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Automatic Safety Slide Deck Generator



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Business Use Case

Health Authorities require Sponsors to monitor cumulative study data for patterns and trends that can hint at possible unknown toxicities of drugs still in development.

Old process

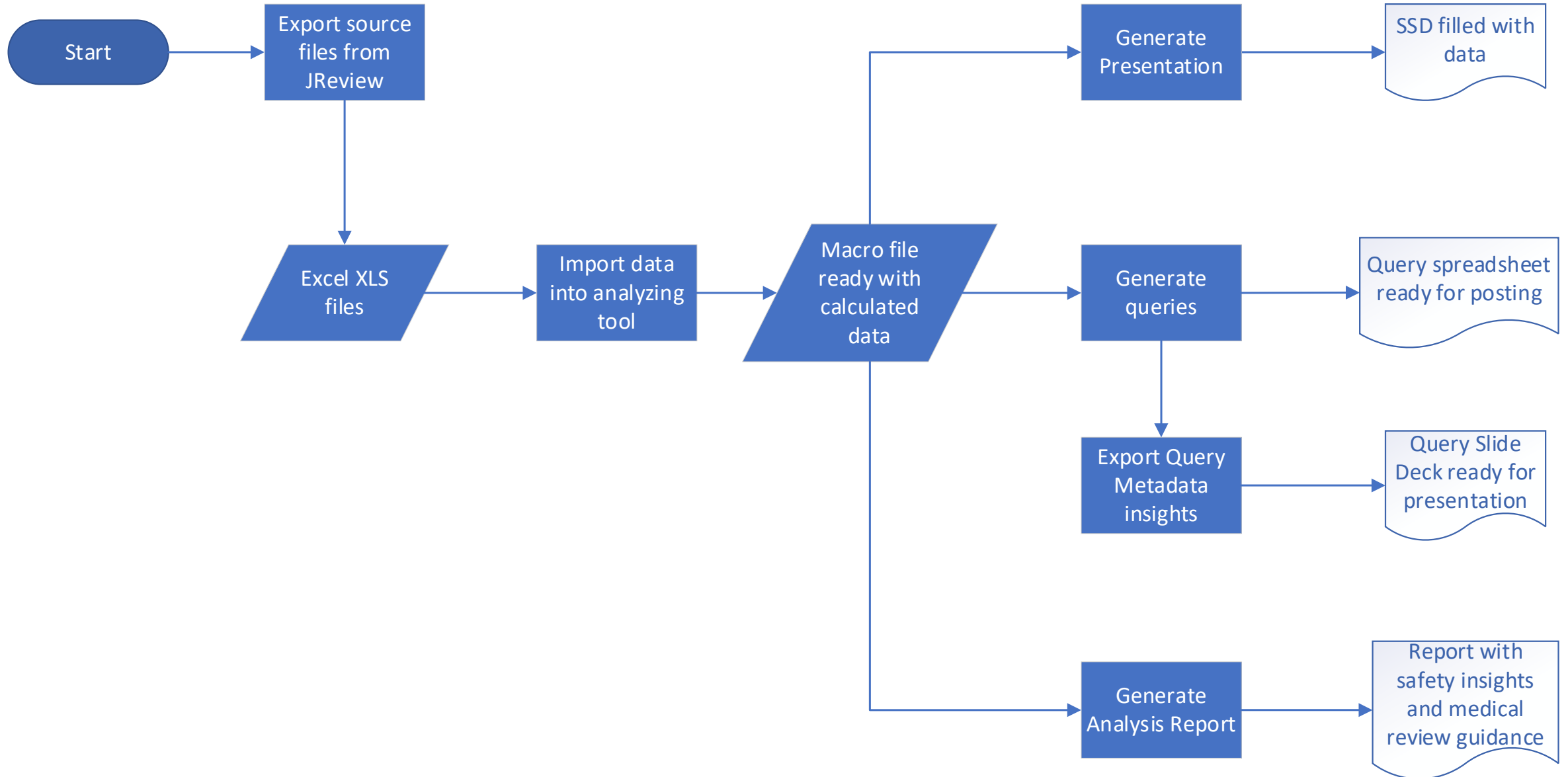
- Medical personnel responsible for all process steps/tasks
 - Cumulative data review
 - Query writing/posting/data cleaning
 - Processing JReview data into meaningful TLFs that convey the findings from data review
 - Writing detailed report describing those findings and conclusions
 - Report further circulates through multiple reviewers for approval/several rounds back and forth until finalized.
- Medical personnel → time spent on non-medical tasks

