Dartmouth
GEISEL SCHOOL OF MEDICINE

Dartmouth-Hitchcock
NORRIS COTTON CANCER CENTER

CTMS/EMR Integration:

Notifying the Research Team and Providers about Clinical Trial Participation and Potential SAEs

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Administrative Director

Office of Clinical Research

Norris Cotton Cancer Center

Geisel School of Medicine at Dartmouth

Norris Cotton Cancer Center

Office of Clinical Research

The mission of the Office of Clinical Research (OCR) is to assist with protocol development, activation, implementation, conduct, analysis and compliance of all clinical trials involving cancer treatment and care.

Key Quality Initiatives:

- Decrease Time to Activation of Clinical Trials
- Peer Monitoring of NCTN Studies
- CTMS/EMR Integration

Office of Clinical Research

Daily Workload

- Active Protocols 375
- Active Subjects 350
- Follow up Subjects 900
- Protocols Pending Activation 45-60
- ~ 50 % of all institutional trials are Cancer Center trials

CTMS/EMR Integration

The Office of Clinical Research (OCR) has developed an integrated system of clinical care and research using our EMR (Epic called **eDH**), billing and scheduling systems (GE), and clinical trials management system (Velos eResearch).

Notifications from CTMS to Research Teams

- Changes in study status updated every 2 hours
- Study Activations
- Time to activation (business days) for last 10 studies
- Enrollment (active, screen failure, follow up) for entire Cancer Center
- “Monday morning” Investigator Report
- Investigational Pharmacy Scheduling
- Investigational order sets status

Notifications every 2 hours

The following events happened between 02:00pm and 04:00pm on Thursday, June 4, 2015

- 03:16 - Erin Lynch: F14132 status CCRC - Submitted to Expedited Review effective 06/04/2015 Organization: DHMC-Lebanon
  Note: Protocol Amendment 3, dated 09 OCT 2014. eel

- 03:37 - Courtney Davis: E2511 status IRB - Submitted: Revision effective 06/04/2015 Organization: DHMC-Lebanon
  Note: Submitted Addition of Manchester as site; Manchester ICF 4Jun15; addition of Manchester study staff. --cd

- 03:48 - Nancy Rollings: D13236 status Active/Enrolling effective 06/03/2015 Organization: DHMC-Lebanon

QA Report

- NRG-GU001 [Alan Hartford] took 36 days to be activated on 5/19/2015. Additionally, it took 31 days for IRB Approval, 2 days from the budget/contract received to activation, 28 days from the resource meeting to activation and 2 days from the finalized budget/contract to activation.
- F15068 [John Seigne] took 81 days to be activated on 5/18/2015. Additionally, it took 1 days for IRB Approval, 81 days from the budget/contract received to activation, 1 days from the resource meeting to activation and 1 days from the finalized budget/contract to activation.
- R1010 [Bassem Zaki] took 44 days to be activated on 5/7/2015. Additionally, it took 37 days for IRB Approval, 2 days from the budget/contract received to activation, 36 days from the resource meeting to activation and 2 days from the finalized budget/contract to activation.
- W15080 [Frederick Lansigan] took 45 days to be activated on 5/6/2015. Additionally, it took 44 days for IRB Approval, 2 days from the budget/contract received to activation, 2 days from the resource meeting to activation and 2 days from the finalized budget/contract to activation.

QA Report

The last 10 studies took a median of 63 days to activate while the previous 10 took a median of 78 days to activate.

So far this month, we have had 5 consents signed, 3 enrollments. There are 11 awaiting enrollment.

