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!!Say No to Stale Data!!

Implementation of automated GxP data pipelines using KNIME

Sumitomo Pharma
Innovation today, healthier tomorrows

Oct 30th, 2024

Agenda

- Introduction to Sumitomo Pharma America
- Explore Traditional Data Flow
- Proposal of New Data Flow at SMPA
- Use Cases of KNIME at SMPA
- Components Built by SMPA
- GxP Validation Process

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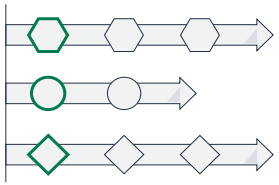
About Sumitomo Pharma America, Inc. (SMPA)

We are curious, bold, and share a passion for thinking *differently.*

Our Focus Areas

We accelerate scientific and therapeutic breakthroughs addressing areas of critical need.



High Impact Portfolio

We aim to address a wide range of conditions where treatment options remain limited or nonexistent.

Building on a Deep Sumitomo Pharma Heritage

Our parent company, Sumitomo Pharma Co., Ltd., was established in 1897 and has an extensive history of supporting health and wellbeing.

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Our Areas of Focus

Women's Health

Urology

Oncology

Neurology

Psychiatry

Rare Disease

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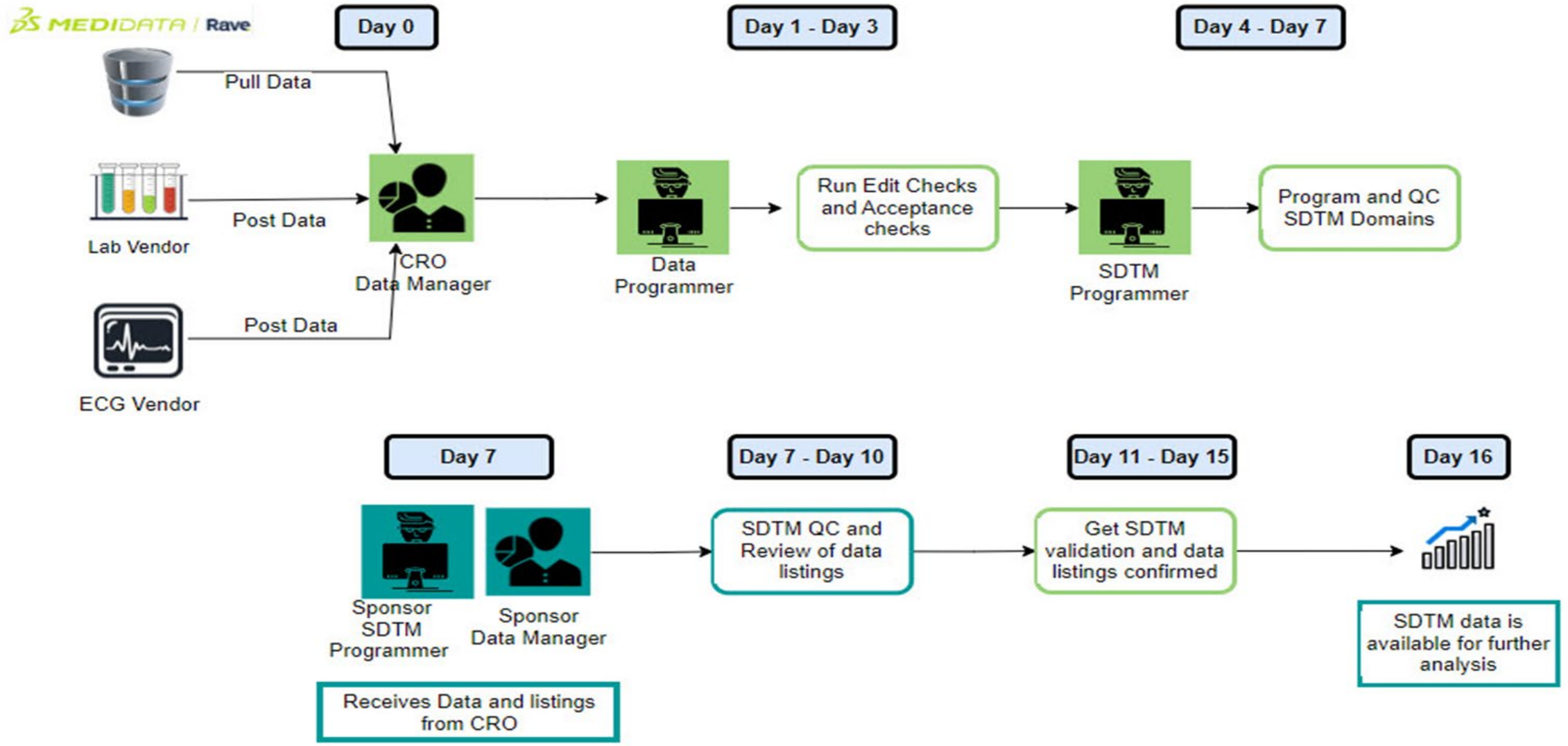
Traditional Data Flow



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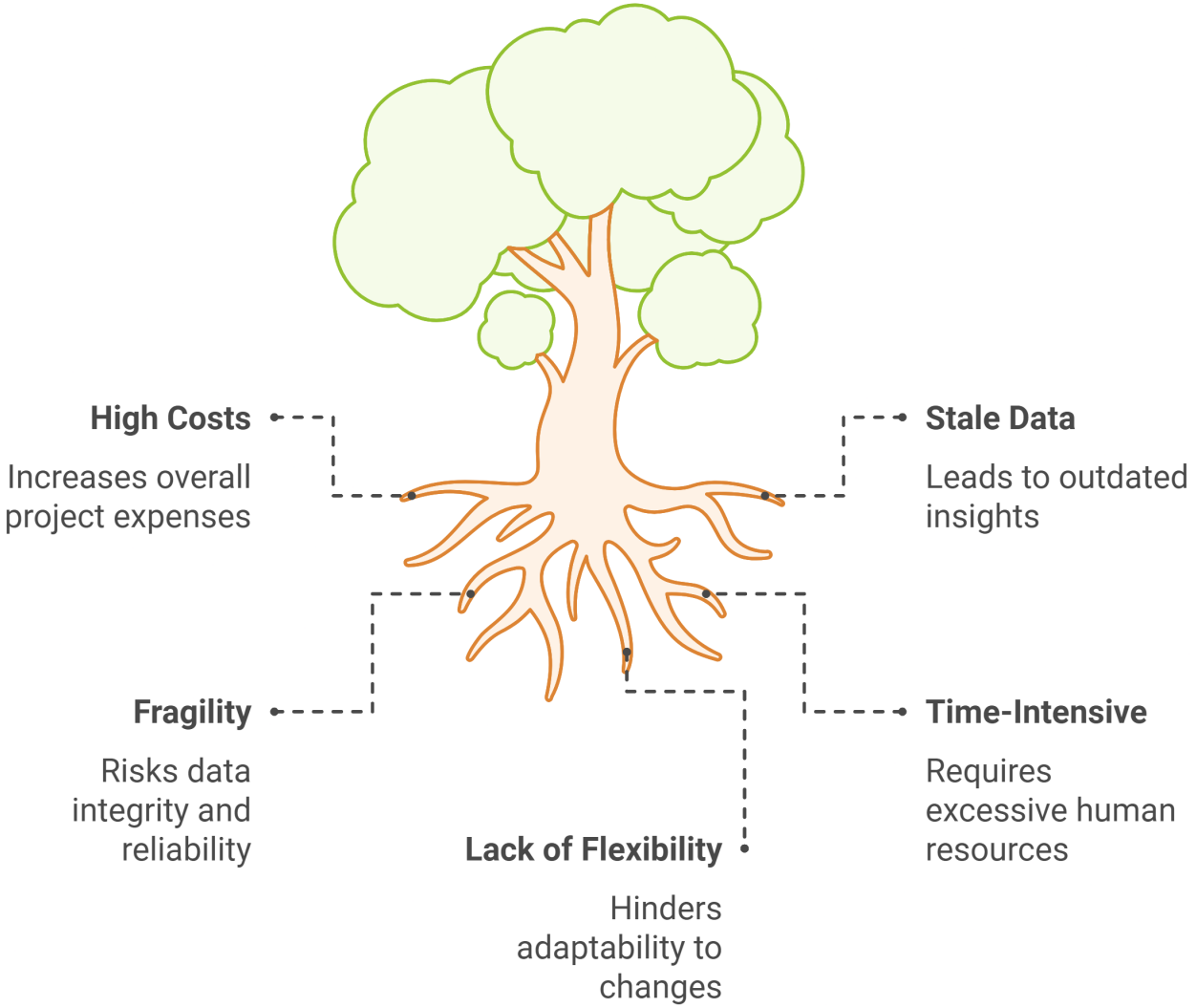
Challenges in Traditional Data Flow