New proposal

- In house Excel-based VBA prototype
 - Ingests key source files from JReview
 - Data processing/variable calculation
 - Standardized TLFs built upon calculated variables in the background
 - TLFs are output to PPT slide deck ready for presentation across stakeholders
 - Data inconsistencies translated into automated queries ready to be posted
 - Data insights further made available as additional reports/decks for presentation
- Medical personnel → focus on data review only

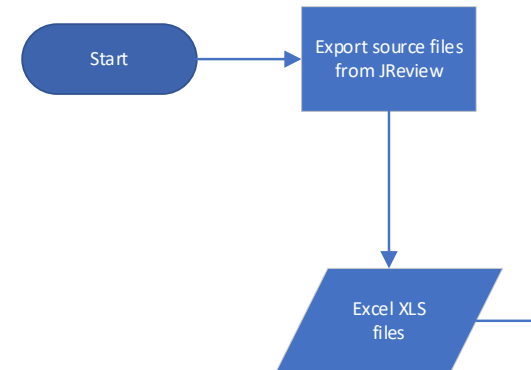
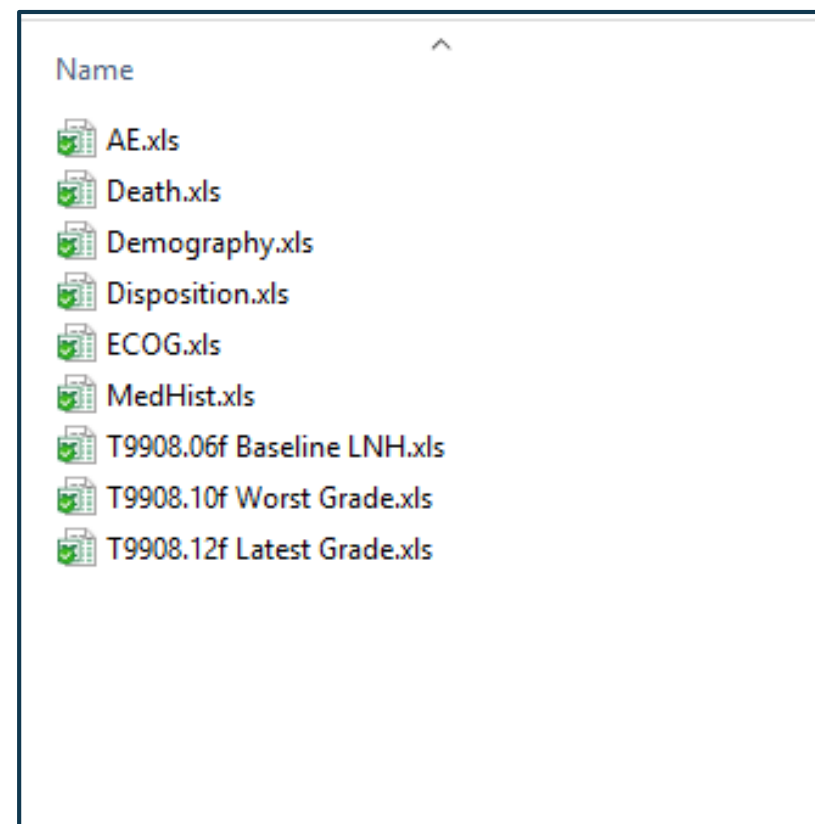
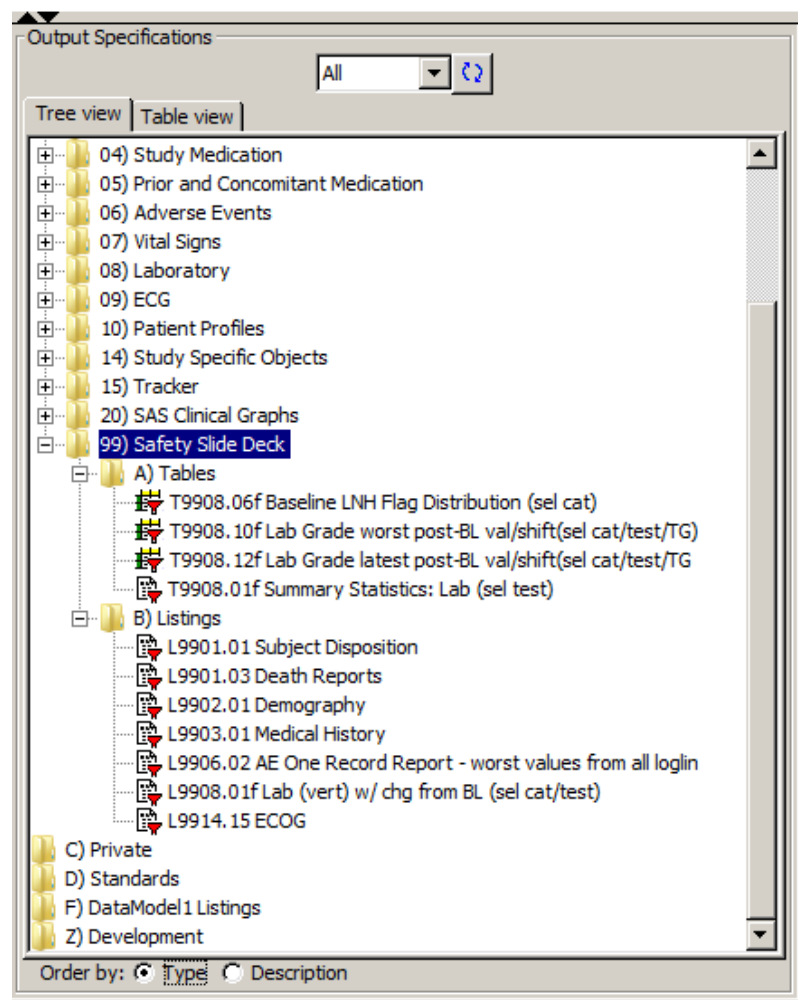


