**IBDnet: Study Outline for Clinical Trials**

I. Trial Synopsis

|  |  |
| --- | --- |
| Applicant/Coordinating investigator |  |
| Title of trial |  |
| Medical condition |  |
| Objective(s) |  |
| Intervention(s) |  |
| Key inclusion and exclusion criteria |  |
| Outcome(s) |  |
| Trial type |  |
| Statistical analysis |  |
| Sample size |  |
| Trial duration |  |
| Participating centers |  |

II. Background and Objectives

*Primary outcome*

*Secondary outcome*

*Outcome measures*

III. Study Design and Study Population

*Type of study design*

*Inclusion criteria*

*Exclusion criteria*

IV. Study Procedure and Clinical Assessments

*Schedule of study visits*

*Study duration*

*Clinical assessment*

*Special procedures*

*Laboratory assessments*

V. Data Collection and Data Analysis

*Method of data collection*

*Proposed sample size*

*Power calculations*

VI. Budget

|  |  |
| --- | --- |
| Item | Total funding period (CHF) |
| Clinical project management |  |
| Project management |  |
| Case payments |  |
| Data management |  |
| Biostatistics |  |
| Quality assurance |  |
| Travel |  |
| Materials |  |
| Trial drugs |  |
| Fees and insurance |  |
| Other |  |
| **Total** |  |

*Co-financing of the trial by a company or other sources (if applicable)*