The current breakdown of studies is as follows:

187:	Active/Closed to Enrollment
15:	Active/Enrollment Restricted
17:	Open/Data Analysis Only
36:	Pending: Planned
12:	On Hold
21:	Active/Enrollment Suspended
160:	IRB - Termination Acknowledged
168:	Active/Enrolling

The current breakdown of patient statuses is as follows: (NCCC Only, Study Completed/Retired omitted)

205:	Active/No Treatment
87:	Active/Treatment
124:	Enrolled
906:	In Follow-Up
49:	Informed Consent Signed
4415:	Off Study
23:	Off Treatment
5:	Re-enrolled
568:	Screen Failure
11:	Screening

Investigator Report

Dr. Dragnev,

Last week, there were 7 consents signed in the cancer center:

Alan Hartford consented a patient at DHMC-Lebanon on 5/27/2015 for study NRG-GU001 [PI=Alan Hartford].
J Marc Pipas consented a patient at DHMC-Lebanon on 5/26/2015 for study F14087 [PI=J Marc Pipas].
Richard Barth consented a patient at DHMC-Lebanon on 5/27/2015 for study D0928 [PI=Richard Barth].
Richard Barth consented a patient at DHMC-Lebanon on 5/28/2015 for study D12052 [PI=Richard Barth].
Thomas Davis consented a patient at DHMC-Lebanon on 5/26/2015 for study D1022 [PI=Thomas Davis].

Also, there were 6 enrollments in the cancer center:

Julie Kim enrolled a patient at DHMC-Lebanon on 5/27/2015 for study ANBL0032 [PI=Sara Chaffee].
Kenneth Meehan enrolled a patient at DHMC-Lebanon on 5/29/2015 for study B0942 [PI=Kenneth Meehan].
Mary Chamberlin enrolled a patient at DHMC-Lebanon on 5/26/2015 for study D12030 [PI=Mary Chamberlin].
Richard Barth enrolled a patient at DHMC-Lebanon on 5/28/2015 for study D12052 [PI=Richard Barth].
Thomas Davis enrolled a patient at DHMC-Lebanon on 5/26/2015 for study D1022 [PI=Thomas Davis].

Investigational Pharmacy Scheduling

Protocol	Inv Pharmacy (IS) (Description	Research Nurse (or Therapeutic Area)	Notes	Scheduling Info
F14009	IS-Intravenous (IV)	Kathryn Abraham Carpenter	Bavituximab Supplied, Docetaxel Commercial Stock [STV]	[PENDING-INF] 08:30:00 LEB HEM/ONC: LEB INFUSION THERAPY Study (SOC) (2)-DOCETAXOL BAVITUXIMAB STUDY F14009

- The scheduling information comes from GE, and is queried in real-time.
- GE scheduling data is merged with the patient calendar based upon MRN and visit date.
- The investigational pharmacy receives this report Monday through Friday morning.

Order Set Tracking

NCCC CTIOSC ORDER SET TRACKER FOR NCCC CLINICAL STUDIES as of 5/27/2015

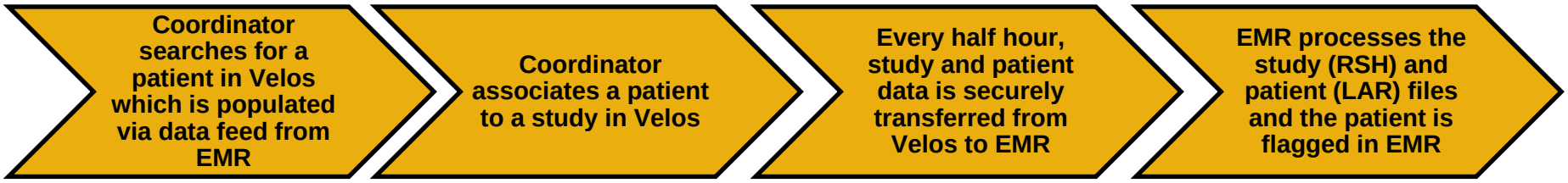
STUDY #	PI	STUDY TITLE	STUDY STATUS	ORDER SET NAME	ORDER SET STATUS	NUMBER OF ACTIVE PTS
F15032	Thomas Davis	A Phase II, Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy, Tremelimumab Monotherapy, and MEDI4736 in Combination with Tremelimumab in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	Pending: Planned	tremelimumab	Required, waiting status entries	0
F15032	Thomas Davis	A Phase II, Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy, Tremelimumab Monotherapy, and MEDI4736 in Combination with Tremelimumab in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	Pending: Planned	tremelimumab + MEDI4736	Required, waiting status entries	0
F15042	J Marc Pipas	A 3-Arm Phase 2 Double-Blind Randomized StudY of Gemcitabine, Abraxane? Plus PlacebO versuS GEMcitabIne, Abraxane? plus 1 or 2 TruncatEd Courses of Demcizumab in Subjects with 1st-Line Metastatic Pancreatic Ductal Adenocarcinoma	Pending: Planned	abraxane gemcitabine	Draft submitted to Inv Pharm for editing	0

