



and CAPA Records.

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Abstract

This study uses sophisticated analytics and process optimization techniques to try to mitigate the quality management problems that Ethicon, a Johnson & Johnson subsidiary located in Guaynabo, Puerto Rico, is facing. The study accomplishes its goals in full by using the ThoughtSpot AI-powered analytics platform and the methodical use of the DMAIC (Define, Measure, Analyze, Improve, Control) paradigm. ThoughtSpot integration makes it possible to analyze data in real time, giving stakeholders the ability to quickly assess non-conformances and remedial measures across many international locations. Time studies carefully document the dynamics of the process and show significant efficiency advantages from the ThoughtSpot installation, which results in a 468-hour yearly reduction in analyst burden. ThoughtSpot's effective implementation speeds up problem detection, tracking, and resolution, which leads to increased operational effectiveness and strict adherence to quality standards. This study emphasizes how AI-driven analytics can revolutionize the medical device sector by accelerating decision-making and increasing operational efficacy.

Key Terms — DMADV method, forecast, quota tracker, and sales quota.

Problem Statement

As of right now, the Quality System Department is tracking and evaluating metrics regarding Non-Conformances, Corrective Actions, and Preventive Actions (CAPA) pertaining to Suppliers at locations across the globe. In order to attain the desired percentage in terms of metrics, each Nonconformance and CAPA record must be closed within a specific time frame. They are analyzing and tracking all this data that they continuously use by an Excel sheet, which is not always precise and requires a lot of time to obtain the information. ThoughtSpot is one of the finest possibilities for streamlining this process, which is why it is so critical. The Artificial Intelligence (AI)-powered analytics business.

Objectives:

- Integrate ThoughtSpot AI-powered analytics platform to replace manual Excel-based data tracking, ensuring real-time insights and accuracy.
- Reduce 468 Hours/year
- Enhance operational efficiency and decision-making speed within the Quality System Department.

Figure 1: Current Excel Sheet

Methodology

We use the DMAIC methodology to accomplish the research goals. The DMAIC (Define, Measure, Analyze, Improve, Control) framework, a systematic approach to process improvement that is extensively used in a variety of sectors, serves as the foundation for the technique. The DMAIC framework offers a methodical approach to problem-solving and ongoing enhancement, which is in line with the goals of this study, which are to improve Ethicon, J&J's quality management system.

In Table 1, we can learn a brief definition of the five phases of the DMAIC methodology. Figure 1 shows the project timeline propose for this project.

Table 1: DMAIC Methodology		Timeline (2024)
DEFINE	Define the process and establish goal	March 03–March 09
MEASURE	Collect data: Time study of process	March 13 – March 17
ANALYZE	Analyze the data to find the inefficiencies in process.	April 1 – April 14
IMPROVE	Implement ThoughtSpot, AI, as data analnastic.	April 15 – April 30
CONTROL	Establish Monitoring and Control Mechanisms	April 30 – May 8

DEFINE PHASE

Table 2 Project Charter	
Project Description	Design and implementation of ThoughtSpot AI program to replace current format using the DMAIC methodology for this project.
Project timeline	March 2024 – May 2024
Project Goal	<ul style="list-style-type: none"> Integrate ThoughtSpot AI-powered analytics platform to replace manual Excel-based data tracking, ensuring real-time insights and accuracy. Reduce 468 Hours/year Enhance operational efficiency and decision-making speed within the Quality System Department.
Benefits	<ul style="list-style-type: none"> Real Time insights Increased Accuracy Reduction on time consumption Quicker Issue Resolution
Stakeholders	Source Quality Management, Ethicon Inc. , Employee performing task
Project Member	Jose Ortiz Cabrera

