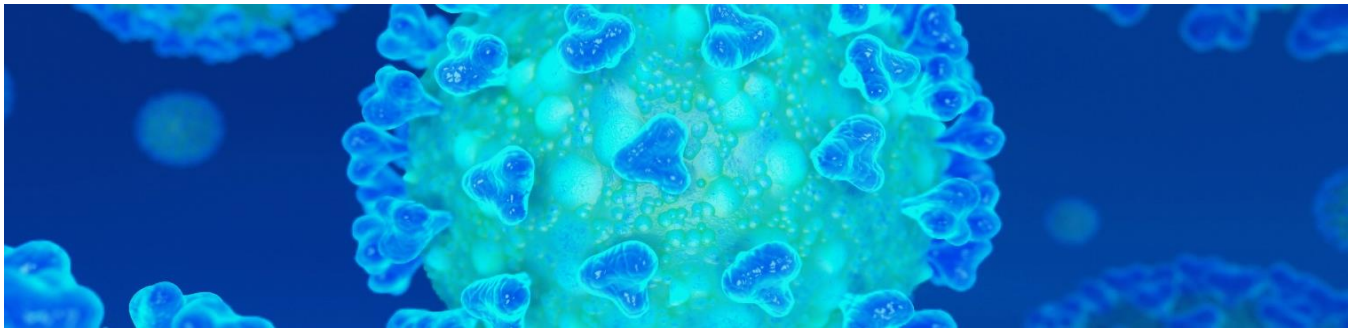
The Future is Now: Patient-Centered Trials, Telemedicine, & Moving into the Home

Lessons Learned from a Virtual Town Hall held on April 17, 2020



There's no denying that the COVID-19 pandemic has spurred tremendous innovation across our industry.

Even more impressive is the pace at which we've been able to implement technology solutions that can facilitate continued progress in our critical activities and trials. Most importantly, the expansion of telemedicine and virtual solutions is enabling us to meet our patients' needs while also maintaining patient safety, study integrity, and data quality.

During Halloran's 5th Virtual Town Hall, expert panelists discussed the telemedicine technology landscape before the COVID-19 outbreak, considerations around vetting and implementing these solutions during the pandemic, and the future of virtual visit technology as shaped by the current environment.

Telemedicine Pre-COVID

What did the technology landscape look like in clinical trial conduct before COVID-19?

- **Fortunately, the technology in demand now has been in flight since the early 2000s**. Home visit coordination, at-home procedures (infusions, blood draws, etc.), self-report solutions, video visits, and digital endpoints surfaced long ago. Until now, the barriers were chiefly regulatory obstacles around implementation and the business case necessary to drive change management internally.
- Sponsor uptake of technology to enable virtual visits was historically incremental, and successful launch required a **7-8-month planning runway**.
- Where solutions were implemented, **patient uptake was slow**.

- **According to an article published in Nature Digital Medicine, less than 0.4% of active trials in clinicaltrials.gov used a tech solution** such as telemedicine platforms, wearables, or smartphone data mining.
- There's an opportunity to expand the use of these technologies.

Telemedicine During COVID

What is the argument for the use of telemedicine/virtual visit technology?

- Home visits used to be cutting edge, but the current situation is forcing us to innovate further – many trial teams now must either find a way to support virtual visit elements or resign to either canceling or putting the study on hold.
- **Conservation of personal protective equipment (PPE) and protecting the integrity of our healthcare system** so it can serve those in acute need.
- The technology is **widely available** and, for the most part, **familiar** (i.e. video platforms, email, online shared spaces).
- Regulators have **loosened restrictions** on the use of virtual platforms.
- **Patients want and expect options now.**
    - Recent data shows that patients still want to participate in clinical trials. Even under the current circumstances, more than half of surveyed patients indicated they'd be willing to participate in a trial within the next month. The vast majority supported an increase in telehealth services and digital solutions. Only 22% indicated discomfort participating amid the COVID-19 pandemic.

What should sponsors consider when planning the use of a telemedicine or virtual visit solution?

