Version: 1.0

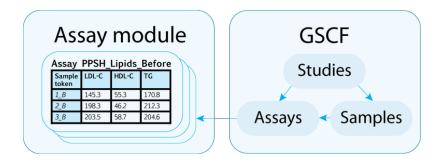
Date: 13/10/2011

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GSCF User Guide

This User Guide provides an overview of features of the Generic Study Capture Framework (GSCF). Use the content list to enter detailed information on how to use GSCF.

Attached to GSCF there are several modules. The image below illustrates how GSCF and modules are related. The output of GSCF (assays and samples) are used in different modules. Users can easily import for example bulks of numerical data from Excel files. The Simple Assay Module (SAM) is used to store clinical data, such as Rules Based Medicine assays, but also physical measurements such as body weight of mice.



Through the studies menu you can either create, view or import studies (or study data). 'Create a new study' will guide you through several steps (study wizard) to include your study into the system.

General note: Templates are available at all steps of the create study wizard. With these templates you can define the information you want to store on your study. You can add extra fields to a template or make a new template if necessary. If possible, choose existing templates/field to allow comparison between studies.

→ For any questions that could not be answered through this guide, email support@thehyve.nl

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1 Create a new study (wizard)

Click on Create > Create a new study using the menu on top. This will start the 6-step study wizard.

General points to keep in mind;

- Use next and previous (at the bottom of the page) to navigate, or use 'quick save' at any time during the wizard, to complete it at another point in time.
- ➤ Hovering over question marks will show additional information on required fields.
- > Use the upper left icon to select all rows in a table



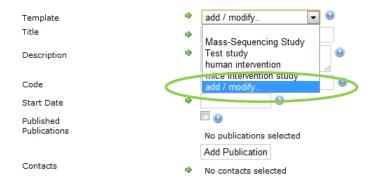
➤ Use 'import study data' to import large datasets (for example: many subjects) from an excel sheet into your study (see also 3 Import part of study design).

Step 1: Start



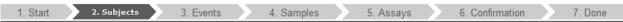
Define basic properties of your study. Fields indicated by an arrow are required.

You can choose an appropriate template, or create a new template. This will allow you to add and modify fields.

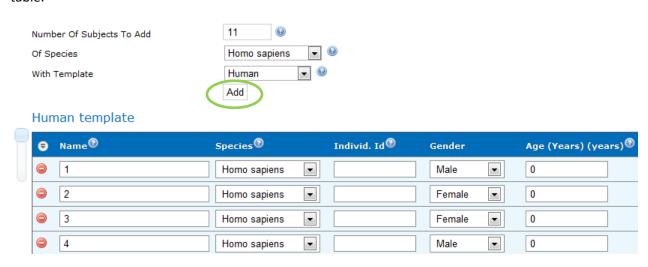


In some browsers (Firefox 4, Safari and Chrome) fields can be enlarged by dragging the indicated (lower right) corner of the text field.

Step 2: Subjects



Use this step to manually add a number of subjects: report the number of subjects in your study and choose the template. Then add these subjects to your study and fill out the required information in the table.



If you have an excel file with subject list, a separate importer can be used. Especially, when you have detailed subject information, this importer can be used very efficiently. See Topic 3 - Import part of study design (page 9).

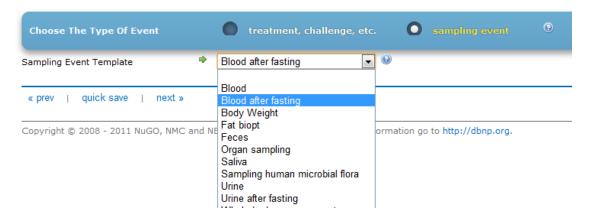
Step 3: (Sampling) Events



Any treatment, challenge or occurrence in your study can be defined in the events step. Choose the appropriate sample template. Each sampling event should be added separately.

An *event* is defined as anything that happens to subject(s) in your study that is not resulting in a sample. Whereas *sampling* events if the event results in extraction of samples, where you want to store measurements upon.

Important: A combination of sampling events, subjects and groups, will automatically create samples.



After you have added an event or sampling event, it will appear in a list below, and you can modify this event if necessary.

Here, you also need to create any event groups that occur in your study. Make sure that each event is linked to a group. Only then subjects can be added into this group (see next step).



Subjects into event groups

This in-between-step allows you to select subjects and indicate to which event group they belong.



Note: event groups are created in Step 3, and between 3 and 4, you can fill these groups with subjects.

Step 4: Samples



This step gives a table with all the samples that were created. Note that a combination of sampling events, subjects and groups, automatically created your samples.

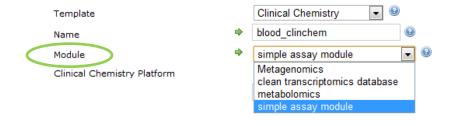
You can make any adjustments, or fill out empty fields when necessary.

