AGENDA

• Background
• What is Study Designer
• Short demo
• For the techies
• Current status
• What’s ahead
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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