2025 Global Harmonization Center Clinical Trials Webinar

Trends in Clinical Trials & Updates on ICH Guidelines

DCT in Action: From Concept to Clinical Integration

Kwunho Jeong, CEO of JNPMEDI

Clinical Trial Evolution:
Brief history of Clinical Trials

Short History of Clinical Trials

1747
James Lind's Scurvy Trial
First controlled clinical trial

1863
Dr. Flint's Dummy Remedy
First use of placebo

1938
Federal Food Drug Cosmetics Act
First outline for drug safety

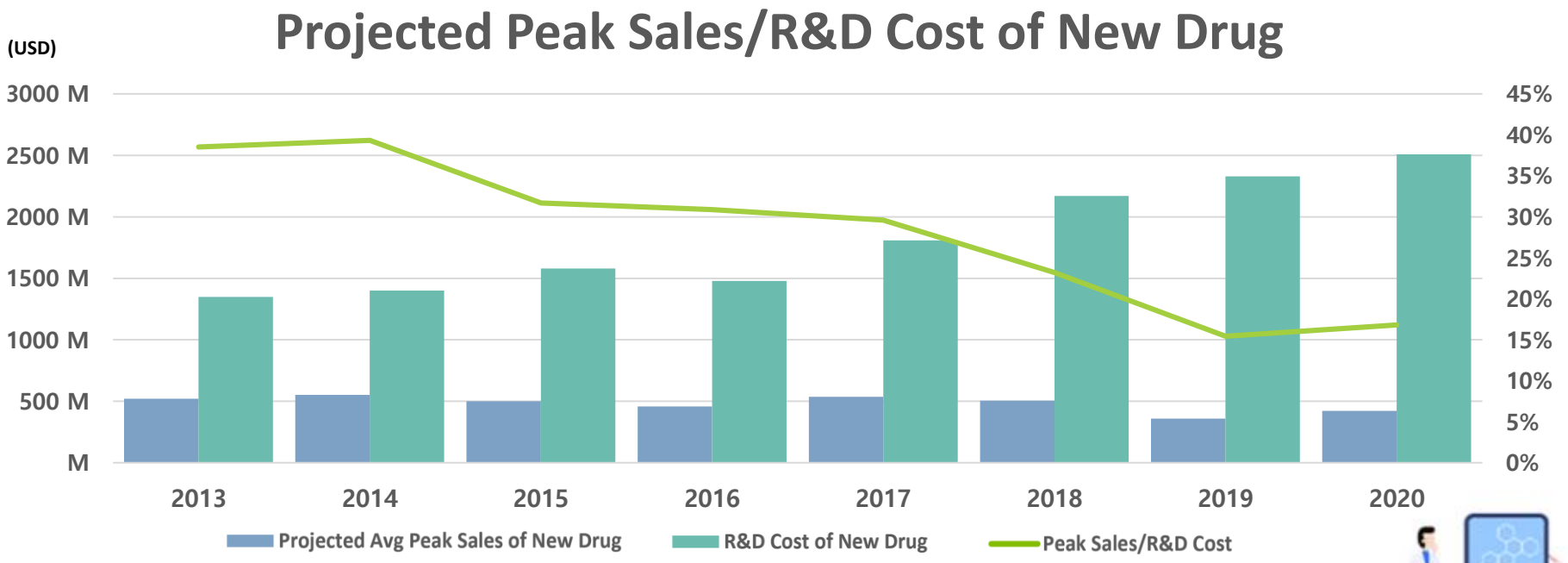
1943
MRC's Patulin Trial
First double-blinded trial

1946
MRC's Streptomycin Trial
First RCT

Sustainability of Current R&D Scheme

Early Discovery	Non-Clinical	Clinical Phase 0	Clinical Phase 1	Clinical Phase 2	Clinical Phase 3	Approval
5 y	1.5 y	6 y				2 y

14.5 y Total



Extraordinary COVID-19 R&D Efforts

spikevax™ COVID-19 Vaccine, mRNA		COMIRNATY® (COVID-19 Vaccine, mRNA)
Jan 23, 2020	**R&D Start**	Jan 13, 2020
Dec 19, 2020	**FDA Approval***	Dec 02, 2020
11.2 months	**Total Duration**	**10.8 months**

* FDA authorization for vaccination against COVID-19 in U.S

Extraordinary COVID-19 R&D Efforts

U.S. FOOD & DRUG ADMINISTRATION

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

"

Conducting **telephone/video contact visits** for safety monitoring rather than on-site visits

Home delivery of IP that would not raise any new safety risks may be implemented

We recommend (*omission*) use of **electronic informed consent**

eCOAs can be conducted remotely in clinical trials

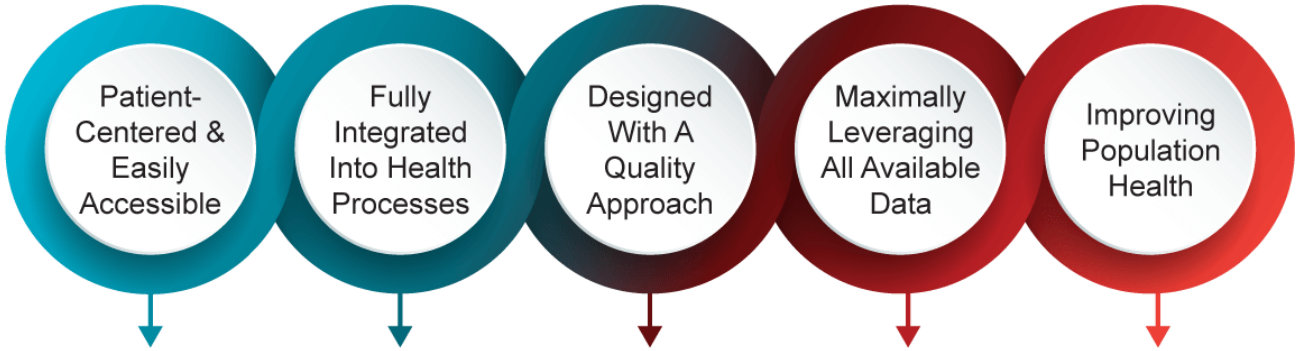
"

