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

Study participant **safety at risk**

**Data quality** could be compromised
Reducing risk for patients safety during containment needs a shift towards remote trials.

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
Health authorities worldwide offer guidance. Patient safety remains paramount across regulatory agencies.

**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 FDA guidance March 2020

**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 EMA guidance V1 March 2020

**MHRA**

“Using phone calls instead of protocol-directed in-person study visits is acceptable where possible.”

3 MHRA guidance March 19, 2020

**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 AIFA - Notice March 12, 2020

Statements are excerpts and not advertisement from Medable. Applicable source documentation from regulatory agencies should be consulted.
Response options for in-flight studies
Build and design around the risk assessment for your study and patients, not one size to fit all

Planned Schedule of Assessments (SOA)

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

Amended SOA

Visit 1  Visit 2  Visit 3 (Risk mitigation assessment)

Day 0  Day 120

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

Alison Holland
Head of Decentralized Trials
Response options for in-flight studies

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

Planned Schedule of Assessments (SOA)

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

Amended SOA

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

Response Options / Protocol Amendment

Visit 4  Visit 5  Visit 6  EOS  FUP

Day 0  Day 120

Risk mitigation assessment

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

Alison Holland
Head of Decentralized Trials
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.
Rapid virtualization
A global response to enable continued patient assessment and collection of endpoint data within the pandemic

1. Patients are invited through digital recruitment
2. Clinician schedules Televisit based upon protocol SOA
3. Patient safety and data collection continued to support submission
4. BYOD - Patient downloads application and consents
5. Patient and clinician conduct Televisit
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

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

Risk Mitigation Assessment

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

---

**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
Thank you for your time.

Visit us @ www.endpointclinical.com

Visit us @ www.medable.com

Follow us on LinkedIn