



REGAIN CONTROL  
OF YOUR DATA

# Data Preparation & Publishing Best Practices for a Successful RBM Implementation

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# Agenda

- Introduction & Definitions
- Data Flow
- Data Preparation
- Analytics
- User Actions
- Questions ?
- References

# Disclaimer

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# Introduction & Definitions

- **Risk Based Monitoring (RBM)<sup>1</sup>**

The proactive method of clinical trial monitoring called risk-based monitoring (RBM) is an adaptive approach that directs monitoring focus and activities to the evolving areas of greatest need which have the most potential to impact patient safety and data quality.

- **Key Risk Indicator (KRI)<sup>2</sup>**

A metric to quantify risk associated specific to any activity.

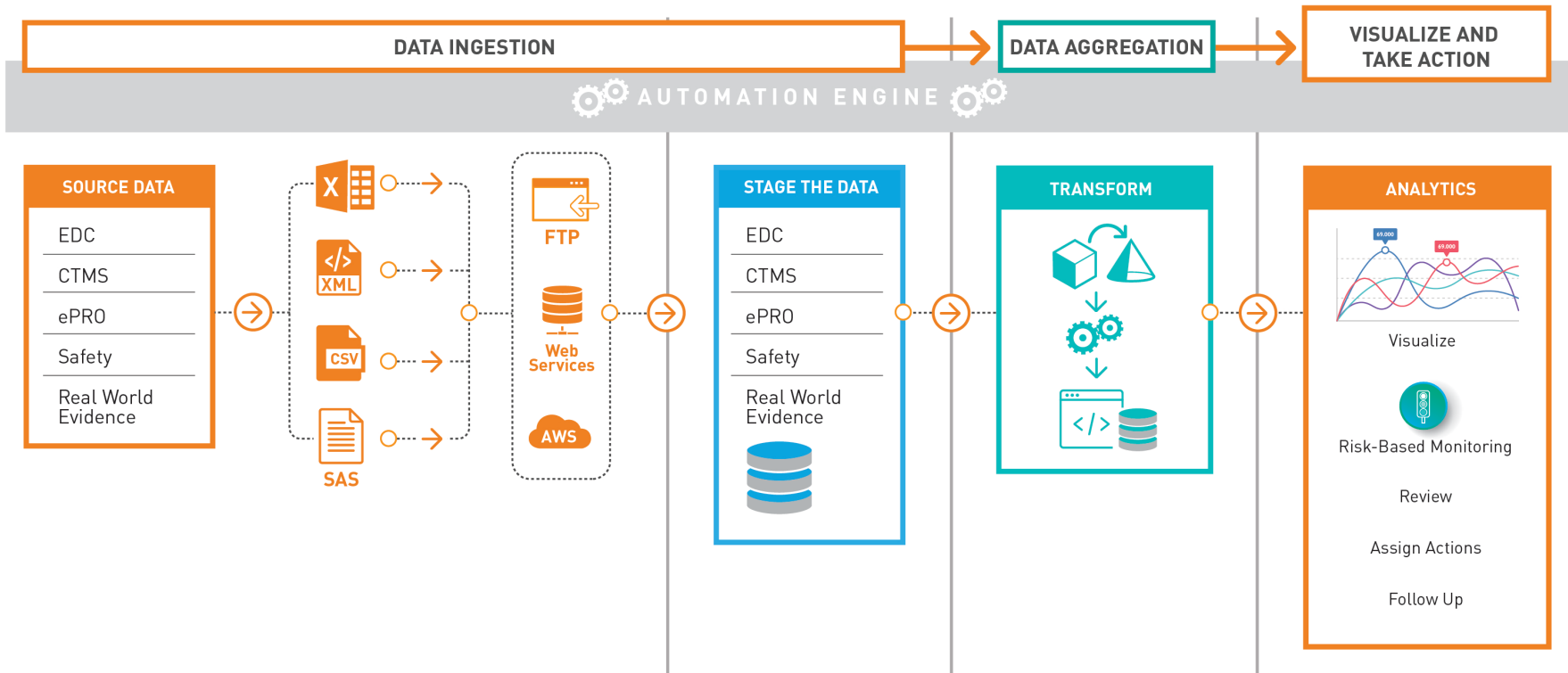
- **Data Preparation**

The process of parsing the data from different sources, normalizing and transforming into structures required.

