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Using eConsent to improve patient comprehension and solving issues for introduction, with special attention to the COVID-19 pandemic: A questionnaire survey by the Japan Pharmaceutical Manufacturers Association

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Abstract: The environment surrounding clinical trials is evolving rapidly with the advancement of digital transformation (DX). Especially during the COVID-19 pandemic, digital methods are effective in promoting multiregional clinical trials (MRCT). eConsent is an electronic tool for obtaining informed consent that is expected as a key solution to improve patient understanding. According to the report by Pietrzykowski *et al*., patient understanding in clinical trials is surprisingly low, and this is a significant ethical problem. Despite the current situation, the use of eConsent has not significantly progressed at least in Japan. This study aimed to identify the current issues for eConsent and consider measures to solve them. In January 2022, an online questionnaire survey was sent to 69 member companies of the Japan Pharmaceutical Manufacturers Association (JPMA), and 52 companies (75.4%) responded. Thirteen companies (25.0%) conducted a trial using eConsent. Among the 13 companies, 17 trials were conducted by 8 companies after the COVID-19 pandemic (summer 2020), compared to 8 trials by 5 companies before the pandemic. We found that the biggest obstacles to the spread of eConsent are the lack of awareness of eConsent use and the development of provisions for treating electronic files as source records in medical institutions. In conclusion, we need to encourage medical institutions to update provisions for handling electronic source documents and to notify them of the importance of eConsent. Thus, further promotion of eConsent is needed to increase patient understanding and enable more efficient clinical trials.

***Keywords*:** electronic signature, patient centricity, patient protection, decentralized clinical trial (DCT), multi-regional clinical trials (MRCT)

Introduction

The environment surrounding clinical trials is evolving rapidly with the advancement of digital transformation (DX) (*1*). Especially during an infectious emergency such as the COVID-19 pandemic, digital methods are effective in promoting multiregional clinical trials (MRCT). Furthermore, it is widely believed that in the near future, decentralized clinical trials (DCT) (*2*), in which clinical trials are conducted with subjects making few visits to medical institutions, will become a reality. Among the various technological developments, eConsent is a vital component because it increases the participant's understanding of clinical trials and, in principle, enables remote informed consent (*3*).

In the Use of Electronic Informed Consent in Clinical Investigations - Questions and Answers published by the Food and Drug Administration (FDA) in 2016 *(4)*, the importance of ensuring the rights, safety, and welfare of patients and improving their understanding of clinical trials was emphasized. However, Pietrzykowski *et al.* reported that the level of comprehension regarding informed consent components, such as voluntary participation, blinding, and freedom to withdraw, was

low, being understood by only 50% of patients (*5*). In light of the philosophy of the Declaration of Helsinki (*6*), this would seriously undermine the ethical basis of the current practice for obtaining informed consent in clinical trials.

Since eConsent can interactively combine not only documents but also various types of content such as animation, video, and audio, it can provide the necessary explanations for informed consent very effectively and is considered to be a method that greatly contributes to the improvement of the understanding of the participants. However, the traditional paper written informed consent requires the clinical research associates (CRAs) of the pharmaceutical company or the clinical research organization (CRO) to visit the research sites in person to confirm the original written consent form and related information, which is problematic in terms of efficiency and information management. Therefore, we believe that eConsent needs to be promoted more aggressively.

Despite the current situation, the use of eConsent has not progressed in Japan. We thought it necessary to understand the current situation more accurately to overcome this situation. Therefore, we conducted a questionnaire survey of all 69 pharmaceutical companies that belong to the Japan Pharmaceutical Manufacturers Association (JPMA) to investigate current practices and initiatives related to eConsent and to identify the issues that need addressing and measures that can be taken to solve them. Furthermore, the summer of 2020 was defined as the time when the first wave of the COVID-19 pandemic began, and Japan decided to postpone the Olympic Games by one year. Based on these experiences, many business behavior changes occurred during or after the summer of 2020, so we asked questions based on before, during or after the summer of 2020. We also asked if and why the COVID-19 pandemic affected the implementation of eConsent.

