



Microsoft

A Cloud for Global Good

Navigating your way to the cloud in healthcare

A practical guide for the healthcare industry in Japan

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Being the “World’s Most Advanced IT Nation”: A digital transformation in healthcare in Japan

We live in a period of dramatic progress in the quest to improve healthcare services through technology.

As one of the most advanced markets for technology adoption in the Asia-Pacific region and, indeed, the world, Japan is already reaping the benefits of the digital transformation of healthcare. Powered by the Government’s “World’s Most Advanced IT Nation” vision, an increasingly supportive regulatory environment and a commitment to universal broadband access, healthcare providers across Japan are poised to leap forward in healthcare services delivery.

Across Japan, healthcare providers¹ are deploying digital platforms and services to optimise clinical and operational effectiveness, empower care teams, engage with patients and raise the quality of care. Saiseikai Kumamoto Hospital has transformed its relationship with patients and achieved operational efficiencies through Microsoft Dynamics, a cloud-based customer relationship management system. The National Cancer Center Hospital East has realised substantial cost reduction and heightened its effectiveness by using Microsoft Azure for its Source Data Verification process, in which records and reports on clinical trials are checked against original documents.

To a large extent, this digital transformation is powered by cloud technologies. Cloud computing holds the promise to drive enormous societal and economic benefits at an unprecedented scale and pace. At Microsoft, we believe that to ensure the benefits of cloud computing are broadly shared, a balanced set of policy and technology solutions that will promote positive change is necessary. Japan’s experience exemplifies this. The digital transformation of Japan’s healthcare industry has been complemented by an increasingly transparent and supportive regulatory framework. The Asia Cloud Computing Association has once again ranked Japan as one of the top markets for cloud computing in the Asia-Pacific region in its latest annual Cloud Readiness Index.²

In the past, the pace of cloud adoption in Japan’s healthcare industry was slower than in other regulated sectors, largely because of concerns about the regulatory environment. These concerns typically focused on perceived barriers to the transfer of data outside of Japan and on the ability of cloud services providers to ensure a high level of security and privacy in relation to sensitive information held by healthcare providers. Fortunately, those perceptions have changed. Whilst matters such as data privacy and security remain at the core of the healthcare regulatory environment in Japan and must be addressed as part of any technology adoption, there is now widespread acceptance that cloud services can comply with (and even enhance the level of compliance with) the necessary regulatory requirements in Japan.

¹ In this paper, we use the term “healthcare providers” broadly to refer to the full spectrum of public and private sector healthcare providers in Japan.

² See: http://www.asiacloudcomputing.org/images/documents/cr2016_accu.pdf

The positive outlook for the healthcare industry in Japan inspires us. Having partnered with healthcare providers on many high-profile technology projects in Japan, we have cultivated knowledge and developed a pool of practical resources to help healthcare providers navigate the landscape for cloud adoption.

This regulatory experience supplements our deep understanding of the business needs of healthcare providers. In collaboration with McKinsey's healthcare practice leads and subject matter experts, we have created the Digital Maturity Model to enable healthcare customers to focus on the components of a digital transformation that are most likely to have the greatest impact.

“There is now widespread acceptance that cloud services can comply with (and even enhance the level of compliance with) the necessary regulatory requirements in Japan.”

This paper is a further contribution to the digital transformation of Japan's healthcare sector. Designed as a practical roadmap, it will help Japan's healthcare providers take full advantage of the transformational benefits of cloud technologies based on a full understanding of the regulatory framework. We also share examples of how cloud technologies are already transforming the way healthcare services are provided in Japan.

We hope this paper is useful and look forward to continuing the conversation as we seek to realise our mission of helping Japan's healthcare providers in their journey towards a digital future. We are committed to ensuring that the healthcare providers in the country will benefit from this new wave of innovation. Delivering a cloud that is trusted, responsible and inclusive is a key part of our commitment to this digital transformation and to a cloud that serves the global good.

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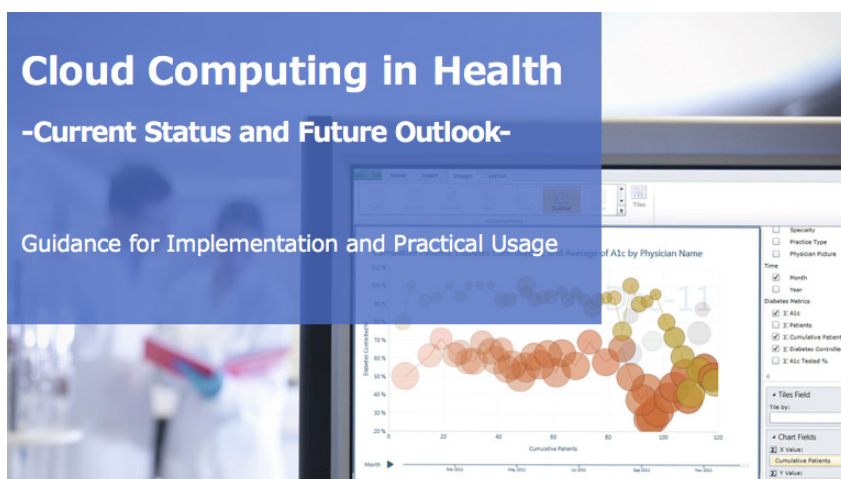
Why cloud?

To promote state-of-the-art medical care such as cancer treatment, and to reduce medical expenses that are expected to reach about 60 trillion yen in 2025, while maintaining the quality of medical care, the government is planning to adopt new medical and nursing care systems with a focus on prevention, healthcare and independence support, by 2020.

Based on this, the Digital Health Reform Promotion Headquarters (Ministry of Health, Labour and Welfare), established in January, 2014, conducted a roundtable meeting on the “Promotion of ICT Utilization in the Health and Medical Field” and proposed the development of a next-generation healthcare system leveraging ICT. Through this system, the government aims to deliver healthcare using big data and AI, telemedicine and monitoring, all through a nationwide healthcare, medical care and nursing care information network for the public.

The next-generation healthcare system will cover 3 key aspects relating to data – “making” data (the generation of data to provide clinical support using big data analysis and AI), “connecting” data (the integration of basic healthcare data of patients into the system), and “Hiraku” (the safe and open use of data). The use of cloud technology, with its much stronger computing power, would be essential to realizing this system. The need to use cloud in home medical care and to develop a cloud environment for AI development was also clearly articulated in the Future Investment Conference (7th April 14, 2014).

