



DBMS Consulting OUG 2006 Vendor Presentation

DBMS Consulting Overview and
OLS Support Solutions and
Cartesian Datalens Overview



Introduction

- Sunil G. Singh of DBMS Consulting, Inc.
- Specialize in Oracle Life Sciences and E-Business implementations and long-term support.
- Thanks to the OCUG for this demo/discussion opportunity.



Agenda

- Present an overview of DBMS Consulting
- Present an overview of DBMS Consulting's OLS Support capabilities
 - "Classic" OPA
 - eClinical
 - 24 x7 based support including India and China
- Present an overview of Cartesian DataLens

Overview of DBMS Consulting

- Consulting organization specializing in OLS and Oracle E-Business Suite Apps 11i implementations.
- Specialize in migrations, installation and configuration, technical and functional support and customized training.
- Support can be either long-term on-site support or remote support on an as needed basis.

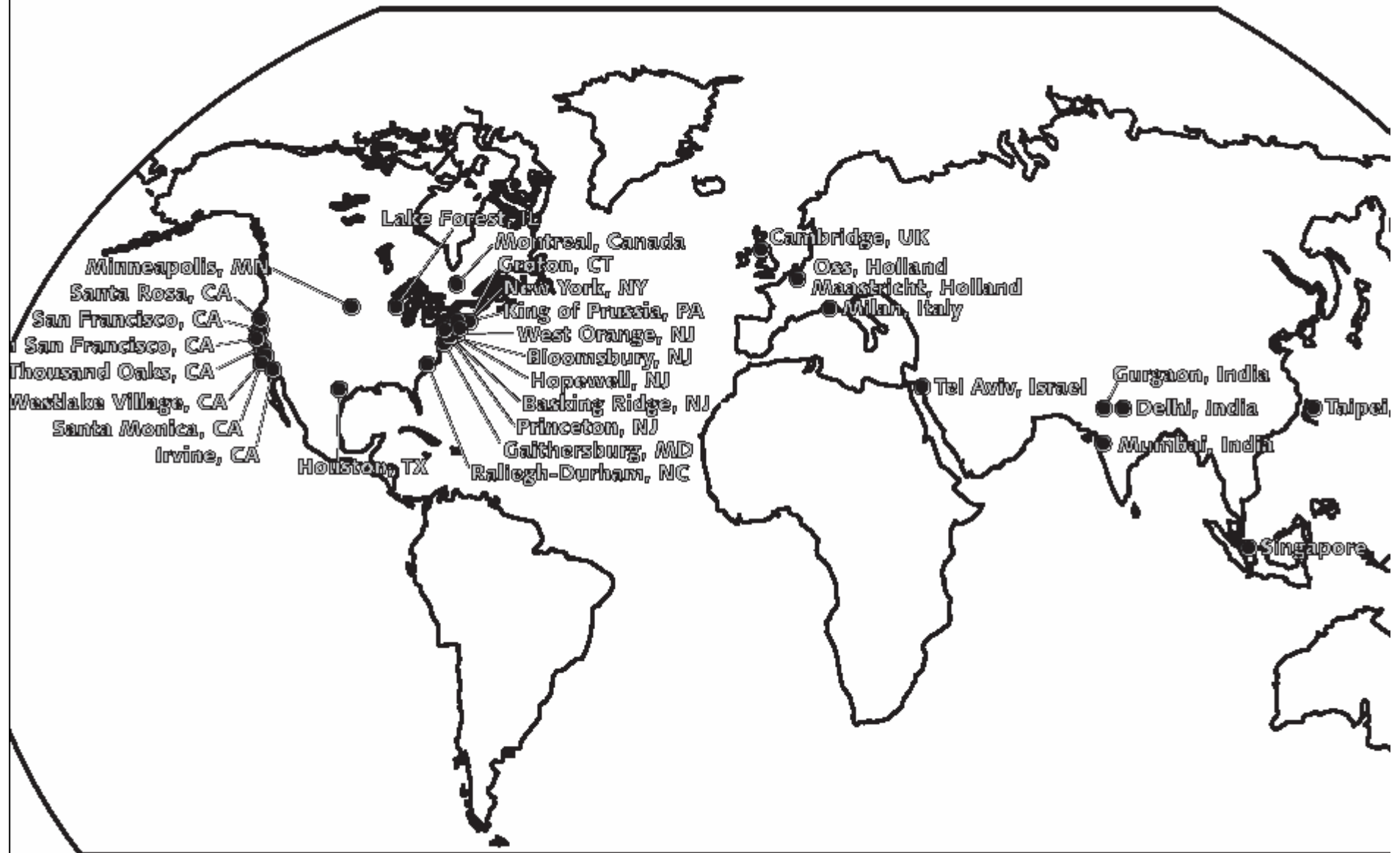
Overview of DBMS Consulting (2)

