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CHINA
INTERCHANGE
BEIJING | 25-26 AUGUST

Efficient Data Standardization Through AI

Presented by 朱博贡, Chief Business Architect, 耀乘健康科技

Meet the Speaker

朱博贡

Title: Chief Business Architect

Organization: 耀乘健康科技（yaocheng.cn）

朱博贡先生作为前睿理健康科技中国的重要技术骨干，于2020年共同创办了上海耀乘健康科技有限公司，任技术副总裁、首席业务架构师，负责耀乘健康的产品及技术研发工作，以及开发运营管理等方面工作。

在加入耀乘健康科技之前，朱博贡先生就职于谷歌（Google）集团超过13年，负责过Ads、Cloud AI等领域的各种项目。离开谷歌后在睿理健康科技中国（谷歌母公司旗下专注于生命科学领域的创业公司）任技术主管。

Disclaimer and Disclosures

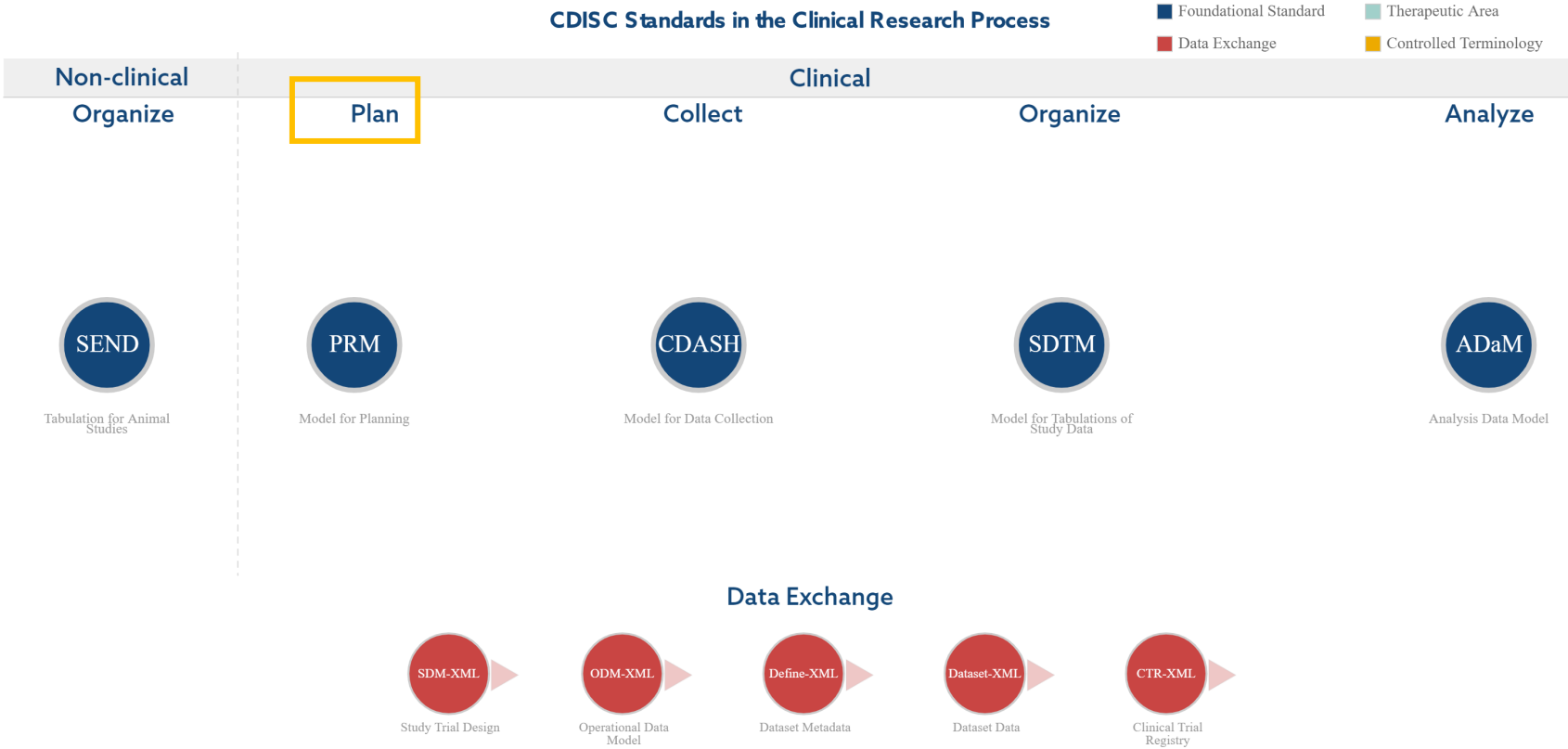
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Efficient Data Standardization Through AI

