UHN Princess Margaret Cancer Centre
Clinical Trials Support Unit

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.

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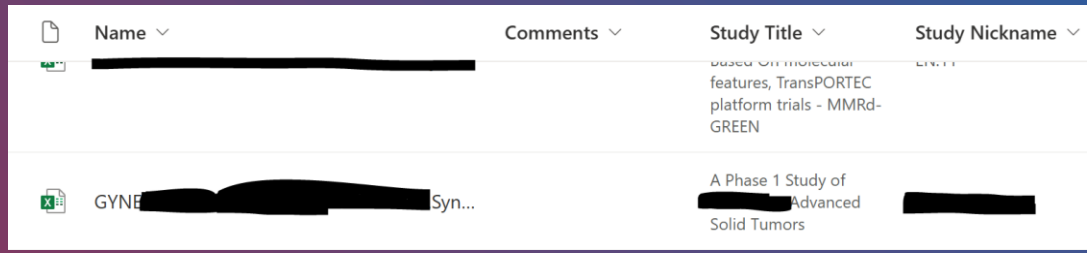
Initial Beacon Treatment Plan Build:

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.



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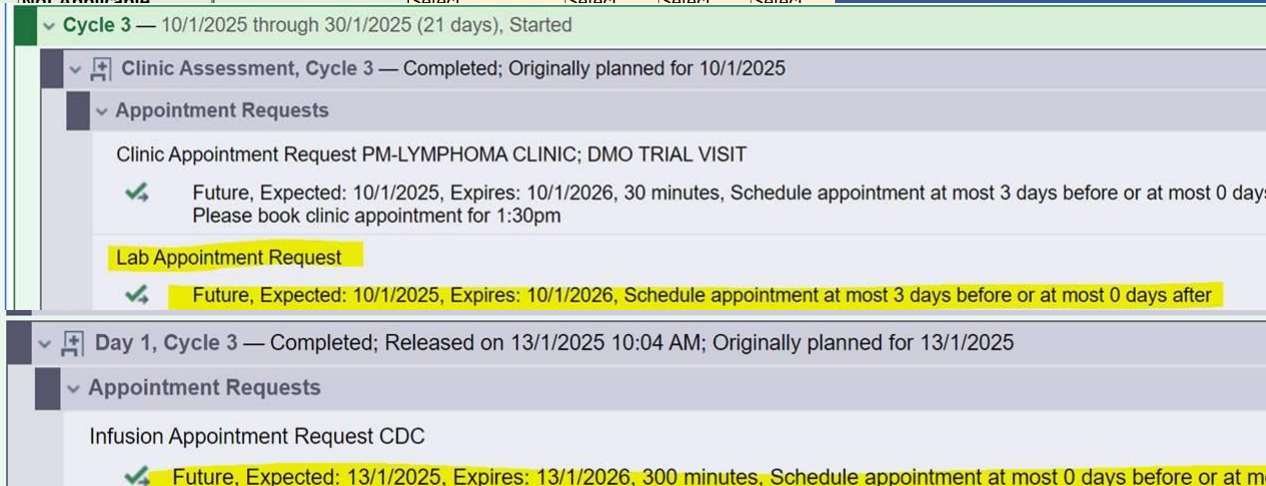
Initial Beacon Treatment Plan Extract and EPIC View:

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.

	Visit Type	Visit Type	Comments	Cycle Number/Name	Cycle 1			
				Cycle Length	X days			
				Day Name	Clinic Day	Day X	Day X	Day X
				Window	+/- X	+/- X	+/- X	+/- X
					Duration of Visit / Frequency			
Hospital Visits	OP Clinic- Disease Site Clinic	Select			Select	Select	Select	Select
	OP Clinic- Auto Day Hospital	Select			Select	Select	Select	Select
	OP Clinic- 18 B Same Day	Not Applicable			Select	Select	Select	Select
	OP Clinic-Phase 1 Appointment Request	Not Applicable			Select	Select	Select	Select
	CDC-Treatment	Not Applicable			Select	Select	Select	Select
	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							
	Out Patient Lab- Bloods and ECG Team							
	Overnight Stay							
	Overnight Stay							



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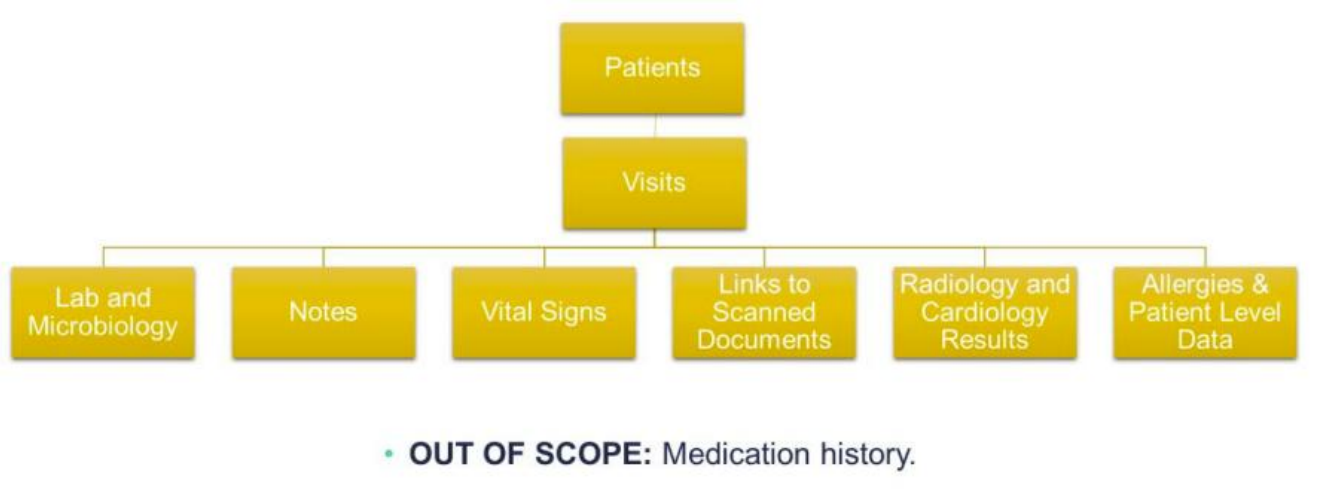
Clinical Trial EPIC Data Structure:

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 occuring prior to 01-Jan-2017 will be found here as read-only.

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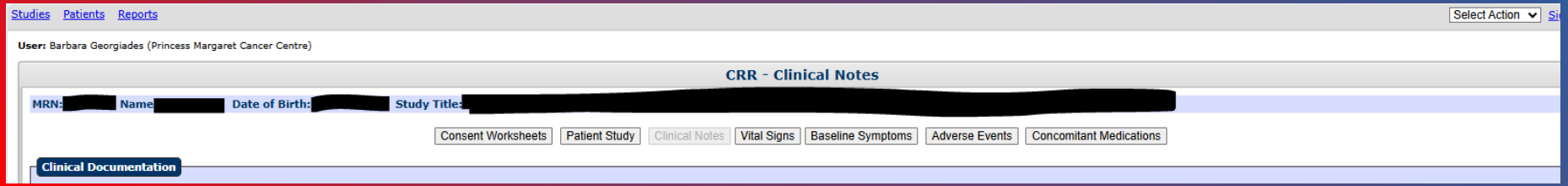
Clinical Trial EPIC Data Structure:

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.



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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 efaxes.

