CTX

Delivery new medicine to the patient faster

2026/02

Japan Clinical Trial Transformation Research Society

- For Delivering New Medicines To Patients Faster -

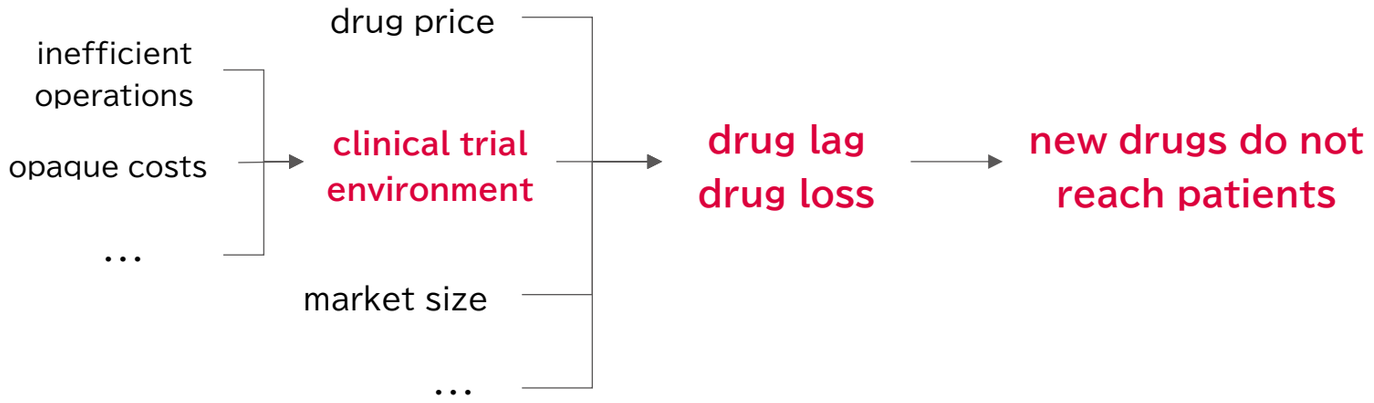
Introduction of the Second Period of our activities

Mitsubishi Research Institute

Concern about a future in which Japan “is no longer chosen for global clinical trials”

Japan’s rate of participation in global clinical trials is low and is becoming one cause of drug loss

- If drug loss occurs, new drugs do not reach patients in Japan
- For that reason, it is necessary for Japan to put in place a clinical trial environment in Japan in order to be “chosen for global clinical trials”



The rate of participation in global clinical trials (2023)	
US	81.5%
Germany	42.8%
France	42.1%
UK	38.3%
Japan	26.9%
China	20.9%

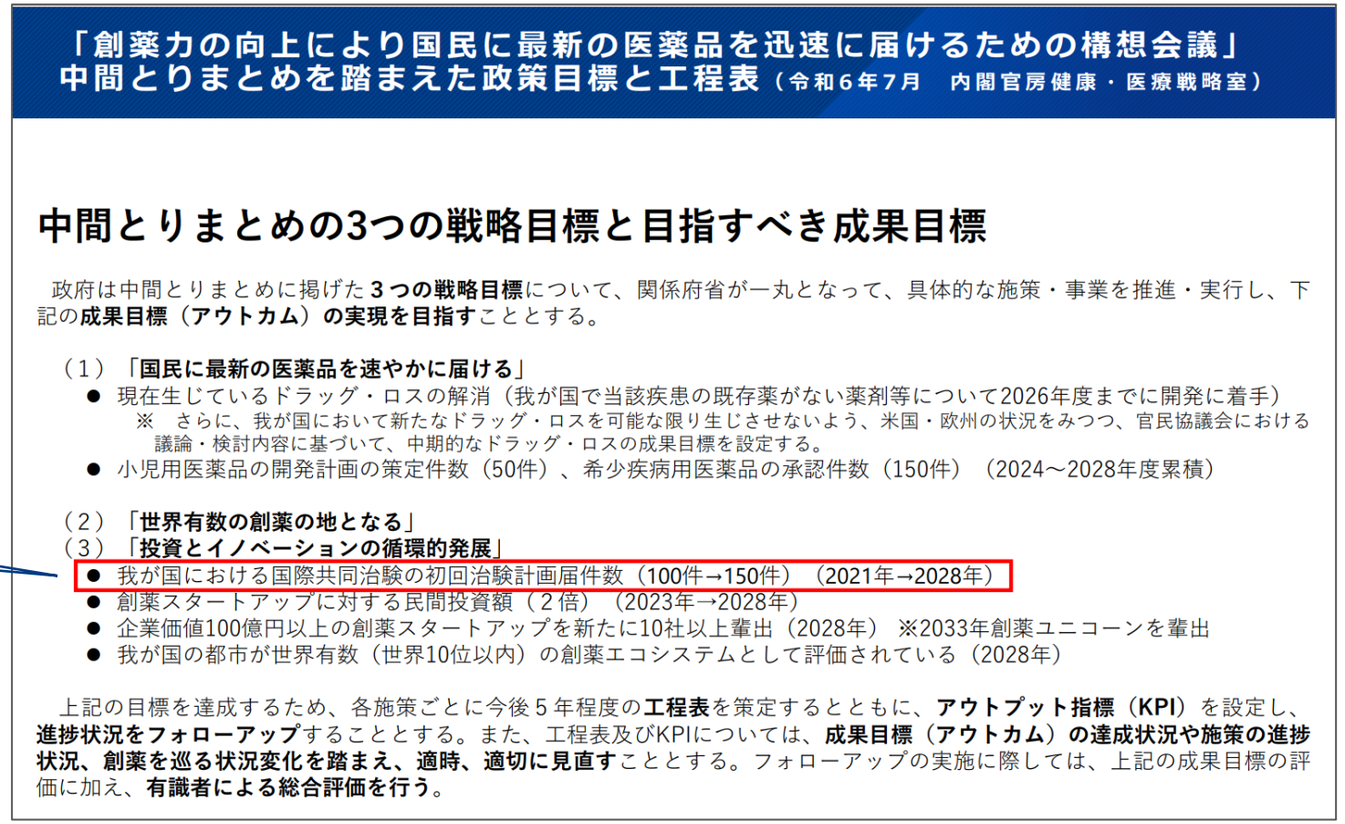
Source) OPIR Views and Actions No.73, Novebver 2024, Azuma, Shiraishi, “近年における国際共同治験の動向調査-2023年までの動向とアジア地域について-”

