

# Recipe - Predictive Enrollment Planning for Clinical Protocols

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## Executive 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, up-to-date protocol documentation.

## Introduction

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 AI-driven protocol planning can greatly enhance accuracy and efficiency. The AI 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.

## Challenge: Optimizing Protocol Planning with Accurate Enrollment Predictions

- High dropout rates and unexpected recruitment delays prolong timelines and increase costs.
- Inaccurate enrollment predictions and site variability impact planning and resource allocation.
- A user-friendly chatbot powered by Oracle Digital Assistant (ODA) simplifies protocol information gathering.
- AI-driven enrollment predictions enhance planning accuracy and optimize resource use.
- Common protocol challenges, including delays and variability, are mitigated through predictive insights.

## Workflow Overview

- CRA selects a Protocol record from Siebel CTMS UI.
- A notification is received from Embedded ODA widget.
- User provides details for new enrollment by interacting with ODA.
- ODA calls Enrollment prediction model and provides decision insights to CRA.
- CRA confirms the new details and the Protocol record gets updated with new values.

## Key Technologies Involved

item	Description
ODA	A ODA widget is embedded in the Siebel CTMS UI for interaction between ODA skill created to handle User interactions and CRA
ODA Custom Component	Custom Component created in ODA to invoke and Pre-Process Clinical Protocol API response and invoking Enrollment Prediction Model and Update Protocol Record

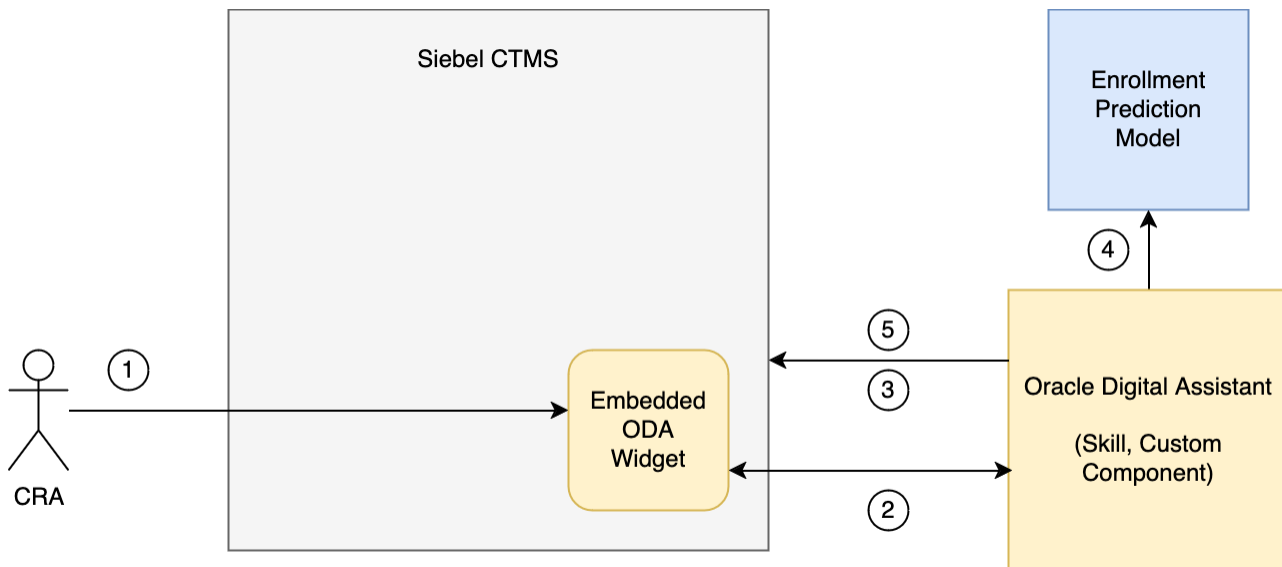
Enrollment Prediction Model	A machine learning model for providing Enrollment AI insights and Enrollment probabilities
CTMS UI Customization	Siebel Open UI PR file for UI Customizations

## Implementation Strategy

The implementation of this flow involves

- Designing ODA Skill flow
- ODA Custom Component to Call Clinical Protocol REST APIs, Pre-Process the response, Call Enrollment Prediction Model
- Embedding the ODA Widget
- Siebel CTMS Open UI Customisations

## Architecture Diagram



1. CRA opens the ODA Widget window after selecting a Protocol record (ODA Sends a Notification).
2. ODA connects to the ODA Skill via the Channel ID and Skill ID configured.
3. ODA Custom Component calls the Clinical Protocols REST API to get the details for current protocol program
4. ODA Custom Component calls Enrollment Prediction Model to get the Prediction results
5. After confirmation from the CRA the ODA Updates the Protocol record with new values.

