PowerTrials

Cerner Impact



Project Overview



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

PowerPlan built with the orderables required by the study



Sample Research Summary

Research:On Study

HSISTEST, AT	Т		
Isolation:			
Allergies: Latex,	Paper,	Sulfamag	

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

P Custom Information: HSISTEST, ATT	×
- Clinical Trial/Studu Enrollment History for Patient	
	_
Protocol Name Enrollment ID On Study Date Off Treatment Date Off Study Date Contact Info	-
UABTSTTT test1 9/1/2016 Caterinicchia, Valerie RN	-
	-
	-

Knowledge that will change your world

Clinical Trial Summary for UAB 15111 Protocol Number

<u>Title of Protocol</u>: 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.

<u>Trastuzumab</u> 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

hone: 4-2992	Pager: 4079	Email: esreasor@uabmc.edu	
udy Coordinator: Fe	licia Witherspoon		
none: 4-4317	Pager: 3119	Email: fwithers@uab.edu	

Sample PowerPlan

PowerOrders

🕂 Add | Reconciliation 🕶 | 🛅 External Rx History 🕶 | 🦑 Rx Plans (0): In Process

N	\$	8	Component	Status	Dose	Details
View	⊿ Research	- I3000	00905 - UAB1790, Screening (Planned)			
r Orders for Signature	Last upd	ated on:	3/28/2018 8:43 by: Burton, Anna			
Plans	⊿ Laborato	ry				
🗄 Medical			🖄 CBC WITH DIFF			Routine collect, Blood, Q1
Research - I300000905 - UAB1790			Prothrombin Time (PT)			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Screening (Planned)			🛛 РТТ			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 1 Day 1 (Planned)			Phosphorus Serum			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 1 Day 8 (Completed)			🖉 Magnesium Serum			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 2 Day 1 (Planned)			Comprehensive Metabolic Panel 2 (CMP)			Routine collect, Blood, Q1
Cycle 2 Day 8 (Planned)			HBV Quant			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 3 Day 1 (Planned)			Hepatitis C Antibody			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 4 Day 1 (Planned)			HCV QNT (HCV RNA Quantitative)			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 5 Day 1 (Planned)			Urine Pregnancy Test			Routine collect, Urine, I300000905; I300000905/680608109318/60852895
Cycle 6 Day 1 (Planned)			Adrenocorticotropic Hormone			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 7 Day 1 (Planned)			Thyroid Stimulating Hormone			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 7 Day 1 (Planned)			Thyroxine Free			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 8 Day 1 (Planned)			Z CA 125			Routine collect, Blood, Q1
Cycle 9 Day 1 (Planned)	⊿ Radiolog	у	~			
- Cycle 10 Day 1 (Planned)			CT Rsh Chest with contrast METRIC			bill to insurance, IRB #I300000905, Q1
- Cycle 11 Day 1 (Planned)			CT Rsh Body with contrast METRIC			bill to insurance, IRB #I300000905, Q1
Cycle 12 Day 1 (Planned)			MR Rsh Body with contrast METRIC			B00000905 – Nonstandard imaging protocol, Q1
· Cycle 13 Day 1 (Planned)	⊿ Research	n - I3000	00905 - UAB1790, Cycle 1 Day 1 (Planned)			
- Cycle 14 Day 1 (Planned)	Last upd	ated on:	3/28/2018 8:43 by: Burton, Anna			
Cycle 15 Day 1 (Planned)	⊿ Laborato	ry	~			
Cycle 16 Day 1 (Planned)			CBC WITH DIFF			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
Cycle 17 Day 1 (Planned)			Phosphorus Serum			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
- Cycle 18 Day 1 (Planned)			Comprehensive Metabolic Panel 2 (CMP)			Routine collect, Blood, I300000905; I300000905/680608109318/60852895
EOT (Planned)			Urine Pregnancy Test			Routine collect, Urine, I300000905; I300000905/680608109318/60852895
Month 1 (Planned)	⊿ Research	n - I3000	00905 - UAB1790, Cycle 1 Day 8 (Completed) 3/2	8/2018 8:43 - 3/28/201	8 9:10	
Month 3 (Planned)	Last upd	ated on:	3/28/2018 9:04 by: Christopher, Hollie W			
	⊿ Laborato	ry				

LABMEDICINE

How does PowerTrials Team know when to build my PowerPlan?

