

ACCORD Database

Version 2.2.9



User Manual

Version September 2011

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PREFACE

This software users' manual describes how to use the ACCORD Database Version 2.2.9

1 INTRODUCTION

The Australian Comprehensive Cancer Outcomes and Research Database (ACCORD) is a reliable, easily accessible dataset on all cancer patients treated at contributing hospital sites. It has been developed for hospitals that require a simple data collection and entry system, and allows clinicians to analyse the clinical and demographic characteristics of cancer patients. ACCORD is a web based system which allows users to enter data from any hospital networked computer, thus can be used in clinics.

The ACCORD system allows you to enter, edit and review a patients cancer episode. To query the data use MS Access for identified data or BioGrid (SAS software) for de-identified data (see www.biogrid.org.au).

The information in this manual is presented to assist health care professionals caring for cancer patients with collecting and accessing the data entered into ACCORD. The manual was written, reviewed and edited by Project Officers, Data Managers and Software Developers working in colorectal cancer settings, and has been reviewed by Oncologists and Surgeons. Feedback, positive or critical, from users of the manual is welcomed. Please email your comments to enquiries@biogrid.org.au

1.1 Audience

This document is intended for users who have no previous experience with the ACCORD Database. It should give the reader a basic understanding of the following concepts:

- What the ACCORD Database is
- How to enter data
- How to manage user access
- How to edit user-managed drop down lists
- How to access information from the ACCORD Database

2. GETTING STARTED

The following subsections describe the recommended system requirements and user configurations necessary for your organisation to utilise the ACCORD database.

2.1 Technical requirements

For detailed technical requirements, refer to the technical user manual (in installation CD) or see your IT department.

2.1.2 Internet Connection

56Kbps or higher

2.1.3 Browsers

ACCORD uses CSS (style sheets) to display the database's web interface. Older and experimental browsers that do not handle CSS correctly will have display problems.

ACCORD is tested with these browsers:

- Mozilla Firefox 3.0.8 or higher (recommended)
- Internet Explorer v6 or higher
- Safari (commonly used on Apple Macintosh) V3.2 or higher

2.1.4 PC Setup

Processing speed of 500Mhz or higher

Monitor resolution set at 1024x768 or higher

Windows 98SE/ME/2000/XP

128MB of RAM for Windows 98SE/ME; 256MB of RAM for Windows 2000/XP

2.2 User Roles/Permission

The following is a list of user types and the roles they are assigned to.

- **Administrator:** These users create and manage ACCORD database user accounts. They are also responsible for maintaining user-controlled field lists to ensure standardisation across ACCORD sites.
- **Data Manager:** These users can add, edit and view information held on the ACCORD database for the cancer stream(s) they are authorised to manage. These users can allocate data entry rights to other users (for their cancer streams) and can also run clinic lists to identify returning patients.
- **Read only:** This is the default user setting. These users can view information held on the ACCORD database for the cancer stream(s) specified. These users can also run clinic lists to identify returning patients. These users can not edit or add data.
- **Data entry:** These users can add, edit and view information held on the ACCORD database for the cancer stream(s) specified. These users can also run clinic lists to identify returning patients. This user type is managed by individual cancer stream data manager(s).
- **Surgeon:** These users have the same privileges as Data Entry users, but can only view their own patients. This user type, is available upon request.
- **Oncologist:** These users can add, edit and view information held on the ACCORD database for the cancer stream(s) specified. These users can also write chemotherapy prescriptions for patients using the ACCORD Chemotherapy Prescribing module. This user type is managed by individual cancer stream data manager(s).

2.3 Chemotherapy Prescribing

The Chemotherapy Prescribing module was developed to enables clinicians to prescribe therapy and record important data that can be used for further research purposes.

The chemotherapy dosages are calculated according to standardised protocols using calculated Body Surface Area (BSA). Regimens are dosed using actual or ideal BSA depending on clinician preference.

The prescriptions are computer generated (.pdf file), in a clear format designed in conjunction with pharmacy and oncology nursing input.

Please refer to the separate Chemotherapy Prescribing user manual for further information.

3. QUERYING

ACCORD does not have an inbuilt querying tool. To query your data, you can use MS Access (identified patient data), BioGrid tools (de-identified patient data) or any other querying tool which can link to SQL tables.

3.1 MS Access set up - Linking ACCORD data to MS Access

To use ACCORD data in MS Access, you will need to make an Open Database Connectivity (ODBC) link between your PC and the server that ACCORD data is stored on. You only need to do this once per PC per user. After you have made the ODBC link, you can then link Access to the ACCORD tables you require.

Refer to appendix B on how to link to ACCORD in MS Access.

If you are unsure of any steps in this process please contact your IT department for help.

Please note: Some tables in Accord are system or reference tables, which do not need to be linked into Access for querying (see the schema in appendix C for the relevant tables to link).

Tables with names which end with the word 'View' have been set up to show you the text entry in a field rather than the background reference number. Use these tables where they exist

The data you see in Access is read-only. Changes made to the data in Access do not change the data in ACCORD.

3.2 Schema

The Schema shows you how to build the relationships in MS Access and other querying tools that enable the querying of fields from different tables within the ACCORD database.

Refer to appendix C for a diagram of the relationships.

4 ADMINISTRATION

An Accord Administrator is appointed at each site and assigned an administrator logon that enables them to add new users, generate passwords and modify drop down boxes. Administrators at each site should maintain contact with administrators at other sites to ensure consistency in drop down box additions, particularly within tumour groups.

4.1 User Management

When logged in as an Administrator, the User Management screen will be displayed. The following subsections describe the functions available on this screen.

4.1.1 User Types

Administrator: The administrator can create new users and edit value lists (drop down box content). The administrator logon does not manage patient data. It is recommended that the administrator(s) at each site coordinate with each other and other sites to standardise the value lists so when data is combined there are standards. It is the administrator's role to allocate Data Manager rights to the appropriate users, when the administrator creates a new user they have read-only rights. Only the data manager for each tumour stream can allocate data entry rights to a user.

Data Manager: A data manager is the key person involved in collecting, managing and maintaining the database for a particular tumour stream. A data manager can add new users and allow users the ability to be a 'data entry' user (add, edit and delete data). They can also allocate a user to be an 'oncologist' (write chemotherapy prescriptions). They have data entry and oncologist user rights.

Read-Only: When the administrator or data manager creates a new user, they are automatically allocated read-only rights to all tumour streams. To gain data-entry or oncologist rights the tumour stream data manager needs to allocate that right (per tumour stream). The user can view all data but not edit, delete or add data and can run clinic lists.

Data Entry: A user allocated data entry rights can add, edit and delete patient's information. Access is granted per tumour stream by the tumour streams data manager. Users can also run clinic lists.

Oncologist: A user allocated oncologist rights can add, edit, delete patient data and prescribe chemotherapy. Access is granted per tumour stream by the tumour streams data manager.

Surgeon: This user is only on Accord versions when requested, it has been developed for a centralised database model and is not used at individual hospitals. Users are allocated as a surgeon can only see their own data when they are entered as the consultant or assistant surgeon for that patient. They can also add new patients.

4.1.2 Adding New User

- Administrators and data managers can add new users. Go to the 'Manage User Access' tab at the top of your screen.
- Click the 'New User' button at bottom of the list of users
- Enter username → this can be selected by the user (usually surname + first initial – e.g. John Smith would have the username smithj)
- Enter Last Name (can only use alphabetic characters)
- Enter First Name (can only use alphabetic characters)
- Enter Password (may use lower and upper case alphabetic characters and numeric characters – please note that the password is case sensitive)

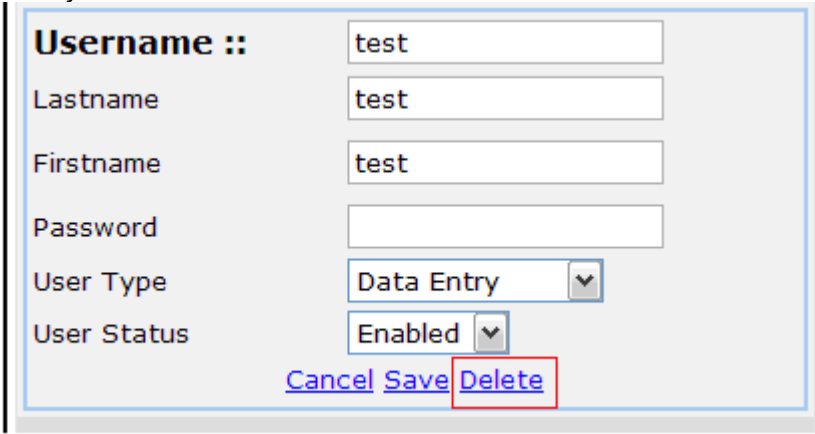
- If user is to be allocated an Administrator role, tick 'Is Administrator' box (note: they will need to allocated a separate logon for accessing to the patient data).
- If the user is a 'Data Manager' (see definition above) then select the tumour stream(s) they manage. **Leave blank if they are not a data manager.**
- If a data manager is creating a new user, you can then give permission for the user to have 'data entry' or 'Oncologist' access to the tumour streams they manage. See definitions above.
- Click on the 'Save' button to add New User

4.1.3 Viewing or Editing User Details

- Users are listed in the Manage User Access area in alphabetical order by username.
- Open a user's profile by clicking the 'Open' link adjacent to their username or their name if you are logged in as a data manger.
- Make changes to the user's profile if necessary. Eg data manager users can allow users to be 'data entry' or 'Oncology' users.
- If any changes are made, click the 'Save' link below the user's details. Otherwise, click the 'Cancel' link.

4.1.4 Deleting a User

- Note: Only the administrator can delete users.
- Click the 'Delete' link adjacent to the user's username on the User Management screen
OR
Open the user's profile as described in 4.1.3 and click the 'Delete' link below the user's details
- A message will appear asking;
"Are you sure you want to delete this user?" → select OK or Cancel



The screenshot shows a user profile form with the following fields and values:

Username ::	test
Lastname	test
Firstname	test
Password	
User Type	Data Entry
User Status	Enabled

At the bottom of the form, there are three links: [Cancel](#), [Save](#), and [Delete](#). The [Delete](#) link is highlighted with a red rectangular box.

4.2 Generating and Changing Passwords

- Your ACCORD administrator will generate and give new users a username and password to gain access to the system.
- The new user should change his or her password when first using the database.
- To change the password, click 'Settings' from Main Menu at top of the screen.
- Enter Current password

- Enter New password
- Retype New password to confirm
- Click on 'Change password' button

4.3 Modifying Drop Down Boxes

- Only administrators can modify drop down selections.
- Click 'Control Data Lists' from Main Menu
- To view or modify the data in drop down boxes, click on the + symbol next to the appropriate form name in the left side column. This will expand the list to display all drop down box data lists for the form.
- Select the relevant data list from the newly displayed options
- To add data, type into the blank boxes at bottom of the data list. '**Name**' refers to the text which will appear in the drop down box on the data entry screen. '**Value**' refers to the data which will be stored in the Accord table.
- Click on 'Add' to save new data to the list
- This will now appear as a selection in the drop down box on the data entry screen.
- **Note: you can not delete selections from drop down boxes so ensure you have entered the correct details before saving.**

The screenshot shows the 'Control Data Table' interface for the 'Adjuvant' form. The interface includes a sidebar with a tree view of forms (Global, Head and Neck, CNS, Colorectal). The main area displays the 'Control Data Table' for 'reasonForStopping_Adjuvant'. It has fields for 'Form Name' (Adjuvant) and 'Table Description'. Below these is a 'Data' table with two columns: 'Name' and 'Value'. The 'Name' column lists reasons for stopping chemotherapy, and the 'Value' column lists the corresponding stored values. An 'Add' button is at the bottom right of the data table. Below the data table is a section for 'Associated Fields on this form' showing 'Incomplete Reason' and 'Reason to stop Chemo'.

Name	Value
Completed planned Rx	Completed planned Rx
Death Other	Death Other
Death Toxicity	Death Toxicity
Other	Other
Patient request	Patient request
Progressive disease	Progressive disease
Toxicity	Toxicity

4.4 Standards for Drop Down Boxes

- Additions to Data Lists can only be made by an Administrator
- Additions should only be made after liaising with other Accord Administrators or tumour groups for consistency across sites.
- Please consult with relevant clinicians or committees before adding new selections.

5 DATA ENTRY

5.1 Patient Records

To access the system, enter your username and password and press the 'Enter' key or click on Login. The Search screen will be displayed. Any field in the search screen can be used to search for a patient. Click the mouse in the particular search field you choose. eg Last Name, UR number, Universal ID etc. You may use a combination of search fields.

5.1.1 Searching Patient Record

- Enter the patient information in the relevant search field and click 'Search' or press the 'Enter' key to check if patient is already entered.

Search Outcomes:

- o If only 1 record found, this will display the Patient Details screen for that patient.
- o If 2 or more records are found, select the correct record from the patient list by clicking on Universal ID.
- o If incorrect patient, click 'Search' from Main Menu at top of screen to return to Search screen.
- o If no match, a 'No records found!' message is displayed at bottom of search box. Click 'Clear Search' to try again or add as New Patient.

Search

Surname	
Given Name	
UR No.	
Universal ID	
Birthdate (dd/mm/yyyy)	/ /
Tumour Type	

Clear Search

Search

5.1.2 Adding New Patient Record

- To enter new record click 'New Patient' from Main Menu to display the blank Patient Details screen.
(This screen is the same for each Tumour Type)
Patient Details
- If ACCORD is linked to your Patient Information System
 - Enter the patient's UR number
 - Select the Campus
 - The patient demographics will be auto-populated
 - Check if the name and details are correct
- If ACCORD is not linked to your Patient Information System, follow the instructions below
 - Enter patient details

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- The mandatory fields are:
Last Name
First Name – can just enter first initial
DOB – must be dd/mm/yyyy
Sex
- Use the 'Tab' key to move through the fields
- Use mouse to make selection from drop down boxes or type in first letter of entry. eg Y for Yes or N for No, M for Male or F for Female
- Please ensure the patient details are entered exactly the same as they are recorded in your hospital's patient management system.
- Update Patient Status field:
Alive – patient is alive with no recurrence or metastases
Dead – patient deceased → also complete death date and cause of death using drop down box.
New primary – patient diagnosed with new primary cancer
Recurrence – patient diagnosed with recurrence
Stage IV – patient has metastatic disease
- Click on Save (or tab to Save and press Enter key) to add New Patient.
- To add a tumour episode, select the New Episode link as shown below.

[New Patient](#) | [Search](#) | [Clinic Lists](#) | [Manage User Access](#) | [Settings](#) | [Logout](#)

Name: Test, Patient a.
ID: 6503

Add New Episode

☐ Patient Details
☒ Bone & Soft Tissue
 19/07/2010
☒ Colorectal 01/07/2006

Patient Details

Universal ID:	6503
Last Name:	Test
First Name:	Patient
Middle Initial:	a
Medicare No:	3423-42342-3
DVA No:	
Date of Birth (dd/mm/yyyy):	26/07/1978
Sex:	Female ▼

Adding a tumour episode

- After you select 'New Episode' select the tumour type, as shown below (1).
- Enter the Episode details and press 'Save' (2)
- The screens for that tumour stream will appear in the left (3), just select the relevant screen you would like to enter data in.

Please select one of the forms for this episode from the left-side tree menu to look at patient's data.

