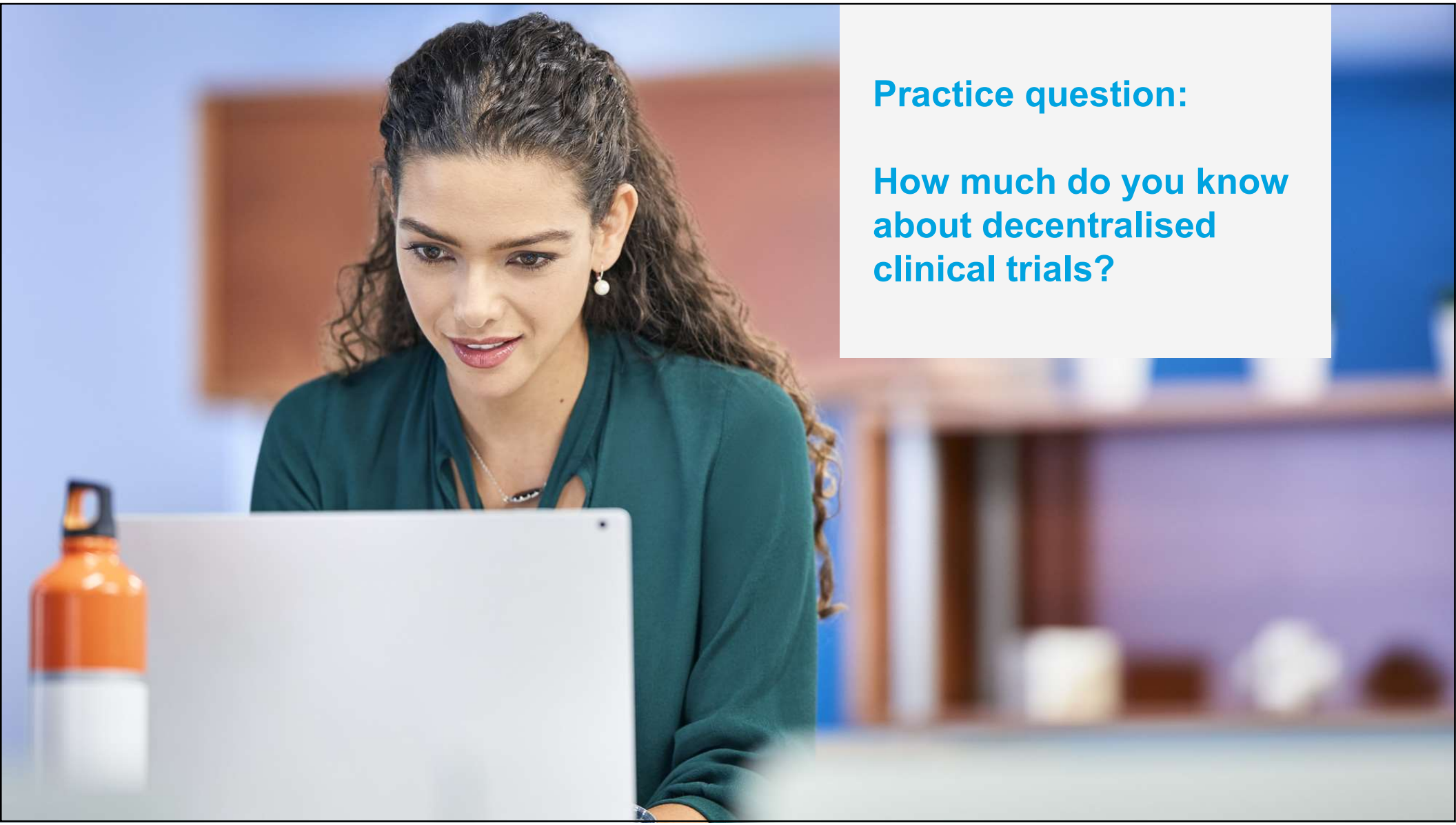
Decentralised Clinical Trials: Myths & Facts about the application and its results

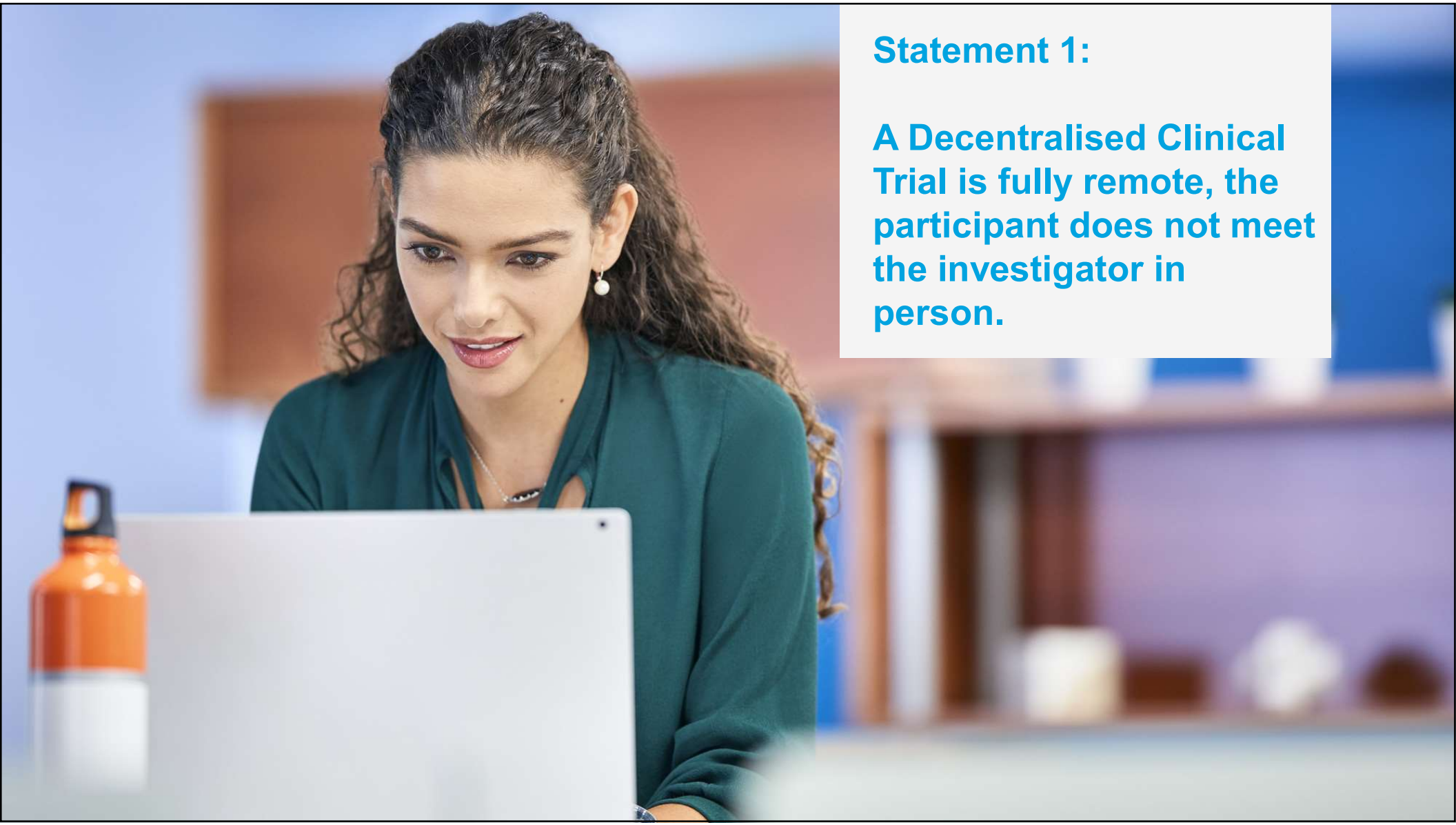
Eric Klaver
Decentralized Clinical Trials Regulatory Director at IQVIA

