Running A Paperless Clinical Trial: From Start to Finish

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Agenda

- Clinical Trial Regulation Changes
- Clinical Trial Challenges
- Myths, Apprehensions & Real Life Considerations
- Practical Tips

MAGI We Can Agree To Save Lives

Where Our Industry is Now: A Typical Investigative Site

Clinical Trial Regulation Changes

- EMA Reflection Paper
  - Changes from sponsors that promote paperless direction
  - Need for investigative site files to be remote and auditable/available for inspection
- Electronic Source Documents/Health Records

Clinical Trial Regulation Changes

- Europe: Moving to Virtual Systems
- FDA No Longer Requires Wet Signatures

Clinical Trial Challenges

- Too Many Vendors – Streamline site activities into a single solution
- Inefficient Reporting Methods
- Too Much Paper at the Site
- Excessive Onsite Monitoring Time
- Cumbersome Study Records Archival/Retrieval
  - Efficient use of technology can improve the process of study closeout

Productivity at Sites Diminished

Myths, Apprehensions & Real Life Considerations

MYTH

- Increase in training time to implement a paperless system

SOLUTION

- Employees experienced with online systems should be mandatory during the hiring process

Myths, Apprehensions & Real Life Considerations

Sites facilitate 1-2 global studies before they bow out of the clinical trial space due to cost inefficiencies

- Paperless trials are easier to run and streamline
- Greater participation in more studies results in more responsibility in documents – paperless systems have more organization

Myths, Apprehensions & Real Life Considerations

Sites will be audited

Sites using paperless systems are more organized and efficient

- Reports
- All movement in the eTMF is auditable – with full trial audit

Paperless systems take up little space

- Elimination of massive filing cabinets

Practical Tips

TIP Increase competitiveness as a site

- Increase chances of being chosen to participate in a study by becoming digital

TIP Start small: Utilize CTMS

- Increase chances of being chosen to participate in a study by becoming paperless

TIP Staff those who are more technologically advanced

- Those with experience with digital systems/web-based tools will prove to be more valuable

THANK YOU!