Patient-centric Solution | Patient-oriented Clinical service

Decentralized Service
Patient-centric Clinical trial
Centralized Monitoring
Clinical Trial Data Curation

Our Mission

01 Company History

02 Organization

03 Management Principles

04 Business Contents

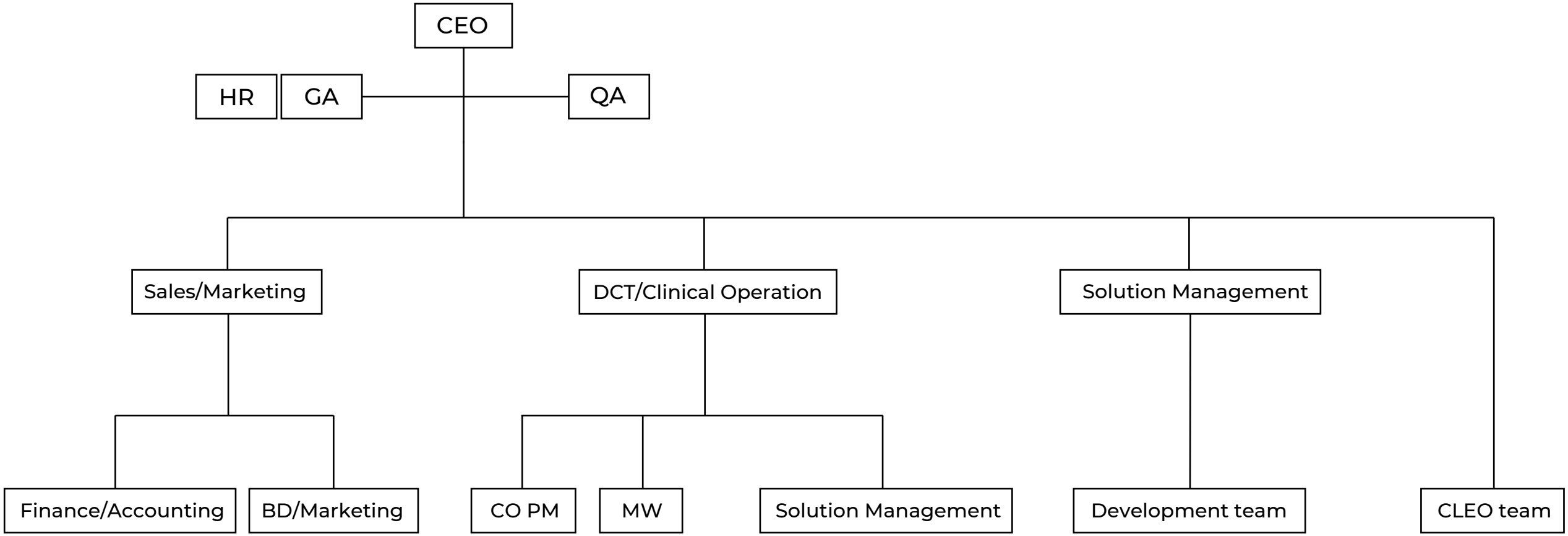
01 Company History

SPERO

SPERO is a clinical trial service company providing the total solution for Decentralized Clinical Trials (DCT)

2021.08	Started CLEO (Patient recruitment service For bioequivalence study)
2021.09	Opened patient recruit web-site, ‘CLEO’
2021.10	Expanded business to DCT (Decentralized Clinical Trial) and changed Company name to SPERO Inc.
2022.04	Introduced DCT eClinical solutions from CRScube (DDC, eConsent, ePRO)
2022.07	Launched a centralized monitoring solution, ‘VIA’ official service
2022.11	cubeDDC 1.0 : won its first overseas license contract
2022.12	cubeCONSENT 3.0 & VIA : won its first domestic license contract
2023	Patient Recruit Service ‘MediCLEO’ official launch (under preparation)

03 Organization



04 Management Principles

GOAL

Better opportunities for All Patient

(Aiming to provide better clinical trials with DCT)

SPERO leads the innovation of patient-centric clinical trials and strives to develop clinical environment in which all participants are happy with the goal of optimizing clinical trial design and operation

MISSION

Be the difference

(Presenting a new patient-centered digital clinical trial paradigm)

SPERO aims to offer a comprehensive customer solution proposal focused on the clinical trials differentiated from traditional processes, challenges new technology development and operational design.

VISION

Patient Centricity

(Patient-oriented clinical service, Patient-centric solution)

SPERO presents a patient-oriented DCT ecosystem and a growth vision as a global company.

04 Business Contents

01

Clinical Dev. service

- Clinical operation
  - Study Start-up
  - Project Management
  - Site Management
  - Medical writing
    (Protocol Development)
    (ICF Development)
    (CSR writing)
  - DM & STAT

02

Pre-screening / Patient Recruitment service (web/mobile)

- MediCLEO

03

DCT Study design, Operation and Technical evaluation

04

Development of DCT products and Service operation support

- Vendor-licensed products
  - eConsent, ePRO
- Co-developed products
  - Centralized Monitoring
- Related e-Clinical solution service
  - eSource Direct Data Capture

