



Predictable Delivery of Clinical Trials



Massachusetts Institute of Technology | Master of Business Analytics | Capstone Project

Capstone Sponsor: Saurabh Awasthi

Faculty Advisor: Prof. Steve Graves

Students: Denis Sai & Edoardo Italia

Better Health, Brighter Future

Agenda



The Challenge



Analytical Approaches



Novel Insights



Impact



Q&A



The Challenge



Analytical Approaches



Novel Insights



Impact

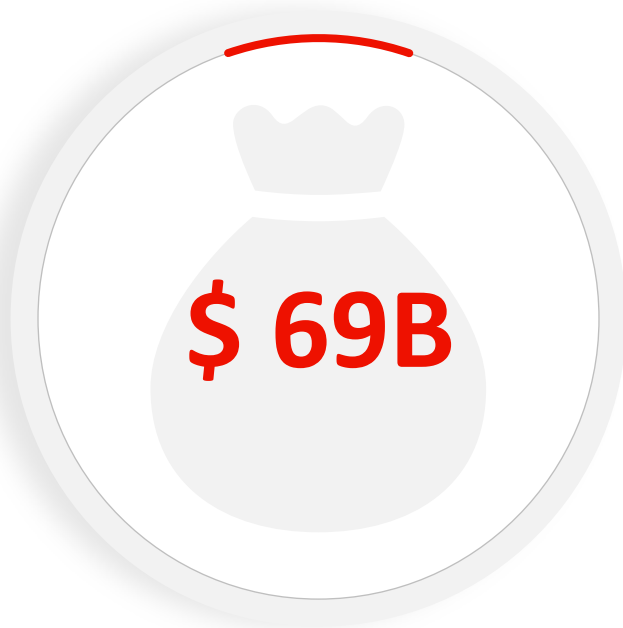


Q&A

Clinical trials are **expensive and risky** – being proactive about uncertainty unlocks significant value

