

A graphic of a dense, branching red structure, resembling a network or a tree, set against a black background. The branches are thin and numerous, creating a complex web. A single, thicker branch extends from the right side of the network.

**Office of Clinical Research
Lunch & Learn**

The Linking of Studies: Keys of the System

Thursday, July 20th, 2023

July 2023 Study of the Month:

Adolescent Migraine Study

The Periscope Study

What

The purpose of this study is to evaluate Ubrogepant for the treatment of migraine in children and adolescents.

Who

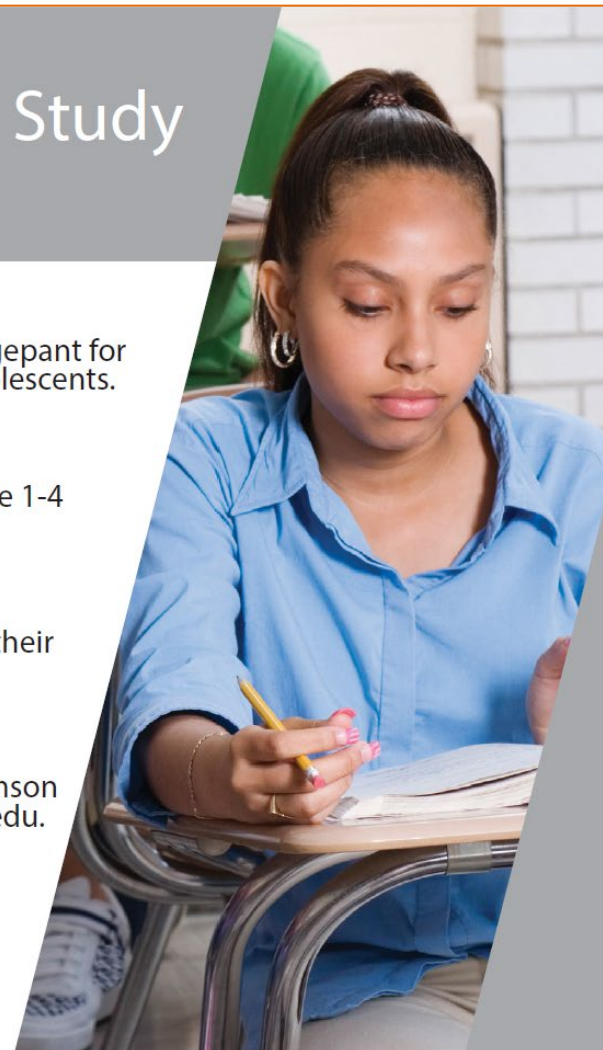
Adolescents aged 12-17 years, who experience 1-4 migraines per month.

Pay

Eligible participants will be compensated for their time and travel.

Details

For more information, contact Heather Williamson at (513) 558-6612 or Heather.Williamson@uc.edu.



SOCRA CRP CERTIFICATION EXAMINATION
Hosted by CCHMC
Tuesday, October 10th, 2023

Please visit the [SOCRA website](#) for more details.

The Registration Deadline is Monday, August 28th, 2023

[Register Here](#)

CCHMC CRP will be hosting open review sessions prior to the exam date for anyone interested in August (Dates and times TBD) hosted on Microsoft Teams (link to be provided).

For any questions or further information, please contact the CCHMC CRP Group at CRP@cchmc.org
or Nate Harris at harrisnl@ucmail.uc.edu



Friday, August 4th , 2023

**The Elephant, the Astronaut, and Shadows of the Cincinnati
General Hospital:**

Curiosities Found in Four Decades at the University of Cincinnati.

David F. Schwallie

**Retired Senior Director and Senior Associate General Counsel
for Corporate Risk Management
Office of General Counsel
UC Health**



Today's Presentation:

The Linking of Studies: Keys of the System

Adam Alexander

**Clinical Research Administrator
Office of Clinical Research**

College of Medicine | University of Cincinnati

Jeffrey Zamor

**Epic Research Analyst
UC Health Office of Clinical Research**

The Linking of Studies

Keys of the System

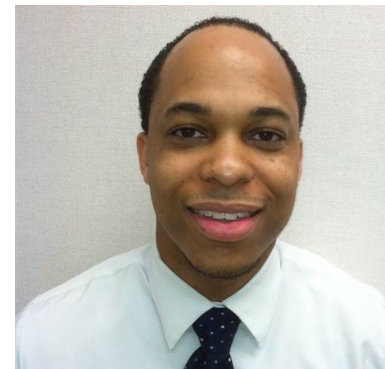
JULY 20, 2023 | ADAM ALEXANDER & JEFFREY ZAMOR | OFFICE OF CLINICAL RESEARCH

TODAY'S PRESENTERS

*TAKING YOU ON AN EPIC JOURNEY
...THROUGH EPIC!*



Adam Alexander
Clinical Research Administrator



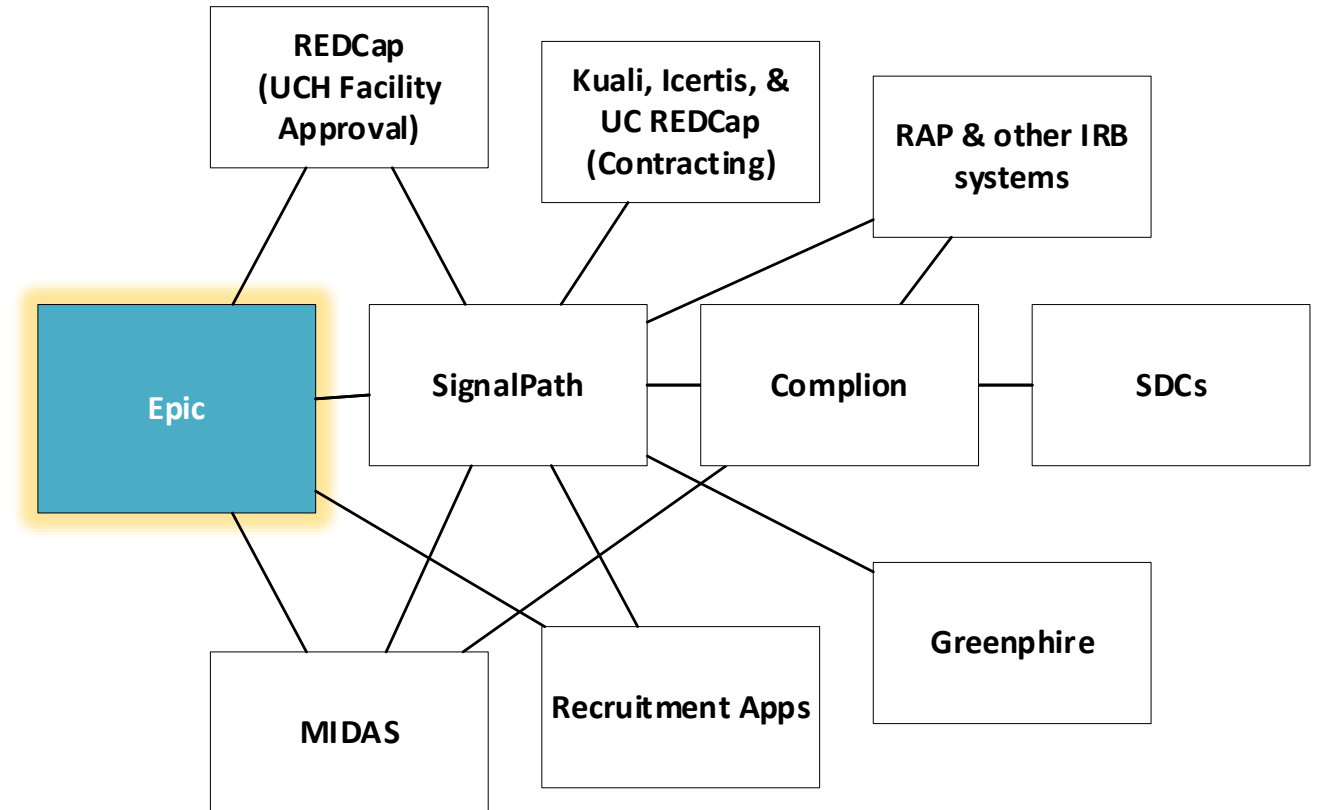
Jeffrey Zamor
Epic Research Analyst

RESEARCH IN EPIC

BEFORE WE CAN LINK

Epic aims to provide a research-enabling platform to “improve patient experience, optimize patient care, and enhance operational research efficiency”.

- Explore Feasibility - Data
- Recruit Participants
- Organize Studies
- Route Billing to appropriate payers
- ...and it records medical information too



