



SHIELD STUDY

On-Line Database Handbook

For eCRF Completion

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GENERAL GUIDANCE

The SHIELD Study on-line database is accessed via the Study website at :
www.shieldstudy.co.uk.

An electronic data capture system (eCRF) is used for this Study. Patient data will be entered directly into the Study database by Site personnel. Source verification will be conducted by Study Centre personnel, both electronically and by on-Site visits. Monitoring visits will be scheduled based on Study enrolment.

A hardcopy of the eCRF may be printed out (before data is entered as a worksheet or after data is collected as a reference) by right clicking on individual screens and selecting PRINT. After the close of the Study and Database-Lock, Sites will receive an electronic copy of their patients' casebooks, containing all the completed CRF's.

About the eCRF

Configuration and brands of computers differ from Site to Site, therefore, loading time and processing time when accessing the Internet may be affected. If you experience prolonged loading time or any other issues with the SHIELD system, please initially contact your Site IT representative then the Study Manager, jennifer.wilkinson@ncl.ac.uk.

The SHIELD website is best viewed using a screen resolution of 1024 x 768 pixels on a true colour display.

Visit our Demonstration Site

www.shieldstudy.co.uk

LOG IN: DemoNurse (case sensitive)

PASSWORD: dnT1W2W3

The eCRF page should be completed using the cursor and mouse button to select the appropriate answers by clicking on a box or selecting an item from a drop-down menu or enter data in a text box.

Not Known or Not Done

When a procedure or data point is not collected (for any reason); NK (not known) or ND (not done) should be entered or selected from the comments box.

Errors

Errors may be corrected by selecting an alternate answer or by using the backspace key which enables deletion and re-entry of the data.

Audit Trail

Can be seen by clicking the Yellow A Button to the right of the data entry

Information on the Data Question

Can be seen by clicking on the Blue I Button on the right of the data entry

Abnormal Values

Can be seen and are indicated by a Red Exclamation Triangle on the right of the data entry

Patient ID number

- A unique patient ID number (UPN) will be assigned by the system to each individual patient enrolled in the Study. The chronological number will be four digits, plus the initials of the patient, (e.g. 1234GH).
- The patient ID number will identify the patient in all communications between the treatment Site and the Study Centre, in lieu of personal identifying information.
- Patients are identified at Site level in the **Navigation Panel** at the left of the screen where:
 - VEPEMB Study patients are represented by a red figure and UPN
 - Registration only patients are represented by a green figure and

UPN

Date fields

All date fields will be represented as day, month, year (12/05/1939).

- If the day or month is a single digit, enter a leading zero prior to the digit (06/03/1939).
- Use 4 digits to indicate the year.

Getting started

[HOME PAGE \(www.shieldstudy.co.uk\)](http://www.shieldstudy.co.uk)

The Home Page contains the latest information on the Study, how to become part of the Study and the Documents Centre which has a comprehensive list of documents necessary for Ethical and R&D approval.

REGISTERING YOUR SITE

To allow your Site to be registered on the database, go to the SHIELD Study website at www.shieldstudy.co.uk and click on:

"NOT SIGNED UP? CLICK HERE TO BEGIN TO REGISTER YOUR SITE AND PARTICPATE IN SHIELD"

You will be directed through a series of fields selecting COUNTRY, NETWORK, SITE details and PRINCIPAL INVESTIGATOR (PI) details.

As PI you will be asked to choose your own USERNAME and PASSWORD.

Please make a note of these.

When the Study Manager receives confirmation of your Site Specific Ethical approval (SSA) and Research & Development approval, your Site will be added to the system and you will be able to ADD OTHER USERS and ADD PATIENTS to the database.

Logging In

When you registered the Site on the database, you will have been directed to choose a USERNAME and PASSWORD for the system. If at anytime you cannot remember your password contact : jennifer.wilkinson@ncl.ac.uk

Having accessed the Site at www.shieldstudy.co.uk, go to the top right hand corner of the screen and click on LOG IN and input your USERNAME and PASSWORD. You will then be automatically directed to the area of the database which is specifically designated for your Site.

Adding Another User

If you are the Principal Investigator you can add another User. Go to the Navigation Panel at the left of the screen and click on the blue figure - USERS. Click on ADD USER. Complete the full details for the User allocating a USERNAME and PASSWORD and a Role.

R70: Site Principal Investigator

R60: Site Investigator (to include Study Nurses etc)

The USERNAME and PASSWORD can and should be changed later by the User when they initially log-on simply by clicking on their name and then EDIT which enables changes to be made to their personal details, their USERNAME and PASSWORD.

