Abbott EPD- Patient Data Center

Our journey to implementation of
Statistical Computing Environment (SCE) & Repository

26 | Nov | 2024

DISCLAIMER

The references and materials presented in this slide deck are not intended as recommendations for implementation or endorsements of any tools or resources.

The primary goal is to share experiences and knowledge, while also learning from the community. Please ensure you conduct thorough research and due diligence if you are exploring solutions or seeking inspiration.

AGENDA

Problem Statement

The Vision

Drivers for Implementation

The Solution

Challenges

Next Steps

Our Journey

Problem Statement

Problem Statement

- ✓ Scattered data across regions

- ✓ Local data copies

- ✓ Lack of traceability

- ✓ Challenging oversight

ABBOTT EPD-PATIENT DATA CENTER

The Vision

ABBOTT EPD —PATIENT DATA CENTER

Patient Data Center

Medical / Commercial

Design Centres

CRO

Clinical Workstreams

Subjects   Investigator

Medication   Imaging

Lab Data

Demographic   Adverse Events

Data Management Workflows

Insights
Dashboards   Reports   A.I.

Data Analytics
Spotfire
Sandbox Environments
SAS   R   Python
Scripts / TLF   Version Control

Management
Data Governance   User Rights   Program Meta data   Data Standards   SOP

Regulations
Data Retention Policy   Consent Management   Audit Trail   Data Privacy e.g. GDPR

Secure Storage
China   Asia   Latin   Russia   Europe   Global
Consented Patient Data

Real World Patient Data Workstreams

Health Consumers   Physicians

Real World Patient Management Workflows

Demographic

Medication

Compliant EPD Patient Data Center

Implementation Drivers

Implementation Drivers

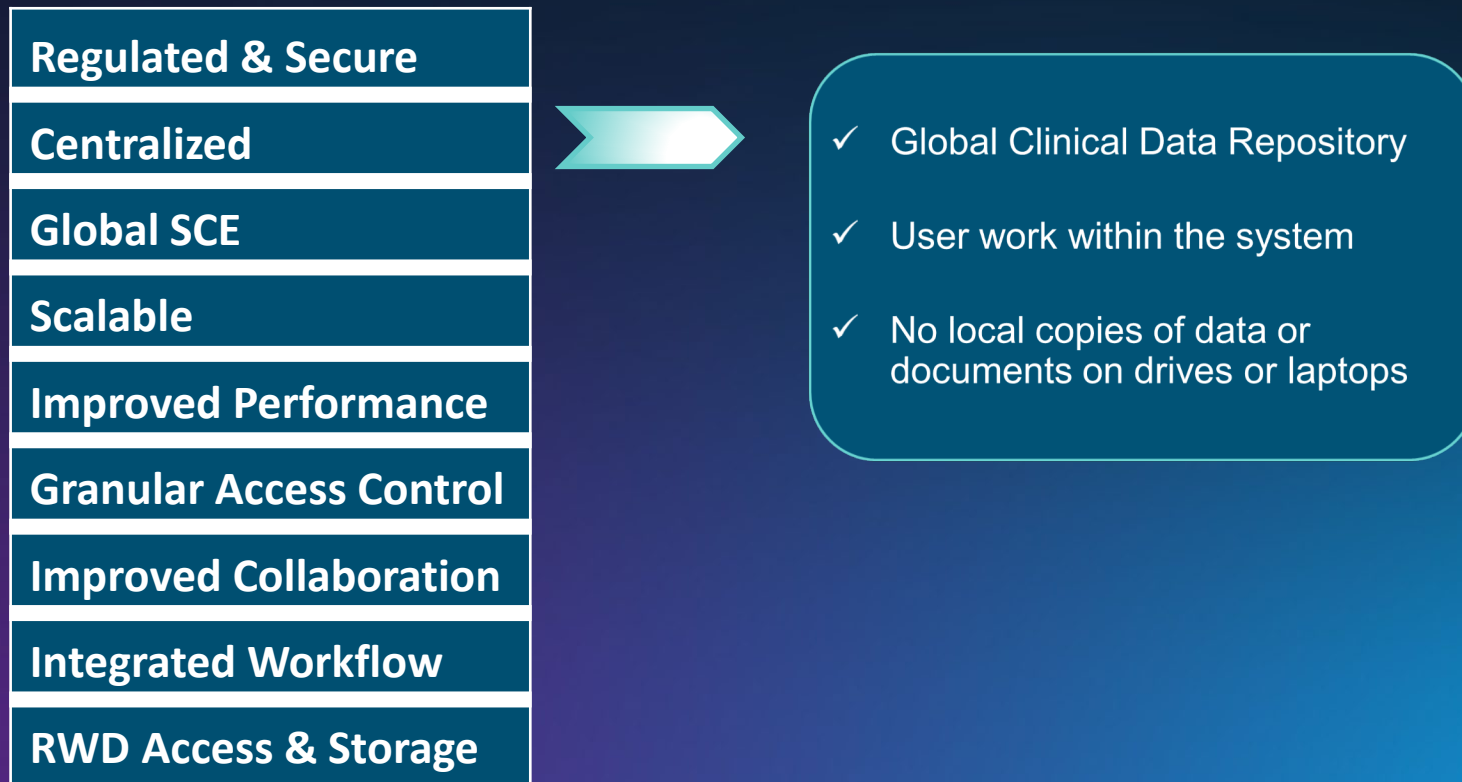| |
|---|
| **Regulated & Secure** |
| **Centralized** |
| **Global SCE** |
| **Scalable** |
| **Improved Performance** |
| **Granular Access Control** |
| **Improved Collaboration** |
| **Integrated Workflow** |
| **RWD Access & Storage** |

- ✓ FDA 21CFR Part11 compliant system.

