# Cloud Connected Analytical Instruments

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## Exploring an Innovative Architectural Design Model for Cloud-Connected Instruments

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# Abstract

Modern laboratories house a diverse array of analytical instruments, frequently across various locations. This poses challenges in providing centralized monitoring and management of these instruments. Cloud-based solutions are becoming more prevalent as they provide a means to integrate distributed data sources securely.

This paper presents an architectural design model that leverages cloud technology to securely connect distributed analytical instruments. It discusses the various integration issues arising from connecting different types and generations of instruments. Benefits accrue in terms of integrated visualization and management across all instruments for real-time data, alarms, test methods, test results, calibration tracking, consumables tracking, utilization tracking, remote diagnostic capability, upgrades, servicing, etc. Designing a common abstraction that works across generations of different types of instruments is a key challenge. A plug-and-play approach that minimizes separate custom software modules is desirable. Authorization and security need to be built into all layers to ensure traceability and immutable test results. A carefully chosen architecture can avoid the pitfalls in future extensibility and scalability.

The authors constructed a prototype solution that is hosted on the AWS cloud. This provided a platform to examine and verify the promise of the cloud in analytical instrument integration. Key results from this investigation are presented.

# Introduction

According to a recent market analysis report by the IMARC Group (2023), the global analytical laboratory instrument market is projected to reach around USD 69.2 Billion by 2028, with a growth rate (CAGR) of 6.89% from 2023-2028 [1].

Laboratory owners often manage numerous instruments in their laboratories across locations. They could be situated in laboratories in multiple cities or manufacturing units in different countries. The laboratory stakeholders can monitor the instruments at a specific site but cannot monitor the instruments across several sites. They have access to location-specific data but do not have access to the data from different locations. This isolated data results in a myopic view of their laboratory data landscape.

A design approach that seamlessly connects these laboratory instruments via on-premises or cloud servers will offer an integrated solution with multifaceted benefits. It will allow the laboratory stakeholders to centrally monitor physical laboratory instruments at different sites from one place, leveraging cloud computing technology if necessary for secure storage and real-time data analysis, and it will give the laboratory stakeholders accurate insights and a centralized and complete view of their laboratory data landscape.

# Challenges of Analytical Laboratories

Efficiently managing a modern analytical laboratory poses numerous challenges, spanning operational issues, efficient data management hurdles, instrument maintenance and tracking, skill development, sample and consumable tracking, and ineffective collaboration. This study focuses on analysing selected challenges in detail to facilitate the development of a common platform aimed at addressing some of these key issues as comprehensively as possible.

## Monitoring Laboratory Data from Multiple Instruments

Skilled technicians are required to operate and maintain laboratory equipment effectively. These laboratory equipments are often complex and diverse. Laboratory technicians have to run analytical experiments and procedures across multiple instruments simultaneously and use control software for managing, monitoring, and calibrating these instruments and running sample analysis, recording their results.

Hiring knowledgeable resources can be challenging for many laboratories. This may lead to extended work pressure on the existing technical workforce, resulting in improper analysis, waste of samples and other consumables, avoidable breakdowns, etc [2].

## Laboratory Owners Disconnect from Their Laboratories' Activities

Laboratory owners and managers need to stay connected with their laboratory activities to understand operational situations and potential risks as quickly as possible. Owners of multiple laboratories require both consolidated and individualized information. However, physical presence for real-time tracking is often impractical. Even if feasible, sifting through large amounts of data often poses a challenge.

The lack of timely relevant information deprives laboratory owners and managers from taking informed decisions. This often results in obscuring critical information, leading to avoidable operational breakdowns and losses.

## Inadequate Knowledge-Sharing Among Laboratory Technicians

In an analytical laboratory, outlier analytical data, events, errors, and their resolutions need to be effectively shared with peers and stakeholders. Best practices also need to be kept in sync among senior scientists and laboratory technicians. However, critical information often remains confined to a limited group and can hinder the wider circulation of experience gained within the laboratories or across multiple laboratories of the same group.

This lack of collaboration can affect efficient teamwork within individual laboratories or distributed groups, leading to missed opportunities for sharing insights and problem-solving solutions [3].

## Inadequate Management and Monitoring of Instrument Calibration

Ensuring high-quality and consistent analytical results requires proper instrument calibration, often involving regular repeatability and reproducibility tests. Calibration may be required before specific sample runs, or they may have to be run periodically for some instruments. In some cases, calibration failures can be further analysed to assess deviations and may be used to identify certain root causes of failures, as needed.

However, this holistic information is often unavailable to laboratory managers. This can lead to flawed analysis results and loss of time, samples, consumables and even instrument downtime.

## Effective Tracking of Instrument Breakdown & Maintenance

Throughput is crucial for the operation of an analytical lab, and this relies on, among other things, the instrument's efficiency, and its uninterrupted availability. If historical records of instrument breakdown and maintenance are easily accessible, they can aid in creating effective maintenance plans and cut down on instrument downtime. However, the lack of such structured data can hamper proper maintenance planning and taking certain preventive actions to counter failures, increasing the risk of repeated avoidable breakdowns [4].

## Easy Management of Methods Across Instruments

Method preparation in analytical laboratories is generally governed by strict protocols. They involve the iterative cycle of drafting, testing, refining, re-testing, and then finally publishing the methods for sample analysis. This process often requires versioning of methods during this process. The task of updating the correct methods across multiple instruments in different locations may also be a labour-intensive process.

