

AVEVA PI WORLD

PI Integration and a Modern Clinical Trial Solution

How Mobile Research Units and the PI System are shaping the future for Lilly's medicines

Presented By: Kevin Baker, Vikram Thakur

AVEVA



Who We Are

Providing life changing medicines around the world



- A heritage 145 years strong, est. 1876



- Headquarters located in Indianapolis, Indiana U.S.A.



- More than 34,000 employees worldwide



- Approximately 8,000 employees engaged in research and development



- Clinical research conducted in more than 55 countries



- Research and development facilities located in 7 countries



- Manufacturing plants located in 7 countries



- Products marketed in 120 countries

Lilly

AVEVA



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Developing New Medicines at Lilly

AVEVA

Navigating the Obstacles of a Pandemic and Clinical Trials



- Residents of long-term care facilities were being disproportionately affected by the pandemic.
- Residents could not leave facilities to participate in research at traditional research locations

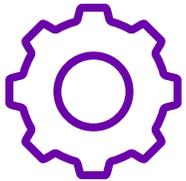
- Prophylactic treatment with a monoclonal antibody could reduce infection rates

- Make the clinical trial mobile





Utilizing PI to Be More Than a Historian



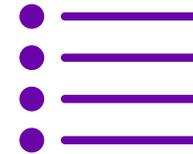
Challenge

- Secure storage for temperature data, directly impacting the integrity of clinical trials
- Data Retention – GMP Regulated Guidelines
- Making data **easily accessible**
- Shortened timeline, same validation expectations



Solution

- Utilize PI OPCUA connector to historize data
- Take advantage of off-the-shelf features of the PI System including
 - PI Asset Framework
 - PI Analysis
 - PI Event Frames
 - PI Notifications
 - PI Vision

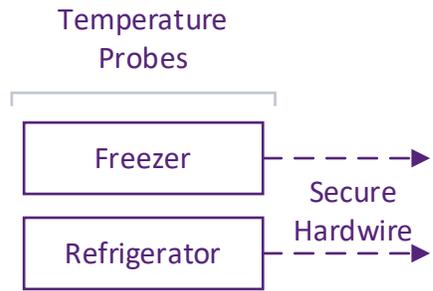


Benefits

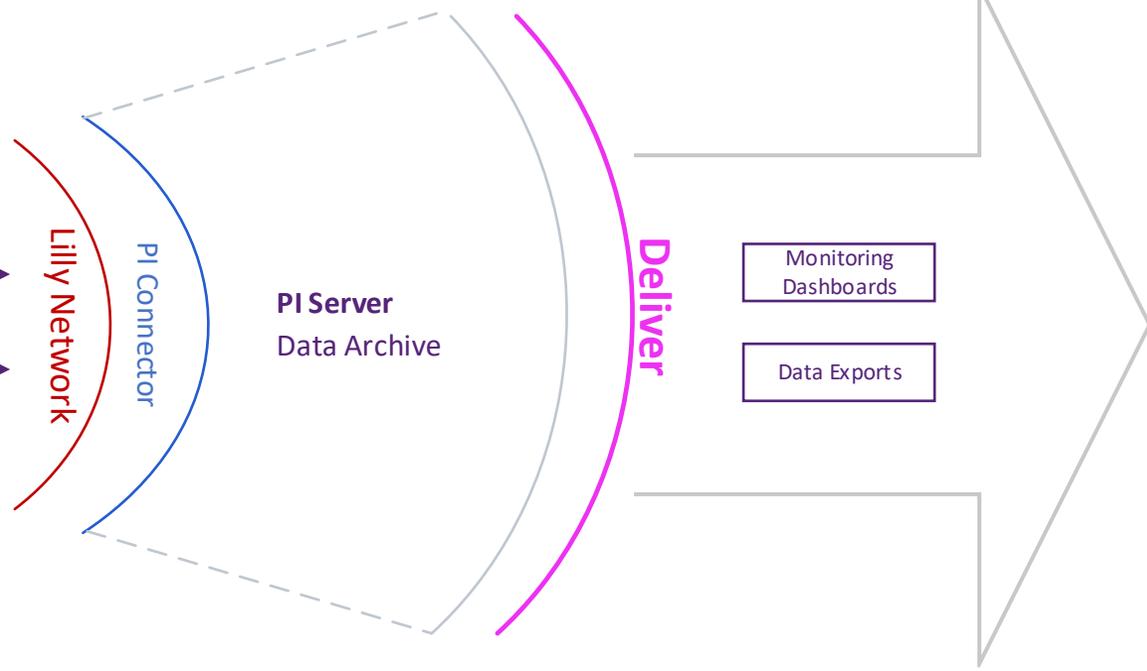
- Event Frame building for temperature excursions
- Notifications directly sent to phone/email
- PI Vision Dashboards for all support personnel
- Reliable long-term storage of data

A Typical Model...

