

# Building Real World Evidence on Cloud in Practice

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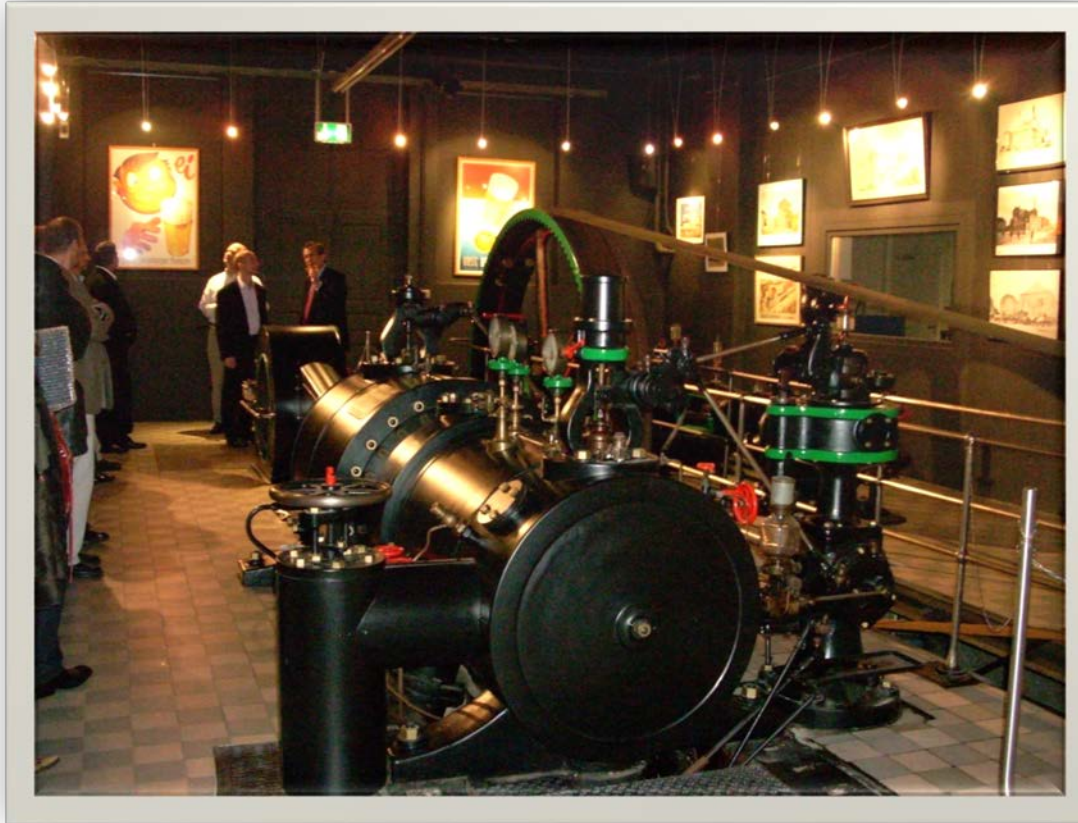
# Goal & Take Away

- The changing healthcare landscape requires healthcare industry companies to be data-driven organizations.
- Cloud has the enabling technologies and Quick Starts to become such organizations.
- What you want from RWE is not to have tools, but to bring out outcomes.
- Try it first anyway! In the cloud, this can be achieved with low risk.

# Why Cloud?

## What is the value of the cloud?

Most companies had electric generation capabilities on-site as differentiating factor



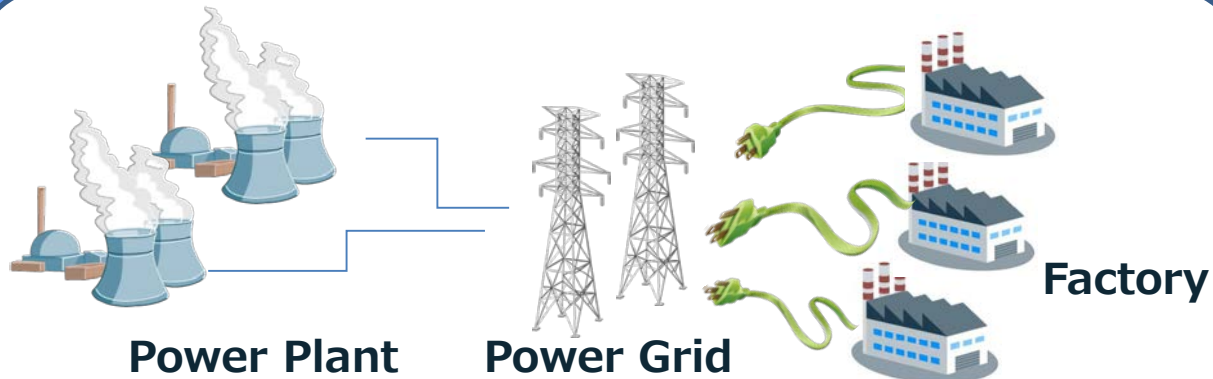
<https://www.informationweek.com/software/information-management/the-cloud-electric-generator-analogy/d/d-id/1075830>

# The emergence of power plants and power grids is a Paradigm Shift

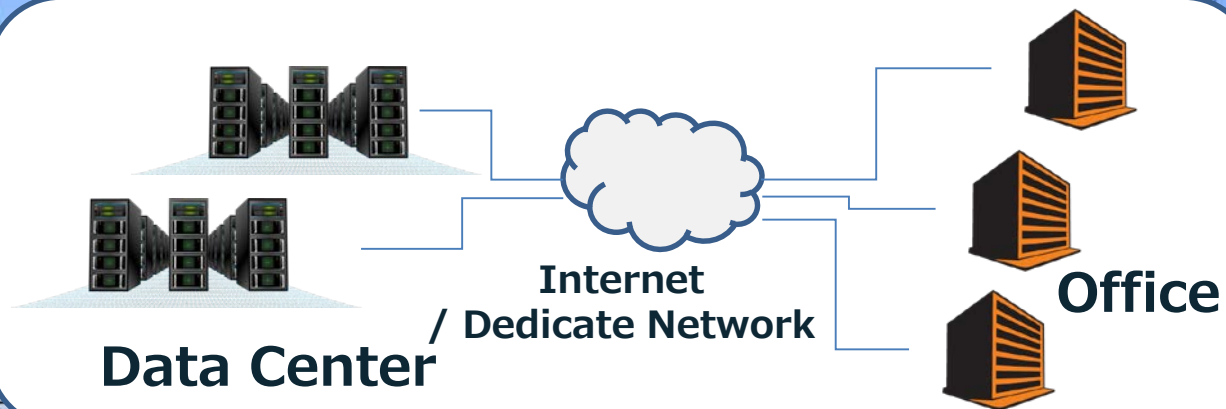


# When you need it, you can use it anytime with a low price

## Electric Power

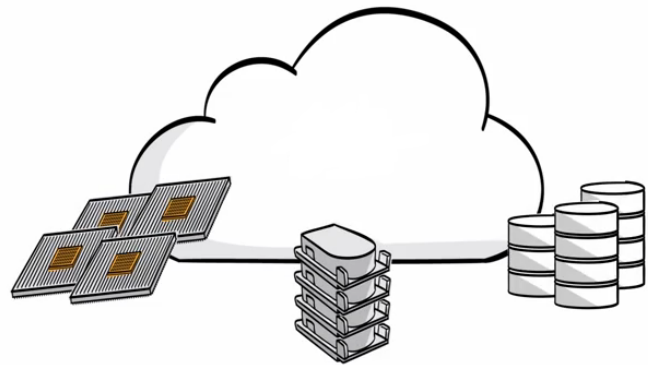
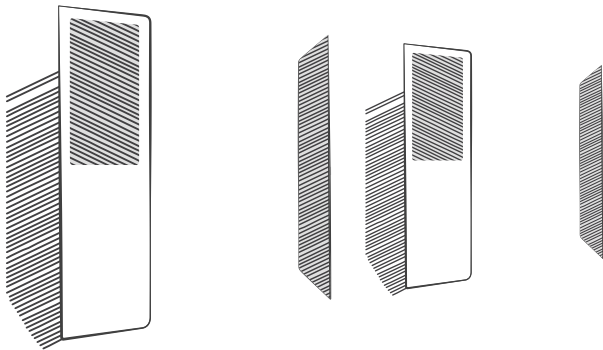