MEASURE PHASE

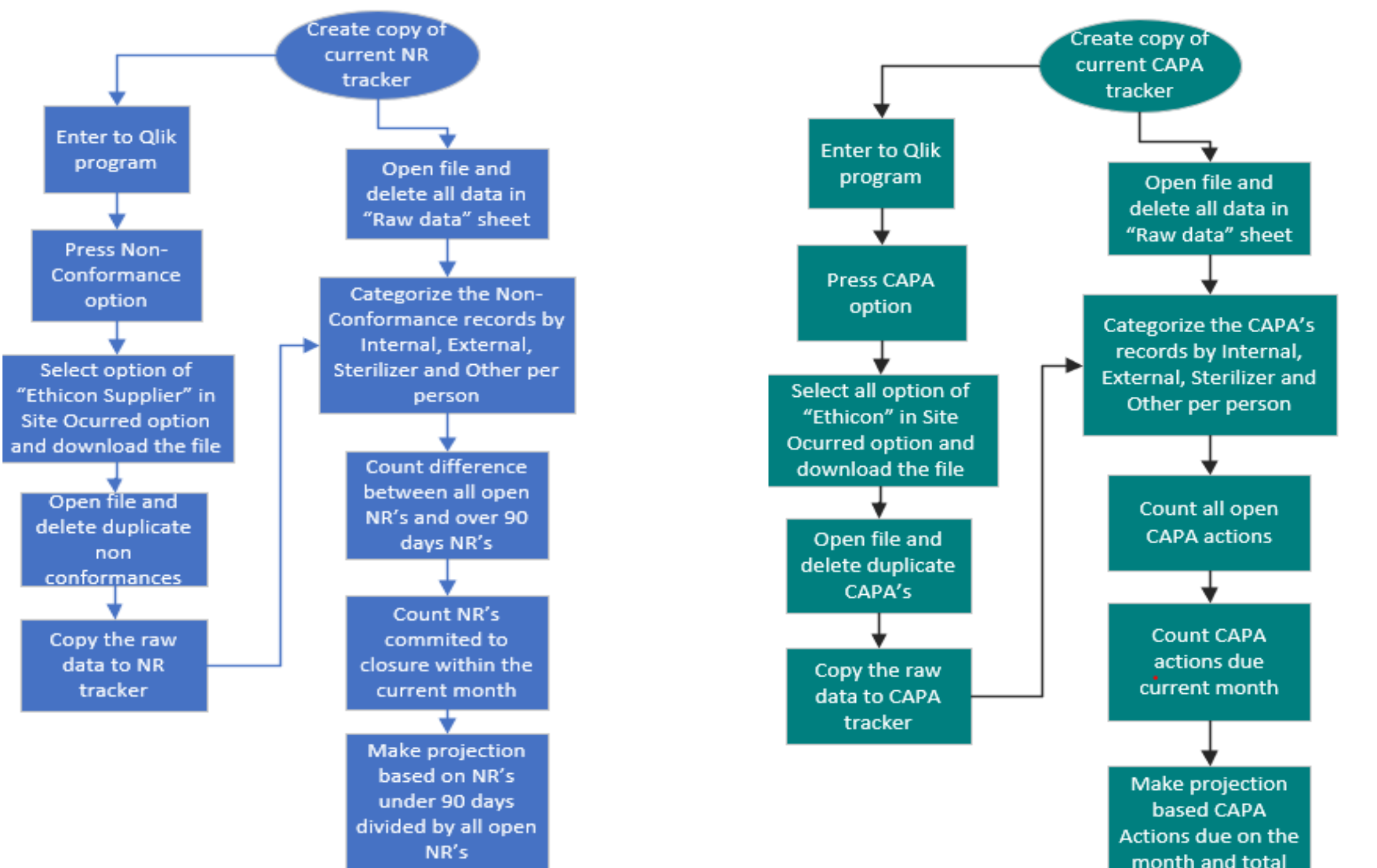


Figure 2: Flow Chart of process to gather metrics of NC

Step	Non-Conformance Process	Time in seconds
Step 1	Create Copy of Current NR Tracker	0.3
Step 2	Enter to Qlik program	43
Step 3	Press Non-Conformance Option	0.7
Step 4	Select option "Ethicon Supplier" in Site Occurred option and download the file	0.7
Step 5	Open file and delete duplicate non-conformance	5
Step 6	Copy the raw data to NR tracker	0.9
Step 7	Open file and delete all data in "Raw data sheet"	27
Step 8	Categorize the non-conformance records by Internal, External, Sterilizer and Other, per person	288
Step 9	Count difference between all open NR's and over 90 days NR's	180
Step 10	Make projection based on NR's under 90 days divided by all open NR's	565
Total of seconds		1111
Total of seconds in minutes		19

Figure 4: Time Study - NC

Figure 3: Flow Chart of process to gather metrics of CAPA

Step	CAPA Process	Time in seconds
Step 1	Create Copy of Current CAPA Tracker	0.3
Step 2	Enter to Qlik program	43
Step 3	Press CAPA Option	0.7
Step 4	Select all option "Ethicon Supplier" in Site Occurred option and download the file	10
Step 5	Open file and delete duplicate CAPA	5
Step 6	Copy the raw data to CAPA tracker	0.9
Step 7	Open file and delete all data in "Raw data" sheet	27
Step 8	Categorize the CAPA records by Internal, External, Sterilizer and Other, per person	288
Step 9	Count all open CAPA actions	19
Step 10	Count CAPA actions due current month	4
Step 11	Make projection based on CAPA actions due on the current month and total CAPA actions	565
Total of seconds		963
Total of seconds in minutes		16

