# CRF Completion Guidelines

SPARTACUS

| Version | Author | Date | Reason for revision |
|---|---|---|---|
| 1 | Lieselot Vanlanduyt | 2020-08-06 | Initial version |
| 2 | Lieselot Vanlanduyt | 2020-11-18 | - Randomization email sent by UZ Ghent Pharmacy was split in 2 emails: 1 for randomization + 1 for medication allocation<br>- New form 'Be-GIANT'<br>- Update on PI approval 'Lock entire record' iso 'Lock all forms' since REDCap update v10 |
| 3 | Lieselot Vanlanduyt | 2020-11-20 | - New form 'Research samples' |
| 4 | Lieselot Vanlanduyt | 2022-01-10 | - New form 'Flare / remission status' to be completed for an 'Unscheduled flare id visit' in Phase B<br>- 'Unscheduled flare id visit' event in Phase B can be completed multiple times. |
| 5 | Lieselot Vanlanduyt | 2022-08-04 | - New event 'Early Discontinuation visit' in Phase A |
| 6 | Lieselot Vanlanduyt | 2022-12-05 | - New administrative form 'Survey Access Codes' |

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# 1 Introduction

This document provides guidance on following items:

- Schedule of CRF completion
- Project-specific guidelines
- Usage of the Electronic Data Capture (EDC) system
- Overview of eCRFs

# 2 Study and study team details

| | |
|---|---|
| **Title Trial** | SPondyloArthritis: inducing drug-free Remission by early TNF-Alpha blockade Under guidance of Single cell RNA sequencing and epigenetic profiling. "The SPARTACUS trial" |
| **Short-title Trial** | SPARTACUS Trial |
| **Sponsor** | Ghent University Hospital |
| **Funders** | VIB Grand Challenges Program |
| **Chief Investigator** | Prof. dr. Van den Bosch Filip |
| **Project Manager** | Kristel De Boeck & Anuschka Van Den Bogaert |
| **Data Manager** | Ilse Ghyselinck |
| **Statistician** | Roos Colman, Cel Biostatistiek, Ghent University |
| **Monitor** | Sanne D'hondt, CTU Ghent University Hospital |

For technical questions concerning the eCRF, please contact redcap@uzgent.be.
For data management related questions, please contact spartacus@uzgent.be.
For medical questions, please contact spartacus@uzgent.be.

# 3 CRF Completion Schedule

Table 1, 2 and 3 outline the availability of the eCRFs and surveys for different time points (in REDCap these are called 'Events').

All available forms are mandatory and should be completed except for

- Phase A: Unscheduled visit
- Phase B: Unscheduled flare id visit
- Phase B: Flare follow up visit/phone call

if these are not done.

- Adverse Events
- Concomitant therapy
- NSAID intake
- Protocol deviation

if these did not occur.

Additional reporting on Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) is done outside of the REDCap system.

## Phase A

| | Visit 1A (screening) | Visit 1B (biopt) | Randomization | Visit 2 (W0) | Visit 3 (W4) | Visit 4 (W8) | Visit 5 (W12) | Visit 6 (W16) | Visit 7 (W20) | Visit 8 (W24) | Visit 9 (W28) | Visit 10 (W36) | Visit 11 (W48) | Visit 12 (W60) | Unscheduled visit | Early discontinuation visit | End of Phase A |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Visit Details Phase A | X | X | | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| Informed Consent | X | | | | | | | | | | | | | | | | |
| Inclusion/Exclusion | X | | | X | | | | | | | | | | | | | |
| Anamnesis | X | | | | | | | | | | | | | | | | |
| Synovial biopsy & US | | X | | | | | | | | | | | | | | | |
| Post biopsie vragenlijst | | | | X | | | | | | | | | | | | | |
| Request randomization | | | X | | | | | | | | | | | | | | |
| Randomization by Pharmacy | | | R | | | | | | | | | | | | | | |
| Medication allocation by Pharmacy | | | R | | | | | | | | | | | | | | |
| Prior SpA Therapy | X | | | | | | | | | | | | | | | | |
| Fibromyalgia exclusion | X | | | | | | | | | | | | | | | | |
| Medical history | X | | | | | | | | | | | | | | | | |
| Latent TB Screening | X | | | | | | X | | | X | | X | X | X | X | X | |
| Physical Examination | X | | | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| Vital Signs | X | | | | | | X | | | X | | X | X | X | X | X | |
| Length & Weight | X | | | | | | X | | | X | | X | X | X | X | X | |
| Smoking & alcohol intake | X | | | | | | X | | | X | | X | X | X | | X | |
| BASMI + Chest Expansion | | | | X | | | X | | | X | | X | X | X | X | X | |
| Psoriatic skin evaluation | | | | X | | | X | | | X | | X | X | X | X | X | |
| Joint Count | X | | | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| Dactylitis | X | | | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| Enthesitis | X | | | X | X | X | X | X | X | X | X | X | X | X | X | X | |
| Physician global assessment | X | | | | | | X | | | X | | X | X | X | X | X | |
| HLA B27, anti-CCP AB, HBV, HCV, HIV, CMV IgG | X | | | | | | | | | | | | | | | | |
| Safety Lab tests | X | | | | X | X | X | X | X | X | X | X | X | X | X | X | |
| Serum Pregnancy Testing | X | | | | | | | | | | | | | | | | |
| ESR, CRP | X | | | | X | X | X | X | X | X | X | X | X | X | X | X | |
| Trial continuation evaluation | | | | | | | X | | | X | | X | X | X | | | |
| Patient global assessment of disease activity | X | | | S | S | S | S | S | S | S | S | S | S | S | | S | |
| Patient global assessment of pain | X | | | S | S | S | S | S | S | S | S | S | S | S | | S | |
| BASDAI | | | | S | S | S | S | S | S | S | S | S | S | S | | S | |
| BASFI | | | | S | | | S | | | S | | S | S | S | | S | |
| Health Assessment Questionnaire | | | | S | | | S | | | S | | S | S | S | | S | |
| ASAS - Health Index | | | | S | | | S | | | S | | S | S | S | | S | |
| EuroQoL 5 dimensions | | | | S | | | S | | | S | | S | S | S | | S | |
| Health VAS | | | | S | | | S | | | S | | S | S | S | | S | |
| Co-morbidity index | | | | S | | | S | | | S | | S | S | S | | S | |
| Healthcare utilization and productivity - baseline/last 6m | | | | S | | | | | | | | | | | | | |
| Healthcare utilization and productivity - follow up/last 3m | | | | | | | S | | | S | | S | S | S | | S | |
| Healthcare utilization and productivity - work | | | | S | | | S | | | S | | S | S | S | | S | |
| Education And Working Status - baseline | | | | S | | | | | | | | | | | | | |
| Education And Working Status - follow up | | | | | | | S | | | S | | S | S | S | | S | |
| End Of Phase A | | | | | | | | | | | | | | | | | X |

*Table 1: Phase A - CRF completion schedule*

Legend:

- X: Form to be completed
- R: Read-only
- S: Survey; can be completed directly by the subject

## Phase B

| | Unscheduled Flare Id Visit | Flare FU visit/phone call | Phase B: Visit 1 (W0) | Phase B: Visit 2 (W12) | Phase B: Visit 3 (W24) | Phase B: Visit 4 (W36) | Phase B: Visit 5 (W48) | Phase B: Visit 6 (W72) | Phase B: Visit 7 (W96) | Phase B: Visit 8 (W120) | Phase B: Visit 9 (W144) | End of Phase B |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Visit Details Phase B | x | x | x | x | x | x | x | x | x | x | x | |
| Physical Examination | x | | | x | x | x | x | x | x | x | x | |
| Length & Weight | x | | | x | x | x | x | x | x | x | x | |
| Smoking & alcohol intake | | | | x | x | x | x | x | x | x | x | |
| BASMI + Chest Expansion | x | | | x | x | x | x | x | x | x | x | |
| Psoriatic skin evaluation | x | | | x | x | x | x | x | x | x | x | |
| Joint Count | x | | | x | x | x | x | x | x | x | x | |
| Dactylitis | x | | | x | x | x | x | x | x | x | x | |
| Enthesitis | x | | | x | x | x | x | x | x | x | x | |
| Physician global assessment | x | | | x | x | x | x | x | x | x | x | |
| Safety Lab tests | x | | | x | | | | | | | | |
| ESR, CRP | x | | | x | x | x | x | x | x | x | x | |
| Flare / remission status | x | | | | | | | | | | | |
| Post flare treatment | | x | | | | | | | | | | |
| Patient global assessment of disease activity | s | | | s | s | s | s | s | s | s | s | |
| Patient global assessment of pain | s | | | s | s | s | s | s | s | s | s | |
| BASDAI | s | | | s | s | s | s | s | s | s | s | |
| BASFI | s | | | s | s | s | s | s | s | s | s | |
| Health Assessment Questionnaire | s | | | s | s | s | s | s | s | s | s | |
| ASAS - Health Index | s | | | s | s | s | s | s | s | s | s | |
| EuroQoL 5 dimensions | s | | | s | s | s | s | s | s | s | s | |
| Co-morbidity index | s | | | s | s | s | s | s | s | s | s | |
| Healthcare utilization and productivity - baseline/last 6m | s | | | | | | | s | s | s | s | |
| Healthcare utilization and productivity - follow up/last 3m | | | | s | s | s | s | | | | | |
| Healthcare utilization and productivity - work | s | | | s | s | s | s | s | s | s | s | |
| Education And Working Status - follow up | s | | | s | s | s | s | s | s | s | s | |
| End Of Phase B | | | | | | | | | | | | x |

*Table 2: Phase B - CRF completion schedule*

## Visit independent forms

| | Drug accountability | Phase independent forms |
|---|---|---|
| Drug accountability - Methotrexate/Placebo | x | |
| Drug accountability - Golimumab/Placebo | x | |
| Concomitant therapy | | x |
| NSAID intake | | x |
| Adverse Event | | x |
| Research samples | | x |
| Be-GIANT | | x |
| Protocol Deviation | | x |
| PI Approval form | | x |
| Patient overview | | R |
| Survey Access Codes | | R |

*Table 3: Visit independent forms - CRF completion schedule*

# 4 Project-specific guidelines

## 4.1 Timing of CRF completion

CRFs related to a patient visit should ideally be completed within 1 week of the visit.

## 4.2 Date and time format

Dates should be entered in dd-mm-yyyy format or chosen from the calendar e.g. 14-02-2020. For dates that could be partially unknown, day and month can be selected from a dropdown where 'unk' is added as an option; year can be added as a number (yyyy).
Time should be entered in 24-hour Clock format (hh:mm) e.g. 14:30.

## 4.3 Decimal numbers

The decimal marker for decimal numbers is . (period / full stop).

## 4.4 Assessments not done

All data entry forms should be completed, even if the visit/test was not done. Each form has the possibility to indicate 'not done' on the form which will hide all other data fields.
If a test/exam was not performed an explanation is required. This should be highly exceptional.
If any surveys (Patient Reported Outcomes) are not completed by the patient, these should be left blank.

## 4.5 Comments

A comments field has been added on each CRF. This field should be used only to provide additional information that cannot be coded into any other data field and that might help clarify the subject's situation, in order to reduce the query load and/or increase the query efficiency.

## 4.6 Clarification regarding time points

### 4.6.1 Phase A

- Visit 1A (screening): data regarding screening should be completed prior to the randomization.
- Visit 1B (biopt): the biopsy should be planned prior to the randomization. Contact the PI if no biopt can be collected.
- Randomization: randomization of the patient can be requested by the site. This should only be done AFTER Visit 1A en Visit 1B are completed. The randomization will be done by UZ Gent Pharmacy and documented in the 'Randomization by Pharmacy' form. More detailed information on the randomization procedure in the section about Randomization.
- Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60): for each visit, the individual CRFs related to this visit should be completed. If a visit is not done, this can be indicated in the 'Visit Details (Phase A)' form.
- Unscheduled visit: this only has to be used if there was an unscheduled visit. Multiple unscheduled visits can be registered.
- Early discontinuation visit: this only has to be completed if there was an early discontinuation visit.
- End of Phase A: if Phase A is terminated, for any reason, this should be documented.

### 4.6.2 Phase B

- Unscheduled Flare Identification Visit: this visit should only be completed if a (possible) flare occurs. Multiple unscheduled flare identification visits can be registered.

- Flare Follow-Up Visit: this visit consist of a phone call to inquiry current medication
- Visit 1 (W0) – Visit 2 (W12) –Visit 3 (W24) – Visit 4 (W36) – Visit 5 (W48) – Visit 6 (W72) – Visit 7 (W96) – Visit 8 (W120) – Visit 9 (W144): for each visit, the individual CRFs related to this visit should be completed. If a visit is not done, this can be indicated in the 'Visit Details (Phase B)' form.
- End of Phase B: if Phase B is terminated, for any reason, this should be documented.

### 4.6.3 Visit independent forms

- Drug accountability: data regarding IMP administration should be registered throughout the trial.
- Phase independent forms: Phase independent forms are forms that are not specifically linked to 1 visit or event. These forms apply for the entire study phase, i.e. concomitant therapy, NSAID intake, adverse event, protocol deviation, PI approval form.

# 5 Electronic Data Capture

Electronic Data Capture (EDC) in this study is done through the Research Electronic Data Capture system (REDCap), provided by Vanderbilt University and installed and maintained by the Health, Innovation and Research Institute of the UZ Ghent.

- REDCap is available via a web browser: https://studiesredcap.uzgent.be
- Please use a recent web browser (preferably Google Chrome)
- REDCap can only be accessed from the IP ranges of the cooperating sites
- Each study staff member will have his own unique username and password

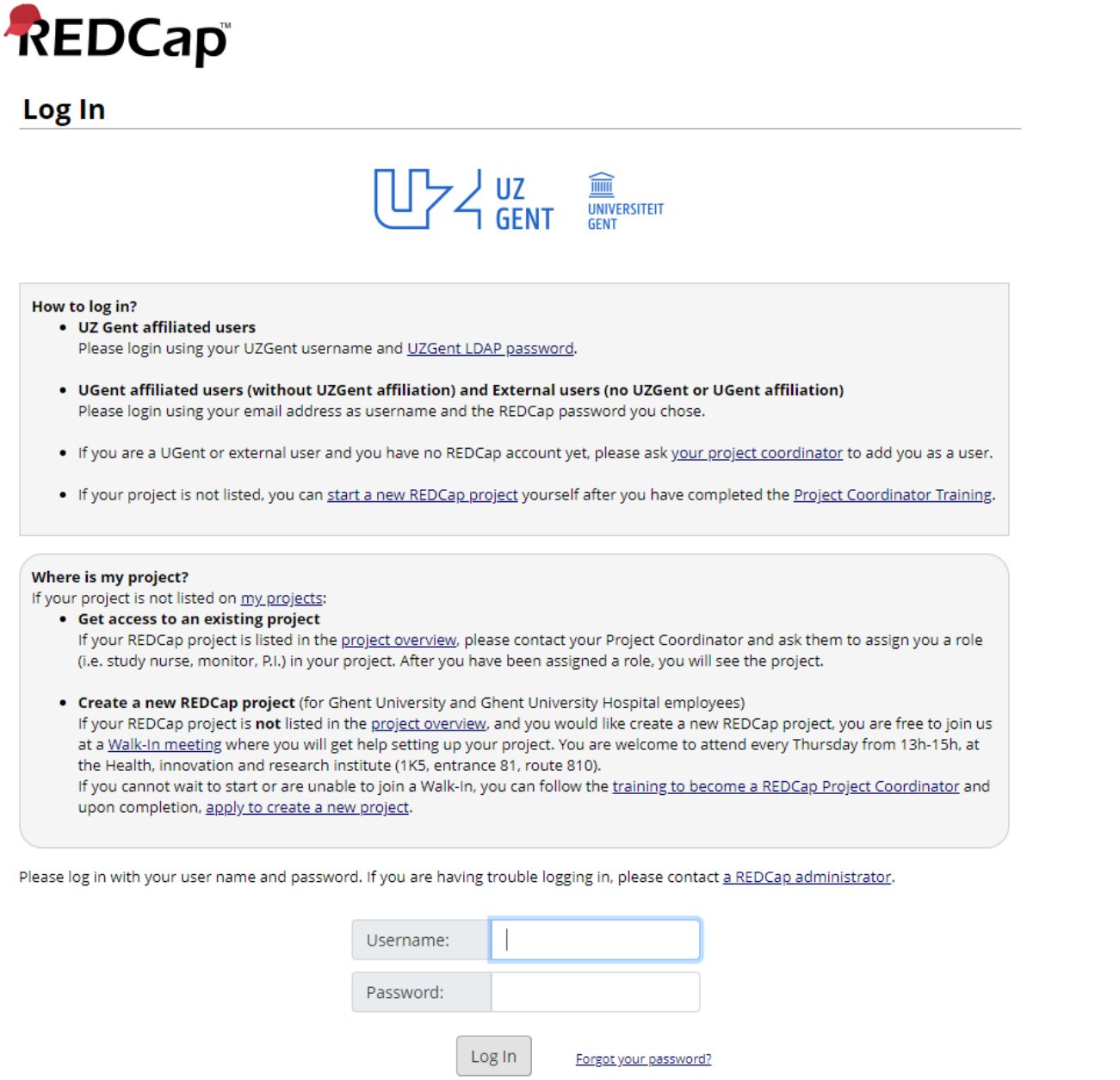
Any issues occurring on the REDCap website can be reported to spartacus@uzgent.be or redcap@uzgent.be.

## 5.1 Getting access to REDCap & SPARTACUS trial

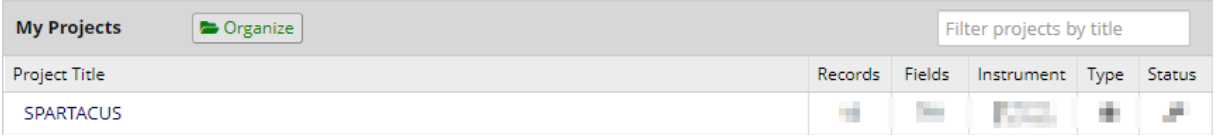
Please note that access to the SPARTACUS trial will only be granted after receipt of a signed Delegation of Authority (DoA) log.