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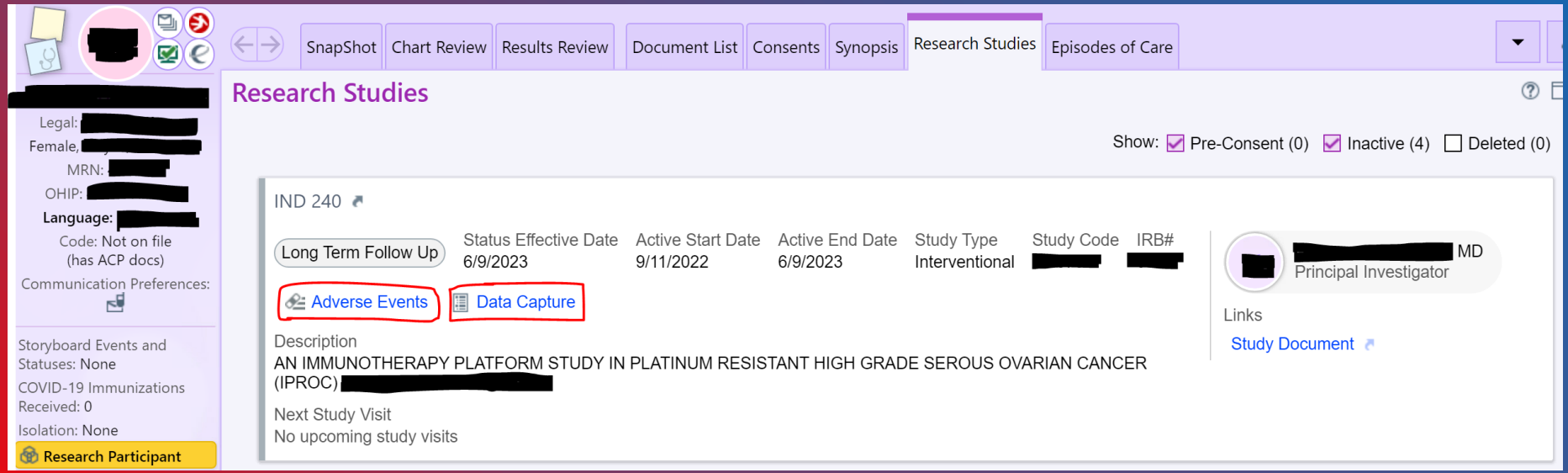
EPIC Research Record:



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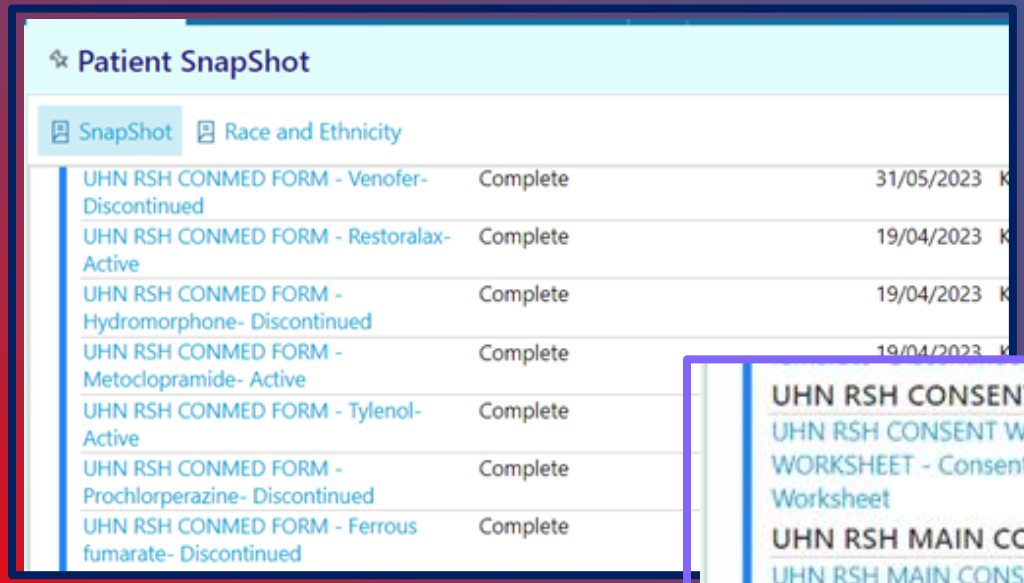
EPIC Research Record:



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EPIC Screening and Enrolment Logs

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

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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 Inactive	4/11/2022
Consented - In Screening - Billing Active	9/11/2022
Enrolled - Active	8/3/2023
Long Term Follow Up	6/9/2023

→ Date Accrued [95188]

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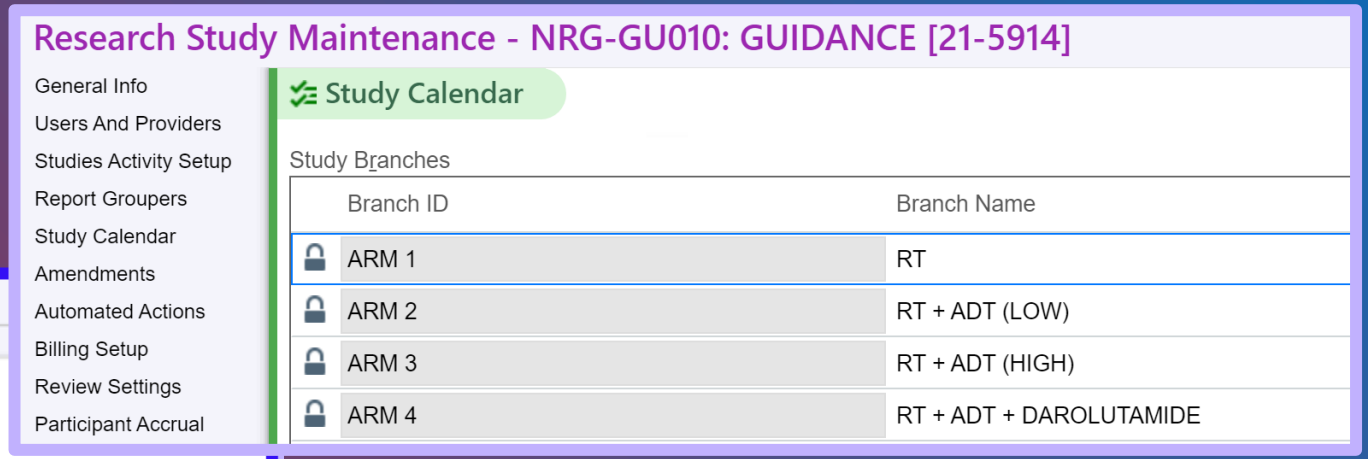
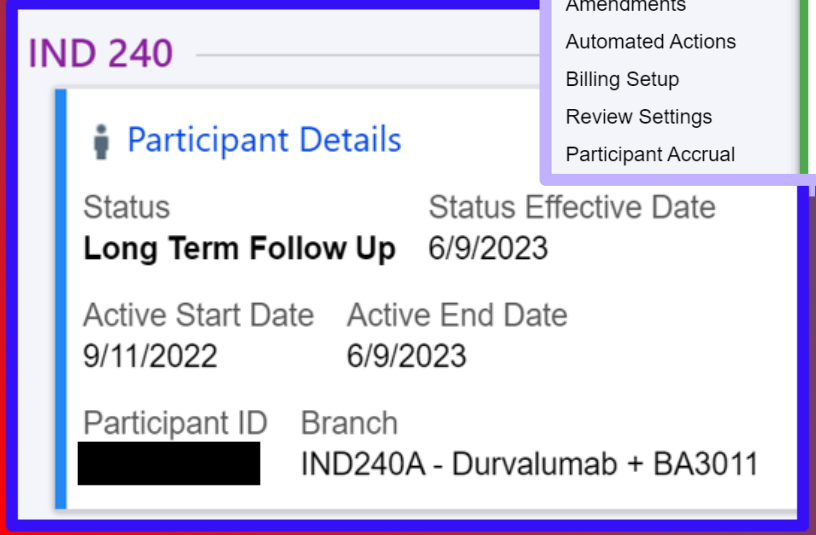
EPIC Screening and Enrolment Logs





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

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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

UHN RSH CTCAE VERSION 5

Medication Attributions

Medication	Restrict to Branch
[redacted]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!

