

# Decentralized Clinical Trials in APAC: *An Emerging Market*

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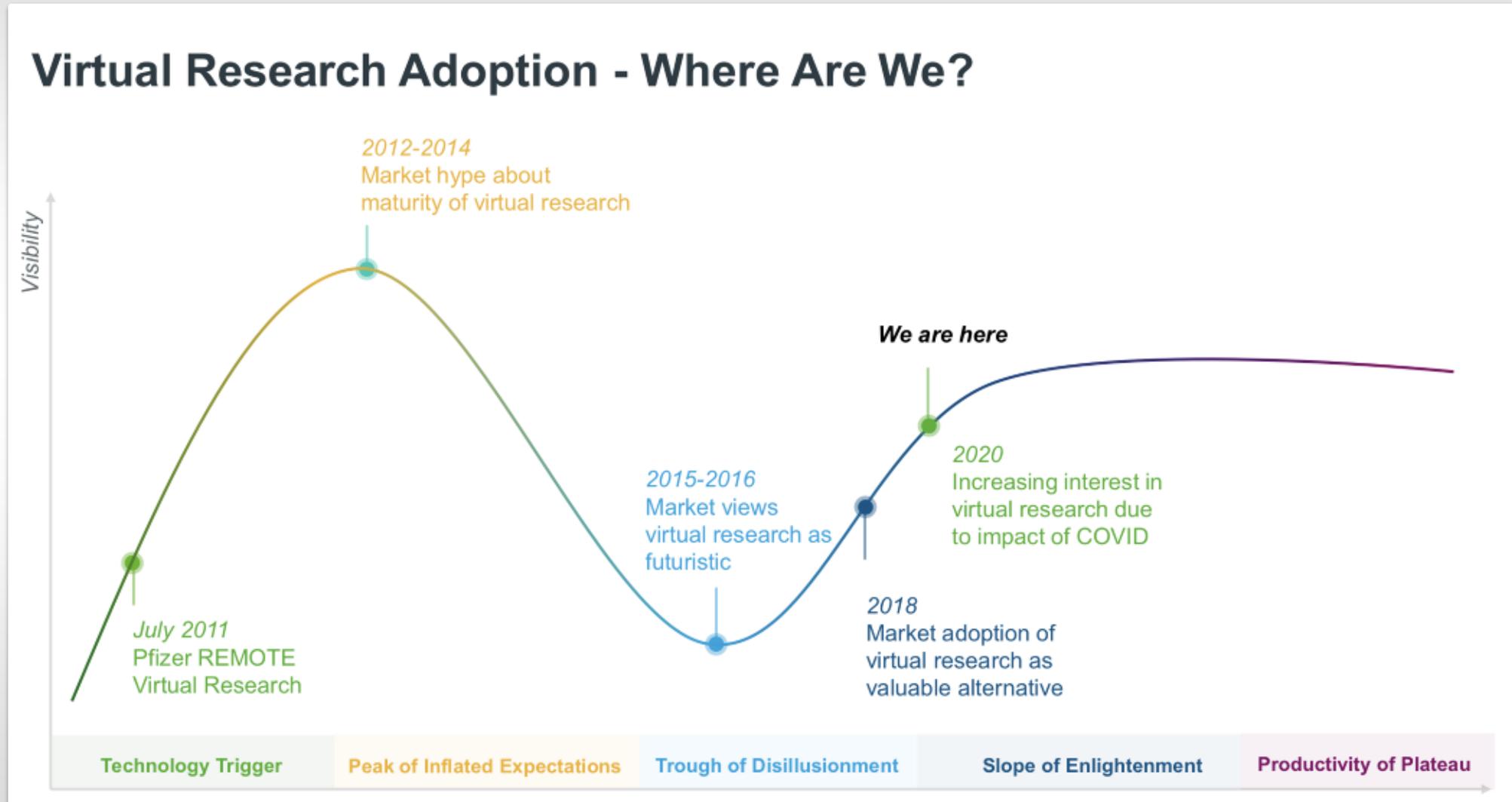
**GMP FORUM** 

# Decentralized Clinical Trials in APAC - An Emerging Market

- Points for discussion
  - Why conduct trials in APAC?
  - Feasibility of DCT and DTP in APAC
    - Supply chain regulations in APAC
    - DTP in key APAC countries
  - Planning and Future for DCT and DTP in APAC

# DCT- The Data Speaks For Itself

*Market research and data collected by IQVIA on where and how sponsors see clinical trial conduct in the future. The current state is an increasing interest in virtual research.*



# DCT- The Data Speak For Itself

Questionnaire conducted by Fierce Biotech in 2020 to determine how likely the consumer/patient would participate in the "Direct to Patient" or "Virtual" or "Decentralized" clinical trial.