* FDA, 2021

Case: ① CTTI (USA)

TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

CTTI Recommendations: Decentralized Clinical Trials

September 2018

Case: ② ACT EU & Trials@Home consortium (EU)

Accelerating Clinical Trials in the EU (ACT EU)

HMA Heads of Medicines Agencies

European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ACT EU multi-annual

Workplan 2022-2026

PA 8: Methodologies

Q4 2022	Decentralised clinical trials (DCT) workshop
Q4 2022	Publication of DCT recommendation paper
Q4 2022	Complex clinical trials Q&A workshop
Q4 2023	Publication of methodology guidance roadmap
Q1 2024	Support to guideline developments
Q1 2025	ICH E9 (R1) Estimands fully implemented

EU Harmonization – ICH DCT Guidance

ICH HARMONISED GUIDELINE

GOOD CLINICAL PRACTICE (GCP)

E6(R3)

Draft version

Endorsed on 19 May 2023

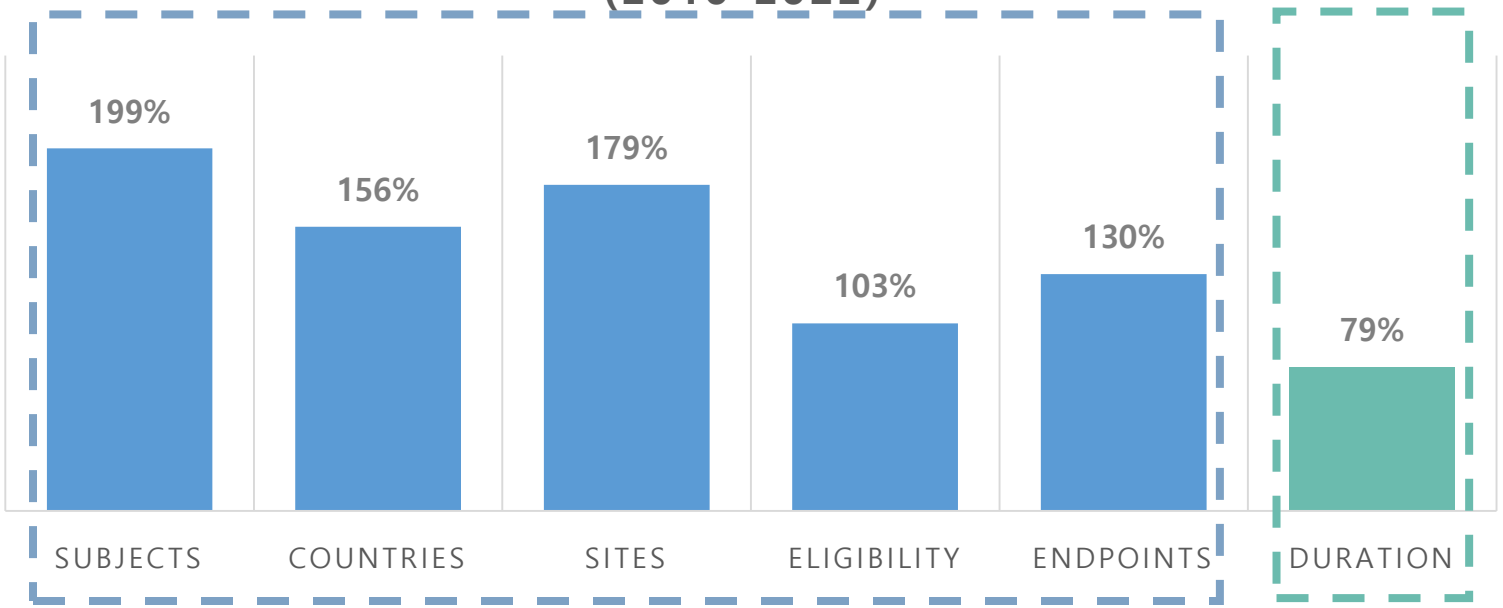
Decentralized Clinical Trial: What it means for clinical Trials

What is DCT?

Category	Decentralized Clinical Trial	Traditional Site-based Trial
Recruitment	Web-based	Hospital and clinics
Patient Population	Unlimited	Local
Pre-screening	Electronic questionnaire	Telephone calls
Study Sites	Site-less	Many
Patient Visits	Visit-less	In-person
Informed Consent	eConsent	In-person
Data Collection	Mobile device	Collected by study team
Cost	Cost-effective	Costly
Outcomes	Connected digital tools	Collected by study team

