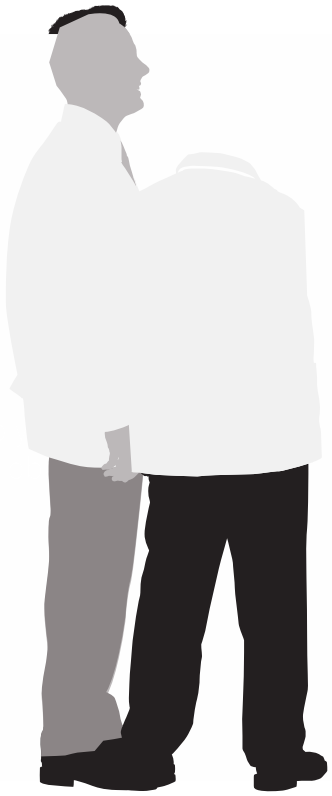
Clinical research - Present status & future challenges

Applying new technologies for cost effectiveness, high data quality and patient safety

Gunjan Jain
Pre Sales Head, South Asia
Oracle Health Sciences



Key R&D Challenges We Hear From Our Customers



Intensifying the Challenges…



AE/SAE, CpoMed, genomic, proteomic, EMR…



Demand for increasingly rapid data collection and delivery

Traditional Solutions Are Lagging Behind Shifts in the Industry

What's Required: Transform Current Capabilities

Cost benchmarking	Activity-based planning
Siloed clinical workflow	Integrated end-to-end workflow
Targeted SDV	Holistic risk-based monitoring
EDC	End-to-end clinical data management
Trial evidence	Genomics, biomarker and EMR data
Static data	Real-time, actionable data
Laptops and PCs	Smartphones and tablets
Manual data entry	Machine-to-machine data
Single-therapy trials	Multi-therapeutic trials

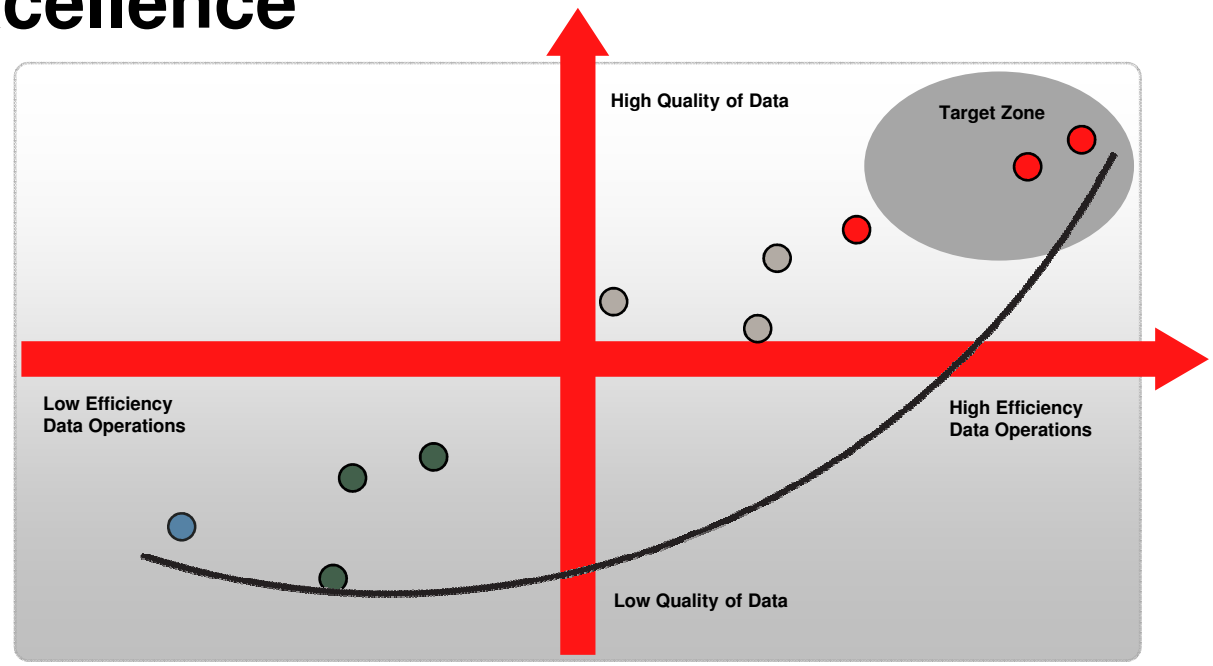
Make precise cost and resource forecasts

Reduce trial timelines by months

Reduce trial cost by millions

Conduct fast, effective audit defense

The Objective: Clinical Research Process Excellence



"Single source of the truth" for data and standards
Advanced query management
Design libraries and templates following best practices
Real-time visibility into data

Data resides in silos; limited use of standards
Some design best practices
Mix of automation and manual processes

Limited query management
Poor design of edit checks, rules, and discrepancy mgt
Lack of visibility to data
Manual, duplicative data entry
Standards not used—data fragmented

Paper-based processes
Full source data verification
Functional silos
Limited reporting

Mix of electronic and manual processes
Some communication across silos and with CROs

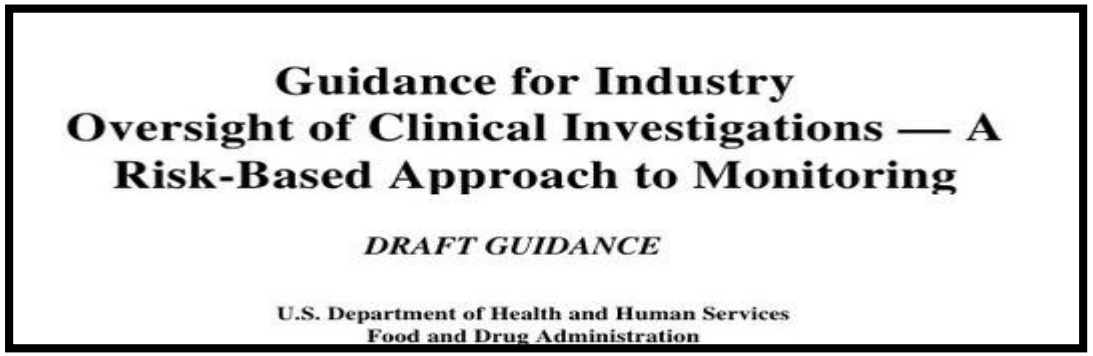
Mostly electronic processes
Some integration and automation of workflow

Integrated, automated, end-to-end data management
Comprehensive reporting and ad hoc reporting
Targeted SDV

