

Case Study - Providing a Full Suite of Clinical Technology Services to a Small Biotech Company



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Agenda

- » **Objectives**
- » **Background**
- » **Key Drivers**
- » **Solution Overview**
- » **Lessons Learned**
- » **Conclusions**

Objectives

- » Describe the challenges faced by a small growing biotechnology company
- » Discuss the benefits a turnkey solution can provide
- » Review lessons learned

Background

» XBiotech – Austin, TX based biotherapeutic company

- One study completed
- Aggressive schedule of forthcoming trials
- Multiple therapeutic areas
- Limited personnel

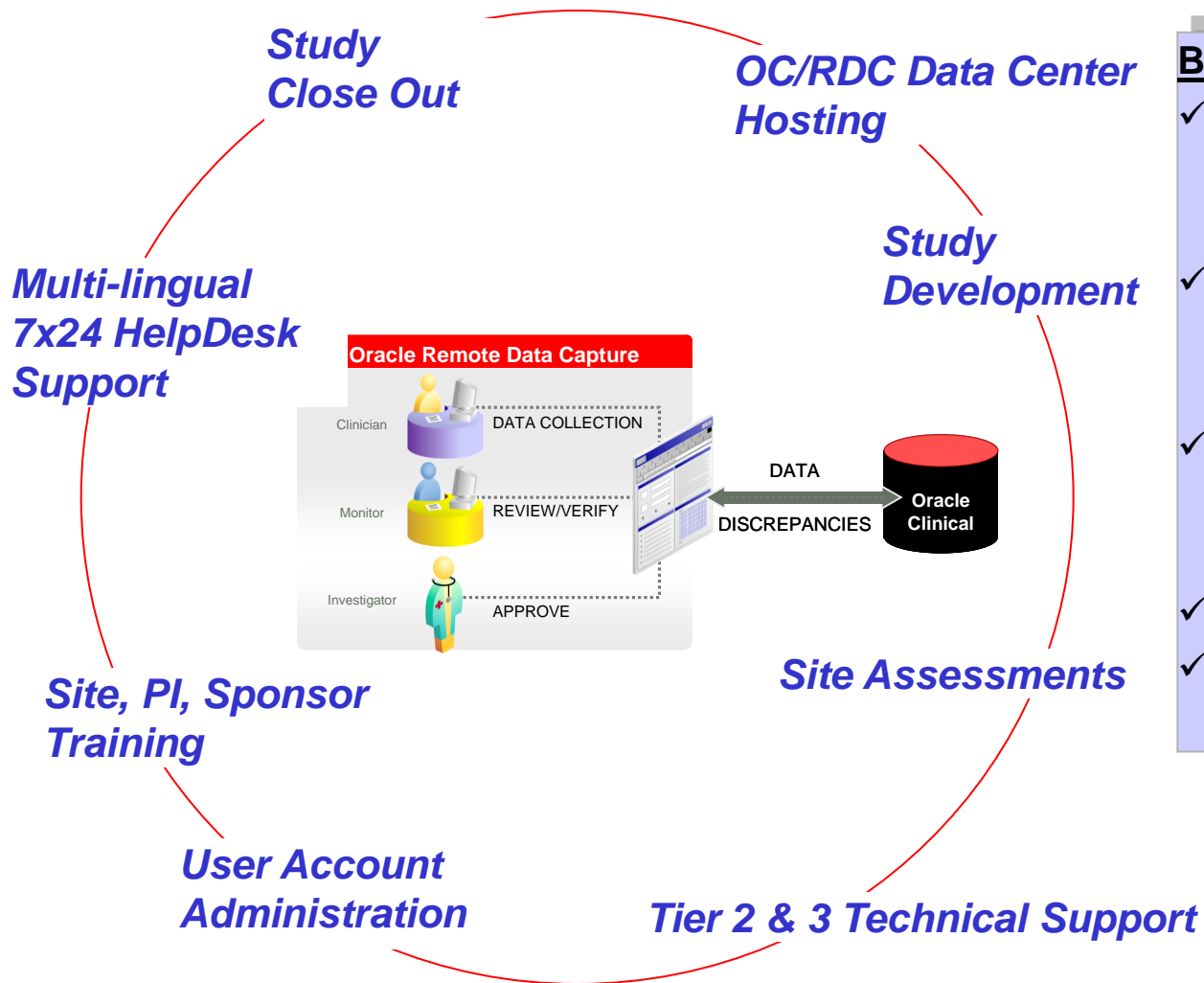
» C3i

- Provider of Clinical Services
- Oracle Partner
- BPO participant
- New solution offering

Key Drivers

- » **Cost**
- » **Efficiency**
- » **Expertise**
- » **User Support**
- » **Training**
- » **GxP/Regulatory Compliance**
- » **Data Management**
- » **Information Technology**

Solution Overview



Benefits

- ✓ Ease of entry & lower up-front investment
- ✓ Grows and adapts as clients add more studies
- ✓ Simple: software delivered as a service
- ✓ No infrastructure
- ✓ Automatic upgrades

Data Center Hosting/Managed Services

- » **System hosting for OC/RDC in fully compliant data centers**
- » **Scheduled/Controlled upgrades**
- » **DBA Services with Backup and Disaster Recovery**
- » **Access to world-leading technology and best-in-class applications that deliver maximum business value**

Licensing

» OC/RDC/TMS Business Processes Outsourcing

- **Benefits of perennial software licensing with the convenience of a service**
- **Ease of entry & lower up-front investment**
- **Grows and adapts as clients add more studies**
- **No infrastructure**
- **Automatic upgrades**

» JReview Admin and Read-only User

- **Short-term license structure**
- **Flexible**

Training

- » **Delivered instructor-led RDC OnSite live over the Internet**
 - **PI-specific training**
 - **SITE-specific training**

- » **Task-based user training for all associated internal roles in CDM, ClinOps, Validation and QA**

Support

- » **24x7 HelpDesk support in five languages**
