Demystifying Decentralized Trials -
IQVIA's Patient-Centric Decentralized Clinical Trial Solutions

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Feb 2022

Sylvie Cornibert – Strategic Site Solutions Manager

Who am I, What does it mean?

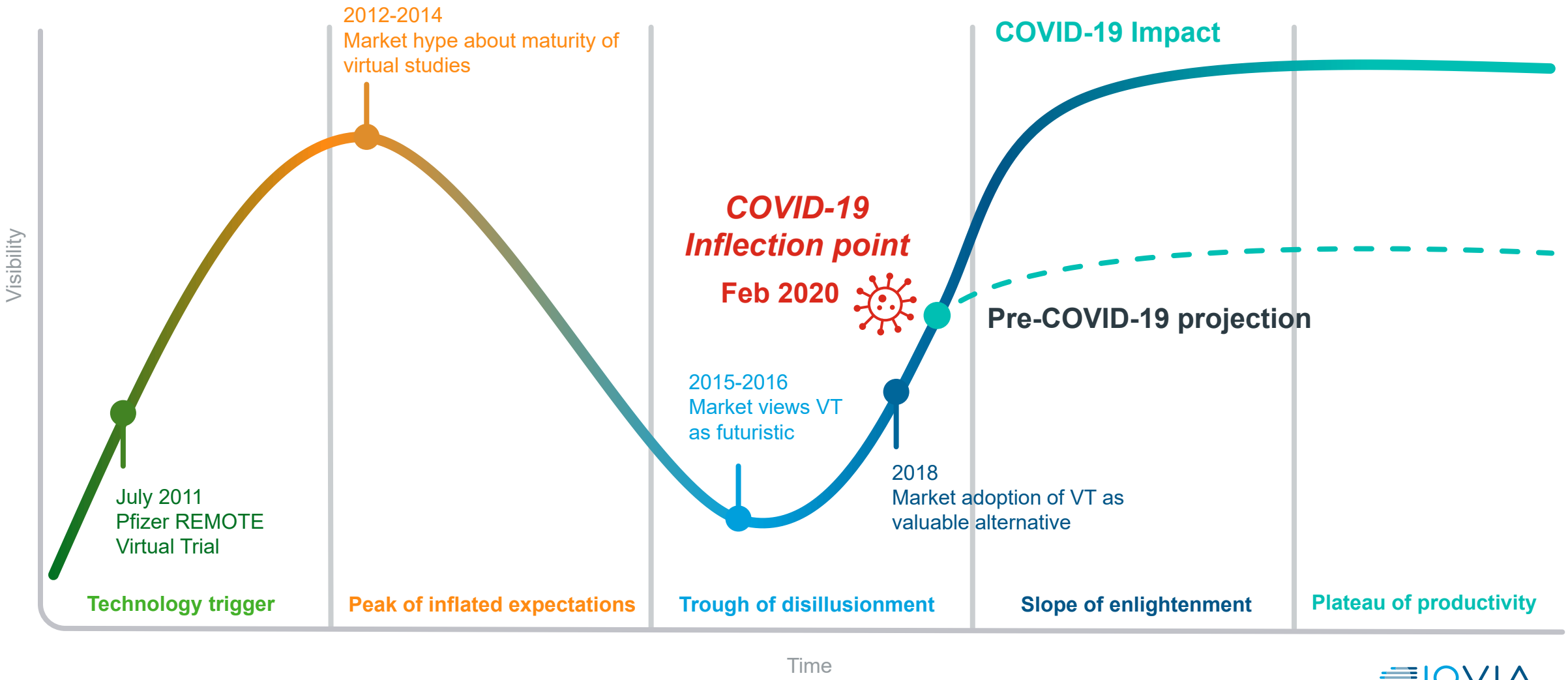
- University of Calgary is a partner site with IQVIA (a Strategic Site)
  - Preferential access to studies
  - Active advocate for University of Calgary within IQVIA
  - MCDA in place for faster Site Identification *(when we can use it)*
  - Point of contact for site-wide or cross-study issues
  - Further escalation point for study issues
  - Regular review of metrics
  - Priority access to new technologies/initiatives
  - Industry point of view

- Someone who knows IQVIA and the Industry, and also University of Calgary - bridge

Decentralized Trials

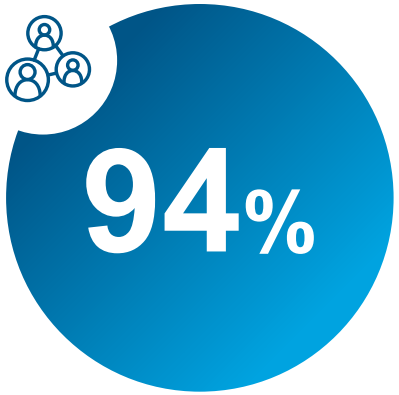
Hype is over, decentralized trials are the new norm

Inflection point of adoption

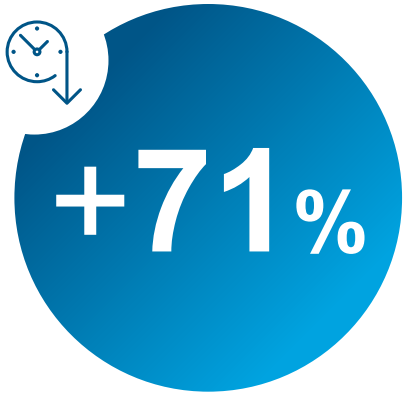


Patients and sites prefer telemedicine

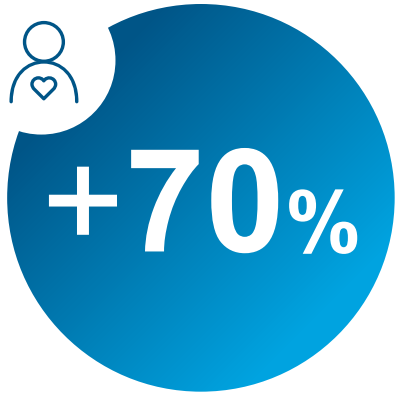
COVID-19 was the catalyst for the change – bringing trials to the patient will be the new norm