Risk Based Monitoring



Regulatory Guidance

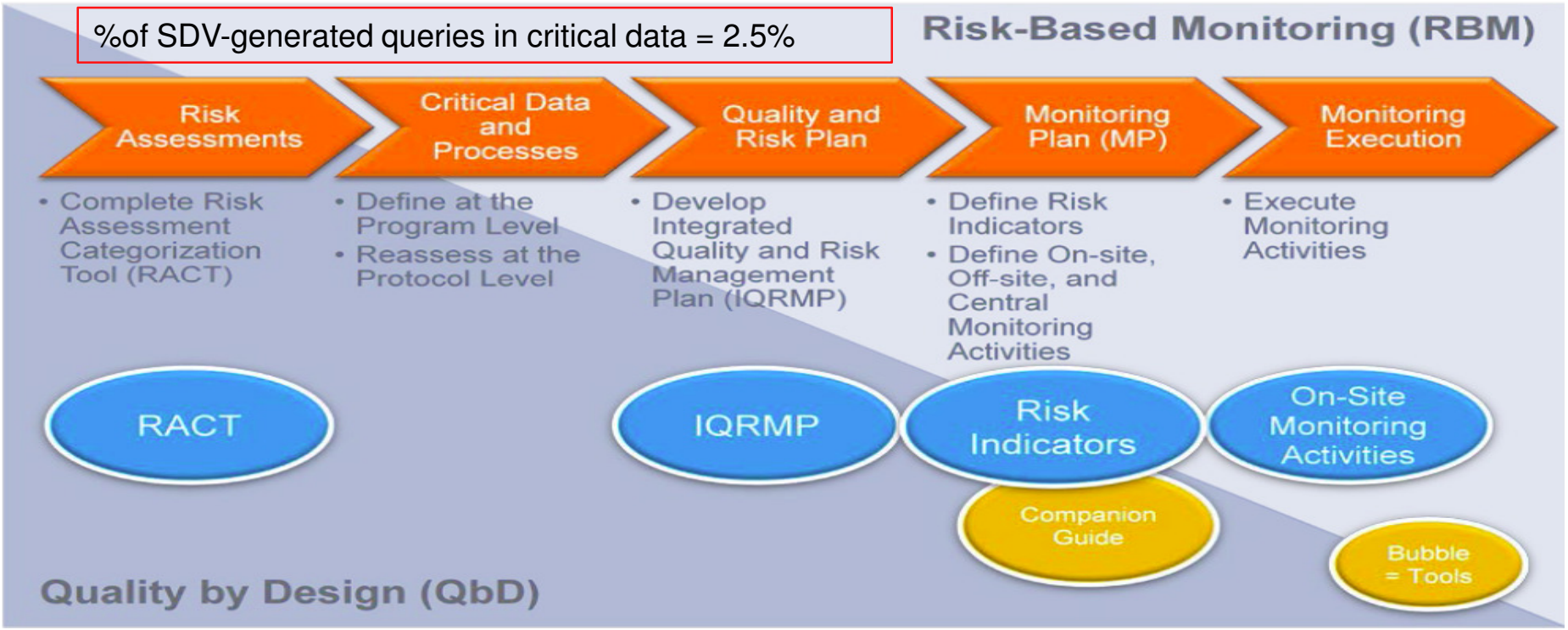


- Flexibility to choose optimal combination of monitoring strategies
- Critical study parameters
- Appropriate use of centralized monitoring and technological advances



- Risk-based approach to quality management
- Systematic, prioritized risk-based approach
- “Targeted use of resources

Risk-Based Monitoring Methodology by *TransCelerate BioPharma consortium (a non-profit org focused on advancing innovation in R&D)*

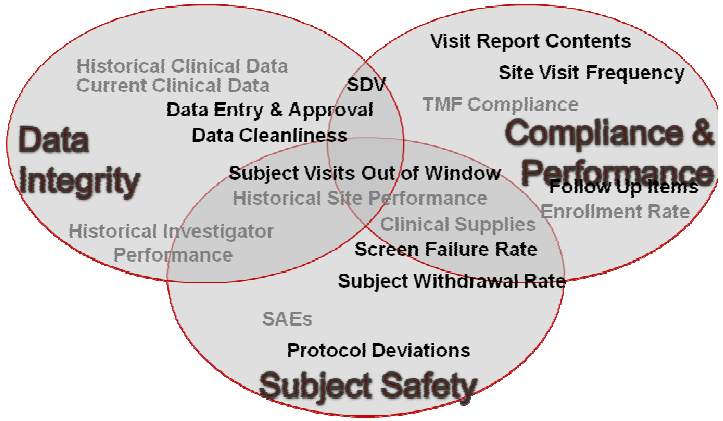


Purpose of Monitoring (from FDA Guidance)

Smart monitoring by QbD!!

Focus on:

- Processes that are critical to protecting human subjects
- Maintaining the integrity of study data
- Compliance with applicable regulations



The findings should be used to correct investigator and site practices that could result in inadequate human subject protection and/or poor data quality.

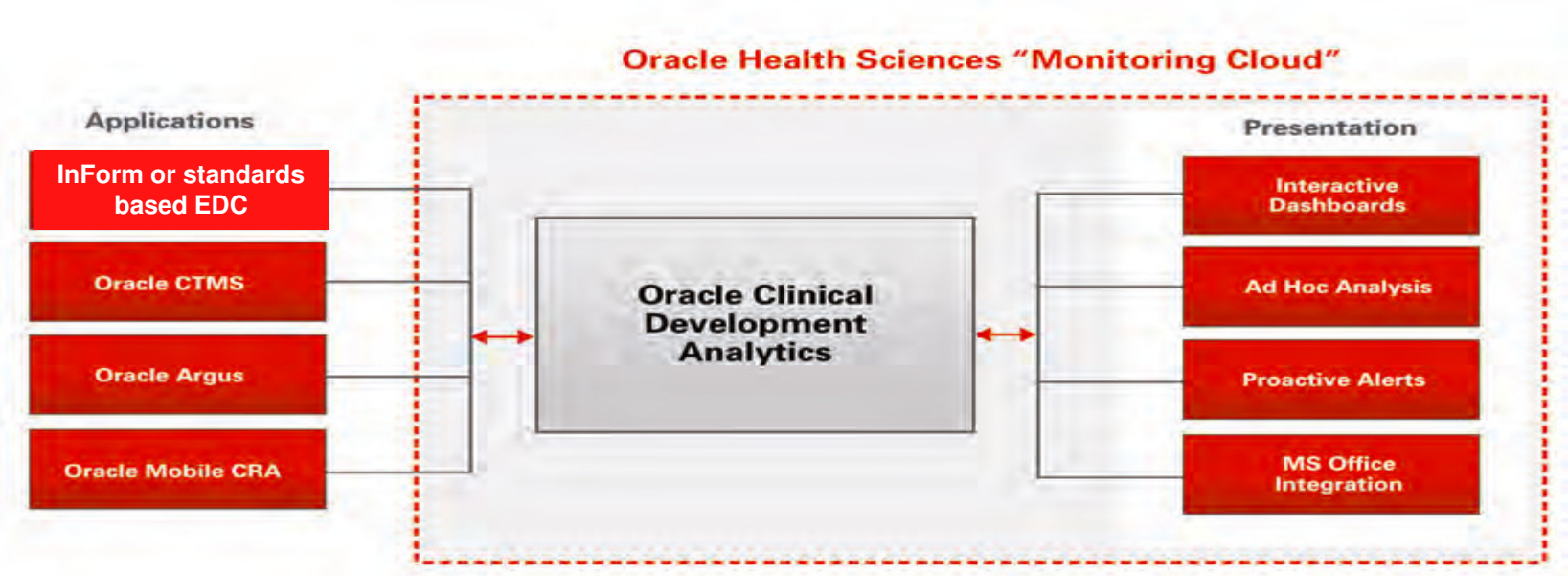
"What could keep you from including a study in your filing?"

