Shire Global OSIsoft PI System Program

Globalizing Past & Future OSIsoft PI System Deployments

Presented by

Who we are and what we do

We are dedicated to serving patients with rare diseases

With our rich heritage and unique expertise, we are champions for the estimated 350 million people worldwide affected by rare diseases.

Our capabilities in other highly specialized conditions enables us to reach more patients who are struggling to live their lives to the fullest.

Shire

We’re proud of the recognition we’ve received so far

Examples:

Scrip Awards
Pharma intelligence | informa

#1

“Pharma Company of the Year”

(12th Annual Scrip Awards - 2016)

AllTrials

#1

pharmaceutical company for clinical trial transparency

(AllTrials - 2016)

Newsweek GREEN RANKINGS 2016

#1

“Green” company in the world based on corporate sustainability and environmental impact

(Newsweek - 2016)

2015 Most Reputable Companies
U.S. TOP 100
RepTrak
Reputation Institute

#1

most reputable healthcare company in the U.S., and 31st most reputable company overall

(U.S. RepTrak® 100 - 2015)

FTSE Nasdaq

TOP 15

on FTSE 100

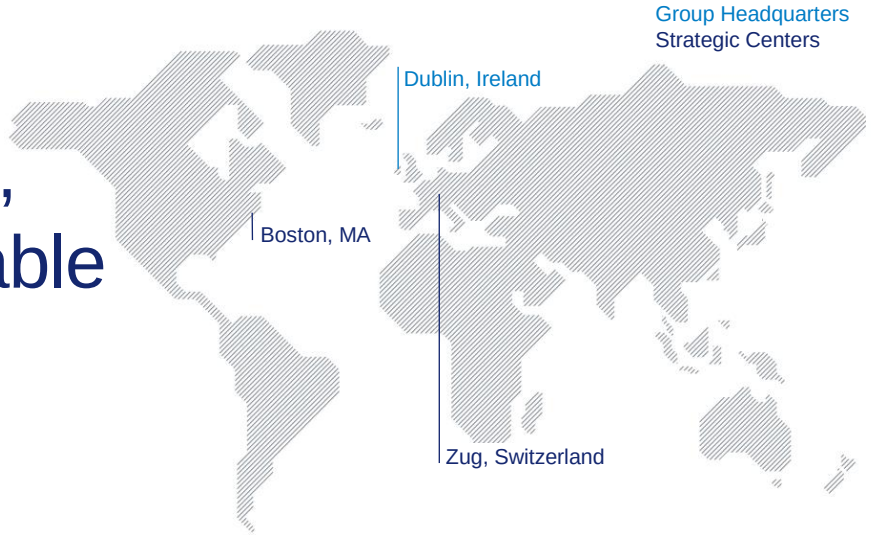
Also added to NASDAQ100 index, October 2016[1]

Shire

(1)Based on market cap values as of 12/20/2016

Our global reach enables us to help more people than ever before

We have nearly 24,000 employees in 65+ countries, and our therapies are available in more than 100 countries.



~40
Marketed products

~40
Clinical programs in the pipeline

17
Manufacturing sites

90+
Plasma collection centers

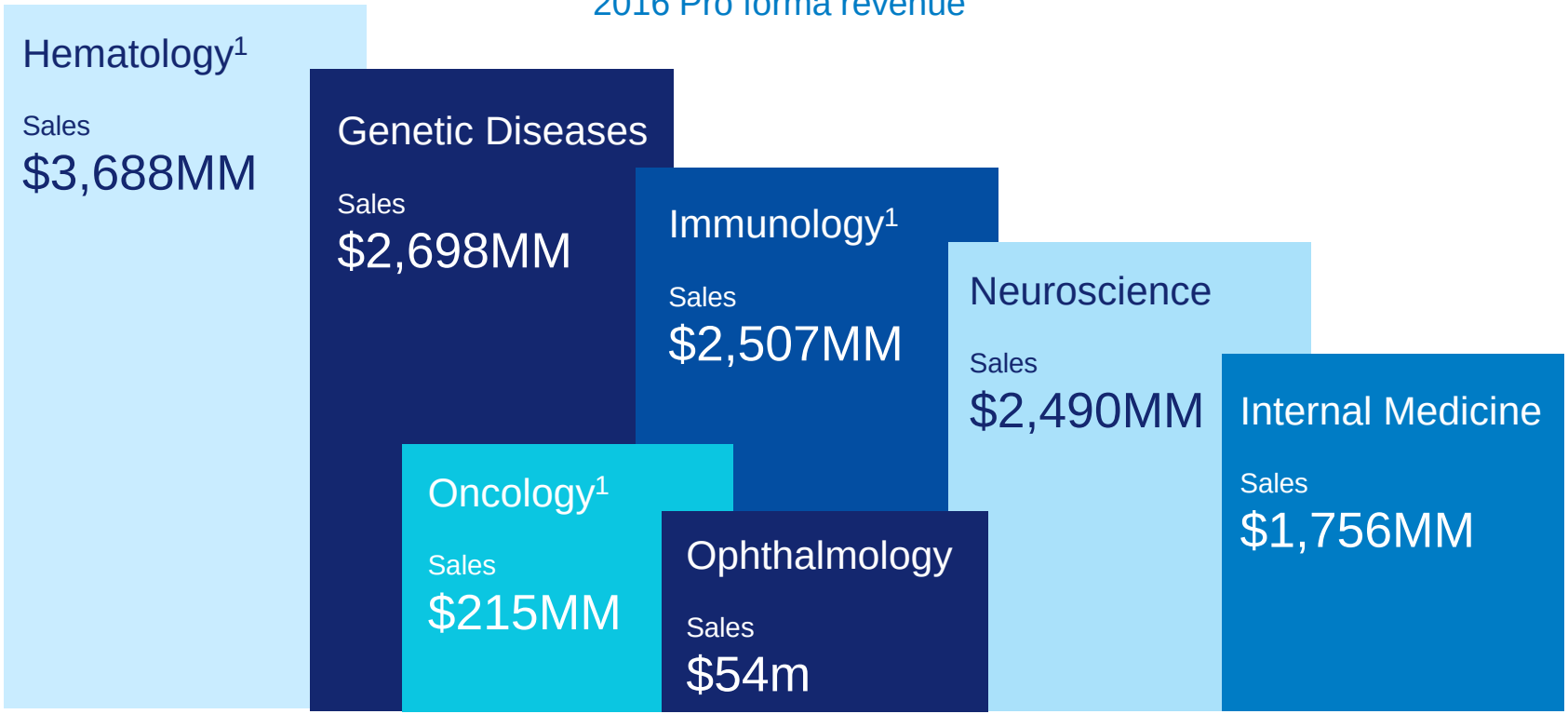
180+
relationships with patient advocacy

