eClinical Forum

Investigator Site **eS**ource-**R**eadiness **A**ssessment

A tool for common assessment across sites and sponsors

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1 INTRODUCTION

1.1 About the eClinical Forum

The eClinical Forum (eCF) is a global not-for-profit and non-commercial, technology independent group representing members of the pharmaceutical, biotechnology, and allied industries. The eClinical Forum's mission is to serve these industries by focusing on those systems, processes and roles relevant to electronic capture, management and submission of clinical data. For further information visit the website at www.eclinicalforum.org .

1.2 Disclaimer, Copyright and License

The information presented in these works draws upon the combined current understanding and knowledge of the eClinical Forum on this topic and is provided as an aid to understanding the environment for electronic clinical research.

2 OVERVIEW

2.1 Why assess investigator site systems against clinical research regulations?

Many of the data points needed for clinical research are originating in Electronic Health Records (EHRs), making the EHRs "eSource" for clinical research. *Even if these data points are not used in their electronic state for clinical research, but are printed from the EHRs and then re-entered into an EDC (Electronic Data Capture) system for a clinical trial, the source of the information must still be confirmed as compliant with standards set forth in regulations and applicable guidance documents.*

The eSource Readiness Assessment (eSRA) contains questions based on regulations and regulatory agency guidelines for clinical research data sources from FDA, EMA, PMDA, and ICH. In July 2018, the FDA issued a Guidance for Industry: Use of Electronic Health Record Data in Clinical Investigations, which states: "Sponsors and clinical investigators should ensure that policies and processes for the use of EHRs at the clinical investigation site are in place and that there are appropriate security measures employed to protect the confidentiality and integrity of the study data." This Guidance further stresses the need for an assessment such as eSRA and identifies key areas that should be assessed, all of which are contained in the eSRA questions. In 2010, the EMA issued a Reflection paper on expectations for electronic source data transcribed to electronic data collection tools in clinical trials which states "Clinical trials can be conducted at institutions that use electronic health record systems. In that case the sponsor must assess the systems in use by investigators to determine how well they meet the requirements of GCP." The EMA made a stronger case in the Sept 2023 Guideline for Computerised Systems and Electronic

Data in Clinical Trials, stating "the sponsor should assess the systems in use by the investigator/institution to determine whether the systems are fit for their intended use in the clinical trial (e.g. include an audit trail). The assessment should cover all computerised systems used in the clinical trial and should include consideration of the rights, safety, dignity and wellbeing of trial participants and the quality and integrity of the trial data.

If the systems do not fulfil the requirements, the sponsor should consider whether to select the investigator/institution. The use of systems not fulfilling requirements should be justified, either based on planned implementation of effective mitigating actions or a documented impact assessment of residual risks."

The eClinical Forum commits to updating the eSRA questions as needed when changes are made to the underlying documents and/or new pertinent documents are released from any of the regulatory authorities listed above. We anticipate releasing an updated eSRA in the first quarter of each year. We strongly recommend that a site updates their eSRA when they upgrade their system and provide the updated report to their sponsors. In addition, a sponsor may request an updated eSRA if the underlying regulations have changed significantly and they determine the new eSRA questionnaire is needed for ongoing trials.

The site should proactively update any impacted eSRA, whenever the assessed EHR system is replaced, significantly modified, or upgraded – even if the system modifications appear not to have an impact on source data. If the system details are outdated on the day of an audit or inspection, sites will get findings. Sites are not only responsible for updating eSRA for every system that is changed, they should also forward the updated versions of their eSRA to the clinical trial sponsor of each trial whose source data is stored or originates in the EHR system.

2.2 If my software vendor is certified, do I still have to fill out an eSRA?

While an EHR system certification (e.g. US ONCHIT certification or EUROREC certification) can indicate a vendor-supplied EHR system will manage data appropriately, it is still necessary for an eSRA to be conducted to demonstrate that the site has set up the vendor system and associated processes appropriately with the necessary process controls to maintain a compliant environment. It is the sponsor's responsibility to ensure that the site environment (both system and process) is appropriate for collecting and managing data used for clinical research. To provide evidence for the sponsor to complete this responsibility, a site will need to answer the questions in the eSRA questionnaire.

The FDA Guidance indicates that any EHR system certifications (both in US and other countries) should be identified in documentation provided by the site to the clinical trial sponsor. eSRA provides an area for a site to complete this information.

