



Outlook on Decentralized Trials

PCRIP, Inc.

ANNA M S L ORDINARIO | 17 FEB 2023

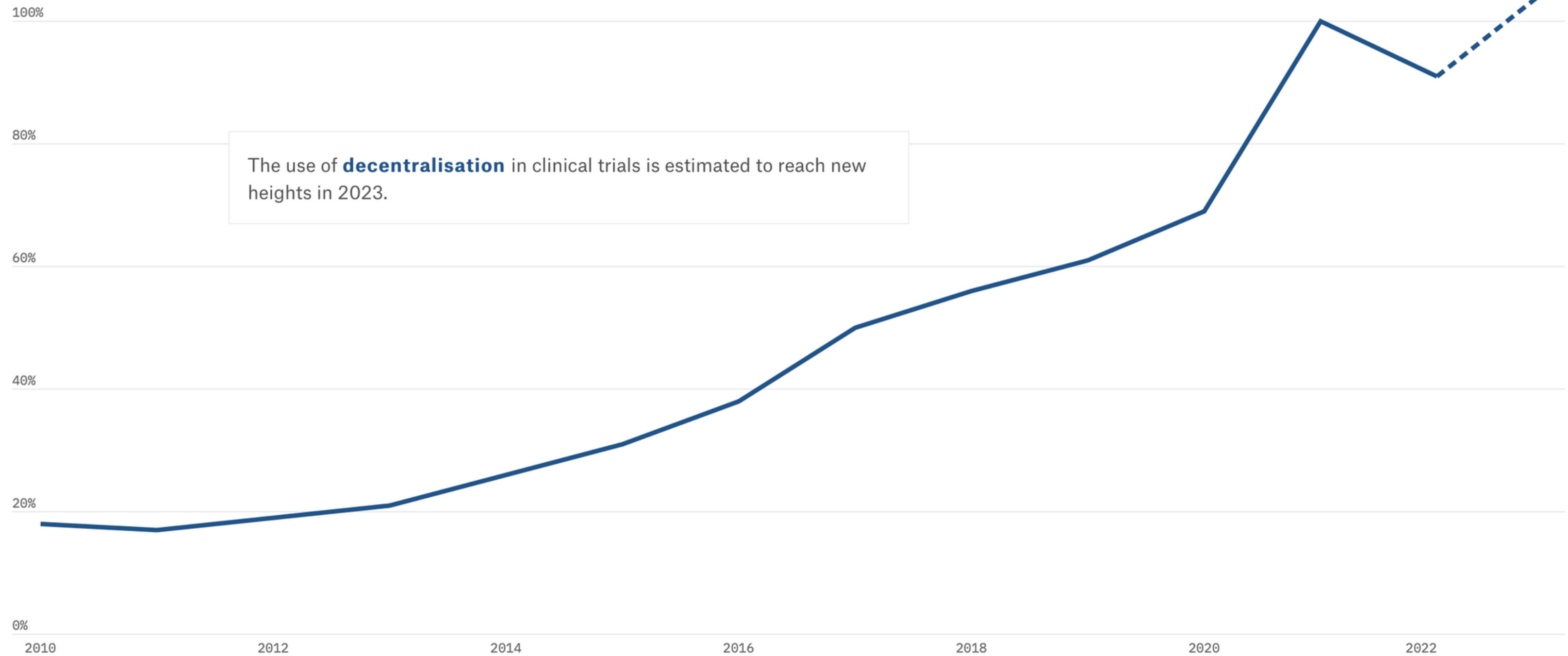


Your most recent
experience?

**The last 10 years has seen a
70% increase in the number
of procedures performed per
participant per visit.**

Getz, K. A., & Campo, R. A. (2017). Trial watch:
Trends in clinical trial design complexity

