

OCUG

Real-world experiences implementing, running, and supporting several large-scale global clinical trials on OC/RDC 4.5



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Introduction

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Agenda

- » **Extensive Experience in supporting OCRDC**
- » **Shorter Site Assessment Lifecycle for RDC 4.5.3**
- » **Decrease on password resets and software issues from 4.5.0 to 4.5.3**
- » **Overall Decrease in Resolution & Escalations Turnaround Times**
- » **Similarities vs. Differences OCRDC 4.5.3. vs. earlier versions**
- » **Case study – LEO Pharma:**
 - » LEO Pharma and its Oracle environment
 - » Business Challenges and C3i solutions
- » **Summary and lessons learned**

Extensive Experience in supporting OCRDC

OCRDC Version	# Users	# Sites
OCRDC 4.5	2 180	610
OCRDC 4.5.1	7 900	3 300
OCRDC 4.5.2	229	70
OCRDC 4.5.3	32 470	11 080

Total of 42 780 users in 15 000 sites supported around the world

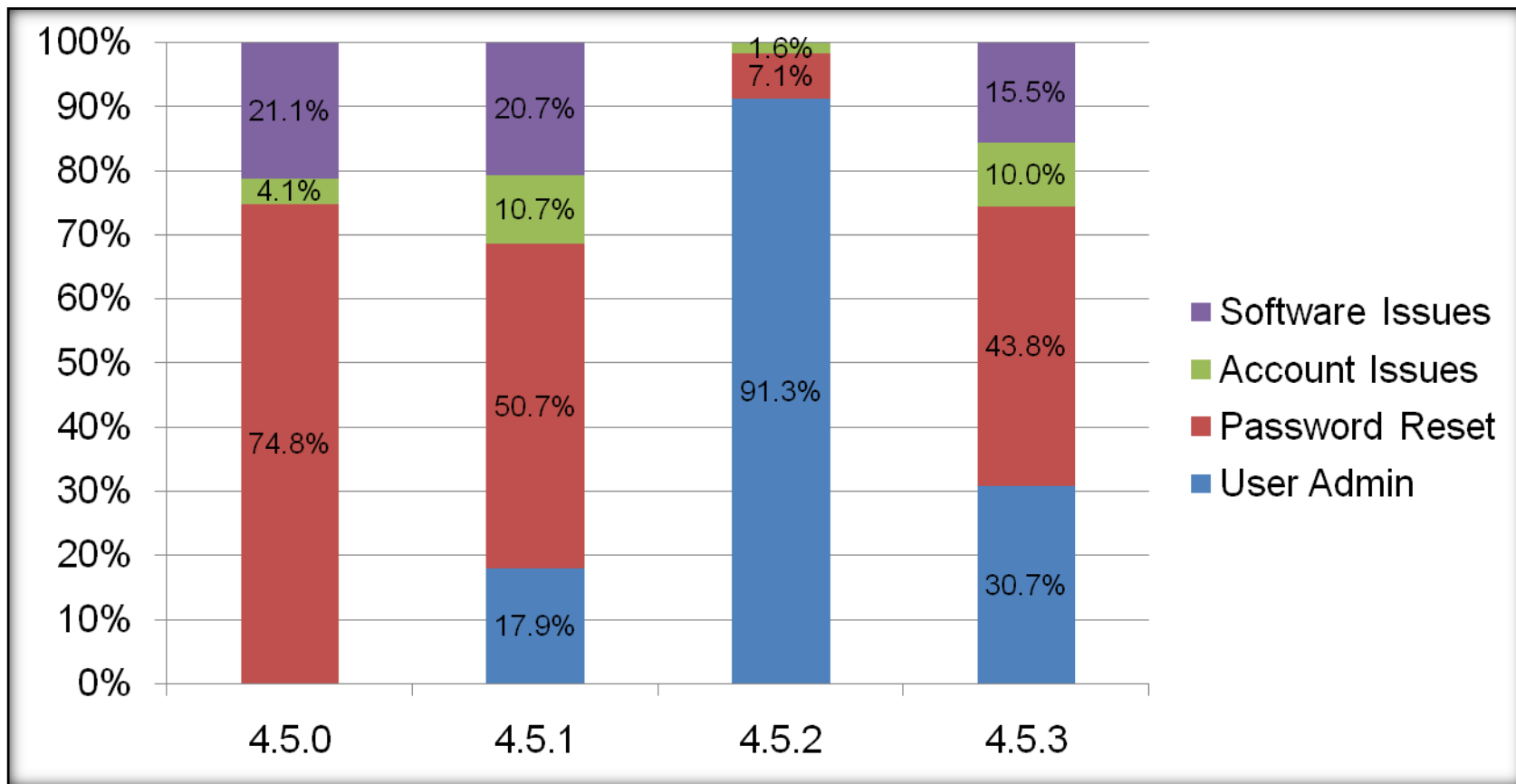
Shorter Site Assessment Lifecycle for RDC 4.5.3

