

## SUPPORTING EMERGING BIOPHARMA (EBP)

#### **CASE IN BRIEF**

COTA partnered with an emerging biopharma (EBP) interested in using RWD to supplement its myelofibrosis trials. COTA worked alongside the EBP to provide analytical, medical, and strategic support, ultimately initiating full-scale abstraction for an ECA.



#### **Partner Profile**

The Company is a small (Market Cap of around 500M) emerging biopharma (EBP) developing a single asset for hematologic myeloid malignancies, including myelodysplastic syndromes (MDS) and myelofibrosis (MF).

#### **THE PROBLEM**

Much of today's investigational cancer therapeutics originates in small biotechnology companies, most of which are innovative and agile by nature, but also lack the financial horsepower, resources, and infrastructure of multinational pharmaceutical entities. Despite these common limitations, The Company was interested in exploring opportunities of using RWE as an External Comparator Arm (ECA) for ongoing and upcoming trials, and partnered with COTA to assess this possibility.

#### **OUR APPROACH**

Working with The Company, COTA undertook a feasibility assessment to address a number of key questions concerning the treatment of myelofibrosis patients in real-world settings. COTA analyzed a random selection of 50 myelofibrosis patients across multiple provider partner sites.

**De-risked** The Company's commitment by stage-gating timelines and project phases: Phase 1 to assess feasibility and clinical trial considerations, Phase 2 to abstract and deliver records

**Collaborated** with The Company's leadership team to explore potential applications of RWD across drug development activities

**Supported** The Company's clinical development process by providing analytical support, medical expertise, and co-defining and prioritizing data elements



# **THE RESULTS**

COTA worked alongside the EBP to provide analytical, medical, and strategic support to validate use of RWE.



Collaboration to understand opportunities and limitations with real-world data, based off analyses of 50 randomly-selected patients



#### CREATION OF MYELOFIBROSIS DATA DICTIONARY

Joint Medical and Analytics effort from COTA & The Company to prioritize clinically-relevant data elements of interest and create standardized naming conventions



#### [ONGOING] ABSTRACTION FOR COHORT CONSTRUCTION

After successful feasibility outcomes, full-speed abstraction initiated to construct myelofibrosis cohort for clinical development

### **COTA** + OUR PARTNERS

COTA is well equipped to support partners anywhere from EBPs to global pharmaceutical companies. Our relationships are founded on collaboration and RWD-driven strategy, and continuously proves to be much deeper than data licensing

#### CUSTOM DATA MODEL

Tailored solutions and customization ensure focus and optimize impact

#### PROVIDER RELATIONSHIPS

Robust partnerships with reputable providers allow accessibility for additional data collection

#### COLLABORATIVE APPROACH

Commitment for mutual successes in partnership enables collaboration and synergy

#### BUSINESS AGILITY

Flexibility and speed drive capability to assess and implement augmentation requests

#### MEDICAL EXPERTISE

Internal and external expertise enables clinically-valuable insight in curation process

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: Martin E. Gutierrez et al., Clinical Lung Cancer, 2017; Martin E. Gutierrez et al., JCO Precis Oncol., 2019 \*Point mutations, indels, fusions, and copy number amplifications