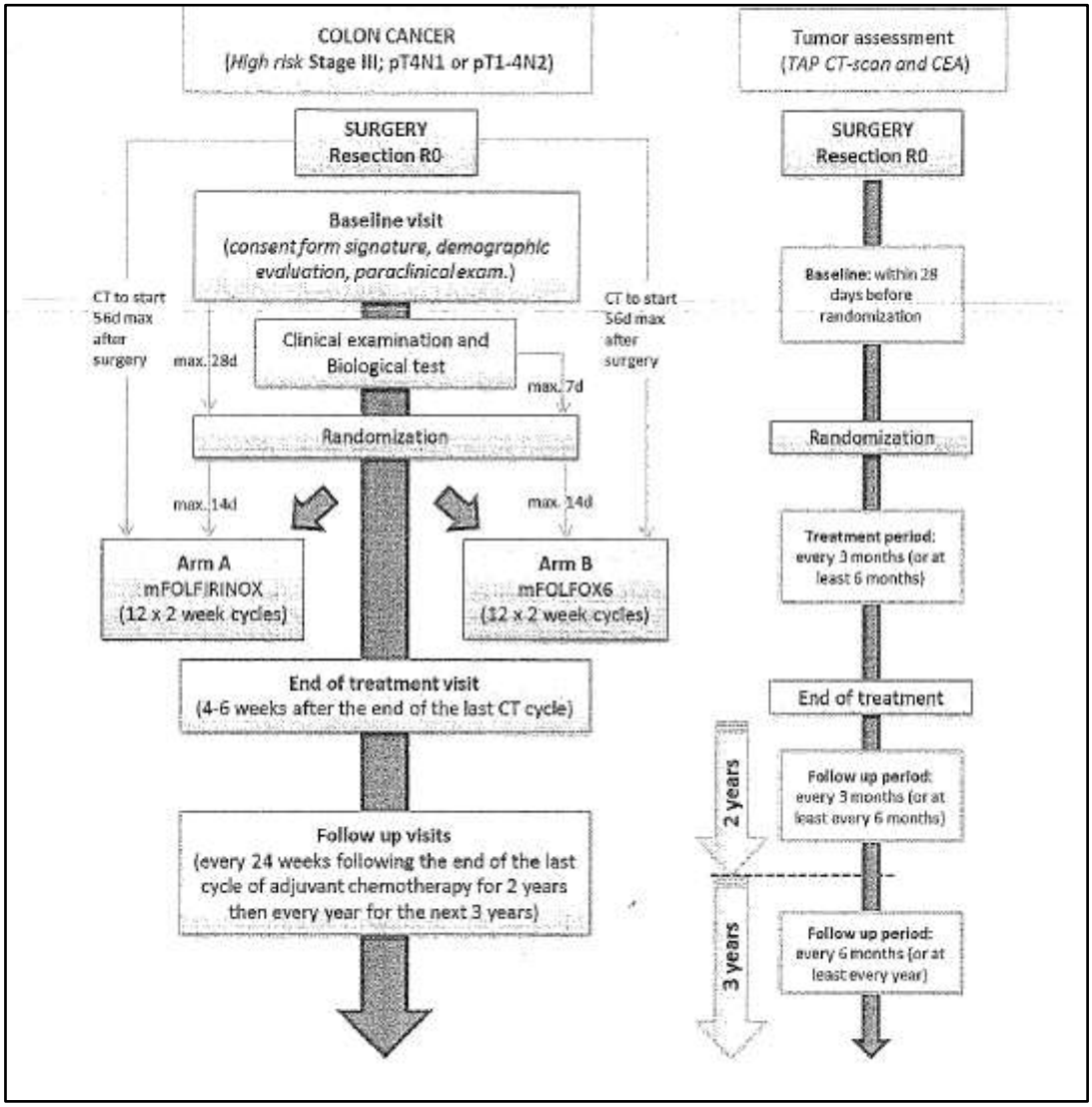
CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE IROCAS**	Identité patient (coller étiquette patient)
Version 1.0 du 27/10/2021	Investigateur en charge du patient : …….. PI : **Dr Leila BENGRINE** Mail : lbengrine@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Céline SCHOUTITH** Poste : 3427

« IROCAS – PRODIGE 52»

Essai de phase III, randomisé, international, comparant une chimiothérapie par mFOLFIRINOX au mFOLFOX en traitement adjuvant chez les patients atteints d'un cancer du côlon de stade III à haut risque.



