



# DECENT Initiative and Clinical Trial Management System at Seoul National University

ソウル大学におけるDECENT  
イニシアチブおよび臨床研究管理システム

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## Clinical Trials

- Not only during development, But also after marketing authorization
  - Not only for marking approval, but also for generating additional information
- Before marketing approval
  - Confirm safety and efficacy of drug for marketing approval from regulatory agencies
- After marketing approval
  - Generate labeling information (additional information) for optimal pharmacotherapy
    - e.g. renal impairment, ethnicity, genetic polymorphism
  - Generate safety/efficacy information of other indications

# Clinical Trials

Growth in Clinical Trials

Growth in Biopharmaceutical industry

- Improvement of domestic drug development
- Investment from global pharma companies
- Promotion/creation of employment (e.g. research coordinator)

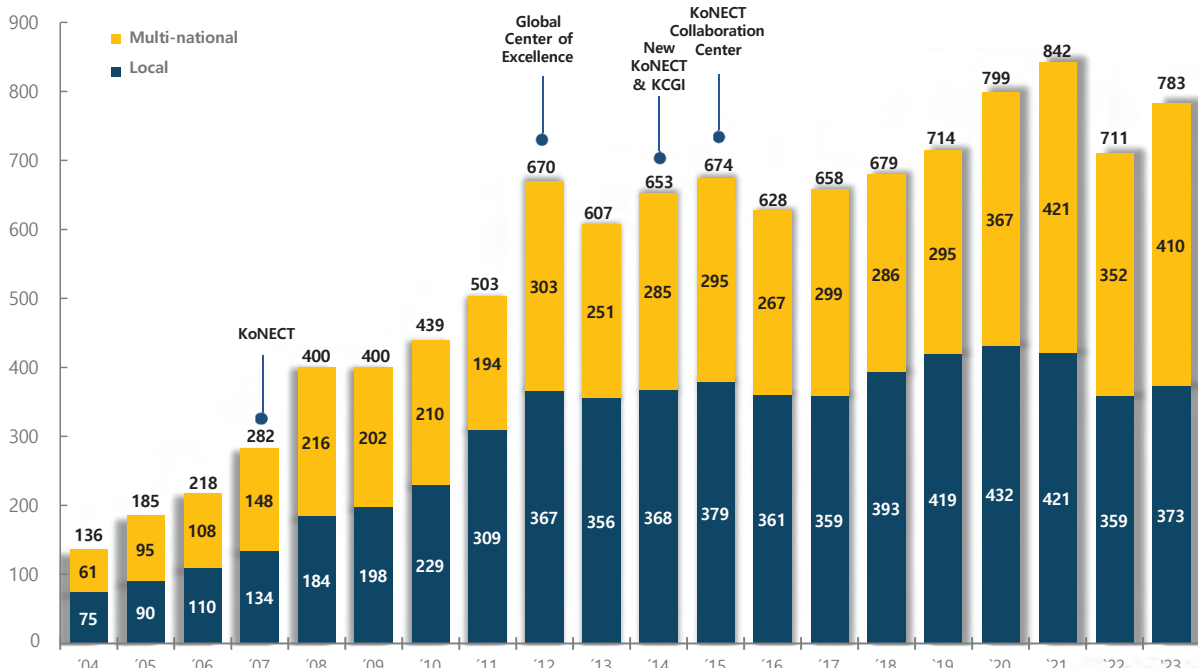
Improvement of Public health

- Earlier access to new treatments
- Availability for precision medicine
- Fostering Healthcare professionals



