Lead CRA/ Administrator Tips

Betsy Barnick, MHSc, CCRP
Jen Dill, BS, CCRP

Loews Hotel, Chicago, IL

Alliance Fall Group Meeting 2018

Presentation Objectives

- Brief overview of financial resources on CTSU
  - Funding sheets, National Coverage Analysis (NCA) resources, and Open funding reports
- Describe site workflow for RCR and DTL
  - Academic vs NCORP
- Review Alliance CRP website training resources
- Discuss general overview of site staff training
  - Training materials and site checklist

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Before we begin

- How many are Academic vs Community?
- How many of you are the administrator?
- How long have you been in your position?
  - 1 year?
  - 5 years?
  - More?
- How many of you feel you've got this figured out?

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Financial Resources on CTSU

- National Coverage Analysis (NCA)
- Funding Sheets
- Open Funding Reports
- For NCORPs - NCORPSys

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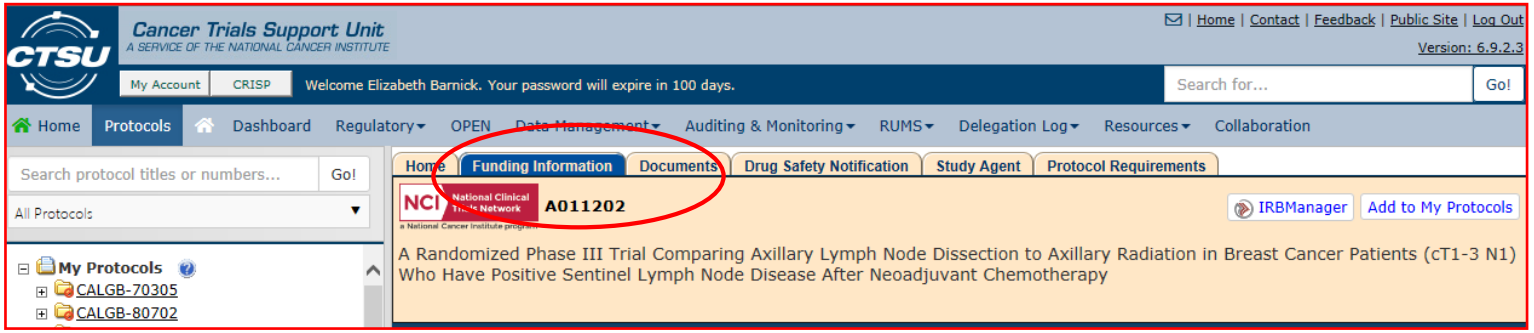
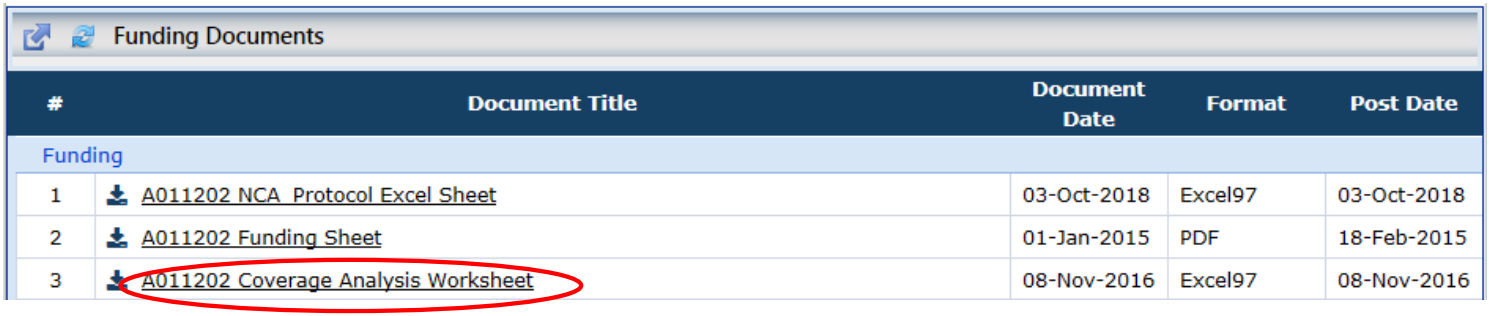
National Coverage Analysis

CTSU → Protocol → Funding Information → Funding Documents





#	Document Title	Document Date	Format	Post Date
Funding				
1	A011202 NCA_Protocol Excel Sheet	03-Oct-2018	Excel97	03-Oct-2018
2	A011202 Funding Sheet	01-Jan-2015	PDF	18-Feb-2015
3	A011202 Coverage Analysis Worksheet	08-Nov-2016	Excel97	08-Nov-2016

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QCT Tab (Qualifying Clinical Trial Analysis)

ALTernate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study			
The National Coverage Decision 310.1, the NCCN Clinical Practice Guidelines and other resources were used to develop this National Coverage Analysis. This NCA is provided by the CTSU as a guidance tool for institutions to assist with billing compliance. Institutions that chose to utilize this tool are responsible for the verification and modification of the coverage analysis in compliance with their institutional guidelines and are ultimately responsible for modifications			
Investigational Item or Service Analysis			
Question	**Answer**		
What is the name and version of the protocol	A011106; version date: 3/10/2017 #6		
What is the version of the funding sheet?	8/4/2015		
What is the Clinicaltrials.gov #?	NCT01953588		
What is the name of the investigational item?	Fulvestrant		
What is the FDA status of the investigational item?	IND Exempt		
If FDA approved, is the investigational item being used off-label?	NA		
Is this study required by Medicare as a part of the "Coverage with Evidence Development" process? (http://cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html)	NA		
Qualifying Clinical Trial Analysis			
Requirement	**Yes**	**No**	**Comment**
Does the investigational item or service fall into a Medicare benefit category? Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).	x		Drugs and Biologicals
Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with Institutional policy?	x		1. To determine whether fulvestrant administered for 24 weeks as neoadjuvant endocrine treatment increases the proportion of endocrine sensitive tumors* relative to patients treated with anastrozole. 2. To determine whether fulvestrant in combination with anastrozole, administered for 24 weeks as neoadjuvant endocrine treatment, increases the proportion of endocrine sensitive tumors* relative to patients treated with anastrozole. 3. If both of the fulvestrant containing arms are found to have an endocrine sensitive disease rate at least 10% higher than that of the anastrozole arm, we will assess whether the endocrine sensitive disease rate is greater with the combination of anastrozole and fulvestrant than with fulvestrant alone. 4. To assess whether the 5-year RFS rate among women treated with anastrozole with a modified preoperative endocrine prognostic index (PEPI) score of 0 following 24 weeks of neoadjuvant treatment is at most 90%. 5. For the fulvestrant containing regimens, a point and interval estimate of the 5 year RFS will be obtained.
Does the study enroll patients with diagnosed diseases?	x		Pathologic confirmation of invasive breast cancer
Is the study a deemed trial? (Study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or supp	x		NCI
Is the study a qualifying clinical trial? (All questions must be answered "Yes" to qualify)	**x**		

