



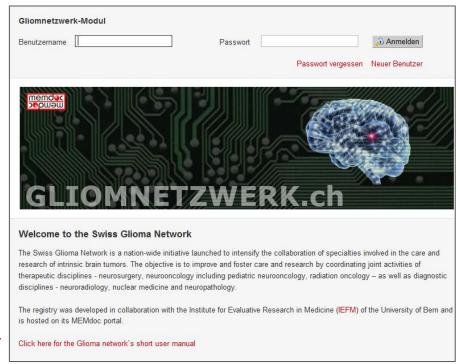
UNIVERSITÄT RERN

### SWISS GLIOMA REGISTRY - USERS GUIDE

### Internet access: www.gliomnetzwerk.ch

#### New user:

- 1. The application itself is available in several languages (EN DE FR IT ES). Upon registration the users indicates his default language. He can temporarily change it during a session on the lower right hand side of the page.
- 2. The SWISS GLIOMA REGISTER physician forms have been implemented in English. The patient forms are available in the three languages DE, FR, IT.



Version - 1.0 -

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#### 1. GENERAL

### 1.1. Hosting location of the register

The register is hosted on the MEMdoc portal of the Institute for Evaluative Research in Medicine IEFM, University of Berne. MEMdoc is a web-based application working with browsers IE8+ or Firefox on PCs, and with Safari on MACs.

The IT solution in use is based on the MEMdoc-Module technology. The concept of MEMdoc-Modules allows the segregation of data into sensitive and non-sensitive data. It was developed in order to fulfill data protection laws and policies of various countries. The sensitive data, related to institution, user, and patient is saved on a physically separate module server at IEFM while the anonymized clinical data – including patients` year of birth and sex - is sent to the central server at IEFM. The two data sets are linked for display in the browser only. The access to the data is controlled by a hierarchical integrated concept of roles and profiles.

# 1.2. Help in the application

**F5**: Click on the keyboard`s F5 in case of a problem in the application. That way a page refresh is per-

formed.

? Page specific help information – click on the symbol ? in the online application window in order to

access the available information.

**Mouse over** Place the cursor on an icon or a grey-colored bar in order to receive information about its function.

A click on an icon or a grey-colored bar will open the next window.

Application

A detailed guide is accessible online on the entry page: https://gliom.memdoc.org

Guide

#### 1.3. Patient identification

Patient identification is done by documentation of the MRN (medical record number of the respective institution). The documentation within the register is patient based. A patient can have multiple online CRFs (case report forms):

- Clinical Entry Form
- Surgery
- Neuroimaging
- Clinical Follow-up
- Pathology
- Molecular Pathology and Genetics
- Medical Therapies
- Radiation Therapy
- Assessment of Progression
- End of Study
- Patient questionnaires: NNIHS, EORTC QLQ-BN20, QLQ-C30

#### 1.4. MRN – medical record number - pseudonym

The institution's internal patient number is used as a pseudonym (MRN – Medical record number). The MRN is saved on the module server only. A one-way hashcode from the MRN is sent to the central database. The two data sets – sensitive and pseudonymized data - are linked for display in the browser only.

### 1.5. Functions available in the application

When positioning the cursor on an icon (mouse over), you will get a help information, i.e. :

#### From the patient list:

Form list Display, enter, and modify electronic forms.

Demographics
See and modify the demographic data (e.g. date of birth).

E-form Insert a new electronic form

OMR form Scan a new OMR-form (optical mark reader)

Delete Delete the demographic data (only possible if all forms have been deleted

previously.

#### From the form list:

Edit Display, modify, and complete the electronic form

Print Print the electronic form

Delete Delete a not yet submitted form (red entry in form list)

Clicking into this symbol or directly into the grey-colored bar opens a pulldown

or an enhanced window.

### 1.6. Languages available in the application

The application works in the languages FR EN ES DE,  $\Pi$  see point 1) on introduction page. Click on the symbols  $A_{-}A$   $A_{+}$  in the upper right corner in order to increase or decrease the visual display.