## Patient Perspective on Virtual Research

Approached about full virtual research



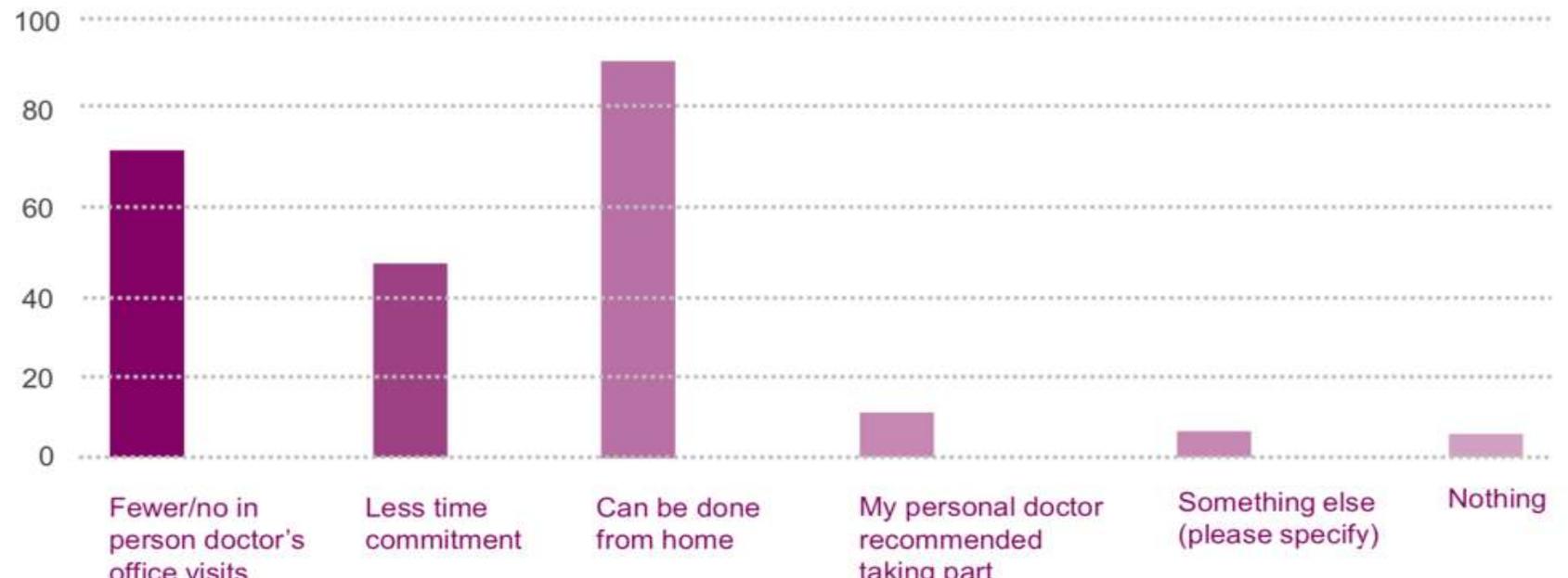
Patients favor a virtual model 2:1



Of patients indicated that virtual visit was of high quality

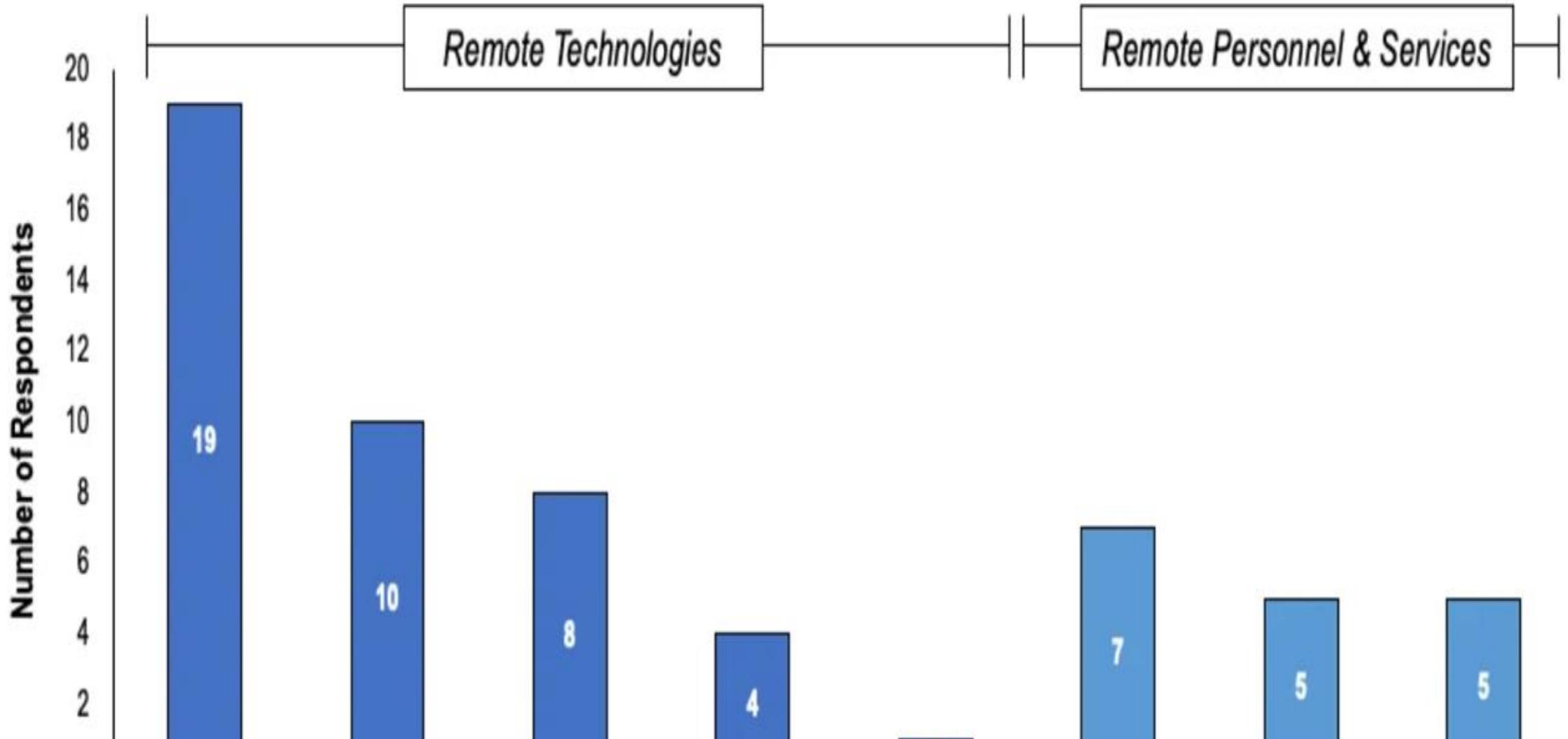
"It's an advantage to have your information at your fingertips, as opposed to having to wait to go into a doctor's appointment. There is a definite advantage. Everything's right there."

- Focus Group Participant



# DCT- The Data Speak for Itself

*POST COVID19: Adoption of remote monitoring technologies and decentralized approaches from 20 stakeholders to implement a wide range of novel remote monitoring technologies and decentralized approaches to make trials more patient-centric in the COVID era. Five in 20, that is 25% of stakeholders chose DTP drug delivery (FierceBiotech in 2020)*

