

ORACLE HEALTH SCIENCES OUTCOMELOGIX ON DEMAND

COMPLETE LATE-PHASE AND
DIRECT-TO-PATIENT DATA
COLLECTION

KEY BENEFITS

FOR SPONSORS

- Scales to a large number of sites and patients. OLX 3.0 has been performance tested with 200,000 patients
- Configurable user experience
- Comprehensive patient/visit completion status
- Enables simple and complex research
- Supports global, multilingual studies
- Improves data quality (21 CFR Part 11)
- Enables real-time reporting and earlier access to safety data

FOR PATIENTS AND SITES

- Intuitive self-enrollment
- Fast, easy, convenient data entry
- At-a-glance data review
- Comprehensive query management
- Online training and support

Oracle Health Sciences OutcomeLogix On Demand is the only scalable, complete solution for late-phase and direct-to-patient data collection

Scalability Ensures Study Success

Late phase studies capture large amounts of data and can go on for decades. As the requirements of post approval programs continue to expand globally, the types and amount of data continue to grow. The data that is collected fuels required regulatory safety reporting as well as meeting the needs of outcomes researchers and medical affairs groups. It is critical to have the reliability and security of Oracle.

Oracle Health Sciences OutcomeLogix On Demand is built to meet the scalability demands of late phase studies. Tested with hundreds of thousands of patient records, the Oracle Health Sciences Cloud can reliably collect large amounts of data for decades.

Ease of Use Improves Data Quality

Mandates for increased post-approval surveillance and the need for observational and health outcomes require that quality data be gathered from physicians and other healthcare providers as well as directly from the patient. The use of traditional EDC systems in late phase research is costly due to additional training and management of users who are inexperienced with data entry.

Oracle Health Sciences OutcomeLogix On Demand uses a patient-centered approach for the design of late phase and direct-to-patient data collection programs. It is so easy to use that patients, physicians, family members, care providers and others can easily contribute critical information without specialized hardware or heavy training requirements.

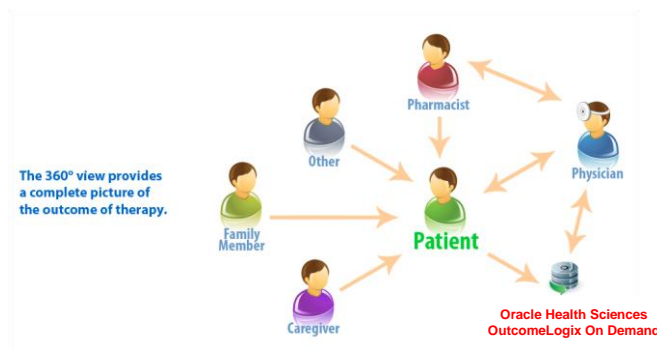


Figure 1. The flexible, Web-based architecture of Oracle Health Sciences OutcomeLogix On Demand makes it easy to deploy to large numbers of sites and patients.

With a common Web browser Oracle Health Sciences OutcomeLogix On Demand provides a user-friendly and familiar interface for data entry. Walking users step-by-step through the data collection process, the solution can deliver a complete picture of a patient's health status. Data may be collected on behalf of a patient in diverse settings such as traditional hospitals, community clinics, or homes. Built in alerts and reminders encourage patients to remain engaged even when life changing events occur, promoting more effective adherence and compliance. For example, when patients move or health plans change, data collection continues even though the enrolling physician may no longer be involved.

Configurable, Simple Interface Connects Patients to Your Brand

You invest heavily in your brand. Every interaction physicians, patients and others have with the brand represents an opportunity for you to communicate value along with important safety and usage information.

Oracle Health Sciences OutcomeLogix On Demand enables you to offer a completely branded experience to anyone entering information. The result is that you can provide a consistent look and feel across your brand that simplifies data input and enables you to understand how patient flows through normal treatment cycles and follows standard of care advice.

The intuitive user interface enables you to manage simple and complex research by accommodating everything from basic questionnaires to sophisticated quality of life data.

The screenshot displays a web-based questionnaire interface. At the top, there is a navigation bar with the 'antea' logo and links for 'Home', 'Edit Profile', 'Help', and 'Logout'. Below the navigation bar, the title of the questionnaire is 'Dreaming and Overall Sleep Quality'. The questionnaire consists of four numbered questions, each with radio button options for 'Yes' and 'No':

1. Do you recall dreaming at any point during the night? (Yes/No)
2. Were you dreaming just before you woke up for the final time? (Yes/No)
3. Do you recall having a frightening or unpleasant dream at any point during the night? (Yes/No)
4. Did you sleep well last night? (Yes/No)

Below the questions, there is a scale for rating overall sleep quality: 'Please rate your overall sleep quality last night by clicking on the scale.' The scale is a horizontal line with 'Very bad' on the left and 'Very good' on the right, with a vertical tick mark in the middle. A 'Submit' button is located at the bottom right of the form.

Figure 2. A user-friendly interface facilitates data entry for patients and physicians. Tested to scale to hundreds of thousands you can rest assured your data will be safe for decades to come.

Multi-Lingual Data Capture Supports Your Global Needs

Therapies are marketed globally providing opportunities and challenges for long term safety surveillance. To be compliant, you need to work across geographical and cultural borders and one of the biggest hurdles is language.

Now your post-approval studies can utilize one data collection system across geographical and cultural borders. This means you can cut costs and improve consistency in how you work with your affiliates. By collecting, managing and analyzing data with Oracle Health Sciences OutcomeLogix On Demand your team sets up the study once, goes to a single application to review information and has a consistent framework for managing business intelligence.

Comprehensive, Web-Based Solution Lowers Costs, Improves Data

Sponsors and CROs must collect data in multiple languages from diverse locations across the globe. It is critical that the data collection be available on the devices patients, physicians, family members and others know and use in everyday life. Once collected, the data must be accessible and usable across organizational boundaries to a variety of roles within the organization that need to take action based on what is collected.

From patient recruitment and enrollment through conduct to database close, Oracle Health Sciences OutcomeLogix On Demand is a complete solution. Its flexible, Web-based architecture simplifies deployment. Stress tested to reliably support hundreds of thousands of patient records, the system easily handles large numbers of sites and patients.

The Oracle Health Sciences Cloud facilitates quick, simple deployment and requires no dedicated hardware. Without the initial and ongoing maintenance costs of hardware - which are particularly burdensome in large scale studies with substantial patient populations – Sponsors and CROs reduce the overhead traditionally associated with post-approval research and direct-to-patient data collection.

Contact Us

For more information about Oracle Health Sciences OutcomeLogix On Demand, visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.



Oracle is committed to developing practices and products that help protect the environment

Copyright © 2011, Oracle and/or its affiliates. All rights reserved.

This document is provided for information purposes only and the contents hereof are subject to change without notice. This document is not warranted to be error-free, nor subject to any other warranties or conditions, whether expressed orally or implied in law, including implied warranties and conditions of merchantability or fitness for a particular purpose. We specifically disclaim any liability with respect to this document and no contractual obligations are formed either directly or indirectly by this document. This document may not be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without our prior written permission. 1011

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Hardware and Software, Engineered to Work Together