

BIENVENIDO WELCOME BIENVENUE WILLKOMMEN

OMNICOMM INNOVATION FORUM EUROPE 2017

BENVENUTI VELKOMMEN WELKOM ברוכים הבאים



OmniComm™
eClinical Solutions for Life™

2ND Annual
Innovation Forum Europe 2017

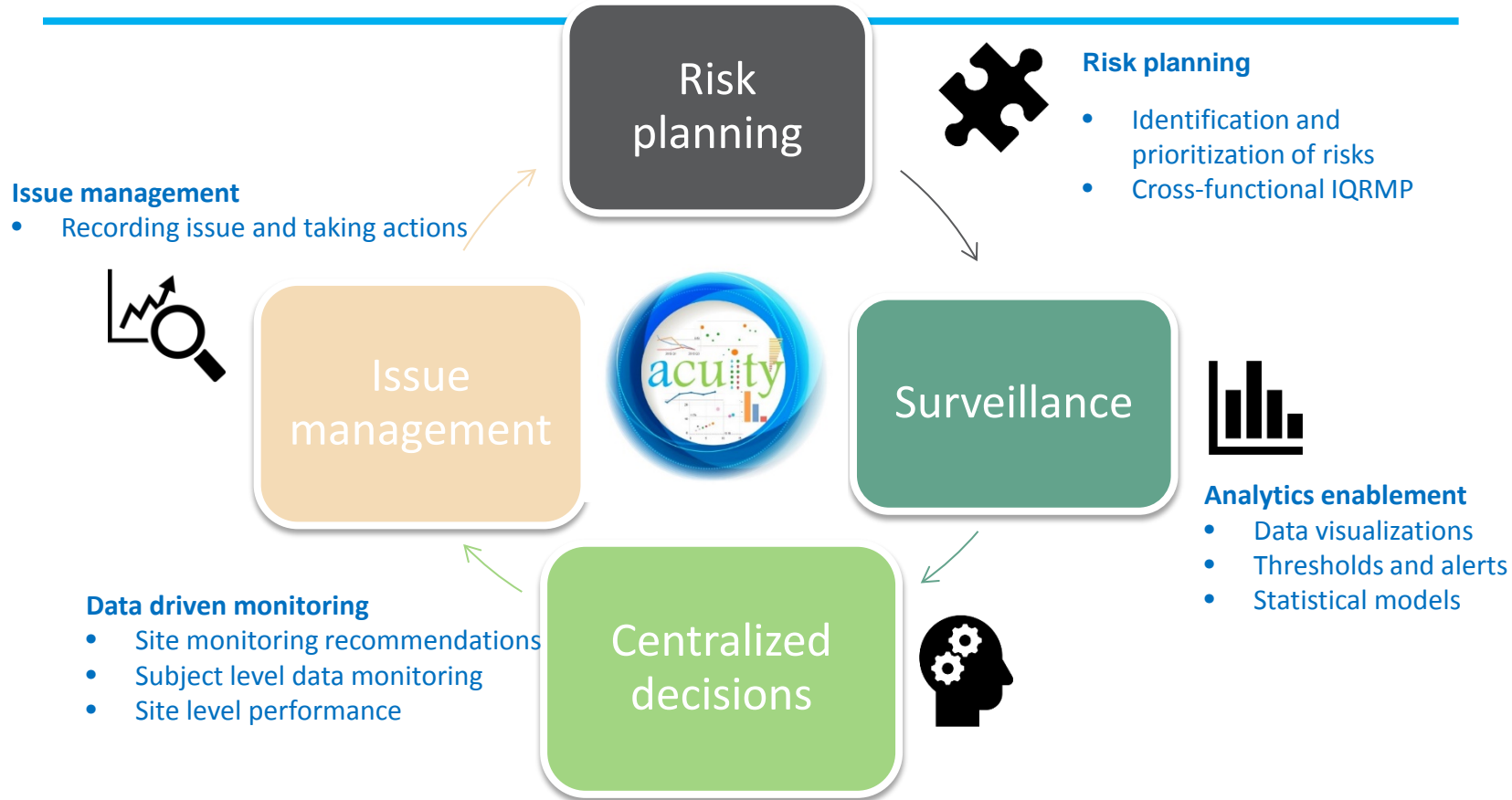
