Implementing eSRA: Sponsor Guide

Common tool across sites and sponsors for assessing the readiness of site systems to be used in the conduct of regulated clinical trials

"**eS**ite System **R**eadiness **A**ssessment" (eSRA)

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DOCUMENT HISTORY

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Dec, 2019	V2019	eClinical Forum eSRA Team	First release
Mar, 2021	V2021	eClinical Forum eSRA Team	Updated sections 3.3, 4.1, 4.1.3, 4.2, 4.3, Appendix 5
Mar, 2022	V2022	eClinical Forum eSRA Team	Minor text clarifications, Appendix 4. Previous Appendix on mapping to other industry Formss has been moved to the eSRA Handbook.
Mar, 2023	V2023	eClinical Forum eSRA Team	Updated License agreement (Appendix 1) and Regulatory mapping (Appendix 4)
Jan, 2024	V2024	eClinical Forum eSRA Team	Updated base statements in EMA Guideline on Computerised Systems and Electronic Data in Clinical Trials (Mar 2023)
Apr, 2025	V2025	eClinical Forum eSRA Team	New eSRA has forms for assessing site eSource systems and site file systems. Updates primarily based on ICH E6 R3 (Jan 2025).
Apr, 2026	V2026	eClinical Forum eSRA Team	Changed title to Sponsor Guide. Updated sections 4.1.1, 4.1.3, 4.2, addition of Appendix 3. General format and typesetting updates.

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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 regulatory submission of clinical data. For further information visit the website at www.eclinicalforum.org.

The eClinical Forum has sought opportunities to promote electronic capture since its inception in 2000. The cross-industry forum has a broad view of research with members - sponsors, contract research organizations (CROs), technology vendors, Academia, and Investigators - and with invited outreach opportunities with global Regulatory representatives.

The eClinical Forum is firmly committed to promoting electronic data in all areas of clinical research. The eClinical Forum endeavors to ease the pain of change by providing clear rationale on implications of regulatory guidance in this area.

1.1 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. While the information provided has been guided and reviewed by members of the eClinical Forum representing all areas of the pharmaceutical and associated support industry and represents many hours of discussion with eSRA stakeholders, the opinions of the author(s) and the eClinical Forum do not necessarily reflect the position of individual companies. Users should assess the content and opinions in the light of their own knowledge, needs and experience as well as interpretation of relevant guidance and regulations.

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2 Overview

Sponsors must assure that there are sufficient processes and documentation in place to ensure data from a site's eSource systems and documents within a site file system are reliable and appropriate for use in regulated clinical trials. 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 should ensure that such data are protected from unauthorised access, disclosure, dissemination or alteration and from inappropriate destruction or accidental loss."

When site staff cannot answer technical questions (e.g., about disaster recovery or audit trails), sponsors must ensure these are formally delegated to appropriate IT or vendor representatives. Sponsors must not encourage guessing or provide answers themselves. The Principal Investigator (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 at the ISF – eSRA provides a increasingly popular template, that has the advantage of being study- and sponsor- agnostic and, by design, re-usable across site protocols.

In addition to the traditional clinical research study models, more and more trials are incorporating Real World Data (RWD) into the design or as a replacement for an arm. The sponsor should verify the RWD data is fit for purpose. A completed eSRA Form/S on a site system that will provide RWD is a good way to provide the sponsor with this information.

The eSRA assessment forms are provided for free from the eClinical Forum and have been created by a team of sponsors and research sites to perform assessments on sites computer systems used in clinical research. The EMA[1], FDA[2],MHRA[3], and ICH have provided guidance on the use of eSource and site files in Clinical Trials.

The eCF eSRA tool provides a standardized approach, aligned with regulatory expectations, that allows sites to assess and document the readiness of their site systems for use in clinical research and to reuse their assessment across their clinical trial sponsors. The re-use of a common site system assessment results in time savings for all users – sites, CROs, sponsors, regulators. This document is intended to provide additional information to sponsors in deciding to implement the eSRA forms for evaluating site system's readiness to provide regulatory-acceptable data for their clinical trials. This document is intended to be used in conjunction with the eSRA Handbook and Forms which can be downloaded from http://eclinicalforum.org/Site Sys Assmts.

[1] June 2010: EMA: Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (europa.eu)
[2] July 2018: FDA: Use of Electronic Health Record Data in Clinical Investigations Guidance for Industry | FDA
[3] MHRA blog on Electronic Health Records: https://mhrainspectorate.blog.gov.uk/2019/07/23/electronic-health-records/

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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 trials.