Risk-based management technologies must execute three functions well

1. Develop
   - Developing an upfront risk assessment that takes into account the critical data and processes involved in the study
2. Design
   - Designing for quality and consistent application of risk assessment practices across the organization
     - e.g. people, partners, processes, and investigator sites,
     - tracking trial workflow (the clinical systems, protocol design and trial design);
3. Evaluate
   - Quickly and easily evaluating the critical data and processes involved in risk assessment.

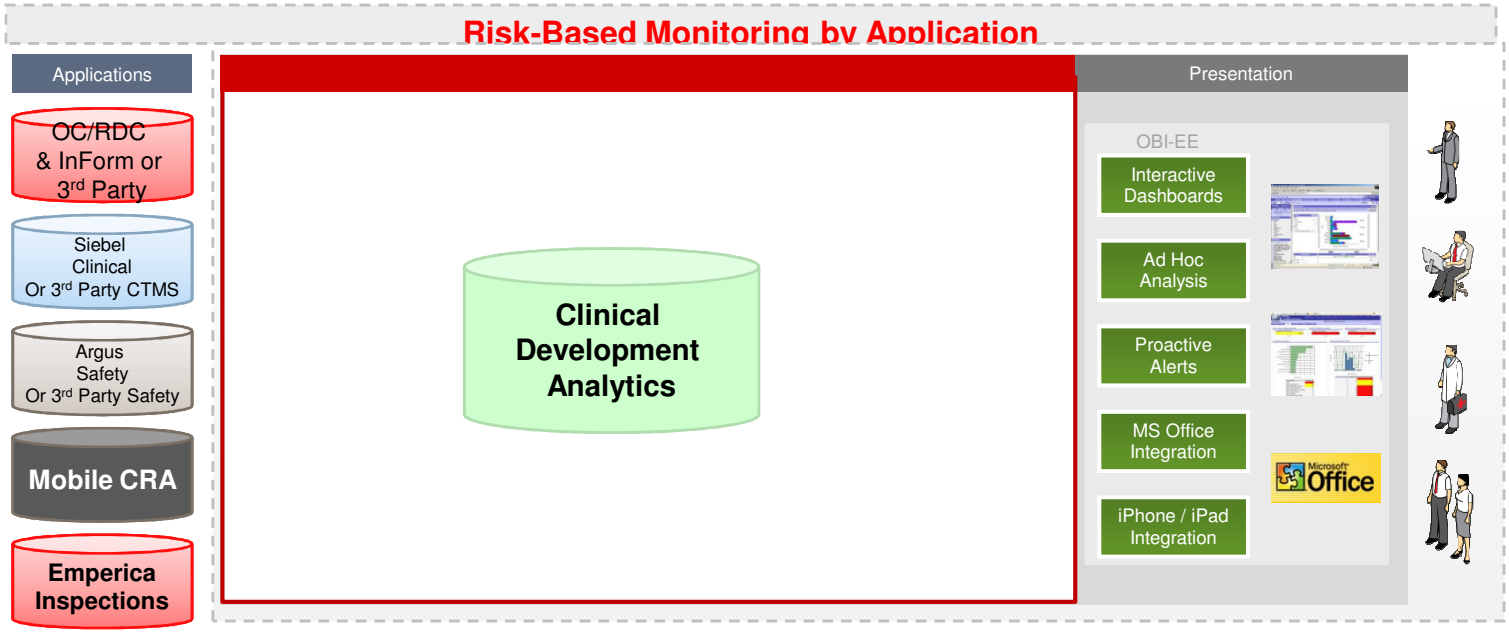
A holistic platform that supports risk based monitoring of clinical trials

This flexible, cloud-based platform integrates key enabling technologies and has the flexibility to evolve to meet the changing requirements of clinical trials.



A holistic platform that supports risk based monitoring of clinical trials

This flexible, cloud-based platform integrates key enabling technologies and has the flexibility to evolve to meet the changing requirements of clinical trials.