ACRON Najaarssymposium 2022
1 November 2022 | Utrecht



Practice question:

How much do you know about decentralised clinical trials?



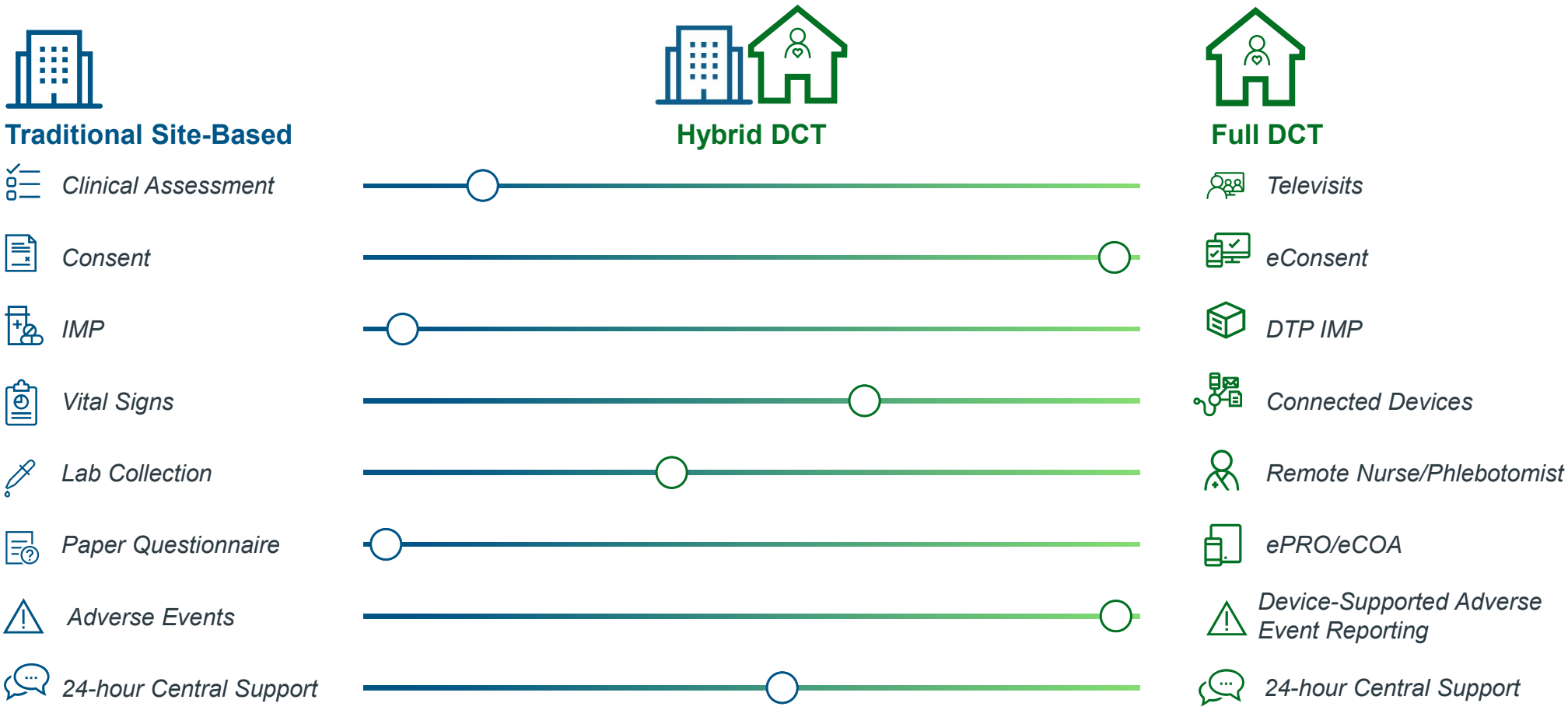
Statement 1:

A Decentralised Clinical Trial is fully remote, the participant does not meet the investigator in person.

Decentralized Clinical Trials (DCT) are defined as:

Any trial that leverages technology and specialized services to engage participants in the community and facilitate patient-centric care, including remote pre-screening, telemedicine visits, at-home treatment, or mobile research nurses and staff. This approach aims to **bring the patient voice into the trial, reduce the burden on sites and patients, and increase representative participation** by expanding traditional site boundaries to deliver a more personalized trial experience.

IQVIA DCT allows for a flexible and patient-centric model



DCT - Designing Trials Around the Participant

A more flexible and efficient approach to clinical research

Initial Screening
eConsent, medical history, conmeds,

Televisits/Home Health
Safety visits, sample collections, adverse events and conmed updates

ePRO & Connected Devices
Questionnaires, vital signs

Laboratory Samples
Safety labs, PK, PD

Baseline Visit
Protocol assessments, obtain any required equipment

Imaging
CT scans, MRI, nuclear medicine scans

Investigational Product
Infusions administered on-site (oral products could be supplied remotely to patients)

Complex Medical Procedures
Certain procedures may still be required to be completed within a hospital/clinic

Meeting the needs patients through a hybrid virtual trial approach

Statement 2:

A DCT Solution is mainly a tech solution.

