

PHUSE APAC Connect 2026 – RE11

Building a Trustworthy RWD Analytics Platform: Key Considerations and Strategies

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Disclaimer

- This presentation reflects the opinions of the presenters and should not be construed or considered to represent regulatory authorities' views or policies.



AGENDA

Regulatory Landscape for the Utilization of RWD/RWE

Key Considerations of a Trustworthy RWD Analytics Platform

Q&A

Real-World Evidence Derived from the Analysis of Real-World Data



RWD are data relating to patient health status and/or the delivery of health care **routinely collected** from a variety of sources. RWE is the clinical evidence regarding the usage and potential benefits, or risks of a medical product derived from analysis of RWD.



[Framework for FDA's RWE Program](#)



...sources include real-world data (such as electronic health records, insurance claims data and data from patient registries), genomics, clinical trials, spontaneous adverse drug reaction reports, social media and wearable devices...



[HMA/EMA Big Data Task Force](#)

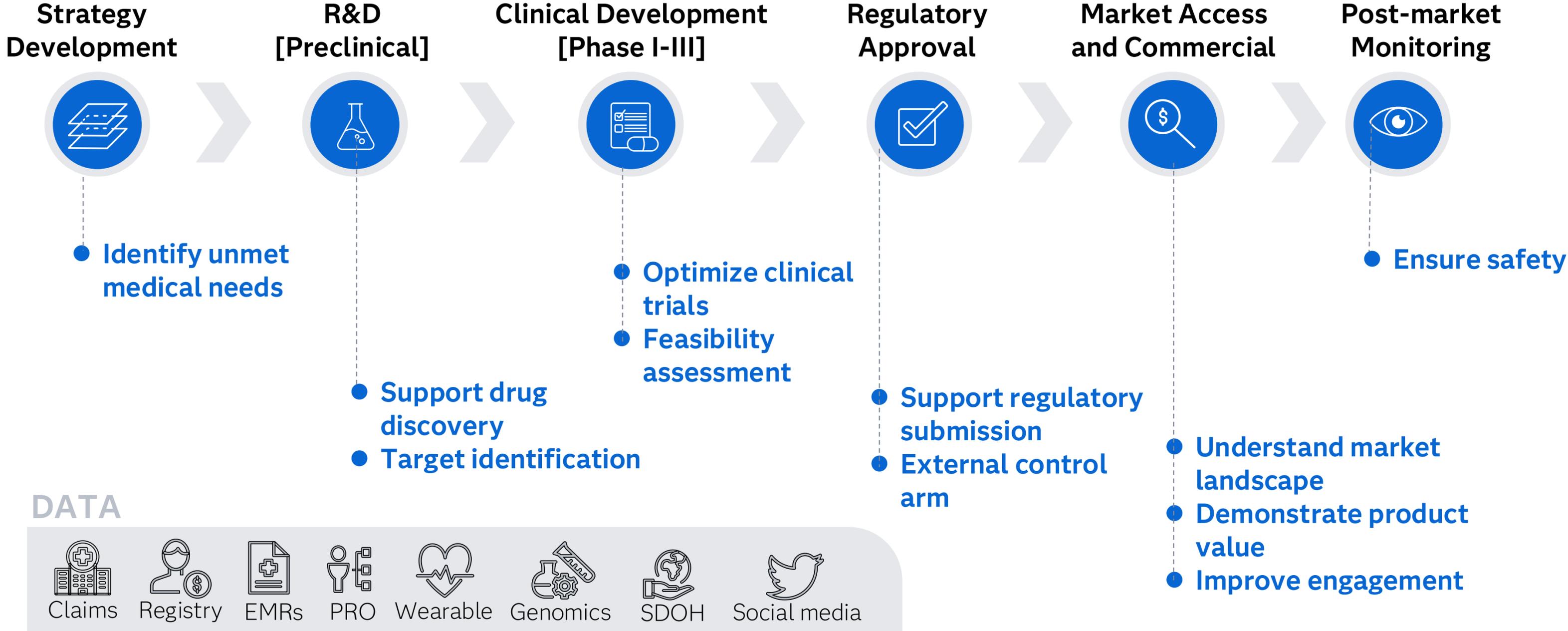


...regulatory issues related to RWD such as utilization of medical information databases. Medical information databases includes electronic medical records, diagnosis procedure combination from hospital information system; Claims for medical fees and dispensing fees; and disease registry.



[Japan PMDA - RWD WG](#)

Utilization of RWE Across the Pharmaceutical Product Lifecycle



PRO: Patient-reported outcome
 SDOH: Social determinants of health
 EMRs: Electronic medical records



US FDA Regulation and Guidance on RWE



In December 2018, FDA evaluates the potential use of RWE to support:

- adding or modifying an indication (e.g. a change in dose, dose regimen, or route of administration)
- adding a new population;
- adding comparative effectiveness or safety information



In December 2024, CDER established a new Center for Real-World Evidence Innovation

FDA NEWS RELEASE

FDA Eliminates Major Barrier to Using Real-World Evidence in Drug and Device Application Reviews

In December 2025, FDA states it will accept RWE without requiring that identifiable individual patient data

- Framework for FDA's Real-World Evidence Program
- Use of Electronic Health Records in Clinical Investigations
- Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products
- Data Standards for Drug and Biological Production Submissions Containing Real-World Data
- Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products
- Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products
- Submitting Documents Utilizing Real-World Data and Real-World Evidence to FDA for Drugs and Biologics
- Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products
- Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
- Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs
- Considerations Regarding Non-Interventional Studies for Drug and Biological Products

Europe EMA Strategy and Guidance on RWE

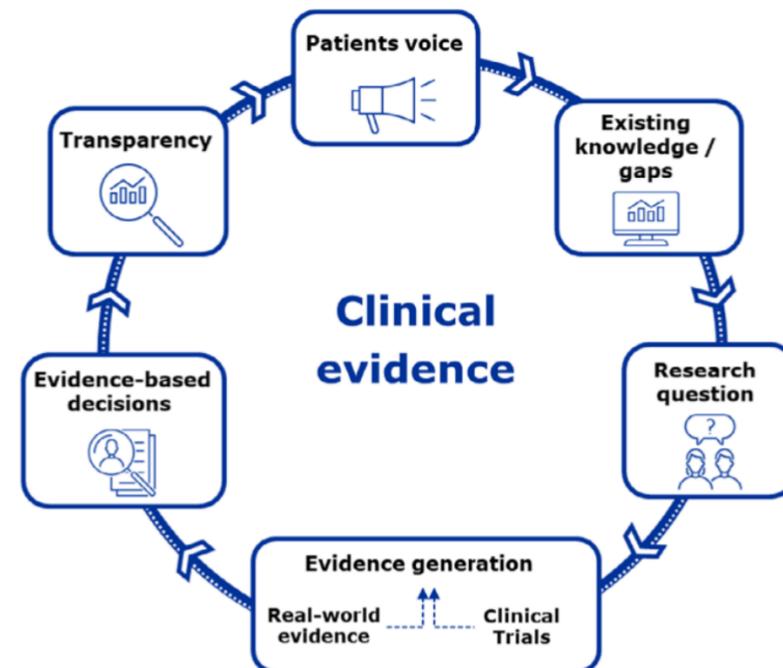


- Data Analysis and Real World Interrogation Network (DARWIN EU)
- EU initiative coordinated by EMA to use RWD for the evaluation and supervision of medicines
- Data network of 31 partners across 16 EU countries, providing access to data from over 188 million patients