Agenda

1. CDISC 关于 Digitized Protocol 的构想
2. Digitize protocol 过程中的挑战
3. AI 可以辅助解决的问题 及 潜在的应用

CDISC 的标准体系


CDISC Standards in the Clinical Research Process
Foundational Standard
Therapeutic Area
Data Exchange
Controlled Terminology
Non-clinical
Clinical
Organize
Plan
Collect
Organize
Analyze
SEND
Tabulation for Animal Studies
PRM
Model for Planning
CDASH
Model for Data Collection
SDTM
Model for Tabulations of Study Data
ADaM
Analysis Data Model
Data Exchange
SDM-XML
Study Trial Design
ODM-XML
Operational Data Model
Define-XML
Dataset Metadata
Dataset-XML
Dataset Data
CTR-XML
Clinical Trial Registry

以方案为中心，基于各类文档的试验体系

一半以上的计划内容来自方案里的信息产出

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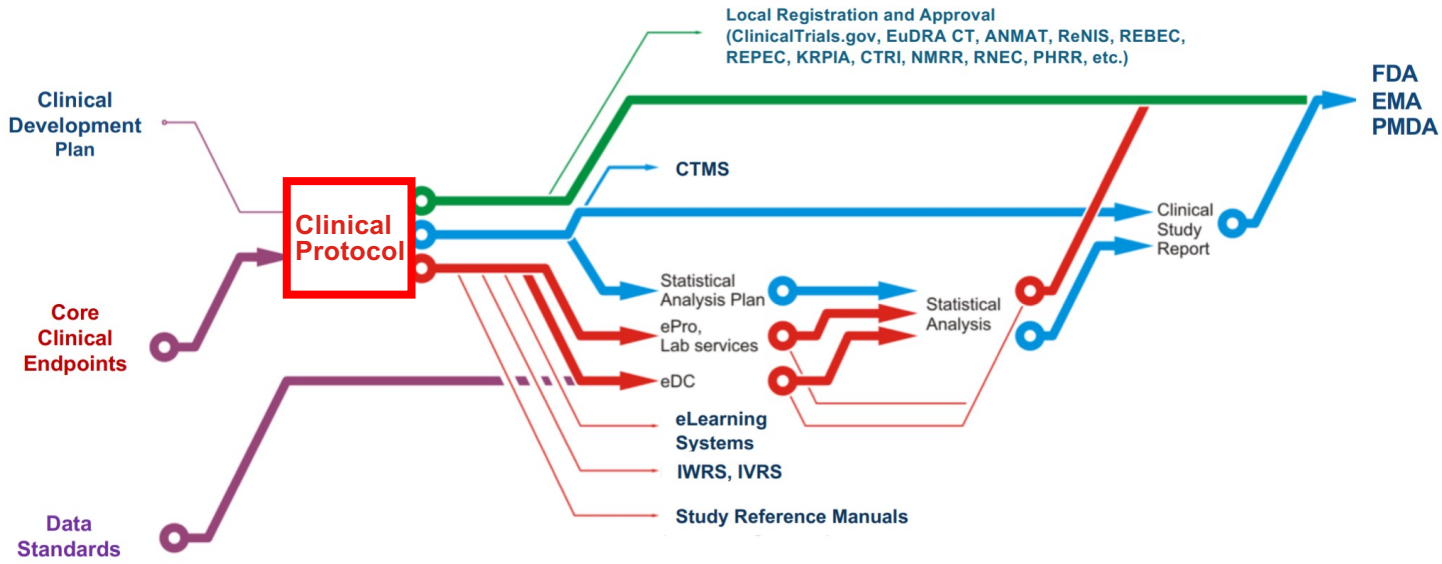