The Challenge

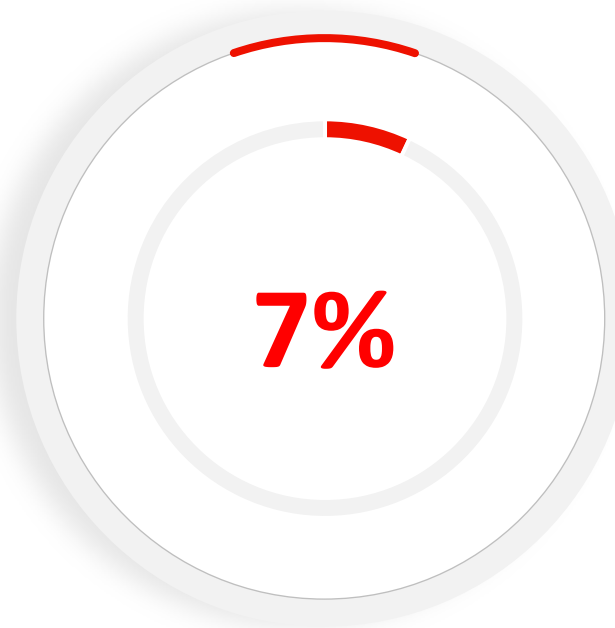
Expensive



in global clinical trial expenses
by 2025

Sources: Nature, FDA

Risky

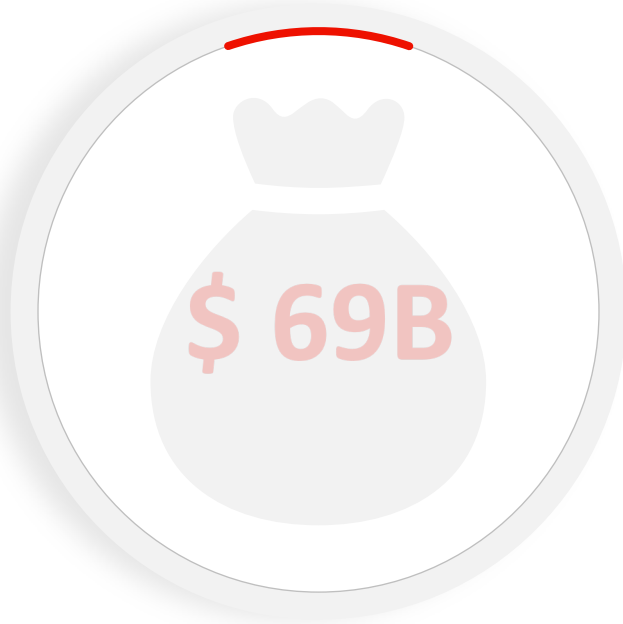


of drug candidates pass all 3
phases

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The Challenge

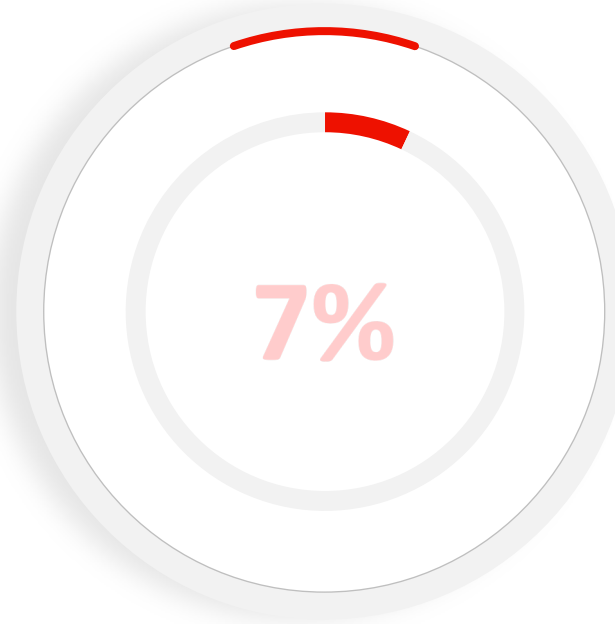
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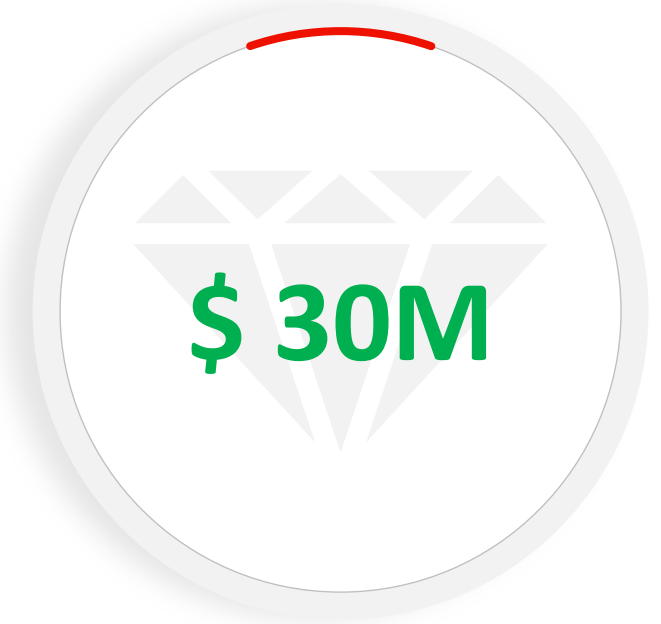
Sources: Nature, FDA

