



Sparking Our Digital Transformation:

Deployment of a Manual Data Entry System

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March 25, 2020



Your Speakers



- Andrew Ambruso
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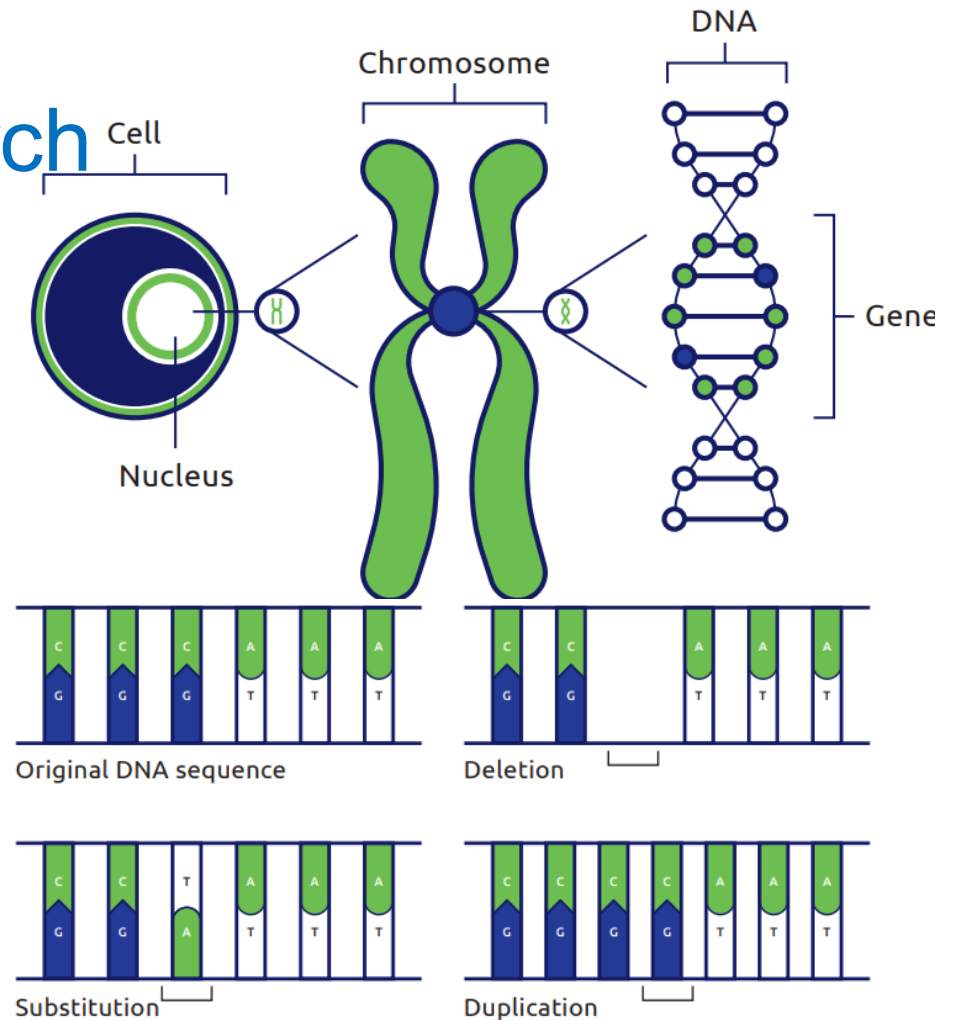
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 - Aztec Technologies
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Agenda

- An Intro to Gene Therapy Research & Spark Therapeutics
- Dark Ages of Data Collection
- Sparking Our Digital Transformation
- Manual Data Entry System
- Iterating Right-Size Solutions
- Review & Questions

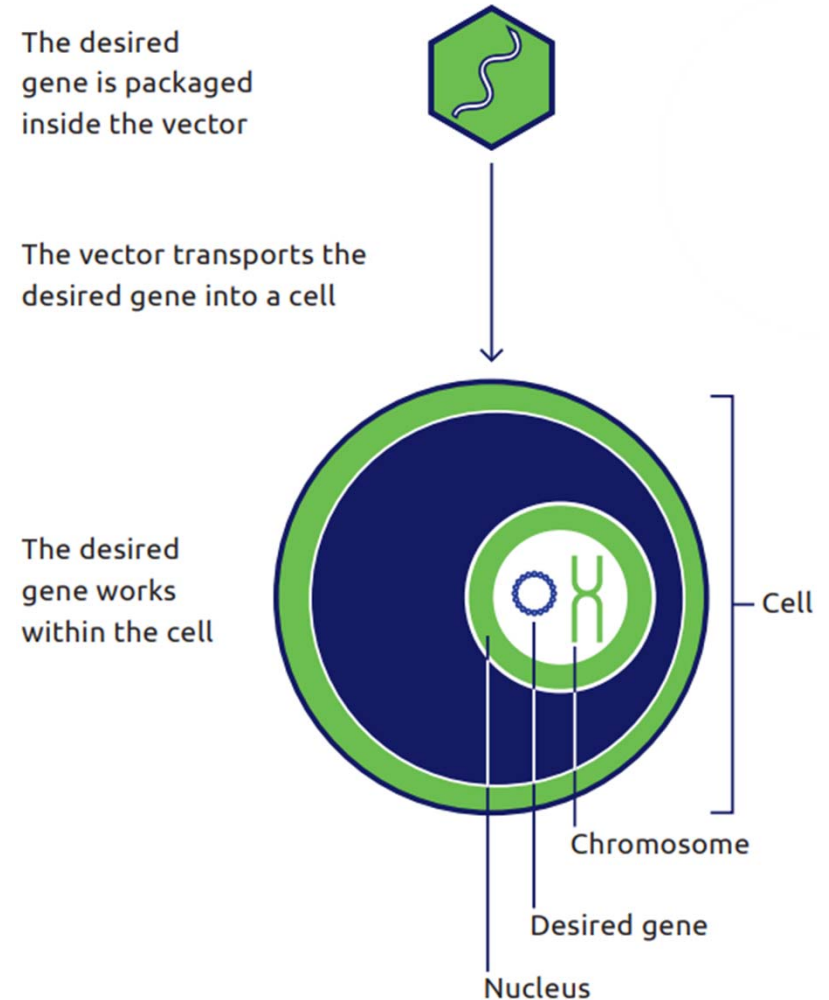
Gene Therapy Research

- Gene
 - DNA Segment
 - Two Copies of Each
- Mutation or Variant
 - Change in DNA sequence
 - Some can result in genetic disease



