DESIGNING EFFICIENT PROCESSES FOR TMF CONTENT WHEN OUTSOURCING CLINICAL TRIALS

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Lisa Mulcahy has a 23-year professional career in the Pharmaceutical Research industry. Content and Records Management independent consultant, particularly in the area of the trial master file. She is skilled in the assessment of client's content and records management TMF processes and programs; advising on areas for improvement and proposing future strategic direction ensuring ICH GCP and regulatory compliance.

She has worked closely with numerous large and small companies providing consultative meetings through to providing an in-depth analysis of the current state of affairs, assisting them in the planning their future state of excellence. She works with clients as they embark on the electronic creation, management, and archival of electronic TMF content. Co-leader of the TMF RM Team.

THE TECHNOLOGY V. THE PROCESS

Much of the way that the content in Trial Master File is collected, created, and managed is contrary to our normal everyday way of thinking and working.

- Consumer rewards cards that connect personal data with usage and purchase data. We like getting some-thing for doing nothing.

- Phones allow us to do banking transactions; including photos to deposit checks.

- Enroll subjects into clinical studies using interactive web technology

THE TECHNOLOGY V. THE PROCESS

For TMF collection, creation, and management many of us are still working in the…

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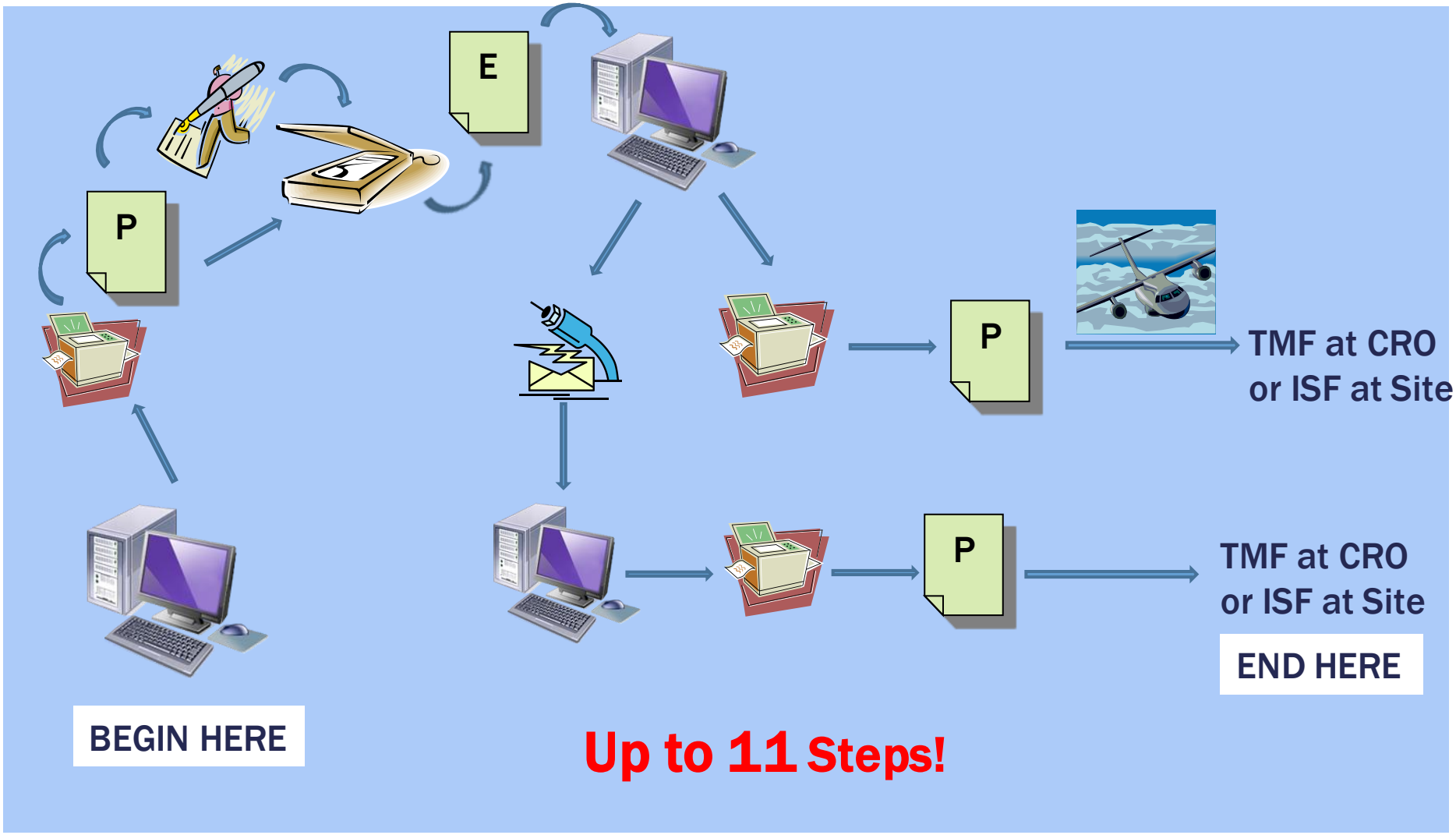
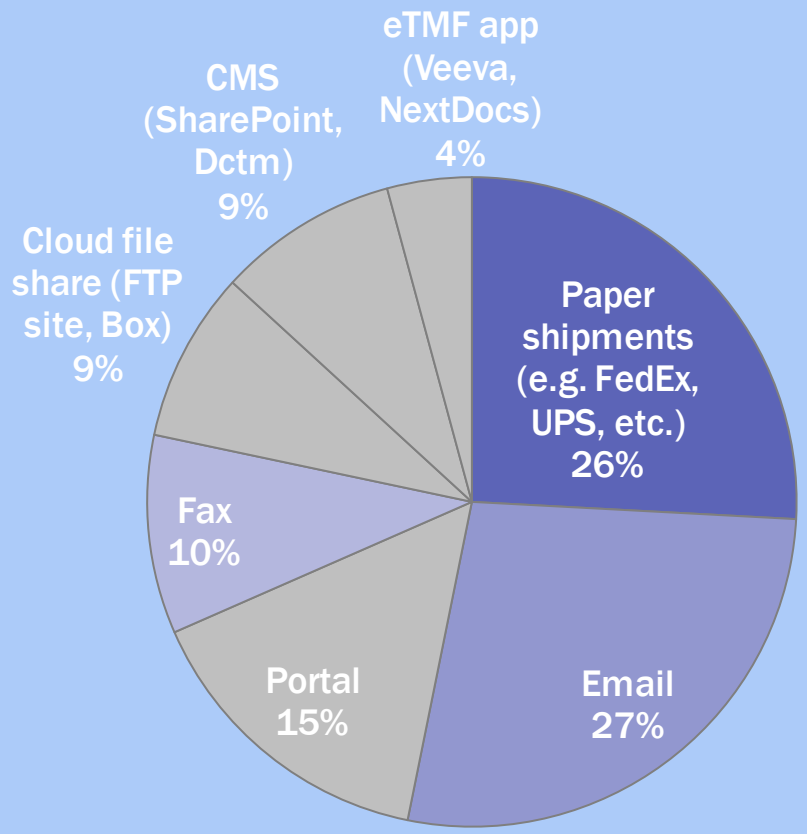
THE "OLD" TMF PAPER-BASED PROCESS

