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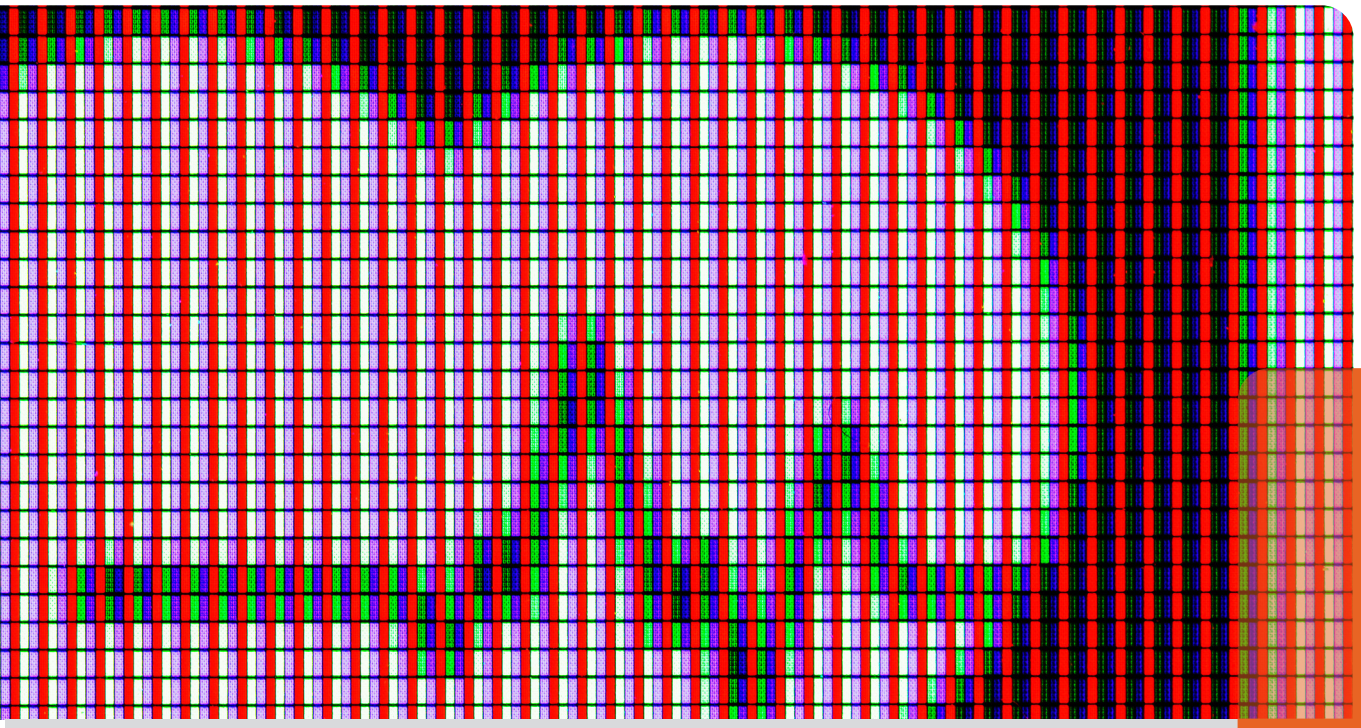

Digital Health

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Introductory Chapter

Expert Analysis Chapters

Q&A Chapters

Japan

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1 Digital Health

1.1 What is the general definition of "digital health" in your jurisdiction?

In Japan, there is no clear legal definition of "digital health". It is generally used as a generic term for products and services related to medicine and healthcare that utilise digital technologies and data.

1.2 What are the key emerging digital health technologies in your jurisdiction?

Regulatory approvals were granted with respect to various software as a medical device ("SaMD"), such as Artificial Intelligence ("AI") programs to assist in the diagnosis of diseases through images and smartphone applications to treat nicotine dependence and hypertension. Such software is being used in medical settings. Also, telemedicine is becoming popular due to deregulation and the difficulty of face-to-face medication during the COVID-19 pandemic. Various wearable devices and smartphone applications for general health promotion purposes outside of medical settings are also widely used.

