

Novartis  
Global Drug Development



# Decentralized Clinical Trials

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臨床評価部会 総会

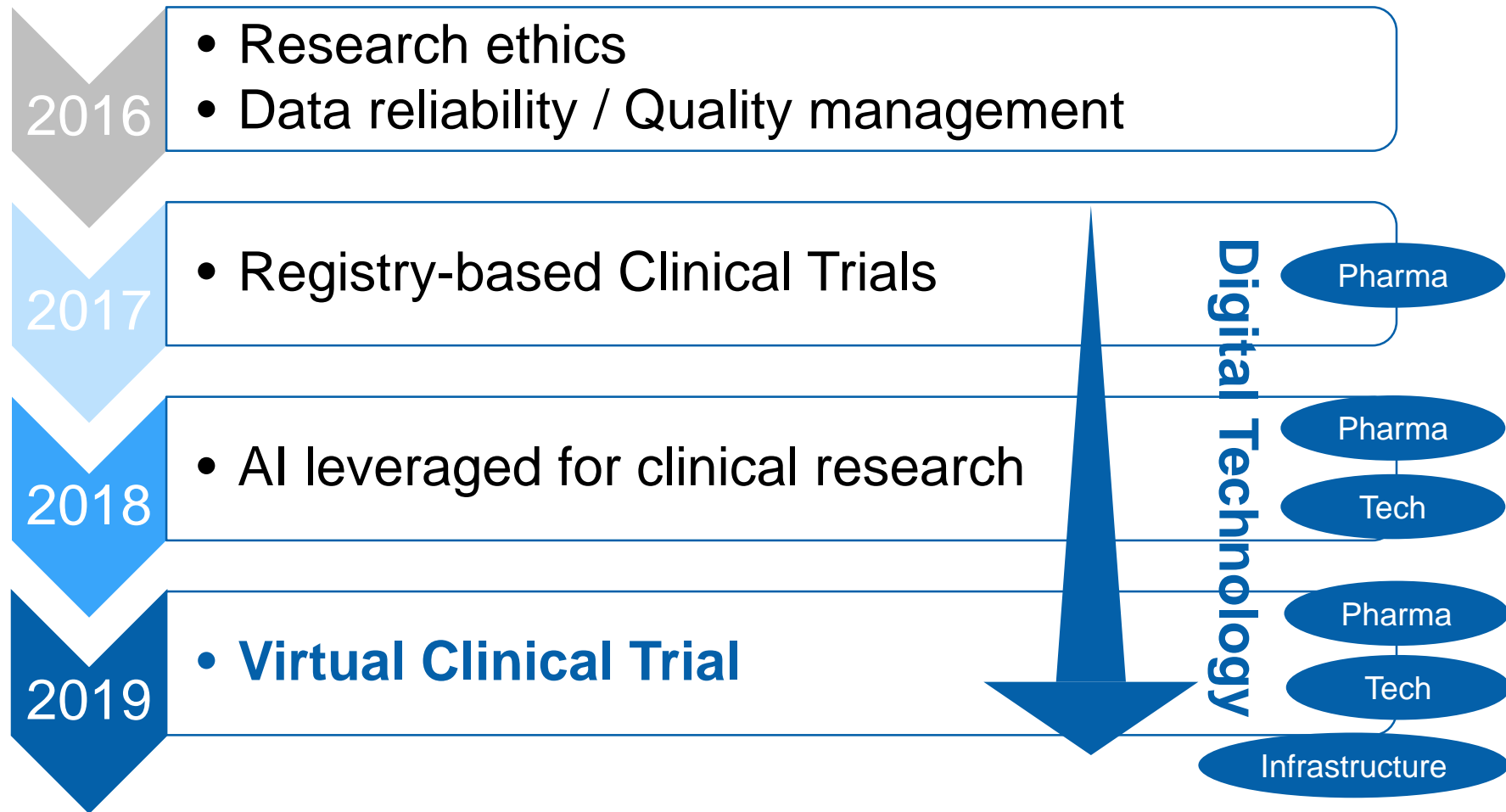
