eClinical Forum

Investigator **e**-**S**ite System **R**eadiness **A**ssessment

A tool for a common assessment across Sites and Sponsors

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Author: eClinical Forum eSite System Readiness Assessment (eSRA) Team

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eClinical Forum

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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

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2 OVERVIEW

2.1 Why assess investigator site systems against clinical research regulations?

The EMA Sept 2023 Guideline on Computerised Systems and Electronic Data in Clinical Trials, states (A6.2) "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."

According to the Jan 2025 ICH E6 Release 3 of Good Clinical Practice, "(t)he investigator retains the ultimate responsibility and should maintain appropriate oversight of the persons or parties undertaking the activities delegated to ensure the rights, safety and well-being of the trial participants and the reliability of data. Moreover, (f)or systems deployed by the investigator/institution that maintain and retain trial data/information, the investigator/institution

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should ensure that such data are protected from unauthorised access, disclosure, dissemination or alteration and from inappropriate destruction or accidental loss. "

However, the Principal Investigator (PI) might not have the information or expertise to determine the complex system technical aspects of electronic health record systems, in particular if those are provisioned by the Institution or the region/state/country of residence of the Site. The PI or appropriate institution delegates must nevertheless retain control and assume responsibility over all aspects of data integrity and privacy, by liaising with those in the institution (or healthcare authority) who understand and manage those aspects for their electronic systems. The resulting risk assessments should be maintained as Essential Records by the PI in the Investigator Site File. eSRA provides 2 increasingly popular templates, (eSRA Form/S for eSource systems, and eSRA Form/F for Site File systems), that have the advantage of being study/trial- and sponsor- agnostic and, by design, re-usable across site protocols.

ICH E6 R3 (GCP) further stresses the need for an assessment such as the eSRA Forms and identifies key areas that should be assessed, all of which are contained in the eSRA questions.

eSRA does not "certify" or "qualify" but merely provides information that the sponsor/CRO can use to determine the appropriateness of using data that originate in a site's computerised system. It is up to each individual sponsor/CRO to review a completed site assessment to determine if the site is appropriate for the sponsor's clinical studies/trials.

2.2 Which Site Systems should be assessed?

eSRA provides 2 Forms: Form/S to evaluate systems that handle eSource study/trial participant records, and Form/F to evaluate Investigator Site File (ISF) or site electronic Trial Master File (TMF) systems. These forms are for assessing site-supplied systems and not sponsor-supplied systems.

Form/S (for site eSource systems … this is the blue form):

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 Systems
- Imaging Systems (e.g., x-ray, CT scan)
- Other Diagnostic Systems (e.g. ECG, scopes)
- Pharmacy Systems (if used to hold records of study/trial participant medication dosing)

Any site system that manages source data that ultimately will end up in a regulated clinical study/trial - regardless who the owner of the system is and what access to the data the site has - should be evaluated to be fit for purpose such that the sponsor and investigator can determine if

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the data is to be used in their clinical study/trial. This includes the entire data journey from source to sponsor, investigator and IRB. For example, lab data that originated in a lab system, may be entered or transferred to an Electronic Health Records (EHR) system and then transferred or transcribed 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 Form/S evaluation. And inversely, any site system that needs to be identified in the Protocol may need an eSRA Form/S.

Many of the data points needed for clinical research are originating in 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 study/trial, the source of the information must still be confirmed as compliant with standards set forth in regulations and applicable guidance documents.*

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 regulated 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.

Form/F (for site file systems… this is the yellow form):

The purpose of the site file system is to collect materials that facilitate the reconstruction of the activities during the lifecycle of a clinical trial. Clinical trial related records shall be retained for a defined and formalised period in compliance with regulatory requirements.

The investigator is responsible for essential records generated at the investigator site and should always maintain control of them.

- Electronic Investigator Site File (eISF)
- Site electronic Trial Master File (eTMF)

2.3 When to update an eSRA Form

The site should proactively update any impacted eSRA forms, whenever the assessed 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 a sponsor audit or regulatory inspection, sites may get findings for improper impact assessment on the change to the system. Sites are not only responsible for updating eSRA forms for every system that is changed, but they should also forward the updated versions of their eSRA forms to the clinical study/trial sponsors they are working with. In addition, a sponsor may request an updated eSRA if the underlying regulations have changed significantly and they determine the new eSRA forms are needed for their ongoing studies/trials.

