

A faint, blue-tinted world map is visible in the background of the top half of the slide. A horizontal line is positioned below the map, separating it from the text below.

Data Driven Monitoring

A Day in the Life

Human Factors
October, 2015

The New Mindset: Responsiveness

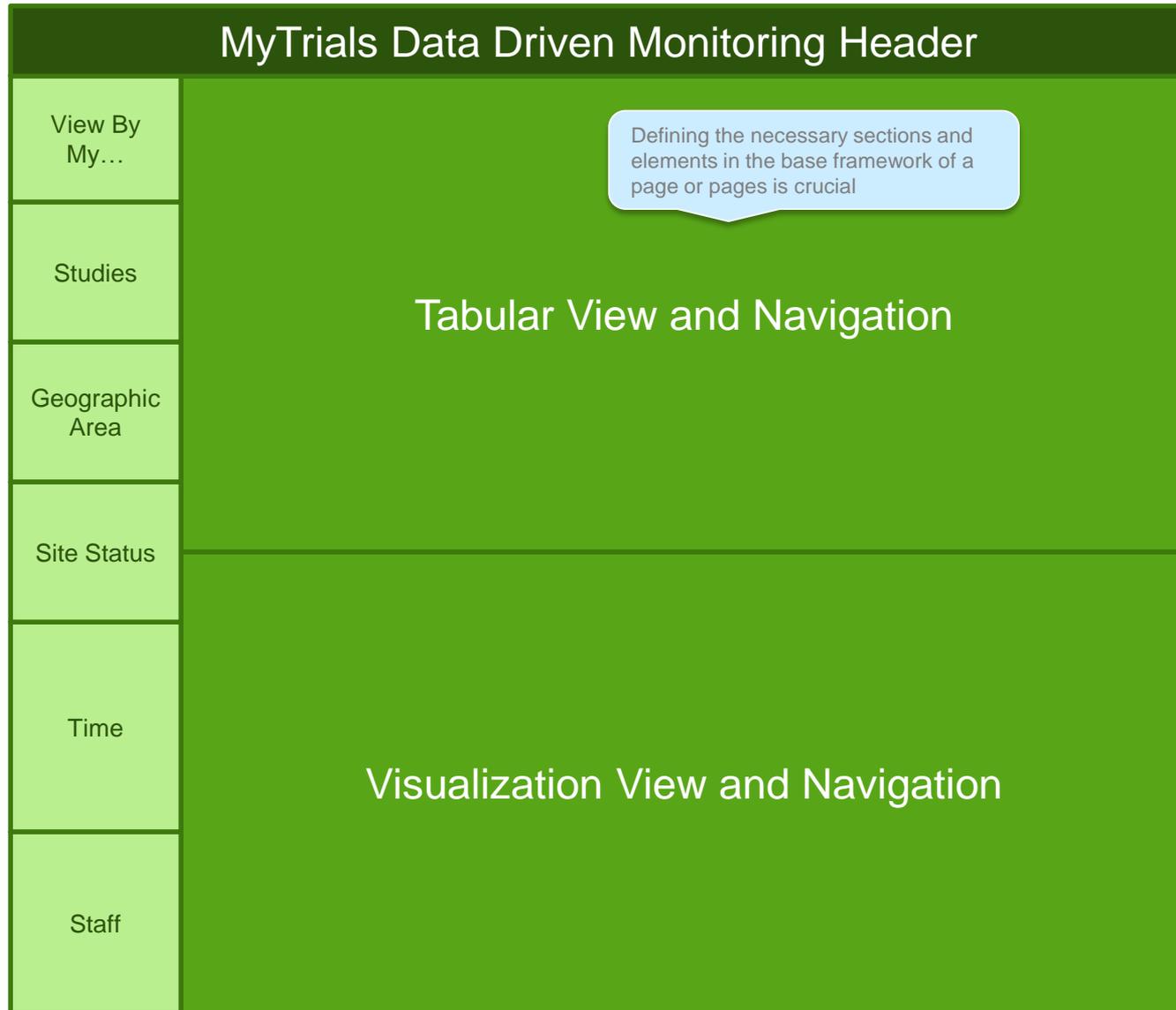
A close-up, profile view of a woman with brown hair, looking thoughtfully to the right. She is holding a white ceramic mug with both hands. A light green thought bubble with a grey outline is positioned above her head, containing text. The background is a soft, out-of-focus white.

I wonder if my strategy
from yesterday is still
appropriate or has
something changed that
I need to be aware of...

Active Interaction Begins



Dynamic Modularity is the Key Component



First Scenario Dashboard to Site List

User focuses on Study B. All dash parts interact.

▲ Studies

- Display All
- Study A
 - Study B
 - Study C
 - Study D
 - Study E
 - Study F

▼ Geographic Area

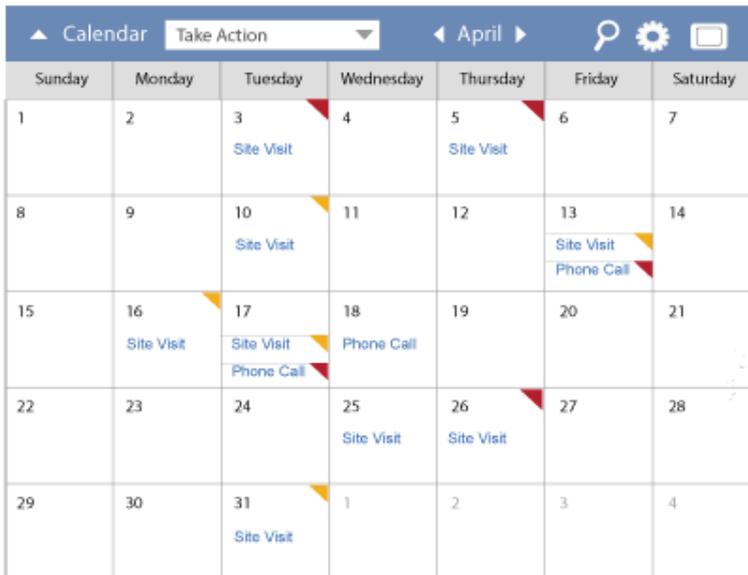
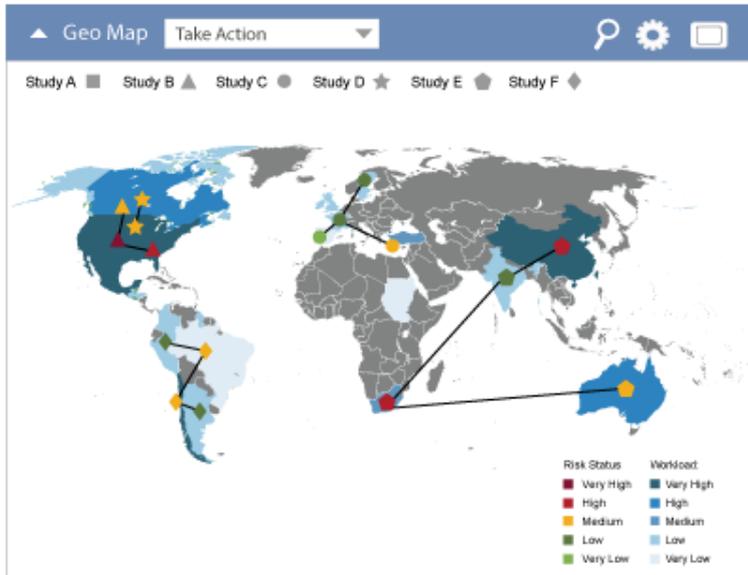
▼ Site Status

- Display All
- Created
 - Initiated
 - Active
 - Closed

▼ Time

▼ Staff

Studies



▲ Notifications Take Action

Description	Site Number	Acknowledgement Details
<input type="checkbox"/> Multiple SAEs Occurred	10001	Visit site to see if there is a problem
<input type="checkbox"/> Drug Accountability	20002	Must be top priority at next visit
<input type="checkbox"/> New SAE Reported	30003	Follow up with site as appropriate
<input type="checkbox"/> Enrollment Delay	40004	Contact site to discuss enrollment planning
<input type="checkbox"/> Multiple SAEs Occurred	50005	Visit site to see if there is a problem
<input type="checkbox"/> New SAE Reported	60006	Follow up with site as appropriate
<input type="checkbox"/> Aging Query	70007	Contact site to discuss query resolution plan
<input type="checkbox"/> SAE Occurred	80008	Call the site to discuss SAE
<input type="checkbox"/> Fraud Detected	90009	Immediate investigation of fraud necessary
<input type="checkbox"/> Slim Chance of Fraud..	10010	Call site to address chance of fraud

User focuses on Study B. All dash parts interact.

Studies

Display All

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Geographic Area

Site Status

Display All

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- Active
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Time

Staff



Calendar

Take Action

April

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3 Site Visit	4	5 Site Visit	6	7
8	9	10 Site Visit	11	12	13 Site Visit Phone Call	14
15	16 Site Visit	17 Site Visit Phone Call	18 Phone Call	19	20	21
22	23	24	25 Site Visit	26 Site Visit	27	28
29	30	31 Site Visit	1	2	3	4

Notifications

Take Action

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<input type="checkbox"/> Multiple SAEs Occurred	10001	Visit site to see if there is a problem
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User focuses on Study B. All dash parts interact.

▲ Studies

Study B x

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- Study E
- Study F

▼ Geographic Area

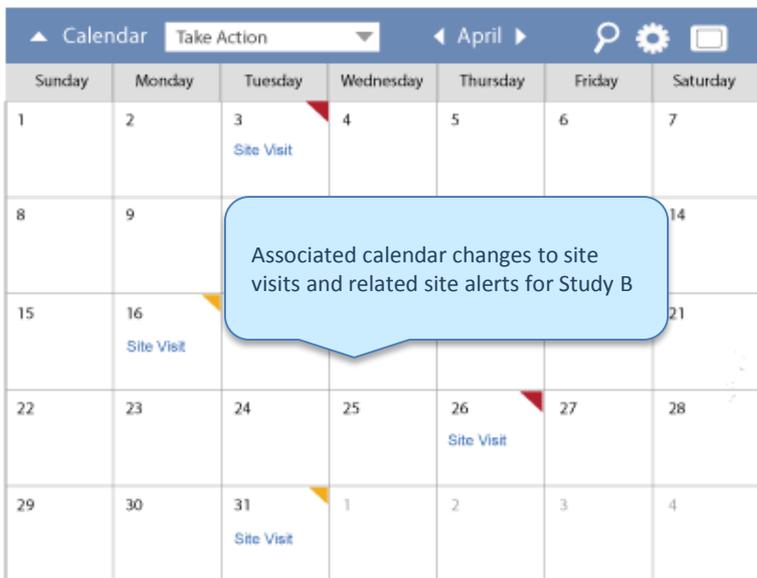
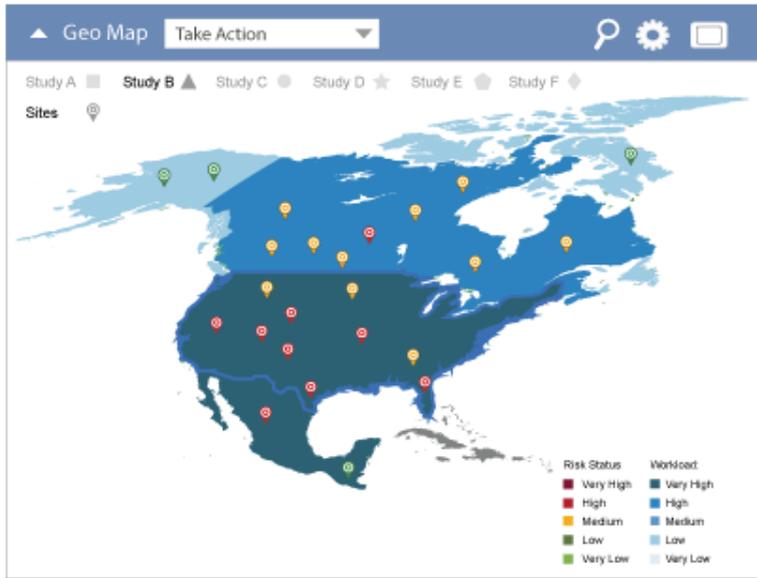
▼ Site Status

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▼ Time

▼ Staff

Studies ▶ Study B



▲ Notifications Take Action

Description	Event Details	Item Details
<input type="checkbox"/> Multiple SAEs Occurred	10001	Visit site to see if there is a problem
<input type="checkbox"/> Drug Accountability	20002	Must be top priority at next visit
<input type="checkbox"/> New SAE Reported	30003	Follow up with site as appropriate
<input type="checkbox"/> Enrollment Delay	40004	Contact site to discuss enrollment planning
<input type="checkbox"/> Multiple SAEs Occurred	50005	Visit site to see if there is a problem

Tasks are related to study B

▲ Studies

Study B x

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▼ Geographic Area

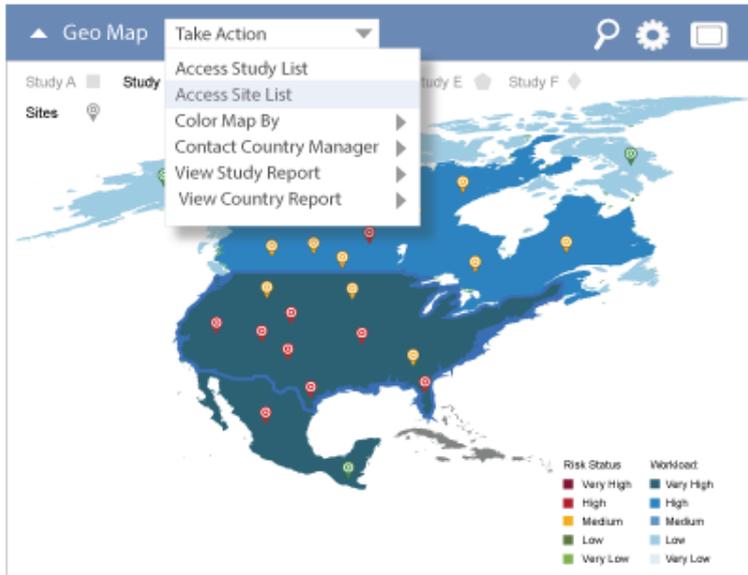
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▼ Staff

