IMPACT User Flow

A Day in the Life

Human Factors
October, 2014

IMPACT

John User Program Manager

PAREXEL

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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Projects

Take Action

	ID	Reference	Description	Type	Status	Therapuetic Area	Product/ Device	All Trials Setup
	1850	Holoid-1	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...	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

Projects Map

View By

IMPACT

John User Program Manager

PAREXEL

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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Projects

Take Action

Go to Trials
Summary Analysis
Detailed Analysis

		erence	Description	Type	Status	Therapuetic Area	Product/ Device	All Trials Setup
	1850	Holoid-1	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...	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

Projects Map

View By

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r Program Manager ▾ PAREXEL

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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Take Action

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

Project > 1850 : Trials Map

View By

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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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Take Action

	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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Project > 1850 : Trials Map

View By

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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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Take Action

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

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat.

Project > 1850 : Trials Map

View By

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- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Take Action

Now John clicks the blue primary center icon related to Trial 1, and reveals the scope of Trial 1 with associated primary centers for each country

				Description	Primary Investigator	Primary Center Name	Therapuetic Area	Phase	Product/ Device	Project Reference
				orem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...	4	Lorem Ipsum	Lorem Ipsum
	rial 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

Countries where Trial 1 is taking place.

Project > 1850 : Trials Map

View By

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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.

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

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

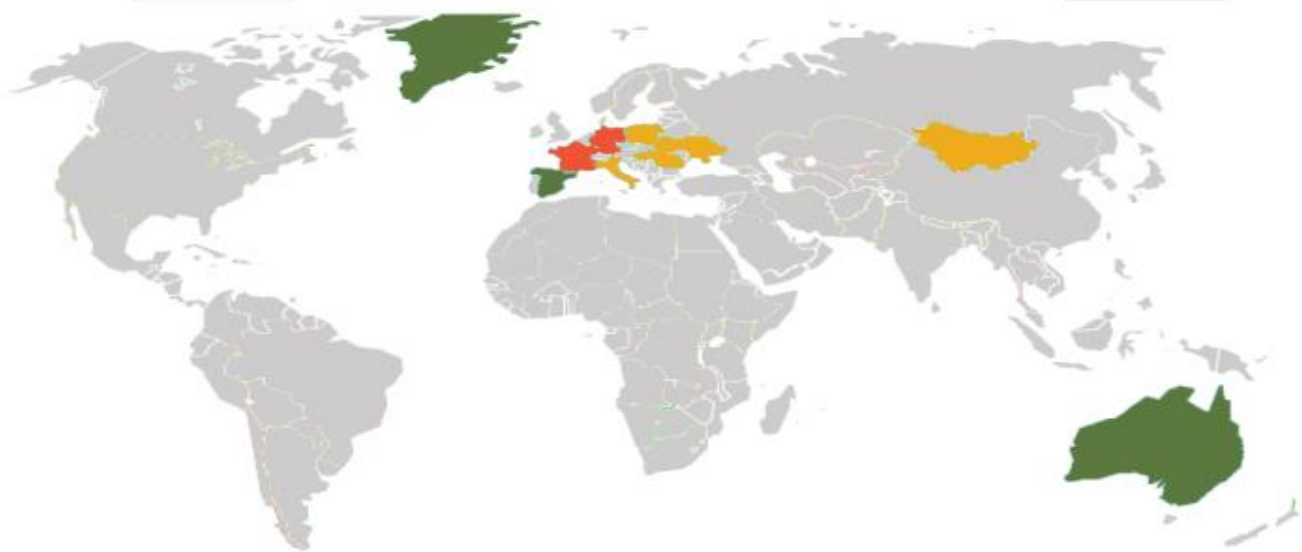
Project > 1850 : Trials

Take Action

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

Project > 1850 : Trials Map

View By



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John User Program Manager

PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

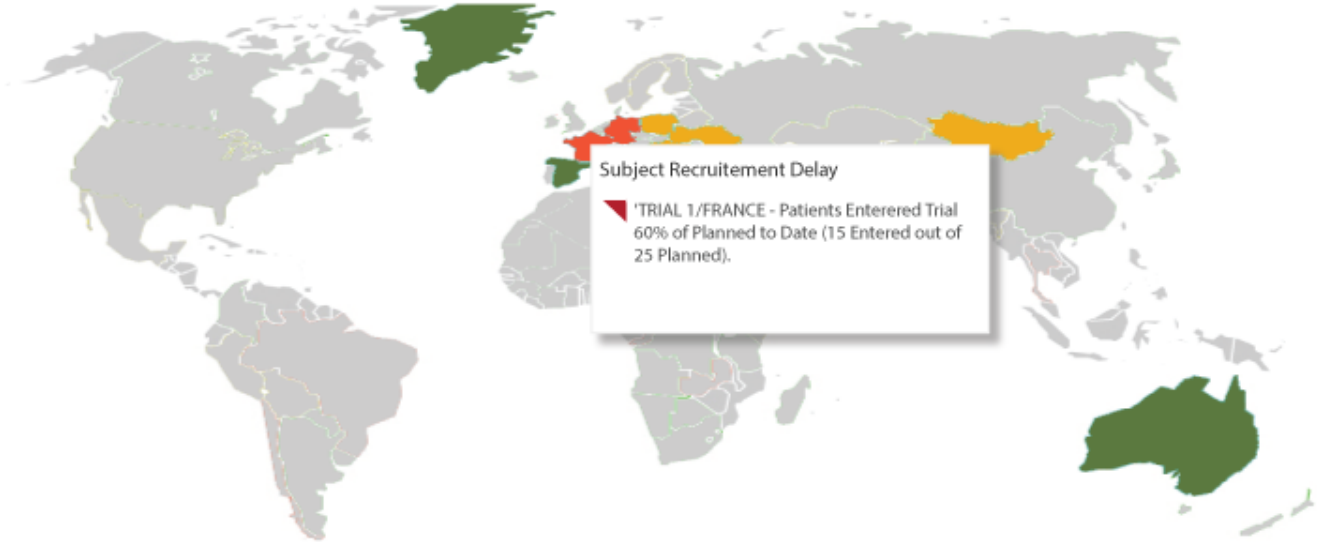
Take Action

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

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.

Project > 1850 : Trials Map

View By



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- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Take Action

	ID	Countries	Alias	Description	Primary	Primary	Therapeutic	Phase	Product/ Device	Project Reference
	Trial 3	England	Lorem Ipsum						Lorem Ipsum	Lorem Ipsum
	Trial 2	United St...	Lorem Ipsum						Lorem Ipsum	Lorem Ipsum
	Trial 1	Australia...	Lorem Ipsum	Lorem Ipsum...			Infectious Dise...	3	Lorem Ipsum	Lorem Ipsum