DCTs are more than just tech

The DCT Solution is designed, developed, and implemented to

- support participants
- support sites
- protect participant confidentiality & privacy

Need for strong human factor involvement to

- enable participants to be successful
- enable sites to be successful
- reduce burden of trial experience

GOAL: Generating credible, verifiable data leading to reliable trial results

Electronic data collection is increasingly remote

And, collected from multiple sources

Increasing data

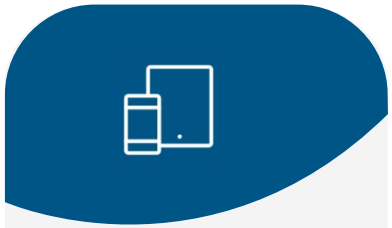
All the data generated between the beginning of time and the year 2000, is the same that is now generated every min of every day.[1]

Data volume

The body of healthcare data is doubling every 2 years.[2]

EDC data capture

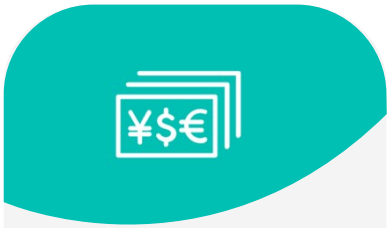
Only 20% – 30% of data points collected in EDC.



Connected Devices

Registered clinical trials using connected devices grew >10x since 2018.[3]

Forecasts suggest sales of wearables will double by 2023.[4]



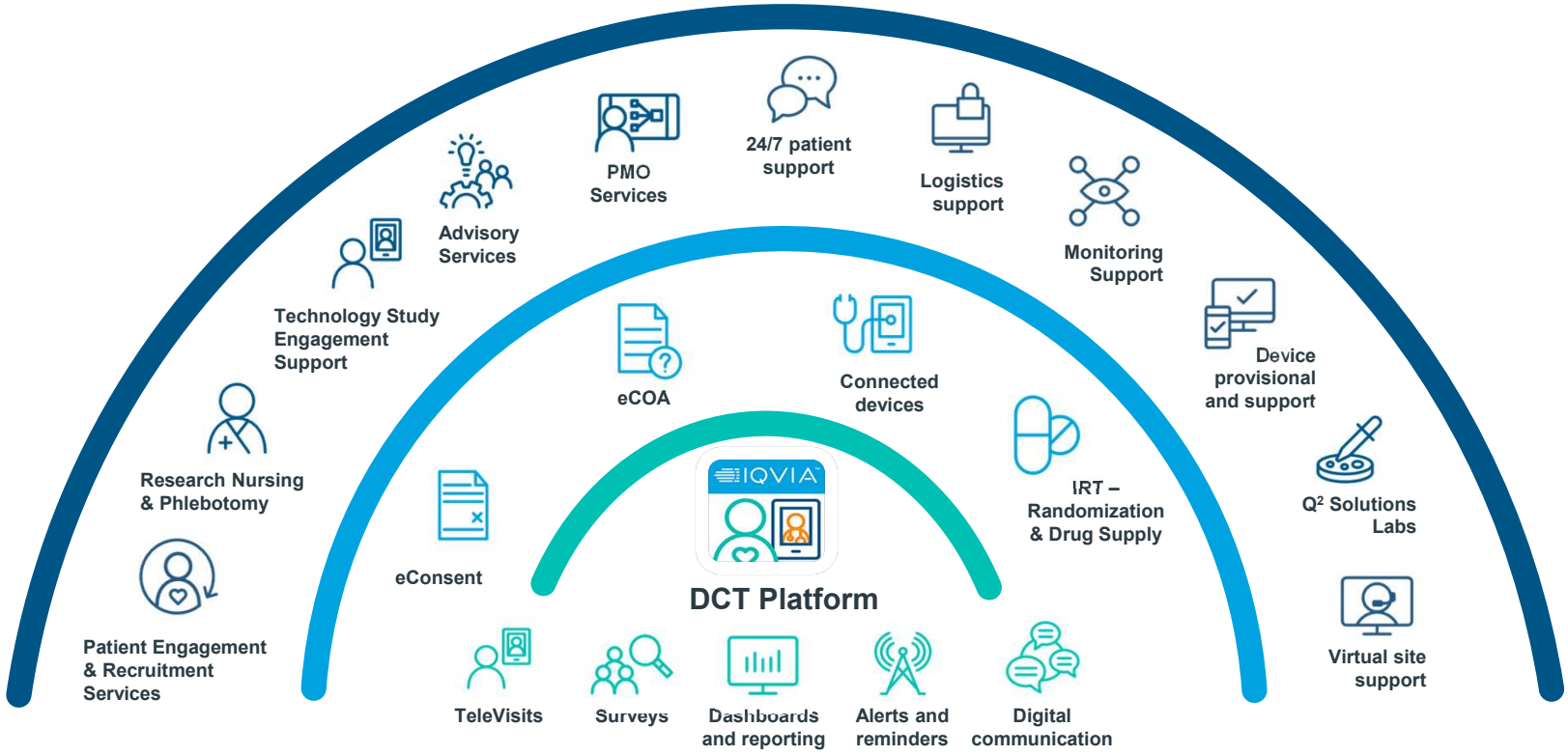
Rising costs

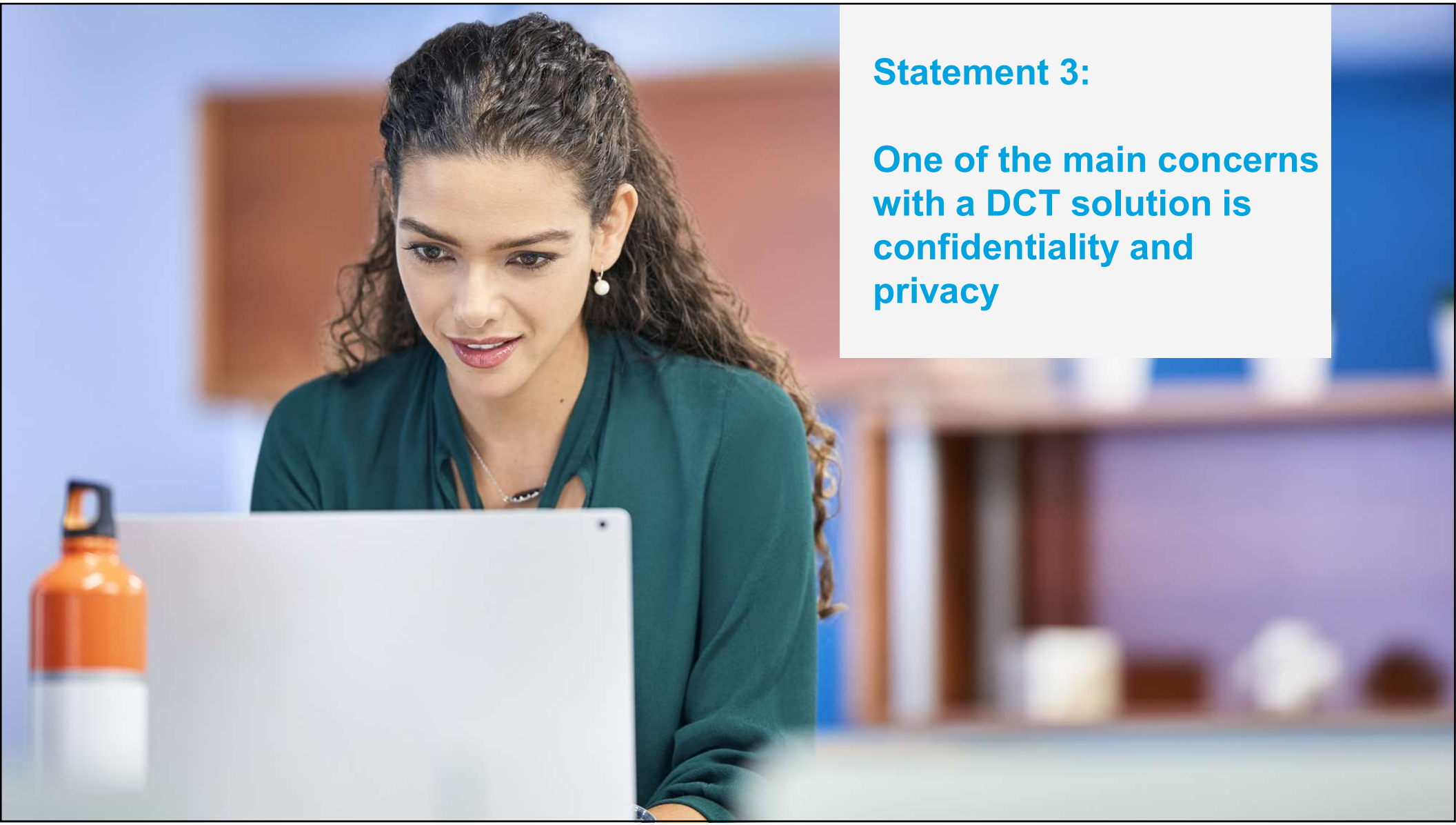
Data collection costs are increasing exponentially.