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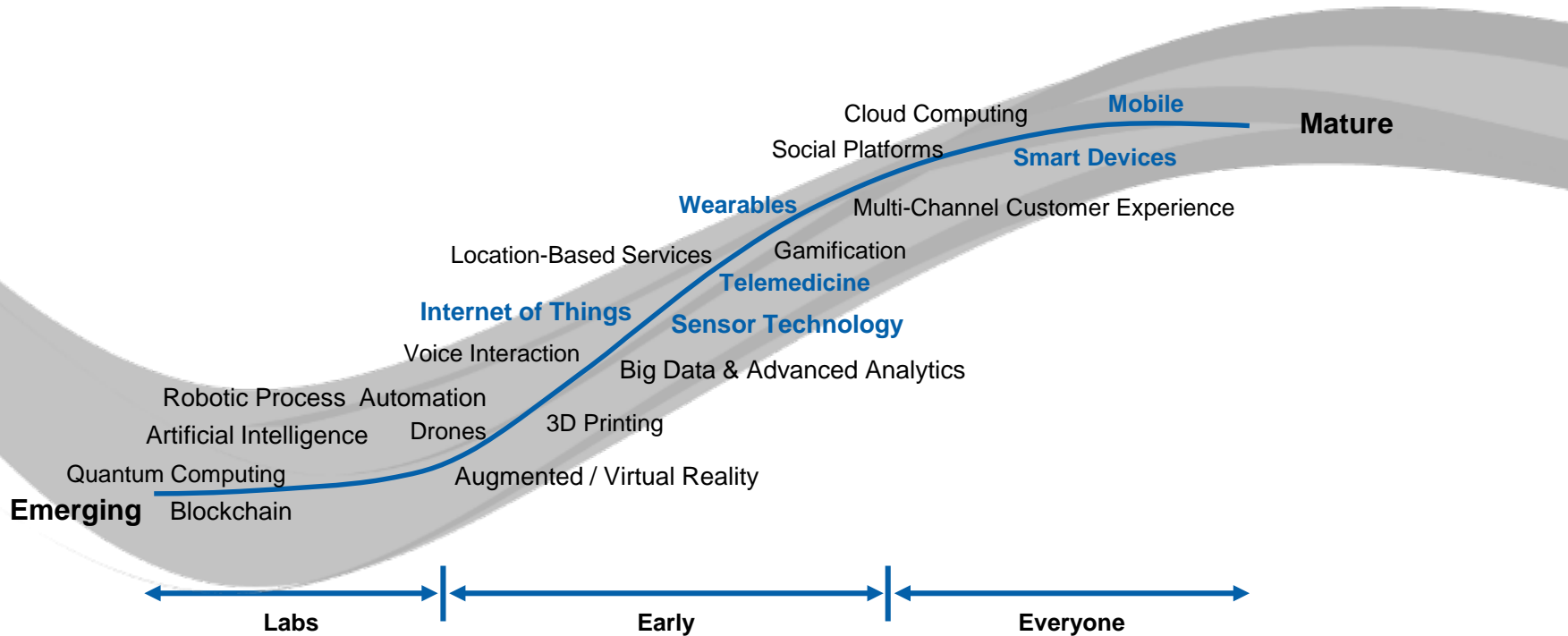
# History of topics in JPMA annual meeting by clinical evaluation committee