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National Coverage Analysis (*NCA*)

Protocol #: A011106														Today's Date: June 2, 2017
Study Title: ALTernate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study														
Principal Investigator: Cynthia X. Ma, MD, PhD														
		All patients: Prior to registration through cycle 2 (week 8)			Patients continuing on Arm I, Arm II or Arm III after week 4 biopsy									
									Post-op follow-up for patients with modified PEPI 0 score			post-op follow-up for patients with a modified PEPI Non-0 score		
Procedure	CPT Codes	No more than 14 days prior to registration	Prior to start of neo-adjuvant endocrine therapy	Neoadjuvant endocrine therapy Day 1 (+/-3) days of Cycle 2	Neoadjuvant endocrine therapy Day 1(+/-3 days) of Cycles 3 to 6	At completion of neoadjuvant endocrine therapy	Discontinuation of neoadjuvant endocrine therapy due to tumor progression	SURGERY	Adjuvant Therapy (per randomization assignment) +/- RT Post-op visit within 2-4 weeks after surgery Every 6 months years 1-5 after the start of adjuvant ET	Clinical Monitoring Yearly for years 6-10 post surgery until disease progression	Following documentation of disease recurrence, patients will enter the survival and disease status follow-up period of the study See Section 9.0	Adjuvant Therapy Every 6 months years 1-5 post surgery	Clinical Monitoring Yearly years 6-10 post surgery	Justification and Comments
EVALUATION & MANAGEMENT														
History & physical exam, height, weight, performance status	99201-99205, 99211-99215, G0463	RC		RC	RC		RC		RC (no height)	RC (no height)	RC (no height)			NCD 310.1 allows for the coverage of routine cost of conventional care. Physical exams at workup, during therapy and follow-up appear reasonable and necessary to monitor disease/ progression. Medical records must document medical necessity and support level of E&M performed. Note that the additional procedures on the same day as the H&P would not be billed separately, but allow billing to assign the higher CPT code to reflect accurately the increased complexity and time that the E&M encounter requires.
Clinical measurements of breast lesion		RC		RC	RC		RC							
Adverse event assessment			RC	RC	RC	RC	RC		RC					
Drug compliance assessment (Arms I and III)				RC	RC	RC	RC		RC					
Clinical breast exam									RC	RC	RC	RC	RC	
LABORATORY														
CBC, Diff, Plts, PT/INR, serum creat, ALT, T. bilirubin	85025, 85027, 85610, 82565, 84460, 82247	RC												NCD 310.1 allows for coverage of routine costs to monitor toxicities of chemotherapeutic agents. It would seem reasonable and necessary to establish a baseline prior to administering agents. Medical records must document medical necessity.
CBC+D, Platelets	85025, 85027													NCD 310.1 allows for coverage of routine costs to monitor toxicities of chemotherapeutic agents. Drugs understudy in this trial can cause anemia, thrombocytopenia, neutropenia and/or kidney, liver disorders. Coverage also generally supported by NCD 190.15. Medical records must document medical necessity.
Serum Creat, T. Bili, ALT	82565, 84460, 82247													
Venipuncture	36415, 36591, 36592	RC												NCD 310.1 allows for the coverage of routine cost of conventional care.
SPECIMENS														
Tumor Biopsies	NA		S	S (week 4)	S			S						Research purposes only; sponsor to pay.

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Key Points

- Know that the QCT and NCA information is available to you
- Your institution may have their own determination
- This does not account for local coverage decisions

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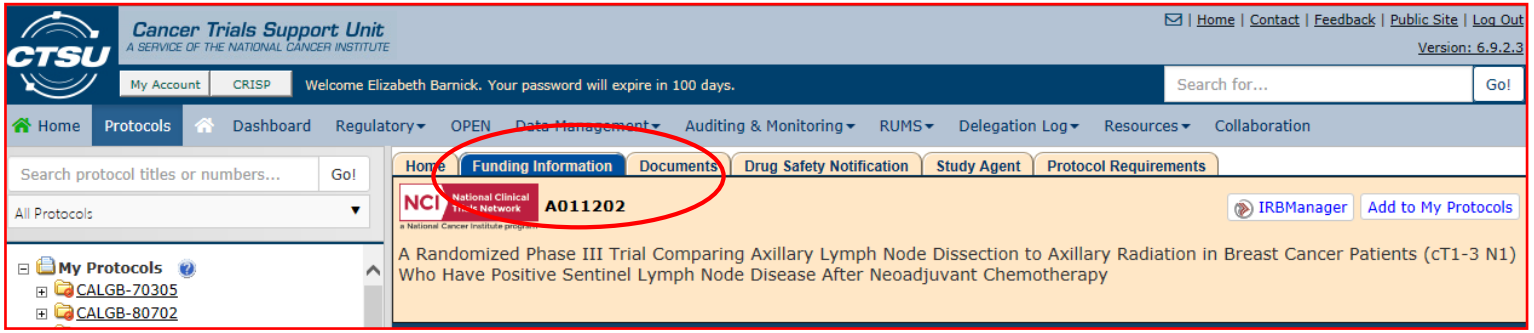
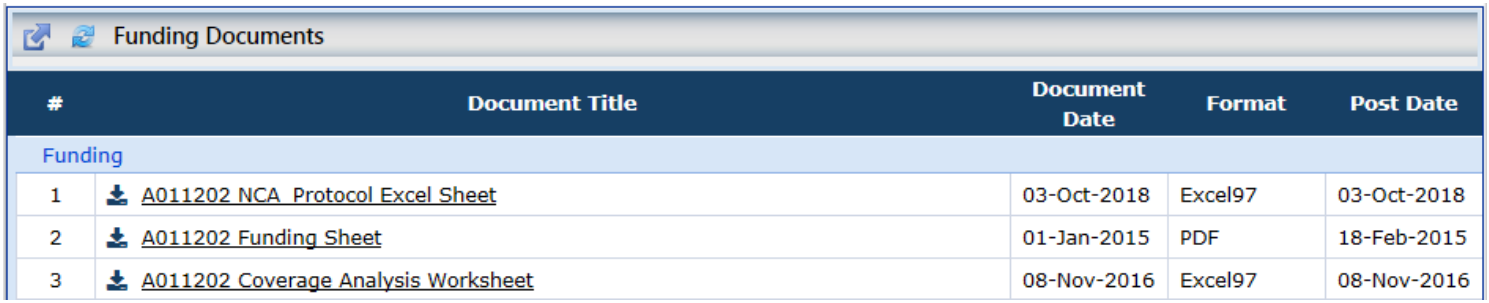
Funding Sheets

