

***Optimizing Quality System Operations:
Exploring the Role of Data Automation in Business Efficiency and
Sustainability***

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In

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DECLARATION

I hereby declare that the work being presented in the dissertation report entitled

"Optimizing Quality System Operations:

Exploring the Role of Data Automation in Business Efficiency and Sustainability"

submitted by me for the award of the degree of Master of Technology in the Department of Biotechnology, Thapar Institute of Engineering & Technology, Patiala is true and original record of my own independent and original research work carried out under the guidance of Mr. Shrinath Chede and Ms. Anindita Roy at Stryker- Stryker Global Technology Center, Gurgaon. Further, I declare that no part of this dissertation has been submitted to any other Institute /University for the award of any degree in India or abroad.

Date: 17 July,2023



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CERTIFICATE

This is to certify that the dissertation work entitled, “*Optimizing Quality System Operations: Exploring the Role of Data Automation in Business Efficiency and Sustainability*” submitted by **Anjali Kanwar (602104001)** in partial fulfillment for the award of the degree of Masters of Technology in Biotechnology from Thapar Institute of Engineering and Technology, Patiala is the record of the candidate’s own independent and original research work carried out under our supervision and guidance. The matter embodied in this dissertation has not been submitted in part to any other University/ Institute for the award of any degree or diploma in India or abroad.



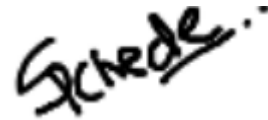
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Abbreviations

Term	Abbreviations
SGTC	Stryker Global Technology Centre
R&D	Research and Development
T&E	Trauma and Extremities
QMS	Quality Management System
ISO	International Organization for Standardization
US	United States
EU MDR	European Union Medical Device Regulation
QS	Quality Systems
CQR	Clinical, Quality and Regulatory
PMQ	Post Market Quality
FDA	US Food and Drug Administration
EMA	European Medicines Agency

KPI	Key performance indicators
DDB	Divisional Database
GIM	Global Item Master
AI	Artificial Intelligence
ML	Machine Learning
VBA	Visual Basic for Applications
BI	Business Intelligence
RPA	Robotic process automation
DPA	Digital process automation
NC	Non-Conformance
CAPA	Corrective and Preventive Action
ELT	Extract-load-transform
ETL	Extract-transform-load
ADF	Azure Data Factory

V&V	Verification and Validation
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Definitions

Med-Tech Company It is a corporation that develops, manufactures, and distributes medical devices, equipment, and technologies. These organizations play an important role in the healthcare business by developing innovative solutions that improve patient care, diagnostics, treatment, and overall healthcare results.

Quality System In the context of a medical device company, a quality system is a structured framework that encompasses all activities related to quality assurance, quality control, and quality management throughout the entire product lifecycle. It is designed to ensure that medical devices are safe, effective, and meet the specified quality standards.

ISO 13485 The International Standard 13485 is an internationally recognized standard for medical device quality management systems (QMS). It specifies the standards for a complete quality management system that ensures the consistent design, development, manufacturing, and delivery of medical devices that fulfill regulatory requirements and customer expectations.

Food and Drug Administration: The Food and Drug Administration, usually known as (FDA or USFDA), is a federal agency of the United States Department of Health and Human Services, one of the federal executive departments of the United States. It is in charge of safeguarding and promoting public health by controlling and supervising food safety, tobacco products, dietary supplements, drugs, vaccinations, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation generating devices, and so on

Data Analytics is a field of data science that deals with the exploration of already present resources and the best utilization of them. In data analytics, the focus is mainly on analyzing the past historical data to understand datasets and getting insights from it so that, an actionable task can be done.

NC/CAPA Nonconformity/Corrective and Preventive Action is abbreviated as NC/CAPA. It is a systematic procedure used in quality management systems to identify, address, and prevent deviations from set quality standards.

Nonconformity is defined as any situation in which a product, process, or technique fails to fulfill the requirements or norms. Corrective actions are steps made to address the core cause of a nonconformity and keep it from happening again. The goal is to resolve the existing problem and return the product, method, or technique to compliance with the relevant standards. Preventive actions, on the other hand, are proactive efforts taken to identify and eliminate potential problems.

Data Lake A Data Lake is a centralized and scalable repository that enables businesses to store and analyze massive amounts of organized, semi-structured, and unstructured data in its raw form. It is intended to handle massive amounts of data from diverse sources without requiring considerable data modeling or schema creation up front. The aim of a Data Lake is to store data in its natural form, keeping its native structure and format. This means that data can be consumed into the Data Lake without first being transformed, allowing for future data analysis and exploration. We can transform the data as per the requirement and then store it in the data lake. That's an advantage because data lake gives us feasibility to store data in any format we change too. The Data Lake serves as a central repository for storing, cataloging, and processing data from many sources.

Data Warehouse A data warehouse is a centralized and structured data store used to support reporting, analysis, and business intelligence activities. It is a separate database system designed exclusively for data analysis and decision-making.

Azure Cloud Microsoft Azure, often known as Azure Cloud, is a comprehensive cloud computing platform supplied by Microsoft. It provides a comprehensive range of cloud services that allow businesses to design, deploy, and manage apps and services using Microsoft-managed data centers.

RPA (Robotic Process Automation) performs numerous automation roles. It automates data entry and manipulation operations, decreasing errors and eliminating manual labor. RPA bots connect to applications and systems, allowing for data interchange and synchronization. They can create reports by extracting data, executing computations, and arranging it into visually appealing reports. By automating data transfer, cleansing, and transformation, RPA aids in data migration and management. Bots carry out rule-based choices and workflows by adhering to specified rules and logic. They automate email handling, including email reading, processing, and response. RPA bots interact with application interfaces, filling out forms and hitting buttons. RPA technologies enable

you to manage bot actions and receive notifications for exceptions by scheduling and monitoring them. Overall, RPA allows firms to streamline procedures and enhance productivity.

Access Database Access Database is a relational database management system (RDBMS) that allows users to store, organize, and manage data. It is also known as Microsoft Access. It includes tools for making tables, forms, queries, and reports. Users can add and amend data using simple forms, run queries to find specific information, and generate reports for data analysis and presentation. Through set rules and limits, access enables for data validation and integrity. It facilitates the creation of linkages between tables, maintaining data consistency. Data exchange and automation are made easier thanks to integration with other Microsoft Office programs. Access is a popular database management system for small to medium-sized databases, and it is suited for personal, departmental, and simple commercial applications. While it offers user-friendly database management capabilities, larger or more sophisticated databases may necessitate additional resources.

“Automation is not the replacement of humans, but the liberation of humans. If we automate the manual work, we can elevate our minds to focus on creativity, innovation, and problem-solving.”

- Sundar Pichai

Abstract

Data analysis and business intelligence are important in today's enterprises. Stryker's Trauma and Extremities Quality Systems Division faces challenges in managing and analyzing vast volumes of data from diverse fields. Manual labor and time-consuming procedures stymie efficiency. The project intends to automate these procedures through the use of tools and services such as Power BI, Power Automate, and Azure Data Factory. These automation tools boost data management, accessibility, and reporting capabilities. The thesis investigates the use of these technologies to improve project tracking and data management within the Quality System Automation Project, thereby facilitating informed decision-making. Power BI, Power Automate, Power Apps, Azure Data Factory, and Data Lake are among the current automation tools used in the project. These solutions allow for the automation of recurrent tasks and the streamlining of operations, which leads to enhanced efficiency and resource optimization. Other challenge includes selection of right tools and methods for the mitigation of these problematic area from the big pool of resources. This project is an umbrella project involving several small and big projects under it, catering to the needs of whole Quality Systems which aims at benchmarking certain processes across Stryker and ultimately give its contribution in the organizational transformation. Many of such projects involves the use of modern day tools such as Power BI, Power Automate, Power Apps, Azure Data Factory, Data Lake that are extensively used in Workspaces to make many day to day recurring tasks more automated and save the precious resource of all time that is time which can be further used to make more informed and creative decisions. The application of automation tools, such as Power BI and other tools, to improve project tracking and data management within the Quality System Automation Project is examined in this thesis. tracking and project status visualization are made possible via the Project Tracker Dashboard. Other automation techniques are used to simplify operations and increase data accessibility and accuracy. In The Divisional Database project consolidated Data Lake is being created, and direct connections to live data sources are being made. The results demonstrate how these technologies improve data management and enable reporting and data-driven decision-making.

Chapter 1 Introduction

Stryker is a US based multinational corporation that is considered as one of the noteworthy medical technology companies in the world. Founded by an orthopedic Surgeon by profession, Dr. Homer Stryker in 1941, Stryker has garnered a big name in the field of Orthopedic Implants with the extended use in Knee, Hip Surgeries along with the Surgeries related to Trauma accidents. The Stryker also offers varied range of innovative neurovascular products, medical devices, patient handling and emergency medical equipment, surgical equipment, endoscopy devices and biologics.

Stryker classifies its reporting into three distinct business segments for reporting purposes: Orthopedics, Medical and Surgical (MedSurg), and Neurotechnology and Spine.

The Orthopedics segment primarily offers implants for hip and knee joint replacements, as well as products for T&E surgeries.

In the MedSurg segment, Stryker provides a range of surgical equipment and surgical navigation systems (Instruments). They also offer endoscopic and communications systems (Endoscopy), patient handling and emergency medical equipment (Medical), and a variety of medical device products used in different medical specialties.

Stryker's Neurotechnology and Spine segment offers a comprehensive portfolio of neurosurgical and neurovascular devices. Their neurotechnology products are designed for minimally invasive endovascular techniques, traditional brain, and open skull base surgical procedures, as well as orthobiologics and biosurgery products, including synthetic bone grafts and vertebral augmentation products. Furthermore, they develop minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke.

With the mission of making healthcare better alongside their customers, Stryker has been running its operations in 75+ countries around the globe and having an ownership of more than 12,000 patents globally.

Quality Management holds an utmost importance in any Medical Device Company and Stryker is no exception in that. According to Stryker's Quality Policy, Quality is first in everything they do.

1.1 Introduction to Quality System

The Quality System at a medical device company is critical for assuring compliance, maintaining product quality and safety, managing risks, driving continuous improvement, and promoting overall customer satisfaction. It is essential to the business' operations and efforts to comply with regulations. These quality operations are managed by Stryker's Quality systems departments.

Throughout the lifecycle of a medical device, quality systems are an organized framework of processes, procedures, and resources that guarantee consistent adherence to quality standards, regulatory requirements, and customer expectations. It includes every facet of quality management within an organization to guarantee the delivery of high-quality, safe products.

1.1.1 Functions of Quality System

A medical device company's quality system performs numerous essential tasks. Several essential duties of a quality system in a medical device company are:

Compliance with Regulatory Requirements: A quality system's principal duty is to assure compliance with regulatory requirements and standards established by regulatory agencies such as the United States Food and Drug Administration (FDA) or the European Medicines Agency (EMA). Throughout the product lifetime, the quality system assists the organization in adhering to applicable requirements and guidelines.

Product Safety and Quality: The quality system is critical in ensuring that medical devices satisfy the highest quality and safety standards. It defines processes and procedures for monitoring and controlling all phases of device manufacture, including as design, development, manufacturing, testing, and distribution. The organization can constantly supply safe and effective medical equipment to the market by using stringent quality control techniques.

Risk Management: A quality system facilitates effective risk management practices within the company. It helps identify potential risks associated with the design, development, and manufacturing processes of medical devices. By implementing risk management strategies and

conducting risk assessments, the company can mitigate and manage risks to ensure patient safety and product quality.

Documentation and Record Keeping: The quality system establishes comprehensive documentation and record-keeping practices. This includes maintaining records of design specifications, manufacturing processes, test results, and post-market surveillance data. Proper documentation ensures traceability, accountability, and enables effective review and auditing processes.

Quality Management: A quality system also encompasses supplier management processes. It ensures that suppliers of components, materials, and services meet the company's quality standards. This includes assessing and selecting suppliers, establishing quality agreements, conducting audits, and monitoring supplier performance to maintain a reliable supply chain.

Post-Market Surveillance: The quality system includes procedures for post-market surveillance and vigilance. It facilitates the monitoring and reporting of adverse events, complaints, and other post-market feedback. This information helps identify potential issues, assess product performance, and implement necessary actions to maintain product safety and efficacy.

Continuous Improvement: The quality system promotes a culture of continuous improvement within the organization. It includes mechanisms for monitoring, measuring, and analyzing quality data, customer feedback, and non-conformities. Through these processes, the company can identify areas for improvement, implement corrective and preventive actions, and drive ongoing enhancements in product quality and operational efficiency.

1.2 Data Analytics

The use of data analytics in a quality system empowers medical device companies to proactively monitor, control, and improve product quality. It enables data-driven decision-making, facilitates root cause analysis, supports predictive capabilities, optimizes processes, enhances supplier management, and aids in regulatory compliance. Process Improvement is crucial in efficiently saving the essential resources as well as the capital. It refers to the process of analyzing large amounts of raw data in order to generate relevant and actionable insights. It is a type of business intelligence that aids in the resolution of specific problems and challenges.

For example, an e-commerce company can utilize data analytics to track customer behavior and use the findings to improve the overall experience. Data analytics tools aid in reflecting on past trends and forecasting future ones. [1]

1.2.1 Data Analytics in Quality Systems

The use of data analytics in a quality system offers innumerable benefits for medical device company. Some of the key areas where expertise of data analytics is utilized on everyday basis.

Quality Monitoring and Control: Data analytics enables the management to monitor and control the quality of their products throughout the manufacturing process. By collecting and analyzing real-time data from various sources quality inspections, companies can identify patterns, trends, and anomalies that may indicate quality issues. This allows for proactive intervention and corrective actions to maintain consistent product quality.

Root Cause Analysis: Data analytics aid in conducting root cause analysis which aims at identifying the underlying factors mainly contributing to quality issues or non-conformities. By analyzing data from distinct stages of the product lifecycle, design, manufacturing, and post-market feedback, companies can pinpoint the root causes of quality problems. This helps in implementing targeted corrective actions to prevent recurrence.

Supplier Performance Management: Data analytics assist in evaluating and monitoring the performance of suppliers. This helps ensure a reliable supply chain and consistent quality of incoming components or materials.

Regulatory Compliance: Data analytics provide support in regulatory compliance efforts by providing insights and evidence of adherence to quality standards and regulatory requirements. By analyzing and presenting data in a structured and accessible manner, companies can demonstrate compliance during audits and inspections.

Process Optimization: Data analytics also helps in optimizing quality control processes by identifying inefficiencies and areas for improvement. By analyzing data on process variables, cycle times, and resource utilization, it can help to identify bottlenecks, streamline workflows, and

optimize resource allocation. This leads to improved process efficiency, reduced variability, and enhanced product quality.

By leveraging data analytics, Quality Systems can drive continuous improvement, reduce risks, and deliver safe and high-quality medical devices.

1.3 Automation in Quality Systems

In Quality Systems, people work with data day in and out and generally Data is gathered from varied sources, which raises the need to organize the vast reserve of data coming from Complaints, Audits, Trainings, Standards Assessments, Document Control and Regulatory reporting along with its storage and efficient analysis. The work of Data Analytics team of T&E QS not only includes the fulfillment of data request requirements from other work divisions, creating data analysis report on regular intervals to maintain the high quality of the product but also looking for the ways of the streamlined and resourceful data usage. In general, the recurring and manual processes are the major hurdles in the path of creating a proficient and economical workflow. With the advent of AI tools and technology, it has become the need of the hour to utilize the highly anticipated and readily available software and tools to ease the burden of manual repetitive tasks which will help to enhance the productivity and creativity of employees. Automation in Quality Systems refers to the integration of technology and automated processes to streamline and enhance various aspects of quality management. It involves leveraging software tools, advanced analytics, and digital solutions to automate tasks, improve efficiency, and ensure consistency in quality-related processes. [2]

There are many key areas where automation can play a huge role such as in Data Collection and its analysis, reporting and the Quality Control processes.

Automation in Quality systems can empower organizations to enhance their quality control and assurance capabilities. It reduces manual effort, increases operational efficiency, and enables better decision-making through data-driven insights. By automating routine tasks and focusing resources on value-added activities, businesses can achieve higher levels of product quality, regulatory compliance, and customer satisfaction.

The work performed in Quality Systems involves the transfer of sensitive data of quality related operations from all the functions working in managing and establishing the quality of the product.

This sensitive information includes Complaints data from Complainants, Regulatory bodies, customers and databases that will be further investigated by the Complaint Investigators. The results of these investigations will be passed on from one end to another in the form of reports, files which are later shared to prepare the reports for the sustenance and compliance of products in the market as the Post Market Surveillance Reports.

The sensitive data of Quality Systems also includes the results, inputs of the internal and external Audits that are being performed regularly to ensure the utmost quality of the product for the end user.

To be compliant with all the regulations set by the regulatory authorities all across the globe, in providing trainings to the employees is one of the major tasks. Record keeping and communicating the results of finished, overdue trainings among the teams, higher management and the regulatory authorities is also huge exercise that also takes a major chunk of time.

A major portion of these tasks are repetitive and recurring which takes away their precious time from employees which can instead be used to perform other important tasks that requires immediate attention and action. The major aim is to identify those bottleneck areas and to develop tools and processes to make these processes more automatized. The major challenge lies in the identification of the key areas where improvement can be done. Other challenge includes selection of right tools and methods for the mitigation of these problematic area from the big pool of resources. This project is an umbrella project involving several small and big projects under it, catering to the needs of whole Quality Systems which aims at benchmarking certain processes across Stryker and ultimately give its contribution in the organizational transformation.

1.4 Quality System Automation Project Overview

1.4.1 Project Summary

- Quality Systems (QS) Team has many metrics, reports and trending charts, that they are being done on regular basis and major portion of such tasks are done manually.
- To identify all the manual work being done across Quality systems. The other objective was to identify the amount of effort or hours that were spent on each such task, to prioritize converting these manual tasks to automated processes using the existing Automation tools and services in the workspace.

1.4.2 Scope of the Project

The Trauma and Extremities Quality Systems of Stryker falls under the scope of this project.

The future aim of the project will be to widen its scope to Clinical, Quality and Regulatory domains of the T&E and benchmark the results across the Stryker's Quality Assurance System.

1.4.3 Project Objectives

Project Requirements

- To ensure a smooth project transition at different stages, it's essential to create a variety of tracking tools or surveys. These tools can be simple or complex systems, all aimed at facilitating the project's progress.
- To manage databases, these databases are the major source of data. The aim is to work on these databases to make them up to date according to standards.
- To develop tools, automated dashboards, reports and workflows for the teams to enhance efficiency at the Quality Systems workspace

1.5 Motivation

According to a survey conducted by Automation Anywhere in 2021, which included over thousands of office workers worldwide, it was found that employees spend approximately 40% of their workweek on manual, repetitive tasks. The survey also revealed that automation has the potential to save considerable time, with an estimated average of 180 hours per year per employee. This highlights the opportunity for automation to optimize productivity by freeing up time for employees to focus on more strategic and high-value activities [3]. Additionally, the McKinsey Global Institute's report on 'AI, Automation, and the Future of Work' in 2018 analyzed various occupational fields and work activities across sectors, indicating that nearly 50% of work activities could be automated, particularly physical work and data-related tasks [4]. This research estimated that automation technologies could eliminate up to 50% of current work activities in different industries, leading to time savings and increased productivity. Reports such as the UiPath Automation Maturity Index (2021) [5] and the Workfront State of Work Report [6] (2020) have also highlighted the potential of automation in saving 20% to 25% of employees' time, enabling them to focus on more strategic work. The emergence of automation tools and AI has opened up new possibilities for businesses to achieve higher levels of efficiency, accuracy, and quality. By automating repetitive tasks and leveraging AI-powered analytics, organizations can streamline processes, reduce errors, and make data-driven decisions, resulting in improved productivity and cost savings. [7] With a focus on scalability, adaptability, and innovation, businesses can leverage automation and AI to gain a competitive advantage and foster sustainability. In the context of Quality Systems, the aim of the project was to explore opportunities for utilizing automation tools to enhance business efficiency and sustainability.

