

EPIC at Princess Margaret's CCRU

Objective: Understand our Beacon flow, our Clinical Trial Data Structure and, the use of the EPIC Reporting Workbench for study-level data pulls.





01 Initial Study Beacon Workflow Extract

02 CCRU Clinical Trial Data Structure



03 Screening and Enrolment Reports

04 Study Adverse Event Report for Data Entry

05 Main Consent Worksheet and Study-level Report

Initial Beacon Treatment Plan Build:

1. **At start-up:** Beacon extract is uploaded into SharePoint – Beacon Channel sorted by disease site.
2. **Research Nurse or Research Nurse Manager** builds the on-study Schedule
3. **Pharmacy** builds the on-study Drug protocols with dosing and preparation communications.
4. **Primary Data Coordinator** sends reminders for Drug and Schedule builds to study team.
5. Once Schedule and Drugs spreadsheets are **complete**, **Primary Data Coordinator** adds the study to a ‘Request for Validation Meeting’ list + status of Beacon extract in SharePoint is changed to ‘Completed’.
6. Beacon Extract is routed to the PI for approval.
7. **Beacon Builds into EPIC are triaged** as ‘just-in time’ when there is a patient identified for protocol tx and SIV is scheduled. **Validation Meeting with Beacon team and clinical team** scheduled with Rsh Nurse, Pharmacist and Investigator only.

Name	Comments	Study Title	Study Nickname
 [Redacted]		Based on molecular features, TransPORTEC platform trials - MMRd-GREEN	EN...
 GYNE [Redacted] Syn...		A Phase 1 Study of [Redacted] Advanced Solid Tumors	[Redacted]

Initial Beacon Treatment Plan Extract and EPIC View:

Indicate the visit timepoints, locations, and durations that are required as per protocol. Copy the Cycle format for additional cycles, and add/Remove rows and columns to to reflect the visits required for the study protocol.

Cycle Number/Name	Cycle 1			
Cycle Length	X days			
Day Name	Clinic Day	Day X	Day X	Day X
Window	+/- X	+/- X	+/- X	+/- X
Visit Type	Visit Type	Comments	Duration of Visit / Frequency	
OP Clinic- Disease Site Clinic	Select		Select	Select
OP Clinic- Auto Day Hospital	Select		Select	Select
OP Clinic- 18 B Same Day	Not Applicable		Select	Select
OP Clinic-Phase 1 Appointment Request	Not Applicable		Select	Select
CDC-Treatment	Not Applicable		Select	Select

Hospital Visits

- OP Clinic- Disease Site Clinic
- OP Clinic- Auto Day Hospital
- OP Clinic- 18 B Same Day
- OP Clinic-Phase 1 Appointment Request
- CDC-Treatment
- MDHU-Treatment
- Auto Day Hospital-Treatment
- 18B-Treatment
- Convergence Centre-non pK/CSP team visit
- pk/CSP Team Appointment Request
- Out Patient Lab- Bloods and ECG Team
- Out Patient Lab- Bloods and ECG Team
- Overnight Stay
- Overnight Stay

▼ Cycle 3 — 10/1/2025 through 30/1/2025 (21 days), Started

▼ Clinic Assessment, Cycle 3 — Completed; Originally planned for 10/1/2025

▼ Appointment Requests

Clinic Appointment Request PM-LYMPHOMA CLINIC; DMO TRIAL VISIT



Future, Expected: 10/1/2025, Expires: 10/1/2026, 30 minutes, Schedule appointment at most 3 days before or at most 0 days after
Please book clinic appointment for 1:30pm

Lab Appointment Request



Future, Expected: 10/1/2025, Expires: 10/1/2026, Schedule appointment at most 3 days before or at most 0 days after

▼ Day 1, Cycle 3 — Completed; Released on 13/1/2025 10:04 AM; Originally planned for 13/1/2025

