New UK SIRT Registry
Quick Start Guide
2013

SIRT Registry: Purpose

- The purpose of the UK Registry is to build a database of patient demographics, primary and secondary diagnoses, treatment details, treatment effects and adverse events in order to evaluate and analyse patient outcomes from SIRT therapy

SIRT Registry: Enrolment

- A page for the SIRT registry on the BSIR website Registries Section has been set up
- Please click the link below to be taken to the enrolment form
- http://www.bsir.org/content/BSIRPage.aspx?pageid=855

Technical Requirements

Access to at least one computer equipped with stable Internet access, email access with one of the following browsing specifications for use in receiving and transmitting data from/to the Registry:

Browser	Version	Operating system
Microsoft Internet Explorer	8 & 9	Window XP (IE8) Windows 7
Google Chrome	24.0.1312.57m latest stable version	Windows XP and Windows 7
Safari	5.1.7 or above	Windows 7
Firefox	14.0.1 or above	Windows XP and Windows 7

SIRT Registry: Test/Production

- Users will receive an email containing a login to both the Test and Production SIRT Registry
- **Test Registry** – used to enter in dummy patients and treatments to allow the user to become familiar with the site
- **Production Registry** – used to enter in real patients and treatments for the purpose of aggregation across site and region

Step 1: Login

- You will receive an email from admin@SIRTregistry.co.uk
  - If you have trouble finding this email check your junk mail folder
  - If after checking your junk mail folder you still can not find the email please contact:

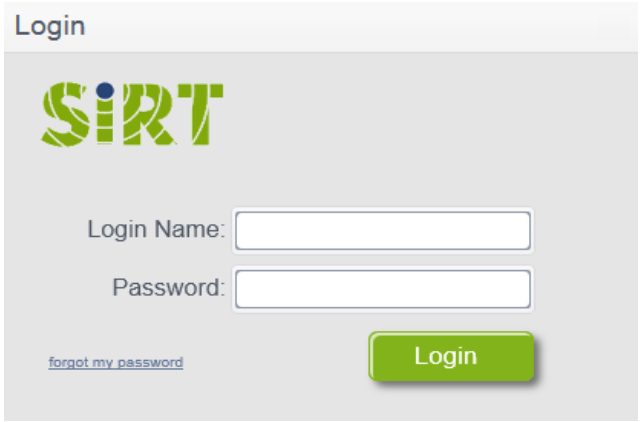
    sirtregistry@hi-iq.com
  - **Subject line of email for test site** – New UK SIRT Registry information (Note: Test Site)
  - **Subject line of email for production site**– New UK SIRT Registry information

Step 1: Login

- The email will contain the following items
  - Link to the registry
  - Login name – The login name will be your email address
  - Temporary password – A 20 character alpha numeric string

Step 1: Login

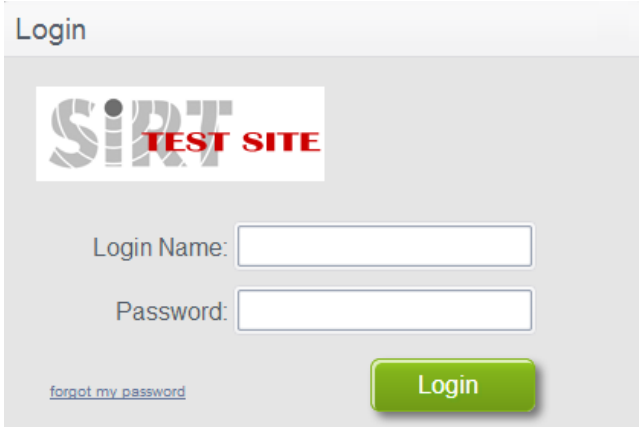
- Link to **Production Registry**
  - https://sirtregistry.co.uk



- Link to **Test Registry**
- Notice different logo

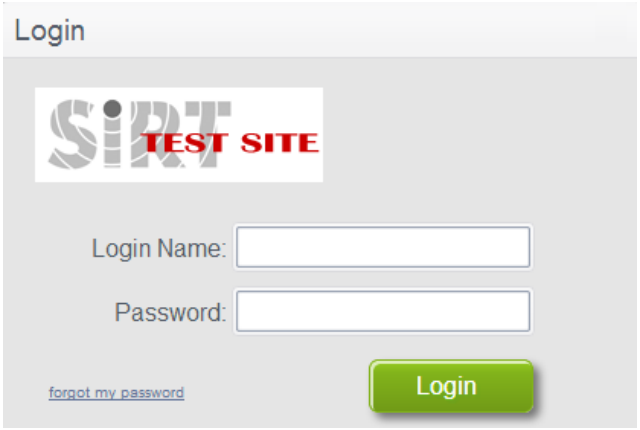
for Test Site

  - https://sirtregistry.co.uk/test



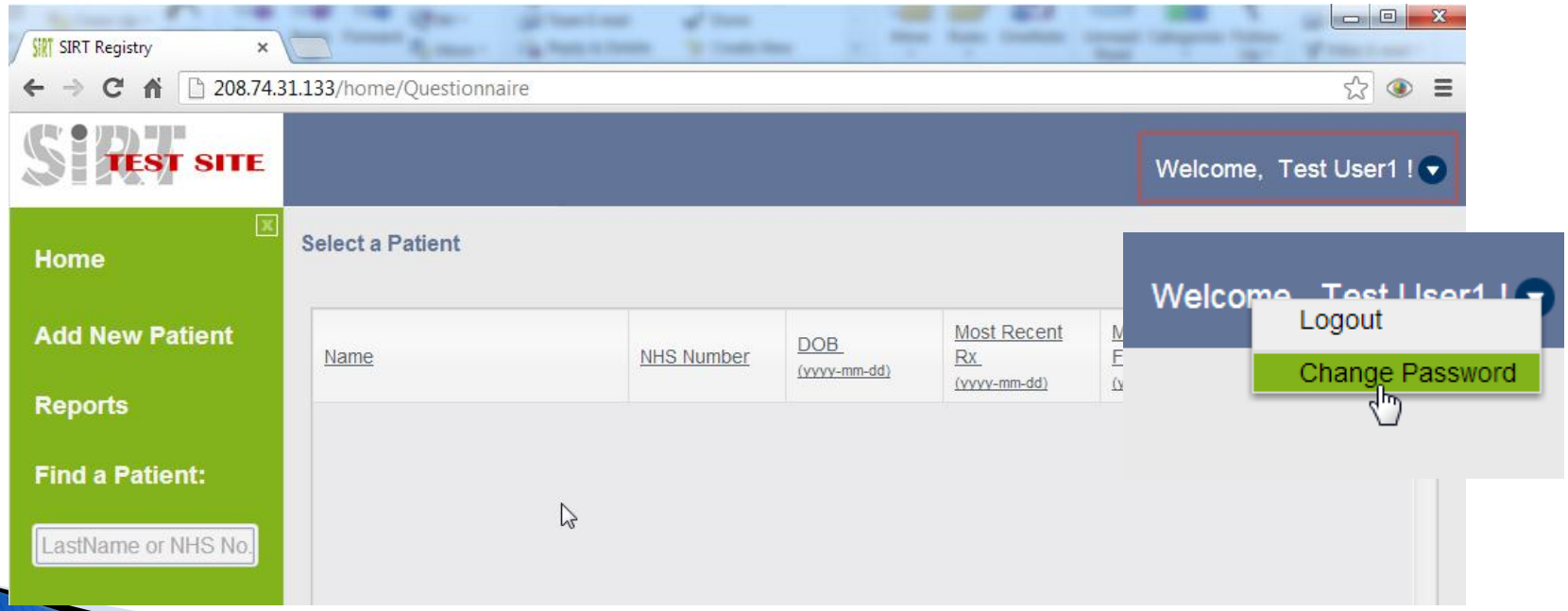
Step 1: Login of Test Registry

- The same steps will apply for the Production Registry
- Navigate to test site – https://sirtregistry.co.uk/test
- Enter in login name
- Enter in temporary password (copy and paste from email)
- Click Login button



