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EHR/ EMR Trends and Future Prospects for eSource Linkage in Clinical Trials



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1. Background

Challenges in New Drug Development

The spread of the new coronavirus had led to awareness that a speed-up in new drug development is essential and we are hearing more and more about the difficulties involved. Development of a new drug involves a lengthy process of research, clinical trials, and efficacy and safety evaluations which can take up to 10 years or more.

Furthermore, although many new drugs have been developed to date, intractable and rare diseases remain “unmet medical needs” with no effective treatment available. Designing a new drug development process to address these “unmet medical needs” is becoming increasingly complex and diversified, leading to lower success rates.

- »» 20 to 30 billion yen for clinical trials
- »» Drug development takes more than 10 years
- »» Success rates lower year by year, and the level of difficulty increases (10 years ago: 1/13,000 and currently: 1/25,000)
- »» R&D expenditures per company are on a constant rise 62.1 billion yen (2004) → 141.4 billion yen (2017)*1

In this business environment, soaring new drug development costs and ensuring data quality have become significant issues for the industry as a whole. Here at NTT DATA we believe there is an urgent need to apply “Digital Transformation” to save labor and improve data reliability in clinical trials.

eSource Data Linkage is Essential for “Digital Transformation”

There has been a recent growing interest in Decentralized Clinical Trials (DCT) or namely clinical trials not relying on visits to medical institutions, as a means for saving time and labor in clinical trial operations. As DCT becomes more widespread, patients can be recruited with less effort and development costs can be reduced.

On the other hand, there are significant challenges in achieving DCT. The fact that the field of clinical trials is not tied to a specific medical institution

means that the sources and locations of case data collection are diverse and widespread. To collect that data as information that can be used for new drug development, we need to collect, structuralize, and link the data electronically.

Establishing “eSource Data Linkage,” as a means to link this case data electronically will prove essential for future digital transformation of clinical studies and clinical trials.

Types of eSource Data Linkage

Well then, what actually is **eSource**, that forms the basis for this Digital Transformation effort? The term **eSource** generally refers to “electronically recorded source data” and the “mechanisms for linking them together”. It includes for example, patient medical information recorded in electronic medical records and a mechanism to link directly to EDC or namely Electronic Data Capture.

In this section, let’s take a more detailed look at the different eSource types. The TransCelerate eSource Initiative classifies eSources into four different types.*2

- **EHR/ EMR**

The current shift to electronic medical records, means that medical information on examinees is increasingly being recorded as Electronic Medical or Electronic Health records. EHR/ EMR is a system that electronically links this medical information to the clinical trial database.

- **Devices & Apps**

Devices & Apps is a system allowing patients to self-assess their own symptoms, physical condition, and quality of life and record all this data using devices such as smartphones and tablets. The ePRO or electronic patient-reported outcome app is one example of how this mobile data collection and reporting works.

- **Non-CRFs**

Data that is collected without being entered into a case report form (CRF) is called Non-CRF and includes imaging data (MRI, CT scans, etc.) and laboratory data (blood tests, urinalysis, etc.). Non-CRF linkage is a system to electronically link all this data into the clinical trial database.

1. Japan Pharmaceutical Manufacturers Association Guide (2010-2017)

2. “eSource”, TransCelerate, <https://www.transceleratebiopharmainc.com/initiatives/esource/>, 28 April 2023.

- **Direct Data Capture (DDC)**

This system allows data collected from patients to be directly entered into mobile applications or via EDC as clinical data by the healthcare facility staff.

Potential for EHR/ EMR linkage

When considering the growth and development of eSource data linkage, we believe that eSource linkage of EHR/ EMRs is essential in cases where accumulating large quantities of data. Suppose for example that this information could be electronically linked to EDC to create a CRF (Clinical Report Form).

This linkage would in that case save vast amounts of labor in clinical studies and clinical trial operations and help to greatly improve data reliability.