- **Publishing**

Posting the normalized data into charts/graphs and listings, for review and action from the end user.

# Data Flow



# Data Preparation

## Data Ingestion

Collect all the data from different data sources and load it into the database or file system, for aggregation and normalization.

Complex clinical trials mean more complex data structures. A few common challenges with Data Ingestion are:

1. Access to real time data
2. Disparate data sources & formats
3. Unexpected changes in structure and incorrect file transmission
4. Self Service

# Data Preparation: Data Ingestion

1. Access to real time data: Integrate using web service call with EDC / Mobile data

Edit Data Source - eCS-ONCODEMO Biostats Gateway

Data Source Type:

- Rave Biostats Gateway
- Amazon S3
- Amazon S3 Outbound
- FTP
- FTP Outbound
- Medrio Web Service
- Merge eClinicalOS Web Services
- Rave Biostats Gateway**
- Rave ODM Adaptor
- Rave Web Services

Username:

Password:

Environment:

# Data Preparation: Data Ingestion

2. Disparate Data Sources & Formats: Build connectors and flexibility to consume different data sources.
  - Delimited Files
  - SAS datasets (sas7bdat, xpt)
  - Excel
  - xml

# Data Preparation: Data Ingestion

3. Unexpected changes in structure and incorrect file transmission: Reconcile with the previously processed files for metadata

| Status: Complete                                               | Created By: admin | Created Date: 21 Aug 2017 14:03:30 | <a href="#">Files in eDrive</a> |            |
|----------------------------------------------------------------|-------------------|------------------------------------|---------------------------------|------------|
| ▲ Domain                                                       | Row Count         | Variable Count                     | Discrepancy                     | Status     |
| ☐ LB                                                           | 185,680           | 31                                 | ☑                               | Integrated |
| [LBORRESU] - Field: Source=LBORRESU, Destination:** Missing ** |                   |                                    |                                 |            |
| [LBSTNRLO] - Field: Source=LBSTNRLO, Destination:** Missing ** |                   |                                    |                                 |            |
| [LBSTNRHI] - Field: Source=LBSTNRHI, Destination:** Missing ** |                   |                                    |                                 |            |
| [LBSTNRC] - Field: Source=LBSTNRC, Destination:** Missing **   |                   |                                    |                                 |            |
| [LBSTAT] - Field: Source=LBSTAT, Destination:** Missing **     |                   |                                    |                                 |            |
| [LBNAM] - Field: Source=LBNAM, Destination:** Missing **       |                   |                                    |                                 |            |
| [LBSPCCND] - Field: Source=LBSPCCND, Destination:** Missing ** |                   |                                    |                                 |            |
| [LBMETHOD] - Field: Source=LBMETHOD, Destination:** Missing ** |                   |                                    |                                 |            |
| [LBBLFL] - Field: Source=LBBLFL, Destination:** Missing **     |                   |                                    |                                 |            |
| [EPOCH] - Field: Source=EPOCH, Destination:** Missing **       |                   |                                    |                                 |            |
| ⬇ File: lb.sas7bdat                                            |                   |                                    |                                 |            |

