# The future of clinical data processing and analysis: Event driven and seamless collaboration between teams

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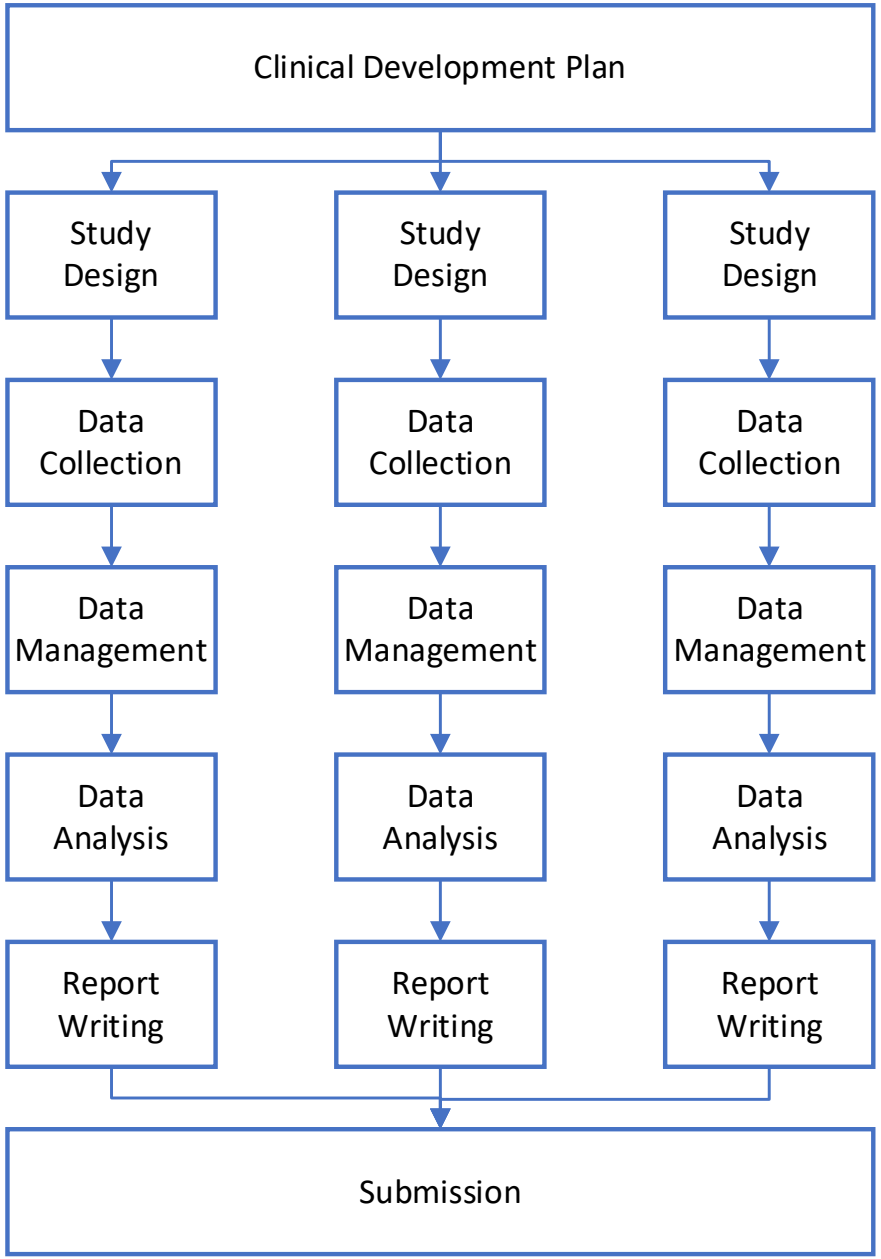
# Content

- Clinical study processes of the future
- Viewpoints and views
- Future examples based on elluminate

