



TRI

*the risk-based
monitoring company*



OPRA

*the risk-based
monitoring platform*

OmniComm Clinical Insights Symposia

June 2015

Presenter: Duncan Hall, CEO TRI

Objectives



- Introduce a pragmatic, operational approach to RBM
- Illustrate the use of RBM software to support the approach
- Take any Q&A



Our Journey

- Founded in 2013
- Sister company to Triumph Consultancy
- Entirely Quality Oversight and RBM focused
- Creators of OPRA RBM platform
- One complete solution
 - Technology
 - Study specific services
 - Implementation services
 - Hosting



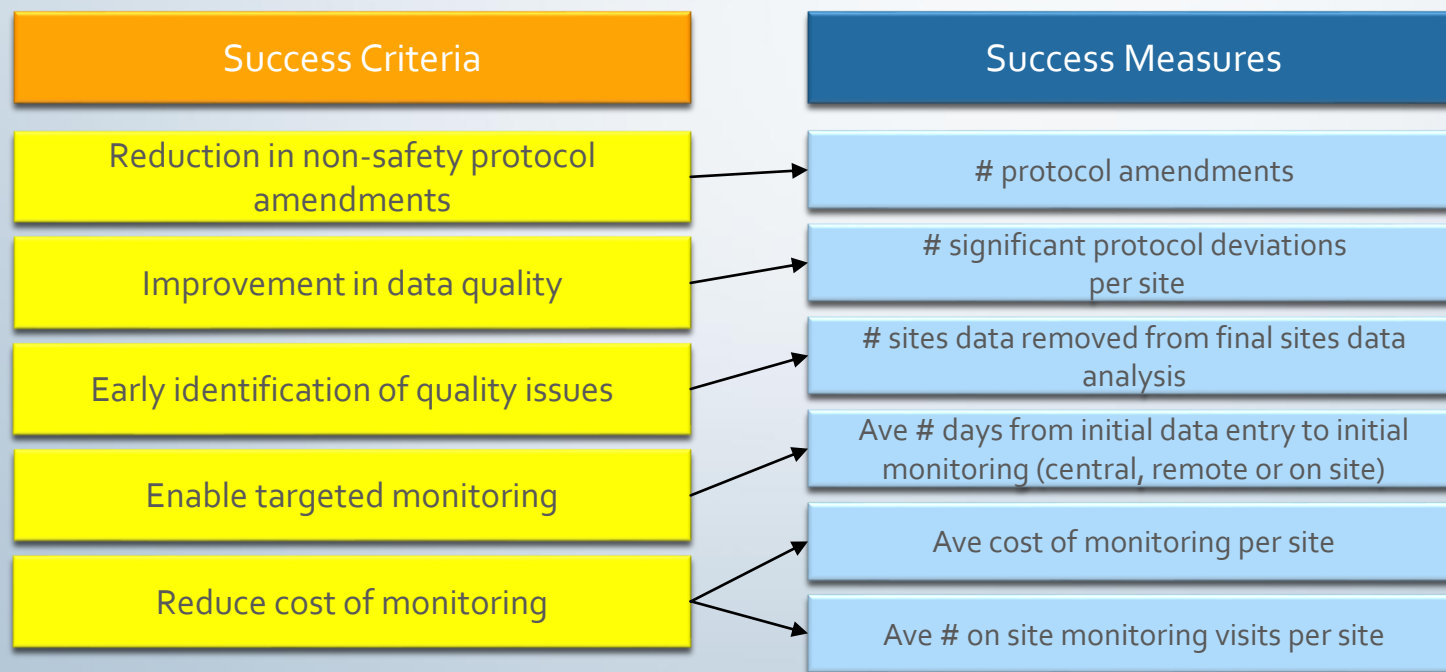
Our simple view:

*RBM is a start to finish
commitment to trial quality which
must be delivered on continually,
dynamically and visibly.*

Before we get started



Whatever model is being implemented, must define what success looks like and how we are going to measure it. For example:



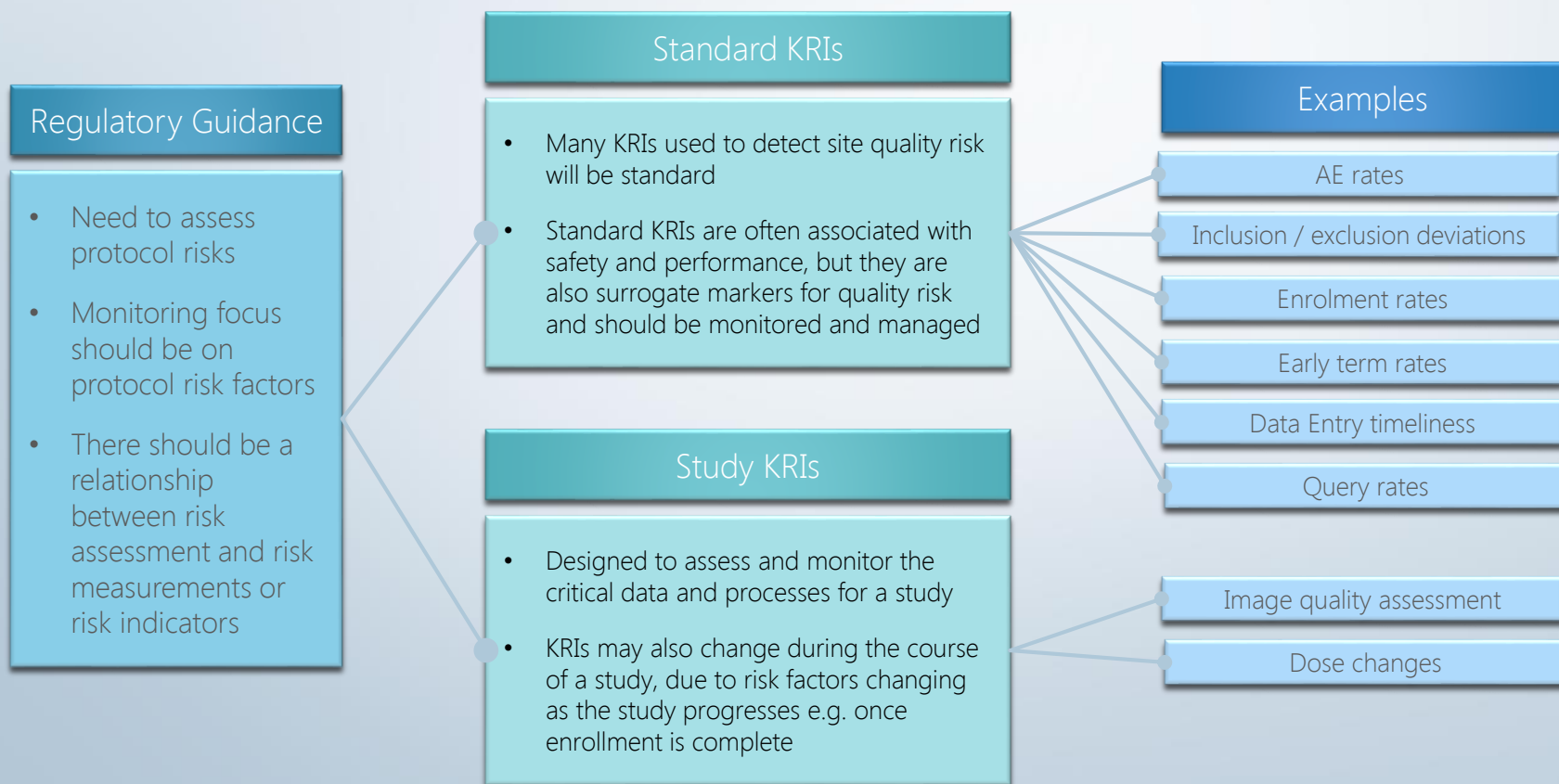
The Four Pillars of RBM

Identify
Manage
Mitigate
Report

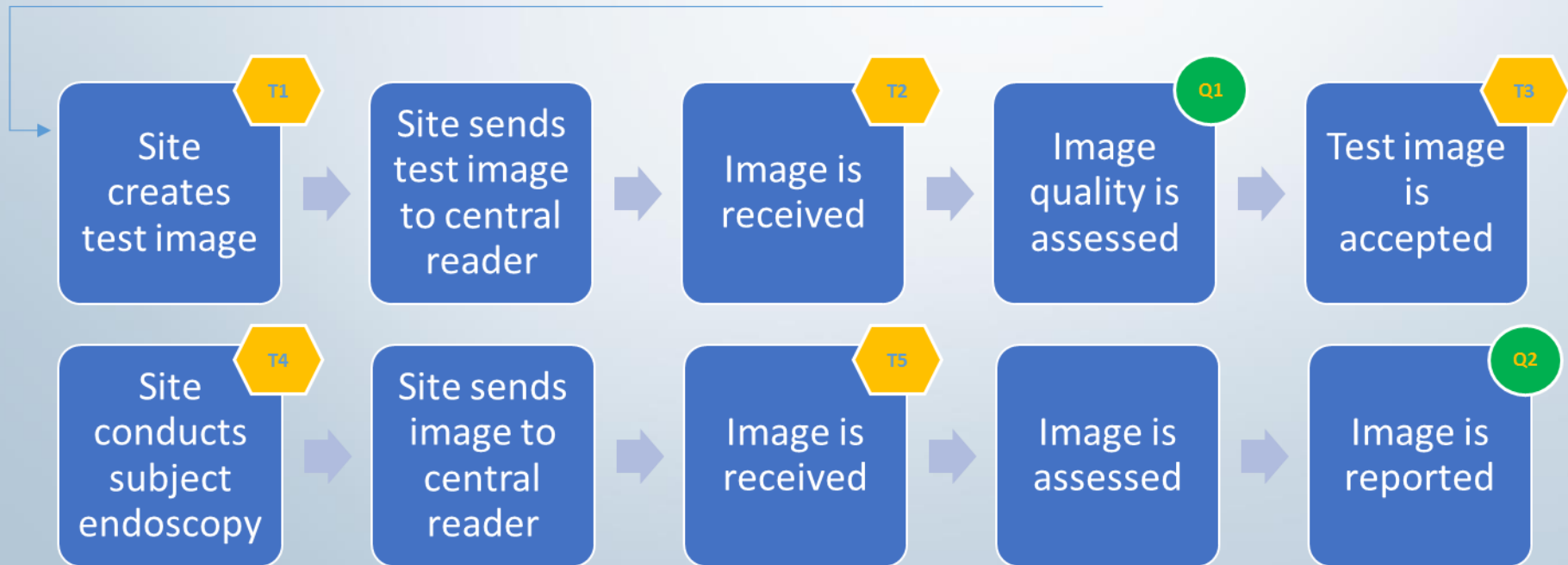
The Four Pillars of RBM

Identify
Manage
Mitigate
Report

Risk Assessment and KRIs



➤ Endoscopy images



Indicator Config / Setup



	Active	Display in Overview	Client	Study	Plot Title	X-Axis Label
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Blood Pressure	Total BP R
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	c	d
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Adverse Events	Randomize
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Medical History	Total Subj
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Concomitant Medications	Randomize
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Protocol Deviations	Randomise
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Physical Exam Findings	Number of Exams
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Electronic Data Capture Change History	CRF Data f
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Number of Queries	CRF Data f
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Adverse Events Distribution	Percentage
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Physical Findings Distribution	Percentage
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Client Two	Study D	Early Termination	Percentage

Reason For Change

adjustment of thresholds

Client

Client Two

Study

Study D

Class

Client

Indicator Type

Count of Values

Indicator Code

MH

Volume Code

MH-V

Plot Title

Medical History

X-Axis Label

Total Subject Population

Y-Axis Label

MHs per Subject

Mild Threshold

95% Confidence

Moderate Threshold

50%

Severe Threshold

2 Standard Deviations : 95.4

Active

1 Standard Deviation : 68.1

Display In Overview

2 Standard Deviations : 95.4

Overview Order

2.5 Standard Deviations : 98.7

Scale Multiplier (Pre)

1

Scale Multiplier (Post)

1

Update

Cancel

Study	Severe Threshold	Type
Study D	95.4	BP
	95.4	BP
	95.4	COV
	95.4	COV
	95.4	COV
	95.4	COV
	86.6	COV
	68.1	COV
	95.4	COV
	95.4	Variability
	68.1	Variability
	95.4	Variability
	95.4	Volume

Study Dashboard

Client

World Tech Bio-Pharma

Study

WD-1034

Assessment Point

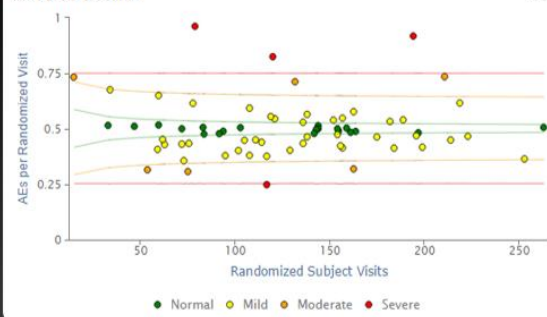
30-Sep-2012



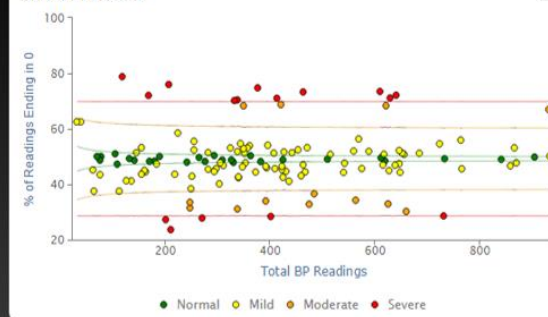
Risk Overview

Site	BP	AE	CM	DV	MH	PE	EDC	QC	Rand. Subj	Score	Country
WD-1034-119	●	●	●	●	—	●	●	●	1	176	GER
WD-1034-021	●	●	●	●	●	●	●	●	15	139	UK
WD-1034-123	●	●	●	●	●	●	●	●	11	129	GER
WD-1034-142	●	●	●	●	●	●	●	●	11	119	CAN
WD-1034-075	●	●	●	●	●	●	●	●	12	111	FRA
WD-1034-046	●	●	●	●	●	●	●	●	10	99	FRA
WD-1034-051	●	●	●	●	●	●	●	●	15	97	GER
WD-1034-140	●	●	●	●	●	●	●	●	12	97	UK
WD-1034-154	●	●	●	●	—	●	●	●	4	96	CAN
WD-1034-082	●	●	●	●	●	●	●	●	16	86	UK
WD-1034-005	●	●	●	●	●	●	●	●	12	85	FRA