Prototype Process flowchart





Source files exported from JReview





Data importing



File Home Layout Tell me what you want to do

Clipboard Font Alignment Number Styles Cells Editing

Dear User,

This is an automatic Safety Slide Deck generator. To use this tool you will need to extract the following listings from JReview:

Mandatory	Optional
L(S)99.01 Subject Disposition	L(S)99.07 ECOG status
L(S)99.02 Death Reports	T(S)99.02 Baseline LNH Flag Dist.
L(S)99.03 Demography	T(S)99.03 Lab Grade worst post BSL
L(S)99.04 Medical History	T(S)99.04 Lab Grade latest post BSL
L(S)99.05 AE One Record Report	Custom AESIS
	L14.18 Subjects on Treatment
	SMQ Listing

When all these listings are available you will need to follow the next steps in order to generate a Safety Slide Deck:

1. Import the required listings into the tool by clicking the **"Import and Analyze Data"** button. You will have to select all the listings at once. Make sure you have all the necessary listings available. Once the importing is done you will be prompted to save the file. The variables will be calculated in the background. A notification will appear when everything is done.
2. Generate the Safety Presentation by clicking on the **"Generate Presentation"** button. This will open a window asking you to open the Presentation template which is provided with this tool. Once open all the variables will be inserted in the template. At the end of this procedure you will be able to adjust the tables/text as you consider necessary and save the file.

Additional function:

If there are some data errors because the data is not "clean" you can generate queries by clicking the **"Generate Queries"** button. New sheets will be created with all the relevant queries. The "Query location" tab shows on which CRF page these are expected to be posted and the "Query Reason" tab displays the reason why the query was raised. Sometimes a Link to Rave can also be provided. Once queries are generated, you can export a short Query Report by clicking the **"Generate a Queries Report"** button and selecting the Query Summary Report template provided with this tool

Control

Import and Analyze Data

Reselect the Labs

Generate Presentation

Add only Labs to the PPT

Generate Queries

Medical Review Analysis

Generate a Queries Report

Export Queries to Databank



Safety Slide Deck Template Walkthrough

Microsoft PowerPoint interface showing the Safety Slide Deck Template Walkthrough.

