



# CTMS/EMR Integration:

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

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Norris Cotton Cancer Center

Geisel School of Medicine at Dartmouth



Dartmouth  
GEISEL SCHOOL OF MEDICINE



Dartmouth-Hitchcock  
NORRIS COTTON  
CANCER CENTER

# 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

Coordinator searches for a patient in Velos which is populated via data feed from EMR

Coordinator associates a patient to a study in Velos

Every half hour, study and patient data is securely transferred from Velos to EMR

EMR processes the study (RSH) and patient (LAR) files and the patient is flagged 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](https://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

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 MANAGEME	Amb-Inpatient, Physician	Appointment			

All encounters loaded.

Snapshot

Chart Review

Results Review

Implants

Demographics

Patient Letters

Patient Station



POC - DH CTO - RESEARCH I.

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Nr-Poc, Shelly

**Nr-Poc, Shelly** MRN: None, SR None RCP: None My Sticky: Health Maintenance Adv Dir: No myD-H: Inactive  
Age: Female, 39 y.o., 03/16/1976 PCP: None Admitted DH: 110-A Allergies: No Known Allergies Code: None Research: Active

Research Studies

Add a new study to list

Enrolled

NCCC-CHAF;AREN0532;COG

Study Code: 193 Principal Investigator: Chaffee, Sara, MD

**Study Description**  
ClinicalTrials.gov information can be found [here](#)  
Research documents (protocol, IBs) can be found [here](#)

Snapshot  
Chart Review  
Results Review  
Implants  
Demographics  
Patient Letters  
Patient Station  
Research Studies

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](mailto:Velos@Dartmouth.EDU)

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# Confidentiality Noted



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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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EPIC - [DH (CT) - 8204000]

Help Desk Patient Lists In Basket My Reports Pt Station Encounter Change Context Pt Research Studies Rsch Admin Web Links

Nr-Poc, Shelly

MRN: None, SR: None Admitted DH: 110-A Health Maintenance: Research Active myD-H: Inactive  
 Age: Female, 39 y.o., 03/16/1976 PCP: None My Sticky Code: None Adv Dir: No  
 RCP: None Allergies: No Known Allergies Scan/Adv/Dir: None

Last refreshed: 6/16/2015 3:13:38 PM

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	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					38549313
Unscheduled Encount				05/05/2015	1517	LEB GIM 3M	Family Medicine, Physic	Appointment					38545578
Orders Only				04/10/2015	1123	LEB GASTRO 4L	Amb-Inpatient, Physician	Appointment					38543335
Orders Only			Closed	03/31/2015	1332	LEB PAIN MANAGEME	Amb-Inpatient, Physician	Appointment					38542356

All encounters loaded.

Demographics

Dartmouth-Hitchcock

Patient Demographics

Address: Home Phone: (Not on file)  
 Work Phone: (Not on file)

SSN: xxx-xx-6945 Ethnicity: (Not on file)  
 E-mail: (Not on file) Race: (Not on file)  
 Religion: (Not on file)  
 Preferred language: (Not on file)

Additional Names

Alias: Npoc, 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



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Thank You

