M-085

Web App for Creating Pharmacometric Analysis Dataset Specification Form

Neelima Thanneer, Lu Chen, Baylea Boyle, Chengke Tang, Balaji Harikrishnan, Erin Dombrowsky

Clinical Pharmacology and Pharmacometrics, Bristol-Myers Squibb, Princeton, NJ, USA

Introduction

- The quality of the pharmacometric analysis dataset specification is crucial for pharmacometric programming, analysis, and eSub datasets.
- Currently, the specification is a word document and it's difficult to validate input in each field
- A new process is necessary to improve the quality and efficiency of the current specification.

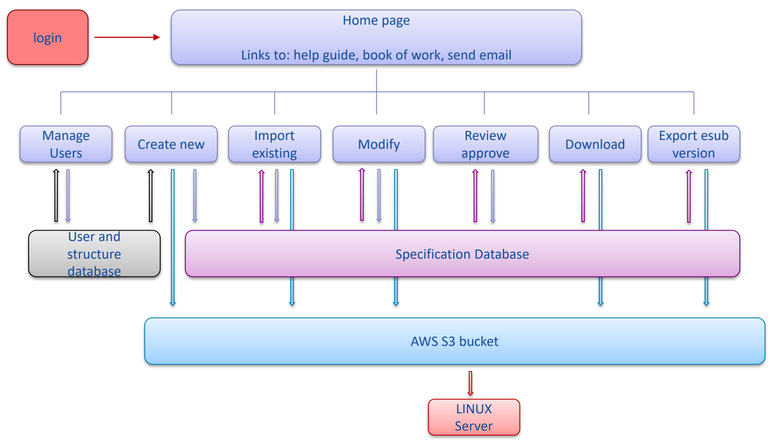
Objectives

- To standardize and pre-populate the pharmacometric analysis dataset specification form in order to minimize the number of iterations between programmers and pharmacometricians.
- To enable automation of information extraction from the specification and programming the dataset

Methods

- This web application is built with PHP, MySQL, UNIX Shell scripts and JavaScript
- It runs on Amazon Web Services (AWS) Elastic Beanstalk environment
- This application will write data into Amazon Relational Database Services (RDS)
- Any attachment and output files will be written to AWS S3 and transferred to Linux server

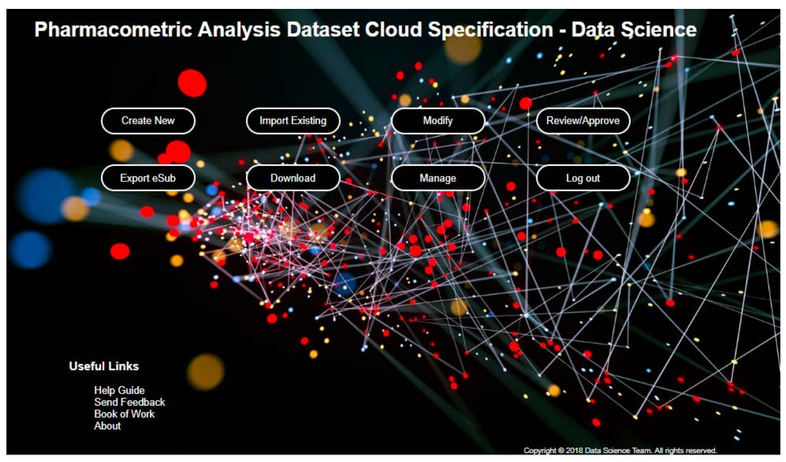
Functionalities:



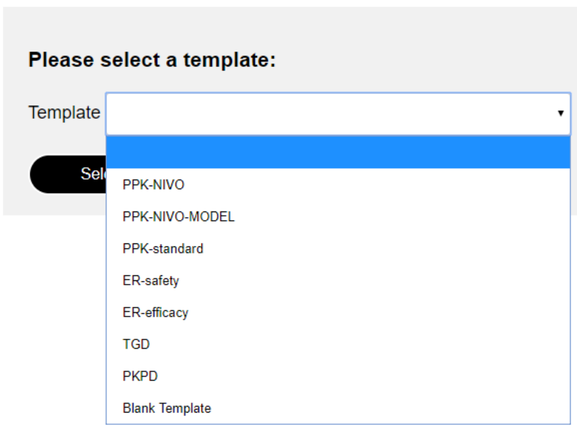
- This tool is designed to pre-populate the data structure, variable names, labels, units, derivations etc. based on the template the user selects.
- Templates for pharmacometric analysis datasets are built into the web application.
- Built-in checks ensure the quality of the specification, e.g. naming conventions, mandatory fields, duplicate variable names/labels and variable/label lengths.

