Signet Accel

True interoperability
realized in healthcare.

UNDER PRESSURE:
MAXIMIZING EXISTING DATA INVESTMENTS IN BIOPHARMA WITH AVEC™

The biopharmaceutical industry is under tremendous pressure. Safety and efficacy in a broader sense are no longer satisfactory. Previously nuanced factors such as race, gender, age, and genetics are now center stage. More robust research methodologies and investigation of new treatments are expected and necessary, as is the need to better understand and predict interactive affects for those with comorbidities and concomitant treatments.

Much of what was once the domain of phase IV, post-marketing continued study, is rapidly becoming expected in the earlier phases of trial. Meanwhile, 50% of clinical trials already do not go forward due to an inability to recruit the patient populations needed to meet acceptable precisions to predict safety and efficacy. Add to this an increasingly critical public eye, financial pressures of fixed payer plans, increased research costs, and smaller market potential, and biopharma finds itself reevaluating investigation as usual.

Since 2009, the federal government has spent $28 billion dollars supporting the adoption of meaningful use and health information technology, with a goal of ensuring interoperability between systems and opening siloed data channels. Regrettably, just as much has been spent by healthcare systems and providers on products believed to be truly interoperable, only to discover they are not. This has meaning and implication for biopharma as well. While it's estimated that 80 percent of healthcare data remains unstructured, and therefore locked and inaccessible, with the existence and application of true interoperability, everything changes—existing data can be mined for new insight, researchers can ask more questions in less time, and previously inaccessible data is now ready for query, all without sacrificing ownership or security. And hardened disparate repositories of existing, yet dormant, data become liquid, connected, meaningful, and useable.

DON'T COMPROMISE, CAPITALIZE

With the biopharmaceutical industry sitting on large repositories of information, the ideal first phase of research is mining for gold within the data you already own but can't maximize today—across the global network, not just in one or two databases—shaping the development of treatment protocols and future trial methodologies, and discovering insights on effectiveness across diverse populations, all while increasing efficiency, lowering cost, and utilizing current resources to their fullest potential.

Next, revisit existing agreements to more quickly identify patients across institutions, both domestically and globally. And then once trials are underway, streamline data sharing on an ongoing basis to allow for speed of discovery, interpretation, collaboration, and adjustment as needed.

Having full access to the data you currently own and collaboration without compromise may both seem like lofty and near-impossible goals, and yet, there's but one solution that can meet this myriad of needs and deliver on expectations once thought nearly unattainable: Signet Accel's unique data sharing and true interoperability platform, Avec™. And it's not ten, or even four years away—it's currently in deployment across the globe.

LET AVEC™ MAKE IT POSSIBLE

While successfully engaging in biopharmaceutical research presents unique challenges, technology no longer need be a barrier to success. Avec™ is a proven, ready-to-deploy, and highly-effective database-agnostic federated data integration platform that delivers true interoperability to your data. Avec™ was purpose-built from the ground up to bring true interoperability to the healthcare ecosystem at large and address the fundamental issues surrounding data sharing in arguably the most complex healthcare and research environment in history.

Initiated at The Ohio State University, in collaboration with investigators and technologists on an international scale, Avec™ eschews traditional data sharing and harmonization approaches to create an entirely new paradigm for distributed, scalable, and high-performance interoperability between both disparate and heterogeneous data resources and stakeholders. We refer to its primary distinguishing attribute as true interoperability, as it delivers all that interoperability was originally intended to do—it truly connects and protects your data, as it is and where it is, regardless of its origin.

*In a research capacity, **true interoperability** capitalizes on existing investments, provides more complete answers, and reduces the time it takes to see real results.*

Avec™ doesn't disrupt the process of collecting data, the manner in which it's stored, where it's stored, how it's structured or, what language the data speaks. And its federated data model means data doesn't need to move…it can remain where it is and as it is. At its core, Avec™ is purpose-built to:

- Allow data generators to control where, when, and how data is shared with others and harmonized across standards and models, enabling such data owners to remain assured that concerns surrounding ownership, stewardship, and valuation can be addressed at a policy level that is fully supported by underlying technologies;
- Distribute the costs and infrastructure for data sharing and interoperability, such that each participant capitalizes on current investments and only supports those expenses directly aligned with their participation in such sharing regimes and the costs and values therein; and
- Scale and evolve gracefully to support constantly changing biomedical big data standards, types, and models in a manner that is fully independent of any and all data-generating technologies.

In addition, Avec™ incorporates an extremely lightweight technology deployment approach, alongside a library of data adapters that can interoperate with current HIT data generation platforms in a turnkey manner (such as common EHRs), thus lowering costs and increasing the benefits of true data interoperability and sharing.

Avec™ provides even greater value by maximizing existing investments in acquiring and maintaining data and ensuring that investments in sophisticated analytics and data visualization tools have full access to all the data possible—presenting the most complete answer, accelerating research, and setting the stage for sustainability and impact.

In an increasingly competitive and resource-constrained environment, Avec™ allows investigators to ask more questions and receive more complete answers in less time. Imagine what researchers could achieve if given the ability to ask 10,000 questions versus ten?