*:According to OPIR Views and Actions No. 72, July 2024, Yoshiura, Azuma, Morimoto, “国内未承認薬の最新動向ー2023年の日米新薬承認状況をふまえてー” in a determination made as of the end of December 2023, 67.5% of New Molecular Entities (NMEs) from the United States were unapproved medications in Japan.

The national government is aiming to expand its participation in global clinical trials

In the government's study panel, the directions for the solution of the drug lag/drug loss problem were presented and the outcome goals were set.

The number of global clinical trial plan notifications increased 1.5 times (2021: 100 ⇒ 2028: 150)



「創薬力の向上により国民に最新の医薬品を迅速に届けるための構想会議」
中間とりまとめを踏まえた政策目標と工程表（令和６年７月　内閣官房健康・医療戦略室）

中間とりまとめの3つの戦略目標と目指すべき成果目標

政府は中間とりまとめに掲げた**３つの戦略目標**について、関係府省が一丸となって、具体的な施策・事業を推進・実行し、下記の**成果目標（アウトカム）の実現を目指す**こととする。

（１）**「国民に最新の医薬品を速やかに届ける」**
- 現在生じているドラッグ・ロスの解消（我が国で当該疾患の既存薬がない薬剤等について2026年度までに開発に着手）
  ※　さらに、我が国において新たなドラッグ・ロスを可能な限り生じさせないよう、米国・欧州の状況をみつつ、官民協議会における議論・検討内容に基づいて、中期的なドラッグ・ロスの成果目標を設定する。
- 小児用医薬品の開発計画の策定件数（50件）、希少疾病用医薬品の承認件数（150件）（2024～2028年度累積）

（２）**「世界有数の創薬の地となる」**
（３）**「投資とイノベーションの循環的発展」**
- 我が国における国際共同治験の初回治験計画届件数（100件→150件）（2021年→2028年）
- 創薬スタートアップに対する民間投資額（２倍）（2023年→2028年）
- 企業価値100億円以上の創薬スタートアップを新たに10社以上輩出（2028年）　※2033年創薬ユニコーンを輩出
- 我が国の都市が世界有数（世界10位以内）の創薬エコシステムとして評価されている（2028年）

上記の目標を達成するため、各施策ごとに今後５年程度の**工程表**を策定するとともに、**アウトプット指標（KPI）**を設定し、**進捗状況をフォローアップ**することとする。また、工程表及びKPIについては、**成果目標（アウトカム）の達成状況や施策の進捗状況、創薬を巡る状況変化を踏まえ、適時、適切に見直す**こととする。フォローアップの実施に際しては、上記の成果目標の評価に加え、**有識者による総合評価を行う**。

Ministry of Health, Labour and Welfare, 36th Committee on Clinical Studies on September 4, 2024, Materials 4 "Future Directions for the Promotion of Clinical Studies and Clinical Trials," https://www.mhlw.go.jp/content/10808000/001298507.pdf (Date viewed: November 18, 2025)

Clinical Trials Transformation

Clinical Trial Transformation (CTX) is required in Japan as one of the means for Japan to remain “chosen for global clinical trials.”

- It has been pointed out that clinical trials in Japan are slow and high cost due to their low potential for case accumulation.*
- For that reason, transformation of the conventional format of clinical trials in Japan in order to increase the international competitiveness of Japan in clinical trials is required.
- CTX does not refer to a specific method; it is a broad concept which refers to new mechanisms for conducting clinical trials more efficiently and effectively.

CTX

Clinical Trials Transformation

- Decentralized Clinical Trial(DCT)
- Quality by Design(QbD)
- Fair Market Value(FMV)
- Real World Data(RWD)
- Sigle IRB
- others

* In the presentation materials of the 20th Conference on CRC and Clinical Trials 2020 in Nagasaki , a seminar jointly hosted by PHRMA/EFPIA JAPAN with the title “How to Avoid being Excluded from Global Trials: Cost Awareness will Revitalize Clinical Trials in Japan ,” it was stated that based on a comparison of the number of registered cases per number of facilities in each country and a comparison of the number of facilities required for the registration of 100 cases in each country, many facilities are necessary in order to obtain the necessary number of cases in Japan.

