

**(Session 101) –
Research Billing Compliance:
*A Case Study at Renown Health
Using the Epic Research Module***

Basic Level

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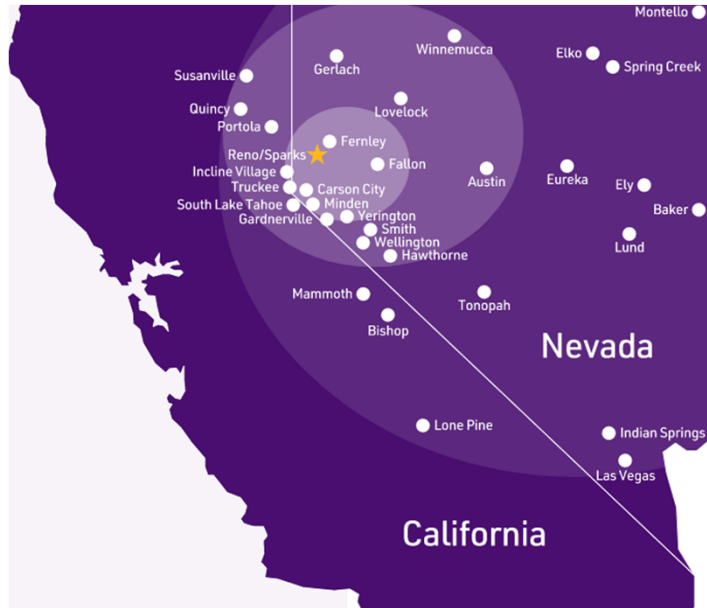
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Objectives

1. *Making it work and work compliantly*--launching the Epic Research Module

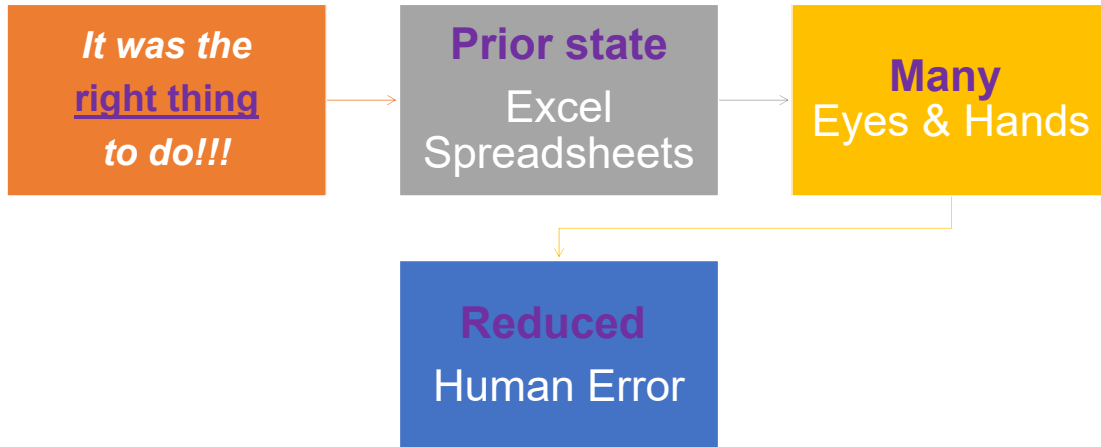
2. *Collaborating* and *engaging* multiple stakeholders--who, when, where, how, and what