Step5: Assays



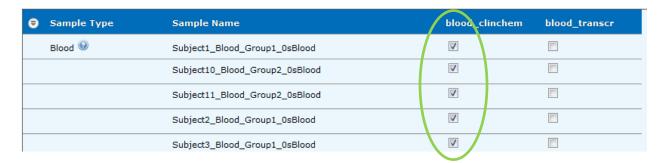
Add assays to your study; e.g. metabolomics on a LCMS platform. Do not forget to indicate both the template (e.g. clinical chemistry) and the module (e.g. simple assay module).

Depending on the assay type and module you choose, you can attach measurements or data files to a set of samples.



Samples into Assays

After you click 'next', an in-between step allows you to select which assays were performed on which samples.



Step 6: Confirmation



Check your data. Any corrections can be made by going back to the corresponding steps in the wizard.

Step 7. Done

You can view or edit the newly created study, or create a new study.

2 Edit a study

To view or edit an already existing study go to Browse > My studies.



Now you can see a list of studies that you created, or you can see as reader. Click on the magnifying glass on the left to view a certain study, or click on the pencil in the middle to enter the wizard. This will allow you to edit this study.



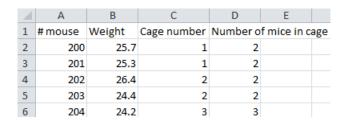
3 Import part of study design

Click on Import > A part of the study design using the menu on top.

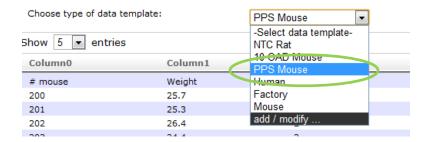


Step 1: Import file

Select your excel file. The excel sheet should have this format: every study, subject, sample or event has its own row. It does not matter in what column which information is stored, as you can map the field in the template on the columns in your excel sheet. It does not matter how many headers are included in your excel sheet, as you can define in which row the first subject/ sample or event can be found.



Make sure to select the correct data template; e.g. a mouse subject template for a mouse study.



Below, the importer will show a preview of your uploaded excel file.

Step 2: Assign properties

Map the information in your excel sheet on the columns, using the dropdowns. If a certain field is missing, in Step 1 you can modify or add fields for this template.



Showing 1 to 5 of 102 entries

Step 3: Add information

Add information to the table when necessary. Multiple rows can be selected by click and dragging.



Step 4: Confirmation

Check whether the information is correctly mapped and click > Next. Click on the study title to view your imported study data.



FAQs

Where can I see a list of my studies?

Click on Browse > My studies to view your studies. It is possible that other users indicate you are reader of a study. These studies also appear in this list.

Where can I update study information?

Click on Browse > My studies, and use the pencil on the left to edit a certain study. Just as creating a new study, this will start the study wizard. Using 'next' and 'previous' you can navigate through your study and update any information from this study.

How can I add more samples to my study?

Click on Browse > My studies, and use the pencil on the left to edit a certain study. Samples are created as a combination of a sampling event, a subject and an event group. Change any of these to your needs and this will create more samples.

For example, if you miss a certain subject, add this subject in Step 2. Then navigate by clicking 'next' and this subject can be selected into a certain eventgroup. By clicking 'next' GSCF now creates new samples based on the new subject that was added to an eventgroup.

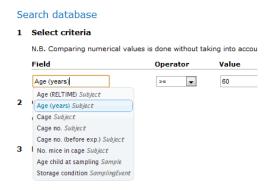
How can I add more samples to an assay?

See previous question how to add more samples into your study. Then go to Step 5, and click 'next'. Now you reach the in-between step, where you can add samples to an assay.

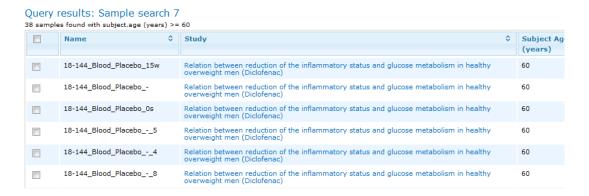
Where can I search among multiple studies?

Click on Search > Advanced Search. Select your GSCF fields and values you want to search for. Then select type of output (based on Studies, Samples or Assays).

For example, show me all samples from subjects that are at least 62 years of age;



This will result in the following output;



My samples do not appear in the module. What can I do?

For samples to appear in a module attached to GSCF, make sure you have selected the right module for this assay. For example, make sure you selected module Simple Assay Module when you trying to view samples in this module (SAM).

Second, make sure the right samples are actually in this assay. You can check this by clicking 'next' in Step 5. Here you can see a list of which samples are in what assay.

If the right samples do not exist for this assay and module, add more samples: Samples are created as a combination of a sampling event, a subject and an event group. Change any of these to your needs and this will create more samples.

For example, if you miss a certain subject, add this subject in Step 2. Then navigate by clicking 'next' and this subject can be selected into a certain eventgroup. By clicking 'next' GSCF now creates new samples based on the new subject that was added to an eventgroup.