Scope

This paper’s goal is to help healthcare and life science companies evaluate which cloud models are best suited to drive innovation as they plan for their future cloud platform needs. The content describes how a cloud platform integrated with big data, analytics, and cognitive services that is purpose-built for healthcare and life sciences can help accelerate innovation.
Market Landscape for Health Clouds

The promise of cloud and cognitive capabilities as a platform for innovation in the future of healthcare delivery is a leading discussion in every IT strategy meeting.

The term “cloud” is broad and spans a myriad of use cases — ranging from basic data storage, application hosting, and compute infrastructure to full-featured SaaS applications.

In the healthcare and life sciences industries, a few service delivery models dominate the landscape. One tier of providers offer HIPAA-grade infrastructure and storage, and pre-defined compute environments where companies can move on-premise workloads to cloud. Major integrators and consultancies offer process transformation solutions that often include customized application hosting services. Health and wellness solutions and fitness trackers use public clouds to support their consumer applications. Most solutions are horizontal, designed to meet the needs of any industry, and have since extended their solutions to target increased adoption by health entities. But to scale effectively, healthcare and life sciences companies will need end-to-end cloud solutions that address the specific challenges faced in their industries.

Business and Technology Drivers

The healthcare and life sciences industries face significant business and technology pressures that are driving them to consider cloud solutions.

- **Rising costs** of research and development along with productivity declines result in delays in discovery, clinical research, and commercialization of novel therapeutics

- **Regulatory environment**: increasing demands on the capture and reporting of key information about patients, their treatment and care such as adverse events

- **Higher expectations for patient care** delivered anywhere and anytime via mobile devices, for a population that is aging with higher incidence of chronic disease

- **Digitization and mobile devices**: increased consumer involvement (devices/data), rapid growth in use of mobile devices in care, and the digitization of data that creates new demands for data management

- **Shifts to value-based care** where big data and analytics are critical to assess factors contributing to overall cost of care across the value chain
• **Time to market and global markets**: increased competition from startups to iterate medical devices and applications quickly, curate evidence, and distribute and control releases globally and at scale

Cloud technologies can help companies increase productivity and efficiency. They can also help enable healthcare and life science companies to take advantage of innovative digital and mobile health IoT technology, provide research and clinical support to help enhance drug pipelines, and help providers and clinicians to improve care.

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**Basic Health Cloud Imperatives**

For healthcare and life sciences companies to adopt a cloud computing model, they must consider whether a cloud vendor provides certain essential attributes. These requirements span not only technology but also provider policies, operating practices, and warranties.

**End-to-end security and trust**

The cloud platform must provide multiple lines of defense — from encryption to intrusion detection, to administrative controls, to physical data center security and monitoring, to strong authentication. A health cloud must also provide all other precautions and controls described in HIPAA and needed to preserve Protected Health Information (PHI). Health cloud providers should go beyond providing these safeguards, and should include rigorous security and business continuity terms in standard contracts.

**Data privacy**

With the myriad industry and international regulations guarding health data, privacy and data governance must be a foundational design point of a successful health cloud.

The cloud provider must have clear documentation describing where and how protected health data can flow. To appropriately manage data governance, customers and providers must work together to ensure proper patient consent or data de-identification.

Customers need assurance that data are safely partitioned from any other cloud tenants. And cloud providers must have clear operating principles defining segregation of duties and controlling what developers, operators, or support personnel can access.

Most importantly, patients and customers must be able to trust that these controls are in place.
Compliance and regulations

Companies that manage systems in-house are responsible for the safeguards required to meet industry regulations and international data privacy laws. A health cloud should provide certain assurances to help customers meet these compliance standards.

The cloud provider can do this by meeting public international standards, such as ISO 2700x (International Organization for Standardization information security protocols), HIPAA, HITECH security framework, and other international privacy regulations.

The cloud provider must provide data center locations to meet industry or regional data residency laws. The new European Union GDPR (General Data Protection Regulation) laws have raised the bar on the level of transparency and accountability required by cloud providers.