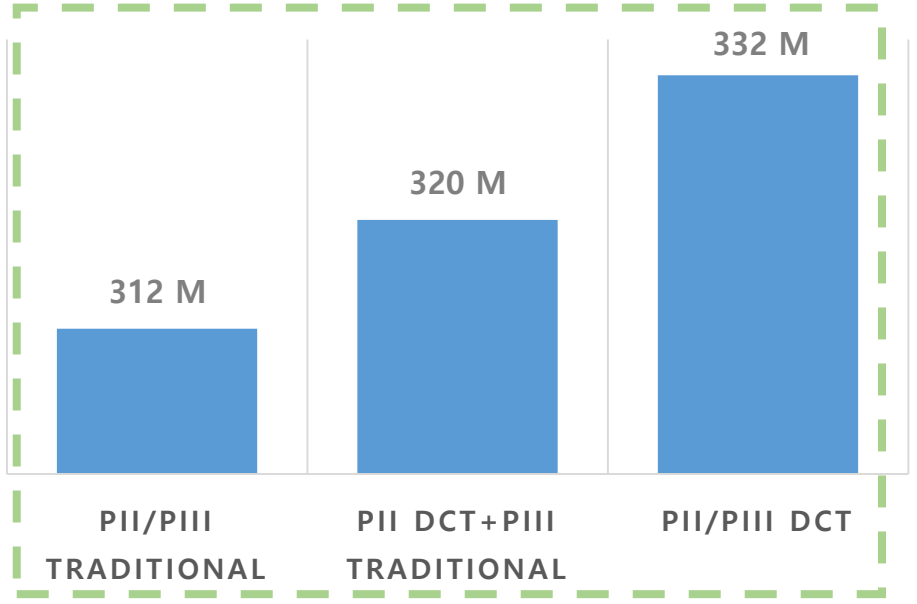
Why DCT?

PII/PIII DCT TRIALS VS TRADITIONAL TRIALS (2010-2022)*



▲Increased scale ▼Decreased duration

PII/PIII RETURN VALUE**



▲Increased ROI

* IQVIA, 2023
** DiMasi et. al. Assessing the Financial Value of Decentralized Clinical Trials. 14 September 2022

Increase of Decentralized Data Collection

Availability of Data

Every minute of every day, the amount of data equal the all data generated from beginning of time to year 2000 is generated*

Volume of Health Data

The amount of healthcare data is doubling every 2 years**

EDC Data Capture

Only 20-30% of available data points are collected in EDC

Connected Device

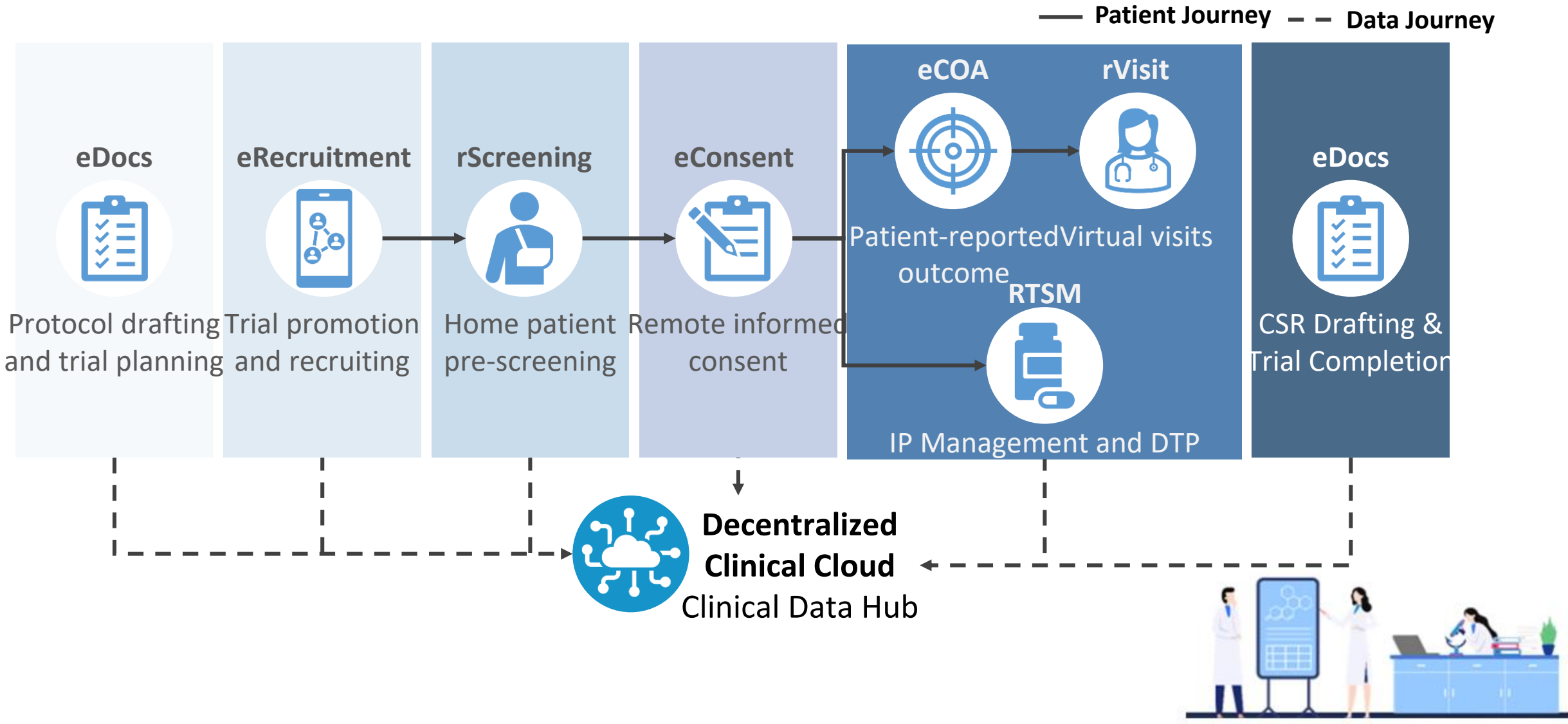
The availability of connectable devices and the number of clinical trials using connected devices grew by more than 10x since 2018***

