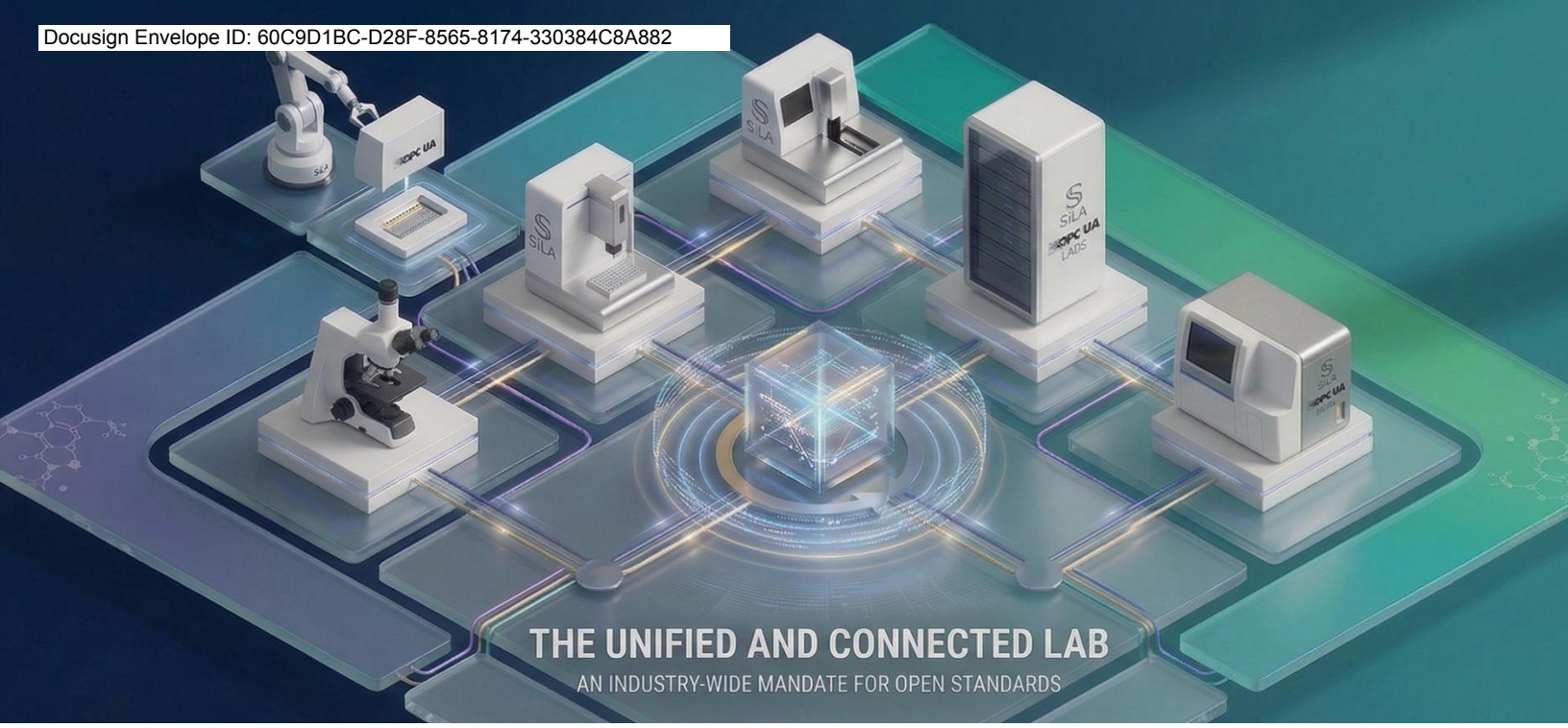

The Strategic Necessity of Open Standards in Lab Automation: A Mandatory Requirement for Connected Labs

Part I: Executive Introduction

The Strategic Imperative: Why We Are Mobilizing

The life sciences sector is entering a decisive phase of digital transformation. Scientific progress across biology, chemistry, automation, and artificial intelligence is accelerating rapidly, creating major opportunities to discover novel therapeutics, improve development speed, and predict biological and chemical interactions with greater precision. Yet the practical bottleneck in many laboratories is more fundamental: instruments, software, and data remain insufficiently connected. [1]

This gap between scientific potential and operational reality has become a defining constraint of modern R&D. Before laboratories can scale orchestration, closed loop experimentation, or AI driven decision making, they need reliable connectivity, interoperable interfaces, and structured data foundations.[2] In that sense, AI is not the starting point of the Lab of the Future, it is one of the outcomes enabled by interoperability.[3]

Today, many laboratories still operate far below that threshold, trapped behind proprietary

communication protocols, closed file formats, and rigid, vendor-specific software. Critical instruments remain isolated data islands, constrained by proprietary protocols, closed file formats, and vendor specific software stacks.[4] As a result, scientists, automation engineers, and integrators still spend disproportionate effort on manual data handling, custom drivers, brittle point to point integrations, and local workarounds instead of focusing on experimental design, analysis, and scalable workflow deployment.[5]

The industry is currently paying a massive "fragmentation tax" and it is not merely technical. It slows the deployment of new workflows, limits the scalability of automation, and delays the translation of scientific insight into operational value. In an environment of compressed timelines and intense competition, even modest delays in integration or workflow enablement can have major consequences, including a slower path to delivering critical innovations to patients.[6]

This is why interoperability is not an IT convenience or a secondary engineering concern. It is a strategic capability. Without it, the Lab of the Future remains a concept rather than an operating model. Mature industries did not achieve scalable automation through proprietary isolation.[7] They did so through layered, standards based interoperability that separates device connectivity, orchestration, and enterprise integration. Life sciences now faces the same architectural challenge and the same strategic opportunity.

