Enablement Strategy for Automation in Analytical Data Management
# Table of Contents

**Introduction**  
2

**The Challenge—Analytical Data in Siloes**  
2  
   Traditional Analytical Data Utilization  
   An ACD/Labs-Enabled Enterprise  
3

**User Process Flows**  
3  
   Data Categories  
   Experiment-Confirmatory Data Access/Analysis  
   Decision Support Access  
      Contemporaneous Access  
      Historical Access  
   Corporate Data Requirements  
4

**Required System Data Flows & Capabilities**  
6  
   Automated Source Monitoring  
   Automated Processing  
      Source Extraction  
      Format Normalization  
      Meta Data Association/Normalization  
   Data Processing  
   Result Structuring  
   Result Routing  
   Storage and Management  
   Context-Specific Staging for Contemporaneous Access  
   Query and Retrieval  
   Visualization/Presentation  
   Reporting  
   User Initiated Processing/Update in Automated Systems  
7

**Spectrus Platform**  
11  
   Relevant Spectrus Platform Subsystems  
      Data Marshalling  
      Data Management—“Finding” Data  
      Data Visualization/Presentation via Spectrus UIs  
8

**Practical Steps for Getting Started**  
13
Introduction
ACD/Labs has assisted a variety of clients with their interests in handling and making analytical data accessible across their R&D organizations. The trigger for an organization to think about their IT systems, integration points, and automation capabilities, both strategically and holistically has varied in ACD/Labs’ experience—it may be a new corporate vision, a cyber-attack, or a natural disaster such as the Covid-19 pandemic. ACD/Labs is working with users (existing and prospective) that are aiming to establish data accessibility, both on-premise and in the cloud—when “data access” requires network access to instrument workstations or to locations where data is stored, their current “access restrictions” make their work experience less than ideal. Regardless of the motivation for an automated analytical data management system (ADMS), it must be approached strategically to ensure long-term success. Moreover, such data accessibility must come with comprehensive measures of cyber security, data integrity, and future usability to ensure long lasting organizational benefit and risk avoidance.

The purpose of this overview is to define:
- The “Data Accessibility” journey—with emphasis on data flow and process flow
- ACD/Labs software and services that can be used to enable data accessibility
- The practical steps an interested organization should follow to begin their journey to an automated ADMS or analytical data-on-demand system

The Challenge—Analytical Data in Siloes
There is a cost to using data. Behind the glamor of powerful analytical insights is a backlog of tedious data preparation. Since the popular emergence of data science as a field, its practitioners have asserted that 80% of the work involved is acquiring and preparing data.1

Analytical data, in particular, is especially challenging for organizations to manage at an enterprise-wide level. Consider the variety of instruments, instrument methods, and techniques that generate a significantly overwhelming number and variety of data formats. From each method/technique/format variant, traditional data utilization efforts require the use of individual commercial software systems for processing, visualization, storage, and management. Contemporary enterprise R&D systems require careful management of this wide variety of siloed information, resulting in multiple analytical data management systems including:

1) Chromatography Data Systems
2) Scientific Data Management Systems
3) Laboratory Information Management Systems
4) Electronic Laboratory Notebooks
5) Substance Registration Systems
6) Inventory and/or Asset Management Systems

Traditional Analytical Data Utilization

In order to effectively decouple analytical data from these systems, a significant degree of abstraction of the insights gleaned from analytical experiments (and the resultant rich datasets) is necessary. Abstraction reduces these very complex datasets to a table of numerical values (e.g., peak tables with numerical attributes like Relative Retention Time, Area Percent, etc.). Moreover, these abstracted results are typically captured in summary reports/documents/memoranda, then stored/managed in Document Management Systems. These systems then require bespoke integration effort to establish and assure conformance to data integrity standards, while decoupling the ability to review, manage, and process this data in real-time.