- PowerTrials specialist receives an <u>automated</u> notification from Oncore once the Oncore Protocol Calendar is completed.
 - Protocol Calendar has orders associated with study visits. It also has <u>who</u> 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 D -28 to -1 Image: C1D1 C1D8 C1D15 C2D1 D1 C1D1 C1D8 C1D15 C2D1 X S X X S X S X X S X S X X S X S X X S X S X X S X S X X S X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X X S X X<				
	Screening 1	@ On Treatme	ent 8 Cycles @2	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
LDH	X	X	X	X	X
Phosphorous	X	X	X	X	X
Magnesium	Х	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	Х				
Calendar Foot Notes	6				
A. If Clinically Indica	ted.				

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.



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: <u>Helpdeskprod@uabmc.edu</u> Sent: 7/31/2018 To: <u>ansanders@uabmc.edu</u> Cc: <u>msjerome@uab.edu</u> 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.

RE: PowerPlan Validation You replied to this message on 1/29/2018 1:17 PM.

I have validated that the PowerPlan orderables and billing match the requirements of the protocol.

Example of PowerPlan Extract:

Unique Plan S PlanTy Versio Begin End Et Availa	e Plan Description: Research - W170621010 - UAB1736 election Display: Research - W170621010 - UAB1736 /pe: Medical n: 1 Effective Date: 1/5/2018 14:14 ffective Date: Current ble at all facilities	Q1: Billed to patient insurance (standard of care)	Cycle Labor	CMP Routine collect, Blood, Q1 Bilirubin Direct Routine collect, Blood, W170621010; W170621010/0680606439318/60852747 e1 Day 8 ratory CBC WITH DIFF Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
Labora	atory			Uric Acid
	CBC WITH DIFF Routine collect, Blood, W170621010; W170621010/0680606439318/60852747			Routine collect, Blood, W170621010, W170621010/0680606439318/60852747 LDH
	PT Routine collect, Blood, W170621010; W170621010/0680606439318/60852747			Routine collect, Blood, W170621010; W170621010/0680606439318/60852747 Phosphorus Serum
	PTT Poutine collect Blood W/170621010: W/170621010/0680606/130318/608527/7			Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	Uric Acid			Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	Routine collect, Blood, W170621010; W170621010/0680606439318/60852747 LDH			CMP Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	Routine collect, Blood, W170621010; W170621010/0680606439318/60852747			Bilirubin Direct Routine collect Blood W170621010 W170621010/0680606430318/60852747
	Routine collect, Blood, W170621010; W170621010/0680606439318/60852747		Cycle	e 1 Day 15
	Magnesium Serum Routine collect. Blood. W170621010: W170621010/0680606439318/60852747			CBC WITH DIFF
	CMP Routine collect_Blood_W170621010; W170621010/0680606439318/60852747	IRB#: Billed to		Routine collect, Blood, W170621010; W170621010/0680606439318/60852747 Uric Acid
	Bilirubin Direct	study		Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	Urinalysis			Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	Routine collect, W170621010; W170621010/0680606439318/60852747 HCG Pregnancy Serum			Phosphorus Serum Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	Routine collect, Blood, W170621010; W170621010/0680606439318/60852747			Magnesium Serum Routine collect_Blood_W170621010; W170621010/0680606439318/60852747
	Urine Pregnancy Test Routine collect, Urine, W170621010; W170621010/0680606439318/60852747			CMP
Radiol	ogy CT Rsh Body wo+w contrast METRIC			Routine collect, Blood, W1/0621010; W1/0621010/0680606439318/60852/4/ Bilirubin Direct
	W170621010; W170621010/0680606439318/60852747		Cvcle	Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	W170621010; W170621010/0680606439318/60852747		Labor	ratory
	CT Rsh Neck wo+w contrast METRIC W170621010; W170621010/0680606439318/60852747			Routine collect, Blood, Q1
Cycle Labora	1 Day 1 atory			Uric Acid Routine collect, Blood, W170621010; W170621010/0680606439318/60852747
	CBC WITH DIFF Routine collect, Blood, Q1	nowledge that will change y	•	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