What the Japan CTX Research Society is aiming to achieve

The Mitsubishi Research Institute, Inc. established the Japan CTX Research Society on October 1, 2023 with the aim of advancing CTX and eliminating drug loss in Japan with the participation of multiple stakeholders.

Purpose

Enhancing participation in global clinical trials by transforming the clinical trial environment in Japan through multi-stakeholder engagement.

Vision

Contributing to the advancement of pharmaceutical development in Japan through policy recommendations and initiatives that support the dissemination of CTX.

Japan CTX Research Society

Mission

Advancing the efficiency of clinical trials through CTX, while enhancing participation in global clinical trials, to deliver new therapeutic options to patients more quickly on a world level.

The Composition of the Research Society

Japan CTX Research Society
(Mitsubishi Research Institute, Inc.)

Members				Observers	Secretariat
Leading companies (product manufacturers including pharmaceuticals/medical devices/regenerative medicine, etc.), startups (biotech/medtech)	CRO SMO	IT vendors	Medical institutions, healthcare professionals, academia	Government agencies, public institutions	Mitsubishi Research Institute, Inc.

Preparation of results (written recommendations, etc.)

Promotion of CTX in Japan

Prospects

In the First Period (October 2023 to September 2024) the society focused on decentralized clinical trials (DCTs) but in the Second Period (October 2024 to September 2025) we will expand the scope of discussion to promote CTX.

- In the First Period we focused on the recent topic of DCTs and generated concrete achievements.
- Going forward, we will gradually expand our research focus regarding the areas where we should promote CTX in line with the objectives of our society, taking into account our priorities and the need for this Research Society to handle them.

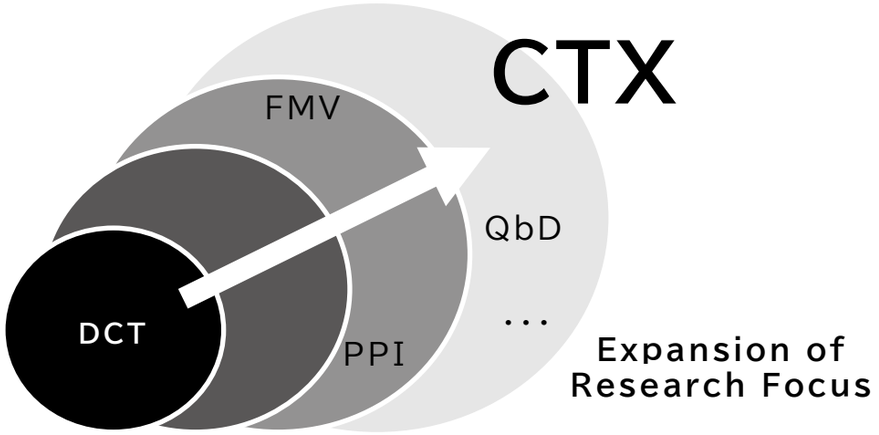
Issues in Japan's clinical trial environment

Transformation to make clinical trials more efficient and effective

Improving Japan's participation in global clinical trials

Providing new drugs to Japanese patients as early as possible

Discussion on Advancing CTX in Japan from the Perspectives of Industry, Government, Academia, and Patients



Content of the activities in the Second Period of the Japan CTX Research Society

The Japan CTX Research Society launched two sectional committees, commenced its Second Period activities in October 2023, and compiled its recommendations.

Sectional Committee ❶ **Identification and elimination of bottlenecks to clinical trial streamlining and acceleration**	● The purpose of this committee is to **consider "transformations necessary to accelerate clinical trials" from a large perspective which anticipates** not only DCTs **but also the appearance of new technologies**. ● Based on this purpose, the committee is aiming to clarify what Japan should do in order to continue participating in global clinical trials and to determine the next actions. ● Its activities include identifying bottlenecks to the streamlining and acceleration of all the processes in clinical trials in Japan, and presenting and communicating the solutions.
Sectional Committee ❷ **Environmental development of the soft aspects necessary for the implementation of DCTs**	● The purpose of this committee is to **organize the environmental development of the soft aspects (human resources, development of structures, etc.) necessary in medical institutions** for the implementation of DCTs. ● Based on this purpose, the committee is aiming to build an environment in which medical institutions can easily conduct DCTs. ● Its activities include presenting and communicating the division of roles, structures, etc. necessary for the skill sets and oversight required when introducing DCTs.

List of members in the Second Period

In the Second Period, 21 companies, five medical institutions (including universities), and 13 researchers from academia participated.