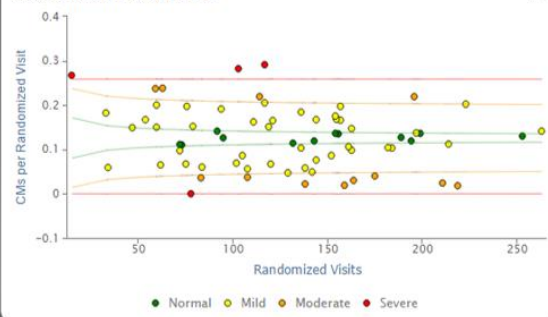
Adverse Events



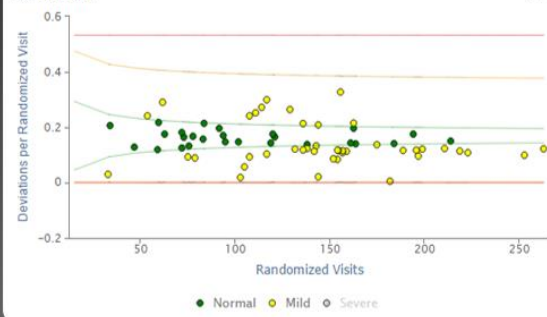
Blood Pressure



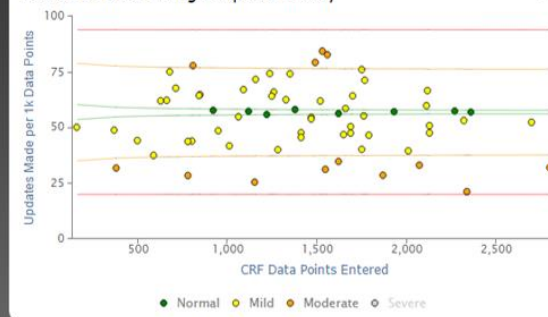
Concomitant Medications



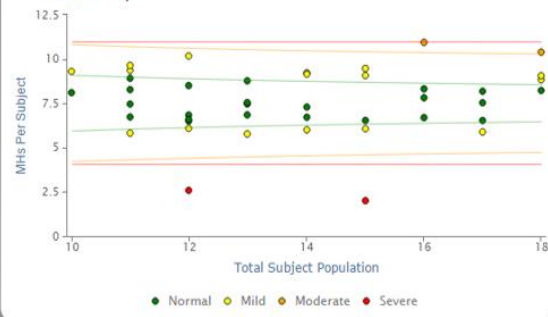
Deviations



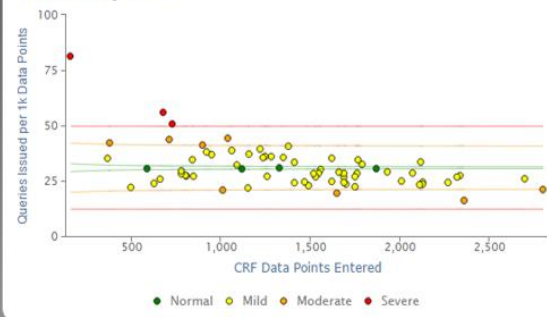
Electronic Data Change Capture History



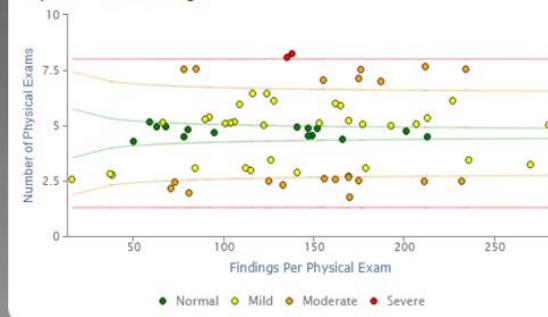
Medical History



Number of Queries



Physical Exam Findings



Hidden



The Four Pillars of RBM

Identify
Manage
Mitigate
Report

Having identified a site we want to investigate further, we can mark the site in the user interface.....

TRI

Study Dashboard

Client

Client Two

Study

Study D

Assessment Point

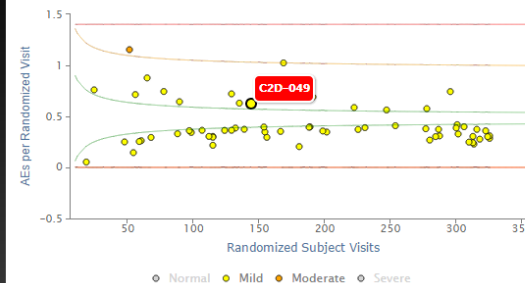
30-Sep-2013

TRI

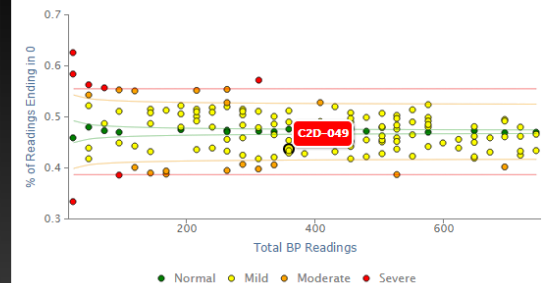
Risk Overview

Site	DV	AE	BP	CM	QC	PE	EDCHx	Rand. Subj	Score	Country
C2D-049	●	●	●	●	●	●	●	15	134	FRA
C2D-120	●	●	—	●	●	●	●	1	121	UK
C2D-027	●	●	●	●	●	●	●	12	114	GER
C2D-052	●	●	●	●	●	●	●	12	96	CAN
C2D-006	●	●	●	●	●	●	●	18	91	CAN
C2D-126	●	●	●	●	●	●	●	18	89	GER
C2D-117	●	●	●	●	●	●	●	31	85	CAN
C2D-144	●	●	●	●	●	●	●	26	82	GER
C2D-088	●	●	●	●	●	●	●	18	81	GER
C2D-154	●	●	●	●	●	●	●	24	80	UK
C2D-061	●	●	—	●	●	●	●	2	76	GER