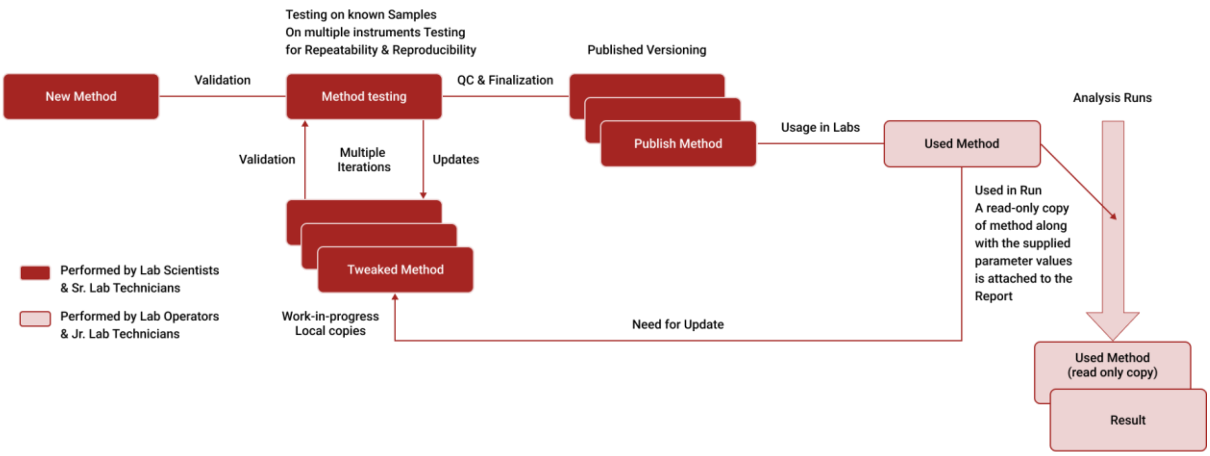


*Figure 1: Method Lifecycle*

Regarding storage, the methods of stand-alone instruments are stored within the instrument's file system or database and are generally transferred between instruments using external drives like USB flash drives. Although unique method names exist within a single instrument, identical method names may exist across different units of the same instrument.

In the case of PC-based instrument control software, methods may also be stored on the connected PC's filesystem or database. Without networked connectivity, however, managing identically named methods or publishing one method to multiple instances of control software across multiple instruments or PCs may still become challenging.

The same may be the case for instrument configuration as well.

## Integrating Instruments with Diverse Interface Protocols

In modern analytical laboratories, there is typically a diverse array of instruments, spanning from simple measuring scales to complex devices such as GC and LC-MS. These instruments implement a diverse range of data connectivity interfaces for communication with external systems.

To integrate data from these diverse instruments, laboratories may require different third-party tools and solutions, which is a challenge when it comes to gathering a comprehensive set of data from all laboratory instruments.

Besides traditional LIMS and ELN solutions, there are a few applications that can consolidate all information into one platform. For the LIMS software, the emphasis predominantly lies on laboratory information management for the LIMS-enabled instruments.

## Data Security Outside the Laboratory Environment

Laboratory data must be securely managed according to the organization's data security policy. This necessitates access control mechanisms and data access levels. Also, when sharing data outside the laboratory, such as for troubleshooting reviews by instrument manufacturers, the data must be appropriately masked and anonymized to protect sensitive and proprietary information about the laboratory, instrument parameters, methods and the end client.

# Key Strategies

To address the challenges outlined in the preceding section, Tismo identified three primary strategies aimed at improving the efficiency and effectiveness of instruments and laboratory operations, which can be achieved through the use of modern software infrastructure.

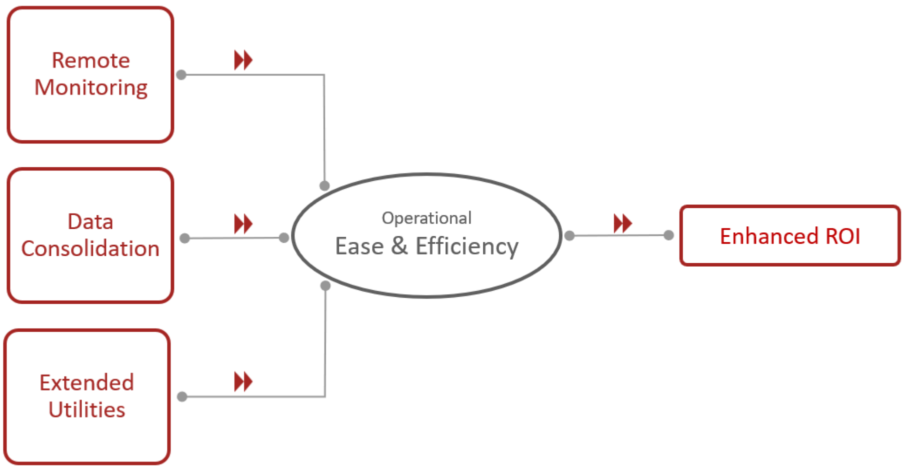


*Figure 2: Key strategies for enhancing operational efficiency*

## Remote Monitoring and Management

Laboratory personnel should possess the capability to access data remotely from any location, further evolving into a comprehensive, real-time overview of instrument activities and health.

## Holistic Data for Informed Decision-Making

Laboratory managers and stakeholders need to have access to consolidated data generated from their laboratories. This can help them run correlations, perform root cause analysis with more parameters, and use them for informed decision-making.

## Providing Utilities for Operational Efficiency

Laboratory personnel should have access to some tools and utilities which can reduce repetitive manual work and help them avoid inadvertent manual errors, which in turn are likely to increase operational efficiency.

