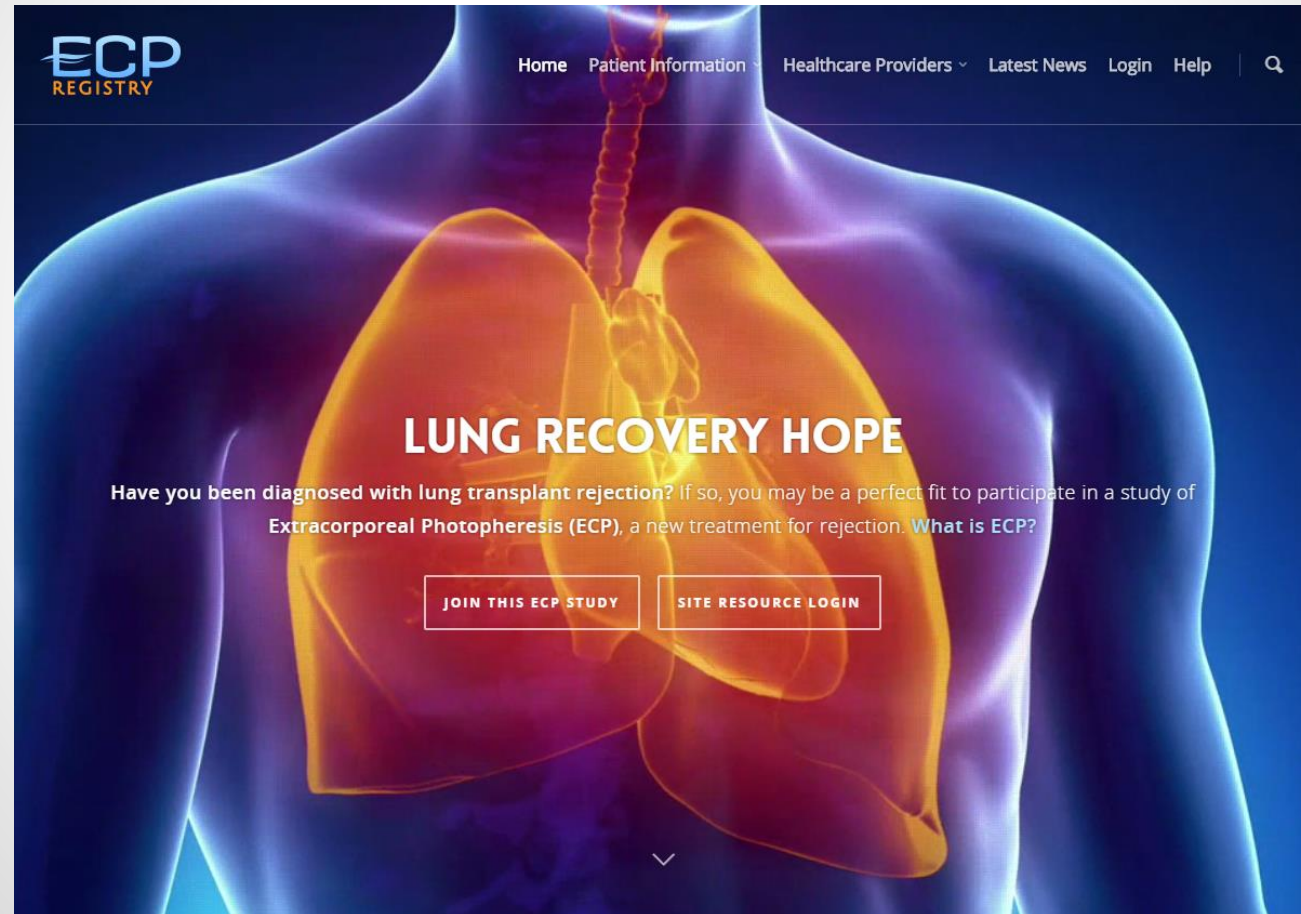


Welcome to the Baseline CRF Training Presentation

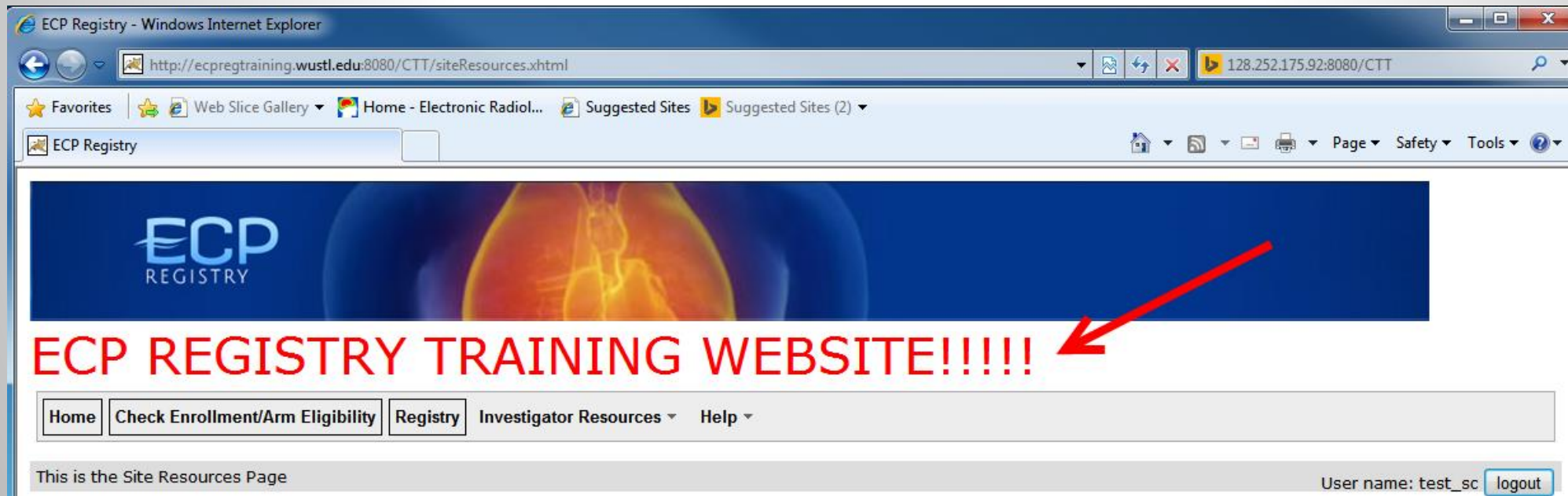


Introduction

- This training presentation provides the staff at ECP-BOS enrollment sites with the process for completing a Baseline Case Report Form (CRF) using the ECP Registry.
- Log in to the ECP Registry training Secure Website <http://ecpregtraining.wustl.edu/wordpress>

Site Resources Page

- Following login, the ECP Training Site Resources Page displays.
- “Training Website” displays across the top of the page in Big Red Letters: **ECP REGISTRY TRAINING WEBSITE**



Baseline Therapy CRF Information

- The Baseline Therapy CRF is one of the CRFs created for both the ECP Treatment and Observational Arm participants after the Confirmation of Eligibility (**COE**) CRF is **DCC VERIFIED**.
- This CRF collects medication data concerning the participant's baseline therapy.
- A Medication Record (or a Clinical note) source document listing the participant's medications is used to fill out this CRF.
- The Medication Record is the only required source document that will be scanned and uploaded to this CRF.

