



Decentralized Clinical Trials

The Digital Patient Suite Experience

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SCOPE 2020

What I'll cover:

- Why Virtual Trials?
- What is a Virtual Trial?
- Key Components of VT
- Regulatory Considerations
- Selecting a Clinical Development Partner



MaryAnne Rizk, Ph.D.

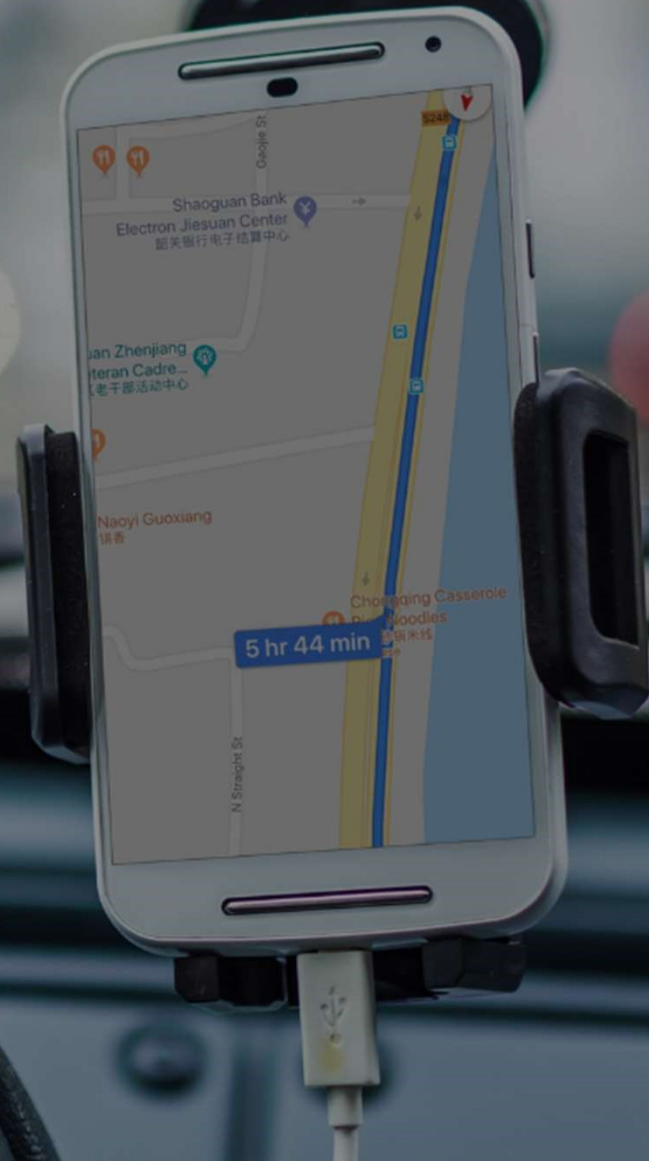
Senior Vice President
Digital Strategy, R&D Solutions

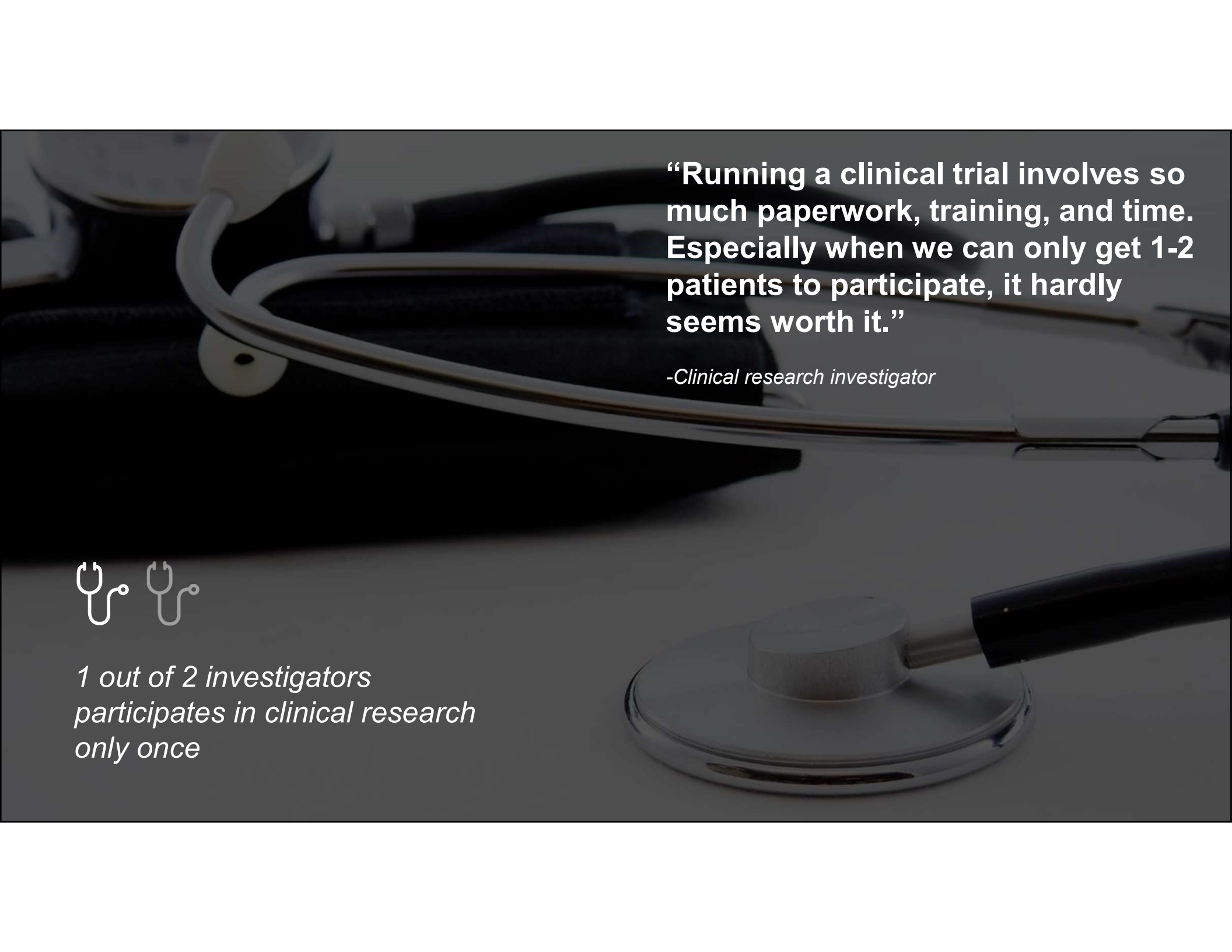
“There’s a study that I’d really like to take part in. But the clinic is 5 hours from my house. It’s just not possible.”

