

Upstream with your statistician and a data visualisation paddle

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Veramed Limited

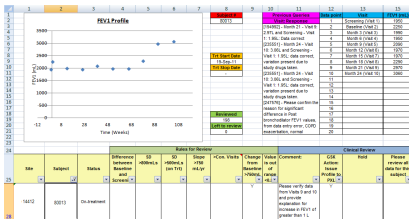
SP03

PhUSE 2016, Barcelona

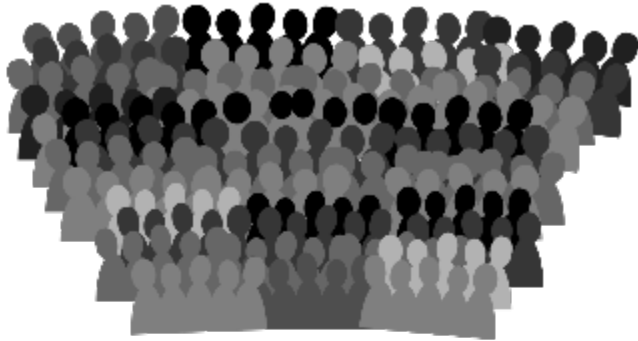
12 October 2016



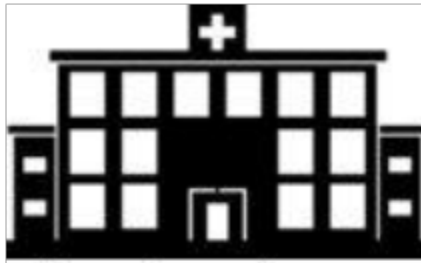
- Outline of clinical trial
- Flow of data
- Data cleaning
- Creating visual tools
 - FEV1
 - Exacerbations
 - Subject eligibility



The trial



>16,000



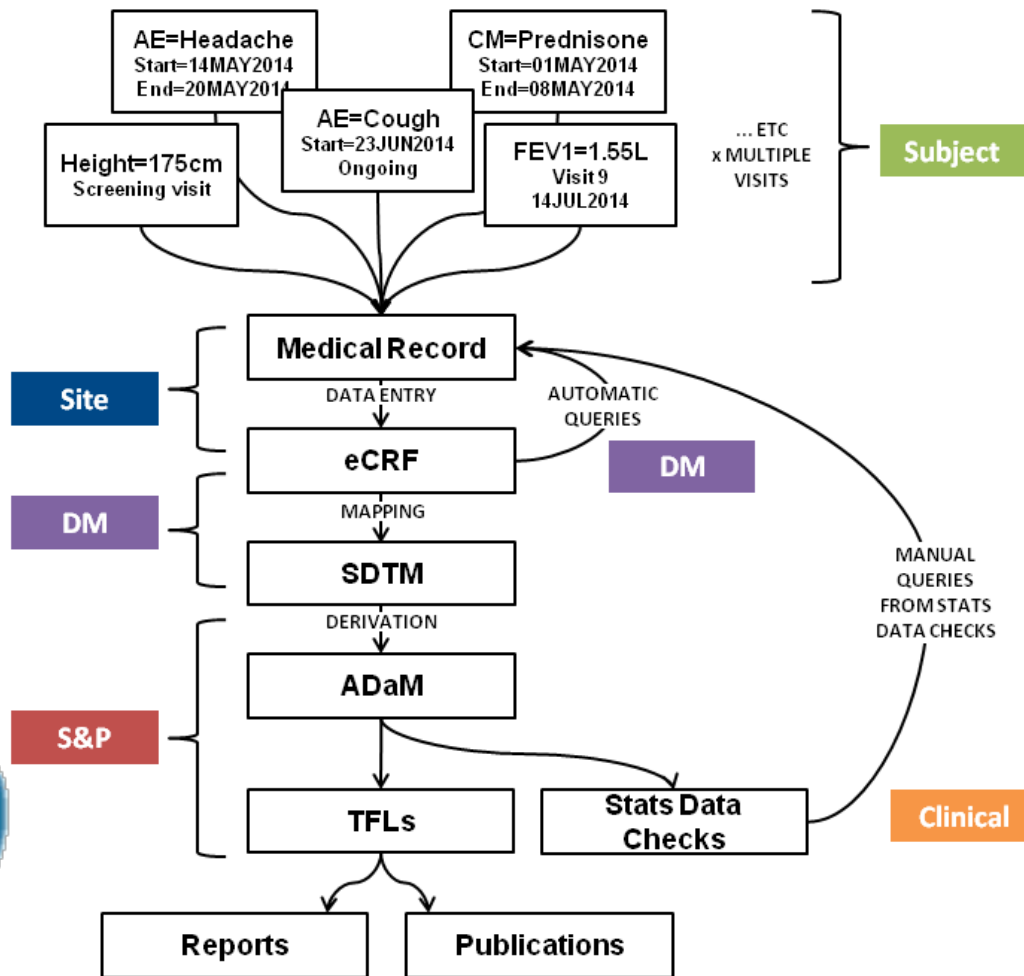
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43