## IT





# The same transformation as electricity is in the IT world !



Initial investment

Surplus / shortage risk

Fixed Cost

No initial investment required

Pay as you go

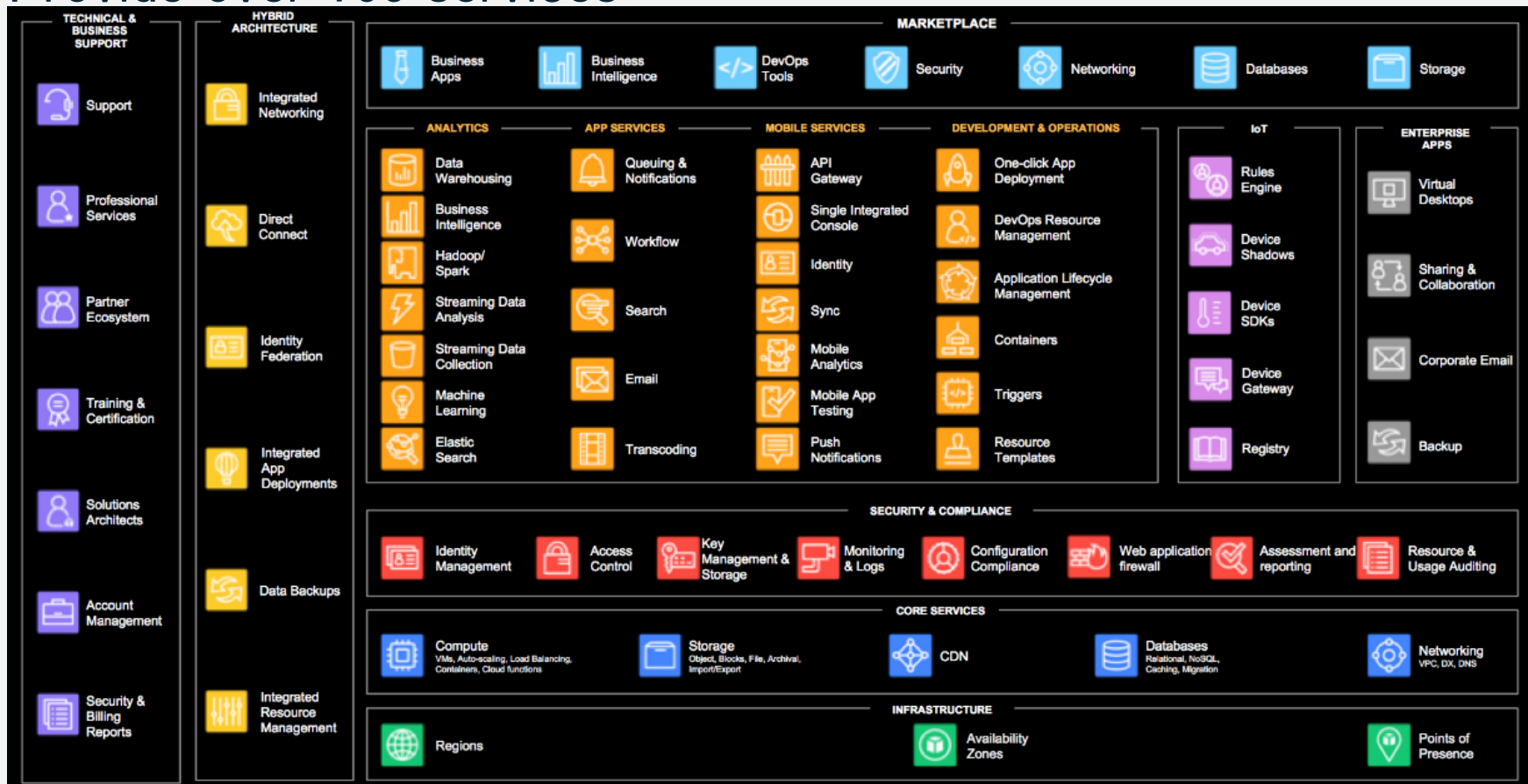
Variable costs

A close-up photograph of a child's hand, wearing a white sleeve, reaching towards a collection of colorful LEGO bricks. The bricks are in various colors including red, blue, yellow, green, and grey, and are scattered on a light-colored, textured surface. The child's hand is positioned near a red brick and a blue brick. The background is a soft, out-of-focus light color.

**The essence of AWS = Building Blocks**  
**You can combine and rapidly build services**



# Provide over 165 services



# Customer of Healthcare & Life Sciences in Japan



SyntheticGestalt



# Real World Evidence on AWS

# Why is the industry investing in Real World Evidence?



## Sustainability

Creating pressure on the healthcare system to produce better overall outcomes



## Reimbursement

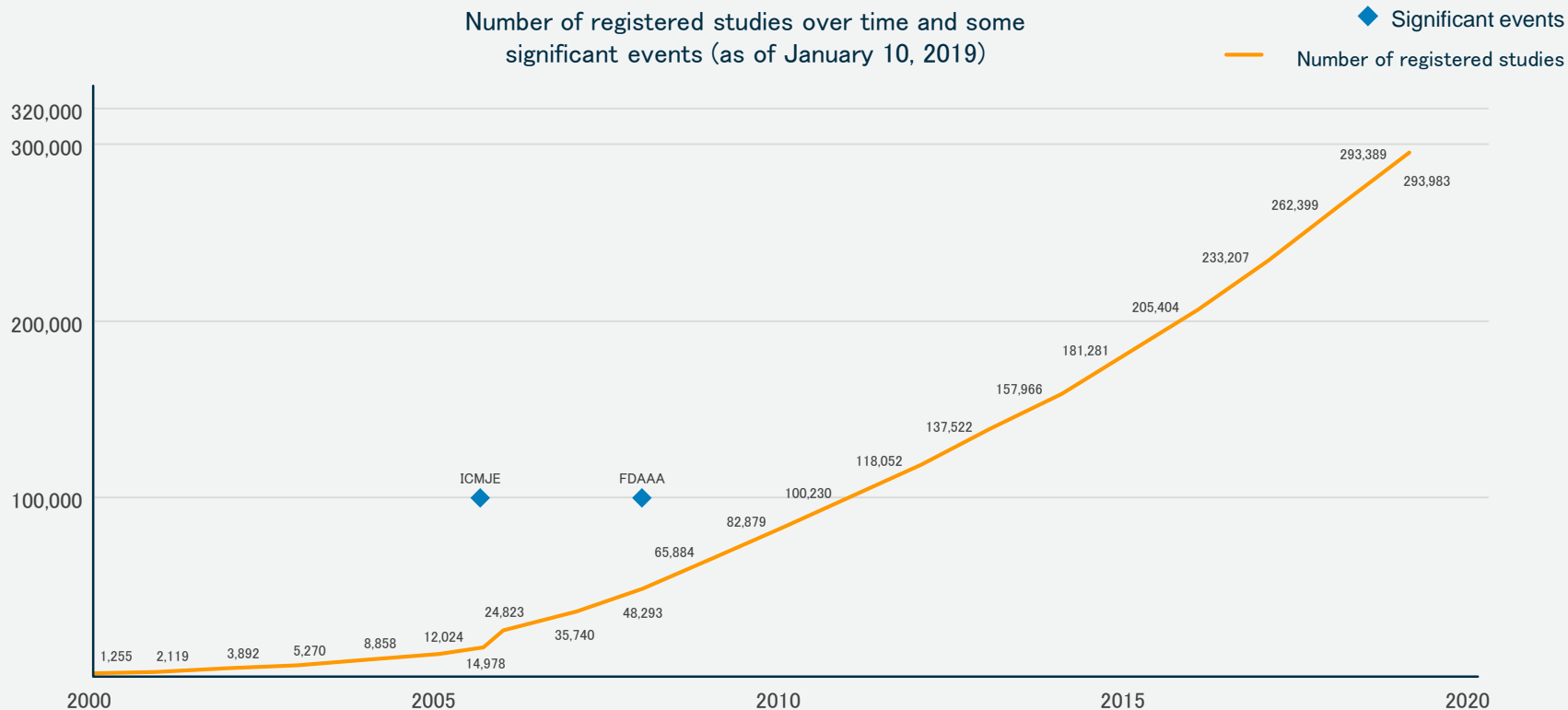
Payers utilizing new data sources to redefine value based payment models and formulary preference



## Healthcare Data is Exploding

44 fold increase from 2009, growing to 35ZB<sup>1</sup> fueling new insights and raising bar for proving outcomes

# Clinical trials activity is increasing across industry



Source: <https://ClinicalTrials.gov>

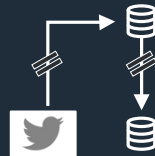
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# New requirements break the traditional approach



Customers need to:

Capture and store new non-relational data at EB scale



Secure and combine data from new and existing sources



Do new types of analysis (ML, big data & real-time)

Traditional approach:

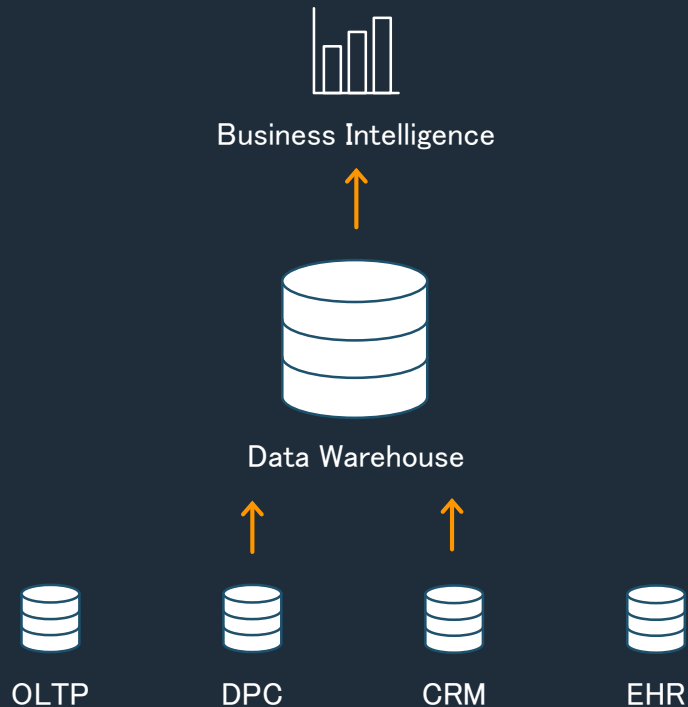
DW is optimized for relational data at PB scale

Data exists in silos, ETL does not scale at EB data volumes

Operational and ad hoc on relational only



# Traditionally, analytics look like this



- Relational data
- TBs-PBs scale
- Schema defined prior to data load
- Operational reporting and ad hoc
- Large initial CAPEX + \$10K-\$50K/TB/Year



A diagram illustrating the Data Lake architecture overlaid on a scenic background of a lake and mountains. The architecture consists of four main components: 'COLLECT' (two red arrows pointing towards the center), 'PROCESS / ANALYZE' (an orange arrow pointing right), 'STORE' (a blue rectangle), and 'CONSUME' (a green arrow pointing right). The 'COLLECT' arrows point towards the 'STORE' component, which then feeds into the 'PROCESS / ANALYZE' and 'CONSUME' components. The background features a calm lake reflecting the surrounding forest and snow-capped mountains under a dramatic sky.