$11B+
Full Year 2016 Revenue[1]

(1) Results include Baxalta (acquired on June 3, 2016) and Dyax (acquired on January 22, 2016)
Numbers as of July 2017

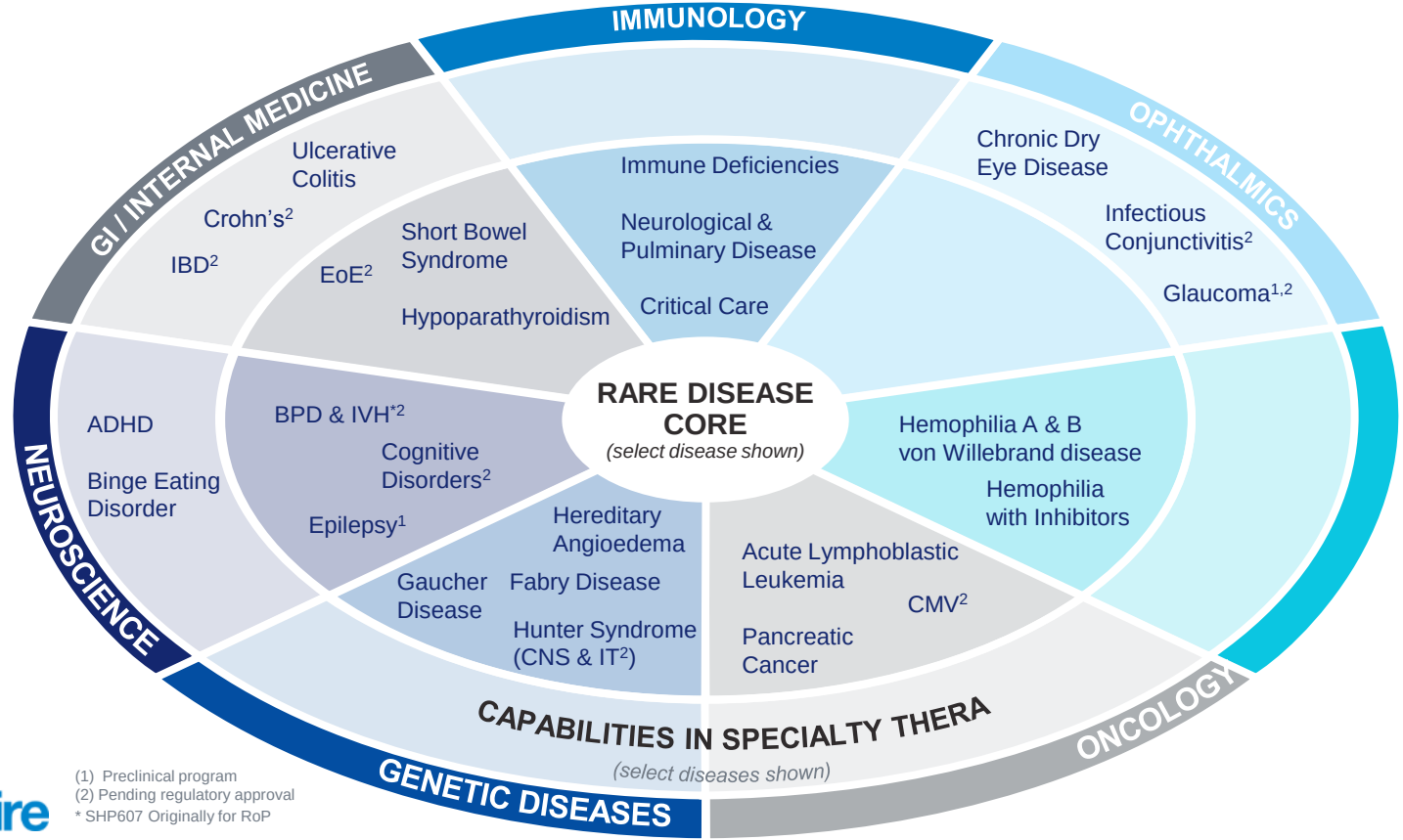
Today we have significant growth drivers across our portfolio

2016 Pro forma revenue



(1) Therapeutic area acquired with Baxalta on June 3, 2016.

Rare diseases are at our core, enhanced by our capabilities in other highly specialized conditions



(1) Preclinical program
(2) Pending regulatory approval
* SHP607 Originally for RoP

Before 2013 (The Dark Ages Pre-EA) → 2013-2016 (Renaissance) → 2017 + (Enlightenment)

COMPANY and GOAL

Shire

1) Global Leader in Rare Disease
2) "Fuel for Growth" Initiative

CHALLENGE

IT Master Plan outlined need to rapidly integrate data across plants as part of a Manufacturing Intelligence Strategy

- 10+ plants across the globe
- Silos of data with little to no integration
- Old systems with minimal batch context or none at all

SOLUTION

Design Enterprise system scaled to meet Highly Available demands of production. Implement standards to harmonize site variances

- HA architecture spanning multiple data centers and regions
- BI to expose PI Syste, data to data lake / data mart
- Standard PI AF and EF Templates

RESULTS

Single point of access to plant data across the globe

- Reduction in manual labor (data entry, investigations)
- Cost avoidance in saved bat
- Integration with MES, Discoverant, Simca, CMMS

A glimpse ahead in Manufacturing Intelligence (MI)

Access process/equipment data and product knowledge as a core asset

Right First Time

Processes are defect-free and free from workarounds. Visibility to poorly performing processes and methods enables the organization to align on improvement activities.

Countinued Process Validation Life Cycle „QbD“

Clearly demonstrate control of risk to product quality and assure continually that the process remains in a state of control.

Real-Time Predictive Process Control

Real-time control and optimization of the processes and alerts through predictive analytics allows operators to adjust parameters enabling higher yields and reduce loss

Optimize External Manufacturing Process

Evolve to a seamless distributed external partner network through a free-flow of data exchange, process collaboration, and product knowledge enabling early detection & improvement, oversight, and control visibility to performance

Targeted Continuous Improvement of Mfg Processes

Leverage data from internal and external sources to enable long term process improvements and cross-site comparability. Utilize dashboards to identify and measure the greatest improvement opportunities.

Sustainable Process Knowledge

Easy access to technical and production documentation. Centralize and share product data and know-how across the functions and across sites.