As a relevant example of the challenge that siloed analytical information presents to organizations, consider the degree to which individual analytical experimental data must be assembled in order to conduct a comprehensive substance characterization. At a minimum, scientists must first identify all components (above the limits of detection based on the methods available), and then quantify those components (above quantification limits). Certainly, no single analytical technique can comprehensively identify and quantify all physical components in any particular substance; such comprehensive investigations require an ensemble of experiments to be performed. Yet, siloed information management systems only exacerbate the problem and treat the individual, technique-specific datasets as islands of data while leaving “relational assemblies” to be accomplished by metadata associations and ultimately time-consuming human-constructed summary reports.

At best, the wealth of deeper insights that organizations can ultimately glean from these data files is relegated to only subject matter experts (SMEs) who possess access to specialized software. At worst, data is relegated to “Cold Storage” archival systems and retrieved only by exceptional request.

For stakeholders interested in effective, data-driven decision making, the ability to decouple from such siloes is a mission-critical capability worthy of investigation and investment.

An ACD/Labs-Enabled Enterprise

An ACD/Labs enabled enterprise empowers organizations to bring together traditionally siloed analytical data and provides democratic access and utilization to users. In order to successfully achieve automated analytical data handling (or install an automated ADMS) a number of factors should be considered:

- The variety of users, instruments, and their requirements from an automated system based on their process flows
- The requirements and capabilities of the system based on data flows

User Process Flows

Industrial R&D scientists use analytical instrumentation to support the characterization of their experimental samples. The ability to interact live with analytical data across various instruments and analytical instrumental techniques is often critical to assure comprehensive molecular characterization is performed effectively. There is also an increasing emphasis on providing remote access to analytical data, due to changes in operational environments.

In order to implement the appropriate IT architecture and infrastructure, a comprehensive accounting of user process flows is required as they relate to analytical data.

**Data Categories**

The first consideration is the datatypes that must be supported by an “analytical data-on-demand” system. Stakeholders should itemize the inventory of instrument/analysis techniques, software versions, method-specific parameters, and their corresponding data formats. Moreover, network information for each data source should be summarized, and if possible standardized in a way for multiple access points.

![Figure 1: Inventory is an important requisite for enabling appropriate processes, and data connections between them.](image)

In order to effectively account for the needs of data consumers, stakeholders and SMEs should also define the specific process flows for each anticipated use case. Some example use cases are described here.

**Experiment-Confirmatory Data Access/Analysis**

The most fundamental use case requires user access to data files which support their individual experimental efforts. Access to this type of analytical data supports confirmatory assessments, like:

- **Reaction Progress Confirmation:** “Do I see my reaction product forming based on observing a chromatographic component whose related mass spectral features correspond to the reaction product MW, MF, and/or chemical structure?”

- **Material Identity:** “Do the spectral patterns of the material I’ve tested conform to its proposed (or assumed) identity?”

- **Material Purity:** “Do the chromatographic patterns observed in the data conform to purity requirements of the substance I’m using, or the substance I’ve made/purified?”

**Decision Support Access**

In addition to individual users’ process flow, the ability for stakeholders to access other users’ datasets is a critical consideration, especially in a remote environment. Typically, cross-functional R&D project teams are required to execute a variety of protocol driven experiments. Teams are comprised of scientists performing, for example, material generation, characterization, process development, and process validation. Their experiments, typically, require a variety of downstream analytical experiments, whereby resulting analytical datasets are reviewed by project team stakeholders. Enterprise infrastructures, therefore, must provide on-demand analytical data accessibility, in combination with other important data attributes. Consider also that in many circumstances, project team stakeholders work in geographically disparate locations; supporting systems must also account for the lack of physical access to either terminal, access to data, or...
to “owners” of critical datasets. This access disparity can only be eliminated by enabling enterprise decision support systems with such data on-demand capabilities.

Figure 2: Analytical data from instruments in different locations must be accessible to scientists and project teams also in different locations.