Before entering a patient on the Study it is advisable to have completed:

ECOG score

Activity of Daily Living Score (Protocol Appendix 4)

Instrument of Daily Living Score (Protocol Appendix 5)

Co-morbidity rating scale (Protocol Appendix 6)

REGISTERING A NEW PATIENT

APPLIES TO VEPEMB AND REGISTRATION-ONLY PATIENTS

Having logged in and entered your Site.

Go to the Navigation Panel and click on the Green and Red men (PATIENTS).

Click on ADD PATIENT. You will be asked for the following information.

Patient initials, date of birth, gender

Weight in kilograms and height in metres

Confirmation of diagnosis and signed consent

Whether patient is being treated with VEPEMB or another regimen

(For Registration Only Patients, Now Move to Page 12 of this Handbook)

Confirmation of Inclusion criteria

Frailty Assessment (A calculator is provided in the system)

You will then be directed to the SCREENING VISIT (Visit 1).

VISIT 1 : SCREENING VISIT

Screening Visit Tabs run horizontally across the screen

The Summary page indicates which questions have been completed

NB: *Visit Details field* will always be designated as *incomplete* whilst the patient is in follow-up phase.

Visit Tab

You will be asked to complete the *date the patient attended Site* for screening.

Clinical Tab

You will be asked to give details of:

ECOG score, Activity of Daily Living Score, Instrument of Daily Living Score, Co-morbidity rating scale (Protocol Appendices 4,5,6)

(Guidance can be found by clicking the green question mark at the left of each item).

Date of Assessment - screening visit date

Histology Tab

You will be asked for details in relation to the patient's histological investigations;

date of primary biopsy, place biopsy taken, histological type, whether biopsy has been reviewed (where and when), was the diagnosis and subtype confirmed and whether or not the bone marrow showed evidence of disease.

Please note the date of the primary biopsy will be taken as the date of diagnosis for Study annual follow-up purposes.

Antigen Profile Tab

Results of:

CD30, CD15, EMA, CD20, EBV status.

Imaging Tab

You will be asked whether the following were performed:

CT & MRI scans, CXR, Abdominal ultrasound;

and for information in relation to:

staging, tumour sites, bulk disease

Haematology Tab

Values will be requested for:

WBC, neutrophils, haemoglobin, platelets, absolute lymphocyte count, ESR

Enter NK for not known and ND for not done.

The blue circle to the right indicates normal parameters.

The system will highlight any abnormalities by showing a red triangle.

Biochemistry Tab

Values will be requested for:

Sodium, potassium, urea, creatinine, urate, total protein, ALT, AST, ALP, CRP, albumin, B2 microglobulin, LDH.

Enter NK for not known and ND for not done.

The blue circle indicates normal parameters.

The system will highlight any abnormalities by showing a red triangle.

QUESTIONS 14 and 15: Please indicate whether 2 x 5mls of blood have been sent for central review to the Study Centre at Newcastle.

Staging/Prognosis Tab

The Hasenclever/Diehl prognostic score will automatically be shown on this screen.

N.B. The screen will indicate which if any values are missing. These values must be entered for the prognostic score to appear.

Primary Treatment Intention Tab

You will be asked how many treatment cycles (3 or 6) of the VEPEMB schedule are planned.

ADVERSE EVENTS

Adverse Events (AE) and Serious Adverse Events (SAE) are official registration of side effects or life threatening patient conditions caused by the use of the Study medication.

ADVERSE EVENT defined as:

"any undesirable sign, symptom, or medical condition occurring after starting Study drug, whether considered Study drug-related or not".

SERIOUS ADVERSE EVENT defined as:

"(a) fatal or life threatening; (b) requires or prolongs hospitalisation; (c) significantly or permanently disabling; (d) a congenital anomaly; (e) any other significant medical event".

If an event occurs, click on ADVERSE EVENTS on the vertical tabs to the left and then ADD A NEW ADVERSE EVENT.

You will be asked for:

Description, Body System, Grade (guidance from Green Question Mark), Onset Date, Outcome Date, Notes, Corrective Measures Used, Study Related Information.

Please notify us of any SAE within 24 hours by faxing SAE form (found at www.shieldstudy.co.uk HOMEPAGE) to SHIELD Study Centre at: 0191 222 5524.

If condition is not resolved, please complete SAE follow-up form at resolution and fax as above. (Found at www.shieldstudy.co.uk HOMEPAGE).