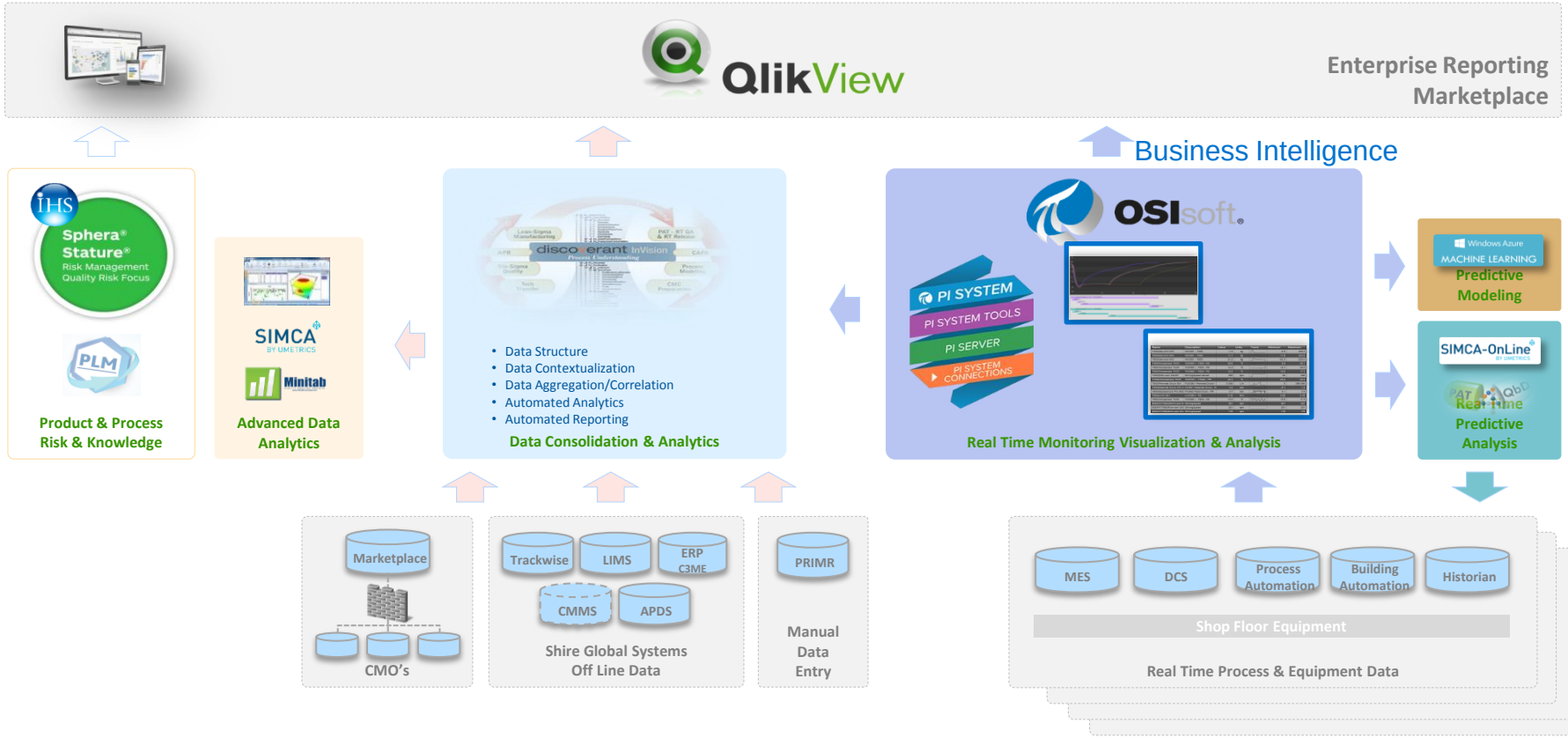
Enable Learning Organization

Enable continuous learning throughout product & process life-cycle to learn from development through qualification and commercialization across all functions and networks.