# Study processes old

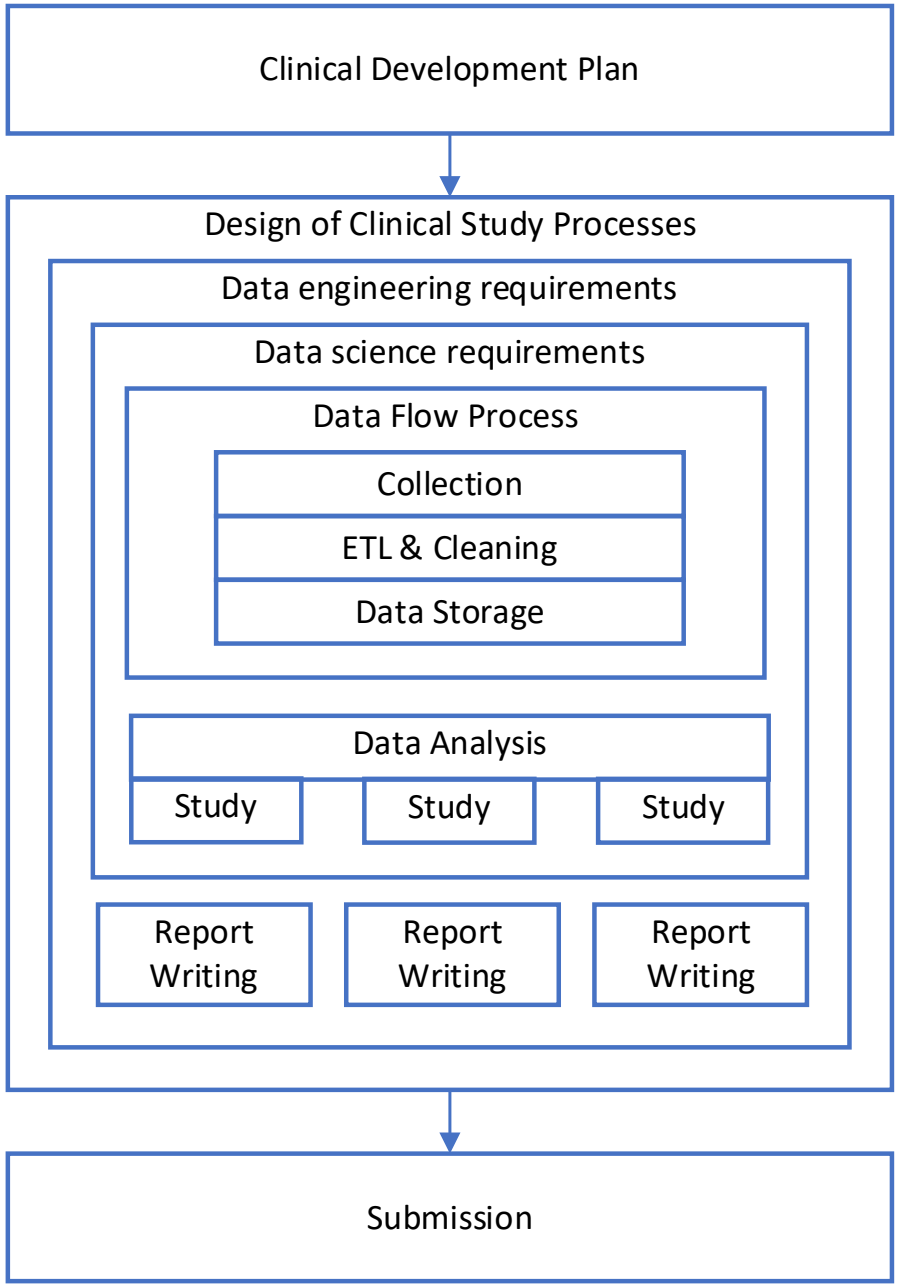
- Study by study
- Silood approach

- No input in previous steps
  - No influence
  - Less accurate data and results
- Finalize before next step
  - No insights in data before handover
  - No pre-prepare of deliverables



# Study processes new

- Reduce inconsistencies
- Limit repeated actions
- Input and alignment in all phases
- Aligns with new study designs
  - Decentralized trials
  - Umbrella and basket trials
  - Real World Data



# Data Chaos

CTMS

Safety

EHR

EDC

EHR

Genomics

eSource

Labs

Images

Wearables

Biomarkers

Labs

eCOA

Biomarkers

ePRO

EDC

Safety

SAS

eCOA

XLS

CTMS

Images

DCTs

# Data

## Old

- Integrate external lab, PK and PD data
- Every source in a different format
- Access and ingestion requires ICT resources
- Manual linkage of different sources
- Difficult version management / no single source of truth

## New

- Integrate many different data sources
- More and more industry standardized formats
- Automated data ingestion after right approval
- Automated linkage with identification and review of issues
- Continuous data exchange between systems enabling single source of truth principle

# Reporting & Analysis

## Old

- Based on templates and macro's
- Re-run a cascade of programs after data updates
- Re-QC of programs and outputs after each data update
- Copying of programs from development to validation to production
- Access rights based on tasks managed by ICT
- QC status and signatures on separate documents

## New

- Automated on-time TLF creation
- Automated run in the correct order of programs after data updates
- Automated alerts when unexpected data is encountered
- Automated version control and indication of status (dev, val, prod)
- Tasks and rights directly managed by department manager
- Automated signatures and QC status directly stored and linked to program

# Views

**Architecture View***

- A representation of a system from the perspective of a related set of concerns
- It is what the stakeholder sees

**Although we work with the same data we need different views for**

- Trial/scientific management
- Risk based monitoring
- Pharmacovigilence
- Data engineering
- Data management
- (Statistical) Programming
- Data science
- Reporting

