



BeiGene

Statistical Analysis Plan (SAP) Automation using Python

BeiGene Biometrics

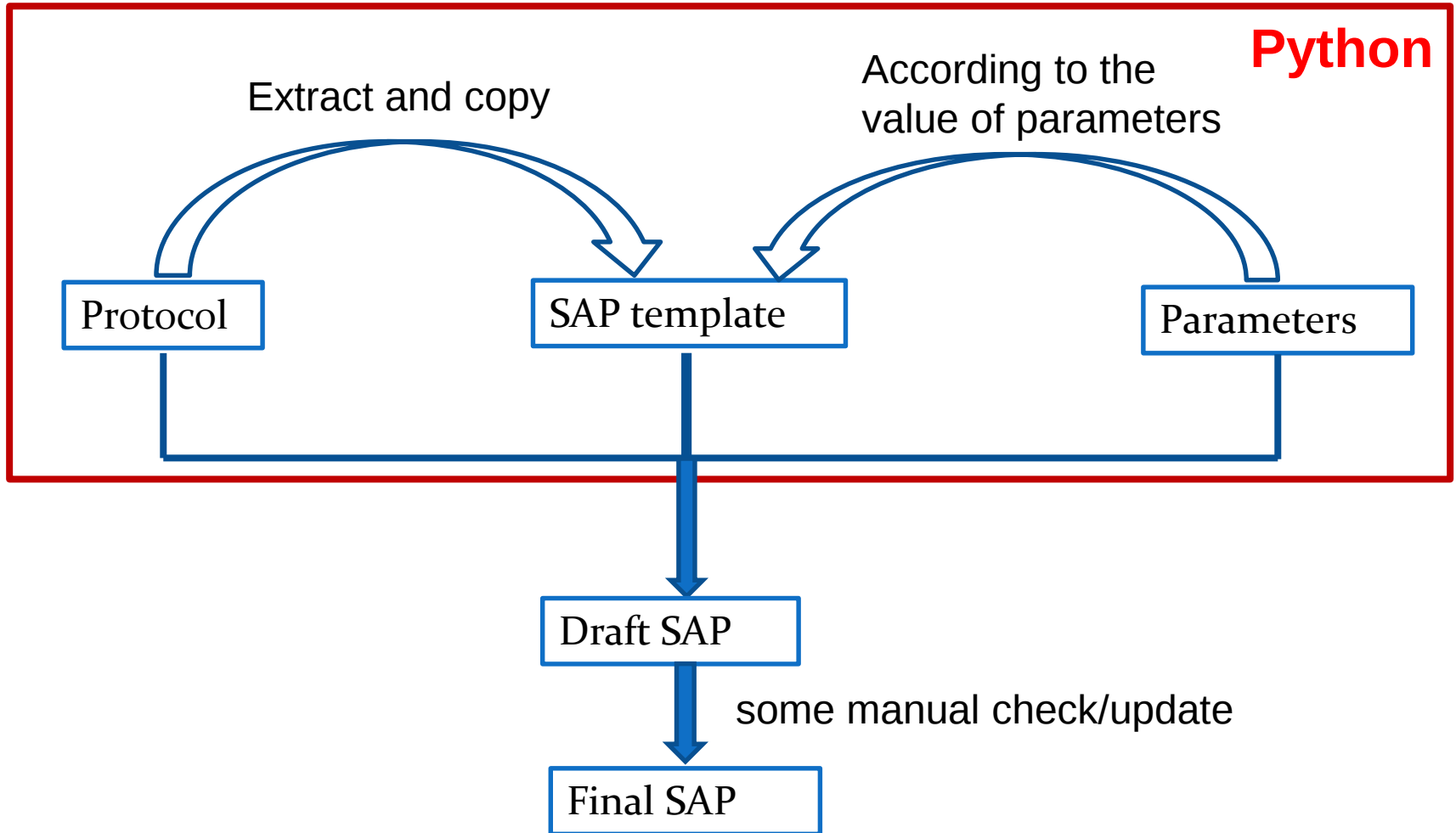
Aide Zhou, Jianfei Zheng, Han Cheng

17-May-2019

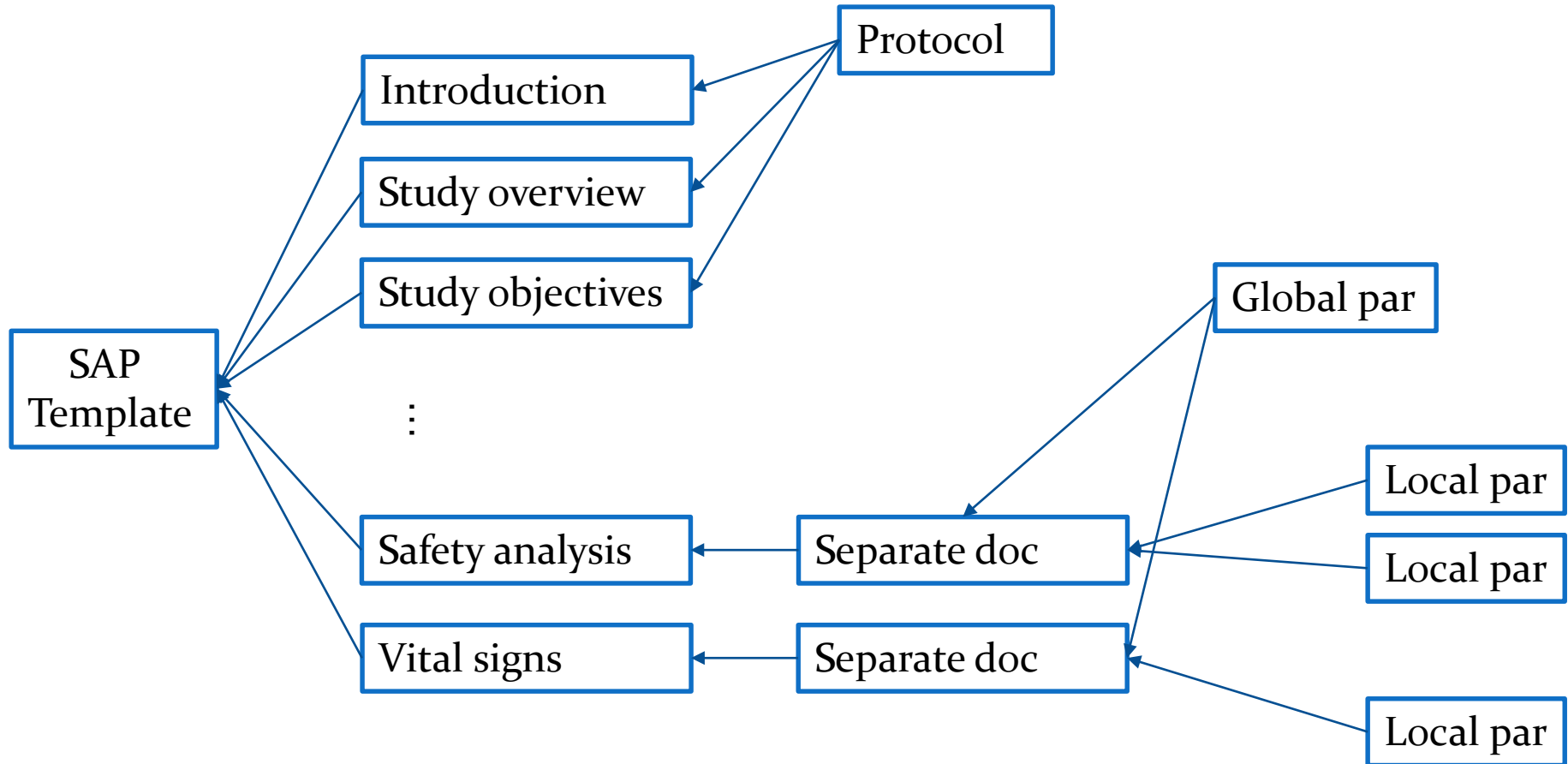
Background information

- Writing Statistical Analysis Plan (SAP) is somehow a time-consuming task for statistician.
- Some information are directly from Protocol
- Start from a company template
- Python