Client 1	Prior to Upgrade (OC RDC 4.5.0)	Post Upgrade (OC RDC 4.5.3)	Change
Average SA Lifecycle (in days)	83	35	-58%
Average # of Call - Inbound	0.85	0.67	-21%
Average # of Call - Outbound	6.82	6.28	-8%
Average # of Email - Inbound	4.36	5.15	18%
Average # of Email - Outbound	10.07	13.76	37%
% of Failing Sites	3%	0%	-3%
Additional Installation Required	Yes (Citrix)	No	-

Client 2	Prior to Upgrade (OC RDC 4.5.1)	Post Upgrade (OC RDC 4.5.3)	Change
Average SA Lifecycle (in days)	48	39	-18%
Average # of Call - Inbound	0.34	0.2	-42%
Average # of Call - Outbound	5.37	2.3	-57%
Average # of Email - Inbound	2.69	3.3	23%
Average # of Email - Outbound	3.62	7.1	96%
% of Failing Sites	20%	4.5%	-78%
Additional Installation Required	Yes (Citrix, Adobe)	No	-

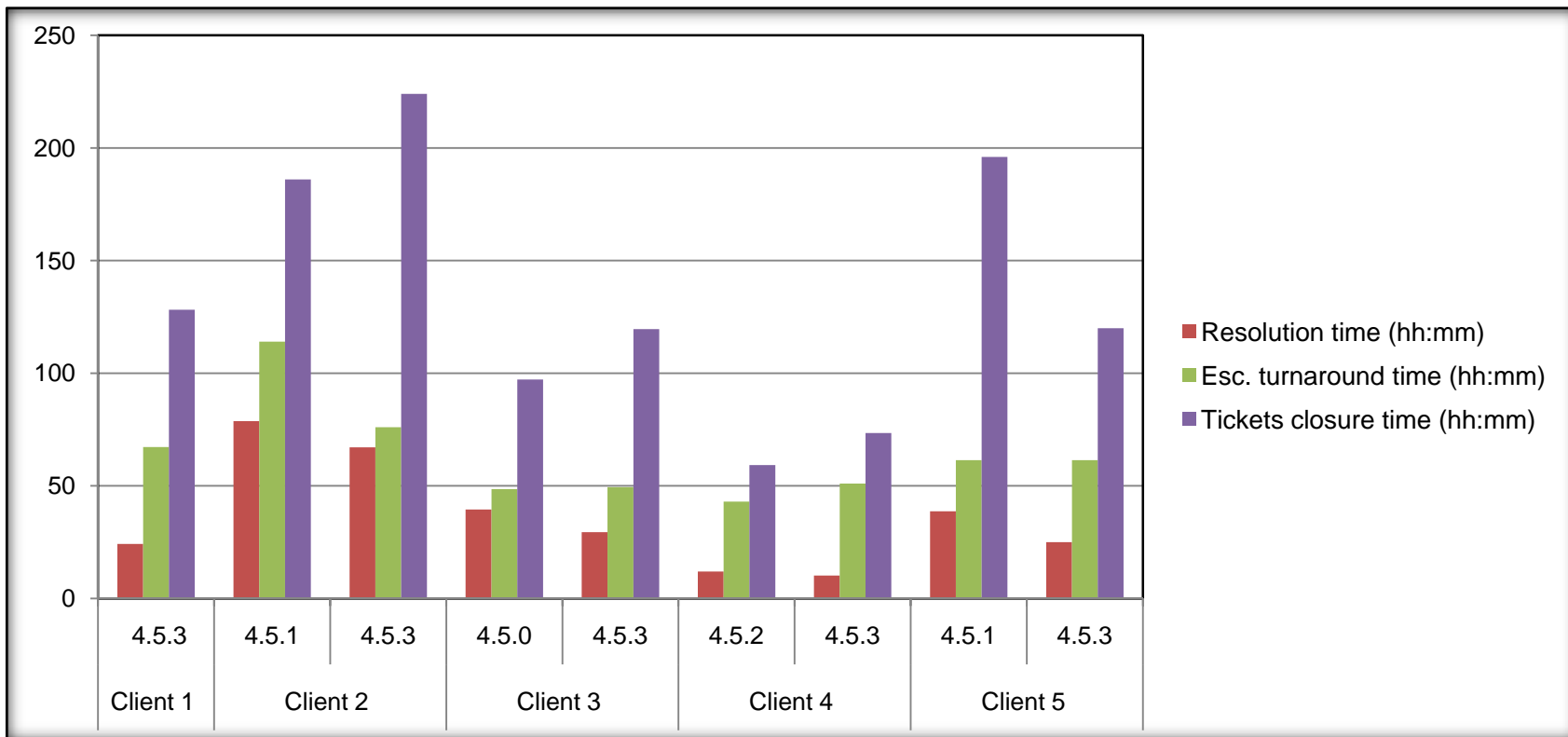
Note: E-mail Inbounds and Outbounds include communication with 3rd party due to procedure

Decrease on password resets and software issues from 4.5.0 to 4.5.3



Data for 4.5.2 is based on 229 users supported

Overall Decrease in Resolution & Escalations Turnaround Times



Resolution Time – the time needed to resolve an issue

Escalation Turnaround time – the time from the escalation to Tier 2 till the issue is resolved

Tickets Closure time – the resolution time + the time user confirmation is obtained

Note: Different processes drive longer resolution times for some clients. Client 5 doesn't track separately the OCRDC version of escalated cases

Similarities vs. Differences