1. Marr, Bernard. Why only one of the 5 Vs of big data really matters. 10 March 2015. http://www.ibmbigdatahub.com/blog/why-only-one-5-vs-big-data-really-matters
2. European Medicines Agency. Identifying Opportunities for 'Big Data' in medicines development and regulatory science. November 14-15 2016. http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/02/WC500221938.pdf https://www.idc.com/getdoc.jsp?containerId=prUS41530816
3. https://www.nature.com/articles/s41746-020-0259-x/figures/2
4. https://www.businesswire.com/news/home/20190516005571/en/World-Market-Connected-Wearables-4th-Edition-Shipments

Scalable, adaptable, patient-centric trials

Integrated clinical technology platform enabling more effective remote clinical trials by supporting patient communication, data aggregation, and workflow efficiencies for PIs and site staff





Statement 3:

One of the main concerns with a DCT solution is confidentiality and privacy

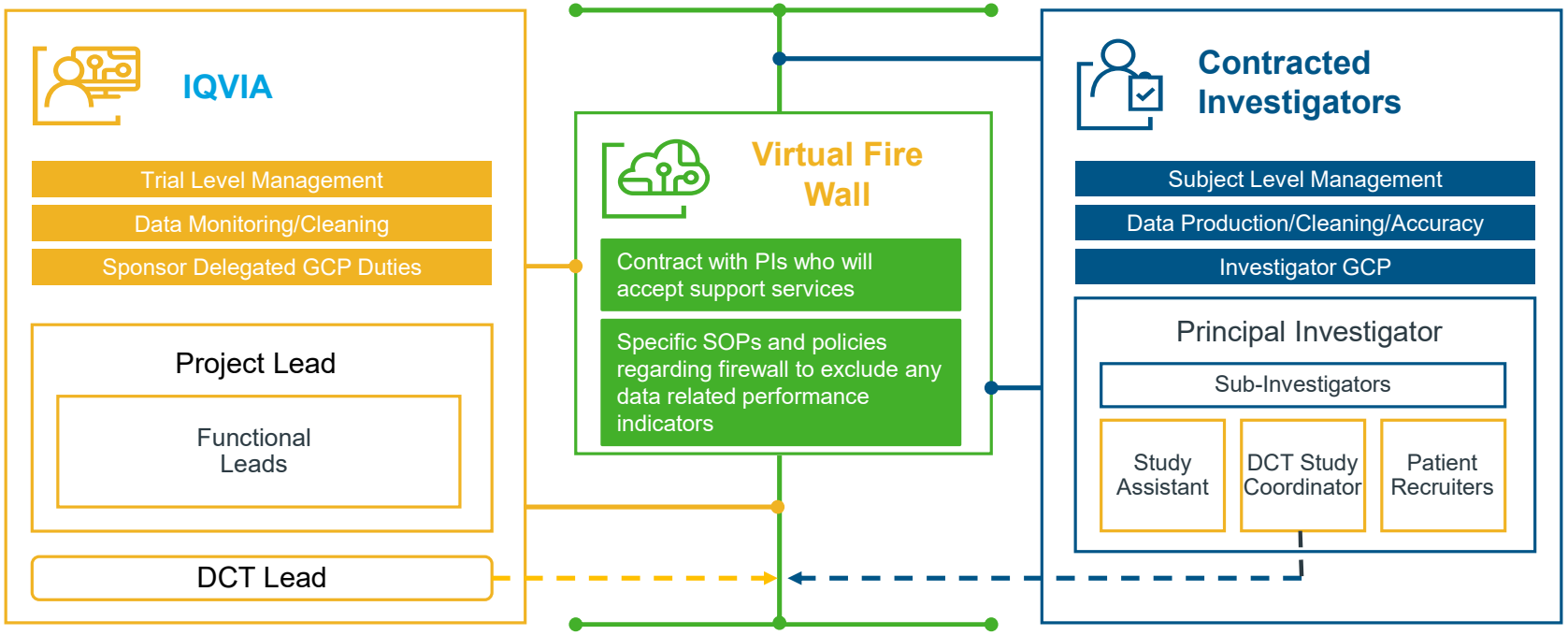
Patient Centricity

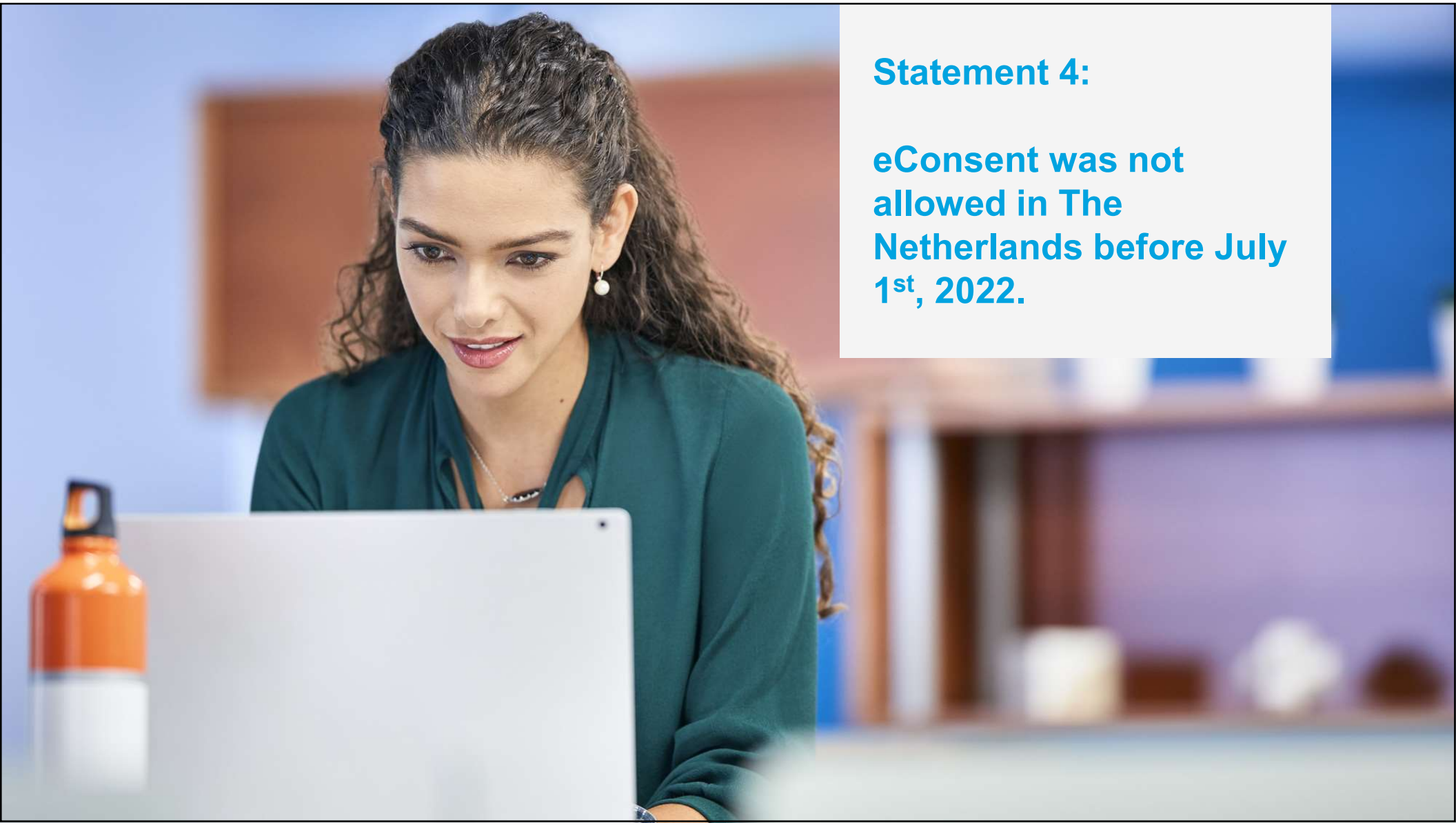
Balancing reducing burdens and protecting rights

- One main aim of DCT is reducing participant burden…
  - … whilst protecting their safety, although more remote
  - … whilst protecting their rights, …
    - … confidentiality
      - GCP, GxP
    - … privacy
      - GDRP etc.

Role-based Firewall

DCT Platforms should leverage role-based security measures to ensure that only appropriate user roles are allowed to access sensitive data.





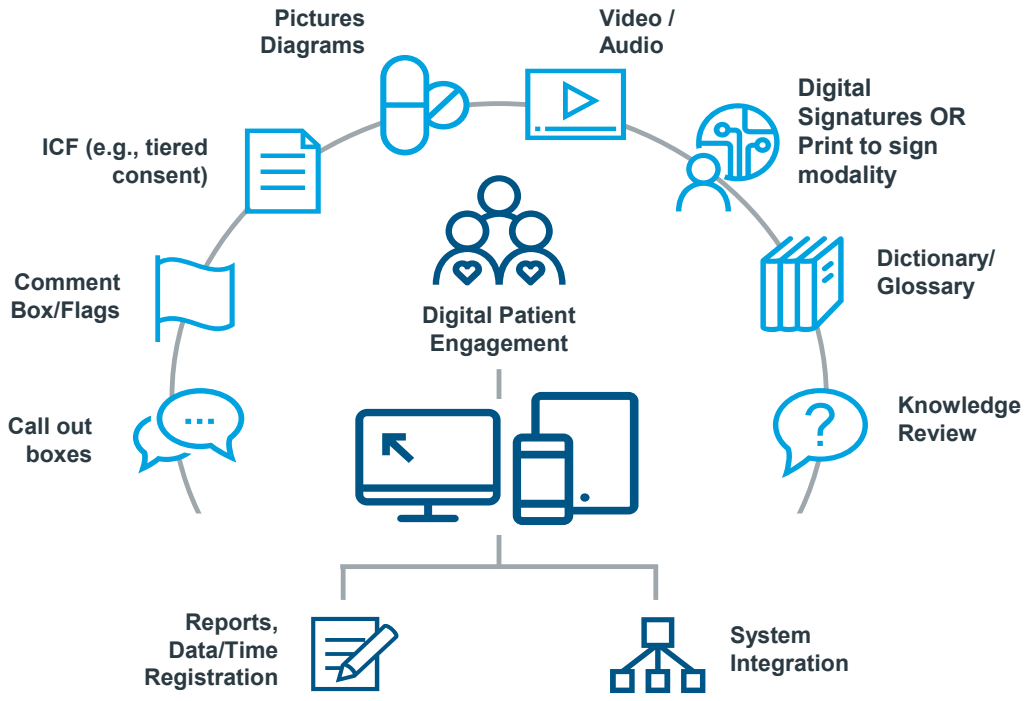
Statement 4:

eConsent was not allowed in The Netherlands before July 1st, 2022.