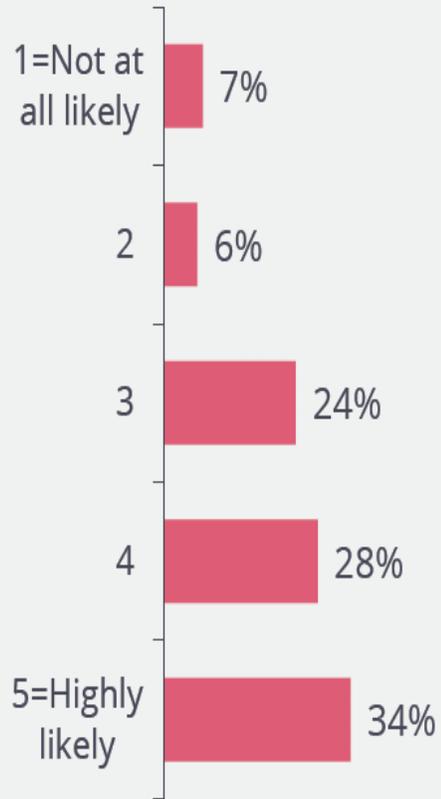


# Why Conduct Trials in APAC?

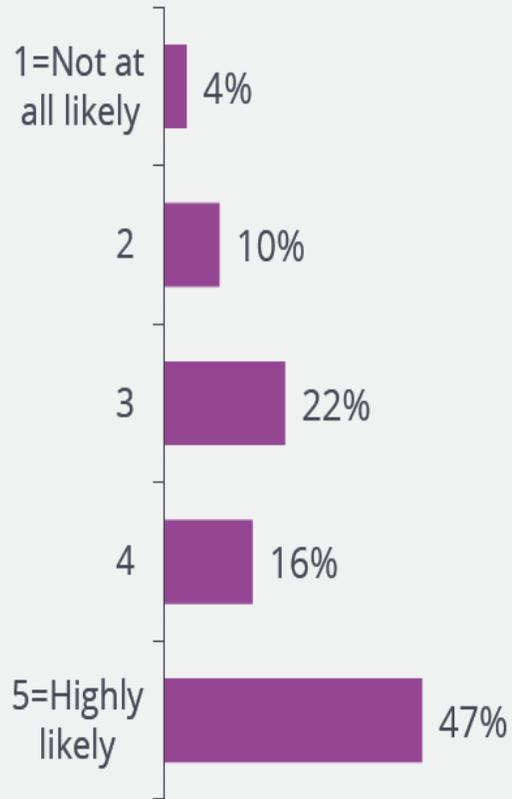
- Increased investment in clinical trials in APAC
- A shift from big pharma to Biotechs, who focus on unmet needs
- Different model: resources & budgets are smaller, outsourcing to facilities and CROs in the region
- Australia is leading this success