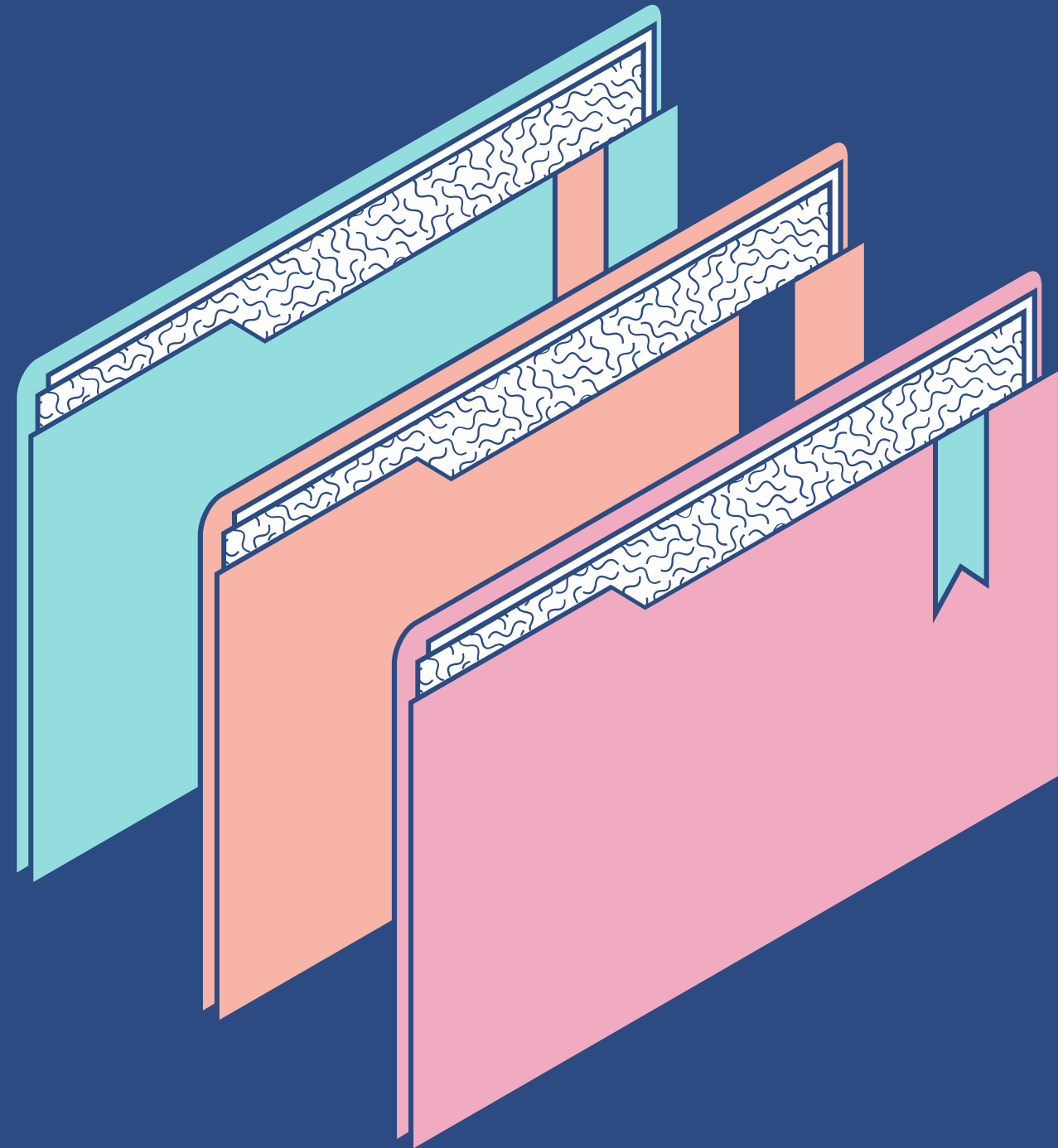
Amount of drug trials with a decentralised component or approach relative to 2021 (100%)



Note: 2023 data is a projection based on activity between 2010 and 2022.



OUTLOOK



Key topics

- What are DCT Trials
- DCT Elements
- Activity - Polls
- Perceived Benefits and Challenges
- Views from Regulators
- Activity - Theme Generation

...Answer the following questions

1

2

3

What elements of DCTs are implemented in the Philippines so far?
In what types of studies, and to what extent are they implemented?

How is our DCT experience in the Philippines so far?

With the Philippine setting in mind, what needs to be in place or needs to happen to successfully implement DCT / DCT elements?



What are DCTs?