Electronic Informed Consent

Feature-rich system to improve participant discussions and the overall quality of the informed consent process

Known as **eConsent**



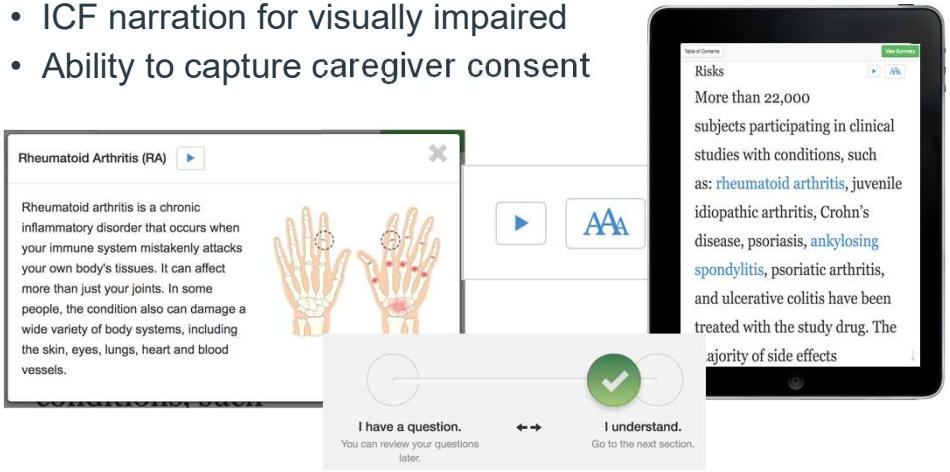
Potential Components of eConsent by TransCelerate

Source: transceleratebiopharmainc.com

User-friendly Technology for all Ages

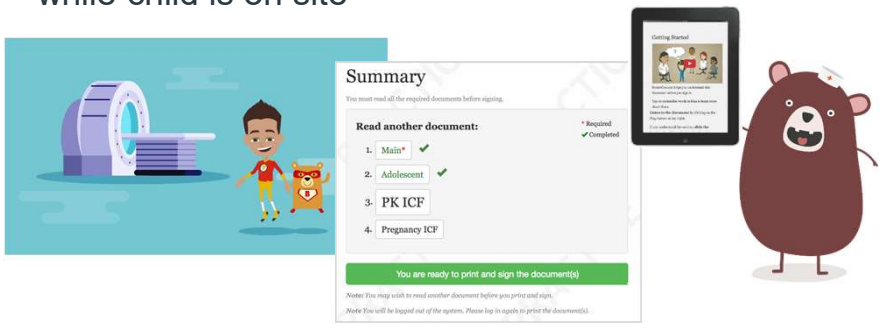
Elderly patients

- Designed with elderly patients in mind - even easy for those with no smart phone or tablet experience
- Text size may be enlarged for easy reading or projected on large screen
- Swiping slider on screen easier than turning pages for painful or weak hands
- ICF narration for visually impaired
- Ability to capture caregiver consent



Pediatric patients

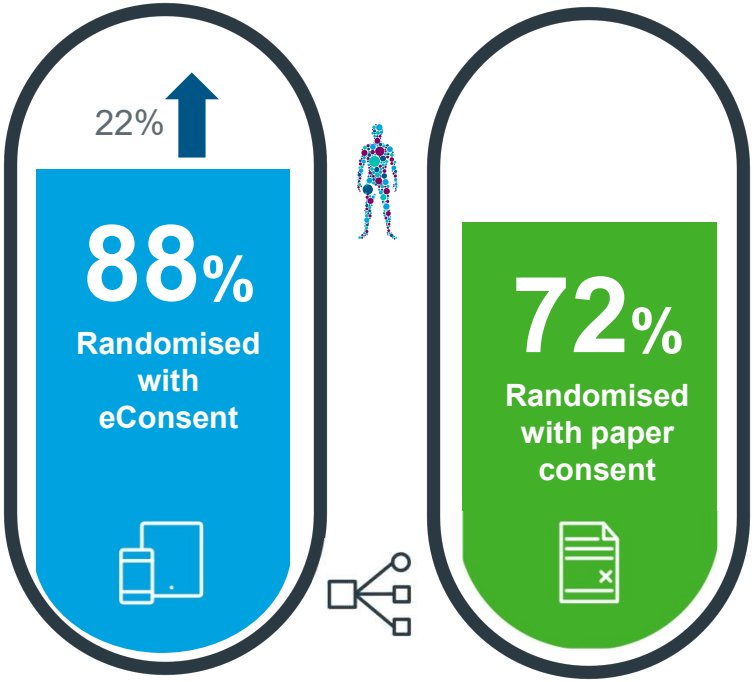
- Familiar, youth-friendly technology engages participants and is easy to use even for the parental generation
- Engaging and Child friendly video and multimedia
- Manage parental consent and child assent with ease.
- Technology enables seamless management of varying age of assent between countries.
- Second parent or caregiver can consent remotely while child is on site



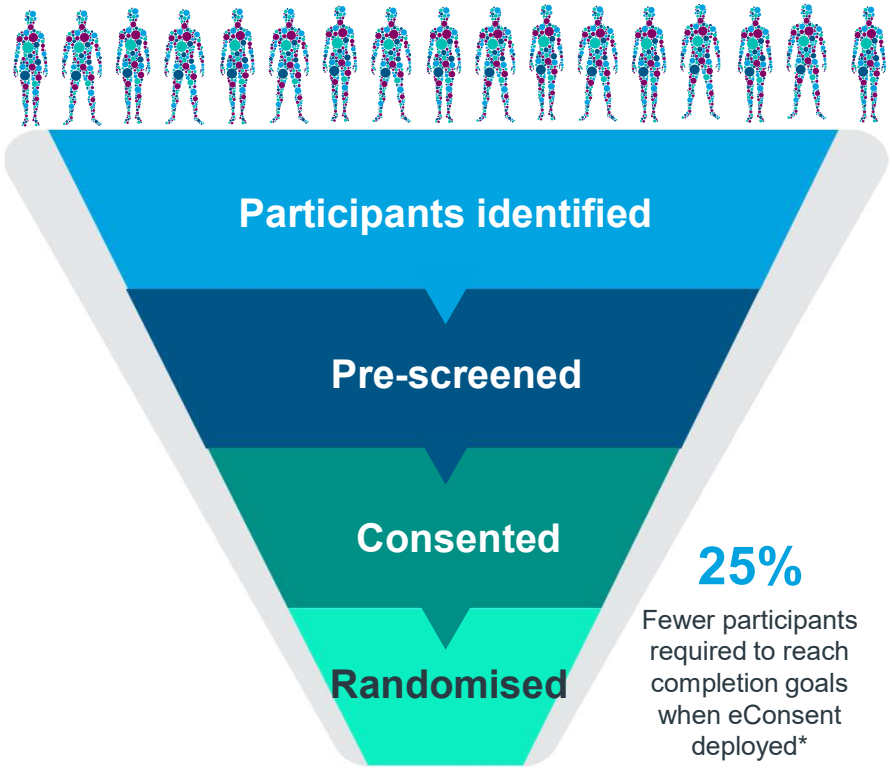
Improving trial funnel metrics with electronic informed consent

Empowering participants to make truly informed decisions and reducing dropout rate

Compare 55 IQVIA trials with electronic consent to all IQVIA trials with paper consent