1.3 What are the core legal issues in digital health for your jurisdiction?

The core legal issue for a digital health product is the applicability of the regulations under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("PMD Act") to such product as a medical device, which may impose a greater burden on the provider. Medical devices authorised under the PMD Act are also usually subject to reimbursement under the National Health Insurance ("NHI") system, which makes it easier to disseminate the product in medical settings.

The core legal issue for a digital health service is whether such service constitutes a medical practice. In principle, medical services can only be provided by physicians or other qualified health care professionals ("HCPs"). In addition, there are certain restrictions on how and where HCPs may provide medical services.

The core legal issue common to both digital health products and services is the regulation of personal information and data. While medical and health-related information would be subject to stricter regulations as sensitive information, the utilisation of personal information and data is essential for the digital health field, and law amendments and special laws were enacted to promote such utilisation.

1.4 What is the digital health market size for your jurisdiction?

We are not aware of any definitive data on the digital health market size in Japan.

1.5 What are the five largest (by revenue) digital health companies in your jurisdiction?

We are not aware of any definitive data on the comparative revenue of digital health companies in Japan.

2 Regulatory

2.1 What are the core healthcare regulatory schemes related to digital health in your jurisdiction?

The PMD Act applies to digital health devices including programs that meet the following criteria for medical devices: (i) the device falls under the devices listed in the Cabinet Order; and (ii) the purpose of use of the device is the diagnosis, treatment or prevention of diseases or is to affect bodily structures or functions. Class I programs are excluded from the definition of medical device. A regulatory notice issued by the Ministry of Health, Labour and Welfare ("MHLW") entitled "Guidelines concerning Applicability of Medical Devices for Programs" provides more detailed criteria including examples of programs not falling under medical devices. The PMD Act requires, among others, obtaining business licences and marketing authorisation for each product, complying with manufacture and quality control standards and conducting pharmacovigilance activities. In addition, false and exaggerated advertisements and advertisements of unapproved medical devices are prohibited. For the details of the regulations, please see the response to question 2.6.

Under the Medical Practitioners Act and the Medical Care Act, medical practices such as the diagnosis, treatment and prevention of diseases may only be provided by physicians and other qualified HCPs. In addition, previously, physicians and patients were required to meet face-to-face at medical institutions when providing medical treatment. However, the regulations have been gradually eased and currently, telemedicine services, in which patients are examined, diagnosed and provided with diagnostic results and prescriptions live through ICT devices, are increasingly permitted provided that the various requirements set forth in the "Guidelines for the Proper Implementation of Online Medical Treatment" published by the MHLW shall be met.

2.2 What other core regulatory schemes (e.g., data privacy, anti-kickback, national security, etc.) apply to digital health in your jurisdiction?

The application of the regulations under the Act on the Protection of Personal Information ("APPI") is a key issue. For the details of the regulations, please see the responses to questions 4.1 through 5.5.

In addition, the prohibition of bribery under the Criminal Code is applicable when the physician is a (deemed) public official, and for certain manufacturers and distributors of medical devices, the regulations under the Fair Competition Code prohibit offering premiums (including money and other benefits) to doctors and medical institutions as a means of unfairly inducing them to trade in medical devices.

2.3 What regulatory schemes apply to consumer healthcare devices or software in particular?

Consumer healthcare devices or software that fall under the category of medical devices are subject to the regulations under the PMD Act. Please see the responses to questions 2.1 and 2.6.

Consumer healthcare devices or software that do not fall under the category of medical devices shall not be advertised as if they are intended to diagnose, treat or prevent diseases. In addition, any other advertisements or representations that falsely claim that the products or services are better than they actually are will be in violation of the Act Against Unjustifiable Premiums and Misleading Representations ("AUPMR").

2.4 What are the principal regulatory authorities charged with enforcing the regulatory schemes? What is the scope of their respective jurisdictions?

The principal regulatory authorities for the PMD Act are the MHLW, the Pharmaceuticals and Medical Devices Agency ("PMDA") and local governments. The principal regulatory authorities for the Medical and Medical Practitioners Law are the MHLW and local governments. The principal regulatory authority for the APPI is the Personal Information Protection Commission ("PPC"). The principal regulatory authority for the Fair Competition Code is the Fair Trade Council. The principal regulatory authority for the AUPMR is the Consumer Affairs Agency.

