

Regulatory and Data Trends

July 27, 2021



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Sites NOW @ Work!

Sites NOW: September 2020 Recap




COLLABORATE FORWARD

SCRS Welcomed 80 clinical research executives to the first Sites NOW program.



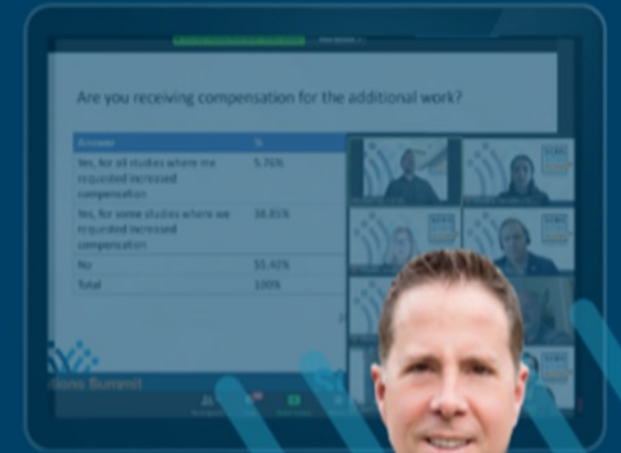
COLLABORATE FORWARD

Thank you to the SCRS Sites NOW Supporters & Featured Speaker:

Michael Jay

Director, Special Project, Society for Clinical Research Sites

Budgets & Contracts



Sites NOW Highlights Issues Impacting Site Operations in September Launch

"Our main goal here is collaboration towards information." With these impactful words, the first-ever SCRS Sites NOW session was launched. In a dynamic session that attracted more than 80 clinical executives, unreleased data and industry perspectives were shared freely in a virtual environment that emulated the face-to-face energy of past Site Solutions Summits.

Sites NOW is a virtual discussion and content project created in response to the COVID-19 pandemic and focused on the changing landscape clinical research sites and industry partners face in 2020.

Over the next 12 months, Sites NOW will provide a forum for content-sharing, open discussion, and networking among industry stakeholders, to include sites, sponsors, CROs, and solution providers. At each session, subject matter experts provide a 30-minute presentation focused on providing meaningful metrics and invaluable insight into one central theme impacting research today.

Following the presentation, attendees participate in team breakout sessions to discuss industry standards, best practices, and pressing questions related to the presentation with the overall objective of providing information for site success.

While advancing site sustainability is the underlying mission of SCRS, Sites NOW delivers a platform to meet, share, and explore solutions that advance thoughts, best practices, and – most importantly – relationships.



The initial session tracked different industry perspectives on one central theme: why sites matter. Industry leader David Vulcano, vice president of clinical research at HCA Healthcare, kicked off the meeting by presenting new data from a recent SCRS Site Survey to convey the rich and varied perspectives on why sites matter in 2020. Mr. Vulcano provided a comprehensive overview of the evolution of the site and how its function has changed congruently with clinical trial format.

WHO OWNS A STUDY?

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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

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Discussion Topics

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

Decentralized Clinical Trials Expand Access to Clinical Research

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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

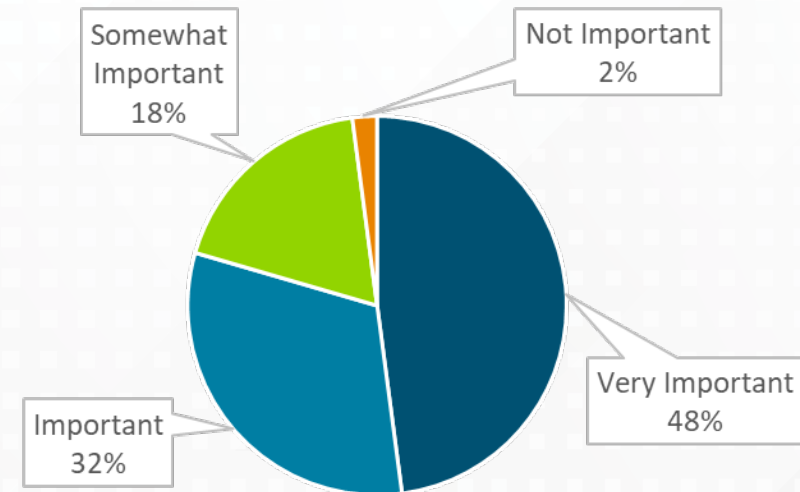
- Mobile technologies have the potential to generate more protected health data than traditional clinical trial data collection methods
- Managing data collected from mobile technologies necessitates IT specialists and other technology vendors outside of the research team have access to patient's protected 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?”