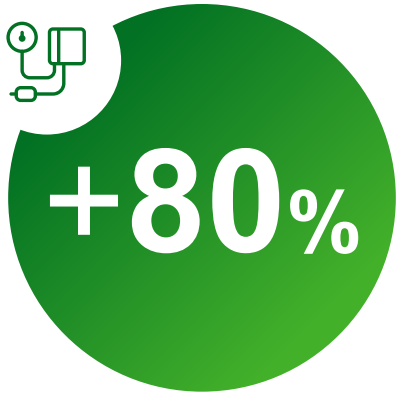
of investigators would be interested in a study using a **Hybrid Decentralized** approach



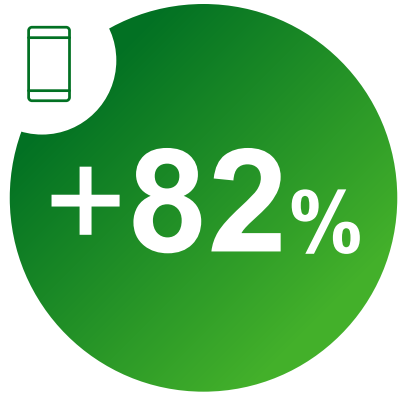
of investigators agree that decentralized trials **reduce the burden on patients**



of investigators agree that decentralized trial designs are **more inclusive of patients** who may not be able to participate otherwise



of patients are **comfortable monitoring and reporting** on their symptoms through an online application

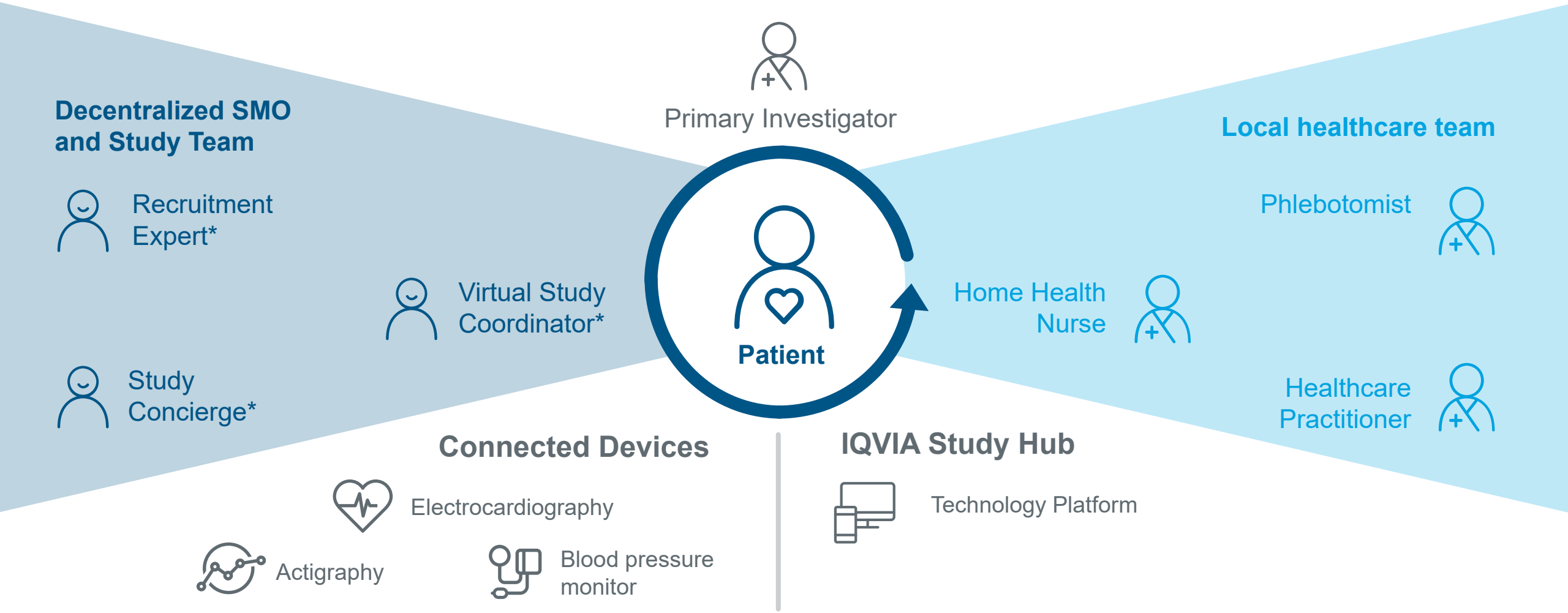


of patients are **comfortable using a mobile device,** such as a smart phone or tablet

Data from a survey of 995 U.S. respondents who are members of IQVIA's patient and site communities, April 2020.