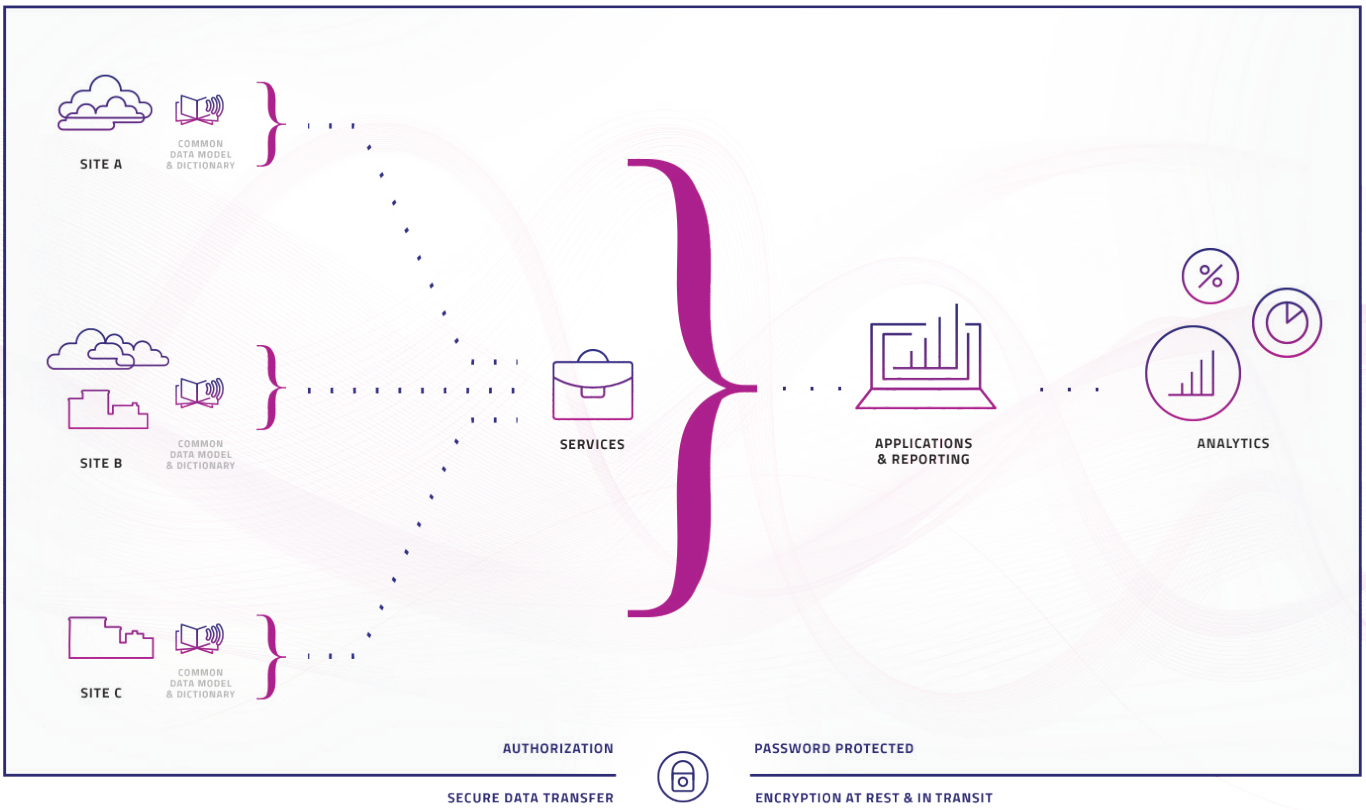
HOW AVEC™ WORKS

Avec™ is the culmination of more than 15 years of government and private-sector research and development targeting the development, deployment, and evaluation of state-of-the-art service-oriented architectures (SOA) for biomedical data federation that spans traditional organizational boundaries. It leverages a variety of open-source and standards-based technologies, augmented by proprietary components, in order to enable data sharing between and among heterogeneous data resources such as application specific databases, data warehouses, electronic health records, and analogous data management systems. The core technologies that underlie Avec™ were designed to enable the sharing of syntactically and semantically annotated data, as well as corresponding analytical resources, via a federated and grid-services framework that also includes shared capabilities such as: user management, common data element publication, service directories, computational workflow orchestration, and a variety of security services. Building upon this technological foundation, Avec™ also incorporates additional technical means of enabling peer-to-peer negotiation of data semantics, as well as the packaging of core technologies into easy-to-deploy "virtual" appliance constructs.