3. After launching, the importance of *continuous review* and *updating standards of work*

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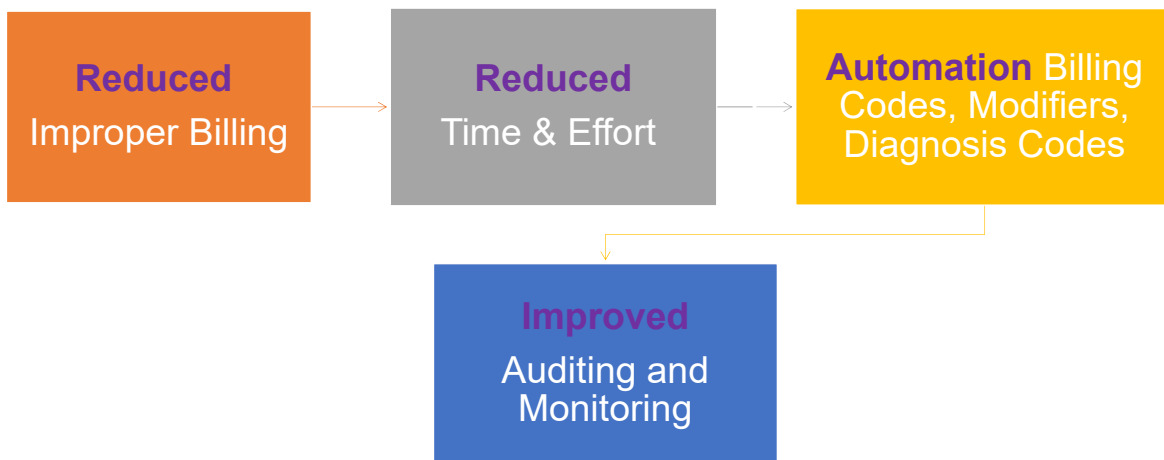
Why?



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Why?



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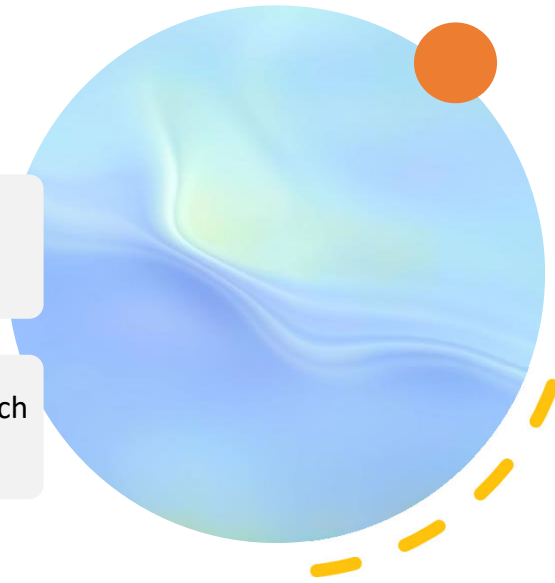
Objective #1



Making it work and work compliantly...



...launching the Epic Research Module



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Preparatory Work before Launching Epic Research Module

- Rationale & Process of using the Epic Research Module for improved billing compliance.
- *Medicare Coverage Analysis (MCA) or Coverage Analysis (CA)*

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What is a Clinical Trial Coverage Analysis?



It is a **Guidance Tool** for institutions to assist with billing compliance

All items and services billable to Medicare or Medicaid **must be supported by** documentation of **medical necessity** in the medical records



Citation: Szczepanek CM, Hurley P, Good MJ, et al., *Journal of Oncology Practice*. <https://doi.org/10.1200/JOP.2016.020313>

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Why did we care about using a CA (MCA)?

A **Coverage Analysis** or *Medicare Coverage Analysis* is **part of a process** was essential in our review including:

1. Local coverage decisions (LCDs)
2. Review of medical necessity
3. Physicians' orders
4. Claim review process prior to submission to payers
5. Was our clinical trial a "deemed" trial?
6. Was the study a qualifying clinical trial?

Citation:

1. Szczepanek CM, Hurley P, Good MJ, et al., *Journal of Oncology Practice*. <https://doi.org/10.1200/JOP.2016.020313>
2. Clinicaltrials.gov <https://www.clinicaltrials.gov/>
3. Medicare Coverage ~ Clinical Trial <https://www.cms.gov/medicare/coverage/clinicaltrialpolicies/downloads/finalnationalcoverage.pdf>

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Decision Points for determining a QCT

Qualifying Clinical Trial Analysis	
1	Is this study interventional or observational?
2	Does the investigational item have an FDA approved IDE?
3	If there is an IDE, is there documented CMS approval?
4	Is the subject or purpose of the trial for the evaluation of an item or service that falls within a Medicare benefit category?
5	Does the trial have therapeutic intent?
6	Does the trial of therapeutic intervention enroll patients with diagnosed disease?
7	Is the clinical trial deemed?
8	Does this study meet the requirement of Medicare's Coverage with Evidence Development (CED) process?
9	Is this study a Qualifying Clinical Trial?