The eSRA forms contain questions based on regulatory agency regulations and guidelines for clinical research data sources from FDA, EMA, PMDA, MHRA and ICH. The eClinical Forum commits to

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updating the eSRA forms 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 updated eSRA forms at the end of the first quarter of each year.

3 eSRA FORM INSTRUCTIONS

The eSRA forms are provided in section 7 of this handbook. ***Please read the following notes before completing a form:***

3.1 General Notes on Completing an eSRA Form

- **One eSRA form per site system**: A separate form should be used for each of the site's systems that will be used in the course of the clinical study/trial for managing data.
- **Did someone else at your site already complete an eSRA?** Sites should retain all completed eSRA forms 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 forms with a central department that is responsible for maintenance of the electronic systems. In this way, any future requests for an eSRA on an 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, the site should first check with the personnel responsible for maintenance of their electronic systems or other central department to find out if an eSRA was previously completed for the same version of the electronic system for the request. If yes, then the site only needs to answer the process questions that are identified by a ^ next to the question number as these pertain to processes within a study team.
- **If the answer to an eSRA question is "No":** A site should be aware that an answer of "No" to a question does NOT mean that the site will be rejected for clinical study/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" (i.e. No*), indicating compliance with this item is "strongly recommended". If the site is not compliant with these questions, your sponsor may recommend that your electronic system(s) are not used as eSource or ISF until the question can be mitigated either through a process or system changes such that it can be answered "Yes". Each question is based on statements from regulatory authority documents. To review the underlying basis for a particular question, especially to determine the criticality of this question in your region, please see the mapping as provided in the document "Comparison of eSRA V2025 with V2024 and regulatory basis" which can be found on the eSRA webpage: Site Sys Assmts
- **If all answers are "Yes", is my system "qualified" for use in a clinical study/trial?:** It is up to each sponsor to decide if a system is suitable for providing data for their regulated clinical studies. The eSRA form does not provide a "qualification" but rather provides information for sponsors to make an informed decision. However, the same completed eSRA form can be given to multiple sponsors who are interested in the same site system for their study/trial data collection.
- **Whose responsibility is it to complete questions about system installation, validation and maintenance?**: Investigator site responsibility with respect to system installation,

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validation and maintenance may be handled by the site's IT personnel /staff and/or a vendor (if system is vendor hosted). In these cases, the investigational clinical research site is still responsible for ensuring that these other parties are fulfilling these responsibilities for any system providing data used in clinical research. The site should also have a contract/agreement if a vendor is responsible for maintenance of the system.

- **Can we give this same completed eSRA form to all the sponsors our site works with?** An investigator can avoid multiple requests from different sponsors for information pertaining to electronic systems used for clinical research as the same completed eSRA form can be given to each sponsor they work with. Investigators should urge their sponsors to use the eClinical Forum eSRA forms rather than a custom questionnaire from the sponsor. eSRA questions are updated annually based on new regulatory information. A list of the updates is provided on the eSRA webpage. The site and/or the sponsor may decide that the updates to the form are significant enough to warrant a review/update of the completed eSRA Forms that are used at a site.
- **If your sponsor does not know about the eCF eSRA Forms and/or is using their own forms for the same purpose,** the site can direct them to the eSRA website document "Implementing eSRA: Sponsor's Perspective" that will provide useful information to sponsors: Site Sys Assmts
- **Q & A from eSRA Users:** Other questions from eSRA users and answers from the eClinical Forum eSRA Team can be found at Questions from eSRA Users (eclinicalforum.org)
- **Feedback to the eClinical Forum** on this eSRA handbook or forms is always welcome and can be sent to: eSRA@eclinicalforum.org.