Corporate report

MHRA Real-World Evidence Scientific Dialogue Programme

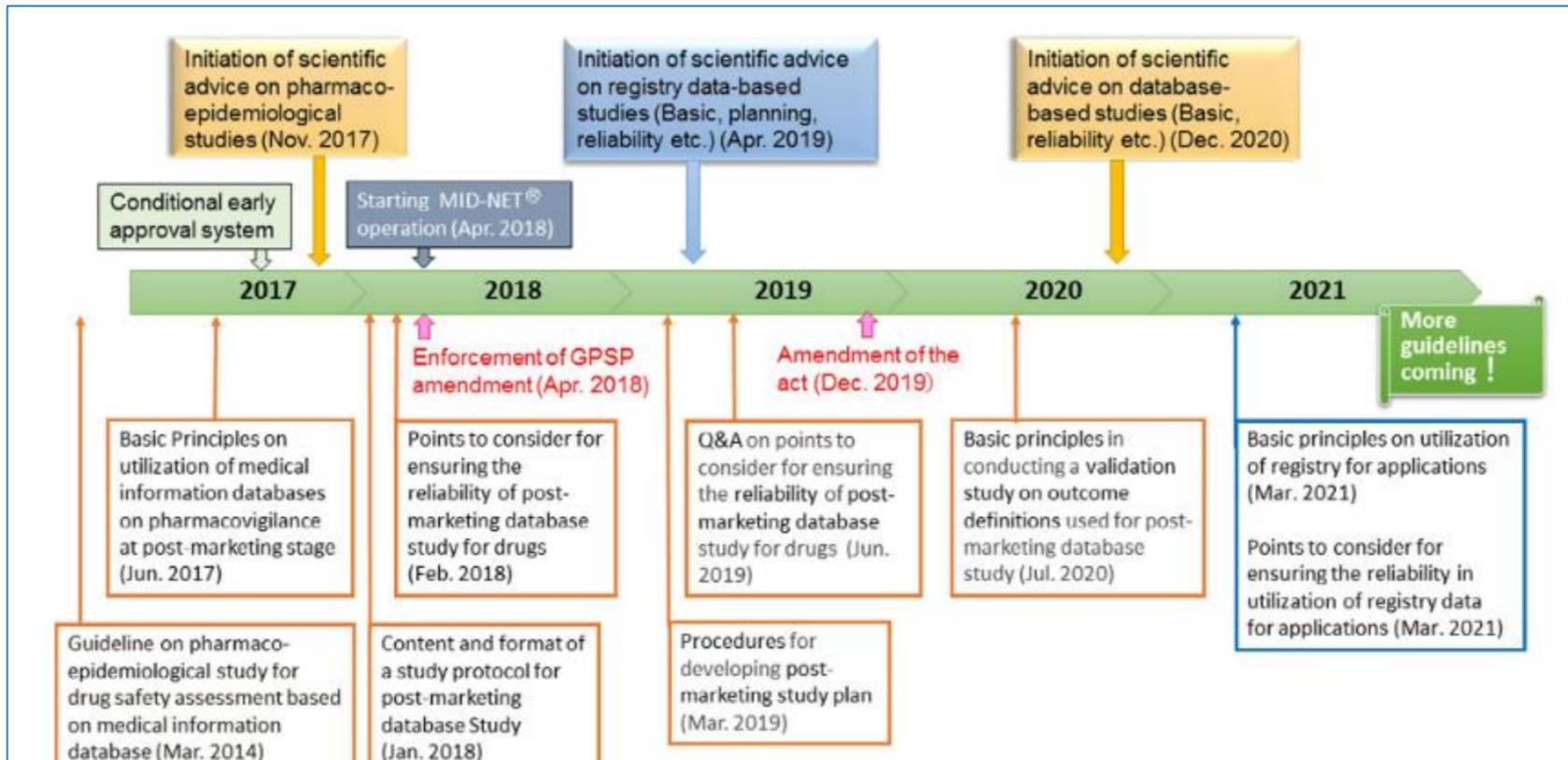
- Promote data-driven innovation and early access to innovative products through real-world evidence (RWE) and proactive approaches to safety surveillance
- a closed-door, confidential virtual meeting with the MHRA



Clinical Evidence 2030

- By 2030, the integration of RWE in clinical evidence generation should follow six guiding principles.

Japan PMDA Regulation and Guidance on RWE



Using claims and EMR databases for Post-Marketing Safety Assessment.

Using registry databases for application

REVIEW

PMDA Perspective on Use of Real-World Data and Real-World Evidence as an External Control: Recent Examples and Considerations

Junichi Asano¹, Hiromi Sugano¹, Hiroyuki Murakami², Atsushi Noguchi³, Yuki Ando¹ and Yoshiaki Uyama^{4,*}

- RWE have been practically utilized as an **external control arm** for drug approval.
- Points to consider in utilizing RWD/RWE
 - Frequent communication
 - Feasibility
 - Minimize bias
 - Study design consideration
 - Sensitivity analysis
 - Personal health information privacy protection
 - Data reliability