How to locate the participant's Baseline Therapy CRF

1. Click the [Registry](#) button to be directed to your **Site Summary** page.



2. For training purpose, **Participant ID 100003** at **Test Site 100** will be used as an example.

How to locate the participant's Baseline Therapy CRF continued

3. On the **Site Summary** page, locate the assigned **Participate ID** and click the [View](#) button to be directed to the **Participant Summary** page.
4. Notice this participant is in the ECP Treatment Arm and 36 New CRFs were created after the **COE** CRF was DCC VERIFIED.

ECP
REGISTRY

ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ECP Reports Help


User name: test_tc [logout](#)

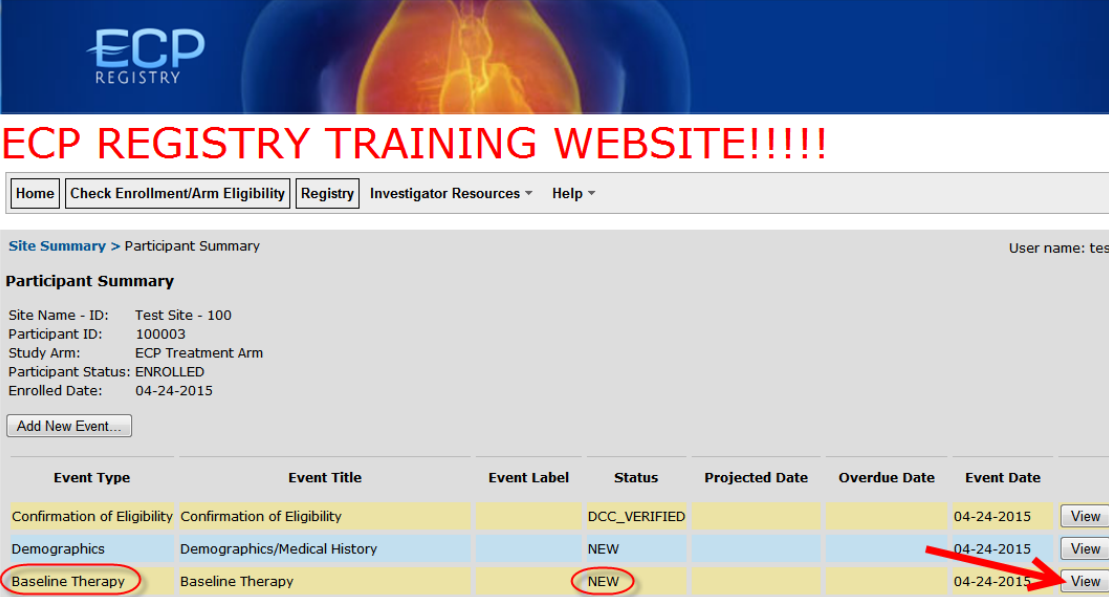
Site Summary

Site Name - ID: Test Site - 100

Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100002	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100003	04-24-2015	ECP Treatment Arm	ENROLLED	36	0	0	0	1	0	0	View

How to locate the participant's Baseline Therapy CRF continued

5. The **Participant Summary** page is displayed with all 36 New CRFs.
6. Locate the **Baseline Therapy** Event Type.
7. Notice the **Baseline Therapy** event **Status** column reads **NEW**, because the CRF has not been started or submitted.
8. Click the  button to be directed to the participant's **Event Summary** page.



ECP REGISTRY TRAINING WEBSITE!!!!




Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary User name: test


Participant Summary

Site Name - ID: Test Site - 100
Participant ID: 100003
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 04-24-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-24-2015	
Demographics	Demographics/Medical History		NEW			04-24-2015	
Baseline Therapy	Baseline Therapy		NEW			04-24-2015	

How to locate the participant's Baseline Therapy CRF continued

9. The **Event Summary** page displays with the **Baseline Therapy** Form listed.
10. Click  button to be directed to the **Baseline Therapy CRF**.



The screenshot shows the ECP Registry Training Website. At the top is a blue banner with the ECP Registry logo and a heart image. Below the banner is a red text overlay: "ECP REGISTRY TRAINING WEBSITE!!!!". A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. Below the navigation bar is a breadcrumb trail: Site Summary > Participant Summary > Event Summary. The main content area is titled "Event Summary" and displays participant and event details in two columns. A table below lists the forms, with a red arrow pointing to the "View" button for the "Baseline Therapy" form.

ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary > Event Summary

Event Summary

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy
Participant ID:	100003	Event Title:	Baseline Therapy
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	04-24-2015	Event Date:	04-24-2015

Form Type	Form Title	Status	Date	
Baseline Therapy	Baseline Therapy Form	NEW	04-24-2015	

Baseline Therapy CRF Example

- The **Baseline Therapy** CRF displays.
- Note all forms on the training website have bright red banners to distinguish from the ECP Registry website.

ECP REGISTRY TRAINING WEBSITE!!!!

Home | Check Enrollment/Arm Eligibility | Registry | Investigator Resources | Help

Site Summary > Participant Summary > Event Summary > Baseline Therapy Form

User name: test_sc | Logout

Form Summary

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy	Form Type:	Baseline Therapy
Participant ID:	100003	Event Title:	Baseline Therapy	Form Title:	Baseline Therapy Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	04-24-2015

Extracorporeal Photophoresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

BASELINE THERAPY - Case Report Form (CRF)

Baseline Therapy

Please include the following types of source documents:

1. Clinical Note or Medication Record Form

Source Document Type	Document Name	Submission Date
Select Source Document Type	Clinical Note or Medication Record Form	
Attach Source Document:	Browse...	Upload
Save	Submit	