▼ Appointment Requests

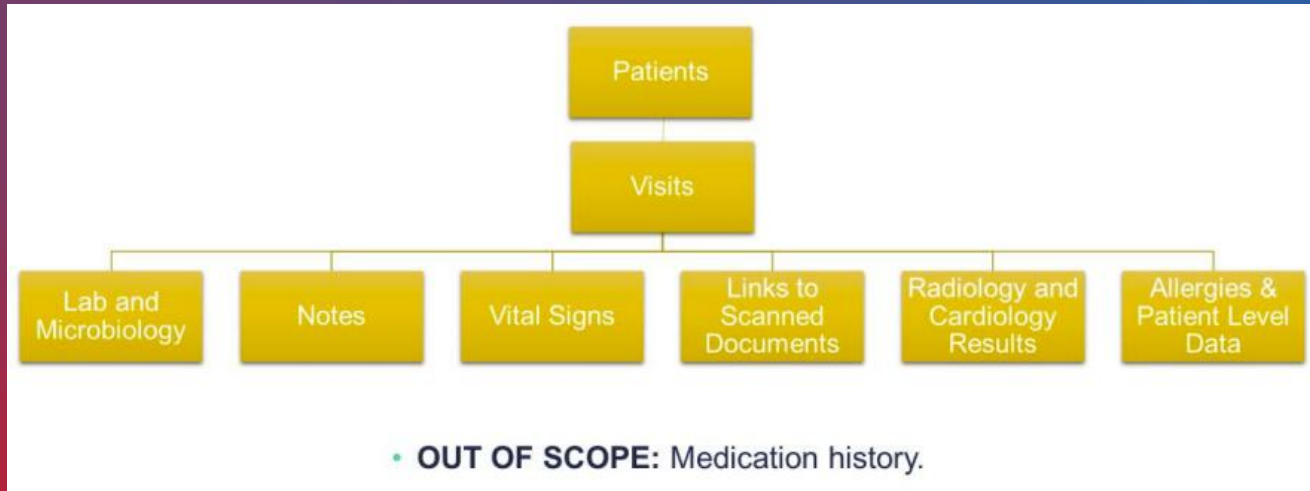
Infusion Appointment Request CDC



Future, Expected: 13/1/2025, Expires: 13/1/2026, 300 minutes, Schedule appointment at most 0 days before or at most 0 days after

Clinical Trial EPIC Data Structure:

1. **EPIC:** All patient data from 01-Jan-2017 and onward will be available including:



2. **EPR (Electronic Patient Record):** Medication History prior to June 2022 and all clinical encounters occurring prior to 01-Jan-2017 will be found here as read-only.

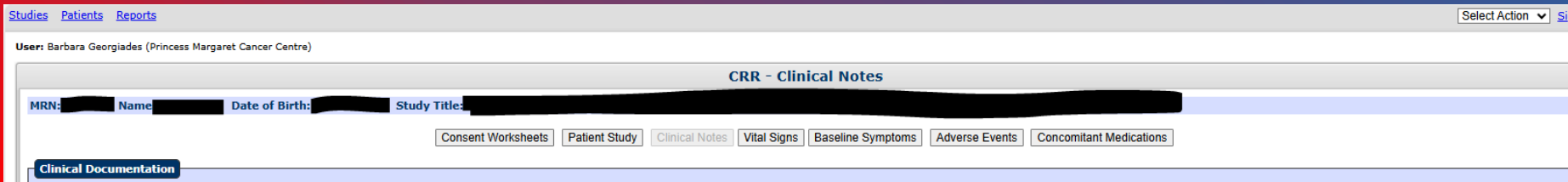
Clinical Trial EPIC Data Structure:

3. UHN Software: Clinical Research Record (Research Note, AEs & CONMEDs):

Overall golden rule:

If the patient has been enrolled prior to **04June2022** than all research source documentation (research notes, AEs, and CONMEDs) will be maintained in CRR.

If the patient is enrolled after **04Jun2022** will have their research source documentation maintained in EPIC.



The screenshot displays the EPIC Clinical Research Record (CRR) interface. At the top, there are navigation links for "Studies", "Patients", and "Reports", along with a "Select Action" dropdown menu. Below this, the user's name "User: Barbara Georgiades (Princess Margaret Cancer Centre)" is shown. The main header reads "CRR - Clinical Notes". A patient information bar includes fields for "MRN:", "Name", "Date of Birth:", and "Study Title:", all of which are redacted with black boxes. Below the patient information, there is a row of navigation tabs: "Consent Worksheets", "Patient Study", "Clinical Notes", "Vital Signs", "Baseline Symptoms", "Adverse Events", and "Concomitant Medications". At the bottom left, there is a "Clinical Documentation" button.

Clinical Trial EPIC Data Structure:

4. Paper Research Charts

These are still maintained at our CCRU and contains:

- ✓ Wet-signed ICFs,
- ✓ Screening worksheet if required,
- ✓ Medication diaries,
- ✓ Completed QoLs,
- ✓ Queries
- ✓ Eligibility Checklists
- ✓ Source regarding methods of external beam radiotherapy used ie. SBRT, VMAT, IGRT
- ✓ Central Radiotherapy or Correlatives Testing reports ie. Biomarker screening
- ✓ Registration Confirmation
- ✓ Labs completed outside UHN printed from ConnectingOntario or from efares.

EPIC Research Record:

The screenshot displays the EPIC Research Record interface. At the top, a navigation bar includes tabs for SnapShot, Chart Review, Results Review, Document List, Consents, Synopsis, Research Studies (selected), and Episodes of Care. The main content area is titled "Research Studies" and shows a list of studies. The first study, "IND 240", is highlighted. Its details include: Long Term Follow Up status, effective date of 6/9/2023, active start date of 9/11/2022, active end date of 6/9/2023, and an interventional study type. The study code and IRB# are redacted. The principal investigator is identified as [redacted] MD. The description of the study is "AN IMMUNOTHERAPY PLATFORM STUDY IN PLATINUM RESISTANT HIGH GRADE SEROUS OVARIAN CANCER (IPROC) [redacted]". The next study visit is listed as "No upcoming study visits". Two buttons, "Adverse Events" and "Data Capture", are highlighted with red boxes. On the right side, there are filters for "Show: Pre-Consent (0)", "Inactive (4)", and "Deleted (0)". A "Study Document" link is also visible.

