BREAKING THE ICE
Exploring the depths of quality

DCTs and the Evolving Regulatory Acceptance

DCT MAKES CLINICAL RESEARCH WARM

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Japan Society of Quality Assurance (JSQA)

GCP Subcommittee
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RQA #RQA2023

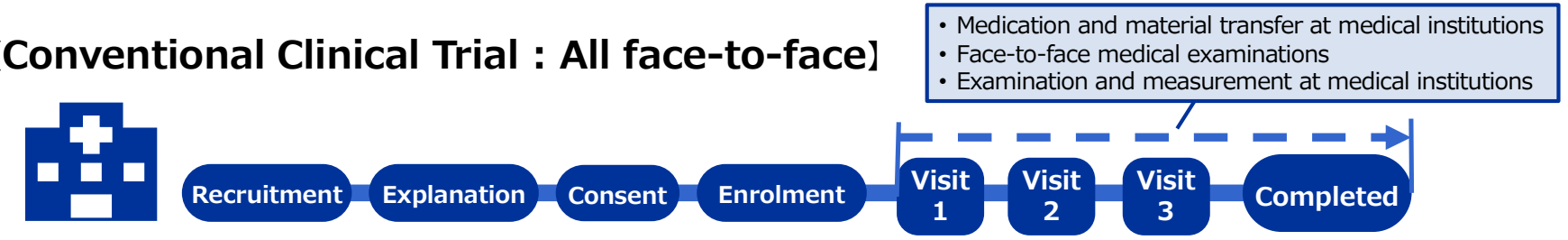
Background of the study

Decentralized Clinical Trials (hereinafter referred to as “DCTs”), which minimize patients’ opportunities to visit medical institutions, are becoming popular mainly in Europe and the United States, and active discussions on DCTs in Japan started between 2018 and 2019. We discussed challenges in promoting DCTs from the perspective of minimum requirements for quality assurance in order to ensure that DCTs would be common practice in Japan and all stakeholders involved in the clinical trials can benefit from them.

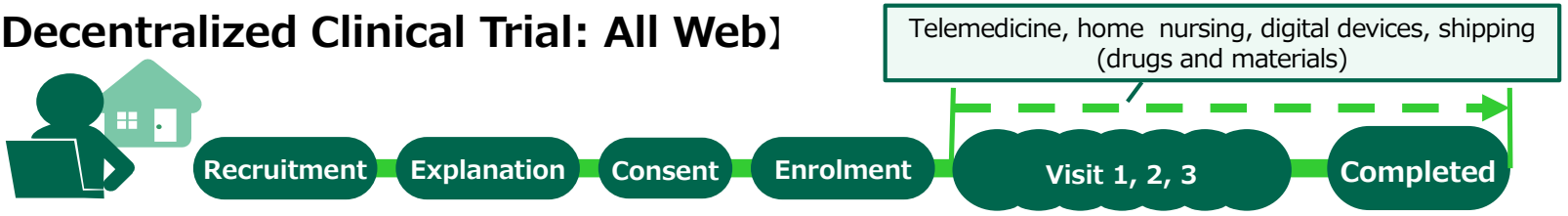
- DCTs consist of a combination of multiple technologies (methods), and various methods and components were picked up and discussed.
- Challenges in the operation of DCTs from the viewpoint of quality assurance were identified for each technology (method) and component.
- Examples of discussion items: Measures to address problems, suggestions to the stakeholders related to the clinical trial including the regulatory authorities, approach/concept for quality assurance of the clinical study using each technology (technique).

What is a DCT?

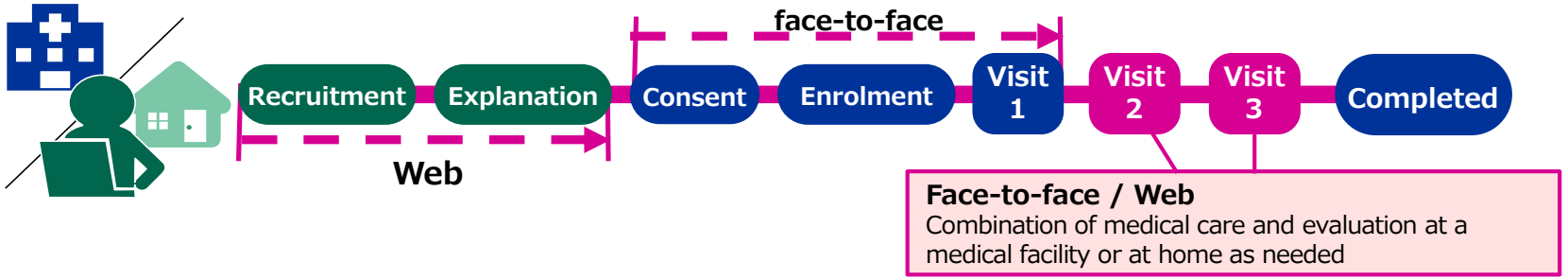
【Conventional Clinical Trial : All face-to-face】