RESEARCH IN EPIC

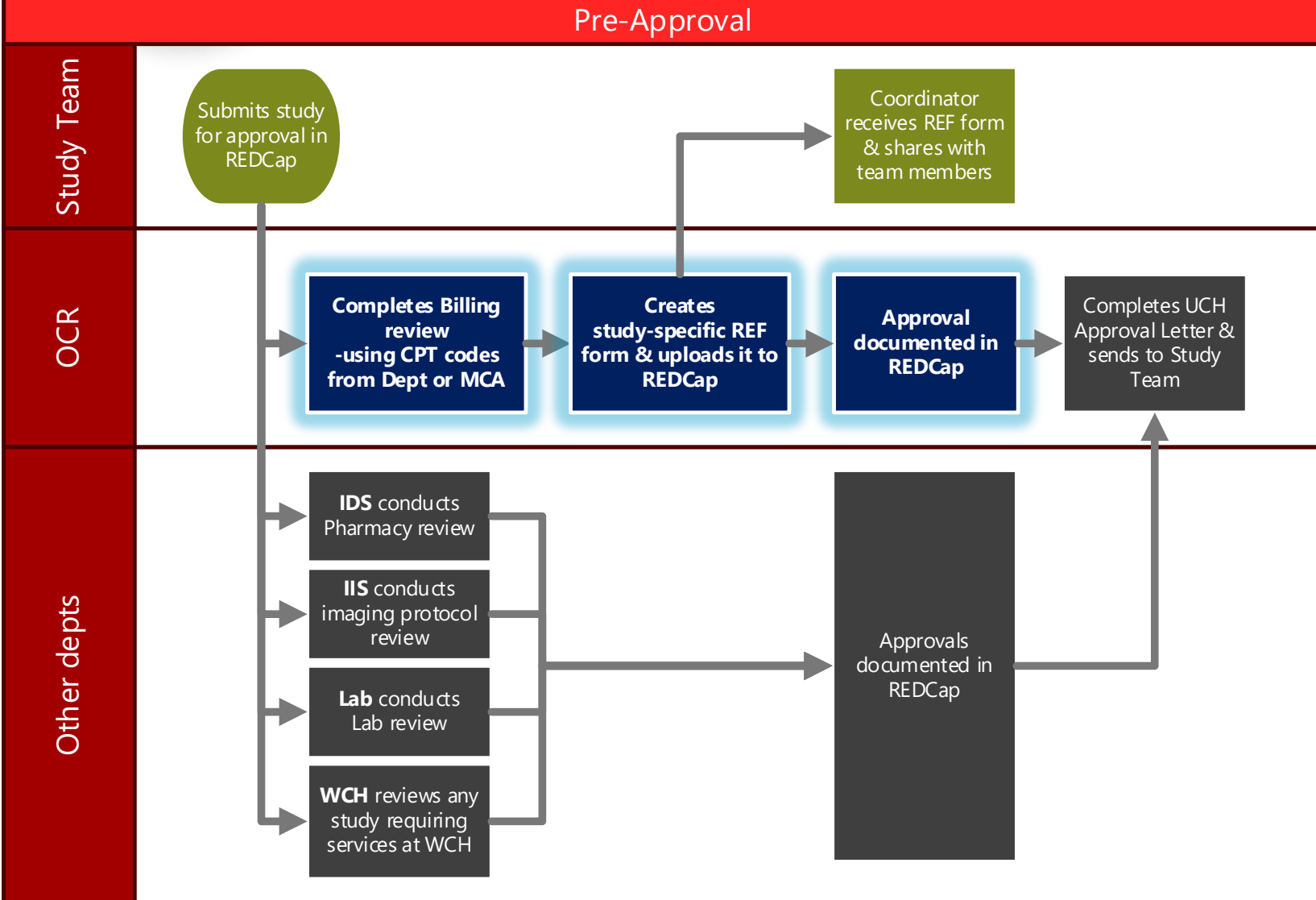
WHAT DOES EPIC NEED TO PERFORM ITS ROLE? ANYTHING ELSE?

- Needs to know about the study
- Needs to know which patients are associated with the study
- Needs to know which encounters are associated with the study
- Needs to know which orders are associated with the study
- Which users need access to study info
 - Monitor access too
- Charges/fee schedules for research billing
- Related adverse events?
- Research consents?

“...So, what’s the process?”

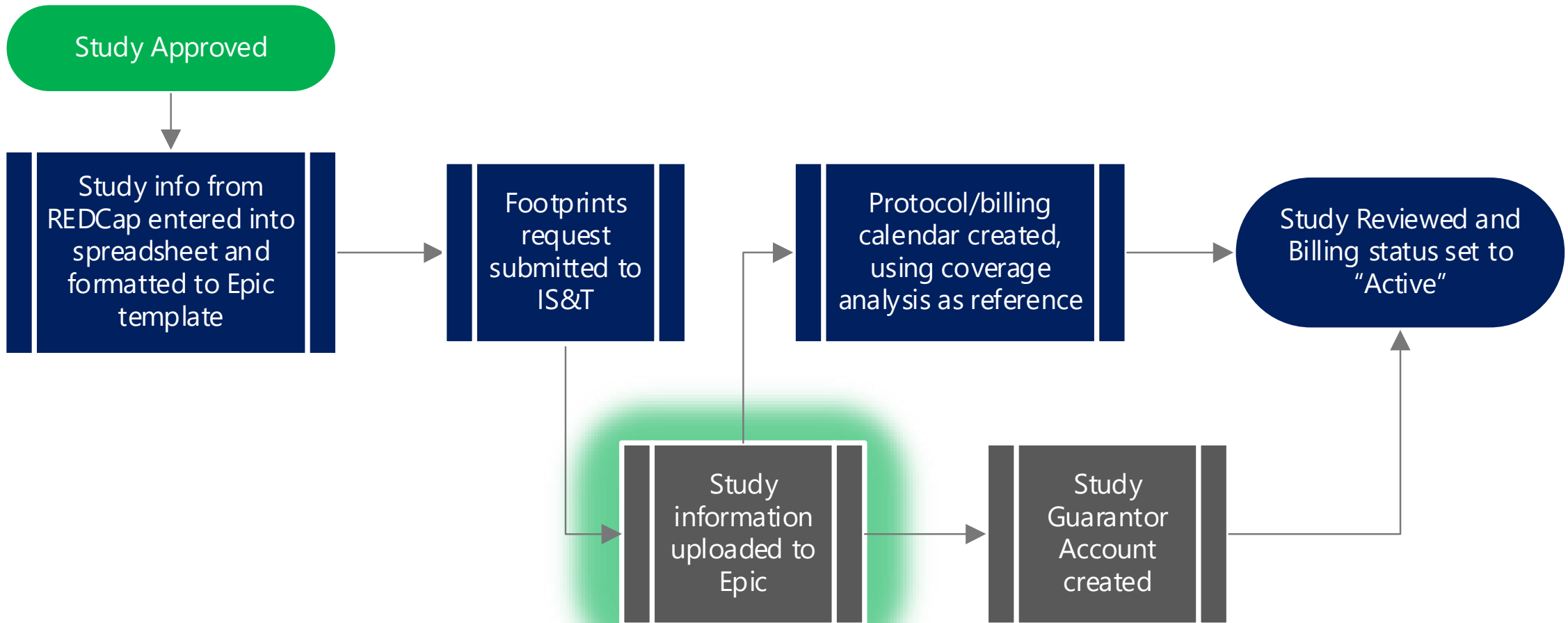
- KARA BAKER

UCH Research Approval



**AND
THEN WHAT
HAPPENS?**

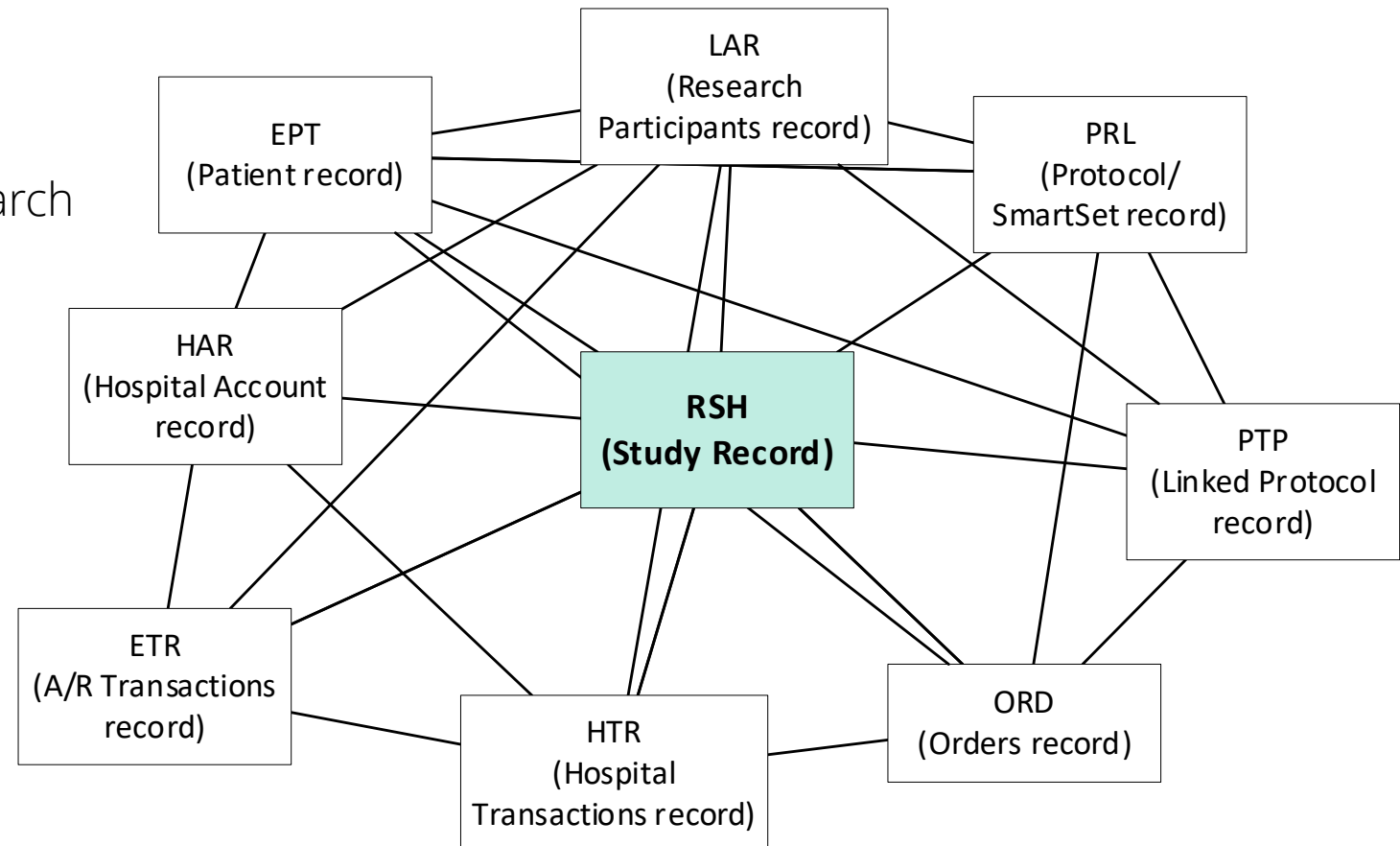
EPIC STUDY SETUP



EPIC RESEARCH FILE STRUCTURE

Research Workflows cover a wide variety of Epic modules

- Examples of areas impacted by Research
 - Cadence
 - EpicCare Ambulatory
 - EpicCare Inpatient
 - Hospital Billing
 - Prelude
 - Professional Billing
 - Radiant
 - Willow Inpatient



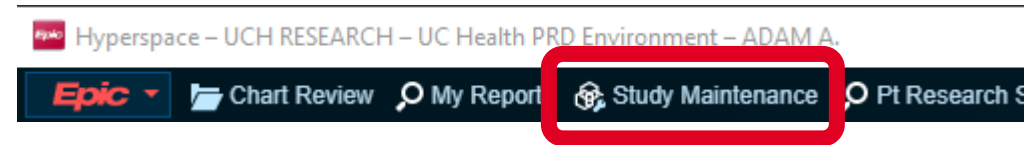
EPIC STUDY MAINTENANCE ACTIVITY

The place to update study info in Epic.