Risky



of drug candidates pass all 3
phases

Value



in added Net Present Value if
process is 30 days shorter

Improving clinical trials requires substantial efforts **across the board**

The Challenge

Scientific



*Drug
discovery*



*Patient
response*

Operational



*Trial
Planning*

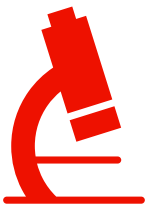


*Data
submissions*

Improving clinical trials requires substantial efforts **across the board**

The Challenge

Scientific



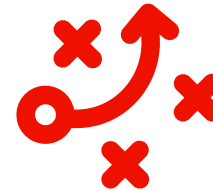
*Drug
discovery*



*Patient
response*

Our focus

Operational



*Trial
Planning*



*Data
submissions*

We have focused our efforts on a **specific segment** of clinical trials

The Challenge

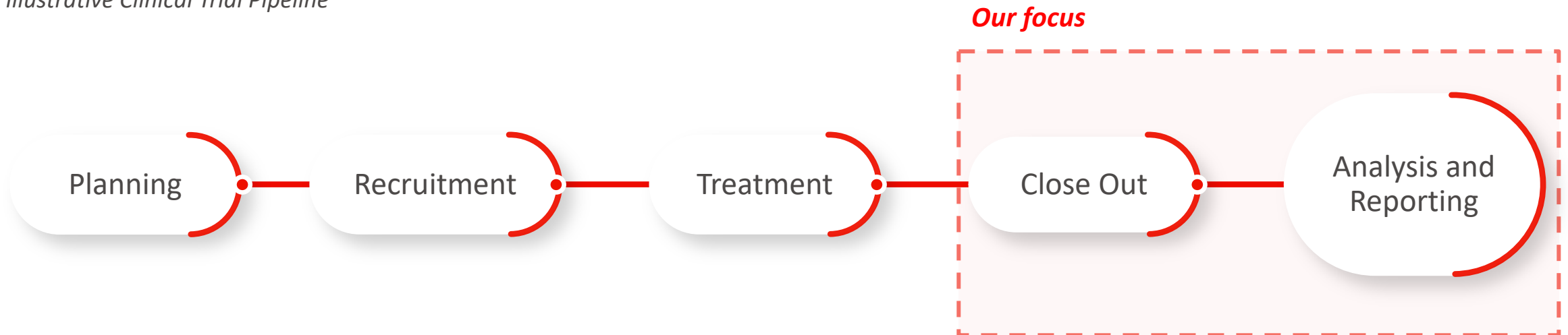
Illustrative Clinical Trial Pipeline



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The Challenge

Illustrative Clinical Trial Pipeline





The Challenge



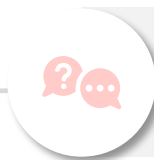
Analytical Approaches



Novel Insights



Impact



Q&A

We aimed to analyze and predict **trial cycle times** with **advanced analytics**...

Analytical Approaches



Characterize indicators
of trial slowdowns



Predict missed
operational milestones



Prescribe course
of action

We aimed to analyze and predict **trial cycle times** with **advanced analytics**...
...but were confronted with a **complex data landscape**

Analytical Approaches



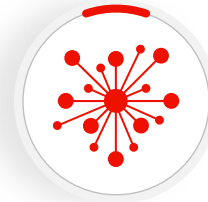
Characterize indicators
of trial slowdowns



Predict missed
operational milestones



Prescribe course
of action



Varied and **disconnected**
data structures



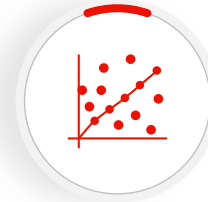
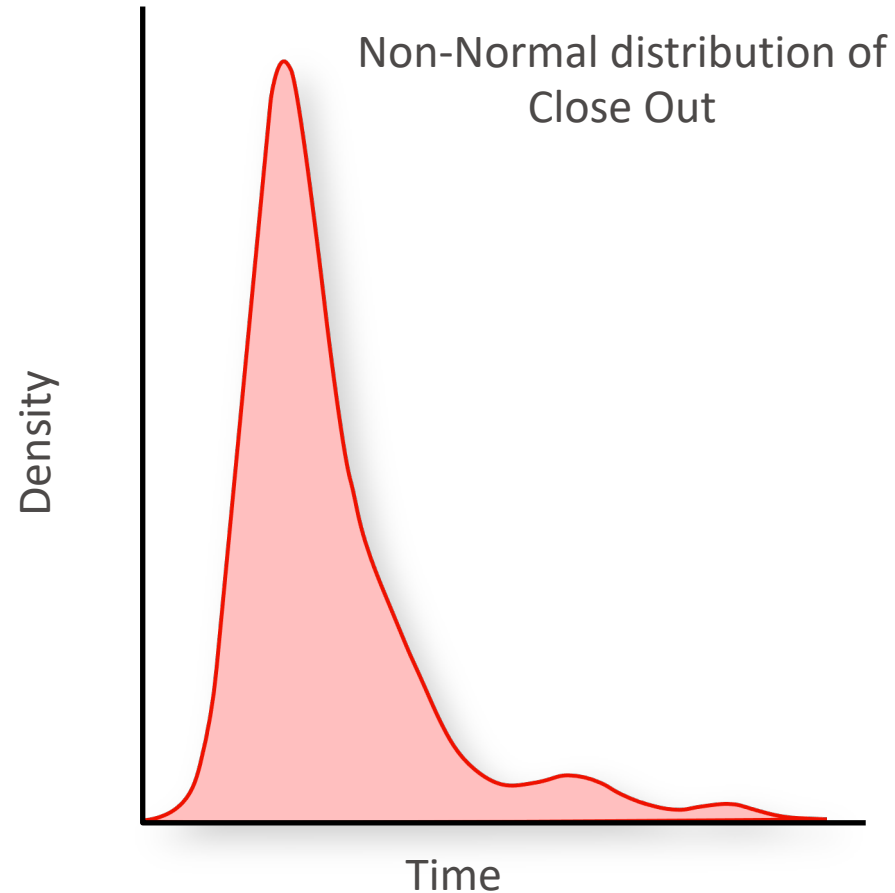
Few observations but
many features



