

## Case Study:

### Electronic Publishing of a Clinical Study Report (CSR) for a Biopharmaceutical Company

#### Client

An US based  
Biopharmaceutical Company

#### Product

Drug intended for patients  
with relapsed or refractory  
multiple myeloma

#### Product Category

Small molecule

#### Countries of Interest

USA

#### Services offered

Electronic Publishing of CSR

#### Client Situation

The Client is a Biopharmaceutical company headquartered in Las Vegas, Nevada committed to giving patients access to innovative therapies with a number of their products currently at different phases of clinical trials. They were seeking a regulatory partner who could urgently support them with electronic publishing of a Phase-2 Clinical Study Report (CSR) for one their drugs.

#### Aariya's Solution

A CSR consists of a set of critical documents that describe the methodology and results of a clinical trial in drug development. It is a detailed report, incorporating tables and figures either in the main text of the report or at the end of the text and also includes appendices containing the protocol, sample case report forms, investigator related information, details related to the investigational drug including active control/comparators, technical statistic documentation and details such as derivations, computations, and analyses, etc. Aariya's dedicated publishing and submission team is specialized both in document level and report level publishing and can assist organizations with the publishing and submissions of their CSRs at an affordable pricing.

Aariya performed the following activities to ensure steady work:

#### Electronic Publishing

- Our team performed document level publishing (DLP) of all the CSR components.
- Aariya completed report level publishing (RLP) and validation of the full CSR using one of the world's leading publishing software, eCTD Office™.

#### QC Review

- Post the RLP activity, Aariya performed multi-level Quality Check (QC) of the entire published CSR.
- The reviewed final published output was then shared with the Client for onward submission to the health authority.

#### Key Highlights

- Aariya's rich experience in electronic publishing of CSRs helped complete the designated fast-track publishing activity for the Client as per desired Health Authority specifications within stipulated timeline.