

# Oncology Patient Enrollment Network (OPEN) Overview

Diana Meyer  
OPEN Administrator

Sushmita De  
Systems Analyst

## The purpose of the OPEN System is...

To Provide a  
Standardized Web-based Environment  
for Enrollment of all Patients in Clinical Trials  
Across the NCI-sponsored  
Cooperative Group Clinical Trials Program

## Centralized web-based system



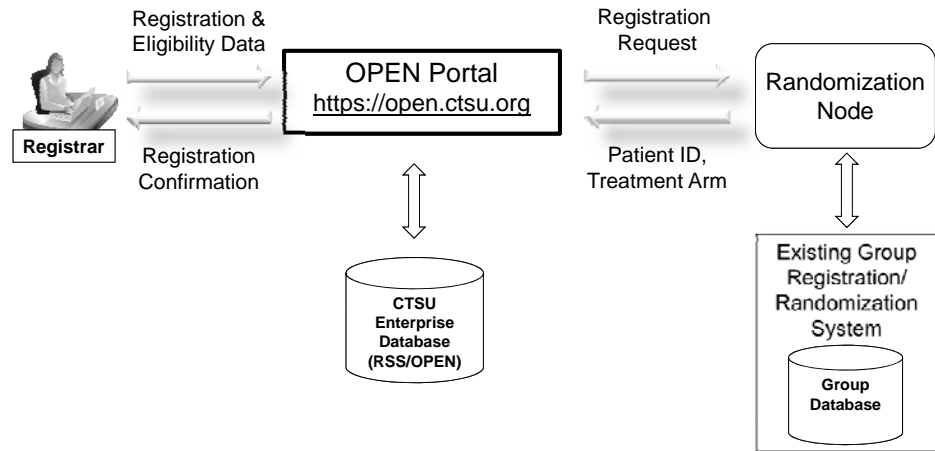
- Single web address.  
<https://open.ctsu.org>
- Uniform interface for all Cooperative Group studies
- Uniform implementation of Credentialing rules
- Increased availability and flexibility through multiple means of access

## Benefits to Sites



- Learn a single system for enrollments
- Maintain single password - standard CTEP-IAM
- Enroll patients to *all* Cooperative Group Trials
- Available 24/7 from the OPEN web site
- View all your OPEN enrollments across all Groups.
- Seamless integration with existing Group registration and randomization systems
- Phone and FAX-based processes being phased out

## How does OPEN Work?



## How Do I Get My Roles in OPEN?

If you are affiliated with the Protocol Lead Group

Contact the Lead Group. Your role assignments are handled through the Lead Group

Your Lead Group's roster is maintained in RSS by the Lead Group

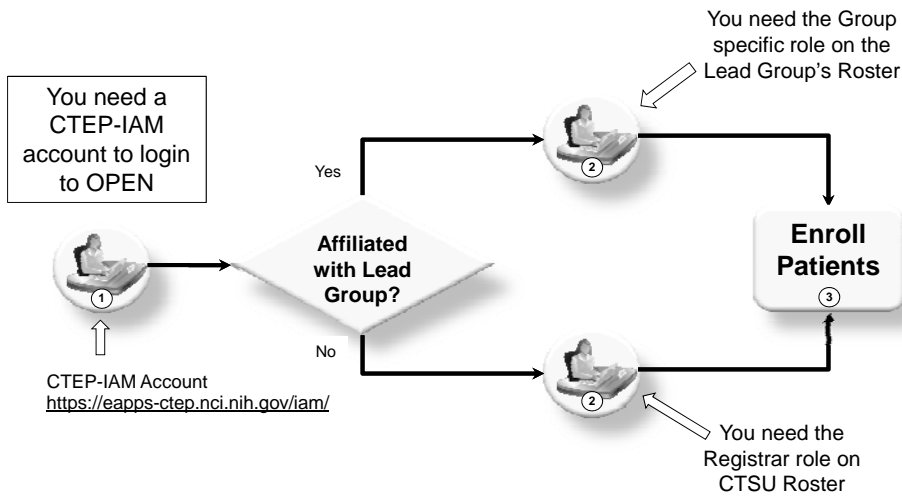
If your site is not affiliated with the Protocol Lead Group  
(For non-Lead Group enrollments)