# Benefits of Connected Laboratories

To achieve the key objectives, Tismo performed an analysis of the various processes of an analytical laboratory to identify areas and aspects where the effects of digital connectivity solutions can deliver the maximum benefits while rendering minimum impact on the actual process flows of the instruments and the laboratories.

This can be considered to be a non-invasive solution for the laboratory and instrument, as any process changes may result in the revalidation and recertification of the whole system.

The diagram below describes the information flows that are considered within the scope of this solution and applicable to any typical analytical instrument.

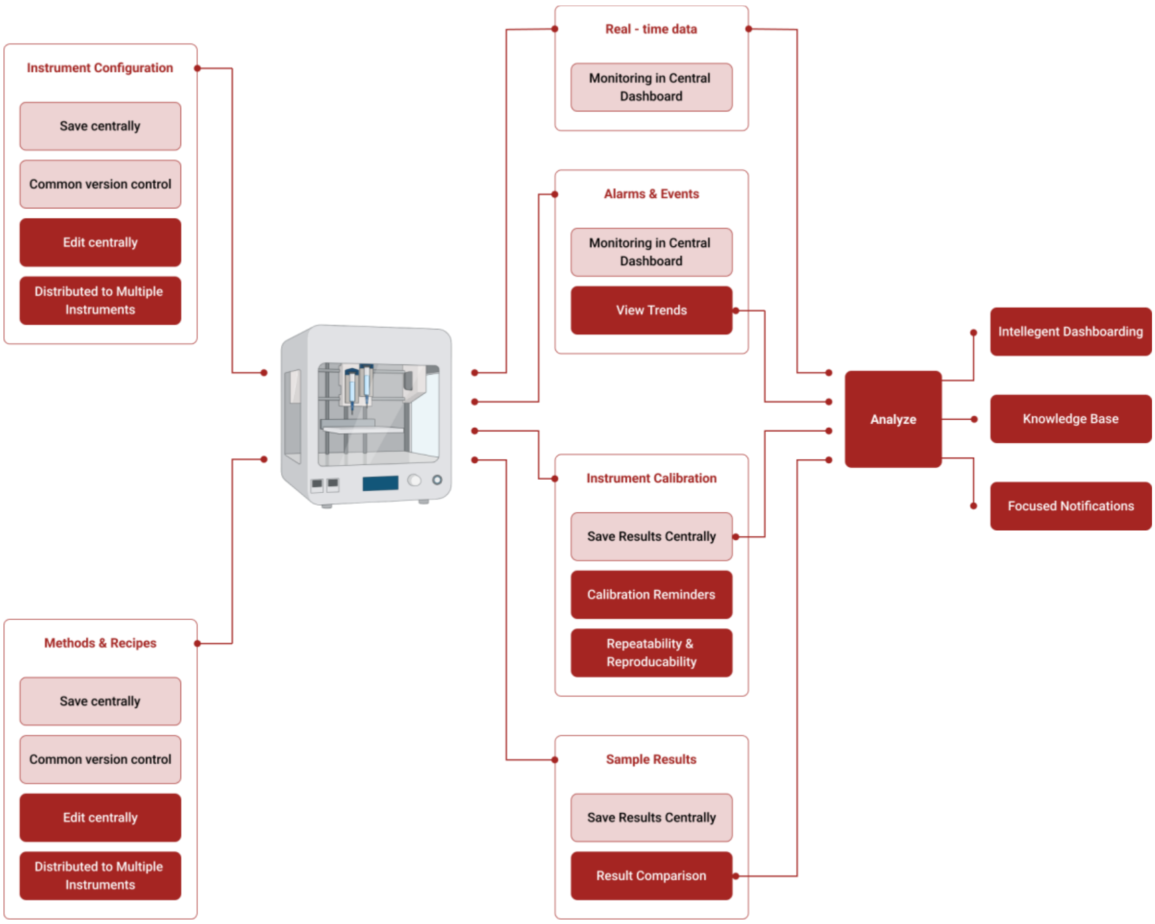


*Figure 3: Aspects of an Analystical Laboratory benefiting from a connected solution*

The functionalities depicted in light red indicate areas where basic benefits can be achieved with relatively easy generic handling of the information.

The functionalities depicted in dark red indicate advanced functionalities that can be added as custom implementations, requiring a relatively longer effort but delivering much higher levels of benefits and return on investment for the stakeholders.

# Tismo's Cloud Connect Approach

Tismo's proposed Cloud Connect approach is a software solution which addresses some of the hurdles discussed in the earlier section. Taking inspiration from the industrial IoT scenario, this approach envisions the implementation of a software solution that enables connecting diverse analytical instruments in a laboratory into a central system, keeping into consideration the specific process, topology, and security aspects of the analytical industry. This model attempts to support a host of key features, based on the availability of the digital interfacing options of the target instruments. It starts with a default implementation and offers a custom plugin-based approach to ensure the extendibility of features based on the end customer's needs.

On one hand, the model integrates the laboratory data into a central server, allowing laboratory technicians to monitor, review and manage various aspects of the varied instruments of the laboratory from one portal. On the other hand, the model also allows group operations encompassing tasks such as uniform applications of configuration, method sharing, maintenance scheduling, and software upgrades across multiple similar or related instruments. Access to all features shall be dictated by the user's access rights, ensuring security and control over instrument management activities and access to instrument data.

## Remote Management Using a Central Dashboard

A real-time dashboard can allow lab personnel to instantly view all relevant data from the connected instruments. As a result, comparatively fewer laboratory personnel will be able to keep an eye on the status of more instruments and can attend to the needs of the instruments when needed.