Companies/Startups

- Accelight Inc.
- A2 Healthcare Corporation
- Buzzreach Inc.
- CMIC Co., Ltd.
- Eli Lilly Japan K.K
- EPS Corporation
- Falma Co., Ltd.
- IQVIA Site Solutions Japan G.K
- Janssen Pharmaceutical K.K.
- Linical Co., Ltd.
- Medical Research Network Japan K.K
- MICIN.Inc.
- Mirai Iryo Research Center Inc.
- Nippon Boehringer Ingelheim Co., Ltd.
- NTT DATA Japan Corporation
- Pfizer R&D Japan G.K.
- SHIN NIPPON BIOMEDICAL LABORATORIES, LTD
- Sophiamedi Corp.
- Suvoda Japan
- TechDoctor, Inc.
- TEIJIN LIMITED

Medical institutions

- Aichi Cancer Center
- KINDAI University Hospital
- Nippon Medical School
- Okayama University Hospital
- Tokyo Center Clinic

Individual members

13 reserchers

Secretariat

- Mitsubishi Research Institute, Inc.

Release of written recommendations regarding the streamlining and acceleration of clinical trials and the social implementation of DCTs

In the second period, the results of the Research Society included the release of two written recommendations in September 2025.

- **Sectional Committee 1 ”Recommendations for the streamlining and acceleration of the clinical trial environment in Japan”**
  - The committee considered measures to realize the acceleration and streamlining of clinical trials based on the following three points.
    - Utilization of clinical data
    - Utilization of a clinical trial network
    - Enlightenment of/and information provision to the public, patients, and healthcare professionals concerning clinical trials
- **Sectional Committee 2 ”Recommendations for developing the clinical trial environment in order to promote the introduction of DCTs”**
  - The committee organized the roles and functions necessary in medical institutions in order to encourage the introduction of Decentralized Clinical Trials (DCTs) in medical institutions in Japan.

The four elements necessary for enhancement of the potential for case accumulation

The committee recommended necessary initiatives going forward regarding the four elements necessary for enhancement of the potential for case accumulation of Japan.

DCTs

- Reduce the need for hospital visits to reduce the burden of patients and increase the number of patients who can participate in clinical trials
- Reduce the number of implementing medical institutions through collaboration with partner medical institutions

Clinical data

- Utilize registries and RWD to efficiently formulate highly precise clinical trial plans and select facilities

Enhancement of the potential for case accumulation

Clinical trial networks (NWs)

- Recruit clinical trial participants nationwide through collaboration with partner medical institutions and patient referrals

Provision of information to the public and healthcare professionals

- Keep healthcare professionals informed about the DCT approach, etc. and also collaborate with medical institutions which do not conduct clinical trials
- Carry out information provision appropriately so that patients can consider clinical trials as an option

Why is the organization of ”functions and roles” necessary?

Both institutional design and role design tailored to the field are essential for the implementation of DCTs in medical institutions.

1 ”Mechanisms” alone are not enough for the implementation of DCTs

- It is necessary to clarify not only the institutions and mechanisms but also ”who” will do ”what” in the medical institutions.

2 Experience, structures, and issues differ in each medical institution, so clarification of division of roles and the responsibilities is necessary

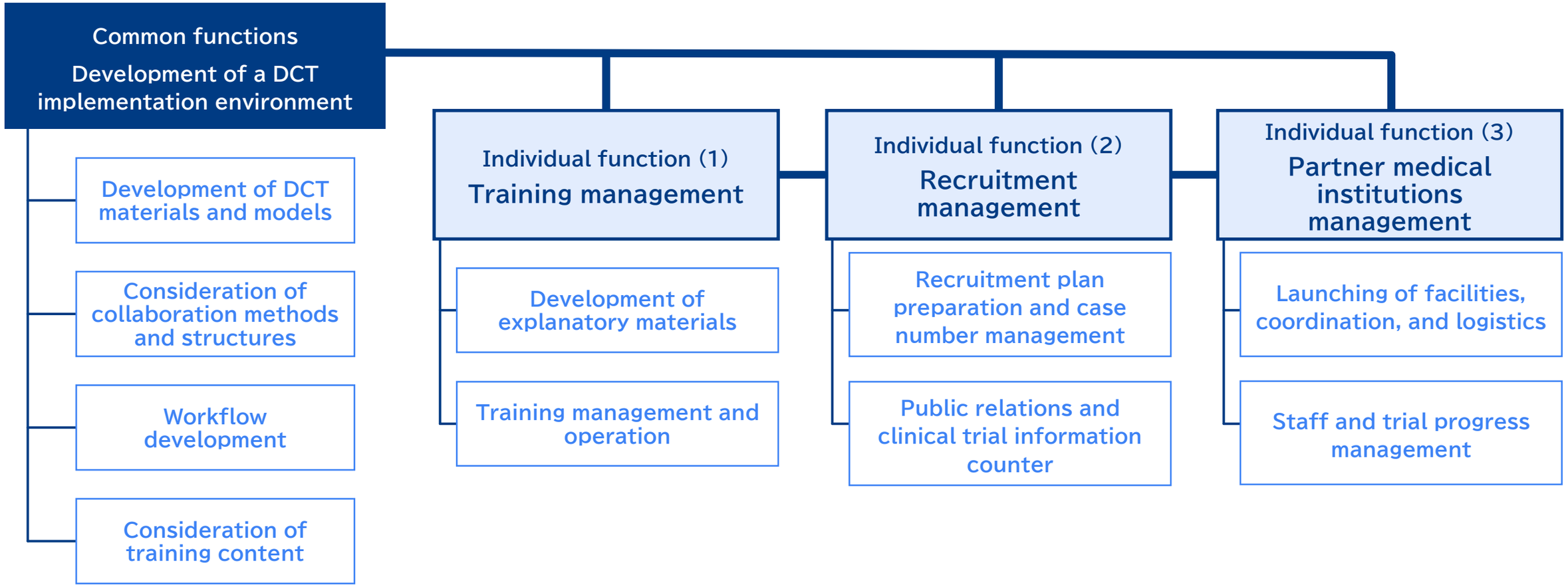
- Structures, etc. differ in each medical institution, so nationwide unified operations are not possible.