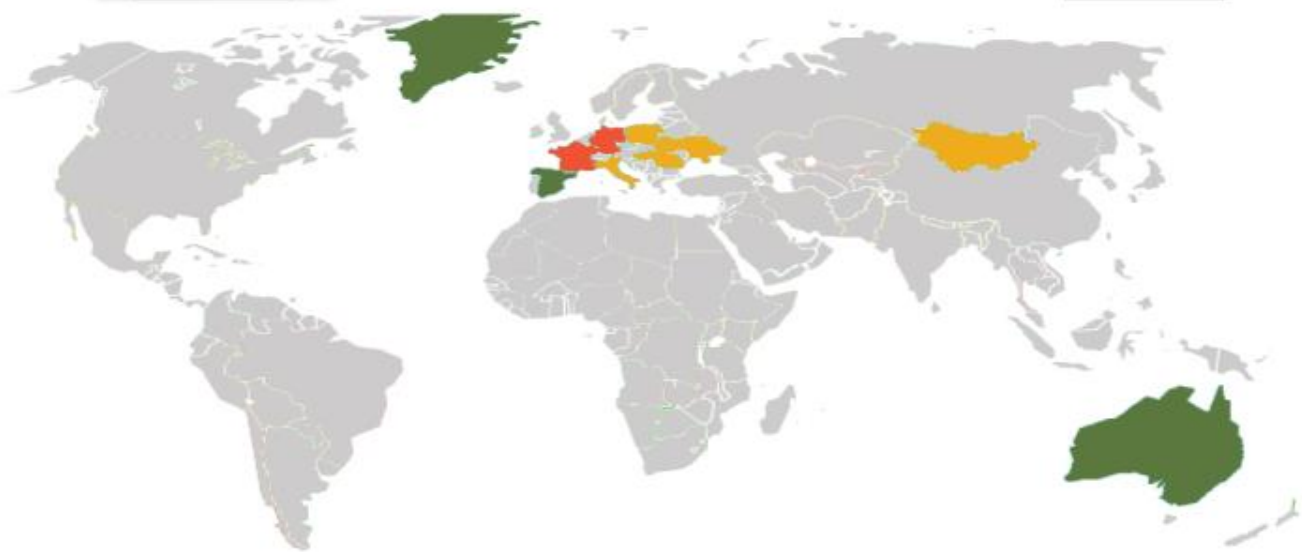
Now that John understands the trials problematic countries, he selects those countries from the associated drop-down list to get more information (effectively drilling in with confidence) in a comparative format.

- Australia
- Belarus
- France
- Germany
- Greenland
- Italy
- Mongolia
- Poland

Go

Project > 1850 : Tr...

View By



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- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials > Trial 1 : Countries

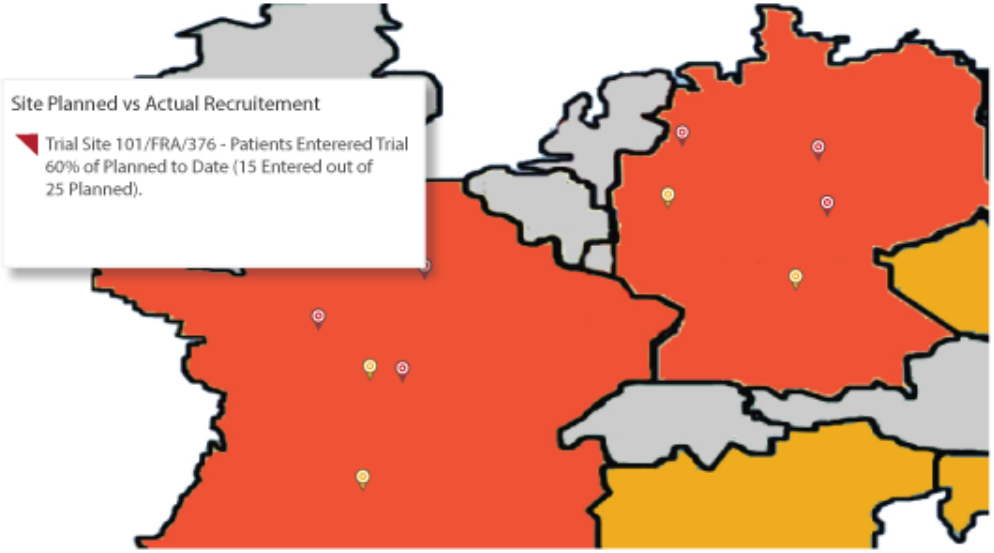
Take Action

	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

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.

Project > 1850 : Trials > Trial 1 : Countries Map

View By



IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials > Trial 1 : Countries

Take Action

	Countries	Primary Contact	Primary Investigator	All Sites Set Up	Planned # Sites	Actual # Sites	Confirmed Sites
	France	Wes Anders...	Dole Bailey...	No	50	5	3
	Germany	Jennifer Fion...	Richard Hoon...	No	50	5	2

Configuration & Customization

Trial Configuration

- New Trial
- New Trial Country
- Design
- Delay/Cancel Stop
- Personnel

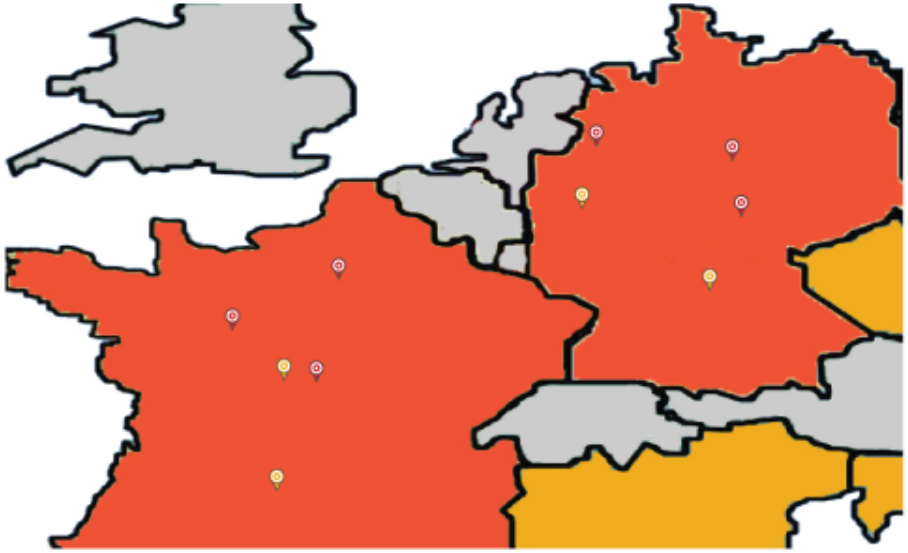
Trial Customization

- Save Set
- Table Column Display
- Top/Bottom Display
- Export/Print Display

John now checks the configuration for the system and his view by clicking the cog icon. He decides to look at what other informational table columns are available so he clicks Table Column Display.

Project > 1850 : Trials > Trial 1 : Countries Map

View By



IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials > Trial 1 : Countries

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

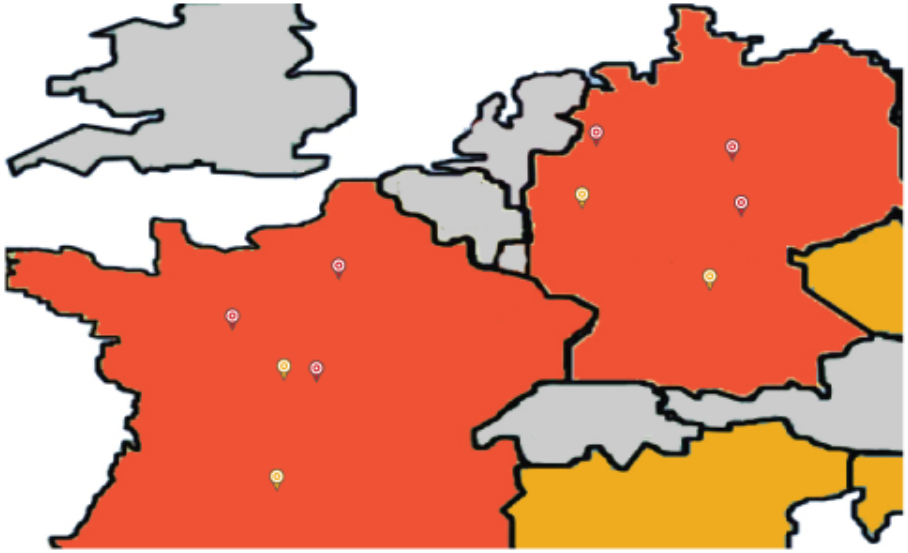
- Countries
- Primary Contact
- Principal Investigator
- All Sites Set Up
- Planned # Sites
- Actual # Sites
- Confirmed Sites
- Unconfirmed Sites
- TRC add. item
- TRC add. item
- TRC add. item
- TRC add. item

The Table Column Display menu is presented. John can return to the previous main configuration menu by clicking the arrow. He can deselect currently displayed columns or select additional columns for display to enhance his personal experience. He can also reorder the columns by dragging the items in the list to reorder or he can simply move the columns in the table to different positions.