Regulatory Submission with RWE

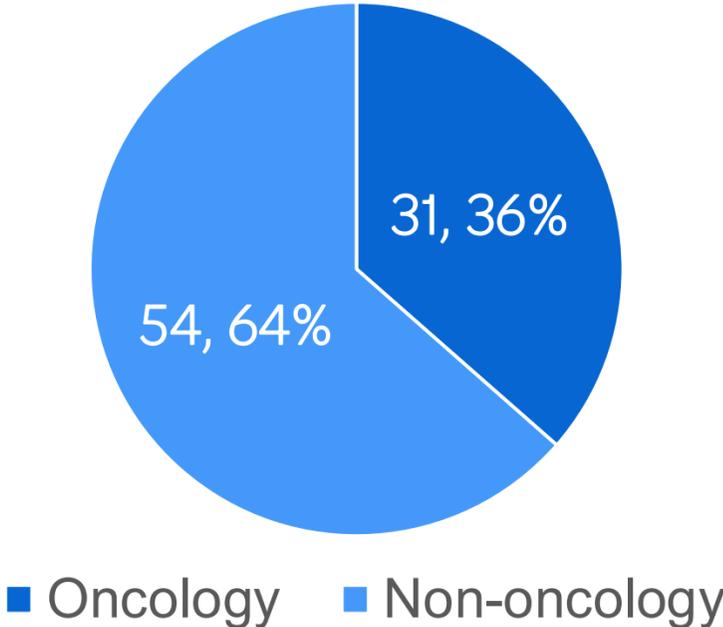
ARTICLE

**Real-world evidence to support regulatory submissions:
A landscape review and assessment of use cases**

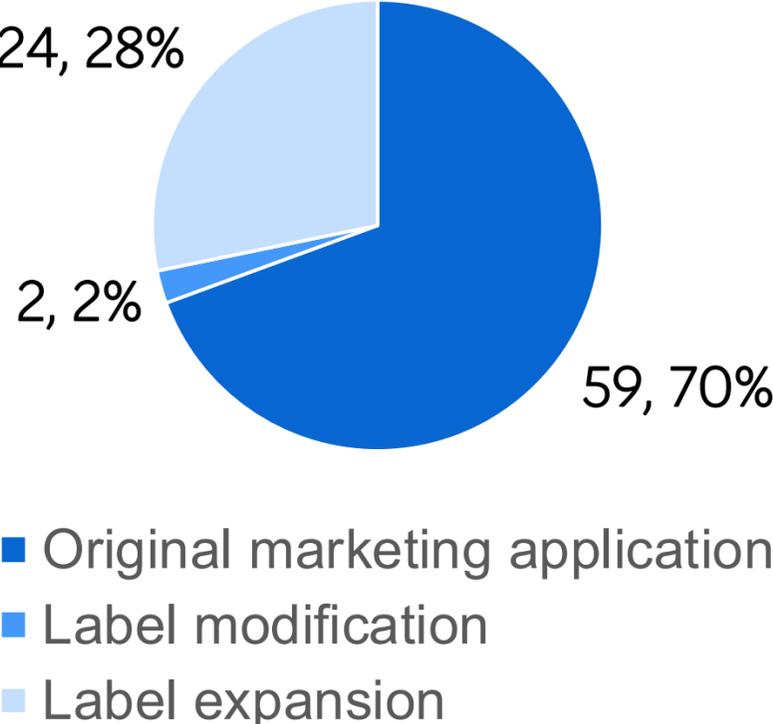
Golnoosh Alipour-Haris^{1,2} | Xinyue Liu² | Virginia Acha² | Almut G. Winterstein¹
Mehmet Burcu²

- Reviewed and characterized current uses of RWE for regulatory submission.
- A total of 85 relevant use cases identified from 2016 to 2022.

Therapeutic Area

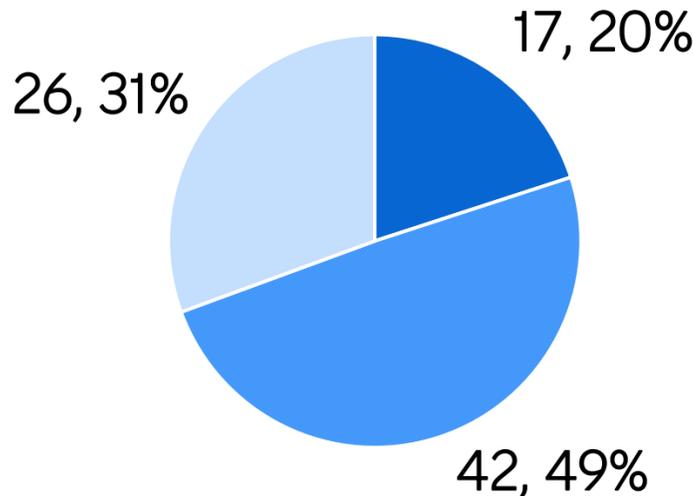


Purpose



Rationale

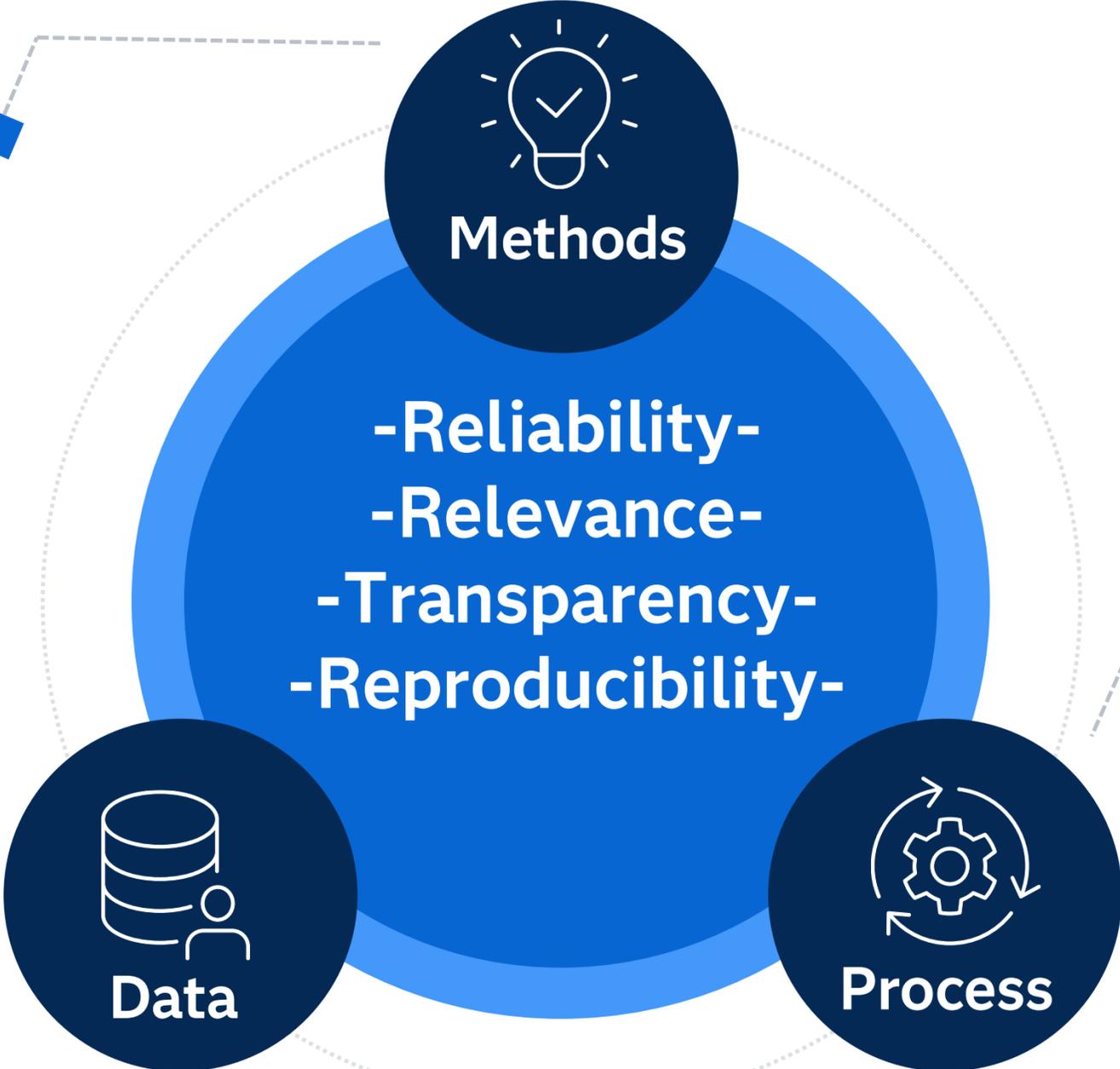
- As primary evidence
- Support single-arm trial
- As supplementary data to RCTs