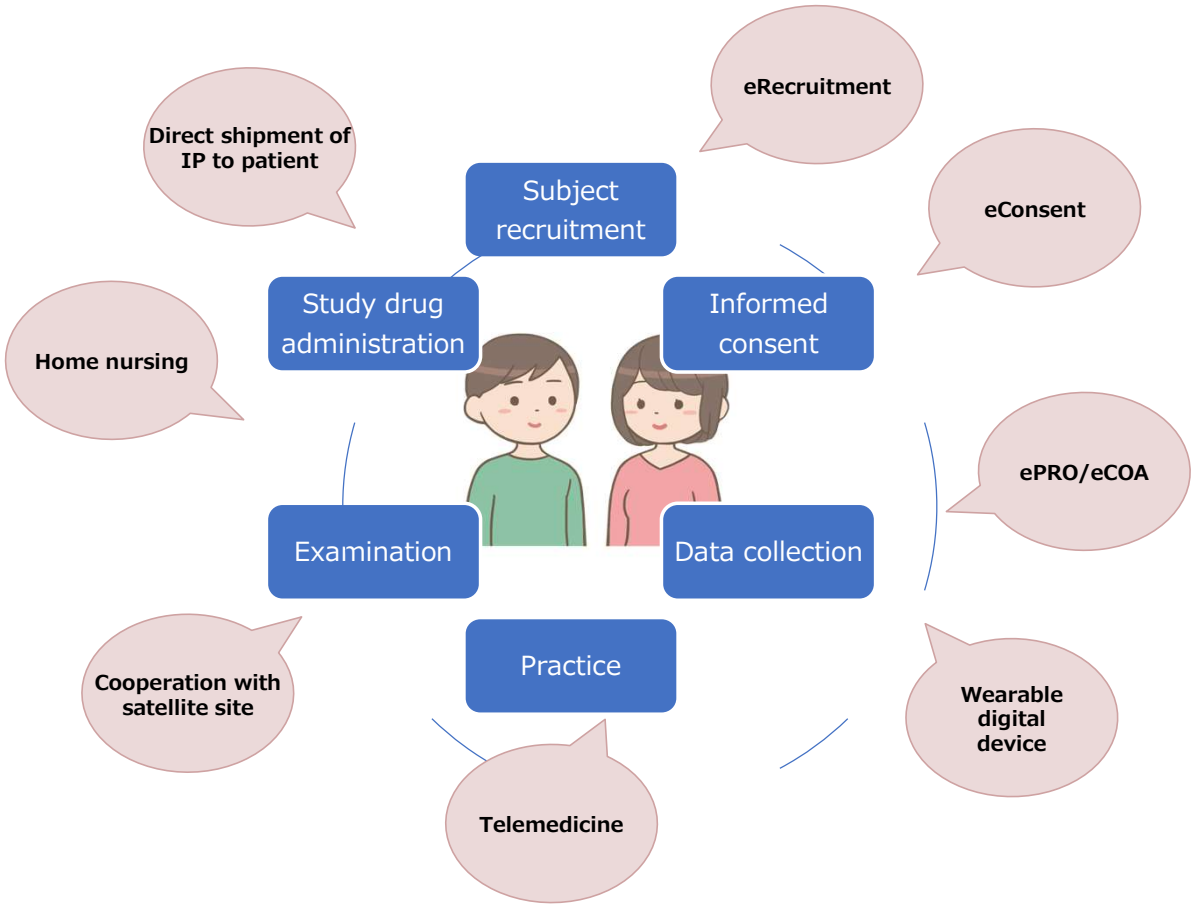
【Decentralized Clinical Trial: All Web】



【Clinical trials that do not rely on medical office visits (DCT, hybrid) 】

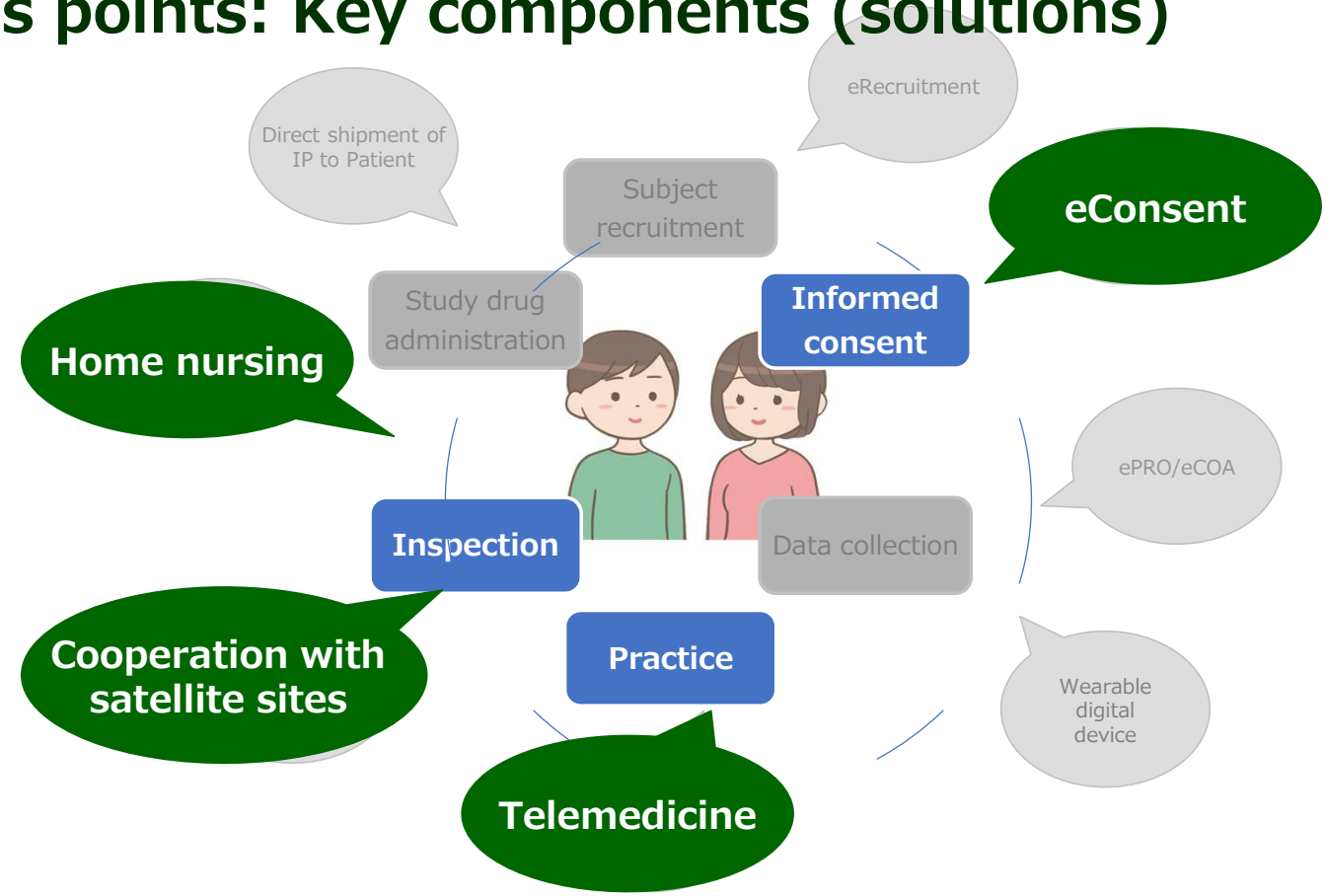


DCT Components (Solutions)



Current regulations, guidelines, and what to check for during implementation

Focus points: Key components (solutions)



Japanese regulations and guidelines for key solutions

	Referenced law	J-GCP	Referenced guidelines and guidelines	Other references, guidelines, etc.
eConsent	○		○	○
Telemedicine	○		○ (For general medical care)	
Cooperation with satellite sites			○ (For general medical care)	
Home nursing	○		○ (For general medical care)	

There are no specific regulations or guidelines focused on each solution. Just references.

Drafting DCT Checklist

confidential material restricted access

DCTチェックリスト（Draft）　eConsent、オンライン診療、近隣医療機関（治験実施医療機関外の医療機関）との連携と訪問看護にフォーカスして、DCT実施の際の課題、留意点を整理

