PowerTrials

Cerner Impact

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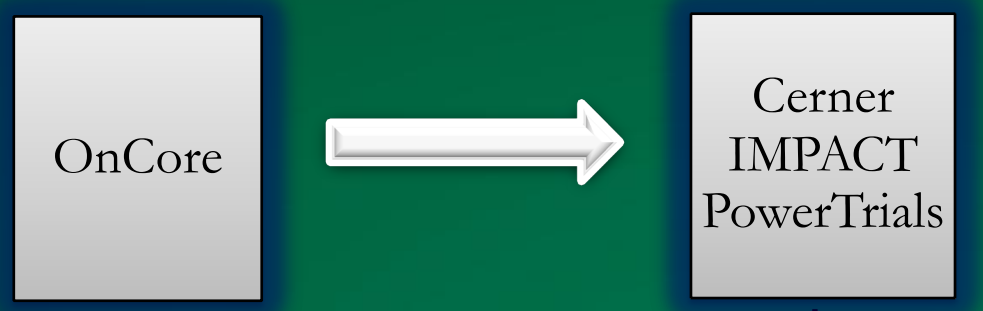
Project Overview



Research study built in OnCore

PowerChart

1. Banner Bar
2. Research Summary

Patient placed “on study” in banner bar, linked to research summary

Build & Test Research PowerPlans

PowerPlan built with the orderables required by the study

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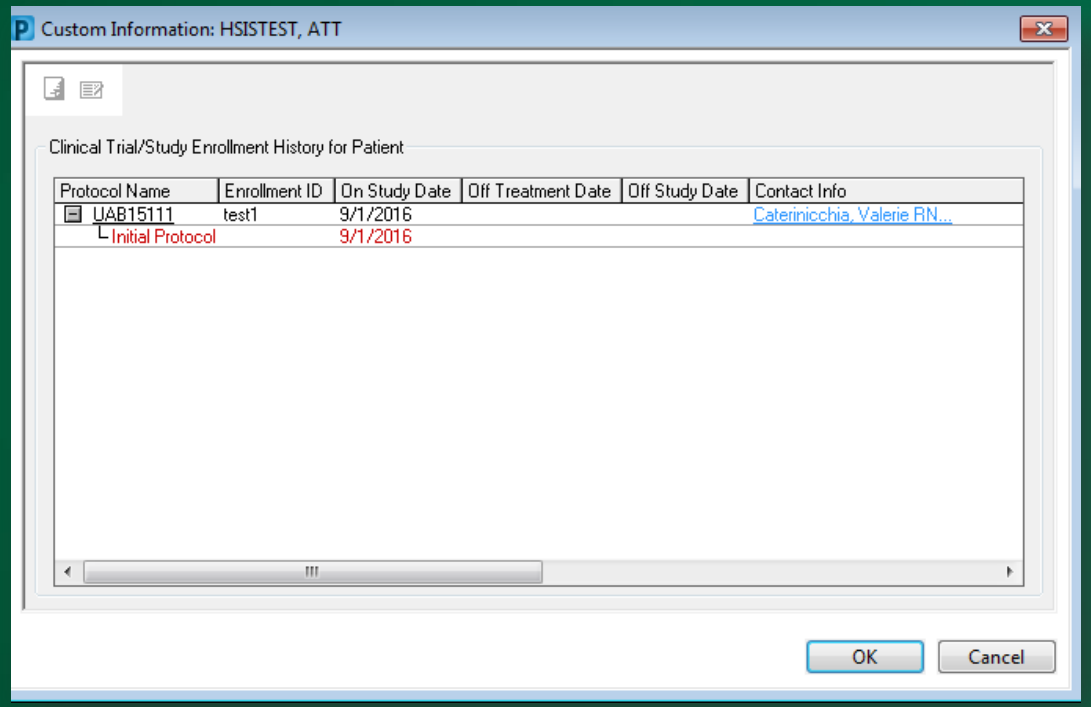
Sample Research Summary

HSISTEST, ATT
Isolation:
Allergies: Latex, Paper, Sulfamag

Age:65 years
Portal:Active Account
Blood Type:O POS

Research:On Study



Clinical Trial Summary for UAB 15111

Protocol Number

Title of Protocol: **Phase 2 Randomized, Double-Blinded, Controlled Study of Tucatinib vs Placebo in Combination with Capecitabine and Trastuzumab in Patients with Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma**

Study Agents (Drug or Device):

1. **Tucatinib**
2. **Capecitabine (Xeloda)**
3. **Trastuzumab (Herceptin)**

Purpose/Objective of Study:

The purpose of the study is to assess the survival and clinical benefit of tucatinib versus placebo when combined with capecitabine and trastuzumab in patients with advanced HER2+ breast cancer.

Mechanism of Drug Action/Device Description:

Tucatinib is a highly selective oral reversible HER2 tyrosine kinase inhibitor. It has >1000 fold increase in potency for HER2 inhibition compared to EGFR and blocks HER2 signaling while avoiding EGFR-related side effects.

Capecitabine is an oral prodrug of fluorouracil that infers with DNA and RNA synthesis.

Trastuzumab is an anti-HER2 monoclonal antibody that binds to the HER2 extracellular domain and blocks HER2 cleavage, stimulating antibody-dependent, cell-mediated cytotoxicity, and inhibits HER2-mediating mitogenic signaling. Trastuzumab is administered intravenously.

Toxicities/Side Effects:

Tucatinib: diarrhea, rash, extremity pain, nausea, fatigue, cough, hepatotoxicity, heart failure

Capecitabine: diarrhea, cardiotoxicity, hand-foot syndrome, pancytopenia, hyperbilirubinemia

Trastuzumab: infusion reactions, infections, dyspnea, myalgias, congestive heart failure

Caution:

Do not place patient on Coumadin (other anticoagulants are ok).

CYP3A4 or CYP2C8 inducers or inhibitors are **NOT** permitted on study (e.g. gemfibrozil, clarithromycin, azoles, barbiturates). Please ask your study coordinator before starting any new medications.

KEY CONTACTS:

Principle Investigator: Dr. Erica Stringer-Reasor
Phone: 4-2992 Pager: 4079 Email: esreasor@uabmc.edu
Study Coordinator: Felicia Witherspoon
Phone: 4-4317 Pager: 3119 Email: fwithers@uab.edu