3 Benefits of Implementing eSRA for Sponsors

Using eSRA has many benefits to sponsors of clinical research. Sponsor benefits include 1) leveraging ongoing compilation and interpretation of requirements, 2) consistent expectations with sites interacting with multiple sponsors and 3) decreased time to receive site's system assessments as part of site evaluation and initiation.

3.1 Ongoing Compilation and Interpretation of Regulatory Requirements

Identifying and keeping track of all global requirements of healthcare systems can be a daunting task for sponsors. The eClinical Forum, comprised of member companies from pharmaceutical, CRO, technology vendor and clinical research site organizations, has a specialized regulations team that is keeping track of all the guidelines and regulations regarding computerised systems in clinical trials. They map these requirements to the central Requirements for Electronic Data for Regulated Clinical Trials[4] and keep the list updated. The eCF eSRA team maps the requirements into questions and updates the eSRA forms as needed annually. Sponsors can significantly reduce time and duplicative work on checking regulations and keeping their own assessment forms up-to-date by using the eSRA forms. Sponsors can also take advantage of a uniform interpretation of regulations to meet expectations from regulators, by leveraging the content eClinical Forum gathers and makes available.

3.2 Consistent Expectations for Sites

eSRA enables consistent expectations for sites, across sponsors, for the assessment of healthcare systems used to support their clinical trials. As the use of site systems expands and regulatory expectations become clearer, the broad use of eSRA across sponsors and sites enables sites to have clearer understanding of what is needed for their systems to be used as the source of data for their clinical trials. This can avoid confusion and enable more partnership with sites to mitigate risks to ensure data quality and integrity for clinical research.

3.3 Decreased Time for Sponsors to Receive Site Assessment

The reusability of the eSRA forms at sites for studies within and across sponsors decreases effort and time for receiving site system assessments. Currently, sites are being asked to complete different and time-consuming system evaluation forms from each sponsor and sometimes for each clinical trial. If a site can reuse an already completed assessment across studies and sponsors, the sponsor will receive it sooner! Additionally, a site that has previously completed an eSRA may have implemented

[4] eCF Requirements for Electronic Data in Clinical Trials Downloads (eclinicalforum.org)

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remediation to meet requirements (if needed), thus decreasing effort for the subsequent sponsors or studies.

eSRA has been in use since 2016 for site eSource systems, and since 2024 for site file systems. While it is not required for a sponsor or site to notify eClinical Forum that they are using eSRA, we keep an email notification list of individuals who have specifically requested to receive eSRA update notifications. From this, we know that eSRA is being used in over 50 countries. In 2020, the eSRA Handbook was translated into Japanese and this has greatly increased its use there. During 2024 eSRA was viewed on the eClinical Forum website well over 7,000 times.

Due to privacy laws in different countries, eClinical Forum has decided not to keep a copy of completed eSRAs or a list of sites who have completed an eSRA. We supply the eSRA forms, free of charge, to anyone who wants to use them. We encourage sponsors to keep a list for themselves of which sites they have received completed eSRA forms from. We encourage sites to store their completed eSRA forms in a central location (such as their IT department) such that other groups within the same organization and using the same electronic eSource or electronic file systems can re-use the completed eSRA. In the case of a site re-using an eSRA that was completed by a different clinical trial/study within the same organization, it is recommended that the questions pertaining to site processes are answered newly from each clinical trial group. These process questions are identified in the eSRA forms with a "^".

4 Considerations for implementing eSRA

Once a sponsor decides to use eSRA, there are several considerations on how best to implement it. These include updates to the site assessment/qualification process and handling sponsor-specific questions.

4.1 Incorporating eSRA into site assessment/qualification process

Incorporating eSRA into the site assessment/qualification process should include setting expectations with potential sites, reviewing the completed eSRA forms, and handling of documentation. Based on the experience of one global pharma company that currently requires the eSRA as a part of the pre-trial assessment activities for all their sites worldwide, the following processes may allow for efficient use of this tool during the site selection process. The eClinical Forum eSRA team is providing the following recommendations, however each sponsor is encouraged to use eSRA in a way that fits best into their own processes.

4.1.1 Setting Expectations for Sites

First, the process should include instructions to have initial correspondence with sites being considered for clinical trial participation that includes the expectation to complete the eSRA forms as a part of the site qualification process, or for the site to provide a copy of previously completed eSRA forms.