- ✓ Versioning

- ✓ Audit Trails

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

✓ Global Clinical Data Repository

✓ User work within the system

✓ No local copies of data or documents on drives or laptops

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

✓ Integrated Statistical Computing environment

✓ Flexible Programming platforms (SAS, R, Python)

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

On demand computing storage for :

✓ Traditional Data / Evolving data sources

✓ User Experience

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

✓ Access to data for programming & Analysis (Optimal Performance)

✓ Work within a controlled environment, no need to download data locally.

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

✓ Role based access to data and files

✓ Users only see what they need to see, no need for multiple copies of data

✓ Easy access /Data Search capabilities at metadata level

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

✓ Improves the collaboration within Abbott and External parties (CROs)

✓ Everyone looks at single source of truth

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

Reliable lifecycle management for

- ✓ Data
- ✓ Programs
- ✓ Documents

Implementation Drivers

Regulated & Secure

Centralized

Global SCE

Scalable

Improved Performance

Granular Access Control

Improved Collaboration

Integrated Workflow

RWD Access & Storage

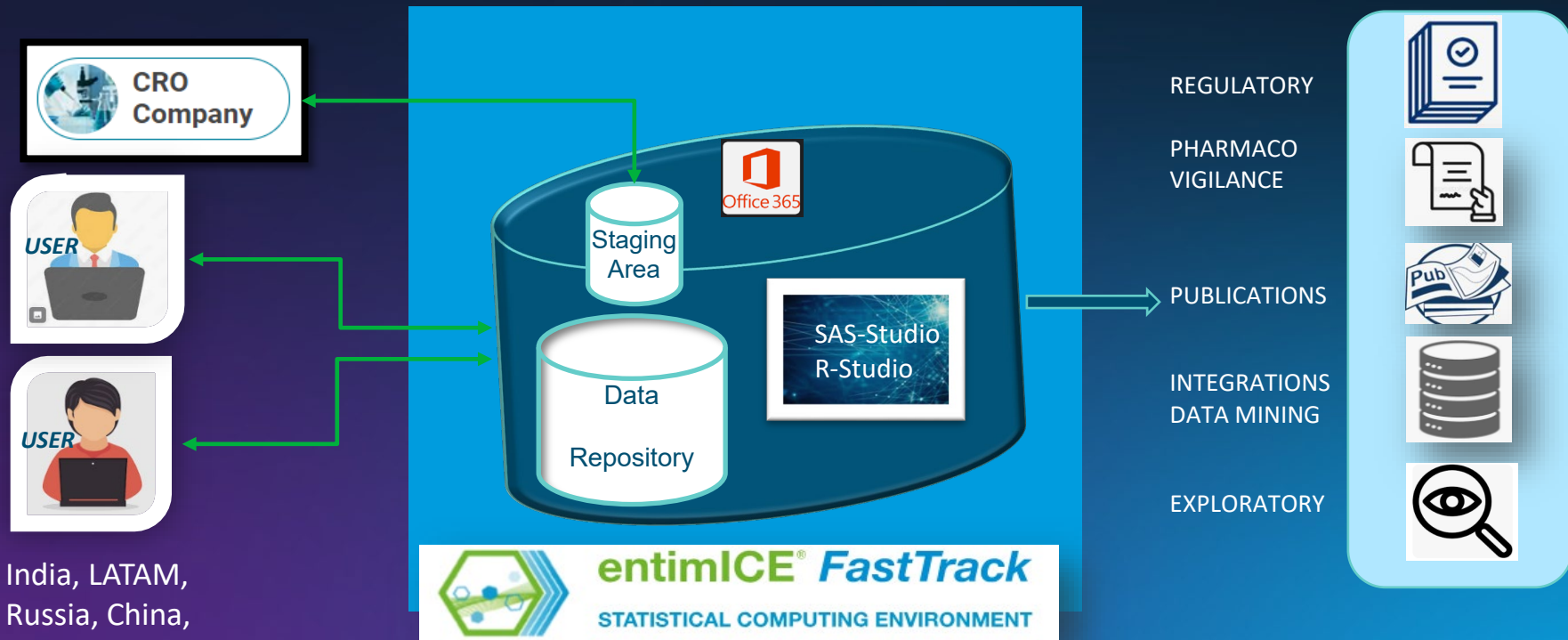Foundation for evolving data sources, Real world data from digital devices, health consumers.