# Data Preparation: Data Ingestion

## 4. Self Service

Imports

Manual File Import

Run

Schedule

Edit

Delete

New

New From Template

| Name                                                                  | Source                        | Type                  | Data Store | Last Run                        | Last Run Status    | Last Modified                      |
|-----------------------------------------------------------------------|-------------------------------|-----------------------|------------|---------------------------------|--------------------|------------------------------------|
| <input checked="" type="checkbox"/> eCS-ONCODEMO Rave Biostats Import | eCS-ONCODEMO Biostats Gateway | Rave Biostats Gateway | Clinical   | 15 Feb 2019 10:11:00 sgudapati  | Ready To Integrate | 30 Jul 2018 14:45:06 skakulavarapu |
| <input type="checkbox"/> eCS-ONCODEMO Rave ODM Import                 | eCS-ONCODEMO Rave ODM Adapter | Rave ODM Adaptor      | ODM_Stage  | 25 Apr 2018 15:55:19 admin      | Complete           | 05 Feb 2018 11:47:13 skakulavarapu |
| <input type="checkbox"/> Import FTP SDTM Datasets                     | FTP SDTM Datasets             | FTP                   | Reporting  | 31 Jul 2018 14:13:24 SGUDAPATI  | Complete           | 31 Jul 2018 14:13:01 sgudapati     |
| <input type="checkbox"/> Lab Vendor File                              | Lab Vendor File               | FTP                   | Clinical   | 31 Jul 2018 13:53:59 SGUDAPATI  | Complete           | 06 Feb 2018 10:28:07 skakulavarapu |
| <input type="checkbox"/> Outstanding                                  | Outstanding                   | File                  | Clinical   | 07 Aug 2018 13:51:09 NMUPPIRALA | Complete           | 07 Aug 2018 13:50:53 NMUPPIRALA    |

Active Import for eCS-ONCODEMO Rave Biostats Import

Status: Ready To Integrate

Created By: sgudapati

Created Date: 15 Feb 2019 10:11:00

Integrate

Delete

| Domain             | Row Count | Variable Count | Discrepancy | Import?                             | Status |
|--------------------|-----------|----------------|-------------|-------------------------------------|--------|
| <div>AE</div>      | 998       | 116            |             | <input checked="" type="checkbox"/> | OK     |
| <div>AEYN</div>    | 43        | 33             |             | <input checked="" type="checkbox"/> | OK     |
| <div>B2MIG</div>   | 42        | 77             |             | <input checked="" type="checkbox"/> | OK     |
| <div>B2MIG_C</div> | 0         | 53             |             | <input checked="" type="checkbox"/> | OK     |

# Data Preparation: Data Ingestion

## Example:

- To identify the sites that have patients who are behind on ePRO completion for more than two assessment periods.

## Data Sources Integrated:

- a. Rave clinical data through web service
- b. ePRO data through SFTP
- c. Static file from user