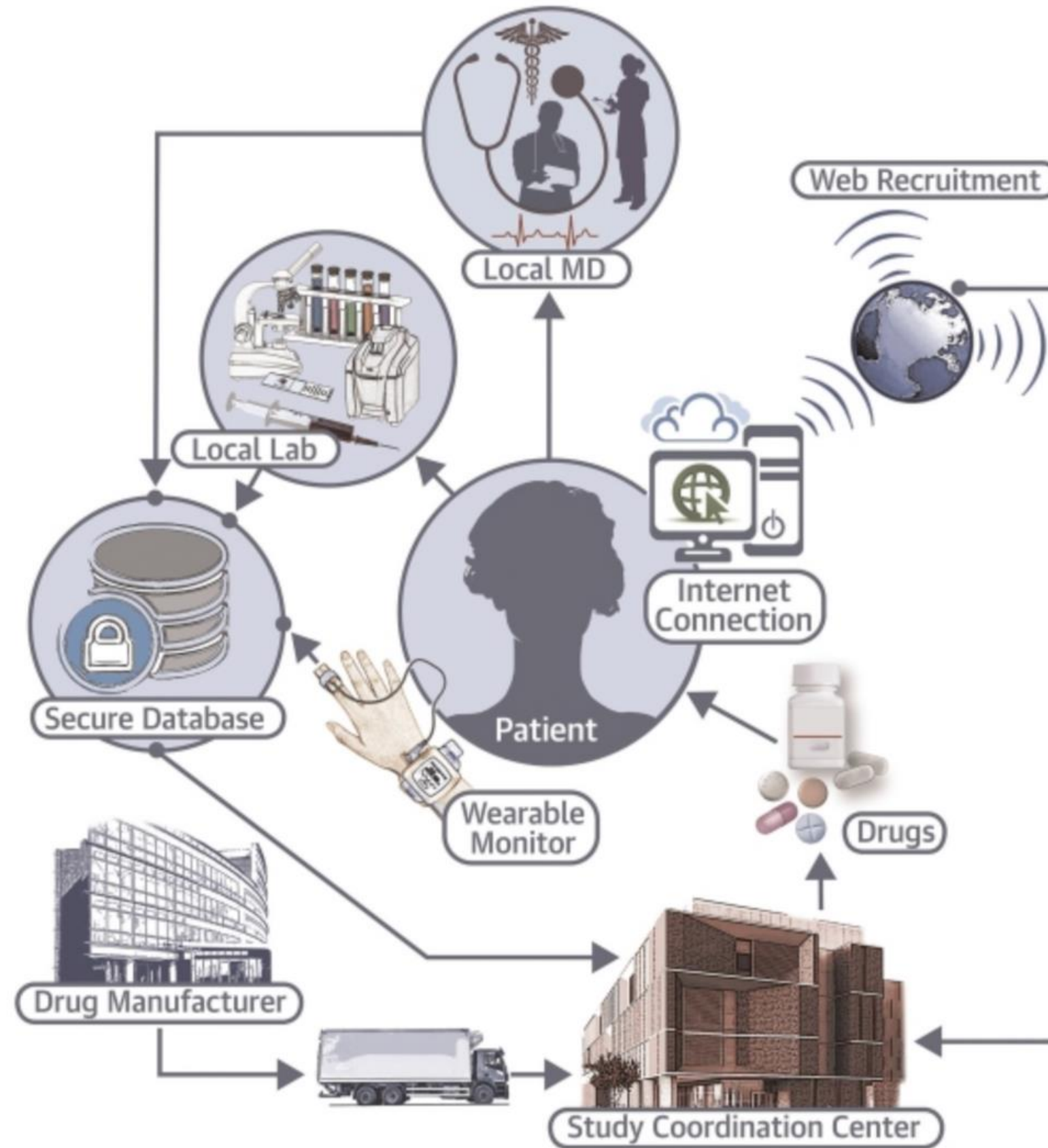


Decentralized Clinical Trial (DCT)

A clinical trial utilizing technology, processes, and/or services that create the opportunity to reduce or eliminate the need for participants to physically visit a traditional research site

DTRA
Glossary

CENTRAL ILLUSTRATION Decentralized Clinical Trials



Van Norman, G.A. J Am Coll Cardiol Basic Trans Science. 2021;6:384-387.

