



# Decentralized Clinical Trial Myth or Reality ?

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**The Promise of Clinical Trials:  
Transforming Tomorrow's Health**

**SCRI Clinical Trials Symposium 2024**

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# OVERVIEW

- What are DCTs?
- Why DCTs? The importance of DCTs
- DCT Global Market Size and Trends
- DCTs Opportunities
- Benefits vs Challenges of DCTs
- DCTs Iceberg Model for APAC
- Key Players in the DCTs Space
- DCT Case Study
- Innovation and Future trends in APAC

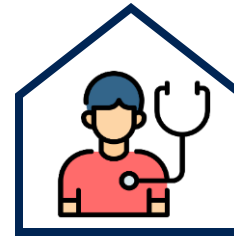
# WHAT ARE DECENTRALISED CLINICAL TRIALS?

- A DCT is a clinical trial that utilize technology, processes, and services that minimize or eliminate the need for patients to physically visit a traditional research site
- DCTs represent a modern, 'patient-centered' approach to conducting clinical research, compared to traditional clinical trials

According to the FDA, DCTs are "the **decentralization** of clinical trial operations where **technology** is used to **communicate** with study **participants** and **collect data**."

# WHAT ARE DECENTRALISED CLINICAL TRIALS?

- Key characteristics and components of decentralized clinical trials are:
  - ✓ Remote Participation
  - ✓ Patient-Centricity
  - ✓ Use of Digital Technologies/Virtual Tools
  - ✓ Decentralized Data Collection
  - ✓ Risk-Based Monitoring
  - ✓ Hybrid Approaches



DCTs





# WHY DCTs? DCTS address key unsolved issues of current randomized clinical trials

## Focus on patient

- At-home delivery increases participation
- Direct-to-patient approach accelerates recruitment
- Personalized interaction maximizes retention and fosters better medical adherence
- Virtual study team facilitates patient journey

## Improve data quality

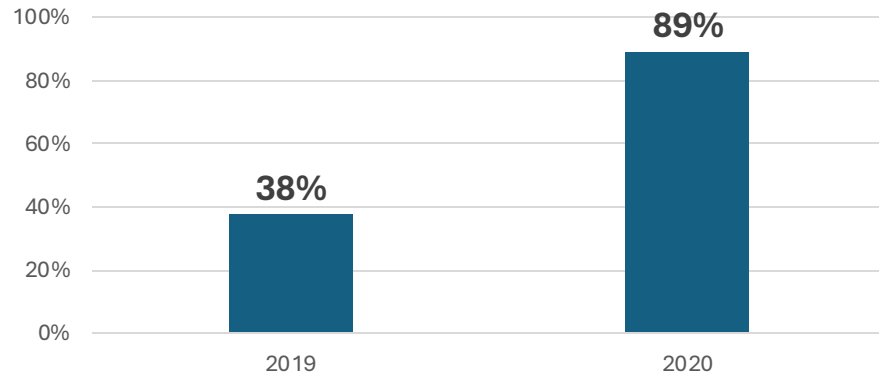
- Mobile, connected devices enhance data gathering
- Centralized collection reduces variability
- Near real-time access enhances safety signal detection
- Increased data completeness and accuracy
- Better study results with greater patient diversity

## Reduce overall trial cost

- Streamlined engagement, enrollment, trial management
- Fewer physical site visit costs
- Centrally managed workflows, monitoring and communications improve efficiency