Contact your Site and/or Data Administrators to request a role assignment

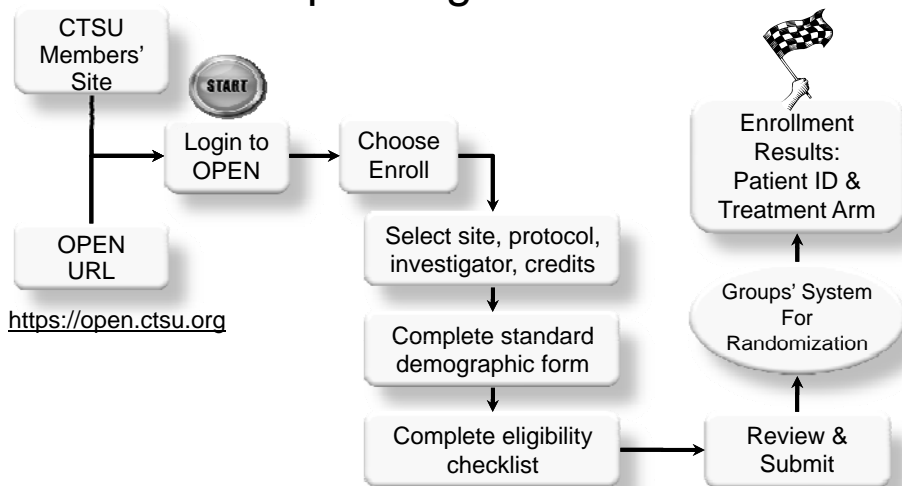
Role assignments are made via Roles maintenance under the RSS tab on the CTSU Members' web site

Your role assignments are to be set up only once per Lead Group – Not for each protocol

## How Do I Enroll Patients Using OPEN?



## Example Registration Flow



## Some Features..

- **OPEN has a “Practice” mode so sites can learn the system and review protocol enrollment forms. The Practice mode will be indicated by an orange colored menu bar and watermark on screen**

**Start Practice** to practice test enrollments!

- **The system will maintain registrations that are in-progress**
  - Registrations that are not completed can be saved and finished at a later date
  - Will maintain pending registrations for 7 calendar days

My five recent "In Progress" enrollments				
Track #	Protocol	Site	Status	Status Date
55014	E1505	GA024	SUBMITTED	08/07/2009 10:43
55008	E1505	GA024	SUBMITTED	08/06/2009 09:52
55000	RTOG-0521	GA024	SUBMITTED	08/05/2009 16:02
54970	PACCT-1	VT004	SUBMITTED	07/28/2009 15:36
54968	PACCT-1	VT004	SUBMITTED	07/28/2009 15:36

## Some Features.. (Cont)

- **OPEN can now support Ancillary Studies...**
  - Embedded Ancillary Study: a sub study that is incorporated into the main study (protocol). Does not require separate CTEP review or IRB approval from the main study
  - Stand Alone Ancillary Study: A sub study that is conducted in conjunction with one or more treatment study and requires separate CTEP review and IRB approval
  - Delayed Enrollments: Ancillary study enrollment which is not completed at the time of the main study enrollment. Requires separate CTEP review and IRB approval

## Some Features.. (Cont)

- Downloadable history of enrollments and reports will be added
- Access to regulatory status and other information that is currently available through the CTSU web site

Home | **Enroll** | History | Reports | RSS | Form Setup | Admin | Help | ruddb@ctsuesy

Browse | Summary | Demography | Checklist

Please select a registration to start with... **Download**

\* For registrations that have NOT been completed, click on the Download icon -> In Progress tab.