- Some examples of fields in Study Maintenance:

YOU ALL HAVE ACCESS TO THIS!

- IRB #
- NCT #
- Study PI
- Study Coordinator(s)
 - Used for access, e.g. MyChart recruitment reports
- Billing Contact Info
- Links (e.g. to research imaging protocols)



Research Study Maintenance - LEARNING [LEARNING]

General Info
Users And Providers
Studies Activity Setup
Report Groupers
Study Calendar
Amendments
Automated Actions
Billing Setup
Review Settings

General Information

Study Information

Study Name: LEARNING Study Code: LEARNING

Discount Percent: Approved Amount:

IRB Approval Information

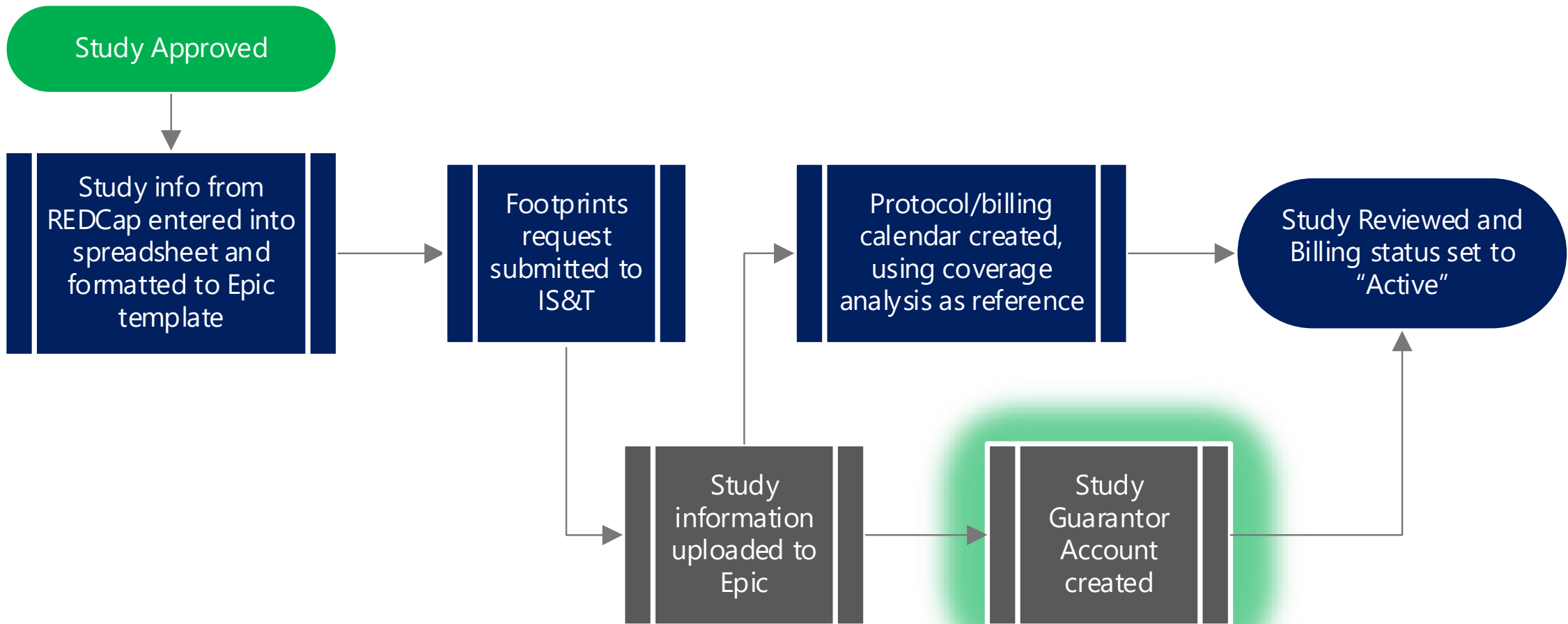
Approval Number: Approval Date: Expiration Date:

Show Date History

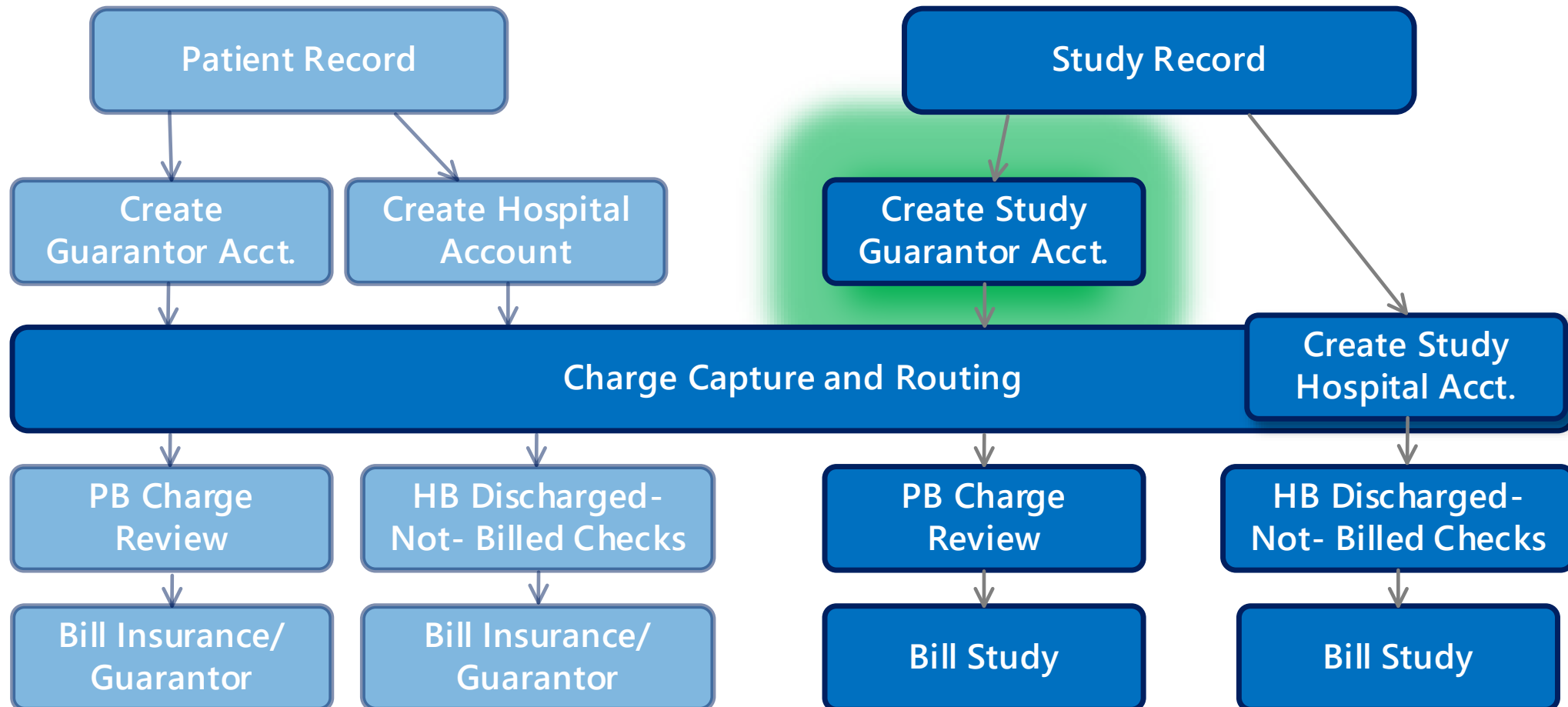
Send Bills To... Contact: Address: State: ZIP:

Description: A phase four, randomized study to assist in the learning and launch of the SignalPath application at your research center
null

EPIC STUDY SETUP



EPIC STUDY SETUP – STUDY GUARANTOR ACCOUNT



EPIC STUDY SETUP – STUDY GUARANTOR ACCOUNT

Billing Setup

Guarantor type:

Debit GL string:

HB fee schedule:

PB pricing contract:

Credit GL string:

HB fee schedule usage:

Service Areas
⌵

Service Area	Hospital Account Location	Guarantor
UC HEALTH SERVICE AREA [10]	UNIVERSITY HOSPITAL PARENT LOC LOCATI...	REVILLA-ENROLL HD-UCMC,RESEARCH [631]
<input type="text"/>	<input type="text"/>	<input type="text"/>

