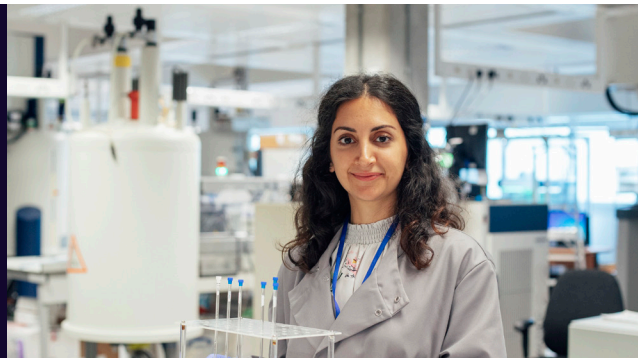
COTA

CASE STUDY

MULTIPLE MYELOMA EXTERNAL COMPARATOR COHORT

CASE IN BRIEF

Real-world data (RWD) in Oncology proves to be a vital source for clinical decisions and program decisions. COTA partnered with a Top 5 Pharma company to curate a custom multiple myeloma real-world cohort for use as a synthetic control arm regulatory filing. COTA ultimately delivered more relevant patients than other RWD vendors.



PARTNER PROFILE

The Company is a leading global biopharma company committed to discovering, developing, and delivering innovative medicines. The Company is at the forefront of oncology (within top 5 oncology pharma) with an extensive portfolio of investigational compounds and approved medicines, focusing on both solid and liquid cancers.

THE PROBLEM

The Company was conducting a phase 2 pivotal study in heavily pretreated relapsed/refractory multiple myeloma (RRMM) patients and looked to construct an external control arm (ECA), i.e., a global, noninterventional, and retrospective cohort to assess treatment patterns in real-world RRMM patients with characteristics similar to those of the active treatment arm.

OUR APPROACH

COTA was selected as one of two main providers of MM real-world data to construct this synthetic control. COTA prioritized open communication and collaboration, employing the following steps to create the comparator cohort:

1. Joint effort with partner to determine Real World Data (inclusion/exclusion criteria, including line of therapy, molecular markers).

2. Fit-for-purpose data model.

3. Data delivery to incorporate feedback into data model, and iterations of data model based on feedback from sponsor program team.

4. Longitudinal quarterly refresh of data deliverable.

5. Final data delivery concordant with agreed upon data model.

THE RESULTS

A pooled analysis was conducted from the two primary RWD providers — COTA and Vendor 2. COTA contributed more relevant matching patients. In April 2020, this cohort was submitted to the FDA and EMA in support of The Company's investigational agent. The application was accepted for Priority Review with a target decision date in March 2021.

What Really Matters: 20% of COTA top line volume qualified into the final cohort, compared to 10% of Vendor 2

Selection Criteria	COTA	Vendor 2
MM patients (18+) daratumumab-exposed	473	766
Attrition Variable #1	381	658
Attrition Variable #2	328	458
Attrition Variable #3	193	270
Attrition Variable #4	101	83
Final cohort of patients that matched the clinical trial investigational arm	**98**	**80**

WHY DID COTA DATA PRESENT WITH LOWER RATES OF ATTRITION?

Our Data Source: >50% records sourced from tertiary referral centers means more complex, advanced, and rare cancers, with greater rigor & completeness in EMR documentation and higher genomic profiling capabilities

Our Abstraction: Technology-enabled human abstraction allows for nuances in unstructured data to be captured manually by medical professionals, with stringent oversight on QA, qualification, and completeness

Our Curation Depth: Curation process is driven by clinical relevancy, which means COTA's standard-level dataset goes deeper than other vendors and includes the flexibility to add custom element

COTA

A leading provider of oncology real-world data and analytics.

Founded in 2011 by doctors, engineers, and data scientists with the goal of bringing clarity to cancer care, COTA today produces research-grade real-world data (RWD) and is driving innovation alongside some of the world's most renowned oncology organizations.

To learn more, reach out to us at lifesciences@cotahealthcare.com

Source: Attrition variables are blinded to preserve confidentiality; numbers shown represent best estimates of counts as provided by partner The Company