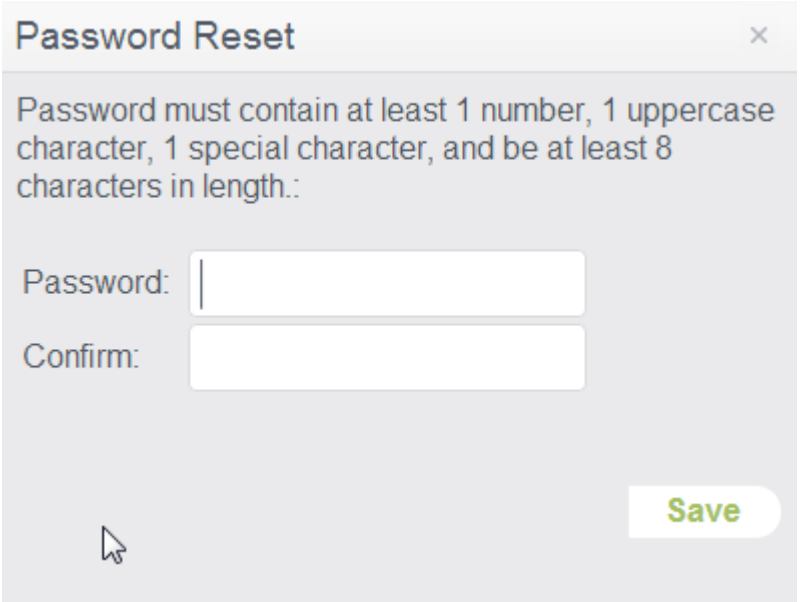
Step 2: Change Password

- Select the white arrow on the right hand side next to Welcome, [your name] and a dropdown will appear to either Logout or Change Password
- Select Change Password



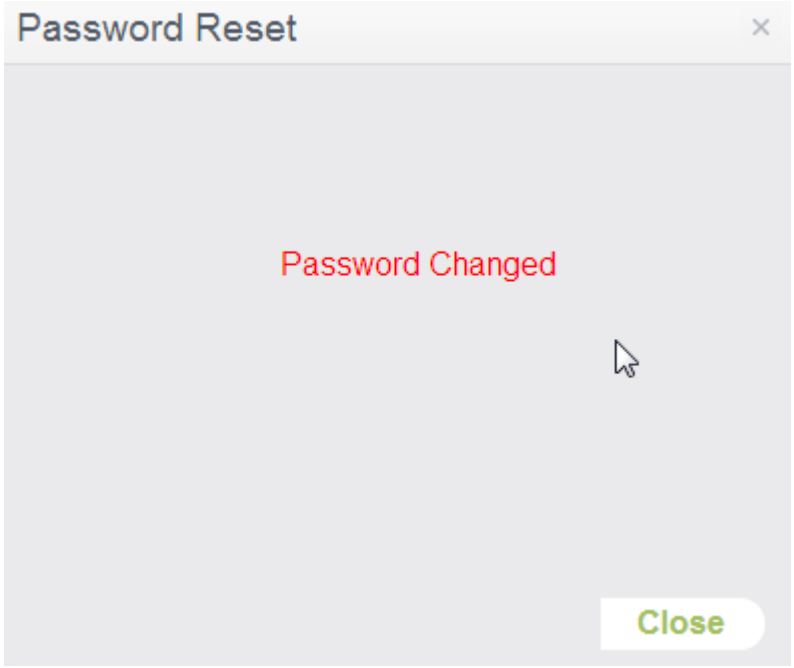
Step 2: Change Password

- Enter in a new password following the password strength rules
- Re-enter the password to confirm
- Click Save



Step 2: Change Password

- You will receive password change confirmation
- Click Close

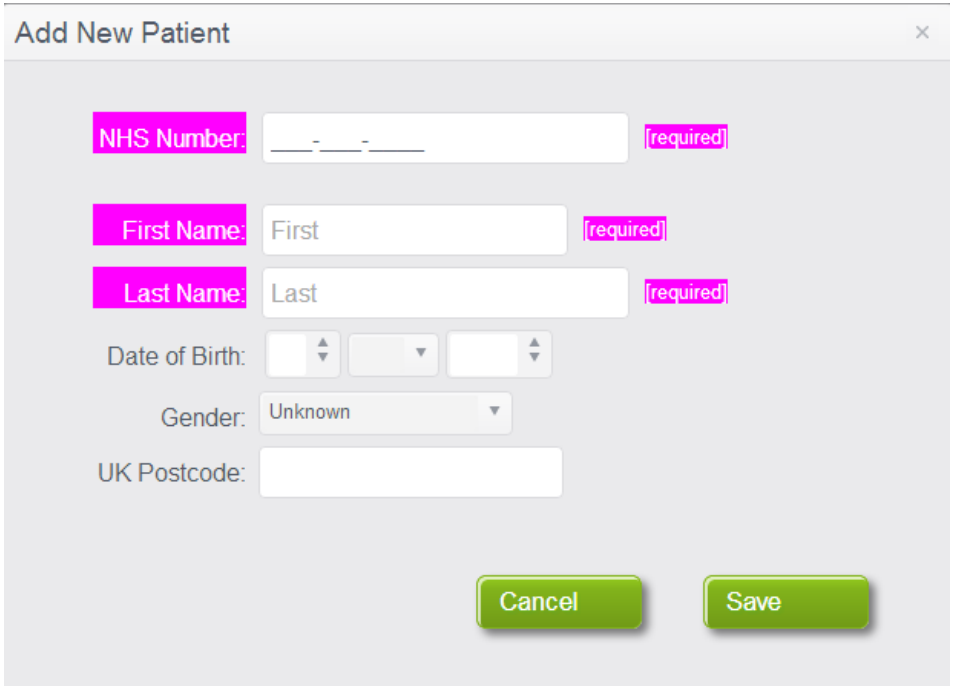


Step 3: Add a New Patient

- On the Home screen select the Add New Patient button from the left hand navigation menu