Sponsors are encouraged to direct sites to the eClinical Forum website. However, Sponsors may distribute the official eSRA Handbook and Forms directly to sites to facilitate initiation, provided the

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document is kept intact (Handbook + Forms) and the Sponsor verifies they are distributing the current version. Sponsors should not distribute extracted pages or partially pre-filled forms.

Sites are expected to complete the entire eSRA form – one Form/S for each eSource system, and one Form/F for their investigator site file system. Sponsors are taking a risk if they accept a form that has not had all the fields completed.

All eSRA questions are based on regulatory authority documents. We provide a document "Comparison of eSRA V2026 to V2025 and regulatory basis" which will provide a mapping from each eSRA question to the underlying regulatory document statements. This is on the eSRA webpage: Site Sys Assmts.

Critical Note on Data Integrity: Sponsors must NOT pre-fill any portion of the eSRA form for the site, even if the Sponsor has prior knowledge of the site's systems from other trials. Pre-filling forms invalidates the PI's attestation and transfers liability for system validation to the Sponsor. The assessment must be a genuine reflection of the site's current understanding and configuration

4.1.2 Use of sponsor-specific online site-assessment checklist with eSRA

If a sponsor already has their own online site-assessment checklist which is used by the sites to answer questions regarding their site systems, and would like to continue using this system instead of directing the site to complete the eSRA forms from the eClinical Forum site, we *highly recommend* that they consider replacing their assessment questions in their online system with the exact wording (and numbering) of the eSRA questions. This will greatly facilitate the site's ability to re-use an already completed eSRA and thus save the site a lot of time. In addition, it better enables the sponsor benefits as listed in the section above. If eSRA is not used directly from the eClinical Forum website, then the sponsor process will need to include steps to maintain their system in alignment with annual updates to the eSRA.[5] Please review the License agreement in Appendix 1. The eCF eSRA team has labored over each question; the exact wording, how it maps to regulatory document statements, and how sites will interpret it. These are reviewed annually by both the eCF eSRA team and the eCF Regulatory Advisory Group and updated if needed. For this reason, it is required that any reproduction include all eSRA questions and exact text and provide credit to the eClinical Forum.

Some sponsors may have a system that tracks site capability and includes embedded sponsor quality processes and applications such as decision trees, pointers to alerts, consultations with data privacy and data security functional units, etc. In this case, the sponsor may have a mapping between the eSRA questions that a site will complete via the eSRA form, and the sponsor quality system activities. The site would still complete the eSRA via the link from the eClinical Forum website and the sponsor will indicate the results in their internal quality system.

As per ICH E6(R3) Good Clinical Practice (Jan 2025), 3.16.1.vi: "Assess whether such systems, if identified as containing source records in the trial, (e.g., electronic health records, other record keeping

[5] Annual eSRA updates are anticipated to be released by the end of the first quarter each year. eSRA users can be notified of release of the latest eSRA by being added to an eSRA communications list by sending an email to eSRA@eclinicalforum.org. This notification list is only used for eSRA communications and not shared.

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systems for source data collection and investigator site files) are fit for purpose or whether the risks from a known issue(s) can be appropriately mitigated. This assessment should occur during the process of selecting clinical trial sites and should be documented".

The site should retain their completed eSRA assessment forms for each trial within the site's Investigator Site File (ISF). In addition, we recommend that the site retains their initial assessment and all subsequent versions thereof (i.e. when EHR systems are upgraded or changed) in a central location for the site, such as their IT department. In this way, other areas/potential trials at a site can get access to a previously completed eSRA form. eSRA forms should be accompanied by a clear site process (i.e., site standard operating procedure (SOP)). They should be generated, modified, and maintained according to regulatory requirements.

4.1.3 Sponsor Review and Documentation of the completed site eSRA

Finally, the process should include that a monitor will review the completed eSRA during the pre-trial assessment visit.

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 trials.

If the pre-trial assessment visit will be conducted via phone, then the completed eSRA forms should be obtained by the monitor in advance of the phone call (e.g., the current version emailed to the monitor) so that any questions can be answered by the site before the monitor can consider the eSRA final and complete. These monitor-facing requirements can be listed in a SOP document that dictates the sponsor-required activities during a pre-trial assessment visit. Some sponsors may want to keep a copy of the completed eSRA forms in their Trial Master File (TMF) (in addition to the copy the investigator is keeping) to accompany any contact reports and communication regarding the mitigation. As mentioned above, a sponsor might also wish to keep a central list and/or forms of all sites that have completed eSRA, to expedite future trials at that same site.