Gene Therapy Research

- Gene Therapy
 - Delivery of a new gene into a cell
 - To replace or inactivate mutated gene
- Vector
 - Virus with viral genes removed
 - Desired gene is packaged within



Our Company



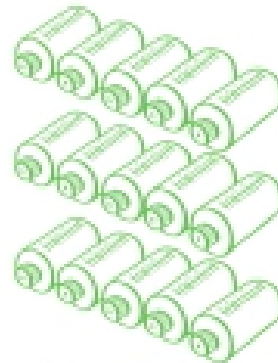
- Gene Therapy Research
 - Adeno-Associated Virus (AAV) Vector
- Founded 2013
- Philadelphia, PA
- 450+ Employees
- Member of the Roche Group

Our Vision: A world where no life is limited by genetic disease.

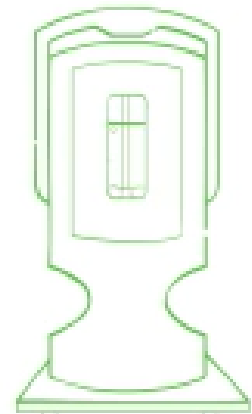
Our Process

- Propagating cells
 - Establishing workforce
 - Keeping them happy

Cells in Culture



Adherent Approach



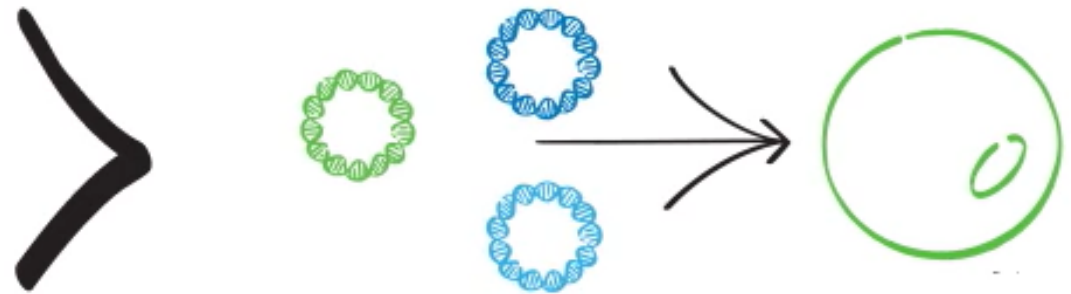
Suspension Approach

Our Process

Cells in Culture



Transient Transfection



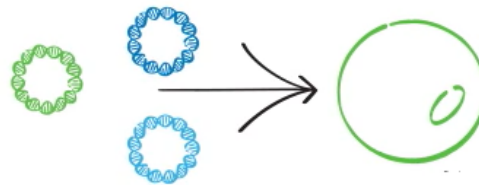
- Vector production
 - Provide instructions/materials for manufacture of product