Tumour Type CNS

CNS Episode

UR No: 123456 Campus: MP Date of Diagnosis: 06/05/2008

ECOG: 0 Consultant:

Referral

Comments:

Save Cancel Delete

Complete Incomplete

General Information

- Each patient can have more than one episode of cancer, episodes can be seen on the navigation tree on the left of screen and are identified by tumour type and diagnosis date.
- Date of Diagnosis is a mandatory field at a particular point for each tumour stream.
- Some fields may be hidden if a previous selection indicates that it is not applicable.
- The Comments box allows free text. Any information relevant to this patient's episode can be added here.
- If all fields are entered, use the Mouse to click the 'Complete' radio button at the bottom-right of the screen to indicate that the form is complete. Most tumour streams will highlight incomplete forms in red on the left hand navigation tree.
- 'Save' saves the data and remains on the current screen, 'Save and Next' will move to the next form.

5.1.3 Viewing/Editing an existing Record

- To edit or view an existing record, search patient as per 5.1.1
- After opening the patient's record, select appropriate data entry screen from the Navigation Tree in the left side column
- Browse onscreen form and make changes or additions to the data by clicking mouse in relevant field.
- Press the 'Save' or 'Update' button at the bottom of the screen to save any changes

5.1.4 Deleting an existing Patient or Episode

Deleting a patient:

- To delete an existing record, search patient as per 5.1.1
- After opening the patient's record, in the 'patient details' screen, click on Delete at bottom of screen
- A pop-up message will appear asking:

“Are you sure you want to delete this patient? All data about this patient will be gone”

- Click the 'OK' or 'Cancel' button on the message

Deleting an episode:

- To delete an existing episode (not the Patient Details or other tumour types), select the episode you want to delete (tumour type and data of diagnosis in the navigation tree).
- Click on Delete at bottom of screen
- A pop-up message will appear asking:
“Are you sure you want to delete this entire Episode?”
- Click the 'OK' or 'Cancel' button on the message

5.2 Data Entry Standards

5.2.1 Blank Fields

- Only leave fields blank if the data is still being followed up.

5.2.2 Not Applicable

- Use N/A in a field when you have tried to find the data, but it cannot be found in the medical records or at consultant's private rooms (if applicable), or where the field is not applicable to this patient.

5.2.3 Complete and Incomplete Radio Button

- A completion status indicator is available on some screens. Users can use this field to determine whether they want to include incomplete data in their queries.
- To use this field correctly:
 - o Select Complete when all fields have been filled, including N/A (where applicable).
 - o Select Incomplete if fields are still blank. This indicates that the data is either being followed up or patient still receiving treatment – and so data is periodically updated.
 - o Incomplete forms are highlighted in 'red' on the left hand screen navigation (for most tumour streams)

5.2.4 Data field definitions

- Some fields throughout ACCORD have a '?' symbol on the field label. To view the definition(s) of these fields just click on the '?'. The definition will appear in a pop up box, if this does not occur try unblocking popups in your web browser or holding down the 'Ctrl' key when you click the '?'.
- A full data dictionary is available for each tumour module. You can download them at www.biogrid.org.au.

6 CLINIC LISTS

6.1 How to run a clinic list

- From main menu at top of screen select Clinic Lists.
- Select your campus' name from the Campus drop-down list.
- The drop down list of Clinics for that Campus will be displayed.
- Select required clinic and click on Patient List.
- Use your web browser's Page Setup feature to set list as a Landscape or Portrait document for printing
- Click on Print button at top of screen (right hand corner)

6.2 Clinic list columns defined

- Patient List is displayed with:
 - Universal ID – Accord ID or N/A if not entered on database*
 - Status – N = new patient, R = returning (returning to clinic and in ACCORD), O = old (returning to clinic but not in ACCORD)*
 - Last Name*
 - First Name*
 - DOB*
 - Appointment Date – check if correct clinic*
 - Appointment Time*

6.3 Open a return patient

Click on the universal ID to go to the patient record for data entry.

Universal ID	Status UR No	Last Name	First Name	Date of Birth	Appointment Date	Appointment Time
N/A	N	*****	*****	/ /1931	20/08/2007	2:30 PM
N/A	N	*****	*****	/ /1933	20/08/2007	2:30 PM
N/A	N	*****	*****	/ /1915	20/08/2007	2:30 PM

6.4 How are the lists generated?

- Clinic lists are generated by your facility's Hospital Management System
- To add a clinic to ACCORD, please contact your IT department
- See the ACCORD installation manual for details on how to set up the clinic list function.

7 GENERAL INFORMATION

7.1 Session Time Out

- If the database is open and not used for 30 minutes, the session is timed out.

7.2 Logging Off

- Click on 'Logout' from Main Menu at top of screen
- The logout page displays a message to close the browser. There is also a facility to 'Click here to login again'. This will take you back to the Accord Welcome and Login screen.

Appendix A

This appendix should be read in conjunction with the main body of the user manual to gain the most understanding of how to utilise this database.

A 1 - COLORECTAL

A1.1 Preoperative Data

- Complete as many fields as you can.
- Some fields will display further drop down boxes if 'yes' is selected.
- Click on Save or Save and Next (to move to the next form).

A1.2 Operation Report

- Click on Add New to add tumour site details. If more than one tumour, click on Add New again after saving first tumour site (see diagram below).
- *Note* – Anastomosis method and type are located at bottom of Tumour Site data form
- Date of Diagnosis is automatically populated from the Preoperative screen.
- To enter more than one metastatic site in the Tumour Staging section, hold down the Ctrl key and click the appropriate sites from the list using the mouse.
- If Bowel Management is not applicable (only applicable for Rectal and Lower Colon tumours), click tick box to the right of the Bowel Management field label. This will automatically answer all related fields N/A.
- If all fields are entered, use the Mouse to click that the form is complete.
- Click on Save or Save and Next (to move to the next form).

The screenshot shows the 'Operation Report' form. At the top is a header 'Operation Report'. Below it is a section 'Tumour sites'. Inside this section, there is a list of tumour sites. The first site is 'Sigmoid Colon' with a red arrow pointing to it labeled 'Tumour 1'. The second site is 'Tumour Site :: Rectum-Middle Third' with a red arrow pointing to it labeled 'Tumour 2'. Below the list, there are fields for 'Cm from anal verge(rigid sigmoidoscopy) cm' (value 15), 'Primary Tumour Rectum', 'Anastomosis Method', and 'Anastomosis Type'. To the right of these fields are three dropdown menus: 'Mobile', 'Handsewn', and 'End-End'. Below the dropdowns are buttons 'Cancel', 'Save', and 'Delete'. At the bottom of the 'Tumour sites' section is a button 'Add New' with a red arrow pointing to it labeled 'Click to add new tumour site'. Below the 'Tumour sites' section is a section 'Surgery Details' with fields for 'Date of Diagnosis' (value 21/05/2009), 'Date of Surgery' (value 01/06/2009), and 'Urgency' (value Elective).

A1.3 Surgery Outcomes

- If fields are completed with Yes, drop down boxes are displayed. All fields should be completed.
- If the 'Other' field in the Surgical Complications and Medical Complications sections is answered Yes, the 'Type' field is displayed. Make a selection from the drop down list.

A1.4 Adjuvant Therapy

- If treatment is not offered, select reason.
- If treatment is offered and accepted, the adjuvant chemotherapy and adjuvant radiotherapy forms are displayed.
- Enter either the Preop or Postop (or both) data.
- To select more than one Regimen, hold down the Ctrl key and click the appropriate regimens from the list using the mouse.

A1.5 Pathology

- For the Pathology form to be displayed the tumour site details must be entered (see Operation report). Complete pathology data for each tumour site.
- If M stage is entered as 1, then ACPS will default to Stage D.
- Radial margin will only be displayed if tumour site is Rectal or Rectosigmoid.
- Pathologic response will only be displayed if Rectal or Rectosigmoid site.
- If entering data for multiple tumours, click 'Save and Next' after entering first tumour site details to display next tumour site (see below).

New Patient | Search | Clinic Lists | Manage User Access | Settings | Logout

Name: SIMPSON, HOMER . ID: 7819

ACCORD@

New Episode

Patient Details

- Colorectal 21/05/2009
 - Minimum Dataset
 - Preoperative Data
 - Operation Report
 - Surgery Outcomes
 - Adjuvant Therapy
 - Pathology
 - Sigmoid Colon
 - Rectum-Middle Third
 - Followup
 - Recurrence Summary
 - New Form
 - Prescriptions

Pathology

Date of Diagnosis: 21/05/2009 Tumour Site: Sigmoid Colon

Staging

T: 3 M: 0

N: 0 ACPS: B

Metastases

Biopsy confirmed distant metastases: No

Resected metastases: No

Margins

Distal: Not involved

Distance(mm): 0.5 ☐ Less Than

Tumour Size

Length(mm): 10 Width(mm): 15 Depth(mm): 2

A1.6 Routine Follow Up

- To enter new Follow Up visit click on Add New to display the form.
- Date of Visit mandatory.
- Evidence of Recurrence should be completed Yes or No.
- Enter follow up test results, if not performed then enter N/A.
- Click on Save

A1.7 Recurrence Summary

Recurrence details are entered either at time of diagnosis if patient is Stage IV disease or at anytime a patient is diagnosed with a recurrence. There can be multiple episodes of recurrence.

Recurrence

- To add a new recurrence click 'New Form' under Recurrence Summary on the left navigation menu.
- Details on the sites of Loco/regional recurrence and Distant Metastases sections are shown if 'Yes' is selected for the 'Loco/regional recurrence' or 'Distant Metastases' fields.
- Under Distant Metastases there is an Other field. If Yes selected, please specify.
- Under Method of Detection there is an Other field. If Yes selected, please specify.
- If Treatment Planned answered Yes, a Treatment Type list is displayed. To select more than one treatment type, hold down the Ctrl key and click the appropriate treatments from the list using the mouse. eg Chemotherapy & Radiotherapy
- If Treatment Planned answered No, select from the list of Reasons. To select more than one reason, hold down the Ctrl key and click the appropriate reasons from the list using the mouse.
- If all fields are complete, click on 'Complete'
- Click 'Save'

Treatment Given

- To enter Treatment details, click on Add New in the Treatment Given section.
- Complete details of 1st line treatment from data collection form.
- To enter additional treatments (2nd line, 3rd line etc), click on Add New.
- Each line of treatment will be saved and listed separately.
- Click on Open to view or edit details.

Surgical Resection

- To enter Surgical Resection details click on Add New.
- To select more than one Resection site, hold down the Ctrl key and click the appropriate sites from the list using the mouse.

A1.8 Minimum Dataset

If your site chooses to enter the minimum colorectal dataset two screens are available to enter this data, it is a selection of the information that is recorded in the comprehensive dataset and is saved in the same fields/tables.

- Add a new tumour by selecting 'Add New' under the Tumour Sites heading.
- Navigate between the two screens by selecting 'Page 1' or Page 2' as shown below.
- Save each screen when data entry is completed.

The screenshot displays the 'CSSANZ Minimum Dataset' form. On the left, a sidebar menu under 'New Episode' lists various data entry categories. A red arrow points to 'Minimum Dataset'. The main form area has tabs for 'Page 1' and 'Page 2', with red arrows pointing to them. The 'Page 1' tab is active, showing fields for 'Episode' (UR No: 123456, Campus: RMH, Date of Diagnosis: 21/05/2009, ECOG: 1, Consultant:), 'General Information' (Insurance: Public, Tumour diagnosed by screening FOBT: No), 'Tumour sites' (Sigmoid Colon, with 'Open Delete' and 'Add New' buttons), and 'Surgery Information' (Surgery Performed: Yes). A red arrow points to the 'Add New' button in the 'Tumour sites' section.

A-2 CENTRAL NERVOUS SYSTEM (CNS)

This appendix should be read in conjunction with the main body of the user manual to gain the most understanding of how to utilise this database.

A2.1 Preoperative

- Selecting 'Yes' for past history questions will reveal further questions.
- Tumour size allows for two decimal places.
- Height and weight can be entered as whole numbers only.

A2.2 Operation Report

- Select one or more tumour site, click box to select and un-select.

A2.3 Surgery Outcomes and Pathology

- If heading fields are answered with yes, drop down boxes are displayed. All fields should be completed.
- If the 'other' field is selected in the surgical and medical complications sections is answered 'yes' the 'type' field is displayed, enter type.

A2.4 Adjuvant Therapy

- If treatment not offered select reason
- If treatment is offered and accepted, the adjuvant chemotherapy and adjuvant radiotherapy fields are displayed.
- Enter the Preop or Postop (or both) data.
- To select more than one drug on the Chemotherapy form, hold down the ctrl. Key and select the appropriate drugs from the list.

A2.5 Routine Follow-up

- To enter new Follow Up visit click on 'Add New' to display the form.
- Date of Visit is mandatory.
- Evidence of Recurrence and following fields should be completed Yes or No.
- Add any relevant comments and click 'save'.

A2.6 Treatments at time of Recurrence/Progression.

Recurrence details are entered either at time of diagnosis if patient is Stage IV disease or at anytime a patient is diagnosed with a recurrence. There can be multiple episodes of recurrence.

- For new Recurrence/Progression select 'New Form' under 'Treatment at time of Recurrence/Progression' on the navigation tree.
- 'Date Detected' is a required field.
- Enter 'method for initial detection'. If 'other' is selected specify type.

Treatment Planned

- If no treatment is planned, reason should be given.
- If treatment is planned, enter type(s) of proposed treatment. If 'other' is selected, specify type.

Treatment Given

- When New Treatment is given, select 'Add New'
- Number of Line of Chemotherapy is a required field (including N/A).
- To select more than one regimen hold down ctrl. Key and select appropriate regimens from list.
- If Surgery is performed, select 'Add New'
- Surgery Date is a required field. Select type of surgery performed an press 'Add'.

Treatment Planned		Yes ▾
Surgical resection	Yes ▾	Chemotherapy Yes ▾
Radiotherapy	No ▾	Other No ▾

Treatment Given	
1st Line ← Existing chemotherapy treatment	Open Delete
Add new chemotherapy → Add New	

Surgery	
27/08/2008 ← Existing surgery	Open Delete
Add new surgery → Add New	

Recurrence Summary data read successfully.

A-3 HEAD AND NECK

This appendix should be read in conjunction with the main body of the user manual to gain the most understanding of how to utilise this database.

Remember to save each page after entering data and to save edits.

A3.1 Preoperative Details

- This section is intended to collect data when the patient first presents and is diagnosed with a H&N cancer. This section is completed once for each primary episode.
- Presentation is a mandatory field.
- For 'Primary Tumour Site', Select site then specify location(s). Selections made will appear in 'Selections Made' box beneath. Press 'close' when selections completed. To remove a site, un-tick the box.

Diagnosis and Staging

Presentation: New primary

Primary Tumour Site

[Hypopharynx](#)
[Larynx](#)
[Lip](#)
[Nasal Cavity and Sinuses](#)
[Nasopharynx](#)
Oral Cavity
[Oropharynx](#)
[Other](#)
[Salivary Glands](#)
[Skin](#)
[Unknown](#)

☐ Buccal mucos, retromolar areas
☐ Buccal mucosa, bucco-alveolar sulci, upper and lower
☐ Buccal mucosa, mucosal surfaces of cheeks
☐ Buccal mucosa, mucosal surfaces of upper and lower lips
☐ Floor of mouth
☐ Hard palate
☒ Lower alveolus and gingiva
☐ Tongue, dorsal surface and lateral borders, anterior to vallate papillae (anterior two-thirds)
☐ Tongue, inferior surface
☐ Upper alveolus and gingiva

[Close](#)

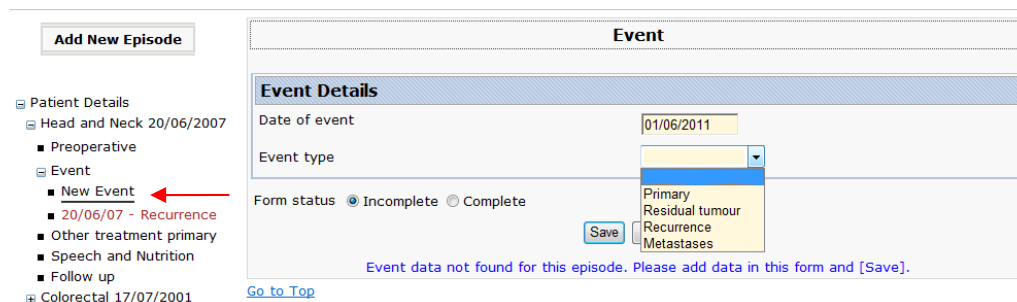
Selections Made

Nasal Cavity and Sinuses
 Oral Cavity
 Maxillary sinus
 Lower alveolus and gingiva

- If 'yes' is selected for 'Gross Nodal Involvement' select site(s) involved.
- 'Planned Initial Treatment' is a required field.