Barcelona
March 23-24 2017

αlgorics

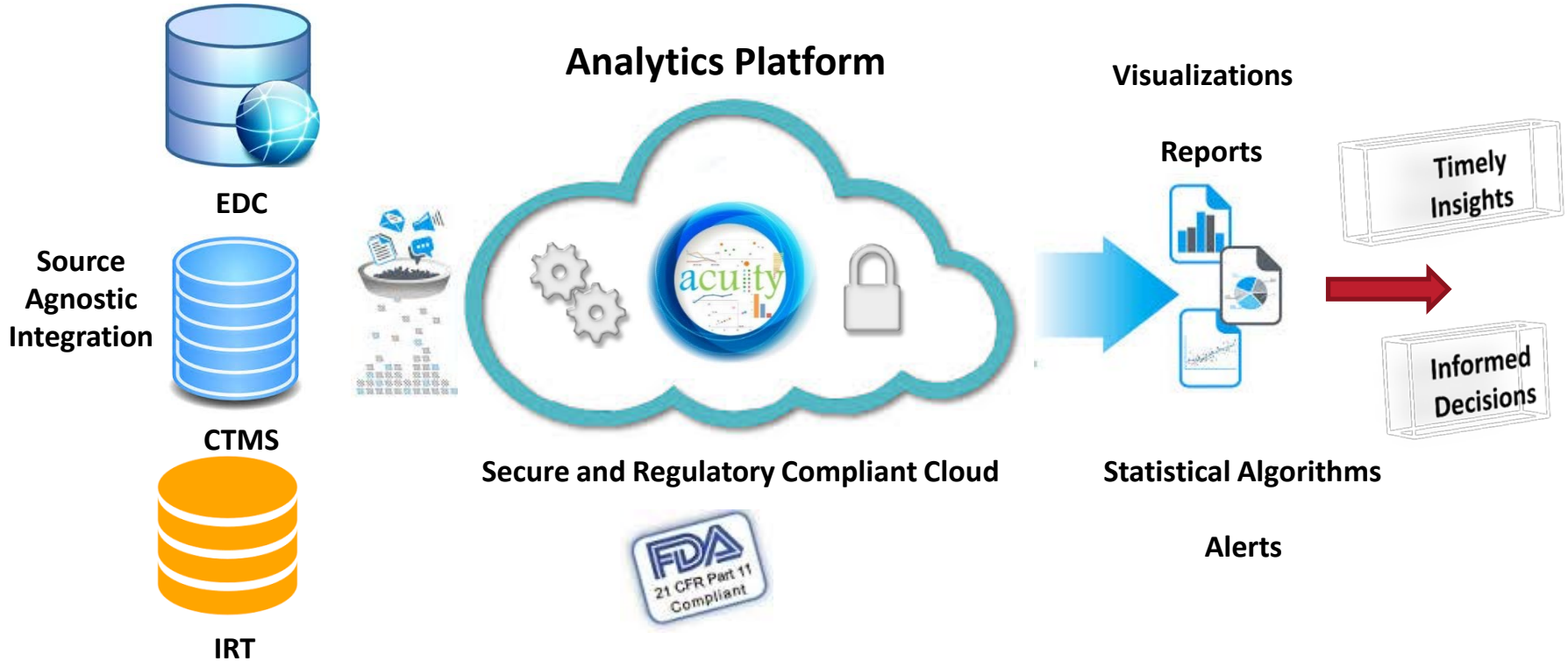
Risk Based Monitoring – are we there yet?

Rob Nichols

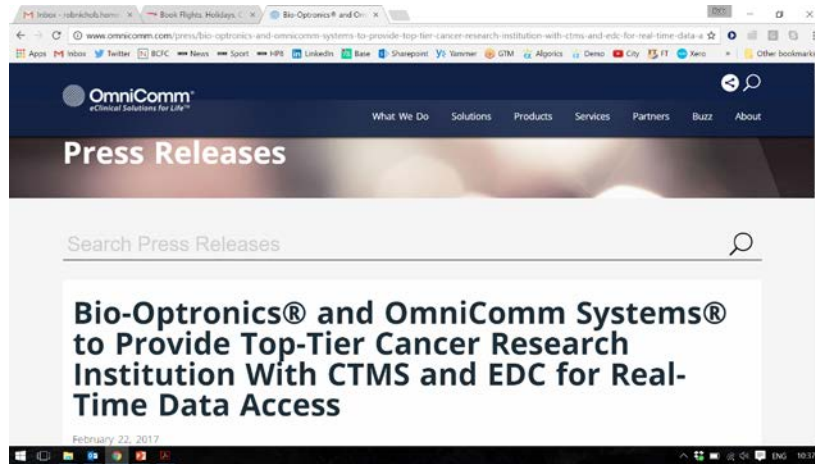
Current state end-to-end RBM



How to do RBM?



