Research Billing II: The RBC Process

Clinical Research Resources Office

13 March 2024

Poll 1: What description best fits your role?*

1. Clinical research coordinator
2. Clinical research financial analyst/manager
3. Regulatory specialist, study team, or department
4. IRB administrator or compliance professional
5. Department administrator
6. Investigator
7. Other

**If your title differs, please choose the role most closely relevant*

Poll 2: Does your role include attention to research billing?

1. Yes, directly
2. Yes, indirectly
3. No
4. I am not sure

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Primary objectives

1. Contextualize the BMC/BUMC research billing process to research billing compliance (RBC) history and requirements

2. Describe the front-to-back-end steps of the research billing process

3. Identify the crucial roles of the study team and the Clinical Trial Office (CTO) in process performance

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RBC process preliminaries

Recap of Part I: the most basic rules of RBC

Never bill to patient/insurer an item that is **not "routine" (SOC)**

- Must be medically necessary and not prohibited by law, regulation, coverage determination
- Misbilling:
  - violates research ethics
  - erodes participant/community trust
  - damages institutional reputation
  - is subject to stiff federal penalties

Claims related to most clinical trials must include **research-specific modifications***

3. **Give something free**, in absence of formal financial needs assessment, must give the same to **every federally insured patient**

**More than mention of claims modifications is outside of the scope of this presentations; details are available in the Appendix of this presentation*

Operationalizing research billing compliance (RBC)

2000-present: institutions

- slowly catch on to RBC requirements
- assign staff to RBC assurance

2008-present: RBC staff network to

- Untangle the complexities
- Forge methods to comply with requirements
- **Identify stakeholders** and work toward buy-in
- Collaborate in development of **RBC-assurance systems**
- Lobby federal payers for clarification and consistency

Over time, an RBC process outline has emerged

- Basic steps are common
- **Each site's is unique** and still **evolving**

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BMC/BUMC systems directly involved in research billing

Epic: Electronic Health Record System (EHR)

- Comprehensive patient care, billing, and reporting tool
- Integrates clinical and financial data for efficient management

Velos Clinical Trial Management System (CTMS)

- Specialized for clinical research management
- Tracks study details, patient enrollment, and financial information

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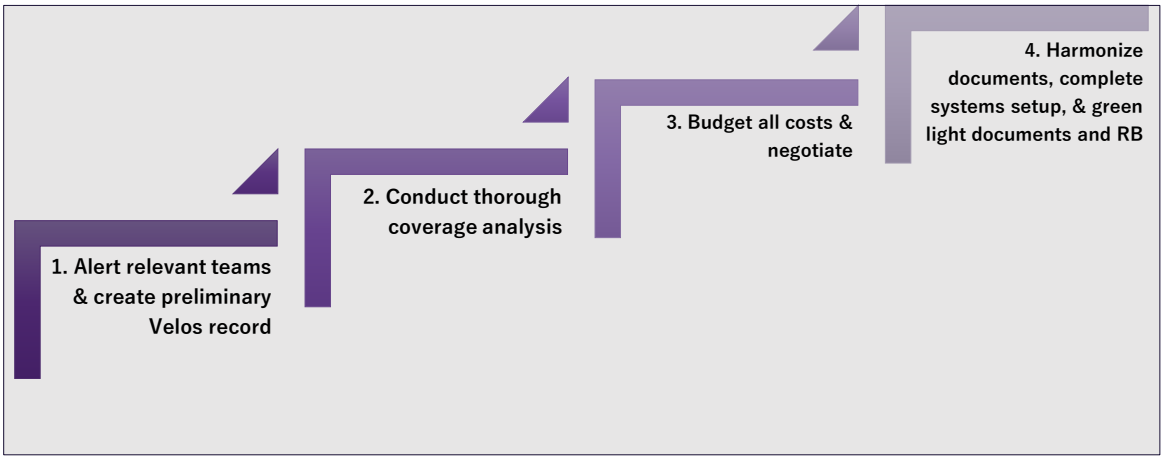
Comprehensive RBC process: a snapshot

