

## CLIENT

US-based Oncology focused biotech

## SCOPE

To transform the clinical data of an SIK inhibitor therapy for Ovarian cancer to submission-ready state



# END-TO-END DATA SERVICES

## CASE STUDY



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## BUSINESS PROBLEM

- An early-stage oncology biotech with a promising SIK inhibitor therapy for ovarian cancer and were looking for a partner to support all their data and statistical needs
- Being a virtual team, resources and budgets were limited
- They already had nine patients enrolled, using the site-based data system but needed a scalable partner to take the data to an FDA submission-ready state

## ALGORICS SOLUTION

- A team of expert statisticians, data managers, and two statistical programmers was formed to deliver end-to-end data management, biostatistics & statistical programming
- Our team delivered the Veeva CDMS database on time and migrated existing patients from the site-based system into Veeva
- Built SAP and statistical guidance for protocol amendments
- Supported data reporting needs for IB updates and annual IND updates
- Acted as a sponsor point of contact for all statistical and programming deliverables

## CLIENT BENEFITS

- Smooth and efficient handling of the data including transition and transformation
- Audit ready submission package ready in record time
- Top-notch expert support throughout the project until submission
- Robust communication and governance right from the management, the execution leaders and co-ordinators

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