3 Design of ”who will do what” is important for the dissemination of partner medical institutions

- Involved parties such as partner medical institutions and in-home nurses will increase, so it is necessary to set up the ”progress management,” ”where the responsibilities lie,” ”cost burdens,” etc. in advance.

Roles and functions necessary for implementation of DCTs in medical institutions

[Common functions] that are common to all of the facilities/trials and [individual functions] that are tailored to individual facilities/trials are necessary for the introduction of DCTs in medical institutions.



Roles and functions necessary for implementation of DCTs in medical institutions

We organized the current issues, necessary items, To Do items, points to note, and nice to have items for the four functions.

Organization of the current issues and required matters for each function

03. DCTに必要な機能・役割の提言 ＞【共通機能】DCT環境整備

【共通機能】DCT実施環境の整備

DCTを新たに導入するために、医療機関において整備が必要な事項が多々あるが、先行事例が乏しくハードルが高い。そのため、第一歩としてDCT実施環境の整備が重要となる。

現状課題	●医療機関で新たにDCTを導入するために、院内スタッフおよびパートナー医療機関や訪問看護ステーション等の院外関係者のDCTへの理解が不可欠であるが、先行事例が少なく、ハードルが高い。 ●治験主管部署だけでなく、各診療科や事務担当部署、医療情報部等、院内全体の理解が不足しており、実施体制の構築が進まない。 ●他の院内業務も担う中で、試験実施体制の検討や全体管理、試験運用に関するリソースや時間が不足している。 ●パートナー医療機関を活用したDCTでは、安全性の高いデータ連携環境が求められるが、治験関連文書の連携はFAXや郵送などアナログな運用となっており、CRC等のスタッフの業務を圧迫している。
必要とされる機能	●DCTを導入するための第一歩として、**DCT実施環境を整備**することが重要である。 ●DCTで必要となる資料をゼロから作成することは負担が大きいため、統一化された**資料や雛形の整備**が、効率的かつ継続的なDCTの実施には求められる。 ●資料整備だけではなく、利用システムや連携窓口の確立等、サイトオウンドな**ワークフローの整備**が求められる。 ●院内および院外スタッフのDCTに対する理解醸成のため、DCT説明資料や**トレーニング内容の検討**が求められる。 ●パートナー医療機関や訪問看護ステーション等の活用を検討する際、**連携方法が整備**されていることでスムーズな体制構築が実現可能となる。

Organization of the actions and points to note necessary for implementation of the DCTs

03. DCTに必要な機能・役割の提言 ＞【共通機能】DCT環境整備

【共通機能】①DCT資料・雛形整備

DCT特有の文書を整備し、SOPや契約書の標準化・業務委託範囲の明確化を通じて、継続的かつ効率的なDCT運用を実施するための基盤整備を目指す

To Do		●通常の治験と異なり、DCTで新たに準備する必要がある資料を一覧化し、雛形を作成する。 （例：標準業務手順書（SOP）、業務委受託契約書（パートナー医療機関用、訪問看護用等）、フィージビリティ調査票、規定、IRB審査用書類、等） ●上記に加え、各資料の承認者（IRB審議資料、依頼者承認必要書類、医療機関で初認可能な資料、等）の整理・確認。 ●継続的かつ効率的にDCTを実施するため、各資料の雛形を整備。他の医療機関でも汎用可能な雛形となることがDCT普及において望ましい。
留意点		●医療機関ごとに異なるSOPが作成されると、運用も異なってしまうため、可能な限り施設間で共通したSOPが作られるとよい。 ●実施医療機関が全ての資料を作成するには多くのリソースが必要となるため、CROやDCTベンダーへの業務委託の可能性についても検討を視野に入れる。 ●DCTベンダーに各資料作成を委託する際は、院内SOPと齟齬が発生しないよう事前のすり合わせが必要である。 ●ICF共通テンプレートの活用を推進する動きがあり、業界全体で統一化を目指している点に留意する必要がある。
Nice to Have	業界全体	・ICF共通テンプレートのように、業界としてDCT資料を統一化する流れができるとよい。
	医療機関	・先進的にDCTに取組んでいる医療機関（例：愛知県がんセンター、国立がん研究センター、等）の資料を参考にできるとよい。
	依頼者	・-
	治験推進事業者	・試験スケジュールと各種資料整備進捗との調整や、各資料が依頼者の要件を満たすかの確認がなされるとよい。 ・訪問看護ベンダーは、必要となる資料を一覧化し、雛形を作成し医療機関に提供することで医療機関の負荷軽減に繋がる。

Clinical data

Development of structures enabling the efficient utilization of existing registries is necessary

Streamline the ascertaining of the number of medical institutions and patients by organizing and utilizing the information in the existing registries.