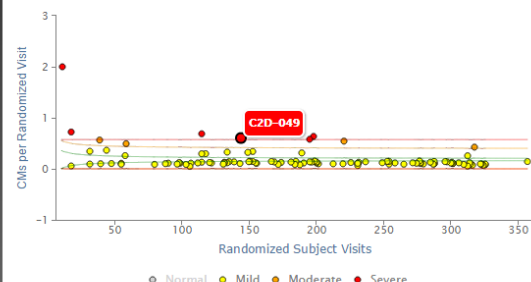
Adverse Events



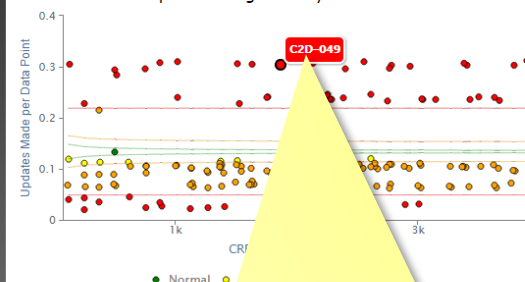
Blood Pressure



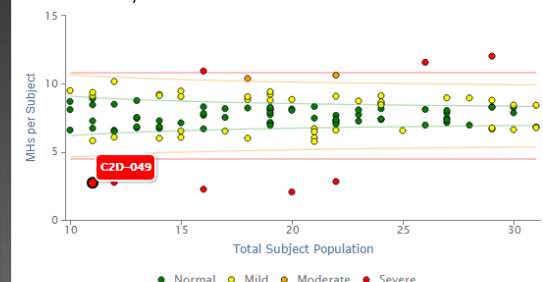
Concomitant Medications



Electronic Data Capture Change History



Medical History



...and then see how that site looks across each indicator, compared to the rest of the study sites.

OPRA

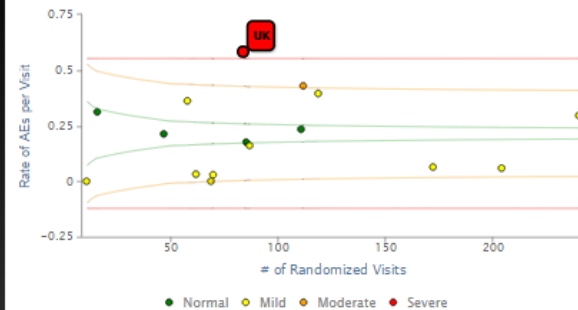
We can also look at our data on a country by country basis to look for regional quality risks

Country Dashboard

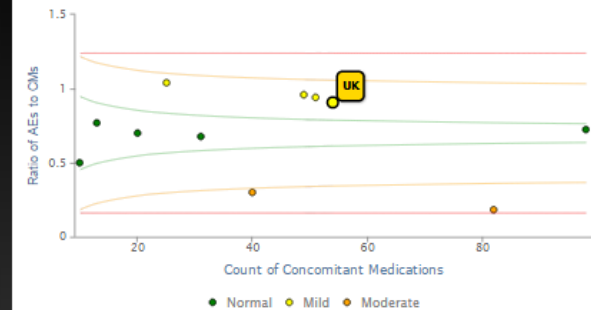
Risk Overview

Site	BP	AE	CM	AER	MH	QC	DV	EDC	Rand. Subj	Score
UK	●	●	●	●	●	●	●	●	18	172
Sweden	●	●	●	●	●	●	●	●	3	105
Russia	●	●	●	●	●	●	●	●	12	99
Czech Republic	●	●	●	●	●	●	●	●	20	94
Canada	●	●	●	●	●	●	●	●	23	79
Ukraine	●	●	●	●	●	●	●	●	55	79
Bulgaria	●	●	●	●	●	●	●	●	18	78
Norway	●	●	●	●	●	●	●	●	9	75
Poland	●	●	●	●	●	●	●	●	61	74
Belarus	●	●	●	●	●	●	●	●	71	73
Denmark	●	●	●	●	●	●	●	●	25	70
Hungary	●	●	●	●	●	●	●	●	21	67