Baseline Therapy Date: 04-24-2015

1. Check all immunosuppressive drugs that are currently being used by the participant:

<input type="radio"/> YES	<input type="radio"/> NO	Tacrolimus	
<input type="radio"/> YES	<input type="radio"/> NO	Prednisone	If yes, enter daily dose: <input type="text"/> mg (input range: 0-150)
<input type="radio"/> YES	<input type="radio"/> NO	Sirolimus (Rapamycin)	
<input type="radio"/> YES	<input type="radio"/> NO	Everolimus	
<input type="radio"/> YES	<input type="radio"/> NO	Azathioprine	
<input type="radio"/> YES	<input type="radio"/> NO	Cyclosporine A	
<input type="radio"/> YES	<input type="radio"/> NO	Methotrexate	
<input type="radio"/> YES	<input type="radio"/> NO	Macrolide Antibiotic, Azithromycin	
<input type="radio"/> YES	<input type="radio"/> NO	Mycophenolate Mofetil (Cellcept or Myfortic)	
<input type="radio"/> YES	<input type="radio"/> NO	Total Lymphoid Irradiation	

2. Is the participant taking an anticoagulant drug? ☐ YES ☐ NO

If yes, list drugs:

Name anticoagulant 1:

Name anticoagulant 2:

Name anticoagulant 3:

3. Is the participant taking an anti-platelet drug? ☐ YES ☐ NO

If yes, list drugs:

Name anti-platelet 1:

Name anti-platelet 2:

Name anti-platelet 3:

4. Comments:

Save Submit

Completing the Baseline Therapy CRF

1. The **Baseline Therapy Date** is automatically populated by the system on this CRF with the same date as the **COE CRF**.



The screenshot displays the ECP Registry Training Website interface. At the top, there is a blue header with the ECP Registry logo and a background image of a human torso with a glowing heart. Below the header, a red banner reads "ECP REGISTRY TRAINING WEBSITE!!!!". A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The main content area shows a breadcrumb trail: Site Summary > Participant Summary > Event Summary > Baseline Therapy Form. Under the "Form Summary" section, a table lists details: Site Name - ID: Test Site - 100, Participant ID: 100003, Study Arm: ECP Treatment Arm, Participant Status: ENROLLED, Enrolled Date: 04-24-2015, Event Type: Baseline Therapy, Event Title: Baseline Therapy, Event Label: Baseline Therapy, Event Status: NEW, Event Date: 04-24-2015, Form Type: Baseline Therapy, Form Title: Baseline Therapy Form, Form Status: NEW, and Form Date: 04-24-2015. A red box highlights the study title: "Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts" and the form title: "BASELINE THERAPY - Case Report Form (CRF)". Below this, it says "Baseline Therapy". A section titled "Please include the following types of source documents:" lists "1. Clinical Note or Medication Record Form". A table with columns "Source Document Type", "Document Name", and "Submission Date" is shown. The "Source Document Type" is set to "Clinical Note or Medication Record Form". Below the table, there are fields for "Attach Source Document:" with a "Browse..." button and an "Upload" button. At the bottom, there are "Save" and "Submit" buttons. A red arrow points to the "Baseline Therapy Date:" field, which is populated with "04/24/2015".

ECP REGISTRY TRAINING WEBSITE!!!!

Home | Check Enrollment/Arm Eligibility | Registry | Investigator Resources | Help

Site Summary > Participant Summary > Event Summary > Baseline Therapy Form

Form Summary

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy	Form Type:	Baseline Therapy
Participant ID:	100003	Event Title:	Baseline Therapy	Form Title:	Baseline Therapy Form
Study Arm:	ECP Treatment Arm	Event Label:	Baseline Therapy		
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	04-24-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

BASELINE THERAPY - Case Report Form (CRF)

Baseline Therapy

Please include the following types of source documents:

1. Clinical Note or Medication Record Form

Source Document Type	Document Name	Submission Date
Select Source Document Type	Clinical Note or Medication Record Form	

Attach Source Document:

Baseline Therapy Date: 04/24/2015

Completing the Baseline Therapy CRF continued

2. There are 3 questions and a comments box on this CRF.
3. Use the mouse to navigate and click the appropriate radio button to answer the questions and fill in the boxes as required.
4. For training purpose, enter the values shown in the example below.

The screenshot shows a web-based form titled "Baseline Therapy CRF". At the top, there are "Save" and "Submit" buttons. Below them is a green header bar with the text "Baseline Therapy Date: 04/24/2015". The form contains four numbered questions:

- 1. Check all immunosuppressive drugs that are currently being used by the participant:**
This question has a list of drugs with radio buttons for "YES" or "NO". The drugs listed are: Tacrolimus, Prednisone (with a sub-question "If yes, enter daily dose: [] mg (input range: 0-150)"), Sirolimus (Rapamycin), Everolimus, Azathioprine, Cyclosporine A, Methotrexate, Macrolide Antibiotic, Azithromycin, Mycophenolate Mofetil (Cellcept or Myfortic), and Total Lymphoid Irradiation. In the example, "YES" is selected for Tacrolimus, Prednisone, Sirolimus, Everolimus, Azathioprine, Cyclosporine A, Methotrexate, Macrolide Antibiotic, and Mycophenolate Mofetil. "NO" is selected for Total Lymphoid Irradiation.
- 2. Is the participant taking an anticoagulant drug?** ☒ YES ☐ NO
If yes, list drugs:
Name anticoagulant 1: coumadin
Name anticoagulant 2: []
Name anticoagulant 3: []
- 3. Is the participant taking an anti-platelet drug?** ☐ YES ☒ NO
If yes, list drugs:
Name anti-platelet 1: []
Name anti-platelet 2: []
Name anti-platelet 3: []
- 4. Comments:**
[]

At the bottom of the form, there are "Save" and "Submit" buttons.

Completing the Baseline Therapy CRF continued

5. If you wish to return to this document to complete it later, click **Save** button at either the top of or bottom of CRF.

The screenshot displays a web-based form titled "Baseline Therapy CRF". At the top, there is a green header bar with the text "Baseline Therapy Date: 04/24/2015". Below this, the form contains several sections of questions and input fields. The first section, "1. Check all immunosuppressive drugs that are currently being used by the participant:", lists various drugs with radio buttons for "YES" or "NO". The second section, "2. Is the participant taking an anticoagulant drug?", has a "YES" button selected and includes input fields for the names of anticoagulants. The third section, "3. Is the participant taking an anti-platelet drug?", has a "NO" button selected and includes input fields for the names of anti-platelet drugs. The fourth section, "4. Comments:", is a large text area. At the top left of the form, there is a "Save" button, and at the bottom left, there is another "Save" button. Red arrows point to both "Save" buttons, indicating where to click to save the document.