Figure 5: Time Study - CAPA

ANALYZE PHASE

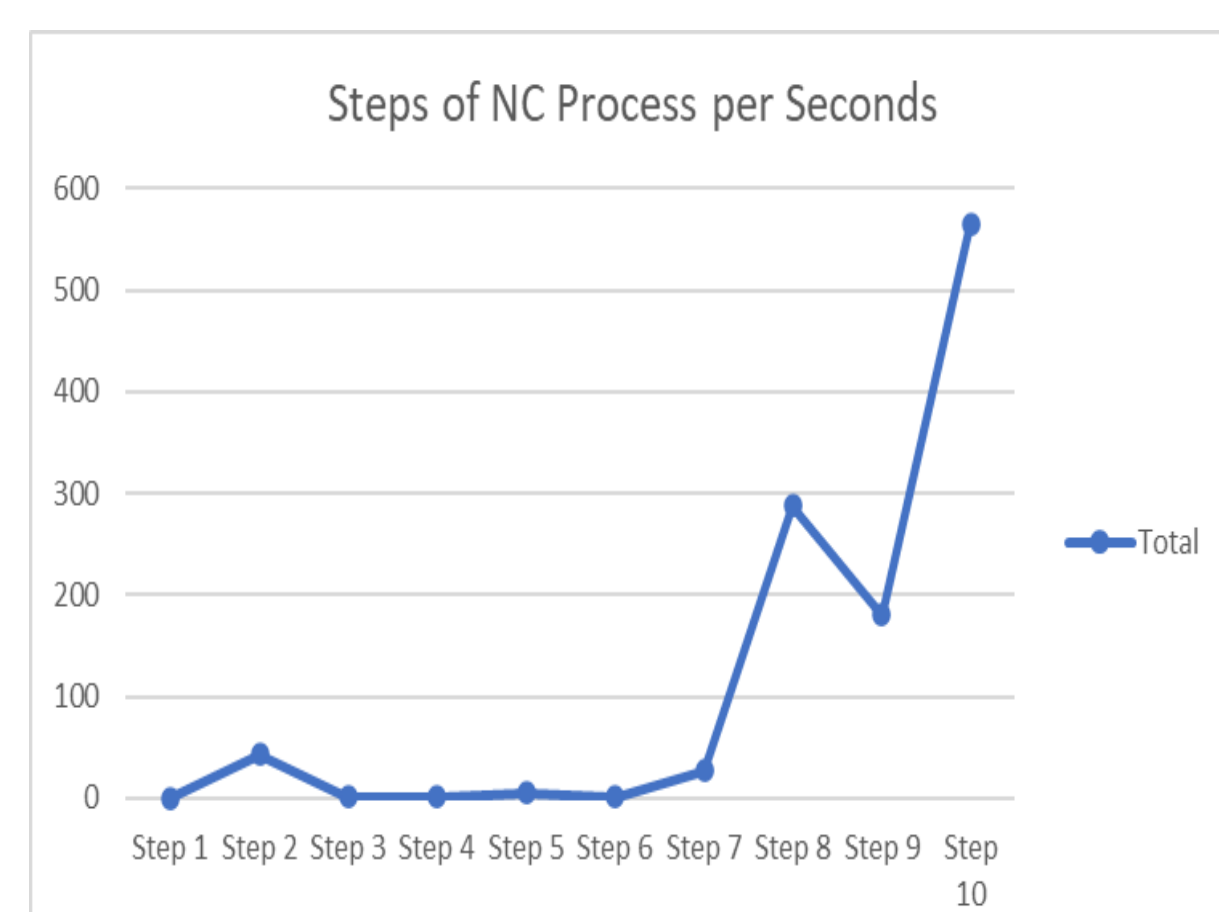


Figure 6: Graphic of Steps of NC Process per seconds

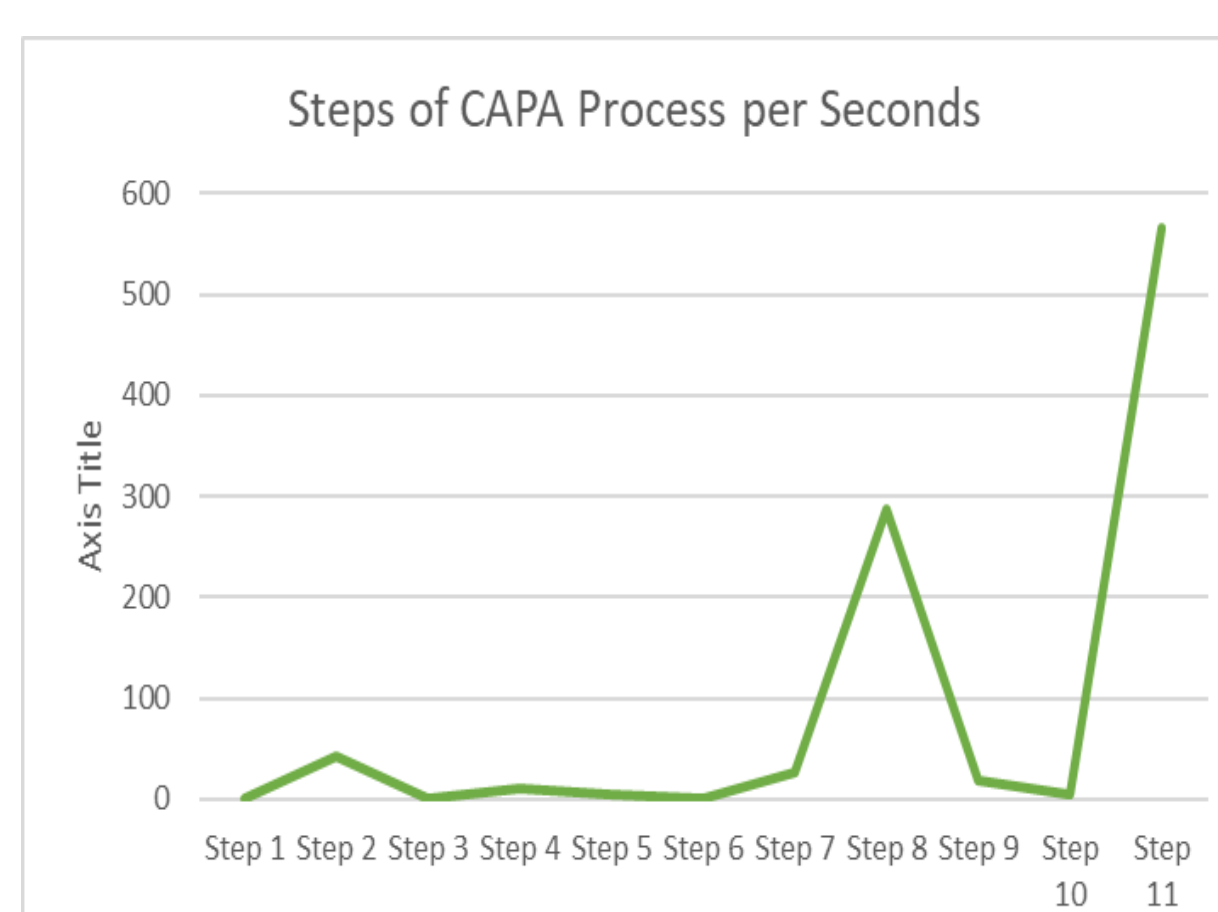


Figure 7: Graphic of Steps of CAPA Process per seconds

Results and Discussion

IMPROVE PHASE

The ThoughtSpot program was already integrated into the business, and two QUALIFI data sets—ETQI NC/CAPA Info and APR/PQR Data—are accessible for ThoughtSpot MVP. The upcoming images will outline ThoughtSpot's architecture.