Studies ▶ Study B



Calendar

Take Action

April

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
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8	9	10	11	12	13 Site Visit Phone Call	14
15	16 Site Visit	17	18	19	20	21
22	23	24	25	26 Site Visit	27	28
29	30	31 Site Visit	1	2	3	4

Notifications

Take Action

Description	Site Number	Acknowledgement Details
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Studies

Studies > Study B: Sites Take Action

- Study B
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Geographic Area

Site Status

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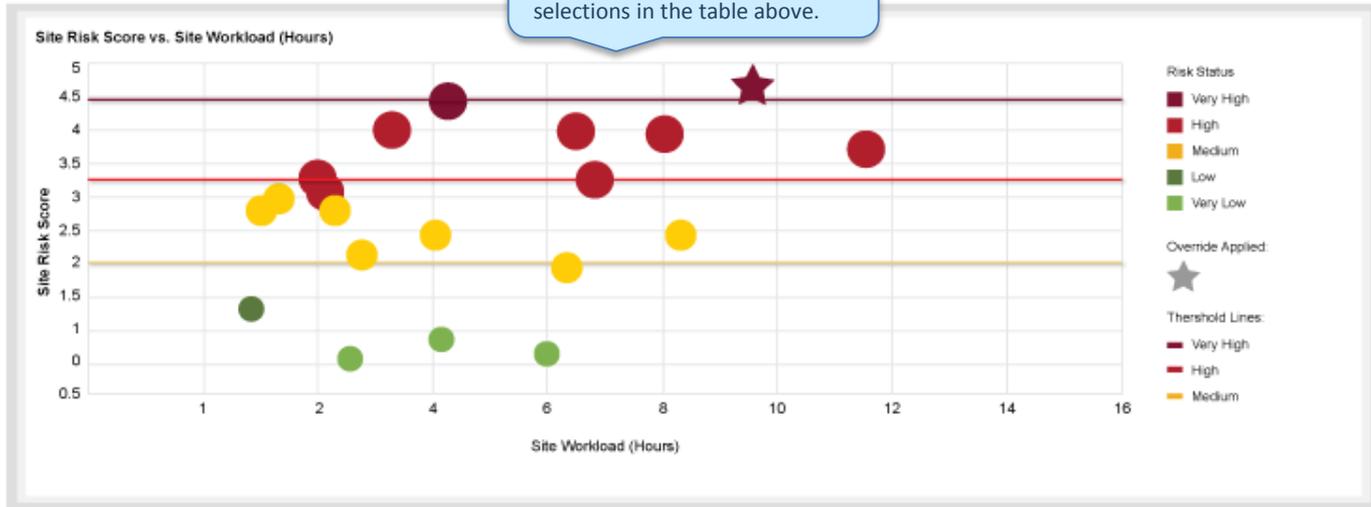
Staff

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
<input type="checkbox"/> 10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
<input type="checkbox"/> 20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
<input type="checkbox"/> 30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
<input type="checkbox"/> 40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
<input type="checkbox"/> 50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
<input type="checkbox"/> 60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	.40	.40	0	.40
<input type="checkbox"/> 70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
<input type="checkbox"/> 80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
<input type="checkbox"/> 90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.2	-3.0	3.3	1.5	1.5	1.1	1.5
<input type="checkbox"/> 10000		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0	1.0	3.0	1.0

Linked breadcrumb trail allows the user to return to the previous view.

Visualization corresponds and dynamically flows when making selections in the table above.

Studies > Study B: Sites Take Action



Studies

Studies Study B: Sites Take Action

- Study B x
- Display All
 - Study A
 - Study B
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 - Study D
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Geographic Area

Site Status

- Display All
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 - Active
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Time

Staff

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	4.0	4.0	0	4.0
70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.2	-3.0	3.3	1.5	1.5	1.1	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0	1.0	3.0	1.0

Studies Study B: Sites Take Action

Mousing a scatterplot point displays meaningful information to make further informed choices.



Mousing the Risk Score's alert icon displays a tooltip with meaningful information

Studies

- Study B
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- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

Geographic Area

Site Status

- Display All
- Created
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- Active
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Time

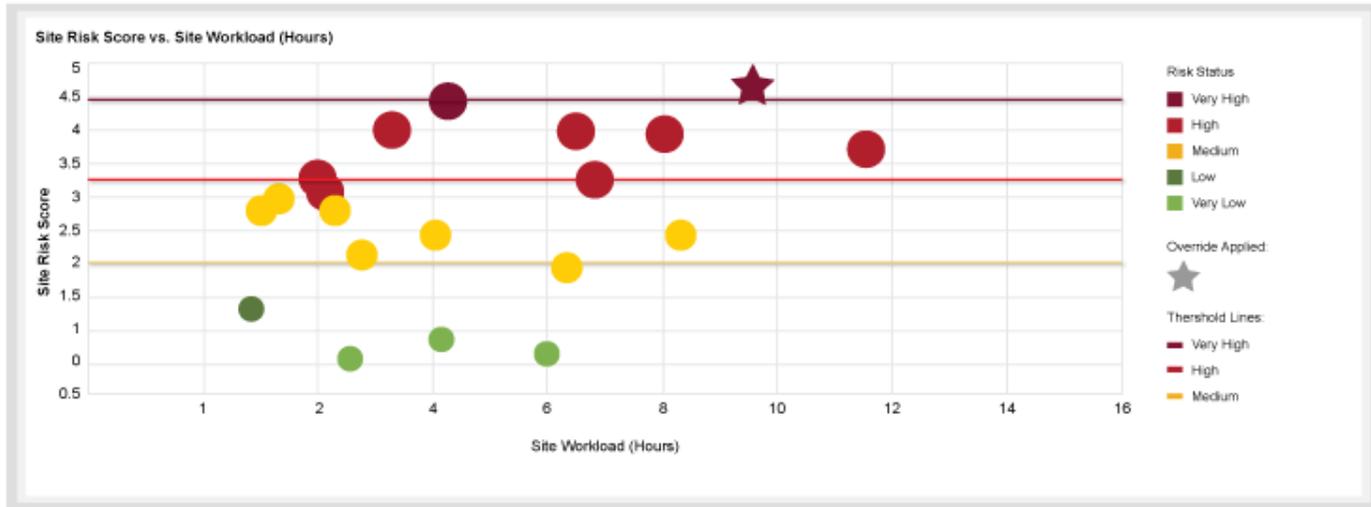
Staff

Studies > Study B: Sites

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
<input type="checkbox"/> 10001		Site One	Investigator One	United States	CRA One	CRA One										
<input type="checkbox"/> 20002		Site Two	Investigator Two	United States	CRA Two	CRA Two										
<input type="checkbox"/> 30003		Site Three	Investigator Three	United States	CRA Three	CRA Three										
<input type="checkbox"/> 40004		Site Four	Investigator Four	United States	CRA Four	CRA Four										
<input type="checkbox"/> 50005		Site Five	Investigator Five	United States	CRA Five	CRA Five										
<input type="checkbox"/> 60006		Site Six	Investigator Six	United States	CRA Six	CRA Six										
<input type="checkbox"/> 70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven										
<input type="checkbox"/> 80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight										
<input type="checkbox"/> 90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine										
<input type="checkbox"/> 10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten										

Risk Override: Very High
Monitoring Interval: 54
Warning Period: 10

Studies > Study B: Sites

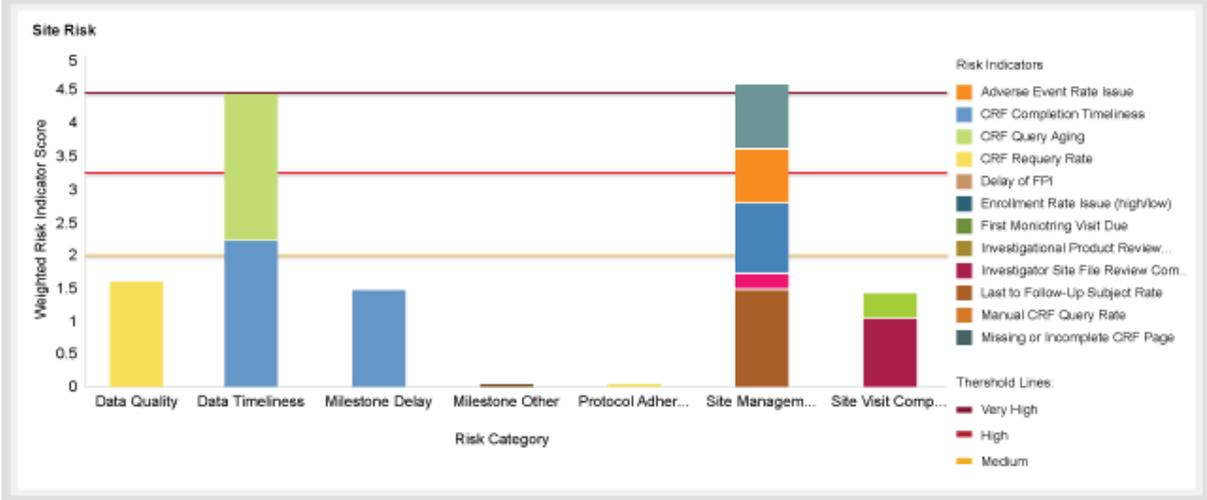
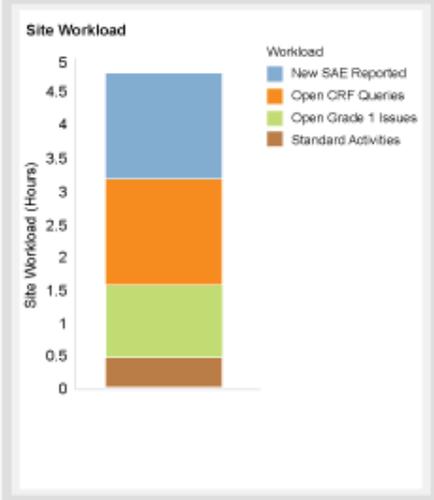


A single site is selected from the list and the visualization changes to Site Workload and Site Risk bar charts with categorical data that makes up total displayed workload and risk indicators that make up the respective risk categories.

Studies ▶ Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	4.0	4.0	0	4.0
70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.2	-3.0	3.3	1.5	1.5	1.1	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0	1.0	3.0	1.0

Studies ▶ Study B: 10001 Take Action



- Studies
- Study B x
- Display All
- Study A
- Study B
- Study C
- Study D
- Study E
- Study F
- Geographic Area
- Site Status
- Display All
- Created
- Initiated
- Active
- Closed
- Time
- Staff

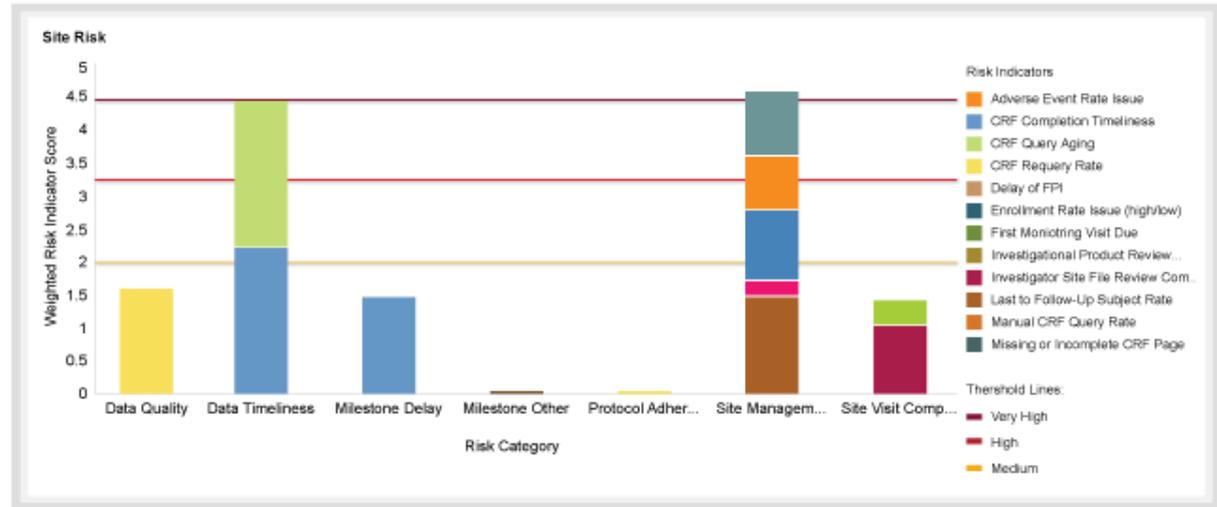
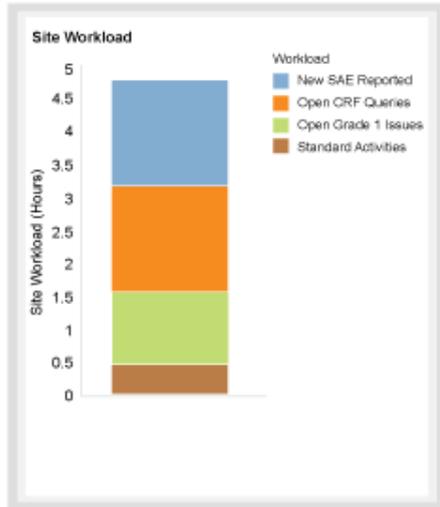
The CRA clicks on the Investigator Name cell for site 10001 and is presented with options for contacting the investigator

- ▲ Studies
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- ▼ Geographic Area
- ▼ Site Status
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- ▼ Staff

Studies ▶ Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator Name	Country	Assigned CRA	Assigned CMA	Days since last Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	4.0	4.0	0	4.0
70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.2	-3.0	3.3	1.5	1.5	1.1	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0	1.0	3.0	1.0

Studies ▶ Study B: 10001 Take Action



- Risk Indicators**
- Adverse Event Rate Issue
 - CRF Completion Timeliness
 - CRF Query Aging
 - CRF Requery Rate
 - Delay of FPI
 - Enrollment Rate Issue (high/low)
 - First Monitoring Visit Due
 - Investigational Product Review...
 - Investigator Site File Review Com...
 - Last to Follow-Up Subject Rate
 - Manual CRF Query Rate
 - Missing or Incomplete CRF Page
- Threshold Lines:**
- Very High
 - High
 - Medium

- Studies
 - Study B
 - Study A
 - Study B
 - Study C
 - Study D
 - Study E
 - Study F
- Geographic Area
- Site Status
 - Display All
 - Created
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 - Closed
- Time
- Staff

Studies Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator Name
10001		Site One	Investigator One
20002		Site Two	Investigator Two
30003		Site Three	Investigator Three
40004		Site Four	Investigator Four
50005		Site Five	Investigator Five
60006		Site Six	Investigator Six
70007		Site Seven	Investigator Seven
80008		Site Eight	Investigator Eight
90009		Site Nine	Investigator Nine
10010		Site Ten	Investigator Ten

Popup can be minimized or moved around the screen, and also docked to the left-hand side.

