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Developing CDISC-CRF of special disease to promote the ecology construction of real-world data in China

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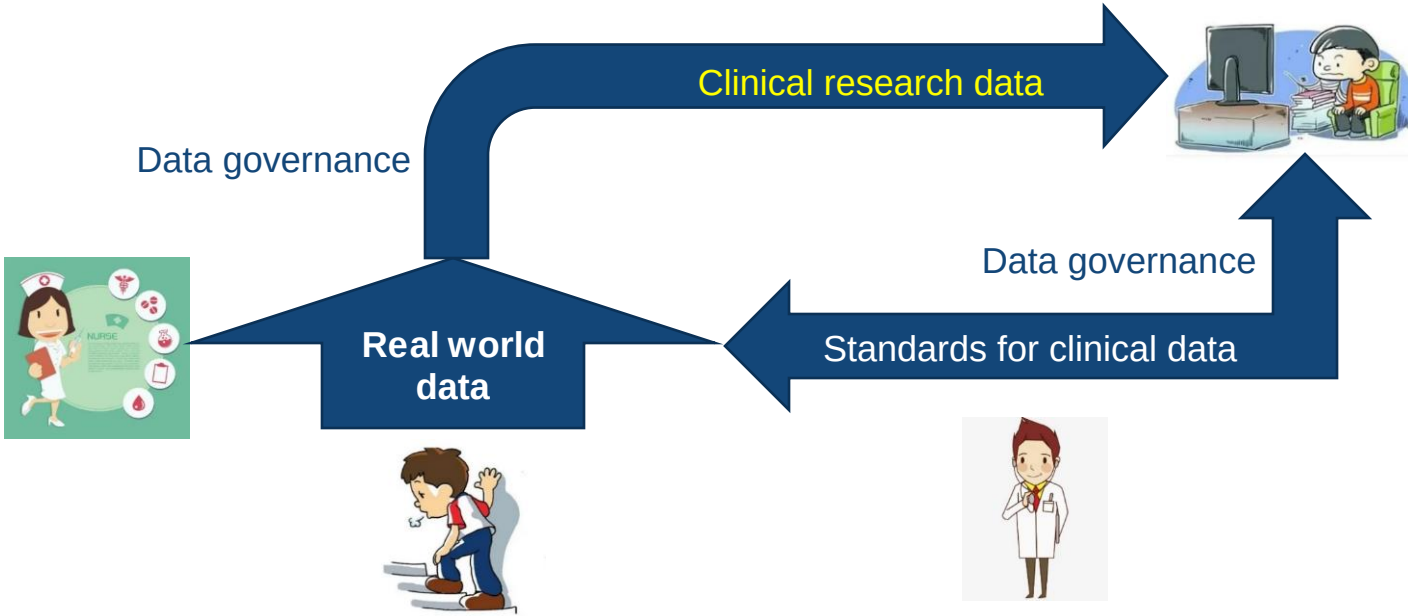
- *The author(s) have no real or apparent conflicts of interest to report.*

Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in health care decisions

- FDA uses RWD and RWE to monitor postmarket safety and adverse events and to make **regulatory decisions**.
- The health care community is using these data to support coverage decisions and to **develop guidelines and decision support tools** for use in clinical practice.
- Medical product developers are using RWD and RWE to support clinical trial designs (e.g., large simple trials, pragmatic clinical trials) and observational studies to **generate innovative, new treatment approaches**.

US FDA. Real-World Evidence [EB/OL]. (2020-11-30) [2020-07-21]. https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence.

