

IC11

Beyond the Hype: A Pragmatic Approach to Leveraging AI/ML for Data Review

Robert Musterer,
eClinical Solutions, Mansfield, CT, USA

Beyond the Hype: A Pragmatic Approach to Leveraging AI/ML for Data Review

Abstract:

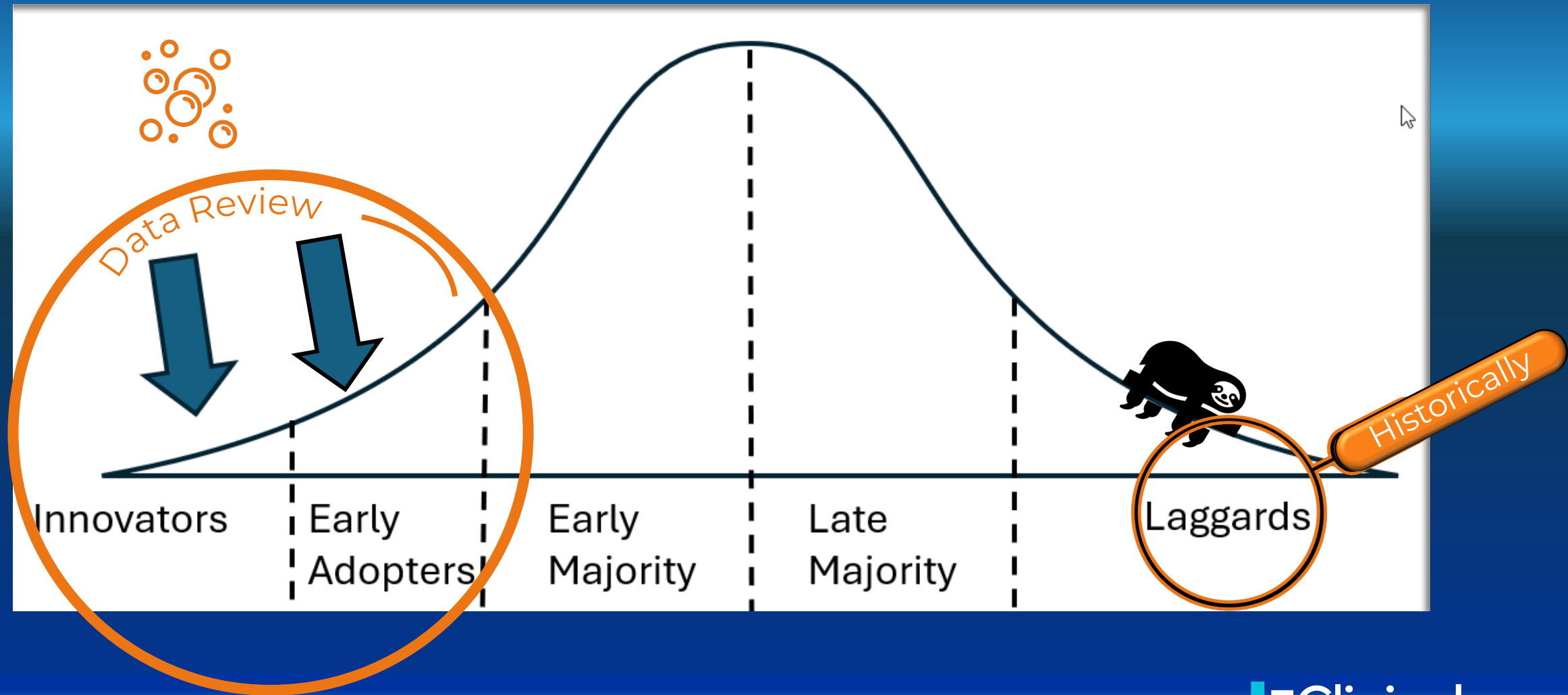
There is still a lot of hype around the potential of AI/ML to transform the life sciences industry and while advancements in clinical development have accelerated in recent years, the adoption of innovative technologies has lagged. Hype aside, taking a pragmatic approach to AI/ML enables life sciences companies to adopt new capabilities and accomplish objectives in a more efficient, cost-effective manner. This session will cover how a top 20 Sponsor partnered with eClinical Solutions to leverage the AI/ML capabilities to enhance clinical data review processes for greater efficiency using fewer resources. With these capabilities, high quality data is produced in near real-time to support accelerated submission and collaboration with the FDA. We will discuss the pragmatic approach to adoption including how the AI-enabled data review use cases were selected and evaluated, the validation process for ensuring accuracy of the AI/ML models, and the resulting efficiency gains

