MEDABLE endpoint

Implementing technology to support remote trials

A guide for remote and decentralized trials

PRESENTATION FOR

endpoint Clinical Webcast

Questions we'll help you answer during this webcast

Vincent Puglia
Sr. Director, Strategic Alliances
endpoint Clinical

Alison Holland
Head of Decentralized
Trials, Medable

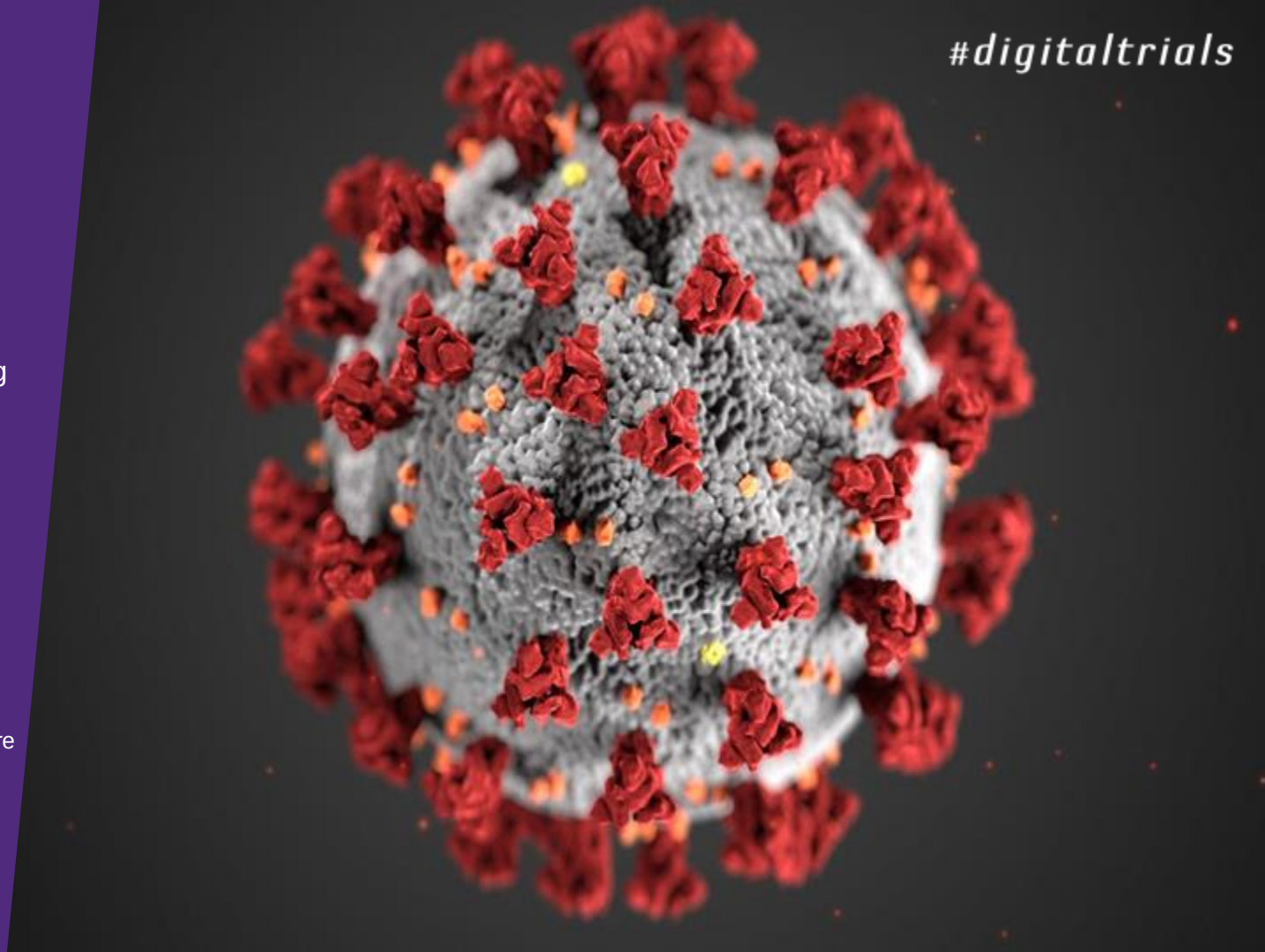
- What are our options for technology support on ongoing trials?
- What is the hot topic and solutions that everyone is talking about?
- How realistic are the technology solutions and are there barriers to adoption?
- How do you convert a standard live trial in progress to one that employs televisits. How does it impact the protocol?
- How do you deploy multiple solutions to meet multiple different needs?