- Currently have a total of 12 Full and part time consulting staff
- Share administrative tasks internally to reduce costs
- Technically categorized as a Systems Integrator (SI) for OLS
- Maintain presence in New York, Southern California, New Jersey, China and India, through small offices or home offices



Overview DBMS Consulting (3)

- All full-time staff travel extensively to client sites and are usually on-call 24-hours.
- DBMS Consulting currently maintains a long-term presence in several companies.
- Additionally, 24 x 7 remote support and OLS Application Support Outsourcing is provided to several organizations.
- Total number of companies that have employed the services of DBMS Consulting for OLS related work is over 30, including CROs, Biotechs, Pharmaceuticals, Medical Device Companies and Academic Institutions



Locations of DBMS Consulting's Successful OPA™ W

Overview DBMS Consulting (4)

- GSA Certified and eligible for all US Government contracts
- Alliance Member Partner of Oracle Corporation
- Channel Alliance Partner with Mercury Interactive
- DBMS is very price competitive and cost-conscious. Tremendous effort to reduce expenses to customers
- Guarantee customer satisfaction on all work or no billing for that work

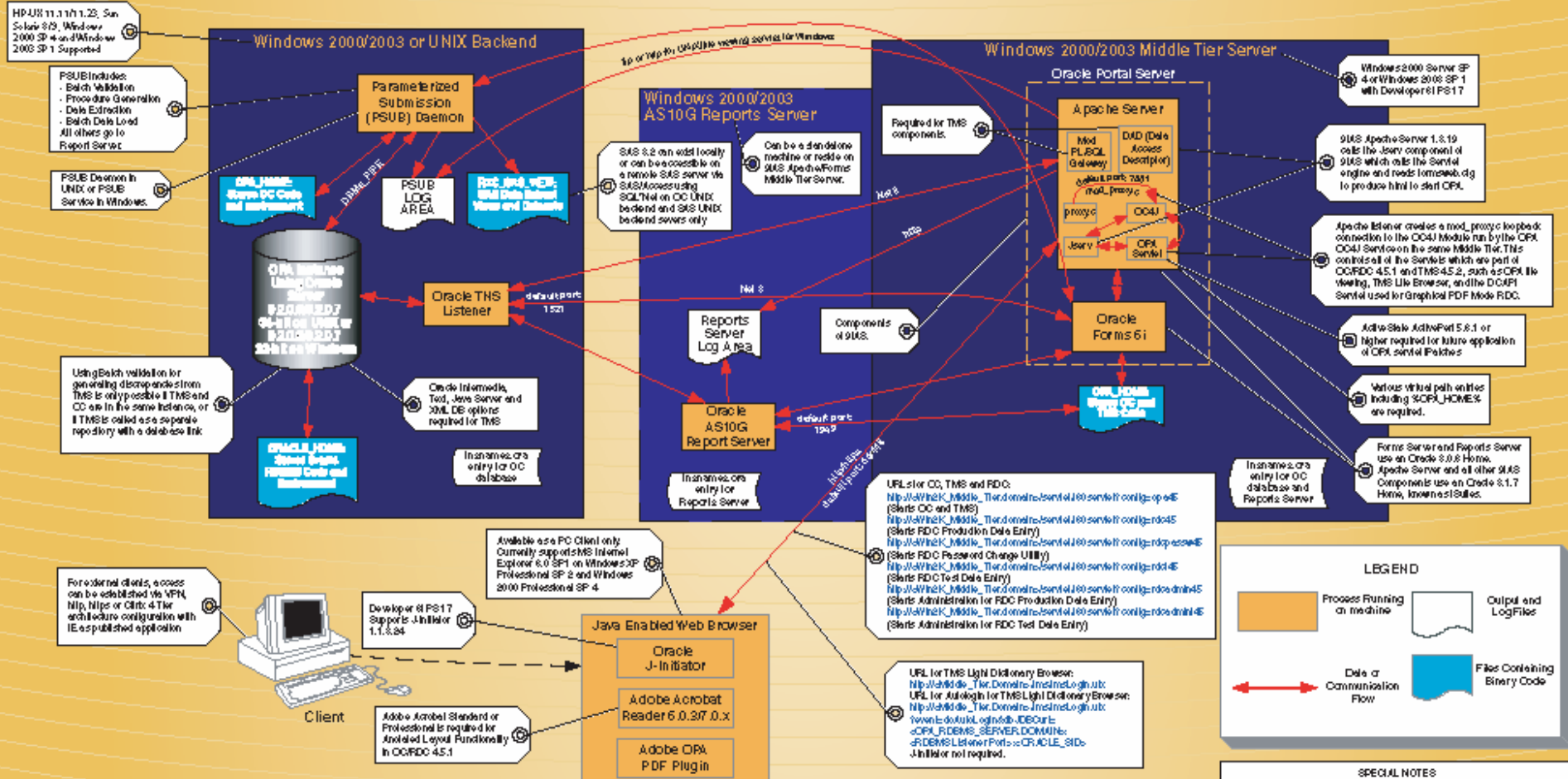


Overview DBMS Consulting (5)

- Tremendous technical and functional expertise in Oracle, with most members of DBMS having an Oracle DBA or Development background or Oracle Functional background in either the Pharmaceutical or Financial sector.
- Typically, we are called to solve the most difficult technical and functional issues or to offer strategic implementation advise.
- Created a series of architecture diagrams for the OLS to assist customers with the true understanding of OLS and the myriad configuration options available.



OC/RDC 4.5.1, TMS 4.5.2 3-Tier Configuration



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Overview of DBMS Consulting: Management Consulting (6)