In 2014, Microsoft Japan produced a “Healthcare Cloud Introduction and Utilization Guidance”, which found, based on opinions of experts in the Medical Society and the clinical field, that the use of cloud was required for not only information processing, but also security, again emphasizing the point that the use of cloud would be indispensable for the development of future medical systems.



- **Dr. Ryuichi Yamamoto, President of the Medical Information System Development Center, Associate Professor of The University of Tokyo**
“The public cloud is practical and it is time to consider its application in medical care seriously. Healthcare workers have been freed from managing computer systems, and now we can see an era when they can freely use their information processing capabilities as a service.”
- **Mr. Jun Chugo, CIO of Tesshokai Kameda Medical Center**
“The medical information cloud is inevitable, and the perception that the cloud is more secure than the hospital’s own information management is becoming more common.”

- **Dr. Shinsuke Muto, Chairman of Yu Home Clinic**

"In the field of medical care and nursing care, if you put the structure and know-how of Japan on the IT network and the cloud, I think we will be able to deliver to the rest of the world a valuable advanced technology and service for the aging society."

- **Dr. Tokiharu Miyahara, Associate Professor of Kawasaki Medical University**

"In the future, medical care will shift to people's home, and the cloud infrastructure to support the site at home will be important. An easy and fast cloud platform where clinics can share patient information with each other is needed."

- **Yoshinori Yamashita, Deputy Director of Medical Informatics of Fukui University Hospital**

"The cloud delivers the functionality, efficiency, safety, flexibility, and cost benefits that healthcare requires. From now on, I think medical and non-medical sectors will be underpinned by cloud services."

Meti "Next-generation health Care Industry Council-Interim Roundup" (June 5, 2014)

Japan Economic revitalization Division "Future Investment Conference (2nd)"
(H28.11.10 <http://www.kantei.go.jp/jp/singi/keizaisaisei/miraitoshikaigi/>)

Ministry of Health and Welfare (1st)
(H29.01.12 <http://www.mhlw.go.jp/stf/shingi2/0000148424.html>)

Microsoft "Healthcare Cloud deployment and utilization guidance--current status and prospects of cloud use in healthcare"
(https://www.microsoft.com/ja-jp/business/industry/healthcare/cloud_wp.aspx) * Affiliation/title is at the time of the interview in August-October 2014.

Why Microsoft?

Microsoft has expanded its cloud business in more than 90 countries worldwide, has more than 100 data centers, invested more than 150 million dollars, and is compliant with the laws of each country. Many of our customers include government agencies and financial institutions with high standards of security, as well as healthcare providers. We have established a datacenter in Japan, and we allow customers to select the Tokyo District Court as the court having jurisdiction over disputes arising out of the customer contract, so as to provide comfort and assurance to customers in Japan who are concerned about the transfer of data to foreign countries and being subject to overseas laws. Microsoft is also certified to Japan own domestic standard the Cloud Security Gold Mark, which requires a rigorous certification process. Customers can further assure themselves of the security of our cloud services, and our compliance with the "3 Ministries 4 Guidelines", by referring to the security reference guide published by the Mitsubishi Research Institute, Inc. and Japan Business Systems Co., Ltd., covering Microsoft Azure and Office 365. A further security reference guide for Dynamics CRM Online is scheduled to be published in June 2017. For more information about Microsoft confidentiality and security, you can access the Microsoft Trust Center at microsoft.com/ja-jp/TrustCenter/

With Microsoft, customers can also leverage the advantages of hybrid cloud technology. A hybrid cloud is one that uses both a private cloud (e.g., a customer's own datacenter) and a public cloud service. With a hybrid cloud, customers can choose to keep and process more sensitive data on-premises, while harnessing the power and efficiencies of the cloud to handle the bulk of their computing requirements. A further advantage that customers gain when moving to the Microsoft cloud is that we can implement

in the private cloud the same technology we use for our public cloud services. Under this common environment that synergizes private cloud and public cloud, customers can also rely on our skills and wealth of experience to run their operations more efficiently.

It is also possible for a customer to use our Closed Network Connection service (Expressroute) as an extension of the customer's own data center. For more information, please see <https://azure.microsoft.com/ja-jp/overview/datacenters/> and <https://www.microsoft.com/en-us/cloud-platform/global-datacenters>.

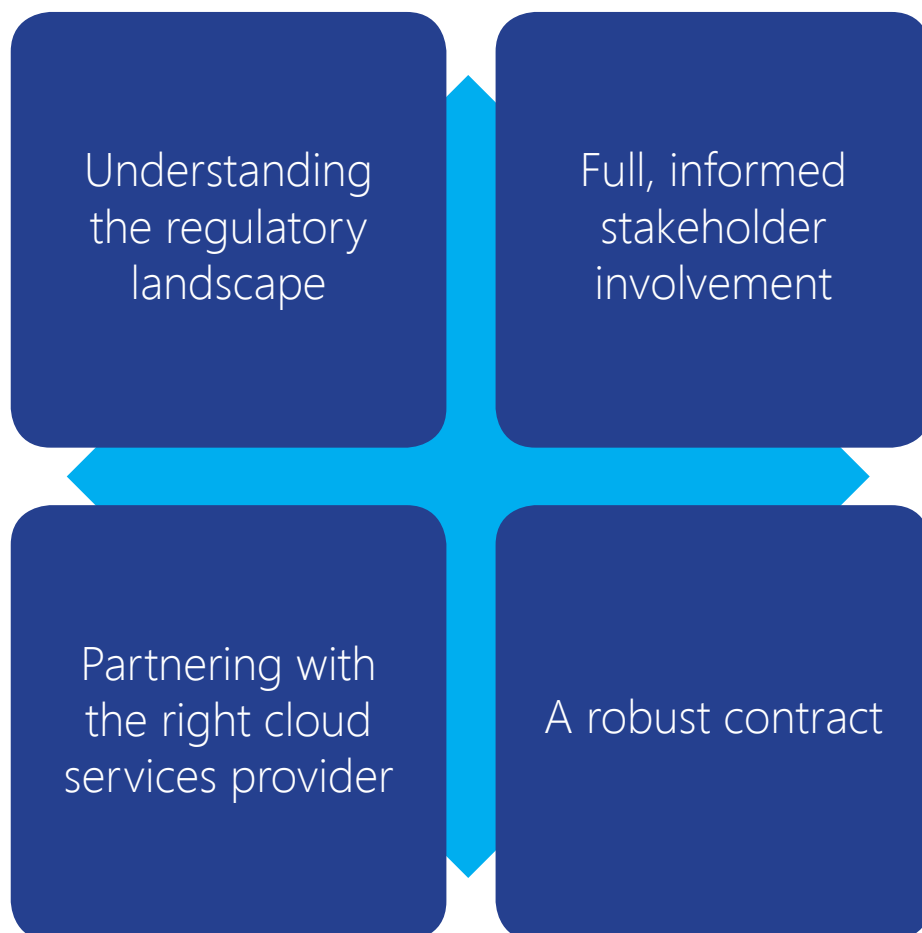
OVERVIEW

The four pillars of a successful cloud adoption

Based on Microsoft's experience of working with healthcare providers in Japan and around the world, a successful cloud adoption rests on four pillars, as shown below.

