

Important Considerations when choosing an OC RDC Helpdesk Provider



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Clinical Support Scale



Help Desk Highlights

- **7 x 24 x 365 support**
- **20 + languages available**
- **140 + countries**
- **7,000 + trials supported**
- **178,000 + sites supported**
- **600,000 + end users**
- **4 million + service interactions per year**

The OC RDC Clients Portfolio

- » **Clients vary from small to large Pharmaceutical companies, consulting companies to Global CROs**
 - **Experience with electronic, hybrid and paper studies**
 - **Oracle Clinical applications:**
 - Oracle Clinical Remote Data Capture (OC RDC) v 4.5.3
 - Oracle Clinical Remote Data Capture (OC RDC) v 4.6
 - used by Client employees, Sponsors, CROs and site personnel
- » **Tier 1 and Tier 2 support for various complexity levels of issues**
- » **Support provided to Site Coordinators, Investigators, Site Monitors, Data Managers and Sponsor Reviewers**
- » **Large variety of Therapeutic areas (Cardiology, Endocrinology, Gastrointestinal, Hematology, Immunology, Neurology, Oncology, Ophthalmology, Orthopedic, Psychology, Psychiatric disorders, Respiratory, Women's Health)**
- » **Studies from Phase 1 to Phase 4**

Help Desk Performance and Supported languages

» Service Level Agreement rates:

- **Customer Satisfaction Rate:** > 90%
- **Call Abandon Rate:** < 8%
- **% Calls Answered < 45 seconds:** > 90%
- **Complexity level 1 issues resolved under 1 hour:** > 90%

» Multilingual support: Supported languages

- **English and Bulgarian** 24/7
- **Spanish** – European and Latin American Business Hours
- **Italian, German, French, Dutch and Danish** – European Business Hours
- **Romanian, Polish, Czech and Slovakian** – East European Business Hours
- **Russian**
- **Mandarin, Korean and Japanese** in extended local business hours

Help Desk Processes to ensure Quality: Optimizing Customer Satisfaction

» Detailed quality management processes that help increase customer satisfaction:

- **Training** – the technicians need complex training on technology, clinical business, GCPs
- **Mock Calls** – the New Hire Training includes handling and documenting mock help desk cases
- **Quality Assurance** – Trainers review the quality of the interactions handled
- **Customer Satisfaction survey process** – End users have the word on Helpdesk Quality
- **Dissatisfied Customers follow up process** – any comment or negative Survey is reviewed for the root cause and the dissatisfaction reason is investigated
- **Complaint Management Process**- single point of contact (DL including both client and helpdesk management) with supervisory monitoring function. Periodic analysis on cases is reported

Help Desk Processes to ensure Quality: Reporting/Analytics

Reporting and Analysis is a cornerstone for all business processes as it provides the input for making informed decisions. It varies from monitoring Service Levels metrics such as Average Speed of Answer, Customer Satisfaction, First Contact Resolution, Ticket Volumes to individual quality and quantity agent performance. Main challenges are related to data integrity, continuity, storage.

» **Streaming / collecting data from multiple sources and storing into a single Data Warehouse, readily available for:**

- **daily reporting purposes by making use of a set of pre-defined reports covering every aspect of operations**
- **ad-hoc analysis by utilizing business intelligence reporting tools**

» **Accessibility and visibility of data in real time for day-to-day work**

» **Comprehensive report development for client specific contractually defined purposes**

Help Desk Processes to ensure Quality: Adding Value with Integrated Tier 1 and 2 Support

Cost Reduction on Integrated Services

- Integrating Tier 1 and Tier 2 services on the same vendor leads directly to cost reduction on the Support Delivery Service
- Relocation of Tier 2 Support Delivery to Cost-Saving location, while ensuring enhancement of Delivery Quality on both Tier 1 and Tier 2 layers of Support by mutual cooperation and interaction

Increased End-User Satisfaction

- By increasing the knowledge base on the integrated Tier 1 and Tier 2 Delivery structure, assurance on:
 - Transparency on Issue Resolution with Site Personnel
 - Clearly defined Prioritization Strategy, focused on Business Strategy
 - Highly experienced and educated personnel providing personalized support

Decreased Issue Turnaround Time

- By applying the market's Best Practices and following Extensive Training on the account's specifics, the integration of Tier 1 and Tier 2 has considerable reduction on Issue Resolution, while ensuring the constant and steady growth on Customer Satisfaction

Periodical Adaptive Reporting

- By Outsourcing Tier 1 and Tier 2 Support Delivery structure there is a guarantee on the continuation and improvement of Visibility towards the Day-to-Day of the Operations, including increased detailed communication on Risk Issues, Volume Metrics and Customer Satisfaction Reports.

Help Desk Services provided

Important to have:

- » **Hosting OC RDC and Building OC RDC studies**
- » **Integrated Tier 1 and 2 support**
- » **eLearning OC RDC**
 - **Modules for individual online training**
- » **User Account Management**
 - **Account creation/ deactivation/ modification requests**
 - **Locked accounts & password reset**
- » **OC RDC Technical Support**
- » **Multilingual support**
 - **European and Asian languages**
 - **Monitoring of the customers' needs and adding new languages**
- » **Study Close Out**

Good to have:

- » **Patient Unblinding and Randomization**
- » **Site Assessment**
 - **Computer and connectivity assessment**
- » **Provisioning**
 - **Hardware and Internet connectivity**
- » **Other support services:**
 - » **Study Dedicated Portal Support**
 - » **IVRS**
 - » **CTMS**