AUTOSAP process



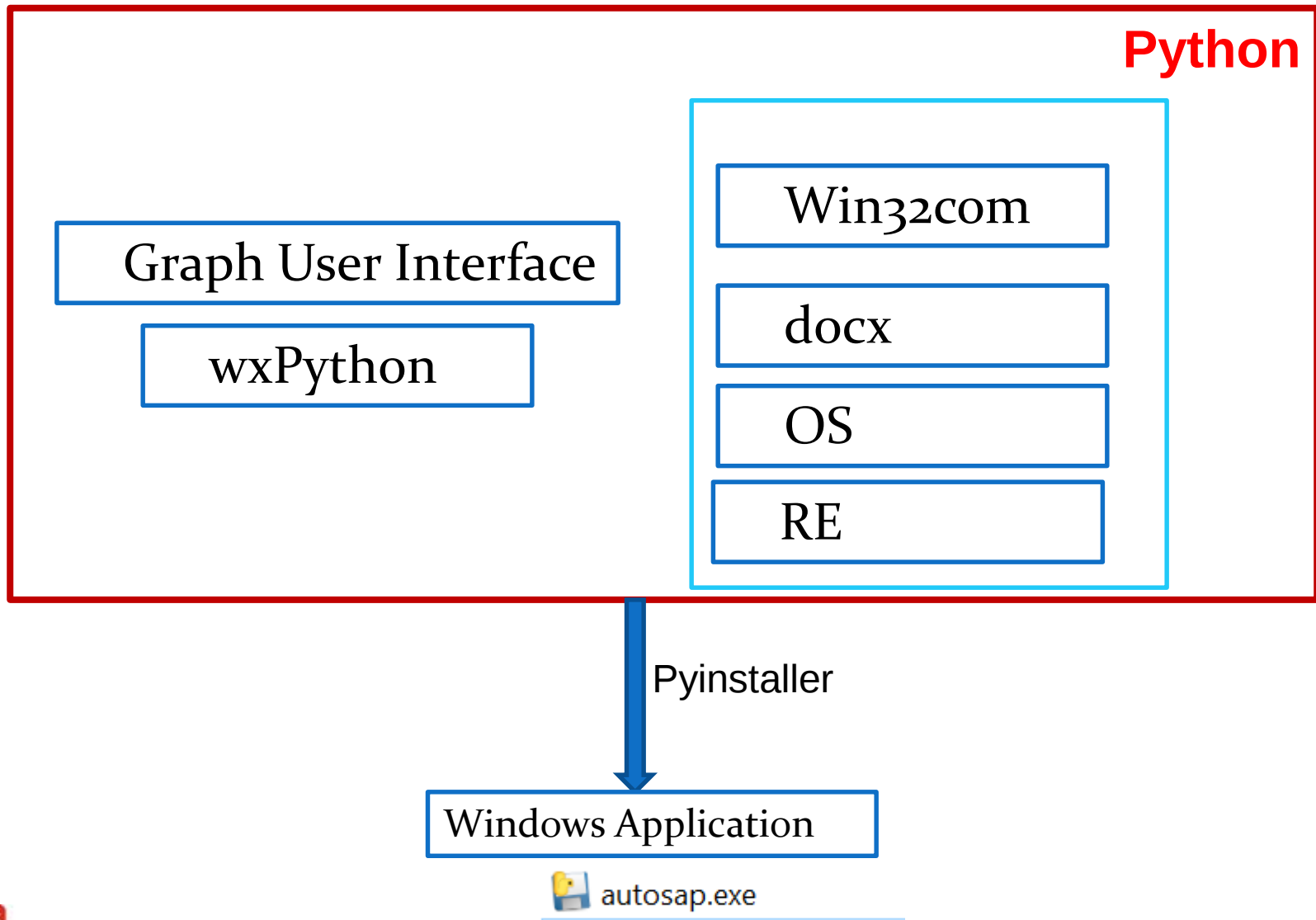
AUTOSAP process



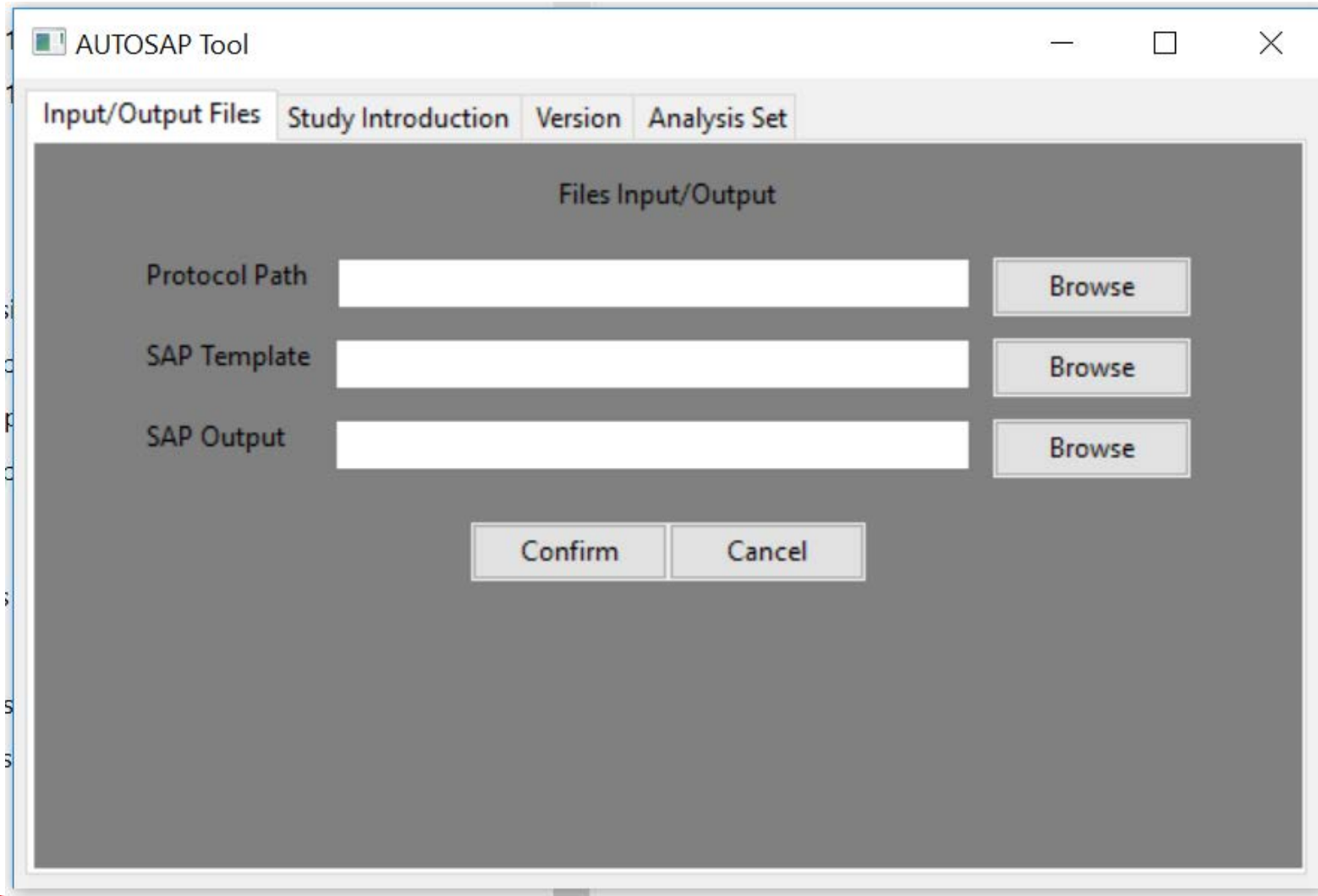
Sections extracted from protocol

- Cover page
 - Study protocol number
 - Study Protocol Title
- Study overview
- Study Objectives
 - Primary Objectives
 - Secondary Objectives
 - Exploratory Objectives
- Study Endpoints
 - Primary Endpoints
 - Secondary Endpoints
 - Exploratory Endpoints

