e-book

Demystifying FDA Guidance on eSource Data in Clinical Trials

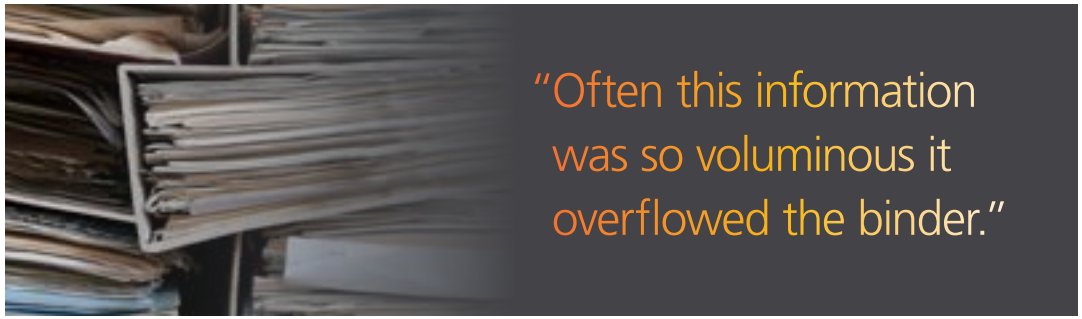
ENTER

OPTUM®

Utilizing eSource data in clinical trials

In 2013, the FDA finalized guidance around capturing source data in electronic form to be very clear on how these records would be accepted as the "source of truth" in clinical trials.

Prior to the wholesale acceptance of electronic health records (EHR), in part as a result of the Affordable Care Act in March 2010, most health care systems and nearly all private physician offices used paper documents as the source of record.

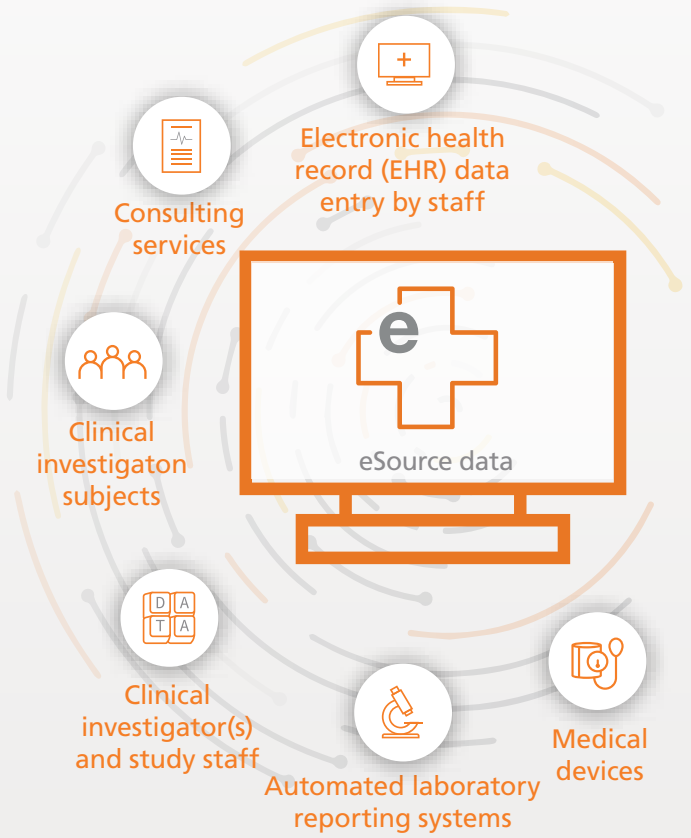


"Often this information was so voluminous it overflowed the binder."

The paper document was an original record that was passed from person to person to record information, including office visit records, in-hospital nursing notes, records of phone conversations, therapist notes, physician progress notes, paper printouts of lab results and reports from procedures, such as ECG reports, chest x-rays, MRIs, etc. Often this information was so voluminous it overflowed the binder.

An eSource is an electronic source record for study data, rather than a paper source, and is defined as data from an authorized data originator.

Click the circles below to see examples of authorized data sources



In the paper source, medical record changes were managed by a single line cross-through with updated information associated, and an initial and date of the author recording when and why the record was changed. No obstruction of the original data using "white-out" was permitted.

The paper source was the one and only record, until it eventually found its way onto microfiche. In the event of a natural disaster this "source of truth" could be greatly impacted, such as when Hurricane Katrina resulted in the loss of an untold number of paper medical records. For more information about Katrina and the need for EHR, click here.

With the move to EHRs, the FDA no longer had a paper source. It needed to provide guidance on the characteristics of the electronic records that would be acceptable as sources of data for clinical investigations.

> "In an effort to streamline and modernize clinical investigations, this guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity and traceability of data from electronic source to electronic regulatory submission."
>
> *— Electronic Source Data in Clinical Investigations, 2013*

This guidance addresses source data in clinical investigations used to fill the predefined fields in either a paper or an electronic case report form (eCRF), or as part of an electronic data capture (EDC) system, according to the protocol.