See section 3.4 for additional information on completing an eSRA if your system has been evaluated for 21 CFR Part 11 or Japan's "Security Management Guideline for Medical Information Systems" (MHLW SMG).

2.3 Which Site Systems should be assessed?

Any site system that manages subject source data that ultimately will end up in a regulated clinical trial - regardless of who the owner of the system is and what access to the data the site has - should be evaluated for suitability such that the sponsor can determine if they are comfortable if source data from this system is used in their trial. This includes the entire data journey from source to sponsor. For example, lab data may originate on a lab system, then sent to an EHR system and then transferred into the site's clinical research warehouse prior to being given to sponsors. In this case, each system that manages the data (the lab system, the EHR system, and the site's clinical research warehouse) would need to have a separate eSRA evaluation. And inversely, any site system that needs to be identified in the Protocol may need an eSRA.

Please note: Only areas / modules of an electronic system that are being used to enter, store, manage, or otherwise handle records that will be used for clinical research need to be evaluated. For example, the portion of an EHR system that might be used to handle insurance claims or other payments would not need to be evaluated.

Following is an example list, but not an exhaustive list of source systems that might provide data or manage data used for regulated clinical research:

- Electronic Health Record Systems (EHRS) or Electronic Medical Record Systems (EMRS)
- Laboratory/Diagnostic Systems
- Imaging Systems (e.g., x-ray, CT scan)
- Pharmacy Systems (if used to hold records of subject medication dosing)
- Radiology Systems

3 ESRA INSTRUCTIONS

The eSRA questionnaire is provided in section 5 of this handbook. ***Please read the following notes before completing the questionnaire:***

3.1 General Notes on Completing eSRA

- **One eSRA per site system**: A separate questionnaire should be used for each of the site's systems that will be used as source for clinical research subject records.
- **Did someone else at our site already complete an eSRA?** Sites should retain all completed eSRA assessments for use in improving their systems and processes and to assist them with future system assessments. We strongly recommend that a site stores their completed eSRA with a central department that is responsible for maintenance of the electronic system. In this way, any future requests for an eSRA on this electronic system, by any part of that site's organization, can benefit by starting with the previously completed eSRA. When a site is requested by a sponsor to complete an eSRA, they should first check with the department responsible for maintenance of their electronic system to find out if an eSRA was previously completed for the same version of the electronic system they are using. If so, they need only to answer the process questions that are identified by a ^ next to the question number.

- **If the answer to an eSRA question is "No":** A site should be aware that a "No" answer to a question does NOT mean that the site will be rejected for clinical trial participation, but rather that the sponsor will work with the site to ensure that any potential risk is mitigated. Some questions have an asterisk * next to the "No" (No*), indicating compliance with this item is "strongly recommended". If a site is not compliant with these questions, your sponsor may recommend that your electronic system is not used to source clinical research data until this item can be mitigated either through a process or system correction such that it can be answered "Yes".
- **If all answers are "Yes" is my system "qualified"?:** It is up to each sponsor to decide if a system is suitable for providing source data for their regulated clinical trials. eSRA does not provide a "qualification" but rather provides information for sponsors to make this decision. However, the same completed eSRA can be given to multiple sponsors who are interested in using data from the same site system.
- **Whose responsibility is it to complete questions about system installation, validation and maintenance?**: Investigator site responsibility with respect to system installation, validation and maintenance may be handled by the site's IT department and/or a vendor. In these cases, the investigational site is still responsible for ensuring that these other parties are fulfilling these responsibilities for any systems providing data used in clinical research.
- In addition to completing an eSRA, it is recommended that sites have a documented site process regarding how source data are collected and managed.
- **Can we give this same completed eSRA to all the sponsors our site works with?:** An investigator can avoid multiple requests from different sponsors for information pertaining to regulatory appropriateness of their system**s** and processes, as the same completed eSRA can be given to each sponsor they work with. Investigators should urge their sponsors to use the eClinical Forum eSRA questionnaire rather than a custom questionnaire from the sponsor. The eSRA website has a document "Implementing eSRA: Sponsor's Perspective" that will be very useful to sponsors.
- **Q/A from eSRA Users:** Other questions from eSRA users and answers from the eSRA Team can be found at Questions from eSRA Users (eclinicalforum.org)
- **Feedback to the eClinical Forum** on this eSRA handbook or questionnaire is always welcome and can be sent to: eSRA@eclinicalforum.org.

