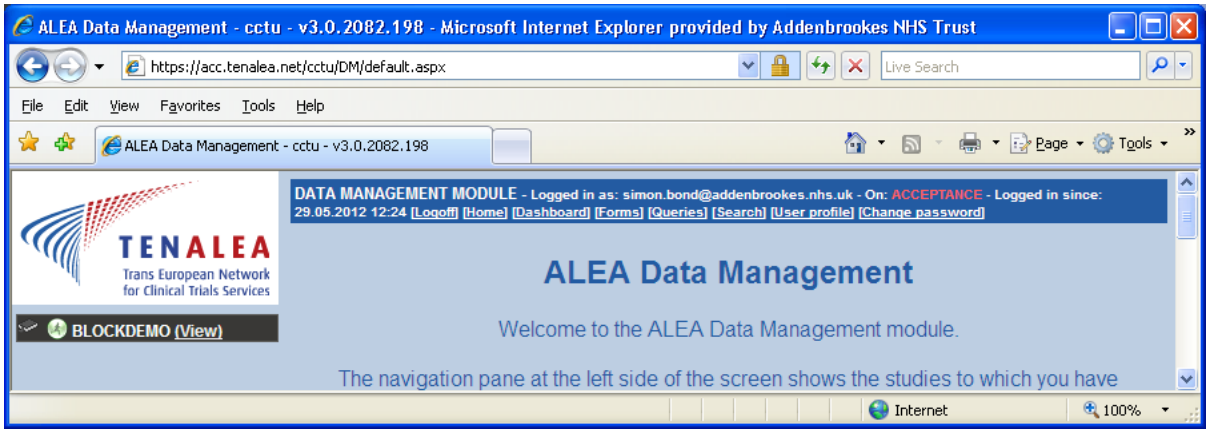
Chapter 2: Selecting forms and Data entry (ALL)

After logging on (see Chapter 1), the 'Data Management' module is displayed (see Picture 2.0.1).



Picture 2.0.1. TENALEA Data Management module. On the left, the navigation pane with study names for which the user has access permissions. In this example the study name 'BLOCKDEMO' is displayed.

The left part of the Data Management module contains a list of all studies for which a user has access permissions (see Picture 2.0.2). Instances have occurred on the first log-in where this menu does not appear. Hitting the browser refresh button after logging-out and -in resolves this bug.

Picture 2.0.2. Left navigation menu of the TENALEA Data Management module. The list contains all management areas of the study for which the user has access permissions.

2.1 Selecting study, forms, and Enrolling a patient (INV/RN/RM)

A study can be selected by clicking the study name in the left navigation menu. After clicking the Patient Management, a list of all investigators for which the user is granted permission to enter data is displayed, as shown in Picture 2.1.3.

Picture 2.1.3. Selecting a study within the TENALEA Date Management module (left) displays the three management menus (A). Middle: The Patient management menu lists all names of investigators (B) for which the user has permission to enter data. Right: after selecting an investigator, the list of previously registered patients is shown (C): Selecting a patient shows the study forms (D). A new patient can be registered by clicking Add patient (E). This will display the Registration form.

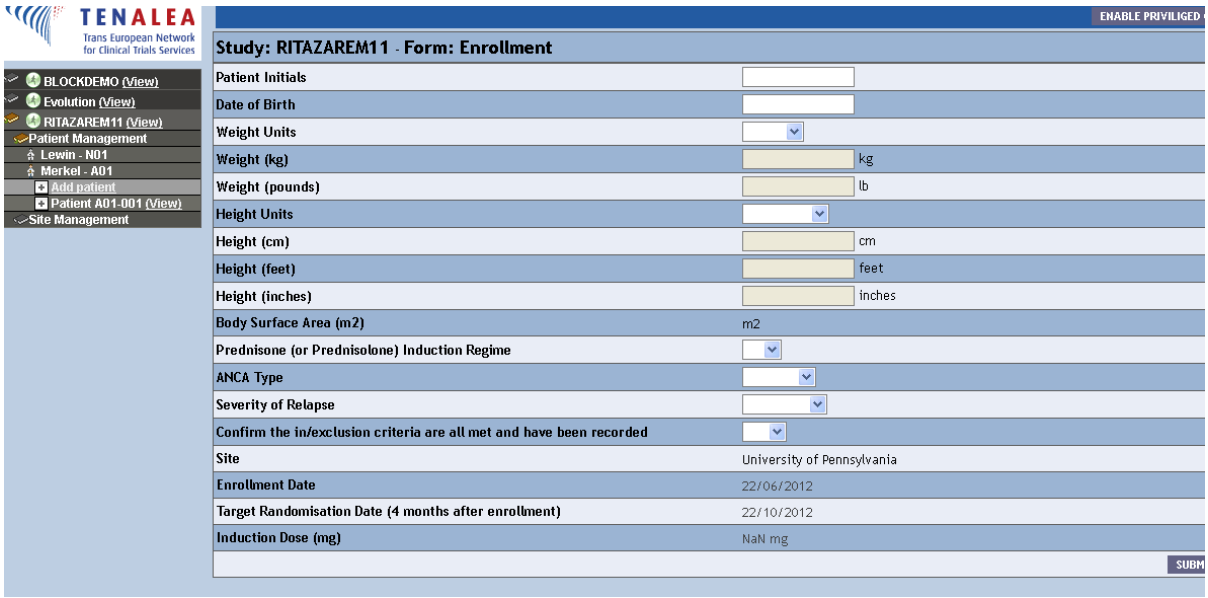
Select an investigator/clinician by clicking the name. If no patients have been registered for the

investigator/clinician yet there will be no entry under the selected clinician.