# Data Preparation: Aggregation

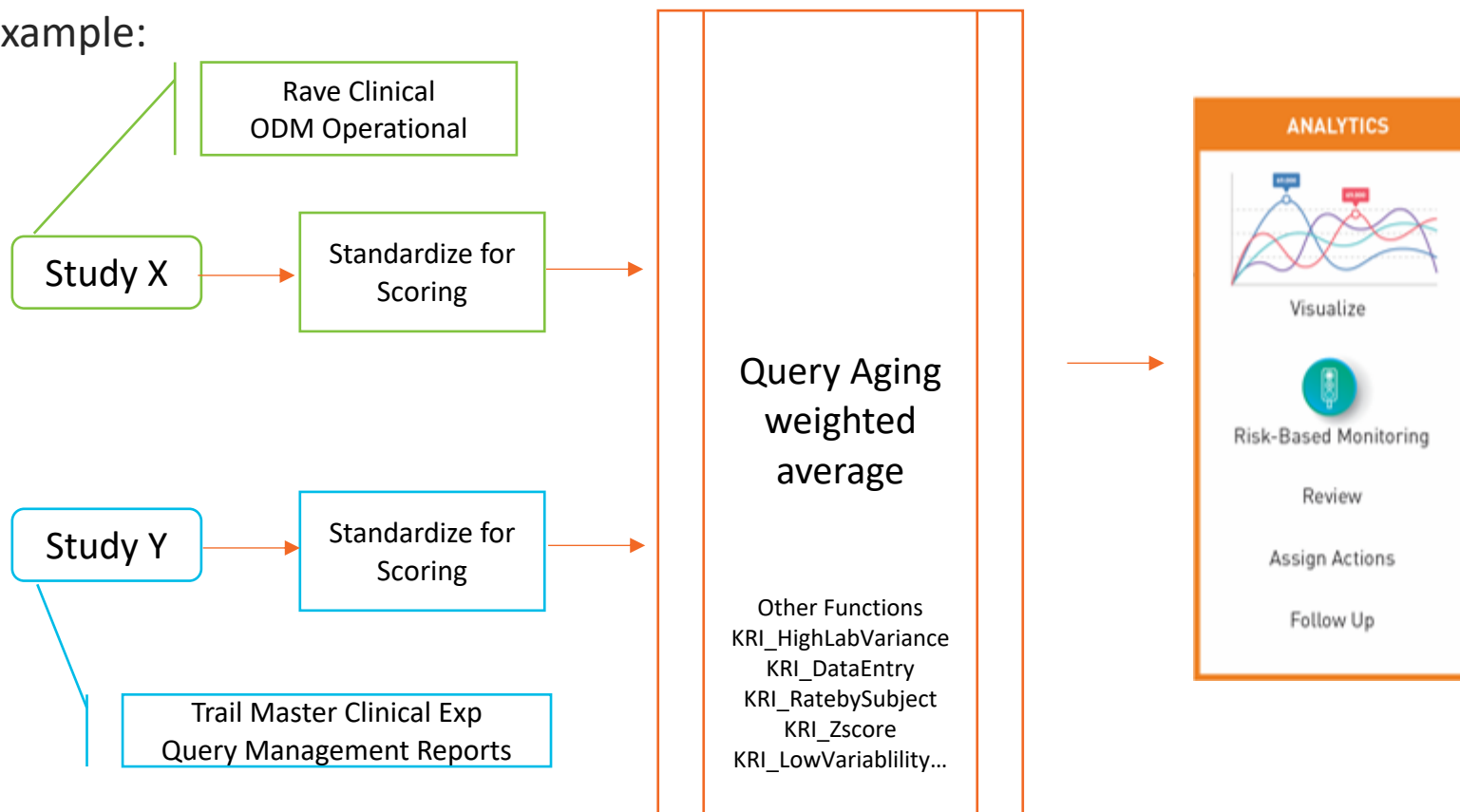
## Data Aggregation

The step to summarize and process data through any statistical or algorithmic approaches can be done using any robust ETL tool. Here are a few common challenges and the processes that worked for different implementations.

1. Modularization: Break down the code into reusable components to gain efficiencies
  - Quality
  - Development time
  - Maintenance

# Data Preparation: Aggregation

Example:



# Data Preparation: Aggregation

2. Automation & Self Service: Every data integration should be tightly integrated with transformation to keep output as up to date as source.
  - Nightly batch refresh
  - On-demand self service