2.5 What are the key areas of enforcement when it comes to digital health?

As for the medical device regulations, the key enforcement areas are the determination of whether a program qualifies as a medical device and the regulation of device advertisements.

As for the data regulations, the key enforcement areas are the implementation of the necessary procedures for handling healthcare-related information and the implementation of the security control measures therefor, especially at medical institutions.

2.6 What regulations apply to software as a medical device and its approval for clinical use?

In order to market SaMD in the Japanese market, it is necessary to obtain both business licences for the relevant entities/sites and a marketing authorisation for each product. As to the business licence, the company that markets the SaMD must obtain a marketing business licence. In addition, a manufacturing business licence must be obtained for each manufacturing facility and a sales business licence must be obtained for each sales office.

There are two pathways in respect of the marketing authorisation for SaMD products. Marketing Certification is the pathway for Class II or III medical devices for which the MHLW specified and published the evaluation and specification standards. Marketing Approval is the pathway for (a) Class II or III medical devices not subject to Marketing Certification, and (b) Class IV medical devices.

Clinical trials are usually required to be conducted for novel types of SaMD. When conducting clinical trials, medical device GCP must be observed. Recently, the MHLW published evaluation indices for the safety and efficacy of SaMD that induces behavioural changes for disease treatment.

2.7 What regulations apply to artificial intelligence/machine learning powered digital health devices or software solutions and their approval for clinical use?

The regulatory framework is essentially the same as that for SaMD. The MHLW published evaluation indices for the safety and efficacy of medical image diagnosis support systems using AI technology. In addition, an expert committee at the PMDA is currently discussing methods for the examination of adaptive AI devices that are intended to autonomously change their performance after being marketed.

3 Digital Health Technologies

3.1 What are the core legal or regulatory issues that apply to the following digital health technologies?

- **Telemedicine/Virtual Care**
  Please see the response to question 2.1.
- **Robotics**
  If the product falls under medical device, the PMD Act shall apply.
- **Wearables**
  If the product falls under medical device, the PMD Act shall apply.
- **Virtual Assistants (e.g. Alexa)**
  If the product falls under medical device, the PMD Act shall apply.
- **Mobile Apps**
  If the product falls under medical device, the PMD Act shall apply.
- **Software as a Medical Device**
  Please see the response to question 2.6.
- **Clinical Decision Support Software**
  Please see the responses to questions 2.6 and 2.7.
- **Artificial Intelligence/Machine Learning Powered Digital Health Solutions**
  Please see the response to question 2.7.
- **IoT (Internet of Things) and Connected Devices**
  If the product falls under medical device, the PMD Act shall apply.
- **3D Printing/Bioprinting**
  If the product falls under medical device, the PMD Act shall apply.
- **Digital Therapeutics**
  Please see the response to question 2.6.
- **Digital Diagnostics**
  Please see the response to question 2.6.

- **Electronic Medical Record Management Solutions**
  If the product falls under medical device, the PMD Act shall apply.
- **Big Data Analytics**
  If the product falls under medical device, the PMD Act shall apply.
- **Blockchain-based Healthcare Data Sharing Solutions**
  If the product falls under medical device, the PMD Act shall apply.
- **Natural Language Processing**
  If the product falls under medical device, the PMD Act shall apply.

3.2 What are the key issues for digital platform providers?

The "Safety Management Guidelines for Providers of Information Systems and Services that Handle Medical Information" issued by the Ministry of Economy, Trade and Industry ("METI") and the Ministry of Internal Affairs and Communications ("MIC") are applicable to providers of medical information systems and services. The guidelines contain stipulations such as the risk management process required upon the provision of medical information systems to medical institutions.

4 Data Use

4.1 What are the key legal or regulatory issues to consider for use of personal data?

Under the APPI, personal information can only be used within the scope of the purpose specified in relation to the obtainment of personal information, and the principal's consent is required when such information is used for any other purpose. In addition, personal information related to medical or health matters falls within the category of sensitive personal information and the consent of the principal is required for the obtainment of such sensitive personal information.