Enhance Subject Safety and Compliance

- Flag Patient's Study Enrollment in EMR
- Provide Direct Access to Protocols and Other Study Documents in the EMR to be Accessible to Clinical Providers
- Serious Adverse Event Email Notification from EMR to Study Team

Real time research participant information

Flag Patient's Study Enrollment in EMR



Access to Study Documents in EMR

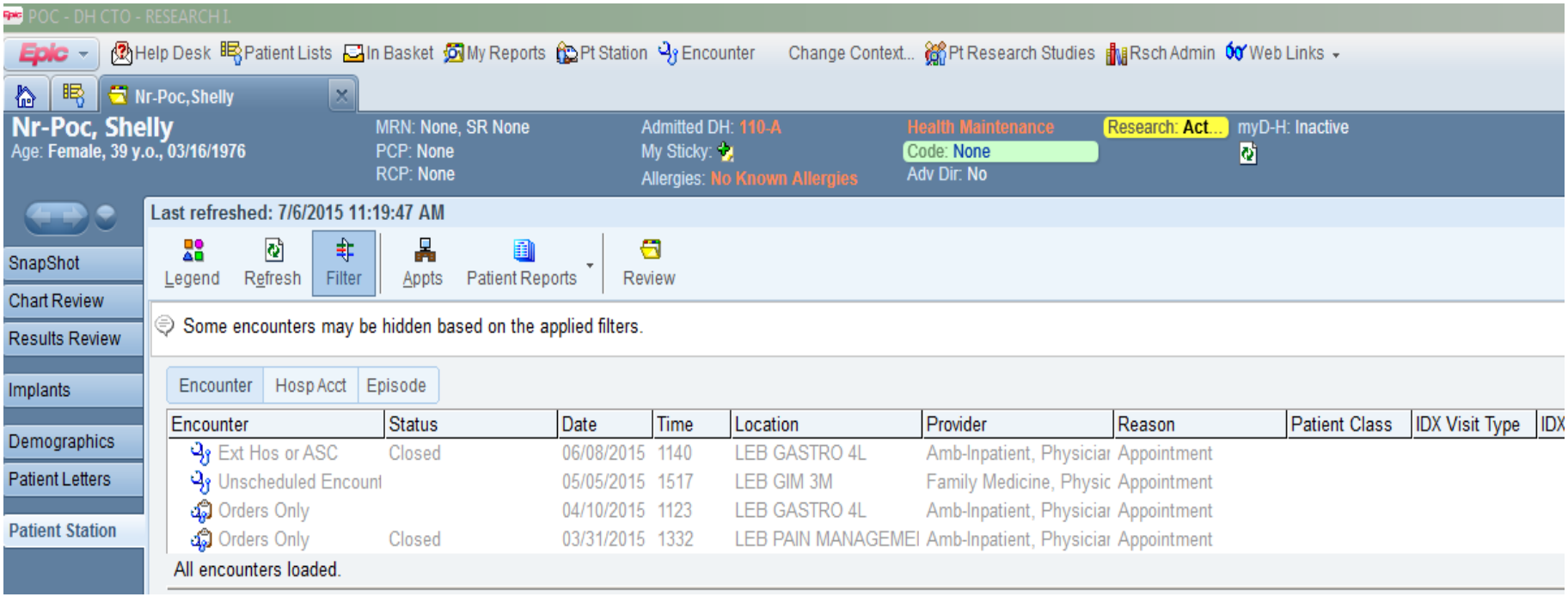
Study data transferred to EMR contains

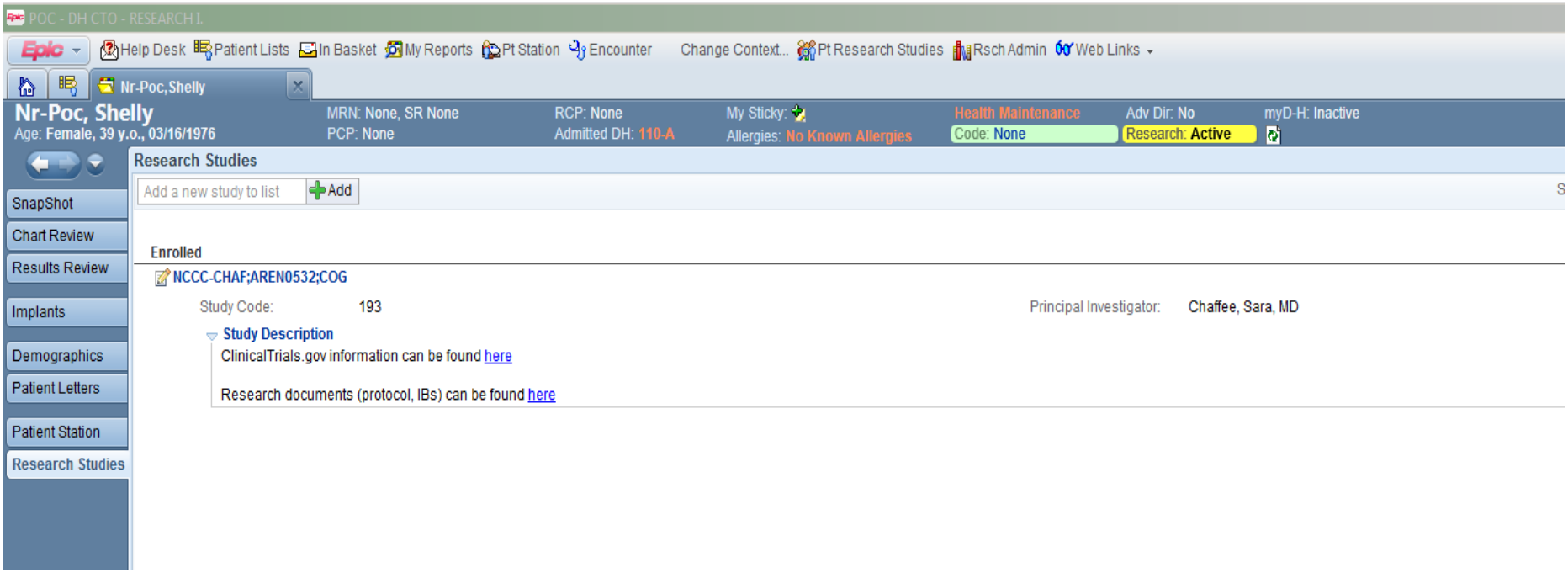
- Short study name
- Study status Active, Completed, Inactive
- IRB number
- Study team members- PI, Coordinator, Research Nurse, Sub-I
- Description field with links to ClinicalTrials.gov and Study Documents
- ICF held in EMR in different location as a scanned document
- Currently over 6000 study documents in EMR

Access to Study Documents in EMR

When a user clicks on the study documents link, they are taken to an internal website at which point:

- Group membership is inspected in Active Directory
- Certain groups are blocked from accessing study documents
- A dynamic page is built that has active documents: Protocols, Investigators Brochure, IRB Study Plan, Protocol Supplement