The need for EHR/ EMR linkage will increase in particular in oncology clinical trials. Since clinical information on cancer patients also simultaneously serves as medical treatment information, it should be managed as data integrated into EHR/ EMR. These eSources accumulated in EHR/ EMRs therefore have great potential for use in clinical studies and clinical trial operations.



2. Research and Development Status

R&D Status in the World

To what extent are EHR/ EMR linkage solutions being investigated, developed, and applied? First, let's look at the real world.

The United States was likely the first country to turn its attention to this field. In 2018, the FDA issued guidelines on using EHR data as source data in clinical research (Use of Electronic Health Record Data in Clinical Investigations) well ahead of other countries.

Besides developing guidelines, another feature of EHR/ EMR linkage in the United States is that the government provides backing for its study and application. Examples of this include the government-funded Boston Children's Hospital Computational Health Informatics Program and the Harvard Medical School Department for Biomedical Informatics announced SMART which is an open technology platform that facilitates EHR and EDC linkage. This platform will promote interoperability and create a linkage solution between EHR and EDC.*3

Development of EHR/ EMR solutions based on collaboration with public agencies is making progress

as seen by the OneSource project, a partnership between the University of California, San Francisco; and the FDA, which has demonstrated approaches for sending structured data to electronic data capture (EDC) systems for clinical trials.*4

Turning to Europe, EIT Health, a community of the European Organization for Innovation and Technology (EIT), has established the EHR2EDC consortium to promote research in this area.

The consortium has selected University College London Hospitals NHS Foundation Trust, IgniteData, and AstraZeneca as vendors to conduct demonstrations of EHR and EDC linkage.*5

In 2021, these companies succeeded in running EHR and EDC linkage in a test environment and announced plans to automate data transfer to AstraZeneca's EDC for oncology research. This verification study will soon be providing its final results since the research study will be completed by the end of January 2023.*6

Research on EHR/ EMR linkage is therefore making rapid strides in Western countries backed up by public organizations aiming to establish guidelines and hold demonstration experiments.

Company Name	Overview of EHR/ EMR Solution
Oracle Corporation	The centralization of medication information and patient data from various sources including EHRs.
PAREXEL International Corporation	They work to consolidate information from various sources, including EHRs, data gathered during the daily care process, and mapping EHR data to EDC data, to ensure the success of the RWD study.
Medidata Solution, Inc.	In-house EDC system; announced plans regarding Rave Companion (patent pending) in which structured and unstructured EHR data would be sent to Rave EDC.
ICON	Possesses interoperability among systems, including EHR, EDC, and IRT.
OpenClinica	Automates data capture from EHR to EDC and eCRF. Supports laboratory data, drug information, and patient attributes. They are supported by major EHR vendors.
REDCap	Provides a module for real-time transfer of structured EHR data to REDCap. Works basically in the same fashion as Epic, Cerner, and other FHIR-compliant EHRs. The "App Orchard" from Epic allows linkage without creating an FHIR app if using Epic.

Figure 1
EHR/ EMR Solutions

3. "EHRs and EDCs", The TRIBune, <https://www.tech-res.com/TRIbune/spring-2019/TRITribune-spring2019-Article1.html>, 28 April 2023.

4. "Source Data Capture from EHRs: Using Standardized Clinical Research Data", U.S. Food & Drug Administration, <https://www.fda.gov/media/132130/download>, 28 April 2023.

5. "University College London Hospitals Collaborate with AstraZeneca and IgniteData to Test SMART ON FHIR Based Tech", Applied Clinical Trials, <https://www.appliedclinicaltrialsonline.com/view/university-college-london-hospitals-collaborate-with-astrazeneca-and-ignitedata-to-test-smart-on-fhir-based-tech>, 28 April 2023.

6. "Advances in Source Interoperability Between EHR and EDC", Applied Clinical Trials, <https://www.appliedclinicaltrialsonline.com/view/advances-in-source-interoperability-between-ehr-and-edc>, 28 April 2023.