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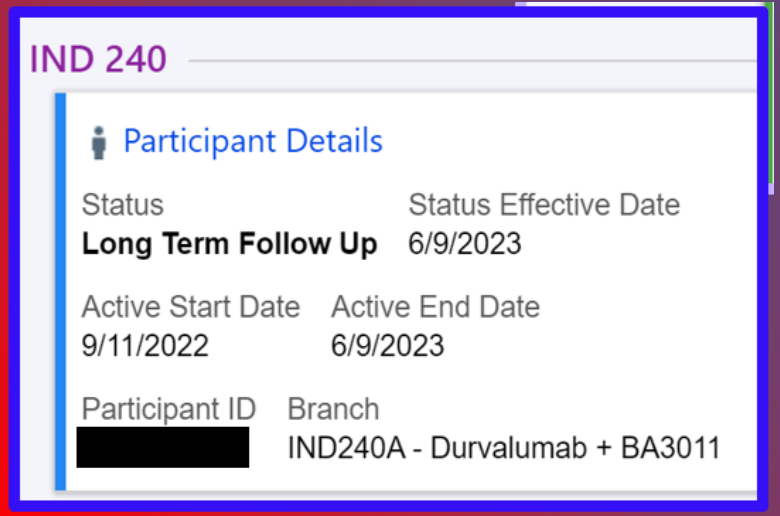
EPIC Screening and Enrolment Logs

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



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

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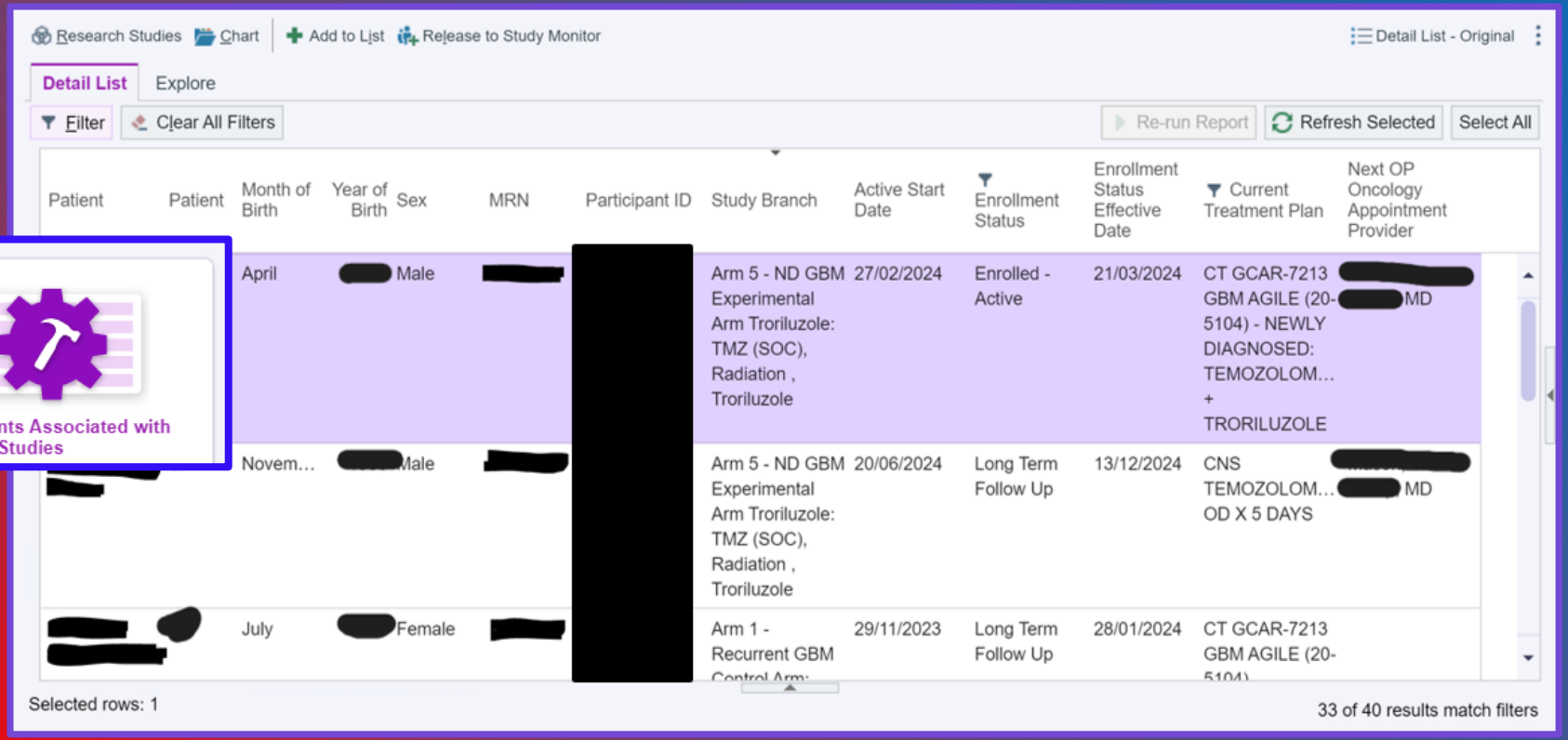
EPIC Screening and Enrolment Logs



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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 ---------- UHN ONCBCN DISPLAY ONCOLOGY TREATMENT 1 AND 2 EPISODE COLUMN (use if pt has multiple active txs ex. Apheresis and chemotherapy)	101194 ---------- 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

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[redacted]			Male	2	Cohort 1 -	2024-03-22		Safety Follow Up
			Male	3	Cohort 2 -	2024-04-06		Safety Follow Up
			Male	4	Cohort 1 -	2024-04-21		Safety Follow Up
			Female	1	Cohort 1 -	2024-06-15		Safety Follow Up
			Male	2	Cohort 1 -	2024-06-30		Safety Follow Up
			Male	3	Cohort 1 -	2024-07-15		Long Term Follow Up
			Female	4	Cohort 2 -	2024-07-30		Long Term Follow Up
			Female	5	Cohort 2 -	2024-08-14		Safety Follow Up
			Female	6	Cohort 2 -	2024-08-29		Safety Follow Up
			Female	7	Cohort 2 -	2024-09-13		Safety Follow Up
			Male	8	Cohort 1 -	2024-09-28		Long Term Follow Up
			Male	9	Cohort 2 -	2024-10-13		Safety Follow Up
			Male	10	Cohort 2 -	2024-10-28		Safety Follow Up
			Male	11	Cohort 1 -	2024-11-12		Long Term Follow Up
			Female	12	Cohort 1 -	2024-11-27		Safety Follow Up
			Female	13	Cohort 1 -	2024-12-12		Long Term Follow Up
			Female	14	Cohort 2 -	2024-12-27		Safety Follow Up