POC - DH CTO - RESEARCH I.
Epic
Help Desk
Patient Lists
In Basket
My Reports
Pt Station
Encounter
Change Context...
Pt Research Studies
Rsch Admin
Web Links
Nr-Poc,Shelly
Nr-Poc, Shelly
Age: Female, 39 y.o., 03/16/1976
MRN: None, SR None
PCP: None
RCP: None
Admitted DH: 110-A
My Sticky:
Allergies: No Known Allergies
Health Maintenance
Code: None
Adv Dir: No
Research: Act...
myD-H: Inactive
Last refreshed: 7/6/2015 11:19:47 AM
SnapShot
Chart Review
Results Review
Implants
Demographics
Patient Letters
Patient Station
Legend
Refresh
Filter
Appts
Patient Reports
Review
Some encounters may be hidden based on the applied filters.
Encounter
Hosp Acct
Episode
Encounter
Status
Date
Time
Location
Provider
Reason
Patient Class
IDX Visit Type
IDX
Ext Hos or ASC
Closed
06/08/2015
1140
LEB GASTRO 4L
Amb-Inpatient, Physician
Appointment
Unscheduled Encount
05/05/2015
1517
LEB GIM 3M
Family Medicine, Physic
Appointment
Orders Only
04/10/2015
1123
LEB GASTRO 4L
Amb-Inpatient, Physician
Appointment
Orders Only
Closed
03/31/2015
1332
LEB PAIN MANAGEMEI
Amb-Inpatient, Physician
Appointment
All encounters loaded.



Active Directory Inspected
Dynamic Page Created

VELOS eRESEARCH STUDY DOCUMENTS

STUDY NUMBER: AREN0532

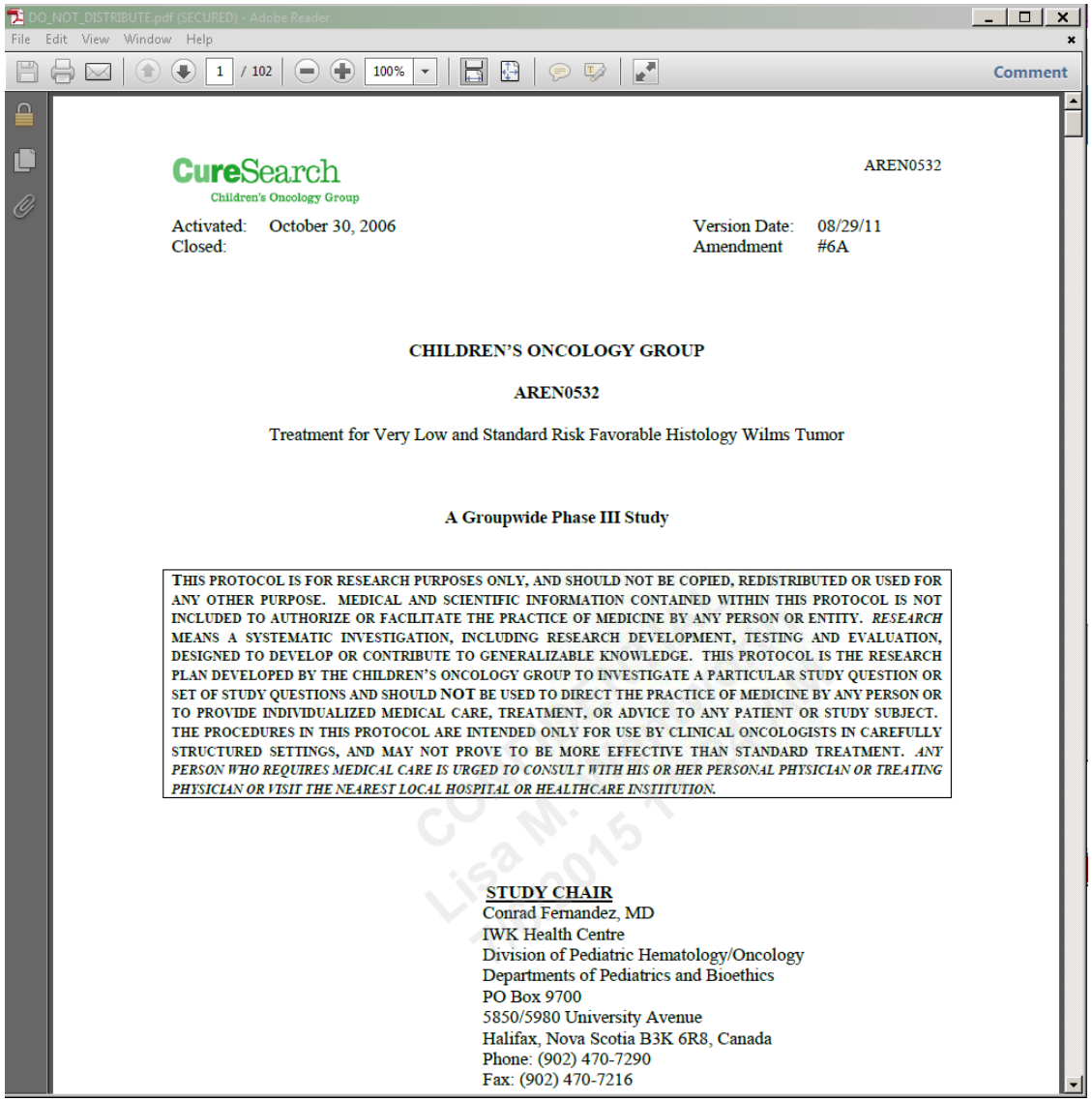
WARNING: You are going to be viewing confidential documents. These documents are not to be copied or distributed.