Site 10001 > Site One: Data Timeliness

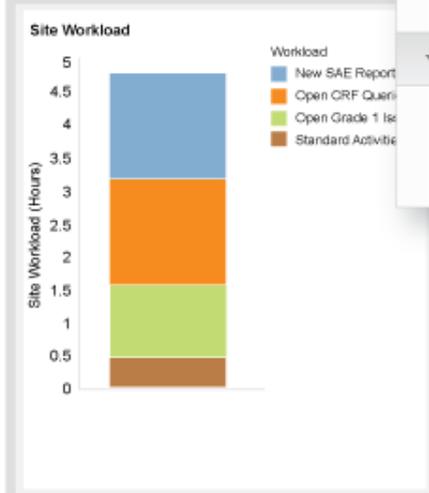
CRF Query Aging

Risk Indicator Score: 5.00
Weighted Risk Indicator Score: 2.50
Description: Average CRF Query Resolution Timeliness per CRF entry guideline

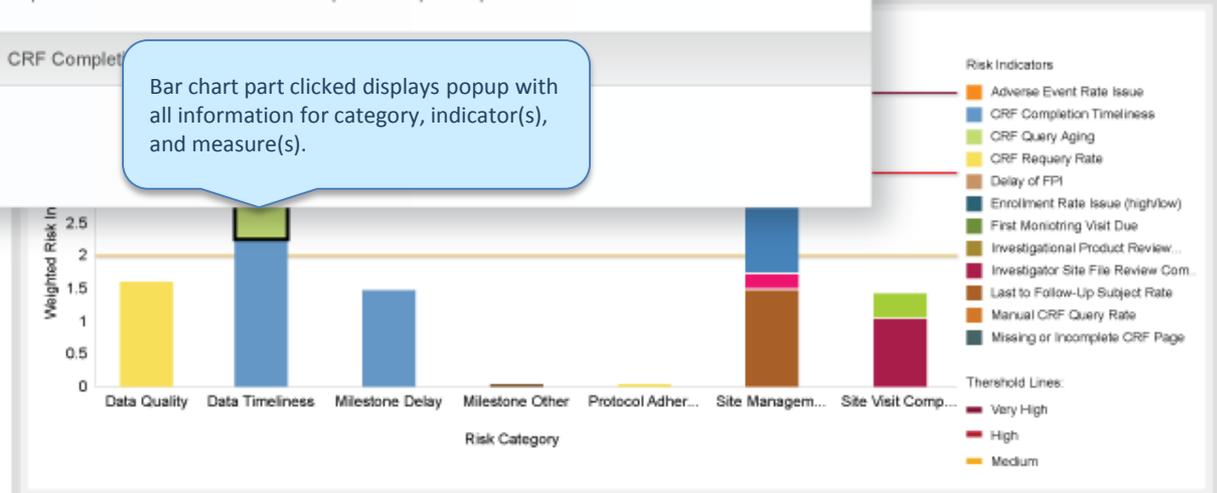
Site Measure 1
Name: Age of open CRF queries
Value: 6000
Description: Count of the total number of days per site for current open CRF queries.

Site Measure 2
Name: Number of open CRF queries
Value: 124
Description: Count of the total number of open CRF queries per site.

Studies Study B: 10001 Take Action



Bar chart part clicked displays popup with all information for category, indicator(s), and measure(s).



The Take Action menu allows the user to select from an alphabetized list of context specific actions.

▲ Studies

Study B x

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▼ Geographic Area

▼ Site Status

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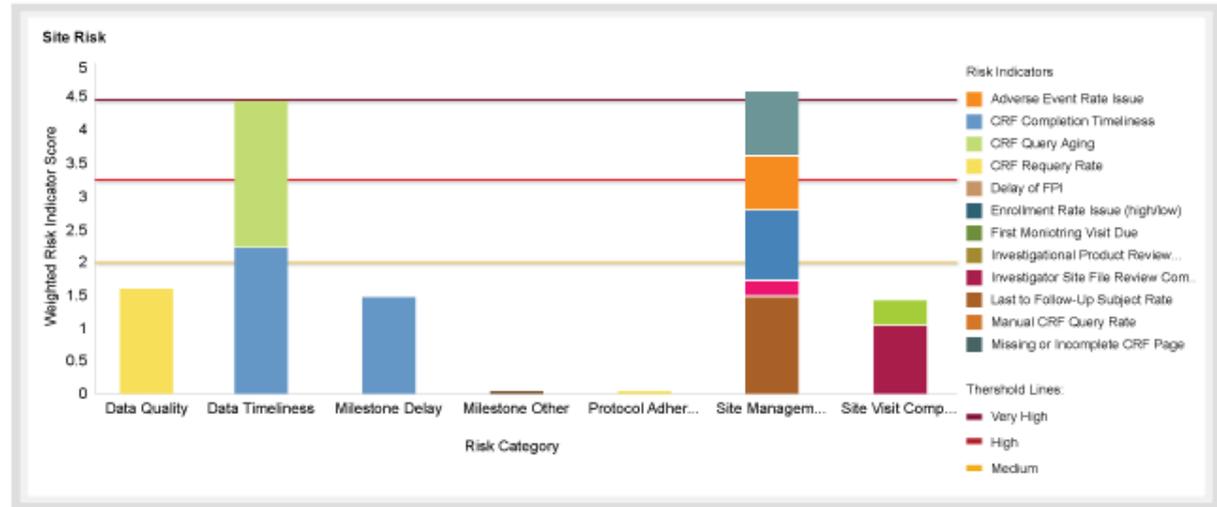
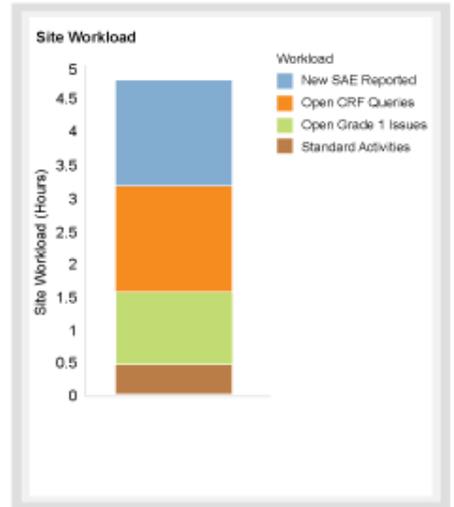
▼ Time

▼ Staff

Studies ▶ Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator	Country	RA	CRA	Days Unit Max	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
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50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
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80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
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10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0	1.0	3.0	1.0

Studies ▶ Study B: 10001 Take Action



Meaningful icons in line with selections tell the story of the possible journey. The arrow for Export Site Table indicates a sub-menu. The square icon (page or monitor like) with curved arrow denotes a journey out of the system

Studies

Study B x

- Display All
- Study A
- Study B
- Study C
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- Study F

Geographic Area

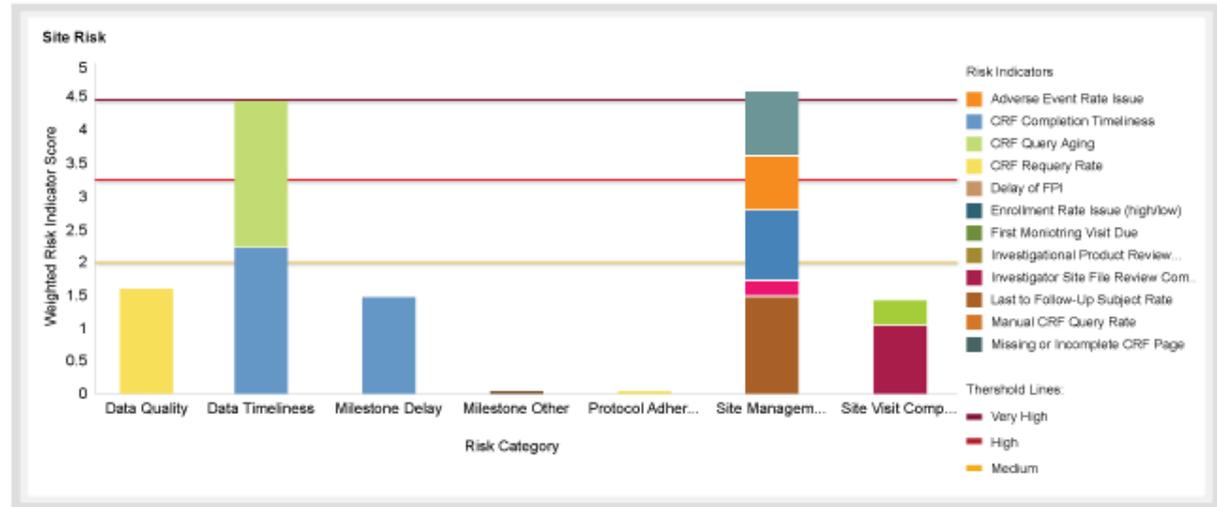
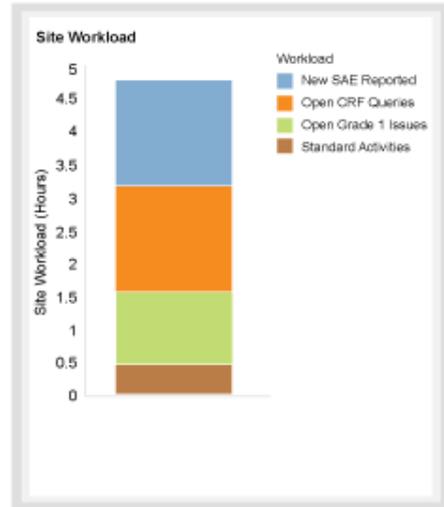
Site Status

- Display All
- Created
- Initiated
- Active
- Closed

Studies Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator	Country	CRA	RA	Score	Quality	Timeliness	Delay	Other	Adherence
10001		Site One	Investigator One	United States	CRA One	RA One	10	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	RA Two	48	1.9	3.0	3.0	1.2	3.0
30003		Site Three	Investigator Three	United States	CRA Three	RA Three	-38	2.0	3.2	3.2	4.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	RA Four	-38	2.5	1.6	1.6	0	1.6
50005		Site Five	Investigator Five	United States	CRA Five	RA Five	13	2.0	2.0	2.0	4.8	2.0
60006		Site Six	Investigator Six	United States	CRA Six	RA Six	11	1.8	4.0	4.0	0	4.0
70007		Site Seven	Investigator Seven	United States	CRA Seven	RA Seven	38	3.5	3.9	3.9	1.7	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	RA Eight	17	1.1	2.5	2.5	1.3	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	RA Nine	99	3.3	1.5	1.5	1.1	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	RA Ten	44	3.5	1.0	1.0	3.0	1.0

Studies Study B: 10001 Take Action



Allowing users to incrementally reveal paths cuts down on cognitive overload. From the main list a user is able to digest and make a choice while also understanding where the path will take them. Descendant menus within the system reveal richer choices within a singular selection, all without producing unnecessary stress.

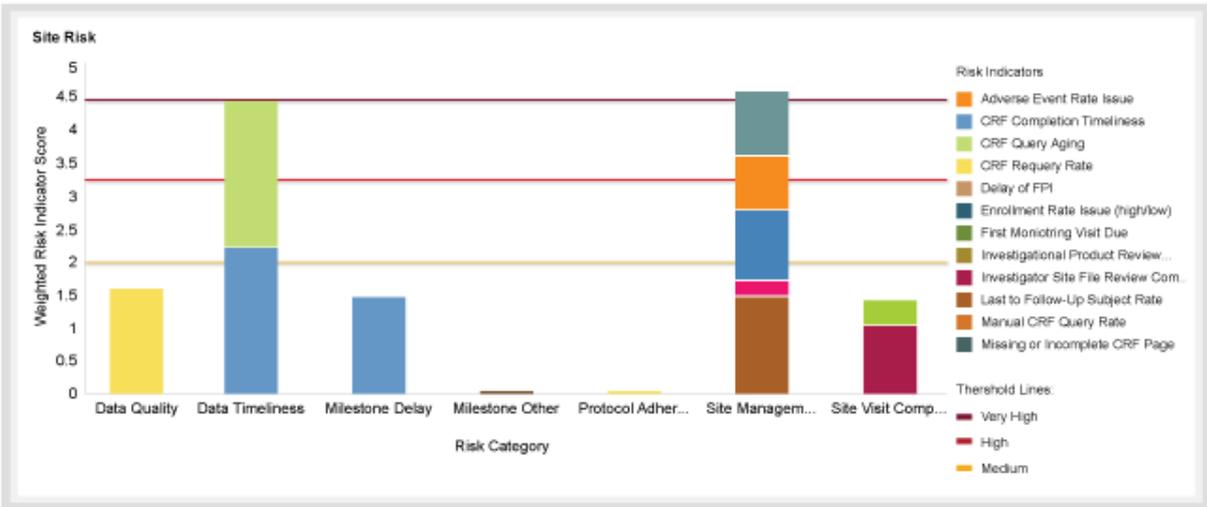
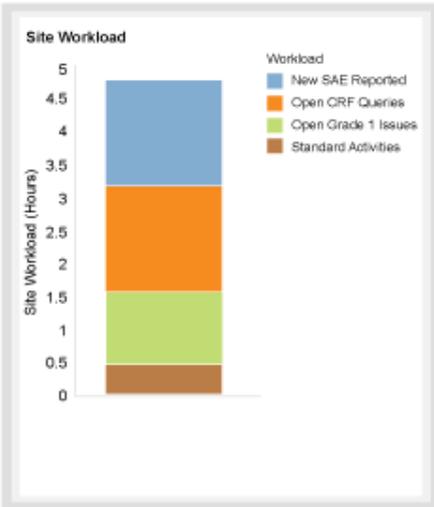
- ▲ Studies
- Study B x
- Display All
- Study A
- Study B
- Study C
- Study D
- Study E
- Study F
- ▼ Geographic Area
- ▼ Site Status
- Display All
- Created
- Initiated
- Active
- Closed
- ▼ Time
- ▼ Staff

