

# Medidata Professional Services Helps Ambit Biosciences Successfully Rescue Three Critical Oncology Studies

## THE CHALLENGE

### FULLY TRANSITION THREE ONCOLOGY TRIALS ALREADY IN PROGRESS

Parting ways with a large pharmaceutical partner, Ambit Biosciences was challenged to fully transition three critical oncology trials already in progress. Per their agreement, the transition period was to last six months during which a complete transfer of knowledge, documentation, and data was to take place. However, because of its size and limited resources, Ambit found itself running out of time to migrate the study data and much of the documentation for the three studies. Additionally, Ambit had just hired a new director of data management who had been tasked with managing the organization’s electronic data capture (EDC) system, Medidata Rave®, and all the related data for these trials. The director had not been privy to any of the discussions or negotiations prior to his onboarding but he had to hit the ground running. Fortunately, he had worked with Rave and Medidata Coder® as well as with Medidata Professional Services in the past and was aware of the extensive support Medidata offered that could be leveraged to help successfully transition these three studies.

## THE TRANSFORMATION

### IMPLEMENTATION OF MEDIDATA’S RESCUE STUDY METHODOLOGY

As part of the transition agreement, Ambit was not permitted to copy the Rave EDC URLs. Thus, three new studies had to be created within Rave on a new Ambit URL and all of the existing data was transferred from the previous databases. Medidata Professional Services helped Ambit successfully transition the studies quickly and efficiently by focusing on three key areas:

- Medidata reconfigured the roles and workflows for each of the three studies to fit the specific needs of Ambit. Ambit’s partner was a large and organizationally complex pharmaceutical company. Ambit needed fewer roles and more efficient workflows that could be managed by fewer people.
- The Rave databases for each study had to be restructured and all of the data transferred quickly and without error. During the restructuring, the professional services team detected elements in the core configuration and marking groups that had been missing from the original setup.
- Once the databases were set up correctly, the data was successfully loaded using Rave Web Services. Synonym tables used with Coder were created and uploaded. Medidata provided a level of transparency around the data transfer process that enabled Ambit to assure the study sites that the data wasn’t compromised during the transition.

**“The Medidata Professional Services team made recommendations based on our specific needs and style of working. Collaborating with them was easy and I would recommend them to anyone searching for top-notch services. I couldn’t have done it without them.”**

Mar Reyes,  
Director of Data Management,  
Ambit Biosciences

# #1

CLINICAL DEVELOPMENT SERVICES

# 17K+

TRIALS

# 100+

PROFESSIONAL SERVICES EXPERTS

- Medidata Professional Services stepped in to facilitate and accelerate the knowledge transfer. The project manager set up and adhered to a strict timeline, as all tasks were on a critical path and there was no room for delays. Professional Services lead the Ambit team step by step through each part of the transition, providing the sponsor with the available options at each step and offering recommendations based on their deep rescue study experience.

Medidata Professional Services worked with Ambit to prioritize the studies based on level of complexity and developed a timeline for each. The project manager was able to keep Ambit on track to meet those timelines and to minimize time lost during the transition of the studies. Ambit was provided guidance as to the documentation they should be requesting and assisted in securing it before the end of the transition period (e.g., audit trail documentation).

## THE RESULTS

### TRANSPARENCY ENSURED A RISK-FREE AND SEAMLESS ENVIRONMENT

Medidata Professional Services provided leadership and expertise in not only getting the customer through the study setup process successfully, but also doing so within the extremely tight timeline constraints. Additionally, the Professional Services team drew on their extensive experience across study phase and therapeutic area and leveraged Ambit's current infrastructure to provide a unique and tailored solution based on Ambit's specific needs. Medidata Professional Services applied their proven rescue study methodology that has been developed and refined over many years.

Ambit realized many benefits through its relationship with Medidata. The Professional Services team was able to successfully transition the databases, as they existed with their partner with no apparent data loss. Further, the transition was fully transparent -providing assurance to the entire study team, including sites, that the process was seamless and reduced risk of error.

Ambit remarked on the depth of expertise provided by Medidata Professional Services as well as the ease of working with the Medidata team. "The Medidata Professional Services team lead us through the transition process step by step and provided us options along the way," said Mar Reyes, director of data management. "They made recommendations based on our specific needs and style of working. Collaborating with them was easy and I would recommend them to anyone searching for top-notch services. I couldn't have done it without them."

## ABOUT AMBIT BIOSCIENCES

Ambit Biosciences is a biopharmaceutical company focused on the discovery, development and commercialization of drugs to treat unmet medical needs in oncology, autoimmune and inflammatory diseases by inhibiting kinases that are important drivers for those diseases. Their pipeline currently includes three programs, each discovered internally and each aimed at the inhibition of validated kinase targets. The lead drug candidate, quizartinib, is a once-daily, orally administered FMS-like tyrosine kinase 3, or FLT3, kinase inhibitor.

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