

## Overview documents for submission to Ethics Committee Local Opinion

### Initial submission

Document	Number
Protocol	3
Investigator's Brochure	3
Patient Information & Informed Consent in Dutch	3
Protocol Synopsis in Dutch	3
EudraCT Application Form	1
CV Principal Investigator	1
Agreements	1
Insurance	1
Proof of Payment	1
Checklist EC	3
Electronic version of submitted documents via e-mail or CD-ROM	1

### Amendment

If substantial amendment with AZ Sint-Lucas Brugge as additional site: complete file as initial submission.

Document	Number
Protocol Amdt	1
Updated Investigator's Brochure	1
Updated Patient Information & Informed Consent in Dutch	1

### Fees

Interventional trial: € 407,86 (excl. of VAT) - € 493,51 (incl. of VAT)

Non-interventional trial: € 135,97 (excl. of VAT) - € 164,52 (incl. of VAT)

In order for the hospital to provide a correct invoice, please give the correct invoice data to the EC.