



IBD Cancer and Severe Infections in Europe

I-CARE SUBSTUDY

Name

Project referent:

Country of referent:

Affiliation:

I-CARE Investigator code:

Submission date:

1. Background and Hypothesis

2. Objectives (main and secondary)

3. Methods

- **Composition of the Scientific team of the project (including the methodologist, see SciCom rules of procedures)**
- **Study design**
- **Eligibility criteria**
- **Major and secondary endpoints**
- **Sample size justification**

I-CARE substudy draft_template_20200108_project name_project referent



- **Specific data/material to be recorded in addition to those of the general I-CARE database (if necessary)**

- **Statistical plan**

4. Feasibility according to the data recorded in I-CARE

5. Ethics/ERB – Specific country procedures (if necessary)

6. Logistics

7. Budget and planned funding applications (if appropriate)

8. Chronogram

9. Expected results and significance according to previous studies (with references)



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10. References (5 to 10 references)

Date of receipt by I-CARE team:

Date of examination by Executive committee (feasibility only):

Substudy can be submitted to scientific committee: YES/NO

Date of project presentation to scientific committee: ECCO 2019/UEGW 2019

Approval by scientific committee: YES/NO



I-CARE IBD Cancer and Severe Infections in Europe

SUBMISSION PROCESS

- 1/ Complete the I-CARE substudy draft template.
- 2/ Sent your I-CARE substudy proposal to icare@getaid.org
- 4/ Feasibility and methodological examination of substudy proposal by Executive committee.
- 5/ List of substudies presented during ECCO/UEGW and substudy draft sent to scientific committee.
- 6/ 5 slides of the project will be presented to scientific committee during ECCO or UEGW congress to approval by a vote.