Coverage Analysis QCT questions format prepared by WCG for Renown Clinical Research Office (de-identified)
CMS Clinical Trial Policy <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=1&ncdver=2&fromdb=true>

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*What is used
in creating a
Clinical Trial
Coverage
Analysis?*

- National Coverage Decision 310.1
- Oncology: NCCN Clinical Practice Guidelines
- Other resources
- Contract
- Budget
- Protocol
- Calendar/Schedule of Events

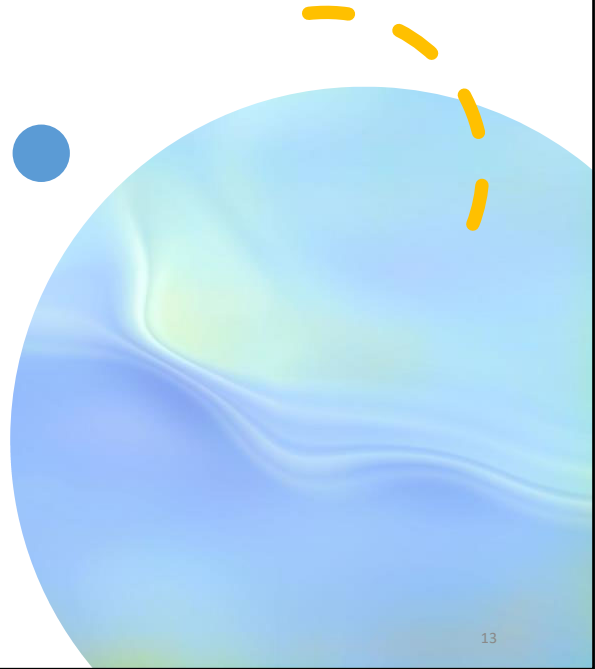
At Renown Health, we use a CA vendor!

Citations: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=1&ncdver=2&fromdb=true>; https://www.nccn.org/guidelines/category_1; Szczepanek CM, Hurley P, Good MJ, et al., *Journal of Oncology Practice*. <https://doi.org/10.1200/JOP.2016.020313>

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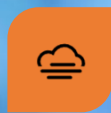
Objective #2



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What was the expectation?



BE REALISTIC



REVIEW
VENDORS/DEMOS



COLLABORATE



FOLLOW
THROUGHPUT



FUNCTIONALITY



COMPLIANCE



TRAINING/SUPPORT



FEEDBACK &
UPDATES

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Who?

Multiple stakeholders

Project Champions & Facilitator

Committees:

Workgroups:

Multiple Representatives:

PROJECT CHAMPIONS (RESEARCH DIR. & MNGR.)

COMPLIANCE CHAMPION (CCO)

FINANCE CHAMPIONS (CFO)

PROJECT FACILITATOR

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Project Management

Milestones	Timeline
Vendor Platform Selection	Day: <120> - 0
Develop	Days: 120
Train	Days: 60
Go-live	Selected: Date/Time
Post-live	Days: 90
Project Close	Selected: Date/Time
Continuous Improvement	Every day

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Who?

Multiple stakeholders

Project Champions & Facilitator

Committees:

Workgroups:

Multiple Representatives



RESEARCH ADVISORY
COMMITTEE



EPIC STEERING
COMMITTEE



IT PROJECT
MANAGER

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Who?

Multiple stakeholders

Project Champions & Facilitator

Committees:

Workgroups:

Multiple Representatives:



CLINICAL (PHYSICIANS, RNS, CRC, REGULATORY)



BILLING (PB, HB, REV CYCLE, MNGRS, DIR., AUDIT)



COMPLIANCE, DATA, & PRIVACY



IT PROJECT TEAM



IT ANALYST TEAM

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Who?

Multiple stakeholders

Project Champions & Facilitator

Committees:

Workgroups:

Multiple Representatives:

Internal SMEs:

- Audit & Compliance
- Epic Trainers
- HIM
- Interface Analyst
- IT
- Lab
- Pharmacy
- Imaging
- Research Analysts **SMEs**

External Consultants:

- Epic **SMEs**

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When?

Right time???

**There is never
a right time
for everyone**



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Where & How?

Meetings...
Meetings...
Meetings...
Meetings...