3.2 How to save a completed eSRA questionnaire without this Handbook

Once completed, the easiest way to make an immutable copy is to print the file to a .pdf. This will produce a .pdf file that cannot be changed through ordinary means.

The easiest way for SITES[1] is to:

[1] Sponsors must provide the entire Handbook and Questionnaire to their sites such that sites have the information needed to complete the eSRA. Only sites should remove the questionnaire from the Handbook.

1) Download/Save the entire file - handbook and questionnaire

2) Complete the questionnaire in this file

3) *Save to an immutable .pdf*

- *By choosing "Print to pdf" from your print facility rather than using the "Save" feature, you are making a copy that cannot be changed through ordinary means*
- Sites can choose to print-to-pdf only the completed eSRA pages; it is not necessary for a site to retain the handbook once eSRA has been completed.

3.3 Completing the eSRA Fields

Official Institution Name, Official Site Name	The exact name of the clinical research institution as it appears on contracts should be entered here.
Centre Number, Sponsor Organization Name, Clinical Trial Number(s)	These are optional fields. If the site is completing this assessment for a specific research sponsor, then identifying information from the sponsor can be entered here. If the site is completing this assessment to provide to all of their research sponsors, these fields should be left blank.
Institution Address	The address of the clinical research institution as it appears on contracts.
User Contact Details	The contact information of the person responsible for the upkeep of this assessment. Please also enter a backup person to be contacted if the main contact is not/no longer available.
Developer/Vendor Company Name	The exact name of the system vendor as it appears on contracts.
System Name	The complete name of the system. Please complete a separate assessment for each system currently used with clinical research data. Note: Sponsor-supplied systems do not need to be assessed by the clinical research site.
Modules applicable to this Assessment	Only modules that have the potential to collect, manage, or store data that could be used as clinical research source data need to be assessed. For example, a module related to healthcare insurance would not be part of the eSRA assessment.
If this system is certified by ONC or other authorizing certification body, list the certification body name, certification name and version, date of certification.	USA Office of National Coordinator (ONC) requires that organizations receiving Medicare must use ONC-certified EHR systems. Other countries may also require certification. *Please note: if at any time this system is decertified, all sponsors must be notified of the reason for decertification. This eSRA must be updated.*
eSRA Criteria Questions	Please review and reply to each question. *No questions may be skipped.*
Notes	Where appropriate, additional information has been provided to help clarify the question.
Investigator Site Response "No"	If the system, as supplied by the vendor, and implemented at the site does not satisfy the eSRA criterion, this answer must be

	"No". If there is a procedural workaround, it can be described in the comment. In some cases, you may want to request your system vendor to provide the capability in a future release of their system.
No*	This criterion is strongly recommended: If the question has an asterisk * next to the "No" and the site response is "No", it is recommended that this system is ***not*** used to source clinical research data until this item can be answered "Yes".
Additional comments from Site	This area is for any comments about any portion of this assessment or about the system that the site staff would like to convey to sponsors. If there are areas that are non-compliant, the site should indicate plans to improve compliance. If the system vendor has provided a statement or certification regarding compliance to any regulatory requirements (e.g., 21 CFR Part 11), the site should indicate this, and attach the proof from the system vendor.

3.4 If a site is under the jurisdiction of MHRA

If you are under the jurisdiction of MHRA, please be advised of these additional recommendations.

Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency) Published 26 November 2020 Last updated 8 September 2021: EMA Guideline: Access to Electronic Health Records by Sponsor representatives in clinical trials

Remote direct access to Electronic Health Records (EHR) by Sponsor Monitors (or Auditors) in clinical trials: ICH GCP requires[1] and GCP principles[2] expect direct access to trial participant medical/health records for the sponsor's representatives, who are Monitors and Auditors, employed by the sponsor or delegated/contracted third-party. Remote direct access to the medical/health records of clinical trial participants allows source data review (SDR) and source data verification (SDV) to occur without the Monitor (or Auditor) having to visit the investigator site/institution.

Remote direct access to the health records of clinical trial participants may be undertaken by the Monitor (or Auditor) logging into the EHR system ('Log-in Access') remotely rather than onsite or via video calls, where investigator site/institution personnel use screen sharing of EHR systems ('Guided Access') or to display original paper records. Log-in Access requires far less investigator site/institution personnel involvement during the review so it is preferable and should be fully considered and discounted prior to using Guided Access.