3.2 How to save a completed eSRA form without this Handbook

Once an eSRA form is 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] to complete the form:

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

2) Complete the form 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 form pages; it is not necessary for a site to retain the handbook with the form once the eSRA form has been completed.*

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

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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.
Center Number/ Department	The center and/or department that is participating in this clinical study/trial
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 of 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 system is certified by a national authorizing body (e.g., the U.S. ONC Health IT Certification Program), 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.	USA Office of National Coordinator (ONC) requires that organizations receiving Medicare must use ONC-certified EHR systems. Other countries may also require certification or may provide certification if a national EHR system is used throughout the country. *Please note: if at any time this system is decertified, all sponsors must be notified of the reason for decertification. This eSRA must then be updated.*
eSRA Criteria Questions	Please review and reply to each question. *No questions may be skipped.*
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". This response requires an explanation, including any procedural workaround that may be employed. 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", then based on clinical research regulations and guidances, it is strongly recommended to mitigate this item, dependent on the nature of the study, prior to using eSource from this system.
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

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	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 with any regulatory requirements (e.g., FDA 21 CFR Part 11), the site should indicate this and attach the proof from the system vendor.

3.4 If a site is using a national system

As outlined in section 2.1, the investigator has the ultimate responsibility over the study/trial data, regardless of whether the computerised system is maintained by their site or is a national system. We recommend that site petition those responsible for the national computerised system to complete eSRA forms such that they are available to all sites using that system. However, any eSRA questions with a ^ indicate it is a process question that should be answered by the site.

4 Mapping of each question to regulatory authority statements

Please see document "Comparison of eSRA V2025 with V2024 and regulatory basis" on the eSRA website page: Site Sys Assmts for an explanation of how to review the underlying regulatory document statements for each eSRA Form question.

5 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 study/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/trial absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
CRO	Contract Research Organization (CRO): A person or an organization (commercial, academic, or other) contracted by the

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	sponsor to perform one or more of a sponsor's study/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.
Data Originator	A person, a computer system, a device, or a lab instrument that is authorised to enter, change, or transmit data elements (also sometimes known as an author).
Electronic Investigator Site File (eISF)	An electronic Investigator Site File (eISF) contains essential documents which show that the clinical study/trial site and Investigator are following the regulatory requirements set out by the ICH GCP guidelines.
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 study/trial. eSource: Electronic source data (eSource) are data initially recorded in electronic format.
Investigator	A person responsible for the conduct of the clinical study/trial. If a study/trial is conducted by a team of individuals at a 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: *Subject A123, sample ref X789 taken 30/Jun/24 at 1456hrs. 3.5mg. Analyst: J Smith 01/Jul/24*

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Readily Available	Able to be produced for auditor review in a reasonable and/or agreed upon timeframe.
Research Protocol	(Also called Clinical Study/Trial Protocol) A document that describes the objective(s), design, methodology, statistical considerations, and organization of a study/trial. The protocol usually also gives the background and rationale for the study/trial, but these could be provided in other protocol referenced documents. In this document, the term protocol refers to protocol and protocol amendments.
Sponsor	Clinical research sponsor (e.g., bio-pharmaceutical company)
Unsuccessful vs Unauthorised access attempt	This refers to questions 12 and 13 on Forms S and F. An "unsuccessful" access attempt refers to a legitimate user forgetting their access information (e.g., their username or password). An "unauthorised" access attempt refers to a non-user attempting to gain access (e.g., through hacking).
Validation	ICH E6 (R3): 1.65 Validation of Computerised Systems: A process of establishing and documenting that the specified requirements of a computerised 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.

5.1 Additional Resources

- Documents available from https ://eclinicalforum.org/site-sys-assmts (Site Sys Assmts)
  - Implementing eSRA, Sponsor Perspective
  - Comparison of eSRA V2025 and V2024 and regulatory basis
  - Q/A – Questions from eSRA users
  - Industry publication articles in English and Japanese

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7 ESRA FORMS

Clinical Research Sites should complete an assessment form for each system used in the clinical study/trial 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.