- » **Tier 2 – Application Technical Support**
- » **Tier 3 – System Technical Support**
- » **Integrated support model provides all levels with integrated escalation paths**
- » **Directly manages resolution of Oracle Service Requests (SRs)**
- » **Client-specific knowledge objects**

Data Management Services

- » **Study design support from staff augmentation to full partnership, study design and on-study management ops**
- » **Industry best practices ensure that your protocol is designed to meet endpoints, utilizing OC/RDC**
- » **Study is created and validated to ensure proper data collection and compliant reporting**
- » **Full study design process supported by Quality Mgt system that minimizes audit-risk**

Lessons Learned

- » **Integrated solution provides real benefit to small organizations**
- » **Single vendor provides:**
 - **One point of contact**
 - **Enhanced cooperation**
 - **Deep understanding of client's processes, strengths, weaknesses**
 - **Advantageous economics**
- » **Growth potential for client and vendor**

Conclusions

- » **Small, start-up organizations focused on ClinOps and MedAffairs of the clinical trial**
- » **Many are challenged to extend capabilities and infrastructure to build and manage a top-level CDMS**
- » **Dedicated third-party clinical services company can provide:**
 - **Hosting and subscription-based licensing**
 - **Logistics**
 - **Data management**
 - **Training**
 - **Support**
- » **The combination of organizations and expertise minimizes risk and optimizes results**

Biography

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» Kevin has been involved in the Pharmaceutical/Life Science industry for eleven years, with an emphasis on creating solutions utilizing clinical technology for to enhance clinical trials. He has expertise in Oracle Life Sciences application solutions, particularly Oracle Clinical, Oracle RDC, Oracle TMS, and Siebel Clinical. At C3i, Kevin manages clients, delivers clinical services incorporating hosting, managed services, training, support, clinical data management and clinical operations.

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