* TOGAF Foundation

# Viewpoint

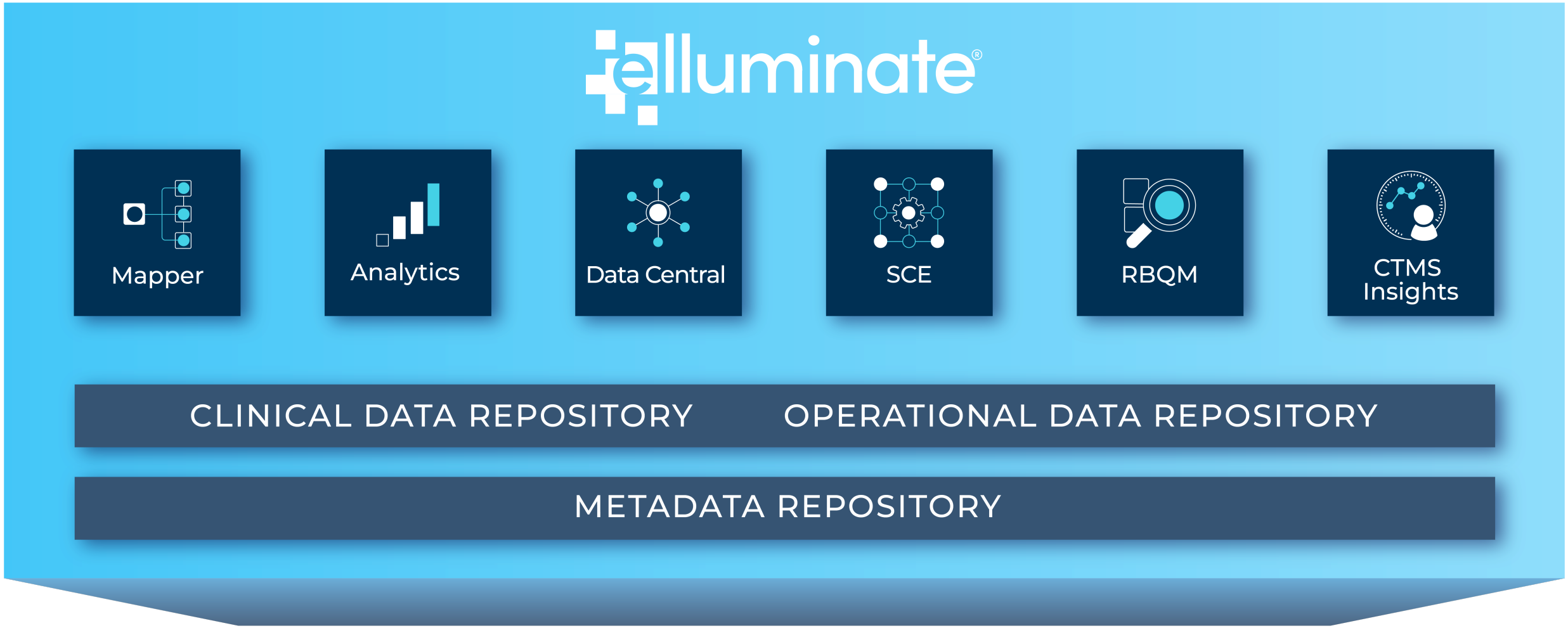
**Architecture Viewpoint***

- Is the specification of conventions for a particular kind of architecture view
- Effectively defines the perspective from which an architecture view is taken

**Stakeholder management**

- Current activities
- Concerns
- Improvement ideas
- Implementation
- Optimization