Whatever would work!!!!!!
Onsite
Offsite
Hybrid



Informal or Formal
...Email
...Phone
...Coffee

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Objective #3: After Launching...

the importance
of ***continuous
review...***

and ***updating***
standards
of work

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Internal non-clinical Epic Trainers

- Created "Tip Sheets"
- Created "Test Environment"
- Validated "Breaks" system or training needs
- Audited Test Environment process flow

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Clinical Research Office: Billing Roles

Tier I: "Study Team Reviewer"



Tier II: "Biller Review"



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Research Billing Reporting Home

Biller Review

Report completed: Fri 3/25 08:32 AM | Results expired: Fri 3/25 09:32 AM

5 Patients Awaiting Biller Review

1,207 Total Balance Awaiting Biller Review

Study Team Review

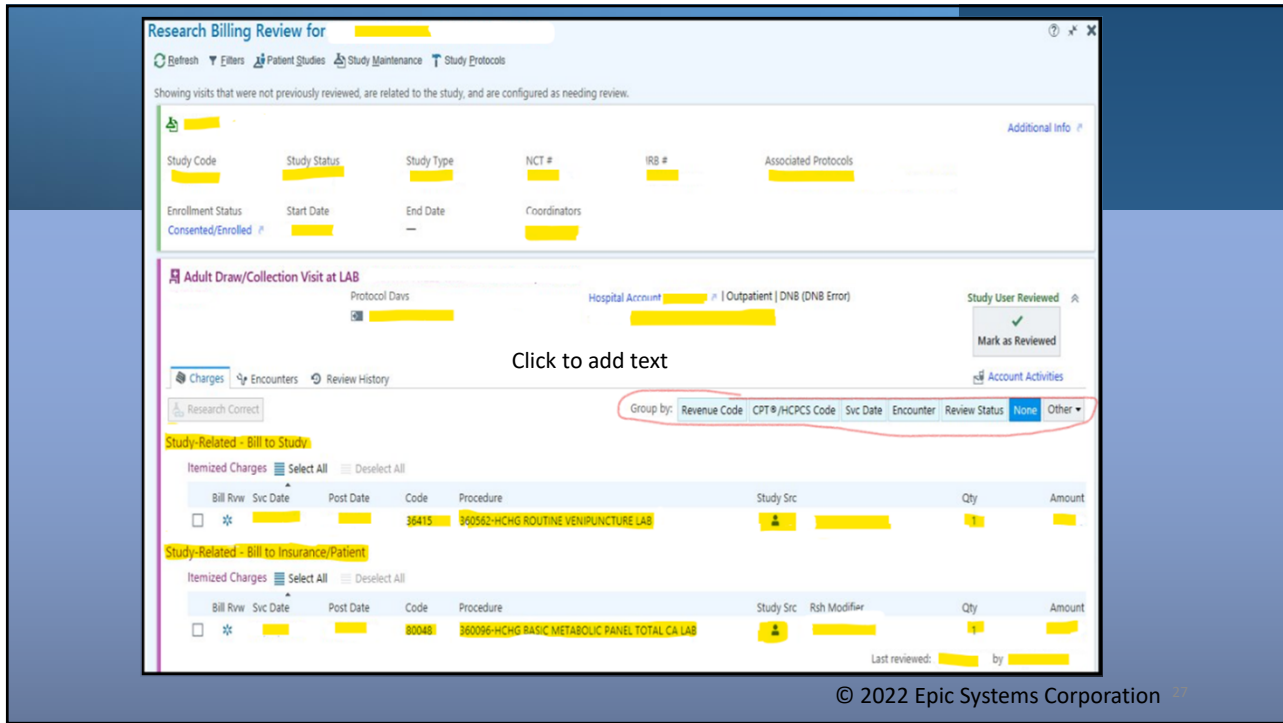
Report completed: Fri 3/25 08:50 AM

4 Patients Awaiting Study Team Review

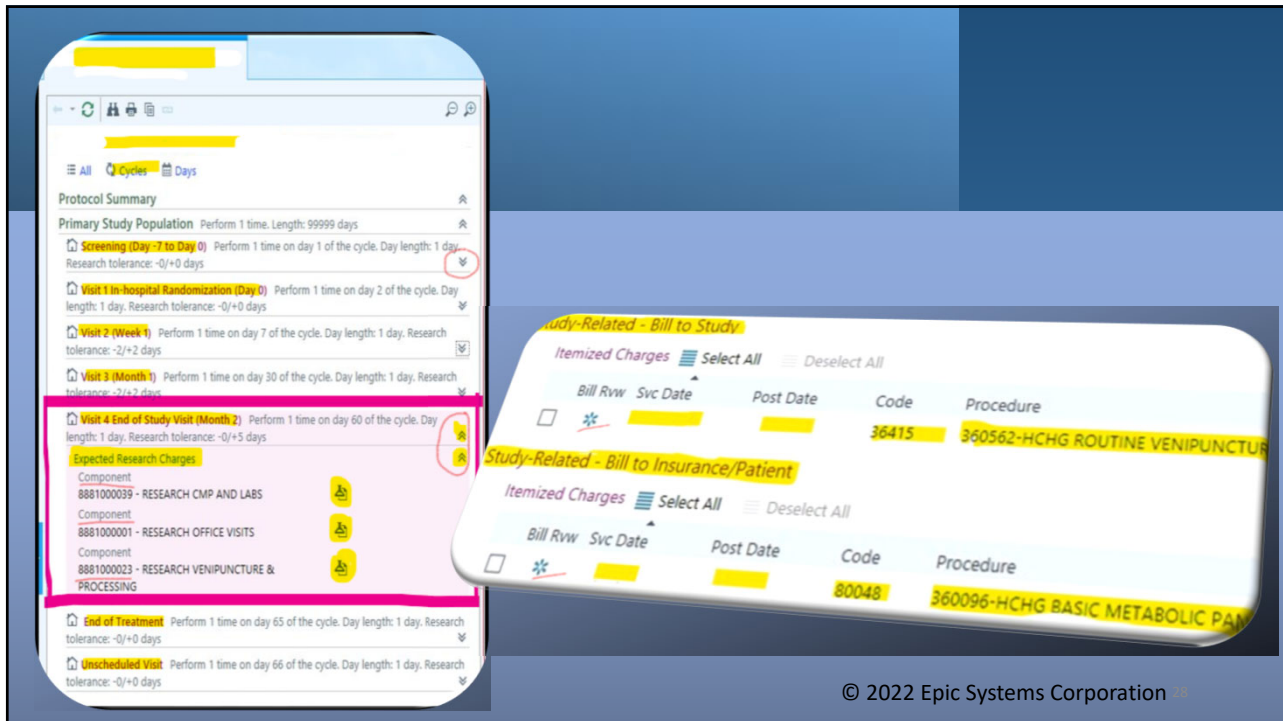
71,053 Total Balance Awaiting Study Team Review

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Research Billing Review for [REDACTED]

Refresh Filters Patient Studies Study Maintenance Study Protocols

Showing visits that were not previously reviewed, are related to the study, and are configured as needing review.

[REDACTED] Additional Info

Study Code	Study Status	Study Type	NCT #	IRB #	Associated Protocols