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

Detail List | Explore

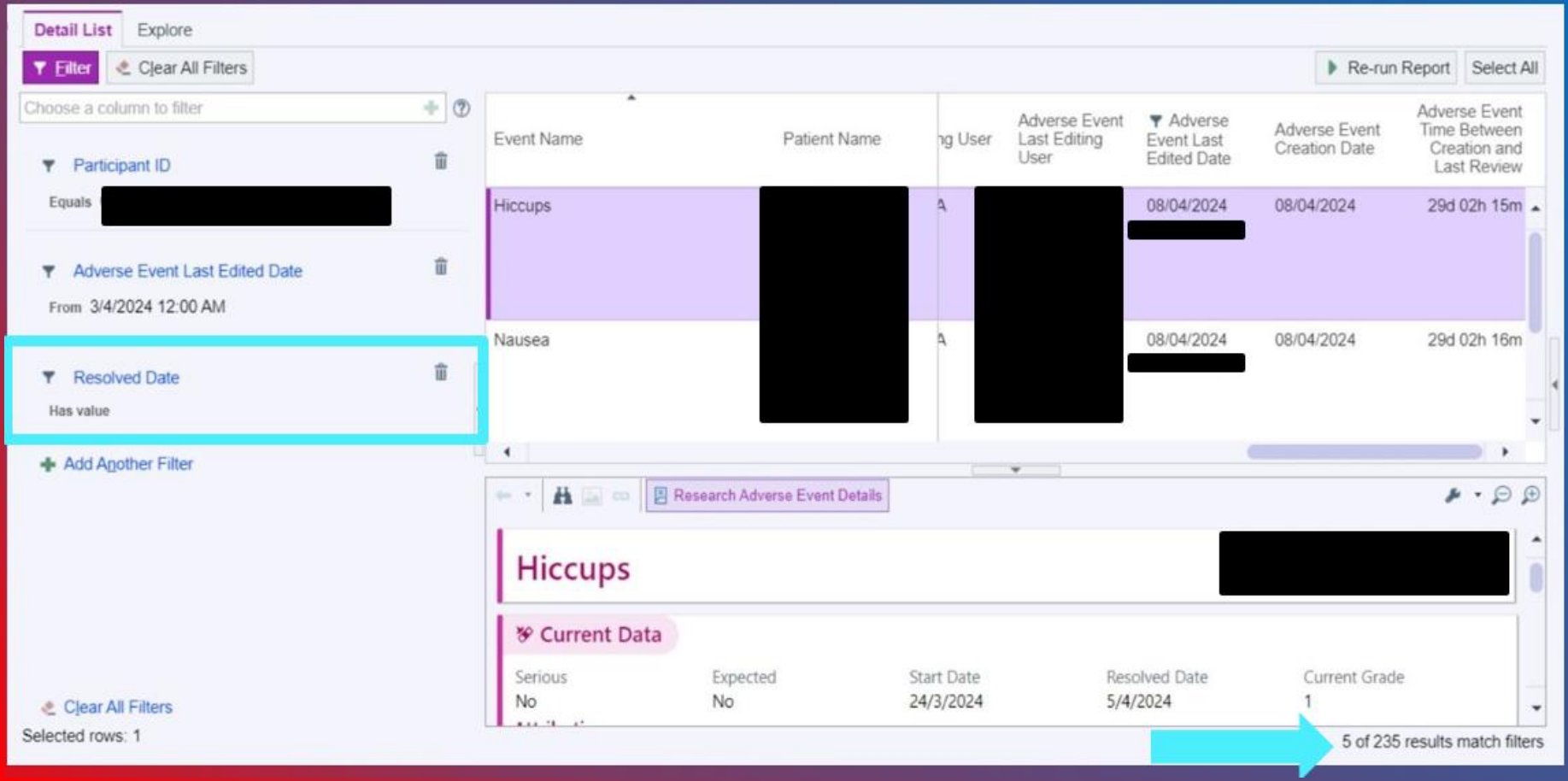
Filter | Select All

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

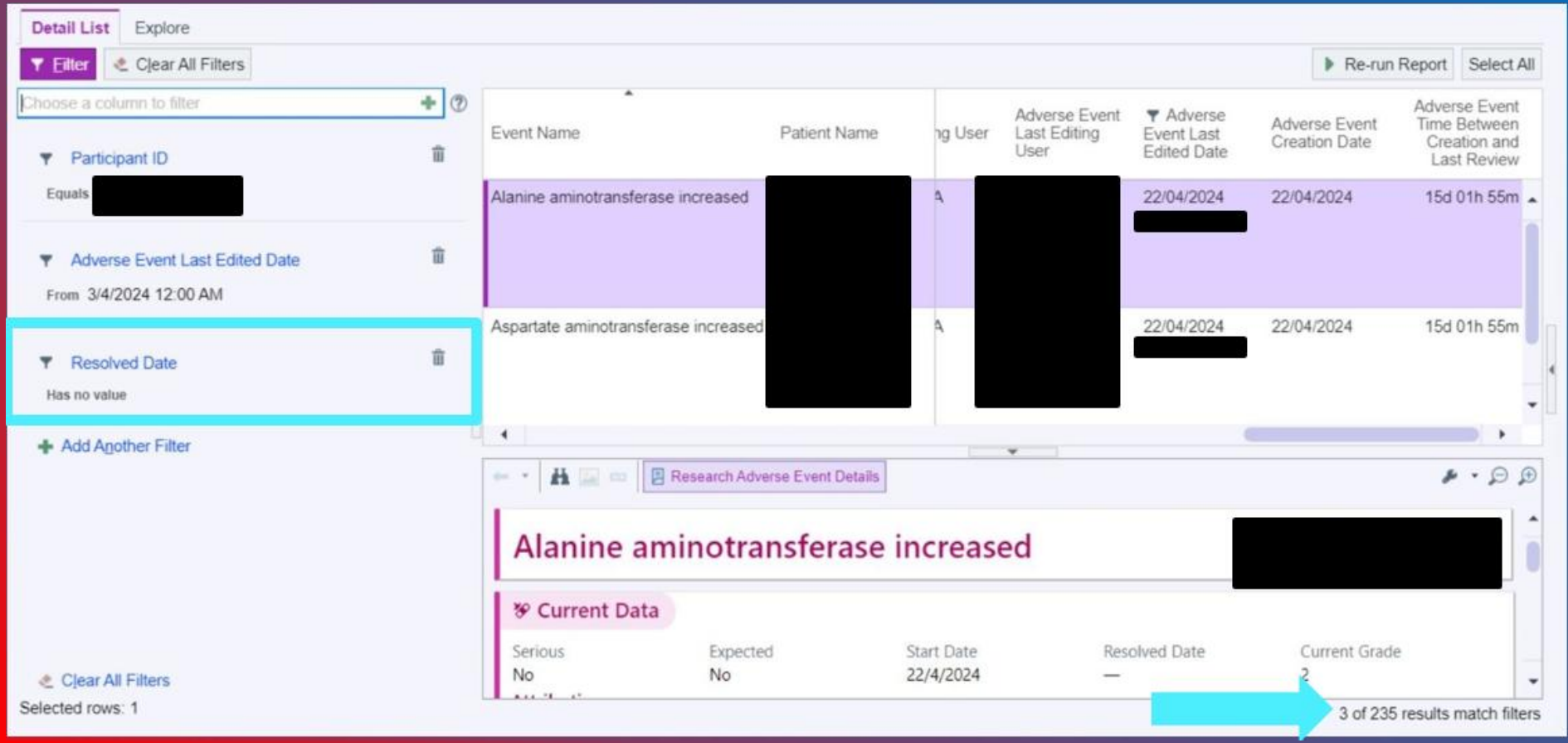
Event Name										
Abdominal pain	[redacted]		Resolved	No	Mild [1]	22/08/2022	Mild [1]	22/08/2022	23/05/2023	INV (21-5914) (NRG-GU010) darolutamide tablet: Possible leuprolide acetate: Possible goserelin acetate: — Radiation: Possible
Abdominal pain	[redacted]		Resolved	Yes	Moderate [2]	22/11/2022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



Filter for **Unresolved** AEs



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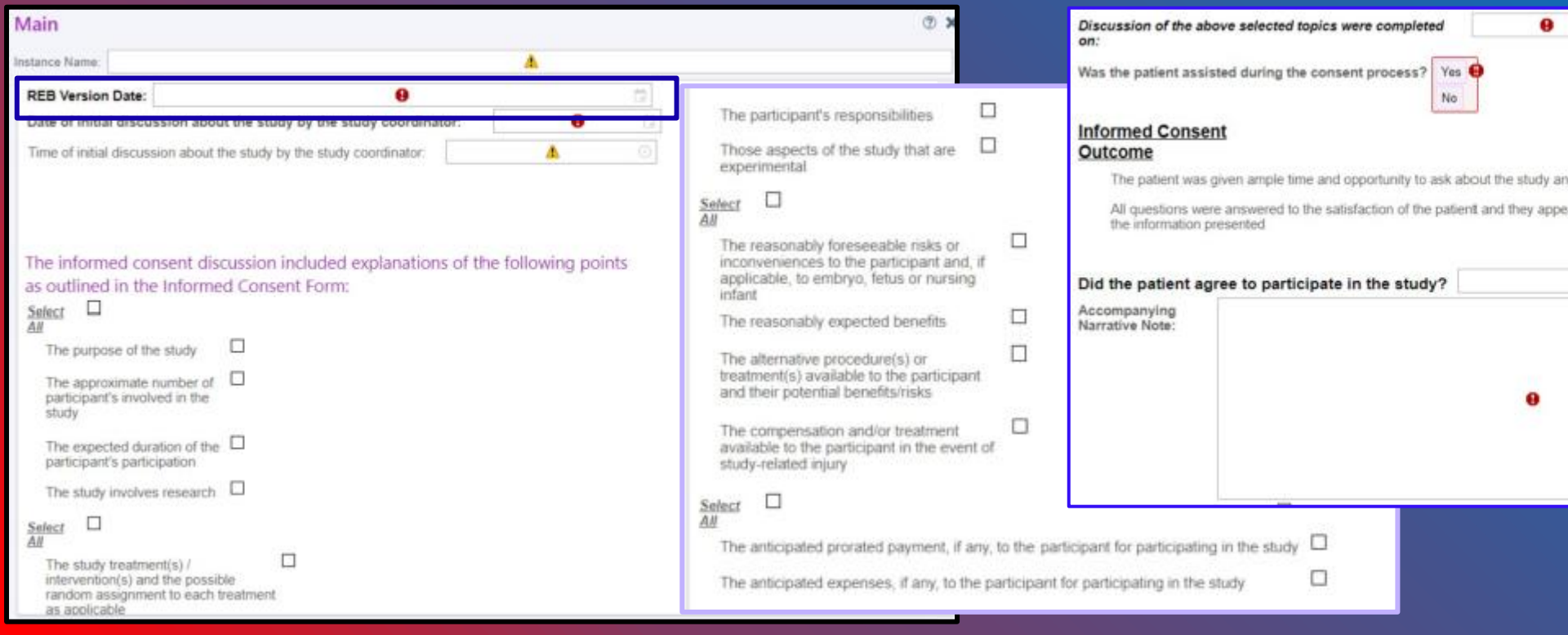
EPIC Data Capture Form – Main Consent Worksheet



