Agenda

• Enhancing Clinical Research Capacity and Compliance
• Types of Studies and their set-ups in Velos
• Update on Charge Hold
• Research lab ordering
Enhancing Clinical Research Capacity
Clinical Research...

- One of the Strategic Research Plan’s goals
- A priority for current and incoming chairs, search for cancer center director, and others
- Barriers and opportunities
  - Epic implementation
  - CTMS design and implementation
  - Policy drivers (especially NIH)
  - Impact of Einstein integration with Montefiore
  - Need to improve regulatory oversight processes
Scope of Clinical Research

- Velos data on >1,300 studies (includes both Einstein + BRANY IRBs)
- New full-board approved: ~400 protocols/year

- Annual patients/participants in research:
  - Based on progress reports: 38,000 persons/year
  - Full-board projects 2015: >12,000 active
Foster safe, effective, and sustainable clinical research

• Institutional goals should mesh with value-add for investigators
  – Reducing risk exposure benefits all of us
  – Automating and hardening electronic workflows will pay off in efficiencies
  – Infrastructure for innovative research (data, recruitment, etc.)

• Beyond building IT tools…
  – Standardized research fee schedules for clinical tests
  – Unified compliance program with regulatory support team to assist investigators proactively
Improvements to help investigators

- **IRB/Human Research Protection Program (HRPP)**
  - One piece of an integrated compliance program
  - Re-organized IRB staff, AAHRPP accreditation
  - SMART IRB (central/reliance IRB model), other cIRBs
  - Expanded BRANY tools (*e.g.*, CITI training, protocol builder)

- **Other developments**
  - OCT → new CTSA Trial Innovation Network (ICTR)
  - Velos/CTMS → Biorepository (samples), and Pharmacy (INDs)
  - EHR integration → Pragmatic trials
  - Epic → Genetic test result integration
  - New patient engagement/recruitment tools
Reality

- We are playing catch-up
  - Our Epic implementation replaced antiquated processes that needed major rethinking
  - Changing standards for trials/research funding (eg, requirements for data sharing)
  - Tightening regulatory mandates
  - Budgetary constraints delayed implementation
- First Principles: To build sustainable and scalable resources that all investigators need, we must have common processes and platforms.
Velos and Types of Studies
Different Flavors of CR

- Basic IRB Info (Data Analysis, Anonymous Surveys)
- Study Summary, Document Upload (e.g. Agreements, Contracts)
- Study Summary, Documents
- Patient Registration
- Submit Study to Epic (clinical trials)

IRB

IRB Exempt

OCT Managed

Consented

Consent Exempt (Verbal Consent)

Set Summary, Document Upload (Pragmatic trials)

- Study Summary, Upload Documents
  No Epic Submission
  Patient Registries (Through incremental upload/update strategies)

All Research Process & NO SOC & No Epic Order

All SOC

No Hold (Pragmatic trials)

No SOC

• No Hold
  • (Order sent to outside entity)

Some SOC

Hold for Review

Unverifiable

Hold for Review (follow up visits)

Protected Study (e.g. AIDS)

Observational Trials

Biobanking

Survey Only/Observational

Protected Study

De-identified Study

Involves Epic Order

Patient Registration

Submit Study to Epic (clinical trials)
Velos CTMS: status and next steps

- CTMS currently includes multiple study prototypes (data-only, SOC, survey, fully loaded protocols, etc)
- Building processes: Epic → Velos → IRB → Patient
- Next steps → Work with individual departments or research units:
  - Pediatrics
  - Medicine (Diabetes)
  - Neurology
Charge Hold Update
Lab orders for Research
Updated Research billing policy is being drafted to account for the new IT systems and processes.

Determination of which types of studies can be “exempted” from billing review remains under discussion.

Needed components in Velos and Epic to support the policy determination will follow.

For now, “standard of care” only studies have been updated to remove charge hold and review process.

Increased collaboration between Investigators, Compliance and Revenue Cycle is essential.
Research Lab Ordering

• For most studies where labs are performed by MMC lab, orders are placed in Epic, marked as associated to the study, charges are routed to the research account and resulted back to Epic.
• For studies where labs are performed by MMC lab but results are confidential, orders are placed on paper requisitions, sent to the lab, with results sent back to investigator outside of Epic.
  – What criteria define confidential results for Research?
  – How are these study related charges accounted for?
• Does this change with the replacement of Soft lab with Epic’s Beaker module next year?
  – Beaker will support the same workflow as long as the “submitting entity” is identified as a research trial.
  – As in the current scenario, this bypasses the Epic research account.
  – Epic is evaluating an enhancement request from MMC to improve this workflow.
• Are there other research lab workflows that should be evaluated viz a viz a new lab system?