Problem Statement

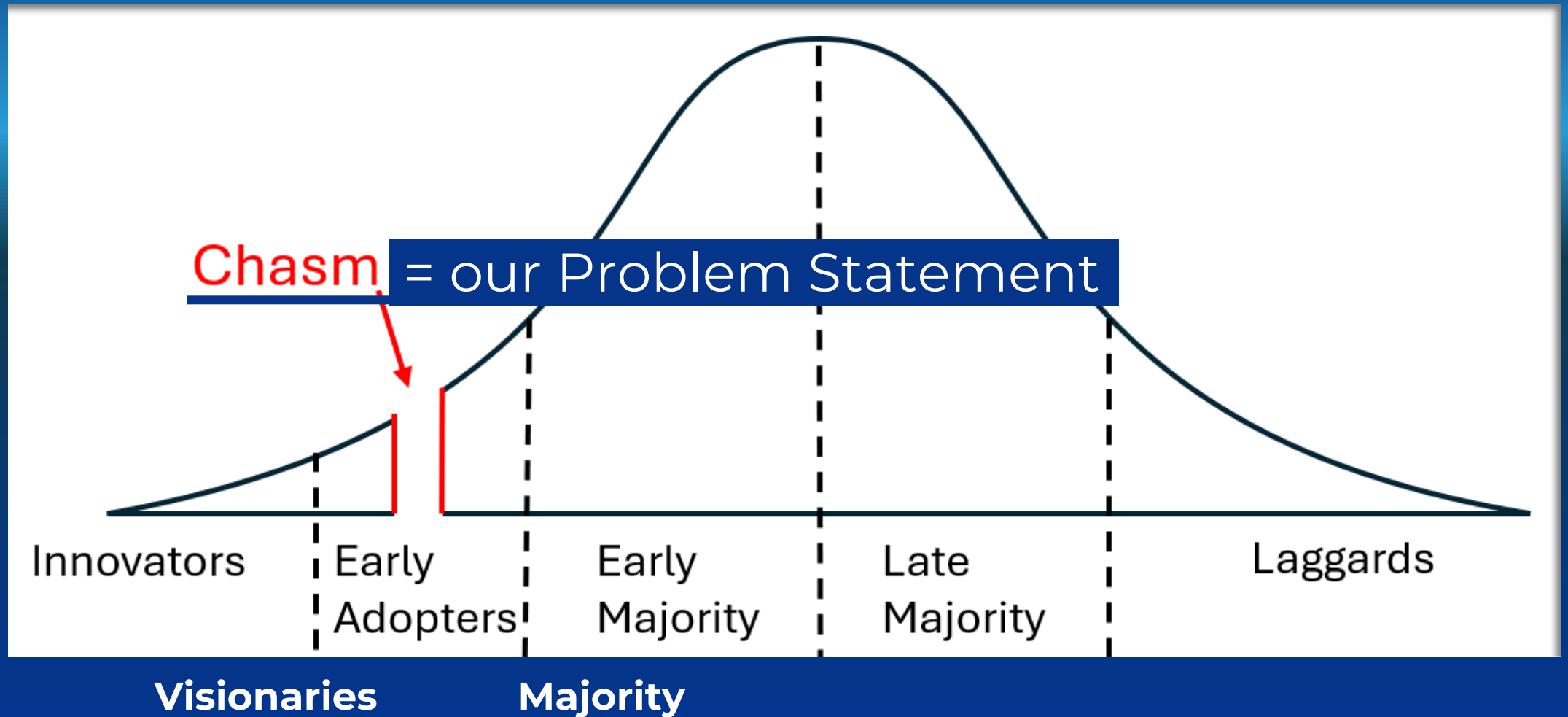
Adoption !