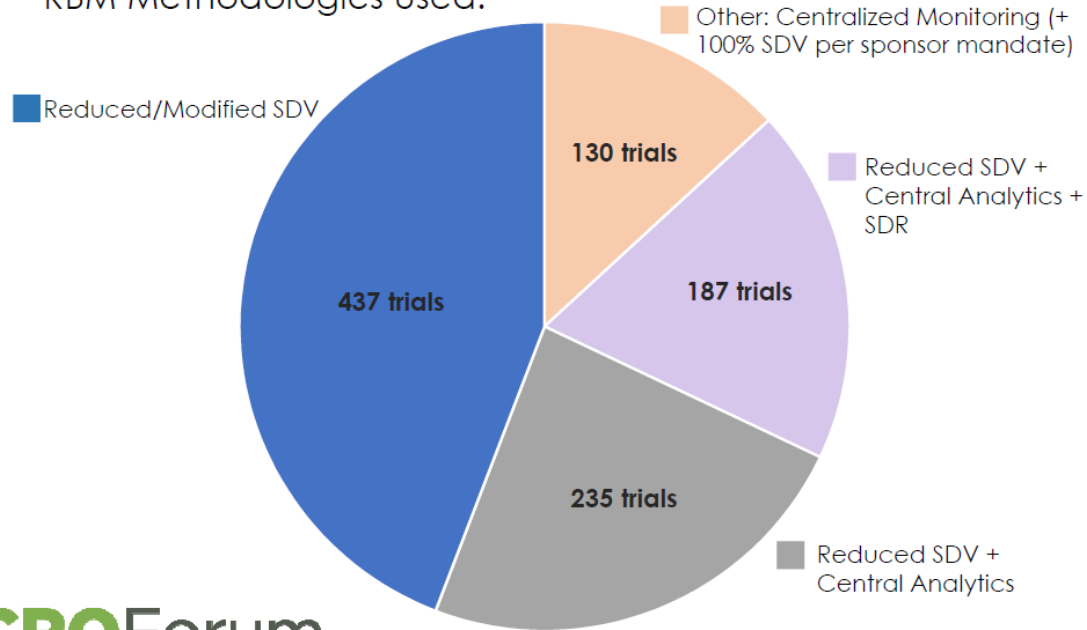
Clinical and Operational



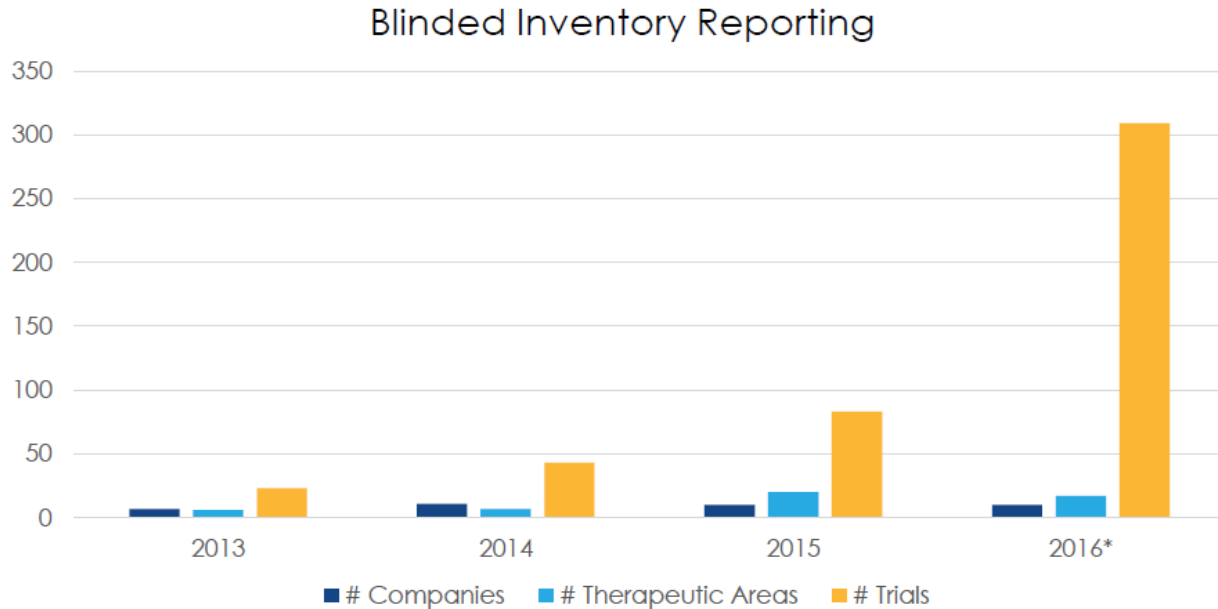
“EDC is typically the primary data source to recognize fundamental clinical metrics, such as patient accrual, open query counts, patient visit dates and even reports of adverse experiences. CTMS serves as the operational hub for a clinical trial. It tracks and reports on numerous components of a clinical trial, including study progress, completed visits, enrollment, financial activity and regulatory compliance. The integration between EDC and CTMS allows individuals responsible for clinical operations to more proactively manage activities, such as site initiation, patient recruitment, patient safety, site payments, capacity planning and risk-based monitoring.