Global Spread of Solutions

EHR/ EMR linkage solutions are being deployed, mainly by US companies with this R&D serving as a foundation. The players range from global CROs to clinical trial software companies, and solutions have been announced that are designed to work with their own EDC systems as well as those intended for general-purpose linkage.*7

However, we seldom find that these solutions have been put to practical use. The general market view is that EHR/ EMR linkage is still only in the research and development stage. According to results from our own interviews with experts, it is difficult to claim that use of EHR/ EMR linkage solutions is widespread even in Western countries, and we believe a substantial amount of time will be needed for these to take root as a standard system.

Spread of Solutions in Japan

Survey results targeting the Japanese market also show in the same way that few companies have yet to implement EHR/ EMR linkages. Moreover, very few companies and medical institutions plan to adopt such a system.

These facts of course indicate a low penetration rate compared to other linkage methods. For example, 50% of the surveyed companies have adopted Devices & Apps (ePRO/eCOA), yet only one out of 50 pharmaceutical companies and one out of 13 CROs have adopted use EHR/ EMR.

In our interview survey of experts (medical institutions/ pharmaceutical companies/CROs), we confirmed that DDC solutions have been adopted, but we also received several comments stating that EHR/ EMR linkage is still in the experimental stage and that there are only limited examples of its use.

	Usage status by CRO	Usage status by pharmaceutical companies	Usage status by medical Institution
(1) EHR/ EMR	Among 13 companies Actual usage: 1 company No plans: 9 companies	Among 50 companies Actual usage: 1 company No plans: 39 companies	Among 76 cases Actual usage: 1 case No plans/not sure: 74 cases
(2) Devices & Apps	Among 65 companies Experience in actual usage ePRO/eCOA: 33 companies Experience in usage of wearable devices: 13 companies		-
(3) Non-CRF	Among 65 companies Diagnostic imaging at a non-clinical research facility: 12 companies Clinical laboratory test at a non-clinical research facility: 3 companies		-
(4) DDC	Among 13 companies Actual usage: 6 companies No plans: 5 companies	Among 50 companies Actual usage: 9 companies No plans: 33 companies	Among 76 cases Actual usage: 5 cases No plans/not sure: 69 cases
	Among 65 companies Experience in actual usage of DDC: 10 companies		

Figure 2
Diffusion of eSource Collaboration in Japan by eSource Linkage Classification*8

7. "Oracle Unveils Clinical One Data Collection Cloud Service", Oracle, <https://www.oracle.com/corporate/pressrelease/clinical-one-data-collection-cloud-service-061820.html>, 28 April 2023.
 "Getting real-world data into clinical research", parexel, https://www.parexel.com/application/files/9516/0978/6172/WW8_Value_of_RealWorld_Data_Whitepaper.pdf, 28 April 2023.
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 "ICONDigitalPlatfor", ICON, <https://www.iconplc.com/innovation/icon-digital-platform/>, 28 April 2023. "OpenClinicaUnite™", OpenClinica, <https://www.openclinica.com/solutions/unite-ehr-esource/>, 28 April 2023.
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 "CLINICAL DATA INTEROPERABILITY SERVICES (CDIS)", REDCap, <https://projectredcap.org/software/cdis/>, 28 April 2023.

8. JAPMA "Current Status and Issues of DDC/EHR Data Linkage", "Data Flow in DCT and Ensuring its Reliability" "Toward the Widespread Use of ePRO"

3. Driving Factors and Challenges

Factors Facilitating EHR/ EMR Linkage and Challenges

While there are variations in the level of research, development, and dissemination from country to country, EHR/ EMR linkage has still not yet been firmly established on a global level. So, what elements are

needed to promote EHR/ EMR linkage, which has been less accepted than other eSource linkage methods?