IQVIA Decentralized Trials global solution

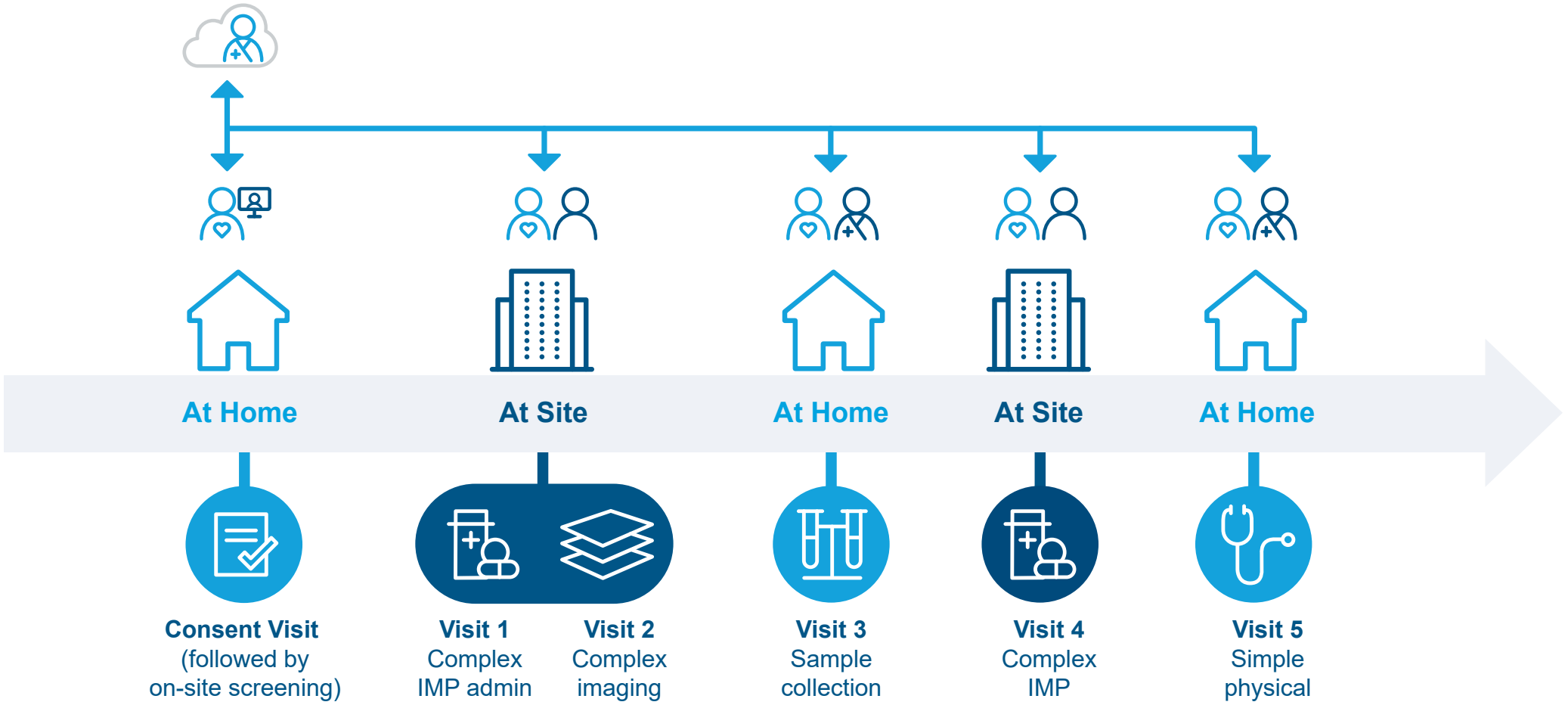
A foundation for hybrid and fully remote patient-centric trials



* IQVIA staff.

Hybrid trial: A site-based study with decentralized components

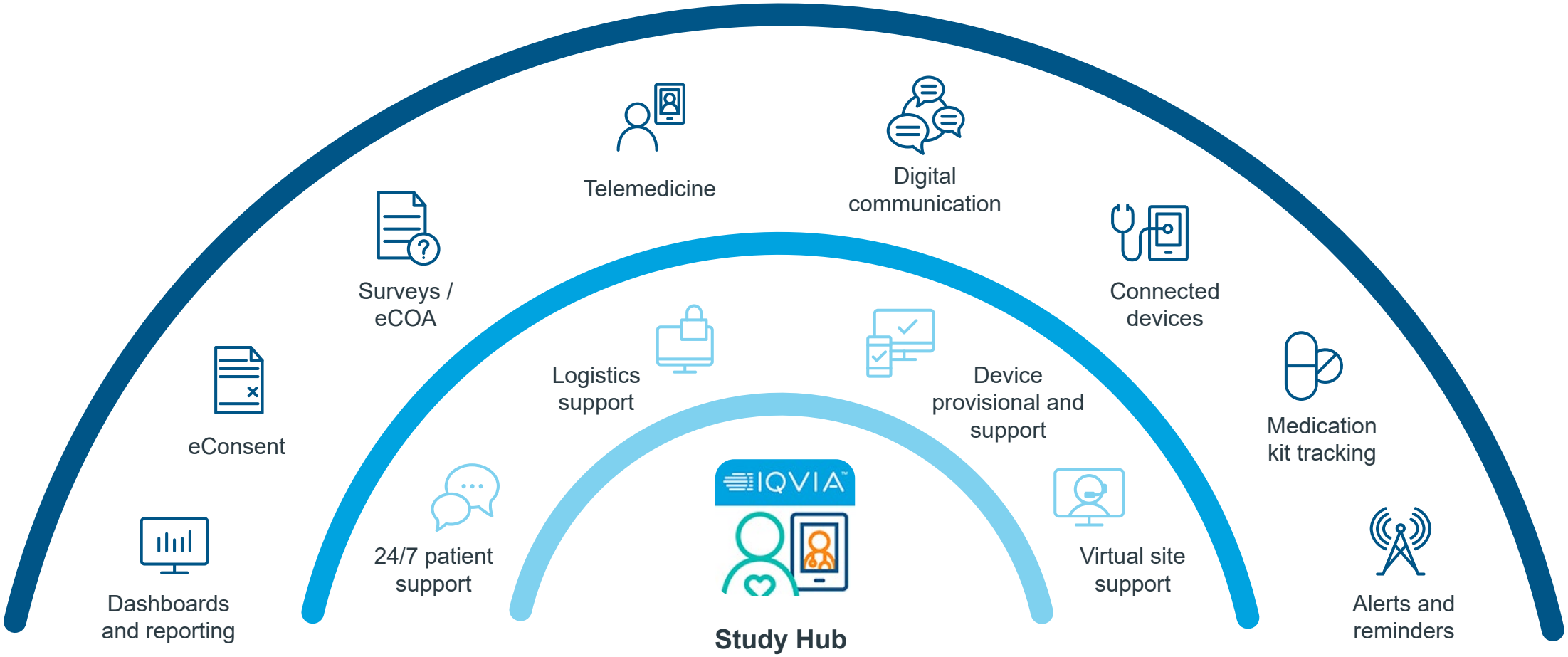
A hybrid trial combines remote, home-based visits along with traditional site visits to reduce patient burden and streamline operational execution