WHY

01 The need for DCT

02 Market status of DCT

03 SPERO DCT service

04 eClinical Solution

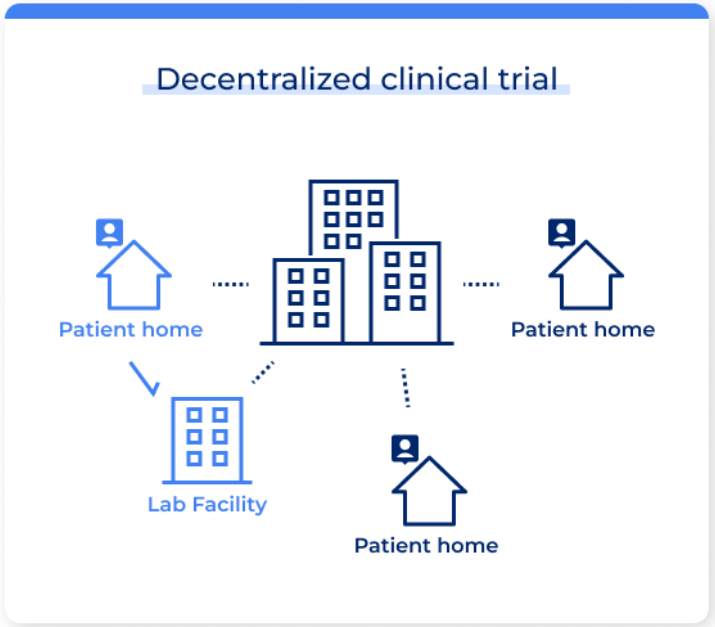
05 Customer value

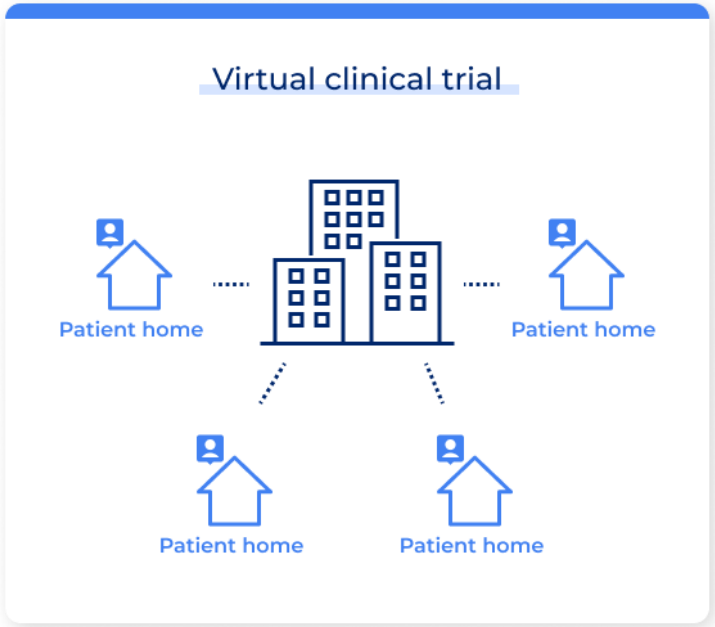
06 Key personnel & Core technology

01 The need for DCT

Definition of Decentralized Clinical Trials

- To accelerate the development of new drugs and new medical devices, decentralized clinical trials are conducted through reflection of subjects' opinions, optimization of digital health technology, and collaboration with clinical trial sites
- Decentralized clinical trials are operated through patient-centered remote operations differentiated from the traditional on-site process, in terms of its participation and operation such as patient engagement and data management

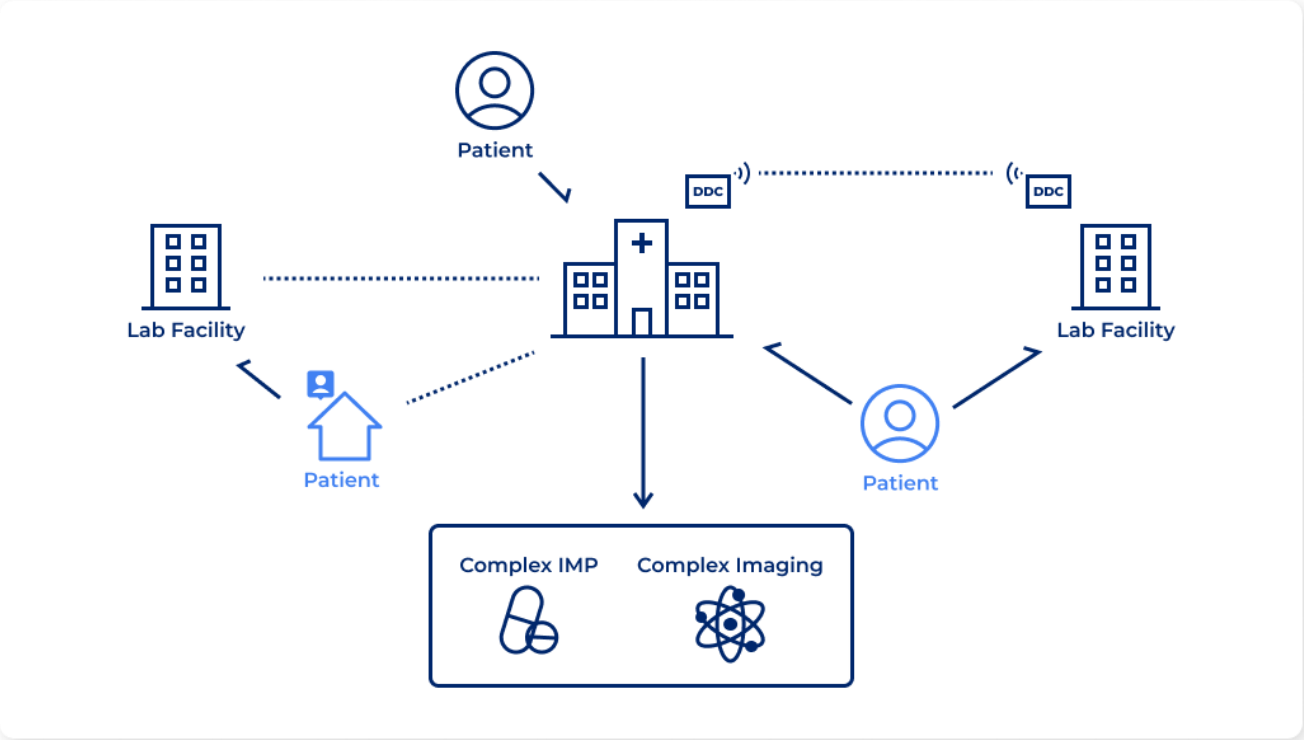




01 The need for DCT

Hybrid Decentralized Clinical Trials

- Customized service that takes into account the operational environment of each clinical trial, in the form of a combination of conventional process and decentralized clinical trial methods.
- If strict management of investigational medicinal products and some tests that are difficult to do at patient's home or at a local facility are required, on-site visit can be used together.



01 The need for DCT

Flexible operation of clinical trials

Traditional clinical trials are designed centering around clinical sites, and the recruitment of patients is also progressed leading by sites

The geographical location and distance from the clinical sites are the most important factors in determining applicants' participation in clinical trials, increasing accessibility difference among potential participants and limiting their diversity

Improved Patient recruitment and retention

Approximately 85% of clinical trials worldwide fail to recruit and retain sufficient subjects at the enrollment timeline

Lack of guidance and motivation to retain subjects until the end of clinical trials, and underrepresentation of critical demographic groups

Enhanced data diversity and reliability

Existing site-centered clinical trials collect subject data at a specific point of time in the day, on a specific day during a month, and have an typical operational pattern dependent on the number of visits

Temporal-spatial constraints and limitations of data collection

Improve operational efficiency and reduce Cost of clinical trials

Traditional clinical trials have procedural inefficiencies such as data re-entry (Transcription) and on-site monitoring-based SDV process

Increased time and cost burden for clinical data collection and clinical trial operation