CONCOMITANT MEDICATIONS

Record key drugs used to ease the side effects of trial Study medication or in relation to adverse events. This includes blood and platelet transfusions.

- Key pharmacological agents include anti-emetics and GCSF, either prophylactic or for neutropenia.
- For infective adverse events record antibiotic use.
- Where the event qualifies as an SAE then drug recording is required on the SAE form as indicated and on the electronic system also.

We appreciate the elderly may require many additional agents for example laxatives, sleeping tablets etc. It is not critical to the Study to record all such medicines.

You will be asked for:

Generic name, reason for prescribing, dose and units, start date, frequency, end date and notes.

DOSE INDICATOR

When the patient's height and weight are added to the data, the system will automatically give the *CALCULATED DOSE* of each drug to be given. This is a guide only please use your own in house method for cross checking the dose calculation.

There is also a column to complete for each drug to indicate the *ACTUAL* amount of each drug which will be given to the patient.

DOSE CHANGES

This screen is populated by the system and shows all Study medication dose changes that have been logged in specific eCRF sections (*Cycle Notes* at the end of each cycle) throughout the duration of the Study.

INFO: CHEMOTHERAPY CYCLE

This is an information page giving usual dose and guidance on *GCSF* prophylaxis.

CYCLES OF TREATMENT

Visit 2, [Cycle 1]

This is the visit on which the patient has the first part of *Cycle 1* chemotherapy. You will be asked:
date, haematology (WBC, neutrophils, haemoglobin, platelets) and clinical status.

Cycle 1 Notes

If the patient's condition is satisfactory, indicate whether full cycle doses given. If the patient's condition is not satisfactory, please record this by clicking on vertical notes tab.

Visit 3, [Cycle 1]

This is a visit which the patient makes to the clinic between *Part 1* and *Part 2* of *Cycle 1*. (The patient may make more than one visit, if treatment is delayed. Record the visit closest to the next visit where the second half of the treatment is given. If the patient does not make a visit between treatments, please indicate this in the *Cycle Notes*.)
You will be asked:
date, haematology (WBC, neut, Hb, plts) and clinical status.

Visit 4, [Cycle 1]

This is the visit on which the patient has the second part of *Cycle 1* chemotherapy.
You will be asked:
date, haematology (WBC, neut, Hb, plts) and clinical status.

Cycle 1 Notes

If the patient's condition is satisfactory, indicate whether full cycle doses given. If the patient's condition is not satisfactory, please record this by clicking on vertical notes tab.

Visit 5, [Cycle 1]

This is a visit which the patient makes to the clinic between Cycle 1 and the beginning of Cycle 2. (The patient may make more than one visit, if treatment is delayed, or may inadvertently miss this visit)

You will be asked:

date, haematology (WBC, neut, Hb, plts) and clinical status.

CYCLE NOTES

Cycle Notes is the point at which doses of drug given can be confirmed or dose changes entered. It also allows recording of treatment delays, and provides a section for other clinically relevant comments.

This section is repeated at the end of each cycle and is of particular value to the Study team to rapidly assess any difficulties being experienced. Your comments here will be most helpful.

Visit 6, [starts Cycle 2]

This is the commencement of Cycle 2, see as for Cycle 1 above. Remember to complete Cycle Notes for each Cycle of therapy.

Visit 10 (starts cycle 3)

Cycle 3 will be the last chemotherapy for those patients with early stage disease (Stage I and II) prior to radiotherapy. The treatment will be deemed completed for them post-radiotherapy, if radiotherapy is indicated.

Visit 14 - ASSESSMENT VISIT

Completed only for advanced stage disease patients.

Early stage disease patients, go next to Visit 27 Assessment.

Visits 15 to 26

Relate to advanced stage chemotherapy cycles 4-6 which are not relevant to early stage patients.

REMEMBER TO COMPLETE CYCLES 4-6 NOTES, AS ABOVE.

Visit 27 ASSESSMENT

This visit is the time at which patients with early stage and advanced disease have the end of treatment evaluations recorded, approximately one month post-treatment.

You will be asked for the following information:

*Date of visit, details of radiotherapy if given
ECOG Score and clinical response,*

Whether the following investigations were done:

*CT Scan, MRI Scan, CXR, abdominal ultrasound, radiological response,
Any radiological comments*

Haematology Values of:

WBC, Neutrophils, Haemoglobin, Platelets, Absolute Lymphocyte count

Biochemistry Values of:

*Sodium, Potassium, Urea, Creatinine, Urate, ALT, AST, ALP, Albumin, B2
microglobulin, LDH.*

FOLLOW UP ASSESSMENTS

Following the end of treatment, patients will be seen at:

monthly intervals for **3 months**; **3 monthly for 6 months** and thereafter follow-up will be **annually**. (If possible to coincide with the anniversary of diagnosis, i.e. date of primary biopsy).