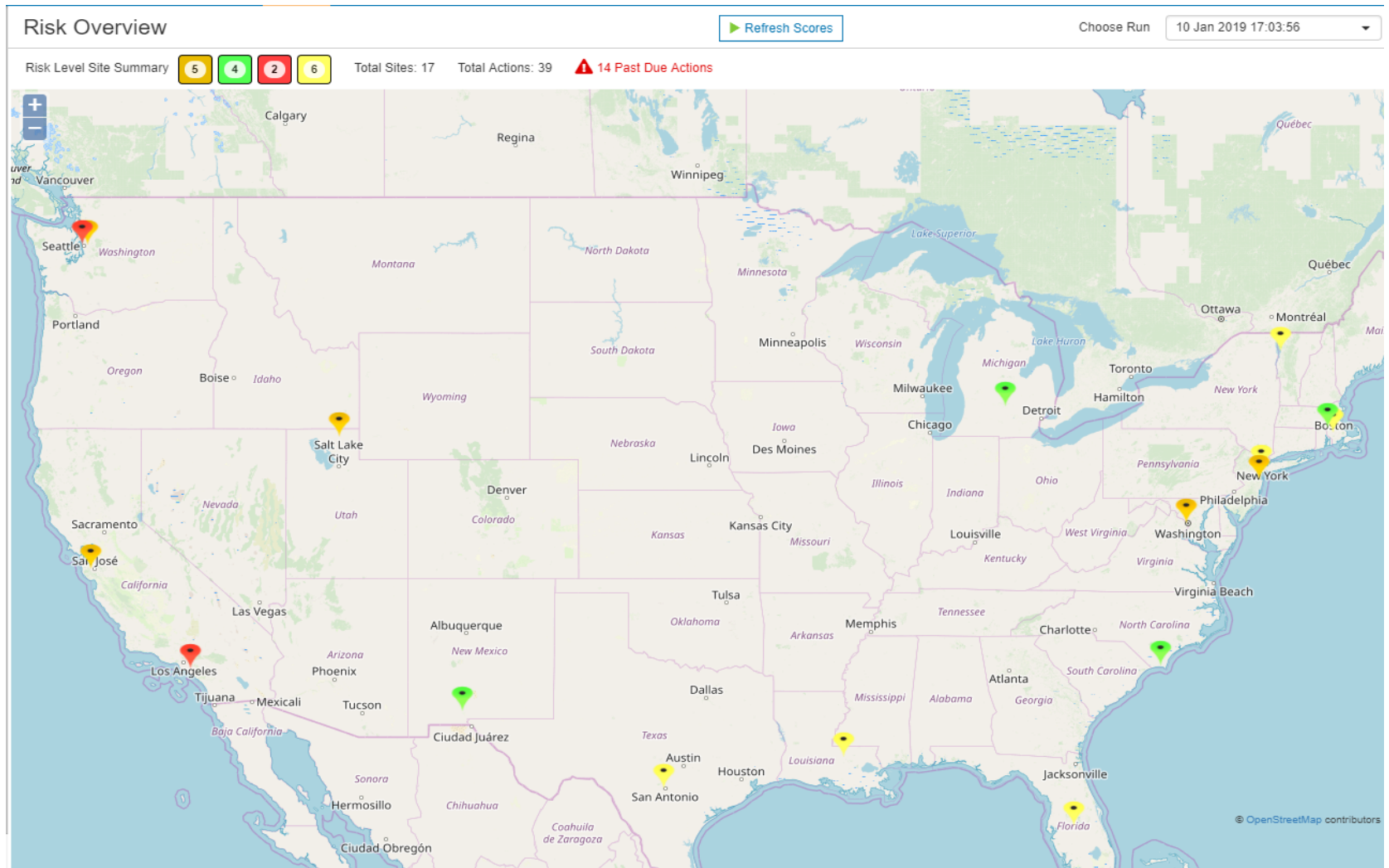
# Publishing & User Action

## Publishing

The interactive presentation of data in charts, graphs, and listings. Irrespective of the methods used for risk calculation, here are few key practices that help adoption:

- Simple and intuitive
- Visualization using a unified data model
- Interactive
- User connection with data