The intent of the sponsor review of the eSRA is to ensure controls are sufficient for use of data from the system for eSource (Form/S) and/or for eISF (Form/F). Some eSRA questions have an asterisk * next to the "No" (No*), indicating that compliance with this item is "strongly recommended". 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. A table is provided in the document "Comparison of eSRA V2026 to V2025 and regulatory basis" (found on the eCF webpage: Site Sys Assmts) showing the basis (mapping) to the regulatory statements for each question. These should additionally be reviewed to determine the criticality of this item in the country/region where the site is located.

The sponsor review process should include who is responsible for this review. The responsibility of eSRA review commonly falls to the sites' monitor/clinical research associate during the pre-trial assessment period. Assigning this responsibility to the monitor can be problematic in the absence of sponsor-provided training and documented guidance/SOPs regarding the sponsor's definition of acceptable eSRA responses for a site participating in that specific sponsor's clinical trials. Sponsors should train monitors that a 'No' (or 'No*') response is a valid data point that triggers a **Mitigation**

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Discussion, not a site disqualification. Monitors should be provided with a 'Mitigation Job Aid' that outlines standard workarounds for common 'No' answers (e.g., if Audit Trail = No, mitigation = Print and Sign). Monitors must not pressure sites to change a 'No' to a 'Yes' to avoid this paperwork, as this obscures compliance risk. When determining the level of risk incurred by any "No" answer, a sponsor should review the underlying regulatory document statements associated with that eSRA form question. This mapping is outlined in the document "Comparison of eSRA V2026 with V2025 and regulatory basis" found on the eCF webpage: Site Sys Assmts.

It is recommended that training, guidance, and support for monitors be part of the implementation to better enable monitors in the review of the eSRA. For training, it is recommended that monitors are provided with content on how to interact with sites regarding eSRA completion, review and possible remediation activities and how to properly document this within the sponsor's TMF.

For guidance to the monitors, one suggestion is to have a representative of the sponsor's IT group and/or Business Technology and/or Quality group assist the monitors by providing an annotated eSRA that identifies eSRA responses from the site that would require mitigation activities in order to proceed with using data from the site, in the opinion of the sponsor. This is a risk-based evaluation, and each sponsor will want to provide their own determination. For this reason, the eCF eSRA team will not make recommendations on how to review the completed eSRA. Additionally, the monitors should be provided with an IT/Business Technology /Quality or other suitable contact to further discuss the site's "No*" or other concerning responses and to discuss opportunities for the site to make changes that would better qualify the site from a site system standpoint thus allowing the site to participate in the sponsor's clinical trial.

Sponsors/CROs should work with their sites to ensure that potential risk is mitigated. The site may be given a period of time to make necessary adjustments to comply with eSource standards based on the completed assessment and may ultimately comply such that the system can be used for source data for clinical research.

Regarding sponsor documentation, a mere note of acknowledgement of a completed eSRA (or just a copy thereof- even if it is a certified copy) would ***not*** suffice and exonerate sponsor responsibilities for ensuring the site's system and associated processes are sufficient for use of the system's data for clinical trial purposes. In the case of an eSRA in which there are responses that indicate some mitigation is necessary, the sponsor's processes and/or SOPs should include retention of the risk evaluation criteria and mitigations put in place (such as adaptation to the extent or frequency of monitoring, site audits). Sponsor records should include outcomes such as corrective and preventive action plans. If a sponsor decides to "accept the risk" of using a site whose system doesn't meet the minimum sponsor requirements, then rationale for accepting the risk should also be retained.

The eSRA responses can provide inputs to a large variety of sponsor-specific qualification processes and can trigger corrective or preventive actions by multiple sponsor functional units (Monitoring, Audit/QA, Data Management, IT). Sponsor tools and processes will invariably generate additional essential records, specific to the trial and stored in the TMF or other sponsor files. *We recommend that sponsors store information regarding site system's eSRA and associated mitigation and risk acceptance in a way such that all areas of the sponsor's clinical operations can have access to it – to avoid rework in the case that a site is re-used for another clinical trial.*

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4.2 Handling Sponsor-Specific Questions for Site Assessment

All eSRA questions are based on regulatory authority document statements, making eSRA a set of minimum questions for sponsors to ask sites to determine that source from site systems can be used for regulated clinical research. See Appendix 4 for a mapping of questions on each of the eSRA forms (S and F) to regulatory document statements.

Sponsors may want to ask the sites additional questions to determine if a site is fit for clinical research and/or to prepare for a good relationship with the site. If a sponsor chooses to gather additional information from a site beyond the eSRA forms, it is recommended that any additional questions are prepared in a separate sponsor or trial-specific questionnaire for sites to complete, to make it easier for sites by preserving the eSRA consistency from sponsor to sponsor.