Decrease Costs

The cost of physical operation of a clinical trial is exponentially increasing and unsustainable but can be avoided with decentralized data capture

* Marr, Bernard. Why only one of 5 Vs of big data really matters. 10 March 2015.
** European Medicines Agency. Identifying Opportunities for 'Big Data' in medicines development and regulatory science. November 14-15 2016.
*** https://www.nature.com/articles/s41746-020-0259-x/figures/2

DCT Technologies



Benefits of DCT

Room for Improvement in Traditional Clinical Trial

Recruitment

Patient Engagement and Retention

Speed to Market

Cost Efficiencies

DCT Case Studies:
DCT implementation globally and locally

Landmark DCT Cases

2011 **Pfizer's REMOTE Trial**

- First IND-approved RCT to utilize DCT elements
- Utilized DTP, eConsent, Regional HCP, and Idology, GA, US A (a subject identification tool)

2016 **DCRI's ADAPTABLE Trial**

- First fully decentralized clinical trial
- 15,000 subjects (avg age 67) participated with 0 visits
- 95% participation rate

2020 **Moderna's COVE Trial**

- Full clinical trial cycle in 12 weeks during COVID-19
- 30,000 subjects participated
- Utilized EDC, eCOA, and CSA

DCT Direction in Korea

Public Sector - 5 y Roadmap by MFDS

- Establish technical and regulatory support for a Smart Clinical Trial system

'19	Preliminary research for establishing an IoT and AI-based Smart Clinical Trial	→	'23	Establish guideline to govern DCT performance	→
'24	Enhance efficiency and quality of clinical trial through Smart Clinical Trials				

Private Sector-led Regulatory Advancement Platform

- MFDS established ARICTT (Advanced Regulatory Innovation for Clinical Trial Transformation)
- Goals
  1. Identify issues and offer solutions
  2. Provide a platform for discussion
  3. Build case-driven guidelines
  4. Advance infrastructure for seamless clinical trial

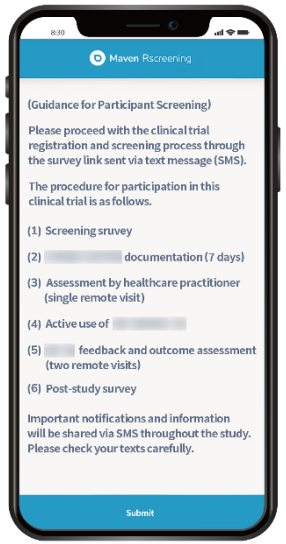
ARICTT
Advanced Regulatory Innovation for Clinical Trials Transformation