Filter by: All Search Clear

Action	V	Track #	Protocol	Site	Credit	Step	PID	Arm	Eligibility	Status	Status Date	Registrar
Select		55052	E1505	GA045	CTSU	1	15344	B	ELIGIBLE	REGISTERED	08/24/2009 17:38:42	SUSHMITA
Select		55047	S0777	AR006	SWOG	1	218928	2	ELIGIBLE	REGISTERED	08/14/2009 17:01:11	NAIRJ
Select		55045	E1505	GA024	ACOSOG	1	15342	B	ELIGIBLE	REGISTERED	08/14/2009 13:27:26	SUSHMITA
Select		55043	S0777	WI116	NCCTG	2	212669	3	ELIGIBLE	REGISTERED	08/11/2009 16:26:34	NAIRJ
Select		55041	S0777	WI031	ECOG	2	212085	3	ELIGIBLE	REGISTERED	08/11/2009 16:35:09	NAIRJ

## OPEN Login

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

**CTSU** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE  
Linking practice to progress

**OPEN** Oncology Patient Enrollment Network

**Welcome to the Oncology Patient Enrollment Network (OPEN) Portal system**

OPEN is the web-based registration system for patient enrollments onto NCI-sponsored Cooperative Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Cooperative Groups' registration/randomization systems for patient registration/randomization. OPEN provides the ability to enroll patients on a 24/7 basis.

**Training and Demonstration Materials:**

- [User Guide](#) » This users guide has a linkable Table of Contents that will bring you to any topic you choose, or you can scroll through and/or print the entire guide.
- [Demo Video](#) » This 15 minute video will walk you through a basic patient enrollment using OPEN Portal.
- [Frequently Asked Questions \(FAQ\)](#) » Frequently asked questions about OPEN Portal.
- [Access & Crediting Guidelines](#) » Guidelines for OPEN Portal Access and Crediting.

**OPEN Portal Authentication**

IAM User:

Password:

[Forgot your password?](#)

[Reset password?](#)

**Useful links and updates**

[Need a CTEP-IAM Account?](#)

[CTSU Members Site](#)

[CTEP-IAM Fast Fact Sheet](#)

Contact Us | Privacy Notice | Disclaimer | Accessibility | Application Support

Version 2.0.4.1 [20100404]

**OPEN** Oncology Patient Enrollment Network

**CTSUS** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE  
Linking practice to progress

## OPEN Home Page

TEST db

Contact | Members Site | Log off

**OPEN** Oncology Patient Enrollment Network

Site: VT004:University of Vermont    Role: Site Registrar

Home | Enroll | History | Reports | RSS | Help    patrichuk@ctrustet

Welcome | Profile

Start Practice    No practice test enrollments!

My five recent "In Progress" enrollments

Track #	Protocol	Site	Step	Status	Date
No recent activities!					
<a href="#">Create New Registration</a>					

Practice Registration Feature

Message of the day:  
In order to enroll patients via OPEN, you must be affiliated with at least one institution and carry the role of "registrar" at the institution(s).

If you have any questions please contact the [CTSUS Help Desk](#) at 1-888-823-5923.

Registration	RSS	Other
<ul style="list-style-type: none"> <li>Create New Registration</li> <li>In Progress Registrations</li> <li>Registration History</li> <li>Override Management</li> </ul>	<ul style="list-style-type: none"> <li>Person Search</li> <li>Site Registration Search</li> </ul>	<ul style="list-style-type: none"> <li>CTEP IAM</li> <li>Reports</li> </ul>

Recent "in progress" registrations for your site

OPEN Overview      CALGB Group Meeting – 06/24/2010      13

**OPEN** Oncology Patient Enrollment Network

**CTSUS** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE  
Linking practice to progress

## Create New Registration

1: Select Institution/Protocol combinations

Tracking Number: [ ]    Registrar: Meyer Diana [ ]

\* Institution CTEP ID: VT004    Institution Name: University of Vermont

\* Protocol Number: [CALGB-140503]    [ ] Protocols Missing?

Protocol Title: A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (<= 2 cm) Peripheral Lung Cancer

Protocol Note(s): [ ]

\* Registration Step: [1 - Registration]    [ ] Steps Missing?

2: Add persons associated with this enrollment [ ]

- Only one treating investigator\* and one drug shipment investigator can be associated
- Press [ ] to add a person, or press [ ] to remove
- If a shipping investigator is not selected, the shipping address will default to the treating investigator's address
- Protocol specific instructions: Protocol CALGB-140503 has the following association(s):  
 Treating Investigator (required), Site Registrar (required), Drug Shipment Investigator (optional). To add optional persons, please click the green plus icon.