Step 1: Select Documentation Encounter

TESTINGPRO, TANG Isolation: Allergies: Allergies Not F	O Recorded		Age:52 years Portal:Never Invi Blood Type:	Research: ted	Gender:F DOB:12/19/1964 Weight:		Loc:DOCUMENTATIO	DN	Att: Document Resus Stat	ation [<no us:Full Res</no
Р	< > 🝷 者 Ord	ers								
<u>^</u>	PowerOrders									
Summary rs Results	🕂 Add Reconciliat	P Custom Informati	ion: TESTINGPRO, TANGO							×
5		Visit Type	Location	Est Arrive Date	Admit Date	Discharge Date	FIN	Service	Visit Reason	
ts	Orders for Signature	1 Time OP	ECO	10/2/2017 05:30:00	10/2/2017 12:30:00		680603077275	GI-25	DIARRHEAH	
ing Reports	-Plans	Documentation	DOCUMENTATION							
ca ISite	Suggested Plans (0)									
ssessment Results	Orders				III					<u> </u>
nd Documents	Vital Signs		GENER	AL INFORMATION						
formation	- Activity	Full Name:	TESTINGPRO, TANGO	EMC:						
	- Food and Nutri	Reg Date/Time:		EMC Phone:						
on Profile	Continuous Inf	D.O.S.:		Fin Number:						
;heet	Medications Meds Tx Comb	Nurse Unit: Room:	DOCUMENTATION							
imary	- Laboratory									



Step 2: Go to Orders tab and 'Add'

TESTINGPRO, TANGO 🛛 🛪 Age:52 years Loc:DOCUMENTATION **TESTINGPRO, TANGO** Research: Gender:F **Isolation: Portal:Never Invited** DOB:12/19/1964 Fin#: Allergies: Allergies Not Recorded MRN:000060852421 Blood Type: Weight: д A Orders Menu Orders PowerOrders Inpatient Summary 🕂 Add | Reconciliation - | 🛄 External Rx History - | No Check -Last 2 Days Results Vital Signs K Display: All Orders (All Statuses) - ... View Lab Results Orders for Signature 🕅 Order Name \$ Dose ... Details Status Rad/Imaging Reports Plans No orders currently meet the specified filter Suggested Plans (0) Images aka ISite Orders Clinical Assessment Results Admission/Discharge/Transfer Reports and Documents Vital Signs Activity



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



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

HSISTEST, ATT	Age:65 years	Research:On Study	Gender:F	Loc:DOCUMENTATION
Isolation:	Portal:Active Account		DOB:11/10/1952	Fin#:
Allergies: Latex, Paper, Sulfamag	Blood Type:O POS		Weight:115.67 kg	MRN:000001710929