Help Desk Services: eLearning modules on OC RDC

Challenges:	Solutions:
<i>Develop Validated eLearning modules</i>	System Validation: <ul style="list-style-type: none">- the system was developed and tested according to the Client approved URDs- Test summary reports provided based on test cases and the results of them
<i>Develop Generic content - to be able to use it for many studies</i>	For every new study the PM team is advised to review the modules content in order to confirm all is Protocol compliant
<i>Prove of Training needed for audit purposes</i>	Training Certificate developed and implemented
<i>eLearning modules created for Site Users Roles only</i>	Adding additional roles for Reviewer, Sponsor, CRA due to internal demand
<i>Site participants already have knowledge on the RDC application</i>	CRAs confirm training is completed for other Study/Sponsor by signing a form; Quick Reference Guide was developed for quick user tips

Help Desk Services: User Account Management

Process includes account creation/ deactivation/ modification requests

Challenges:	Solutions:
<i>Clinical world demands accuracy in this process</i>	All account creations/modifications are quality checked by specially trained technician
<i>Insufficient information provided by the requestor results in the need for time-consuming follow ups before an account can be created/modified</i>	Account registration page implemented with all the necessary information as required. Account Modification Template implemented for all Modification requests
<i>Help Desk is not always informed about site users leaving the study team in order to deactivate access</i>	Regular updates from Clinical PM regarding approved site users and people no longer participating
<i>Requests from sites to lock/create accounts often coming as bulk requests without heads up in advance and with urgency</i>	Communication and regular updates and heads up about upcoming bulk requests

Help Desk Services: OCRDC Technical Support

Challenges:	Solutions:
<p><i>High-quality support of OC RDC is essential and requires:</i></p> <p><i>1. Good knowledge on:</i></p> <ul style="list-style-type: none"> ➤ <i>clinical practices – security, patients privacy</i> ➤ <i>Technical requirements</i> ➤ <i>OC RDC navigation, functions, search capabilities</i> <p><i>2. Ability to react adequately to study specific issues which might increase call volume:</i></p> <ul style="list-style-type: none"> • <i>Study specific features</i> • <i>Study start-up</i> • <i>Database lock and other deadlines</i> 	<p>Continual training on the Client's OC RDC application</p> <ul style="list-style-type: none"> ➤ Extensive New Hire training on Clinical and GCP specifics ➤ Training accounts with CRA, INV and SITE privileges created for the Help Desk in order to practice and replicate issues ➤ Browse access to all studies in OC RDC ➤ Advance notice of important events in the study calendar
<p><i>Help Desk level of access not enough in order to support users effectively</i></p>	<p>Desktop sharing in place in order to improve turnaround time or issue resolution</p>
<p><i>Effective communication between the different Tiers of support (C3i-Client)</i></p>	<p>Regular knowledge calls between Tier 1 and Tier 2 (C3i and Client) to speed up the resolution of issues</p>

Help Desk Services: Study Close Out

Study Close Out: Process of extracting PDRs for closed studies and shipment of CD with this data to sites and Data managers

Challenges:	Solutions:
<p><i>Sites do not confirm the CD is received and data is correct</i></p> <p><i>Help Desk is referred from one person to another until the right person is able to provide confirmation</i></p>	<p>Help Desk to be provided in advance with main point of contact for CD confirmation at Site</p> <p>Study teams/Monitors got involved in the Study Close Out process as escalation point</p>
<p><i>Multilingual communication: Inability to communicate with some of the site users</i></p>	<p>Multilingual support needs to be contracted by the end of the Study Close out activities</p>
<p><i>Minimize Site Interactions</i></p>	<p>Ensure shipping address is confirmed when requesting a closeout to avoid delays afterwards</p>

Help Desk Services: Multilingual and Staffing Challenges and Solutions

Challenges:	Solutions:
<i>Hiring multilingual technicians</i>	Ensure the necessary level of language skills in partnership with professional language experts
<i>Common volume fluctuations create staffing surplus/deficiencies that change month over month</i>	<ul style="list-style-type: none">- Keep a number of employees cross-trained on several clients and use them when/where needed- Identify generic processes across the different clients that can be serviced by a single team- Recruit and train “on demand” employees- Keep a number of Part Time employees and use them Full Time when needed
<i>Low volume, multiple languages supported per clients</i>	Shared model of support
<i>Ramp-up of new employees to full production mode takes time</i>	<ul style="list-style-type: none">- High quality training plans and materials- Solid Knowledge Management process speeds up the ramp-up time- Good recruitment process ensuring the right level of proficiency- Dedicated Account Trainers

In Summary: Help Desk Advantages

For OC RDC end users:

- » 1 place support solution for several Clinical trial processes
- » 24/7 support, Multilingual services
- » Time and resource saving: clinical teams can focus on study specific issues

For the CRO or Sponsor:

- » Hosting OC RDC and building studies allow focusing on the trial specifics
- » Adds value to the services provided to their clients
- » Time and resource saving:
 - lowers overall support costs
 - client's technical support teams can focus on higher level issues
- » Customized clinical call tracking system:
 - regulatory auditing
 - classification and prioritization of issues
- » Standardized customer service

Contact information

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Anna Stoyanova is a Client Manager for OCRDC clients. The helpdesk teams that she coordinates support 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 5 years. In addition to providing live support for OCRDC, she has been instrumental in building internal knowledge bases, contributing to C3i's OCRDC eLearning solutions, and developing ongoing training to C3i's internal personnel who support OCRDC. She is a main point of contact for Clinical Study Managers for any Helpdesk procedural questions. She graduated with a major in Social Work, Bulgarian Language and Literature. She is fluent in English, Bulgarian, and Italian.