

Are Site Assessments Antiquated for Clinical Trials Utilizing OC-RDC 4.5.3 or 4.6?



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Toronto, Ontario, CAN
October 2011

Overview

- » **Is your organization still using Site Assessments to determine if your study participants have the required hardware and connectivity while running OC-RDC 4.5.3 or 4.6?**
- » **Are Site Assessments are still necessary for Trials who are utilizing 4.5.3 or 4.6, and if so at what level of detail?**
- » **Quantitative data will be used to show how much time is spent on Site Assessments.**
- » **Some conclusions will be drawn about the need for Site Assessments based on best practices drawn from what is currently being used from Sponsors and CRO's.**

Definitions

- » **For the purpose of this presentation the following measurement and qualifications are being used**
- **Technical Site Assessment – The process to certify that a participating trial site has the necessary technical components to run Oracle Clinical – Remote Data Capture.**
 - **Zero Footprint – Meaning that additional software does not have to be loaded or maintained in order to run the system (4.5.3 or higher) from the end users perspective**

Executive Summary

- » **Technical Site Assessments are a time consuming process for all parties**
- » **Technical Site Assessments are still needed, even though versions 4.5.3 and higher are labeled as “Zero Footprint”**
- » **Most Organizations are using different site assessment questionnaires with different requirements**
- » **Some Organizations can simplify Technical Site Assessment Processes, which will in turn shorten the process and prepare the site for First Patient Visit quicker**
 - **Automated Site Assessment Survey**
 - **CRA’s Complete the Assessment onsite before the study begins**

The Customer and its Oracle Environment

- » **9 different Organizations Currently Supported**
 - 4 CRO's
 - 5 Sponsors
- » **How many on 4.5.3 vs. 4.6**
 - 5 of 9 on 4.53
 - 4 of 9 on 4.6
- » **How many were supported on systems less than 4.5.3?**
 - 2 of the organizations were on 4.5.1 while supported by C3i

Business Problem

- » **Site Assessments provided by C3i (Tier I) Technical Support are very time consuming.**
- » **Some of these Site Assessments are overly complex in nature.**
- » **Simplifying the process as much as possible using the benefits of 4.5.3/4.6 would greatly improve services**

Differences between (4.5.1 vs 4.5.3+)

- » **The main differences between OC/RDC in versions prior to 4.5.3 are the two configuration files.**
 - Oracle JInitiator
 - Oracle PDF Plugin
- » **These had to be installed and configured on the web client in order to access the system.**

Site Assessment Questionnaire Profile Post Upgrade

Site Assessment Questionnaire Profile										
Client Name	#1	#2	#3	#4	#5	#6	#7	#8	#9	Pct of Clients
Internet Browser	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	88.9%
Operating System	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	88.9%
Connectivity Speed Test?	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	88.9%
Memory	No	Yes	No	Yes	Yes	Yes	No	Yes	Yes	66.7%
Adobe Software	No	Yes	No	No	No	Yes	No	No	Yes	33.3%
Internet Toolbars?	No	No	Yes	No	No	No	No	No	No	11.1%
Latency	No	No	No	No	No	No	No	No	Yes	11.1%
CPU Speed	No	Yes	No	No	No	No	No	No	No	11.1%
Monitor Resolution	No	Yes	No	No	No	No	No	No	No	11.1%
Hard Drive Space	No	Yes	No	No	No	No	No	No	No	11.1%

» The similar questions being asked on most Site Assessments are:

- Internet Browser Version
- Operating System
- Connectivity Speed

» A lot of other questions are asked on various SA's, mainly due to performance concerns

Site Assessment Questionnaire Profile Pre Upgrade

Site Assessment Questionnaire Profile (Pre-Upgrade)			
Client Name	#1	#7	Pct of Clients
Internet Browser	Yes	Yes	100.0%
Operating System	Yes	Yes	100.0%
Connectivity Speed Test?	Yes	Yes	100.0%
Memory	Yes	Yes	100.0%
Latency	Yes	No	50.0%
CPU Speed	Yes	No	50.0%
Hard Drive Space	Yes	No	50.0%
Internet Toolbars?	No	No	0.0%
Adobe Software	No	No	0.0%
Monitor Resolution	No	No	0.0%

» **Both Clients had more complex Site Assessments prior to the upgrade to versions 4.5.3**