Issues
● Information from existing registries has not been consolidated. ● Overview information about registries, such as the data items and number of data items, has not been released. ● Data provision for and contracts, etc. takes time.

		The nature of registries in ascertaining the number of medical institutions and patients (utilization of existing registries)
Gathering	Completeness	• Higher is better.
	Data items	• Basic information (disease name, stage of progression, age, sex, medical institution name, etc.) is registered. *The medical institution name is required. • It is even better if additional data gathering in accordance with needs is possible.
	Quality	• Data updating and cleaning is carried out regularly. • It is not necessary to ensure data quality to the same extent as with approval application data.
	Consent, etc.	• **The medical institutions participating in the registries have agreed to provide information such as the names of the medical institutions and the number of patients per medical institution to third parties**. • The registries operate in accordance with Japanese laws, regulations, and ethical guidelines.
Provision	Cost	• Registries offer a reasonable price compared to existing services, including commercial services.
	Time	• **Data can be provided in accordance with the schedules of users**. (Example: simple patient count data can be provided in about one week)
	Provision structure	• Registries have structures (human resources) capable of smooth communication and data provision on schedule. • **Registries release information about completeness, data items, and available applications, etc**.

Measures for solution of the issues
● Improvement of the operational structure to reduce the workload of researchers and shorten the lead time for data provision ● Information sharing with registry owners and the industrial world about registry utilization results and examples ● Consideration of new registry utilization methods leading to more efficient clinical trials

Sharing cases pertaining to the construction of new registries and consideration of a sustainable operational model

Streamline clinical trial recruitment by constructing new registries that gather the information necessary for clinical trials.

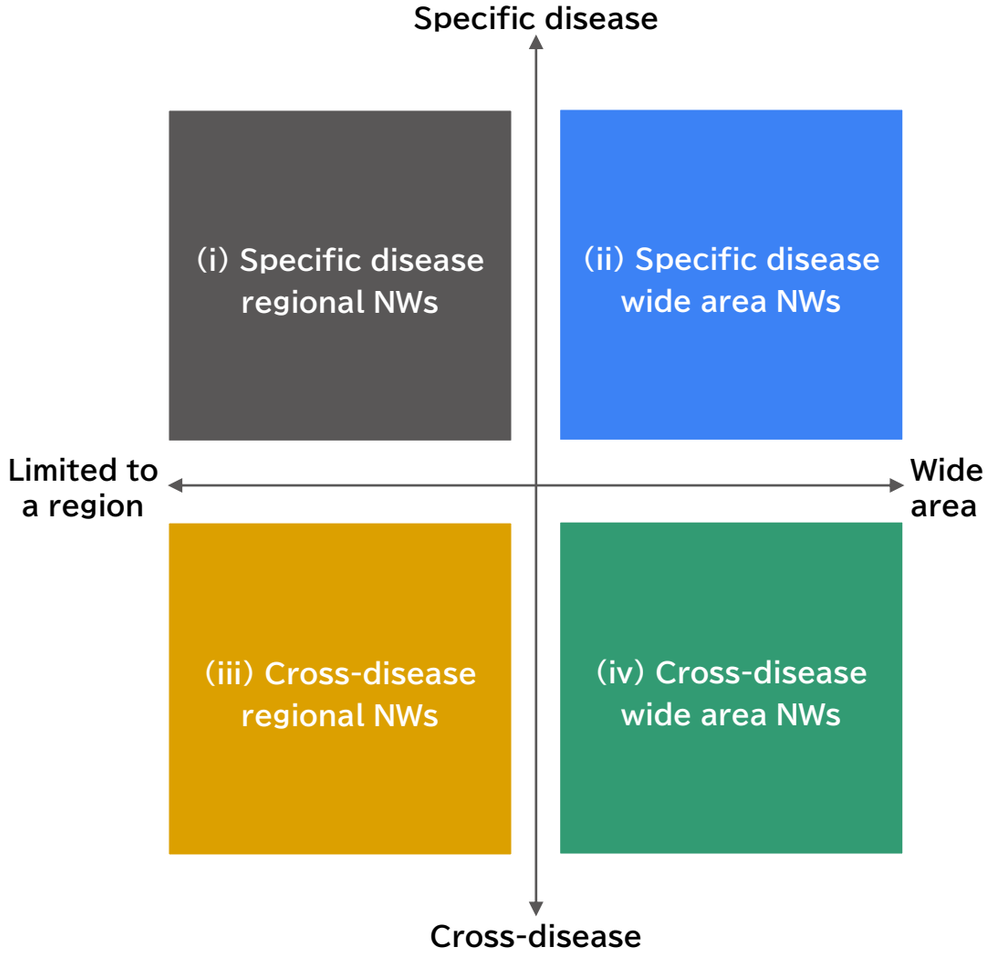
Issues	● It takes time from registry construction to data acquisition, which does not fit within clinical trial schedules. ● There is a lack of predictability regarding cost, the period required for preparation, risks, etc. ● Due to the lack of experience of both the clinical trial sponsors and academia, it is difficult to create registry specifications that suit the purpose of use. ● The data items do not have much versatility and cannot be diverted for other purposes.