Technology

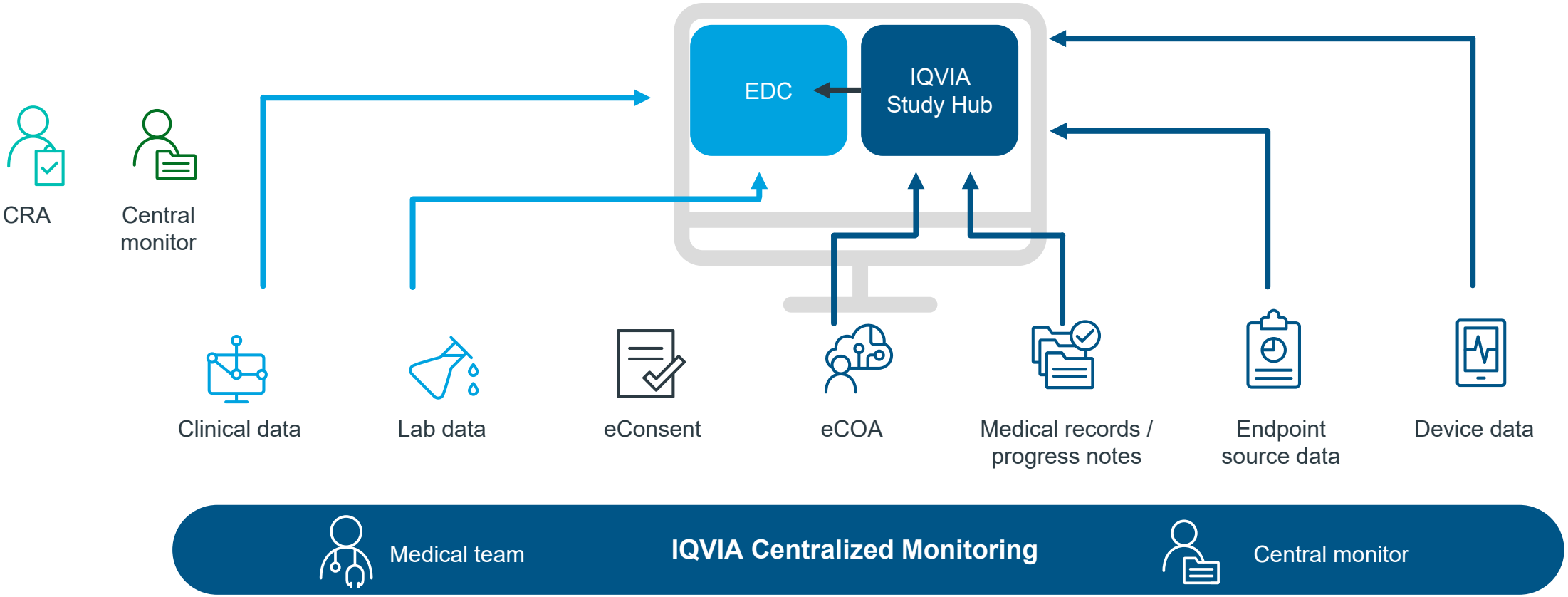
IQVIA's Patient-Centric DCT Platform

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



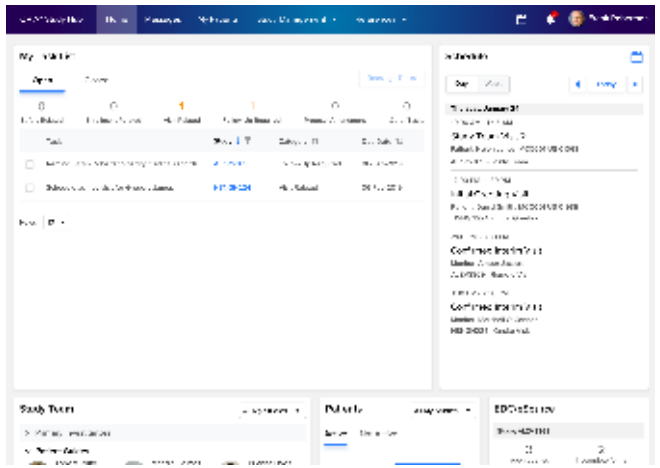
Decentralized trial data collection

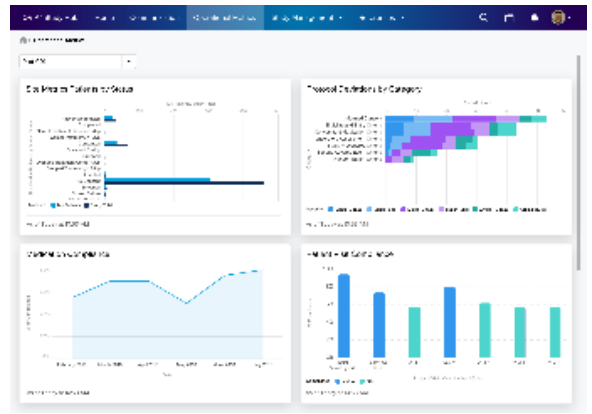
Leveraging capabilities in centralized and remote reviews to deliver monitoring plan