- UZ Gent employees
  - Users log in using their LDAP user name and password
  - After receipt of the DoA log, the Data Manager grants appropriate access to the project
- Collaborators at other sites
  - Users are created with a table-based login. The Data Manager will request the creation of new users through the procedures of the Health, Innovation and Research Institute.
  - After receipt of the DoA log, the Data Manager grants appropriate access to the project

## 5.2 Logging in to REDCap & accessing the trial

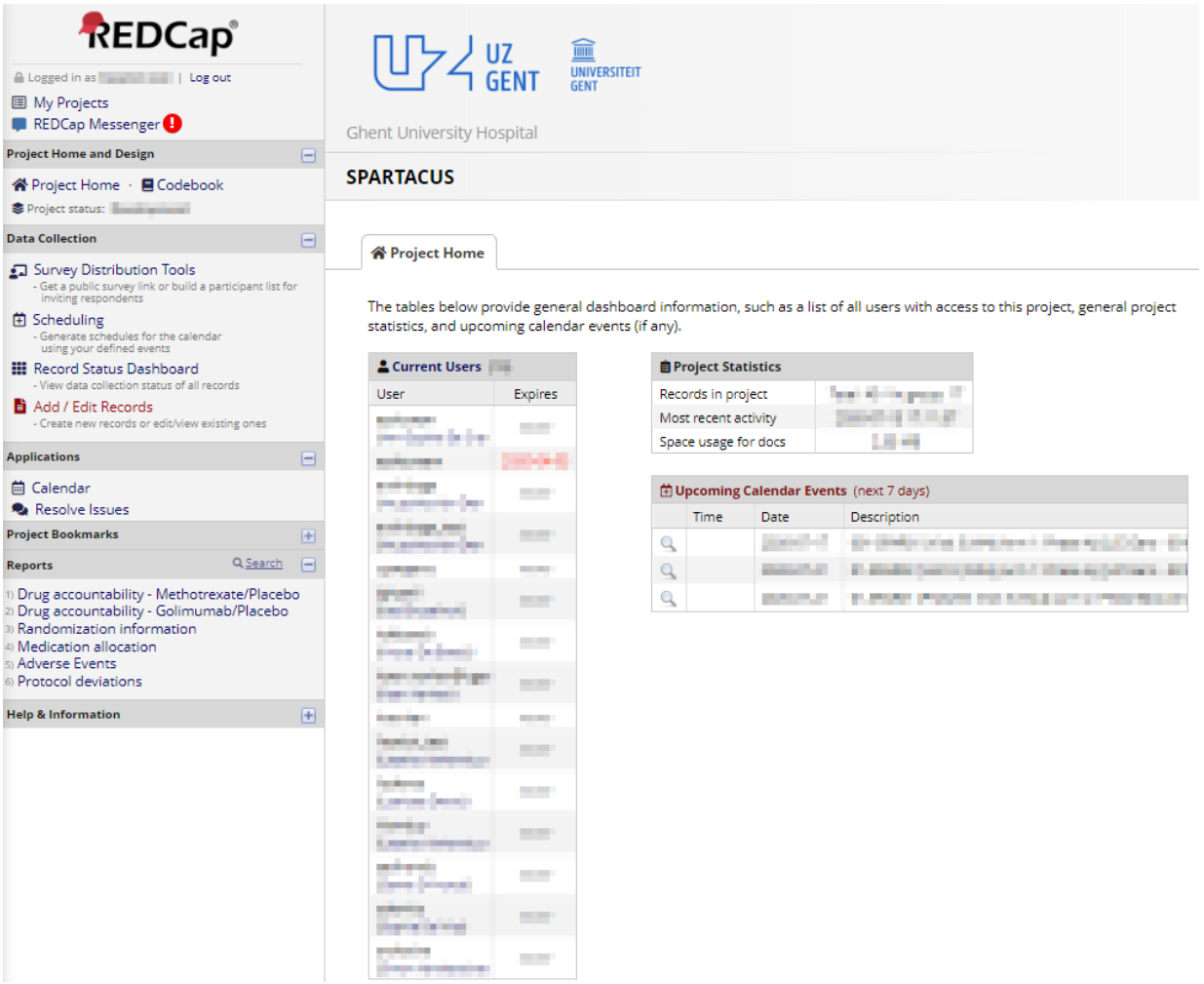



1. Navigate to https://studiesredcap.uzgent.be
2. Enter your username and password and click 'Log in'. You will be taken to the 'My Projects' webpage, which shows an overview of all projects you currently have access to.




3. Select the SPARTACUS project. You will be taken to the Project Home page.

## 5.3 Project Home

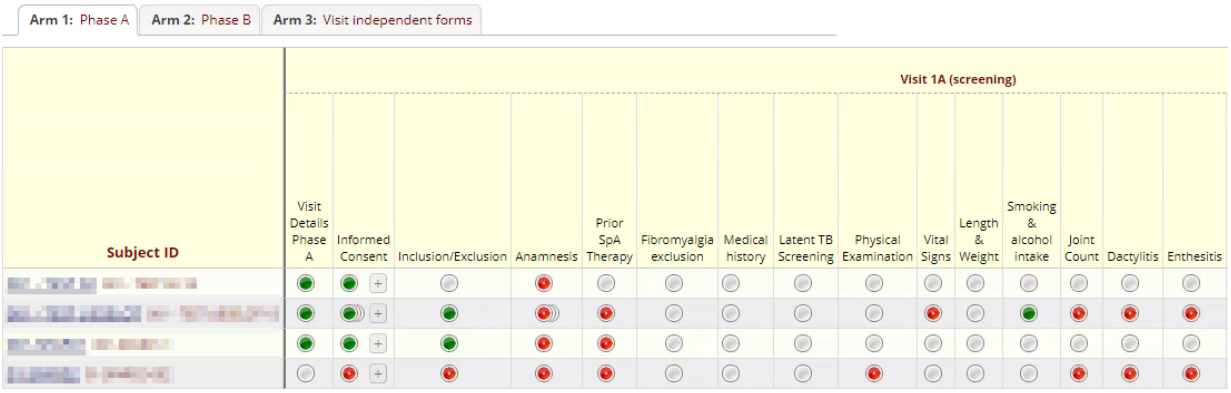


On the Project Home Page, the menu on the left side provides quick links to all sections you have access to (sections in bold will be explained in detail in further chapters):

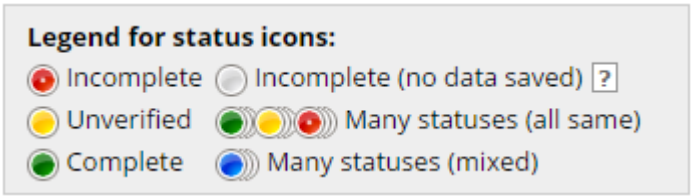
- My Projects
- REDCap Messenger
- Project Home and Design
    - Project Home
    - Codebook
- Data Collection
    - Survey Distribution Tools
    - **Scheduling**
    - **Record Status Dashboard**
    - **Add / Edit Records**
- Applications
    - **Calendar**
    - **Resolve Issues**
- **Reports**
- Help & Information
    - Help & FAQ
    - Video Tutorials
    - Suggest a New Feature
- Contact REDCap administrator

## 5.4 Record Status Dashboard

The Record Status Dashboard displays a table, listing all existing subjects and their status for every CRF and visit. You may click any of the coloured buttons to open a new tab/window in your browser to view that record on that particular CRF. Alternatively, you can go to the subject's Record Home Page by clicking on the Subject ID.

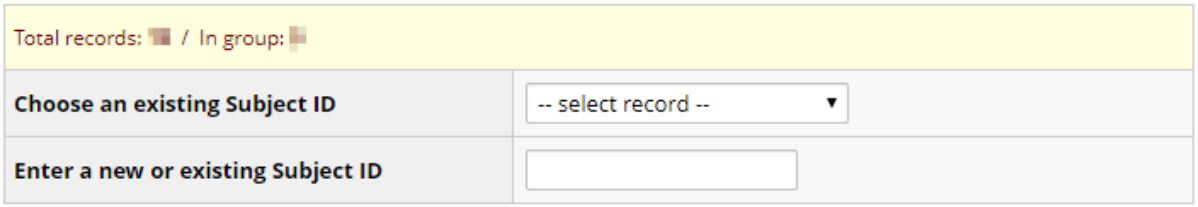



The colours of the buttons are based on the Form Status that is collected at the bottom of every CRF.

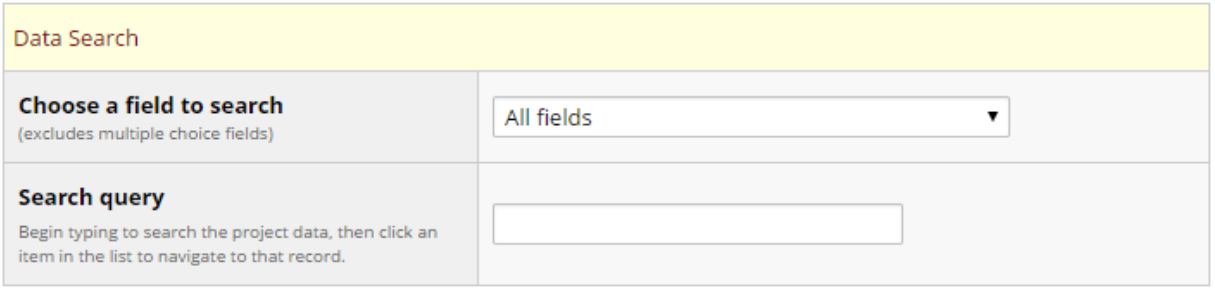


## 5.5 Add / Edit Records

'Add/Edit Records' provides an alternative way (beside through the Record Status Dashboard) to find existing subjects or add a new one. You may view an existing record by selecting it from the drop-down list. To create a new record, click the 'Add new record' button.

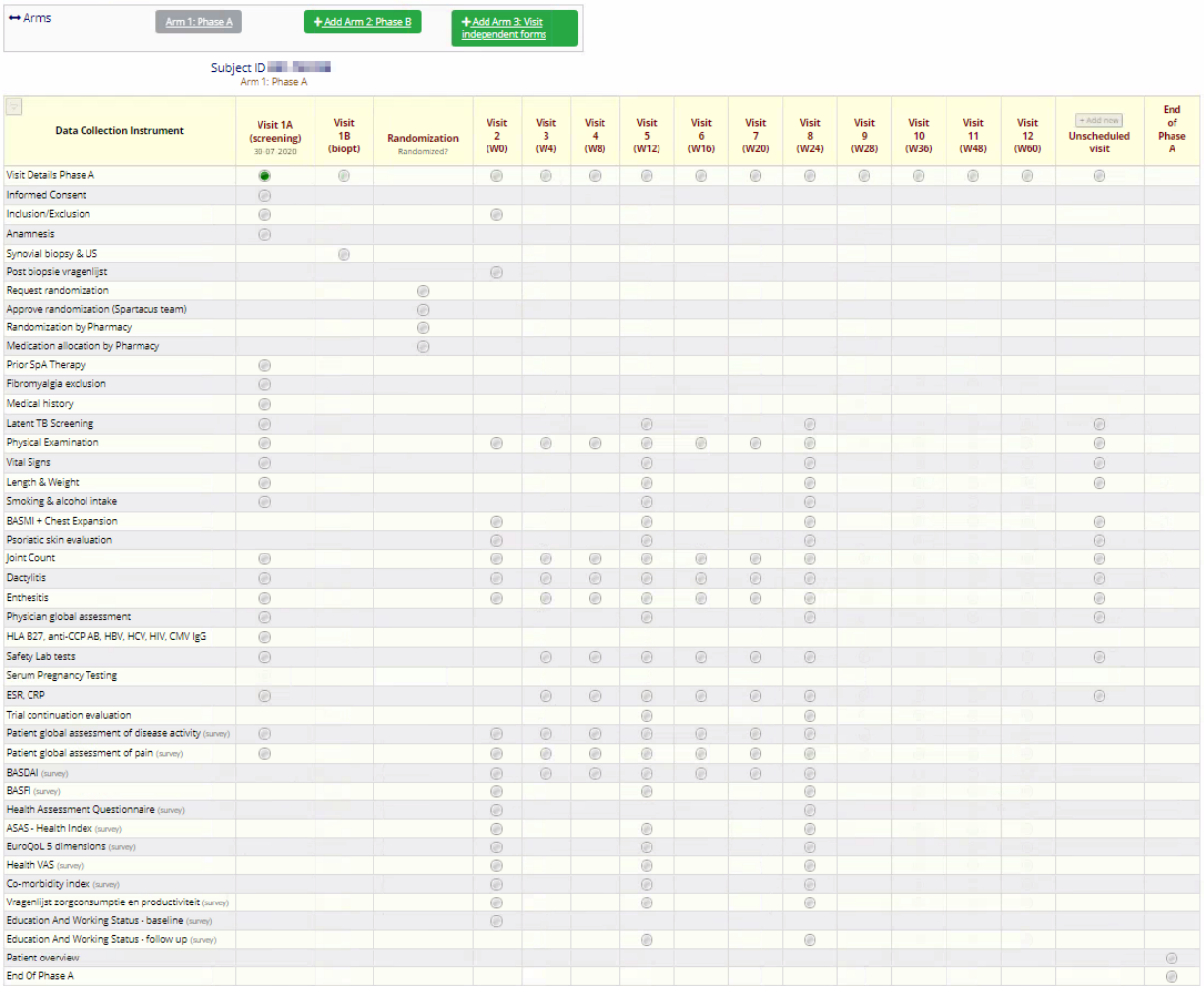



Alternatively, if the subject ID is unknown, it is possible to find a subject by searching through a field for which you know the value for that particular subject (e.g. subject's birth year).

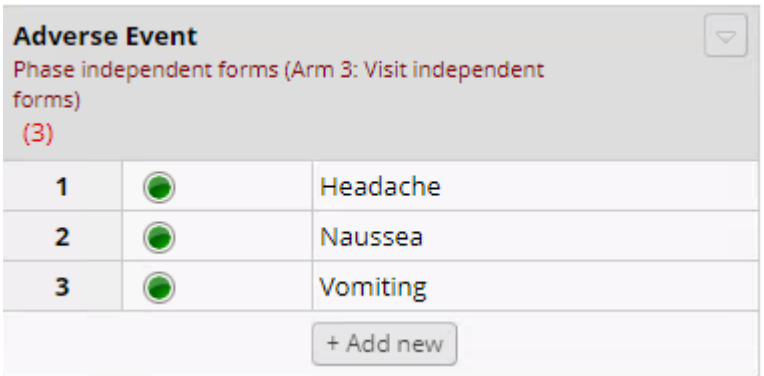



## 5.6 Record Home Page

After selecting a subject (by clicking the subject ID on the Record Status Dashboard, selecting an existing subject on the Add / Edit Records page, or adding a new record on the Add / Edit Records page), you are taken to the Record Home Page. The grid displays the form-by-form progress of data entered for the selected record. You may click on the coloured status icons to access that form/visit. The colours of the buttons are based on the Form Status that is collected at the bottom of every CRF.



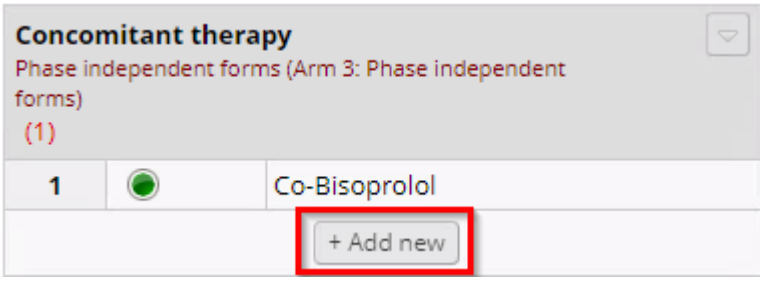

Below this grid, an overview table of the completed repeating CRFs is shown per visit and per CRF. The CRFs in these tables are shown in the order in which they were entered. In the example below, all completed Adverse Event forms are shown in a table for the Adverse Event Log.




Adding a new repeating form can be done by clicking on the '+' sign in the Record Home Page.




Or, clicking by '+ Add new' in the overview of reported repeated forms at the bottom of the Record Home Page.

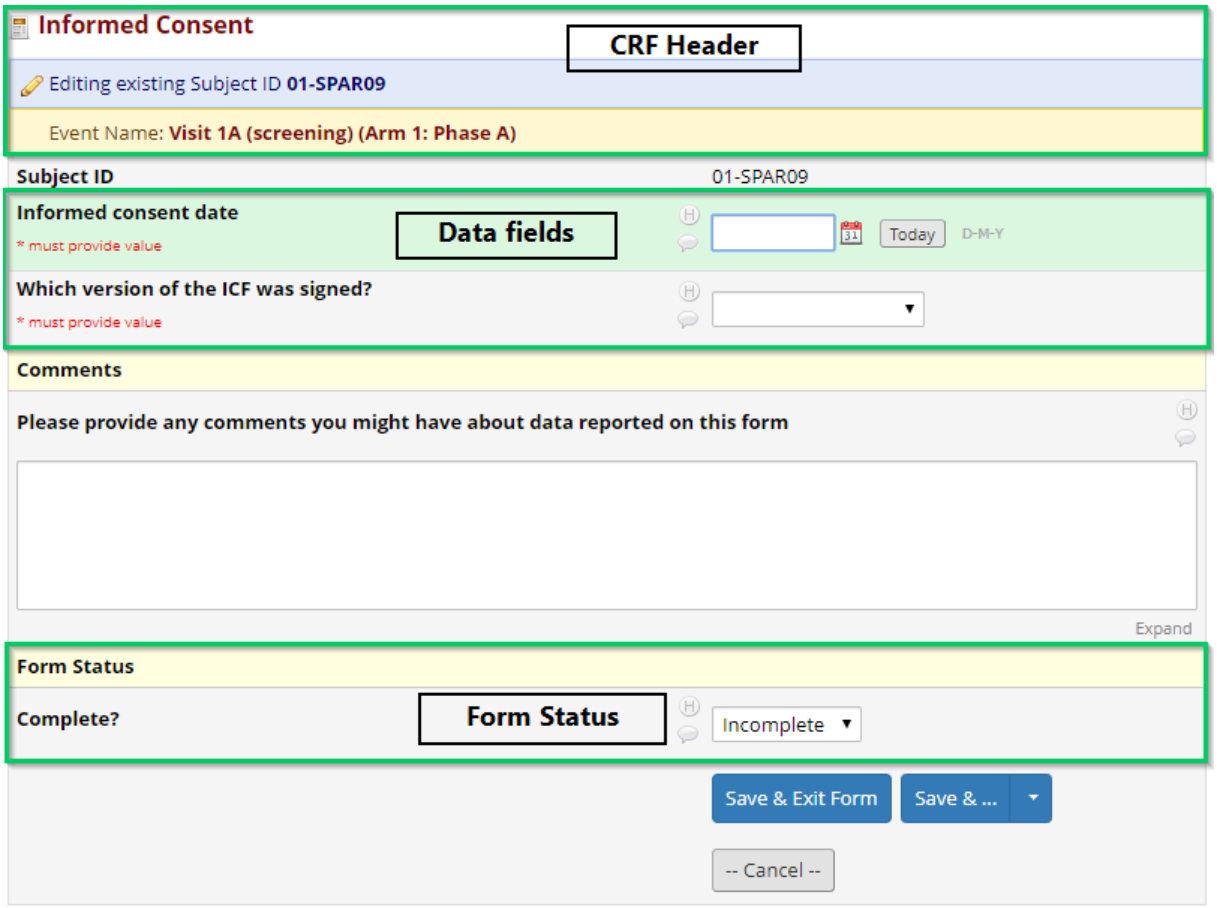



Additional forms can be added as needed.