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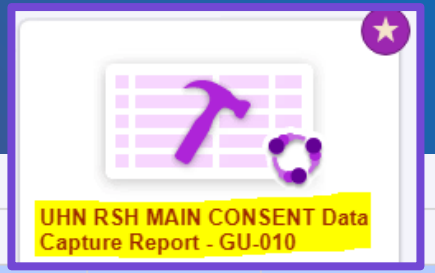
Main Consent Worksheet Report can Flag Patients Needing Re-Consent

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 [redacted]	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]		Withdrawn	initial consent	UHN RSH MAIN CONSENT WORKSHEET	15 Mar 2022	08 Nov 2022	Complete [4]	28 Oct 2022

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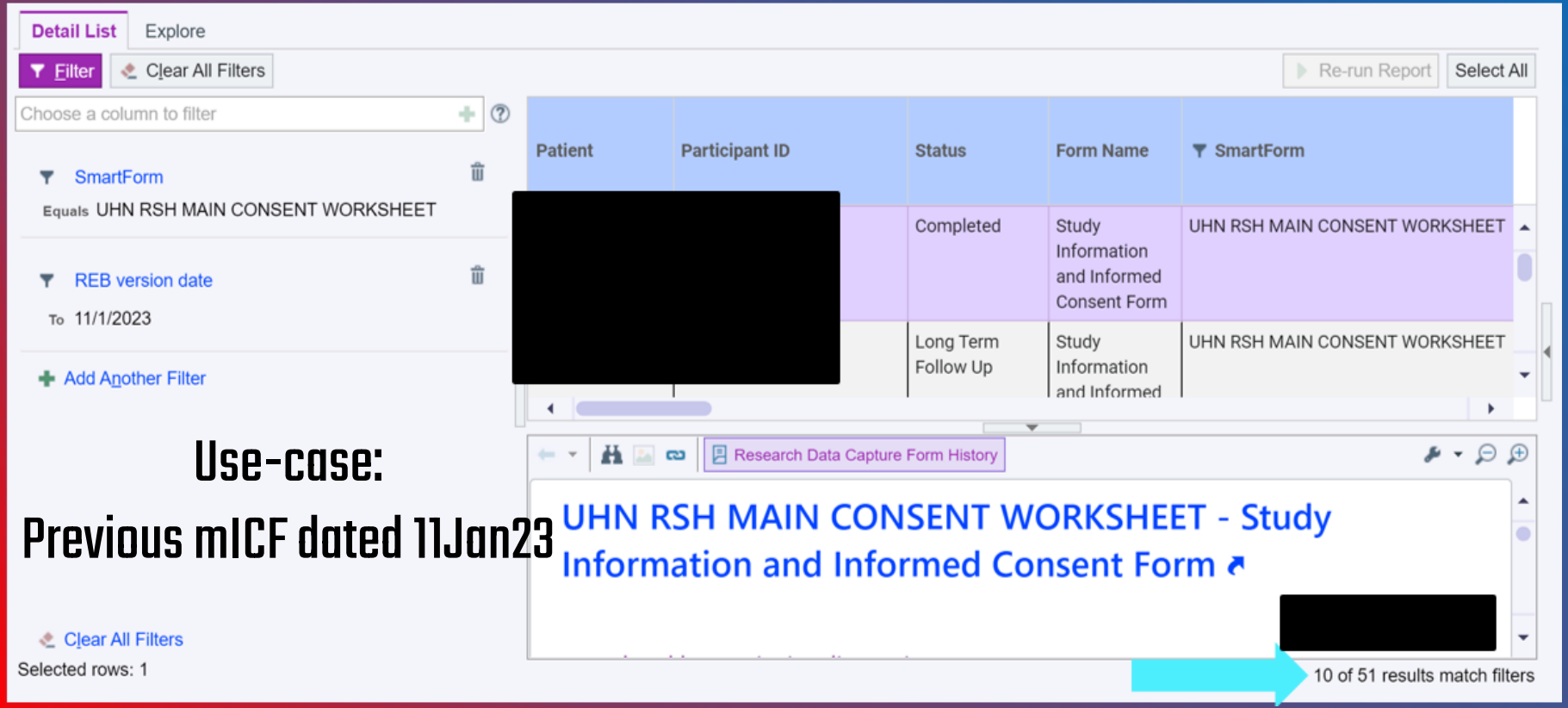
Main Consent Worksheet Report can Flag Patients Needing Re-Consent



Use-case:

Previous mICF dated 11Jan23

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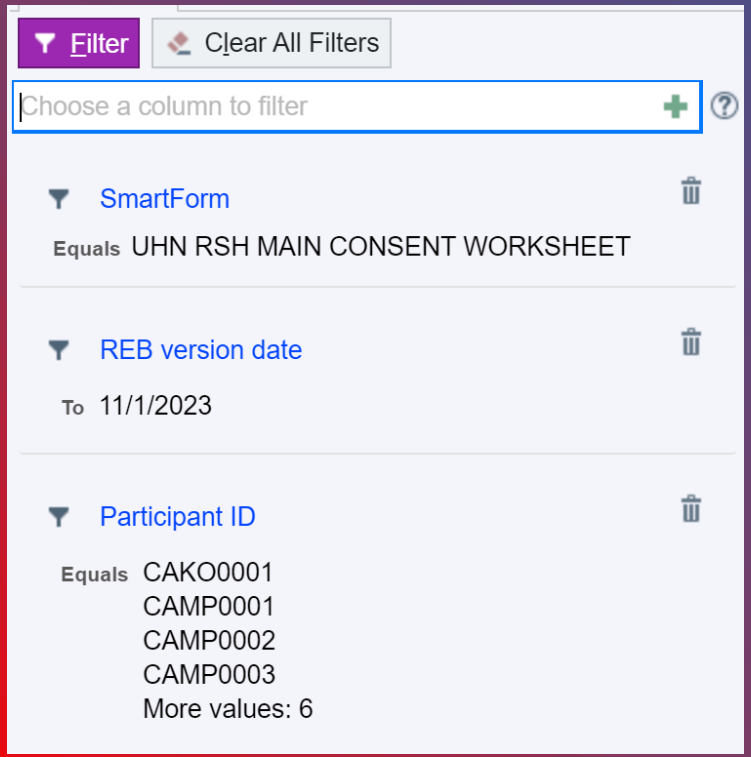
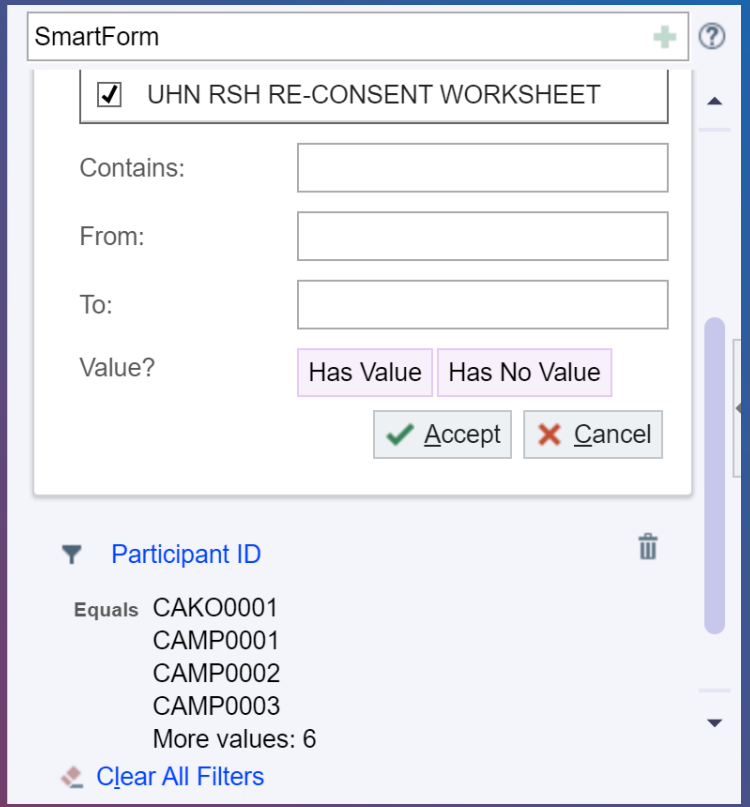
QC-ing Re-Consent Worksheets: Report Filter Combo