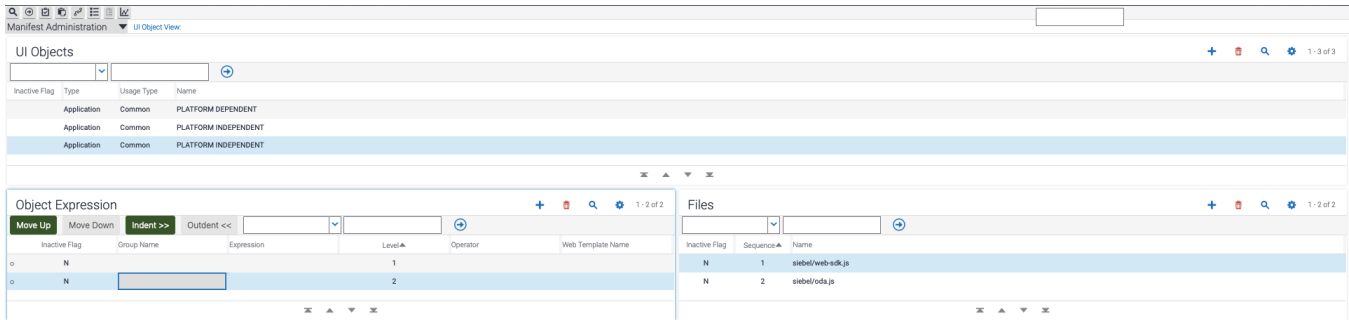
## Siebel Customisations

Leveraging Siebel Open UI, a Physical Renderer File is used to Embed the ODA Widget in Siebel CTMS UI and make it available in all the Views for the CRA to interact. Following functionalities are achieved

1. ODA Widget Embedding.
2. Collecting User information (Name) and Current Selected Protocol Row ID to be passed to ODA.
3. Some fields are given fading Highlighting effect when Protocol record is updated with new values.
4. Entry of the ODA Web SDK file and PR file in the Manifest administration and Manifest Files.
5. Styling changes in ODA Widget UI (Buttons, Color Branding, Date Picker)

## Configuring PR File and ODA Web SDK

1. Place the below ODA Web SDK and PR file inside SAI Container in location: [sai-ENT:/siebel/mde/applicationcontainer/siebelwebroot/scripts/siebel-oda.js](#) OR Download latest from <https://www.oracle.com/downloads/cloud/amce-downloads.html>
2. Add the file entries in Manifest Files and Manifest Administration of type: Application, Usage Type: Common, Name: PLATFORM INDEPENDENT.



## ODA Configurations

ODA Skills and Custom component responsible for interacting with the User as well as the Prediction Model

### ODA Skill

Import the below ODA Skill in an ODA instance and intake the necessary changes required which includes and not limited to

[https://securefiles.oracle.com/documents/link/LDE1D9EC3BC7D36518AACBBB58DE669FAB8BCB883E43/fileview/D09FBAA0C168540C8706244679FC898B5ABC78C53078/\\_CTMSSkill.zip](https://securefiles.oracle.com/documents/link/LDE1D9EC3BC7D36518AACBBB58DE669FAB8BCB883E43/fileview/D09FBAA0C168540C8706244679FC898B5ABC78C53078/_CTMSSkill.zip)

1. Changing the ODA Skill Flow as per requirement.
2. Updating the Custom component with new Clinical Protocol REST Endpoint, Prediction Model REST Endpoint.