The eClinical Forum updates the eSRA Handbook and Forms annually, at the end of the first quarter. To be sure that a site is using the most current information, sponsors are requested to not hand out the eSRA Handbook and Forms to sites, but rather to direct sites to download from the eClinical Forum website where there are additional resources available for sites, if needed.
www.eclinicalforum.org/site-sys-assmts

End of Handbook

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eSource Readiness Assessment Form/S

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

About the eSRA Checklist…

This eSRA Form/S 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 Form/S form for each system that will be used as the source for data in a clinical trial.

	Day	Month	Year
Date of eSRA Completion			

Your Institution

Official Institution Name

Official Site Name (*within institution)*

Address line 1

Centre Number *(Optional)*

Address line 2

Site Description

City

State / Region

Postal Code

Country: Denmark

User Contact Details

Backup User Contact Details

First Name

Last Name

Phone Number (*optional)*

E-mail Address

Role

System Details

System Name: Sundhedsplatformen, SP

Developer/Vendor Company Name: EPIC System Corporation

Version Number: EPIC May2025

Release Date: Day 01 Month 10 Year 2025

Modules applicable to this assessment: EPIC Inpatient (+EMR), EpicCare Ambulatory (+EMR), ASAP, MyChart, Beacon, Cogito, FHIR Services, Interfaces

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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 a national authorising body (e.g., the U.S. ONC Health IT Certification Program), 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 this form must be updated.

Details of Epic's ONC certifications are publicly available at either of the following websites: https://chpl.healthit.gov/ or https://www.epic.com/mu/

eSource System Criteria

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

Assessment Question	Investigator Site Response	Comment -- If response is "No", additional information and/ or plans to correct deficiencies are required. (Max: 120 char)

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 ** [ ]

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* [Policy based]

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 a readable, readily available, and indelible audit trail to include recording date/time/originator?

(●) *Yes* ( ) *No ** [All system interaction is logged and the log for specified events can be retrieved from the IT department.]

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 change of any trial participant data change or deletion if this is legally required in your region?

( ) *Yes* (●) *No ** ( ) *N/A* [If necessary, it can be investigated further from the log]

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.*

5. 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* [The system has clock protection.]

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.*

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

(●) *Yes* ( ) *No* ( ) *N/A* [ ]

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.*

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Assessment Question	Investigator Site Response	Comment -- If response is"No", additional information and/ or plans to correct deficiencies are required. (Max: 120 char)

Access Control

7. 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 *

User rights and systems functions are based on users' professional roles.

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 organisation). 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.*

8. 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 *

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

9. Is there a policy/procedure/training that each account is assigned to one dedicated user and that instructs users not to share their account or to leave their account open for others to use?

(●) Yes ( ) No

A compulsory e-learning course on information security.

10.^ 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*

Read only access is gained on request and only to the specific trial via user management

Note. *The investigator (or appropriate delegate) should be available to browse the patients' 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.*

11. ^ 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

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.*

12. Is there a limited number of unsuccessful log-in attempts permitted by the system?

(●) Yes ( ) No *

Policy based and controlled

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.*

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

(●) Yes ( ) No

Note. *An example of an unauthorised 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.*

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

Policy based and controlled

- [x] Require password change (indicate interval in the comment block)
- [ ] Fingerprint
- [ ] Face Recognition
- [ ] Device (e.g. smartphone code)
- [x] Single Sign-on
- [ ] Same Sign-on
- [x] Other Two-factor login

Note. *Site must ensure that this feature is installed and turned on. If access is provided via a password, site is responsible for establishing reasonable intervals. If managing password updates via a process, the site must provide and enforce a documented site process requiring password change.*

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

(●) Yes ( ) No *

Policy based. "Procedure for håndtering af brud på persondatasikkerheden".

16. 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 log-off.

(●) Yes ( ) No *

Policy based

Note. *Site must ensure that this automatic feature is installed and turned on. If using password protected 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.*

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Assessment Question	Investigator Site Response	Comment -- If response is "No", additional information and/ or plans to correct deficiencies are required. (Max: 120 char)

Data Review

17. 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

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

18. Are there sufficient system and/or process controls for backup and recovery procedures, that includes documentation that can be produced for inspection by a monitor, auditor or inspector?

- (●) Yes
- ( ) No *

Standard operating procedure

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

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

- (●) Yes
- ( ) No *

Data are saved indefinitely and beyond the statutory requirement of at least 10 years . Access log is policy based.