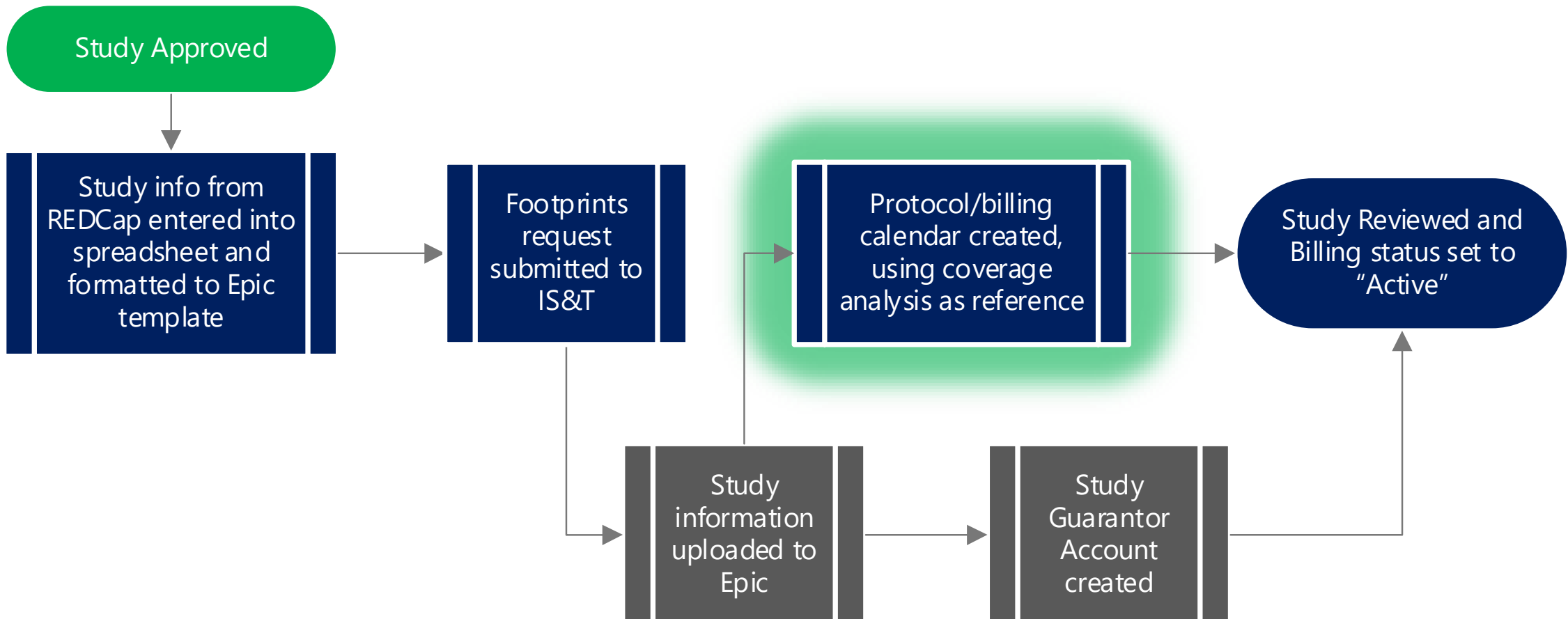
Administrative patient record: REVILLA-ENROLL HD-UCMC,RESEARCH [E2308978]

[Create Billing Records](#)

Allowed Procedures

Procedure	Allowed Count
<input type="text"/>	<input type="text"/>

EPIC STUDY SETUP



RESEARCH STUDY MCA/BILLING GRID

CONCEPTUAL DIAGRAM OF THE MCA/BILLING GRID

In a research billing protocol, you can list:

- **(RSH) Research** Whether a charge is covered by the study and should route to the research account, or...
- **(SOC) Standard-of-Care** If the charge is not covered by the study but is done in the context of the study and should route to the patient's non-research account.

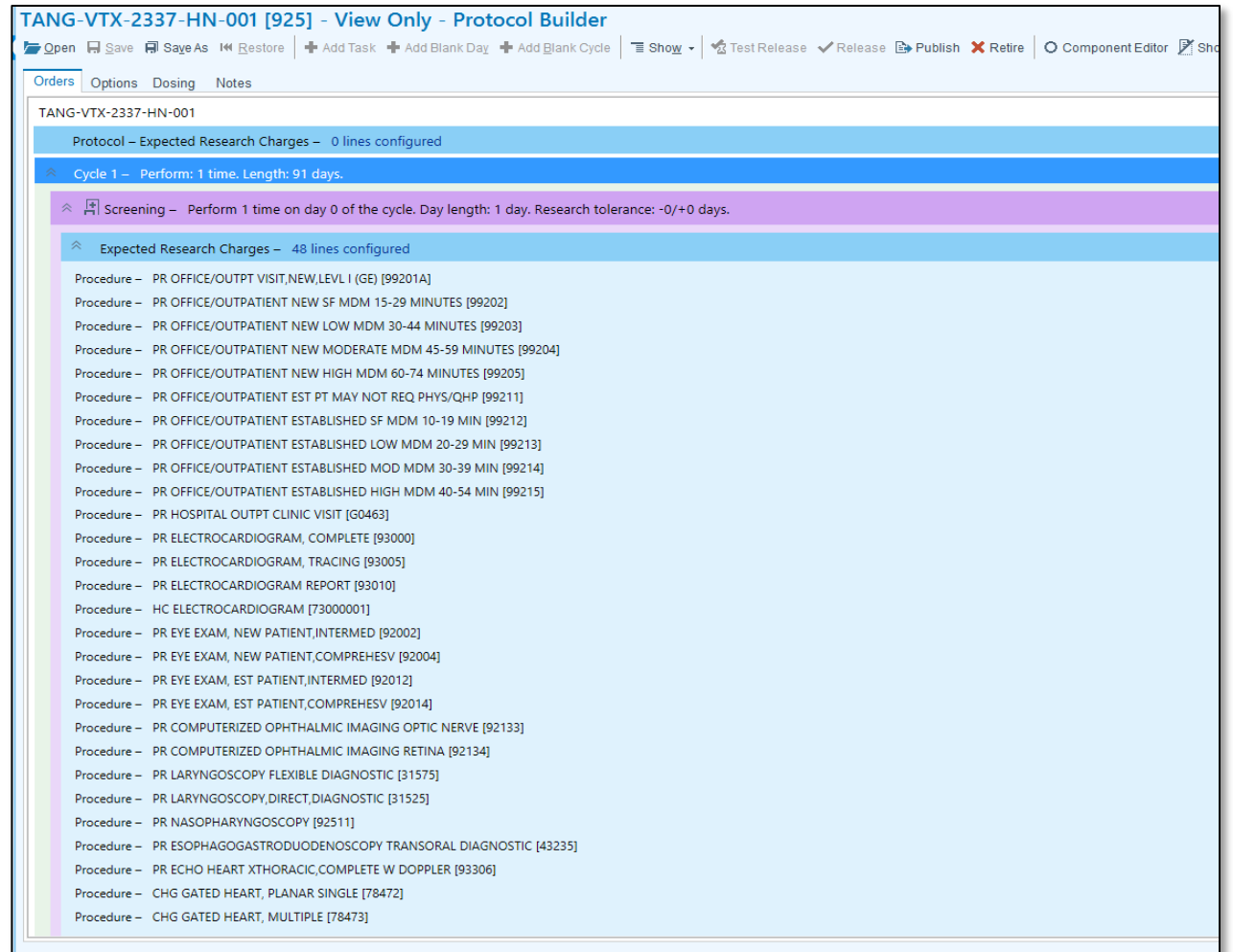
This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, co														
Protocol Related Items and Services	CPT / HCPCS (Sample codes)	Screening Period	Cycle 1				Cycle 2		Cycle 3+	Post-treatment Follow-up				1. Support for Coverage un 2. Routine costs to be justif Complications with source 3. Additional support or Lin
			D1	D3	D8	D15	D1	D1	EOT	SFU (28 days after EOT)	Every 8 weeks after EOT	Every 6 months after EOT		
			-28d to -1d			± 3d	± 3d	± 7d	+7d	+7d	± 14d	± 30d		
Procedures / Evaluation Management														
12-lead ECGs; Triplicate	93000-93010	S	S		S	S	S	S - C3 then Q2C	S	S				* ECG performed in triplicate * Billable to sponsor.
12-lead ECGs; Triplicate (additional) - Part 1 only	93000-93010		S		S									For Part 1: Cycle 1 Day 1 and ONO-7018 administration a * ECG performed in triplicate * Billable to sponsor.
2D-echocardiogram	93306-93307	S					S	S - C5 then Q3C	S	S				* NCCN NHL Guidelines do r * NCCN CLL/SLL Guidelines * Per ONO-7018 IB (v1.0), n * CGS L34338 [ECHO] limits * Protocol mandated assess * Billable to sponsor.
Bone marrow examination or other sites (if applicable) - NHL Subtypes	38220-38222 88305, 88313, 88311, 85097, various	S					S - CR/PD				S - CR/PD			Screening: * NCCN NHL Guidelines do r * Protocol mandated assess * Billable to sponsor. CR/PD: * LUGANO response criteria (NHODG-C). * Unclear all study participa * Billable to sponsor.
Bone marrow examination or other sites (if applicable) - WM	38220-38222 88305, 88313, 88311, 85097,	Q1					Q1 - CR S - PD				Q1 - CR S - PD			Screening: * NCCN WM Guidelines v1.1 * NCD 310.1 allows for the c * Medical record must justi CR: * NCCN WM Guidelines v1.1 Macroglobulinemia (WM/L * NCD 310.1 allows for the c

RESEARCH STUDY PROTOCOL BUILD

CONCEPTUAL DIAGRAM OF EPIC PROTOCOL BUILD

In a research billing protocol:

- A billing only research protocol defines how charges related to the research study should be handled.
- In combination with the patient's study timeline, the protocol enables epic to evaluate the charges for a specific patient should be directed to the study account, patient's account as related to research, or the patient's account as not related to research.



The screenshot displays the Epic Protocol Builder interface for protocol TANG-VTX-2337-HN-001. The interface shows a list of expected research charges, categorized by procedure. The list includes various medical procedures such as office visits, electrocardiograms, eye exams, and imaging studies, each with a corresponding CPT code and description.

TANG-VTX-2337-HN-001 [925] - View Only - Protocol Builder

Protocol – Expected Research Charges – 0 lines configured

Cycle 1 – Perform: 1 time. Length: 91 days.

Screening – Perform 1 time on day 0 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.