The investigator site/Institute may upload scanned or electronic copies of source documents into a secure portal ('Upload Access'). This however would not be considered direct access unless it is a complete and certified copy of the EHR system in an investigator provided portal.

1. INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) November 2016, 1.21, 4.8.10 (n), 4.9.7, 5.1.2, 5.15.1, 5.15.2, 6.10.
2. UK Statutory Instrument 2004/1031 (as amended) 31A, (8) and Schedule 1, Part 2, (9).

Controls Implemented by Investigator Site/Institution for remote direct Log-in Access to EHR system by the Monitor (or Auditor).

- The investigator site/institution should ensure that the EHR system installation facilitates remote Log-in Access.
- In order to allow remote direct Log-in Access to the EHR system by the Monitor (or Auditor), the investigator site/institution must verify the identity of the Monitor (or Auditor) as part of creation of the read-only user account for the EHR system. Functionality for date/ time restricted Log-in Access to the EHR system for the read-only user role should be in place.
- EHR system design should ensure research monitor access is limited to only the records of clinical trial participants and that this access is auditable. Where EHR systems are not yet able to restrict monitor access to the records of only their clinical trial participants, resorting to printouts from the EHR is not an appropriate mitigation or safeguard. This should be addressed in organization (or EHR) level risk assessments and short-term mitigations implemented pending system update.
- The investigator site/institution should implement formal procedures to manage the set up and deactivation of the Monitor (or Auditor) user accounts by the EHR system administrator and to conduct a regular audit of users of the EHR system.

3.5 If a Site has another industry questionnaire for this system

The following industry questionnaires have been mapped to the current version of eSRA and can be of assistance in completing an eSRA, if a site already has one of these completed.

3.5.1 FDA 21 CFR Part 11

If the site system vendor has provided a statement/certification that their system is compliant with FDA 21 CFR Part 11, the site may skip some of the eSRA questions, provided that this vendor statement/certification is attached to the eSRA such that it is permanently saved with the eSRA. The site must indicate on eSRA (in the comment block at the end) that supporting documentation is attached and specify exactly what this is. The sponsor should store this statement/certification with the completed eSRA for that site. A 21 CFR Part 11 certification from a vendor can only ensure that the electronic system provided by the vendor meets 21 CFR Part 11 criteria. It does not provide information about the system as installed and used at the site and for this reason, many of the eSRA questions must still be answered by a site using a 21 CFR Part 11 certified system.

For eSRA V2024, the following questions can be skipped by the site, only if a vendor statement/certification of 21 CFR Part 11 is provided: 3, 6, 7, 8, 9, 15, 16, 32

3.5.2 Japan MHLW's Security Management Guideline for Medical Information Systems

In Japan, healthcare institutions are expected to follow "Security Management Guideline for Medical Information Systems" (MHLW SMG) which lists requirements and recommendations to ensure authenticity, readability and retainability of the electronic records in the medical information systems. Many of them overlap with eSRA questions. A mapping and recommendation for how to use the MHLW SMG to complete the eSRA is provided in a separate document that can be found on the eClinical Forum eSRA page: www.eclinicalforum.org/esra. This is updated annually after eSRA has been updated and may additionally be updated when MHLW updates the SMG.

3.6 Glossary of Terms used in eSRA

Audit trail / Audit log	A secure, computer generated, time-stamped electronic record that allows reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record.
Certification	A quality labeling process provided by an independent, unbiased, professional and trustworthy organization that will indicate that a system has met a specific set of criteria. (eSRA is not a certification.)
Certified Copy	A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.
Clinical trial	Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
CRO	Contract Research Organization (CRO) A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.
Data Breach	From the EU General Data Protection Regulation (GDPR) Personal data breach means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored, or otherwise processed.
EHR	Electronic Health Record (EHR): EHRs are electronic platforms that contain individual electronic health records for subjects and are maintained by health care organizations and institutions. For example, a typical EHR may include a subject's medical history, diagnoses, treatment plans, immunization dates, allergies, radiology images, pharmacy records, and laboratory and test results. EHRs can be used by health care institutions to integrate real-time electronic health care information from medical devices and different health care providers involved in the care of subjects.
EMR	Electronic Medical Record (EMR): Some healthcare organizations have or refer to their electronic system as an EMR (Electronic Medical Record). EMRs are typically narrower in scope than an EHR, however for purpose of this assessment, the terms EHR and EMR are interchangeable.
eSource / Source Data	Source Data: All information in original records and certified copies of original records of clinical findings, observations, or