COLLECT

COLLECT

PROCESS /  
ANALYZE

CONSUME

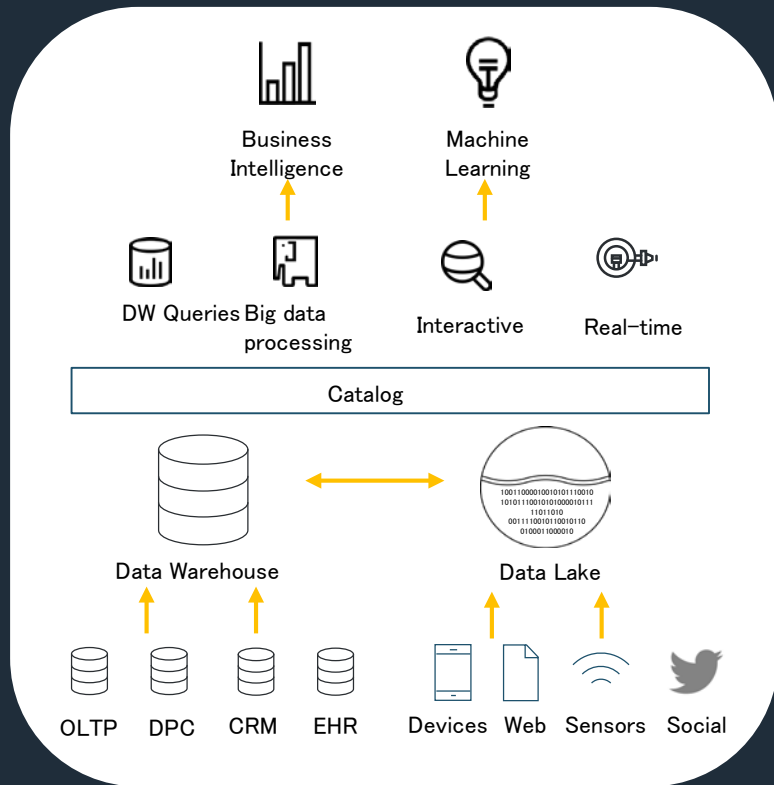
STORE

# Data Lake

# Building a Data Lake on AWS



# Data Lakes extend the traditional approach



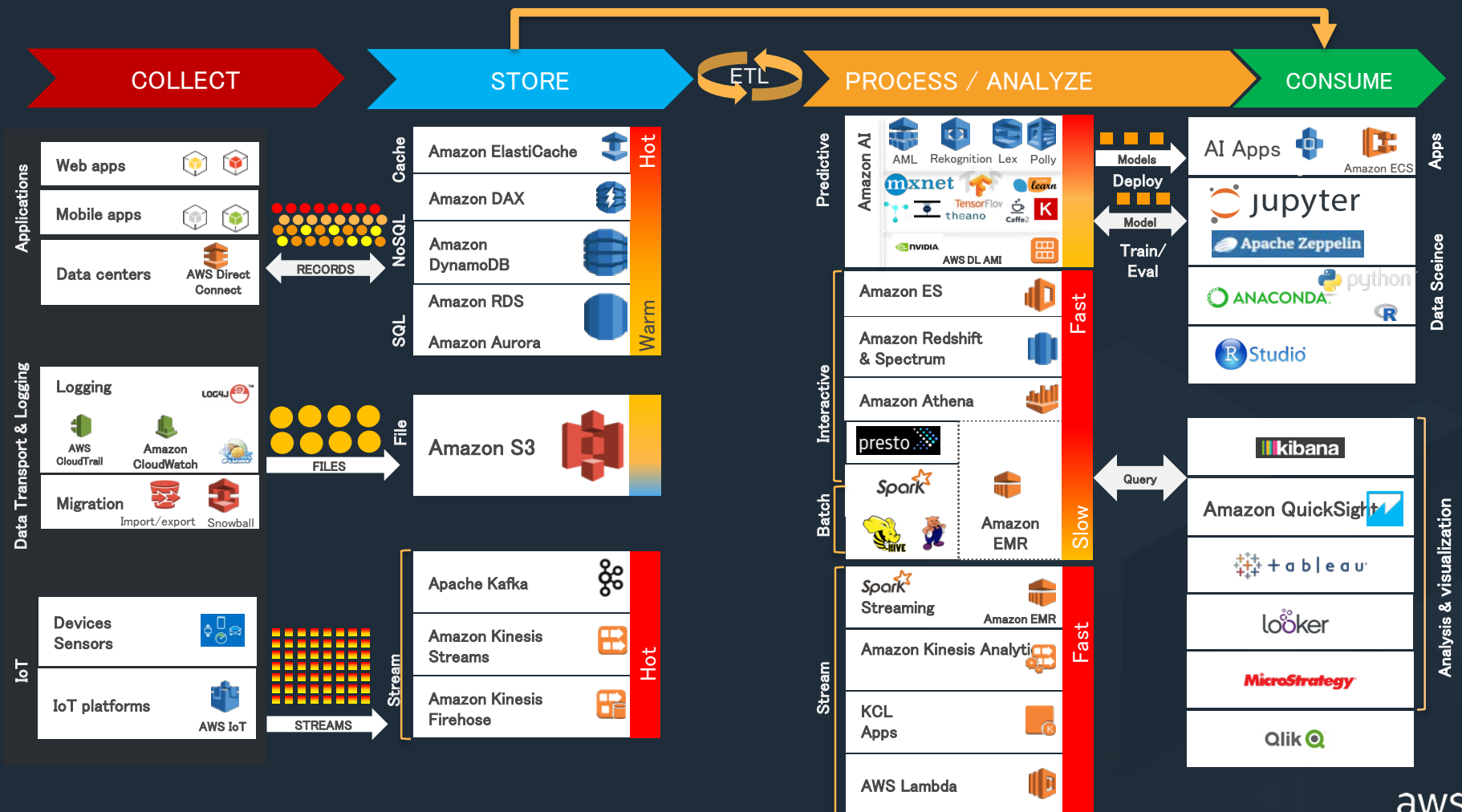
Relational and non-relational data

TBs-EBs scale

Schema defined during analysis

Diverse analytical engines to gain insights

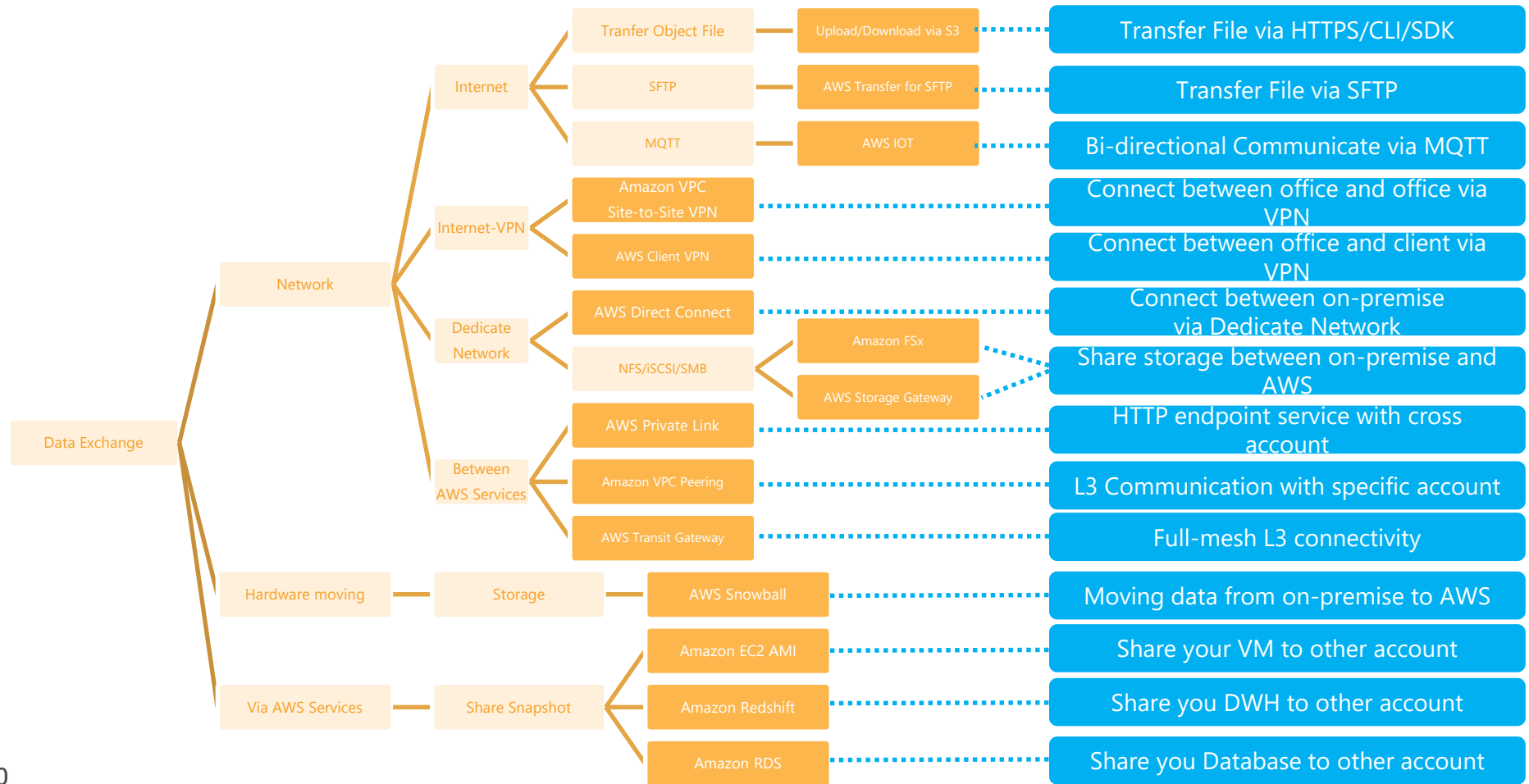
Designed for low cost storage and analytics