Front-end RBC workflow



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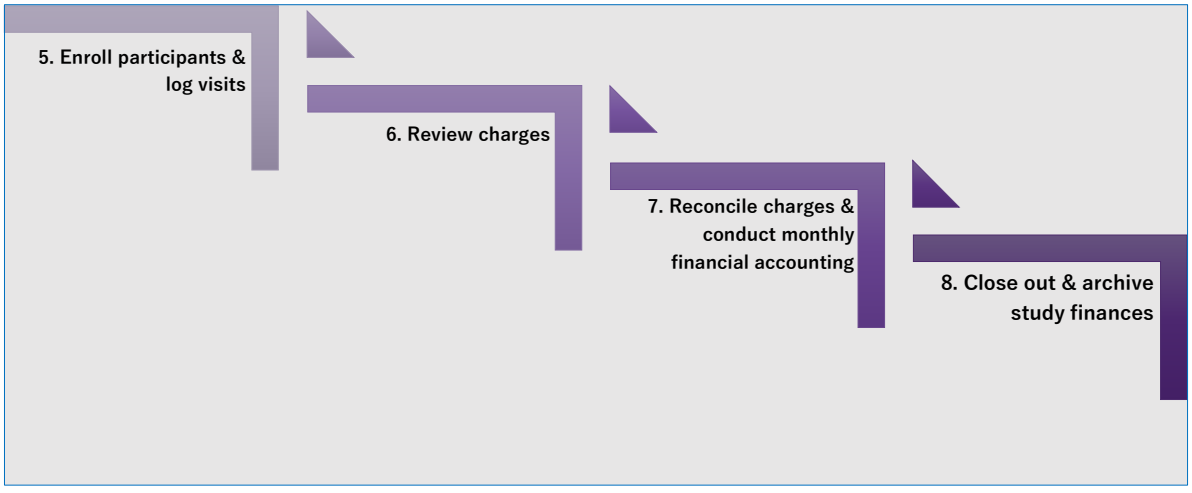
Back-end RBC workflow



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Front-end RBC process: from protocol acceptance to CTO clearance to enroll participants

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Front-end: RBC step 1

Shared responsibility

a. **Preliminary Velos set-up: study team**
- CTMS record creation alerts CTO to initiate RBC process: Study team

b. Queue up relevant teams for RBC readiness: CTO
- Crucial for compliance assurance and efficiency
  - All RBC-relevant documents must be **consistent, comprehensive** prior to commencement of study enrollment
  - Early attention saves time, effort, confusion, **error**
- Collaborators:
  - Coverage analyst: without which, **budgeting** is delayed
  - Regulatory: Informed Consent Form (ICF) **costs/injury language, protocol-consistent clinical services**
  - Contracting/legal**:** Clinical Trial Agreement (CTA) **costs/injury language** and **sponsor budget**

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Front-end: RBC step 2

CTO responsibility

Coverage Analysis

a. Commences with **protocol review** for all clinical services

b. Determines services billable as routine: **prospective reimbursement analysis** (PRA)

Items and Services	Visit 1 Day 0 Screen	Visit 2 Day 1 Baseline	Visit 3 Day 8	Visit 4 Day 15	Visit 5 Day 29	Visit 6 Day 60	Visit 7 Day 90 EOS
Informed Consent	SP						
Inclusion/Exclusion	SP	SP					
Demographics	SP	SP					
Physical Exam	SOC	SOC	SP	SP	SOC	SOC	SP
ECG (12-lead w/ rhythm strip)	SOC			SP	SP	SP	SP
Echocardiogram	SP				SP	SP	SP
Venipuncture	SOC	SP	SP	SP	SOC	SOC	SP
CBC with Differential and Platelets	SOC		SP	SP	SOC	SOC	

c. Identifies whether study is a **"qualifying" clinical trial** (QCT)*
- Most clinical trials meet the federal QCT criteria; other insurers follow
- Results in requirement to add research modifications to claim
- Facilitates federal (and commercial) insurer research billing audits