# Likelihood of Increased Clinical Outsourcing in the Next 3 Years

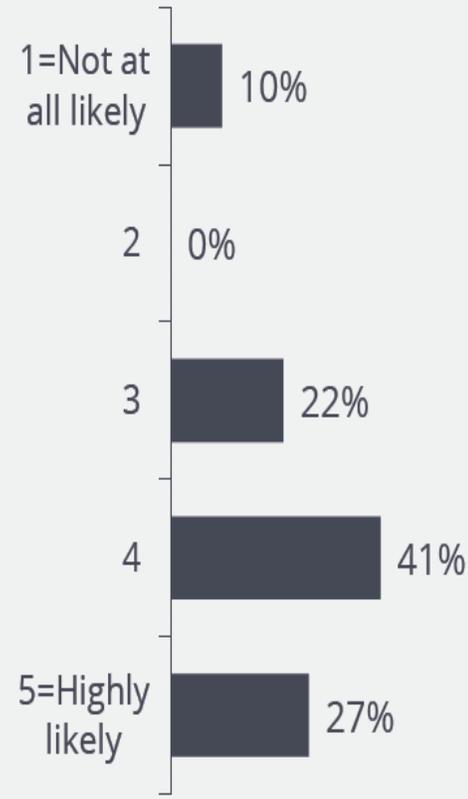
## All Respondents



## Based in Asia-Pacific



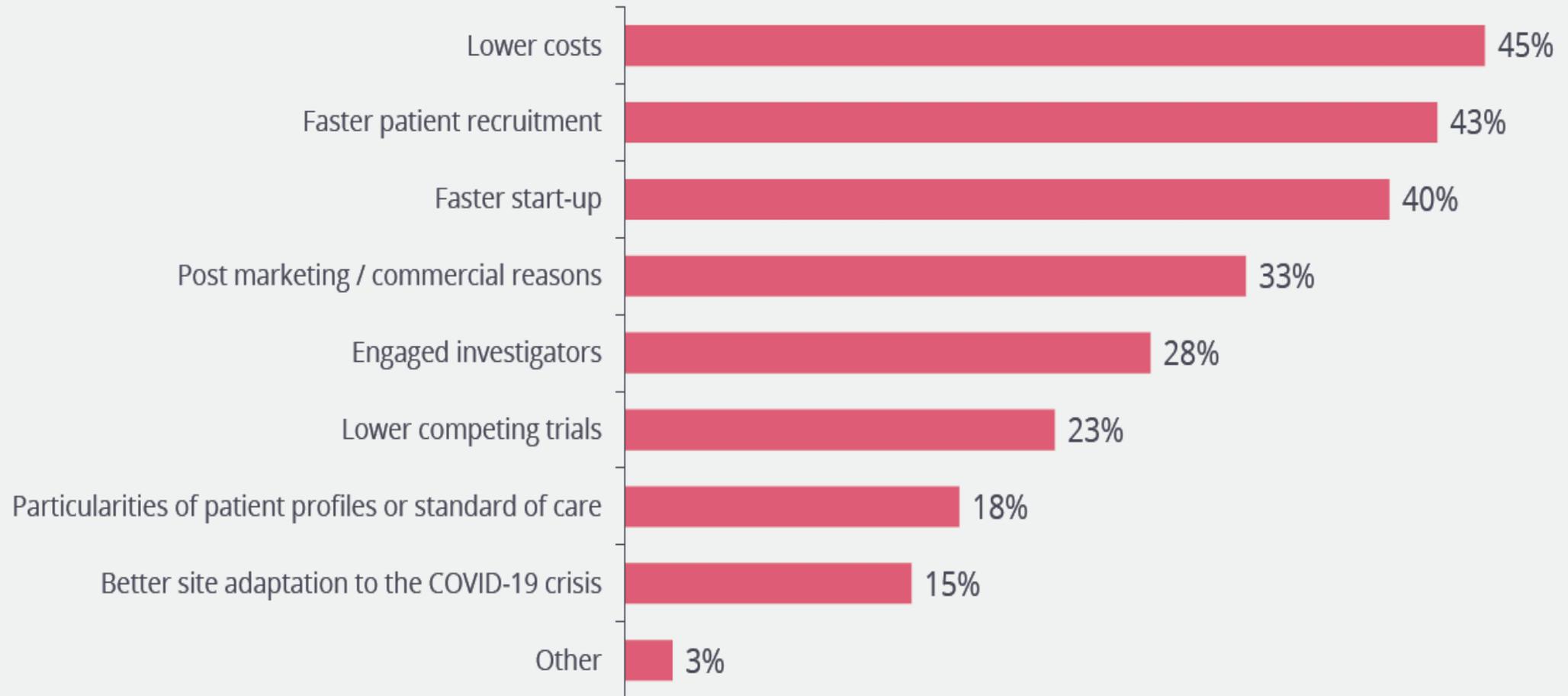
## Based in North America



## Based in Europe



### Figure 3: Motivators For Running Future Trials In Asia-Pacific



**Question** What would motivate you to consider the Asia-Pacific region for future clinical trials? (Select all that apply.):

Base: Respondents not running clinical trials in the Asia-Pacific region (n=40); multiple answers permitted.

# Several Countries; standardizing the process-WIP

- Australia/New Zealand
- Japan
- China
- Taiwan
- Hong Kong
- S.Korea
- Thailand/Malaysia/Vietnam
- Singapore



# Australia most popular destination, why?

- Quality medical research infrastructure and a skilled workforce
- Key opinion leaders across most therapeutic areas
- A world class health system
- Attractive research and development (R&D) tax incentives for clinical trials
- A fast, pragmatic regulatory pathway (within 6 weeks from application to CTN approval)
- Clinical data which complies with the highest international standards
- Strong capability in manufacturing of products to be trialled
- A strong intellectual property system
- An ethnically diverse, English-speaking population
- Proximity to Asia (emerging markets China, Korea and Japan)

# Feasibility of DCT and DTP in APAC

- All stakeholders need to be on-board
- Logistics
  - Investigational Product to patient-how?
  - Mobile nurses/home health care service
- Site and Site PI still have overall responsibility
- Delegation of responsibilities/duties log
- Lots of technology required, overwhelming patients with technology?