Expected Research Charges – 48 lines configured

- Procedure – PR OFFICE/OUTPT VISIT,NEW,LEVL I (GE) [99201A]
- Procedure – PR OFFICE/OUTPATIENT NEW SF MDM 15-29 MINUTES [99202]
- Procedure – PR OFFICE/OUTPATIENT NEW LOW MDM 30-44 MINUTES [99203]
- Procedure – PR OFFICE/OUTPATIENT NEW MODERATE MDM 45-59 MINUTES [99204]
- Procedure – PR OFFICE/OUTPATIENT NEW HIGH MDM 60-74 MINUTES [99205]
- Procedure – PR OFFICE/OUTPATIENT EST PT MAY NOT REQ PHYS/QHP [99211]
- Procedure – PR OFFICE/OUTPATIENT ESTABLISHED SF MDM 10-19 MIN [99212]
- Procedure – PR OFFICE/OUTPATIENT ESTABLISHED LOW MDM 20-29 MIN [99213]
- Procedure – PR OFFICE/OUTPATIENT ESTABLISHED MOD MDM 30-39 MIN [99214]
- Procedure – PR OFFICE/OUTPATIENT ESTABLISHED HIGH MDM 40-54 MIN [99215]
- Procedure – PR HOSPITAL OUTPT CLINIC VISIT [G0463]
- Procedure – PR ELECTROCARDIOGRAM, COMPLETE [93000]
- Procedure – PR ELECTROCARDIOGRAM, TRACING [93005]
- Procedure – PR ELECTROCARDIOGRAM REPORT [93010]
- Procedure – HC ELECTROCARDIOGRAM [73000001]
- Procedure – PR EYE EXAM, NEW PATIENT,INTERMED [92002]
- Procedure – PR EYE EXAM, NEW PATIENT,COMPREHESV [92004]
- Procedure – PR EYE EXAM, EST PATIENT,INTERMED [92012]
- Procedure – PR EYE EXAM, EST PATIENT,COMPREHESV [92014]
- Procedure – PR COMPUTERIZED OPHTHALMIC IMAGING OPTIC NERVE [92133]
- Procedure – PR COMPUTERIZED OPHTHALMIC IMAGING RETINA [92134]
- Procedure – PR LARYNGOSCOPY FLEXIBLE DIAGNOSTIC [31575]
- Procedure – PR LARYNGOSCOPY,DIRECT,DIAGNOSTIC [31525]
- Procedure – PR NASOPHARYNGOSCOPY [92511]
- Procedure – PR ESOPHAGOGASTRODUODENOSCOPY TRANSORAL DIAGNOSTIC [43235]
- Procedure – PR ECHO HEART XTHORACIC,COMPLETE W DOPPLER [93306]
- Procedure – CHG GATED HEART, PLANAR SINGLE [78472]
- Procedure – CHG GATED HEART, MULTIPLE [78473]

STUDY CALENDAR TIMELINE

TANG-VTX-2337-HN-001-UCMC

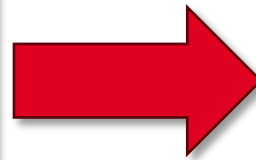
Participant Details Additional Info Past Updates

Status
Enrolled

Study Calendar

No study visits

[+ Create a Timeline](#)

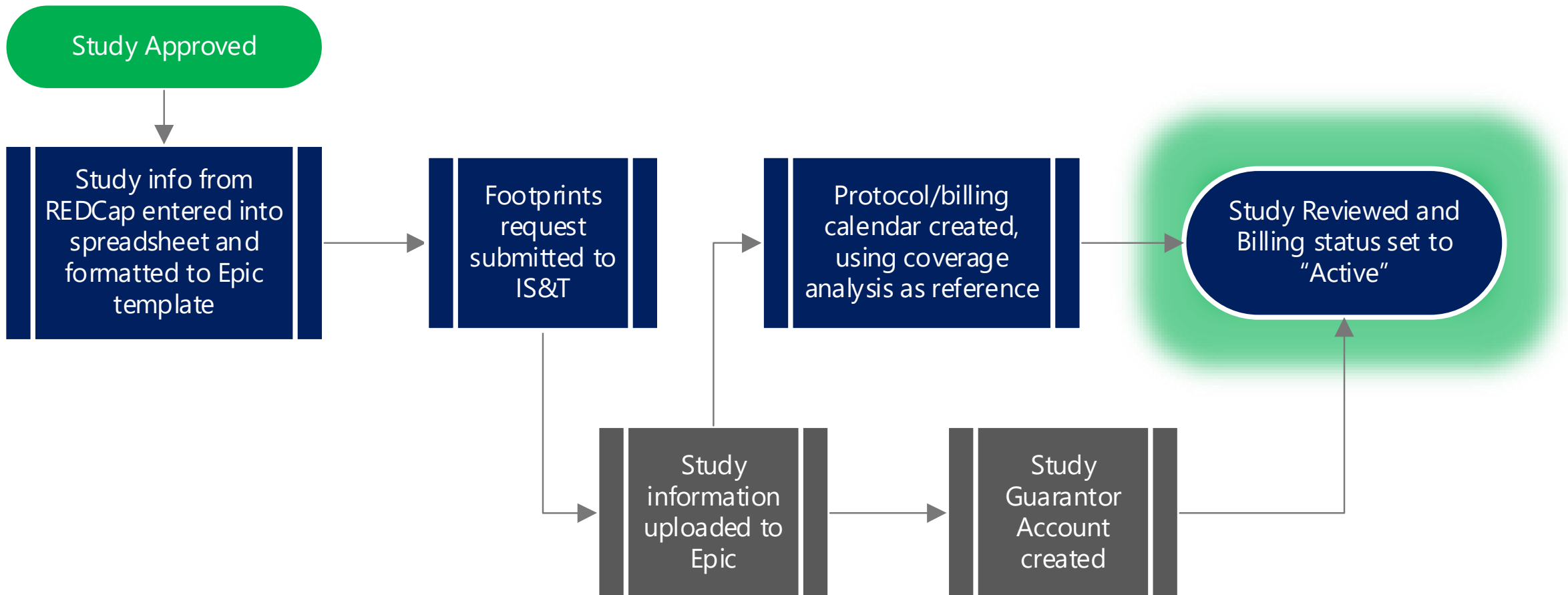


Edit TANG-VTX-2337-HN-001 (Ver. 1 of 1)

Day	Expected	Tolerance
Cycle 1 (Length in weeks: 13)		
Screening	5/26/2021 (±0)	5/26/2021 to 5/26/2021
Day 1	5/27/2021 (-0/+7)	5/27/2021 to 6/3/2021
Day 8	6/3/2021 (-0/+7)	6/3/2021 to 6/10/2021
Day 15	6/10/2021 (-0/+7)	6/10/2021 to 6/17/2021
Day 22	6/17/2021 (-0/+7)	6/17/2021 to 6/24/2021
Day 24 (day of surgery)	6/19/2021 (-0/+7)	6/19/2021 to 6/26/2021
30 Day Follow Up	6/25/2021 (-0/+7)	6/25/2021 to 7/2/2021
90 Day Follow Up	8/24/2021 (-0/+7)	8/24/2021 to 8/31/2021

[Accept](#) [Cancel](#)

EPIC STUDY SETUP - RECAP



LINKING OVERVIEW

What is Linking?

- Also known as “associating” a patient, encounter, or order with a study
- Epic’s way of matching certain data to a study to allow for correct attribution of study activities

Why is it Important?

- Associating research-related activities is crucial for billing the proper entity
- Failure to bill the study for non-standard-of-care research activities = billing fraud
- So, we need to make sure our billing is accurate!

