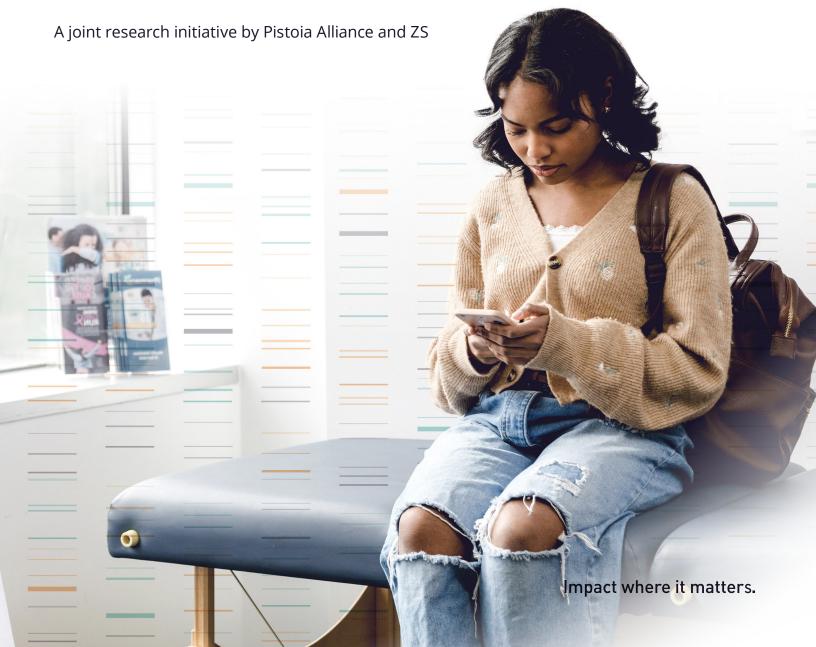


# Are misaligned incentives preventing better patient outcomes in life sciences R&D?

The hidden barrier to full human data integration



# **Executive summary**

In this white paper, we set out to explore what it would take to fuel the future of R&D innovation through near-real-time integration of all dimensions of human health data. In this future, we envision that drug companies will leverage the full breadth and depth of human health data to develop new therapies faster, including for rare diseases, and healthcare providers (HCPs) will combine each patient's complete health data with deeper disease understanding to offer truly personalized medicine.

To understand the feasibility of seamlessly fusing research data, clinical data and real-world data (RWD) at a human level, we conducted 25 one-hour discussions with industry leaders from across pharma and biotech R&D, regulators, patient advocacy groups, health system administrators and physician key opinion leaders. We intentionally curated our interviews to capture the point of view of the C-suite, senior vice presidents and vice presidents, while also including individuals immersed in day-to-day execution and operations in R&D. (A list of representative job titles and the types of organizations they work at, appears in the appendix.)

We interviewed our experts about the current data integration landscape, asking them to imagine the use cases that would unlock this future vision for integrated human data and the transformations needed to bridge any gaps. Specifically, they answered these three questions:

- How is your organization using data to drive better R&D outcomes today?
- What prevents your organization from unlocking the full potential of the data to which you have access?
- What does the ideal future state look like for R&D data, and what outcomes and value would it allow you to realize?

What we learned was both sobering and surprising. While pockets of progress exist, a consensus formed among our interviewees that we're farther from this vision than we initially believed. What's more, many of the most formidable barriers are of our own making. Again and again, interviewees expressed that the technical challenges of integrating comprehensive health data are less daunting than the human and organizational ones, namely: misaligned incentives that discourage stakeholders from across the research, development and clinical ecosystem from doing so.

# Imagine R&D in a world featuring complete, fully integrated patient-level data

It's 2030, and Olivia has just been diagnosed with Hodgkin's lymphoma. The good news is she receives her diagnosis not when her symptoms appear but years before, when her doctor notices an elevated biomarker that's been shown to predict the disease years into the future. Based on Olivia's unique biology and thousands of real-world studies showing responses in similar patients, doctors prescribe a personalized course of treatment before Olivia experiences her first sign of illness.