Click Add subject to display the first form (This may be just a registration or a combined registration/randomisation form) form.

Completing and submitting the Enrollment form (see Picture 2.1.4) registers the following details on the system:

- Patient Initials; up to 3 letters
- Patient DoB; in dd/mm/yyyy
- Current Date Is recorded automatically
- Site is recorded automatically
- Choice of Weight Units(kg/lb)
    - Weight in Kg
    - Or Weight in Lb
- Choice of Height units (cms / feet&inches)
    - Height (in cm)
    - or Height(feet) & Height (inches)
- Selected prednisone (or prednisolone) induction regimen (1A or 1B)
- ANCA type (anti-PR3 ; anti-MPO)
- Relapse Type(Severe, Non-Severe)
- Omnibus confirmation that the general in/exclusion criteria are met.



Picture 2.1.4. Evolution Registration form.

As the form is completed the following fields will be calculated:

- Body Surface area (DuBois Formula)
- Induction dose
- Enrollment Date
- Target Date for Randomisation = Enrollment Date+ 4months

The screen displayed on submitting the form provides the Subject Number and the information entered and calculated. An email confirmation of this is sent to the appropriate roles

Form names can appear in the left menu bar in two different fonts, each indicating a different form status. Table 2.1.5 lists the different form statuses and the fonts that are associated with them.

Table 2.1.5 Fonts (i.e. italics or no italics) appearing in the navigation menu of the TENALEA Data Management service, indicating a specific form status.

Font	*Description of forms status*
1. **Empty forms**	These are forms which are either empty, unsaved, not validated or not submitted.
2. ***Completed forms***	Forms that could have been completed or not, but already have been either saved, validated or submitted and can be edited if necessary.

Using the left menu to select and open a form, the form opens in Edit mode; data can be entered (or selected) and altered.

View form

When pressing the (view) button (next to study name), the form opens in a new (browser) window or tab. This is to allow viewing multiple forms while keeping the Data Management module the central page.

Submitting

'Submitting' a form will transfer its data to Central Data Management. If needed, these forms can still be modified afterwards, provided a reason for the modification is specified.
A message such as the one shown below in Picture 2.1.6 indicates a form has been submitted successfully.

Form Enrollment has been submitted.

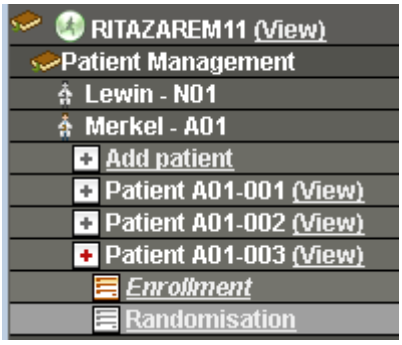
The subject has been enrolled and assigned the study ID A01-003

Questions	Answers
Patient Initials	sdf
Date of Birth	04/08/1982
Weight Units	Pounds
Weight (kg)	
Weight (pounds)	180
Height Units	cm
Height (cm)	200
Height (feet)	
Height (inches)	
Body Surface Area (m2)	2.17
Prednisone (or Prednisolone) Induction Regime	1A
ANCA Type	anti-MPO
Severity of Relapse	Severe
Confirm the in/exclusion criteria are all met and have been recorded	yes
Site	University of Pennsylvania
Enrollment Date	22/06/2012
Target Randomisation Date (4 months after enrollment)	22/10/2012
Induction Dose (mg)	814 mg

Picture 2.1.6. Confirmation of a successful randomisation, including the allocated patient kit

2.2 Randomisation (INV/RN/PHARM/RM)

Four months after enrollment (to within +/- 14 days) randomisation can take place. The relevant form on is found by navigating through the Ritazarem -> Investigator -> Subject Id -> Randomisation.



The extra information to be collected at randomisation is:

- Prednisone Dose: must be <=10mg to be eligible
- BVAS-WG score: must be <=1
- Confirmation that the patient meets the criteria for randomisation

Study: RITAZAREM11 - Form: Randomisation	
Patient Date of Birth	04/08/1982
Patient Initials	sdf
ANCA Type	anti-MPO
Severity of Relapse	Severe
Prednisone Induction Regime	1A
Prednisone Dose (mg)	mg
BVAS-WG Score	
Target Randomisation Date (4 months after enrollment)	22/10/2012
Days after(+) or before(-) the Target Randomisation Date	-122
Confirm that patient details are correct and you want to randomise	

Upon completion of the form the following screen is displayed showing what treatment the subject has been assigned to. An email confirmation is sent.

Form Randomisation has been submitted.

The Subject has been assigned Azathioprine

Questions	Answers
Patient Date of Birth	04/08/1945
Patient Initials	asd
ANCA Type	anti-PR3
Severity of Relapse	Severe
Prednisone Induction Regime	1A
Prednisone Dose (mg)	5
BVAS-WG Score	0
Target Randomisation Date (4 months after enrollment)	22/06/2012
Days after(+) or before(-) the Target Randomisation Date	0
Confirm that patient details are correct and you want to randomise	yes
Randomisation: Randomisation	Azathioprine