1.6 Research Project Objective

The objective of this research project is to conduct a comprehensive investigation to identify specific areas within Quality Systems where automation tools can be effectively utilized to enhance business efficiency and sustainability. The study aims to analyze the potential impact of automation on various aspects of Quality Systems, including process optimization, productivity improvement, data accuracy enhancement, and the promotion of sustainable practices.

This research project will involve a detailed examination of the existing processes and tasks within Quality Systems, with a specific focus on identifying areas that involve repetitive and time-consuming activities. The goal is to leverage automation tools, such as Office 365 tools, to streamline and automate these manual tasks, leading to significant improvements in operational efficiency.

Furthermore, the research project will investigate the potential benefits of automation in terms of reducing errors, minimizing resource waste, and enhancing overall data accuracy within Quality Systems. By automating data collection, analysis, and reporting processes, organizations can ensure consistent and reliable data, which in turn facilitates better decision-making and improved quality outcomes.

In addition to efficiency gains, the research project will also assess the potential of automation to contribute to sustainability objectives within Quality Systems. This includes analyzing how automation tools can optimize resource utilization, reduce energy consumption, minimize waste generation, and support eco-friendly practices. By integrating sustainability considerations into the design and implementation of automation processes, organizations can align their Quality Systems with broader environmental and social responsibility goals.

Overall, the research project aims to contribute to the existing body of knowledge on automation in Quality Systems and provide practical guidance for organizations to effectively leverage automation tools, enhance business efficiency, and promote sustainability in their operations.

1.7 Outline

The thesis is divided into 6 Chapters, this section will provide you with the insights and introduction to all the chapters.

Chapter 1- Introduction- This chapter provides an introductory overview of Quality Systems and explores the current and future potential of automation in managing data related to Quality Management Systems within the context of the Medical Technology industry. The chapter aims to shed light on the existing landscape of automation in Quality Systems, including the utilization of digital tools, software solutions, and emerging technologies. It aims to lay the groundwork for further exploration and analysis of automation techniques, enabling the adoption of innovative approaches to enhance efficiency, compliance, and sustainability in Quality Systems. It examines how automation can contribute to improving data management processes, enhancing operational efficiency, and driving sustainable practices within the Medical Technology domain.

Chapter 2 – Literature Review- In Literature review, work has been done to identify if such kind of automation projects has been done in any work domain in the past. The review also focuses on the previously used automation tools and their transition to the highly advanced new-age tools.

Chapter 3-- Methodology

3.1-Architecture- The architecture section includes the overview of interaction among all these automation tools and services with user and among themselves. The architectural overview of the process workflow and connection building of the mentioned automation tools.

3.2- Implementation- This section will consist of the distinct phases of the project. The methodology employed to drive the project, the verification and validation processes that were followed during the deployment of the project.

Chapter 4- Result This section will throw light on the results and objectives achieved after the successful completion of the project. It will also give a brief about the achievements for the ongoing projects.

Chapter 5- Conclusion The conclusion section will conclude the importance and potential impact of the proposed solutions during the duration of the project and the upcoming aspirations of the ongoing or future projects.

Chapter 6- Summary This section will summarize the projects and the work performed.

Chapter 2 Literature Review

Throughout history, the pursuit of reducing human effort and streamlining tasks has been an ongoing endeavor. From 18-19th century, the Industrial Revolution to the very breathtaking advancements in arena of ML and AI in recent decades, automation processes have been completely revolutionized the diverse work fields spanning from the innovation to healthcare, manufacturing etc. The aim has been to leverage these advancements to alleviate the burden of repetitive and time-consuming mundane work. The history of automation reflects a continuous quest to optimize processes, reduce human effort, and improve productivity across various industries and sectors. It is an ongoing journey driven by technological advancements, changing economic landscapes, and the pursuit of efficiency and innovation [8].

2.1 Areas where Automation has been done

There are several areas where the automation work has been performed to ease the steps in the workflow in various different kind of manufacturing, healthcare industries, IT fields, Banks, Robotics and office spaces using the tools and services already present in the market. [9]

The studies on Automation projects where the dedicated Quality Systems workflow in Med-tech Industry is taken into consideration for reducing manual efforts, are not significantly done. The aim of the project is to look out for previously used tools and to search for opportunities to leverage the advance tools newly introduced in the market. [10]

2.1.1 Automation Tools previously used

The process of reducing efforts to perform tasks in a workspace has long started with the utilization of the tools and services. These in-built suite services made the process of data collection, processing and its remediation, transformation, validation, and presentation a lot easier for the everyday tasks. [11] Over the years these tools and services kept on improving and changed the complete perspective of workspace utilities. These technologies and tools have laid the foundation for the modern-day data analytical tools for automation. [7]

MS Excel

Excel is a popular data analytics tool because it allows users to conduct calculations, make charts, and analyze data using formulas and functions. It is popular for minor automation jobs since it includes basic data processing and analysis capabilities.

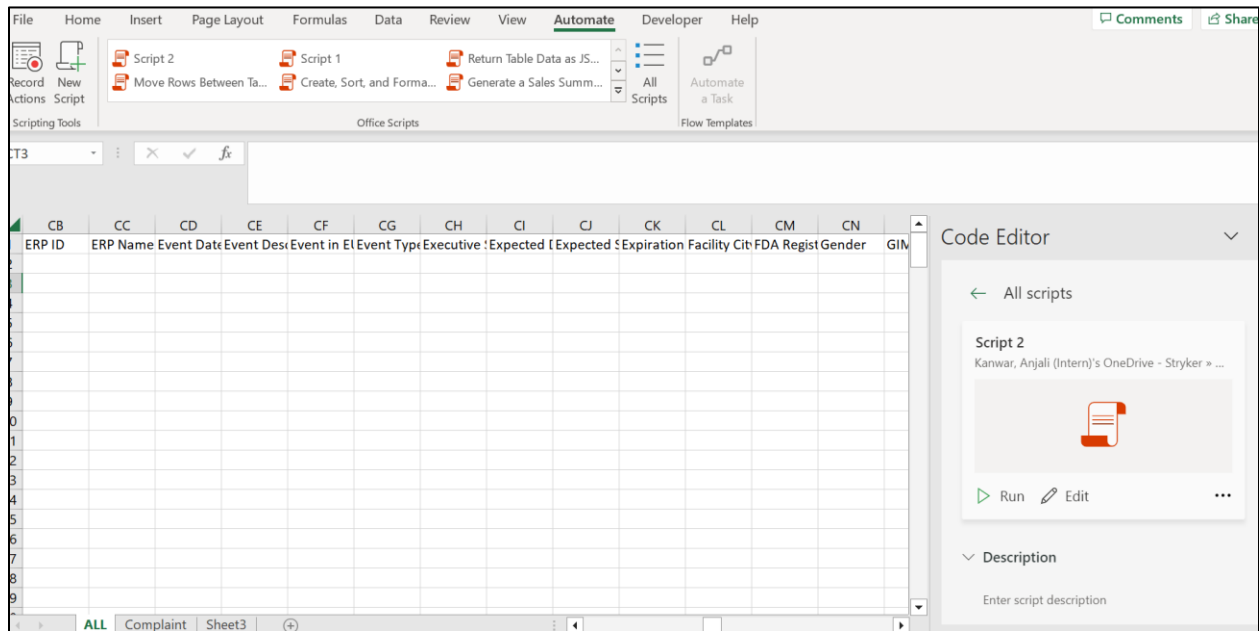


Figure 1 Interface for VBA Scripting in Excel

MS Access

Access Database is an RDBMS that allows users to store, organize, and manage data. Microsoft Access is another name for it. It comes with tools for creating tables, forms, queries, and reports. Users can use simple forms to enter and edit data, perform queries to identify specific information, and generate reports for data analysis and presentation. Access allows for data validation and integrity via set rules and constraints. It makes it easier to create links between tables while keeping data consistency. Integration with other Microsoft Office apps facilitates data sharing and automation. Access is a popular database management system for small to medium-sized databases that is suitable for personal, departmental, and basic commercial applications. By using objects provided by other components, MS Access provides automation. It enables users to display information on Access forms or reports by integrating MS Access with other programs like Microsoft Excel. Data communication and interaction between various components are made possible through automation [[12].

MS Access' automation features provide users the freedom to design and personalize their own database systems. Users can establish user interactions, apply business logic, and develop automated workflows to fulfill particular needs. Users are empowered by automation to customize their databases to meet their specific needs. Automation, formerly known as OLE Automation, is supported by Microsoft Access. Additionally, to allow the use of objects provided by other components, it also makes its own objects available to other COM components. The major automation components of MS access are VBA and Macros

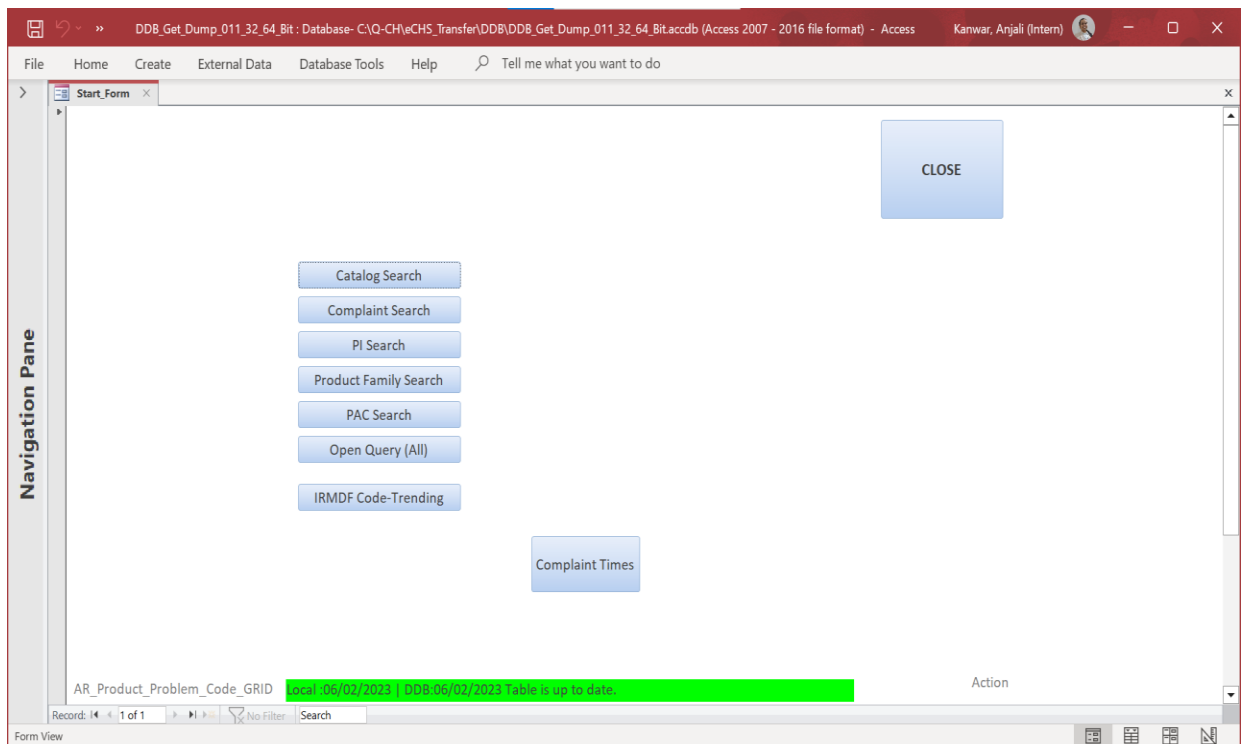


Figure 2 Interface of MS Access based Divisional Database

VBA Tools

VBA, a subset of the Visual Basic programming language, is used to create macros, which are then performed within the Office application environment VBA in MS Access can interface with Excel files, allowing users to automate Excel-related operations. Users can alter Excel workbooks, format cells, do calculations, and save files to specific locations by writing VBA code [R].

VBA automation in MS Access allows users to rearrange and filter data within Excel reports or Access databases. VBA code can be written by users to filter specific data, retrieve useful

information, and change existing files depending on predefined formats or criteria. Through methods and properties, VBA enables users to handle objects made available by the application [R]. Users can carry out a variety of tasks with VBA, including applying formatting, modifying data, interacting with outside data sources, and producing new documents [R].

```

Microsoft Visual Basic for Applications - [Form_Start_Form (Code)]
File Edit View Insert Debug Run Tools Add-Ins Window Help
Ln 1, Col 1
Project - CIN_Update_Client.XLS (General) (Declarations)
CIN_Update_Client_001
  Microsoft Access Class
  Form_Remediation
  Form_Start_Form
  Form_Update_cont
a.WriteLine ("</tr>")
Set rst = New ADODB.Recordset
rst.Open "select [Monitoring Project], [PR ID], [Date Opened], [Project],[PR State], [Awareness Date], [Event Date], [Catalog #]

Do Until rst.EOF
MonitoringProject = rst.Fields("Monitoring Project")
PRID = rst.Fields("PR ID")
DateOpened = rst.Fields("Date Opened")
Project = rst.Fields("Project")
PRState = rst.Fields("PR State")
AwarenessDate = rst.Fields("Awareness Date")
EventDate = rst.Fields("Event Date")
Catalog = rst.Fields("Catalog #")
ProductLongDescription = rst.Fields("Product Long Description")
Brand = rst.Fields("Brand")
SubBrand = rst.Fields("Sub-Brand")
CMC = rst.Fields("CMC")
PAC = rst.Fields("PAC")
Manufacturer = rst.Fields("Manufacturer")
SubmittedOn = rst.Fields("Submitted On")
DateClosedInitial = rst.Fields("Date Closed (Initial)")
SubmittedOnInitial = rst.Fields("Submitted On (Initial)")
Owner = rst.Fields("Owner")
InvOwner = rst.Fields("Investigation Owner")
Dateofviewing = rst.Fields("Date of viewing")

CSubmState = rst.Fields("Country Submission State")

If PAC = "Kiel, Germany" Then
PACField = "border:solid black 1.0pt;background:#00F5FF;"
ElseIf PAC = "Selzach, Switzerland" Then

```

Figure 3 VBA Code in MS Access to store data

Macros Office software provides a macro recording capability that may be used to make macros. For instance, users can construct a macro in Excel by going to the Developer tab, selecting the

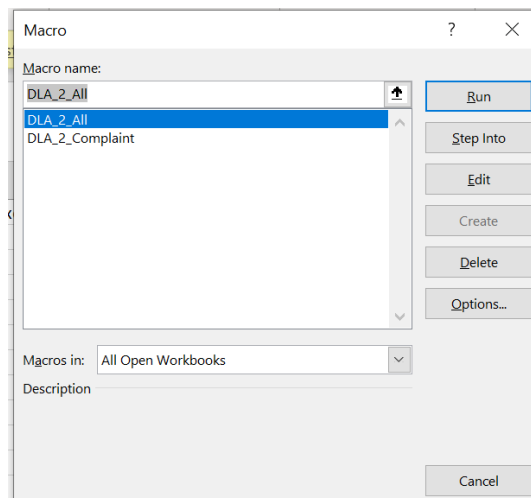


Figure 4 Macros Recorded in Excel for data sorting

Record Macro button, giving the macro a name, and then beginning to record their actions. All user actions are recorded by the macro recorder as VBA code, which can be played back.

R Tool

In Simple terms, a Tool created by using the statistical R language is generally known as R Tool. RTools is a collection of Windows toolchains for creating R and R packages from source. It includes the tools and facilities required to compile R code and package dependencies. You can automate certain activities within the application as well as extend to other Office products and even other applications that accept VBA, enabling cross-application automation. Automation with R has various advantages, including the ability to simplify operations, save time, and improve efficiency. R's broad package library and ability to manipulate data make it an excellent choice for automating office and corporate procedures.

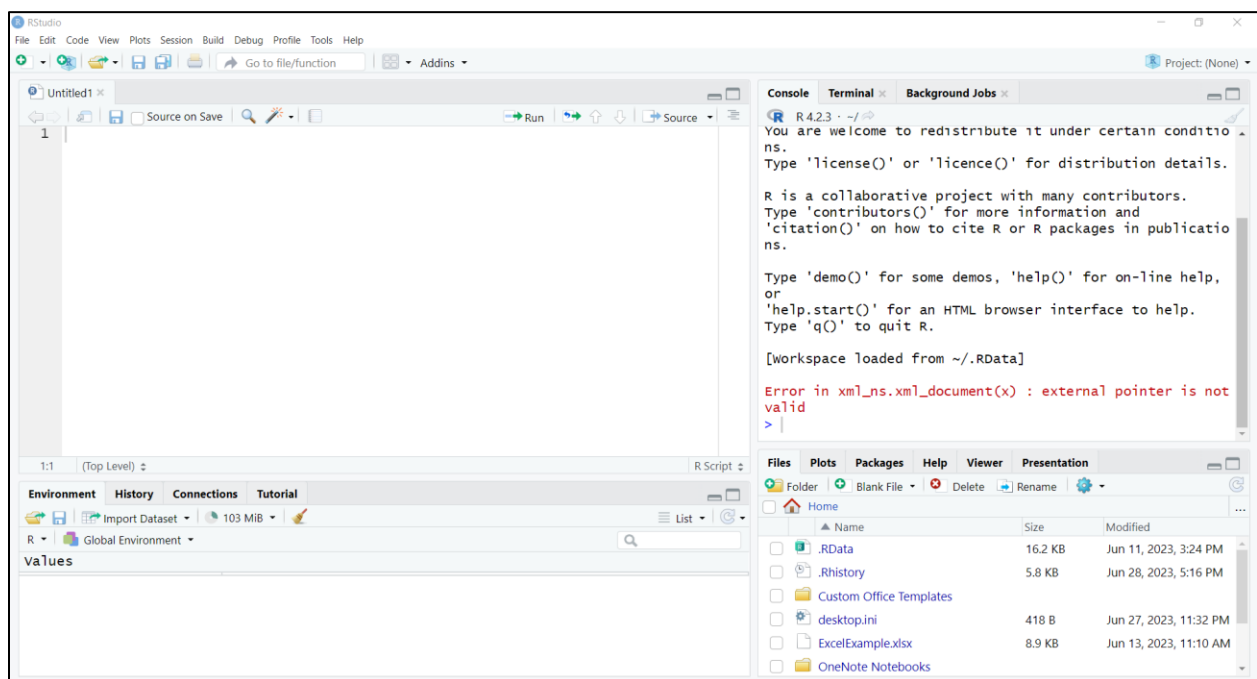


Figure 5 R Studio homepage

2.1.2 Advanced Automation tools in the Market

With the release of AI tools in the market, Automation tools have become much more advanced tending to the user needs in never before fashion. According to Gartner Magic Quadrant for Analytics and Business Intelligence Platforms 2023, in which Microsoft emerges as a leader among all the Analytics and Business Intelligence (ABI) Platforms. It was analyzed among all the

ABI platforms against multiple capabilities and voted as a winner due to its at-par features provided to communicate and share insights while modeling, analyzing, exploring, sharing, and managing data, all while using IT and artificial intelligence (AI)[26]. The Microsoft Office 365 suite, Teams and Azure Cloud Services has enabled their extensive usage in office workspaces and the domain of Quality Systems is not an exception in this. The major automation tools, workflows and technologies that will be discussed and were analyzed are mostly belongs to Microsoft Services.