-Patient diagnosed with a rare disease



*About 1 out of 5 patients drops out
(phase II, II/III and III studies)*



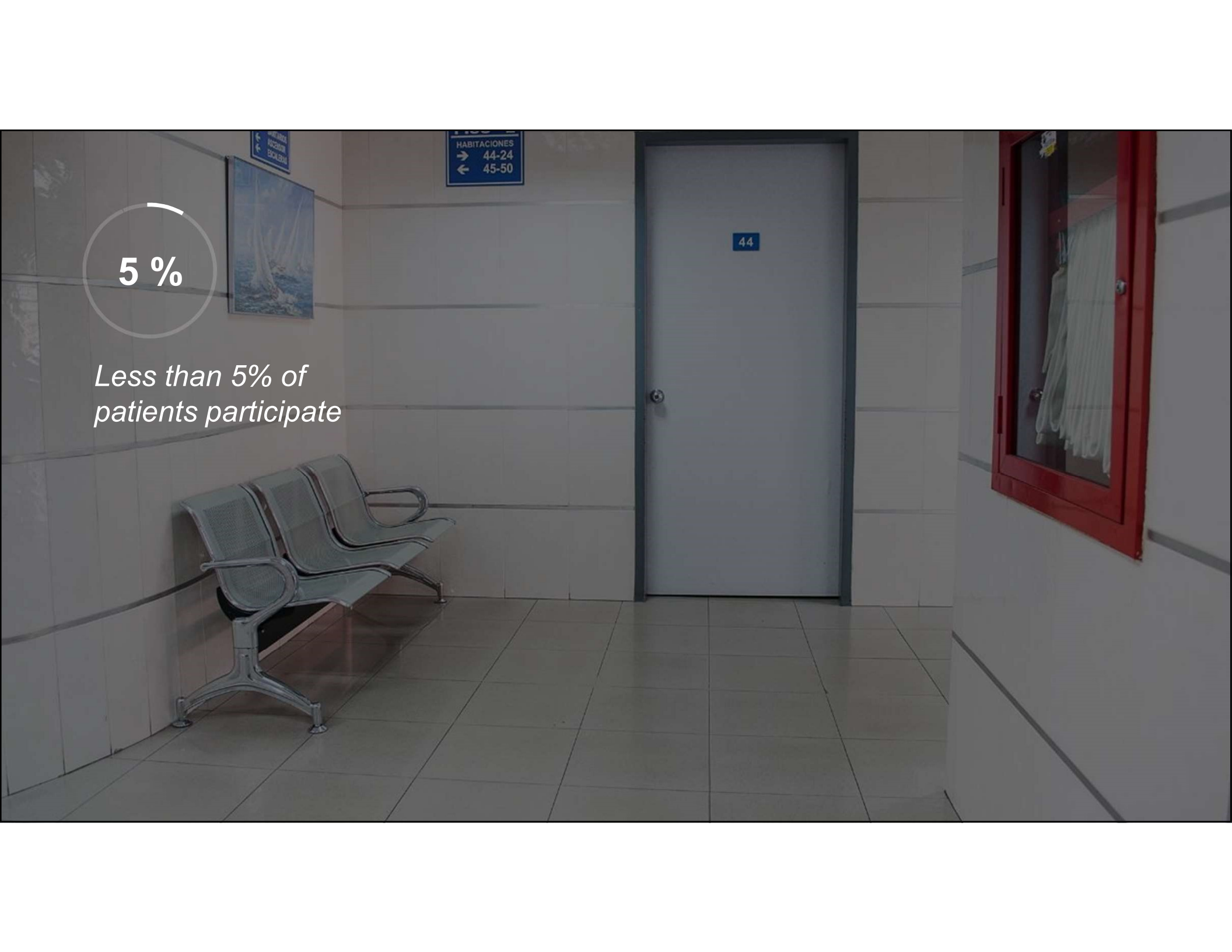
A close-up, slightly blurred photograph of a stethoscope resting on a dark, reflective surface. The stethoscope's tubing is coiled, and its chest piece is visible in the lower right foreground. The background is dark and out of focus.

“Running a clinical trial involves so much paperwork, training, and time. Especially when we can only get 1-2 patients to participate, it hardly seems worth it.”