A3.2. Adding and Event

- Each event and it's related information can be recorded, events are described as:
 - o Primary
 - o Residual tumour
 - o Recurrence
 - o Metastases
- To add a new event click on the 'New Event' under Event in the left hand tree, see picture below.



- You must enter the date of the event and the type of event, then press save.
- You will then be able to enter details of biopsies, surgery, pathology, recurrence summary (if applicable) associated with this event

A3.3. Adding a Biopsy (within an event)

- Select 'new biopsy' or edit existing biopsy by selecting the 'edit' link next to the selected biopsy date.
- Once you have entered an event you will be able to enter one or more biopsies associated with that event.
- Click on the 'new biopsy' button.
- Enter data and press 'save biopsy' button.
- Multiple biopsies can be entered per event then edited or deleted.

A3.4. Adding Surgery Details (within an event)

- Select 'new surgery' or edit existing surgery by selecting the 'edit' link next to the selected surgery date.
- If 'Yes' is selected for 'Prior Treatment', enter details.
- When selecting Operative Procedure(s), select the procedure type first, then the sub-types will appear on the right, tick the appropriate type(s). Selections will appear beneath under the 'selections made' heading. To remove a procedure; un-tick the selection.
- When selecting 'Reconstruction Techniques' follow above process.
- Multiple surgeries can be entered per event, then edited or deleted by selecting the link next to the surgery.
- Enter the Pathology details if available (see A3.5)

Operative Procedures ?

[Biopsy of Primary Tumour](#)
☐ Maxillectomy, bilateral
[Cheek Resection](#)
☐ Maxillectomy, partial
[Ethmoidectomy](#)
☒ Maxillectomy, total
[Floor of Mouth](#)
[Close](#)
[Infratemporal Fossa](#)
[Larynx](#)
[Mid Face](#)
[Nasopharynx](#)
[Neck Surgery](#)
[Orbital Exenteration](#)
[Other](#)
[Palate Resection](#)
[Parotidectomy](#)
[Pharynx](#)
[Temporal Bone Resection](#)
[Tongue Resection](#)
[Tracheostomy](#)

Selections Made

Mid Face	Maxillectomy, total
Palate Resection	Hard Palate

A3.5. Adding Pathology Details (within an event, within a surgery)

- To enter the pathology, select the 'edit' link next to the surgical procedure date which the pathology belongs to (in the event). Scroll down to the bottom of the surgical details and tick the 'Pathology' check box to view the pathology fields.
- Enter data and press the 'save' or 'update surgery' button.

A3.6. Adding Recurrence/metastases Summary (within an event)

- This section will only appear in events 'recurrence' or 'metastases'.
- Select 'new recurrence summary' or edit existing summary by selecting the 'edit' link next to the selected recurrence summary date.
- If sites of nodal recurrence/progression is yes then tick the appropriate sites.
- If a treatment plan has been decided, select yes and indicate the use of each treatment.

A3.7. Other Treatment for Primary Tumour

- This section records the chemotherapy and radiotherapy treatment for the primary tumour.
- If radiotherapy is given, select yes and complete the fields.
- If chemotherapy is given, select yes and complete the fields.

A3.8. Speech and Nutrition

- To add the initial assessment information select the "Initial Assessment" button and complete the fields. This can only be completed once.
- The date of initial assessment is compulsory.
- To add further reviews, select the 'Add review' button. Multiple reviews can be entered.

A3.9. Follow-up

- Select the 'New Follow-up' button at each visit to add the visit data.
- The date of follow-up is compulsory.

A-4 BONE AND SOFT TISSUE

A4.1 General Information

Adding data

Click the required page title on the navigation menu eg First consultation.
Enter data into as many fields as possible.

Editing/updating data

Click the required page title on the navigation menu eg Diagnosis.
Enter or change data as required.

Saving data

Click the **Save** button to save the data or click the **Save and Next** button to save the data and open the next form.

A4.2 First consultation

This form captures information regarding the patient's first consultation at a clinic of your sarcoma service.

- The date of the consultation (*First clinic consult*) must be recorded.
- If you select 'Yes' for any of the *Surgery*, *Chemotherapy* or *Radiotherapy* fields, additional fields will be displayed for the recording of the patient's count of the relevant treatment types.
- If you select 'Yes' for the *Other cancers (if yes, specify types)* field, a list of cancer types will be displayed.
- If you select 'Yes' for *Genetic syndromes*, a list of genetic syndromes will be displayed.
- If you select 'Yes' for any of the fields within the *Symptom history* section, the *Duration of symptoms* field will be displayed.
- If you select 'Yes' for the *Prior to first consult at this sarcoma service clinic* field, *Procedure performed* fields for the various imaging procedures will be displayed.
- If you select 'Yes' for a *Procedure performed* field, the associated *Evidence of disease* field will be displayed.

A4.3 Further consultation

This form captures information regarding the imaging procedures performed on or after the date of the patient's first consultation at a clinic of this sarcoma service.

- If you select 'Yes' for *On or after day of first consult at this sarcoma service clinic* field, *Procedure performed* fields for the various imaging procedures will be displayed.
- If you select 'Yes' for a *Procedure performed* field, the associated *Evidence of disease* field will be displayed.

A4.4 Diagnosis

This form captures information regarding the patient's diagnosis of a malignant or benign disease of the bone or soft tissue.

- The date of diagnosis that was recorded on the *Episode* form is shown on this form.
- You must select a value from the *WHO classification* drop-down list.

- To narrow the list of values shown in the *WHO classification* drop-down list, type a keyword into the field marked *Filter* and then use the drop-down list (see figure below).
 - o Example 1: To restrict the list to diseases of the bone, type 'bone.'
 - o Example 2: To restrict the list to osteosarcomas, type 'osteosarcoma.'
 - o You may remove your filter by clicking the *Clear* button.
- If you select a value from the *WHO classification* drop-down list that does not appear under the word 'Benign,' the *Fill for malignancies only* section will be displayed.

The screenshot shows the 'Diagnosis' form. At the top, there's a header 'Diagnosis'. Below it, there are fields for 'Date of diagnosis' (27/08/2008) and 'WHO classification'. A 'Filter' field contains the text 'Lipoma', and next to it is a 'Clear' button. Below the filter field, a dropdown list is open, showing a hierarchy of tumor types: 'Soft Tissue', 'Adipocytic Tumours', 'Benign', '3. Lipoma', 'Intermediate (locally aggressive)', '5. Atypical lipomatous tumour / Well differentiated liposarcoma', 'Fibroblastic/Myofibroblastic Tumours', 'Intermediate (rarely metastasizing)', and '14. Solitary fibrous tumour and haemangiopericytoma (incl. lipomatous haemangiopericytoma)'. Red arrows point to the 'Filter' field with the text 'Enter diagnosis key word' and to the dropdown list with the text 'Any diagnosis which includes the key word will appear in the drop down list'. A 'Go to Top' link is visible at the bottom left of the form.

A4.5 Occurrences

This form captures information regarding the occurrences of the diagnosis of bone or soft disease (i.e. benign lesion, primary malignancy, metastasis, local recurrence).

Multiple occurrences may be recorded. A summary of the patient's occurrences will be displayed once data has been saved.

Occurrence details

This section allows you to record the characteristics (i.e. stage, grade, invasion etc.) of an occurrence.

Multiple sets of this information may be recorded for each occurrence (e.g. you may wish to record information that was obtained from pre-treatment imaging and also information that was obtained from resection pathology).

A summary of the occurrence detail records for an occurrence will be displayed on that occurrence's form once data has been saved.

Adding Occurrence data

- Click the *Occurrences* item on the navigation menu. Click the *New occurrence* button.
- Enter data into as many fields as possible.
- Save the data or add occurrence details and then save.

Occurrence details

- From an open occurrence form, click the *New occurrence detail* button.
- Enter data into as many fields as possible.
- Click the *Add occurrence detail* button to temporarily save the data. The data will be permanently saved when you save the occurrence form data.

Occurrences		
Occurrence type	Date of diagnosis	Occurrence site
Local recurrence	01/05/2009	Soft Tissue > Hand
Metastasis	06/05/2009	Metastases - Sites not specified above > Lung

View or edit the occurrence

[Edit](#) [Delete](#)

[Edit](#) [Delete](#)

Add a new occurrence

Edit Occurrence details

- Click the *Occurrences* item on the navigation menu.
- Click the *Edit* link located to the right of the relevant occurrence listing.
- Click the *Edit* link located to the right of the relevant occurrence details listing.
- Add or change data as required.
- Click the *Update occurrence* button to temporarily save the data. The data will be permanently saved when you save the occurrence form data.

Occurrence details					
Date	Information source	Timing	Stage	Grade	Depth
01/05/2009	Imaging				
02/05/2009	Resection		Soft Tissue - TNM > IV		
04/06/2009	Clinical exam		Soft Tissue - TNM > IV		

View or edit occurrence detail

[Edit](#) [Delete](#)

[Edit](#) [Delete](#)

[Edit](#) [Delete](#)

Add new occurrence detail

Special notes

- If you select 'Metastasis' for the *Occurrence type* field, the *Extent of disease* field will be displayed.
- If you select 'Primary malignancy' for the *Occurrence type* field when 'Primary' has been selected for the *Basis of diagnosis* field (*Diagnosis* form), the *Date of diagnosis* field will be populated by the system.
- If you select 'Benign lesion' for the *Occurrence type* field, the *Date of diagnosis* field will be populated by the system.
- If you select 'Benign lesion', 'Primary malignancy' or 'Local recurrence' for the *Occurrence type* field, you will be able to select from a list of sites of either bone or soft tissue. Whether the list contains sites of bone or soft tissue is determined by the selection for the *WHO classification* field.
- If you select 'Metastasis' for the *Occurrence type* field, you will be able select from sites of the bone, soft tissue and other locations.
- If you select 'No' for the *Treatment planned* field, a list of reasons for why treatment was not planned for that occurrence will be displayed.
- If you select 'Yes' for the *Initial diagnostic biopsy* field, a section will open for recording information about the initial diagnostic biopsy.
 - If you select 'Yes' for the *Earlier non-diagnostic biopsies* field, a list of biopsy types will be displayed.
- Occurrence details
 - The *Procedure/exam date* and *Information source* fields must be completed.
 - If you select 'Resection' for the *Information source* field, the *Resection details* section will be displayed.
 - If you select 'After chemo/RT' for the *Information timing* field, the *Post-treatment necrosis* field will be displayed.
 - If you select 'Yes' for the *Post-treatment necrosis* field, a field will display for recording the percentage of post-treatment necrosis.

A4.6 Treatments

This form captures information regarding the treatments provided to the patient for his diagnosis of bone or soft tissue disease. It may be used to record information regarding treatments delivered at any point in time and by any provider.

Multiple treatments may be recorded. A summary of the patient's treatments will be displayed once data has been saved.

You will have access to this form once an occurrence record has been saved.

The system will only allow occurrences with a 'Yes' value for the *Treatment planned* field (*Occurrences* form) to have treatment data recorded.

Adding data

- Click the *Treatments* item on the navigation menu.
- You will be presented with a list of the occurrences that have been saved.
- Click the checkbox adjacent to each occurrence that is related to this treatment (e.g. if the treatment is a course of chemotherapy that has been given to treat the primary malignancy and a metastasis, click the checkboxes adjacent to the primary malignancy occurrence and the metastasis occurrence).
- Select a value from the *Treatment type* field. A section related to the selected treatment type will be displayed.
- Enter data for as many fields as possible and save the data.

Summary of treatments

Treatment type	Treatment date	Therapy timing	Occurrence type	Occurrence site	Date of diagnosis
Surgical Procedure	04/06/2009	-	Primary malignancy	Bone > Femur, distal	08/05/2006

[Edit](#) [Delete](#)

[Add treatment \(past or present\)](#)

Adding treatment (past or present)

Related occurrence(s)

Occurrence type	Date of diagnosis	Occurrence site	Treated?
☐ Primary malignancy	08/05/2006	Bone > Femur, distal	Yes
☒ Metastasis	05/05/2008	Metastases - Sites not specified above > Lung	Yes

Treatment type

Select the type of treatment

Chemotherapy
Radiotherapy
Surgical Procedure

[Go to Top](#)

Adding surgery details for a surgical procedure

- From an open surgical procedure form, click the radio button next to the appropriate surgery or click the radio button next to 'New surgery.'

Assigning neo-adjuvant and adjuvant therapies to their surgery

- Neoadjuvant or adjuvant treatments must be assigned to a surgery.
- Assignments are made from the summary section of the *Treatment* form.
- Click the *Assign surgery* link that is located on the listing for the relevant treatment. This will open a list of saved surgeries.
- Click the radio button adjacent to the appropriate surgery and then click the *Confirm* button.
- You may undo incorrect assignments by clicking the *Unassign* link that is located on the listing for the relevant treatment.

Treatments														
Treatment type	Treatment date	Therapy timing	Occurrence type	Occurrence site	Date of diagnosis									
Surgical Procedure	04/06/2008	-	Primary malignancy	Bone > Femur, distal	08/05/2006									
Edit Delete														
Chemotherapy	31/07/2008	Adjuvant	Primary malignancy	Bone > Femur, distal	08/05/2006									
Edit Delete														
Assign surgery														
Assign surgery <table border="1"> <thead> <tr> <th>Date</th> <th>Hospital/Campus</th> <th>Lead surgeon</th> </tr> </thead> <tbody> <tr> <td>☒ 04/06/2008</td> <td>MMH</td> <td>Mr. Surgeon</td> </tr> <tr> <td>☐ 03/06/2009</td> <td></td> <td></td> </tr> </tbody> </table> Confirm Cancel						Date	Hospital/Campus	Lead surgeon	☒ 04/06/2008	MMH	Mr. Surgeon	☐ 03/06/2009		
Date	Hospital/Campus	Lead surgeon												
☒ 04/06/2008	MMH	Mr. Surgeon												
☐ 03/06/2009														
Surgical Procedure	03/06/2009	-	Metastasis	Metastases - Sites not specified above > Lung	05/05/2008									
Edit Delete														

Assigning concurrent chemotherapy and radiotherapy treatment relationships

- Chemotherapy or radiotherapy treatments that are given as concurrent therapy must be assigned to each other.
- A treatment may have a concurrent assignment with more than one treatment.
- Assignments are made from the summary section of the *Treatment* form.
- Click the *Assign concurrent therapy* link that is located on the listing for the relevant treatment. This will open a list of saved treatments that have the same *Timing* value (i.e. either neoadjuvant, adjuvant or N/A).
- Click the radio button adjacent to the appropriate treatment and then click the *Confirm* button.
- You may undo incorrect assignments by clicking the *Unassign* link that is located on the listing for the relevant treatment.