More participants randomized

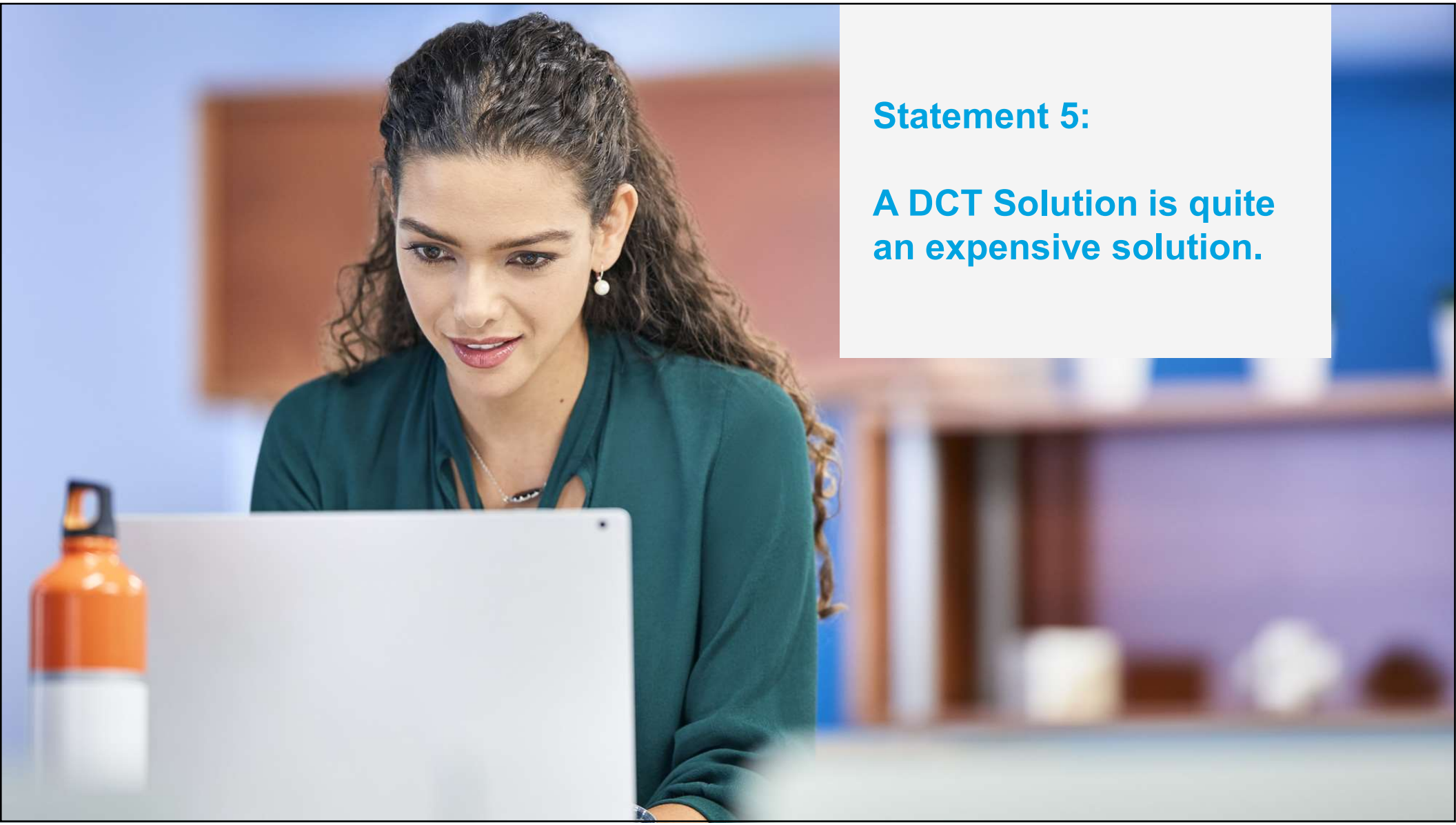


25%

Fewer participants required to reach completion goals when eConsent deployed*

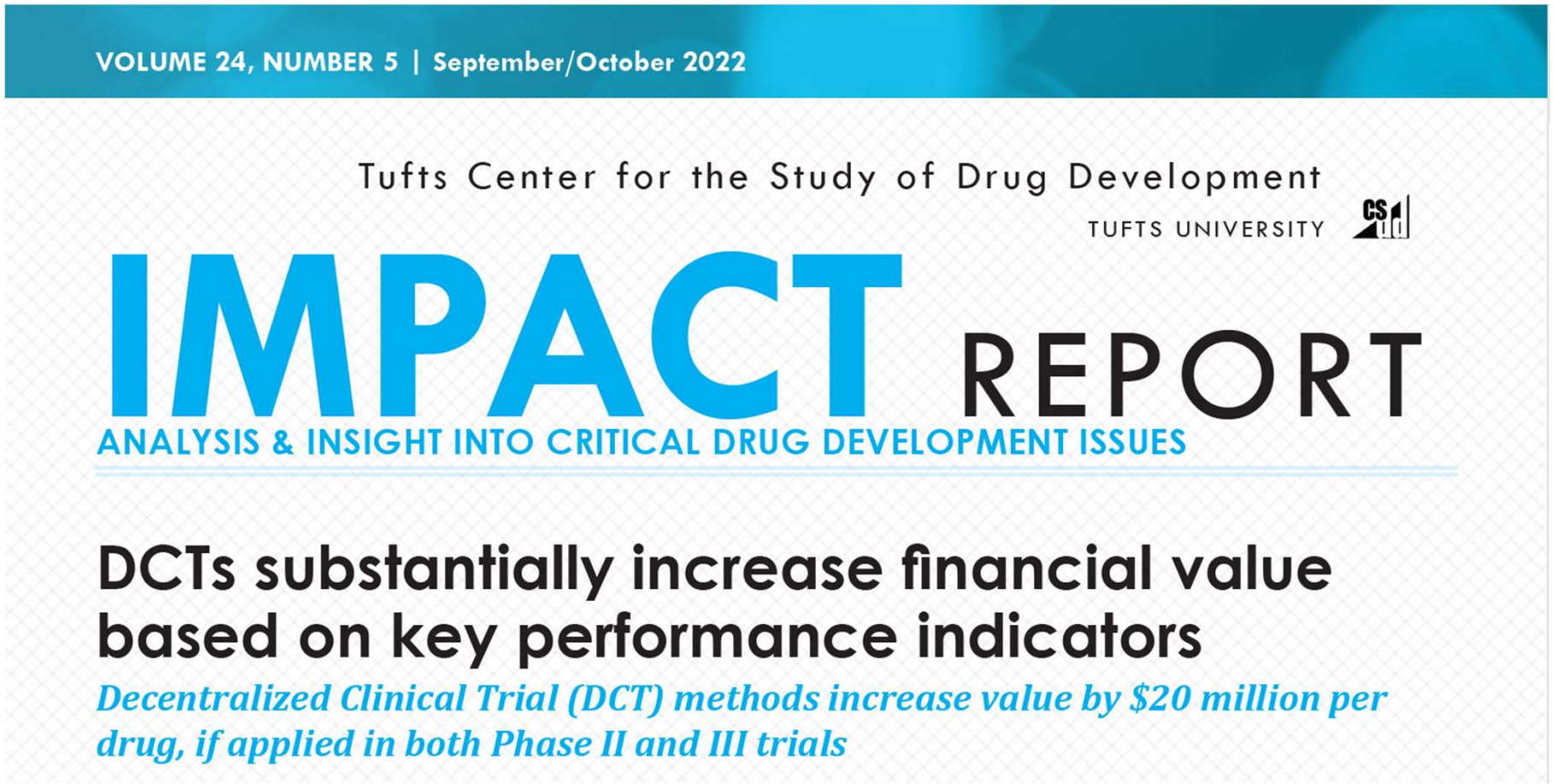
Fewer participants drop out

*Centrewatch: J. S. Brady, "Multimedia Delivery Can Enhance the Consent Process," Applied Clinical Trials, 36-42 (January 2003)



Statement 5:

A DCT Solution is quite an expensive solution.