	other activities (in a clinical investigation) used for the reconstruction and evaluation of the trial. eSource: Electronic source data (eSource) are data initially recorded in electronic format.
Internal and External Systems	Internal systems are systems maintained by the site's IT-support staff; it does not mean the systems are developed in-house, but that the site's IT support staff have the responsibility of administration, support, maintenance and documentation of the system life cycle. (The site IT-staff be internal staff or outsourced to another company via contract in which they behave as an internal IT-department.) External Systems are provided by another Party (i.e. the Clinical Research Sponsor), the Investigator has no organizational control of the system administrators, but the expectation remains that the Investigator and all delegates have control and documentation on system use and risk management.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
IT, Site IT	Information Technology. Investigator Site IT should include a Data Privacy/Protection Officer and Records Retention staff particularly during set-up and maintenance of the system.
Metadata	Metadata are data that describe the attributes of other data and provide context and meaning. Typically, these are data that describe the structure, data elements, inter-relationships and other characteristics of data (e.g., audit trails). Metadata also permit data to be attributable to an individual (or if automatically generated, to the original data source). Example: *Trial subject A123, sample ref X789 taken 30/06/14 at 1456hrs. 3.5mg. Analyst: J Smith 01/Jul/14*
ONC	Office of the National Coordinator for Health Information Technology (U.S.) – provides a program of Health IT certification
Readily Available	Able to be produced for auditor review in a reasonable and/or agreed upon timeframe.
Research Protocol	(Also called Clinical Trial Protocol) A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. In this document, the term protocol refers to protocol and protocol amendments.
SOP	Standard Operating Procedure
Sponsor	Clinical research sponsor (e.g., bio-pharmaceutical company)
Unsuccessful vs Unauthorized access attempt	This refers to questions 13 and 14. An "unsuccessful" access attempt refers to a legitimate user forgetting their access information (e.g., their username or password). An

	"unauthorized" access attempt refers to a non-user attempting to gain access (e.g., through hacking).
Validation	ICH E6 (R2): 1.65 Validation of Computerized Systems: 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. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.

3.7 Additional Resources

- Documents available from www.eclinicalforum.org/eSRA:
  - Implementing eSRA, Sponsor Perspective
  - Differences between eSRA V2024 and V2023
  - Regulatory documents used as a basis for the eClinical Forum eSource Readiness Assessment (eSRA) Version 2024
  - This Handbook, translated into Japanese (V2023 … V2024 will be coming)
  - Industry publication articles in English and Japanese

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5 ESRA QUESTIONNAIRE

Clinical Research Sites should complete this assessment and provide a copy to each of their research sponsors. Sites should retain a copy in their files (in a central location, such as with the Site IT department) to assist with future updates.

Sponsors, we request that the eSRA questionnaire (below) is not removed from this handbook prior to sending to sites as it should not be distributed without the instructions and license agreement provided in this handbook.

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 systems that provide data for clinical research. Sponsors and sites will use the assessments to discuss any risks and appropriate solutions.

Investigator Site

Please complete one eSRA form for each system that will be used as the source for data in a clinical trial.

Date of eSRA Completion — Day | Month | Year

Your Institution

Official Institution Name

Official Site Name (*within institution)*

Address line 1

Centre Number *(Optional)*

Address line 2

Sponsor Organisation Name *(Optional)*

City

Clinical Trial Number(s) *(Optional)*

State / Region

Postal Code

Country

Site Description

User Contact Details

Backup User Contact Details

First Name

Last Name

Phone Number (*optional)*

E-mail Address

Role

System Details

System Name: Nervecentre

Developer/Vendor Company Name: Nervecentre

Version Number

Release Date — Day | Month | Year

Modules applicable to this assessment: Research

Description of System

- (●) Electronic Health Record System (EHRS) or Electronic Medical Record System (EMRS)
- ( ) Laboratory/Diagnostic System
- ( ) Imaging System (e.g., x-ray, CT scan)
- ( ) Pharmacy System (if used to hold records of subject medication dosing)
- ( ) Radiology System
- ( ) Other eSource System (specify) _____

If system is certified by the U.S. ONC Health IT Certification Program or other authorizing body, list the certification body name, certification name and version, date of certification.
Note: If this system becomes decertified, all sponsors must be notified of the reason and eSRA must be updated.

eSRA CRITERIA

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

eSRA Criteria	***Investigator Site Response***	
Asssessment Question	***Investigator Site Response***	***Comment -- Required if response is "No" (Max: 160 characters)***

Records for Clinical Research

1. Can all patient records captured in the EHR system be retrieved and reviewed in a way that is attributable to one trial subject.