The world has changed

Our Mission
Accelerate the clinical development process, leading to faster decisions on therapeutic effect.

Dr. Michelle Longmire
CEO & Co-founder

MEDABLE



Reducing risk to patients safety during containment needs a shift towards remote trials

Alison Holland
Head of Decentralized Trials

Study participant **safety at risk**

Data quality could be compromised

Reducing risk for patients safety during containment needs a shift towards remote trials

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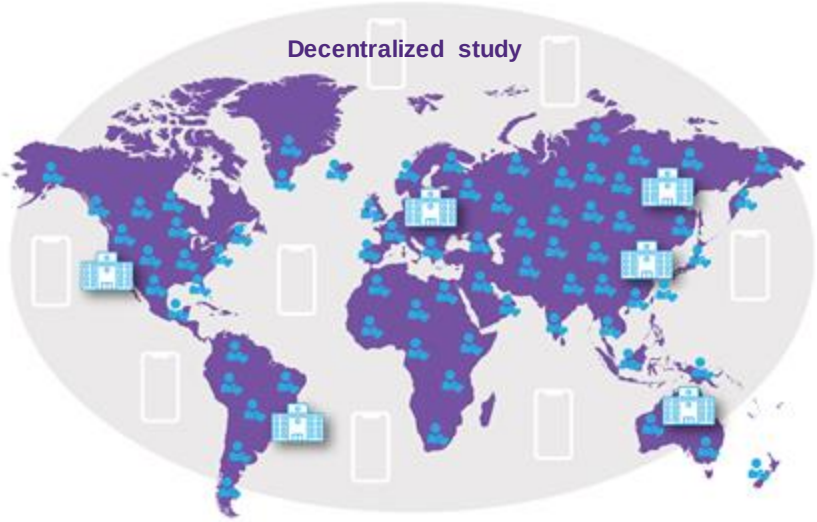
Traditional study

Decentralized study



Study participant **safety at risk**

Data quality could be compromised

Mitigate patient safety and data quality risks with televisits and remote patient monitoring

*"... using digital technologies to bring clinical trials to the patient, rather than always requiring the patient to travel to the investigator. **This is an FDA priority.**" (Jan 2019)*

Scott Gottlieb, M.D. | Commissioner, FDA

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Health authorities worldwide offer guidance

Patient safety remains paramount across regulatory agencies

Alison Holland
Head of Decentralized Trials

FDA

"Ensuring the safety of trial participants is paramount. Sponsors should consider each circumstance, focusing on the potential impact on the safety of trial participants, and modify study conduct accordingly." [1]

EMA

"Pragmatic actions may be required to deal with the challenges of conducting research, and in ensuring the rights, safety and wellbeing of participants." [2]

