

IMPACT User Flow A Day in the Life

Human Factors October, 2014

John selects project 1850 because he sees an alert that calls him to investigate. FYI: He could have moused over the red triangle icon to get information about the alert.

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▼ Saved Sets

Projects

Projects Map

- ▲ Filters
- ♥ Projects
- ▼ Trials
- ▼ Trial Countries
- ▼ Trial Sites

Take Action 🛛 Reference Description Product/ All Trials ID Type Status Therapuetic Area Device Setup 1850 Holoid-1 Lorem Ipsum Cardiovascular... Lorem Ipsum... Lorem Ipsum Lorem Ipsum Yes 1993 Shen-3 Lorem Ipsum... Lorem Ipsum Lorem Ipsum Dermatology Lorem Ipsum Yes 4576 Australia... Lorem Ipsum... Lorem Ipsum Lorem Ipsum Infectious Dise... Lorem Ipsum Yes



View By w.



John selects project 1850 because he sees an alert that calls him to investigate. FYI: He could have moused over the red triangle icon to get information about the alert.

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▼ Saved Sets	Projects
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▼ Trials	

▼ Trial Countries

▼ Trial Sites

e Action 🐨 to Trials Product/ All Trials erence Description Type Status Therapuetic mmary Analysis Area Device Setup tailed Analysis Holoid-1 Lorem Ipsum 1850 Lorem Ipsum... Lorem Ipsum Cardiovascular... Lorem Ipsum Yes 1993 Shen-3 Lorem Ipsum... Lorem lpsum Lorem Ipsum Dermatology Lorem Ipsum Yes 4576 Australia... Lorem Ipsum... Lorem Ipsum Lorem Ipsum Infectious Dise... Lorem Ipsum Yes



The trials for project 1850 display and John sees that the problem lies with Trial 1. He takes stock of the new iconography for Primary Center Name and sees the relation to the new icons displayed on the map for trials.

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▼ Saved Sets

Project > 1850 : Trials

- ▲ Filters
- ▼ Projects
- ▼ Trials
- ▼ Trial Countries





To start his analysis, John mouses over the Description cell for Trial 1 (interaction is evident from the ellipses trailing after the first words of the description. A layer is displayed providing full details about Trial 1. This layer could be sectioned off for better reading and could also included links to take action based on the description.

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▼ Saved Sets

Project > 1850 : Trials

▲ Filters

♥ Projects

- ▼ Trials
- ▼ Trial Countries

▼ Trial Sites

ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Phase	Product/ Device	Project Reference
Trial 3	England 💌	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	4	Lorem Ipsum	Lorem Ipsum
Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology	3	Lorem Ipsum	Lorem Ipsum
Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum		Infectious Dise	3	Lorem Ipsum	Lorem Ipsum

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At this point John mouses over the red triangle icon/cell for Trial 1 and gets information about the problem that raised the alert for Trial 1. The user can click the cell to get cell visualizations, click the blue square to reveal Primary center information, or click the red triangle to reveal alert information. The same multiple views can be achieved by making a selection from View By in the map section.

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- ▼ Saved Sets
- ▲ Filters
- ♥ Projects
- ▼ Trials
- ▼ Trial Countries

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	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Phase	Product/ Device	Project Reference
	Trial 3	England 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	4	Lorem Ipsum	Lorem Ipsum
	Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem lpsum	Lorem Ipsum	Dermatology	3	Lorem Ipsum	Lorem Ipsum
	Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum		Infectious Dise	3	Lorem Ipsum	Lorem Ipsum

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Project > 1850 : Trials





Project > 1850 : Trials

ID

John now understands more about Trial 1 without ever having left the page. He has investigated the description, understands the Therapeutic Area, what phase the trial is in, what geographic area the trial covers, and what constitutes the alert/problematic aspect of trial 1.