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QCT is a complex construct; see appendix for QCT status requirements

Front-end RBC: step 3

Shared responsibility

Budgeting

a. Internal cost budget: Figures study costs comprehensively

Costs are by effort or price; priced items often need add'l effort costing

Items and Services	Visit 1 Day 0 Screen	Visit 2 Day 1 Baseline	Visit 3 Day 8	Visit 4 Day 15	Visit 5 Day 29	Visit 6 Day 60	Visit 7 Day 90 EOS
Informed Consent	$ 360						
Inclusion/Exclusion	$ 100	$ 100					
Demographics	$ 35	$ 35					
Physical Exam	SOC	SOC	$ 268	$ 268	SOC	SOC	$ 268
ECG (12-lead w/ rhythm strip)		$ 35					
Echocardiogram		$ 70			$ 70	$ 70	$ 70
Venipuncture	SOC	$ 167	$ 167	$ 167	SOC	SOC	$ 167
CBC with Differential and Platelets	SOC		$ 48.00	$ 48.00	SOC	SOC	

SOC items are not cost-free: add line item for effort required to bill appropriately

b. Budget negotiation

- Retains CA integrity
- Ensures BMC is not cost-sharing

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Front-end: RBC step 4

CTO* responsibility

a. Document harmonization*

- Reviews, signs off on **comprehensive consistency** of – or returns for correction:
  - CA
  - Internal budget
  - CTA sponsor budget/injury language
  - ICF costs/injury language
- Confirms fully approved CA as **final billing plan**
  - For Velos calendar and research billing review (RBR)

b. Study project/account entered into financial system

*Sponsored Programs Administration (SPA) sets up government, foundation projects

Note: Successful completion of document harmonization is a necessary but insufficient condition of study enrollment approval

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Front-end: RBC step 4, continued

CTO responsibility

d. Velos study calendar set-up, sign-off

- **"Research Record" sent to Epic**
- Epic research record is manually activated

Items and Services	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
	Day 0	Day 1	Day 8	Day 15	Day 29	Day 60	Day 90
	Screen	Baseline					EOS
Informed Consent	SP						
Inclusion/Exclusion	SP	SP					
Demographics	SP	SP					
Physical Exam	SOC	SOC	SP	SP	SOC	SOC	SP
ECG (12-lead w/ rhythm strip)	SOC			SP	SP	SP	SP
Echocardiogram	SP				SP	SP	SP
Venipuncture	SOC	SP	SP	SP	SOC	SOC	SP
CBC with Differential and Platelets	SOC		SP	SP	SOC	SOC	

Coverage Analysis for Calendar: New Test

Event	CPT code	Visit 1 (Screening	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
Informed Consent	N/A	X SP						
Inclusion/Exclusion	N/A	X SP	X SP					
Demographics	N/A	X SP	X SP					
Physical Exam	99202	X SOC	X SOC	X SP	X SP	X SOC	X SOC	X SP
ECG (12-lead w/ rhythm strip)	93000	X SOC			X SP	X SP	X SP	X SP
Echocardiogram	93306	X SP					X SP	X SP
Venipuncture	36415	X SOC	X SP	X SP	X SP	X SOC	X SOC	X SP
CBC with Differential and Platelets	85025	X SOC		X SP	X SP	X SOC	X SOC	

e. Study team notification: Participant **enrollment may commence** (upon IRB approval)

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17

Back-end RBC process: from first participant enrollment through study finance closure

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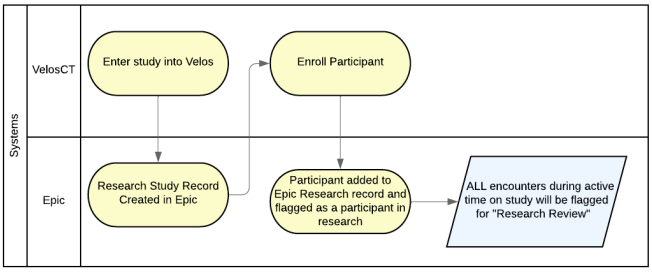
Back-end: RBC step 5

