

## Our expert staff

Oracle's Life Sciences Consulting Practice has been assisting customers for over 9 years with the implementation of Oracle's Life Sciences Applications – Oracle Clinical, Thesaurus Management System (TMS) and Remote Data Capture (RDC). As a partner to Oracle's Life Sciences application development organization, we are involved in the design, development, support, and quality review of new releases of the Life Sciences applications. We are also responsible for all industry application training, and continually update training materials, as the product line evolves.

Our pharmaceutical industry knowledge and expertise is unparalleled within major software vendors. In addition to our technology expertise, our staff includes professionals with significant depth of experience in data management, trials management, dictionary coding, biostatistics, regulatory submissions, validation and 21CFR Part 11 compliance.

## A strong beginning

The success of your initial pilot studies, along with the impact to users, management, and external partners will ultimately dictate the commitment of your organization towards this technology. Your organization will adopt those processes and standards that are created during the initial implementation of this software. The initial investment in the design of your infrastructure, creation of global libraries, definition of roles, design standards, infrastructure support, knowledge transfer, and training will realize time and cost savings during trial execution.

## Oracle Clinical Fast Track Implementation

The Oracle Clinical Fast Track Implementation is designed for small companies to deploy Oracle Clinical into production quickly. A typical fourteen-week fast track implementation includes the following services:

- **Architecture & Project Planning** – We will work with your team up front to develop and review a project plan, assign and review roles and responsibilities, set assumptions, and define key project milestones. Also, we will verify that you have an appropriate network and hardware infrastructure, and a configuration that adequately supports development, testing, training, and production environments. (1 week)
- **Installation** – Oracle will work with your database administrator and systems administrator to set up three database environments (Production, Test, Development), install Oracle Clinical and TMS onto the middle tier and install the applications onto the database server. Oracle will perform an installation qualification and provide a detailed engagement summary. (2 weeks)
- **Training** – Oracle will provide a one-week instructor lead with hands-on exercises training to your core

implementation team to establish the basic knowledge bases for the implementation effort. (1 week)

- **Design and Configure** – Our consultants will work with your end user community to design and configure standard libraries, processes, and metadata that will ensure that you fully leverage your investment in Oracle Clinical. Typical activities during the design phase will be based on the selected as the pilot study. These activities include: Application Security and access, Global Library Setup, Protocol Definition, Question, Code List, and Metadata Modeling, Case Report Form Modeling, Validation and Derivation Procedure Setup, Lab System Definition, Batch Load Preparation, Discrepancy Management Planning, Data Extraction Preparation, and Database Locking and Freezing. (6 weeks)
- **Pilot Study Deployment and Support** - Oracle will work with your team to facilitate conducting the pilot study. Typical pilot activities include data entry, execution of validation checks, and resolution of discrepancies, database lock and freeze, and creation of standard data extracts. Oracle will also continue support your organization once the pilot study is in place for additional support such as lab data management and batch data loading. (4 weeks)

Oracle will support the production deployment of Oracle Clinical, by ensuring that your user community is prepared to adopt the new technology platform and work with the new clinical procedures and existing metadata. (2 weeks)

## Fast track assumptions

The standard fast track implementation requires that the following assumptions be met:

- A small user community with a dedicated project lead - approximately 5 end users
- Required hardware and software infrastructure in place and IT organization support. Oracle consulting will install up to 3 database instances.
- A moderate complex pilot study with 15 CRFs.
- No data migration
- No integration with 3<sup>rd</sup> party applications

## TMS services

Customers implementing TMS will likely want to take advantage of our TMS implementation service offerings.

- **TMS Overview Training** – This course is designed for the general user of TMS. TMS Overview topics include dictionary creation, linking TMS and Oracle Clinical, maintaining and modifying dictionaries, workflow and administration. The class format is lecture and hands-on exercises. (3 days)
- **TMS Classification Workshop** – This workshop is designed for the end user. TMS Classification is targeted for employees whose primary responsibility is classifying verbatim terms. The class format is informal lecture and hands-on exercises and focuses on dictionary modification and classification. (3 days)
- **TMS Dictionary Load Services** - Our service provides consultation on dictionary structure and configuration settings that best meet your company's needs. Once your appropriate configuration is determined, PL\SQL scripts are written to spec. Our service accommodates legacy data as well as "Out of the Box" dictionary loads. The TMS dictionary loading will provide you with the IQ and UAT test scripts. (2 days per dictionary)
- **TMS Dictionary Upgrade/Versioning** - Our service provides consultation on strategy and management of Dictionary upgrade and versioning process. Our service will provide PL\SQL scripts for the dictionary upgrade/versioning and IQ and UAT test scripts. (5 days per dictionary for standard format)

## Training Options

We have developed a series of courseware to deliver either "as is" or in a customized fashion to your clinical and technical communities. Our classes include the following:

- Oracle Clinical Overview – this training consists of instruction supplemented with hands-on exercises conducted against a pre-populated training database. Topics covered include a System Overview, Basic Study Setup, Global Library Management, Simple and Complex CRF Modeling, Data Entry Overview, Batch Data Load, Discrepancies and Data Clarification Forms, Validations and Derivation Procedures, Lab Data Management, Data Extraction, Data Locking, and Application Security. This course is typically held at a customer site and requires a training room equipped with a PC for each student and the instructor. (1 week)
- New Features in Oracle Clinical from 4.0 to 4.5 (3 Days)
- PDF CRF Design Workshop (2 Days)
- Remote Data Capture Workshop (Sponsor or Site (2 Days each)
- TMS Dictionary Loading (3 Days)

- TMS Integration Development Workshop (1 Day)
- TMS Data Model Workshop (1 Day)
- Oracle Clinical System Administration (1 Day)
- Advanced Procedures Workshop (2 Days)
- Oracle Clinical Data Modeling Workshop (5-10 Days)

Our objective is to provide you with knowledge and expertise so that you can manage the application effectively and train new personnel internally on an ongoing basis.

We also offer client-specific custom training services including analysis, design, development, and delivery. Programs for Oracle Clinical support personnel, train-the-trainer, user certification, and distance learning options are available.

## Pharmaceutical consulting services

Oracle Consulting offers a host of installation, training, implementation, and validation services surrounding Oracle's industry leading suite of pharmaceutical products:

- Oracle Clinical and/or Remote Data Capture (RDC)
- Thesauruses Management System (TMS)
- Adverse Event Reporting System (AERS)
- Life Science Hub (LSH)
- CTMS (SiteMinder, Siebel Clinical)

## Optional services

Larger customers of Oracle Clinical may want additional support rolling out a global safety solution. Our consulting group offers the following optional services:

- Regulatory Assessment and Full service system validation
- Multi-Site (distributed) installation
- Custom training curriculum
- RDC Quick Start Services
- Data migration / conversion
- Custom report development or Integration with other applications
- Project Management
- Business Process assessment and development

## GETTING STARTED

For further information, please contact the following:

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