Experience with eTMF and Site Archiving

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TransPerfect

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Agenda

- EDM and eTMF - where are we now?
- Investigative Site challenges
- Survey
- Moving ahead

The evolution from paper…

What is Wrong with this Picture?

Developmental Timeline of EDM

1994: Initial appearance as an electronic alternative to paper-based records

2003: Industry-wide approval via the FDA's Guidance for Providing Regulatory Submissions in Electronic Format - shift in life sciences to implement EDM to streamline clinical development.

2006: ICH validates web-based solutions as the best implementation platform for an electronic common technical document (eCTD) delivery system

2008 (US)/2009 (EU): eCTD is established as the mandatory method of electronic submissions within the US and the EU.

2007-Present: EDM solutions continually improve feature and functionality offerings in the life sciences industry. Other eClinical technology offerings also emerge (and hopefully evolve): eTMF, CTMS, cloud-based platforms, and other forms of online, collaborative workspaces.

Still in an evolving state and limited global adoption

Parallel Changes with eTMF

2003: Industry-wide approval via the FDA's Guidance for Providing Regulatory Submissions in Electronic Format, pointing to a definitive shift in life sciences to implement electronic document management to streamline clinical development.

2005: The Good Clinical Practice (GCP) Directive establishes that the trial master file (TMF) consists of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated" [2005/28/EC]

2009: The DIA launches a clinical trial master file reference model for use by the industry, and it included guidelines for the structure and content of an electronic version of the TMF.

2011-Present: Today's unnecessarily complicated environment with its multiple data entry programs, points, and portals is a step backwards. The eTMF aims now to move towards a cohesive platform for all study needs.

Yet, if we are running studies so efficiently, then why do most investigative sites still look like this?

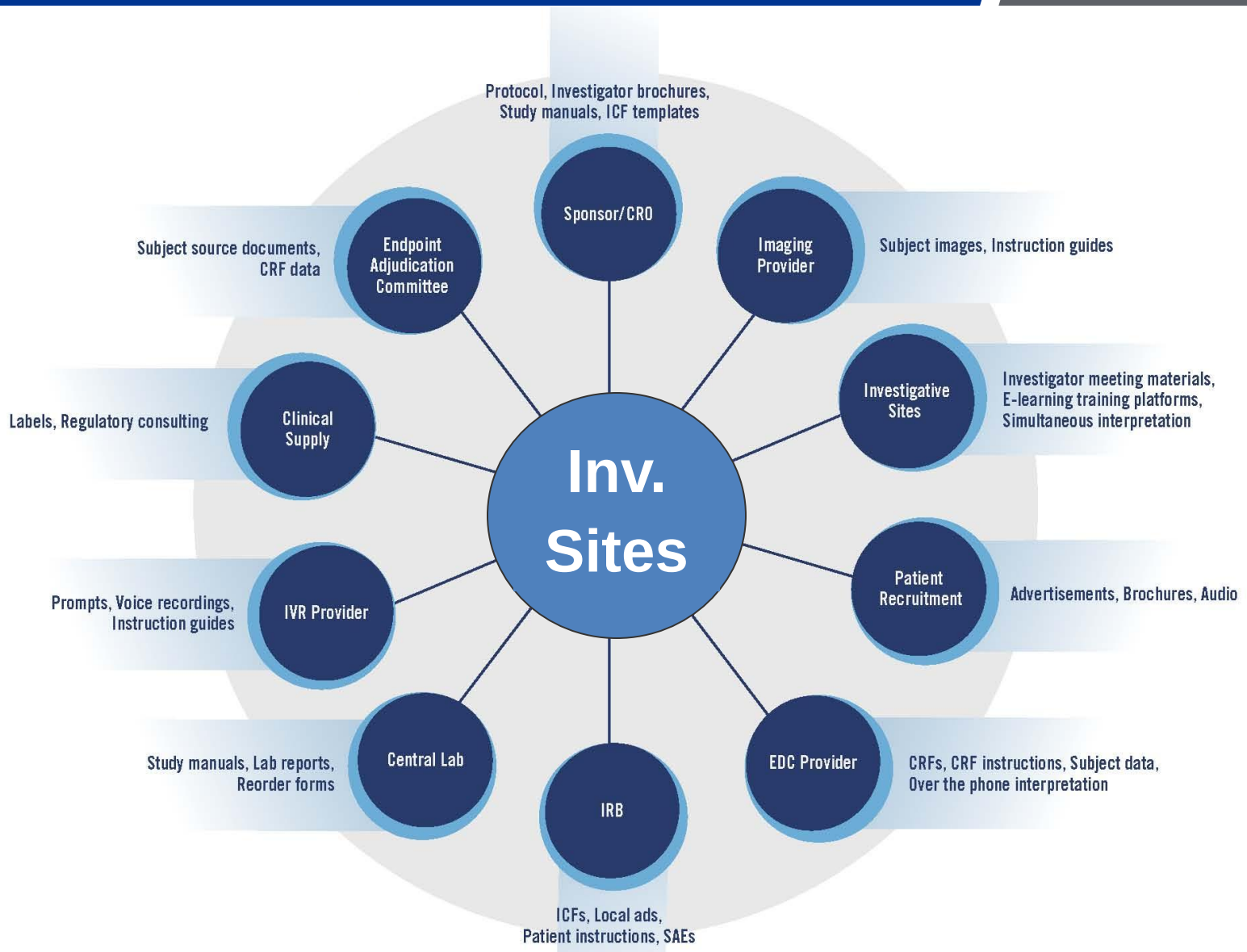
Investigative Site Files: Typical Study Site