Source: *https://www.cdisc.org/sites/default/files/pdf/DDFPublicReview-FINAL.pdf*

Digitized Protocol構想

The Clinical Trial Information Flow

从 Human Readable 到 Machine Readable 的鸿沟

PROTOCOL SYNOPSIS

TITLE:	**A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE SAFETY AND EFFICACY OF TOCILIZUMAB IN PATIENTS WITH SEVERE COVID-19 PNEUMONIA**
PROTOCOL NUMBER:	WA42380
VERSION NUMBER:	*3*
EUDRACT NUMBER:	2020-001154-22
IND NUMBER:	148225
IND NUMBER:	NCT04320615
TEST PRODUCT:	Tocilizumab (RO4877533)
PHASE:	Phase III
INDICATION:	Severe COVID-19 pneumonia
SPONSOR:	F. Hoffmann-La Roche Ltd

Objectives and Endpoints

This study will evaluate the efficacy, safety, pharmacodynamics, and pharmacokinetics of tocilizumab (TCZ) compared with a matching placebo in combination with standard of care (SOC) in hospitalized patients with severe COVID-19 pneumonia. Specific objectives and corresponding endpoints for the study are outlined below.

Efficacy Objectives

Primary Efficacy Objective

The primary efficacy objective for this study is to evaluate the efficacy of TCZ compared with placebo in combination with SOC for the treatment of severe COVID-19 pneumonia on the basis of the following endpoint:

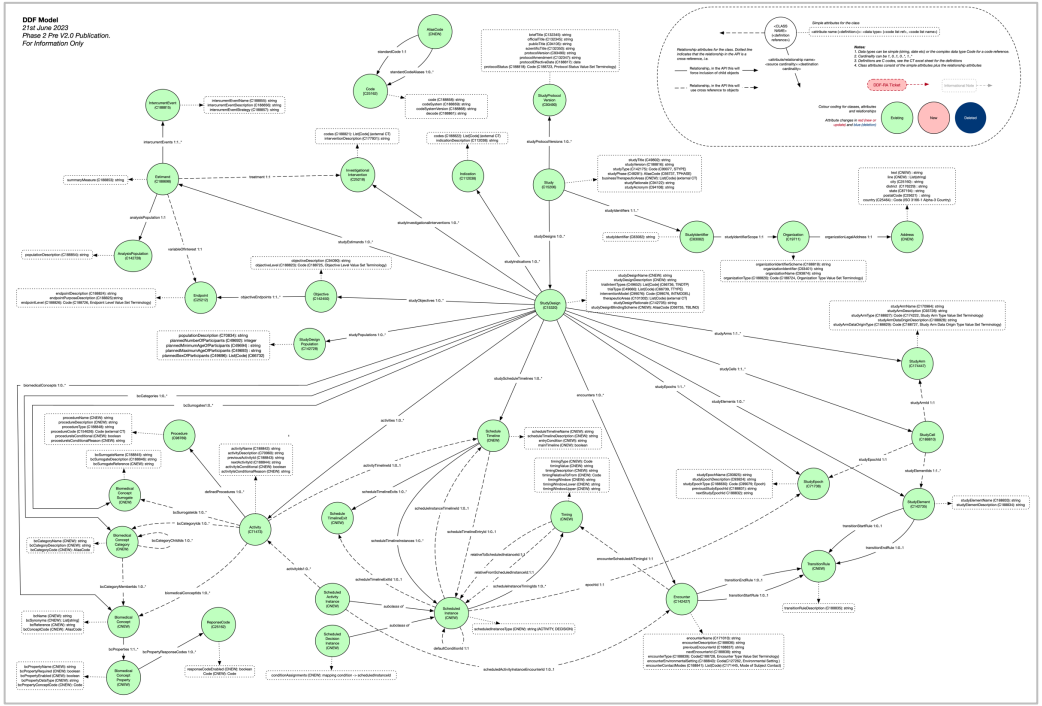
- Clinical status assessed using a 7-category ordinal scale at Day 28