DCT Implementation in Korea

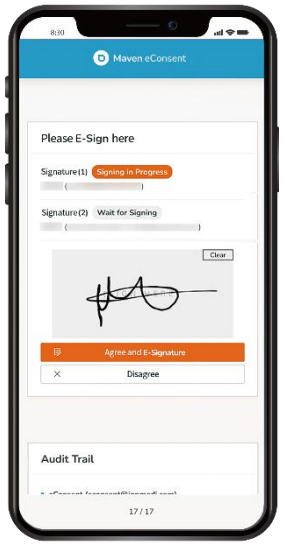
Decentralized Clinical Trial of WELT-I

Maven eRecruitment™

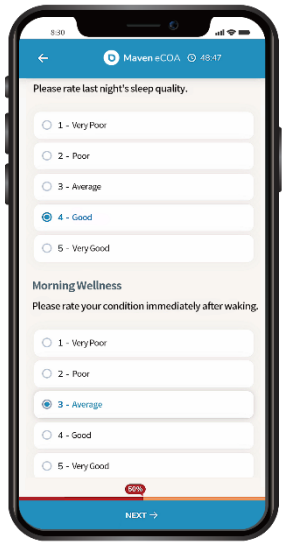
Maven rScreening™



Maven eConsent™



Maven eCOA™



Maven Clinical Cloud

* JNPMEDI, 2022

DCT Implications in Korea-Opportunity

Opportunities Observed

50%+

Reduction in time to recruitment

- Increased patient pool
- Increased diversity
- Faster consenting process

66%+

Reduction in site visits

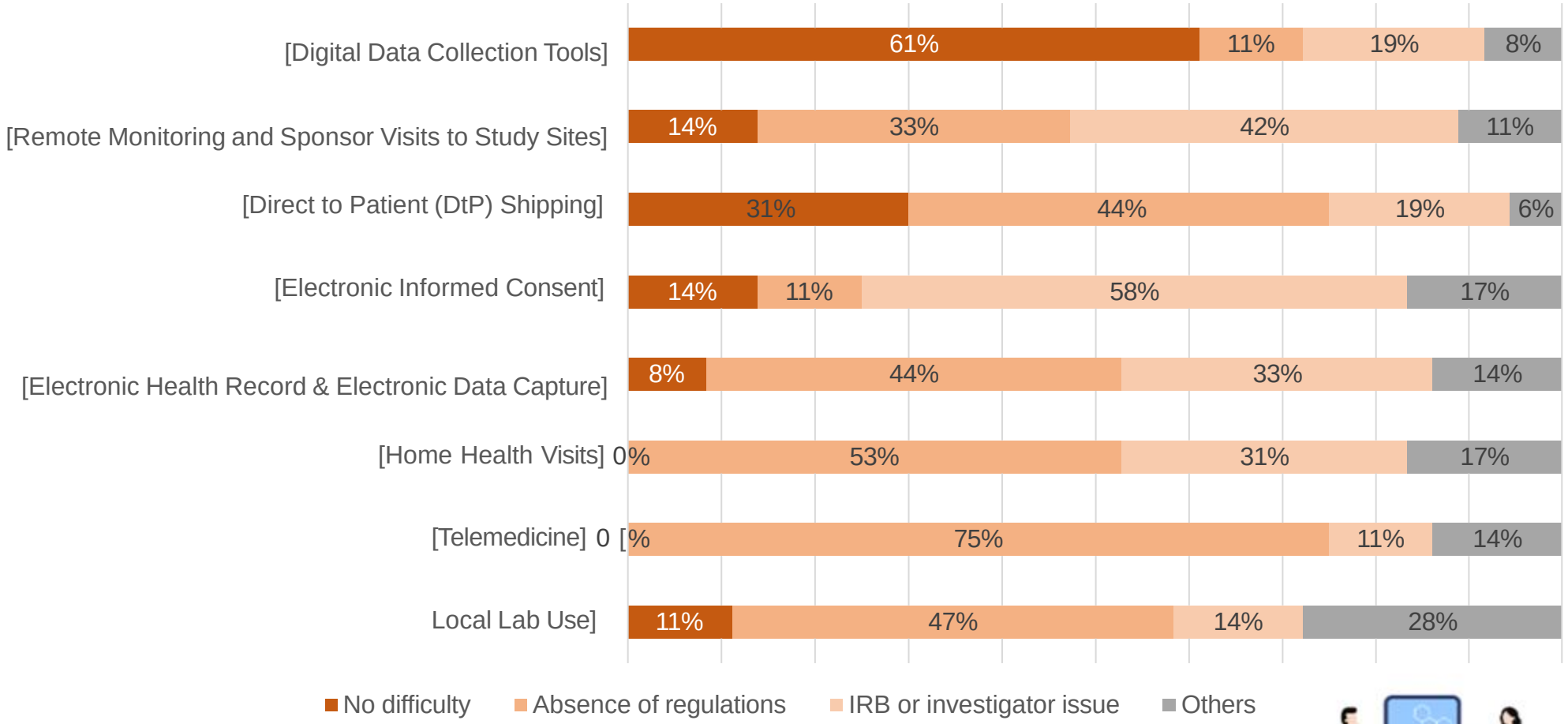
- Reduced number of sites
- Reduced resource input

40%+

Reduction in Patient dropout

- Patient-centric clinical trial
- Increased QoL
- Increased accessibility
- Increased adherence