OCRDC 4.5.3. vs. earlier versions

- **Differences:**

- **Interface and search are fundamentally different and require in-depth training**
- **Additional Software not required for newer versions**
- **Fewer System Requirements for the newer versions**
- **Lower Number of logins and Less password complications**

- » **Similarities:**

- **Processes and Functions of the system**
- **eCRFs concept**
- **User Account Creation process is the same**

Summary of the experience supporting RDC 4.5.3 vs. older versions

- » **Site Assessment process for 4.5.3 was much less cumbersome for investigator site personnel**
- » **Less help desk call volume during startup (in & out)**
 - No need to install plug-ins**
 - No need to install Citrix**
 - No need to deal with investigator staff lacking Administrator rights on their PC**
- » **Reduced need to provision laptops to sites**
- » **Training is still very critical**
 - For site satisfaction**
 - For keeping help desk call volume low after study startup**

Case study

LEO Pharma and its Oracle Environment

» Denmark-based pharmaceutical company

Operates globally

Experience with over 30 electronic and 230 paper studies

Over 300 active EDC sites in 20 countries primarily in Europe & North America:

- 18% in North America
- 82% in Europe

Over 900 OC RDC users: Project Managers, Clinical Research Associates (CRAs), Data Managers, Sponsor representatives, investigators, site coordinators, etc.