Study team responsibility

a. Participant enrollment in Velos

- Associate participant with a study calendar
  - **MUST** be completed by the end of the day that consent was signed!
- Automatically triggers Velos to send data to Epic, associating patient with Epic study record
- Also flags patient's Epic record as **"Research Active"**
- Segregates **ALL** participant encounters for RBC review until pt's enrollment is ended **in Velos**



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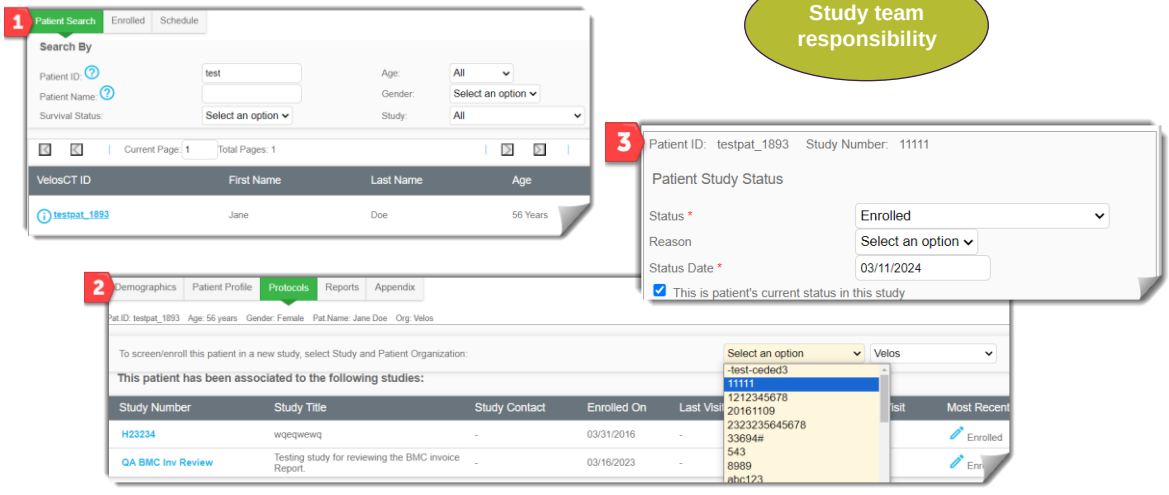
Participant enrollment in Velos

Study team responsibility



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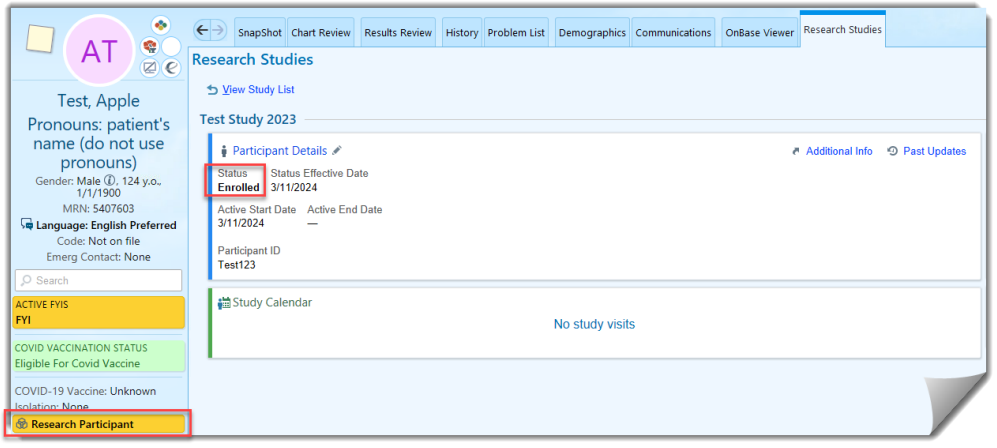
Participant enrolled in Epic via Velos data push



