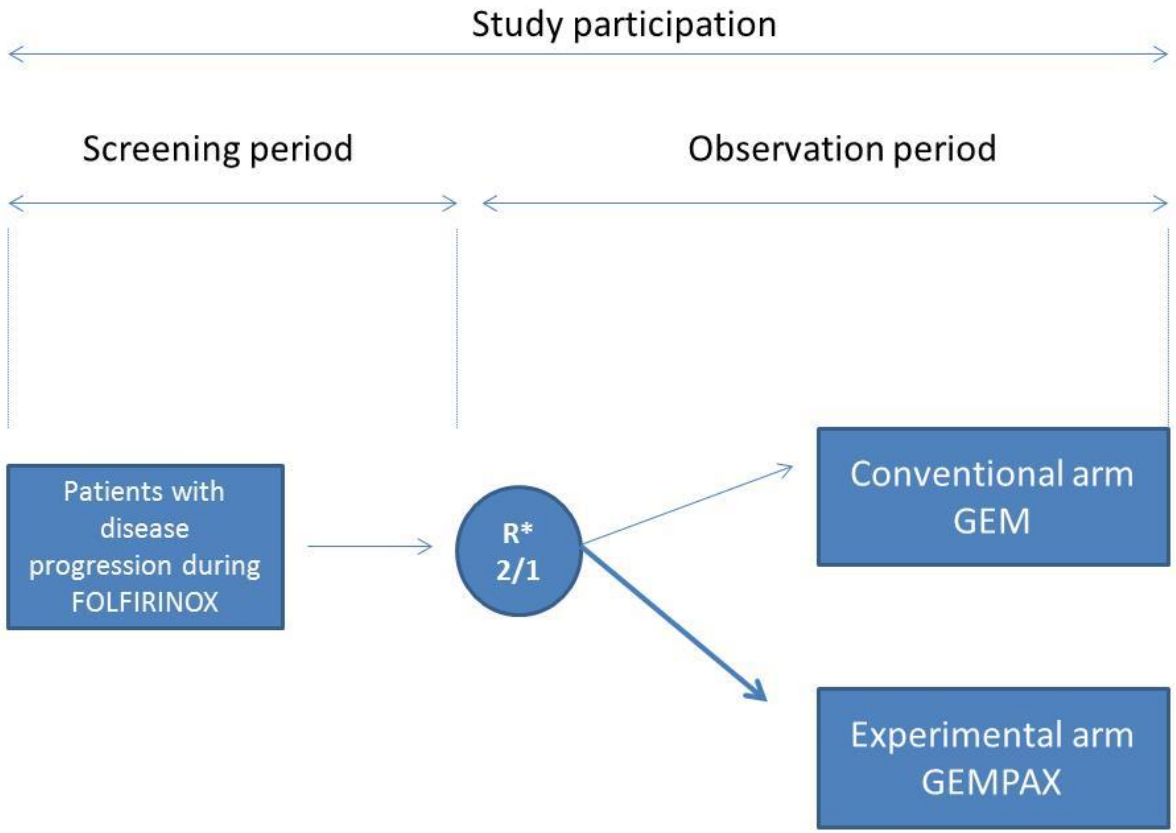
PRODIGE 65 - UCGI 36 - GEMPAX

A Phase III randomized study assesing gemcitabine and paclitaxel versus gemcitabine alone in Metastatic Pancreatic Adenocarcinoma after FOLFIRINOX failure

Coordinating Investigator: Dr. C. De La Fouchardière, Centre Léon Bérard, Lyon, FR

Co-coordinating investigators: Pr L. Dahan (FFCD); Pr P. Hammel (GERCOR)

Design:



Study timelines:

Start date of inclusions: June 2019

End of inclusions: June 2020

Number of patients to be randomized : 210

Number of sites expected : 21

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Primary objective:

To show the superiority in terms Overall Survival (OS) of gemcitabine + sb-paclitaxel over gemcitabine alone in metastatic pancreatic adenocarcinoma after FOLFIRINOX failure

Secondary objectives:

