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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](mailto: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:

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| --- | --- |
| **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/" \l "revising-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&umdw/) * 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](mailto: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