# Clinical Trials in Korea

- The number of clinical trials approved by MFDS

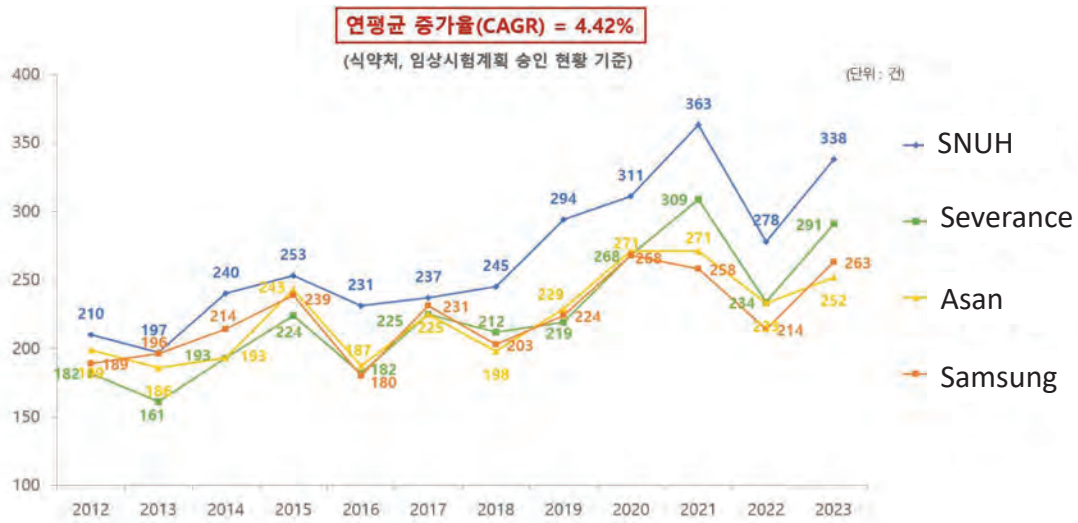


Source: MFDS 2024 media release. Modified by KoNECT

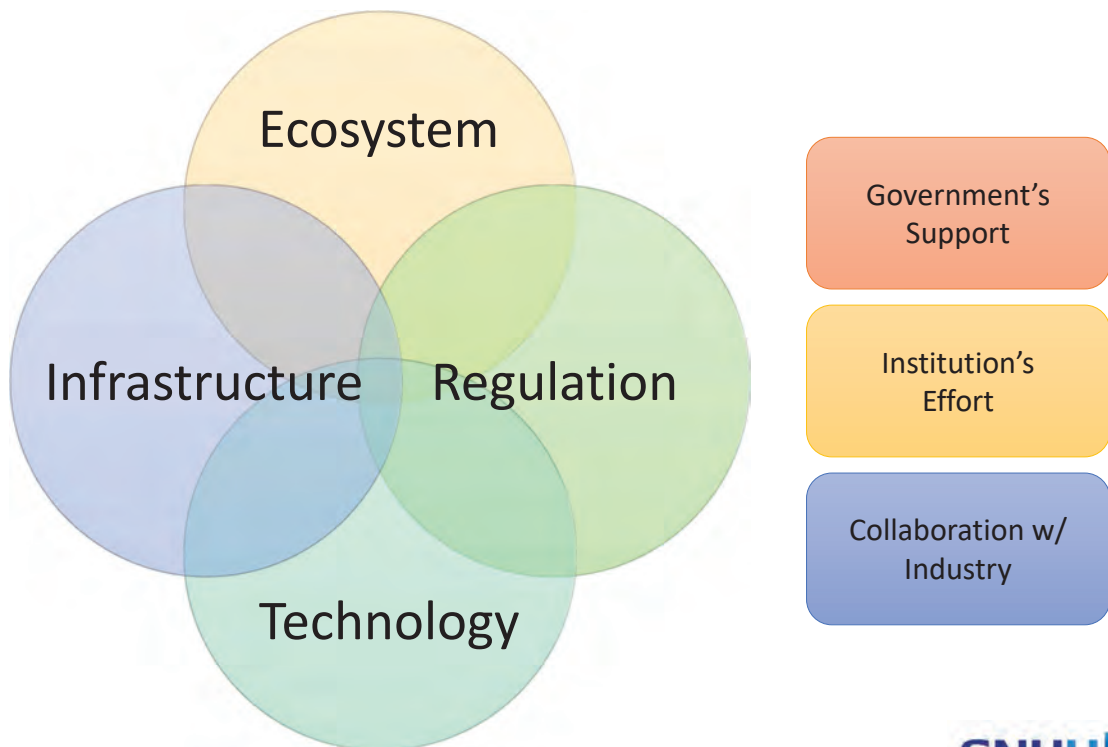


## Clinical Trials at SNUH

- The number of clinical trials at SNUH approved by MFDS



## How has SNUH grown clinical trials?



## Government Initiatives

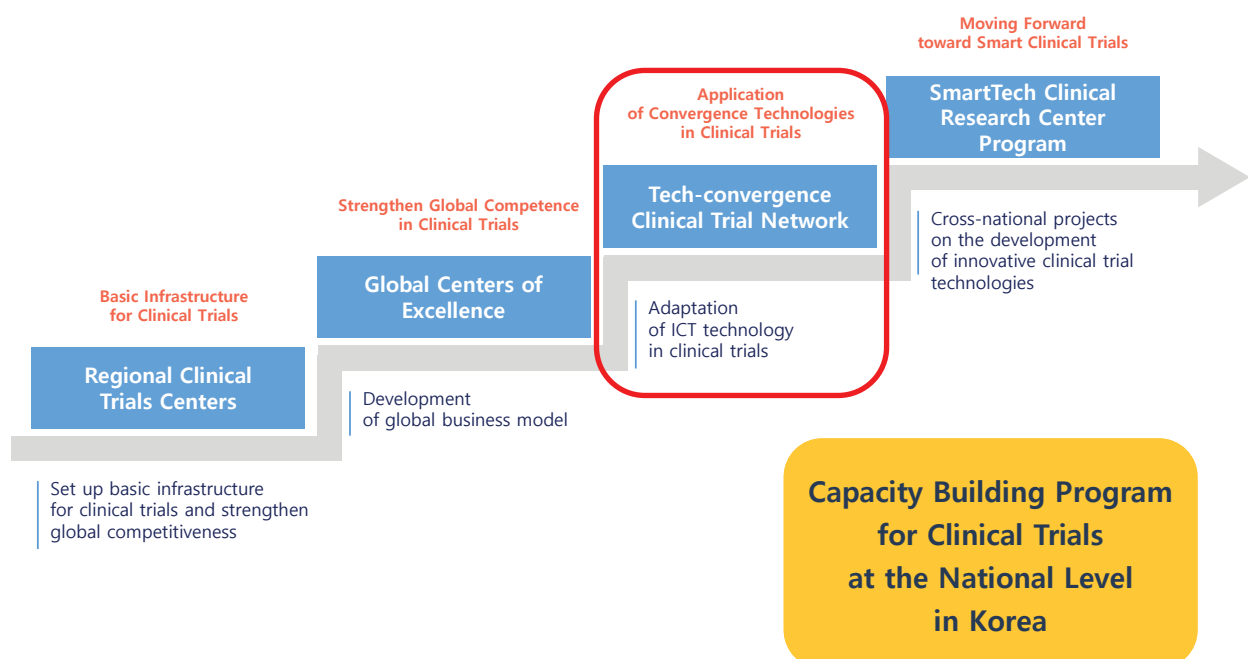
- Korea National Enterprise for Clinical Trials (KoNECT)
  - A non-profit organization funded by MOHW (Ministry of Health and Welfare) to advance and to promote the country's clinical trial capabilities
  - Established in 2007
- National program for establishment of clinical trials centers at academic institutions by KoNECT
  - Facilities and equipment
  - Human resources
  - Operational systems



<https://www.konect.or.kr>



## Government Initiatives



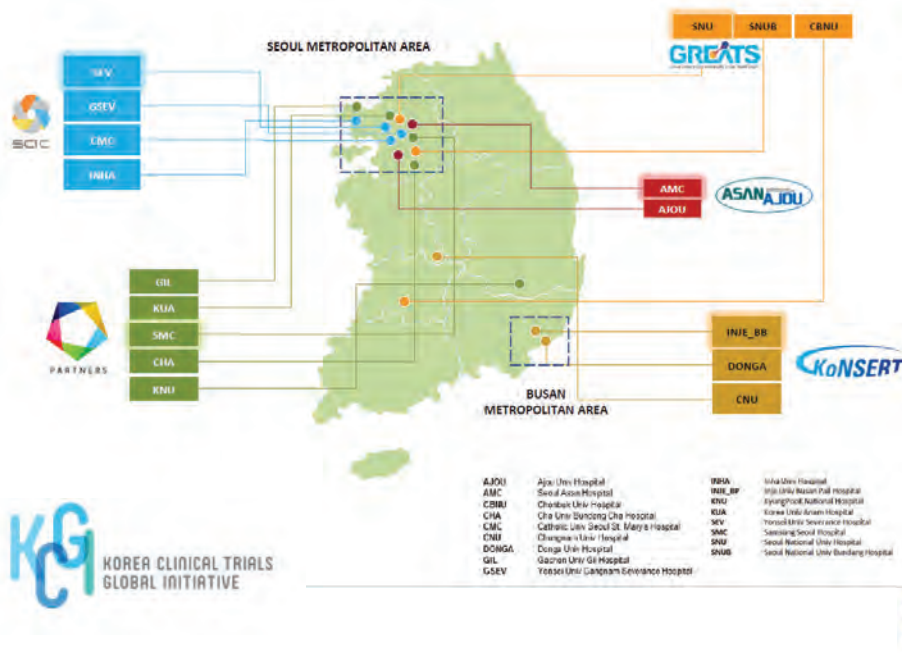
# Regional Clinical Trial Center Program

- Regional Clinical Trial Center Program (2004~ 2014)
  - Designate 15 institutions as 'Regional Clinical Trial Center'
    - 8 centers in Seoul metropolitan area & 7 centers in other regions
  - Support 4 million USD/center/5 years with hospital matching



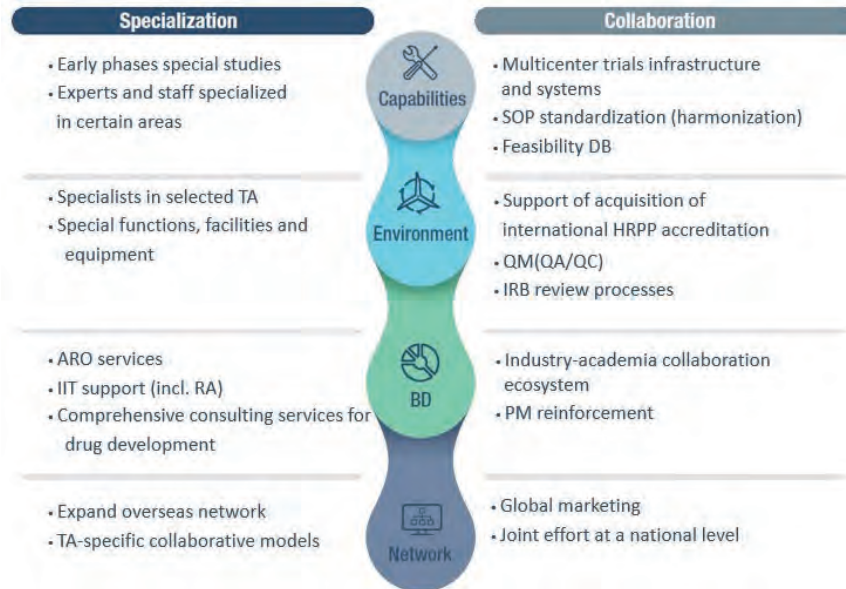
# Clinical Trial Global Centers of Excellence Program

- Clinical Trial Global Centers of Excellence Program (2014~2019)
  - Designate 5 Consortia as 'Global Clinical Trial Center'
  - Support 45 million USD to 5 Consortia



## Clinical Trial Global Centers of Excellence Program

- Clinical Trial Global Centers of Excellence Program (2014~2019)
  - Each consortium specializes in strengths
    - e.g. SNUH consortium -> Early phase clinical trials