CTSU → Protocol → Funding Information → Funding Documents





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ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

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Study Activation: 12/13/2013

Funding Source and Study Component		Mandatory/Mandatory Request or Event/ Optional	Study Specific Notes	Enter Date in OPEN ?	NCTN Funding Amount per Patient (a) Standard/ LAPS	NCORP Funding Amount per Patient (b) Std/HP
Federal	Base Intervention (Standard/ High Performance (HP) LAPS & NCORP)	Mandatory		No	$2250 / $4000	$2500 / $4000
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Federal	Biospecimen – Tissue - At time of surgery two formalin core biopsies, two frozen core biopsies, and 10 fixed tumor tissue slides	Mandatory Event	2	Yes	$ 450	$ 450
Federal	Biospecimen – Tissue at disease progression	Optional	3	Yes	$ 150	$ 150
Federal	Biospecimen – Blood - Serum, plasma and whole blood	Optional	4	Yes	$ 150	$ 150
Total Potential Federal Funds					$5200/ $6950	$5450 / $6950
Non-Federal	Alliance Foundation funds – Week 12 Core biopsy	Optional	5	No	$ 557	$ 557
Non-Federal	Alliance Foundation funds- Neoadjuvant Chemotherapy Group who receive paclitaxel- Day 2 of Cycle 1 core biopsy	Optional	5	No	$557	$557
Total Potential Non-Federal Funds (c)					**$ 1114**	**$ 1114**
Total Potential Funds (d)					**$6314 / $8064**	**$6564 /$8064**

General Notes:

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2. See information contained in Protocol Section 7.3 and 7.4 for biospecimen collection information.
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5. Sites will receive funds up to $557 from the Alliance Foundation for optional core biopsies submitted at the following time points (per protocol Sections 7.5 and 7.6):
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Total Potential Non-Federal Funds (c)					$ 1114	$ 1114

NCTN vs NCORP

NCTN gets straight $

Total Potential Funds (d)	**$6314 / $8064**	**$6564 /$8064**

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.18

.06

NCORPs – Federal generally = credits (unless a footnote) $2500=1 credit

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These component “pieces” show up on open reports but the credits aren’t in there.

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Enter date in OPEN
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3. See information contained in Protocol Section 7.7 for biospecimen collection information.
4. See information contained in Protocol Section 7.8 for biospecimen collection information.
5. Sites will receive funds up to $557 from the Alliance Foundation for optional core biopsies submitted at the following time points (per protocol Sections 7.5 and 7.6):
   - Week 12,
   - Day 2 of Cycle 1, for those in the Neoadjuvant Chemotherapy Group who receive neoadjuvant paclitaxel

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Funding Sheet

ALTernate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: a phase III study

Study Activation: 12/13/2013

Funding Source and Study Component		Mandatory/Mandatory Request or Event/ Optional	Study Specific Notes	Enter Date in OPEN ?	NCTN Funding Amount per Patient (a) Standard/ LAPS	NCORP Funding Amount per Patient (b) Std/HP
Federal	Base Intervention (Standard/ High Performance (HP) LAPS & NCORP)	Mandatory		No	$2250 / $4000	$2500 / $4000
Federal	Biospecimen – Tissue – Pre-treatment core biopsy-(BIQSFP funds paid to all sites including LAPS & NCORP)	Mandatory Event	1	Yes	$ 1100	$ 1100
Federal	Biospecimen – Tissue – Week 4 core biopsy - (BIQSFP funds paid to all sites including LAPS & NCORP)	Mandatory Event	1	Yes	$ 1100	$ 1100
Federal	Biospecimen – Tissue - At time of surgery two formalin core biopsies, two frozen core biopsies, and 10 fixed tumor tissue slides	Mandatory Event	2	Yes	$ 450	$ 450
Federal	Biospecimen – Tissue at disease progression	Optional	3	Yes	$ 150	$ 150
Federal	Biospecimen – Blood - Serum, plasma and whole blood	Optional	4	Yes	$ 150	$ 150
Total Potential Federal Funds					**$5200/ $6950**	**$5450 / $6950**
Non-Federal	Alliance Foundation funds – Week 12 Core biopsy	Optional	5	No	$ 557	$ 557
Non-Federal	Alliance Foundation funds- Neoadjuvant Chemotherapy Group who receive paclitaxel- Day 2 of Cycle 1 core biopsy	Optional	5	No	$557	$557
Total Potential Non-Federal Funds (c)					**$ 1114**	**$ 1114**
Total Potential Funds (d)					**$6314 / $8064**	**$6564 /$8064**

General Notes:

(a) NCTN (Non- NCORP) Institutions receive federal funds through their NCTN Group or LAPS grant. For LAPS Main Members and Integrated Components, once the target for high performance intervention accrual is reached, subsequent base interventions will be paid at the standard rate.