Studies ▶ Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator	Country	CRA	Score	Quality	Timeliness	Delay	Other	Triggers	Adherence
10001		Site One	Investigator One	United States	CRA One	48	3.0	4.0	4.0	3.9	4.0	
20002		Site Two	Investigator Two	United States	CRA Two	2.6	1.9	3.0	3.0	1.2	3.0	
30003		Site Three	Investigator Three	United States	CRA Three	-38	2.0	3.2	3.2	4.0	3.2	
40004		Site Four	Investigator Four	United States	CRA Four	-38	2.5	1.6	1.6	0	1.6	
50005		Site Five	Investigator Five	United States	CRA Five	13	2.0	2.0	2.0	4.8	2.0	
60006		Site Six	Investigator Six	United States	CRA Six	11	1.8	4.0	4.0	0	4.0	
70007		Site Seven	Investigator Seven	United States	CRA Seven	38	3.5	3.9	3.9	1.7	3.9	
80008		Site Eight	Investigator Eight	United States	CRA Eight	17	1.1	2.5	2.5	1.3	2.5	
90009		Site Nine	Investigator Nine	United States	CRA Nine	99	3.3	1.5	1.5	1.1	1.5	
10010		Site Ten	Investigator Ten	United States	CRA Ten	44	3.5	1.0	1.0	3.0	1.0	

- Add New Site Issue
- Export Site Table
- Modify Site Action
- Schedule Site Action
- View Last Onsite Visit
- View Last Onsite Visit Report
- View Open Issues
- View Site Summary Report
- View Study Summary Report
- Excel
- PDF

Studies ▶ Study B: 10001 Take Action



The user selects the Risk Score cell for site 10001 and the Site Risk Score Over Time and Risk Category Score charts display.

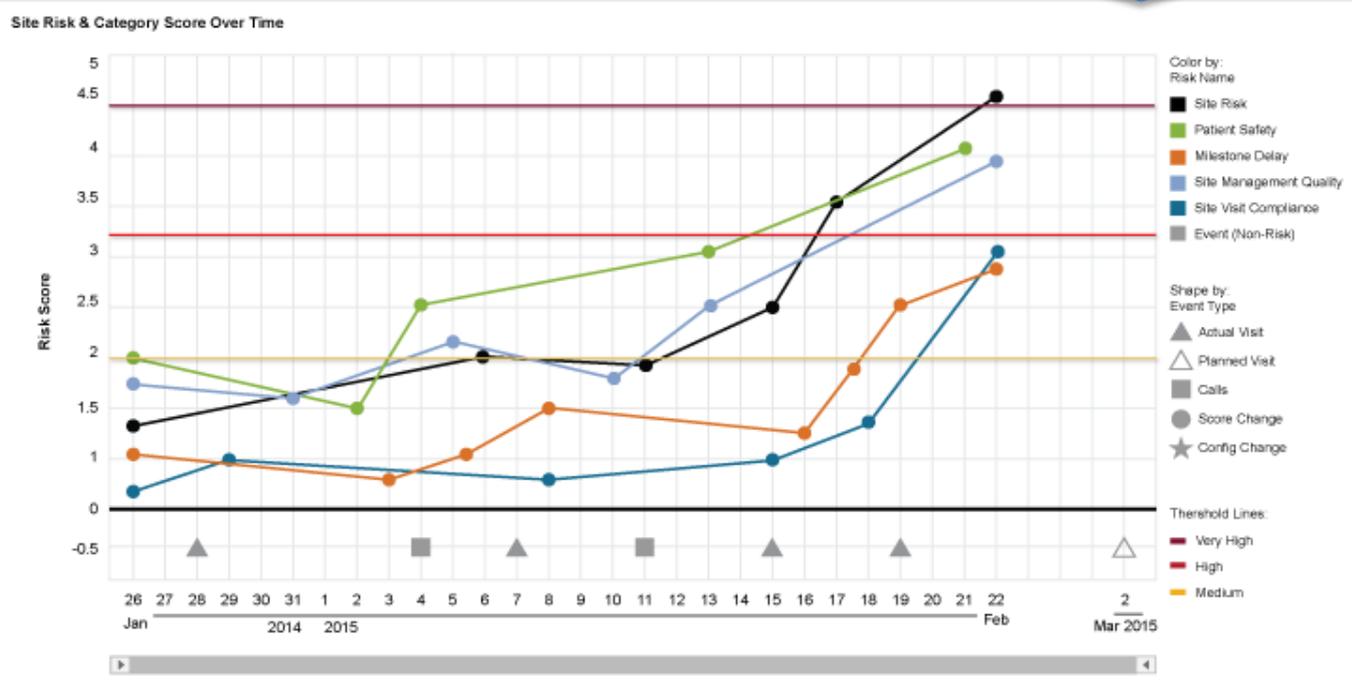
- ▲ Studies
- Study B x
- Display All
- Study A
- Study B
- Study C
- Study D
- Study E
- Study F
- ▼ Geographic Area
- ▼ Site Status
- Display All
- Created
- Initiated
- Active
- Closed
- ▼ Time
- ▼ Staff

Studies ▶ Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	.40	.40	0	.40
70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.8	2.0	3.3	1.5	1.5	1.1	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.2	2.0	3.3	1.5	1.5	1.1	1.5

With the Site Risk Score Over Time chart, the user can see the overall site risk score and compare it to the Site Risk Category Score Over Time.

Studies ▶ Study B: 10001 Take Action



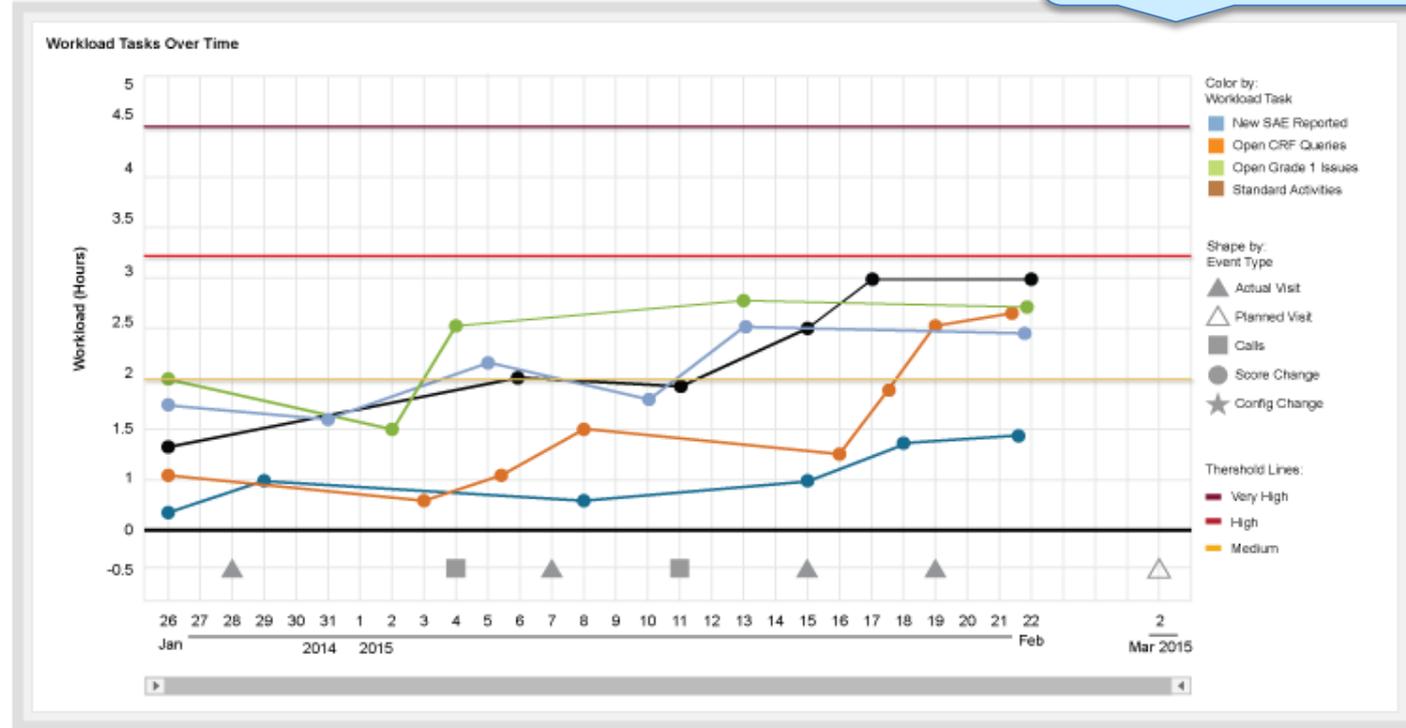
The user selects the Workload (Hours) cell for site 10001 and Site Workload Over Time and Workload Tasks Over Time charts display.

Studies ▶ Study B: 10001 Take Action

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA						Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence	
10001		Site One	Investigator One	United States	CRA One	CRA One	10		2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48		2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38		6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38		5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13		3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11		2.1	2.3	1.3	0	1.8	.40	.40	0	.40
70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38		1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17		4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99		2.0	4.3	3.8	3.0	3.3	1.5	1.5	1.1	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44		1.9	6.2	3.0	3.0	3.3	1.5	1.5	1.1	1.0

With the Site Workload Over Time chart, the user can see the overall workload hours for a site and compare it to the Workload Tasks Over Time.

Studies ▶ Study B: 10001 Take Action



Second Scenario

Dashboard to Study List

User is alarmed with the level of high level alerts and wants to view a grid layout of each study

▲ Studies

Display All

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

▼ Geographic Area

▼ Site Status

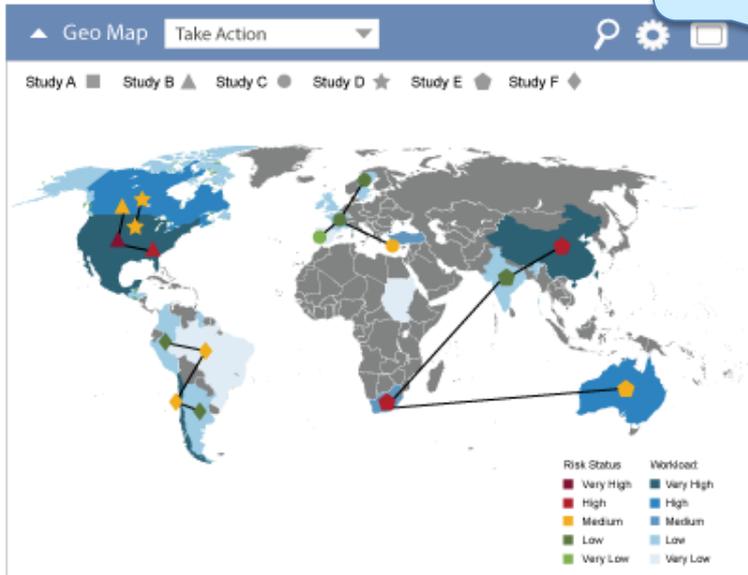
Display All

- Created
- Initiated
- Active
- Closed

▼ Time

▼ Staff

Studies



▲ Calendar Take Action

◀ April ▶

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3 Site Visit	4	5 Site Visit	6	7
8	9	10 Site Visit	11	12	13 Site Visit Phone Call	14
15	16 Site Visit	17 Site Visit Phone Call	18 Phone Call	19	20	21
22	23	24	25 Site Visit	26 Site Visit	27	28
29	30	31 Site Visit	1	2	3	4

▲ Notifications Take Action

Description	Site Number	Acknowledgement Details
<input type="checkbox"/> Multiple SAEs Occurred	10001	Visit site to see if there is a problem
<input type="checkbox"/> Drug Accountability	20002	Must be top priority at next visit
<input type="checkbox"/> New SAE Reported	30003	Follow up with site as appropriate
<input type="checkbox"/> Enrollment Delay	40004	Contact site to discuss enrollment planning
<input type="checkbox"/> Multiple SAEs Occurred	50005	Visit site to see if there is a problem
<input type="checkbox"/> New SAE Reported	60006	Follow up with site as appropriate
<input type="checkbox"/> Aging Query	70007	Contact site to discuss query resolution plan
<input type="checkbox"/> SAE Occurred	80008	Call the site to discuss SAE
<input type="checkbox"/> Fraud Detected	90009	Immediate investigation of fraud necessary
<input type="checkbox"/> Slim Chance of Fraud..	10010	Call site to address chance of fraud

Focus is on the Tree map and risk status. Information could be derived per category by mousing, for example, the large red tree block under Patient Safety, but this user wants to take action now.