Selections/deselections made here are automatically saved by the system.

Project > 1850 : Trials > Trial 1 : Countries Map

View By



IMPACT

John User Program Manager

PAREXEL

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

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

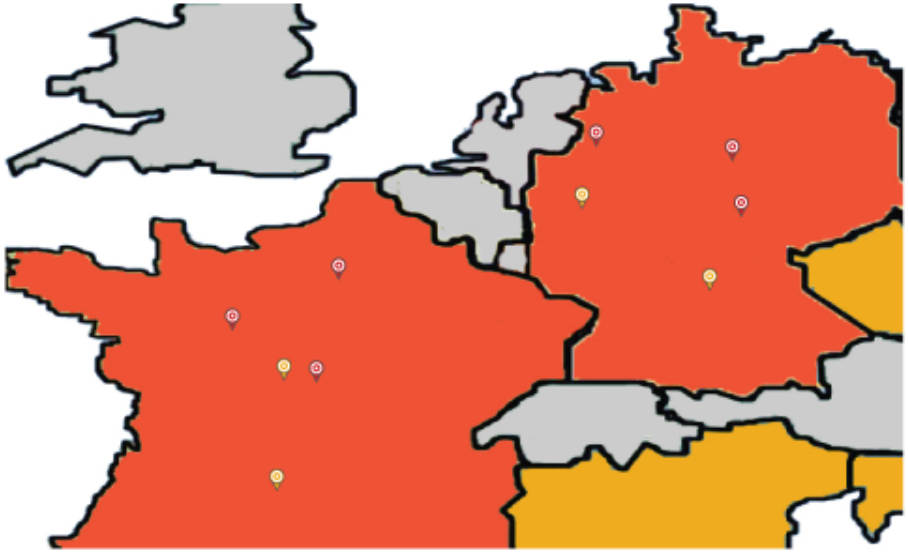
Project > 1850 : Trials > Trial 1 : Countries

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

Project > 1850 : Trials > Trial 1 : Countries Map

View By



IMPACT

John User Program Manager

PAREXEL

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

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials > Trial 1 : Countries

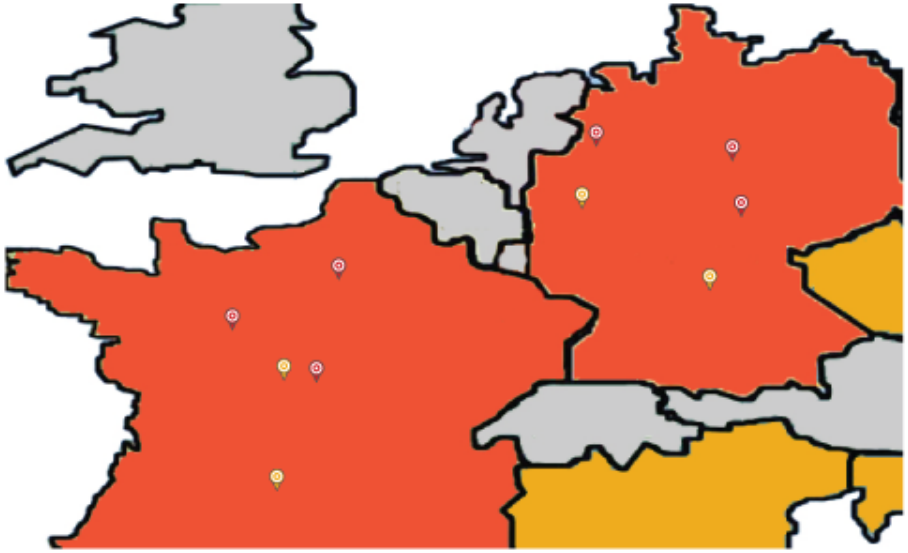
Take Action

Go to Sites
Summary Analysis
Detailed Analysis

		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

Project > 1850 : Trials > Trial 1 : Countries Map

View By



IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

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

Take Action

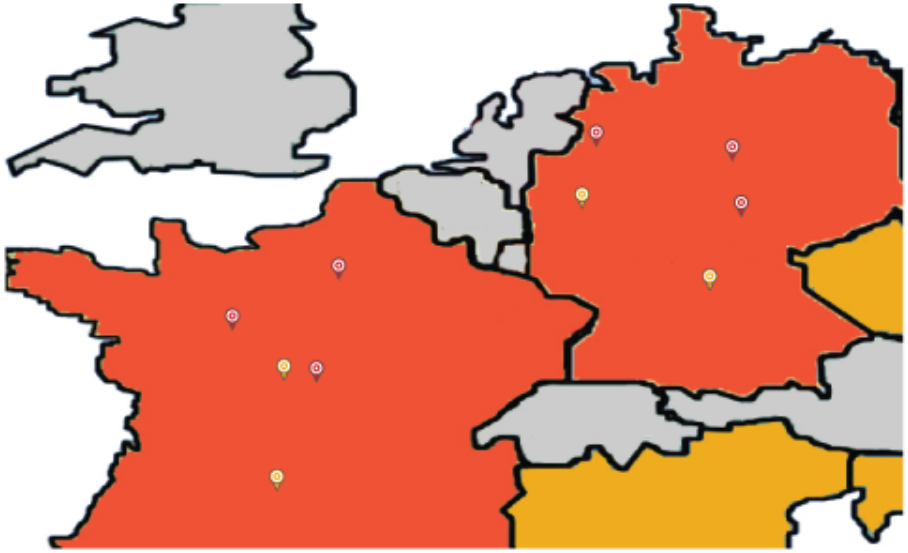
Site Name	Client ID	Country	Site Reference	Primary Investigator	Primary Contact	Trial Site Status	Confirmed Status	Subjects Set Up	Recommended By Data Source	Alliance Site
Site One	397a	France	Lorem Ipsum	Dole Bailey...	Wes Anders...	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
Site Two	be45	France	Lorem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

The specific sites located in in France are displayed and John can use all of the tools and concepts previously detailed to investigate the sites view.