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- ▼ Saved Sets
- ▲ Filters
- ♥ Projects
- ▼ Trials
- ▼ Trial Countries
- ▼ Trial Sites

He then clicks the Trial ID cell for Trial 1 and sees specifically where the problem lies apparanhically, and in relation to the other areas of the trial

tion *		nes ge	ographically, a						
	Countries	Alias	Description	investigator	Primary Center Name	Therapuetic Area	Phase	Product/ Device	Project Reference
Trial 3	England 💌	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	4	Lorem Ipsum	Lorem Ipsum
Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology	3	Lorem Ipsum	Lorem Ipsum
Trial 1	Australia_ 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum		Infectious Dise	3	Lorem Ipsum	Lorem Ipsum



Saved Sets

Project > 1850 : Trials

▲ Filters

▼ Projects

- ▼ Trials
- Trial Countries

▼ Trial Sites

ID .	Countries	Allas	Description	Investigator	Center Name	Area	Phase	Device	Refere
Trial 3	England 🛛 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	4	Lorem Ipsum	Lorem
Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology	3	Lorem Ipsum	Lorem
Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum		Infectious Dise	3	Lorem Ipsum	Lorem

John mouses over France on the map, drawn there by the red indicator coloring the country, and a tooltip is displayed that provides summary information about subject recruitment delay.



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Project > 1850 : Trials > Trial 1 : Countries

▲ Filters

Projects

- ▼ Trials
- ▼ Trial Countries

Trial Sites

Project > 1850 : Trials >

e Action ▼								
Countries	Primary Contact	Primary Investigator	All Sites Set Up	Planned # Sites	Actual # Sites	Confirmed Sites	Unconfirmed Sites	TRC add. item
France	Wes Anders	Dole Bailey	No	50	5	3	1	Lorem Ipsum
Germany	Jennifer Fion	Richard Hoon	No	50	5	2	2	Lorem Ipsum

France and Germany are displayed with their associated alerts, which can be moused to derive more information. John understands the primary contact s and primary investigators for each country as well as other meaningful information. He is also dynamically presented with a map view that focuses on the related countries and shows the actual # of sites for each country. John could also have selected both countries in the previous map view to get this same page view. Whatever user interaction takes place in the map or the table effects the other.



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- ▲ Filters
- ▼ Projects
- Trial Countries

▼ Trial Sites

Project > 1850 : Trials > Trial 1 : Countries

John didn't make any changes to the table, but he does click the checkbox associated with France to access site information.

Take /	Action 🔻								
	Countries	Primary Contact	Primary Investigator	All Sites Set Up	Planned # Sites	Actual # Sites	Confirmed Sites	Unconfirmed Sites	TRC add. item
	France	Wes Anders	Dole Bailey	No	50	5	3	1	Lorem Ipsum
	Germany	Jennifer Fion	Richard Hoon	No	50	5	2	2	Lorem Ipsum



Lorem Ipsum

Lorem Ipsum

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aved Sets	Project > 1850 : Tria	als > Trial 1 :	Countries
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nters	Go to Sites		
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France

Germany

Wes Anders...

Jennifer Fion...

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Richard Hoon... No

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▼ Trials

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Trial Countries

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John didn't make any changes to the table, but he does click the checkbox associated

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▼ Saved Sets	Project > 1850 :	Trials > Trial 1	: Countries > F	rance : Sites							Ŷ
▲ Filters	Take Action 🔻										
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▼ Trials											
- Thild control of	Site One	397a	France	Lorem Ipsum	Dole Bailey	Wes Anders	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
 Trial Countries 	Site Two	be45	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
▼ Trial Sites	Site Three	2341	France	Lorem Ipsum	Dole Bailey	Wes Anders	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
	Site Four	397a	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
	Site Five	be45	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
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Project > 1850 : Trials > Trial 1 : Countries > France : Sites



- ▼ Projects
- Trial Countries
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	Site One	397a	France	Lorem Ipsum	Dole Bailey	Wes Anders	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ip
Ī	Site Two	be45	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ip
	Site Three	2341	France	Lorem Ipsum	Dole Bailey	Wes Anders	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ip
Ī	Site Four	397a	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ip
Ī	Site Five	be45	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ip



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Project > 1850 : Trials > Trial 1 : Countries > France : Sites

▲ Filters

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	Site Name 🚔	Client ID	Country	Site Reference	Primary Investigator	Primary Contact	Trial Site Status	Confirmed Status	Subjects Set Up	Recommended By Data Source	Alliance Site
1.	Site One	397a	France	Lorem Ipsum	Dole Bailey	Wes Anders	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
	Site Two	be45	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
	Site Three	2341	France	Lorem Ipsum	Dole Bailey	Wes Anders	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
	Site Four	397a	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
	Site Five	be45	France	Lorem Ipsum	Dole Bailey	Wes Anders	3	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum

John now clicks a specific site pin in France and detailed SAE information is reported to him. Note that the cell for site three is also selected when he clicks the related site pin. If he had clicked Site Three in the grid, the information layer would have been displayed from there and the pin would have highlighted on the map.