Business continuity

A health cloud architecture must be designed with built-in capabilities to handle disasters or emergencies, including high availability, data backup, and disaster recovery. It is important to understand how quickly a cloud can recover from a denial-of-service (DoS) attack or data corruption. That capability is critical to whether higher classes of medical devices can be provisioned on clouds.

Interoperability and scalability

The cloud must provide ways to bring data in, and to integrate with on-premise systems such as identity management, directories, and sign on. Secure mechanisms are needed to onboard data to the cloud. And the cloud needs to easily scale to handle customer data growth or geographic expansion.
Transforming Health Takes More Than a HIPAA-Ready Cloud Environment: The Case for a Purpose-Built Cloud

The largest cloud providers today got their start in desktop productivity software, video and game streaming, online shopping, and financial and customer relationship management applications. Their solutions then expanded to add HIPAA and other controls, or broadened applications to target population health use cases.

But a cloud solution designed for health goes beyond basic security imperatives. The stakes are higher for health data. International privacy laws and industry regulations are not easily shared with a cloud provider. Processes for validating regulated medical devices still must be followed, compounded with the complexities of using a service provider.

When done right, a purpose-built health cloud can help customers speed time to compliance. When paired with big health data and the power of cognitive computing, a purpose-built health cloud offers a place to truly innovate.

Watson Platform for Health on the IBM Cloud

Watson Platform for Health on the IBM Cloud harnesses the power of cognitive computing to help solve the world’s biggest health challenges. It was designed from the ground up.

Built-in support for health data integration and standards

Watson Platform for Health is designed to support prevalent and emerging health data standards. It supports turnkey ingestion from popular EMR systems, and formats such as HL7 and FHIR (Fast Healthcare Interoperability Resources).

To gain insights from big health data, the cloud platform provides integration tools that take data in different speeds and formats, then normalize to a common data model for analytics.

Built-in tools and automation ease the burden of data mapping. Health terminology services provide a sharable service to map coding systems into a common language. Master data management provides the ability to track longitudinal patient records in an Enterprise Master Patient Index.

IBM provides a data reservoir with a Unified Data Model for Healthcare (UDMH), which defines a logical model to represent essential entities and relationships of the healthcare industry. IBM provides this capability in the
standard edition of Watson Platform for Health. This model is one of the tools that helps clients normalize data across data sets for use in analytics. Customers can also leverage the Observational Medical Outcomes Partnership (OMOP) common data model for observational and research data.

**Open, extensible architecture optimized for health data**

Support for open health data standards goes beyond enabling interoperability. It also helps customers protect IT investments. A health cloud not only needs to provide data privacy and security, but also to offer open mechanisms that allow customers to move data, to integrate with existing systems, and to harness existing IT investments.

**Watson Platform for Health does so through:**

- Open data frameworks and standards for interoperability
- Security and identity management protocols that integrate with systems the customer may be using on-premise today (LDAP directories, SAML-based authentication)
- Support for common consumer identity provider protocols such as Open Authentication (OAuth) or Open ID identity providers
- Application Program Interfaces (APIs) and specific services that are required for health-specific applications — such as patient and provider registry and medical ontology
- Program interfaces and gateways to help data move in a secure manner to and from the cloud data stores
- Integrated open source data analytics tools, such as Jupyter Notebook, R, Python

**Mobile, IoT, and application development**

A cloud platform designed for health needs to provide application development environments that facilitate emerging trends in health.

Watson Platform for Health includes entitlement in its base license — access to development, production, and disaster recovery cloud environments. Customers can flexibly add other environments as needed for validation or specific test needs.

Watson Platform for Health plans to support the IBM Bluemix Dedicated cloud development experience — as a way for enterprise customers and systems integrators to build solutions that extend the Watson Health Platform.

Increasingly, life sciences companies are seeing the value of providing “smart devices” to their patients. Customers creating mobile applications can use a HIPAA-ready edition of the IBM Mobile Foundation. Watson Platform for Health makes available APIs that HIPAA-enabled IoT and wellness tracking devices companies can use to integrate with the cloud platform. Applications using published APIs such as ResearchKit®, CareKit™ or HealthKit® can readily integrate with the Watson Platform for Health using mobile devices to help transform medical research and patient care.