		The nature of registries in patient recruitment (new registry construction)
Gathering	Completeness	• Higher is better.
	Data items	• Items that correspond to the Inclusion criteria and exclusion criteria for clinical trials have been registered. In particular, the items that require time for the recruitment of the patients. • It is better if measures to lower the data input burden, such as transcription from e-worksheets and electronic medical records, etc., have been taken.
	Quality	• Quality in accordance with the purpose of use has been guaranteed.
	Consent, etc.	• **Consent enabling data utilization by companies**, including clinical trial recruitment, **has been acquired**.
Provision	Cost	• Registries are at reasonable prices when compared with existing services, including commercial services.
	Time	• Registry construction and data acquisition **back calculated from the schedule for the conducting of clinical trials** are possible.
	Provision structure	• Even in academia, registries secure the resources necessary for coordinating with the schedule for the conducting of clinical trials. • Registries receive support from academia, etc., which have proven track records, regarding the lack of knowledge in the area of registry construction. • It is necessary to consider the future policies, including whether to maintain the registry after use for the initial purpose has ended.

Measures for solution of the issues	● Strengthen structures which can offer advice and support for matters of concern for the clinical trial sponsors and academia concerning registry construction. ● In the case that a registry is maintained after the end of its use for its initial purpose when it was constructed, it is necessary for the clinical trial sponsors and academia to consider in advance the nature of the cost burden and the methods of reducing the operational load, and to consider a sustainable registry operational model.

Types of clinical trials that have an affinity with the categories of clinical trial NWs

The types of clinical trials that are suitable differ depending on geographical scope and target diseases covered by the NW.



(i) **Specific disease regional NWs | Clinical trials of diseases which have specialist doctors in each region and are treated in municipal hospitals**
- NWs with a small geographical scope
- There are specialist medical institutions in each region (example: cancer)
- These networks start from ties between the doctors in the region

(ii) **Specific disease wide area NWs | Clinical trials of rare diseases for which highly specialized doctors recruit patients nationwide**
- NWs with a large geographical scope
  Examples: Pediatric Clinical Trials Network, MASTER KEY project
- These networks start from ties between specialist doctors such as research groups, etc.

(iii) **Cross-disease regional NWs | Clinical trials in which core medical institutions in each region serve as the implementing medical institutions**
- NWs with a small geographical scope
  Example: Council for Medical Alliance, Okayama
- These networks start from ties between medical institutions within a region based on hospital-hospital collaboration and hospital-clinic collaboration

(iv) **Cross-disease wide area NWs | Clinical trials for which large-scale patient recruitment is necessary**
- NWs with a large geographical scope
  Examples: hospital groups, National Hospital Organization clinical trial network
- These networks start from management ties between medical institutions
- These networks are able to handle in bulk those clinical trials for which a particularly large number of patients are necessary, such as vaccine trials

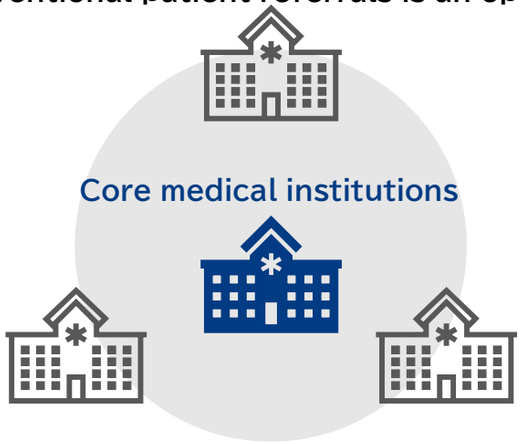
Enhancement of the potential for case accumulation through construction of clinical trial NWs, including the utilization of DCTs, etc.

NWs are required that enable patients nationwide to consider clinical trials through collaboration among diverse medical institutions.

(i) Specific disease regional NWs / (iii) Cross-disease regional NWs

- Regional hospitals are participating, medical institutions with no experience of clinical trials are also anticipated, and not all of the NWs are compatible with the operations of the partner medical institutions.
- These are NWs inside prefectures, and they have a comparatively narrow geographical scope.

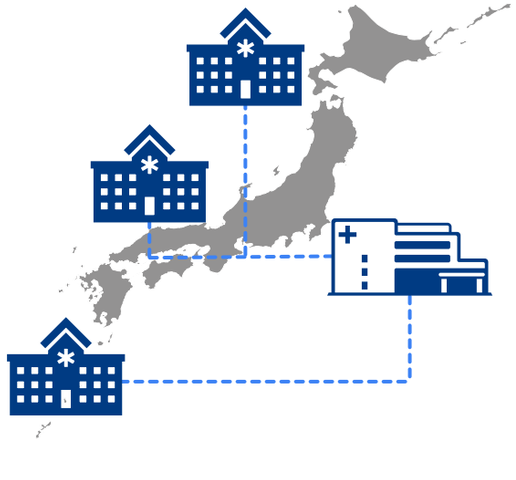
Clinical trial participation not only through partner medical institutions but also through conventional patient referrals is an option



(ii) Specific disease wide area NWs

- These NWs collect cases of rare diseases from several implementing medical institutions nationwide.
- They have a large geographical scope, so hospital visits impose a large burden on patients.

These NWs utilize partner medical institutions to reduce the burden of hospital visits, etc.