The Core Problem: The "Black Box" Paradigm

For decades, the standard procedure for laboratory integration has been a costly exercise in custom engineering. Integrating a liquid handler from Vendor A with a plate reader from Vendor B and a Laboratory Information Management System (LIMS) from Vendor C typically requires months of development. System integrators must write custom drivers based on wrong or incomplete documentation, reverse-engineer proprietary communication strings, or rely on fragile file-based data exchanges, such as parsing CSV files dropped into a watched folder, which is prone to errors and data loss.[7] This approach fundamentally violates the principles of modern software architecture and data integrity.[5]

Proprietary interfaces create a scenario known as "Vendor Lock-in." Once a lab has invested heavily in a specific vendor's software ecosystem—by customizing workflows, training staff, and building data pipelines around their specific file formats—the costs of switching to a competitor become prohibitively high.[10] This lock-in stifles innovation by forcing lab managers to buy inferior or more expensive instruments simply because they are compatible with an existing, closed software environment.[13] Furthermore, vendor lock-in poses a significant operational risk. If a vendor discontinues a product line, the lab is vulnerable, as the "knowledge" of how to communicate with the instrument is locked inside proprietary binary drivers that may no longer be supported.[9]

The Vision: A Networked Reference and modular Architecture

To solve this crisis, the industry is looking beyond its own borders for inspiration. Mature sectors like automotive manufacturing, oil and gas, and discrete manufacturing have long achieved levels of efficiency and predictability that remain unmatched in life sciences R&D.[8] They achieved this not through proprietary isolation, but through rigorous standardization and layered architectures that separate physical control from operational logic.[6]

We envision a Lab of the Future that adopts a Networked Reference and fully modular Architecture. This architecture introduces scalability and predictability into laboratory automation by defining clear layers of control and data exchange—from the physical device up to the enterprise planning level and back.[12] By abstracting these layers, we aim to prevent the custom, time-consuming development that currently plagues every new automation project.[3] We strive to decouple the instrument from the integration logic, enabling a modular ecosystem where components can be swapped, upgraded, and orchestrated very fast without having to rebuild the entire system.[14]

In this future state, instruments, software, and robotics interact seamlessly.[16] Integration is not a hurdle to be overcome, but a standard feature that is assumed. We are moving toward a modular, flexible, and data-centric ecosystem where "Plug and Play" is a technical reality, not a marketing slogan. A new mass spectrometer or robot arm should be plugged into the lab network and immediately recognized by the orchestration software, "announcing" its features and capabilities (e.g., "measure sample," "calibrate," "move plate") without manual driver installation or complex configuration.

What is Happening Now? The Collective Action!

Several major life sciences, crop science, and chemical companies are initiating a fundamental shift in how the industry procures and integrates laboratory technology. We are moving from a model of bespoke integration to one of holistically industrialized standardization. We are aligning our requirements and needs through standards to speak with "One Industry Voice" to our vendors and strategic partners. This collective action is necessary to break the market deadlock; no single customer, however large, can easily force a global shift in standards alone. However, an industry consortium presenting a unified set of requirements completely changes the market dynamics.

This report serves a dual purpose. First, it presents a unified Open Letter and Declaration in Part II, a high level mandate intended for ratification by executive leadership across major life sciences, crop science, and chemical companies. This declaration signals to the vendor community that the era of proprietary lock in is ending. We call for open standards, specifically

SiLA 2 and OPC UA LADS, and for an end to recurring fees for basic connectivity. We also set a target for the initial availability of compliant systems by 2027.

Open standards should be understood as a multi layer requirement. We are not only calling for standards at the application layer, but for standards based interoperability across device connectivity, network discovery and onboarding, secure communication, and machine readable data semantics. SiLA 2 and OPC UA LADS are central standards for the communication layer, and their value increases further when combined with structured data models such as Allotrope or AnIML where relevant.

Open standards are not only beneficial for laboratories, they also create tangible upside for suppliers. Vendors that offer standards based interfaces reduce customer specific integration work, shorten sales cycles, lower support overhead, and make their products easier to deploy in heterogeneous environments. In modern laboratory ecosystems, customer loyalty is increasingly created by compatibility, reliability, security, and lifecycle fit, not by technical lock in alone. Open standards based products therefore expand the addressable market for vendors while reducing the long tail cost of proprietary custom integrations.

