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eSRA – Answering the Call

(of FDA Use of Electronic Health Record Data in Clinical Investigations Guidance)

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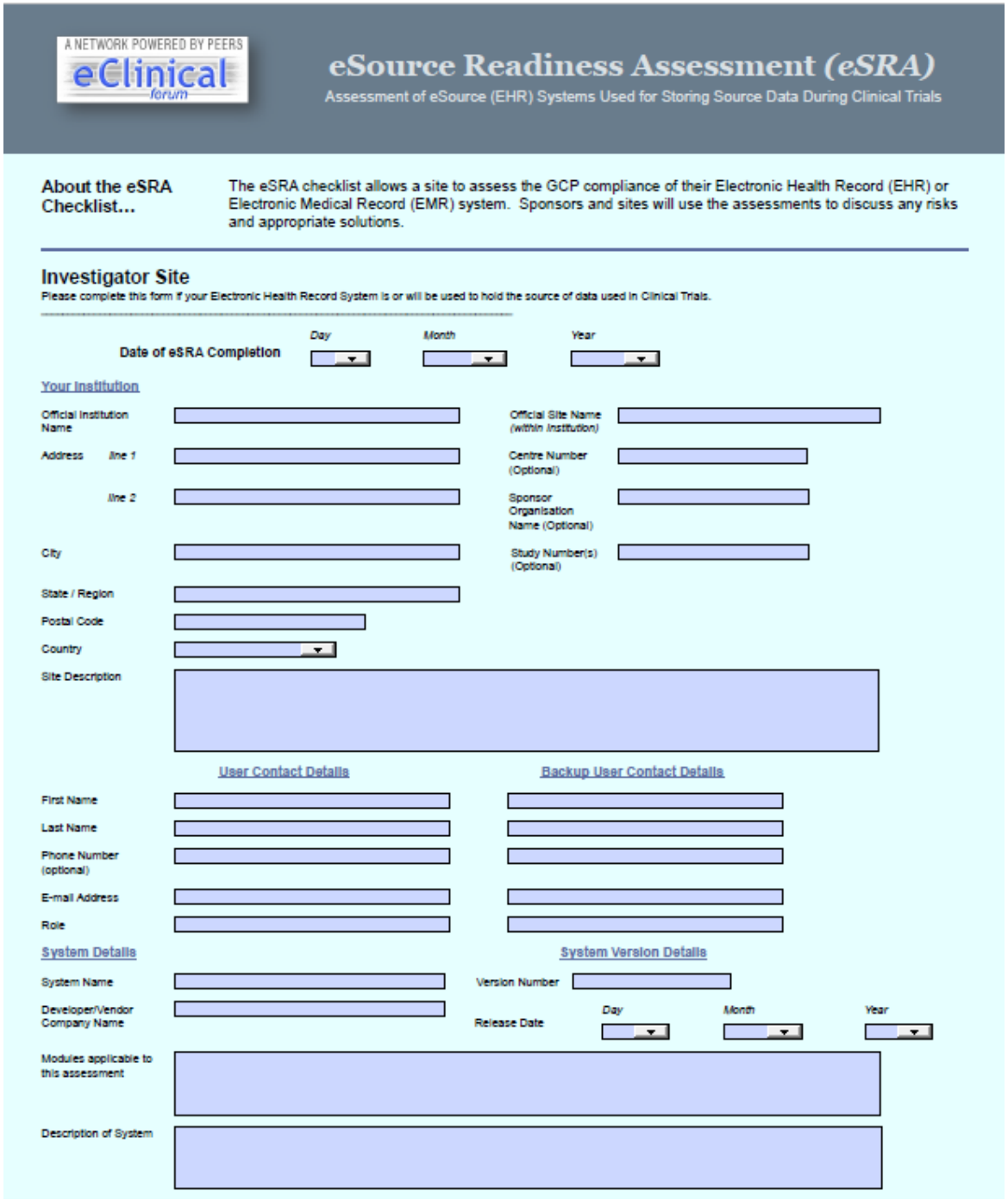
FDA Use of Electronic Health Record Data in Clinical Investigations Guidance

This guidance provides recommendations on … Deciding whether and how to use EHRs as a source of data in clinical investigations …

- Sponsors should include in their data management plan a list of EHR systems used by each clinical investigation site in the clinical investigation. Sponsors should document the manufacturer, model number, and version number of the EHR system and whether the EHR system is certified by ONC (Office of the National Coordinator for Health IT)
- … And then specifically lists areas that sponsors should review the EHR system for …
- EHR systems not certified by ONC, including EHR systems at foreign clinical sites, can provide adequate data to inform FDA's regulatory decisions provided that adequate controls are in place to ensure the confidentiality, integrity, and security of data. Specifically, for EHR systems not certified by ONC, sponsors should consider whether such systems have the … privacy and security controls in place to ensure that the confidentiality, integrity, and security of data are preserved.

eSRA – eSource Readiness Assessment

- Tool to assess readiness of **site systems** to provide eSource for clinical trials, and evaluate and manage the risk.
- Provided for free by the eClinical Forum to all sites, sponsors, CROs globally
- Questionnaire based on FDA, EMA, PMDA, and ICH regulations and guidance documents.