Key Considerations for RWE in Regulatory Submission

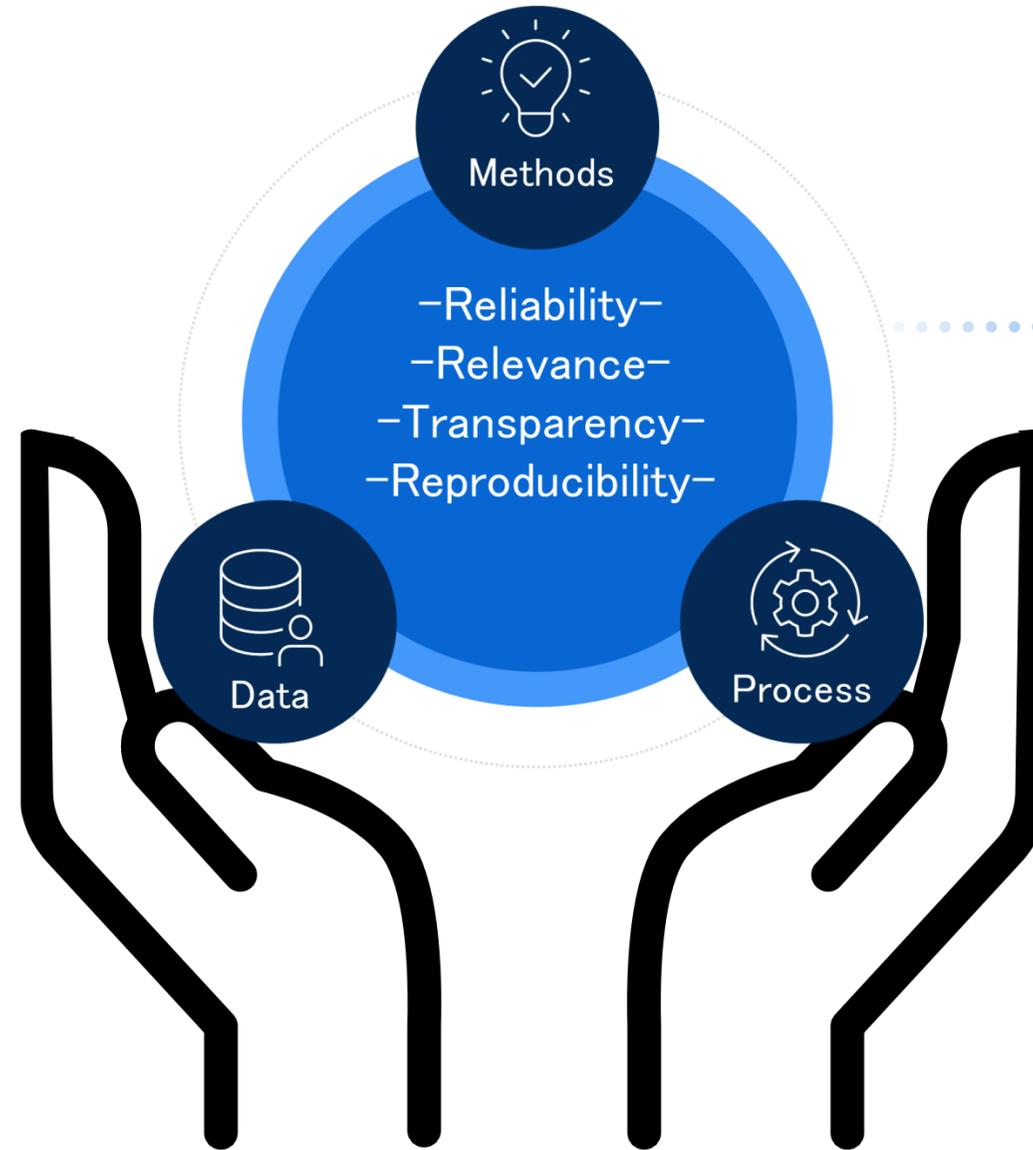
Whether the trial or study design used to generate RWE can provide adequate scientific evidence to answer or help answer the regulatory question

Whether the RWD are fit for use



Whether the study conduct meets regulatory requirements

A Trusted & Modern RWD Analytics Platform can help...



