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| --- |
| **SiteVault Accepting a Study Invitation and Completing Regulatory Documents Email Template Instructions** |
| **Remove this table prior to sending****\*Remove information about Safety Letter Distribution if customer is not using the Safety Letter Distribution feature\*****Purpose:** This memo can be sent to a site as a guide to accept their Study Invitation and provide steps for completing their Regulatory Document Package. Sponsor/CRO customers are not responsible for answering SiteVault related questions from sites, Sponsor/CRO users should direct sites with questions to Veeva Site Support (sitevaultsupport@veeva.com). Sites with study specific questions should be directed to the correct Sponsor/CRO contact.**Timepoint:** Directly after Site Selection or in conjunction with a Site Selection Letter. It is helpful if this is sent before the Study Invitation is sent from Clinical Vault.**Role Responsible to Sending:** Veeva recommends this is sent by the Study Team member responsible for notifying the site of selection. |

Re: Study Name and Number

Dear Dr. Investigator Name or Site Contact,

Now that you have signed up for SiteVault and been selected for Study Name and Number with <Customer>, we need to connect with your SiteVault for this study. In the coming days your Regulatory Team will receive a Study Invitation task in SiteVault. By accepting and approving this invitation, we will be able to send your Initial Regulatory Package to your SiteVault for completion. Below we have created a checklist to help guide your Regulatory Team through next steps:

|  |  |
| --- | --- |
| **What do I need to have done already?** | * Complete the [sign up](https://sites.veeva.com/sitevault-free-sign-up/) for Veeva SiteVault, specify <Customer> in the “How did you hear about SiteVault?” field
* Check your inbox for an email from vault-emails@veeva.com with your username and temporary password, then login
* [Complete live or on-demand training sessions](https://sites.veevavault.help/gr/resources/training-resources/) to get setup
* Add your team to SiteVault. [Step by Step Guide here](https://sites.veevavault.help/gr/profiles/managing-users/)
* Add Profile and Organization documents to SiteVault so they can be associated to Studies that each appropriate person or organization are working on. [Step by Step Guide here](https://sites.veevavault.help/gr/documents/profiledocs/)
* **Remove if not using Safety Letter Distribution:** Confirm if your site would like to automatically acknowledge Expedited Safety Reports. [Step by Step Guide here.](https://sites.veevavault.help/gr/connected-studies/confirming-safety-documents/#enabling-auto-confirmation-of-safety-documents)
 |
| **How do I create a Connected Study?**  | * Accept and Approve your Study Invitation so we can send you your Regulatory Package. [Step by Step Guide here](https://sites.veevavault.help/gr/connected-studies/accepting-study-invitations/)
* Add your Study Team, Study Organizations to your study and move them from Proposed to Active to automatically send your teams Profile Documents. [Step by Step Guide here](https://sites.veevavault.help/gr/studies/managing-studies/#managing-study-assignments-products-and-organizations)
 |
| **How do I complete the documents I’ve been sent?** | * Find and accept the Regulatory Document Package task in your Home Tab for Study Name and Number
* Complete the **Documents to Return Section**:
	+ Revise and send back documents requiring updates. [Step by Step Guide here](https://sites.veevavault.help/gr/connected-studies/regulatory-document-requests/%22%20%5Cl%20%22revising-and-returning-a-document)
	+ Complete requests for site-original documents. [Step by Step Guide here](https://sites.veevavault.help/gr/connected-studies/regulatory-document-requests/#providing-an-original-document)
	+ Process other received documents like Informed Consent Form or Financial Disclosure Form Templates. [Step by Step Guide here.](https://sites.veevavault.help/gr/connected-studies/regulatory-document-requests/#processing-other-received-documents)
* File and complete the **Other Received Documents Section**:
	+ Finalize other remaining documents in the Received from Sponsor/CRO state. [Step by Step Guide here](https://sites.veevavault.help/gr/connected-studies/regulatory-document-requests/#processing-other-received-documents)
	+ Send Training Material documents for a Read and Understood workflow to your team. [Step by Step Guide here](https://sites.veevavault.help/gr/documents/r%26umdw/)
* Send any other documents back to us using the Send to Sponsor/CRO document action. [Step by Step Guide here](https://sites.veevavault.help/gr/connected-studies/sending-documents/)
 |
| **What should I do for Safety Reports?** | **Remove if not using Safety Letter Distribution:*** Expedited Safety Reports will be sent to your SiteVault and can be acknowledged automatically or through a task based on the preference of your site. [Step by Step Guide here](https://sites.veevavault.help/gr/connected-studies/confirming-safety-documents/)
 |
| **More questions?** | * Reach out to [Veeva’s Site Support Team](https://sites.veevavault.help/gr/resources/support/) via phone, email, or chat bot with any additional questions.
 |

Please have all documents back to us using SiteVault by DDMMMYYYY. If you need additional support completing your Regulatory Document Package, please reach out to Veeva Site Support at sitevaultsupport@veeva.com. Should you have any study related questions, please do not hesitate to contact me at ###-###-#### or <Study Team Email>.

Sincerely,

Sponsor/CRP Study Team Contact

Title