Treatments					
Treatment type	Treatment date	Therapy timing	Occurrence type	Occurrence site	Date of diagnosis
Surgical Procedure Edit Delete	04/06/2008	-	Primary malignancy	Bone > Femur, distal	08/05/2006
		Unassign			
Chemotherapy Edit Delete Assign surgery	31/07/2008	Adjuvant	Primary malignancy	Bone > Femur, distal	08/05/2006
		Assign concurrent therapy			
		Unassign			
Assign concurrent therapy Therapy type ☒ Radiotherapy Therapy date 10/07/2008 Timing Adjuvant Confirm Cancel					
Surgical Procedure Edit Delete	03/06/2009	-	Metastasis	Metastases - Sites not specified above > Lung	05/05/2008
Radiotherapy Edit Delete Assign surgery	10/07/2008	Adjuvant	Primary malignancy	Bone > Femur, distal	08/05/2006

Group concurrent Chemotherapy and Radiotherapy

Editing/updating data

- Click the *Treatments* item on the navigation menu.
- Click the *Edit* link located on the relevant treatment listing.
- Add or change data as required.
- Click the *Update treatment* button to save the data.

Special notes

- Chemotherapy
 - o The *Start date*, *Timing* and *Intent* fields must be completed.
 - o If you select 'Neoadjuvant' or 'N/A' for the *Timing* field, the *Best response* field will be displayed.
 - o If you select 'N/A' for the *Timing* field, the *Intent* field will be populated with the value 'Palliative.'
 - o If you select 'Palliative' for the *Intent* field, the *Line* field will be displayed.
 - o The *Line* field must be completed when it is displayed.
 - o You will be able to enter a line number for the first course of palliative intent chemotherapy recorded. The *Line* field will be populated by the system for subsequent palliative course entries.
 - o If you select 'Toxicity' for the *Reason for stopping* field, the *Complications* field will be populated with the value 'Yes.'
 - o If you select 'Death' for the *Reason for stopping* field, fields related to the death of the patient will be displayed. Of these fields, *Death date* must be recorded.
 - o If you select 'Yes' for the *Complications* field, a list of complications will be displayed.
- Radiotherapy
 - o The *Start date*, *Timing* and *Intent* fields must be completed.
 - o If you select 'N/A' for the *Timing* field, the *Intent* field will be populated with the value 'Palliative.'
 - o If you select 'Death' for the *Reason for stopping* field, fields related to the death of the patient will be displayed. Of these fields, *Death date* must be recorded.
- Surgical procedure
 - o The *Procedure* field must be completed.
 - o You must add or select related surgery data before saving (see 5.2.2).
 - o If you select 'No' for the *Margins involved* field, the *Min. clearance (mm)* field will be displayed.
 - o Surgery
 - The *Date* field must be completed.
 - If you select 'Yes' for the *Post-operative complications* field, the *Nerve palsy present*, the *Blood loss present* and the *Other complications* fields will be displayed.
 - If you select 'Yes' for the *Nerve palsy present* field, the *Expected* and *Sites* fields will be displayed.
 - If you select 'Yes' for the *Blood loss present* field, the *Units* field will be displayed.
 - If you select 'Yes' for the *Other complications* field, a list of complications will be displayed.

A4.7 Treatment Groups

This page does not capture information. It provides a summary of the treatments that have been saved. Treatments groups listed within boxes.

Assignments (see 4.6) are represented by the grouping of multiple treatments into a single box. These boxes will have a heading that describes the assignment(s) (see figure below).

Treatment groups		
Treatment type	Date	Therapy timing
Surgery by itself		
Surgical Procedure	03/06/2009	-
Surgery + Chemo + Radio concurrent		
Surgical Procedure	04/06/2008	-
Chemotherapy	31/07/2008	Adjuvant
Radiotherapy	10/07/2008	Adjuvant

A4.8 Reconstructions

This form captures information about the reconstructions and prostheses provided to the patient in relation to surgical procedures.

Multiple reconstruction/prostheses may be recorded. A summary of the patient's reconstructions/prostheses will be displayed once data has been saved.

Adding data

- Click the *Reconstructions* item on the navigation menu.
- Click the *New Reconstruction/Prosthesis* button.
- You will be presented with a list of surgical procedures that have been performed on the patient.
- Click the checkbox adjacent to each surgical procedure that is related to this reconstruction/prosthesis.
- Select the type of reconstruction/prosthesis from the drop-down list and save the data.

Editing/updating data

- Click the *Reconstructions* item on the navigation menu.
- Click the *Edit* link that is located on the top-right-hand corner of the reconstruction/prosthesis box.
- Add or change data as required and save the data.

Special notes

- If you attempt to save a combination of reconstruction/prosthesis and procedure(s) that has already been saved, the system will ask you to confirm whether the entry represents a further reconstruction/prosthesis of the same type for the selected procedure(s).

A4.9 Followup

This form captures information about the patient's disease status at post-treatment follow-up occasions.

Multiple follow-up occasions may be recorded. A summary of the patient's follow-up occasions will be displayed once data has been saved.

Adding data

- Click the *Followup* item on the navigation menu.
- Click the *Add new* button.
- Enter data for as many fields as possible and save the data.

Editing/updating data

- Click the *Followup* item on the navigation menu.
- Click the *Open* link that is located on the right-hand side of the follow-up occasion listing.

- Add or change data as required and save the data.

Special notes

- The *Follow-up date* field must be completed.
- If you select 'Alive – Distant disease,' 'Alive – Local and distant disease' or 'Alive – Local disease' for the *Status* field, you will be prompted to complete an occurrence record(s).
- If you select 'Dead' for the *Status* field, fields related to the death of the patient will be displayed. Of these fields, *Death date* must be recorded. You will not be able to add further follow-up records after saving this record.

A-5 RENAL

A5.1 General Information

Adding data

Click the required page title on the navigation menu eg Initial diagnosis.
Enter data into as many fields as possible.

Editing/updating data

Click the required page title on the navigation menu eg Status at Registration.
Enter or change data as required. Some pages have multiple events, select the *edit* button next to the event to open the page to edit.

Saving data

Click the Save button to save the data or click the *Save and Next* button to save the data and open the next form. Please ensure you save your data or it will be lost.

Incomplete form flags

Incomplete forms are flagged as red by displaying the form name in red coloured font on the navigation menu. At the bottom of each form there is a forms status radio button, which defaults to incomplete. If you have completed all possible fields on the page change the flag to complete; the form name in the navigation bar will change to black. See picture below.

The screenshot shows the ACCORD Database interface. On the left is a navigation menu with a list of forms. The form 'Initial Investigations and Staging' is highlighted in red, indicating it is incomplete. A red arrow points to this form. On the right is the form itself, titled 'Disease recurrence since primary diagnosis and treatment'. The form contains several sections: 'Disease present' with a dropdown for 'Site(s) of disease' (options: Bone, Brain, Kidney, Liver, Lung); 'Staging (clinical)' with dropdowns for 'T stage' (3b), 'N stage' (0), and 'M stage' (1 Distant metastasis); 'Tissue bank consent obtained' with a dropdown for 'Yes' or 'No'; 'Measurements' with input fields for 'Height' (170 cm) and 'Weight' (65 kg); and 'Management plan' with checkboxes for 'Clinical trial', 'Cryotherapy', 'Embolisation', 'Observation', 'Radiofrequency ablation', 'Radiotherapy', 'Surgery', 'Symptomatic / palliative', and 'Systemic therapy'. At the bottom of the form, there is a 'Form status' section with radio buttons for 'Incomplete' and 'Complete', and buttons for 'Save', 'Cancel', and 'Save and next'. A red arrow points to the 'Form status' section.

Date accuracy indicators

Most date fields in the module are accompanied by a *Date accuracy indicator* field. These fields allow the accuracy of entered dates to be recorded.

Values in these fields take a DMY format. The letter D in this format represents the day component of the date, the M represents the month component and the Y represents the year component.

Each component of the value can be filled by the letter A, E or U. The letter A stands for accurate, E stands for estimated and U stands for unknown.

Example:

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Value:	AAE
Meaning:	The day and month are accurate, but the year is estimated.

A list of each value and its meaning can be viewed by clicking the [?](#) link adjacent to the *Date accuracy indicator field*. This will open a pop-up window.

A5.2 Initial diagnosis

This form captures information regarding the patient's diagnosis, cancer history, comorbidities and the clinical features of his/her disease.

- The date of diagnosis that was recorded on the *Episode* form is shown on this form.
- If you select 'Transplant' for the *Further specification* field, the *Organ origin* field will be displayed for recording specifics.
- If you select 'Yes' for the *History of other cancer(s)* field, a list of tumour sites will be displayed for recording specifics.
- If you select 'Yes' for the *Family history of renal cancer (1st degree relatives)* field, fields for recording which family members have had specific types of renal cancer will be displayed.
- If you select 'Yes' for the *History of smoking* field, the *Packet years* and *Is the patient a current smoker* fields will be displayed for recording specifics.
- If you select 'Yes' for the *Other comorbidities* field, a list of comorbidities will be displayed for recording specifics.
- If you select 'Yes' for the *Other illness* field, a list of illnesses will be displayed for recording specifics.
- If you select 'Yes' for the *Autoimmune disorders* field, a list of autoimmune disorders will be displayed for recording specifics.

A5.3 Initial investigations and staging

This form captures information regarding the diagnostic imaging and laboratory tests performed the time of initial diagnosis (if known). The clinical tumour stage is also recorded on this form. This form is designed ensure details of the initial diagnosis is captured, regardless of when the initial diagnosis was discovered ie two years ago vs this week. The *Status at registration* form captures the details of disease at the current point in time.

- If you select 'Yes' for the *Preoperative lab tests* field, fields related to specific laboratory tests will be displayed for recording specifics.
- If you select 'Normal' or 'Abnormal' for the *Corrected serum calcium* field, the *Result* field will be displayed for recording the result.
- If you select '1 Distant metastasis' for the *M stage* field, a list of metastasis sites will be displayed for recording specifics.
- Staging definitions may be viewed by clicking a [?](#) link. Once clicked, a pop-up window will open.

A5.4 Status at registration

This form captures information regarding the patient's disease status, body measurements and consent for tissue banking at the time of hospital registration. The patient's management plan is also recorded on this form.

- The *Assessment date* field must be completed.
- If you select 'No' for the *Disease recurrence since primary diagnosis and treatment* field, the *Staging unchanged since diagnosis* checkbox will be displayed.
- If you tick the *Staging unchanged since diagnosis* checkbox, the system will copy your staging selections from the *Investigations and staging at time of initial diagnosis (if known)* form.

- If you select 'Yes' for the *Disease present* field, a list of disease sites will be displayed for recording specifics.
- Staging definitions may be viewed by clicking a [?](#) link. Once clicked, a pop-up window will open.

A5.5 Surgery and pathology

This form captures information regarding the surgeries the patient underwent for his/her primary renal cancer and the pathological findings of those surgeries.

Multiple surgeries may be recorded. A summary of the patient's surgeries will be displayed once data have been saved.

Adding data

- Click the *New surgery* button and enter data into as many fields as possible.
- Save the data or add a pathology record and then save.
- To add a new Pathology; at the bottom of the surgery form, click the *New pathology* button.
- Enter data into as many fields as possible and click the *Add pathology* button to save the pathology data. The data will be permanently saved when you save the surgery form data.

Editing data

- To edit the surgery data click the *Edit* link on the right located on the relevant surgery listing.
- To edit pathology, open relevant surgery and click the *Edit* link located on the right of the pathology listing.
- Enter or change data as required.
- Click the *Update pathology* button to temporarily save the data. The data will be permanently saved when you click the *Update surgery* button.

Surgery section

- The *Laterality* and *Date of surgery* fields must be completed.
- If you select 'Partial' from the *Method* field (*Actual surgery* section), the *Partial nephrectomy details* section will be displayed. This section will allow you to record details of the partial nephrectomy.
- If you select 'Yes' for the *IVC explored* field, the *Tumour involvement* field will be displayed.
- If you select 'Yes' for the *Tumour involvement* field, a list of involvement levels will be displayed for recording specifics.

Pathology section

- The *Laterality* field must be completed.
- If you select 'No' for the *Limited to kidney* field, a list of other involved sites will be displayed for recording specifics.
- If you select 'Yes' for the *Molecular markers done* field, the *Primary and secondary RCC and Types* field will be displayed for recording specifics.
- If you select 'Multiple for chromophobe Ca.' from the *Types* list, the *Karyotype result for Multiple for chromophobe Ca.* field will be displayed.
- If you select '1 Distant metastasis' for the *M stage* field, a list of metastasis sites will be displayed for recording specifics.
- Auto-population of the T-stage field occurs if all fields in the Involvement and Further Details sections are completed. If these are not completed the stage can be manually selected
- Staging definitions may be viewed by clicking a [?](#) link. Once clicked, a pop-up window will open.

A5.6 Surgery outcomes

This form captures information regarding the outcomes and complications related to the patient's surgery for primary renal cancer.

Each surgery has a separate outcomes record. A summary of records will be displayed once surgery data have been saved.

Adding/editing outcome data

The *Surgery Outcomes* item will only appear in the navigation tree after a surgery has been recorded (see 5.5).

- If surgeries have been entered a list of the surgeries will be available to select from.
- Click the *Add outcome* to add new data or the *Edit outcome* link to edit exiting data, on the right for the relevant surgery listing.
- The *Date of admission* field must be completed.
- If you select 'Yes' for the *General complications* field, a list of complications will be displayed for recording specifics.
- If you select 'Haemorrhage' from the list of general complications, the *Haemorrhage transfused* field will be displayed.
- If you select 'Yes' for the *Other intraoperative complications* field, a list of complications will be displayed for recording specifics.
- If you select 'Yes' for the *Urinary system complications* field, a list of complications will be displayed for recording specifics.
- If you select 'Acute renal impairment' from the list of urinary system complications, the *ARI requiring dialysis* field will be displayed.
- If you select 'Yes' for the *Gastrointestinal complications* field, a list of complications will be displayed for recording specifics.
- If you select 'Yes' for the *Respiratory complications* field, a list of complications will be displayed for recording specifics.
- If you select 'Yes' for the *Cardiovascular complications* field, a list of complications will be displayed for recording specifics.
- If you select 'Arterial embolus' from the list of cardiovascular complications, the *Arterial embolus site* field will be displayed.
- If you select 'Yes' for the *In-patient death* field, the *Date of death* and *Cause of death* fields will be displayed for recording specifics.
- The *Date of death* field must be completed if displayed.
- If you select 'Due to cancer' for the *Cause of death* field, the *Death due to* field will be displayed for recording the specific cancer.
- The *Death due to* field must be completed if displayed.
- If you select 'Other cause, cancer present' for the *Cause of death* field, the *Cancer present* field will be displayed for recording the specific cancer(s).

A5.7 Other treatment primary

Systemic therapy section

This form captures information regarding systemic therapies provided to the patient for the management of the primary renal cancer.

- Multiple systemic therapies may be recorded. A summary of the patient's systemic therapies for primary renal cancer will be displayed once data have been saved.
- To add a new systemic therapy, click the *New Systemic Therapy* button, a form will appear for you to complete.
- To edit an existing treatment click the *edit* link for the relevant treatment.
- A new systemic therapy can not be entered if there is an ongoing treatment in progress ie a stop date must be entered before a new treatment can be added.
- The *Intent* and *Timing* fields must be completed.
- If you select 'Palliative' for the *Intent* field, the *Line* field will be displayed.