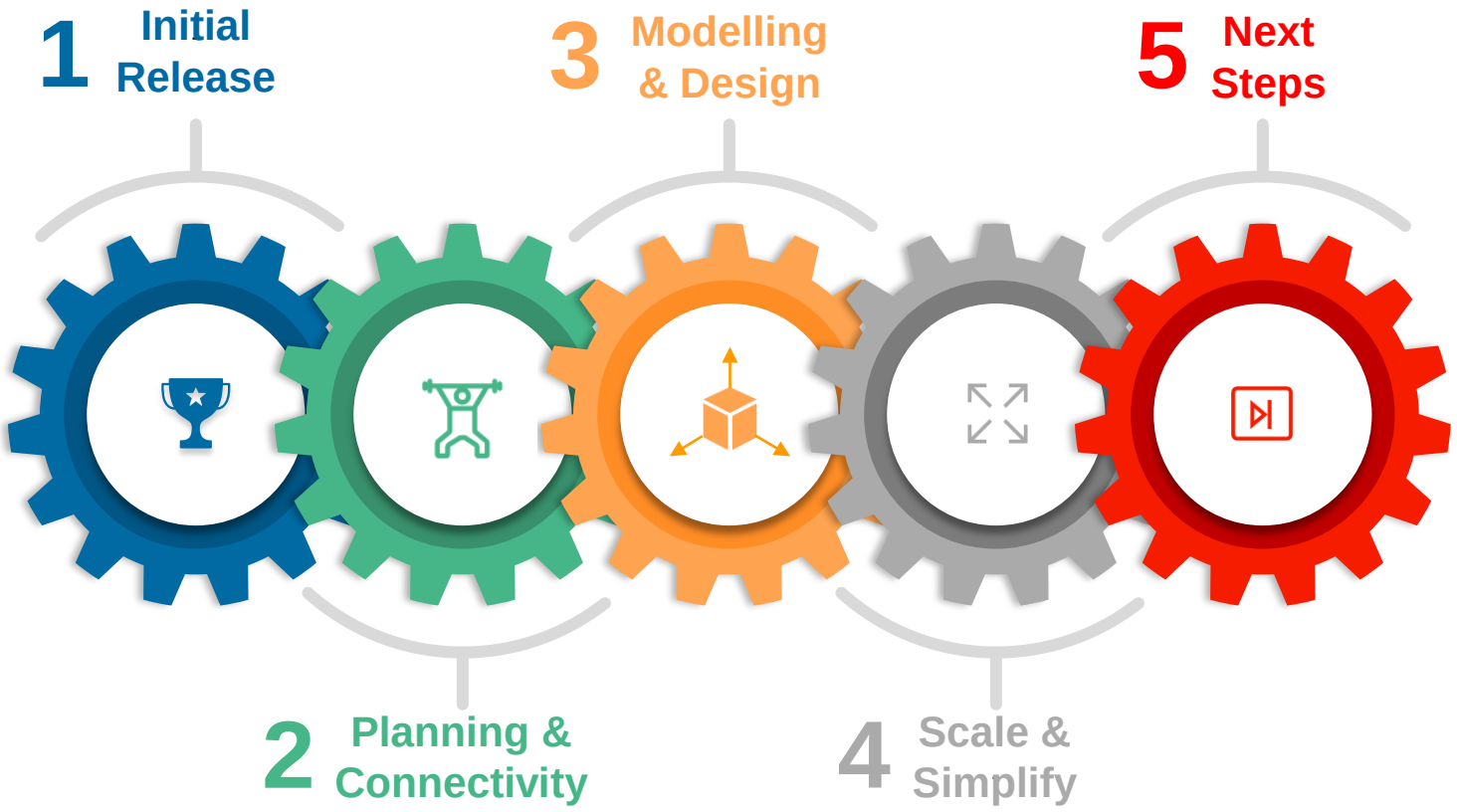
Predictive Maintenance

Utilizing a connected factory (Internet of Things) and self diagnostic capabilities, monitored machinery has the ability to ensure predicted product quality and automatically schedule just-in-time (JIT) maintenance and calibration to minimize equipment downtime

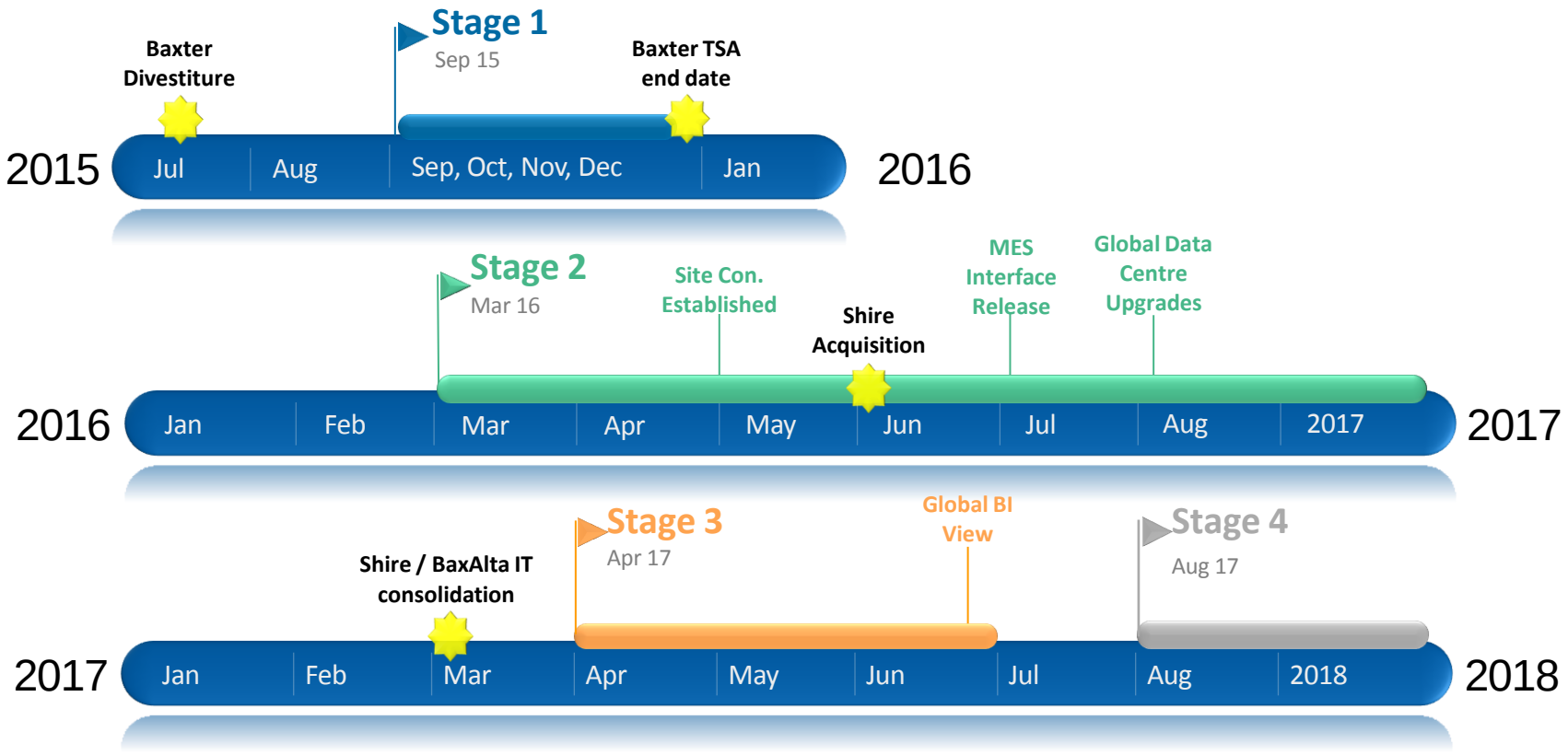
MI IT Architecture & Solutions (Simplified)



Shire Global OSIsoft PI System Program Overview



Program Timeline



Planning for Success

Mission Statements

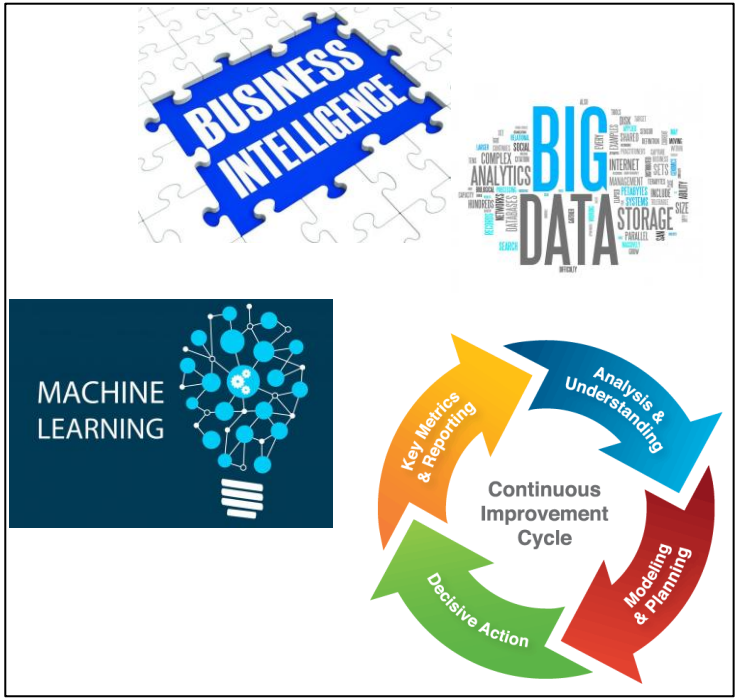
- Create a Single Point of Access
- Design to be non-Blocking
- Plan for Scale and Agility
- Standardize, template and Rollout