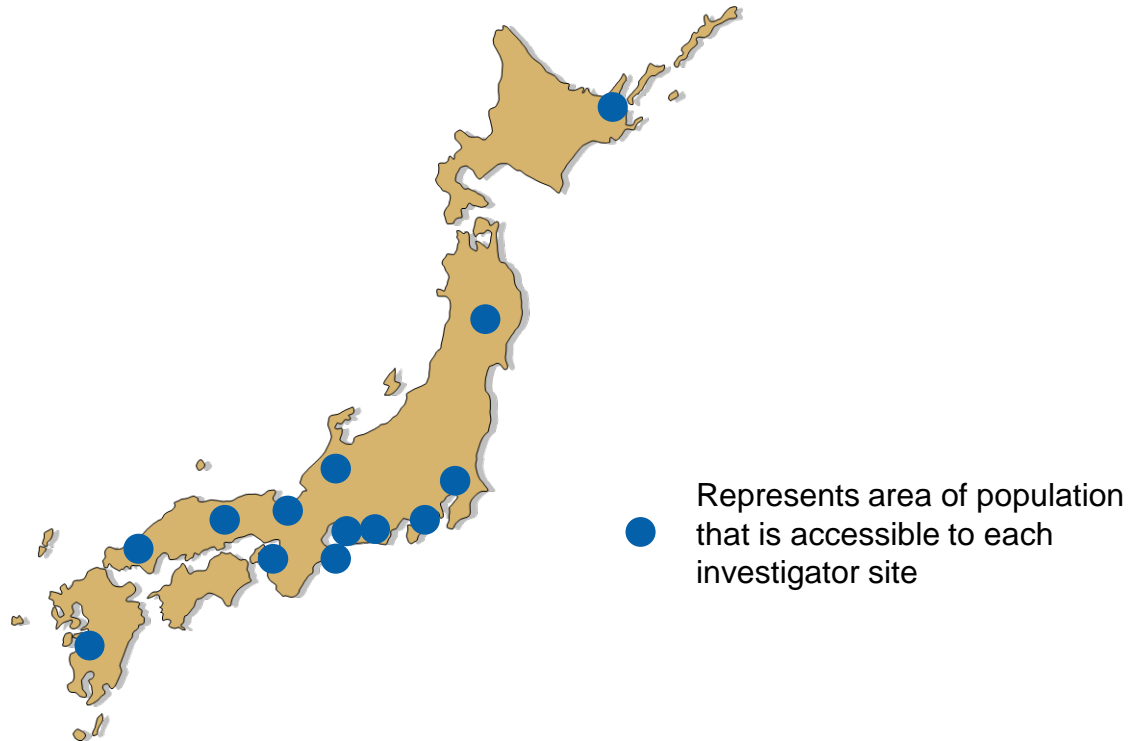
# Agenda

- The need for change & problem set
- Definition of Decentralized Clinical Trial (DCT)
  - Key enablers
  - Several DCT models
- Case study
- Moving ahead to Next Generation Trials?

# Technology is rapidly evolving, providing opportunities to reimagine pharma R&D

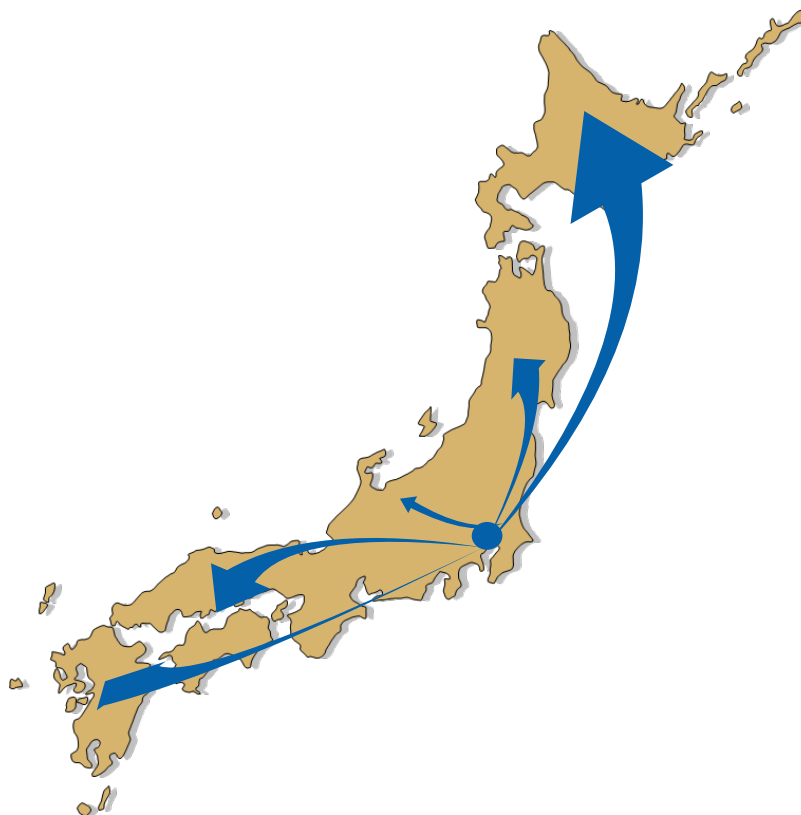


# Our current site model



# What if...

**We transformed our current multi-site model into a faster moving, patient centric solution that builds clinical trial that are convenient and accessible to patients**