Results

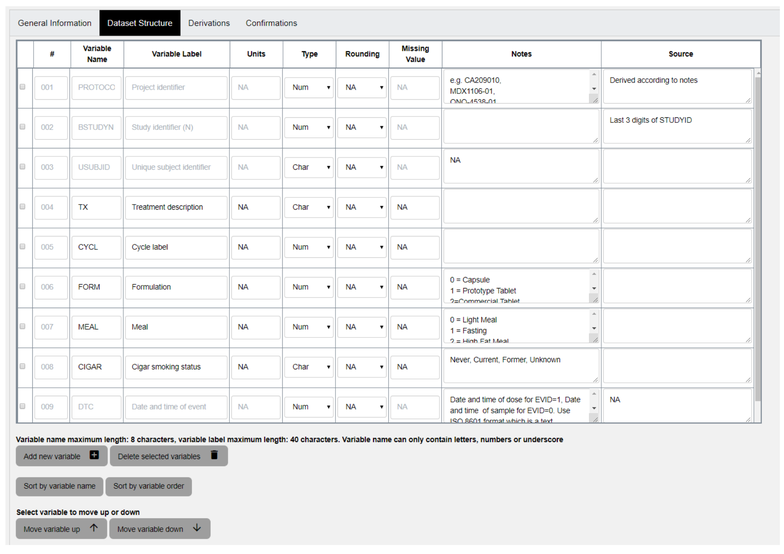
Application User Interface



Built in templates to select from

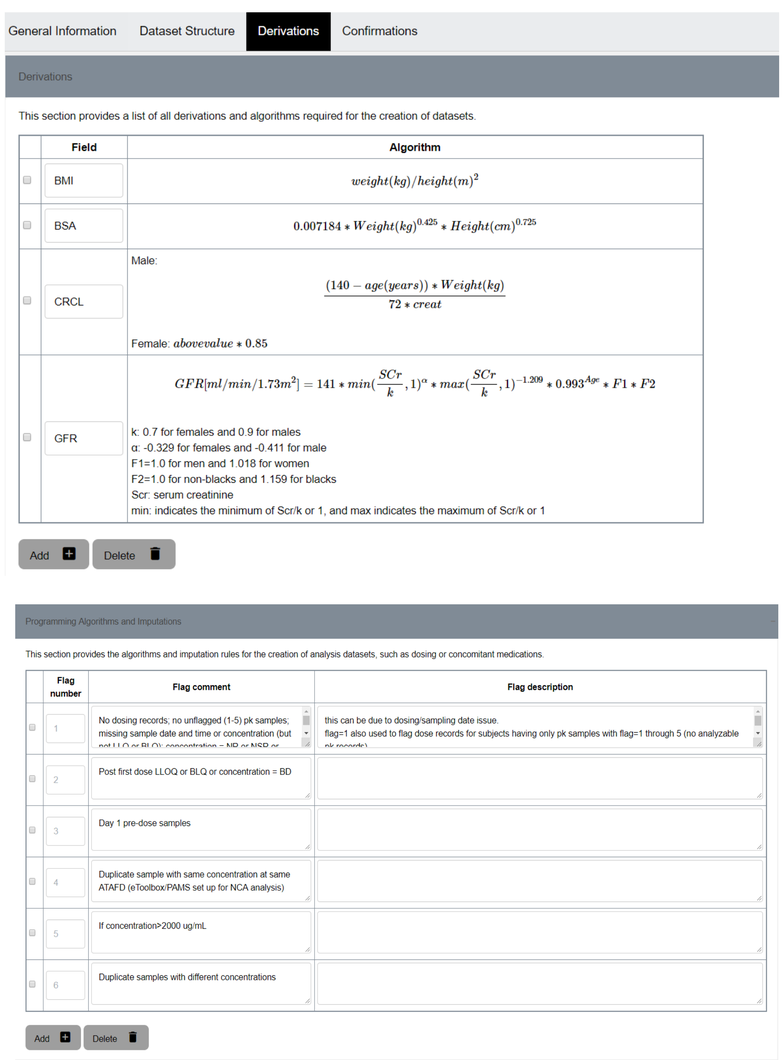


Auto populates dataset specification based on the selected template



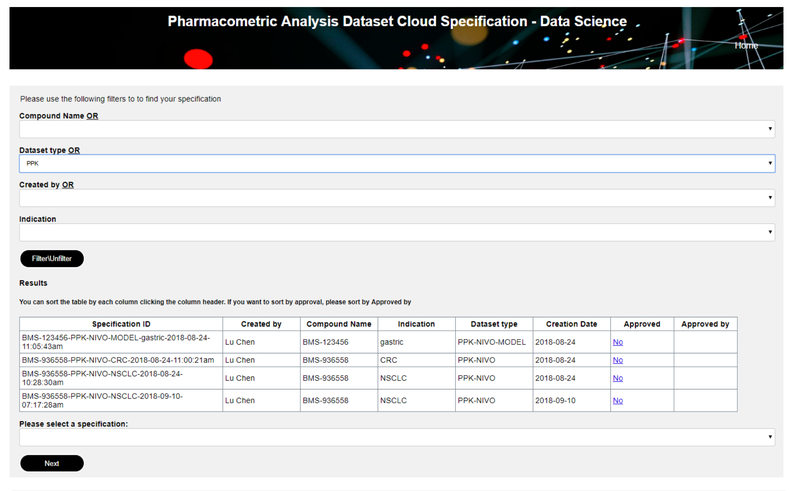
- To enforce standards some variables and attributes are made non-editable and greyed out
- Users can add new variables or select from optional variables list
- Can remove any non standard variable
- Can sort the variables, move them up/down

Pre-populates derivations, flags and imputations



- User's can add new derivations, flags and delete not applicable flags.
- User's can not delete standard flags

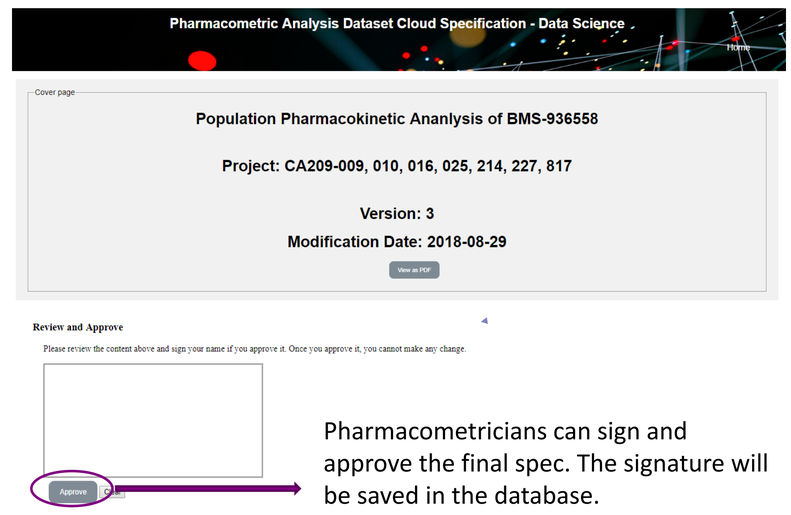
Filters to search the specification database



Import Exiting, Modify, Review/Approve, Export eSub specs for define.pdf