IQVIA Study Hub – Remote trial technology platform

Comprehensive solution components linked to deliver fast and high quality results





Patient-Centricity

- Native mobile App
- Available in 35+ languages
- Patient reported outcomes (ePRO)
- Medical records management
- Direct-to-Patient shipment of IMP
- Self-eConsent
- Connected end-point devices

Communication

- Digital communication platform
- Task reminders and alerts
- Integrated televisit technology

Study operations

- Source forms (for Home Nurse Data)
- Protocol deviations
- Safety (AE/SAE) notification
- Electronic investigator site file
- Regulatory document management
- Centralized safety and monitoring
- IRT / DTP integration

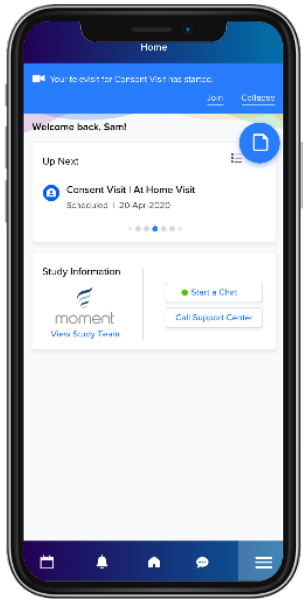
Trial design

- Decentralized and Hybrid trial design
- Trial database
- Fully scalable
- Global delivery
- Long term follow-up trial design

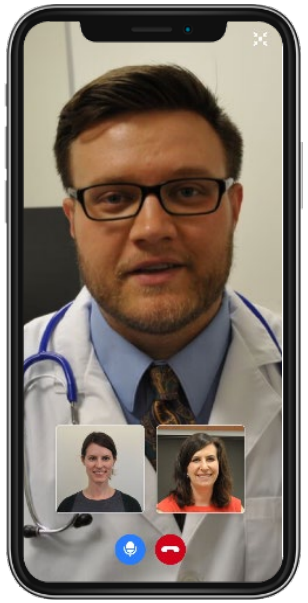
Simplified patient experience for consent