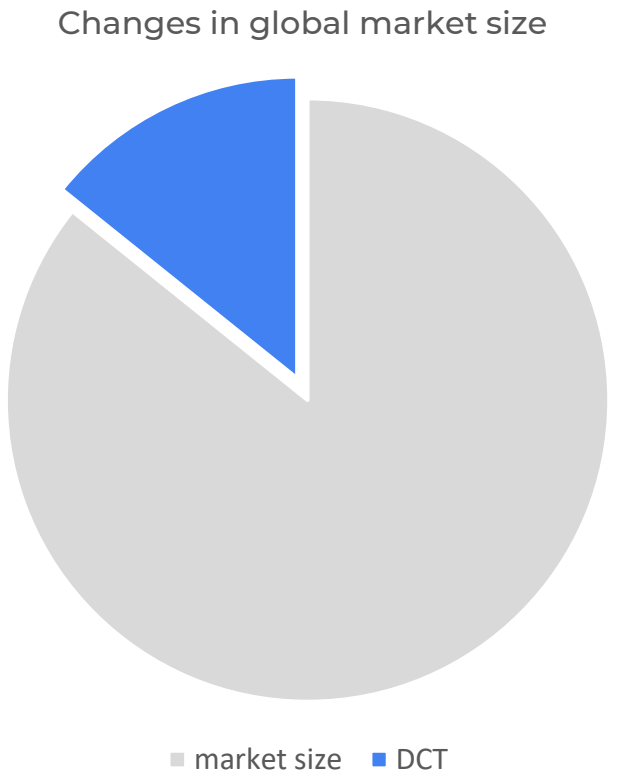
02 Market status of DCT

Changes in global market size of decentralized clinical trials

- 2021 Global DCT Market Size : $7.8B
  / $47B (total global clinical trial market size)
- Market Size by Region : US $3.5B
- ~2030 Global Market CAGR Forecast: 5.7% to 14.8%
- Market Distribution by TA : Oncology (25.2%) > Cardiovascular > Other (2021)

Market Trends

- Increasing number of infectious disease-related non-face-to-face clinical trials due to COVID-19:
  - Increased use of telemedicine and patient engagement solution, mobile health & home nursing service, and electronic consent forms
- Phase III > Phase II (Phase trend)
  - Phase II studies scaled to Phase III with sensor/device digital data collection and remote monitoring increased



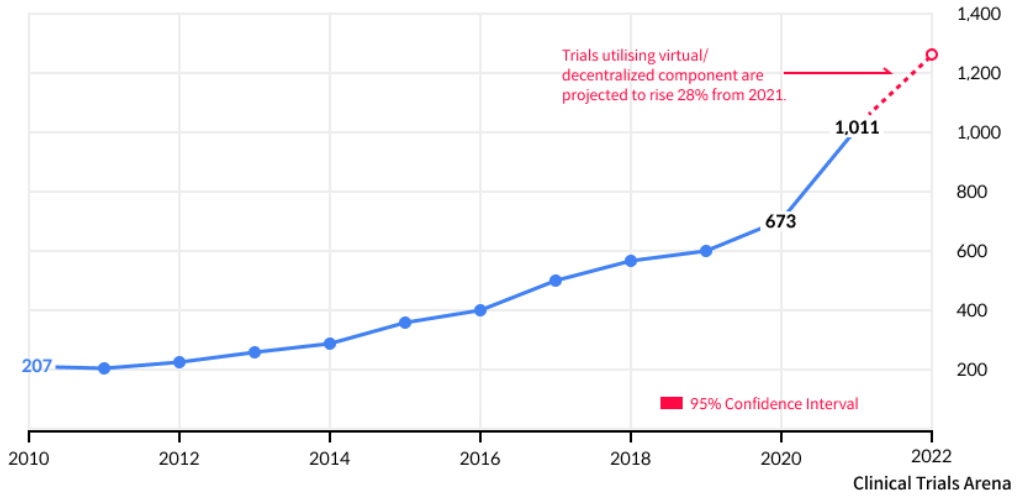
02 Market status of DCT

Changes by decentralized clinical trials components

- Digital Data Collection : Operated in 300 studies (2021,the data below are same)
- Remote Monitoring : 250 studies
- eConsent, ePRO, eCOA : 460% increase in eConsent and 448% increase in ePRO compared to be
- Site : About 50 studies of DtP(Direct to Patient) and home nursing
- Telemedicine : non-face-to-face medical solution, 450 studies (largest)
- Case : Moderna Spikevax COVID-19 Vaccine
  - Early patient recruitment and early vaccine development using e-clinical solutions such as EDC, eCOA, CSA(Central Statistical Analytics: monitoring solution)

Present state of Korean market

- Under the Covid-19 pandemic, the ratio of decentralized clinical trials among domestic and multinational clinical trials conducted over the past two years is 1.2 percent and 6.4percent, respectively, which is lower than that of OECD countries.
- Regulatory constraints on telemedicine, lack of home-based healthcare and clinical infrastructure
- The government TF team for DCT was organized and government sponsored projects are going on led by KoNECT(Korean National Enterprise for Clinical Trials)