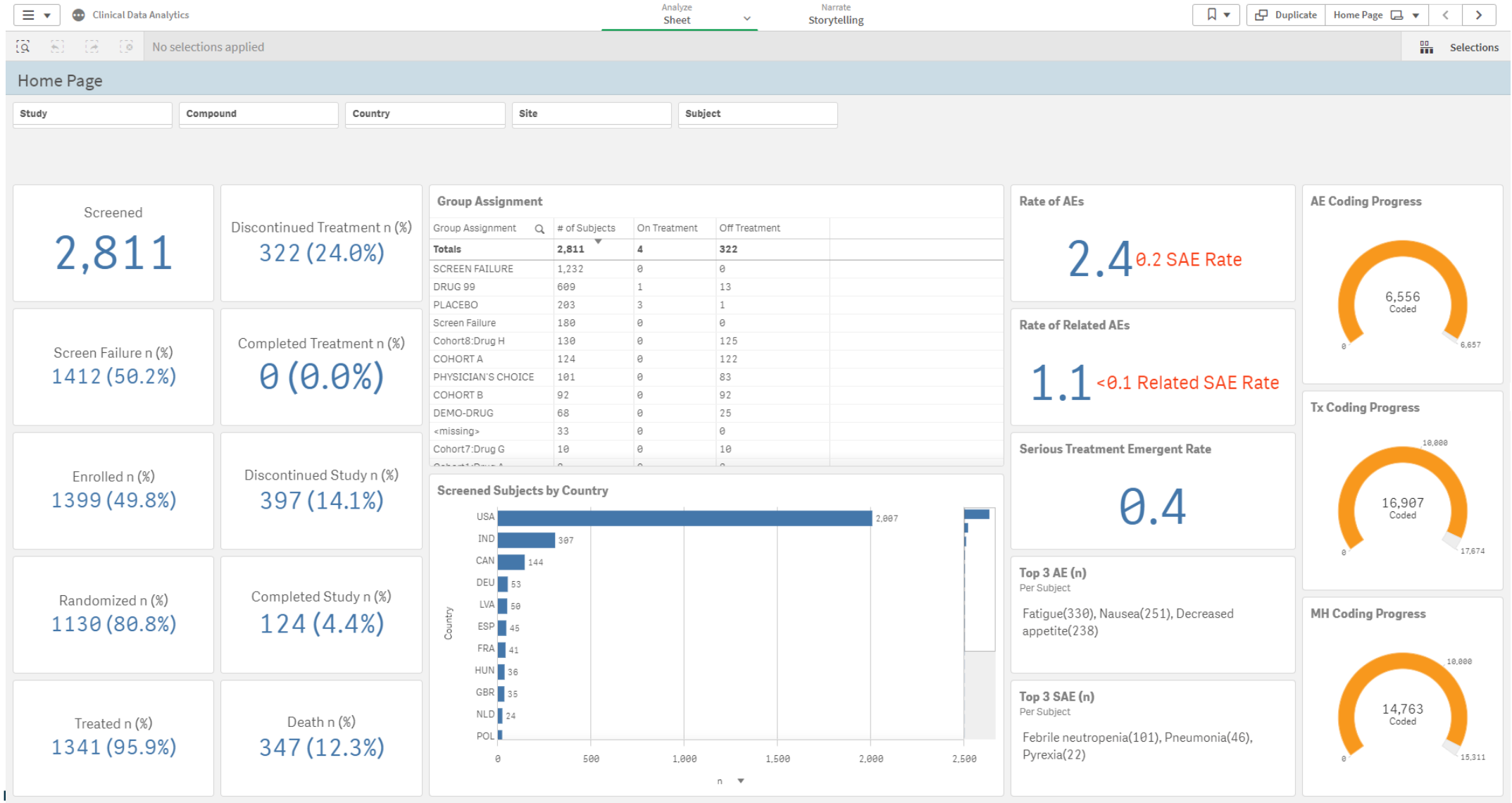
*TOGAF Foundation




# The Foundation of Digital Trials

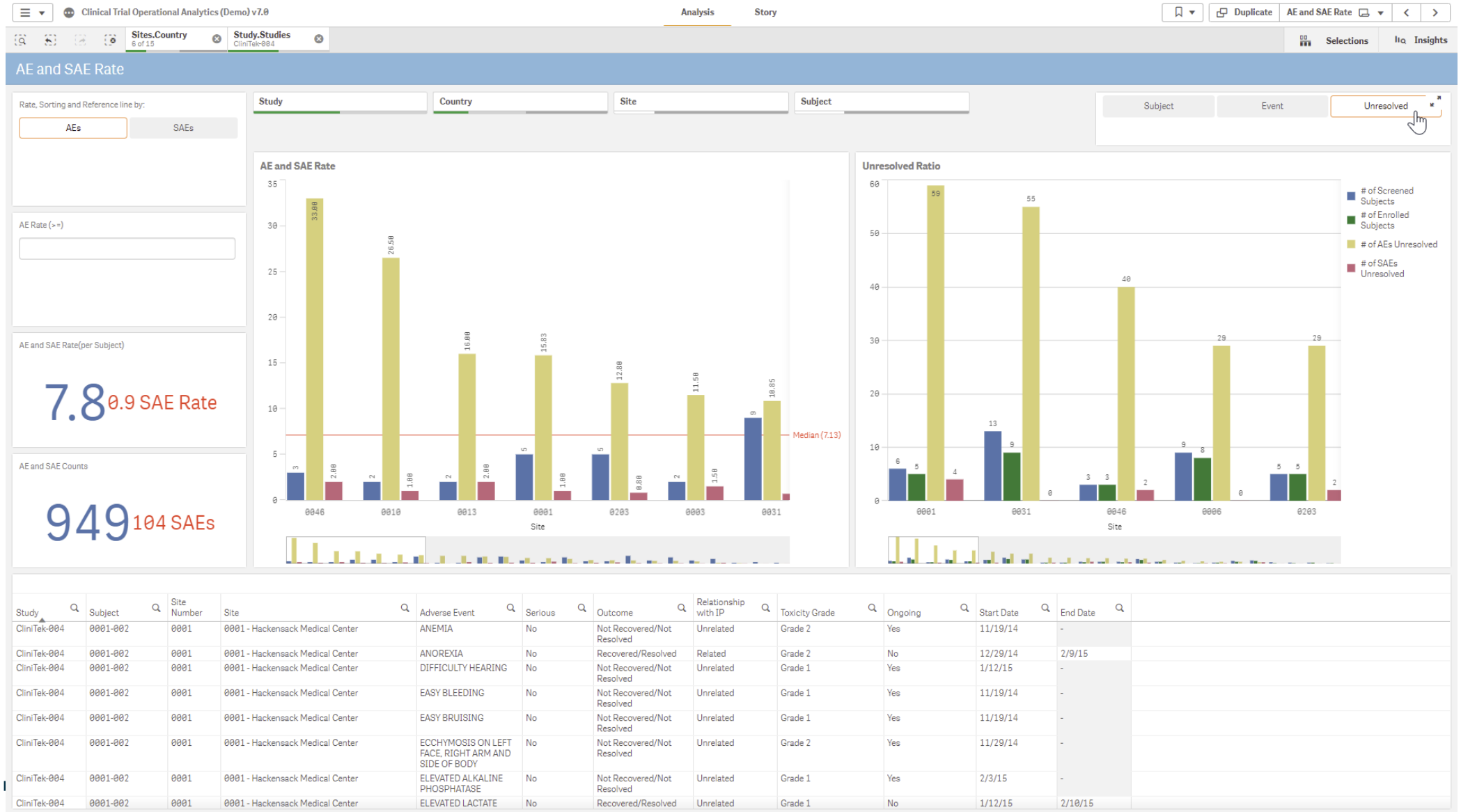
# Viewpoints and views for adverse events data