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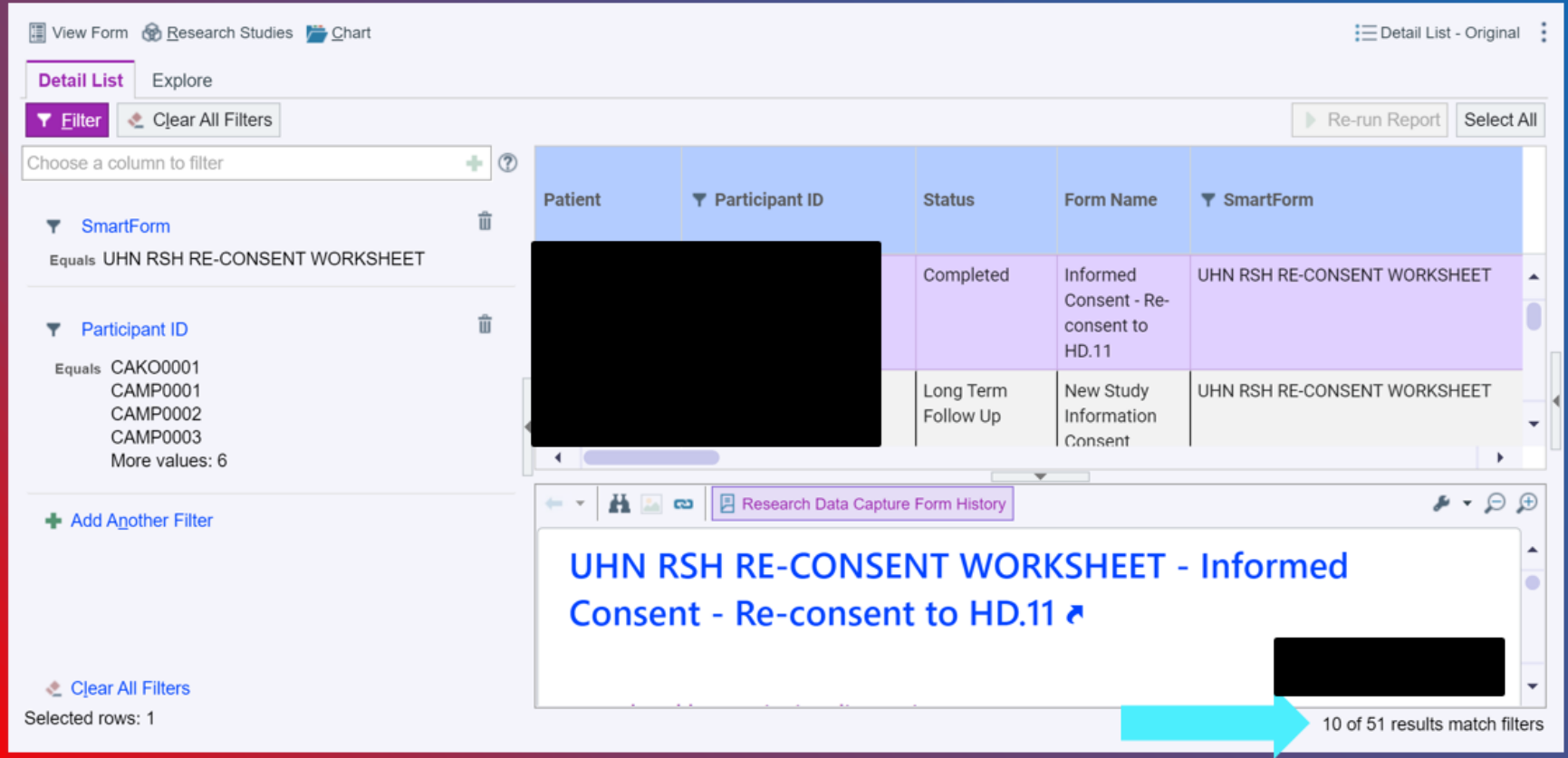
QC-ing Re-Consent Worksheets



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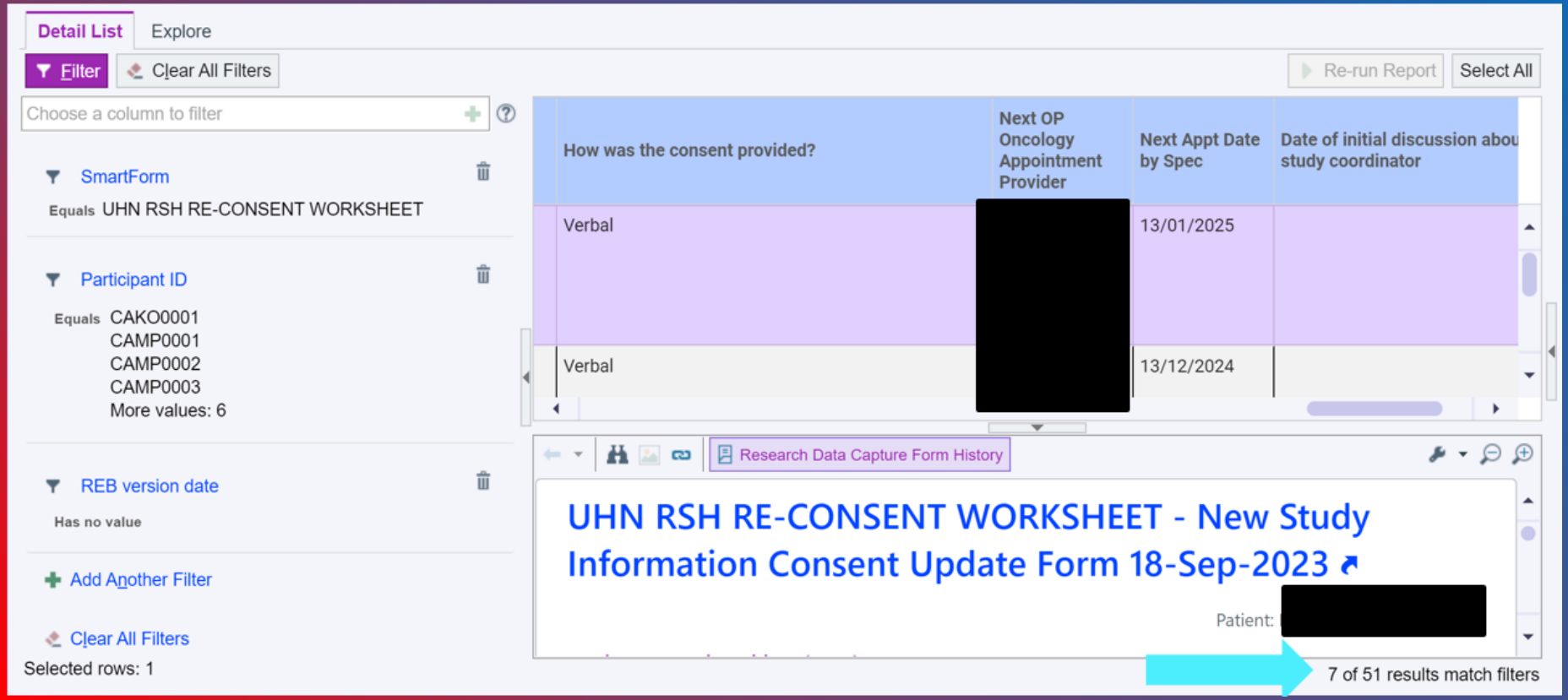
QC-ing Re-Consent Worksheets



