Democratize advanced analytics for everyone while maintaining the integrity and reproducibility of evidence using SAS

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Toru Tsunoda
Trend of Life Science Industry
Real World Evidence

“Real World Evidence (RWE) is the clinical evidence regarding the usage and potential benefits, or risks, of a medical product derived from analysis of Real World Data (RWD)”

(Framework for FDA’s Real-World Evidence Program, 2018)
Trend of Life Science Industry
Acceleration of RWE Usage

Changes in external environment

Sophistication of needed information & insight
- Need for medical evaluation from various perspectives such as long-term outcomes and QOL
- Need for actual clinical information that contributes to personalized medicine
- Need for precise understanding of pathology for more complex and sophisticated treatment

Increase of opportunities to generate insight through data analysis
- Advances in machine learning and other advanced analytics
- Increased data processing speed
- Development of a data utilization platform as a national policy
- Creation of diverse data, from pre-disease to post-disease

R&D-related departments
(drug discovery, clinical development, etc.)
- Profiling of patient attributes based on diverse information
- Development of clinical prediction models for each patient attribute
- Identification of unmet medical needs and characterization of the patient profile
- Realization of single-arm study

Other departments
(MA, Safety, Sales, etc.)
- Detailed description of Patient Journey to evaluate business potential and refine product positioning
- Early establishment of product profile/economic value under actual practice
- Propose disease management based on the behavioral characteristics of patients

Application examples

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Not everyone necessarily has programming skill.
Challenges for RWE
Typically, big data

### Examples of Japanese RWD

<table>
<thead>
<tr>
<th>Type</th>
<th>DB name</th>
<th>Data provider</th>
<th>Total number of registered patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider-base</td>
<td>MIA</td>
<td>National Hospital Organization</td>
<td>About 20M</td>
</tr>
<tr>
<td></td>
<td>RWD Database</td>
<td>Medical Data Vision</td>
<td>About 21M</td>
</tr>
<tr>
<td></td>
<td>EBM Provider®</td>
<td>Medical Data Vision</td>
<td>About 33M</td>
</tr>
<tr>
<td>Payer-base</td>
<td>National Database</td>
<td>MHLW</td>
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<tr>
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<td>JMDC Claims Database</td>
<td>JMDC</td>
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</tr>
<tr>
<td>Pharmacy-base</td>
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<td>INTAGE Real World</td>
<td>About 39M</td>
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<tr>
<td></td>
<td>IQVIA NPA data</td>
<td>IQVIA Solutions Japan</td>
<td>About 33M</td>
</tr>
</tbody>
</table>

Existing H/W cannot support and then must leverage the latest technologies.

Challenges for RWE
Reliability of analysis results

Pfizer Uses EHR Data to Support Expanded Indication for Breast Cancer Drug

“The approval is based on the EHR database and post-marketing reports. Data were sourced from three databases: IQVIA, Flatiron Health Breast Cancer database and the Pfizer global safety database”

Reference: “Real World Evidence in Clinical development, life cycle management and/or repurposing”

SAS Health: Cohort Builder
The solution specialized for RWE
Cohorts Are *Not* the Goal!!!
SAS® Health
Reimagining health analytics in the cloud.

Easily and confidently build patient subsets within a unified analytics platform

- Interactive, drag-and-drop capability to support complex cohort queries with temporal relationships – no coding required
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- Leverage and extend your own analytic assets
- Gain fast, easy access to advanced health analytics and visualizations
SAS Viya

Provide the entire set of functions and software required to promote data utilization on a single platform

- **data management**
- **analytics**
- **visualization**

Search and Insight

- Aggregation, Filtering, Statistical analysis, Machine/deep learning, Prediction, Optimization, Natural language processing

**Data preparation**

- Access
- Data catalog and data processing
- Cleansing

**Deployment and application**

- Model management, automation and monitoring

**In-memory analysis engine**

- Integrated repository

**parallel distributed processing**

Automation, Security, Governance, Metadata Management, Workflow

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Two Viya engines including SAS Compute and CAS

Viya can support not only big data & AI/ML but also traditional bio-stat programs developed by SAS 9.
How can you use **SAS Health: Cohort Builder**?