DCT Elements

Performance of trial-related interventions outside the trial site

- Trial visits using telemedicine
- Home health visits and Home healthcare professionals
- “Mobile labs”
- Satellite facilities
- Source data recording and archiving
- Remote patient ID verification
- Digital endpoints

Data capture outside the trial site using mobile technologies

- Connected medical devices and digital endpoints
- ePRO / eCOA
- Use of software as medical devices, may be assisted by AI (prediction)
- eSignature

Dispensing and administration of the IMP outside the trial site

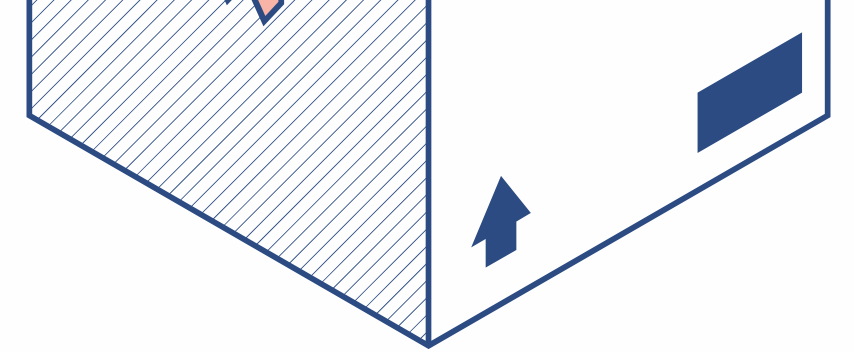
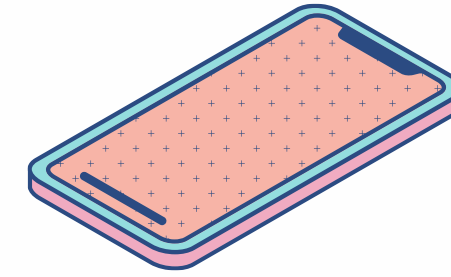
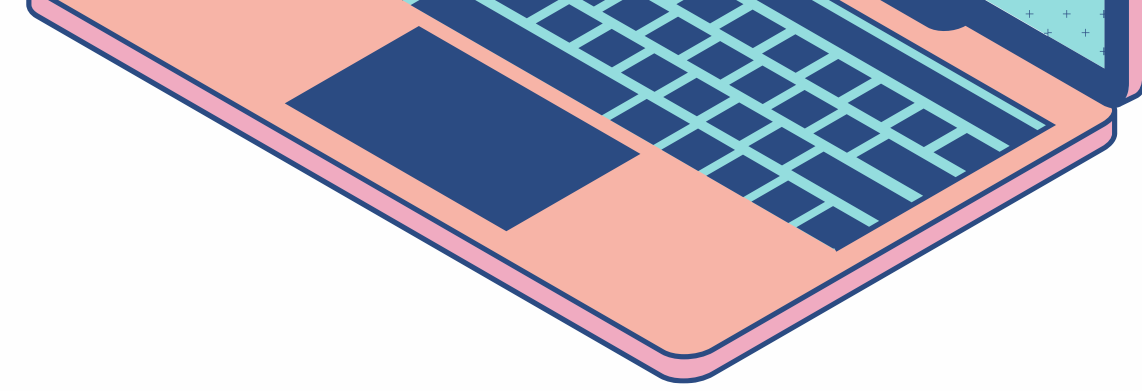
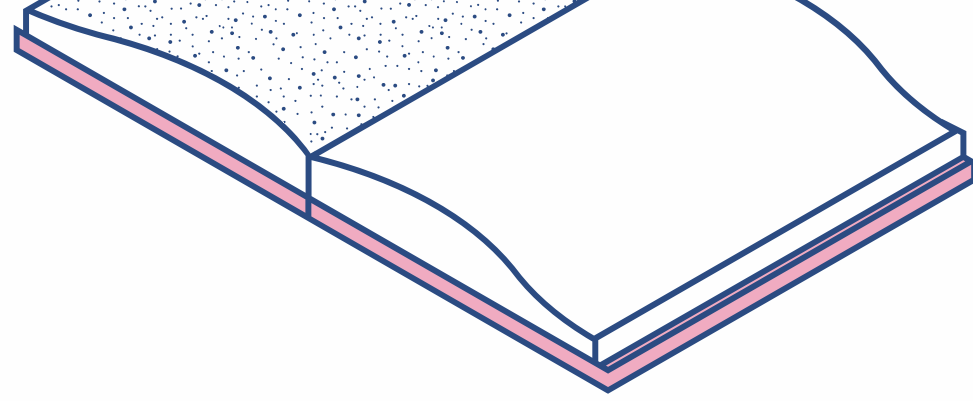
- Direct delivery to home
- Delivery to a local Pharmacy
- Pick-up (subject or study nurse)