Remote eConsent journey

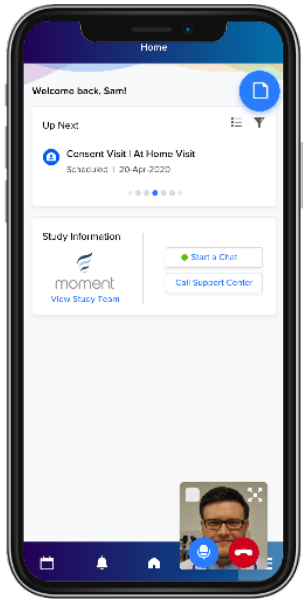
Join televisit



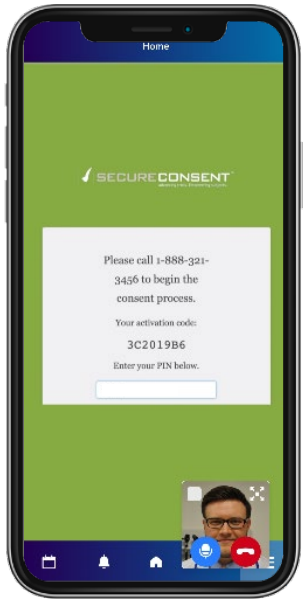
Minimize televisit



Access and tap eConsent URL link

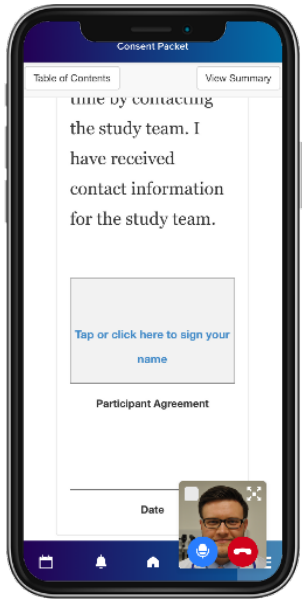


Verbally provide activation code



Enter activation code, generate PIN, and verbally provide PIN

Enter PIN, review ICF, and provide eSignature

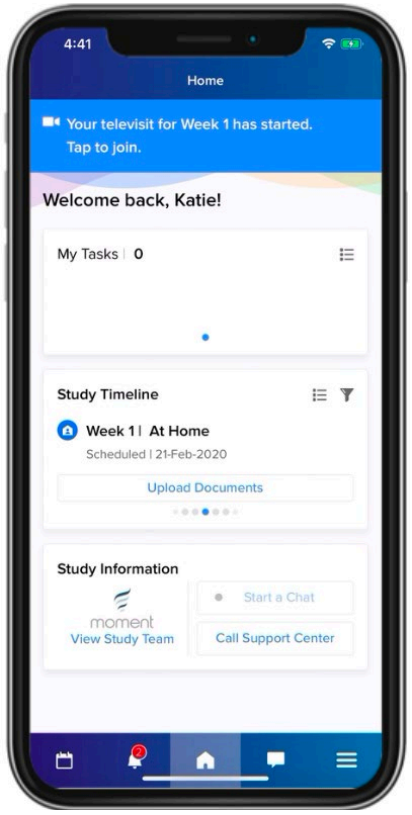


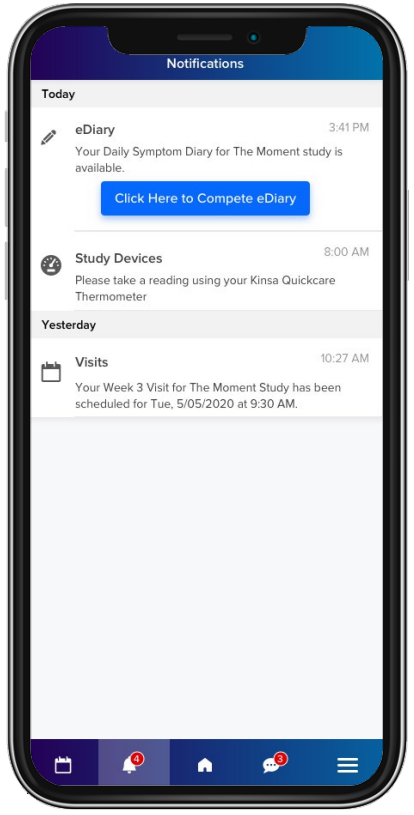
Provides Counter eSignature

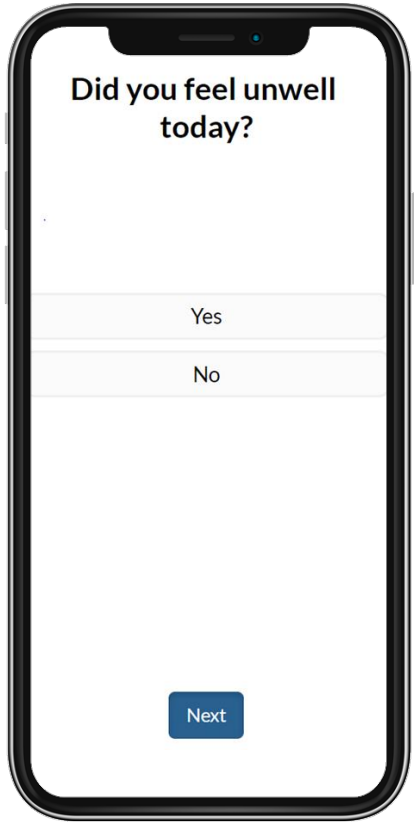
Simplified patient experience for ePROs

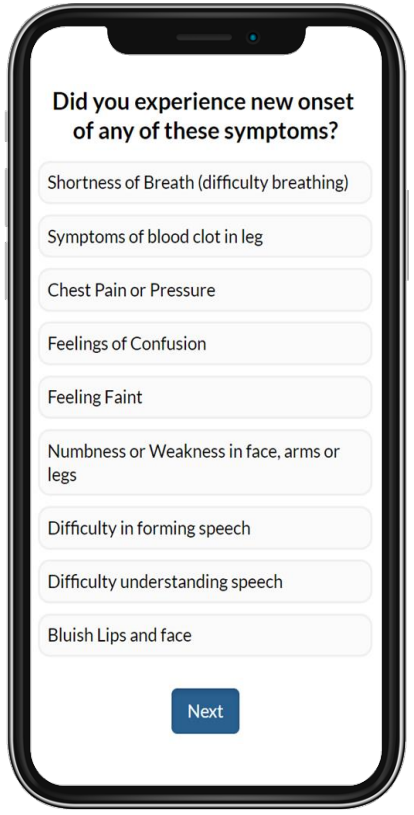
IQVIA eCOA single sign-on integration with Study Hub

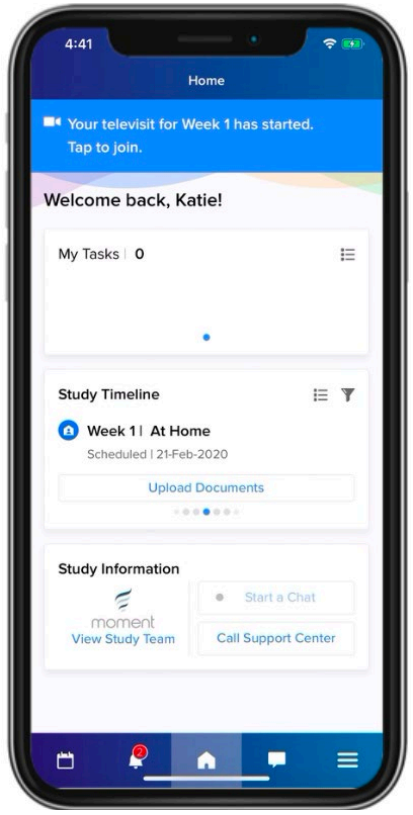
1. Study Hub Home Page
2. Study Hub notification & link to complete eDiary
3. eDiary automatically surfaces
4. Subject completes symptoms diary
5. Study Hub automatically surfaces











IQVIA Decentralized Trials Experience

As of Dec 2021

Dedicated operational team

- DCT Study Leads
- DCT Study Coordinators
- Study Concierges

40+ countries worldwide

US, UK, Canada, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, Poland, Ukraine, Belgium, Hungary, Romania, Georgia, Ukraine, Norway, Denmark, Finland, Austria, Switzerland, Bulgaria, Czech Republic, Brazil, Peru, Chile, Argentina, Columbia, Australia, China, India, Philippines, S. Korea, Taiwan, Singapore, NZ, Hong Kong, Japan, Israel, Malaysia, Portugal, Egypt, Moldova, Puerto Rico, South Africa