Enabling Operational Performance Management from Sites to Execs

Executive Team



→ **Organizational Progress**

Head of Clinical Operations



→ **Departmental / Regional Progress**

CRA / Data Manager

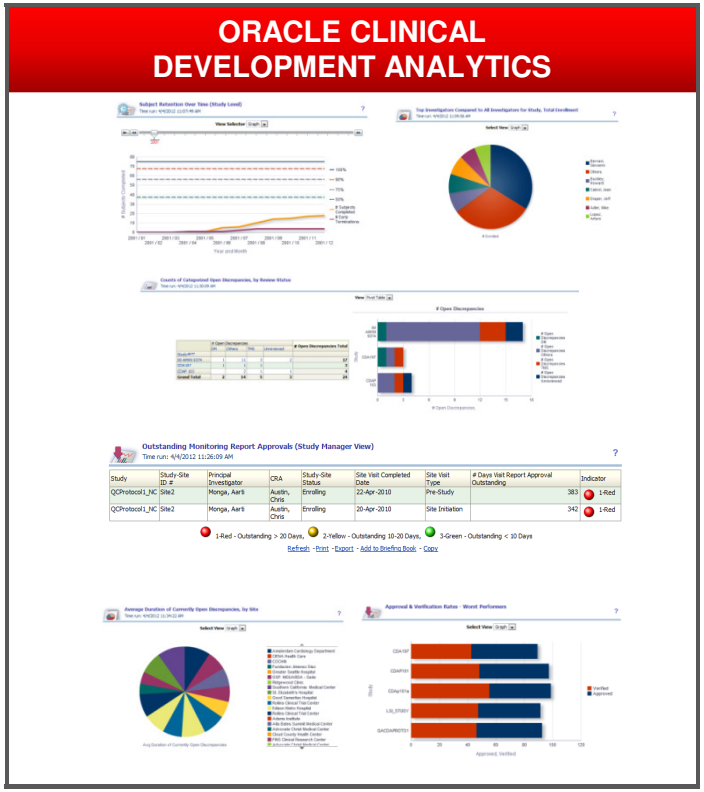


→ **Study Progress**

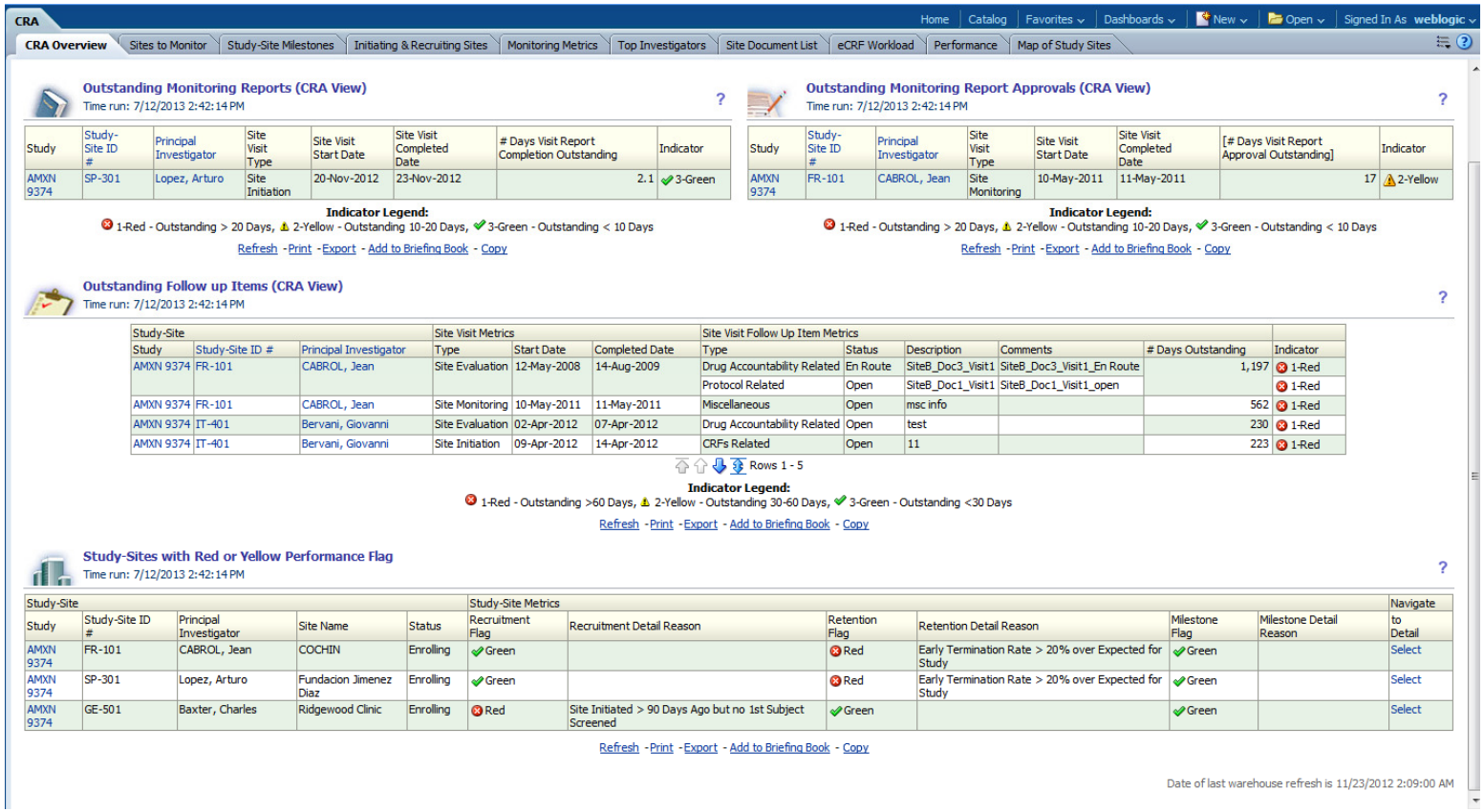
Clinical Sites



→ **Site Progress**



CRA Overview



CRA

Home | Catalog | Favorites | Dashboards | New | Open | Signed In As weblogic

CRA Overview | Sites to Monitor | Study-Site Milestones | Initiating & Recruiting Sites | Monitoring Metrics | Top Investigators | Site Document List | eCRF Workload | Performance | Map of Study Sites

Outstanding Monitoring Reports (CRA View)
Time run: 7/12/2013 2:42:14 PM

Study	Study-Site ID #	Principal Investigator	Site Visit Type	Site Visit Start Date	Site Visit Completed Date	# Days Visit Report Completion Outstanding	Indicator
AMXN 9374	SP-301	Lopez, Arturo	Site Initiation	20-Nov-2012	23-Nov-2012	2.1	3-Green

Indicator Legend:
1-Red - Outstanding > 20 Days, 2-Yellow - Outstanding 10-20 Days, 3-Green - Outstanding < 10 Days

Refresh - Print - Export - Add to Briefing Book - Copy

Outstanding Monitoring Report Approvals (CRA View)
Time run: 7/12/2013 2:42:14 PM

Study	Study-Site ID #	Principal Investigator	Site Visit Type	Site Visit Start Date	Site Visit Completed Date	[# Days Visit Report Approval Outstanding]	Indicator
AMXN 9374	FR-101	CABROL, Jean	Site Monitoring	10-May-2011	11-May-2011	17	2-Yellow

Indicator Legend:
1-Red - Outstanding > 20 Days, 2-Yellow - Outstanding 10-20 Days, 3-Green - Outstanding < 10 Days