SPONSOR TO CRO OR SITE



SPONSOR & CRO COLLABORATION



Paper – 26%

Email – 27%

Fax – 10%

63%!!
Still paper-based

Source: Paperless TMF – An Industry Benchmark, 2014

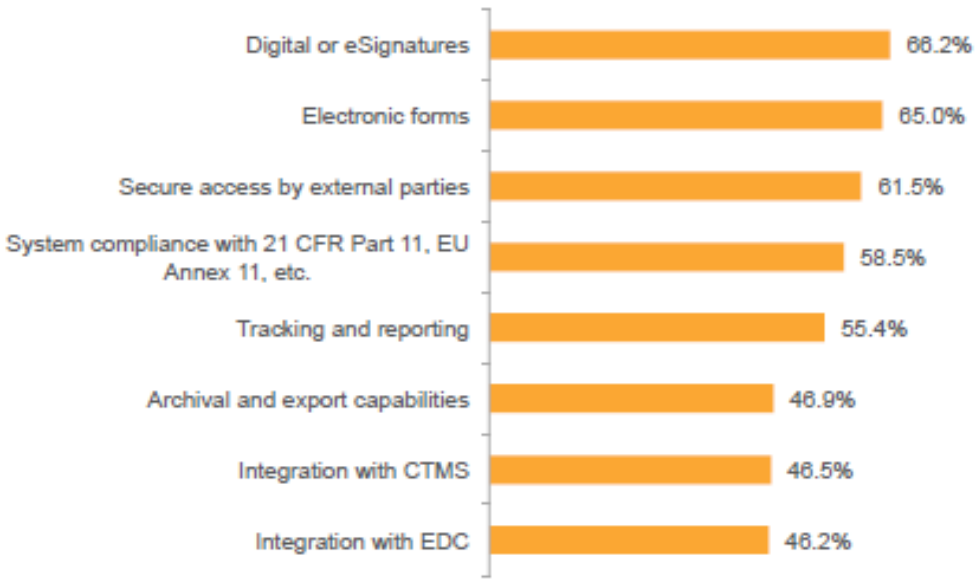
RETHINK PROCESS

Rethink processes to enable sponsors, CROs, and sites to create and contribute efficiently to the TMF -- without paper or email attachments

Create – Review - Approval – Collect - Submit

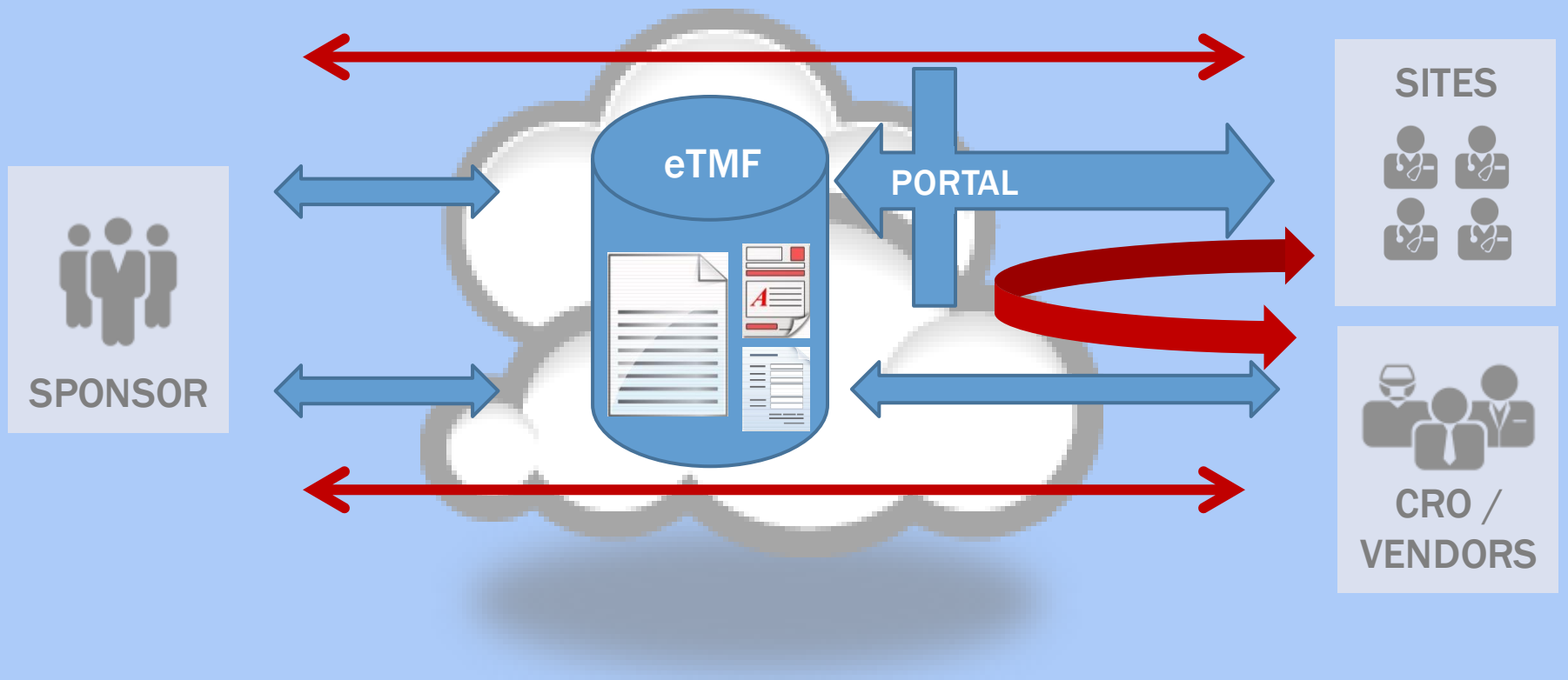
Distribute - Consume – Acknowledge - Report