(iv) Cross-disease wide area NWs

- These NWs coordinate the medical institutions participating in the clinical trials and the implementing medical institutions, in accordance with the necessary number of cases and the characteristics of the clinical trials.

Construction of efficient structures for each clinical trial (number of partner medical institutions, implementing medical institutions, etc.)

Construction of clinical trial NWs leading to enhancement of the potential for case accumulation

Utilize existing clinical trial NWs and ties between medical institutions and doctors. Consider centralization of information and procedures and medical institution burden reduction and incentives.

Issues	• Previous clinical trial NWs had limited effects on ”enhancement of the potential for case accumulation” and ”streamlining of clinical trial procedures.”

	Nature of a clinical trial NW
Scope of the NW	• Set the scope of the NW and the diseases covered by the NW in accordance with the characteristics of the ”ties” between doctors and medical institutions. • Collaboration by multiple NWs to accumulate cases in a small number of medical institutions over a broader scope is anticipated.
Partner medical institutions	• The introduction of partner medical institutions may not be required, depending on the clinical trial experience of the medical institution and geographical factors. The referral of patients for clinical trials could also become a tool for the accumulation of patients in NWs. • It is desirable that medical institutions without any clinical trial experience be also able to participate in clinical trial NWs and that cases can be accumulated from more medical institutions.
Functions necessary for the NW	• Through the centralization of procedures, including Single IRB, and information sharing, the NWs function like one medical institution (a mega-hospital). • NWs do not have many functions; rather they flexibly respond in accordance with the needs of diverse clinical trial operations by collaborating with external parties. (Pharmacies, in-home nurses, IT services, etc.)

Measures for solution of the issues	● Share perceptions of the sense of crisis with respect to drug lag/loss and the importance of enhancement of the potential for case accumulation within the ”ties” between doctors and medical institutions which form the basis of the NW. ● Establish incentives for patient referrals and participation in clinical trials by partner medical institutions. ● Reduce the burden of introduction by sharing among medical institutions previous examples of Single IRB and the centralization of contract procedures. ● Create and release a common format concerning the structures and track records of medical institutions so that it becomes easier for clinical trial sponsors to investigate the characteristics and track record of each clinical trial NW.

Information provision to people who have not been exposed to clinical trial information

Collaboration between the people involved in clinical trials and a wide range of medical institutions nationwide is essential for the provision of clinical trial information to patients and their families.

- It is necessary to inform a wide range of healthcare professionals about the current status of pharmaceutical development and initiatives for new clinical trials, to build momentum for accumulating cases nationwide

The information provision route that patients and their families can trust is the ”primary doctor.”

primary doctor

Provision of clinical trial information to patients and their families

patient

Clinical trial participation becomes an option through exposure to clinical trial information

From discussions in the clinical trials industry to discussions in the healthcare industry

primary doctor with no clinical trial participation experience

- Understanding the current situation of drug lag/drug loss
- Understanding the significance of clinical trials
- Knowledge concerning new clinical trial initiatives, including DCTs, etc.
- Human ties with implementing medical institutions

Discussions are also held at academic conferences on medical information and academic conferences in each profession, etc., and information and issues regarding clinical trials are shared throughout the healthcare industry.

Promotion of cross-industry, long-term enlightenment activities for groups that information is not reaching

An approach for delivering information that is not currently being delivered, in accordance with the enlightenment targets, is required.

Issue	• With regards to enlightenment activities concerning current clinical trials, the information is not reaching members of the general public who have no interest in clinical trials or healthcare professionals who are not participating in clinical trials.

	Desirable enlightenment/nature of information provision
Indifferent patients and their families	• Information concerning clinical trials is reliably provided to patients and their families by providing information to and collaborating with primary-care physicians • At the same time, enlightenment/information provision to primary-care physicians is encouraged
Indifferent non-healthcare professionals who are not patients or families	• There are opportunities, such as school education, etc., to provide information regardless of whether the individual is interested or not • The content provided becomes more sophisticated by age, so by the time individuals enter the workforce, they will be able to gather information concerning clinical trials themselves (i.e., they will be able to use clinical trial information to make decisions if they become ill themselves) • Even without individuals having to search for it themselves, the relevant information will be in public view at nearby facilities, etc., and the information will be updated even after the individuals enter the workforce
Healthcare professionals with no/little clinical trial participation	• The current status of clinical trials is broadly known and discussed among all healthcare professionals, not only people involved in clinical trials • The sense of crisis concerning drug loss and the necessity of enhancing case accumulation are shared regardless of participation in clinical trials • The option of clinical trial participation can be presented to patients at any medical institution nationwide

Measures for solution of the issues	● Consider ”who will be responsible” for the enlightenment and the ”realization methods” for information provision in school education and other education settings, and then devise concrete methods of realization. ● Because enlightenment activities are a non-competitive domain, create initiatives to collaborate across companies and organizations in order to appeal to the entire public. ● Consider methods which enable continuous and long-term utilization by the industry overall of the content, etc. created by a variety of entities to date. ● Collaborate with academic conferences which are not focused on clinical trials, and hold joint industry, government, and academia symposiums, and other events on clinical trials.

Japan Clinical Trial Transformation Research Society

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