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.*

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

- (●) Yes
- ( ) No

and also a BCA-system functionality in Sundhedsplatformen

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 confirm and request immediate remediation if there is nothing already in place and/or if the process has not been tested.*

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

- (●) Yes
- ( ) No

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 confirm and request immediate remediation if there is nothing already in place and/or if the process has not been tested.*

System Development & Maintenance

22. ^ 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

All employees are finformed and trained in how to handle data properly - by policy, training and mandatory courses.

23. Does the site utilise 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 *

We have a strategy for testing and document in a test-tool (ALM)

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.*

24. Are there processes to address computerised system incidents through to their resolution?

- (●) Yes
- ( ) No

ITIL processes along with ServiceNow is used to manage incidents and change requests

25. Is there a process to periodically review and affirm the continued suitability of the computerised 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

Release Management proces controls releases and changes to the system

26. Are there sufficient information security practices to manage, preclude, and report security issues?

- (●) Yes
- ( ) No

The region has a secure set up and a process to handle incidents when they occur

Note. *This may be handled via the site operating system and associated procedures. The site should ensure the method employed is working and documented. Site should check with their IT support that cyber security measures are in place and updated regularly.*

27. 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

all electronic data received from other systems (internal or external) comes thru validated and testet integrations

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Assessment Question	Investigator Site Response	Comment -- If response is "No", additional information and/ or plans to correct deficiencies are required. (Max: 120 char)

28. ^ If this computerised 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 Service Provider's GxP-related subcontractors) and 2) oversight of the Service Provider?

- (●) Yes
- ( ) No
- ( ) N/A

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.

29. If electronic signatures are used in this 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), 5) system can recognise if a record has been altered and make the signature invalid.

- (●) Yes
- ( ) No *
- ( ) N/A

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

I have assessed this completed document and I accept the risks and mitigations identified in this document as per ICH E6 R3 2.12.10 and 3.16.1.vi and vii.

Principal Investigator signature and date

*** Based on clinical research regulations and guidances, it is strongly recommended to mitigate this item, dependent on the nature of the study, prior to using eSource from this system..**

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

Instructions and License Agreement pertaining to this Assessment can be found in the eSRA Handbook which can be downloaded from https://eclinicalforum.org/site-sys-assts.

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Investigator Site File Assessment Form/F

About the ISF Assessment…

This Form/F allows a site to assess the GCP compliance of their Electronic Investigator Site File (eISF) system. Sponsors and sites will use the assessments to discuss any risks and appropriate solutions.

Investigator Site

Please complete this form if your Investigator Site File System is or will be used to hold essential records for Clinical Trials.

Date of ISF Assessment Completion Day Month Year

Your Institution

Address line 1

line 2

City

State / Region

Postal Code

Country

Official Institution Name

Official Site Name (*within institution*)

Centre Number *(Optional)*

	User Contact Details	Backup User Contact Details
First name		
Last Name		
Phone Number (*optional)*		
E-mail Address		
Role		

System Details

System Name

Developer/Vendor Company Name

Version Number

Release Date Day Month Year

Is your system hosted (web-based) or on-site (local)?

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eInvestigator Site File Criteria

Please provide an answer for each question in order for the assessment to be considered complete.
Note: Multiple roles within your organization may be needed to complete this form, such as study coordinator and site IT, or other roles.

Assessment Question	*Investigator Site Response*	*Comment -- If response is "No", additional information and/or plans to correct deficiencies are required. (Max = 120 char)*

Audit Trail

1. Does the system have a readable, readily available, and indelible audit trail to include recording date/time/originator?

- ○ *Yes*
- ○ *No **

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.*

2. Does the audit trail include the reason for any record change or deletion if this is required by regulation in your region?

- ○ *Yes*
- ○ *No**
- ○ *N/A*

3. Does the system audit trail include record viewing and downloading?

- ○ *Yes*
- ○ *No*

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.*

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

- ○ *Yes*
- ○ *No*

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.*

5.^ Does the system and/or process adequately provide for identifying the local time?