"Anonymously Processed Information" is the information that is processed so that it cannot be restored to re-identify a specific individual, and it is treated as non-personal information to which the above-mentioned limitation on the purpose of use does not apply. "Pseudonymously Processed Information" is the information that is processed so that a specific individual cannot be identified without cross-checking with other information, and it can be used for purposes other than those specified in relation to an obtainment without the principal's consent, provided that the modified purpose is publicly announced. These types of information are expected to be utilised in the fields of medicine and healthcare.

In addition to the APPI, when personal information is obtained and used for life sciences and medicine-related research, regulations based on Ethical Guidelines issued by the Ministry of Education, Culture, Sports, Science and Technology, the MHLW and the METI, such as Institutional Review Boards approval and informed consent, would also apply.

4.2 How do such considerations change depending on the nature of the entities involved?

The above-mentioned restrictions under the APPI do not apply to the use of personal information for academic research purposes by academic research institutions, such as universities (including university hospitals).

4.3 Which key regulatory requirements apply?

Business operators that handle personal information (including medical institutions and academic research institutions) must take safety control measures, and they are required to supervise their employees and contractors.

Special obligations are imposed on business operators that handle Anonymously Processed Information or Pseudonymously Processed Information, such as the prohibition of acts that re-identify the principal.

4.4 Do the regulations define the scope of data use?

Apart from certain exceptions stipulated in the APPI, the use of personal information is limited to the specified purpose. Exceptions include cases where the use is particularly necessary for the improvement of public health and when it is difficult to obtain the consent of the principal. In a Q&A recently published by the PPC, it was indicated that the use by pharmaceutical companies for the purpose of research on rare diseases or the like may fall within this exception.

4.5 What are the key contractual considerations?

It is advisable to confirm that (i) the provided personal data has been acquired appropriately, and (ii) the provision thereof has been authorised properly through the necessary procedures (e.g., consent of the principal) under the APPI and Ethical Guidelines, as applicable, and to request warranties from the counterparty, as necessary.

When outsourcing the handling of personal information, it is advisable to stipulate the security control measures to be taken by the contractor, as well as the reporting obligation and audit provisions to confirm the compliance status.

4.6 What are the key legal issues in your jurisdiction with securing comprehensive rights to data that is used or collected?

In regard to the securing of comprehensive rights to use personal information and data, the key point is to define the purpose as broadly as possible. Having said that, according to the guidelines published by the PPC, it is not sufficient to merely specify the purpose of use in an abstract or general manner, instead, it is desirable to specify the purpose in such a way that the principal can generally and reasonably assume the kind of business and the purpose the information will ultimately be used for.

4.7 How are issues with data inaccuracy, bias and/or discrimination addressed by the regulatory authorities in your jurisdiction?

The APPI stipulates that efforts must be made to keep personal data accurate and up to date. The APPI also prohibits the use of personal information in a manner that may encourage or induce illegal or unjustifiable acts, which include the use of personal information to illegally discriminate against a person.

4.8 What are data-usage legal or regulatory issues that are unique to generative AI companies and how are those issues being addressed in your jurisdiction?

Among the various issues, the issues under the Copyright Act

and the APPI are important. The issues under the Copyright Act include (i) whether a copyright infringement occurs when a generative AI uses a work for learning, (ii) the risk of an AI-generated product infringing on a third party's copyright, and (iii) whether the AI-generated product itself constitutes a copyrighted work. The various discussions related thereto are ongoing. With respect to the APPI, it is important to check whether the principal consented to certain uses of personal information by a generative AI for learning. It is also important to check whether the input of prompts containing personal information into a generative AI constitutes (a) a purpose other than those that were presented to the principal, or (b) the provision of such personal information to a third party (in both cases (a) and (b), the principal's additional consent is required). The PPC has issued a warning related thereto. In addition, the government is now preparing guidelines for businesses regarding the appropriate uses of generative AI.