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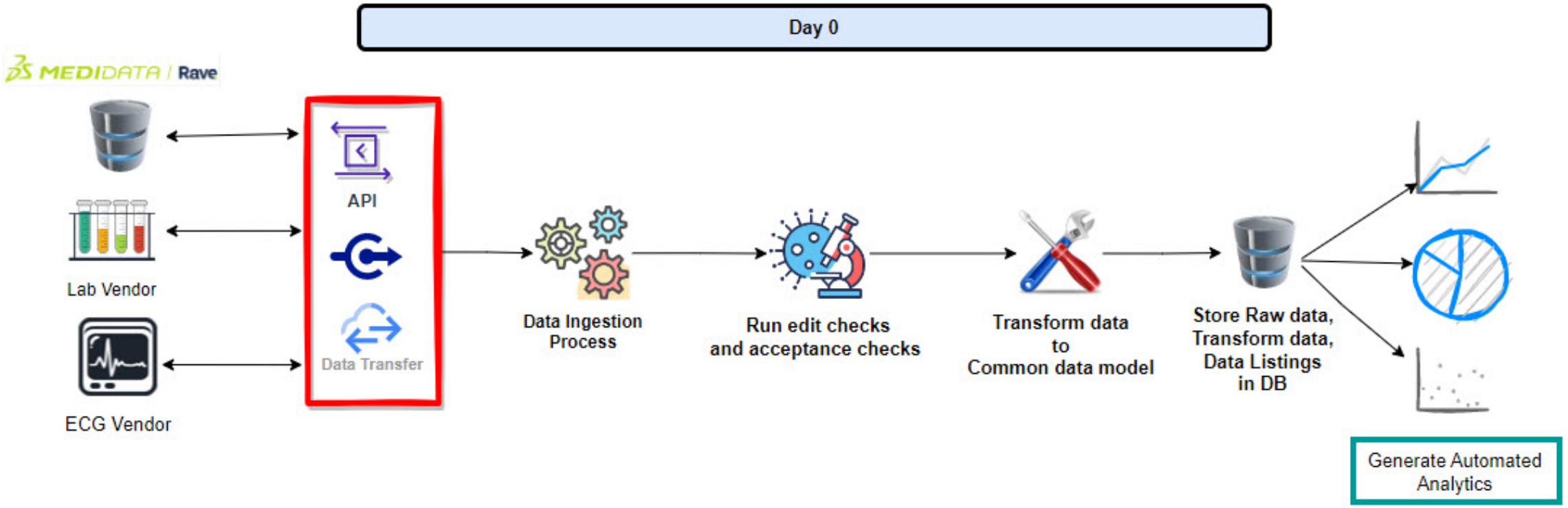
New Data Flow at Sumitomo Pharma America for Raw Data



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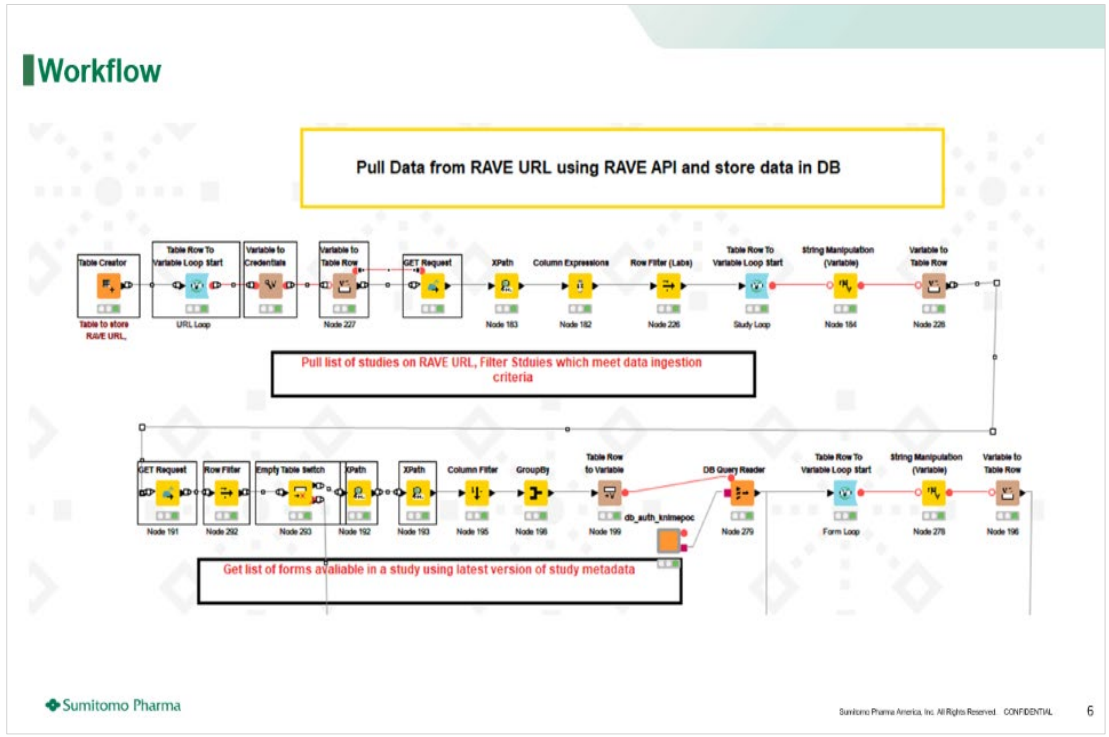
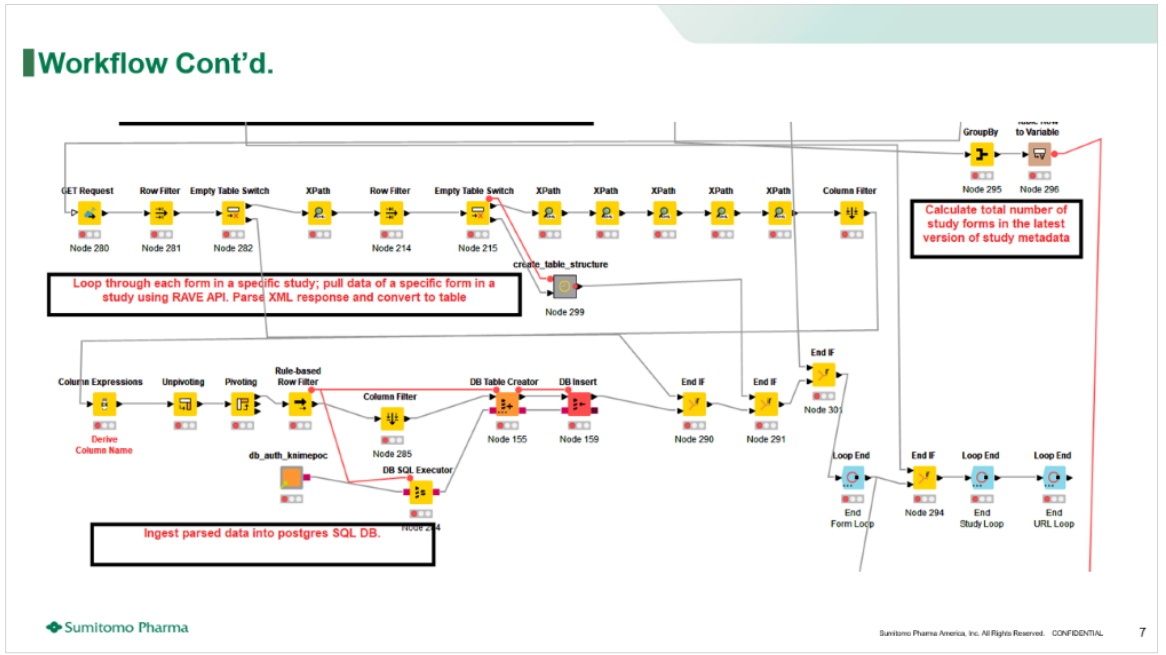
Use Case 1 – Ingest Data from RAVE