Ecosystem for clinical research data



- The adoption of data standards is one of the cornerstones supporting the leverage of real world data

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Guideline for clinical trial data management in China

目 录

(四) 数据转化

数据转化是将经过数据清洗后原始数据的数据格式标准、医学术语、编码标准、衍生变量计算，按照分析数据库中对应标准进行统一转化为适用真实世界数据的过程。

对于自由文本数据的转化可使用可靠的自然语言处理算法，在保障数据转化准确、可溯源的前提下，提高转化效率。

在进行衍生变量计算时，应明确用于计算的原始数据变量及变量值、计算方法及衍生变量的定义，并进行时间戳管理，以保障数据的准确性和可追溯性。

National Medicine and Production Administration. Technical guide for clinical trial data management. http://www.cde.org.cn/zdyz.do?method=largePage&id=20c3cd5ea30a51f9

Gaps from real world data to clinical research data

Lack of data interoperability: According to the respondents, different platforms or hospitals may use different data standards, and it is difficult to share data across information systems in general practice. The data stored in the EMR uses data coding and data storage schemes that are incompatible with the coding and storage formats of EDC systems. The lack of interoperability between different terminologies or coding schema used in information systems causes a great challenge in EMR data usage.

Different platforms or hospitals may use different data standards, so data cannot be used across settings. For me, the value of data from other systems is limited. - Intermediate doctor 114

Data security concerns: The information department staff reported that any private patient-related data should not be exported to clinicians unless they adhered to the full protocol to obtain access to data. These respondents believe that they will be responsible for data leaks, and they do not know how doctors will use the data. Thus, EMRs and EDC systems cannot communicate. Strong security concerns generate complicated approval procedures for data access, leading speciality departments to use an external company platform to manage their data.

EMR contains the private information of patients, and we will not allow doctors to download the data because the hospital does not have policies. Therefore, clinicians can only collect and transcribe the data. - IT (information technology) 313

Unstructured EMR data: EMR is used for clinical practice but not for clinical research. The doctors reported that there are many problems when using hospital EMRs for clinical research data collection. Many laboratory test or imaging test data are stored in PDF format or image files in EMR and must be manually transcribed.

The information recorded in the EMR includes pictures, such as ECG or laboratory examination. The results in these pictures cannot be directly presented in EMR. - Senior doctor 601

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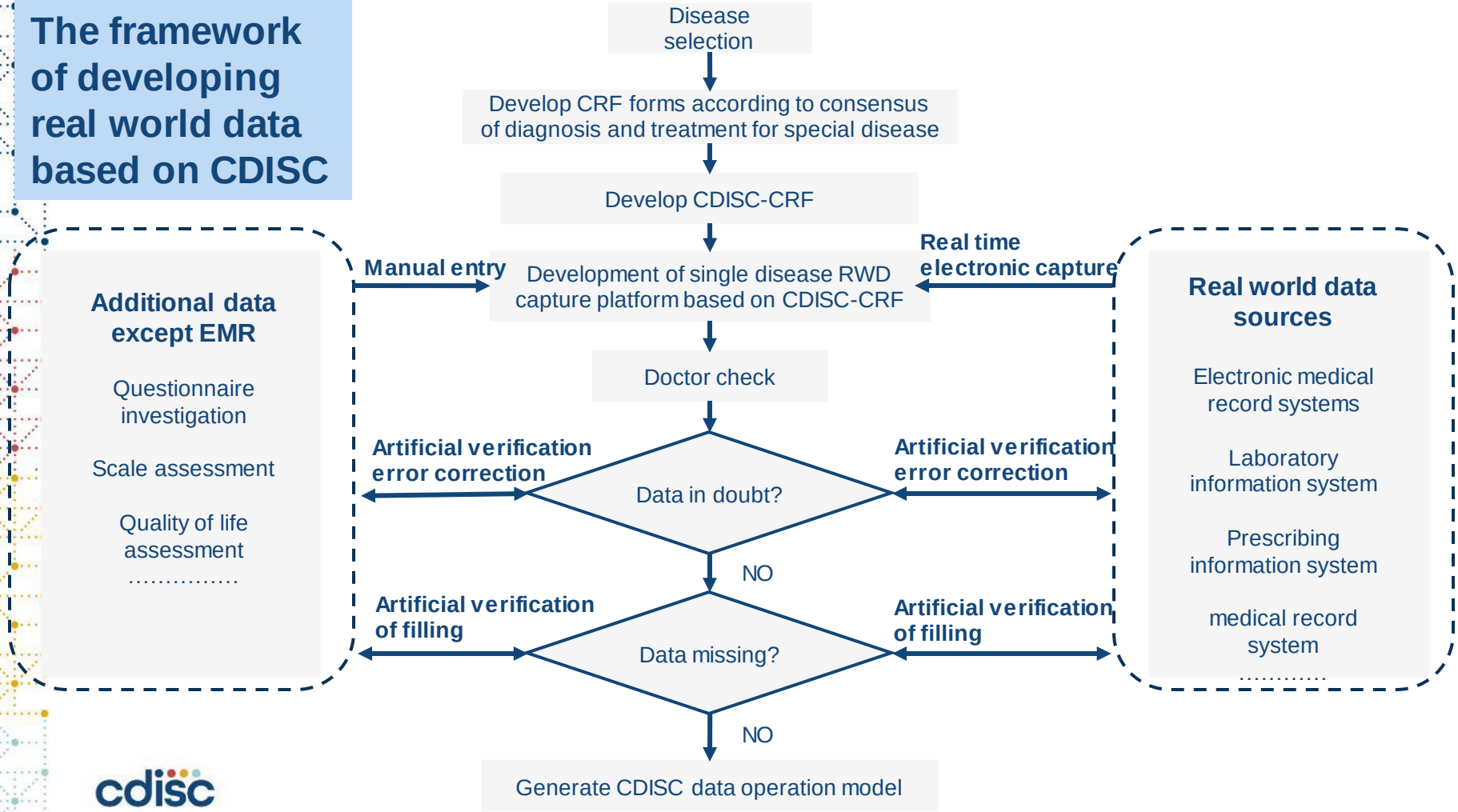
Jin F, Yao C, Yan X, et al. Gap between real-world data and clinical research within hospitals in China: a qualitative study. BMJ Open 2020;10:e038375.