- (●) *Yes*
- ( ) *No **

Additional comments and/or plans to correct deficiencies

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 given to the sponsor via electronic or manual means de-identified, such that they do not contain any patient-identifiers that are prohibited by the country in which the clinical trial is taking place?

- (●) *Yes*
- ( ) *No*

Additional comments and/or plans to correct deficiencies

Note. *If access to an electronic site system by a sponsor/CRO results in files being automatically downloaded to their laptop, the answer to this question would be "no". It is not permissible for personal health information to be downloaded (even inadvertently) to a sponsor/CRO personal computer.*

Audit Trail

3. Does the system have an audit trail recording date, time, and originator of any patient data creation, change, or deletion?

- (●) *Yes*
- ( ) *No **

Additional comments and/or plans to correct deficiencies

Note. *Site must ensure that audit trail (audit log) functionality has been installed and is working correctly. If an appropriate audit trail is not available additional process controls such as a signed and dated print out, will have to be introduced to maintain the information.*

4. Does the audit trail include the reason for changes / deletions?

- (●) *Yes*
- ( ) *No **

Additional comments and/or plans to correct deficiencies

5. Is the audit trail human-readable and readily accessible to the end user to be able to retrieve and allow reconstruction of events with a reasonable effort?

- (●) *Yes*
- ( ) *No*

Additional comments and/ or plans to correct deficiencies

Note. *If an appropriate audit trail is not available additional process controls such as a signed and dated print out, will have to be introduced to maintain the information.*

6. Does the system prevent new audit trail information from over-writing previous information such that previous data can be accessed?

- (●) *Yes*
- ( ) *No*

Additional comments and/ or plans to correct deficiencies

Rollback enabled.

System Date/Time as recorded in Audit Trail

7. ^ Are there processes and/or system controls in place that prevent the modification of the audit trail or turning off the audit trail or changing system date/time?

- (●) *Yes*
- ( ) *No*

Additional comments and/or plans to correct deficiencies

Note. *This may be handled via the site operating system and associated procedures or via a hosting vendor. The site should ensure the method employed is working.*

8. Does the system and/or process adequately provide for identifying the local time of patient events?

(●) Yes ( ) No ( ) N/A

Additional comments and/or plans to correct deficiencies:

Note. *Where the system use may span time zones or the system may be located in a different time zone than where the study is being conducted, the time zone of the investigative office (e.g., local time to the patient) should be used in the audit trail , or there must be a clearly documented consistent way to derive the local time from the timestamp on the audit trail.*

Access Control

9. Does the system have the ability to create, maintain, apply and revoke the roles, access permissions and capabilities of each user that accesses the system, such that users have access only to those system functions and data that are appropriate to their role?

(●) Yes ( ) No *

Additional comments and/or plans to correct deficiencies:

Note. *Sites must ensure that accounts are configured so that users have access to only those features that they should have access to (often referred to as roles). Also, there should be an administrator to grant accounts to users upon justification of their need for an account. A process should be in place to ensure that access is removed when an employee no longer has justification for using the system (such as getting assigned to a different area or leaving the organization). If you are using a hosted system, be sure that the vendor will provide the user administration and that you understand and employ the process for obtaining and removing accounts.*

10. ^ Is there policy/procedure/training that instructs users, who create/modify/delete records, not to share their unique access method or not to leave their account open for others to use?

(●) Yes ( ) No *

Additional comments and/or plans to correct deficiencies:

11. Is there a policy that states that there must not be any shared/group accounts that are used by >1 person?

(●) Yes ( ) No *

Additional comments and/or plans to correct deficiencies:

12 . ^ Can the monitor, auditor and inspector, within reasonable timeframe, obtain direct read-only access to records of only subjects of this clinical trial?

(●) Yes ( ) No

Additional comments and/or plans to correct deficiencies:

Note. *The investigator (or appropriate delegate) should be available to browse the patient's record on demand in case of audit, inspection or for monitoring purpose. It is recommended this requirement be part of the contract between the sponsor and the investigator (or the study center). If you are under the jurisdiction of MHRA, please see additional information in Section 3.4 of the eSRA Handbook.*

13. ^ Is there a documented site procedure in place to ensure clinical trial staff are not unintentionally unblinded in trials where this is a requirement?