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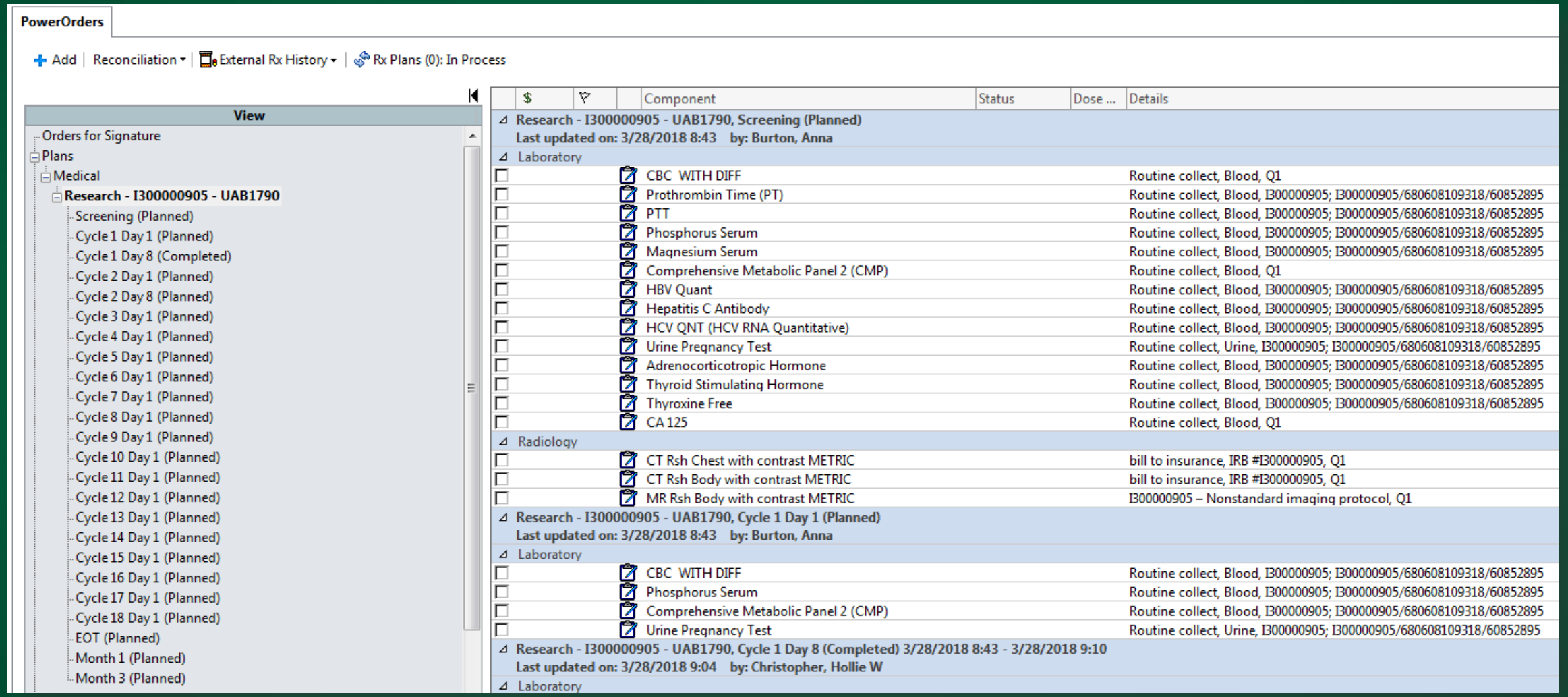
Sample PowerPlan



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How does PowerTrials Team know when to build my PowerPlan?

- PowerTrials specialist receives an **automated** notification from Oncore once the Oncore Protocol Calendar is completed.
  - Protocol Calendar has orders associated with study visits. It also has who to charge for each order. (Sponsor vs patient)
  - **Study Coordinator (SC) needs to validate Protocol Calendar to make sure orders are correct.**
  - The PowerTrials team might request validation of the Protocol Calendar if the study team is not building the Protocol Calendar.

Protocol Calendar used for PowerPlan build plan:

Study No.: UAB1736					
Arm: Arm A					
	Screening 1@	On Treatment 8 Cycles @28Days			
Re-labelled visits	D -28 to -1				
	D1	C1D1	C1D8	C1D15	C2D1
CBC/Plt + Manual Diff	X	S	X	X	S
PT	X				
Aptt/INR	X				
Uric Acid	X	X	X	X	X
LDH	X	X	X	X	X
Phosphorous	X	X	X	X	X
Magnesium	X	X	X	X	X
CMP	X	S	X	X	S
Direct Billirubin	X [A]	X [A]	X [A]	X [A]	X [A]
U/A w/micro	X				
Serum Preg Test	X				
Urine Preg Test	X				
Venipuncture	X	S	X	X	S
Neck CT w/contrast	X [A]				
Chest Ct w/contrast	X				
Abdm/Pelvis CT w/contrast	X				
Calendar Foot Notes					
A. If Clinically Indicated.					

X: bill to sponsor

S: bill to patient's insurance (Standard of Care)

Important – Builders need to know the length and # of cycles. For example – this one has 8 cycles and each is 28 days.

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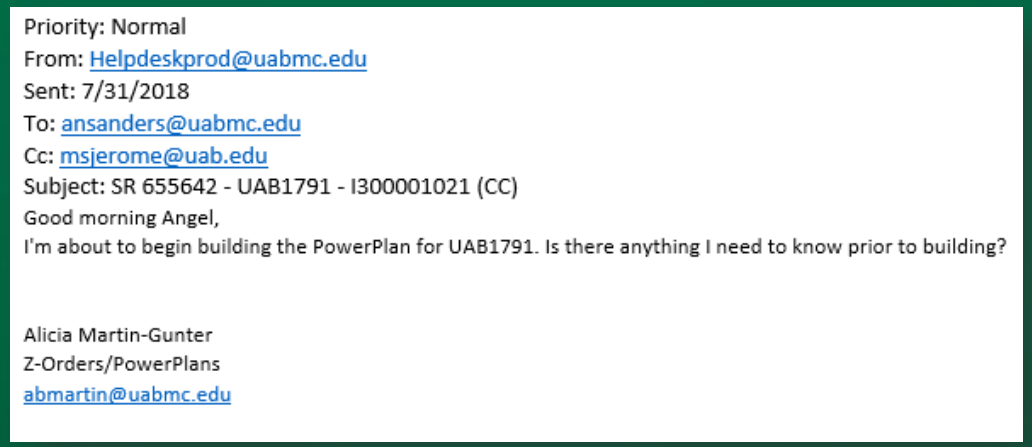
Email Notification:

- If the Calendar contains Lab and/or Rad orders, the PowerTrials specialist will notify the SC by email, that the PowerTrials team has received the notification and is in the process of building the PowerPlan.
  - Feel free to make suggestions.



Priority: Normal
From: Helpdeskprod@uabmc.edu
Sent: 7/31/2018
To: ansanders@uabmc.edu
Cc: msjerome@uab.edu
Subject: SR 655642 - UAB1791 - I300001021 (CC)
Good morning Angel,
I'm about to begin building the PowerPlan for UAB1791. Is there anything I need to know prior to building?

Alicia Martin-Gunter
Z-Orders/PowerPlans
abmartin@uabmc.edu

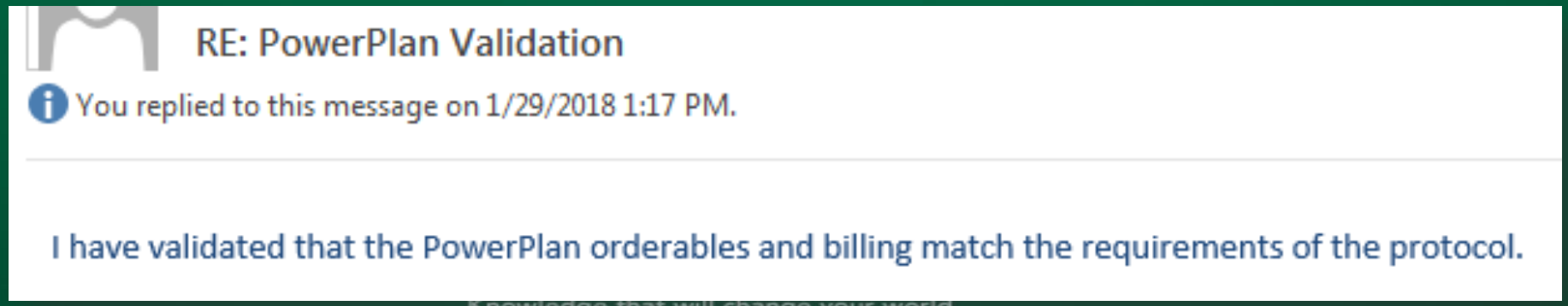
Power Plan:

- A specialist builds PowerPlan according to the validated Protocol Calendar specifications.
- If the study has more than one Arm, a PowerPlan will be built for each Arm separately.
- If the Screening visit will occur prior to Arm randomization, please let us know and a separate PowerPlan will be built for Screening.

- Research PowerPlans have modifiers built into orders that will be billed to the patient's insurance or the IRB account. **Because Research PowerPlan orders are pre-coded with Q1 and Research modifiers, they cannot be modified by the end-user.**

Validation Email sent to SC

- A request for validation email is sent to SC who is assigned to the study in OnCore. If no SC has been assigned, then we will reach out to the Research Manager.
- Will include Validation Workaid
- Validation must be completed within 2 weeks.
- Reply All to validation request email.