Materials and Methods

In January 2022, an online questionnaire was sent to 69 member companies of the JPMA. The questionnaire contents are shown in the Supplemental File (*https://www.ghmopen.com/site/supplementaldata.html?ID=66*). Responses to the questionnaire were provided once per company. The first question (the trigger question) asked the participants about their previous experience with eConsent implementation; and the subsequent question was based on their answer. The answer choices for the trigger questions included: [1] Studies were conducted with eConsent (*e.g.*, eConsent was used for informed consent in actual studies), [2] Challenges for the introduction of eConsent were made (*e.g.*, selection of eConsent vendors and so on), but actual studies were not conducted with eConsent, and [3] No studies were conducted or considered with eConsent.

To elicit free and candid opinions when responding to the questionnaire, free-text responses were allowed. We extracted the essence of these free-text responses, categorized and tabulated them. To avoid personal bias, all categorizations were repeatedly reviewed by all the authors until everyone agreed.

For companies that responded to the trigger question with answer choice [1] studies were conducted with eConsent: We asked about their experience with "hybrid operations" and the number of trials they conducted in such manner. Here, "hybrid operation" means that all studies did not necessarily operate only electronically, such as using paper or electronic consent for some sites, or using paper only for consent signature.

Companies that responded that they used "hybrid operations" were asked about their experience using paper only for consent signatures, including the number of studies conducted and the reasons why paper was used only for consent signatures.

Among the eConsent studies, we asked whether they were conducted before the COVID-19 pandemic (summer 2020), the number of studies conducted, their study phase (I, II, III, IV, PMS, and others), and whether the studies were Japanese domestic or international collaborative studies. We also asked the same question during or after the COVID-19 pandemic (summer 2020). As we described in the introduction, in this study, we set summer 2020 as the starting point for "the COVID-19 pandemic" because the first wave of the COVID-19 pandemic began in Japan, and the Japanese government decided to postpone the Olympic Games by one year. Based on these experiences, many business behavior changes occurred after the summer of 2020. We also defined the "during or after COVID-19 pandemic" period as the period from the summer of 2020 through the end of 2021, when the questionnaire survey was conducted.

For companies that responded to the trigger question with answer choice [1] Studies were conducted with eConsent or [2] Considerations for introducing eConsent were made, but actual studies were not conducted with eConsent: When conducting (or considering) studies with eConsent, we asked about any issues encountered and their details. We asked if there was anything that should be improved with eConsent and what and how it should be improved.

For companies that responded to the trigger question with answer choice [3] No studies were conducted or considered with eConsent: We asked why they had not conducted or considered studies with eConsent.

For all companies: We asked if they would use (or consider using) eConsent in the future, and why.

Results

The online questionnaire survey on eConsent was sent to 69 JPMA companies between January 5, 2022 and January 25, 2022, and 52 companies (75.4%) responded.

When asking companies about their eConsent

experience (the trigger question) we found that [1] 13 companies (25.0%) had conducted trials using eConsent, [2] 7 companies (13.5%) considered the introduction of eConsent (*e.g.*, the selection of eConsent vendors was considered), but actual studies were not conducted with eConsent, and [3] 32 companies (61.5%) did not conduct or consider studies using eConsent (Figure 1).

For the 13 companies that responded to the trigger question with answer choice [1] Studies were conducted with eConsent

When asked about their experience with "hybrid operations" and the number of trials they conducted, 12 companies had experience with hybrid operations, with an average of 1.8 hybrid studies (maximum 6, minimum 1) per company. Only one company operated completely electronically.

When the 12 companies that responded that they had experience with "hybrid operations" were asked about their experience using paper only for consent signatures, nine companies used paper only for consent signatures, and the average number of studies was 1.4 (maximum 3, minimum 1). The reasons given for using paper only for consent signatures were "sites' implementation for eConsent is not in place" (4 companies), "site specific forms" (3 companies), "concerns about personal information protection" (3 companies), "pilot trials" (2 companies), "concerns about obtaining electronic consent (companies)" (2 companies), and "time constraints". The reasons for using paper only for consent signatures are shown in Table 1.