## Publishing & User Action



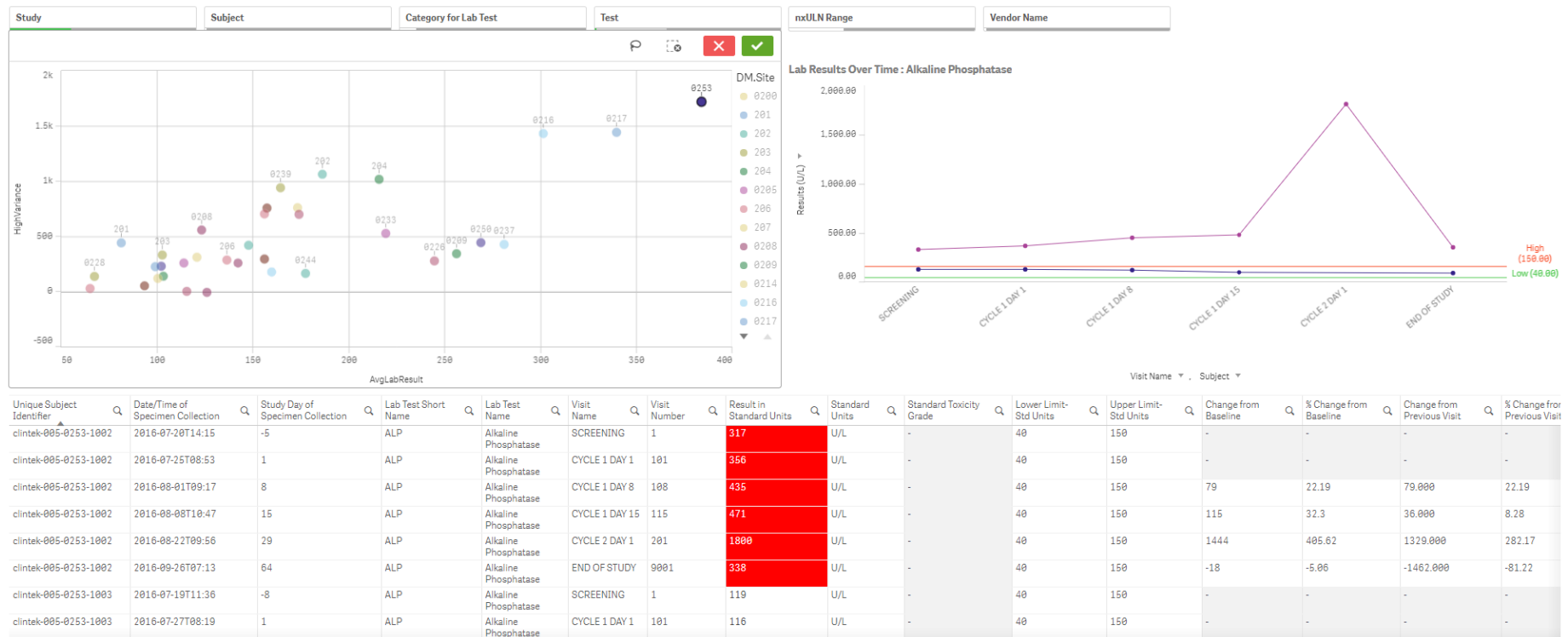
# Publishing & User Action

## Site level detail

| 1 - Toronto General Hospital             |              |
|------------------------------------------|--------------|
| ▼ Site Score: 0.88                       | 8 Indicators |
| Indicator                                | Score        |
| Blood Pressure                           | 2.00         |
| Drug Related Blood Pressure Events       | 2.00         |
| Renal Safety Data                        | 0.00         |
| Treatment Emergent Adverse Events        | 0.00         |
| Hemoconcentration data (indirect method) | 2.00         |
| Plasma Volume Results (direct method)    | 1.00         |
| Enrollment of diabetic patients          | 0.00         |
| Missing data per visit per patient diary | 1.00         |