Specifically, the guidance discussed:

How to define authorized source data originators

Creating data element identifiers to facilitate examination of audit trail

Capturing source data in the eCRF using either manual or electronic methods

Understanding the responsibilities of clinical investigator(s) with respect to reviewing and retaining electronic data

Using and describing computerized systems in clinical investigations

In planning clinical trials, sponsors should include information (for example, in the protocol, data management plan or investigational plan) about:

- The intended use of computerized systems during a clinical investigation
- A description of the security measures employed to protect the data
- A description or diagram of the electronic data flow

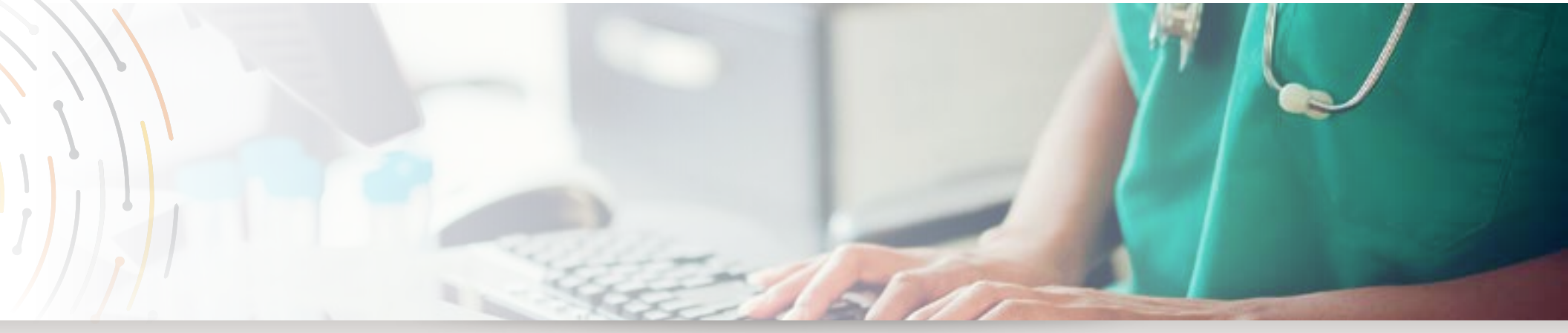
Click for more information about the actual guidance document.