-Clinical research investigator

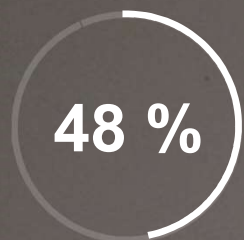


*1 out of 2 investigators
participates in clinical research
only once*

A photograph of a hospital hallway. On the left, there is a metal waiting bench. The wall is covered in light-colored tiles. A door in the center is labeled with a blue sign '44'. Above the door, a blue sign indicates directions for 'HABITACIONES' (44-24 and 45-50). To the right of the door is a red fire alarm pull station. On the left wall, there is a framed picture and a small blue sign. The floor is made of large, light-colored tiles.

5 %

*Less than 5% of
patients participate*

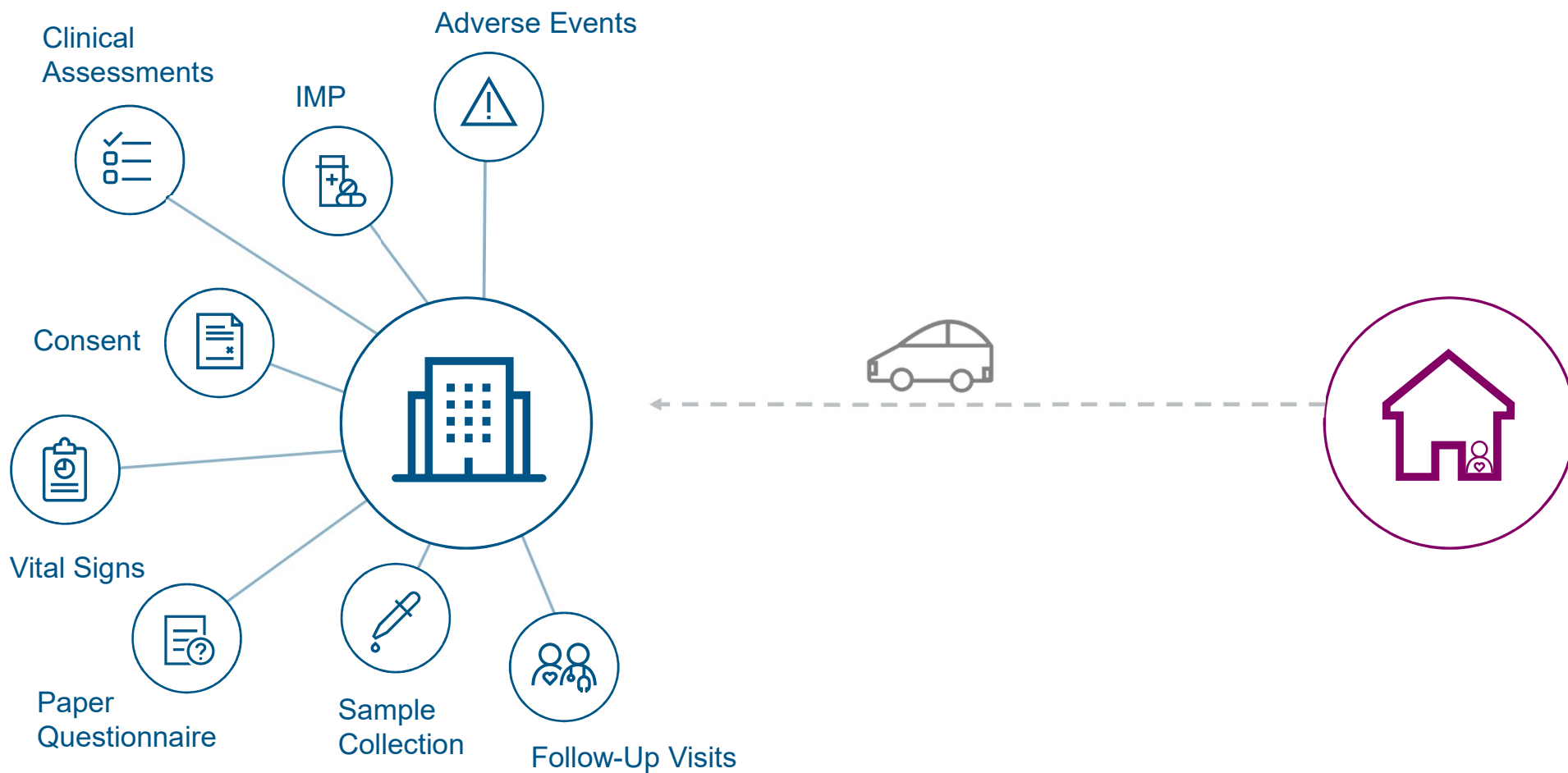


*of studies take
significantly longer
to meet enrollment targets*

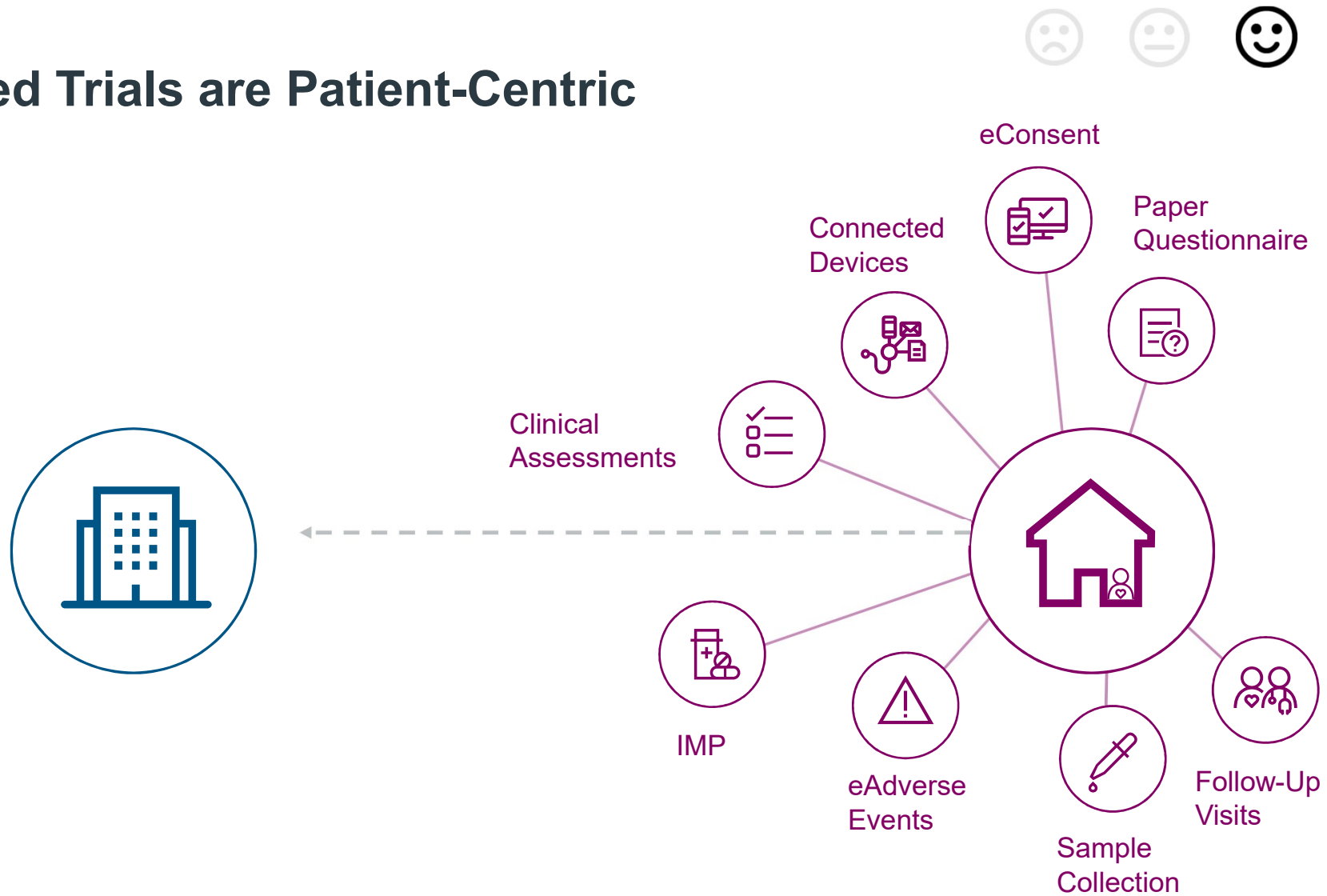




Traditional Clinical Trial Model is Location-Centric



Decentralized Trials are Patient-Centric



IQVIA Virtual Trials are Designed Around the Patient

A more efficient, more flexible approach to clinical research



Site-Based

 Clinical Assessment

 Consent

 IMP

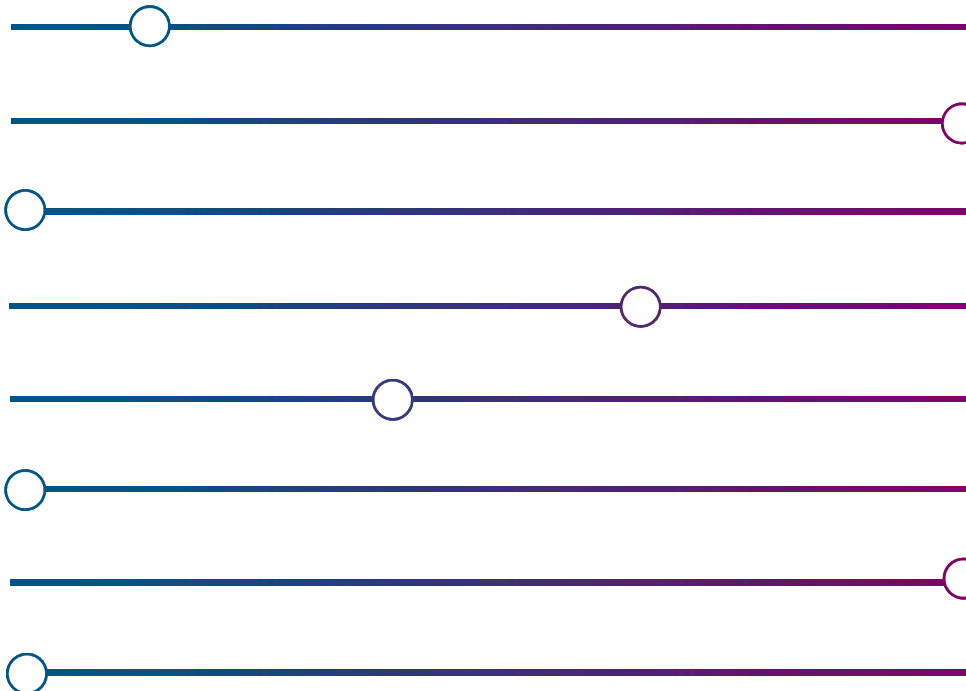
 Vital Signs