- Overall Response rate (RECIST 1.1 criteria) (ORR)
- Progression-Free Survival (PFS)
- Disease Control Rate (DCR) at 4 months
- Evolution of biomarkers (prognostic value & predictive value)
- Dose intensity of chemotherapy
- Safety and tolerability of treatment
- Patient reported Quality of Life (QoL)
- Rate of subsequent chemotherapy
- Translational research (cell-free circulating DNA, CTCs, plasma cytokines)

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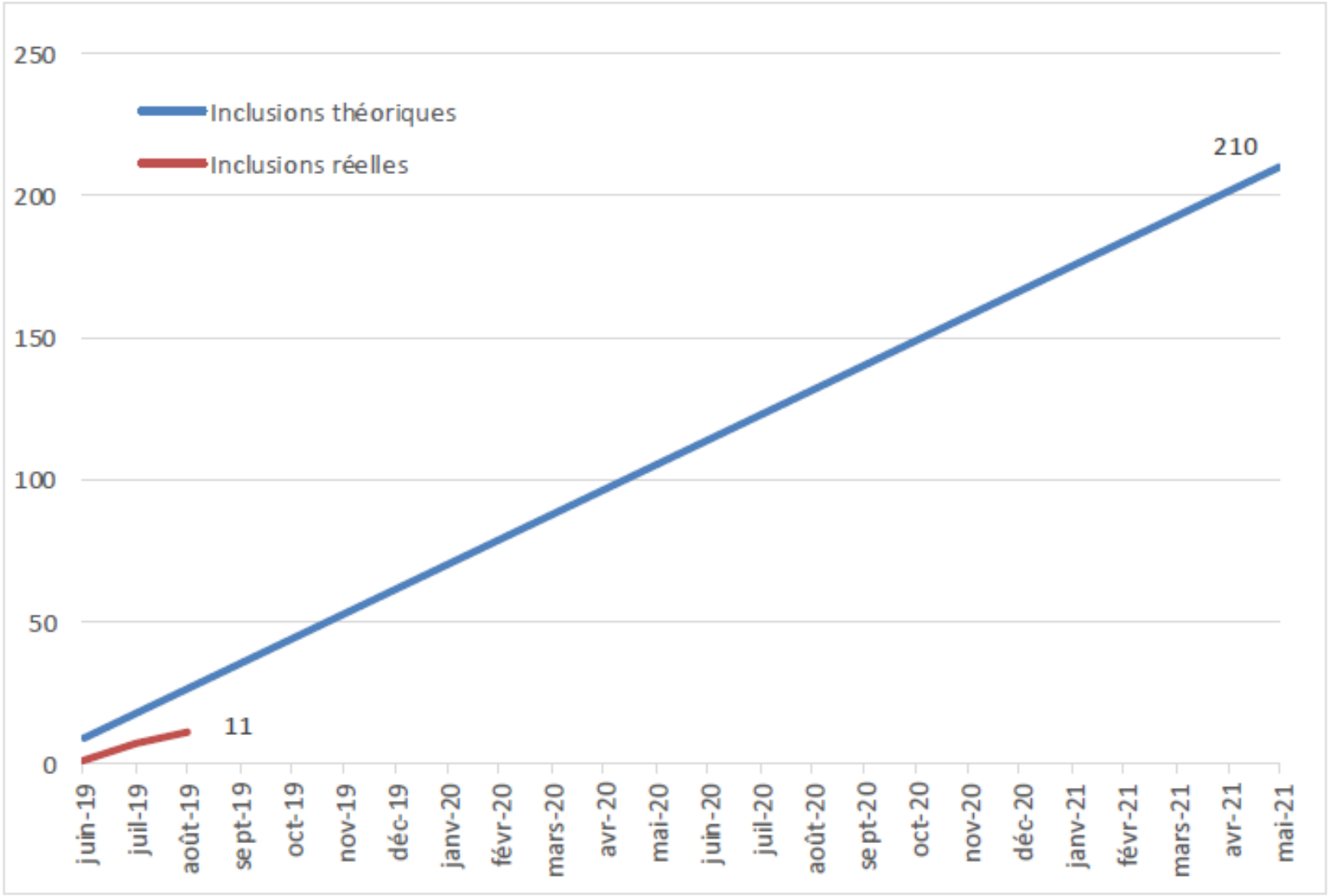