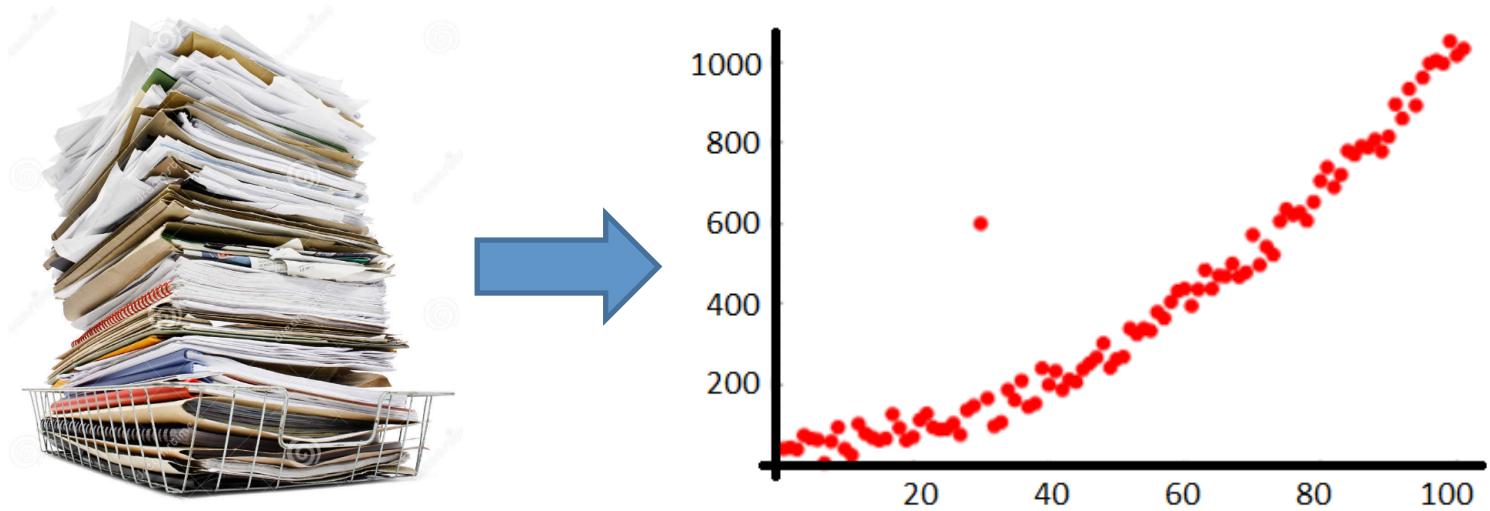
- Primary endpoint: **Survival**
- Other endpoints involved **FEV1** and **COPD exacerbations**
- **Over 4 years of data collection**