# DCT GLOBAL MARKET SIZE AND TRENDS

Raise In Virtual Trials In Pandemic  
- A Survey In Dec 2019

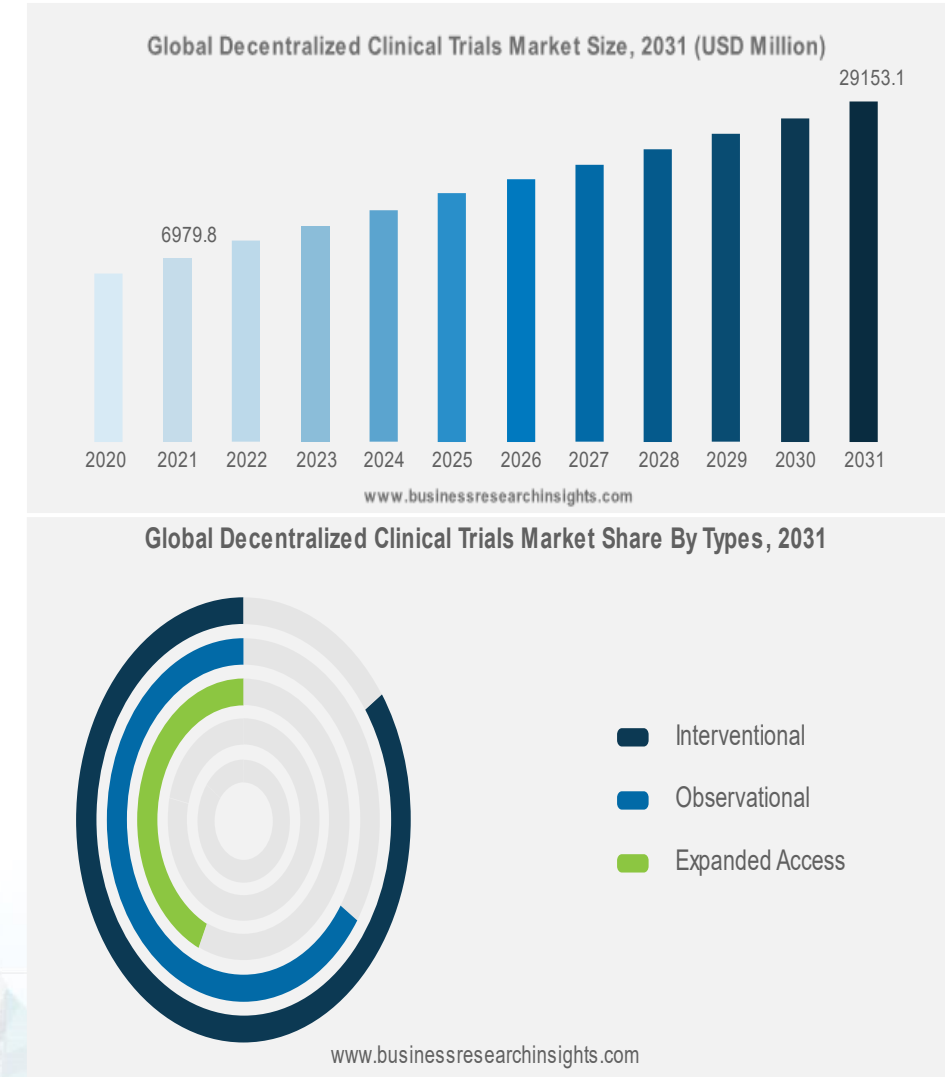


## Latest trends

- Evolving technology and services to lead market growth

## Driving factors

- Increased interaction with virtual systems to propel growth



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source: [www.businessresearchinsights.com](http://www.businessresearchinsights.com)

# DCTs OPPORTUNITIES

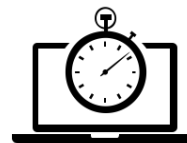
Key opportunities associated with decentralized trials:



Enhanced Patient  
Access and Diversity



Improved Patient  
Engagement and Retention



Real Time Data Collection



Efficiency and Cost  
Savings



Integration of Real-World  
Evidence (RWE)



Remote Site Monitoring and  
Quality Oversight



Patient-Centric Trial Design



Facilitation of Innovative  
Trial Designs



Regulatory Support and  
Frameworks

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# BENEFITS VS CHALLENGES OF DCTs