## 5.7 CRF data entry

To open a data collection instrument, click on an icon in the Record Home Page.

When entering data, use either <Tab> or the mouse to navigate between fields; <Enter> will close the form.




### 5.7.1 CRF header

Every CRF has a header, containing following items:

- The name of the CRF
- The Subject ID (either *Adding new* or *Editing existing Subject ID x-y*)
- The time point (called Event Name in REDCap)

### 5.7.2 Data field types

The eCRF contains a number of different field types. Please find an overview below.

#### *5.7.2.1 Text fields*

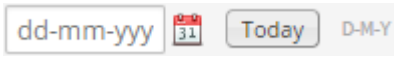


Text fields can contain any type of text.

#### *5.7.2.2 Numerical fields*

Numerical fields essentially look the same as text fields, but should be completed with an integer or a number (depending on the question) and may have a minimum and maximum allowed value assigned to them. If a value does not match the defined validation rule(s), a warning will be displayed. This warning can be ignored, but an out-of-range value will eventually result in a query from the Data Manager.

#### *5.7.2.3 Date fields*

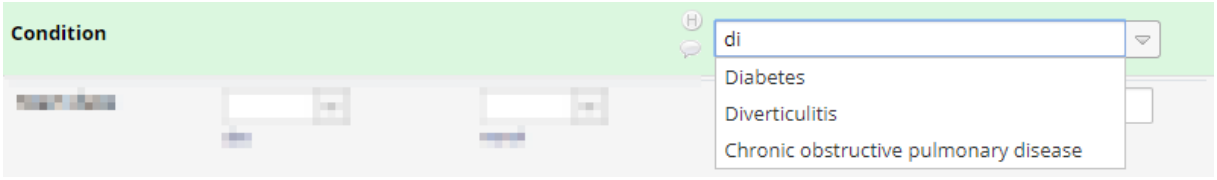



Date fields should always be completed in the format dd-mm-yyyy. A date can be completed by typing in the value, choosing a date from the date chooser (calendar icon) or clicking the button 'Today'.

For dates that could be partially unknown, day and month can be selected from a dropdown where 'unk' is added as an option, year can be added a as number (yyyy).

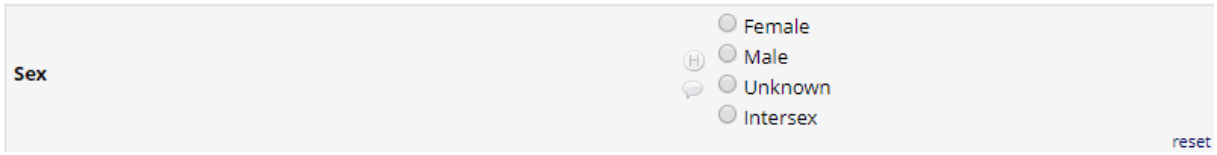



### 5.7.2.4 Drop-down list (single answer)



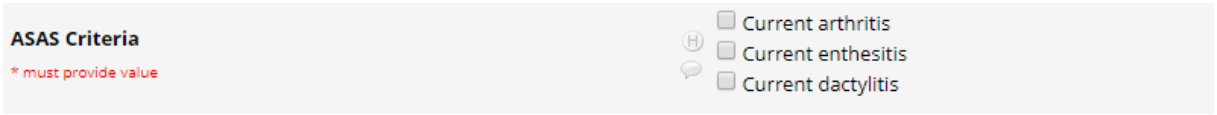

Drop-down lists allow you to select a single answer from a list of pre-specified possibilities. Some drop-down lists allow you to start typing your answer to narrow down the list of possibilities to choose from.

### 5.7.2.5 Radio buttons (single answer)

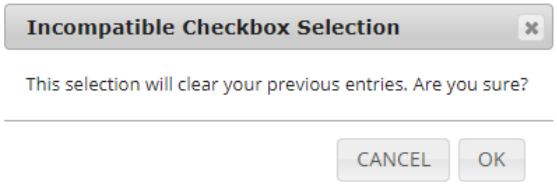



Radio button lists immediately show all possible values, allowing you to easily select the correct value.

### 5.7.2.6 Checkboxes (multiple answers)

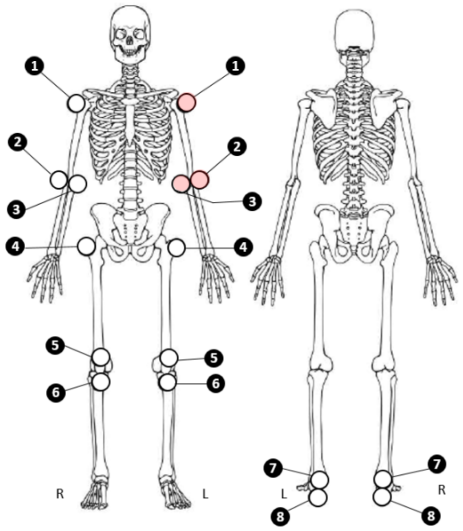



Checkboxes allow you to select multiple answers from a list of possibilities.
Some checkboxes in this studies contain the answer option 'No'/'None'. When 'No'/'None' is selected first and then another option is selected, REDCap will automatically remove the answer 'No'/'None' without warning. When another option is selected first and then 'No'/'None' is selected, a warning will be displayed.



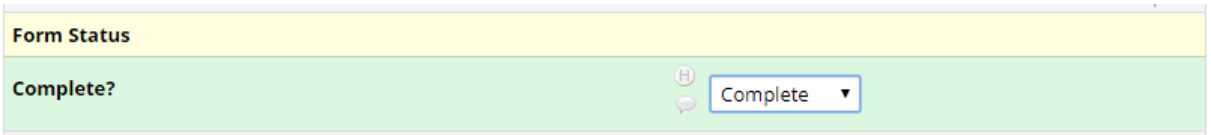

### 5.7.2.7 Image maps

An image map is an image with clickable areas. Depending on the type, one or more areas of the image can be selected. Selected areas will be highlighted in red or blue. Clicking again will deselect an area.

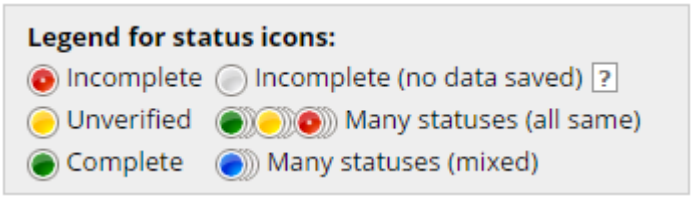



### 5.7.3 Form status

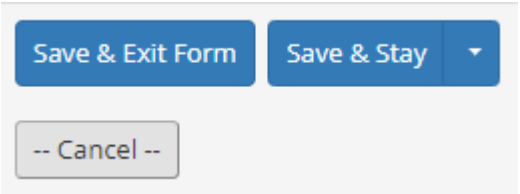
At the bottom of each form, a form status can be assigned.




This can be used to reflect the status of data entry.




### 5.7.4 Closing the form



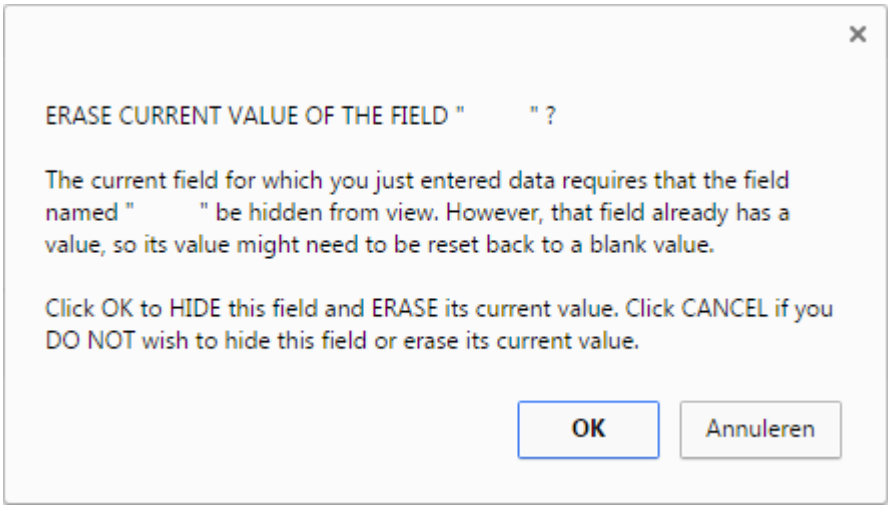

Click one of the options at the bottom of the form to save or cancel the data entry. Click the down arrow button to view more save options. The option chosen for this button will become the default when you open another form.

<Enter> will also close the form.

### 5.7.5 Sections

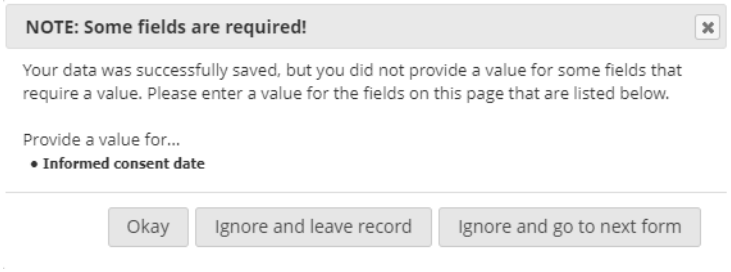
Every CRF is divided into smaller sections of related questions. All CRFs in this study use branching logic to show relevant sections and hide irrelevant sections depending on answers from other questions. If an irrelevant section is shown or a relevant section is not shown, please check your previous answers for correctness.

If an answer is modified that results in hiding fields with previously completed values, your web browser will show a pop-up requesting to erase the values from the fields (1 pop-up per field). Clicking 'OK' will erase the field's value. Clicking 'Cancel' will not erase the value, but will eventually result in a query from the Data Manager.




### 5.7.6 Required fields

Fields that must be completed on a particular CRF are marked as * must provide value. If a required field on a CRF is not completed, a warning will be displayed upon saving the CRF. This message can be ignored, but leaving a required field empty will eventually result in a query from the Data Manager.




### 5.7.7 Data history

If the icon (H) next to a data field is clicked, the data history for that field is shown. The data history is displayed in a table containing all changes to a data field (date/time of change, user & data changes made).

| Date/Time of Change | User | Data Changes Made |
|---|---|---|
| 09.05.2017 14:34 | [redacted] | No (0) |
| 09.05.2017 14:54 | [redacted] | Yes (1) |
| 10.05.2017 10:34 | [redacted] | No (0) |

### 5.7.8 Data resolution workflow

Clicking the speech balloon next to a data field will open the related Data Resolution Workflow pop-up. This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a

documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.
Fields can have several data resolution workflow icons next to them:

- No query
- Open query, unresponded
- Open query, responded
- Closed/resolved query

### 5.7.9 Data Quality Rules

Upon saving a form, a set of rules to ensure data quality (the so-called Data Quality Rules) are executed. If a Data Quality Rule is violated, a pop-up error message is displayed. This pop-up shows the violated rule(s) and the field(s) involved. To close the issue, you can close the pop-up, correct the field(s) causing the Data Quality Rule violation and save the form again.
If a Data Quality Rule is violated while the field(s) involved are correctly completed, you can close the pop-up and continue working on other forms by clicking the '-- Cancel --' button. After a query by the Clinical Data Manager requesting clarification, the issue will be closed.



## 5.8 Registration of subjects in the database

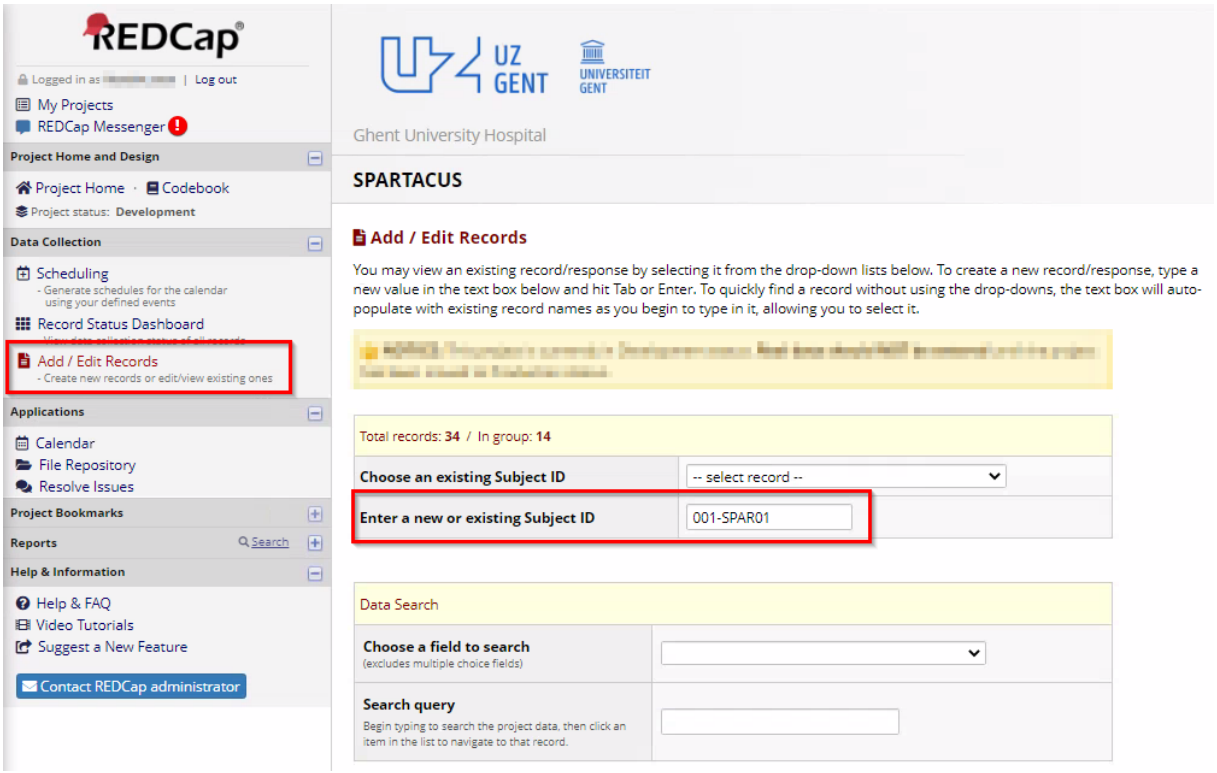
All subjects who signed the Informed Consent Form (ICF) should be registered in the clinical database. When a patient is registered in REDCap a subject ID should be given as following:

XXX-SPAR##

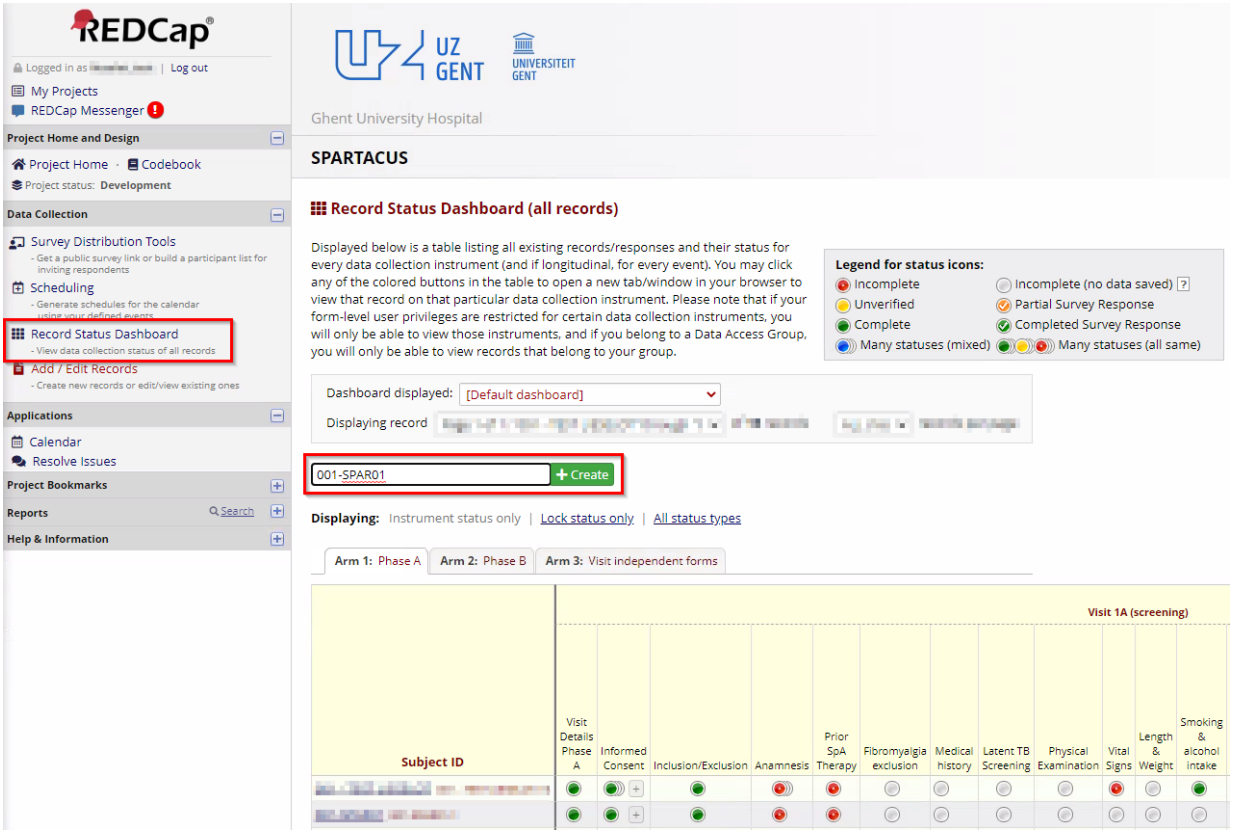
XXX: site code
SPAR: trial abbreviation
##: consecutive number of patients screened at your site
e.g. 001-SPAR01

A new subject can be added via 'Add/Edit Records' or via 'Record Status Dashboard'.