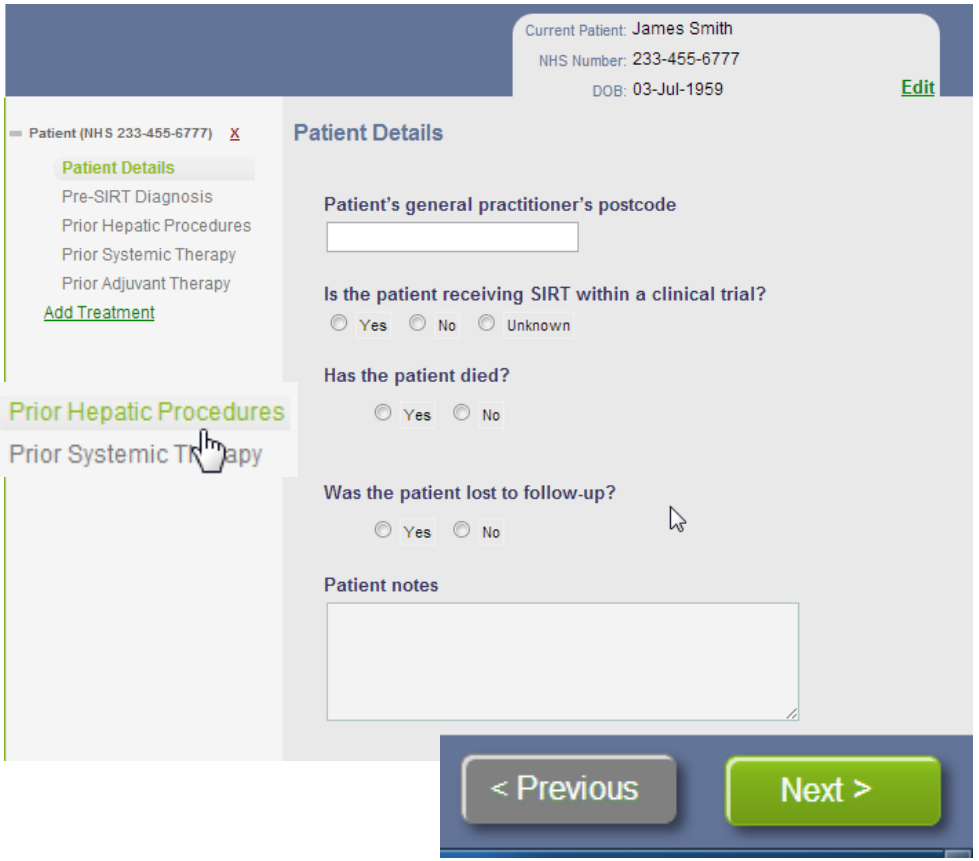
Step 3: Add a New Patient

- Enter in required fields – highlighted in pink
- Enter in additional fields DOB, Gender and UK Postcode for report purposes
- Click Save



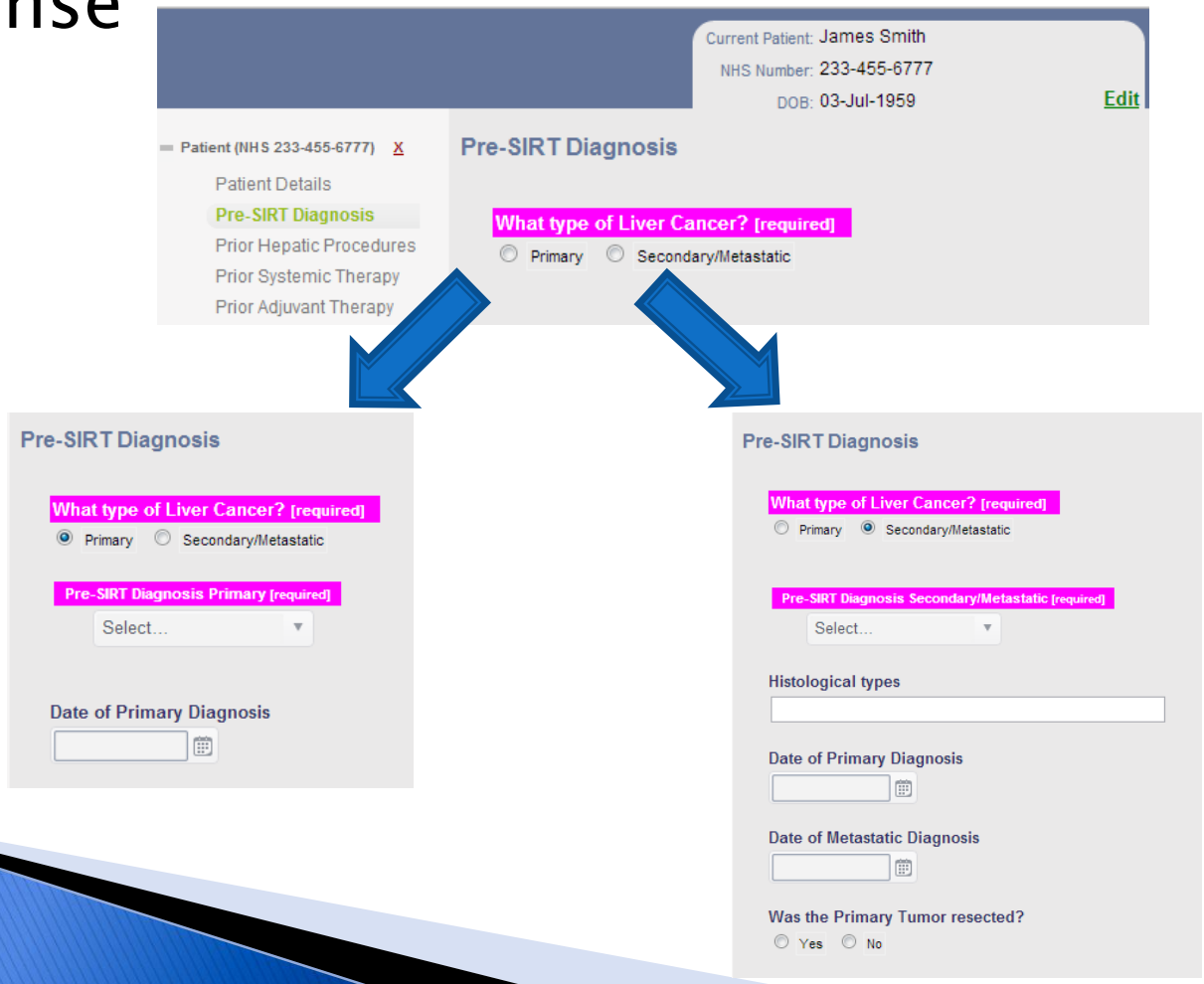
Step 3: Add a New Patient

- Enter in Patient Details
- Enter in all required fields
- Utilise the left navigation or next/previous buttons to walk through forms