The slide deck is titled "Safety Slide Deck" and features the Bayer logo. The main content area displays the following text:

Study #: Enter IMPACT number

Study name: Enter study short name

Date of preparation: DD-MM-YYY (enter date when slide deck is ready to be presented to CDL and GSL)

The slide deck is marked as **RESTRICTED** in the bottom right corner.

The slide deck is divided into sections:

- 1. Safety Slide Deck
- 2. Study Status
- 3. Demographics
- 4. 10 most frequent Medical History MedDRA PT
- 5. Overview of AEs
- 6. 10 most frequent TESABs

The interface includes a ribbon with tabs: File, Home, Insert, Draw, Design, Transitions, Animations, Slide Show, Review, View, and Classification. The status bar at the bottom indicates "Slide 1 of 18" and "English (United States)".



Safety Slide Deck Presentation Deck Generation

Macro file
ready with
calculated
data

Generate
Presentation

SSD filled with data

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Buttons available in the interface:

- Import and Analyze Data
- Reselect the Labs
- Generate Presentation
- Add only Labs to the PPT
- Generate Queries
- Medical Review Analysis
- Generate a Queries Report
- Export Queries to Databank



Safety Slide Deck Presentation Deck Walkthrough

File Home Insert Draw Design Transitions Animations Slide Show Review View Classificat

Clipboard Slides Font Paragraph Drawing Editing

Share Comments

1

2

3

4

5

6

Safety Slide Deck

Study #: Enter IMPACT number

Study name: Enter study short name

Date of preparation: DD-MM-YYY (enter date when slide deck is ready to be presented to CDL and GSL)

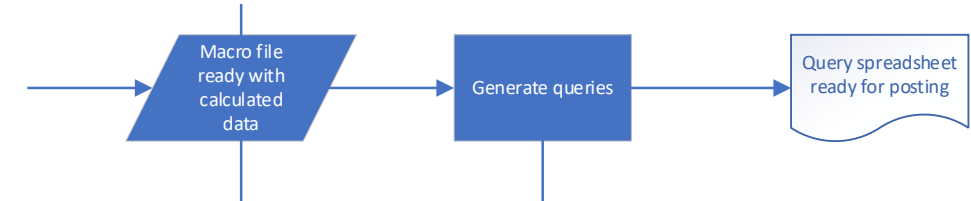
STUDY: xDEMO / Slide Deck v.1.0 / DD-MM-YYYY

RESTRICTED

Slide 1 of 26 English (United States) 114%



Query Management



The screenshot shows a Microsoft Excel spreadsheet with a text box containing instructions for using the Safety Slide Deck generator. The text box is titled "Dear User," and contains the following text:

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The interface also features a sidebar with the following buttons:

- Import and Analyze Data
- Generate Presentation
- Generate Queries
- Generate a Queries Report
- Export Queries to Databank
- Reselect the Labs
- Add only Labs to the PPT
- Medical Review Analysis

The bottom of the spreadsheet shows a row of tabs: Control, AE, Death, Demography, Disposition, ECOG, MedHist, Lab Baseline, Lab Worst Change, Lab Latest Change, AE Description, and a plus sign for additional tabs. The status bar at the bottom indicates "Select destination and press ENTER or choose Paste".



Query Metadata Report Presentation

Generate queries

Export Query
Metadata insights

Query Slide Deck
ready for
presentation

File Home

Clipboard: Paste, Copy, Format Painter

Font: Calibri, 11, A⁺, A⁻, Bold, Italic, Underline, Text Color, Background Color

Alignment: Wrap Text, Merge & Center

Number: General, Currency, Percentage, Decimals, Fractions, Scientific, Text, Custom

Conditional Formatting: Format as Table, Neutral, Calculation, Check Cell, Explanatory...

Styles: Normal, Bad, Good, Followed Hy...

Cells: Insert, Delete, Format

Editing: AutoSum, Fill, Clear, Sort & Filter, Find & Select

Share, Comments

CAN'T SAVE: There was a problem saving and AutoSave was disabled. Please Save As or close and reopen the file. Save As...

L12

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Control Queries DoubleCheck Queries AE Death Demography Disposition ECOG MedHist Lab Baseline Lab Worst Change ...