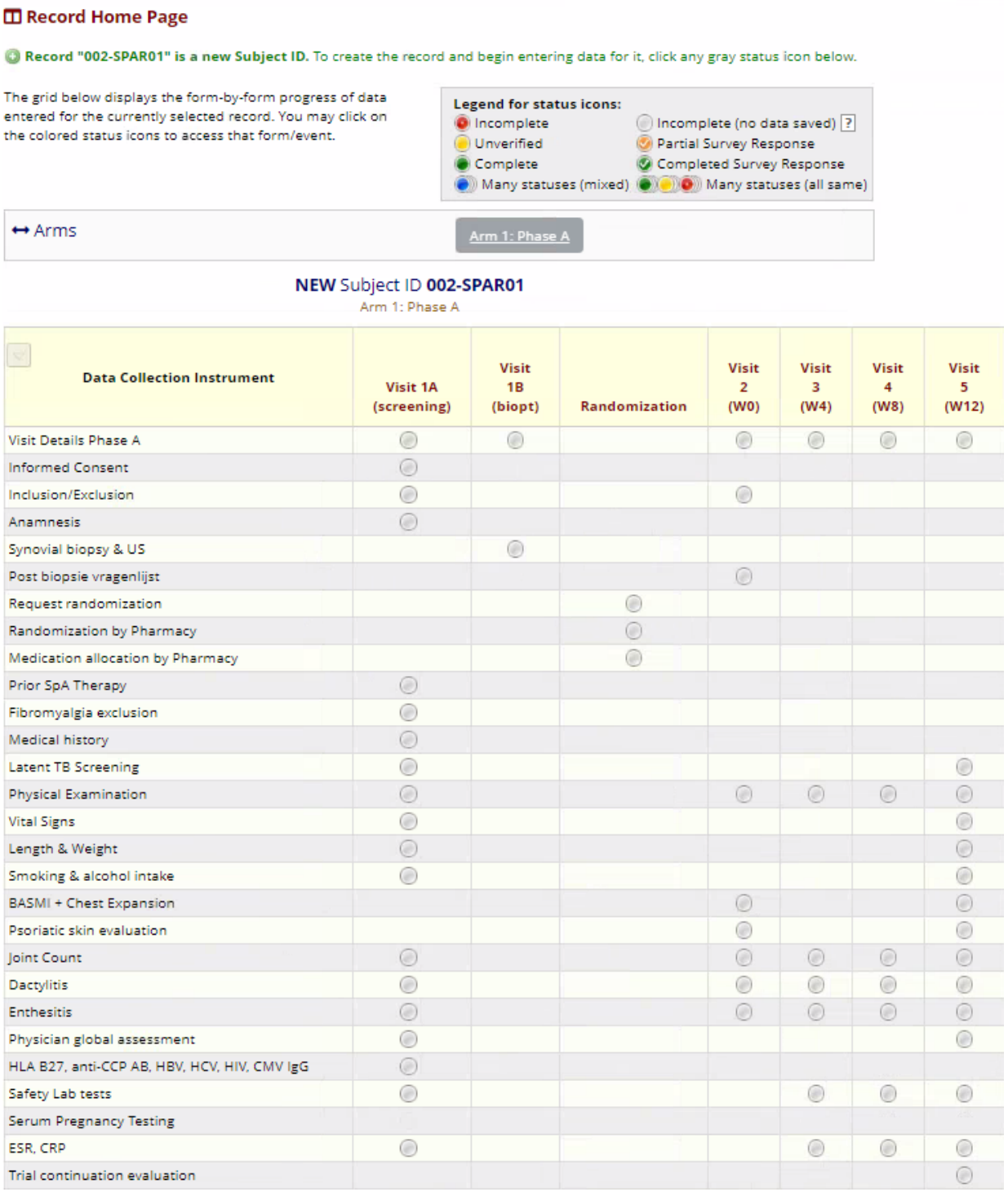
1) Via 'Add/Edit Records'
   - Enter the Subject ID and press enter on your keyboard




2) Via 'Record Status Dashboard'
   - Enter the Subject ID and click Create or press enter on your keyboard




After creating a new Subject, the 'Record Home Page' of the new subject opens.
The Record Home Page displays an overview of all forms the will need to be filled out for the new subject. Data collection instruments are displayed in rows, visits or other study specific events are displayed in the columns. The grey icons represent a data collection form that needs to be filled out for this visit/event.



Record Home Page

Record "002-SPAR01" is a new Subject ID. To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Legend for status icons:
Incomplete | Incomplete (no data saved) | Unverified | Partial Survey Response | Complete | Completed Survey Response | Many statuses (mixed) | Many statuses (all same)

Arms | Arm 1: Phase A

NEW Subject ID 002-SPAR01
Arm 1: Phase A

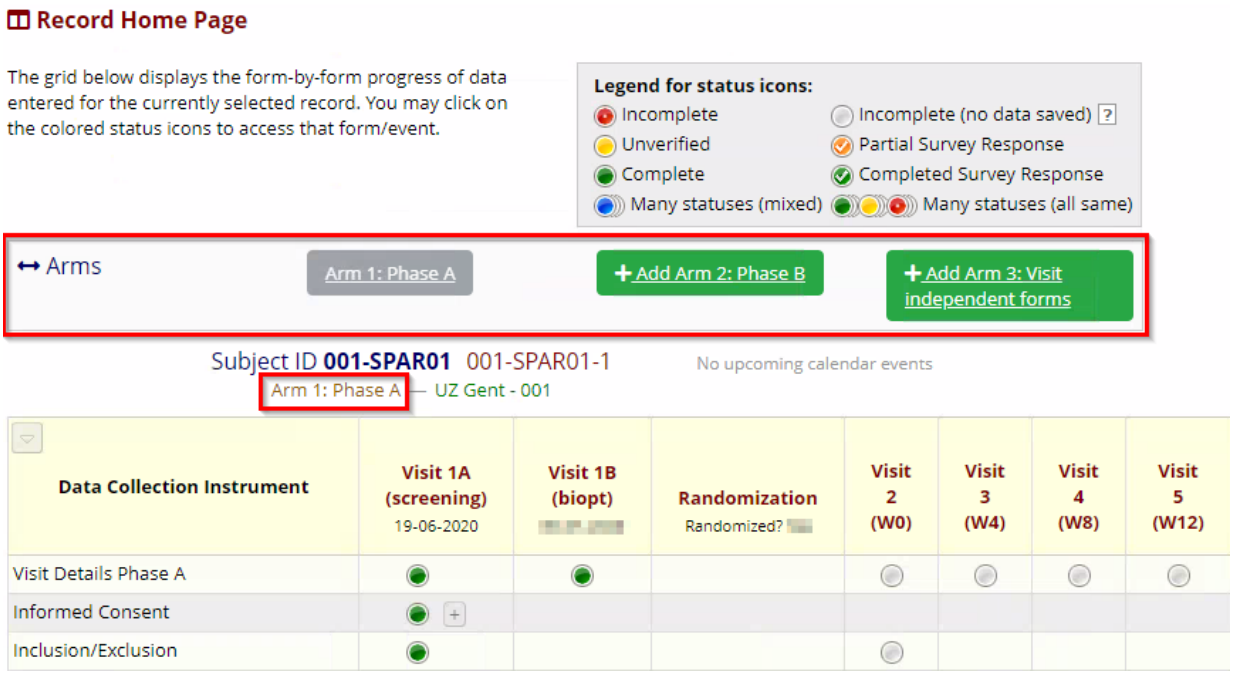
| Data Collection Instrument | Visit 1A (screening) | Visit 1B (biopt) | Randomization | Visit 2 (W0) | Visit 3 (W4) | Visit 4 (W8) | Visit 5 (W12) |
|---|---|---|---|---|---|---|---|
| Visit Details Phase A | ○ | ○ | | ○ | ○ | ○ | ○ |
| Informed Consent | ○ | | | | | | |
| Inclusion/Exclusion | ○ | | | ○ | | | |
| Anamnesis | ○ | | | | | | |
| Synovial biopsy & US | | ○ | | | | | |
| Post biopsie vragenlijst | | | | ○ | | | |
| Request randomization | | | ○ | | | | |
| Randomization by Pharmacy | | | ○ | | | | |
| Medication allocation by Pharmacy | | | ○ | | | | |
| Prior SpA Therapy | ○ | | | | | | |
| Fibromyalgia exclusion | ○ | | | | | | |
| Medical history | ○ | | | | | | |
| Latent TB Screening | ○ | | | | | | ○ |
| Physical Examination | ○ | | | ○ | ○ | ○ | ○ |
| Vital Signs | ○ | | | | | | ○ |
| Length & Weight | ○ | | | | | | ○ |
| Smoking & alcohol intake | ○ | | | | | | ○ |
| BASMI + Chest Expansion | | | | ○ | | | ○ |
| Psoriatic skin evaluation | | | | ○ | | | ○ |
| Joint Count | ○ | | | ○ | ○ | ○ | ○ |
| Dactylitis | ○ | | | ○ | ○ | ○ | ○ |
| Enthesitis | ○ | | | ○ | ○ | ○ | ○ |
| Physician global assessment | ○ | | | | | | ○ |
| HLA B27, anti-CCP AB, HBV, HCV, HIV, CMV IgG | ○ | | | | | | |
| Safety Lab tests | ○ | | | | ○ | ○ | ○ |
| Serum Pregnancy Testing | | | | | | | |
| ESR, CRP | ○ | | | | ○ | ○ | ○ |
| Trial continuation evaluation | | | | | | | ○ |

To start data collection, click any grey icon.

**WARNING**: If you click the 'Create' button, but subsequently you do not enter any data on any CRF, the new record and its related subject ID are NOT saved. A subject ID is only assigned and saved when data is entered.

**WARNING**: If you enter a subject with a wrong Subject ID, you will not be able to change this after data has been entered. Please contact spartacus@uzgent.be for assistance.

A new subject is automatically entered in Phase A of the trial. When the first data has been entered, additional buttons will appear in the Record Home Page.

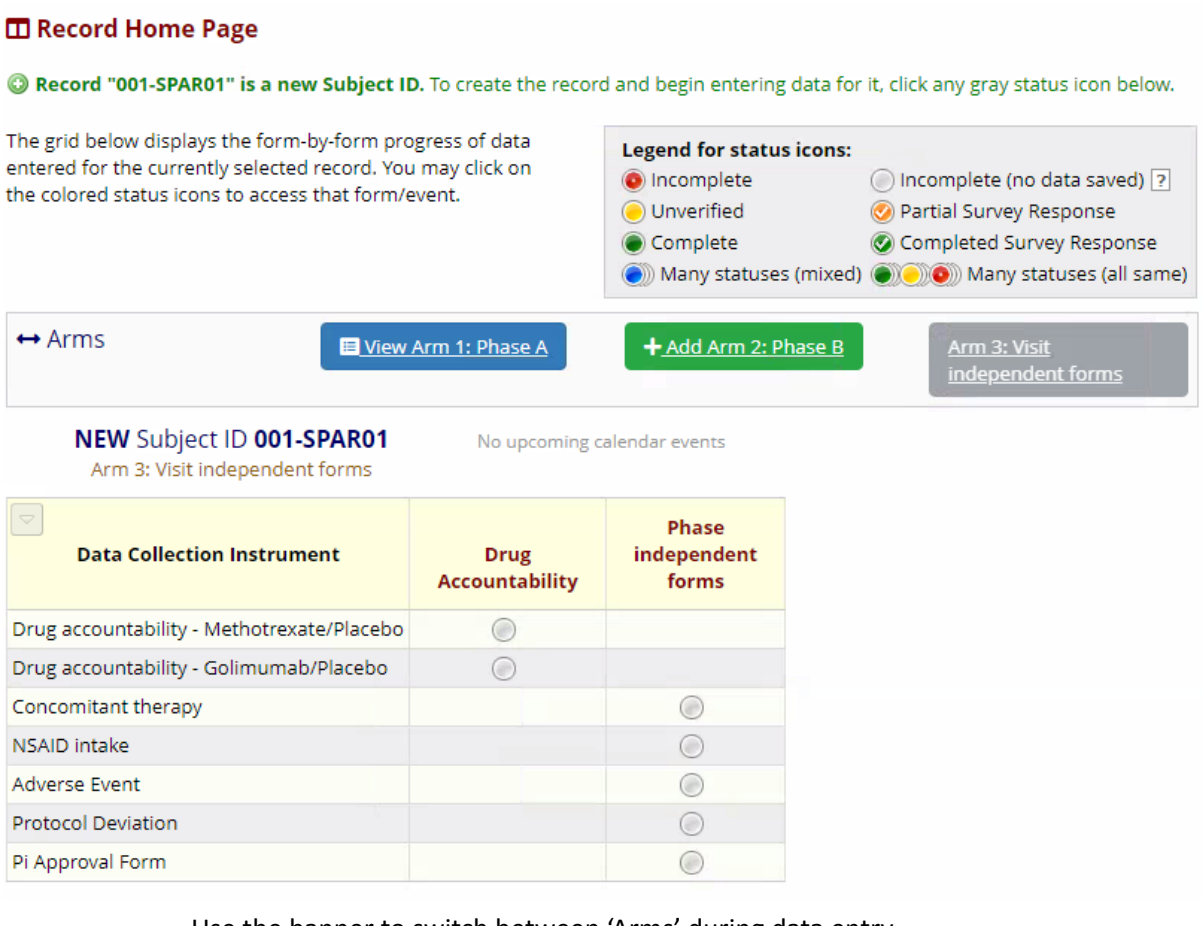



‘ + Add Arm 2: Phase B’ should be used when the patient moves from Phase A to Phase B (see Move subject from Phase A to Phase B)

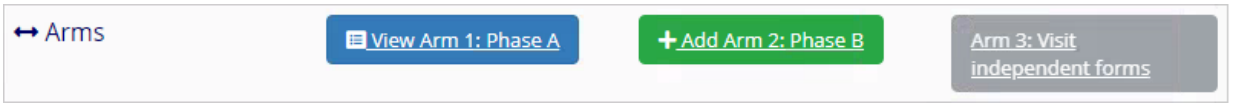
‘ + Add Arm 3: Visit independent forms’ contains information collected for both Phase A and Phase B and should be added during Phase A to register:

- Drug accountability
- Concomitant therapy
- NSAID intake
- Adverse Events
- Protocol Deviations

- Click the green button to add this arm




Use the banner to switch between 'Arms' during data entry.

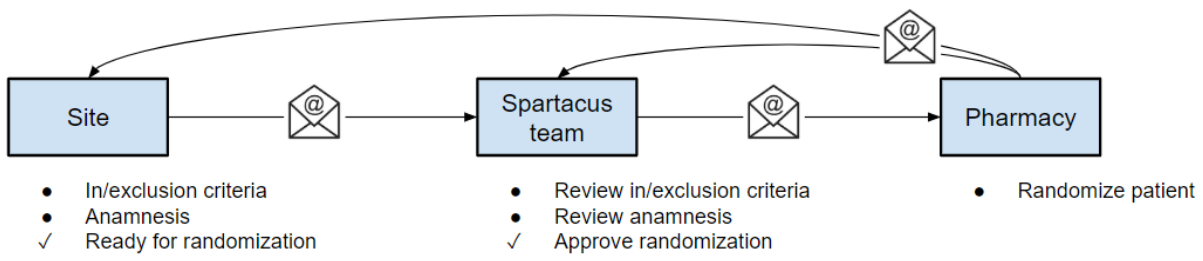



## 5.9 Randomization

If a patient is deemed eligible for randomization in the trial; the randomization procedure can be initiated by the site.

The randomization procedure has 3 steps:

1) Request randomization done by the site
2) Approval for randomization by the Spartacus team
3) Randomization of the subject by UZ Ghent Pharmacy

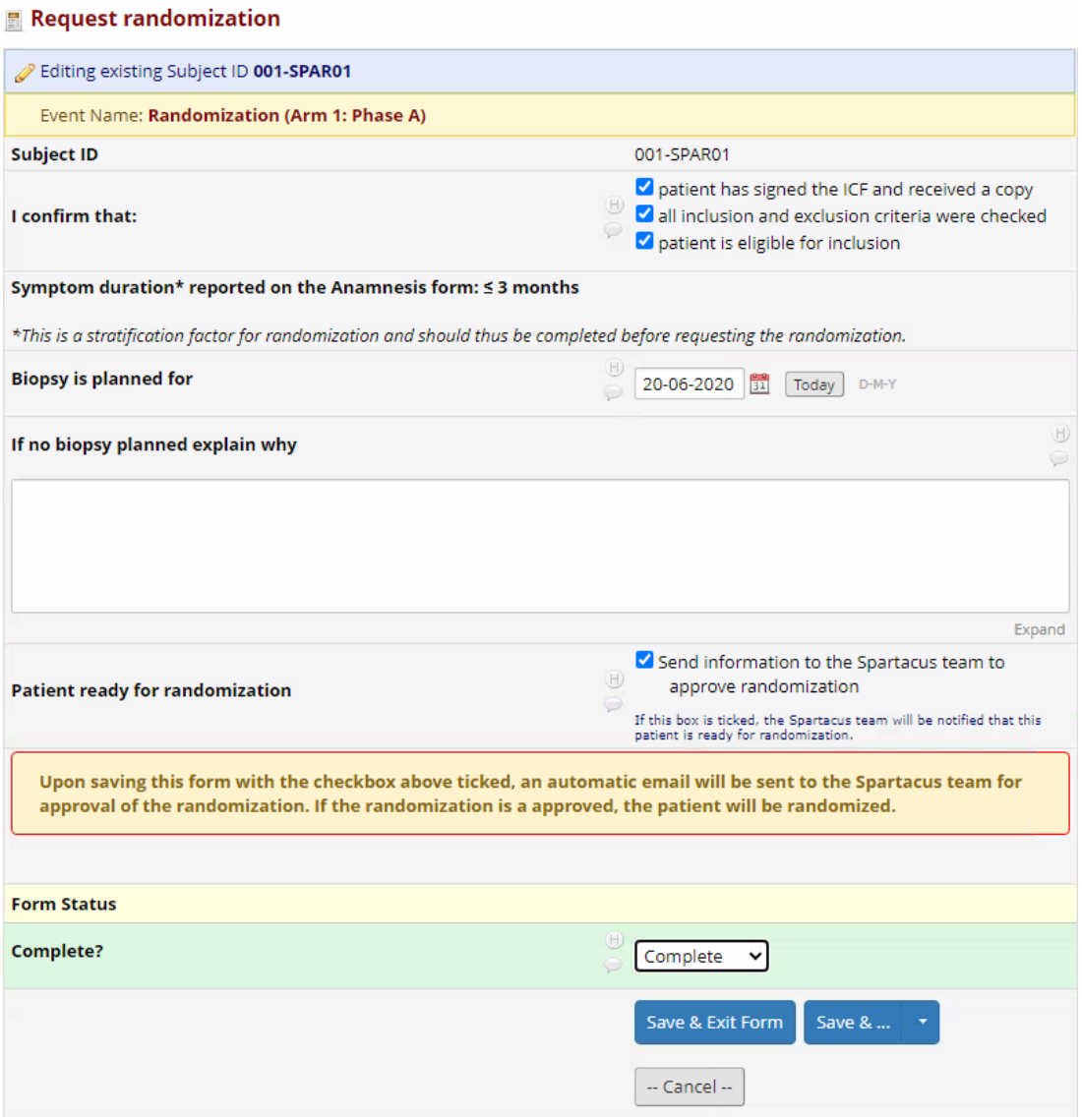


The emails sent during the randomization procedure can be sent to site specific email addresses as desired. This will be set up at the start of the trial. If you are not receiving the emails as expected or you wish to change the email list, please contact spartacus@uzgent.be.

