

 <b>World Health Organization</b>	<b>REGULATION AND PREQUALIFICATION DEPARTMENT</b>
	Owner: ePQS Manager
<b>Guidance</b>	
<b>External Guidance – General Guidance on Wizards</b>	
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## External Guidance – General Guidance on Wizards

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## Scope of Guidance

The guidance is intended to provide users with a general overview of how application wizards function within the portal, their purposes and common features.

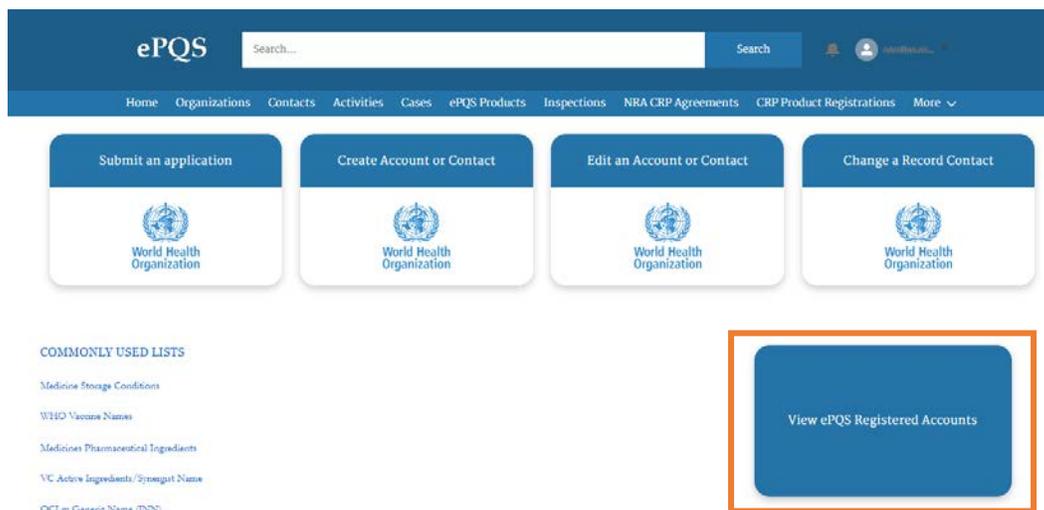
Although wizards follow a similar series of steps, specific information is gathered for different applications. Therefore guidance on each specific wizard should be consulted before commencing.

## Prerequisites

Applications wizards are accessed via the ePQS Portal – <https://who.my.site.com/ePQS/s/login/>. Therefore access to the ePQS portal must be granted first.

Some types of applications have prerequisite conditions. For instance, a post-prequalification change application can only be created if there exists in the ePQS system at least one accepted or prequalified product for the applicant account.

Many wizards include steps that require the applicant to select an account from within the ePQS database. For instance, when an applicant wishes to create a product site for a product, or nominate a reference authority. Users can verify these accounts exist before commencing an application by referring to the spreadsheet available from the “View ePQS Registered Accounts” tile, as indicated in figure 1.



*Figure 1. The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts”*

Should the account not be found, please contact the ePQS administrator at [ePQS@who.int](mailto:ePQS@who.int). If the account does not exist in the system the user will need to request creation of such Account(s).

## What is a wizard, who and when to use it?

Wizards are step-by-step tools that assist and guide applicants to create and submit application records, within the ePQS database. Some wizards involve not only the creation of the application record but also an associated product record.

The system will detect the account (organisation) to which the user belongs and any applications created by the user will be for this Account. If a user is associated with more than one account, the wizard will request the user to select the account to be used.

The application wizards only pertains to the creation and submission of the application. Responses to questions for an existing application are handled differently. User should not create a new application to respond to request for information.