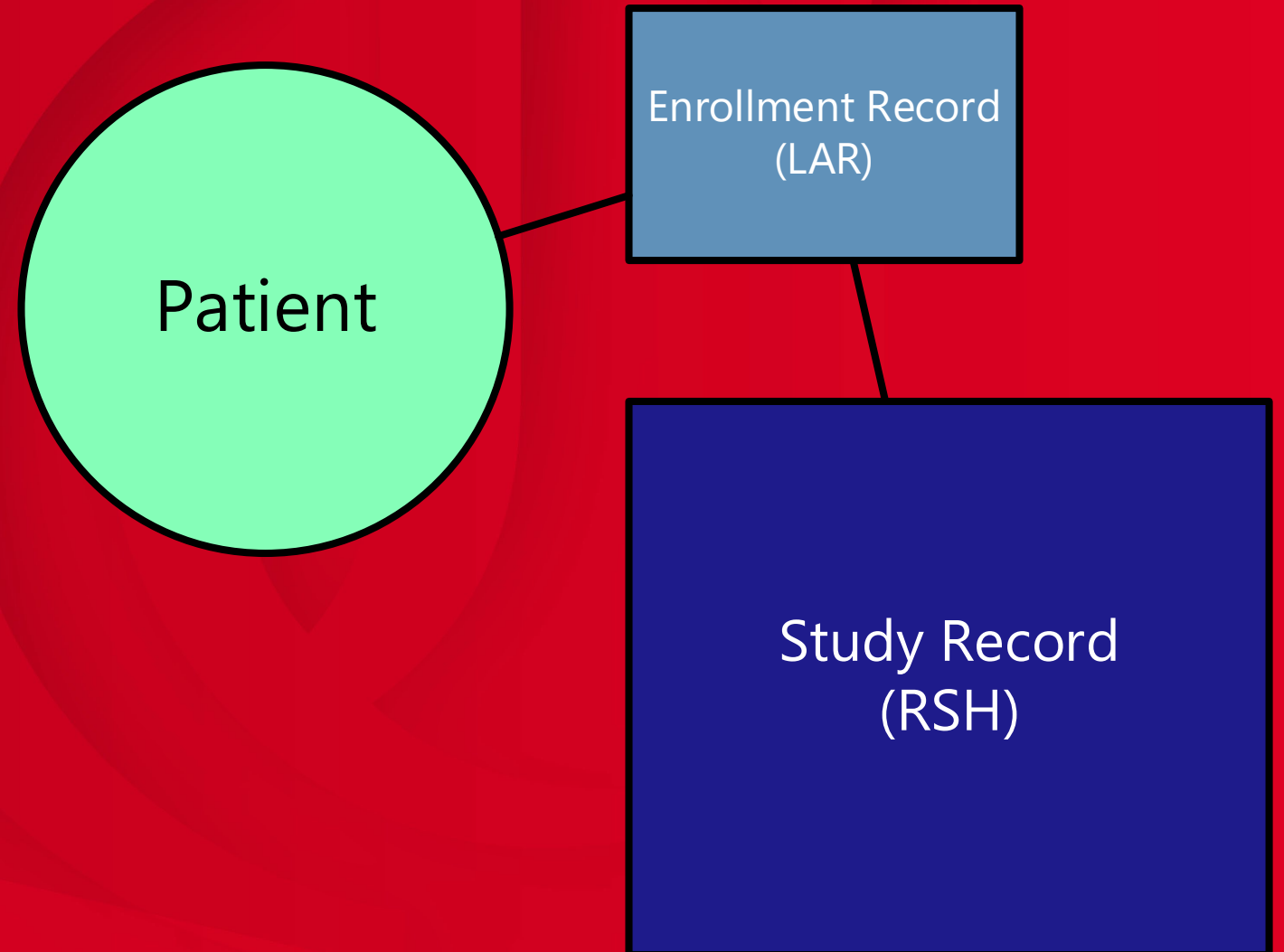
THERE ARE 3 KINDS OF LINKING

1. PATIENT

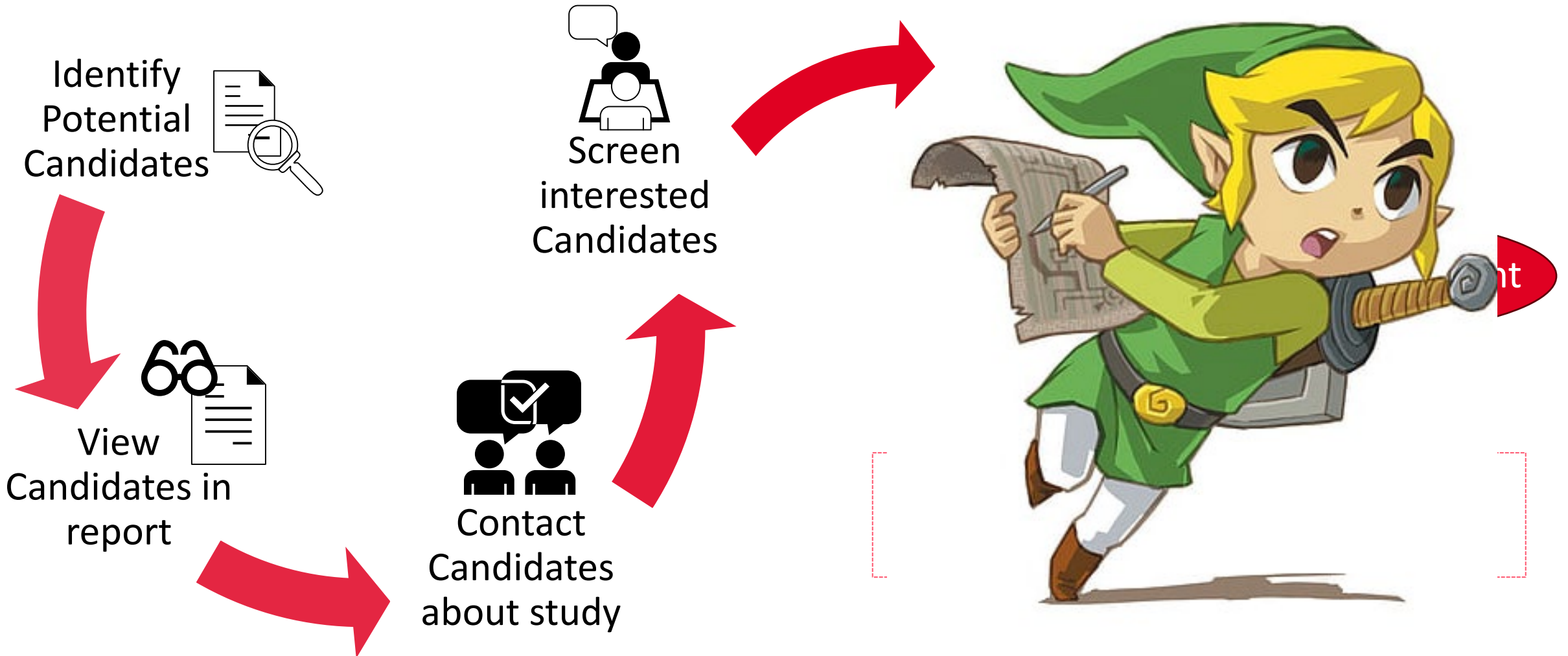
2. VISIT

3. ORDER

Patient Linking



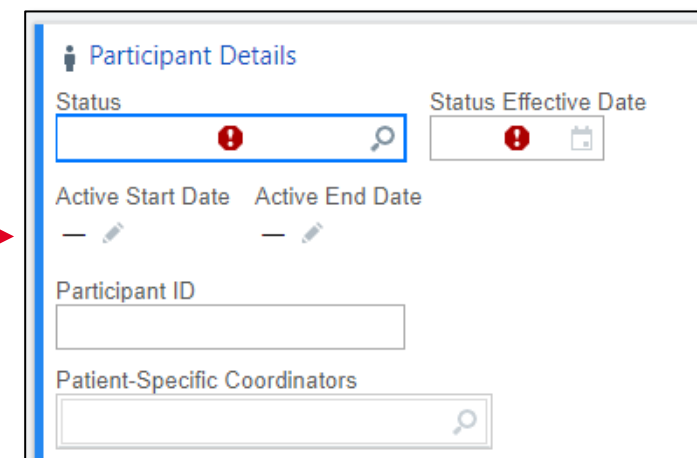
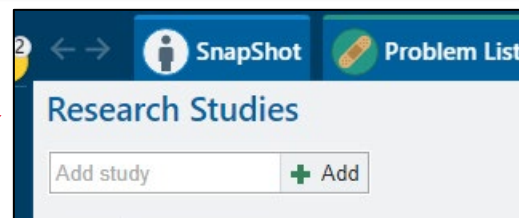
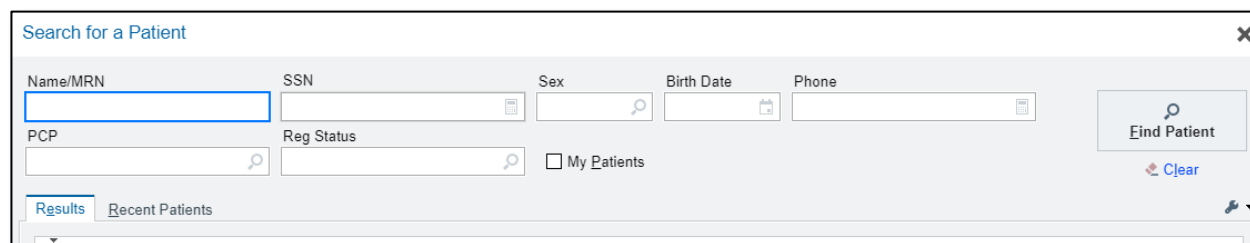
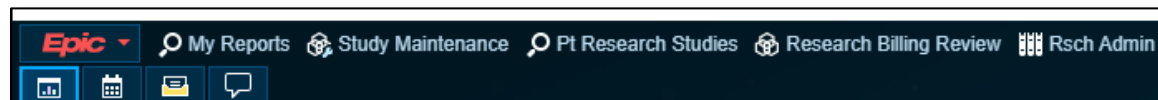
RESEARCH IN EPIC – PATIENTS, PARTICIPANTS, & A PROCESS



RESEARCH IN EPIC – ASSOCIATING PATIENTS WITH A STUDY

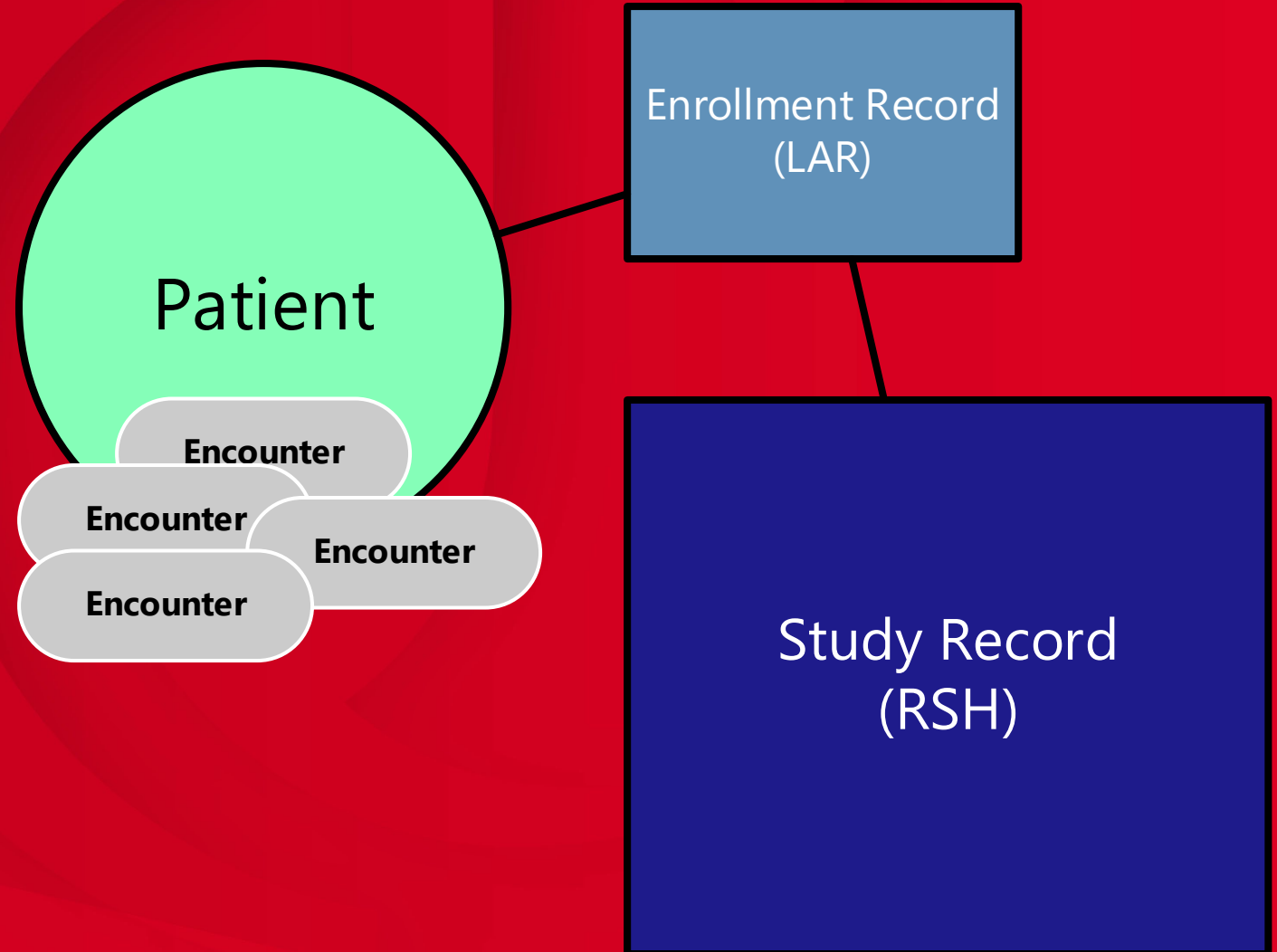
THE PROCESS

1. Click the Research Studies activity in the toolbar
2. Find your patient using the patient search tool
3. In the Research Studies activity, Search for the study you would like to add the patient to
4. Add participant details and click Accept