**1) Request randomization by the site**

- Complete the 'Request randomization' form in REDCap

| Data Collection Instrument | Visit 1A (screening) 30-07-2020 | Visit 1B (biopt) | Randomization Randomized? |
|---|---|---|---|
| Visit Details Phase A | ● | ○ | |
| Informed Consent | ● + | | |
| Inclusion/Exclusion | ● | | |
| Anamnesis | ● | | |
| Synovial biopsy & US | | ○ | |
| Post biopsie vragenlijst | | | |
| Request randomization | | | ○ |
| Randomization by Pharmacy | | | ○ |
| Medication allocation by Pharmacy | | | ○ |




- Please note that the checkbox 'Patient ready for randomization' will only be available if the checkboxes
  - patient has signed the ICF and received a copy
  - all inclusion and exclusion criteria were checked
  - patient is eligible for inclusion

  are checked AND
  - Symptom duration

  has been completed on the Anamnesis form.

- Saving the form with the checkbox 'Send information to the Spartacus team to approve randomization' will trigger an email to start the randomization procedure.

### 2) Approval for randomization by the Spartacus team

After receipt of the randomization request email, the Spartacus team will confirm the eligibility of the patient. If the patient is approved for randomization, an email will be sent to UZ Ghent Pharmacy.

### 3) Randomization of the subject by UZ Ghent Pharmacy

UZ Ghent Pharmacy will randomize the patient and allocate a study number.

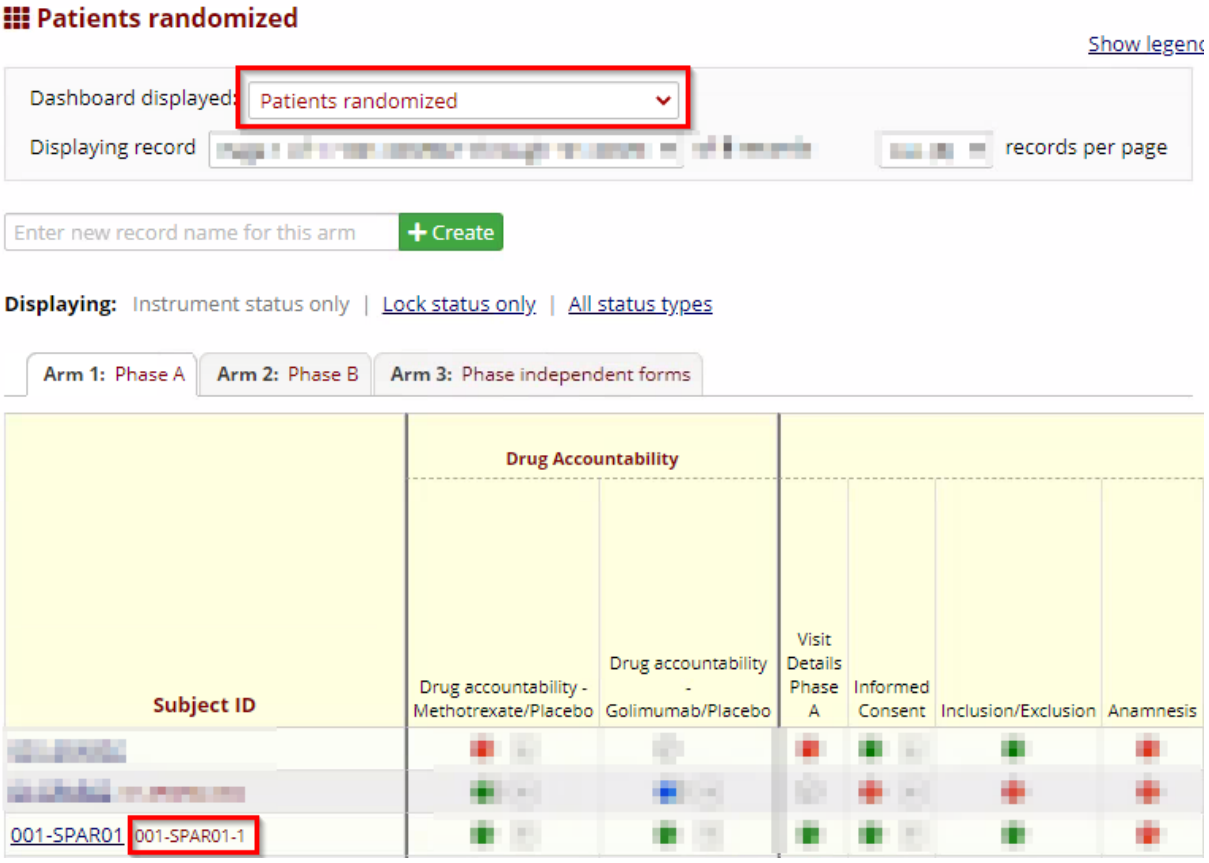
In REDCap, the full record id will be made automatically based on the study number allocated.
The full record id has following format: XXX-SPAR##-R

XXX: site number
##: site screening number
R: randomization number/study number given by UZ Pharmacy

This information will be registered in REDCap by UZ Ghent Pharmacy in the 'Randomization by Pharmacy' form.
An automatic email will be sent to the site to notify the site about the randomization status. If the patient is randomized, a second email will be sent with the information about the medication allocation and the date the study medication will be sent. (see Medication allocation).

Please note that the full record id in REDCap is added in the Record Status Dashboard.

Some custom dashboards are available for specific overviews, f.e. 'Patients randomized'.




## 5.10 Medication allocation

After the patient is randomization, the initial medication allocated for this patient will be registered in REDCap in the 'Randomization by Pharmacy' form.

Before each visit, the allocated medication will be completed in the 'Medication allocation' form by the Pharmacy. Please check this when preparing the study visit and contact spartacus@uzgent.be is any issues arise.

**Medication allocation by Pharmacy**

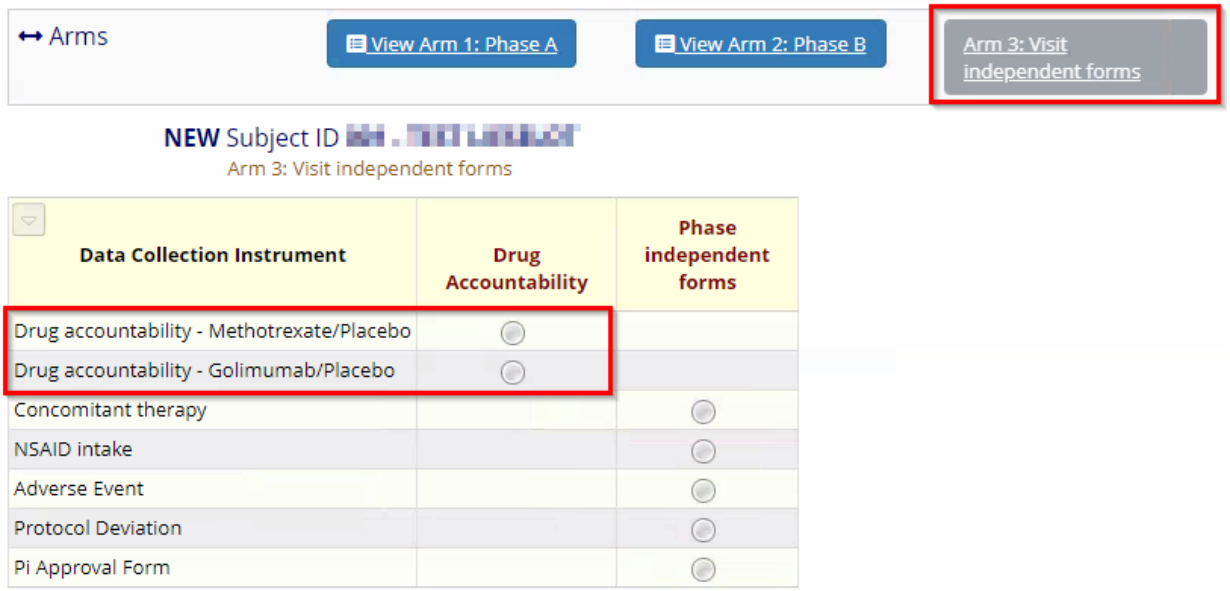
Editing existing Subject ID [redacted]

Event Name: **Randomization (Arm 1: Phase A)**

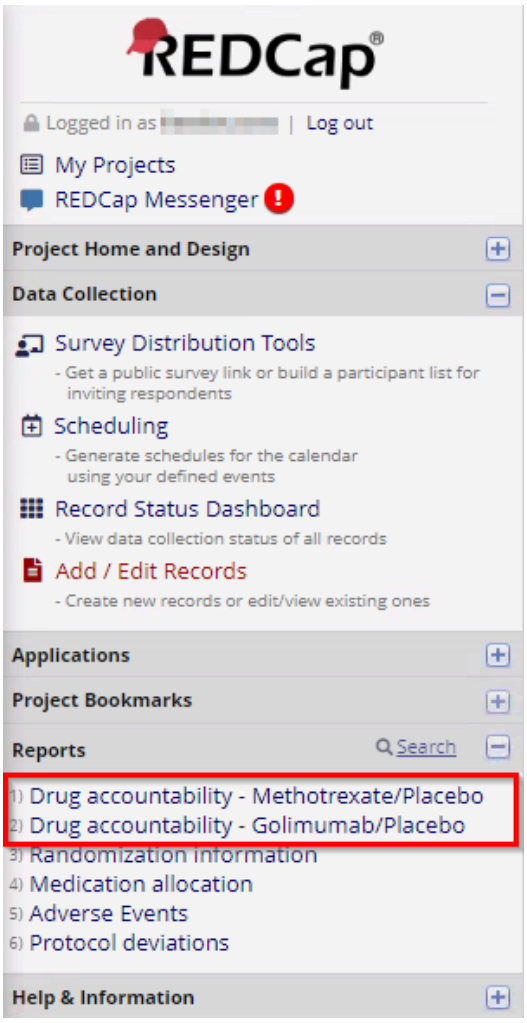
**Subject ID** [redacted]

| Visit | Treatment period | Methotrexate / Placebo bottles | Golimumab / Placebo syringes |
|---|---|---|---|
| **Visit 2 (W0)** | **Week 0 - Week 4** | **1** | **2** |
| **Visit 3 (W4)** | **Week 5 - Week 8** | 2 | **3** |
| **Visit 4 (W8)** | **Week 9 - Week 12** | 3 | **4** |
| **Visit 5 (W12)** | **Week 13 - Week 16** | 4 | **5** |
| **Visit 6 (W16)** | **Week 17 - Week 20** | 5 | **6** |
| **Visit 7 (W20)** | **Week 21 - Week 24** | 6 | **7** |
| **Visit 8 (W24)** **Please contact the Pharmacy by phone if blinded treatment is continued** | **Week 25 - Week 28** | | **8** |
| **Visit 9 (W28)** | **Week 29 - Week 32** | | 9 |
| **Visit 9 (W28)** | **Week 33 - Week 36** | | 10 |

During the trial, drug accountability should be registered on the 'Drug accountability - Methotrexate/Placebo' and 'Drug accountability - Golimumab/Placebo' forms. For each administration period, a new form should be added.




An overview of registered drug accountability can also be consulted in the 'Reports' section in the left-hand menu.

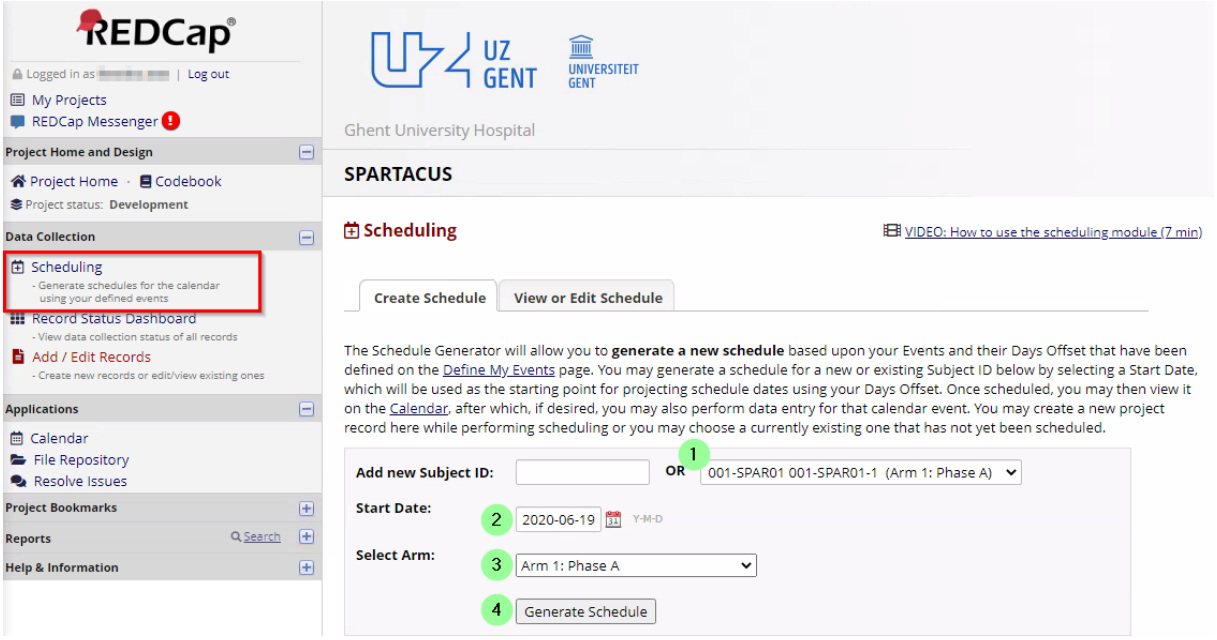


## 5.11 Scheduling

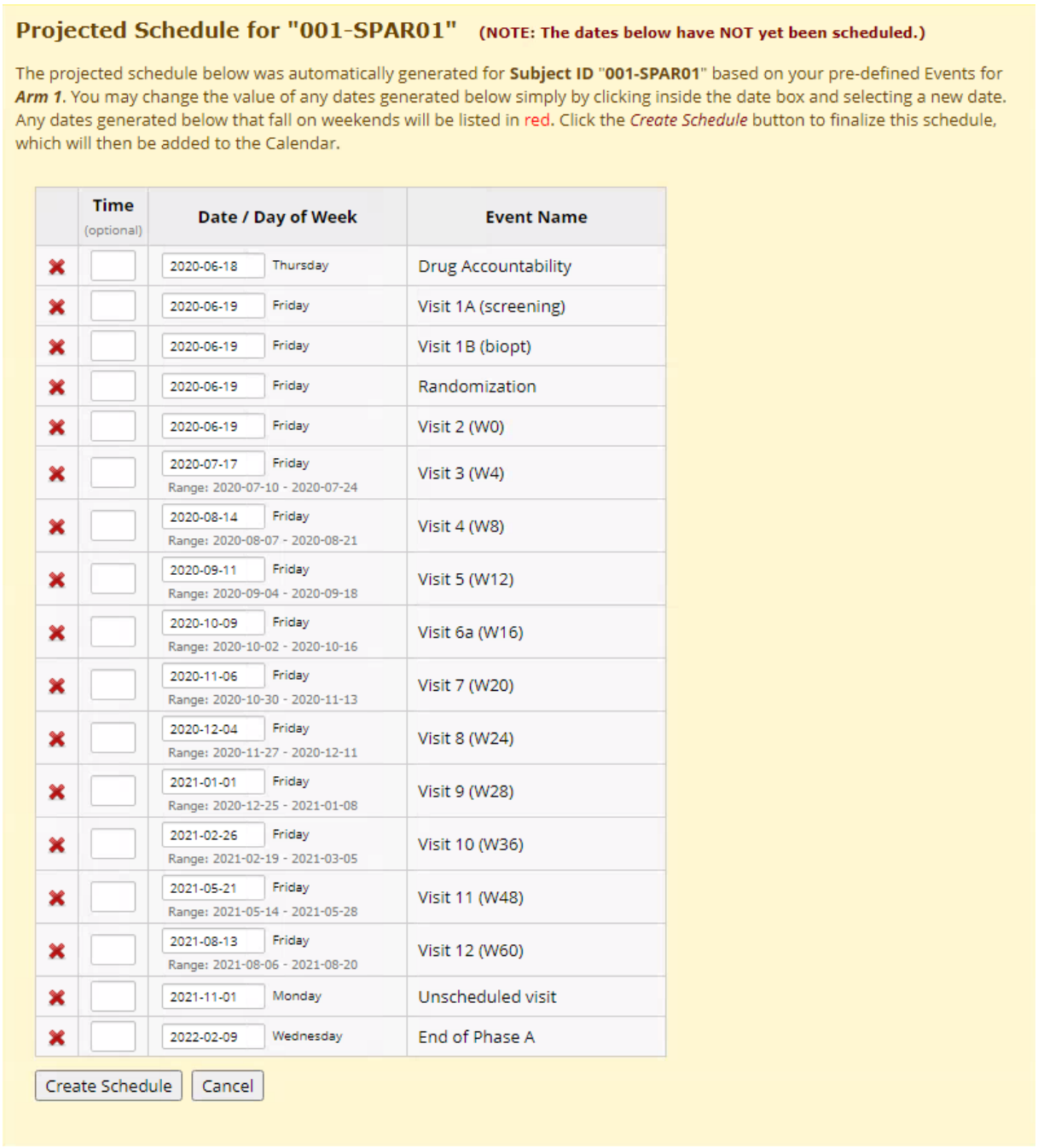
When scheduling a patients study visit, the scheduling module in REDCap can be used.