 Sample Collection

 Paper Questionnaire

 Adverse Events

 Visit Follow Up



Home-Based

 Televisits

 eConsent

 DTP IMP

 Connected Devices

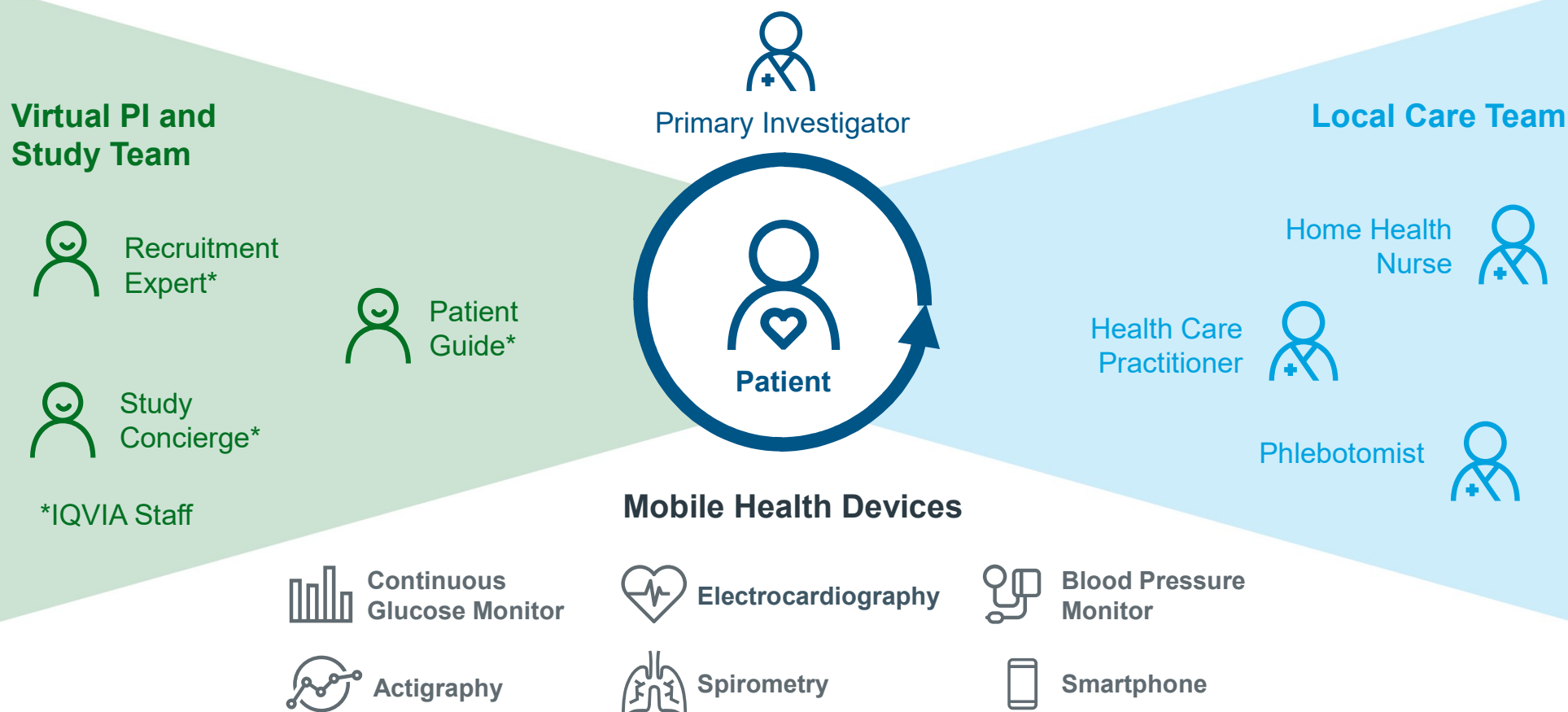
 Home Health Nurse

 ePRO/eCOA

 eAdverse Events

 Chat

IQVIA Virtual Trials: Putting the Patient at the Center



IQVIA Virtual Trial Study Models

1

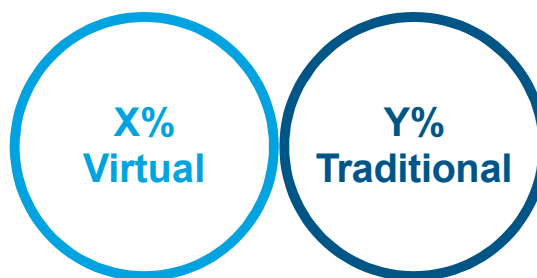
Pure Virtual



Example: 100 patients,
all U.S. in virtual model

2

Side-by-Side



Example: 50 patients in U.S.
virtual model, 50 patients in
EU traditional model

3

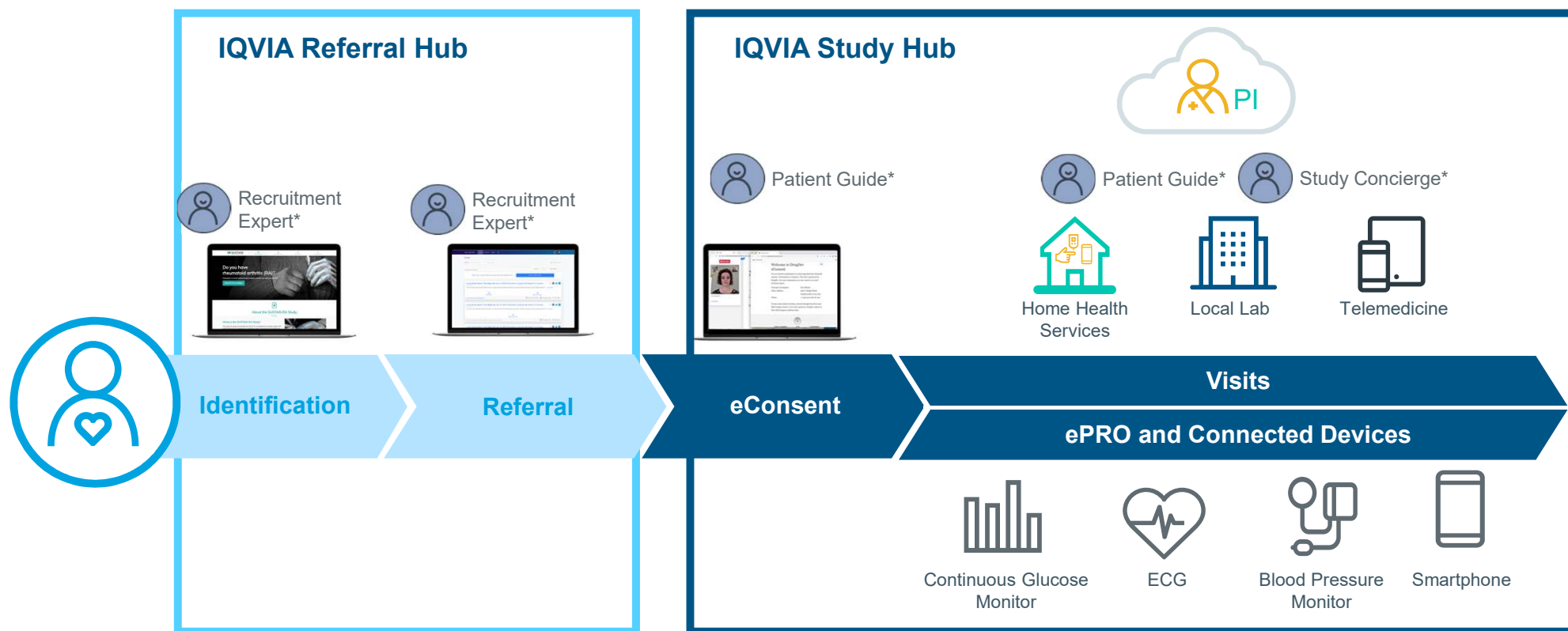