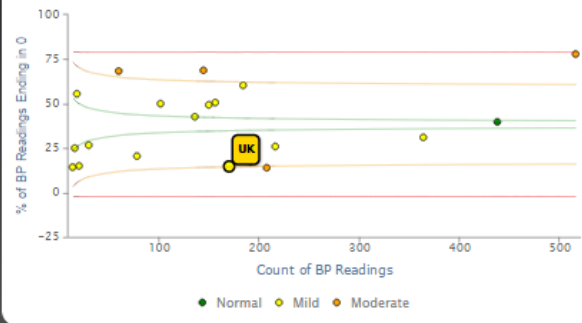
Adverse Events



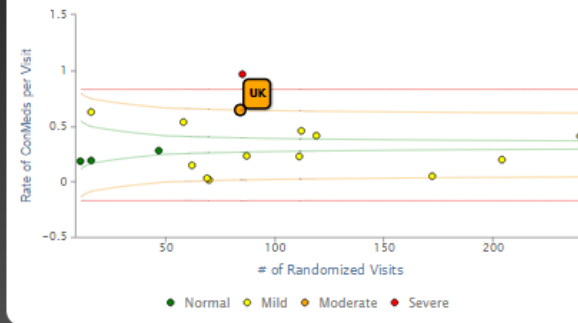
Adverse Events Ratio to ConMeds



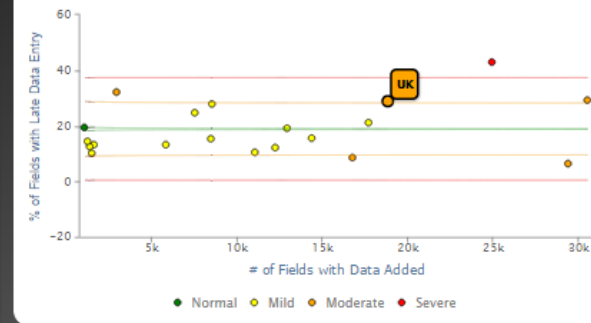
Blood Pressure



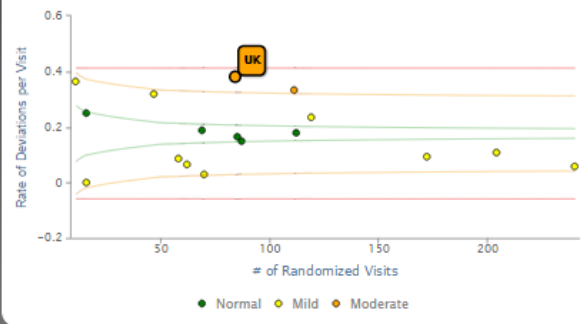
Concomitant Medications



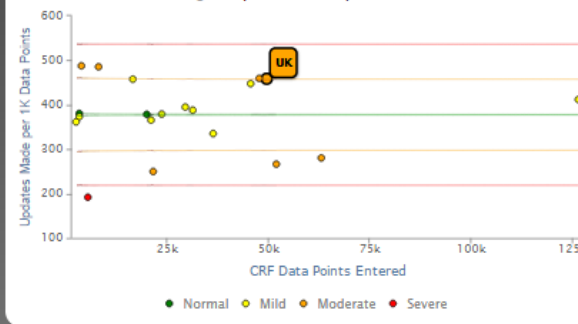
CRF Data Entry



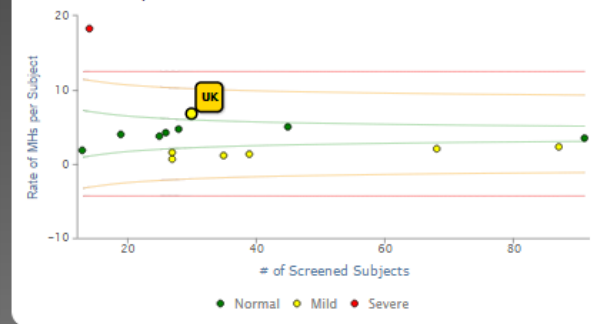
Deviations



Electronic Data Change Capture History



Medical History

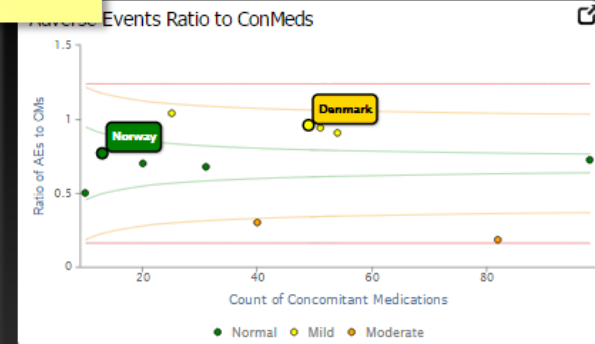
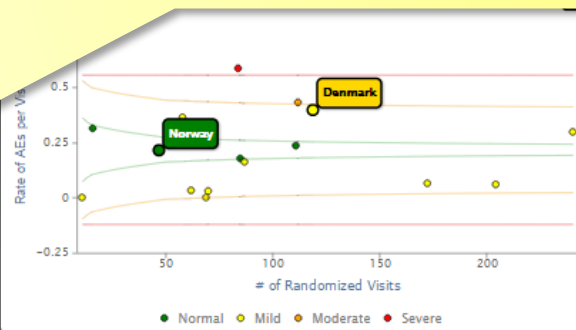


Country Dashboard

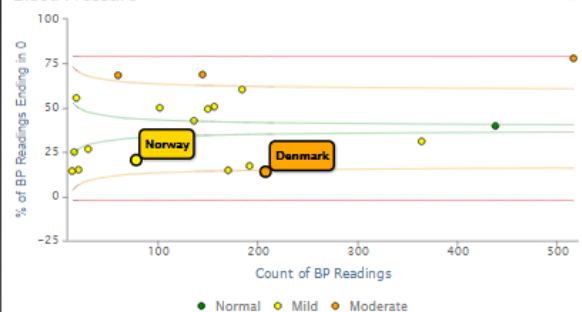
We can also use the country view to compare behaviour between countries

Risk Overview

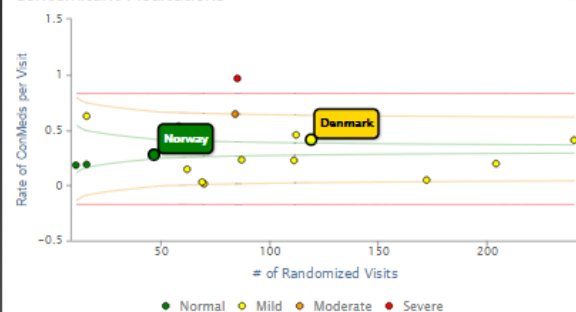
Site	BP	AE	CM	AER	MH	QC	DV	QRT	CRF	EDC	Rand. Subj	Score
UK	●	●	●	●	●	●	●	●	●	●	18	
Sweden	●	●	●	●	●	●	●	●	●	●		
Russia	●	●	●	●	●	●	●	●	●	●		
Czech Republic	●	●	●	●	●	●	●	●	●	●		
Canada	●	●	●	●	●	●	●	●	●	●		
Ukraine	●	●	●	●	●	●	●	●	●	●	55	79
Bulgaria	●	●	●	●	●	●	●	●	●	●	18	78
Norway	●	●	●	●	●	●	●	●	●	●	9	75
Poland	●	●	●	●	●	●	●	●	●	●	61	74
Belarus	●	●	●	●	●	●	●	●	●	●	71	73
Danmark	●	●	●	●	●	●	●	●	●	●	25	70
Hungary	●	●	●	●	●	●	●	●	●	●	21	67



