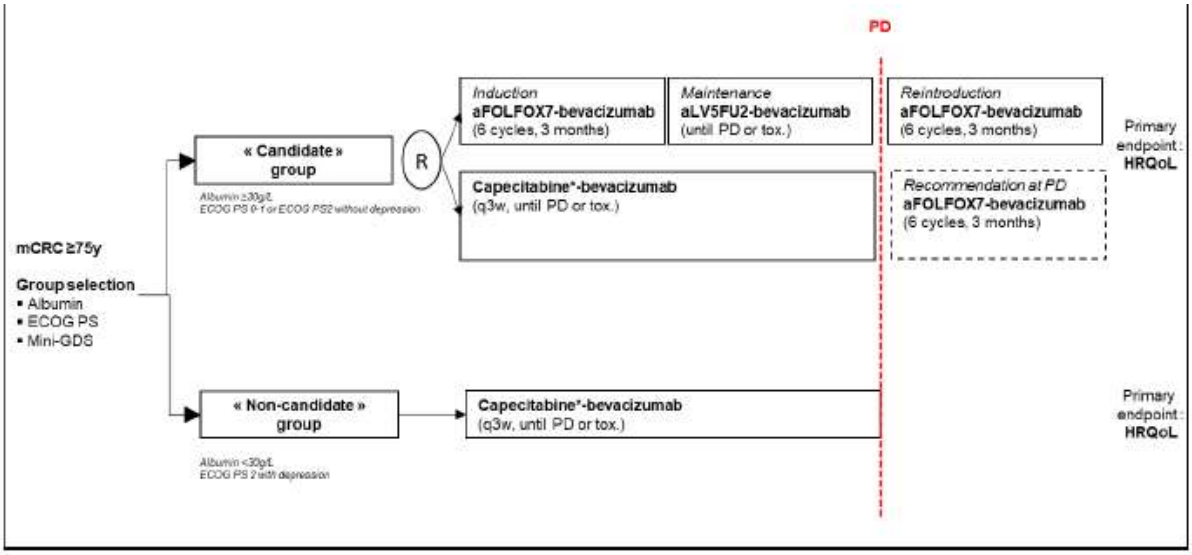
	CRITERES DE SELECTION **ETUDE COLAGE**	Identité patient (coller étiquette patient)
Version 1.0 du 25/10/2021	Investigateur en charge du patient : …….. PI : **Pr GHIRINGHELLI** Mail : fghiringhelli@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Kevin LE BERRE** Poste : 3465

« COLAGE»

Phase III study to evaluate the Quality of Life in elderly patients with metastatic colorectal cancer receiving first-line therapy based on simplified geriatric parameters



VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion :

Signed and dated informed consent, and willing and able to comply with protocol requirements	□ oui □ non
Histologically proven colorectal adenocarcinoma	□ oui □ non
Confirmed metastatic disease,	□ oui □ non

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Patients with no detected dihydropyridine dehydrogenase (DPD) deficiency	□ oui □ non
No prior therapy for metastatic disease (in case of previous adjuvant chemotherapy, interval between the end of chemotherapy and relapse must be > 6 months for fluoropyrimidine alone or > 12 months for oxaliplatin-based chemotherapy,	□ oui □ non
Duly documented unresectable metastatic disease i.e., not suitable for complete carcinological surgical resection,	□ oui □ non
Age ≥ 75 years	□ oui □ non
ECOG PS 0-2,	□ oui □ non
Hematological status: neutrophils □ 1.5 x 109/L; platelets □ 100 x 109/L, and hemoglobin > 9 g/dL	□ oui □ non
Adequate renal function: serum creatinine level < 150 □mol/l, and creatinine clearance (Cockcroft and Gault or Modification of Diet in Renal Disease (MDRD) formula > 30 mL/min)	□ oui □ non
Adequate liver function: total bilirubin level < 1.5 x upper normal limit (ULN), serum alkaline phosphatase (ALP) level < 5 x ULN,	□ oui □ non
Proteinuria < 2+ (dipstick urinalysis) or ≤ 1g/24h,	□ oui □ non
Regular follow-up feasible. The registered patient must be treated and	□ oui □ non

followed at the participating center	
Registration in France with the French National Health Care System (including dispositive PUMA - protection Universelle Maladie).	□ oui □ non

Critères de non inclusion :

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History or evidence upon physical examination of central nervous system (CNS) metastasis (e.g. non- irradiated CNS metastasis, seizure not controlled with standard medical therapy), unless adequately treated,	□ oui □ non
Neuropathy grade > 1,	□ oui □ non
Patient with known dihydropyridine dehydrogenase (DPD) deficiency or history of severe and unexpected reactions to a fluoropyrimidine-containing regimen, or in case of clinically significant active heart disease or myocardial infarction within 6 months or if patient treated with sorivudine or its clinically related analogues, such as brivudine	□ oui □ non
Uncontrolled hypercalcemia,	□ oui □ non
Uncontrolled hypertension (defined as systolic blood pressure > 150 mmHg and/or diastolic blood pressure > 100 mmHg), or history of hypertensive crisis, or hypertensive encephalopathy,	□ oui □ non
Medical history of other concomitant or previous malignant disease, except adequately treated in situ carcinoma of the uterine cervix, basal or squamous cell carcinoma of the skin, or cancer in complete remission for ≥ 5 years,	□ oui □ non

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History of arterial thrombotic and/or embolic event (e.g. myocardial infarction, stroke…) within 6 months prior to randomization,	□ oui □ non
History of abdominal fistula, GI perforation, intra-abdominal abscess or active GI bleeding within 6 months prior to randomization,	□ oui □ non
History or evidence of inherited bleeding diathesis or significant coagulopathy at risk of bleeding,	□ oui □ non
Major surgery (open biopsy, surgical resection, wound revision or any other major surgery involving entry into body cavity) or significant traumatic injury within the last 28 days prior to randomization, and/or minor surgical procedure including placement of a vascular device within 2 days of first study treatment,	□ oui □ non
Concomitant administration of prophylactic phenytoin,	□ oui □ non
Treatment with sorivudine or its chemically related analogues, such as brivudine,	□ oui □ non
Patients with known allergy/hypersensitivity to any component of study drugs,	□ oui □ non
Concomitant unplanned anti-tumor treatment,	□ oui □ non
Participation in another clinical trial with any investigational drug within 30 days prior to randomization,	□ oui □ non
Other serious and uncontrolled non-malignant disease,	□ oui □ non

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Patient under guardianship, curatorship or under the protection of justice.	□ oui □ non

Date : _____

Signature de l'investigateur : _____