## Ownership and rights

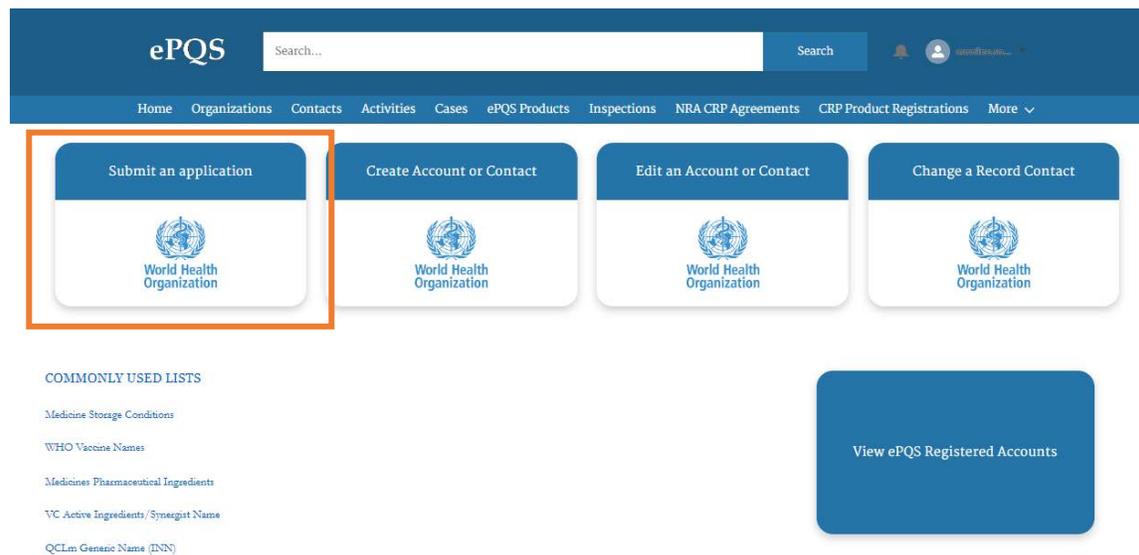
Ownership of a record typically provides a user with the ability to edit aspects of that record.

Whilst the application and products records are being created using the wizard, the applicable records have a status of Draft and are owned by the submitting user.

Therefore, until the application is submitted, many details associated with these records can be edited directly on the record. Caution is advised therefore when reviewing draft records, lest unintended changes are made that result in the application failing screening post-submission.

Once the application is submitted, the status changes from Draft to Under Screening (for the majority of applications) and the ownership of the record changes to the appropriate internal PQT team. Therefore, once the applications is submitted the user now has only read access to the record.

## Creating a new application with a wizard



*Figure 2. Commence the application process by selecting the Submit an Application tile*

An application can be initiated by selecting the Submit an Application tile from the portal as indicated in Figure 2.

During the initial wizard steps no records are created and leaving the wizard leaves no draft record in the system. The wizard will warn the user when a record is about to be created. See section Deleting unwanted records.

### Steps in wizard

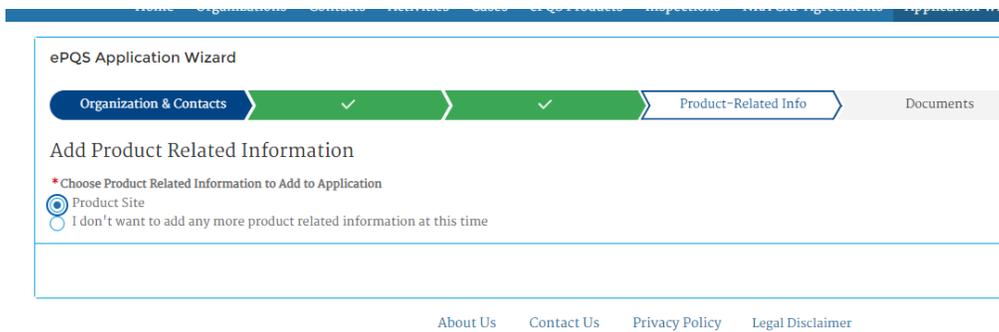
In general wizards follow the following sequence.

- Selection of applicable product type
- Selection of applicable application for the selected product-type
- Selection of contacts for the application
- Creation and completion of application and related records
- Creation and completion of product and related records (depends on application type)
- Submission of documents
- Submission of application

As records are created these will be visible in the portal under the applicable menu item.

### Creation of related records

Many wizards include repeating steps in which related records are created. For instance, the creation of product sites.