Power Automate

Microsoft Power Automate, formerly Microsoft Flow, is a cloud-based workflow automation platform. Users utilize Power Automate to automate numerous processes and tasks across several applications and services. Its capabilities include workflow automation, robotic process automation (RPA), and digital process automation (DPA). [14]Power Automate can be used to start automation flows depending on unforeseeable events, such as receiving an email. Power Automate can communicate with Microsoft ERP technologies such as MS Dynamics in order to retrieve data and include it into the automation workflow. This method improves case handling speed and reliability. Users can save time, boost productivity, and streamline their company activities with Power Automate. [15]

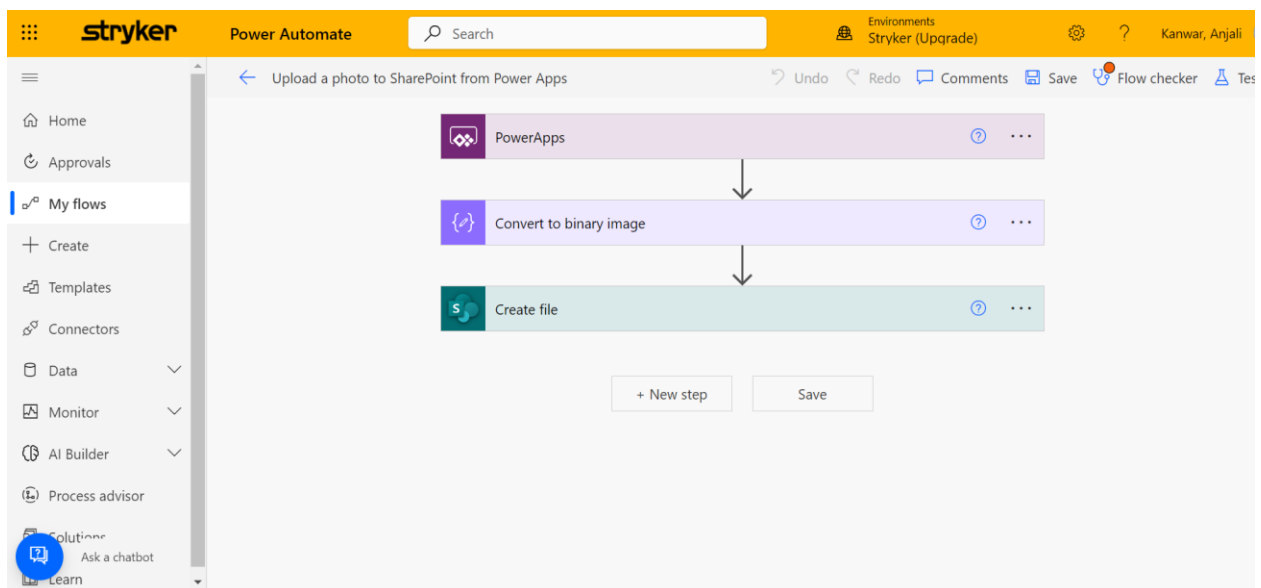


Figure 6 Automation flow created in Power Automate

Power Apps

Power Apps is a Microsoft platform that allows users to create custom business applications without requiring considerable coding experience. Power Apps can be utilized to design and customize business applications using a no-code or low-code approach. It enables users to create interactive and responsive apps that can link to a variety of data sources, including databases, SharePoint, and cloud services. Power Apps is intended to improve user experiences by streamlining business operations, increasing productivity, and streamlining business processes.

The screenshot shows a Power Apps interface for a 'New Change Request Form'. The app is titled 'T&E Periodic Updates App' and features the Stryker logo in the top right corner. The form is organized into several sections:

- Change Request ID:** A text field containing '26022023MS1'.
- Date Added:** A date picker field showing '6/7/2023'.
- Project ID/Program:** A text field containing 'VariAS Instruments'.
- Request Made By:** A dropdown menu with the placeholder text 'Search by Last Name or Email'.
- Approvers Needed:** A dropdown menu with the placeholder text 'Search by Last Name or Email'.
- Subject:** A text field containing 'Replanning of Documents'.
- Change Request Description:** A large text area with the placeholder text 'Provide a description of the change being requested.'
- Reason for Change:** A large text area with the placeholder text 'What is the reason for the change to be made?'.
- Propose Action(s):** A large text area with the placeholder text 'What is the proposed action item to complete this Change Request?'.
- Impact:** A large text area with the placeholder text 'Provide information regarding how the change will impact the project/programs identified.'
- Impact Category:** A dropdown menu with the placeholder text 'Select Impact Category from Dropdown'.
- Attachments:** A section with the text 'There is nothing attached.' and an 'Attach file' button.

At the bottom of the form, there are three buttons: 'Save Draft', 'Submit Form', and 'Clear Form'. A small asterisk and the text '* - Required Data' are located below the form fields.

Figure 7 Interface created on Power Apps

Power BI

Power BI automation enables users to optimize and automate numerous procedures inside Power BI reports. Power Automate Visual is a Power BI capability that allows users to trigger automated flows directly from a Power BI report. These visual lets users add a button to the report that, when clicked, initiates a pre-defined flow. The flow can be data contextual, which means that the inputs might be dynamic based on the end-users' filters. The Power Automate Visual, which facilitates automation in Power BI, allows users to start automated flows inside their reports. Users can personalize the automation process depending on their individual needs by creating and updating flows, making their reports more interactive and dynamic.

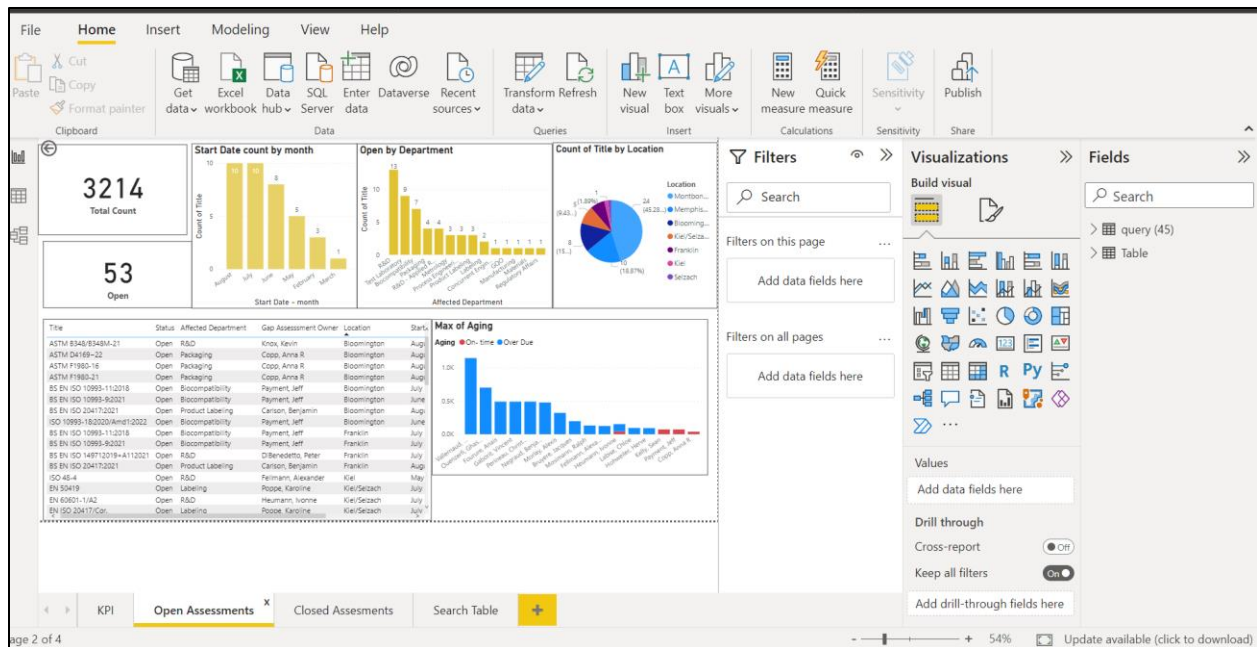


Figure 8 Power BI dashboard

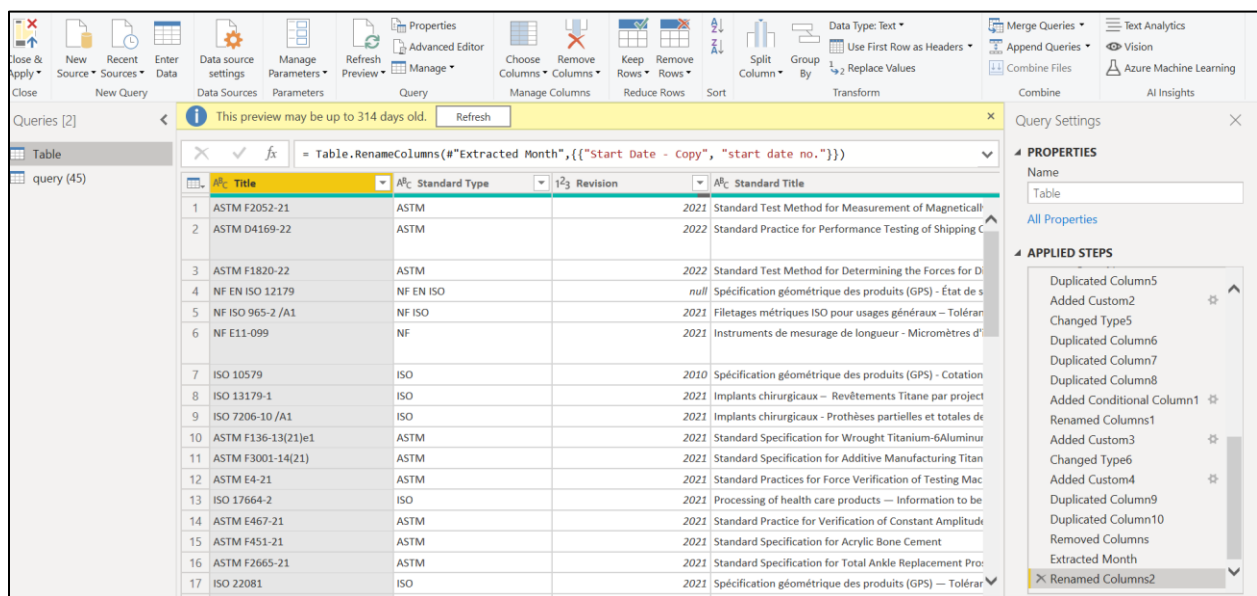


Figure 9 Data Tables in Power BI

Azure Cloud

Azure Automation is a cloud-based automation solution that enables the deployment and management of infrastructure, the response to events, and the orchestration of processes in Azure and non-Azure environments. Process automation, configuration management, update management, and other functions are included: Process automation in Azure Automation enables

customers to automate time-consuming, error-prone management operations. It allows you to deploy, configure, and manage end-to-end processes by integrating Azure services and third-party systems[24]. Runbooks can be created using graphical, PowerShell, or Python programming languages.

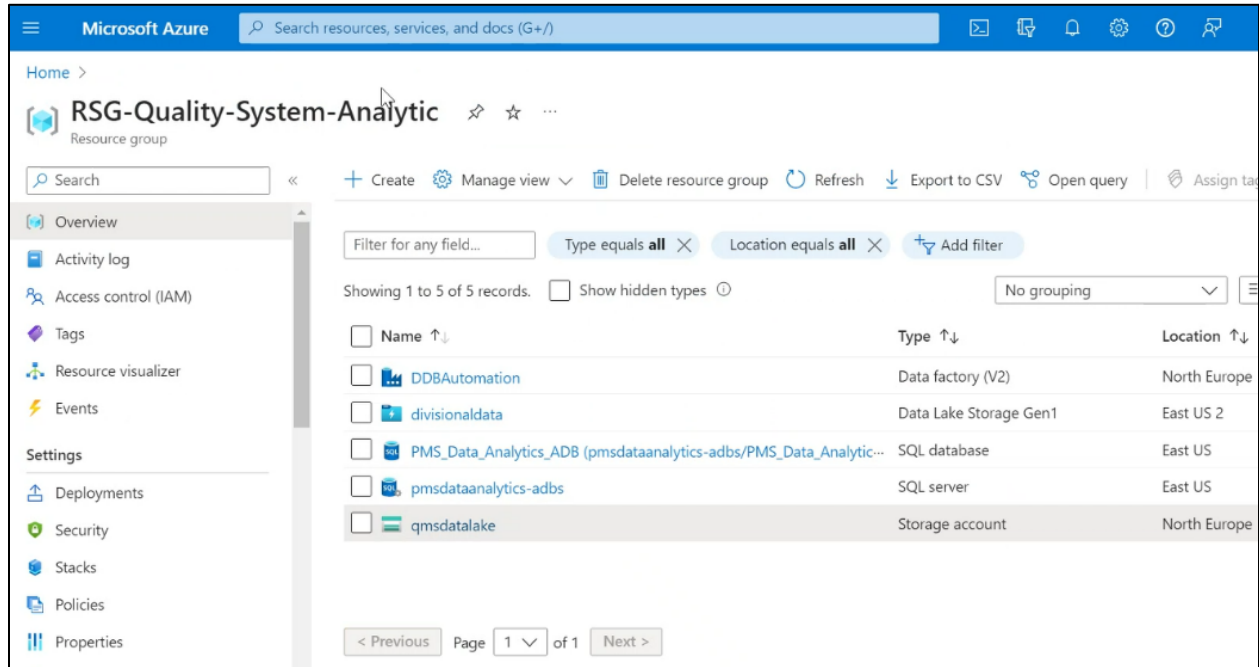


Figure 10 Azure User Interface

Chapter 3 Methodology

3.1 Architecture

The whole integration of tools by Microsoft for Business Intelligence has been in use since their inception. Microsoft Office 365 has been used extensively by the companies for their day-to-day operations, given the ease of usage and the variety of features provided to employees, catering to their everyday needs. MS Word, MS Excel is some of the tools that are still relevant as they were at the time of their release. The architecture of how these tools is compatible with each other and can interact within themselves to fulfill all the user related requirements has evolved drastically. [16] [17]

The study was done to look for the automation tools that are most extensively used at workspaces.

3.1.1 Automation Tools

The automation tools has been categorized into multiple categories based on their function and the methodology used to create them. [18]

3.1.1.1 RPA- Robotic Process Tools

Robotic Process Tools, often known as RPA tools, are software applications that automate repetitive, rule-based operations within corporate processes. These tools employ software robots or "bots" to simulate human interactions with computer systems, allowing them to do tasks such as data entry, data extraction, data validation, report production, and others. [19] Workflow automation, exception management, scheduling, monitoring, and reporting are common aspects of RPA technologies. [20] They assist firms in streamlining procedures, reducing manual labor, improving accuracy, and increasing production. Some of the tools based on RPA technology are follows. Here the glimpse of these tools is given as they have been discussed before in detail

