



WHITEPAPER

Digital platform strategy

Modernize life sciences product development with APIs



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Introduction

Life sciences organizations stand at a crossroads. On the one hand, these organizations are aiming to capitalize on unparalleled opportunities for growth across innovative net product lines such as targeted therapies. Clinical trials are at an all-time high — in the U.S., for example, the number of trials registered with the Food and Drug Administration has increased by 186% over the past 10 years.

On the other hand, the costs for developing these new types of products continues to increase. According to a study performed by the Tufts Center for the Study of Drug Development, over the past 10 years, per-drug research and development (R&D) costs have increased at an average of 8.5% per year above inflation, bringing the estimated average out-of-pocket R&D cost per approved new compound to more than [\\$2.8 billion dollars](#).

The challenges this cost problem presents only grow in magnitude when considered in light of the fact that, increasingly, life sciences product development has skewed away from the commercialization of mass-market blockbuster drugs and toward personalized drugs like targeted therapies, which have a smaller addressable market to capture.

Downward price pressures driven by private payers and government regulations further exacerbate this challenge.

The combination of increasing costs and downward price pressures have forced a paradigm shift in how life sciences organizations seek to run clinical trials, and the role that technology must play to support business strategy.

It takes a village (and a platform) to develop a drug

Drug development has always been a collaborative enterprise, requiring coordination of efforts across internal researchers, clinical trials, and patients to uncover the evidence required to move a drug through regulatory approvals. As the number of trials and the complexity of the products increase, the challenges of directly orchestrating the interactions across these parties have created an enormous operational overhead for product development. This has played a significant role in the sharp increase in R&D cost described above.

Organizations used to focus exclusively on how they could more effectively run clinical trials through internal efforts; now leading life sciences companies are looking to scale product development by harnessing the power of contract research organizations and development partners to accelerate trial execution.

Indeed, we see this transition taking place across the industry. Historically, the majority of clinical trials have been run directly by the sponsoring company, but a report by JZ Med indicated that by 2020, more than 70% of trials will be outsourced to contract research organizations.

On the surface, this new model may seem to address the challenges life sciences companies face around bringing drugs to market faster and at lower cost. However, many life sciences organizations are finding that the complexity of partnering with these organizations creates unexpected cost. As the contract research organization (CRO) market is highly fragmented (with the top 10 CROs controlling less than 60% of the market), the costs of interfacing with this growing number of partners, each of which must carefully orchestrate an already complex

ecosystem of investigators and patients, has, in some cases, outweighed the benefit of scale that they can afford.

Adding to this complexity is the fact that the R&D space has seen a proliferation of increasingly specialized technologies for addressing self-contained aspects of the clinical trial process. Modern cloud technologies like Greenphire, which manage clinical trials payments, or SecureConsent, which enable patients to digitally provide informed consent, provide the opportunity for life sciences companies to increase efficiency and reduce costs, but only if these applications are configured in such a way that they can scale across the complex ecosystem of R&D stakeholders.

How should life sciences companies deal with the increase in complexity across their development ecosystem and supporting technology?

Through its work with leading pharmaceutical companies, MuleSoft has found that by transforming R&D from a function owned end-to-end by the company to a platform capability, organizations can transform their vast ecosystem of partners and technologies from a bottleneck that increases complexity and cost to an asset that allows them to supercharge product development speed. This platform approach enables different partners to access the study, site, patient, or product data they need to more effectively deliver on their roles within the drug development life cycle.

One leading pharmaceutical company that MuleSoft worked with saw tremendous impact from employing such an approach; transforming the speed at which it can conduct studies by building a digital platform unlocks key study data from its on-premises legacy systems. With this digital platform, investigators and partners — and the applications they use to do their jobs — can consume subject, study, and site data in real-time without needing to rely on researchers and their supporting IT function to provision access. As new partners are onboarded, and as existing partners bring on new technologies

to help them better run studies, they can seamlessly plug into this digital platform, removing the sponsoring life sciences firm as an innovation bottleneck.

