



# Business Process Outsourcing Oracle® Clinical/RDC



## Why choose C3i?

We support more than 160,000 clinical investigative sites worldwide.

### **Can you manage effectively the cost and time needed to set-up electronic trials worldwide?**

Today's economics and global trends continue to challenge the life sciences industry. Sponsors and Clinical Research Organizations (CROs) are focused more than ever on efficient clinical trials that must be managed within constrained budgets and timelines, yet continue to manage the increasing emphasis on efficacy, safety, and signal detection. You need to conduct more narrowly-targeted trials, increase efficiency and lower costs—all at the same time. Are you up to it?

As clinical trials continue to expand in worldwide scope, electronic capture is the accepted and preferred method to collect and clean data, leveraging investigative site personnel more in the process. While sponsors and CROs focus on the unique skills needed to develop compounds and run clinical trials, the realities of regionally limited resource pools, benefits of centralised IT and Clinical Data Management (CDM) operations, and continually changing regulatory landscape are just a few of the challenges. It's clear that outsourcing is an optimal solution to mitigate the financial variability associated and focus on core capabilities.

### **C3i's business process outsourcing combines world class software with a complete set of services required to run the technology aspect of clinical trials.**

C3i's Oracle Clinical (OC) / Remote Data Capture (RDC) Software-as-a-Service (SaaS) model offers flexible pricing with no infrastructure capital investment. Our model leverages virtualisation to minimise ramp-up time and ensure efficient, validated software maintenance. Our teams have the expertise and experience to ensure your protocol is designed to correctly utilise OC/RDC and that the study is created to ensure proper data collection and cleaning, compliant reporting, all in a fully validated manner.

In addition to OC/RDC hosting, our solution is comprised of: pre-packaged web-based training, global 24x7 multi-lingual support, technical site assessments, laptop provisioning and administrative support.

Let us do the technical work while you get back to concentrating on designing and running clinical trials.

**Oracle's world class software, delivered by C3i as a service, allows lower investment, easy acquisition of Electronic Data Capture (EDC) capabilities, flexibility for business changes, and delivers always-current technology and training.**

# C3i's Advantages

## LONG-TERM RELATIONSHIP WITH ORACLE

As an Oracle partner since 1998, C3i continues to build its strong relationship with Oracle by becoming one of the few Oracle Life Sciences Business Process Outsourcing (BPO) providers.



## LIFE SCIENCES FOCUS AND EXPERIENCE

The life sciences industry is C3i's exclusive focus. Over 15 years of experience in the life sciences arena gives us superior insight, knowledge and familiarity with the issues you face.

## INDUSTRY LEADER

C3i manages the lifecycle of technology deployed to life sciences companies. More than half of the world's top pharmaceutical and clinical organizations rely on C3i for implementing, training and supporting critical information technology systems. C3i's full commitment to customer satisfaction results in high renewal rates and long term key partnerships.

# Contact C3i

C3i's outsourcing services helps the healthcare industry dramatically improve technology usage while lowering the total cost of customer relationship management environments. Only C3i provides a complete portfolio of systems integration, technology training, multilingual help desk, asset management, hardware provisioning and technical site assessments exclusively tailored for the needs of healthcare professionals.

C3i has global operations centers in Europe, India and the United States. For more information, please visit C3i's website at [www.c3i-inc.com](http://www.c3i-inc.com).

# C3i's Oracle Clinical/RDC Services

## OC/RDC BUSINESS PROCESSES OUTSOURCING

Delivers the benefits of EDC software with the convenience of a service

- Offers system hosting services for OC/RDC in fully compliant data centres.
- Leverages virtualisation to minimise ramp-up time and ensure efficient, validated software maintenance.
- Access to world-leading technology and best-in-class applications that deliver maximum business value.

## STUDY DESIGN AND ON-STUDY MANAGEMENT

Provides the right study and support for your needs

- Study design support, from staff augmentation through full partnership, in the study design process and on-study management operations.
- The expertise to ensure your protocol is designed to correctly utilise OC/RDC and that the study is created to ensure proper data collection and cleaning, and compliant reporting, all in a fully validated manner.
- Full study design process supported by Quality Management System that minimises audit-risk.

## HELP DESK SUPPORT

Speeds incident resolution while reducing support costs

- Worldwide 24x7 help desk support in more than 20 languages.
- Integrated support model provides Tier 1, 2, and 3 levels to handle all escalation paths internally, and directly manages resolution of Oracle support Service Requests (SRs).

## APPLICATION ADMINISTRATION

Integrates Tier 2 and help desk support to resolve incidents faster

- Supplies real-time resets and changes to passwords, and creates and deletes user accounts.
- Stores account activation requests, signatures and completed training records in a customised clinical call tracking system for regulatory auditing purposes.

## SITE ASSESSMENT AND CONNECTIVITY ASSISTANCE

Accelerates time to site initiation

- Assesses the technical infrastructure of investigators' sites and determines ramp-up requirements for access to clinical applications.
- Facilitates Internet connectivity procurement for sites.

## HARDWARE PROVISIONING

Maintains hardware to improve the productivity of clinical end-users

- Develops and loads software images and ships hardware globally.
- Offers ongoing break-fix and warranty repair.
- Tracks assets through the life of the study.
- Employs remote diagnosis and repair capabilities.

## WEB-BASED TRAINING

Enhances study ramp-up and on-study operational efficiency

- Delivers clinical-related software instruction live over the Internet.
- Provides task-based user training for all associated roles in CDM, ClinOps, Validation, and QA.