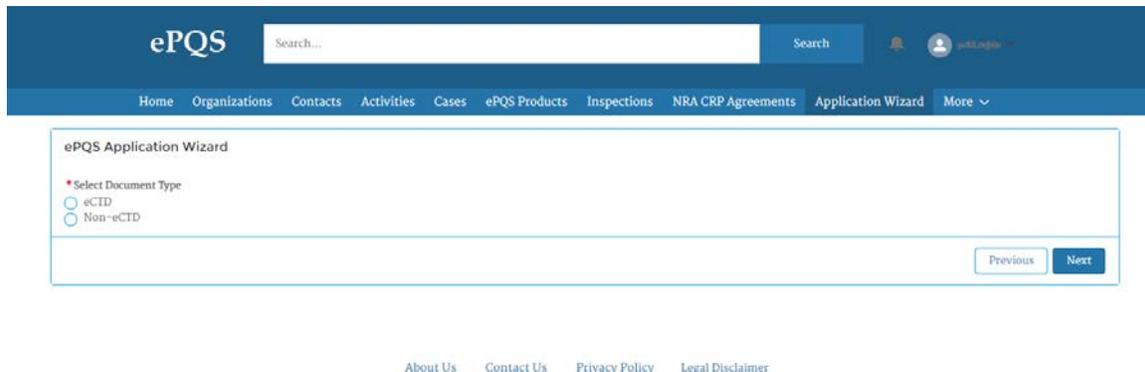
*Figure 3. An example of a repeated step in the wizard where additional related records can be created.*

The types of related-records varies between product and application type. Please check the individual wizard guidance

## Documents

In the final sequence of the wizard, users will be prompted to upload documents in support of their application. The documents required to be uploaded are indicated on the PQT website. The wizard