Secondary Efficacy Objective

The secondary efficacy objective for this study is to evaluate the efficacy of TCZ compared with placebo in combination with SOC for the treatment of severe COVID-19 pneumonia on the basis of the following endpoints:

- Time to clinical improvement (TTCI) defined as a National Early Warning Score 2 (NEWS2) of ≤ 2 maintained for 24 hours
- Time to improvement of at least 2 categories relative to baseline on a 7-category ordinal scale of clinical status
- Incidence of mechanical ventilation
- Ventilator-free days to Day 28
- Incidence of intensive care unit (ICU) stay
- Duration of ICU stay

Source: *https://classic.clinicaltrials.gov/ct2/show/NCT04320615*



Source: *DDF USDM Reference Architecture v2.0*

从 Human Readable 到 Machine Readable 的鸿沟

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Source: *https://classic.clinicaltrials.gov/ct2/show/NCT04320615*

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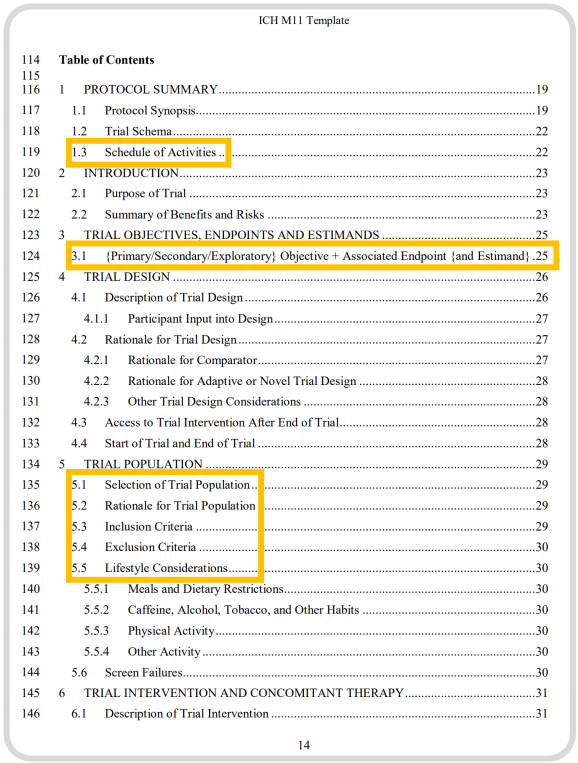
Source: *DDF USDM Reference Architecture v2.0*

Human Readable + AI → Machine Readable



ICH M11 Template

Table of Contents

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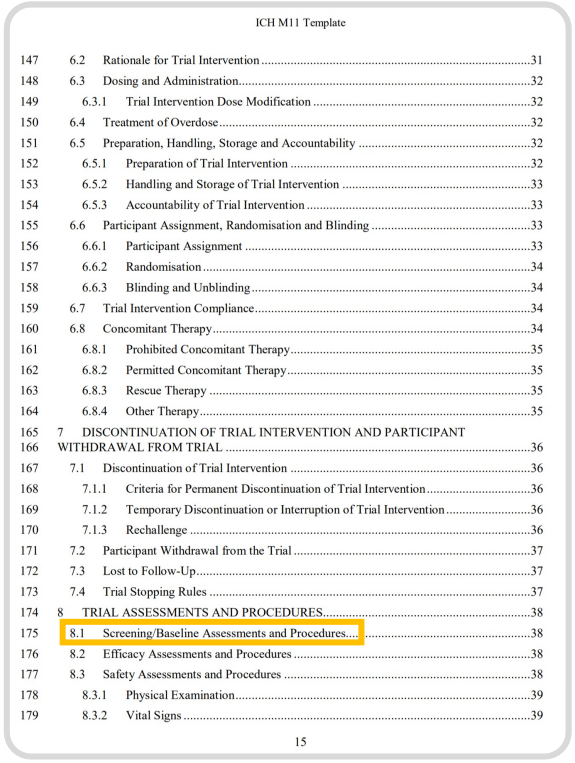

