

We only accept electronical submission
Checklist for the submission of clinical trials

	AZ ST JAN Brugge Oostende AV <u>LEADING</u> ECP SO				AZ ST JAN Brugge Oostende AV <u>NON LEADING</u> ECP LO				Not according to the Belgian Law	
	Interventional	Amend ²	Non interventional	Amend ²	Interventional →	Amend ²	Non interventional ←	Substantial amendment AZ St.-Jan AV new centre	Initial	Amend ²
Local Questionnaire	X		X		NOT REQUIRED				X	
Protocol	X		X		X		X	X	X	
Amendment		X		X		X			X	X
Investigator's Brochure	X		X		X		X	X	X	
Patient information and informed consent in Dutch	X	X	X	X	X	X	X	X	X	X
Protocol synopsis (preferably in Dutch)	X		X		X		X	X	X	
Patient cards and questionnaires	X		X		X		X	X	X	
National application format	X	X			X	X		X		
CV local investigator	X		X		X		X	X	X	
CV national coordinator	X		X		X		X	X		
Contracts	X		X		X		X	X	X	
Insurance documents	X		X		X		X	X	X	
Advice of FGOV (medical devices)	X		X		X		X	X	X	
GCP certificate	X	X	X	X	X	X	X	X		
Research question and statistical plan including power analysis	X	X	X	X						
Fees ¹	€1280.23	€320.05	€512.09	€128.04	€384.07		€128.04	Fee according to type of trial	€1280.23	€320.05

= not applicable

1= only applicable for commercial trials

2= all new relevant documents should be submitted (ex. IB, insurance, IC's)

!WE ONLY ACCEPT ELECTRONIC SUBMISSION VIA MAIL (ethisch.comite@azsintjan.be) OR RW CDROM (1 copy)!

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