Of the 13 companies that used eConsent, 5 companies used it for 8 studies before the COVID-19 pandemic (summer 2020), compared to 8 companies and 17 studies during or after the COVID-19 pandemic (summer 2020). Before the COVID-19 pandemic, there were 0, 2, and 6 studies for phases I, II, and III, respectively. During or after the COVID-19 pandemic (summer 2020), there were 3, 3 and 11 studies for Phase I, II, and III respectively. In addition, before the COVID-19 pandemic, there were 2 studies in Japan and 6 studies internationally. During or after the COVID-19 pandemic (summer 2020), there were 4 studies in Japan and 13 studies internationally. The number of studies using eConsent before, and during or after the COVID-19 pandemic (summer 2020) is shown in Table 2.

For the 20 companies that responded to the trigger question with answer choices [1] Studies were conducted with eConsent (13 companies) and [2] Considerations for introducing eConsent were made, but actual studies were not conducted with eConsent (7 companies)

When conducting (or considering) studies with eConsent,

Table 1. The reasons given for using paper only for consent signatures

Reason	Frequency (multiple answers allowed) $n = 9$
Sites' implementation for eConsent is not in place	4
Site specific forms	3
Concerns about personal information protection	3
Pilot trials	2
Concerns about obtaining electronic consent (companies)	2
Time constraints	1
Total	15

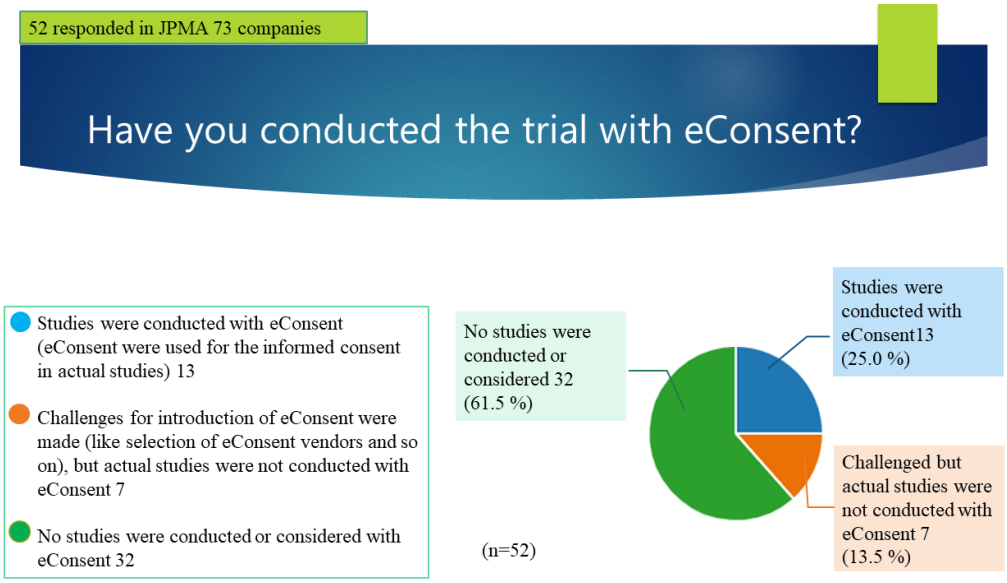

Figure 1. The online questionnaire survey on eConsent for 52 JPMA companies between January 5, 2022 and January 25, 2022.