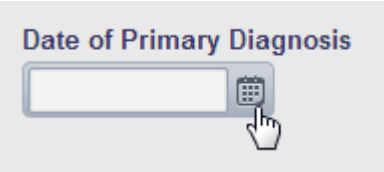
Conditionalisation of Questions

- Questions may appear based on a previous response

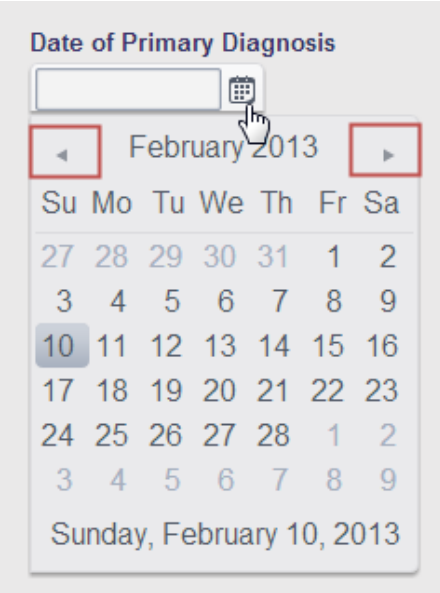


Calendar Control

- To enter in a date select any part of the calendar control



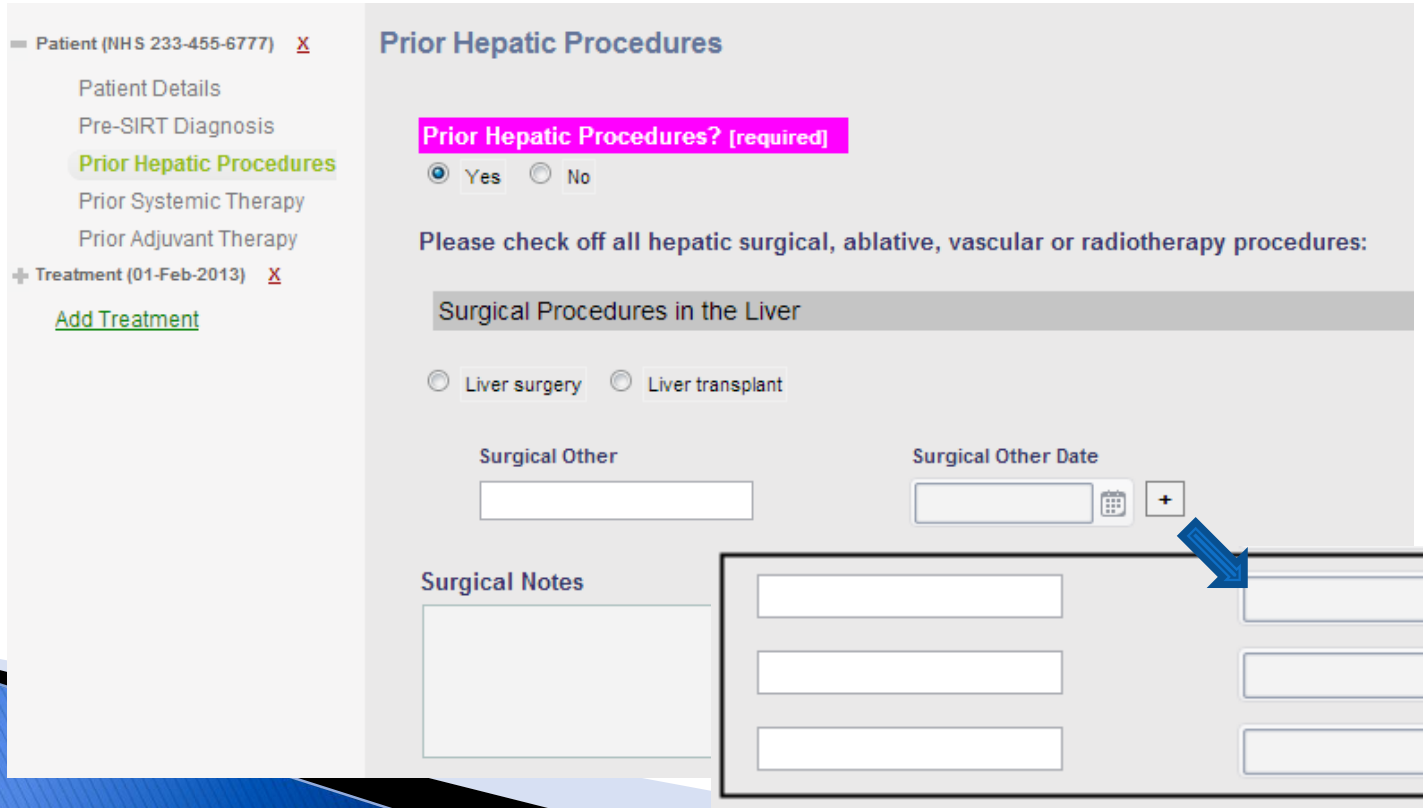
- Select a date or maneuver to another month using the arrows



- Future dates are not allowed

Adding Additional Items

- Ability to enter in multiple values
- Click the + to add an extra line
- Click the – to remove a line

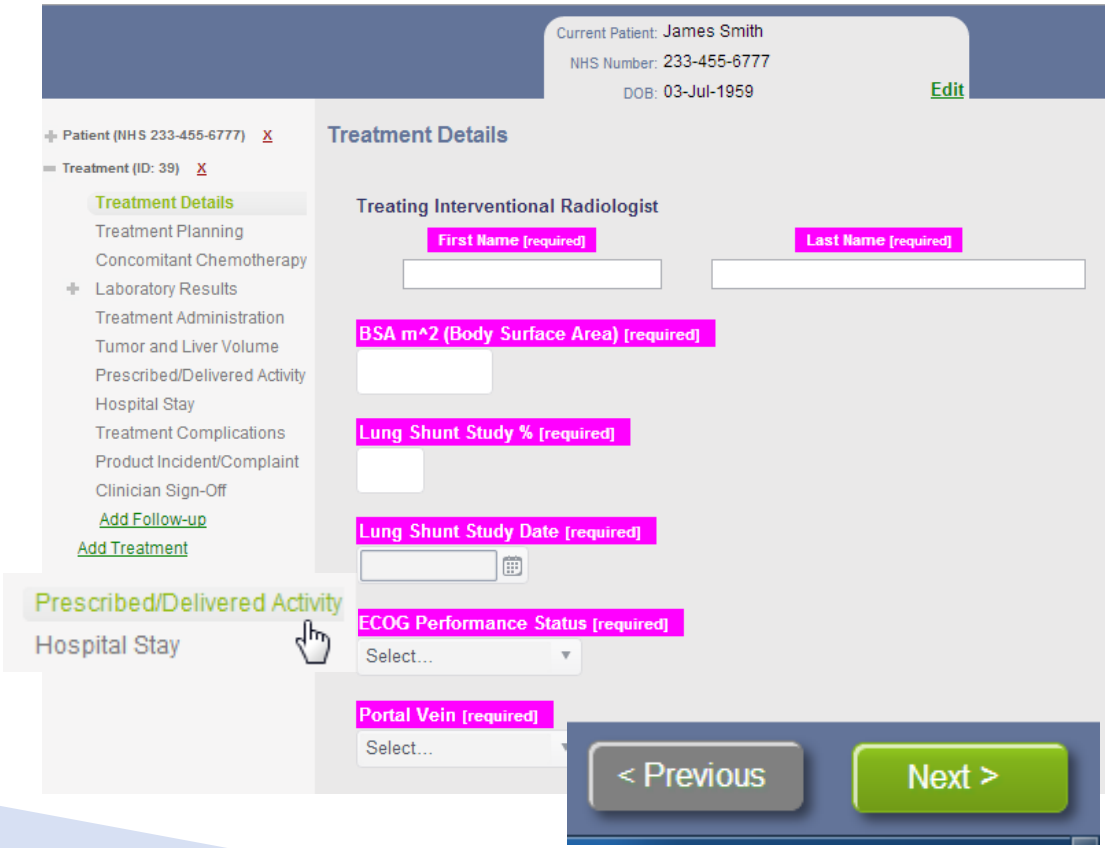


Step 4: Add a Treatment

- Once all patient specific information has been entered click the Add Treatment link to add a new treatment
- Patients can have multiple treatments

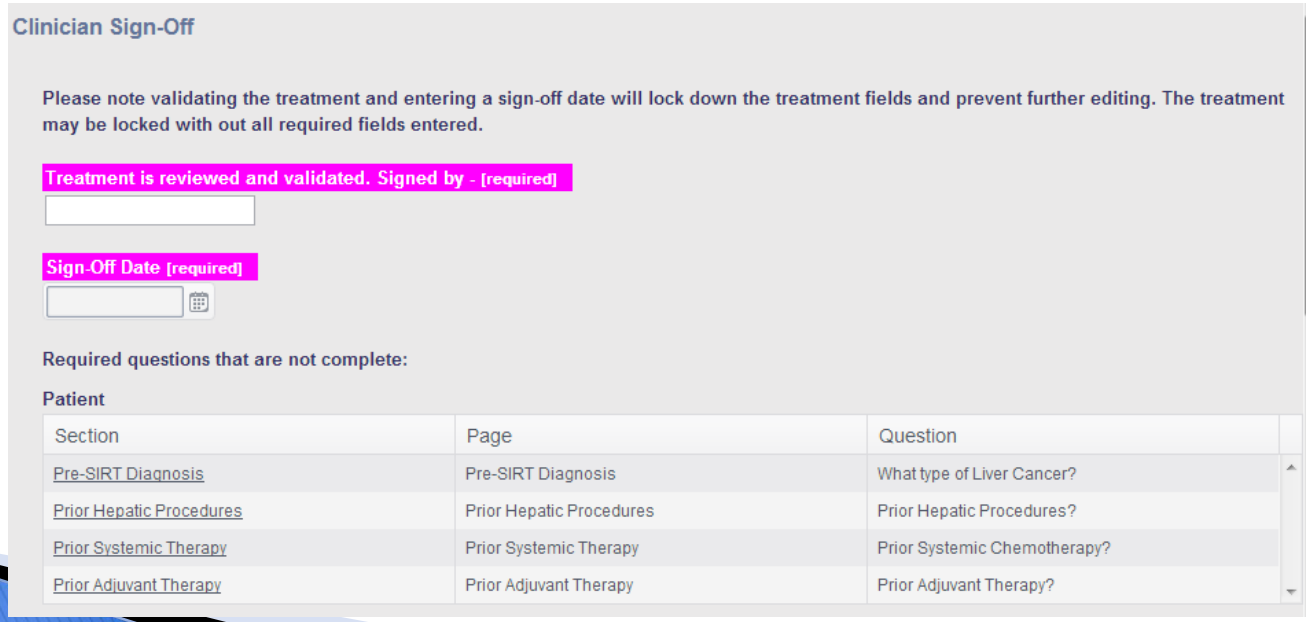
Step 4: Add a Treatment

- Enter in Patient Details
- Enter in all required fields
- Utilize the left navigation or next/previous buttons to walk through forms