Variability in the approach to RBM

RBM Methodologies Used:



TransCelerate – RBM adoption

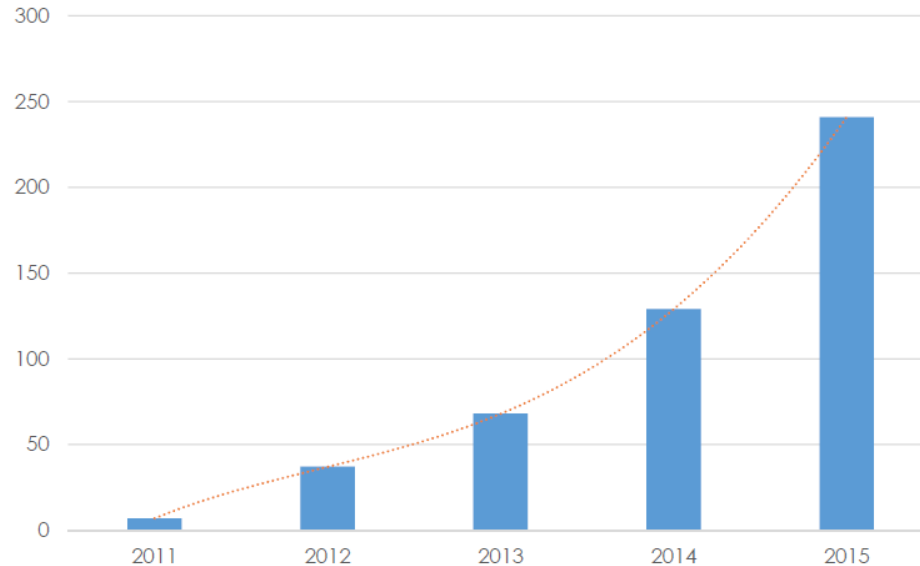


Note: Reporting of trial inventory is voluntary

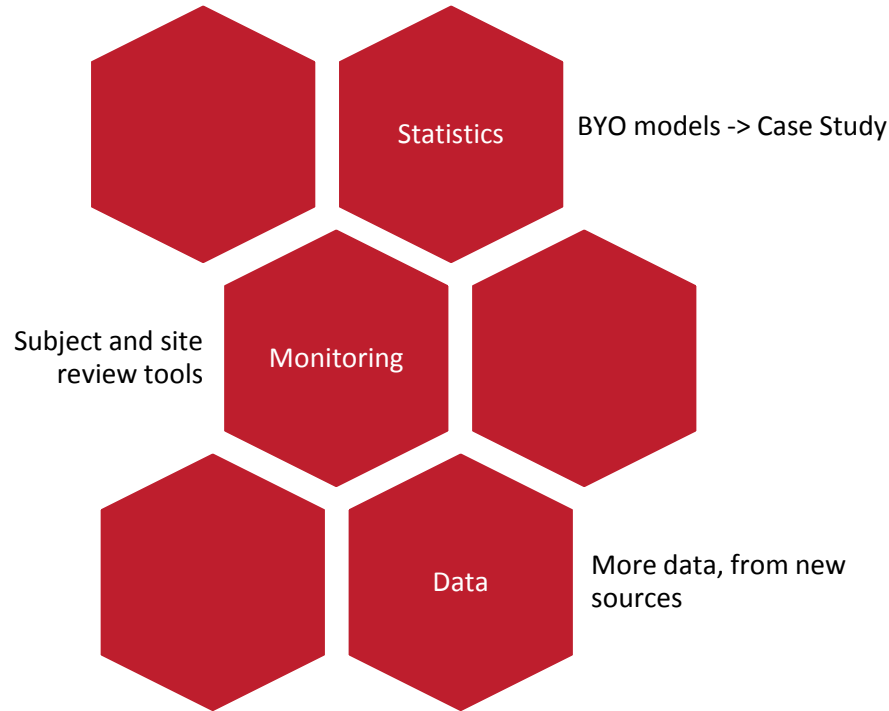
Note: Implementation of RBM has been voluntary and companies that have implemented may be in various stages (all 18 member companies are either implementing or plan to implement RBM)