**Data governance**

Watson Platform for Health provides tools to facilitate the process of managing patient consent and identity masking. The identity masking service is designed specifically to work with protected health data, with the ability to separate name identifiers from data and place them in a separate encrypted data store. To help clients use the data for analytics, tools are designed to support anonymization tokens for future provenance tracking. The offering is also designed to support emerging innovative technologies such as blockchain to manage consent and data governance.

The ability to track individual patient consent, combined with granular administration and role-based access, helps organizations use the cloud for multiple innovative purposes. For example, life sciences companies can use the same cloud platform to perform drug discovery research and to work digitally with prescribing providers. Sensitive health information remains protected from audiences that don’t have rights to view or use it.
Cognitive services designed for the health data scientist

The healthcare and life sciences industries have a unique need for cognitive services. Cognitive models designed specifically for health can help speed time to insight from health data. Understanding unstructured medical data requires specific terminology, taxonomies, and targeted uses, all of which must be delivered in compliance with regulatory requirements.

To tap the full power of cognitive computing to unique healthcare and life sciences use cases, a range of health-specific cognitive services are needed. IBM’s approach to health cognitive services is to offer a suite of services that can be used flexibly to support health use cases requiring multiple dimensions of cognitive capabilities. An example is the ability to extend the benefits of speech to text to the next level, where concepts and entities of clinical interest could be extracted using both health specific annotators and natural language processing. More advanced cases could dynamically use multiple cognitive services to support changing needs for care — for example using natural language processing and classifiers to support electronic patient communications, then extending to use concepts, and ultimately information for providers’ and clinicians’ consideration in support of their recommendations for actions.

To power a client’s ability to creatively adapt health cognitive services to their specific innovation solutions, IBM’s health cognitive services are designed to be highly flexible supporting fine-grained up to very broad capabilities. As IBM’s health cognitive services are already trained on health-specific corpuses and data sets, they can be set up quickly to support clients’ applications.

Over time, new adaptations and needs for cognitive services will emerge, requiring the ability to customize the content that the service is trained on. IBM’s approach enables a customization layer enabling clients to decide which elements are needed, the ability to exclude those that aren’t important, and to add additional elements to the cognitive service. Clients retain full control of proprietary data and derived insight.

Clients need to assess whether the cognitive services will support the multi-dimensional data types relevant to health — structured, semi-structured, unstructured — and the services’ readiness to work with their data. IBM’s focus is to enable cognitive services to work across the many data types in health — ranging from annotators that scan structured and unstructured clinical notes to identify insights to using cognitive services on images to detect and enable the reconciliation of differences between clinical diagnosis and the patient’s EMR problem list and recorded diagnosis.

Cognitive models are most effective when designed with deep domain knowledge — found among the skilled professionals assembled on the Watson Health team.

Medical device and pharmaceutical GxP and compliance requirements

Medical device and life sciences companies follow Quality System Regulations to manage complex risks and must maintain documentation of validation. IBM, as a purpose-built health cloud provider, helps those companies meet their quality management requirements by providing documentation to support validation under a quality management system compliant with FDA and for application and development requirements for international standards such as ISO 13485 (requirements for a quality management system for medical devices) and 21 CFR part 11. The cloud provider must meet applicable external audit requirements and help assure that data privacy and integrity is not compromised — whether in a dedicated or in a multi-tenant cloud environment.

A cloud data platform that is GxP-enabled for electronic records can offer life sciences companies a significant time to value over building a custom solution and performing all validation and maintenance work themselves. Time to market is greatly reduced by enabling clinical studies and trials to be conducted and evidence to be collected on the same platform on which the medical devices are provisioned.

IBM plans to provide this in a version of Watson Platform for Health enabled for GxP.
Fully managed cloud stack — reducing risk in the seams between vendors

Given the speed of change and competitive pressures in the healthcare and life sciences industries, time to value is essential. But it must be done in a way that meets compliance requirements.

Cloud infrastructure providers offer many raw materials that can be assembled into a full solution that meets security, privacy, operations, audit, documentation, control and business continuity requirements dictated by compliance bodies.

But building and managing through multiple environments, development and support teams can be labor intensive.