does not scrutinize the type or completeness of the documents uploaded.

Users submitting medicine or vaccine related applications may be asked to specify if the documents are in eCTD or non-eCTD format. See separate guidance on eCTD submissions.



*Figure 4. During some medicine or vaccine related applications, users will be asked if eCTD formatted documents are being submitted.*

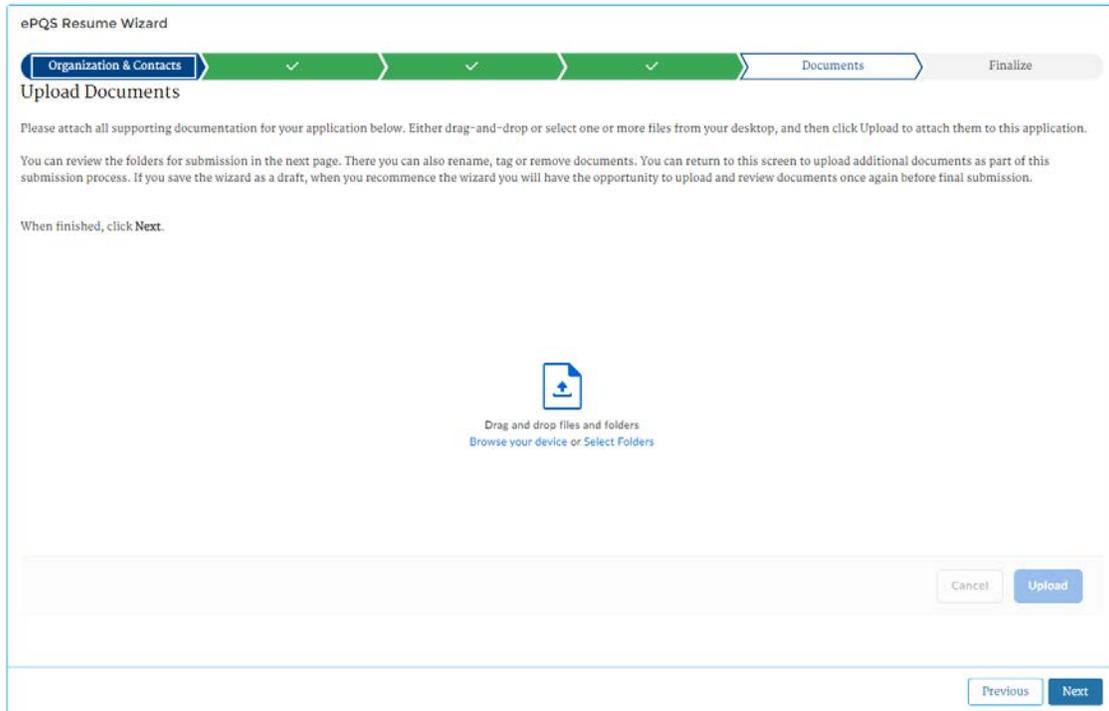
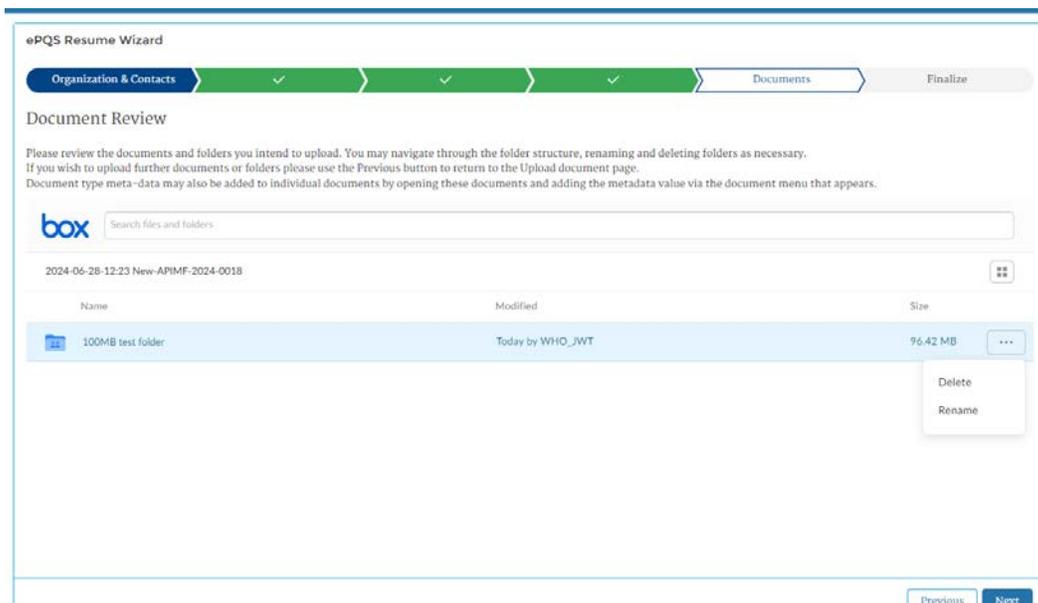