5 Data Sharing

5.1 What are the key issues to consider when sharing personal data?

Under the APPI, apart from certain exceptions, such as outsourcing or joint use, personal data may not be provided to third parties without the consent of the principal. On the other hand, Anonymously Processed Information may be provided to third parties without the consent of the principal, whereas the provision of Pseudonymously Processed Information to third parties is prohibited.

When providing personal data to a third party outside Japan, apart from certain exceptions, it is necessary to obtain consent from the principal even in the case of outsourcing or joint use.

The regulations based on Ethical Guidelines may also apply in the domains of life sciences and medicine-related research.

5.2 How do such considerations change depending on the nature of the entities involved?

The above-mentioned restrictions under the APPI do not apply to the provision of personal data to academic research institutions or provision by academic research institutions to a third party for academic research purposes.

5.3 Which key regulatory requirements apply when it comes to sharing data?

Apart from certain exceptions stipulated in the APPI, the provision of personal data without the consent of the principal is not permitted. Exceptions include cases where the use is particularly necessary for the improvement of public health and when it is difficult to obtain the consent of the principal. In a Q&A recently published by the PPC, it was indicated that the provision to pharmaceutical companies for the purpose of research on rare diseases or the like may fall within this exception.

In obtaining consent for international transfer, information must be provided to the principal in advance regarding the personal data protection system in the country where the third party is located and the measures to be taken by such third party to protect the personal data.

5.4 Are there any governmental initiatives to establish standards for creating, maintaining and sharing healthcare data in your jurisdiction?

Under the APPI, the provision of medical information to a third party requires the opt-in consent of the principal. However, the Next Generation Medical Infrastructure Act ("NGMIA") allows an opt-out process instead of opt-in consent for the provision of medical information to a certified entity performing anonymous processing of medical information to enhance the utilisation of Anonymously Processed Information in medical fields. Since the 2023 amendment to the NGMIA, a similar regime also applies to Pseudonymously Processed Information in medical fields. It is expected that, in some respects, Pseudonymously Processed Information, where the deletion of outlier information is not required upon processing, may be more useful than Anonymously Processed Information in medical fields.

5.5 What are the key issues to consider with respect to federated models of healthcare data sharing?

In principle, healthcare data itself constitutes personal information and when such data is to be shared, the consent of the principal is required under the APPI. Even in respect of federated learning, where only parameters and/or learned models excluding personal information are to be shared with third parties, it is necessary to confirm whether the use of healthcare data for federated learning will be within the purpose of use that was presented to the principal.

6 Intellectual Property

6.1 What is the scope of patent protection for digital health technologies?

Under the Patent Act of Japan, inventions are classified into three categories: an "invention of a product"; an "invention of a method"; and an "invention of a method for producing a product". In the case of an invention of a product, to act in such a way as to constitute direct patent infringement is to produce, to use, to "Assign, etc." (i.e. to assign or to lease, including, in the case where the product is a computer program, to provide through an electrical communication line), to export, to import or to offer to "Assign, etc." the product as part of one's business. For an invention of a method, on the other hand, to act in such a way as to constitute direct patent infringement is to use the method as part of one's business. In the case of an invention of a method for producing a product, to act in such a way as to constitute direct patent infringement is to use the method as part of one's business or to use, to "Assign, etc.", to export, to import or to offer to "Assign, etc." the product produced by the method as part of one's business. When the allegedly infringing product or method meets all the elements of the patented invention, the above-mentioned acts constitute acts of literal patent infringement. Even when a part of a patent claim does not correspond to the allegedly infringing product and the product does not literally fall within a patent claim, the scope of protection of the patent claim extends to the product under the doctrine of equivalents if (i) the non-corresponding part is not the essential part of the patented invention, (ii) the purpose

of the patented invention can be achieved by replacing this part with a part in the product and an identical function and effect can be obtained, (iii) a person skilled in the art could easily come up with the idea of such replacement at the time of the production of the product, (iv) the product is not identical to the technology in the public domain at the time of the patent application or could have been easily conceived at that time by a person skilled in the art, and (v) there were no special circumstances such as the fact that the product had been intentionally excluded from the scope of the patent claim in the course of the prosecution. A patent owner can seek injunctive relief and/or compensation against an infringer through court proceedings.