Involving over 213,000+ participants

32 Unique indications

12 Therapeutic areas

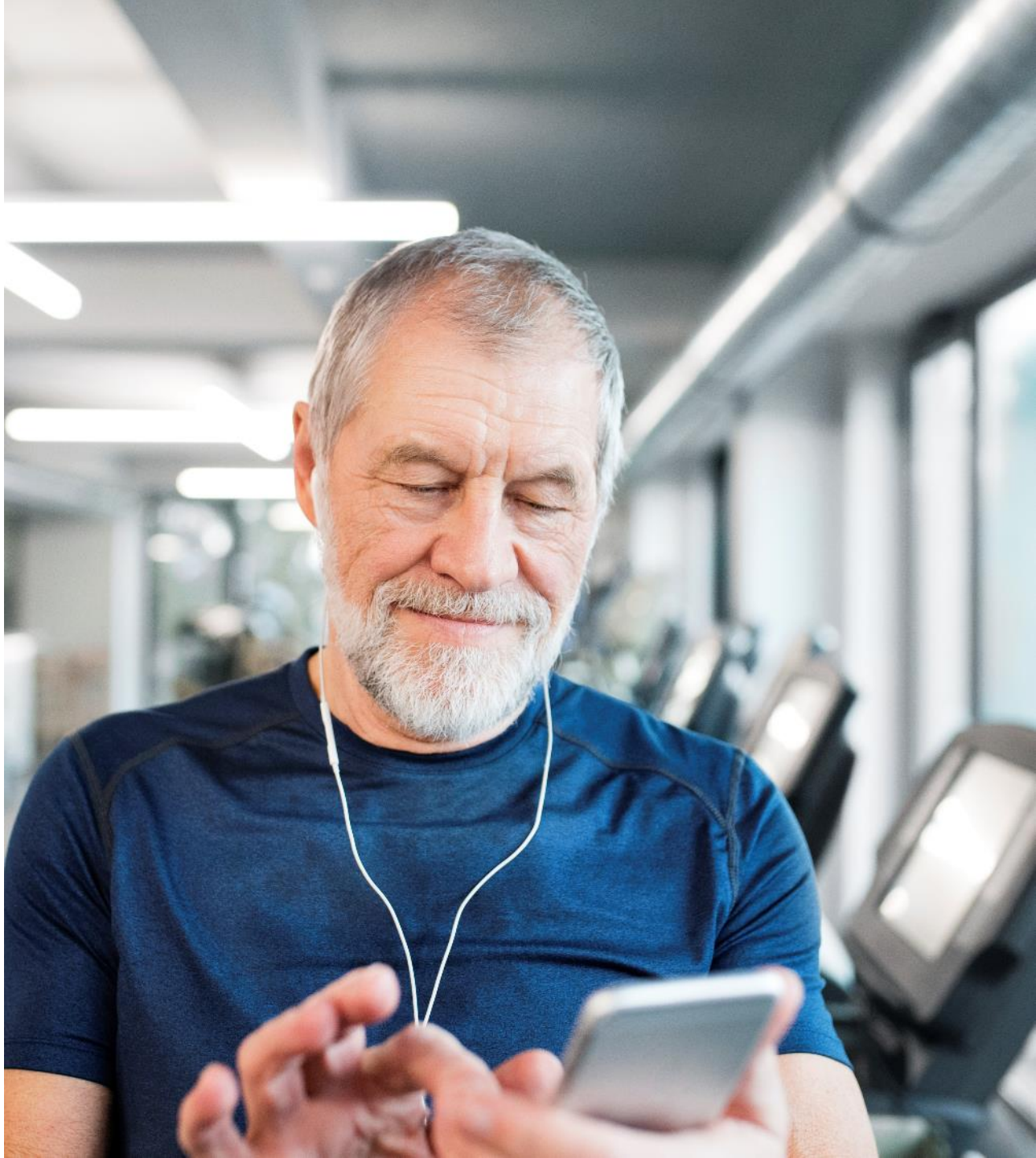
50+ studies with home health nursing

80+ trials underway

- Local to global
- Small to large: 20 to 50K participants

From the promise of DCTs to realized benefits

- **Reduces time burden** – reduces investigator and patient time commitments
- **Patient-centric –** 2:1 patients prefer a decentralized model
- **Risk management** - Hybrid model offers onsite assessments when needed
- **Investigator-centric –** 94% of investigators would be interested in a study using a hybrid virtual approach
- **Greater efficiency –** centralized team enables performance consistency
- **Paperless** – increases data quality



What does it mean for you, the site staff?

- DON’T PANIC! - Need for traditional studies, sites and visits for the foreseeable future
  - Not all studies/indications are suitable for Decentralized Trials
  - Hybrid model is by far the most popular

- Virtual Trials/Decentralized Trials frees you to take on more studies/complex studies due to less study visits/workload

- Additional patient profiles available to recruit from for a study due to less patient burden:
  - Ability to recruit patients coming from further away
  - Greater flexibility of timing of assessments for busy patients (24/7 support for Decentralized visits)

- Need to be technology savvy
- Need to coordinate with IQVIA (or other) support staff and technology – yet another system?

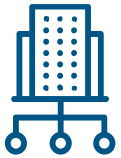
Questions?