That same year, a leading biotech company uses data from other companies' failed clinical trials to conduct sophisticated predictive modeling on its phase 1 assets. Based on this exercise, the company halts development on dozens of experimental compounds, allowing the company to increase its probability of technical and regulatory success dramatically for phase 1 assets and to save billions in development costs—money that will be passed along to patients in the form of less-expensive therapies.

Meanwhile, the company has also built a massive data lake that makes research and development data accessible to every employee in the company. This drives fast, robust decision-making and frees researchers to work on higher-impact activities directly linked to delivering therapeutic innovation faster.

This future isn't science fiction, it's just science enhanced by the free flow of data within and across the healthcare system.

# Imagine a future where universal patient data informs all aspects of biopharma R&D

The world where we can deliver personalized care to people like Olivia is also a world where advanced molecular profiling and high-resolution imaging technologies are universal, offering every healthcare consumer a detailed picture of their individual health risks and disease predispositions. In this future state, each of us would receive a truly personalized health roadmap that guides disease prevention, diagnosis and treatment based on our unique biological, environmental and lifestyle traits. Doctors prescribe therapies with personalized dosages based on a patient's specific disease, their unique biological signature and insights drawn from the clinical and real-world outcomes of thousands of patients whose own biology resembles theirs in ways only detectable using advanced AI modeling.

In this world, drug companies leverage data from research, clinical trials, multiomics (e.g., genomics, proteomics and metabolomics), imaging and RWD to power algorithms that turbocharge research and development teams. They harness the power of this data with advanced AI to execute fully in silico clinical trials, allowing them to move substantially more assets through clinical development at unprecedented speeds and lower costs. By

building knowledge management systems with standardized ontologies and leveraging RWD, biobanks and peer-reviewed publications to understand mechanisms of action more deeply, researchers develop finely tuned patient subtypes that will predict how individual patients will respond to treatment.

This healthcare nirvana isn't possible only in some hazy, distant future. It's possible today, with data we've already collected and technology currently deployed across healthcare. Making this vision a reality means equipping every healthcare consumer with their own comprehensive health "passport." It depends on bringing together three elements:

- **Informed consent.** Enabling a holistic, patient-level dataset that includes each health data point across every person's lifespan will only be possible if patients understand and consent to how their health data will be used to advance research.
- **Data integration.** All patient data must be anonymized to protect privacy and integrated to make it useful in aggregate.
- **Data FAIRification.** Data must be findable, accessible, interoperable and reusable (FAIR) to ensure it's accessible and usable within life sciences R&D.

We say this is technically possible, not that it will be easy. It's a far cry from today's reality, where R&D organizations rely on an array of fragmented data sources to inform drug discovery and clinical development and where doctors default to broad-stroke clinical guidelines because it's the best they can do using the available data.

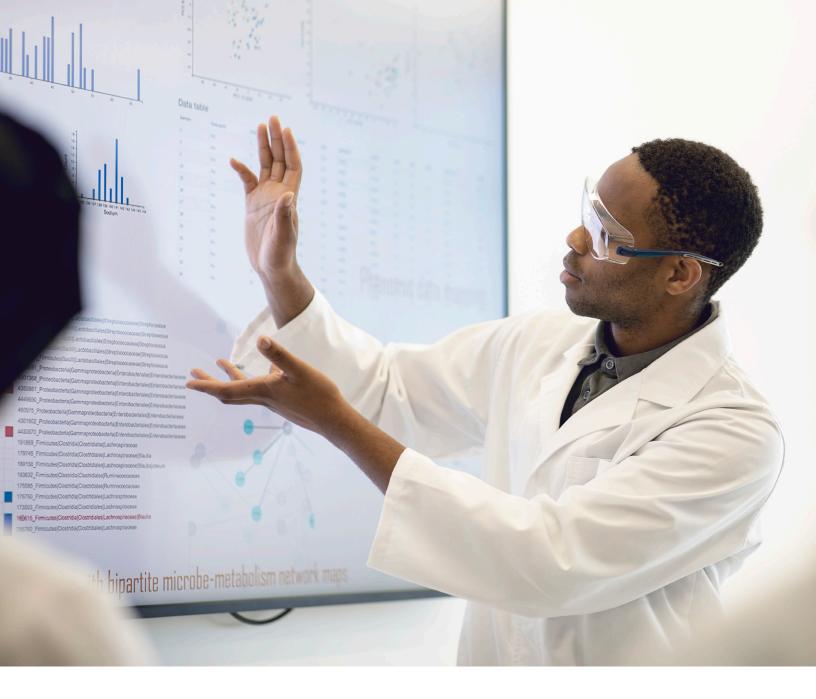
So, why does the vision of uniting preclinical data, clinical data and RWD feel so close and yet so far away, a shimmering mirage pinned to the horizon? And, more importantly, what's stopping us from making it our reality?