Reviewing the Global Footprint

Key Data Centre

Manufacturing Plant

Understanding our Goals



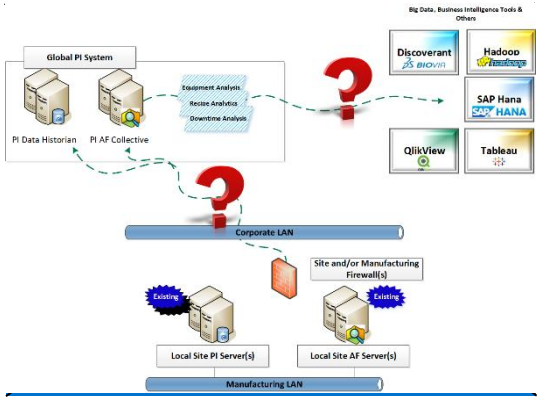
Enabling Global OSIsoft PI System

Enabling Business Intelligence Tools

Get Manufacturing Data to BI Tools

Shire wanted to get data from all manufacturing plants to Business Intelligence Tools

1) Shire had multiple tools supporting analytics
2) To eliminate multiple overlapping projects, a one-fit all solution was needed



Questions Posed

Do we need to move all the data to one place ?

How do we do provide it at scale for every tool ?

- How would we securely gain access ?
- How do we minimize impact to plants, both in cost and time ?
- Can we do all site's at once ?

How we Answered

No. The need was now, and the data already existed.

BI Tools can pull from RDB's, but not all had direct links to the PI System.

- We would leverage Windows Authentication from Global to Local Systems
- We would pull data out, rather than asking them to push it up
- Yes !

What Tools were used

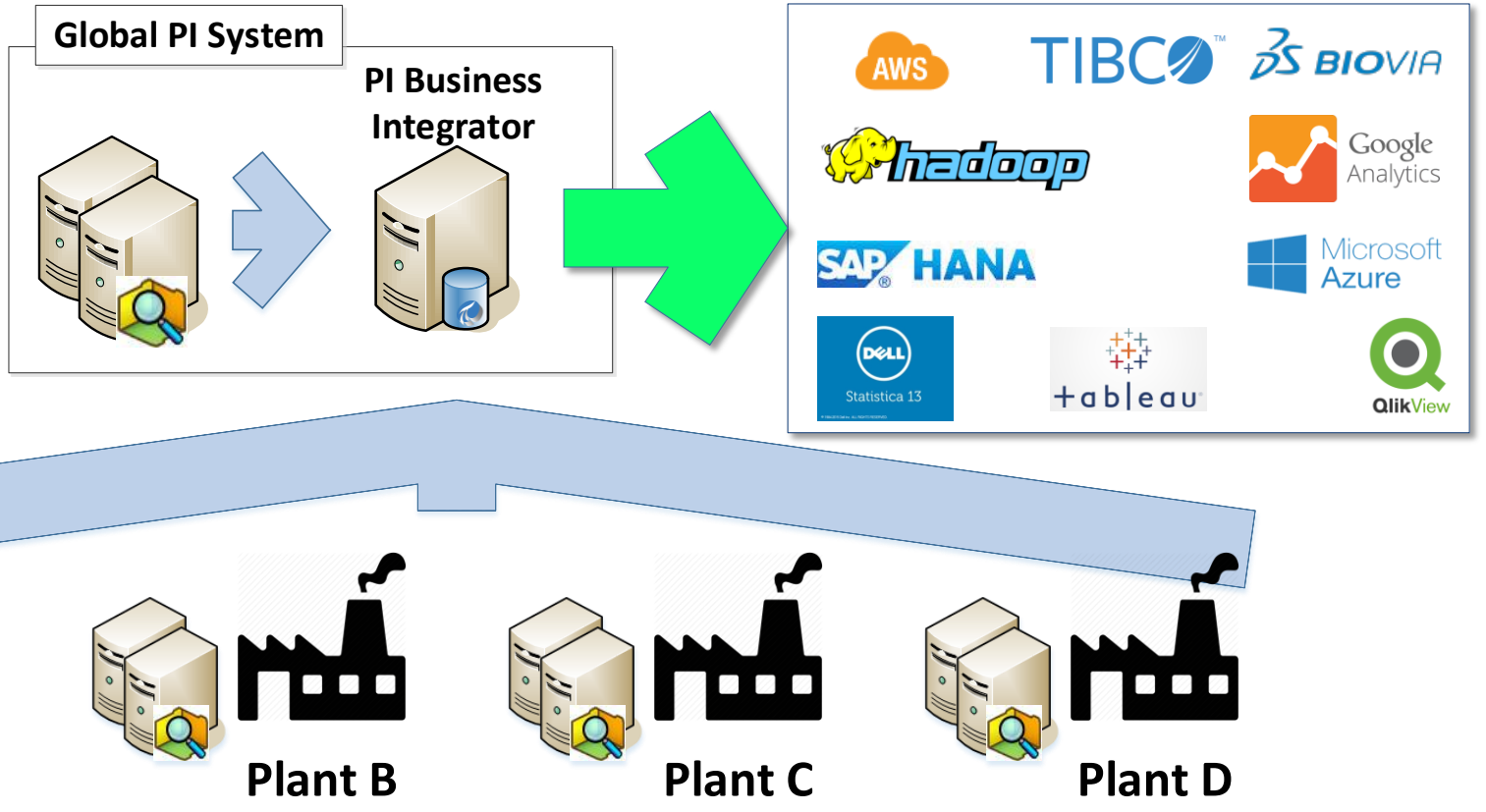
PI Integrator for Business Analytics

PI Asset Framework

PI BES Interfaces

- **Other Benefits :**
  - –Min. 2 other tools had projects to connect global sites
  - –No Change Control needed @ local ; no project costs

Enabling Business Intelligence Tools

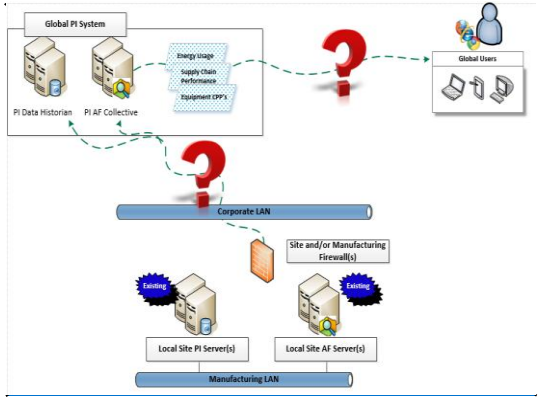


Creating Single Point of Access

Provide true Global PI System

Shire wanted a modern, scalable PI System, that met users where they were

1) Shire needed to support site's globally
2) To eliminate silo's, the system needed to have services and data common to each location



Questions Posed

How do we provide common services across Data Centres ?