* Please note that it might take a few seconds for the PDF to arrive and viewing documents is audited.

View Protocol (AREN0532_Amd6a ChangeMemo_082911.pdf) : Dated 8/29/2011
View Protocol (AREN0532_Amd6a_Prot_pv29Aug11.pdf) : Dated 8/29/2011

Questions about this page can be directed to Velos@Dartmouth.EDU

Confidentiality Noted



DO_NOT_DISTRIBUTE.pdf (SECURED) - Adobe Reader

File Edit View Window Help

1 / 102 100% Comment

CureSearch
Children's Oncology Group

AREN0532

Activated: October 30, 2006
Closed:

Version Date: 08/29/11
Amendment #6A

CHILDREN'S ONCOLOGY GROUP

AREN0532

Treatment for Very Low and Standard Risk Favorable Histology Wilms Tumor

A Groupwide Phase III Study

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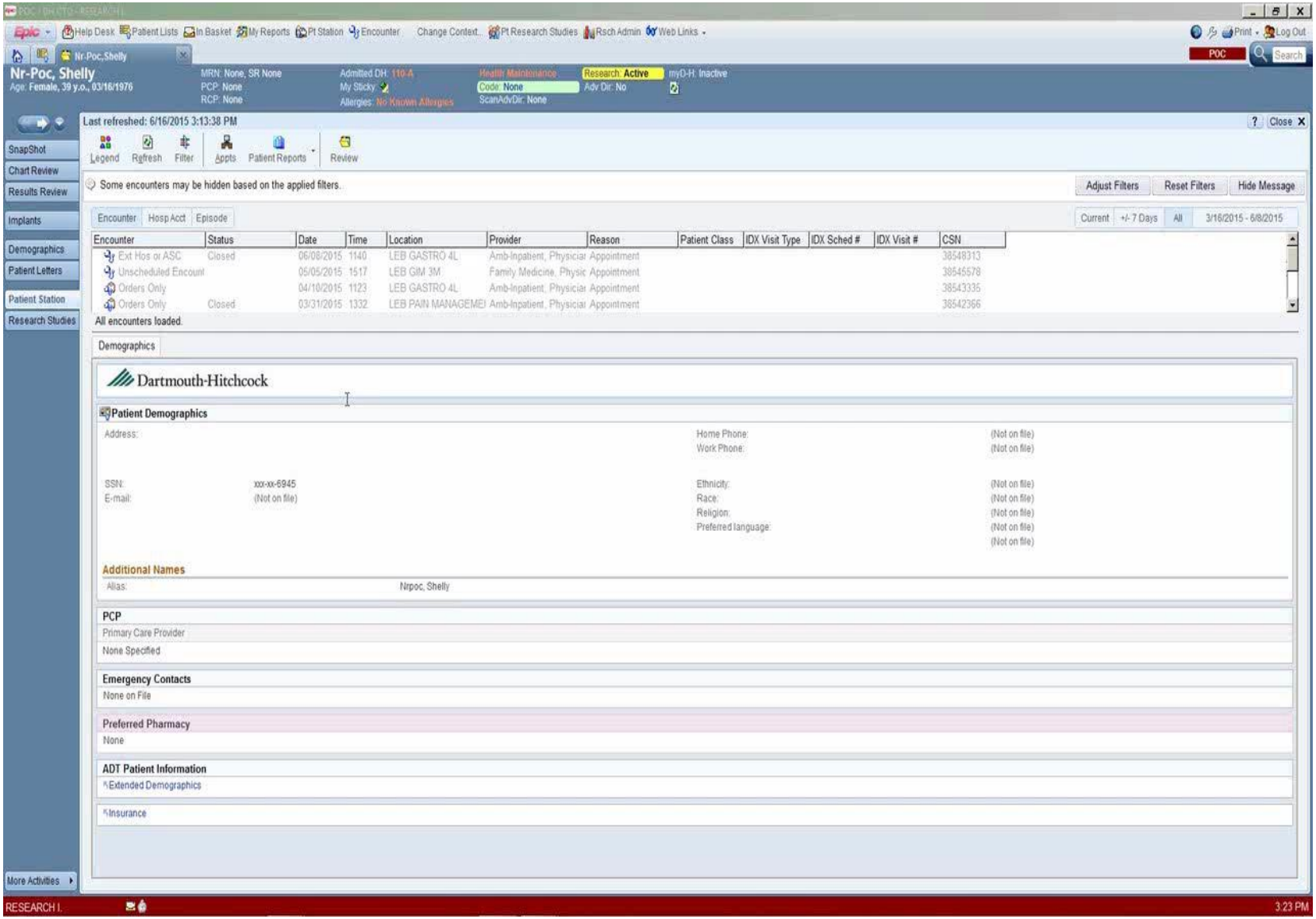
Help Desk
Patient Lists
In Basket
My Reports
Pt Station
Encounter
Change Context...
Pt Research Studies
Rsch Admin
Web Links
Print
Log Out
Nr-Poc,Shelly
POC
Search
Nr-Poc, Shelly
Age: Female, 39 y.o., 03/16/1976
MRN: None, SR None
PCP: None
RCP: None
Admitted DH: 110 A
My Sticky:
Allergies: No Known Allergies
Health Maintenance
Code: None
ScanAdvDir: None
Research: Active
Adv Dir: No
myO-H: Inactive
Last refreshed: 6/16/2015 3:13:38 PM
Close
SnapShot
Chart Review
Results Review
Implants
Demographics