14 companies in the 20 companies of [1] and [2] said they encountered some issues, and 6 said they did not. The 14 companies that used eConsent reported the following issues, with the number of companies reporting that issue: system (language): 2, systems (individual customization): 2, sites' implementation for eConsent is not in place: 2, communications environments: 2, cost: 1, content issues (not suitable for Japan): 1, system (bug): 1, installation schedule: 1, inability to fully comply with Japanese regulatory requirements electronic records/ electronic signatures (ER/ES): 1, lack of understanding of monitors: 1, patient request (if symptoms make it impossible to operate, patients request paper-based informed consent): 1, concern about personal information protection by company: 1, and site-specific form: 1. On the other hand, [2] the seven companies that considered introducing eConsent, but did not conduct studies with eConsent reported the following issues: system (bug): 1, sites' implementation for eConsent is not in place: 1, cost: 2, concern about BYOD (bring your own device support: 1, benefits are reduced by half due to hybrid operations: 1, and not seeing the significance of eConsent as it requires face-to-face signatures: 1. Details of the issues encountered when introducing eConsent are presented in Table 3.

When these 20 companies were asked if there were any improvements to be made in relation to eConsent, 17 companies said there were points to be improved, and 3 companies said there were no points to be improved. The following details for improvements were suggested, followed by the number of companies reporting that suggestion. [1] The 13 companies that conducted studies with eConsent reported the following: a lack of coordination of awareness of eConsent use (sponsors/ medical institution): 5, eConsent systems were not up to the required level in Japan: 5, the cost of introduction was high: 3, guidelines were not developed: 2, systems take a long time to build: 2, sites' implementation of eConsent is not in place: 2, remote consent should be allowed with video calls: 1, cost of device rentals is significant: 1, system errors are frequent: 1, and the process of re-consent with eConsent is complicated: 1. On the other hand, [2] the seven companies that considered introducing eConsent, but did not conduct studies with eConsent reported the following: a lack of coordination of awareness of eConsent use (sponsors/ medical institution): 2, eConsent systems were not up to the required level in Japan: 2, the cost of introduction was high: 1, guidelines were not developed: 1, systems take a long time to build: 1, and remote consent should

Table 2. The number of studies using eConsent before, and during or after the COVID-19 pandemic (summer 2020)

Study phase / type	Before COVID-19 Pandemic (Summer 2020) (5 Companies)	During or after COVID-19 Pandemic (Summer 2020) (8 companies)
Phase I (Japan only)	0	2
Phase I (International)	0	1
Phase II (Japan only)	1	1
Phase II (International)	1	2
Phase III (Japan only)	1	1
Phase III (International)	5	10
Total	8	17

In this study, we set the summer 2020 as the starting point for "the COVID-19 pandemic". We also defined the "after COVID-19 pandemic" period as the period from the summer 2020 through the end of 2021, when the questionnaire survey was conducted.

Table 3. Issues encountered when introducing eConsent

Details of Issues	(1) Companies that conducted studies with eConsent (Multiple answers allowed) $n = 13$	(2) Companies that considered introducing eConsent, but actual studies were not conducted with eConsent (multiple answers allowed) $n = 7$
System (Language)	2	1
System (Individual customization)	2	
Sites' implementation for eConsent is not in place	2	1
Communications environments	2	
Cost	1	2
Content issues (not suitable for Japan)	1	
System (bug)	1	
Installation schedule	1	
Inability to fully comply with Japanese regulatory requirements (ER/ES) that is developed based on 21 CFR Part 11	1	
Lack of understanding of monitors	1	
Patient's request (if symptoms make it impossible to operate, patients request paper-based informed consent)	1	
Concern about personal information protection by company	1	
Site specific form	1	
Concern about BYOD support		1
Benefits are reduced by half due to hybrid operations		1
Not seeing the significance of eConsent as it requires face-to-face signatures.		1
Total	17	7

BYOD, bring your own device; CFR, Code of Federal Regulations, ER/ES, electronic records/electronic signatures

be allowed with video calls: 1. The points to be improved are listed in Table 4.

Five companies reported that the COVID-19 pandemic had an impact on their eConsent implementation, however, 15 companies reported no impact. Companies that reported an impact cited the use of eConsent to prevent infection among the medical staff, and the pandemic promoted the use of DCT as the main reasons. However, companies that did not report the impact of the pandemic indicated that eConsent had been in place before the pandemic and did not change much after the pandemic, as in-person consent signatures were still required in most cases.