2022, KoNECT

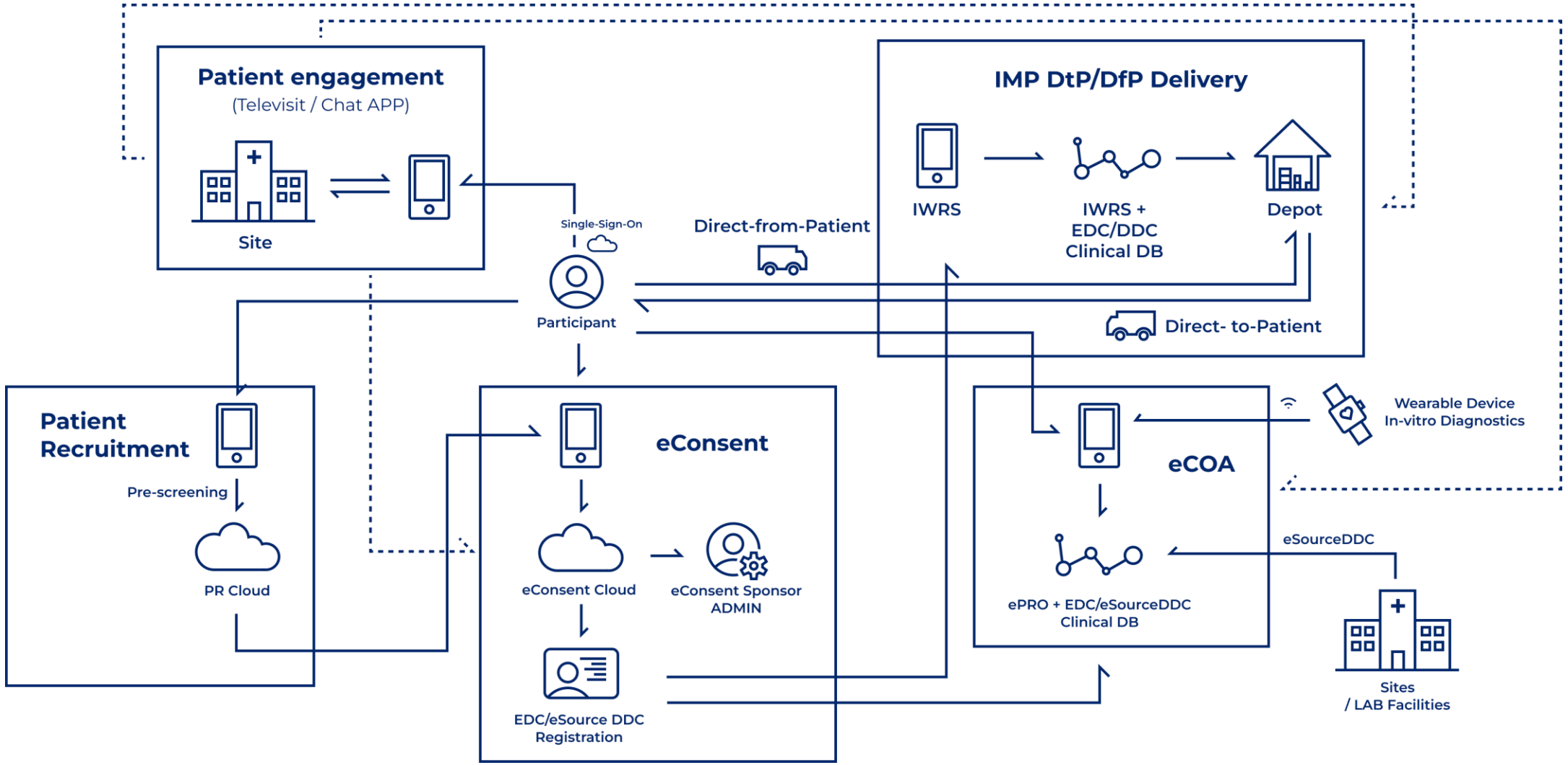
03 SPERO DCT Service

SPERO DCT Service

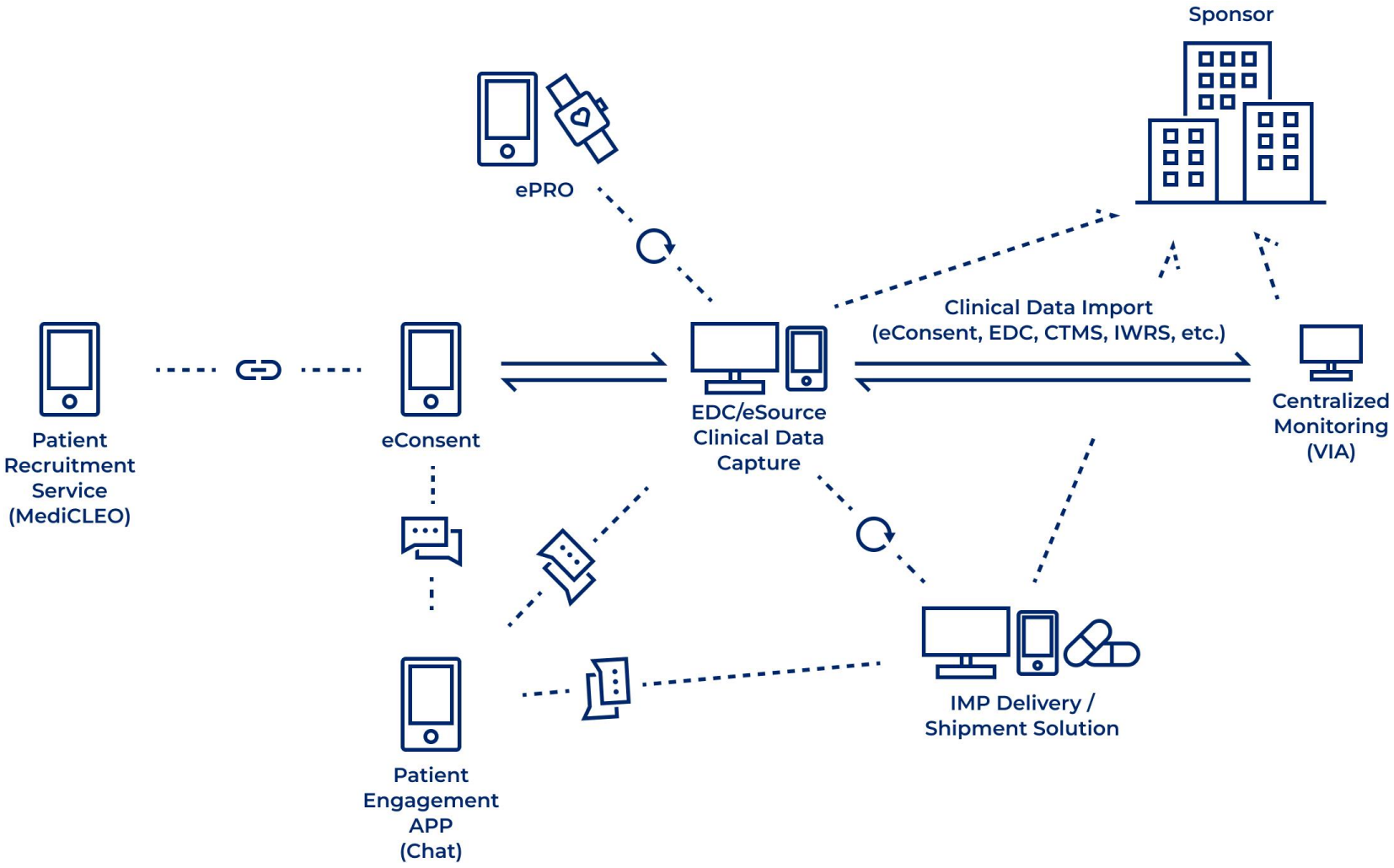
1. SPERO is a specialized CRO providing e-clinical solutions and optimal operating environments for decentralized clinical trials

2. Customizable, scalable hybrid DCT clinical trial service (effective use of existing clinical trial process and DCT elements)

03 SPERO DCT Service – Overview (Operational flow)



03 SPERO DCT Service – Overview (Data flow)



03 SPERO DCT Service – Details

DCT Operational Service

Study Start-up

Preparation and submission of IRB documents, Site contract

Project Management

Site Management

Medical Writing

DM & STAT

Quality Assurance

Centralized Monitoring

Consulting Service

DCT e-Clinical Solutions

Patient e-Recruitment (MediCLEO)

Online remote patient recruitment and pre-screening service.
About 160 studies performed in Korea. New application service is in preparation (TBD)

eConsent (cubeCOSENT)

Mobile application both for on-site and remote process.
Embedded editor, document version control and management, SMS remote authentication.