Go to ‘Scheduling’ in the left-hand menu.

1. Choose the subject id from the list
2. Select the start date. This should be the date for Visit 2 - Week 0
3. Select the Arm: Arm 1: Phase A
4. Click ‘Generate Schedule’




A schedule is proposed.



**Projected Schedule for "001-SPAR01"** **(NOTE: The dates below have NOT yet been scheduled.)**

The projected schedule below was automatically generated for **Subject ID** "**001-SPAR01**" based on your pre-defined Events for ***Arm 1***. You may change the value of any dates generated below simply by clicking inside the date box and selecting a new date. Any dates generated below that fall on weekends will be listed in red. Click the *Create Schedule* button to finalize this schedule, which will then be added to the Calendar.

| | Time (optional) | Date / Day of Week | Event Name |
|---|---|---|---|
| ✖ | | 2020-06-18 Thursday | Drug Accountability |
| ✖ | | 2020-06-19 Friday | Visit 1A (screening) |
| ✖ | | 2020-06-19 Friday | Visit 1B (biopt) |
| ✖ | | 2020-06-19 Friday | Randomization |
| ✖ | | 2020-06-19 Friday | Visit 2 (W0) |
| ✖ | | 2020-07-17 Friday<br>Range: 2020-07-10 - 2020-07-24 | Visit 3 (W4) |
| ✖ | | 2020-08-14 Friday<br>Range: 2020-08-07 - 2020-08-21 | Visit 4 (W8) |
| ✖ | | 2020-09-11 Friday<br>Range: 2020-09-04 - 2020-09-18 | Visit 5 (W12) |
| ✖ | | 2020-10-09 Friday<br>Range: 2020-10-02 - 2020-10-16 | Visit 6a (W16) |
| ✖ | | 2020-11-06 Friday<br>Range: 2020-10-30 - 2020-11-13 | Visit 7 (W20) |
| ✖ | | 2020-12-04 Friday<br>Range: 2020-11-27 - 2020-12-11 | Visit 8 (W24) |
| ✖ | | 2021-01-01 Friday<br>Range: 2020-12-25 - 2021-01-08 | Visit 9 (W28) |
| ✖ | | 2021-02-26 Friday<br>Range: 2021-02-19 - 2021-03-05 | Visit 10 (W36) |
| ✖ | | 2021-05-21 Friday<br>Range: 2021-05-14 - 2021-05-28 | Visit 11 (W48) |
| ✖ | | 2021-08-13 Friday<br>Range: 2021-08-06 - 2021-08-20 | Visit 12 (W60) |
| ✖ | | 2021-11-01 Monday | Unscheduled visit |
| ✖ | | 2022-02-09 Wednesday | End of Phase A |

Create Schedule | Cancel

Proposed dates can be adjusted and time slots that are not applicable or already passed can be deleted by clicking the red x.

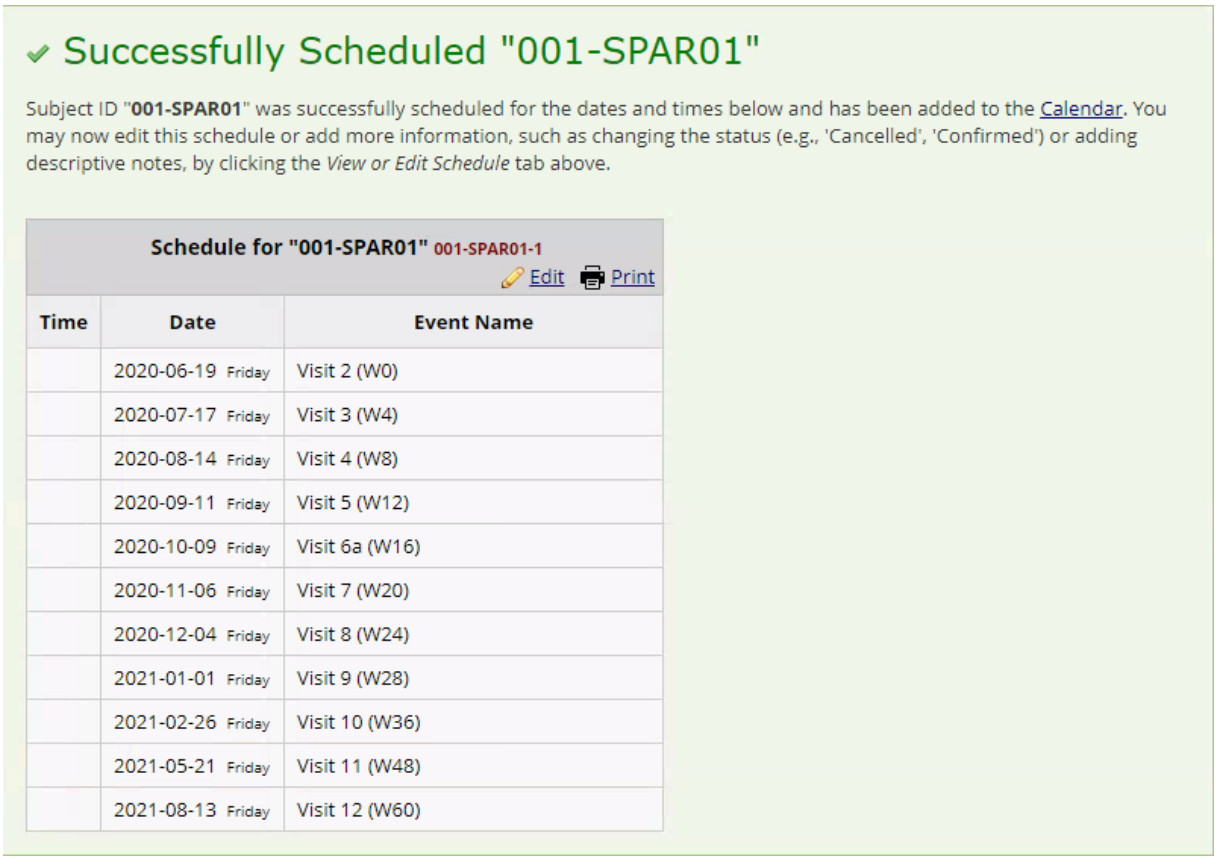
When the schedule is adjusted, click ‘Create Schedule’.

## Projected Schedule for "001-SPAR01" (NOTE: The dates below have NOT yet been scheduled.)

The projected schedule below was automatically generated for **Subject ID** "**001-SPAR01**" based on your pre-defined Events for ***Arm 1***. You may change the value of any dates generated below simply by clicking inside the date box and selecting a new date. Any dates generated below that fall on weekends will be listed in red. Click the *Create Schedule* button to finalize this schedule, which will then be added to the Calendar.

| | Time (optional) | Date / Day of Week | Event Name |
|---|---|---|---|
| ✖ | | 2020-06-19 Friday | Visit 2 (W0) |
| ✖ | | 2020-07-17 Friday<br>Range: 2020-07-10 - 2020-07-24 | Visit 3 (W4) |
| ✖ | | 2020-08-14 Friday<br>Range: 2020-08-07 - 2020-08-21 | Visit 4 (W8) |
| ✖ | | 2020-09-11 Friday<br>Range: 2020-09-04 - 2020-09-18 | Visit 5 (W12) |
| ✖ | | 2020-10-09 Friday<br>Range: 2020-10-02 - 2020-10-16 | Visit 6a (W16) |
| ✖ | | 2020-11-06 Friday<br>Range: 2020-10-30 - 2020-11-13 | Visit 7 (W20) |
| ✖ | | 2020-12-04 Friday<br>Range: 2020-11-27 - 2020-12-11 | Visit 8 (W24) |
| ✖ | | 2021-01-01 Friday<br>Range: 2020-12-25 - 2021-01-08 | Visit 9 (W28) |
| ✖ | | 2021-02-26 Friday<br>Range: 2021-02-19 - 2021-03-05 | Visit 10 (W36) |
| ✖ | | 2021-05-21 Friday<br>Range: 2021-05-14 - 2021-05-28 | Visit 11 (W48) |
| ✖ | | 2021-08-13 Friday<br>Range: 2021-08-06 - 2021-08-20 | Visit 12 (W60) |

Create Schedule | Cancel



✔ Successfully Scheduled "001-SPAR01"

Subject ID "**001-SPAR01**" was successfully scheduled for the dates and times below and has been added to the Calendar. You may now edit this schedule or add more information, such as changing the status (e.g., 'Cancelled', 'Confirmed') or adding descriptive notes, by clicking the *View or Edit Schedule* tab above.

**Schedule for "001-SPAR01"** 001-SPAR01-1

Edit Print

| Time | Date | Event Name |
|---|---|---|
| | 2020-06-19 Friday | Visit 2 (W0) |
| | 2020-07-17 Friday | Visit 3 (W4) |
| | 2020-08-14 Friday | Visit 4 (W8) |
| | 2020-09-11 Friday | Visit 5 (W12) |
| | 2020-10-09 Friday | Visit 6a (W16) |
| | 2020-11-06 Friday | Visit 7 (W20) |
| | 2020-12-04 Friday | Visit 8 (W24) |
| | 2021-01-01 Friday | Visit 9 (W28) |
| | 2021-02-26 Friday | Visit 10 (W36) |
| | 2021-05-21 Friday | Visit 11 (W48) |
| | 2021-08-13 Friday | Visit 12 (W60) |

This schedule is transferred to the Calendar.

In the Calendar, scheduled visits can be edited or more information can be added.

**WARNING**: There are no alerts linked to the scheduled visits. The Calendar should be consulted to see upcoming visits or adjust the status. Data entered in the Schedule / Calendar is not part of the study data and will not be analysed. Dates reported on the eCRF should be the correct dates.

However, it is import to **use the Scheduling and Calendar functionality and keep this up to date** in order for the Spartacus team to monitor scheduled visits and notify UZ Ghent Pharmacy to allocate the medication for upcoming visits.

Please note the no schedule should be made for Arm 3: Visit independent forms

## 5.12 Patient Reported Outcomes

WARNING: The survey link is unique per participant and per visit!

! Please note that the participants date of birth needs to be completed in the 'Anamnesis' form; in order for the participant to be able to log in to the survey.

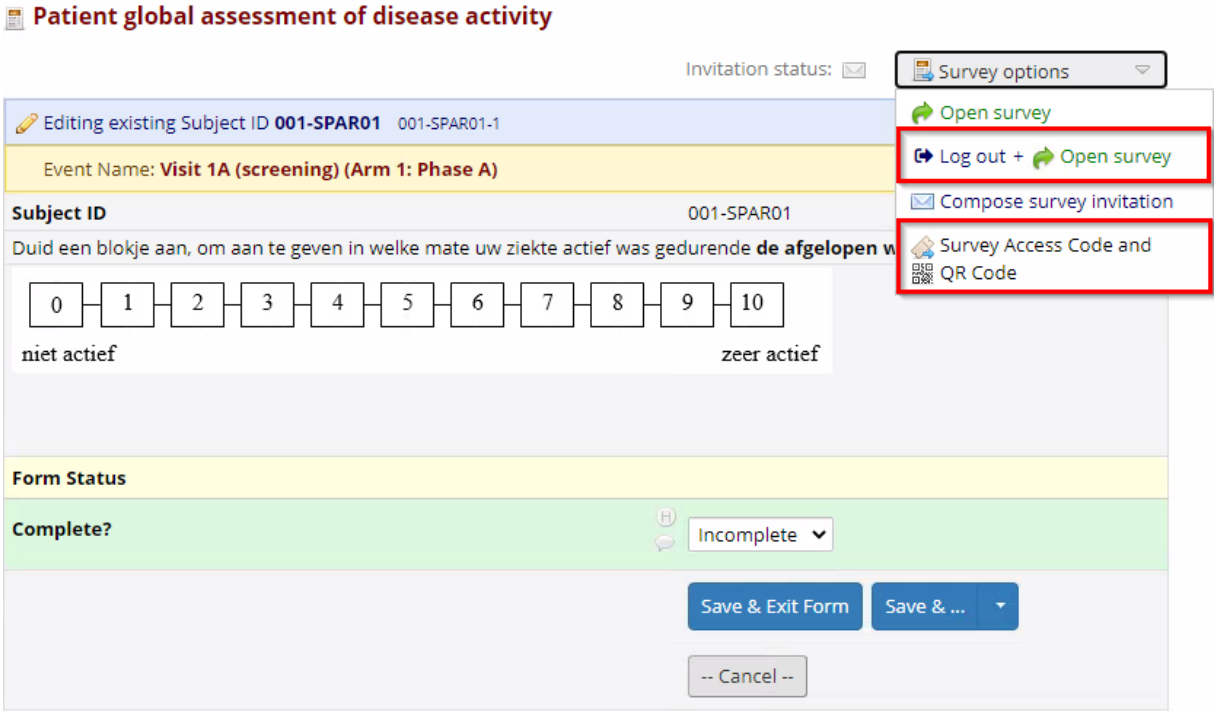
The surveys in the same visit are linked with an auto continue function. This means **only the first survey should be opened** (Patient assessment of global disease activity). Thereafter, the next survey will automatically open until all surveys for that visit are completed.

To open the first survey for a specific patient:

1) Go to the Record Home Page and open the first survey by clicking the grey icon.

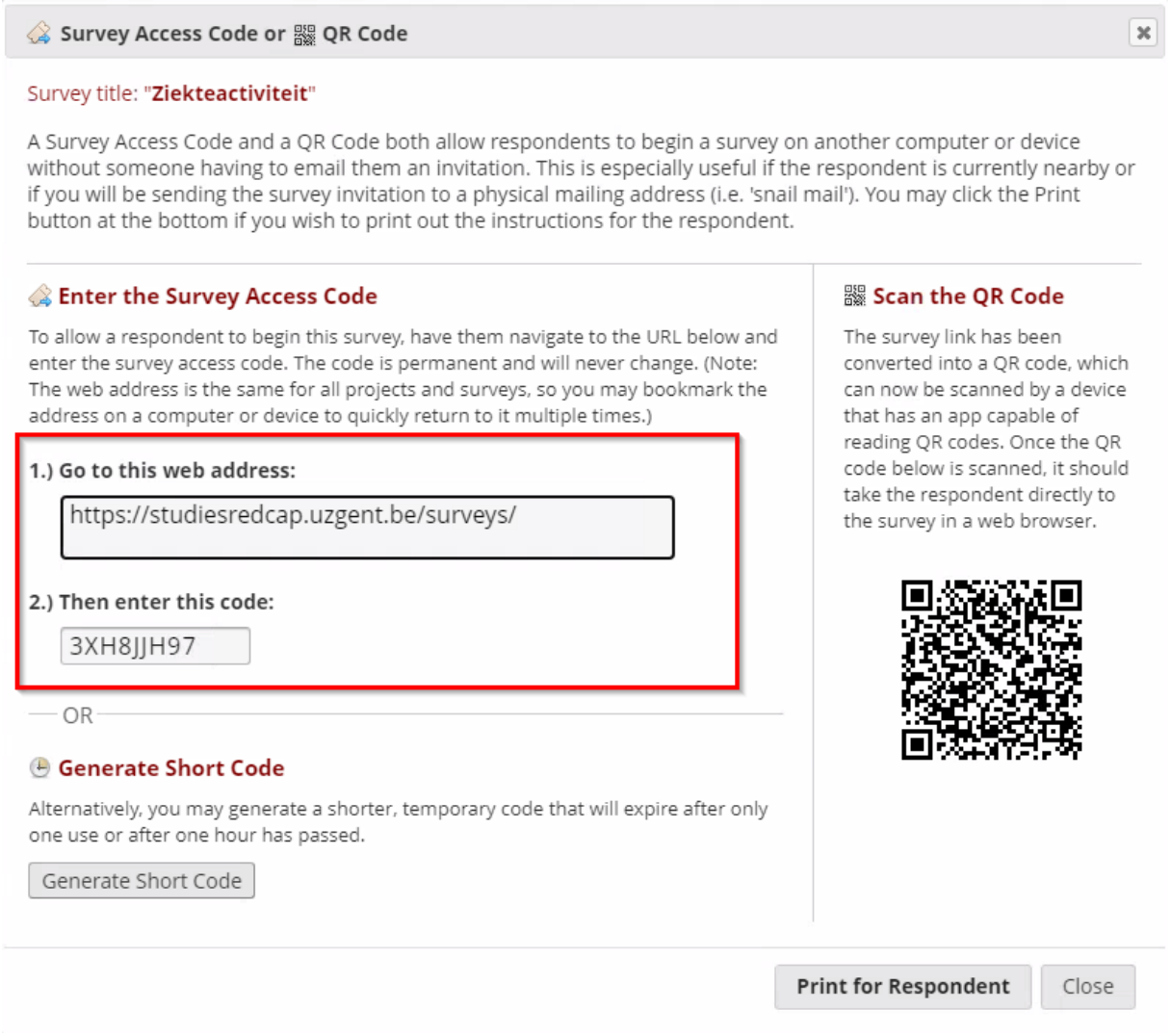



2) Open the survey options. For this trial, 2 options can be used to open the survey for a participant.



1. Option 1: Log out + open survey
   This immediately opens the survey for the participant to complete. Make sure this is done on a device that can be given to patient in order to complete the surveys. Don't forget to choose the 'Log out' options to prevent the participant from seeing other study information.