Importantly, Microsoft recognises that each of these pillars is inter-related and inter-dependent. For example, assurances made by a cloud services provider in response to selection criteria will need to translate into binding commitments set out in a robust contract.

By focusing on these four pillars, healthcare providers in Japan can move to the cloud in a way that addresses the key regulatory and compliance considerations.



The following pages describe these pillars in greater detail.

PILLAR 1

Understanding the regulatory landscape

Summary

A successful cloud adoption begins by understanding the regulatory landscape for the adoption of technology by healthcare providers. We set out below further details of the regulatory environment and the process for cloud adoption in Japan, with the goal of making the entire process more streamlined for healthcare providers.

The regulatory landscape

Are cloud services permitted?

Yes. One of the most common misconceptions regarding cloud adoption in Japan is that healthcare providers are prevented by legislation from moving sensitive health information to the cloud. In fact, there is no blanket regulatory impediment to hosting patient records or other health information in the cloud.

Who are the relevant regulators and authorities?

- The Ministry of Internal Affairs and Communication (MIC)
- The Ministry of Health, Labour and Welfare (MHLW)
- The Ministry of Economy, Trade and Industry (METI)
- The Personal Information Protection Commission (PIPC)

What regulations and guidance are relevant?

The applicable regulations and guidance are spread across a number of sources, including the following:

- Act on Protection of Personal Information (and associated guidelines)³
- Circulars for the retention of medical records⁴
- Security management guidelines for information processing providers dealing with medical information⁵
- Guidelines on the proper handling of personal information for medical and nursing care service providers⁶
- Security management guidelines on the medical information system⁷
- Guidelines applicable to electronic communication businesses relating to the protection of personal information⁸

³ See: <http://www.ppc.go.jp/en/legal/>

⁴ See: http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryuu/iyakuhin/dl/01-08.pdf

⁵ See: http://www.meti.go.jp/policy/it_policy/privacy/iryougi.pdf

⁶ See: <http://www.mhlw.go.jp/file/06-Seisakujouhou-12600000-Seisakutoukatsukan/0000144825.pdf>

⁷ See: http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000119598.pdf

- Information security guidelines in relation to the ASP/SaaS services⁹
- Guidelines for cooperation among ASP/SaaS service providers¹⁰
- Guidelines on service level agreements (SLAs) for users of SaaS¹¹
- Sample SLAs based on the security management guidelines for ASP/SaaS providers dealing with medical information¹²
- Guidelines dealing with disclosure of information and the safety and reliability of cloud services¹³
- Information security guidelines for cloud services¹⁴
- Information security management guidelines for the use of cloud computing services¹⁵
- Security management guidelines for ASP/SaaS providers dealing with medical information¹⁶

Are transfers of data outside of Japan permitted?

There appears to be no express legal prohibition against the offshoring of data. While MIC has issued a guideline requiring patient data to be “stored in a place where Japanese law is applicable”, it is unclear (1) what effect this guideline has under law and (2) whether this translates into an actual prohibition against the offshoring of patient data. Notwithstanding this ambiguity, Microsoft has invested in data centers in both East and West Japan to allow our customers to store and process data in the Japan geography. With this, customers can remain compliant with any regulations requiring the localisation of data (even if the regulations are unclear on this requirement).

Is regulatory approval required?

No.¹⁷

⁸ See: http://www.soumu.go.jp/main_content/000365000.pdf

⁹ See: <http://www.mhlw.go.jp/shingi/2008/07/dl/s0730-18l.pdf>

¹⁰ See: http://www.soumu.go.jp/main_content/000165935.pdf

¹¹ See: <http://www.meti.go.jp/committee/materials/downloadfiles/g80207c05j.pdf>

¹² See: http://www.soumu.go.jp/main_content/000095028.pdf

¹³ See: http://www.soumu.go.jp/menu_news/s-news/01ryutsu02_02000030.html

¹⁴ See: http://www.soumu.go.jp/main_content/000283647.pdf

¹⁵ See: <http://www.meti.go.jp/press/2013/03/20140314004/20140314004-2.pdf>

¹⁶ See: http://www.soumu.go.jp/main_content/000095031.pdf

¹⁷ The only situation in which an approval requirement could apply is with respect to the provision of LGWAN-ASP category services to public healthcare providers, from the Japan Agency for Local Authority Information Systems (J-LIS).

Are public cloud services secure?

Yes. When undertaking due diligence, many of our customers have found that Microsoft's public cloud services offer an increased level of operational security, risk management and compliance relative to a private or on-premises solution, for both sensitive information such as patient records, and non-sensitive information.

How Microsoft helps

Close cooperation with regulators and healthcare providers in relation to a number of successful cloud adoptions in Japan has given Microsoft an in-depth understanding of the regulatory framework and process. Issuing this paper is part of Microsoft's commitment to its healthcare industry customers to help them navigate and comply with the regulatory framework as it applies to cloud services. As a further commitment to its customers in Japan, and as mentioned above, Microsoft has invested in data centers in both East and West Japan to allow our customers to store and process data in the Japan geography. Healthcare providers can therefore be confident that, when they use Microsoft cloud services, they will remain compliant with any regulations (even where these are unclear) concerning the localisation of data.

Microsoft's team will be on-hand throughout the process of cloud adoption to help you with any questions you may have along the way. For information on how Microsoft cloud services comply with the relevant regulations in the healthcare industry in Japan, please visit microsoft.com/ja-jp/business/industry/gov/azurelist.aspx. You can also access the Microsoft Trust Center at microsoft.com/trust,¹⁸ which includes detailed security, privacy, and compliance information for all Microsoft cloud services.

¹⁸ See: microsoft.com/ja-jp/TrustCenter/ for the Japanese version.

PILLAR 2

Full, informed stakeholder involvement

Summary

Microsoft's experience is that a smooth cloud adoption depends on full, informed stakeholder involvement from the outset, with decisions being based on a complete understanding of the proposed cloud solution. A key part of this is a detailed understanding of the proposed technology solution. Although this is not a specific regulatory requirement, putting the right team in place and understanding all aspects of the proposed technology are essential for the healthcare provider to satisfy itself that the cloud adoption meets the necessary requirements. Microsoft believes that it is the responsibility of the cloud services provider to provide detailed product and service information to ensure that the key decision-makers have all of the materials they need to make an informed choice.