Legal: [redacted]
Female: [redacted]
MRN: [redacted]
OHIP: [redacted]
Language: [redacted]
Code: Not on file (has ACP docs)
Communication Preferences: [redacted]

Storyboard Events and Statuses: None
COVID-19 Immunizations Received: 0
Isolation: None
Research Participant

Research Studies

Show: Pre-Consent (0) Inactive (4) Deleted (0)

IND 240	Status	Effective Date	Active Start Date	Active End Date	Study Type	Study Code	IRB#
Long Term Follow Up	6/9/2023	9/11/2022	6/9/2023	Interventional	[redacted]	[redacted]	

[Adverse Events](#) [Data Capture](#)

Description
AN IMMUNOTHERAPY PLATFORM STUDY IN PLATINUM RESISTANT HIGH GRADE SEROUS OVARIAN CANCER (IPROC) [redacted]

Next Study Visit
No upcoming study visits

Principal Investigator: [redacted] MD
Links
[Study Document](#)

EPIC Research Record:

✧ Patient SnapShot

SnapShot
 Race and Ethnicity

UHN RSH CONMED FORM - Venofer- Discontinued	Complete	31/05/2023	K
UHN RSH CONMED FORM - Restoralax- Active	Complete	19/04/2023	K
UHN RSH CONMED FORM - Hydromorphone- Discontinued	Complete	19/04/2023	K
UHN RSH CONMED FORM - Metoclopramide- Active	Complete	19/04/2023	K
UHN RSH CONMED FORM - Tylenol- Active	Complete		
UHN RSH CONMED FORM - Prochlorperazine- Discontinued	Complete		
UHN RSH CONMED FORM - Ferrous fumarate- Discontinued	Complete		

UHN RSH CONSENT WITHDRAWAL WORKSHEET

UHN RSH CONSENT WITHDRAWAL WORKSHEET - Consent Withdrawal Worksheet	In Progress	—	
UHN RSH MAIN CONSENT WORKSHEET			
UHN RSH MAIN CONSENT WORKSHEET - Study Information and Informed Consent Form Substudy A v. 19 Sep 2022	Complete	15/02/2023	K
UHN RSH MAIN CONSENT WORKSHEET - Pre Screening Informed Consent Form v. 22 Jun 2022	Complete	09/11/2022	L

EPIC Screening and Enrolment Logs

Patient	Month	Year of I	Sex	Participant ID	Study B	Consent Date	Registration Date	Enrollment Status
BA	July	1998	Male	1	Cohort 1 - C	2024-03-07		Safety Follow Up
			Male	2	Cohort 1 - C	2024-03-22		Safety Follow Up
			Male	3	Cohort 2 - F	2024-04-06		Safety Follow Up
			Male	4	Cohort 1 - C	2024-04-21		Safety Follow Up
			Female	1	Cohort 1 - C	2024-06-15		Safety Follow Up
			Male	2	Cohort 1 - C	2024-06-30		Safety Follow Up
			Male	3	Cohort 1 - C	2024-07-15		Long Term Follow Up
			Female	4	Cohort 2 - F	2024-07-30		Long Term Follow Up
			Female	5	Cohort 2 - F	2024-08-14		Safety Follow Up
			Female	6	Cohort 2 - F	2024-08-29		Safety Follow Up
			Female	7	Cohort 2 - F	2024-09-13		Safety Follow Up
			Male	8	Cohort 1 - C	2024-09-28		Long Term Follow Up
			Male	9	Cohort 2 - F	2024-10-13		Safety Follow Up
			Male	10	Cohort 2 - F	2024-10-28		Safety Follow Up
			Male	11	Cohort 1 - C	2024-11-12		Long Term Follow Up
			Female	12	Cohort 1 - C	2024-11-27		Safety Follow Up
			Female	13	Cohort 1 - C	2024-12-12		Long Term Follow Up
			Female	14	Cohort 2 - F	2024-12-27		Safety Follow Up

EPIC Screening and Enrolment Logs

Enrollment Details

Status:	Long Term Follow Up (6/9/2023)	Participant ID:	[REDACTED]
Active Start Date:	9/11/2022	Active End Date:	6/9/2023
Branch:	IND240A - Durvalumab + BA3011		
Last Modified:	6/9/2023		[REDACTED]

Enrollment Status History

Status	Status Effective Date
Waiting for Consent - Billing	4/11/2022
Inactive	
<u>Consented - In Screening - Billing</u>	<u>9/11/2022</u>
<u>Active</u>	
Enrolled - Active	8/3/2023
Long Term Follow Up	6/9/2023

 **Date Accrued [95188]**

EPIC Screening and Enrolment Logs

Research Study Maintenance - NRG-GU010: GUIDANCE [21-5914]

General Info

Users And Providers

Studies Activity Setup

Report Groupers

Study Calendar

Amendments

Automated Actions





Billing Setup

Review Settings

Participant Accrual

Study Calendar

Study Branches

Branch ID	Branch Name
 ARM 1	RT
 ARM 2	RT + ADT (LOW)
 ARM 3	RT + ADT (HIGH)
 ARM 4	RT + ADT + DAROLUTAMIDE

IND 240

Participant Details

Status **Long Term Follow Up** Status Effective Date **6/9/2023**

Active Start Date **9/11/2022** Active End Date **6/9/2023**

Participant ID **[REDACTED]** Branch **IND240A - Durvalumab + BA3011**

Reports are only as good as the data entered at the front-end.