Download spec in PDF or CSV format to Linux server

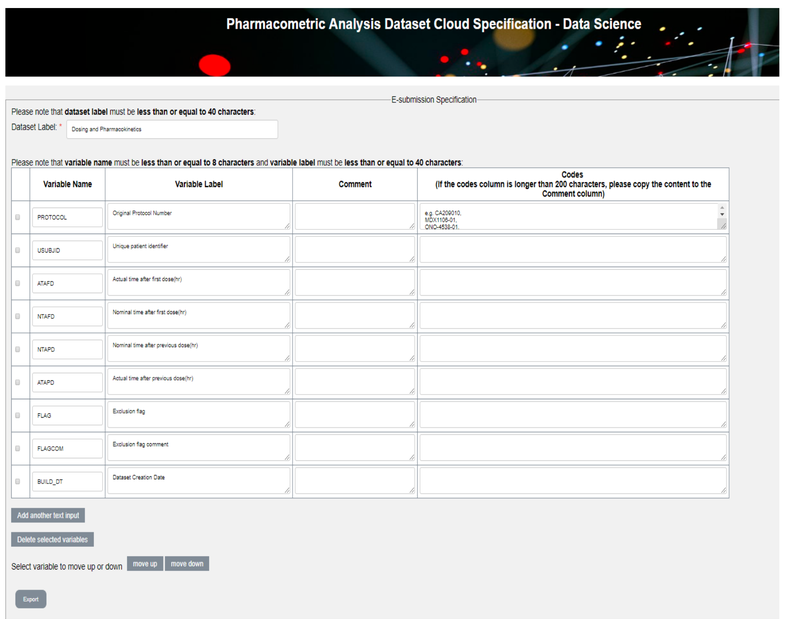
Review and approve the specification form



Pharmacometricians can sign and approve the final spec. The signature will be saved in the database.

- Spec can be reviewed in pdf and/or HTML format

Export eSub dataset spec for define.pdf creation



- Export eSub option creates and exports esub specs for the creation of define.pdf .

Conclusions

- This app has brought efficiency and quality in specification creation, enforced standards across projects and enables automation of dataset creation.
- The built-in templates eliminate the burden on pharmacometricians to manually populate all the standard variables, attributes, derivations, flags and imputation rules.
- Enables automation of define.pdf

Email: neelima.thanneer@bms.com

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