MMC-Einstein Research IT Forum

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Agenda

• QA audits for Epic and Velos
• Updating subject start dates
• New insights into Charge Hold and Review
• Moving forward
• Research IT Forum schedule
QA Audit results

One clinical trial in Cardiology was reviewed with respect to compliance with research documentation and coding

- Mismatch between number of subjects enrolled in Velos vs Epic
- Subject start date prior to date of signed consent
- Milestone visit dates in Epic not associated to the research study
- Research coding missing to indicate subject in a clinical trial
- Study charges mis-assigned to research vs insurance
- Missing documentation in Epic and Velos that study milestones were reached
- Study status not current, e.g. deceased patient listed as active
- Zero charges assigned to expensive devices
- Routine code applied instead of investigational

Meeting scheduled with study team to review issues and remediate.
Study subject start date

- As of 6/22/17, there were 420 patients enrolled/consented to research studies in Epic with no start date.
- This will prevent study status to be updated in Epic, i.e. one cannot enter an end date if no start date exists.
- Patients with missing start dates will be provided to each PI
  - The study team should update the start date on spreadsheet or in Velos directly.
Velos-Epic Processes for Different Types of Clinical Research

All IRB Reviewed Studies (Monte/Einstein and BRANY)

Non MMC/Einstein PI (e.g. Ferkauf) and non MMC patient
- No Action Required in Velos

MMC/Einstein PI or MMC patients
- IRB Approval Required
  - Participants consented
  - Procedures/consent performed at MMC/Einstein
  - Study Documentation in Velos
    - Study Summary
    - Study Team Verification
    - No Epic Submission

- Consent waived
  - Procedures/consent performed only at another institution
  - Study Documentation in Velos
    - Study Summary
    - Study Team Verification
    - Study Status Activation

- IRB non exempt

- OCT managed
  - No Action Required in Velos

- OCT not managed

- IRB exempt*

Do Not Send to Epic if:
- No Epic Orders (meds/tests/services) and
- No Epic Research Visits and
- No Study Participation Flag (confidential study)

Send to Epic if:
- Interventional (drug/device/treatment) or
- Epic Orders or
- Epic Research Visits or
- Study Participation Flag or

Enter study subjects in Velos
- All Cancer studies
- Other studies where Velos is needed to track subjects

No need to enter study subjects in Velos
- If not a Cancer study
- Subjects do not need to be tracked in Velos

*IRB exempt studies may include:
- Educational practices
- Cognitive testing, Surveys, Interviews
- Study of existing de-identified data, pathological specimens or diagnostic specimens

Contact the IRB Exempt Categories Common Rule 45CRF 46.101(b) for more information
Velos-Epic Processes for Different Types of Clinical Research

**Send to Epic**
- Epic Orders (Meds/Tests/Services)
- Epic Research Visits
- Study Participation Flag

**Enter study subjects in Velos**
- Start date
- Status updates

**No research associated charges**
- Study flag only
- NO charge hold & review

**SOC charges only**
- Epic orders**
- Epic visits
- Study flag
- **Charge hold & review??**
  *Even when charges are covered by insurers, research associated billing modifiers and codes should, ideally, be attached to charges.*

**Mixed SOC and Research charges**
- Epic orders**
- Epic visits
- Study flag
- Charge hold & review

**Research charges only**
- Epic orders**
- Epic visits
- Study flag
- **Charge hold & review**
  *Associating charges to research accounts can only be performed on the charge hold screen.*

**Studies with confidential results**
- Use paper orders/requisitions outside of Epic
- Follow ancillary department workflow to keep results from filing to Epic
Moving Forward

• QA audits can be extended to other high dollar trials with feedback to appropriate study teams.
• Studies with no Epic charges related to research should be identified and removed from the Charge Hold process.
  – Studies listed as “observational” will be reviewed to determine which would generate no Epic charges.
• Adding a “flag” in Velos to mark studies that have no research charges.
• Should studies with Epic charges that are all standard of care be released from Charge Hold until additional coding staff can be brought on board?
• Finalizing invoicing workflow for ancillary charges.
• Will be trialing the Billing Calendar in Pediatrics as a pilot effort to facilitate assignment to research vs health plan account.
• Discussions with Epic R&D being initiated to improve functionality to address
  – Changes in patient status and impact on charge hold
  – Better ways to narrow charge hold to research associated charges
Moving the Research IT Forum schedule

- Wednesdays at 8a conflicts with Pediatric Grand Rounds
- Consideration to move meet to Monday or Tuesday morning at 8a starting in September.