The Solution

The Solution

CRO Company

USER

USER

India, LATAM, Russia, China, EU

Office 365

Staging Area

Data Repository

SAS-Studio R-Studio

entimICE® FastTrack
STATISTICAL COMPUTING ENVIRONMENT

REGULATORY

PHARMACO VIGILANCE

PUBLICATIONS

INTEGRATIONS DATA MINING

EXPLORATORY

Abbott EPD- Patient Data Center -Today

55+ Users

20+ CROs

50+ Compounds

- ✓ Legacy Data migration completed
- ✓ 40 Projects finalized within new system
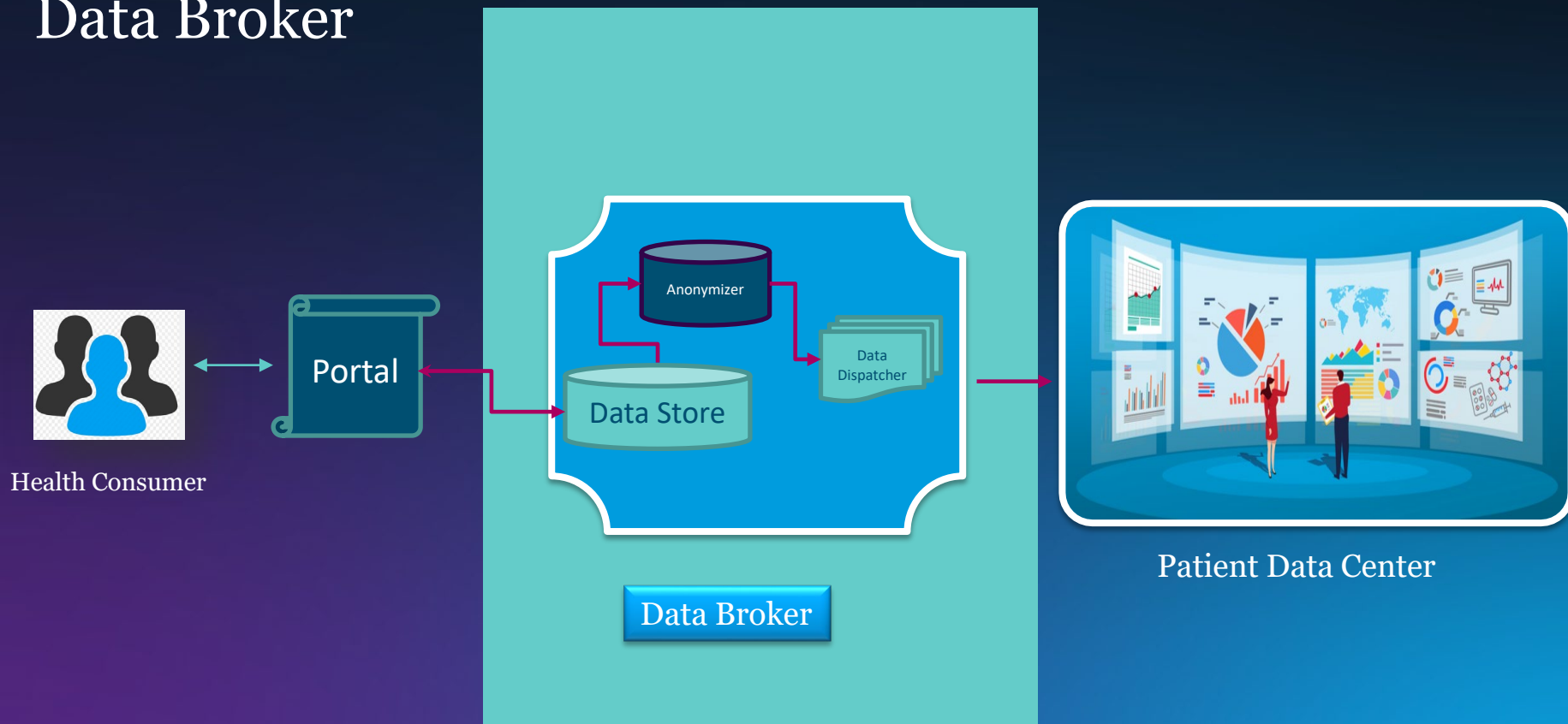- ✓ 10+ Ongoing Projects

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Challenges

Challenges

- ✓ New ways of working

- ✓ Updates to SOPs

- ✓ New Work Instructions, templates

- ✓ Long Learning Curve

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Next Steps

Data Broker

Health Consumer

Portal

Anonymizer

Data Store

Data Dispatcher

Data Broker

Patient Data Center

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Our Journey

Our Journey

START

1 Vendor Selection
(Mar-2022, June-2022

2 Deployment
Jun-2023, Jul-2023

3 Go-Live
Sep-2023, Oct-2023

5 Migration
Nov-2023, Jan-2024

4 User workshop
Oct-2023, Nov-2023

9 **STOP?**

PDC Data Broker
Not Started