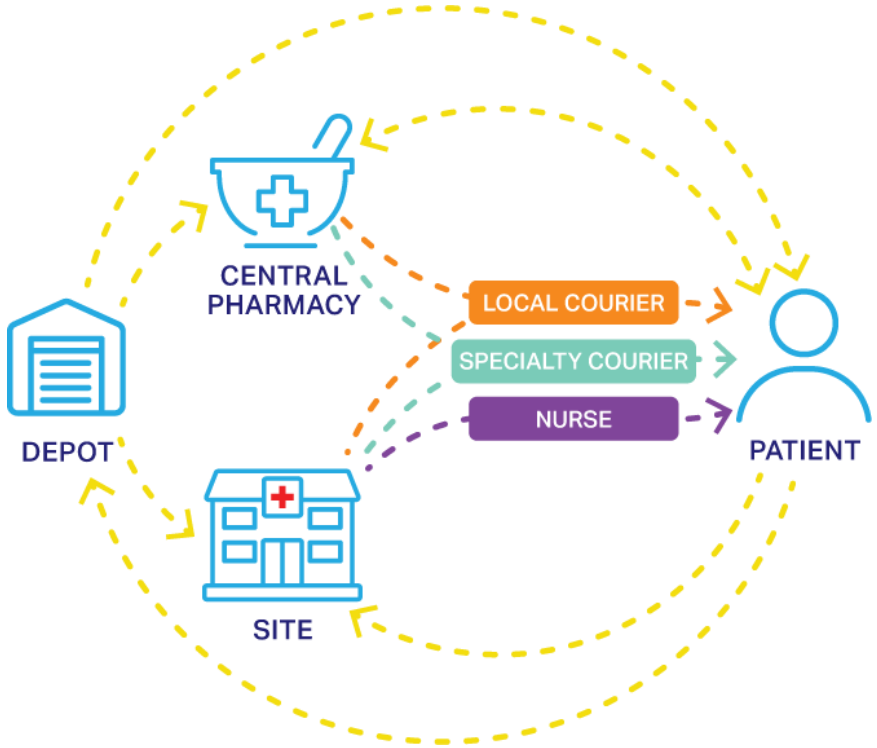
Implementation of DCT in Korea



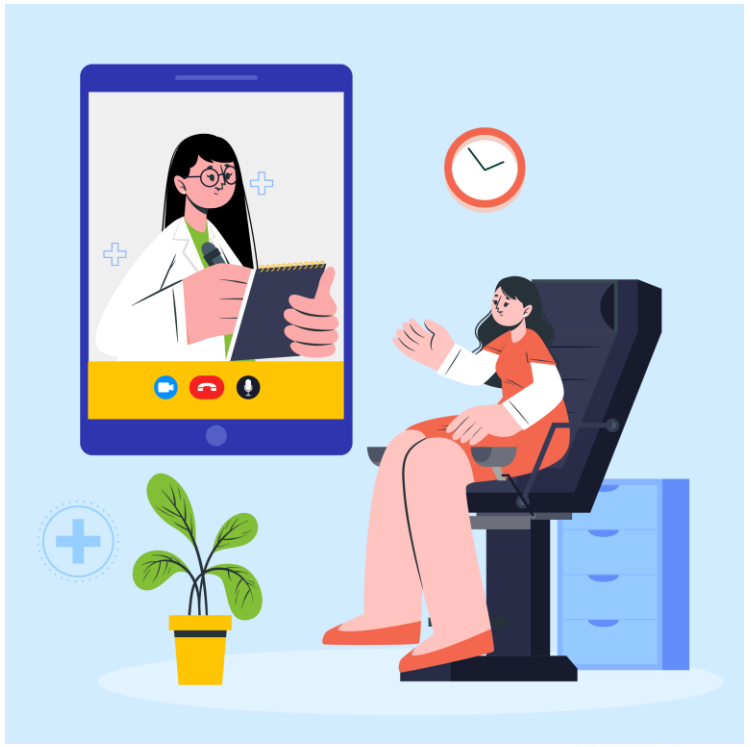
* DCT committee survey in Korea

Barriers: ① Regulations

Example: Direct-to-patient shipping issue



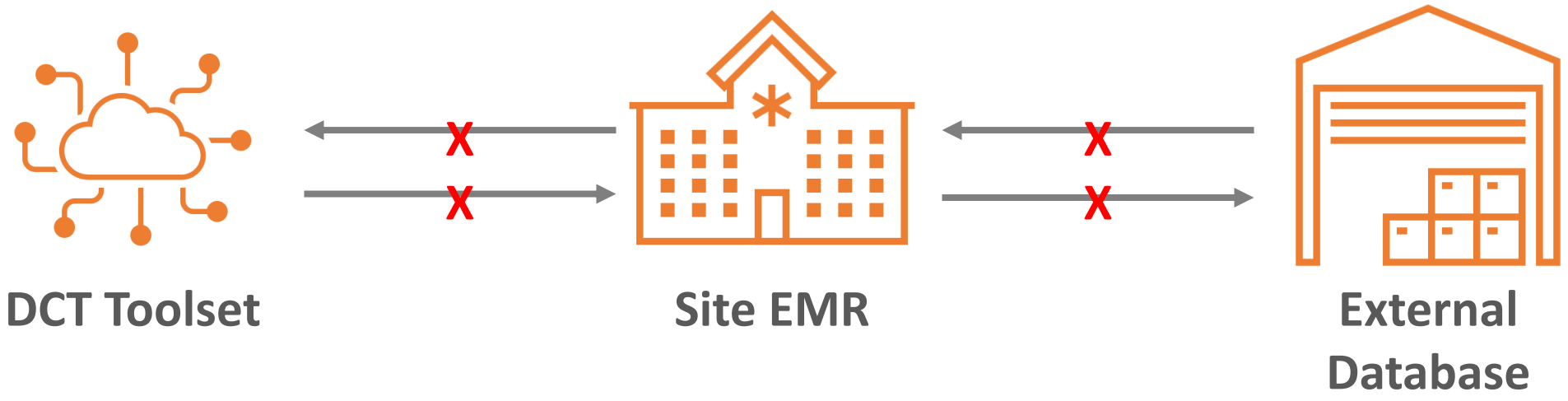
Example: Tele-visit or remote monitoring issue



Barriers: ② Investigators and trial sites

Current KR-Specific Framework

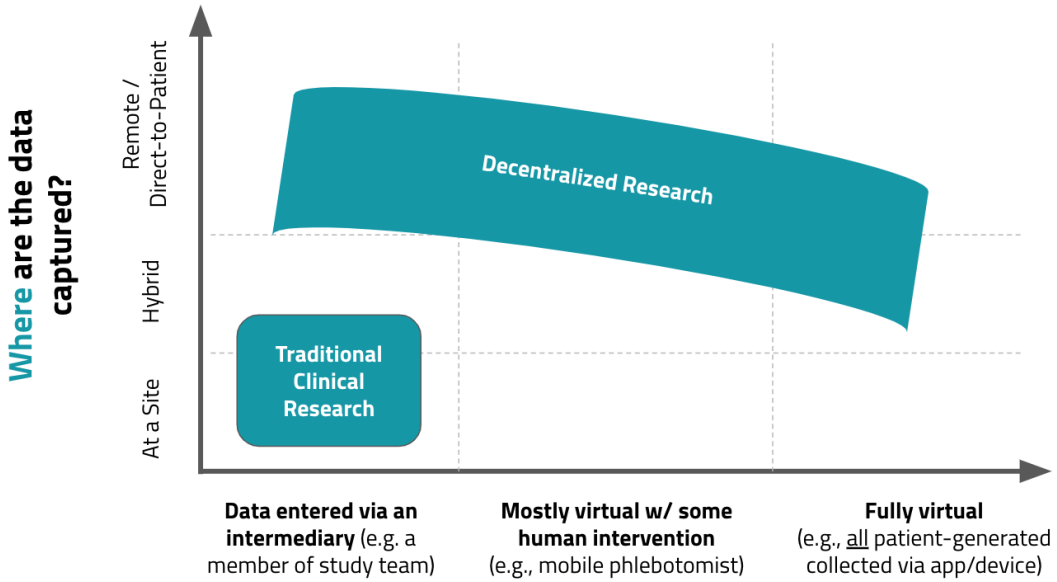
- Integration of site EMR to external database is restricted on grounds of server location
- IP must be distributed by a PI and delegation is restricted