6.2 What is the scope of copyright protection for digital health technologies?

A copyright includes a right of reproduction, a right of stage performance, a right of musical performance, a right of on-screen presentation, a right of transmitting to the public, a right of recitation, a right of exhibition, a right of distribution, a right of transfer, a right to rent out and a right of adaptation. A copyright owner can seek injunctive relief and/or compensation against an infringer through court proceedings.

6.3 What is the scope of trade secret protection for digital health technologies?

In general, the wrongful acquisition, use and disclosure of "Trade Secrets" are regarded as "Unfair Competition" under the Unfair Competition Prevention Act of Japan ("UCPA"). "Trade Secrets" are defined as "technical or business information useful for business activities, such as manufacturing or marketing methods, that are kept secret, and are not publicly known". A person who wrongfully acquired, used or disclosed "Trade Secrets" may be enjoined from using and/or disclosing the "Trade Secrets" and/or be held liable for damages by the court under the UCPA.

6.4 What are the rules or laws that apply to or regulate academic technology transfers in your jurisdiction?

Technology licensing organisations ("TLOs") are organisations that transform the results of research by university researchers into patents and transfer the results to private companies. TLOs can submit plans for the implementation of their technology transfer businesses to the Ministry of Education, Culture, Sports, Science and Technology and the METI and seek their approval. Approved TLOs will be eligible for a discount of annual patent fees. Further, when approved TLOs take out a loan for their approved businesses, an Incorporated Administrative Agency will guarantee the debts incurred by these TLOs.

6.5 What is the scope of intellectual property protection for software as a medical device?

An invention of software can be patented. If an invention of software to be used for a medical device is patented, the scope of patent protection is the same as that for other patents. Please see the response to question 6.1 on the general scope of patent protection. Further, software can be considered as works of computer programming under the Copyright Act of Japan. The scope of copyright protection for works of computer programming is the same as that for other works. Please see the response to question 6.2 on the general scope of copyright protection.

6.6 Can an artificial intelligence device be named as an inventor of a patent in your jurisdiction? Why or why not?

No, an AI device cannot be considered an inventor of a patent under Japanese law. Under Japanese law, only a "person" can own a right and an AI device is not a "person". As an AI device cannot own a right to obtain a patent, an AI device cannot be named as an inventor.

6.7 What are the core rules or laws related to government-funded inventions in your jurisdiction?

With respect to certain intellectual property rights that are associated with the results of government-contracted research and development ("R&D"), or of government-contracted software development, the national government may decide not to acquire such rights in a situation where the contractor promises that (i) if such results have been obtained, the contractor will report them to the national government without delay, (ii) the contractor will grant the national government the right to use such rights free of charge if the national government requests the contractor to do so while making it clear that the reason for doing so is that it is particularly necessary for the sake of the public interest, (iii) the contractor will grant a third party the right to use such rights if the contractor has not used such rights for a considerable period of time and does not have a legitimate reason for not having used such rights for a considerable period of time, and if the national government requests the contractor to do so while making it clear that the reason for doing so is that it is particularly necessary to facilitate the use of such rights, and (iv) when intending to transfer such rights, the contractor will obtain the approval of the national government in advance.

7 Commercial Agreements

7.1 What considerations should parties consider when dealing with collaborative improvements?

In general, when conducting collaborative development or improvements, it is important to stipulate in the contract, among others, the roles and cost allocation of each party, the rights and licence of the deliverables, and the confidentiality obligation. If the rights of one party are restricted during and after the collaboration (e.g., restriction on a similar development), antitrust issues may arise. When collaborating with academia, compensation for non-execution and publication procedure may also be negotiation points.

7.2 What considerations should parties consider when dealing with agreements between healthcare and non-healthcare companies?

Although there is nothing special to note, it would be helpful to note that healthcare companies are highly regulated and the contents of agreements may be affected by applicable regulations.

7.3 What considerations should parties consider when dealing with federated learning healthcare data sharing agreements between companies?