TOP TECHNICAL BARRIERS TO GOING TO A PAPERLESS TMF



Source: Paperless TMF – An Industry Benchmark, 2014

HOW EASY CAN IT BE?
USING TECHNOLOGY TO ITS FULLEST



The technology is already available and will continue to advance

Rethink the Process

SO WHAT'S HOLDING US BACK?

OURSELVES!

QUICK & EASY TARGETS

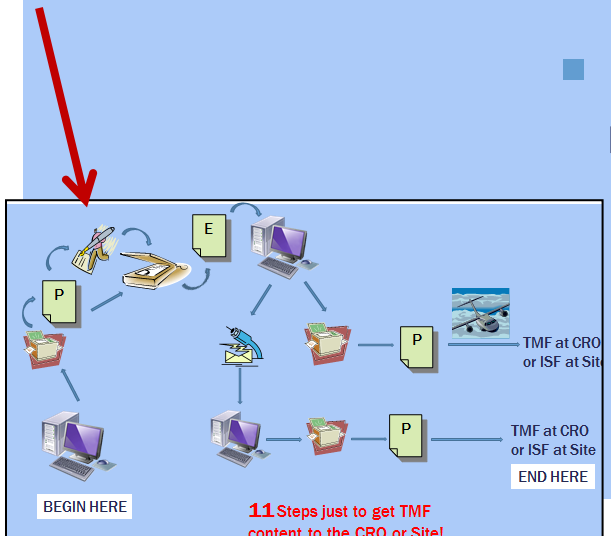
- Eliminate common, costly, and time-consuming pain points
  - Define the full list of TMF content.
    - Use TMF RM to align with industry – why be different?
  - Evaluate each individually.
    - Define purpose, usage/consumption
    - Define movement through lifecycle
    - Ask whether data entered from templates could replace any document
  - Use templates to create content directly within eTMF system.
    - Auto-populate content metadata during creation

BEGIN HERE

QUICK & EASY TARGET: SIGNATURES

- Reduce internal signature requirements
  - Only 7 required per the ICH Guidelines
  - Break ingrained habits. Is a signature required to establish accountability?
  - Audit trials are functionally equivalent – automatically capture name, date, time

- If signatures are absolutely necessary, replace wet-ink with electronic
  - Nearly all regulations accept e-signatures
  - Quicker document approval process



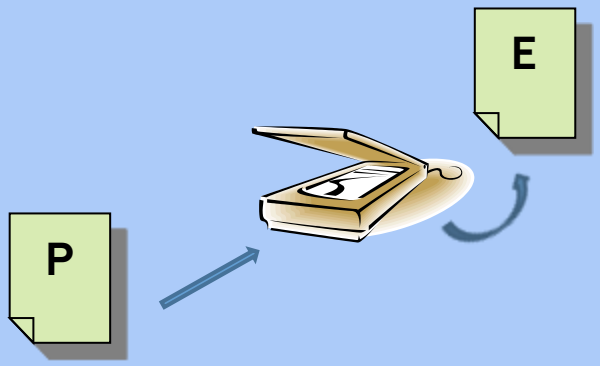
QUICK & EASY TARGET: SIGNATURES

TMF CONTENT – SIGNATURE REQUIRED?	TMF CONTENT – SIGNATURE REQUIRED?
Notification to Investigators of Safety Information	Protocol signature page (Sponsor and Investigator)
Regulatory Submission	Contract with Site
Monitoring Visit Report	Contract with Vendors
Dose Escalation Documentation	Case Report Forms
Trial Management Plan	Regulatory Required Form (ex. Form FDA 1572)
IRB/IEC Approval	Informed Consent