This chapter will look closely at the factors that facilitate EHR/ EMR linkage and their challenges.

We believe that four elements as shown here are necessary to facilitate EHR/ EMR linkage.

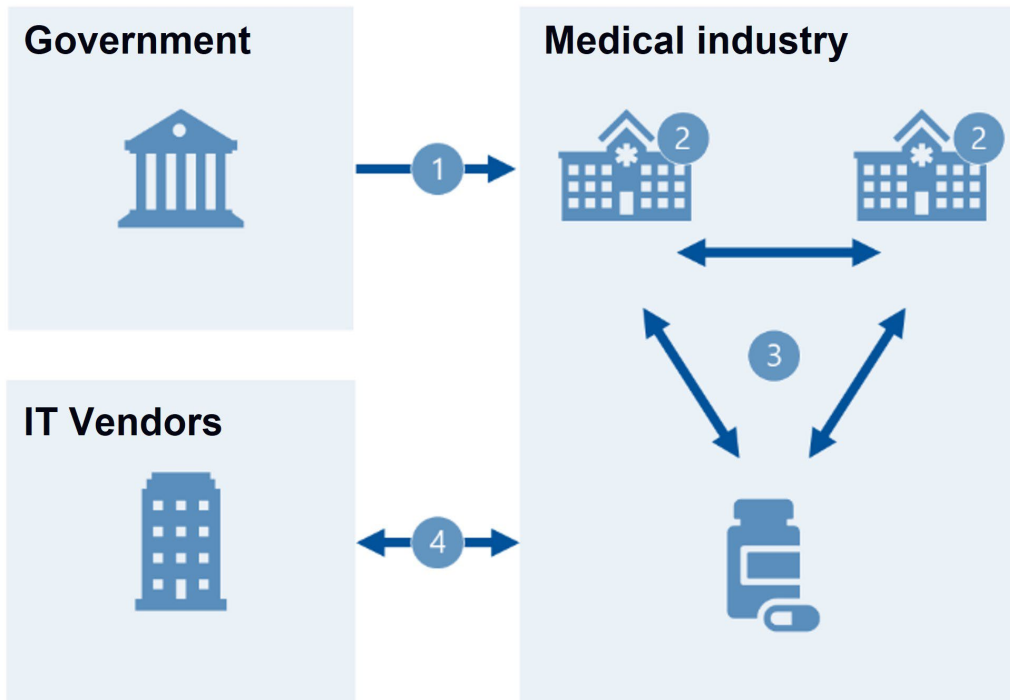


Figure 3
Factors Facilitating EHR/ EMR Linkage

(1)	Development of regulations and guidelines	Clear regulations and guidelines for use of EHR/ EMR for clinical trials to be established by regulatory authorities.
(2)	Improvement of the quality of EHR/ EMR information	The information recorded in the EHR/ EMR at each medical institution should be on a level that can be used in clinical trials.
(3)	Ensuring data interoperability	Unification of communication standards and data description methods for mutual distribution of EHR/ EMR data.
4)	Arousing motivation to implement solutions	To ensure that pharmaceutical companies and medical institutions become aware of the benefits from implementing IT vendor solutions.

Development of regulations and guidelines

There is an urgent need for regulatory authorities to develop regulations and guidelines on utilizing EHR/EMR information.

The following guidelines are already in place in the United States where there are many prior examples

the solutions must comply with each country's regulations.

On the other hand, the implementation of the Clinical Trials Regulation (CTR) for clinical study applications may in general lead to standardizing of regulations over the next few years, making it easier to develop solutions valid across multiple countries.