- **Microsoft Forms**

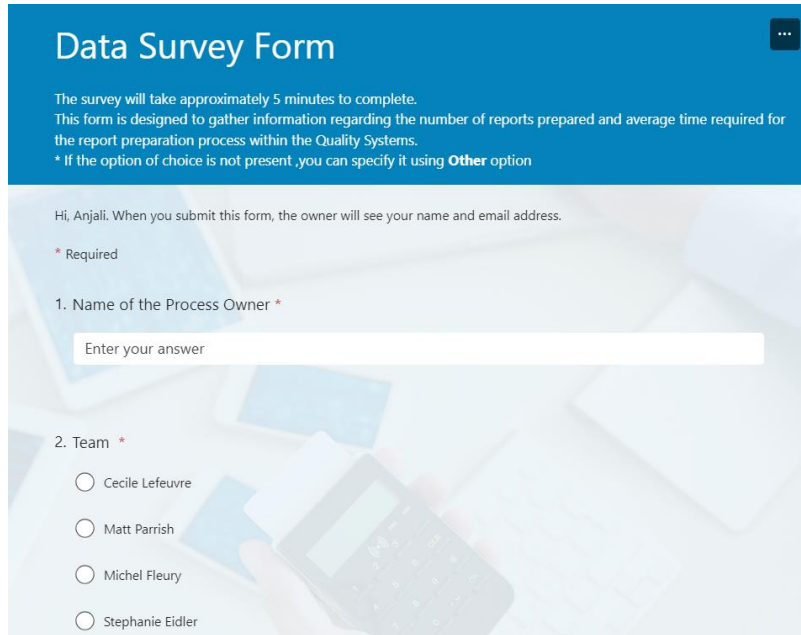


Figure 11 Microsoft Forms

- **Power Automate**

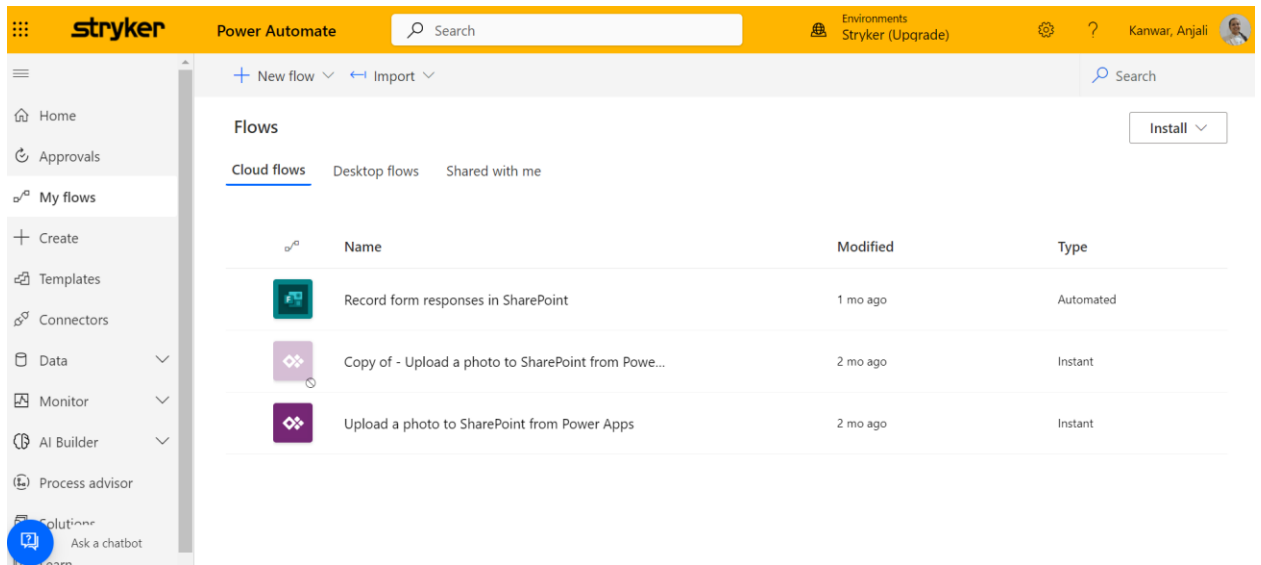


Figure 12 Power Automate Interface with created Flows

- **Azure Workflow**

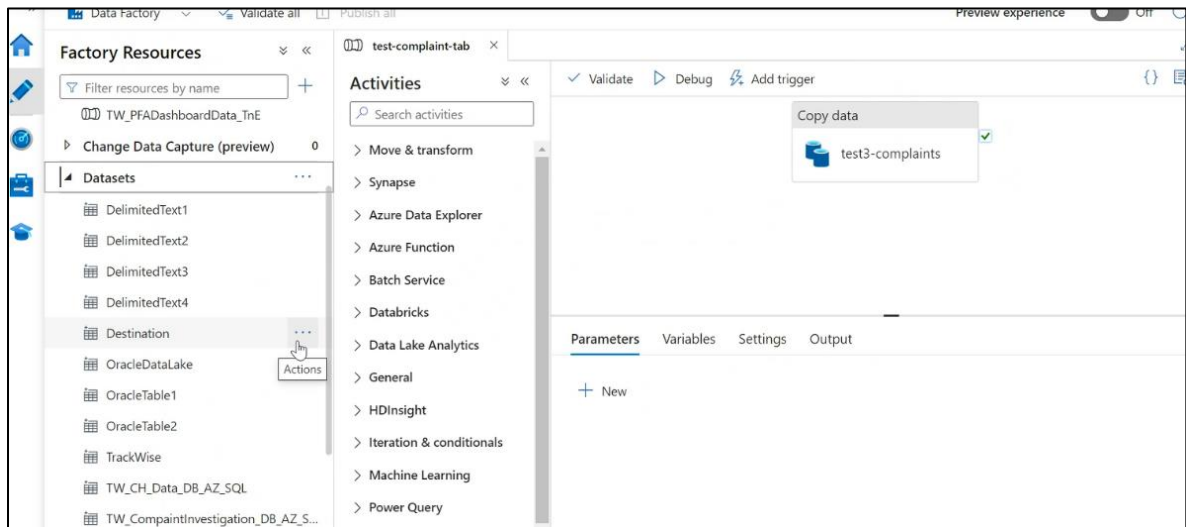


Figure 13 Azure Data Factory Interface

- **Power Apps**

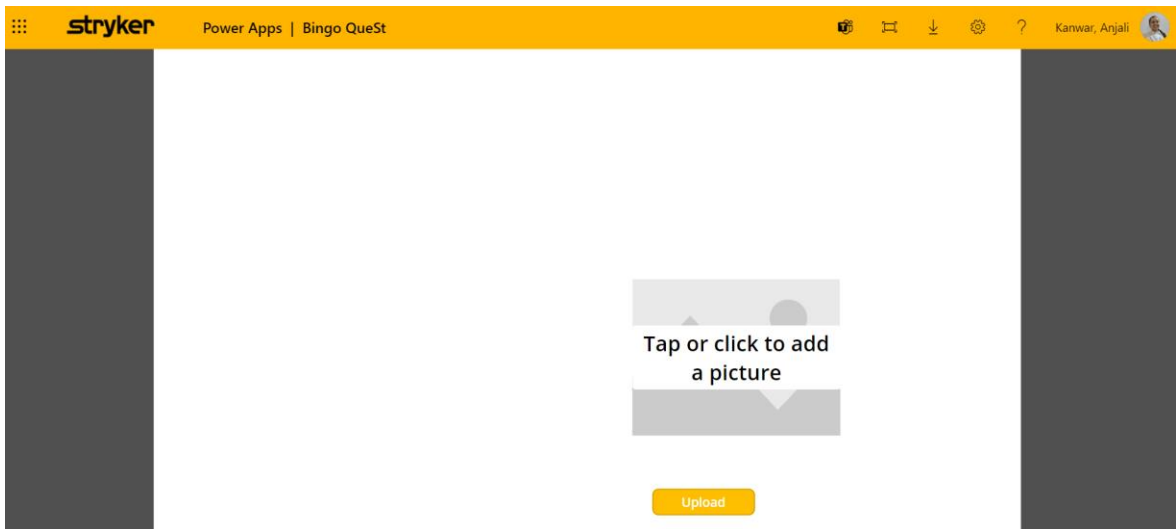


Figure 14 Power Apps User Interface Created to collect pictures

- **Power BI** The automation in report creation and visualization can be done by many tools such as Tableau, Power BI. The use of Power BI has drawn attention to the real-time data analysis done by creating beautiful interactive dashboards from raw data. The business intelligence platform Microsoft Power BI offers non-technical business user tools for data analysis, visualization, aggregation, and sharing. Power BI is an extremely flexible self-

service solution thanks to its deep interaction with other Microsoft products and its user interface, which is simple for Excel users to utilize.[20] Power BI makes data analytics accessible to the all employees. The data analytics professionals use it to create data models for report preparation.

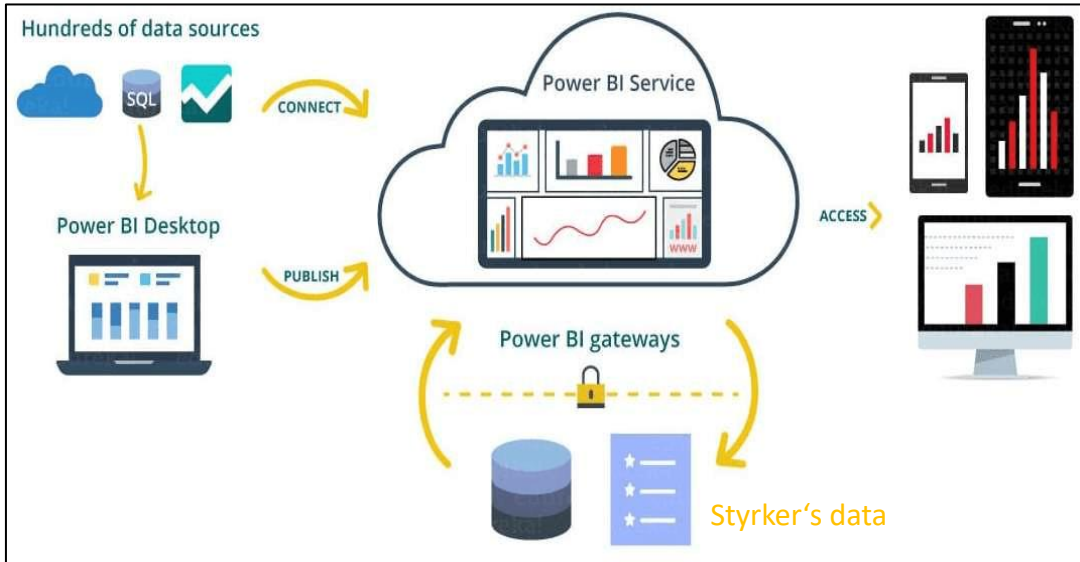


Figure 16 Power BI architecture

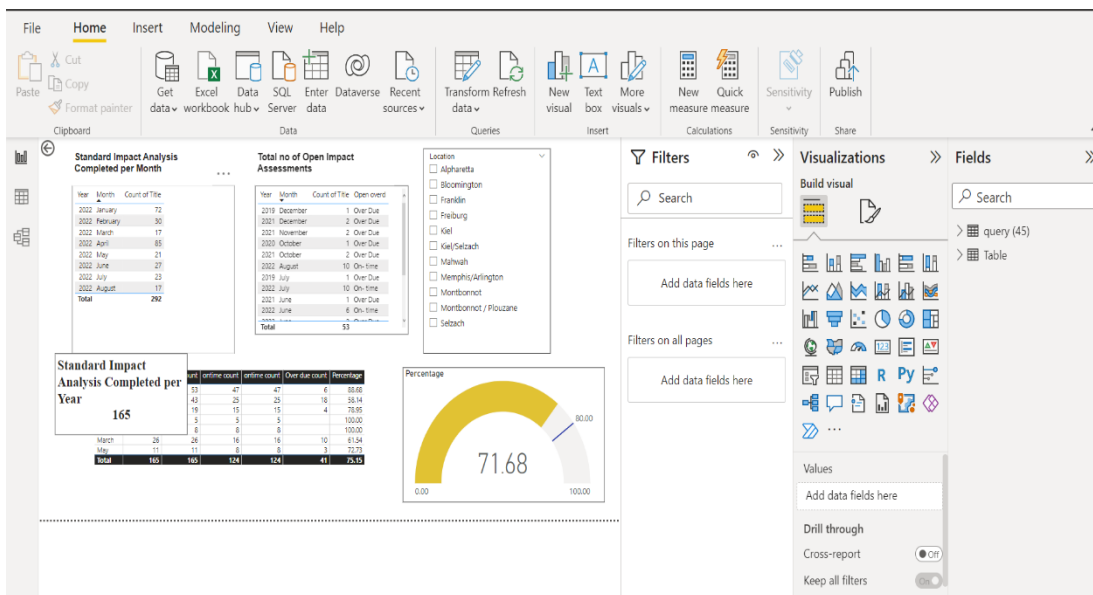


Figure 15 Power BI dashboard with KPIs

3.1.1.2 Project Management Tools-

MS Project

MS Project is a popular project management program with a variety of capabilities for project planning, scheduling, and tracking. Using a visual Gantt chart, project managers may set project goals, allocate resources, and generate timetables. The program allows for work monitoring, progress updates, milestone management, and the identification of potential delays. Collaboration tools enable team members to communicate and share information in real time. MS Project has tools for reporting on project status, resource consumption, and analysis. It can handle projects of all sizes because to its integration and scalability.

3.1.1.3 Document Management Tools- Trackwise/ OnePLM

The document creation and storage are very crucial in Quality Systems. OnePLM is an integrated software solution that facilitates end-to-end product lifecycle management. It offers a centralized platform for collaborative work, data management, and informed decision-making across departments, from product conception to retirement.

In quality system it is used for storing technical documents, regulatory, designs and procedures.

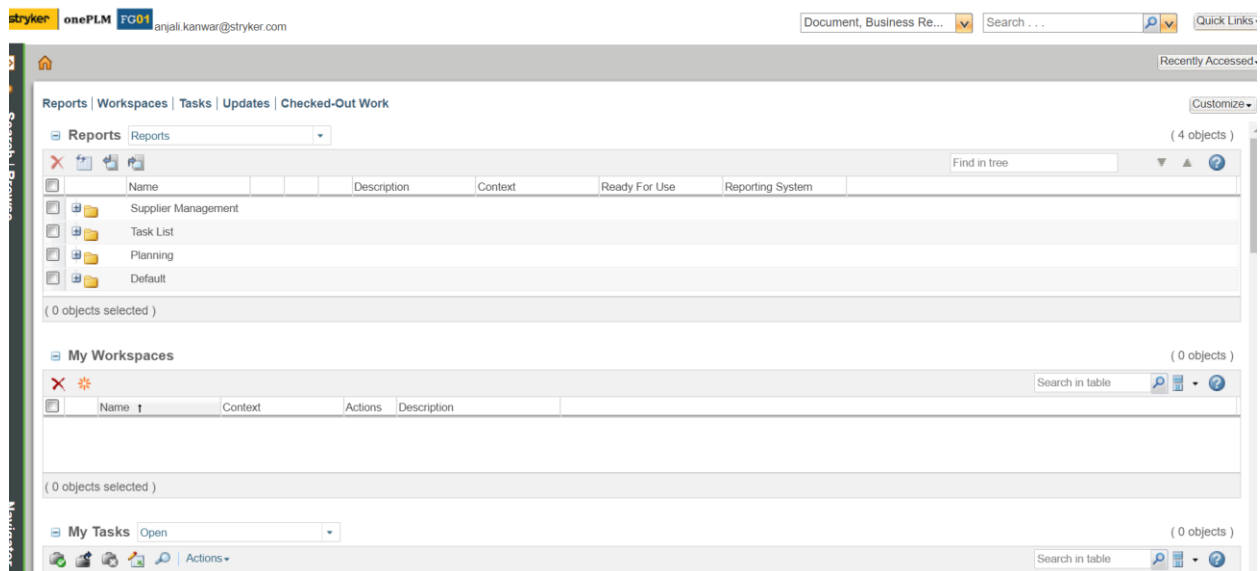


Figure 17 OnePLM interface

TrackWise is a web-based quality management system used by businesses to efficiently handle and track various aspects of quality and compliance processes.

Trackwise is a repository for the complaints, Audits, NC/CAPA information. Here the information is stored in fields and can be downloaded in the system. It is one of the major software to ensure

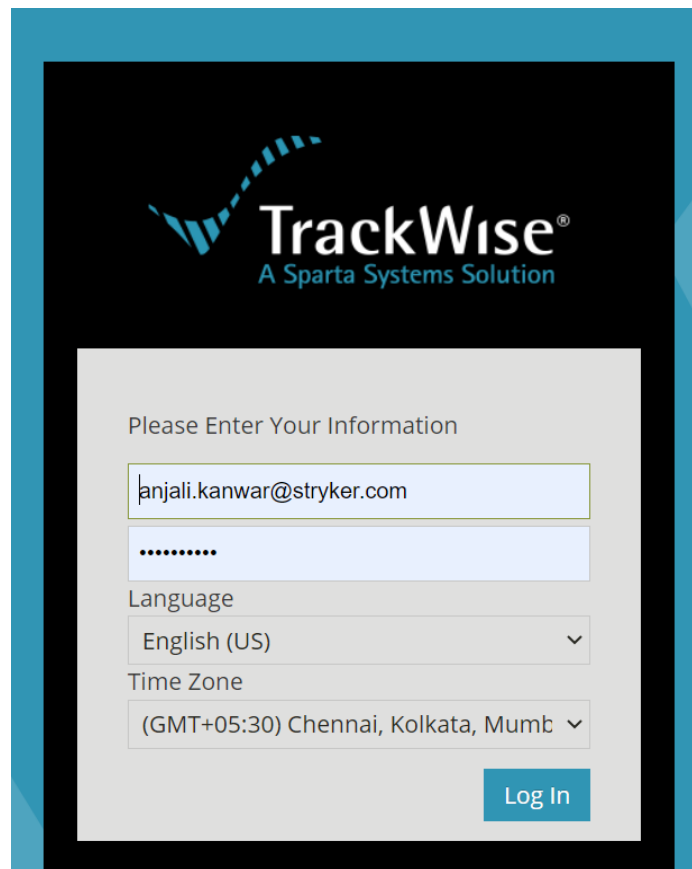


Figure 18 Trackwise Login Page

the quality management of the product and the feedbacks, risks from the customer end.

3.1.1.4 Email Automation Tools

Email automation tools are software platforms that enable T&E division to automate and streamline their email communication processes. These tools allow for the creation, scheduling, and sending of personalized and targeted emails to specific segments of an audience.

3.1.1.5 Help Desk and Ticketing System

IT Help Desk/One Portal

This is help desk and ticketing system where the person can go and generate a ticket or ask for a help in case of any issue related to software, system or access rights. After raising the ticket, The

process flow will start working with the automated assignment of tasks and automated email responses.

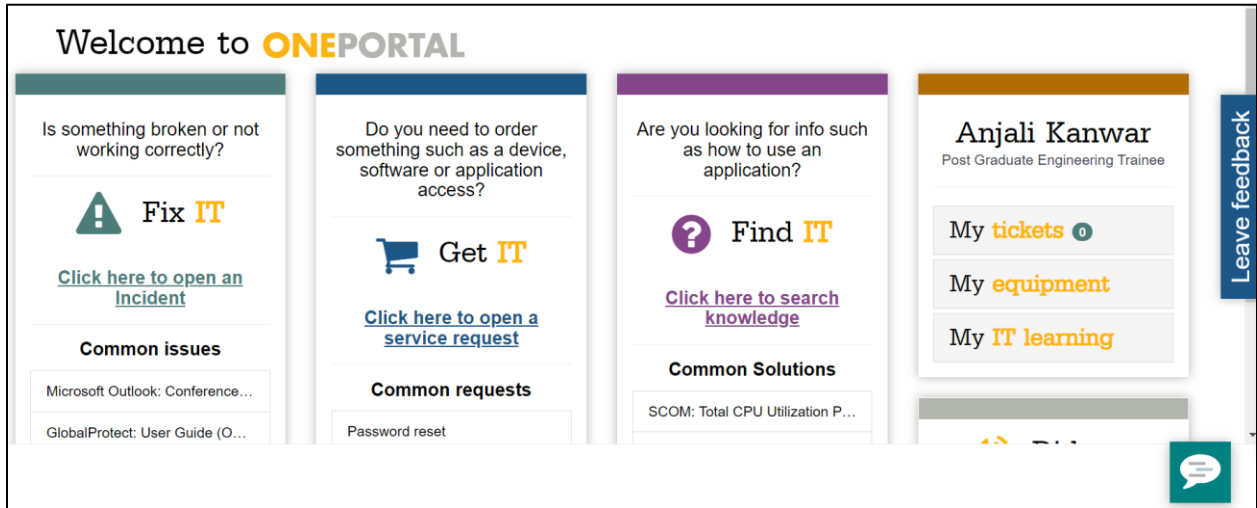


Figure 19 IT OnePortal Interface

3.1.1.6 Virtual Meetings and Collaboration tools –

Teams / Sharepoint/ MS Planner

In order to make the resources and the tasks list accessible to every person in the team resource sharing locations has been set up as Teams, SharePoint and MS Planner.

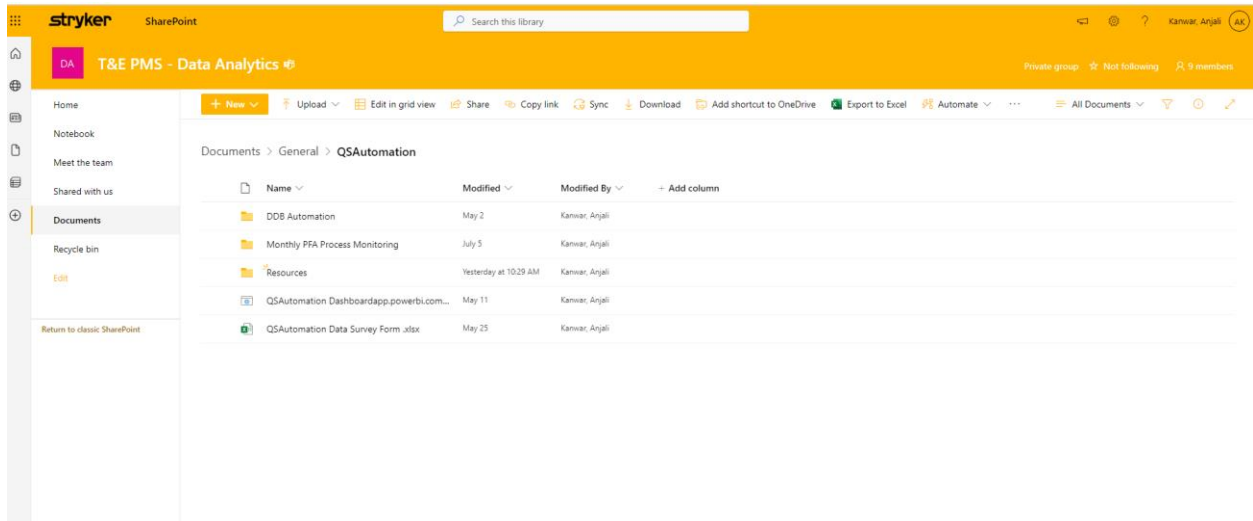


Figure 20 SharePoint Page of Resources

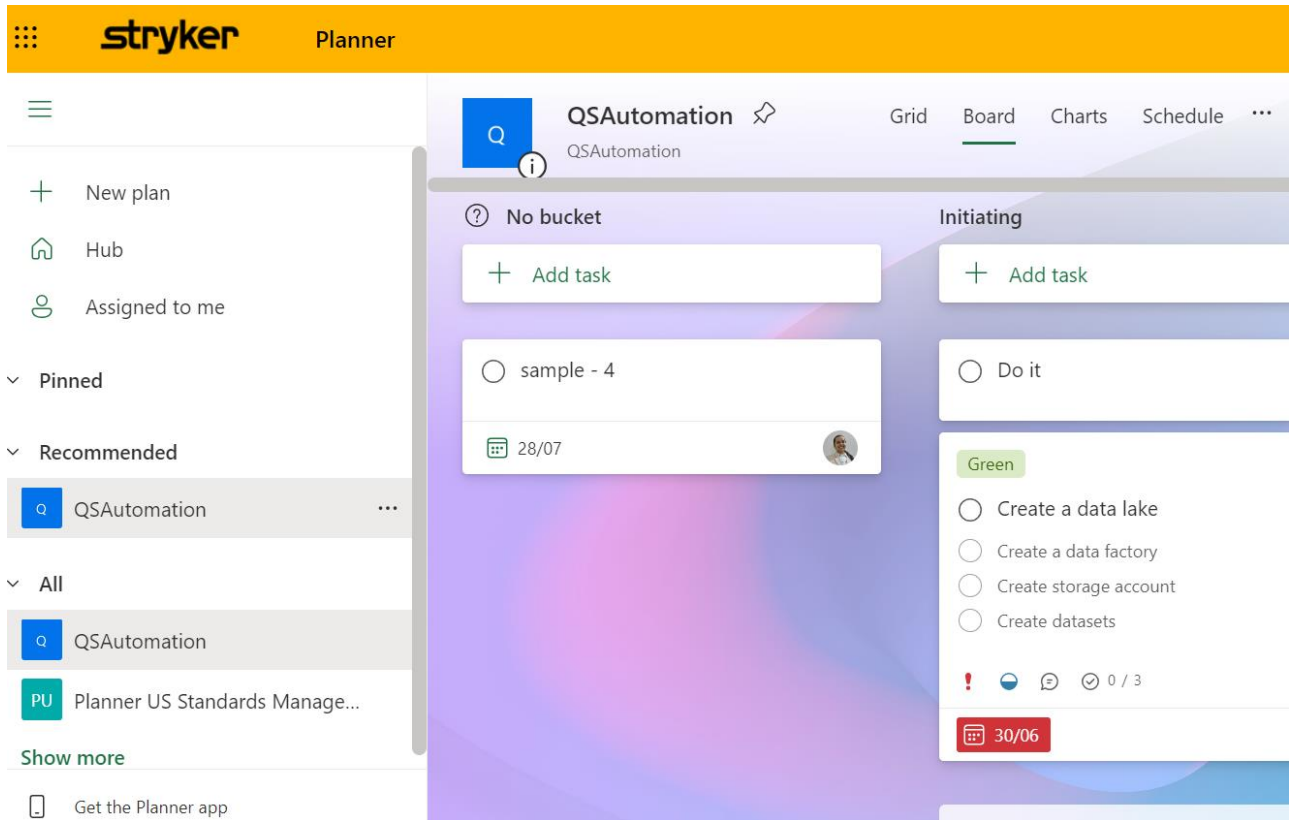


Figure 21 MS Planner Interface for Project Planning

3.2 Implementation

The Implementation Phase of the project commenced with defining the methodology, to be used during the course of the project, identification of the spectrum of the project and understanding the different work domains and their functions, working in the Quality Systems.