How might other companies in the space look to replicate the success realized by this company in transitioning their R&D into a platform capability?

In our experience, APIs are the key to successful implementation of such a strategy.

Building research and development innovation platforms with APIs

APIs are driving operating model transformation across virtually every aspect of the life sciences value-chain, from how products are developed to how they are brought to market. They provide a standardized way to scale access to data and application logic across an ecosystem, enabling the same type of technology innovation that has catapulted companies like Netflix and Airbnb to the top of their respective industries.

One key practice these industry leaders have adopted is to treat these APIs as full-fledged products, not just cogs in the organization's technical engine—regardless of the scope of exposure of these APIs to the ecosystem. Failing to do so will create challenges in driving adoption of these APIs, which will in turn compromise the quality of the digital platform.

To understand the role that these types of APIs can play in supporting the optimization of research and development (R&D), consider the role they might play in surfacing study data across the ecosystem of partners that might need access. First, APIs would help unlock access to the underlying systems that have data relevant to a study, such as operational databases, CTMS, or IRT systems. At MuleSoft, we refer to these types of APIs as “system APIs.” APIs can play a role in aggregating and orchestrating from multiple APIs to provide a single, standardized interface that hides the complexity of the systems the data is coming from. In this example, one might create a “study data” API that aggregates data from the source systems unlocked by system APIs.

This study API, in turn, could be used and reused across the entire ecosystem of researchers, investigators, and CROs that need real-time access to study data in order to be effective. Furthermore, this API could provide access to additional

supporting business functions that require access to this data, from subject marketing and enrollment, to the internal support functions that service investigators and CROs when issues arises as part of a study.

We call this approach “API-led connectivity,” and it has proven to be a critical enabler for developing digital R&D platforms.