Legal/ Guideline Name	Year of issue	Issuing authority	Summary
Use of Electronic Health Record Data in Clinical Investigations	2018	FDA	Document clarifying the FDA's expectations for the use of EHR systems as source data in clinical research. Provides recommended system requirements, etc.
Electronic Source Data in Clinical Investigations	2013	FDA	Recommendations for the electronic acquisition of source data to be entered into the eCRF to help ensure the reliability, quality, integrity, and traceability of the data.
21 CFR Part 11	1997	FDA	A set of requirements to improve the reliability of electronic records and electronic signatures in the pharmaceutical industry that is rapidly transforming into an electronic environment.
The Health Insurance Portability and Accountability Act (HIPAA)	1996	HHS	Establishes regulation and individual rights when handling personal electronic data to improve efficiency in the healthcare industry, improve health insurance, protect the privacy of patients and insurance subscribers, and ensure the safety of health information.
Health Information Technology for Economic and Clinical Health Act (HITECH)	2009	HHS	Expanded HIPPA law with enhanced coverage and penalties. Hospital EHR adoption rates that were once around 10%, have increased to around 80% due to the financial incentives and penalties provided by this law. On the other hand, while there were more than 1,000 EHR vendors more than a decade ago, that number has currently decreased to 400.

Figure 4
Regulatory Trends in the U.S.

Name of Law/ Guidance	Year of issue	Issuing authority	Summary
Good Manufacturing Practice (GMP) Annex 11	1992	EU	This document presents the minimum standards that the systems used by drug manufacturers in their manufacturing processes must comply with due to the increasing usage and complexity of computer systems.
General Data Protection Regulation (GDPR)	2016	EU	This stipulates regulations on data privacy and security to maintain the rights of individuals under the European Convention on Human Rights even under the widespread use of the Internet.
eSource Direct Data Capture (DDC) qualification opinion	2019	EMA	Recommendations for obtaining clinical trial data by DDC. ➤ This specifies that eSource DDC systems and applications must be customized, validated, tested for user acceptability, kept secure, and maintained in accordance with local legal requirements and the ICH GCP.
Guideline on computerized systems and electronic data in clinical trials	*Drafted in 2021	EMA	Draft guidelines covering computerized systems (including equipment, software, and services) in the creation/retrieval of electronic data used in clinical trials including DDC.

Figure 5
Regulatory Trends in the Europe

of EHR/ EMR linkage. The above mentioned "Use of Electronic Health Record Data in Clinical Investigations" in particular provides guidelines on establishing and supplying EHR/ EMR linkage services.

When looking at Europe, the development of eSource-related guidelines by the authorities seems to lag behind progress made in the United States. Currently, finding new solutions poses a real challenge because

Clinical Trial Regulations

- »» Standardization of processes for evaluating and supervising clinical trials throughout the EU.
- »» Instead of having to submit individual clinical trial applications to governmental authorities and Ethics Committees (EC) in each country for obtaining regulatory approval to conduct a

clinical trial; in the coming years, sponsors will be able to apply for EU and European Economic Area (EEA) authorization in up to 30 countries with just a single application.

The development of regulations and guidelines is a significant factor in promoting EHR/ EMR linkage, and delays in developing these regulations and guidelines have hindered its widespread adoption.

With Western countries in the vanguard, these regulatory reforms will likely make steady progress from here onwards.

Improvement in the quality of EHR/ EMR information

With the establishment of regulations and guidelines, the next issue is the quality of information stored in electronic medical records.

Here we turn our attention to Japan. The low quality of electronic medical record information in Japan is one of the significant challenges it faces. In particular, the fact that items required for clinical trials are not always recorded in the electronic medical records is a significant problem. According to a study conducted by Kyoto University Hospital, the disease names listed in the electronic medical records do not always accurately reflect the patient’s actual condition and under the current circumstances such data is not at a level where it can be validly used in clinical trials.

Does this mean that the quality of descriptions is being maintained in electronic medical records in Western countries? What is worth noting here is the differences

among national systems regarding incentive payments for good medical treatment results.

In countries that have adopted a Pay for Performance system (“P4P system”), where physicians are rewarded for treatment results, there is an incentive for physicians to record information correctly. During such tasks, the information required for clinical trials is in most cases accurately entered into the electronic medical record.