Step 4: Add a Treatment

- Clinician Sign-Off will lock down the treatment to prevent further editing
- Used to determine what required fields have not been completed

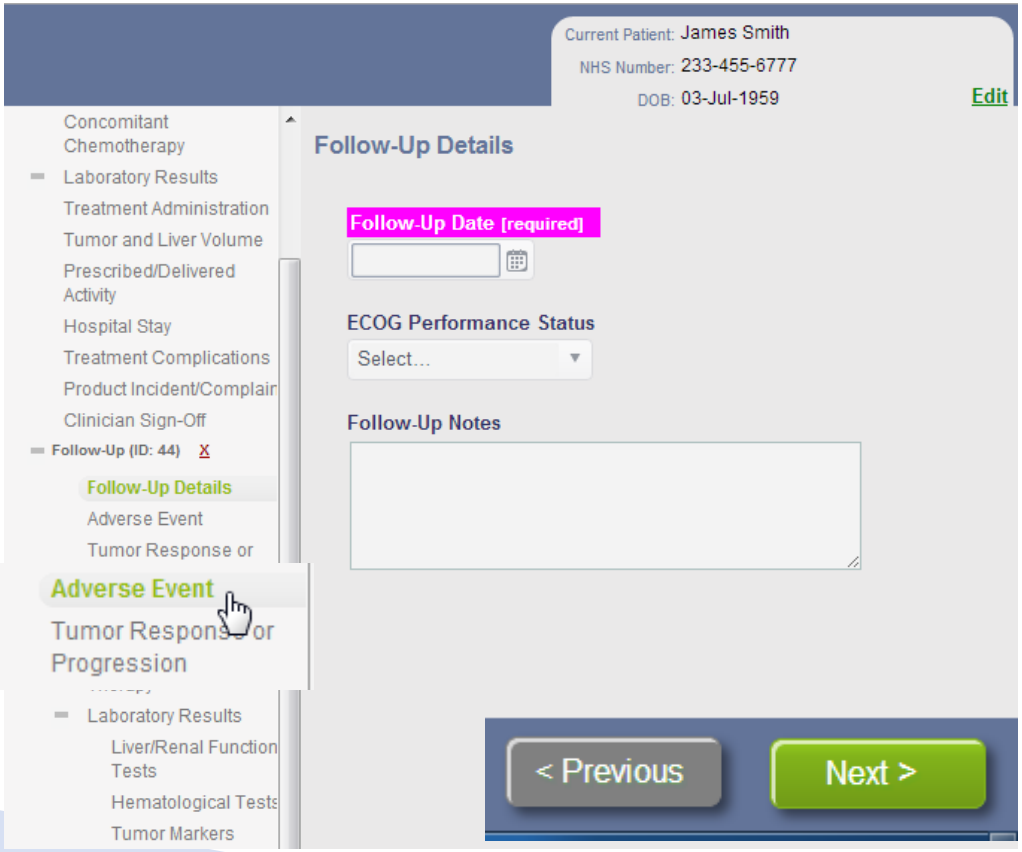


Step 5: Add a Follow-up

- Click the Add Follow-up link to add a new treatment
- Treatments can have multiple Follow-ups

Step 5: Add a Follow-up

- Enter in Patient Details
- Enter in all required fields
- Utilize the left navigation or next/previous buttons to walk through forms



Done Button

- At any time while working on patient, treatment or follow-up data entry the user can click the

button and return to the patient grid

Patient Selection Grid

- Clicking the

button will also return the user to the patient grid

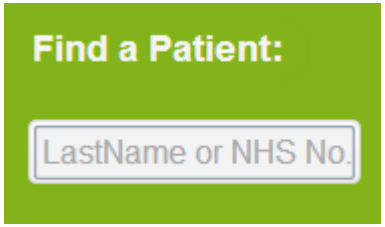
- The patient grid columns are sortable by a simple click on the header

Select a Patient

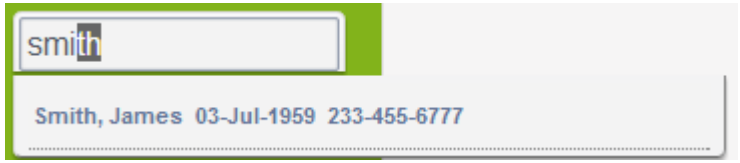
Name	NHS Number	DOB (yyyy-mm-dd)	Most Recent Rx (yyyy-mm-dd)	Most Recent F/U (yyyy-mm-dd)	Required Fields Complete?
Smith, James	233-455-6777	1959-07-03			No

Find a Patient

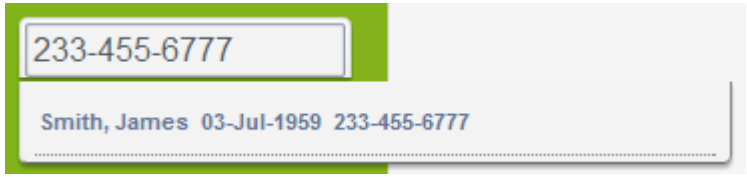
- Enter in Last Name or NHS No. into the Find a Patient: text box



- Last Name is an Auto-Complete search, it starts searching as soon as 2 characters are typed



- Enter in complete NHS No.



Delete

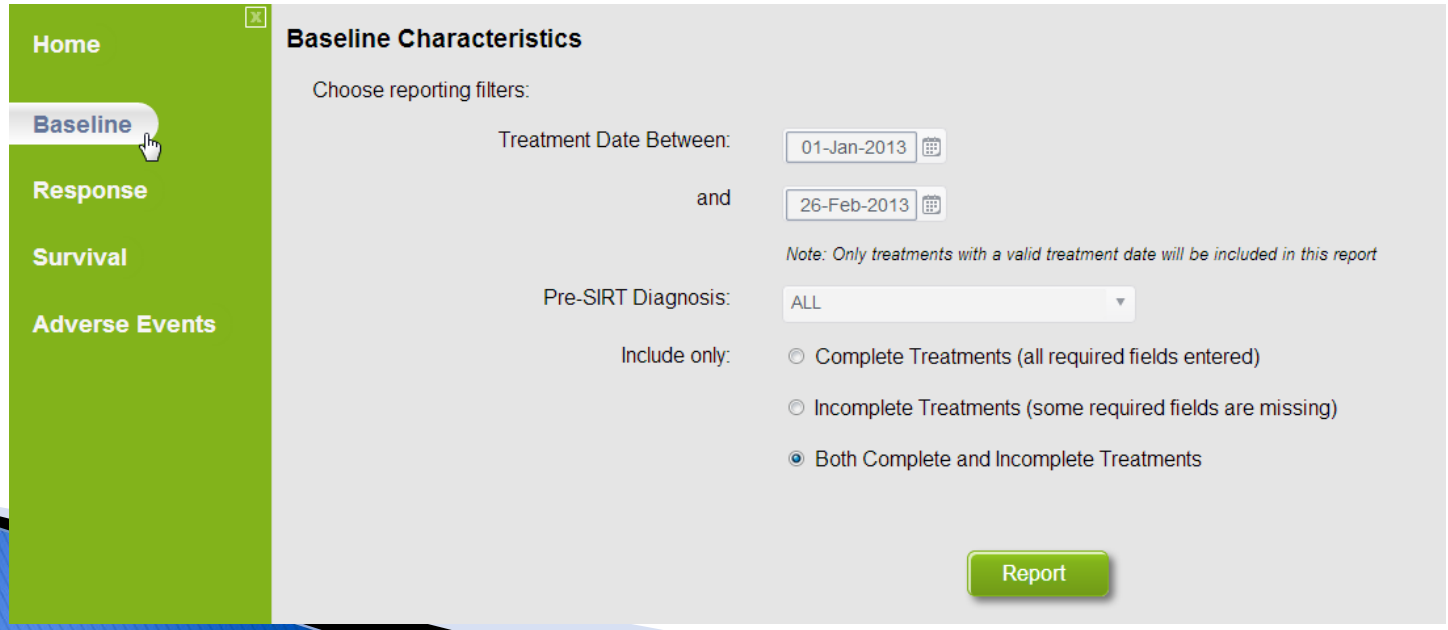
- User has the ability to delete Patients, Treatments and Follow-Ups
- Click the red X next to the Patient, Treatment or Follow-Up
- User will receive a confirmation delete message