To serve a growing customer base, how do we allow for future scale ?

- How do we scale growing data access needs ?
- How can we scale applications to support global customers ?

How we Answered

Modern Infra. and database-services, we can provide HA services across DC's.

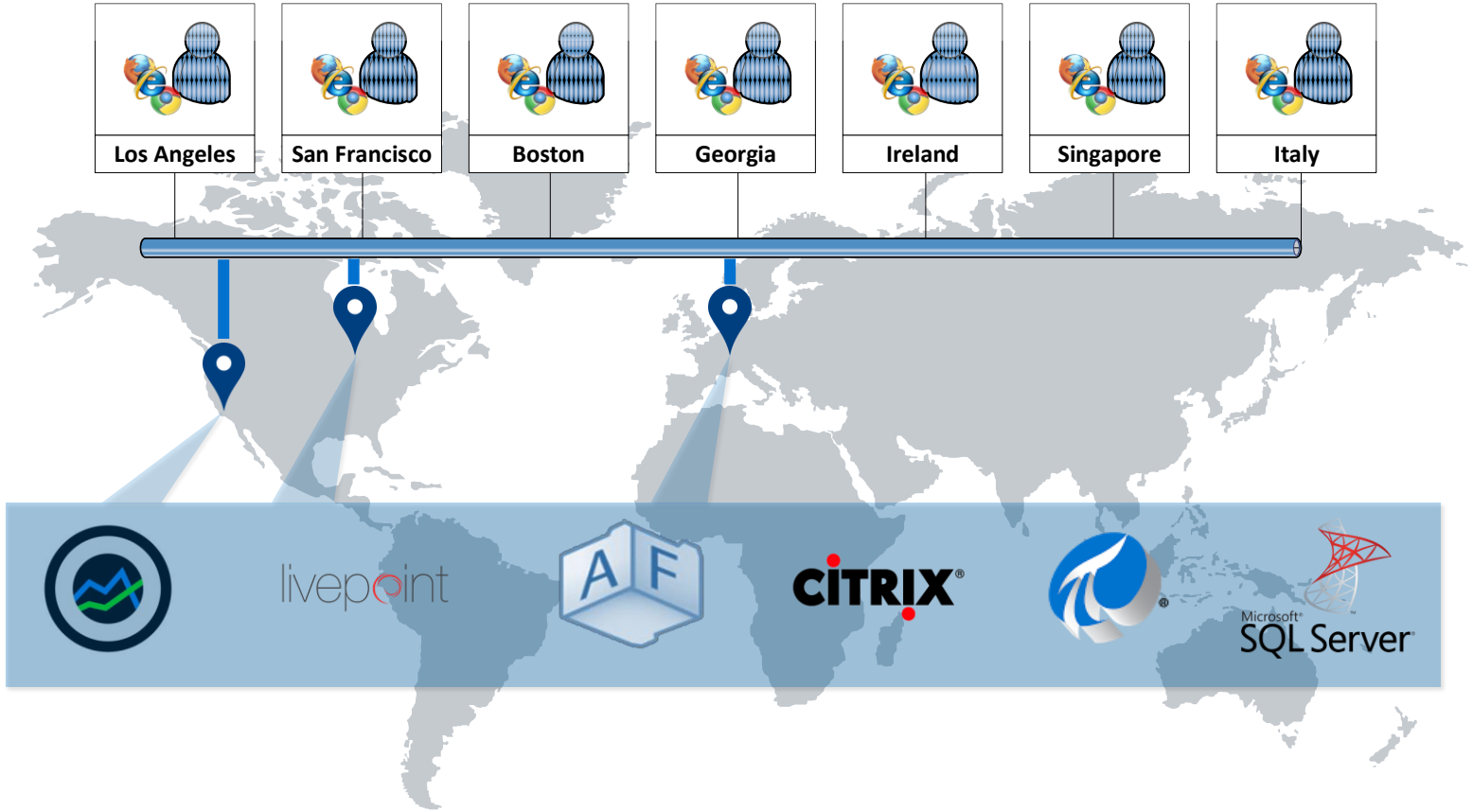
Standard Doc and validation library.

- Load Balance PI Asset Framework across all DC's, data retrieved from co-located Historians
- Full HA. Services used must provide HA and be failure-tolerant

What Tools were used

- BIG-IP DNS & BIG-IP LTM
- MS SQL Always-On
- Windows Server Failover Clustering
- HP ALM
- TQS Standard Design Documentation
- TQS OSIsoft PI System Validation Library
- VMWare

Location-Based Services

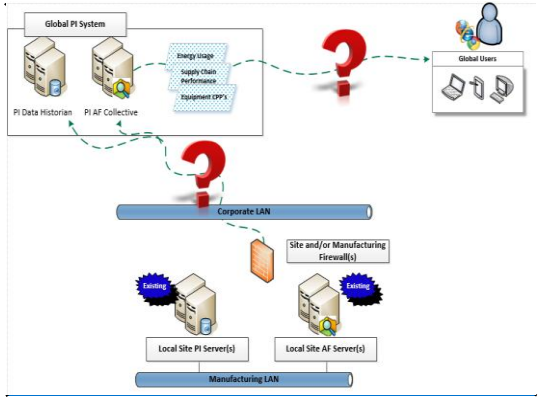


Creating Standards & Templates

Design and Roll-out Templates

Shire wanted the ability to leverage existing infrastructure, and design best-practice templates that could be leveraged by all

1) Design should be able to cover global and local requirements



Questions Posed

How do we allow for different designs for local vs global?

What is the best way roll out quickly, and without affecting sites ?

- Where should templates be located ?

How we Answered

Template inheritance will allow deployment of Global Templates side-by-side with any pre-existing templates.