- Built and scheduled a KNIME workflow to pull data from RAVE URLs for the studies published on them on a daily frequency.
- RAVE web services provide data in XML format, workflow will transform data into tabular structure and store in SMPA data lake.





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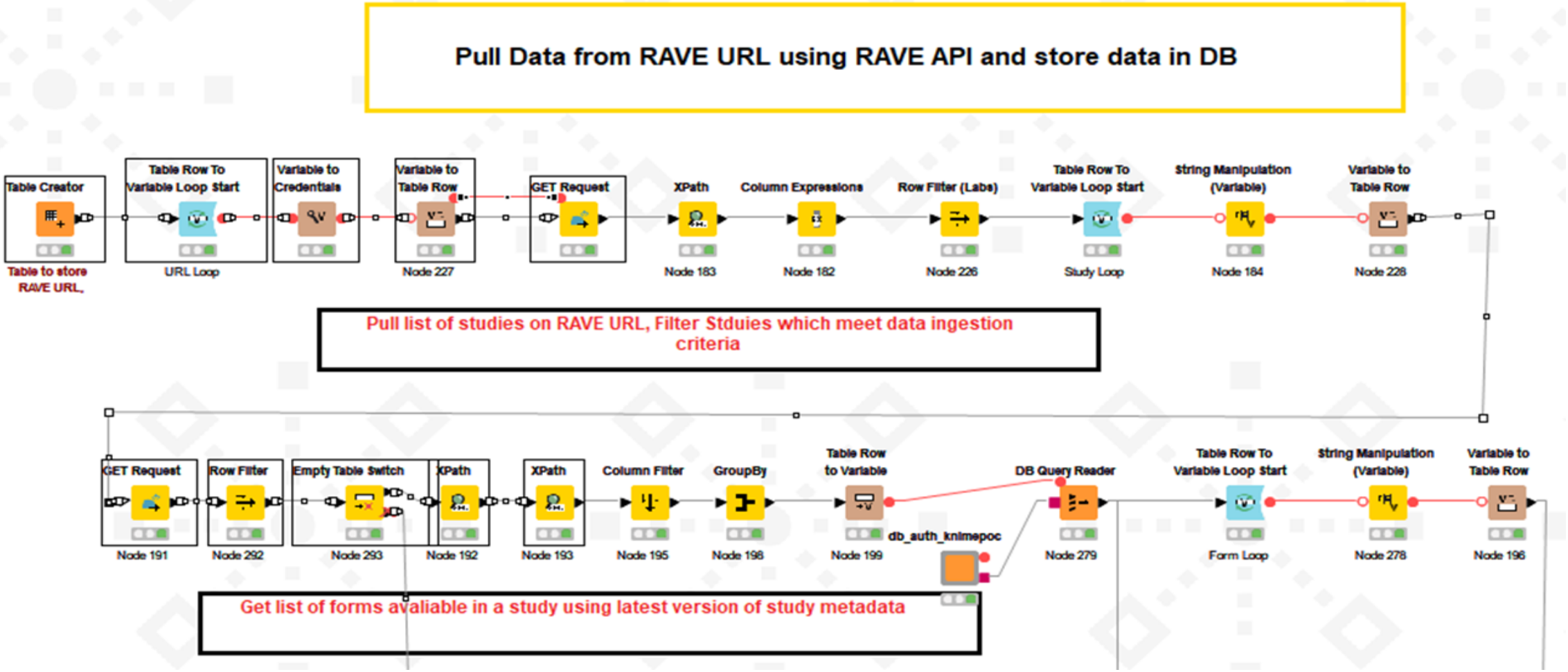
Workflow



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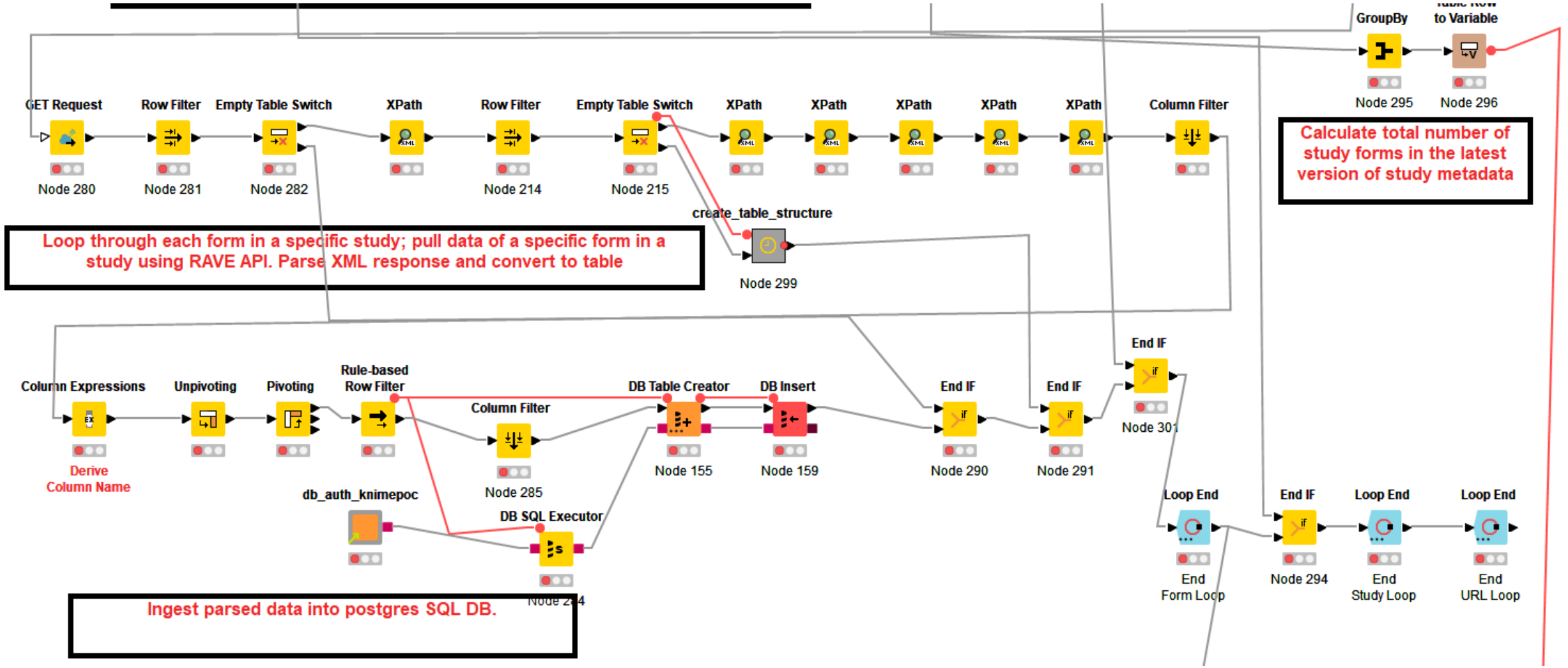
Workflow Cont'd.