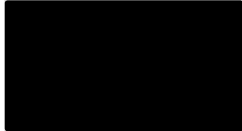
EPIC Study Branch Restrictions

Protocols [Open Selected Protocol](#)

Protocol	Protocol Order	Restrict to Branch
CT NRG-GU010 (GUIDANCE) (21-5914) ARM 2 AND 3 - RT + GOSERELIN OR LEUPROLIDE [1151010374]		RT + ADT (LOW)
CT NRG-GU010 (GUIDANCE) (21-5914) ARM 2 AND 3 - RT + GOSERELIN OR LEUPROLIDE [1151010374]		RT + ADT (HIGH)
CT NRG-GU010 (GUIDANCE) (21-5914) ARM 4 - RT + GOSERELIN OR LEUPROLIDE + DAROLUTAMIDE [11510103...		RT + ADT + DAROLUTAMIDE

Term Set

Medication Attributions

Medication	Restrict to Branch
 10) DAROLUTAMIDE 300 MG TABLET (UHN)	RT + ADT + DAROLUTAMIDE

Procedure Attributions

Procedure	Restrict to Branch
UHN RSH RADIATION REPORTING	

Staff Uptake improved when this EPIC Feature was known!

EPIC Screening and Enrolment Logs

Data entry standardization for Patient Statuses is also a must for a rich, report-pullable data set.

IND 240

Participant Details

Status **Long Term Follow Up** Status Effective Date 6/9/2023

Active Start Date 9/11/2022 Active End Date 6/9/2023

Participant ID XXXXXXXXXX Branch IND240A - Durvalumab + BA3011

Cancer Clinical Research Unit

Type/Bucket	Epic Patient Status	Definition
Inactive	Declined	The participant declined participation prior to signing consent
Pre-Consent	Waiting for Consent - Billing inactive	The study team is waiting for the participant to sign the consent
Active	Waiting for Consent - Billing active	The study team has verbal consent to book orders for the patient and billing is active. Patient is yet to sign a consent formally.
Active	Consented - In Screening - Billing Active	The participant has been consented and billing is active; eligibility is being determined (to be used when study billable procedures may be ordered).
Inactive	Consented - In Screening - Billing Inactive	The participant has been consented but billing is inactive; eligibility is being determined (to be used when no study billed procedures are required).
Inactive	Consent process stopped (patient neither accepted nor declined)	The patient was deemed ineligible before signing a consent.
Inactive	Ineligible (post-consent)	The participant has consented, but was never enrolled.
Active	Enrolled - Active	The participant has been enrolled and is currently involved in some sort of study intervention/treatment
Inactive	Withdrawn	Full consent withdrawal from all study activities; no further contact with the patient

EPIC Screening and Enrolment Logs

Research Studies | Chart | Add to List | Release to Study Monitor | Detail List - Original

Detail List | Explore | Filter | Clear All Filters | Re-run Report | Refresh Selected | Select All

Patient	Patient	Month of Birth	Year of Birth	Sex	MRN	Participant ID	Study Branch	Active Start Date	Enrollment Status	Enrollment Status Effective Date	Current Treatment Plan	Next OP Oncology Appointment Provider
[Redacted]	[Redacted]	April	[Redacted]	Male	[Redacted]	[Redacted]	Arm 5 - ND GBM Experimental Arm Troriluzole: TMZ (SOC), Radiation , Troriluzole	27/02/2024	Enrolled - Active	21/03/2024	CT GCAR-7213 GBM AGILE (20-5104) - NEWLY DIAGNOSED: TEMOZOLOM... + TRORILUZOLE	[Redacted] MD
[Redacted]	[Redacted]	Novem...	[Redacted]	Male	[Redacted]	[Redacted]	Arm 5 - ND GBM Experimental Arm Troriluzole: TMZ (SOC), Radiation , Troriluzole	20/06/2024	Long Term Follow Up	13/12/2024	CNS TEMOZOLOM... OD X 5 DAYS	[Redacted] MD
[Redacted]	[Redacted]	July	[Redacted]	Female	[Redacted]	[Redacted]	Arm 1 - Recurrent GBM Control Arm:	29/11/2023	Long Term Follow Up	28/01/2024	CT GCAR-7213 GBM AGILE (20-5104)	[Redacted]

Selected rows: 1 | 33 of 40 results match filters



Find Patients Associated with Research Studies

EPIC Screening and Enrolment Logs

Screening and Enrollment Report Column Guide

Required Columns

Column Name	Column ID
Patient Name	1004
IMG Patient Initials	52505
Patient Month of Birth	4017
Patient Year of Birth (EPT)	2296
Patient DOB	54500
Patient Sex	54501
Patient MRN	1003
Participant ID	95000
Research: Patient Study Branch	95076
Active Start Date (Date of CONSENT)***	95008
Active End Date (Status = 'Completed')	95009
Enrollment Status	95003
Enrollment Status Effective Date	95184
Time Since Status Change	95185
Current Oncology Treatment Plan -----	101194 -----
UHN ONCBCN DISPLAY ONCOLOGY TREATMENT 1 AND 2 EPISODE COLUMN (use if pt has multiple active txs ex. Apheresis and chemotherapy)	11502074

*If highlighted in green, these stay in your screening and enrollment log when exported to excel. This can be filed in regulatory binders.