Studies

Display All

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

Geographic Area

Site Status

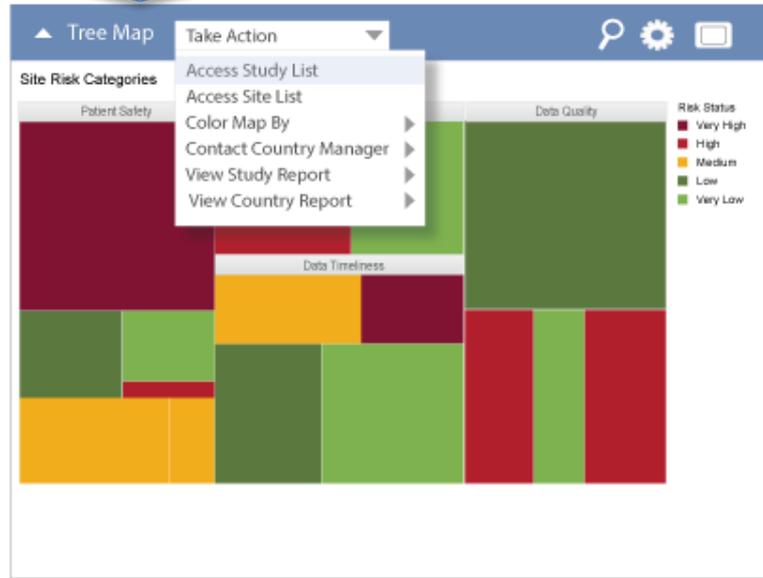
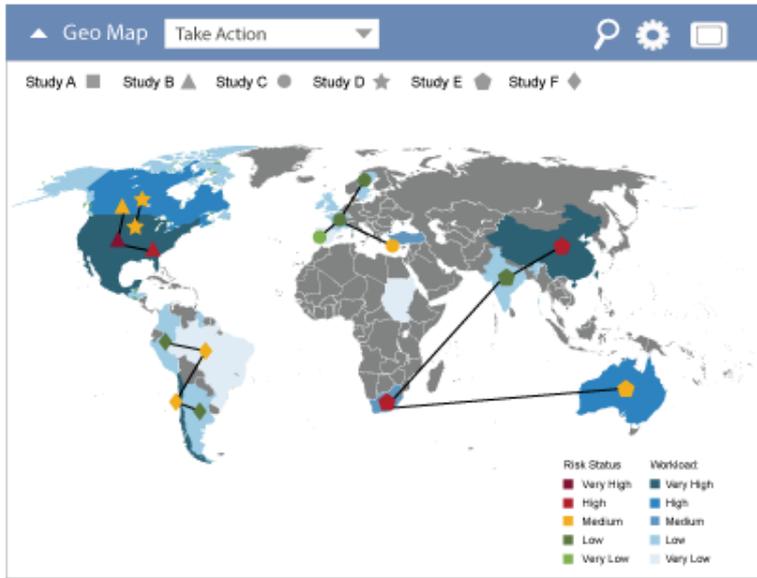
Display All

- Created
- Initiated
- Active
- Closed

Time

Staff

Studies



Calendar

Take Action

April

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3 Site Visit	4	5 Site Visit	6	7
8	9	10 Site Visit	11	12	13 Site Visit Phone Call	14
15	16 Site Visit	17 Site Visit Phone Call	18 Phone Call	19	20	21
22	23	24	25 Site Visit	26 Site Visit	27	28
29	30	31 Site Visit	1	2	3	4

Notifications

Take Action

Description	Site Number	Acknowledgement Details
<input type="checkbox"/> Multiple SAEs Occurred	10001	Visit site to see if there is a problem
<input type="checkbox"/> Drug Accountability	20002	Must be top priority at next visit
<input type="checkbox"/> New SAE Reported	30003	Follow up with site as appropriate
<input type="checkbox"/> Enrollment Delay	40004	Contact site to discuss enrollment planning
<input type="checkbox"/> Multiple SAEs Occurred	50005	Visit site to see if there is a problem
<input type="checkbox"/> New SAE Reported	60006	Follow up with site as appropriate
<input type="checkbox"/> Aging Query	70007	Contact site to discuss query resolution plan
<input type="checkbox"/> SAE Occurred	80008	Call the site to discuss SAE
<input type="checkbox"/> Fraud Detected	90009	Immediate investigation of fraud necessary
<input type="checkbox"/> Slim Chance of Fraud..	10010	Call site to address chance of fraud

▲ Studies

Studies Take Action

- Display All
- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

Study Number	Protocol Number/ID	Study Name	Sponsor Name	Next Interim Analysis	Database Lock	Max. Site Workload (Hours)	Max. Site Risk Score
<input type="checkbox"/> Study A	P123456	Respiratory Study	Pharma Co. 12	2015-03-04	2015-08-14	129.03	4.50
<input type="checkbox"/> Study B	P1234567	Cardiovascular Study	Pharma Co. 13	2015-03-18	2015-11-27	126.96	2.98
<input type="checkbox"/> Study C	P12345678	Dermatology Study	Pharma Co. 14	2015-03-31	2016-01-11	126.96	1.34
<input type="checkbox"/> Study D	P123456789	Asthma Study	Pharma Co. 15	2015-04-10	2016-02-18	129.03	1.29

▼ Geographic Area

▼ Site Status

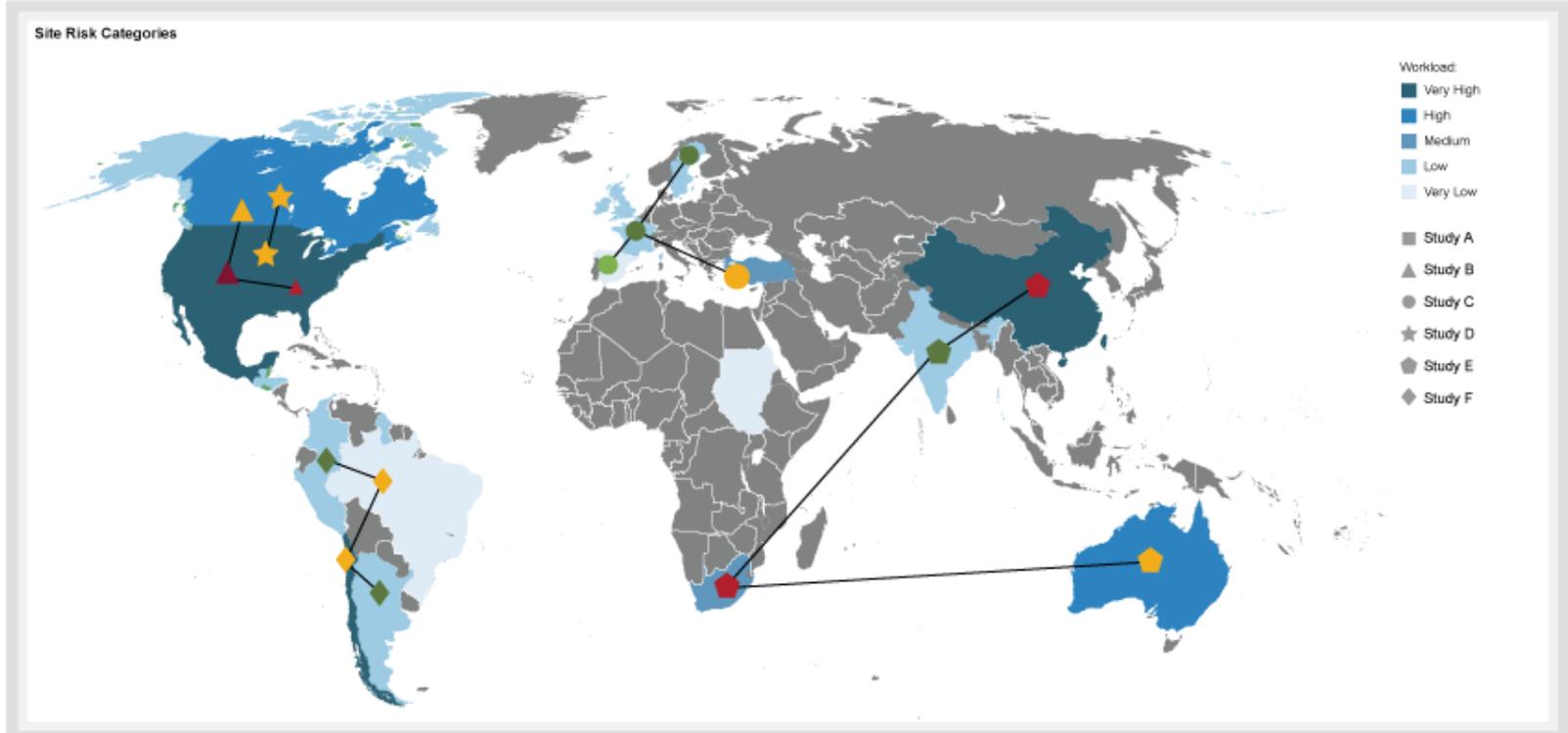
- Display All
- Created
- Initiated
- Active
- Closed

▼ Time

▼ Staff

Because the user accessed the Study page via the Tree Map, the display on the study page does not present redundant data, but rather offers a different view. If the user had accessed the study page via the Geo Map,

Studies Take Action



Studies

Studies **Take Action**

Study Number	Protocol Number/ID	Study Name	Sponsor Name	Next Interim Analysis	Database Lock	Max. Site Workload (Hours)	Max. Site Risk Score
<input type="checkbox"/> Study A	P123456	Respiratory Study	Pharma Co. 12				
<input type="checkbox"/> Study B	P1234567	Cardiovascular Study	Pharma Co. 13				
<input type="checkbox"/> Study C	P12345678	Dermatology Study	Pharma Co. 14				
<input type="checkbox"/> Study D	P123456789	Asthma Study	Pharma Co. 15				

This option (alternate to full geo map) shows a focus on workload and monitoring as well as risk via the geo map. There is also the addition of an animation button below the geo map allowing the user to play through the time frame. Example shows July 2014 to June 2015. Animation will show how risk and workload arrived at the point it is currently at.

Geographic Area

Site Status

Site Status

Time

Staff

Studies **Take Action**

Top Workload Contenders Across Studies

New SAE Reported

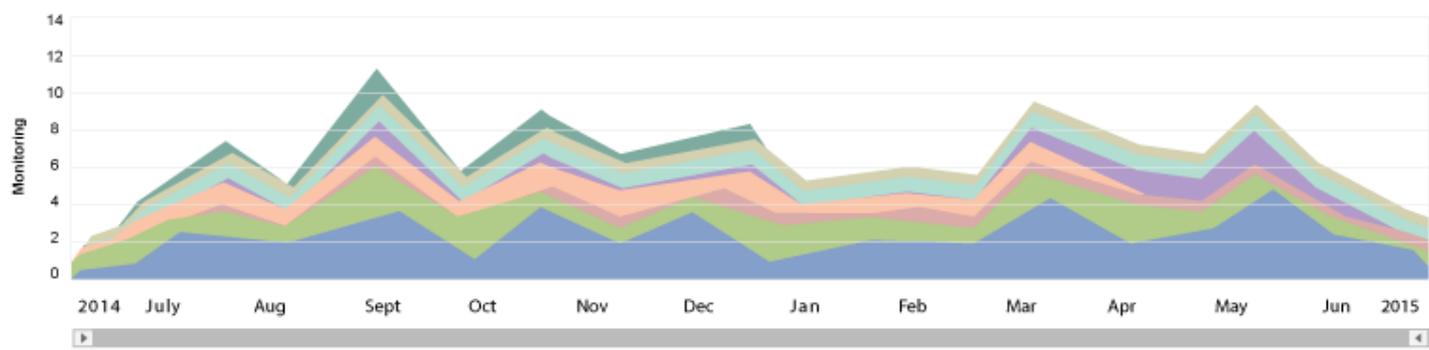
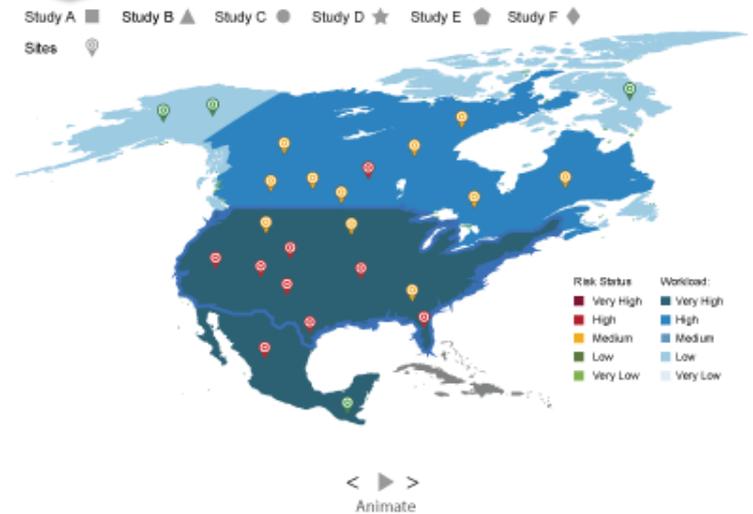
Studies	Last 12 Months	Variance from Plan
Study A		
Study B		
Study C		
Study D		

July 2014 June 2015

Open CRF Queries

Outstanding SDV Pages

Standard Activities



Studies

Studies Take Action

Study Number	Protocol Number/ID	Study Name	Sponsor Name	Next Interim Analysis	Database Lock	Max. Site Workload (Hours)	Max. Site Risk Score
<input type="checkbox"/> Study A	P123456	Respiratory Study	Pharma Co. 12	2015-03-04	2015-08-14	129.03	4.50
<input type="checkbox"/> Study B	P1234567	Cardiovascular Study	Pharma Co. 13	2015-03-18	2015-11-27	126.96	2.98
<input type="checkbox"/> Study C	P12345678				2016-01-11	126.96	1.34
<input type="checkbox"/> Study D	P123456789				2016-02-18	129.03	1.29

The most useful information based on the signal calling attention is, why did this happen?