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VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion :

Patient ≥18 years and < 71years	□ oui □ non
Patient with ECOG ≤1	□ oui □ non
Pathologically confirmed high-risk stage III colon adenocarcinoma, restricted to pT4N1 or pT1-4N2 tumor.	□ oui □ non
Curative R0 surgical resection.	□ oui □ non
Patients who have undergone surgery for colon cancer, defined as a tumor location >12 cm from the anal verge by endoscopy and/or above the peritoneal reflection at surgery (high rectum), without gross or microscopic evidence of residual disease after surgery with curative intent	□ oui □ non
Start of study drug treatment has to be performed less than 56 days after surgery.	□ oui □ non
No prior chemotherapy.	□ oui □ non
No prior abdominal or pelvic irradiation.	□ oui □ non
Patient with adequate organ function: □ Absolute neutrophil count (ANC) ≥ 2 x 109/L □ Haemoglobin ≥9 g/dL □ Platelets (PTL) ≥100 x 109/L □ AST/ALT ≤2.5 x ULN □ Alkaline phosphatase ≤2.5 x ULN □ Total Bilirubin ≤1.5 x ULN (Upper Limit of Normal) □ Creatinine clearance ≥50 mL/min (Cockcroft and Gault formula) □ Kalemia, magnesemia, calcemia ≥ 1 LLN (Lower Limit of Normal)	□ oui □ non

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□ Carcinoembryogenic antigen (CEA) ≤10ng/mL after surgery (during screening period)	
Adequate contraception if applicable.	□ oui □ non
Patient able and willing to comply with study procedures as per protocol	□ oui □ non
Patient able to understand and willing to sign and date the written voluntary informed consent form at screening visit prior to any protocol-specific procedures	□ oui □ non
Life expectancy of > or = at 5 years	□ oui □ non
Uracilemia < 16 ng/ml (only for french centers)	□ oui □ non
Public or private health insurance coverage	□ oui □ non

Critères de non inclusion :

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Major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to study treatment start. Incompletely healed wounds or anticipation of the need for major surgical procedure during the course of the study	□ oui □ non
Metastatic disease	□ oui □ non
Presence of inflammatory bowel disease and/or ileus	□ oui □ non
Known hypersensitivity reaction to any of the components of study treatments.	□ oui □ non
Pregnancy (absence to be confirmed by β-hCG test) or breast-feeding period	□ oui □ non

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Clinically relevant coronary artery disease or history of myocardial infarction in the last 12 months, or high risk of uncontrolled arrhythmia (for men: QTc ≥450 msec, for women: QTc ≥470 msec)	□ oui □ non
Previous malignancy in the last 5 years except curative treated basal cell carcinoma of the skin and/or in situ carcinoma of the cervix	□ oui □ non
Medical, geographical, sociological, psychological or legal conditions that would not permit the patient to complete the study or sign informed consent	□ oui □ non
History or current evidence on physical examination of central nervous system disease or peripheral neuropathy ≥ grade 1 Common Toxicity Criteria for Adverse Events (CTCAE) v4.03.	□ oui □ non
Any significant disease which, in the investigator's opinion, would exclude the patient from the study.	□ oui □ non
Patient with a DPD deficiency or UGT1A1 homozygous 7/7; the test should be done for all patients before 5-FU administration, according to ANSM communication regarding recommendation about high risk of no testing DPD in patient before 5-FU administration; (Appendices 8 to 11).	□ oui □ non
Patients already included in another therapeutic trial involving an experimental drug	□ oui □ non

Date : _____Signature de l'investigateur : _____