Site Assessment Complexity by Client

Site Assessment Questionnaire Profile					
Client Name	# of Questions	# of Pages	Delivery Method	Time to complete	Complexity Level
Client # 1	14	2	Attached Email	8-10 Mins	Easy
Client # 2	16	7	Attached Email	30-45 Mins	Hard
Client # 3	8	4	Attached Email	15-20 Min	Med
Client # 4	8	1	Attached Email	5-7 Mins	Easy
Client # 5	7	1	Attached Email	5-7 Mins	Easy
Client # 6	11	2	Attached Email	6-8 Mins	Easy
Client # 7	0	0	CRA's Complete	NA	None
Client # 8	7	1	Attached Email	5-7 Mins	Easy
Client # 9	8	1	Automated Survey	3 Mins	Easy

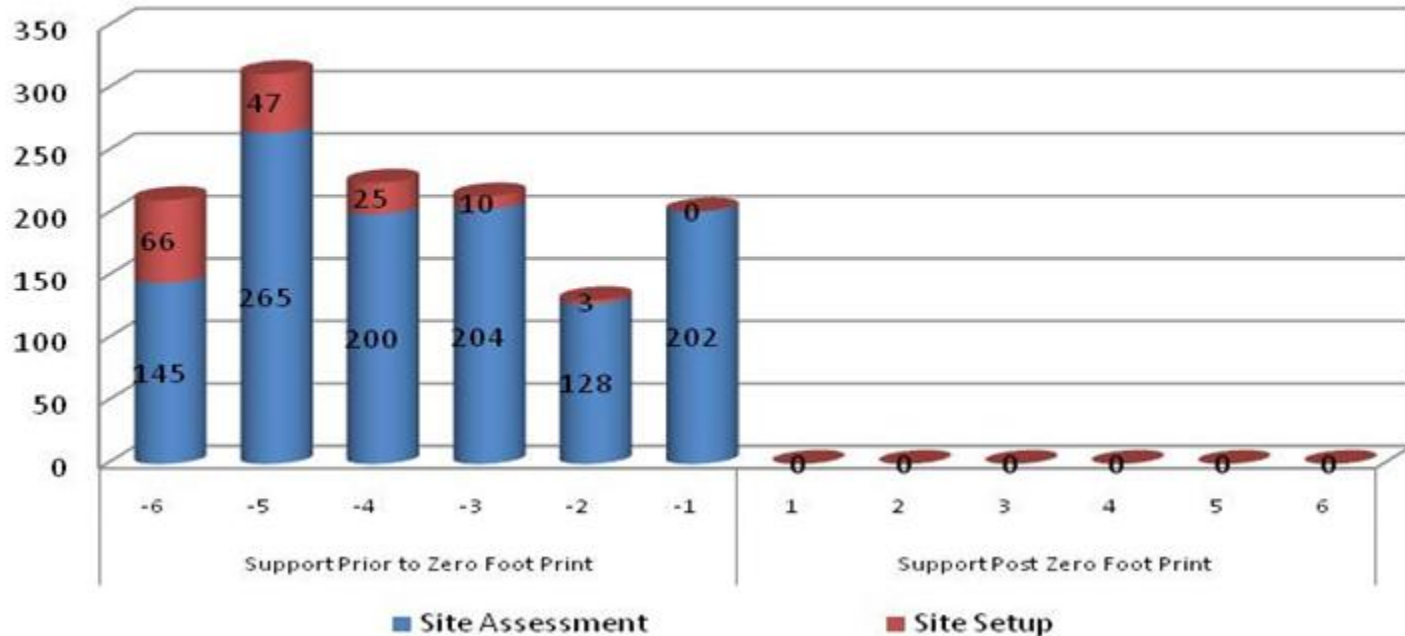
- » **Site Assessment Procedures vary tremendously in each organization**
- » **Some require tests throughout the day and the installation of software**
- » **Others are easy, automated through a survey which grabs information from the users computer**

A Closer Look – No Technical Site Assessment

- » **One of our Clients has decided a “No Technical Site Assessment” Approach**
- » **Sites will be responsible to guarantee the availability of internet access and of a computer for data entry**
- » **Minimum hardware, software and internet connection requirements will be communicated to the sites during the pre-study visit**
- » **Site monitors will verify site staff access to the internet and RDC On-Site during the PSEV**
- » **6 countries remain on an automatic provisioning list:**
 - **China, India, Mexico, Russia, Turkey, and Ukraine**
- » **Staff in those countries continue to assess each site's technology capabilities, encourage self-provisioning, and only provision when that isn't possible**

A Closer Look – No Technical Site Assessment

Site Assessment & Site Readiness Verification Cases
(6month prior & post 4.5.3 Implementation)



- » Allows for early look at technology capability of sites; discussion at site selection.