Visit 28 Assessment

Two months post-treatment for both early stage and advanced stage patients.

You will be asked for the following information:

Date of Visit

Status of Patient - alive or dead

Has patient developed another malignancy - if so details

*Clinical status - Complete Response, Partial Response, Relapsed Progression or,
Not assessed.*

Whether the following investigations were done:

CT Scan

Date of CT Scan

Haematology Values of:

Haemoglobin, WBC, Platelets, LDH.

Visit 29 Assessment

Three months post treatment
Provide information as at Visit 28 above.

Visit 30 Assessment

Six months post treatment
Provide information as at Visit 28 above.

Visit 31 Assessment

One year post date of diagnosis
Provide information as at Visit 28 above.

Visit 32 Assessment

Two years post date of diagnosis
Provide information as at Visit 28 above.

Visit 33 Assessment

Three years post date of diagnosis
Provide information as at Visit 28 above.

Visit 34 Assessment

Four years post date of diagnosis
Provide information as at Visit 28 above.

Visit 35 Assessment

Five years post date of diagnosis
Provide information as at Visit 28 above.

Registration Only Patients

At initial registration you will be asked if it is intended that the Patient is to receive VEPEMB treatment.

If the patient is **not** going to receive the Study treatment (VEPEMB) you will be automatically directed to the Registration Only Case Report Form.

VISIT 1 : SCREENING VISIT

Screening Visit Tabs run horizontally across the screen

The Summary page indicates which questions have been completed

NB: *Visit Details field* will always be designated as *incomplete* whilst the patient is in follow-up phase.

Visit Tab

You will be asked to complete the *date the patient attended Site* for screening.

Clinical Tab

You will be asked to give details of:

ECOG score, Activity of Daily Living Score, Instrument of Daily Living Score, Co-morbidity rating scale

(Guidance can be found by clicking the green question mark at the left of each item).

Date of Assessment - screening visit date

Histology Tab

You will be asked for details in relation to the patient's histological investigations;

date of primary biopsy, place biopsy taken, histological type, whether biopsy has been reviewed (where and when), was the diagnosis and subtype confirmed and whether or not the bone marrow showed evidence of disease.

Please note the date of the primary biopsy will be taken as the date of diagnosis for Study annual follow-up purposes.

Antigen Profile Tab

Results of:

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Imaging Tab

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and for information in relation to:

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Haematology Tab

Values will be requested for:

WBC, neutrophils, haemoglobin, platelets, absolute lymphocyte count, ESR

Enter NK for not known and ND for not done.

The blue circle to the right indicates normal parameters.

The system will highlight any abnormalities by showing a red triangle.

Biochemistry Tab

Values will be requested for:

Sodium, potassium, urea, creatinine, urate, total protein, ALT, AST, ALP, CRP, albumin, B2 microglobulin, LDH.

Enter NK for not known and ND for not done.

The blue circle indicates normal parameters.

The system will highlight any abnormalities by showing a red triangle.

QUESTION 5: Please indicate NO to availability of stored serum.

Staging/Prognosis Tab

The Hasenclever/Diehl prognostic score will automatically be shown on this screen.

N.B. The screen will indicate which if any values are missing. These values must be entered for the prognostic score to appear.

Primary Treatment Intention Tab

You will be asked:

What treatment patient is to receive instead of VEPEMB

Is it intended to use radiotherapy (if yes, field and dose)

Enter any relevant details to comments area.

FOLLOW UP

VISIT 2

This is recorded one year after date of screening or first visit.

You will be asked:

Visit date

If the patient is alive or dead

Confirmation of treatment intention at the beginning of therapy

Number of planned courses of treatment

Number of courses

Details of treatment courses given

Did patient enter remission during 1st year

Did patient relapse during 1st year

Is patient in relapse at time of visit.

FOLLOW UP

VISIT 3

This is recorded two years after screening or first visit.

You will be asked:

Visit date

Is the patient alive or dead

Has the patient developed another malignancy

Did patient require additional treatment during the year

If yes, indicate the type of treatment

Did patient relapse during this year

Date of documented response

Is patient in remission at two year follow-up point

FOLLOW UP

VISIT 4, 5 AND 6

Recorded at three, four and five years post screening or first visit.

You will be asked for information:

As Visit 3 above.