**Only column to manually input is the 'enrollment/registration date' for patients.

*** date of consent = date screened as well to satisfy required institutional enrollment log standards.

Columns to-add for additional use-cases

Column Name	Column ID	Additional Use-Case
CE Status	72500	If a patient has an important medical event at an external hospital with

EPIC Screening and Enrolment Logs

Patient	Month	Year of I	Sex	Participant ID	Study B	Consent Date	Registration Date	Enrollment Status
BA	July	1998	Male	1	Cohort 1 - C	2024-03-07		Safety Follow Up
			Male	2	Cohort 1 - C	2024-03-22		Safety Follow Up
			Male	3	Cohort 2 - F	2024-04-06		Safety Follow Up
			Male	4	Cohort 1 - C	2024-04-21		Safety Follow Up
			Female	1	Cohort 1 - C	2024-06-15		Safety Follow Up
			Male	2	Cohort 1 - C	2024-06-30		Safety Follow Up
			Male	3	Cohort 1 - C	2024-07-15		Long Term Follow Up
			Female	4	Cohort 2 - F	2024-07-30		Long Term Follow Up
			Female	5	Cohort 2 - F	2024-08-14		Safety Follow Up
			Female	6	Cohort 2 - F	2024-08-29		Safety Follow Up
			Female	7	Cohort 2 - F	2024-09-13		Safety Follow Up
			Male	8	Cohort 1 - C	2024-09-28		Long Term Follow Up
			Male	9	Cohort 2 - F	2024-10-13		Safety Follow Up
			Male	10	Cohort 2 - F	2024-10-28		Safety Follow Up
			Male	11	Cohort 1 - C	2024-11-12		Long Term Follow Up
			Female	12	Cohort 1 - C	2024-11-27		Safety Follow Up
			Female	13	Cohort 1 - C	2024-12-12		Long Term Follow Up
			Female	14	Cohort 2 - F	2024-12-27		Safety Follow Up

CRF Completion with AE Reports – patient AEs since last study visit:

Detail List | Explore

Filter

Filter for **Resolved** and **Unresolved** AEs

Event Name	Resolved	Yes/No	Severity	Start Date	End Date	Resolution Date	Notes
Abdominal pain	Resolved	No	Mild [1]	22/08/2022	22/08/2022	23/05/2023	INV (21-5914) (NRG-GU010) darolutamide tablet: Possible leuprolide acetate: Possible goserelin acetate: — Radiation: Possible
Abdominal pain	Resolved	Yes	Moderate [2]	22/11/2022	22/11/2022	22/11/2022	leuprolide acetate: Unrelated goserelin acetate: Unrelated Radiation: Unrelated
Abdominal pain	Resolved	Yes	Moderate [2]	17/12/2022	17/12/2022	20/12/2022	leuprolide acetate: Unrelated goserelin acetate: Unrelated Radiation: Unrelated
Alanine aminotransferase increased	Resolved	No	Mild [1]	12/1			
Alanine aminotransferase increased	Resolved	No	Severe [3]	20/12/2022			goserelin acetate: Unrelated Radiation: Unrelated



Since using this I have never referred to the AE section in patient charts!

Filter for Resolved AEs

Detail List | Explore

Filter | Clear All Filters

Re-run Report | Select All

Choose a column to filter

- Participant ID
Equals [Redacted]
- Adverse Event Last Edited Date
From 3/4/2024 12:00 AM
- Resolved Date**
Has value

Add Another Filter

Event Name	Patient Name	Reporting User	Adverse Event Last Editing User	Adverse Event Last Edited Date	Adverse Event Creation Date	Adverse Event Time Between Creation and Last Review
Hiccups	[Redacted]	A	[Redacted]	08/04/2024	08/04/2024	29d 02h 15m
Nausea	[Redacted]	A	[Redacted]	08/04/2024	08/04/2024	29d 02h 16m

Research Adverse Event Details

Hiccups

Current Data

Serious	Expected	Start Date	Resolved Date	Current Grade
No	No	24/3/2024	5/4/2024	1

Selected rows: 1

5 of 235 results match filters

Filter for Unresolved AEs

Detail List | Explore

Filter | Clear All Filters | Re-run Report | Select All

Choose a column to filter

- Participant ID
Equals [Redacted]
- Adverse Event Last Edited Date
From 3/4/2024 12:00 AM
- Resolved Date**
Has no value

+ Add Another Filter

Event Name	Patient Name	Reporting User	Adverse Event Last Editing User	Adverse Event Last Edited Date	Adverse Event Creation Date	Adverse Event Time Between Creation and Last Review
Alanine aminotransferase increased	[Redacted]	[Redacted]	[Redacted]	22/04/2024	22/04/2024	15d 01h 55m
Aspartate aminotransferase increased	[Redacted]	[Redacted]	[Redacted]	22/04/2024	22/04/2024	15d 01h 55m

Research Adverse Event Details

Alanine aminotransferase increased

Current Data

Serious	Expected	Start Date	Resolved Date	Current Grade
No	No	22/4/2024	—	2

Selected rows: 1

3 of 235 results match filters

EPIC Data Capture Form - Main Consent Worksheet

Main

Instance Name:

REB Version Date:

Date of initial discussion about the study by the study coordinator:

Time of initial discussion about the study by the study coordinator:

The informed consent discussion included explanations of the following points as outlined in the Informed Consent Form:

Select

All

The purpose of the study

The approximate number of participant's involved in the study

The expected duration of the participant's participation

The study involves research

Select

All

The study treatment(s) / intervention(s) and the possible random assignment to each treatment as applicable

The participant's responsibilities

Those aspects of the study that are experimental

Select

All

The reasonably foreseeable risks or inconveniences to the participant and, if applicable, to embryo, fetus or nursing infant

The reasonably expected benefits

The alternative procedure(s) or treatment(s) available to the participant and their potential benefits/risks

The compensation and/or treatment available to the participant in the event of study-related injury

Select

All

The anticipated prorated payment, if any, to the participant for participating in the study

The anticipated expenses, if any, to the participant for participating in the study

Discussion of the above selected topics were completed on:

Was the patient assisted during the consent process? Yes No

Informed Consent Outcome

The patient was given ample time and opportunity to ask about the study and

All questions were answered to the satisfaction of the patient and they appreciate the information presented

Did the patient agree to participate in the study?