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Back-end: RBC step 5, continued

Study team responsibility

b. Comprehensive study visit documentation in Velos

- **ALL clinical services and dates of service**
  - Unscheduled visits
  - Canceled/rescheduled visits
  - Services not specified in protocol, eg, services related to study-related **adverse events**
  - Protocol-specified services not performed
- For **life of study**

The importance of this step cannot be overemphasized

Accurate recording of events and **timely entry**:

Saves time, reduces misbilling risk, is **required by policy***

Best practice: simultaneous with clinical documentation in Epic

** https://bostonmedicalcenter.policytech.com/dotNet/documents/?docid=4619*

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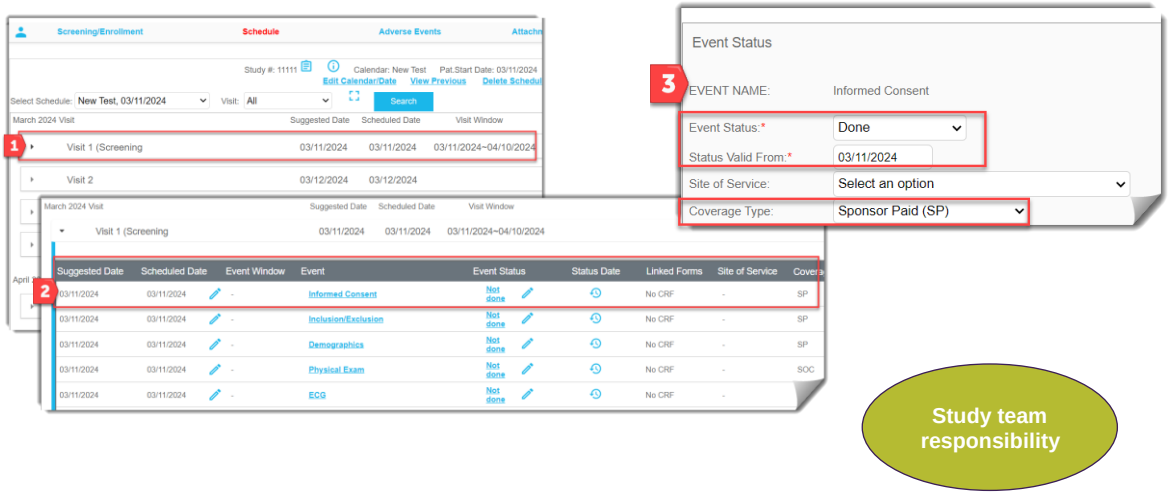
[Velos] must be used as required by all internally or externally sponsored research that includes one or more prospective clinical services and by all industry-initiated human research. In addition, as authorized by BMC Revenue Cycle or Health Information Management, use of the CTMS is required to meet Centers for Medicare and Medicaid (CMS) claims rules.

Requirements are set forth in Research Operations' CTMS trainings and job aids. The BMC CTMS training is a prerequisite to CTMS access.

Use of the Clinical Trials Management System, BMC policy, March 2023

Velos visit log



Study team responsibility

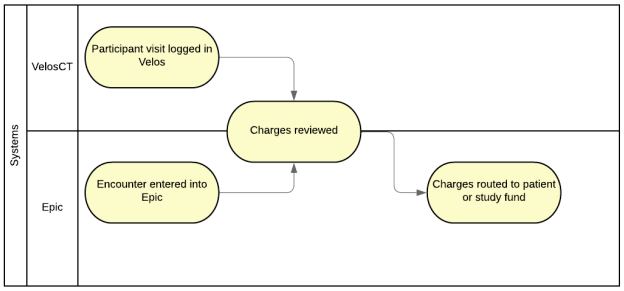
Back-end: RBC step 6

CTO responsibility

Study team may need to clarify log

a. Research billing review (RBR)

- All charges of patients have been segregated
- They are compared to recorded study activities for accuracy
- Research claims modifications for qualifying studies



