



WRIGHT AVENUE
— PARTNERS —

PRESENTATION NAME
DATE | LOCATION

AGENDA

- Background
- What is Study Designer
- Short demo
- For the techies
- Current status
- What's ahead



WRIGHT AVENUE



- Established in 2015
- Cary, NC
- Focus in pharma/biotech
- Clinical data innovation through technology
- Staffing



What is Study Designer?



- Study Designer is a cloud-based web application that facilitates the collection and storage of metadata associated with biostatistics deliverables
- What is metadata?
 - data about data?
 - define.xml?
 - *To Study Designer, metadata is the story you tell about your study*
- In contrast to Excel as a data entry tool, the Study Designer interface *solicits* this story from the user in a manner and sequence that is meant to reflect a structure within which design of studies and data naturally takes place,
- Study Designer creates a dialog between user and metadata consumer (e.g. FDA), inviting the user to tell the story of the study's data, thereby maximizing accuracy and value of the resulting metadata.
- Let's take a peek



For the Techies

- AWS EC2 cloud instances
- HTML/CSS (with Bootstrap framework)/Javascript
- Django web framework
- Python server-side script
- Neo4j graph database with Cypher query language

CURRENT STATUS



- Basic functionality in place
 - Define ADaM (IG version 1.1) data sets with all levels of metadata
 - Deployed on customer-specific cloud servers
 - Ability to generate Excel-based programming spec and define.xml (version 2.0)
 - Software-as-a-service model where Wright Avenue works with and trains customers in its use and solicits feedback for further development



WHAT'S AHEAD

2019 Q1

- Generation of SAS scripts for zero-observation data sets
- Additional collected metadata
- Improvements to generated programming spec
- Additional editing capabilities
- User interface enhancements
- Support for additional versions of standards

2019 Q2

- SDTM Dataset design
- Re-use (studies, datasets, variables, methods, etc.)
- Improved user input validation
- User interface enhancements
- Support for ADaM Other data sets

WHAT'S AHEAD

2019 Q3

- Import support (custom standards, studies, etc.)
- Track Changes

2019 Q4

- SDTM Trial Designer
- Define.xml v2.1

2020 Q1

- Take advantage of variable relationships
(e.g. PARAMCD/PARAM/PARAMN)

2020 Q4

- TLF Designer (analysis results metadata, display metadata, etc)

2021 Q4

- Protocol Designer



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- Customers, testers, listeners

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