Second, Part III provides the technical and strategic foundation behind the declaration. It describes the Networked Reference Architecture and gives vendors and internal architects a concrete blueprint for how these requirements can be implemented. We are not simply asking for better drivers. We are defining a new architectural contract between buyers and suppliers, one that supports modularity, interoperability, and scalable automation. The Lab of the Future is no longer just a vision. It is a set of engineering requirements, and this document is the roadmap to making it real.

A Collective Call for Standardization and Open Interfaces in Laboratory Automation

To: The Executive Leadership, R&D Divisions, and Product Managers of Laboratory Instrumentation and Software Companies

Preamble

We, the undersigned, represent a global community of scientists, engineers, executive and strategic leaders dedicated to advancing human health, sustainable agriculture, and scientific innovation. Our scientific environments are the engines of discovery, where the products and solutions of tomorrow are developed. However, our ability to innovate is currently constrained by a systemic barrier: the lack of interoperability among the tools we use. For too long, the laboratory ecosystem has been fragmented by proprietary communication protocols, closed file formats, and restrictive software licensing and integration models. This fragmentation creates data silos, inflates integration costs, stifles automation, and impedes the deployment and implementation of artificial intelligence. In an era where data is our most valuable asset, we can no longer accept "black box" instruments. We need a shared language for science.

Our Vision

We envision a **Lab of the Future NOW** that is modular, flexible, and data-centric. In this lab instruments, software, and robotics interact seamlessly, adhering to the principles of **FAIR Data** (Findable, Accessible, Interoperable, Reusable) by design. We envision an ecosystem where integration is not a hurdle to be overcome, but a standard feature that is assumed. To achieve this, we put forth an industrially-inspired architecture designed to enhance the fast scalability and predictability of lab automation.

Our Requirements

To realize this vision, we are aligning our procurement strategies and technical roadmaps. Effective immediately, the undersigned organizations will prioritize and, where feasible, **mandate** the following capabilities in our evaluation of laboratory equipment and software:

1. Adoption of Open Communication Standards

We require instruments to support open, vendor-neutral communication standards. Specifically, we advocate for:

- **SiLA (Standardization in Lab Automation):** For dynamic, service-oriented interactions, rapid integration in R&D environments, and ease of scripting.
- **OPC UA LADS (Laboratory and Analytical Device Standard):** For robust, secure, and scalable integration in process development, manufacturing, and enterprise monitoring environments.

These standards are not experimental concepts. SiLA has been part of the lab automation

landscape since the first release of SiLA in 2009, while LADS brings the new established OPC UA interoperability framework into analytical and laboratory equipment through a manufacturer-independent companion specification.

Requirement: We expect **Native Support** for these standards directly on the device firmware or embedded controller. Reliance on external "driver PCs", third-party middleware converters, or "wrapper" software is considered a legacy solution and is strongly discouraged.

2. Open APIs and Documentation

- **APIs for Instrument Control and Data Access Must Be Cost-Effective and Standard:** Programmatic control of laboratory instruments and the retrieval of data via APIs has to be a foundational, standard capability of the hardware. We expect those to be available through a one-time enablement fee. Recurring Fees are not an option.
- **Comprehensive Documentation:** APIs must be fully and correctly documented, public, and accompanied by standard descriptions (e.g., SiLA Feature Definitions, OPC UA NodeSets) to enable self-service integration without vendor intervention.

3. Freedom from Vendor Lock-In

We explicitly reject "walled garden" ecosystems that artificially restrict compatibility with third-party software (LIMS, ELN, Orchestrators/Schedulers). Our laboratories are multi-vendor environments; our equipment must be capable of operating within a heterogeneous technology stack.

The Path Forward

We recognize that such a transition requires time and investment. However, the cost of inaction, measured in lost efficiency, delayed discoveries, and fragmented data, is far higher. We invite all vendors to join us in this transformation.

- **To Early Adopters:** We commend vendors who have already embraced SiLA2 and/or OPC UA LADS. You are our preferred strategic partners, and we will actively seek to showcase your success.
- **To Legacy Providers:** We urge you to release detailed roadmaps demonstrating your commitment to adopting open standards. We recognize that this process requires time and potentially new technical expertise. To facilitate this transition, we are ready to offer assistance, including engaging in pilot programs and providing necessary feedback. We anticipate initial progress and results to be evident by 2027.

By signing this letter, we affirm our commitment to an open, standardized, and interconnected future. We ask you to build the tools that will empower us to solve the world's most pressing scientific and global challenges, from human health to sustainable chemistry and agriculture. If this approach proves to be successful, we aim to develop a similar initiative focusing on Semantic Interoperability and Data Integrity.