Clinical Data Collection (cubeCDMS & cubeDDC)

EDC and EDC-synced eSource Direct Data Capture (DDC) solutions.
Remote and simultaneous operation is possible between sites and nearby local clinics.

Patient reported outcomes (cubePRO)

EDC-integrated DB management. Special libraries for DCT studies provided.

Centralized Monitoring (Via)

Remote centralized monitoring system. About 120+ customizable CORE indicators provided.
Embedded mapper (3-week mapping service), EDC interoperable (daily auto-updates)

IP & Device DtP logistics (TBD: cubeIWRS, cubeIWRSm)

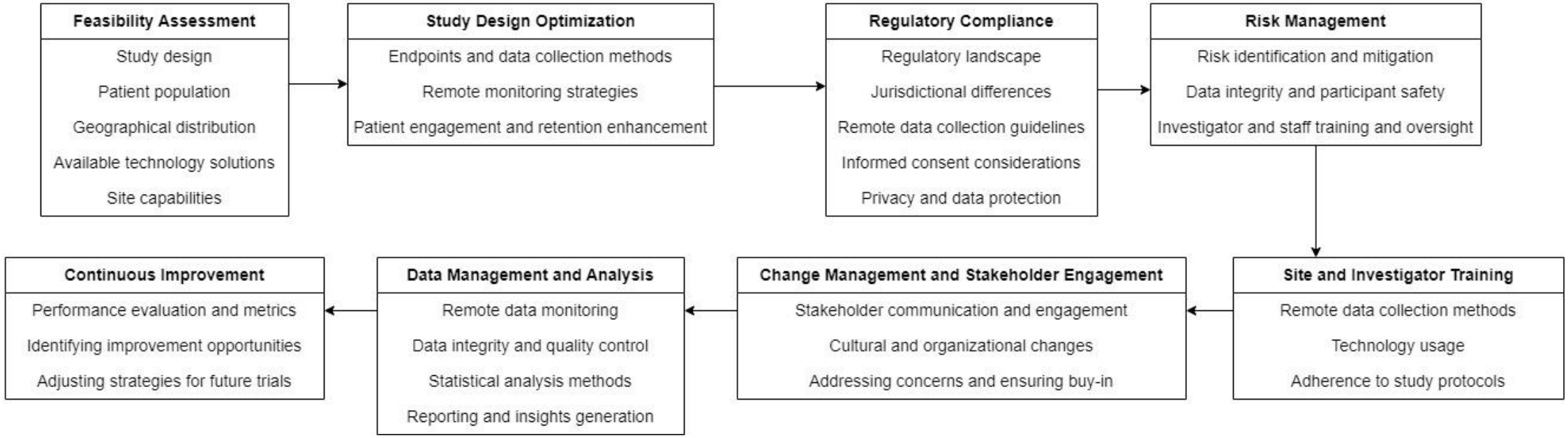
Direct IP delivery to patients' home and nearby local clinics (Prohibited by regulation in Korea)

Telemedicine (TBD)

Provide integrated communication environment for patients during DCT studies.
(Prohibited by regulation in Korea)