Everett M. Rogers' bell curve

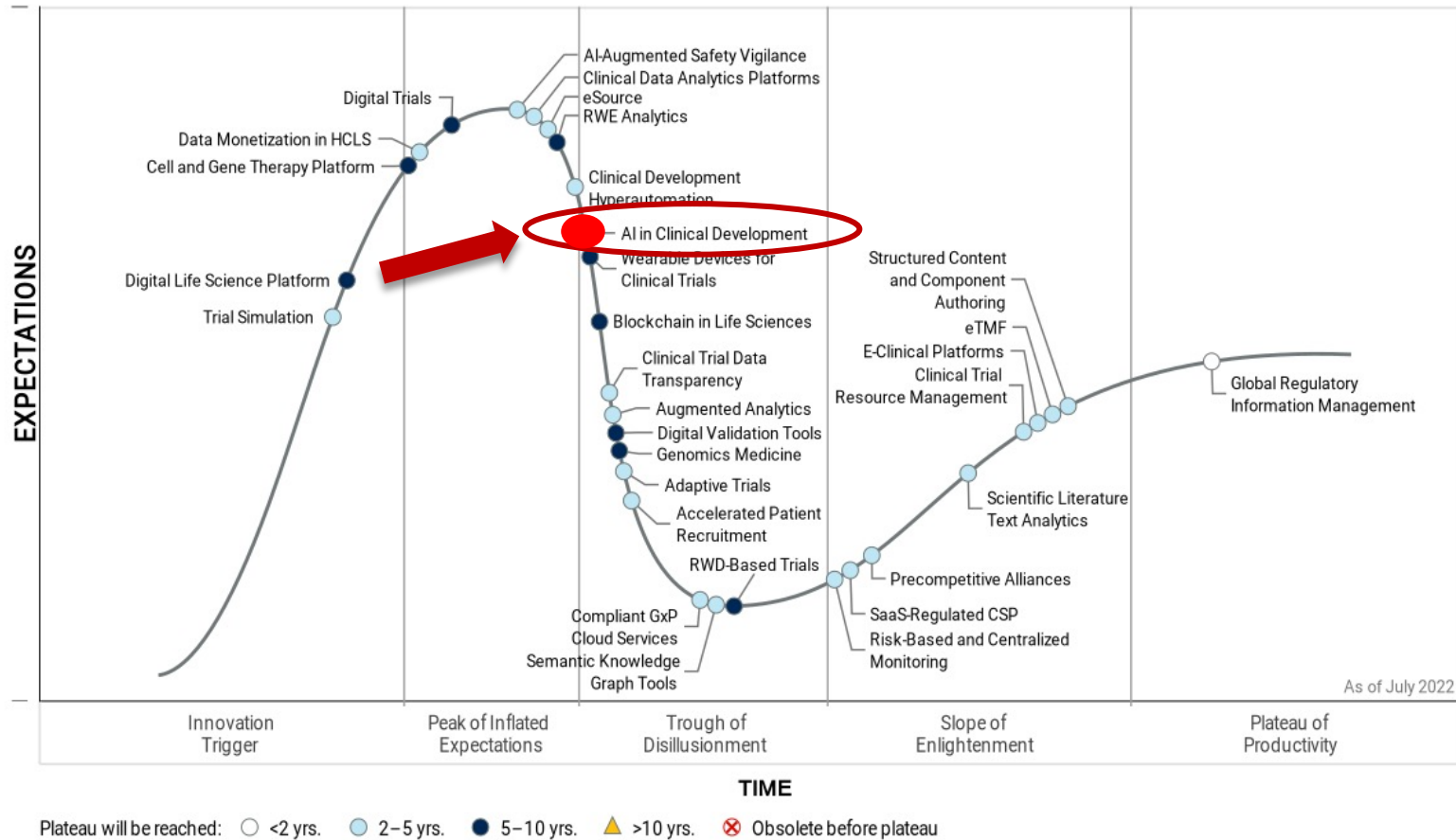


Geoffrey Moore, Crossing the Chasm



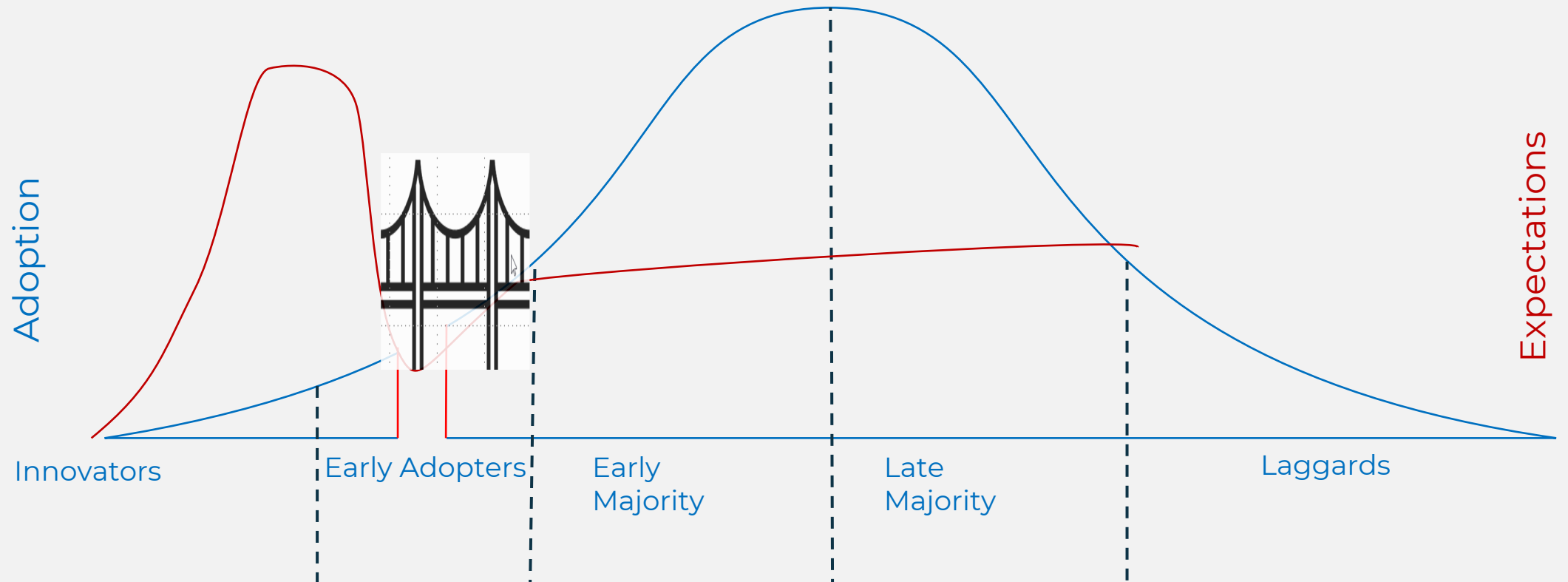
Gartner Hype Curve

Hype Cycle for Life Science Clinical Development, 2022



Gartner

Overlaying: Chasm & Trough of Disillusionment



Pragmatic Approach

Emphasizes:

- Efficiency
- Explainability and validation
- Reusability
- Metadata driven automation
- Complementation & Supplementation with AI/ML

Pragmatic Approach (by the numbers)

Feature 1: Automated Data Classification

Feature 2: Edit checks

Feature 3: Exception Listings

Feature 4: AI/ML Review models

Feature 5: Data Management Workbench

Feature 6: Clinical Data Analytics

Feature 1: Automated Data Classification

Feature 2: Edit checks

Feature 3: Exception Listings

Feature 4: Data validation

Feature 5: Data archiving

Feature 6: Data backup

Acceptance Driver: Inclusion of a human adjudication step provides assurance that the identification is correct.

Feature 1: Automated Data Classification

Feature 2: Edit checks

Feature 3: Exception Listings

Feature 4: Data Quality

Feature 5: Data Governance

Feature 6: Data Security

Acceptance Drivers:

- Provides comfort of a well known and accepted process,
- Reduces time to define full set of edit checks,
- Extends scope of data that can be checked,
- Reduces reliance on manual review of exception listings,
- Automates generation of queries,
- Automates closing of queries.

Feature 1: Automated Data Classification

Feature 2: Edit checks

Feature 3: **Exception Listings**

Feature 4: AI/ML Review models

Feature 5:

Feature 6:

Acceptance Drivers:

- Provides comfort of a well known and accepted process,
- Reduces time to define full set of exception listings.