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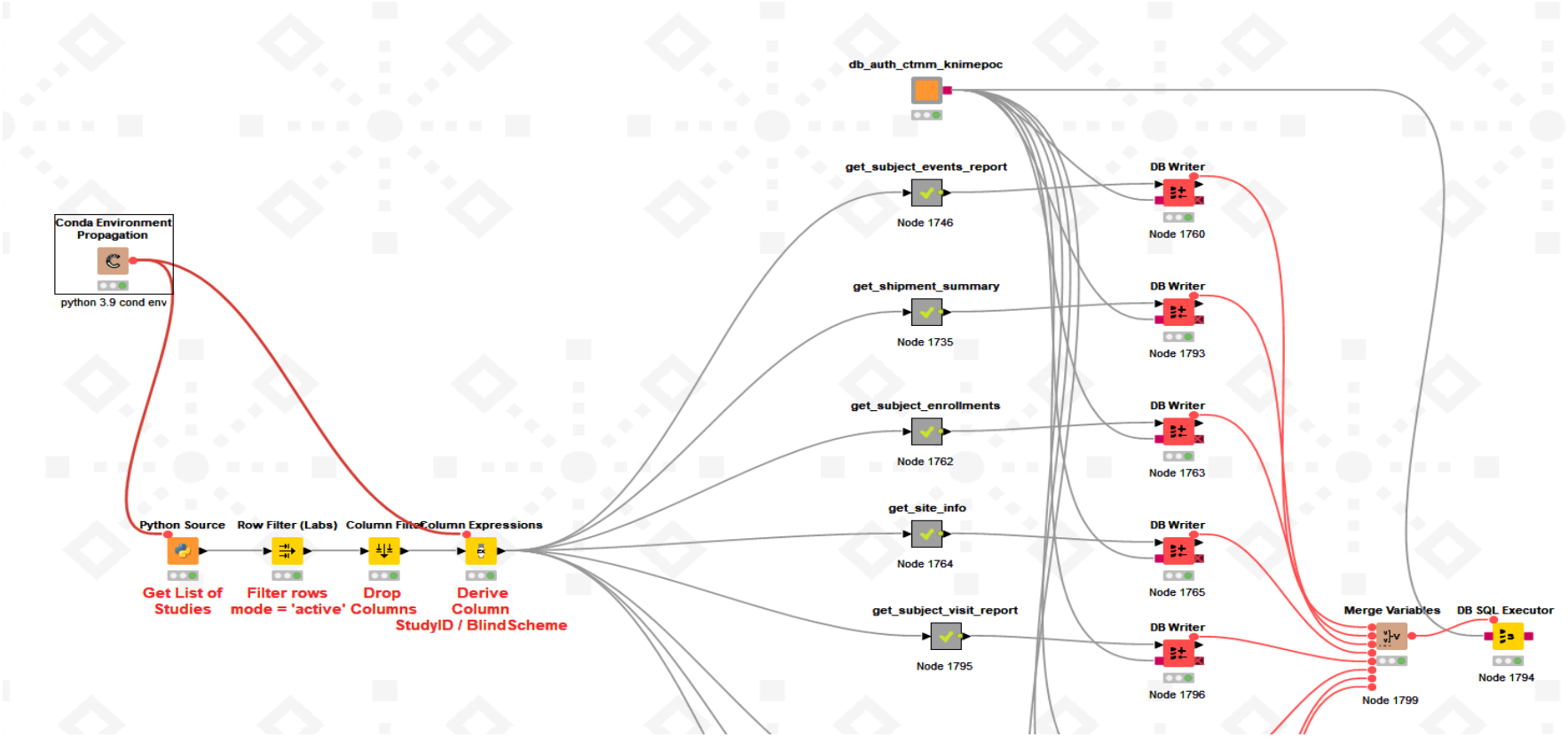
Use Case 2 – Ingest Data Oracle Clinical One

- Built KNIME workflow to ingest data from “**Oracle Clinical One**” for the SMPA studies.
- Data from about 15+ different source tables are being ingested daily.
- Business rules and Data Quality checks are designed in the WF to support different business needs.



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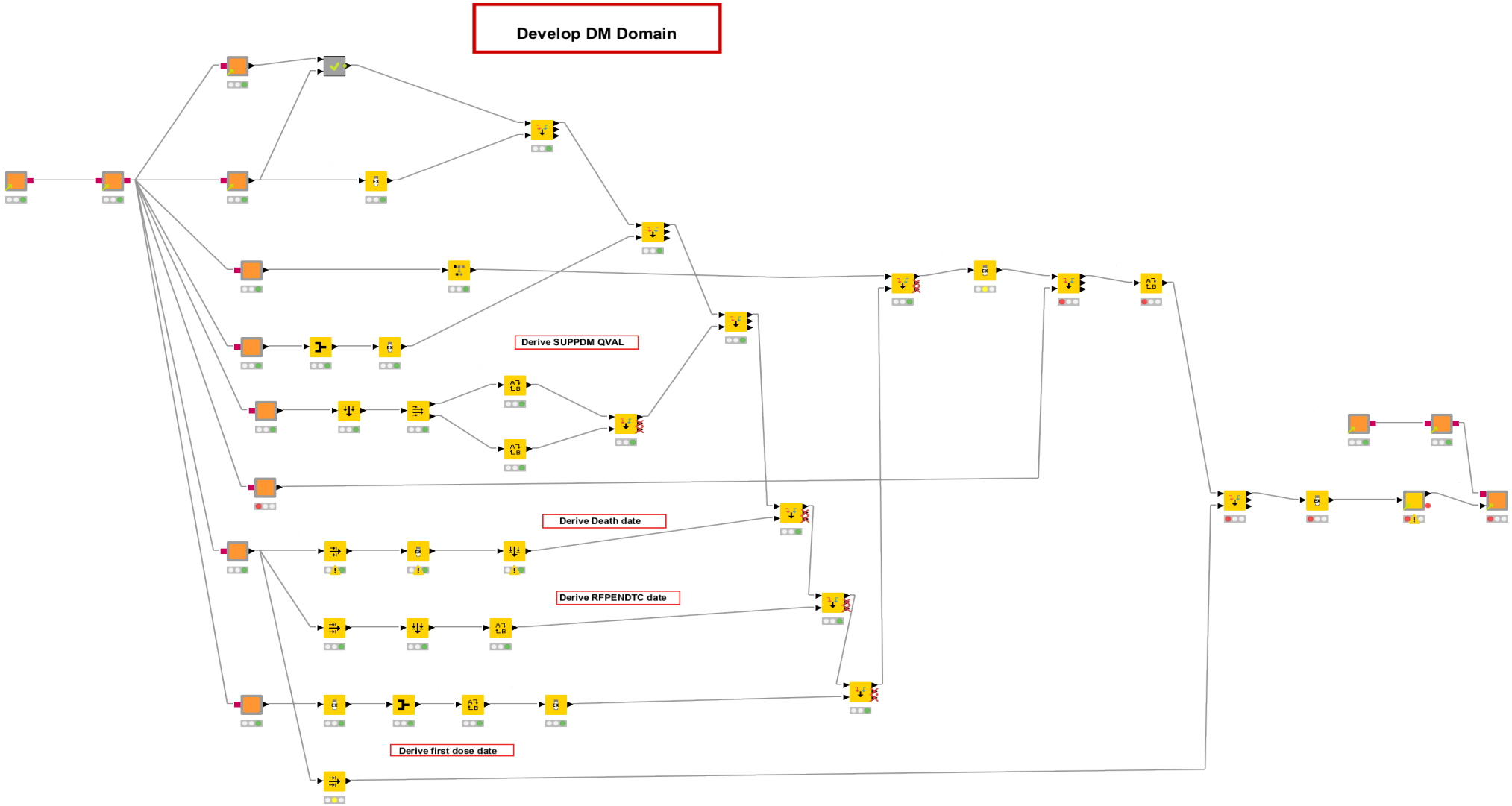
Use Case 3 – Develop SDTM Domain(s)