Real-time dashboards may additionally provide the option for each instrument to be partially controlled if it is allowed within the process. This implies that users do not need to be physically present in front of the instrument and can remotely perform minor instrument controls. This improves operational flexibility and efficiency, particularly when quick or minor adjustments are needed.

To guarantee usefulness and simplicity of navigation for all users, the dashboard might be created with a uniform generic flow for all instruments. Such dashboards can reduce the learning curve for users of all expertise levels by offering standard layouts, formats, and user interfaces for commonly monitored instrument parameters, as well as encouraging intuitive interaction. By centralizing the monitoring activity and providing real-time insights, these dashboards can optimize resource usage, and enhance the total productivity and operational efficiency of the laboratory.

## Alarm and Event Notifications

A solution that can notify laboratory stakeholders to receive immediate alerts and events for the instrument can ease the task of monitoring multiple analyses running in the laboratory and reduce the risk of possible instrument downtime. The consolidation of such data improves the laboratory's ability to quickly react to breakdowns, take prompt corrective actions, and bring in operational efficiency.

A system that can store the instrument alarms over time can also enable laboratory managers to analyse the trends of past alarms and events and use this information to investigate the root causes of failures.

## Central Method and Configuration Repository

A central repository can provide laboratory personnel with a safe and secure platform to store, organize and maintain instrument methods and configurations. Having all the methods of related instruments in one location also helps in easier tracking of this key component required for analysis runs.

Proper access control of the repository ensures that the instrument methods are viewed or edited by authorized personnel only, and these can be used in analysis runs only if they are published after proper review, qualification and approval.

The central repository can also version control the methods. This can help in tracking the changes made to the methods over time. Specific business logic can be built into the system to highlight the changes between two method versions, which can be helpful during the method creation process or when optimizing methods.

Transfer of methods and configurations between similar instruments can become easier and safer since the method can be transferred to a newly connected instrument from the central repository directly without the need to manually create new copies of the method or to copy the methods from one instrument to another using pen drives.

Given the complexity of the structures of some instrument methods, custom developed method screens can be provided by the system for creating and editing methods specific to the instrument.

Like methods, instrument configuration can also be handled the same way by providing a central configuration repository. This is especially helpful if there are multiple instruments of the same type in the laboratory that have similar configurations.

## Common Result Viewer

A comprehensive analysis result viewing module can add value to laboratory personnel.

Results from different similar instruments can be easily compared to assess the consistency and reliability of the analysis, especially using standard samples.

The central result viewing utility can also help in collating the results of similar samples into related result groups for easier dispatch to end clients. Such result groups can provide a holistic view of the sample's characteristics as analysed on multiple different instruments.

Providing a central place to perform result exports into PDF, CSV etc. can help in the process of uniformly branding results or exporting data for further analysis of the results in spreadsheets or other tools from one place.

## Effective Utilization of Log Data

Retention and easy access to logs of instrument events like configuration changes, error messages, and system events can result in early detection of a wide range of trends and frequent process lapses, which have the potential to create eventual failures.

Combining this data with similar information from other instruments in the laboratory brings insights into even bigger operational issues that the laboratory may be facing. Information like chronic delays in instrument calibration or regular occurrences of alarms not getting resolved in time for multiple instruments may highlight lapses in the process adherence itself.

## Remote Software Upgrade and Service Schedulers

All instruments may not require software upgrades which require re-qualification and extended follow-up processes. For such instruments, a centrally managed software update utility can potentially streamline the overall process of software updates for all connected instruments. With this approach, instead of manually updating the instrument software one by one, whenever there is a software upgrade, the model can automatically inform the relevant instruments to upgrade their software from a centrally predefined repository and on confirmation by authorized laboratory personnel, the software upgrade process can be triggered by the central system. This can save valuable time and ensure that the instrument software always stays up to date.

Central software modules can also track the past service dates for each instrument and notify the laboratory personnel and, if allowed by the laboratory's process norms, the instrument manufacturer as well, when the subsequent service due date approaches.

## Health Monitoring and Remote Diagnostics

The software can provide the technician with the option to switch on or off sensors (like temperature sensors, and pressure sensors) or LED lights, to open or close valves or gates, to turn on the buzzer and so on, to manually check if the hardware peripherals are working as expected.

This software module can display the instrument details like model name, serial number, firmware version, software version, etc. If relevant, battery-related details like capacity, voltage, current, temperature, and cycle counts can be displayed.

The system can also remotely display the connection status of different components in the system, the health of these components, and the performance of the system as well. This value-added feature will allow the instrument manufacturer to monitor the instruments' critical operating parameters, proactively respond to issues and remotely diagnose issues with the connected instruments. This will ensure minimal downtime for the instruments.

The instrument manufacturer can improve the quality of their instruments through failure analysis. At the same time, the laboratory's measurement data will remain secure and inaccessible to the instrument manufacturer due to role-based access restrictions.

## Predictive Maintenance

The software can be designed and developed to continuously monitor the relevant data of critical instruments over time and to establish a baseline parameter for the normal operation of the instrument. Any subsequent anomalies or deviations from this baseline can then be detected by the software and reported as potential issues. These can be typically relevant for instruments that run repetitive processes 24x7.

Predictive algorithms trained based on large volumes of data may also be intelligent enough to predict when an instrument is likely to fail or malfunction. This will be based on patterns and trends found in a large volume of historical data. When a potential issue is identified, relevant alerts and notifications can be generated based on the severity of the issue and recommended actions.

the model can be further extended in future to incorporate embedded anomaly detection intelligence within the Data Capture Agents by the use of Rule-based Algorithms or ML at Edge. This will reduce the data traffic outside the laboratory environment while enabling a quicker overall response time.