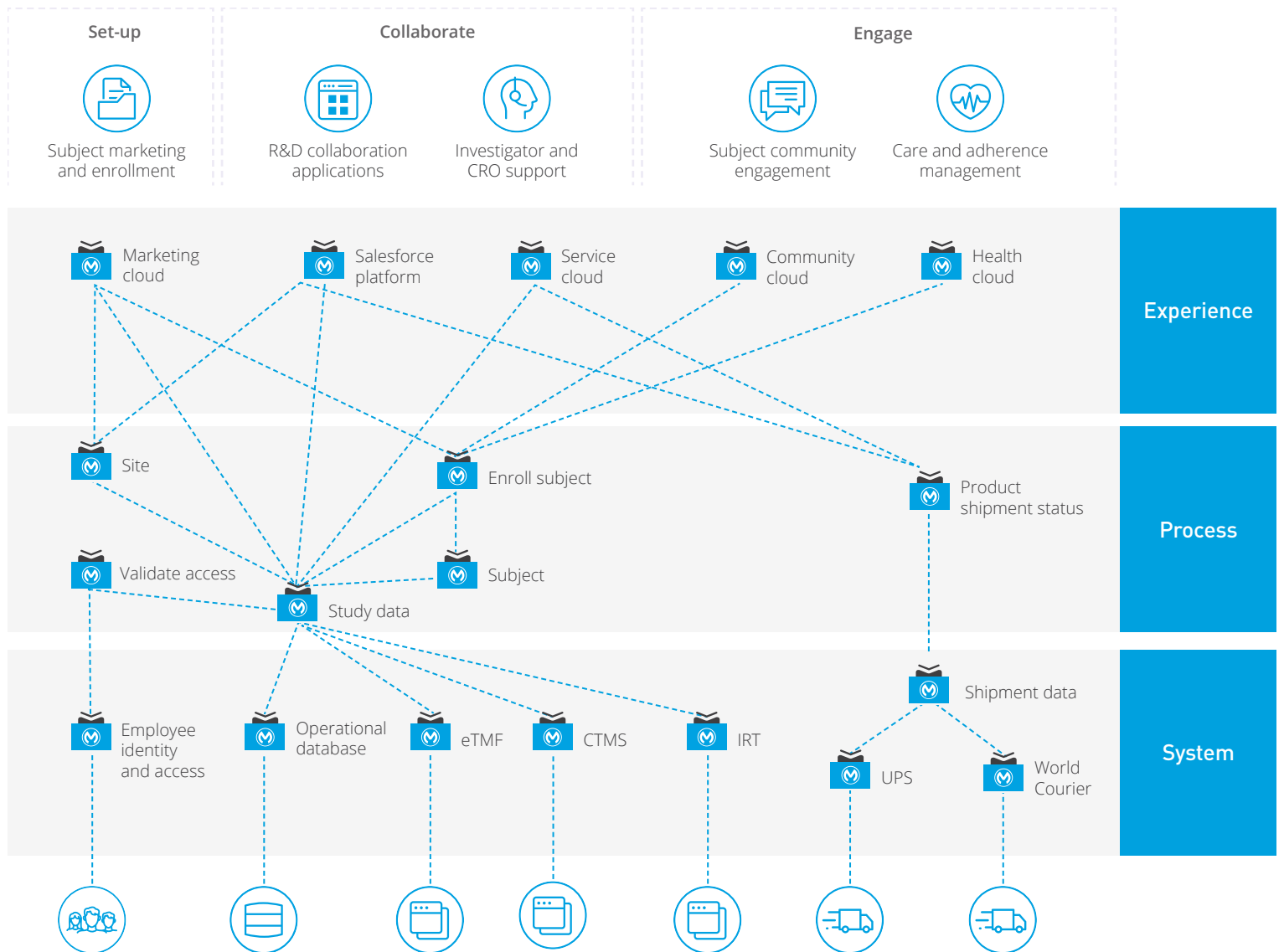


Figure 1: API-led connectivity: Pharmaceutical company

APIs were instrumental in helping the pharmaceutical company we discussed earlier to develop their R&D platform. With API-led connectivity, they were able to build system APIs that unlocked access to their operational database and IRT and orchestrate these capabilities into a “study API” that could be reused across multiple digital channels, including applications designed to drive recruitment and engagement.

These represent a small portion of the broader platform that the company has enabled their investigators with. By providing an end-to-end set of data and services unlocked through APIs,

each individual study team can compose these components in a way that best meets the needs of their own business processes, application ecosystem, and the specific study they are running.

MuleSoft's 4-step strategy for building an R&D platform with APIs

Based on our experience helping organizations like the one described above to build digital platforms with APIs, we recommend a four-step strategy for effectively building such a platform and maximizing the value that it creates for the business.

Step 1: Establish your digital strategy

Counter-intuitively, building APIs is not the first step toward establishing a successful R&D API platform. In fact, what some have found is that by rushing straight to development instead of first aligning on overall digital strategy, the API platform that IT builds does not end up driving the intended business outcome.

Instead, MuleSoft recommends that organizations first start by establishing their overarching digital strategy, aligning on what business challenge the API platform ought be designed to solve. Improving investigator and patient experiences during the clinical trial process, for example, will call for a different type of enabling digital platform than if the goal was to improve collaboration with CROs.

After aligning on the business challenge, organizations must align on how their digital strategy will support that challenge. For example, to improve CRO efficiency in running clinical trials, a pharmaceutical company could think about a number of different digital strategies, from enabling access to a standardized set of digital productivity tools to support trial administration (such as SecureConsent for informed consent logging), to providing self-service access to data for CROs to be more effective in using their own in-house applications.

Once the business challenge and platform solution are clearly defined, both business and IT must align on the target audience for the digital platform they design. This audience must be kept front and center when designing, sharing, and updating the APIs supporting your digital platform.

Step 2: Align organization and culture

For many, APIs represent a paradigm shift in how the business meets its objectives and how IT delivers projects. Ultimately, the people in your organization responsible for driving this shift in thinking will play a much more significant role in program success or failure than any technology implementation considerations.