It is **not** recommended to mix sponsor/trial-specific questions with eSRA questions in a sponsor questionnaire provided to a site or using eSRA in any way except with the exact wording and question numbers provided by eClinical Forum. Sponsors should consider the implications of reuse of eSRA across sponsors, if some sponsors chose to include other content beyond the eSRA. Potential implications include content that may be confidential or otherwise not appropriate to share with other sponsors being inadvertently shared by a site. In addition, having additional content added to the eSRA would make reuse more complicated for sites since it would require deciphering eSRA content from other sponsor-specific content. Sponsors must caution monitors against 'Circular Validation'—the practice of suggesting answers to Site B based on the responses of Site A. Even if sites use the same vendor (e.g., Epic), local configurations, security policies, and versions often differ. Each site must verify its own instance. Providing answers from other sites constitutes prohibited content generation.

We recommend that sponsors direct sites to download the eSRA Handbook and Forms directly from the eCF website: Site Sys Assmts in order that the site is getting the most current information provided by eClinical Forum. In the case that a site has issues accessing the eClinical Forum website, the eSRA Handbook and Forms can be requested directly from eClinical forum via email to eSRA@eclinicalforum.org.

4.3 Requesting sites to update their eSRA Forms

The eSRA Handbook and Forms are updated annually, based on changes to the underlying regulatory authority expectations. The eClinical Forum will post a list of changes when the new release is updated, at the end of the first quarter of each year. Sponsors are encouraged to review the list of updates to the eSRA forms to determine if anything is significant enough to warrant asking their sites to redo their eSRAs with the updated forms. This decision can be made on an annual basis, depending on the depth of regulatory expectations that had changed that year. In addition, we recommend that sites that have updated their system to a new version, should complete a new eSRA form.

The list of changes from the previous version can be found at Site Sys Assmts in the file “Comparison of eSRA V2026 to V2025 and regulatory basis”.

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5 What are the site responsibilities for maintaining eSRA?

The following procedures are outlined in the eSRA Handbook and sponsors should be sure to make the sites aware of them.

- eSRA is primarily intended as a risk assessment initiated and maintained by the site as an Essential Document in the Investigator Site File/ Site Trial Master File.
- An eSRA should be completed for every site system that can originate data or documents for the clinical trial. One eSRA form cannot pertain to multiple systems, or multiple versions or implementations of the same system, even if they might co-exist at the site. The reason is simply that one question may not be answered the same for all systems or versions of one system, and therefore each unique system/version must be assessed separately.
- The site should proactively update any impacted eSRA, whenever the assessed site system is replaced, significantly modified, or upgraded – even if the system modifications appear not to have an impact on source data/documents. 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/documents are stored or originate in the assessed site system.
- The site should retain their completed eSRA assessment forms for each trial within the site's Investigator Site File (ISF). In addition, we recommend that the site retains their initial assessment and all subsequent versions thereof (i.e. when EHR systems are upgraded or changed) in a central location for the site, such as their IT department. In this way, other areas/potential trials at a site can get access to a previously completed eSRA form. eSRA forms should be accompanied by a clear site process (i.e., site standard operating procedure (SOP)). They should be generated, modified, and maintained according to regulatory requirements.

It is important that the sites apply the above principles, not only for their active studies, but also for locked/past trials if the source data/documents are subject to legal retention of records per applicable legislation (i.e., EU CT Regulation).

6 Improving eSRA and Its Use

eSRA is a resource intended to make users most effective and efficient. The eClinical Forum's goal is to have all sites and all sponsors using eSRA such that the following are accomplished:

- Completed eSRAs can be shared by sites to all their sponsors so sponsors do not need to "wait" for an eSRA to be completed
- Sites are not receiving non-eSRA assessment forms to fill out regarding their eSource Systems, meaning less duplicate work for the site

To facilitate widespread use of eSRA and gain all the benefits described above, the eClinical Forum's eSRA team needs to hear feedback from all sponsors, *particularly* if a sponsor reviews eSRA and all its materials, and decides not to implement it.

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The eClinical Forum eSRA team wants to know feedback on the following:

- Are all the questions currently in eSRA needed?
- Are there missing questions? (based on your read of the regulations/guidances … please provide us with a regulatory document reference addressing the need for the suggested question)
- Is there a more clearer way to phrase a question?
- What "work-arounds" have you seen for non-technical approaches to satisfy a question?
- What "odd" situations have been hard to fit into an eSRA question?
- Has anyone had technical issues with using eSRA?
- What overall challenges have you had in completing the eSRA?
- Do you have ANY suggestions for the eSRA forms, documentation or process improvement?