### 1.7. Form processing status

**Form processing status:** A form knows 3 different processing statuses. These statuses are represented in the form list by the corresponding symbols (meaning of symbol see below).

**Subform processing status**: A subform knows 5 different processing statuses. These subform statuses show up on top of the opened form in a sequential subform list (meaning of symbol see below).

Subform	Form	
Processing status	Processing status	Description
0		Subform has not been filled yet
0		Subform has been filled partially, but has not been saved.
		**By closing the open case (going back to form list) without saving and reopening it again, the en-
		tered data will be lost. By switching to another subform without saving a modified subform, and
		switching back to the modified subform again, the data will still be there.
<b>-</b>		Subform has been saved, but there is missing data.
•		Subform is complete and saved.
•		Data modification in a previously saved subform.
	<b>-</b>	Form incomplete - not all the subforms are completed and saved.
	•	Form completed - all the subforms are completed and saved and the form is ready for submission.
	<u></u>	Form completed and submitted – its information is regarded for online statistics queries. You can only
		view the data but not edit it anymore. There is no possibility to change the data or to add data to a
		submitted e-form, at the exception of having a profile allowing to re-open a submitted case again
		(administrator profile).

### 1.8. Functions - profiles - access rights

In the MEMdoc-application we distinguish different profiles with different access levels. The profiles are customizable by the module administrator. The main profiles are:

- Module Administrator administration of all users of a specific module Re-opening of submitted cases / forms online statistics comparison with the anonymous data of the entire pool access to administration tools.
- Clinical Administrator administration of user in the respective clinic download of the institution's data online statistics with data from the institution comparison with the anonymous data of the entire pool.
- Department Administrator administration of users of the respective department download of the department's data online statistics with data from the department.
- **Doctor** (surgeon) data entry submission of cases online statistics with data from the institution download of own data.
- Study Nurse data entry.

The profile 'Study nurse' has by default no rights to submit a completed case; if desired the function 'submission of cases' can be added to that profile.

The profile 'Doctor' is allowed to submit the individual completed electronic form. A submitted form will no longer be modifiable by the user. The profile 'Doctor' also has access to the 'online statistics' tool.

During the registration process, the user chooses a profile, such as Doctor or Study Nurse (or Clinical Administrator, Department Administrator). The user has the possibility to ask for multiple profiles. The access rights and access levels depend on the activated profiles. The right to activate/deactivate certain functions depends on a user's profiles. A new user needs to be activated by the 'Module administrator'. It is in the responsibility of the module or clinical administrator to keep the users` accesses up to date.

### 1.9. Navigation bar in MEMdoc application

Having logged into MEMdoc, the navigation bar on the left appears. The tools available depend on the activated profile. The navigation bar includes the main tools:

- Enter data New patient Search patient
- Clinical tools Data download Online statistics Add-on question Form viewer
- Admin tools Clinic settings User activity Study activity
   The administrator has access to enhanced tools.
- User tools Modify account (change password) Add profile
- Logout

By mouse click the user selects the tool he wants to work with.

### 1.10. Data entry - interfaces

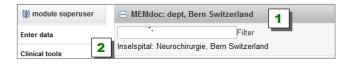
A registry in MEMdoc can contain multiple studies. In MEMdoc 3 types of interfaces are supported:

- Online data entry interface
- Hybrid online/OMR data entry interface (OMR = optical mark reader)
- Web service (electronic data entry via interface to external systems)

# 1.11. Documenting from multiple institutions

Based on his role(s) the user can set up one or multiple profiles in one or multiple institutions attached to his registration in MEMdoc. Having logged in the user is in his default institution. He can switch into another institution by:

- 1) Clicking into the dark-grey bar on top and the available institutions appear in a list
- 2) Selecting the institution he foresees to work in



