**SUBMISSION OF RESEARCH PROJECT**

**RA BIODAM**

**TITLE OF THE PROJECT :**

**PRINCIPAL INVESTIGATOR OF THE PROJECT**

**First name/Family Name:** **Birth date:**

**Personal address:**

**Phone number: Fax: Email:**

**Position:** 🖵**Professor** 🖵**Staff doctor** 🖵**Associate professor** 🖵**Assistant professor** 🖵**Fellow**

🖵**Other (Please specify)**

**SHORT CV OF THE PRINCIPAL INVESTIGATOR OF THE TEAM:**

(Please provide the medical and/or scientific degree course, current position, and awards or grants…)

**Abstract:**

**Scientific background and rationale**

**Aim**

**Description of the project methodology**

**Expected results**

**References (Optional)**

**Detailed scientific and technical description of the project :**

Plan

► Title of the project

► Background

► Specific aims of the project

► Description of the research project (Patients, technical aspects, methodology)

► Expected results and potential impact

► Schedule

(To follow with 5 pages at most)

**TASK OF THE PRINCIPAL INVESTIGATOR AND CONTRIBUTION OF EACH PARTNER:**

(Task of each partner)

► **Principal investigator:**

**► Partners (optional):**

**PUBLICATIONS OF THE PRINCIPAL INVESTIGATOR:**

**► 5 Main publications:**

**► Publications linked to the theme of the project:**

**ESTIMATED BUDGET FOR THE RESEARCH PROJECT:**

**1. Total budget:** **Estimated duration of the project (years):** ……

► **Equipment costs:**

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► **Operating costs**:

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► **Salary / grants:**

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**2. Budget obtained with other Institutions:**

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**3. Budget requested through other institutions:**

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**DATA WHICH ARE NECESSARY FOR THE COMPLETION OF THE RESEARCH PROJECT:**

**Which data do you need?**

 **NUMBER OF PATIENTS:** …… ……………

For the two tables below, check the appropriate boxes matching your request:

* Database file type :

|  |  |
| --- | --- |
| SAS |  |
| CSV |  |

* Needed set of variables (please find the index attached):

|  |  |
| --- | --- |
| **THEME** | **VISIT** |
|  | **M0** | **M3** | **M6** | **M9** | **M12** | **M15** | **M18** | **M21** | **M24** |
| Cohort characteristics |  |  |  |  |  |  | - | - | - |
| Disease history |  | NA | NA | NA | NA | NA | NA | NA | NA |
| Concomitant treatment |  |  |  |  |  |  | - | - | - |
| Comorbidities and medical history |  |  |  |  |  |  | - | - | - |
| Demographic data |  |  |  |  |  |  | - | - | - |
| Quality of life (SF36) |  |  |  |  |  |  | - | - | - |
| Clinical exams (SJC, TJC) |  |  |  |  |  |  | - | - | - |
| Inclusion-exclusion criteria |  |  |  |  |  |  | - | - | - |
| Laboratory analysis (CRP, RF, ESR, CCP) |  |  |  |  |  |  | - | - | - |
| X-Rays (central reading) (DvHm-SHS score) |  | NA |  | NA |  | NA | - | NA | - |
| Sonography |  | - |  | - |  | - | - | - | - |
| Functional indices (HAQ, RAID) |  |  |  |  |  |  | - | - | - |
| Disease activity (DAS28, DAS44, CDAI, SDAI) |  |  |  |  |  |  | - | - | - |
| Quality of life indices |  |  |  |  |  |  | - | - | - |
| Treatment |  |  |  |  |  |  | - | - | - |
| Physician global |  | - | - | - | - | - | - | - | - |
| Patient self-report (global, pain, fatigue) |  | - | - | - | - | - | - | - | - |

**BIOLOGIC DATA (stored serum, DNA, RNA, urine)**

 **🖵 Serum**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit** | **M0** | **M3** | **M6** | **M9** | **M12** | **M15** | **M18** | **M21** | **M24** |
| **Volume requested :** |  |  |  |  |  |  |  |  |  |

 **Justification  :** ……………………………………………………………………………………………………………………… ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

 **🖵 DNA**

Quantity requested: …… ……………

**Justification**  : ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

 **🖵 RNA**

Quantity requested: …… ……………

**Justification**  : ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**🖵 Urine**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit** | **M0** | **M3** | **M6** | **M9** | **M12** | **M15** | **M18** | **M21** | **M24** |
| **Volume requested :** |  |  |  |  |  |  |  |  |  |

**Justification**: ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**RADIOLOGIC DATA (stored images)**

***IMPORTANT: Checking one of the following boxes will mean that you require the original DICOM images in order to perform the reading yourself***

**🖵 Radiological data (X-rays)**

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| **Visit** | **M0** | **M6** | **M12** | **M18** | **M24** |
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**Justification**  : ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**JUSTIFICATIONS FOR USING DATA FROM THE BIODAM COHORT**

Please provide the reasons why your research needs to be performed specifically on the BIODAM cohort.

**STATEMENT OF AGREEMENT:**

I, the undersigned ……………………………………………………………, will hereby fulfil the following commitments:

- I accept to sign an agreement with CaRE Arthritis Ltd regarding appropriate use and custodianship of the study materials

- I will mention the name « BIODAM » in the title or subtitle of all publications relying on the BIODAM cohort, as well as the names of 2 investigators from the BIODAM scientific committee

- I will address publications to the BIODAM scientific committee 3 weeks before submission.

**Name of the principal investigator:** **Signature:**