Varying degrees of
sparsity

We have exhausted the suitable **machine learning** approaches

Analytical Approaches



Interpretable regressions



Count and ensemble models



Binary and multiclass classification



The Challenge



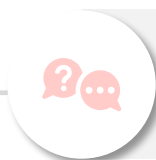
Analytical Approaches



Novel Insights



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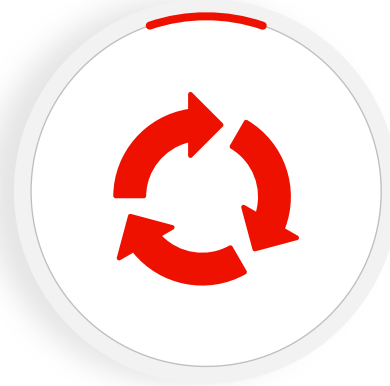
Q&A

Descriptive analysis signals **impacts from COVID-19** and operational **hurdles**

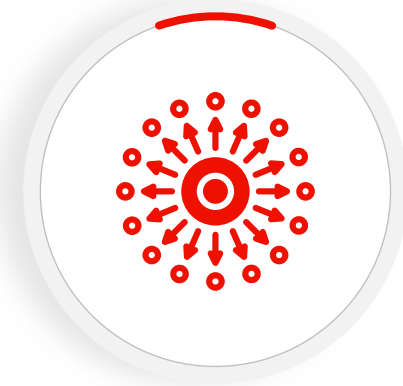
Novel Insights



Increased variance due to COVID-19



Decomposed and compared cycle times with industry



Identified prevalence of operational hurdles

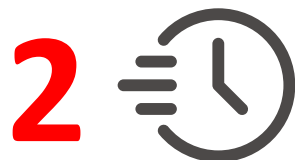
Sources: Team analysis

We discovered multiple statistically significant features with **high predictive power**