- **Speed to insight**
- **Risk mitigation**
- **Maximize ROI**

Subject Matter Experts



Trusted RWD Analytics Platform



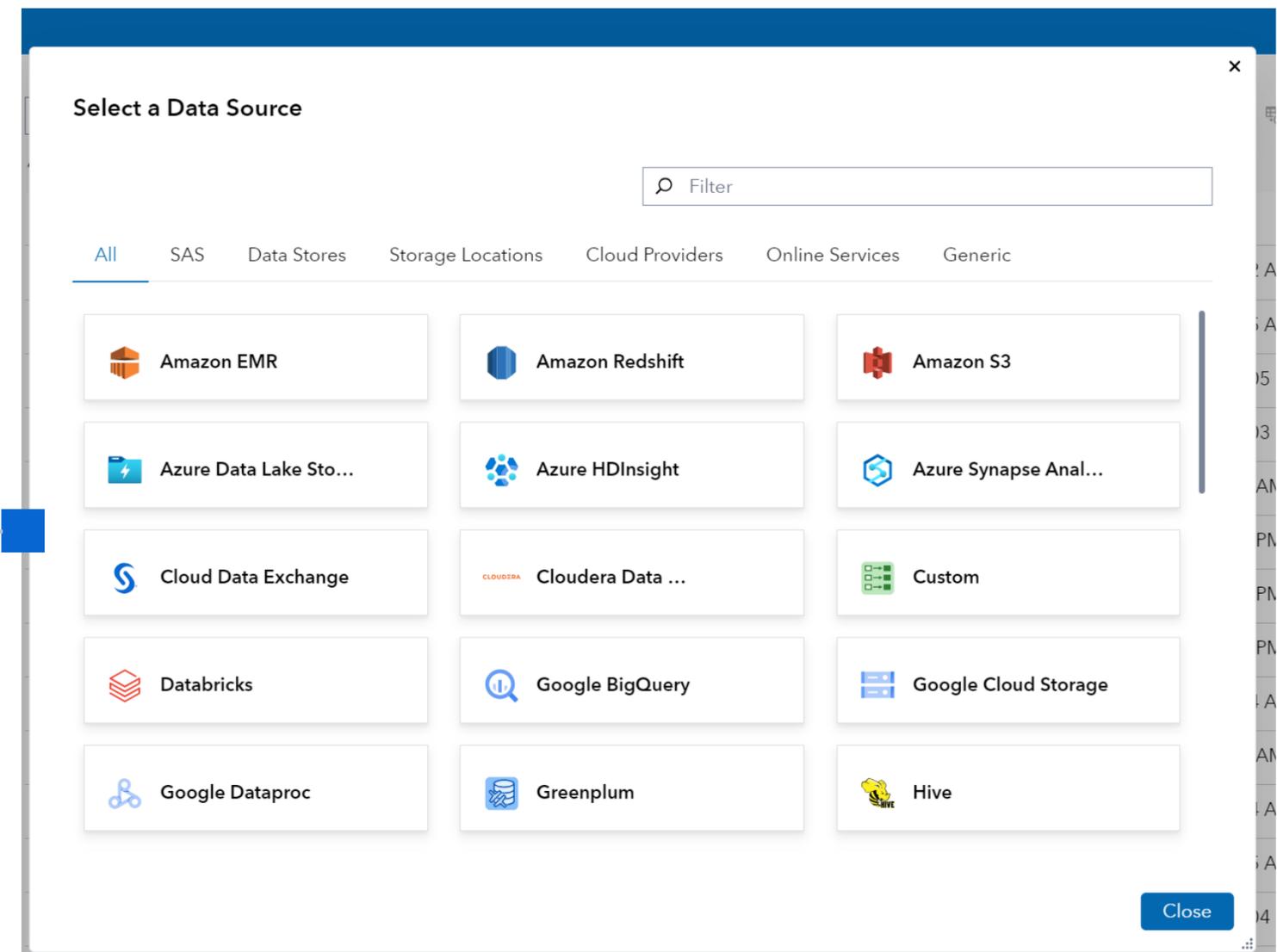
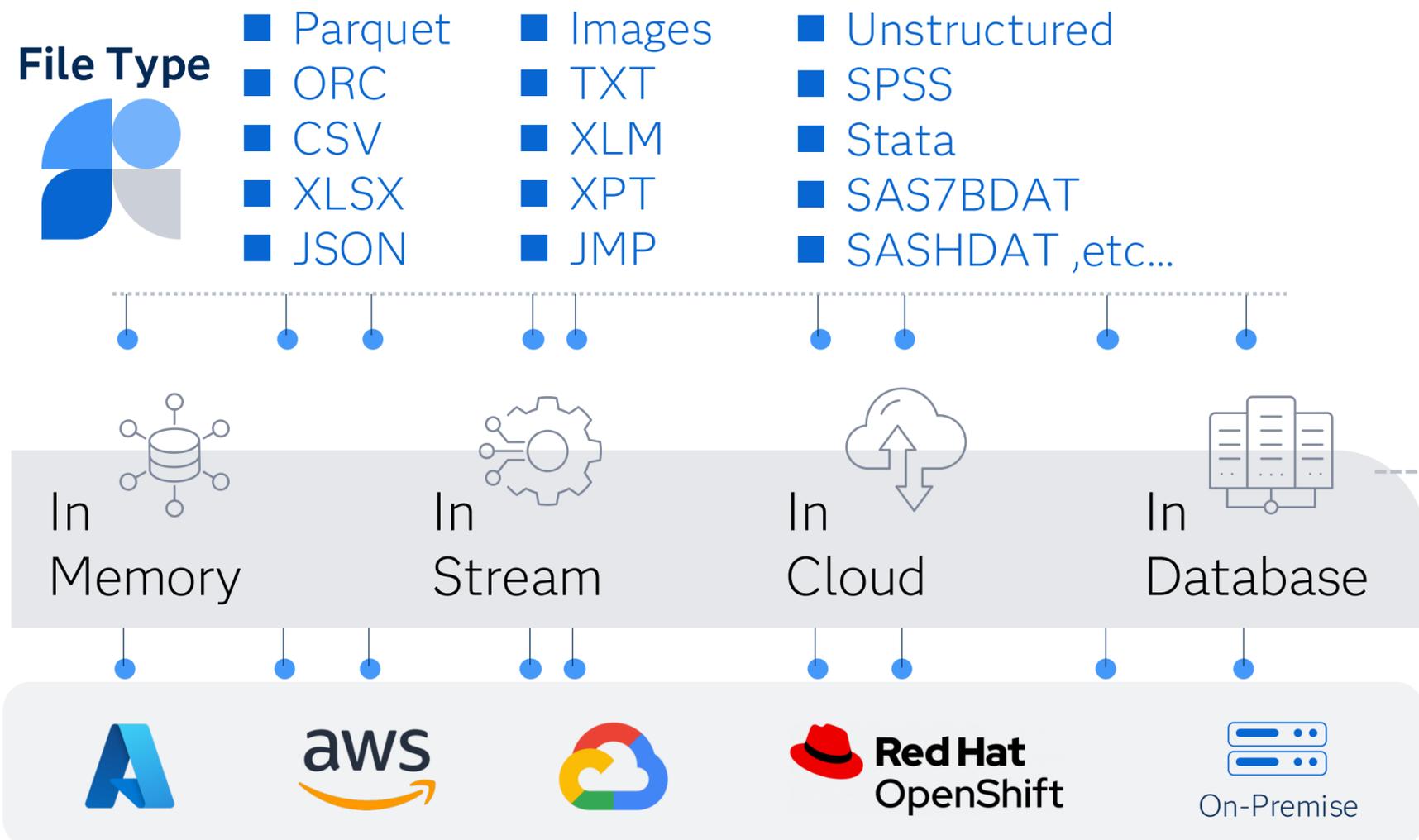
Features of A Trusted & Modern RWD Analytics Platform

You can...

Consume multiple types of data from a wide variety of environments and sources

so that...

Leverage more diverse RWD in large volume to gain deeper insights



Features of A Trusted & Modern RWD Analytics Platform

You can...

Quickly profile and analyze large volumes of data via interactive visualization and automated analytics

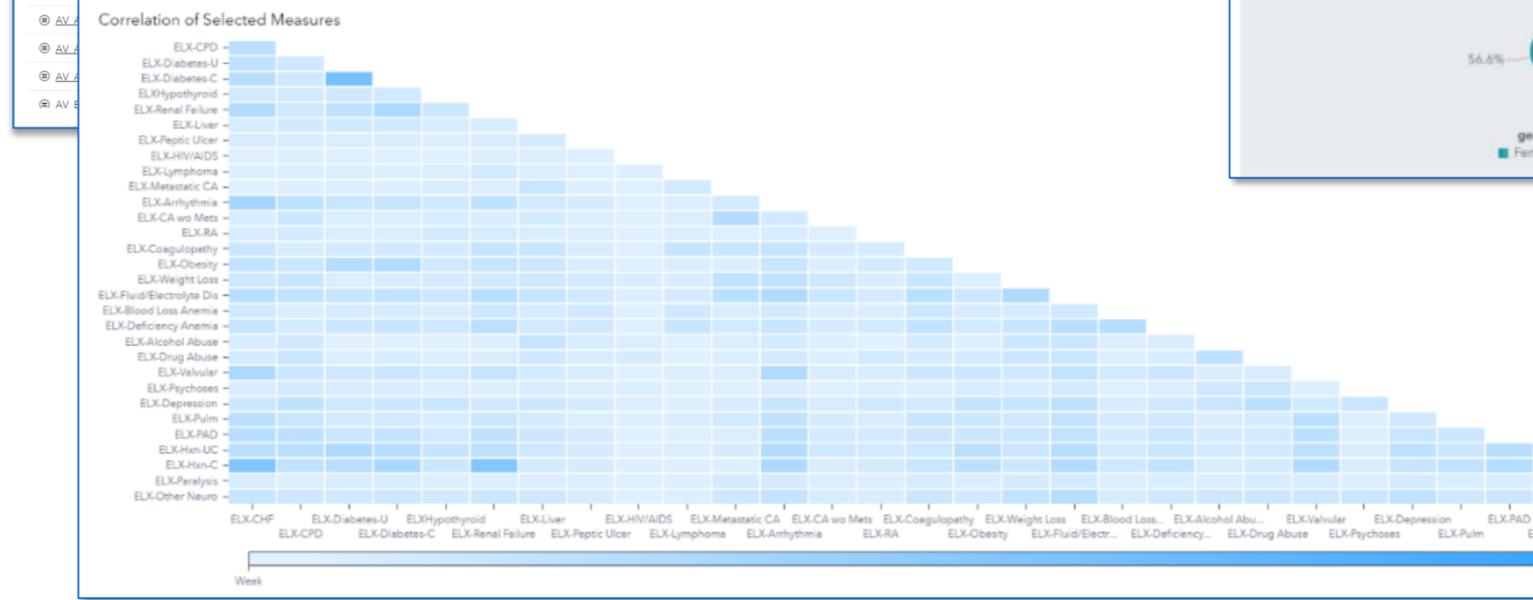
so that...