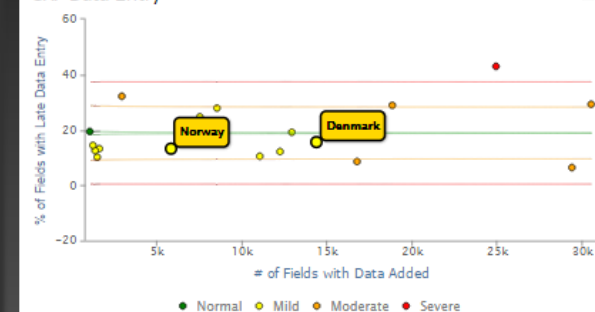
Blood Pressure



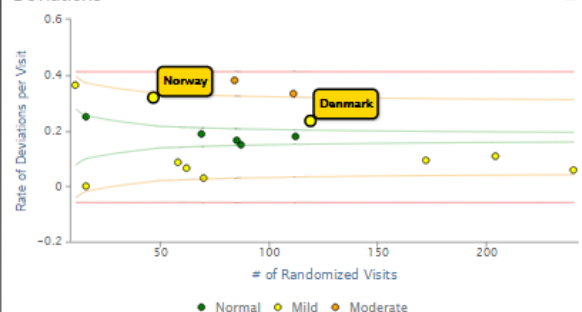
Concomitant Medications



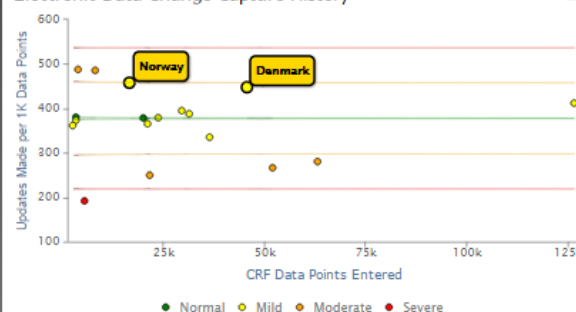
CRF Data Entry



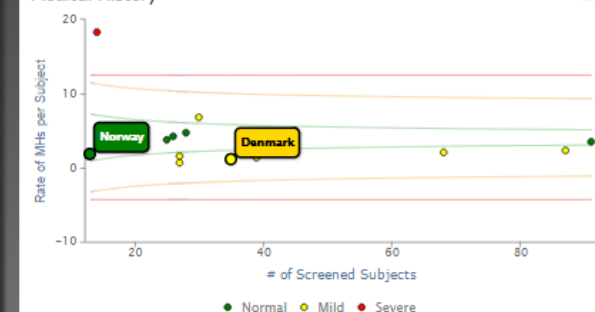
Deviations



Electronic Data Change Capture History



Medical History



Data Set Review



Study
WD-1034

Assessment Point
30-Jun-2014

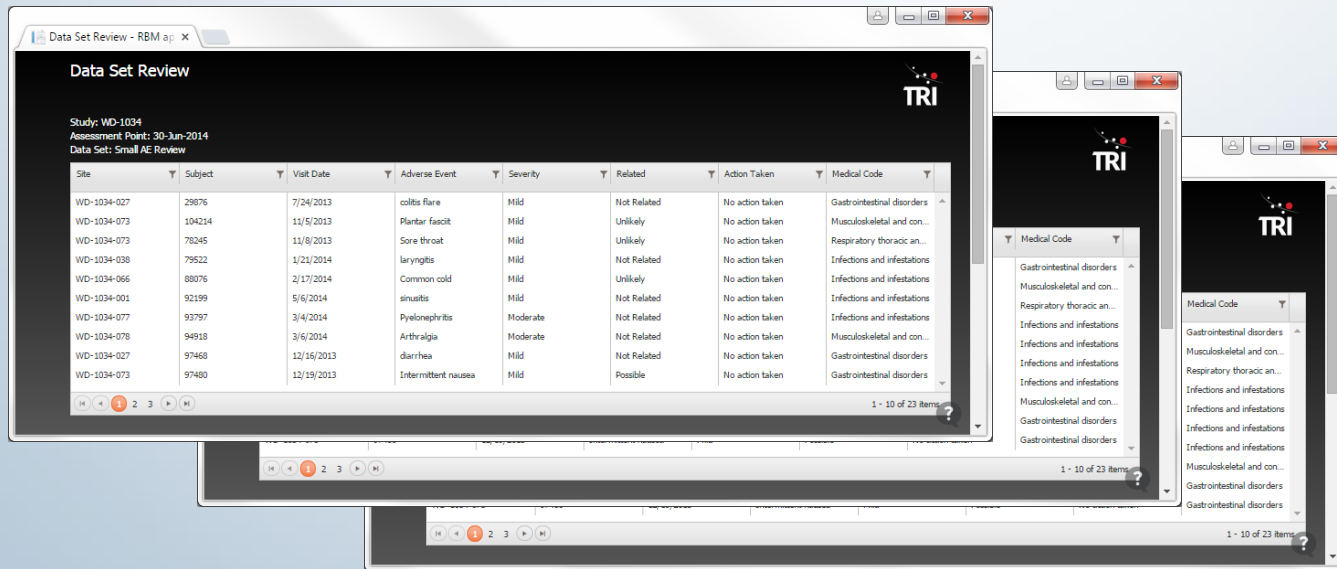
DataSet
Small AE Review

GO

New Tab

Site	Subject	Visit Date	Adverse Event	Severity	Related	Action Taken	Medical Code
WD-1034-027	29876	7/24/2013	colitis flare	Mild	Not Related	No action taken	Gastrointestinal disorders
WD-1034-073	104214	11/5/2013	Plantar fasciit	Mild	Unlikely	No action taken	Musculoskeletal and connective tiss...
WD-1034-073	78245	11/8/2013	Sore throat	Mild	Unlikely	No action taken	Respiratory thoracic and mediastin...
WD-1034-038	79522	1/21/2014	laryngitis	Mild	Not Related	No action taken	Infections and infestations
WD-1034-066	88076	2/17/2014	Common cold	Mild	Unlikely	No action taken	Infections and infestations
WD-1034-001	92199	5/6/2014	sinusitis	Mild	Not Related	No action taken	Infections and infestations
WD-1034-077	93797	3/4/2014	Pyelonephritis	Moderate	Not Related	No action taken	Infections and infestations
WD-1034-078	94918	3/6/2014	Arthralgia	Moderate	Not Related	No action taken	Musculoskeletal and connective tiss...
WD-1034-027	97468	12/16/2013	diarrhea	Mild	Not Related	No action taken	Gastrointestinal disorders
WD-1034-073	97480	12/19/2013	Intermittent nausea	Mild	Possible	No action taken	Gastrointestinal disorders

1 - 10 of 23 items



We can now click on the site
and track an observation

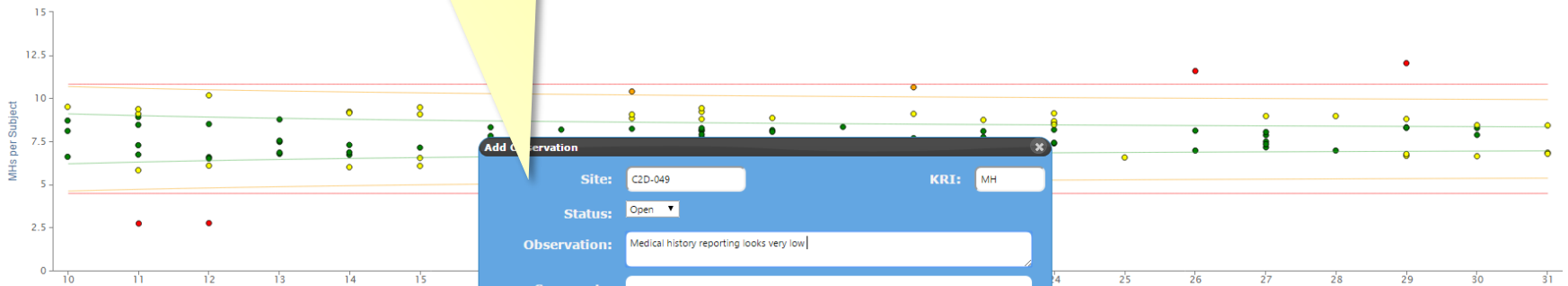
TRI

Risk Indicator

Client: Client Two Study: Study D Assessment Point: 30-Sep-2013

TRI

Medical History for Study : Study D / Assessment Point : 30-Sep-2013



Add Observation

Site: C2D-049 KRI: MH

Status: Open

Observation: Medical history reporting looks very low

Comments:

Save

	Site ID	Obs ID	KRI	Observation	Opened Date	Closed Date	Recent Action	Open Actions
	C2D-049	1114	MH	Very low occurrence of medical history reporting, even	13-Oct-2014			0/0
	C2D-107	101	MH	Observation of MH	15-Sep-2014	15-Sep-2014		0/0

Expanding the Risk Overview panel gives a detailed view of the site risk rankings

Risk Overview

Client: Client Two Study: Study D Assessment Point: 30-Sep-2013

TRI

Drag a column header here to group

	Site	DV	AE	MH	BP	CM	QC	PE	EDCHx	Rand. Subj	Score	Country
	C2D-049	●	●	●	●	●	●	●	●	15	134	FRA
	C2D-120	●	●	—	●	●	●	●	●	1	121	UK
	C2D-027	●	●	●	●	●	●	●	●	12	114	GER
	C2D-052	●	●	●	●	●	●	●	●	12	96	CAN
	C2D-006	●	●	●	●	●	●	●	●	18	91	CAN
	C2D-126	●	●	●	●	●	●	●	●	18	89	GER
	C2D-117	●	●	●	●	●	●	●	●	31	85	CAN
	C2D-144	●	●	●	●	●	●	●	●	26	82	GER
	C2D-088	●	●	●	●	●	●	●	●	18	81	GER
	C2D-154	●	●	●	●	●	●	●	●	24	80	UK

1 - 10 of 160 items

	Site ID	Obs ID	KRI	Observation	Comments	Opened Date	Closed Date	Recent Action	Open Actions
	C2D-120	87	RO	Observation	Comments	02-Sep-2014			0/0
	C2D-010	82	RO	With 123 Randomized patients, overall score of 14.5 is good	Each individual metric looks great.	22-Aug-2014		22-Aug-2014	0/1
	C2D-009	81	RO	BP risk score is elevated	Investigation may be necessary for risk score.	22-Aug-2014			0/0
	C2D-008	80	RO	All is green	green is good	22-Aug-2014			0/0
	C2D-007	79	RO	All green	MH not applicable	22-Aug-2014			0/0

We can define and track observations on the insight we gain at the site level



The Four Pillars of RBM

Identify
Manage
Mitigate
Report



Study quality management is all about centralised review of the quality risk signals we are seeing, agreeing appropriate actions and tracking those actions to completion.