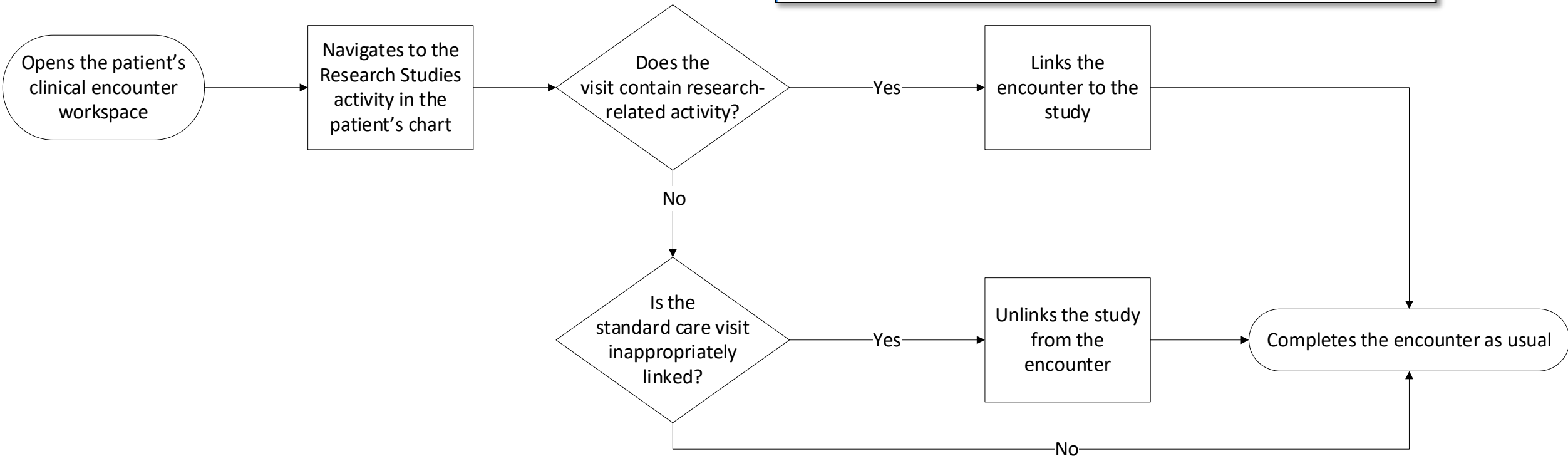
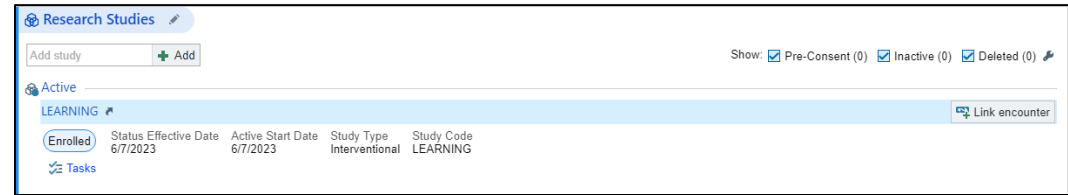


Active				
LEARNING				
Enrolled	Status Effective Date	Active Start Date	Study Type	Study Code
	6/7/2023	6/7/2023	Interventional	LEARNING

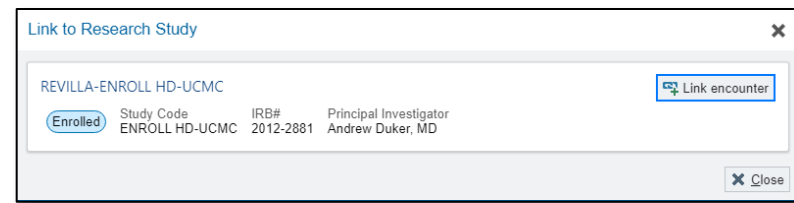
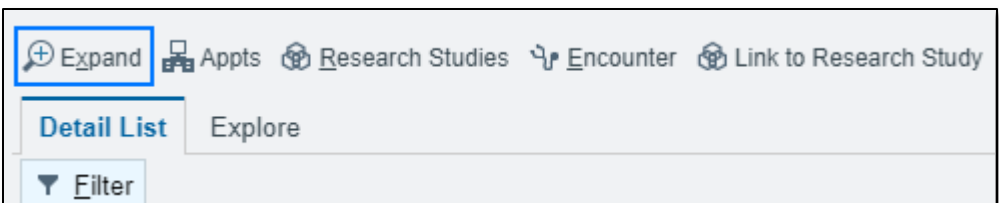
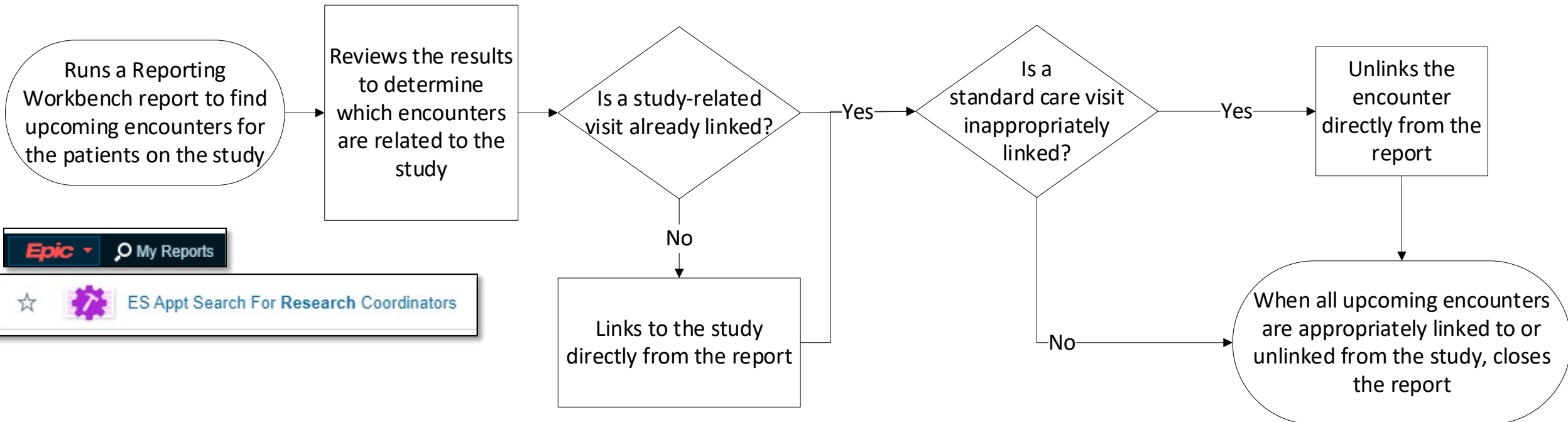
Visit Linking



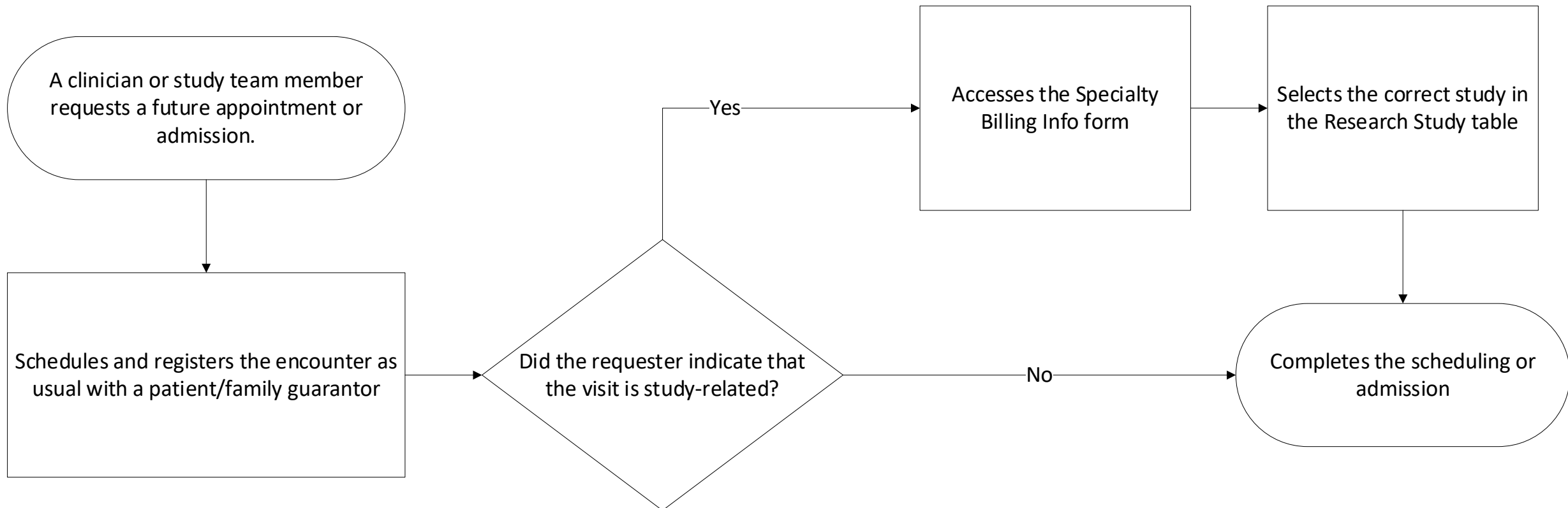
LINKING VISITS – WORKFLOW 1 (WITHIN CHART)