» Oracle clinical environment:

Oracle Clinical Remote Data Capture v4.5.3 (OC RDC) – used by LEO employees throughout DM, Clinical Operations, Global Patient Safety and site personnel

Currently both 4.5.2 and 4.5.3 are available

Coding is done using Oracle TMS



Case study

LEO Pharma's decision to use RDC 4.5.3

- **Why implement RDC 4.5.3**
 - Ease of implementation at site level
 - PDF versions of CRF's
- **DB admin consideration and challenges for RDC 4.5.2 vs. 4.5.3**
 - 4.5.2 Minor installation (Add-on)
 - 4.5.3 Full application server installation + some technical challenges. Requires more maintenance
- **Investigator Training considerations**
 - Different approached applied in various countries
- **Site participants feedback for the new version**
 - Ease of implementation is a benefit
 - Enhanced layout



Case study

LEO Pharma's Business Challenges

Business Challenges

Prior to 4.5.3:

Challenges installing 4.5.2 at site

Challenge getting CRF data in submission ready format

LEO based user support not feasible due to workload

After 4.5.3:

Still technical issues occur with respect to:

- Group approval
- Run-away processes
- Internet explorer 8

Patch implementation is pending and expected to resolve issues

C3i Solutions

C3i was awarded the role of full services vendor.

- User Administration – account creation, modification and de-activation
- RDC Technical support including general computer assistance in order to facilitate coordinators' and investigators' work related to the studies
- Unbinding
- Randomisation
- Study Close Out – data extract and CD distribution



Summary

» Business problem(s)

With any clinical study, ensuring that the study sites are well trained and equipped to handle the use of an RDC system is essential for the success of a trial.

» Solution(s)

The goal was to not only provide the necessary support for use of the RDC system but to also ensure that inexperience with computers did not hinder the progression of the study.

» Results

Provided the highest level of customer support, including general computer assistance as needed, to give the coordinator a comfort level with both the RDC system and the computer.

» Lessons Learned

LEO Pharma plans to introduce the drug into the market in the fourth quarter of 2009. This approval is directly related to the hard work and commitment of C3i to ensure that the sites were successful in their use of RDC



For additional questions or copies of presentation please contact:

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Anna Stoyanova is a Client Relations Manager supporting OCRDC along with other business-critical applications and processes associated with clinical trials. She has been an integral part of the C3i Clinical Support Services team for 3 years. In addition to providing live support for OCRDC 4.5.1 and 4.5.3, she has been instrumental in building internal knowledge bases, contributing to C3i's OC-RDC eLearning solutions, and developing/delivering ongoing training to C3i's internal personnel who support OC-RDC. She graduated with a major in Social Work, Bulgarian Language, and Literature. She is fluent in English, Bulgarian, and Italian.

Dave Hanaman

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Dave Hanaman is Co-Founder and Chief Sales & Marketing Officer of C3i, Inc. At C3i, Dave is responsible for sales, marketing, product development, and alliances. Additionally, Dave consults directly with many of C3i's blue-chip clients. Dave is experienced in a wide variety of subjects related to clinical support operations, focusing on the technology environment, performance improvement, and return on investment. A graduate of the University of California at Berkeley, Dave also served as an intelligence officer in the US Navy. A frequent lecturer, and prolific writer, Dave has developed and taught courses for universities, speaks at industry conferences, has written numerous articles, and is frequently quoted in the industry press.

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Morten Nielsen has been with LEO for five years and in current position one year. Previous experience in LEO relates to working primarily with IT implementations throughout the organization. Projects include labeling for clinical trial supplies, documentum based system for QA documents and the general upgrade to Windows Vista. Morten holds a M.Sc. Engineering from Technical University of Denmark.