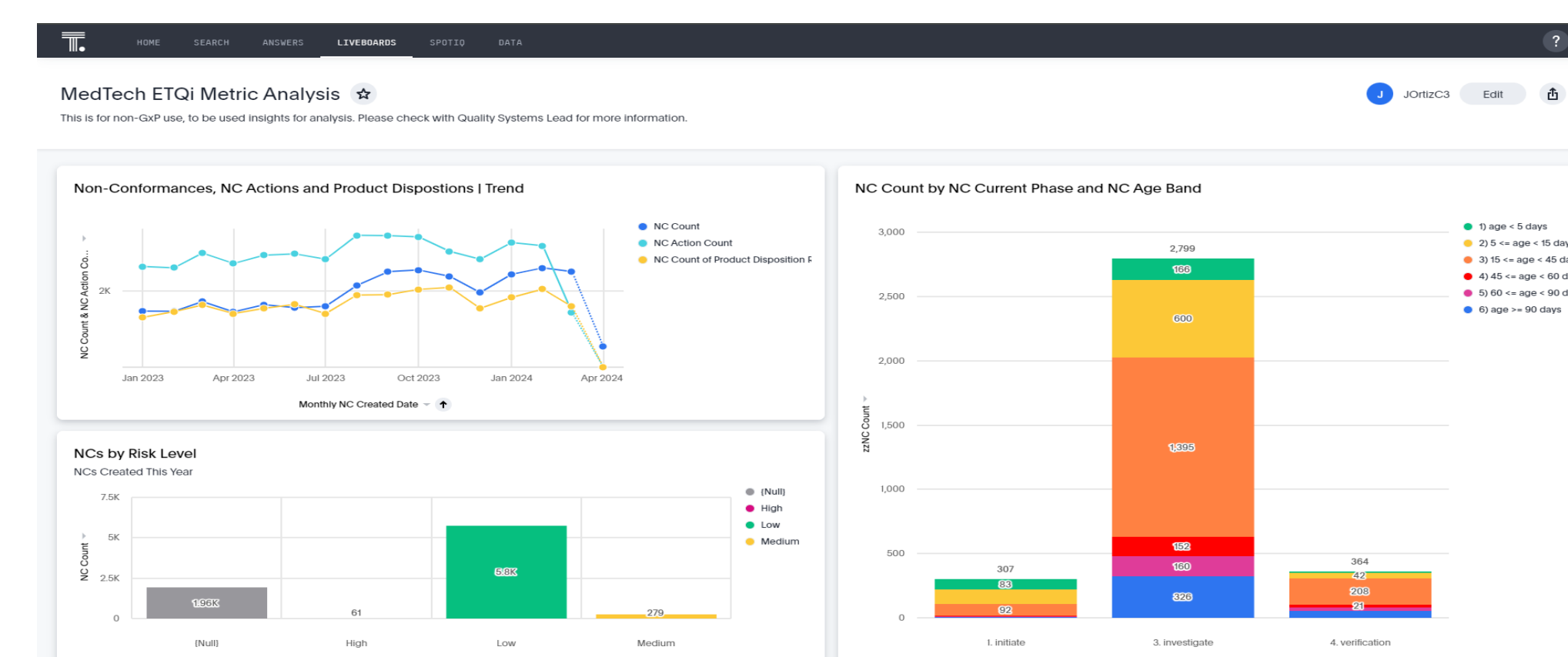


Figure 8: NC Section: Trend, Age Band & Risk Level

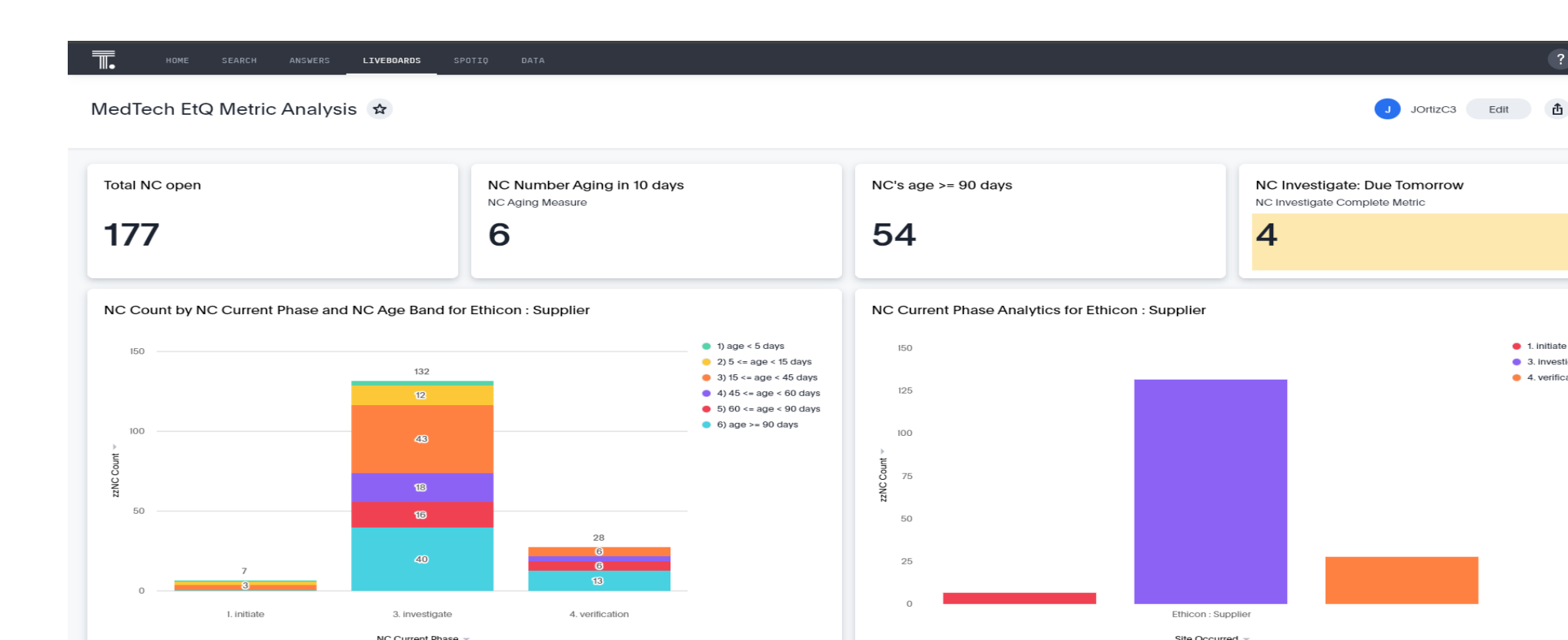


Figure 9: NC Section: Total NC, NC Aging in 10 Days, NC Due tomorrow and NC per phase