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

Map

Serious Adverse Events SAEs



IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

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

Take Action

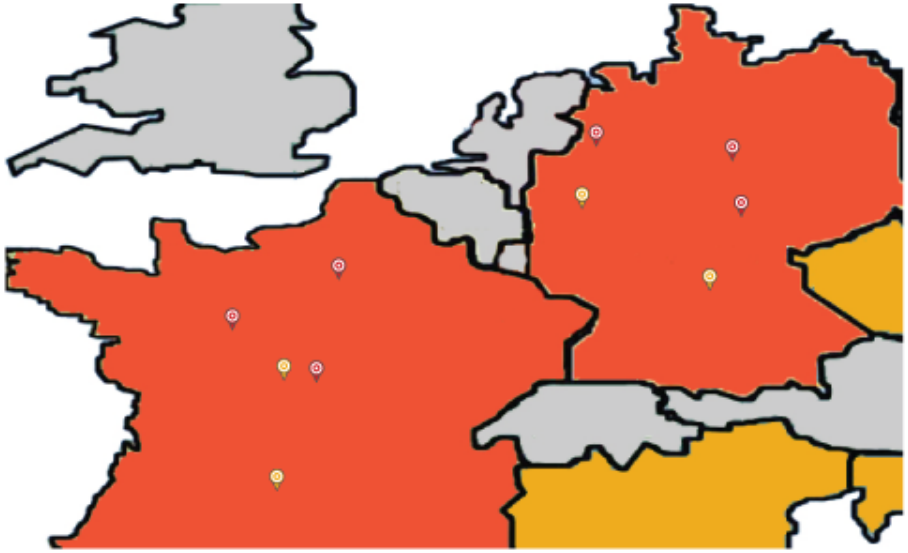
Site Name	Client ID	Country	Site Reference	Primary Investigator	Primary Contact	Trial Site Status	Confirmed Status	Subjects Set Up	Recommended By Data Source	Alliance Site
Site One	397a	France	Lorem Ipsum	Dole Bailey...	Wes Anders...	4	Lorem Ipsum	No	Lorem Ipsum	Lorem Ipsum
Site Two	be45	France	Lorem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

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

Map

View By

- Serious Adverse Events (SAEs)
- Issues
- Site Enrollment



IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

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

Take Action

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
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.

Project > 185

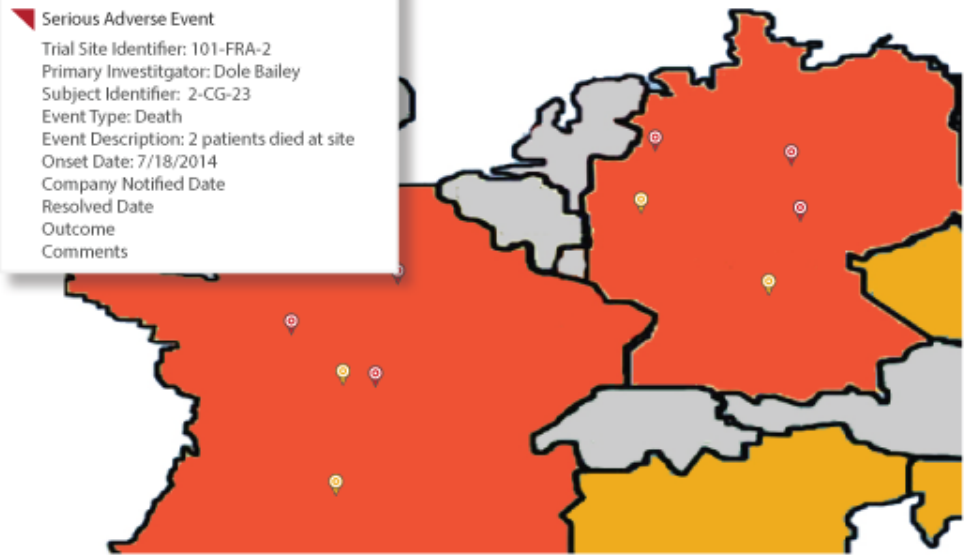
Map

Serious Adverse Events SAEs

Site Three

Serious Adverse Event

Trial Site Identifier: 101-FRA-2
Primary Investitgator: Dole Bailey
Subject Identifier: 2-CG-23
Event Type: Death
Event Description: 2 patients died at site
Onset Date: 7/18/2014
Company Notified Date
Resolved Date
Outcome
Comments



IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

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

Take Action

Site Name	Client ID	Country	Site Reference	Pri Inv						Alliance Site
Site One	397a	France	Lorem Ipsum	Dole					m	Lorem Ipsum
Site Two	be45	France	Lorem Ipsum	Dole Bailey...	Wes Ander	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				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

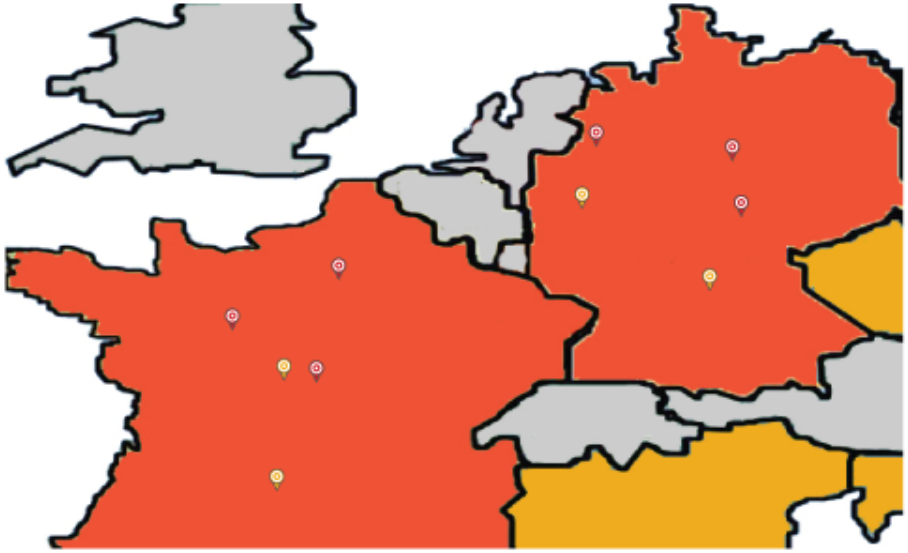
John decides that for Site Three, he wants to take the action of calling the Primary Investigator, Dole Bailey. He mouses over the respective cell and gets all the information he needs.

The phone icon has a drop down arrow for multiples – work, 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

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

Map

Serious Adverse Events SAEs



Alternate Course of Pursuit

IMPACT

John User Program Manager ▾ PAREXEL

▲ Saved Sets

Set A [default] ■

Set B □

Set C □

▲ Filters

▼ Projects

▲ Trials

Trial 1
Trial 2
Trial 3
Trial 4
Trial 5
Trial 6
Trial 7
Trial 8
Trial 9
Trial 10

▲ Trial Countries

Australia
Belarus
France
Germany
Greenland
Italy
Mongolia
Poland
Romania
Ukraine

▼ Trial Sites

Project > 1850 : Trials > Trial 1 : Countries

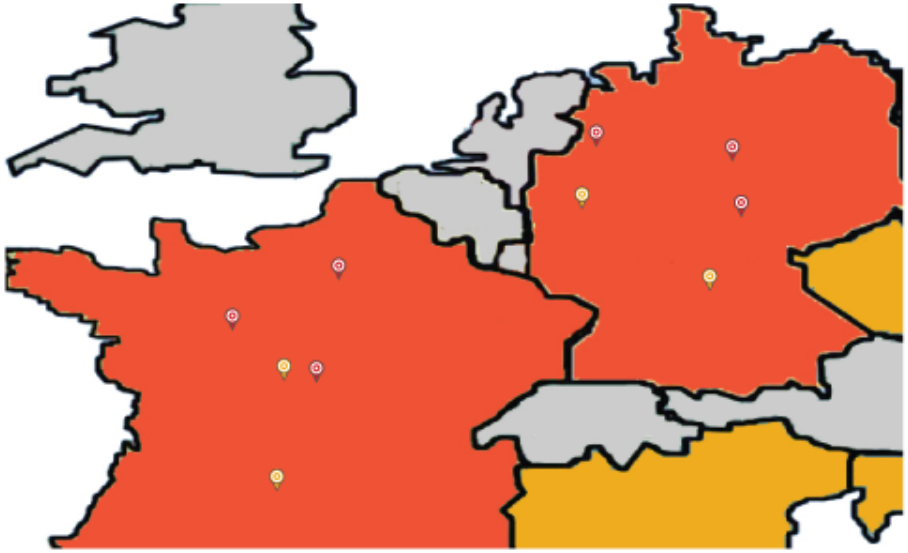
Take Action

	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

Alternatively to the previous flow, John could have pursued this course at first login. In this view, John already has saved sets and pursues an analysis of France and Germany as part of Trial 1 in Project 1850 by effecting the left-hand filtering to instantly display that specific view. He does not pursue the more granular course of drilling in by directly effecting the table and map. Both scenarios have their merit and purpose. They are dependent on need, knowledge level, and efficiency.