## Benefits



**Reduce Patient Burden**



**Increase Patient Retention**



**Increase Patient Diversity**



**Increase Patient Engagement**



**More efficient leading to cost- savings**

## Challenges



**Technology Failure**



**Ensuring Data Quality**



**Regulatory Hurdles**



**Data Privacy & Security Concerns**



**Integration with Healthcare Systems**

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# DCT ICEBERG – APAC



- Till date, not a single complete DCT trial has been conducted in APAC
- The success of DCT in APAC hinges on the early engagement of stakeholders, including sponsors, investigators, patients, vendors, CROs, and regulators

# KEY PLAYERS OPERATING IN DCTS SPACE



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source: [www.precisionbusinessinsights.com](http://www.precisionbusinessinsights.com)



# DCT CASE STUDY

## Fully Virtual Trial

**Target:** Home-use device.

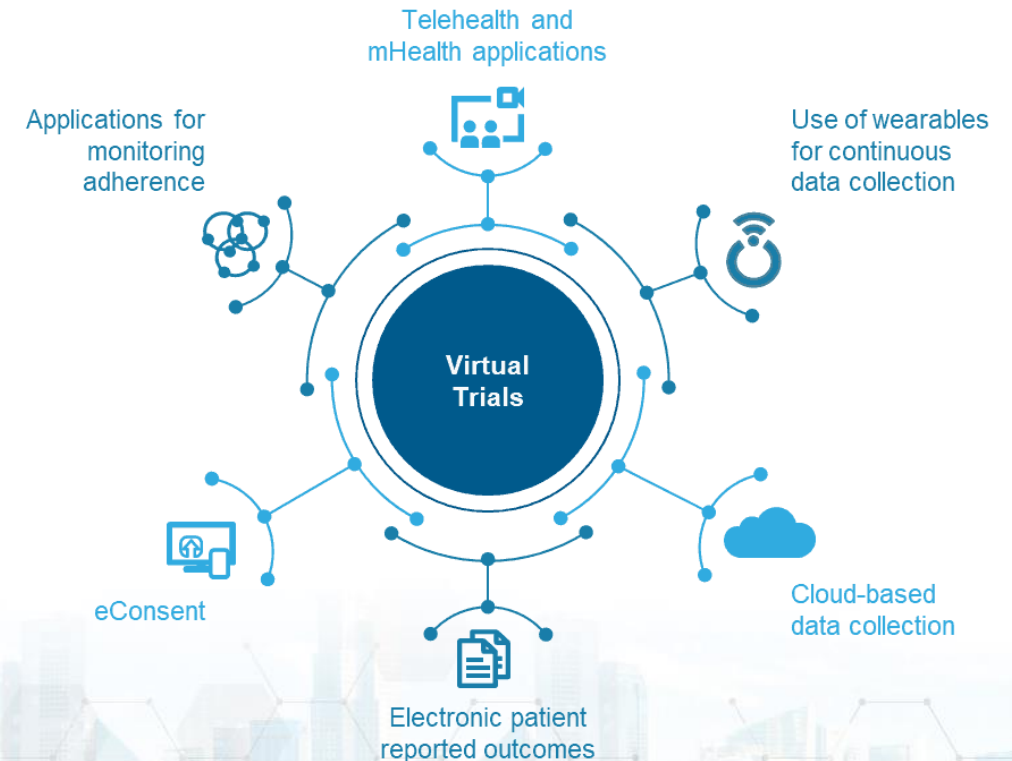
**Recruitment:** Participants were identified via social media with pre-screening questions.