For the 32 companies that responded to the trigger question with answer choice [3] Did not conduct or consider studies with eConsent

When we asked why they had not conducted studies with eConsent in the past, the reasons included lack of necessity, regulatory challenges, cost, support for elderly patients, overseas initiative, lack of experience among Japanese CROs, and time constraints.

For all companies (52 companies)

When asked whether they would use (or are considering using) eConsent in the future and why, all 13 companies that conducted studies using eConsent answered that they would consider using eConsent in the future, citing the following reasons: realization of DCT: 6, monitoring industry trend: 3, compatibility with studies: 2, improved understanding of subjects: 2, making efficient study management tasks: 1 (management of informed consent form (ICF) versions and consent acquisition status), establishment of site implementation for eConsent: 1, and improvement of clinical trial efficiency: 1. Six of [2] the seven companies that considered introducing eConsent, but did not conduct studies with eConsent reported that they would consider using eConsent in the future for the following reasons: realization of DCT: 2, compatibility with studies: 1, improved understanding of participants: 2, making efficient study management tasks: 1 (management of ICF versions and consent acquisition status), development of guidelines: 2, consideration in a global implementation trial: 1, clarification of user benefits: 1, and cost benefits: 1. One of [2] the seven companies that considered introducing eConsent, but did not conduct studies with eConsent reported that they would not consider using eConsent in the future, and the reason for this was that face-to-face informed consent is indispensable. Furthermore, 21 of [3] the 32 companies that responded that they did not conducted a trial or were not considering eConsent reported that they would consider using eConsent in the future, with the main reasons cited as realization of DCT: 7, monitoring industry trend: 6, reduced burden on subjects: 4, improved understanding of subjects: 3, making efficient study management tasks (management of ICF versions and consent acquisition status): 6, and cost benefits: 2. Eleven of [3] the 32 companies that responded that they had not conducted a trial or were not considering eConsent reported that they would not consider using eConsent in the future due to the following: monitoring industry trend: 1, compatibility with studies: 2, cost disadvantage: 2, overseas initiative: 2, no clinical trial: 2, no necessity: 2, must be implemented in combination with online medical care to be beneficial: 1, burden on organization from the introduction of new technology (securing resources for consideration): 1, and delayed response to digitization: 1. The future plan for eConsent and its reasons are listed in Table 5.

Discussion

Our study has four major findings. First, although our study showed that the number of studies with eConsent increased before, and during or after the COVID-19 pandemic (summer 2020), the study participants reported that the pandemic did not significantly affect the implementation of eConsent. Second, the results suggest that raising the awareness of eConsent in medical

Table 4. Points to be improved

Points to be improved	(1) Companies that conducted studies with eConsent (Multiple answers allowed) $n = 13$	(2) Companies that considered introducing eConsent, but actual studies were not conducted with eConsent (multiple answers allowed) $n = 7$
Lack of coordination of awareness of eConsent use (sponsors / medical institution)	5	2
eConsent systems were not up to the required level in Japan	5	2
The cost of introduction was high	3	1
Guidelines were not developed	2	1
Systems take long time to build	2	1
Sites' implementation for eConsent is not in place	2	
Remote consent should be allowed with video calls	1	1
Cost of device rentals is significant.	1	
System errors are frequent	1	
Process of re-consent with eConsent is complicated	1	
Total	23	8

institutions is vital. Third, the cost of using eConsent is one of the major issues preventing pharmaceutical companies from introducing eConsent. Fourth, our results indicated that the most of the hybrid operations used paper only for consent signatures.