- Provide detailed Management Consulting, Process Re-Engineering Support, and Strategic Direction/Insights answering key high-level management questions for current and potential OLS customers such as:
 - How do we cost justify implementation of OLS?
 - How do we measure ROI when implementing OLS?
 - Developed a set of key metrics for use against legacy systems to compare Data Entry, Data Management, time to analysis, time to reporting and submission, and Medical coding metrics to quantitatively measure costs and ROI, as well as intangible factors
 - What process re-engineering is required to deploy an EDC/RDC solution?
 - Developed a 16 step process for deploying and implementing RDC



Overview of DBMS Consulting: Management Consulting (7)

- How do we choose a strategic partners for OLS?
 - Hardware and Network Systems Vendors
 - CROs
 - Data Management
- How do we cost-effectively capitalize on emerging trends in Outsourcing model?
 - What is the value of an outsourced and/or off-shore model?
 - What activities should be outsourced ?
 - Should we develop “outsourced” centers internally ?
 - How do we choose an off-shore partner? What do we look for? What questions should we ask?
- How do we make strategic decisions for the future use of OLS given acquisitions and possible product de-support of the global Oracle organization?
- How do we get the most value for the time and money we have spent on OLS?



What are the Advantages of DBMS Consulting over larger OLS Service providers?

- Personalized attention and direct access to all resources who can help with a critical issue (“flat team approach”).
- 24 x 7 on-call support for all customer production issues.
- Access to direct knowledge of other real-world implementations and issues.
- Willingness to share useful information, and to contact other resources as well as other customers to find solutions.
- Dedication to work only with OLS products and support.
- All experienced team members > 5 years



What are the Advantages of DBMS Consulting over larger OLS Service providers?

