



2023

KOREA

INTERCHANGE

SEOUL | 11-14 DECEMBER



CDISC Journey at Clinical Trial Center of Hospital in South Korea

Presented by Min-Gul Kim, Director of Clinical Trial Center,
Jeonbuk National University Hospital



Meet the Speaker

Min-Gul Kim

Title: Professor, Director of Clinical Trial Center

Organization: Jeonbuk National University Hospital

Min-Gul Kim is an Associate Professor in the Department of Pharmacology at Jeonbuk National University School of Medicine, and he serves as the Director of the Clinical Trial Center at Jeonbuk National University Hospital. With over 15 years of experience, he has been responsible for more than 200 clinical trials as the Principal Investigator.

He graduated from Jeonbuk National University School of Medicine and earned his doctoral degree in Pharmacology from Seoul National University Graduate School. Currently, he holds the position of Information Director at the Korean Society of Clinical Pharmacology and serves as the Clinical Trial Director at the Korean Society of Medical Informatics.



Disclaimer and Disclosures

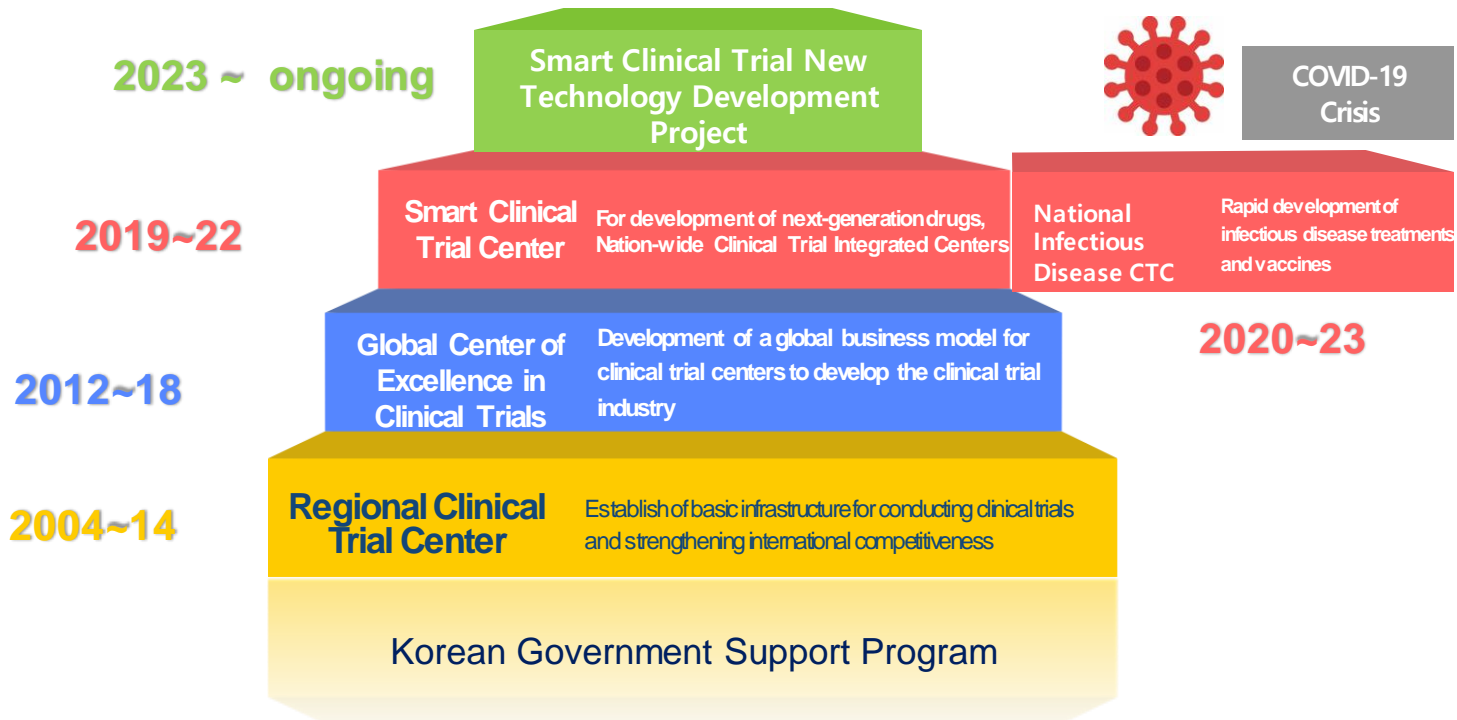
- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of Jeonbuk National University Hospital.*