In the United States, P4P systems include Hospital Quality Incentive Demonstrations (HQID) and those incentives defined by each state and insurance company.

In the United Kingdom, the P4P system has been initiated for general practitioners (GPs). Under this system, the general opinion is that GPs are required to submit accurate medical records which suggests that the P4P system has contributed to a certain level of improvement in electronic medical record quality.

Ensuring data interoperability

Even if the information necessary for a clinical trial is comprehensively recorded in the electronic medical records, the value of EHR/ EMR linkage will never be fully attained unless its interoperability is ensured. We therefore believe that both “standardization of data communication rules” and “standardization of data description methods” are essential for ensuring interoperability.

There is a movement toward international standards to unify data communication standards.

	Adoption of HL7 FHIR	Public API Development	Participation in global projects on interoperability	Availability of laws and regulations regarding the adoption of the following			Incentives and penalties to ensure interoperability with national systems
				Terminology standard	Specific telegram message	Interoperability with national systems	
Costa Rica	None	None	No participation	Yes			None
Hungary	None	Yes	EU Projects	Yes			Penalties are applicable
Japan	Under consideration	None	IHE, GDHP	Available in disease code and test master			Need to comply in obtaining reimbursement points
Portugal	None	Yes	IHE, GDHP, EU projects	None	Yes	None	None
Slovenia	None	None	EU Projects	Yes			No report
Switzerland	Under consideration	None	IHE, GDHP	Yes			Yes
Turkey	No	Yes	IHE	Yes			Yes
USA	HL7 CDA is adopted	None	IHE, GDHP	Not applicable			Incentive programs available
Australia	Yes	Yes	GDHP	None			Incentive programs available
Canada	Yes	Yes	GDHP	No report			None
United Kingdom	Yes	Yes	IHE, GDHP	Yes			Develop and enforce certification standards when procuring EHRs
China	None	-	IHE	-	-	None	-

Figure 6
Standardization Trends in Each Country

The international standard HL7 FHIR for example, has attracted attention for its ability to standardize the linking of medical data on the Web.

In the United States and United Kingdom where EHR/EMR collaboration is relatively advanced, HL7 FHIR utilization is promoted by developing FHIR-compliant APIs in government-run information systems and deploying implementation guides and sandbox environments.⁹ These developments will contribute to forming the groundwork for linking of EHR/EMR.

Furthermore, to ensure data interoperability, it is necessary to unify the code values of disease and surgery names and also unify the description methods for numerical data such as vital signs. Making these description rules more uniform and standardized will contribute to the greater spread of EHR/EMR linkage. As mentioned earlier, the standardizing of these rules is relatively advanced in countries such as the United States which has in fact adopted the P4P system.

Can we therefore assume that EHR/EMR linkage will make greater strides and become widespread once standardized and uniform description rules are in place? We believe there is another major barrier to deal with. That barrier is the existence of “unstructured data” in medical records.

Information such as adverse events for instance is currently entered into records as free text and will likely continue to be managed as unstructured data.

Adverse event information is critical in clinical trials, so if this information cannot be obtained in a structured manner, then the true value of eSource collaboration

will never be achieved. This is one reason why EHR/EMR linkage has still not become widespread.

Arousing motivation to implement solutions

In countries where the use of EHR/EMR linkage solutions is relatively advanced such as the United States, solutions are currently being adopted in the form of investments in medical institutions by pharmaceutical companies. Therefore, arousing motivation to implement solutions will also prove an essential element in development of the market.

How can we increase the motivation for such investments?

A solution that is only a good fit for just one EHR/EMR vendor will fail to arouse investment motivation among pharmaceutical companies. This is because each medical institution would need to implement a different solution so the costs would outweigh the benefits.

In recent years, the number of sites for each Phase 1 study has also been increasing in the oncology field.