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- The *Line* field must be completed if displayed.
- You are able to enter a line for the first palliative record. The system will automatically populate the *Line* field for subsequent palliative records.
- If you select 'Single' for the *Therapy* field, a list of systemic therapy agents will be displayed. You will be able to select one agent from this list.
- If you select 'Combined' for the *Therapy* field, a list of systemic therapy agents will be displayed. You will be able to select multiple agents from the list.
- If you select 'Yes' for the *Is part of clinical trial* field, a list of clinical trials entered on the *Clinical Trial* form will be displayed for recording the specific trial.

Radiotherapy section

This form captures information regarding radiotherapy treatments provided to the patient for the management of his/her primary renal cancer.

- Multiple radiotherapy treatments may be recorded. A summary of the patient's radiotherapy treatments for primary renal cancer will be displayed once data have been saved.
- To add a new radiotherapy, click the *New Radiotherapy* button, a form will appear for you to complete.
- To edit an existing treatment click the *edit* link for the relevant treatment.
- The *Start date*, *Intent* and *Timing* fields must be completed.
- If you select 'Yes' for the *Is part of clinical trial* field, a list of clinical trials entered on the *Clinical Trial* form will be displayed for recording the specific trial.

A5.8 Clinical trial

This form captures information regarding the clinical trials in which the patient participated.

- To add a clinical trial for the patient, click the *New clinical trial* button.
- The *Start date* field must be completed.

A5.9 Recurrence / progression

This form captures information regarding the nature and treatment of the patient's recurrent or progressive disease.

Multiple occurrences of recurrent or progressive disease may be recorded. A summary of the patient's disease recurrences or progressions will be displayed once data have been saved.

- Add a new recurrence by selecting the *New disease recurrence / progression* button, to edit a recurrence select the *edit* link next to the appropriate recurrence.
- There are three forms which will appear if you select (tick box) the treatment as a part of the management plan:
 - o Systemic therapy - captures information regarding the systemic therapies provided to the patient for the management of his/her recurrent or progressive disease. See A5.7 for details on this section.
 - o Radiotherapy sub-form - captures information regarding the radiotherapy treatments provided to the patient for the management of his/her recurrent or progressive disease. See A5.7 for details on this section.
 - o Surgery sub-form - captures information regarding the surgical interventions the patient underwent for the management of his/her recurrent or progressive disease.

A5.10 Follow-up

This form captures information regarding the patient's disease status and recent therapeutic interventions at the time of a follow-up encounter.

- Click the *New follow-up* button to add a new follow up visit.
- To edit a follow-up visit click the *Edit* link that is located on the relevant visit.
- The *Follow-up date* field must be completed.
- If you select 'Yes' for the *Therapeutic interventions since last visit* field, additional fields will be displayed for recording the specific treatments which have been given.
- If you select 'Yes' for *Radiotherapy*, the *Ongoing* field will be displayed.
- If you select 'Yes' for *Systemic therapy*, the *Ongoing* field will be displayed.
- If you select 'Yes' for *Clinical trial*, the *Ongoing* field will be displayed.
- If you select 'Deceased' for the *Uro-oncology clinic discharge status*, additional fields will be displayed for recording the specifics of the patient's death.
- The *Death date* field must be completed if displayed.
- If you select 'Due to cancer' for the *Cause of death* field, the *Death due to* field will be displayed for recording the specific cancer.
- The *Death due to* field must be completed if displayed.
- If you select 'Other cause, cancer present' for the *Cause of death* field, the *Cancer present* field will be displayed for recording the specific cancer(s).
- Pop up boxes will indicate if further data is required to be entered on other forms.

A-6 PROSTATE

A6.1 General Information

This section of the ACCORD user manual should be read in conjunction with the main body of the manual, particularly the Data Entry section.

Adding/Editing data

Click the required page title on the navigation menu eg Initial diagnosis.

Enter data into as many fields as possible.

Click the *Save* to save the data and remain on the same screen or *Save and Next* button to save the data and go to the next screen.

To edit/update the data make the required changes and save the data as described above.

Complete Form Flags

The module flags incomplete forms by displaying the form name in red coloured font on the navigation menu. Flags remain red until the user indicates the 'form status', at the bottom of each page, is 'complete'.

A6.2 Presentation

This form captures presentation visit information regarding the patient's symptoms, prior diagnostic and therapeutic procedures, social history, family history of cancer, clinical examination, and diagnostic histology. The patient's management plan is also recorded.

- The *PSA date* field must be completed.
- You may manually enter a value into the *SHIM* field or use the module's inbuilt calculator. To open the calculator, click the *Calculate* link located next to the field. This will open a pop-up window. Record a response to each of the questions and then click the *Done* button. The pop-window will close and a value will be recorded in the *SHIM* field.
- You may manually enter a value into the *IPSS* field or use the module's inbuilt calculator. To open the calculator, click the *Calculate* link located next to the field. This will open a pop-up window. Record a response to each of the questions and then click the *Done* button. The pop-window will close and a value will be recorded in the *IPSS* field.
- If you select 'Yes' for the *Prior histology performed* field, a section will be displayed for recording specifics.
- The third *Gleason* field records the Gleason score. The value for this field is automatically calculated from the recorded Gleason grades.
- If you select 'Yes' for the *Prior prostate procedure(s) performed* field, a list of procedures will be displayed for recording specifics.
- If you select 'Yes' for the *History of prior pelvic radiotherapy* field, a list of pelvic sites will be displayed for recording specifics.
- If you select 'Current' or 'Past' for the *Cigarettes* field, the *Packet years* field will be displayed for recording specifics.
- If you select 'Yes' for the *Prostate cancer* field, fields will be displayed for recording the number of relatives diagnosed with prostate cancer.
- If you select 'Yes' for the *Family history of breast or ovarian cancer* field, fields will be displayed for recording the number of relatives diagnosed with these cancers.
- If you select 'Yes' for the *Other cancer(s)-Primary relatives only* field, a list of cancer sites will be displayed for recording specifics.
- If you select 'Yes' for any of the *Performed* fields, the associated *Distant disease* field will be displayed for recording the investigation's result.
- If you select 'Cassettes' or 'Cores' from the *Pathology report describes* field, fields will be displayed for recording the number of cassettes or cores taken and positive.
- The third of the *Gleason (highest)* fields records the Gleason score. The value for this field is automatically calculated from the recorded Gleason grades.

- If you select 'Yes' for the *Initial intervention(s) planned?* field, a section will be displayed for recording specifics.
- If you select 'Yes' for the *Surgery* field, fields will be displayed for recording the planned surgery date and whether the patient is a potential tissue bank donor.
- You may obtain the value definitions for a staging field by clicking the [?](#) link adjacent to the field. This will open a pop-up window which describes the definitions.

A6.3 Medication summary

This form captures information regarding the medications the patient is taking at the time of his presentation visit.

The form has two sections. The first section records a summary of the patient's medications and the 'detail medications' section captures more detailed information about each medication including the dose, frequency and duration. Entering data into the detailed information section is optional.

- Select the drug classes of the medication the patient is taking.
 - If you tick the *Lipid lowering agent*, *Anti-coagulation* or *Analgesia* checkboxes, additional checkboxes will be displayed for recording the specific details.
- If entering the details of drugs click the *New medication* button
- Enter data into as many fields as possible.
 - The *Name* field must be completed.
 - The *Frequency* and *Dose* items are both composed of a number and a unit field. If these items are used, both fields belonging to the item must be completed
- Click the *Add medication* button to temporarily save the data.
- Press the *Save* button at the bottom of the screen to save all data.
- To edit the details of a saved drug, click the *edit* link to the right of the drug entry.

A6.4 Surgery, outcomes and pathology

This form captures information regarding the patient's surgery for primary prostate cancer, the outcomes of his surgery and the pathologist's findings.

Multiple surgeries may be recorded. A summary of the patient's surgeries for primary prostate cancer will be displayed once data have been saved.

- The *Date* field must be completed.
- If you select 'Yes' for the *Nerve sparing* field, additional fields will be displayed for recording specifics.
- If you select 'Yes' for the *Transfused* field, a field will be displayed for recording the number of units transfused.
- If you select 'Yes' for the *In-dwelling catheter* field, additional fields will be displayed for recording specifics.
- You may view value definitions for the *Clavien grade* field by clicking the [?](#) link located next to the field. This will open a pop-up window which describes the definitions.
- If you select 'Yes' for the *Surgical complications* field, a section will be displayed for recording specifics.
- Surgical complications section
 - If you select 'Yes' for the *Urine leak* field, the *Persisted for* field will be displayed for recording specifics.
 - If you select 'Yes' for the *Wound infection* field, the *Persisted for* field will be displayed for recording specifics.

- o If you select 'Yes' for the *Bowel complication* field, a list of complications will be displayed for recording the specific complication.
- o If you select 'Yes' for the *Other* field, a list of complications will be displayed for recording the specific complication(s).
- If you select 'Yes' for the *Medical complications* field, a list of complications will be displayed for recording the specific complication(s).
- If you select 'Other' from the list of medical complications, a list of complications will be displayed for recording the specific complication(s).
- If you select 'Yes' for the *Return to theatre* field, additional fields will be displayed for recording specifics, you must complete the *Date* field in the *Return to theatre* section.
- If you select 'Yes' for the *In-patient death* field, fields related to the patient's death will be displayed for record specifics, you must complete the *Death date* field.
- If you select 'Due to cancer' for the *Cause of death* field, the *Death due to* field will be displayed for recording the specific cancer, the *Death due to* field must be completed.
- If you select 'Other cause, cancer present' for the *Cause of death* field, the *Cancer present* field will be displayed for recording the specific cancer(s).
- If you record a non-zero number in the *Number positive* field, a list of lymph node sites will be displayed for recording specifics.
- If you select 'Negative' for the *Margins* field, the *Minimum distance clear* field will be displayed for recording specifics.
- If you select 'Positive' for the *Margins* field, additional fields will be displayed for recording the regions involved by cancer.
- If you select 'Yes' for the *Tissue banking sample(s)* field, a list of sample types will be displayed for recording specifics.

A6.5 Radiotherapy and endocrine therapy

This form captures information about the radiotherapy and castration treatments for the treatment of his primary prostate cancer.

All data in the *Radiotherapy and Endocrine therapy* section will be permanently saved when you click the Save button at the bottom of the main form.

Radiotherapy

If the patient has undergone radiotherapy, select 'Yes' in the *Radiotherapy to Prostate* field. You can then add treatments for EBRT or Brachytherapy.

EBRT

This section captures information regarding the external beam radiotherapy treatments given to the patient for the treatment of his primary prostate cancer. Select the *New EBRT* button to add a treatment.

Multiple EBRT treatments may be recorded. A summary of the patient's EBRT treatments for his primary prostate cancer will be displayed once data have been saved.

Brachytherapy

This section captures information regarding the brachytherapy treatments for primary prostate cancer. Select the *New Brachytherapy* button to add a treatment.

Multiple brachytherapy treatments may be recorded. A summary of the patient's brachytherapy treatments for his primary prostate cancer will be displayed once data have been saved.

- The *Date of implant* field must be completed.
- If you select 'HDR' for the *Dose rate* field, the *Isotope* and *Fractions* fields will be displayed for recording specifics.
- If you select 'LDR' for the *Dose rate* field, the *Isotope* field will be displayed for recording specifics.

- To select multiple Adverse effects, hold down the Ctrl key and select all that apply.

Androgen Deprivation (AD)

This section captures information regarding the medical and surgical castration treatments of primary prostate cancer.

Indicate if the patient has received AD by selecting the appropriate radio button. If *AD Provided* is Yes, then you have the options of selecting if the patient had Surgical or Medical Castration.

If *Medical Castration* is Yes, then select the *New Medical Castration Treatment* button to add a treatment, multiple treatment may be recorded. The *start date* is compulsory and is used to differentiate between treatments. A summary of the patient's medical castration treatments for his primary prostate cancer will be displayed once data have been saved.

- If you select 'Yes' for the *Adverse Event on Rx* field, a list of adverse events will be displayed for recording specifics.
- If you select 'No' for the *Completed therapy* field, the *Not completed due to adverse effects* field will be displayed for recording specifics

A6.6 Routine follow-up post initial management

This section captures follow-up visit information regarding the patient's disease status, genitourinary system functionality and treatments.

Multiple follow-up visits may be recorded. A summary of the patient's follow-up visits will be displayed once data have been saved.

Click the *New followup* button.

- The *Visit date* field must be completed.
- You may manually enter a value into the *IPSS* field or use the module's inbuilt calculator. To open the calculator, click the *Calculate* link located next to the field. This will open a pop-up window. Record a response to each of the questions and then click the *Done* button. The pop-window will close and a value will be recorded in the *IPSS* field.
- If you select 'Yes' for the *Continence pad worn* field, a field will be displayed for recording the number of pads the patient wears per day.
- You may manually enter a value into the *SHIM without erectile aid* field or use the module's inbuilt calculator. To open the calculator, click the *Calculate* link located next to the field. This will open a pop-up window. Record a response to each of the questions and then click the *Done* button. The pop-window will close and a value will be recorded in the *SHIM without erectile aid* field.
- If you select 'Yes' for the *Erectile aid used* field, the *SHIM with erectile aid* and *Aid* fields will be displayed for recording specifics.
- You may manually enter a value into the *SHIM with erectile aid* field or use the module's inbuilt calculator. To open the calculator, click the *Calculate* link located next to the field. This will open a pop-up window. Record a response to each of the questions and then click the *Done* button. The pop-window will close and a value will be recorded in the *SHIM with erectile aid* field.

A6.7 Recurrent or metastatic non castrate resistant disease

This section captures information regarding the diagnosis, sites and treatment of the patient's recurrent or metastatic non-castrate resistant disease.

Multiple instances of recurrent or metastatic non-castrate resistant disease may be recorded. A summary of these instances will be displayed once data have been saved. When new data is entered or an episode of recurrence or metastatic non castrate resistance disease is updated, ensure you save (or update if editing) the data with the button at the bottom of the screen. The screen will close and summary displayed once saved.

Detailed screens to enter specific treatment data will appear once selected in the 'treatments offered' section.

- To edit existing records, click 'Edit' link at the right of the instance of recurrent or metastatic non-castrate resistant disease required.
- The *Date of Dx of recurrence* field must be completed.
- If you select 'Yes' for the *Loco-regional disease* field, a list of sites will be displayed for recording specifics.
- If you select 'Yes' for the *Distant metastases* field, a list of sites will be displayed for recording specifics.
- If you select 'No' for the *Androgen ablation offered* field, a list of reasons will be displayed for recording the reason.
- If you select 'Yes' for *Androgen ablation offered*, the *Patient accepted* field will be displayed for recording whether or not the patient accepted the treatment offer.
- If you select 'Yes' for the *Patient accepted* field, additional fields will be displayed for recording the types of treatment given and the reason for the treatment(s).
- If you select 'Yes' for the *Medical castration* field, a button for adding records to the hormone therapy sub-form will be displayed.
- If you tick the *Bisphosphonates* checkbox, a button for adding records to the bisphosphonate therapy sub-form will be displayed.
- If you tick the *Radiotherapy to mets* checkbox, a button for adding records to the radiotherapy sub-form will be displayed.
- If you tick the *Isotope therapy* checkbox, a button for adding records to the isotope therapy sub-form will be displayed.
- If you tick the *Surgery for mets* checkbox, a button for adding records to the surgical resection of metastases sub-form will be displayed.

Hormone therapy

This section captures information regarding the hormone therapy treatments given to the patient for the treatment of his recurrent or metastatic non-castrate resistant disease.