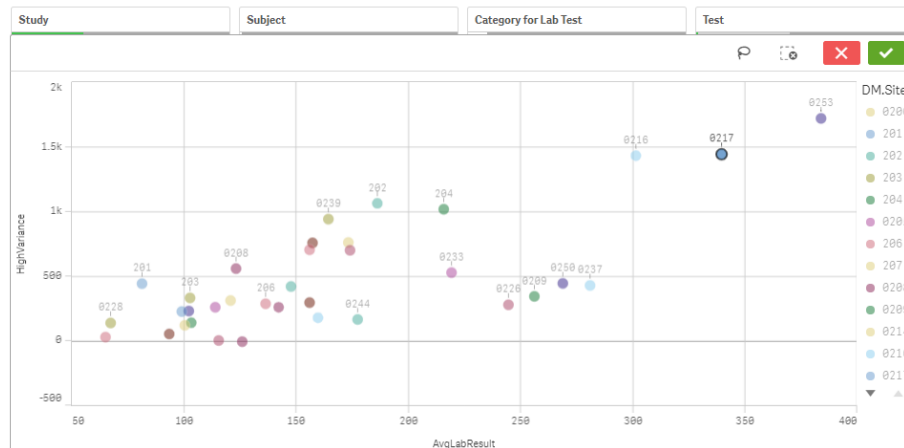
# Publishing & User Action

## Unified data model – Lab Visualization



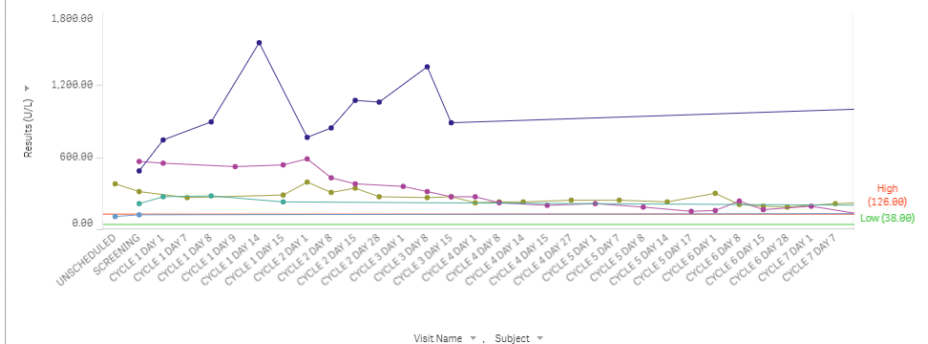
# Publishing & User Action

## Unified data model – Lab Visualization



nxULN Range Vendor Name

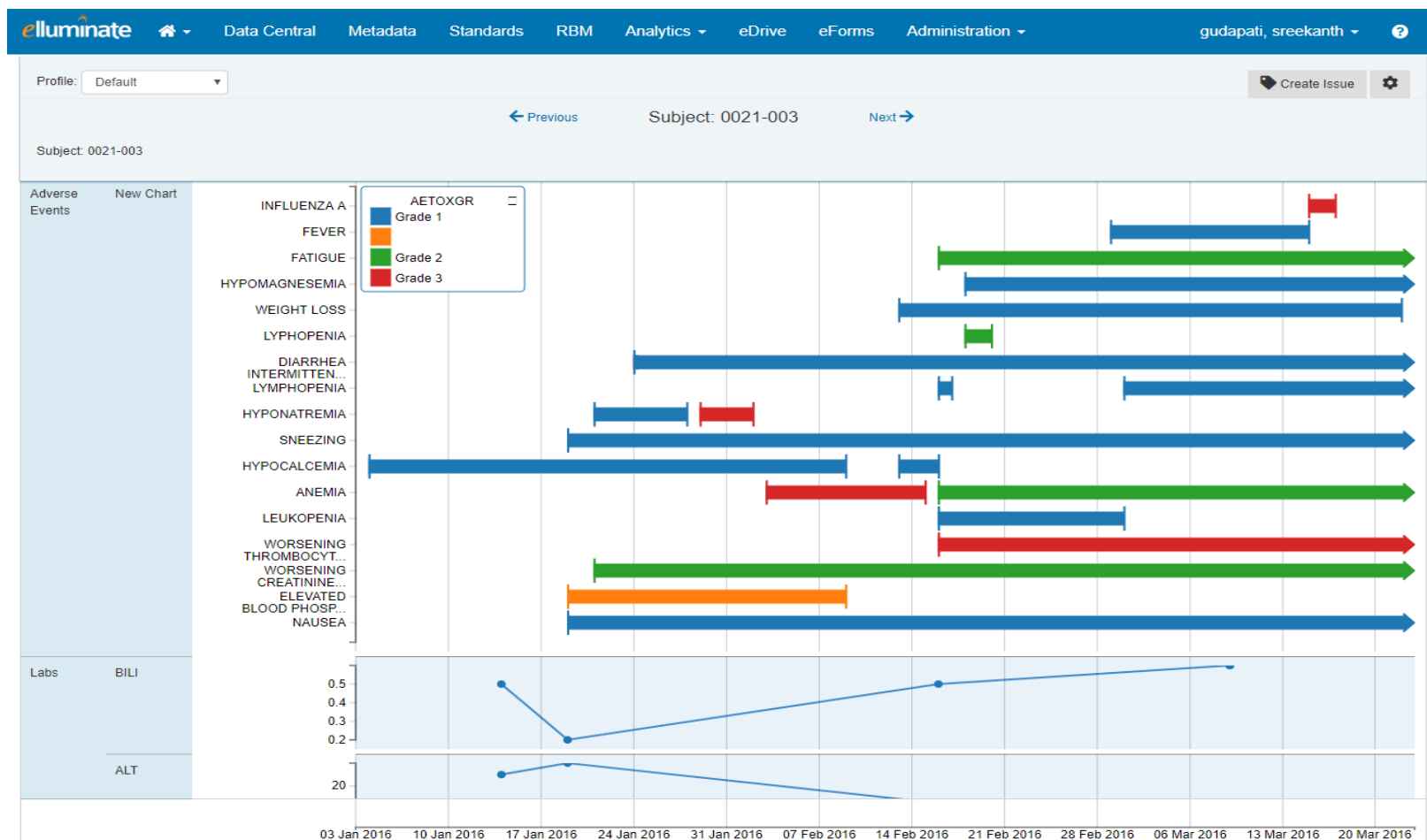
Lab Results Over Time : Alkaline Phosphatase