An overview of the functional architecture for Avec™ is provided in **Figure 1**. Of note, as the Avec™ technology stack has matured, it has been adopted and adapted by a variety of stakeholder groups and organizations, such as academic health centers, integrated delivery networks, multi-site research consortia, professional medical associations, biopharmaceutical companies, and other private-sector entities. A key feature set of the Avec™ model is a method and technology tooling that facilitates a rapid and platform-independent approach to the deployment of data sharing "wrappers" for each targeted data resource in a data sharing and interoperability framework or enterprise. This approach involves a series of activities that are purpose-built to involve the direct participation of knowledge workers in the design and deployment of said technologies, including:

1) The creation of technology-independent logical models for targeted data sets and their annotation with relevant semantic and data codification standard, using purpose built model-driven architecture tooling;
2) The translation of such models into scalable and high performance and automated data extraction and harmonization processes, implemented within the Avec™ ETL engine, and leveraging a proprietary library of data mappings that correspond to common database management and clinical information system, such as commonly utilized EHRs;
3) The execution of such data extraction and harmonization processes by the Avec™ virtual appliance, deployed alongside targeted data resources, so as to populate secure and high-performance staging databases;
4) The configuration of fine-grained data access and security/confidentiality controls by each data steward via a user-friendly web-based configuration portal, thus ensuring complete transparency and continuous monitoring of such technical policies;
5) The publication, discovery, query, and monitoring of distribute query capabilities, targeting the preceding staging databases representing a network of data resources and governed by the aforementioned fine-grained data access and security/confidentiality controls, using the Avec™ distributed data interoperability infrastructure; and
6) The configuration of complex data query and analytics "pipelines," using standards-based APIs, computational orchestration languages, and workflow engines, thus supporting a full spectrum of big data analytics needs and end-points.

Figure 1: *Overview of the functional architecture Avec™, a data sharing and true interoperability platform.*



An unmatched solution in clinical research:

1. Extract greater value of the data you already have
2. Conduct trials with international data without storing data stateside
3. No need to map a unique path for each EHR in a healthcare organization—connect and share EHRs in a HIPPA-compliant fashion

In a clinical trial setting, Avec™ offers:

1. Fluid access to existing patient data within a pharmaceutical company, while maintaining necessary permissions
2. Multi-site pharmaceutical companies can connect their own disparate data sources (data types include genome, molecular and clinical data, biospecimens, EMRs, clinical notes and more)
3. Deliver dynamic real-time information when determining the validity of pursuing a clinical trial
4. More accurate and faster selection of patients :
   a. Improve decision-making with respect to clinical trial candidacy
   b. Uncover links in research in less time
   c. Broader range of patients, more suited to testing

A NEW NORMAL

Once any given molecule is identified and patented, the time clock begins. The element of time only increases the pressure to usher a safe and effective drug to market before the patent expires, while still being mindful of all of the above challenges and regulatory requirements. And—you're expected to do it all with less money, under a microscope. This is the reality of biopharmaceuticals today.

So how does the biopharmaceutical industry conduct more robust research even though it already struggles to conduct the less robust research it wants to do? If the era of the blockbuster drug is behind us, and the future of biopharmaceuticals lies in treating subsets of the population, where market size decreases and cost of creation rises, what is the key to sustainably?

Is doing more with less even a viable option? The answer to all of the above is a resounding yes—with Avec™.

Avec™ brings order to disparate data once singularly applied and allows you to capitalize on data amassed through years of investment and hard work.

Avec™ makes it easy for investigators to find, see, and use the wealth of insights hidden in your data, regardless of its location or number of sites.

We help large organizations span the divide of their own departments and silos with ease and unite geographically dispersed divisions and external collaborators without compromising privacy, ownership, or security.

Avec ™ respects your partnerships and facilitates collaborative data sharing by honoring the most complex agreements. We enable individual-based permissions at site level, establishing both access and restrictions that bring momentum to shared insights. And just as powerfully, our platform provides immediate and complete access to patient population data—in a single query—and our services are aligned to address even the most stringent data use requirements and inclusion criteria.

Those organizations that succeed in coordinating, deepening, and accelerating discovery in this new normal for biopharma—mindful, cooperative yet highly competitive, and geographically disparate—will achieve both sustainability and biopharmaceutical breakthroughs. Let Avec™ make it possible.

YOUR QUERY ENDS HERE.

At Signet Accel, it's our mission to bring true interoperability to healthcare that emboldens discovery at the bench and beyond—profoundly affecting the ability of investigators and clinicians to understand, treat, and cure.

We are honored by the world's leading healthcare academic institutions, hospitals, and research networks that have trusted us to help them solve this problem. We know that this isn't easy. It takes a diversity of skills—not unlike the diversity of data we work with—and that is why we have assembled a team of expert technologists, researchers, and engineers with a shared focus and depth of experience in healthcare. We stand ready to show you what is truly possible when it all comes together. Experience true interoperability with Avec™.

CONTACT: Kimberley Ferguson | kferguson@ signetaccel.com | 619.722.1666

ABOUT SIGNET ACCEL

Signet Accel's Avec™ platform is true interoperability realized in healthcare. As the sole alternative to traditional, centralized data management solutions, Avec™ delivers the industry's only purpose-built commercial federated data integration platform, developed and refined over 12 years at The Ohio State University. Signet Accel's software products and services power the work of consortia, institutions, and health professionals around the world with unmatched security, sharing capability, and speed of discovery—advancing academic research, achieving meaningful use objectives, and enabling the continuum of care. Learn how to make your data meaningful and achieve true interoperability with Signet Accel.

Written in cooperation with Philip R.O. Payne, PhD, FACMI, Co-Founder, Signet Accel LLC.