**Enrollment:** Conducted via telehealth visits.

**Training:** Provided through virtual video sessions.

**Management:** Managed virtually by a CRO using telehealth and e-Diary/ePRO platforms.

**Safety:** Self-reported by participants, overseen by CRO's Safety Officer

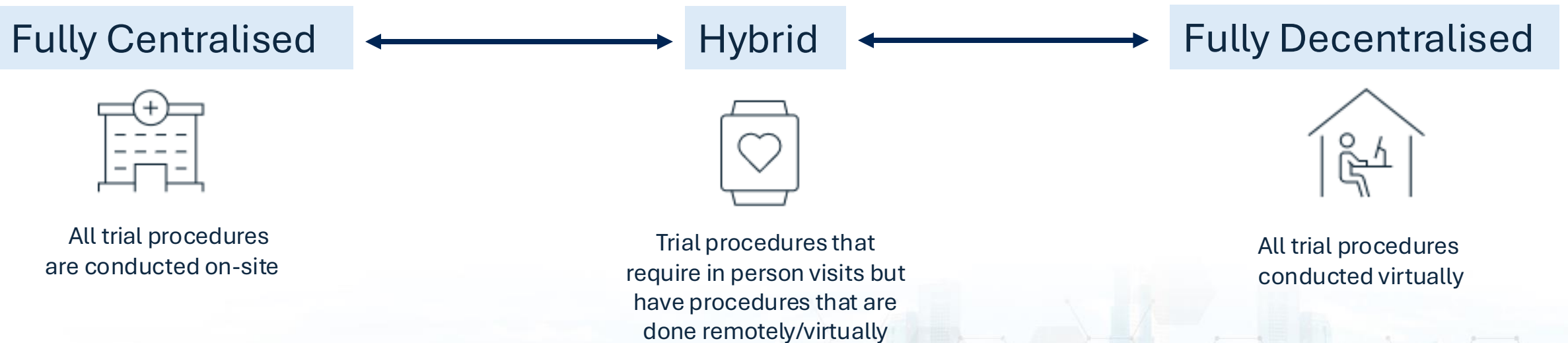


# INNOVATION AND FUTURE TRENDS IN APAC

- ✓ APAC countries are increasingly embracing digital health technologies..
- ✓ Regulatory bodies in APAC countries are increasingly supportive of DCTs.
  - ✓ *e.g., Japan, South Korea, and Singapore*
- ✓ Expansion of telemedicine infrastructure in APAC countries.
- ✓ Innovations in patient engagement platforms tailored to local languages and cultural preferences
- ✓ Expected increase in partnerships between pharma companies and CROs specializing in DCT solutions
- ✓ Exploration of real-world data (RWD) sources such as electronic health records (EHRs) into clinical trials.
- ✓ Hybrid Trial Designs is gaining popularity in APAC