# The high cost of today's disconnected healthcare data ecosystem

The first thing we learned from our interviews is that companies are making tangible progress collecting increasingly rich data about patients. They are using this data to deepen their understanding of the mechanisms of disease, identify new targets and discover new molecules. In certain disease areas, such as oncology, organizations are using this data to improve their ability to identify patient subtypes with clearly defined biologic characteristics that may respond to a specific treatment. Collectively, this work is driving more personalized care decisions.

Said one executive at a top-10 biopharma company: "We're doing things on an everyday basis we could only have dreamed of five years ago."

Unfortunately, too much of this progress is happening in isolated pockets, limiting progress toward the vision we've outlined. "There's a separation between the people who are driving



the research and the people who are passionate about what the data can do," said the global head of digital strategy and enablement for another large biopharma company. "We need to encourage the convergence of those two groups."

R&D organizations today rely on a diverse array of data sources to inform drug development. While clinical trial data remains central, other sources spanning the clinical, preclinical, real-world and digital realms play an increasingly large role. This includes biomarker data as well as RWD from electronic health records (EHRs), claims data, wearables and more. Social drivers of health data, patient-reported outcomes and outputs from imaging technologies must also be integrated, which further increases data heterogeneity.

The figure below depicts just some of the patient outcomes a fully integrated human dataset could power.

FIGURE:

# A labyrinth of disconnected data sources powers today's R&D processes

#### Building a fully integrated human dataset starts with connecting a fragmented data ecosystem

#### Clinical trials data

- Electronic data capture (EDC)
- Clinical data repository (CDR)
- Clinical trial management system (CTMS)
- Laboratory information management system (LIMS)

#### Research data

- In vitro data
- In vivo data
- Pharmacokinetic and pharmacodynamic data
- Academic research

#### RWD

- Claims
- EHRs
- Biobank
- Patient registries
- Wearable data
- Social media and online platform data

Overcoming the barriers preventing widespread data sharing would yield a...

#### Fully integrated human dataset

## A sampling of use cases this data could power

#### **Patient subtyping**

Increased precision to identify novel patient subgroups and tailor drug development

#### LLM-powered chatbots

Real-time analysis on all R&D data to inform decision-making and accelerate drug development

\*Large language models

#### **Predictive safety**

Improved drug safety profiling and reduced trial protocol amendments

#### Deterministic medicine

Algorithmic approach to treatment decisions based on precise understanding of biological, environmental and lifestyle factors

### Digital twins

Digital patient copies to simulate clinical trials

#### Health data passport

Seamless patient access to their entire health dataset and the ability to share with doctors and researchers



### Fully integrated human data would drive a range of positive patient outcomes

Early diagnosis and intervention

Precision care based on individual biology and lifestyle

Access to personalized, affordable therapies faster

Ability to share health data to benefit research This fragmented ecosystem is one factor that is fueling significant increases in cost, risk and inefficiency in today's drug discovery and development life cycle. Just think:

- The average non-oncology treatment takes nearly eight years to move from phase 1 trials through phase 3, per internal ZS analysis. For oncology therapies, it's nearly 12 years.
- Clinical trials account for <u>roughly 40%</u> of the overall R&D budget for U.S. pharmaceutical companies, with the average approved drug costing around \$2.5 billion to bring to market.
- Al tools, advanced analytics and decentralized technologies are revolutionizing clinical development by automating data analysis, optimizing trial design and enabling synthetic trial arms and digital endpoints. And yet, 90% of drug candidates fail to progress through all phases of clinical trials to reach regulatory approval.
- On average, scientists explore <u>about 10,000 new compounds</u> to yield just a single approved therapy.
- Return on investment for pharma R&D has been on a steady decline since the early 2000s.

"There's going to come a point in the 2030s when cancer care will become unaffordable for many, in part because developing new therapies has become too expensive. Can we change the cost equation before this happens?"

- Medical doctor, professor of health informatics and advocate for health data innovation

Of the roughly 90% of clinical compounds that fail to win regulatory approval, 40%-50% fail due to lack of clinical efficacy, 30% due to unmanageable toxicity and 10%-15% due to poor drug-like properties. Integrating preclinical, clinical and RWD would help reverse these worrisome trends in R&D. With access to failed clinical trials data—including data on patient stratification strategies, dosing regimens and adverse events—R&D teams could pause development of nonviable assets earlier, design smarter trials, identify potential hazards sooner and make more informed go versus no-go decisions. Integrating longitudinal RWD, meanwhile—including data from EHRs, registries and connected devices—would allow researchers to correlate clinical outcomes with biomarkers, comorbidities and lifestyle factors.

This level of insight is critical for pinpointing patient subtypes who are more likely to respond to experimental therapies and for excluding individuals who may not respond or are more likely to experience serious adverse effects. Cross-referencing trial outcomes with multiomics data can reveal predictive biomarkers that guide precision medicine approaches.

Enriching datasets with wearable sensor data and patient-reported outcomes, meanwhile, can add another layer of granularity that allows researchers to assess real-time treatment adherence, symptom progression and quality of life. Taken together, integrated insights like these can directly inform R&D decisions, improve trial efficiency and accelerate the development of targeted therapies.

"What we need is a hunger to learn from the data," an interviewee who leads a nonprofit focused on driving innovation through health data, told us. "Think of a cancer patient seeing multiple doctors over multiple years, and none of that data is interoperable. We need to create the drivers to learn from the data. This is the most critical element."

# Currents driving progress in healthcare data collection and connection

To realize the full potential of patient health data today, life sciences companies must work toward building integrated datasets across the R&D value chain—from disease state understanding to regulatory approval and commercialization of therapeutics. Fortunately, several trends are already pushing us in the right direction. Among our interviewees, approximately 60% identified increasing data collection as a cause for optimism, while approximately 50% identified innovations in AI, machine learning and advanced analytics. Only 20% mentioned collaboration.

- **Breadth and depth of data collection.** The industry is already leveraging cloud computing and distributed databases to gather and store vast amounts of clinical trial data, multiomics data and RWD, enabling (among other things) synthetic control arms that allow more patients to receive the cutting-edge therapies under investigation.
- **Wearables and mobile apps.** The growing use of devices such as continuous glucose monitors, smartphones and smartwatches with electrocardiogram sensors creates a pathway for more robust real-time data capture, augmenting physician and lab-collected biometric data.
- Advances in analytics, AI and machine learning. Gen AI has unlocked new
  opportunities in clinical research and development, for instance by fueling de novo
  molecule design, using historical data to predict patient responses and RWD to match
  patients with increasingly narrow inclusion and exclusion criteria in clinical trials. Based on
  this promise, companies are investing heavily in the data infrastructure to support these
  data-intensive analytics.
- Organic, grassroots cross-industry collaboration. It's becoming increasingly
  common for individuals at the grassroots level to reach across organizations to promote
  collaborative development of open-source packages, analytical methods and vocabularies
  to support ontologies, all in a way that preserves intellectual property. A perfect example
  is the Pharmaceutical General Ontology, an industrywide initiative to identify preferred
  vocabularies for communitywide standardization of core R&D concepts.