**Short demo**

**Cohort Builder**
- *To apply one of inclusion criteria using GUI*
  - The patients whose ages are over 40 when diagnosed as “atrial fibrillation” (≒ index event)
  - Also, the patients are males
  - However, the patients are not hypertension

**Add-in**
- *To execute advanced analytics with no / low codes*
  - To predict patients who will experience the stroke
### Population Cohorts

<table>
<thead>
<tr>
<th>Status</th>
<th>Name</th>
<th>Description</th>
<th>Count</th>
<th>Data Source</th>
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### Index Event Cohorts

<table>
<thead>
<tr>
<th>Status</th>
<th>Name</th>
<th>Description</th>
<th>Count</th>
<th>Index Event</th>
<th>Data Source</th>
<th>Owner</th>
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<td>Afib Dx9</td>
<td>DOUBLE</td>
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</tbody>
</table>
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Merit about SAS Health: Cohort Builder

• Not only skilled programmers but also domain experts such as epidemiologists can execute cohort building & advanced analytics
  – Trials and errors in development of research question

• Validated programs can be widely used within organizations

• High performance visualization & analytics can be available through leveraging SAS Viya
SAS Office Analytics: Enterprise Guide and Access Interface
The solution specialized for SAS programming/DB
Solution Overview: SAS Office Analytics

Support not only power but also light users for efficient collaboration

- **heavy user**
  
  Creating efficient analysis flows with GUI tools
  
  - (1) Enterprise Guide

- **light user**
  
  Easy data analysis with Office add-ins
  
  - 3) Add-in for Microsoft Office
    
    ✓ Call up the shared flows from familiar tools such as Excel, and analyze it while changing conditions for filtering, etc.

- **2) SAS Studio**
  
  Development of SAS programs using a web browser

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SAS Enterprise Guide

Versatile tool covering data preparation, visualization & analysis

- SAS Enterprise Guide is a highly ad-hoc analysis tool that covers a wide range of data processing functions, reporting functions such as tabulation and graphing, and even statistical analysis functions.
- The analysis process is visualized as a flow, which makes it easy to share, prevents dependency, and promotes democratization of data and analysis.

Main Functions

- Data processing
- Advanced analysis using statistical methods
- Quick statistics (data profiles)
- Ad hoc data exploration
- Various graphs
- Report writing
- Stored process creation
- Analysis Process Flow Sharing
- Create/edit/run SAS code
- Project management in conjunction with GIT
② SAS Studio
Web-based highly functional SAS editor

✓ Access from a web browser. SAS programming on the go, even from a Mac.
✓ Similar feel to DMS (conventional SAS screen)
✓ Various program support functions
  ✓ input completion function
  ✓ Automatic display of syntax help
  ✓ Tasks such as graphs
  ✓ SQL edit screen
  ✓ Customizable code snippets
  ✓ process flow
✓ Processing is done on the server, so high performance processing
✓ SAS execution logs are automatically output to the server to ensure security
③SAS Add-in for Microsoft Office

Analyze against server data from familiar Excel

It is possible to extract SAS data on the server and execute SAS programs on the server from MS Office tools, and can be used by a wide range of users regardless of their skills.

Main Functions

- Extraction of data on the server (no limit on the number of rows)
- ad hoc query
- Advanced analysis using statistical methods
- Execute custom processes registered with the server, and Get the latest analysis results
- Create optimal graphs automatically by simply selecting items. Graph output in Excel format
- Graph gallery with a list of graphs that can be created
- Save, share, and re-execute settings and results of analysis processes, etc.
- Free report creation by linking with Office functions
- Data exploration and reporting with SAS Visual Analytics reporting integration

Running a stored process
One-click execution of unique processes registered in the server beforehand

Data extraction process
Handling data beyond the functional limits of Excel

Data analysis processing
Perform advanced analysis and aggregate processing using statistical methods
Office Analytics can access to databases.

- When install SAS Office Analytics and SAS Interface modules, you can use databases via SAS.
- For example:

  - PC/Server: PC Files, SAS Dataset
  - Azure: Synapse Analytics, SQL Server Big Data Clusters
  - AWS: Amazon Redshift, Aurora

### Tools:
- Enterprise Guide
- SAS Studio
④ Other function: SAS Interface
How to use databases

- It is so easy. After access modules installed, you only set up the library. The following sample is used in Enterprise Guide.

1. Resisted library

2-a. GUI on Enterprise Guide

2-b. SAS program
Other function: SAS Interface

Merit about SAS Office Analytics

- We don’t need to learn a new program language. We can use SAS programming in Enterprise Guide or SAS Studio.

- Using SAS Enterprise Guide, we don’t need programming skill. Only GUI.

- Collaborate any other department via SAS product.
  - We can share the SAS program and SAS datasets via SAS Server.
Thank you