- Any virtual or remote solution that sponsors develop should be **patient-centered** above all else. Sponsors must communicate with patients to understand how their needs are evolving.
- In the context of a sponsor needs assessment, virtual visit technology solutions can be grouped into three levels, increasing in complexity:
    - Level 1: Forms available for patients to complete at home to capture critical data, and a platform to house the data collected via the forms.
    - Level 2: Bringing phlebotomists and other medical professionals into the patient's home to perform medical procedures that would traditionally be executed in the clinic.
    - Level 3: Migrating all clinic/hospital data to platforms amenable to at-home use.
- Consider the **ABC metaphor for virtual visit planning**:
    - **Airway – delivering the solution**: How can you most effectively connect with the patient? Phone/video platform?
    - **Breathing – operationalizing the solution**: How will you monitor your critical variables and collect meaningful data?
    - **Circulation – making the solution continue to work**: How will you move this data to a useful and accessible location?

- **“Apps don’t draw blood”**. Consider the complexity of the study’s clinical assessments, biometrics, functional studies, imaging, etc. to choose a technology, or combination of solutions, that will be most effective for the specifics of the study in question.
    - Biopsies, imaging, and blood draws are some of the most challenging procedures to execute virtually.
- **Have a robust communication plan.** Sponsors must remember that patients are also adjusting to the rapidly changing pandemic environment. Study teams transitioning to at-home or virtual visits must recognize the criticality of over-communicating with the patients in order to quell concerns around safety, equipment availability, logistics, personal hygiene, and other anxieties related to COVID-19 and the patient’s condition.
    - **For home-visits, consider a two-way opt-in policy under which the visiting healthcare provider and the patient opt-in or out to each home visit before it takes place.** This empowers both parties to be the agent of their decision-making and have more control over their environment.
- Decision-making is often a rate-limiting factor. Operationally, most tech solutions can be launched in 5-7 business days. The hold-up is typically organizational politics and clunky decision-making processes. We have now eliminated those organizational barriers and should acknowledge that the aspirations of the past are now a reality.

What should sponsors consider when selecting a telemedicine / virtual visit vendor or methodology?

- Some **suggested vendor selection criteria**:
    - CFR Part-11-compliant
    - Patient-friendly and easy to use
    - Accessible via a patient’s personal device (BYOD – bring your own device) – no hardware purchase necessary
    - E-consent compatible
    - Low administrative burden for site staff – may be simpler than their normal procedures
    - Compliant with HIPAA / regional regulations
    - Central monitoring features included to enable remote SDV

What technology is in-flight currently?

- Phone; email; various video solutions such as WhatsApp, Zoom, FaceTime
- There are plenty of telemedicine platforms built specifically for clinical research that is more tightly controlled than publicly accessible chat and video apps. These solutions are HIPAA-compliant and typically include a robust support structure.

Telemedicine Post-COVID

How will we ensure that the innovation spurred by COVID-19 endures into the future?

- Prove to industry and regulators that we can take an idea and **execute efficiently and effectively**
- Take advantage of the fact that industry stakeholders and regulators are poised and motivated to move quickly and adapt generously.

- **Execute flawless transitions** that hold patient safety and data integrity measures intact, and ideally **outperform old conventions**.
- Maintain a "parking lot list" of learnings to embed into our future organizations and enable effective scaling of these solutions. We must hold ourselves accountable to this parking lot list and **truly adapt** processes, vendor selection, protocol development, endpoint planning, etc. to reflect relevant changes.
- **Collaboration across industry players** is the only way forward. Without cooperation between sites, patients, providers, sponsors, regulators, and CROs, there will be no progress.
- Sponsors must design patient-centered virtual capabilities into all future trials, from the start of study planning.

While COVID-19 is devastating to our industry in many ways, we can choose to answer the call-to-arms that this situation has presented: we must collaborate in order to make true change in our industry. The opportunity for disruptive innovation is at our doorstep, and we have all the tools we need to build real change in the way we design and conduct clinical trials.

We must work together to realize the potential that we have to create enduring solutions that will better meet the needs of the patients we serve.

Please reach out to us if we can help in any way or would like to be included in any of our upcoming town halls.

CONTACT US

Laurie Halloran, CEO | lhalloran@hallorancg.com
Greg Dombal, President & COO | gdombal@hallorancg.com
Paola Murphy, Chief Client Officer | pmurphy@hallorancg.com
Katie McCarthy, Chief Development Officer | kmccarthy@hallorancg.com
Sheila Gwizdak, VP, Quality | sgwizdak@hallorancg.com
Kim Raymer, VP, Regulatory Affairs | kraymer@hallorancg.com
Jason Milovanovic, VP, Clinical Development | jmilovanovic@hallorancg.com

GIVE US A FOLLOW

Halloran CONSULTING GROUP

266 Summer Street, 8th Floor
Boston, MA 02210
hallorancg.com | 617.648.7879