## Operational



# Viewpoints and views for adverse events data

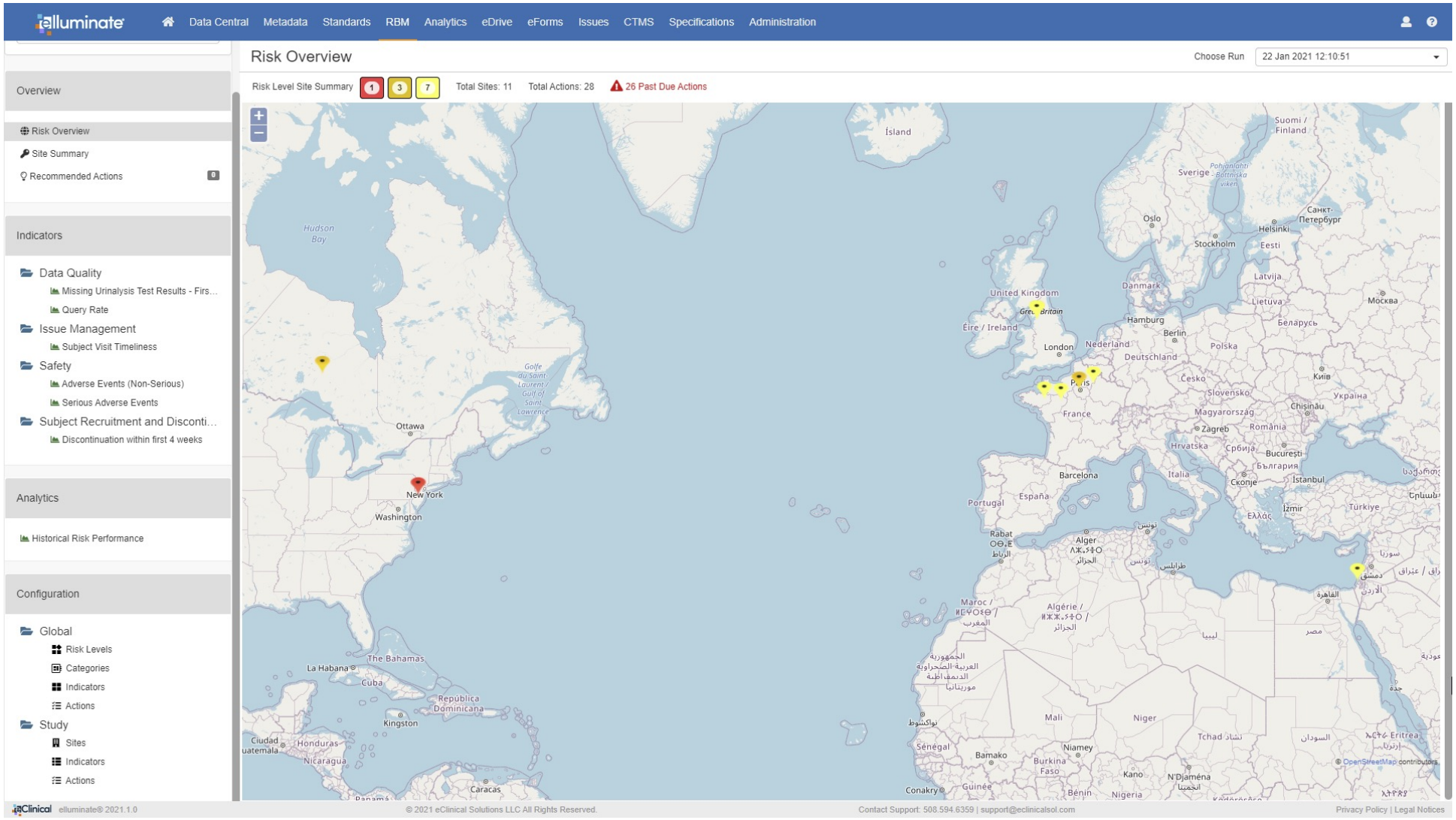
## Clinical Trial Management




| Study | Subject | Site Number | Site | Adverse Event | Serious | Outcome | Relationship with IP | Toxicity Grade | Ongoing | Start Date | End Date |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | ANEMIA | No | Not Recovered/Not Resolved | Unrelated | Grade 2 | Yes | 11/19/14 | - |
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | ANOREXIA | No | Recovered/Resolved | Related | Grade 2 | No | 12/29/14 | 2/9/15 |
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | DIFFICULTY HEARING | No | Not Recovered/Not Resolved | Unrelated | Grade 1 | Yes | 1/12/15 | - |
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | EASY BLEEDING | No | Not Recovered/Not Resolved | Unrelated | Grade 1 | Yes | 11/19/14 | - |
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | EASY BRUISING | No | Not Recovered/Not Resolved | Unrelated | Grade 1 | Yes | 11/19/14 | - |
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | ECCHYMOSIS ON LEFT FACE, RIGHT ARM AND SIDE OF BODY | No | Not Recovered/Not Resolved | Unrelated | Grade 2 | Yes | 11/29/14 | - |
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | ELEVATED ALKALINE PHOSPHATASE | No | Not Recovered/Not Resolved | Unrelated | Grade 1 | Yes | 2/3/15 | - |
| CliniTek-004 | 0001-002 | 0001 | 0001 - Hackensack Medical Center | ELEVATED LACTATE | No | Recovered/Resolved | Unrelated | Grade 1 | No | 1/12/15 | 2/10/15 |

