

# Manual for submission to SPREAD

## 1: Log in.

Via <https://spread.crp-sante.lu> log in to the SPREAD website. Username is your email address. The password will be provided by email by the database manager.

## 2: Explanation of the menu

**Home:** shows an overview of your submissions. You can select patients based on their status:

- Closed: submitted during previous rounds; editing not possible.
- Included: submitted during current round. Patient can be included in analysis as all mandatory information is available. Editing of data still possible.
- Error: submitted during current round. To include the patient in analysis, the errors that are still in the data need to be corrected. Please edit the data of this patient.
- Warning: submitted during current round. Patient can be included in analysis after checking of the warnings in the data.

You can also select patients based on date. This will make it easy for you to go back to your last submission.

**Documents:** Access to several documents, including the data collection form, the metadata description file for explanations on submission by file and the manual for submission.

### **Dataset:**

- **'Browse patients':** shows an overview of all patients in your dataset.
  - Edit individual patients by clicking on the **'edit'** button.
  - The overview can be sorted by a particular column by clicking on the name of the column as shown on the top.
  - *Planned function:* Add a filter to show only a selected group of patients
  - *Planned function:* Make an export of your dataset to an excel file
- **'Statistics':** provides statistics on your dataset.  
*This part is under construction.*
- **'Interactive map':** shows statistics on a European level.  
*This part is under construction.*

### **Submission:**

- **'Inclusion criteria':** lists the inclusion criteria of the SPREAD program as a reminder.
- **'Submit patient (form)':** fill out the data collection form electronically for individual patient. For further instruction see part 3.

- [‘Submit patients \(file\)’](#): submit file with data of multiple patients. For further instruction see part 4.

### **Sent a message to the SPREAD team:**

- Help: if you need help, you can type your question in the textbox which will be send directly to the database manager (Daniel Struck) and to the current SPREAD coordinator (Marije Hofstra).
- Suggestion: if you have suggestions for improvement of the website, you can type your suggestion in the textbox and your message will be automatically send to the SPREAD team. Every month all suggestions are evaluated.

### 3: Submission by form

If you want to submit an individual patient, you can fill out the data collection form electronically by clicking on [‘submit patient \(form\)’](#). All questions of the data collection form are listed on one page.

- Mandatory fields are shown in bold (e.g. **Unique Patient Identification**).
- Further explanations of variables are provided at the right side of the form.
- Categorical variables are shown as drop down menus where you can select the correct option. For AIDS defining illness, STDs and transmission routes multiple options can be selected, which are shown as boxes to be checked.
- All dates need to be provided in the same format, as shown in the explanation (YYYY-MM-DD) and for all dates it is possible to only provide year and month (YYYY-MM).
- Important to note is that we request the sequence sample date: the date when the sample was drawn that was used for sequencing.
- The sequence can be provided as whole protease-RT, or you can provide protease and RT separately. If available, an integrase sequence can be provided.

After completing the form, you press the button [‘submit patient’](#), that is at the bottom of the form. Then an automatic data verification will be performed. If there are no errors in the form, you will be automatically directed to the overview of your dataset (at dataset - browse patients) and the status of the patient in the overview will be ‘included’. You can submit the next patient by clicking on [‘submit patient \(form\)’](#) again.

### **Errors and warnings**

If there are possible errors in the form, you will stay on the page of the data collection form. At the top it will state one or both of the following messages:

- You must fix the errors highlighted in red before the patient can be included in analysis
- Please review the warnings highlighted in orange.

## Errors

A patient cannot be included in analysis if there are still error messages. An error can for example be that a mandatory variable is missing. An overview of all possible errors is provided at part 5. After you solved the errors, you can press on [‘submit patient’](#) again and the automatic data verification will be repeated. If you cannot fix the errors immediately, you can save the patient by checking the box [‘check this box to save the patient’](#) and subsequently press [‘submit patient’](#). This patient will then have the status [‘error’](#) in the browse overview, and you will need to fix the errors to allow the patient to be included in analysis.