Flow of data in a clinical trial



Creating visual tools

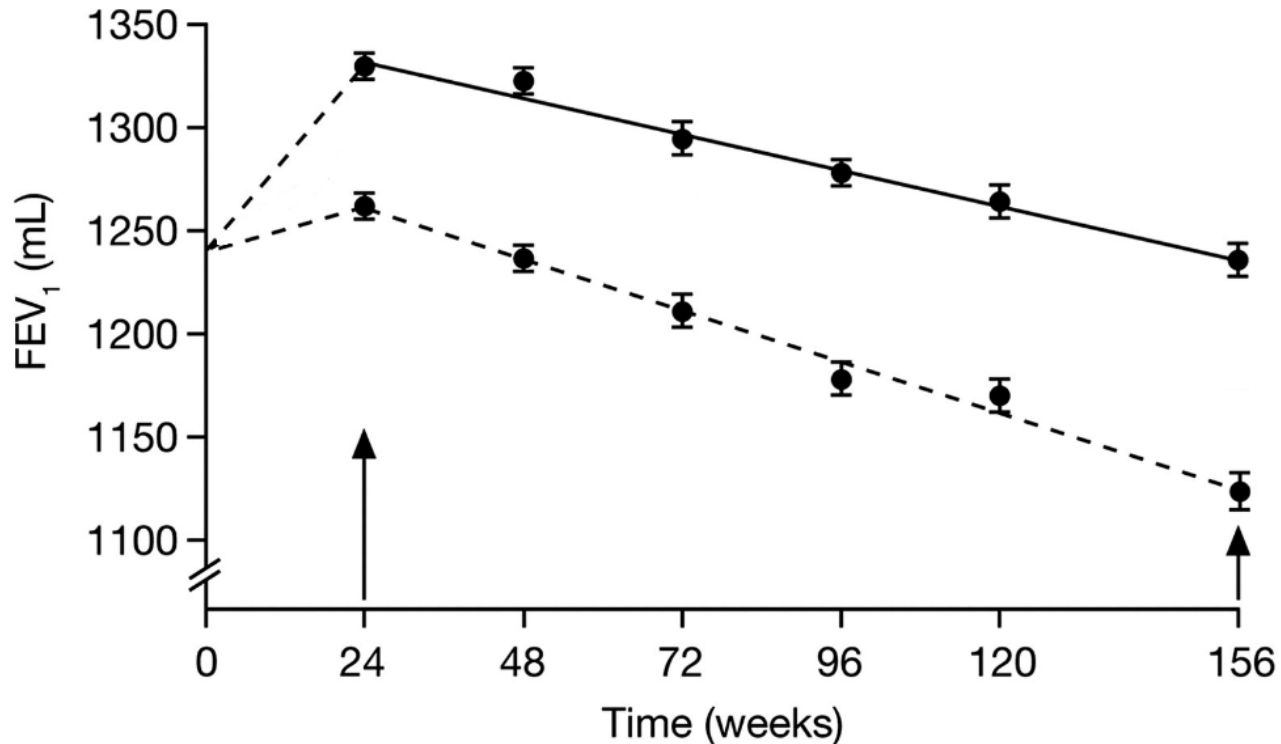
- Communicating data to non-statisticians



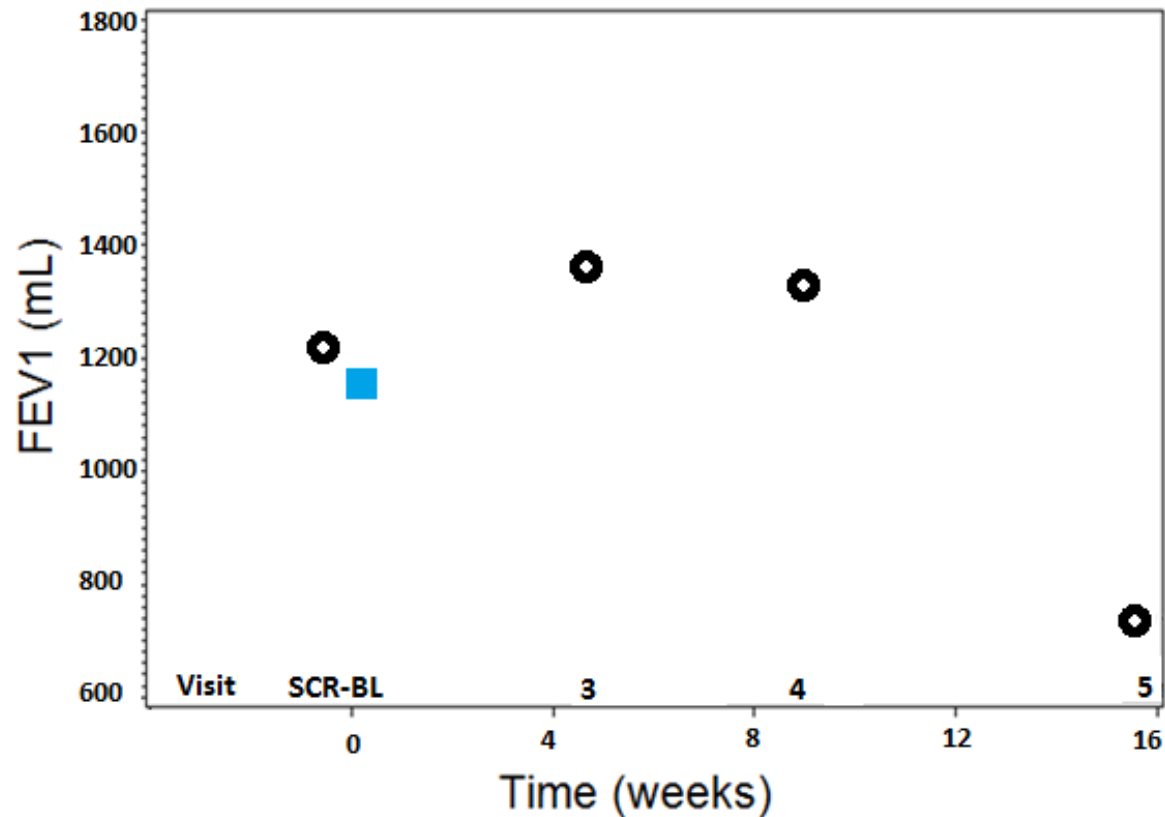
- Allows creativity in programming new tools
- Data analysis mindset