Action	Person Type*	Person Name [ID] [Group]	Drug Shipping Address
[ ]	Treating Investigator	Wood, Marie Elizabeth [18223] [CALGB,CTSUS,GOG,NSABP]	Dr. Marie Elizabeth Wood c/o Ryan Daley Ritcher Allen Health Care Hematology/Oncology Clinic 111 Colchester Avenue AFC Main Pavilion Level Two Burlington, VT 05401 US
[ ]	Site Registrar	Walsh, Jane Elizabeth [514536] [CTSUS,NSABP]	

Persons on the selected site roster will display in OPEN

3: Specify credits

\* Cooperative Group Credit: [CALGB]    CCOP Accrual: NO



\* Credit Investigator: Wood, Marie Elizabeth [18223] [CALGB,CTSUS,GOG,NSABP]

4: Enter case notes

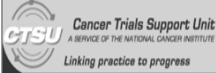

Case Notes: [ ]

Cancel    Start Over    Continue

OPEN Overview      CALGB Group Meeting – 06/24/2010      14

## Credentialing Confirmation


TEST db



Site: VT004:University of Vermont    Role: Site Registrar

[Home](#) [Enroll](#) [History](#) [Reports](#) [RSS](#) [Help](#)

[In Progress](#) | [Create New](#) | [Summary](#) | [Demography](#) | [Checklist](#) | [Review & Submit](#) | [Result](#) | [Overrides](#)



**Information**  
 \* CALGB-140503 Step 1 registration - tracking number #69624  
 \* Click on [Continue] button to continue to fill out the demography module

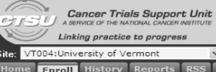

 Please click on the printer icon to print tracking number

Tracking  
Number

OPEN Overview
CALGB Group Meeting – 06/24/2010
15

## Demography Screen


TEST db


Site: VT004:University of Vermont    Role: Site Registrar

[Home](#) [Enroll](#) [History](#) [Reports](#) [RSS](#) [Help](#)

[In Progress](#) | [Create New](#) | [Summary](#) | [Demography](#) | [Checklist](#) | [Review & Submit](#) | [Result](#) | [Overrides](#)

Selected Tracking # 69624    Details    Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
CALGB-140503	---	---	1		VT004	Wood, Marie	NEW	05/25/2010

               Existing Patient ID:    

Expand/Collapse all Modules

Standard\_Patient\_Identifier

\* Last     \* First     Middle

Patient SSN     Patient Hospital No.

Standard\_Demographics

\* Patient's Date of Birth  /  /

\* Ethnicity  
 Hispanic or Latino  
 Not Hispanic or Latino  
 Not reported  
 Unknown

\* Gender of a Person  
 Female Gender  
 Male Gender  
 Unknown

\* Country of Residence     ZIP Code

Standard\_Race

\* Race  
 American Indian or Alaska Native  
 Asian  
 Black or African American  
 Native Hawaiian or other Pacific Islander  
 White

OPEN Overview
CALGB Group Meeting – 06/24/2010
16

**OPEN** Oncology Patient Enrollment Network

**CTSUS** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE  
Linking practice to progress

## C140503 Online Registration Form

Selected Tracking # 69624    Details    Summary

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
CALGB-140503		DD-	1		VT004	Wood, Marie	INCOMPLETE	05/25/2010

Message(s)  
Cannot submit until all data entry errors are resolved.

Validation Messages  
 \* Eligibility checklist form has validation errors/alerts  
 \* [Protocol Administration] module has 1 error(s)

System will display validation errors and alerts.

Expand/Collapse all Modules  
 Protocol Administration  
 \* ERROR-9: HIPAA Authorization Date is required for US residents.