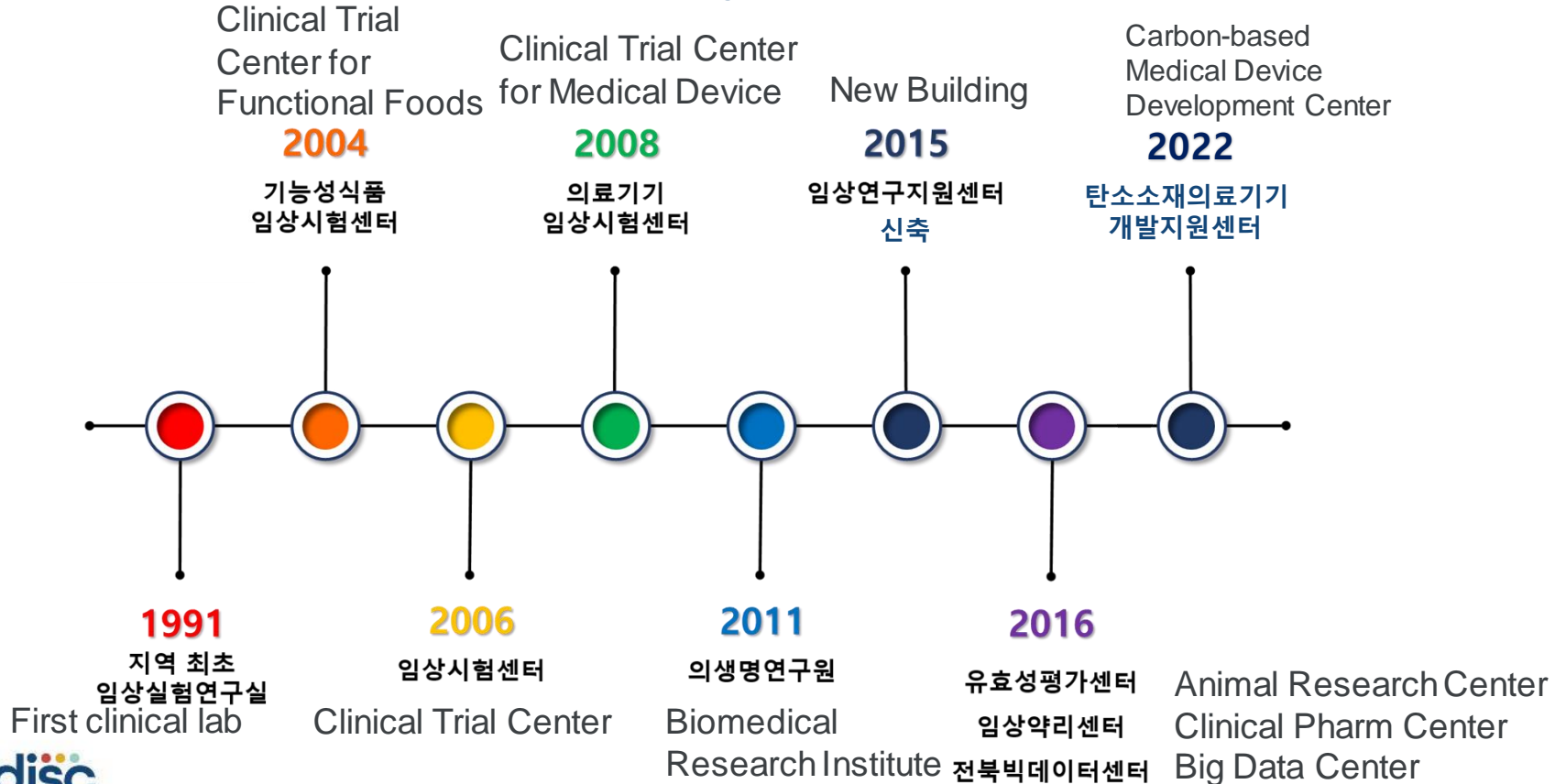
Agenda

1. Clinical Trial Infrastructure in Korea
2. Clinical Trials at Jeonbuk National University Hospital
3. Data Standardization in Clinical Trials

Clinical Trial Infrastructure Development Project in South Korea



Clinical Trials Infrastructure Development Process in Jeonbuk National University Hospital