ICH M11 Template

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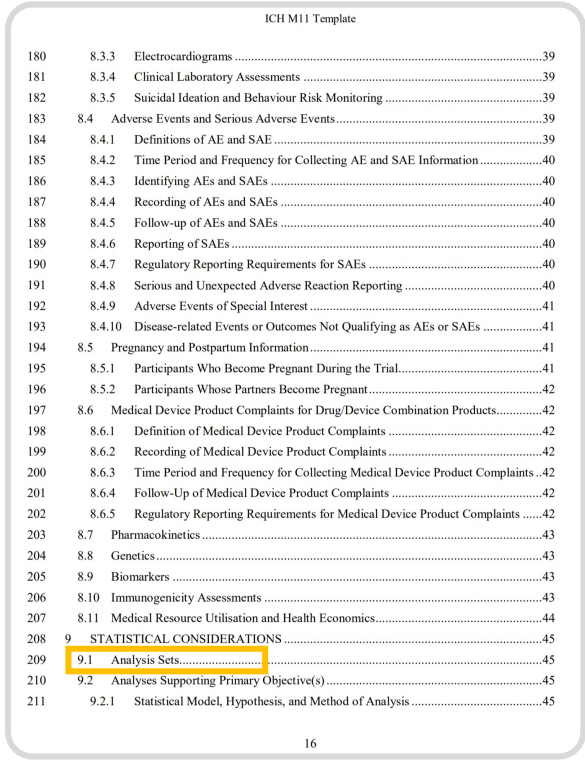

ICH M11 Template

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Source: 2023 CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (DRAFT) M11 Template, CDE