PAREXEL John decides that for Site Three, he wants to take the action of <u>{</u> Project > 1850 : Trials > Trial 1 : Countries > France : Sites Saved Sets calling the Primary Investigator, Dole Bailey. He mouses over the Take Action 🛛 🔻 respective cell and gets all the information he needs. ▲ Filters ded Alliance Site Name 🍦 Client ID Country Site Prir The phone icon has a drop down arrow for multiples – work, Reference rce Site Projects Inv mobile, fax. Email is next, then location/address, and finally chat. Note that chat is diffuse because Dole is not online/available to chat. Colors could be used as well Trials Dole Lorem Ipsum Site One 397a France Lorem Ipsum Trial Countries be45 France Dole Bailey... Wes Anderso Lorem Ipsum No Site Two Lorem Ipsum Lorem Ipsum Lorem Ipsum Site Three 2341 France Lorem Ipsum Dole Bailey... Wes Anders... 4 Lorem Ipsum No Lorem Ipsum Lorem Ipsum Trial Sites France No Site Four 397a Lorem Ipsum 9 Lorem Ipsum Lorem Ipsum Lorem Ipsum

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Project > 1850 : Trials > Trial 1 : Countries > Australia : Sites Map

France

Site Five

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Serious Adverse Events SAEs 🤝

Lorem Ipsum

Lorem Ipsum

John User Program Manager 🔻

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New Trial/Edit Trial

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♥ Projects

- ▼ Trials
- ▼ Trial Countries

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▼ Trial Sites



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John User Program Manager 🝷 PAREXEL IMPACT :03 ▼ Saved Sets Project > 1850 : Trials ▲ Filters Primary Center Lookup **?** X ▼ Projects New Trial 👂 Primary Center Lookup Center Number Town/City ▼ Trial Countries Province/State/County Center Short Name Ŧ ▼ Trial Sites Center Department Country Ŧ Ŧ Clinical Personel 8 Purpose

Available Center Locations

	Number	Short Name	Center	Department	Location	Address	Town/ City	Province/ State/County	Country	Location/ Purpose	Committee Type
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Search

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Project > 1850 · Trials

▲ Filters

♥ Projects

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▼ Trial Sites

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	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Phase	Product/ Device	Project Reference
	🖉 Trial 3	England 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	4	Lorem Ipsum	Lorem Ipsum
	Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology	3	Lorem Ipsum	Lorem Ipsum
	Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum		Infectious Dise	3	Lorem Ipsum	Lorem Ipsum



Saved Sets Filters Edit Trial	Project > 1850 : Trials	Normally, the Edit Trial information. Also note that Therape set at the project level	modal page would be pre-popu utic Area would be protected fro	ulated with om change if	2 X	\$
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Trial Vendors and Contacts (Existing Look and Feel)



Browser > Active Substance > Clinical Plan > Trial

🍫 Trial	New Tria	l Sponsors					
Trial Summary	Clinical Pla 10582	n Number	Clinical Plan Referenc HOLOID-1	e Description To establish the efficacy	of holotaxel in various tumours		
New Trial Country	Trial Numb	er	Trial Alias	Trial Description			
Trial Parameters	11025 Trial Status	5	HOLOID-ABC-1	Advanced breast cancer	, holotaxel vs. mitoxantrone		
Plan for Trial	► 1st Patier	nt 1st Visit					
People	Single Count	try Trial					
Company Personnel	Select	Sponsor Code	Sponsor Name	Sponsor Company	Address	Country	
Responsibilities		PHY4	Phytopharm Incorporated France	Phytopharm Incorporated France	28 Rue Blanc Paris	France	
Sponsor and Contacts		PHY5	Phytopharm Incorporated Italy				
Trial Configuration	clear	cancel				sa	ave