Remote source data verification

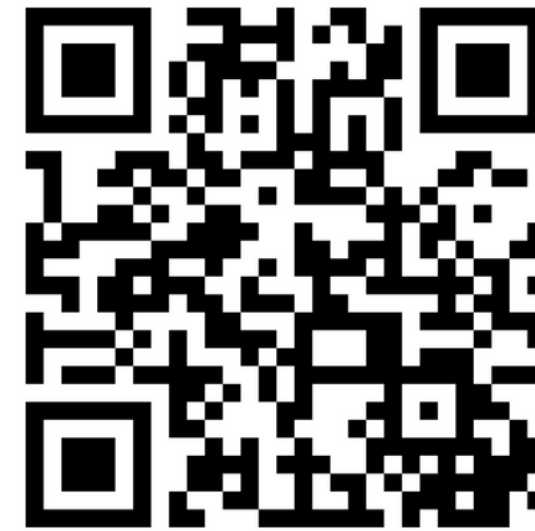
- Review of uncoded data outside the trial site
- AI/ML data review, analytics
- EMR-EDC connection

Recruitment through digital channels

- Online recruitment portals
- Electronic screening
- Electronic Informed Consent and eSignature

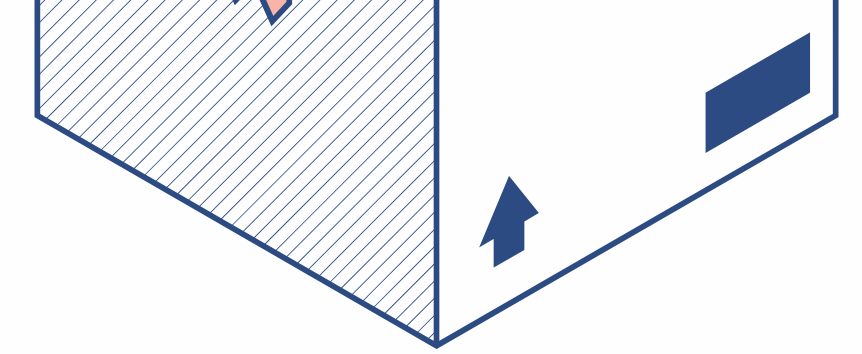
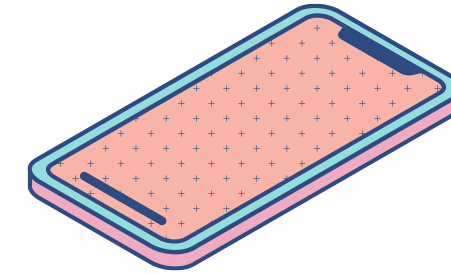
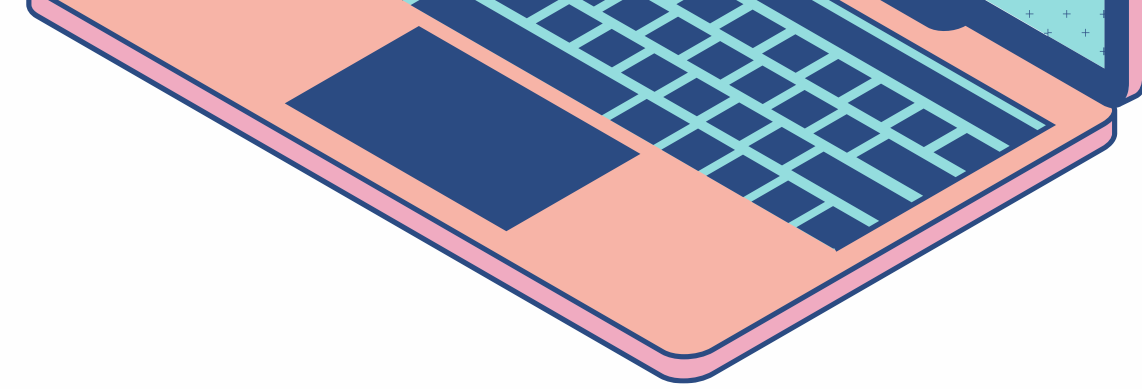
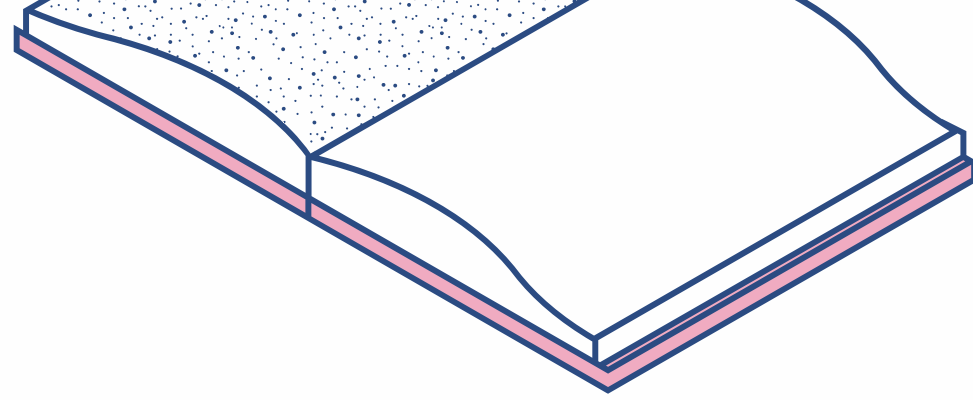


