

# Predictive Enrollment Planning for Clinical Protocols

February, 2025, Version [1.0] Copyright © 2025, Oracle and/or its affiliates Public



# **Purpose statement**

This document has been created by the Siebel Center of Excellence team for informational purposes only. It aims to provide valuable insights and guidance on the subject matter while serving as a reference for stakeholders. This document does not constitute a binding agreement or official policy.

#### **Disclaimer**

This document in any form, software or printed matter, contains proprietary information that is the exclusive property of Oracle. Your access to and use of this confidential material is subject to the terms and conditions of your Oracle software license and service agreement, which has been executed and with which you agree to comply. This document and information contained herein may not be disclosed, copied, reproduced or distributed to anyone outside Oracle without prior written consent of Oracle. This document is not part of your license agreement nor can it be incorporated into any contractual agreement with Oracle or its subsidiaries or affiliates.

This document is for informational purposes only and is intended solely to assist you in planning for the implementation and upgrade of the product features described. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, timing, and pricing of any features or functionality described in this document remains at the sole discretion of Oracle. Due to the nature of the product architecture, it may not be possible to safely include all features described in this document without risking significant destabilization of the code.



# **Summary**

As organizations aim to enhance Clinical Protocols planning and execution, providing a streamlined approach to protocol management becomes essential. When Clinical Research Associates (CRAs) plan new protocols for a specific program, leveraging insights from an enrollment prediction model can greatly improve accuracy and efficiency. By integrating an interactive Oracle Digital Assistant, CRAs can engage in guided conversations to refine protocol details and make data-driven decisions. At the end of the interaction, the assistant automatically updates the protocol records, ensuring seamless integration and reducing manual effort. This innovative approach not only highlights the effective use of AI in clinical trial planning but also improves productivity and ensures accurate, upto-date protocol documentation.

### **Overview**

In Siebel CTMS, creating and managing protocols can be time-consuming and prone to inefficiencies. When CRAs need to plan new protocols, manual efforts often lead to increased costs and delays. Introducing an automated system for enrollment prediction and Al-driven protocol planning can greatly enhance accuracy and efficiency. The Al insights provides the Enrollment prediction insights when provided with details of the Protocol record values. For example, when a Clinical Research Associate (CRA) plans a new protocol for an existing program, the system uses an advanced ML Prediction model to provide data-driven insights to predict Subjects turnouts given the protocol record values like # of sites, Subjects, Disease, etc. These predictions are delivered via an interactive Oracle Digital Assistant, allowing CRAs to explore enrollment scenarios, optimize site selection, and refine protocol parameters. At the end of the interaction, the system automatically updates protocol records, ensuring a seamless workflow with minimal manual intervention.

A practical use case is seen in large-scale clinical trials. When designing a protocol, the system analyzes historical enrollment data and site performance, generating actionable insights that reduce costs and improve trial outcomes. These recommendations help CRAs make informed decisions, resulting in better resource allocation and higher protocol success rates.

By automating enrollment predictions and integrating Al-driven insights, this solution enhances productivity, ensures consistency in protocol planning, and improves overall trial efficiency.

# Challenge: Optimizing Protocol Planning with Accurate Enrollment Predictions

Protocol planning presents several challenges, such as subject turnover, inaccurate enrollment predictions, and site variability. High dropout rates and unexpected delays in recruiting eligible participants can lead to prolonged timelines and increased costs. An interactive chatbot, powered by Oracle Digital Assistant (ODA), addresses these issues by gathering protocol information through a user-friendly chat interface and delivering Al-driven enrollment predictions. This approach enhances planning accuracy, optimizes resource allocation, and mitigates common protocol-related challenges.



# **Collecting Protocol Information via ODA Widget**

The ODA widget is seamlessly embedded within the Siebel CTMS, enabling CRAs to interact with it directly. The chatbot collects all the necessary information required by the machine learning model for enrollment prediction. Inputs are gathered through an interactive UI featuring buttons, date pickers, and other user-friendly elements, ensuring a streamlined data collection process.

## **Delivering AI Insights and Automating Protocol Updates**

When a CRA selects a protocol record from the list and navigates to the protocol detail page, the ODA triggers a popup, offering assistance. The CRA engages with the chatbot to receive Al-driven insights on enrollment predictions. After reviewing these insights, the CRA confirms whether the protocol should be updated. The ODA then automatically applies the updates to the protocol, eliminating manual intervention and enhancing efficiency.

#### **Benefits**

- **Enhanced Protocol Accuracy:** By using Al-driven enrollment predictions, the system ensures more accurate planning and resource allocation, reducing the risk of protocol delays and cost overruns.
- Improved Decision-Making: All insights provided by the ODA assist CRAs in making better-informed decisions, ultimately optimizing enrollment strategies and increasing the likelihood of protocol success.
- Automated Protocol Updates: The ODA automates the protocol update process, saving CRAs valuable time and effort while ensuring that protocol records are always up to date with minimal manual intervention.
- Streamlined Data Collection: The interactive ODA widget simplifies the process of gathering protocol
  information, making it quicker and more efficient for CRAs to input the necessary data through a userfriendly interface

#### Conclusion

By integrating Oracle Digital Assistant (ODA) and Al-powered insights into the protocol planning process, organizations can significantly enhance the efficiency and accuracy of clinical trial planning. The seamless interaction between the CRA and the ODA widget streamlines data collection, improves decision-making with Aldriven predictions, and automates protocol updates. This innovative approach not only saves time and reduces costs but also increases the likelihood of successful trials, ensuring more effective and timely protocol execution.



#### Connect with us

Call +1.800.ORACLE1 or visit oracle.com. Outside North America, find your local office at: oracle.com/contact.

**B** blogs.oracle.com

facebook.com/oracle

twitter.com/oracle

Copyright © 2025, Oracle and/or its affiliates. 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.

 $Oracle, Java, MySQL, and \ Net Suite \ are registered \ trademarks of \ Oracle \ and/or \ its \ affiliates. \ Other \ names \ may \ be \ trademarks of \ their \ respective \ owners.$ 

5 Predictive Enrollment Planning for Clinical Protocols / Version [1.0] Copyright © 2025, Oracle and/or its affiliates / Public