Save Submit

Baseline Therapy Date: 04/24/2015

1. Check all immunosuppressive drugs that are currently being used by the participant:

☒ YES ☐ NO Tacrolimus

☒ YES ☐ NO Prednisone If yes, enter daily dose: mg (input range: 0-150)

☐ YES ☒ NO Sirolimus (Rapamycin)

☐ YES ☒ NO Everolimus

☐ YES ☒ NO Azathioprine

☐ YES ☒ NO Cyclosporine A

☐ YES ☒ NO Methotrexate

☐ YES ☒ NO Macrolide Antibiotic, Azithromycin

☒ YES ☐ NO Mycophenolate Mofetil (Cellcept or Myfortic)

☐ YES ☒ NO Total Lymphoid Irradiation

2. Is the participant taking an anticoagulant drug? ☒ YES ☐ NO

If yes, list drugs:

Name anticoagulant 1: coumadin

Name anticoagulant 2:

Name anticoagulant 3:

3. Is the participant taking an anti-platelet drug? ☐ YES ☒ NO

If yes, list drugs:

Name anti-platelet 1:

Name anti-platelet 2:

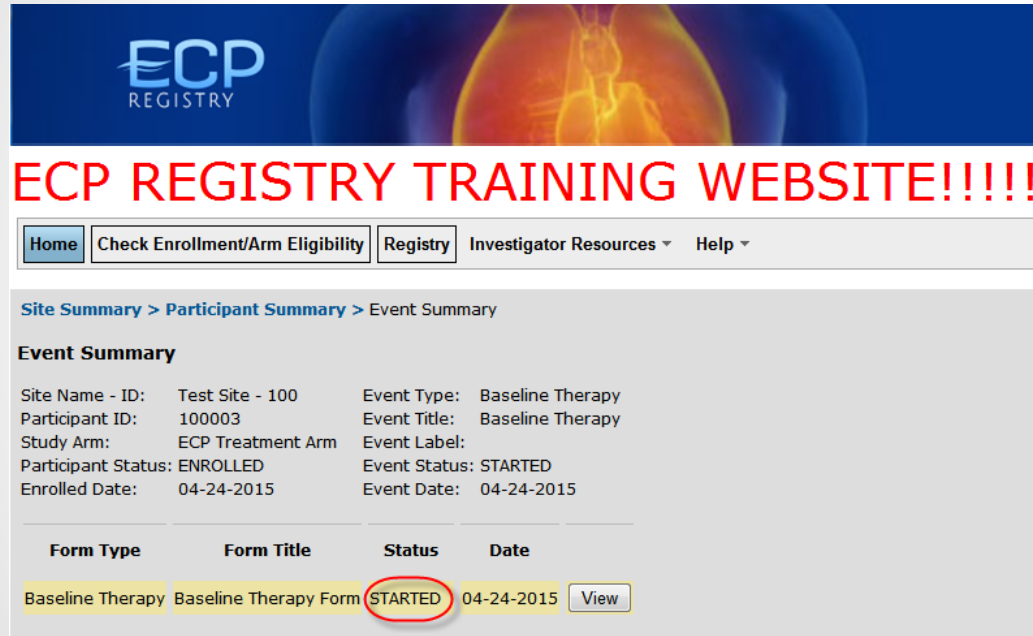
Name anti-platelet 3:

4. Comments:

Save Submit

Completing the Baseline Therapy CRF continued

- Once the **Save** button is clicked, the **Status** of the CRF will be changed to **Started**. You may then return to the document later and complete it or make changes.



The screenshot shows the ECP Registry Training Website interface. At the top, there is a blue header with the ECP Registry logo and a background image of a human torso. Below the header, the text "ECP REGISTRY TRAINING WEBSITE!!!!" is displayed in red. A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources, and Help. The main content area shows the breadcrumb "Site Summary > Participant Summary > Event Summary" and the title "Event Summary". Below this, there is a table of metadata:

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy
Participant ID:	100003	Event Title:	Baseline Therapy
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	STARTED
Enrolled Date:	04-24-2015	Event Date:	04-24-2015

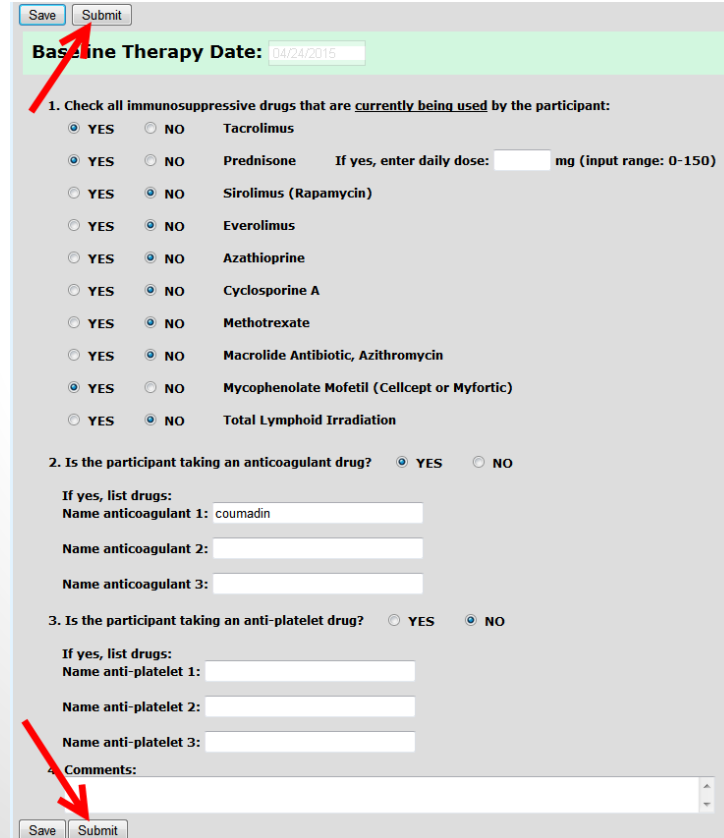
Below the metadata table is a table with four columns: Form Type, Form Title, Status, and Date. The first row shows "Baseline Therapy" for Form Type, "Baseline Therapy Form" for Form Title, "STARTED" for Status (circled in red), and "04-24-2015" for Date. A "View" button is located to the right of the Date column.

Form Type	Form Title	Status	Date
Baseline Therapy	Baseline Therapy Form	STARTED	04-24-2015

- Before submitting the CRF, scan and upload the required Medication Record source document. See slide #18 "Scan Source Documents into pdf Files" & slides #19-21 "Uploading PDF Files of Scanned Source Document".

Completing the Baseline Therapy CRF continued

8. Confirm that all data entered is accurate and that the required source document PDFs have been uploaded.
9. No changes can be made to this CRF once this **Submit** button is clicked.
10. Click the **Submit** button at either the top of or bottom of CRF.