Example of PowerTrials Tab Impact Menu

PTTESTING, D Age:39 years Gender:F	DOB:11/17/1978 Blood Type:	:		MRN:000060852531 Phone: Portal:Never Invited	Research:C	On Study	Fin#: BMI: Isolati
Menu P	< > - f	PowerTrials					
Patient Care Summary							
Documentation 🕂 Add							
Histories	Clinical Trial/Stud	ly Enrollment Histo	ry for Patient				
Pregnancy Summary	Protocol Name		Enrollment ID	On Study Date Off Treatment Date	Off Study Date	Contact Info	
Neonate Admission History	UAB15111	teeel	005-bbTEST	12/1/2017	12/10/2017	Caterinicchia, V	Valerie RN.
Microbiology Viewer	UAB16121		0002	12/21/2017	12/10/2017	Let & Charles	<u>A MD</u>
Pilot ICU Summany	L Initial Pro	tocol	008	12/21/2017 12/18/2017		Burton, An	
	- Initial Pro	tocol		12/18/2017			
Horizon Summary	🔲 016-130000	0520-PIONEERIII tocol	784970501	1/21/2018		Frazier, Patrick	. RN.
PatientKeeper		0520-PIONEERI	78497082487	1/23/2018		Frazier, Patrick	. <u>BN</u>
Health Maintenance	Linitial Pro	tocol	70407100007	1/23/2018		Every Detriet	DN
OB Overview	L 016-130000	USZU-PIUNEERII Itocol	78497120887	1/23/2018		Frazier, Patrick	<u>. HN</u>
Ambulatos, Summan	016-130000 Lipitial Pro	0138-ENVISAGE	78497031421	1/23/2018		Frazier, Patrick	. <u>BN</u>
		(000)		1/23/2010			
Media Manager 🚽 Add							
Newborn Summary							
Blood Bank Info							
Neonate Summary							
Glucose Management View							
Patient Education Summary							
Perioperative Doc							
Insulin Calculator							
Provider View - Primary Care							
Pilot eSignature							
Encounter Summary							
Platinum VP							
naviHealth							
PowerTrials							

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:

HSISTEST, ATT	Age:65 years	Research:On Study	Gender:F	Loc:DOCUMENTATION
Isolation:	Portal:Active Account		DOB:11/10/1952	Fin#:
Allergies: Latex, Paper, Sulfamag	Blood Type:O POS		Weight:115.67 kg	MRN:000001710929

Orders Medication List

Cycle 19 Day 1 (Planned)

Cycle 20 Day 1 (Planned)

		View
		Research - W160325006 - UAB15
		Screening (Planned)
Ordering Physician		·· Cycle 1 Day 1 (Planned)
• , , <u> </u>		· Cycle 1 Day 12 (Planned)
Deeree 10/160225006 110 D15111	Finter the physician and	· Cycle 2 Day 1 (Planned)
Research - W100325000 - UABI5111		Cycle 2 Day 12 (Planned)
*Physician name	Protocol/Standing Order	Cycle 2 Day 21 (Planned)
	riotocot/standing order.	Cycle 3 Day 1 (Planned)
L		Cycle 4 Day 1 (Planned)
to I D (T'		Cycle 5 Day 1 (Planned)
"Order Date/Time		-Cycle 6 Day 1 (Planned)
01/29/2018 🔺 🚽 1151 🛋		Cycle 6 Day 21 (Planned)
	I he PowerPlan will	Cycle 7 Day 1 (Planned)
*Communication type		·· Cycle 8 Day 1 (Planned)
	appear under the	- Cycle 8 Day 21 (Planned)
Med Student		· Cycle 9 Day 1 (Planned)
Protocol/Standing Order	Orders tab in the View	Cycle 10 Day 1 (Planned)
VORB		Cycle 11 Day 1 (Planned)
Written	Menu in Impact under	Cycle 11 Day 21 (Planned)
Discern Expert	menta in impact ander	Cycle 12 Day 1 (Planned)
	Active orders	Cycle 15 Day 1 (Planned)
	Active orders.	Cycle 14 Day 21 (Planned)
OK Cancel		Cycle 15 Day 1 (Planned)
		Cycle 16 Day 1 (Planned)
		- Cycle 17 Day 1 (Planned)
		Cycle 17 Day 21 (Planned)
		Cycle 18 Day 1 (Planned)