Refresh - Print - Export - Add to Briefing Book - Copy

Outstanding Follow up Items (CRA View)
Time run: 7/12/2013 2:42:14 PM

Study-Site			Site Visit Metrics			Site Visit Follow Up Item Metrics					
Study	Study-Site ID #	Principal Investigator	Type	Start Date	Completed Date	Type	Status	Description	Comments	# Days Outstanding	Indicator
AMXN 9374	FR-101	CABROL, Jean	Site Evaluation	12-May-2008	14-Aug-2009	Drug Accountability Related	En Route	SiteB_Doc3_Visit1	SiteB_Doc3_Visit1_En Route	1,197	1-Red
						Protocol Related	Open	SiteB_Doc1_Visit1	SiteB_Doc1_Visit1_open		1-Red
AMXN 9374	FR-101	CABROL, Jean	Site Monitoring	10-May-2011	11-May-2011	Miscellaneous	Open	msc info		562	1-Red
AMXN 9374	IT-401	Bervani, Giovanni	Site Evaluation	02-Apr-2012	07-Apr-2012	Drug Accountability Related	Open	test		230	1-Red
AMXN 9374	IT-401	Bervani, Giovanni	Site Initiation	09-Apr-2012	14-Apr-2012	CRFs Related	Open	11		223	1-Red

Rows 1 - 5

Indicator Legend:
1-Red - Outstanding >60 Days, 2-Yellow - Outstanding 30-60 Days, 3-Green - Outstanding <30 Days

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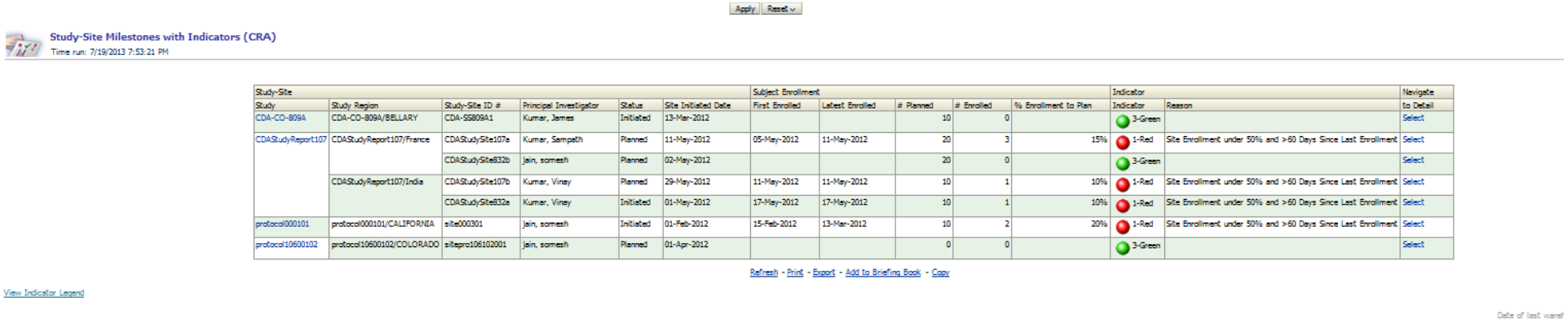
Study-Sites with Red or Yellow Performance Flag
Time run: 7/12/2013 2:42:14 PM

Study-Site					Study-Site Metrics						Navigate
Study	Study-Site ID #	Principal Investigator	Site Name	Status	Recruitment Flag	Recruitment Detail Reason	Retention Flag	Retention Detail Reason	Milestone Flag	Milestone Detail Reason	to Detail
AMXN 9374	FR-101	CABROL, Jean	COCHIN	Enrolling	Green		Red	Early Termination Rate > 20% over Expected for Study	Green		Select
AMXN 9374	SP-301	Lopez, Arturo	Fundacion Jimenez Diaz	Enrolling	Green		Red	Early Termination Rate > 20% over Expected for Study	Green		Select
AMXN 9374	GE-501	Baxter, Charles	Ridgewood Clinic	Enrolling	Red	Site Initiated > 90 Days Ago but no 1st Subject Screened	Green		Green		Select

Refresh - Print - Export - Add to Briefing Book - Copy

Date of last warehouse refresh is 11/23/2012 2:09:00 AM

Study Site Milestone


Apply Reset

Study-Site Milestones with Indicators (CRA)
Time run: 7/19/2013 7:53:21 PM

Study-Site						Subject Enrollment					Indicator		Navigate
Study	Study Region	Study-Site ID #	Principal Investigator	Status	Site Initiated Date	First Enrolled	Latest Enrolled	# Planned	# Enrolled	% Enrollment to Plan	Indicator	Reason	to Detail
CDA-CO-809A	CDA-CO-809A/BELLARY	CDA-SS809A1	Kumar, James	Initiated	13-Mar-2012			10	0		3-Green		Select
CDAStudyReport107	CDAStudyReport107/France	CDAStudySite107a	Kumar, Sampath	Planned	11-May-2012	05-May-2012	11-May-2012	20	3	15%	1-Red	Site Enrollment under 50% and >60 Days Since Last Enrollment	Select
		CDAStudySite832b	jain, somesh	Planned	02-May-2012			20	0		3-Green		Select
	CDAStudyReport107/India	CDAStudySite107b	Kumar, Vinay	Planned	29-May-2012	11-May-2012	11-May-2012	10	1	10%	1-Red	Site Enrollment under 50% and >60 Days Since Last Enrollment	Select
		CDAStudySite832a	Kumar, Vinay	Initiated	01-May-2012	17-May-2012	17-May-2012	10	1	10%	1-Red	Site Enrollment under 50% and >60 Days Since Last Enrollment	Select
protocol000101	protocol000101/CALIFORNIA	site000301	jain, somesh	Initiated	01-Feb-2012	15-Feb-2012	13-Mar-2012	10	2	20%	1-Red	Site Enrollment under 50% and >60 Days Since Last Enrollment	Select
protocol10600102	protocol10600102/COLORADO	sitepro106102001	jain, somesh	Planned	01-Apr-2012			0	0		3-Green		Select