# Defining Decentralized Clinical Trials (DCTs)

**“Decentralized Clinical Trials are those conducted with the patient located *outside of clinical research centers* for either some or all of the required trial procedures“**



# Traditional Study Visit Model

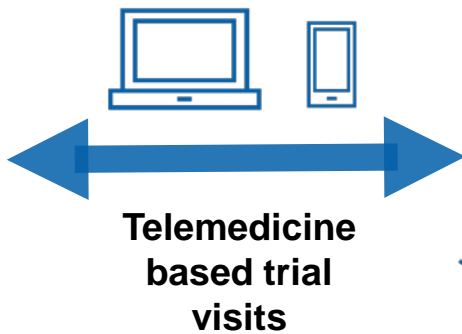


# DCT Models - Fully Remote Trials



# DCTs-What's enablers?

**Trial conducted in whatever setting is best for participant and study**



**Digital Recruitment**



**Remote Consent**



**Direct to Patient Drug Delivery**



**ePRO & Engagement**



**Connected Sensors & Novel Endpoints**



**Home Nursing & Local Care Providers**

# Flexible DCT models

## -Not one-size-fits-all approach

### Traditional Visit Model



### Hybrid Visit Model



# DCTs-What's benefit?

Patient

Reduces the number of onsite visits and site burden



Reduces patient burden & increases willingness to participate and be compliant

Investigator & Regulatory

Increases opportunity for contextually relevant data capture



Narrows gap between clinical trial & real world experience

Sponsor

Expands access to eligible participants



Reduces cost to setup and manage sites



# DCT Settings Case Study

A study to compare conventional & patient-centered remote study models

## Low Back Pain



### Patient-Centered Remote Arm

### Conventional Arm

Pre-screening call

↓ eICF by email

eICF Signed

↓ Study equipment shipped

Patients ready to use eDiary

Tele Visit

Tele Visit

Study equipment shipped back

eICF signed at clinic  
Patients take home study equipment for use

Tele Visit

Site Visit

Study equipment returned onsite

eICF



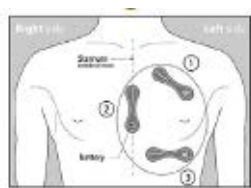
ePRO (eDiary)



Direct Data Capture



Wearable Device



2wks  
Data collection

Sources:

Adapted from: Sommer C et al. Contemporary Clinical Trials Communications, 11: 120-6, 2018



# PCRT Settings Case Study

A study to compare conventional & patient-centered remote study models

## Key Results

- **>3 times** higher recruitment rate achieved in decentralized model vs conventional model (18 pts vs 5pts)
- **~30% of patients** from decentralized arm recruited from rural areas
- **Successful remote consent process**
- **Use of sensors & ePRO feasible**

Recruitment metrics	Decentralized	Conventional
Enrolled Number (city/town/rural)	18 (8/5/5)	5 (4/1/0)
<b>Average enrolled number of patients per month</b>	<b>4.5</b>	<b>1.25</b>
Completed Number	16	3
Discontinued Number	3	2
<b>Completing study recruitment rate</b>	<b>89%</b>	<b>60%</b>

Sources:

Adapted from: Sommer C et al. Contemporary Clinical Trials Communications, 11: 120-6, 2018

# SWOT Analysis for DCT in Japan

## Strength

- Technology-advanced
- High-prevalence of mobile devices
- Highly-experienced, globally-renowned medical experts

## Opportunity

- Super-aging society
- The highest clinical study costs
- Demand for transforming ways in all stakeholders

## Weakness

- No regulatory platform / guidance
- Insufficient infrastructure / limited experiences of remote clinical diagnosis

## Threat

- Too conservative mindset
- Behind global advance including not only US, but also China, EU etc.



Thank you