Why Are We Still Here?

- Accepting the status quo. Doing what we've always done.
- Concerns about regulatory risk
- Poor job of addressing cost and time inefficiencies to senior management

A combination of all of the above are responsible for this. Cost inefficiencies are leading to staffing reductions and in some cases company closure

Several Interactions At Investigative Site



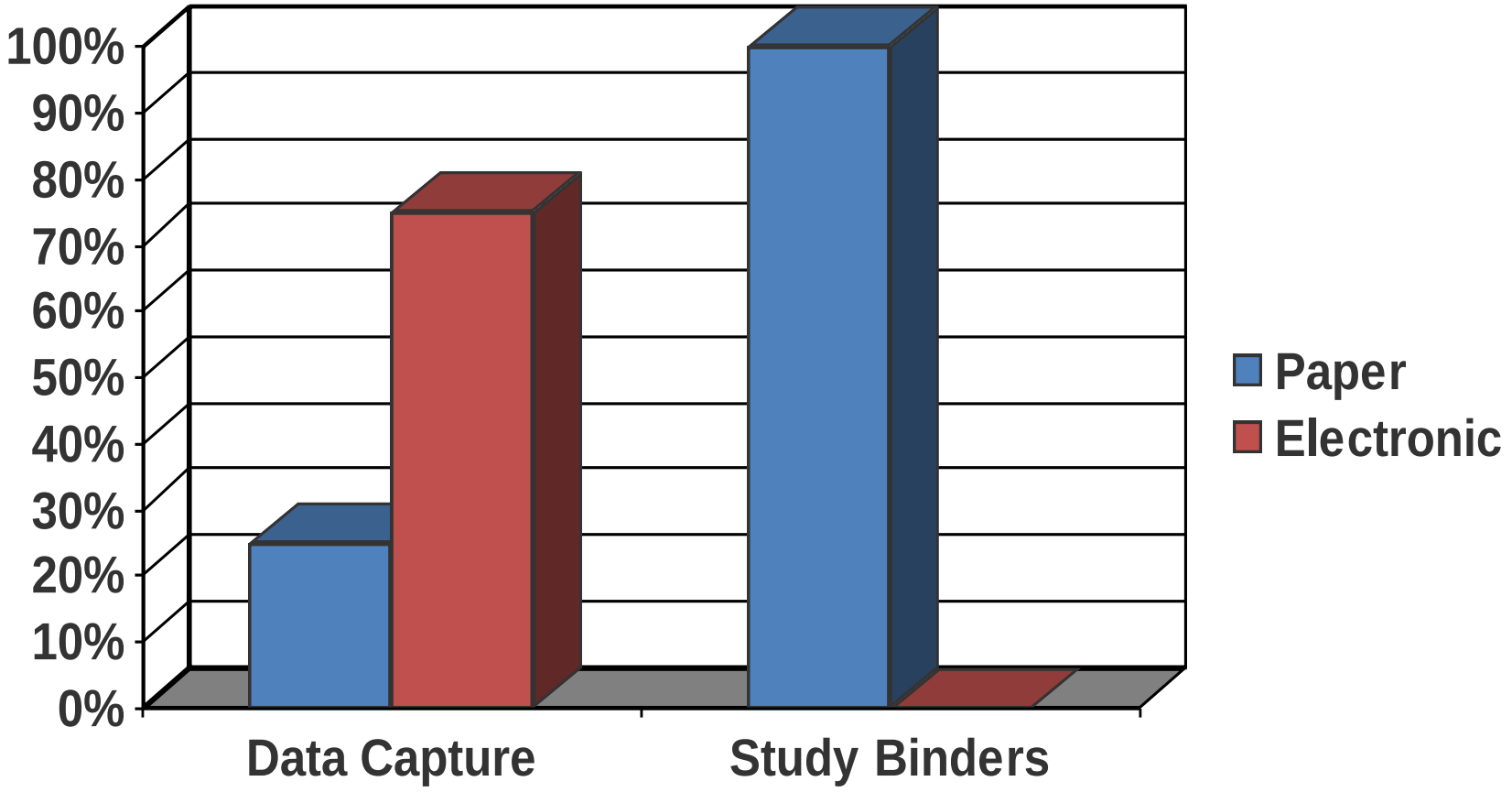
Investigator Site Survey

The lack of centralization is a legacy that originates from a tradition of paper-based systems for clinical trial development that affects sponsor, CRO, vendor partners and investigative sites alike.

Global site survey results: challenges in using paper vs. electronic tools

- Current studies observe a 75/25 split on EDC and paper
- “Greatest pain point with electronic document management: duplication creates needless labor, since the monitor still has to come to the site to verify”
- “We don’t want the paper yet sponsors and CROs *continue* to ship it to us"
- Online tools with passwords are considered most effective/secure method to send study documents yet results in inefficiencies:
  -- repetitive staff training
  -- accumulation of various portals, logins, user licenses

Technology at the Investigative Site



Based on survey of 121 investigative sites

“Portals” are Already in Use

- The majority of sites rely on electronic means for 75% or more of their data collection and processing.
- Sites use several “portals” within a given study: for IRBs, labs, sponsor/CRO, IVR, EDC providers, etc. However this generally does not apply to electronic Investigative Site Files, which primarily remain in paper.