Analytical Approaches

Interpretability

Time predictions



Statistically significant
components

Trial delivery



Statistically significant
parameters

Predictive Power

Trial delivery



*Out-of-Sample
Area-Under Curve*

Sources: Team analysis



The Challenge



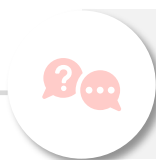
Analytical Approaches



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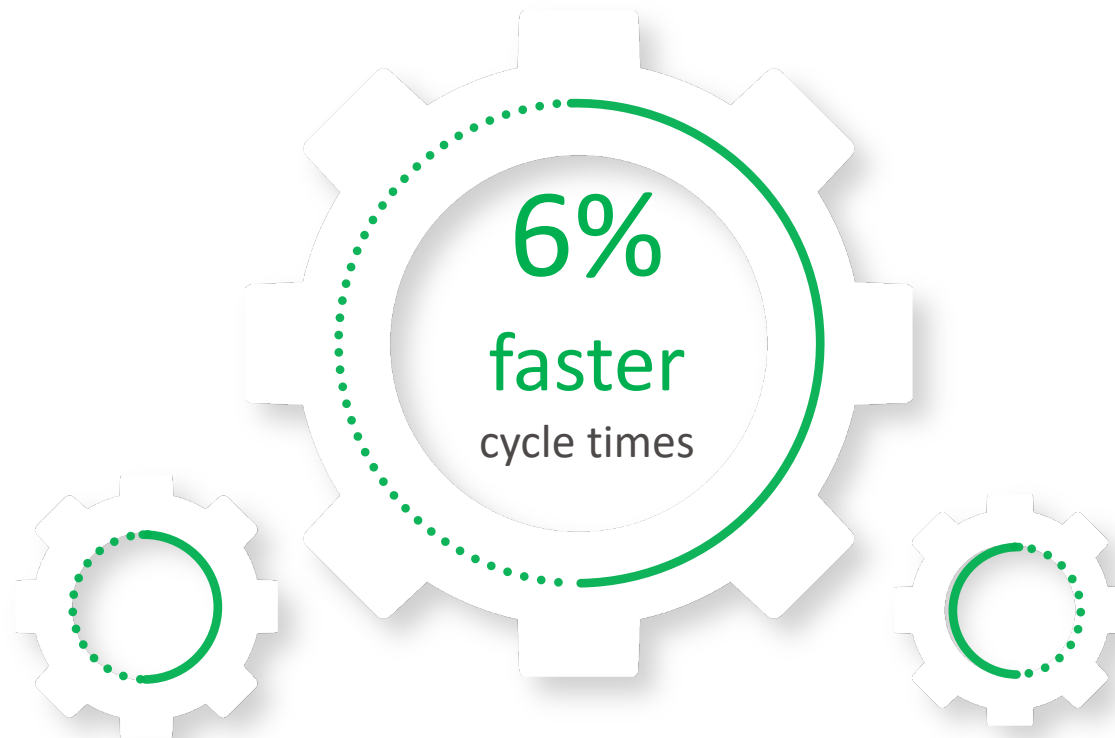
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Q&A

Upon a minimization of the key hurdles, **we observe marked improvements**

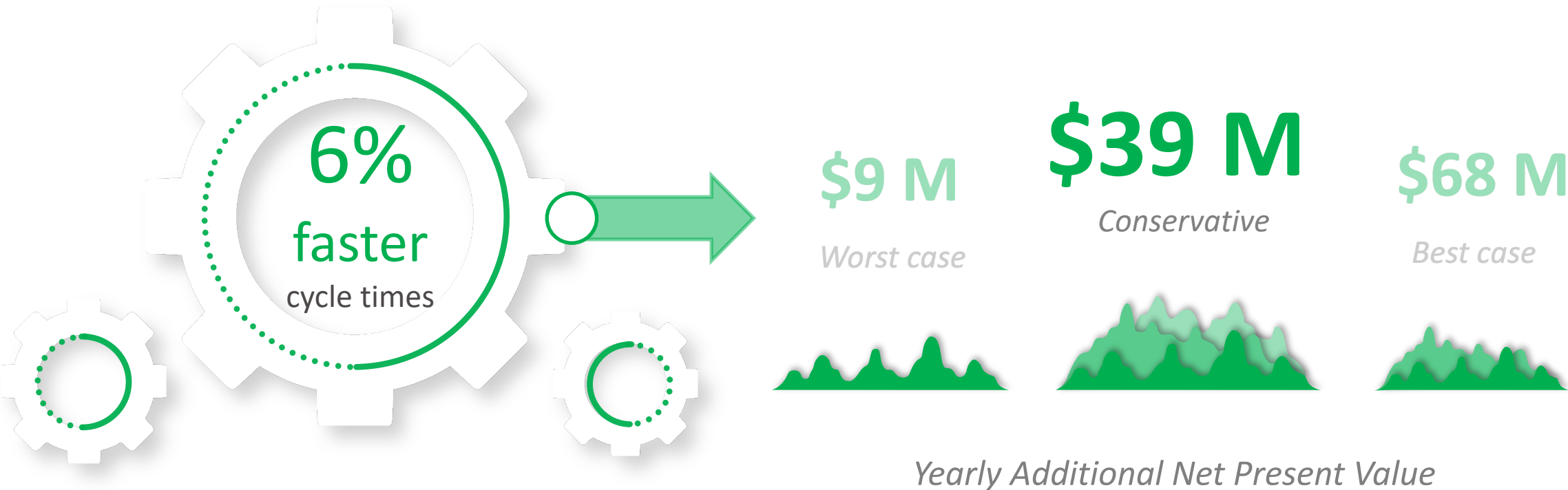
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Upon a minimization of the key hurdles, **we observe marked improvements**

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Sources: Team analysis

Thank you for the support and mentorship throughout this experience!