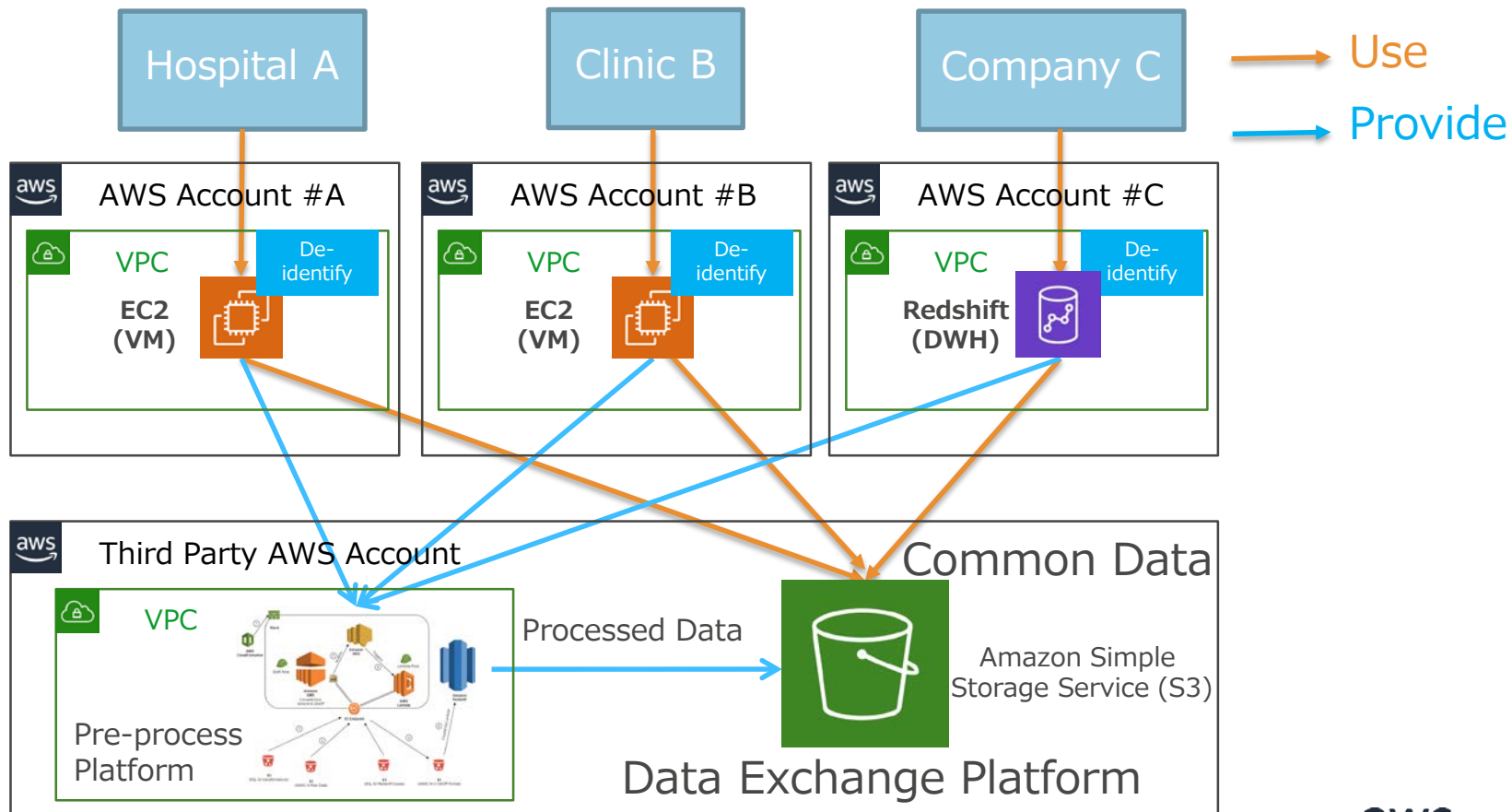
# Functions that enable Data Exchange

What you can do with other companies

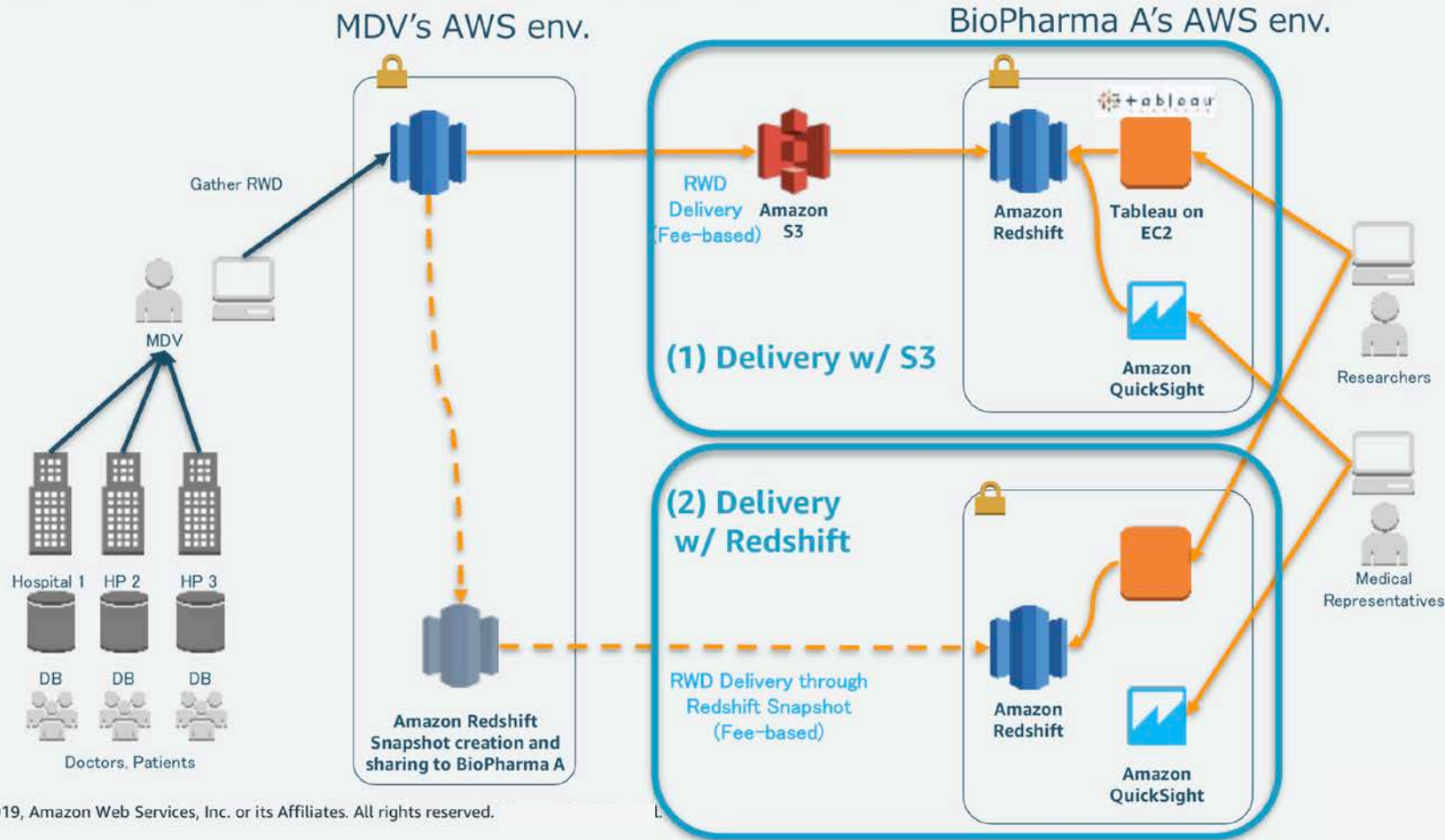




# Data Exchange Platform



# Provide data (MDV's online delivery of Real World Data (RWD))



# Use Case: Takeda Pharmaceutical Company / Data Hub

- AWS is adopted as a data analysis infrastructure.
- Provides data transparency, data-driven decision making, analytical standardization, and automation.

**BUSINESS INTERFACES (SAMPLE)**

The slide displays several sample business interfaces from the AWS re:Invent Data Hub, including:

- A dashboard with key metrics: \$389.7M, \$1,422M, and 143,475.
- A bar chart showing data across categories.
- A map of the United States with regional data points.
- A line chart showing trends over time.
- A circular diagram showing the drug development process: Learn, Research, Develop, and Execute.