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Enrollment Status Start Date End Date Coordinators

CT PET60 Protocol Days [REDACTED]

Charges Encounters Review History

Research Correct

Study-Related - Bill to Study

Itemized Charges Select All Deselect All

Bill Rvw Svc Date Post Date Code Procedure Study Src Rsh Modifier Qty Amount

Procedure 70543 (CPT®) - PR MRI, FACE, NECK, COMBO
 Procedure 78815 (CPT®) - PR PET IMAGING CT ATTENUATION SKULL BASE MID-TH* Routine

Study User Reviewed
 Mark as Reviewed
 Account Activities
 Review Status None Other

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Research Billing Review for [REDACTED]

Refresh Filters Patient Studies Study Maintenance Study Protocols

Showing visits that were not previously reviewed, are related to the study, and are configured as needing review.

[REDACTED] Additional Info

Study Code	Study Status	Study Type	NCT #	IRB #	Associated Protocols
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Enrollment Status Start Date End Date Coordinators

Consented/Enrolled

Chemo Visit at Children's Infusion SVCS with [REDACTED] Study-Related Guarantor [REDACTED]

Charges Encounters

Research Correct

Group by: Service Provider CPT#/HCPCS Code Encounter Review Status Bill Area None Other

Non-Study Charges

Itemized Charges Select All Deselect All

Billr	Study	Svc Date	Post Date	Code	Procedure	Study Src	Qty	Amount
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	99214	PR OFFICE/OUTPATIENT ESTABLISHED MOD MDM 30-39 MIN	[REDACTED]	1	[REDACTED]