■ Very Important ■ Important ■ Somewhat Important ■ Not Important

International Privacy Regulations Impact on Research

Where Does GDPR Apply?



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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>

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Computer Software Validation & FDA 21 CFR 11 Compliance

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More “eEverything” in Research

eReg

eSource

eCRF

eTMF

eCOA

eConsent

eDiary

ePRO

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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.!**

Guidance for Industry
Computerized Systems Used in
Clinical Investigations

**General Principles of Software
Validation; Final Guidance for
Industry and FDA Staff**

Guidance for Industry
Part 11, Electronic Records;
Electronic Signatures — Scope
and Application

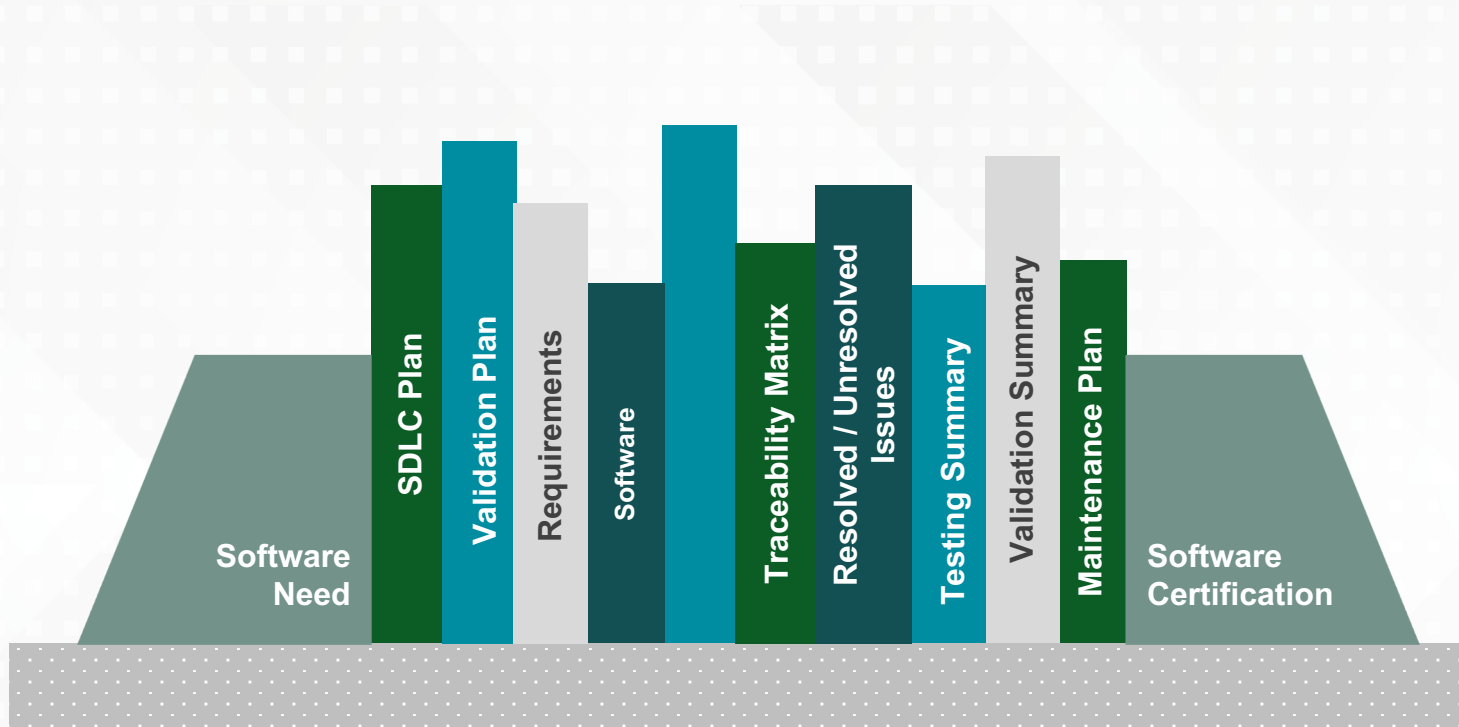
**ICH and Annex 11
have similar broad
applicability**

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.

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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.