Required by ICH Guidelines

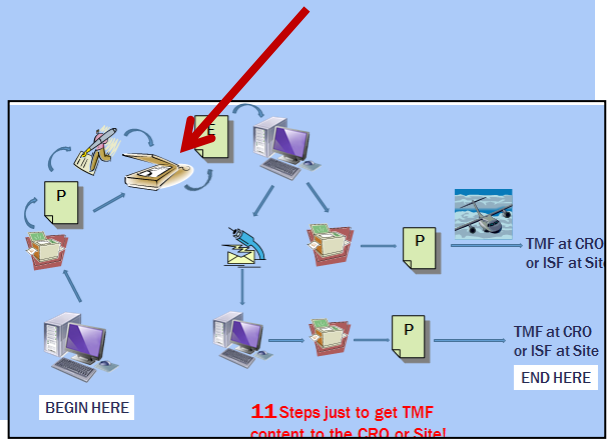
Which ones can be signed electronically? **ALL!**

QUICK & EASY TARGET: SCANNING



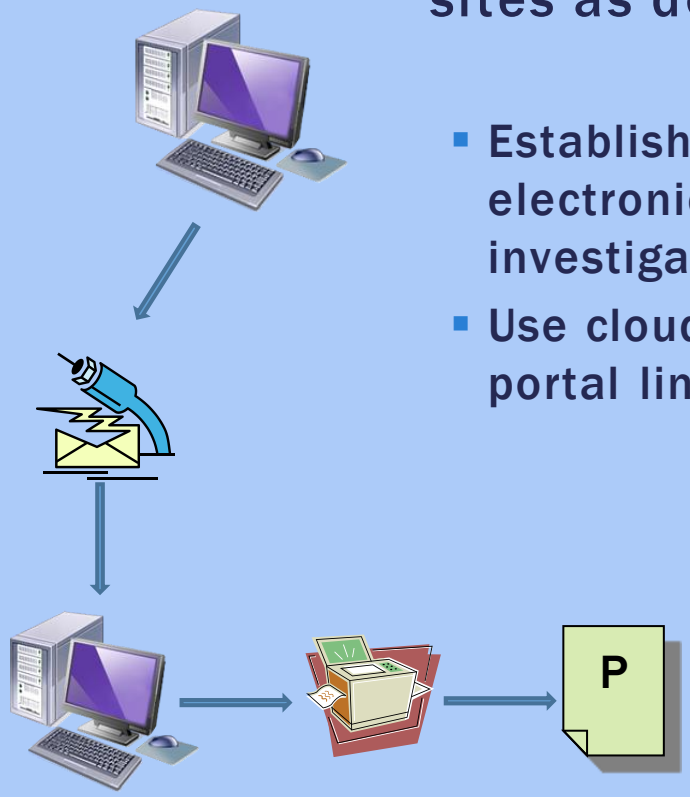
- Stop scanning electronically created documents – manage them electronically
  - Cost of inefficient resource utilization v. implementation of an 21CFRP11 compliant repository such as eTMF

