Regulatory and Data Trends

July 27, 2021

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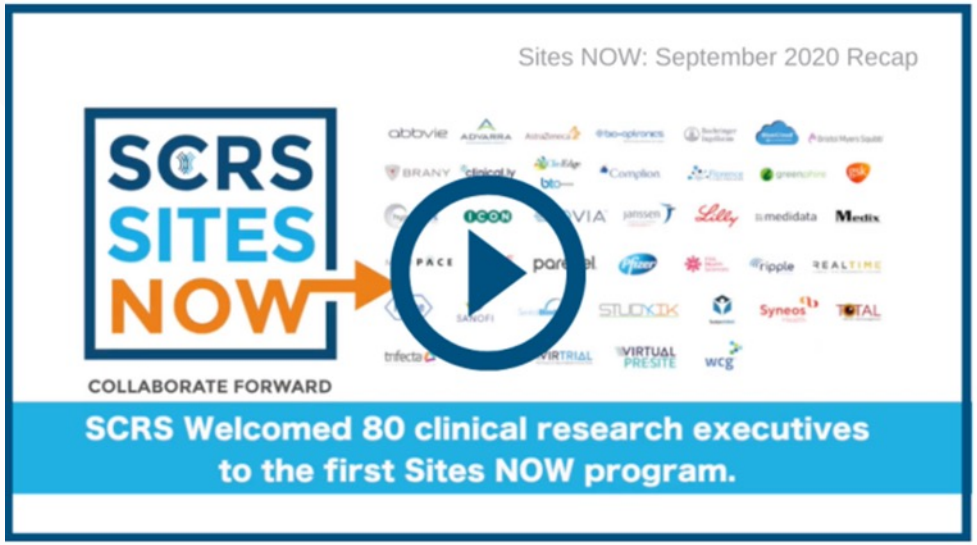