The purpose of use of the AI models provided by AI developers to the data holders should be limited to the purpose of

federated learning. In addition, it would be preferable for the AI developers not to limit the purpose of use of the learned AI models provided by such data holders to such AI developers to the extent possible in order to eliminate restrictions on business development. It would also be important to provide representations, warranties and covenants regarding compliance with data privacy regulations.

7.4 What considerations should parties consider when dealing with the use of generative AI in the provisioning of digital health solutions?

It should be noted that, if the personal information to be used by a generative AI contains sensitive information such as medical data, the consent of the principal is required to obtain and provide such data to a third party under the APPI. In addition, since the output from the generative AI cannot be controlled in principle, it would be necessary to take care in respect of the risk of the output rising to a level where it would constitute a diagnosis, which could lead to issues regarding the generative AI unintentionally constituting a medical device and/or medical service.

8 Artificial Intelligence and Machine Learning

8.1 What is the role of machine learning in digital health?

Machine learning is playing a role in improving the accuracy of diagnosis using images such as CT and MRI. Machine learning is also expected to improve the accuracy of disease diagnosis by learning from past electric medical records, and to identify mental illness by performing natural language processing of patients' statements. In addition, machine learning is expected to play a role to efficiently perform a vast amount of analysis and work in pharmaceutical R&D and the genome analysis area.

8.2 How is training data licensed?

Training data may be protected under the Copyright Act of Japan. The Copyright Act provides that a database that involves creativity, by reason of the selection or systematic construction of information contained therein, is protected as a work. Training data may fall under a database and its selection of data or systematic organisation of data may involve creativity. In such situation, the training data can be treated and licensed as a copyrighted work. Even when training data is not treated as a copyrighted work, there is a possibility that training data is treated as "Shared Data with Limited Access" under the UCPA. Wrongful acquisition, use and disclosure of "Shared Data with Limited Access" can be treated as "Unfair Competition" under the UCPA, and the person who wrongfully acquired, used or disclosed the data may be enjoined to do so and/or be held liable for the damages under the UCPA. "Shared Data with Limited Access" is defined as "technical or business information that is accumulated to a significant extent and is managed by electronic or magnetic means as information to be provided to specific persons on a regular basis (excluding information that is kept secret)". In the case where the training data falls under this definition, the training data can be licensed as "Shared Data with Limited Access". Even when training data does not fall under a copyrighted work or "Shared Data with Limited Access", some businesses still enter into a "licence agreement" on training data. However, as use of such training data without authorisation does not cause any liability, such "licence agreement" is just a declaration that the "licensor" will not object to the use of the training data by the "licensee".

8.3 Who owns the intellectual property rights to algorithms that are improved by machine learning without active human involvement in the software development?

If there is no active human involvement in the software development at all, no intellectual property rights will arise. However, if the development of the software falls under the act of "adaptation" of an original work, the copyright holder of the original work holds rights on the developed software including the right of reproduction, the right of transmitting to the public and the right of adaptation. This means that, for example, the developed software cannot be reproduced without obtaining a licence from the copyright holder of the original work.

8.4 What commercial considerations apply to licensing data for use in machine learning?

In transactions of licensing data, the following issues should be considered: (i) rights to deliverables; (ii) liability for defective data; (iii) losses derived from licensed data; and (iv) limitations on the purposes of use.

9 Liability

9.1 What theories of liability apply to adverse outcomes in digital health solutions?

In general, liability can arise in tort (either under the Civil Code or under its special law, the Product Liability Act ("PLA")) or under contract. Since "products" for which a claim under the PLA can be asserted are limited to movable property, a claim based on the PLA cannot be filed for an adverse outcome caused by programs unless there exists a device in which such program is incorporated and a defect in the program leads to a defect in the device itself.

An administrative notice recently issued by the MHLW provides that even when a patient is treated using a program that provides AI-based diagnosis and treatment support, the physician is responsible for the final decision for those acts.

9.2 What cross-border considerations are there?

Under the conflicts of laws principle in Japan, the governing law of a tort is the law of the place where the adverse consequence of the tortious act occurred. On the other hand, the parties' agreement takes precedence over the decision of the governing law of the contract.