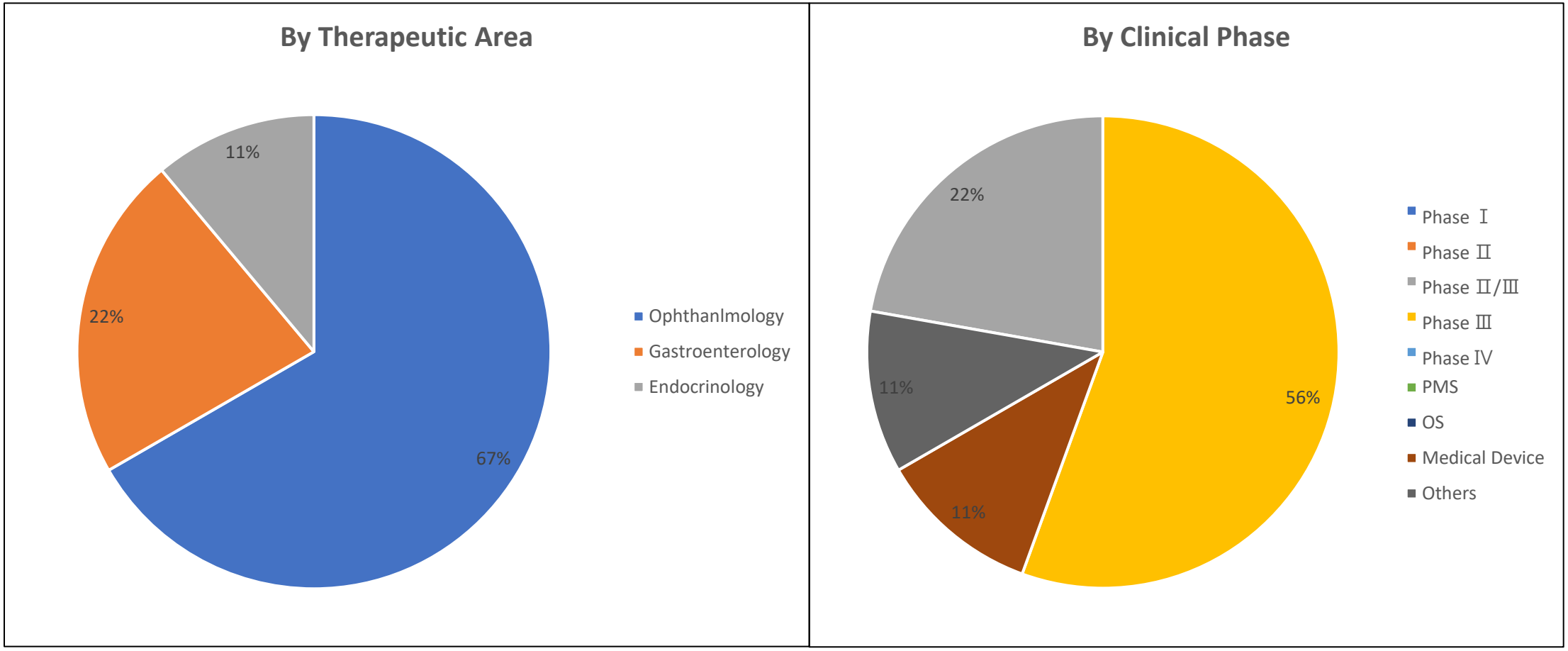
03 SPERO DCT Service – Details

DCT Operational Service



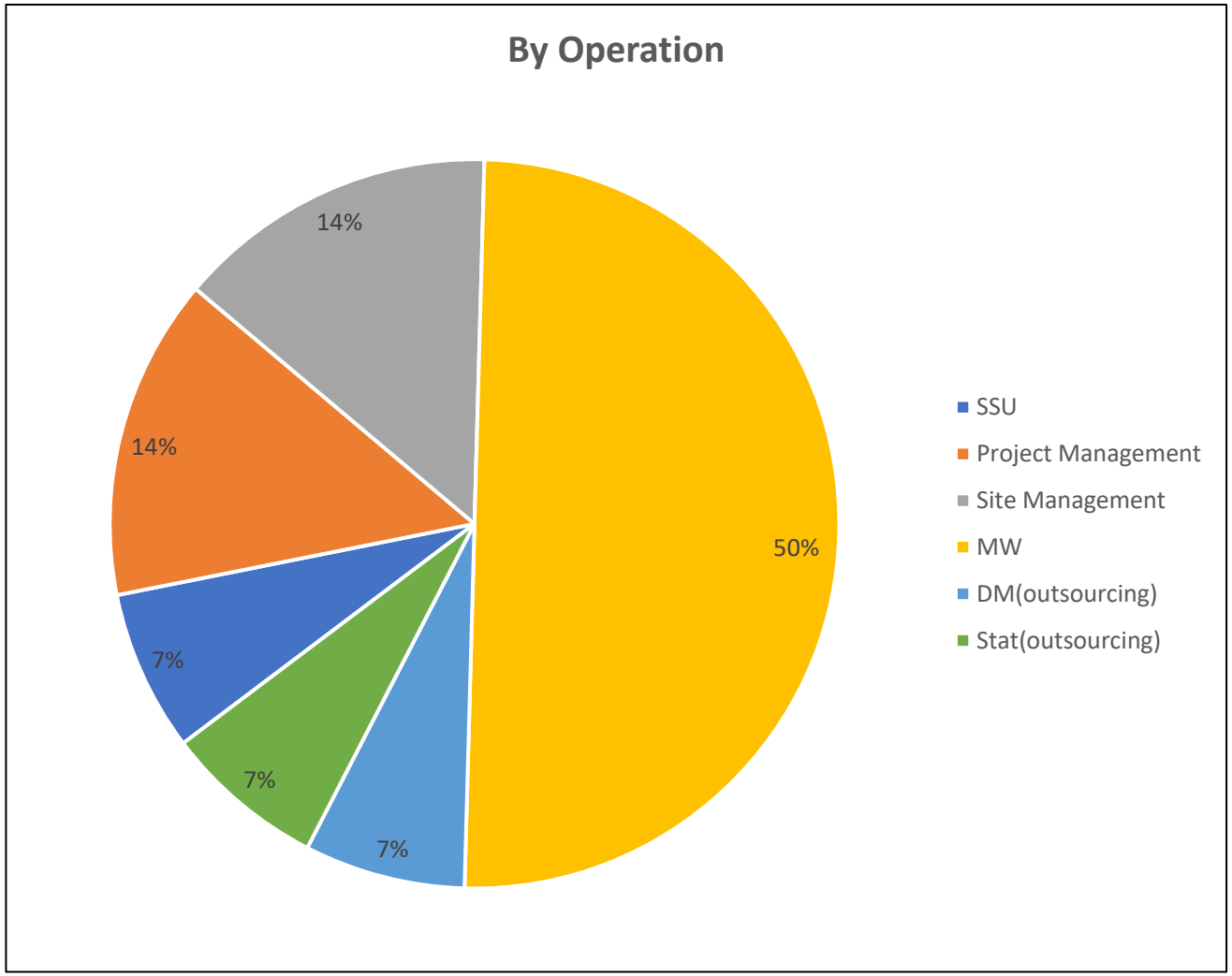
03 SPERO DCT Service – Performance

By Therapeutic Area and Phase (2023.07)

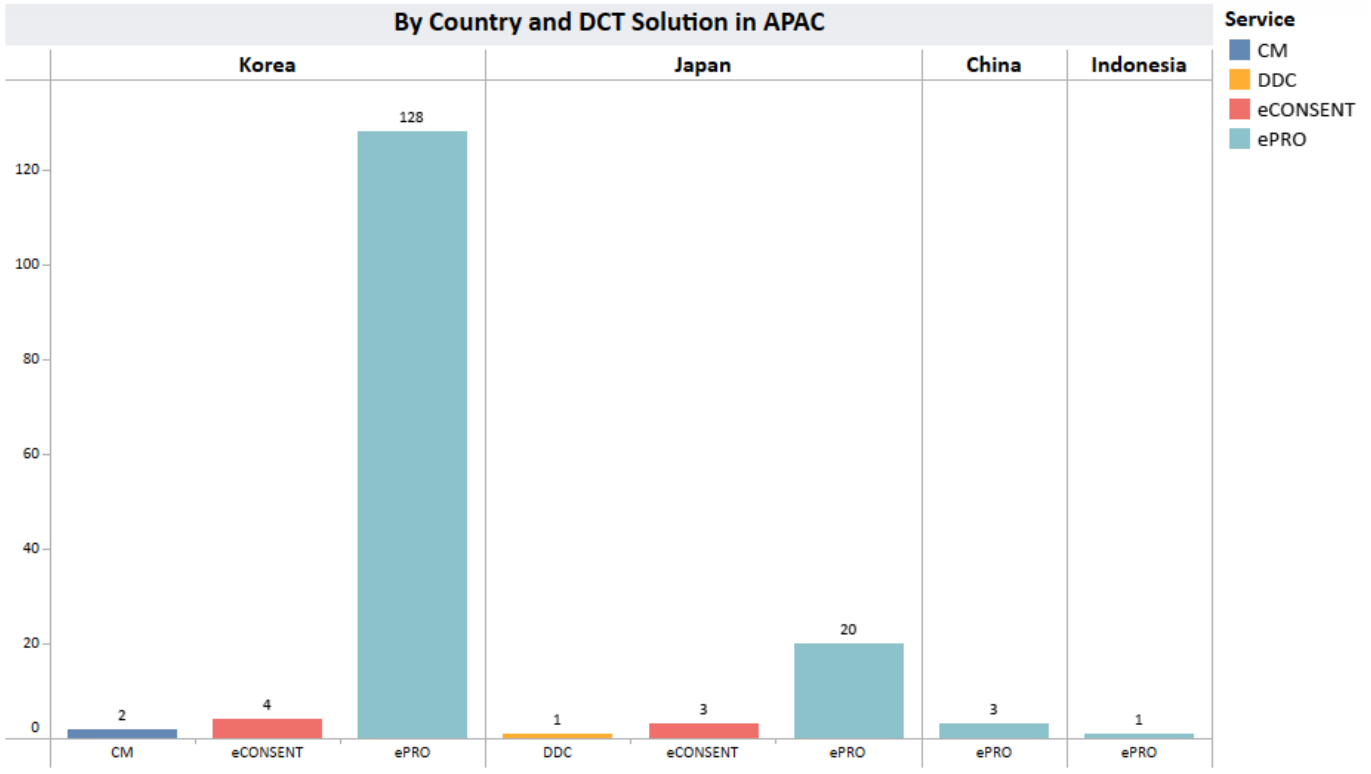


03 SPERO DCT Service – Performance

By Clinical Operation (2023.07)



03 SPERO DCT Service – Performance



Service	Korea	Japan	China	Indonesia	Grand Total
CM	2				2
DDC		1			1
eCONSENT	4	3			7
ePRO	128	20	3	1	152
Grand Total	134	24	3	1	162

By country and DCT solution in APAC (2023.05)

04 eClinical Solution - MediCLEO

MediCLEO, the best solution for quick and accurate patient recruitment and early dropout prevention

Patient recruitment service providing clinical trial information
that best meets the needs to every applicants.