Feature 1: Automated Data Classification

Feature 2: Edit checks

Feature 3: Exception Listings

Feature 4: **AI/ML Review models**

Feature 5: Data Management Workbench

Feature 6: **Acceptance Drivers:**

- Replaces some of the exception listings,
- Improves upon exception listings by doing a better job of narrowing the set of records to be reviewed and, with feedback over time, automate the generation of questions when appropriate,
- Expands the scope to include conditions that weren't anticipated and hence not covered by an exception listing,
- Incremental expansion of models over time provides a path for users to become comfortable with adopting this new approach.

Use Case Selection

- Look at various documented sets of Review Objectives.
- Exclude objectives that are deterministic.
- Focus on ones that are listed as having the greatest number of hours required for manual review.
- Refine this list based on ones that are likely to have sufficient data to develop models for.
- Verify with representative users that they see value in pursuing these.

AI/ML Review models

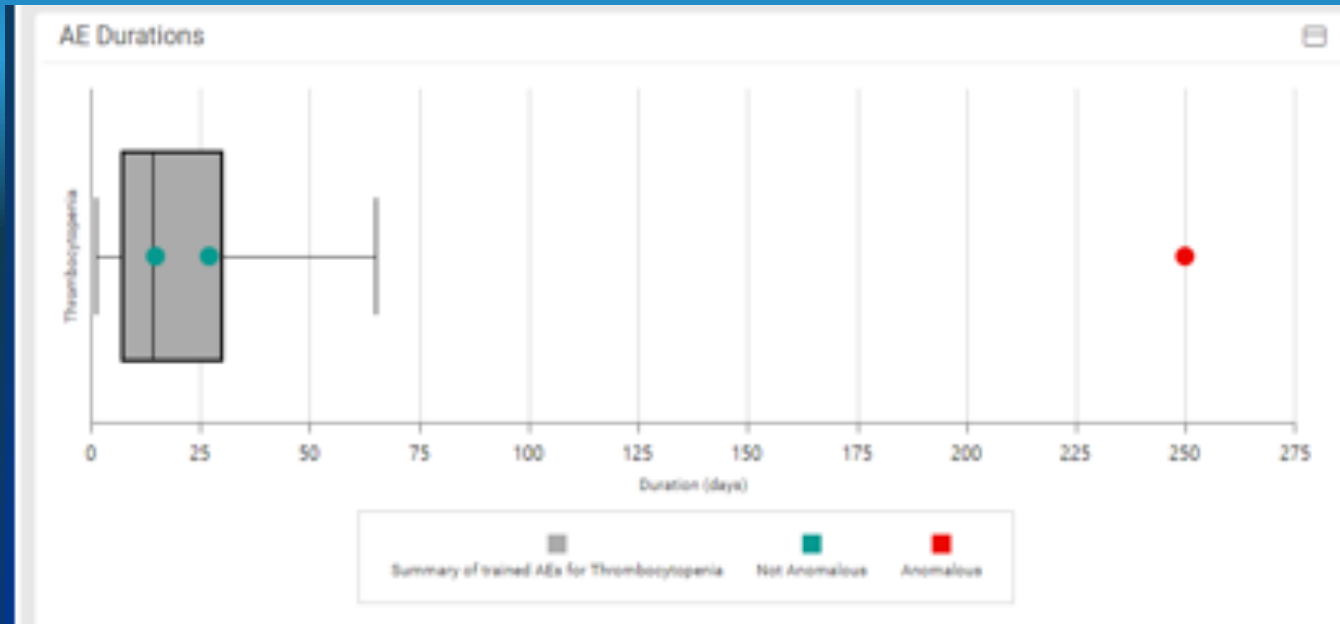
Start with high-level details on model results to highlight effectiveness
filtered reduction