September 1, 2014

Browser > Active Substance > Clinical Plan > Trial

-								
	🎨 Trial	Trial Sponse	or and Contacts				Set Name: My Trials	
Ē	Trial Summary	Clinical Plan N	umber Clinic	al Plan Reference	Descripti	ion		
		10582	HOLO	ID-1	To establi	sh the efficacy of holotaxel in various tur	nours	
	New Irial Country	Trial Number	Trial	Alias	Trial Des	cription		
	Trial Parameters	11025	HOLO	ID-ABC-1	Advanced	breast cancer, holotaxel vs. mitoxantron	ne	
		Trial Status						
	Plan for Trial	1st Patient 1s	t Visit					
	People	Single Country T	Trial					
	Company Personnel	new sponsor						
	Responsibilities							
	Sponsor and Contacts	Sponsor Code	Sponsor Name	Sponsor Company		Address	Country	
1	Trial Configuration	PHY2	Phytopharm Incorporated Egyp	Phytopharm Incorporated E	gypt	25 Large Pyramid Cairo	Egypt	sponsor
	****			12345678901234567890123	34567890			contacts
	Design					40 Carriage Lane Burnsville Minnesota	United States of	sponsor
	Tracking	PHY3	Phytopharm Incorporated USA	Phytopharm Incorporated U	JSA	55306	America	contacts
	Management							

Sponsor

Phytopharm Incorporated Egypt

new contact											
Contact Name	Contact	Telephone/Fax	Role	E-mail							
Mr B Spender	01902 694837 ext 109	01792 678477 (mobile) 01902 694838 (fax)	Financial Controller	me@myemail.com	<u>details</u>						
Mr A Spender	01902 694837 ext 105	01902 694837 ext 105	Finance Director	me2@myemail.com	<u>details</u>						
close											

ber 1, 2014		Session time remaining: 00:15	:00	C	urrent Version / Bu
r > <u>Active Substance</u> > <u>Clinical Plan</u>	> <u>Trial</u>				
Trial	Trial Sponsor Contact	Details			
Trial Commence	Clinical Plan Number	Clinical Plan Reference	Description		
Trial Summary	10582	HOLOID-1	To establish the efficacy of holotaxel in	various tumours	
New Trial Country	Trial Number	Trial Alias	Trial Description		
Trial Parameters	11025	HOLOID-ABC-1	Advanced breast cancer, holotaxel vs. r	nitoxantrone	
	Trial Status				
Plan for Trial	1st Patient 1st Visit				
People	Single Country Trial				
Company Personnel	Sponsor				
Responsibilities	Phytopharm Incorporated Egy	pt			
Sponsor and Contacts					
Trial Conference	Contact Details				
Trial Configuration	Code	1	Reference	REF567	
Design	Name	Mr N Droid	Country	Egypt	
Tanakina	Job Title	Lead Trial Co-ordinator			
Tracking	Role	Principal investigator			
Management					
Monitoring	Responsibilities				
сст					
CST					
Document and Pack Tracking	Contact	01902 345346	Telephone (Work)	01902 345345	
dek fracklig	E-mail	narioa@notonplanet.com	Telephone (Mobile)	01902 345345	
Reports	rax	01902 345345	relephone (Home)	01902 345345	
	close				edit

Current Version / Build

Browser > Active Substance > Clinical Plan > Trial

P	🔖 Trial	Т	rial Sponsor Contact Upda	te					
ě	Trial Summary	Cli 10	inical Plan Number	Clinical Plan Reference HOLOID-1	Description To establish the efficacy of holotaxel in various tumours				
	New Trial Country	/ Tr	rial Number	Trial Alias	Trial Description				
Ī	Trial Parameters	11 Tr	.025 rial Status	HOLOID-ABC-1	Advanced breast cancer, holotaxel vs. mitoxantrone				
	Plan for Trial	•	1st Patient 1st Visit						
	People	Sir	ngle Country Trial						
	Company Person	nel S	ponsor						
	Responsibilities	Ph	nytopharm Incorporated Egypt						
	Sponsor and Con	tacts	contact Details						
	Trial Configura	tion Co	ode	1	Reference	REF567			
	Design	Na	ame	Mr N Droid	Country	Egypt			
	Tracking	Jo Ro	ob Title ole	Lead Trial Co-ordinator Principal investigator [PI]					
	Management								
	Monitoring	Pe	esponsibilities						
	сст	K	caponalonnica						
	сят								
	Document and	Pack Tracking Co	ontact		Telephone (Work)	01902 345345			
		E-	mail	ndriod@notonplanet.com	Telephone (Mobile)	01902 345345			
	iiiii Keports	Fa	ax	01902 345345	Telephone (Home)	01902 345345			