"We are collecting a massive amount of data ripe for use in R&D, especially genomic data. So, we have the data we need to do amazing things, but we can't exploit it."

- Research IT leader at a large pharma company



# Why uniting data to fuel research breakthroughs feels so far away: Holistic-patient-level data's incentive problem

When we began this endeavor, our goal was to learn what it would take to create a fully integrated human dataset. Based on our interviews, what's holding us back has less to do with data per se and more to do with misaligned incentives that discourage data sharing. This disconnect hampers collaboration within life sciences organizations, across life sciences organizations and across the healthcare ecosystem.

"Appealing to the greater good isn't a sufficient trigger," the head of a company that builds Al models for biopharma R&D said of what does and does not motivate companies to share data. "Here's what biopharma companies care about, in order of importance: One: Will it create a security threat if you use my data? Two: If I share my data, will it indirectly benefit my competition? And three: What's in it for me? So, we must create a trade: If you give us your data, we'll give you access to the types of insights you're interested in."

In reality, here's how misaligned incentives hamper data sharing in healthcare.

1. Within life sciences organizations. Within life sciences organizations, functional silos, data ownership and legacy systems inhibit R&D teams' ability to integrate their own data from research, clinical trials and RWD. Three factors are primarily to blame:

Functional silos. Too often, preclinical, clinical, regulatory and safety functions operate independently of one another. Roughly two-thirds of the leaders we interviewed cited functional silos as a top barrier. This owes partly to a lack of horizontal data integration, which means clinical trial insights, regulatory documentation and postmarket surveillance results are often unavailable to discovery teams early in the R&D process. This stifles learning across the drug development life cycle, limiting the ability of AI models to identify promising compounds or anticipate regulatory hurdles. Misaligned incentives across teams—for instance, discovery teams that are incentivized to generate as many drug candidates as possible working against portfolio management teams incentivized based on clinical success rate—further discourages data sharing and collaboration.

Data ownership and FAIRification. Pharma companies have invested in making their data FAIR, but these efforts are in early stages and uneven across the industry. About half of our interviewees cited this as a top barrier. Data sharing remains a pain point, as some functions restrict access to data out of either a misguided belief that controlling it increases its value or fear of others misinterpreting the data out of context. This often comes from an academic mindset that prevails among scientists, who traditionally have seen publication as their end goal. Most companies lack incentives that would encourage researchers to think differently about their data.

"We need to move people from thinking of themselves as 'data owners' to thinking of themselves as 'data generators' or 'data stewards."

- CTO, top-10 pharma company

Legacy systems. Many pharmaceutical companies struggle with technical debt from outdated systems that are poorly suited for modern data integration. These legacy systems, originally designed for isolated processes, lack interoperability and inhibit the smooth flow of data across departments. Nearly 60% of leaders in our survey said legacy systems are holding them back. The challenge is so severe, our interviewees observed, that it is often more cost-effective to conduct new experiments rather than clean or reformat existing datasets for their reuse. While fresh data can sometimes be valuable, interviewees said the benefit rarely justifies the cost of running new experiments.

The problem is further compounded by a lack of return-generating use cases to justify the investment needed to modernize technology stacks. Without clear business cases such as measurable efficiencies from data reuse or enhanced patient outcomes from predictive models—R&D teams struggle to secure funding for IT modernization initiatives.

# "The ability to create impactful business cases is a problem."

- SVP in clinical technology solutions for a multinational pharma company

2. Across life sciences organizations. From one life sciences company to the next, the absence of standardized data formats and incentives to work together encourage data hoarding and stifle collaboration that might otherwise produce win-win use cases.