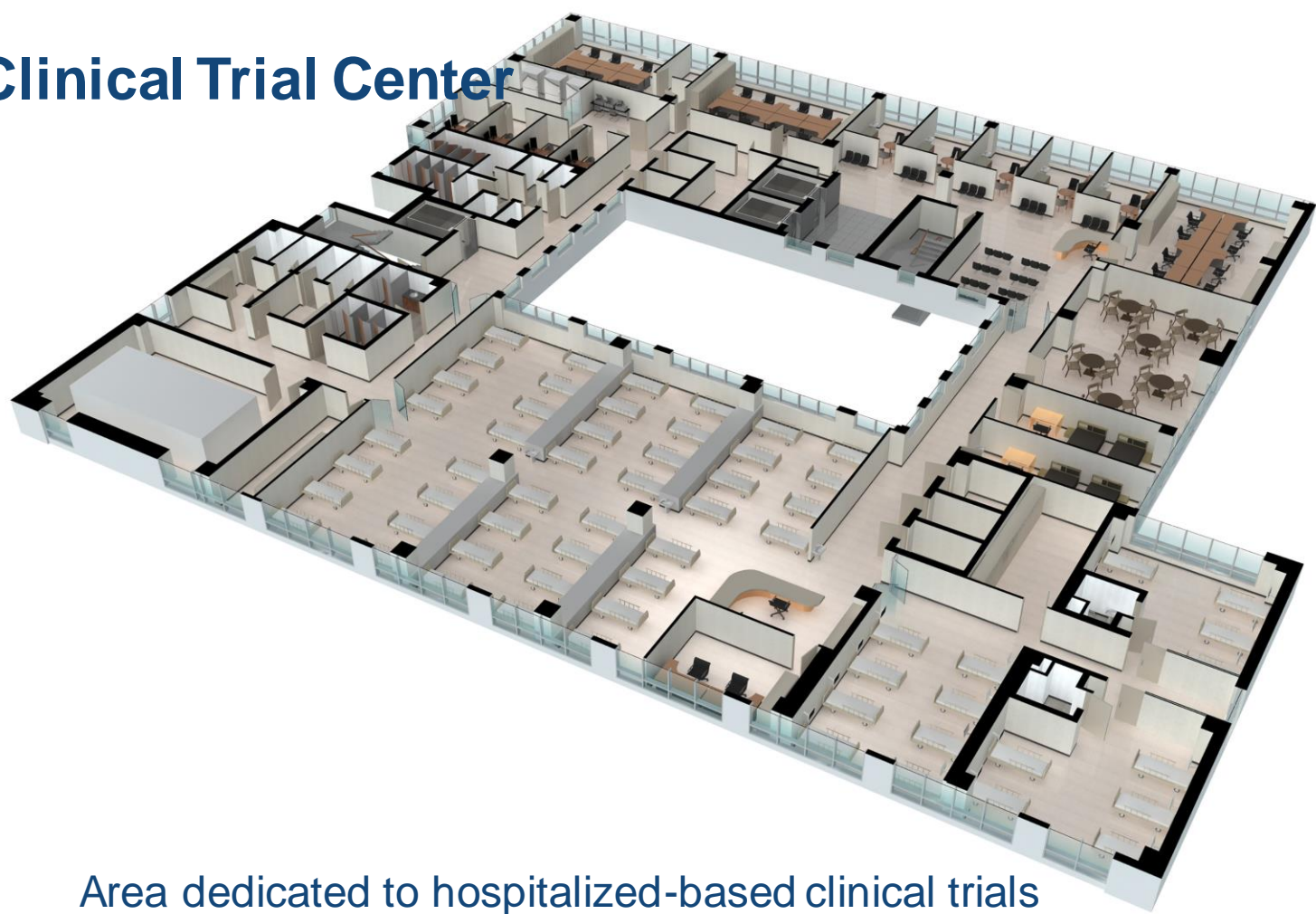


Jeonbuk National University Hospital Clinical Research Support building



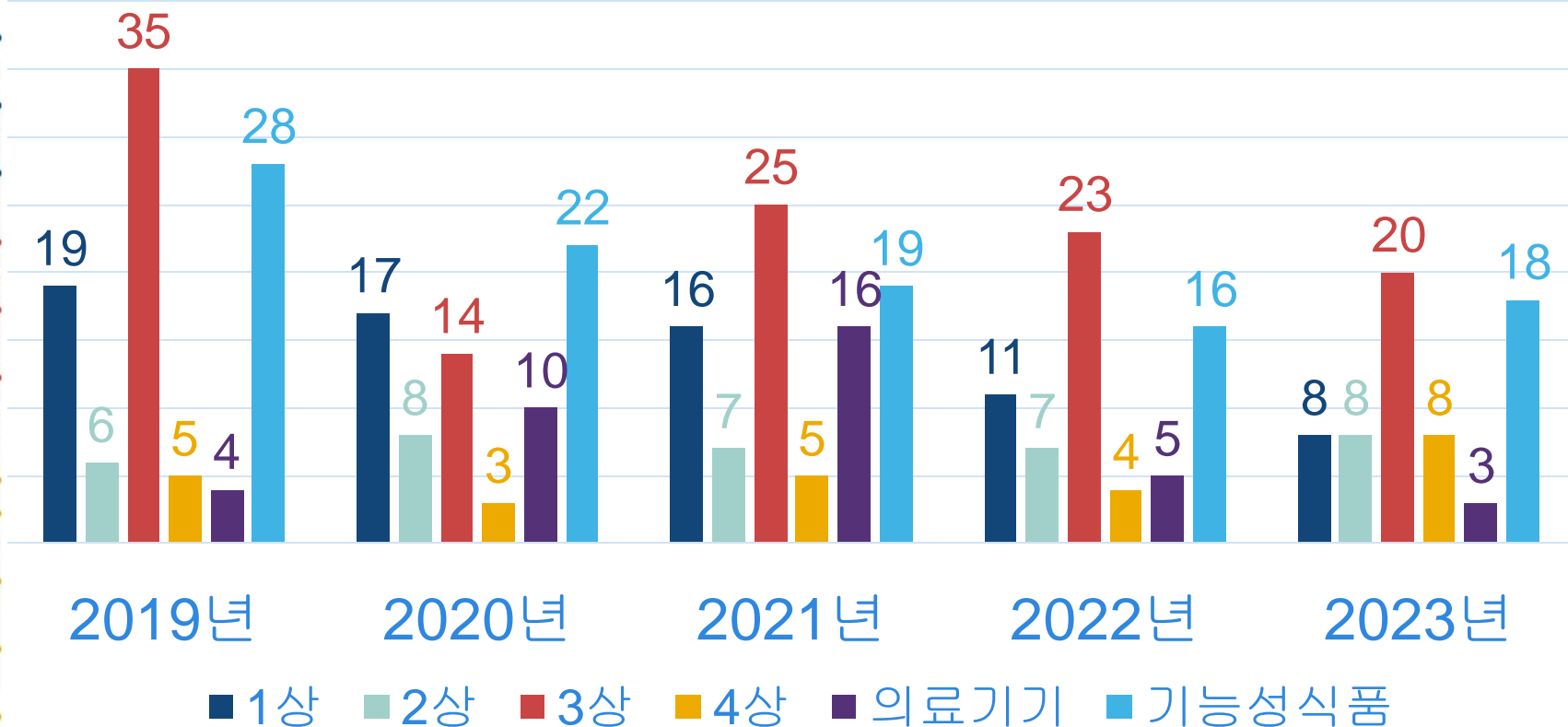
Opening in May 2015

Space for Clinical Trial Center



Area dedicated to hospitalized-based clinical trials
(approximately 1,800 m²)

Clinical Trials status at JNUH



Collaboration with CRO

- Clinical trial electronic data processing workshop with **Seoul CRO**
 - Definition and necessity of data management
 - Purpose of electronic data processing



Medidata Korea MOU signed with JNUH

Signed on November 9, 2015

To improve electronic data processing system capabilities

Consider system compatibility with CDISC



Preparing for Global Standardization of Clinical Trial Data Management

- CDISC international standards-based clinical trial data management
