Freeing up Investigators' Time to Engage with Patients

Michael Smyth

TransPerfect

DIA®
www.diahome.org

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.

Agenda

- The State of Affairs
- Investigative Site Challenges
- Investigative Site Surveys
- Potential Solutions
- Evolution in the Life Sciences Industry

Where Society is Now: iPhone 5

Speed, user friendly interface

- PassPort
- It's all in the "Cloud"
- Ability to download apps – restaurants near study sites
- Siri gives you directions, remembers where you are, your appointments, etc.

Where Our Industry is Now: Regulatory Paper Binders at a Typical Investigative Site

Evolution of eClinical Technologies

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: eTMF, CTMS, cloud-based platforms, and other forms of online, collaborative workspaces.

The life sciences industry is in pursuit of developing products faster and more cost effectively while retaining high quality data with a watchful eye on patient safety…

Several Interactions at Investigative Site

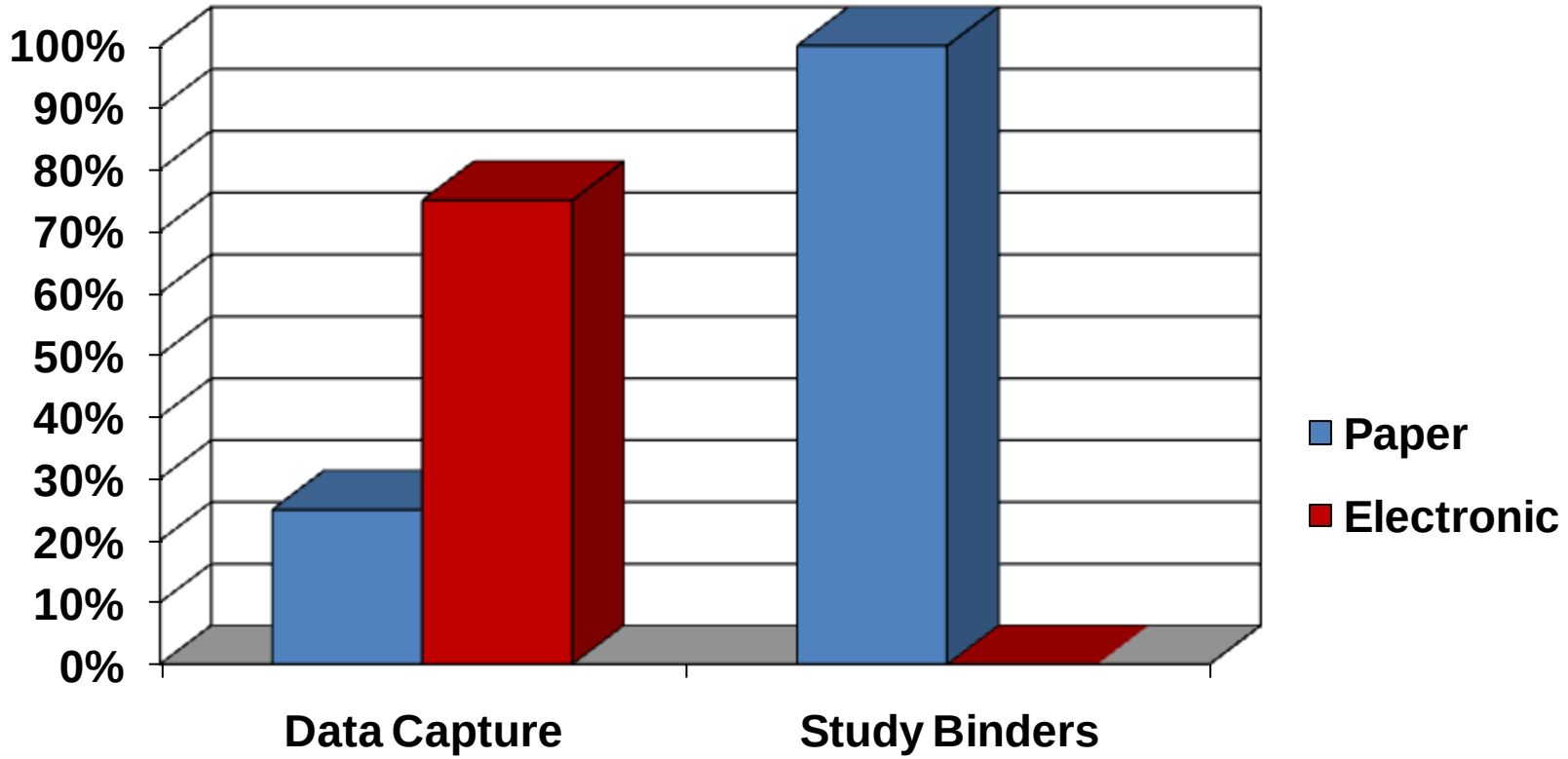
Investigator Site Survey

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

Productivity at Sites Diminished

Global Challenges: Opportunities for Improvement

Dissatisfaction with a Clinical Trial Activity

Motives for Participation	US Sites	Asia Pacific Sites
Tracking clinical trial costs against the budget	30%	31%
Accurately forecasting study budget	27%	35%
Timely collection of billables against milestones	26%	20%
SAE reporting	26%	10%
SAE follow-up	5%	10%
Patient recruitment	22%	21%
Patient retention	4%	10%
Study monitor time at sites	12%	18%
Tracking clinical trial supplies	9%	16%
Study closeout	8%	10%

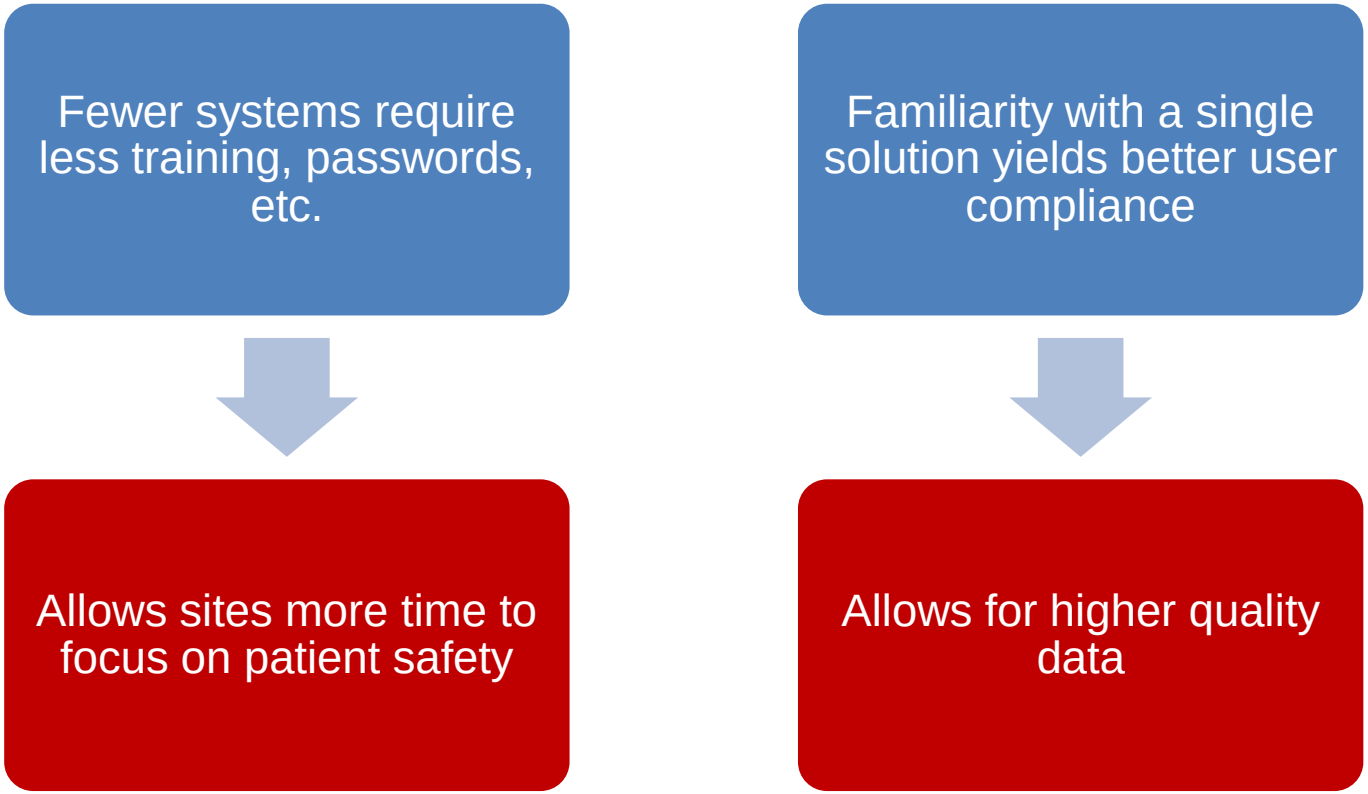
Source: Harold E. Glass and Jesse M. Glass