Life Sciences, Crop Science & Chemical Companies

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Head of Lab Automation and Digitalization

Botnar Institute of Immune Engineering

Part II: The Open Letter to Industry

Vendors & Integrator Company's

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Part III: Appendix

1. The Strategic Context: From Data Islands to Connected Ecosystems

1.1 The High Cost of Fragmentation

For decades, the standard operating procedure for laboratory integration has been a costly, inefficient exercise in custom and sometimes even reverse engineering. Integrating a liquid handler from Vendor A with a plate reader from Vendor B and a Laboratory Information Management System (LIMS) from Vendor C typically requires months of development. System integrators must write custom drivers, reverse-engineer proprietary communication strings, or rely on fragile file-based data exchanges, such as parsing CSV files dropped into a watched folder, which are prone to failure and without any data integrity or even causes data loss.[1]

The economic and operational costs of this fragmentation are staggering and manifest in several critical areas:

1.1.1 Integration Latency and Opportunity Cost

The time required to integrate a new instrument into an automated workflow is often measured in months. This "integration latency" directly delays the start of critical innovation projects and scientific workflows. In a competitive landscape where rapid R&D is essential and patent life is finite, a three-month delay in setting up an analytical or screening platform can translate to millions of dollars in lost revenue and, more importantly, a significant delay in delivering transformative solutions to the market.[1] The "Lab of the Future" cannot operate at the speed of custom driver development; it requires the "Plug and Play" immediacy that open standards facilitate.[12]

1.1.2 The "Vendor Lock-in" Trap

Proprietary interfaces create a scenario known as "Vendor Lock-in". Once a laboratory has invested heavily in a specific vendor's software ecosystem, customizing workflows, training staff, and building data pipelines around their specific file formats, the cost of switching to a competitor becomes prohibitive.[9] This lock-in stifles innovation. A lab manager may be forced to purchase an inferior or more expensive instrument simply because it is compatible with their existing, closed software environment, rather than choosing the best-in-class technology available on the market for the dedicated purpose.[13]

Furthermore, vendor lock-in poses a significant operational risk. If a vendor discontinues a product line, goes out of business, or fundamentally changes their licensing model, the laboratory is left vulnerable. Without open standards, the "knowledge" of how to communicate with the instrument is locked inside proprietary DLLs or binary drivers that may no longer be supported.[9]

1.1.3 Data Integrity and the "Black Box" Problem

Proprietary formats often strip metadata. A raw data file might contain the absorbance values from an experiment but lose the context of the instrument settings, operator identity, or environmental conditions (temperature, humidity) at the time of measurement.[1] This violation of ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate) creates a "Black Box" where data is generated without sufficient provenance. In a regulatory environment that increasingly demands complete traceability, especially in GxP (Good Practice) environments, this lack of transparency is a compliance liability.[14]

1.2 The Vision of the "Lab of the Future" needed today

The industry's collective vision, often termed "Lab 4.0," "SmartLab," or the "Connected Lab", relies on the concept of a cyber-physical and secure system where digital and physical assets are seamlessly intertwined. This vision is not merely about "automating" manual tasks; it is about creating an intelligent and agile ecosystem that can reason, adapt, and optimize.[16]

1.2.1 Plug-and-Play Connectivity

In the ideal future state, a new mass spectrometer or robotic arm should be connected to the laboratory network and immediately recognized by the orchestration software. The device should "advertise" its capabilities (e.g., "measure sample," "calibrate," "move plate") without manual driver installation or complex configuration.[7] This concept, borrowed from consumer electronics (like plugging a USB mouse into a computer), is technically feasible today through standards like SiLA 2 but remains unimplemented by many vendors who prefer to protect their proprietary service revenue.[18]

1.2.2 Holistically Orchestrated and Mobile Automation

The modern lab is moving beyond static "workcells" where robots are bolted to tables. We are seeing the rise of Autonomous Mobile Robots (AMRs) that move materials between instruments in different rooms or buildings.[19] For an AMR to interact with a centrifuge, both the robot and the centrifuge must speak a common language. The robot needs to ask, "Is the door open?" and the centrifuge needs to reply, "Door opening now." Without a standardized protocol like SiLA or OPC UA, this interaction requires complex, custom middleware for every single device pair.[19]

1.2.3 AI-Ready Data Streams and Closed Loops

Perhaps the most critical driver and motivation for the “Lab of the Future” is Artificial Intelligence. AI algorithms are voracious consumers of meta and experiment data, but they require that data to be structured, labeled, and contextualized.[1] An AI agent cannot easily "read" a proprietary binary file or interpret a PDF report intended for human eyes. It needs a structured data stream where "Temperature" is clearly defined as a floating-point number with a unit (e.g. Celsius). The

"Lab of the Future" connects instruments directly to AI models, allowing for "closed-loop" science where the AI analyzes the results of Experiment A and automatically programs the parameters for Experiment B.[1] This is impossible without the semantic interoperability provided by open standards.

1.3 The Role of the Life Sciences Consortium

The fragmented nature of the scientific instrument market means that no single customer, however large, can easily force a global shift in manufacturing standards. An individual company requesting a "SiLA 2 interface" might be told by a vendor that it is a "single custom request" with a high price tag and slow realization. However, a consortium of Life Sciences companies, presenting a unified set of requirements, changes the market dynamic entirely.[23]

By issuing this report and the accompanying Declaration, the industry signals a fundamental shift in procurement strategy. We are moving from a model of "requesting" driver standards to "requiring" native compliance. Future purchasing decisions will favor vendors who adopt open standards, creating a competitive disadvantage for those who cling to proprietary isolation.[18] This collective action is necessary to break the deadlock and create a market where openness is a baseline expectation, not a premium feature.