- No “dead stop” for OLS support questions for custom developed applications, other 3rd party tools, or integrated applications.
- No interest in sales of a product or pre-defined sales quota. An objective evaluation of OLS’s strengths and weaknesses at all times. (“honest broker”)
- Tremendous flexibility in cost negotiations, discounts, long term and deferred payments with consideration to customer’s budgets.
- 100% Commitment to meeting OLS customers’ needs. No location is off-limits.

Why seek help with OLS Support outside of Oracle?

- There are gaps in the level of support currently provided by OLS
 - There is a need for immediate assistance with complex OLS related issues "Need an answer now Gap"
 - Global users do not have support from OLS for customizations "OLS Customization Gap"
 - There is no direct access to OLS development through OLS Support "Developer access Gap"
 - No Support for integrated applications with OLS



Why seek help with OLS Support outside of Oracle? (2)

- OLS is constantly in a development and deployment mode, especially in the context of Project Fusion. Unlike other applications which reach a “plateau of stability”, the nature of OLS requires that there is an ongoing cycle of
 - Request for changes, enhancements, bug fixes, or maintenance upgrades/patches
 - Validation
 - Deployment
 - Training



Why seek help with OLS Support outside of Oracle? (3)

- OLS Customers are Pharmaceutical/Biotech/Medical Device/CROs/Research/Educational/Government organizations, not IT Service Providers and not Application Support Providers
 - OLS Customers have strategically aligned themselves with Oracle in the concept of OLS as a Commercial Off-the-Shelf (COTS) system.
 - However, many OLS Customers find themselves in an ever increasing role to support and maintain all various aspects of OLS, from routine maintenance of user accounts and security, to formal or de-facto testing new enhancements and functionality on behalf of Oracle.

DBMS Consulting's 24 x 7 support Capabilities in China and India

- Presence in China and India
 - Started DBMS Consulting China, Ltd, based in Shanghai supporting APAC (Dr. Letian Liu)
 - Started DBMS Consulting India, Private Limited based in New Delhi supporting India (Mr. PS Shivaramkrishnan)
 - supporting Asia-based OLS customers, in a reverse outsourcing/reverse off-shore model
- Provides all aspects of implementation expertise and long term support for several OLS customers
- Developed the knowledge Life Sciences Industry in China and India:
 - direct and first-hand experience on the major infrastructure providers in the region
 - local and regional regulations, environmental and infrastructure factors and politics



DBMS Consulting's Experience in OLS Support

- DBMS Consulting already provides OLS Support on an on-call 24 x 7 basis to several companies.
 - CROs which demand real-time support but can not afford on-site consulting resources
 - Medical Device companies where assistance for on-line OLS support and ad-hoc SQL reporting
 - Large Pharmaceuticals with broadband VPN access that provide laptops for connectivity into their environments where on-site support staff may not be available
 - Large Biotech companies which need both Oracle DBA and Oracle OLS support
 - Asian based Pharmaceuticals and Government Institutions which have limited OLS support in their time zones.
- DBMS Consulting provides OLS implementation support to 4 of 9 known OC customers in India today



DBMS Consulting's Experience in Siebel support

- DBMS Consulting team members Steven F. Munley and Dr. Letian Liu have extensive experience in the deployment and support of all Siebel ePharma applications
- DBMS Consulting has facilitated integration of Siebel eClinical and OC **before** the acquisition of Siebel by Oracle
- Retained dedicated staff specialized in Siebel applications



Remote OLS Administrations and DBA/SA Activities related to OLS

- Provide support to OLS System Administration in real time basis, using
 - VPN Connectivity
 - On-Line Connectivity (e.g., Web-Ex, NetMeeting)
 - Phone, e-mail and IM Connectivity
- To connect directly into customer's sites and work directly with OLS Admins, DBAs/SAs
- Provide "call queues" to reach someone on a 24x7 basis
- Provide assistance from Reference Codelists, back-end configuration, /etc/system, http.conf, bc4j.xcfg, to Oracle RDBMS to Win2K/2003.