EMR-external database Integration Restricted

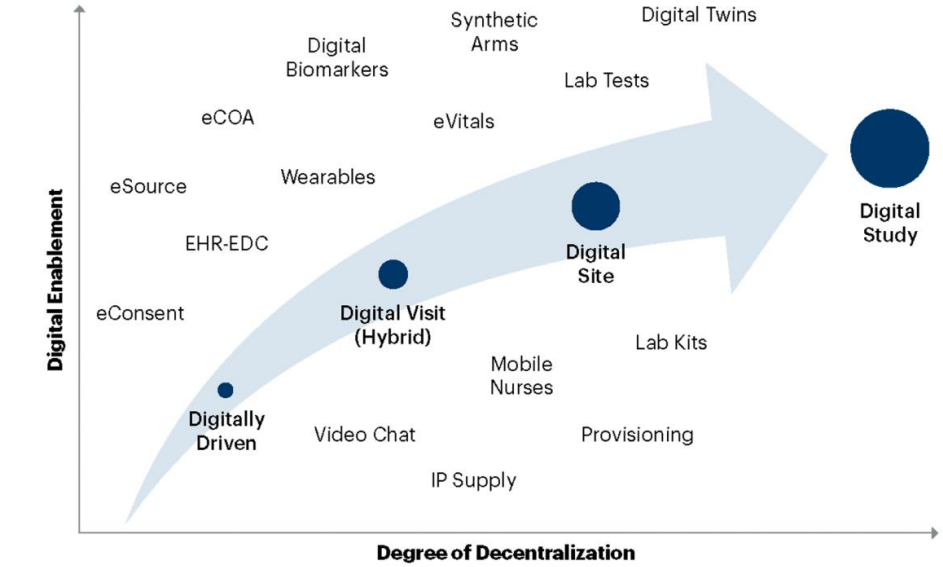
Barriers: ③ Oversight capability of digital products

Decentralized studies have two components: decreased reliance (1) on an intermediary and (2) on a physical location