 - Implementation of Medidata Rave EDC System

medidata




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 Signature Min-Gul Kim
 Print Name
 Organization Chonbuk National University Hospital 2019@ch.co.kr
 Representative's email
 Date 2019-01-04

Please sign, scan and email this Member Agreement to membership@cdisc.org.

Clinical Data Interchange Standards Consortium, Inc.
 402 W. 320th St, Suite 879 Austin, TX 78701
 512.363.5526



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Our Members

CDISC would not be possible without the support of our members. We are grateful to all who help us bring clarity to data.

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CDISC Membership: [Charter Members](#) | [20+ Years](#) | [15+ Years](#) | [10+ Years](#) | [5+ Years](#)

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Japan Agency for Medical Research and Development

Industry Type: Government

Membership Level: Platinum

August 2014



Jazz Pharmaceuticals

Industry Type: Pharmaceutical

Membership Level: Platinum

March 2010



Jeonbuk National University Hospital

Industry Type: Academic Institution

Membership Level: Gold

December 2016

CDISC Public Training

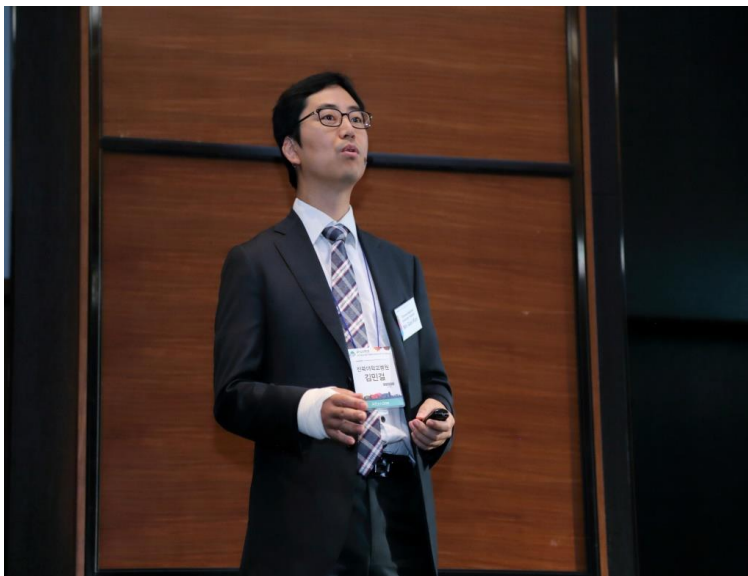


- CDISC Public Training in Vietnam (March 2016).
- CDISC Public Training in London, UK (March 2017)
 - CDASH Implementation Course, SDTM Theory & Application Course



Need for Standardization of Clinical Trial Data

- Medidata Symposium KOREA 2016 (July 7, 2016)
 - Suggestion of the need for a CDISC standardization system for phase 1 clinical trials.