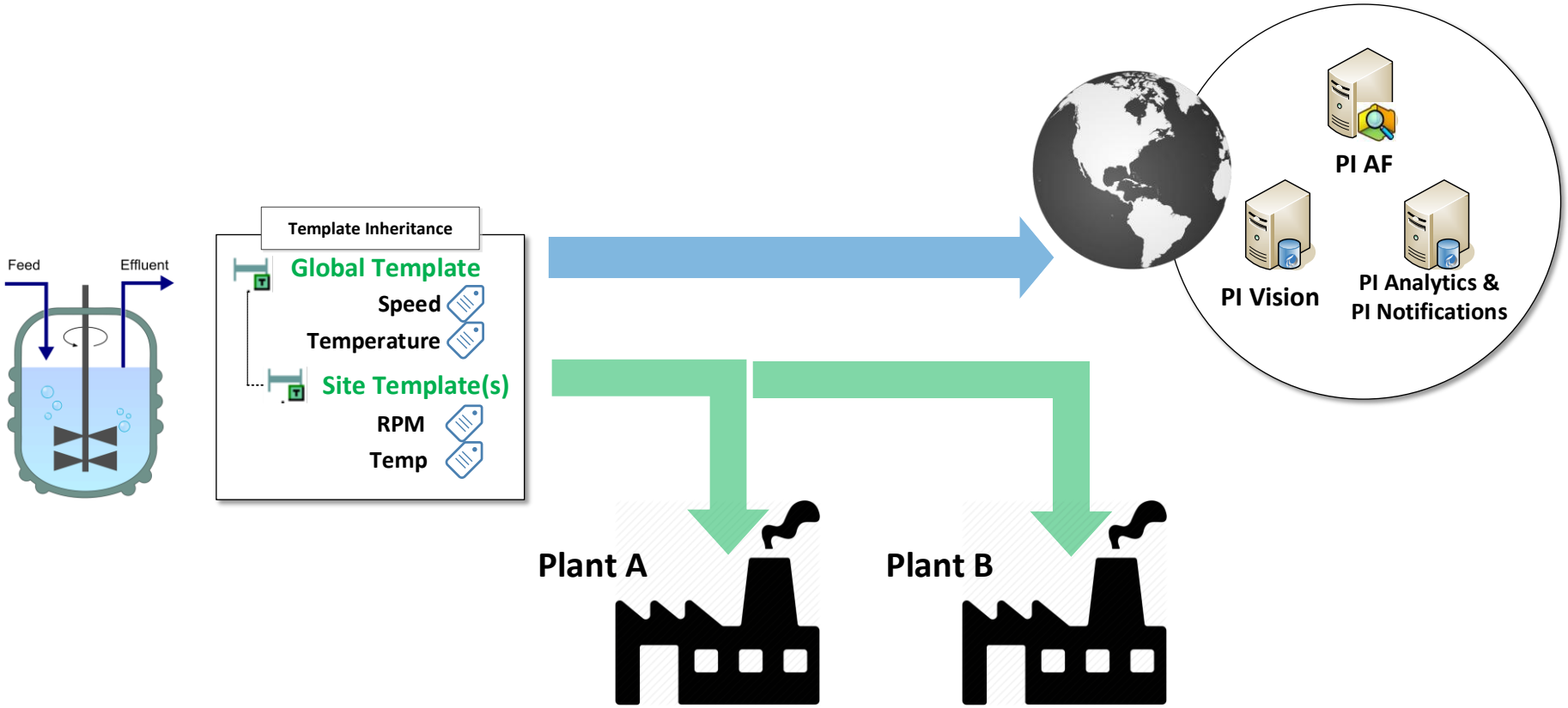
Global Template Design team leverages Global System Access to design across all plants.

- Controlled by Global, and rolled down to local PI AF's, where needed

What Tools were used

- BIG-IP DNS & BIG-IP LTM
- MS SQL Always-On
- Windows Server Failover Clustering
- HP ALM
- TQS Standard Design Documentation
- TQS OSIsoft PI System Validation Library
- VMWare

PI AF Template Standards

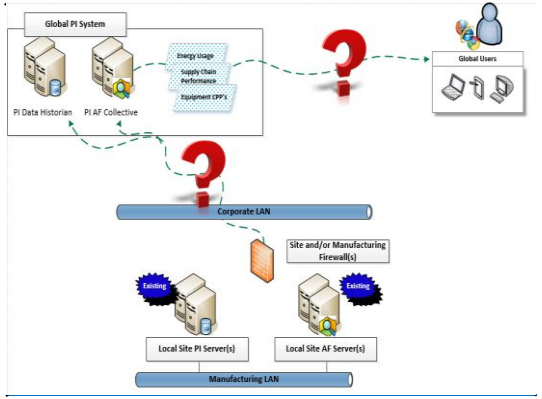


Integrating Manufacturing Execution System

Replace bespoke reporting systems

Shire wanted the consolidate the access and use of MES Data

1) BI Tools needed access to MES data across plants
2) Manual recording steps being added, not removed



Questions Posed

What is needed to gather MES data ?

How would the data be accessible to BI tools in a consolidated manner ?

- Where should interfaces be located ?
- How could we integrate with data from BES ?

How we Answered

We would only meet req's by developing an interface.

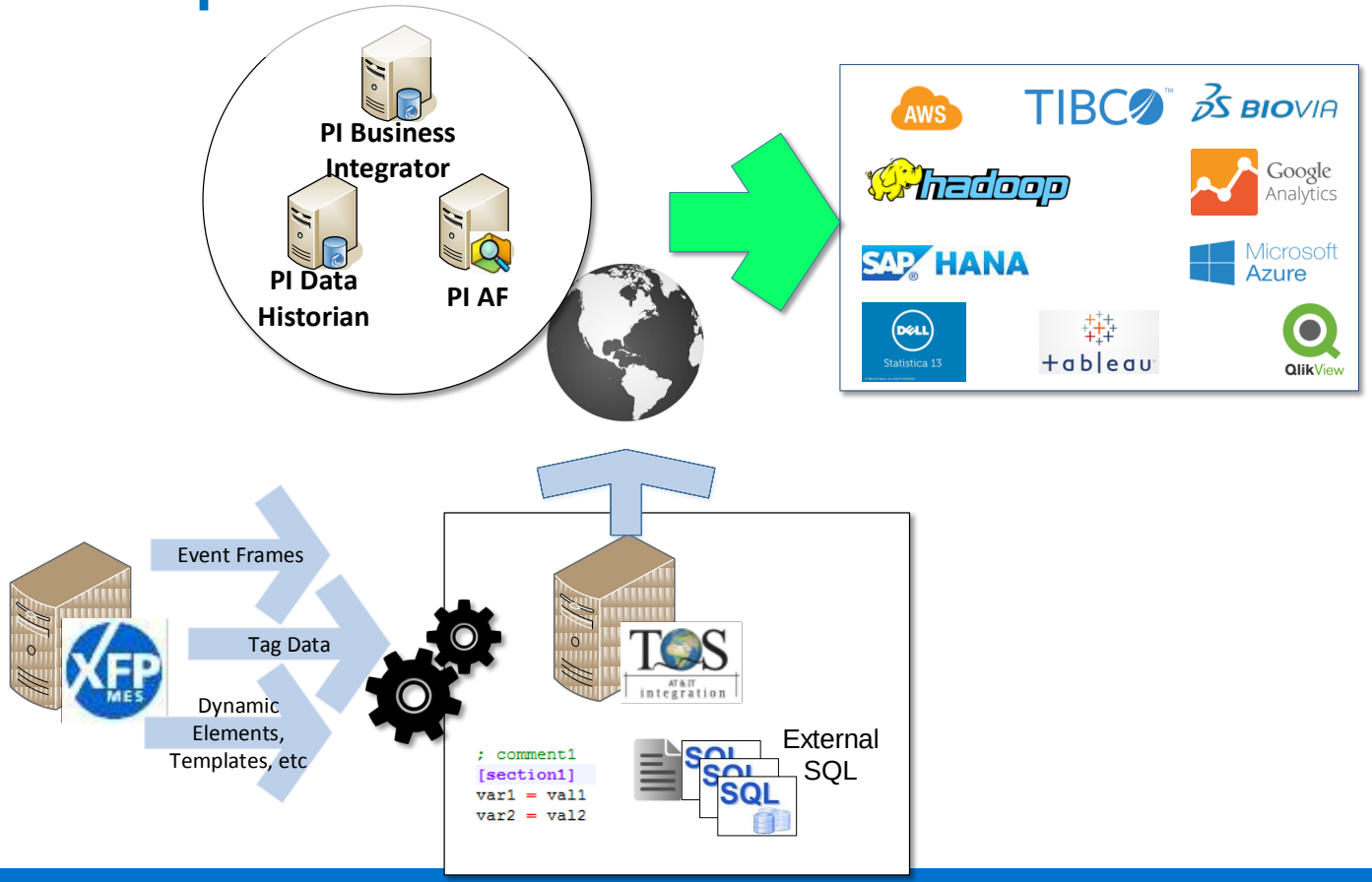
Interface would dynamically generate Event Frames, tags, elements, categories ; everything needed to export on request.