COVID-19 pandemic effects on the use of eConsent

An online questionnaire on eConsent was sent to 69 companies of the Japan Pharmaceutical Manufacturers Association on January 5, 2022, and 52 companies (75.4%) responded. This study reconfirmed that use of eConsent is not widespread, at least in Japan. For the 20 companies that responded to the trigger question with answer choices [1] studies were conducted with eConsent (13 companies) and [2] considered the introduction of eConsent, but actual studies were not conducted with eConsent (7 companies), we have shown that 5 companies indicated that the COVID-19 pandemic affected their eConsent implementation, and 15 companies indicated that it did not. One of the companies that indicated that the pandemic did affect their eConsent implementation cited the prevention of infection among medical staff as their reason.

However, even when eConsent was used, the results of this study show that, at present, there are many instances of face-to-face use of eConsent. Although eConsent reduces the time of direct contact with patients, there is still a certain amount of face-to-face time; therefore, its significance in preventing infection is considered to be limited.

However, several companies reported that the COVID-19 pandemic had no impact on them and cited the fact that they had been working on eConsent before the COVID-19 pandemic and were currently obtaining informed consent with eConsent face-to-face as the reasons. The number of companies that reported no impact of eConsent implementation was three times greater than those that did.

Although the COVID-19 pandemic may have affected people's mindset, the global trend toward digitalization began before the COVID-19 pandemic, and the increase in the number of eConsent implementations observed during or after the COVID-19 pandemic was considered consistent with this major trend toward digitalization. As the trend toward digitalization is expected to continue,

Table 5. Whether companies would use (or are considering using) eConsent in the future and why

	(1) Companies that conducted studies with eConsent (Multiple answers allowed) $n = 13$	(2) Companies that considered introducing eConsent, but actual studies were not conducted with eConsent (multiple answers allowed) $n = 7$		(3) Companies that did not conduct or consider studies with eConsent ($n = 32$)	
Would you consider using eConsent in the future? (Y/N)	Y ($n = 13$)	Y ($n = 6$)	N ($n = 1$)	Y ($n = 21$)	N ($n = 11$)
Realization of decentralized clinical trial (DCT)	6	2		7	
Monitoring industry trend	3			6	1
Compatibility with studies	2	1		2	2
Improved understanding of subjects	2	2		3	
Making efficient of study management tasks (management of informed consent form versions and consent acquisition status)	1	1		6	
Establishment of sites' implementation for eConsent	1			1	
Improvement of clinical trial efficiency	1				
Development of guidelines		2		1	
Consideration in a global implementation trial		1			
Clarification of user benefits		1			
Cost benefits		1		2	
Cost demerit					2
Cost unknown				1	
Face-to-face informed consent is indispensable			1		
Reduced burden on subjects				4	
Overseas initiative				1	2
Expanding options for subjects				1	
Improved engagement with subjects				1	
No clinical trial					2
No necessity					2
Must be implemented in combination with online medical care to be beneficial					1
Burden on organization from introduction of new technology (securing resources for consideration)					1
Delayed response to digitization					1
Total	16	11	1	36	14

we believe that the introduction of eConsent will be further promoted in the future. Of the 52 companies that responded, 40 said that they would continue to consider adopting eConsent for DCT in the future, revealing high expectations for future DCT, reducing the burden on participants, increasing participant understanding, and conducting more efficient clinical trials. Therefore, we believe that the promotion speed of eConsent needs to be accelerated within industry, government, and academia for the appropriate and efficient conduct of clinical trials.

Raising awareness in medical institutions

Our results repeatedly pointed out that one of the major impediments to the implementation of eConsent was the acceptance of medical institutions and the development of standard operating procedures (SOPs) or provisions in medical institutions (Tables 1, 3, 4, and 5). Even if pharmaceutical companies tried to promote eConsent, there seems to be many cases where it was not acceptable to use electronic documents and signatures as source records because it is expected that the SOPs or provisions in medical institutions stipulate that the source records should be paper. eConsent can be seen as a significant benefit to medical institutions. In addition to protecting participants and promoting better understanding, consent forms or records can be managed online and are less likely to be lost. They can also manage online which participants have given re-consent and which have not, such as version control, when re-consent is required, thus enabling efficient management. The audit trail is automatically captured, including login information, time spent reading materials, time signed, and question exchanges. Furthermore, it allows the reduction of the response time to source data verification (SDV) by pharmaceutical companies or CRO and reduces the paper storage space. In fact, when you experience an electronic file as a source record, you do not want to return to the paper world. Therefore, it is necessary for the pharmaceutical industry and academia to enlighten medical institutions about the significance of eConsent, improve their understanding of the subject, and propose concrete measures for improvement, such as proposing a model for propositions or SOPs that allow electronic files as source records.