How to solve this problem underlying cornerstones?

- Which standard for clinical research data?
  - CDISC or others?
- Where begin?
  - Information system of hospital?
  - Special disease?

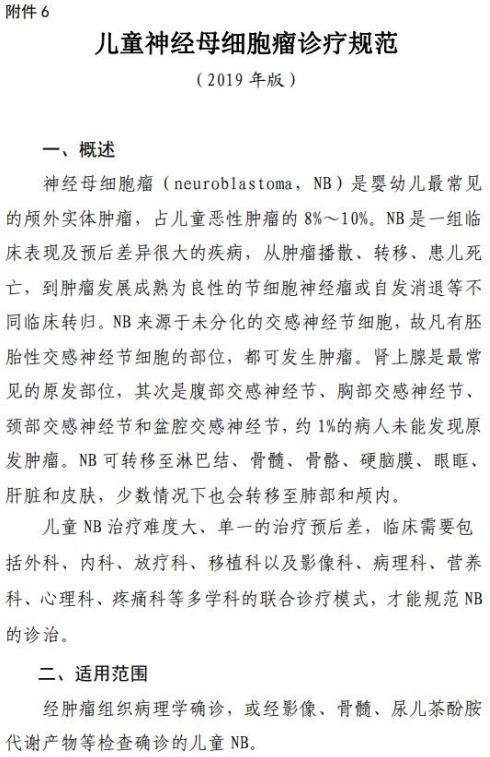
The framework of developing real world data based on CDISC



Select applicable diseases

- For this disease, whether there are major problems that need further study?
- For this disease, is there a clinical practice guideline or consensus for diagnosis and treatment?
- For this disease, is the framework feasible?

