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 <u>admin@SIRTregistry.co.uk</u>
 - 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

<u>https://sirtregistry.co.uk</u>

- Link to Test Registry
 Notice different logo
 for Test Site
 - <u>https://sirtregistry.co.uk/test</u>

Login	
SIRT	
Login Name:	
Password:	
forgot my password	
Login	

Login				
S R.	т ѕіте			
Login Nam	e:			
Passwor	d:			
forgot my password		Log	in	

Step 1: Login of Test Registry

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

Login	
S TEST SITE	
Login Name:	
Password:	
forgot my password	

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

SIRT Registry ×		anima y'tan		fam tester :	Same Same Same	
← → C ⋒ 🗋 208.74.3	31.133/home/Questionnaire					☆ ■
S TEST SITE					Welcome,	Test User1 ! 🗨
Home	Select a Patient				Welcom	
Add New Patient	Name	NHS Number	DOB (yyyy-mm-dd)	Most Recent Rx (yyyy-mm-dd)	Ν Ε Ω	Logout Change Password
Reports Find a Patient:						4)
LastName or NHS No.		Ç≽				

Step 2: Change Password

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

Password	Reset	×
Password m character, 1 characters ir	ust contain at least 1 number special character, and be at I n length.:	, 1 uppercase east 8
Password:		
Confirm:		
N		Save
3		

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

S TEST SITE					We	elcome, Test User	1! 🔽
■ Home	Select a Patient						
Add New Pat	me	NHS Number	DOB_ (vyvy-mm-dd)	Most Recent Rx (yyyy-mm-dd)	Most Recent F/U (yyyy-mm-dd)	Required Fields Complete?	
Reports Add	d New Patient						*
LastName or NHS No.							

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

dd New Patient					×
NHS Number:				[required]	
First Name:	First		[req	uired]	
Last Name:	Last			[required]	
Date of Birth:	× ·	•	Ť		
Gender:	Unknown	٣			
UK Postcode:					
			Cancel	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
 - Date of Primary Diagnosis
- 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

— Patient (NHS 233-455-6777) X	Prior Hepatic Procedures		
Patient Details Pre-SIRT Diagnosis Prior Hepatic Procedures	Prior Hepatic Procedures? ves No	[required]	
Prior Adjuvant Therapy + Treatment (01-Feb-2013) X	Please check off all hepati	c surgical, ablative, vascular or radiotherapy p	rocedures:
Add Treatment	Surgical Procedures in th		
	Surgical Other	Surgical Other Date	
	Surgical Notes		

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

Clinician Sign-Off					
Please note validating the treatment and enter may be locked with out all required fields enter	Please note validating the treatment and entering a sign-off date will lock down the treatment fields and prevent further editing. The treatment may be locked with out all required fields entered.				
Treatment is reviewed and validated. Signed	by - [required]				
Sign-Off Date [required]					
Required questions that are not complete:					
Patient					
Section	Page	Question			
Pre-SIRT Diagnosis	Pre-SIRT Diagnosis	What type of Liver Cancer?	*		
Prior Hepatic Procedures	Prior Hepatic Procedures	Prior Hepatic Procedures?			
Prior Systemic Therapy	Prior Systemic Therapy	Prior Systemic Chemotherapy?			
Prior Adjuvant Therapy	Prior Adjuvant Therapy	Prior Adjuvant Therapy?	Ŧ		

Step 5: Add a Follow-up

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

- Patient (NHS 233-455-6777) X
- Treatment (ID: 39) X

Treatment Details

Treatment Planning

- Concomitant Chemotherapy
- Laboratory Results
 Treatment Administration
 Tumor and Liver Volume
 Prescribed/Delivered Activity
 Hospital Stay
 Treatment Complications
 Product Incident/Complaint
 Clinician Sign-Off
 Add Follow-up
 Add Treatment

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 (vyvy-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
Find a Patient:

astName or NHS No.