Lack of data standards. Even when companies are willing to share data, the relative scarcity of widely accepted standards for research and clinical data formats prevents efficient cross-study analyses. Current standards such as Clinical Data Interchange Standards Consortium's (CDISC) Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) for clinical development, Standard Exchange of Nonclinical Data (SEND) for nonclinical development data, and Simplified Molecular Input Line Entry System (SMILES) or the Hierarchical Editing Language for Macromolecules (HELM) for drug discovery are in themselves insufficient to enable the seamless sharing of more complex datasets, including genomic data. Three out of four interviewees blamed the lack of widely accepted standards for slowing their progress.

The reliance on bespoke internal data models further complicates interoperability. One company's pharmacokinetic models, for example, might not align with another's. This hinders opportunities for meta-analyses that could inform better patient outcomes or predictive simulations of new compounds. While efforts to develop harmonized ontologies are underway, the lack of coordination between companies, regulatory bodies and technology providers slows adoption.

"What we need is industrywide alignment on what the right path forward is—to help develop the ontologies and standards. This will save us years of experimentation. An organization like the Pistoia Alliance is primed to do this."

- A senior director in R&D for a multinational pharma company

Lack of incentives for collaboration. Many companies remain hesitant to share data, even in a precompetitive context, due to a lack of understanding of what they should classify as proprietary to protect their competitive advantage. Yet most of our interviewees were quick to highlight that "data" is not the same as "insights." While insights should be considered proprietary, more data needs to be shared precompetitively to drive better outcomes for patients. The instinct to hoard data is leading to missed opportunities for industrywide innovation.

Precompetitive collaboration could accelerate progress by pooling historical datasets to inform AI models that simulate absorption, distribution, metabolism, excretion and toxicity (ADMET) of new compounds. Failed clinical trial data—often discarded could be reused to improve patient safety, optimize trial designs or reduce redundant research efforts. "At some point, we need to come together to share the data," a senior R&D leader told us. "Choose any disease; no single company will ever be able to understand it in isolation."

The absence of shared incentives or reward mechanisms means that companies view data sharing as a cost rather than a value generator. Unsurprisingly, more than 60% of those we surveyed cited this as a significant impediment. Regulatory frameworks are slowly evolving to encourage data sharing, but the lack of a consistent, enforceable model for data reciprocity discourages widespread participation.

3. Across healthcare systems. The fragmented landscape of data privacy laws and informed consent frameworks across countries—GDPR in Europe, HIPAA in the U.S., and PIPL in China—creates significant challenges for life sciences companies. Inconsistent enforcement and varying interpretations by pharma company legal departments force companies to develop region-specific protocols, complicating cross-border data sharing and increasing costs. About half our interviewees pointed to regulatory challenges as a significant hindrance, and about 10% mentioned disparities in healthcare infrastructure.

Disparities in data infrastructure also obstruct the collection of diverse datasets. While some countries have robust EHR systems, others rely on paper-based records or fragmented healthcare networks, creating data silos. This limits the ability to generate RWD and hampers the development of generalizable models for precision medicine, which rely on diverse, multiethnic datasets.

# Fixing the underlying incentives problem hampering R&D data sharing won't be easy

No healthcare entity can single-handedly bring together the data needed to fuel an R&D revolution through free-flowing health data. Creating the conditions for it requires two key elements.

First, healthcare consumers must believe that sharing their data will produce value, either to the general public in the form of new therapies or to themselves in the form of more personalized care—or both. ZS's annual survey of doctors and healthcare consumers in the U.S., the U.K. and elsewhere consistently shows that people are willing to share their data if they perceive a benefit.

Second, life sciences and healthcare stakeholders must come together to strengthen the value of the existing data standards and drive cross-industry collaboration to create and implement new ones that encompass research and RWD. While FAIRifying data is a worthy and achievable objective, it's not a sufficient solution on its own. To encourage the behavior shifts needed to capitalize on FAIRification, strong incentives must be in place for doing so.

Based on our interviews, this is how we suggest leaders think about creating the change to harness the power of universal health data sharing for patient benefit.