Distractions for Site Personnel

1. Too many vendors (and tasks/training involved with each new system)
2. Inefficient SAE collection and reporting methods
3. Too much paper
4. Excessive onsite monitoring time
5. Cumbersome study archival and retrieval for record retention

1. Too Many Vendors

Streamline site activities into a single solution



2. Inefficient SAE Collection, Reporting Methods

- Eliminate / reduce training sites go through as SAEs are standard across studies
- Many still use fax forms for completion of SAE reports. Technology can allow more rapid completion, submission and near-real time retrieval of any SAE reports
- Online redaction of subject identifying data can be done to meet HIPAA regulations
- Global – any documentation needing to be translated can be done in real time in order to meet regulatory reporting requirements
- Easy traceability to confirm investigators review Safety Notifications and submitted to IRBs/ECs
- One phone number for the study, including SAEs streamlines the contacts site personnel need to call for SAE reporting and follow up

3. Too Much Paper at the Site

"Portals" already exist: apply this technology to other site administrative activities.

- Sites use several "portals" within a given study: IRBs, labs, sponsor/CRO, IVR, EDC providers, etc.
- The majority of sites rely on electronic means for 75% or more of their data collection and processing.
- Email/fax used for sending/receiving essential and regulatory documents and there is a trend towards online delivery and submission.
- Portal usage can reduce reliance on paper

4. Excessive Onsite Monitoring Time

- Remote access for clinical study documents means less monitoring time required at the site

- Benefits include:
  - Sites spend less time hosting CRAs, more time focusing on patients
  - All study stakeholders (sponsor, CRO, site) have access to same files
    - Better version control
    - Multiple users can simultaneously view a document/file

5. Cumbersome Study Records Archival/Retrieval

- Efficient use of technology can improve the process of study closeout visit
- Eliminating the use of paper Regulatory Binders would reduce misplacing documents and pages
- Site focused portal would allow aggregation of all ISF files into one location
- Audit preparation and retrieval of documents would be markedly improved
- All documentation in one location across sponsors would make it easier for investigative site personnel and regulatory authorities (when needed)

Global Trial Direction: eClinical and Clinical Initiatives

Sponsor selects single functional technology provider to supply across several functional areas:

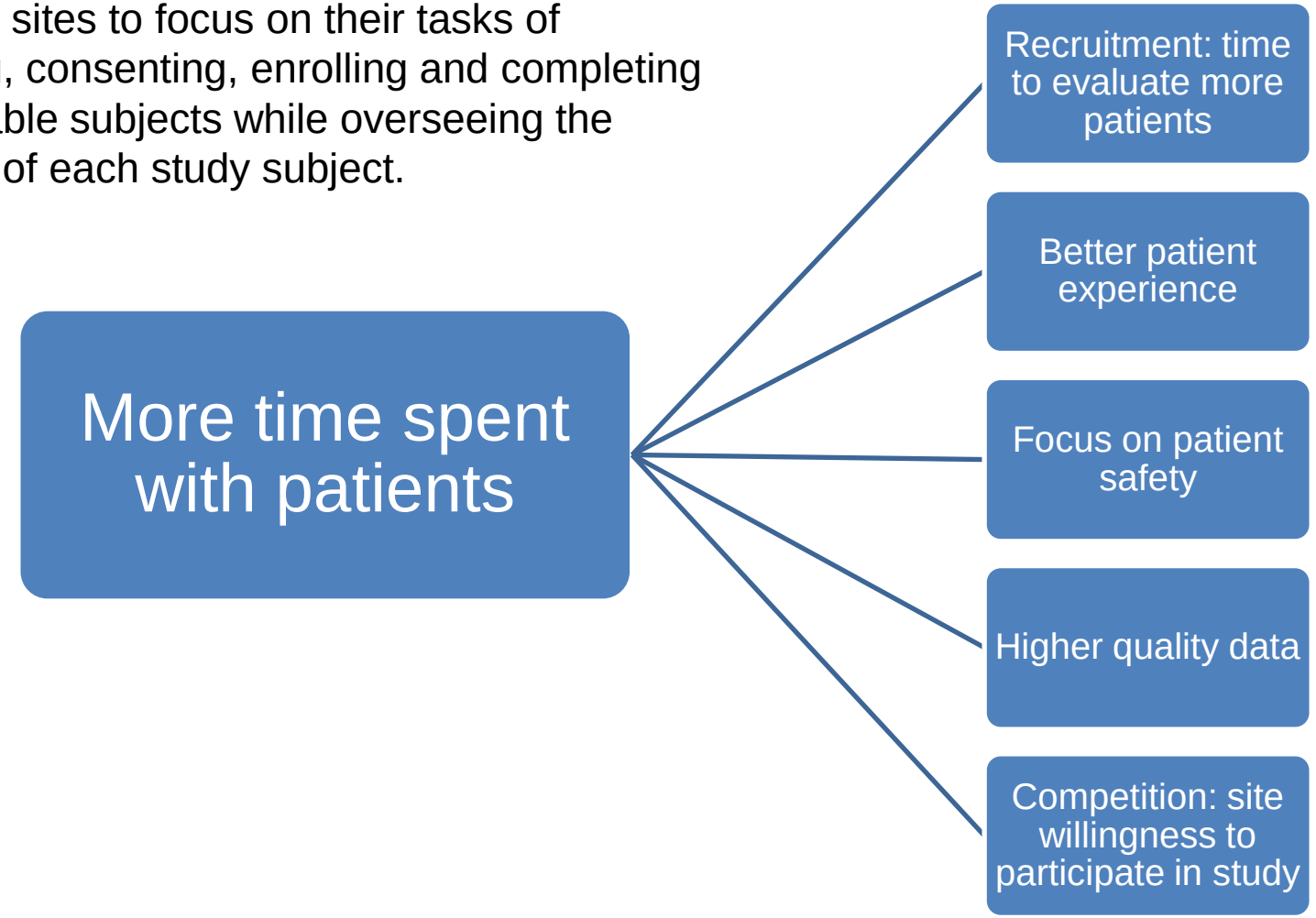
- ↓ number of systems ↑ user adoption
- Consume fewer resources
- Central access to investigative site files via portals
  - Eliminates need for most paper files
  - Streamline the archive and audit process
  - Real-time access
- Integrated solutions benefit CROs and Sponsors of all sizes – large/global, midsize, small/virtual

eClinical initiatives localized

- Need to find, develop and train new sites, especially in emerging markets
  - Train to GCP standards
  - Too much focus on same sites across sponsors
- Wider use of mobile devices, smartphones, iPads… think iPhone 5

Global Trial Direction

Allows sites to focus on their tasks of finding, consenting, enrolling and completing evaluable subjects while overseeing the safety of each study subject.



Technology within Our Industry's Reach

"Siri, for study 1234, what procedures do I need to do for Visit 1?"

"Siri, what subject visits do I have today?"

"Siri, what monitoring visits are scheduled this week?"

"Siri, can you let me know the best flights for the investigator meeting I have in Oct?"

Thank You!