Paperless Validation
The ones and zeros

Aaron Jordan

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Paperless Validation

"There is a way to do it better — find it"

- Thomas Edison

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Paperless Validation

- Lots of Paper
  - **Approx 20-30K protocol pages generated – Initial 8 NYA**

- Data Integrity
  - **Contemporaneous Entry**
  - **Legibility**
  - **Traceability of changes**
  - **Loss of Protocols**

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Price Waterhouse Coopers Study:

$122 spent on finding a lost document
~ 7.5% of all company documents are lost completely
Assume 10,000 documents (a very light figure) = 750 lost document
Costing the company $91,000

American Records Management Association:

- 7-14% of total costs is spent on processing in a paper environment
- Average organization spends 280 hours annually per employee looking for lost documents

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Logistics and Clerical
- Physical movement of protocols
- Scanning for accessibility/approval
- Protocol attachment references
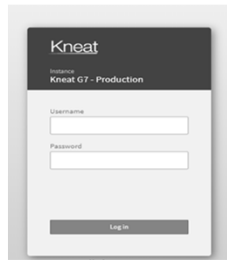- Spreadsheets for tracking

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IVT Network Case Study:

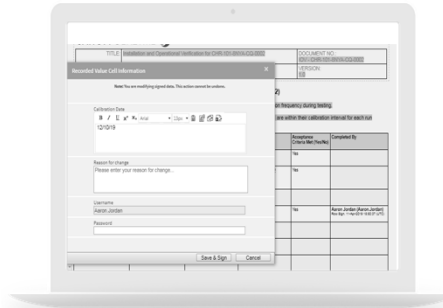| Protocol Stage	Compared to Paper
Pre-execution Approval	48% reduction on average
Post Execution Approval	58% reduction on average

Overall	Compared to Paper
Test Protocol Cycle Time	60% reduction on average
Time savings per protocol	23 hours based on their workflow

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More and More Improvements!

- Accessibility of documents
- Scalable
- Simultaneous review and approval
- Email notifications
- Shared information across documents
- Drives consistency of approach

efficiency

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Validation processing step	Average processing time saved	Areas where savings realized
Protocol Generation	3	Content populated across multiple protocols simultaneously, template use, auto smart numbering
Protocol Routing for approval to execute	3	tracking, reporting, metrics, embedded submittals in protocols to aid review
Protocol Execution and Compiling	6	No exhibit referencing, no protocol number referencing, no printing, no organizing/compiling
Non Conformance (NC) processing	1	tracking, routing
Protocol final report writing	3	NCs summarized automatically
Protocol final report routing for rev/approval	3	tracking, reporting, metrics, exhibits embedded into test table
Post approval management	4	scanning, records management, uploading to doc management system, ship offsite
Total Average Per Protocol Savings (hours)	**23**	

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Paperless Validation

Trials and Tribulations

- What to do with the remaining paper?
  - **Keep or Destroy?**

- Generation of protocols
  - **Forward thinking important.**
    - E.g. No line out of tables

- Culture change
  - **Manage Expectations – What would we do on paper?**
  - **Approval of a document – Does QA need to be last?**
  - **Infrastructure Challenges – Internet availability**

- Challenges when considering complexity
  - **Linkages to other applications?**

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Questions?

Please use the microphone indicated so our recording includes audio of your question

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