The screenshot shows a web-based form titled "Baseline Therapy CRF". At the top, there are "Save" and "Submit" buttons. Below them is a green header bar with the text "Baseline Therapy Date: 04/24/2015". The main content area contains several sections of questions and input fields. A red arrow points to the "Submit" button at the top left. Another red arrow points to the "Submit" button at the bottom left. The form includes sections for checking immunosuppressive drugs, anticoagulant use, and anti-platelet use, each with "YES" and "NO" radio buttons and corresponding input fields for drug names and doses.

Save Submit

Baseline Therapy Date: 04/24/2015

1. Check all immunosuppressive drugs that are currently being used by the participant:

☒ YES ☐ NO Tacrolimus

☒ YES ☐ NO Prednisone If yes, enter daily dose: mg (input range: 0-150)

☐ YES ☒ NO Sirolimus (Rapamycin)

☐ YES ☒ NO Everolimus

☐ YES ☒ NO Azathioprine

☐ YES ☒ NO Cyclosporine A

☐ YES ☒ NO Methotrexate

☐ YES ☒ NO Macrolide Antibiotic, Azithromycin

☒ YES ☐ NO Mycophenolate Mofetil (Cellcept or Myfortic)

☐ YES ☒ NO Total Lymphoid Irradiation

2. Is the participant taking an anticoagulant drug? ☒ YES ☐ NO

If yes, list drugs:

Name anticoagulant 1: coumadin

Name anticoagulant 2:

Name anticoagulant 3:

3. Is the participant taking an anti-platelet drug? ☐ YES ☒ NO

If yes, list drugs:

Name anti-platelet 1:

Name anti-platelet 2:

Name anti-platelet 3:

4. Comments:

Save Submit

Completing the Baseline Therapy CRF continued

11. If the CRF is incomplete or contains values out of range, the submission will not be accepted.
12. The document will display error messages in red to prompt you to correct or enter the values.

2. Is the participant taking an anticoagulant drug? ☐ YES ☐ NO

If yes, list drugs:

Name anticoagulant 1:

Name anticoagulant 2:

Name anticoagulant 3:

☒ Please enter anticoagulant.

3. Is the participant taking an anti-platelet drug? ☐ YES ☐ NO

If yes, list drugs:

Name anti-platelet 1:

Name anti-platelet 2:

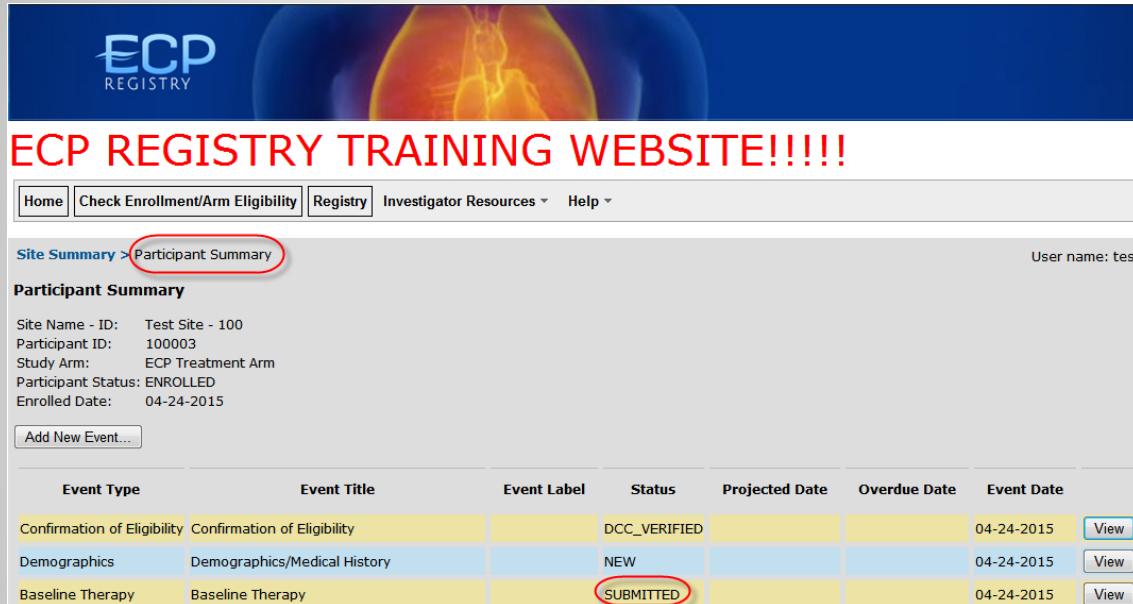
Name anti-platelet 3:

☒ Please enter anti-platelet.

13. Complete and/or fix the out of range values and click the **Submit** button again.
14. After submitting the CRF, you are directed back to the **Participant Summary** page.

Completing the Baseline Therapy CRF continued

15. The **Status** of the CRF will be changed to **Submitted** on the **Participant Summary** page and the **Event Summary** page.



ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary User name: test

Participant Summary

Site Name - ID: Test Site - 100
Participant ID: 100003
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 04-24-2015

Add New Event...

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date
Confirmation of Eligibility	Confirmation of Eligibility		DCC_VERIFIED			04-24-2015 View
Demographics	Demographics/Medical History		NEW			04-24-2015 View
Baseline Therapy	Baseline Therapy		SUBMITTED			04-24-2015 View



ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary > Event Summary

Event Summary

Site Name - ID: Test Site - 100
Participant ID: 100003
Study Arm: ECP Treatment Arm
Participant Status: ENROLLED
Enrolled Date: 04-24-2015

Event Type: Baseline Therapy
Event Title: Baseline Therapy
Event Label:
Event Status: SUBMITTED
Event Date: 04-24-2015

Form Type	Form Title	Status	Date
Baseline Therapy	Baseline Therapy Form	SUBMITTED	04-24-2015 View

16. After the CRF has been submitted, the DCC Staff may need to communicate with you using a CRF Data Verification process if data entry errors are found. Once the CRF is error free, the **Status** of the CRF is changed to **DCC VERIFIED**. See Data Verification slides #25-28 for more information.