Diagnosis and treatment of Consensus for Neuroblastoma



附件 6

儿童神经母细胞瘤诊疗规范

（2019 年版）

一、概述

神经母细胞瘤（neuroblastoma，NB）是婴幼儿最常见的颅外实体肿瘤，占儿童恶性肿瘤的 8%～10%。NB 是一组临床表现及预后差异很大的疾病，从肿瘤播散、转移、患儿死亡，到肿瘤发展成熟为良性的节细胞神经瘤或自发消退等不同临床转归。NB 来源于未分化的交感神经节细胞，故凡有胚胎性交感神经节细胞的部位，都可发生肿瘤。肾上腺是最常见的原发部位，其次是腹部交感神经节、胸部交感神经节、颈部交感神经节和盆腔交感神经节，约 1%的病人未能发现原发肿瘤。NB 可转移至淋巴结、骨髓、骨骼、硬脑膜、眼眶、肝脏和皮肤，少数情况下也会转移至肺部和颅内。

儿童 NB 治疗难度大、单一的治疗预后差，临床需要包括外科、内科、放疗科、移植科以及影像科、病理科、营养科、心理科、疼痛科等多学科的联合诊疗模式，才能规范 NB 的诊治。

二、适用范围

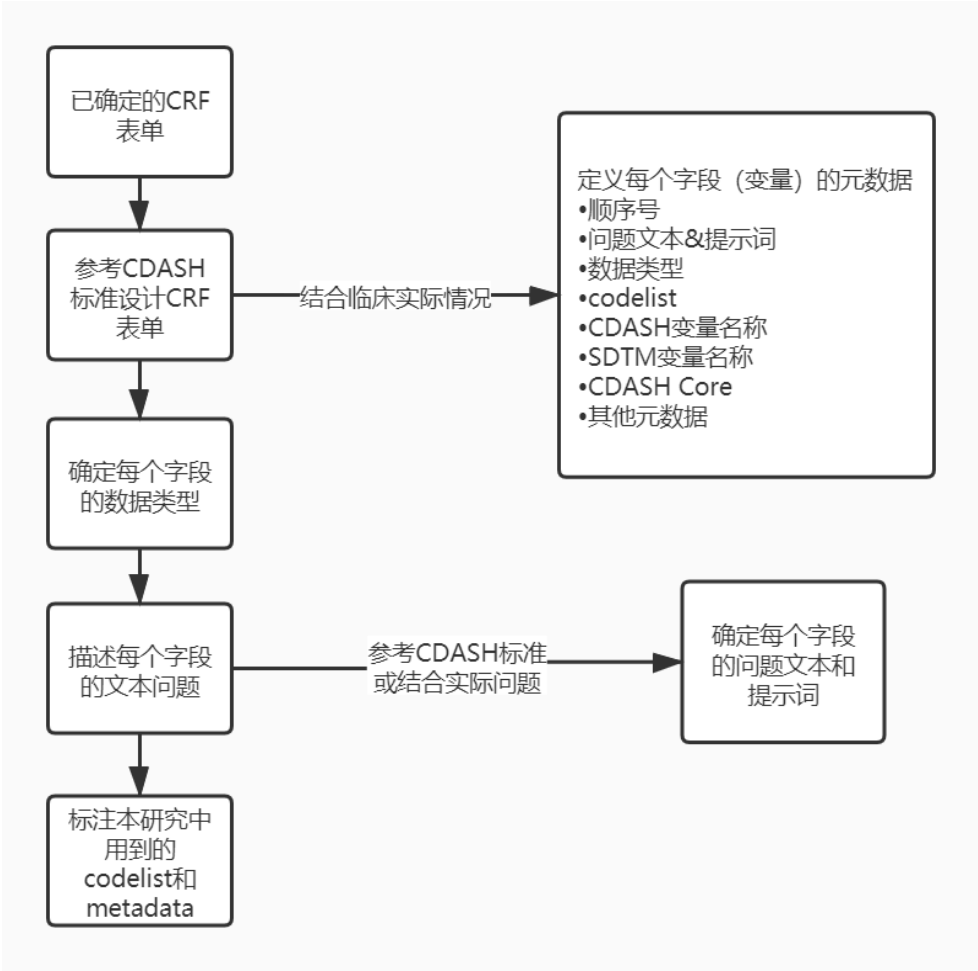
经肿瘤组织病理学确诊，或经影像、骨髓、尿儿茶酚胺代谢产物等检查确诊的儿童 NB。