Predictive maintenance will help reduce downtime, avoid disruptions to ongoing work and save costs.

## External Software Access

The solution can have the ability to enable third-party software clients to access the centralized data by exposing well-documented, application programming interfaces (REST APIs). This client-server communication will be stateless and will support TCP over HTTPS.

# Proposed Implementation

We propose the Tismo Cloud Connect solution to improve laboratory operations with a plug-and-play strategy, reducing dependence on external software components. This approach enables lab staff to customize their working environment by choosing capabilities that meet the unique needs of their instruments.

## Architecture

The following diagram provides a top-level view of the overall software architecture of the system.

The blocks in light red represent the core module.

The blocks in dark red represent the interface layers.

The blocks in white represent components which are outside Tismo Cloud Connect.

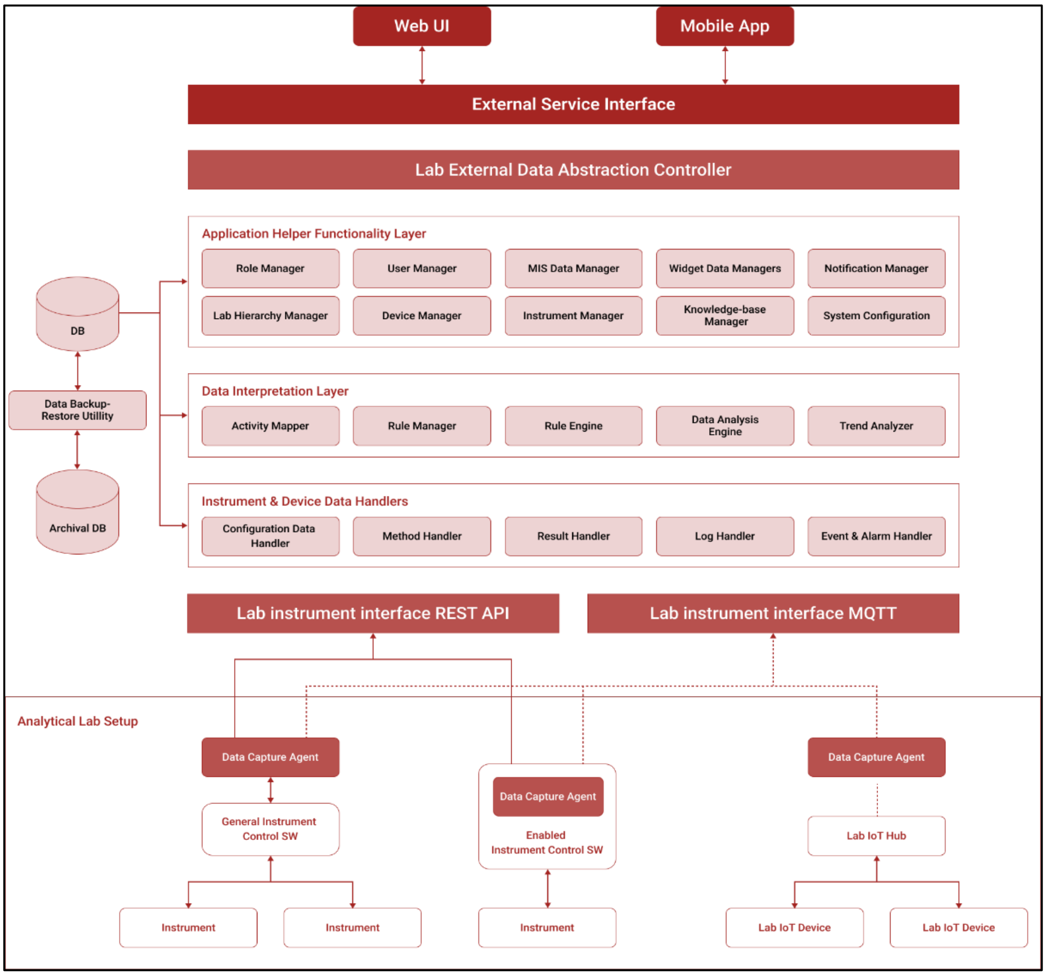


*Figure 4: Connected Instrument Solution Software Architecture*

## Data Acquisition Agents

Within the Tismo Cloud Connect solution, the role of data-gathering agents is pivotal for the efficacious extraction of data from the control software of laboratory instruments. These agents utilize a variety of methods to adapt to the specific capabilities of each Instrument Control Software (ICS). These methods encompass serial/TCP outputs, API (Application Programming Interface) calls, and CSV (Comma-Separated Values) data dumps, tailored to interface effectively with the ICS's functionalities such as reading log files, executing API calls, and accessing databases of the instruments.

To facilitate seamless data transmission to the Tismo Cloud Connect server, a specialized communication library will be developed. This library serves as a critical interface, channelling data from a diverse array of instruments to the server. It effectively packages data into a format compatible with cloud-based storage, ensuring both standardization and security in data transfer processes. Furthermore, it addresses the complexities associated with maintaining secure and abstract communication channels between the laboratory instruments and the Tismo Cloud Connect communication layer, thereby underpinning the integrity and efficiency of data transfer within the proposed solution.

# Core Application Layer

## Lab Instrument Interface Layer

The laboratory instrument interface layer manages a diverse array of data types, encompassing real-time statuses, readings, events, and alarm data from laboratory instruments. This layer encapsulates incoming data into a standardized format, assigning unique identifiers and timestamps before routing the data to designated queues for subsequent analysis.

Furthermore, this interface layer processes various data categories, including analytical results, instrument configurations, and methodological data, directing these to specific endpoints tailored for each data type. These endpoints facilitate the intake of data by the Data Gathering service, operating on the instrument side to streamline data input processes.

