

We only accept electronical submission via ResearchManager

Checklist for the submission of clinical trials in 2026 – Law of 07 May 2004

	AZ SINT-JAN Brugge AV <u>LEADING</u> ECPSO (Ethics Committee Providing Single Opinion)		AZ SINT-JAN Brugge AV <u>NON</u> <u>LEADING</u> ECPLO (Ethics Committee Providing Local Opinion)	
	Initial application	Amendment ²	Initial application	Amendment ²
Cover letter	X	X	X	X
Protocol + amendments	X	X	X	X
Protocol synopsis in Dutch	X	X	X	X
Investigator's Brochure/summary of product characteristics (if applicable)	X	X	X	X
Information and consent form(s), other patient documents, e.g. recruitment material, questionnaires, ...	X	X	X	X
Up-to-date CV of the principal investigator	X	X	X	X
Valid GCP certificate of the principal investigator (< 3 years)	X	X	X	X
Insurance documents (including reference to the Law of 07 May 2004!)	X	X	X	X
Contract(s)/financial agreements	X	X	X	X
Invoice information ¹	X	X	X	X
Fees ¹	Interventional: € 1676,70 Non interventional: € 670,68	Interventional: € 419,16 Non interventional: € 167,69	Interventional: € 503,01 Non interventional: € 167,69	Interventional: € 419,16 Non interventional: € 167,69

1= only applicable for commercial trials

2= all new relevant documents should be submitted (e.g. for IB, insurance document, ICF's)

!WE ONLY ACCEPT ELECTRONIC SUBMISSIONS VIA RESEARCHMANAGER!

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