## Warnings

A warning message in orange means that we have found values that need additional verification. For example a very high CD4 count (>1000). However, in contrast to errors, the patient can be included in analysis even though warnings are shown. If you corrected the warnings, you can press the button [‘submit patient’](#) and the patient will be shown as [‘included’](#) in the overview. In case the data that generated the warning is the correct data, you can check the box at the bottom of the page [‘check this box to submit the patient \(warnings are okay\)’](#) and then press the button [‘submit patient’](#). In the patient overview, the patient will in this case still be listed with status [‘warning’](#).

## **Edit data**

Every submitted patient will be shown in the dataset overview at [‘browse patients’](#). You can still edit the data of a patient from the current round by clicking on the [‘edit’](#) button for that patient. This will bring you back to the completed data collection form where you can edit the information. You can save the changes by clicking on [‘modify patient’](#). Before the changes are saved, the automatic data verification will be performed.

## 4: Submission by file

If you want to submit data of many patients simultaneously, you can upload your data file by clicking on [‘submit patients \(file\)’](#). Here you can download the metadataset that provides a description of how to format your data. Two example files that are formatted in the correct way are also available.

## **Upload file**

You can select a file by clicking on [‘browse’](#) and select the correct file. Then press [‘start upload’](#).

## **Normalization check**

First a normalization check will be done to check if the file is provided in the correct format. If the file is not in the right format you will see the following message:

**‘You must fix the following normalization errors before submission:’**

It will list for which patients which column is not in the right format. The metadataset will provide you the necessary information how to transform the data in the file. After

making the necessary changes, you can submit by selecting the file and pressing [‘start upload’](#).

### Automatic data verification

If the normalization check is ok, the automatic data verification is performed. It will for every patient show the errors and warnings in the file that need to be fixed.

Similar to the data verification with submission by form, errors need to be solved before submission is possible. Warnings need to be verified but submission is still possible. You can make the necessary corrections in the file, select the file and press [‘start upload’](#) again.

With every new upload after corrections the data verification will be repeated. When there are only warnings left that are verified and do not need to be changed, you can start uploading the final file by checking the box [‘check this box to submit the patient \(warnings are okay\)’](#) and press [‘start upload’](#).

### Edit data

Every submitted patient from the file will be shown in the dataset overview at [‘browse patients’](#). Even if you submitted by file, you can still edit the data of an individual patient as the data from the file has been translated for every patient to a data collection form. By clicking on the [‘edit’](#) button of a patient in the overview, you will see the completed data collection form for this particular patient and you can edit his or her data.

You can save the changes by clicking on [‘modify patient’](#). Before the changes are saved, the automatic data verification will be performed.

## 5: Data verification: errors and warnings

Before you submit a patient (by form as well as by file) automatic data verification will be performed to check for possible errors. **Errors** need to be solved before a patient can be included in the analysis. Below is a list of all possible errors.

Variable	Possible error message
Unique patient identification	Unique patient identification is a mandatory field that cannot be left open. Please provide a code.
	This ESAR code was already used for this center.
Center	Center is a mandatory field that cannot be left open. Please provide the center.
Submitter initials	Submitter initials is a mandatory field that cannot be left open. Please provide the initials of the submitter.
	Submitter initials can only be composed of letters and the dot symbol.
Year of birth	Year of birth is a mandatory field that cannot be left open. Please provide the year of birth.
	Year of birth can only be composed of numbers
	The year of birth must be between 1920 and now. Please provide the correct year of birth.
	The patient must be at least 18 years old at time of diagnosis to be included in the study. Please check year of birth and date of first positive test. If the patient is indeed below 18 years of age, the patient cannot be submitted.
History of ART	The patient must be therapy naive to be included in the study. If the patient did not take ART, please change the answer to No. If the patient has taken ART, the patient cannot be submitted.