Project > 1850 : Trials > Trial 1 : Countries Map

Serious Adverse Events SAEs



New Trial/Edit Trial

IMPACT

John User Program Manager ▼ PAREXEL

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

Project > 1850 : Trials

Take Action ▼

	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area
	Trial 2	United St... ▼	Lorem Ipsum	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Dermatology
	Trial 1	Australia... ▼	Lorem Ipsum	Lorem Ipsum...	Lorem Ipsum		Infectious Dise...

Configuration & Customization

Trial Configuration

- New Trial
- New Trial Country
- Design
- Delay/Cancel Stop
- Personnel

Trial Customization

- Save Set
- Table Column Display
- Top/Bottom Display
- Export/Print Display

Project > 1850 : Trials Map ▼

View By ▼

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

New Trial

X

New Trial ▸

Protocol ID *

Trial External ID

Description *

Primary Investigator

Primary Center

Special Name

Investigational Product Development Name

Project Reference

Single Country Trial ☐ Single Unit Trial ☐ Last Country Setup ☐

Therapeutic Area

Phase

Trial Type Code

Comments

Create

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Primary Center Lookup

X

New Trial ▸ Primary Center Lookup

Center Number

Center Short Name

Center Department

Purpose

Town/City

Province/State/County

Country

Clinical Personel

Search

Available Center Locations

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

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Clinical Personnel Lookup

X

New Trial ▸ Primary Center Lookup ▸ Clinical Personnel Lookup

Personnel Number

First Name

Town/City

Province/State/County

Country

Potential Investigator Yes

Center

Last Name

Therapeutic Interest Group

Therapeutic Interest

Specialist Field

Investigator List

Search

Available Clinical Personnel

Quality & Compliance	Trial Experience	Number	Name	Investigator	Financial Disclosure	Town/ City	Province/ State/County	Country

IMPACT

John User Program Manager ▼ PAREXEL

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

Project > 1850 : Trials

Trial 3 has been successfully created. X

Take Action ▼

	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

Project > 1850 : Trials Map ▼

View By ▼

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets
Filters
Projects
Trials
Trial Countries
Trial Sites

Project > 1850 : Trials

Normally, the Edit Trial modal page would be pre-populated with information.

Also note that Therapeutic Area would be protected from change if set at the project level

Edit Trial

X

New Trial

Protocol ID *

Protocol Title *

Description *

Primary Investigator

Primary Center

Special Name

Investigational Product Development Name

Project Reference

Single Country Trial ☐ Single Unit Trial ☐ Last Country Setup ☐

Therapeutic Area

Phase

Trial Type Code

Historic Trial ☐ Ready to Enroll ☐ Ready to Exchange ☐

Authors Author 1 × Author 2 ×

Comments

Finish

Trial Vendors and Contacts
(Existing Look and Feel)

IMPACT® | browser | contacts | visits | cct | cst | misc | reminder summary | reminder list | overview | rdt | investigator | refere

September 1, 2014 | Session time remaining: 00:15:00 | Current Version / Build

Browser > Active Substance > Clinical Plan > **Trial**

menu

- **Trial**
  - Trial Summary
  - New Trial Country
  - Trial Parameters
  - Plan for Trial
- **People**
  - Company Personnel
  - Responsibilities
  - Sponsor and Contacts
- **Trial Configuration**

New Trial Sponsors

Clinical Plan Number	Clinical Plan Reference	Description
10582	HOLOID-1	To establish the efficacy of holotaxel in various tumours
Trial Number	**Trial Alias**	**Trial Description**
11025	HOLOID-ABC-1	Advanced breast cancer, holotaxel vs. mitoxantrone
Trial Status		
1st Patient 1st Visit		

Single Country Trial

Select	Sponsor Code	Sponsor Name	Sponsor Company	Address	Country
☑	PHY4	Phytopharm Incorporated France	Phytopharm Incorporated France	28 Rue Blanc Paris	France
☑	PHY5	Phytopharm Incorporated Italy			

clear | cancel | save

IMPACT® | browser | contacts | visits | cct | cst | misc | reminder summary | reminder list | overview | rdt | investigator | refere

September 1, 2014 | Session time remaining: 00:15:00 | Current Version / Build

Browser > Active Substance > Clinical Plan > **Trial**

menu

- **Trial**
  - Trial Summary
  - New Trial Country
  - Trial Parameters
  - Plan for Trial
- **People**
  - Company Personnel
  - Responsibilities
  - Sponsor and Contacts
- **Trial Configuration**
- **Design**
- **Tracking**
- **Management**

Trial Sponsor and Contacts

Set Name: My Trials

Clinical Plan Number	Clinical Plan Reference	Description
10582	HOLOID-1	To establish the efficacy of holotaxel in various tumours
Trial Number	**Trial Alias**	**Trial Description**
11025	HOLOID-ABC-1	Advanced breast cancer, holotaxel vs. mitoxantrone
Trial Status		
1st Patient 1st Visit		

Single Country Trial

new sponsor

Sponsor Code	Sponsor Name	Sponsor Company	Address	Country	
PHY2	Phytopharm Incorporated Egypt	Phytopharm Incorporated Egypt 1234567890123456789012345678 90	25 Large Pyramid Cairo	Egypt	sponsor contacts
PHY3	Phytopharm Incorporated USA	Phytopharm Incorporated USA	40 Carriage Lane Burnsville Minnesota 55306	United States of America	sponsor contacts

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	details
Mr A Spender	01902 694837 ext 105	01902 694837 ext 105	Finance Director	me2@myemail.com	details

close

Trial Sponsor Contact Details

Clinical Plan Number	Clinical Plan Reference	Description
10582	HOLOID-1	To establish the efficacy of holotaxel in various tumours
Trial Number	**Trial Alias**	**Trial Description**
11025	HOLOID-ABC-1	Advanced breast cancer, holotaxel vs. mitoxantrone

Trial Status
1st Patient 1st Visit

Single Country Trial

Sponsor

Phytopharm Incorporated Egypt

Contact Details

Code	1	**Reference**	REF567
Name	Mr N Droid	**Country**	Egypt
Job Title	Lead Trial Co-ordinator		
Role	Principal investigator		
Responsibilities			
Contact	01902 345346	**Telephone (Work)**	01902 345345
E-mail	ndriod@notonplanet.com	**Telephone (Mobile)**	01902 345345
Fax	01902 345345	**Telephone (Home)**	01902 345345

close | edit

September 1, 2014 | Session time remaining: 00:15:00 | Current Version / Build

Browser > Active Substance > Clinical Plan > Trial

menu
- Trial
  - Trial Summary
  - New Trial Country
  - Trial Parameters
  - Plan for Trial
- People
  - Company Personnel
  - Responsibilities
  - Sponsor and Contacts
- Trial Configuration
- Design
- Tracking
- Management
- Monitoring
- CCT
- CST
- Document and Pack Tracking
- Reports

Trial Sponsor Contact Update

Clinical Plan Number	Clinical Plan Reference	Description
10582	HOLOID-1	To establish the efficacy of holotaxel in various tumours
Trial Number	**Trial Alias**	**Trial Description**
11025	HOLOID-ABC-1	Advanced breast cancer, holotaxel vs. mitoxantrone