Understand key data elements, size of population, data issues and gain insights quickly

ACS_COHORT_STRINGENT

Report: 08/03/22 10:33 AM

Column	Unique	Null	Blank	Pattern Count	Mean	Median	Mode	Standa...	Standa...	Minimum	Maximum	Data #
age_at_death	17.47% (51)	99.12% (33,0)			73.39	74.00	67.00	10.70	0.63	37.00	98.00	dout
age_at_index...	0.23% (78)	0			72.66	73.00	68.00	12.40	0.07	24.00	101.00	dout
age_at_study...	0.24% (79)	0.64% (212)			74.16	75.00	70.00	12.40	0.07	25.00	103.00	dout
age_at_study...	0.24% (79)	0			72.16	73.00	68.00	12.39	0.07	23.00	101.00	dout
AGEGROUP_10	0.02% (8)	0	0	2			70-79			20-29	90+	char
AV_Anthracy...	100.00% (33,3)											dout
AV_ANTHRA...	<0.01% (1)	0			0.00	0.00	0.00	0.00	0.00	0.00	0.00	dout
AV_Anthracy...	100.00% (33,3)											dout
AV_Anthracy...	100.00% (33,3)											dout
AV_Anthracy...	100.00% (33,3)											dout
AV_Antiarb...	92.86% (91)	99.71% (33,2)			18,08...	18,07...		219,53	22,18	17,638,00	18,533,00	dout
AV_Antiarb...	0.01% (2)	0			0.00	0.00	0.00	0.05	0.00	0.00	1.00	dout
AV_Antiarb...	92.86% (91)	99.71% (33,2)			18,08...	18,07...		219,53	22,18	17,638,00	18,533,00	dout
AV_Antiarb...	92.86% (91)	99.71% (33,2)			18,08...	18,07...		219,53	22,18	17,638,00	18,533,00	dout
AV_Anticoag...	89.72...	98.77% (32,2)			18,06...	18,06...		248,57	7,57	17,547,00	18,619,00	dout



Features of A Trusted & Modern RWD Analytics Platform

You can...

Use a systematic approach to control data quality, secure data provenance and automate repetitive tasks for data preparation

so that...

Increase confidence in the resultant data during data curation and data transformation

The screenshot displays the SAS RWD Analytics Platform interface. At the top, a search bar shows 'abnormal_liver_enzyme_data 500' with a completeness of 100%, 6 columns, 500 rows, and a size of 23.4 KB. The main view is 'Column Analysis' for the 'GGT' column, showing data quality metrics: 135 distinct values, 100% completeness, and 27% uniqueness. It also displays deviation from normality metrics: Skewness (0.04862), Kurtosis (-1.21906), and Standard Deviation (40.22928). A frequency distribution histogram and a full distribution box plot are visible. A data pipeline diagram is overlaid, showing a sequence of steps: 'Count AE by Subject' (receiving input from 'AE' and 'DM'), 'Join AE Count with DM', 'Replace Missing with 0', 'Order & Label Columns', 'AE_DM', and 'Box Plot of AEs by Tx'. A 'New Trigger' dialog box is open, configuring a 'Daily trigger' with a frequency of 'Daily', interval of '1' day, time of '12:01', time zone of '(UTC-05:00) New York', start date of 'Sep 23, 2020', and end condition of 'After number of times' (1). A checklist on the right shows the following steps completed with green checkmarks: 1. Parsing, 2. Casing, 3. Standardize, 4. Standardize, 5. Convert Column, and 6. Manage columns.

Features of A Trusted & Modern RWD Analytics Platform

You can...

Efficiently manage analytical assets generated from multiple projects and develop standard templates

so that...

Leverage validated analytic assets to produce reliable results and establish best practices for studies (e.g., routine, simple, complex)

Statistics

- Analysis of Covariance
- ANOVA Statistical Power
- Canonical Correlation
- Cluster Variables
- Coin Toss Simulation
- Combinations
- Compute Similarities and Distances
- Confidence Intervals Statistical Power
- Correlation Analysis
- Correspondence Analysis
- Cox Regression Statistical Power
- Custom Tests Statistical Power
- Decision Tree
- Dice Roll Simulation
- Distribution Analysis
- Equivalence Tests Statistical Power
- Estimate Within-Cluster Covariances
- Factor Analysis
- Hierarchical Clustering
- K-Means Clustering
- Linear Regression
- Logistic Regression
- Multidimensional Preference Analysis
- Multiple Regression Statistical Power
- Nonparametric One-Way ANOVA
- One-Way ANOVA
- One-Way Frequencies
- Pearson Correlation Statistical Power
- Permutations
- Poker Hand Probability
- Principal Component Analysis
- Same Birthday Probability
- Summary and Level Statistics
- Summary Statistics
- Summary Tables

Transform Data

- Branch Rows
- Calculate Columns
- Filter Rows
- Insert Rows
- Manage Columns
- Mask Data
- Query
- Rank Data
- Recode Ranges
- Recode Values
- Remove Duplicates
- Select Random Sample
- Sort
- Split Columns
- Stack Columns
- Transpose Data
- Union Rows

The screenshot displays the SAS Studio interface. On the left, a workflow diagram shows a sequence of steps: 'Initial Setup' (VAERS_SAMPL E), 'Checklist - Patient Outcome' (Checklist 0: Patient...), 'Checklist - Storage' (VAERS_SAMPL E, Checklist 1: Product..., VAERS_CHEC KLIST_YN_1, Filter Rows, VAERS_CHEC KLIST_YN_1), 'Checklist - Administration' (VAERS_SAMPL E, Checklist 3: Coronavirus, VAERS_CHEC KLIST_YN_3, Filter Rows, VAERS_CHEC KLIST_YN_3), 'Checklist - Coronavirus', 'Checklist - Acute Respiratory Failure', 'Checklist - Abnormal Blood Pressure', 'Checklist - breakthrough infections', 'Checklist - Shingles Vaccine', 'Checklist - Pain around Injection site', and 'Checklist - Not an Adverse Event' (VAERS_SAMPL E, Checklist 10: Not an..., VAERS_CHEC KLIST_YN_10). On the right, the 'Checklist 1: Product Storage' configuration panel is visible, showing parameters like 'VAERS_NARRATIVE' and prompts for system and user instructions.