PRODIGE 58 – UCGI 35 - REGIRI

A randomized phase II trial assessing REGorafenib combined with IRInotecan as second-line treatment in patients with metastatic gastro-esophageal adenocarcinomas

Coordinating Investigator:

- Dr Emmanuelle SAMALIN-SCALZI (ICM Montpellier, FR)

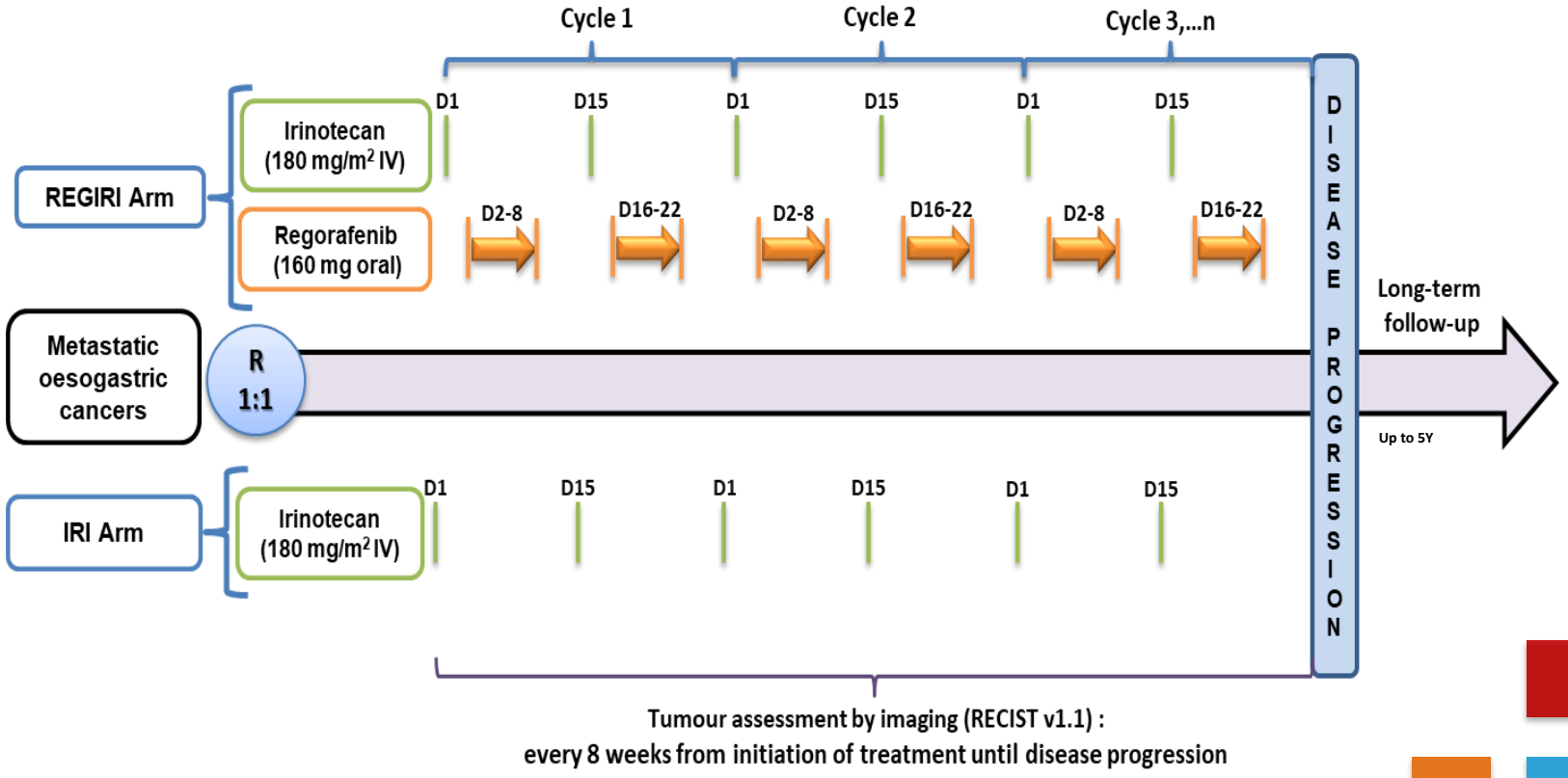
Co-coordinating investigators: Dr A. LOPEZ (FFCD); Dr A. TURPIN (GERCOR)