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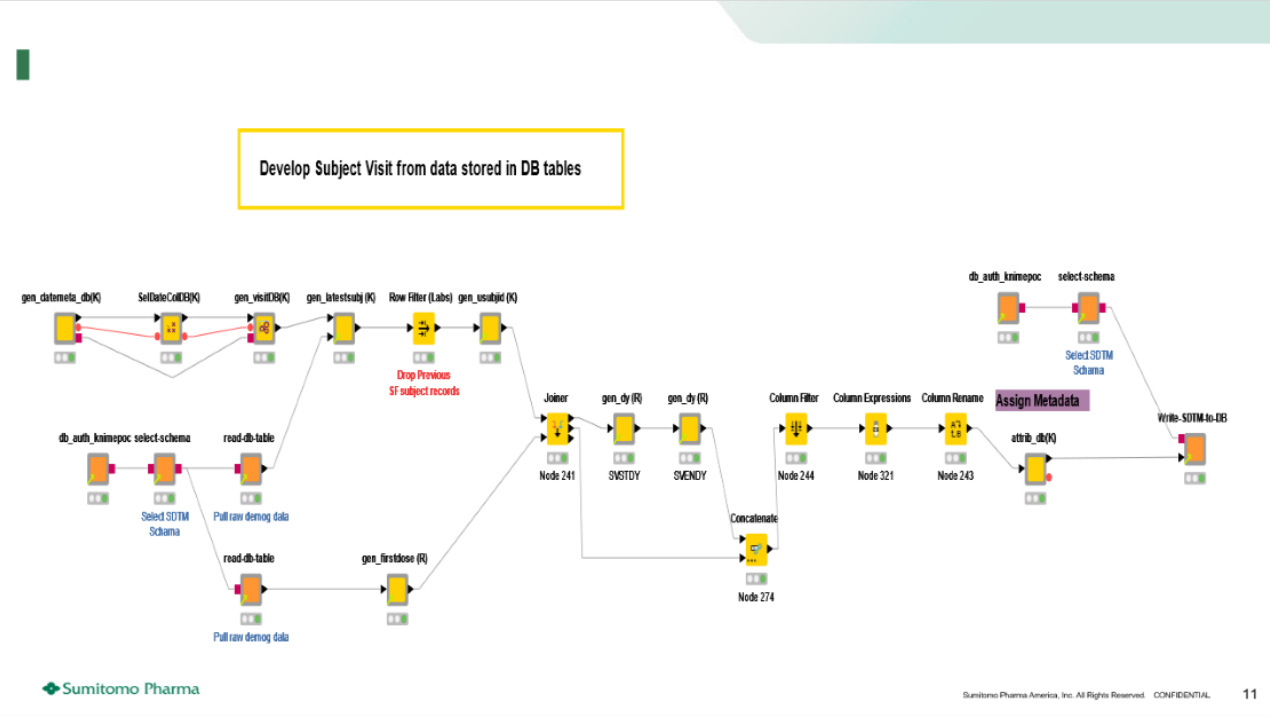
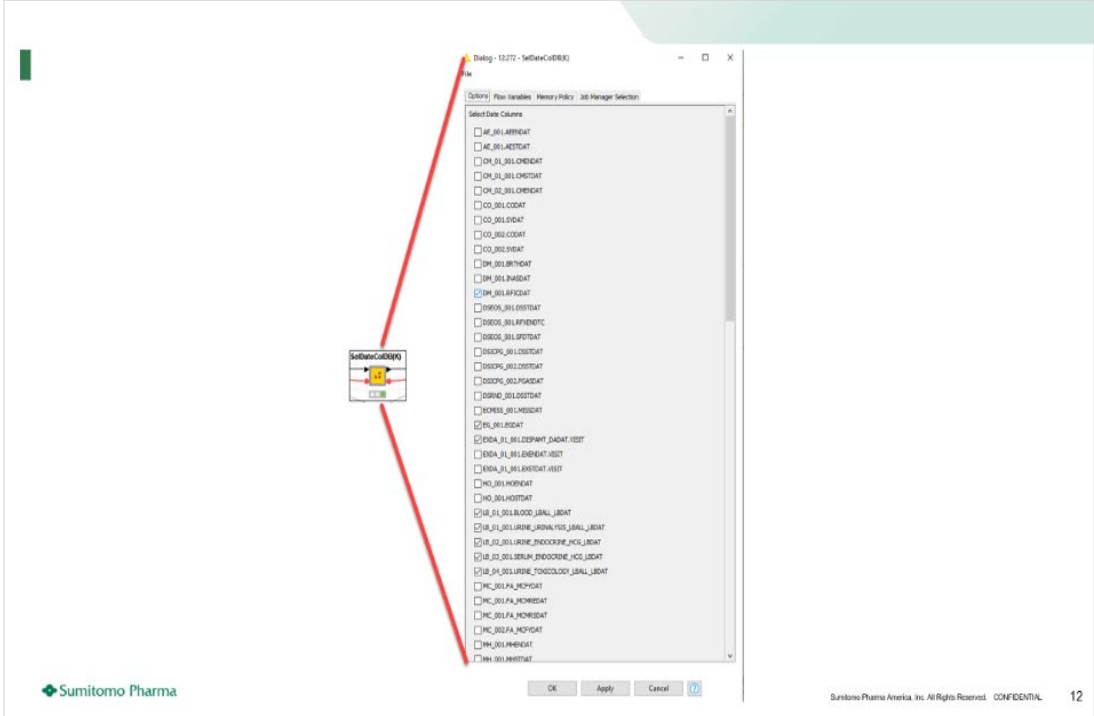
Use Case 3 – Develop Subject Visits (SV) Domain

- Developed SV domain workflow with user configuration that can be used across different studies





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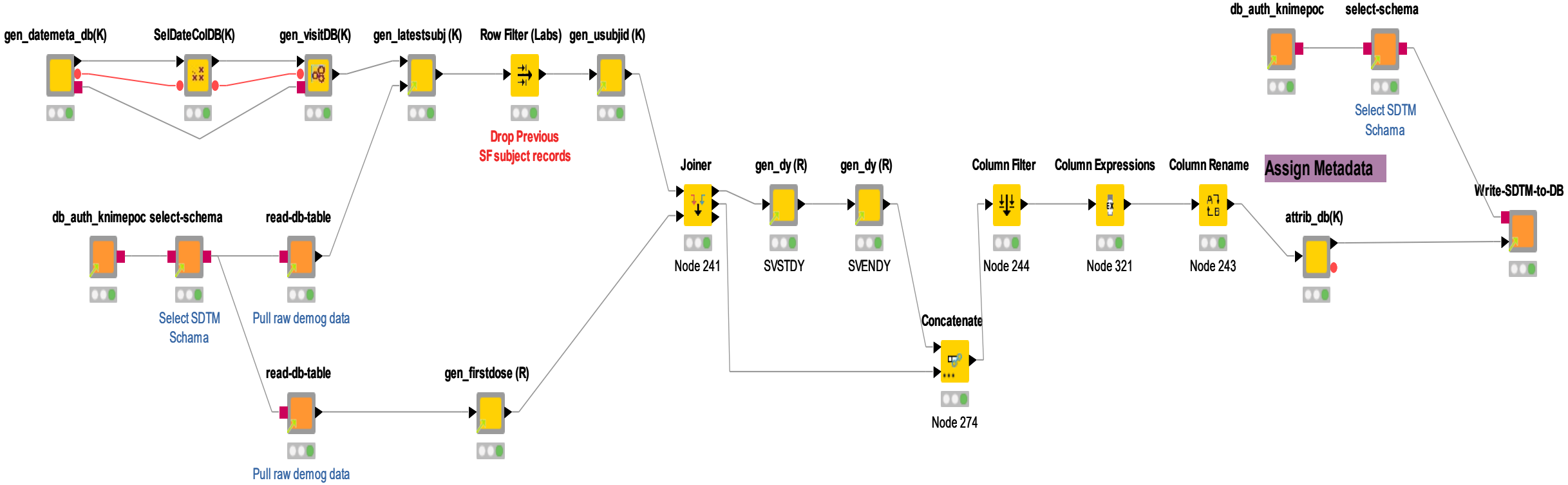
Develop Subject Visit from data stored in DB tables