This is why it's so important to instill an API-driven culture. It starts from the top: organizations that can obtain and evangelize an executive mandate for the use of APIs will ultimately be much more successful at implementing this type of culture. One need look no further than the now infamous "Bezos Mandate" where Amazon CEO Jeff Bezos dictated to his internal development teams that "All teams will henceforth expose their data and functionality through service interfaces." Because of this, APIs have been a fundamental driver of business model transformation at Amazon over the past 15 years, playing a significant role in its rise to market dominance.

For your digital strategy to succeed, APIs cannot be viewed as just cogs in the organization's technical engine. Regardless of the scope of exposure to the R&D ecosystem (whether APIs are being offered to internal consumers, external consumers, or both), they are treated as full-fledged products unto themselves.

Typically, for example, when a company offers some product to its customers, that product has to:

- Be designed with the intended customer in mind.
- Be packaged and marketed in a way that attracts targeted customers.

- Provide the customer with a great experience that inspires confidence in the brand .
- Be backed by guarantees it will work as advertised.
- Come with whatever support is necessary when customers have problems.

Furthermore, it is not enough for organizations to merely adopt the increased use of APIs. A more API-centric operating model introduces a new set of security considerations, with APIs introducing new surface area for malicious hackers to attack. This, in turn, calls for a corresponding cultural shift that allows for organizations to take advantage of the benefit APIs can provide without increasing the risk of compromising trial or subject data. Organizations must prioritize trust, security, and privacy as organizational values, and back up their commitment to these values through investment in security technologies such as vulnerability detection, threat prevention, and data-loss prevention. These technology investment, in turn, must be supported by strictly enforced security best practices, which are consistently tested for adherence.

How should life sciences organizations think about staffing to deliver this type of cultural change? Typically, we have seen organizations see greatest success by investing early in the following roles:

- Chief digital officer, or equivalent
- API product manager
- API developer
- API security specialist

With the right people in place, these organizations should then, and only then, look to implement programs, processes, and technology in support of the broader digital platform strategy.

Step 3: Evaluate and build supporting technology

Now comes the fun part: designing your API architecture and building the supporting APIs.

To enable the effective implementation of your API platform, we recommend designing according to the architectural principles of API-led connectivity. This design model allows for IT to more rapidly develop APIs for ecosystem partners to consume by enabling reuse across a supporting set of internal APIs that developers can use to unlock standardized access to core systems of record.

Once the architecture is defined, the next step is to buy or build a full lifecycle API platform that enables the development and management of your APIs.

Full lifecycle API management can be broken down into the phases listed below:

- Planning and initial design
- Test-driven development
- Flexible deployment
- Secure operation
- Governance and monetization
- Analysis and testing
- Developer engagement
- Versioning and retirement

Note that your successful execution of the API lifecycle will depend on the selection and deployment of a comprehensive platform for full lifecycle API management. This is where the business and technical teams will need to collaborate. Whereas the technical team will have its own set of concerns to address, the business team must be assured that the chosen solution is capable of supporting the aspirations identified in the digital strategy. For example, if the digital strategy depends on thousands of unknown software developers gaining self-service

access to certain APIs, does the management solution automate the provisioning of self-service registration?

The decision on build/buy, and if “buy,” which vendor to move forward with, should be informed by a number of business and technical considerations, including:

- **Time to market requirements:** Depending on the needs of the business, organizations may need to prioritize solutions which allow for the faster development of the initial APIs supporting their platform, as well as the ability to quickly update and version these APIs in response to API customer feedback.
- **API availability and uptime:** Depending on how mission-critical your API platform will be in supporting business operations, firms should ensure they implement a solution that minimizes downtime.
- **Security considerations:** For organizations in regulated industries like life sciences, which deal with highly privileged data, MuleSoft recommends that APIs be secured at multiple levels—through the implementation of individual API policies, edge gateways, as well as via tokenization and encryption of the data flowing in and out of these APIs.

In our experience and in light of the above considerations, in the vast majority of cases, organizations are no more suited to building their own API management solutions than they would be building their own database management solutions (as opposed to turning to Oracle or MySQL) or their own content management systems (as opposed to using Wordpress or Drupal).