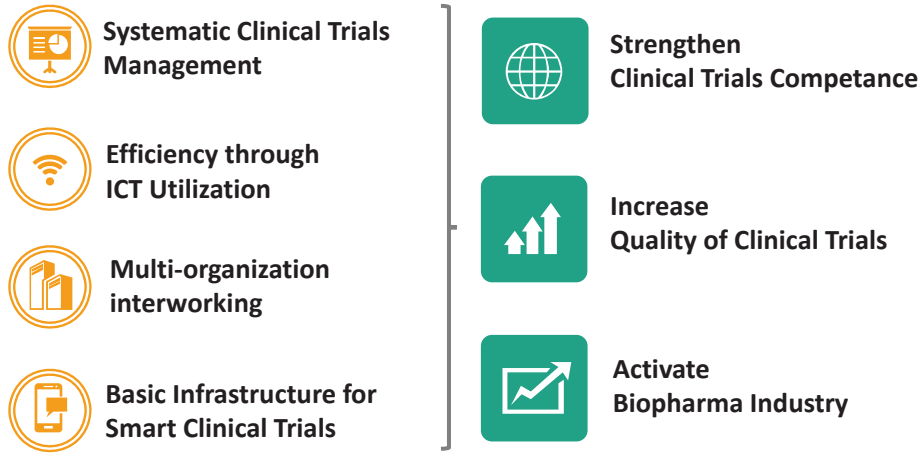


## Tech-convergence Clinical Trial Network

- Tech-convergence Clinical Trial Network (2019~2022)
  - A pilot program for SMART Clinical Trial Center Program
  - Focus on clinical trial technology using ICT
    - CTMS (Clinical Trial Management System)
    - e-consent
    - EDC – bed-side data capture
    - Mobile application for PRO
    - Wearable ECG
    - ...

# Clinical Trial Management System (CTMS)

- Background

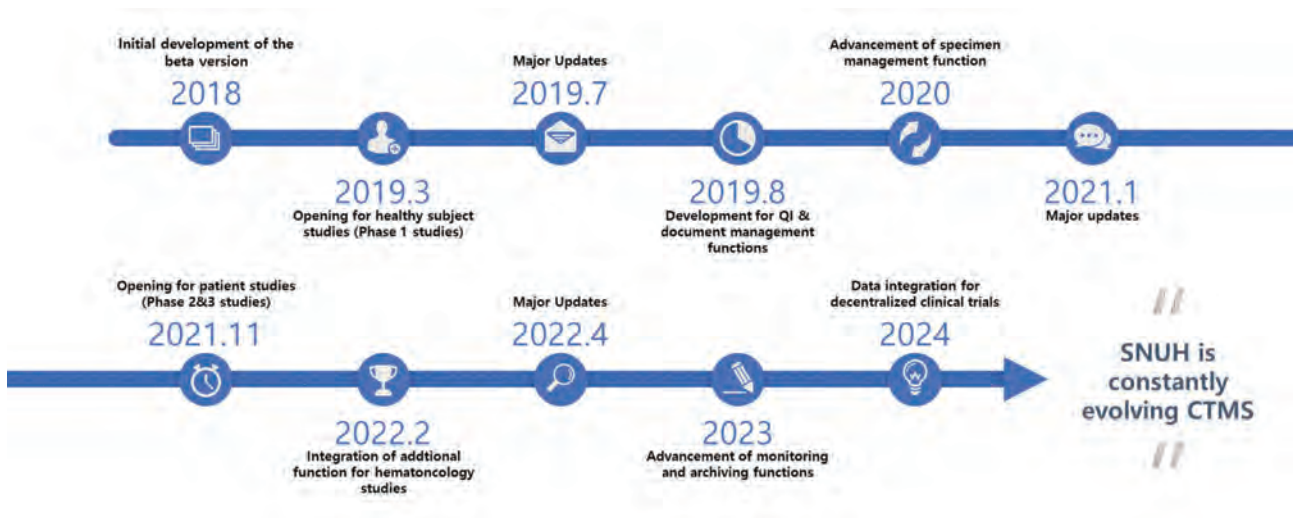


Development of clinical trial management system suitable for not only at SNUH but also other clinical trial centers in Korea



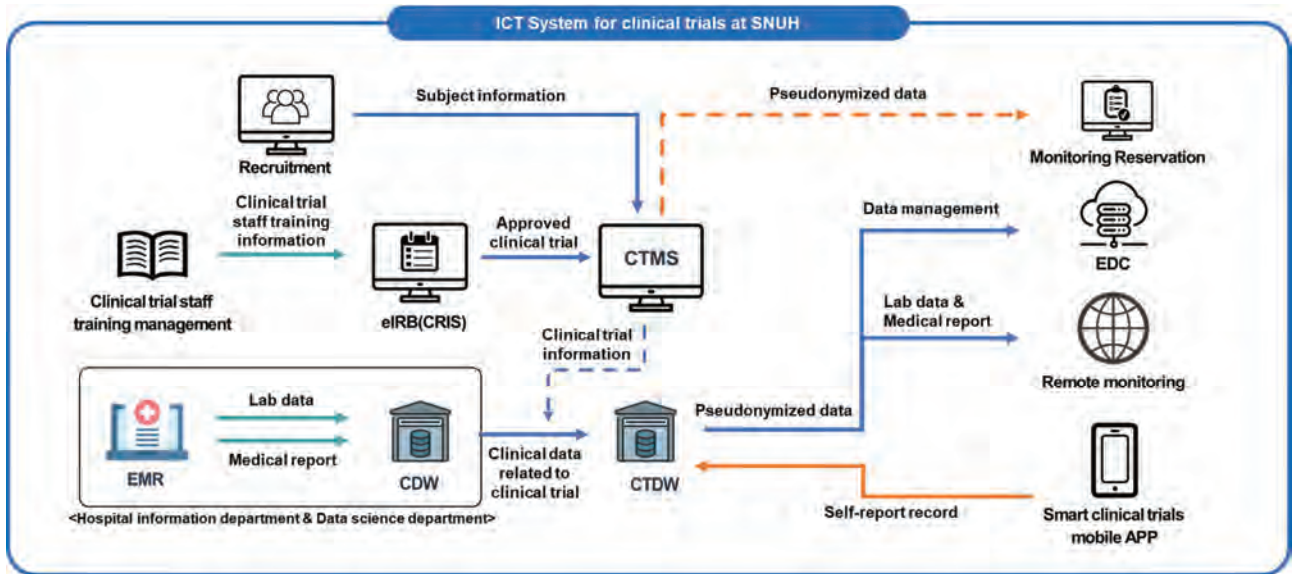
## CTMS

- Development History



# CTMS

- Architecture



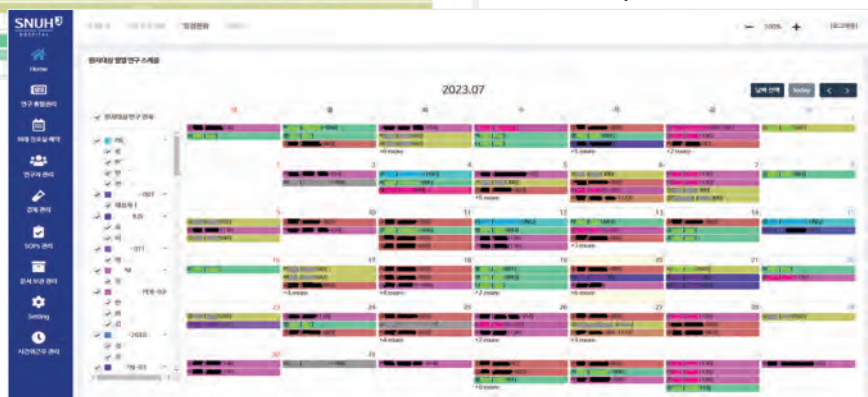
# CTMS

- Study schedule and Process management

< Early phase studies >

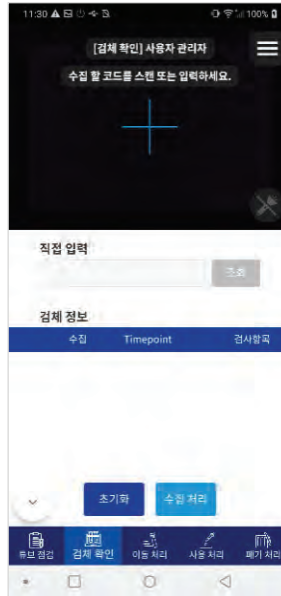


< Late phase studies >



# CTMS

- Sample(specimen) management
  - CTMS + Mobile application



Scan subject wristband label



Scan label on sample tube



# CTMS

- Special functions for oncology studies



# CTMS

- Workload management
  - Development of scorecard for each task

The screenshot displays the CTMS workload management interface. On the left, a table lists various tasks with columns for task ID, name, and status. On the right, a summary dashboard provides key metrics:

- 업무량수 (Task Volume):** 124,414
- 발문량수 (Question Volume):** 108,414
- 과제량수 (Assignment Volume):** 14.5
- Back-up:** 0
- RR Submission:** 0
- MFDS Submission:** 0
- Event:** 1.5

Below the summary, a table lists specific tasks with columns for task ID, name, and volume. Key tasks include:

- 06-2024-0780:** 48.9
- 06-2022-3060:** 6.9
- 06-2021-0670:** 21.567
- 06-2021-2390:** 11.057

# CTMS

- Document (SOP, Protocol...) management

The screenshot displays the CTMS document management interface. It shows details for a specific SOP and a list of other SOPs.

