

Comparison of eSRA Forms “S” and “F” V2026 question text with V2025 question text

The eClinical Forum eSRA Team evaluated the questions on each of the eSRA forms (Form S “eSource” and Form F “eFile”) to determine updates for the 2025 version. The 2025 updates are based on:

- eSRA-Form S: Question 14 updated to remove ‘same sign-on’ option. Note to added to ‘About the eSRA Checklist’ section.
- eSRA HANDBOOK: Formatting/Typesetting and logo updates, no other changes…
- eSRA Site System Sponsor Guide: Updated sections 4.1.1, 4.1.3, 4.2, and addition of Appendix 3. General format and typesetting updates….
- No updates and additions to the underlying regulatory authority documents as identified by the eClinical Forum Regulatory Advisory Group.

We are committed to continue to improve eSRA. Please provide feedback via email to eSRA@eclinicalforum.org.

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Regulatory Basis for eSRA Questions: To review the underlying regulatory document statements that support each eSRA Forms question, please use the table below. Column A "eCF Req C#" indicates the associated Criteria in the document "Requirements for Electronic Data for Regulated Clinical Trials" (also known as "eCF Requirements". This document can be found in the Downloads section of the eClinical Forum website: Downloads. Please note – only the previous year release of this document is publicly available. eClinical Forum members may use the current year version logging into the Members section of the eClinical Forum website.

REG #	"S" V25 #	FORM S 2025 TEXT	"S" V26 #	FORM S 2026 TEXT	"F" V25 #	FORM "F" 2025 TEXT	"F" V26 #	FORM "F" 2026 TEXT
C1	1	Can all patient records captured in the HER system be retrieved and reviewed in a way that is attributable to one trial subject.	1	No Change				(Not on Form F)
C2	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?	2	No Change				(Not on Form F)
C4	3	Does the system have a readable, readily available, and indelible audit trail to include recording date/time/originator?	3	No Change	1	Does the system have a readable, readily available, and indelible audit trail to include recording date/time/originator?	1	No Change
C4	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?	4	No Change	2	Does the audit trail include the reason for change of any record change or deletion if this is required by regulation in your region?	2	No Change
C44		(not on Form S)		(not on Form S)	3	Does the system audit trail include record viewing and downloading?	3	No Change
C13	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?	5	No Change	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?	4	No Change

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REG #	"S" V25 #	FORM S 2025 TEXT	"S" V26 #	FORM S 2026 TEXT	"F" V25 #	FORM "F" 2025 TEXT	"F" V26 #	FORM "F" 2026 TEXT
C14	6	Does the system and/or process adequately provide for identifying the local time of patient events?	6	No Change	5	Does the system and/or process~~es~~ adequately provide for identifying the local time?	5	No Change
C16	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?	7	No Change	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?	6	No Change
C23	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?	8	No Change	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?	7	No Change
C17	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?	9	No Change	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?	8	No Change
C11		(not on Form S)		(not on Form S)	9	Is there is a system and/or process to ensure the investigator has oversight of and continuous access to eISF records for the full retention period?	9	No Change

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C18	10	Can the monitor, auditor and inspector, within reasonable timeframe, obtain direct read-only access to records of only subjects of this clinical trial?	10	No Change	10	Can the monitor, auditor and inspector, within reasonable timeframe, obtain direct access to eISF records in order to perform their regulatory duties?	10	No Change
	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?	11	No Change	11	Is there a documented site procedure in place to ensure study staff are not unintentionally unblinded in studies where this is a requirement?	11	No Change
C19	12	Is there a limited number of unsuccessful log-in attempts permitted by the system?	12	No Change	12	Is there a limited number of unsuccessful log-in attempts permitted by the system?	12	No Change
C20	13	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?	13	No Change	13	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?	13	No Change
C21	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 _____	14	'[] same sign-on' removed	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 [] other _____	14	No Change

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C40	15	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?	15	No Change	15	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?	15	No Change
C22	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.	16	No Change	16	Is there an automatic log-off or other access lock (e.g., password protected screen saver) after a period of inactivity?	16	No Change
C25	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?	17	No Change		(not on Form F)		(not on Form F)
C26 and C27	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?	18	No Change	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?	17	No Change

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REG #	"S" V25 #	FORM S 2025 TEXT	"S" V26 #	FORM S 2026 TEXT	"F" V25 #	FORM "F" 2025 TEXT	"F" V26 #	FORM "F" 2026 TEXT
C28	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? 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	No Change	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? 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.	18	No Change
C29	20	Is there a documented process for continuing operations if the system is not accessible?	20	No Change	19	Is there a documented process for continuing operations if the system is not accessible?	19	No Change
C30	21	Is there a documented and tested process for recovery from a disaster or unexpected system unavailability?	21	No Change	20	Is there a documented and tested process for recovery from a disaster or unexpected system unavailability?	20	No Change
C31	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)?	22	No Change	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)?	21	No Change

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REG #	"S" V25 #	FORM S 2025 TEXT	"S" V26 #	FORM S 2026 TEXT	"F" V25 #	FORM "F" 2025 TEXT	"F" V26 #	FORM "F" 2026 TEXT
c32	23	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?	23	No Change	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?	22	No Change
C45	24	Are there processes to address computerised system incidents through to their resolution?	24	No Change	23	Are there processes to address computerised system incidents through to their resolution?	23	No Change
C43	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.	25	No Change	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.	24	No Change
C35	26	Are there sufficient information security practices to manage, preclude, and report security issues?	26	No Change	25	Are there sufficient information security practices to manage, preclude, and report security issues?	25	No Change
C36	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?	27	No Change	26	If electronic data 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?	26	No Change

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C37	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?	28	No Change	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?	27	No Change
C39	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.	29	No Change	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.	28	No Change

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