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Code: 2630 8210

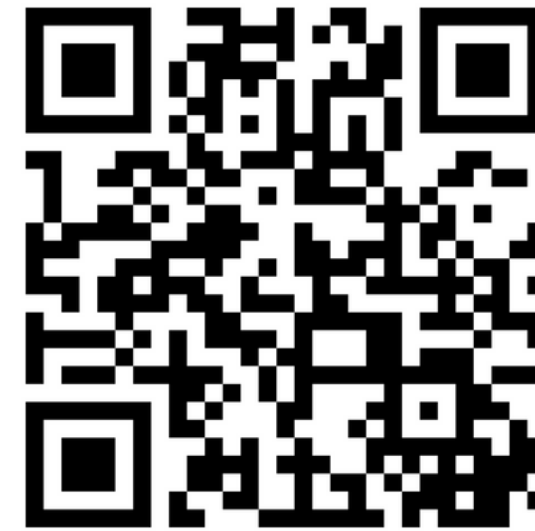


What elements of DCTs have you experienced / seen in your studies so far (In the Philippines)?

In which Therapy Areas / Study types do we see DCT / DCT elements (In the Philippines)?
[TA/Disease study] [DCT element] [Provider]*optional



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**How is our DCT experience in the Philippines so far
(Comment about your experience as CRAs, what you're hearing
from experience of Investigators, Site Teams, Patients, other
stakeholders)?**