Multiple hormone therapy treatments may be recorded. A summary of the patient's hormone therapy treatments for his recurrent or metastatic non-castrate resistant disease will be displayed once data have been saved.

Prerequisite: 'Yes' must be selected for the *Androgen ablation offered*, *Patient accepted* and *Medical castration* fields under 'Initial treatment plan at Dx of recurrent/metastatic disease' heading.

Click the *New hormone therapy* button and enter data into as many fields as possible.

Click the *Add hormone therapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

- The *Line* field is automatically completed by the system.
- The *Start date* field must be completed.
- If you select 'Death' for the *Reason for stopping* field, additional fields will be displayed for recording specifics about the patient's death.
- If displayed, the *Death date* field must be completed.
- If you select 'Due to cancer' for the *Cause of death* field, the *Death due to* field will be displayed for recording the specific cancer. The *Death due to* field must be completed.

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- If you select 'Other cause, cancer present' for the *Cause of death* field, the *Cancer present* field will be displayed for recording the specific cancer(s).
- To edit existing entries, select the 'Edit' link to the right of the hormone therapy summary.

Bisphosphonate therapy

This sub-form captures information regarding the bisphosphonate therapy treatments given to the patient for the treatment of his recurrent or metastatic non-castrate resistant disease.

Prerequisite: The *Bisphosphonates* checkbox in the 'treatment offered' section must be ticked for the sub-form to be displayed.

From the main form, click the *New bisphosphonate therapy* button and enter data into as many fields as possible.

Click the *Add bisphosphonate therapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

- The *Start date* field must be completed.
- If you select 'Death' for the *Reason for stopping* field, additional fields will be displayed for recording specifics about the patient's death.
- If displayed, the *Death date* field must be completed.
- If you select 'Due to cancer' for the *Cause of death* field, the *Death due to* field will be displayed for recording the specific cancer. The *Death due to* field must be completed.
- If you select 'Other cause, cancer present' for the *Cause of death* field, the *Cancer present* field will be displayed for recording the specific cancer(s).

Radiotherapy

This sub-form captures information regarding the radiotherapy treatments provided to the patient for the management of his recurrent or metastatic non-castrate resistant disease.

Multiple radiotherapy treatments may be recorded. A summary of the patient's radiotherapy treatments for his recurrent or metastatic non-castrate resistant disease will be displayed once data have been saved.

Prerequisite: The *Radiotherapy to mets* checkbox on the main form must be ticked for the sub-form to be displayed.

From the main form, click the *New radiotherapy* button and enter data into as many fields as possible. The *Start date* field must be completed

Click the *Add radiotherapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

Isotope therapy

This sub-form captures information regarding the isotope therapy treatments provided to the patient for the management of his recurrent or metastatic non-castrate resistant disease.

Multiple isotope therapy treatments may be recorded. A summary of the patient's isotope therapy treatments for his recurrent or metastatic non-castrate resistant disease will be displayed once data have been saved.

Prerequisite: The *Isotope therapy* checkbox on the main form must be ticked for the sub-form to be displayed.

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From the main form, click the *New isotope therapy* button and enter data into as many fields as possible. The *Start date* field must be completed.

Click the *Add isotope therapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

Surgical resection of metastases

This sub-form captures information regarding the surgical resections of metastatic non-castrate resistant disease underwent by the patient.

Multiple surgical resections may be recorded. A summary of the patient's surgical resections for his metastatic non-castrate resistant disease will be displayed once data have been saved.

Prerequisite: The *Surgery for mets* checkbox on the main form must be ticked for the sub-form to be displayed.

From the main form, click the *New surgical resection of metastases* button and enter data into as many fields as possible. The *Date* field must be completed

Click the *Add resection* button to temporarily save the data. The data will be permanently saved when you save the main form data.

A6.8 Treatment of metastatic or recurrent disease chemotherapy

This section captures information regarding the diagnosis, sites and treatment of the patient's recurrent or metastatic castrate resistant disease.

Multiple instances of recurrent or metastatic castrate resistant may be recorded. A summary of these instances will be displayed once data have been saved.

- The *Date of castrate resistant disease* field must be completed.
- If you select 'Yes' for the *Loco-regional disease* field, a list of sites will be displayed for recording specifics.
- If you select 'Yes' for the *Distant metastases* field, a list of sites will be displayed for recording specifics.
- If you select 'No' for the *Chemotherapy offered* field, a list of reasons will be displayed for recording the reason.
- If you select 'Yes' for the *Chemotherapy offered* field, the *Patient accepted* field will be displayed for recording whether or not the patient accepted the treatment offer.
- If you select 'Yes' for the *Patient accepted* field, the *Primary reason for commencing chemotherapy* field and a button for adding records to the chemotherapy sub-form will be displayed.
- If you tick the *Bisphosphonates* checkbox, a button for adding records to the bisphosphonate therapy sub-form will be displayed.
- If you tick the *Radiotherapy to mets* checkbox, a button for adding records to the radiotherapy sub-form will be displayed.
- If you tick the *Isotope therapy* checkbox, a button for adding records to the isotope therapy sub-form will be displayed.
- If you tick the *Surgery for mets* checkbox, a button for adding records to the surgical resection of metastases sub-form will be displayed.

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Chemotherapy

This sub-form captures information regarding the chemotherapy treatments given to the patient for the treatment of his recurrent or metastatic castrate resistant disease.

Multiple chemotherapy treatments may be recorded. A summary of the patient's chemotherapy treatments for his recurrent or metastatic castrate resistant disease will be displayed once data have been saved.

Prerequisite: 'Yes' must be selected for the *Chemotherapy offered* and *Patient accepted* fields on the main form.

From the main form, click the *New chemotherapy* button.

Enter data into as many fields as possible.

Click the *Add chemotherapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

To Edit data, click the *Edit* link located on the relevant disease listing. Click the *Edit* link located on the relevant chemotherapy listing, enter or change data as required.

Click the *Update chemotherapy* button to temporarily save the data. Click the *Update treatment of metastatic or recurrent disease chemotherapy* button to permanently save the data.

- The *Line* field is automatically completed by the system.
- The *Date* field must be completed.
- If you make a selection from the *Regimen* field, the *Subsequent dose reduction* section will be displayed for recording which (if any) agents were dose reduced during treatment.
- The agents you select from the *Regimen* field will be displayed in the *Subsequent dose reduction* section.
- If you tick an agent checkbox in the *Subsequent dose reduction* section, the associated *Reason for reduction* field will be displayed for recording the reason for the dose reduction.
- If you select 'Death' from the *Reason for stopping* field, additional fields will be displayed for recording specifics about the patient's death.
- If displayed, the *Death date* field must be completed.
- If you select 'Due to cancer' for the *Cause of death* field, the *Death due to* field will be displayed for recording the specific cancer. The *Death due to* field must be completed.
- If you select 'Other cause, cancer present' for the *Cause of death* field, the *Cancer present* field will be displayed for recording the specific cancer(s).

Bisphosphonate therapy

This sub-form captures information regarding the bisphosphonate therapy treatments given to the patient for the treatment of his recurrent or metastatic castrate resistant disease.

Prerequisite: The *Bisphosphonates* checkbox on the main form must be ticked for the sub-form to be displayed.

From the main form, click the *New bisphosphonate therapy* button.

Enter data into as many fields as possible.

Click the *Add bisphosphonate therapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

- The *Start date* field must be completed.
- If you select 'Death' from the *Reason for stopping* field, additional fields will be displayed for recording specifics about the patient's death.
- If displayed, the *Death date* field must be completed.
- If you select 'Due to cancer' for the *Cause of death* field, the *Death due to* field will be displayed for recording the specific cancer. The *Death due to* field must be completed.
- If you select 'Other cause, cancer present' for the *Cause of death* field, the *Cancer present* field will be displayed for recording the specific cancer(s).

Radiotherapy

This sub-form captures information regarding the radiotherapy treatments provided to the patient for the management of his recurrent or metastatic castrate resistant disease.

Multiple radiotherapy treatments may be recorded. A summary of the patient's radiotherapy treatments for his recurrent or metastatic castrate resistant disease will be displayed once data have been saved.

Prerequisite: The *Radiotherapy to mets* checkbox on the main form must be ticked for the sub-form to be displayed.

From the main form, click the *New radiotherapy* button.

Enter data into as many fields as possible. The *Start date* field must be completed.

Click the *Add radiotherapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

Isotope therapy

This sub-form captures information regarding the isotope therapy treatments provided to the patient for the management of his recurrent or metastatic castrate resistant disease.

Multiple isotope therapy treatments may be recorded. A summary of the patient's isotope therapy treatments for his recurrent or metastatic castrate resistant disease will be displayed once data have been saved.

Prerequisite: The *Isotope therapy* checkbox on the main form must be ticked for the sub-form to be displayed.

From the main form, click the *New isotope therapy* button.

Enter data into as many fields as possible. The *Start date* field must be completed.

Click the *Add isotope therapy* button to temporarily save the data. The data will be permanently saved when you save the main form data.

Surgical resection of metastases

This sub-form captures information regarding the surgical resections of metastatic castrate resistant disease underwent by the patient.

Multiple surgical resections may be recorded. A summary of the patient's surgical resections for metastatic castrate resistant disease will be displayed once data have been saved.

Prerequisite: The *Surgery for mets* checkbox on the main form must be ticked for the sub-form to be displayed.

From the main form, click the *New surgical resection of metastases* button.

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Enter data into as many fields as possible. The *Date* field must be completed

Click the *Add resection* button to temporarily save the data. The data will be permanently saved when you save the main form data

A-7 CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL)

A7.1 General Information

This section of the ACCORD user manual should be read in conjunction with the main body of the manual, particularly the Data Entry section.

Adding/Editing data

Click the required page title on the navigation menu eg Clinical.

Enter data into as many fields as possible.

Click the *Save* to save the data and remain on the same screen or *Save and Next* button to save the data and go to the next screen.

To edit/update the data make the required changes and save the data as described above.

Complete Form Flags

The module flags incomplete forms by displaying the form name in red coloured font on the navigation menu. Flags remain red until the user indicates the 'form status', at the bottom of each page, is 'complete'.

A7.2 Registration: Clinical

This form captures the patient's registration information. Fields cover personal and family medical history, comorbidities, symptoms, previous treatments, and lymphatic measurements. Blood parameter, symptom and staging information related to the patient's original presentation is also recorded. The original presentation may or may not be the patients first visit to a specialist.

- The *Registration date* field must be completed.
- If you select 'Yes' for the *History of benign blood disease* field, additional fields will be displayed for recording specifics.
- If you select 'Yes' for the *Other (History of benign blood disease)* field, a free-text field will be displayed for recording the specific condition.
- If you select 'Yes' for the *Family history of blood cancer* field, a list of blood cancers will be displayed for recording specifics.
- If you select 'Yes' for the *Other cancers* field, the *New other cancer* button will be displayed.
- To add details of a prior cancer diagnosis:
 - o Click the *New other cancer* button.
 - o Enter data into as many fields as possible.
 - o Click the *Add cancer* button.
 - o Additional prior cancer diagnoses may be recorded by repeating the above steps.
- If you select 'Current' or 'Past' for the *History of smoking* field, the *Packet years* field will be displayed for recording further details.
- If you select 'Yes' for the *History of alcohol use* field, the *Drinks per week* field will be displayed for recording further details.
- Cumulative Illness Rating Scale (CIRS) section:
 - o A pop-up window, which lists definitions for the body system ratings, may be viewed by clicking the ? link.
 - o The *Total* field is automatically calculated by system.
 - o The database treats blank body system rating fields as missing data.
 - o If you click the Set all blank fields to 0 link, the system will enter 0 into each blank body system rating field.
- If you select 'Yes' for the *Symptoms (Original presentation)* field, additional fields will be displayed for recording specifics.
- A pop-up window, which lists value definitions for the *ECOG* field (Registration visit section), may be viewed by clicking the ? link.

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- If you select 'Yes' for the *Symptoms* (Registration visit) field, a list of symptoms will be displayed for recording specifics.
- If you select 'Yes' for the *Previous transfusions* field, the *Units* field will be displayed for recording specifics.
- If you select 'Yes' for the *Major infections in past 12 months* field, additional fields will be displayed for recording specifics.
- If you select 'Yes' for the *Other(s)* (Major infections in past 12 months) field, a free-text field will be displayed for recording the specific infection(s).

A7.3 Registration: Investigations

This form captures information about the investigations which the patient underwent at registration. Fields cover blood tests, biopsies and imaging. The final conclusions about the patient's diagnosis are also recorded.

- If you select 'Abnormal' for the *SPEP* field, additional fields will be displayed for recording specifics.
- If you select 'BM' or 'PB' for a *Sample* (Prognostic markers) field, additional fields will be displayed for recording additional details about the specific marker.
- If you select 'Yes' for the *Bone marrow biopsy performed* field, the *New bone marrow biopsy* button will be displayed.
- To add details of a bone marrow biopsy:
 - o Click the *New bone marrow biopsy* button.
 - o Enter data into as many fields as possible.
 - o Click the *Add bone marrow biopsy* button.
 - o Additional bone marrow biopsies may be recorded by repeating the above steps.
- If you select 'Yes' for the *Other biopsy performed* field, the *New other biopsy* button will be displayed.
- To add details of an other (i.e. non-bone marrow) biopsy:
 - o Click the *New other biopsy* button.
 - o Enter data into as many fields as possible.
 - o Click the *Add other biopsy* button.
 - o Additional other biopsies may be recorded by repeating the above steps.
- If you select 'Yes' for a *Performed* (Imaging) field, additional fields will be displayed for recording details about the specific imaging procedure.
- If you select 'Yes' for the *Autoimmune complications* field, a field will be displayed for recording the specific complication.
- If you select 'Yes' for the *Other complications* field, a free-text field will be displayed for recording the specific complication.

A7.4 Past treatment

This form maintains a summary of treatments which the patient has previously undergone for the management of his or her chronic lymphocytic leukaemia.

In the past treatment summary section select if the patient has had chemotherapy, radiotherapy and splenectomy as a part of their treatment before being seen at this institution.

If you select 'Yes' for any of the past treatments a button will appear so you can add the details of past treatment(s). The details of each section are below. To edit existing past treatments click *Edit* on the right of the record you wish to edit.

Chemotherapy

This sub-form captures information about the prior chemotherapy treatments which had been given to the patient for the management of chronic lymphocytic leukaemia.

Multiple prior chemotherapy treatments may be recorded. A summary of the patient's prior chemotherapy treatments will be displayed once data have been saved.

Prerequisite: 'Yes' must be selected for the *Chemotherapy* field in the 'treatment summary' section.

Click the *New chemotherapy* button.

- The *Start date* field must be completed.
- More than one chemotherapy agent may be selected by holding down the *Ctrl* keyboard key while clicking the agent values.
- If you select 'Yes' for the *Infection* field, additional fields will be displayed for recording specifics.
- If you select 'Yes' for the *Autoimmune complication* field, an additional field will be displayed for recording the specific complication.
- If you select 'Yes' for the *Response* field, additional fields will be displayed for recording specifics.

Splenectomy

This sub-form captures information about the patient's prior splenectomy.

Prerequisite: 'Yes' must be selected for the *Splenectomy* field on the main form.

Click the *New splenectomy* button to add details. The *Date* field must be completed.

Radiotherapy

This sub-form captures information about the prior radiotherapy treatments which had been given to the patient for the management of chronic lymphocytic leukaemia.

Multiple prior radiotherapy treatments may be recorded. A summary of the patient's prior radiotherapy treatments will be displayed once data have been saved.

Prerequisite: 'Yes' must be selected for the *Radiotherapy* field on the main form.