#### 2. REGISTRATION

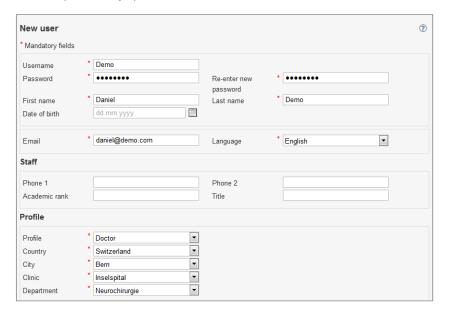
Once the registration has been completed the users account will be validated (enabled) by the module administrator. Subsequently the user receives a corresponding email at the exception that the registration is done in the tool: **Admin tools**: 'create new user' or 'Manage studies' wherein a suppression of the email notification is feasible. The registration of user and institution is a one-time step.

# 2.1. Registration of a new user

In the situation where the user does the registration himself in order to participate in the 'Swiss Glioma Register', he accesses the Glioma register website – page 1 - and clicks on «**New user**» (different wording depending on language selection). In the situation where the administrator does the registration for the user, see point 2 above.

Complete the online registration form entering all the required information:

- Username and Password
- First name, last name, date of birth, e-mail, language (your preference)
- and add the designated Profile
- required information is marked by (\*)
- If your 'City / Clinic' does not exist in the drop down list, please select 'Add', fill in all the mandatory fields (marked by \*) and select → + Add.



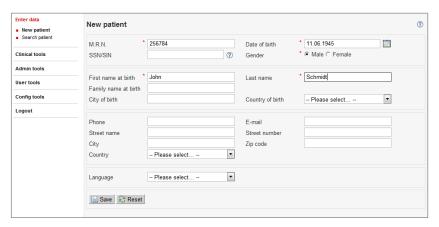
### 3. ENTER PATIENT DATA

# 3.1. Create a new patient - demographic data

#### **Enter Data -**

New patient

Click on **« New patient »** in the left navigation bar. Enter the MRN (clinic internal medical record number) into the provided field. The fields marked with (\*) are mandatory, all others are optional.



Click the « Save » button in order to finalize the inscription of the demographic patient data.



Confirm the storage of the demographic data by clicking on **« OK ».** Then you will be guided automatically into the form list of the patient in question wherefrom you create a **new questionnaire**.

### Creation of new questionnaire:

- 1. Click on **« + E-Form »** in order to create a new electronic form
- 2. Choose the form you wish to create online
- 3. Not requested in all registers: Select the anatomic location (right, left)



#### 3.2. Quick search

#### Enter data -

Search patient

Click on the « Search Patient » button in the left navigation bar. Leave the "Quick search" field empty or enter some key information, such as:

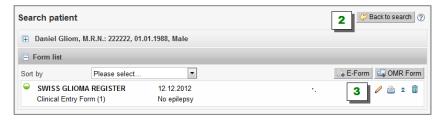
- « Medical Record Number (MRN) » or
- « a substring of the MRN followed by \*; i.e.: 987\* » or
- « Date of Birth » or
- « Name »



- 1. Click on « Search » or on 'Last 10 patients' in order to proceed to the result list of the executed search. The search results shows a list of all patients matching your search criteria. If there is only one patient found, the respective form list of this patients is opened automatically.
- 2. Click onto 'Back to search' brings you back to the search mask
- 3. The available functions from the level 'form list' are
  - create a new e-form by clicking on the « + E-Form » button
  - complete or modify an existing form by clicking onto the icon



- print a form
- upload images belonging to that case
- delete a form which is not submitted yet



#### 3.3. Advanced search

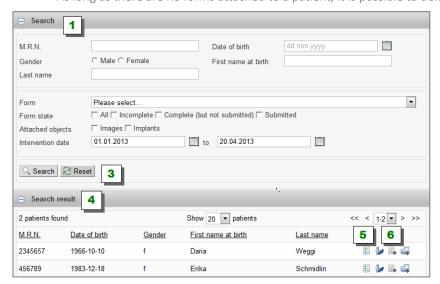
#### Enter data -

Search patient

Click on the **« Search Patient »** button in the left navigation bar.

