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MMC-Einstein Research IT Forum

February 1, 2017

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Barrett Katz, Executive Director, Office of Clinical Trials
Vic Hatcher, Associate Dean for CME and Research Administration
Parsa Mirhaji, Director, Clinical Research Informatics
Matt Berger, Medical Director, MIT and Epic
Agenda

• Purpose of the Research IT Forum
• Epic and Velos
• What defines a research patient that should be registered in Epic
• How does a study get entered into Velos
• Basic functions in Epic and Velos
• Updates to charge hold and review
• How to obtain training
• Comments and discussion
• Future agenda items
Purpose of the Research IT Forum

• The implementation of Epic and Velos changes how research staff, PI’s and coordinators manage their studies and subjects.
• These systems and other non-IT initiatives require a more centralized and standardized approach for research workflows.
• The departmental liaisons are responsible for communication between Research IT and other research governing bodies and their department’s research staff:
  – New workflows
  – Policy updates
  – Required training
• The departmental liaisons should bring feedback from their research staff to this forum to ensure that the systems and policies are meeting their requirements.
• This meeting, while initially focused on IT systems, will be broadened to include a variety of research governance issues.
New IT Systems

Velos

- Montefiore-Einstein Clinical Trials/Research Management System.
- Single source of information re: institutional research.
- Centralizes research activities (administrative, investigational, clinical, financial and compliance).
- Integrates with relevant systems, e.g. IRB, Epic.
- Ultimately, a “one stop shop” for clinical research management.
- Functionality to support
  - Billing compliance
  - Financial management
  - Regulatory requirements
  - Automated processes for IRB, Recruitment, Study calendar, Invoicing
  - Data analytics
New IT Systems

Epic

• Montefiore Electronic Medical Record System.
• Enables scheduling, ordering, result reporting and charge capture for research associated encounters.
• Supports segregation of charges into separate accounts for standard of care and for research.
• Data analytics
• Decision support to facilitate recruitment
• Documentation tools
Which studies belong in Velos?
Which subjects belong in Epic?

- All IRB approved research studies will be stored in Velos via interface
- Subjects should be registered in Epic if their participation includes
  - Scheduling research visits to MMC provider offices/research sites/hospitals that use Epic
  - Ordering of tests (labs, imaging, etc.) performed at MMC
  - Ordering of referrals to MMC providers
  - Ordering of medications (standard and investigational)
1350 ACTIVE STUDIES – Protocol Includes Ppt Enrollment

**Study Status**
- **IRB Approved**: 744
- **Active Enrolling**: 321
- **Closed To Accrual**: 279
- **Other**: 6

**Research Type**
- **Externally Peer Reviewed**: 938
- **Industrial**: 148
- **Institutional**: 76
- **National**: 155
- **None**: 13
- **Other**: 0

**Clinical Trial Status**
- **Informed Consent Exists**: 715
- **Clinical Trial**: 635

**Clinical Research Category**
- **Ancillary or Correlative**: 941
- **Interventional**: 323
- **Non Clinical Research**: 66
- **None**: 0
- **Observational**: 0
High level Velos workflow

• Approved studies are electronically sent to Velos from the MMC-Einstein IRB and the BRANY IRB
• For all studies--PI/regulatory coordinator must update Velos with
  – Summary: Complete study summary information
  – Study team: Verify staff and access roles
  – Attachments: Upload non-IRB generated documents
  – Study status: Activate the study
• For studies that recruit patients
  – Assign patients to the study
  – Update patient status (informed consent signed/screening/screen failure/enrolled/active on treatment/follow-up/off-study).
  – For OCT studies, mark visit completion in Velos.
  – For BRANY studies, mark visit completion in SMART.
  – For other studies ?? ??
High level Epic workflow

- Study records and patient association from Velos
- Visits in Epic should be marked as “Research” during scheduling.
- Orders placed in Epic should be marked as “Research Associated”
- Patients enrolled in research have “all” charges held in a work queue review to confirm that research and standard of care charges were appropriately separated and assigned.
- Invoice generation and payment posting
IRB-Epic-Velos interfaces

- IRB→Velos: Approved studies
- Epic→Velos: Patient records
- Velos→Epic: Study records, study staff and patient status

<table>
<thead>
<tr>
<th>IRB</th>
<th>Velos</th>
<th>Epic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study approval</td>
<td>Study management</td>
<td>Patient encounters</td>
</tr>
<tr>
<td>Patient recruitment</td>
<td>Services/procedures</td>
<td>Charge capture and routing</td>
</tr>
<tr>
<td>Financial management</td>
<td></td>
<td>Oncology protocols</td>
</tr>
<tr>
<td>Regulatory compliance</td>
<td></td>
<td></td>
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<tr>
<td>Internal/External reporting</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Scheduling Patient Encounters

- Scheduled appointment is associated to the research study (either at time of scheduling or subsequently).
- The appointment displays the “lab flask” icon.

![Link to Study](image)

<table>
<thead>
<tr>
<th>Linked</th>
<th>Study Code</th>
<th>Study</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ABC-123</td>
<td>Acne Test Study</td>
<td>Enrolled</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Naz Khan, MD</td>
<td></td>
</tr>
</tbody>
</table>

![Appointment Details](image)

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Len</th>
<th>Visit Type</th>
<th>Provider</th>
<th>Dept</th>
<th>Appt Notes</th>
<th>Other</th>
</tr>
</thead>
</table>
Associating an Order with the Study

- Tests, procedures, medications or referrals
- Associate the order to “research”.