Study population:

- 154 adult patients
- Metastatic gastro-esophageal adenocarcinoma
- Second-line treatment after failure of first-line 5-FU + Pt

Design

- Open label, Randomized (1:1): Irinotecan +/- Regorafenib, Treatment until disease progression



PRODIGE 58 – UCGI 35 - REGIRI

A randomized phase II trial assessing REGorafenib combined with IRInotecan as second-line treatment in patients with metastatic gastro-esophageal adenocarcinomas

Study objectives:

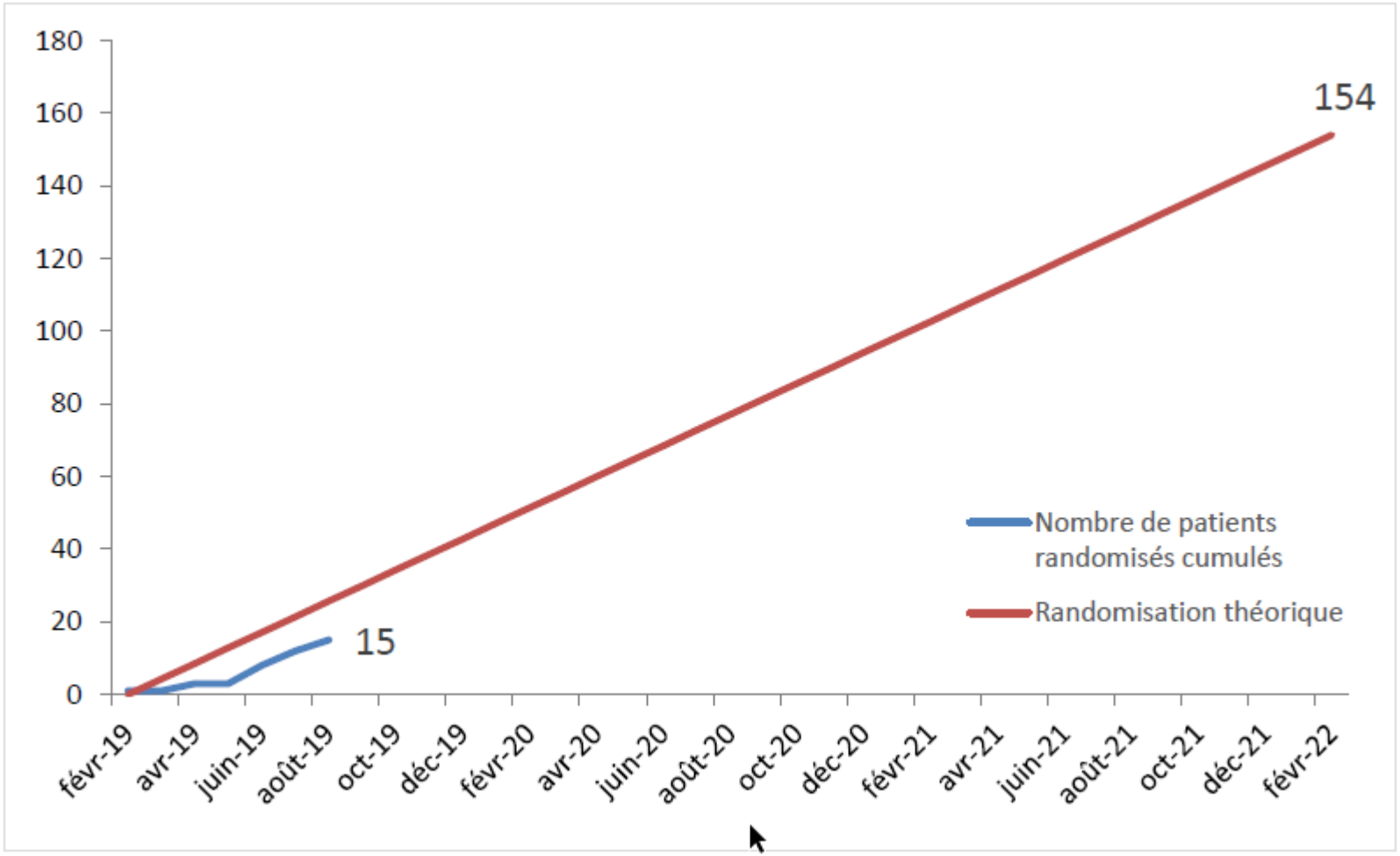
- **Primary objective: Overall Survival**
- **Secondary objectives:**
  - Efficacy: PFS, DCR, ORR according to RECIST 1.1 (no central review)
  - Safety
  - QoL
- **Ancillary studies:**
  - PK (regorafenib + irinotecan), Cyclin D1 polymorphisms, PG (biopsies)