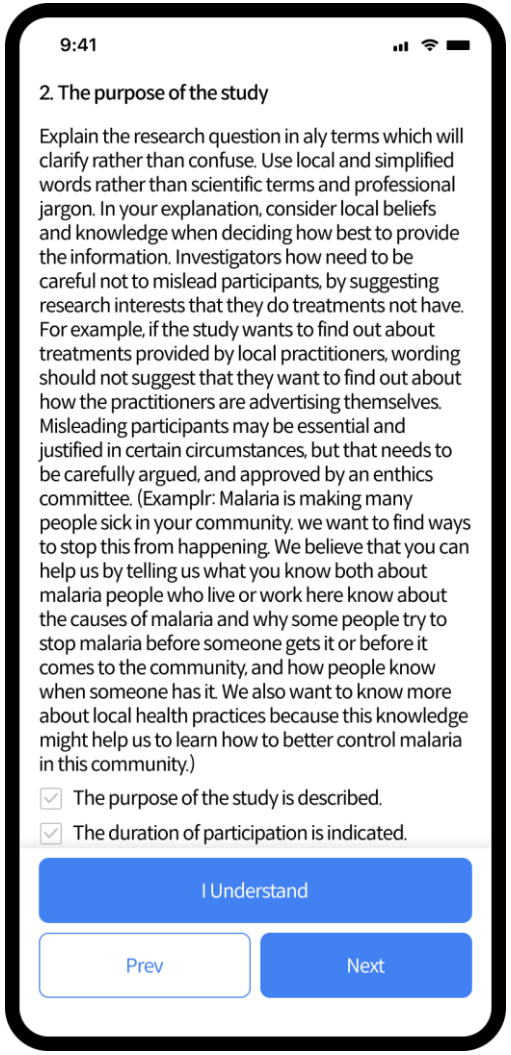
- Customized study information to the best-fit applicants (customized notification)
- Easy online application process
- Help service (phone / chat)
- Reasonable recruitment fee (Pay For Success)
- Pre-screening service
- Applicants' list and recruitment status report

04 eClinical Solution – eConsent

eConsent, for seamless Face-to-Face and Remote consent process

Face-to-face & remote electronic consent application that allows consent process for clinical trials to proceed without a patient's visit to the site.
Maximize patient engagement with two separate, independent applicant and investigator apps.

- Simplified e-sign consent process
- Improved applicants' understanding with multimedia assistance
- Generate and update informed consent forms (version control)
- Consent process monitoring and archiving status check in real time : Adminitrative interface provided



04 eClinical Solution – DDC

eSource clinical data capture solution that does not require EDC re-entry

Web and mobile application that enables investigators and clinical research coordinators to quickly and remotely enter clinical data.

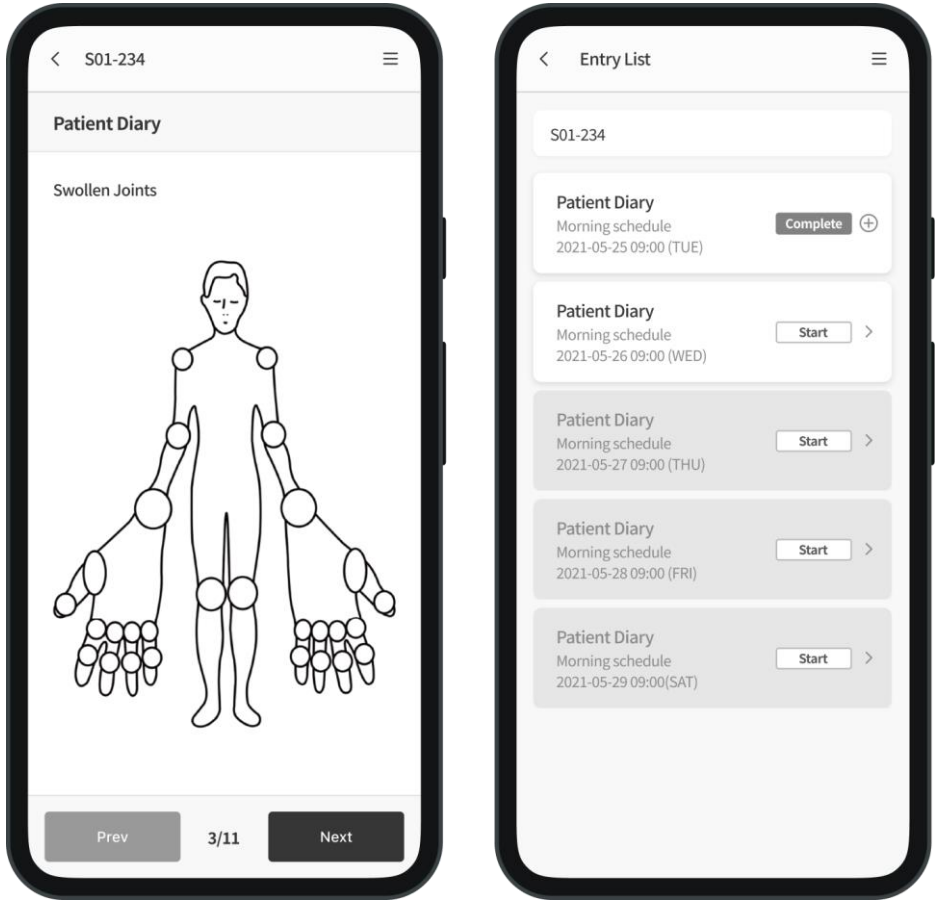
- Reduction of input time
- BSE (Bulk Subject Entry) : Multiple subjects' eCRFs can be selectively identified and entered in bulk
- Subject Navigation : Quick move from one subject to another to enter data
- Submission List : Server submission of captured eSource clinical data all at once.