An additional dimension worth considering is the timing of required on-demand data access, as described below:

**Contemporaneous Access**

Project teams’ current tasks may require immediate (or as fast as system/network specifications allow) access to data to make decisions based on recently conducted analytical experiments. Examples include:

- **Material batch/lot release**—recently registered test articles that will be subjected to a battery of performance assays. Project team stakeholders must confirm that test article identity and purity is appropriate for ensuring that the results of such performance assays will be usable in downstream decision making. For certainty, this need spans the entire product lifecycle—from research projects conducting lead optimization studies, through commercial development, and ultimately to commercial manufacturing.

- **Process validation**—when new processes have been developed, pivotal process validation experimental results must be reviewed by project team stakeholders prior to the approval and implementation of these new processes. On-demand access to analytical data is critical in supporting an efficient process-parameter-to-process-output results assessment.

Enterprise infrastructure should account for the expected timing of such “data on-demand” requirements that the above process flows require. Certainly, an exhaustive accounting of stakeholder process flows should be undertaken to assure that resultant infrastructure investments (systems and networks) can support all process flows according to user experience expectations.

**Historical Access**

In addition to contemporaneous access requirements, enterprise infrastructures must also support access to data across various time domains. Fundamentally, observing “quality trends” across the lifecycle—as directly observable by presenting live analytical data in a series array—provides decision makers with rapid quality assessment capability. There are also certain regulatory and quality assurance requirements which
force project stakeholders to report historical trends: for material composition, stability, and physical form variability. Such Lot History summaries can be effectively augmented with supporting analytical data thus reducing the amount of requests from regulatory and quality assurance stakeholders to furnish supporting analytical data after initial submission review.

Figure 3: Luminata software from ACD/Labs provides pharmaceutical development teams with Lot History data that is connected with the related chromatographic data, for convenient QA/QC investigation and decision-making.

Corporate Data Requirements

Finally, in addition to individual scientist and project stakeholder process flow accountancy, infrastructure enablement efforts should also factor in all relevant corporate policy standards. Typical factors that must certainly be considered are:

• **Data/System Security and Access-Permission Management**—systems must support the granularity of system user roles and corresponding data access restrictions/limitations. Moreover, systems will likely require integrations to single-sign-on and related permission management systems.

• **FAIR Conformance**—informatics stakeholders must account for FAIR (Findable, Accessible, Interoperable, and Reusable) standards, and ensure that system requirements are articulated to assure conformance. Additionally, specific query, visualization, and reporting system requirements for envisaged systems must account for FAIR standards. This usually requires traceability from business and standards requirements to, ultimately, user acceptance testing documentation.

Required System Data Flows & Capabilities

With an understanding of the process flows that must be supported by an automated system for analytical data handling, stakeholders can move on to considering its data flow and capability requirements.

Automated Source Monitoring

To comprehensively characterize materials, it is common that organizations obtain a variety of data from a significant number and variety of instruments, usually across a range of locations. Those instruments are assets but so is the data they generate. For a combination of reasons, including effective use of data acquisition systems and the ability to access and secure source data, it is ideal practice not to retain data

on source systems but to rapidly transfer them to data center locations where they are backed-up while being made available for use in subsequent data flows. One straightforward approach is to implement automated services that monitor data source instrument computers for new data, typically at defined time intervals corresponding roughly to expected instrument use patterns or duty cycles. Arrivals of new data trigger automated processes to recognize and transfer data to appropriate locations and, where appropriate, to initiate additional automated processing actions.

Advanced Monitoring—At true enterprise scale, a dashboard for defining data source locations, anticipated data types, and information for potential processing operations is desirable. In such an environment it might also be useful if each data source system can provide information about its status or availability.

Automated Processing
Information from the data is inevitably more valuable and useful than just the raw data itself. To obtain that kind of information from data, some automated process operations are necessary.