Remote OLS Administrations and DBA/SA Activities related to OLS (2)

- Perform major tasks, such as
 - OLS migrations,
 - character set conversions,
 - database/instance cloning,
 - middle tier rebuilds
- Provide remote system testing/stress testing and simulate user testing for public facing systems

Support for Global RDC Deployments

- Provide on-call support for sponsors of Global RDC studies using the same methods provided for DBA and SA support (VPN, On-Line, Phone, e-mail, IM)
- Provide a backup level to existing or planned implementation of user and site support desks, where specific or more difficult calls are routed directly to DBMS Consulting, and one-to-one support directly with users is provided
- Provide training and simulations for internal/external RDC Help desk to reduce “ramp-up” time for global deployments
- Provide strategic consulting for choosing large call centers and help desk providers, or
- Manage large RDC Help Desk and Support Centers through DBMS Consulting’s strategic alliances.



Support for Global RDC Deployments

- Guidance and facilitation of Citrix 4-Tier deployments of RDC
- Work with specific sites which have connectivity or application related issues
- Facilitate and liaison with specific sites Network and Desktop administrators to resolve specific RDC related issues
- Provide strategic planning for implementation of long-term and immediate RDC support

CDM related Support

- DBMS Consulting provides remote development services for any OLS application related activity:
 - Study Design and Development
 - RDC Graphical and Classic Mode pilot studies
 - Legacy or paper based studies migrated to OC/TMS/RDC
 - Validation/Derivation Procedure Development
 - DX view configuration and testing
 - AERS Workflow Configuration and testing
 - TMS Dictionary Loading and Domain configuration

CDM related support (2)

- Provide guidance into building “internal” support centers based in India and China
 - How to cost justify this model
 - How to locate and identify qualified resource
 - How to reduce turnover ratio
 - How to protect intellectual property
 - How to provide regulatory compliance
- Provide strategic training and management guidance for the internal centers
- Provide back-up level support for these internal centers



Other OPA-Related Products and Services

- OLS Support Services and OLS Support Outsourcing Services
- Validation Services and Materials for OLS, including OC, TMS, RDC, AERS, eClinical/ePharma (formerly Siebel)
- Standard and complex Custom development for OLS (Menu Roles, DCFs, to integration with other legacy systems)
- TMS dictionary loading, updating, migration for standard and customized dictionaries
- TMS Autoencoding development, from standard to complex search objects and external system integration



Other OPA-Related Products and Services

- Flat-rate customized functional and technical OLS training.
- Partnership with the WHO-UMC to develop certified loading and update scripts for all WHO dictionaries for TMS, including updating WHODrug Type B to WHODrug Type C Dictionaries already loaded in TMS. (Mr. Anders Hansson also present as part of the DBMS Consulting team)
- Partnership with Cartesian Software to distribute Data Lens Reporting tools.
- Technical recruiting for Oracle-related requirements
- Customized automated testing development, using Mercury Interactive toolsets.

Cartesian Data Lens



Overview

- Reporting in OC and AERS can be difficult and generally not intuitive
- Aggregation can be difficult and performance intensive
- Easy to use interface for generative true ad-hoc reporting and analysis of OLS-based data
- Combined Reporting/Browsing with aggregation