Study timelines

- Inclusion period: 3 years (January 2019 – January 2022)
- Number of patients expected: 154 randomized patients // 3 patients randomized May 2019
- Number of sites expected: Around 15 sites (10 patients/site)

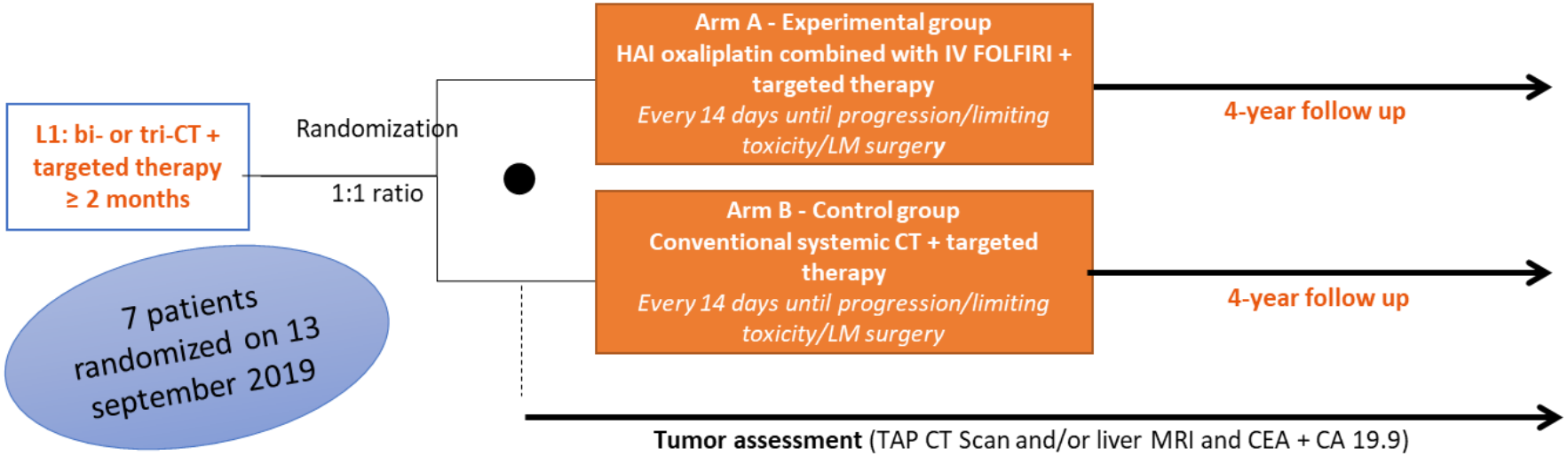
PRODIGE 58 – UCGI 35 - REGIRI

I. BILAN GLOBAL DES INCLUSIONS



PRODIGE 53 -UCGI 30- SULTAN

A randomized phase II study comparing treatment intensification with hepatic arterial infusion chemotherapy plus systemic chemotherapy to systemic chemotherapy alone in patients with liver-only colorectal metastases considered still non resectable after at least two months of systemic induction chemotherapy