**THE OPPORTUNITY**

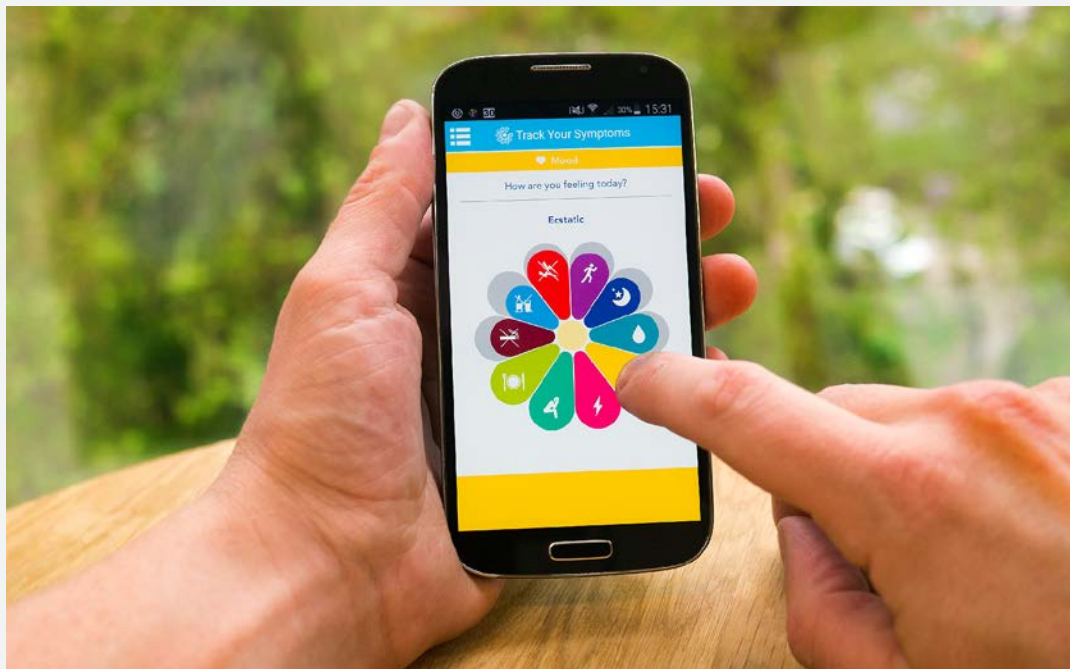
The slide lists several opportunities for data-driven decision making:

- Predictive Modeling
- Targeted Patient Enrollment
- Real Time Trial Monitoring
- Data Flow Across Boundaries (functional & organizational)
- Scale up CRDs to Demand
- Open Collaboration with Partners and Academia

The slide also features the AWS re:Invent logo and the AWS logo.

- ✓ <https://www.youtube.com/watch?v=chDWbAfFp8>
- ✓ <https://www.slideshare.net/AmazonWebServices/abd209accelerating-the-speed-of-innovation-with-a-data-sciences-data-analytics-hub-at-takeda>

# uMotif drives research and increases data quality



“

We had 5,000 people register to join the clinical study in the first seven days, and we scaled the AWS infrastructure accordingly, no problem. In total, **13,500 people participated.** ”

**Bruce Hellman,**  
Chief Executive Officer



**umotif**



# Customer Problems

1.2 B unstructured clinical documents created per year

Critical information “trapped” in these documents

Difficult to extract insights

# Amazon Comprehend Medical

## Named Entities

```
aws comprehend-medical detect-entities --region  
us-east-1 --text "<Insert Text Here>"
```



Mr. Smith is a 63-year-old gentleman with coronary artery disease and hypertension. CURRENT MEDICATIONS: taking a dose of LIPITOR 20 mg once daily

## Protected Health Information (PHI)

Mr. Smith: **Name**

63: **Age**

## Anatomy

Coronary artery: **System Organ Site**

## Medical Condition

Coronary artery disease: **Dx Name**

Hypertension: **Dx Name**

## Medication

Lipitor: **Brand Name**

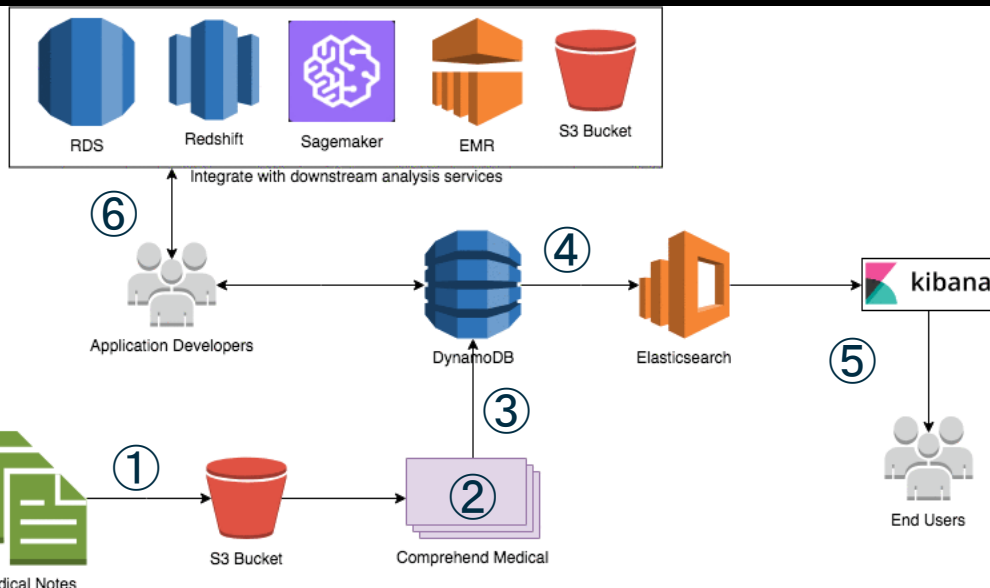
20 mg: **Dosage**

Once Daily: **Frequency**



# Extract and visualize clinical entities using Amazon Comprehend Medical

- 1) Upload Clinical notes to Amazon S3
- 2) Use Comprehend Medical API to extract various clinical entities
- 3) Extracted entities file is parsed and insert into Amazon DynamoDB table
- 4) DynamoDB has a stream attached to it. This stream is parsed using an AWS Lambda that is triggered by stream event
- 5) Lambda function inserts the records into Amazon Elasticsearch Service
- 6) Kibana dashboard visualize the clinical entities.



<https://aws.amazon.com/jp/blogs/machine-learning/extract-and-visualize-clinical-entities-using-amazon-comprehend-medical/>

# Extract and visualize clinical entities using Amazon Comprehend Medical

heradr2-database-16ST172K1WQUS [Close](#)

Overview **Items** Metrics Alarms Capacity Indexes Global Tables Backups Triggers Access control Tags

[Create Item](#) Actions ▾

Search: [Table] heradr2-database-16ST172K1WQUS: ROWID Viewing 1 to 100 items >

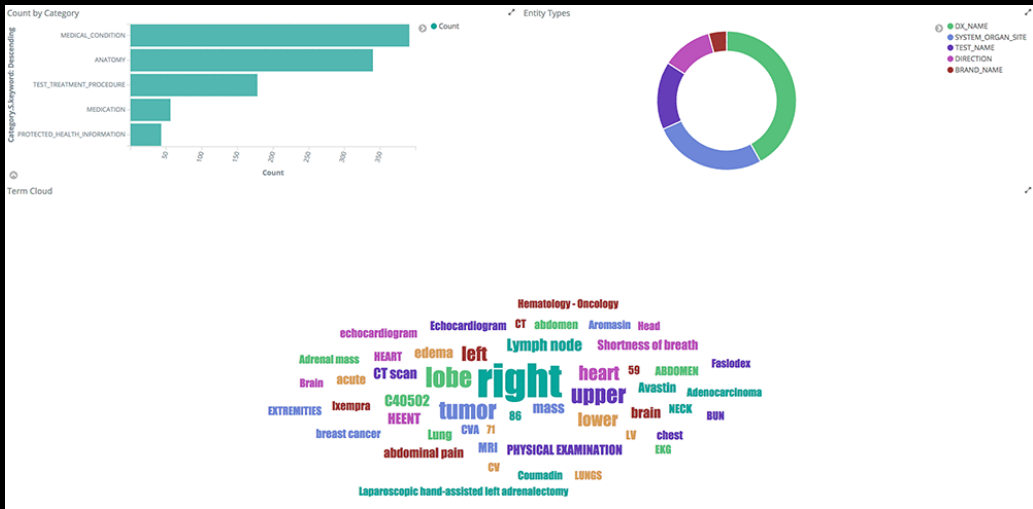
Scan ▾ [Table] heradr2-database-16ST172K1WQUS: ROWID ▴