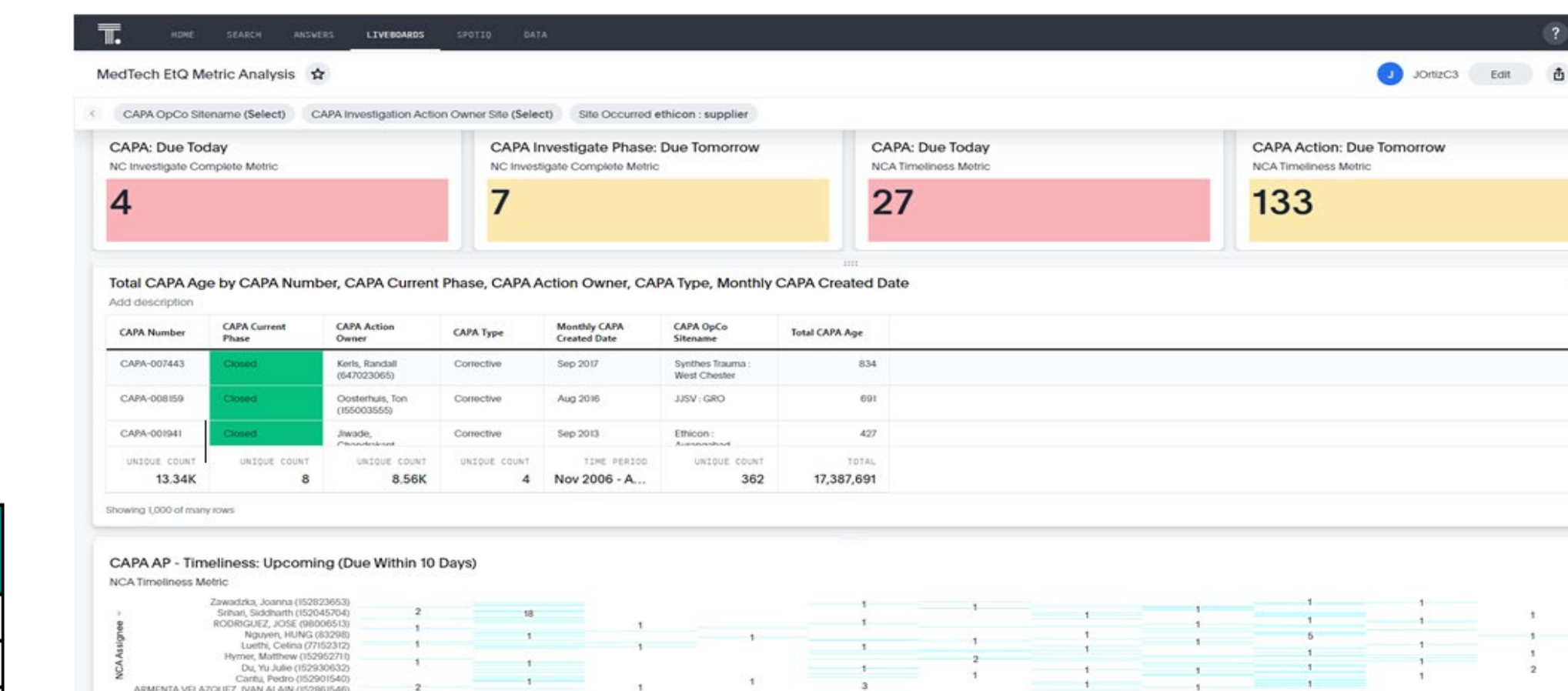


Figure 10: CAPA Count: Due Tomorrow, CAPA AP timeliness, Total CAPA

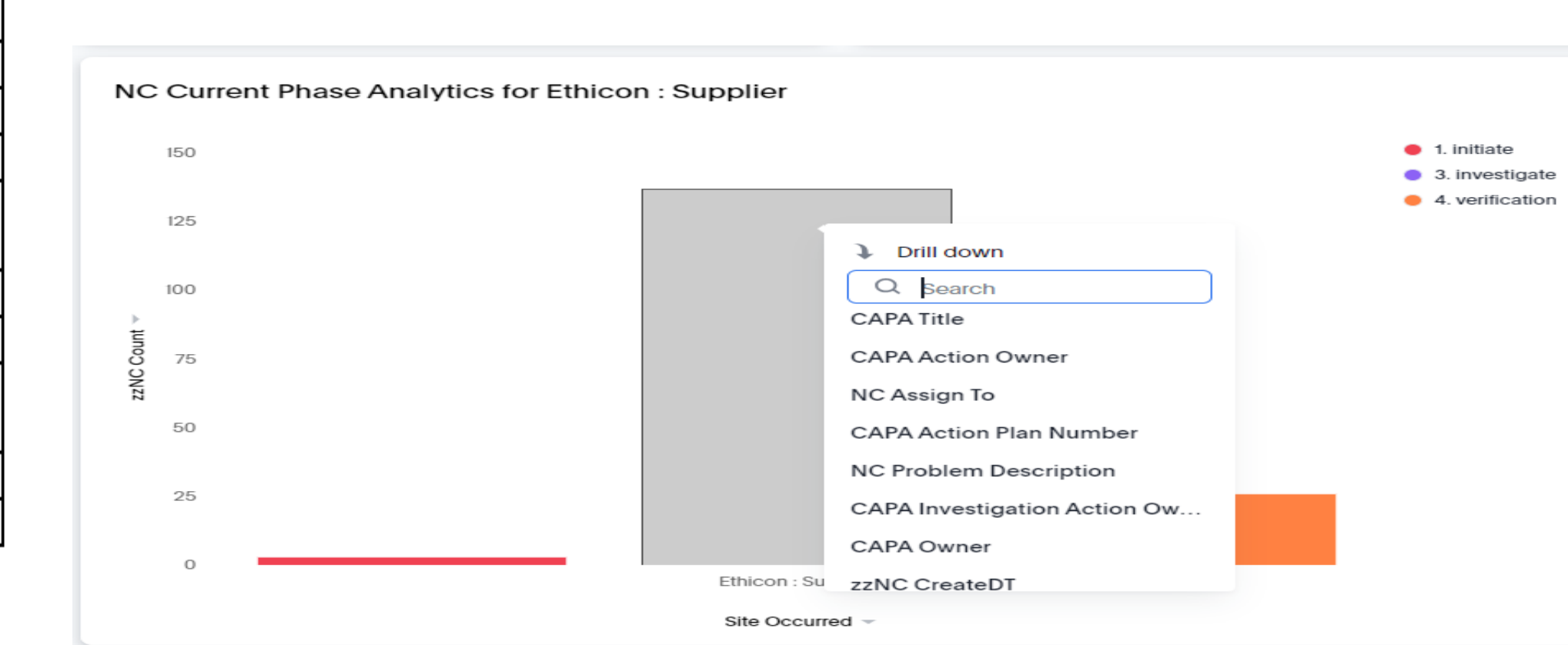


Figure 11: Drill Down Options

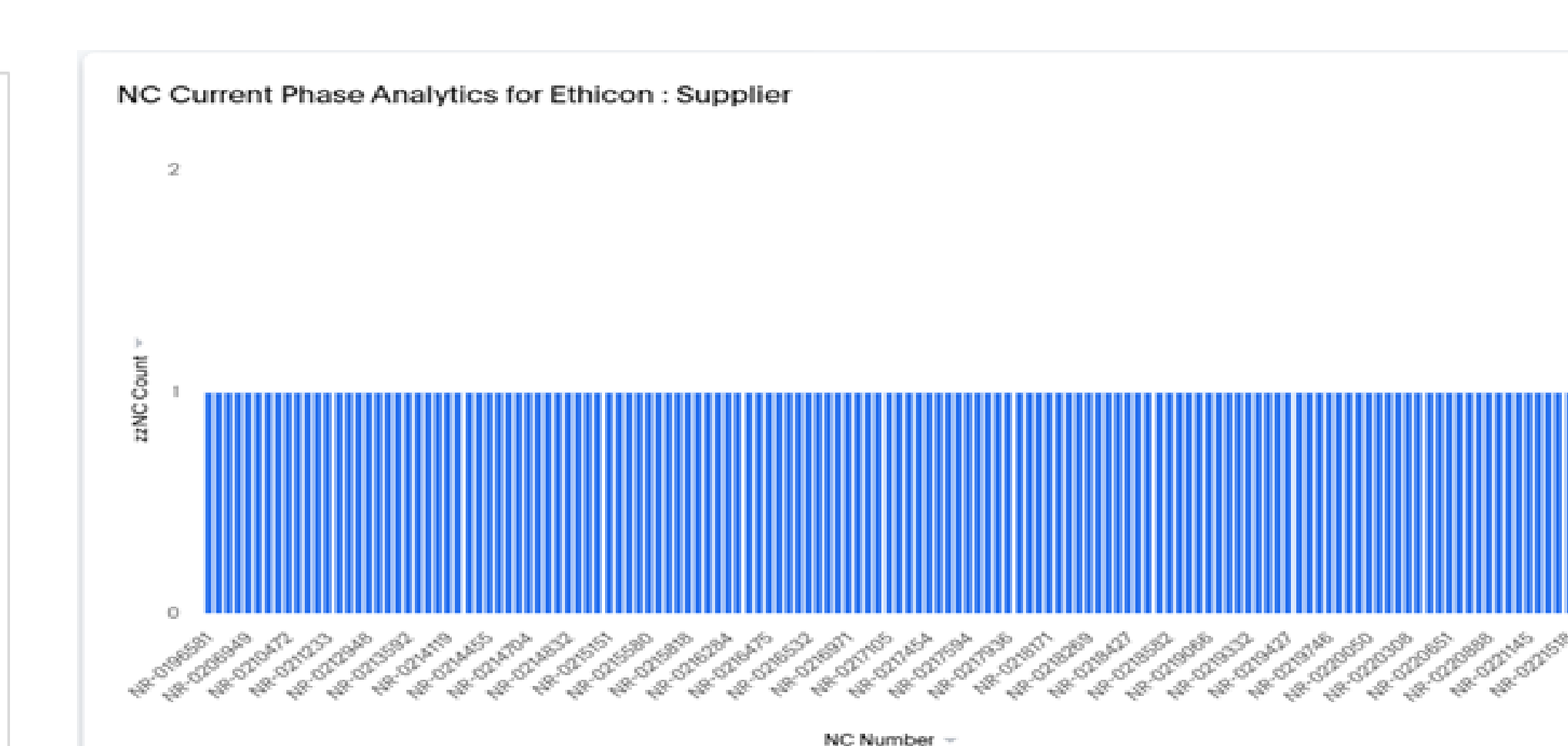


Figure 11: Drill down option used.

CONTROL PHASE

- Periodic assessments will be carried out to appraise the efficacy of the recently implemented protocols and pinpoint opportunities for enhancement.
- Ethicon will periodically evaluate industry rules and standards that are pertinent to the medical device sector. To preserve the integrity of the system, any deviations or problems found during these assessments shall be immediately resolved.
- We will actively seek user and stakeholder feedback to find areas where the ThoughtSpot platform may be improved or optimized. To find areas that still require improvement, audits and assessments will be carried out on a regular basis.

Conclusions

The integration of the ThoughtSpot Platform with Ethicon's DMAIC methodology for Corrective and Preventive Actions (CAPA) and Non-Conformance Reports (NRs) metric analysis brings significant benefits to the Quality Systems team.