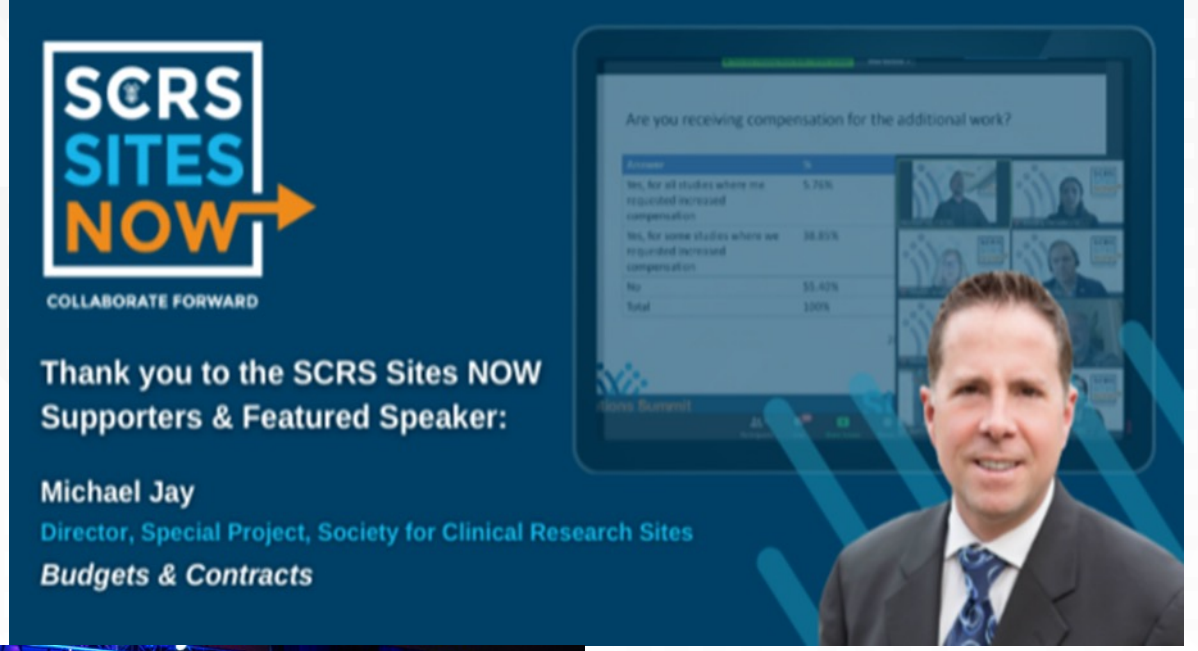

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Site Solutions Summit

PARTNERING FOR SUCCESS

October 1 – 3, 2021
Hollywood, FL

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Today's Presenters

James Riddle, MCSE, CIP, CPIA, CRQM

VP of Research Services & Strategic Consulting

Henry Kravchenko

CEO, Clinical.ly

Denise Snyder, MS, RD, LDN

Associate Dean for Clinical Research, Duke University School of Medicine

Discussion Topics

- Decentralized Clinical Trials
- New International (and some US) Privacy Regulations
- Computer Software Validation

Decentralized Clinical Trials Expand Access to Clinical Research

Benefits of Using Mobile Technology in Clinical Trials

PATIENT CENTRICITY

- High-quality, patient-centric endpoints
- Endpoints that matter to patients
- Reduced participation burden
- Fewer barriers to participation
- Better, more complete info

EFFICACY

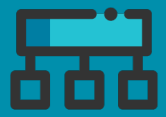
- Improved predictability rates
- Increase in number of potentially successful treatments

EFFICIENCY

- Generation of data needed by payers to make coverage determinations
- Prevention of delays in coverage, payment, and use decisions
- Patient access to medicines

Informed Consent

- **What participants need to know about mobile technologies**
  - Description of technologies
  - Data privacy and confidentiality
  - Data access and commercialization
  - Data sharing with participants and providers
  - Safety monitoring (and whether real time)
  - Technical support access



A tiered consent approach may help convey information clearly.

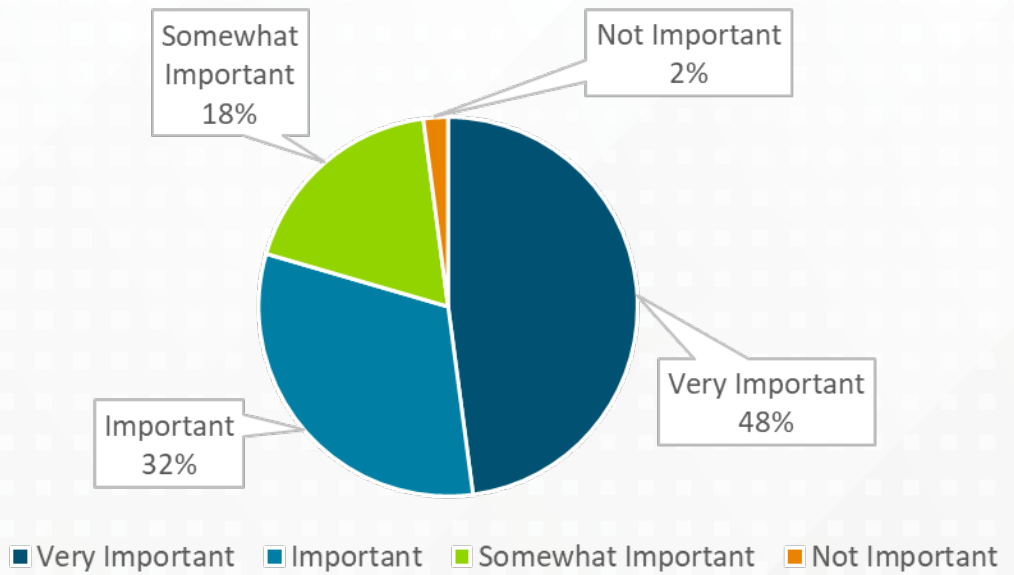
Data Privacy and Confidentiality

- Mobile technologies have the potential to generate more protected health data than traditional clinical trial data collection methods
- Managing data collected from mobile technologies necessitates IT specialists and other technology vendors outside of the research team have access to patient's protected health data
- Beyond trial participants, mobile devices may capture the images or voices of individuals who have not consented to participate in the trial (bystander data)

Data Privacy and Confidentiality

- **Has a plan been developed for how, when, and what types** of health-related information will be returned to participants?
- **Can real-time access to individual results be provided** in a way that maintains study integrity and participant safety?
- Have **other ways to return value** to participants been identified?