Central to the laboratory instrument interface layer are two primary mechanisms of communication: the REST (Representational State Transfer) API, WebSockets and MQTT (Message Queuing Telemetry Transport). The REST API is engineered to aggregate a wide spectrum of data, ranging from instrument results, methods, and log data to integration with Laboratory Information Management Systems (LIMS) and Electronic Lab Notebooks (ELN). It is particularly adept at managing real-time data, including events and alarms. Conversely, the MQTT and WebSocket interface specializes in the rapid transmission of high-volume real-time data, such as events, alarms, and sensor readings from various laboratory instruments. It efficiently channels this data into distinct queues, focusing on distribution rather than processing.

## Instrument Data Handler Layer

The instrument data handler layer is tasked with the processing and storage of a wide range of data types emanating from analytical instruments. This layer is composed of specialized services designed to handle distinct data types, including events, results, configurations, method data, and instrument logs. Each service is equipped with capabilities for queue monitoring, data processing tailored to specific instrument requirements, and storing data with appropriate identifiers.

**Service-specific Functions**

- **Real-time parameter and event data handler**: This service focuses on processing real-time event data, which is then stored in the instrument event table. It facilitates the aggregation and dissemination of event information for notification and further analysis via designated communication channels.
- **Configuration Handler:** The configuration handler is responsible for managing data related to instrument configurations, ensuring it is stored alongside detailed metadata that includes the instrument type and identifier. This functionality is augmented by the ability to create custom plugins for specific instrument types, which improves centralized configuration management.
- **Result Handler:** This service oversees the management of result data from a variety of instruments, depositing it into the instrument result table complete with relevant metadata. It is adept at accommodating the variance in data structures across different instruments, runs, and configurations, with support for raw data parsing provided by UI plugin components.

- **Method Handler:** Dedicated to processing and storing method data in the instrument method table, this service incorporates instrument metadata and versioning details. It enables method-specific data processing and supports raw data parsing through UI plugins.

- **Log Handler:** The log handler service is tasked with recording data into the instrument log table. It does so without processing the raw log data, thereby ensuring a comprehensive record of instrument activities is maintained.

## Data Interpretation Layer

The data interpretation layer analyzes, contextualizes, and aggregates data, besides generating alarms based on predefined conditions and ensuring the storage of this processed information for subsequent utilization.

**Component Services and Their Functions**

- **Activity Manager:** It is central to the recording of various activities, such as instrument configurations and method executions. It archives this information in the instrument activity table, accompanied by comprehensive metadata that encompasses the instrument type, identifier, activity type, and date. The meticulous organization and storage of this data are fundamental for the generation of diverse reports, offering invaluable insights into laboratory operations.

- **Rule Manager:** Tasked with the management and implementation of business rules. This organization not only simplifies the retrieval and amendment of rules but also underpins crucial decision-making processes. By evaluating rules and initiating custom events and alarms, the rule manager facilitates proactive management and response strategies within the laboratory environment.

- **Rule Engine:** Its function is to assess rules against incoming data or events, thereby determining compliance. This evaluation process is pivotal in identifying deviations from expected parameters and enabling timely interventions and adjustments.

- **Trend Analysis Service:** It collates data across various instruments and activities and transforms raw data into actionable insights. This service is critical for the generation of reports and the development of insights, aiding in the identification of trends and patterns that can inform strategic decisions and operational improvements.

## Application Helper Functionality Layer

The application helper functionality layer orchestrates the business logic inherent to the Tismo Cloud Connect's Lab Service Interface layer. This layer comprises several key services, each dedicated to specific aspects of laboratory and data management:

- **User Manager:** This service is tasked with the management of Tismo Cloud Connect users, including their authentication and authorization processes, ensuring secure access to the system.

- **Role Manager:** Overseeing the assignment and management of user roles within the system, the role manager ensures that users have appropriate access levels according to their responsibilities.

- **Notification Manager:** Responsible for the orchestration of system notifications, this manager ensures timely communication of alerts and updates to users.

- **MIS Data Manager:** This service handles the organization and management of Management Information System (MIS) data, facilitating the oversight of laboratory operations and administrative information.
- **Lab Hierarchy Manager:** Managing the structural hierarchy within individual laboratories or groups of laboratories, this service focuses on the organization of locations and procedural frameworks.
- **Instrument Manager:** Dedicated to the oversight of laboratory instruments, this manager ensures their proper maintenance, calibration, and operational readiness.
- **Device Manager:** This service manages laboratory environment sensors, such as temperature and humidity monitors, supporting the correlation of instrument performance with environmental conditions.
- **Knowledge-Base Manager:** Offering a repository for managing a knowledge base, this service provides users with access to common errors, resolutions, and best practices specific to the laboratory and its instruments.
- **Widget Data Manager:** Handles the customization and management of widgets, including their configurations and data mappings, enhancing the user interface and experience.
- **System Configuration Manager:** Oversees the management of various system configuration details, ensuring the system is tailored to meet the specific needs and workflows of the laboratory.

## External Service Interface Layer

The external service interface layer facilitates data integration with Web UI and mobile platforms, presenting detailed information about instruments, including their status, configuration, methods, and real-time parameters. This layer provides access to Application Programming Interfaces (APIs) for core functionalities, encompassing authentication, and user and instrument management, and supports integration with third-party authentication services such as Google and Microsoft. This interface is structured into two distinct sublayers to optimize data flow and management:

- **WebSockets Sublayer:** Employed for managing high-throughput data streams, this sublayer is designed to handle real-time data such as alarms, events, and instrument parameters efficiently. WebSockets enable a continuous, bidirectional communication channel between the client and the server. They facilitate the immediate transmission of data updates and notifications.
- **REST APIs Sublayer:** Focused on handling requests for authentication, user and role management, and instrument management, as well as retrieving results, methods, and system configuration information. REST APIs provide a stateless architecture, making them ideal for requests that require processing resources, data retrieval, and modifications across a distributed environment.