**SOP 문서 정보 (SOP Document Information):**

- 실분류 (Actual Classification):** GEN
- SOP 코드 (SOP Code):** SNUH\_CTC/GEN/GEN.0010
- SOP 제목 (SOP Title):** [Redacted]
- 등록일 (Registration Date):** 2021-04-12
- 등록자 (Registration User):** 0
- 효력상태 (Effective Status):** 유효 (Valid)
- 효력기간 (Effective Period):** 2023-05-26 ~ 2025-05-25
- 수정일 (Modification Date):** 2023-05-25
- 수정자 (Modification User):** [Redacted]

**SOP 문서이력 이력 (SOP Document History):**

버전 (Version)	이력 사유 (History Reason)	SOP 파일 (SOP File)	효력기간 (Effective Period)	상태 (Status)
13	관련규정 및 지침 4.3 최신의 개정사항 반영, 별첨 9.5(2)의 표준적업지침서 교육 기록 관련 문서의 부록코드 삽입 및 보란 경소-영향	[Redacted]	2023-05-26 ~ 2025-05-25	수정 (Modified)
12	경의 6.3 실 책임자에 CRC 운영팀과 행정팀 추가, 담당자 7(2) 행정관리실장-행정팀원) 용어 변경 및 CRC 운영팀장 추가, 별첨 9.1(12) CTMS 활용한 SOPs 초의 추가	[Redacted]	2021-05-28 ~ 2023-05-25	수정 (Modified)
11	본문 서식 표준화, 의약품 등의 안전에 관한 규정 개정으로 관련규정 및 지침 4.1 11 생활학적 동등성 시험에의 적용 식제, 6.5 임상시험 코드에의 적용 추가, 6.6 연구진보서 형식 수정, 7(4) 담당자에 임상시험 코드에의 적용 추가	[Redacted]	2020-01-01 ~ 2021-05-27	수정 (Modified)

**SOP 문서목록 이력 (SOP Document List History):**

SOP 버전 (SOP Version)	부록 번호 (Appendix No.)	부록 코드 (Appendix Code)	부록 제목 (Appendix Title)	부록 파일 (Appendix File)	효력기간 (Effective Period)	등록일 (Registration Date)
13	1	SNUH_CTC/GEN/GEN.0010-13/TEXT.001	표준적업지침서 작성서식	[Redacted]	2023-05-26 ~ 2025-05-25	2023-05-25
13	2	SNUH_CTC/GEN/GEN.0010-13/FORM.001	표준적업지침서로부하의 이력신청서	[Redacted]	2023-05-26 ~ 2025-05-25	2023-05-25
13	3	SNUH_CTC/GEN/GEN.0010-13/FORM.002	표준적업지침서 개정기록	[Redacted]	2023-05-26 ~ 2025-05-25	2023-05-25

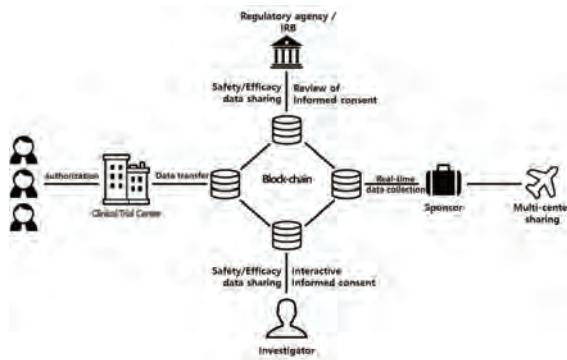
# CTMS

- Archiving room management

The screenshot displays the '연구문서 목록' (Research Document List) and '연구문서 상세조회' (Research Document Detailed View) screens. The list screen shows columns for document ID, date, investigator, and status. The detailed view screen shows a list of related documents with columns for document ID, date, investigator, and status.

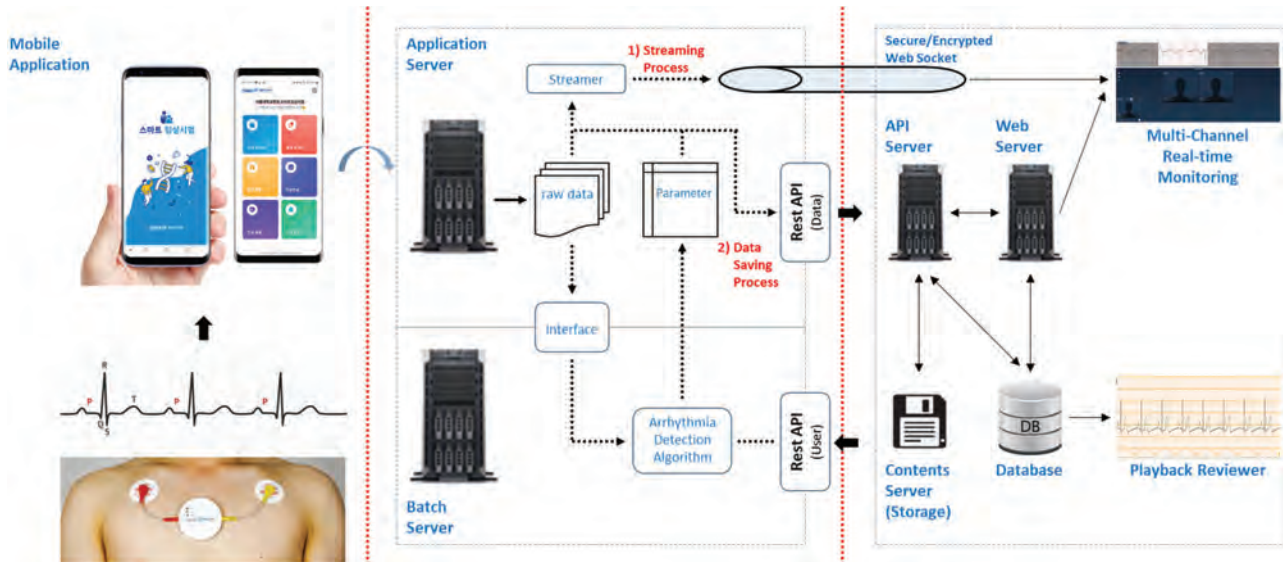
# eConsent System

- Blockchain-based Dynamic Consent
  - Interactive e-consent platform + Blockchain-based archiving system



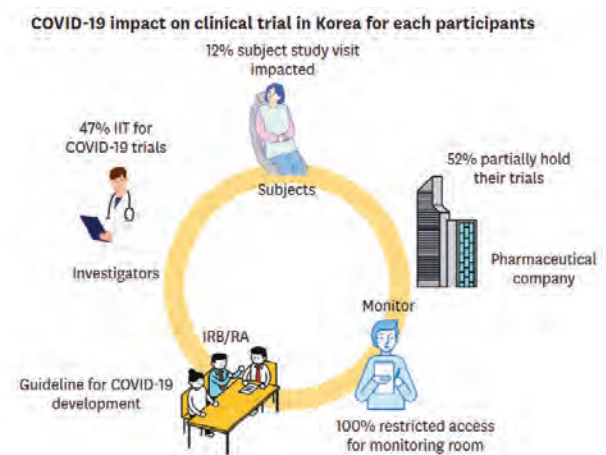
# Remote Patient Monitoring System

- Monitoring with Wearable/Mobile devices
  - Continuous cardiovascular safety monitoring & data collection