RBM adoption – CRO Forum

Year over year the number of RBM trials conducted by our members has exponentially increased



RBM – Next Stages



Case Study

- Collaboration with Neuroscience Trials, a not-for-profit clinical research organization that specializes in neuroscience clinical research located in Melbourne, Australia
 - Multiple Sclerosis (MS) patients with stable/controlled disease
 - A Multicentre, Randomised, Blinded, Placebo-Controlled, Cross-Over Design, Phase II
 - Primary Outcomes-response to clinical scales/ questionnaires
 - Secondary Outcomes-safety and efficacy

- THE TRUSTED CLINICAL TRIALS BUSINESS RESOURCE -

**APPLIED
CLINICAL TRIALS**

<http://www.appliedclinicaltrials.com/case-study-examines-two-rbm-frameworks>

Evolving RBM framework

Isolated
Intuition

Site visit
driven

CM via
Excel

Systematic
methodology

CM via
Acuity
viz

Complex to bring data
sources together, still
'by eye'

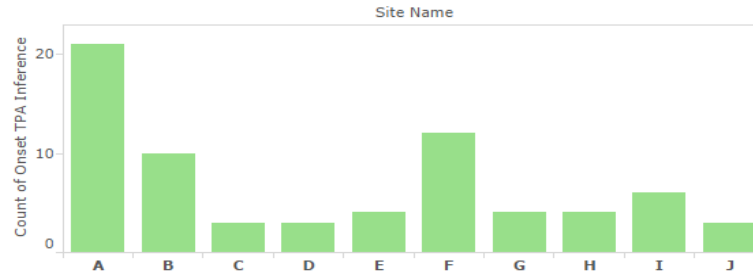
Risk driven review

- Deviation from stroke on-set to tPA administration

Time from stroke onset to drug (tPA) administration



Sitewise Deviations - Time from stroke onset to drug (tPA) administration



Deviation Inference

Normal

Deviation

(All)

Site Name

(All)

Treatment Group

(All)

Patientwise Deviations - Time from stroke onset to drug (tPA) administration

Patient	Time Stroke onset	Time arrival ED	Time CT Brain	Time tpa start	Time taken from Onset to TPA
A1010	8/21/2012 1:40:00 PM	8/21/2012 2:12:00 PM	8/21/2012 2:14:00 PM	8/21/2012 2:32:00 PM	●
A1011	12/5/2012 6:30:00 AM	12/5/2012 9:43:00 AM	12/5/2012 9:50:00 AM	12/5/2012 9:57:00 AM	●
A1012	1/6/2013 10:00:00 AM	1/6/2013 10:42:00 AM	1/6/2013 10:49:00 AM	1/6/2013 11:07:00 AM	●
A1013	2/22/2013 12:30:00 PM	2/22/2013 1:40:00 PM	2/22/2013 1:56:00 PM	2/22/2013 2:02:00 PM	●
A1014	3/13/2013 9:30:00 AM	3/13/2013 10:51:00 AM	3/13/2013 11:01:00 AM	3/13/2013 11:04:00 AM	●
A1015	5/24/2013 1:00:00 PM	5/24/2013 2:18:00 PM	5/24/2013 2:28:00 PM	5/24/2013 2:32:00 PM	●
A1016	6/5/2013 2:00:00 PM	6/5/2013 3:31:00 PM	6/5/2013 3:52:00 PM	6/5/2013 3:54:00 PM	●
A1017	7/14/2013 3:00:00 PM	7/14/2013 4:46:00 PM	7/14/2013 5:03:00 PM	7/14/2013 5:30:00 PM	●
A1018	8/22/2013 2:00:00 PM	8/22/2013 3:11:00 PM	8/22/2013 3:06:00 PM	8/22/2013 3:11:00 PM	●
A1019	10/7/2013 11:00:00 AM	10/7/2013 11:58:00 AM	10/7/2013 12:07:00 PM	10/7/2013 12:08:00 PM	●
A1020	10/10/2013 2:30:00 PM	10/10/2013 5:05:00 PM	10/10/2013 5:16:00 PM	10/10/2013 5:20:00 PM	●
A1021	11/15/2013 11:00:00 AM	11/15/2013 12:50:00 PM	11/15/2013 12:54:00 PM	11/15/2013 12:58:00 PM	●