- 1. Open the window ,Advanced Search' by clicking on the icon which is located in the dark-grey bar or into the bar directly
- 2. Enter the patient search criteria or search for specific forms and their 'Form state' to administer/complete/submit your data
- 3. Click on « Search » to execute the search
- 4. The search result shows all the patients which match the search criteria (Patient List)
- 5. Click on the icon in order to open the form list of a patient
- 6. Click on the icon in order to add a new e-form to that patient

  As long as there are no forms attached to a patient, it is possible to delete a patient file by clicking on



## 4. CREATE QUESTIONNAIRE

#### 4.1. Create a new form - clinical data

Search for or create a patient, open the form list:

- 1. Click on the « E-Form » button or
- 2. Click on the icon in the patient list in order to add a new electronic form to the patient in question.

#### 4.1.1. Fill in the electronic form

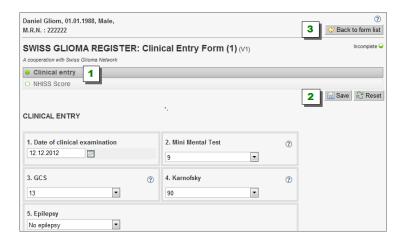
A click on « **E-Form** » displays the online form on the screen. On top of the form appears the structure of the form and it shows the subforms to be filled out, example:

- Clinical Entry
- NHISS Score

ically to the following subform.

The subform on top is opened for data entry automatically; saving a subform guides the user to the next subform.

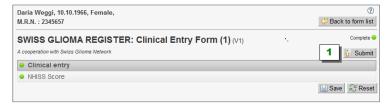
- Click onto the grey bar of a subform in order to view/open a subform.
   The form has a modular structure. The symbol shown on the left side of the subform name in the grey bar indicates the processing status of the subform (see 1.8).
   Only when all mandatory questions are answered, the data can be saved and the user will be guided automat
- 2. «Save » the subform if the subform has been completed. A validation will be executed. If all the data is correct the saving will be executed and the user will be guided to the next subform. If not, an error list will be displayed.
- 3. In order to return to the form list, click on the button «Back to form list ».



#### 4.2. Submit a form

When all subforms are successfully saved, the light in the subform list becomes , the form's status changes to 'complete' and the button **« Submit »** appears on the screen. Within the form list, the case entry is displayed in black now. By clicking on **« Submit »**, the documentation of the case is finished. If the form's status changes to 'submitted', it is no longer possible to edit the data. However it is still possible to view or print the data entered. Only the **submitted** cases are considered in the clinical tool **«** Online statistics **»** .

- 1. Once the form is **submitted**, the symbol in the form list changes to
- 2. Opening a submitted form using the **unsubmit** function needs administrator rights.

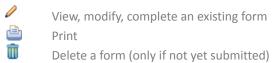


## 4.3. Complete or modify an existing form

There are two possibilities to modify an existing form:

- 1) Access from the patient list:
- Click on the icon in order to view the form list and access a specific form.
- 2) Access from the form list:
- Search the patient in question, indicating the MRN (partially or entirely), you arrive in the form list and access a specific form.

Click on:

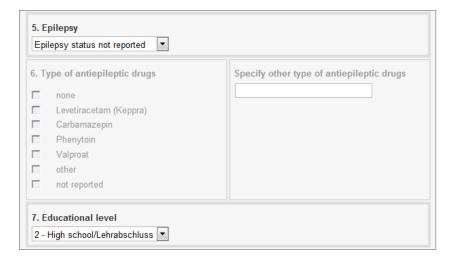




# 4.4. Data validation - exclusion of questions and answers

The complex data validation, which is being executed in the background of the application, excludes certain sections, questions and/or answers by logic. Activated exclusions exclude sections, questions and/ or answers. The excluded items appear inactive and greyed out in the electronic form and cannot be accessed.