3.2.1 Methodology

The function of methodology in project management is critical because it provides structure, consistency, risk management, resource optimization, effective communication, quality assurance, and possibilities for continual development. It acts as a guide for project teams, allowing them to efficiently traverse complex tasks and accomplish desired goals. Use of Methodology can raise project success rates, improve stakeholder satisfaction, and drive continuous improvement in the project management procedures by following a well-defined approach.

3.2.1.1 Agile Methodology

Agile Methodology has been implemented during project. Agile methodology is a way of project management and development that is iterative and flexible. Agile technology, rooted in Agile methodologies, is an iterative project management approach emphasizing collaboration, adaptability, and continuous improvement. Agile teams break projects into phases, promoting open communication, cross-functional collaboration, and self-organization. Agile is not defined by specific practices but by a commitment to feedback cycles and improvement. Agile advantages include managing changing priorities, increased project visibility, improved business alignment, delivery speed, and project risk reduction [4] Agile practices have extended beyond software development and are applied in various industries. Each team tailors Agile practices to their needs while embracing the core values of continuous improvement and flexibility. Here team collaboration and input are prioritized, allowing improvements to be implemented and assuring remarkable results. Agile techniques accept change as a natural element of the project and prioritize requirements based on their importance. Agile encourages collaboration, promotes openness, and allows teams to identify and manage risks early on. Furthermore, the iterative nature of Agile enables ongoing learning and improvement, resulting in high-quality project deliverables. Its emphasizes on flexibility, collaboration, and progress makes this methodology as the best choice to incorporate the project [21]

3.2.2 Cycle of Data Automation

The cycle of Data Automation is a concept that was created with underlying principles based on the Agile methodology. The automation of processes follows the cyclic approach with each phase defined by the methodology. In case if the solution deployed did not perform according to the expectations, then everything will start from the first phase with continually improving the methods based on the feedback received.

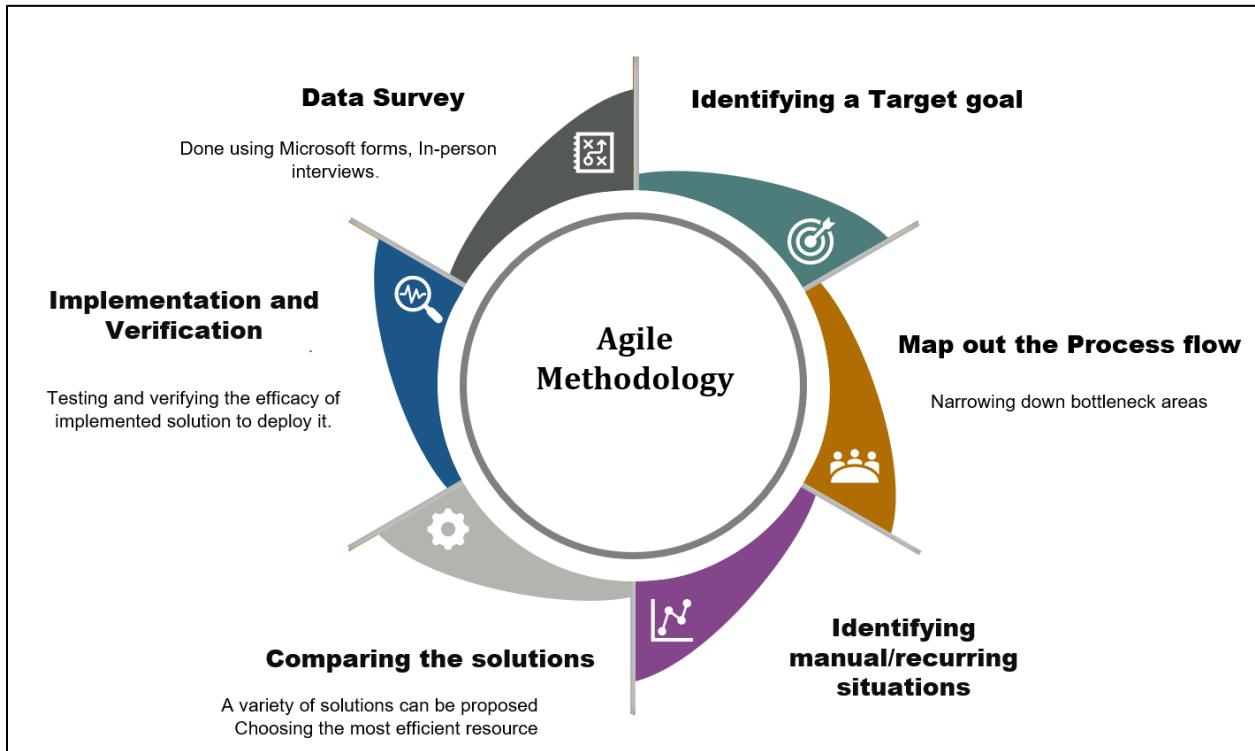


Figure 22 Cycle of Data Automation

3.2.2.1 Data Survey

To kick-start any project, the requirement gathering is the first step to understand the objectives and expectations from the project. This is the major and most defining step in the data analytics. Choosing the problematic area to work at clearly defines the future roadmap of the project. Identification of the bottleneck areas can be done using various modern-day tools such as online forms or by creating surveys, questionnaires, case-studies, observations, and documents. Traditional way of talking to people(interviewing) facing the issues in-person can be time-consuming but at the same time can help to better understand the problem at hand and weak links

wherever present. The selection of such tools depends on the analyst's choice along with time and resources at hand. This step commenced with rolling out the Microsoft Forms to look for the bottleneck areas in which everyone across the Quality Systems gave their input about the manual and recurring tasks done in their work stream having a chance of complete or partial automation. The data collection was done from each team involving Complaints, Post Market Safety, Standards Management, Trainings, Change Management, Audits and NC/CAPA departments.

3.2.2.2 Identification of the Target Goal

The image shows a screenshot of a Microsoft Forms survey titled "Data Survey Form for PMS". The form is designed to gather information about report preparation. It includes the following fields and options:

- 1. Name of the Process Owner * (Text input field)
- 2. Designation * (Text input field)
- 3. Field of Work * (Text input field)
- 4. Number of average reports prepared and sent in a week * (Text input field, with a note: "If reports are not weekly please specify the frequency(monthly/quarterly)")
- 5. Title/Aim of the report(s) * (Text input field)
- 6. Types of Data used in the report * (Multiple choice checkboxes: Tables, Charts, Excel Files, Word Files, and Other)

Figure 23 Data Survey Form created through MS Forms

The collected data paved the way for the selection of the target goal to work on the priority basis. The target identification was done based on multiple defining criteria such as the compliance associated with the task, numbers of hours spent on recurring tasks, impact of the work on the final product quality. These parameters were considered along with the future impact of the particular accomplished project on the whole Quality Systems Team. After the identification of the target project is done, the requirement gathering is done from the specific teams which includes

collecting the information about the scope, Stakeholders, Problem description, Current process, proposed solution, tools and services required and the priority of the project.

3.2.2.3 Metrics Mapping

It involved the use of the gathered information to map the complete current process flow of all the tasks performed in workflow of specific domain. The processes are mapped to simplify the process to better understand the involvement of shareholders, contributors and the number of steps in a particular process.

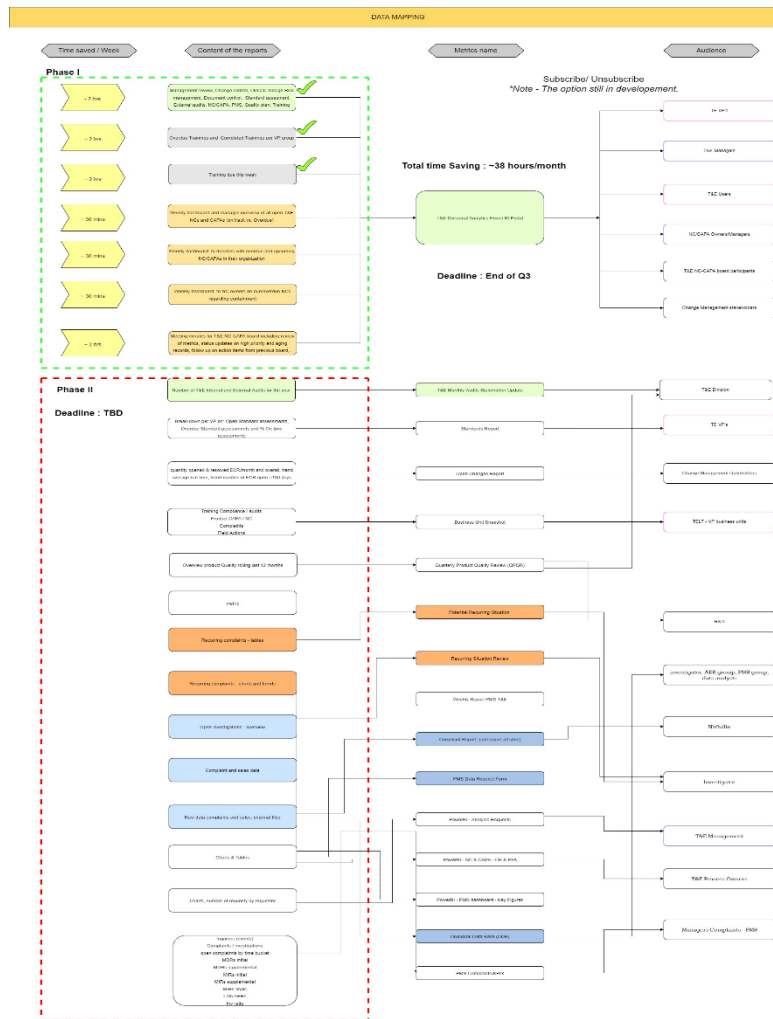


Figure 24 Mapping of Process Flow within team

3.2.2.4 Identification of Bottlenecks

During the process of defining the process flow, it becomes crucial to identify the bottlenecks and the manual recurring tasks which takes away lot of time to be done. These tasks will be identified

based on their repetitive occurrence and the resource time required in order for them to be established and performed.

3.2.2.5 Research and Proposal of prospective Solutions

The attempts to find and provide potential solutions to the specific project problem were made. The underlying issues were distinguished, and A methodical methodology was used in this study to examine the problem, review current tools and services that are readily available, and provide alternative solutions. To ensure objectivity and rigor in the analysis and proposal, the research adopted a scientific and systematic process. The outcomes of study helped to effectively address the problem while also encouraging future discovery and development of solutions.

3.2.2.6 Verification and validation of Solution's Efficiency

The goal is to evaluate and ensure the effectiveness and efficiency of offered solutions to a specific problem. Verification seeks to verify whether the solution fits the defined requirements, whereas validation seeks to validate that the solution achieves the desired results. This project takes a methodical and scientific approach to evaluate the efficacy of proposed solutions, ensuring their dependability and effectiveness. The study's findings will help to build trust in the efficacy of the recommended solutions and their likelihood of success in implementation.

As mentioned before, Quality System Automation Project is an umbrella project which encompasses several small and big automation projects under it. The two major and crucial projects underlying it will be discussed here.

3.4 Project 1 Creation of Power BI based Project Tracker

3.4.1 Project Description-

The data collection which was done during the initial data survey at the beginning of the project was performed through Microsoft Forms and the inputs from the team members are stored in Excel file. In order to prepare the report to check the progress of the Quality System Automation project, an automated dashboard needs to be prepared from where the complete progress report can be collected. The KPIs of the project will be also included in the report to work and look for any improvements required.

3.4.2 Proposed Solution

The solution that was proposed was to build an automated interactive dashboard using the Power BI which will not only enhances the visualization front of the report but also can be easily accessible by the team across the division. The requirement gathering was done to figure out which KPIs, Visualizations are required into the dashboard.

Introduction to Microsoft Power BI

Microsoft Power BI is used to discover insights inside an organization's data. Power BI may assist in connecting different data sources, transforming, and cleaning the data into a data model, and creating charts or graphs to visualize the data. All this information may be shared with other Power BI users in an organization. [22] [23]

3.4.3. Design and Development

Phases of Automation through Power BI

The process of the quality data automation using Power BI can be categorized into 3 main phases.

- **Phase 1**

Establishing dataflow to Power BI

The flow of datasets from the pool, which is created by transferring the data from hundreds of different data sources to the Power BI is generated. This specified data will be directly transferred to the Power BI without manual feeding. This automated process not only makes the process much faster but more efficient. The pulling of the required data from the data pool is automated using the in-built functions .

- **Phase 2**

Transformational Analysis of Data

After the extraction of data, it needs to undergo certain transformational steps So that, the value from this raw data can be derived for the use. Data Transformation is a multi-step process where several formulas, rules are defined. Power queries are generated to clean the data. The relationship analysis is done to map out the whole data processing procedure. The interconnections are built between different tables and data sets to regulate the flow of such data values. The predefined procedures are followed, and the requisite information can be then drawn out from the system. In

this phase the connection was built with the excel file as the data source for the Power BI dashboard.

- **Phase 3**

Dashboard creation for data visualization

To examine the results of analysis of data, dashboard is created. A dashboard is an interactive interface which consists of several visual representations such as charts, graphs and tables. Through these visualizations, story is narrated to the target audiences. These dashboards are intuitive in data presentation. The data values can be drilled down by focusing on a single representation. The major feature of these dashboards is that they are customizable, catering to the needs of the different people in the organization. The visualizations were incorporated into the dashboard to measure the progress/status of overall projects, assigned project owners and the timelines defined for each project. The required data modelling and transformation was done to create the progress dashboard for the data analytics automation project on the Power BI desktop.

3.4.4 Verification

Verification includes different steps to undergo:

- a. **Internal Verification:** It is done to determine whether the produced Power BI dashboard conforms with the defined company's regulations, standards, specifications, and terms. This entails an internal review procedure to ensure that the design and development are in accordance with the original criteria and standards.
- b. **Testing and Simulation:** The tests and simulations are run to ensure that the dashboard works as it should. This includes testing the dashboard's data connections, calculations, visualizations, and interactions. The automated refresh cycle is also verified for the Auto-update.
- c. **Review and Analysis:** Here, the verification results for discrepancies, mistakes, and departures from the intended design are examined. Any required modifications and refinements were made to solve any concerns that have been found.

All these Verification steps will be performed through Azure DevOps.

Azure DevOps for verification of Power BI dashboard involves utilizing the Azure DevOps platform to ensure the accuracy, quality, and reliability of Power BI dashboards. It enables teams to automate testing, version control, and collaboration processes for Power BI projects, enhancing the verification of data accuracy, visualization integrity, and overall functionality of the dashboards before deployment. This integration streamlines the verification process, reduces errors, and facilitates seamless collaboration between development and verification teams.

3.4.5 Validation

Alike Verification, Validation is also performed at various levels to ensure the quality and integrity of information to be communicated through these dashboards.

a. User Acceptance Testing (UAT): It involve the target users and stakeholders in testing and providing feedback on the Power BI dashboard. To check to see if the dashboard satisfies their operational specifications and provides the needed information and functions.

b. Suitability Assessment: It is done to determine the dashboard's compatibility with external clients and designated stakeholders and to check whether the dashboard meets their approval criteria and meets their specific needs.

c. Iterative Refinement: It is done to use feedback from users and stakeholders to improve the dashboard and make modifications to improve usability, performance, and alignment with the intended goal.

b. Review and Analysis: It involves examining the verification results for discrepancies, mistakes, and departures from the intended design. To perform any necessary revisions and refinements to solve any concerns that may have been found.

All these Validation steps will be performed through ValGenesis.

ValGenesis is a specialized tool tailored for validating data analytics tools like Power BI and the associated procedures for metrics generation. It offers a structured framework to verify the accuracy and reliability of analytical outputs, particularly Power BI dashboards. ValGenesis aids in documenting, testing, and confirming the processes used to create metrics, contributing to data accuracy and adherence to industry standards. By simplifying the validation process, this tool

supports compliance efforts and bolsters the credibility of analytical outcomes and performance metrics.

3.5 Project 2 Automation in Update Cycle of Divisional Database

3.5.1 Project Description- Divisional Database is an Access database developed exclusively for the PMS team of the T&E Quality Systems which constitutes all the data from various sources related to Complaints ,Product Field Action, NC/CAPA, Sales of the Product and the master data on all the inventory and the products produced by the company.