Example of PowerPlan Extract:

Unique Plan Description: Research - W170621010 - UAB1736
Plan Selection Display: Research - W170621010 - UAB1736
PlanType: Medical
Version: 1
Begin Effective Date: 1/5/2018 14:14
End Effective Date: Current
Available at all facilities

Screening
Laboratory

- ☐ CBC WITH DIFF
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ PT
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ PTT
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Uric Acid
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ LDH
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Phosphorus Serum
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Magnesium Serum
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ CMP
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Bilirubin Direct
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Urinalysis
  Routine collect, W170621010; W170621010/0680606439318/60852747
- ☐ HCG Pregnancy Serum
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Urine Pregnancy Test
  Routine collect, Urine, W170621010; W170621010/0680606439318/60852747

Radiology

- ☐ CT Rsh Body wo+w contrast METRIC
  W170621010; W170621010/0680606439318/60852747
- ☐ CT Rsh Chest wo+w contrast METRIC
  W170621010; W170621010/0680606439318/60852747
- ☐ CT Rsh Neck wo+w contrast METRIC
  W170621010; W170621010/0680606439318/60852747

Cycle 1 Day 1
Laboratory

- ☐ CBC WITH DIFF
  Routine collect, Blood, Q1

Q1: Billed to patient insurance (standard of care)

IRB#: Billed to study

- ☐ CMP
  Routine collect, Blood, Q1
- ☐ Bilirubin Direct
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747

Cycle 1 Day 8
Laboratory

- ☐ CBC WITH DIFF
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Uric Acid
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ LDH
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Phosphorus Serum
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Magnesium Serum
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ CMP
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Bilirubin Direct
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747

Cycle 1 Day 15
Laboratory

- ☐ CBC WITH DIFF
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Uric Acid
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ LDH
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Phosphorus Serum
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Magnesium Serum
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ CMP
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ Bilirubin Direct
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747

Cycle 2 Day 1
Laboratory

- ☐ CBC WITH DIFF
  Routine collect, Blood, Q1
- ☐ Uric Acid
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
- ☐ LDH
  Routine collect, Blood, W170621010; W170621010/0680606439318/60852747

Scheduling Testing:

- SC that will utilize Power Plan is required to attend testing.
  - **Backup** SC should attend as well
- Testing must be done in General Services Building (GSB) due to the testing platform only working in GSB.
- Will take less than an hour!
- After one testing/training event in GSB, the SC can be given privileges to test remotely.

Testing:

- One-on-one assistance by your PowerTrials specialist
- Script outlining each step of testing process

How To Order PowerPlan

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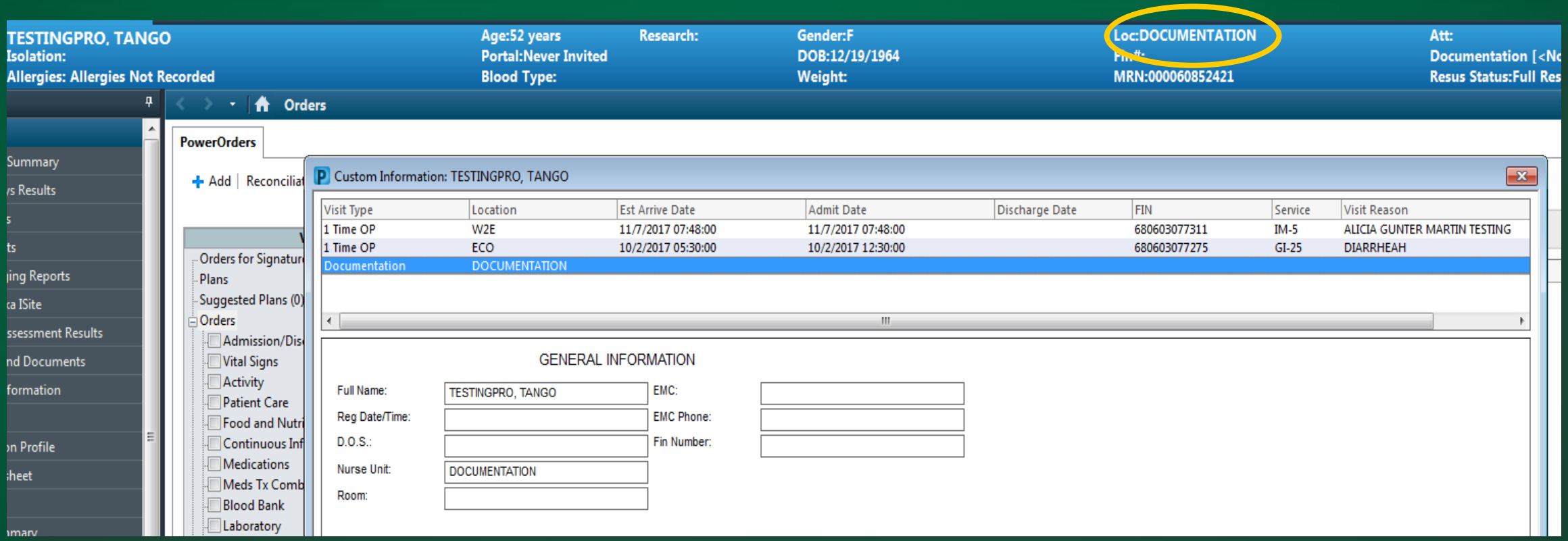
Step 1: Select Documentation Encounter



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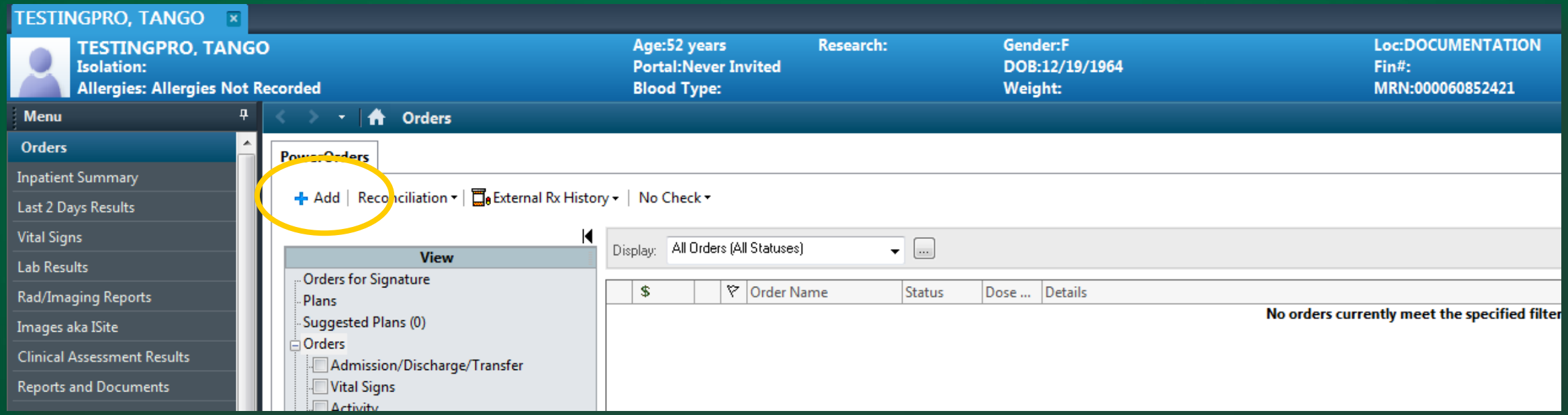
Step 2: Go to Orders tab and ‘Add’