Real-time insights provided by ThoughtSpot eliminate the reliance on outdated Excel sheets, ensuring decision-makers have access to the most recent data. Furthermore, ThoughtSpot's AI-powered analytics enhance accuracy in tracking non-conformances and corrective actions, thus improving the reliability of metrics and informed decision-making. By streamlining data tracking and analysis, ThoughtSpot increases operational efficiency, allowing staff to focus on strategic projects and facilitating quicker issue resolution through proactive identification and tracking of non-conformances and CAPA records.

Through real-time data analysis and automation, ThoughtSpot accelerates the detection, tracking, and resolution of issues, ensuring smoother integration with existing systems and processes. Mechanisms for monitoring and controlling performance metrics are established to ensure continued adherence to quality requirements, facilitating continuous improvement initiatives and enabling Ethicon to identify improvement opportunities more efficiently. By leveraging AI-powered analytics, Ethicon maintains a competitive edge in the dynamic medical device market, enhancing operational performance and responsiveness to market demands.

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References

- M. Dziak, "Quality Management," Salem Press Encyclopedia, <https://research.ebsco.com/c/sygyvy/viewer/html/nzcyi2giz> (accessed Jan. 30, 2024).
- Hindawi, "Artificial intelligence edge computing for innovative applications," Hindawi, <https://www.hindawi.com/journals/mpe/si/392784/>
- A. Ettalibi, A. Elouadi, and A. Mansour, "AI and Computer Vision-based Real-time Quality Control: A Review of Industrial Applications," Procedia Computer Science, vol. 231, pp. 212–220, Jan. 2024, doi:10.1016/j.procs.2023.12.195.
- "12 Challenges of data analytics and how to fix them." <https://www.clearrisk.com/risk-management-blog/challenges-of-data-analytics-0>
- I. Nasios, "Analyze mass spectrometry data with artificial intelligence to assist the understanding of past habitability of Mars and provide insights for future missions," Icarus, vol. 408, p. 115824, Jan. 2024, doi:10.1016/j.icarus.2023.115824.
- "ThoughtSpot | the AI-Powered analytics platform," ThoughtSpot, Jan. 30, 2024. <https://www.thoughtspot.com/>
- Office of the Commissioner, "U.S. Food and Drug Administration," U.S. Food And Drug Administration. <https://www.fda.gov/>