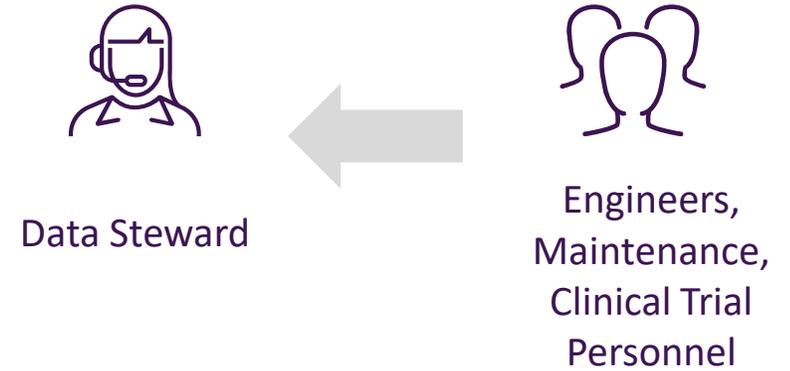
Data Source



Data Historizing



Typical PI Support Relationship

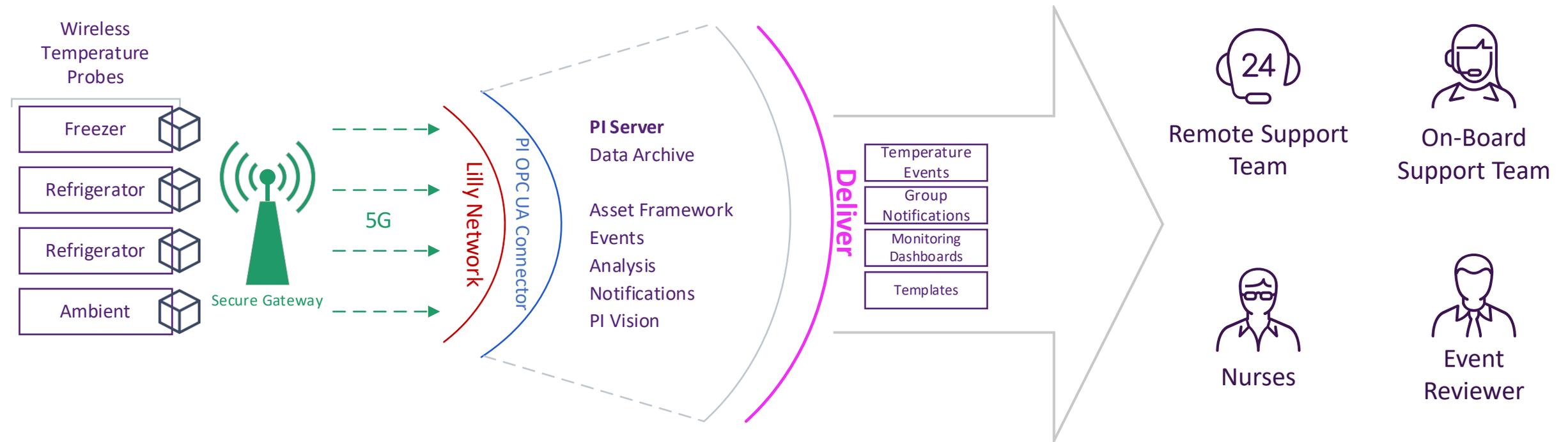


...Now on Wheels!