2. Option 2: Survey Access Code and QR code
   Information to access the survey can be printed in preparation of the visit.
   During the visit, use a recent web browser (preferably Google Chrome) to go to the web address below and enter the code.
   **Keep in mind that the survey link is unique per visit, so if you print the information for multiple visits at once; make sure it is clear which information corresponds to which visit. Please be aware that the Subject ID is not printed on the form, so you might want to add this to make sure the correct Access Code is used.**




For both options, the survey participant will first need to enter his or her birth date as a survey login. The birth date entered to access the survey is checked with the birth date entered in the 'Anamnesis' form in REDCap.




If a patient fails to login,

- check if the birth date on the Anamnesis form matches the birth date the participant enters;
- check if the correct access code has been provided

**WARNING**: The surveys are only available on device linked to your hospital network. This is the same as for the data entry part of REDCap. (Electronic Data Capture)

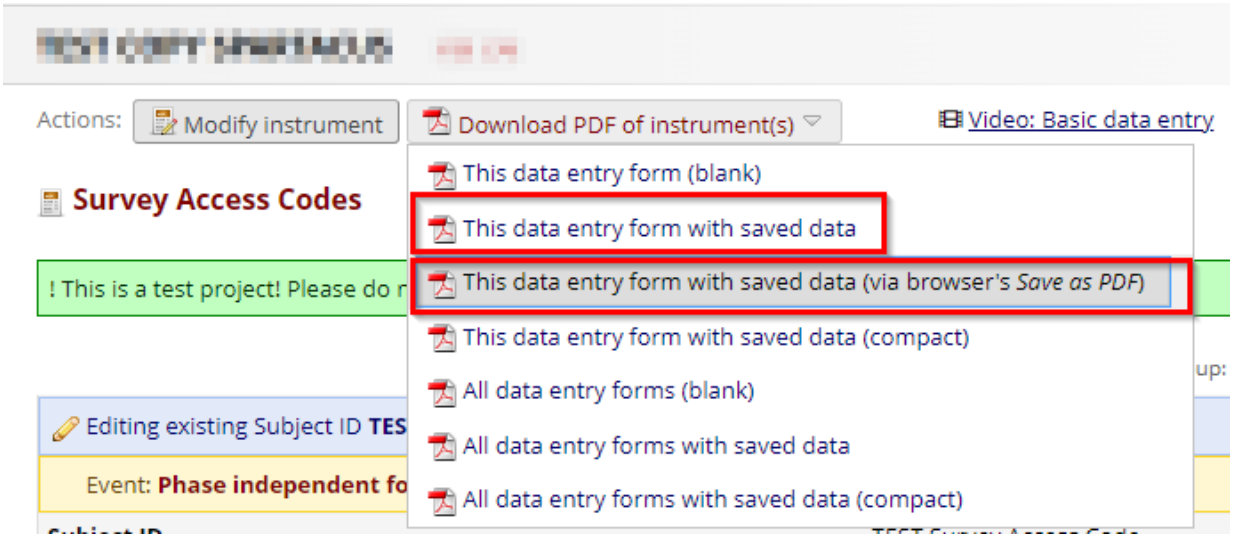
**WARNING**: Please disable the autocomplete function in the web browser you are using for completing the surveys. If autocomplete is not disabled, the browser might suggest to autocomplete answers of previous participants.

! If the subject fills out the questionnaires on paper; data entry does NOT have to be done through the survey functionality. Please enter the data the same way as non-survey forms.

### Overview of survey access codes

As of 05-12-2022, it is possible to see and print an overview per patient of the survey access codes for all visits.

The overview can be found under 'Arm 3: Visit independent forms'. Once opened this can be printed via 'Download PDF of instrument(s)' > 'This data entry form with saved data' or 'This data entry form with saved data (via browser's Save as PDF)'. The last option will have the survey access codes in table format.




Please note that survey access codes are available for all visits, even if the patient does not need to complete them. Please always verify the actual visit scheme of the patient.

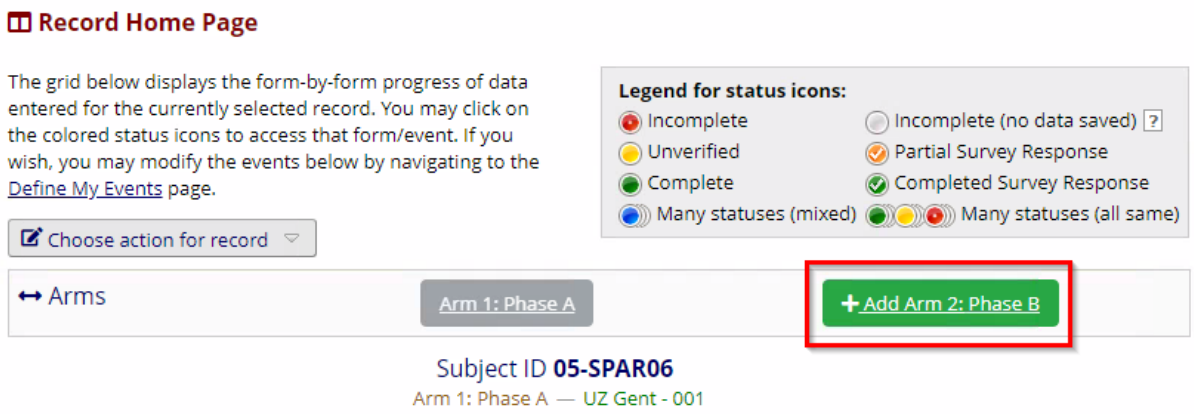
## 5.13 End of Phase A

If a patient is at the end of Phase A, for any reason, the 'End of Phase A' form should be completed. Forms for visits that are not done because the patient is no longer in Phase A can be left empty.

## 5.14 Move subject from Phase A to Phase B

When a patient is in sustained clinical remission; phase A of the SPARTACUS trials ends and the patient moves to phase B.

1. Complete the 'End of Phase A' form
2. In the Recond Home Page, click on the button 'Add Arm 2: Phase B'




The forms and visits for Phase B are visible in the Record Home Page.

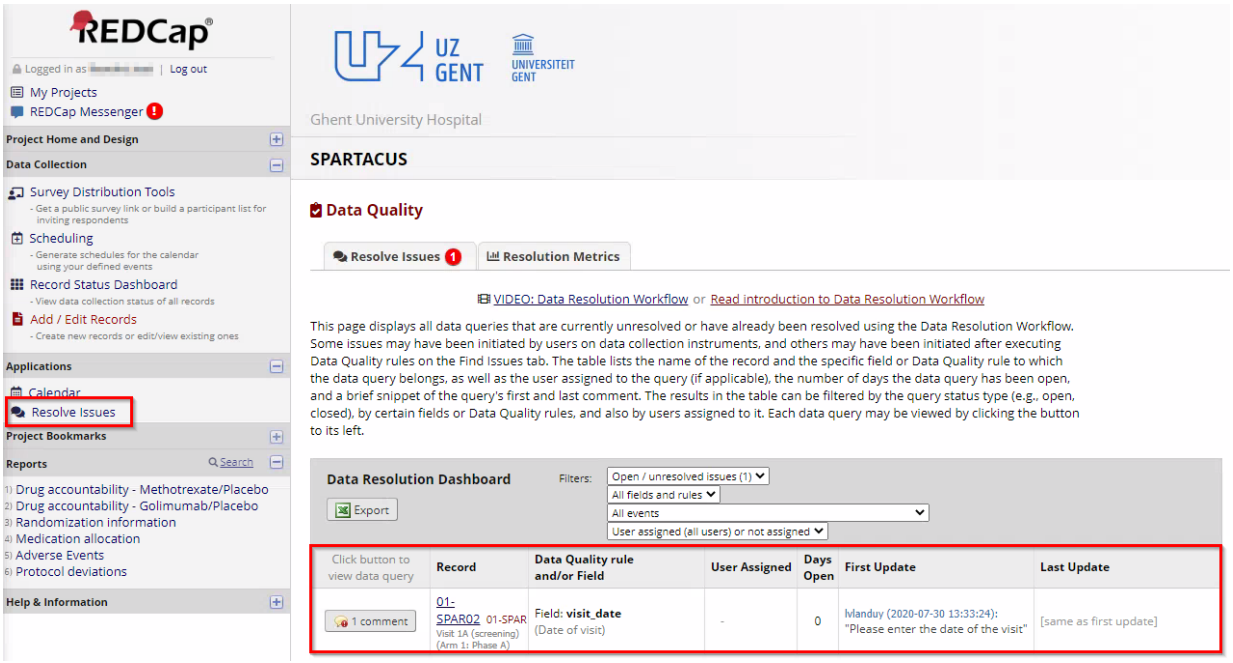
Phase independent data should be kept up to date in 'Arm 3: Visit independent forms'.

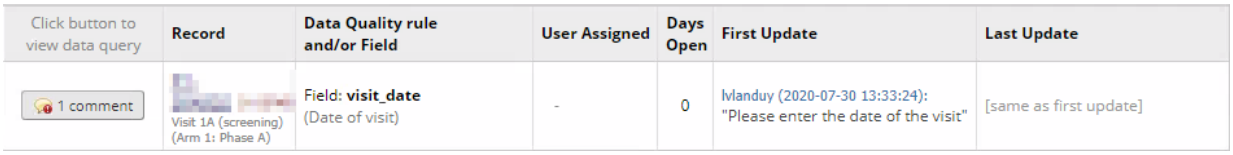
## 5.15 End of Phase B

If a patient is at the end of Phase B, for any reason, the 'End of Phase B' form should be completed. Forms for visits that are not done because the patient is no longer in Phase B can be left empty.

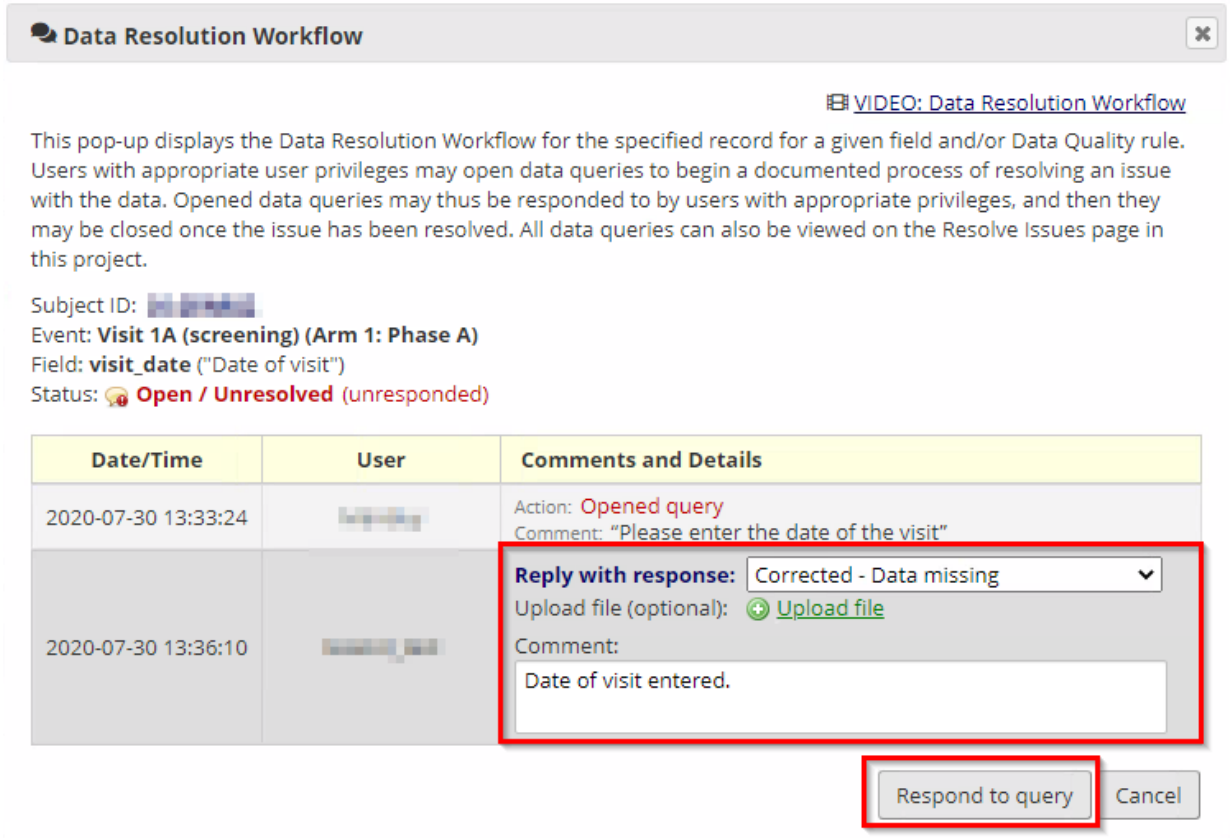
## 5.16 Resolve Issues

This page displays all data queries that are currently unresolved or that have already been resolved using the Data Resolution Workflow. Some issues may have been initiated by users on data collection instruments, others may have been initiated after executing a Data Quality rule. The table lists the name of the record and the specific field or Data Quality rule to which the data query belongs, as well as the user assigned to this query (if applicable), the number of days the query has been open, and a brief snippet of the query's first and last comment. The results in the table can be filtered by query status type (e.g. open, closed), by certain fields or Data Quality rules, and also by users assigned to it.




Each data query may be viewed by clicking the button to its left. This will open a pop-up showing details about subject ID, event, field & status of the query, as well as the history of the field & query.




For queries related to a single field, clicking the subject ID (in the column Record) will take you to this field. Subsequently, the field can be corrected and the query can be answered.



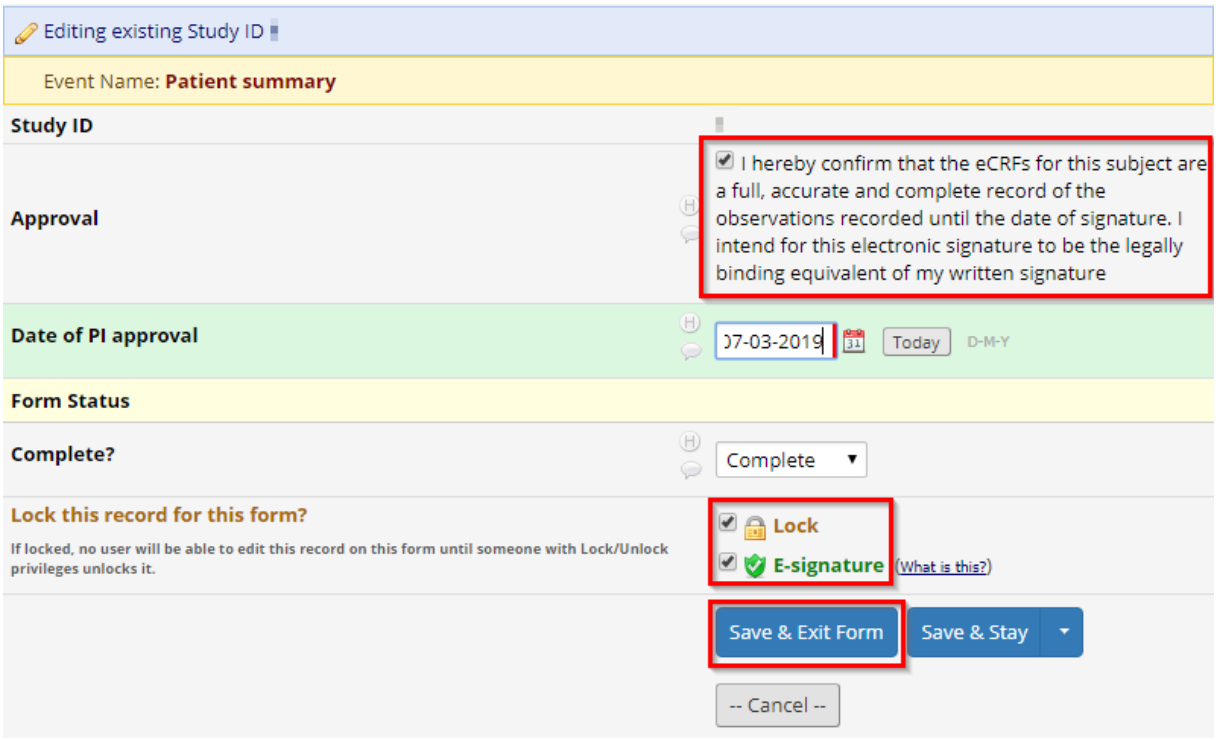

## 5.17 Approval by Principal Investigator

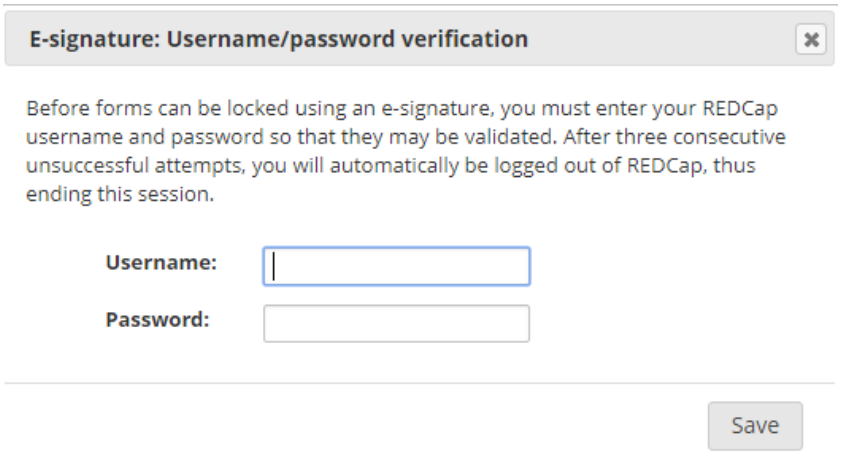
Before the final analysis the PI must approve the reported data for each subject.
Subject's data can be approved if

- Data is considered 'Clean' by the Data Manager
- Monitoring has been done and issues have been resolved
- No additional data is expected

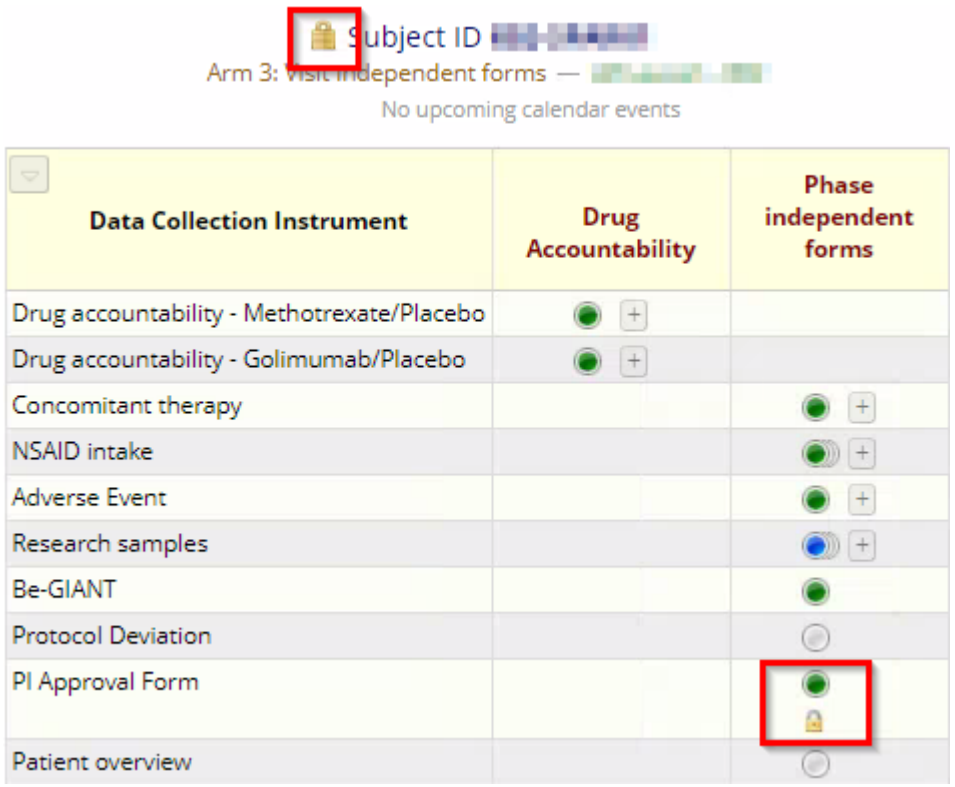
The Data Manager will provide a list of subjects ready for approval by the PI.
To approve a subject's data, users with the role 'Principal Investigator' will have write access to the 'PI approval form'. Other users will only have read access to this form.