Our Process

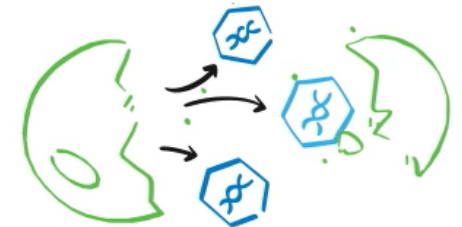
Cells in Culture



Transient Transfection



Cell Collection



- Harvest of cells
- Extraction of vector

Our Process



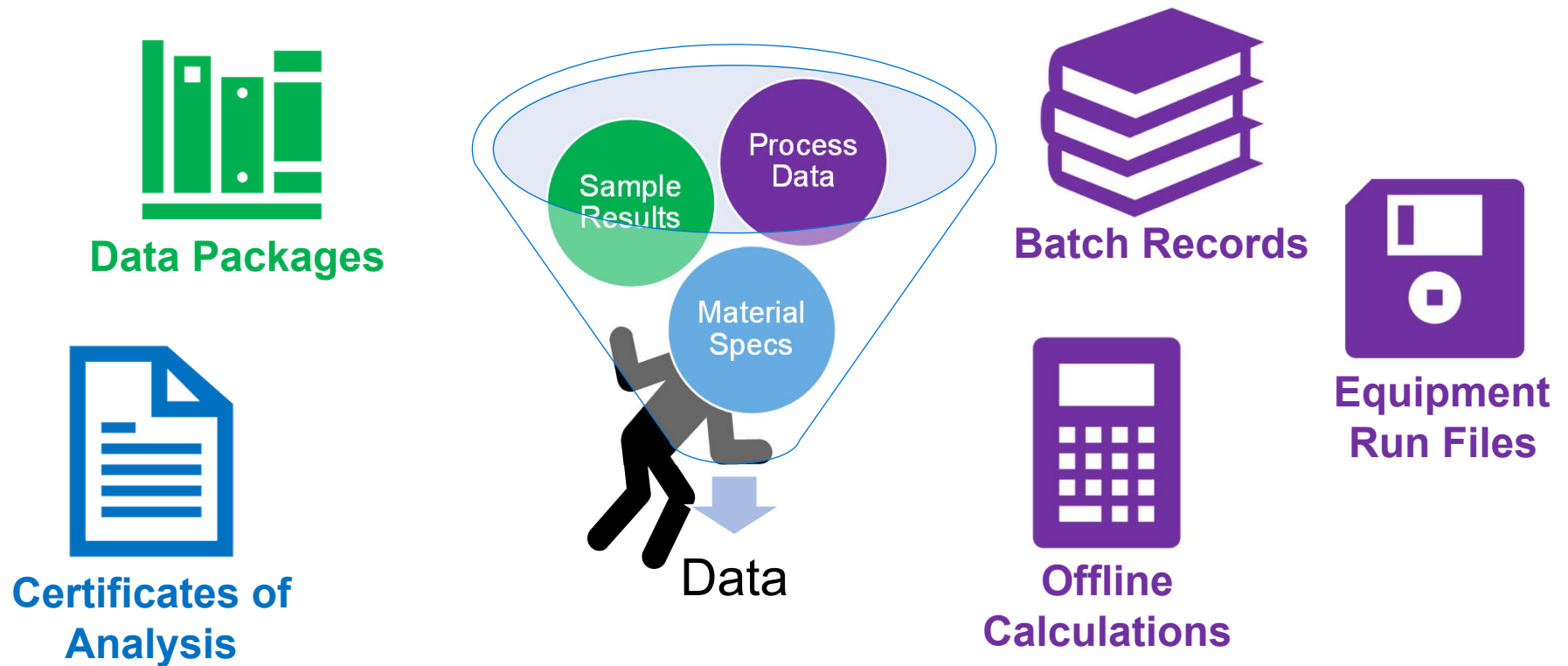
- Filtration
- Chromatography
- Centrifugation

Our Data

- Paper Batch Records
 - Electronic & Analog Equipment Readings
 - Manual Calculations

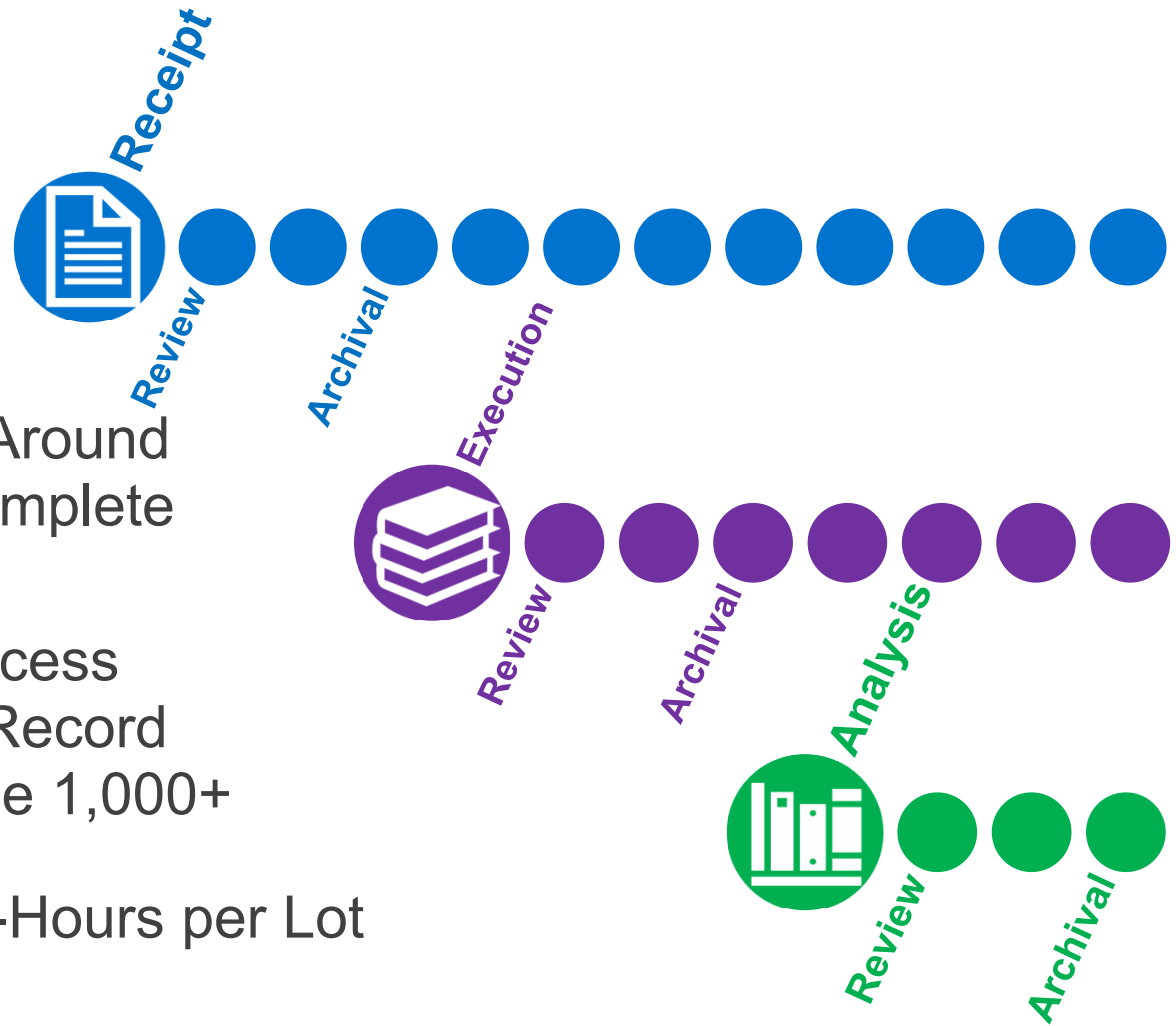


The Dark Ages of Data Collection



Batch & Queue

- Record Reviews
 - Mgmt. & Quality
 - Three Week Turn-Around
 - Archived When Complete
- Hunting for Data
 - No Notification Process
 - Physically Locate Record
 - Manually Transcribe 1,000+ Points per Lot
 - Requires ≥ 24 Man-Hours per Lot



The diagram illustrates a three-step process flow: **Compile** (represented by a person at a laptop), **Analyze** (represented by a grid and a line graph with a red **x50+** multiplier), and **Report** (represented by a document icon with a red **100+ Pages** multiplier). Arrows indicate the sequential flow from Compile to Analyze to Report.