Trial Delay/Cancel/Stop



▲ Filters

▼ Projects

▼ Trials

▼ Trial Countries

▼ Trial Sites

Tal	ke Action 👻										
	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Trial Configuration New Trial New Trial Country Design	T S T T	rial Customization ave Set able Column Displa op/Bottom Display	
	Trial 3	England 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	Delay/Cancel Stop Personnel	5 E	Export/Print Display	
	Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology				
	Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum		Infectious Dise	3	Lorem Ipsum	Lorem Ipsum	



IMPACT				John User Program Ma	nager 🔻	PAREXEL
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▼ Projects	Delay/Cancel/Stop >	layer with status of ch	langes, who made them, and when.			
▼ Trials	Project ID	Ŧ	Authorized By:	▼		um .
▼ Trial Countries	Protocol ID	$\overline{\nabla}$	Internal 🔾	External 🔿 Both 🔿		.m
▼ Trial Sites	Country	Ŧ	Role	Ψ		m
	Trial Site	$\overline{\mathbf{v}}$	Personnel #	▼		
	Event Type	V	Name	Ψ		
	Event Date YYYY	▼ DD ▼	Title	Ψ		
			Medical Unit	▼		
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Company Personnel Assign to Study and Maintain Master File

If the user selected a trial and then clicked Personnel from the Configuration & Customization menu (or any link for that matter), the modal that displays - in this case Personnel - would be contextual to the selection with the trial details filled in on the form. John User Program Manager 🔻

PAREXEL

- Saved Sets
- ▲ Filters
- ▼ Projects
- ▼ Trials
- Trial Countries

Pr	Project > 1850 : Trials contextual to the selection with the trial details filled in on the form.							Configuration & Customi	tion & Customization			
	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Trial Configuration New Trial New Trial Country Design	Trial Customization Save Set Table Column Display Top/8ottom Display			
	Trial 3	England 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	Delay/Cancel Stop Personnel	Export/Print Display			
	Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology					
	Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Infectious Dise	3 Lorem I	psum Lorem Ipsum			

▼ Trial Sites


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Tr Project ID	~	, Trial Coun	try	Ŧ	
Protocol ID	٧	Trial S	ite	Ψ	"Copy to" checkboxes are context sensitive. If you select
				Search	a study country, only the site checkbox would be enabled.
		Security			Copy to
Name	Trial Role	Role	Start Date	End Date	Studies Countries Sites
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IMPACT						John User Prog	ıram Manager 🔻	PAR	EXEI
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Tr Project ID 12	3456	T	Trial Country	United Stat	es	v			
Protocol ID		Ŧ	Trial Site		ĺ	▼ Search			
0	Next, user d tool to look f	ecides to use Lookup or personnel to assign.	Security		6	5-10-4-	Copy to	- C irc	
Richard S	mith v	Global Admin 🔻	n/a	٣	10-Sep-2014 V	10-Sep-2015 V		s sites	
Patricia S	utton 🔻 ዖ	Global Admin 👻	n/a	v	10-Sep-2014 🔻	10-Sep-2015 🔻			
Daniel Th	omas 🔻 P	Global Admin 🔻	n/a	Ŧ	10-Sep-2014 ♥	10-Sep-2015 🔻			
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 Trial Countries 	Maintain Company Personnel Company Personnel Lookup		im
▼ Trial Sites	Trial Role Last Name	Medical Unit Medical Unit Oliternal External Both	im
		Search	

Available Company Personnel

C	ID	Title	Last Name	First Name	Medical Unit	Trial Role	Notes

Add Selected

▼ Sa	ived Sets	Project > 1850 : Trials		\$ <u>0</u> }
▲ Fi	Personnel	User has closed Lookup modal.	0	х
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▼ Tr	Assign to Study	O Maintain Master File		
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	Protocol ID	▼ Trial Site ▼		
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▼ Trial (Assign to Study	Maintain Master File		
▼ Trial S	First Na	ame	Last Name*	

User Name		Company Personnel Number		
Trial Role		٩	🔿 Internal 🔿 External 🔿 Both	
Business Unit	▼	8		Search