MHRA

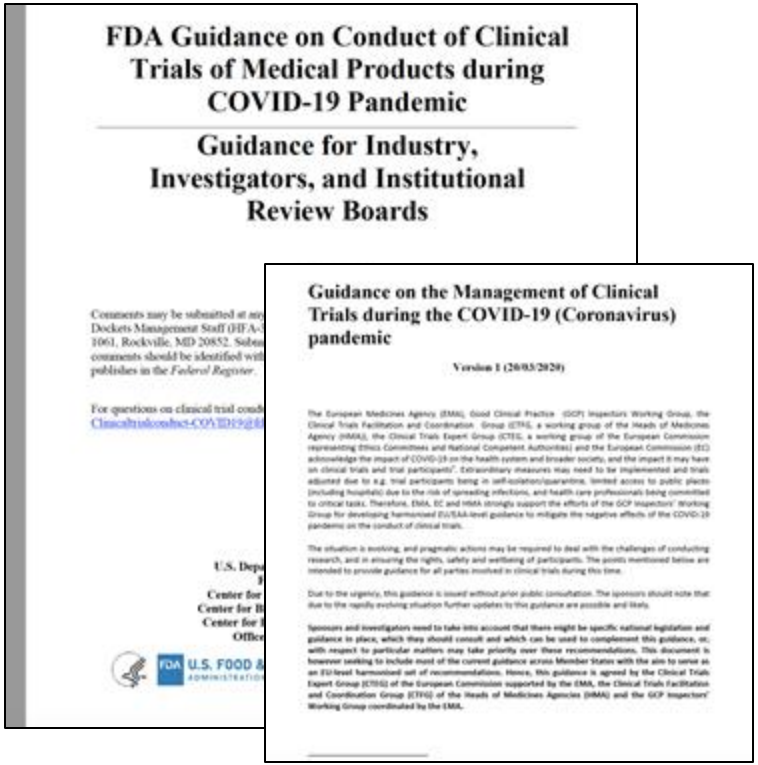
"Using phone calls instead of protocol-directed in-person study visits is acceptable where possible." [3]

AIFA

"First of all, it should be assessed whether in-situ monitoring visits can be replaced by an enhanced centralised monitoring or whether such local visits can be postponed." [4]

Statements are excerpts and not advisement from Medable.
Applicable source documentation from regulatory agencies should be consulted.

[1] FDA guidance March 2020
[2] EMA guidance V1 March 20, 2020
[3] MHRA guidance March 19,2020
[4] AIFA - Notice March 12, 2020



FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

Guidance for Industry, Investigators, and Institutional Review Boards

Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic

Version 1 (20/03/2020)

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Response options for in-flight studies

Build and design around the risk assessment for your study and patients, not one size to fit all

Alison Holland
Head of Decentralized Trials

Planned Schedule of Assessments (SOA)

Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | EOS | FUP

Day 0 → Day 120

Amended SOA

Visit 1 | Visit 2 | Visit 3

Risk mitigation assessment

Traditional on-site visit | At patient's home visit supported by home nurse | Tele visit | At patient's home visit

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Response options for in-flight studies

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Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | EOS | FUP