Trial Status
1st Patient 1st Visit

Single Country Trial

Sponsor

Phytopharm Incorporated Egypt

Contact Details

Code	1	**Reference**	REF567
Name	Mr N Droid	**Country**	Egypt
Job Title	Lead Trial Co-ordinator		
Role	Principal investigator [PI]		
Responsibilities			
Contact		**Telephone (Work)**	01902 345345
E-mail	ndriod@notonplanet.com	**Telephone (Mobile)**	01902 345345
Fax	01902 345345	**Telephone (Home)**	01902 345345

clear | cancel | save

Trial Delay/Cancel/Stop

IMPACT

John User Program Manager ▼ PAREXEL

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

Project > 1850 : Trials

Take Action ▼

	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area			
	Trial 3	England ▼	Lorem Ipsum	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...			
	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

Configuration & Customization

Trial Configuration

- New Trial
- New Trial Country
- Design
- Delay/Cancel Stop
- Personnel

Trial Customization

- Save Set
- Table Column Display
- Top/Bottom Display
- Export/Print Display

Project > 1850 : Trials Map

View By ▼

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Delay/Cancel/Stop

X

Project and Trial ID will be pre-populated. Change History displays a flyout layer with status of changes, who made them, and when.

Delay/Cancel/Stop ▸

Project ID

Protocol ID

Country

Trial Site

Event Type

Event Date YYYY MM DD

Authorized By:

Internal External Both

Role

Personnel #

Name

Title

Medical Unit

Reason

Change History

Finish

Company Personnel

Assign to Study and Maintain Master File

IMPACT

John User Program Manager

PAREXEL

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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area			
	Trial 3	England	Lorem Ipsum	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...			
	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 Ipsum	Lorem Ipsum

Configuration & Customization

Trial Configuration

- New Trial
- New Trial Country
- Design
- Delay/Cancel Stop
- Personnel

Trial Customization

- Save Set
- Table Column Display
- Top/Bottom Display
- Export/Print Display

Project > 1850 : Trials Map

View By

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

Assign to Study | Maintain Master File

Project ID

Protocol ID

Trial Country

Trial Site

Search

"Copy to" checkboxes are context sensitive. If you select a study country, only the site checkbox would be enabled.

	Name	Trial Role	Security Role	Start Date	End Date	Copy to		
						Studies	Countries	Sites

Add All

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

User has filled some data fields and clicked search.

Assign to Study | Maintain Master File

Project ID: 123456

Trial Country: United States

Protocol ID:

Trial Site:

Search

Next, user decides to use Lookup tool to look for personnel to assign.

Name	Trial Role	Security Role	Start Date	End Date	Copy to Studies	Copy to Countries	Copy to Sites
Richard Smith	Global Admin	n/a	10-Sep-2014	10-Sep-2015			
Patricia Sutton	Global Admin	n/a	10-Sep-2014	10-Sep-2015			
Daniel Thomas	Global Admin	n/a	10-Sep-2014	10-Sep-2015			

Add All

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

System opens Lookup modal.

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

Maintain Company Personnel ▸ Company Personnel Lookup

Trial Role

Medical Unit

Last Name

Internal External Both

Search

Available Company Personnel

	ID	Title	Last Name	First Name	Medical Unit	Trial Role	Notes

Add Selected

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

User has closed Lookup modal.

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

◉ Assign to Study ○ Maintain Master File

Project ID: 123456

Trial Country: United States

Protocol ID:

Trial Site:

Search

	Name	Trial Role	Security Role	Start Date	End Date	Copy to Studies	Copy to Countries	Copy to Sites
	Richard Smith	Global Admin	n/a	10-Sep-2014	10-Sep-2015			
	Patricia Sutton	Global Admin	n/a	10-Sep-2014	10-Sep-2015			
	Daniel Thomas	Global Admin	n/a	10-Sep-2014	10-Sep-2015			

Add All

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Filter

Proje

Trials

Trial

Trial

Project > 1850 : Trials

Personnel

X

Company Personnel

User next selects Maintain Master File

port Personnel

Assign to Study

Maintain Master File

First Name

Last Name*

User Name

Company Personnel Number

Trial Role

Internal External Both

Business Unit

Search

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	
12347	Mr. Thomas Grant	Database Administrator	Business Unit 3	
56789	Mr. Peter Jackson	No Occupation Security	Business Unit 4	
12349	Dr. Michelle Klein	Update Allowed	Business Unit 5	
98765	Mr. Paul Martins	Database Administrator	Business Unit 6	
12351	Mr. Stephen Perkins	No Occupation Security	Business Unit 7	

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Filter

Proje

Trials

Trial

Trial

Project > 1850 : Trials

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

○ Assign to Study ◉ Maintain Master File

First Name: Martin

Last Name*: Cooper

User Name:

Company Personnel Number:

Trial Role:

○ Internal ○ External ○ Both

Business Unit:

Search

User enters a first and last name, and clicks Search button

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	
12347	Mr. Thomas Grant	Database Administrator	Business Unit 3	
56789	Mr. Peter Jackson	No Occupation Security	Business Unit 4	
12349	Dr. Michelle Klein	Update Allowed	Business Unit 5	
98765	Mr. Paul Martins	Database Administrator	Business Unit 6	
12351	Mr. Stephen Perkins	No Occupation Security	Business Unit 7	