In Japan and the United States, the number of cases per site is small compared to other countries, so clinical trials must be conducted at multiple sites in order to collect a sufficient number of cases.

To respond to this situation, developing EHR/EMR solutions that provide multi-site applicability will prove one key to a successful outcome. IT vendors therefore need to understand the requirements of this market before developing EHR/EMR linkage solutions.

	Japan	USA	Europe
Injury/ disease name	Mixed codes and notations Different masters have different code systems for the same disease, and the names of injuries and diseases are inconsistent.	Domestic standards available There is ICD-10-PCS based on ICD-10 created by WHO	Varies by country Variations in standards adopted from country to country including Germany's own ICD-10-GM
Pharmaceutical product	Mixed code More than 10 types of drug codes exist for different purposes including YJ codes to identify products and JAN codes to identify providers.	Domestic standards available There is a National Drug Code defined by the FDA. Submission of information to the FDA is required for the sale of drugs in the U.S.	EU mandates the use of international standards ISO-IDMP, an international standard, is mandatory for EU member states and companies that conduct business in the EU.
Medical practice; examinations, surgeries, procedures	Mixed code The receipt system and electronic medical record master have different code systems.	Domestic standards available HL7 recommended standard LOINC for laboratory identification and SNOMED-CT for non-numeric laboratory information.	Varies by country Variation from country to country, e.g., SNOMED-CT, is used in the UK and the Netherlands.

Figure 7
Standardization Trends of Medical Codes^{*10}

9. “HL7 FHIR Research Study Package Final Report”, Fujitsu Research Institute, <https://www.mhlw.go.jp/content/12600000/000708279.pdf>, 28 April 2023.

10. Medical Fee Information Service, “Standardization of Medical Terminology and Codes”, March 2023, European Medicines Agency HP “Data on medicines (ISO IDMP standards): Overview”, March 2023, Centers for Medicare & Medicaid Services “ICD-10 and CMS eHealth: What’s the Connection?” 2013.7, U.S. Food & Drug Administration HP “National Drug Code Directory”, March 2023, Federal Institute for Drugs and Medical Devices HP “ICD-10-GM”, March 2023

4. Towards Advancement

Toward Promoting EHR/ EMR Linkage

So far, we have seen that four elements promote EHR/ EMR linkage: (1) developing regulations and guidelines, (2) improving the quality of EHR/ EMR information, (3) ensuring data interoperability, and (4) arousing motivation to implement solutions.

It has also been mentioned that barriers to element (3) ensuring data interoperability include handling “unstructured data”, and barriers to element (4) arousing motivation require finding solutions that provide multi-site applicability, so at this stage we must await development of solutions.

Finally, for future perspectives on promoting further EHR/ EMR linkage, let’s take a look at the visible signs of solutions to these challenges.

Toward handling unstructured data

There is a growing focus on applying AI-based data structuring techniques to handling “unstructured data.”

Here at NTT DATA, we are also researching and developing a function by which AI handles navigation tasks from the input stage so that information entered by physicians in free text is registered as structured data.

Suppose we could achieve the first such system. In that case, we believe we could then make it possible for physicians to obtain sufficient data for clinical trials without even being consciously aware of any differences while administering regular medical treatment.

As further progress in DCT is made and various facilities participate in clinical trials in the future, these functions will become even more vital.

Toward the development of solutions with multi-site applicability

Finally, we are pleased to introduce PhambieLINQ, a comprehensive clinical trial platform that we currently have under development.