Hybrid



Example: 100 patients U.S.
traditional model with
televisit from sites

The IQVIA Virtual Trial: Patient-Centric Study Delivery

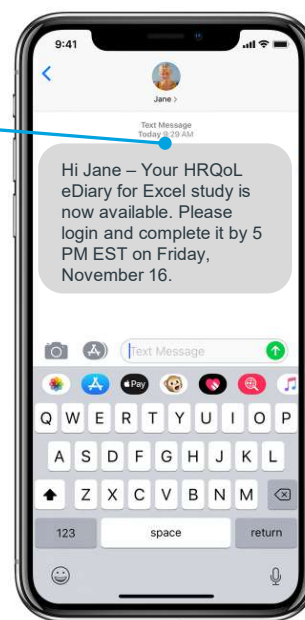
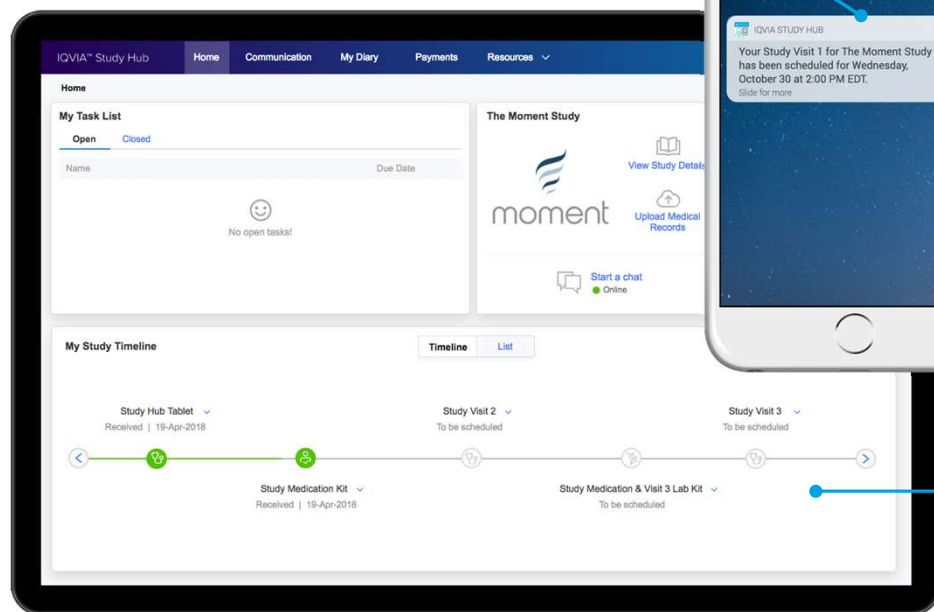
Flexibility to put patient needs at the center of clinical research



* IQVIA Study Team

Patient Engagement, Reminders, and Compliance

Built-in **reminders** and **alerts** to help ensure patient study activities are completed



My Study Timeline offers clear visibility into milestones and visits for entire study.



