



Oracle Life Sciences User Group

Enhanced Reporting for Oracle Clinical

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Prasad Inampudi
Practice Director, Life Sciences
Oracle Consulting

Sameer Singhal
Sr Principal Consultant
Oracle Consulting

Agenda

- Technology in Clinical Trials
- Challenges in Analysis & Reporting of Clinical Data
- Overview of the 'Offering'
- Introduction to Discoverer
- Solution Details
- Example Engagement
- Conclusion/ Q&A

The Promise of e-Clinical Technology

- Shorter Cycle Times
- Automated Processes
- Improved Data Quality
- Improved Security and Confidentiality
- Greater Cost-Efficiency Through Reengineered Processes

For most part, customers have begun to reap these benefits

But Something's Missing!

While we've improved process efficiencies,
we have not addressed the overall effectiveness!!

- Lack of ability to analyze information to support decision-making
- Broad trends not identifiable
- Lack of actionable intelligence

Analysis & Reporting Challenges for Clinical Data

- Oracle Clinical has several 'canned' reports
- Data extracts into SAS provide additional opportunity for analysis
- However, both are inadequate
 - For e.g. little to none cross-study comparison
 - No useful information to monitor progress of studies
 - What about data that is logged but not reconciled?
 - Reports are static, not interactive, i.e. cannot dynamically change attributes

Examples of Useful Analysis & Reporting

- Analysis of Global Libraries
 - A list of Studies that utilized a parameterized question, question group, or particular DVG subset
 - A list of comparison between Global Library DCM/DCI vs. a study DCM/DCI
- Study Design reports
 - A list of comparison between any two studies such as DCI/DCM and procedures
 - Complete list for whole study, including DCI Books, DCI book page number, DCI, question, DVG values
 - List of procedure and question and question group used in the procedure per study

Examples of Useful Analysis & Reporting Contd..

- Trial Management Reports
 - Trial progress report
 - Patient status report
 - Outstanding queries report
- Data Management reports
 - Status of CRF pages
 - Discrepancy listing
 - Patient data

Examples of Useful Analysis & Reporting Contd..

- Lab Reports
 - Comparison of normal ranges between two labs
 - List of Lab forms and lab ranges it assigned to
 - List of Lab tests that doesn't have any valid normal ranges
- Data Management reports
 - List of studies and dictionary mapped
 - List of studies that doesn't have dictionary mapped
 - Listing of uncoded terms

Overview of the Offering

- 4-6 Week consulting service engagement that will enable you to interactively analyze data from Oracle Clinical using Oracle Discoverer
- Pre-built subject areas
- Realtime analysis
- 100% Web access – Not required to be a Oracle Clinical user
- Run reports ‘on demand’ or ‘as scheduled’
- Extendable to other data sources

Rich text editor toolbar with icons for bold, italic, underline, bulleted list, numbered list, link, unlink, and other text formatting options.

ABC Pharma
Study Wise Discrepancies
As On : 16-MAY-05 04.55.26 PM

Study	# of Discrepancies
Acess1_45 for Validation	7
Conduct1_45 for Validation	18
DEPLIY_DCM Design	44
Demo study 2	96
FUN1_45 for Validation	2
RDC1_45 FOR VALIDATION	16
SECURITY1_45 FOR VALIDATION	2
Study to demonstrate and practice llearning	1
TMS Validation Study	16

Toolbar with icons for file operations, editing, and formatting. Below the icons is a formula bar with mathematical symbols like Σ, Min, Max, %, +, -, ×, ÷, =, ≠, <, ≤, >, ≥, and ∇.

ABC Pharma
Study Wise / Site Wise Discrepancies
 As On : 16-MAY-05 04.56.00 PM

Study	Site	# of Discrepancies
Acess1_45 for Validation	Site 1	7
Conduct1_45 for validation	Site 1	18
DEPUY DCM Design	Site 1	23
DEPUY DCM Design	Site 2	21
Demo study 2	Site 1	69
Demo study 2	Site 2	27
FUN1_45 for Validation	Site 1	1
FUN1_45 for Validation	Site 2	1
RDC1_45 FOR VALIDATION	Site 1	11
RDC1_45 FOR VALIDATION	Site 2	4
RDC1_45 FOR VALIDATION	Site 3	1
SECURITY1_45 FOR VALIDATION	Site 1	1
SECURITY1_45 FOR VALIDATION	Site 2	1
Study to demonstrate and practice llearning	Site 1	1
TMS Validation Study	Site 1	16

Toolbar with icons for file operations, editing, and formatting. Below the icons is a text area with the following settings: Arial font, size 10, bold (B), italic (i), underline (U), and various alignment and bullet point options.