# Feasibility of DCT and DTP in APAC

- Choose your CRO locally or in country with most difficult regulations
- Choose your CMO and depot locally
- Regulatory requirements for conducting traditional clinical trials especially privacy and security
- Apply the DTP for that specific country

# In Australia and New Zealand

- Can do from site to patient's home
- From pharmacy to patient's home
- Depots cannot ship IP to patient's home, a registered pharmacy premises must be involved

# In China

- Eastern part has more developed transportation and health delivery infrastructure compared with the West
- Can only do from site to patient's home
- Can do depot to patient-GDP must be observed

# In Japan

- More interaction is required between clinical site and CMO and organizations than any other country
- English is typical language spoken
- Can only do from site to patient's home

# In Singapore

- A great hub for import, export, reverse logistics (returns)
- Can be used by S.Korea, Taiwan and Thailand as a base for import, export and destruction of returns
- Flexibility exists with DTP from site, depot and pharmacies

# Planning and Future for DCT

- DCT and DTP should be developed as the study protocol is being developed
- A clinical supply partner pivotal in assisting the sponsor in defining the clinical supply strategy to build in maximum supply chain flexibility and identifying logistical hurdles
- Still need solid proof and evidence that DCT is working, this space is still evolving
- Still early days however we can see Patient Retention in trials is improving significantly

# QUESTIONS and DISCUSSION

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