Patient Survey:
"How important or not important is it that you are shown the information collected about you by the mobile technology?"



International Privacy Regulations Impact on Research

Where Does GDPR Apply?

http://www.metaphorix.co.uk/gdpr-construction/

Application to US Research Organizations

- GDPR applies to the processing of personal data of data subjects by a controller or processor not established in the EEA, when processing activities are related to:
  - Offering of goods or services—irrespective of whether payment of the data subject is required—to such data subjects in the EEA, or
  - Monitoring of data subjects' behavior as far as their behavior takes place within the EEA.

Data Subject Rights

Access

Restriction

Rectification

Erasure

Portability

Objection

Other International Regulations Impacting Research – USA!!

California Consumer Privacy Act of 2018,
Cal. Civ. Code §§ 1798.100 et seq. (CCPA)
Effective January 1, 2020
Enforcement begins July 1, 2020

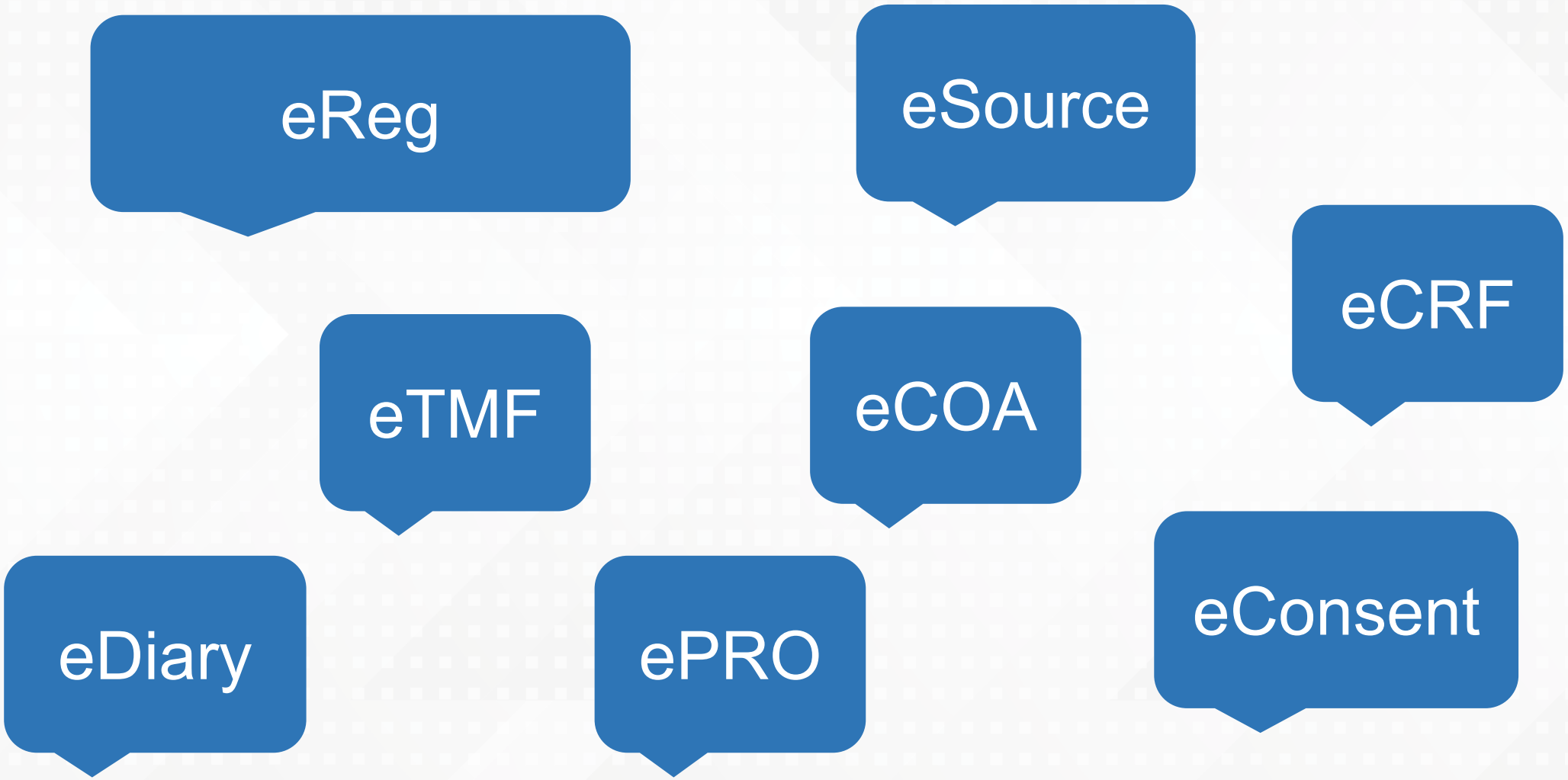
- Applicable to **all** organizations of certain characteristics
  - For profit businesses that earn $25,000,000 or more a year in revenue, or
  - Businesses that annually buy, receive, sell or share personal information of 50,000 or more consumers, households or devices for commercial purposes, or
  - Business that derive 50% or more of its annual revenue from selling consumer personal information