ABC Pharma
Study Wise / Site Wise / Patient Wise Discrepancies
 As On : 16-MAY-05 04.56.25 PM

Study	Site	Patient ID	# of Discrepancies
TMS Validation Study	Site 1	4650	16
Acess1_45 for Validation	Site 1	7650	3
Acess1_45 for Validation	Site 1	7750	1
Acess1_45 for Validation	Site 1	7850	3
Conduct1_45 for Validation	Site 1	11650	2
Conduct1_45 for Validation	Site 1	11950	2
Conduct1_45 for Validation	Site 1	13850	2
Conduct1_45 for Validation	Site 1	14650	1
Conduct1_45 for Validation	Site 1	14750	2
Conduct1_45 for Validation	Site 1	14850	5
Conduct1_45 for Validation	Site 1	14950	1
Conduct1_45 for Validation	Site 1	15150	1
Conduct1_45 for Validation	Site 1	31150	2
DEPUY DCM Design	Site 1	47450	4
DEPUY DCM Design	Site 1	47550	11
DEPUY DCM Design	Site 1	47650	5
DEPUY DCM Design	Site 1	47750	3
FUN1_45 for Validation	Site 1	68750	1
RDC1_45 FOR VALIDATION	Site 1	379750	4
RDC1_45 FOR VALIDATION	Site 1	380150	5
RDC1_45 FOR VALIDATION	Site 1	380650	2
SECURITY1_45 FOR VALIDATION	Site 1	383750	1

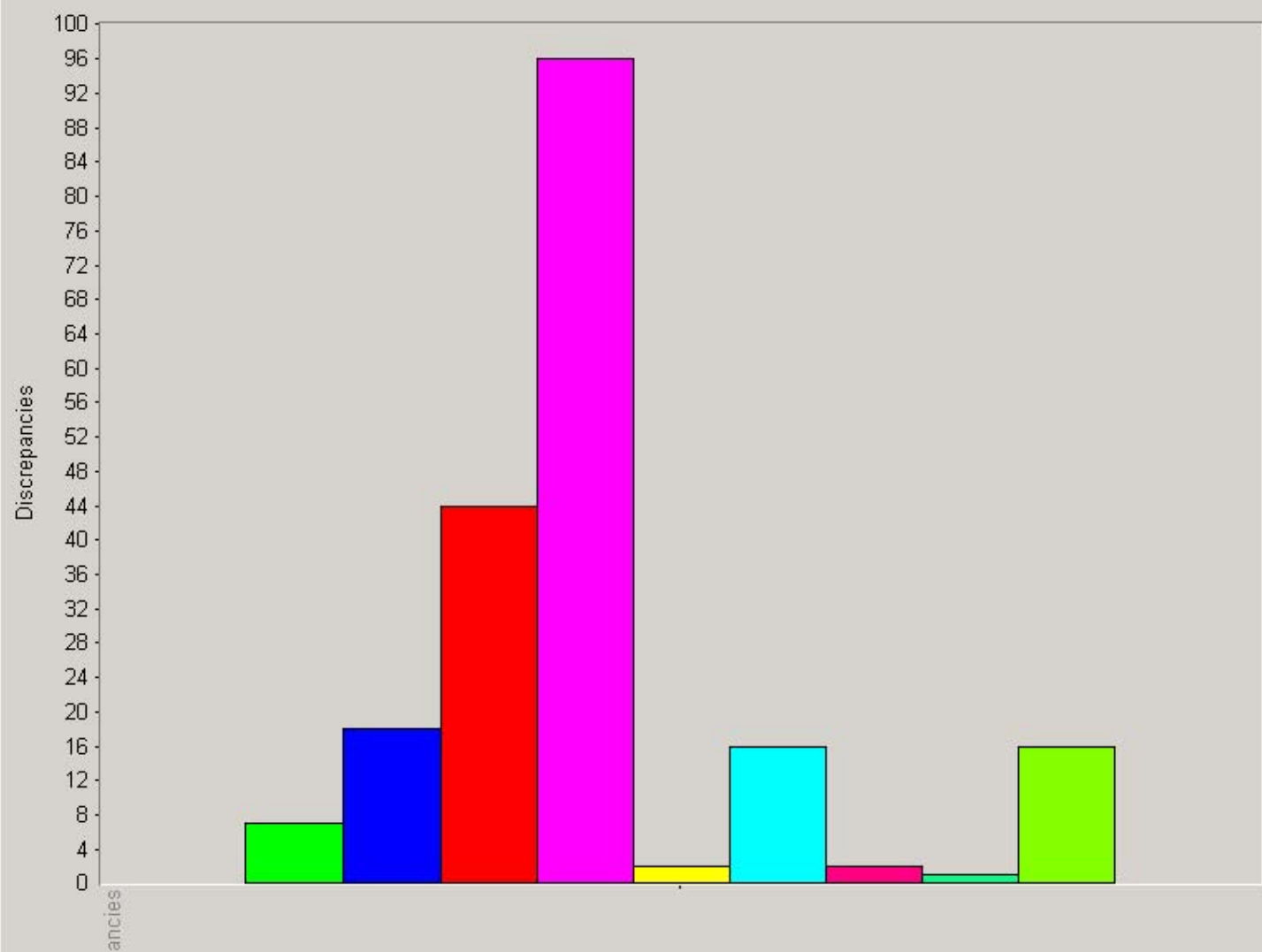
Toolbar with icons for file operations, editing, and formatting. Below the icons is a formula bar with mathematical symbols like Σ , Min , Max , $\%$, $+$, $-$, \times , \div , $=$, \neq , $<$, \leq , $>$, \geq .