MIT Faculty Advisor



Prof. Steve Graves

Professor of Operations Management
Sloan School of Management

MIT

Capstone Sponsor



Saurabh Awasthi

Head of Strategy and Operations
Global Development Office

Takeda

All team members!





The Challenge



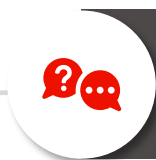
Analytical Approaches



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Impact



Q&A

Appendix



We leveraged a **comprehensive** data wrangling and modelling pipeline

Appendix

March

July

August



Data Wrangling

Descriptive Analysis

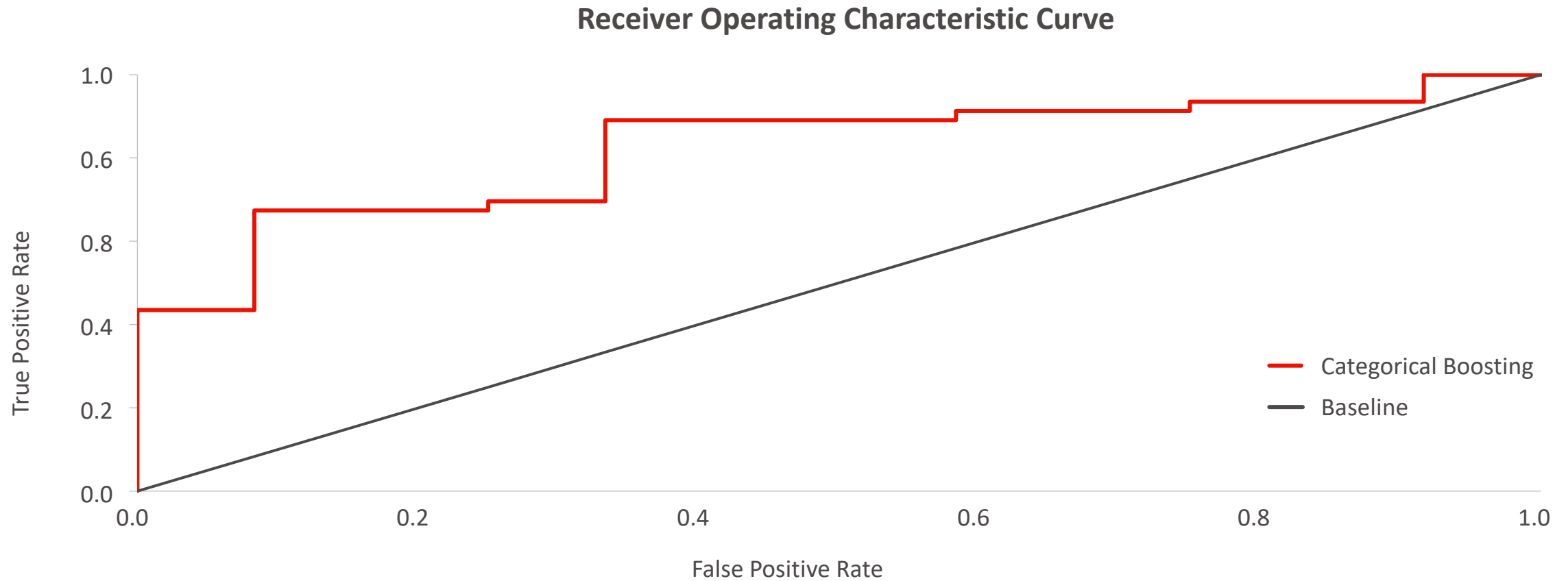
Feature Engineering

Machine Learning

Result Interpretation

Categorical Boosting demonstrates a strong ROC-Curve

Appendix



Sources: Team analysis