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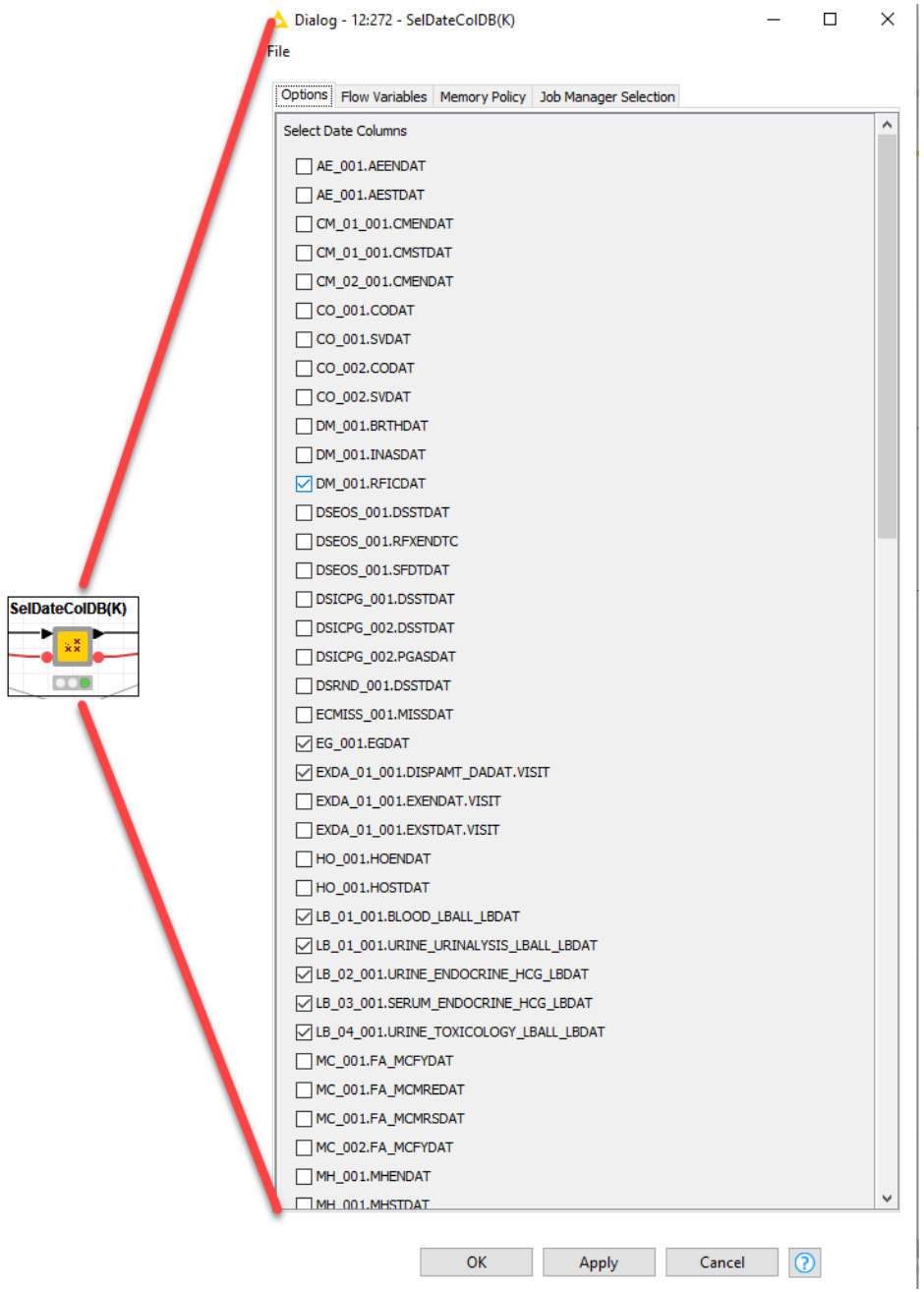

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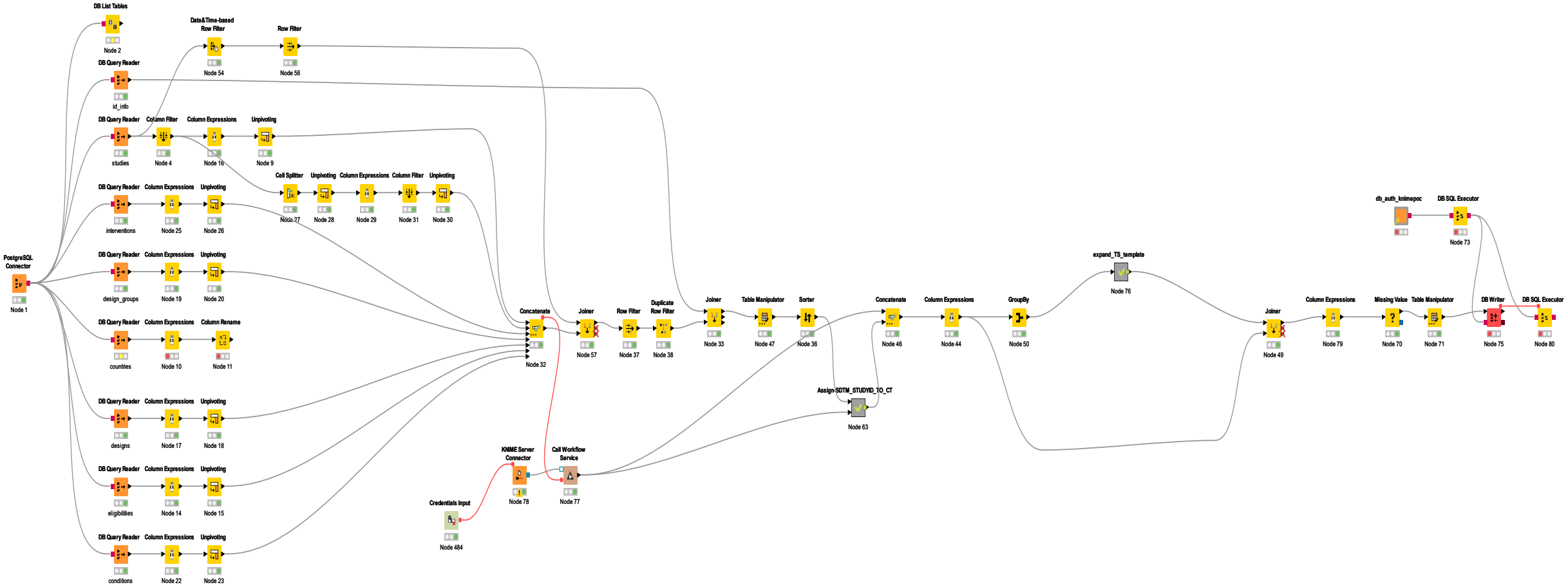
Use Case 4 - Develop Automated Trial Design (TS) Domain