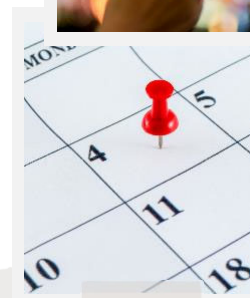
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Wrap-up: Staying Compliant

Follow the money: Research Billing

- Research **encounter/visit #1** (*Consent?*)
- **All** calendar/schedule of events/time point
- **End-of** research participation
- **30-days**: SAE reporting requirements, as applicable
- **Close-out**: Research billing status review
 - Outpatient: 60-days
 - Inpatient: 120-days



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Summary of the Case Study at Renown Health Using the Epic Research Module

Our Billing Process Identifies and Captures:

- **Research**: Study-Only encounters/charges
****do not double bill—avoid refunds & fines****
- **Research**: Billable to Insurance/Patient encounters/charges
****apply correct modifier(s), condition & diagnosis codes, & NCT # ****
- **Non-Research** encounters/charges
****revenue stream—avoid holding claims****

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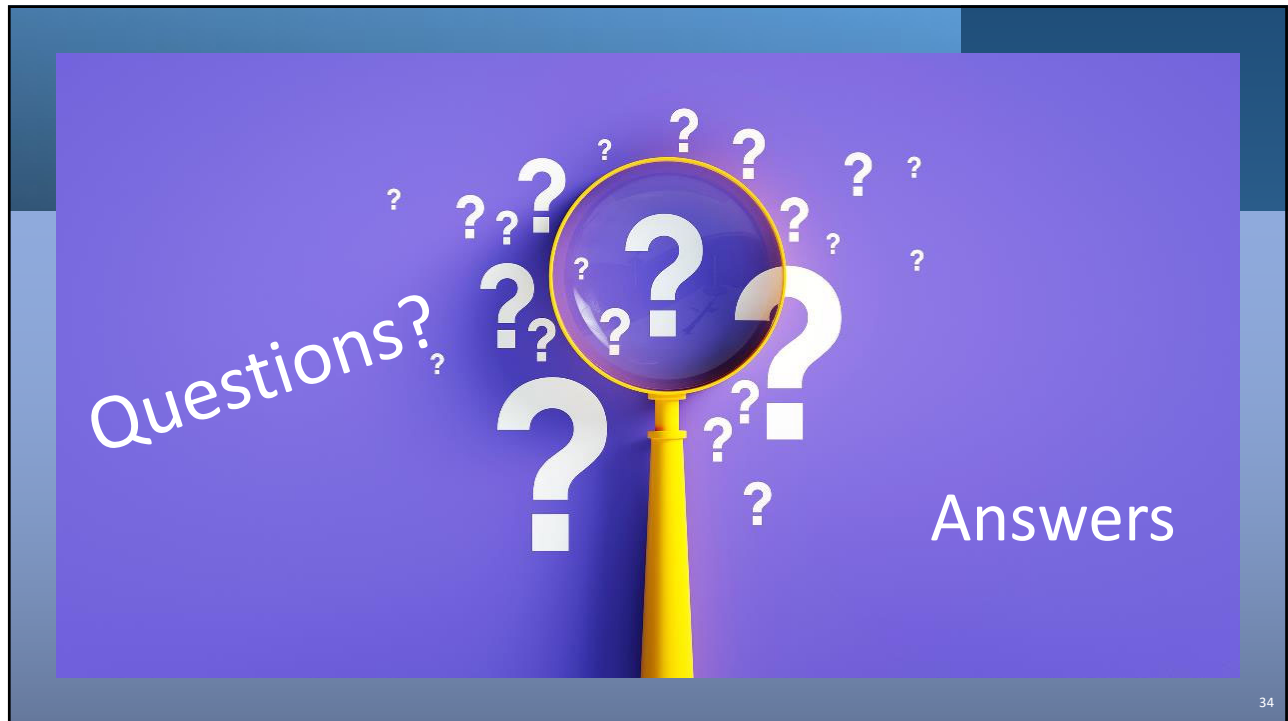


Thank you to all our Teammates
for making the
Epic Research Module
Go-Live Successful

- Many people from across the organization
- Project Management
- Clinical Research Office
- Senior Application Specialist
- Hospital Billing
- Professional Billing
- Epic Trainers
- Pharmacy
- Renown Health Institutions:
Cancer, Cardiology, & Neurology

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Questions?

Answers

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Contact Information

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