Source Extraction
Analytical instrument raw data is typically acquired in a proprietary binary format that has been optimized by its manufacturer for efficient acquisition, storage, and use by the manufacturer’s software application. So, Extract, Transform, and Load (ETL) processes are used to make the relevant data (e.g., values and units, spectra, traces, 3D data) and metadata (e.g., method parameters, sample, and user identifiers), available for access by other software applications. What is deemed relevant will depend upon the particular primary and secondary use cases established and envisaged for the data. Although there is an increasing push toward having all data and metadata available for future data science activities (e.g., data mining, AI, and machine learning) the extent of extraction should focus on ensuring that the expected uses of the data can be achieved first and foremost.

Format Normalization
One of the major challenges in comprehensive material characterization is to assess several different types of analytical instrument data and results in one software environment. Almost all modern instruments are...
now generating digital data. However various chemical, electrical, optical, physical, or thermal properties may be detected across time and need to be transduced with appropriate coordinates. For example, a HPLC-UV chromatogram may be represented by a set of XY points corresponding to (relative) abundance and time. While it is occasionally possible to reduce the information from some types of data to an extremely simplified subset of result values, connections to the underlying live data are then often limited or lost. The alternative of viewing static images of analytical data has its own set of limitations: fidelity limits, lack of single-view data comparison, etc.

**Meta Data Association/Normalization**

Two kinds of metadata are of utmost importance in relation to analytical data. The first is instrument and method parameters, which provide a basis to understand and be able to repeat a particular measurement. The second is metadata that describes the context of the analysis including identifying any roles played by each sample of analyzed material. Some of the metadata will be with the data from the source system whereas it may be useful to have an informatics integration with other data/metadata sources and create associations that facilitate the steps of processing described in the following section.

**Data Processing**

This is the activity users most commonly have in mind for the subject of automated processing. It is generally understood to mean mathematical and statistical treatments of raw data to recognize, extract, and collect signals from noise. Such treatments may involve one or more transformations known as pre-processing. Subsequent steps involve algorithms that relate the collected signals, for instance, into peaks, features, and spectra. Further automated interpretation may also be possible when chemical information, e.g., molecular structure(s), are provided concurrently with the analytical data.

**Result Structuring**

The ability to bring together features, spectra, and interpretations from more than one type of data is one key aspect for comprehensive material characterization. Source data systems designed to acquire one type of data truly don’t require this capability. Systems that can manage many different kinds of data and results do need some automation configuration to allow the appropriate business logic and business rules in the data structuring process.

![Diagram](image-url)

**Figure 6**: An automated analytical data management system (ADMS) should be able to bring together spectra, structures/material identifiers, and interpretations from multiple data types.
An example of this process is to automatically assess whether an expected compound is in a particular sample based on a combination of results from its analysis by HPLC, using both UV and MS detectors.

**Result Routing**

Results are often used for decision-making and inevitably abstracted so as to summarize salient information from larger amounts of data. To achieve this in a human-friendly manner, they are often crafted and presented in the form of reports and notifications. Data-rich reports may consist of a mixture of text, tables, graphs, and images, which may be arranged together into one or more common types of outputs, e.g., Adobe PDF files, Microsoft Word or other documents, CSV files, or spreadsheets. Review of these by embedded views is often preferable to switching between application interfaces.

**Storage and Management**

Storing data and documenting results post-analysis often seems like a tedious additional step to scientists, so doing it automatically after analysis and/or review steps are completed can be ideal. There are several reasons and very different use cases for storing or retrieving data and results.

Master data must be persistently stored but accessible quickly for reference and comparisons to newly acquired data. The latter are typically relevant for the immediate characterization of a particular material, so it is imperative to have easy and rapid access to newly acquired data.

When data is no longer immediately needed, but regulatory requirements demand it, long-term storage in a data archive is appropriate. In these cases, specific but limited metadata allows retrieval of that data, with priorities becoming data integrity and storage efficiency, rather than very rapid access.