Patient Letters
Patient Station
Research Studies
More Activities
Legend
Refresh
Filter
Appts
Patient Reports
Review
Some encounters may be hidden based on the applied filters.
Adjust Filters
Reset Filters
Hide Message
Encounter
Hosp Acct
Episode
Current
+/- 7 Days
All
3/16/2015 - 6/8/2015
Encounter
Status
Date
Time
Location
Provider
Reason
Patient Class
IDX Visit Type
IDX Sched #
IDX Visit #
CSN
Ext Hos or ASC
Closed
06/08/2015
1140
LEB GASTRO 4L
Amb-Inpatient, Physician
Appointment
38548313
Unscheduled Encount
05/05/2015
1517
LEB GIM 3M
Family Medicine, Physic
Appointment
38546578
Orders Only
04/10/2015
1123
LEB GASTRO 4L
Amb-Inpatient, Physician
Appointment
38543335
Orders Only
Closed
03/31/2015
1332
LEB PAIN MANAGEMEI
Amb-Inpatient, Physician
Appointment
38542366
All encounters loaded.
Demographics
Dartmouth-Hitchcock
Patient Demographics
Address:
Home Phone:
(Not on file)
Work Phone:
(Not on file)
SSN:
xxx-xx-6945
E-mail:
(Not on file)
Ethnicity:
(Not on file)
Race:
(Not on file)
Religion:
(Not on file)
Preferred language:
(Not on file)
(Not on file)
Additional Names
Alias:
Nrpoc, Shelly
PCP
Primary Care Provider
None Specified
Emergency Contacts
None on File
Preferred Pharmacy
None
ADT Patient Information
Extended Demographics
Insurance
RESEARCH I.
3:23 PM