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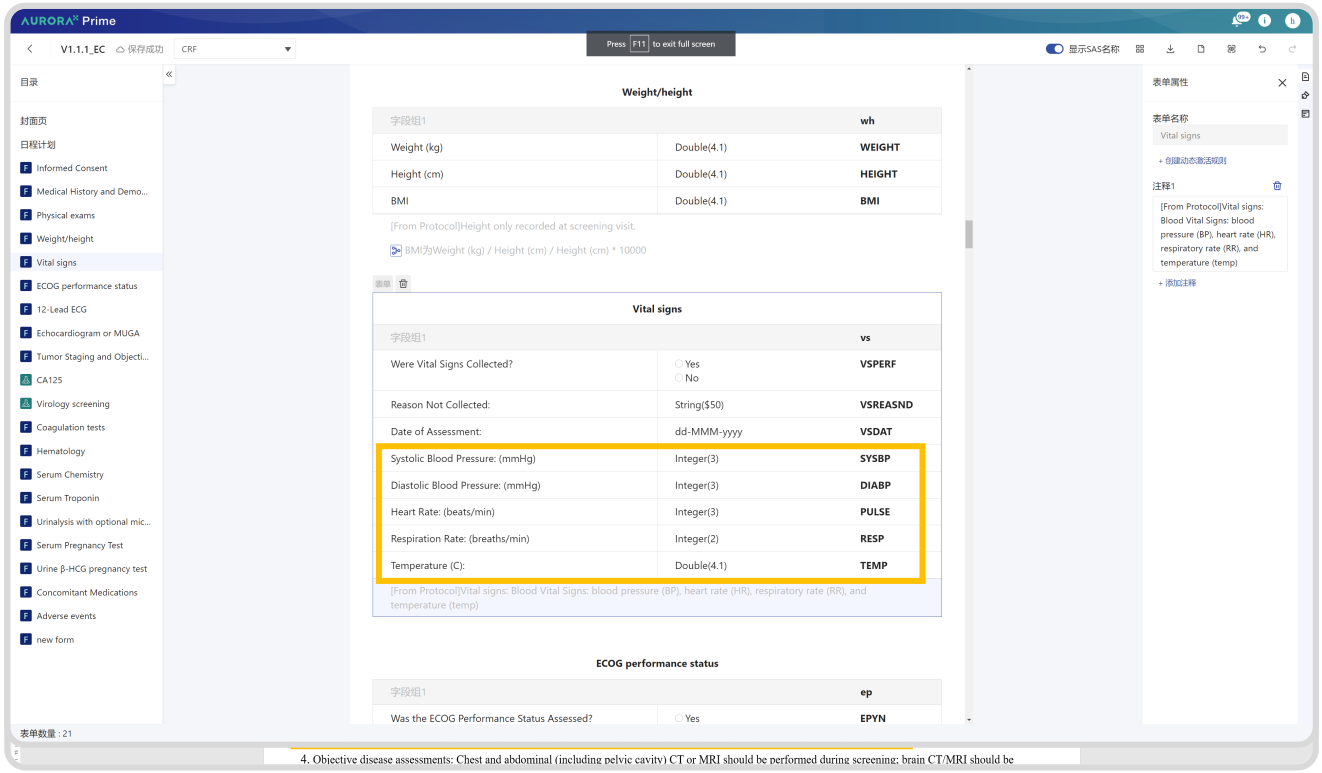
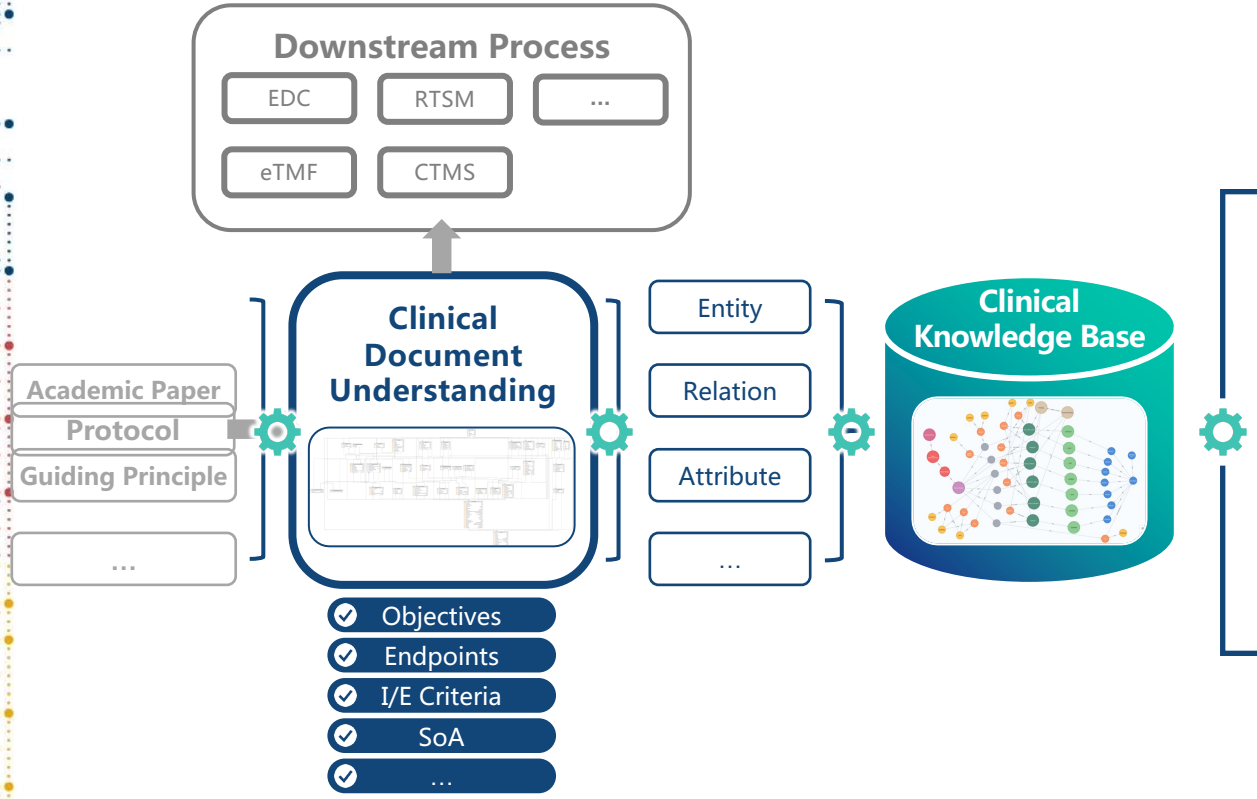
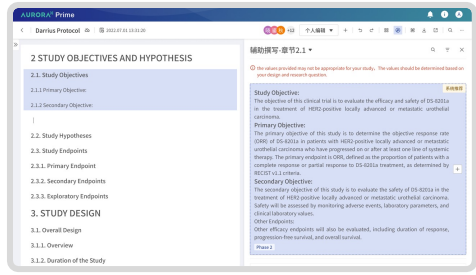
Schedule of Activities (SoA) 的转换示例