Step 1: Build a Venn Diagram

The screenshot shows the Data Lens application window. The title bar reads "Data Lens". The menu bar includes "File", "Venn Diagrams", "Reports", "Administration", and "Windows". The "Tasks" pane shows a tree view of databases: "AERS Datawarehouse", "Oracle Clinical Mirror Test", "CV101" (selected), "CV101-001", "CV101-002", "CV101-003", and "Oracle Clinical Test (Direct)". The main workspace is titled "Adverse Events by SOC | Adverse Events by SOC Venn Builder". It contains a list of "Database Fields" for the selected table, including "Active Dose Date", "Adverse Event" (highlighted), "Action", "Adverse Event Study Day", "Intensity", "Relationship To Study Drug" (highlighted), "Treatment Required", "Verbatim Term", "Visit Label", "Adverse Event End Date", "Adverse Event Start Date", "Birth Date", "Chest Xray", "Chest Xray Date", "Concomitant Medication", "Consent", "Consent Date", "CTC Version3", "Enrollment", and "Labs". The "Venn Builder" panel on the right has a "Venn Circle Name" field set to "At Least Likely". Below it, the "Relationship To Study Drug" section has a search box and a "Find" button. A list of relationship types is shown with checkboxes: "CERTAIN" (checked), "NOT LIKELY", "NOT RELATED", "NOT RELTED", "POSSIBLE" (checked), and "PROBABLE" (checked and highlighted).



Step 2: View First Venn Criteria

Adverse Events by SOC | Adverse Events by SOC | Venn Builder

Database Fields:

- Active Dose Date
- Adverse Event
 - Action
 - Adverse Event Study Day
 - Intensity
 - Relationship To Study Drug
 - Treatment Required
 - Verbatim Term
 - Visit Label
- Adverse Event End Date
- Adverse Event Start Date
- Birth Date
- Chest Xray
- Chest Xray Date
- Concomitant Medication
- Consent
- Consent Date
- CTC Version3
- Enrollment
- Labs

Conditions and Values

New Venn Diagram

At Least Likely

Venn Diagram Settings

Diagram Name:

Group: Cartesian

Access: Private



Adverse Events by SOC | Adverse Events by SOC | Venn Builder | Concomitant Medications

Database Fields:

- Active Dose Date
- Adverse Event
- Adverse Event End Date
- Adverse Event Start Date
- Birth Date
- Chest Xray
- Chest Xray Date
- Concomitant Medication
 - DMSNM
 - Generic Term
 - Use Of Medication
 - Verbatim Term
- Consent
- Consent Date
- CTC Version3
- Enrollment
- Labs
- MedDRA
- Medical History
- Medication End Date

Conditions and Values

Venn Circle Name: Con Med Drug B

Verbatim Term

= B

Venn Diagram

New Venn Diagram

At Least Likely

Venn Diagram Settings

Diagram Name:

Group: Cartesian

Access: Private

Step 3: Add 2nd Venn Criteria



Step 4: View New Venn Diagram

Adverse Events by SOC | Adverse Events by SOC | Venn Builder | Concomitant Medications

Database Fields:
+ Active Dose Date
+ Adverse Event
+ Adverse Event End Date
+ Adverse Event Start Date
+ Birth Date
+ Chest Xray
+ Chest Xray Date
- Concomitant Medication
 - DMSNM
 - Generic Term
 - Use Of Medication
 - Verbatim Term
+ Consent
+ Consent Date
+ CTC Version3
+ Enrollment
+ Labs
+ MedDRA
+ Medical History
+ Medication End Date

Conditions and Values

New Venn Diagram

Venn Diagram Settings

Diagram Name:

Group: Cartesian

Access: Private

Step 5: Add 3rd Venn Criteria

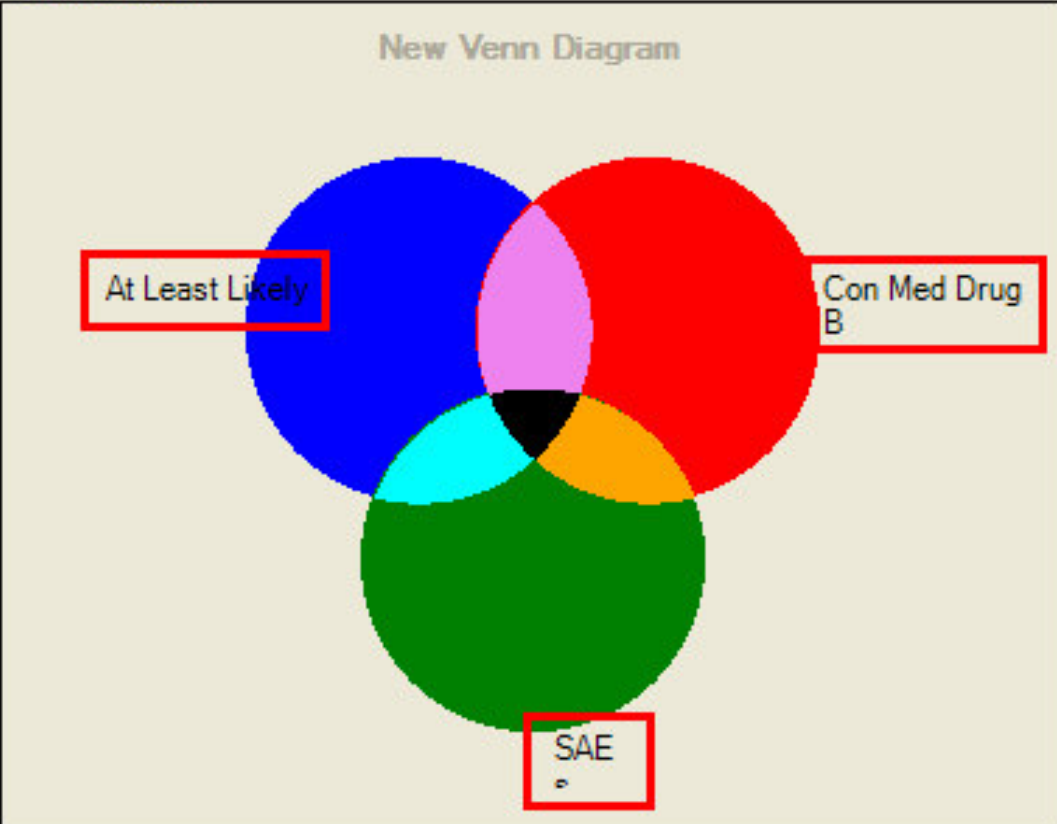
The screenshot shows the 'Venn Builder' window with the following components:

- Database Fields:** A list of fields on the left, including 'Active Dose Date', 'Adverse Event' (with sub-fields like Action, Intensity, etc.), 'Adverse Event End Date', 'Adverse Event Start Date', 'Birth Date', 'Chest Xray', 'Chest Xray Date', 'Concomitant Medication' (with sub-fields like DMSNM, Generic Term, etc.), and 'Consent'.
- Venn Circle Name:** A text box containing 'SAEs'.
- Intensity:** A section with a search box labeled 'Enter Search Text' and a 'Find' button.
- Conditions and Values:** A list of criteria with checkboxes:
 - GRADE 2
 - GRADE
 - GRADE 1
 - GRADE 2
 - GRADE 3
 - GRADE 4