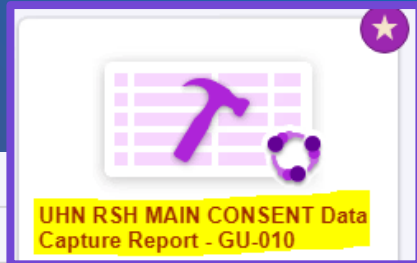
Accompanying Narrative Note:

Main Consent Worksheet Report can Flag Patients Needing Re-Consent

Use-case:

Previous mICF dated 11Jan23;

***New* Consent Update to sign= 18Sep23.**



Detail List Explore

Filter

Patient	Participant ID	Status	Form Name	SmartForm	REB version date	Consent date	UHN RSH Form Status	Date of initial disc coordinator
[REDACTED]	[REDACTED]	Withdrawn	Initial Consent	UHN RSH MAIN CONSENT WORKSHEET	15 Mar 2022	20 Jul 2022	Complete [4]	19 Jul 2022
[REDACTED]	[REDACTED]	Safety Follow Up	consent	UHN RSH MAIN CONSENT WORKSHEET	15 Mar 2022	14 Feb 2024	Complete [4]	15 Feb 2024
[REDACTED]	[REDACTED]	Withdrawn	initial consent	UHN RSH MAIN CONSENT WORKSHEET	15 Mar 2022	20 Dec 2023	Complete [4]	20 Dec 2023
[REDACTED]	[REDACTED]	Withdrawn	initial consent	UHN RSH MAIN CONSENT WORKSHEET	15 Mar 2022	08 Nov 2022	Complete [4]	28 Oct 2022

Main Consent Worksheet Report can Flag Patients Needing Re-Consent

Detail List | Explore

Filter | Clear All Filters

Choose a column to filter

- SmartForm
Equals UHN RSH MAIN CONSENT WORKSHEET
- REB version date
To 11/1/2023
- Add Another Filter

Patient	Participant ID	Status	Form Name	SmartForm
[REDACTED]	[REDACTED]	Completed	Study Information and Informed Consent Form	UHN RSH MAIN CONSENT WORKSHEET
[REDACTED]	[REDACTED]	Long Term Follow Up	Study Information and Informed	UHN RSH MAIN CONSENT WORKSHEET

Research Data Capture Form History

UHN RSH MAIN CONSENT WORKSHEET - Study Information and Informed Consent Form

Selected rows: 1

10 of 51 results match filters

Use-case:

Previous mICF dated 11Jan23



QC-ing Re-Consent Worksheets: Report Filter Combo

Filter Clear All Filters

Choose a column to filter + ?

- SmartForm** 🗑️
Equals UHN RSH MAIN CONSENT WORKSHEET
- REB version date** 🗑️
To 11/1/2023
- Participant ID** 🗑️
Equals CAKO0001
CAMP0001
CAMP0002
CAMP0003
More values: 6

SmartForm + ?

UHN RSH RE-CONSENT WORKSHEET

Contains:

From:

To:

Value? Has Value Has No Value

✔ Accept ✘ Cancel

- Participant ID** 🗑️
Equals CAKO0001
CAMP0001
CAMP0002
CAMP0003
More values: 6

Clear All Filters

QC-ing Re-Consent Worksheets

View Form | Research Studies | Chart | Detail List - Original

Detail List | Explore

Filter | Clear All Filters | Re-run Report | Select All

Choose a column to filter

- SmartForm
 - Equals UHN RSH RE-CONSENT WORKSHEET
- Participant ID
 - Equals CAKO0001
 - CAMP0001
 - CAMP0002
 - CAMP0003
 - More values: 6

+ Add Another Filter

Clear All Filters

Selected rows: 1

Patient	Participant ID	Status	Form Name	SmartForm
[REDACTED]	[REDACTED]	Completed	Informed Consent - Re-consent to HD.11	UHN RSH RE-CONSENT WORKSHEET
[REDACTED]	[REDACTED]	Long Term Follow Up	New Study Information Consent	UHN RSH RE-CONSENT WORKSHEET

Research Data Capture Form History

UHN RSH RE-CONSENT WORKSHEET - Informed Consent - Re-consent to HD.11

10 of 51 results match filters

QC-ing Re-Consent Worksheets

[Detail List](#) [Explore](#)

[Filter](#) [Clear All Filters](#)
[Re-run Report](#) [Select All](#)

Choose a column to filter + ?