一般社団法人 日本QA研究会 GCP部会 第2分科会（電子） Aグループ（研究テーマ：DCTの品質保証）
作成・更新日：2023年6月21日

管理番号	カテゴリ	規制要件	カテゴリ・工程	依頼者・CROの立場から		医療機関・SMOの立場から		JSQAとしての見解
				DCTを適用したい場合の課題	DCTを適用する際の留意事項（チェック項目）	DCTを適用したい場合の課題	DCTを適用する際の留意事項（チェック項目）	
5-2	eConsent	<日本> ・「人を対象とする生命科学・医学系研究に関する倫理指針」（2021年3月23日発出）により医学系研究ではeConsent許可済 ・治験及び製造販売後臨床試験における電磁的方法を用いた説明及び同意に関する留意点について（薬生薬審発 0330 第6号、薬生機審発 0330 第1号 令和５年３月30日） ・医薬品、医療機器又は加工細胞等に係る治験の計画の届出に関する質疑応答集（Q＆A）について（事務連絡、令和５年３月30日） ・オンライン診療の適切な実施に関する指針（平成30年３月（令和５年３月一部改訂）） 治験責任医師等は、情報通信システム、汎用サービスの適切な利用 のため、「オンライン診療指針」のⅤ.２.（５）.１）を参照すること。 ・参照すべき規制 ※ER/ES指針：「医薬品等の承認又は許可等に係る申請等における電磁的記録及び電子署名の利用について」（厚生労働省 平成17年4月1日 薬食発第 0401022号） ※e文書法：「民間事業者等が行う書面の保存等における情報通信の技術の利用に関する法律」（平成16年法律第149号）と「民間事業者等が行う書面の保存等における情報通信の技術の利用に関する法律の施行に伴う関係法律の整備等に関する法律」（平成16年法律第150号） ※電子署名及び認証業務に関する法律（平成12年法律第102号） ※ 21 CFR part 11 (FDA regulations regarding electronic records and electronic signatures) ・参照文書：「医療機関への実施に依存しない臨床試験手法の活用に向けた検討－日本での導入手引き－」（日本製薬工業協会・医薬品評価委員会臨床評価部会2021年7月作成） <米国> ・FDAのガイダンス Use of Electronic Informed	対面での同意説明・取得 -説明は紙で取得は電子 -説明も取得も電子 （-説明は電子で取得は紙）	①eConsentの実装経験がない。	① □参照となる各種ガイドラインを読み込む。動画等が説明文書に含まれる場合は治験届に添付が必要となるため、動画等は説明文書に含まれるのか、参考資料として説明文書に含まれないか取り扱いを明確にしておくこと。	①eConsentを使用した同意説明・同意取得の手順及び資料（同意書原本）の保管方法について、施設の規定がない。	① □自施設におけるeConsent及び電磁的記録（同意書原本の取り扱い）に関する手順書の作成 □同意書（写）の提供方法について依頼者に確認する。	ガイダンスから外れる又はガイダンスにない運用でeConsentを適用とする場合は規制当局へ事前相談が必要であるが、ガイダンスに則っていれば事前の相談は不要で適用可能である。 実装にあたっては、周到な事前準備、特にサービスプロバイダと事前に十分協議・確認が必要であり、施設の手順やインフラが整っており、eConsent使用に理解が得られていなければならず、システムトラブルや被験者の要望に応じて紙も準備する必要がある。 電子(動画を用いた)説明は、様々な年齢層で受け入れられるものと考えるが、文章を読む事や対面で担当医師やCRC説明される事よりも理解が浅くなる可能性等も考えられる。動画の内容や構成等の改善も必要ではあるが、適宜、対面での補足等も行いながら電子での説明を導入することを推奨したい。また、電子での署名についてはすでに様々な場面において導入が進んでいる事もあり、治験での同意についても今後取り入れるべく推奨するものとする。
				②施設からeConsent使用について理解（メリット）が得られない。	② □被験者、医療機関、依頼者社内へのeConsent導入メリット、操作方法などの理解促進のための啓蒙活動を検討する。 □eConsentによる同意取得プロセスについて治験スタッフが正しく理解するためのトレーニングの実施とマニュアルの準備を行う。 □必要に応じて被験者向けのマニュアルを準備する。 □施設スタッフからの問い合わせやトラブル時のサポート体制を構築する。	②ICFの自施設フォーマットを使用したい。	② □施設選定時に施設のICFフォーマットの使用可否について依頼者に確認する。	
				③IRBの事前レビュー（ヒアリング）時に必要なもの・情報が揃わない。	③ □治験審査委員会によりeConsentに関するビデオや音声、Webサイトを含めた全ての資料が審査され、同意取得プロセスについて承認が得られているかを確認する。なお、動画等が説明文書に含まれるか、参考資料として説明文書に含まれないか取り扱いを明確にしておくこと。	③eConsentによる同意取得の経験不足・プロセスの理解不足	③ □被験者対応を行うための施設手順に関するスタッフへのトレーニング。	
				④eConsentセットアップ完了まで時間がかかる。	④ □ICF施設版の使用の可否及び使用可能な場合にセットアップまでのプロセスやタイムラインを確認する。ICF改訂時や複数の同意説明文書・同意書（任意も含めて）がある場合、メインと合わせて準備し、メインと同様に対応・確認する。	④eConsent使用時のテクニカルな問題（インターネット環境、デバイスの不具合や使用方法についての不明点）に対して懸念がある。	④ □eConsent使用時のテクニカルな問題に関する問い合わせ先を依頼者に確認しておく。	
				⑤使用するデバイス（サービスプロバイダ）によって仕様が異なるが、使用経験がないと何をどう確認・準備してい	⑤ □使用するデバイス（サービスプロバイダ）が決まったら、	⑤患者さんがeConsentを使いたくない、使うのが難しい。	⑤ □被験者への説明資料を依頼者とともに準備する。	

eConsent

eConsent – Japanese Regulatory Requirements

カテゴリ	法令・ガイドライン名称
Related laws	Act on the Protection of Personal Information (Implemented on April 1, 2022)
	Act on Utilization of Telecommunications Technology in Document Preservation, etc. Conducted by Private Business Operators, etc.” (Act No. 149 of 2004)
	“Act on the Improvement, etc. of Relevant Laws Associated with the Implementation of the Act on the Utilization of Telecommunications Technology in Document Preservation, etc. Conducted by Private Business Operators, etc.” (Act No. 150 of 2004)
	Act on Electronic Signatures and Certification Business (Act No. 102 of 2000)
J-GCP	**(No provisions specific to eConsent)**
Related Guidelines	・About points of Concern Regarding Consent and Explanation through Telecommunication for Clinical Trials and Post-marketing Clinical Trials (PSFB/Evaluation and Licensing Division Notification 0330 No. 6 and No. 1; March 30, 2023)
	・About Q&A Regarding Submission of Clinical Trial Proposal Involving Pharmaceuticals, Medical Devices, and Processed Cells. (Office Contact, March 30, 2023)
	・Policy for Appropriate Administration of Telemedicine (March 2013 (Partially Revised March 2023)) Physicians overseeing clinical trials should refer to Ver.2.(5).1 of the “Telemedicine Policy” for appropriate use of information and telecommunications systems and general-use services.
	Guidelines for the Appropriate Management of Computerized Systems for Manufacturers and Distributors of Pharmaceuticals and Quasi-Drugs (PFSB/CND Notification 1021 No. 11; October 21, 2010; Ministry of Health, Labour and Welfare)
	ER/ES Guidelines “Use of Electromagnetic Records and Electronic Signatures in Applications for Approval or Licensing of Pharmaceuticals, etc.” (PFSB Notification No. 0401022; April, 1, 2005; Ministry of Health, Labour and Welfare)
Other reference guidelines, etc.	“Ethical Guidelines for Life Science and Medical Research Involving Human Subjects” (Issued March 23, 2021)