# Strong impact of COVID-19 on Clinical Trials

- Impact of COVID-19 on clinical trials
  - More than 60% of clinical trial milestones were affected
  - 52% of clinical trials were suspended
  - Clinical trial monitoring was virtually impossible
- Increased need for non-face-to-face clinical trial methods
  - Remote monitoring
  - Telemedicine
  - Direct-to-patient shipping (IPs, study materials)

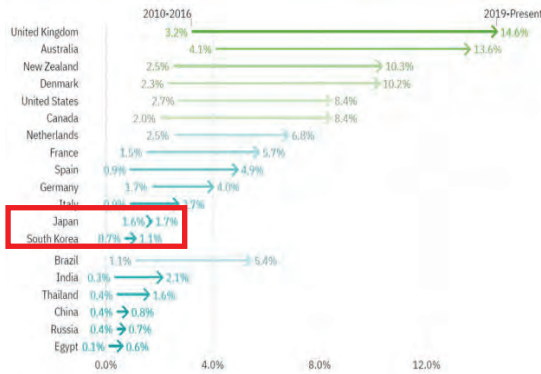


Jeon et al., J Korean Med Sci. 2020 Sep 14;35(36):e329.

# Global Trend in DCTs

- Relatively less active in DCTs compared to Western countries

\*Percentage of trials involving DCT elements in single-center trials



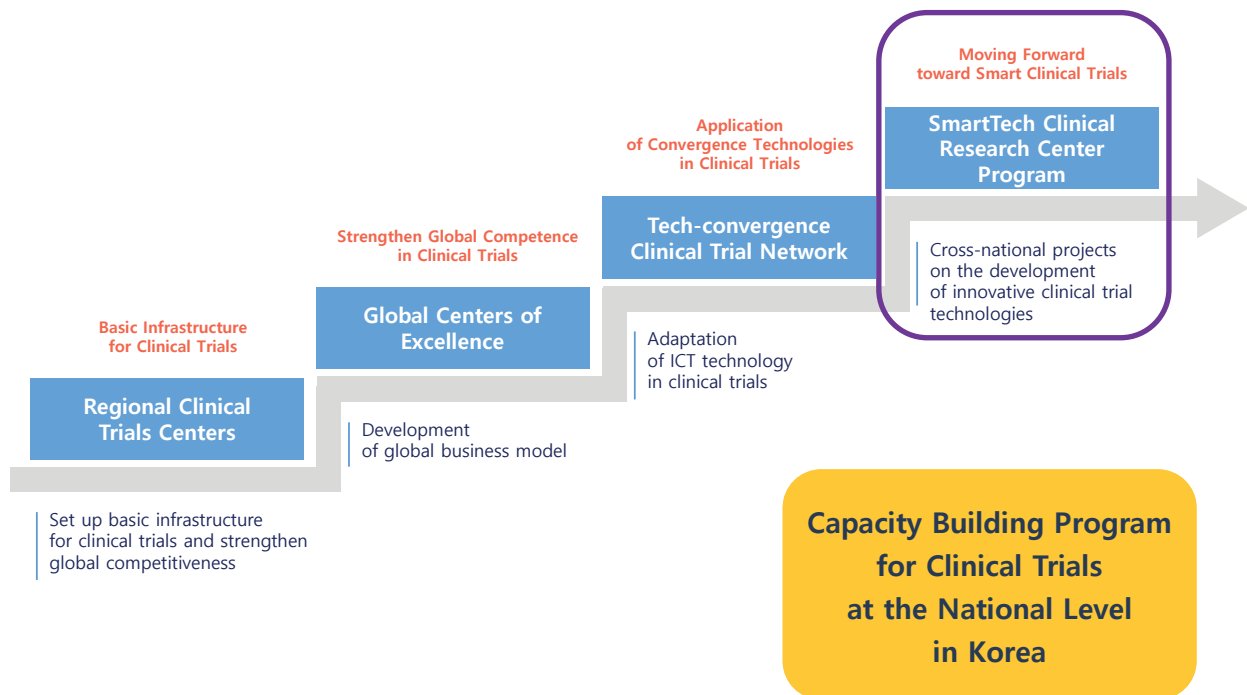
\*Percentage of trials involving DCT elements in multi-center trials



ClinicalTrialsArena Analysis. (<https://www.clinicaltrialsarena.com/analysis/dct-adoption-tracker-who-and-what-is-at-the-crest-of-the-trial-decentralisation-wave/#>)

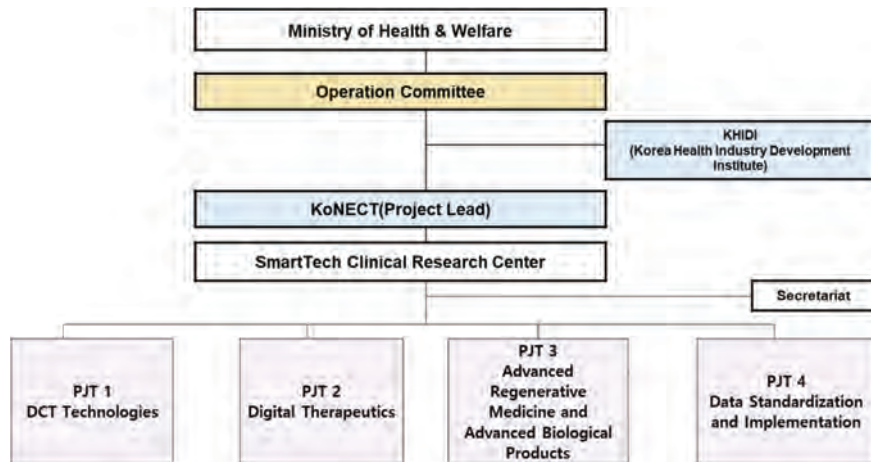


# Government Initiatives



## SmartTech Clinical Research Center Program

- SmartTech Clinical Research Center Program (2023~2027)
  - Support new drug development through cross-national research projects on the development of innovative technologies for clinical trials
  - DCT / Digital therapeutics / Innovative drug development / RWE
  - 20 million USD/year for 5 years



## SmartTech Clinical Research Center Program

- SmartTech Clinical Research Center Program (2023~2027)

### PJT1. DCT Technologies

- Development of the nationwide decentralized clinical trial technologies including remote monitoring platform

### PJT2. Digital Therapeutics

- Development of Clinical Trial Technology for DTx for Neuropsychiatric and Physical Disease

### PJT3. Advanced Regenerative Medicine and Advanced Biological Products

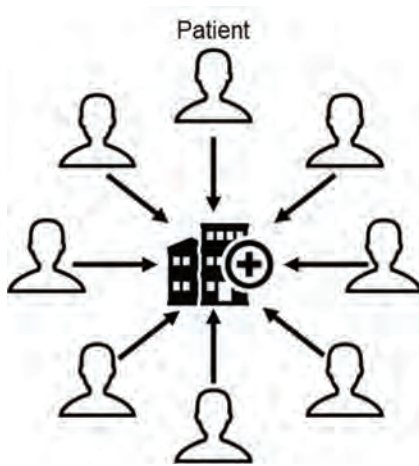
- Development of technologies regarding early clinical trials in the field of advanced biotechnology

### PJT4. Data Standardization and Implementation

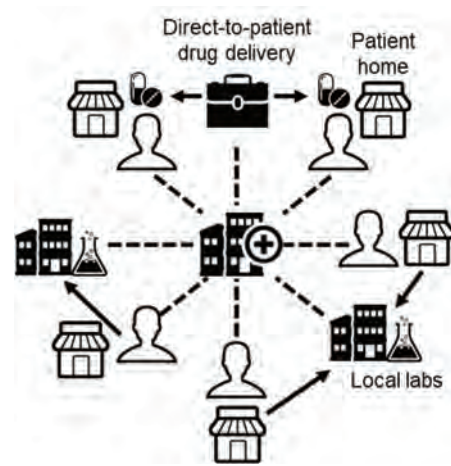
- Development of data-based clinical trial design platform through CDMCDISC-based model