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eSource Readiness Assessment (eSRA)

Assessment of eSource (EHR) Systems Used for Storing Source Data During Clinical Trials

About the eSRA Checklist…

The eSRA checklist allows a site to assess the GCP compliance of their Electronic Health Record (EHR) or Electronic Medical Record (EMR) system. Sponsors and sites will use the assessments to discuss any risks and appropriate solutions.

Investigator Site

Please complete this form if your Electronic Health Record System is or will be used to hold the source of data used in Clinical Trials.

Date of eSRA Completion — Day / Month / Year

Your Institution

Official Institution Name
Address line 1
line 2
City
State / Region
Postal Code
Country
Site Description
Official Site Name (within institution)
Centre Number (Optional)
Sponsor Organisation Name (Optional)
Study Number(s) (Optional)

User Contact Details | **Backup User Contact Details**

First Name
Last Name
Phone Number (optional)
E-mail Address
Role

System Details | **System Version Details**

System Name
Developer/Vendor Company Name
Version Number
Release Date — Day / Month / Year
Modules applicable to this assessment
Description of System

"Sponsors should document the manufacturer, model number, and version number of the EHR system and whether the EHR system is certified by ONC"

(eSRA V2019 will include question regarding system certifications)

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eSRA CRITERIA

Please provide an answer for each question in order for the assessment to be considered complete.

eSRA Criteria	Investigator Site Response		
Assessment Question	Suggested Responder	Investigator Site Response	Comment -- Required if response is "No" (Max: 160 characters)
Records for Clinical Research			
1. Can all records attributable to a patient captured in the EHR system be retrieved and reviewed?	Site Coordinator	○ Yes * ○ No	Comment if response is No
Note: ALL patient records do not need to be stored in this system, however all records in the system must be able to be attributed to a particular patient. This is NOT about linking to a clinical patient ID, but rather about being sure that all records are attributable to an individual.			
2. Are all records that are given to the sponsor via electronic or manual means de-identified, that is, they do not contain any patient-identifiers that are prohibited by the country in which the study is taking place?	Site Coordinator	○ Yes ○ No	Comment if response is No
Note: This does not mean all site EHR records must be de-identified, but that what is given electronically or via paper to a sponsor must be de-identified. If a CRA goes physically to a hospital and does source verification with the EHR system, he/she will see identified data, but if records are sent to the sponsor, then they must be de-identified. In addition, sites should take actions to ensure that no information pertaining to patients not on a clinical trial is shared with sponsors.			

"… sponsors should consider whether such systems have the … privacy and security controls in place to ensure that the confidentiality, integrity, and security of data are preserved."

Records for Clinical Research (2)
Audit Trail (5)
System date & time (4)
Access Control (9)
Data Review (2)
Data Backup, Retention & Recovery (6)
System Development & Maintenance (7)

www.eclinicalforum.org/eSRA

eSRA (eSource Readiness Assessment) Handbook and Assessment Template

Version 2018.1

This handbook provides needed information for

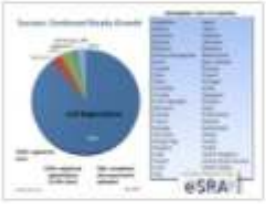
- Sites to complete an eSource-Readiness Assessment (eSRA) to self-assess their healthcare computerized systems (EHR/EMR) for readiness to originate or handle electronic data that could become part of a clinical research study.

- Sponsors/CROs to evaluate a completed eSRA from a site, to determine if data that originated in the site's healthcare computerized system complies with clinical research regulations

Regulatory documents used as a basis for the eClinical Forum eSource Readiness Assessment (eSRA)

Release 2018.1

eCF eSRA Release 2018.1 is based on regulatory documents from FDA (USA), EMA (European Union), PMDA (Japan) and ICH (International). The eClinical Forum will continue to monitor new releases and updates of regulatory documents from these agencies to determine if the eSRA template questions should be updated.



eSRA Use is Growing!

Feb 2018 Statistics on use of eSRA around the globe

eClinical Forum has provided a free assessment tool for clinical research sites to self-assess their computerized systems for readiness to originate or handle data that could become part of a regulated clinical trial. This tool is called the "eSource-Readiness Assessment" or "eSRA" and has been available since August 2015. As of February 2018, it has been used by over 1140 sites in 47 countries.

eSRA V2019 will include mapping to FDA EHR Guidance … however eSRA V2018 already includes what FDA is asking for!

What about You?

Is your company using eSRA?

… If not, why not?

… Consider this … your company has likely not spent as much *time and thought* on whatever they are using to assess sites as the eSRA Team has spent (and will spend) on eSRA…

… If you are using your own tool… we would love for you to do a comparison and give us feedback. Thanks!

Have you personally looked at it?

… what is your experience?

… join the Round Table and community "**Assessing a site's EHR system used in clinical research"**

Q&A

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