Recommendations

Build the core stakeholder team and develop the business case

A multi-disciplinary team should be put in place from day one.

The **technology** and **procurement** teams should take the lead in developing the business case, with a focus on the operational, commercial and patient care factors driving the decision to adopt cloud services.

The **legal, risk** and **compliance** teams should be involved in these discussions from the outset, to map the proposed solutions against legal and regulatory requirements and to build in the necessary timeframes to engage with regulators. Many technology projects have been delayed by involving the legal, risk and compliance functions too late in the process.

The **board** and **senior management** of the healthcare provider will typically require early reassurance in general terms regarding the business need for the use of cloud services and the oversight, review, reporting and response arrangements to be put in place with the cloud services provider.

Understand the technical solutions available

Any technology procurement project requires that all of the key decision-makers have a full understanding of the technology solution to be deployed.

This begins by ensuring that every member of the core team has a clear understanding of the proposed cloud service and deployment models. A range of options exists, including public, private, hybrid and community cloud, but given the operational and commercial benefits to customers, public cloud is increasingly seen as the standard deployment model for most organisations.

¹⁹ See: microsoft.com/ja-jp/TrustCenter/ for the Japanese version.

	<p>You can access more information about the service and deployment models on offer through the Microsoft Trust Center at microsoft.com/trust.¹⁹</p>
<p>Consider data categorisation</p>	<p>As outlined under Pillar 1, there is no blanket regulatory impediment to hosting patient records or other health information in the cloud. Nonetheless, as with any technology project (whether on-premises or in the cloud), healthcare providers should consider which categories of data will be stored and processed and what processes will be in place to protect this data.</p>
<p>Obtain detailed product and service information</p>	<p>Having understood the technical solutions at a high-level, the healthcare provider should also obtain detailed product and service information from the cloud services provider. Not all cloud services are (or will be) accepted for use by healthcare providers in Japan so it is important to have a detailed understanding of the cloud solution to ensure that it meets the relevant regulatory requirements. We expand on this in the next pillar, "Partnering with the right cloud services provider".</p>

How Microsoft helps

A digital transformation is a journey. Like all journeys, we must know where we are starting from, and we must have a destination in mind.

Microsoft's expert team is on hand to support you throughout your cloud project, right from the earliest stages of initial stakeholder engagement through to the rollout of the solution. Our cloud product range spans all cloud service and deployment models and, with our Japan-based data centers and transparent approach to data location, we provide cloud customers with the flexibility to decide how and where their data will be stored and processed. We have developed a range of materials, including product fact sheets and online trust centers, designed to ensure that you have access to all the information needed to make an informed decision. Our subject-matter experts are available to meet with you and your core stakeholders to provide specific and detailed information on the technical, contractual and practical aspects of your proposed cloud project.

For healthcare providers seeking end-to-end advice and support in relation to transformative digital projects, we have developed the Digital Maturity Model (DMM). Developed in association with healthcare practice leads and subject matter experts from McKinsey, as well as Microsoft's own subject matter experts, the DMM is designed to help our customers focus on the components of a digital transformation that are most likely to have the greatest impact.

The DMM allows for the evaluation of where customers are in their digital transformation journey by examining their efforts across four key pillars:

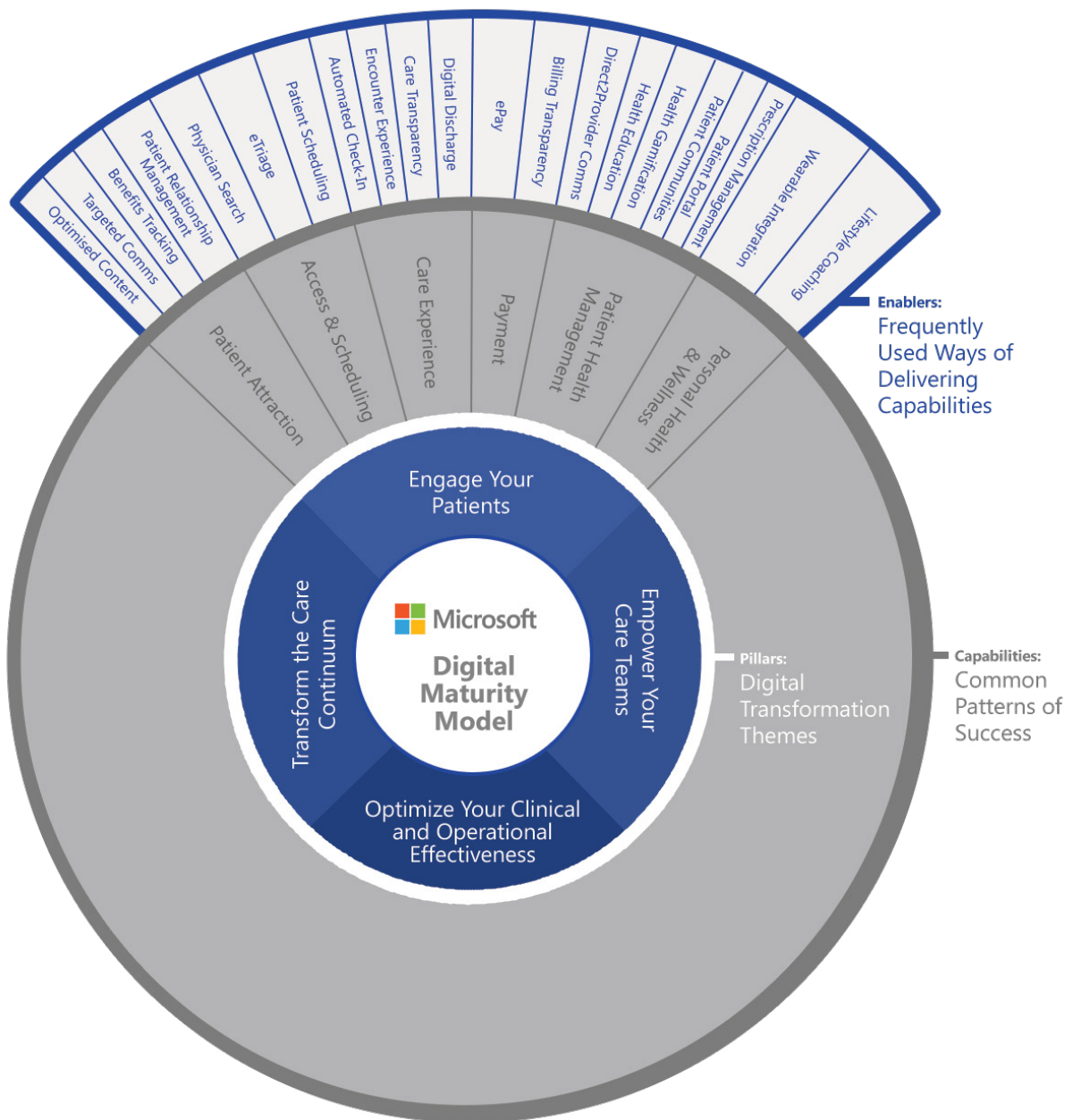
- **Engage your patients:** patient-centric delivery to get patients healthy and help them stay healthy;
- **Empower your care teams:** applying digital capabilities to improve care team productivity;