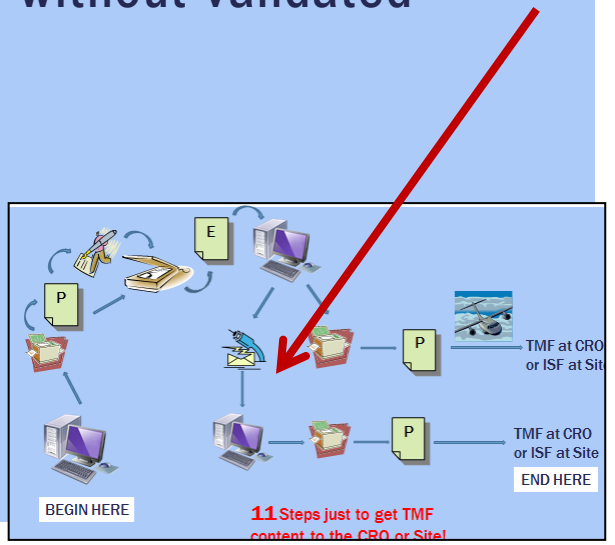
- If you have to scan, rethink the process…document by document
  - Does every document HAVE to be scanned?
  - Ex. How many people are actually using scanned site feasibility documentation again after collection??



QUICK & EASY TARGET: EMAIL

- Cut use of email and unofficial collaboration sites as document exchange vehicles.
  - Establish process to exchange TMF content and electronic signature with CROs, vendors, and investigative sites electronically
  - Use cloud-based eTMF with or without validated portal linked to eTMF





QUICK & EASY TARGET: SHIPPING

- Stop sending paper TMF content by air
  - $$$ to pay for transport
  - $$$ and time for preparers to prepare
  - $$$ and time for receivers to receive

- ROI easily calculated if transport costs are replaced with the "send" button within an eTMF system or portal
  - 50 sites X 10 shipments/year
    $20 per shipment= $10K in transport costs
  - Easily scalable

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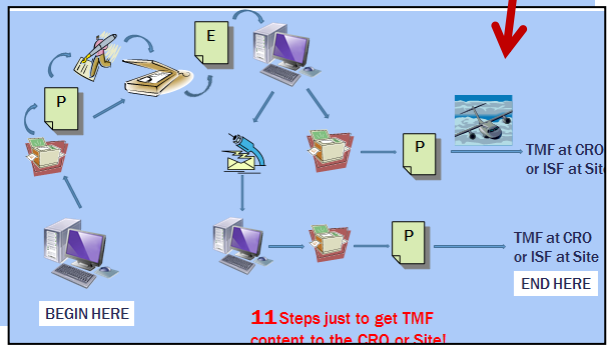
TMF at CRO
or ISF at Site



WHAT COULD ONE RETHOUGHT PROCESS LOOK LIKE?

- Rethink how a typically paper TMF document with a wet-ink signature component could be created and finalized?
  - The Clinical Trial Agreement - critical to timelines