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2. Technical Architecture of the Solution: The Standards Stack

The industry has coalesced around two primary, complementary standards that serve as the backbone of modern lab automation: **SiLA 2** and **OPC UA LADS**. Understanding the distinct but overlapping roles of these technologies is essential for vendors, IT architects, and decision-makers. They are not competitors; they are the "left hand and right hand" of the connected laboratory.

2.1 SiLA 2: The Service-Oriented Standard for R&D Agility

SiLA 2 (Standardization in Lab Automation) is a communication standard designed specifically for the dynamic, service-oriented nature of the life science laboratory. It builds upon established, modern web technologies, specifically HTTP/2 and Protocol Buffers (gRPC), to create a lightweight, efficient, and highly readable mechanism for device interaction.[3]

Feature	Description	Benefit
Microservice Architecture	Treats every instrument and software component as a "Server" offering "Features" (services) to "Clients." (Software Applications)	Decouples implementation from interface; enables plug & play modularity.
Feature Definition Language (FDL)	An XML-based format that formally describes what a device *can do* (commands, parameters, return types).	Allows for "self-describing" devices; clients can learn device capabilities at runtime.
Wire Protocol	Uses gRPC (Google Remote Procedure Call) over HTTP/2.	High performance, low latency, supports streaming data, widely supported by IT libraries & state of the art technology.
Discovery	Supports Zero-Configuration networking (mDNS/DNS-SD).	Enables "Plug and Play" functionality; devices are automatically found on the network.

Table 1: Key Technical Characteristics of SiLA 2.[3]

2.1.1 The "Feature" Concept

In SiLA 2, capabilities are grouped into "Features." A simple balance might have a Weighing feature and a Calibration feature. A complex liquid handler might have features for Aspiration, Dispensing, TipHandling, and UserInteraction. Because these Feature Definitions are standardized (e.g., a standard SiLA:LockInterface feature), any client software that understands the standard feature can immediately control any device that implements it, regardless of the manufacturer.[7] This promotes code reuse and dramatically simplifies the job of the system integrator or even democratizes lab automation to the end users.

2.1.2 The "Native" vs. "Wrapper" Distinction

A critical distinction in this report, and a key demand of the Declaration, is between **SiLA Converters/Drivers** and **Native SiLA Support**.

- **Wrappers/Drivers:** Currently, many legacy devices are "SiLA-enabled" via an external PC or bridge software that translates proprietary commands (e.g., RS232 strings) into SiLA messages.[27] While this is a necessary stopgap for older equipment, it adds complexity, hardware cost, and a point of failure.
- **Native Support:** The industry demand is for **Native SiLA implementation**. This means the SiLA server runs directly on the instrument's firmware or embedded controller. The device "speaks" SiLA out of the “ethernet port”. This eliminates the need for intermediate PCs, simplifies validation, and ensures that the "truth" of the device's state is directly accessible to the network.[18]

2.2 OPC UA LADS: The Industrial Bridge to Manufacturing

While SiLA 2 excels in the flexible, ad-hoc nature of R&D workflows, **OPC UA (Open Platform Communications Unified Architecture)** is the global standard for industrial automation and manufacturing. **LADS (Laboratory and Analytical Device Standard)** is the OPC UA Companion Specification specifically designed to model laboratory instruments.[6]

2.2.1 The Convergence of Lab and Factory

As a drug candidate moves from discovery (R&D) to production (QC/Manufacturing), the technology stack often shifts from flexible lab tools to rigid industrial control systems like SCADA (Supervisory Control and Data Acquisition) and MES (Manufacturing Execution Systems). Historically, this required a complete re-engineering of the automation, as R&D instruments used different protocols than factory machines.

OPC UA is the native language of the factory floor. By adopting LADS, instruments can bridge this gap. A LADS-compliant spectrometer can be used in the R&D lab for method development and then transferred to the QC lab for batch release testing without changing the software interface. This streamlines the "tech transfer" process and ensures data consistency across the product lifecycle.[3]

2.2.2 Security and Information Modeling

OPC UA LADS brings two critical capabilities to the lab:

1. **Enterprise-Grade Security:** OPC UA includes a robust security model built-in, including X.509 certificate exchange, encryption, and granular role-based access control. This is essential for protecting intellectual property and ensuring data integrity in networked environments, satisfying strict IT security policies.[30]

2. **Semantic Information Modeling:** LADS does not just move data; it *models* the device. It defines a "Spectrometer" or a "Robot" as an object with standard properties, methods, and states. This "device-agnostic" modeling allows an orchestration system to command a "generic centrifuge" without knowing the specific brand or model, provided it complies with the LADS profile. It transforms the integration problem from "how do I talk to this specific box?" to "how do I interact with this *type* of capability?".[8]

2.3 The Synergy: Why We Need Both

Often mistakenly viewed as competitors, SiLA 2 and OPC UA LADS are complementary.