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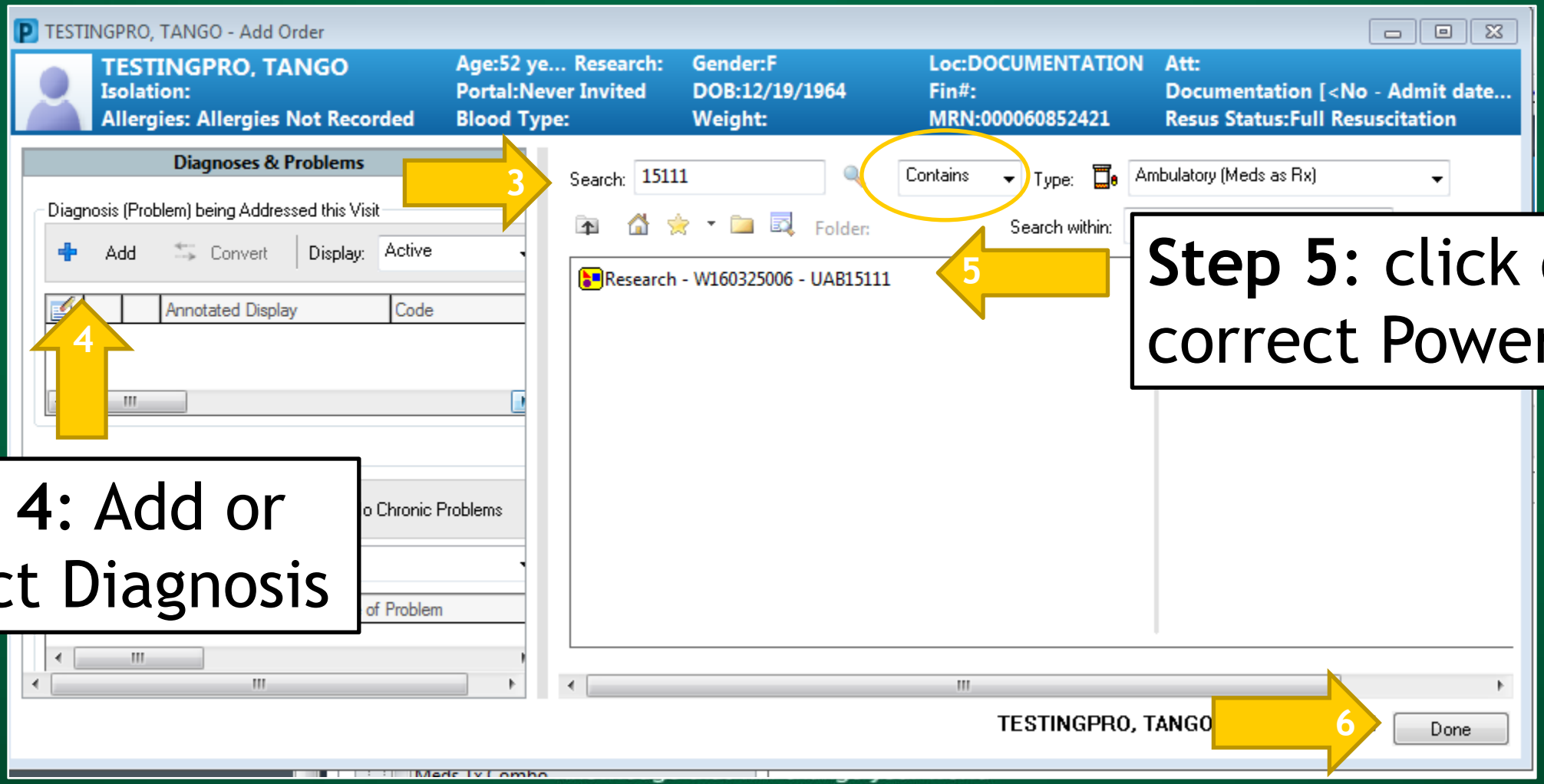
Step 3: Enter Study Name, IRB#, or Protocol # into Search field (make sure 'Contains' is selected)



Step 4: Add or Select Diagnosis

Step 5: click on correct PowerPlan

Is your patient **"On Study"?**

- When a patient is placed "On Study" in OnCore, OnCore sends this information to Cerner Impact.
- There are two ways to tell:
  - the PowerTrials Tab in the Impact Menu
  - "On Study" in the banner bar
- For patients undergoing initial Screening visits, and that have not been entered into OnCore, there will be a pop up box requiring an override reason.

Example of **"On Study"** in the **banner bar**

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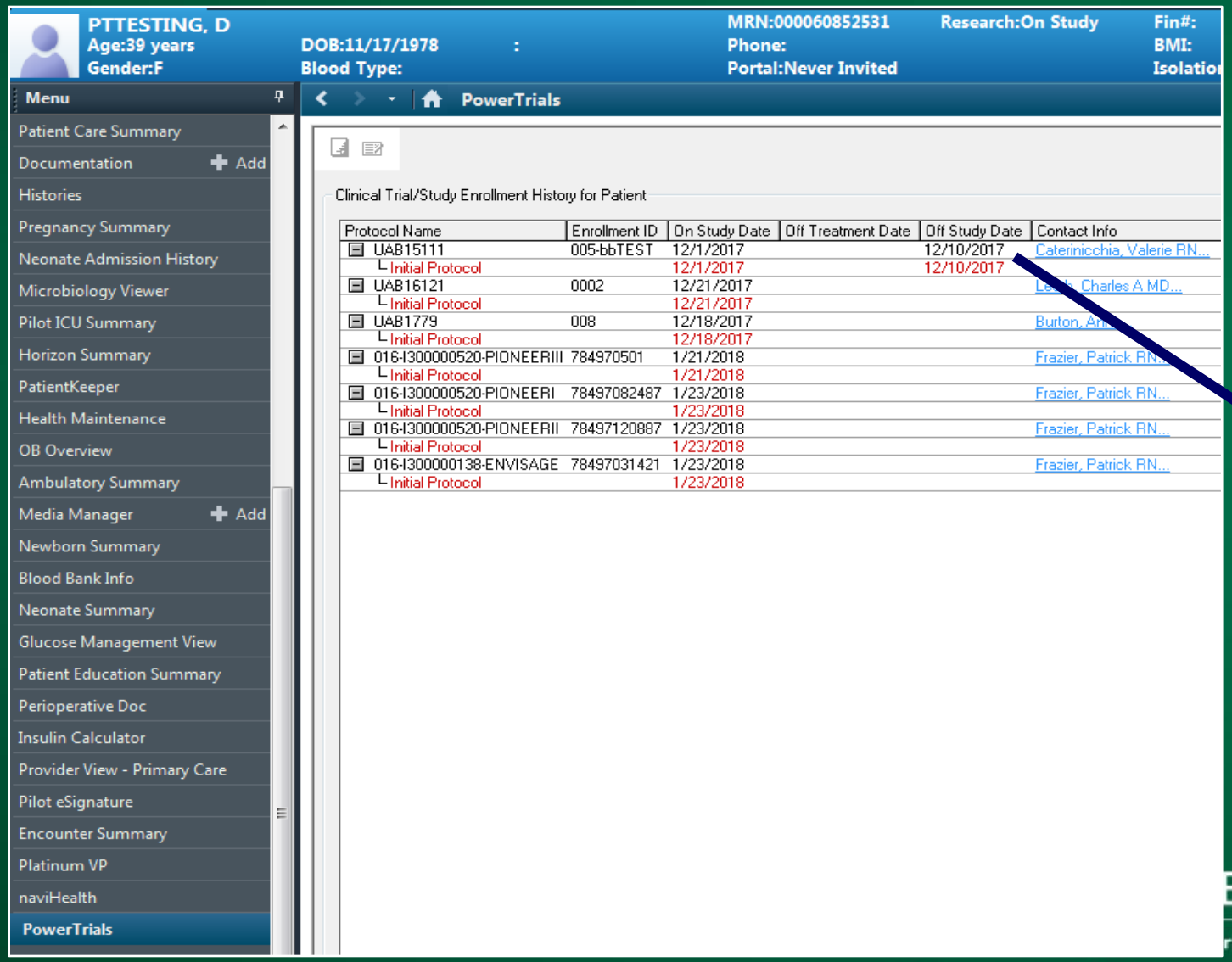
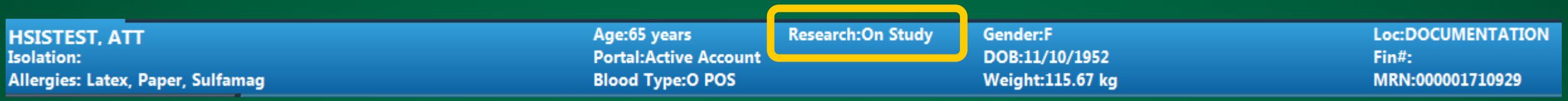
Example of **PowerTrials Tab Impact Menu**