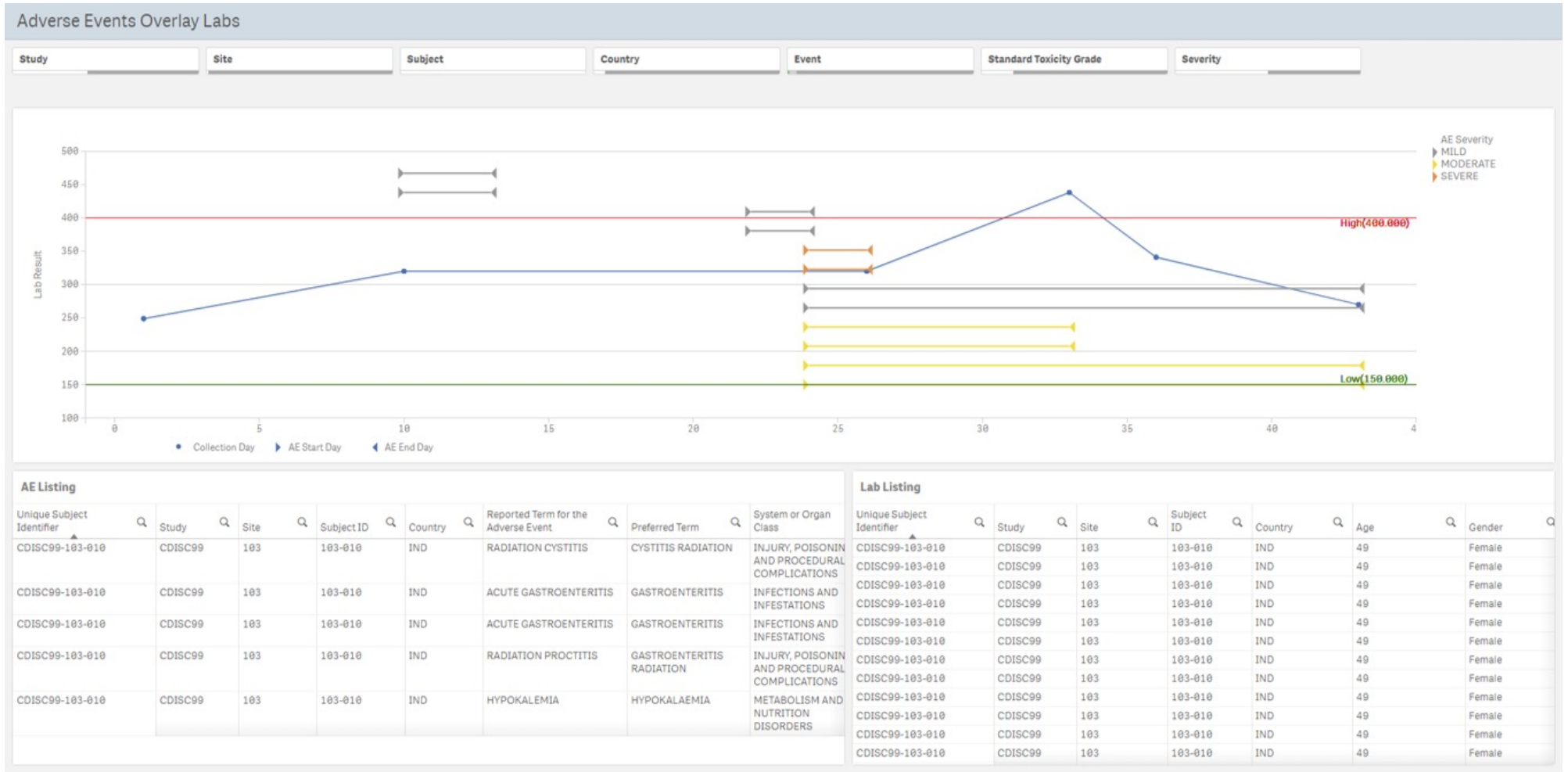
# Viewpoints and views for adverse event data