A recent IBM study indicated that it can cost clients 2X more, and take up to 75% longer to assemble a similar solution themselves. If that solution must meet GxP and 21 CFR part 11 compliance guidelines, it is even more expensive.

Bringing in additional vendors to help manage different parts of the cloud brings additional risk: Who is responsible when there is a breach or delivery gap, the infrastructure cloud vendor or the managed service provider that is hosting the application?

A cloud platform designed for health offers a fully managed cloud stack that increases the reusability of applications and data to help increase speed of developing new innovations. A single provider manages updates and maintenance and ensures service levels from infrastructure up through applications to help reduce risks and costs.

Watson Platform for Health is designed to deliver all of these capabilities.
Platform for Innovation

Watson Health’s Software as a Service solutions are built on the Watson Platform for Health – extending the platform’s benefits to accelerate solutions that address specific health problems.

**Watson Care Manager** leverages cognitive services to analyze structured and unstructured clinical notes to deliver personalized insights and evidence-based guidelines for more impactful care plans and effective use of care management resources.

**Watson for Patient Safety**, now in development, leverages cognitive services to help clients protect patient health by reading, extracting, and evaluating the hundreds of thousands of adverse event reports. Combining data extraction with natural language processing enables companies to focus on analyzing and acting on reports instead of extracting, normalizing, and manually creating case reports. IBM intends for Watson Patient Safety to combine the data from companies with real world electronic health record and administrative claims data sets to help improve detection, validation, and understanding of safety signals so companies can act earlier and with greater confidence to protect patient well-being.

**Watson for Drug Discovery** leverages cognitive capabilities to read through millions of pages of medical literature and abstracts to extract information and draw relationships and patterns between previously disconnected points of data to help accelerate the discovery of new libraries of drug targets that can be further screened for clinical viability. The screening process to identify new chemical compounds that can be tested is labor and time intensive. Using cognitive capabilities such as natural language processing and machine learning to accelerate discovery of new drug targets with a data-driven process is designed to help companies streamline spending and processes to bring new drugs to market.

**Watson for Oncology** leverages cognitive capabilities to provide physicians with ranked, evidence-based treatment options for cancer for consideration. Combining attributes from patients’ medical records with clinical expertise, external research, and data, the solution retrieves and ranks relevant treatment options based on expert training from Memorial Sloan Kettering. By implementing a more patient-centric cancer care model and using recommended evidence-based treatment options to help reduce variability, Watson for Oncology enables physicians to deliver cancer care at scale.
Customer Example

Medtronic is piloting a cognitive application that uses information from Medtronic diabetes devices to provide individualized guidance in understanding and helping manage elements of daily diabetes decisions. As the Sugar.IQ application uncovers behaviors associated with glucose patterns, personalized messages will be delivered in near-real time to help people with diabetes understand how specific actions and habits affect their glucose levels.

Summary

Cloud platforms offer healthcare and life science companies significant benefits to help improve agility and reduce costs.

But to achieve the breakthrough benefits needed to transform health and improve care, cloud platforms need to address the explosion of data, with the ability to work with and analyze many data types and use cognitive technologies to understand, reason, learn, and interact across data types and systems. IBM Watson Platform for Health offers a suite of cloud services designed to address the obstacles associated with big data and harness the power of analytics and cognitive to create new innovative solutions that can transform health. These cloud services are

- **Purpose built for health data:**
  Watson Platform for Health was designed and built from the ground up to meet rigorous security, privacy, and compliance requirements for health data. Identity masking, consent management, and sophisticated access controls for data governance provide safeguards companies need to innovate with health data while still operating within privacy mandates.

- **Designed for health data scientists:**
  This includes capabilities to ease data ingestion, curation, and normalization — to help get from data to insight rapidly.

- **Based on open standards** to help protect customer investments and promote interoperability of services and systems.

- **Focused on business continuity** to help reduce worry knowing the entire solution stack is designed, implemented, managed, and retained to HIPAA and other standards, not just the cloud storage and compute foundation.
Additional Resources

IBM. “A growth engine for healthcare: How cloud computing can help the industry navigate change.” January 2015.