Day 0 → Day 120

Amended SOA

Visit 1 | Visit 2 | Visit 3 | Risk mitigation assessment

Response Options / Protocol Amendment

Visit 4 | Visit 5 | Visit 6 | EOS | FUP

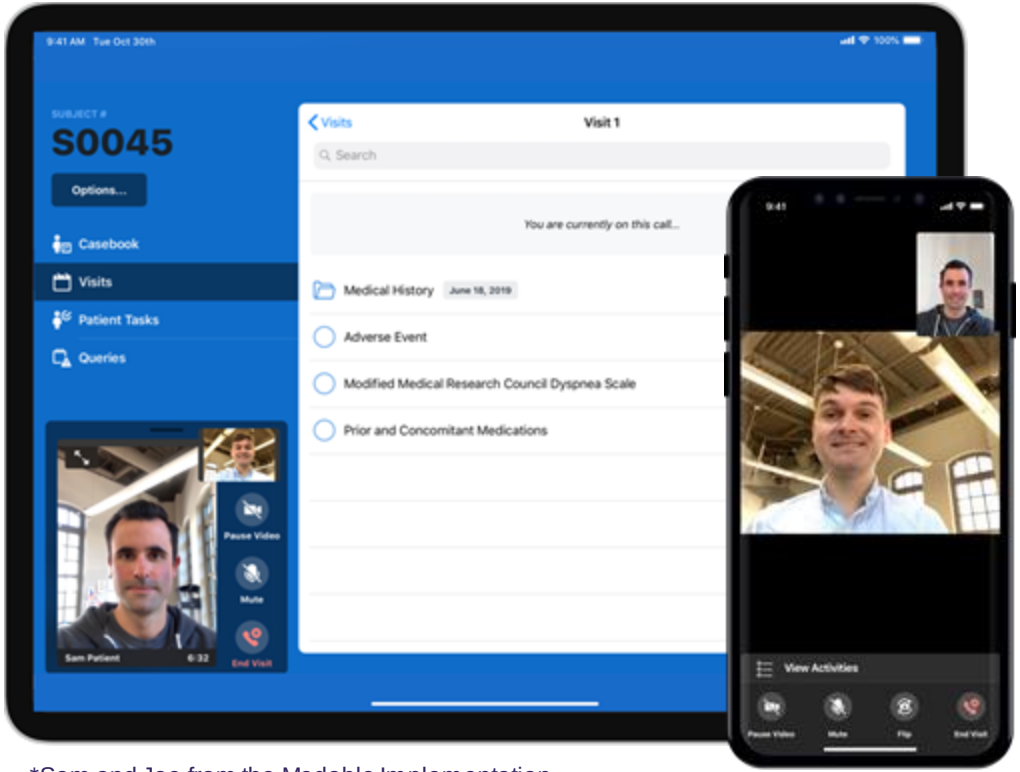
- Traditional on-site visit
- At patient's home visit supported by home nurse
- Tele visit
- At patient's home visit

MEDABLE

Global Trial-Fit™ Telemedicine with Televisit

Medable's Televisit solution connects patients and sites together for increased communication and collaboration:

- Secure virtual visits between site and patient
- Questionnaire within workflow to increase communication
- Increase patient retention and patient access by reducing burden on patient

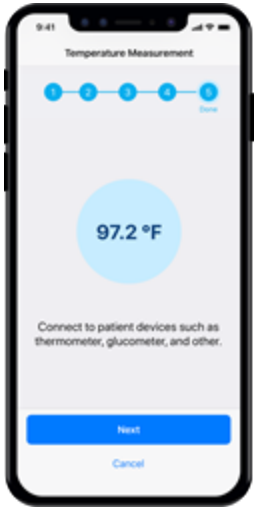


*Sam and Joe from the Medable Implementation Team during a live demo

Flexible ePRO for the most complex protocols

Medable's ePRO platform has undergone rigorous user testing, delivering a superior patient experience to optimize engagement and improve data quality:

- Validated instrument library for quick deployment
- Consumer grade UX for increased patient engagement and retention
- Secure communication with site
- Better compliance with alerts and reminders
- Increased patient access with multi-language and global support
- Real-time analytics and patient monitoring



Connect to patient devices such as thermometer, glucometer and other monitoring devices

Patient diaries and logging ensure audit and traceability

Seamless login experience to ensure ease-of-use and security

Our solution is designed for the clinician, by the clinician

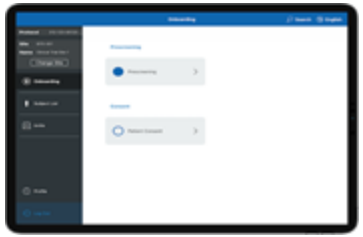
Medable's site app delivers capabilities that ease site burden, simplify enrollment, and accelerate data entry and solves the multi-device problem

Consent patient at site electronically or remotely

Fill out COA Clinical Reported Outcome

Communicate directly with patients via Telemedicine

Consent | Enroll and Randomize | Assess | Monitor | Remote Visit | Support



Determine patient eligibility, and randomize with integrated endpoint IRT in the same workflow