\* Date Informed Consent Signed (MM DD YYYY) February (02) / 04 / 2010

HIPAA Authorization Date (MM DD YYYY)

Notes:  
 Name of VATS lobectomy credentialed surgeon (If VATS lobectomy is planned, provide the following:)

CRA Name

CRA Phone

CRA e-mail

OPEN Overview                      CALGB Group Meeting – 06/24/2010                      17

**OPEN** Oncology Patient Enrollment Network

**CTSUS** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE  
Linking practice to progress

## Review Screen

CTSUS Cancer Trials Support Unit                      TEST db                      Contact | Members Site | Log off  
 OPEN Oncology Patient Enrollment Network

Site: VT004:University of Vermont    Role: Site Registrar

Home | Enroll | History | Reports | RSS | Help

In Progress | Create New | Summary | Demography | Checklist | Review & Submit | Logout | Overrides

Review Message(s)  
 \* The checklist form has been validated  
 \* Please review checklist for accuracy and click [Submit] for eligibility. To make changes click [Checklist] button or their sub-tabs.

Step 1 Registration Information: [Tracking # 69624]    Checklist    Submit

Patient ID: Not yet assigned  
 Treatment Arm: Not yet assigned  
 Institution: University of Vermont  
 Protocol Number: CALGB-140503  
 Protocol Title: A Phase III Randomized  
 Registration Step: 1 (Registration)  
 Registration Status: READY on 05/25/2010

Associated Persons:

Person Type	Person Name	Status
Site Registrar	Walsh, Jane	ACTIVE
Treating Investigator	Wood, Marie	ACTIVE

Drug Shipping Address: Dr. Marie Elizabeth Wood  
 c/o Ryan Daley  
 Fletcher Allen Health Care  
 Hematology Oncology Clinic  
 111 Colchester Avenue  
 ACC Main Pavilion Level Two  
 Burlington, VT 05401 US

Registration Initiated By: MEVERDI on 05/25/2010 12:02 PM EDT  
 Updated By: MEVERDI on 05/25/2010 12:19 PM EDT  
 Cooperative Group Credit: CALGB  
 Credit Investigator: Wood, Marie  
 CCOP Accrual: NO  
 Other Payment Group:

System will ask you to verify all credentialing and checklist information upon selecting submit

Registration and Checklist information can be modified until final submission

OPEN Overview                      CALGB Group Meeting – 06/24/2010                      18

## Registration Confirmation

TEST db

[Contact](#) | [Members Site](#) | [Log off](#)

[meyerdi@ctstut](#)

Site: VT004:University of Vermont Role: Site Registrar

Home | [Enroll](#) | [History](#) | [Reports](#) | [RSS](#) | [Help](#)

[Browse](#) | [Summary](#) | [Demography](#) | [Checklist](#)

Selected Tracking # 69624 [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
CALGB-140503	120903	DD-	1	N/A	VT004	Wood, Marie	REGISTERED	05/25/2010

**Information**

- ✦ Group response for tracking #69624
- ✦ This registration can now be found in the HISTORY section
- ✦ Click on [View Summary] to view the complete registration summary

**Group Response(s)**

Eligibility:	Eligible
Ineligibility Reason:	None
Patient ID:	120903
Treatment Arm:	N/A
Site Instruction:	N/A
Node Error Message:	

Please let us know your enrollment experience by completing this survey [which should not take more than 2 minutes!](#)

[View Summary](#)

Patient ID #

Please take a few moments to complete the survey after enrolling a patient. We want your feedback!

OPEN Overview
CALGB Group Meeting – 06/24/2010
19

## Registration History

TEST db

[Contact](#) | [Members Site](#) | [Log off](#)

[meyerdi@ctstut](#)

Site: VT004:University of Vermont Role: Site Registrar

Home | [Enroll](#) | [History](#) | [Reports](#) | [RSS](#) | [Help](#)

[Browse](#) | [Summary](#) | [Demography](#) | [Checklist](#)

Selected Tracking # 69624 [Details](#) [Summary](#)


Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
CALGB-140503	120903	DD-	1	N/A	VT004	Wood, Marie	REGISTERED	05/25/2010


\* For registrations that have NOT been completed, please go to the [Enroll -> In Progress](#) tab.