Drill down into details

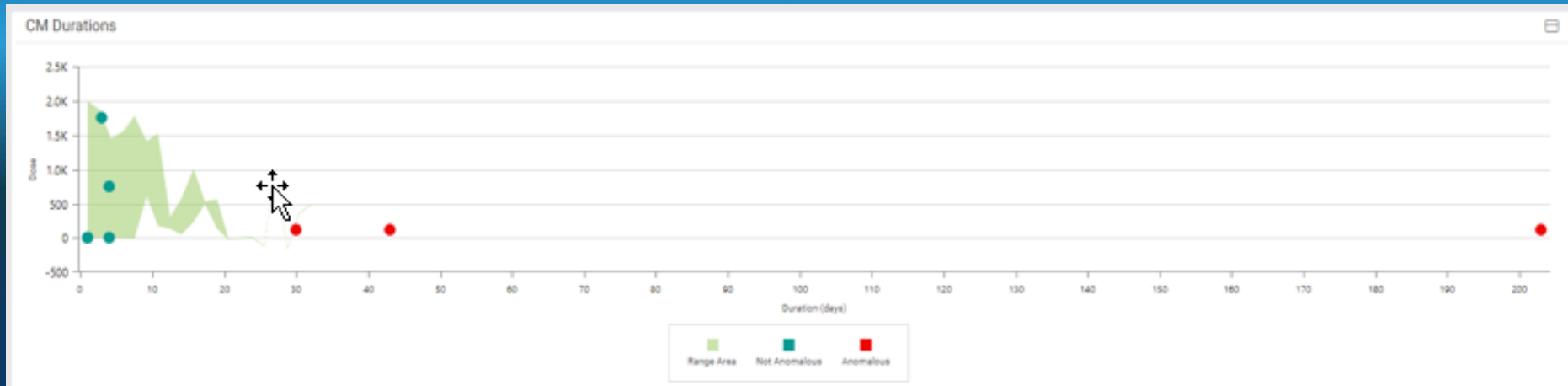
Show complementary details for full perspective, such as graphical patient profiles



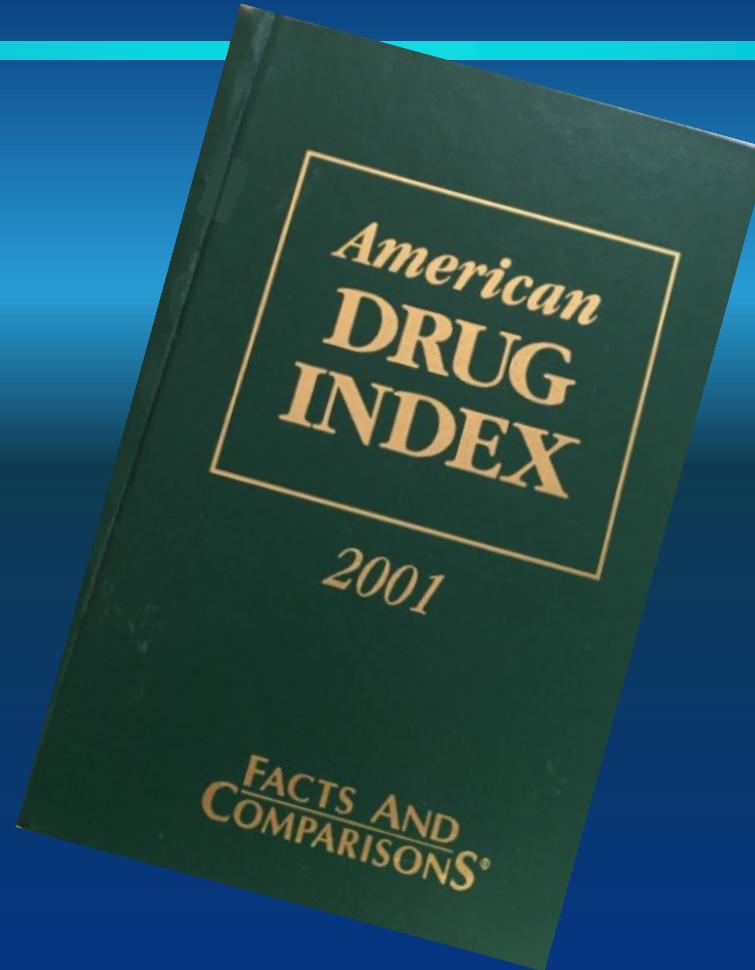
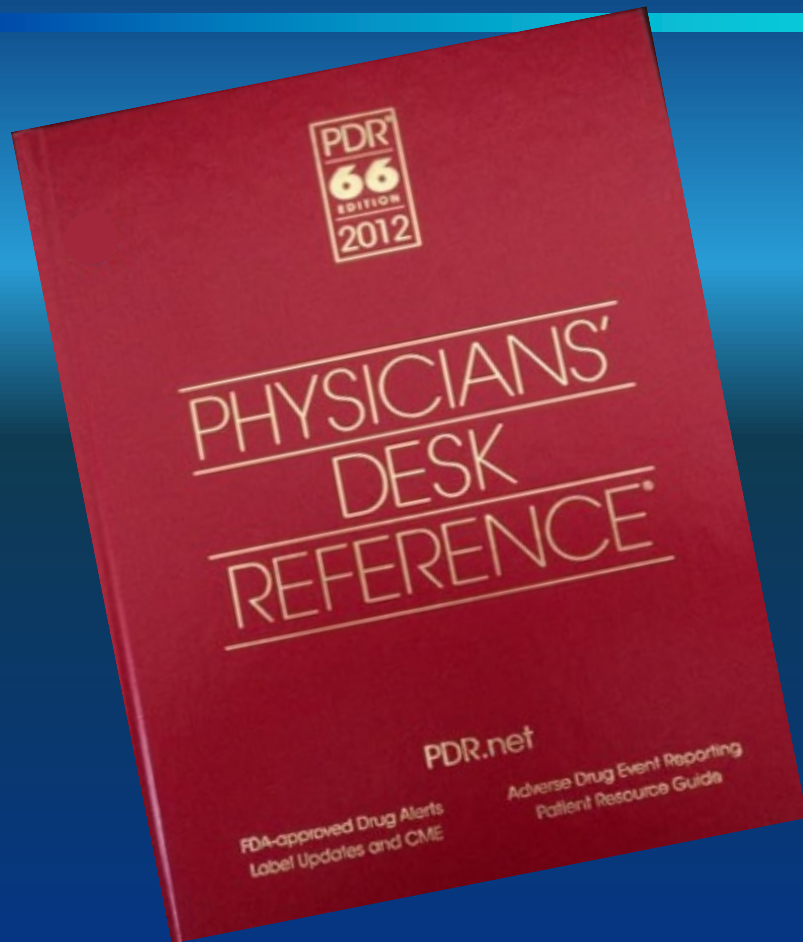
Example Anomalous AE Durations