- Developed draft TS Domain from data sourced from AACT (ClinicalTrials.GOV) and SDTM datasets



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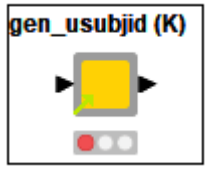
Sample List of Components Built at Sumitomo Pharma America



Generate **USUBJID**

Generate **Study Day**

Populate **LBTEST** and **LBTESTCD** from **LOINC** leveraging **CDISC Library API**

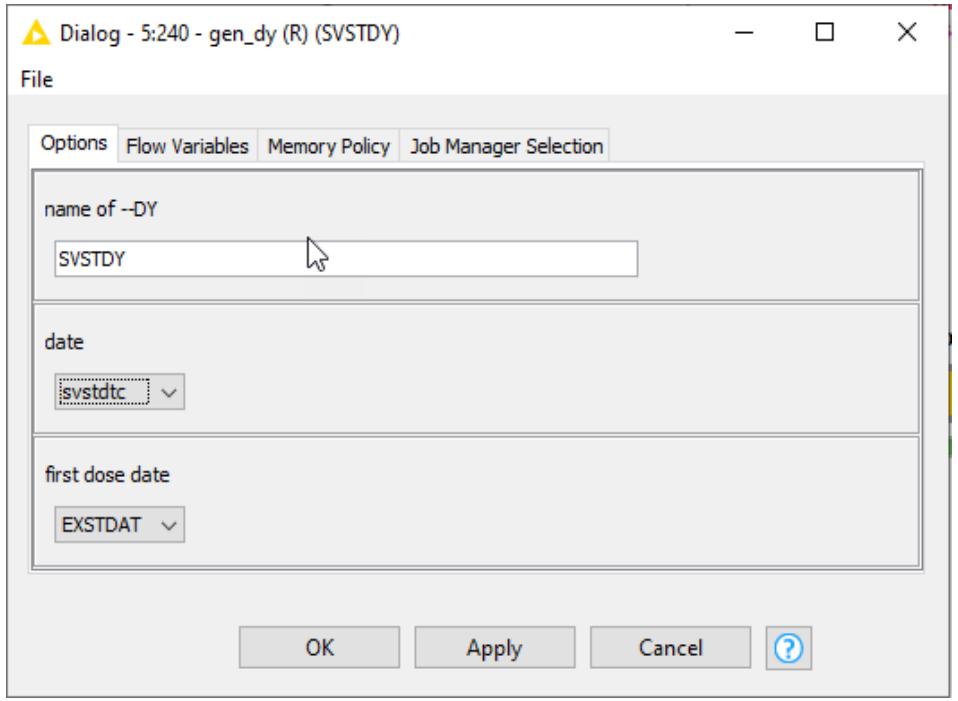
Generate **Latest Subject Number** when multiple screenings are done in the study

Generate First Dose of the Subject **RFSTDTC** and **RFXSTDTC**

Generate **EPOCH** based on dates and SE domain configuration

Assign **SDTM metadata** to the final data table

Components may have **configurations** to be managed by user . Configurations will add **flexibility to component**



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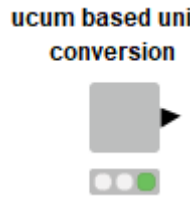
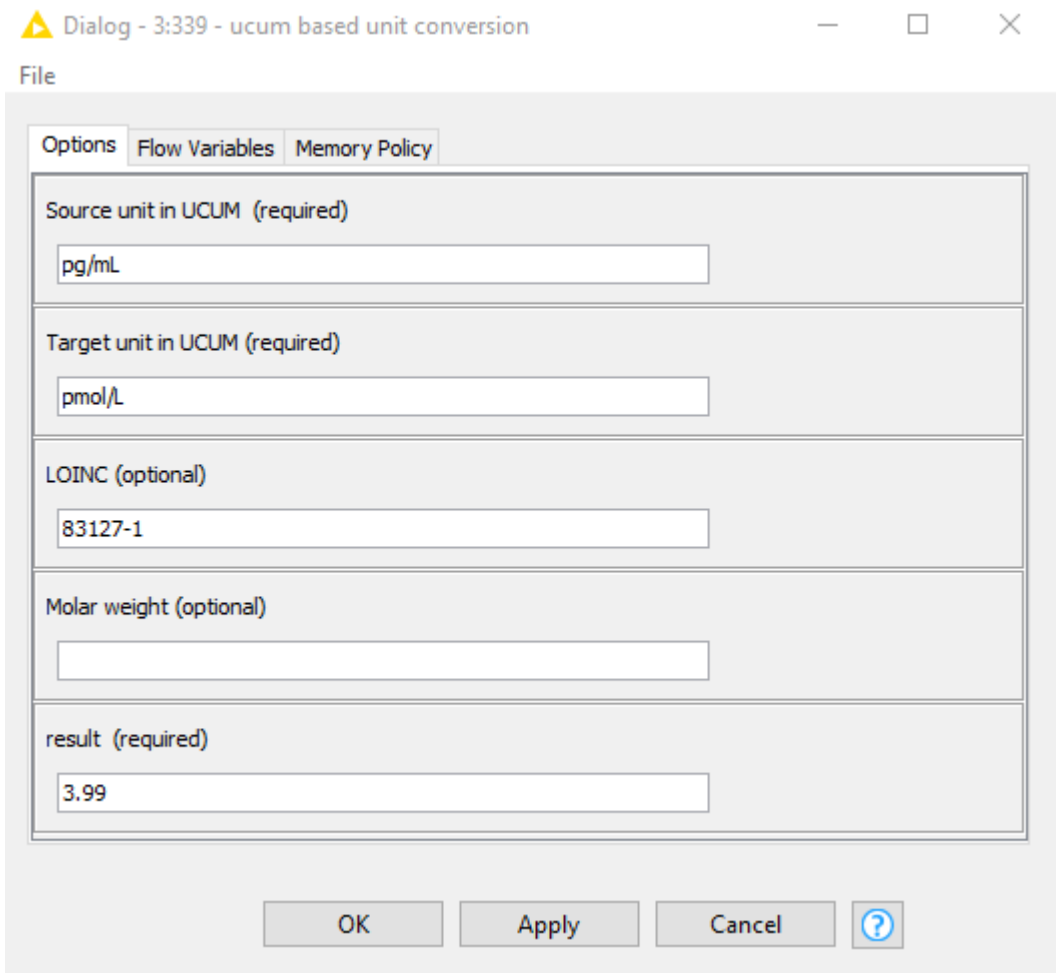