Charge Routing Options
Non-Study Charges **OR**
Study-Related – Bill to Study **OR**
Study-Related – Bill to Insurance/Patient

b. Transfer of sponsor charges to study team

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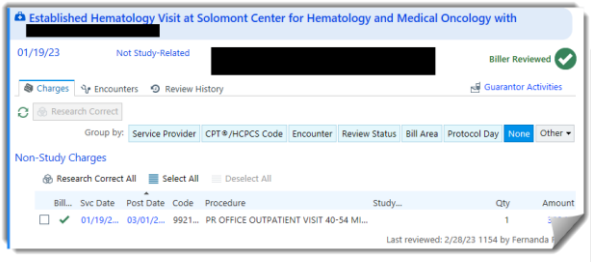
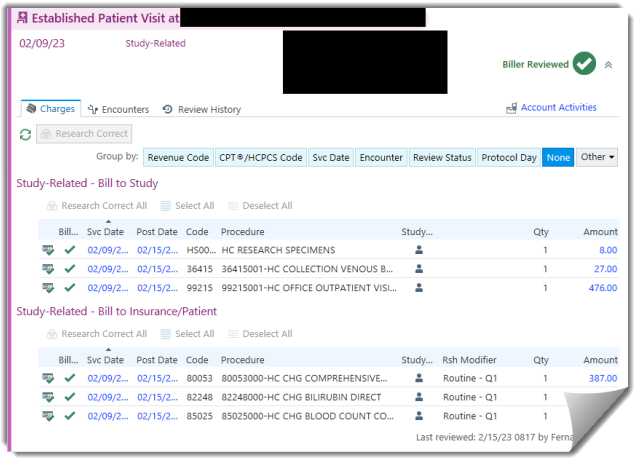
From RBR to transfer of charges to sponsor

CTO responsibility





All charges routed as "Study-Related – Bill to Study" are:

- Transferred from the patient's guarantor account to **two monthly study accounts** – one for professional and one for hospital billing (PB, HB)

CTO then:

- **exports the study charges** to an Excel file
- sends it to study team for charge reconciliation

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Back-end RBC: step 7

Shared responsibility

a. Study charge reconciliation

Upon receipt of sponsor charges, **study team**:

- Reviews for accuracy: Are ALL sponsor – and ONLY sponsor charges – included on the Excel file?
  - A missing charge indicates potential misbilling of patient and requires follow-up
  - No "Study-related – Bill to Insurance/Patient" or "Non-study Charges" items should be present
  - (Besides using up study funds, they violate the "no free items" federal rule)
- Reports any error or 100% accuracy to CTO

CTO investigates and corrects error(s)

- Identifies **one-off error** or **systemic issue**
- Corrects error; as needed, analyzes and resolves systemic issue
- **Documents** error, correction, and **reports resolution** to study team

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Back-end: RBC step 7, continued

CTO responsibility

b. Monthly finance and accounting, industry-negotiated clinical research*

- Pays service providers, via journal entry in financial system
- Invoices sponsors/tracks auto-payments
- Processes sponsor payments
- Reconciles study- and visit-level revenue and expenses

CTO collaborates with Sponsored Programs Finance (SPF) team on finance and accounting of government and foundation awards that include clinical provisions

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Back-end: RBC step 8

CTO responsibility

Closing the finances of clinical research study

System Closures
- Confirm all patient visits and procedures are captured and billed in Epic
- Close out study in Velos
- Reconcile accounts in financial system and ensure no pending transactions exist

Final Invoices and Payments
- Send final invoices to the sponsor including all outstanding charges
- Confirm receipt of all expected payments

Final Billing Reconciliation
- Compare actual revenue and expenses against budgeted amounts
- Adjust entries for any overages or shortages
- Document final financial status in study files for audit purposes