ABC Pharma
Study Wise / Site Wise / Patient Wise Discrepancies
As On : 16-MAY-05 04.56.51 PM

Study	Site	Patient ID	Comment Text
FUN1_45 for Validation	Site 1	68750	Value of 00-00-1970 for Date of Blrth is an incomplete date or time
FUN1_45 for Validation	Site 2	69250	Termination Data Check
RDC1_45 FOR VALIDATION	Site 1	379750	Value of YES for Inclusion not found in Y,N,NA
RDC1_45 FOR VALIDATION	Site 1	379750	Value of N/A for Temperature is not a valid NUMBER
RDC1_45 FOR VALIDATION	Site 1	379750	Value of 120 for Diastolic above expected maximum of 110
RDC1_45 FOR VALIDATION	Site 1	379750	Value of WHITE for Race not found in CAUCASIAN,AFRICAN AMERICAN,HISPANIC,ASIAN,NATIVE AMERICAN,OTHER
RDC1_45 FOR VALIDATION	Site 1	380150	Value of YES for Inclusion not found in Y,N,NA
RDC1_45 FOR VALIDATION	Site 1	380150	Value of N/A for Temperature is not a valid NUMBER
RDC1_45 FOR VALIDATION	Site 1	380150	Value of NA for Height Units not found in LB,IN,CM
RDC1_45 FOR VALIDATION	Site 1	380150	Value of 120 for Diastolic above expected maximum of 110
RDC1_45 FOR VALIDATION	Site 1	380150	Value of WHITE for Race not found in CAUCASIAN,AFRICAN AMERICAN,HISPANIC,ASIAN,NATIVE AMERICAN,OTHER
RDC1_45 FOR VALIDATION	Site 1	380650	Value of N/A for Temperature is not a valid NUMBER
RDC1_45 FOR VALIDATION	Site 1	380650	Value of 120 for Diastolic above expected maximum of 110
RDC1_45 FOR VALIDATION	Site 2	380750	Value of YES for Inclusion not found in Y,N,NA
RDC1_45 FOR VALIDATION	Site 2	381150	Value of YES for Inclusion not found in Y,N,NA
RDC1_45 FOR VALIDATION	Site 2	381250	Value of N/A for Temperature is not a valid NUMBER
RDC1_45 FOR VALIDATION	Site 2	381250	Value of 120 for Diastolic above expected maximum of 110
RDC1_45 FOR VALIDATION	Site 3	381750	Value of YES for Inclusion not found in Y,N,NA
DEPUY DCM Design	Site 1	47450	Check to determine if systolic < diastolic
DEPUY DCM Design	Site 1	47450	Value of KGS for Weight Unit not found in LB,IN,CM