Mitigation Maturity

- There is a desire to standardize the interpretation of risk/KRIs and associated actions
- However, it has only been 2 years since the guidance to industry was finalized
- Identifying correlation between KRIs, Root Cause and Monitoring Actions is a very mature model
- It is the direction we should be moving towards but will take time and further data analysis and modeling



We must keep this in mind as we expand and mature our RBM models to ensure we are collecting relevant data to achieve the vision (planning for success)

Overall site risk trend – are our interventions being effective?

Client

World Tech Bio-Pharma

Study

WD-1034

Assessment Point

30-Jun-2014

Site

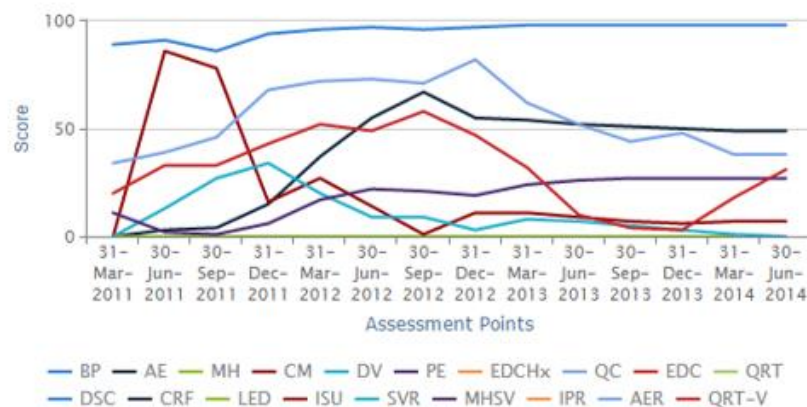
WD-1034-001



Overall Site Risk Trend



Risk Indicator Trends

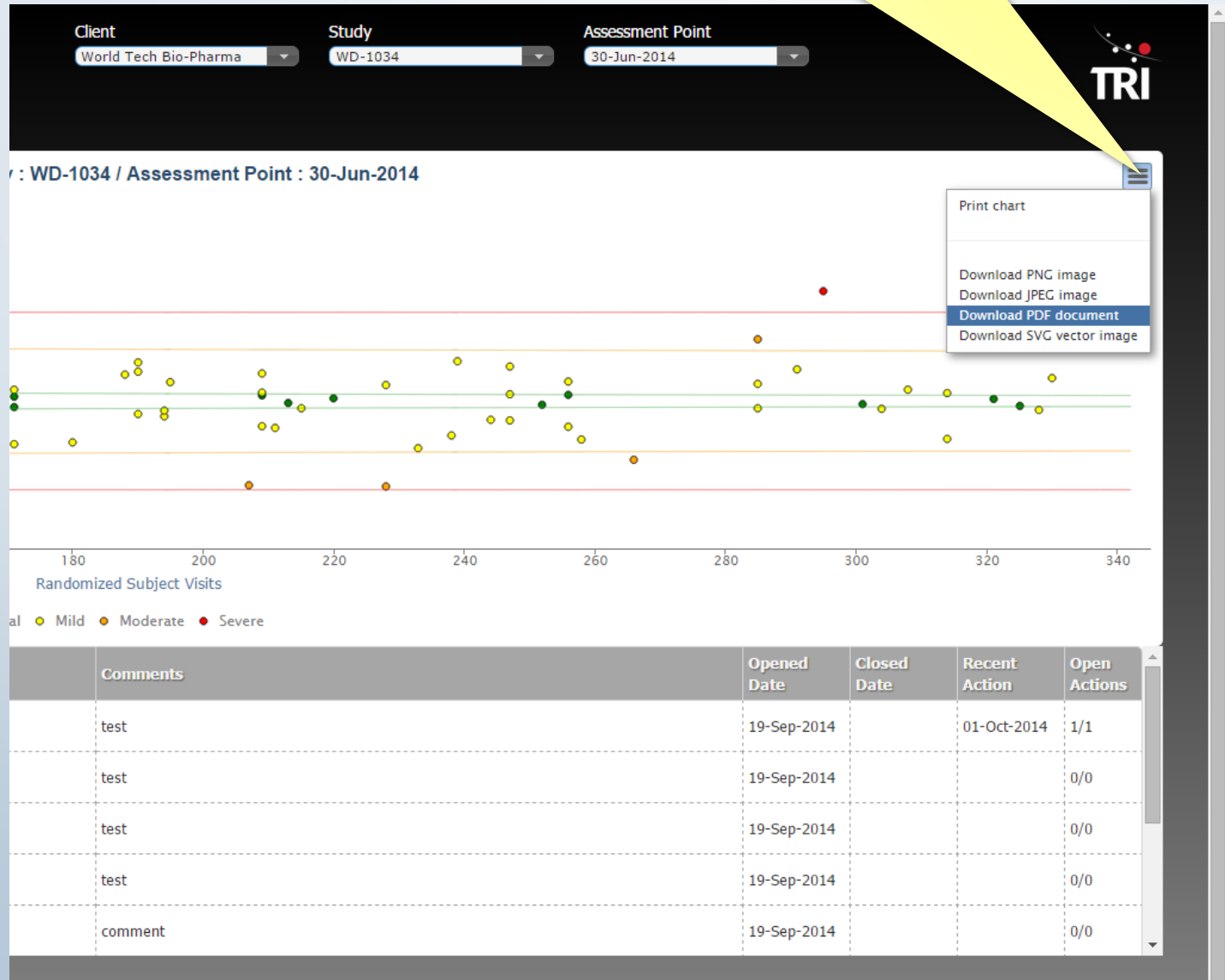


Individual indicator trends – are we being more effective in some areas than others?

The Four Pillars of RBM

Identify
Manage
Mitigate
Report

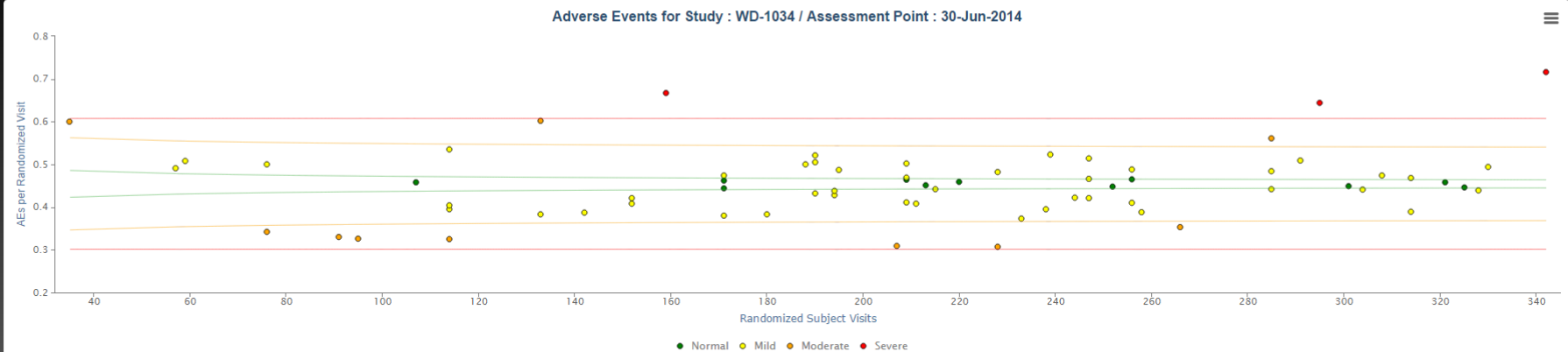
Each chart can be output as an image or pdf file



The system always defaults to the current assessment point.....