Refresh - Print - Export - Add to Briefing Book - Copy

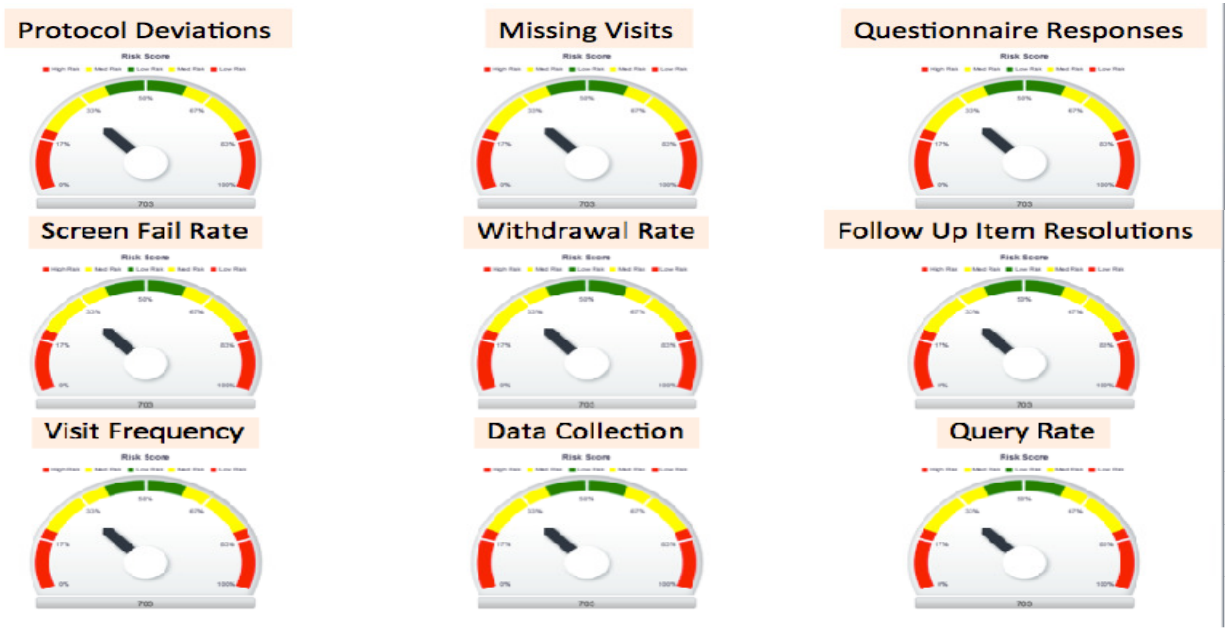
View Indicator Legend

Date of last wareh

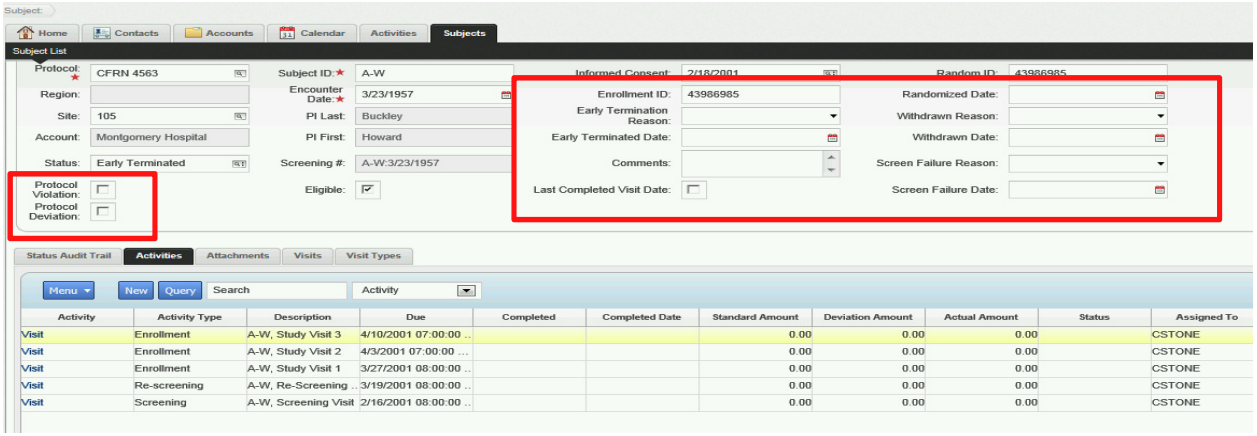
Subject Recruitment and Discontinuation	***Subject Recruitment*** Outliers in screen failure rate / enrollment rate ▪ Number of screen failures compared to average across sites – protocol dependent ▪ Planned versus actual enrollment ▪ Inconsistent recruitment
	Subject Discontinuation Outliers / trends in ratio of subjects discontinued to subjects randomized ▪ Reason for discontinuation (e.g. number per each category vs. total number of discontinuations)

