

Preclarus[®] Patient Data Dashboard Enhances Safety Monitoring in Dose Escalation Study



BACKGROUND

PPD was approached by a large pharmaceutical company interested in fully outsourcing a randomized Phase I asthma dose escalation study, containing eight different cohorts. Because the study included dose escalations, being able to quickly and efficiently review visualizations of patient safety data to determine when patients could move to the next dose was critical.



OBJECTIVE

To introduce the client to the Preclarus[®] patient data dashboard, which would allow them to conduct rapid and high-quality monitoring and reviews of safety data in near real-time, which would assist in helping the client to determine when it was appropriate to escalate doses for various patients.*



CHALLENGES

The client was hesitant to utilize the patient data dashboard for safety monitoring as they preferred using their own in-house safety monitoring system and did not want to invest significant time in learning to navigate Preclarus. Importing study data into the client's system was possible, but would result in a weeks-long lag time. A lag time of this magnitude would greatly impact the currency of the data being reviewed and would therefore delay decisions regarding dose escalation.

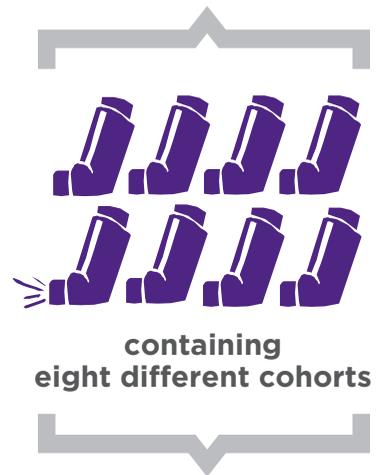


STRATEGY

PPD's study team presented information on the patient data dashboard to the client and highlighted the benefits that it would bring to the study, including the ability to access near real-time data and dynamic data visualizations. The clients were then given a comprehensive demo on the functionality of the dashboard to showcase its detailed level of data surfaced and user-friendly interface.

* Please note, in situations such as this, a validation of the final decision should be performed via the usual programming routes.

**Randomized
Phase I asthma
dose escalation study**



**containing
eight different cohorts**



**real-time data
and dynamic
data visualizations**

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THE RESULTS

The client responded positively to the demo of the patient data dashboard, quickly agreed to use it and subsequently received an in-depth training session on how to navigate the dashboard. After the training session and initial data import, the client began using the dashboard and because they found the dashboard to be very user-friendly, no additional training was needed. The clients were able to begin using the safety data presented in the dashboard shortly after gaining access and were able to make the rapid decisions needed for patient dose escalations.

[THE RESULTS]

Using the patient data dashboard instead of importing data into their internal system



saved the client significant time, in a study where making quick decisions was paramount



and allowed the clients to dive into their study data and make decisions based on that data quickly and easily