Geographic Area

Site Status

Studies Take Action

Top Workload Contenders Across Studies

New SAE Reported

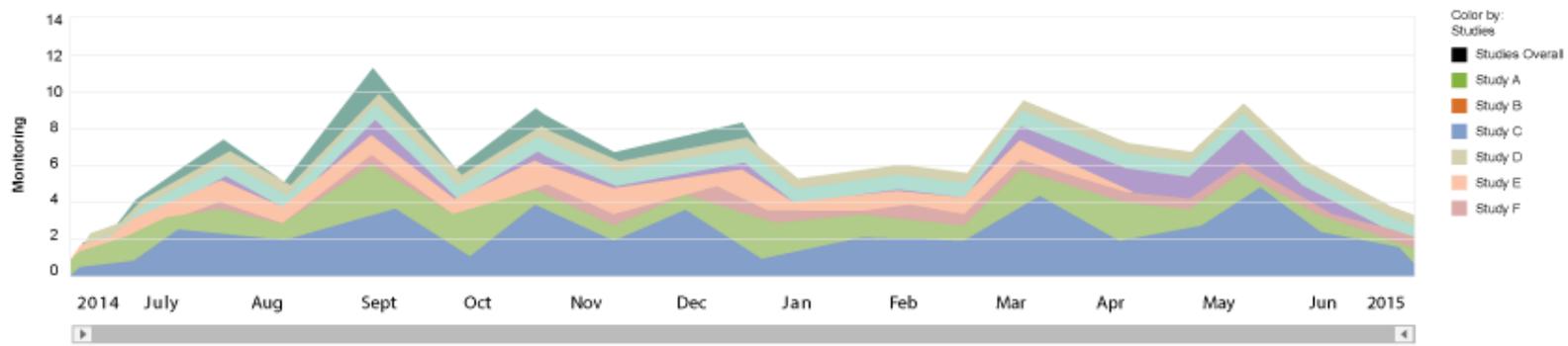
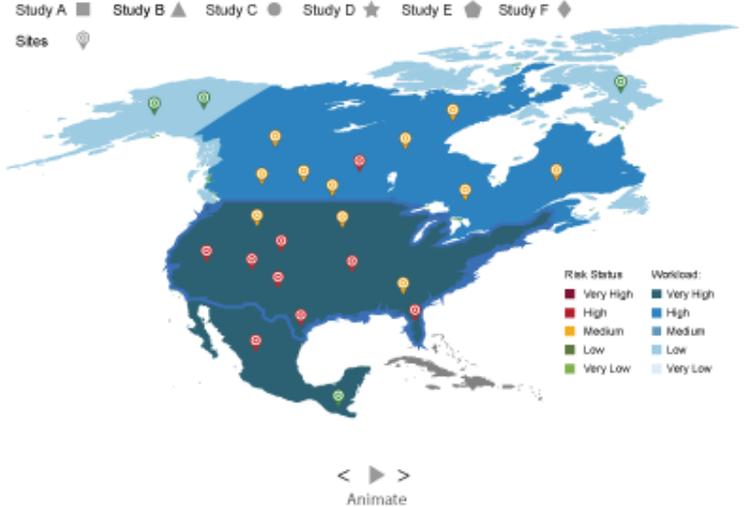
Studies Last 12 Months Why? Variance from Plan

July 2014 June 2015

Open CRF Queries

Outstanding SDV Pages

Standard Activities



- Studies
- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

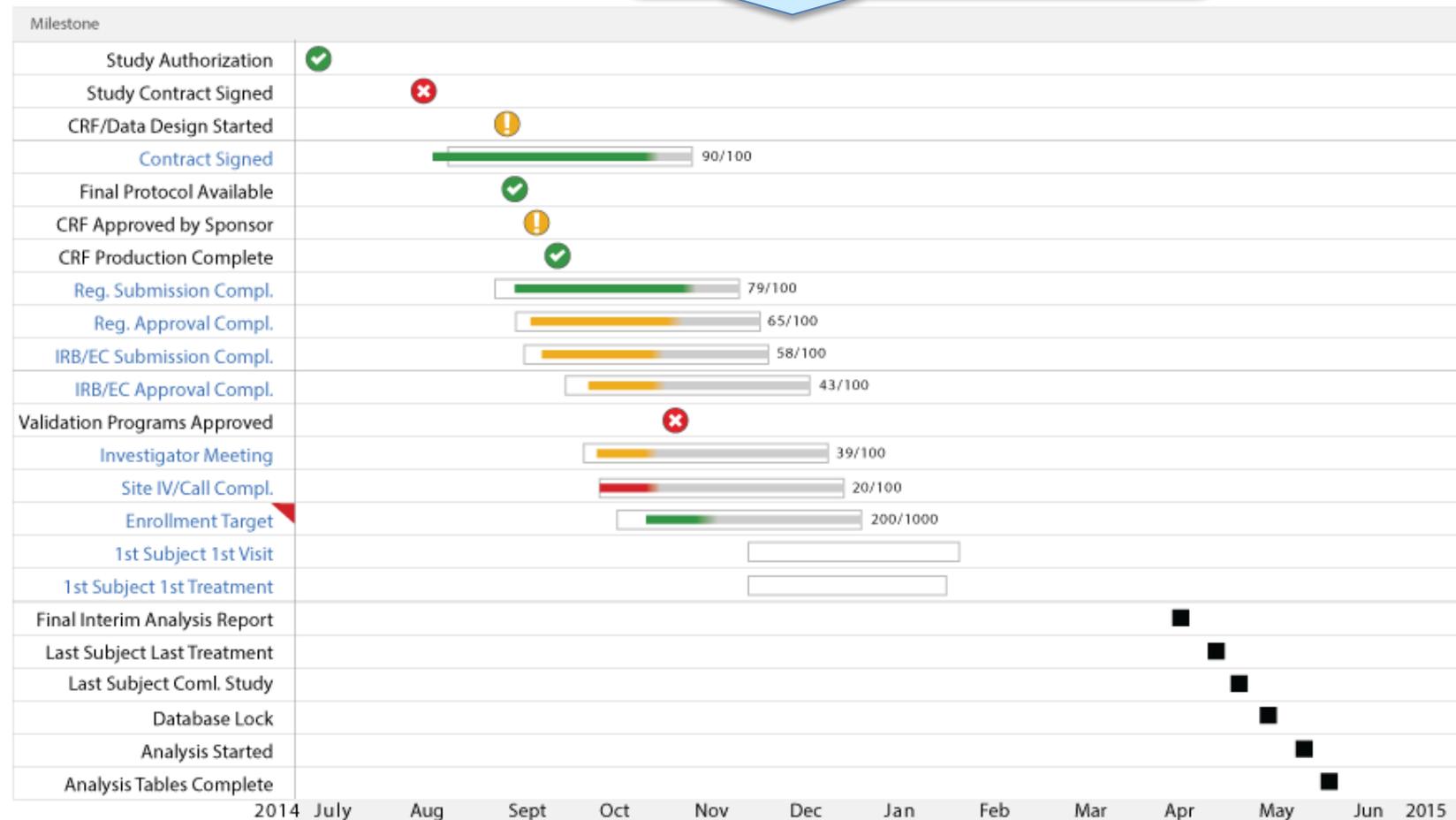
Study B Take Action

Study Number	Protocol Number/ID	Study Name	Sponsor Name	Next Interim Analysis	Database Lock	Max. Site Workload (Hours)	Max. Site Risk Score
<input type="checkbox"/> Study A	P123456	Respiratory Study	Pharma Co. 12				
<input checked="" type="checkbox"/> Study B	P1234567	Cardiovascular Study	Pharma Co. 13				
<input type="checkbox"/> Study C	P12345678	Dermatology Study	Pharma Co. 14				
<input type="checkbox"/> Study D	P123456789	Asthma Study	Pharma Co. 15				

List of milestones displays when focus is put on a single study, and from there a user can access the site list, either contextually by focusing on a particular milestone or for the overall study from the Take Action menu.

- Geographic Area
- Site Status
- Time
- Staff

Study B Take Action



Third Scenario Deeplinking

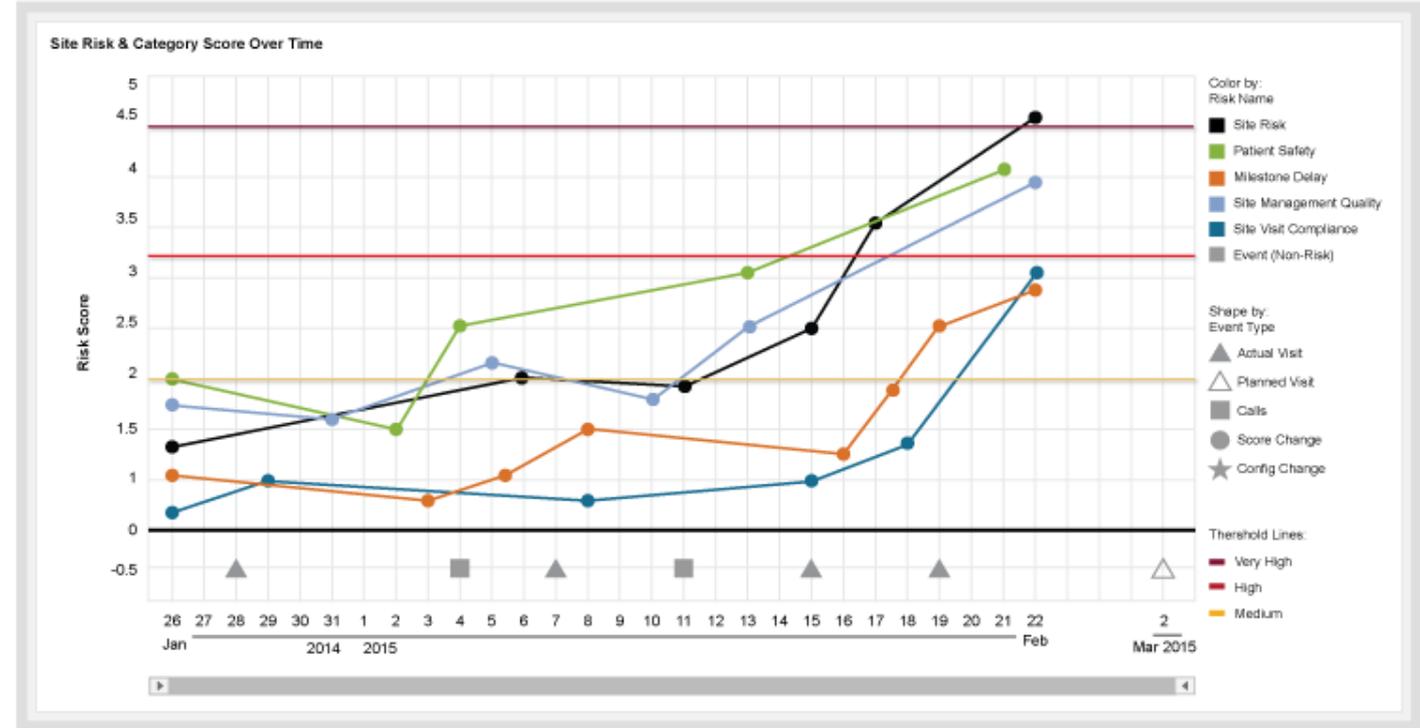
User accesses the high risk score over time visualization because of the high and affected score

- ▲ Studies
- ▼ Geographic Area
- ▼ Site Status
- ▼ Time
- ▼ Staff

Studies ▶ Study B: Sites Take Action ▼

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	4.0	4.0	0	4.0
70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.2	-3.0	3.3	1.5	1.5	1.1	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0	1.0	3.0	1.0

Studies ▶ Study B: Sites Take Action ▼



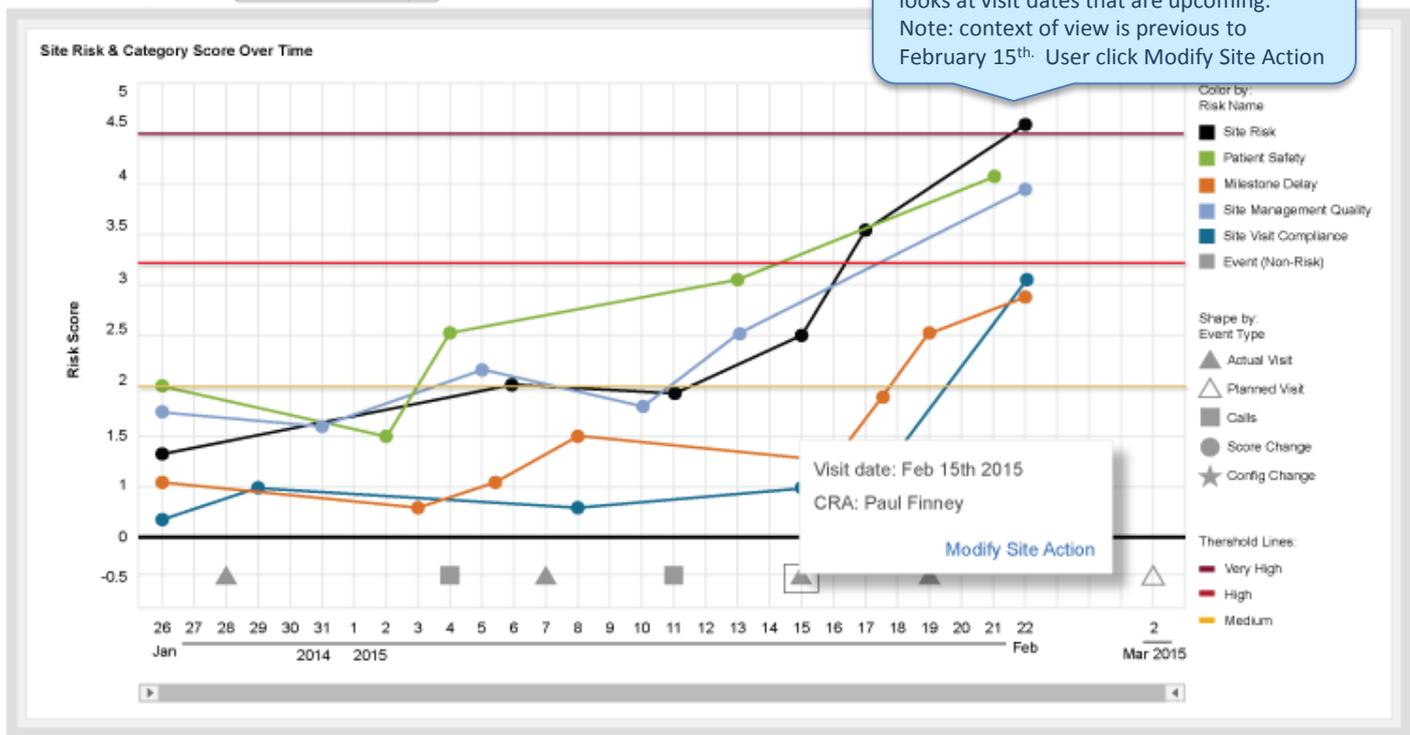
- ▲ Studies
- Study B
- Study A
- Study B
- Study C
- Study D
- Study E
- Study F
- ▼ Geographic Area
- ▼ Site Status
- Site Status
- ▼ Time
- ▼ Staff

Studies ▶ Study B: Sites Take Action

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Score	Risk Change	Data Quality	Data Timeliness	Milestone Delay	Milestone Other Triggers	Protocol Adherence
<input type="checkbox"/> 10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0	4.0	3.9	4.0
<input type="checkbox"/> 20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0	3.0	1.2	3.0
<input type="checkbox"/> 30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2	3.2	4.0	3.2
<input type="checkbox"/> 40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6	1.6	0	1.6
<input type="checkbox"/> 50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0	2.0	4.8	2.0
<input type="checkbox"/> 60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	.40	.40	0	.40
<input type="checkbox"/> 70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9	3.9	1.7	3.9
<input type="checkbox"/> 80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5	2.5	1.3	2.5
<input type="checkbox"/> 90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.2	-3.0	3.3	1.5	1.5	1.1	1.5
<input type="checkbox"/> 10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0	1.0	3.0	1.0

Looking at the upward trending, the user looks at visit dates that are upcoming. Note: context of view is previous to February 15th. User click Modify Site Action

Studies ▶ Study B: Sites Take Action



TASKS

INFORMATION

- Trial Site Summary
- Properties
- Clinical Personnel
- Locations
- Recruitment
- Enrolment Plan
- Event Dates
- Visits
- Additional Information
- Project Subject Visits

ACTIONS

Visit Start Date

Trial Site Time Zone

Visit Start Time

Visit End Date

Visit Conducted Yes No Not Known

Cancel Visit

Visit Type

Primary Monitor

Additional Monitors

Comments

After logging in, the user accesses the contextual location in MySites from DDM. No need to open MySites separately and click through/search for contextual area, in this case Site 10001.