- **SiLA 2** is the preferred choice for rapid integration of benchtop R&D instruments where ease of use, human readability, and quick reconfiguration are paramount. Its reliance on gRPC makes it very developer-friendly for modern software stacks (Python, C#, Java) used by data scientists.[20]
- **OPC UA LADS** is the choice for high-reliability, continuously running automated lines, and integration with enterprise manufacturing systems (MES/ERP). It excels in environments requiring strict user management, audit trails, and deterministic communication.[1]

The Industry Requirement: We do not mandate one over the other in isolation. Rather, we require that vendors support **open standards based on these frameworks**. Ideally, a device would offer a "Dual Stack" or "Hybrid" approach.[20]

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3. The Data Integrity Dimension: Semantics and FAIR Principles by Design

Connectivity, the ability to move bytes from A to B, is only half the battle. The other half is **Semantics**, the ability to understand the *meaning* of those bytes. A "Lab of the Future" cannot function if the orchestration system receives a number "8" without knowing if it is a temperature, a pH value, or an error code.

3.1 The Role of Data Standards (Allotrope & AnIML)

To achieve true interoperability, communication standards (SiLA/OPC UA) must transport standardized data formats. The industry has aligned around several key data initiatives, most notably the **Allotrope Foundation** and **AnIML (Analytical Information Markup Language)**.[33]

- **Allotrope Foundation:** The Allotrope Framework provides a standard ontology and format for analytical data. The **Allotrope Simple Model (ASM)** is a JSON-based standard that structures instrument data using controlled vocabularies. It ensures that metadata (who, what, when, how) travels with the raw data, creating a self-contained, statistically complete

record of the experiment.[3]

- **Integration with Comms Standards:** Recent technological breakthroughs have demonstrated the encapsulation of Allotrope ASM data *within* OPC UA LADS and SiLA messages. This means an instrument can send a result that is not just a value, but a fully contextualized, standards-compliant data package ready for long-term archiving and AI analysis.[34]

3.2 FAIR Data Principles

The life sciences industry and adjacent laboratory-intensive sectors are deeply committed to the **FAIR Data Principles** (Findable, Accessible, Interoperable, Reusable). These principles are not just academic concepts; they are operational requirements for maximizing the return on investment (ROI) of R&D data.[5]

Principle	Requirement for Automation
Findable	Data must have unique identifiers and rich metadata. LADS and SiLA provide the mechanism to tag data at the source (the instrument).
Accessible	Data must be retrievable via open protocols (APIs), not locked in proprietary software. Open standards ensure data is accessible even if the vendor software is obsolete.
Interoperable	Data must use shared vocabularies (ontologies). Integration of Allotrope models into SiLA/OPC UA ensures different systems "speak the same language."
Reusable	Data must maintain its context (provenance) so it can be used in future studies or AI training. This requires the "Contextual Integrity" that open standards preserve.

Table 2: Alignment of Open Standards with FAIR Principles.[5]

Vendors who persist in using closed, proprietary formats are actively obstructing their clients' ability to meet these FAIR obligations. By locking data into formats that require specific software

to read, they render that data "Un-FAIR", hard to find, inaccessible without a license, non-interoperable, and single-use.[14]

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4. The Business Case: Why Vendors Must Adapt

We anticipate resistance to this mandate. Historically, vendors have viewed drivers, proprietary software interfaces, and closed data formats as "competitive advantages" that create customer stickiness and generate revenue through licensing fees. We argue that this business model is obsolete, dangerous, and ultimately self-defeating and therefore not acceptable anymore.

4.1 The "Ecosystem" Advantage

In the consumer technology world, the value of a smartphone lies not in its proprietary quirks, but in the ecosystem of apps and services it supports. Similarly, laboratory instruments that "play well with others" become exponentially more valuable to the customer on one hand and increase market potential for vendors on the other hand.

- **Reduced Sales Friction:** A lab manager, automation experts and procurement colleagues are far more likely to approve the purchase of a device that can "drop into" their existing automation workflow with zero integration cost than one that requires a $50,000 custom engineering project and a six-month delay.[3]
- **Focus on Core Competency:** Vendors should compete on the quality (e.g. their science, better optics, faster robotics, lower detection limits, higher sensitivity) not on the obscurity of their software drivers. By adopting standards, vendors can stop maintaining legacy custom drivers for hundreds of customers and focus their R&D budget on improving the actual instrument performance and portfolio.[40]

4.2 The Threat of Obsolescence

The "Open Letter" approach signifies a collective market shift. As major life sciences companies align their sourcing strategies, vendors who do not offer standard interfaces will find themselves systematically excluded from Request for Proposals (RFPs). The risk of losing access to the "Big Pharma" market far outweighs the marginal revenue generated from proprietary driver licenses or custom integration services.[23]

4.3 Mutual Benefit: Reducing Vendor Support Overhead

While this declaration demands a shift in product strategy, it offers substantial long-term savings for vendors. Currently, instrument manufacturers invest heavily in developing and maintaining hundreds of custom drivers and "one-off" integrations for different customers. By adopting a universal standard like SiLA or OPC UA, vendors can shift engineering resources

away from low-value maintenance tasks. Instead of troubleshooting proprietary connections at individual customer sites and debugging with integrators who is in charge to fix errors, R&D budgets can be redirected toward core innovation and instrument differentiation. A standardized interface means "build once, deploy everywhere," drastically lowering the total cost of ownership for the vendor's software stack.