⊕ Add filter

Start search

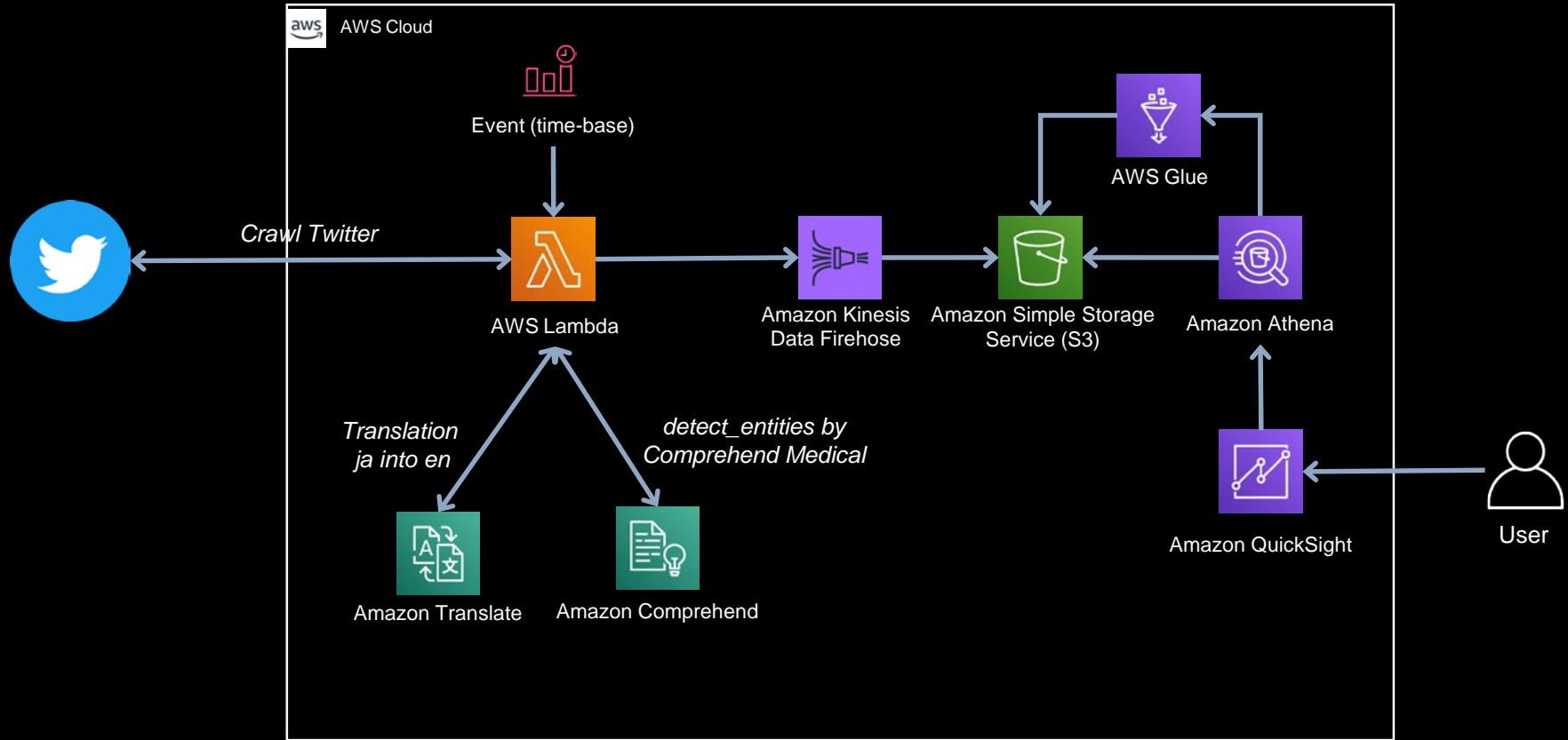
ROWID	Attribute_List	Category	ID	Score	Text
32	[TEST_VALUE:80.9°, TEST_UNIT:kg]	MEDICAL_CONDITION	40	0.9962009029556274	well-nourished
47	[TEST_VALUE:80.9°, TEST_UNIT:kg]	MEDICAL_CONDITION	50	0.9997739159582669	cyanosis
54	[TEST_VALUE:80.9°, TEST_UNIT:kg]	MEDICAL_CONDITION	84	0.6004368662834167	refractory ITP
62	[ROUTE_OR_MODE:infusion°, DOSAGE:400 to 500 mg]	TEST_TREATMENT_PROCEDURE	63	0.7623682022034727	platelets
69	[DOSAGE:several units]	TEST_TREATMENT_PROCEDURE	69	0.9738008973982666	Immunosuppressive regime
89	[DOSAGE:several units]	MEDICATION	103	0.9966021056656565	Tylenol
110	[TEST_VALUE:700°, TEST_UNIT:mg/dL]	TEST_TREATMENT_PROCEDURE	4	0.99766356555526733	appendectomy
113	[TEST_VALUE:700°, TEST_UNIT:mg/dL]	ANATOMY	26	0.97732023128509521	left
117	[TEST_VALUE:700°, TEST_UNIT:mg/dL]	MEDICATION	15	0.3613143861293793	Anesthetics
118	[TEST_VALUE:700°, TEST_UNIT:mg/dL]	TEST_TREATMENT_PROCEDURE	5	0.7343666553497314	Anesthetics
122	[TEST_VALUE:700°, TEST_UNIT:mg/dL]	MEDICATION	17	0.9759067893028259	Dermol
130	[ROUTE_OR_MODE:PO]	MEDICATION	51	0.9814012050628662	Fish Oil
131	[DOSAGE:500 mg, ROUTE_OR_MODE:PO°, FREQUENCY:QID]	MEDICATION	59	0.9997069239516394	sulfasalazine
135	[DOSAGE:600 mg, ROUTE_OR_MODE:PO°, FREQUENCY:QID]	ANATOMY	62	0.9788829412851062	EYES

You can see the extracted entities from the notes. We get the attributes like Category, Type and also a confidence score.



You will see the dashboard with visualizations generated from the extracted entities.

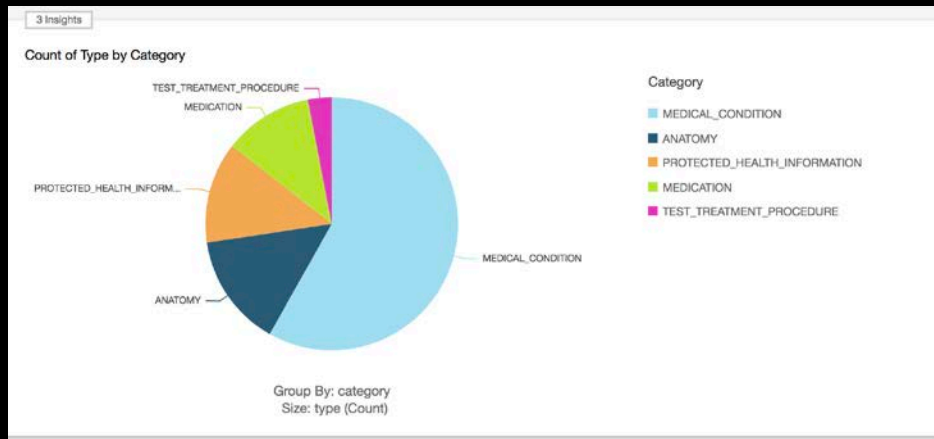
# Architecture : SNS Analytics using Comprehend Medical Demo



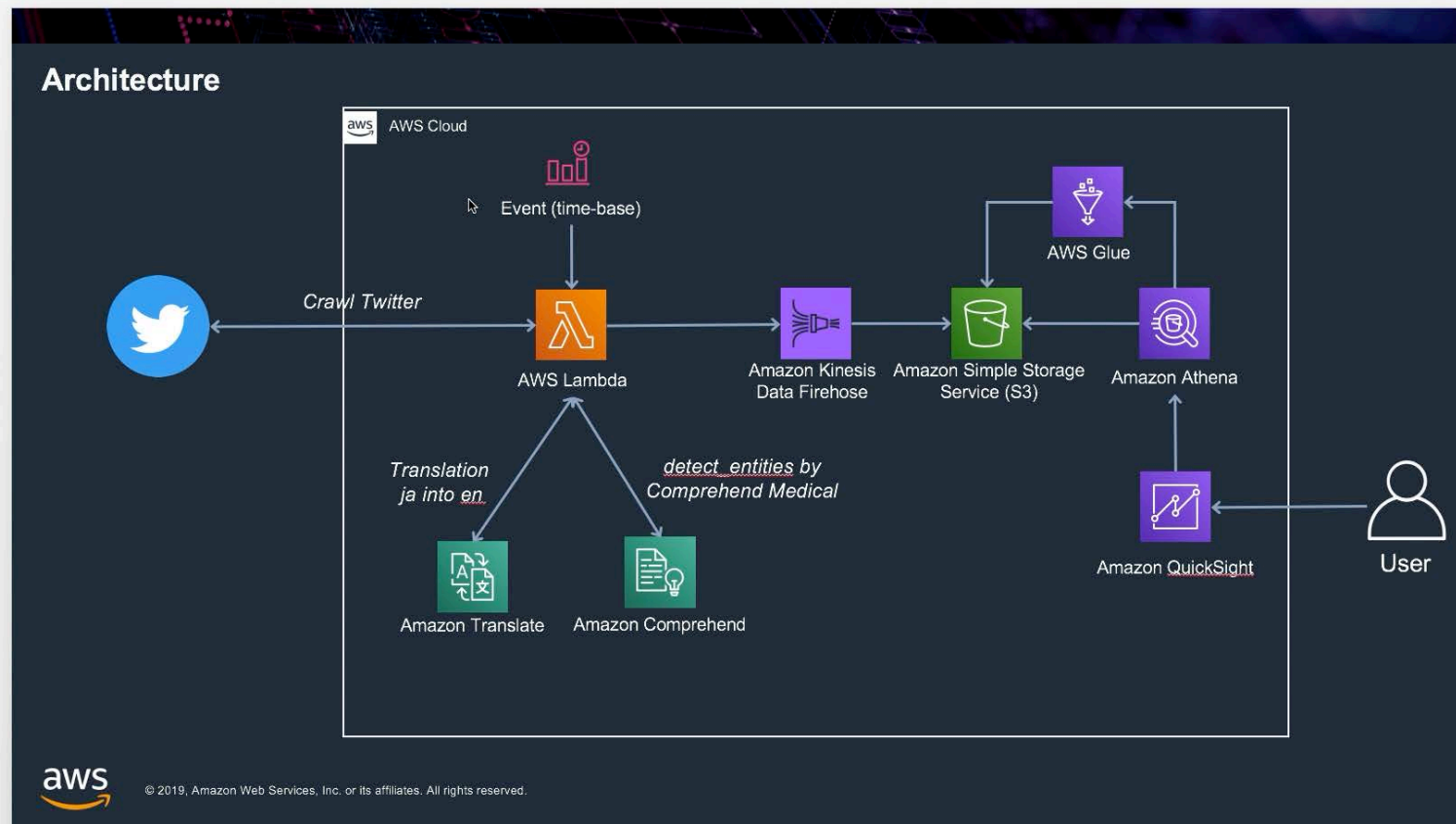
# Demo - Comprehend Medical

- Twitter (in this demo, # anticancer drug side effects, #hay fever) is crawled regularly, and natural language processing specialized in the medical field is performed at Amazon Translate and Amazon Comprehend Medical
- Analyze and visualize results with Amazon Athena, Amazon QuickSight