Clinical Study

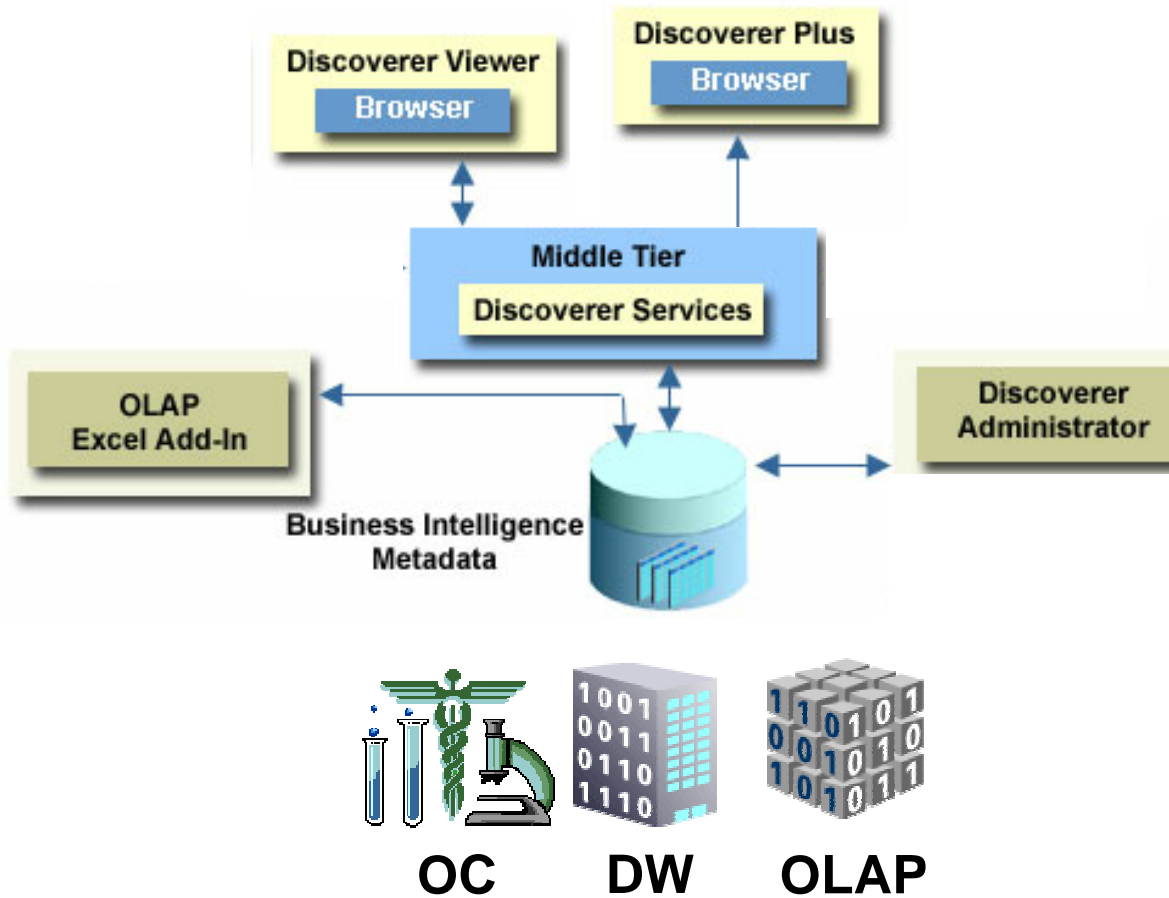


- Access1_45 for Validation
- Conduct1_45 for Validation
- DEPUY DCM Design
- Demo study 2
- FUN1_45 for Validation
- RDC1_45 FOR VALIDATION
- SECURITY1_45 FOR VALIDATION
- Study to demonstrate and practice learning
- TMS Validation Study

Overview of Discoverer

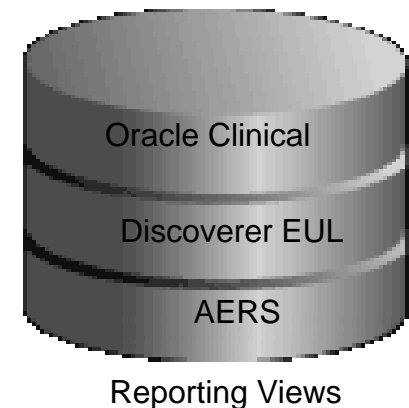
- Intuitive ad-hoc query, reporting, analysis, and Web-publishing tool
- Empowers business users at all levels of the organization
- Access to information from data marts, data warehouses and online transaction processing systems