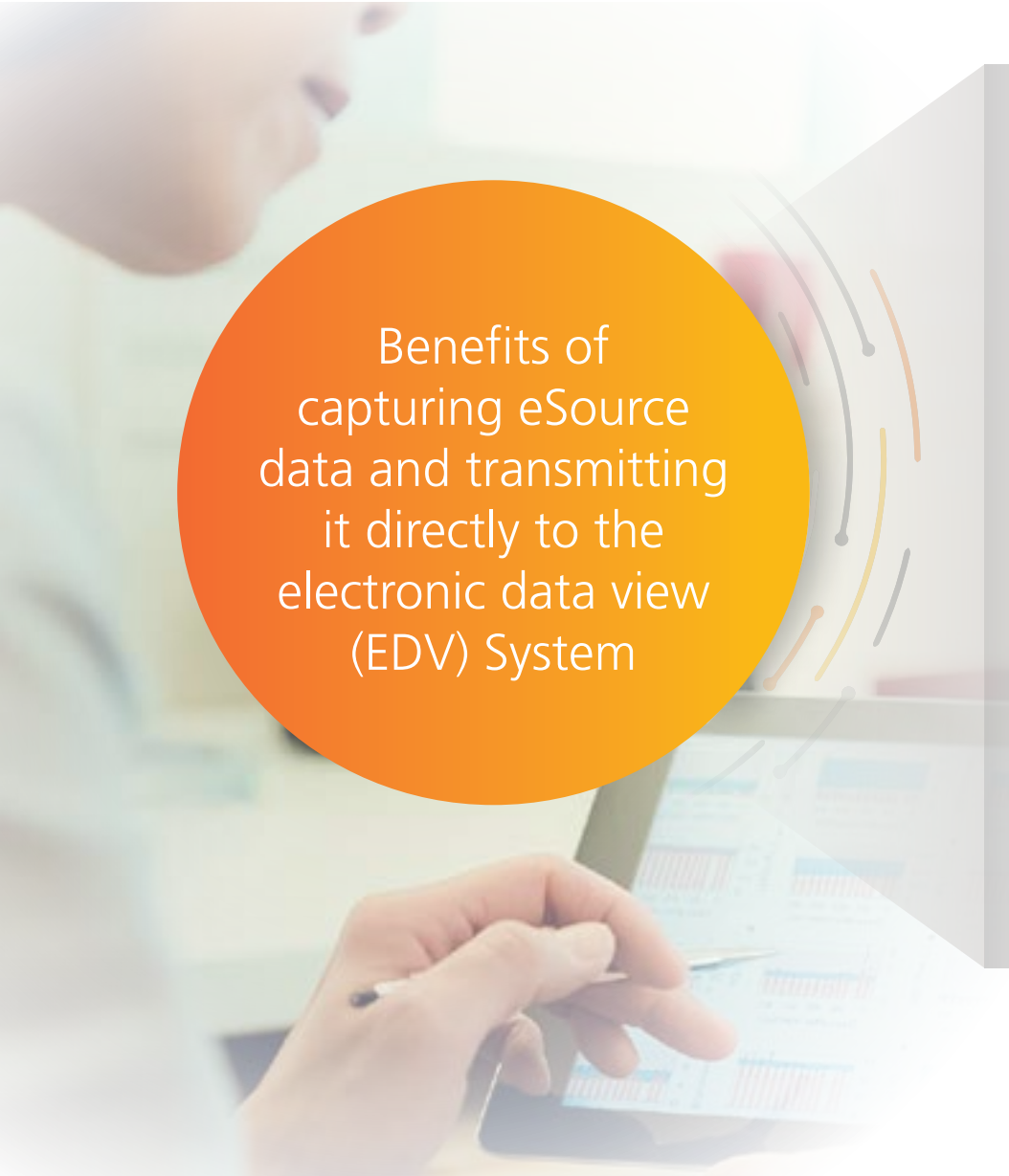
Understanding eSource requirements

ESOURCE REQUIREMENT	ACTIONS FOR COMPLIANCE
Source data should be **A**ttributable, **L**egible, **C**ontemporaneous, **O**riginal and **A**ccurate **(ALCOA).**	Must meet the regulatory requirements for recordkeeping. Data must continue to be available for audits and inspection years after the trial is completed.
When a system populates a field in the eCRF, a data element identifier should be created that identifies the system, device or instrument as the originator of the data element.	A list of all data originators (i.e., persons, systems, devices, and instruments) should be developed and maintained by the sponsor and made available at each clinical site.
EHRs can use intervening processes (for example, algorithms to select appropriate data elements).	The EHR is the source, and data for the subjects in a study need to be available to review in the EHR during an FDA inspection.

Table continues on next page

ESOURCE REQUIREMENT	ACTIONS FOR COMPLIANCE
When data that is entered in the eCRF changes, a field should be available for data originators to describe the reason for the change (for example, transcription error).	Automatic transmissions between EHR and ECD should have traceability and controls via the audit trail to reflect the reason for the change, and the audit trail must be updated.
Prompts are recommended to alert the data originator of missing data, inconsistencies, inadmissible values (eg, date out of range), and to request additional data where appropriate (for example, by prompting a clinical investigator to complete an adverse event report form triggered by a critical laboratory result).	Prompts in the EDC system should alert the data originator of issues and if the data is correct as recorded, the clinical investigator(s) should have the ability to enter comments about issues associated with the data for example when an out of range laboratory test is correct in the EMR).
To comply with the requirement to maintain accurate case histories, clinical investigator(s) should review and electronically sign the completed eCRF for each subject before the data are archived or submitted to FDA.	Use of electronic signatures must comply with 21 CFR part 11. Signatures must be voided when data is changed on a signed record. The meaning of the signature must be documented. Signers must use two-factor authentication when initiating a signing session, etc. (see 21 CFR Part 11).





Benefits of capturing eSource data and transmitting it directly to the electronic data view (EDV) System

- Eliminates unnecessary duplication of data (EHR and EDV system are not integrated so if EHR changes, they will be out-of-sync.)
- Reduces manual transcription errors
- Encourages entering source data to be used for trials during a subject's visit
- Eliminates requirement to transcribe eSource data into an eCRF
- Enables remote monitoring of data as the EDV system=the EHR eSource
- Promotes real-time access for data review to assist in identifying data collection issues or misunderstandings of protocol requirements
- Facilitates the collection of accurate and complete data

The Optum Digital Research Network can help you realize the benefits of eSource data capture in your clinical investigations

Our DRN technology platform leverages existing EMR systems to find patients, accelerate their enrollment, and capture their data directly in the DRN electronic data view system.

Our systems will allow you to:

- Test your clinical trial protocol inclusion/exclusion criteria by searching real-world evidence on 86 million de-identified patients EHR records including:
  - More than 350 lab tests with curated results and standardized units
  - Codes (ICD Dx and Proc, HCPCS, CPT)
  - Medications prescribed/administered/filled
  - Thousands of natural language processing-derived observations and measurements from notes to optimize study feasibility
- Activate and mobilize more research-ready patients by prescreening for eligibility through our proprietary provider network.
- Get a head start on your clinical trial with pre-approved research ready sites, a central IRB, and an existing network of near real-time EHR to electronic data view system integrated capability.
- Gain precision and predictability, and redefine eSource by utilizing the point-of-care electronic data capture workflow present in the EHR data.

Learn more about Optum Digital Research Network:

optum.com/drn

OPTUM®

optum.com

11000 Optum Circle, Eden Prairie, MN 55344