AUTOSAP Program



Interface

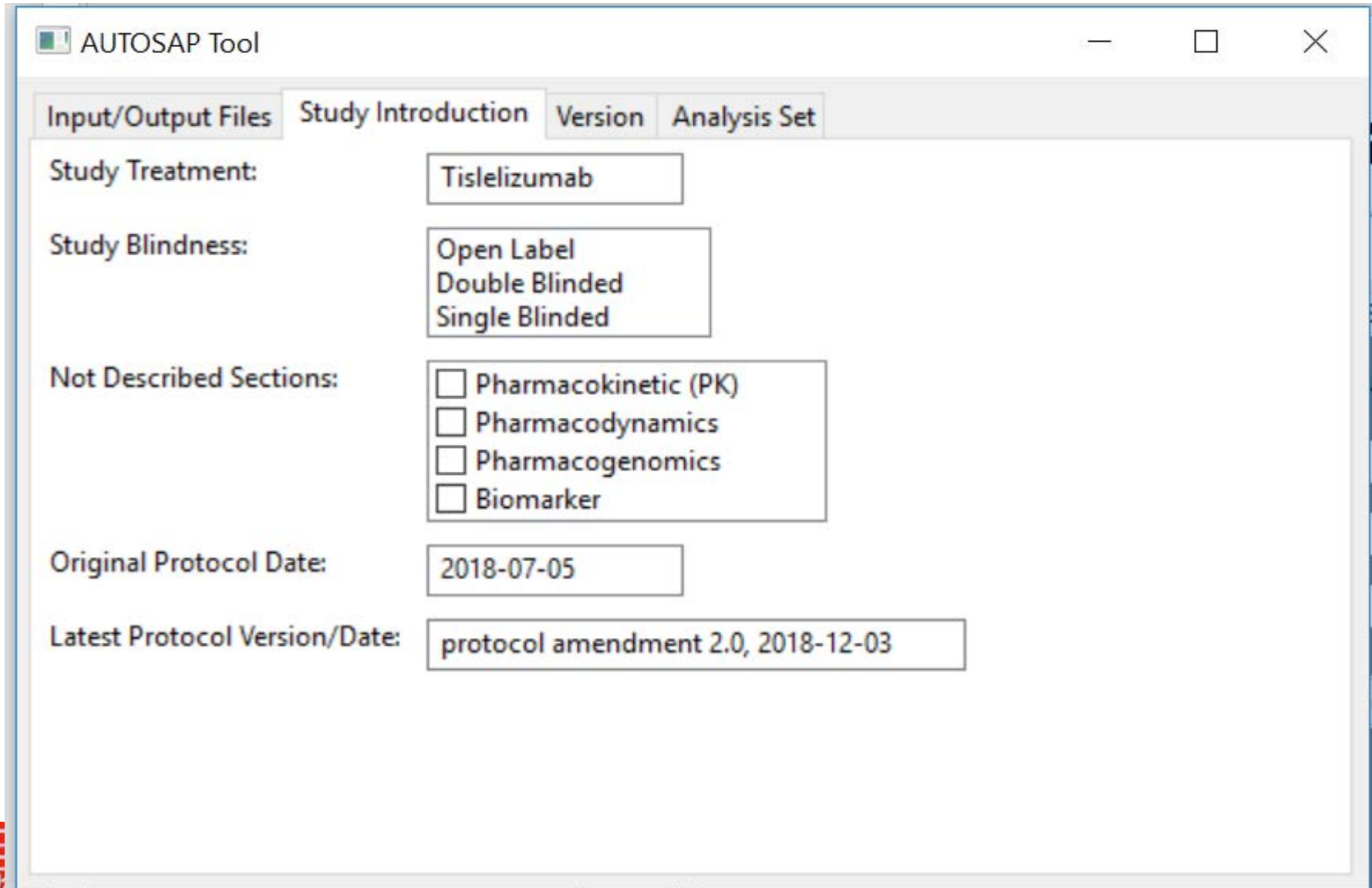


The screenshot displays the 'AUTOSAP Tool' window with the 'Input/Output Files' tab selected. The window has a title bar with standard minimize, maximize, and close buttons. Below the title bar, there are four tabs: 'Input/Output Files', 'Study Introduction', 'Version', and 'Analysis Set'. The main content area is titled 'Files Input/Output' and contains three rows of input fields with corresponding 'Browse' buttons:

- Protocol Path: Browse
- SAP Template: Browse
- SAP Output: Browse

At the bottom of the main content area, there are two buttons: 'Confirm' and 'Cancel'.

Interface



The screenshot displays the 'AUTOSAP Tool' window with the 'Study Introduction' tab selected. The interface includes a header bar with four tabs: 'Input/Output Files', 'Study Introduction', 'Version', and 'Analysis Set'. The 'Study Introduction' tab contains several input fields and a list of checkboxes. The 'Study Treatment' field is set to 'Tislelizumab'. The 'Study Blindness' field is set to 'Open Label', with 'Double Blinded' and 'Single Blinded' also listed as options. The 'Not Described Sections' field has four unchecked checkboxes: 'Pharmacokinetic (PK)', 'Pharmacodynamics', 'Pharmacogenomics', and 'Biomarker'. The 'Original Protocol Date' field is set to '2018-07-05'. The 'Latest Protocol Version/Date' field is set to 'protocol amendment 2.0, 2018-12-03'.

AUTOSAP Tool

Input/Output Files Study Introduction Version Analysis Set

Study Treatment: Tislelizumab

Study Blindness: Open Label
Double Blinded
Single Blinded

Not Described Sections:
☐ Pharmacokinetic (PK)
☐ Pharmacodynamics
☐ Pharmacogenomics
☐ Biomarker