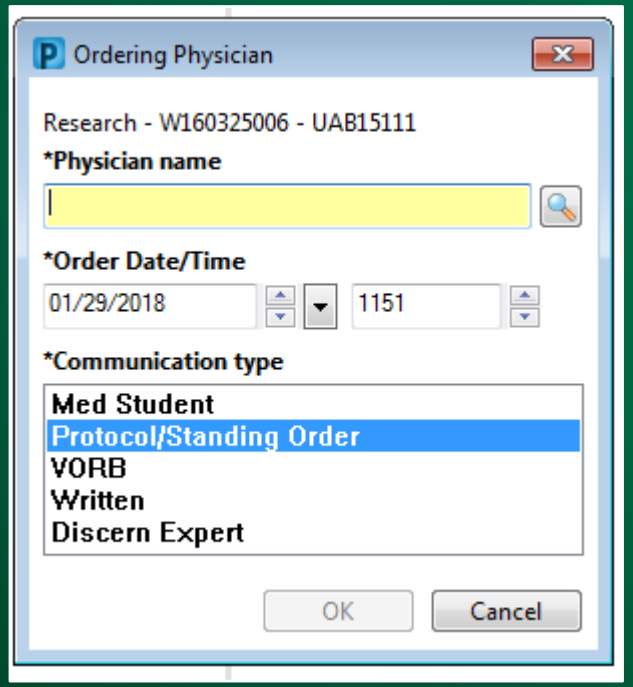


A patient can be on more than one study. Make sure your specific study is listed.

When the patient has an “Off Study” indicator in OnCore, 15 days later, the “On Study” in the banner bar will expire. The patient’s enrollment in the study will be available in the PowerTrials tab in Impact’s Menu

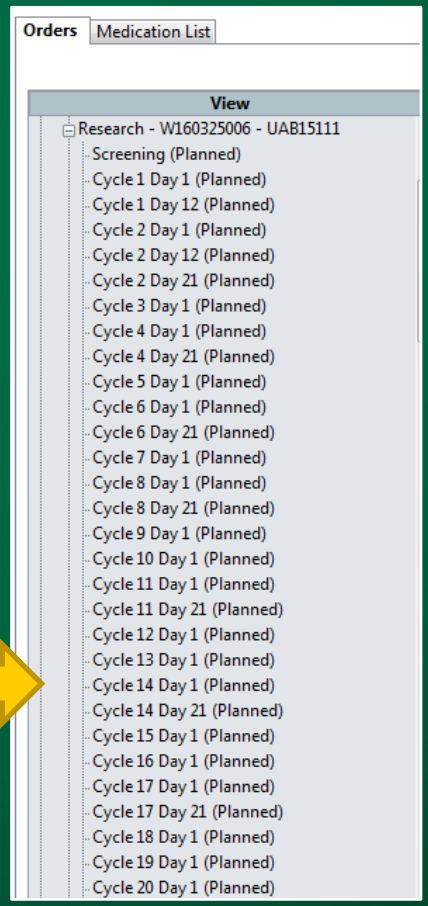
Step 7: If patient is listed as On Study in OnCore for the study associated with the PowerPlan:





Enter the physician and Protocol/Standing Order.

The PowerPlan will appear under the Orders tab in the View Menu in Impact under Active orders.



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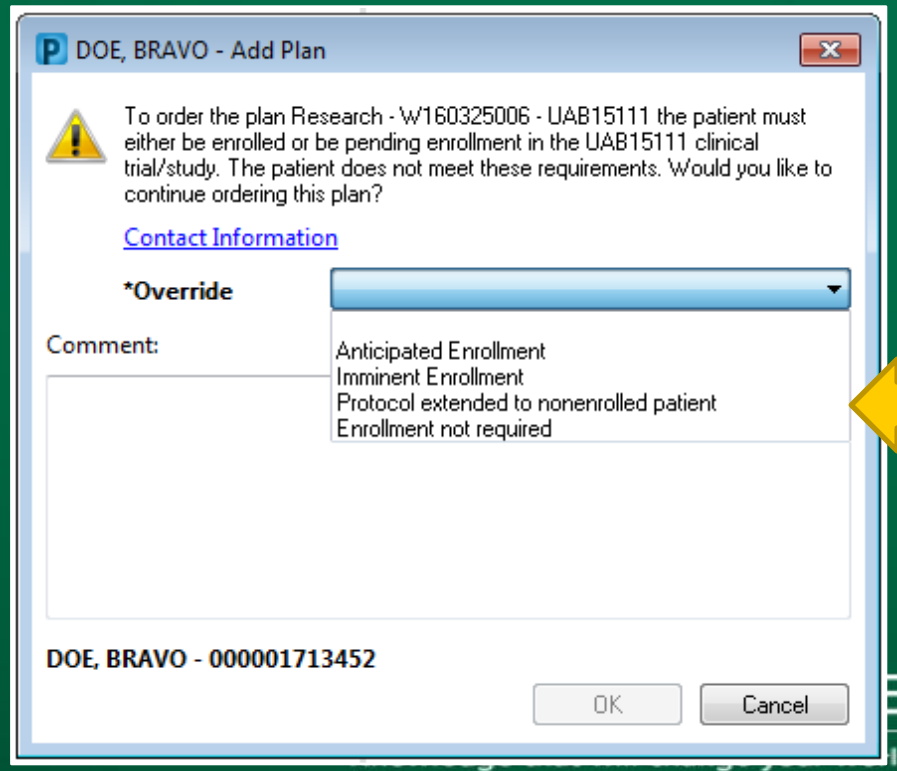
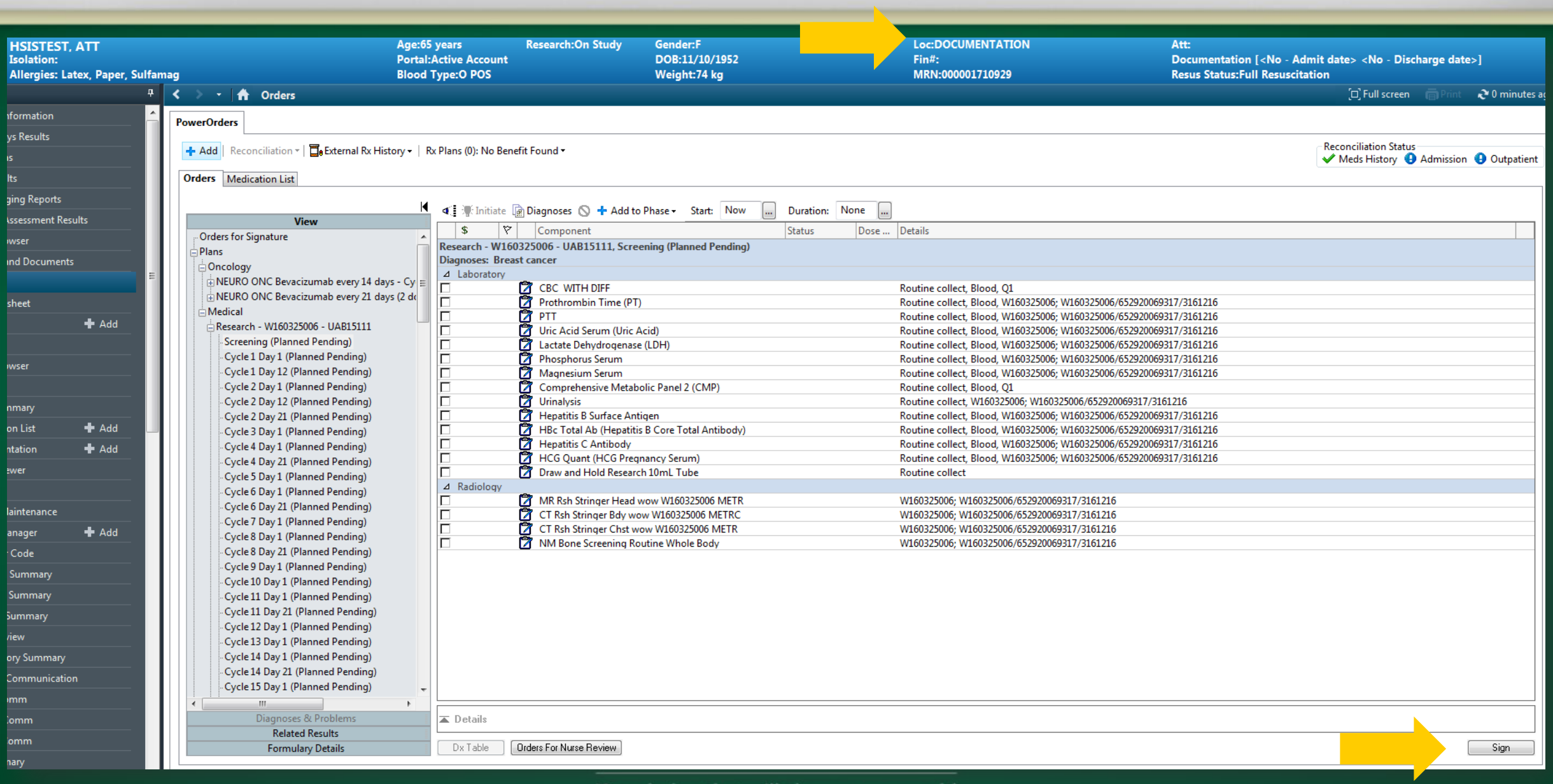
Step 7: If patient is **not** listed as On Study in OnCore for the study associated with the PowerPlan:

DOE, BRAVO	**Age:10 years**	**Research:**	**Gender:F**	**Loc:DOCUMENTATION**
Isolation:	**Portal:Never Invited**		**DOB:5/9/2007**	**Fin#:**
Allergies: Allergies Not Recorded	**Blood Type:**		**Weight:**	**MRN:000001713452**



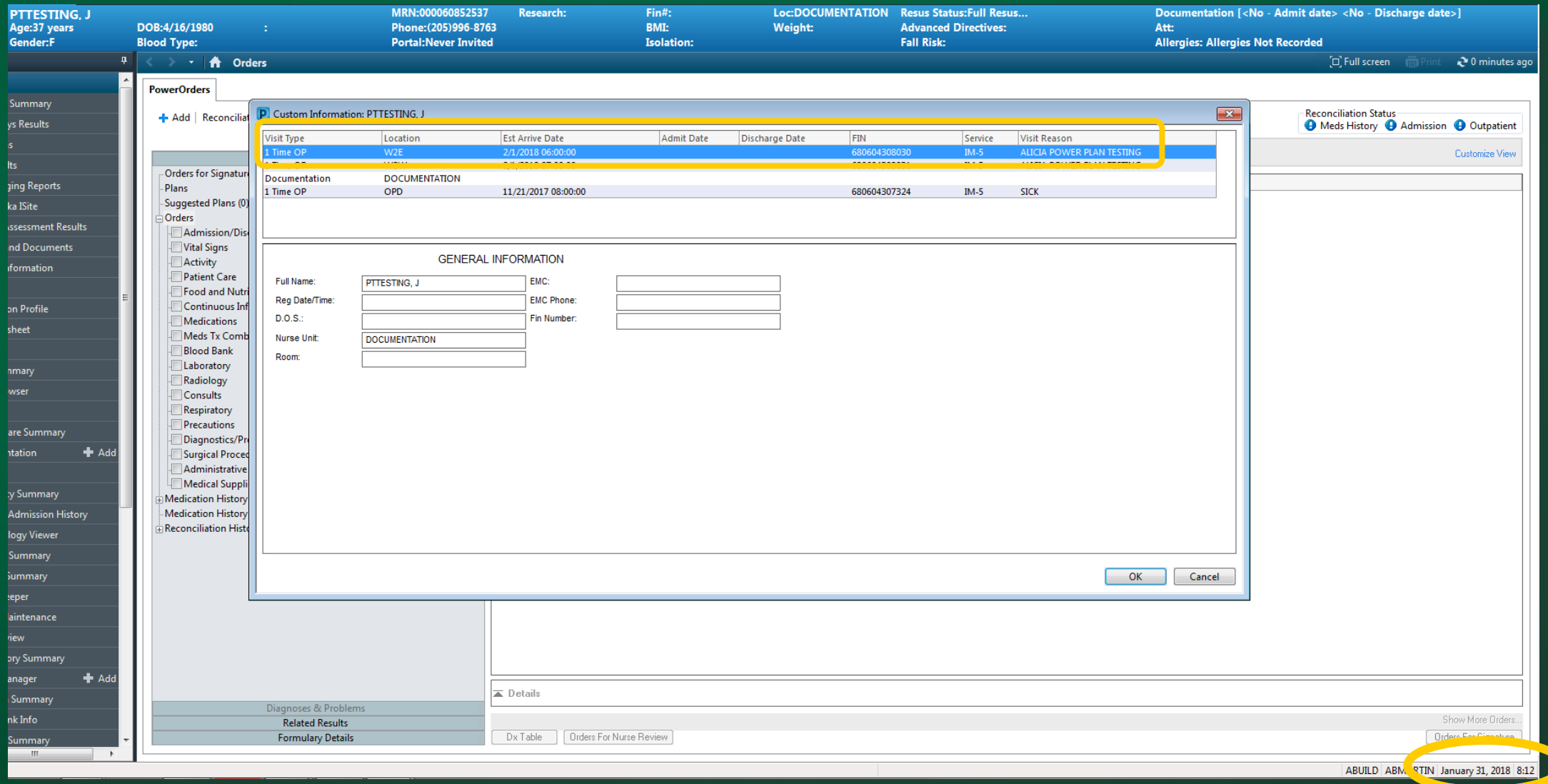
A warning box will appear requiring and Override reason

Step 8: Sign the PowerPlan on the Documentation Encounter!!