## Risk based monitoring



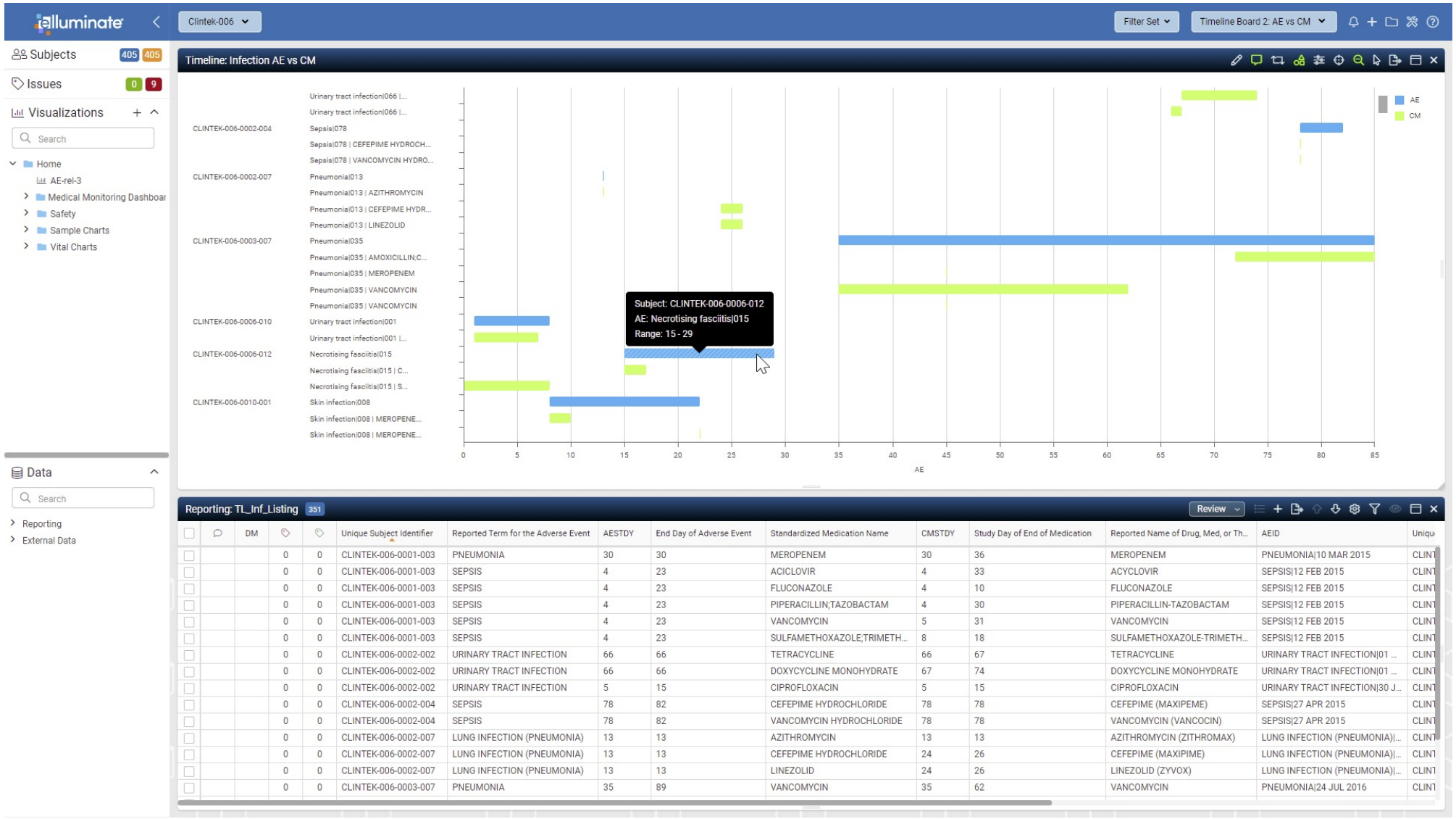
# Viewpoints and views for adverse event data