Convert results in one unit to another unit

Search controlled terminology

Get LOINC metadata from loinc.org and CDISC library



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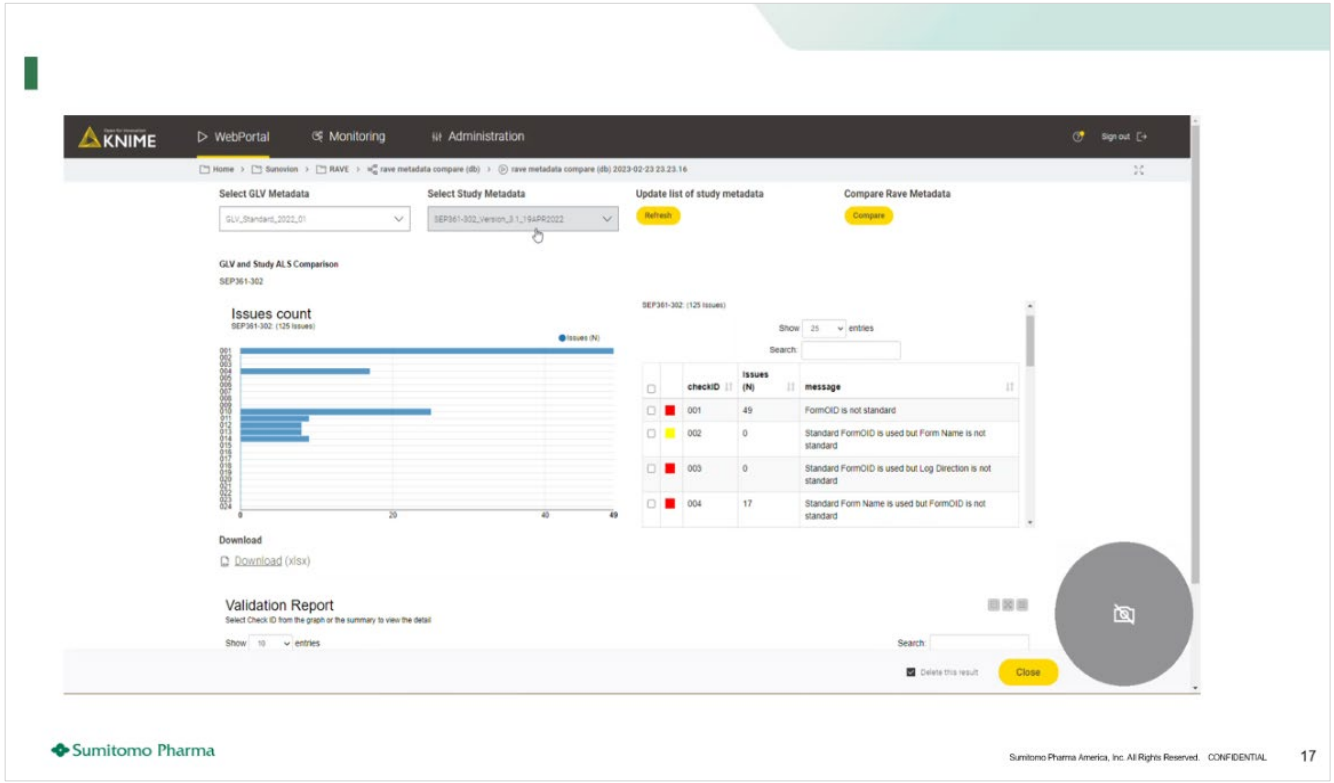
Data Apps

- Data Apps provide a user interface to perform scalable and shareable data operations, such as visualization, data import, export, and preview.
- Provide actionable insights to end users whenever they need them.
- Through KNIME Server you can also share your Data App with 5, 10, or 1000 end-users.
- Data App to compare metadata of a study with GLV and generate discrepancy report.



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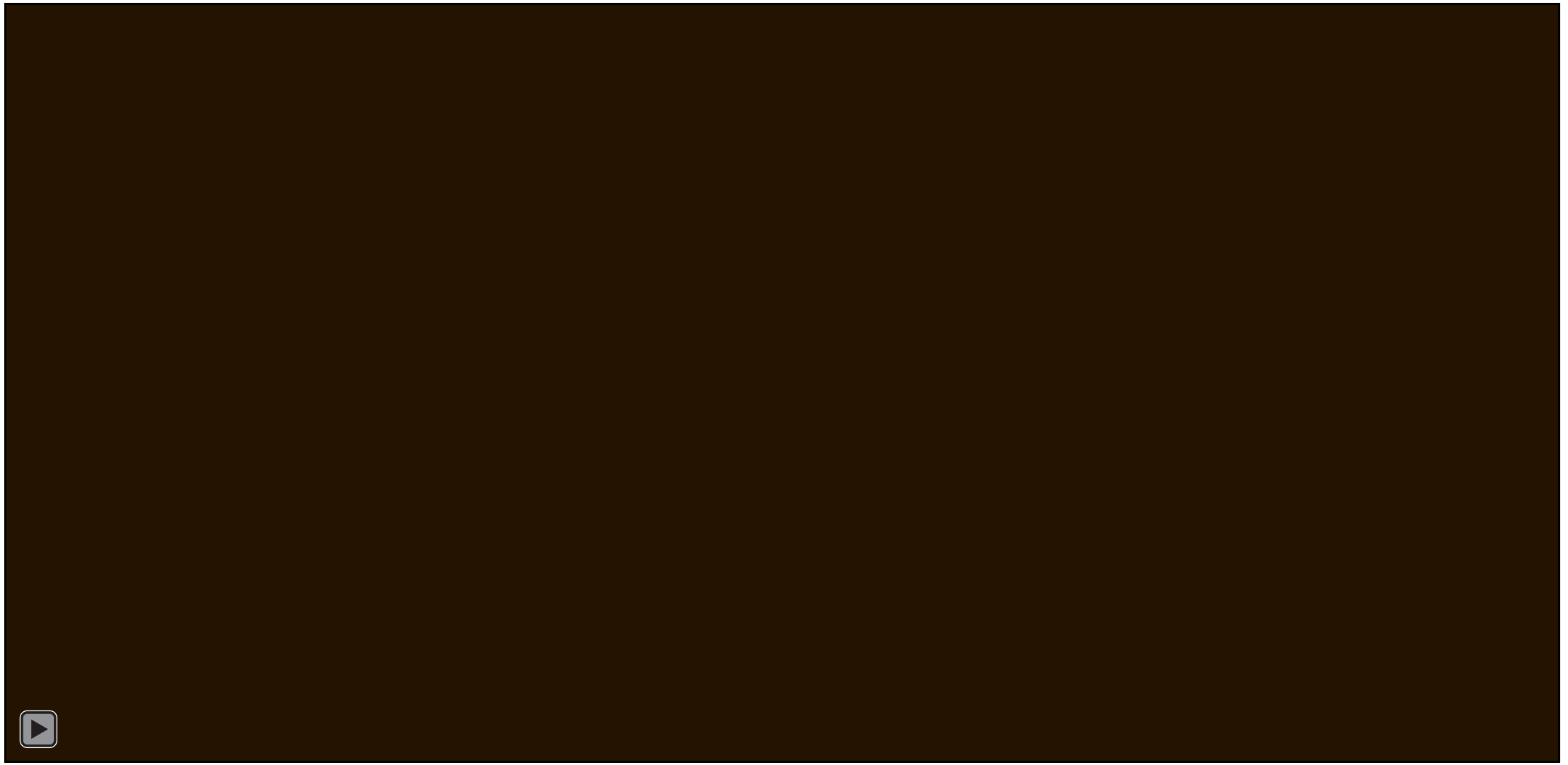

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GxP – Features on KNIME Server

Authentication

- Users can be authenticated using existing systems and can be added into defined user groups.

Versioning

- KNIME WF's can be versioned and restored to any previous versions on KNIME server.
- Different versions of KNIME WF's can be compared and generate report.

Access Control

- Folders and workflows can be provided with Read, Write, Execute permission to Users and User groups.

Audit

- All events on KNIME server including WF's ownerships, Folder and File access permissions, WF executions, WF updates are stored.
- All the audit data can be accessed and pulled out of server using predefined REST API.

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Acknowledgements

- **Clinical Data Programming SMPA -** Cindy Ma, Jyotsna Bhate, Doris Menke, Sam Tomioka, Sravani Koganti and Jeff Xiong for their support in building workflows and components.
- **SMPA IT team –** For their extensive help in setting up infrastructure to support business needs.
- **KNIME Team -** Norbert Sas, Martyna Pawletta for their continued guidance and support.

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References

KNIME Community Hub – Find workflows, nodes, components from user community

https://hub.knime.com/

KNIME Blog

https://www.knime.com/blog?page=3

Nodepit – Over 5K nodes, 19K workflows from user community and partners

https://nodepit.com/

https://medium.com/low-code-for-advanced-data-science/why-knime-98c835afc186

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