Original Protocol Date: 2018-07-05

Latest Protocol Version/Date: protocol amendment 2.0, 2018-12-03

Interface

AUTOSAP Tool

Input/Output Files Study Introduction Version Analysis Set

MedDRA version: 18.1

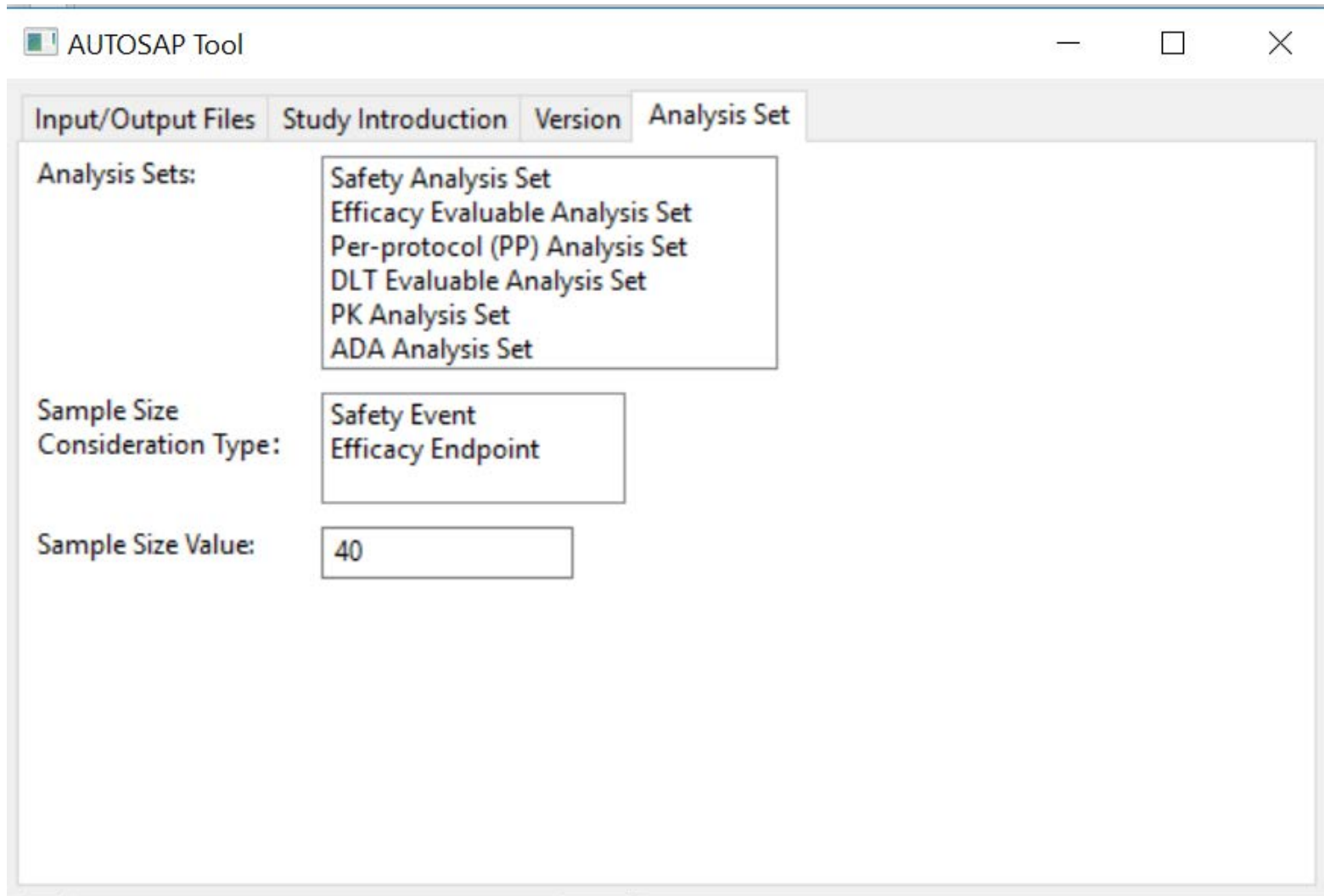
CTCAE version: v4.03

WHODD version: 3Q2016

RECIST version: v1.1

SAS version: 9.4

Interface



The screenshot displays the AUTOSAP Tool interface. The window title is "AUTOSAP Tool". The "Analysis Set" tab is selected, showing a list of analysis sets: Safety Analysis Set, Efficacy Evaluable Analysis Set, Per-protocol (PP) Analysis Set, DLT Evaluable Analysis Set, PK Analysis Set, and ADA Analysis Set. Below this, the "Sample Size Consideration Type" is set to "Safety Event" and "Efficacy Endpoint". The "Sample Size Value" is set to 40.

AUTOSAP Tool

Input/Output Files Study Introduction Version Analysis Set

Analysis Sets:

- Safety Analysis Set
- Efficacy Evaluable Analysis Set
- Per-protocol (PP) Analysis Set
- DLT Evaluable Analysis Set
- PK Analysis Set
- ADA Analysis Set

Sample Size Consideration Type:

- Safety Event
- Efficacy Endpoint

Sample Size Value:

40

Acknowledgement

- Biostatisticians
 - Tony Guo; Jeannie Qiu, Jianfei Zheng
- Han Cheng, Huadan Li, Eric Li

Thank you