04 eClinical Solution – ePRO

Electronic patient-reported outcomes validated through local and multinational clinical trials

Android/iOS based mobile application with real-time EDC integrated DB management and robust edit check functions

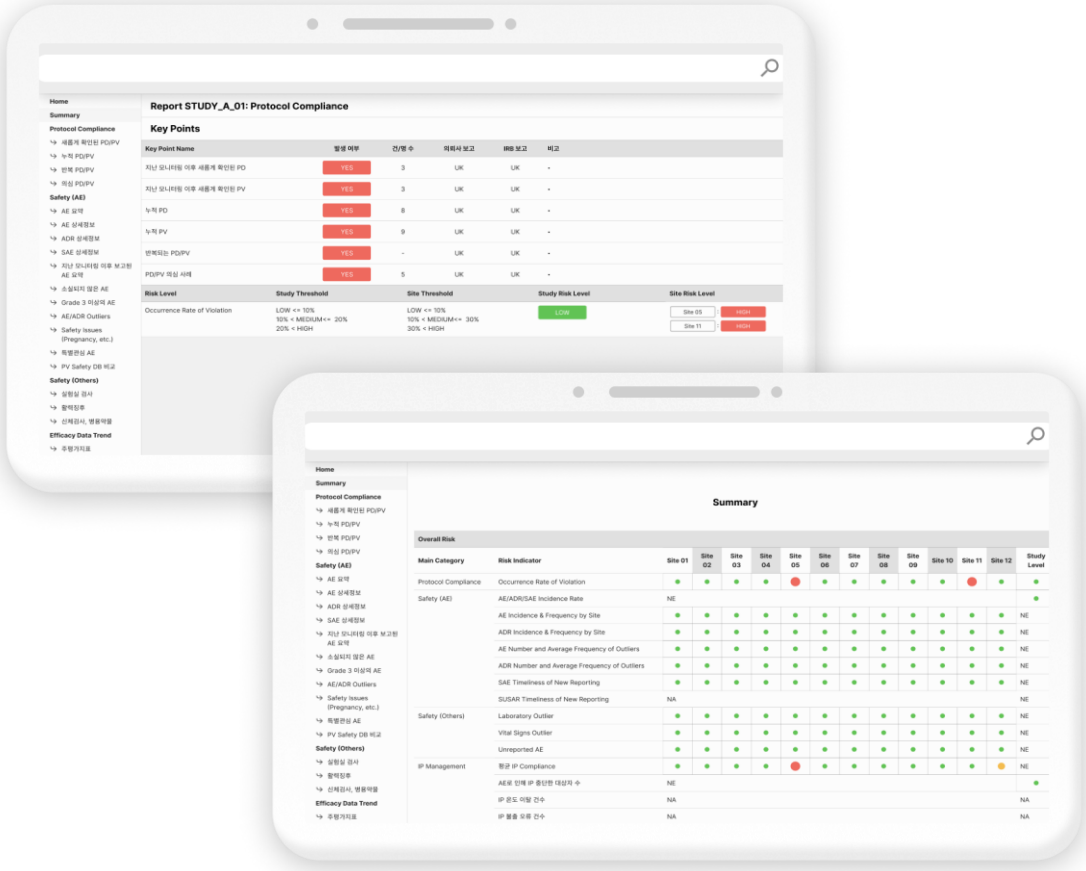
- Convenient data entry & various input forms
- Unified data management
  - EDC Integration & Edit-checks for data cleaning
  - Data entry schedule management & alarms



04 eClinical Solution – CM

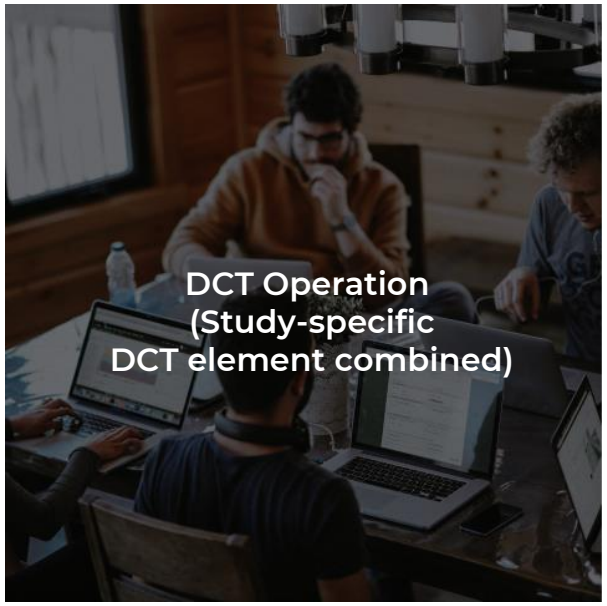
VIA, a centralized monitoring solution customizable, scalable according to each clinical trial and its step of progress

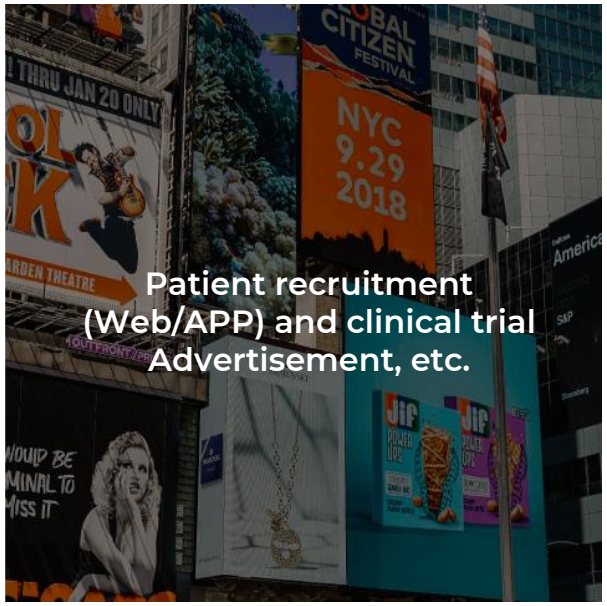
A centralized monitoring system with customizable risk indicators and monitoring categories, providing optimal reports for each study and site.



- Clinical data visualization and outlier detection
- Integrating risk-based approach and centralized monitoring methods
  - Protocol-based customizable risk indicator design
  - Real time remote monitoring with eClinical DCT solutions : eConsent, DDC, and ePRO.

05 Customer value





06 Key personnel & Core technology

DCT Clinical operation team

- Medical Writer, Clinical Project Manager, Auditor, Data Manager, Product (Solution) Manager

CORE technology

- Patient Recruit Service Platform (Service Development)
- Centralized Monitoring Solution Design & Product Manager (Service Development)
- Direct Data Capture (DDC), eConsent (eIC), ePRO Solution Planning Operation (Product planning, Study buildup and operation)

Thank You :)