2019 대한임상약리학회 추계학술대회



2019
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추계학술대회

◀ PREVIOUS 2020년도 대한임상약리학회 춘계학술대회

▶ NEXT 2019년도 대한임상약리학회 추계학술대회

2019년도 대한임상약리학회 추계학술대회

일시 2019년 11월 14일(목)-16일(토)

장소 여수컨벤션센터

☰ 목록으로

행사 상세

1상 임상시험 데이터 표준화를 위한 CDISC

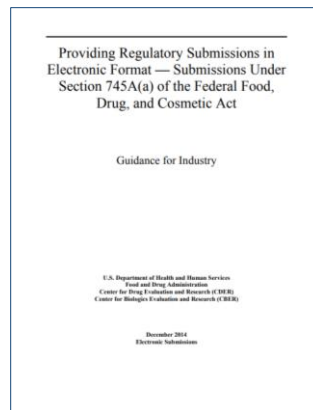
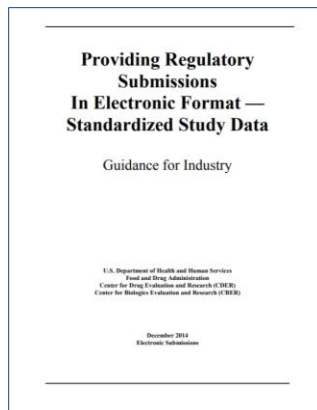
	시간	주제	연/좌장	소속
워크샵(14일 목)	09:00~09:10	CDISC에 대한 소개		김민걸 전북대학교병원
	09:10~10:30	Study Data Tabulation Model (SDTM)의 이해와 1상 임상시험 데이터에의 적용: 초급과정		송운찬 전북대학교병원
	10:40~12:00	Analysis Data Model (ADaM)의 이해와 1상 임상시험 데이터에의 적용: 초급과정		임용진 전북대학교병원

CDISC is the Global Standard !!

At the end of 2019

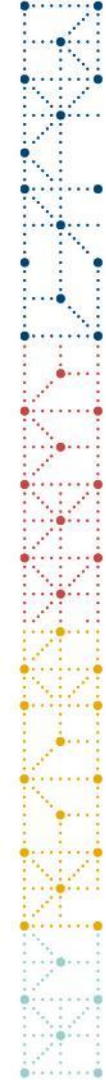


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



US FDA & Japan's PMDA Require CDISC Standards
China's NMPA and EU EMA Recommend CDISC Standards

Now ...



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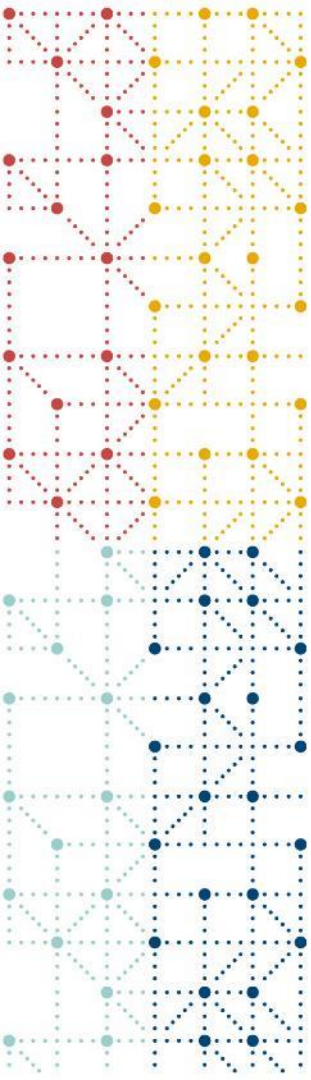
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 NanumSpace Industry Type: CRO Membership Level: Gold	 National Cancer Center Industry Type: Academic Institution Membership Level: Platinum December 2013	 National Cancer Institute Industry Type: Government Membership Level: Platinum January 2010
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Thank You!

cdisc