[GitHub Repository - SAS analytic templates](#)

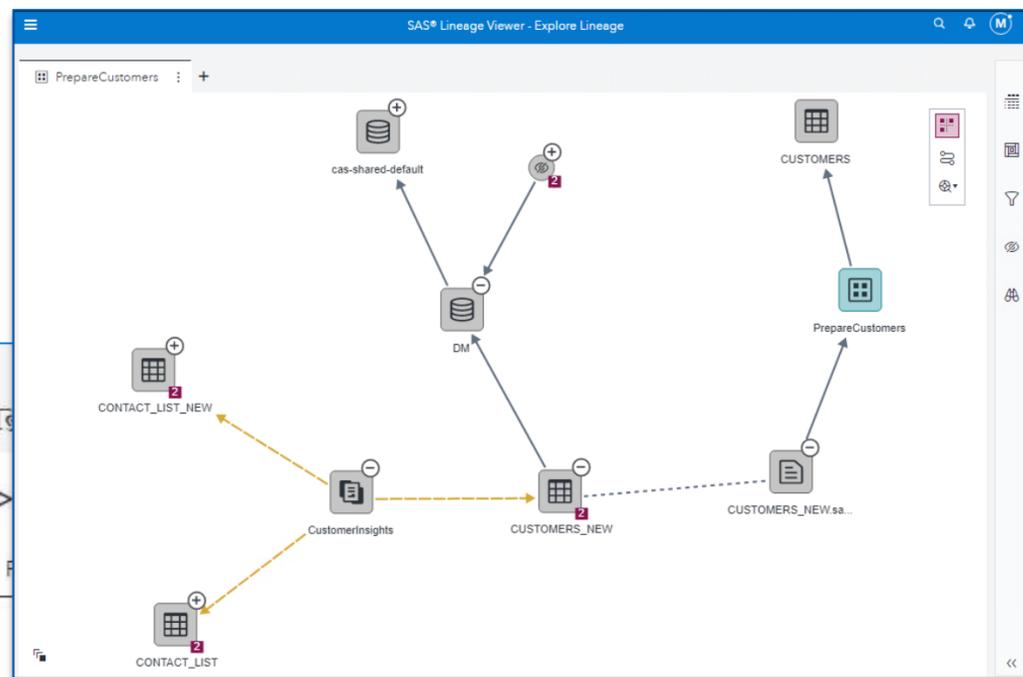
Features of A Trusted & Modern RWD Analytics Platform

You can...

Ensure a clear governance on data and analyses on a central environment

so that...

Increase transparency, reproducibility and traceability of the analyses



Data Matching: Model - ALT

Data Pipelines Pipeline Comparison Insights

Intermediate Advanced Basic Intermediate - No Text Score Advanced - No Text Score Basic - No Text Score +

View [dropdown] [grid icon]