(b) The dollar value varies for standard and high performance (HP) NCORP Sites. One (1.0) credit equals $2,500 for standard NCORPs and $4,000 for high performance NCORPs for the base intervention. For HP NCORPs, once the credit target referenced in the initial Notice of Award is reached, subsequent base intervention credits will be set at 1.0 credit equals $2,500. The credit for any other funding category (e.g., biospecimen) is set at 1.0 credit and is equal to $2,500.

(c)) When available, Non-Federal Funds are distributed by the Lead NCTN Group to the NCTN Group credited by the enrolling site (including all LAPS and NCORP sites)

(d) All sites participating in a trial with components that have a payment after initial enrollment, (such as a biospecimen collection) MUST enter the collection date in the OPEN funding screen to verify compliance and verify funding. If the trial component consists of a series of submissions over time, such as a QOL study, the site only needs to enter the date the first CRF is submitted.

Study Specific Notes:

1. Sites will be reimbursed $1,100 from BIQSFP federal funding per required core biopsy performed at the following time points (per protocol section 7.1 and 7.2): Pre-treatment and Week 4.
   Reimbursement to sites for the Pre-treatment and Week 4 biopsies will be based on a BioMS-generated report of research biopsies submitted per site, and will not require submission of an invoice by sites.
2. See information contained in Protocol Section 7.3 and 7.4 for biospecimen collection information.
3. See information contained in Protocol Section 7.7 for biospecimen collection information.
4. See information contained in Protocol Section 7.8 for biospecimen collection information.
5. Sites will receive funds up to $557 from the Alliance Foundation for optional core biopsies submitted at the following time points (per protocol Sections 7.5 and 7.6):
   - Week 12,
   - Day 2 of Cycle 1, for those in the Neoadjuvant Chemotherapy Group who receive neoadjuvant paclitaxel

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Key points

- NCTN/LAPS – Dollars you see are what you get
- NCORPs – some credits, some dollars or both
  - Federal = Credits
  - Non-Federal = $
- Pay attention to special notes (BIQSFP funds *paid to all sites including LAPS & NCORP*)
- If you think you are due money, check OPEN first to see if the date of procedure was entered in OPEN, that entry triggers the payment.

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Open Reports – Administrator Perspective

- Three key reports
  - History Report – gives full list of patients, gives base interventions and pre-reg (which don't count as accruals)
  - Screening (NCORP Only) – gives DCP information. Number of patients x credit value
  - Funding – These are the credit "pieces"
- Typically export these reports

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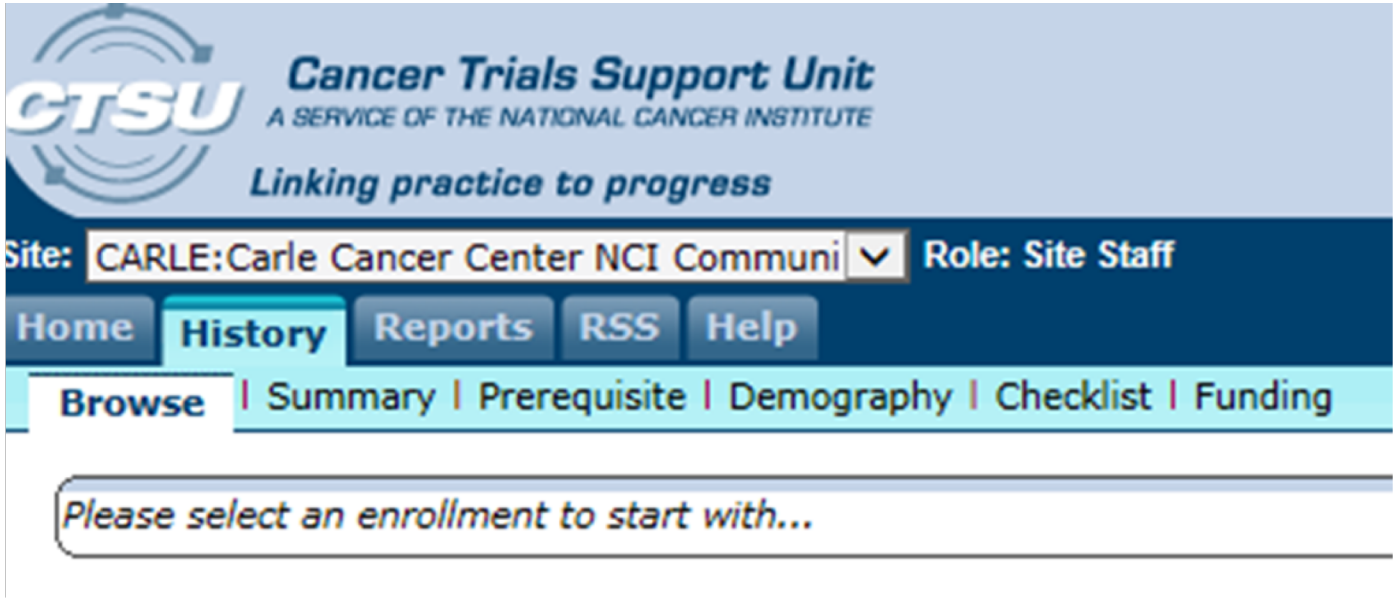
Open Reports - History



Go to OPEN - History/Browse tabs

- Gives all patient enrollments
- Includes Step 0, pre-registrations
- Includes Base Interventions

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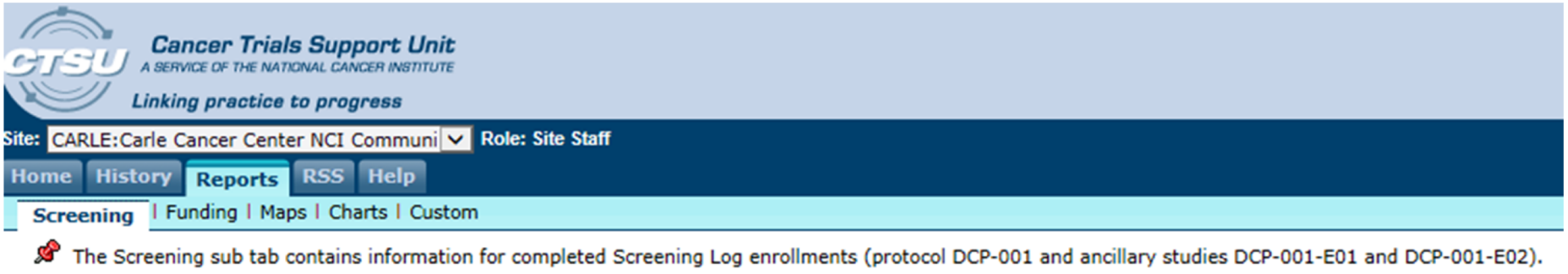
Open Reports - Screening