Remotely monitor patient progress with dashboards

Global helpdesk and integrated in-app support
(24x7 - any language)

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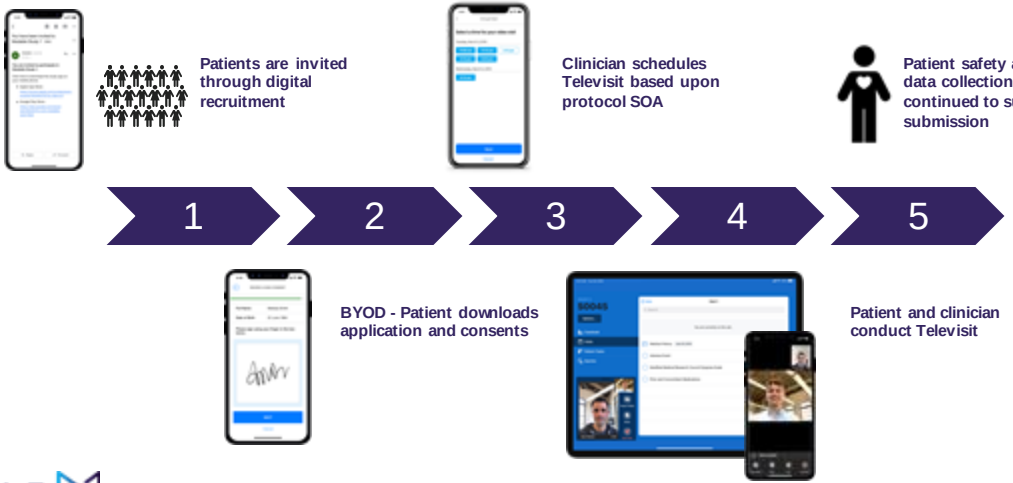
Case Study

Rapid virtualization

A global response to enable continued patient assessment and collection of endpoint data within the pandemic



10 Days
Kickoff to Go-live

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Risk assessment and mitigation planning

Prioritization of patient safety, preservation of data integrity, anytime, anywhere

Protocol Risk Assessment

- Patient safety risk
- IMP (and comparator) availability and accessibility to patient
- Primary endpoint availability (can this be collected digitally?)
- Timelines and length of study to run
- Enabling care of existing patients and/or new patient enrollment

Risk Mitigation Assessment

Deployment Risk Assessment

- Geographic spread
- Timelines for priority patient engagement
- Local country logistics (on the ground travel/accessibility)
- Local regulations and IRB recommendations
- Device usability
- Data privacy considerations
- Site staff availability (and location)
- Contracting and quality assessment status of parties

Implementation

Mitigation Activities

- Pragmatic scoping to rapidly deploy generic televisit for PI:Patient connectivity
- Comprehensive project plan for roles and responsibilities to meet deployment goals and timelines (Medical, Study, Site, Patient, QA, Contracting, IT, DM)
- Accelerated change management!
- Real-time communication
- Don't forget training and site/patient support

An integrated platform to support remote and decentralized trials

Patient app & connected devices
Connect patients to trials remotely with native iOS and Android apps

Site app
Enable site-based staff to conveniently screen, enroll and enter patient data in a user friendly format

Study manager for sponsors (or CRO)
View real-time patient data and leverage next generation analytics

Application Layer

Clinical Data Cloud Platform and Interoperability

Capabilities

- eRecruitment
- eConsent
- Televisit
- **Wearables & Sensors**
- Medication Tracking
- **ePRO & Diaries**
- **Notifications & Reminders**
- **Geofencing**
- Remote Nursing
- Training & LMS

System Integrations

- **EDC**
- IRT endpoint
- Labs & Diagnostic
- eSource & EHR

Medable

Provisioning | Scale Management | Implementations | Integrations | Translations | Help Desk | Training

Security & Compliance (HIPAA, GxP, etc)

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