| Unique Subject Identifier | Date/Time of Specimen Collection | Study Day of Specimen Collection | Lab Test Short Name | Lab Test Name        | Visit Name     | Visit Number | Result in Standard Units | Standard Units | Standard Toxicity Grade | Lower Limit-Std Units | Upper Limit-Std Units | Change from Baseline | % Change from Baseline | Change from Previous Visit | % Change from Previous Visit |
|---------------------------|----------------------------------|----------------------------------|---------------------|----------------------|----------------|--------------|--------------------------|----------------|-------------------------|-----------------------|-----------------------|----------------------|------------------------|----------------------------|------------------------------|
| clintek-005-0217-1001     | 2015-03-31T13:56                 | -15                              | ALP                 | Alkaline Phosphatase | SCREENING      | 1            | 485                      | U/L            | -                       | 38                    | 126                   | -                    | -                      | -                          | -                            |
| clintek-005-0217-1001     | 2015-04-08T11:12                 | -7                               | ALP                 | Alkaline Phosphatase | SCREENING      | 1            | 608                      | U/L            | -                       | 38                    | 126                   | -                    | -                      | -                          | -                            |
| clintek-005-0217-1001     | 2015-04-15T11:57                 | 1                                | ALP                 | Alkaline Phosphatase | CYCLE 1 DAY 1  | 101          | 532                      | U/L            | -                       | 38                    | 126                   | -                    | -                      | -                          | -                            |
| clintek-005-0217-1001     | 2015-04-23T09:54                 | 9                                | ALP                 | Alkaline Phosphatase | CYCLE 1 DAY 9  | 109          | 502                      | U/L            | -                       | 38                    | 126                   | -30                  | -5.64                  | -30.000                    | -5.64                        |
| clintek-005-0217-1001     | 2015-04-29T07:52                 | 15                               | ALP                 | Alkaline Phosphatase | CYCLE 1 DAY 15 | 115          | 518                      | U/L            | -                       | 38                    | 126                   | -14                  | -2.63                  | 16.000                     | 3.19                         |
| clintek-005-0217-1001     | 2015-05-13T10:02                 | 29                               | ALP                 | Alkaline Phosphatase | CYCLE 2 DAY 1  | 201          | 570                      | U/L            | -                       | 38                    | 126                   | 38                   | 7.14                   | 52.000                     | 10.04                        |
| clintek-005-0217-1001     | 2015-05-20T07:22                 | 36                               | ALP                 | Alkaline Phosphatase | CYCLE 2 DAY 8  | 208          | 410                      | U/L            | -                       | 38                    | 126                   | -122                 | -22.93                 | -160.000                   | -28.07                       |
| clintek-005-0217-1001     | 2015-05-27T08:30                 | 43                               | ALP                 | Alkaline Phosphatase | CYCLE 2 DAY 15 | 215          | 365                      | U/L            | -                       | 38                    | 126                   | -167                 | -31.39                 | -45.000                    | -10.98                       |
| clintek-005-0217-1001     | 2015-06-10T08:25                 | 57                               | ALP                 | Alkaline Phosphatase | CYCLE 3 DAY 1  | 301          | 340                      | U/L            | -                       | 38                    | 126                   | -192                 | -36.09                 | -25.000                    | -6.85                        |

# Publishing & User Action

## Unified data model – Patient Profile



# Publishing & User Action

## User Actions

- Assign for action
- Analyze data for additional information
- Follow-up action
- Snooze a KRI
- Acknowledge & suspend

# Questions?

Session AR05 – Thank You



Contact Details:



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# References

1. TransCelerate – RBM Interactive Guide
2. A Risk Based approach for to Monitoring - FDA