Noteworthy additional data management interests may include the iterative development of incremental queries on stored analytical data and metadata. What is enabled, and how, can depend on the objectives. A primary use is to conduct data mining to investigate and classify some unknown material from its peak(s), feature(s), or spectra. Secondary propositions are to investigate reasons for material variation or statistical trends and outliers in results, as well as to maintain and assess instrument and data assets in utilization and performance. Lastly, using machine learning approaches on properly structured and good quality data has shown to yield some unexpected predictions of new materials or conditions that can be explored or exploited to yield future innovations.

**Context-Specific Staging for Contemporaneous Access**

The two essential aspects of securing data and contemporaneously/immediately making it available for users may present challenges. Private clouds are an increasingly key part of Enterprise data ecosystems. They can provide secure access and elastically large storage capabilities, but it should be noted that network connections will generally need low latency and substantial bandwidth to efficiently transfer large volumes of instrument data, raw and/or processed. Considering the increased rate of data generation (especially with the advent of sub-5 min duty cycles in LC/UV/MS instrumentation), any significant delays in user access to data may be met with concern and frustration. Presuming that users require rapid access simply for preliminary inspection of the data and not more extensive processing, creative solutions, can involve staging data, rapidly but temporarily, to a location that is immediately accessible to a user. Simultaneously, the data will be transferred to a more remote central location where further data processing can be performed. If user processing of the data is expected to occur while it is in the staging area, there needs to be an approach to perform reconciliation between that enhanced data and the source data which has been moved to secured storage and perhaps undergone other processing. This is an aspect for appropriate management of the necessary business rules and business logic to avoid redundancy while ensuring usefulness.
Query and Retrieval

Comparisons allow confirmation, verification, identification, and classification of materials. In order to accomplish those one needs to be able to query, find, and retrieve data. As noted in the processing section, “master data” provides evidence of what is expected for comparison with data acquired for any new material. A related reason to query various pieces of data and meta data is in investigations, where it can help identify and classify new and unexpected materials by similarity. A secondary use for querying is based on using a collection of data from different sources to understand any trends or variations. This can help improve instrument usage, method selection, and assist in recognizing materials and process risks. Retrieval by systems that train and apply artificial intelligence approaches, including machine learning, on quality structured data can be then used to explore and uncover unexpected statistical correlations between materials and conditions that can fuel innovation.

Visualization/Presentation

User interfaces (UI) and user experience (UX) are software’s most tangible aspects to a human user. For analytical data and results, the aim is to allow a user to intuitively see and understand their experiments and analyses of materials. When data are pre-processed via automation there may be large quantities to review. While these automated processing/interpretation workflows can enable a “review-by-exception” paradigm, the need to appropriately support effective visualization remains. Standardized menu layouts, navigation panels, workflow ribbons, and flexible data layouts all contribute to effective review by users. Dynamically refreshing views when users drill into data and reduction of high-dimensionality data (e.g., 2D NMR or LV-UV) can help. As noted above, embedded views showing data rich reports may be one way to rapidly review results without switching between application interfaces.

Reporting

Reports are often the medium of choice for scientists and decision-makers seeking to have a systematic summary about a sample/samples, more generally about a material, or about a process being used to make a material or set of materials at any given point in time. The advantage of reports is that they have an expected layout and typically contain specific pieces of data the user deems most important to see, e.g., a spectrum, chromatogram, table/list of identified peaks, and/or compounds.

An automated system may generate (and store) reports from newly acquired data by following allotted workflows, business rules, and logic. Under some circumstances a user may wish to first inspect data and results via a client interface and then generate a report. Of course, as a third option, a report could be created automatically, and a user may (after some kind of reprocessing) generate a new/replacement report that takes into account any revisions or new data and interpretations.