eConsent – What sponsors should check

Matters to be specified during the planning stage

- Preliminary consultation with regulatory authorities is recommended when obtaining eConsent.
- Consider educational activities, including how to operate eConsent tool to promote understanding of the benefits of introducing eConsent into subjects, medical institutions, and client companies.
- Prepare to obtain paper-based consent in case of problems with Internet connections or equipment, or when subjects wish to use paper ICF.
- When obtaining consent from a subject remotely, the method of personal identification should be specified.

eConsent – What sponsors should check

Operation side

- Ensure that the institution has procedures for the use of eConsent and electromagnetic records.
- Ensure that a copy of the consent form at the time of obtaining eConsent can be appropriately provided to subjects.
- Provide training and prepare manuals to help the site staff have a better understanding of the eConsent process.
- Prepare a manual for subjects as necessary.
- Check whether there are any problems with the Internet environment at the medical institution where the clinical trial will be conducted and at the remote location where informed consent will be obtained.
- Ensure that all documentation, including video, audio, and websites related to eConsent have been reviewed by the IRB and approved for the consent process.

eConsent – What sponsors should check

Matters related to the IT system to be utilized

- Ensure that the IT system that will be used for eConsent meets applicable regulatory requirements in advance.
- Check whether the eConsent includes the same elements as face-to-face consent.
- Confirm whether there is a system to ensure that the consent process has been properly implemented.
- When obtaining consent from a subject remotely, confirm in advance whether there is a system for obtaining consent after the subject sufficiently understands the content.
- Confirm whether a process and operation have been established for reconsenting, withdrawing consent, or revising the ICF.

eConsent – JSQA's Opinion

While prior consultation with regulatory authorities is required when applying use of eConsent in instances deviating from guidelines or in instances not listed in established guidelines, **prior consultation is not required and eConsent can be applied when established guidelines are followed**!
Furthermore, it is recommended that both processes for providing and obtaining informed consent be performed remotely.
However...

- Thorough **advance preparation** is needed, and prior sufficient consultation and confirmation is needed especially when dealing with service providers.
- Facility protocol and **proper infrastructure must be established,** and an **understanding** on the use of eConsent is mandatory.
- Paper versions of all consent forms must be prepared for times of system error and for when requested by test subjects.
- It is also perceived that use of electronic explanations (via video) can result in a weaker understanding, therefore, supplementary accommodations must also be made available as needed to provide proper face-to-face explanations.
- Extensive and careful attention to detail is necessary for confirming the test subject's identity, level of understanding, and **their current situation** when using fully-remote eConsent.
- While it is considered possible to acquire eConsent remotely from the first encounter, preparations must be made to have methods ready for directly communicating with test subjects, including video calls and excluding voice-only real-time communication.

As it is possible to search for potential test subjects who haven't been provided with informed consent explanations, it is believed that explaining and obtaining informed consent remotely is possible. **This means that patients would have more opportunities to participate in clinical trials, and both sponsors and medical institutions partaking in clinical trials would see clinical trials speed up.**

Telemedicine

Category	Name of Laws & Guidelines	
Related laes	"Act on Utilization of Telecommunications Technology in Document Preservation, etc. Conducted by Private Business Operators, etc." (Act No. 149 of 2004)	
J-GCP	**(No provisions specific to telemedicine)**	
Related guidelines	Guidelines for the Appropriate Management of Computerized Systems for Manufacturers and Distributors of Pharmaceuticals and Quasi-Drugs (PFSB/CND Notification 1021 No. 11; October 21, 2010; Ministry of Health, Labour and Welfare)	
	ER/ES Guidelines "Use of Electromagnetic Records and Electronic Signatures in Applications for Approval or Licensing of Pharmaceuticals, etc." (PFSB Notification No. 0401022; April, 1, 2005; Ministry of Health, Labour and Welfare)	
	Q&A Pertaining to Conducting Clinical Trials on Pharmaceuticals, Medical Devices and Regenerative Medicine Products Under the Influence of the Novel Coronavirus Infection	Gen. Practice
	Guidelines on the Appropriate Implementation of Telemedicine (Health Policy Publication 0330 No. 4; March 30, 2023; Ministry of Health, Labour and Welfare)	Gen. Practice
	Q&A on the "Guidelines on the Appropriate Implementation of Telemedicine " (Health Policy Publication 0330 No. 1; March 30, 2023; Ministry of Health, Labour and Welfare)	Gen. Practice
	Handling of Inappropriate Medical Practices in Telemedicine (Health Policy Publication 1226 No. 2; December 26, 2018; Ministry of Health, Labour and Welfare)	Gen. Practice
	About the Temporary and Exceptional Handling of Medical Treatment, etc. Using Telephones and Information Communication Equipment During the Spread of Novel Coronavirus Infections (Office Contact; April 10, 2020; Ministry of Health, Labour and Welfare)	Gen. Practice
	About the Revision of Temporary and Exceptional Handling of Medical Treatment, etc. Using Telephones and Information Communication Equipment During the Spread of Novel Coronavirus Infections (Part 3) (Office Contact; September 30, 2022; Ministry of Health, Labour and Welfare)	Gen. Practice
	Handling of Sign Language Interpreters, etc. Participating in Telemedicine (Office Contact; August 24, 2020; Ministry of Health, Labour and Welfare)	Gen. Practice
	Precautions, etc. on Temporary and Exceptional Handling of Medical Treatment, etc. Using Telephones and Information Communication Equipment During the Spread of Novel Coronavirus Infections (Office Contact; August 26, 2020; Ministry of Health, Labour and Welfare)	Gen. Practice
	Report on the Implementation Status and Thorough Adherence to Regulations for Use of Telephones and Information Communication Equipment for Primary Diagnosis Medical Care with regard the Temporary and Exceptional Handling of Medical Treatment, etc. Using Telephones and Information Communication Equipment During the Spread of Novel Coronavirus Infections (Public Release) (Office Contact; March 8, 2023)	Gen. Practice
	About Basic Policy for Promotion of Additional Forms of Remote Telemedicine (Health Policy Publication 0630 No. 3; June 30, 2023:Ministry of Health, Labour and Welfare)	Gen. Practice
Other guidelines for reference	–	