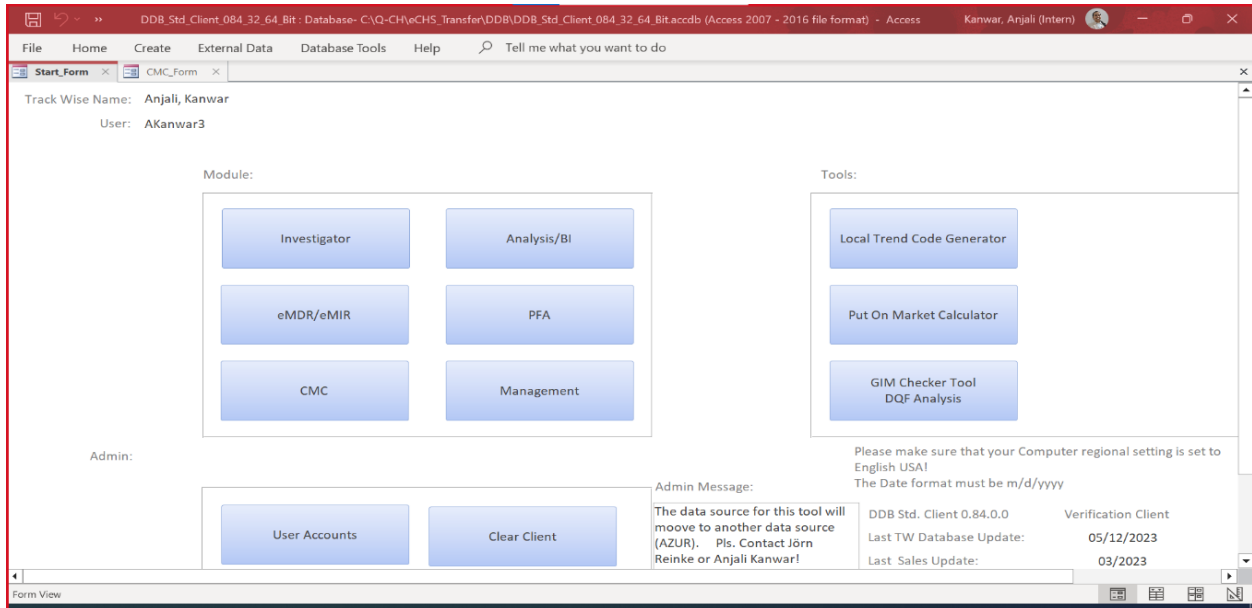


Figure 25 DDB Interface

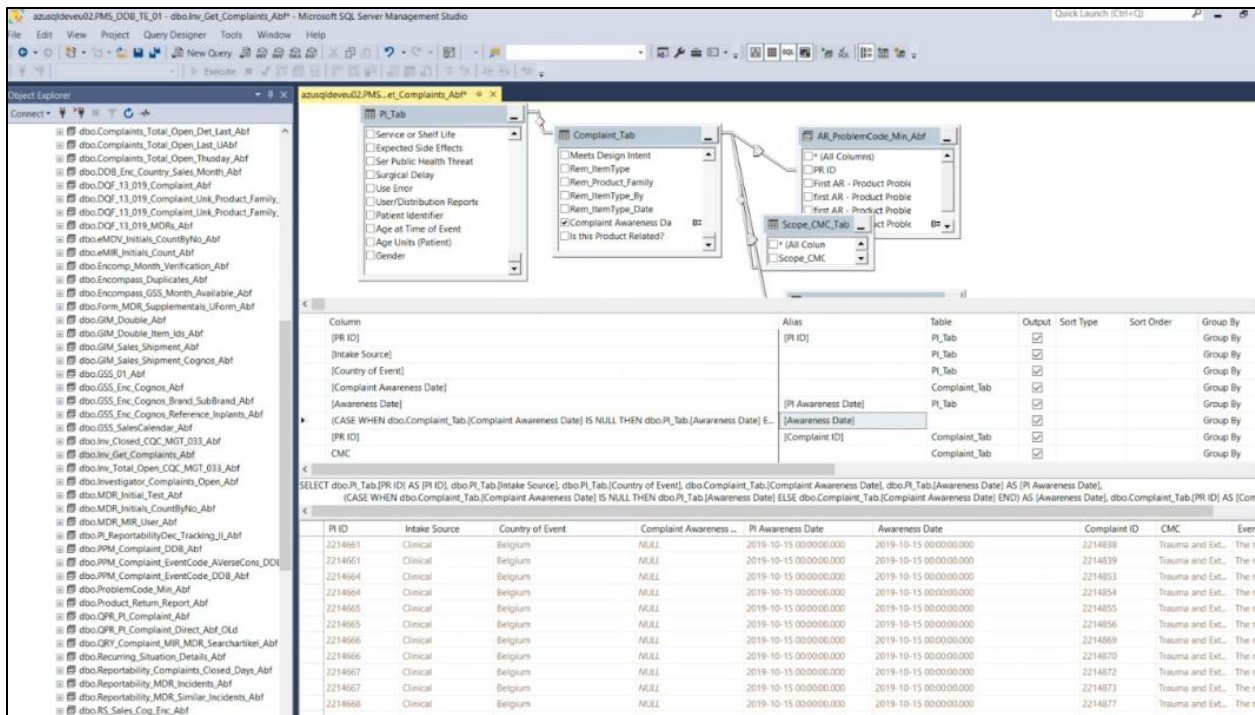


Figure 26 DDB Data Source Connections and Mapping

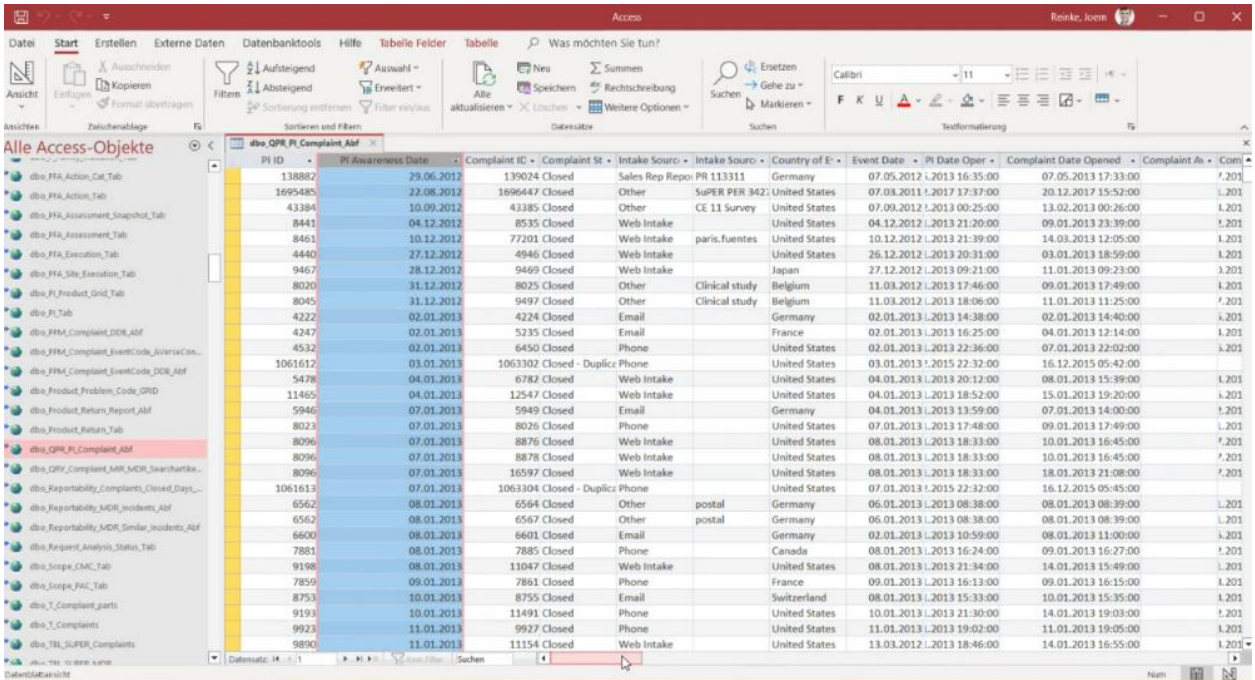


Figure 27 Data tables in DDB

The users of this Database ranges from Data Analytics, Complaint Investigators, Regulatory and Reporting department, and the Upper management to look into the activity and performance of product in the market. The data from this database acts as a primary source for report making in all the work streams in QS.

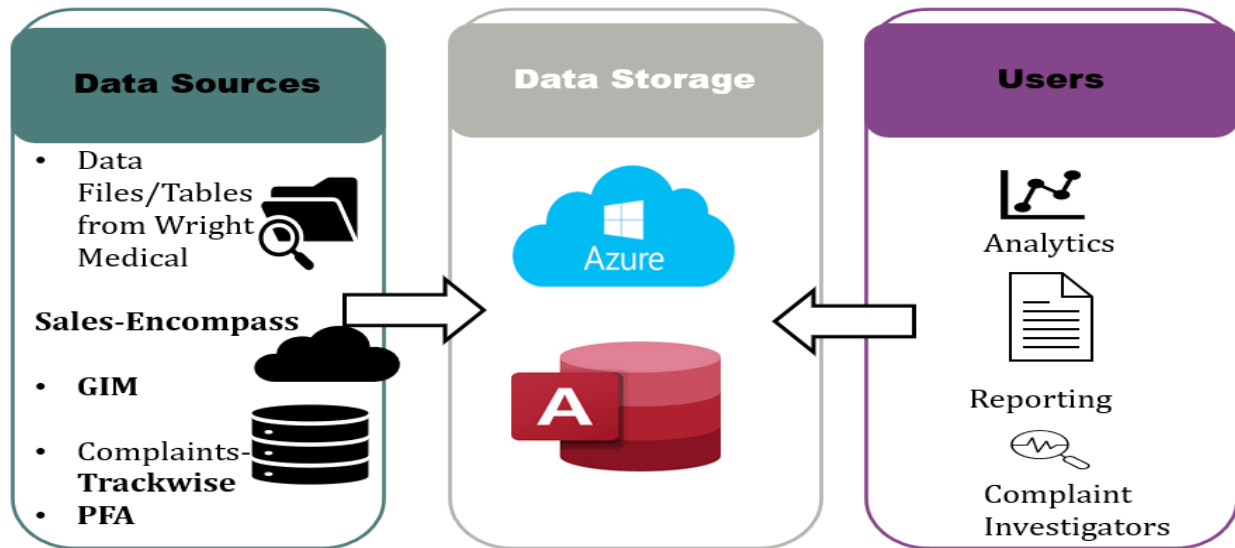


Figure 28 Sources and User group of DDB

As this database is an Access database with its connection to the server, it needs to be updated manually to make the fresh data available to the users for their use. The update process is recurring as well as very time consuming.

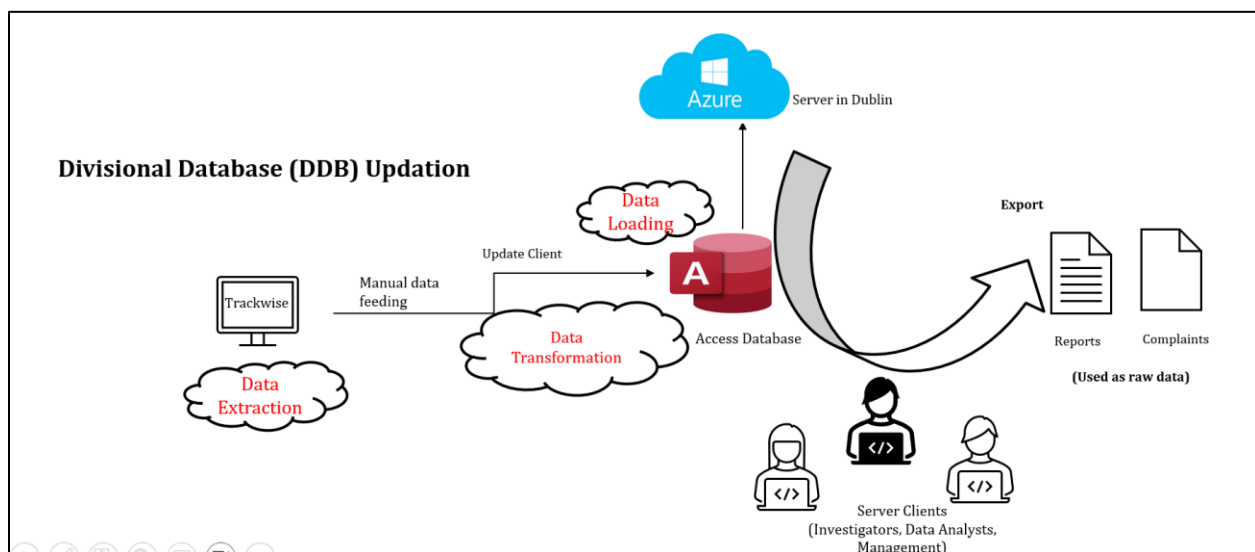


Figure 29 Updation process of DDB

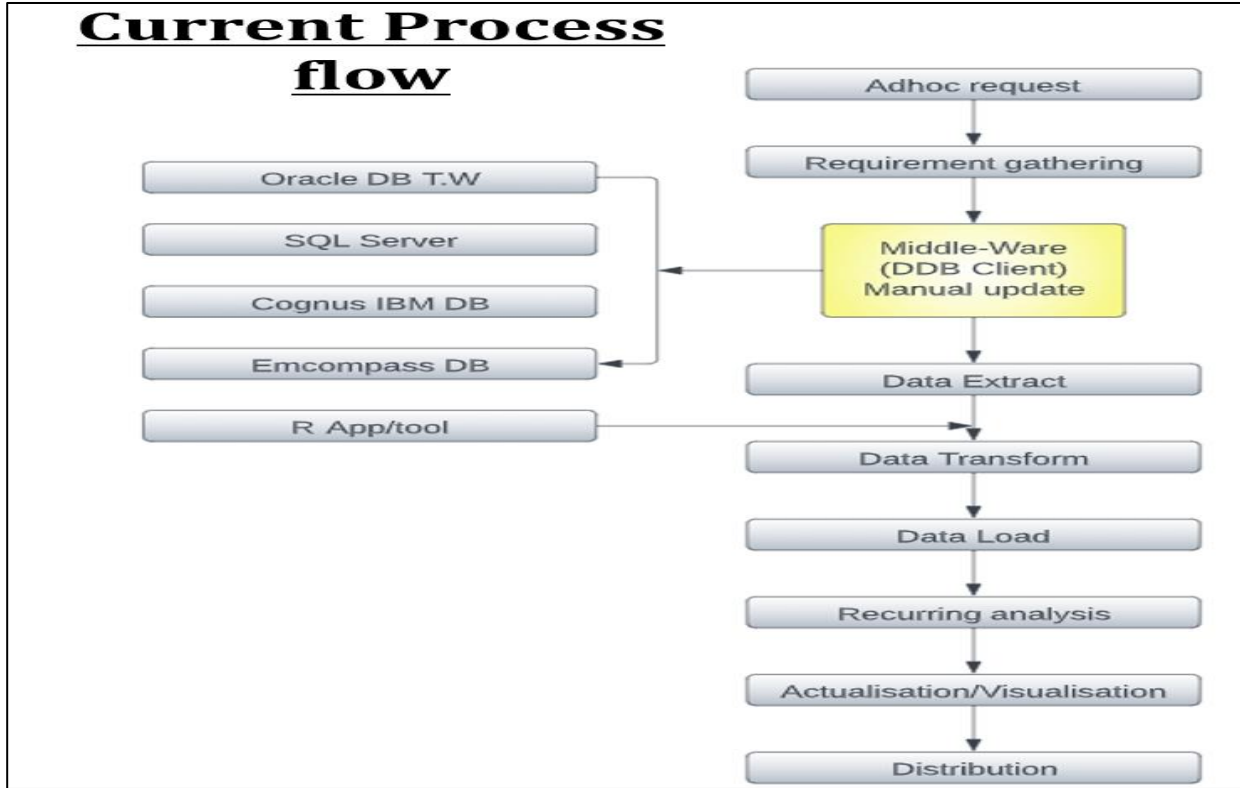


Figure 30 Current Process Flow in DDB

3.5.2 Proposed Solution- As Access database requires the manual downloading and uploading of the documents, it will be a better approach to fetch the data directly from the multiple data sources by building direct connections using new technological tools such as Data Factory and Data Lake.

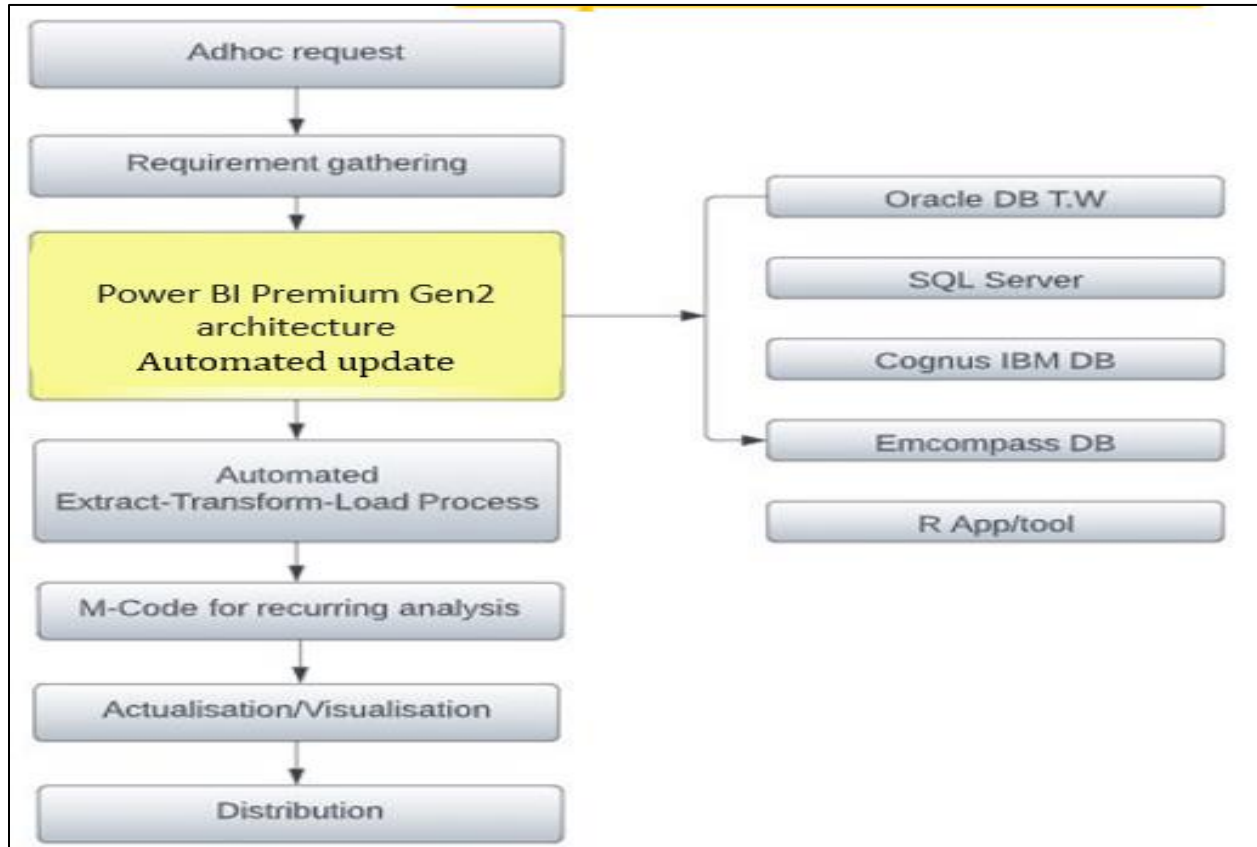


Figure 31 Proposed Process Flow for DDB

The link from the data storage source can be directly established to the Power BI dashboards to visualization the live data and pull-out reports with the fresh data every time.

3.5.3 Data Sources

- **Trackwise** Sparta Systems' TrackWise software is an enterprise quality management solution (EQMS) that acts as a storage for all the Complaints, NC/CAPA, Audit data and aims to optimizes quality, guarantees compliance, and minimizes costs, it is used extensively in a variety of industries.
- **Global Item Master** It contains comprehensive data on an inventory item using item master maintenance. It also consists of the system to store the data on new goods, updating

existing ones, placing objects in various areas, and keeping track of vendor information such part numbers.

- **Encompass** Encompass is a database which keeps a record of all the sales and shipments data of the products sold by the company across the globe. All the sales, import and export information can be fetched from this source about any product or system.
- **Data Files/Tables** These data files and tables are remediated and consists of the archive data from the previous tools and software that have now been decomposed or deactivated. The data from all these sources help to keep the past records of the product.
- **Product Field Action Files-** These files consist of the information on the all the past and recent product field actions performed on the product till date.