score	text	category	type
0.820244550704956	U.S. National Complementary	PROTECTED_HEALTH_INFORMATION	ADDRESS
0.9708576202392578	Ishigaki Island	PROTECTED_HEALTH_INFORMATION	ADDRESS
0.2258729189634323	Glaxo	MEDICATION	BRAND_NAME
0.2956674088968506	ADiMy3oqha	MEDICATION	BRAND_NAME
0.5027686357498169	Mylan	MEDICATION	BRAND_NAME
0.6231828331947327	Elprat	MEDICATION	BRAND_NAME
0.656606137752533	Allerbi	MEDICATION	BRAND_NAME
0.8726202845573425	Ryupurin	MEDICATION	BRAND_NAME
0.998677501678467	Adriamycin	MEDICATION	BRAND_NAME
0.6272539496421814		PROTECTED_HEALTH_INFORMATION	DATE
0.43949946761131287	inner	ANATOMY	DIRECTION
0.916235089302063	below	ANATOMY	DIRECTION
0.9232311844825745	posterior	ANATOMY	DIRECTION
0.2681172490119934	cold ones	MEDICAL_CONDITION	DX_NAME
0.31557729840278625	cold	MEDICAL_CONDITION	DX_NAME
0.35009491443634033	foreign objects are easily penetrating	MEDICAL_CONDITION	DX_NAME
0.3520383834838867	terrible side effects	MEDICAL_CONDITION	DX_NAME
0.37599289417266846	colon and rectal cancer	MEDICAL_CONDITION	DX_NAME

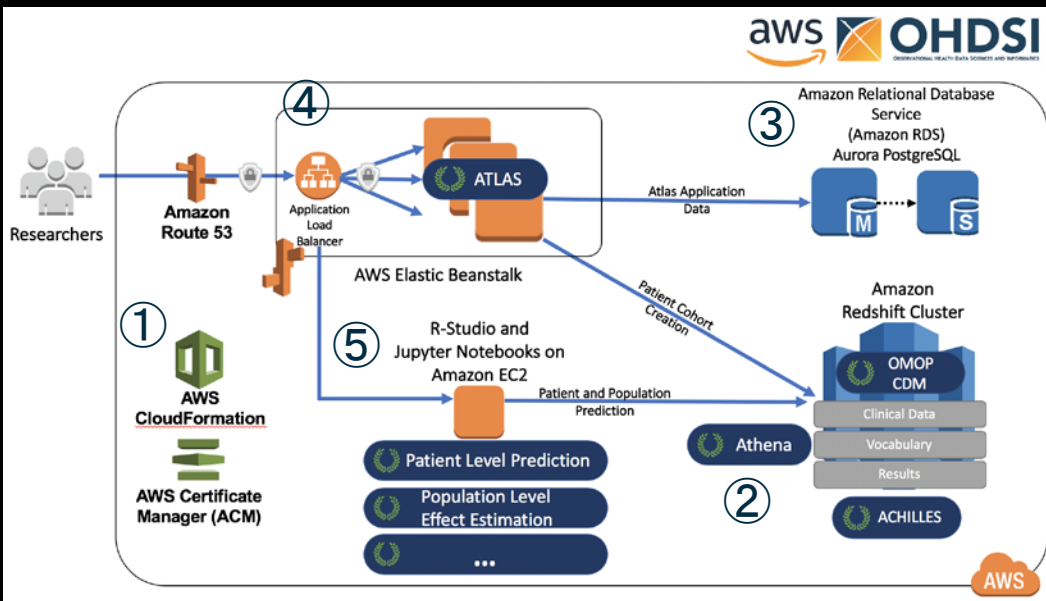


# Demo: Twitter analysis using Comprehend Medical



# Create data science environments on AWS for health analysis using OHDSI

✧ The Observational Health Data Sciences and Informatics (OHDSI) program and community are working toward this goal by producing data standards and open-source solutions to store and analyze observational health data.

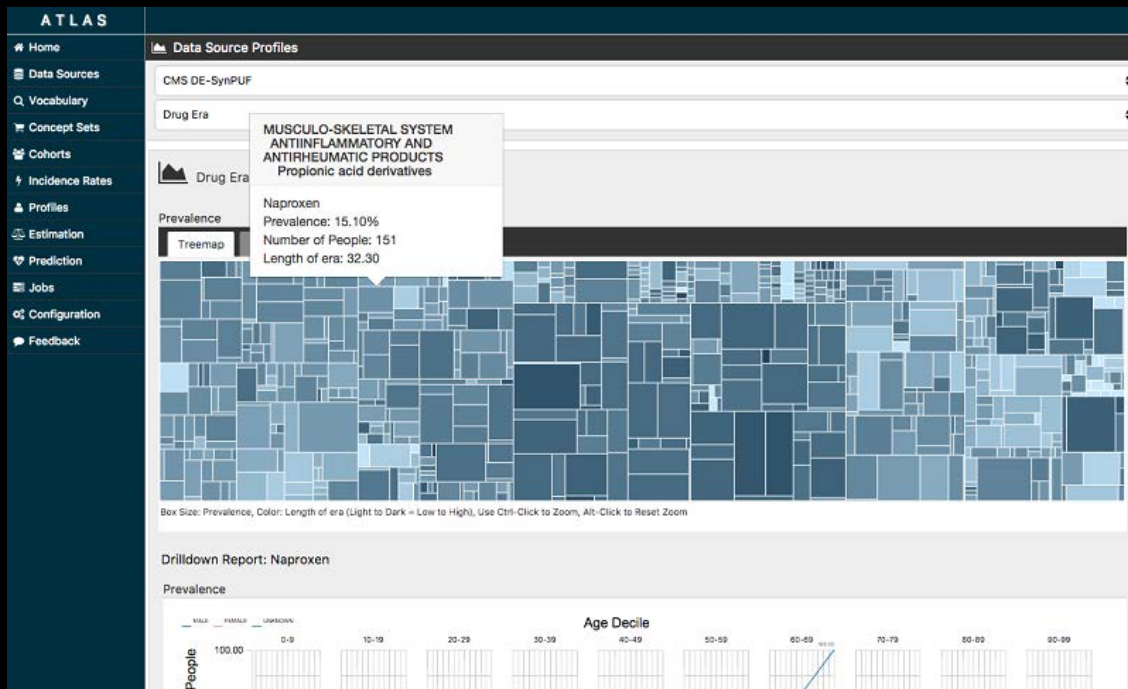


- 1) CloudFormation build this architecture automatically in about 30min.
- 2) Load data as OMOP format.
- 3) Build DB for Atlas application.
- 4) Use ATLAS for visualization
- 5) Execute prediction using R-Studio and Jupyter notebook.

<https://aws.amazon.com/ip/blogs/news/creating-data-science-environments-on-aws-for-health-analysis-using-ohdsi/>



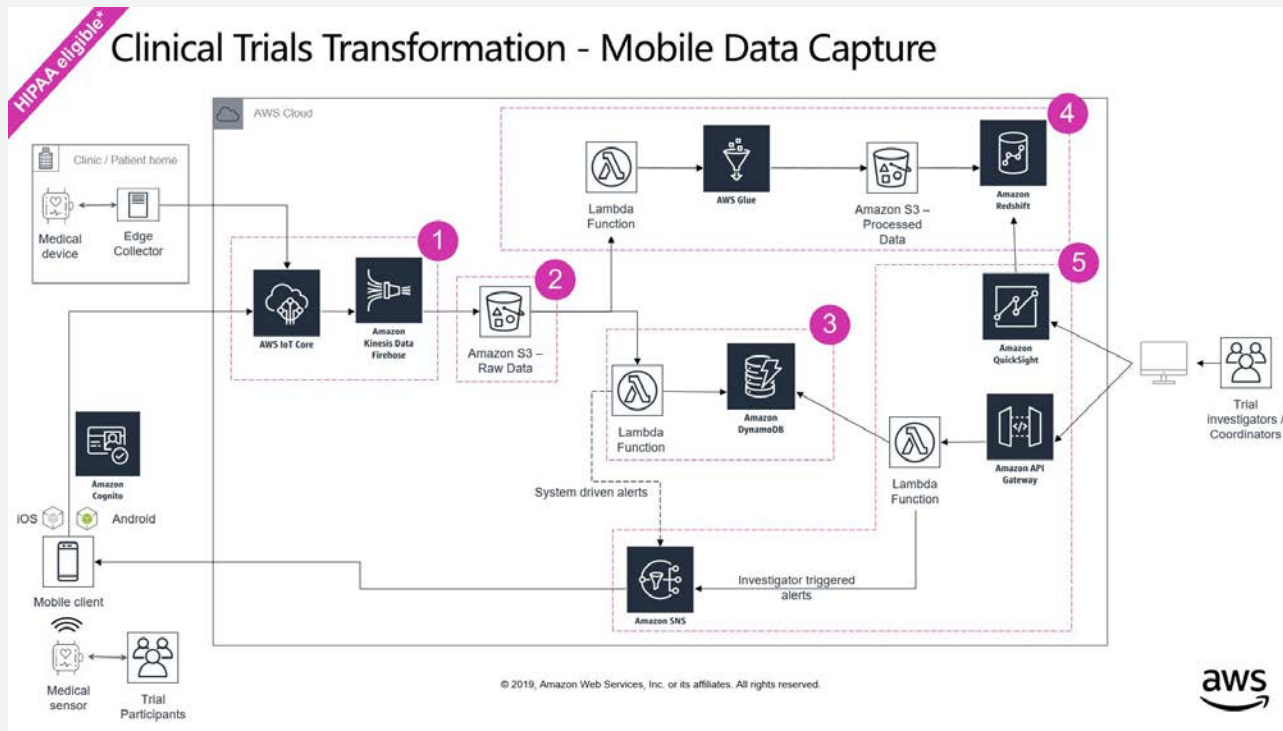
# Sample: Healthcare data visualization using ATLAS



• The following screenshot is just one example of the population health analysis that is possible with the OHDSI tools. This Atlas visualization shows the prevalence of various drugs within the given population of people. This information helps researchers and clinicians discover trends and make informed decisions about patient health.