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Contact the speakers

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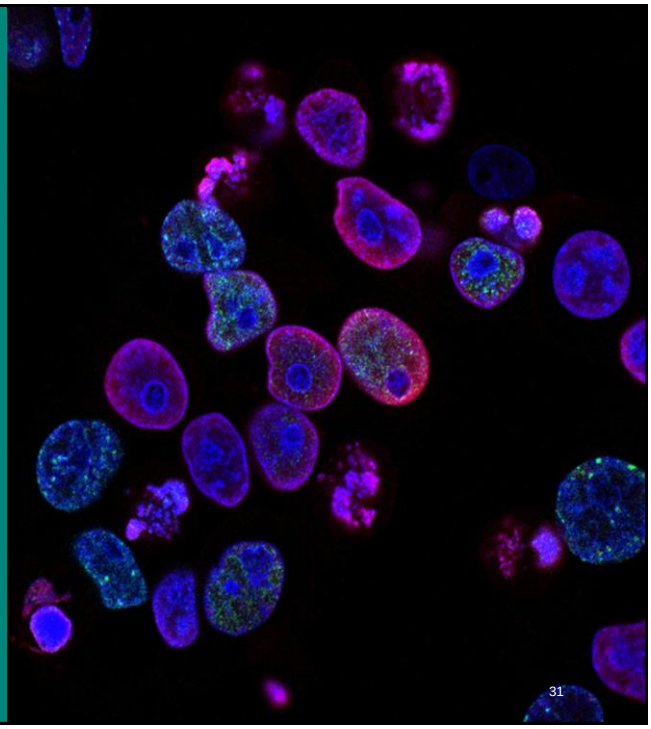
References

- 1995: U.S. allows Medicare billing related to investigational devices: 42 CFR 405.201-213 Medicare Services Coverage Decisions That Related to Health Care Technology (amended 2004, 2013, 2021)
- 2000: Medicare extends billing to “clinical trials”, National Coverage Determination 310.1 (amended 2007)
- Medicare Claims Processing Manual, Chapter 32, especially §§68-69 (investigational devices; qualifying clinical trials)



Appendix

a. Research billing review flowchart

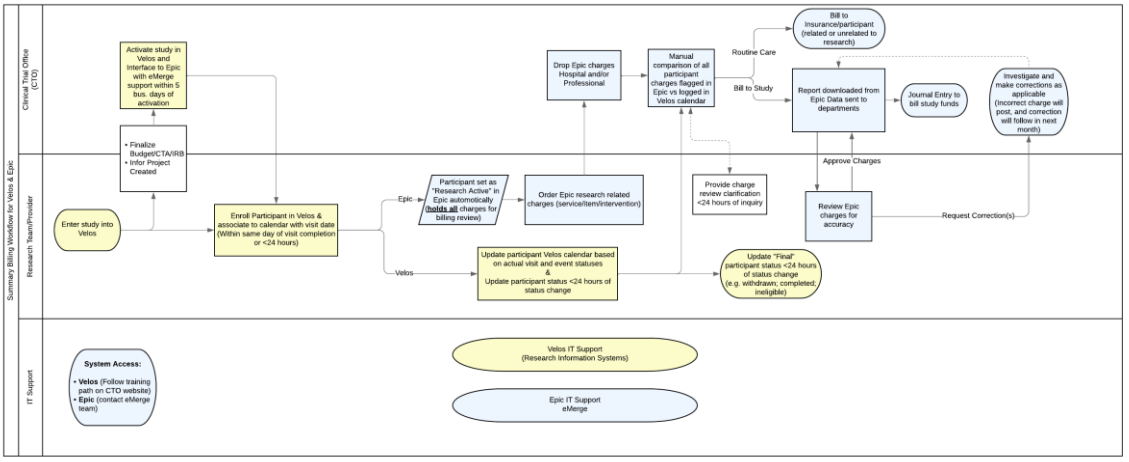
b. Research-specific claims modifications