FEV1

- Forced expiratory volume in 1 second
- Rate of decline in FEV1 over time



FEV1 Profile Review Tool



NOTE: Blue square represents baseline value

Comments:

Please review data at last visit. Reduction in FEV1 is not consistent with normal rate of decline for subject

PI Comments & Signature:

Exacerbations

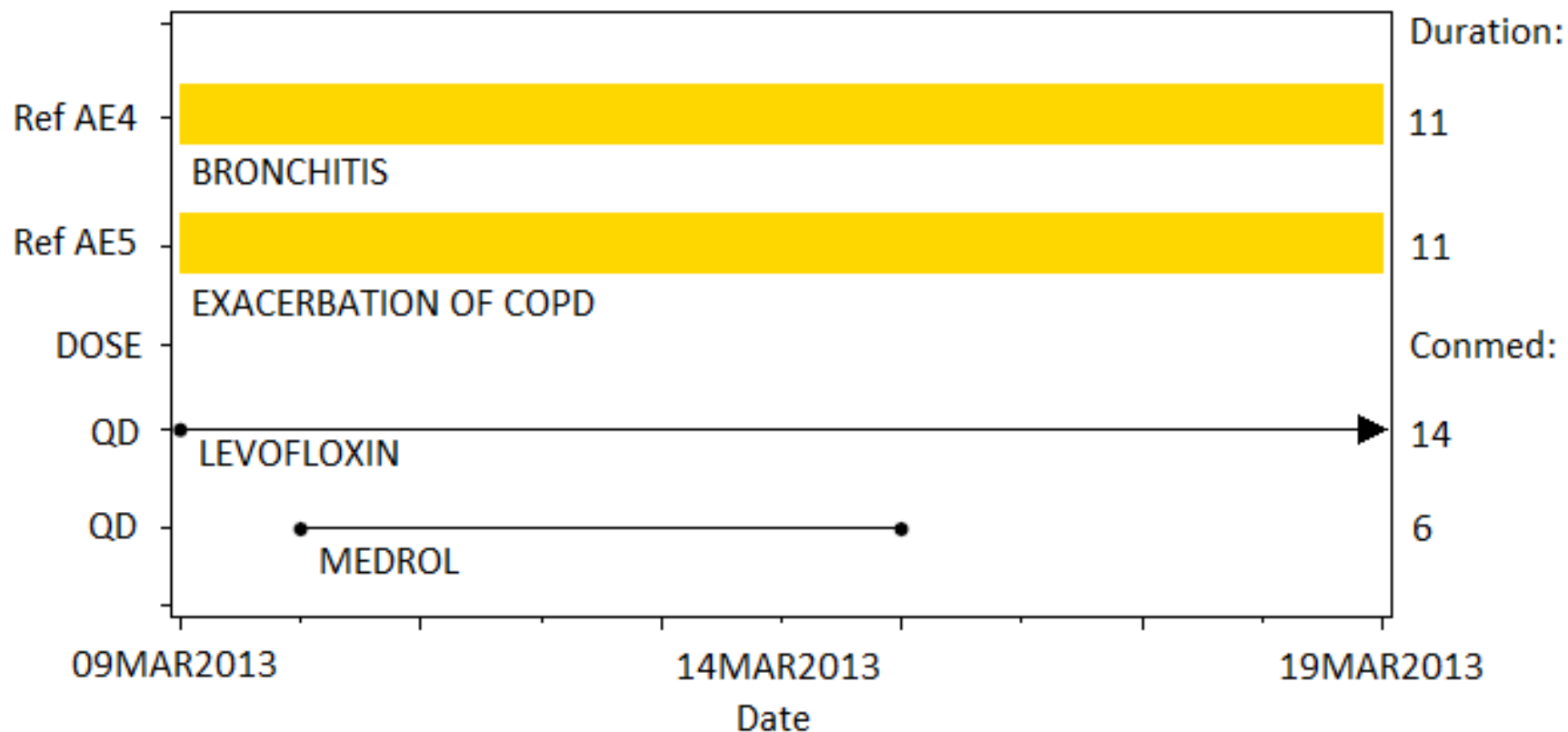
- Protocol defined:

Adverse event of worsening of symptoms of COPD requiring Antibiotics or Systemic Corticosteroids (moderate) or hospitalisation (severe)

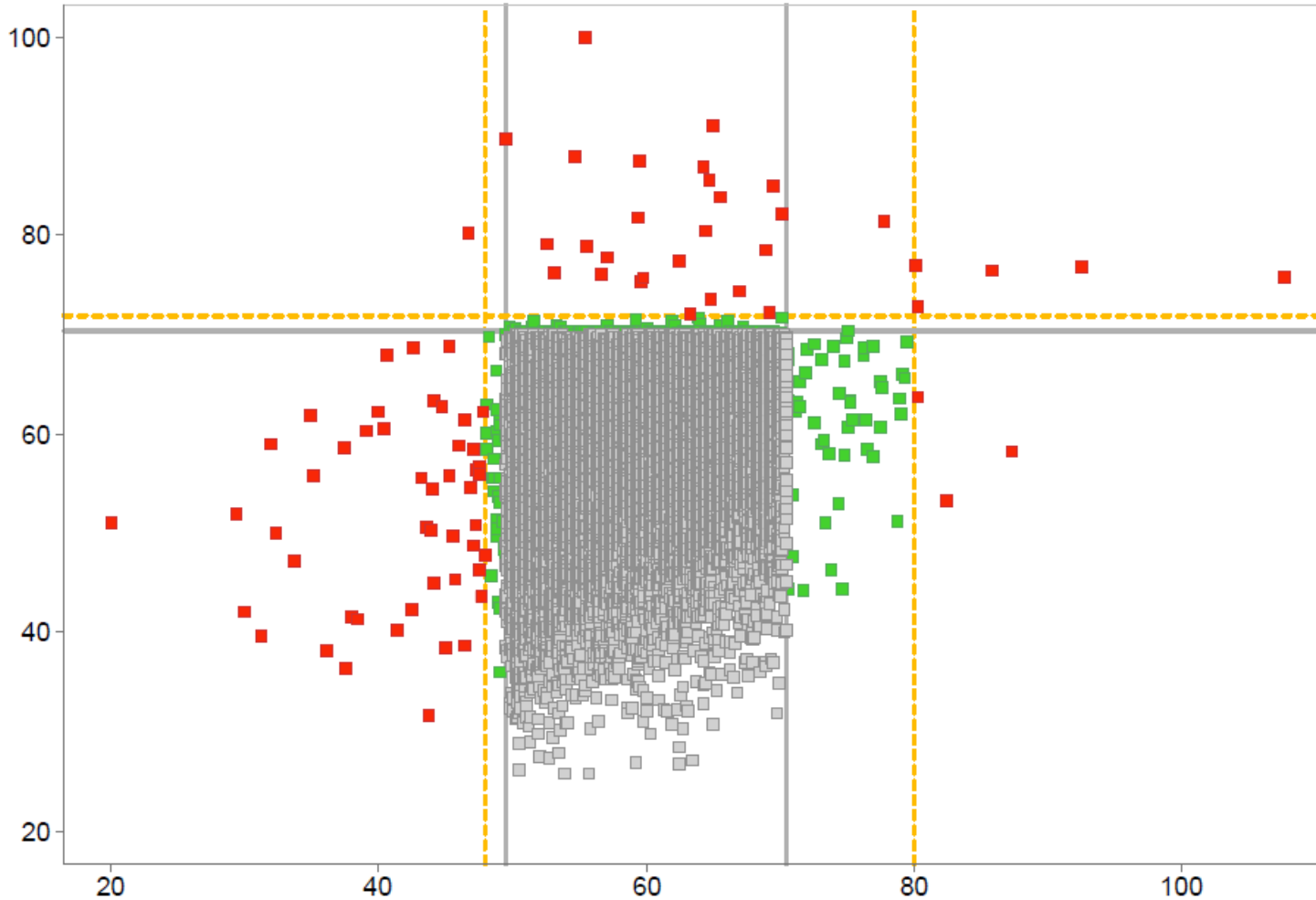
- Endpoints: *Rates and Time to First*
- Collected on adverse event CRF page:
“Did this AE meet the definition of a moderate / severe COPD exacerbation?”

Exacerbations Patient Profile

Subject 12345 Site 123 (United States: John Doe)



Subject eligibility tool



Summary

- Data flows in a trial from subject to TFLs
- Data cleaning benefits from involvement from statisticians who perform data analysis
- Visual tools ease review of data issues and allow for programming creativity

Thank you

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