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



ΟK

Cancel

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

HEIETEET	ATT		Age:65 years	Research:On Study	Gender: F			Δ++-		
TSISTEST,	ATT		Portal: Active Account	Research.on Study	DOR-11/10/1052		Ein#-	Documentation [No. Ad	mit dates «No Discharge dat	las 1
Allorging Lat	toy Danar Sulfan				Wojaht 74 ka		FIII#. MPN-00001710020	Bosus Status: Full Posussit	mit date> <no -="" dat<="" discharge="" td=""><td>(e>]</td></no>	(e>]
Allergies. La	tex, Paper, Sullan	nag l	siddu Type.0 POS		weight./4 kg		MRN.000001710929	Resus Status.Full Resuscit		
	ų.	< 👻 🕇 Orders							[D] Full screen 🛛 👘 Print	ninutes ag
nformation	^	PowerOrders								
ys Results									- Reconciliation Status	
IS		Add Reconciliation • Get External Rx Histor	y 🕶 Rx Plans (0): No Bene	efit Found •					Meds History 😲 Admission	n 🕒 Outpatient
lts		Orders Medication List								
ging Reports										
ssessment Resi	ults	View	📕 ∢ 🐺 Initiate 🛛	📄 Diagnoses 🔷 🕂 Add to	Phase - Start: Now .	. Duration: None				
(sacasificiti rest		Orders for Signature	\$ 7	Component		Status Dose	Details			
owser		Plans	Research - W160)325006 - UAB15111, Scree	ening (Planned Pending)					
ind Documents			Diagnoses: Brea	st cancer						
	E	DIFUED ONC Bevacizumab every 14 days	△ Laboratory	~						
		INFURO ONC Bevacizumab every 11 days		💆 CBC WITH DIFF			Routine collect, Blood, Q1			
sheet		Hedro Olic Devacizumab every 21 days		Prothrombin Time (PT)			Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
	Add			💆 PTT			Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
		- Research - W100325000 - UAB15111		🕎 Uric Acid Serum (Uric A	(cid)		Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
		Screening (Planned Pending)		Lactate Dehydrogenase	e (LDH)		Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
wser		Cycle 1 Day 1 (Planned Pending)		💆 Phosphorus Serum			Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
Waci		Cycle 1 Day 12 (Planned Pending)		💆 Magnesium Serum			Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
		Cycle 2 Day 1 (Planned Pending)		Comprehensive Metabo	olic Panel 2 (CMP)		Routine collect, Blood, Q1			
omary		Cycle 2 Day 12 (Planned Pending)		🖄 Urinalysis			Routine collect, W160325006; W160325006/6529200	069317/3161216		
		Cycle 2 Day 21 (Planned Pending)		Hepatitis B Surface Ant	igen		Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
on List	+ Add	- Cycle 3 Day 1 (Planned Pending)		HBc Total Ab (Hepatitis	B Core Total Antibody)		Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
ntation	Add	Cycle 4 Day 1 (Planned Pending)		Hepatitis C Antibody			Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
		Cycle 4 Day 21 (Planned Pending)		HCG Quant (HCG Prequence)	nancy Serum)		Routine collect, Blood, W160325006; W160325006/6	552920069317/3161216		
ewer		- Cycle 5 Day 1 (Planned Pending)		Draw and Hold Researc	h 10mL Tube		Routine collect			
		Cycle 6 Day 1 (Planned Pending)	⊿ Radiology	~						
		Cycle 6 Day 21 (Planned Pending)		MR Rsh Stringer Head v	vow W160325006 METR		W160325006; W160325006/652920069317/3161216			
laintenance		Cycle 7 Day 1 (Planned Pending)		CT Rsh Stringer Bdy wo	w W160325006 METRC		W160325006; W160325006/652920069317/3161216			
anager	🕂 Add	Cycle 8 Day 1 (Planned Pending)		T Rsh Stringer Chst we	ow W160325006 METR		W160325006; W160325006/652920069317/3161216			
		Cycle 8 Day 21 (Planned Pending)		NM Bone Screening Ro	utine Whole Body		W160325006; W160325006/652920069317/3161216			
Code		Cycle 0 Day 21 (Planned Pending)								
Summary		Cycle 9 Day 1 (Planned Pending)								
Summany		Cycle 10 Day 1 (Planned Pending)								
Summary		Cycle 11 Day 1 (Planned Pending)								
Summary		Cycle 11 Day 21 (Planned Pending)								
/iew		Cycle 12 Day 1 (Planned Pending)								
-		Cycle 13 Day 1 (Planned Pending)								
ory Summary		Cycle 14 Day 1 (Planned Pending)								
Communication		Cycle 14 Day 21 (Planned Pending)								
		Cycle 15 Day 1 (Planned Pending)	-							
mm			•							
lomm		Diagnoses & Problems	▲ Details							
omm		Related Results		0 . F.N. B.:]						
220/		Formulary Details		Urders For Nurse Review						Sign
liary										