- **Optimise your clinical and operational effectiveness:** using digitised processes to drive better diagnoses and treatment; and

- **Transform the care continuum:** redefining care delivery through platforms that provide insight.

Two further layers of detail turn the DMM into a key tool in shaping each customer's digital transformation, guided by the customer's own priorities:

- A set of capabilities for each pillar and a maturity scale of 1 (Laggard) to 4 (Best Practice) for each capability; and
- The approaches to deliver each capability.



More information about the Digital Maturity Model is available from your Microsoft contact upon request.



“With the introduction of the Azure Rights Management System, everyone can access their emails from outside the hospital while maintaining a high level of security. Our staff have become more aware of key developments since they each received an email address that allowed them to access electronic medical records on Office 365 from multiple devices.”

Mr. Masanori Hashimoto

Deputy Director
National Center for Global Health and Medicine

CASE STUDY 1

National Center for Global Health and Medicine (NCGM)

The National Center for Global Health and Medicine has been the pinnacle of medical care and nursing in Japan for the past 150 years. The Center promotes highly integrated medical care, as it consists of laboratories, clinical research centers, center hospitals, Kohnodai Hospital, the International Medical Cooperation Bureau and the National Nursing College of Nursing.

The National Center for Global Health and Medicine had a vision of empowering their care team to access medical records from any device and anywhere, to enable more collaboration and efficiency. To achieve this goal, they needed to integrate the two different systems that they had for email and electronic medical records while ensuring that the integrated system would be able to securely protect confidential information.

In April 2016, the National Center decided to adopt Microsoft’s Office 365 for this integration. The adoption of Azure Multi-Factor Authentication and Azure Rights Management System (RMS) assured them that the solution would be secure.

According to Mr. Kengo Miyoshi, Medical Information Management Division Director, Special Assistant and Center Hospital Director for the National Center for International Medical Research under the National Institute of Research and Innovation, the Center chose Azure Multi-Factor Authentication because it offers flexibility for both users and administrators. It is also able to distinguish the appropriate security level required, such that normal authentication is enabled when the user is in a hospital facility and multi-factor authentication is only required for user access outside of the hospital. This creates more convenience for users.

Information sharing and transmission is the foundation for better medical environments and the development of medical technology. With about 2,000 users accessing the new mail system, the professionals at the center have benefited from greater flexibility and collaboration without sacrificing security.

In transitioning their mail system to Office 365, the Center recognises how the cloud has created a stronger collaborative environment for the organisation. They are now looking to further utilise Azure RMS to realise more secure information sharing throughout the organisation. They are also working on migrating the Center’s intranet to SharePoint Online.

PILLAR 3

Partnering with the right cloud services provider

Summary

Healthcare providers need to carry out appropriate due diligence to ensure that the cloud services provider can meet the operational security, risk management and compliance requirements in Japan. To ensure that they are getting a compliant solution, the healthcare provider should develop a set of due diligence and selection criteria mapped against the key regulatory requirements.

Recommendations

Whilst a summary of all applicable compliance obligations is outside the scope of this paper, the table below summarises what we believe are the key cloud services provider selection criteria, based on the underlying regulations and guidance and our conversations with customers. Healthcare providers may wish to refer to these criteria as part of their cloud procurement.

Confidentiality and Security Standards

Given the sensitive nature of information that is held by healthcare providers, it goes without saying that the chosen cloud solution needs to be secure. The due diligence process should focus on ensuring that the cloud services provider has measures in place to ensure compliance with the required confidentiality and security standards in Japan. These include:

- requirements under the Act on Protection of Personal Information to ensure that organisational, personnel, physical and technical measures are taken to protect personal data;
- professional duties imposed on healthcare practitioners to keep information confidential, depending on the nature of their work; and
- various MHLW, MIC, METI and PIPC safety management guidelines and circulars, focusing primarily on the security of patient information.

Compliance with international security standards such as ISO/IEC 27001, ISO/IEC 27018, and the Cloud Security (CS) Gold Mark in Japan, has become an industry standard in Japan and around the world.

Supervision

The healthcare provider will want to ensure that the cloud services provider has in place appropriate measures to enable the healthcare provider to supervise the cloud services provider. This is both good operational practice and a specific requirement under the regulations in Japan. At a practical level, healthcare providers will also want to consider whether the cloud services provider is assessed by independent third parties and whether it shares the results of these assessments with its customers.

Data Location and Transparency

Although there appears to be no express legal prohibition against the offshoring of data, as described in Pillar 1, some healthcare providers may prefer to store certain categories of data within Japan. These healthcare providers will want to check whether the cloud services provider is transparent as to its approach to data location and whether it can configure the service to ensure that certain categories of data are stored within the Japan geography.

Limits on Data Use

Cloud services providers should not use the healthcare provider's data for any purpose other than that which is necessary to provide the cloud service. The cloud services provider should therefore commit not to use it for any secondary purpose, such as advertising. This is both a specific requirement of Japan's regulations and good business practice.

Data Segregation

There are no specific requirements concerning segregation of data under the regulations, which means that all cloud deployment models, including public cloud, are permitted. Healthcare providers will want to ensure that whichever cloud deployment model is used, the cloud services provider has in place appropriate technical and logical measures to ensure that the confidentiality and security of data is not compromised.

Resilience and Business Continuity

The resilience of healthcare providers' systems is of utmost importance given the nature of their operations. As such, Japan's regulations require that healthcare providers have a business continuity plan in place to ensure that relevant individuals can access medical information in case of emergency. It is therefore essential that the healthcare provider works with a cloud services provider that offers a high degree of availability and resilience, provides the healthcare provider with access to and control of data, and regularly tests its own business continuity and disaster recovery plans. This ensures that the use of third party services does not threaten the continuity of the healthcare provider's operations.