The PI needs to complete the approval form for each subject and check both 'Lock' and 'E-signature' boxes. Upon saving the form, a pop up will appear requesting PI to confirm by entering his/her username and password.




Locking and providing an e-Signature will trigger a notification to the Spartacus team who will subsequently lock all forms for the approved subject.
Once locked, no data can be entered or modified without unlocking the data. In that case, the PI will have to review the changes and sign the approval form again.
Data Manager, Monitor and Principal Investigator have the rights to unlock data.




## 5.18 Reports

For this study, some custom reports have been created:

1) Drug accountability - Methotrexate/placebo
2) Drug accountability - Golimumab/placebo
3) Randomization information
4) Medication allocation
5) Adverse Events Log: this displays all reported Adverse Events and related data
6) Protocol Deviation Log: this displays all reported Protocol Deviations and related data

Other reports can be added throughout the trial.

If you would like another report to be available, please ask the Spartacus team.

# 6 Overview of eCRFs

In this chapter, each eCRF's purpose is summarized, along with the time point(s) when the CRF can be completed and some specific guidance (if necessary).

## 6.1 Visit Details (Phase A)

| | |
|---|---|
| **Purpose** | Document general information about the study visit in Phase A |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) – Visit 1B (Biopt) – Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Unscheduled visit - Early discontinuation visit |
| **Repeating** | No |

**Specificities**

- The Visit Details form **should be completed for all visits, except the Unscheduled Visit**, if there was no unscheduled visit. If a visit was not done, this can be indicated in the form.

## 6.2 Visit Details (Phase B)

| | |
|---|---|
| **Purpose** | Document general information about the study visit in Phase B |
| **Study Phase** | Phase B |
| **Time point** | Visit 1 (W0) – Visit 2 (W12) –Visit 3 (W24) – Visit 4 (W36) – Visit 5 (W48) – Visit 6 (W72) – Visit 7 (W96) – Visit 8 (W120) – Visit 9 (W144) – Unscheduled Flare Id Visit – Flare Follow-Up Visit |
| **Repeating** | No |

**Specificities**

- The Visit Details form **should be completed for all visits, except the Unscheduled Flare Id Visit and the Flare Follow-Up Visit**, if there was no flare. If a visit was not done, this can be indicated in the form.

## 6.3 Informed consent

| | |
|---|---|
| **Purpose** | Document subject's informed consent |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) |
| **Repeating** | Yes, if a new version of the informed consent is signed, a new form should be added. |

## 6.4 Inclusion/Exclusion

| | |
|---|---|
| **Purpose** | Document subject's eligibility |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) - Visit 2 (W0) |
| **Repeating** | No |

**Specificities**

- Inclusion/Exclusion criteria should be completed on Visit 1A (Screening) and Visit 2 (W0). When opening the form for Visit 2 (W0), the fields initial values are set to the values entered for Visit 1A (screening). All criteria should be checked and adjusted accordingly.

Please note that initial values are only set the first time the form at Visit 2 (W0) is opened and saved. Subsequent changes of values on Visit 1A (screening) will not be reflected automatically.

## 6.5 Anamnesis

| | |
|---|---|
| **Purpose** | Document information about subject's anamnesis |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) |
| **Repeating** | No |

**Specificities**

- The question 'How long have SpA symptoms been ongoing?' should be completed BEFORE the randomization can be requested.

## 6.6 Synovial biopsy & US

| | |
|---|---|
| **Purpose** | Document information on synovial biopsy & US |
| **Study Phase** | Phase A |
| **Time point** | Visit 1B (Biopt) |
| **Repeating** | No |

## 6.7 Request randomization

| | |
|---|---|
| **Purpose** | Request subject's randomization |
| **Study Phase** | Phase A |
| **Time point** | Randomization |
| **Repeating** | No |

**Specificities**

- Completing the 'Request randomization' form will trigger the Randomization workflow. This is described in detail in the section about Randomization.

## 6.8 Randomization by Pharmacy

| | |
|---|---|
| **Purpose** | Document subject's randomization |
| **Study Phase** | Phase A |
| **Time point** | Randomization |
| **Repeating** | No |

**Specificities**

- This form will be **completed by UZ Gent Pharmacy**. It is visible in read-only mode for study staff.
- This form is part of the Randomization workflow. This is described in detail in the section about Randomization.

## 6.9 Medication allocation by Pharmacy

| | |
|---|---|
| **Purpose** | Document information allocation medication for this patient. |
| **Study Phase** | Phase A |
| **Time point** | Randomization |
| **Repeating** | No |

**Specificities**

- This form will be **completed by UZ Gent Pharmacy**. It is visible in read-only mode for study staff.
- Allocated medication will be updated during the trial.

## 6.10 Prior SpA Therapy

| | |
|---|---|
| **Purpose** | Document information about the prior SpA therapy |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) |
| **Repeating** | No |

## 6.11 Fibromyalgia exclusion

| | |
|---|---|
| **Purpose** | Document information about fibromyalgia |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) |
| **Repeating** | No |

## 6.12 Medical history

| | |
|---|---|
| **Purpose** | Document information about subject's medical history |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) |
| **Repeating** | Yes, for each condition, a new form should be added. |

## 6.13 Latent TB screening

| | |
|---|---|
| **Purpose** | Document information about subject's latent TB screening |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) – Visit 5 (W12) – Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit |
| **Repeating** | No |

## 6.14 Physical examination

| | |
|---|---|
| **Purpose** | Document information about subject's physical examination |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 1A (screening) – Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>– Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.15 Vital signs

| | |
|---|---|
| **Purpose** | Document information about subject's vital signs |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) – Visit 5 (W12) – Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit |
| **Repeating** | No |

## 6.16 Length and weight

| | |
|---|---|
| **Purpose** | Document information about subject's length and weight |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Length:<br>Visit 1A (screening) |
| | Weight:<br>Visit 1A (screening) – Visit 5 (W12) – Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.17 Smoking and alcohol intake

| | |
|---|---|
| **Purpose** | Document information about subject's smoking and alcohol intake |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Phase A: Visit 1A (screening) – Vist 2 (W0) – Visit 5 (W12) – Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) |
| **Repeating** | No |

**Specificities**

- The data entered on this form is transferred to the next visit and should be adjusted for each visit if smoking and alcohol intake status changed since the previous visit.

## 6.18 BASMI + Chest Expansion

| | |
|---|---|
| **Purpose** | Document information about subject's BASMI + Chest expansion exam |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 5 (W12) –Visit 8 (W24) –Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.19 Psoriatic skin evaluation

| | |
|---|---|
| **Purpose** | Document information about subject's psoriatic skin evaluation |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 5 (W12) –Visit 8 (W24) –Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit |

| | |
|---|---|
| | Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.20 Joint count

| | |
|---|---|
| **Purpose** | Document information about subject's joint count |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 1A (screening) – Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.21 Dactylitis

| | |
|---|---|
| **Purpose** | Document information about subject's dactylitis |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 1A (screening) – Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.22 Enthesitis

| | |
|---|---|
| **Purpose** | Document information about subject's enthesitis |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 1A (screening) – Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- Indicate sites of enthesitis by clicking the image. The selected area will be presented in red. Click again to deselect.

## 6.23 Physician global assessment

| | |
|---|---|
| **Purpose** | Document information about physician global assessment of disease activity |
| **Study Phase** | Phase A – Phase B |

| | |
|---|---|
| **Time point** | Visit 1A (screening) – Visit 5 (W12) –Visit 8 (W24) –Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.24 HLA B27, anti-CCP AB, HBV, HCV, HIV, CMV IgG

| | |
|---|---|
| **Purpose** | Document information about HLA B27, anti-CCP AB, HBV, HCV, HIV, CMV IgGtesting |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) |
| **Repeating** | No |

## 6.25 Serum pregnancy testing

| | |
|---|---|
| **Purpose** | Document information about serum pregnancy testing |
| **Study Phase** | Phase A |
| **Time point** | Visit 1A (screening) |
| **Repeating** | No |

**Specificities**

- This form should only be **completed for female patients of childbearing potential**. This is indicated on the Anamnesis form.

## 6.26 Safety lab tests

| | |
|---|---|
| **Purpose** | Document information about subject's safety lab tests |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 1A (screening) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) |
| **Repeating** | No |

**Specificities**

- Safety lab tests to be performed may vary on different visits as described in the protocol.

## 6.27 ESR, CRP

| | |
|---|---|
| **Purpose** | Document information about subject's ESR, CRP testing |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 1A (screening)– Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) – Unscheduled Visit - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |

| | |
|---|---|
| **Repeating** | No |

## 6.28 Trial continuation evaluation

| | |
|---|---|
| **Purpose** | Document information about subject's clinical remission status |
| **Study Phase** | Phase A |
| **Time point** | Visit 5 (W12) –Visit 8 (W24) –Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) |
| **Repeating** | No |

**Specificities**

- Based on the information in REDCap, a **suggestion** for trial continuation will appear in the form. Please note that this suggestion only takes reported data on PASSI, CR and SCR in account. Trial continuation is at the discretion of the PI or local rheumatologist. **The study flow chart should always be followed.**

## 6.29 Post flare treatment

| | |
|---|---|
| **Purpose** | Document information about subject's post flare treatment |
| **Study Phase** | Phase B |
| **Time point** | Flare follow up visit/phone call |
| **Repeating** | No |

## 6.30 Patient global assessment of disease activity (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 1A (screening) – Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- At the screening visit this should be completed by the patient on paper and then transferred to the eCRF.
- For other visits, these forms can be completed directly by the patient through an online survey. For guidance on how to provide the link to the survey to the participant see chapter on Patient Reported Outcomes.
  ! Please note that the survey link is unique per participant and per event!
- The participant will need to log in to the survey by entering his/her date of birth before he/she can complete the survey. For that reason, the date of birth needs to be completed in the 'Anamnesis' form, before providing the link to the participant.

## 6.31 Patient global assessment of pain (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |

| | |
|---|---|
| **Time point** | Visit 1A (screening) – Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.32 BASDAI (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 3 (W4) – Visit 4 (W8) – Visit 5 (W12) – Visit 6 (W16) – Visit 7 (W20) – Visit 8 (W24) – Visit 9 (W28) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.33 BASFI (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 5 (W12) –Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.34 Health Assessment Questionnaire (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0)–Visit 8 (W24)– Visit 11 (W48) |

| | |
|---|---|
| | Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.35 ASAS – Health index (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 5 (W12) –Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.36 EuroQoL 5 dimensions (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 5 (W12) –Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.37 Co-morbidity index (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 5 (W12) –Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.38 Healthcare utilization and productivity - baseline/last 6m (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0)<br><br>Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.39 Healthcare utilization and productivity - follow up/last 3m (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 5 (W12) –Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.40 Healthcare utilization and productivity - work (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 2 (W0) – Visit 5 (W12) –Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60) - Early discontinuation visit<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.41 Education and working status - baseline (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A |
| **Time point** | Visit 2 (W0) |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.42 Education and working status - follow up (survey)

| | |
|---|---|
| **Purpose** | Patient Questionnaire |
| **Study Phase** | Phase A – Phase B |
| **Time point** | Visit 5 (W12) –Visit 8 (W24) – Visit 10 (W36) – Visit 11 (W48) – Visit 12 (W60)<br><br>Phase B: Visit 2 (W12) – Phase B: Visit 3 (W24) – Phase B: Visit 4 (W36) – Phase B: Visit 5 (W48) – Phase B: Visit 6 (W72) – Phase B: Visit 7 (W96) – Phase B: Visit 8 (W120) – Phase B: Visit 9 (W144) – Unscheduled Flare Id Visit |
| **Repeating** | No |

**Specificities**

- This form can be completed by the subject through an online survey. For guidance on how to provide the link to the survey to the participant see chapter Patient Reported Outcomes.

## 6.43 End of Phase A

| | |
|---|---|
| **Purpose** | Document date and reason for end of phase A |
| **Study Phase** | Phase A |
| **Time point** | End of Phase A |
| **Repeating** | No |

**Specificities**

- If the reason is linked to a protocol deviation or an adverse event, this should be documented on the appropriate form.
- At the end of each Phase, all concomitant therapy forms which still have ongoing medication should be checked an adjusted is necessary.

## 6.44 End of Phase B

| | |
|---|---|
| **Purpose** | Document date and reason for end of phase B |
| **Study Phase** | Phase B |
| **Time point** | End of Phase B |
| **Repeating** | No |

**Specificities**

- If the reason is linked to a protocol deviation or an adverse event, this should be documented on the appropriate form.

- At the end of each Phase, all concomitant therapy forms which still have ongoing medication should be checked and adjusted if necessary.

## 6.45 Drug accountability - Methotrexate/Placebo

| | |
|---|---|
| **Purpose** | Document information about subject's drug accountability for Methotrexate/Placebo |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | Yes, for each treatment period a new form should be added |

**Specificities**

- Data on Methotrexate/Placebo accountability should be collected throughout the trial.

## 6.46 Drug accountability - Golimumab/Placebo

| | |
|---|---|
| **Purpose** | Document information about subject's drug accountability for Golimumab/Placebo |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | Yes, for each treatment period a new form should be added |

**Specificities**

- Data on Golimumab/Placebo accountability should be collected throughout the trial.

## 6.47 Concomitant therapy

| | |
|---|---|
| **Purpose** | Document information about subject's concomitant therapy |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | Yes, for each concomitant therapy a new form should be added |

**Specificities**

- Data on concomitant therapy should be collected throughout the trial.
- During each visit, check the concomitant therapy forms. If concomitant therapy has been stopped since the previous visit, adjust the status 'ongoing' and enter a stop date.
- If this concomitant therapy is restarted at a later time during the trial, add a new concomitant therapy form.

## 6.48 NSAID intake

| | |
|---|---|
| **Purpose** | Document information about subject's NSAID intake |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | Yes, for each NSAID intake period a new form should be added |

**Specificities**

- Data on NSAID intake should be collected throughout the trial.
- During each visit, check the NSAID log of the patient and enter data in the eCRF. Each line on the paper log corresponds to 1 NSAID intake form in the eCRF.

- If NSAID intake of the same NSAID is restarted at a later time during the trial, add a new NSAID intake form.

## 6.49 Adverse event

| | |
|---|---|
| **Purpose** | Document information about subject's adverse events |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | Yes, for each adverse event a new form should be added |

**Specificities**

- Data on adverse events should be collected throughout the trial.
- MEDDRA term: the data manager will add the MEDDRA term corresponding to the adverse event description given.
- In case the adverse event is considered serious, this should be reported to the Sponsor within 24 hours. Please use the SAE form available in the eCRF or in the Investigator Site File to report this.
- If medication was given for this adverse event, each individual medication should be reported on a concomitant therapy form.

## 6.50 Protocol deviation

| | |
|---|---|
| **Purpose** | Document protocol deviations for this subject (if applicable) |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | Yes, for each protocol deviation a new form should be added |

**Specificities**

- Data on protocol deviations should be collected throughout the trial.

## 6.51 PI Approval form

| | |
|---|---|
| **Purpose** | Approval of reported data by the PI |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | No |

**Specificities**

- This form should only be completed and signed by the PI when data collection is done and data is considered 'clean'. For guidance on how to complete and sign the form see chapter Approval by Principal Investigator

## 6.52 Patient overview

| | |
|---|---|
| **Purpose** | Give an overview of some key data points for the subject |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | No |

**Specificities**

- This form shows some key data points reported in other forms. No data can be added or changed in this form.

## 6.53 Be-GIANT

| | |
|---|---|
| **Purpose** | Register the subject number in the Be-GIANT study |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | No |

## 6.54 Research samples

| | |
|---|---|
| **Purpose** | Indicate which research samples were taken |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | Yes, for each timepoint of sample collection a new form should be added |

## 6.55 Flare / remission status

| | |
|---|---|
| **Purpose** | Document information about subject's flare or remission status |
| **Study Phase** | Phase B |
| **Time point** | Unscheduled Flare Id Visit |
| **Repeating** | No |

## 6.56 Survey Access Codes

| | |
|---|---|
| **Purpose** | Give an overview of the survey access codes for all visits |
| **Study Phase** | Visit Independent (arm 3) |
| **Time point** | NA |
| **Repeating** | No |

**Specificities**

- This form shows survey access codes for the different visits of a patient. No data can be added or changed in this form.
- Please note that survey access codes are available for all visits, even if the patient does not need to complete them. Please always verify the actual visit scheme of the patient.
- For guidance on how to use this form, please see chapter Overview of survey access codes