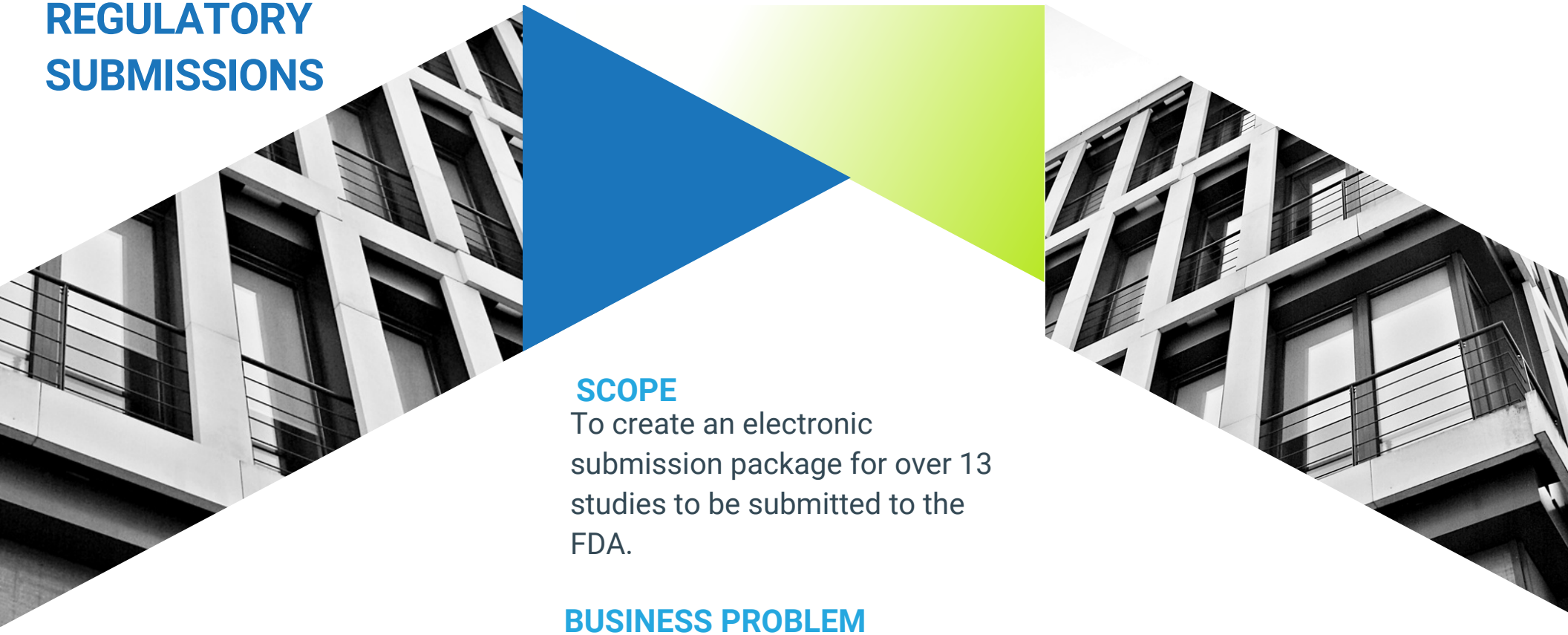
CASE STUDY

EXPEDITING COMPLEX REGULATORY SUBMISSIONS

CUSTOMER

US headquartered biotech specializing in opthalmology

MetaVate



SCOPE

To create an electronic submission package for over 13 studies to be submitted to the FDA.

BUSINESS PROBLEM

- This client needed Algorics to create an electronic submission of 13 studies to the FDA
- Out of those 13 studies, 11 studies had only SDTM datasets and the remaining 2 studies both SDTM and ADaM datasets
- The need was to create a submission data package which included define, XPT files, annotated CRF, reviewers' guides for regulatory submission, for all the studies

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ALGORICS SOLUTION

- Each of the 13 studies were reviewed and a metadata mapping between datasets, both in SDTM and ADaM were created
- This helped us get a complete picture of the gaps across all 13 studies
- Subsequently, these mappings were fixed to conform to the required CDISC standards

CUSTOMER BENEFITS

This project was delivered in time using MetaVate. Disparity in standards across studies was effectively remedied and the regulatory submission package was successfully delivered

In a normal define.xml project, it would take 5 – 7 business days per study, whereas using MetaVate on these 13 studies, took an average effort of 2 - 3 days per study, including Pinnacle 21 validation.

Define.pdf created by MetaVate Define module was provided in a human readable format with easier navigation and hyperlinks to datasets, annotated CRFs, and XPT files

ABOUT ALGORICS

Headquartered in the US, Algorics is an agile, innovation driven data and biostatistics solutions partner to healthcare and life sciences industry. Supported by our homegrown technology and a highly experienced team, we provide end to end data solutions to fast track your regulatory submission

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