# Mobile data capture with AWS

## Clinical trials transformation: mobile data capture (HIPAA eligible)



### 1. Collect data

Collect real-time, streaming data from medical devices and personal wearables

### 2. Store data

Store raw data on Amazon S3 for future analysis

### 3. Data processing—fast lane

Process and move actionable KPIs in Amazon DynamoDB (real-time, sliding window basis)

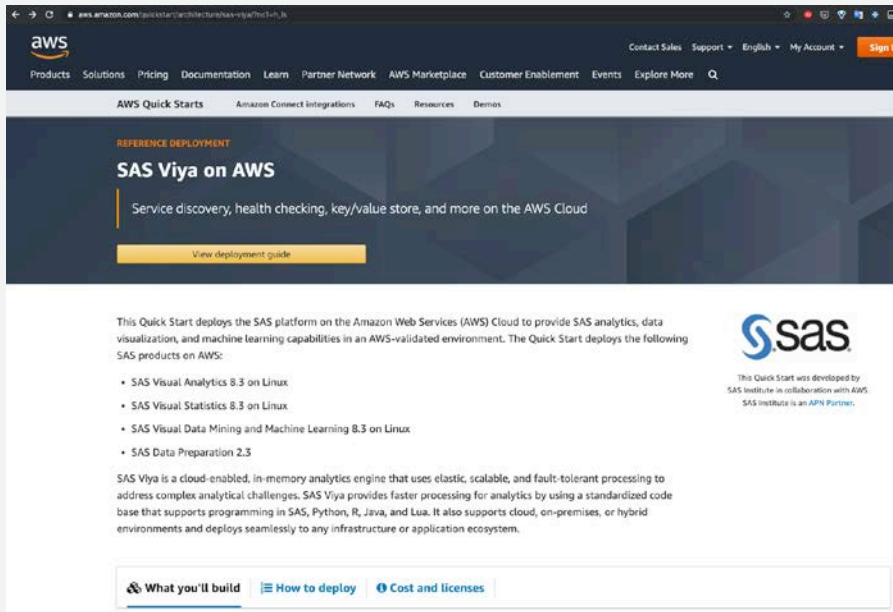
### 4. Data processing—batch

Extract, transform, and load (ETL) data using AWS Glue and move to Amazon S3. Load data in Amazon Redshift for detailed analysis

### 5. Visualize and act on data

Leverage Amazon QuickSight (or other BI tools) for data visualization. Provide real-time feedback via emails and text messages using Amazon SNS

# SAS Viya on AWS



The screenshot shows the AWS Quick Start page for SAS Viya on AWS. The page header includes the AWS logo and navigation links. The main content area features the title "SAS Viya on AWS" and a description: "Service discovery, health checking, key/value store, and more on the AWS Cloud". Below this is a yellow button labeled "View deployment guide". The page also lists the SAS products on AWS: SAS Visual Analytics 8.3 on Linux, SAS Visual Statistics 8.3 on Linux, SAS Visual Data Mining and Machine Learning 8.3 on Linux, and SAS Data Preparation 2.3. A section titled "What you'll build" is visible at the bottom.

**REFERENCE DEPLOYMENT**

## SAS Viya on AWS

Service discovery, health checking, key/value store, and more on the AWS Cloud

[View deployment guide](#)

This Quick Start deploys the SAS platform on the Amazon Web Services (AWS) Cloud to provide SAS analytics, data visualization, and machine learning capabilities in an AWS-validated environment. The Quick Start deploys the following SAS products on AWS:

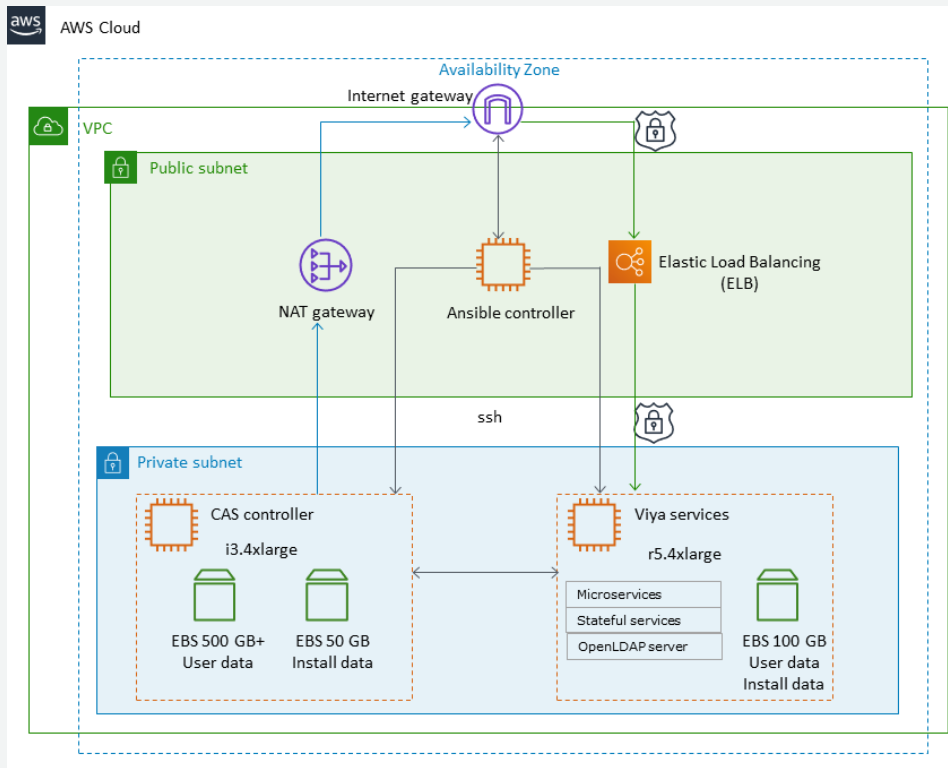
- SAS Visual Analytics 8.3 on Linux
- SAS Visual Statistics 8.3 on Linux
- SAS Visual Data Mining and Machine Learning 8.3 on Linux
- SAS Data Preparation 2.3

SAS Viya is a cloud-enabled, in-memory analytics engine that uses elastic, scalable, and fault-tolerant processing to address complex analytical challenges. SAS Viya provides faster processing for analytics by using a standardized code base that supports programming in SAS, Python, R, Java, and Lua. It also supports cloud, on-premises, or hybrid environments and deploys seamlessly to any infrastructure or application ecosystem.

[What you'll build](#) [How to deploy](#) [Cost and licenses](#)

<https://aws.amazon.com/jp/quickstart/architecture/sas-viya/>

## It will take just 30 min !



# Security / Compliance

# How Does AWS Approach Compliance?

A COMBINATION OF AWS CERTIFICATIONS, RESOURCES AND SUPPORT IN ADDITION TO CUSTOMER DUE DILIGENCE



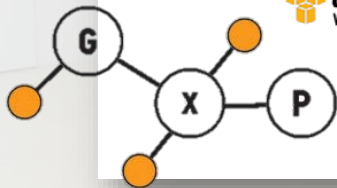


# GxP on AWS (Japanese Version)

## Considerations for Using AWS Products in GxP Systems

AWS 製品を  
GxP 関連システムにおいて  
使用する際の考慮事項

2016 年 1 月



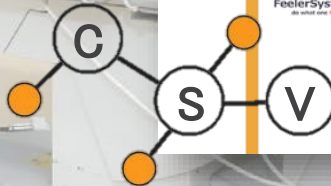
## CSV on AWS Reference From Partners

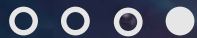


医薬品医療機器等法対象企業様向け  
AWS 利用リファレンス

**NTT DATA** 株式会社 NTT データグローバルソリューションズ  
**JSOL** 株式会社 JSOL  
**b-en-g** 東洋ビジネスエンジニアリング株式会社  
**HITACHI** 株式会社日立システムズ  
**FeelerSystemZ** フィラーシステムズ株式会社

2016 年 4 月 第 1 版





# Reduce risk.





Move fast.

OR

Stay  
secure.





Move fast.

AND

Stay  
secure.

# Access a deep set of cloud security tools

## Networking



**Virtual Private Cloud**  
Isolated cloud resources



**Web Application Firewall**  
Filter Malicious Web Traffic



**Shield**  
DDoS protection



**Certificate Manager**  
Provision, manage, and deploy SSL/TSL certificates

## Encryption



**Key Management Service**  
Manage creation and control of encryption keys



**CloudHSM**  
Hardware-based key storage



**Server-Side Encryption**  
Flexible data encryption options

## Identity & Management



**IAM**  
Manage user access and encryption keys



**SAML Federation**  
SAML 2.0 support to allow on-prem identity integration



**Directory Service**  
Host and manage Microsoft Active Directory



**Organizations**  
Manage settings for multiple accounts

## Compliance



**Service Catalog**  
Create and use standardized products



**Config**  
Track resource inventory and changes



**CloudTrail**  
Track user activity and API usage



**CloudWatch**  
Monitor resources and applications



**Inspector**  
Analyze application security



**Macie**  
Discover, Classify & Protect data

# Goal & Take Away

- The changing healthcare landscape requires healthcare industry companies to be data-driven organizations.
- Cloud has the enabling technologies and Quick Starts to become such organizations.
- What you want from RWE is not to have tools, but to bring out outcomes.
- Try it first anyway! In the cloud, this can be achieved with low risk.



**Thank you!**