Cloud Services Provider Reputation and Competence

Healthcare providers will want to carefully consider the cloud services provider's track record in the healthcare industry, not just in Japan but also around the world. This is important not only for complying with the necessary due diligence requirements but also for providing valuable insight into the cloud services provider's global dealings and standing.

Conditions on Subcontracting

While there are no specific requirements on subcontracting imposed by the regulations in Japan, there is little value in finding the right cloud services provider if that cloud services provider will simply subcontract all of its obligations to a third party that may not meet the necessary requirements. Seeking a comprehensive list of subcontractors will often be impractical (not least since those subcontractors may change for operational reasons) and is not required by regulation or guidance.

However, healthcare providers will want to ensure that the cloud services provider takes primary responsibility for compliance from a contractual perspective and only uses subcontractors that are subject to controls that are equivalent to those applied by the cloud services provider itself.

Conditions on Termination

While healthcare providers will often look at cloud services as a long term solution, they should be prepared for a scenario where the cloud services are terminated. Guidance from the regulators in Japan addresses this issue by recommending that the cloud services provider commits to return and delete data when the cloud services terminate.

How Microsoft helps

Microsoft understands that, wherever you are on your journey to the cloud, it is vital to work with a service provider that you can trust. Not all clouds are created equal — it is crucial to check the facts and know what you are getting.

Microsoft confirms its ability to meet all of the criteria specified above. Our understanding of the healthcare industry, based on experience of working closely with healthcare providers and industry stakeholders over a number of years, is market-leading. Microsoft has over 40 years of IT experience, including decades as a cloud services provider running some of the largest online services in the world, and a proven track-record of successful cloud rollouts for healthcare providers in Japan and globally. We are proud of leading the way when it comes to offering cloud services that help healthcare providers maintain compliance with applicable laws, regulations, and key international standards.

We build our cloud services based on the core principle of trust. We are committed to ensuring that your data stays secure, that it stays private and under your control, and that if you use the Microsoft cloud, you stay compliant, even as regulations and standards evolve. We are also committed to being transparent about our security, privacy, and compliance practices. We make sure you know how your data is stored, accessed, and secured, and that you can independently verify this.

We are also committed to reliability and choice. That is, our software and services are robust to ensure you can access your data and services when you need to, and we give you the final say in decisions that impact compliance.

Microsoft invests heavily in compliance to meet multiple regulatory standards. We design and build services using a common set of controls, making it easier to achieve compliance across a range of regulations, even as they evolve. Our approach to security compliance includes test and audit phases, security analytics, risk management best practices, and security benchmark analysis. We have been able to maintain and expand a rich set of third-party certifications and attestations that you can point to in order to demonstrate compliance readiness to your customers, auditors, and regulators. These include the Cloud Security Gold Mark, ISO/IEC 27001, ISO/IEC 27018, SOC 1 and SOC 2. As part of our commitment to transparency, we share third-party verification results with our customers.