User Preferences



User accesses their preferences.

Manage Studies/Sites

User Preferences

Study Preferences

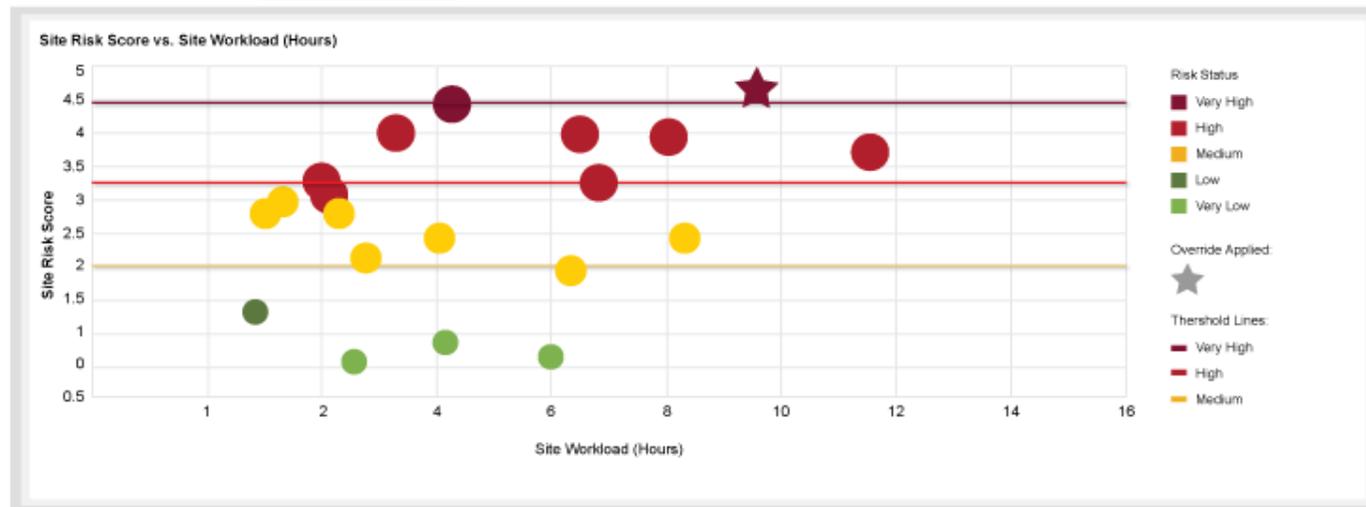
Roles & Privileges

Logout

Studies Study B: Sites Take Action

Site Number	Notifications	Site Name	Investigator Name	Country	Approved CRA	Assigned CMA	Days until Max Visit Interval	Workload (Hours)	Workload Change	Risk Change	Data Quality	Data Timeliness	
10001		Site One	Investigator One	United States	CRA One	CRA One	10	2.9	2.0	4.5	-1.0	3.0	4.0
20002		Site Two	Investigator Two	United States	CRA Two	CRA Two	48	2.6	2.4	2.3	1.2	1.9	3.0
30003		Site Three	Investigator Three	United States	CRA Three	CRA Three	-38	6.0	-2.3	2.8	2.0	2.0	3.2
40004		Site Four	Investigator Four	United States	CRA Four	CRA Four	-38	5.0	-1.9	2.5	1.7	2.5	1.6
50005		Site Five	Investigator Five	United States	CRA Five	CRA Five	13	3.0	2.0	3.5	-3.0	2.0	2.0
60006		Site Six	Investigator Six	United States	CRA Six	CRA Six	11	2.1	2.3	1.3	0	1.8	.40
70007		Site Seven	Investigator Seven	United States	CRA Seven	CRA Seven	38	1.9	4.0	3.1	2.0	3.5	3.9
80008		Site Eight	Investigator Eight	United States	CRA Eight	CRA Eight	17	4.0	-7.8	2.4	0	1.1	2.5
90009		Site Nine	Investigator Nine	United States	CRA Nine	CRA Nine	99	2.0	4.3	3.2	-3.0	3.3	1.5
10010		Site Ten	Investigator Ten	United States	CRA Ten	CRA Ten	44	1.9	6.2	3.9	-2.9	3.5	1.0

Studies Study B: Sites Take Action





▲ Studies

Study B x

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

▼ Geographic Area

▼ Site Status

Site Status

▼ Time

▼ Staff

User has the ability to configure their page layout to optimize their working environment by selecting 1 of 4 appealing layouts – “essentially a desk top”

User Preferences

Page Layout

Table Column Order & Display

▼ Study Table Columns

▲ Site Table Columns

- Site Information** [Hide](#)
- Site Number [Hide](#)
- Notifications [Hide](#)
- Site Name [Hide](#)
- Investigator Name [Hide](#)
- Country [Hide](#)
- Assigned CRA [Hide](#)
- Assigned CMA [Hide](#)
- Compliance** [Hide](#)
- Days Until Max. Visit Interval [Hide](#)
- Workload** [Hide](#)
- Workload (Hours) [Hide](#)
- Workload Change [Hide](#)
- Risk** [Hide](#)
- Risk Score [Hide](#)
- Risk Change [Hide](#)
- Site Management Quality [Hide](#)
- Data Quality [Hide](#)

Set Reset Cancel

Site	Protocol Adherence
	4.0
	3.0
	3.2
	1.6
	2.0
	.40
	3.9
	2.5
	1.5
	1.0

▲ Studies

Study B x

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

▼ Geographic Area

▼ Site Status

Site Status

▼ Time

▼ Staff

User Preferences

Page Layout

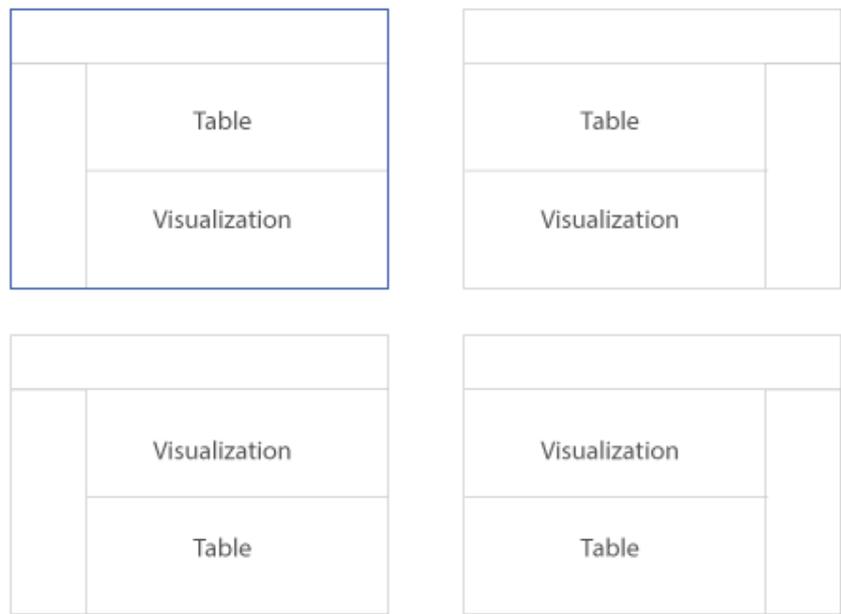


Table Column Order & Display

▼ Study Table Columns

▲ Site Table Columns

- Site Information
 - Site Number
 - Notifications
 - Site Name
 - Investigator Name
 - Country
 - Assigned CRA
 - Assigned CMA
- Compliance
 - Days Until Max. Visit Interval
- Workload
 - Workload (Hours)
 - Workload Change
- Risk
 - Risk Score
 - Risk Change
 - Site Management Quality
 - Data Quality

Buttons: Set, Reset, Cancel

User clicks Hide for Site Name in the Site Information section.

Site Name	Protocol Adherence
	4.0
	3.0
	3.2
	3.9
	2.5
	1.5
	1.0



▲ Studies

Study B x

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

▼ Geographic Area

▼ Site Status

▼ Time

▼ Staff

User Preferences

Page Layout

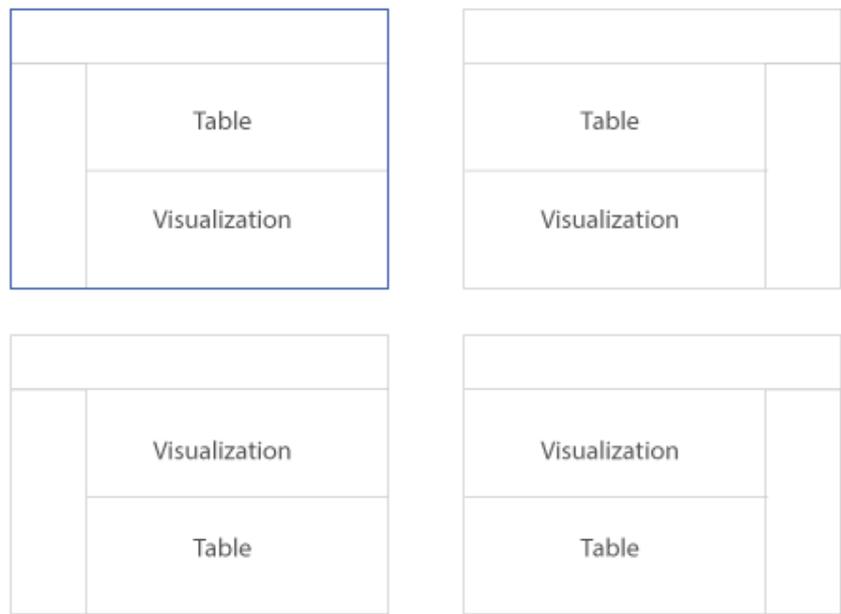


Table Column Order & Display

▼ Study Table Columns

▲ Site Table Columns

Site Information

- Site Number
- Notifications [Hide](#)
- Site Name (hidden) [Show](#)
- Investigator Name [Hide](#)
- Country [Hide](#)
- Assigned CRA [Hide](#)
- Assigned CMA [Hide](#)

Compliance

- Days Until Max. Visit Interval [Hide](#)

Workload

- Workload (Hours) [Hide](#)
- Workload Change [Hide](#)

Risk

- Risk Score [Hide](#)
- Risk Change [Hide](#)
- Site Management Quality [Hide](#)
- Data Quality [Hide](#)

[Set](#) [Reset](#) [Cancel](#)

Now that the Site Name column has been set to hidden, when the user clicks Set, the column will not display in the table.



▲ Studies

Study B x

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

▼ Geographic Area

▼ Site Status

▼ Time

▼ Staff

User Preferences

Page Layout

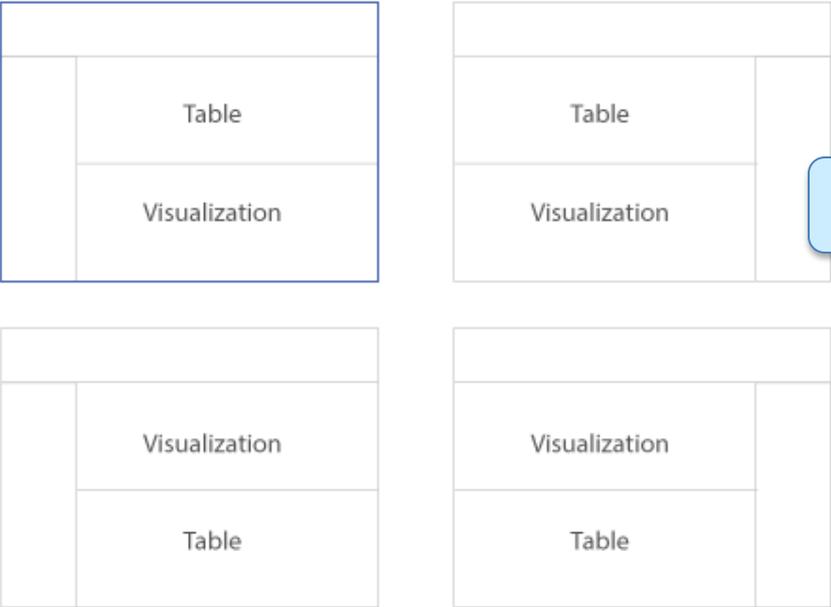


Table Visualization

Table Visualization

Visualization Table

Visualization Table

Table Column Order & Display

- Study Table Columns
- Site Table Columns
- Site Information [Hide](#)
- Country [Hide](#)
- Assigned CRA [Hide](#)
- Assigned CMA [Hide](#)
- Compliance [Hide](#)
- Days Until Max. Visit Interval [Hide](#)
- Workload [Hide](#)
- Workload (Hours) [Hide](#)
- Workload Change [Hide](#)
- Risk [Hide](#)
- Risk Score [Hide](#)
- Risk Change [Hide](#)
- Site Management Quality [Hide](#)
- Data Quality [Hide](#)

User can drag items from the list up or down to change the order of the table columns.