Coordinating investigator: Docteur Valérie BOIGE (Gustave Roussy, Villejuif, France)

Co-coordinating investigator: Pr Julien Taïeb (HEGP, FFCD)

Pathology: liver-only colorectal metastases

Design : National, multicenter, randomized, phase II trial

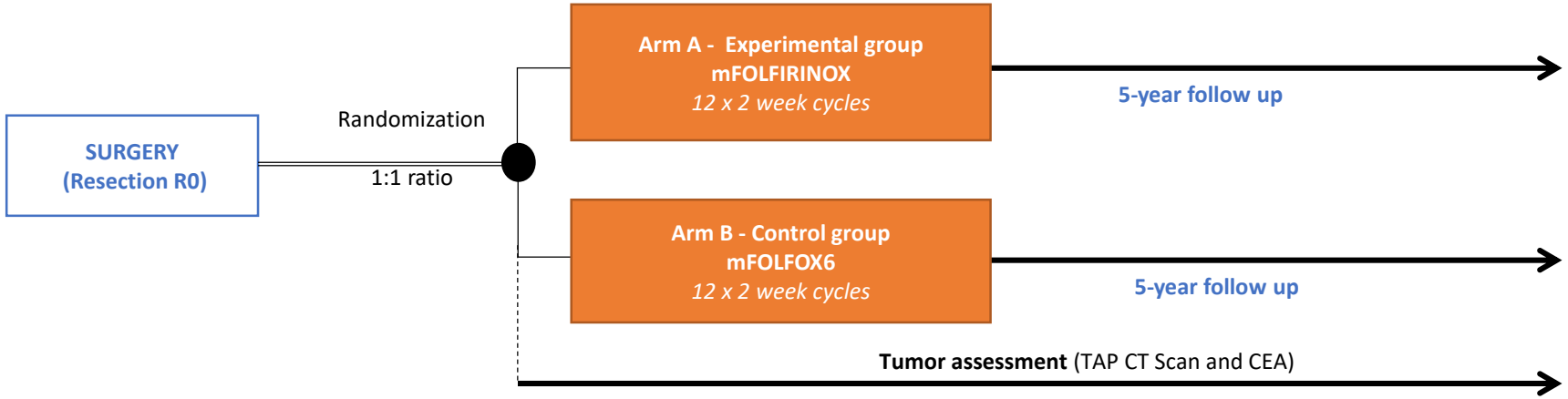
Primary objective: to compare the efficacy of CT intensification combining HAI oxaliplatin plus IV FOLFIRI plus targeted therapy (i.e. anti-EGFR or bevacizumab) to conventional systemic CT alone plus targeted therapy (i.e. anti-EGFR or antiangiogenic antibody)

PRODIGE 52 - UCGI 29- IROCAS/ CO.27

A Randomized Phase III, international trial, comparing mFOLFIRINOX triplet chemotherapy to mFOLFOX as adjuvant chemotherapy in high risk stage III colon cancer

Pathology: High-risk stage III colon cancer (pT4N1; pT1-4N2)

Design : phase III, multicenter, open–labeled randomized trial



Coordinating investigator UCGI: Pr J. BENNOUNA CHU Hôtel Dieu, Nantes

Co-coordinating investigators: Pr. J. TAIEB (FFCD); Pr T. ANDRE (GERCOR)

Objectives:

- Primary objective: Disease Free Survival at 3 years
- Secondary objective: Disease-free-Survival at 2 years / Overall Survival / Toxicity (The incidence of haematological toxicities, GI toxicities, peripheral neuropathy)

Study timelines:

- Inclusion period: March 2017 / March 2021
- Number of patients expected : **640**; number of patients recruited: **209** (August 31, 2019)
- Number of sites open: 60 sites in France and 14 sites in Canada

Italy: 10 sites to be open September 2019