[illegible]

Sparking Our Digital Transformation

- Need Controlled Data Bank
 - Accommodate Manual Systems
 - Backfill Paper Records
- Parallel Needs for Electronic Systems
 - Electronic Data Collection

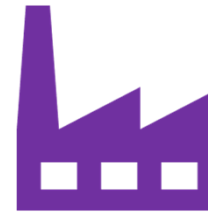


**Lab
Information
Management
System**

N-SPK-US-510028



Data Lake



**Manufacturing
Execution
System**



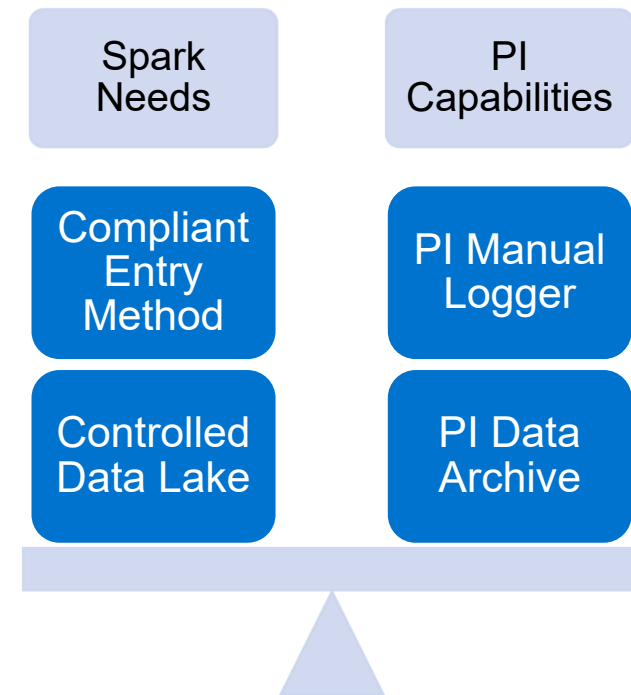
**Electronic
Lab
Notebook**

Matching Needs to PI System Solutions

PI Manual Logger?


GxP Data

- Demands 21 CFR Part 11 Compliance
- Verification
- Electronic Signatures
- Audit Logs



Manual Data Entry Software (MDES) Features

- Web-based User Interface
- 21 CFR Part 11 Compliant Solution
- Limit checking and notification
- Capability to approve data before committing to PI Archive (single points or groups of points) with confirmation of Approver via credentials
- Three levels of users (Operator, Supervisor, Admin)
- Ability to capture reasons for data changes/approval/rejection
- Notifications on login to provide updates of pending approvals, rejections, etc



MANUAL DATA ENTRY SOFTWARE

User Id

User Id

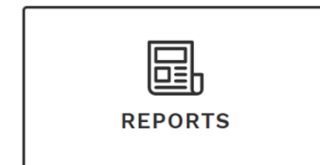
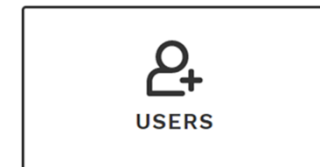
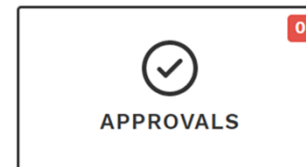
Password

Password

LOGIN

MDES Development

- Developed by Aztec Technologies with support from software development partner
- Intended to close gaps observed with PI Manual Logger solutions
- Ongoing development plans to introduce additional features, including support for mobile devices, EF and batch context, and enforced entry sequence



Data Entry

Server

PAVWOSIPI-DAV

Tagset

Test Tagset

Approver

PISupervisor

Test Tagset - Test Tag Group 2

| Tag Name | Previous Value | Current Value | Data Type | Engineering Units | Timestamp | |
|------------|----------------|----------------------|-----------|-------------------|------------------------|--|
| Test Tag 2 | 350 | Input Range: 0 - 100 | Float64 | | 13th Feb 2020 12:03:24 | |
| Test Tag 3 | 360 | 101 | Float64 | | 13th Feb 2020 12:03:24 | |

☐ Same as Previous Value
 ☒ Single Timestamp

1
 2
 Go to:
 Test Tag Group 2

Comments:

CANCEL

SAVE

Notifications

Notification Message

☒ Tag [Test Tag 1] value [DEMO] on [2020-02-06 16:48:42] from Tagset [Test Tagset] has been rejected by test supervisor due to Double-check value.