### Ask: "How can my organization prioritize enterprisewide data sharing?"

As one example, researchers typically view publication as the path to recognition within R&D—a carryover from their predominantly academic backgrounds. This mindset leads them to view the data they generate as "theirs." To foster broader collaboration, it will be essential to encourage researchers and others with similar perspectives to shift their focus toward maximizing the data's value across the entire organization.

### Do: Create incentive systems tied to data sharing.

R&D leaders should look to introduce data sharing incentive programs tied to performance reviews and bonuses. These programs should incentivize individuals, teams and departments not only on their individual achievements, such as publications, but also on how well they contribute data to cross-functional projects or enterprisewide datasets. To promote data as a shared, reusable resource, R&D leaders should think about developing internal data citation systems where datasets reused by other teams earn recognition and rewards for the original generators—similar to how citations work in academic publications.

# Ask: "How can we facilitate cross-functional collaboration by aligning around a common set of goals and objectives?"

As long as research, development and commercialization teams lack a common set of objectives, they will continue to work in silos to achieve their own narrow goals.

### Do: Create shared objectives.

R&D leaders should look to implement organizationwide KPIs linked to shared objectives, such as shortening clinical trial timelines or improving patient outcomes. They should also consider making a portion of each department's performance metrics dependent on crossfunctional collaboration outcomes. This will push teams to ensure that success is contingent on the cooperation of multiple departments. Aligning incentives so that commercial teams benefit from early R&D success, and vice versa, is just one example of how R&D leaders can encourage data sharing across the drug development life cycle.

# Ask: "Once I've solved the human issues hindering data sharing, how do I prioritize the right investments in technology to harness the power of integrated data?"

Given that all systems are made up of people, processes, technology and data, R&D leaders need to engineer all these components in a coordinated and integrated way. This means providing technologies that are intuitive, align with existing workflows and make data sharing the easiest path to follow.

### Do: Align technology roadmaps with data-sharing aspirations.

Companies should establish governance groups that include IT, R&D, regulatory and commercial teams, to ensure technology investments align with both data-sharing goals and business priorities. They also should ensure that APIs, data lakes and metadata management frameworks enable integration and traceability, while data access, anonymization and compliance measures balance openness and privacy.

# Ask: "How do I challenge my own organization's beliefs about intellectual property to create precompetitive collaboration opportunities with other companies?"

No research entity holds the in-house data and expertise to perfectly understand, on its own, any disease. Life sciences companies spend billions of dollars generating data, but much of it won't be used to its fullest potential because it isn't shared across the industry to fill knowledge gaps. The intellectual property is in the insights and knowledge we learn from the data, not the data itself. Too often, leaders protect the data as their competitive advantage, whereas scientific advances require more data than any one company possesses.

#### Do: Calm worries over intellectual property.

To ensure maximum data utility, companies should create precompetitive data consortia that collect and curate nonproprietary datasets, such as failed trial and chemical structural data, in a shared, neutral repository governed by third-party organizations. To do this, they first would need to develop common data schemas and knowledge graphs that allow participating companies to extract insights without revealing sensitive intellectual property. R&D leaders

must also educate internal stakeholders about the nature of distributed, decentralized AI models, such as "swarm" and "federated," that allow parties to train a shared model without compromising raw data and other intellectual property. Pharma industry legal departments and others often make unnecessarily restrictive decisions to prevent data sharing when methods exist to safeguard intellectual property and data privacy.

# Ask: "How might we shift our thinking to recognize the long-term benefit of investing in a strong data foundation?"

Once incentives are in place to empower R&D personnel to think about data as a product with utility outside of the generator, companies need to invest in modernizing the technology stack associated with data—a significant outlay that will yield value over the long term. However, it should be noted it might be difficult sometimes to persuade the C-suite. While it's a stretch to expect executives to entirely disregard the importance of shorter-term financial performance, there are things R&D leaders can do to reinforce the long-term value of investing in data-sharing infrastructure today.