(●) Yes ( ) No ( ) N/A

Additional comments and/or plans to correct deficiencies:

Note. *If your site does now or may in the future handle blinded studies, this question must be answered. For example, information on pharmacy distribution should not be available for study staff to see.*

14. Does the system limit the number of unsuccessful log-in attempts? If "yes", please indicate in the comment block the number of unsuccessful attempts allowed.

(●) Yes ( ) No *

Additional comments and/or plans to correct deficiencies:

Note. *An example of an unsuccessful log-in attempt is a forgotten password. This may be handled via the site operating system and associated procedures or via the EHR system. Site must ensure that this feature is installed and turned on.*

15. Does the system keep a log of unauthorized access attempts and is there a process in place to periodically review the log of unauthorized access attempts?

(●) Yes ( ) No *

Additional comments and/or plans to correct deficiencies:

Note. *An example of an unauthorized access attempt is a hacking attempt.This may be handled via the site operating system and associated procedures or via the EHR system. Site must ensure that this feature is installed and turned on.*

16. Does the system require secure access via (check all that apply)?

(●) Yes ( ) No * ( ) N/A

Additional comments and/or plans to correct deficiencies:

- [ ] Require password change (indicate interval in the comment block)
- [ ] Fingerprint
- [ ] Face Recognition
- [ ] Device (e.g. smartphone code)
- [x] Single Sign On
- [x] Other MFA

Note. *This requirement is not relevant when a biometric component is used to control user access (e.g. fingerprint, palm print, retina, etc.). Site must ensure that this feature is installed and turned on. The site is responsible for establishing reasonable intervals. If managing this via process, the site must provide and enforce a documented site process requiring password change.*

17. Does the location where data for this site is stored follow physical security best practices?

(●) Yes ( ) No *

Additional comments and/or plans to correct deficiencies:

18. ^ Is there a process that in case of security incident that exposes privacy data, the sponsor and/or relevant data protection supervisory authority are notified?

( ) Yes
( ) No *

Additional comments and/or plans to correct deficiencies

Note. *In absence of a national supervisory authority, the site process should indicate to report any data breach to the sponsor.*

19. Is there an automatic log-off or other access lock (e.g., password protected screen saver) after a period of inactivity? If "yes", please indicate in the comment block the period of inactivity before the automatic logoff.

( ) Yes
( ) No *

Additional comments and/or plans to correct deficiencies

Note. *Site must ensure that this automatic feature is installed and turned on. If using password-enabled screen-saver function from your laptop or desktop system to satisfy this requirement, users should not have the ability to turn off the password-protected screen saver functionality.*

20. Is there a process to periodically produce and review a list of all users, including past users, their access level/rights and the start and end date of these access rights?

( ) Yes
( ) No *

Additional comments and/or plans to correct deficiencies

Note. *The site personnel log should also include other non-site persons who may have access to the clinical research electronic source data. This report does not have to be kept by the investigator, but should be available, upon request, from the IT dept or vendor which maintains the system.*

Data Review

21. Does the system have the ability to produce a copy of data (which includes associated audit trails and any decoded data) in appropriate file format that facilitates review, searching and analysis?

( ) Yes
( ) No

Additional comments and/or plans to correct deficiencies

Note. *If your system does not provide this, a documented site process should address how a certified copy could be produced.*

Data Backup, Retention and Recovery

22. Is the system backed up at appropriate and regular time intervals via a verified (tested) process by either the system vendor or the site such that the integrity of the backup and recovery can be assured? If "yes", please indicate in the comment block the backup interval.

( ) Yes
( ) No *

Additional comments and/or plans to correct deficiencies

Note. *This may be handled via the site operating system and associated procedures or via the eSource system.*

23. ^ Are there process or system controls in place to ensure that data and metadata (including audit trail) are enduring, continue to be available, human-readable and understandable and are retained in an archive for the legal period?

( ) Yes
( ) No *

Additional comments and/or plans to correct deficiencies

Note. *Sites are responsible for knowing the legal retention period for clinical research source records and for ensuring that methods employed to meet this requirement are working.*

24. ^ Is there a documented process for continuing operations if the system is not accessible?

( ) Yes
( ) No

Additional comments and/or plans to correct deficiencies

Note. *There should be a documented site process/plan describing how to handle an emergency or unexpected shutdown. The site should have access to these documents. The site should check with their QA support and request immediate remediation if there is nothing already in place and/or if the process has not been tested.*

25. ^ Is there a documented and tested process for recovery from a disaster or unexpected system unavailability?