Completing the Baseline Therapy CRF continued

Notice now that this CRF has been submitted, your **Site Summary** page displays for **Participant ID 100003** at **Test Site 100**:

- 35 **NEW** CRFs (still to do)
- 1 **Submitted** CRF (the Baseline Therapy just submitted)
- 1 **DCC Verified** (the COE CRF)



ECP
REGISTRY

ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾ Help ▾

Site Summary User name: test_sc logout

Site Name - ID: Test Site - 100

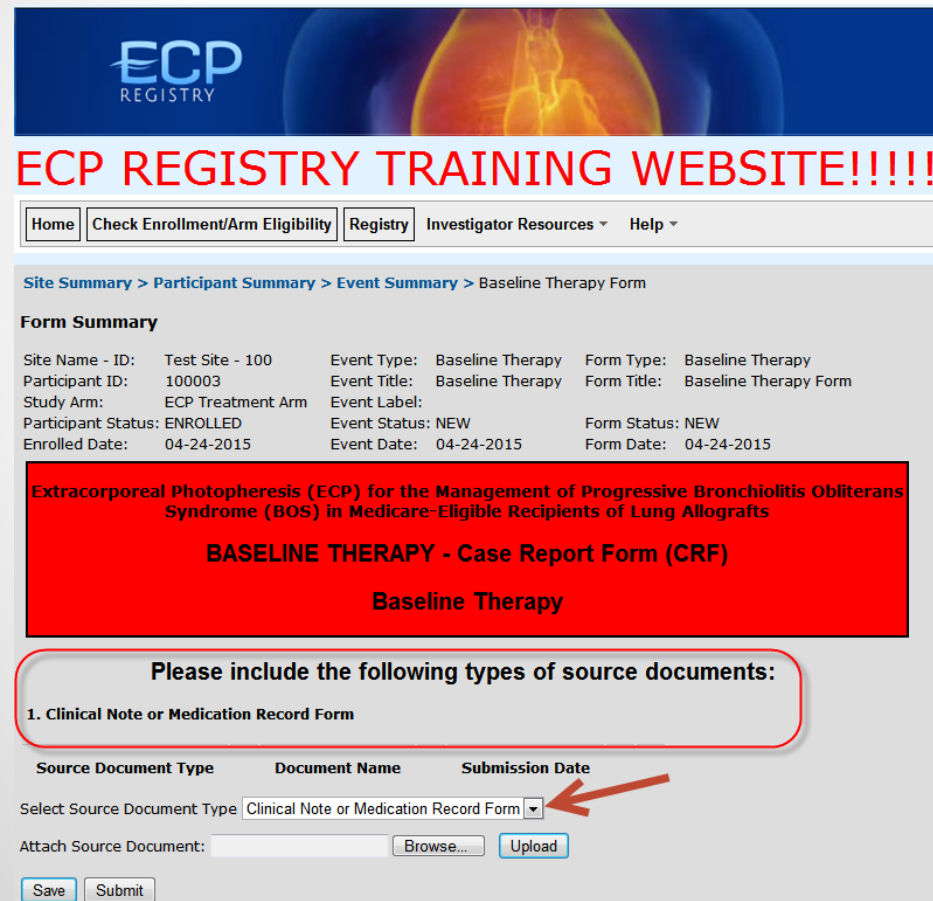
Participant ID	Enrolled Date	Study Arm	Status	New	Started	Submitted	CRF Query	DCC Verified	PI Approved	Not Required	
100001	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100002	04-20-2015	Observational Arm	ENROLLED	1	0	0	0	0	0	0	View
100003	04-24-2015	ECP Treatment Arm	ENROLLED	35	0	1	0	1	0	0	View

Scan Source Documents into pdf Files

- Source documents are required to support and verify subject data. The specific source documentation required is identified at the top of each CRF.
- To scan source documents into pdf format:
 - Copy the source document(s).
 - **Remove all personal identifiers on the source documents including name, date of birth, account or hospital number with a sharpie or china marker.**
 - **All de-identified source documents must include an ECP source document label available on the ECP Registry website <http://ecpregistry.wustl.edu> located under INVESTIGATOR RESOURCES drop down menu.**
 - Scan de-identified documents.
 - Save as a pdf file using the suggested naming convention of MEDS_participantid#_mmddyyyy.pdf

Upload pdf Files of Scanned Source Documents

- A list of required source documents is provided on each CRF page and also listed in the **Select Source Document Type** drop down menu.



ECP
REGISTRY

ECP REGISTRY TRAINING WEBSITE!!!!

Home Check Enrollment/Arm Eligibility Registry Investigator Resources Help

Site Summary > Participant Summary > Event Summary > Baseline Therapy Form

Form Summary

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy	Form Type:	Baseline Therapy
Participant ID:	100003	Event Title:	Baseline Therapy	Form Title:	Baseline Therapy Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	NEW	Form Status:	NEW
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	04-24-2015

Extracorporeal Photopheresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

BASELINE THERAPY - Case Report Form (CRF)

Baseline Therapy

Please include the following types of source documents:

1. Clinical Note or Medication Record Form

Source Document Type	Document Name	Submission Date
Select Source Document Type	Clinical Note or Medication Record Form	

Attach Source Document:

Upload pdf Files of Scanned Source Documents

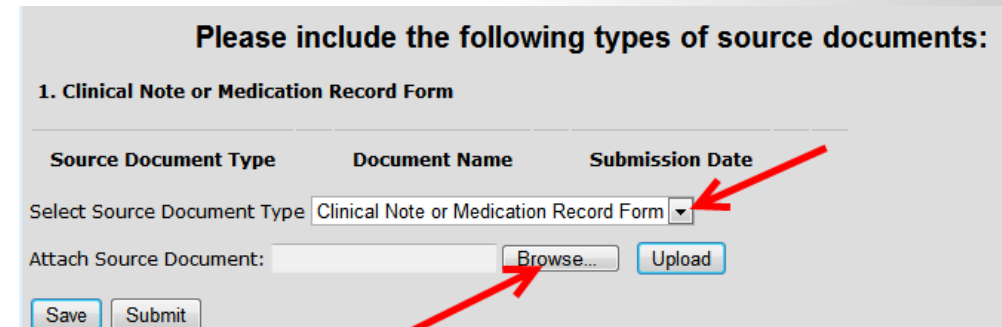
- If a source document has more than one page, only upload the page(s) that contain the data relevant for that specific CRF.
- Select the **Source Document Type** from the drop down menu for the pdf. Notice there is only one choice for the Baseline Therapy CRF.

- Click the **Browse** button.
- Locate the saved source document in pdf format and double click it.
- You will be directed back to the CRF page and the path to the pdf file displays next to the **Browse** button.
- Click the **Upload** button.