3.5.4 Design and Development

Azure Data Factory (ADF) is a managed cloud service designed to organize and operationalize big data data integration and mobility activities. It is capable of handling sophisticated hybrid extract-transform-load (ETL), extract-load-transform (ELT), and data integration tasks [12]

The concept of pipelines, which are data-driven workflows for orchestrating data transportation and transformation, is central to the design of Azure Data Factory. These pipelines can consume data from a variety of sources, both on-premises and in the cloud, and can be scheduled to run daily or triggered by specific events such as file arrivals [24] [25]

To perform data transformations, Azure Data Factory connects with various data stores and computation services. It allows data to be moved between relational, non-relational, and other storage systems. It enables Users can create complicated ETL processes by leveraging computing services such as Azure HDInsight Hadoop, Azure Databricks, and Azure SQL Database.

A data lake is a store for vast amounts of raw data in its natural format. It can handle organized, semi-structured, and unstructured data and is optimized for scaling to terabytes and petabytes of data. Unlike traditional data warehouses, a Data Lake maintains data in its raw, unprocessed form, allowing for greater flexibility in data exploration and analysis [18].

Azure Data Lake Storage Gen2 is a component of Azure Blob storage that offers data analytics capabilities. It supports both file system and object storage paradigms, allowing for simple data

interaction. Data Lake Storage is integrated with Azure Data Factory which interfaces with Data Lake Storage Gen2 to simplify the loading of data into the Data Lake [20].

The following steps are involved in the development process:

1. Connect to and collect data from many data sources, including on-premises and cloud-based systems, with Azure Data Factory. It has pre-built connectors and allows users to design their own connections. Data from these sources is transferred to a centralized location for processing [19].
2. Ingestion and transformation of data: Azure Data Factory enables the building of pipelines that describe data movement and transformation logic. To process and convert the data, users can utilize visual data flows or compute services such as Azure HDInsight, Azure Databricks, and Azure SQL Database. Data is loaded into Azure Data where it is stored as raw data.[19]
3. Data exploration and analysis: Users can examine the data stored in Azure Data Lake Storage Gen2 by creating queries and performing various analytics jobs. Azure Data Lake Storage Gen2 is designed for high-throughput data intake and can manage massive amounts of data for processing and analysis. [20].

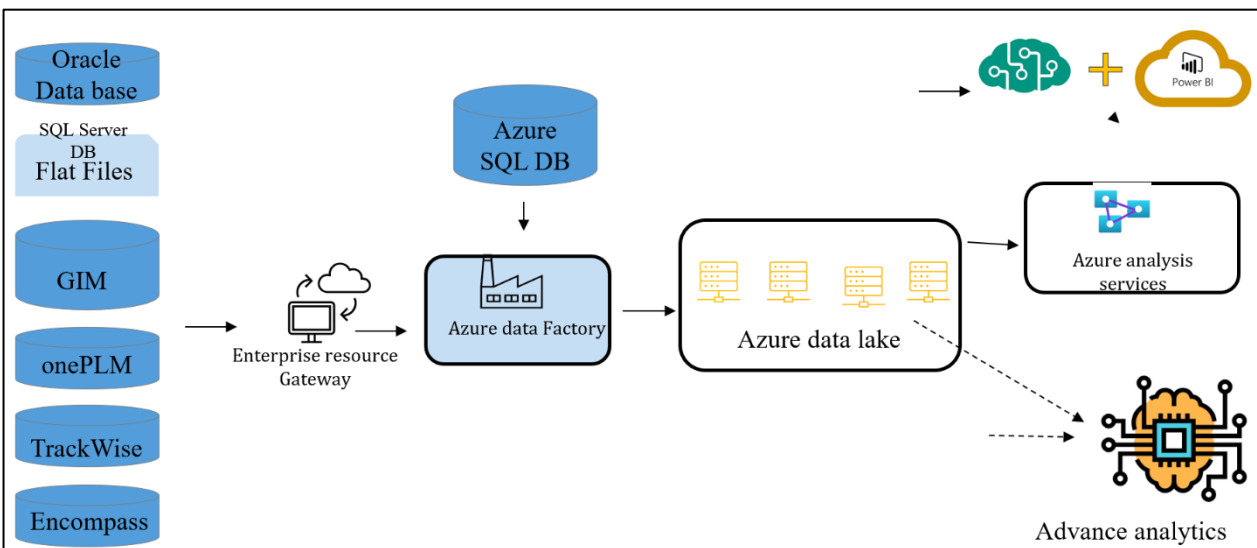


Figure 32 Flow of data from different sources in Azure Data Lake

4. Data consumption and reporting: Data that has been changed and processed can be consumed by downstream applications and services. The converted data may be published

to data stores such as Azure Synapse Analytics or linked with Power BI desktop for business intelligence (BI) applications to generate reports and draw insights for enhanced decision-making [[26].

For organizing and processing massive data, Azure Data Factory and Azure Data Lake together offer a complete solution. It enables businesses to derive insights from unstructured data, promotes data-driven workflows, and enables the large-scale integration and transportation of data.

3.5.5 Verification and Validation

The steps to verify and validate (V&V) the results of the newly built data connections will vary depending on the user requirements. The process of verifying and validating the PRODUCTION data connections is ongoing and the work has been undergoing to strategize the processes to follow for V&V.

Chapter 4 Results

4.1 Creation of Power BI based Project Tracker

In this case, the Project Tracker Dashboard was created and all the KPIs and visualizations helped in easy tracking and keeping a record of the completed, ongoing and pending projects under the Quality System Automation Project. The direct link with the data sources will automatically update the dashboard in case any latest information is entered or updated.

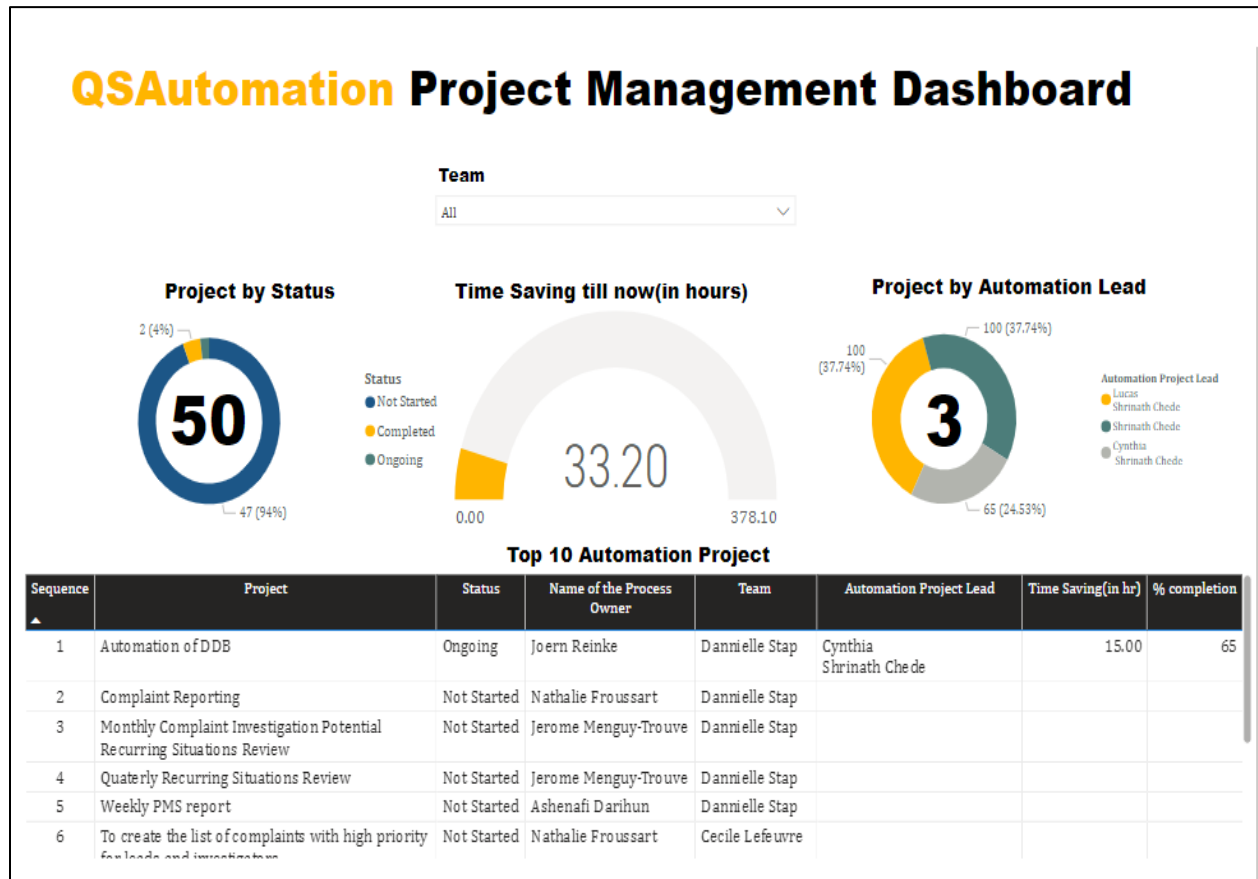


Figure 33 Dashboard for QS Automation

Resources

Project: All Automation Project Lead: All

Team: All Name of the Process Owner: All

Sequence	Project	Automation Project Lead	Start Date	End Date	Status	Name of the Process Owner	Time Saving(in hr)
1	Automation of DDB	Cynthia Shrinath Chede	16/1 /23	30/06/23	Ongoing	Joern Reinke	15.00
2	Complaint Reporting				Not Started	Nathalie Froussart	
3	Monthly Complaint Investigation Potential Recurring Situations Review				Not Started	Jerome Menguy-Trouve	
4	Quaterly Recurring Situations Review				Not Started	Jerome Menguy-Trouve	
5	Weekly PMS report				Not Started	Ashenafi Darihun	
6	To create the list of complaints with high priority for leads and investigators				Not Started	Nathalie Froussart	
7	Internal team that will provide a accuracy to external Regulatory Bodies.				Not Started	Anna Jusinski	
8	Rectification required before approving				Not Started	Yilka	
9	Show Compliance and progress with actions				Not Started	Thomas Karle	
10	KPI reporting				Not Started	Pawel Barycza	
11	Report training Compliance rate and inform users of open trainings.				Not Started	Tinka Mihova-Luedi/Jiten	
12	IQA form Automation,Power BI is used to display relevant data				Not Started	Mireille Laval	
13	1.) Daily Update Sheet onePLM 2.) ECR/ECN Report 3.) CIDT				Not Started	Evelyne Sanchez/Mathulan	
14	QPQR XXXX-QX				Not Started	Michael Proietto Plaza	
15	Route and Release documentation, prints, labels, BOMs, etc.				Not Started	Miranda Sanchez	
16	Gathering metrics data for documents that have been processed through				Not Started	Star Dowell	

Figure 34 Data visualization regarding multiple Projects

4.2 Automation of the Divisional Database

Building direct connections with the live data sources is a huge task which requires granting of a lot of access information and rights. After the data start flowing through the pipelines, which have been built to create Data Lake. This Data Lake can function as a sole source of data for every team. Rather than connecting and accessing the data and information from multiple sources, Data Lake will become the only source of data for all type of reports and dashboard creation.

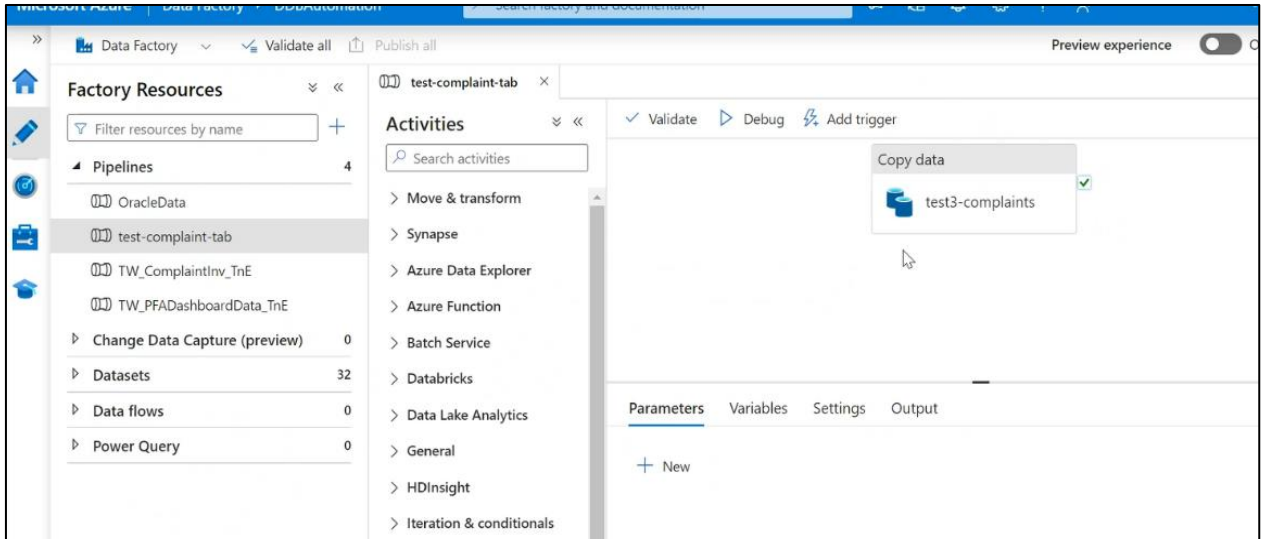


Figure 35 Data Factory Interface

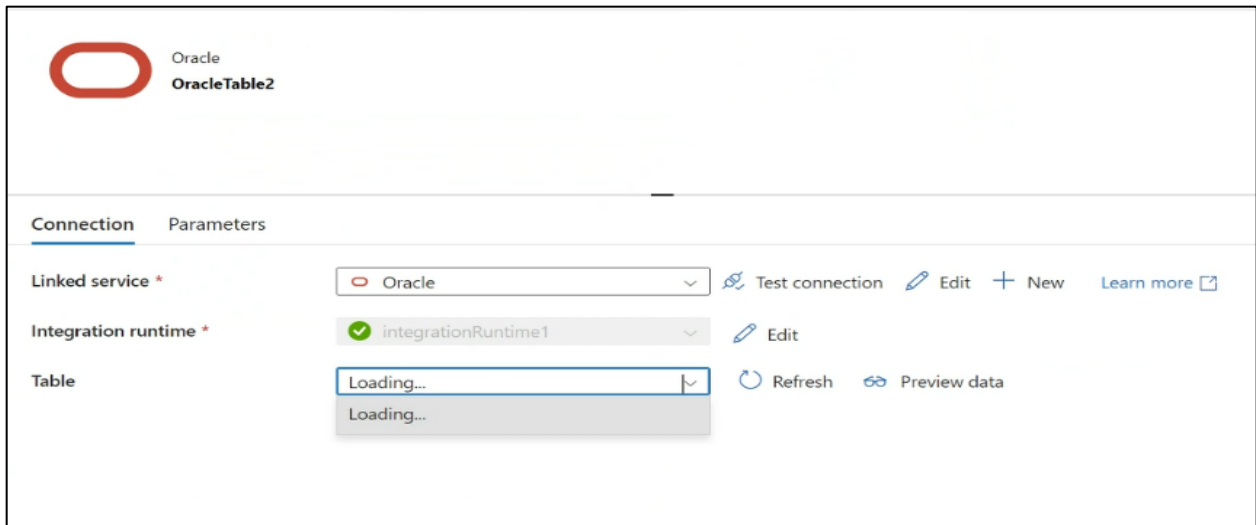


Figure 36 Database Connection Setup

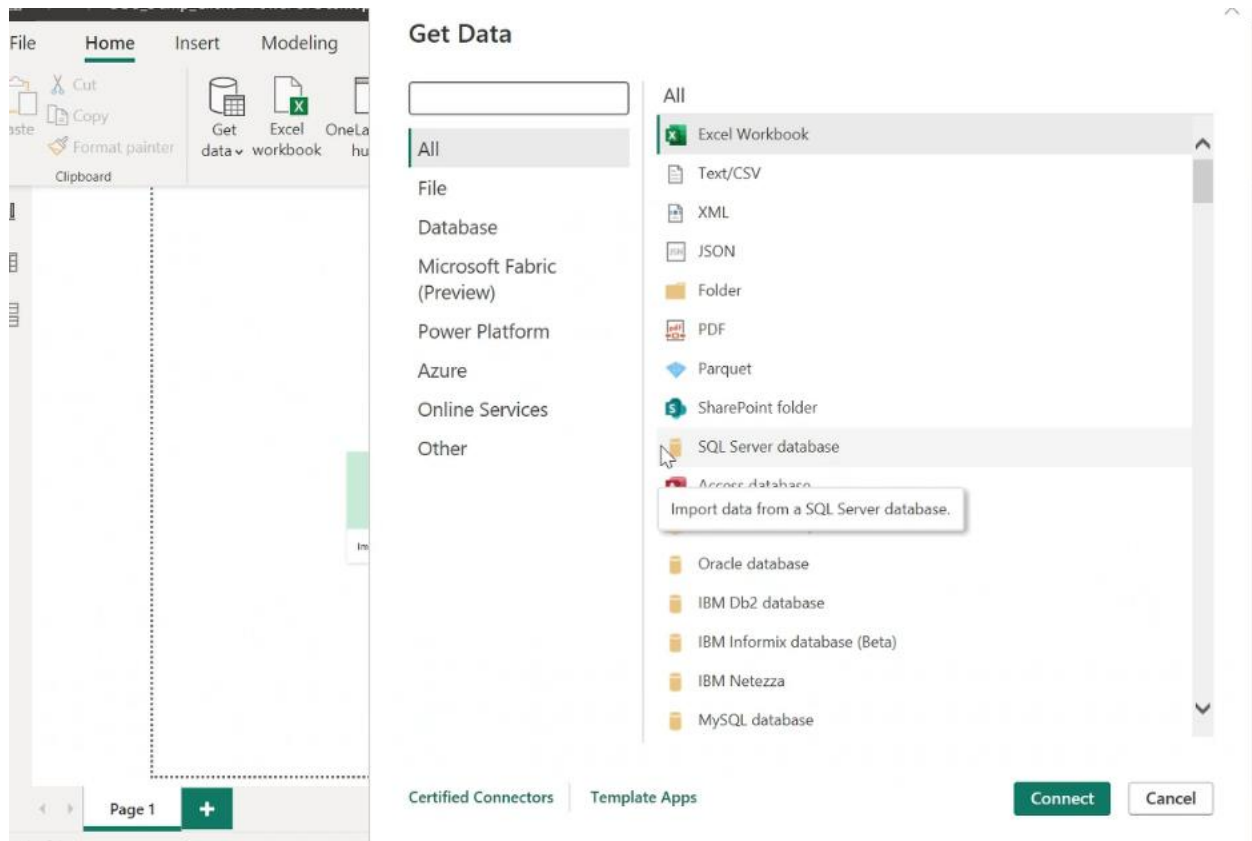


Figure 37 Power BI data connection setup

The Connection set up link the data sources.