# SCALING DECENTRALISED CLINICAL TRIALS

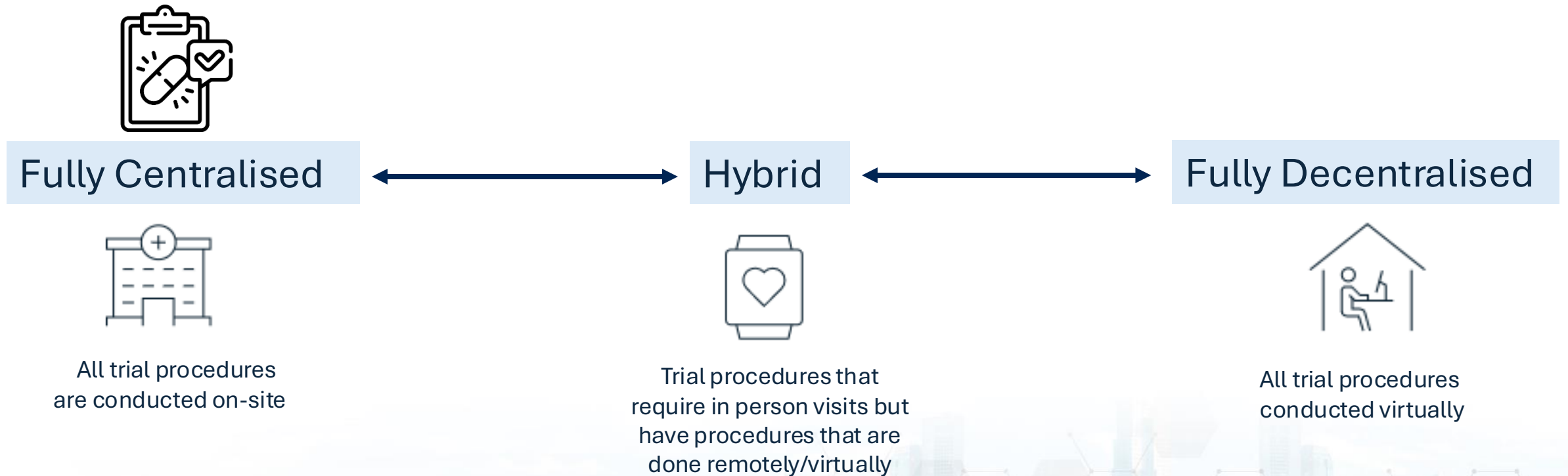


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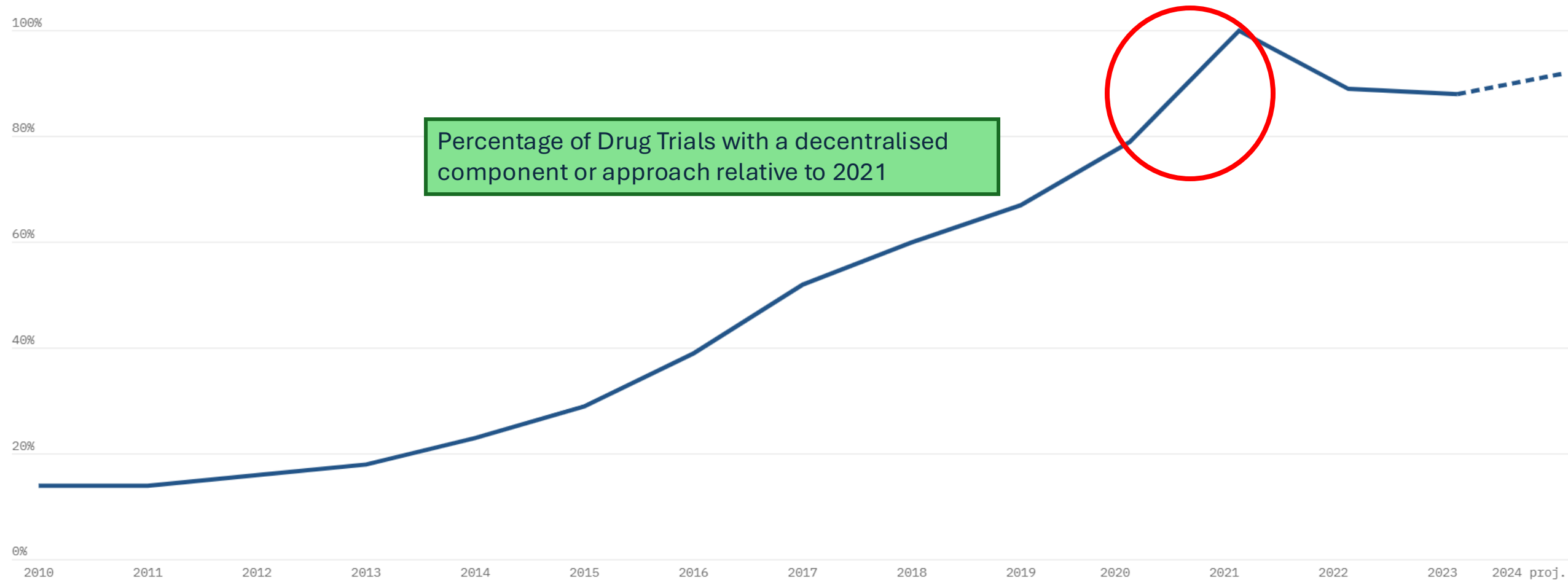
<https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials>

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# DCT PROJECTION FOR THE FUTURE