Step 9: When a patient is scheduled for a visit

Select upcoming encounter

PTTESTING, J Age:37 years Gender:F	DOB:4/16/1980 Blood Type:	:	MRN:000060852537 Phone:(205)996-876 Portal:Never Invited	Research: 3	Fin#: BMI: Isolation:	Loc:DOCUM Weight:	MENTATION Resu Adva Fall	s Status:Full Re Inced Directive: Risk:	esus 5:	Documentation [Att: Allergies: Allergie	<no -="" admit="" date=""> <no -="" date="" discharge="">] :s Not Recorded</no></no>
Ę	🖣 < 🔿 🚽 👫 Orde	275									🗇 Full screen 🛛 👘 Print 🛛 🗞 0 minutes ago
	PowerOrders										
Summary ys Results	+ Add Reconciliat	Custom Informati	ion: PTTESTING, J							×	Reconciliation Status
s		Visit Type 1 Time OP	Location W2E	Est Arrive Date 2/1/2018 06:00:00	Admit Date	Discharge Date	FIN 680604308030	Service IM-5	Visit Reason ALICIA POWER PLAN TESTI	NG	Customize View
lts ying Reports ka ISite	- Orders for Signature - Plans - Suggested Plans (0)	Documentation 1 Time OP	DOCUMENTATION OPD	11/21/2017 08:00:00			680604307324	IM-5	SICK		
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formation	- Activity		GENERAL	INFORMATION							
	- Patient Care - Food and Nutri	Full Name:	PTTESTING, J	EMC:							
on Profile	Continuous Inf	D.O.S.:		Fin Number:							
sheet	- Meds Tx Comb	Nurse Unit:	DOCUMENTATION								
nmary	Laboratory	Room:									
wser	- Consults										
	- Respiratory Precautions										
are Summary ntation 🕈 Add	- Diagnostics/Pro										
	Administrative										
:y Summary	Medication History										
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Summary		Diagnoses & Proble	ems								
nk Info		Related Results	s	Dx Table Orders For	Nurse Beview						Show More Orders Orders Ser Simolyre
III 🕨		7 officiary Details									
											ABUILD ABM RTIN January 31, 2018 8:12

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

PowerOrders			
🕂 Add Reconciliation - 🛄 External Rx Histor	y 🗸 No Check 🔻	3	
I	🔹 🐼 Initiate	🗿 Diagnoses 🚫 🕂 Add to Phase 🗸 Start: Now 🛄 Duration: None 🛄	
View	\$ 7	Component Status Dose	Details
Orders for Signature	Research - W16	225006 - LIAR15111 Screening (Planned Pending)	becans
⊖ Plans	A Laboratory	525000 • OADISIII, Screening (Fianneu Fending)	
i Medical			Routine collect Blood O1
🖻 Research - W160325006 - UAB15111		Prothromhin Time (PT)	Routine collect, Blood, Q1
Screening (Planned Pending)			Routine collect, Blood, W160325006, W160
Cycle 1 Day 1 (Planned Pending)		Uric Acid Serum (Uric Acid)	Routine collect, Blood, W160325006; W160
- Cycle 1 Day 12 (Planned Pending)		Lactate Debydrogenase (LDH)	Routine collect, Blood, W160325006; W160
Cycle 2 Day 1 (Planned Pending)		Phosphorus Serum	Routine collect, Blood, W160325006; W160
Cycle 2 Day 12 (Planned Pending)		Magnesium Serum	Routine collect, Blood, W160325006; W160
Cycle 2 Day 21 (Planned Pending)		Comprehensive Metabolic Panel 2 (CMP)	Routine collect, Blood, Micosission, Micos
Cycle 3 Day 1 (Planned Pending)			Routine collect, W160325006, W160325006,
Cycle 4 Day 1 (Planned Pending) ≡	ସ	Hepatitis B Surface Antigen	Routine collect, Blood, W160325006; W160
Cycle 4 Day 21 (Planned Pending)	- -	HBc Total Ab (Hepatitis B Core Total Antibody)	Routine collect, Blood, W160325006; W160.
Cycle 5 Day 1 (Planned Pending)		Hepatitis C Antibody	Routine collect, Blood, W160325006; W160
Cycle 6 Day 1 (Planned Pending)		HCG Ouantitative (HCG Pregnancy Serum)	Routine collect, Blood, W160325006; W160.
Cycle 6 Day 21 (Planned Pending)		Draw and Hold Research 10mL Tube	Routine collect
Cycle 7 Day 1 (Planned Pending)	⊿ Radiology		
Cycle 9 Day 1 (Planned Pending)		MR Rsh Stringer Head wow W160325006 METR	W160325006; W160325006/652920069317/3
Cycle 8 Day 1 (Planned Pending)		CT Rsh Stringer Bdy wow W160325006 METRC	W160325006; W160325006/652920069317/3
Cycle 8 Day 21 (Planned Pending)		CT Rsh Stringer Chst wow W160325006 METR	W160325006; W160325006/652920069317/3
Cycle 9 Day 1 (Planned Pending)	V	MM Bone Screening Routine Whole Body	W160325006; W160325006/652920069317/3

