

Visualization for Success: Driving KPIs and Organizational Process Improvements via Portfolio-level Analytics

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ABSTRACT

Cloud-based data diagnostic platforms enable organizations to build institutional memory and drive process improvements. Platforms that passively aggregate metrics spare teams from having to "wrangle KPIs" and instead visualize the macro-level trends in their data quality, conformance, standards adoption, submission risks, and team activity at a glance. This poster highlights how these data are showcased in P21 Enterprise's built-in Analytics module and suggests actionable steps based on these trends to support inter- and intra-departmental process improvements. It also demonstrates how the various portfolio-level reports, filters, and views now available within the application support organizations in their coordination efforts and the development of best practices. Impactful use cases include: benchmarking data quality across therapeutic areas and over time, eliminating Reject Issues, monitoring the uptake of new standards, prioritizing Issues for which to create standardized explanations, developing guidance for frequently occurring Validation Rules, visualizing efforts to balance workloads, and encouraging documentation through "gamification."

INTRODUCTION

In standardizing and submitting clinical trial data, one can assess resource investment, productivity, and success via milestone monitoring or labor time tracking, without necessarily relying on byproducts of data conformance and quality validation. However, such byproducts can inform and color the overall assessments, leading to multi-departmental process improvements that improve the quality and timeliness of submission data while reducing overall costs and risks.

USING CROSS-STUDY ANALYTICS AND METRICS: CASES FROM THE FIELD

Many organizations throughout the pharmaceutical industry experience similar trials and tribulations related to data standardization, data validation, and submitting clinical trial data. Several different tools have been developed to aid in the various processes needed to bring new therapies to market, however, it is often the case that the organization within companies implemented to produce efficiencies within a specific area may actually end up siloing employees or departments, leading to those inefficiencies sought to be avoided in the first place. By the time standardized datasets have been produced and are ready for validation, several departments have contributed to the creation of these deliverables and the resulting validation metrics can be a great point at which to analyze data from because of the intersection of all the contributors. Here, we will present problem statements and practical user stories with the goal of inspiring our readers to identify gaps in and refine processes within their own company using Pinnacle 21 Enterprise's portfolio-level validation analytics.

PROJECTED SCORES

Problem Statement: We have different standards teams based on Therapeutic Area, and we'd like to allocate more resources to help boost our Scores. Fortunately, we find ourselves in the advantageous position of having the bandwidth to do this, but we need to identify which areas could use the most improvement.

User Story: The Projected Scores report allows us to filter by TA across data packages validated within the past year to see which TA's Projected Scores fall below the median baseline. With this information, we're able to determine where to concentrate our efforts and create more robust standards or provide further TA-specific training. Our effectiveness will be verified through the same report during the following year, where the updated analysis should show increased baseline Projected Scores across those chosen TA's.

Projected Scores

See your portfolio's overall data quality and submission readiness.
Allocate more resources to areas whose fitness you want to boost.

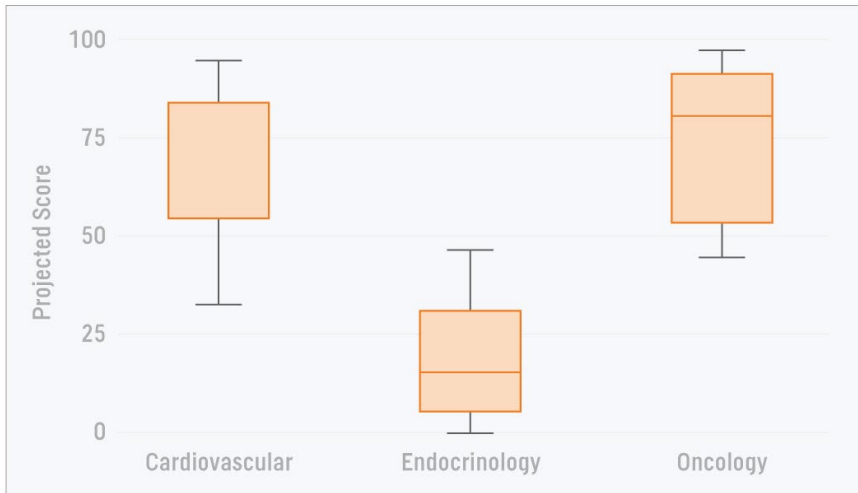


Figure 1. Projected Scores Box and Whisker Plot by Therapeutic Area

VALIDATION FREQUENCY

Problem Statement: We oversee several different studies, each with its own unique timelines for submission and want to be sure validations are occurring as needed to meet specific milestones.

User Story: By comparing our Master Study List to the Validation Frequency report, we're able to ensure that as critical time points in each study approach, the number of validations increases. The ability to quantify this in real-time also gives us the power to recognize when validations are not occurring as expected and proactively work to resolve any discrepancies.

Validation Frequency

Be sure validations occur as needed to meet specific milestones.

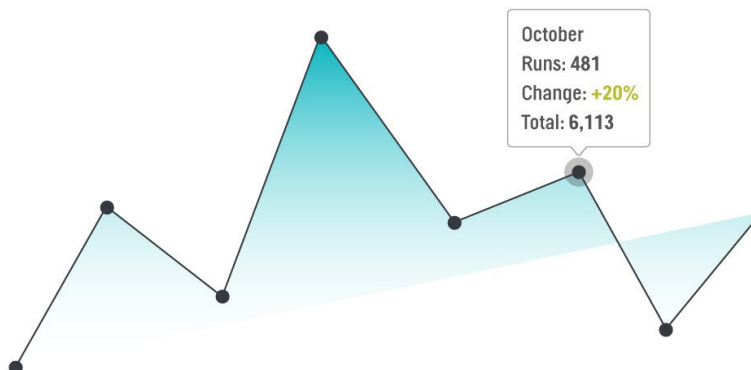


Figure 2. Validation Frequency Line Graph

TOP UNRESOLVED ISSUES

Problem Statement: We would like to develop our own Fix Tips and Explanations to guide our users and standardize more of the justifications for issues being sent to the agencies via the Data Reviewer's Guides. However, it is too cumbersome to go through every single Rule ID or combine reports to find our portfolio's most prevalent issues.