Please include the following types of source documents:

1. Clinical Note or Medication Record Form

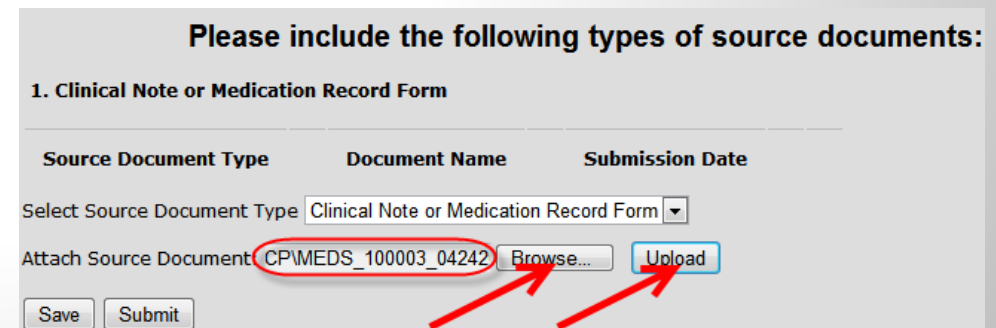
Source Document Type	Document Name	Submission Date
Select Source Document Type	Clinical Note or Medication Record Form	
Attach Source Document:	<input type="text"/>	<input type="button" value="Browse..."/> <input type="button" value="Upload"/>
<input type="button" value="Save"/> <input type="button" value="Submit"/>		



Please include the following types of source documents:

1. Clinical Note or Medication Record Form

Source Document Type	Document Name	Submission Date
Select Source Document Type	Clinical Note or Medication Record Form	
Attach Source Document:	CPWEDS_100003_04242	<input type="button" value="Browse..."/> <input type="button" value="Upload"/>
<input type="button" value="Save"/> <input type="button" value="Submit"/>		



Upload pdf Files of Scanned Source Documents

- Once uploaded, a highlighted entry displays for the source document with the name of the pdf.
- To confirm that the correct pdf has been uploaded, click the **View** button next to the highlighted entry.
- Click the **Delete** button next to the highlighted entry if it is the wrong pdf and re-upload the correct one.

Please include the following types of source documents:

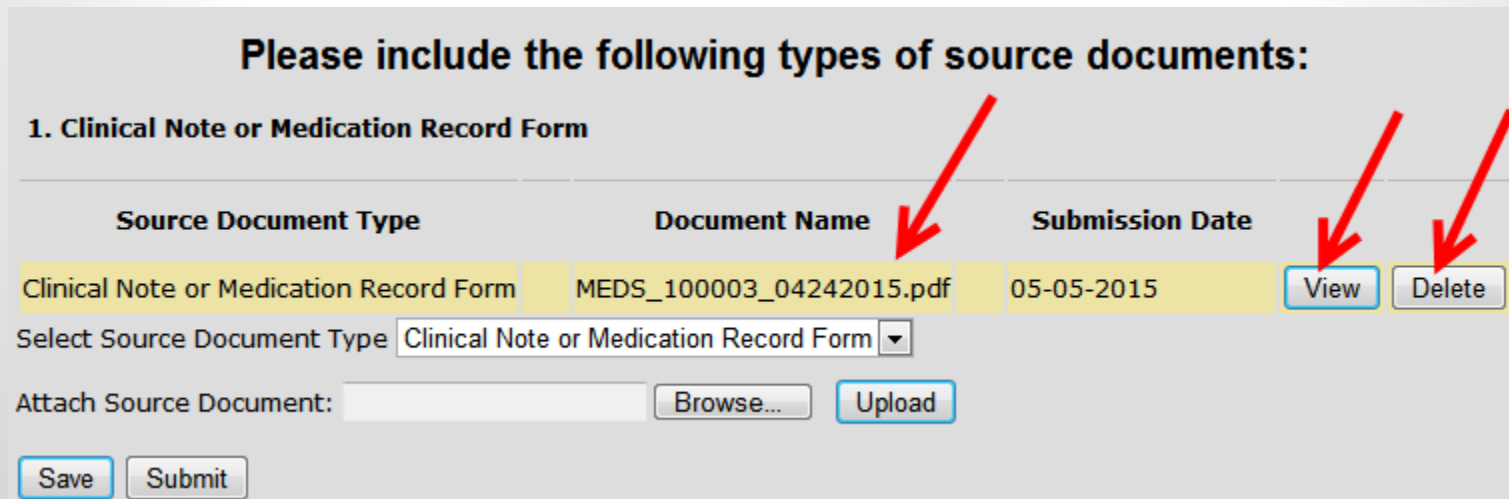
1. Clinical Note or Medication Record Form

Source Document Type	Document Name	Submission Date		
Clinical Note or Medication Record Form	MEDS_100003_04242015.pdf	05-05-2015	View	Delete



Select Source Document Type

Attach Source Document: [Browse...](#) [Upload](#)

[Save](#) [Submit](#)



Example of Baseline Therapy CRF with PDF Uploaded



ECP REGISTRY TRAINING WEBSITE!!!!

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[Site Summary](#) > [Participant Summary](#) > [Event Summary](#) > Baseline Therapy Form User name: test_sc [logout](#)

Form Summary

Site Name - ID:	Test Site - 100	Event Type:	Baseline Therapy	Form Type:	Baseline Therapy
Participant ID:	100003	Event Title:	Baseline Therapy	Form Title:	Baseline Therapy Form
Study Arm:	ECP Treatment Arm	Event Label:			
Participant Status:	ENROLLED	Event Status:	SUBMITTED	Form Status:	SUBMITTED
Enrolled Date:	04-24-2015	Event Date:	04-24-2015	Form Date:	04-29-2015

Extracorporeal Photophoresis (ECP) for the Management of Progressive Bronchiolitis Obliterans Syndrome (BOS) in Medicare-Eligible Recipients of Lung Allografts

BASELINE THERAPY - Case Report Form (CRF)

Baseline Therapy

Please include the following types of source documents:

1. Clinical Note or Medication Record Form

Source Document Type	Document Name	Submission Date	
Clinical Note or Medication Record Form	MEDS_100003_04242015.pdf	04-29-2015	View

Select Source Document Type: Clinical Note or Medication Record Form

Attach Source Document: [Browse...](#) [Upload](#)

Baseline Therapy Date:

1. Check all immunosuppressive drugs that are currently being used by the participant:

<input checked="" type="radio"/> YES	<input type="radio"/> NO	Tacrolimus	
<input checked="" type="radio"/> YES	<input type="radio"/> NO	Prednisone	If yes, enter daily dose: <input type="text"/> mg (input range: 0-150)
<input type="radio"/> YES	<input checked="" type="radio"/> NO	Sirolimus (Rapamycin)	
<input type="radio"/> YES	<input checked="" type="radio"/> NO	Everolimus	
<input type="radio"/> YES	<input checked="" type="radio"/> NO	Azathioprine	
<input type="radio"/> YES	<input checked="" type="radio"/> NO	Cyclosporine A	
<input type="radio"/> YES	<input checked="" type="radio"/> NO	Methotrexate	
<input type="radio"/> YES	<input checked="" type="radio"/> NO	Macrolide Antibiotic, Azithromycin	
<input checked="" type="radio"/> YES	<input type="radio"/> NO	Mycophenolate Mofetil (Cellcept or Myfortic)	
<input type="radio"/> YES	<input checked="" type="radio"/> NO	Total Lymphoid Irradiation	

2. Is the participant taking an anticoagulant drug? ☒ YES ☐ NO

If yes, list drugs:

Name anticoagulant 1:

Name anticoagulant 2:

Name anticoagulant 3:

3. Is the participant taking an anti-platelet drug? ☐ YES ☒ NO

If yes, list drugs:





Name anti-platelet 1:

Name anti-platelet 2:

Name anti-platelet 3:

4. Comments:

ECP Navigation

- If need to come back to a CRF, always click the  button at the top of the page to direct you to your **Site Summary** page.
- Click the  button next to the **Participant ID** to direct you to the **Participant Summary** page.
- Click the  button next to the **Event Type** of the CRF to direct you to the **Event Summary** page.
- Click the  button next to the **Form Type** of the CRF to direct you to the CRF page.