Site	Protocol Adherence
	4.0
	3.0
	3.2
	1.6
	2.0
	.40
	3.9
	2.5
	1.5
	1.0



▲ Studies

Study B x

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

▼ Geographic Area

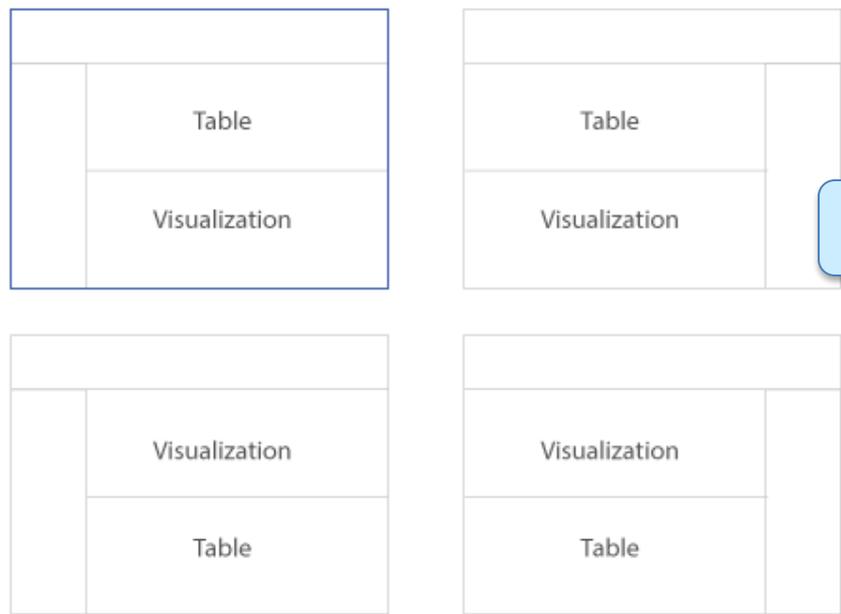
▼ Site Status

▼ Time

▼ Staff

User Preferences

Page Layout



1 2 4 6 8 10 12 14 16               

Site Workload (Hours)

Table Column Order & Display

- ▼ Study Table Columns
- ▲ Site Table Columns
- Site Information [Hide](#)
- Site Number [Hide](#)
- [Hide](#)
- [Hide](#)
- [Show](#)
- [Hide](#)
- [Hide](#)
- Assigned CMA [Hide](#)
- Assigned CRA [Hide](#)
- Compliance [Hide](#)
- Days Until Max. Visit Interval [Hide](#)
- Workload [Hide](#)
- Workload (Hours) [Hide](#)
- Workload Change [Hide](#)
- Risk [Hide](#)
- Risk Score [Hide](#)
- Risk Change [Hide](#)
- Site Management Quality [Hide](#)
- Data Quality [Hide](#)

User has dragged Assigned CRA to display after Assigned CMA.

Site	Protocol Adherence
	4.0
	3.0
	3.2
	1.6
	2.0
	.40
	3.9
	2.5
	1.5
	1.0

▲ Studies

Study B x

- Study A
- Study B
- Study C
- Study D
- Study E
- Study F

▼ Geographic Area

▼ Site Status

▼ Time

▼ Staff

User Preferences

Final outcome before clicking Set. All changes will display automatically after popup closes.

Page Layout

Table Column Order & Display

▼ Study Table Columns

▲ Site Table Columns

- Site Information** [Hide](#)
- Site Number [Hide](#)
- Notifications [Hide](#)
- Site Name (hidden) [Show](#)
- Investigator Name [Hide](#)
- Country [Hide](#)
- Assigned CMA [Hide](#)
- Assigned CRA [Hide](#)
- Compliance** [Hide](#)
- Days Until Max. Visit Interval [Hide](#)
- Workload** [Hide](#)
- Workload (Hours) [Hide](#)
- Workload Change [Hide](#)
- Risk** [Hide](#)
- Risk Score [Hide](#)
- Risk Change [Hide](#)
- Site Management Quality [Hide](#)
- Data Quality [Hide](#)

Site Workload (Hours)

Site	Protocol Adherence
	4.0
	3.0
	3.2
	1.6
	2.0
	4.0
	3.9
	2.5
	1.5
	1.0

Taking Action

PAREXEL Empowering Users

PAREXEL Solution – Empowered to take action

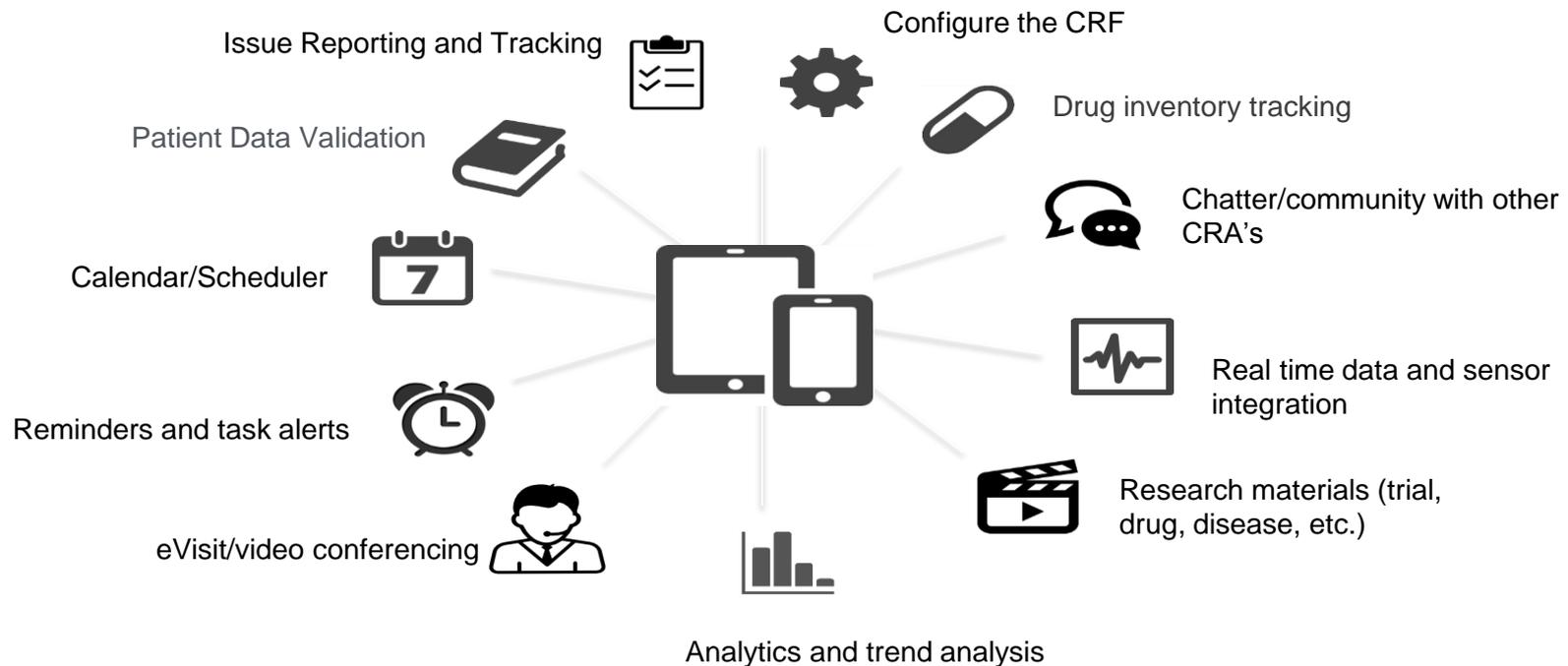
- **Unification of Multiple Disparate Systems** – Allows insights and singular access flow to multiple systems (e.g., IMPACT, DataLabs, Clinphone). Leverage data integration for a clear view.
- **Communication/Collaboration** – This is a key element to greater efficiency, return on investment, and fewer risk and workload issues. Multiple avenues in context.
- **Standardization of Products, Processes, and Measurements** – Building a PAREXEL suite of products with a common look and feel aids in consistency, relevance, and quick recognition. This applies not only to devices, but to code/framework, interfaces, and interaction quality.
- **Feedback** – Provide a consistent avenue for recorded feedback so that PAREXEL can move with the needs, wants, and desires of internal and external customers (e.g., user interviews, usability testing, surveys). This process decreases many stop gaps, including circumventing the prescribed tool or process.
- **Dynamic Modularity** – One size doesn't fit all, whether in a mobile or office scenario. Understanding what the consumer wants and values leverages the quality and key strengths of users.
- **Sophisticated Technology Concepts** – Combine rather than add to current devices requirements. For example, remove scanners and provide device to access data and scan. Phone? Tablet? Laptop? They all have scanning ability that can be integrated.

Collaboration/Contact Scenarios in DDM

- CRA sees that there has been a significant change in a site and needs to contact COL.
- CRA sees changes in several sites that will necessitate need to change travel plans/or to request help for visiting the site – contact the COL or possibly LM.
- CRA has a notification showing in DDM that the monitoring plan requires an email to COL, or other team members – the ability to initiate that email from within DDM would be very helpful.
- If the CRA could have IMs, and possibly invite multiple participants (CMA/COL/ maybe even PL or LM), this would be very efficient; there is the potential for quicker resolutions.
- The PQL (Project Quality Lead) will also have access to DDM for a study they are responsible for. There could be times when the ability for them to contact a CRA/COL directly would potentially save a lot of “email questions” regarding decisions the CRA has made for site visits, etc.
- COL should have ability to contact CRA/CMA directly from the tool – this is actually a feature that will be used very frequently; the COL will frequently reach out to CRA/CMA with specific questions/actions needed regarding the sites.

CRA Mobility Needs

A highly tailored, modularized, intelligent mobile solution that provides CRA's with the right tool at the right time for trial management.



Let's Talk Site Investigator

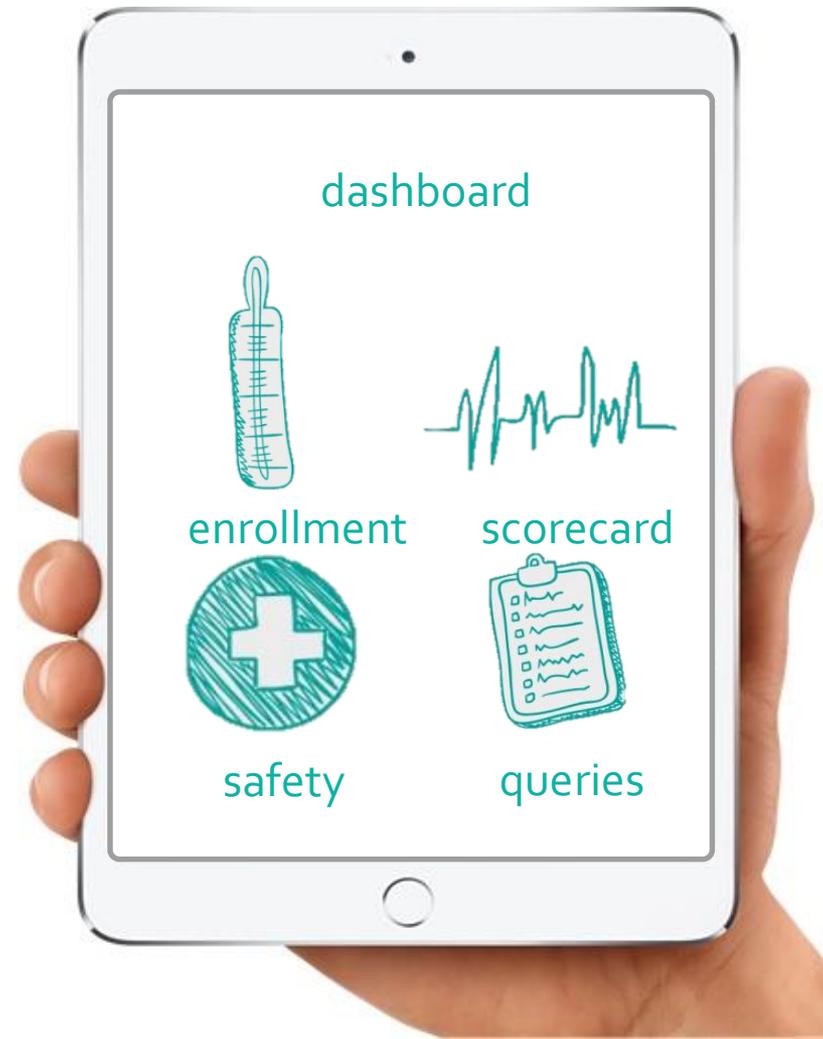
Site Investigators have a competitive nature. They like to achieve or even over achieve. Engaging this mindset and their strengths is important.

They want their sites to:

- Be the fastest
- Have the fewest queries
- Have the lowest screen failure rates

A Site Investigator's dashboard would:

- Be a **time saver** for sites
- Have **actionable** links to open queries
- Provide insight into **their site's** performance



Process to Success

Human-Centered Product Design & Development

User and Task Analysis

Activities:	Documents	Team
<ol style="list-style-type: none"> 1. Interviews 2. Contextual Observation 3. Focus Groups 	<ol style="list-style-type: none"> 1. User roles detailed <ol style="list-style-type: none"> 1. Map of user roles to functions 2. Personas 	<ol style="list-style-type: none"> 1. Lead: BA, UX, Product Owner 2. Supporting: Stakeholders, SMEs

User Stories

Activities:	Documents	Team
<ol style="list-style-type: none"> 1. Write user stories and create maps 2. Prioritize essential work 3. Write high-level stories 	<ol style="list-style-type: none"> 1. Story Maps 2. User stories 3. Low-fidelity Wireframes 4. Work flows 	<ol style="list-style-type: none"> 1. Lead: Product Owner, UX, Users, BAs & Developers 2. Supporting: Stakeholders, SMEs

User-Centered Design

User Stories & Story Maps



Working with SME, PO, BA & DEV



Wireframes & Story Boards

UX: Designed Enough?



User Testing

All team members invited

Backlog Prioritizing & Sprint Planning

Sprint



Developers



Proposed Change To UI Design



UX

UX: Developed Correctly?



User Testing



Agreed Change To UI Design (retest as needed)