A Closer Look – Automated Survey

The below information is needed to determine if the current equipment at site meets the requirements to participate in the RDC trial OC

	Answer	Comment
1. Do you have a computer you can use for the purpose of this RDC trial?	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
1.1. Has your site received a laptop for another RDC trial that you can use for the purpose of this trial? If yes, please provide the most recent RDC protocol number (e.g., CAB123A1234)	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
2. Does the computer at the site meet the RDC Onsite (HTML) minimum system requirements below?		
2.1. Client Browser: Internet Explorer 6 or higher. Older versions of Internet Explorer as well as other browsers such as Opera or Mozilla Firefox have not been formally certified by Oracle at this time.		Internet Explorer 7
2.2. Operating System: Windows 2000 Pro SP 4; Windows 2003 Server R2 SP2; Windows XP Pro 2002 SP 1, 2 & 3; Vista; Windows 7.		Windows XP
2.3. RAM: Does your computer have RAM memory of at least 512MB?	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="text"/>
3. For optimum RDC response times, a minimum bandwidth of 512 Kbps and a maximum latency of 100 ms is recommended.		
3.1. Bandwidth [test] (e.g. 640 Kbps, 2.3 Mbps)		<input type="text"/>
3.2. Latency		Host is unreachable
4. Does your computer have Adobe Acrobat Reader installed? If yes, which version?	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="text"/>

- » Sent as a link via email
- » Some info. obtained via automated back end process
- » Takes just a few minutes to complete and submit
- » No need to print/fax records
- » Once submitted, e-mail is sent to Technical Service Desk with answers to process

Site Assessment Turnaround Time Per Client

Site Assessment Duration				
Client Name	Delivery Method	Complexity Level	Avg # of Site Assessments per Month	Avg Turnaround Time (Days)
Client # 1	Attached Email	Easy	31	7
Client # 2	Attached Email	Hard	150	40
Client # 3	Attached Email	Med	3	1.8
Client # 4	Attached Email	Easy	106	1
Client # 5	Attached Email	Easy	10	11
Client # 6	Attached Email	Easy	25	7
Client # 7	CRA's Complete	None	0	0
Client # 8	Attached Email	Easy	5	10
Client # 9	Attached Email	Med	150	18
Client # 9	Automated Survey	Easy	TBD	TBD

- » **Site Assessments on average are taking about 7-10 days to complete**
- » **Data from Automated Survey Process still in process of collection, but process should take considerably less time than Attached E-mail method**

Recommendations

- » **Although Site assessments are still needed for versions 4.5.3+, a much slimmer/paired down version should be employed**
- » **Rather than Sending out complex site assessments with multiple pages and instructions, a simple automated site assessment is easier on both the end user and the administering support desk.**
- » **The time saved on each site assessment provides an excellent return on investment for the organization using it.**

Summary

- » **When Oracle moved to 4.5.3, they were able to label it “Zero Footprint” due to removing the need for the end user to load a PDF plug-in and JInitiator.**
- » **Although it is labeled “Zero Footprint” there are still some considerations such as Internet Browser, and Operating System**
- » **The Technical Site Assessment process should be easy for the end user to complete and the Technical Support Desk to Process**
- » **An Automated Survey is a recommended way to complete the Site Assessment process, as it is easy for the end user, and the Technical Support Desk to process**

Presenter's Bios

- » **Tom Staada is an Account Director at C3i, Inc. At C3i, Tom manages the day-to-day relationship between a large CRO and the C3i Support Desk. Tom has over 7 years of Operations experience, including over 5 years in clinical support operations. Tom has presented at OHSUG in 2009 and 2010. Tom is experienced in a wide array of support related areas such as forecasting, knowledge base development, call avoidance and software upgrades just to name a few. Tom graduated from the University of Delaware where he received his Bachelors of Science in Health and Exercise Science.**

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