User Story: Using the Top Unresolved Issues report, we're able to view the top 50 issues by standard, date last validated, and data package status that are most frequently occurring across all studies. Sorting by Type further provides a starting point at which we can perform any root cause analyses to aid in the adjustment of our standards, forging of Fix Tips, or establishment of our Explanations.

Top Unresolved Issues

Standardize more of the justifications for Issues being sent to agencies.













Rule ID	Message	Type	Fix Tips	Explanations	Data Packages Affected
		Warning	2/5	0/5	68.7%
		Error	2/5	4/5	54.2%
		Notice	0/5	0/5	52.8%
		Warning	4/5	3/5	49.6%
		Warning	2/5	4/5	47.3%
		Error	1/5	2/5	44.1%

Table 1. Top Unresolved Issues

REJECT ISSUES

Problem Statement: Studies cannot be successfully submitted with any issues that have an Impact or Severity of Reject; therefore, it is essential to monitor these types of issues across all trials to ensure they are being resolved as early in the validation life cycle as possible.

User Story: With the Reject Issues report, we're able to easily view the quantity of Reject issues present within a Project, the breakdown of this total by study and data package, and the sum of Reject issues that are Unaddressed (present with a Status of Open, To Close, or Closed). We can delve deeper and view a table containing each Reject issue found in the Project and use this to quickly triage these issues so that they're routed to the appropriate team member for resolution.

Reject Issues

Know which Studies have Issues with an Impact or Severity of Reject. Studies with even one Reject issue cannot be successfully submitted.

Project	Source	Unaddressed	Studies Affected	Data Packages Affected	Actions
		223/226	5	12	View
		61/62	3	2	View
		45/45	6	12	View
		30/35	2	2	View
		21/28	1	3	View
		5/10	1	2	View

Table 2. Reject Issues

STANDARDS ADOPTION

Problem Statement: Our standards team has spent countless hours developing and maintaining standards for our organization, and we would like to know how many studies have employed each version of our standards.

User Story: On the Standards Adoption report, we're able to see the number of data packages configured with each version of the selected standard across Projects and Studies. Comparing this report against a Master Study list, we can also easily determine if any data packages have been configured with an incongruent version of a standard and request a team member take corrective action.

Standards Adoption

Know how many studies have employed each version of your standards.

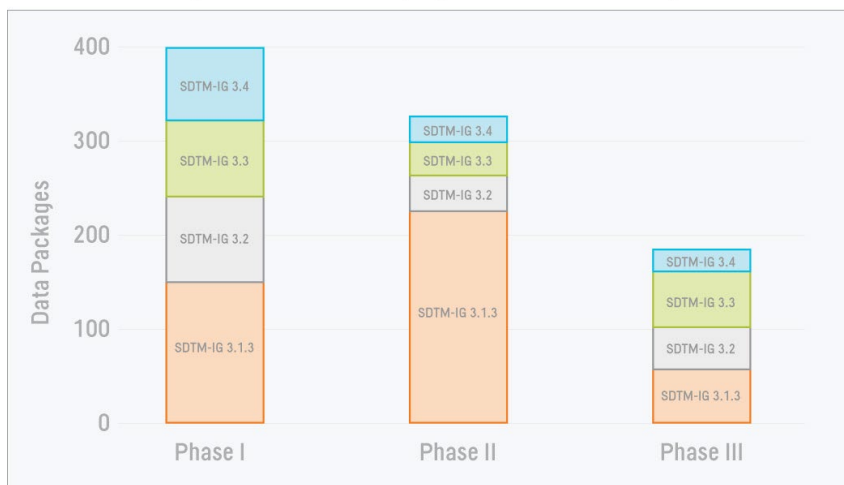


Figure 3. Standards Adoption Stacked Graph

LEADERBOARDS

Problem Statement: We've been asked to provide a list of names of internal employees, as well as those within our FSP CRO's, who should be presented with the opportunity to bear the special title of Pinnacle 21 Enterprise Guru and provide input on training materials, mentoring, and user feedback for our organization.

User Story: By examining the Leaderboards report, it's easy to see whom the most active users in our environment are based on the number of validations run, issues managed, and define/spec changes made. These categories will also allow us to indicate the specialty of each Guru and the visibility of each user's email address allows us to determine each leader's affiliation.

CONCLUSION: PINNACLE 21 ENTERPRISE ANALYTICS OF THE FUTURE

As P21 Enterprise evolves, we plan to incorporate our industry's needs and technology in the expansion of our Analytics offerings. Imagine the ability to automatically plug CTMS data directly into P21E to view study-specific milestones within relevant reports. Or how rewarding and reassuring it would feel to see your data package's Data Fitness Score compared with other, similar de-identified Data Fitness Scores from across the industry, matched at similar study milestones, including at the time of submission to different regulatory agencies. This is all within our reach, as the data exist, they simply need to be transformed into metrics and harnessed through the power of analytics, ingenuity, and a little imagination.

ACKNOWLEDGMENTS

We would like to thank Ed Rempfer for designing the stellar graphics included within this paper and on our poster.

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