0	Company Personnel No	Name	Trial Role Code	Business Unit	Discontinued Flag	
🥖 🙁	12345	Mr. Arthur Bentley	No Occupation Security	Business Unit 1		*
🥖 🙁	45678	Dr. Cooper Davis	Update Allowed	Business Unit 2		
/ 0	12347	Mr. Thomas Grant	Database Administrator	Business Unit 3		
0 🖉	56789	Mr. Peter Jackson	No Occupation Security	Business Unit 4		=
0	12349	Dr. Michelle Klein	Update Allowed	Business Unit 5		
0	98765	Mr. Paul Martins	Database Administrator	Business Unit 6		
0	12351	Mr. Stephen Perkins	No Occupation Security	Business Unit 7		-

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	Company Personn	Clinical Personnel Import P	Personnel					- 1
▼ Trial (Assign to Study 	 Maintain Master File 						
▼ Trial S	First Nan	Martin	Last Name*	Cooper				
	User Nan)е	Company Personnel Number			User enters a first and name, and clicks Searc	ast h button:	
	Trial Ro	le	8	🔘 Internal 🔘 External	 Both 			-

Company Personnel No Name 12345 Mr. Arthur Bentley No Occupation Security Business Unit 1 45678 Dr. Cooper Davis Update Allowed Business Unit 2 Database Administrator 12347 Mr. Thomas Grant Business Unit 3 56789 Mr. Peter Jackson No Occupation Security Business Unit 4 Dr. Michelle Klein Update Allowed 12349 Business Unit 5 Mr. Paul Martins Database Administrator Business Unit 6 98765 12351 Mr. Stephen Perkins Business Unit 7 No Occupation Security •

▼ P

Business Unit

Search

IMP	ACT						John User Program Manager 🕚	PAR	EXEI
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	•		Company Personnel No	Name	Trial Role Code	Business Unit	Discontinued Flag		
	/ O		45678	Dr. Cooper Davis	Update Allowed	Business Unit 2			
	/ O		98765	Mr. Paul Martins	Database Administrator	Business Unit 6			

IMP	AC System opens the Add Company Personnel modal.				John U	lser Program Manager 🔻	PAREXEL
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▼ Proje ▼ Trials	Company Personnel No.	Title 🔻 Initials	
▼ Trial (First Name Martin	Last Name Cooper	
▼ Trial	User clicks on first accordion to expand it.	Discontinuation Date	
	 Other Names 		
	Title 2	ν.	
	First Name 2	Last Name 2	
	Title 3	F Lot Name 2	
	First Name 3	Last Name 3	
	▼ Contact Details		
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Trials Company Personnel No. Eirst Name Martin	lat Name	Cooper	 Initials 	
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Primary Address	Address Line 2			
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State/County Country/Code	Postal ZIP Code			
Telephone No.	Email Address			- 1
Telephone No. 2	Email Address 2			
Telephone No. 3	Email Address 3			
Telephone No. 4	Email Address 4			
Telephone No. 5	Email Address 5			
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▼ Trial (First Name	Martin	Last Name	Cooper			
▼ Trial S	Discontinued Flag		Apply Discontinuation Date	YYYY V MM V DD	•	1	
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	accordion to expand it.						
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	Security Role Code	v	Business Unit		~		
						User can save or o information.	clear
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Clinical Personnel Assign to Study and Maintain Master File

If the user selected a trial and then clicked Personnel from the Configuration & Customization menu (or any link for that matter), the modal that displays - in this case Personnel - would be contextual to the selection with the trial details filled in on the form. John User Program Manager 🔻

PAREXEL

- Saved Sets
- ▲ Filters
- ▼ Projects
- ▼ Trials
- Trial Countries

Pr	oject > 1850 : 1	Trials cor	ntextual to the	selection with	n the trial deta	ails filled in on	the form.	Configuration & Customi	zation	ŝ
	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Trial Configuration New Trial New Trial Country Design	Trial Customization Save Set Table Column Display Top/8ottom Display	
	Trial 3	England 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	Delay/Cancel Stop Personnel	Export/Print Display	
	Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology			
	Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Infectious Dise	3 Lorem I	psum Lorem Ipsum	

▼ Trial Sites



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▲ Fil	Personnel	User next selects Clinical Personnel tab.	J				Ø	х
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	0	Ы	Name	Trial Role	Role	Start Date	End Date	Studies	Countries	Sites
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John User Program Manager 🝷 PAREXEL