Develop CRF forms according to diagnosis and treatment of consensus for Neuroblastoma

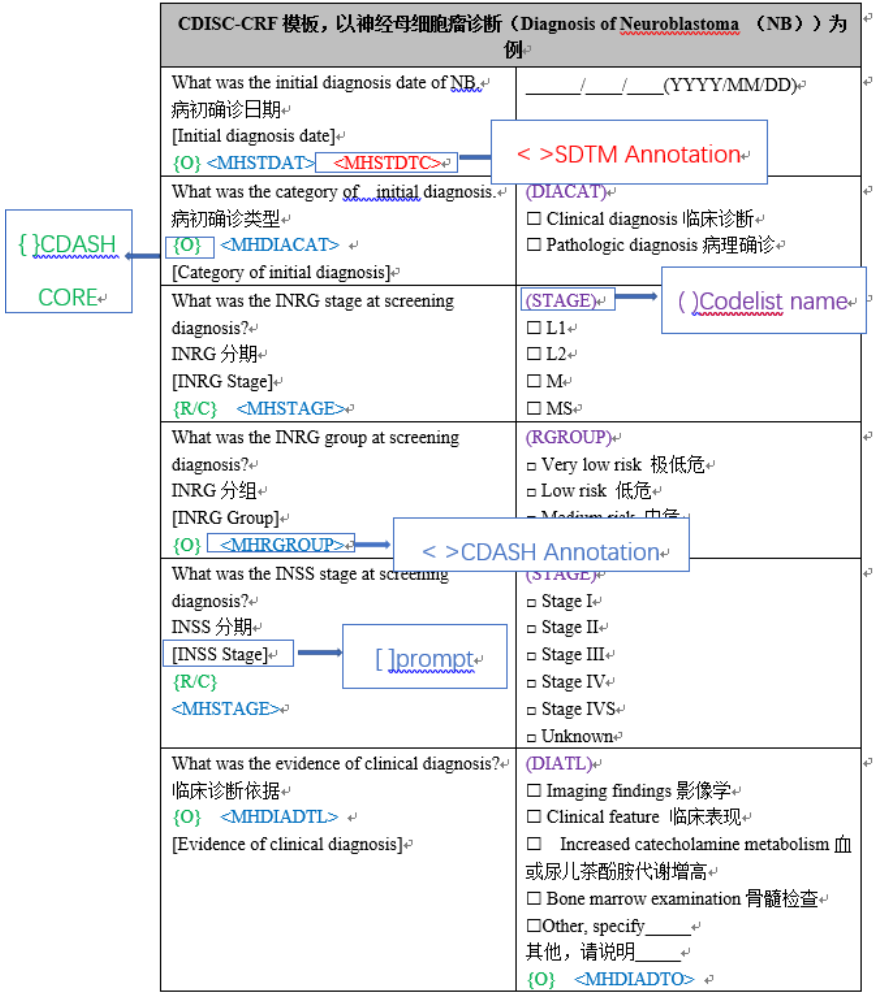
Domain name	Contents
Participants	Inclusion and exclusion criteria
	Informed consent
	Randomization
Basic information	Demography
	Medical history
	Vital signs
	Physical examinations
Diagnosis	Confirmed diagnosis of NB
Therapy	Medicine researched
	Drugs combined in therapy
	Non-drug therapy
	Drug delivery
	Surgery
	Radiotherapy
Follow-up	Visiting time
	Effective assessment of NB
	Survival follow-up
	Death information

	primary lesion
	metastatic lesion
	Adverse events
	Biomarks of NB
	Morphological examination of bone marrow
	Minimal bone marrow lesions
	MIBG scaning
	Electrocardiogram
	Echocardiography
	Hearing examination
	Myocardial enzyme
	Immunoglobulin
	Coagulation function
	CD
	CRP
	Blood cell analysis
	Serum biochemistry
	Stool routine
	Urine routine
End of research	End of research
	End of therapy