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Filter

Proje

Trials

Trial

Trial

Project > 1850 : Trials

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

○ Assign to Study ◉ Maintain Master File

Last Name* Cooper

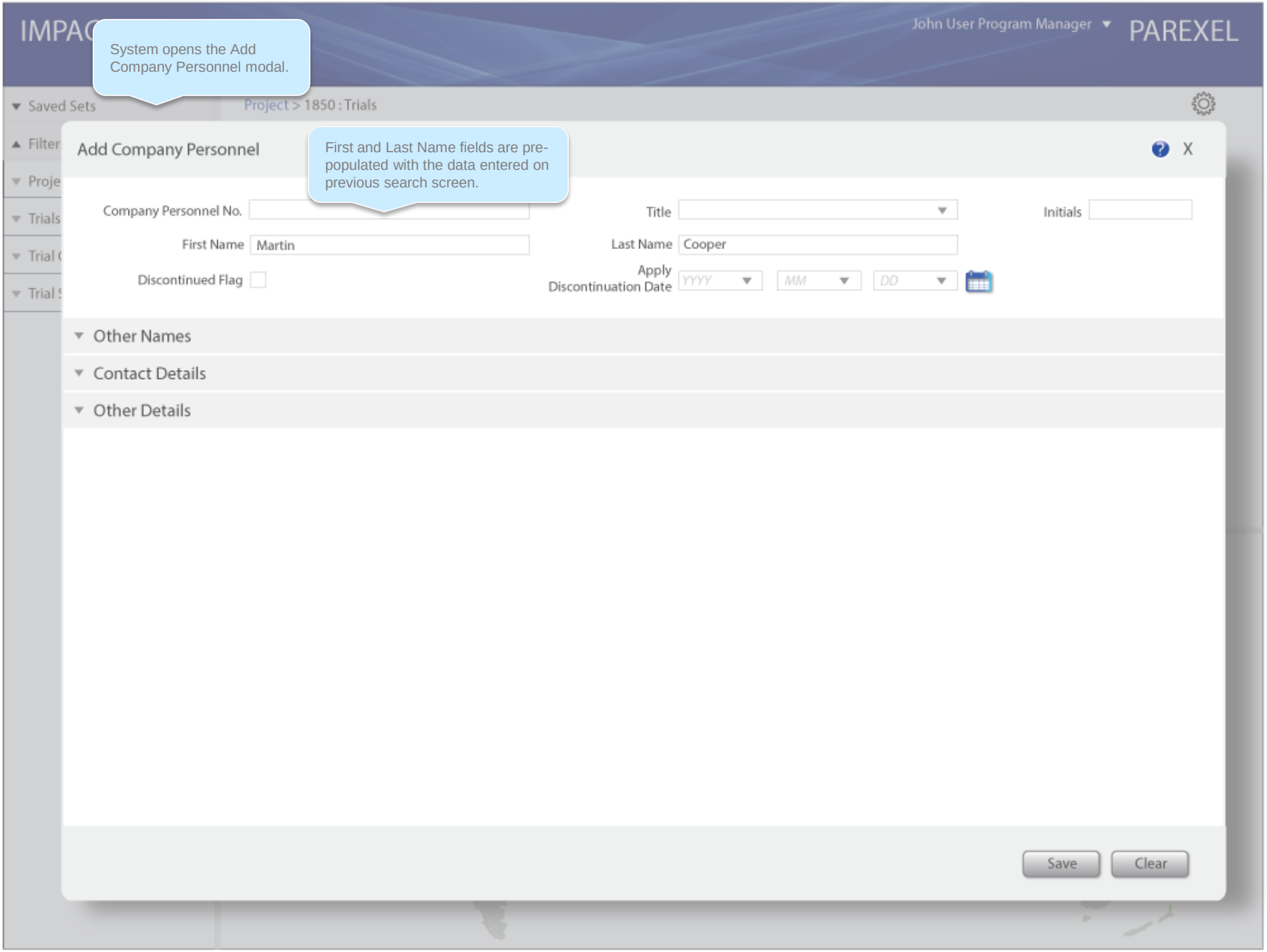
Company Personnel Number

○ Internal ○ External ○ Both

Search

After initiating a search, the Add button becomes enabled. Results are not the person user was looking for, so he clicks the Add icon to add new company personnel.

Company Personnel No	Name	Trial Role Code	Business Unit	Discontinued Flag
45678	Dr. Cooper Davis	Update Allowed	Business Unit 2	☐
98765	Mr. Paul Martins	Database Administrator	Business Unit 6	☐


IMPAC
John User Program Manager
PAREXEL
System opens the Add Company Personnel modal.
Saved Sets
Project > 1850 : Trials
Filter
Proje
Trials
Trial
Trial
Add Company Personnel
First and Last Name fields are pre-populated with the data entered on previous search screen.
X
Company Personnel No.
Title
Initials
First Name
Martin
Last Name
Cooper
Discontinued Flag
Apply Discontinuation Date
YYYY
MM
DD
Other Names
Contact Details
Other Details
Save
Clear

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial

Trial

Add Company Personnel

X

Company Personnel No.

Title

Initials

First Name Martin

Last Name Cooper

Apply Discontinuation Date YYYY MM DD

User clicks on first accordion to expand it.

Other Names

Title 2

First Name 2

Last Name 2

Title 3

First Name 3

Last Name 3

Contact Details

Other Details

Save Clear

IMPACT

John User Program Manager ▾ PAREXEL

▾ Saved Sets

Project > 1850 : Trials

▲ Filter

▾ Proje

▾ Trials

▾ Trial (

▾ Tria

User clicks on second accordion to expand it.

Add Company Personnel

X

Company Personnel No.

Title

Initials

First Name Martin

Last Name Cooper

Discontinued Flag

Apply Discontinuation Date YYYY MM DD

▾ Other Names

▲ Contact Details

Primary Address

Address Line 2

Address Line 3

Address Line 4

Province/ State/County

Town/City

Country/Code

Postal ZIP Code

Telephone No.

Email Address

Telephone No. 2

Email Address 2

Telephone No. 3

Email Address 3

Telephone No. 4

Email Address 4

Telephone No. 5

Email Address 5

Fax No.

▾ Other Details

Save Clear

IMPACT

John User Program Manager ▾ PAREXEL

▾ Saved Sets

Project > 1850 : Trials

▲ Filter

▾ Proje

▾ Trials

▾ Trial

▾ Trial

Add Company Personnel

X

Company Personnel No.

Title

Initials

First Name Martin

Last Name Cooper

Discontinued Flag

Apply Discontinuation Date YYYY MM DD

User clicks on third accordion to expand it.

▲ Other Details

Internal/External

Trial Role Code

Security Role Code

Business Unit

User can save or clear information.

Save Clear

Clinical Personnel

Assign to Study and Maintain Master File

IMPACT

John User Program Manager

PAREXEL

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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area			
	Trial 3	England	Lorem Ipsum	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...			
	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 Ipsum	Lorem Ipsum

Configuration & Customization

Trial Configuration

- New Trial
- New Trial Country
- Design
- Delay/Cancel Stop
- Personnel

Trial Customization

- Save Set
- Table Column Display
- Top/Bottom Display
- Export/Print Display

Project > 1850 : Trials Map

View By

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

User next selects Clinical Personnel tab.

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

◉ Assign to Study ○ Maintain Master File

Project ID

Protocol ID

Trial Country

Trial Site

Search

Name	Trial Role	Security Role	Start Date	End Date	Copy to		
					Studies	Countries	Sites

Add All

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Filter

Proje

Trials

Trial

Trial

Project > 1850 : Trials

User next selects Clinical Personnel tab.

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

○ Assign to Study ◉ Maintain Master File

First Name

Last Name

Address

Town/City

Province/State/County

Postal ZIP Code

Country

Center

Primary Role

Discontinued Flag Yes

Search

ID

	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
	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

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial

Trial

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

Assign to Study Maintain Master File

First Name: John

Last Name: Adams

Address:

Town/City:

Province/State/County:

Postal ZIP Code:

Country:

Center:

Primary Role:

Discontinued Flag: Yes

ID:

User enters a first and last name, and clicks Search button

Search

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
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
471	Michelle Jones	Nurse		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
247	Dr. Amy Martins	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
207	Dr. Allen Matthews	Pr. Investigator	Belo Horizonte	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial

Trial

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

Assign to Study Maintain Master File

First Name: John

Last Name: Adams

Address:

Town/City:

Province/State/County:

Postal ZIP Code:

Country:

Center:

Discontinued Flag: Yes

Search

After initiating a search, the Add button becomes enabled. Results are not the person user was looking for, so he clicks the Add button to add new clinical personnel.

	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
	515	Mr. Peter Johnson	Administrator		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial

Trial

Add Clinical Personnel

First and Last Name fields are pre-populated with the data entered on previous search screen.

X

Clinical Personnel No. 987

Title

Suffix

First Name John

Last Name Adams

Discontinued

Discontinued Date YYYY MM DD

Last Updated By

Last Updated Date YYYY MM DD

- Other Names
- Contact Details
- Experience
- Other Details
- Medical Licenses

Save Clear

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial

Tri

User clicks on first accordion to expand it.

Add Clinical Personnel

X

Clinical Personnel No. 987

Title

Suffix

First Name John

Last Name Adams

Discontinued

Discontinued Date YYYY MM DD

Last Updated Date YYYY MM DD

Other Names

Title 2

First Name 2

Last Name 2

Title 3

First Name 3

Last Name 3

First Center

Copy address and contact details from first center

Primary Address

Town/City

Province/ State/County

Postal ZIP Code

Country

Contact Details

Experience

Save

Clear

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial

Trial

Add Clinical Personnel

X

Clinical Personnel No. 987

Title

Suffix

First Name John

Last Name Adams

Discontinued

Discontinued Date YYYY MM DD

Last Updated By

Last Updated Date YYYY MM DD

User clicks on second accordion to expand it.