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0		ID	Name	Primary Role	Town/City	Country Code	Discont.	Center Clinical Personnel	Specialist Fields	Therapeutic Interest	
/ 🤇		248	Dr. Adam Browne	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest	^
/ 🤇		205	Charles Daniels	Nurse	Rio de Janeiro	Brazil - [BRA]	Yes	Center Clinical Personnel	Specialist Fields	Therapeutic Interest	
/ 🤇		246	Dr. Isaac Francis	Sub Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest	
/ 🕻		515	Mr. Peter Johnson	Administrator		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest	1
/ 🤇		471	Michelle Jones	Nurse		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest	
/ 🤇		247	Dr. Amy Martins	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]	Yes	Center Clinical Personnel	Specialist Fields	Therapeutic Interest	
/ 🤇		207	Dr. Allen Matthews	Pr. Investigator	Belo Horizonte	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest	Ŧ

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0		ID	Name	Primary Role	Town/City	Country Code	Discont.	Center Clinical Personnel	Specialist Fields	Therapeutic Interest
/ 🤇		248	Dr. Adam Browne	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
/ 🤇		205	Charles Daniels	Nurse	Rio de Janeiro	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
1		246	Dr. Isaac Francis	Sub Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
1		515	Mr. Peter Johnson	Administrator		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
0		471	Michelle Jones	Nurse		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
1		247	Dr. Amy Martins	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
0		207	Dr. Allen Matthews	Pr. Investigator	Belo Horizonte	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest

11	ЛРA	ACT									John User P	Program	Manager 🔻 🛛	PARI	EXE
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		/ 0		248	Dr. Adam Browne	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fi	ields	Therapeutic Inf	terest	
		/ 🛛		515	Mr. Peter Johnson	Administrator		Brazil - [BRA]		Center Clinical Personnel	Specialist Fi	ields	Therapeutic Inf	terest	

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	Telephone No. 2				Email Address 2							
	Telephone No. 3				Email Address 3							
	Telephone No. 4				Email Address 4							
	Telephone No. 5				Email Address 5							
	Preferred Language			V	Time Zone					Ŧ		18
	Best contact time	Monday		Telephor	ne 🔻							
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	Other Names User clicks on fourth accordion to expand it.		•					
	▲ Other Details							
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	 Medical Licenses 							
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▼ Saved	Sets F	Project > 1850 : Trials							ŝ
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	 Other Names Contact Details 								
t	User clicks on fifth accordion to expand it.								
	 Medical Licenses 								_
	Medical License No. Medical License Status		Me	dical License Country ovince/State/			▼ ▼		
	Medical License Expiration Date	YYYY V MM V DD V		Checked	Last updated by	Mr. Henry Higgins 10	-Jul-2014		
	Licensing Body			Delete		Add another	license		
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John User Program Manager 🝷 PAREXEL

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	Province/State/Co	ounty		Postal ZIP Code		v			
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		ID	8						

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(o	ID	Name	Primary Role	Town/City	Country Code	Discont.	Center Clinical Personnel	Specialist Fields	Therapeutic Interest
0	3	248	Dr. Adam Browne	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
0	8	205	Charles Daniels	Nurse	Rio de Janeiro	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
1	8	246	Dr. Isaac Francis	Sub Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
1	3	515	Mr. Peter Johnson	Administrator		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
1	8	471	Michelle Jones	Nurse		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
0	3	247	Dr. Amy Martins	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
1	3	207	Dr. Allen Matthews	Pr. Investigator	Belo Horizonte	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest

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John User Program Manager 🔻 PAREXEL

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	Province/State/County	Ŧ	Therapeut	tic Interest			•	
	Country		Spec	ialist Field				
	Potential Investigator Yes 🔻					Se	arch	
	Available Clinical Personnel							
	Quality & Trial		Financi	al Town/	Province/			
	Compliance Experience ID	Name	Investigator Disclos	ure City	State/County	Country		
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Import Personnel

If the user selected a trial and then clicked Personnel from the Configuration & Customization menu (or any link for that matter), the modal that displays - in this case Personnel - would be contextual to the selection with the trial details filled in on the form. John User Program Manager 🔻