Discoverer Architecture



Solution Building Blocks

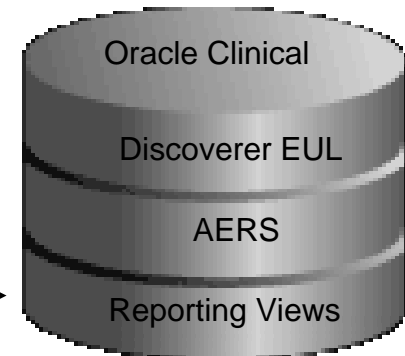
- Oracle Clinical / AERS Database
- Solution Database Views
- Discoverer End User Layer
 - Business Areas
- Discoverer Administrator
- Discoverer Desktop
- Discoverer Viewer



Database Views

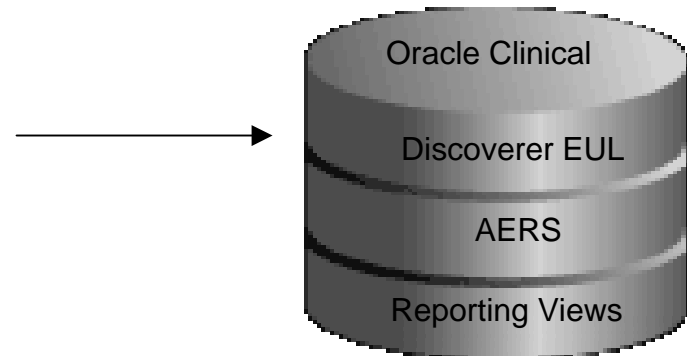
- Predefined Solution Views
- Saved as database objects
- Basis for reports
- Integrated with Discoverer

```
Select
    b.study,
    e.program_code, ...
From
    discrepancy_entries a, ...
Where .....
```



End User Layer - Business Areas

- Business Areas are groups of logically organized subject areas
- Example Clinical Analysis Areas include :
 - Trial Status Analysis
 - Discrepancy Management
 - Lab Test Analysis
 - Patient Enrollment Analysis
 - CRF Page Analysis



Admin and User Components

- **Discoverer Administrator**
 - Enables the administrator to maintain the business areas, end user layer and all the metadata
 - Accessible via client software
- **Discoverer Desktop/ Plus**
 - Enable business users to query, graph and create reports via a client software connection/ Web
- **Discoverer Viewer**
 - Enables business users to view the workbooks, graphs via a web session

Example Engagement

- Review the environmental pre-requisites
 - Patches
 - Discoverer Components and versions
- Import pre-built Database Views
- Import pre-built EUL into customer's environment
 - Business areas required for offered Clinical reporting
 - Discoverer reports for the typical analysis
- Modify pre-built Clinical Reporting Views as necessary

Example Engagement Contd..

- Implementation of Security
- Scheduling of reports for quick access
 - Runs the process at pre-defined time
 - Provides quick access w/o impacting Clinical/AERS transactions
- Testing & Documentation

Solution Extension

The Clinical Analysis solution can be extended to include :

- Additional clinical business areas
- Additional workbooks, metrics
- Additional hierarchies for aggregation
- OLAP analysis using 9i OLAP capabilities

Oracle Clinical - Discoverer Access Matrix

Oracle Clinical	Oracle Database	Application Server	Discoverer
4.5	9.2.0.3		9i
	9.2.0.5	9iAS 1.0.2.2.2a	
	9.2.0.6		
4.0.X	8.1.7.2.0	1.0.2.2.2a	4i
	8.1.7.4.0	9iAS 1.0.2.2.2a	9i / 4i

Oracle AERS - Discoverer Access Matrix

AERS	Oracle Database	Application Server	Discoverer
4.5	9.2.0.3		9i
	9.2.0.5	9iAS 1.0.2.2.2a	
	9.2.0.6		
4.3	8.1.7.4.0	9iAS 1.0.2.2.2a	9i/4i

Benefits of Using Discoverer

- Integrated with Oracle database
- Extensive calculation engine which can use the entire Oracle database functionality for calculations
- Aggregation hierarchies created once and used everywhere
- New release 10g integrates relational & OLAP reporting into Discoverer
- Scheduling of reports allows quicker access

Next Steps

Contact Information:

Prasad Inampudi

Prasad.inampudi@oracle.com

(732) 726 2443

Sameer Singhal

Sameer.singhal@oracle.com