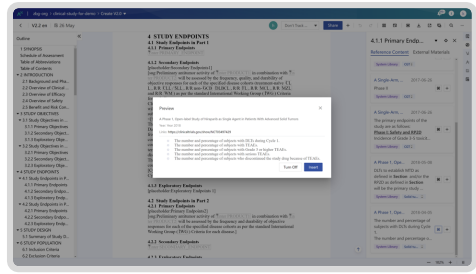






Content Reuse & Generation

- ✓ From Synopsis to the Main section
- ✓ Related documents, e.g. CSR
- ✓ ...

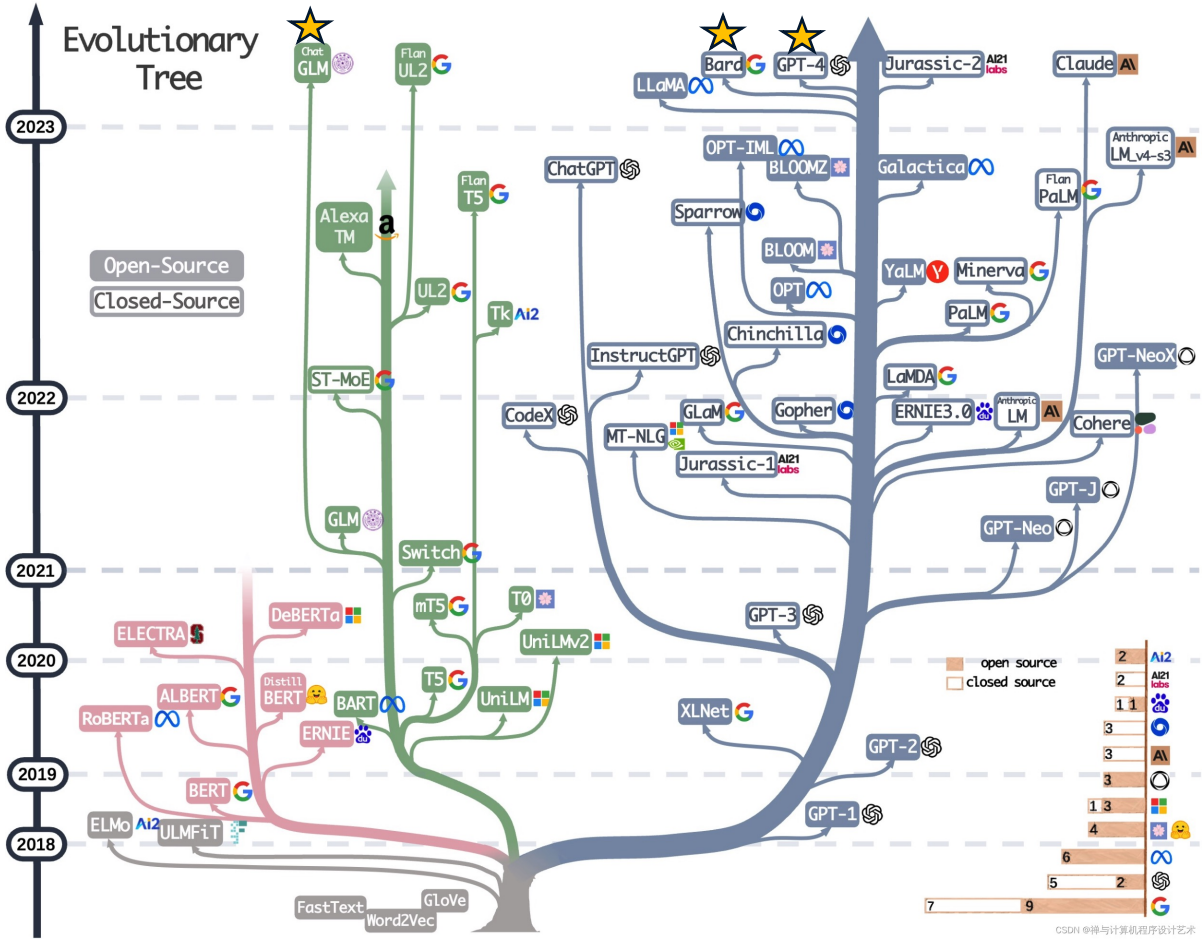


Reference

- ✓ What's the popular endpoints of a particular biological target ?
- ✓ What's the most used I/E criteria of a particular indication ?
- ✓ ...

如何选择模型

- 哪个模型的效果好 ？
- 哪个模型的性价比好 ？
- 哪个模型适合我的使用场景 ？



从 Document & Manual Flow
迈向 Digital & Automated Flow

Today

Protocol Document

Study Design & Protocol Authoring

RTSM EDC CTMS DCT

Document-based

Clinical Document Understanding

Clinical Knowledge Base

DCT CTMS EDC RTSM

Digitalized

Tomorrow

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效率 + 合规 → 价值

FDA 正持续与业界展开探讨

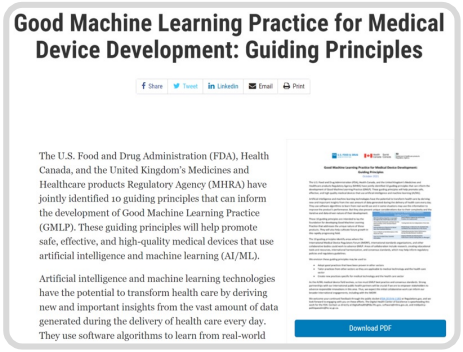
FDA Releases Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing

Source: FDA 2023-05-10

Solicit feedback on 3 key areas

1. Human-led governance, accountability, and transparency
2. Quality, reliability, and representativeness of data
3. Model development, performance, monitoring, and validation

器械已有相关指导原则: GMLP