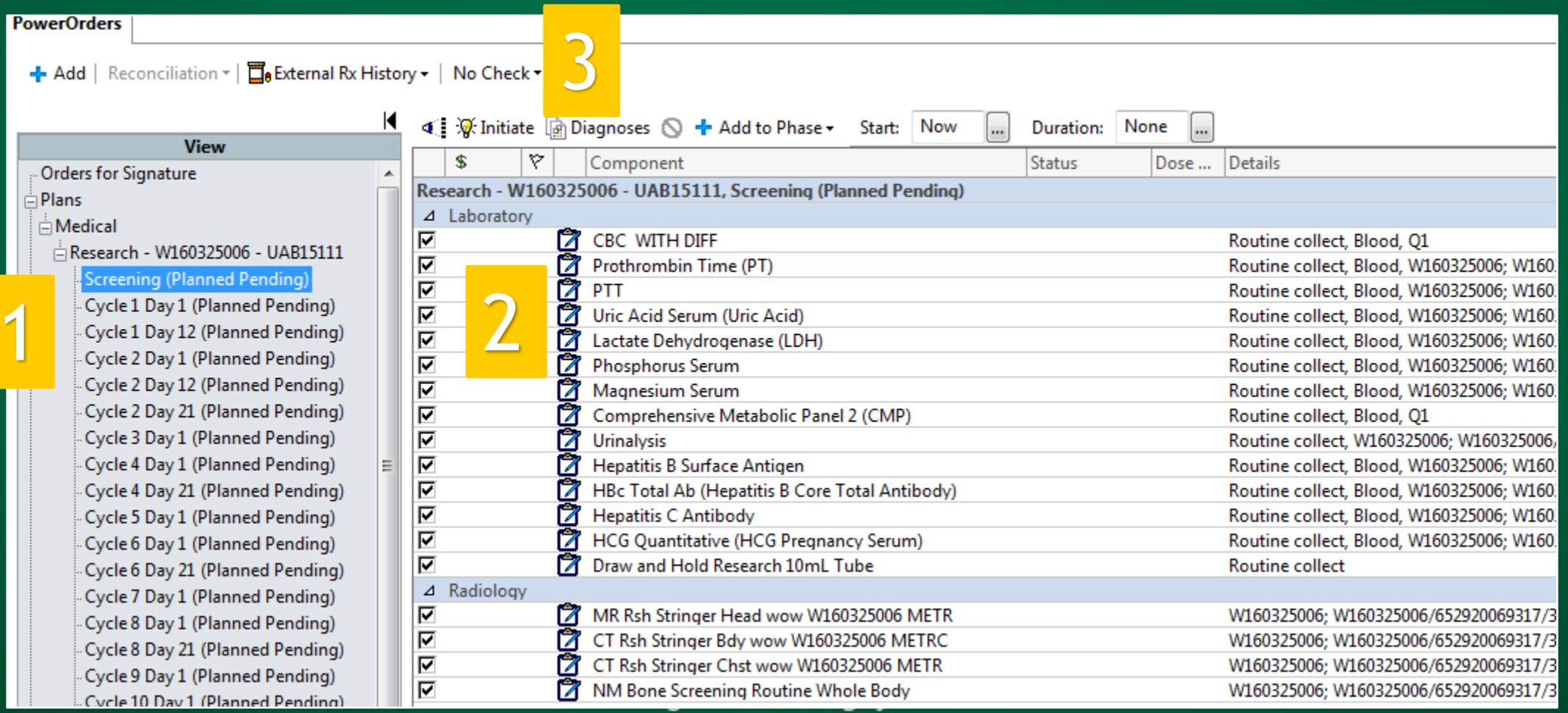


Step 9: When a patient is scheduled for a visit

- Select upcoming encounter



Step 10: Select Screening or Cycle in PowerPlan(1). Click box beside each order to be performed (2). Click 'Initiate' (3).

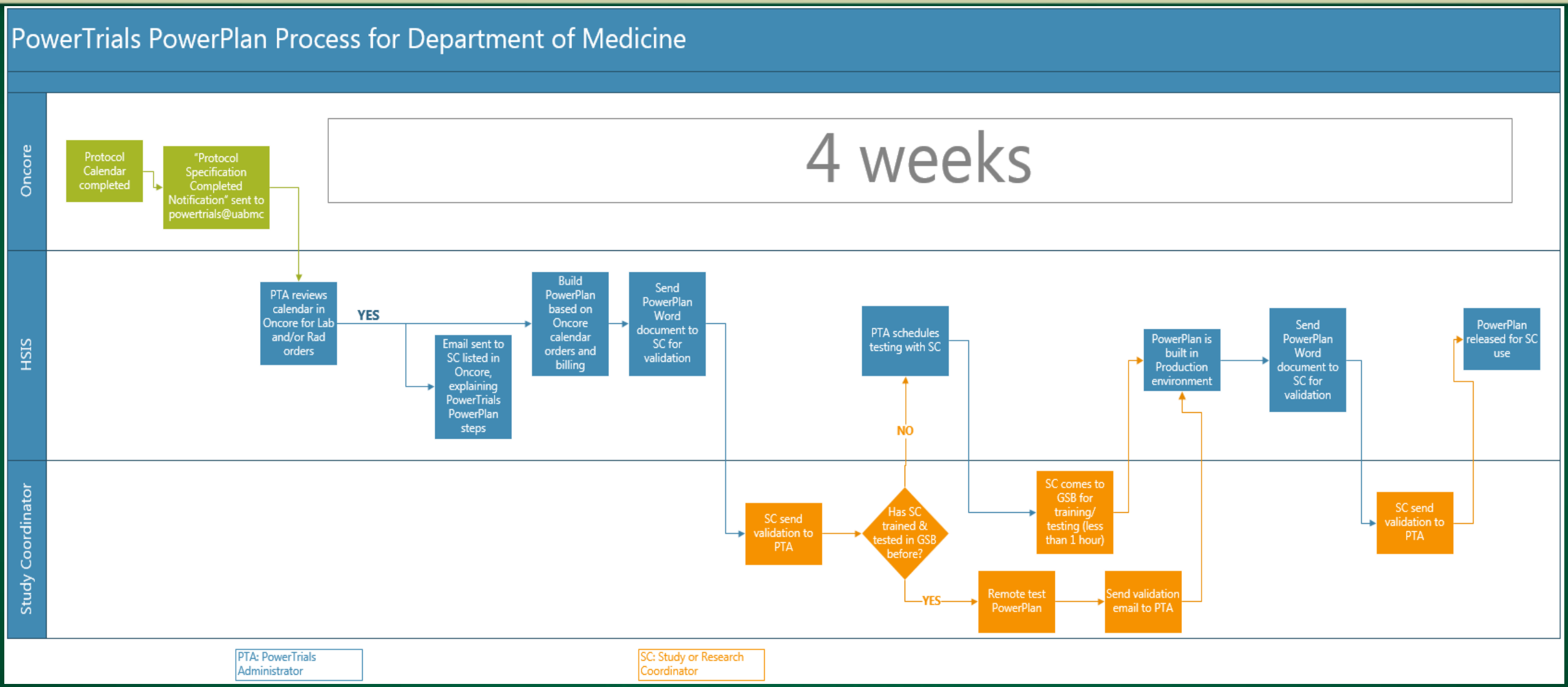


Successful Testing

- The testing event for the SC is considered completed after SC orders the PowerPlan on the test patient in the testing domain and initiates a pre-selected Cycle or Visit set for each Arm and tests a null patient (not On Study).

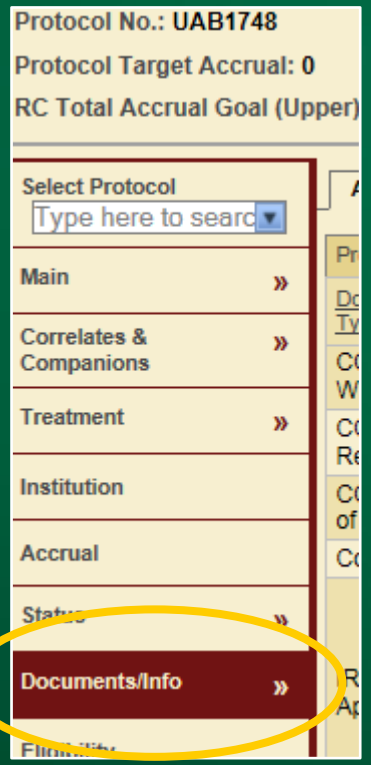
- After successful testing validation, the PowerTrials Specialist will build the PowerPlan in the Production environment. *(Production is the current Impact environment being used by SCs daily.)* **Needs to be validated as well.**

PowerTrials Flowchart for the Department of Medicine



In the event of Downtime:

- An email has been sent to policies@uabmc.edu with PowerPlan in the Word document format, used for validation.
- And has been uploaded to OnCore:



Other Type Document	UAB1748 - I300000197 - Cerner Impact PowerPlan.rtf	UAB1748 Cerner Impact PowerPlan for Downtime	11/16/2017		12/06/2017	ABMARTIN

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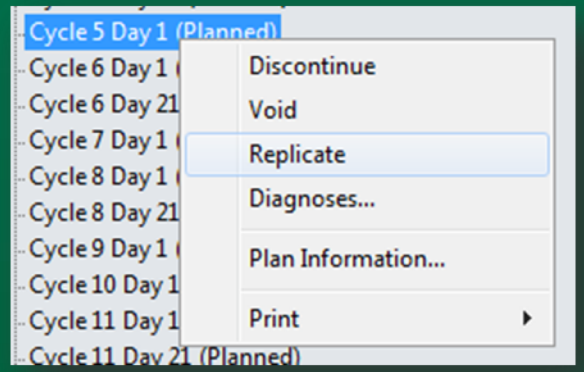
Amendment

- If there is an amendment to the study that affects the orderables in the PowerPlan, the OnCore calendar builders will email the PowerTrials team at powertrials@uabmc.edu
- The PowerTrials specialist will build a new PowerPlan, reflecting the changes and send to the SC for validation.
- Once validated, the PowerPlan will be released for SC use.
- The SC should then discontinue the first version of the PowerPlan on the patients and order the new version, starting with the next appropriate phase.