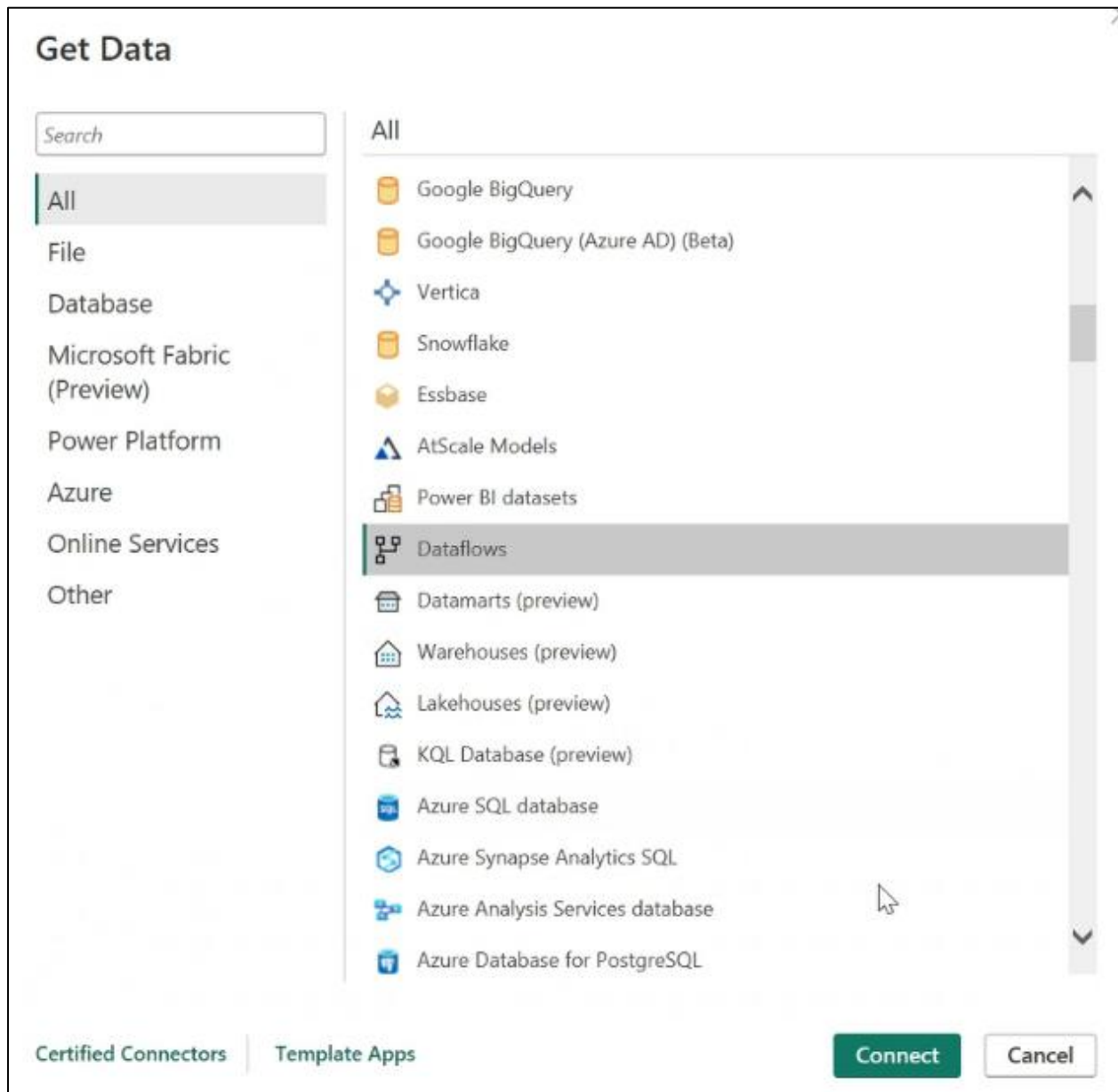


Figure 38 Selection of Data sources

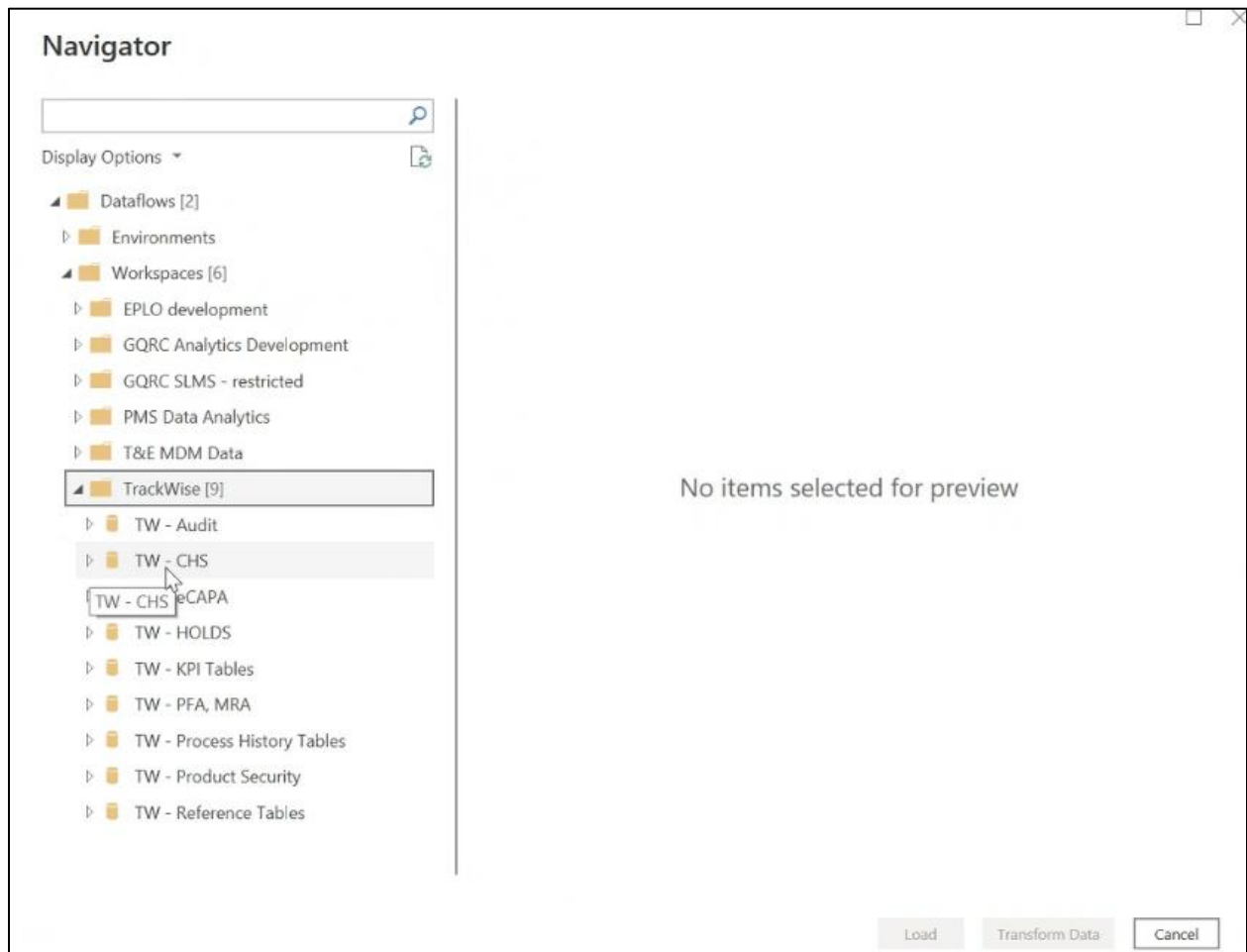


Figure 39 Selection of Data Tables from Sources

Navigator

Display Options ▾

- GQRC SLMS - restricted
- PMS Data Analytics [7]
- T&E MDM Data [3]
- ▾ TrackWise [9]
 - TW - Audit
 - ▾ TW - CHS [6]
 - trackwise comp_mv
 - trackwise comp_sv_grid_flex
 - trackwise emdr
 - trackwise emir
 - trackwise pi_sv
 - TWAER/Country Submissions
 - TW - eCAPA
 - TW - HOLDS
 - TW - KPI Tables [9]
 - TW - PFA, MRA
 - TW - Process History Tables
 - TW - Product Security
 - TW - Reference Tables

trackwise comp_sv_grid_flex

COMP PR ID	PI PR ID	COMP CURRENT STATE	COMP CMC
2180385	2180347	Closed	Joint Replacement-Robotics
2388738	2387618	Closed	Instruments
2258274	2256948	Closed	Instruments
2161905	2161904	Closed	Medical - Redmond
2136140	2135974	Closed	Medical - Kalamazoo
2214869	2214666	Closed	Trauma and Extremity
2188603	2188484	Closed	Medical - Redmond
2134718	2123587	Closed	Joint Replacement-Implant Instruments
2134718	2123587	Closed	Joint Replacement-Implant Instruments
2134719	2123587	Closed	Joint Replacement-Implant Instruments

i The data in the preview has been truncated due to size limits.

Load Transform Data Cancel

Figure 40 Data Tables in Power BI to be transformed.

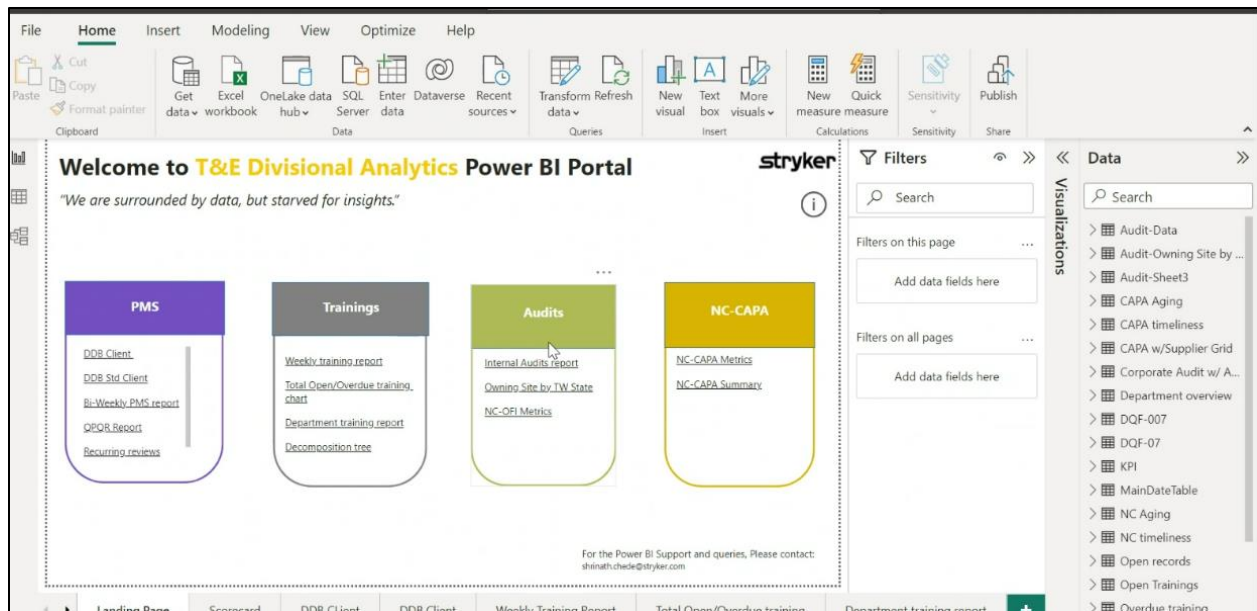


Figure 41 Prospective Power BI dashboard with DDB

In conclusion, the Power BI-based Project Tracker deployment brought immediate benefits, while the ongoing automation of the Divisional Database project holds promising possibilities for improved data management. These solutions show the organization's dedication to employing modern technologies and automation for improved project tracking and data-driven decision-making.

As the automation of the Divisional Database project progresses, it is anticipated that it will contribute to increased efficiency, data accuracy, and streamlined processes. Ultimately, the successful completion of this project will lead to a more robust and integrated data management system, benefiting the organization as a whole. data-driven landscape.

Chapter 5 Conclusion

Finally, by implementing the development of a Power BI-based Project Tracker and establishing the early phases of automation for the Divisional Database (DDB) project, this thesis has successfully met its objectives. Within the Quality System Automation Project, these technologies have showed substantial potential in terms of increasing data tracking, accessibility, and reporting.

During the initial survey that was done, around 300+ manual hours/week of work has been identified with the capability, by using the current architecture, showed that almost 70% of those manual steps can be automated. These 300+ hours saved will not help in raising financial benefits but also will impact the resource benefits. Along with resulting in empowering sustainable business development.

The Project Tracker Dashboard solution has given an effective and user-friendly platform for project tracking and management. The addition of key performance indicators (KPIs) and visualizations has made it possible to easily monitor project progress. The direct connection to data sources enables real-time updates, which keeps the dashboard up to date, providing current status.

The Divisional Database project's continued automation efforts have begun to yield prospective benefit. The project intends to expedite data management operations and provide a single source of data for reporting and dashboard generation by establishing direct linkages with live data sources and establishing a Data Lake. While the Divisional Database project is still in development, it is vital to recognize the progress done thus far and the prospective influence on data accessibility and management. The creation of data pipelines and the early stages of the Data Lake provide the framework for future improvements.

Moving ahead, additional efforts will be necessary to properly finish the Divisional Database automation project. Continuous monitoring, testing, and refinement will be required to guarantee that the automated procedures are effective and efficient. Regular review and communication with stakeholders will aid in the resolution of any issues and the alignment of the project with changing requirements.

Chapter 6 Summary

This thesis investigated the use of automation tools, such as Power BI, to improve project tracking and data management inside the Quality System Automation Project. The objectives are met by developing a Power BI-based Project Tracker and integrating additional automation tools. The Project Tracker Dashboard monitors and visualizes project status in real time, allowing for more effective tracking and administration. Furthermore, the use of other automation technologies, such as Power Automate, Power App and other Office 365 tools, helps to streamline operations and improve data accuracy and accessibility, whilst Divisional Database Automation attempts to expedite data management operations by establishing direct linkages with live data sources and creating a consolidated Data Lake. Implementing these solutions improves data accessibility, accuracy, and reporting capabilities. Ongoing efforts in the Divisional Database automation project show hopeful signs of progress. For successful completion and refinement, ongoing monitoring, testing, and cooperation with stakeholders are required. The findings of this thesis contribute to the organization's dedication to data-driven decision-making and project management efficiency.

Chapter 7 References


1. [Online]. Available: <https://emeritus.org/in/learn/what-is-data-analytics/>.
2. [Online]. Available: <https://www.dasca.org/world-of-big-data/article/automated-data-analytics-how-when-and-why>.
3. "Deloitte Automated Reporting," [Online]. Available: <https://www2.deloitte.com/cz/en/pages/strategy-operations/solutions/automated-reporting.html>. [Accessed 2023].
4. "Skill shift: Automation and the future of the workforce| Discussion Paper," McKinsey Global Institute, May 2023. [Online]. Available: <https://www.mckinsey.com/featured-insights/future-of-work/skill-shift-automation-and-the-future-of-the-workforce> [Accessed 2023].
5. "UI Path Impact Report," [Online]. Available: https://assets.ctfassets.net/5965pury2lcm/34eNwerswtEXifQUFh2Vn9/bda459f4c874b409c519ef564cd2c1d2/UiPath_2021_Impact_Report.pdf. [Accessed 2023].
6. "Nintex Process Discovery, UI Path Finder Report," 2019. [Online]. Available: <https://www.nintex.com/wp-content/uploads/2019/05/451-Research-Pathfinder-Report-May-2019.pdf>.
7. S. S. Beygenov, "Audubon Data Project Final Report.," 2018.
8. M. Zisman, "Office automation: Revolution or evolution?" 1978
9. Gordon, "Workflow automation for a virtual hypertension management program.," *Applied Clinical Informatics* pp. 12(05), pp, 2021.
10. N. Xiaochun, " Workflow Automation and Management in the Real Estate Office Automation System.," in *Third International Symposium on Intelligent Information Technology Application Workshops* (pp. 322-324). IEEE., 2009.
11. K. A. Nanda, "Workflow Automation of Routing Rules in the Accounting Process for Online Travel Agency," in *2021 9th International Conference on Reliability, Infocom Technologies and Optimization (Trends and Future Directions, 2021, September*.
12. D. e. Tsihrizis, "Office automation: concepts and tools.," Springer Science & Business Media., 2012.
13. [Online]. Available: <https://learn.microsoft.com/en-us/power-automate/getting-started>.

14. M. Pearson, " Introduction to power automate. Pro Microsoft Power Platform: Solution Building for the Citizen Developer," pp. pp.73-78, 2020.
15. S. a. C. S. Critchley, "Dynamics 365 Essentials: Getting Started with Dynamics 365 Apps in the Common Data Service," Power Automate. pp. pp.507-524, , 2020. .
16. Amvrossiev, " Automation of the Microsoft's Office programs.," 2018.
17. Vojdani, "Tools for real-time business integration and collaboration," IEEE Transactions on Power Systems, pp. pp.555-562., 2003.
18. N. "A systematic literature review on intelligent automation: Aligning concepts from theory, practice, and future perspectives.," Advanced Engineering Informatics, vol. 47, p. p.101246., 2021.
19. S. S. Sharma, "Applications, Tools and Technologies of Robotic Process Automation in Various Industries," in 2022 International Conference on Decision Aid Sciences and Applications (DASA), Chiangrai, Thailand, 2022.
20. "Agile Methodology," [Online]. Available: <https://www.atlassian.com/agile>)
21. [Online]. Available: <https://powerbi.tips/2020/12/power-bi-architecture-in-a-data-solution/>.
22. [Online]. Available: <https://data-flair.training/blogs/power-bi-architecture/>.
23. "Azure Automation Overview," Microsoft, [Online]. Available: <https://learn.microsoft.com/en-us/azure/automation/overview>.
24. "Microsoft Azure," [Online]. Available: <https://learn.microsoft.com/en-us/azure/automation/overview>.
25. " Automate document processing by using Azure Form Recognizer," Microsoft, [Online]. Available: <https://learn.microsoft.com/en-us/azure/architecture/example-scenario/ai/automate-document-processing-azure-form-recognizer>.
26. <https://www.cxtoday.com/data-analytics/gartner-magic-quadrant-for-analytics-and-business-intelligence-platforms-2023/>

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Analysis of Quality Data Automation for Business Efficiency and Sustainability

Introduction

Stryker is a US based multinational corporation that is considered as one of the noteworthy medical technology companies in the world. Founded by an orthopedic Surgeon by profession, Dr. Homer Stryker in 1941, Stryker has garnered a big name in the field of Orthopedic Implants with the extended use in Knee, Hip Surgeries along with the surgeries related to Trauma accidents. The Stryker also offers varied range of innovative neurovascular products, medical devices, patient handling and emergency medical equipment, surgical equipment, endoscopy devices and biologics. Stryker classifies its reporting into three distinct business segments for reporting purposes: Orthopedics, Medical and Surgical (MedSurg), and Neurotechnology and Spine.

The Orthopedics segment primarily offers implants for hip and knee joint replacements, as well as products for trauma and extremity surgeries.

In the MedSurg segment, Stryker provides a range of surgical equipment and surgical navigation systems (Instruments). They also offer endoscopic and communications systems (Endoscopy), patient handling and emergency medical equipment (Medical), and a variety of medical device products used in different medical specialties.

Stryker's Neurotechnology and Spine segment offers a comprehensive portfolio of neurosurgical and neurovascular devices. Their neurotechnology products are designed for minimally invasive endovascular techniques, traditional brain, and open skull base surgical procedures, as well as orthobiologics and biosurgery products, including synthetic bone grafts and vertebral augmentation products. Furthermore, they develop minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke.

With the mission of making the healthcare better alongside their customers, Stryker has been running its operations in 75+ countries around the globe and having an ownership of more than 12,000 patents globally.

Quality Management holds an utmost importance in any Medical Device Company and Stryker is no exception in that.

According to Stryker's Quality Policy, Quality is first in everything they do.

1.1 Introduction to Quality System

The Quality System at a medical device company is critical for assuring compliance, maintain safety, managing risks, driving continuous improvement, and promoting overall customer satisfaction. These quality operations are managed by the business' operations and efforts to ensure quality systems departments.

Annie

Schede

Anjali