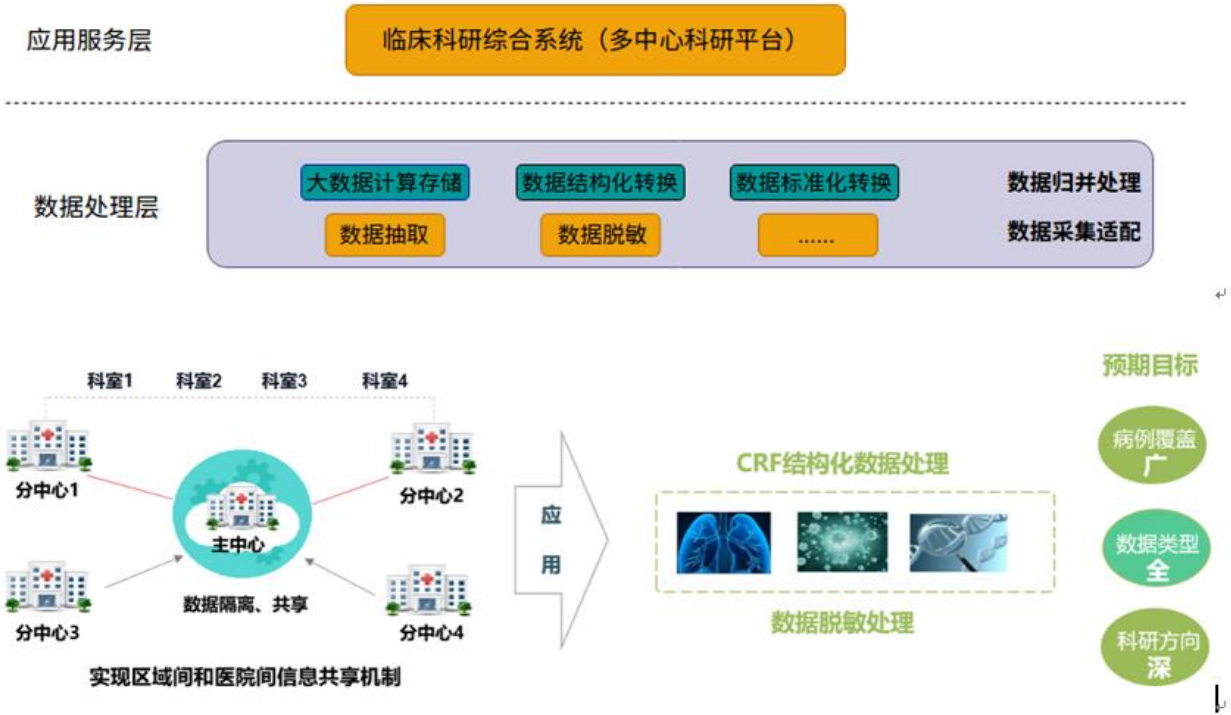
Developing CDISC-CRF forms



Example of CDISC-CRF forms



Data capture platform for one disease based on CDISC-CRF



Online test for the data platform

A structured and standard real world data platform

Paper and Computer Software's Registration

开发专病CDISC-CRF助力我国真实世界数据生态建设

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【摘要】 真实世界数据是指在日常医疗活动、生活与工作等环境下产生的数据。真实世界数据在临床与公共卫生研究中一直被广泛应用，但真实世界数据质量相关问题，如不完整性、不一致性和准确性等会影响真实世界研究的真实性。为了应对真实世界源数据缺乏标准化带来的挑战，本文基于当前被广泛应用的数据标准，即临床数据交换标准协会（CDISC）开发的CDISC标准开发了专病CDISC-病例报告表（CRF），以提高真实世界源数据标准化水平，助力我国真实世界数据生态建设。我们阐述了如何应用数据标准弥补真实世界数据到真实世界证据之间的裂痕；设计了基于专病CDISC-CRF建设真实世界数据生态的流程，重点介绍了CDISC-CRF表单的开发技术；并就基于专病CDISC-CRF建设真实世界数据的应用前景及意义进行了描述。