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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
[redacted]	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	[redacted]		[redacted]	Other (see comment)	Inactive			Curative	Hodgkin lymphoma UNSTAGED
	CT HD.11 (22-5318) GDP				Toxicity/Com...	Inactive	02/11/23	Clinic Assessment, Cycle 2	Curative	Hodgkin lymphoma UNSTAGED
	CT HD.11 (22-5318) GDP				Other (see comment)	Inactive	29/01/24	Day 8, Cycle 3	Curative	Hodgkin lymphoma UNSTAGED
	CT HD.11 (22-5318) GDP				Progressive Disease	Inactive	16/08/23	Clinic Assessment, Cycle 4	Curative	Hodgkin lymphoma
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Other (see comment)	Inactive	13/10/23	Day 1, Cycle 3	Curative	Hodgkin lymphoma UNSTAGED
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Therapy Complete	Inactive			Curative	Hodgkin's lymphor UNSTAGED
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Therapy Complete	Inactive	30/04/24	Day 1, Cycle 4	Curative	Hodgkin lymphoma UNSTAGED
	CT HD.11 (22-5318) Brentuximab + Pembrolizumab				Therapy Complete	Inactive			Curative	Hodgkin lymphoma UNSTAGED
	CT HD.11 (22-5318) GDP				Progression	Inactive	17/07/23	Clinic Assessment, Cycle 4	Curative	Lymphoma Hodgkin lymphoma UNSTAGED
	CT HD.11 (22-5318)				Therapy	Inactive			Curative	Hodgkin lymphoma

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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		Home	11	Confirmed	Scheduled/...	Hodgkin lymphoma	
24/03/2024	Emergency	Discharged	24/03/2024		Home	1	Confirmed	Urgent/Eme...		3
03/01/2025	Emergency	Admission			Home	1	Confirmed	Urgent/Eme...		2
28/12/2024	Inpatient	Discharged	31/12/2024		CritiCall	3	Confirmed	Urgent/Eme...	Hodgkin lymphoma	
19/06/2024	Inpatient	Discharged	07/07/2024		Home	18	Confirmed	Scheduled/...	Lymphoma	
08/05/2024	Inpatient	Discharged	17/05/2024		Other	9	Confirmed	Urgent/Eme...	Bacteremia	2
22/09/2024	Inpatient	Discharged	29/09/2024		Home	7	Confirmed	Urgent/Eme...	Non Hodgkin's lymphoma	
24/01/2024	Inpatient	Discharged	09/02/2024		Home	16	Confirmed	Scheduled/...	Hodgkin lymphoma	
23/02/2024	Inpatient	Discharged	09/03/2024		Home	15	Confirmed	Scheduled/...	Hodgkin lymphoma	
01/06/2024	Inpatient	Discharged	05/06/2024		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 still maintained in CRR).	**One time for patients maintained in EPIC.**

Research Adverse Event Report Column Guide

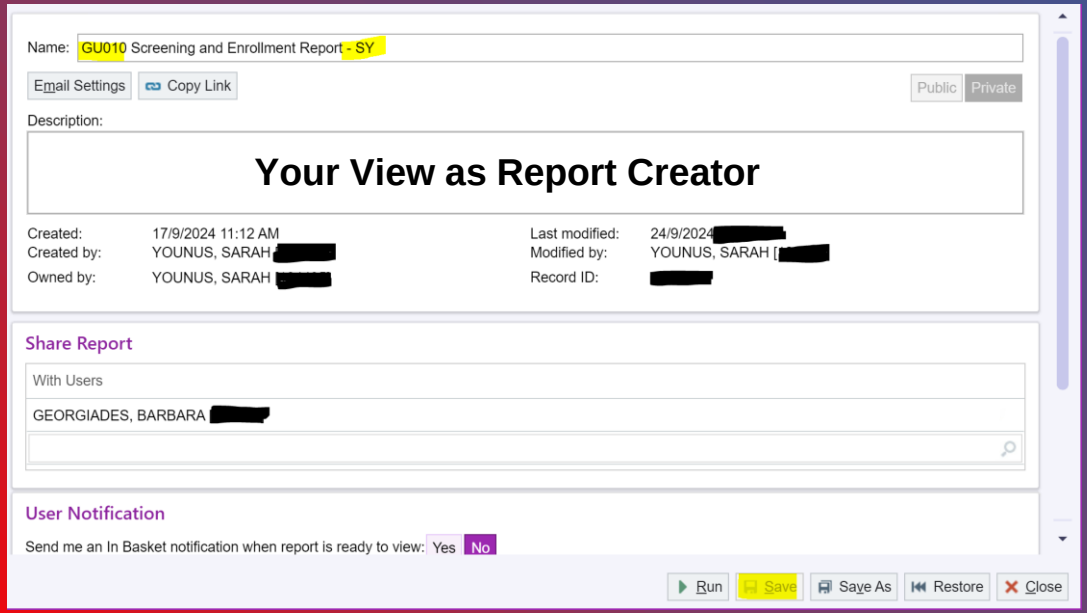
Required Columns

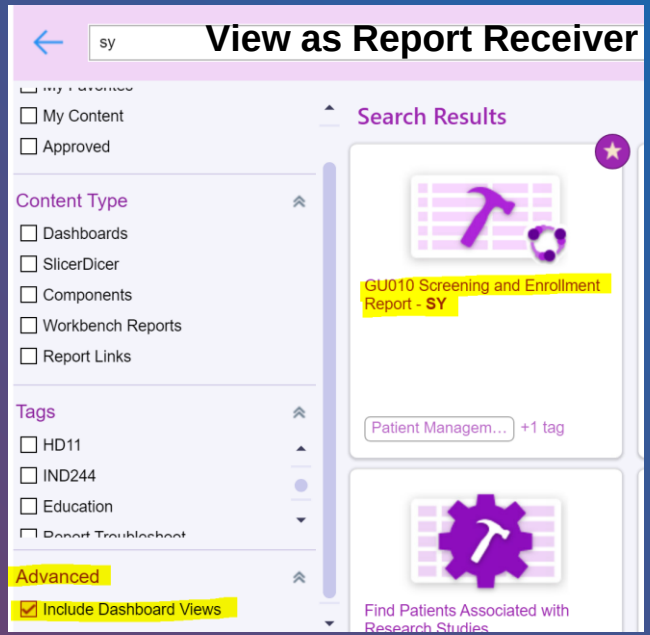
Column Name	Column ID
Adverse Event Name	95014
Participant ID	95000
Patient Name (EPT)	85
Patient MRN	1003
Problem Status	95075
Serious Adverse Event	95015
Adverse Event Current Grade	95058
Adverse Event Current Grade Start Date	95057
Adverse Event Grade History	95056
Adverse Event Grade Start History	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’:

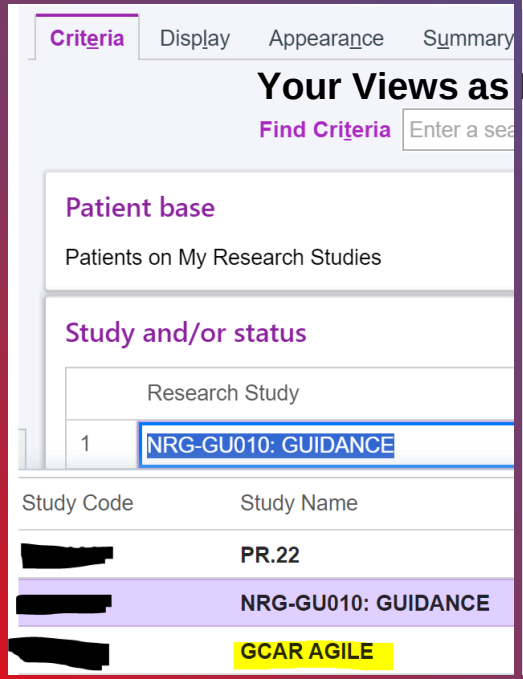
1. Already Includes Standard Columns

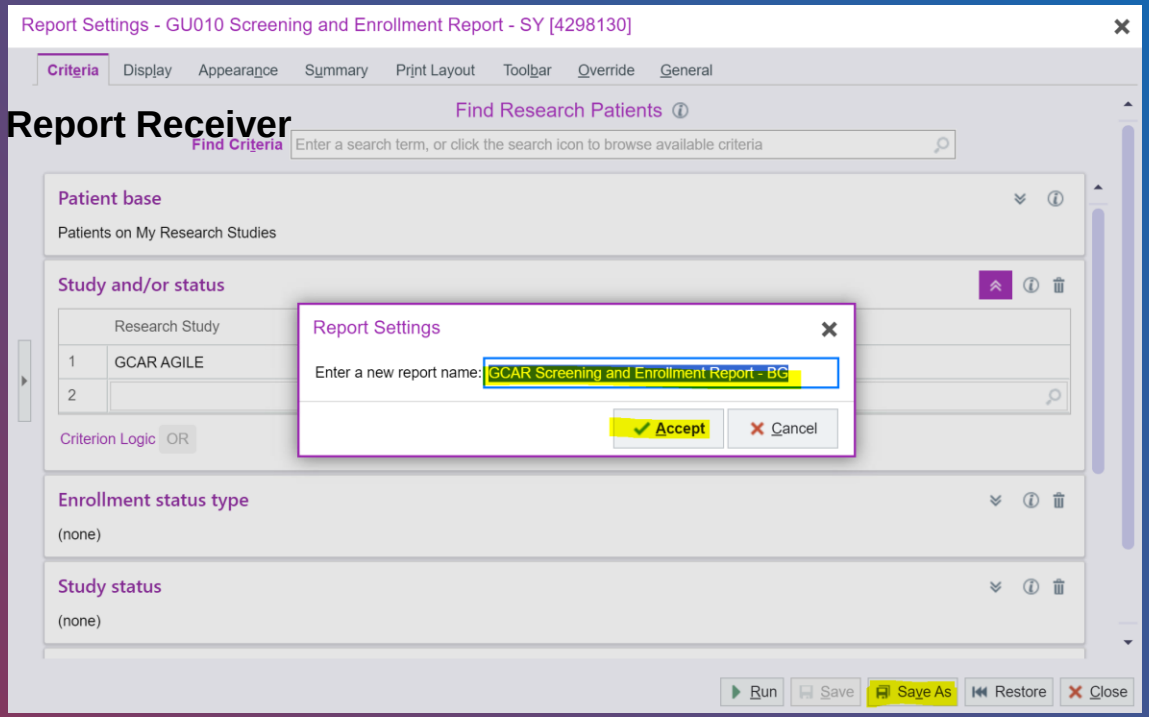




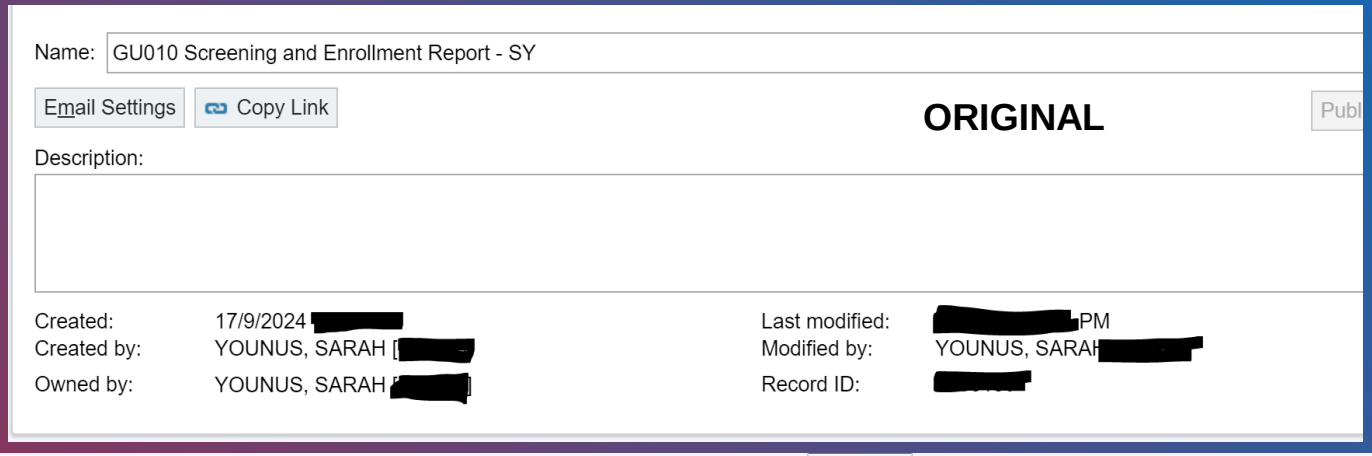
CTSU EPIC Research Report Sharing for Staff:

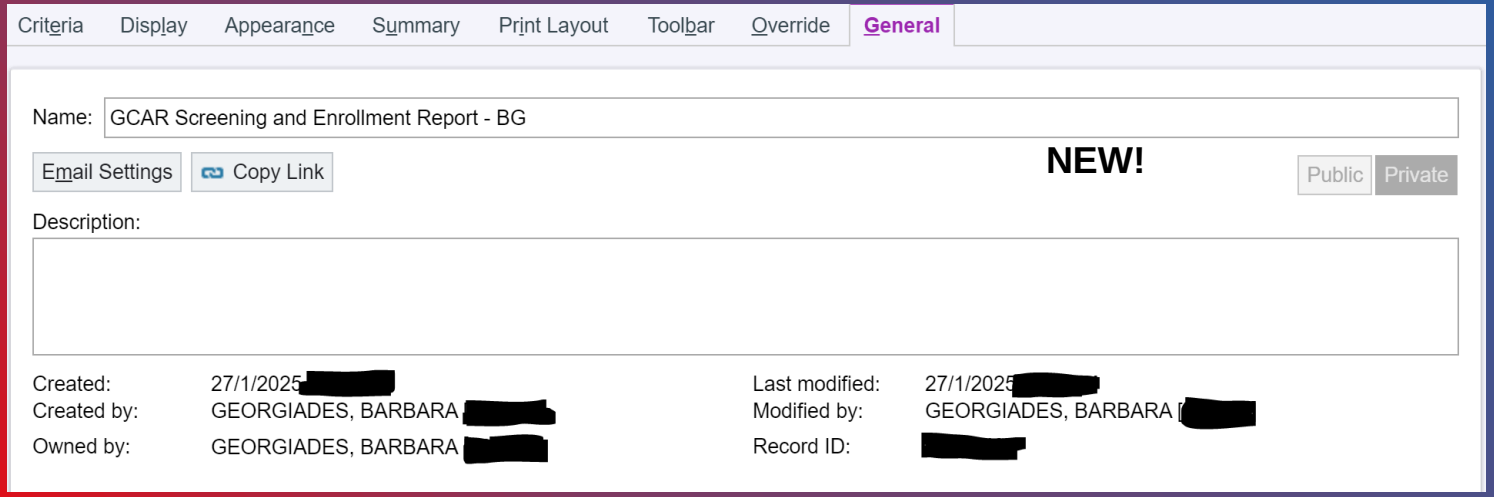
Transferring a Report Template to your team is possible through ‘Share Report’:
2. Team Member needs to switch Research study Criteria to their study and ’Save As’ to then own the report.





CTSU EPIC Research Report Sharing for Staff:





Thank You!

Do you have any questions? Email us!

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