☐ Select All ☐ Deselect All

[BACK](#)
[MARK AS READ \(1\)](#)

Approval

| Tag Name | User Id | Entry Time ↓ | Comments | Value | Overwritten | Value Timestamp | |
|---|----------------------|-----------------------|--------------|-------|----------------------|-----------------------|--|
| <input type="text"/> | <input type="text"/> | | | | <input type="text"/> | | |
| <input checked="" type="checkbox"/> Test Tag 1 | test.operator2 | 6th Feb 2020 16:49:26 | PIWRLDSF2020 | DEMO | false | 6th Feb 2020 16:49:13 | <input checked="" type="checkbox"/> <input type="checkbox"/> |
| <input type="checkbox"/> Select All <input type="checkbox"/> Deselect All | | | | | | | |

CANCEL

APPROVE (1)

Approval

| Tag Name | User Id | Entry Time ↓ | Comments | Value | Overwritten | Value Timestamp | |
|--|----------------------|-----------------------|----------|-------|-------------|-----------------------|--|
| <input type="text"/> | <input type="text"/> | | | | | | |
| <input checked="" type="checkbox"/> Test Tag 1 | test.operator2 | 6th Feb 2020 16:49:13 | | | | 6th Feb 2020 16:49:13 | <input checked="" type="checkbox"/> <input type="checkbox"/> |

CONFIRMATION

Please confirm your credentials to proceed

User Id

Password

CANCEL

DONE

☐ Select All ☐ Deselect All

CANCEL

APPROVE (1)


Rejection

| Tag Name | User Id | Entry Time ↓ | Comments | Value | Overwritten | Value Timestamp | |
|---|----------------------|-----------------------|--------------|-------|----------------------|-----------------------|--|
| <input type="text"/> | <input type="text"/> | | | | <input type="text"/> | | |
| <input type="checkbox"/> Test Tag 1 | test.operator2 | 6th Feb 2020 16:49:26 | PIWRLDSF2020 | DEMO | false | 6th Feb 2020 16:49:13 | <input checked="" type="checkbox"/> <input type="checkbox"/> |
| <input type="checkbox"/> Select All <input type="checkbox"/> Deselect All | | | | | | | |

CANCEL

APPROVE

Rejection

| Tag Name | User Id | Entry Time ↓ | Comments | Value | Overwritten | Value Timestamp | |
|-------------------------------------|----------------------|-----------------------|--------------|----------------------|---|-----------------------|--|
| <input type="text"/> | <input type="text"/> | | | <input type="text"/> | | | |
| <input type="checkbox"/> Test Tag 1 | test.operator2 | 6th Feb 2020 16:49:26 | PIWRLDSF2020 | DEMO |  false | 6th Feb 2020 16:49:13 | <input checked="" type="radio"/> <input type="radio"/> |

REASON FOR REJECTION

Please provide a reason to proceed

CANCEL

DONE

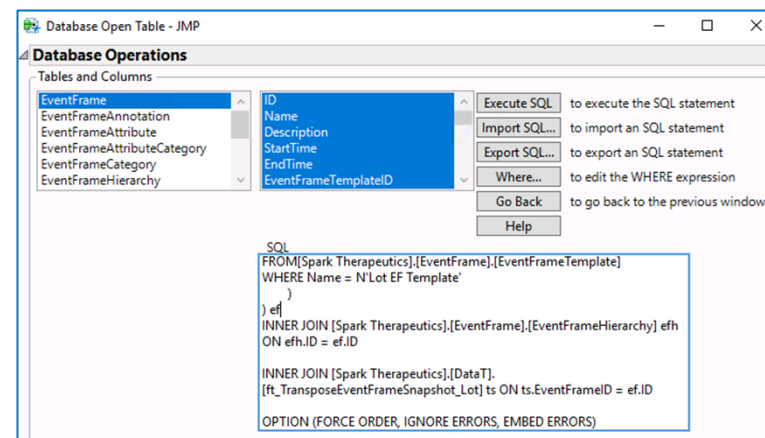
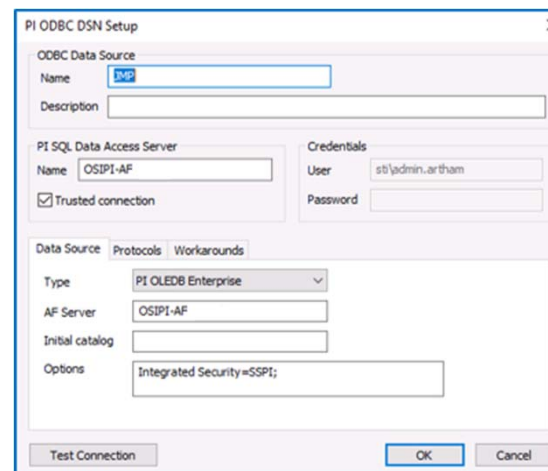
☐ Select All ☐ Deselect All

CANCEL

APPROVE

JMP Connectivity

- To support Spark's required data analysis, a connector was configured between OSI PI and JMP using SQL scripting built into JMP.
- This provided a mechanism of securely transferring the data set for analysis without the need to use a CSV or spreadsheet which could be inadvertently changed.



Audit Logs

- MDES supports multiple audit logs for capturing the following items:
 - Audit Log captures creation and deletion of tag sets, entry of tag values, approval/rejection, etc
 - Security Log captures all user login/logout events
 - Security Audit captures creation, deactivation, deletion, or other changes associated with user account details