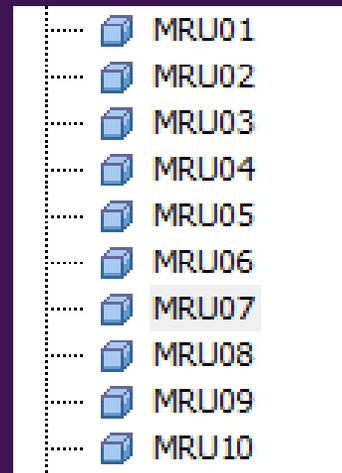
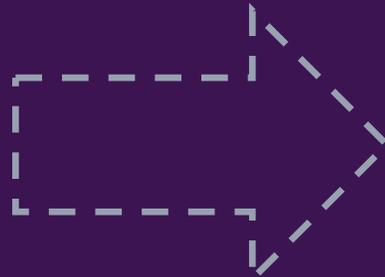
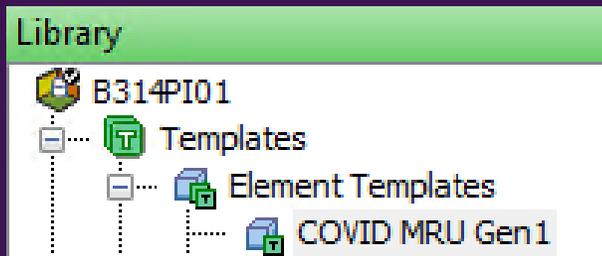
From the MRU to PI

Empowering the MRU Team

Information Access for All



Templates Make Quality (and Us) Happy



A screenshot of the 'MRU07' configuration window. It has tabs for 'General', 'Child Elements', 'Attributes', 'Ports', 'Analyses', and 'Notification'. The 'Attributes' tab is active. Below the tabs is a 'Filter' section. A table displays the attributes for MRU07:

| | Name | Value |
|---|----------------------------|---------|
| | Asset Name | MRU07 |
| + | Freezer Temperature | 23.8 °C |
| + | HVAC Temperature | 25.3 °C |
| + | Refrigerator Temperature | 23.5 °C |
| + | Saline Storage Temperature | 25.0 °C |

Easy Replication!

Analysis and Notifications

The screenshot shows the configuration interface for MRU07. The 'Notification Rules' tab is active, displaying a list of rules on the left and configuration details for 'Refrigerator Temperature' on the right. The 'Analysis Type' is set to 'Event Frame Generation'. Below, a table lists various triggers for refrigerator temperature.

| Name | Expression | True for | Severity |
|------------------------------------|-------------------------------|------------|----------|
| Start triggers | | | |
| Refrigerator Temperature Low Low | 'Refrigerator Temperature' <= | 15 minutes | Critical |
| Refrigerator Temperature Low | 'Refrigerator Temperature' <= | 15 minutes | Warning |
| Refrigerator Temperature High | 'Refrigerator Temperature' >= | 15 minutes | Warning |
| Refrigerator Temperature High High | 'Refrigerator Temperature' >= | 15 minutes | Critical |

Analysis w/ Parameter Thresholds

The screenshot shows the configuration for a notification message titled 'Refrigerator Temperature - Message - COVID MRU Alarm'. The 'Subject' field is populated with 'Target:Name notification "Event Frame:Trigger Name" Notification Rule:Message for Closed Notification'. Below, a table defines the message content with placeholders for event frame data.

| | |
|---------------------------|--------------------------------|
| ServerDatabase | AF Server:Name \ Database:Name |
| Target Element | Target:Path |
| Notification Name | Notification Rule:Name |
| Trigger Name | Event Frame:Trigger Name |
| Trigger Expression | Event Frame:Trigger Expression |
| Start Time | Event Frame:Start Time |
| Severity | Event Frame:Severity |

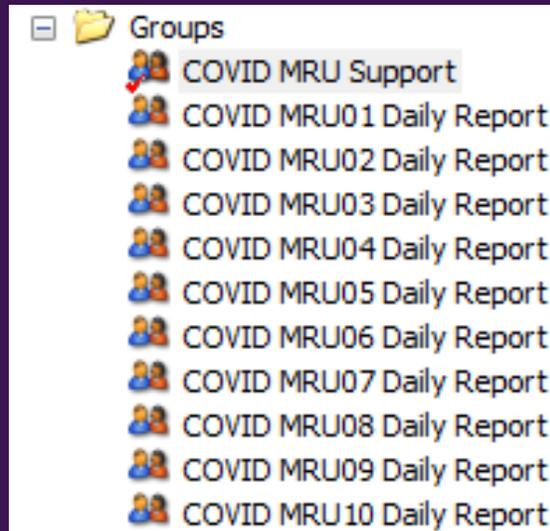
Primary displays for the units are:

- PI Vision:Hyperlink:Gen1 MRU01 to 10
- PI Vision:Hyperlink:Gen2 MRU11 to 20

You can review/acknowledge the event frame using this

Event Notifications

Analysis and Notifications



Custom Contact Groups

Daily Report for COVID MRU15

B314PINotifications@lilly.com
To Vikram Thakur

Retention Policy Inbox (60 days) Expires 10/26/2021

Red Category

COVID MRU15 summary data for the 24 hour period ending at 27-Aug-2021 06:00:00.

| Temperature | Minimum (Deg C) | Average (Deg C) | Maximum (Deg C) |
|--------------------------|-----------------|-----------------|-----------------|
| Freezer - Probe 1 | -24.3 | -22.9 | -16.9 |
| Freezer - Probe 2 | -25.0 | -23.3 | -17.8 |
| Refrigerator A - Probe 1 | 21.6 | 21.9 | 22.1 |
| Refrigerator A - Probe 2 | 21.7 | 21.9 | 22.2 |
| Refrigerator B - Probe 1 | 21.7 | 21.9 | 22.2 |
| Refrigerator B - Probe 2 | 21.6 | 21.7 | 22.0 |
| Saline | 21.1 | 23.2 | 25.7 |

Daily Reports

Bringing it Together Through PI Vision



MRU07+ ▼

Switch Asset ⚙️

From
MRU07 ▼

To

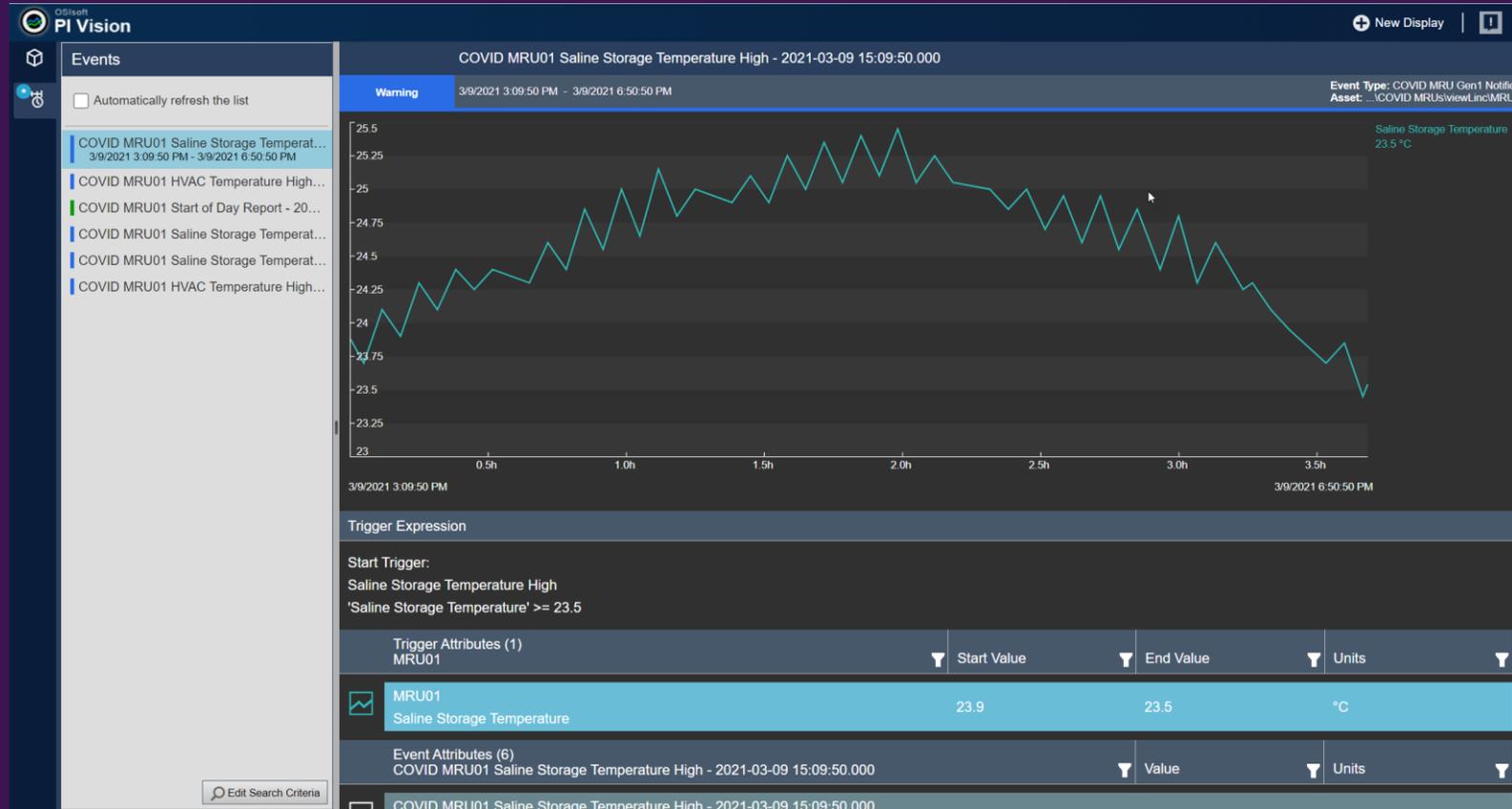
- MRU01
- MRU02
- MRU03
- MRU04
- MRU05
- MRU06
- MRU08
- MRU09
- MRU10