![Unsigned Orders screenshot](image)
Marking research associated
Marking the diagnosis
Order associated to research study

Unsigned Orders

Orders and Prescriptions Procedures (3 Orders)

- CBC, Automated
  - Expected-10/13/2015, Expires-9/29/2016, Lab Collect
- Lipid Profile
- Urine, Pregnancy
  - Order details
  - Last Reviewed by Naz Khan, MD on 9/29/2015 at 11:39 AM

Mark All Taking ✔️ Mark as Reviewed

Click here to select a pharmacy

Order Entry

Associate Research Association Edit Multiple Providers

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Charge Review

Charge review screen shows which charges were marked as research and which were not—update, confirm and mark as reviewed.

<table>
<thead>
<tr>
<th>Study code</th>
<th>Status</th>
<th>Start date</th>
<th>End date</th>
</tr>
</thead>
<tbody>
<tr>
<td>16222-DECEMBER TEST RESEARCH</td>
<td>Enrolled</td>
<td>1/26/16</td>
<td>2016-222</td>
</tr>
</tbody>
</table>

12/07/16

<table>
<thead>
<tr>
<th>Study-related</th>
<th>Code</th>
<th>Description</th>
<th>Qty</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30685384</td>
<td>HC FIBRINOGEN ACTIVITY</td>
<td>1</td>
<td>220.00</td>
</tr>
<tr>
<td></td>
<td>30085347</td>
<td>HC COAGULATION TIME ACTIVATED</td>
<td>1</td>
<td>34.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-study Charges Grouped By Revenue Code</th>
<th>Code</th>
<th>Description</th>
<th>Qty</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0305</td>
<td>LABORATORY - HEMATOLOGY</td>
<td>2</td>
<td>235.00</td>
<td></td>
</tr>
</tbody>
</table>

Encounters
Updates to charge hold

At present, all charges are held for patients enrolled in research studies.
• Allows for a final review to confirm that charges are appropriately separated and assigned to either research or standard of care.
• Most of the $’s held in charge review are clinical, not research.
• Most of the studies that account for charge hold are in Oncology.

Going forward, charge hold will be limited to those studies where it makes most sense, i.e. trials where research and standard of care charges are highly intermixed.

• Proposed criteria for studies excluded from charge hold
  – All expected charges are standard of care (including studies where investigational drug is marked as “no charge”).
  – All expected charges are covered by the grant (coordinators/PIs must reliably mark visits and orders as research)
  – No clinical charges are generated as part of the study protocol

• Proposed criteria for studies that apply charge hold
  – Oncology studies
  – Studies that include hospital admission
How to obtain training

Epic
- For coordinators and front desk staff request via EpicTrainingDept@montefiore.org
- For PI’s, contact Evelyn Koestenblatt at ekoesten@montefiore.org

Velos
- http://ephpublic.aecom.yu.edu/velos_ctms
  (access only from a Monte or Einstein network device)
VELOS USER SYSTEM ACCESS REQUEST - Authorization Form

Data Entry Date
1/30/2017

Requester Full Name

Email

Phone (Enter as ###-###-####)

Requested Action:
Select from Drop Down List
Create New User Account

If Other Specify Reason Or New Organization

I. General Information: Please provide information about the user for whom you are requesting access

First Name

Last Name

Phone Number (Enter as ###-###-####)

Department

New User Access Request (Check all that apply)

☐ MNC employee
☐ Einstein employee
☐ Vendor *
☐ Consultant *
☐ Temp or Non MNC Personnel *
☐ Medical student
☐ Volunteer or under 18 years of age
☐ Observer/Auditor
☐ Regulatory Coordinator on a Research Study
☐ Study Coordinator on a Research Study
☐ Pharmacy Staff for a Research Study
☐ PI of a Research Study
☐ Co-Investigator of a Research Study
☐ Physician Associated with a Research Study
☐ Other Staff with a Research Study
☐ Other

* If Consultant/Vendor/Temp/External Personnel, please provide the company name and an expiration date

Company

Date

** For Investigators Only: Click here to view online Investigator Training Materials

III. Application Access

Does this person currently have access to an EMR data system (EPIC, Carecast etc.)? ☐ Yes ☑ No

IV. Infrastructure - IS VPN Access Required? Yes ☐ No ☑

SSL VPN

Yes ☑ No ☐

You may complete online training at this link: Click here to view online Investigator Training Materials

Sign here to indicate that the Applicant understands and agrees to abide by all stated & applicable policies

Signature of Person for Whom Access is Required

Date: / / 

To print this form, right-click mouse and select "Print".

Once completed, please fax to 718-430-2521 or scan it and email to veloshelp@montefiore.org

All applicants will be contacted to schedule training.

Investigator Only: You may complete online training at this link: Click here to view online Investigator Training Materials and sign the certification box below. You will be notified when your account has been created.

Certification: To Be Signed Only After Applicant Completes Applicable Training:

APPLICANT HAS READ THE VELOS POLICIES/PROCEDURES CERTIFICATION FORM & AGREES TO ABIDE BY ALL STATED & APPLICABLE POLICIES

Signature of Person for Whom Access is Required

Date: / / 

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Comments and Discussion
Between now and next meeting

• Share information with the researchers in your department.
• Identify studies that should be exempt from charge review and send to Evelyn Koestenblatt ekoesten@montefiore.org who will organize a review team.
• Ensure that research staff in the department have attended training and are using Velos and Epic.
• Send questions to
  – Epic: Evelyn Koestenblatt ekoesten@montefiore.org
  – Velos: veloshelp@montefiore.org
• Provide agenda items for next meeting(s) to Matt Berger mabberger@montefiore.org
Future agenda items

• Continue to define studies for charge hold/review
• Invoicing process Epic vs Velos
• Full research revenue cycle
• Confidential results
• Collaboration with MMC revenue cycle
Meeting Schedule

First Wednesday of each month 8a to 9a alternating between Price Center and Tishman Learning Center.

Next meeting

Wednesday, March 1, 2017  TLC room 5, Moses