Appendix

IQVIA's lessons learned

Insights from delivering decentralized and hybrid trials, keeping the patient at the center at all times

Executing decentralized trials is highly complex, more than just technology



Hybrid studies require close alignment between operational and remote teams

Start early to avoid amendments & delays

Validate endpoints – primary vs. Secondary

Identify and align internal champions

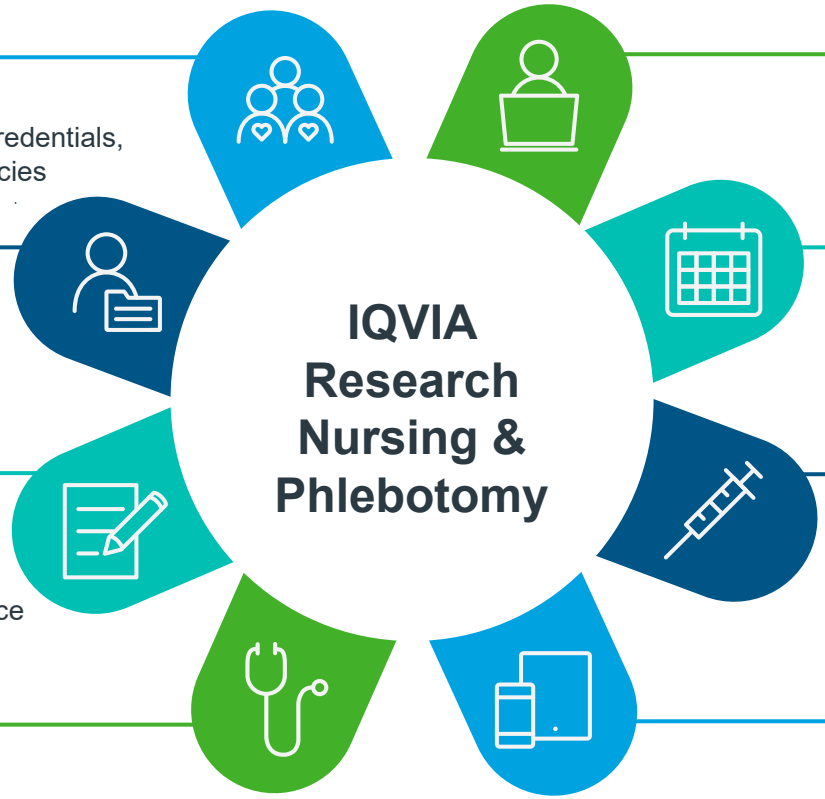
Understand what you want to achieve with decentralized approach

Plan thoughtfully for system integrations

No two studies are the same

IQVIA Research Nursing & Phlebotomy Solutions

Global research nursing and phlebotomy solutions underpinned by technology and supported by a network of regional care providers



Nurse network
Mixed model: Global network of IQVIA staff with nursing credentials, third party services providers, and nurse recruitment agencies

Project management
Project management responsible for successful delivery of services from upfront planning through completion

Quality assurance
Technology enabled quality oversight of nurse visit activities and data collections, ensuring protocol compliance

Medical oversight
Overall medical oversight of IQVIA nursing services program

Training
Protocol-specific training activities completed by home nurses through cloud-based LMS

Scheduling
Cloud-based technology enabling seamless scheduling between nurse and patients

Logistics management
Management of medical equipment and kits needed for home study visits

Digital data collection
IQVIA Study Hub technology supporting electronic visit data capture and televisit with Principle Investigator

Direct-to-patient extension study in oncology

Combining interventional and observational phases for a light-touch long-term extension solution

Client challenge

- Continue access to treatment for patients with solid tumors and follow those patients that had completed treatment to **understand long-term clinical benefit**.
- Conduct this study in a **cost-effective and light-touch manner**.

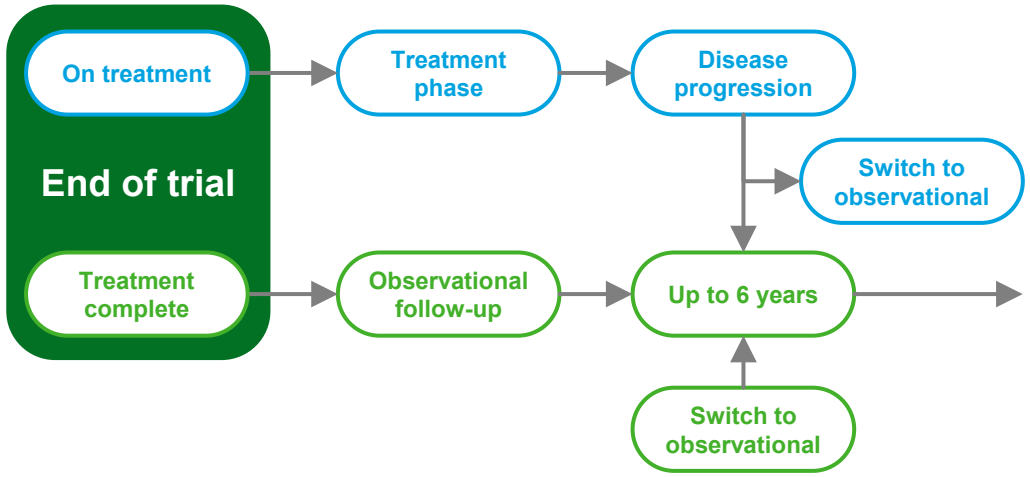
IQVIA solution

- A **hybrid design** to enable continued site-based treatment for patients until disease progression, and long-term survival follow-up direct-to-patient.
- IQVIA's **global direct-to-patient infrastructure** enabled a light-touch long-term follow-up strategy through its experienced call center.

Results

Treatment until disease progression or unacceptable toxicity; survival

- **Total number of indications: 4**
- **Total number of patients: ~300**
- **Total number of countries: 25**



Accelerate timelines with decentralized trial model

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

Sponsor objectives

Improve patient recruitment

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

Strengthen patient engagement and retention

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

Results and 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 weeks

All patients randomized within **4 weeks** from referral date

All patients enrolled

10% ahead of schedule