- Similar rules and privacy protection concepts as GDPR
- Failure to comply could bring fines of up to $7500 per user per "piece" of data
- Similar to GDPR – Protects any California resident and is applicable ex-CA to any business conducting activity in California regardless of where company is headquartered

https://www.wired.com/story/ccpa-guide-california-privacy-law-takes-effect

Computer Software Validation & FDA 21 CFR 11 Compliance

More “eEverything” in Research

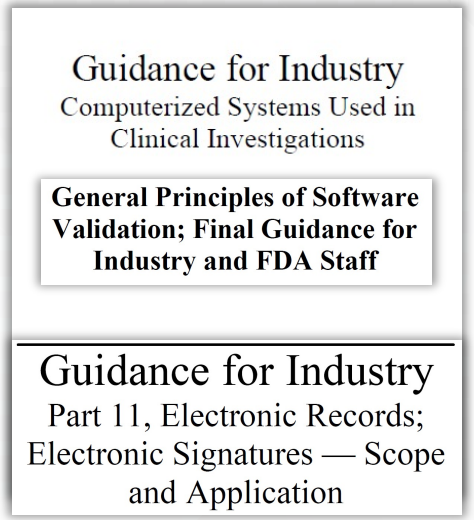


Applicability at the Site Level?

21 CFR Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in the FDA regulations.

PART 11 COMPLIANCE requires both procedure controls (notification, training, SOPs, administration) and administrative controls to be put in place in addition to the technical controls that exist in the system.

- Each electronic signature shall be **unique to one individual** and shall not be reused by, or reassigned to, anyone else
- The organization must **verify the identity** of an individual before an electronic signature may be utilized
- **Certification must be provided to FDA** that the electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature
- **Systems must be validated**
- **Etc.!**