As the eSRA team reviews feedback, it is possible for the team to provide additional information to the person providing the feedback. For example, a question may be requested to be added and the eSRA team can provide information on if the question already has an eSRA basis for this or if the eSRA team has previously discussed it, what their interpretation of the regulatory documents regarding this question is, or if it is being considered for a future release of eSRA.

Companies that are eClinical Forum members are welcome to participate on the eSRA team.

All feedback to the eCF eSRA team can be sent to eSRA@eClinicalForum.org

7 Conclusion

In conclusion, eSRA is a universal tool to assess sites systems and processes used in clinical trials and it offers many advantages for sponsor companies in terms of saving resources and meeting the growing expectations, by regulatory agencies, for sponsors to verify that site systems used in clinical trials comply with requirements. All eSRA questions are based on regulatory document statements, thus providing a normalized set of questions necessary to determine if a site system is up to the challenge of providing source data/documents for clinical research. It offers a method for sponsor assessment of site system compliance and closer partnership with both investigational sites as well as across pharma. The use of eSRA is strongly recommended for all sponsors who strive to present a harmonized and efficient compliance assessment in mutual recognition of quality standards.

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Appendix 2: Glossary of Terms

Term	Meaning
eCF	eClinical Forum, a not-for-profit "think tank" organization working to progress electronic support for clinical research. Home (eclinicalforum.org)
EHR	Electronic Health Records (in practice, sites may also refer to this as "EMR" Electronic Medical Records) An electronic record for healthcare providers to create, import, store, and use clinical information for patient care, according to nationally recherized interoperability standards. NOTE: The EHR has the following distinguishing features: able to be obtained from multiple sources, shareable, interoperable, accessible to authorized parties.
eSRA	eSite System Readiness Assessment (Handbook and assessment Forms provided by the eClinical Forum:Site Sys Assmts)
eTMF/TMF	(electronic) Trial Master File
eISF/ISF	(electronic) Investigator Site File
RWD/RWE	Real-world data/evidence refers to observational data as opposed to data gathered in an experimental setting such as a randomized controlled trial.
SOP	Standard Operating Procedure

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Appendix 3: Investigator e-Site System Readiness Assessment for RWE/RWD

The primary use of the Investigator e-Site System Readiness Assessment is to determine if the Investigator site system that will provide data or manage data for regulated clinical research is fit for purpose. The Sponsor and Investigator can then determine if the data can be used clinical study/trials. However, there has been an increase in non-invasive Sponsor studies where Sites would be providing RWE/RWD (Real World Evidence/Data) to a Sponsor. Though these types of studies do not typically fall under the GCP regulations, Sponsors should still be able to receive quality data that has integrity to perform needed analysis. This is even more crucial if Sponsors engage with Sites who do not typically conduct clinical studies and are not aware of GCP regulations.

The e-Site System Readiness Assessment form (Form/S) can be used to evaluate systems from where RWE/RWD would be received by the Sponsor. However, if the data is to be used for a synthetic arm of a clinical study, then the assessment form would be highly recommended to be completed as the arm would fall under GCP regulations. If the data is to be used for exploratory purposes (e.g. writing an article), then using the assessment form is only recommended.

Notes for Sites completing the assessment that will provide RWE/RWD to a Sponsor.

The entire form is focused on GCP compliance, therefore there may be some sections/questions that will not apply.

Page 1: “Investigator Site” fields are all applicable

Page 2: “Records for Clinical Research” and “Audit Trail”, all questions to be answered as applicable.

Page 3: “Access Control”, all questions to be answered as applicable. For #15, if there is a security incident, a notification should go to IT security staff, site management and 3rd party that would receive the RWE/RWD (e.g. Pharmaceutical Sponsor, Data Broker, Independent Researcher)

Page 4: “Data Review”, “Data Backup, Retention and Recovery”, all questions to be answered as applicable.

Page 5: Questions #28 and #29 are a continuation of the previous page, to be answered as applicable. “Additional Comments from Site” field, here sites can state that this assessment was completed for the intent of providing RWE/RWD to a 3rd party. Naming the 3rd party should not be noted. If the Principal Investigator chooses to sign the assessment, an additional statement can be entered that states that ICH E6 R3 is not applicable due to the type of data being provided.

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