Go to OPEN - Reports/Screening tab

- Shows DCP-001 enrollments
- Shows if patients consent to DCP-001 or not
- Use for determining credits accrued to DCP-001

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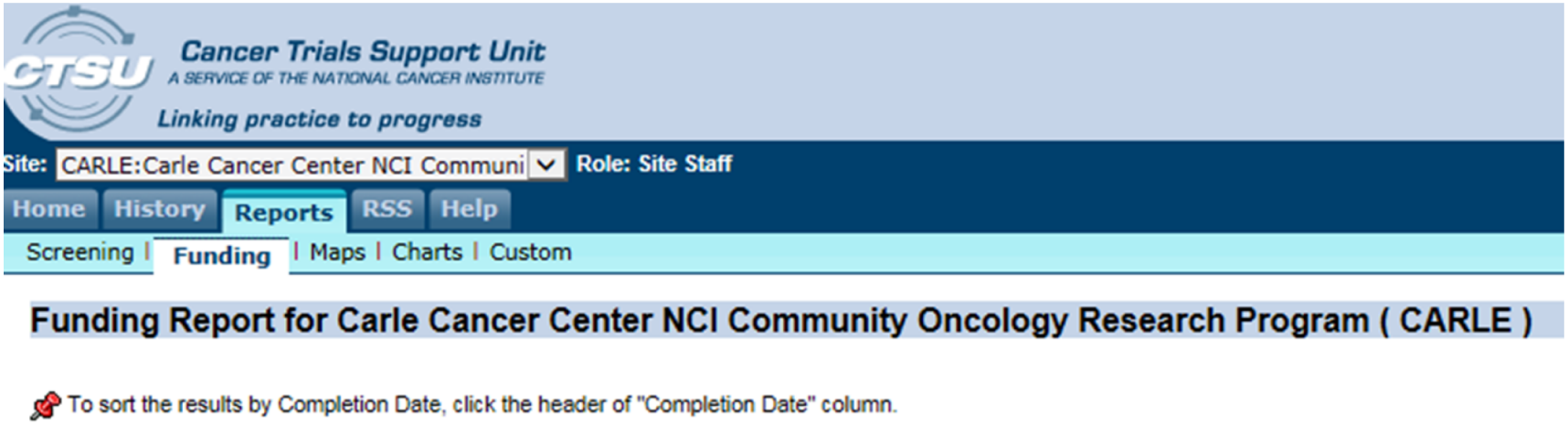
Open Reports - Funding



Go to OPEN - Reports/Funding tab

- If you have a registration selected back on the History tab, this report will show all ancillary credits possible for that site.
- Shows completion dates (from the dates entered into OPEN)

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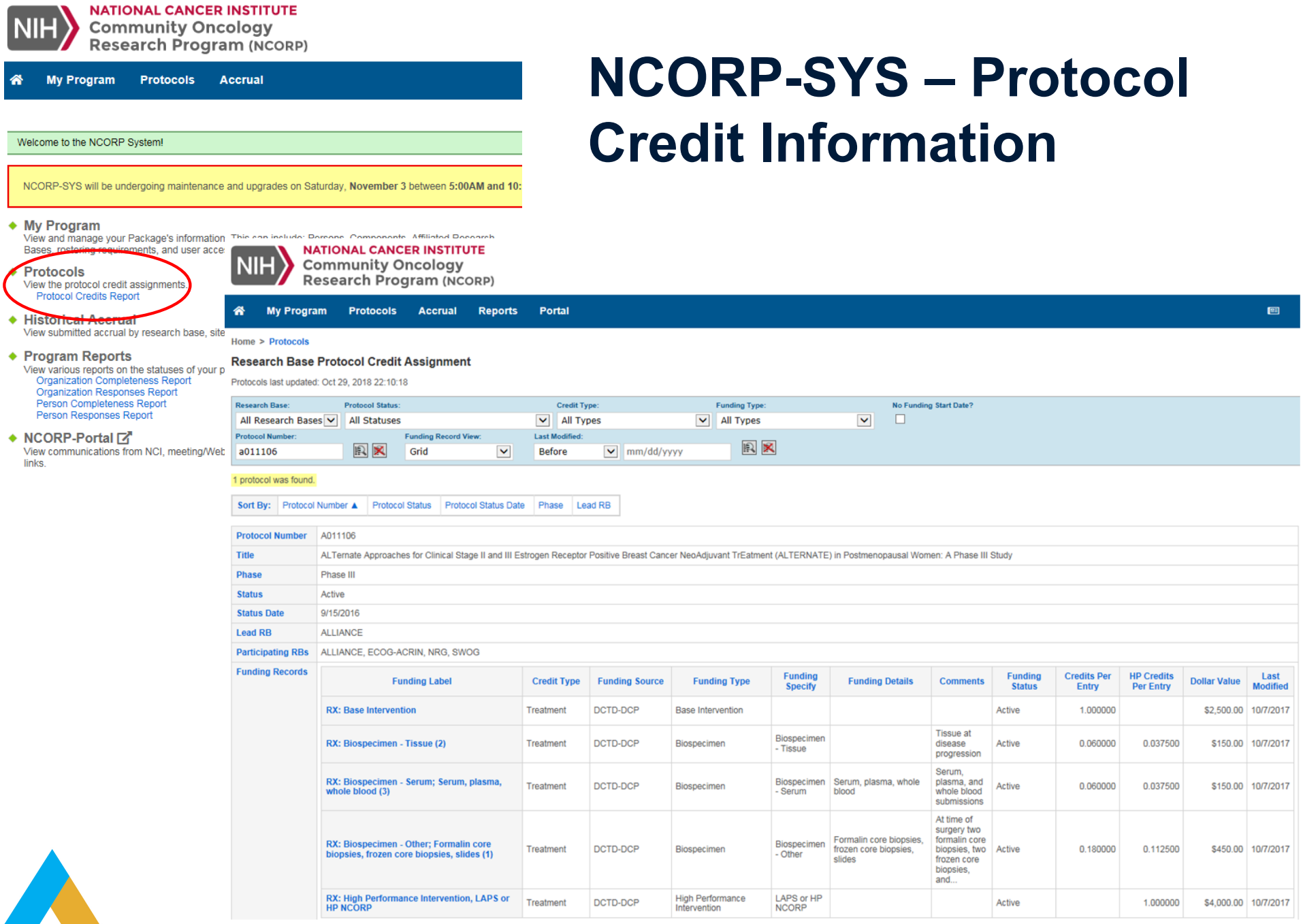
NCORP-SYS – Protocol Credit Information