REPORTS



Audit Log

Security Log

Security Audit

Benefits

- Single Entry Point



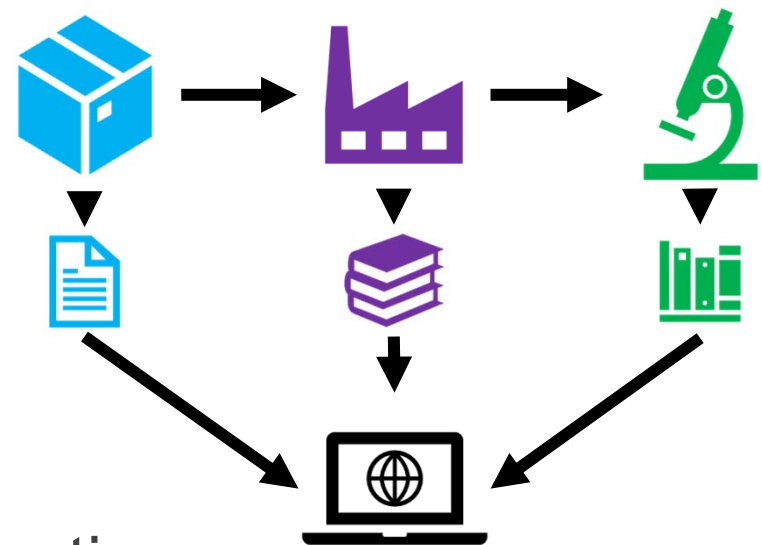
Benefits

- Single Entry Point
- From Manual to Electronic



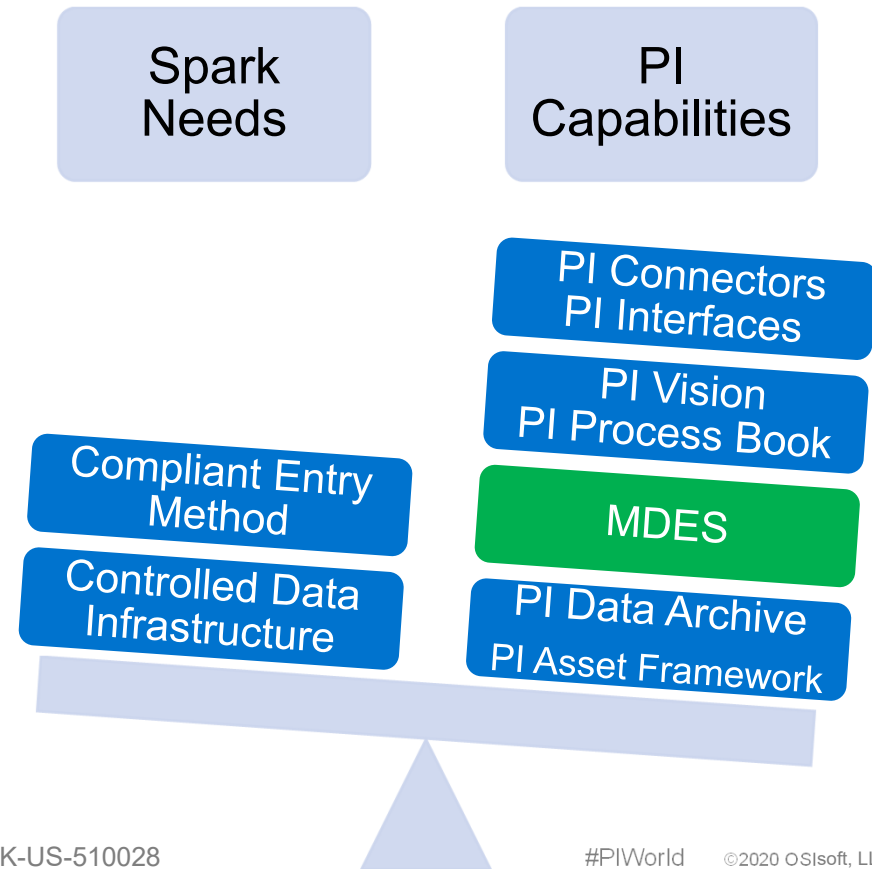
Benefits

- Single Entry Point
- From Manual to Electronic
- Real-Time Entry & Review
 - Parallel to Process
 - Continuous Collection
- MDES Enables Change in Practice
 - Stakeholders Must Accept Ownership Shift
 - Early Buy-In is Critical to Success