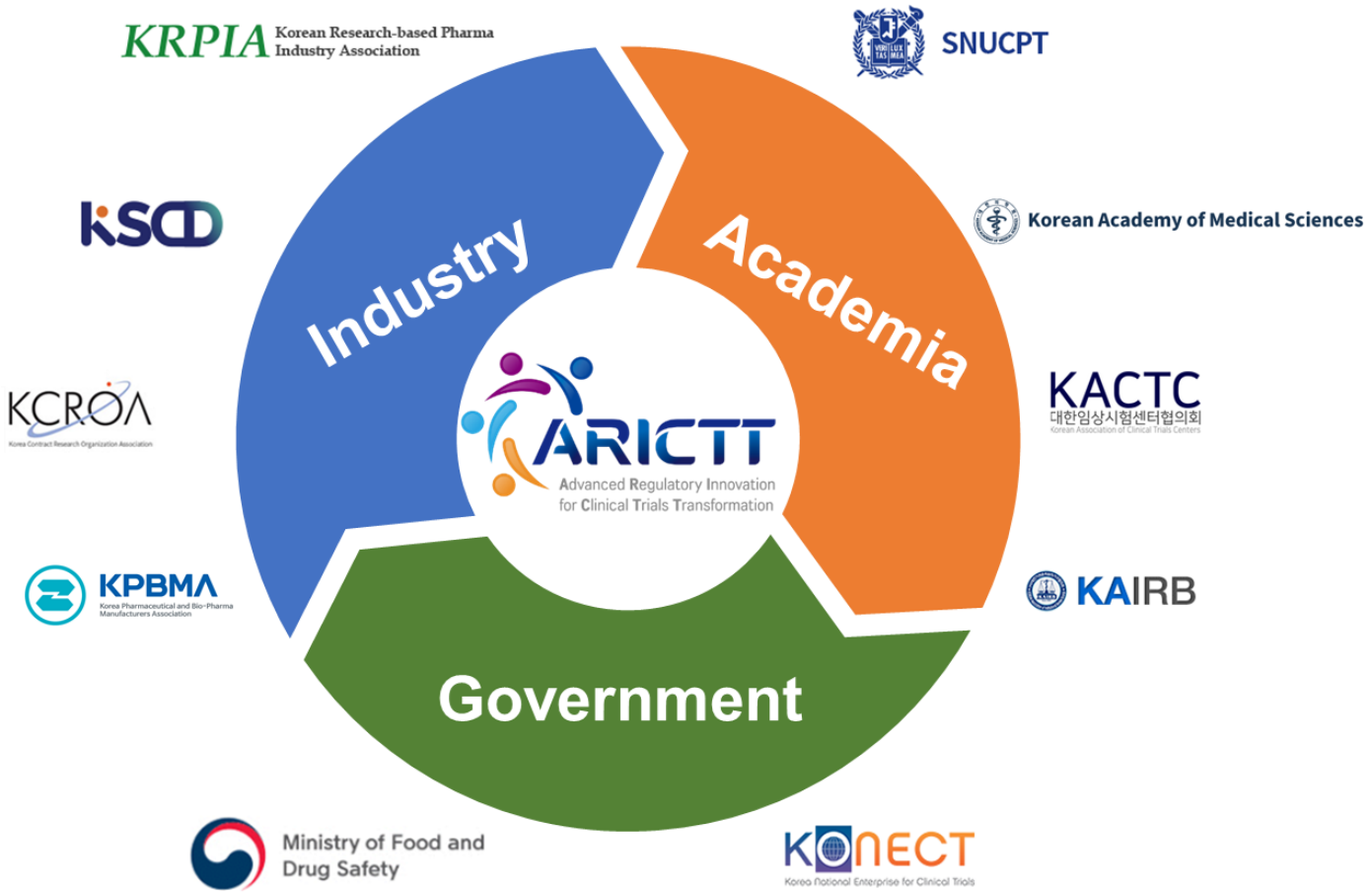
elektralabs

Figure 1. Maturing Your Digital Trials Approach to Be More Patient-Centric

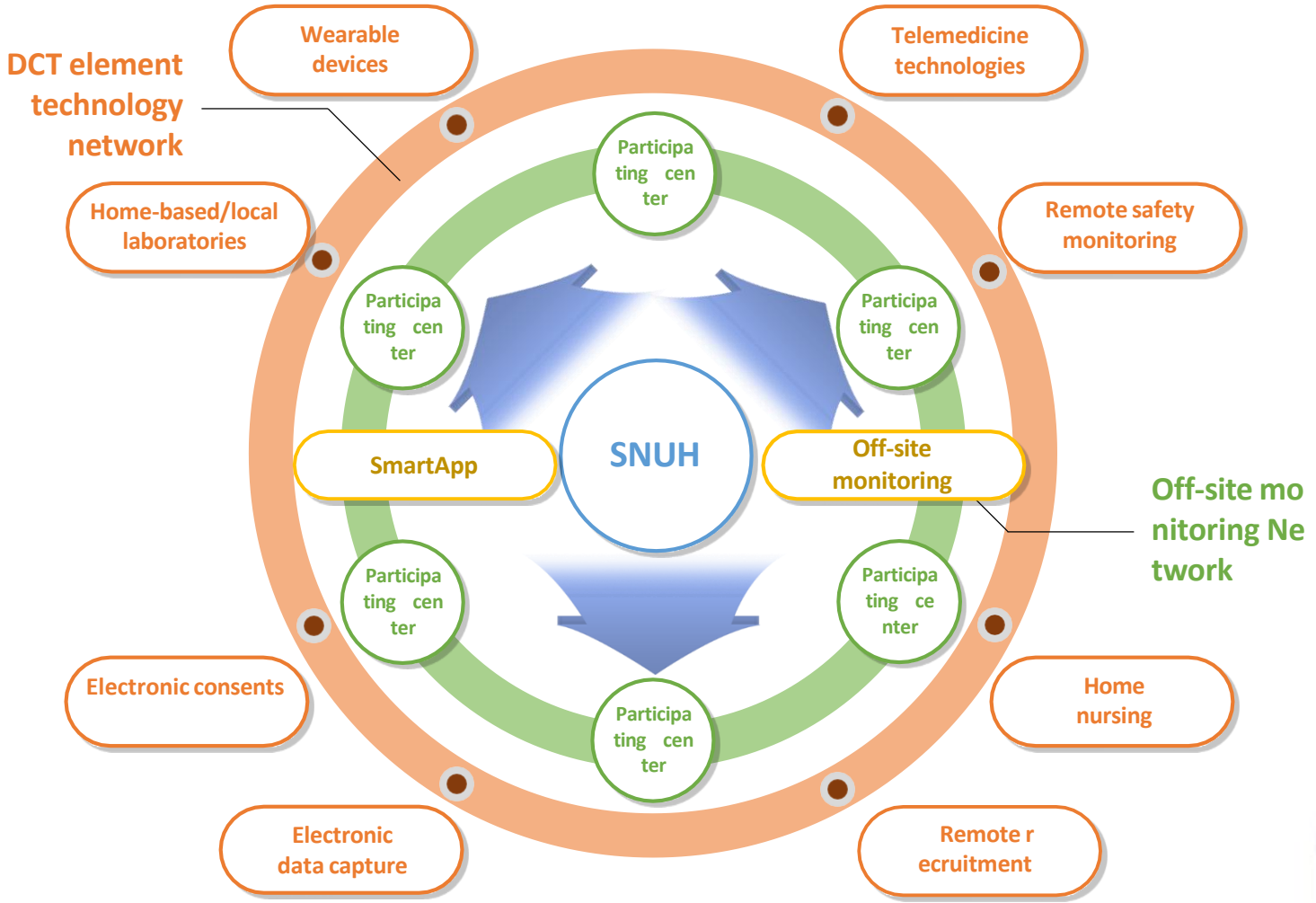


eCOA = electronic clinical outcomes assessment; EHR-EDC = electronic health records to electronic data capture; IP = investigational product
Source: Gartner
719103_C

Efforts in Korea: ① ARICTT



Efforts in Korea: ② DECENT



Fit for DCT

	Increased Timepoints and Subject QoL	Patient Recruitment	Reduced Site Visits	Increased Connectivity
Benefits of DCT				
Candidate Studies	• Chronic Disease • Oncology • Studies with Mobility-challenged subjects	• Rare Disease • Studies including areas with low population density	• Self-administered IP • Registry studies • PMS/OS	• Digital therapeutics • RWE/RWD studies

DCT Implications in Korea-Risks

Risks to Mitigate

1. **Lower data quality from faulty collection**
   Device error, subject accessibility
2. **Inaccuracy in assessment**
   Possible methodological error in assessment
3. **Bias from population selection**
   Population skew due to tech-literacy
4. **Dropout from lack of “clinical trial experience”**
   Lack of subject community and isolation

Selection of a knowledgeable Vendor is key
open communication from clinical trial planning

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