Lakeridge Health

3CTN G.A.P.P Webinar Series

Remote Monitoring

One System.
Best Health.

April 7, 2021

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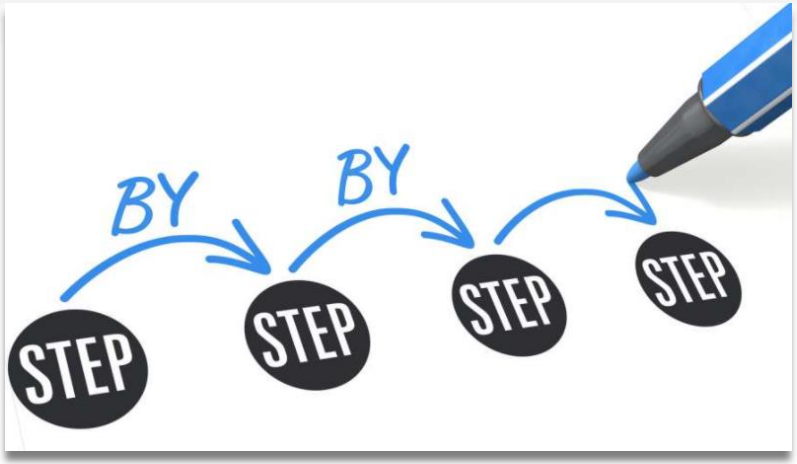
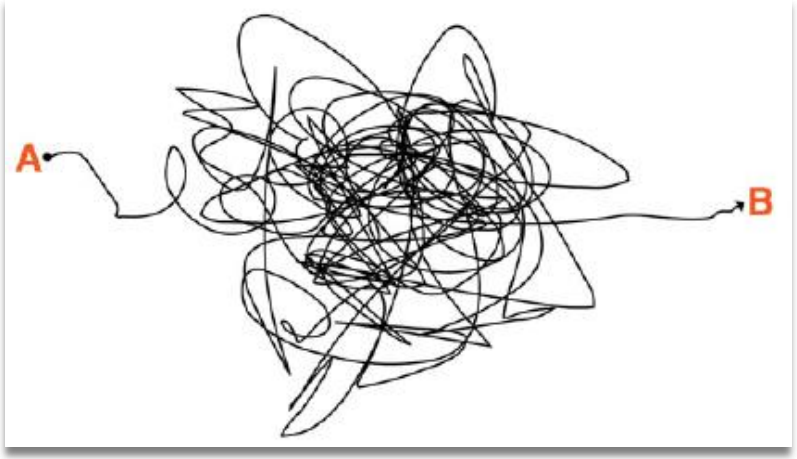
Developing the Remote Monitoring Process



The Vision…

vs.



The Reality…

What steps did we take to set this up?

- **Consult with IT**
- **Consult with Privacy**
- **Consult with Sponsor**
- **Consult with Research teams**
- **Draft documents**
- **Review with sponsor and Research teams; incorporate revisions**
- **Finalize documents and processes**
- **Disseminate information and documents; conduct training as needed**

What documents were created to achieve this?

- **Verbal consent script for studies which specify that monitoring is only performed onsite (language approved by local REB and OCREB; ensure new studies going forward do not have such restrictive language)**
- **Verbal consent log for tracking patient responses**
- **Remote access agreement for sponsors**
- **Remote monitoring checklist for Research Team**
- **Remote monitoring note-to-file (NTF) for sponsors**
- **Certification log to attest that scanned copies are true to the original document**

Let’s breakdown the operational process…

- Outline site remote monitoring process to sponsor.
- If sponsor is not agreeable, explore what processes are not meeting their expectations and try to adjust/accommodate, or provide further clarifications.
- If agreeable, send remote access agreement and remote monitoring NTF.
- Once signed agreement is returned, send to IT to set up remote access (same remote login system that staff use; for access to electronic medical record).
- Documents (source, regulatory, ethics, certification log, subject identification log) are shared via SharePoint link (monitor receives read-only access to study folder; security key sent to email address to gain access).

Remote Monitoring Process Cont'd…

- **Sponsor to send list of requested documents** 1 week prior to monitoring visit (2 weeks prior to initial visit due to higher volume of material).
- **Site staff scan requested documents** into a folder titled the date of monitoring visit (sub folders are created within this monitoring visit folder organized by patient number, regulatory, etc). Once the folder is prepared, it is **dropped into the SharePoint folder** ahead of the visit.
- **A certification log is completed** with the date of the monitoring visit, and details of what is included in each folder is included in a description column. Staff sign the log to attest that all scanned material is accurate and true to original documents.
- Research staff assist monitors with connectivity issues for their first visit; subsequent IT issues are addressed directly with site IT department.
- Staff schedule set times to check-in with monitors via phone or MS Teams.

Challenges & Feedback

Challenges:

- Finding a system that satisfies all stakeholders – IT, Privacy, Sponsor, Research Team.
- Smaller centre = no QA/trial support units to facilitate or create the process.
- Amount of time it takes staff to scan material and prepare for visits.

Staff and Sponsor Feedback:

- Sponsor feedback: positive feedback so far (except for one sponsor). Connectivity issues have been limited to initial visits so far.
- Staff feedback:
  - PROS: user-friendly, efficient, don't have to sit with monitors for the whole visit
  - CONS: can be quite tedious due to the volume of scanning; staff working remotely need to spend more time onsite preparing for remote visits.

Areas for improvement/discussion

- Certification log: Current process requires site to save folders by “monitoring visit date” – as more and more visits occur, it becomes challenging to locate specific documents from previous visits unless you recall the monitoring visit it was attached to.

- Should sites be invoicing sponsors for the additional time to prepare for visits, or is this considered “the cost of doing business”?

- How do sites continue with studies where onsite monitoring is not permitted and the sponsor doesn’t accept site’s remote monitoring process?


Thank you
Any questions…?