Protection of Information

- Protections of the documents
- PDF
- Watermarked Confidential
- Not printable or able to be copied
- Protections of who sees the information
- Audit of all users accessing information
- Identified groups denied access.
- All users covered by institutional confidentiality agreement
- General Counsel and Institutional Compliance approved use.

USERNAME	FK_STUDYAPNDX	VIEWDATE
Mark A. Carey	82570	6/4/2015 11:01:23 AM
Joel E. Brown	82560	6/4/2015 10:22:37 AM
David C. Chan	81631	6/4/2015 10:18:30 AM
Joel E. Brown	81868	6/4/2015 9:51:23 AM
David C. Chan	80516	6/4/2015 9:29:25 AM
David C. Chan	69598	6/4/2015 9:21:12 AM
Joel E. Brown	80516	6/4/2015 9:07:26 AM
Joel E. Brown	69598	6/4/2015 8:53:48 AM
Joel E. Brown	82560	6/4/2015 8:33:20 AM

Notification of Potential Serious Adverse Events

An ADT feed from EMR populates and updates the Velos eResearch patient demographic information. This feed allows emails notifications to study team members when a patient is admitted, dies or is transferred to an intensive care unit.

Patient data sent:

- MRN
- Patient Study Status
- Start and end date [usually informed consent date and off study date]

Study data sent:

- Study name
- Study status [active, active/closed to enrollment]
- IRB study number
- PI, Sub-I, Coordinators, Research nurses
- Description

Potential Serious Adverse Events

From: Velos Notifier
Sent: Wednesday, June 2, 2015 08:16 PM
Subject: WARNING: INPATIENT TRANSFER FROM ED to ICU FOR RESEARCH PATIENT

The following event was recorded for research patient xxxxxxx (MRN yyyyyyy) at 06/20/2012 08:16 pm:

Inpatient transfer from ED to ICU

This may indicate a Serious Adverse Event. Please refer to protocol for SAE reporting requirements. Please check eD-H for details.

This patient is associated with the following study:

A071101: A Phase II Randomized Trial Comparing the Efficacy of Heat Shock Protein-Peptide Complex-96 (HSPPC-96) (NSC #725085, ALLIANCE IND# 15380) Vaccine Given With Bevacizumab Versus Bevacizumab Alone in the Treatment of Surgically Resectable Recurrent Glioblastoma Multiforme (GBM)

Status: Enrolled Treating Physician: Camilo Fadul

Future Direction

- Billing and scheduling system will be moved to EMR from GE
- Creating study participant calendars in the EMR with automatic routing of charges
- Click Commerce (Sponsored Research and IRB) and Velos integration (study information, documents-currently double entry for both)
- Real time interface

Thank You