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Got it?

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Wait, there's more!

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Regulatory Credentialing Repository (RCR)

- Replaces old paper Investigator packet
- electronic submission of NCI registration documents for NCI-sponsored clinical trials
- meets FDA regulatory requirements for annual registration to allow investigators to quickly participate on research trials, increase efficiency and lower the cost of conducting clinical trials

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Biomarker Resources
Cancer/Clinical Trial Information
Cancer Trials Support Unit (CTSU)
Career Development Opportunities
Childhood Cancer Resources
CIRB/Study Participant Protections
Conflict of Interest Policy
Funding Links
Funding Opportunities
Investigator's Handbook
Registration and Credential Repository
Research Organizations

CTEP Branches and Offices

Clinical Investigations Branch
Clinical Trials Monitoring Branch
Clinical Trials Operations and Informatics Branch
Investigational Drug Branch
Pharmaceutical Management Branch
Regulatory Affairs Branch

Last Updated: 09/08/17

NCI Registration and Credential Repository (RCR)

Food and Drug Administration (FDA) regulations require IND sponsors to select qualified investigators. NCI policy requires all persons participating in any NCI-sponsored clinical trial to register and renew their registration annually.

Registration is accomplished via the NCI **Registration and Credential Repository (RCR).**

RCR utilizes FIVE person registration types.

- **Investigator (IVR)** — MD, DO, or international equivalent
- **Non-Physician Investigator (NPIVR)** — advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD)
- **Associate Plus (AP)** — clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications (e.g., RUMS, OPEN, RAVE, TRIAD)
- **Associate (A)** — other clinical site staff involved in the conduct of NCI-sponsored trials
- **Associate Basic (AB)** — individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems

RCR requires the following registration documents:

Documentation Required	IVR	NPIVR	AP	A	AB
FDA Form 1572	✓	✓			
Financial Disclosure Form	✓	✓	✓		
NCI Biosketch (education, training, employment, license, and certification)	✓	✓	✓		
HSP/GCP training	✓	✓	✓		
Agent Shipment Form (if applicable)	✓				
CV (optional)	✓	✓	✓		

Delegation of Task Log (DTL)

- FDA Guidance documents
  - Statement of Investigator (FDA 1572 FAQ)
  - Investigator responsibilities
- 21 CFR 312.53 - selection of investigators

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What's on the DTL

- Online application within the CTSU website that is used to delegate tasks at the protocol and site level
- Identify Clinical Investigator (CI) for each protocol
- Complete list of study team for the protocol at the site
- Record study-specific responsibilities
- Verify qualifications of study personnel
- Record of protocol-specific training (if applicable)

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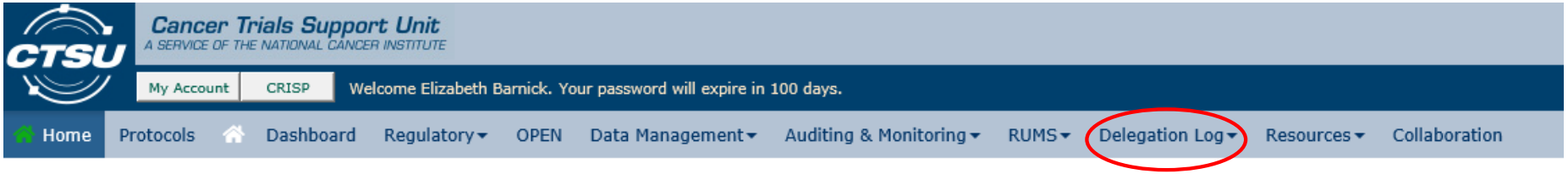
Where can you find the DTL?



Site: All User Sites | LPO: All user LPOs | Protocol: All viewable pro... | Protocol Status: All Protocol Statuses | DTL Status: All DTL Statuses | Go