Telemedicine – What sponsors should check

Matters to be specified during the planning stage

- During study protocol preparation, the restriction of telemedicine should be considered, and whether safety and efficacy endpoints can be appropriately determined should be fully discussed.
- Consider the policy on compensation in the case of no visit.
- The retention of clinical trial records (items examined in telemedicine, etc.), including records of deviations at the medical institution, should be specified in advance in the protocol, etc.
- Establish measures for AE/SAE required treatment during the visit.
- The protocol should provide information on the benefits and potential disadvantages of telemedicine for patients and their families.

Telemedicine – What sponsors should check

Operation side

- Consent shall be obtained after the subjects have a proper understanding of the advantages and possible disadvantages of telemedicine.
- In order to prevent spoofing (confirmation of personal identity), in principle, both doctors and patients shall confirm their personal identities using identification documents and record the confirmation results.

Telemedicine – What sponsors should check

Matters related to the IT system to be utilized

- When evaluating system vendors, ensure that their IT systems used in telemedicine meet applicable regulatory requirements.
- Specify the operation of the system.
- Specify the measures to be taken in the event of a system failure.

Cooperating with Nearby Medical Institutions/Home-visit Nursing Care Services – Points of Note when Auditing/Being Audited in Decentralized Clinical Trials (DCT)

<Applies to Sponsors, Medical Institutions Participating in Clinical Trials, and Nearby Medical Institutions>

- The **scope of business must be clarified** when analyzing the clinical trial implementation system along with confirmation of whether parties involved have entered into a contract based on Article 13 of the **Contract for Clinical Trials** or Section 2 of Article 39 of an **Outsourcing Contract**.
- Confirmation of **home-visit nursing care service selection and their selection record** is required. This includes recording if an at-home clinical trial vendor will participate or not, and if not, then consultations must be held with local hospitals and clinics regarding cooperation (regional cooperation).
- There must be **a clear breakdown of roles shared** for each **and the organization of the clinical trial implementation system** involving satellite medical institutions, home-visit nursing care services, home-visit clinical trial vendors, etc.
- Exploration of creating **a supplementary required procedural manual for emergency care response, among other instances,** in addition to existing procedural manuals must occur. (Example: Procedures for at-home administration, procedures for transferring and safekeeping of investigational new drugs, etc.)
- The sponsor **will assume responsibility for training and management,** while either the sponsor or the medical institutions participating in clinical trials and/or nearby medical institutions will implement **home-visit nursing care station training.** (Nursing care to be provided under the direction of the core clinical hospital)

Telemedicine – JSQA's Opinion

- Thorough analysis is to be performed for each individual clinical trial, and it is thought that **revisions will be necessary, as proper countermeasure review will be needed for stakeholders** and regulatory authorities when issues arise. In that event, individuals **will also refer to related notices** for telemedicine with regard to standard medical treatment.
- It is recommended to **refer to case studies** as they relate to telemedicine.
- It is thought that there will need to be a feasibility analysis, and both sponsors and medical institutions participating in clinical trials will have a mutual reconciling regarding **cost of compensation/reimbursements for expenses incurred, telemedicine medical itemization surcharges, and infrastructure cost burden necessary for telemedicine.**

Satellite Sites

Collaborate with Satellite Sites/Home Nursing – Japanese regulatory requirements

Category	Name of laws and guidelines
Related laws	Health Insurance Act (Act No. 70 of 1922) general practice
	Long-Term Care Insurance Act (Act No. 123 of 1997) general practice
J-GCP	**(No specific regulations for cooperating with neighboring medical institutions/home-visit nursing)**
Related guidelines	Q&A Pertaining to Conducting Clinical Trials on Pharmaceuticals, Medical Devices and Regenerative Medicine Products Under the Influence of the Novel Coronavirus Infection general practice
Other reference guidelines, etc.	N/A

Working with Satellite Sites – What sponsors should check

Matters to be specified during the planning stage

- The roles and responsibilities of satellite sites in clinical trials should be clarified.

