

Running A Paperless Clinical Trial: From Start to Finish

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MAGI WE CAN AGREE TO SAVE LIVES

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



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

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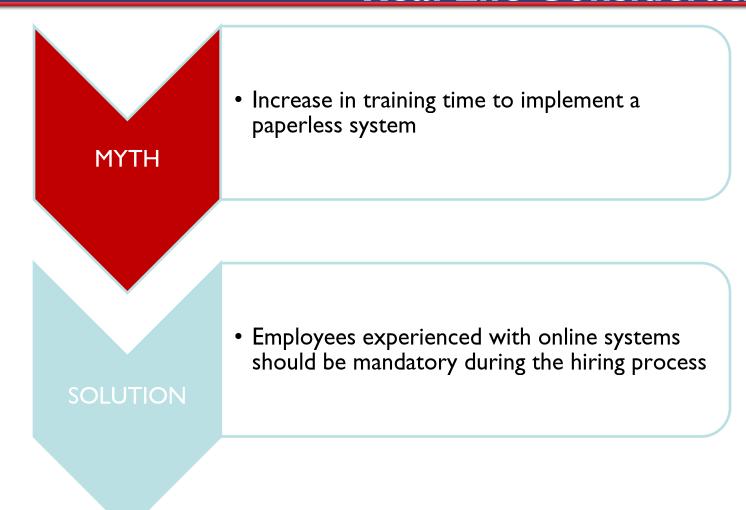
Clinical Trial Challenges

- 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





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

- Increase competitiveness as a site
 - Increase chances of being chosen to participate in a study by becoming digital
- Start small: Utilize CTMS
 - Increase chances of being chosen to participate in a study by becoming paperless
- Staff those who are more technologically advanced
 - Those with experience with digital systems/web-based tools will prove to be more valuable



THANK YOU!