Click the *New radiotherapy* button to add details. The *Start date* field must be completed.

A7.5 Treatment / Follow-up

This form captures information about the patient's hospital visits for treatment or follow-up visits. General health measures, blood test results, lymphatic measurements, treatment details, complications and disease response data are collected by the form.

Follow-up visits, Splenectomy, first course of a chemotherapy or radiotherapy regimen

Click the *New Followup / Treatment* button

Enter data into as many fields as possible and save the data.

Subsequent courses of a chemotherapy or radiotherapy regimen

Click the *Continue therapy* link located to the right next to the relevant regimen listing, DO NOT ADD A NEW FOLLOW UP/TREATMENT.

Enter data into as many fields as possible and save the data.

Recording post-treatment data (end treatment) for a chemotherapy or radiotherapy regimen

Click the *End therapy* link located to the right of the relevant regimen listing.

Enter the response data at the end of treatment.

Click the *Update* button.

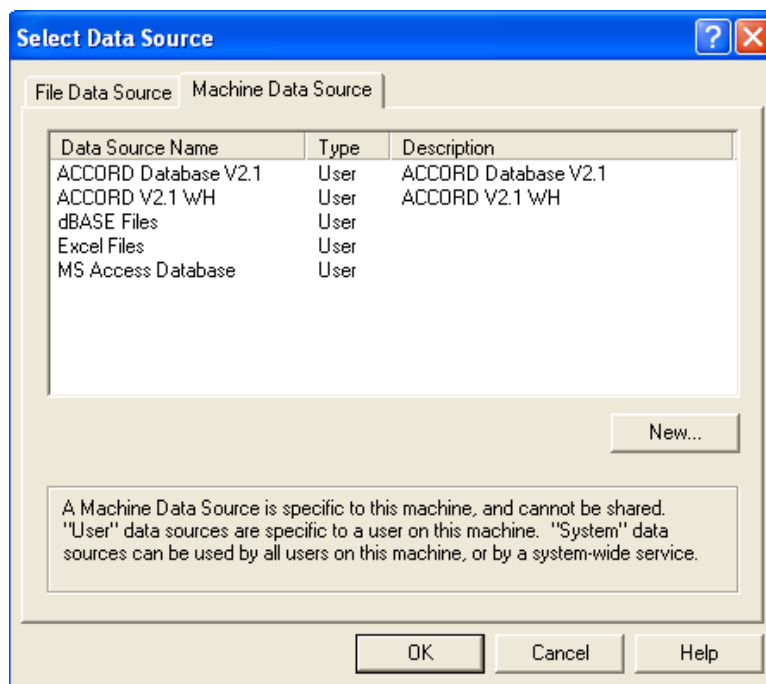
- To edit existing visit or treatment click *Edit* on the right of the record you wish to edit.
- The *Visit / Treatment date* and *Treatment* fields must be completed.
- A pop-up window, which lists value definitions for the *ECOG* field, may be viewed by clicking the ? (first section of form) link.
- If you select 'Yes' for the *Infection(s) since last visit* field, an additional field will be displayed for recording further details.
- If you select 'Watch' for the *Treatment* field, an additional field will be displayed for recording whether the patient's cancer has progressed.
- The *Disease has progressed since the last encounter* field must be completed if it is displayed.
- If you select 'Treat' for the *Treatment* field, the *Treatment details* section will be displayed for recording details about a chemotherapy, splenectomy or radiotherapy treatment.
- The *Treatment type* field must be completed if it is displayed.
- Additional fields relevant to a particular type of treatment will be displayed once you have made a selection for the *Treatment type* field.
- Chemotherapy:
 - o The *Agents* field must be completed.
 - o More than one chemotherapy agent may be selected by holding down the *Ctrl* keyboard key while clicking the agent values.
 - o The *Course number* field is automatically completed by the system.
 - o Items related to the last course of a regimen:
 - The *Date (of last confirmed test result)* field must be completed.
 - If you select 'Yes' for the *Other complications* field, a free-text field will be displayed for recording the specific complication.
 - If you select 'No' for the *Planned treatment completed* field, a list of reasons for non-completion will be displayed for recording further details.
 - More than one reason for non-completion may be selected by holding down the *Ctrl* keyboard key while clicking the reason values.
- Splenectomy
 - o The *Date (of last confirmed test result)* field must be completed.
- Radiotherapy
 - o The *Radiotherapy site* field must be completed.
 - o More than one radiotherapy site may be selected by holding down the *Ctrl* keyboard key while clicking the site values.
 - o The *Course number* field is automatically completed by the system.
 - o The *Date (of last confirmed test result)* field must be completed if it is displayed.
 - o Items related to the last course of a regimen:
 - The *Date (of last confirmed test result)* field must be completed.

Appendix B

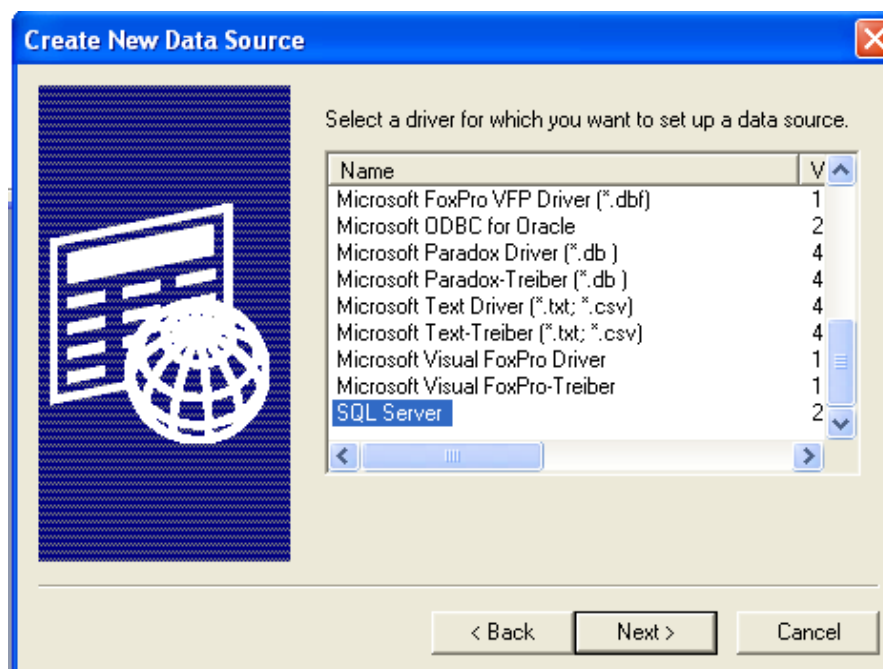
Part 1 - QUERYING ACCORD USING ACCESS - SETUP

You will need to perform this set up procedure only once per PC. This procedure sets up the link between the ACCORD tables and your PC.

1. Open a new blank MS Access file.
2. Click File and go to **"Get external data"** section and select **"Link tables"**
3. It will open a dialogue box requesting to link a database
4. Go to the **"files of type"** displayed at the bottom of the text box and scroll to the bottom.
5. Select **"ODBC Database ()"**. Select the Machine Data Source, the window shown below should appear (the data sources will differ).



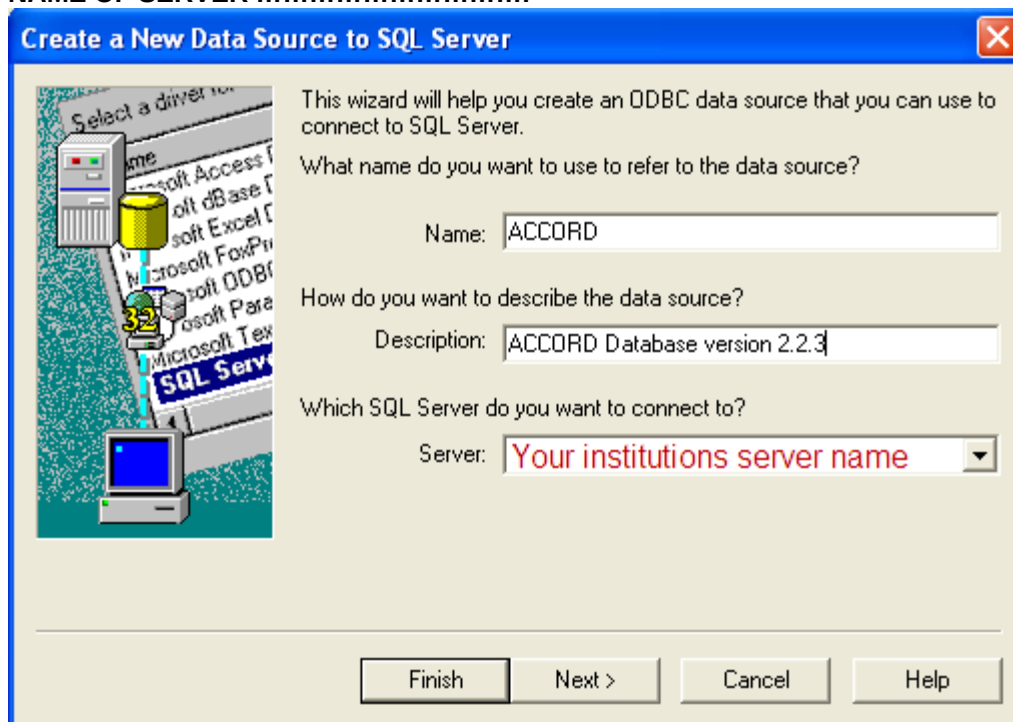
6. Click the **"New"** button on the right.
7. Select the **"User Data Source"** then select **"Next"**
8. Scroll down and select **'SQL Server'** as shown below.



9. Select the **"Next"** and then **"Finish"** button.
10. Enter the Name and Description of the database as shown below. Select the Server ACCORD has been installed from the Server pull down box. Press **"Next"** button.

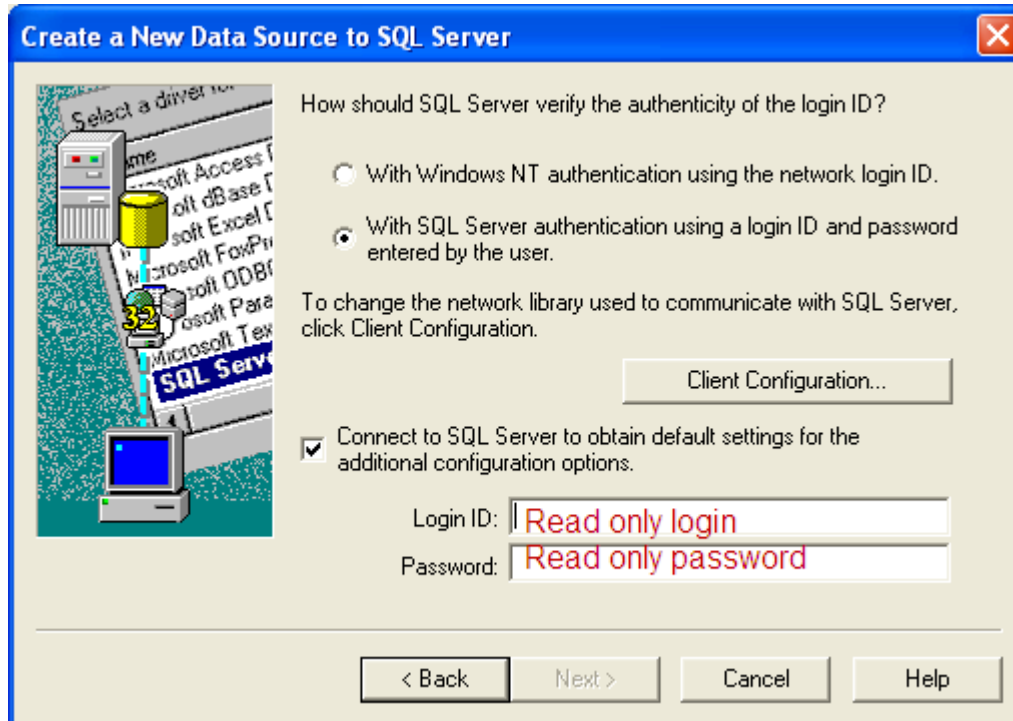
Note: You will need to ask your IT department the name of the server ACCORD is installed on.

NAME OF SERVER

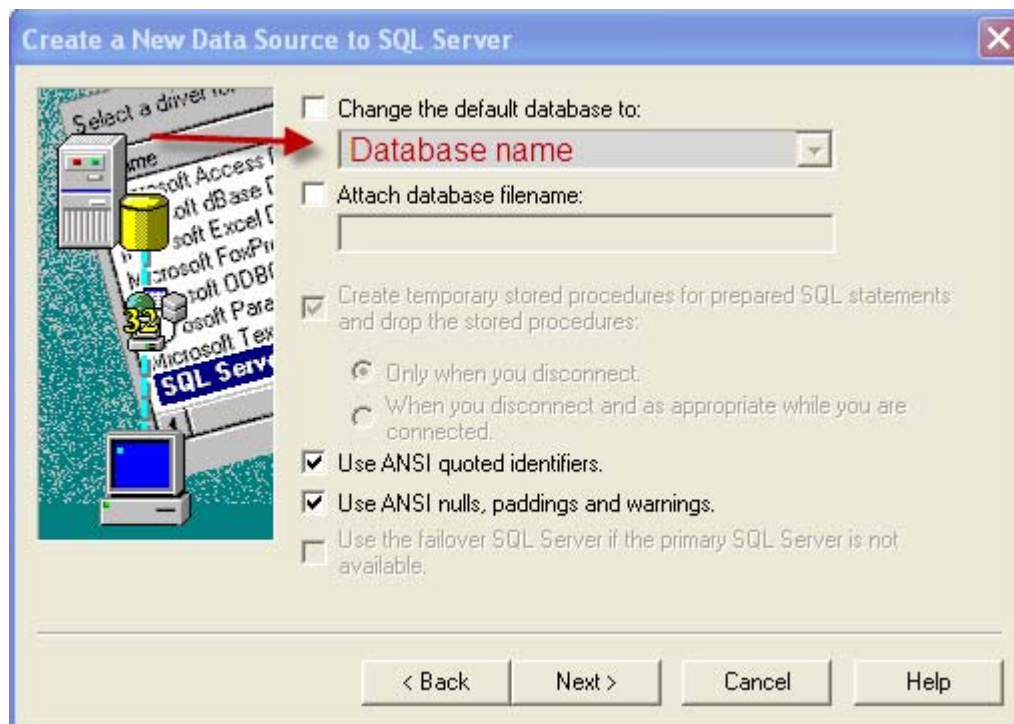


11. Choose 2nd radio button “**With SQL Server authentication using a login ID and password entered by the user**”. Enter the login ID: and password: as issued by your IT department (or ask the Administrator) and select “**Next**”

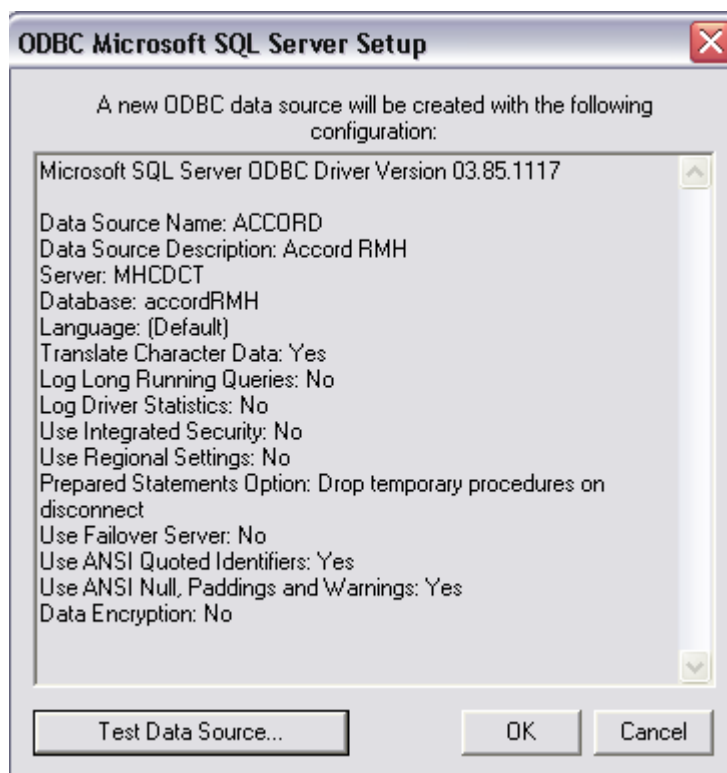
Note: Please keep this password in a safe place to protect against unauthorized use of the database.