Payer

**ISO 27001/
ISO 27018
EU Model Clause
HIPAA BAA
FedRAMP**



Provider

**ISO 27001/
ISO 27018
EU Model Clause
HIPAA BAA**



**Public Health &
Social Services**

**ISO 27001/
ISO 27018
EU Model Clause
HIPAA BAA
FedRAMP**



**Life Sciences &
Pharmaceuticals**

**ISO 27001/
ISO 27018
EU Model Clause
HIPAA BAA**

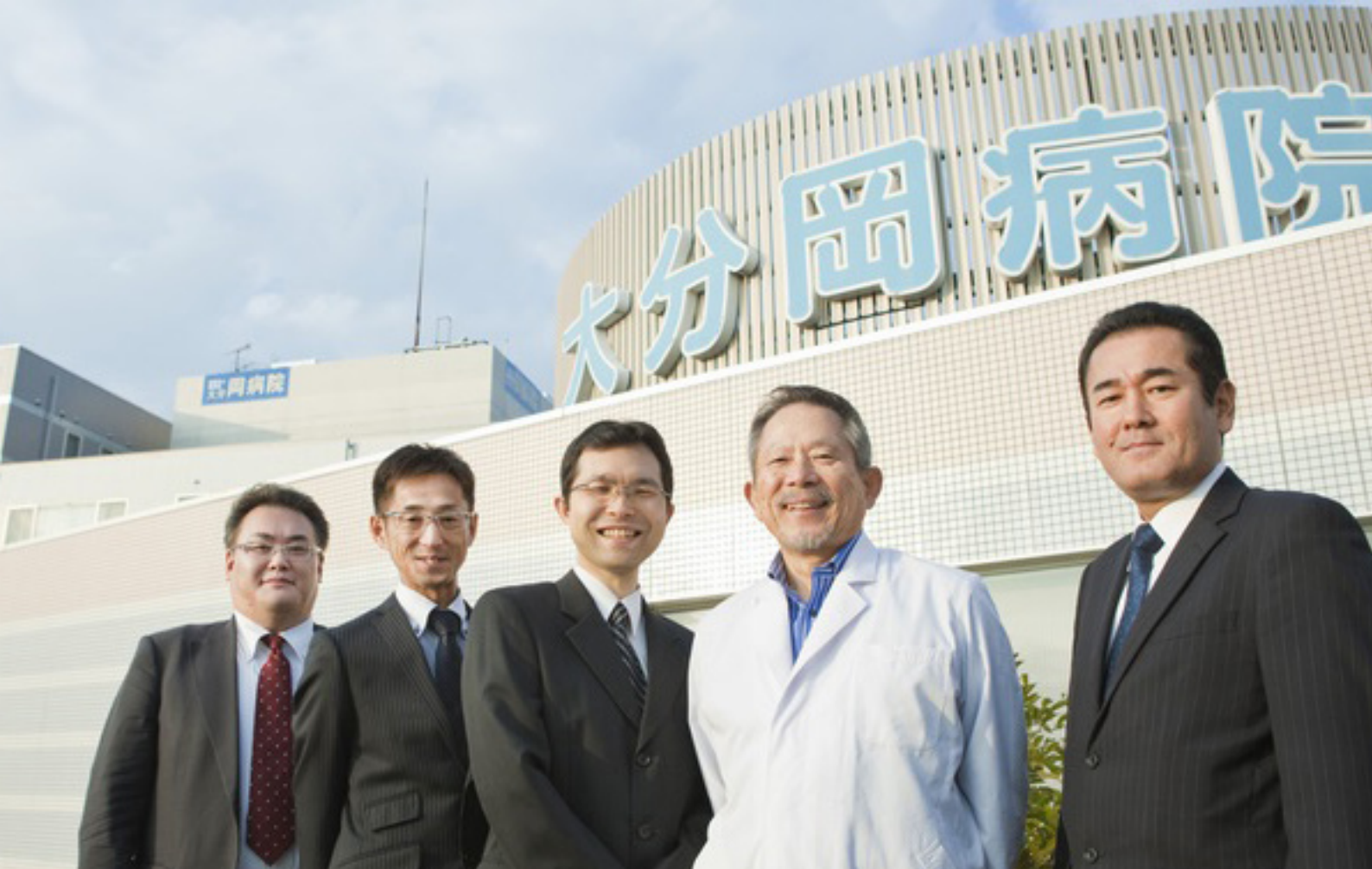


Global

**Australia Gov IRAP/ISM
Singapore MTCS
UK G-Cloud
Article 29 WP
Japan CS Gold Mark**

In 2016, Mitsubishi Research Institute Inc. and Japan Business Systems Co., Ltd. published a “Security Reference Guide for Healthcare Institutions”, which includes detailed reports on how Microsoft Azure and Office 365 comply with the “3 Ministries 4 Guidelines”. A further security reference guide for Dynamics CRM Online is scheduled to be published in June 2017. For more information on the strong confidentiality and security protections at the core of each Microsoft cloud service, please visit the Microsoft Trust Center at microsoft.com/ja/Trustcenter/.

²⁰ See: microsoft.com/ja-jp/TrustCenter/ for the Japanese version.



CASE STUDY 2

Oitaoka Hospital

Healthcare Corporation Keiwa-Kai, Oitaoka Hospital (Oitaoka Hospital) is a leading private hospital in the Oitaoka prefecture. A secondary emergency medical care and regional medical support hospital, it contributes to the acute care of the entire region.

Oitaoka Hospital was in the midst of business continuity planning – an important exercise for a prefecture that is prone to earthquakes. The anticipated Nankai Trough mega-earthquake is expected to cause significant damage. The hospital had typically kept physical copies of all medical records. These records were copied to a tape daily as a back up measure. However, the hospital recognised the need to better ensure continuity of medical treatment for patients in the event of any disasters – this required a new way to backup and restore medical data.

In 2015, Oitaoka hospital decided to digitise their medical records. They created a database using Microsoft Azure that complies with existing ministerial guidelines on cloud computing, enables real-time backup of electronic medical record data and establishes a recovery method to convert every Windows personal computer (PC) into an electronic medical record terminal.

With this move to the cloud, any PC can be used to securely connect to the database and access data. This reduces the risk of information leakage and data falsification as the data management process is now more transparent. It also greatly reduces the hospital's risk of data loss and allows them to securely share its records with other hospitals in the area. As a result, if the hospital was impacted by disasters in future, medical services would still be able to continue for their patients in the region.

“Our hospital was built long before computing technologies were introduced to the medical industry. As a result, the amount of air conditioning equipment for cooling servers, power supply and load capacity for each room increased consistently and our server hardware became enormous. It was also impossible to ensure the secure and stable operation of tapes. Furthermore, our location places us at risk of flooding, which is why we also had a plan to relocate. Now that we have successfully shifted to the cloud, we have eliminated the need to relocate the hospital.”

Mr. Kozo Goto
Secretary General
Oitaoka Hospital

“We hope to continue sharing and utilizing medical data securely and effectively to enhance the quality of communication with our cooperating facilities both within and beyond the Keiwa Foundation. This will improve the quality of the Keiwa healthcare network as we increasingly serve the region.”

Mr. Teruaki Mori
Director
Oitaoka Hospital
and General Director
Healthcare Corporation Keiwa

These benefits are enjoyed by the hospital without any additional operational or cost burdens. The data center is operated by Microsoft. The cost benefit of running Azure, in comparison to an on-premises environment is also significant. Safety is also heightened as the previous scenario where the hospital was backing up to a tape meant that personnel would need to rescue the physical tape during an emergency.

It is expected that using the cloud for electronic medical records will continue to grow in Oita City. The city has an ageing population and demand for home care is expected to increase. Being able to remotely access electronic medical records stored in the cloud will facilitate the collection and verification of various data, even from home, leading to improvements in medical treatment.

PILLAR 4

A robust contract

Summary

Assurances made by the cloud services provider in response to selection criteria must be backed up by appropriate contractual commitments. The cloud contract should include appropriate terms so that the healthcare provider can satisfy itself of compliance with the underlying regulations.

Recommendations

The following terms are those that Microsoft believes to be important, based on the underlying regulations and our discussions with customers in Japan. Healthcare providers will want to put in place a binding cloud contract that, as a minimum, includes these key terms. In practice, the cloud services provider should help by demonstrating how their cloud contract meets these requirements.

Privacy and Data Protection

The contract will need to contain appropriate requirements to enable the healthcare provider to meet its own primary obligations (e.g. ensure that all health information and personal information is dealt with in accordance with applicable privacy and data protection laws).

Security and Data Breach Protocols

The contract should contain appropriate commitments from the cloud services provider to ensure that information and data are kept secure. The cloud contract should also address what happens in the event of a data breach incident – including any applicable notification, investigation and mitigation protocols.

Supervision

The cloud contract should address the ability for the healthcare provider to supervise the cloud services provider. In practice, healthcare providers will typically expect the cloud services provider to ensure that its services are regularly assessed by independent third parties, and that the results of these assessments are shared with the healthcare provider.

Availability

As a matter of good operational practice and to ensure requirements regarding business continuity and resilience are addressed, healthcare providers will want to ensure that the cloud services provider makes binding commitments as to service availability, with specified remedies in the event of an unscheduled service disruption.

Business Continuity

Again, in the interests of ensuring underlying business continuity requirements are met, the contract should provide for a disaster recovery/business continuity plan together with appropriate testing processes.

Confidentiality	In order to comply with patient confidentiality obligations, healthcare providers will want to ensure that the cloud services provider makes binding commitments regarding the confidentiality of information stored in the cloud service.
Termination and Exit	Healthcare providers will want the cloud services provider to commit that information will be securely returned to the healthcare providers or deleted, as described in Pillar 3, above.
Conditions on Subcontracting	While subcontracting is permitted, healthcare providers will want to ensure that the cloud services provider takes responsibility for compliance and ensures that any subcontractors are subject to controls that are equivalent to those applied by the cloud services provider itself.
Remedies	Healthcare providers will want to ensure that the contract is clear as to the remedies to which they are entitled if the cloud services provider breaches its contractual commitments. In practice, remedies typically include service credits and/or termination rights, depending on the nature and circumstances of the breach.