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Generate Queries

Medical Review Analysis

Generate a Queries Report

Export Queries to Databank



Medical Review Report Generation and Walkthrough

Macro file
ready with
calculated
data

Generate Analysis
Report

Report with safety
insights and medical
review guidance

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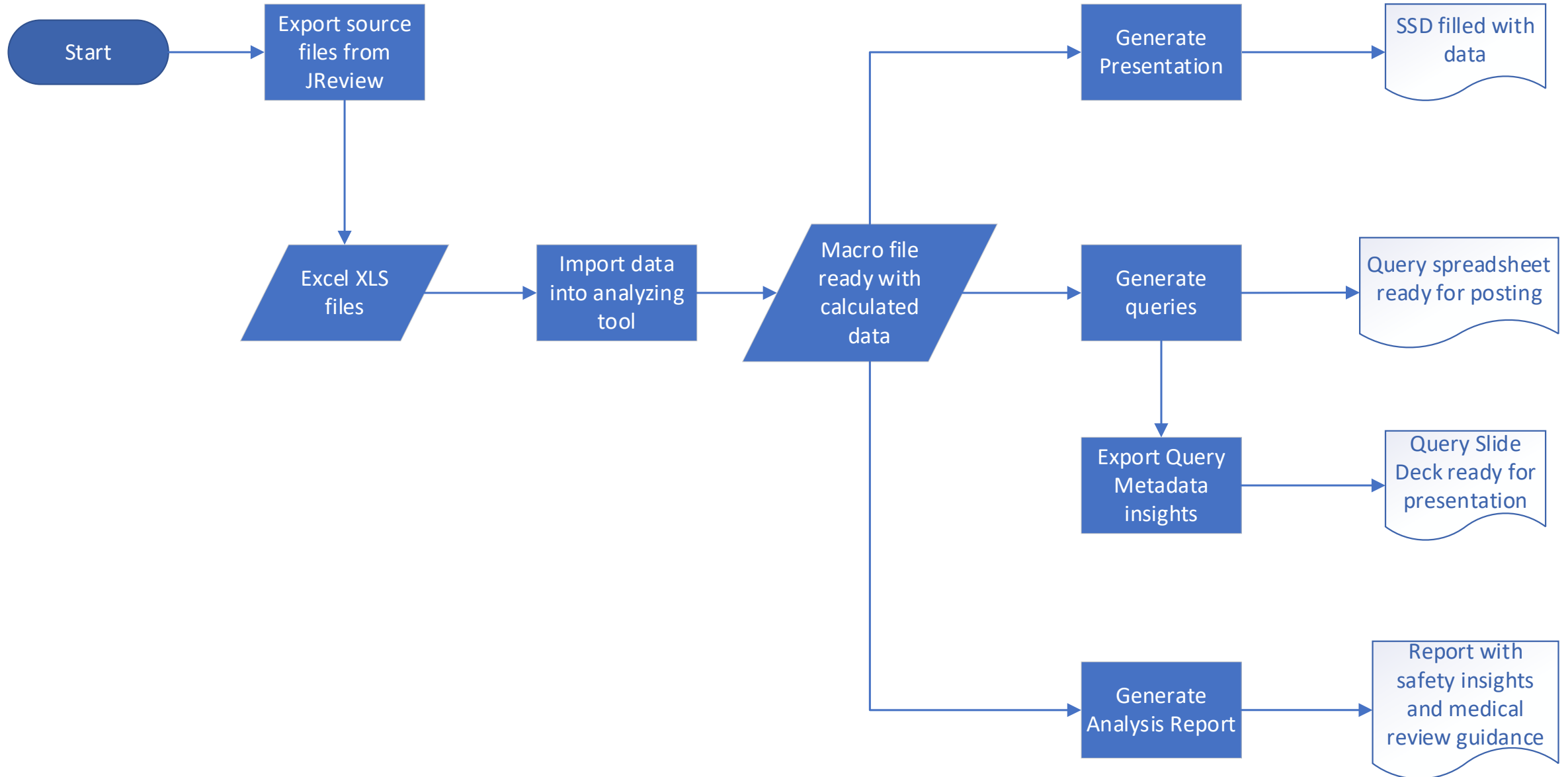
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Control MR_MasterTable MR_Summary Queries DoubleCheck Queries Query Summary AE Death Demography Disposition ECG ...

Select destination and press ENTER or choose Paste



Prototype Process flowchart





Thank you!