1 42

#	Site	LPO	Protocol	Protocol Status	Template Revision	DTL Status	Status Reason	Last CI Approval Date
1	IN198	SWOG	S1418	Active	21-May-2018 02:08 PM	Approved		31-Oct-2018
2	IN194	SWOG	S1418	Active	21-May-2018 02:08 PM	Approved		31-Oct-2018
3	IL393	ECOG-ACRIN	EA8143	Active	24-Jan-2018 12:39 PM	Approved		13-Apr-2018
4	IL235	ECOG-ACRIN	EA8143	Active	24-Jan-2018 12:39 PM	Approved		13-Apr-2018
5	IL406	ECOG-ACRIN	EA8143	Active	24-Jan-2018 12:39 PM	Approved		13-Apr-2018
6	IL405	ECOG-ACRIN	EA8143	Active	24-Jan-2018 12:39 PM	Approved		13-Apr-2018
7	IL168	ECOG-ACRIN	EA8143	Active	24-Jan-2018 12:39 PM	Approved		13-Apr-2018
8	IL168	ALLIANCE	A021602	Active	22-May-2018 04:23 PM	Initiated		
9	IL235	ALLIANCE	A021502	Active	03-Nov-2017 02:42 PM	Retired	Template associated with this DTL is Retired.	13-Apr-2018
10	IL406	ALLIANCE	A021502	Active	03-Nov-2017 02:42 PM	Retired	Template associated with this DTL is Retired.	13-Apr-2018
11	IL168	ECOG-ACRIN	EA5142	Active	21-Feb-2018 11:07 AM	Approved		26-Sep-2018
12	IN183	ALLIANCE	A021502	Active	17-Jul-2018 10:08 AM	Initiated	Some Required tasks are not Active.	
13	IL168	NRG	NRG-HN004	Temporarily Closed to Accrual	30-Oct-2017 01:27 PM	Approved		06-Apr-2018
14	IL393	SWOG	S1418	Active	02-Feb-2018 09:25 AM	Retiring		16-Apr-2018
15	IL235	SWOG	S1418	Active	02-Feb-2018 09:25 AM	Retiring		16-Apr-2018
16	IL406	SWOG	S1418	Active	02-Feb-2018 09:25 AM	Retiring		16-Apr-2018
17	IL405	SWOG	S1418	Active	02-Feb-2018 09:25 AM	Retiring		16-Apr-2018
18	IL406	ALLIANCE	A021502	Active	17-Jul-2018 10:08 AM	Awaiting CI Approval		
19	IL235	ALLIANCE	A021502	Active	17-Jul-2018 10:08 AM	Awaiting CI Approval		

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NCORP Site Workflow

- Site staff pre-populate all documents
- Schedule time to sit with investigator
  - Office visit
  - Before/after patients
  - At a standing research meeting
- With the help of a research coordinator or research regulatory staff, investigator logs in and signs required documents

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Academic Site Workflow

- Two Registration Coordinators Assigned to each physician
  - Each week, sort physicians by Registration Expiration Date and check to see who is coming due soon, update their RCR and schedule a meeting to have them sign their FDF and submit.
- Advantage: Registration Coordinator completing all RCRs ensures all MDs include appropriate site code information for DTL purposes

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DTL

- How do you manage your DTLs?
- How do you use the cloning feature?
- How do you ensure your PI signs off on the DTL?
- How frequently are DTLs updated and signed?

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Alliance Resources for New Coordinator Training

- Email about training materials

Alliance Lead CRPs,

You are receiving this email because you have been identified as the Alliance Lead CRP at your site. My name is Jen Dill and I serve as the Alliance Clinical Research Professionals Committee (CRP) Chair.

Alliance has been working to bring together training and educational materials sites can use to supplement Alliance staff training. We understand how busy your schedule is and that especially if you are short staffed, providing adequate training for new hires or CRPs new to Alliance protocols can be challenging. In order to provide training materials for your staff in situations where you can't sit down with them and train them one on one, we have developed some material you can use to supplement training if it is helpful for your site or your affiliate sites.

In addition to the training email, the Alliance CRP Resources page on the Alliance website has been revamped to find training materials easier and to provide presentations from the Alliance group meetings for those unable to attend the group meeting. This way, Alliance CRPs unable to attend group meetings are still able to receive the information and education provided at the group meeting. Following this email, I will send a second email with the training information. Feel free to use the information in that email as best fits into your site training plan. The email was designed so that you could simply forward the email along to new staff for self-guided training for those times when those responsible for training are unable to focus on training right away. The email will be updated and sent out to Alliance Lead CRAs periodically with the intent that you can have some training materials easily available to help get your Alliance staff trained and oriented to Alliance protocols. Our intention is to help you at your site, so if you have suggestions, please send them my way! We want to be a support to you and the hard work you and your staff do on behalf of Alliance trials.

Thanks,
Jen

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New Coordinator Training

- Email to forward to new CRPs at your site
- Contains:
  - CRP Handbook
  - General Stage of Treatment Summary
  - Alliance Website Training
  - Alliance CRP Orientation
  - Resources for Clinical Research Professionals
  - Glossary of Abbreviations, Acronyms and Terminology

ALLIANCE
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CRP Handbook

Table of Contents

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General Stages of Treatment

- ***Neoadjuvant Therapy:*** Treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy. It is a type of induction therapy.

- ***Adjuvant Therapy:*** Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.

- ***Induction Therapy:*** The first treatment given for a disease. It is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation. When used by itself, induction therapy is the one accepted as the best treatment. If it doesn't cure the disease or it causes severe side effects, other treatment may be added or used instead. Also called first-line therapy, primary therapy, and primary treatment.

- ***Consolidation Therapy:*** Treatment that is given after cancer has disappeared following the initial therapy. Consolidation therapy is used to kill any cancer cells that may be left in the body. It may include radiation therapy, a stem cell transplant, or treatment with drugs that kill cancer cells. Also called intensification therapy and post-remission therapy.

- ***Maintenance Therapy:*** Treatment that is given to help keep cancer from coming back after it has disappeared following the initial therapy. It may include treatment with drugs, vaccines, or antibodies that kill cancer cells, and it may be given for a long time.