Reports

- On the Home screen select the Reports button from the left hand navigation menu

Report 1: Baseline Filters

- Report will default to both complete and incomplete treatments
- Report can be filtered on complete or incomplete treatments (required fields enter or missing)



Report 1: Baseline Results

Baseline Characteristics

Report Parameters:

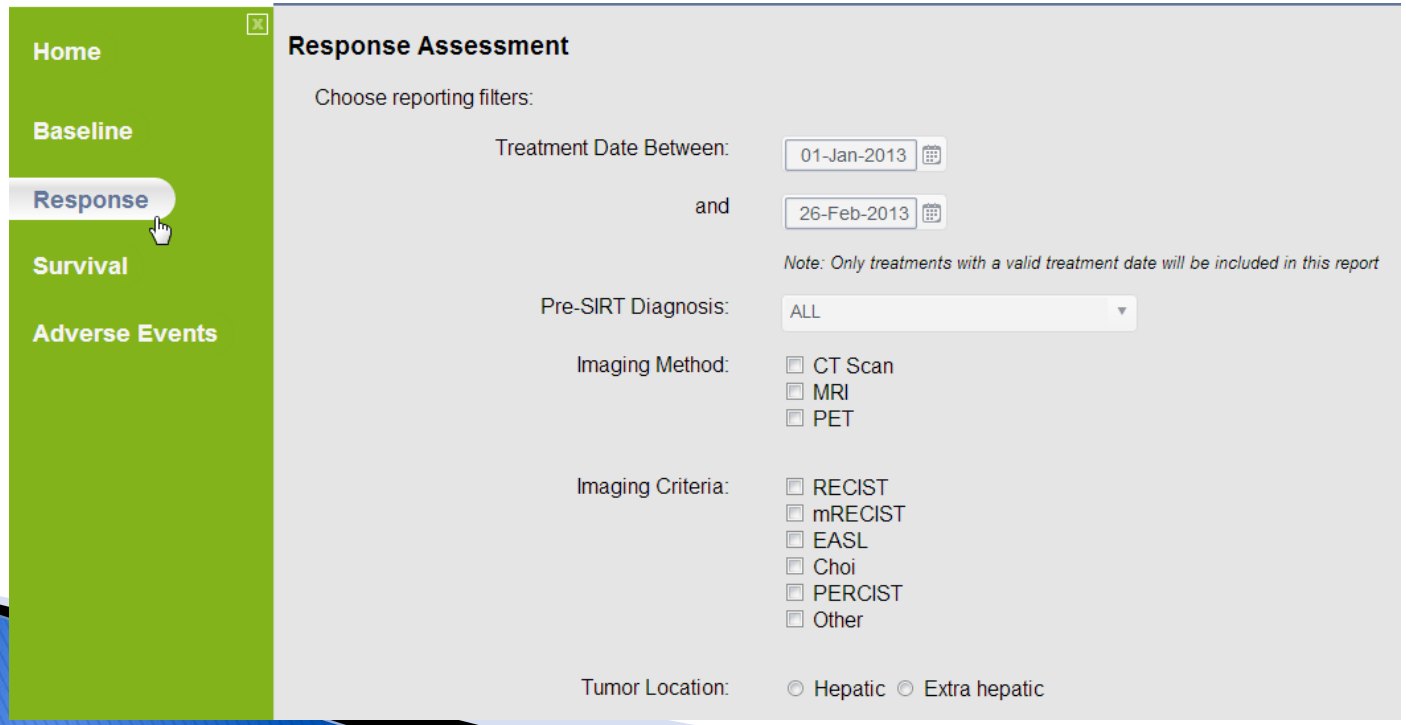
Site:	Hospital1		
Treatment Date Range:	01-Jan-2013	through:	08-Feb-2013
Pre-SIRT Diagnosis:	ALL		
Treatment Included:	Both Complete and Incomplete Treatments		

Report Results:

Baseline Characteristics ver: 2.6.13 04:03pm	**Values**
Total Patients [no., %]	1 (100%)
Total Treatments [no., %]	1 (100%)
Number of SIRT treatments [no., %]	
1	1 (100.0%)
2	0 (0.0%)
3	0 (0.0%)
>3	0 (0.0%)
Age	
Mean	54

Report 2: Response Filters

- One or more imaging method(s) and criteria are required
- Tumor location, hepatic or extra hepatic is required



Report 2: Response Results

Report Parameters:

Site:	Hospital1
Treatment Date Range:	01-Jan-2013 through: 08-Feb-2013
Pre-SIRT Diagnosis:	ALL
Imaging Method:	CT Scan
Imaging Criteria:	mRECIST
Response Type:	Hepatic

Report Results:

Patients Selected: 1
Treatments Selected: 1
Follow-Ups Selected: 1

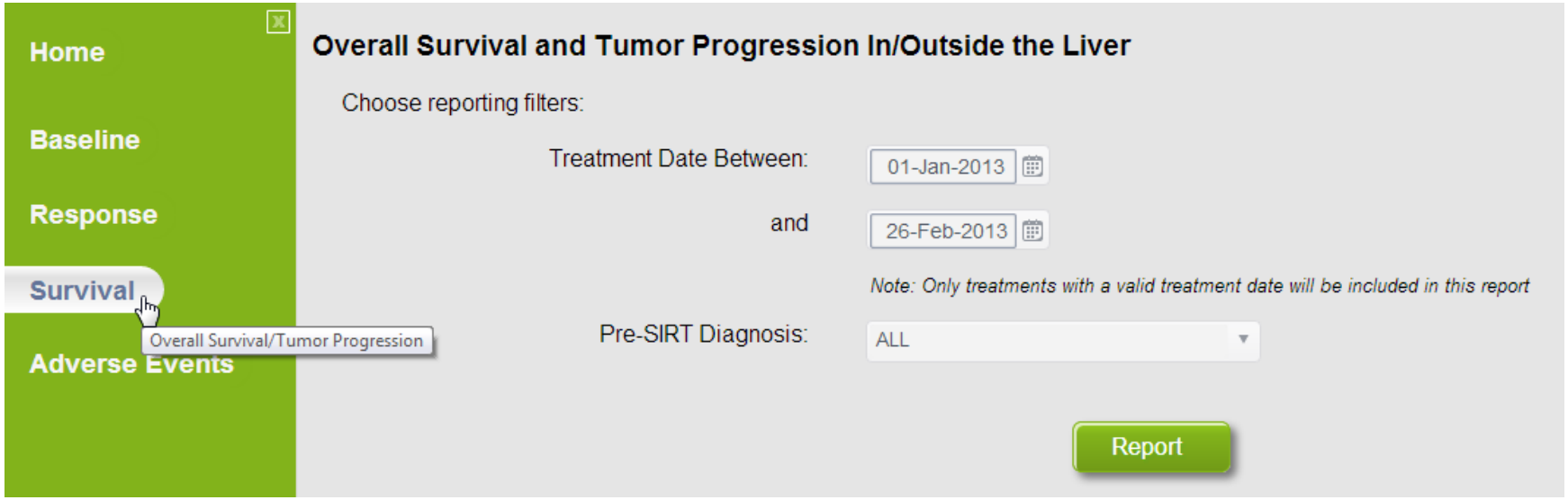
Best response distribution by Patient where Date, Method, Criteria and Response were recorded are shown below: 1