How was the consent provided?	Next OP Oncology Appointment Provider	Next Appt Date by Spec	Date of initial discussion about study coordinator
Verbal	[REDACTED]	13/01/2025	
Verbal	[REDACTED]	13/12/2024	

SmartForm
 Equals UHN RSH RE-CONSENT WORKSHEET

Participant ID
 Equals CAKO0001
 CAMP0001
 CAMP0002
 CAMP0003
 More values: 6

REB version date
 Has no value

[Add Another Filter](#)
[Clear All Filters](#)

Selected rows: 1

[Research Data Capture Form History](#)

UHN RSH RE-CONSENT WORKSHEET - New Study Information Consent Update Form 18-Sep-2023

Patient: [REDACTED]

7 of 51 results match filters

Other Cool Research Reports: Past and Current RSH Treatment Plans

Detail List Explore

Filter Clear All Filters

Linked Participant ID	Plan Name	Plan Start Date	Plan End Date	Plan Discontinued On	D/C Reason	Plan Status	Next Treatment	Next Treatment Day	Treatment Goal	Active Problems
	CT HD.11 (22-5318) GDP	26/02/2024	08/06/2024	11/10/2024 04:04 PM EDT	Therapy Complete	Inactive			Curative	Lymphoma
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Other (see comment)	Inactive			Curative	Hodgkin lymphom UNSTAGED
	CT HD.11 (22-5318) GDP				Toxicity/Com...	Inactive	02/11/23	Clinic Assessment, Cycle 2	Curative	Hodgkin lymphom UNSTAGED
	CT HD.11 (22-5318) GDP				Other (see comment)	Inactive	29/01/24	Day 8, Cycle 3	Curative	Hodgkin lymphom UNSTAGED
	CT HD.11 (22-5318) GDP				Progressive Disease	Inactive	16/08/23	Clinic Assessment, Cycle 4	Curative	Hodgkin lymphom
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Other (see comment)	Inactive	13/10/23	Day 1, Cycle 3	Curative	Hodgkin lymphom UNSTAGED
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Therapy Complete	Inactive			Curative	Hodgkin's lymphom UNSTAGED
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Therapy Complete	Inactive	30/04/24	Day 1, Cycle 4	Curative	Hodgkin lymphom UNSTAGED
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Therapy Complete	Inactive			Curative	Hodgkin lymphom UNSTAGED
	CT HD.11 (22-5318) GDP				Progression	Inactive	17/07/23	Clinic Assessment, Cycle 4	Curative	Lymphoma Hodgkin lymphom UNSTAGED
	CT HD.11 (22-5318)				Therapy	Inactive			Curative	Hodgkin lymphom

Other Cool Research Reports: Admission Reports for Rsh patients

Admission Date	Patient Class	Admit Status	Discharge Date	Department	Point of Origin	LoS	Confirmation Status	Admission Type	Diagnosis	Acuity
18/06/2024	Inpatient	Discharged	26/06/2024	[REDACTED]	Hospital (non-UHN)	8	Confirmed	Urgent/Eme...	Hodgkin lymphoma	
05/06/2024	Inpatient	Discharged	16/06/2024	[REDACTED]	Home	11	Confirmed	Scheduled/...	Hodgkin lymphoma	
24/03/2024	Emergency	Discharged	24/03/2024	[REDACTED]	Home	1	Confirmed	Urgent/Eme...		3
03/01/2025	Emergency	Admission		[REDACTED]	Home	1	Confirmed	Urgent/Eme...		2
28/12/2024	Inpatient	Discharged	31/12/2024	[REDACTED]	CritiCall	3	Confirmed	Urgent/Eme...	Hodgkin lymphoma	
19/06/2024	Inpatient	Discharged	07/07/2024	[REDACTED]	Home	18	Confirmed	Scheduled/...	Lymphoma	
08/05/2024	Inpatient	Discharged	17/05/2024	[REDACTED]	Other	9	Confirmed	Urgent/Eme...	Bacteremia	2
22/09/2024	Inpatient	Discharged	29/09/2024	[REDACTED]	Home	7	Confirmed	Urgent/Eme...	Non Hodgkin's lymphoma	
24/01/2024	Inpatient	Discharged	09/02/2024	[REDACTED]	Home	16	Confirmed	Scheduled/...	Hodgkin lymphoma	
23/02/2024	Inpatient	Discharged	09/03/2024	[REDACTED]	Home	15	Confirmed	Scheduled/...	Hodgkin lymphoma	
01/06/2024	Inpatient	Discharged	05/06/2024	[REDACTED]	Home	4	Confirmed	Scheduled/...	Fever	

CTSU EPIC Research Report Education:



Offered CCRU-wide Education sessions for 5 Reports:

1. The Screening and Enrollment Report (Report Level: Introductory)
2. The Appointments Report (Report Level: Intermediate)
3. The Adverse Events Report (Report Level: Intermediate)
4. The Data Capture Form: CONMED Report (Report Level: Advanced)
5. The Data Capture Form: Consenting Worksheets Report (Report Level: Advanced)

1 hour lecture style with demos in EPIC PLY. Report Creation and 3 Use-Cases are covered.

CTSU EPIC Research Report Education:



Offered 4 In-person EPIC Labs within the CTSU:

1. Creating your Study's Screening and Enrollment Report
2. Use-Case: Using your S+E Report for Annual Renewals and exporting for ISF
3. Creating your Adverse Event Report and Use-case for AE CRF Completion of 3 patient visits.
4. EPIC Study Maintenance: setting Study Branches and Branch Restrictions at Study Start-Up

1 hour in-person and electronic session.