# Decentralized Clinical Trials (DCTs)

- Centralized -> Decentralized



Centralized clinical trial  
(Traditional)



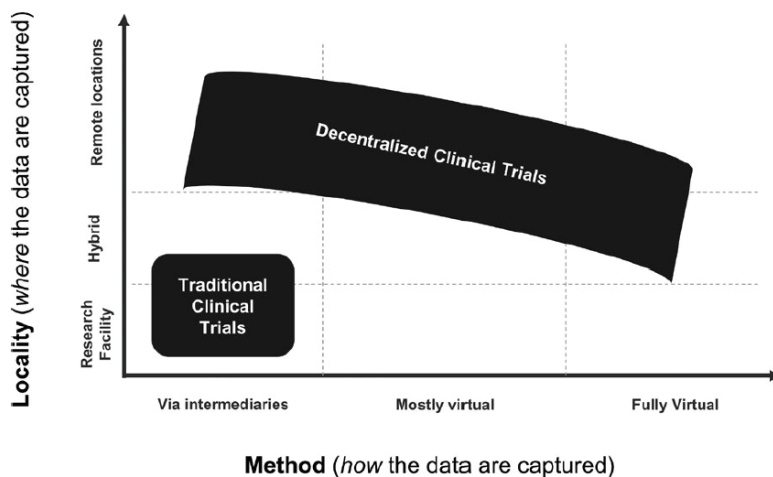
Decentralized clinical trial  
(Innovative)

- Locality: less operational dependency on specific sites
- Methods: less dependency on data collection via intermediaries



## DCTs

- Locality
  - Remote trials / Direct-to-patient trials / Patient-centric trials
- Methods
  - Virtual clinical trials / Digital clinical trials / Smart clinical trials

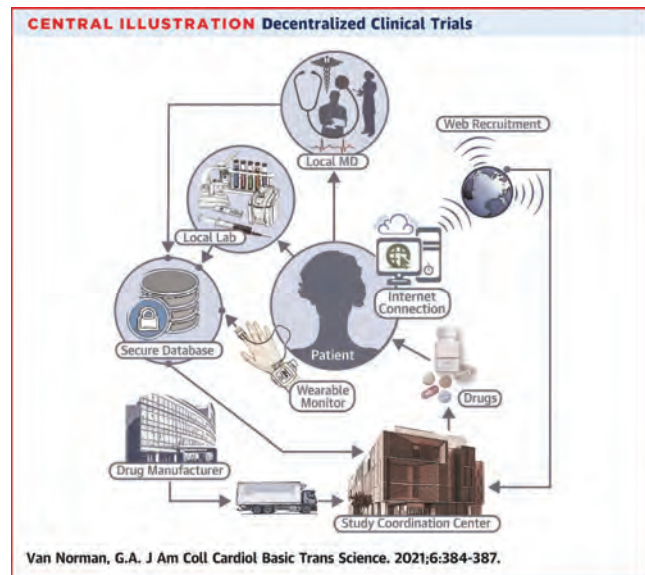


Method (how the data are captured)



## Components of DCT

- Web-based recruitment
- Electronic consents
- Direct-to-patient shipping
- Telemedicine
- Digital data collection tools
- Electronic data capture
- Remote trial/data monitoring
- Local labs
- Home visits

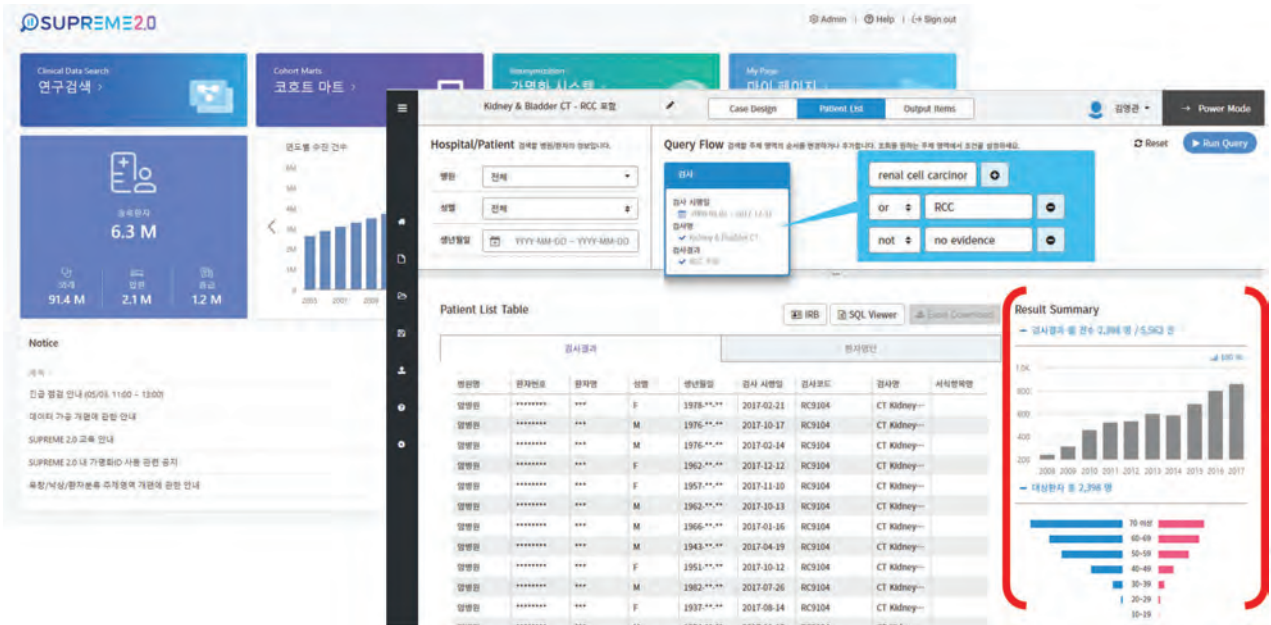


## Core components for DCTs

- ICT infrastructure
- Early technology development & adoption of hospitals and research staffs
- Privacy (personal health information) protection
- Regulatory barriers
- Advocacy groups' interest
- Cost-effectiveness

# ICT infrastructure at SNUH

- Clinical Data Warehouse (CDW)
  - SUPREME: Seoul National University Hospital Patients Research EnvironMent
  - Use RWD/RWE for various research



# ICT infrastructure at SNUH

- Use CDW
  - For feasibility assessment of clinical trials
  - For single-arm trial (Historical control / Synthetic control)