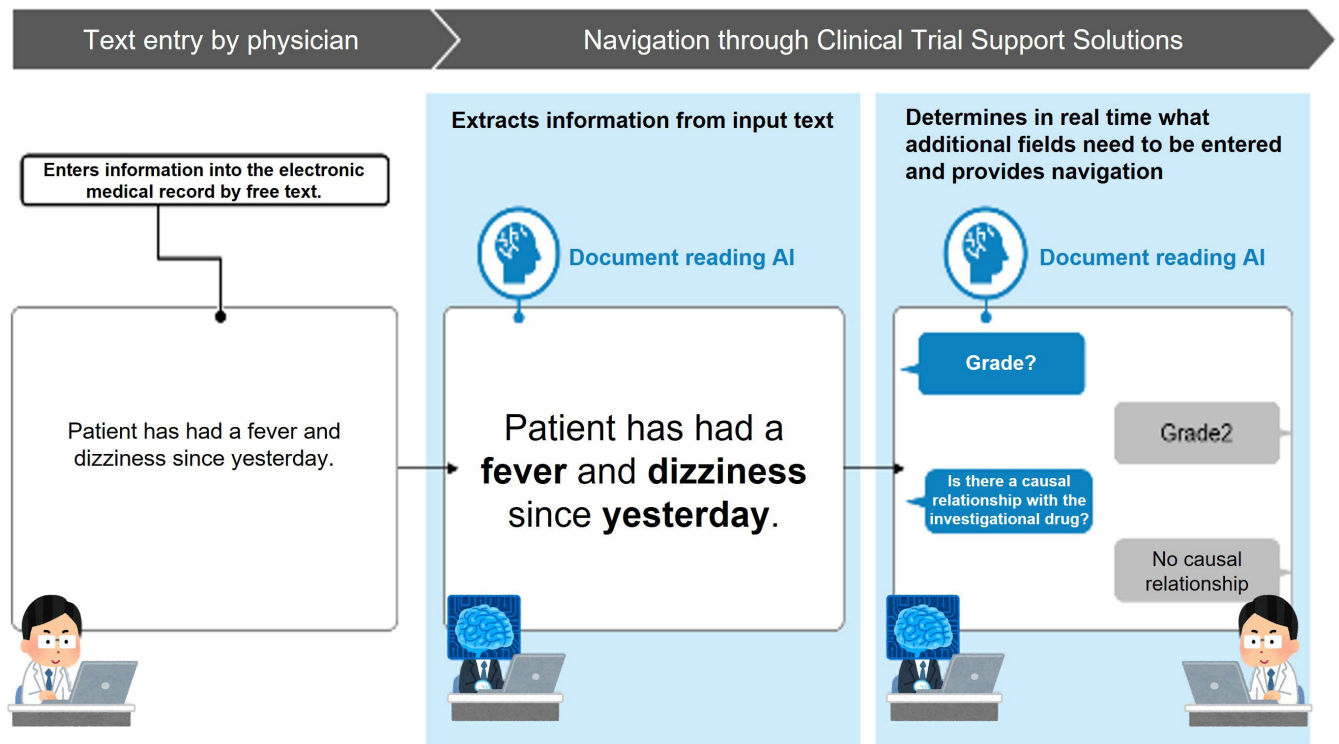


Figure 8
AI Solutions To Support Unstructured Data Collection

PhambieLINQ aims to standardize data output from various electronic health records and link this data output to various EDCs as a multi-site applicable EHR/EMR linkage solution.

Features provided by PhambieLINQ.

- **Connects to electronic medical record systems**

PhambieLINQ electronically links the necessary information from the source documents stored in the electronic medical record system to the study sponsor as a case report form, to streamline and save time and effort in Source Document Verification (SDV) (direct viewing).

- **Multi-vendor support**

We aim to create a platform compatible with various types of electronic medical record systems and EDC systems and usable for any type of study.

To achieve EHR/EMR linkage, the public and private sector reforms must be promoted simultaneously, along with the technical capabilities of IT vendors. While it is true that there are many barriers, there is also a growing movement to overcome them. If all stakeholders seriously address this issue toward achieving a society that can speedily deliver the latest treatments to patients awaiting new drugs, then we will definitely achieve the true “digitalization” of clinical trial operations.





About NTT DATA

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