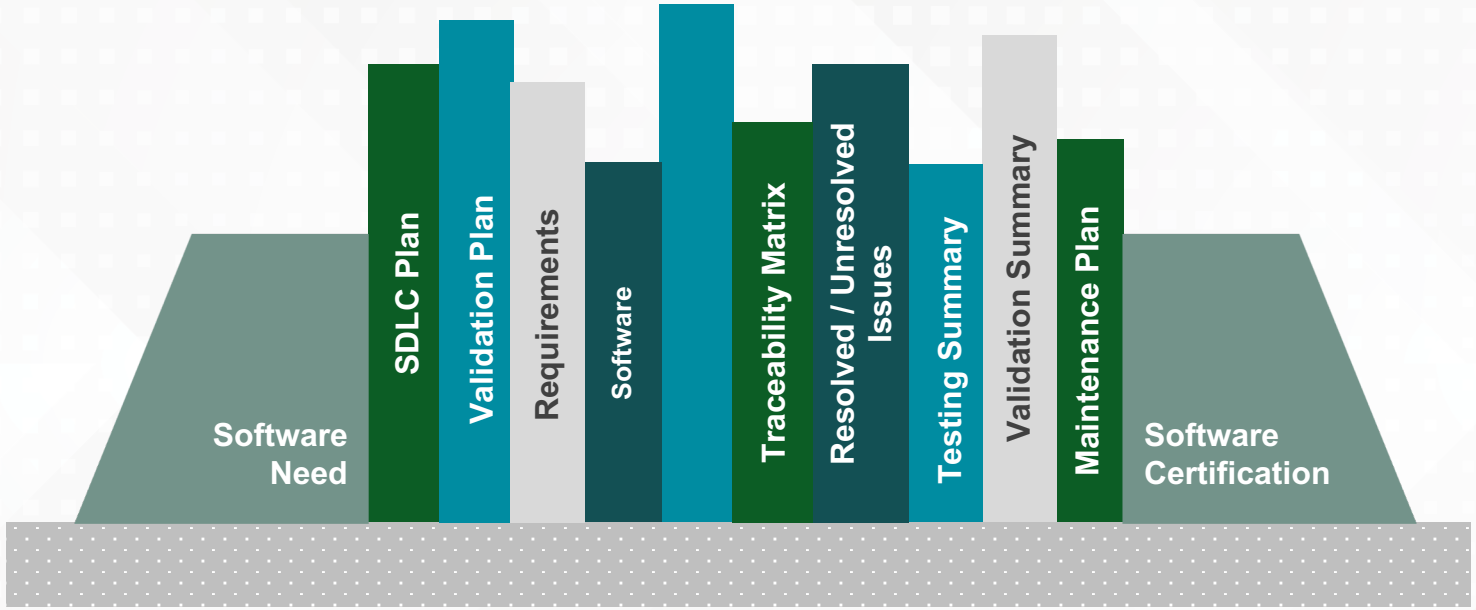
ICH and Annex 11 have similar broad applicability

What is Validation?

FDA: Validation means confirmation by **examination** and provision of **objective evidence** that the particular requirements for a specific intended use can be **consistently** fulfilled. (21 CFR 820.3)

GCP: Validation of computerized systems is a **process** of establishing and **documenting** that the specified requirements of a computerized system can be **consistently** fulfilled from design until decommissioning of the system or transition to a new system. (ICH-GCP E6 (R2) 1.65).

What is Validation?



Validation Produces an Evidence Set

Evidence that will satisfy FDA and EMA the records in the computer system meet the ALCOA standard and can be accepted as equivalent to paper records

What Should Sites Have?

- Implement a basic set of Part 11 related SOPs
  - Policy on Part 11 Compliance and Computer System Validation
  - SOP on Conducting System Inventories
  - SOP on Validation Planning, Testing, and Summary Documentation for Covered Systems
  - SOP on Conducting Vendor Assessments
  - SOP on Training and Quality Assurance (*hint - can be part of broader SOPs)*
  - Business Continuity Plan (*hint – you need this for HIPAA anyway)*
- Records of all validation plans, summaries, and testing results, deployment histories, and training records for each system with essential records. Stored in a binder; ready to hand to the FDA inspector.

I. Data is the lifeblood of research. Sites that have agency over their data tend to have more efficient operations than their peers who exhibit less control.

Well-defined & automated data maintenance procedures improve multiple KPIs and mitigate regulatory and operational risk.

II. Sites approach to 21 CFR Part 11 compliance can be categorized in two broad approaches.

Utilizing validation to learn the system rather than fulfill a regulatory obligation is significantly more efficient & leads to faster adoption.

III. Data maintenance is resource intensive. It's common to underestimate the burden of maintaining quality data.

As study volume grows, challenges to data upkeep grow exponentially, thereby increasing regulatory risk and operational burden.