## ❖ Search in SUPREME

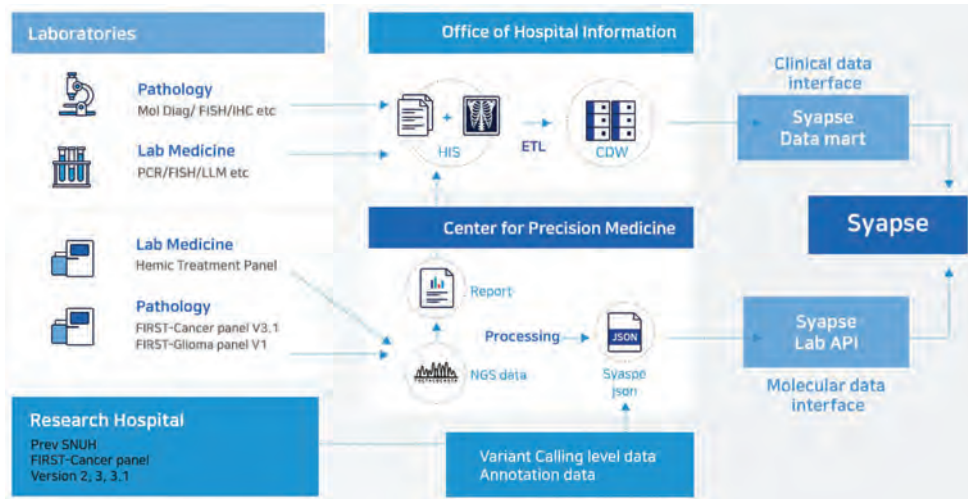


## ❖ Result of feasibility

easibility conditions	patient number
Patients with Type 2 DM and Heart failure whose plasma B-type natriuretic peptide (BNP) $\geq$ 150 pg/ml or NT-terminal (NT-proBNP) $\geq$ 600 pg/ml (Ejection fraction $\leq$ 40% was not screened)	137
Exclude patients who received Angiotensin Converting Enzyme inhibitor (ACE-i), or Angiotensin Receptor Blocker (ARB), beta-blocker, and diuretic for at least 4 weeks	52
Exclude patients whose FPG $>$ 15.0 mmol/L ( $>$ 270 mg/dL)	52
Exclude patients with diabetic ketoacidosis, nonketotic hyperosmolar coma, hypoglycemia, stroke, hypotension, chronic pancreatitis, inflammatory bowel disease	47
Exclude patients with severe renal disease as defined by eGFR $<$ 30 ml/min/1.73 m <sup>2</sup>	41
Exclude patients whose ALT or AST $>$ 2 times the upper limit of ULN or Total bilirubin $>$ 1.5 times the NLN or Amylase and/or lipase $>$ 3 times the ULN	7

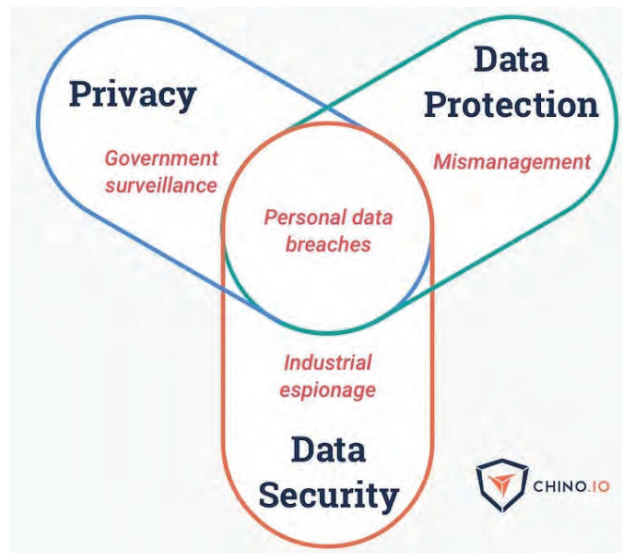
## Early technology development & adoption at SNUH

- Key point of early technology development
  - Governance + Open mind + Scientific interest
- Experience of Syapse (Amazon AWS Cloud Seoul Region)



## Privacy Protection at SNUH

- High level security system
  - Annual audit & inspection by government (Ministry of education, National Intelligence Service...)
- Data Review Board (DRB)



<https://towardsdatascience.com/go-secure-yourself-data-protection-and-data-security-for-digital-health-192f886bb145>

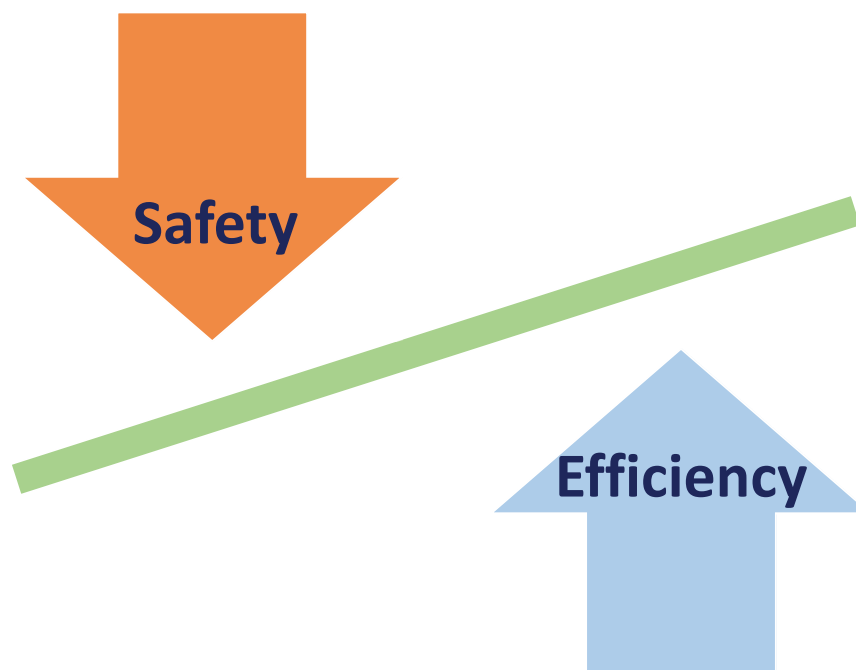


## Regulatory barriers

- Relatively slow change of regulations compared to technical advancement
  - e.g. Home nursing in Korean regulation
    - Nurses who provide home nursing must be professional home nurses in accordance with the “Rules on Recognition of Professional Nurse Qualifications”
    - The professional nurse training course is conducted by a professional nurse training institution designated by the Minister of Health and Welfare, and the training period is at least 2 years.
    - Those who can apply for a professional nurse training course must have at least 3 years of practical experience as a nurse within 10 years prior to receiving training.

## Regulatory barriers

- Safety concerns



## Advocacy groups' interest

- Medical specialist's society
  - Doctors, Nurses, Pharmacists
- Patients' organization
- ICT companies association

약사회, "약배송 담은 약사법 개정 즉각 폐지"

문윤희 기자 | 승인 2022.08.30 13:39 | 댓글 0

'비대면 진료 제도화' 정부 과제 포함에 "심각한 유감"  
"공공심야약국·공공병원 등 대면 중심 의료 확충 나서야"



## Cost-effectiveness

- Is DCT really cost-effective?



- Convenience in patients
- Reduce the cost for investigator/institution



- Inconvenience in staffs (additional education/training)
- Increase the cost for DCT platform/system

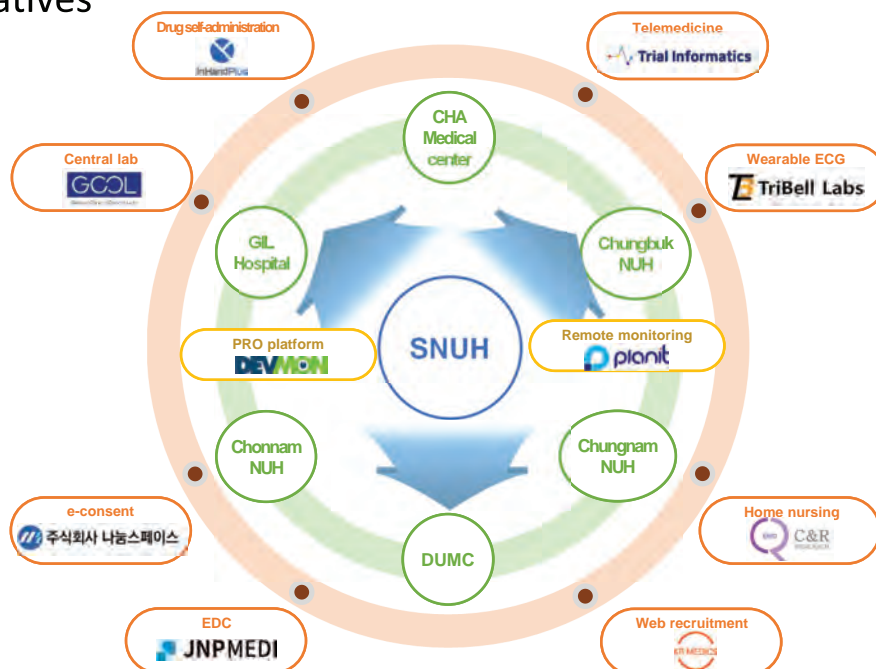
## DCTs in Korea

- Collaboration among government, academia & industry
- Two-track approach
  - Technological advancement & implementation
    - **DECNT Initiative** (2023~)
    - Lead by Ministry of Health & Welfare (KoNECT)
  - Regulatory Innovation
    - **ARICTT** (Advanced Regulatory Innovation for Clinical Trials Transformation) **Program** (2022~2024)
    - Lead by Ministry of Food and Drug Safety (+ Ministry of Health & Welfare)