Risk Indicator

Client: World Tech Bio-Pharma
Study: WD-1034
Assessment Point: 30-Jun-2014



	Site ID	Obs ID	KRI	Observation	Comments	Opened Date	Closed Date	Recent Action	Open Actions
	WD-1034	1138	AE	test	test	19-Sep-2014		01-Oct-2014	1/1
	WD-1034	1138	AE	test	test	19-Sep-2014			0/0
	WD-1034	1138	AE	test	test	19-Sep-2014			0/0
	WD-1034	1138	AE	test	test	19-Sep-2014			0/0
	WD-1034	1139	AE	Observed again	comment	19-Sep-2014			0/0

...but we can also go back and look at how the data looked for any historic assessment point

Risk Indicator

Client

World Tech Bio-Pharma

Study

WD-1034

Assessment Point

30-Sep-2011

30-Jun-2014

31-Mar-2014

31-Dec-2013

30-Sep-2013

30-Jun-2013

31-Mar-2013

31-Dec-2012

30-Sep-2012

30-Jun-2012

31-Mar-2012

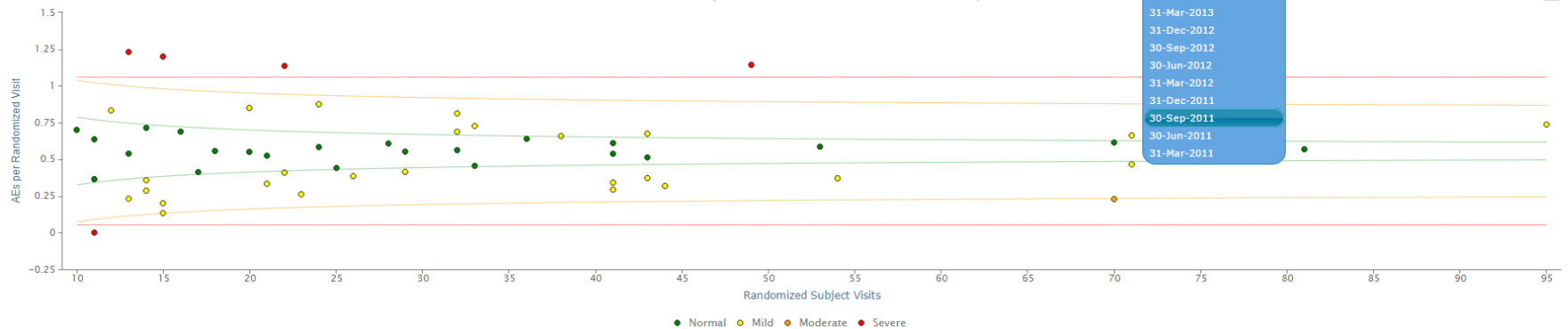
31-Dec-2011

30-Sep-2011

30-Jun-2011

31-Mar-2011

Adverse Events for Study : WD-1034 / Assessment Point : 30-Sep-2011



Site OA Report

Report Date: Feb 4, 2015

Study: WD-1034

Site: WD-1034-001

Site Volume

Randomized Subjects: 3

Observations

Total Observations: 3

Currently Open Observation: 3

Observations Open > 4 Weeks: 3

Actions

Total Actions: 6

Currently Open Actions: 4

Actions Open > 4 Weeks: 1

Observation Listing

Obs ID	KRI	Observation	Comments	Opened Date	Closed Date	Recent Action	Open Actions
101	RO	Several actions need to be taken to reduce risk		30-Sep-2012		07-Jan-2015	2 / 3
102	BP	This should be monitored as it is a significant change from prior behavior. 30Sep2012		30-Sep-2012		15-Dec-2014	1 / 1
103	QC	This may be indicating an issue		30-Sep-2012		15-Dec-2014	1 / 2

Action Listing

Action ID	Action Requested	Requested Date	Completed Date	Action Taken	Root Cause	Obs
1083	Action for RO dated 30Sep2012	30-Sep-2012	03-Oct-2013	The actions were verified as complete		101 ,
1084	Verify the query response protocol with the site 30Sep2012	30-Sep-2012	09-Oct-2013	The site was contacted and the response was verified as correct		103 ,
1085	Verify the BP reading procedure with the site 30Sep2012	30-Sep-2012	04-Dec-2013	The BP was recorded incorrectly. A revised response was received and approved		102 ,
2085	Please check for missing data	15-Dec-2014				103 ,
2090	Conduct a remote monitoring visit	07-Jan-2015				101 ,
2091	Test for OPRA Performance	07-Jan-2015	14-Jan-2015	Task Completed		101 ,

A comprehensive audit trail shows the trail of changes to the indicators over the course of the study

Audit Trail



Client Name	Study	Record Id	Site	Record Type	Field	Action	Old Value	New Value	Username	Date	Reason
World Tech Bio-...	WD-1034	0	WD-103...	Action	RootCause	Added			acefola	01-Oct-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Action	ActionTaken	Added			acefola	01-Oct-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Action	ClosedDateTime	Added		01-Jan-0001	acefola	01-Oct-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Action	CreatedDateTime	Added		01-Jan-0001	acefola	01-Oct-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Action	Action Requested	Added			acefola	01-Oct-2014	
World Tech Bio-...	WP-45007	47		Indicator	YAxisLabel	Modified	Number of Physical Exams	Findings Per Physical Exam	Administrator	23-Sep-2014	
World Tech Bio-...	WP-45007	47		Indicator	XAxisLabel	Modified	Findings Per Physical Exam	Number of Physical Exams	Administrator	23-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Comments	Added		test	ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Status	Added		open	ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Closed	Added			ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Created	Added		9/19/2014 5:05:52 PM	ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Site	Added		WD-1034	ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Observation	Added		test	ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Comments	Added		test	ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Status	Added		open	ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Closed	Added			ballance	19-Sep-2014	
World Tech Bio-...	WD-1034	0	WD-103...	Observation	Created	Added		9/19/2014 4:42:08 PM	ballance	19-Sep-2014	

The Four Pillars of RBM

Identify
Manage
Mitigate
Report

Thank you for your attention



OPRA

*....the Risk-based
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For more information on RBM operations, implementation, training and technology or copies of the slides, please feel free to contact me directly:

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