AF Templates Makes Finding your MRU Easy

Live Data Calculations

| Name | Average | Minimum | Maximum |
|----------------------------------|---------|---------|---------|
| MRU07 Freezer Temperature | -30.7 | -32.5 | -27.8 |
| MRU07 Refrigerator Temperature | 5.6 | 5.2 | 6.9 |
| MRU07 Saline Storage Temperature | 20.6 | 15.4 | 23.7 |
| Name ▲ | Average | Minimum | Maximum |
| B321 Refrigerator Temperature | 5.3 | 5.0 | 5.6 |
| B321 Saline Storage Temperature | 22.1 | 20.4 | 25.0 |

Bringing it Together Through PI Vision

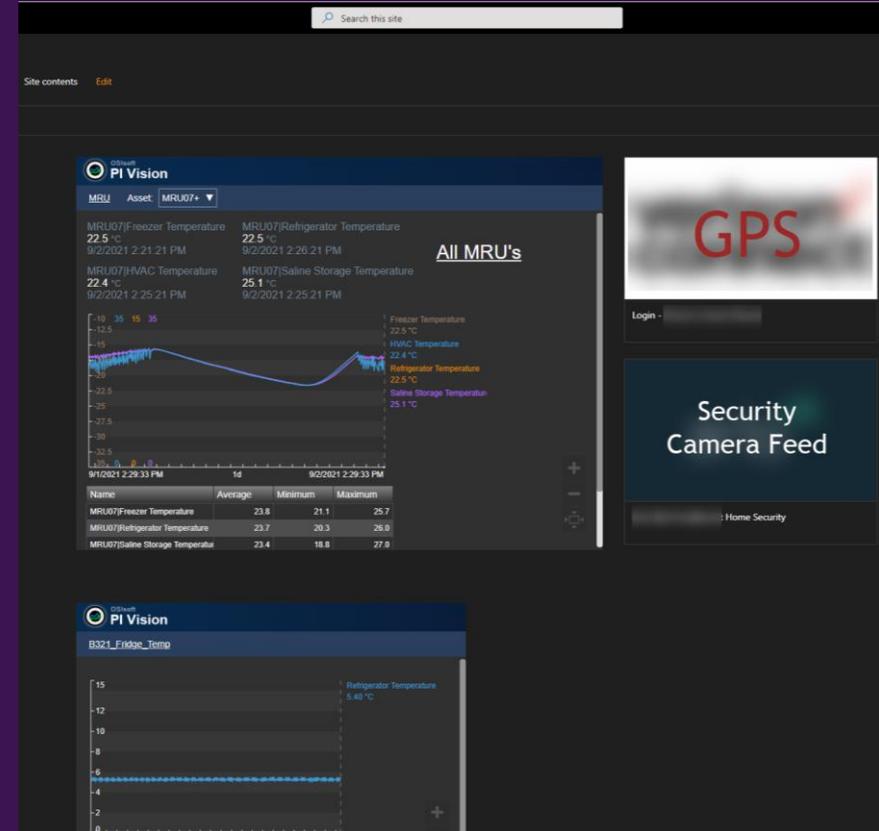


Event-Defined
Information

Bringing it Together Through PI Vision



Mobile View



iFrame Integration into a Custom Dashboard

Conclusions

- PI enabled:
 - Access to data – key to support team
 - GMP Alarm Data
 - Dashboarding/Visualizations
 - Accelerated timeline
- Over 75 deployments
 - Working with hundreds of support and staff members across all vendors
- Proof of concept → Production
- PI System Solution: Enabled in <20 Days!



Acknowledgments

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Thank you!



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