11. Ensure the default database is correct, ask your administrator or IT department.
12. Then press **"Next"**.



13. Then press the **"Finish"** button on the next screen.
14. Once you press the **"Finish"** button. The below window will appear, press **"Test Data Source"** button.



15. The result should be as below:



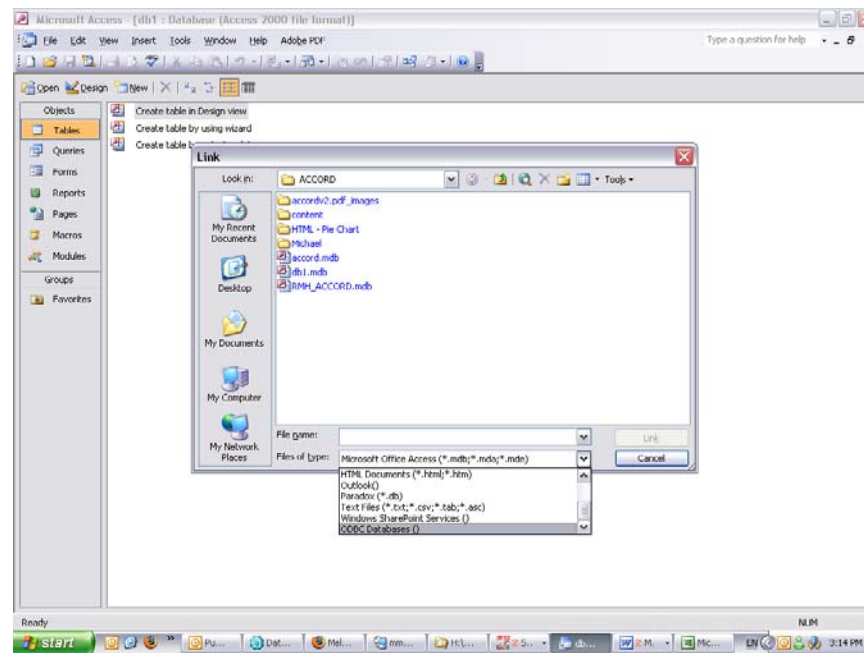
16. You have now linked your PC to the ACCORD database tables.

17. To view the ACCORD tables in Access and run queries and reports, please go to Part 2 of this appendix.

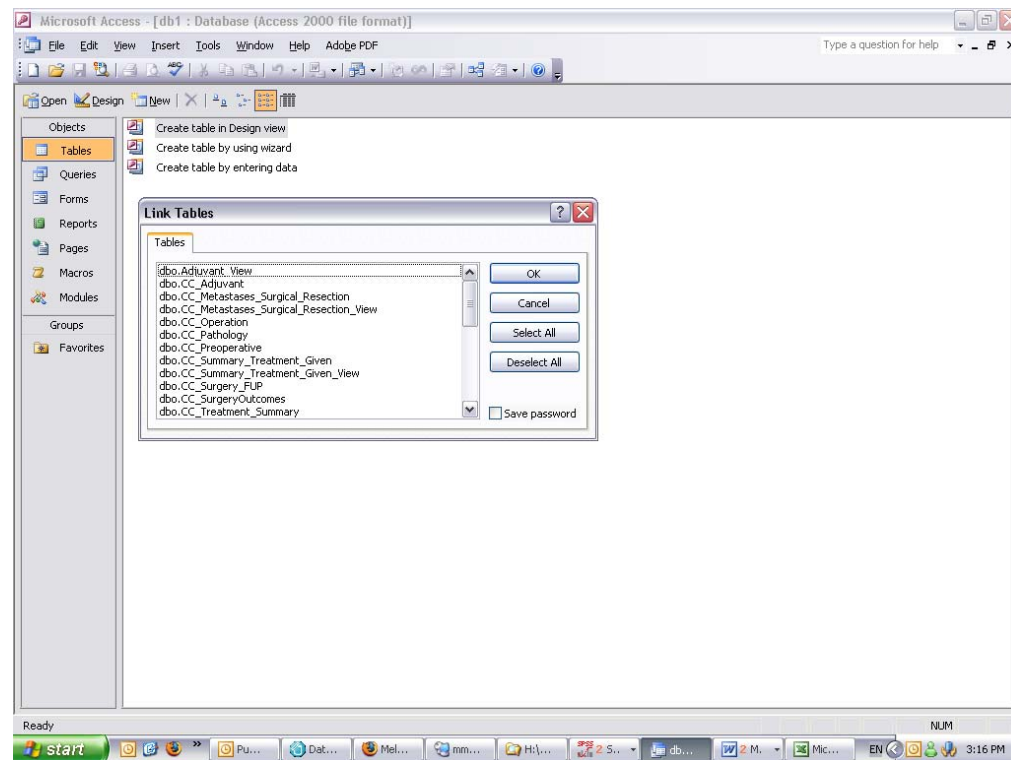
Part 2 - LINKING TO THE ACCORD TABLES

You will need to perform this procedure for each Access database you link to ACCORD.

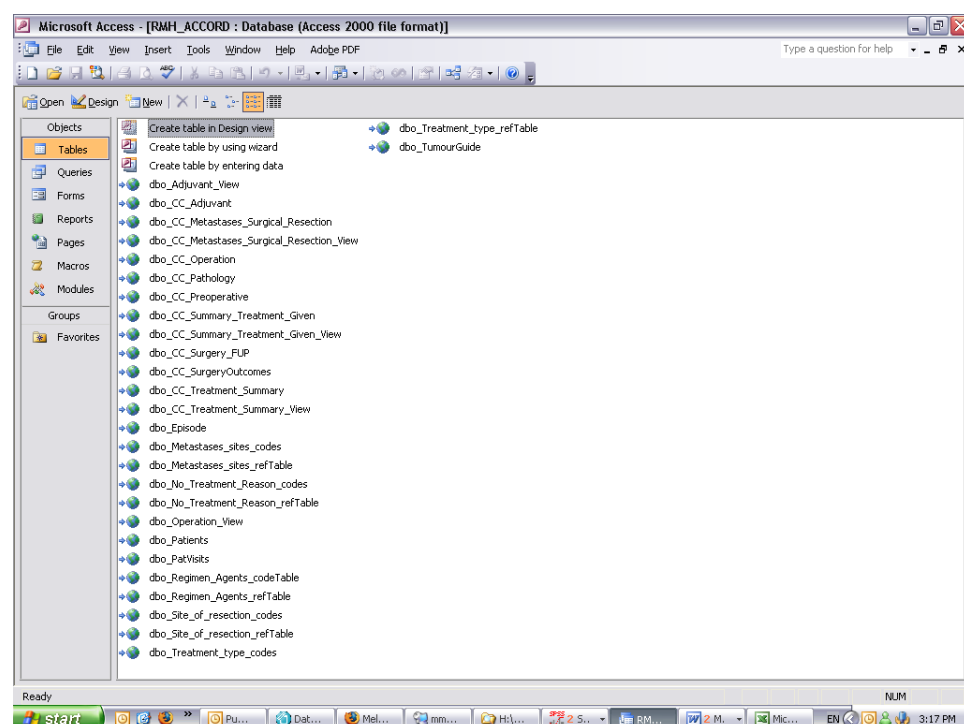
1. Open MS Access
2. Create a new blank database and name and save it as you like.
3. Select 'File', 'Get external data' then 'Link Tables' from the menu bar.
4. At the bottom of the Link box select ODBC Databases from the 'Files of type' pull down box.



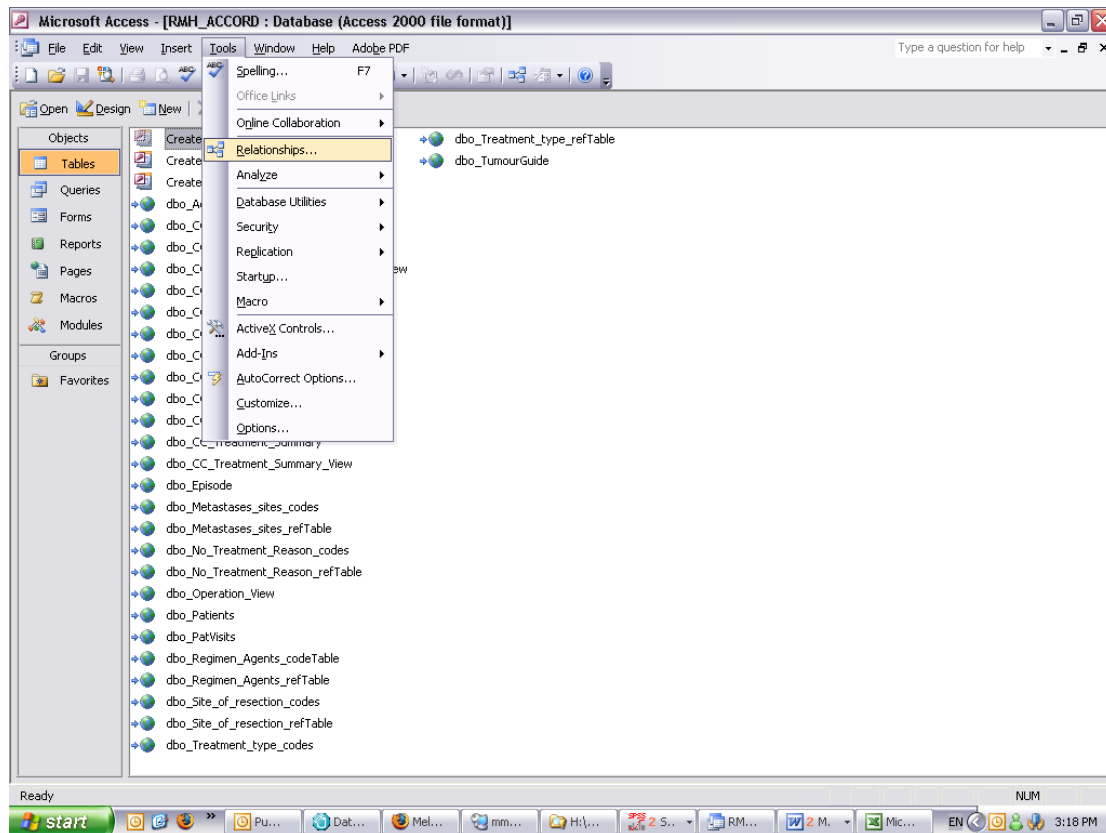
5. A window will appear, select the 'Machine Data Source' tab at the top.
6. Select the ACCORD database from the list and press OK (or whatever you named the ACCORD database link in the previous section).
7. Enter the password: (provided by your Administrator or IT department) and press OK.
8. Select the tables you would like to link (you can use the 'select all' button or hold down ctrl to select individual tables). All tumour types use the 'Patients' and 'Episode' tables. The specific tumour type tables are differentiated by a prefix:
 - a. Colorectal: CC
 - b. Head and Neck: HN
 - c. Central Nervous System: BC
 - d. Bone and Soft Tissue: BST



9. The selected tables will then appear in your Access database and be ready to use as below. The world symbol indicates the tables are linked.



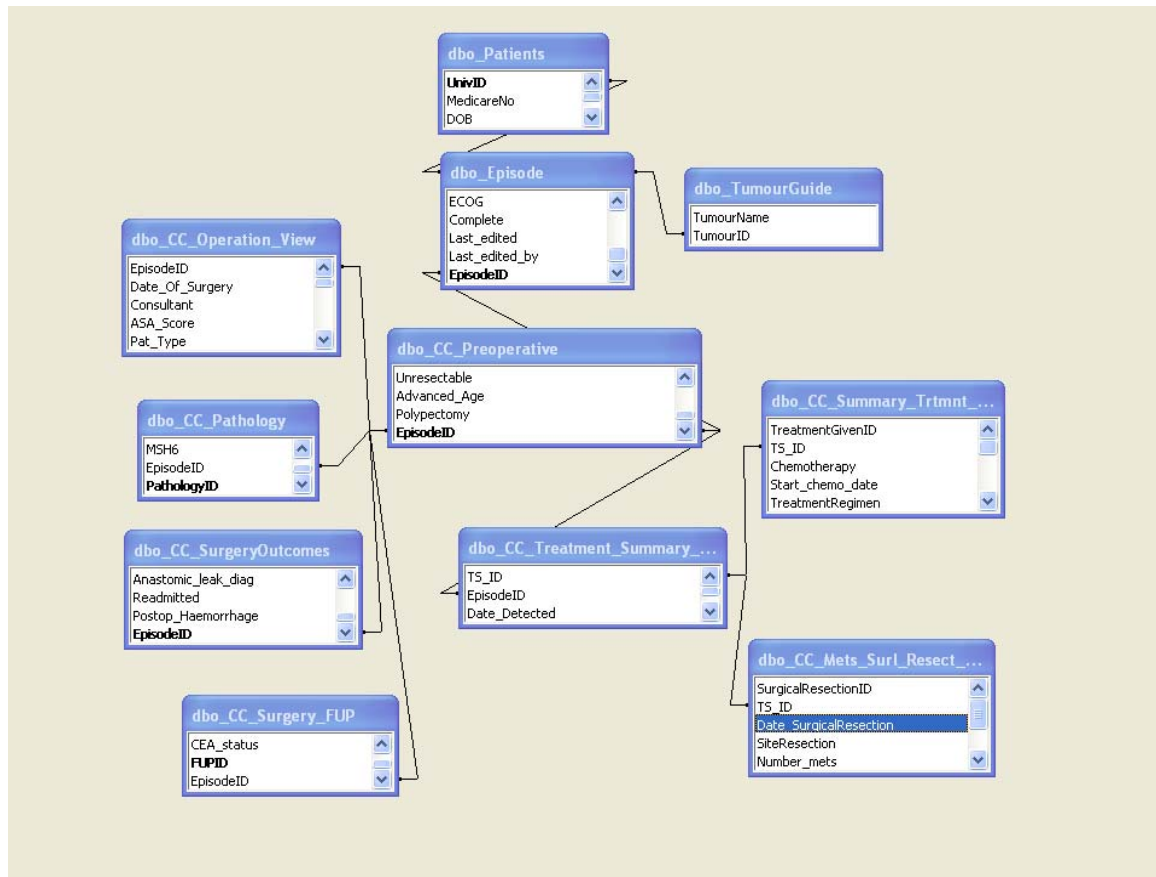
10. Before querying the data you will need to join the tables, go to the tools tab and click on relationship.



11. Please follow the schema provided in Appendix C to join the tables together.
12. Refer to MS Access user manuals on how to query and report using Access.

Appendix C Schemas

Colorectal Schema





Central Nervous System Schema