Response Type	No. Best Response Recorded (%)
Complete Response (CR)	1 (100.0%)
Partial Response (PR)	0 (0.0%)
Stable Disease (SD)	0 (0.0%)
Progressive Disease (PD)	0 (0.0%)
Unevaluable	0 (0.0%)

Overall Response Rate (Complete Response + Partial Response)	1 (100.0%)
Disease Control Rate (Complete Response + Partial Response + Stable Disease)	1 (100.0%)

Report 3: Overall Survival and Tumour Progression

- Overall Survival and Tumor Progression In and Outside the Liver are captured in the report



Report 3: Overall Survival and Tumour Progression Results

Overall Survival and Tumor Progression In/Outside the Liver

Report Parameters:

Site:	ConexSys Test Hospital		
Treatment Date Range:	01-Nov-2012	through:	26-Feb-2013
Pre-SIRT Diagnosis:	ALL		

Report Results:

Patients Selected: 1

Overall Survival:

Number of patients where death has been recorded: 0

Median overall survival (months):

Note: time from date of first recorded SIRT to death: (this is not a Kaplan-Meier analysis)

Tumor Progression In/Outside the Liver:

Number of patients where progression in the Liver has been recorded: 1

Median time to progression in Liver (months): 2.67

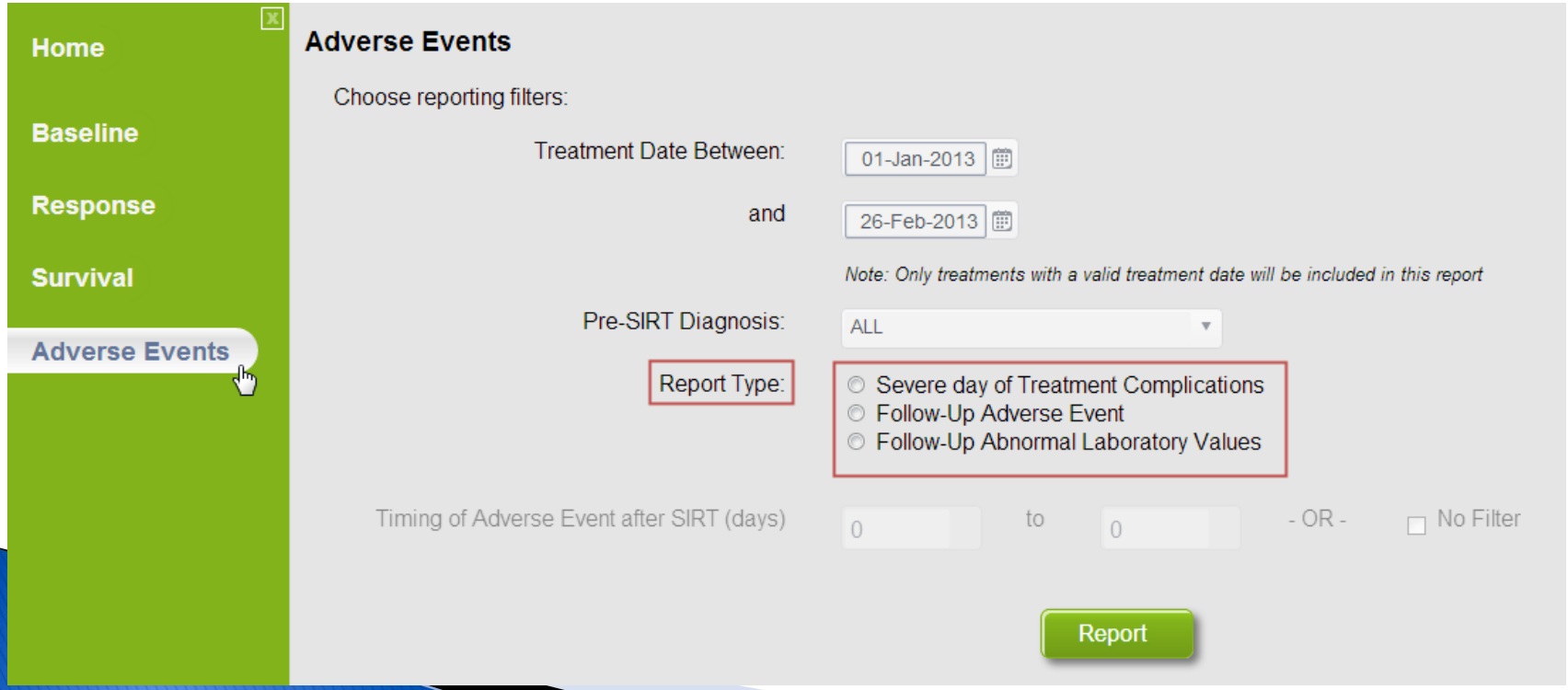
Number of patients where progression outside the Liver has been recorded: 1

Median time to progression outside Liver (months): 2.67

Note: time from date of first recorded SIRT to progression; this is not a Kaplan-Meier analysis

Report 4: Adverse Events

- Three reports in one, select one report type
- Follow-Up Adverse Events and Abnormal Laboratory Values have the option to select Time of AE or No Filter



Report 4a: Severe day of Treatment Complications

Report Results:

Patients Selected: 1
Treatments Selected: 1

Response break-down for the above 1 treatments: Were any severe day of treatment complications experienced?

No: 0
Yes: 1
No response recorded: 0

Response break-down: Were any severe day of treatment complications experienced? - YES(1)

Treatment Complication Description was not recorded: 0
Response distribution where Treatment Complication Description was recorded are shown below: 1

Frequency of Treatment Complications (including only treatment where a definitive response was recorded, n = 1)

Treatment Complication	No. Complications Recorded (%)	Major #(%)	Minor #(%)	Severity not selected
Vascular	1 (100.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)

Treatment Complication	No. Complications Recorded (%)	Grade 3	Grade 4	Grade not selected
Severe Abdominal Pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe Vomiting	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment Complication Description was not recorded	0 (0.00%)	-	-	-

Report 4b: Adverse Events

Report Parameters:

Site:	Hospital1		
Treatment Date Range:	01-Jan-2013	through:	08-Feb-2013
Timing of Adverse Event after SIRT (days):	No Filter		
Pre-SIRT Diagnosis:	ALL		

NOTE: Adverse Events are reported at the highest grade they occur for each patient, within each reported time period.

Report Results:

Patients Selected: 1
Treatments Selected: 1
Follow-Ups Selected: 1

Frequency of Patient Complications (including only Patients where a definitive response was recorded, n = 1)

Follow-Up Adverse Event	No. Adverse Events Recorded (%)	Grade1	Grade2	Grade3	Grade4	Grade5	Grade not selected
Abdominal Pain	1 (100.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fatigue	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fever	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nausea	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vomiting	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gastritis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
GI Ulceration	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Radioembolisation-Induced Liver Disease	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Radiation Pneumonitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Report 4c: Abnormal Laboratory values

Follow-Up Abnormal Laboratory Values

Report Parameters:

Site:	Hospital1		
Treatment Date Range:	01-Jan-2013	through:	08-Feb-2013
Timing of Adverse Event after SIRT (days):	No Filter		
Pre-SIRT Diagnosis:	ALL		

NOTE: Abnormal Lab Values are reported at the highest grade they occur for each patient, within each reported time period.