Step 6: View 3 Criteria Venn Diagram

Venn Diagram

New Venn Diagram



At Least Likely

Con Med Drug B

SAE

Venn Diagram Settings

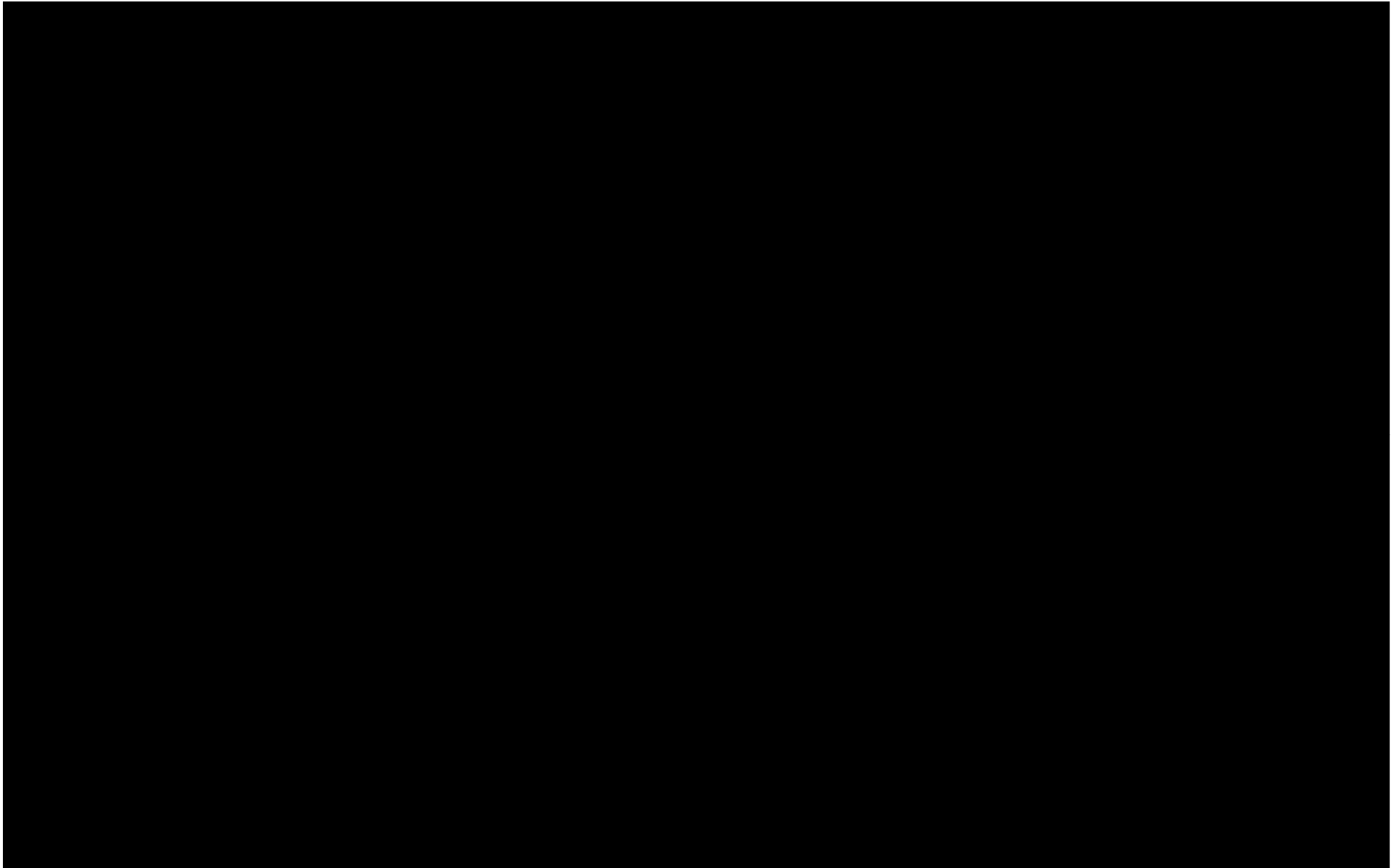
Diagram Name: SAEs and Conmed B

Group: Cartesian

Access: Private

Step 7: Retrieve Report Filtered by Venn Diagram Conditions

The screenshot shows a software interface for building Venn diagrams. On the left, a 'Venn Diagrams' panel lists several filters under 'Miscellaneous': 'White Female on CONMED B', 'Potassium less than 3', 'Older than 50 years', and 'SAEs and Conmed B'. The 'SAEs and Conmed B' filter is highlighted with a red box. The main area displays a Venn diagram titled 'SAEs and Conmed B' with three overlapping circles: a blue circle labeled 'At Least Likely', a green circle labeled 'SAE', and a white circle labeled 'Con Med Drug B'. A red rectangular box highlights the intersection of the 'At Least Likely' and 'Con Med Drug B' circles. To the right of the diagram, a text box labeled 'Currently Applied:' contains the text 'Con Med Drug B who are neither At Least Likely nor SAEs'. A 'Clear Filter' button is located at the bottom right of the diagram area.



 **Q&A.**

- Please come to Vendor booth 21 & 22 with any additional questions and more detailed demos
- Demos available for Cartesian DataLens
- WHO-UMC representative Anders Hansson present for any WHO Dictionary question
- Also for more Brochures, posters and business cards and USB Mouse pads.