【关键词】 真实世界数据； 临床数据交换标准协会标准； 病例报告表

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Further goals

e-Health – For Continuity of Care
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Interconnection of Electronic Medical Record with Clinical Data Management System by CDISC ODM

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Abstract. EDC system has been used in the field of clinical research. The current EDC system does not connect with electronic medical record system (EMR), thus a medical staff has to transcribe the data in EMR to EDC system manually. This redundant process causes not only inefficiency but also human error. We developed an EDC system cooperating with EMR, in which the data required for a clinical research form (CRF) is transcribed automatically from EMR to electronic CRF (eCRF) and is sent via network. We call this system as "eCRF reporter". The interface module of eCRF reporter can retrieves the data in EMR database including patient biography data, laboratory test data, prescription data and data entered by template in progress notes. The eCRF reporter also enables users to enter data directly to eCRF. The eCRF reporter generates CDISC ODM file and PDF which is a translated form of Clinical data in ODM. After storing eCRF in EMR, it is transferred via VPN to a clinical data management system (CDMS) which can receive the eCRF files and parse ODM. We started some clinical research by using this system. This system is expected to promote clinical research efficiency and strictness.

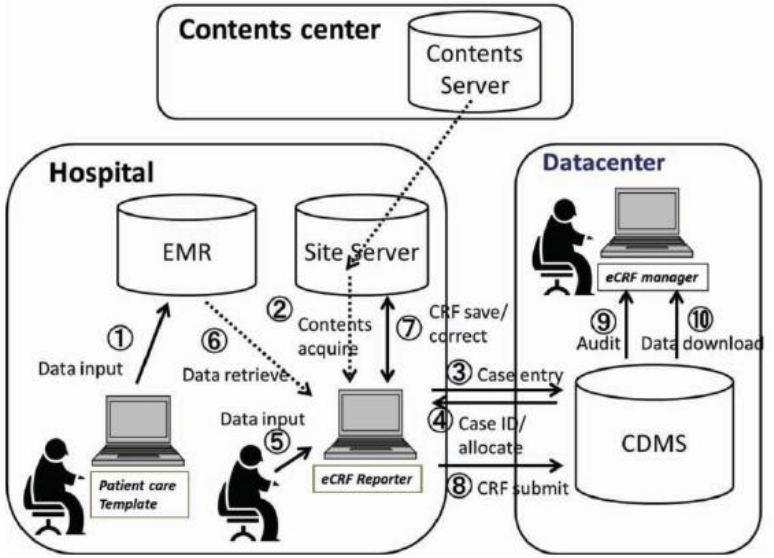

Figure 1. Data flow of the system

Sections
Abstract
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The Use of CDISC Standards for Real-World Data (RWD): Expert Perspectives from a Qualitative Delphi Survey

Rhonda Facile; Erin Elizabeth Muhlbradt; Mengchun Gong; Qing-Na Li; Vaishali B. Popat; Frank Pétavy; Ronald Cornet; Yaoping Ruan; Daisuke Koide; Toshiki, I. Saito; Sam Hume; Frank Rockhold; Wenjun Bao; I. Sue Dubman; Barbara Jauregui

ABSTRACT

Background:

Real World Data (RWD) and Real World Evidence (RWE) have an increasingly important role in clinical research and health care decision making in many countries. In order to leverage RWD and generate reliable RWE, a framework must be in place to ensure that the data is well–defined and structured in a way that is semantically interoperable and consistent across stakeholders. The adoption of data standards is one of the cornerstones supporting high–quality evidence for clinical medicine and therapeutics development. CDISC data standards are mature, globally recognized and heavily utilized by the pharmaceutical industry for regulatory submission in the US and Japan and are recommended in Europe and China. Against this backdrop, the CDISC RWD Connect Initiative was initiated to better understand the barriers to implementing CDISC standards for RWD and to identify the tools and guidance needed to more easily implement CDISC standards for this purpose. We believe that bridging the gap between RWD and clinical trial generated data will benefit all stakeholders.

Thank You!