Visit Notifications



Task Reminders and Alerts



Study Schedule Visibility Bar



Text Message Reminders



Centralized Patient Safety Surveillance



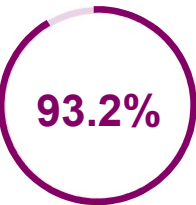
Telehealth Patient Education

Patient Perspective on Virtual Trials

Approached about full virtual trials



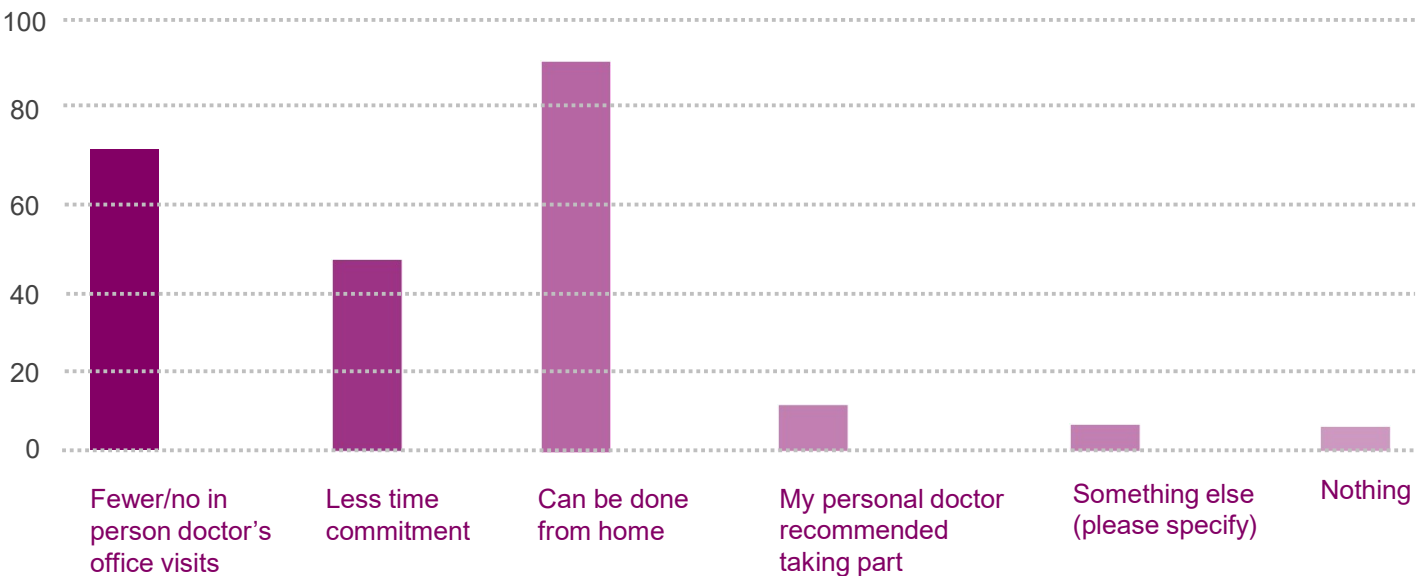
Patients favor a virtual model 2:1



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.”

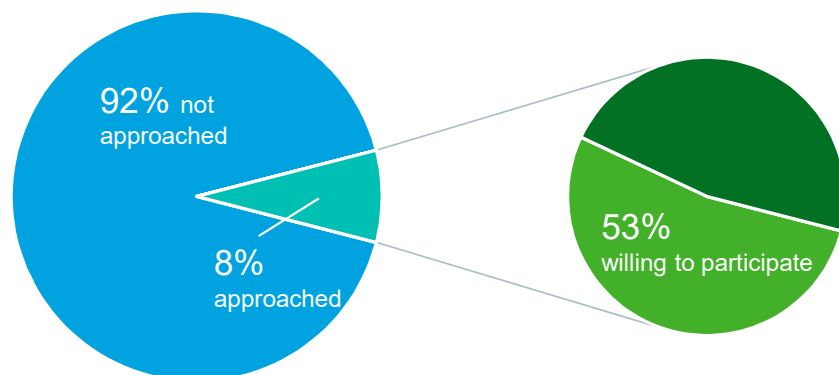
- Focus Group Participant



Site Perspective on Decentralized Trials

SCRS 2019 Study Landscape shows site willingness to participate in DCTs

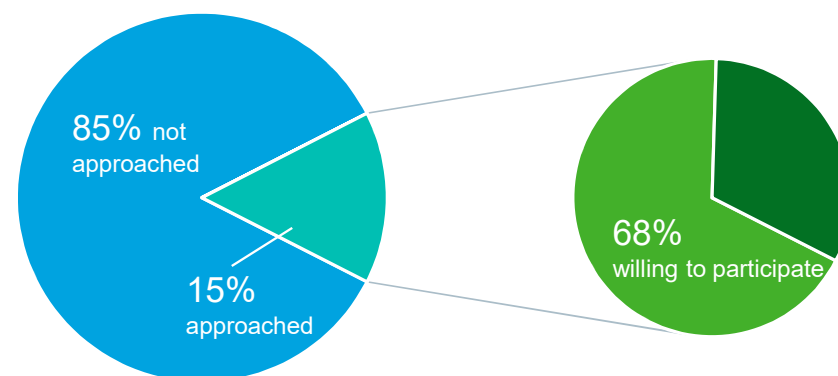
% Sites Approached about Full DCT Study and % Willing



Top reasons for saying “No” to full DCT model:

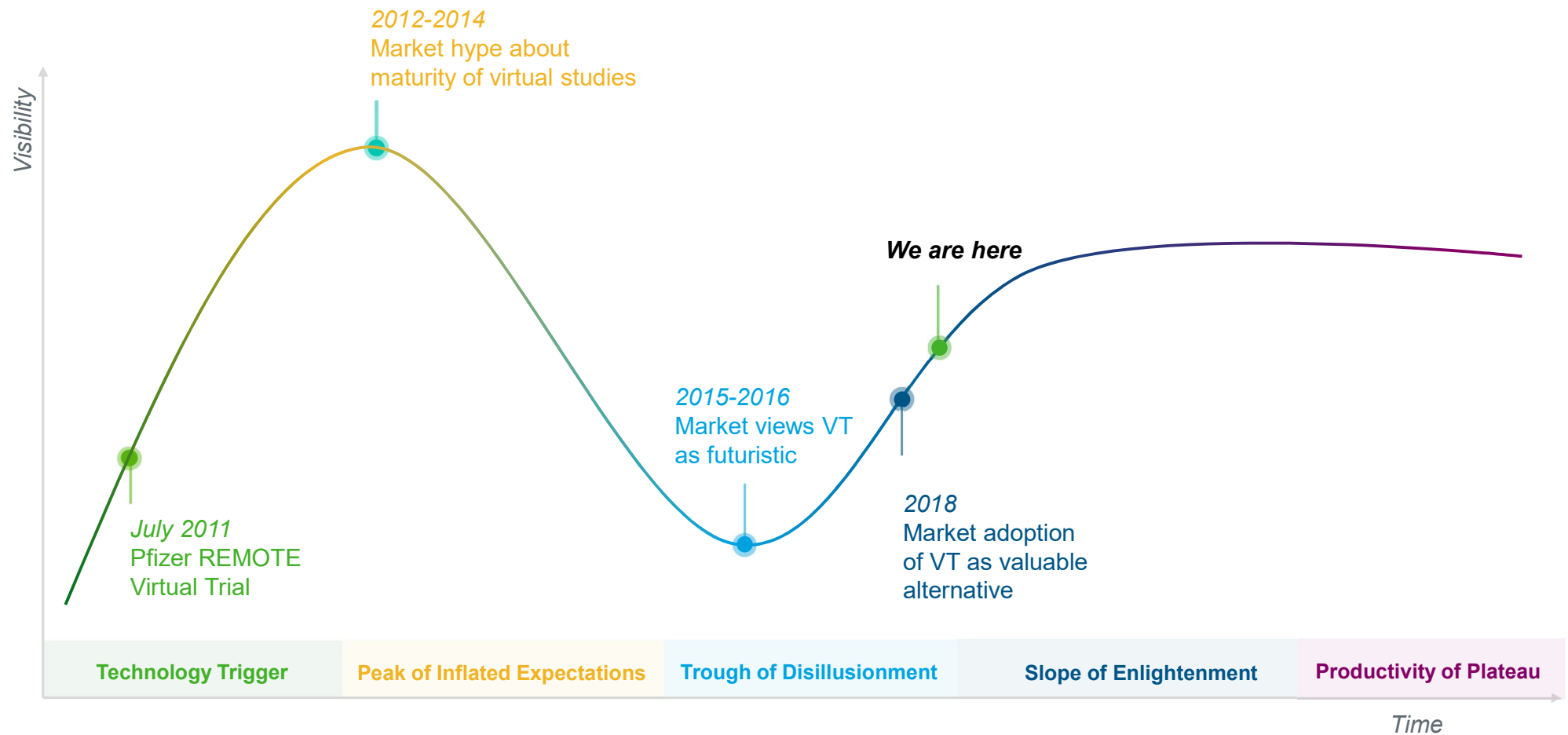
- 1) Low budget,
- 2) Not comfortable with the trial design
- 3) Patient safety/privacy concerns

% Sites Approached about Hybrid DCT and % Willing



Insight: Sites appear slightly more comfortable with hybrid model, which more closely resembles traditional model

Virtual Trial Adoption - Where are we?



Accelerate Timelines with Virtual Trial model

IQVIA + Pear Therapeutics: two feasibility studies for a candidate DTx to treat depressive symptoms in people with Multiple Sclerosis



CASE STUDY

100%
Virtual Trial



Sponsor Objectives



Improve patient recruitment

- Increase geographic reach
- Enhance diversity
- Shorten recruitment & study timelines



Strengthen patient engagement & retention

- Reduce patient burden & barriers for participation
- Improve protocol adherence
- Reduce study drop-out & LTFU

Results & Impact

Study One



All patients screened to
baseline visit completed
50% Faster



First Patient In to
Last Patient Out:
**successfully met
within 6 weeks**

Study Two



Pre-screened referrals:
215 in 8 week.
All patients randomized
within **4 weeks** from
referral date



All patients enrolled
**10% ahead of
schedule**

Key Learnings from Virtual Trial Delivery



Executing Virtual Trials Is Highly Complex,
More Than Just Technology



Many Opportunities Are in Hybrid Models



Start Early to Avoid Amendments & Delays



Validate Endpoints – Primary vs. Secondary



Identify and Align Internal Champions



Understand What You Want to
Achieve with a Virtual Approach



Tremendous Sponsor Interest –
from Phase II to Post Market



No Two Studies Are the Same

What to Look for in a Virtual Trials Partner

Fast-forward your clinical development program



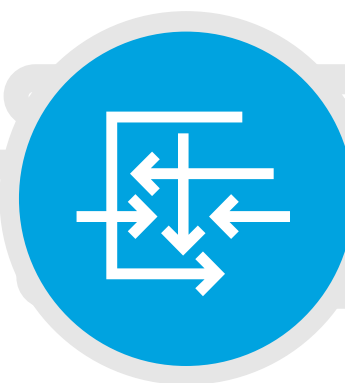
**THERAPEUTIC
EXPERTISE**



**DIGITAL PATIENT
SUITE**



**VIRTUAL STUDY
EXPERTISE**



**LEADING MOBILE
TECHNOLOGY**



**GLOBAL
CAPABILITY**



Thank you!

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