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 <u>policies@uabmc.edu</u> with PowerPlan in the Word document format, used for validation.

• And has been uploaded to OnCore:



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 <u>powertrials@uabmc.edu</u>
- 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

Cycle 5 Day 1 (Planned)
Cycle 6 Day 1	Discontinue
- Cycle 6 Day 21	Void
- Cycle 7 Day 1	Replicate
Cycle 8 Day 1	Diagnoses
Cycle 8 Day 21	
Cycle 9 Day 1 (Plan Information
Cycle 10 Day 1	Print >
Cycle 11 Day 1	(Planned)

Research - W160325006 - UAB15111 Screening (Completed) Screening (Completed) Cycle 1 Day 1 (Discontinued) Cycle 1 Day 12 (Discontinued) Cycle 2 Day 12 (Discontinued) Cycle 2 Day 12 (Discontinued) Cycle 2 Day 21 (Completed) Cycle 3 Day 1 (Discontinued) Cycle 4 Day 1 (Discontinued) Cycle 4 Day 21 (Discontinued) Cycle 5 Day 1 (Discontinued)



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.



-- Cycle 5 Day 1 (Planned) -- Cycle 5 Day 1 (Planned Pending)

	\$	Ÿ		Component
Res	earch - W	/160	325	006 - UAB15111, Cycle 5 Day 1 (Pl
⊿	Laborato	Ŋ		
$\mathbf{\nabla}$			7	CBC WITH DIFF
\Box			7	Uric Acid Serum (Uric Acid)
			7	Lactate Dehydrogenase (LDH)
\Box			7	Phosphorus Serum
			Ø	Magnesium Serum



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

o FAQs!

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



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Clinical Trials Administrative Office

INVESTIGATORS
Clinical Billing Review
Greenphire
Monitor Access to EHR
OnCore Enterprise
Policies/Procedures
PowerTrials
Updates
Resources
FAQs

PowerTrials

PowerTrials is a module of Cerner Millennium (IMPACT at UAB), that provides dual functionality for individuals involved with the research process: indication of patient's participation in a research study in the banner bar (that is connected to a research summary) and a research specific PowerPlan, that contains study-required Lab and Radiology procedures, with automated billing (to either the patient's insurance or the study). The banner bar will provide an extra level of patient safety at the point of care to indicate to health care professionals campus-wide that the patient is enrolled in a clinical trial. Research specific PowerPlans will cut out the step of having to enter each individual order, for each protocol required visit, and will automate billing, streamlining the process for the Research Nurse Coordinator.



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

