

**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 <sup>2</sup>	Non interventional	Amend <sup>2</sup>	Interventional →	Amend <sup>2</sup>	Non interventional ←	Substantial amendment AZ St.-Jan AV new centre	Initial	Amend <sup>2</sup>
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 <sup>1</sup>	<b>€1347.33</b>	<b>€336.82</b>	<b>€538.93</b>	<b>€134.75</b>	<b>€404.21</b>		<b>€134.75</b>	<b>Fee according to type of trial</b>	<b>€1347.33</b>	<b>€336.82</b>

= 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](mailto:ethisch.comite@azsintjan.be)) OR RW CDROM (1 copy)!**

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