Don't be afraid to go DCT, step by step!

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「Why DCT」 Has the potential to create ideal clinical trial implementation environments for both subjects and sponsors.
「What DCT」 The extent to which DCT is used may also depend on the specialization of the clinical trial (disease, protocol etc.).
「How DCT」 Consider how each trial and investigator site 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).

By introducing DCT solutions, 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.

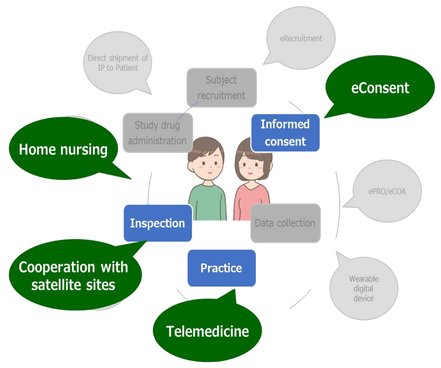
PURPOSE / OBJECTIVES

While Decentralized Clinical Trials (hereinafter referred to as "DCTs") which minimize patient visits to medical institutions when participating in clinical trials are becoming popular mainly in Europe and the United States, 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).

MATERIAL & METHODS

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	○		○ (For clinical trials)	○
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 other than eConsent

RESULTS

Points to consider when auditing/receiving an audit of the study applied DCT solutions

eConsent

<Sponsor>
- Confirm that the IRB reviewed and approved the informed consent process in using eConsent including all materials related to eConsent, such as videos, etc.
- Check the specifications whether the device to be used complies with applicable regulatory requirements.
- Discuss in advance with the service provider about the procedures and documents that need to be prepared, such as manuals for medical institutions and study subjects, and how to deal with system troubles.
- When explaining and obtaining consent remotely, it is necessary to prepare appropriate communication methods, such as video calls and confirm any measures for obtaining consent after confirming that the subject sufficiently understands (question flag function, understanding degree test, etc.)

<Medical Institution>
- It is necessary to establish procedural documents for electromagnetic records (handling of the original consent form) to enable the use of eConsent.
- When explaining and obtaining consent, secure a location where the privacy is protected without any problems in the internet environment.

<Common by Sponsor and Medical Institution>
- Stipulates the method of confirming the identity of the subject, for example, it is possible to present identification documents and in principle, it is necessary for both the investigators and the subjects to confirm each other's identity using the identification documents. Furthermore, it is desirable that specifics to authenticate the identity of the person signing the electronic signature will be established in the information communication system.

Telemedicine

<Preliminary consideration by both the sponsor and the medical institution conducting the trial and provisions in the study protocol >
- When planning study protocol, thoroughly consider whether endpoints for safety and efficacy can be appropriately evaluated by reflecting the limitations in telemedicine.
- Stipulate in the study protocol how to document clinical trial related medical records at the medical institution conducting the clinical trial (items observed through telemedicine, including records of deviations, etc.).
- Determine how to manage the subject's visit when requiring any medical treatment due to AE/SAEAE/SAE.
- Stipulate the benefits of telemedicine and the handling of the disadvantages that may result from it for patients and their families, etc., in the study protocol and ICF beforehand.

Satellite Sites / Home Nursing

<Common items among Sponsor, medical institution and satellite site>
- It is necessary to clarify the clinical trial implementation system and the scope of work whether the contract between sponsor and medical institution is executed in accordance with J-GCP Article 13: Clinical Trial Agreement or Article 39-2: Outsourcing Contract.
- It is necessary to select and confirm the selection records of home nursing stations. If the home nursing vendor is not involved, consult with the medical institution if their cooperation is available.
- It is necessary to establish appropriate structure of clinical trial implementation that utilizes satellite sites, home nursing, home nursing vendors, etc., and to clarify the roles and responsibilities of each party.
- It is necessary to consider and develop procedural documents (e.g., emergency procedure, procedures for home administration, procedures for receiving and storing investigational drugs, etc.) that need to be supplemented with the current procedure.
- The sponsor provides necessary training and ensures that staff in home nursing station* receive training by the sponsor or medical institution or satellite sites. *who performed under the direction of the clinical trial site.

DCT Checklist


DCTチェックリスト（Draft）
eConsent、オンライン診療、訪問医療機関（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）
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SUMMARY / CONCLUSION

<eConsent>

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.

<Telemedicine>
- 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 / Home Nursing>
- 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.