Filter by: All [Search](#) | [Clear](#)

Action	V	Track #	Protocol	Site	Credit	Step	Arm	Eligibility	Status	Status Date	Registrar	
Select	<input checked="" type="checkbox"/>	69624	CALGB-140503	VT004	CALGB	1	120903	N/A	ELIGIBLE	REGISTERED	05/25/2010 12:25 PM	MEYERDI
Select	<input checked="" type="checkbox"/>	69613	CALGB-140503	VT004	CALGB	2	120902	Arm A	ELIGIBLE	REGISTERED	05/25/2010 10:06 AM	LEL
Select	<input checked="" type="checkbox"/>	69612	CALGB-140503	VT004	CALGB	1	120902	N/A	ELIGIBLE	REGISTERED	05/25/2010 09:58 AM	LEL
Select	<input checked="" type="checkbox"/>	69610	CALGB-140503	VT004	CALGB	2	120901	Arm A	ELIGIBLE	REGISTERED	05/25/2010 09:45 AM	LEL
Select	<input checked="" type="checkbox"/>	69609	CALGB-140503	VT004	CALGB	1	120901	N/A	ELIGIBLE	REGISTERED	05/25/2010 09:41 AM	LEL
Select	<input checked="" type="checkbox"/>	69573	E2903	VT004	CALGB	2	29007	C	ELIGIBLE	REGISTERED	05/24/2010 11:29 AM	CHAMT
Select	<input checked="" type="checkbox"/>	69570	E2903	VT004	CALGB	1	29007	A	ELIGIBLE	REGISTERED	05/24/2010 11:24 AM	CHAMT
Select	<input checked="" type="checkbox"/>	69545	E1208	VT004	CALGB	1	12052	X	ELIGIBLE	REGISTERED	05/21/2010 03:48 PM	PATRICHUKL
Select	<input checked="" type="checkbox"/>	69432	E1908	VT004	NSABP	1	19037	A	ELIGIBLE	REGISTERED	05/18/2010 02:20 PM	JANDREWS
Select	<input checked="" type="checkbox"/>	69429	E1908	VT004	NSABP	0	19037	T	ELIGIBLE	REGISTERED	05/18/2010 02:18 PM	JANDREWS
Select	<input checked="" type="checkbox"/>	69426	E1908	VT004	CALGB	1	19036	B	ELIGIBLE	REGISTERED	05/18/2010 01:32 PM	CHAMT
Select	<input checked="" type="checkbox"/>	69425	E1908	VT004	CALGB	0	19036	T	ELIGIBLE	REGISTERED	05/18/2010 01:28 PM	CHAMT
Select	<input checked="" type="checkbox"/>	69421	E1908	VT004	CALGB	1	19034	B	ELIGIBLE	REGISTERED	05/18/2010 12:28 PM	JANDREWS
Select	<input checked="" type="checkbox"/>	69420	E1908	VT004	CALGB	0	19034	T	ELIGIBLE	REGISTERED	05/18/2010 12:26 PM	JANDREWS
Select	<input checked="" type="checkbox"/>	69410	E1908	VT004	CALGB	1	19030	A	ELIGIBLE	REGISTERED	05/18/2010 01:10 PM	CHAMT
Select	<input checked="" type="checkbox"/>	69408	E1908	VT004	CALGB	0	19030	T	ELIGIBLE	REGISTERED	05/17/2010 05:31 PM	CHAMT
Select	<input checked="" type="checkbox"/>	69407	E1908	VT004	CALGB	1	19029	A	ELIGIBLE	REGISTERED	05/18/2010 01:05 PM	CHAMT

OPEN Overview
CALGB Group Meeting – 06/24/2010
20





## C140503 Step 2

1: Select Institution/Protocol combinations

Tracking Number:  Registrar: Meyer Diana

\* Institution CTEP ID: VT004  Institution Name: University of Vermont

\* Protocol Number: CALGB-140503  Protocol Title: A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (<= 2 cm) Peripheral Non-Small Cell Lung Cancer

Protocol Note(s):

\* Registration Step: 2 (Step 2 Registration)

Ancillary protocol selection

- All required ancillary stand-alone/embedded protocols will be auto selected by default

Select	Type	# Days	Reqd.?	Protocol	Group #	Status	Title
<input type="checkbox"/>	EMBEDDED	0	YES	CALGB-140503-E-01	S80602		Embedded Study S80602

2: Add persons associated with this enrollment

- Only one treating investigator\* and one drug shipment investigator can be associated
- Press  to add a person, or press  to remove
- If a shipping investigator is not selected, the shipping address will default to the treating investigator address
- Protocol specific instructions:** Protocol CALGB-140503 has the following association(s):  
 Treating Investigator (required), Site Registrar (required), Drug Shipment Investigator (optional). To add optional persons, please click the green plus icon.