User Initiated Processing/Update in Automated Systems

The aim of processing data is to obtain information from it for making reliable and correct decisions. So, for example, when proper, confident interpretation is not possible due to insufficient information being derived for some portion of samples in sets of gathered analytical data, a reviewing user may instigate reprocessing of data for some or all of the samples in the set. Processing suitability practices should be implemented to prevent data from being processed with completely inappropriate parameters. Nevertheless, processing parameters may need tweaking to accommodate the variabilities in signal and noise that are ever-present in real experimental data. In such cases, an automated batch reprocessing capability is very useful and fresh, results-in-an-instant are much desired.
ACD/Labs Tools and Capabilities—Spectrus® Platform

The ACD/Spectrus Platform offers organizations options that help improve scientists’ data access and utilization experience. In addition to a variety of applications for chemically intelligent analytical data processing and interpretation at the group/individual user level, Spectrus enables research and development organizations to silently automate analytical data collection and processing in a vendor agnostic, multi-technique environment, and an enterprise-wide manner.

Relevant Spectrus Platform Subsystems

Data Marshalling

ACD/Labs’ Automation Server subsystem enables the following critical capabilities:

- Management and collection of instrument data sources—each data source record specifies technique, method, and source-specific data processing routine(s)
- File-based, or database (e.g., CDS or SDMS) monitoring—with the capability to move, copy, delete, import, export, rename, and other miscellaneous fundamental data management tasks
- Automated execution of predefined processing tasks, upon detection of relevant files or database records
- Data processed through Automation Server can either be reported (with relevant document routing) or stored in Spectrus DB
- Creation of custom data scripting and application development interfaces to enable review by exception are available

Data Management—“Finding” Data

Traditionally, archival systems certainly store datasets in a comprehensive fashion, however, the inability to effectively query and retrieve datasets of interest leaves them with limited utility. ACD/Labs proposes the following workflow to enable effective data accessibility.

Figure 7: Spectrus offers silent automation of analytical data—from data collection at the source, through processing and storage, to reporting.
Upon completion of relevant datafile detection, processing, and storage, ACD/Labs Spectrus DB application serves as an enterprise repository for accessing analytical data-on-demand. Users can query metadata (sample information, user information, and method information as relevant examples), chemical data (structures, substructures), or analytical features (peak information, spectral information, etc.).

Data Visualization/Presentation via Spectrus UIs

Upon completion of User Query tasks, Spectrus Processor and Workbook applications allow for rapid visualization of selected analytical datasets and preparation of data-rich reports.

ACD/Labs Capabilities Matrix

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<tr>
<th>Enablement Process Step</th>
<th>Spectrus Platform</th>
<th>Integration Service</th>
<th>Consulting Service</th>
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<td>*Deeper queries in lakes and other depositories; AI/ML analysis</td>
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Practical Steps for Getting Started

As organizations continue to “digitalize,” the challenges of including analytical data in the scope of their transformation can indeed be overcome. The careful considerations and recommendations made herein offer stakeholders with a high-level strategy to make the vision of “analytical data-on-demand”, a reality. ACD/Labs’ products, technologies, and professional services can serve as a set of critical, enabling capabilities that will help ensure reasonable implementation, timeline, and scope. Moreover, by leveraging live-and-rich analytical data as a part of critical decision making, the value of such scoping and implementation efforts can yield value to organizations in a relatively short time scale.

In order to effectively scale analytical data on-demand, across the enterprise, the following engagement steps are recommended:

1. Establish an accounting of all relevant user process flows where analytical data on demand is valuable. These process flows should include both contemporaneous-versus-historical and the variety of data-type categories described above.
2. Establish an accounting of all relevant data flows: laboratory, instrument, method, and software systems which require integration, noting both inputs and desired outputs.
3. Establish an accounting of all relevant user, laboratory, and system locations, and network details.
4. Access the IT informatics landscape, needs, plans, and security considerations for digitization
5. Upon completion of the above steps, establish a project charter with relevant roles and responsibilities for all relevant stakeholders.
6. Conduct strategic planning efforts to ensure traceability from business requirements, to system functional, performance, and network specifications.
7. Finally, upon stakeholder acceptance of the project charter and strategic planning efforts, implement in an iterative fashion through standardized user acceptance testing practices.