Good Machine Learning Practice for Medical Device Development: Guiding Principles

The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). These guiding principles will help promote safe, effective, and high-quality medical devices that use artificial intelligence and machine learning (AI/ML).

Artificial intelligence and machine learning technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. They use software algorithms to learn from real-world

Download PDF

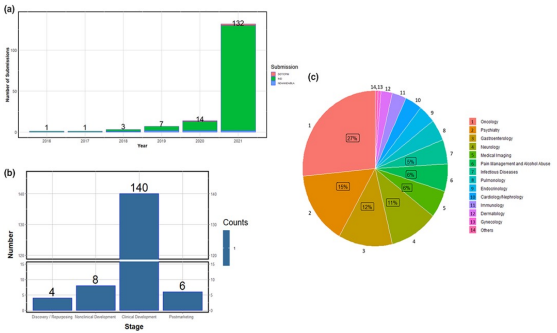
Source: FDA 2021-10-27

10 guiding principles

1. Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle
2. Good Software Engineering and Security Practices Are Implemented
3. ...

大势所趋

The regulatory uses are real: In 2021, more than 100 drug and biologic applications submitted to the FDA included AI/ML components. These submissions spanned a range of therapeutic areas, and sponsors incorporated the technologies in different developmental stages.



Source: Landscape Analysis of the Application of Artificial Intelligence and Machine Learning in Regulatory Submissions for Drug Development From 2016 to 2021