Action	Person Type*	Person Name [ID] [Group]*	Drug Shipping Address
<input type="checkbox"/>	Treating Investigator	Wood, Marie Elizabeth [18223] [CALGB,CTSUS,GOG,NSABP]	Dr. Marie Elizabeth Wood 26 Ryan Daley
<input type="checkbox"/>	Site Registrar	Walsh, Jane Elizabeth [514536] [CTSUS,NSABP]	Fletcher Allen Health Care Hematology Oncology Clinic 111 Colchester Avenue ACC Main Pavilion Level Two Burlington, VT 05401 US

3: Specify credits


\* Cooperative Group Credit: CALGB  CCOF Accrual: NO

\* Credit Investigator: Wood, Marie Elizabeth [18223] [CALGB,CTSUS,GOG,NSABP]

4: Enter case notes


Case Notes:


OPEN Overview
CALGB Group Meeting – 06/24/2010
21





## Step 2 Registration Confirmation





TEST db

Site: VT004:University of Vermont | Role: Site Registrar

Home | Enroll | History | Reports | RSS | Help | meyerd@ctsus

Browse | Summary | Demography | Checklist

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
CALGB-140503	120903	DD-	2	Arm B	VT004	Wood, Marie	REGISTERED	05/25/2010

Ancillary Protocol(s) for tracking # 69633				
Protocol	Group #	Type	Status	Status Date
CALGB-140503-E-01	S80602	EMBEDDED	REGISTERED	05/25/2010

**Information**

- Group response for tracking # **69633**
- This registration can now be found in the HISTORY section
- Click on [View Summary] to view the complete registration summary

Group Response(s)	
Eligibility:	Eligible
Ineligibility Reason:	None.
Patient ID:	120903
Treatment Arm:	Arm B
Site Instruction:	Arm B: Limited Resection
Node Error Message:	

Please let us know your enrollment experience by completing this survey  which should not take more than 2 minutes!

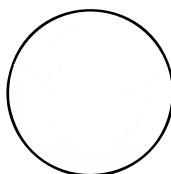
OPEN Overview
CALGB Group Meeting – 06/24/2010
22

## OPEN Resources



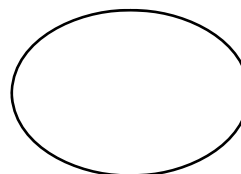
The 'OPEN' tab on the CTSU Members' Web Site

- Information and updates about OPEN
- A link to the Guide to OPEN Access and Crediting
- A link to the OPEN Portal



Training material under the OPEN tab on the members' web site

- OPEN Demonstration Video
- OPEN User Guide
- OPEN FAQ



Training materials within the OPEN application

- Practice Mode
- OPEN User Guide
- OPEN Demonstration Video
- OPEN FAQ
- A link to the Guide to OPEN Access and Crediting

## OPEN Information on the Web Site

OPEN is the web based registration system for patient enrollments onto NCI sponsored Cooperative Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Cooperative Groups' registration/administration systems for patient registration/administration. OPEN provides the ability to enroll patients on a 24/7 basis. Access to the OPEN system is controlled through the CTSU-UMM system and through role assignments in the support system. To access OPEN:

- Site staff will need to be registered with CTSP and have a valid and active CTSP-UMM account.
  - o This is the same account (user id and password) used for the CTSU members' web site.
- To perform registrations, the site user must have been assigned the "Registrar" role on the relevant Group or CTSU roster.
- To perform registrations on protocols for which you are a member of the Lead Group, you must have an equivalent "Registrar" role on the Lead Group roster.
  - o Role assignments are handled through the CTSP on which you are a member.
- To perform registrations to trials accessed via the CTSU mechanism (i.e., non-Lead Group registrations) you must have the role of Registrar on the CTSU roster.
  - o Role and/or Role Administrator can manage CTSU roster roles via the new Site Roles maintenance feature under the "Site Roles" link on the CTSU members' web site. This will allow them to assign staff the "Registrar" role.