4.4 Risk Mitigation and Security

Cybersecurity is a massive concern for the industry. Legacy instruments often run on outdated operating systems (like Windows XP or 7) because the proprietary driver only works on that specific OS version. This creates a massive security vulnerability, a "backdoor" for ransomware into the corporate network. Open standards like SiLA 2 and OPC UA allow the interface to be decoupled from the OS. A device can for example run a modern, secure, stripped-down Linux kernel and expose a safe SiLA interface, significantly reducing the attack surface. IT Security departments are increasingly mandating this architecture, making open standards a requirement for network access.[3]

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5. Detailed Implementation Guidelines for Vendors

To support the demands made in the Open Letter, this report provides technical guidance on what "compliance" entails. This section is intended for the R&D and Product Management teams of the vendor companies, bridging the gap between the strategic demand and the engineering reality.

5.1 Implementing SiLA 2: The Path to Native Agility

Vendors targeting the R&D and flexible automation market should prioritize **SiLA 2**. The implementation path should follow the "Native" route to maximize value.

1. **Define Features with FDL:**
    - Use the SiLA Feature Definition Language (FDL) to map the instrument's capabilities.
    - *Do not reinvent the wheel.* Check the public SiLA repository (SiLA Awesome) for many different and maintained reference implementations and standard generic features (e.g., SiLA:LockInterface, SiLA:Authentication, SiLA:CancelController). Implementing these standard features ensures immediate compatibility with many clients.[3]
    - Define custom features only for the unique capabilities of your device (e.g., a specific "ShakeAndRead" command).
2. **Embedded Server Implementation:**
    - Implement a SiLA Server directly on the instrument's Linux or Windows embedded controller or in the device controlling software application.
    - Leverage open-source libraries available in C++, C#, Python, and Java to accelerate

development. These libraries handle the low-level gRPC/HTTP2 communication, allowing your engineers to focus on the business logic.[26]
    - Ensure the server is lightweight and robust, capable of running for extended periods without memory leaks.
3. **Discovery Service:**
    - Implement the SiLA Discovery Service. This allows the device to announce its presence on the network via mDNS.
    - This is the key to the "Plug and Play" experience. A user should plug in the device and see it appear in their orchestration software within seconds.[7]
4. **Validation:**
    - Use the SiLA Universal Client or Browser and official self validation tools to ensure the interface acts deterministically, handles errors gracefully (returning standard SiLA errors, not generic codes), and strictly adheres to the FDL contract.[41]

5.2 Implementing OPC UA LADS: The Path to Industrial Reliability

For vendors targeting the "industrial life sciences, Pharma 4.0, or high-throughput screening segments", **OPC UA LADS** is essential.

1. **Information Modeling:**
    - Map the device's internal variables and states to the LADS information model.
    - Identify which LADS "Functional Units" apply to your device (e.g., Sensor, Controller, Robot, Centrifuge).
    - The goal is to expose the device as a standard object. A LADS client should be able to identify it as a "Centrifuge" and know exactly which methods (Start, Stop, SetSpeed) are available.[8]
2. **Security Profile:**
    - Implement the OPC UA security stack fully.
    - Ensure support for SignAndEncrypt security policies using X.509 certificates.
    - Implement user authentication and role-based access control. This is non-negotiable for enterprise deployment and GxP compliance.[30]
3. **Companion Specifications:**
    - If the device produces complex analytical data (e.g., a mass spec, a plate reader), do not just expose scalar values (variables).
    - Implement the relevant companion specifications (e.g., LADS + Allotrope) to expose results as structured objects or file nodes that contain the full data context.[34]

5.3 The "Hybrid" Approach: Future-Proofing

For maximum market coverage, a device can support both standards. The underlying control logic (the "business logic" of the instrument) can be wrapped by two different interface layers: a SiLA server for the R&D/Science team and an OPC UA server for the IT/OT team.

- **Scenario:** A scientist uses the SiLA interface via Python to develop a new assay method. Once the method is validated, the device is moved to a production line where the MES controls it via OPC UA LADS using the established parameters.
- **Benefit:** This "Dual Stack" approach covers the entire lifecycle of the product lifecycle and represents the ultimate future-proof strategy.[32]

5.4 Transitional Strategy for Legacy "Brownfield" Environments

We acknowledge that laboratories operate with capital equipment that has lifecycles exceeding 10–15 years. It is not economically feasible to replace functioning "Brownfield" instruments solely for connectivity reasons. Therefore, our procurement mandate applies strictly to new acquisitions.

