CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE IMADGIST**	Identité patient (coller étiquette patient)
Version 1.0 du 10/03/2015	Investigateur :	Arc : Serife tel = 3740

VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion

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1 - Age ≥ 18 years at the day of consenting to the study	☐ oui	☐ non
2 - Patients must have histologically confirmed diagnosis of localized GIST with documented KIT (CD117) positivity (by polyclonal DAKO antibody staining)	☐ oui	☐ non
3 - Documented macroscopically complete surgical R0 or R1 resection of primary GIST lesion with no evidence of residual lesions or metastases on the baseline CT-scan or MRI performed no more than 4 weeks before randomization.	☐ oui	☐ non
4 - Risk of tumor recurrence ≥35% according to National Comprehensive Cancer Network Task Force on GIST (NCCN) risk classification (Demetri et al., 2010) (See Appendix 1)	☐ oui	☐ non
5 - ECOG performance status 0, 1 or 2	☐ oui	☐ non
6 - Patients must be under imatinib treatment (at 300 or 400mg/day) initiated immediately after resection and maintained for 3 years (i.e. 36 months ± 3 months at the time of randomization) with no more than 3 consecutive months or 6 months in total of interruption during these past 3 years.	☐ oui	☐ non
7 - Patients must have normal organ and bone marrow function at baseline as defined below: • Adequate bone marrow function as defined by: - ANC ≥ 1.5 x 109/L, - platelet count ≥ 100.0 x 109/L, - haemoglobin of ≥ 9 g/dL. • Adequate liver function, as determined by:	☐ oui	☐ non

- Serum total bilirubin ≤ 1.5 ULN, - AST and ALT ≤ 3 x ULN (or 5ULN in case of hepatic metastases at time of reintroduction) • Adequate renal function assessed by at least one of the following: - Serum creatinine ≤ 1.5 x ULN **Or** - Creatinine clearance estimate ≥ 50 mL/min (as calculated according to Cockcroft Gault formula or MDRD formula for patients > 65 years).		
8 - Women of childbearing potential are required to have a negative serum pregnancy test within 72 hours prior to randomization. A positive urine test must be confirmed by a serum pregnancy test	☐ oui	☐ non
9 - Patient must use an effective contraception (refer to Appendix 3 for acceptable method of contraception) prior to study entry, during the study participation and for at least 30 days post-treatment (not applicable for women of non-childbearing potential)	☐ oui	☐ non
10 - Ability to understand and willingness for follow-up visits.	☐ oui	☐ non
11 - Covered by a medical insurance	☐ oui	☐ non
12 - Signed and dated informed consent document indicating that the patient has been informed of all aspects of the trial prior to enrolment.	☐ oui	☐ non

Critères de non inclusion

1 - Pregnant or breastfeeding women	☐ oui	☐ non
2 - Patient concurrently using other approved or investigational antineoplastic agents	☐ oui	☐ non
3 - Any contra-indication to imatinib treatment as per Glivec® SPC (Appendix 6)	☐ oui	☐ non

4 - Patient with GIST harboring the mutation D842V in PDGFRA	☐ oui	☐ non
5 - Major concurrent disease affecting cardiovascular system, liver, kidneys, haematopoietic system or else considered as clinically important by the investigator and that could be incompatible with patient's participation in this trial or would likely interfere with study procedures or results.	☐ oui	☐ non
6 - Prior history of other malignancies other than study disease (except for basal cell or squamous cell carcinoma of the skin or carcinoma in situ of the cervix) unless the patient has been free of the disease for at least 3 years.	☐ oui	☐ non
7 - Patient receiving concurrent treatment with warfarin (acceptable alternative: lowmolecular weight heparin) or any prohibited concomitant and/or concurrent medications (see section "Prohibited concomitant/concurrent treatments).	☐ oui	☐ non
8 - Patient has a known diagnosis of human immunodeficiency virus (HIV) infection	☐ oui	☐ non
9 - Major surgery within 2 weeks prior to study entry	☐ oui	☐ non

Date : _____

Signature de l'investigateur : _____