If you have questions about this please contact the CTSU Help Desk.

### Learn More About OPEN

#### Training and Demonstration Materials

- **OPEN User Guide**  
The User Guide contains a linkable Table of Contents that will bring you to any topic you choose, or you can scroll through and/or print the entire guide.
- **OPEN Demo Video**  
This 12 minute video will walk you through a basic patient enrollment using OPEN. If you have difficulty watching this video online, then please download the video to your local machine using the download link: [OPEN Training Video \(Windows Media Video WMV format\)](#)
- **Guidelines for CTSU Access and Crediting**  
This document outlines the set of guidelines for OPEN access and crediting.
- **OPEN FAQs**  
[OPEN Frequently Asked Questions](#)

Site resources

### Connect to OPEN

The following protocols are now active in OPEN for site use:

Protocol ID	Protocol Name	Start Date
0402040101	11/1/2009	
0402040201	01/1/2010	
11101	2/23/2010	
E1202	11/15/2009	
E1306	2/2/2010	
F1504	4/21/2010	
F3804	4/21/2010	
F3904	4/21/2010	
T1304	04/05/2010	
T4104	2/26/2010	
L2004	2/23/2010	
050111	11/15/2009	

Link to OPEN

List of protocols active in OPEN

## CALGB Transition

- C140503 will be released to CTSU registrars in July 2010
- Site release will follow
- Site users will need:
  - For CALGB led trials, appropriate staff have to be active on the CALGB roster
  - For trials led by other organizations, verify appropriate staff are linked to their site on the CTSU roster and have the registrar role if needed
  - All investigators are linked to their treating organizations on the CALGB and/or CTSU roster

## CALGB Roster Roles

- Important Points:
  - **For CALGB-led trials, all associates on the CALGB roster with a role of site registrar will be granted the registrar role, however they must be linked with all of their sites (main sites and child sites) to enroll patients at these sites**
  - **Ensure that all investigators are linked to their treating organizations on the CALGB roster**
  - **For trials led by other organizations, verify that appropriate staff are linked to their site(s) on the CTSU roster and have CTSU registrar role if needed**

## Current Status

- **There are 22 protocols active in OPEN**
- **Over 5,200 enrollments completed in OPEN**
- **Three other protocols are in production with the CTSU Registrars –will be released to sites soon**
  - RTOG-0436
  - N0733
  - NCIC-PR.11
- **During CTSU Registrar Release**
  - Group roster cleanup
  - Uncover any form or connectivity issues
  - Work with each Group to refine communication
  - Finalize site and Group training documentation

## Looking Ahead....



- **Data Update Module - synchronization of enrollment data between Groups & OPEN, post-enrollment data corrections**
- **Facilitate Patient Transfers**
- **More reporting features**
- **Integration with the NCI's Clinical Data Management System**
- **Empower Groups to manage their protocols in OPEN**
- **Activate all new protocols in OPEN**
- **Migrate legacy protocols to OPEN**

## Contacts

- Ravi Rajaram – CTSU Assistant Project Director (Informatics)
  - [RaviRajaram@westat.com](mailto:RaviRajaram@westat.com)
  - (301) 294-2045
- Lucille Patruchuk – Implementation Manager
  - [LucillePatruchuk@westat.com](mailto:LucillePatruchuk@westat.com)
  - (240) 314-2572
- Jayan Nair – OPEN Development Manager
  - [JayanNair@westat.com](mailto:JayanNair@westat.com)
  - (301) 212-2126
- Steve Riordan – CTSU Project Director
  - [SteveRiordan@westat.com](mailto:SteveRiordan@westat.com)
  - (301) 517-4045

## Questions?