- Local. Same as MES.
- Full Work Order hierarchy would be created ; identified steps where BES was triggered

What Tools were used

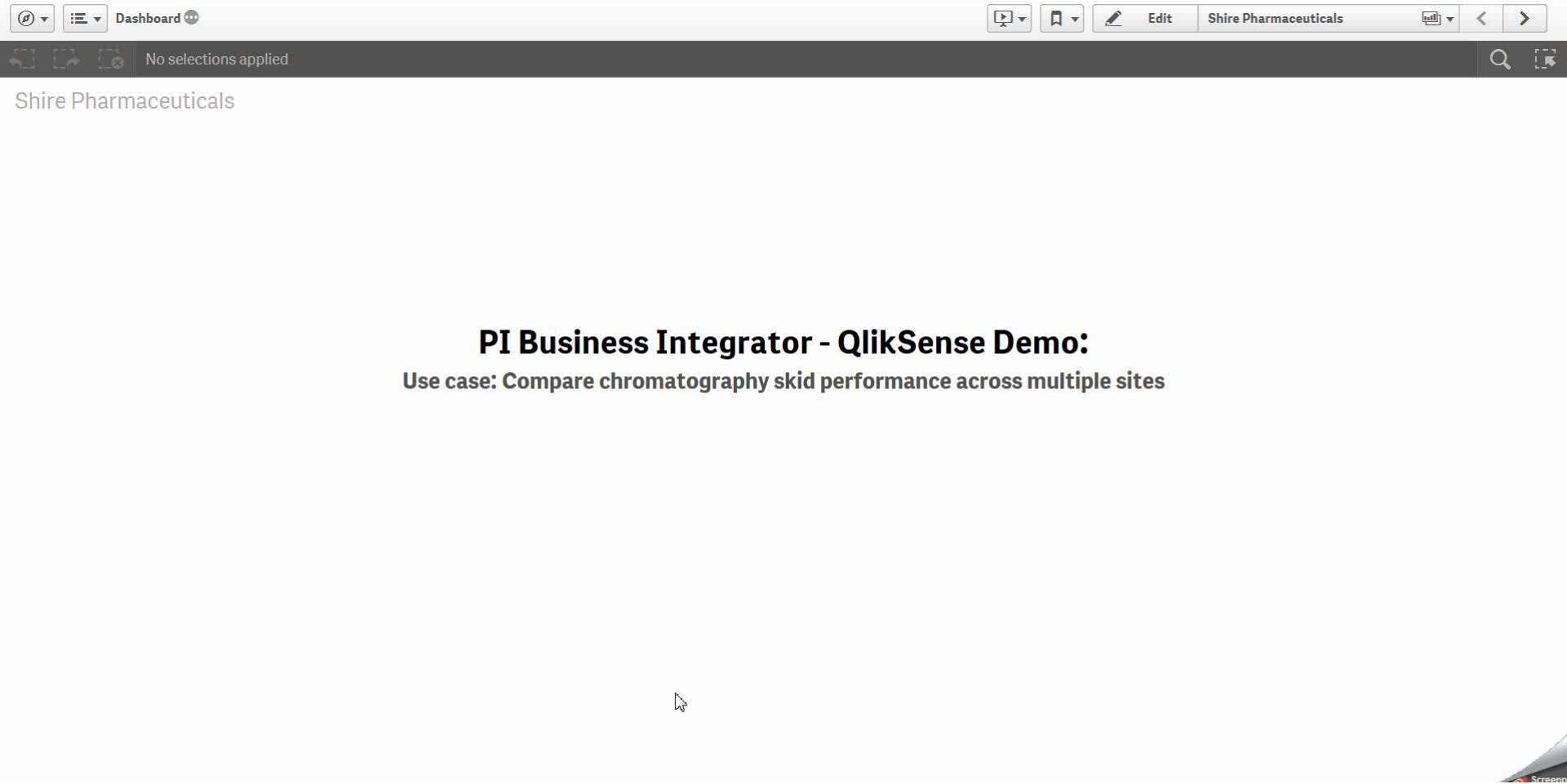
- TQS XFP Interface
- PI Integrator for Business Analytics

MES Data Capture



End Results

- MES to PI Interface eliminated need for custom Siemens datastore
- Data in PI System resulted in reduction of manual data entry resources (Discoverant, MES, others)
- $$$ in saved batches



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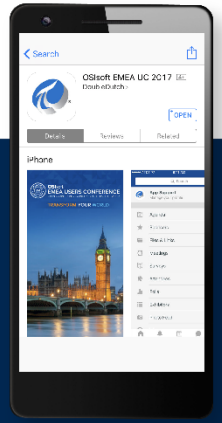
Questions

Please wait for the **microphone** before asking your questions

State your **name & company**

Please remember to…

Complete the Online Survey for this session



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Danke

谢谢

Merci

Gracias

Thank You

ありがとう

Спасибо

Obrigado