Learn more about why Gartner named MuleSoft a leader in the [2018 Magic Quadrant for Full Lifecycle API Management](#).

Step 4: Engage your ecosystem

Many organizations mistakenly take a “if you build it, they will come” approach to the API platforms they build. Actively marketing your APIs and developing the ecosystem that will consume them is a critical last-mile problem that must be addressed in order to ensure that your API platform meets the intended business objectives.

For example, life sciences companies who implement an API platform for accelerating R&D should think about how they can formalize training and certification for how their CROs can consume the APIs they have exposed. Once adoption starts to pick up, they should implement programs designed to gather feedback on these APIs so that they can iterate on what has been built and improve partner engagement and satisfaction.

Doing so creates a flywheel effect, where greater adoption leads to more feedback, which enables firms to update their API platform to drive even greater adoption. And since the platform was designed in a way that tightly aligned to business requirements, this creates a secondary flywheel effect: by driving increased business impact, organizations can justify the investment of more people and budget toward accelerating adoption of and engagement with their API platform.

Evolving your R&D API platform over time

Ensuring the success of your platform depends on setting objectives for each of the four stages of the API strategy blueprint and then rigorously measuring and monitoring the organization's progress against those goals. Each of the four stages will involve different goals and KPIs, which will be very different from one organization to the next. The exercises of KPI identification, goal-setting and goal recalibration should be revisited frequently. For example, in response to successes, failures, market conditions, competition, and customer requirements, your digital strategy will be in a cycle of continuous evolution. Different organizations will certainly have different ways of defining success. But if the habit doesn't take root at the beginning of the journey with some goals, it won't bode well for the rest of the journey.

Building an API platform for life sciences R&D with MuleSoft's Anypoint Platform

MuleSoft's Anypoint Platform was purpose-built to enable the development of an application network through API-led connectivity and is the leading platform for doing so. It delivers an unmatched combination of capabilities that allow organizations to realize this vision, including:

- **Support for the full API lifecycle:** While many solutions in the market focus exclusively on API management, Anypoint Platform supports the full API lifecycle, enabling APIs to be treated like products. Anypoint Platform supports the entire software development life cycle (SDLC) — from designing, collaborating, building, and testing to deploying, publishing, versioning, and retiring APIs. This capability allows life science organizations to realize their vision of creating an internal “API economy” for investigators, CROs, and researchers to consume from.
- **A unified platform:** Anypoint Platform provides enterprise grade connectivity and support for the full API lifecycle on a single platform, eliminating the need to manage multiple products, vendor relationships, and skill sets. Unifying the functionality required to build an application network streamlines development and simplifies application maintenance. According to a leading life sciences company that MuleSoft works with, doing so allowed a 4:1 reduction in their API and integration technology spend through reduced support, licensing, and staff costs.
- **Security by design:** With Anypoint Platform, each individual API can be governed using API policies. Anypoint Platform also enables the implementation of edge gateways that allow for the application of global security policies across all APIs. It enables for data flowing through

APIs to be encrypted and tokenized, protecting against man-in-the-middle attacks and other cyber-threats. These security capabilities allow life sciences companies to build an open platform for R&D innovation that partners can consume from without compromising on security.

With these capabilities in hand, life sciences organizations can feel well-equipped to capitalize on today's market opportunity, leveraging the power of an API platform to power a faster and more cost-effective model for developing new products.



Want to learn more about best practices for developing your API strategy? To learn more, view MuleSoft's [API strategy essentials: A practical guide for winning in the API economy](#)

About MuleSoft

MuleSoft, a Salesforce company

MuleSoft's mission is to help organizations change and innovate faster by making it easy to connect the world's applications, [data](#), and [devices](#). With its API-led approach to connectivity, MuleSoft's market-leading Anypoint Platform™ empowers over 1,400 organizations in approximately 60 countries to build application networks. By unlocking data across the enterprise with application networks, organizations can easily deliver new revenue channels, increase operational efficiency and create differentiated customer experiences.

For more information, visit mulesoft.com

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