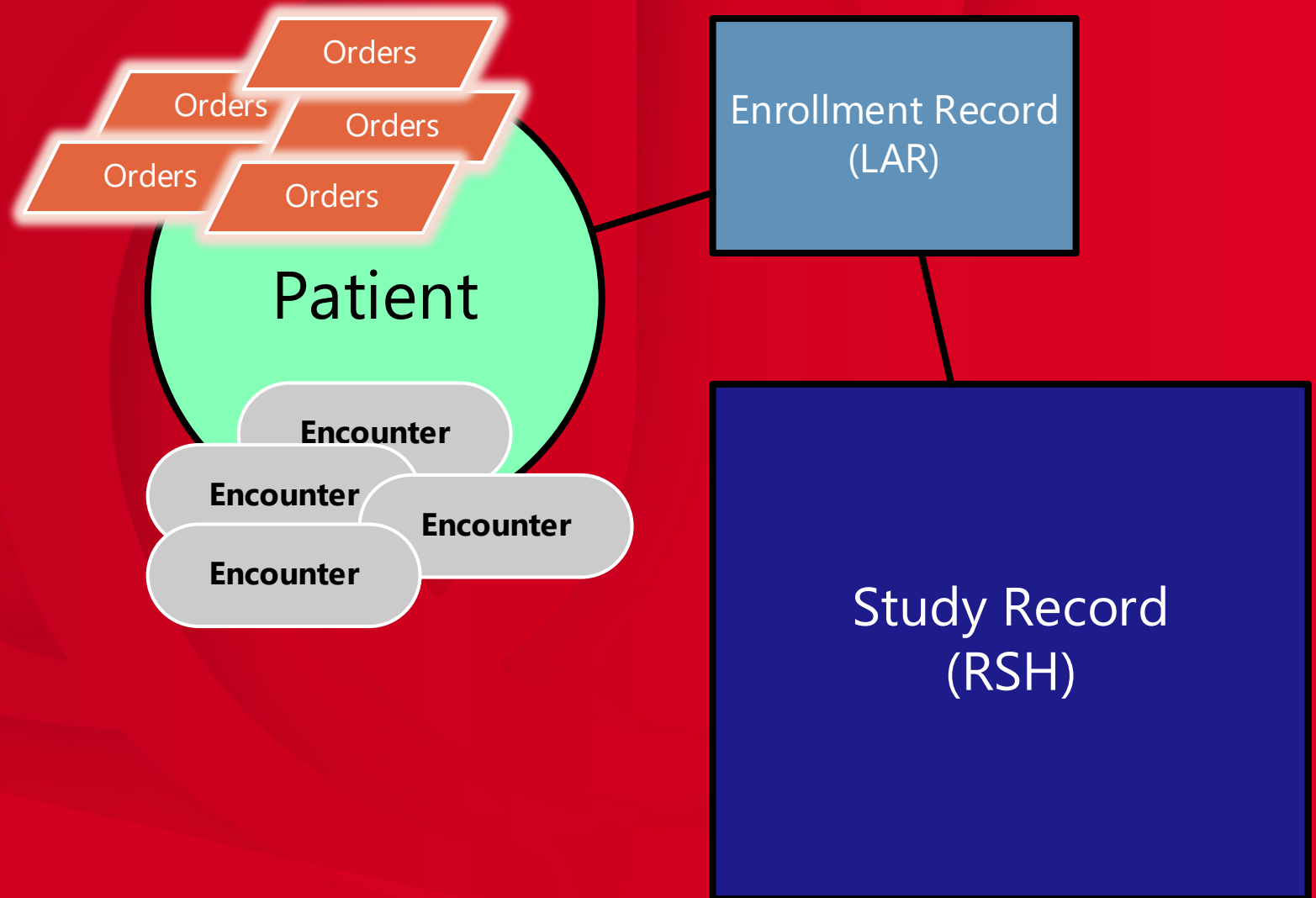
LINKING VISITS – WORKFLOW 2 (REPORTING WORKBENCH)



LINKING VISITS – WORKFLOW 3 (SCHED/REG)





Order Linking



ORDER LINKING

To link an order to a study

1. In an applicable encounter, click 
2. Find/Select your order
3. Click Dx Association & search for "Research" 

Diagnoses Search - XTRAIN,AMY E

research

ID	Name
725319	Research exam
366592	Research requested antenatal ultrasound scan
366593	Research requested ultrasound scan, antenatal
696110	Research study patient

4. Select 'Research study patient' dx and route order for signature as per normal

Order linking is based on the 'Research Study Patient' diagnosis code .

- Research Study patient code =
 - ICD-9 V70.7
 - ICD-10 Z00.6
- Orders must be associated before they are signed!
- Correct study will be selected during billing review
- If you have a visit that is unlinked but orders that are, the visit should be linked

BILLING REVIEW



BILLING REVIEW - OVERVIEW

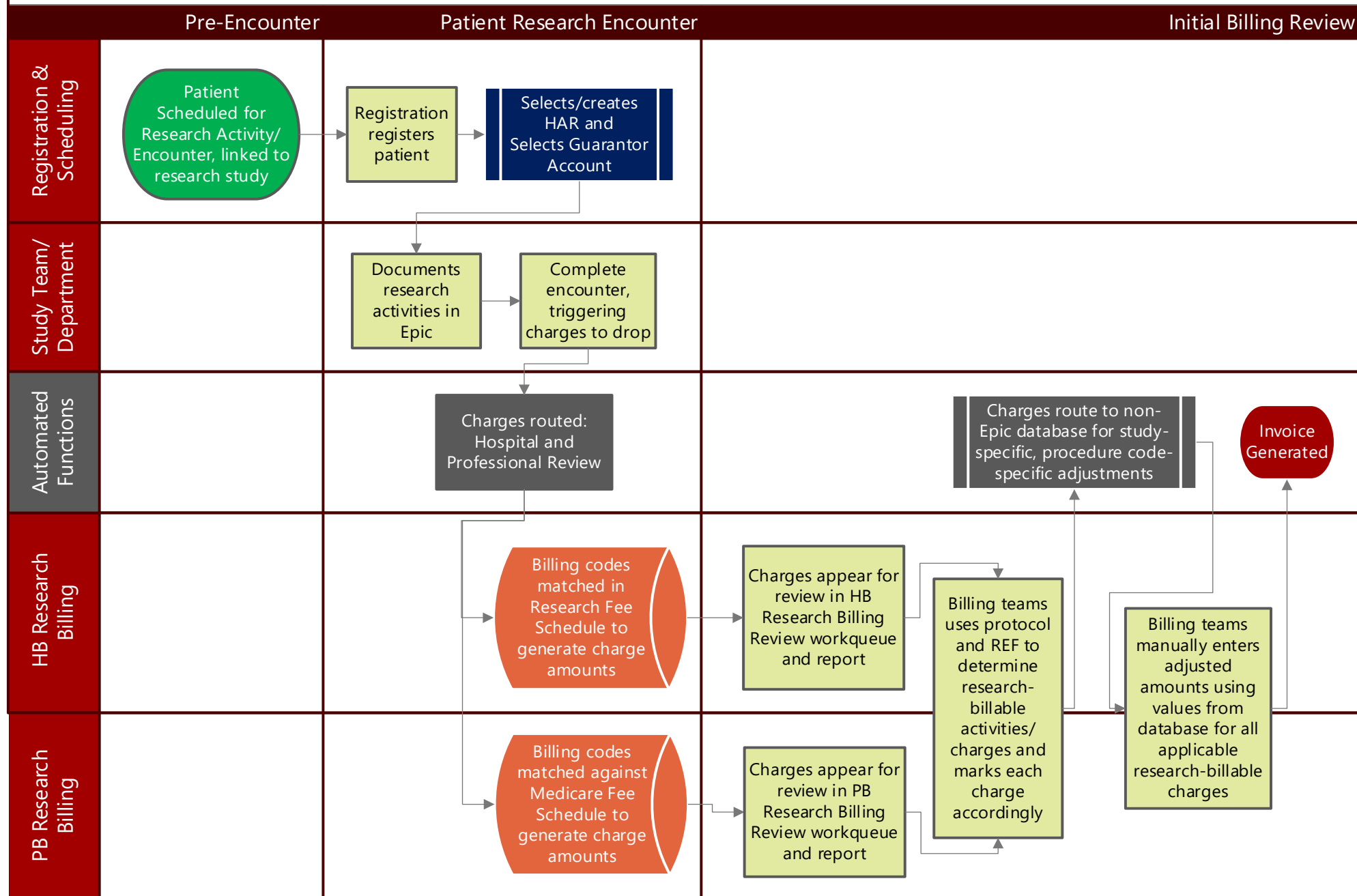
What's the purpose of Research charge review?

- Allows a double check of charges before they are billed to either the study or the patient.
- Verifies the correct modifiers are associated with the charge.

What does Research charge review involve?

- EPIC research billing features leverage research study enrollment, the patient timeline, and research study billing protocols.
- Charges for patients that are linked to research study in EPIC are evaluated through billing and routed to either the study account or patient's account with modifiers when necessary.

BILLING REVIEW WORKFLOW



...AND THEY LINKED HAPPILY EVER AFTER



An aerial photograph of the University of Cincinnati campus, showing various buildings, walkways, and green spaces. The entire image is overlaid with a semi-transparent red filter. The word "QUESTIONS?" is written in large, white, bold, sans-serif capital letters on the right side of the image.

QUESTIONS?

Thank you.

ADAM ALEXANDER
ADAM.ALEXANDER@UC.EDU

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513-319-6121 (c)

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JEFFREY.ZAMOR@UCHEALTH.COM