How Microsoft helps

The contractual terms for Microsoft's cloud services have been developed based on feedback from thousands of cloud customers across the most heavily-regulated industries around the world, including customers in the healthcare industry. Microsoft's expert team will be available throughout the contractual review process to answer any questions you have about how Microsoft's contractual terms for its cloud services provide confidence to cloud customers that they are complying with the applicable regulatory requirements and guidelines.

Putting it into practice

Scenario 1:

Using Azure to unlock data insights that help improve population health

Data-driven diagnostics have the potential to improve patient care, reduce costs, optimise treatments and clinical pathways, and facilitate broad-scale research. The ability to analyse massive amounts of data is vital to the future of healthcare. However, keeping pace with and generating value from increasing volumes of data requires ever-faster computing resources and rapidly increasing storage. These are core cloud capabilities, making cloud services the logical option for healthcare analytics.

Cloud-based analytics bring significant benefits to the healthcare industry. They provide the real-time insights you need to monitor and stratify patients according to risk; deliver more reliable, data-driven diagnostics; identify cost inefficiencies and bottlenecks in care pathways; and detect adverse events or other unexpected substandard patient outcomes. Analytics can also help you delve into the data to manage staff productivity or resource deployment. You can also repurpose data for research into optimisation, or even discovery, of new treatments.

Regulatory considerations

The regulatory obligations for the use of aggregated and de-identified health information are no different in a cloud-hosted model than in a traditional on-premises model. Where the health information relates to the patient as an identifiable individual, misuse of that health information is a prohibited interference with their individual privacy. Information or data that does not relate to a particular individual whose identity can reasonably be determined is not personal information and there are no regulatory restrictions on the use of such information. Under Japanese law, personal, health or other sensitive information is not subject to any privacy regulations if it is de-identified so that it is no longer reasonably capable of identifying a particular individual. Healthcare providers therefore do not need to comply with any additional regulatory requirements to use cloud-hosted analytics, such as those on Microsoft Azure, for research and practice improvements.

Microsoft can provide data analytics services as an optional value-add to our cloud services. These use aggregated and de-identified health information to help your practice or organisation with process improvements, health research and discovery, as well as other applications to drive beneficial health outcomes.

Microsoft is committed to using health information only for the purposes expressly authorised by its customers. Microsoft will not undertake aggregated data analytics unless we have your express permission, on an opt-in basis.

If your organisation chooses to use our data analytics services, Microsoft makes binding contractual commitments to your organisation regarding the use of your data²¹. For almost all of our cloud services, our commitment is to use customer data only for the purpose of providing the service and compatible purposes, such as troubleshooting or malware prevention. However, for a limited set of Azure Cognitive Services, Microsoft has broader rights to use, retain, reproduce and create aggregated, anonymised data to improve the services themselves, as well as to provide the Cognitive Services.

²¹ If your organisation chooses to participate, you are required to obtain each data subject's consent to Microsoft processing the data as set out in the Online Services Terms.

Steps you should take

Your organisation will need to consider whether use of data analytics services is consistent with use limitations that attach to your dataset.

These use limitations will vary depending on:

- Whether the dataset contains health information, personal information that is not sensitive information, or solely de-identified data;
- Whether medical research and analytics were each an express purpose of collection, a directly related and reasonable secondary purpose, or where otherwise permitted under applicable Japanese regulations (e.g., where the dataset is appropriately anonymised).

Scenario 2: Using Office 365 to drive staff productivity

Many healthcare providers are looking to improve the productivity and effectiveness of their clinical, operational and managerial staff by moving to Office 365. With a single secure synchronised inbox across devices, powerful collaboration and communication tools, staff can work much more efficiently in teams. For healthcare providers that have traditionally hosted their data locally at their practice, cloud practice management systems enable much greater opportunity for controlled access such as on mobile, from home or at another practice.

Regulatory considerations

Just as they would for on-premises technology solutions, healthcare providers must comply with general privacy requirements. These include ensuring that they obtain patient consent to the collection, use or disclosure of their data. Healthcare providers must also ensure that data will be kept secure and confidential and, for this reason, Microsoft gives binding contractual commitments regarding the use, disclosure and security of the information.

Although Microsoft's understanding is that there is no express prohibition on the use of data centers located outside of Japan for patient information, some healthcare providers may prefer to configure the cloud services they procure so that certain categories of data are stored at-rest within Japan. Microsoft is pleased to be able to offer this flexibility to its cloud customers.

Steps you should take

- 1 Understand how your organisation is using on-premises equivalents of Office 365 today.
Is the solution secure? Does it provide the range of services and features available via Office 365?
- 2 Consider potential use cases for Office 365.
What productivity and efficiency improvements could be achieved by using a cloud-based solution?
- 3 Consider the categories of data that will be stored and processed.
Will this include patient information?

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Consider whether your organisation wishes to configure the solution so that certain categories of data are stored at-rest within Japan.

Your Microsoft contact can assist you with any questions regarding service configuration.

An unprecedented opportunity to transform Japan's healthcare services

Healthcare providers in Japan have an unprecedented opportunity to take advantage of the full spectrum of cloud-driven technologies, driven by a supportive regulatory framework, excellent technical infrastructure and a growing range of compliant solutions to choose from.

Whether it is operational data analytics to streamline operations and reduce costs; virtual health and telemedicine to better connect patients and care teams; clinical analytics to enable more informed choices at the point of decision; or taking raw data from sequencing machines to produce reports on identified genomic variants, just to name a few recent use cases, the range of opportunities is broad and growing all the time.

At Microsoft, we believe that cloud technologies will play a crucial role in the future of healthcare in Japan, and in the expansion of Japan's vibrant health technology sector locally, regionally and globally. We look forward to continuing our role at the forefront of this digital transformation, deploying trusted, responsible and inclusive cloud solutions for the benefit of our healthcare provider customers in Japan and their patients.

Further information

A Cloud for Global Good | Microsoft: news.microsoft.com/cloudforgood

Microsoft in Health: microsoft.com/health

Digital Transformation in Health: healthdigitaltransformation.com

Trust Center (English): microsoft.com/trust

Trust Center (Japanese): microsoft.com/ja-jp/TrustCenter

Service Trust Portal: aka.ms/trustportal

Online Services Terms: microsoft.com/contracts

Service Level Agreements: microsoft.com/contracts

SAFE Handbook: aka.ms/safehandbook



© Microsoft Corporation 2017. This paper is not intended to be a comprehensive analysis of all regulations and their requirements, nor is it legal advice; rather it is intended to be a summary and to provide guidance to healthcare providers in Japan on the types of issues they should consider.