## Pharmacovigilence



# Viewpoints and views for adverse event data

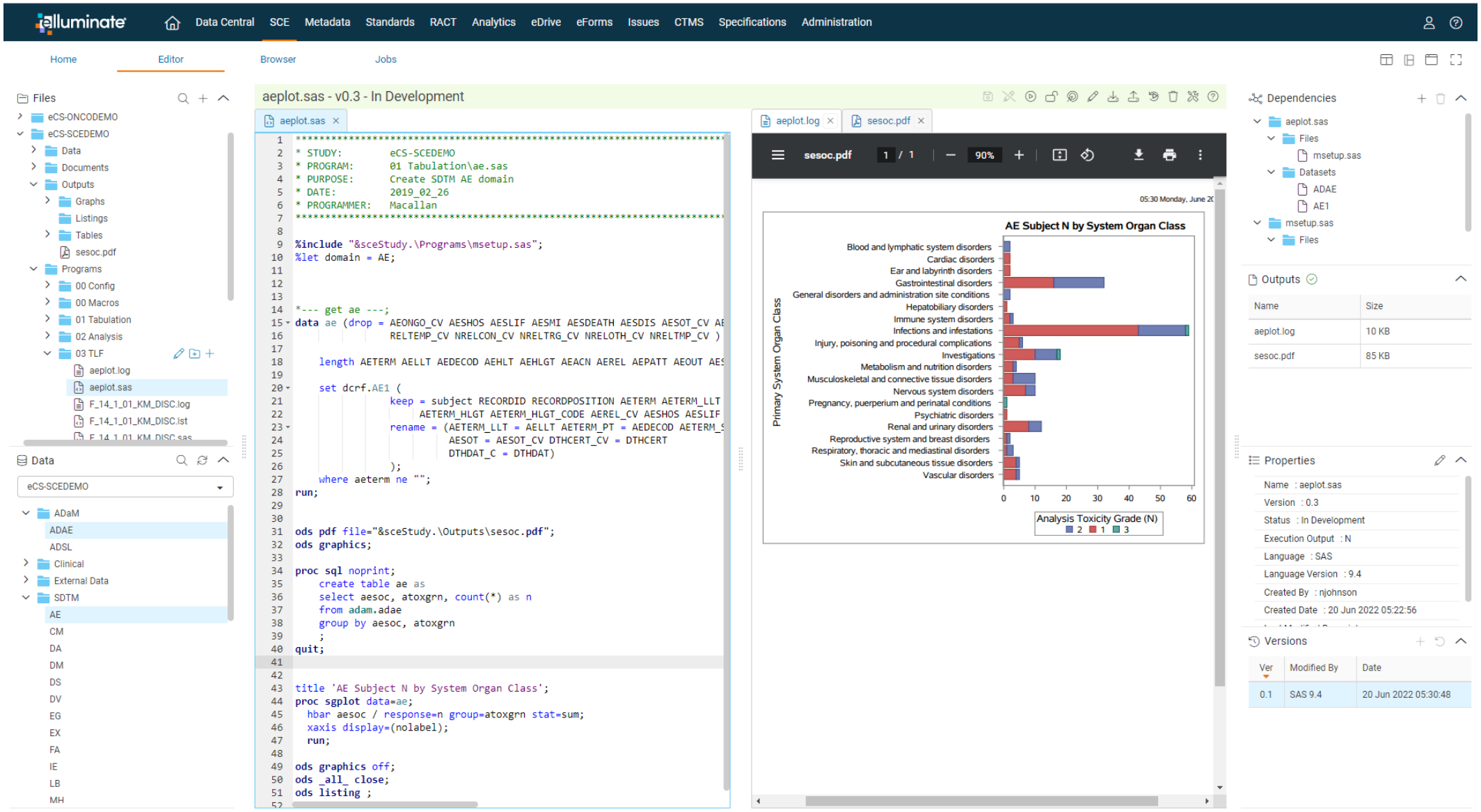
## Data management




| DM | Unique Subject Identifier | Reported Term for the Adverse Event | AESTDY | End Day of Adverse Event | Standardized Medication Name | CMSTDY | Study Day of End of Medication | Reported Name of Drug, Med, or Th... | AEID |
|---|---|---|---|---|---|---|---|---|---|
| 0 | CLINTEK-006-0001-003 | PNEUMONIA | 30 | 30 | MEROPENEM | 30 | 36 | MEROPENEM | PNEUMONIA\|10 MAR 2015 |
| 0 | CLINTEK-006-0001-003 | SEPSIS | 4 | 23 | ACICLOVIR | 4 | 33 | ACYCLOVIR | SEPSIS\|12 FEB 2015 |
| 0 | CLINTEK-006-0001-003 | SEPSIS | 4 | 23 | FLUCONAZOLE | 4 | 10 | FLUCONAZOLE | SEPSIS\|12 FEB 2015 |
| 0 | CLINTEK-006-0001-003 | SEPSIS | 4 | 23 | PIPERACILLIN;TAZOBACTAM | 4 | 30 | PIPERACILLIN-TAZOBACTAM | SEPSIS\|12 FEB 2015 |
| 0 | CLINTEK-006-0001-003 | SEPSIS | 4 | 23 | VANCOMYCIN | 5 | 31 | VANCOMYCIN | SEPSIS\|12 FEB 2015 |
| 0 | CLINTEK-006-0001-003 | SEPSIS | 4 | 23 | SULFAMETHOXAZOLE;TRIMETH... | 8 | 18 | SULFAMETHOXAZOLE-TRIMETH... | SEPSIS\|12 FEB 2015 |
| 0 | CLINTEK-006-0002-002 | URINARY TRACT INFECTION | 66 | 66 | TETRACYCLINE | 66 | 67 | TETRACYCLINE | URINARY TRACT INFECTION\|01 ... |
| 0 | CLINTEK-006-0002-002 | URINARY TRACT INFECTION | 66 | 66 | DOXYCYCLINE MONOHYDRATE | 67 | 74 | DOXYCYCLINE MONOHYDRATE | URINARY TRACT INFECTION\|01 ... |
| 0 | CLINTEK-006-0002-002 | URINARY TRACT INFECTION | 5 | 15 | CIPROFLOXACIN | 5 | 15 | CIPROFLOXACIN | URINARY TRACT INFECTION\|30 J... |
| 0 | CLINTEK-006-0002-004 | SEPSIS | 78 | 82 | CEFEPIME HYDROCHLORIDE | 78 | 78 | CEFEPIME (MAXIPEME) | SEPSIS\|27 APR 2015 |
| 0 | CLINTEK-006-0002-004 | SEPSIS | 78 | 82 | VANCOMYCIN HYDROCHLORIDE | 78 | 78 | VANCOMYCIN (VANCOCIN) | SEPSIS\|27 APR 2015 |
| 0 | CLINTEK-006-0002-007 | LUNG INFECTION (PNEUMONIA) | 13 | 13 | AZITHROMYCIN | 13 | 13 | AZITHROMYCIN (ZITHROMAX) | LUNG INFECTION (PNEUMONIA)\|... |
| 0 | CLINTEK-006-0002-007 | LUNG INFECTION (PNEUMONIA) | 13 | 13 | CEFEPIME HYDROCHLORIDE | 24 | 26 | CEFEPIME (MAXIPIME) | LUNG INFECTION (PNEUMONIA)\|... |
| 0 | CLINTEK-006-0002-007 | LUNG INFECTION (PNEUMONIA) | 13 | 13 | LINEZOLID | 24 | 26 | LINEZOLID (ZYVOX) | LUNG INFECTION (PNEUMONIA)\|... |
| 0 | CLINTEK-006-0003-007 | PNEUMONIA | 35 | 89 | VANCOMYCIN | 35 | 62 | VANCOMYCIN | PNEUMONIA\|24 JUL 2016 |

# Viewpoints and views for adverse event data

## (Statistical) Programming



# Elluminate

Demo by Nathan Johnson

VP digital innovation at eClinical soluations

- Automated run in the correct order of programs after data updates
- Automated alerts when unexpected data is encountered
- Automated version control and indication of status (dev, val, prod)

# Thank you

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