c. Risks associated with research claims modifications

c. Criteria of a qualifying clinical trial

d. Seven characteristics of a well designed clinical trial

Research billing review



Criteria for "qualifying" clinical trials (QCTs)*

- The item under investigation **falls within a Medicare benefit category** and is **not statutorily excluded**, and**
- The trial:
  - Has **therapeutic intent** (and doesn't exclusively text toxicity or disease pathophysiology)
  - **Enrolls patients with diagnosed diseases** rather than healthy volunteers, **and is**: ***
  - Funded by one of seven federal agencies: **NIH, CDC, AHRQ, CMS, DOD, or VA**
  - **Supported by centers or cooperative groups** that are themselves funded by one of the above federal agencies [e.g. National Clinical Trial Network studies]
  - Under **Investigational New Drug** (IND) application, reviewed by the FDA, **or**
  - **IND-exempt** as defined in 21 CRF 312.2(b)(1).****

From Center for Medicare and Medicaid Services, National Coverage Determination, 310.1, 2000/2007, all but fully quoted

****[Medicare benefit categories can be broad, e.g., devices or physician services, or narrow, e.g., eyeglasses after cataract surgery; Statutory exclusions are those found in the Social Security Act, e.g., hearing aids.]***

*****Medicare allows enrollment of healthy individuals in a diagnostic study that requires a control arm***

******Medicare identifies studies that meet one or the last four criteria as being vetted for seven desirable characteristics of a clinical trial. See following slide.***

The seven (or eight) desirable characteristics of clinical trials

"1. The principal purpose of the trial is to test whether the intervention **potentially improves the participant's health outcomes**;

2. The trial is **well-supported** by available scientific and medical information or it is **intended to clarify or establish the health outcomes of interventions already in common clinical use**;

3. The trial **does not unjustifiably duplicate** existing studies;

4. The **trial design is appropriate** to answer the research question being asked in the trial;

5. The trial is **sponsored by a credible organization or individual** capable of executing the proposed trial successfully;

6. The trial is in compliance with Federal regulations relating to the **protection of human subjects**; and

7. All aspects of the trial are conducted according to the **appropriate standards of scientific integrity**."

From Center for Medicare and Medicaid Services, National Coverage Determination, 310.1, 2000/2007

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Research-specific claims modifications*

Items billable to patients/insurers and related to qualifying clinical trials (QCTs) or Investigational Device Exemption (IDE) trials,** require special research-specific claims modifications

- **Per line item**
  - **Q1** = routine item provided in a qualifying clinical trial
  - **Q0** = a covered item (= routine) under investigation
  - **Q0** = an investigational (non-routine) item that is needed on a claim to support a service needed solely for its delivery (e.g. drug administration charge)
  - Research-specific revenue codes on hospital claims (HB)
- **Claim-wide** (needed only once, whenever at least one Q1 occurs)
  - **Z00.6** = diagnosis code indicating research participation
  - **National Clinical Trials number (NCT#)** = study must be posted on clinicaltrials.gov
  - If the charge is HB, **Condition Code (CC) 30**
  - Research-specific value codes (HB)

**Modifications are spelled out in the Medicare Claims Processing Manual, Chapter 32, §§68-69*
***Medicare does not include IDE trials under "QCTs"; they are covered under 1995 federal regulation, whereas QCTs are covered under the 2000 National Coverage Determination 310.1; IDE studies require the same modifications and more, and are thus frequently treated as QCTs*

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Among risks related to QCT/IDE claims modifications

Research modifications facilitate **research billing audits**, raising risk of False Claims Act (FCA) violations

- **NCT#** identifies study uniquely, provides protocol details

Incomplete set of modifications creates **loss or delay of revenue**, reducing institutional resources

- Insurers' electronic claims **edits are set to reject claims** including some but not all applicable modifications, e.g.,
  - Z00.6 without NCT# and at least one Q0 (if one, all three must be present)
  - Revenue Code 624 without the IDE number (or *vice versa*)
  - Provider or biller, knowledgeable about diagnoses codes, but not research billing, adds a Z00.6 a claim

Compliance/legal professionals disagree on whether or not **failure to add research modifications** to a QCT/IDE claim constitutes an FCA violation

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37