The following example illustrates the validation process. In question 5, the answer 'Epilepsy status not reported' excludes the following question 6 abot the type of antiepileptic drugs.



#### 4.5. Data validation - error message

While saving the data, a secondary validation process concerning integrity and correctness of the data in the subform is being executed. The validation is checking if all required data has been entered. In case of a conflict (errors, missing data) a message will appear. Saving will be possible only when the data is accordance with the validation.



#### 5. ADMINISTRATION

#### 5.1. Validate user

This tool needs an administrator profile. The user has at his disposition the 'Validate user tool' allowing him to enable/disable the profile/access of a user.

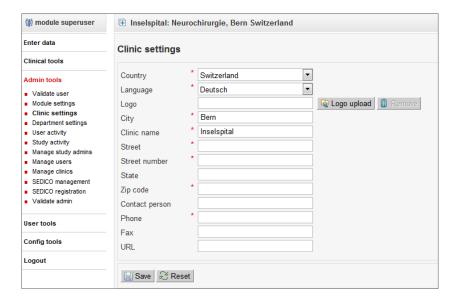
- 1. Click on the left button for validating a new user. Then click on **« Save »** in order to finalize, respectively activate his/her profile.
- 2. Click on the item for deleting the profile



### 5.2. Clinic settings

This tool needs an administrator profile. The user can modify the settings of the clinics.

Click into the dark-grey bar and the available institutions appear in a list, then choose the institution's name for which you want to make a configuration. You can modify the configurations for department settings in the same way.



### 5.3. User activity

This is a monitoring tool and needs an administrator profile. The administrator receives information about the activity of the selected form - from a specific level (user, department, clinic, country). The generated list can be exported to an Excel spreadsheet.

#### Admin tools

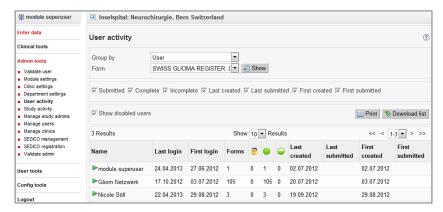
Click on the item « User activity » in the left navigation panel.

Select the level of interest from the dropdown menu, for example:

- User
- Department
- Clinic

Select the form of interest from the dropdown menu, for example:

- 'GLIOM REGISTER INSEL: Basisformular (V1)'
- 'SWISS GLIOMA REGISTER: Clinical Entry Form (1) (V1)'



#### 5.4. Study activity

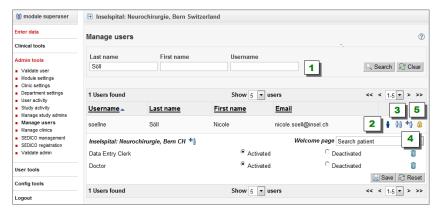
This is a monitoring tool and needs an administrator profile. The user receives information about the activity of the study on the level **country or study** in general and simultaneously at the form level. The generated list can be exported to an Excel spreadsheet.

### 5.5. Manage users

This tool needs an administrator profile. The purpose of the tool is 'user administration'. Functions:

- 1. Search for a certain user
- 2. Click on the item to monitor and update a user (e.g. change the email)
- 3. Click on the item to activate or deactivate a user
- 4. Click on the titem to monitor the profile/clinic and to add/remove a profile
- 5. Click on the item to change the password

A validation of actions undertaken with this tool is not required.



### 5.6. Manage clinics

This tool needs an administrator profile. With this tool you can search and/or monitor profiles/clinics, add/remove profiles or write an email to the respective user(s).

- 1. Add a search criteria to your search window: for example search for a certain profile
- 2. In the 'Search results' list appear always all clinics
- 3. Click onto 'Expand all' to open all the clinics in order to see their users and profiles
- 4. Click onto the grey bar from a certain clinic in order to see its users and profiles
- 5. Click on the blue bar from the department in order to see its users and profiles

In column 'Nr. of users' you can see which clinic has >0 users with the searched profile. You can add a profile to a user, delete a profile from a user, email a user from this tool.