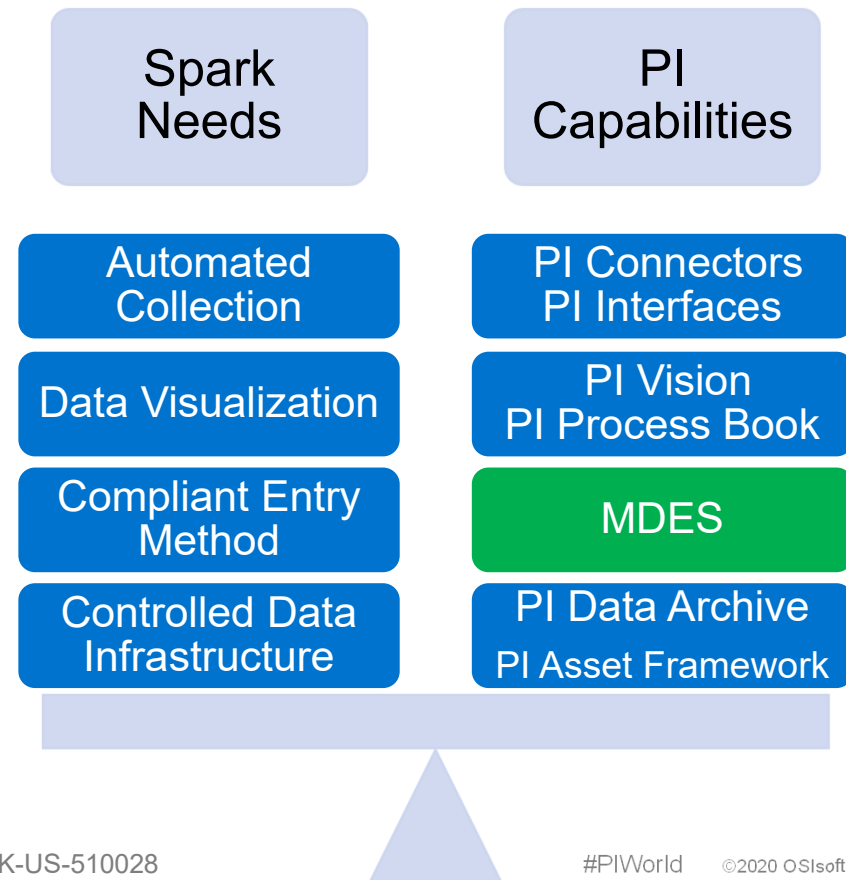
Iterating Right-Size Solutions

- Capabilities Outweigh Current Needs



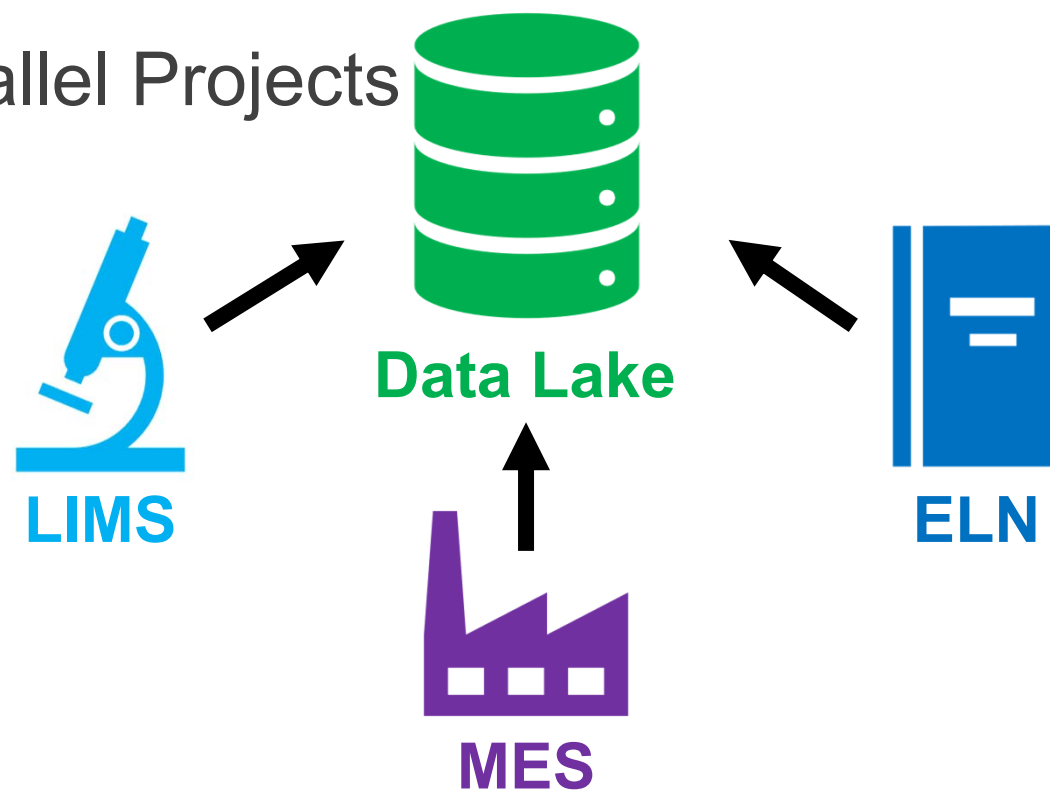
Iterating Right-Size Solutions

- Capabilities Outweigh Current Needs
- Provide Path for Future Needs

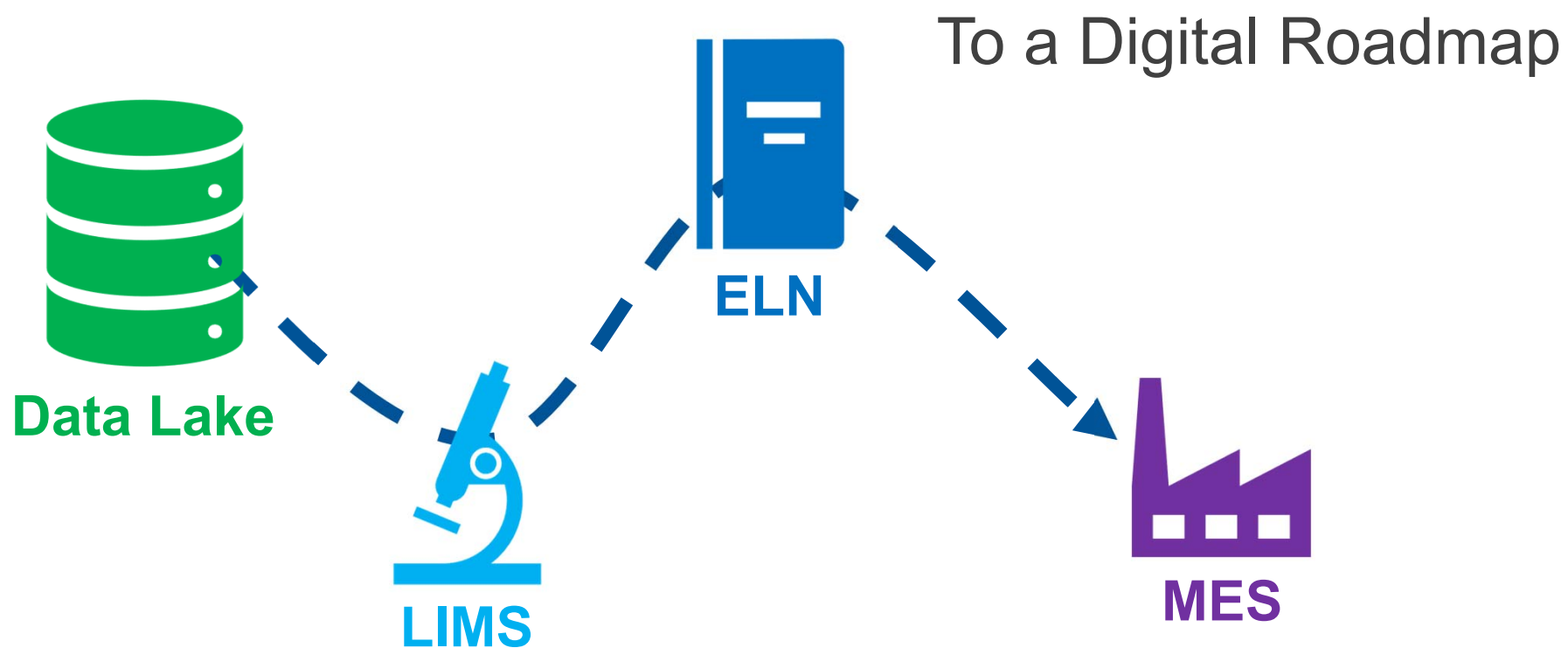


Forming a Digital Roadmap

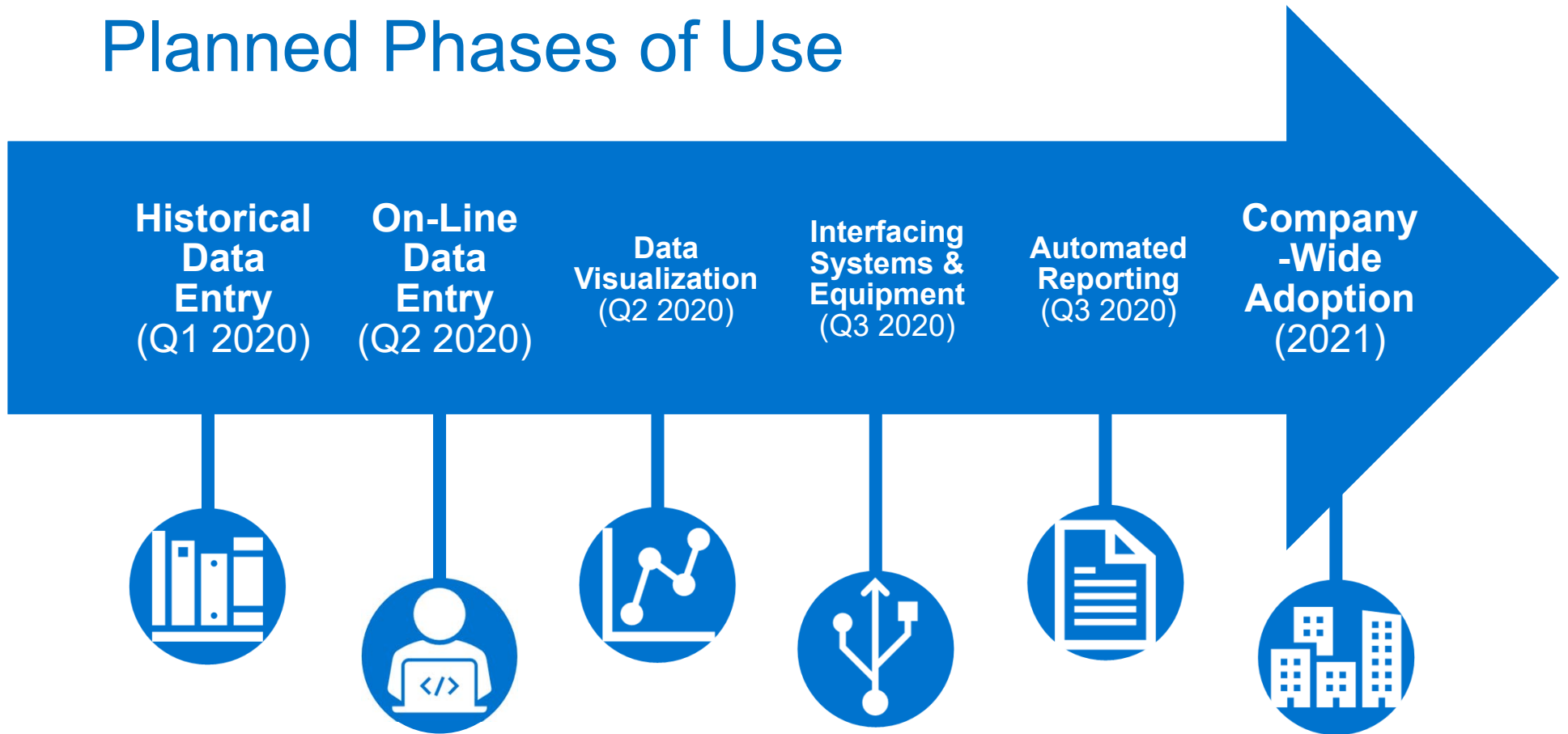
From Parallel Projects



Forming a Digital Roadmap



Planned Phases of Use



Building Your “Digital Lighthouse”

| | |
|-----------------------|--|
| Historical Data Entry | • MFG Process Data |
| Manual Data Entry | • MFG Process Data |
| Visualization | • MFG Process Data |
| System Interfacing | • Environmental Monitoring System |
| Equipment Interfacing | • Manufacturing Science & Technology Lab |



MDES Deployment Overview



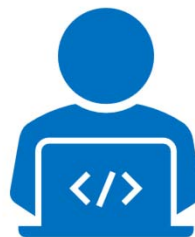
CHALLENGES

- Centralized Digital Data Archive
- Allows for On-Line Manual Entry
- Must be 21CFR, Part 11 Compliant



SOLUTION

- Aztec MDES



BENEFITS

- Simplified, Compliant Data Entry & Access
- Meets Current Needs
- Scalable



Contact us!



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 - MS&T Scientist/Engineer
 - Spark Therapeutics
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- David Stauffer
 - VP of Automation Services
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Questions?

Please wait for
the **microphone**

State your
name & company



Save the Date...



REGISTER YOUR INTEREST

AMSTERDAM

October 26-29, 2020



Questions?

Please wait for
the **microphone**

State your
name & company



Please remember to...

Complete Survey!

Navigate to this session in
mobile agenda for survey