Operation side

- Execute contract with the clinical trial site and/or sponsor.
- Keep the results of lab tests, examinations, etc. performed at satellite sites as source documents for the period specified by GCP. (Article 41, Paragraph 2 of GCP)
- List in the clinical trial notice as the clinical trial site.
- Establish a system and procedures and develop SOPs.

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*Satellite site: A medical institution located close to the patient's home that performs clinical trial-related practices for the patient based on the instructions of, or in cooperation with, the clinical trial site.

Home Nursing – What sponsors should check

Matters to be specified during the planning stage

- Clarify the roles and responsibilities of nurses who perform home nursing in the clinical trial.

Operation side

- Execute contract with a home nursing station, a medical institution that performs home nursing activities, and/or sponsor.
- In order to utilize home nursing specified by the study protocol, the system and procedures should be established and documented between the clinical trial institution and the home nursing station/medical institution.

Cooperating with Nearby Medical Institutions/ Home-visit Nursing Care Services – JSQA's Opinion

- **Clarify the scope of business** and the DCT implementation system. Confirm whether the trial falls under a contract based on Article 13 of the **Contract for Clinical Trials** or Section 2 of Article 39 of an **Outsourcing Contract**.
- Thorough analysis is to be performed for each individual clinical trial, and it is thought that **revisions will be necessary, as proper countermeasure review will be needed for stakeholders** and regulatory authorities when issues arise. Furthermore, **refer to the Health Insurance Act, the Long-Term Insurance Care Act, and related notices.**
- It is recommended to **refer to prior existing case studies** as they relate to cooperation with nearby medical institutions and home-visit nursing care services.

Summary of JSQA's Opinion

「Why DCT」

- **Has the potential to create ideal clinical trial implementation environments for both subjects and sponsors.**

「What DCT」

- **The usage scope of the DCT may also change based on the trial's specialty (disease, protocol).**

「How DCT」

- **Consider how each trial and facility can respond by referring to existing case studies.**

「Shape DCT」

- **Implement feasible components found via accumulated case studies.**

「Future DCT」

- **Create better policies and guidelines by learning from accumulated case studies (including Trial & Error).**

DCT Models

Use of DCT Solutions

表１　海外事例で調査した臨床試験で使用された、実施医療機関への来院に依存しない臨床試験手法のまとめ

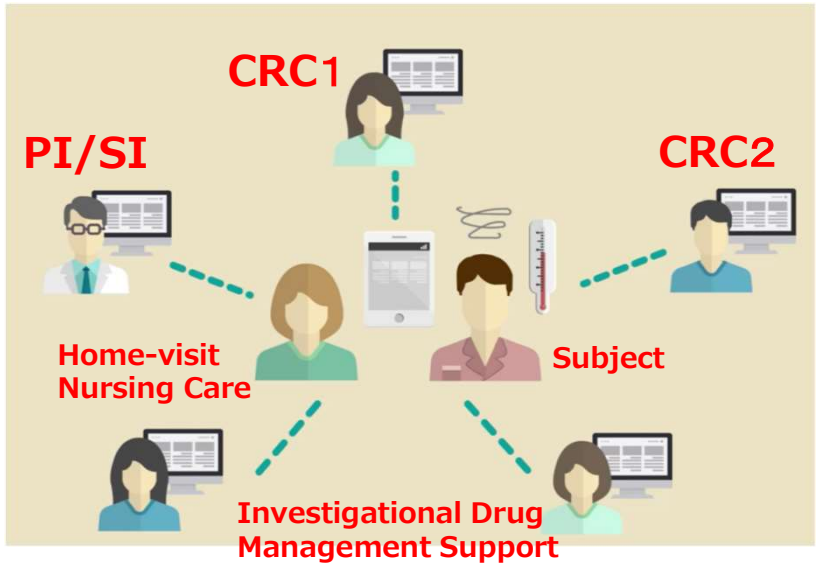
状況※	試験名等	来院の有無	Webや患者レジストリを用いた患者募集	遠隔同意取得	オンライン診療	配送			訪問看護		遠隔データ収集
						試験薬（治験薬）の直送	被験者からの検体回収	デバイスの直送	訪問看護（採血のみ）	訪問看護	
実施済	NCT01302938/REMOTE	無	○	○	×	○	×	○	○	×	○
	NCT01694667	無	○	○	×	○	×	×	×	×	○
	VERKKO	無	○	○	-	-	-	○	-	-	○
	NCT02506244/mSToPS	無	○	○	×	×	×	○	×	×	○
	NCT02376166/M-RePoRT	有	×	×	○	-	-	-	-	-	○
	NCT02727543/MedISAFE-BP	無	○	○	×	×	×	○	×	×	○
	NCT02709330	有	×	×	×	○	×	×	×	×	○
	NCT02832063	無	○	○	○	○	○	-	-	-	○
	NCT03150797/MAP	有	○	×	×	○	-	-	-	-	○
実施中	NCT03090321/MHC	無	○	○	×	×	×	×	×	×	○
	NCT02697916/ADAPTABLE	無	○	○	×	×	×	×	×	×	○
	NCT03728933	無	○	○	○	○	-	-	-	-	○
	NCT03538262/AT-HOME PD	無	×	○	○	×	×	×	×	×	○
	NCT03172026/MAROS	-	-	-	-	-	-	-	-	-	○
	NCT03924414 /TOPAZ	無	○	○	○	-	-	-	×	○	○