Time (Hrs)

Evolving RBM framework

Site
visit
driven

CM via
Excel

1hr/subject

CM via
Acuity
viz

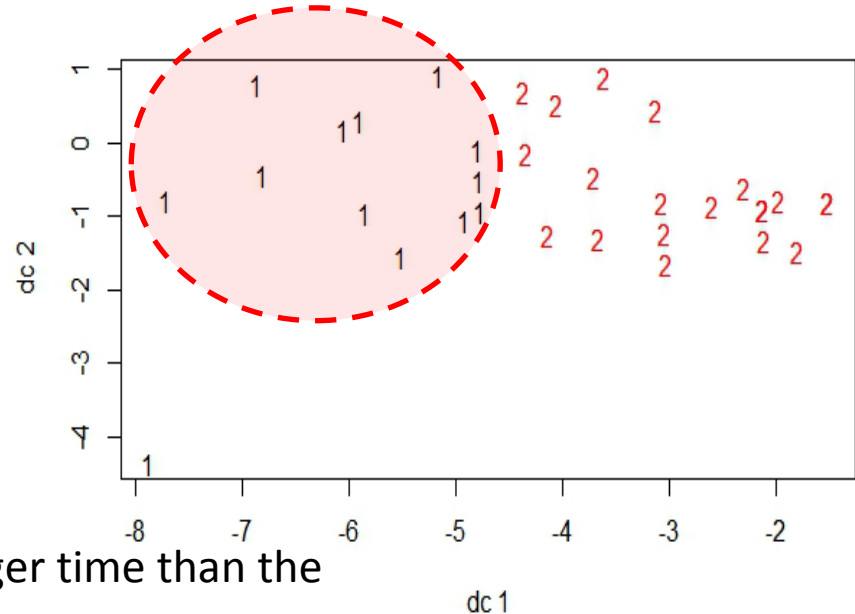
15min/subject

CM via
Acuity
models

Statistically driven review



Cluster	ED to tPA start (mins)	ED to groin puncture (mins)
1	0.98	2.85
2	0.40	1.47



Segregates sites where procedure take longer time than the average of all sites

Do the methods agree

- Agreement in risk assessment at several sites
- Site J may not have sufficient subjects to elicit signal in cluster analysis

Model driven

Site	Risk classification
C	High
D	High
E	High
H	High
B	Medium
F	Medium
G	Medium
A	Low
I	Low
J	Low

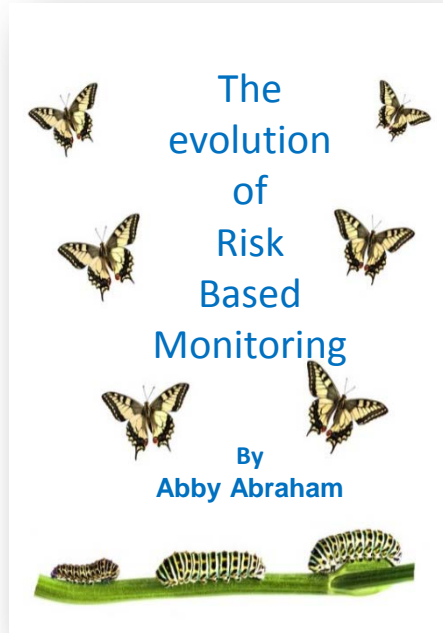
CM review

Site	Risk classification
J	High
E	High
C	High
F	Medium
H	Medium
I	Medium
D	Low
B	Low
A	Low
G	Low

Outcome of RBM

- CM enhanced using data visualization - with considerable time savings
- Model driven approaches provide supplementary scientific signals
- RBM is becoming established but will continue to evolve

Request your copy



End to end solutions provider focused
on clinical data analytics and RBM

A stylized logo consisting of a blue Greek letter alpha with three green lines radiating upwards.

Algorics

rob@algorics.com