For existing legacy instrumentation, the use of "wrappers" or external converters to translate proprietary signals into SiLA/OPC UA is accepted as a transitional measure. However, vendors must commit that all future product generations (released after 2027) will support native connectivity standards out-of-the-box, eliminating the need for such retrofitting in the future.

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6. Operational Benefits: The ROI of Standardization

The shift to open standards is not merely a technical exercise; it drives fundamental business value by an increased opportunity space. To justify the internal costs of upgrading fleets and changing procurement policies, we must look at the Return on Investment (ROI).

6.1 Faster Time-to-Science

In a standardized lab, a new automation cell can be assembled in days rather than months. If a liquid handler fails, it can be swapped for a different model from a different vendor (assuming similar capabilities) with minimal software reconfiguration, provided both adhere to the standard interface contract. This agility directly accelerates scientific discovery and product development timelines.

- *Metric:* Reduction in "setup time" for new experimental workflows from weeks to hours.[1]

6.2 Total Cost of Ownership (TCO) Reduction

While open standards might temporarily increase the initial R&D cost marginally for the vendor, they drastically reduce the TCO for the customer organization:

- **Lower Integration Costs:** Eliminates the need for expensive custom driver development services for every new device.[42]
- **Extended and simplified Lifecycle:** Instruments are not rendered obsolete when a specific proprietary software version is deprecated. A standard interface remains valid as long as

the standard exists. A SiLA 2 device from 2025 will likely still be controllable by a potential SiLA 3 client in 2035.[7]

- **Simplified Validation:** Validating a standard interface (SiLA/LADS) is easier and more repeatable than validating a "black box" custom integration. Validation scripts can be reused across different devices that share the same standard features.[11]
- **Straights forward Debugging:** standardised and available tools for debugging are enabling the possibility to debug unexpected behavior of instrument or software applications. The root cause can be identified fast and vendor agnostic.

6.3 Enabling Artificial Intelligence by design

AI models are central to the future of scientific discovery and product development. They require training data that is structured, labeled, and contextualized.

- **Proprietary Data:** Often hidden in binary files, requiring complex "scraping" or "parsing" that is prone to error and breaks easily.
- **Standardized Data:** SiLA and LADS can enforce the inclusion of metadata at the point of generation. An AI agent can subscribe to a SiLA stream and receive real-time, structured updates.
- **The AI ROI:** The value of AI in life sciences and adjacent sectors is estimated in the billions. Standardization is the "entry ticket" to this value. Without it, AI projects remain stuck in the "data cleaning" phase, never reaching the "insight generation" phase.[1]

Comparison of Integration Approaches

Feature	Legacy Integration	SiLA 2	OPC UA LADS
Communication	Serial (RS232), USB, Proprietary TCP	HTTP/2, gRPC (Service Oriented)	TCP/IP, Binary (Client/Server, PubSub)
Data Format	CSV, Proprietary Binary, Text	Structured Types (Protobuf/XML), FDL	Information Models (Nodes, Objects), XML/Binary
Discovery	Manual Config (COM Ports, IP)	Zero-Conf (mDNS/Service	Local Discovery Server (LDS), GDS

		Discovery)	
Security	None (Air-gapped usually)	TLS Encryption, Token Auth	X.509 Certificates, Role-Based Access
Driver Model	Intermediary PC + Custom Driver	Native (Embedded on Device)	Native (Embedded on Device)
Primary Use	Standalone Instruments	R&D, Flexible Automation, Scripting	Manufacturing, SCADA, Monitoring, Fixed Auto
Adoption Cost	High (Custom Dev & Maint)	Low (Open Source Libraries available)	Medium (Established Industrial Stacks)

Table 3: Strategic comparison of legacy vs. modern connectivity standards.[3]

Part III: Appendix

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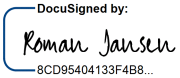
Roman Jansen roaj@novonordisk.com Associate Director Novo Nordisk Security Level: Email, Account Authentication (None)	DocuSigned by:  8CD95404133F4B8... Signature Adoption: Pre-selected Style Using IP Address: 165.225.194.194	Sent: 6/3/2026 3:00:48 PM Resent: 6/19/2026 1:51:08 PM Viewed: 6/23/2026 4:07:20 PM Signed: 6/23/2026 4:07:42 PM
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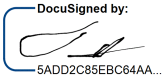
Tore Karlsson trkl@novonordisk.com Head of Operations & Investments Novo Nordisk Security Level: Email, Account Authentication (None)	DocuSigned by:  5ADD2C85EBC64AA... Signature Adoption: Drawn on Device Using IP Address: 147.161.155.75	Sent: 6/3/2026 3:00:49 PM Viewed: 6/8/2026 7:41:35 AM Signed: 6/12/2026 1:20:03 PM
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Zustimmung zum elektronischen Erhalt von Mitteilungen und Auskünften zu widerrufen. Kontaktieren Sie dafür bitte den Absender des Umschlags.

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