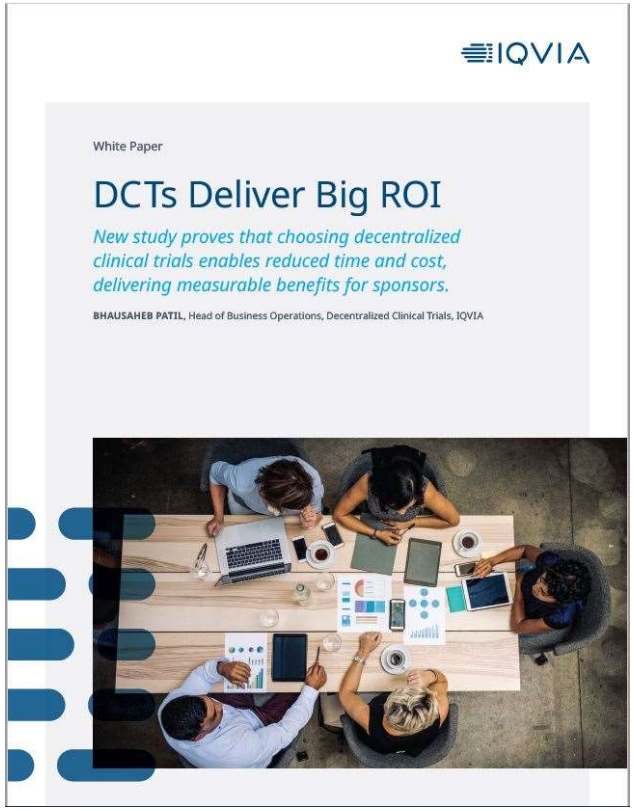

VOLUME 24, NUMBER 5 | September/October 2022
Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY
IMPACT REPORT
ANALYSIS & INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES
DCTs substantially increase financial value based on key performance indicators
Decentralized Clinical Trial (DCT) methods increase value by $20 million per drug, if applied in both Phase II and III trials

DCTs Deliver Big ROI

*New IQVIA Study Demonstrates Cost and Time Savings of Decentralized Trials**

Tech-enabled trials reduce time and cost, delivering measurable benefits for sponsors.

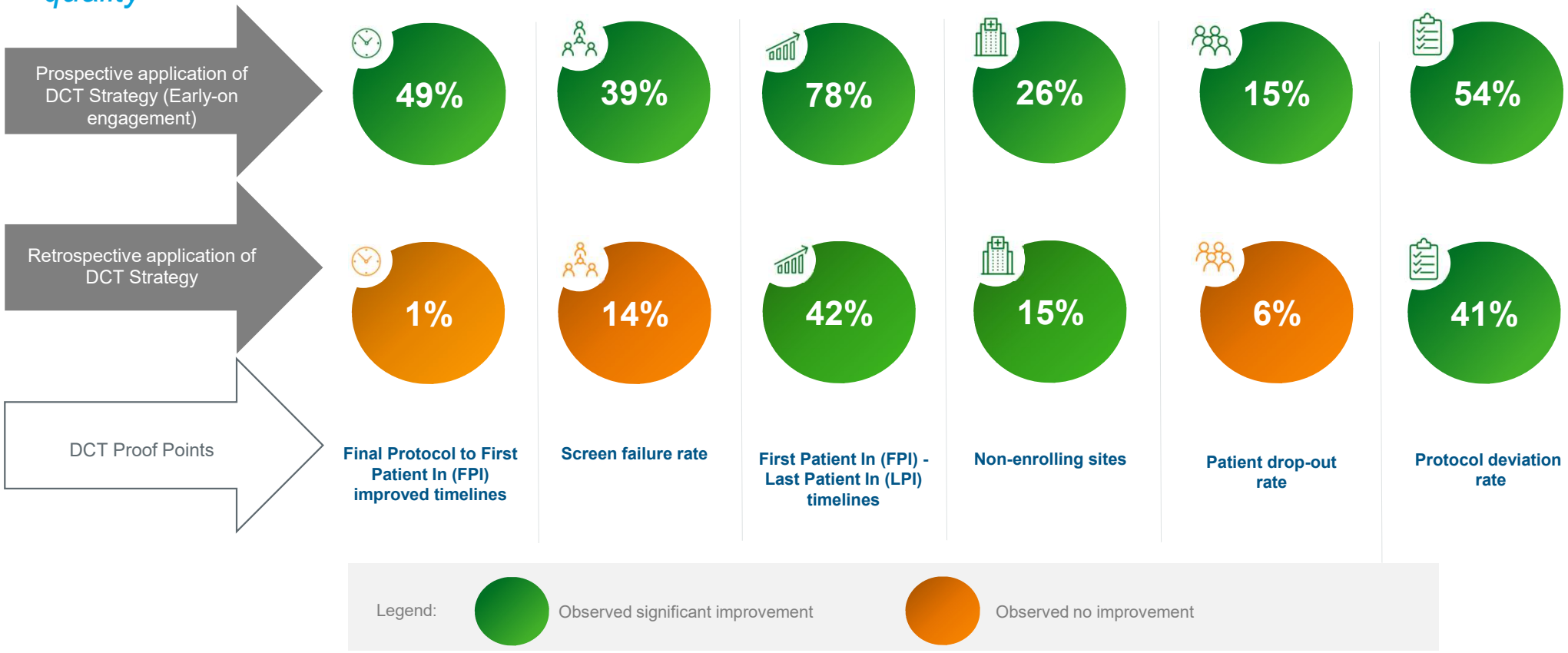
SCAN ME



*Mar 2022 - Based on performance of 12 studies conducted using IQVIA DCT Platform and 1 or more additional DCT services and comparing their data with historical comparator (similar studies conducted under traditional delivery model)

Decentralized Clinical Trials Benefit

*A retrospective strategy provides some but **not** all benefits in improving productivity, delivery & quality*



Thank you

Questions?

Feel free to connect with me directly at eric.klaver@iqvia.com