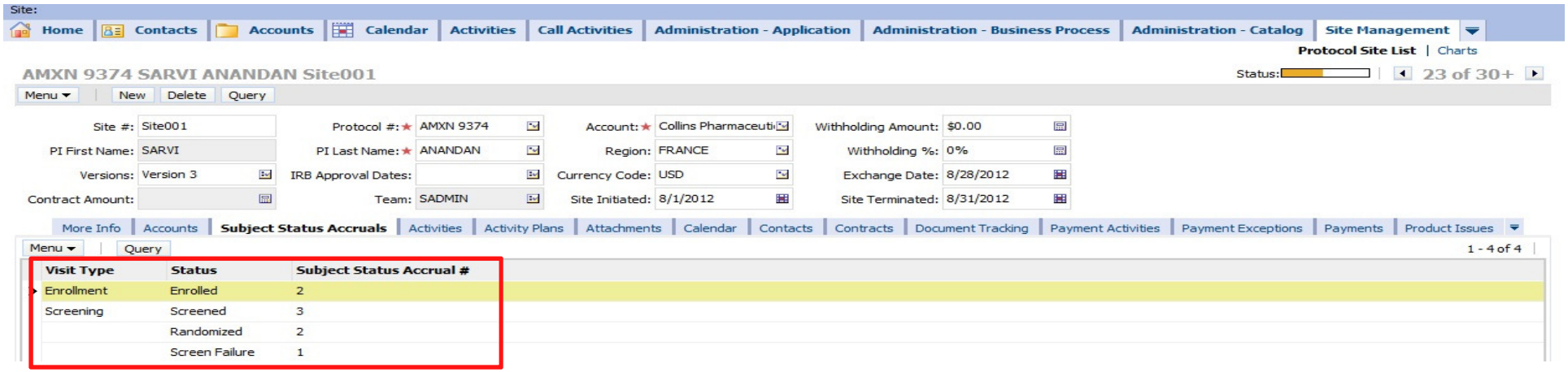
Risk Based Monitoring in CDA

Sample Study Risk Dashboard

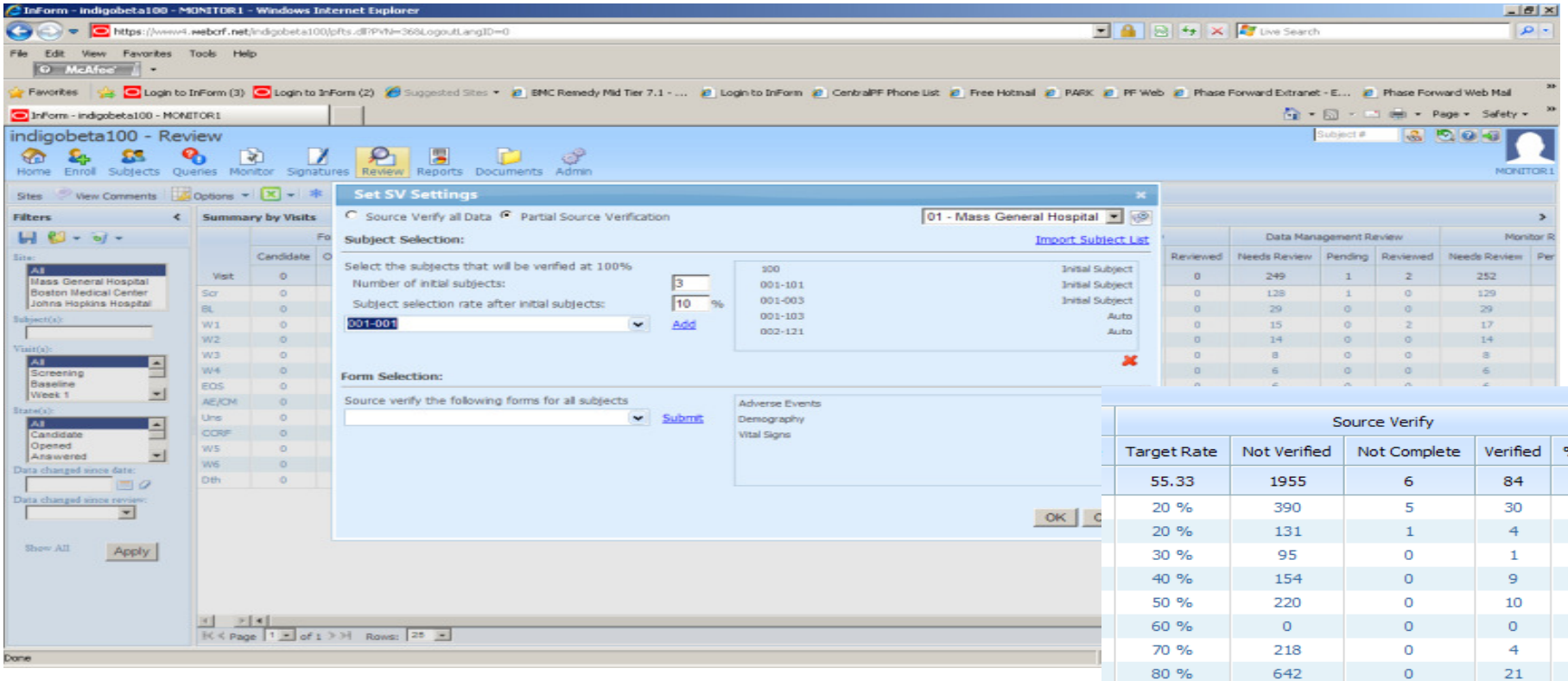


Tracking Site Performance – Quantitative in CTMS



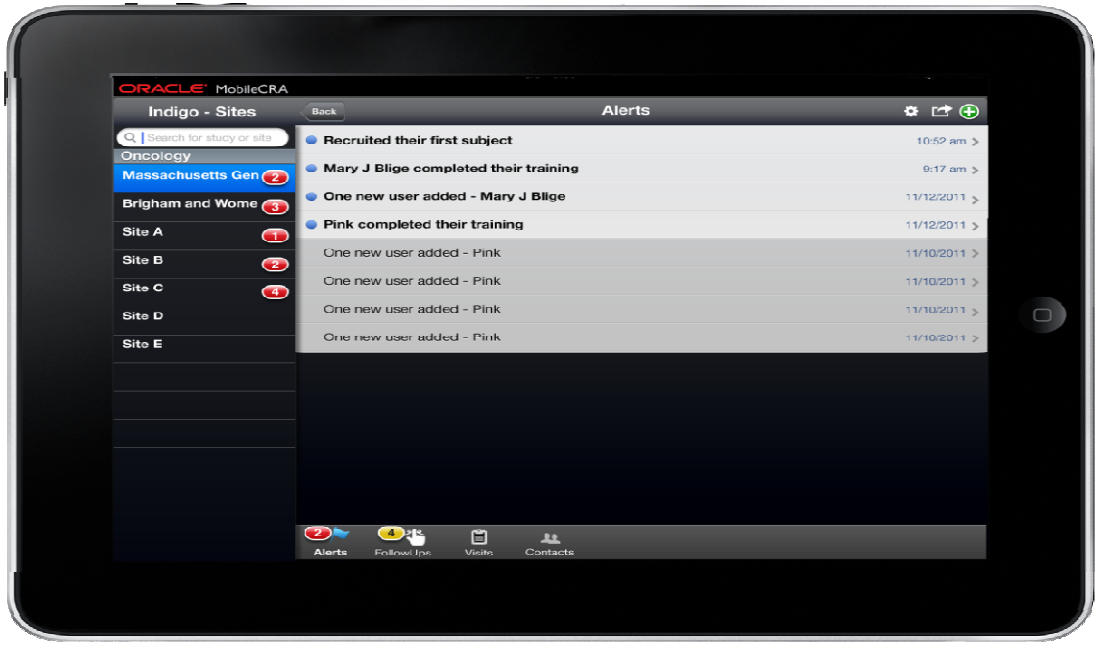


EDC platform enables Risk-Based Monitoring



Source Verify				
Target Rate	Not Verified	Not Complete	Verified	% Verified
55.33	1955	6	84	2.02
20 %	390	5	30	7.1 %
20 %	131	1	4	2.9 %
30 %	95	0	1	1.0 %
40 %	154	0	9	5.5 %
50 %	220	0	10	4.3 %
60 %	0	0	0	0.0 %
70 %	218	0	4	1.8 %
80 %	642	0	21	3.2 %
90 %	0	0	0	0.0 %
100 %	0	0	0	0.0 %
15 %	0	0	0	0.0 %
100 %	0	0	0	0.0 %
100 %	0	0	0	0.0 %

Mobile Monitoring



Access Anywhere

- Enable Tablet Only Site Visits
  - Trip Reporting
  - EDC (SDV / Queries) via tablet
  - Essential documents
  - Contacts / Calendar

Site-At-A-Glance

- Instant access to Site Dashboards
- Configurable KPIs
- Alerts – For CRAs and Sites

Easy Collaboration

- Full CTMS site contacts – frequently used and seldom used
- Study, site, patient, and personal calendars
- Synchronize contacts to smartphone or tablet