Perceived Benefits

Time and Cost

Diversity

Decreased subject burden

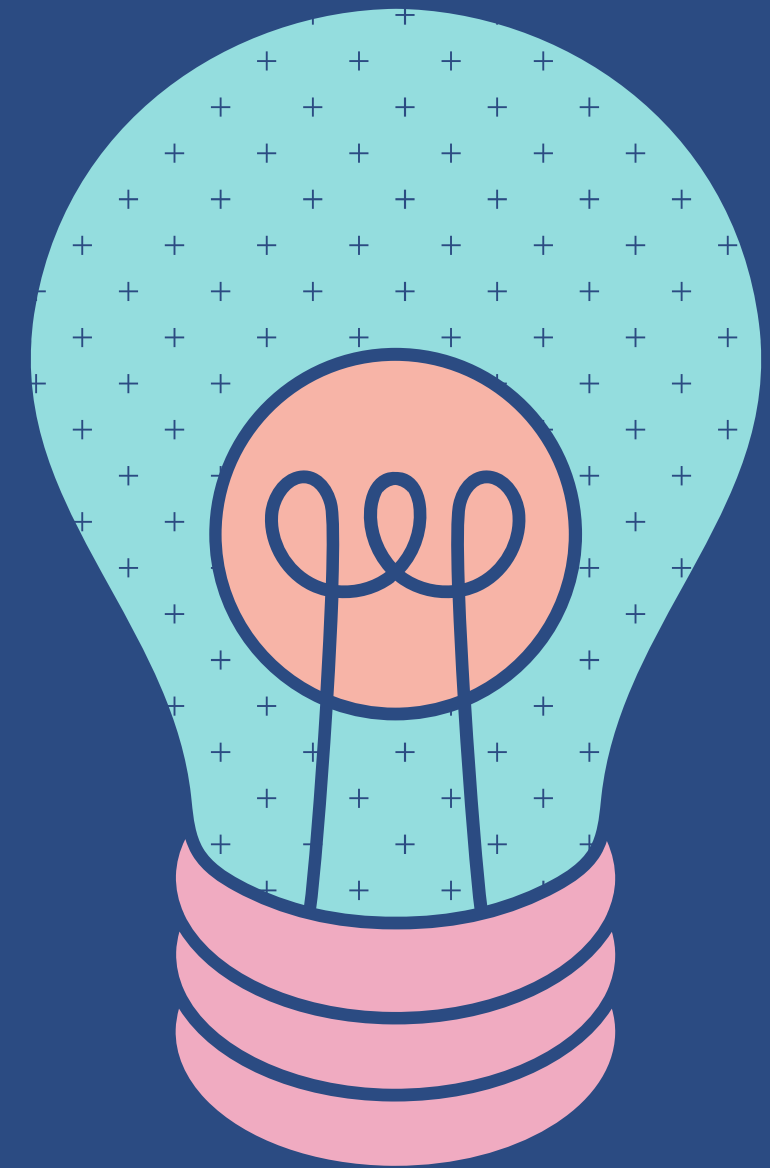
Decreased site burden

Leverage new data sources

Or will it?

Insights...

- Not plug and play
- Will get more...
- Reality of high interest, little adoption



Views from Regulators

Optimal medical care, the rights and safety of subjects must be ensured at all times

The IMP must be safely dispensed, ingested/administered and returned.

The data recorded during the clinical trial must be credible and reliable

The data protection requirements must be met in full

Patient Inclusion

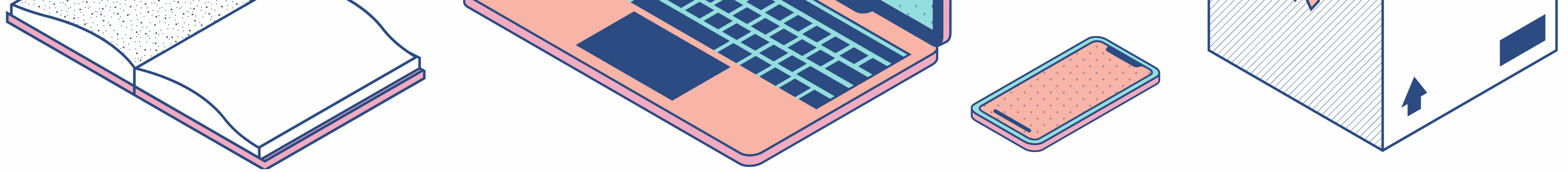
pause



“

**But it's not a faith in
technology.
It's faith in people**

Steve Jobs



Theme Generation

In your tables - choose 1-2 DCT element per table (the one/s you're most interested in)

With the Philippine setting in mind, what needs to be in place or needs to happen to successfully implement this DCT element? (People, Stakeholders, Policies/Process, Capabilities, Infrastructure, Behaviour, etc.)

Just phrases, no need to go in depth
Report back per table on key themes

SCAN ME



Stay Curious!



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