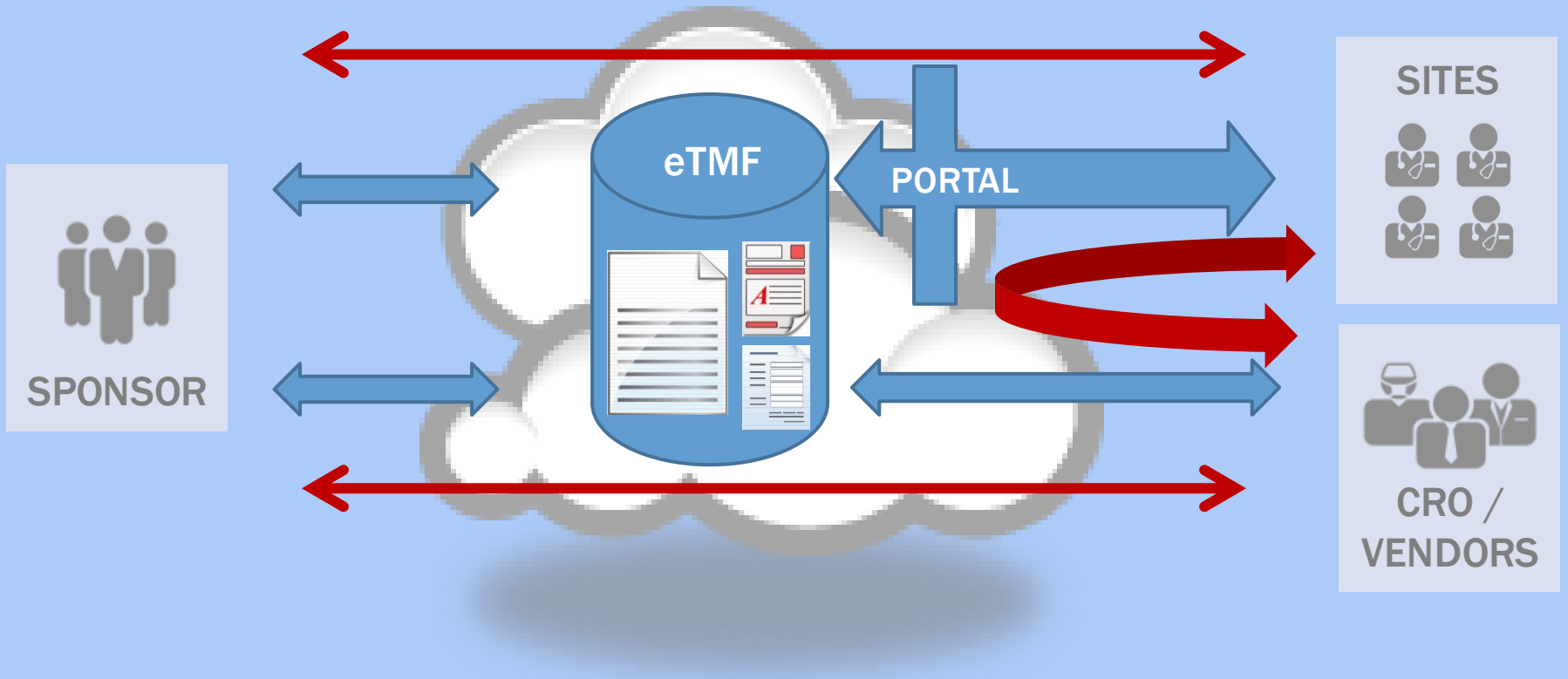
As-Is Process

Creation

Negotiation

Wet-ink Signature

HOW EASY CAN IT BE?
USING TECHNOLOGY TO ITS FULLEST

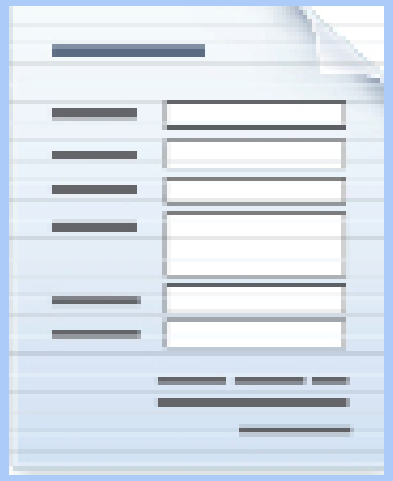


Rethinking processes in which sponsors, CROs, and investigators contribute directly to the TMF

WHAT COULD ANOTHER RETHOUGHT PROCESS LOOK LIKE?

- Rethink TMF content in terms of data sets
  - The creation, collection, distribution of TMF content (data) would focus on the information exchanged and not doc creation/collection
  - Assessing completeness of data instead of document presence

Consider this… investigators enter financial information in a database through an investigator portal.



extract

Financial status report.

Easier and significantly less time and $ resource intensive than collecting and tracking forms.

Replace a wet-ink signed form.

CRITICAL STEPS – OBSTACLES TO AVOID

1.

Company culture cannot be allowed to define the way you rethink your TMF management process. Help your company to break through their old ways of thinking to do some groundbreaking process work

CRITICAL STEPS – OBSTACLES TO AVOID

2.

Technology cannot provide the process.
Technology supports the process

CRITICAL STEPS – OBSTACLES TO AVOID

3.

Engage the consumers of the TMF content when you rethink your process– at the sponsor, the CRO, and the investigative site. What do they actually need?

Like the electronic FDF, consumers might only need data…and not a document.

IN SUMMARY

The technology to collect, create, manage, and exchange efficiently is here and evolving rapidly

We must now rethink the human TMF management processes to best leverage the technology

THANK YOU

- To Veeva for the opportunity they have given me to be here with you today
- To you for being here and being so engaged

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