30 minute lesson then, 30 minute 'click-around time' with staff

CTSU EPIC Research Report Education:



Guidance Documents for each Report:

1. Standardized Column Guides
2. Use-Case Timelines
3. Quick-grab Use-Case Demo Videos in Shared Folder

Screening and Enrollment Report Use-Case Timelines		
Report Use-Case	Clinical Trial Type	Timeline
Routinely Running the Study's Screening and Enrollment Report. Filter Enrollment statuses for: -Consented, -Ineligible, -Interested, -Identified, -Declined, -Disqualified and, -Waiting for Consent	Actively accruing trials	Weekly report runs to have an up-to-date snapshot of upcoming patient enrollments.
Exporting a current screening and enrollment report from EPIC to your computer	Monitored or audited studies	In preparation for the MV to file in your ISF.
Quality Control: checking all study patients are tagged to a study branch -Not required for single arm trials -Required for blinded trials	Actively accruing trials	Every 3 months for new accruals.
	Closed to accrual trials (not applicable to patients enrolled before 04Jun22 and documentation is <u>still</u> maintained in CRR).	One time for patients maintained in EPIC.

Research Adverse Event Report Column Guide

Required Columns

Column Name	Column ID
Adverse Event Name	95014
Participant ID	95000
Patient Name (EPT)	85
Patient MRN	1003
Problem Status	95075
Serious Adverse Event	95015
Adverse Event Current Grade	95058
Adverse Event Current Grade Start Date	95057
Adverse Event Grade History	95056
Adverse Event Grade Start History	95055
Problem Resolved Date	95048
Adverse Event Attributions	95097
Adverse Event Comments	95096
Adverse Event Expected	95020
Adverse Event Last Edited Date	112092

CTSU EPIC Research Report Sharing for Staff:



Transferring a Report Template to your team is possible through 'Share Report':

1. Already Includes Standard Columns

Name: **GU010 Screening and Enrollment Report - SY**

Email Settings [Copy Link](#) Public Private

Description:

Your View as Report Creator

Created: 17/9/2024 11:12 AM
Created by: YOUNUS, SARAH [REDACTED]
Owned by: YOUNUS, SARAH [REDACTED]

Last modified: 24/9/2024 [REDACTED]
Modified by: YOUNUS, SARAH [REDACTED]
Record ID: [REDACTED]

Share Report

With Users

GEORGIADIS, BARBARA [REDACTED]

User Notification

Send me an In Basket notification when report is ready to view: Yes No

[Run](#) [Save](#) [Save As](#) [Restore](#) [Close](#)

View as Report Receiver

sy

- My Favorites
- My Content
- Approved

Search Results

GU010 Screening and Enrollment Report - SY

Patient Managem... +1 tag

Content Type

- Dashboards
- SlicerDicer
- Components
- Workbench Reports
- Report Links

Tags

- HD11
- IND244
- Education
- Report Troubleshoot

Advanced

- Include Dashboard Views

Find Patients Associated with Research Studies

CTSU EPIC Research Report Sharing for Staff:



Transferring a Report Template to your team is possible through 'Share Report':
2. Team Member needs to switch Research study Criteria to their study and 'Save As' to then own the report.

The screenshot displays the 'Report Settings - GU010 Screening and Enrollment Report - SY [4298130]' window. The interface includes tabs for 'Criteria', 'Display', 'Appearance', 'Summary', 'Print Layout', 'Toolbar', 'Override', and 'General'. A search bar labeled 'Find Research Patients' is present. The main content area is divided into sections: 'Patient base' (Patients on My Research Studies), 'Study and/or status' (Research Study table), 'Enrollment status type' (none), and 'Study status' (none). A 'Report Settings' dialog box is open, prompting 'Enter a new report name:' with the text 'GCAR Screening and Enrollment Report - BG' entered. The dialog has 'Accept' and 'Cancel' buttons. At the bottom, there are buttons for 'Run', 'Save', 'Save As', 'Restore', and 'Close'. The 'Save As' button is highlighted in yellow.

Your Views as Report Receiver

Criteria Find Criteria Enter a search term, or click the search icon to browse available criteria

Patient base Patients on My Research Studies

Study and/or status Research Study

Research Study
1 GCAR AGILE
2

Criterion Logic OR

Enrollment status type (none)

Study status (none)

Study Code Study Name

[REDACTED]	PR.22
[REDACTED]	NRG-GU010: GUIDANCE
[REDACTED]	GCAR AGILE

CTSU EPIC Research Report Sharing for Staff:



Name:

ORIGINAL

Description:

Created: 17/9/2024 [REDACTED] Last modified: [REDACTED] PM
Created by: YOUNUS, SARAH [REDACTED] Modified by: YOUNUS, SARAH [REDACTED]
Owned by: YOUNUS, SARAH [REDACTED] Record ID: [REDACTED]

Criteria Display Appearance Summary Print Layout Toolbar Override **General**

Name:

NEW!

Description:

Created: 27/1/2025 [REDACTED] Last modified: 27/1/2025 [REDACTED]
Created by: GEORGIADES, BARBARA [REDACTED] Modified by: GEORGIADES, BARBARA [REDACTED]
Owned by: GEORGIADES, BARBARA [REDACTED] Record ID: [REDACTED]



Thank You!

Do you have any questions? Email us!

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