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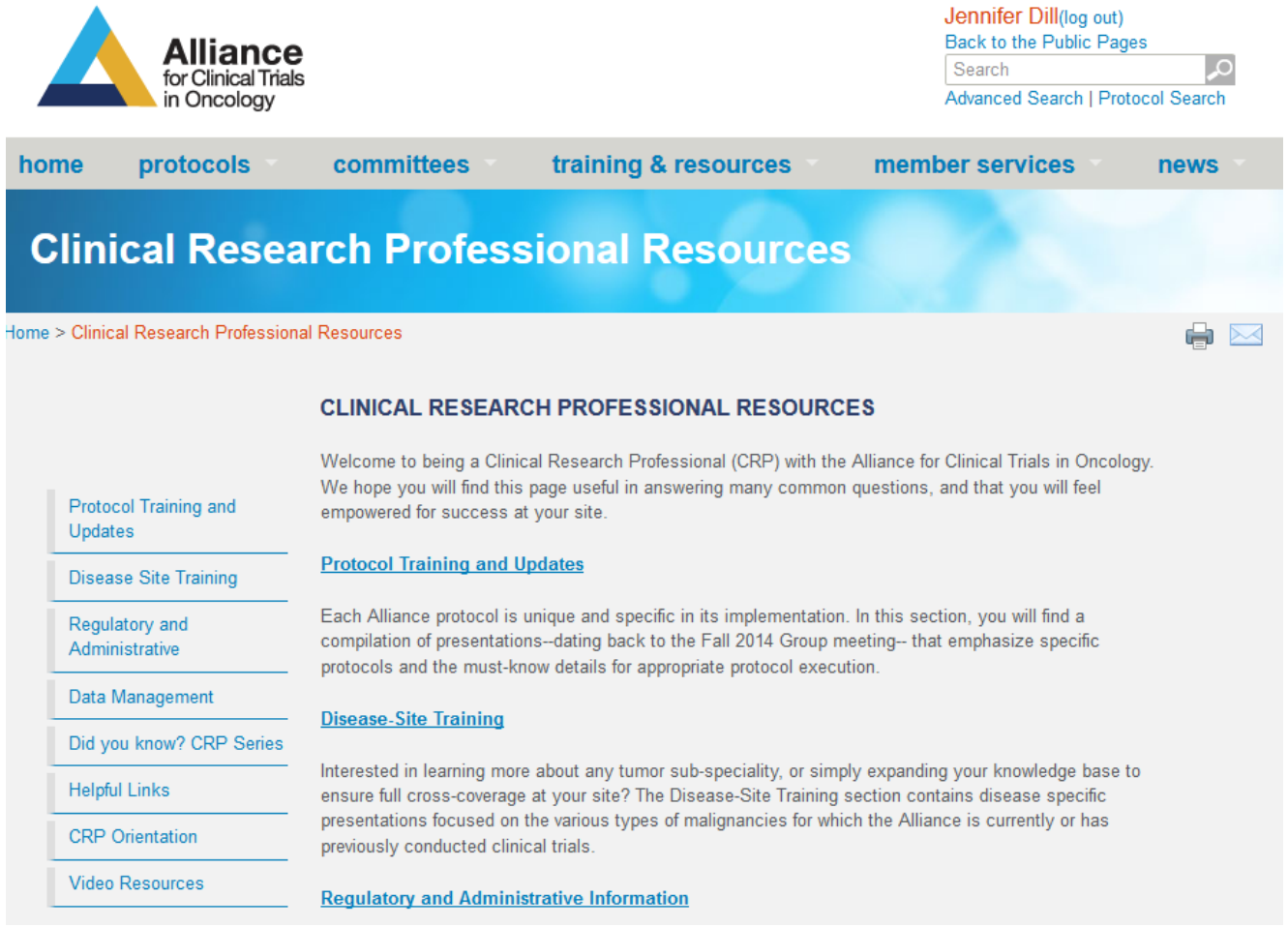
Alliance Website Resources



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Alliance Website Resources

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Alliance Website Resources

Protocol Training and Updates

Home > Clinical Research Professional Resources > Protocol Training and Updates

- Protocol Training and Updates
- Disease Site Training
- Regulatory and Administrative
- Data Management
- Did you know? CRP Series
- Helpful Links
- CRP Orientation
- Video Resources

PROTOCOL TRAINING AND UPDATES

Presentations

AFT	• CANVAS (Fall 2016)
Breast	• A011104 (Fall 2017) • A011203 (Spring 2016) • A011401 (Fall 2016) • A011502 (Spring 2017)
Cancer Control	• A221405 (Spring 2016) • A221208 (Fall 2017)

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Alliance Website Resources

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Staff Training

- Really Important – Don’t eat your young
- Consider a designated trainer if possible
- Incorporate your staff
  - There are different ways of doing things
  - Helps staff get to know one another
  - Distributes the time and effort
- Plan for prolonged training period
- Consider checklist with competencies and milestones

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Benefits

- More confident staff
- More competent staff
- Higher retention
- Improved quality and quantity
- Happier patients
- Happier co-workers
- Happier PI

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Training checklist

Name:_____

Job Title: Clinical Research Coordinator

Preceptor Names	Initials

To be completed by preceptor.

- Date and initial with the appropriate rating in the scale to show progress in meeting evaluation criteria.
- Add additional information and comments as needed to clarify all teaching provided and progress noted.
- Show verification method in "methods" column next to each evaluation criteria
- **Please review this documentation by the end of each orientation day. Current status should be evident at all times.**
- An evaluation of "Competent" must be achieved during the orientation process. The orientee must show independence in **all** evaluation criteria listed.

Verification Method	Rating Scale for Evaluation Progress
V = Verbalization O = Observation C/T = Completion of Class/Test	**Does Not Meet Expectations (DNM)** = Insufficient evidence of basic competence. **specify deficits in comments section.* **Novice (N)** = No experience or background with the skill; needs structure & specific guidelines for performance

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Training checklist

Competency	Instruction Options/References	Evaluation Criteria	Methods	Scale
Effectively navigates the sections of a typical research protocol • Research phases • Cover Page/Contact Information • Background • Rationale • Endpoints/objectives • Schema • Subject eligibility • Strat factors/ Descriptive factors • Treatment/study plan • Dose Mods/ Supportive Care • Adverse event reporting, if any • Response Evaluation • Drug Information	• Review Phase I-IV definitions • Types of therapeutic trials (adjuvant, neoadjuvant, refractory, relapse, metastatic, etc) • Types of chart review and registry studies (retrospective and prospective) • Review various types of protocols (sponsored, NCI, investigator-initiated, etc) and identify similarities and differences • Review the Carle protocol template • Explain how to read a schema (pre-reg, induction, maintenance, arms, cycles, restaging timepoints) • Determine which drugs are provided and not provided • Assess if drug delivery by	**Verify knowledge/ability:** • Identifies likely endpoints of each phase of study • Identifies the key elements of research protocols • Navigates various protocol types to accurately enroll and maintain subjects in trials • Can explain difference between Registration and Randomization; blinded, double blinded, unblended. • Navigates Staging book appropriately • Can determine whether kits need to be ordered and how or whether they need to be made locally		DNM | N | AB | C | P | E **Comments**

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QUESTIONS?