### Clinical Protocol REST API

Please enable Inbound REST Access to Clinical Protocol

```
https://<siebelhost:port>/siebel/v1.0/data/Clinical%20Protocol/Clinical%20Protocol/88-2WGW3
https://hsgbu-phx-565.snphxprshared1.gbucdsint02phx.oraclevcn.com:16691/siebel/v1.0/data/Clinical%20Protocol/Clinical%20Protocol/88-2WGW3
```

## Functionality

1. CRA selects a Protocol Record and opens the Embedded ODA Widget

Protocol List **Administration Protocol Attachments**

AMXN 937423

Status ● + - 🔍 ⚙️ 3 of 7

Protocol No.	AMXN 937423	Title	Treatment of spleen	Products	Amesim	Companion Agent
Program	Amesim	Phase	PIR	Type	Market support	# Planned Sites
Team	CSTONE	Indication	Amesim	Status	In Progress	# Planned Subjects
Currency Code	USD	Exchange Date	1/1/2001	Withholding Amount	\$10.00	Withholding %
Planned Start		Planned End		Actual Start		Actual End
Planned Start		Planned End		Actual Start		Actual End
Planned Budget		Planned Budget		Objective		

Hide hidden content for unlinked users

Attachments

Attachments

Name	Type	Size	Modified	Auto Update	Comments
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2. CRA interacts with ODA with ODA collecting required information from CRA

Protocol List **Administration Protocol Attachments**

AMXN 937423

Status ● + - 🔍 ⚙️ 3 of 7

Protocol No.	AMXN 937423	Title	Treatment of spleen	Products	Amesim	Companion Agent
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Hide hidden content for unlinked users

Attachments

Attachments

Name	Type	Size	Modified	Auto Update	Comments
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Chat

This chat is for AMXN 937423

Hello! I'm AMXN. How can I help you?

A few moments ago

Type a message

### 3. CRA receives AI Insights and ODA Updates the Protocol Record with new values.

The screenshot displays the Oracle Clinical trial management interface. The main section shows the protocol details for 'AMXN 9374'. It includes a table for 'Treatment of subject' with columns for 'Product', 'Amount', 'Type', 'Market support', 'Planned Status', and 'Competitive Agent'. The 'Planned Status' is set to '45'. Below this, there are fields for 'Planned Start Date' (11/26/2024) and 'Planned End Date' (11/26/2025). The 'Status' is 'In Progress'. The 'Exchange Date' is '1/1/2001'. The 'Withholding Amount' is '\$10.00'. The 'Actual Start Date' is '11/26/2024' and the 'Actual End Date' is '11/26/2025'. The 'Planned Budget' is '\$10.00'. The 'Attachments' section shows a file named 'Amxan Protoc... .doc' with a size of '13,367' and a modified date of '3/6/2005 05:14:35 AM'. On the right side, there is an 'AI Insights' widget titled 'Are you fine with above values?'. It displays 'AI Insights' with '45 of Planned Sites', 'Enrollment Duration: 12 months', and 'Predicted Enrollment Rate: 0.20 patients per 100 patients'. Below this, it asks 'Are you fine with above choices and do you want to update CMC with above data?' with 'Yes' and 'No' buttons. At the bottom, it says 'Protocol Record: AMXN 9374 has been successfully updated with new values' and 'Now'.

## Benefits

- **Enhanced Protocol Accuracy**  
By using AI-driven enrollment predictions, the system ensures more accurate planning and resource allocation, reducing the risk of protocol delays and cost overruns.
- **Improved Decision-Making**  
AI 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 user-friendly interface.

## Future Possibilities and Innovations

1. Provide Next Best Actions to the CRA by providing the CRA with Protocol record values that increases the Enrollment prediction probability.
2. Bring your own Model.

## Limitations

1. If the customers are not able to provide the feature values required for Model predictions then the enrollment prediction accuracy decreases.
2. Current Model feature values restriction (Eg. Restricted indications allowed, The CTMS MVG Phase field contains values that are incompatible with the allowed Phase values in the Model.)

## Conclusion

By integrating Oracle Digital Assistant (ODA) and AI-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 AI-driven 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.

## References and Additional Resources

1. <https://www.ateam-oracle.com/post/a-simple-guide-to-connecting-oda-custom-component-to-on-prem-apis>
2. <https://docs.oracle.com/en/cloud/paas/digital-assistant/sdk-js/index.html>
3. <https://www.oracle.com/downloads/cloud/amce-downloads.html>