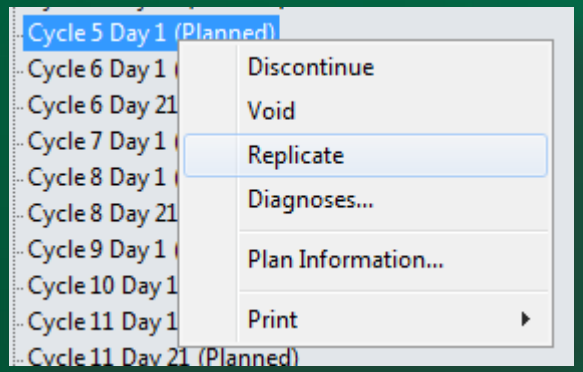
Discontinuing the PowerPlan

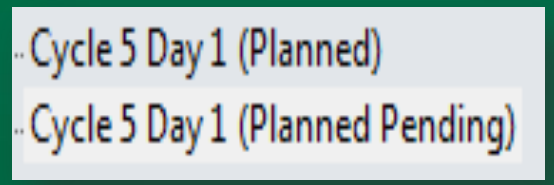
- **To discontinue the remainder of the phased research PowerPlan (or the entire plan)** so that no other orders can be initiated on any visits:
  - Right-click on the main plan name
  - Select **Discontinue**
  - Click **Sign**
  - Click the **Refresh button**

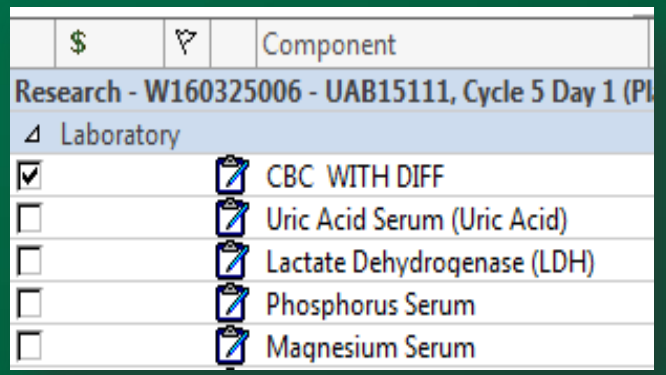


What if my patient has to leave and I need to redo the visit? Replicate!

- Right-click on the phase in the left pane
- Select **Replicate**
- Select only the orders that need to be done.







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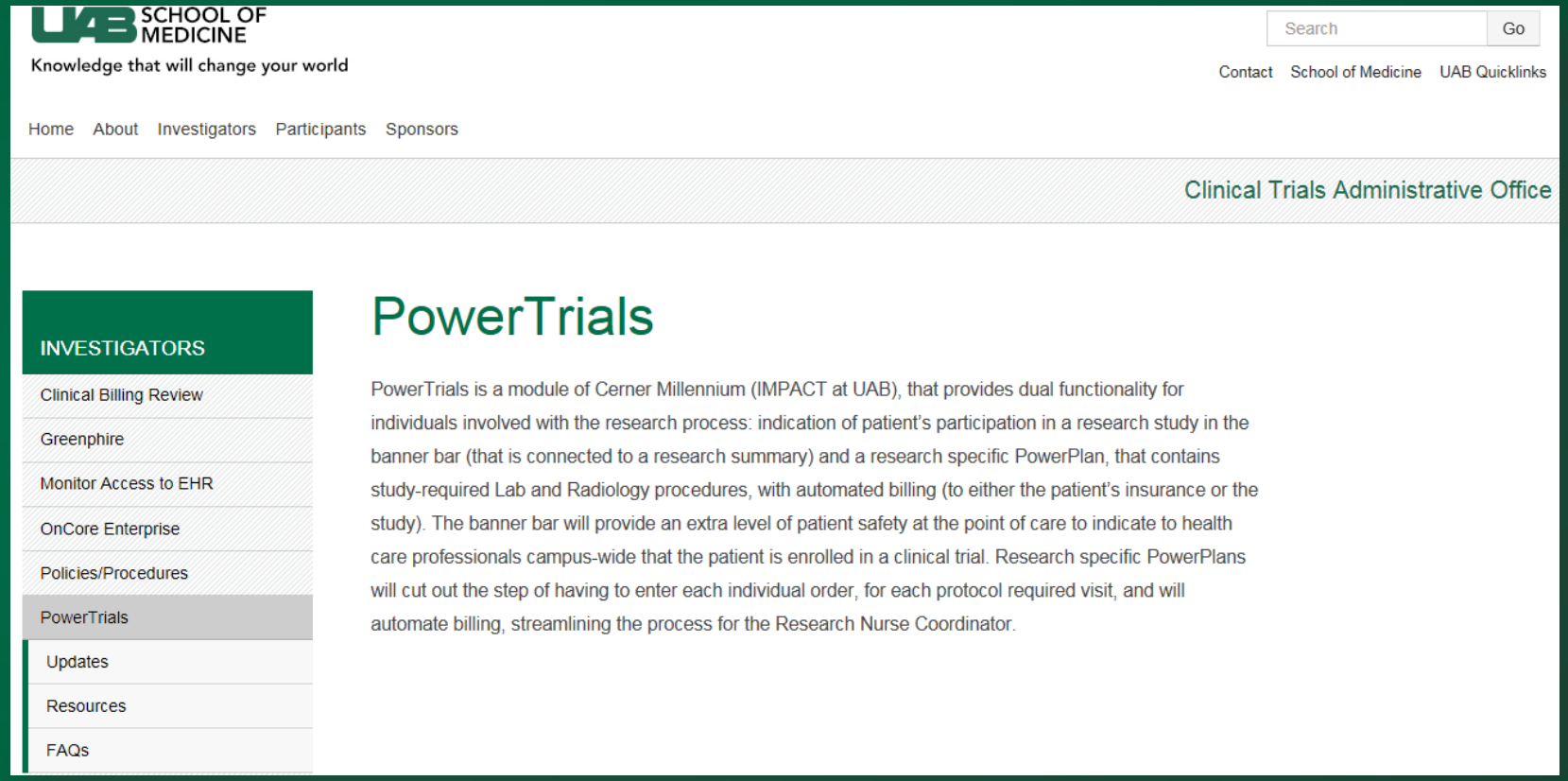
What if my patient has an AE and needs more Lab or Rad orders?

- Follow your current process, outside of the PowerPlan (green sheets for Lab, orders in Impact for Rad, etc.)

PowerTrials Updates

- New PowerTrials website!
  - Updates!
  - Resources!
    - ✓ IMPACT Research Coordinator Resource Manual: Research PowerPlan Ordering
    - ✓ PowerTrials PowerPlan Presentation
    - ✓ PowerTrials Quick Tips and Tricks
    - ✓ PowerTrials Process
  - FAQs!



- http://www.uab.edu/medicine/ctao/investigators/powertrials

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Things to Remember

- Until 100% implementation is completed, some orders will continue to go through the original process (green sheet, order through Impact, etc.)

- Your licensure will determine whether or not you have the privileges to place orders and/or PowerTrials PowerPlans.

Questions

- Questions?

- For further questions or concerns:

Alicia Gunter

PowerTrials Administrator (HSIS)

(205) 996 - 8763 office

abmartin@uabmc.edu