PAREXEL

- Saved Sets
- ▲ Filters
- ▼ Projects
- ▼ Trials
- Trial Countries

Pr	oject > 1850 : 1	Trials cor	ntextual to the	selection with	n the trial deta	ails filled in on	the form.	Configuration & Customi	zation	ŝ
	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Trial Configuration New Trial New Trial Country Design	Trial Customization Save Set Table Column Display Top/8ottom Display	
	Trial 3	England 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	Delay/Cancel Stop Personnel	Export/Print Display	
	Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology			
	Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Infectious Dise	3 Lorem I	psum Lorem Ipsum	

▼ Trial Sites



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IMPACT

▼ Saved Sets

▲ Filters

- ▼ Projects
- ▼ Trials

▼ Trial Sites

 Project > 1850 : Trials
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 Dohn Program Manager selects "To Master File" radio button, then browses and submits a file.
 Import Personnel

 To Study
 To Master File

 Select File
 Browse
 Submit

Filename	Created By	Date Uploaded	Time	Outcome
BulkUpload_Valid_Data.xls	test_user40	28-Sept-2014	12:00 EDT	Incomplete
BulkUpload_Valid_Data.xls	test_user35	28-Sept-2014	12:00 EDT	Validation Failed
BulkUpload_Valid_Data.xls	test_user30	28_Sept-2014	12:00 EDT	Completed
BulkUpload_Valid_Data.xls	test_user25	28_Sept-2014	12:00 EDT	Validation Failed
BulkUpload_Valid_Data.xls	test_user20	28_Sept-2014	12:00 EDT	Completed
BulkUpload_Valid_Data.xls	test_user15	28_Sept-2014	12:00 EDT	Completed
BulkUpload_Valid_Data.xls	test_user10	28_Sept-2014	12:00 EDT	Validation Failed

Saved Sets Project > 1850 : Trials			If the user selected a trial and then clicked Personnel from the Configuration & Customization menu (or any link for that matter), the modal that displays – in this case Personnel – would be	PARE	PAREXE	
			contextual to the selection with the trial details filled in on the form.		\$03	
Filters	Personnel		8	x		
 Projects 	Company Pe	ersonnel Clinical Perso	onnel Import Personnel			
r Trials	Import Personnel	▶ BulkUpload_Valid_Data.xls		- 1		
Trial Cou	🔿 To Study	 To Master File 				
	Protocol ID: PI45	6778 Created By: test_user40	Date Uploaded: 28-Sept-2014 Time: 12:00 EDT Outcome: Completed			

Name	Email		eClinicalRole	Trained	Sites	
Mr. Arthur Bentley	a.bentley@csc.com	+1 978 456-7890	Nurse	Yes	Central State Clinic	Completed
Dr. Cooper Davis	cooper.davis@lh.com	+1 978 456-7891	Sub Investigator	n/a	London Hospital	Validation Failed
Mr. Thomas Grant	t.grant@nyh.com	+1 978 456-7892	Administrator	Yes	New York Hospital	Completed
Mr. Peter Jackson	peter.jackson@ph.com	+1 978 456-7893	Nurse		Paris Hospital	Validation Failed
Dr. Michelle Klein	m.klein@uxbr.com	+1 978 456-7894	Pr. Investigator	Yes	Uxbridge Hospital	Completed
Mr. Paul Martins	paul.martins@fh.com	+1 978 456-7895	Pr. Investigator	n/a	Frankfurt Hospital	Completed
Mr. Stephen Perkins	s.perkins@berlinh.com	+1 978 456-7896	Pr. Investigator	Yes	Berlin Hospital	Validation Failed

Trial Design

▼ Saved Sets

▲ Filters

- ▼ Projects
- ▼ Trials
- ▼ Trial Countries

	Pro	Project > 1850 : Trials						Configuration & Customization			
		ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area	Trial Configuration New Trial New Trial Country Design	Trial Customization Save Set Table Column Display Too Bottom Display	
		Trial 3	England 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Cardiovascular	Delay/Cancel Stop Personnel	Export/Print Display	
		Trial 2	United St 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Dermatology	1 closen cl		
1.		Trial 1	Australia 🔻	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Lorem Ipsum	Infectious Dise	3 Lorem Ip	sum Lorem Ipsum	

▼ Trial Sites


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NEXT STEPS

I think we need to start adding **MASTER DATA** functions – see P21 of Requirement Specification for MyTrials CORE Module (V0.7)

Company Personnel Clinical Personnel Centres Ethics Boards Vendors Investigational Products