- In the process of receiving and sending essential and regulatory documents, many of the respondents have moved away from mail and towards email and fax for their document delivery, and there is a trend towards online delivery and submission.

CRA Productivity @ Site Diminished

One reason why monitoring cannot fix everything…

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Lessons Learned: Site & CRA Perspective

Still an evolving process:

- Improve functionality of EDM platforms with the end-user in mind so the input of data and the storage of documents appears integrated and holistic.

- Central access to Investigative Site Files via portals

  -- Eliminates need for most paper files and can streamline the archive and audit process

  -- Reduces on site time for CRA visits and reconciliation at study close-out

- EDC adoption at the sites is high but still nearly 100% reliance on paper study binders

  -- Adds unnecessary costs and inefficiencies in clinical trial conduct and archival

- No clear standard on archival at the study site for retention period - paper/electronic

Tools for Progress

- Simplicity is zen

  -- Reduce the number of vendor options (and all the mess that comes along with them, i.e. multiple portals, logins and licenses) in favor of one, streamlined product.

- Continued industry education needed

  -- Sponsors, CROs and regulatory authorities to recognize importance of DIA Reference Model and benefits of including investigative sites

- Accessibility drives efficiency

  -- Going paperless allows sites to more easily archive, retain and retrieve investigative site files

We still have a ways to go to make our studies fully electronic and streamline study management, particularly at investigative sites

Thank You!