## Central Database

The central database organizes and stores a diverse array of data crucial for application functionality, lab operations, and instrument management.

**Application-Specific Data:**

- User Data
- User Roles
- Rule Configuration
- Notifications
- Application Settings

**Lab and Instrument Management Data:**

- Laboratory Information
- Instrument Details and Types

**Instrument Operational Data:**

- Results and Methods
- Configuration and Log Entries
- Event, Instrument Parameters, and Activity Records
- Alarm Notifications

**Management Information System (MIS) Data:**

- Trend Analysis Data

## Web UI Layer

The Web UI Layer fulfils a dual function within the system architecture, catering to both general functionalities and instrument-specific capabilities. It handles authentication, authorization, and the management of instruments. To accommodate a wide range of user preferences, it offers sign-in capabilities through Tismo Cloud Connect or via third-party authentication providers, enhancing accessibility and security.

It follows a modular design, featuring predefined components dedicated to the display of data such as events, alarms, and detailed instrument parameters. Additionally, it enables developers to design custom viewers tailored to the unique requirements of different instruments. This flexibility is achieved through plugin-based UI components, allowing for dynamic adaptation to various instrument configurations. The system intelligently loads the relevant plugins for each component, ensuring that users have access to a customized and relevant interface based on the specific context and requirements of their tasks.

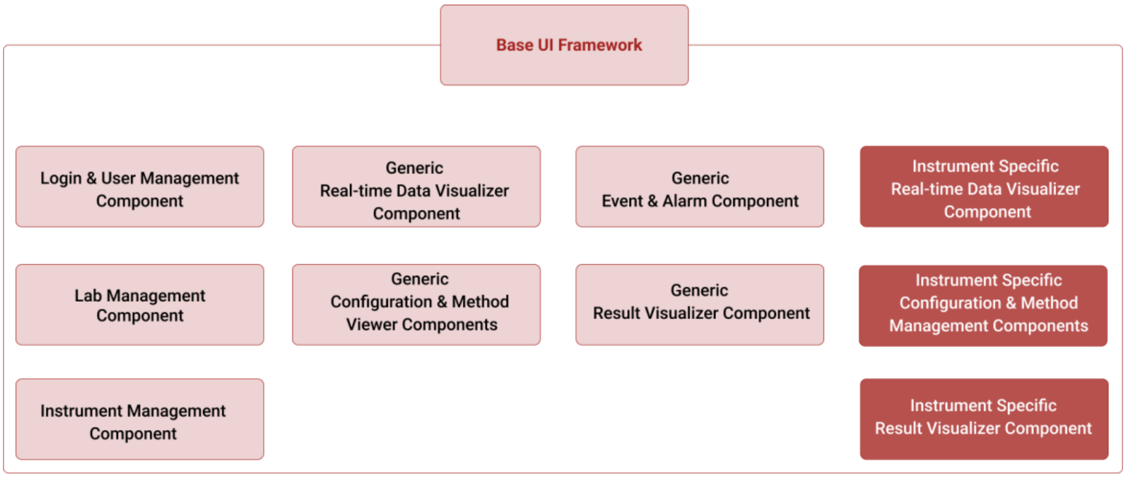


*Figure 5: Overview of UI layer with common and custom components*

In the overview diagram of the UI layer above, the light red components represent the generic components which will be available by default and the dark red components are examples of specific UI plugin implementations which can be additionally custom developed for specific instruments.

## Data Security

The proposed solution can be a combination of private and public clouds, hosted on the intranet and the internet, and, if required, can be a hybrid deployment. This will further control access to sensitive data outside the lab. Key data elements, especially instrument details, configuration and method details, results etc., can be encrypted both in the communication channel and at rest. Since the final result is not real-time data, the overall system's performance will not be significantly impacted.

For cloud-based deployments, the solution will conform to established cloud safety and data management practices, including:

- The application of SSL encryption for API requests and secure data exchange across the lab network encrypts all transmitted data to prevent interception and alteration.
- The deployment of MQTT authentication with a user ID and password for secure instrument-to-server communication ensures that only verified devices can engage and share data.
- The implementation of strategies to prevent SQL injection safeguards the central database against harmful intrusions and ensures that only legitimate queries are executed.
- The management of Cross-origin resource sharing (CORS) policies to block unauthorized requests to safeguard web resources from external vulnerabilities.
- The enforcement of stringent access controls on the database.
- The introduction of role-based access control will limit access to sensitive data, allowing only staff with appropriate clearance to access or alter confidential information.

## Cloud Deployment

This proposed server solution can be hosted on a Linux or a Windows server. Keeping in mind the support for on-premises and cloud-agnostic approaches, the overall server architecture enables the application to be deployed in a Docker container. It can be deployed securely either on the laboratory premises or on the cloud in Elastic instances or Container services.

Based on the product owner's preference, the system can also be developed as a cloud-specific solution, e.g., Amazon Web Services (AWS), taking advantage of full serverless architecture.

- Cloud-hosted MQTT brokers will route the instrument data to the server.
- Lambda functions will typically handle the business logic and communicate with the rest of the system using the AWS SQS service for message queuing and the AWS SNS service for notification.
- External interfaces for REST services and WebSockets will be handled by AWS API Gateways.
- For data storage, any preferred AWS database like RDS or DynamoDB can be used, and AWS S3 service can be used for scalable, durable storage for file-based resources.
- AWE Elastic Cache can be used as an in-memory cache for quick retrieval of frequently used data.