eConsent Installation Cost

This study showed that there are different opinions and positions on the installation cost of eConsent (Tables 3, 4, and 5). Some companies reported that eConsent was expensive, while others reported that they could save money by making it more efficient. The conflicting reasons could depend on how each company views eConsent and how the studies are conducted. In the raw data from the survey responses, there were some cases where it was functionally inadequate, such as the lack of support for Japanese fonts, some systems were not considered to be able to withstand the detailed demands of each site, and that it was not worth the cost or the effort. From the point of view of vendors providing eConsent, it is possible that the level of functionality required by the industry is not consistent, resulting in price instability. Although some aspects of eConsent alone may not be worth the cost at the present time, using eConsent may be necessary when considering increasing participant's understanding, industry-wide improvements in the monitoring efficiency and overall clinical trial scheme and the future of DCT.

Regulatory for eConsent

Our study found that of the 13 companies that said they used eConsent, 9 used it face-to-face, and consent forms were paper-signed in hybrid operations.

The administrative notification of the Pharmaceutical Evaluation and Licensing Division and Medical Devices Evaluation and Licensing Division, the Ministry of Health, Labour and Welfare, dated April 7, 2022 (*7*) states that, "In the case that a clinical trial is to be conducted on patients with infectious diseases, including novel coronavirus infection, and it is difficult to preserve the signed consent documents from the viewpoint of contagiousness of the disease, *etc*., according to the protocol or hospital regulations, if a patient signs the consent document in his/her own handwriting using a tablet device and it is stored electromagnetically", with reference to the "Use of electromagnetic records and electronic signatures in applications for approval or permission for drugs, *etc*." (*8*), the document can be treated as a source record, provided that a procedure manual is in place on how to preserve the document, the document is preserved in a readable condition, and a copy of the consent document (*e.g.*, an output of electromagnetic record) is delivered to the subject in accordance with Article 53 of the "Pharmaceutical GCP Ministerial Ordinance, Article 73 of the Medical Device GCP Ministerial Ordinance", or Article 73 of the "Regenerative Medicine GCP Ministerial Ordinance". This information shows the direction of accepting electronic files signed on tablets as source records. The results in Table 1 also show that there were only two companies with concerns about obtaining electronic informed consent, which suggests that pharmaceutical companies do not have major concerns about having an electronic file signed on a tablet as the source record.

In December 2021, the Cabinet Office Council for Promotion of Regulatory Reform issued a report entitled "Immediate Regulatory Reform Implementation Items" (*9*), which says "guidance should be developed on appropriate methods for physicians at the investigational sites to provide necessary explanations to subjects about the clinical trial and to obtain informed consent non-face-to-face and remotely, and on ensuring the

reliability of the data". On March 30, 2023, the Japanese government issued the guidance "Points to Consider for the Informed Consent Using Electromagnetic Methods in Clinical Trials and Post-Marketing Studies" (*10*) for the implementation of eConsent, we hope that eConsent should become more widespread and implemented.

The limitation of the study is that the questionnaire survey in this study covers only JPMA member companies and does not reflect the opinions of other pharmaceutical companies, medical institutions, or participants.

Conclusion

This study revealed that eConsent is not widely used at least in Japan. It also discovered that one of the reasons why eConsent is not widely used is that medical institutions have not developed their provisions or SOPs to treat electronic files as source records. Since eConsent will help patients to better understand and enable more efficient clinical trials, we need to enlighten medical institutions about the significant merit of eConsent and promote the widespread use of eConsent.

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