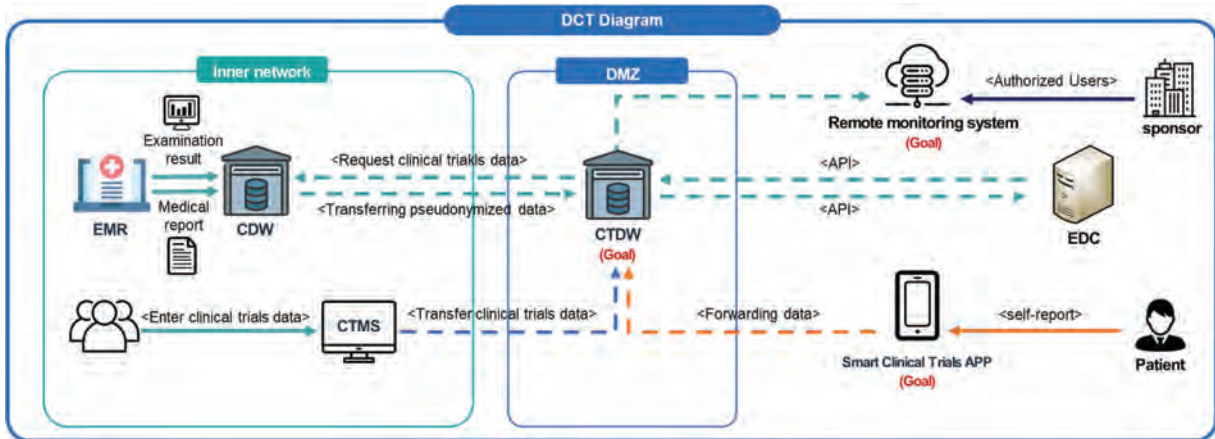
## DECENT Initiative

- DECENT(**D**evelopment of the nationwide **dE**centralized **C**linical trial **tE**chnologies including remote mo**N**itoring pla**T**form) Initiatives



# DECENT Initiative

- Development of the institution's own DCT platform
  - Clinical Trial Data Warehouse (CTDW) + Remote data monitoring system



# DECENT Initiative

- Clinical Trial Data Warehouse (CTDW)
  - Data from participants ONLY
  - Data is transferred from CDW by CTMS' call



연구번호	연구기간	대상자 수	연구목적
연구번호: 2402-085-1512	연구기간: 2024-05-10 - 2024-09-05	대상자 수: 8	연구목적: ...
연구번호: 2403-093-1519	연구기간: 2024-05-07 - 2024-10-21	대상자 수: 24	연구목적: ...
연구번호: 2402-112-1514	연구기간: 2024-07-09 - 2025-10-05	대상자 수: 8	연구목적: ...
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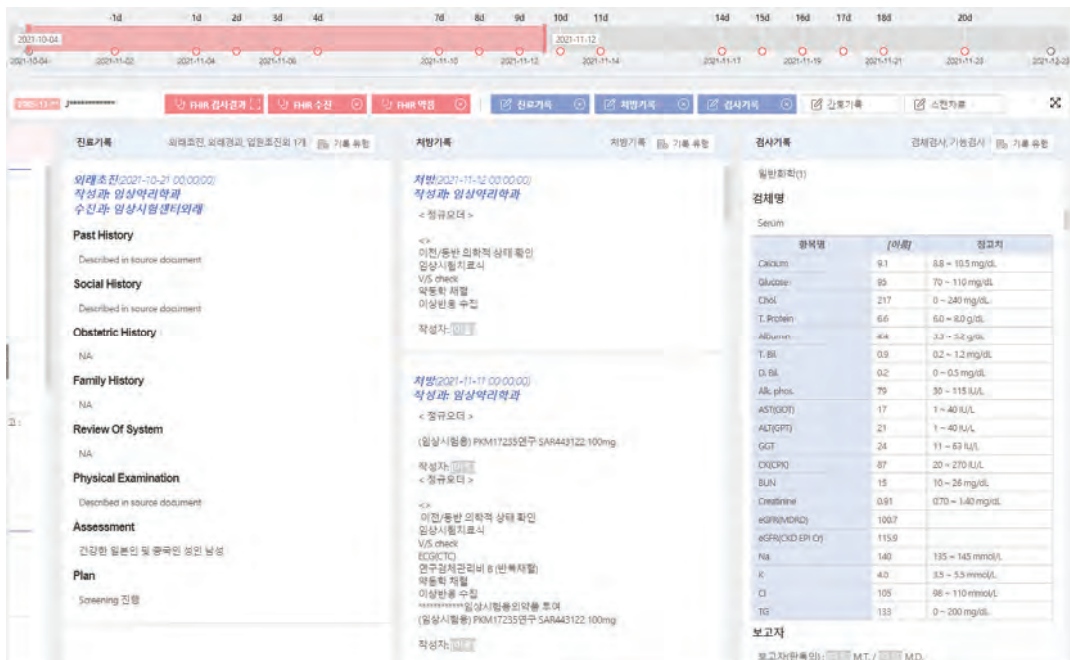
# DECENT Initiative

- Clinical Trial Data Warehouse (CTDW)



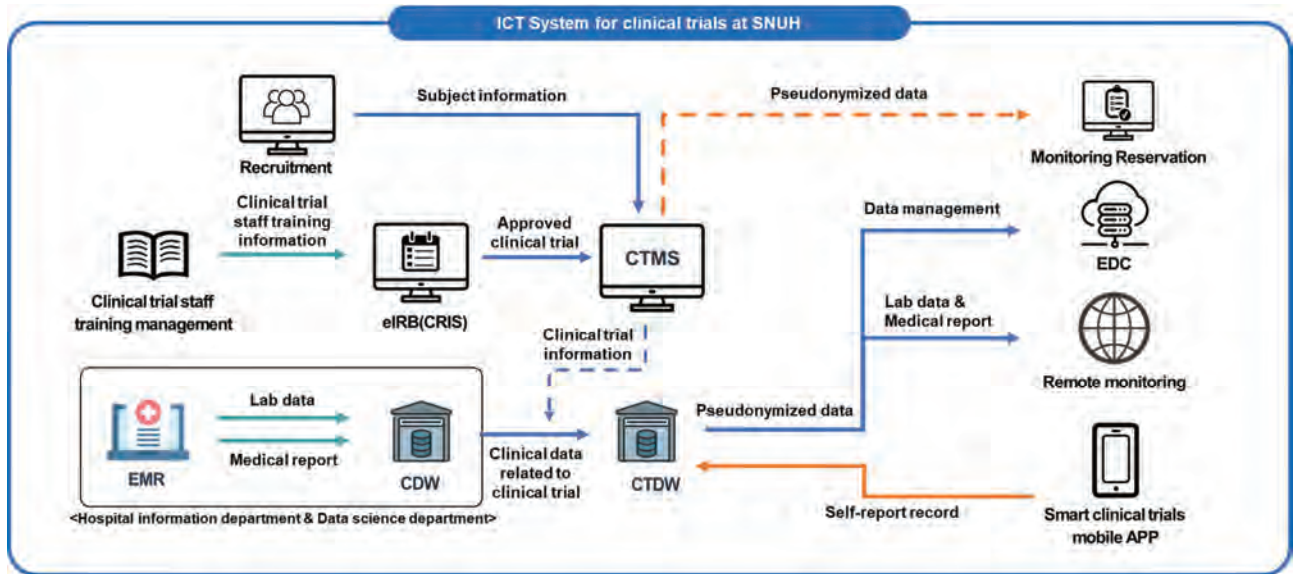
# DECENT Initiative

- Clinical Trial Data Warehouse (CTDW)



# ICT system for Clinical Trials at SNUH

- CTMS + CTDW



Thank you