Date of last negative test	You must provide the date of last negative HIV test in the correct format (YYYY-MM-DD, YYYY-MM, YYYY, NP or MD)
	The date of last negative HIV test must be between 1985 and the present date
Date of first positive test	Date of first positive HIV test is a mandatory field that cannot be left open. Please provide the date of first positive test.
	You must provide the date of first positive HIV test in the correct format (YYYY-MM-DD, YYYY-MM)
	Date of first positive HIV test must be between 2010 and present
	The date of first positive HIV test cannot be before the date of last negative HIV test. Please check and correct both dates.
Clinical stage at time of HIV diagnosis	Stage of HIV infection is a mandatory field that cannot be left open. If the stage is unknown, please select 'Unknown'.
	If you select an AIDS defining illness, the clinical stage of infection should be set to AIDS. Please check and correct the stage and the selected AIDS defining illness.
STDs	If you select an STD, the answer to the STD question should be yes. Please check and correct both fields.
Pregnancy	For every male patient, the pregnancy question is not applicable. Please check and correct gender and the pregnancy question.
Route of infection	Route of infection is a mandatory field that cannot be left open. If the route of infection is unknown, please select 'Unknown'.
	You cannot select unknown when other options are also selected. Please check and correct this.
Viral load	The viral load is a mandatory field that is needed for inclusion. Please provide the baseline viral load.
	The viral load can only exist of numbers. If the viral load exceeds the detection limit of the assay, you can use > symbol with the value (e.g. >700000).
	The patient must have a viral load above 1000 copies/mL to be included in the study. Please check the viral load. If the patient indeed has a viral load < 1000, the patient cannot be submitted.
	The viral load cannot be higher than 11000000. Please check and correct the viral load.
Date of viral load	The viral load date is a mandatory field that cannot be left open. Please provide the date of baseline viral load.
	You must provide the date of viral load in the correct format (YYYY-MM-DD or YYYY-MM).
	The viral load date cannot be in the future. Please correct the date.
	The viral load date cannot be more than two weeks before the date of first positive HIV test. Please check and correct both dates.
	The viral load date must be within 6 months of the first positive HIV test.
CD4 count	The CD4 count can only exist of numbers. Please correct the CD4 count.
	The CD4 count must be between 0 and 3000. Please correct the CD4 count.
Date of CD4 count	You must provide the date of CD4 count in the correct format (YYYY-MM-DD, YYYY-MM, UNK [unknown] or MD [missing data]).
	The date of CD4 count cannot be in the future. Please correct the date.
	The date of CD4 count cannot be more than two weeks before the date of first positive HIV test. Please check and correct both dates.
Sequence sample date	The sequence sample date is a mandatory field that cannot be left open. Please provide the date of when the sample was drawn that was used for resistance testing.
	You must provide the sample date in the correct format (YYYY-MM-DD or YYYY-MM)
	The sample date cannot be in the future. Please correct the date.
	The sequence sample date cannot be more than two weeks before the date of the first positive HIV test.

	The sample date must be within 6 months of the first positive HIV test.
Prot-RT Sequence	Please provide the prot-RT sequence, either as a whole or separately.
	The prot-sequence should cover protein position 10 to 93.
	The RT-sequence should cover protein position 41 to 230.
	There is a stopcodon or frameshift in the {} region of the sequence. Please check the sequence.

**Warnings** are values that need to be verified but not necessarily changed before inclusion in analysis. Below is a list of all possible warnings.

Variable	Possible error message
Gender	The gender is not reported.
	Female patients are not likely to have a hemophiliac transmission route. Please verify gender and route of transmission.
	Female patients are not likely to have a homo/bisexual transmission. Please verify gender and route of transmission.
Last negative HIV test	The source of the last negative HIV test is not reported
First positive HIV test	The source of the first positive HIV test is not reported
Clinical stage at time of HIV diagnosis	You selected stage AIDS but did not specify which disease. If you have this information available, please provide this.
AIDS defining illness	You have selected more than 3 AIDS defining illnesses. Please check this.
STDs	You have selected that the patient had STDs in the last 2 years but did not specify which STD. If you have this information available, please provide this.
CD4 count	The CD4 count is above 1000 or below 10 cells. Please verify this.
Date of CD4 count	The date of CD4 count is not within 6 months of the first positive HIV test. Please check this and provide the baseline CD4 count.
Prot-RT Sequence	This sequence already exists in your dataset (ESAR code: {}). Please check whether this patient may be already submitted.