**Title:**

**Short title (optional):**

**Authors:**

Administrative Information

Corresponding investigator:

Responsible investigator:

*(must be member of SIBDCS, ultimately responsible for admininistration, scientific report)*

Coordinating centre:

Study sites:

Study starting date:

Study duration:

Budget information:

* Grants allocated (donator’s name and amount):

Date of first submission:

**If this is a revised protocol**: Date of resubmission:

\_\_\_\_ **I confirm** that I have read the Guidelines for Project Submission and that the project fulfils all criteria

***(Any issue that might interfere with the guidelines should be discussed in a cover letter)***

**Co-author(s) information:**

The corresponding author must approve that the following statements are fulfilled:

|  |  |  |  |
| --- | --- | --- | --- |
| Name of the co-author | Role the co-author will play in the project | Conflicts of interest of the co-author to be announced in relation to the submitted project | Please put your initials below to confirm that you agree with the submission of the protocol’s current version |
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**If the current version is a revision of a previously submitted proposal:**

Give a point-by-point reply to the comments received from the Scientific Board and highlight the resulting relevant changes in this proposal with yellow.

|  |
| --- |
| Point-by-point reply to the comments from the Scientific Board:  -  -  - |

Summary (structured, max 300 words)

**Background**

*[Present state of knowledge in the area of the proposed research with key references]*

**Study Hypotheses**

*[Description of the hypothesis the project proposes to test]*

**Study Aims and Objectives**

*[Major aim and objectives of the project in relation to state of knowledge. Scientific and practical significance of the proposed research]*

Own Research in the Field

*[Relevant experience and list of publications of the corresponding author. Relevant background information on the other investigators]*

Methodology

* 1. Patients selection

*[Inclusion and exclusion criteria of patients included in the present study. Preliminary enquiry should be made to the Datacentre to evaluate total number of eligible patients. Add details of sample size calculation]*

* 1. Study design

*[Description of the overall study design. Description of the processes for data collection, and the rationale behind this method. Include a flow chart of the project]*

* 1. Outcomes and exposure variables

*[Description of the principal and secondary outcomes, and complete list of exposure factors, with arguments behind the choice]*

* 1. Statistical Analysis

*[Description of the statistical methods]*

Time Frame

*[Detailed description of tasks and timelines]*

Status of Ethical Approval

*[Reference numbers of ethics approval or amendments]*

**Please note that every project (including those using retrospective data only) has to be submitted to the SwissEthics BASEC system:** <https://submissions.swissethics.ch/en/>

Detailed budget

*[Detailed budget available to conduct the study and meet the deadlines]*

Other Information

*[Interim analysis (if applicable). How will results be disseminated (publication in scientific journal, thesis, internal report, conference, etc.). A draft list of authorship should be part of each submitted project. National or international collaborations (if applicable).DTA or MTA (if applicable)]*

*Please attach whatever information you feel would help to support the submission. Such information includes:*

* A covering letter
* The curriculum vitae of the principal investigator (if not already sent before)
* An informed consent form for drug trials
* Approval of the sponsoring institution's and/or the university's ethics review Committee

References

**APPENDIXES:**

* Variables lists and definitions (enrolment & follow-up physician questionnaires)
* Check list for requested biosamples

**Requests for Biosamples from the SIBDCS Biobank – Check-list**

Please include the following documents / information with your request for biosamples ()

Title/ID of the research project: …………………………………………………….

Copy of the approved research proposal

**Members of the SIBDCS consortium:** Copy of the acceptance letter for the project by the Head of the Scientific Committee

 **External requests (Non-SIBDCS Members):** Copy of the signed Material Transfer Agreement (MTA)

 Maximum number of serum samples requested: N = ..................

Minimum amount (in microliter) of serum required per sample ........

 Maximum number of plasma samples requested: N = ..................

Minimum amount (in microliter) of plasma required per sample ........

 Maximum number of DNA samples requested: N = ..................

Minimum concentration of DNA required (determined by nanodrop®) .....ng/µl

Minimum total amount of DNA required per sample .......... ng

 Maximum number of biopsies (in RNA later) requested: N = ..................

(precise localisation and specifications according to information provided to the datacenter in Lausanne)

 Contact for scientific questions) .........................................................................