- AWS Cognito can be used for user management, authentication & authorization.
- The overall system's performance and application logs can be monitored using AWS CloudWatch.

The counterparts of each of these services are available on Microsoft's Azure and the solution can be developed in the Azure Cloud as well. The selected deployment will be tailored to meet the product owner's requirements.

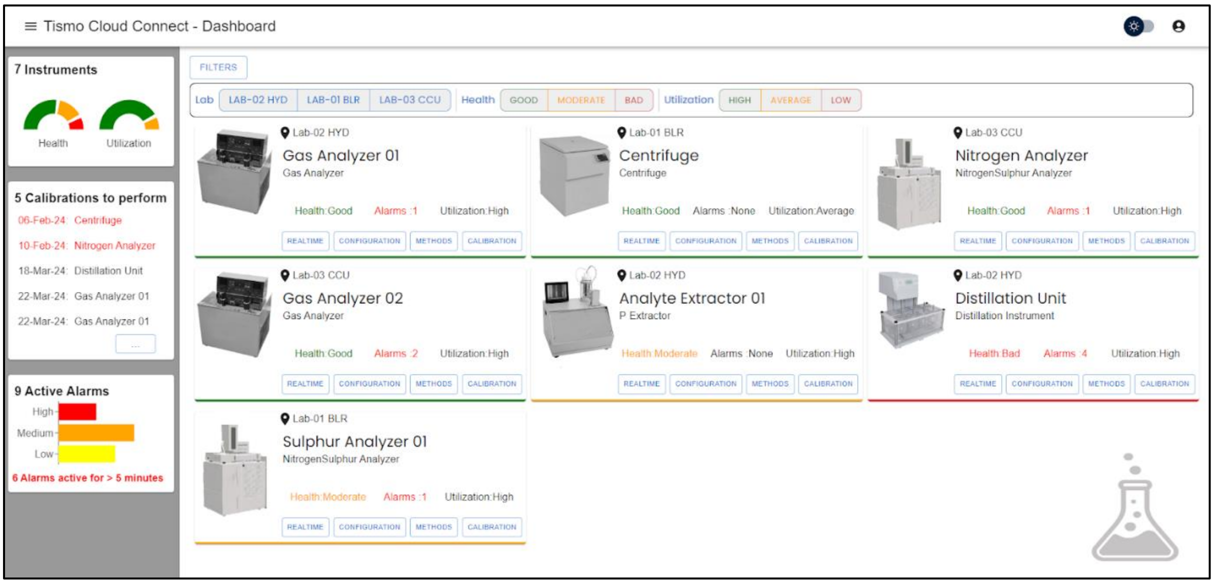


*Figure 6: Tismo's Cloud Connect Application Dashboard*

# Future Scope

The proposed Tismo Cloud Connect solution allows laboratories to customize certain modules and functionalities to align with their specific operational needs. Beyond the capabilities discussed in the previous sections, there is also the scope to develop certain capabilities, based on a laboratory's needs, to adapt the system to fit into the laboratory's current practices. A few of these are outlined below:

## Remote Instrument Control Capability

Remote instrument control, allowing technicians or managers to start, pause, or stop analyses, acknowledge alarms etc., from any location, can be added only if it is safe to control the instrument remotely. For example, remote control may be a requirement to stop a process in an emergency.

## 21 CFR Part 11 Compliance

The main tenet of the FDA's 21 CFR (Code of Federal Regulations) Part 11 is to ensure the authenticity and integrity of electronic records from the point of their creation to the point of their receipt and to ensure that the signatures cannot be transferred to falsify an electronic record (CFR, 2023). This model is designed to comply with the requirements of 21 CFR Part 11 related to user access control, user authorization, workflows, audit trails, and availability of records.

The data will be protected from being altered by unauthorized users. All alterations made by authorized users will be tracked. Electronic signatures will be linked to records through the user's printed name, the timestamp and the roles of reviewer and approver. For e-signatures, each combination of user identification and password will be unique, and they will be revised at regular intervals to prevent password aging.

Standard, 21 CFR Part 11 compliant audit trails will be generated. They will capture the history of user actions like adding, modifying, deleting a method, calibration, running a sample analysis etc. The user action will be displayed along with the timestamp and the name of the user who acted.

# Conclusion

Tismo's Cloud Connect model utilizes modern technologies to securely connect instruments across locations using the external interfaces exposed by them, acquire data and make them available to remote users using intuitive visualization and role-based secured access for further analysis and actions. This model is designed to handle multiple types of instruments and multiple instruments within each type. It will also provide the ability to share data seamlessly between different locations, maximizing efficiency and promoting better collaboration. The goal is to streamline the process of instrument monitoring and enhance overall visibility and control.

Incorporating Tismo Cloud Connect into laboratory infrastructure marks a smooth shift toward superior data management and integration, without invasive modifications to the laboratory's existing methods and workflows. Laboratories retain complete oversight of their data management systems and instrument arrays. Furthermore, Tismo Cloud Connect's introduction bypasses the typically cumbersome recertification processes associated with new system deployments. This advantage allows laboratories to uphold their standard operational routines without disruption.

Tismo Cloud Connect offers a solution that is non-intrusive, customizable, and conducive to maintaining seamless laboratory operations. Its ease of adoption and potential for personalization can make it valuable to laboratories seeking to advance their data management and integration practices without compromising their established operational standards.

# References

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