※：表の「○」は実施していること、「×」は実施していないこと及び「-」は情報が入手できなかったことを意味している。

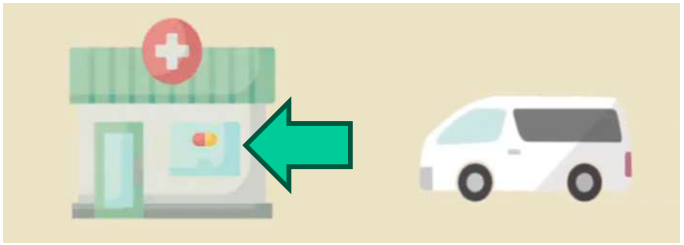
「日本製薬工業協会医薬品評価委員会 部会資料「医療機関への来院に依存しない臨床試験手法の導入及び活用に向けた検討」 別添1.「海外で実施された DCT の個々の試験の要約」より
https://www.jpma.or.jp/information/evaluation/results/allotment/lofurc0000005jr6-att/tf3-cdt_01.pdf

DCT Model/Clinic

Domestic Clinic DCT Model (COVID-19 Investigational Drug Clinical Trial)



1. Subject home-visit via DCT car



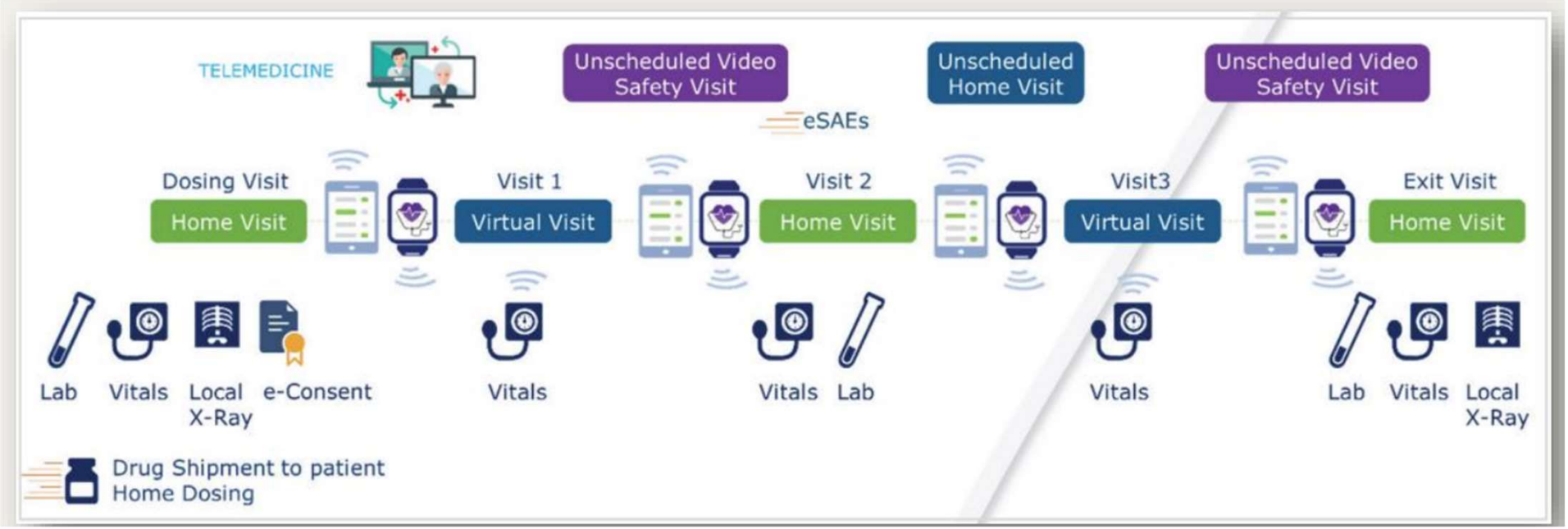
2. Online Meeting System:
   - 2-1 Provide & Obtain Written Informed Consent
   - 2-2 Specimen Collection
   - 2-3 Survey Observation & Recording
   - 2-4 Confirm Investigational Drug Administration

Results are recorded in a timely manner in cloud-based electronic clinical records

Refer to Tokyo center clinic website
https://www.youtube.com/watch?embeds_referring_euri=https%3A%2F%2Ftokyo-center-clinic.studio.site%2F&source_ve_path=Mjg2NjQsMTY0NTAz&feature=emb_share&v=mYAA5Ig4I44

DCT Models

ARO in US



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Concerns on Data integrity in DCT

- Data access
- Data security
- Dispersion of original data and source documents
- Accident response
- Monitoring
- Audit
- PI oversight
- Other risks (Protocol design, Target disease, Characteristics of the investigator site, environment of the subjects, etc.)

Thank you