9.3 What are best practices to minimise liability risks posed by the use of generative AI in the provisioning of digital health solutions?

It would be advisable to include provisions regarding limitation of liability in the terms and conditions for the use of the generative AI. It would also be advisable to include appropriate disclaimers to avoid any misunderstanding about the nature of the subject device/service for digital health solutions using a generative AI.

10 General

10.1 What are the key issues in Cloud-based services for digital health?

The PMD Act regulations of SaMDs would apply to the medical programs provided in a form that allows only the right to use the program in the Cloud without transferring ownership of the program.

In addition, providers of Cloud-based services that handle medical information would be subject to the METI/MIC guidelines described in the response to question 3.2.

10.2 What are the key issues that non-healthcare companies should consider before entering today's digital healthcare market?

When entering the digital health product market, whether the PMD Act is applicable or not is the key issue. When entering the digital health service market, it is necessary to keep in mind that private companies are not allowed to provide services that fall under medical practice.

10.3 What are the key issues that venture capital and private equity firms should consider before investing in digital healthcare ventures?

As the healthcare sector, including digital health, is highly regulated, it is advisable for venture capital and private equity firms to conduct due diligence carefully, especially on regulatory and compliance matters. In addition, as IP would be a key asset for digital health ventures, it is also advisable to carefully examine IP-related matters in due diligence.

10.4 What are the key barrier(s) holding back widespread clinical adoption of digital health solutions in your jurisdiction?

The key barrier is the low predictability of applicable regulations regarding medical devices and medical practice. The MHLW is working to ensure the foreseeability of the applicability to medical device regulation to programs by establishing a consultation service and publicising consultation cases.

10.5 What are the key clinician certification bodies (e.g., American College of Radiology, etc.) in your jurisdiction that influence the clinical adoption of digital health solutions?

The clinician certification body in Japan is the MHLW. Having said that, the Japan Medical Association, a voluntary membership organisation for medical doctors, may have a certain influence on the policy making regarding the clinical adoption of digital health solutions.

10.6 Are patients who utilise digital health solutions reimbursed by the government or private insurers in your jurisdiction? If so, does a digital health solution provider need to comply with any formal certification, registration or other requirements in order to be reimbursed?

Digital health solutions may be reimbursed under the NHI. To be eligible for reimbursement, a digital health solution provider needs to apply to the MHLW for inclusion on the NHI Price List and to undergo a review process by the MHLW.

10.7 Describe any other issues not considered above that may be worthy of note, together with any trends or likely future developments that may be of interest.

In order to accelerate the dissemination of medical device programs, a new regulatory approval framework is being introduced for certain types of medical device programs that are not high-risk. In such framework, (i) first-stage approval may be granted for medical device programs to the extent that evaluation data confirms the probability of a certain level of efficacy, (ii) further evaluation data on efficacy and safety will be collected from actual uses in clinical settings, and (iii) second-stage approval may be granted when the evaluation data collected in clinical settings demonstrates a clinically meaningful degree of efficacy.

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In the area of IP litigation, he handles both IP infringement litigations and IP invalidation litigations before the IP High Court, the Supreme Court, District Courts and the Japan Patent Office. His IP expertise includes a wide variety of IP matters (patents, copyrights, trademarks, design rights, unfair competition and trade secrets) in many areas, such as telecommunications, electronics, social games and pharmaceuticals. He also provides pre-litigation counselling, including infringement/invalidity analysis.
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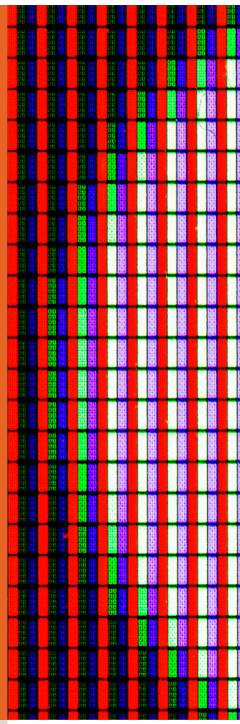

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