..............................................................................................................................

 Shipping address ..............................................................................................

VARIABLES AND DEFINITIONS – ENROLLEMENT AND FOLLOW-UP PHYSICIAN QUESTIONNAIRE

| **Variable** | **Definition** |
| --- | --- |
| **Date of visit** | Date at which the follow-up questionnaire is started to be filled in |
| **Date of last report** | Date at which the last physician questionnaire was filled in, provided that it has been registered and received at the cohort datacenter |
| **Cohort Number (patient identification control)** | Unique number of identification of a patient included into the cohort |
| **Gender** | Gender of the patient |
| **Weight** | Weight of the patient at the date of follow-up visit |
| **Date of birth** | Date of birth of the patient |
| **Diagnosis** | Diagnosis of the patient at the date of follow-up visit |
| **Pregnancy** | Pregnancy status of women and number of weeks of pregnancy at the date of the follow-up visit, if applicable |
| **Conception** | Conception activity of women/men in the period since last report to the cohort |
| **Smoking status** | Smoking status at the date of follow-up visit |
| **Crohn’s disease (CDAI)** | Instantaneous measure of clinical activity at the date of follow-up visit |
| **Ulcerative colitis / Indeterminate colitis (MTWAI)** | Instantaneous measure of clinical activity at the date of follow-up visit |
| **Clinical course** | Monthly evolution of the disease activity since the date of the last report to the cohort till to the date of the current follow-up visit |
| **Past AND current therapies** | List of all therapies, PREVIOUS AND CURRENT, targeted for IBD care, taken by the patient since the last report to the cohort |
| **Drug administration** | Mode of drug administration |
| **Start date** | Date of therapy start |
| **Dosage** | Dosage of the drug therapy |
| **Drug and flare** | Flare management and use of the drug therapy |
| **Conception and pregnancy** | Drug therapy during conception (female and male) and pregnancy |
| **Stop date** | Date of therapy stop |
| **Drug response** | Response to the past drug therapy |
| **Reasons for failure** | Reasons for drug failure |
| **Other reasons for discontinuation** | Reasons for drug discontinuation |
| **Therapy adverse events of stopped therapies** | Adverse events related to drugs that were stopped since last report to the cohort |
| **Supplementation therapy** | Supplementation therapies taken by the patient since the last report to the cohort |
| **Laboratory values** | Most recent core and optional laboratory values obtained for the patient within +/- 3 months |
| **Date of blood sample** | Date of blood sample withdrawal |
| **Time of blood sample** | Time of blood sample withdrawal |
| **Factors related to the last flare** | Specific risk factors for the last reported flare |
| **Date of flare** | Start date of the last reported flare |
| **Management** | Management of the last reported flare |
| **Last disease location assessment** | Method used to newly assess the disease location since the last report to the cohort |
| **Date of disease location assessment** | Date at which the examination was performed to assess the disease location |
| **Endoscopic activity** | Endoscopic activity of unhealthy bowel segments |
| **Histological findings** | Histological findings made during endoscopic or surgical assessment |
| **Intestinal resection surgeries** | Type of performed resection surgeries performed since the date of the last follow-up report |
| **Surgery for fistula and abscesses** | Type of surgeries involving fistula and abscesses performed since the date of the last follow-up report |
| **Other abdominal surgery** | Type of other abdominal surgeries performed since the date of the last follow-up report |
| **Exams** | All new exams performed since the date of the last report to the cohort |
| **Clinical outcomes** | All outcomes originated by a new exam since the date of the last report to the cohort |
| **Extraintestinal manifestations (EIM)** | Indicate all extraintestinal manifestations reported since the date of the last report to the cohort |
| **Type of complications** | Indicate any complications reported since the date of the last report to the cohort |
| **Fistulas, abscesses, fissure** | The location of origin of the complication (fistulas, abscesses and/or fissures), the code number of the complication |
| **Status of fistula, abscesses, and/or fissures** | Status and time point(s) that the complication (fistula, abscesses and/or fissure) occurred since the date of the last report |
| **Stenosis** | Presence and location of stenosis occurred since the date of the last report |
| **Stenosis status** | Status of stenosis (complication) and time point(s) it occurred since the date of the last report |
| **Length of stenosis** | Length of the current stenosis |