WASOBASE.HP_PRICE_HIGH > price_per_hp

Analyze column Refresh

Forward Reverse

Name

HP_PRICE_HIGH.price_per_hp

Impact-Analysis.flw

Branch Rows.price_per_hp

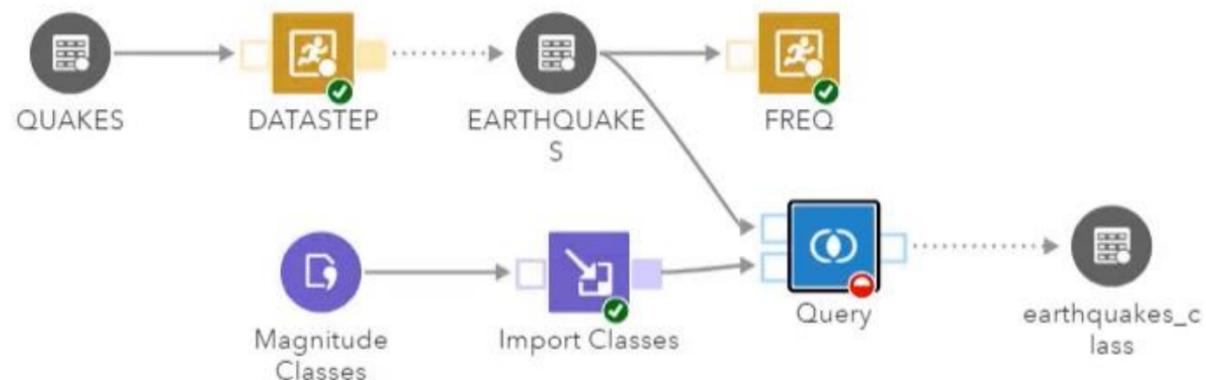
Query.price_per_hp

Branch

CARS.MSRP

Branch

CARS.Horsepower



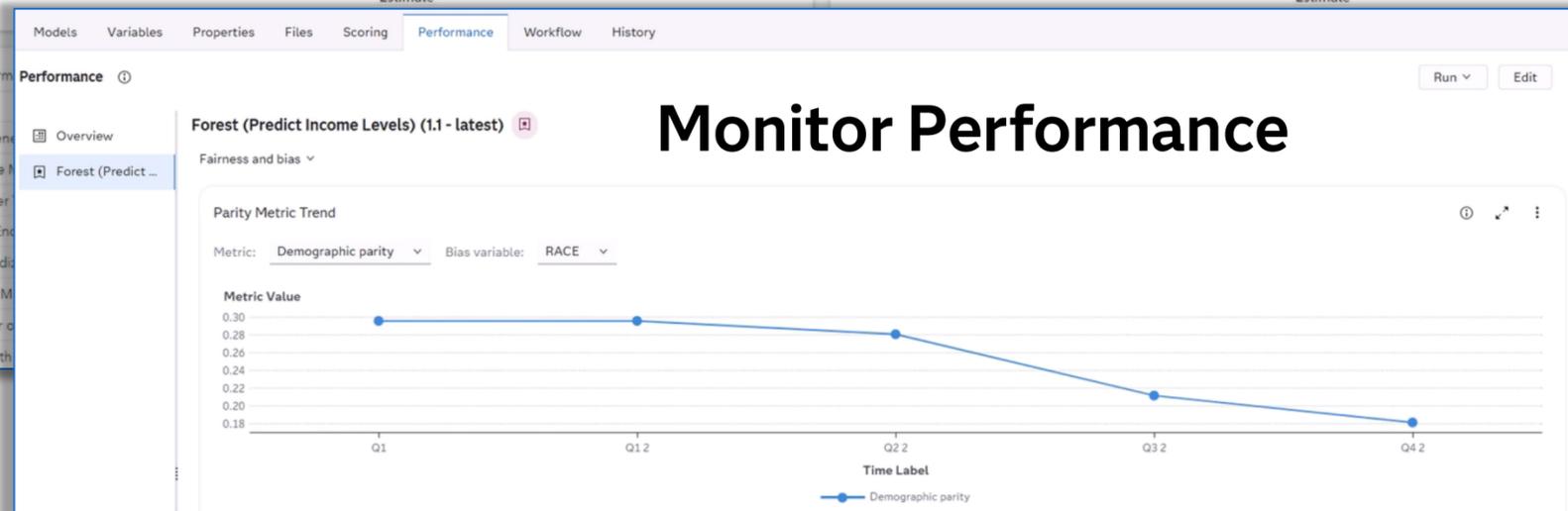
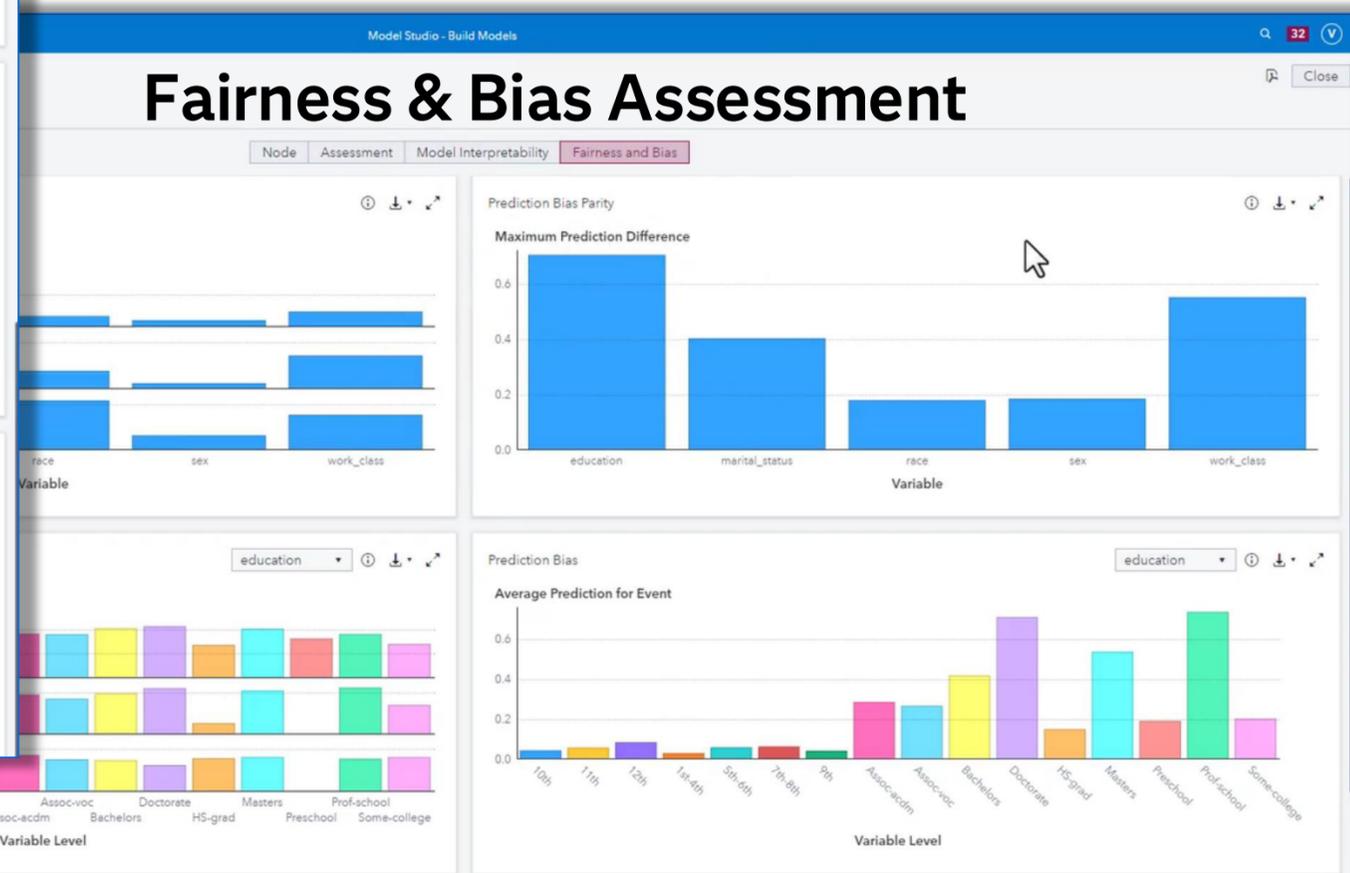
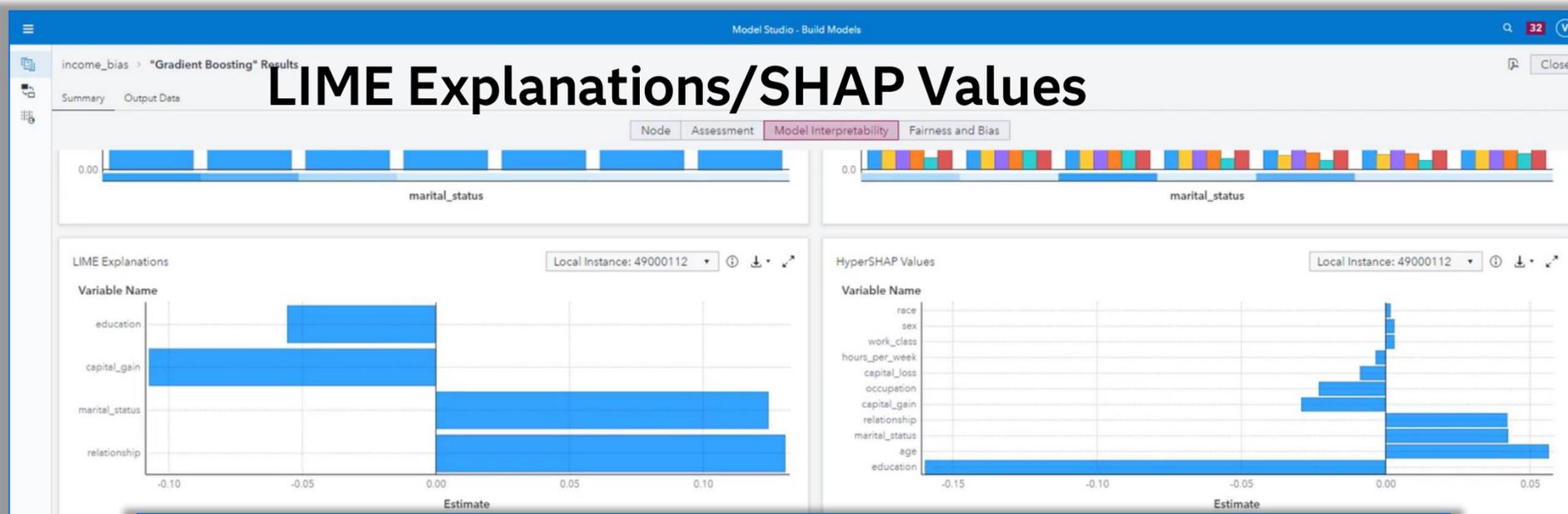
Features of A Trusted & Modern RWD Analytics Platform

You can...

Utilize end-to-end trustworthy AI capabilities, including explainable models, transparent model governance, bias detection, and continuous monitoring

so that...

Develop, validate, and deploy AI for RWD analysis in a consistent, ethical, and scientifically reliable way.



Features of A Trusted & Modern RWD Analytics Platform

CLOUD-NATIVE

- Necessary computing power and storage
- Scalability and Flexibility
- Better performance via in-database and in-memory parallel processing
- Hosting environment to reduce IT burden
- Access to multiple data sources

Statistics + Advanced Analytics

- Descriptive and inferential statistics
- Frequentist and Bayesian statistics
- Forecasting and optimization
- AI/Machine Learning
- Computer vision & Natural language processing

COLLABORATION

- For cross-functional and various skills
- Low-code/no-code UIs and programming interfaces
- Shared access to breakdown silos

OPENNESS

- Multiple programming languages (SAS, R, Python)
- Third-party integration (APIs, MCP)

UNIFIED & TRUSTWORTHY

- Cover end-to-end analytics lifecycle
- Manage analytical assets
- Improve governance with transparency
- Enhance efficiency via automation

Conclusion



Improve Health Outcome

Reliability, Relevance, Transparency, Reproducibility

Data

Method

Process

RWE

RCT

Modern and Trustworthy Analytics Platform

Thank you Any Question?



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