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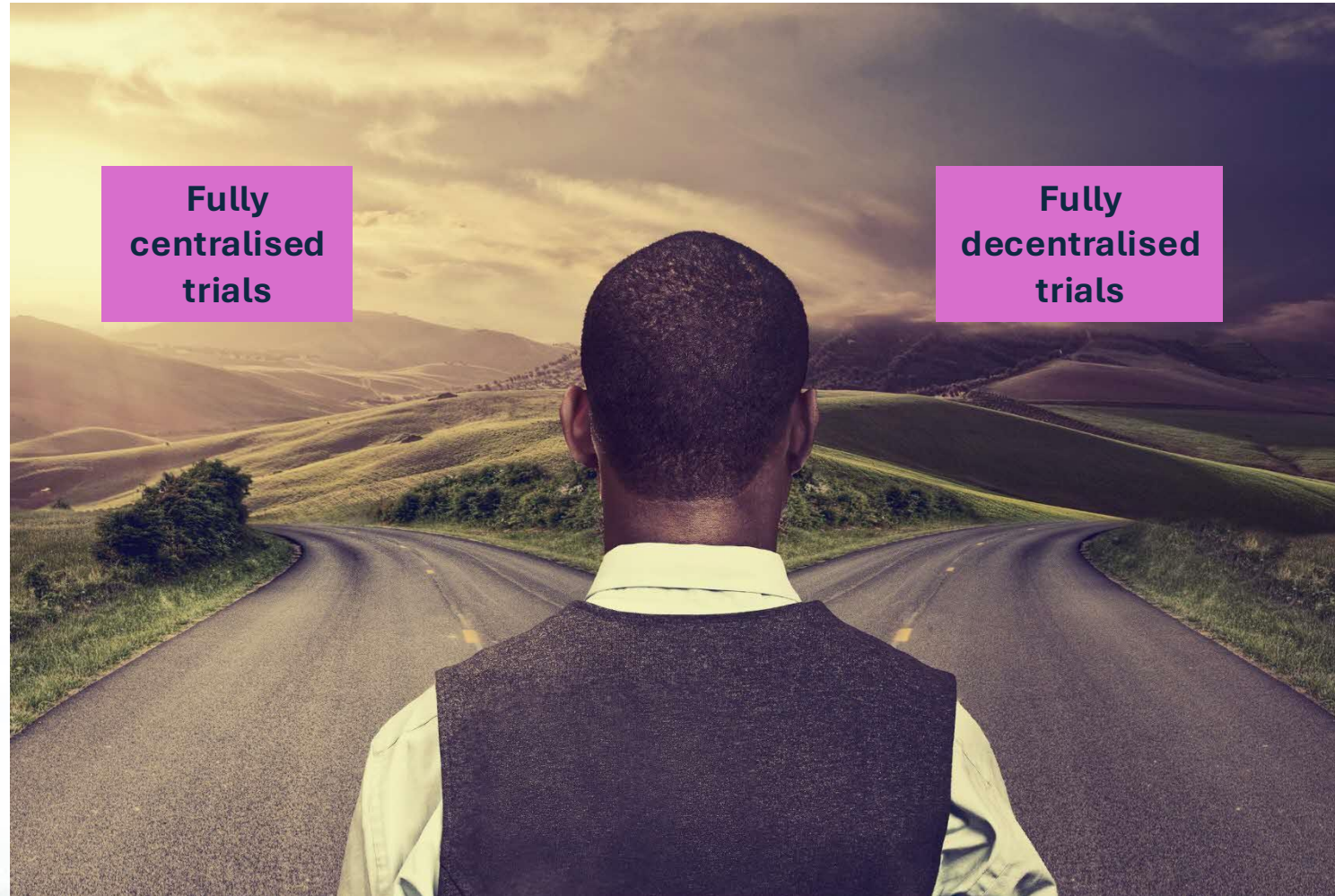
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*Clinical Trials Arena DCT Tracker: 2024 data projection based on activity between 2010 to 2024*



# DCTS: THING OF THE PAST OR THE WAY FORWARD?



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# Thank You!

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