# Do: Continually promote the idea that investments in data-sharing technologies are investments in patient health.

People tend to enter the life sciences to improve lives, not to increase shareholder value. This noble mission can get lost without efforts to embed its ethos into an organization's culture. To rally executives around investing in data infrastructure, R&D leaders also should appeal to their leaders' sense of purpose around helping patients. They also should advocate for regulatory and reimbursement incentives that reward companies for collaborative behavior. Think fast-track approvals or priority review vouchers for clinical trials that incorporate external datasets or involve data sharing across organizations.



# Achieving our healthcare vision: Why now's the time to create the foundation for holistic integrated health data

As the pace of AI development increases and new health data streams emerge, now is the time to build the infrastructure and create the incentives for integrating holistic patient data. At the same time, the growing cost and complexity of therapeutic innovation is straining health system budgets and making new drugs inaccessible to many.

The future we imagined—one in which a patient like Olivia is diagnosed and treated long before her symptoms appear, and in which companies harness the power of research, clinical and RWD to accelerate innovation—is within reach. But it's not guaranteed.

To imagine and realize a future of better healthcare for everyone, we must drive change. We need to better align people, processes, technology and data to create more efficient, effective and patient-centric life sciences R&D and healthcare delivery systems. To this end, the Pistoia Alliance is leading numerous initiatives that aim to FAIRify data across functional silos, address data governance challenges—particularly those imposed by legislation and regulation—and tackle the long-standing, yet still unmet, need for change management. The Pistoia Alliance is eager to collaborate closely with regulators and organizations that share our mission to innovate through collaboration and invites them to join our initiatives.

As a Pistoia Alliance member, ZS supports collaborations, both in principle and in action, by bringing together data, science, technology and human ingenuity to create solutions that unlock life sciences innovation and drive outcomes where they matter most.

For those in R&D who believe in the promise of fueling the future of life sciences R&D through integrated patient health data, the opportunity exists today to build a coalition of like-minded groups united by this noble goal. But the window of opportunity won't last forever. As one interviewee told us: "If we wait to start three or four years from now, we'll be so far behind it will be virtually impossible to catch up."

Another interviewee closed on a more optimistic note: "These are solvable problems." Let's come together as an industry to do it.

The Pistoia Alliance and ZS call for organizations ready to help us move the industry forward to get in touch and to bring project ideas or opportunities for collaboration to help solve the challenges surfaced in this paper.

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- Ann Marie Gray
- Nicolas Zimmerman

# **Appendix**

The following is a representative list of titles of those who have contributed their expert perspectives to this white paper across sponsors, regulators, patient advocates, healthcare providers, and health systems:

- Chief Technology Officer
- Senior Vice President, Clinical Technology Solutions
- Executive Director, AI/ML for R&D
- Executive Director, Clinical IT
- Executive Director, Global Data & Al Ethics, Policy & Governance
- Executive Director, Systems Operations Management
- Vice President, Research IT
- Vice President, Data Strategy & Digital Innovation
- Director, IT for Drug Discovery and Early Development



# **About ZS**

ZS is a management consulting and technology firm that partners with companies to improve life and how we live it. We transform ideas into impact by bringing together data, science, technology and human ingenuity to deliver better outcomes for all. Founded in 1983, ZS has more than 13,000 employees in over 35 offices worldwide. To learn more, visit www.zs.com or follow us on LinkedIn.

# **About Pistoia Alliance**

The Pistoia Alliance is a global, not-for-profit members' organization made up of life science companies, technology and service providers, publishers, and academic groups working together to lower barriers to innovation in life science and healthcare R&D. It was conceived in 2007 and incorporated in 2009 by representatives of AstraZeneca, GSK, Novartis, and Pfizer who met at a conference in Pistoia, Italy. Its projects transform R&D through pre-competitive collaboration. It overcomes common R&D obstacles by identifying the root causes, developing standards and best practices, sharing pre-competitive data and knowledge, and implementing technology pilots. There are currently over 200 member companies; members collaborate on projects that generate significant value for the worldwide life sciences R&D community, using the Pistoia Alliance's proven framework for open innovation. To learn more