Contact Details

Telephone No.

Email Address

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

Time Zone

Best contact time

Monday		-	Telephone
Tuesday		-	Telephone
Wednesday		-	Telephone
Thursday		-	Telephone
Friday		-	Telephone

Save Clear

IMPACT

John User Program Manager ▾ PAREXEL

▾ Saved Sets

Project > 1850 : Trials

▲ Filter

▾ Proje

▾ Trials

▾ Trial

▾ Trial

Add Clinical Personnel

X

Clinical Personnel No. 987

Title

Suffix

First Name John

Last Name Adams

Discontinued

Discontinued Date YYYY MM DD

Last Updated By

Last Updated Date YYYY MM DD

User clicks on third accordion to expand it.

▲ Experience

Degree

CV Date YYYY MM DD

Investigator Flag

Type of Trial Experiance

▾ Other Details

▾ Medical Licenses

Save Clear

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Filter

Proje

Trials

Trial

Trial

Project > 1850 : Trials

Add Clinical Personnel

X

Clinical Personnel No. 987

Title

Suffix

First Name John

Last Name Adams

Discontinued

Discontinued Date YYYY MM DD

Last Updated By

Last Updated Date YYYY MM DD

Other Names

User clicks on fourth accordion to expand it.

Other Details

Patient Population

Has Research Nurse

Financial Disclosure Flag

Medical Registration No. 1

Medical Registration Issuing Body No. 1

Medical Registration No. 2

Medical Registration Issuing Body No. 2

Medical Licenses

Save Clear

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial

Trial

Add Clinical Personnel

X

Clinical Personnel No. 987

Title

Suffix

First Name John

Last Name Adams

Discontinued

Discontinued Date YYYY MM DD

Last Updated By

Last Updated Date YYYY MM DD

Other Names

Contact Details

User clicks on fifth accordion to expand it.

Medical Licenses

Medical License No.

Medical License Country

Medical License Status

Province/State/ County

Medical License Expiration Date YYYY MM DD

Checked Last updated by Mr. Henry Higgins 10-Jul-2014

Licensing Body

Delete

Add another license

User can save or clear information.

Save Clear

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Filter

Proje

Trials

Trial (

Trial S

Personnel

X

User next selects Assign to Study radio button.

inical Personnel | Import Personnel

○ Assign to Study ◉ Maintain Master File

First Name | Last Name

Address | Town/City

Province/State/County | Postal ZIP Code

Country | Center

Primary Role | Discontinued Flag Yes

ID

Search

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
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
471	Michelle Jones	Nurse		Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
247	Dr. Amy Martins	Pr. Investigator	Salvador-Bahia	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest
207	Dr. Allen Matthews	Pr. Investigator	Belo Horizonte	Brazil - [BRA]		Center Clinical Personnel	Specialist Fields	Therapeutic Interest

IMPACT

John User Program Manager ▾ PAREXEL

▾ Saved Sets

▲ Filter

▾ Proje

▾ Trials

▾ Trial (

▾ Trial S

Project > 1850 : Trials

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

◉ Assign to Study ○ Maintain Master File

Project ID

Protocol ID

Trial Country

Trial Site

Search

	ID	Name	Role	Telephone	Start Date	End Date

Add All

IMPACT

John User Program Manager ▾ PAREXEL

▾ Saved Sets

Project > 1850 : Trials

▲ Filter

▾ Proje

▾ Trials

▾ Trial (

▾ Trial S

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

◉ Assign to Study ○ Maintain Master File

Project ID

Protocol ID

Trial Country

Trial Site

Search

	ID	Name	Role	Telephone	Start Date	End Date

Add All

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

Maintain Clinical Personnel ▸ Clinical Personnel Lookup

Personnel Number

Center

First Name

Last Name

Town/City

Therapeutic Interest Group

Province/State/County

Therapeutic Interest

Country

Specialist Field

Potential Investigator Yes

Search

Available Clinical Personnel

	Quality & Compliance	Trial Experience	ID	Name	Investigator	Financial Disclosure	Town/ City	Province/ State/County	Country

Add Selected

IMPACT

John User Program Manager ▾ PAREXEL

▾ Saved Sets

Project > 1850 : Trials

▲ Filter

▾ Proje

▾ Trials

▾ Trial (

▾ Trial S

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

◉ Assign to Study ○ Maintain Master File

Project ID

Protocol ID

Trial Country

Trial Site

Search

	ID	Name	Role	Telephone	Start Date	End Date

Add All

Import Personnel

IMPACT

John User Program Manager

PAREXEL

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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area			
	Trial 3	England	Lorem Ipsum	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...			
	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 Ipsum	Lorem Ipsum

Configuration & Customization

Trial Configuration

- New Trial
- New Trial Country
- Design
- Delay/Cancel Stop
- Personnel

Trial Customization

- Save Set
- Table Column Display
- Top/Bottom Display
- Export/Print Display

Project > 1850 : Trials Map

View By

IMPACT

John User Program Manager ▾ PAREXEL

Saved Sets

Project > 1850 : Trials

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

◉ Assign to Study ○ Maintain Master File

Project ID

Protocol ID

Trial Country

Trial Site

Search

	Name	Trial Role	Security Role	Start Date	End Date	Copy to		
						Studies	Countries	Sites

Add All

IMPACT

John User Program Manager ▾ PAREXEL

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.

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Personnel

X

John Program Manager is going to load site personnel for multiple sites within his study.

Company Personnel | Clinical Personnel | 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

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

Personnel

X

John Program Manager selects “To Master File” radio button, then browses and submits a file.

Con | 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

IMPACT

John User Program Manager ▾ PAREXEL

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.

▾ Saved Sets

Project > 1850 : Trials

▲ Filters

▾ Projects

▾ Trials

▾ Trial Cou

▾ Trial Site

Personnel

X

Company Personnel | Clinical Personnel | Import Personnel

Import Personnel ▸ BulkUpload_Valid_Data.xls

○ To Study ◉ To Master File

Protocol ID: PI456778 **Created By:** test_user40 **Date Uploaded:** 28-Sept-2014 **Time:** 12:00 EDT **Outcome:** Completed

Name	Email	Fax	eClinicalRole	Trained	Sites	Errors
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

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Project > 1850 : Trials

	ID	Countries	Alias	Description	Primary Investigator	Primary Center Name	Therapuetic Area			
	Trial 3	England	Lorem Ipsum	Lorem Ipsum...	Lorem Ipsum	Lorem Ipsum	Cardiovascular...			
	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 Ipsum	Lorem Ipsum

Configuration & Customization

Trial Configuration

- New Trial
- New Trial Country
- Design
- Delay/Cancel Stop
- Personnel

Trial Customization

- Save Set
- Table Column Display
- Top/Bottom Display
- Export/Print Display

Project > 1850 : Trials Map

View By

IMPACT

John User Program Manager ▾ PAREXEL

- Saved Sets
- Filters
- Projects
- Trials
- Trial Countries
- Trial Sites

Trial Design

X

Trial Design ▸

Objectives

Indications

Blinding

Structure

Randomization

Planned Total Number of Bioassays

Conducted on Site ☐

Volunteer Study ☐

Clinical Pharmacology Component ☐

Socioeconomic Component ☐

Additional Design Detail

Subjects

Sex & Age

☐ Female	From	Min	To	Max
☐ Male	From	Min	To	Max

Durations

Screening	#	Months	Baseline	#	Months
Treatment	#	Minutes	Follow Up	#	Months

Treatment

Min. Dosage

Measurement Unit

Max. Dosage

Measurement Unit

Treatment Arms

Treatment Arms Design

Finish

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