ECP Navigation

- Another way to navigate to the **Site Summary** page or the **Participant Summary** page, is to use the breadcrumb displayed at the top of the page. (See circled item in image below.) The **Site Summary** page and the **Participant Summary** page are in blue. These pages are linked to take you back at any time.
- Always **SAVE** your work before clicking on a bread crumb link.



The screenshot shows the ECP Registry Training Website interface. At the top is a blue header with the ECP Registry logo and a medical illustration. Below the header, the title "ECP REGISTRY TRAINING WEBSITE" is displayed in red. A navigation bar contains links: Home, Check Enrollment/Arm Eligibility, Registry, Investigator Resources (with a dropdown arrow), and Help. Below this, a breadcrumb trail "Site Summary > Participant Summary > Event Summary" is shown, with "Site Summary" and "Participant Summary" highlighted in blue and circled in red. The main content area is titled "Event Summary" and displays a table of event details. Below this is a table with columns for Form Type, Form Title, Status, and Date, containing one row of data and a "View" button.

ECP REGISTRY TRAINING WEBSITE

Home Check Enrollment/Arm Eligibility Registry Investigator Resources ▾ Help

[Site Summary](#) > [Participant Summary](#) > Event Summary

Event Summary

Site Name - ID:	Test Site - 100	Event Type:	Confirmation of Eligibility
Participant ID:	100001	Event Title:	Confirmation of Eligibility
Study Arm:	ECP Treatment Arm	Event Label:	
Participant Status:	ENROLLED	Event Status:	NEW
Enrolled Date:	04-03-2015	Event Date:	04-03-2015

Form Type	Form Title	Status	Date	
Confirmation of Eligibility	Confirmation of Eligibility Form	NEW	04-03-2015	View

Data Verification – DCC Staff

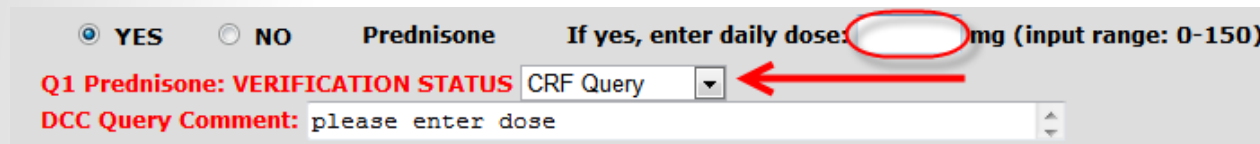
1. The Data Coordinating Center (DCC) is responsible for validating CRF data after it has been submitted.
2. When the status of a CRF becomes **SUBMITTED**, a technical coordinator from the DCC will examine the CRF's data and compare to the uploaded de-identified source documents.
3. For each data field to be evaluated, the technical coordinator will make one of three possible determinations.
 - DCC Verified – The data on the CRF matches the corresponding de-identified source document.
 - CRF Query – The data on the CRF does not match the corresponding de-identified source document.
 - Source Missing – The source document(s) are missing.

Data Verification – Site Coordinators

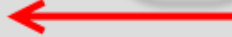
1. Site coordinators must monitor the status of their site's CRFs on the **Site Summary** page looking for Events that are listed as **CRF Query**.
2. CRF data fields with a status of **CRF Query** and **Source Missing** must be corrected and the CRF form re-submitted.
3. Follow steps 1 and 2 above until the status of each CRF is **DCC VERIFIED**.

Data Verification – examples from the CRF

- A CRF data field that is marked CRF Query will also have a comment explaining the nature of the discrepancy.

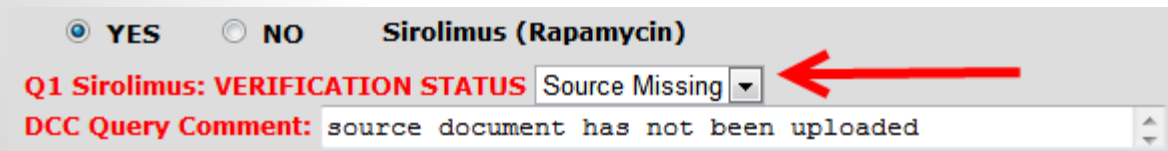


☒ YES ☐ NO **Prednisone** If yes, enter daily dose: mg (input range: 0-150)

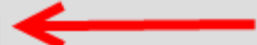
Q1 Prednisone: VERIFICATION STATUS CRF Query 

DCC Query Comment: please enter dose

- If a data field is marked Source Missing, the CRF does not have an uploaded source document to confirm the value in that field.



☒ YES ☐ NO **Sirolimus (Rapamycin)**

Q1 Sirolimus: VERIFICATION STATUS Source Missing 

DCC Query Comment: source document has not been uploaded

Data Verification – examples from the Site Summary page

- Example of an Event Status marked DCC Verified by the DCC staff.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Baseline Therapy	Baseline Therapy		DCC_VERIFIED			05-05-2015	View

- Example of an Event Status marked CRF Query by the DCC staff.

Note: if several data fields are marked either CRF Query and Source Missing, the Status will only display CRF Query.

Event Type	Event Title	Event Label	Status	Projected Date	Overdue Date	Event Date	
Baseline Therapy	Baseline Therapy		CRF_QUERY			05-05-2015	View

For Questions - DCC Contacts

Name	Role	Email	Phone
Joan Moulton	Technical Coordinator and Help Desk Manager	moultonj@mir.wustl.edu	314-362-7185
Mary Wolfsberger	Technical Coordinator and Help Desk Manager	wolfsbergerm@mir.wustl.edu	314-362-7194

Attestation Form

- Thank you for taking the time to review the ECP Registry Electronic Data Capture (EDC) system
- Please sign the Attestation Form located on the ECP website <http://ecpregistry.wustl.edu> under Help drop down menu.
- Keep the original in your ECP Registry Binder.
- Forward a copy to taylorlork@mir.wustl.edu