- ○ *Yes*
- ○ *No*
- ○ *N/A*

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 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

6. 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 **

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.*

7. 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*

8. Is there a policy/procedure/training that each account is assigned to one dedicated user and that instructs users not to share their account or to leave their account open for others to use?

- ○ *Yes*
- ○ *No*

9.^ Is there a system and/or process to ensure the investigator has oversight of and continuous access to eISF records for the full retention period?

- ○ *Yes*
- ○ *No **

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Assessment Question	Investigator Site Response	Comment -- If response is "No", additional information and/or plans to correct deficiencies are required. (Max = 120 char)

10. ^ Can the monitor, auditor and inspector, within reasonable timeframe, obtain direct access to eISF records in order to perform their regulatory duties?

- ○ Yes
- ○ No

Note. *The investigator (or appropriate delegate) should be available to browse the records 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).*

11. ^ Is there a documented site procedure in place to ensure study staff are not unintentionally unblinded in studies where this is a requirement?

- ○ Yes
- ○ No
- ○ N/A

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.*

12. Is there a limited number of unsuccessful log-in attempts permitted by the system?

- ○ Yes
- ○ No *

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.*

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

- ○ Yes
- ○ No

Note. *An example of an unauthorised 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.*

14. Does the system require secure access via (Check all that apply)

- ☐ Required password change (indicate interval in the comment block)
- ☐ Fingerprint
- ☐ Face recognition
- ☐ Device (e.g. smart phone code)
- ☐ Single Sign-on
- ☐ Same Sign-on
- ☐ Other

Note. *Site must ensure that this feature is installed and turned on. If access is provided via a password, site is responsible for establishing reasonable intervals. If managing password updates via a process, the site must provide and enforce a documented site process requiring password change.*

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

- ○ Yes
- ○ No

16. Is there an automatic log-off or other access lock (e.g., password protected screen saver) after a period of inactivity?

- ○ Yes
- ○ No *

Note. *Site must ensure that this automatic feature is installed and turned on. If using password protected 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.*

Data Backup, Retention and Recovery

17. Are there sufficient system and/or process controls for backup and recovery procedures, that includes documentation that can be produced for inspection by a monitor, auditor or inspector?

- ○ Yes
- ○ No *

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

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

- ○ Yes
- ○ No *

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.*

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

- ○ Yes
- ○ No

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

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Assessment Question	Investigator Site Response	Comment -- If response is "No", additional information and/or plans to correct deficiencies are required. (Max = 120 char)

20. Is there a documented and tested process for recovery from a disaster and/or an unexpected system unavailability?

○ Yes ○ No

Note. *The group responsible for backups, recovery plans for 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. Site should have access to these documents.The site should confirm and request immediate remediation if there is nothing already in place and/or if the process has not been tested.*

System Development & Maintenance

21. ^ 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

22. Does the site utilise 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 *

23. Are there processes to address computerised system incidents through to their resolution?

○ Yes ○ No

24. Is there a process to periodically review and affirm the continued suitability of the computerised 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

25 . Are there sufficient information security practices to manage, preclude, and report security issues?

○ Yes ○ No

Note. *This may be handled via the site operating system and associated procedures. The site should ensure the method employed is working and documented. Site should check with their IT support that cyber security measures are in place and updated regularly.*

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

○ Yes ○ No ○ N/A

27. ^ If this computerised 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 Service Provider's GxP-related subcontractors) and 2) oversight of the Service Provider?

○ Yes ○ No ○ N/A

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.*

28. If electronic signatures are used in this 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), 5) system can recognise if a record has been altered and make the signature invalid

○ Yes ○ No * ○ N/A

ADDITIONAL INFORMATION

Additional Comments from Site

I have assessed this completed document and I accept the risks and mitigations identified in this document as per ICH E6 R3 2.12.10 and 3.16.1 vi and vii.

Principal Investigator signature and date

Based on clinical research regulations and guidances, it is strongly recommended to mitigate this item, dependent on the nature of the study, prior to using eSource from this system.

^ indicates a process question that must be answered if the site is using a previously completed eISF assessment or Form/F from another part of their organisation.

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