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





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

The page at 208.74.31.133 says:
Click OK to confirm delete of Follow-Up (01-Feb-2013)
OK Cancel

- Patient (NHS 233-455-6777) X
- Treatment (07-Jan-2013) X

Treatment Details Treatment Planning Concomitant Chemotherapy

Laboratory Results
 Treatment Administration
 Tumor and Liver Volume
 Prescribed/Delivered
 Activity

Hospital Stay

Treatment Complications Product Incident/Complain Clinician Sign-Off

= Follow-Up (01-Feb-2013)



Follow-Up Details

Adverse Event

Tumor Response or Progression

Post-SIRT Hepatic Procedures

- Post-SIRT Systemic Therapy
- Laboratory Results

Add Follow-up



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

S TEST SITE					We	elcome, Test User	1! 🛡
₩ Home	Select a Patient						
Add New Patient	Name	NHS Number	DOB (vyyy-mm-dd)	Most Recent Rx	Most Recent F/U	Required Fields Complete?	
Reports	Smith, James	233-455-6777	1959-07-03			No	*
Find a Report	s 🛺						

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)

Home	Baseline Characteristics	
	Choose reporting filters:	
Baseline	Treatment Date Between:	01-Jan-2013 🗊
Response	and	26-Feb-2013
Survival		Note: Only treatments with a valid treatment date will be included in this report
Adverse Events	Pre-SIRT Diagnosis:	ALL
	Include only:	 Complete Treatments (all required fields entered)
		\odot Incomplete Treatments (some required fields are missing)
		Both Complete and Incomplete Treatments
		Report

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 Incomp	plete 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%)

54

<u>Age</u> Mean

Report 2: Response Filters

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

Home	Response Assessment	
	Choose reporting filters:	
Baseline	Treatment Date Between:	01-Jan-2013
Response	and	26-Feb-2013
Survival		Note: Only treatments with a valid treatment date will be included in this report
Adverse Events	Pre-SIRT Diagnosis:	ALL ×
	Imaging Method:	 CT Scan MRI PET
	Imaging Criteria:	 RECIST mRECIST EASL Choi PERCIST Other
	Tumor Location:	○ Hepatic ○ Extra hepatic

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

Home	Overall Survival and Tumor Progressio	n In/Outside the Liver
	Choose reporting filters:	
Baseline	Treatment Date Between:	01-Jan-2013
Response	and	26-Feb-2013
Survival		Note: Only treatments with a valid treatment date will be included in this report
Overall Survival/Tu Adverse Events	Imor Progression Pre-SIRT Diagnosis:	ALL
		Report

Report 3: Overall Survival and Tumour Progression Results

0	Overall Survival and Tumor Progression In/Outside the Liver				
	port Parameters:Site:ConexSys Test HospitalTreatment Date Range:01-Nov-2012through: 26-Feb-2013Pre-SIRT Diagnosis:ALL				
	port Results:				
	Patients Selected: 1				
	Overall Survival: 0 Number of patients where death has been recorded: 0 Median overall survival (months): 0 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:1Median time to progression in Liver (months):2.6Number of patients where progression outside the Liver has been recorded:1	67			
	Median time to progression outside Liver (months): 2.6	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

Home	Adverse Events	
	Choose reporting filters:	
Baseline	Treatment Date Between:	01-Jan-2013
Response	and	26-Feb-2013
Survival		Note: Only treatments with a valid treatment date will be included in this report
Advence Events	Pre-SIRT Diagnosis:	ALL
Adverse Events	Report Type:	 Severe day of Treatment Complications Follow-Up Adverse Event Follow-Up Abnormal Laboratory Values
	Timing of Adverse Event after SIRT (days)	0 to 0 - OR - No Filter
		Report

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 Record d (%)	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

Baseline Characteristics

ер	ort 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 Characte Total Patients [no., 9 Total Treatments [no	ristics ver: 2.6.13 04:03pm %] _{0.,} %]	Values 1 (100%) 1 (100%)
Number of SIRT tr	eatments [no., %]	
1		1 (100.0%)
2		0 (0.0%)
3		0 (0.0%)
>3	1.1	0 (0.0%)
Age Mean		54
e developed by the makers of: HI-IQ°©ConexSys	Back	

General Options	
Select Printer	
🖶 Send To OneNote 2010	
•	4 III
Status: Ready	Print to file Preferences
Location:	
Comment:	Find Printer
Page Range	
All	Number of copies: 1
Selection	
Pages: 1	Collate
Enter either a single page number or a single	11 22 33
page range. For example, 5-12	

Timeout

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

Your session has timed-out due to lack of activity.
Please Login to resume.
Logi



Located in upper right corner



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

Login	
S TEST SITE	
Login Name:	
forgot my password	
Log out Successful	

BSIR Contact Information

- If you have any questions regarding data input into the registry please contact –
- Barbara Fletcher
- E-mail address <u>glebefacilities@gmail.com</u>
- Telephone number (+44) 07890392332