Medication adherence



Medication Adherence Technology

Ingestible Sensor | **Wearable Sensor** | **Mobile Applications**





Therapeutic Information
- Medication
- Dose
- Timing
- Adherence

Physiologic Information
- …

Mobile Information

ORACLE Health Sciences InForm

ORACLE Health Sciences Proteus Data Option

Kit

Digital Data Option

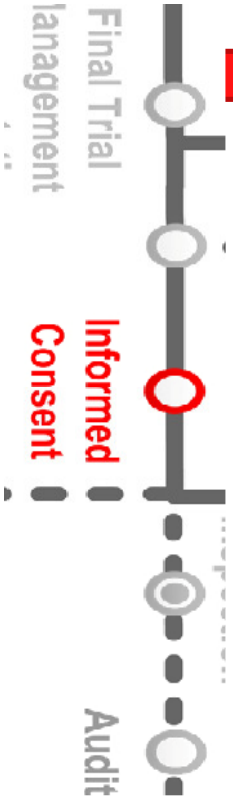
"Did she/he take the pill?"




eICF



eICF technologies



For Volunteers

- Full Signature



- Checkbox



For Researchers

- Podcast
- Embedded comments in ICF
- Videos
- Interactive webpages

Where can it fit ?





Fitment of eICF	
Online survey studies	Patients are asked their activity and pain level 3 months after receiving composite femoral components for hip arthroplasty
Online screening	Potential subjects are asked a series of questions about their health history to determine eligibility in a study testing a novel drug for Rheumatoid Arthritis. Since these screening questions do not require an office visit, potential subjects can be both consented and screened electronically.
Submitting Bio Specimens via mail	company conducting genetics research is collecting buccal samples for analysis
Previously collected tissue research	Cosmetic surgery patients are contacted for their consent to use their discarded tissue to test a new topical drug for hair growth.
In-person paperless survey research	Patients with pancreatic cancer at an outpatient oncology infusion site are provided an iPad in which to answer questions about experienced side effects

Benefits and Challenges of eICF

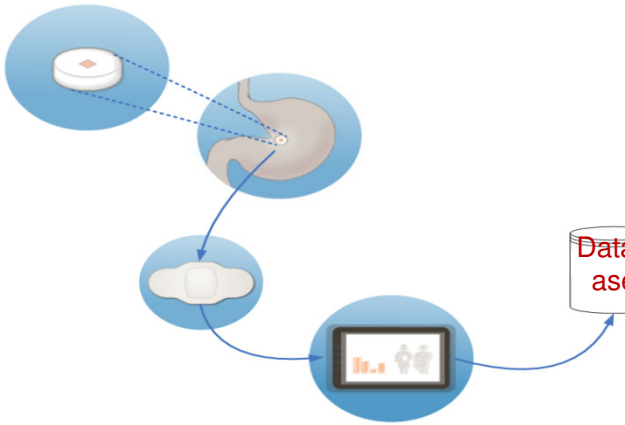


Benefits for patients	Benefits for Researchers	Challenges
Convenience	Higher Enrollment	Expensive
Less pressure and anxiety	True Informed Consent	Verification
More informed	More Compliant Participants	Compliance
More engaged	Convenience	
	Paperless	
	Increased capability	
	Trust factor	

eSource



eSource



Database

SCR BL W1 W2 SC AE/CM UNS DigData

Visit: SCR

Forms:
- DOV
- DM
- DDID
- PREG
- FAMMHX

DIGITAL DATA IDENTIFICATION FORM

1.	Digital Data Study Name	S2839927
2.	Digital Data User Name	P9426
3.	Date of most recent event in digital feedback	Apr/17/2013 20:27:24
4.	Number of ingestions expected per day	2

SCR BL W1 W2 SC AE/CM UNS DigData

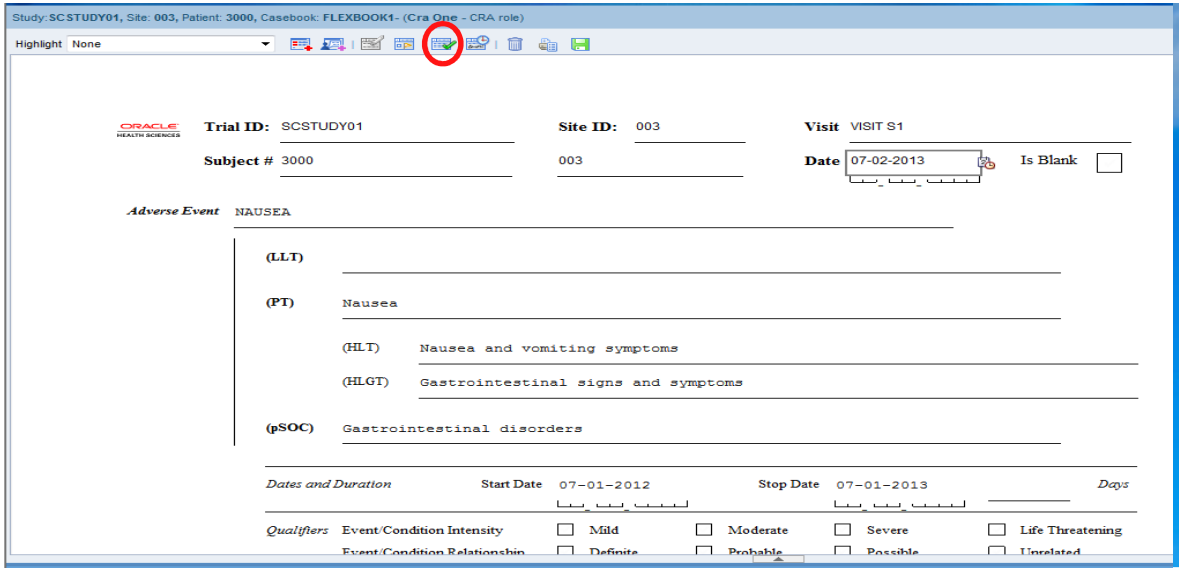
Visit: DigData

Forms:
- INGEST
- TRANSMIT
- CUM ADHERE

INGESTIONS – Unscheduled [Page 1 of 1] [Summary]

#	Date and Time of Ingestion	Ingestion Event Marker ID	Feedback test pill flag
1	Apr/3/2013 20:27:24	490623	No
2	Apr/4/2013 08:58:27	490624	No
3	Apr/5/2013 06:09:00	490625	No
4	Apr/6/2013 07:23:14	490626	No
5	Apr/6/2013 22:16:45	490627	No
6	Apr/7/2013 08:27:35	490628	No
7	Apr/7/2013 20:11:48	490629	No

eSource and Data Verification





How much is right ?





The Shuttle Atlantis Cockpit

Thank You