Report Results:

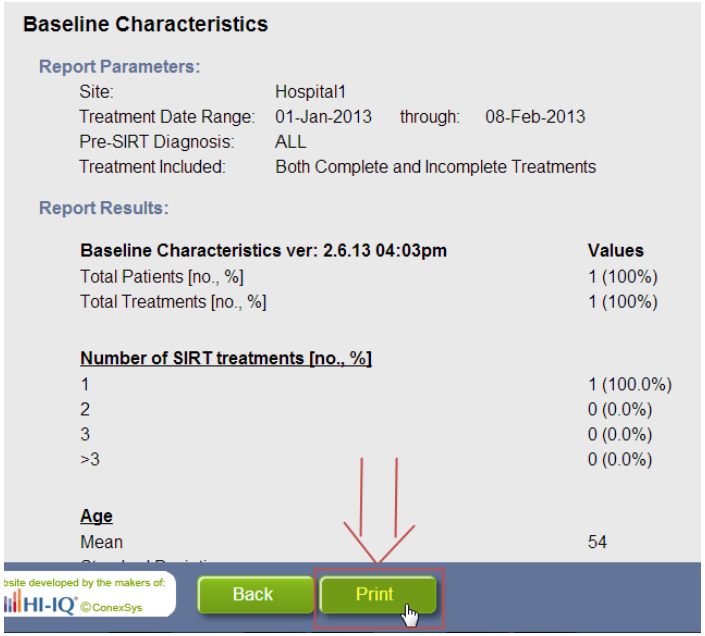
Patients Selected: 1
Treatments Selected: 1
Follow-Ups Selected: 1

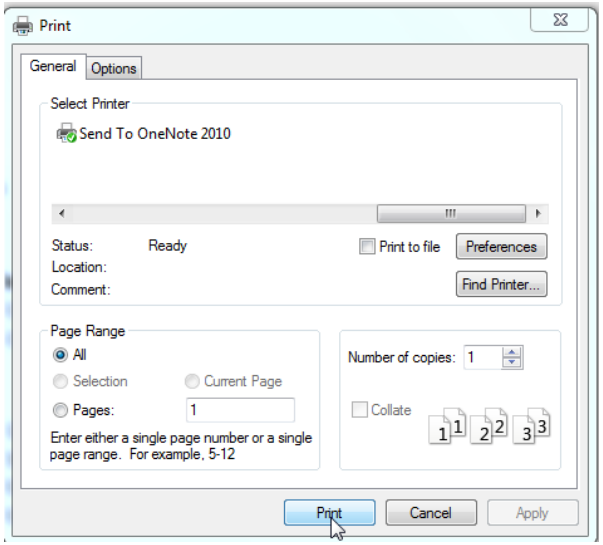
Frequency of Follow-Up Abnormal Laboratory Values (including only Patients where a definitive unique response was recorded, n = 1)

Follow-Up Abnormal Laboratory Values	No. Abnormal Laboratory Values Recorded (%)	Grade1	Grade2	Grade3	Grade4	Grade5	Grade not selected
Hypoalbuminemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hyperalbuminemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ALT increased	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AST increased	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INR increased	1 (100.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Print Reports

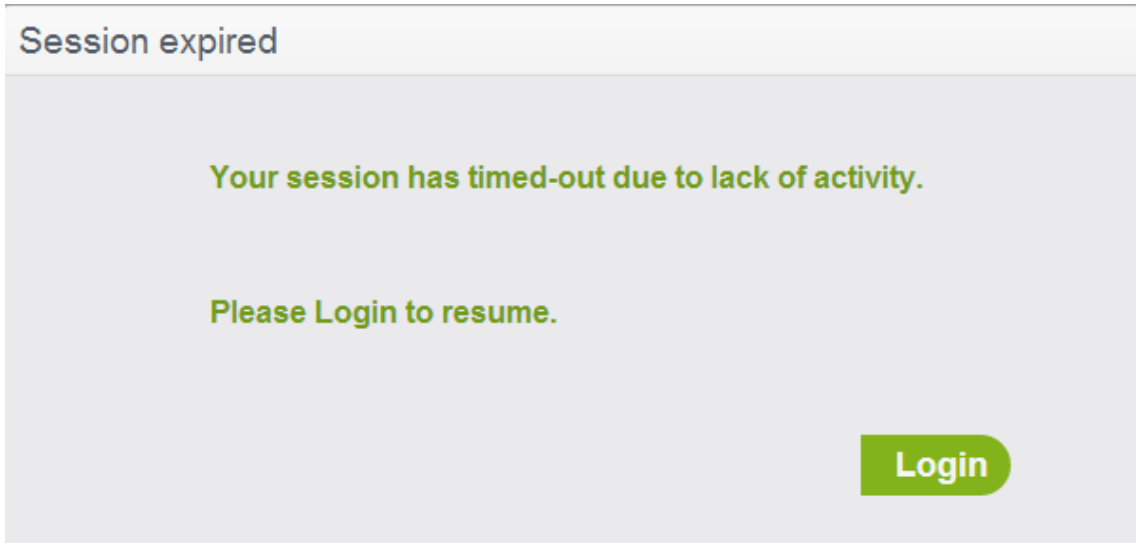
- All reports are printable
- Print button is located on the lower blue strip
- Click Print to bring up print window





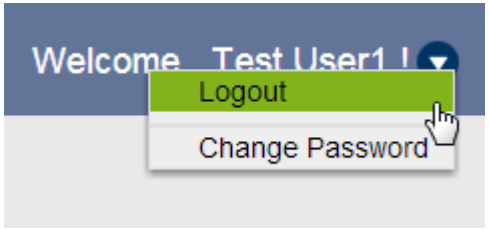
Timeout

- If you are inactive for more that 15 minutes the application will present the following message
- Click Login to resume and re-login

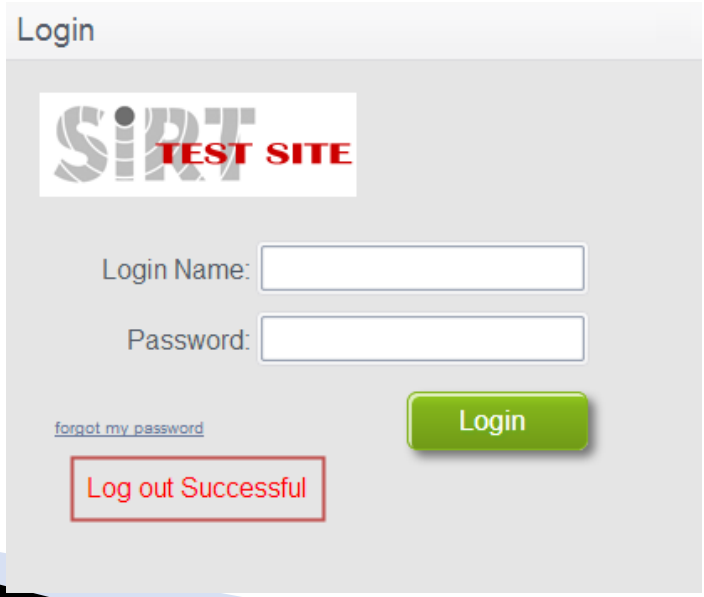


Logout

- Located in upper right corner



- Clicking Logout will present the user with the Login screen and provide a message informing them logout was successful



BSIR Contact Information

- If you have any questions regarding data input into the registry please contact –

- Barbara Fletcher
- E-mail address – glebefacilities@gmail.com
- Telephone number – (+44) 07890392332