Example Concomitant Medication Durations



Example Concomitant Medication Consistency



Feature 1: Automated Data Classification

Feature 2: Edit checks

Feature 3: Exception Listings

Feature 4: AI/ML Review models

Feature 5: Data Management Workbench

Feature 6: Clinical Data Analytics

Acceptance Drivers:

- Provides familiar option to conduct any ad-hoc enquiries assisting with comfort for adoption,
- Provides central location for managing data from all sources,
- Provides central location for tracking review progress,
- Supports sending questions to all source data providers (EDC or other)

Feature 1: Automated Data Classification
Feature 2: Edit checks
Feature 3: Exception Listings
Feature 4: AI/ML Review models
Feature 5: Data Management Workbench

Feature 6: **Clinical Data Analytics**

Cross Trial Visualizations

Acceptance Drivers:

- Provides familiar option to conduct any ad-hoc enquiries assisting with comfort for adoption.

Resultant Quotes

- ✓ “It takes a village to develop and deploy these models”
- ✓ “Traditional CDM approaches won’t scale.”
- ✓ “Reduced listing programs.”
- ✓ “Mitigated risk faster!”
- ✓ “Accelerated data cleaning cycle times.”

Validation Approach

- Training data identified for selected use case
- Data Science team evaluates various models
- Independent team develops ground truth data
- Data Science team selects best performing solution
- Data Science team trains preferred model on training data
- Data Science team assesses model performance against several measures

True Positives

False Positives

Recall

Prevalence

Negative Predicted Value (records correctly not flagged)

True Negatives

False Negatives

Precision

Predicted Negative (records not flagged)

Positive Predicted Value (records correctly flagged)

- SME evaluates result by running on independent test data
- Traditional SQA Testing
- Limited rollout for feedback

Concluding Remarks

In order to combat:

- Industry resistance to innovation
- Pharma company resistance to allow data to be used
- The inherent value to society in improving clinical trial processes

We are interested in working in open forum approach to continue developing AI/ML models for mutual benefit.

Contact details

Robert Musterer
VP Product Management
eClinical Solutions
RMusterer@eclinicalsol.com