( ) Yes
( ) No

Additional comments and/or plans to correct deficiencies

Note. *The group responsible for backup and recovery of the system software/hardware (whether it is your IT department or a vendor) should have a documented site process describing how recovery from an emergency or unexpected shutdown will be handled and proof that this process was tested. The site should have access to these documents.The site should check with their IT and QA support and request immediate remediation if there is nothing already in place and/or if the process has not been tested.*

System Development & Maintenance

26. ^ Are there documented records showing that those maintaining or using the system are qualified (have the necessary training and experience to be able to perform their assigned tasks)?

( ) Yes
( ) No

Additional comments and/or plans to correct deficiencies

27. ^ Does the site utilize a process to demonstrate that the development, hosting, deployment and maintenance (e.g. system changes) of the computerised system is sufficiently validated and documented?

- (●) *Yes*
- ( ) *No **

Additional comments and/or plans to correct deficiencies

Note. *When purchasing or upgrading software, it is typical to have a list of requirements for what it should do and then test to see that it does perform those functions. Validation is a formalization of this process and good business practice. Validation is only required for the parts of the system (modules) necessary to comply with clinical research requirements. All validation/testing activities should be documented such that they can be audited by the sponsor or inspected by a regulatory agency. If the system is upgraded to a new version the changes might require validation, depending on the extent and the scope of the changes. The site must keep track of what version of the system was in place on what date.*

28. ^ Is there a process to periodically review and affirm the continued suitability of the computerized system taking into account the potential cumulative risks and impacts of changes to the system, requirements, version releases, and computing environment of the system.

- (●) *Yes*
- ( ) *No*

Additional comments and/or plans to correct deficiencies

29. Is there anti-malware software installed and updated regularly on all computers used to access or maintain data used for clinical trials?

- (●) *Yes*
- ( ) *No*

Additional comments and/or plans to correct deficiencies

Note. *This may be handled via the site operating system and associated procedures. The site should ensure the method employed is working and documented.The site should check with their IT and QA and Service Provider to ascertain that there is anti-malware software installed and updated regularly; and if this is not the case, it should be corrected immediately.*

30. ^ If electronic data is received from other systems (internal or external), are there appropriate technical or procedural controls to assure confidentiality and integrity of data received from these systems?

- (●) *Yes*
- ( ) *No*
- ( ) *N/A*

Additional comments and/or plans to correct deficiencies

31. ^ If this computerized system is provided by a Service Provider, are there formal agreements in place to clearly define 1) responsibilities of each party (Site and Service Provider) and 2) oversight of the Service Provider?

- (●) *Yes*
- ( ) *No*
- ( ) *N/A*

Additional comments and/or plans to correct deficiencies

Note. *The department responsible can achieve this by an appendix to the contract, an SLA (Service Level Agreement), or in a "statement of work" that can be downloaded from the vendor website.*

32. If electronic signatures are used in your system to fulfill clinical research requirements, are all of the following true: 1) it is permanently linked to its respective record, 2) it includes the name of the signer, 3) it includes the time and date of e-signature execution, 4) the meaning associated with the e-signature is indicated (e.g., creation, confirmation, approval).

- (●) *Yes*
- ( ) *No **
- ( ) *N/A*

Additional comments and/or plans to correct deficiencies

Note. *There is no requirement that electronic signatures are used unless expressly indicated in the protocol. The electronic signature can take various forms, including digital signature, as long as they are legally valid within the jurisdiction where the research is to be conducted.*

ADDITIONAL INFORMATION

Additional Comments from Site

33. What level of risk (low, medium, high) does the site consider their system, based on the deficiencies identified in this assessment?

- ( ) *High*
- ( ) *Medium*
- (●) *Low*

Additional comments and/or plans to correct deficiencies

Principal Investigator signature and date

Sponsor/CRO monitor signature and date

Principal Investigator follow-up review signature and date

Sponsor/CRO monitor follow-up review signature and date

***Strongly recommended -- Based on clinical research regulations and guidances, it is not recommended to use eSource from this system if the answer to this question is "No".**

^ indicates a process question that must be answered if the site is using a previously completed eSRA from another part of their organisation.

Instructions and License Agreement pertaining to this Assessment Form can be found at eclinicalforum.org/esra in the eSRA Handbook.

Model 8