Figure 5. Individual files or folders can be uploaded using the options indicated from this page in the wizard.

Individual files or folders can be uploaded using the options indicated, as indicated in figure 5. Once the upload has been completed there is an opportunity to review the uploaded documents.

The uploaded folders and files can be renamed or deleted on the next screen as indicated in figure 6. All documents can be deleted and the user can return to the upload screen by using the “Previous” button.



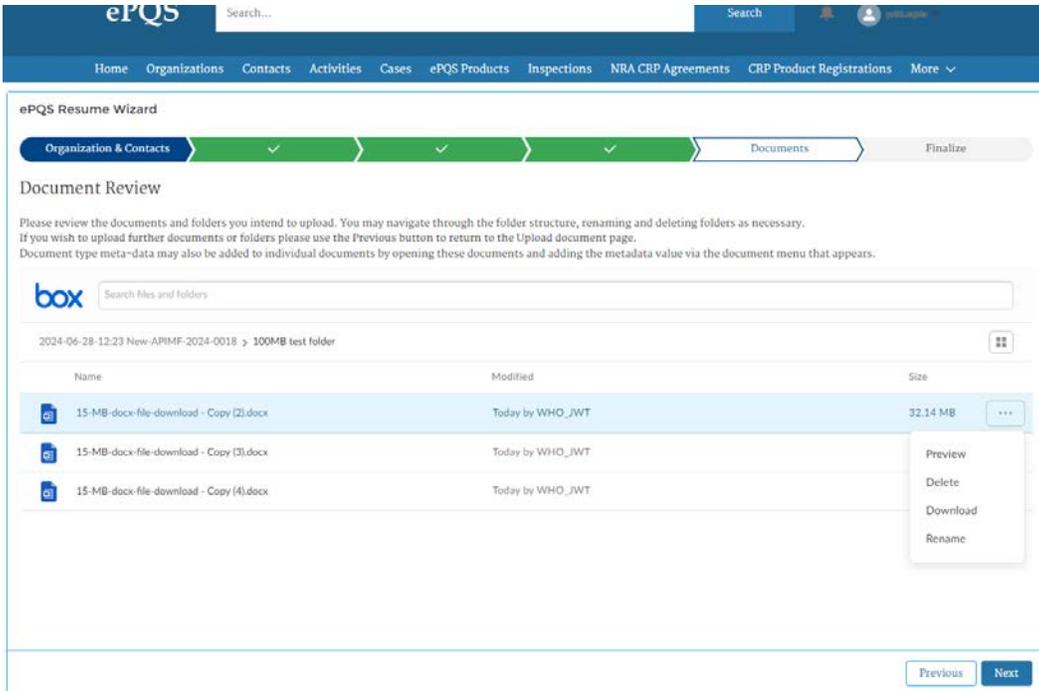


Figure 6. Folders and their contents can be renamed and deleted.

## Saving and restarting a draft application

Draft applications can be restarted from the application record by selecting the Resume Application Wizard button.

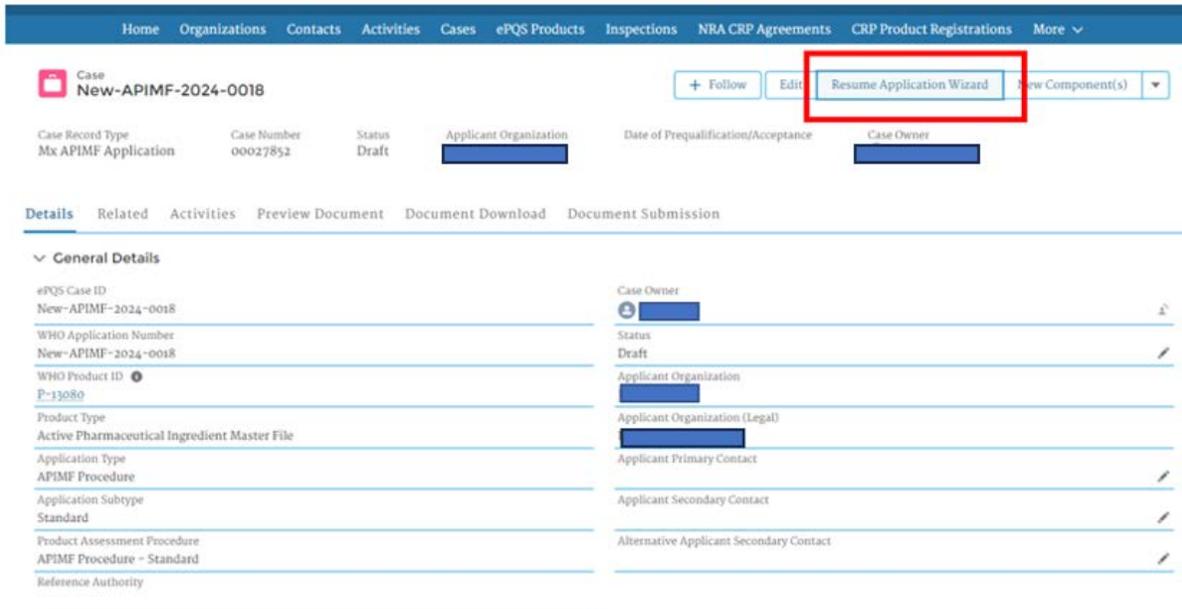


Figure 7. Select the Resume Application Wizard button to recommence the application wizard.

Should the application stay in draft for more than 60 days an email reminder will be sent to the application's primary contact.

## Submitting the application

The screenshot shows the 'ePQS Resume Wizard' interface. At the top, a progress bar indicates the current step is 'Review Application', with 'Organization & Contacts' completed and 'Finalize' as the next step. Below the progress bar, the title 'Review Application' is followed by a paragraph of instructions: 'It is important that you review your application prior to submission. Use the link provided to open it in a new tab and look at the information entered, and also review the related records (click on the Related sub-tab) of which you should be able to open those records too.' Below this, the Case ID is 'New-APIMF-2024-0018' and the Product or Laboratory ID is 'P-13080'. A section titled 'Submit, Save or Discard' asks the user to choose whether they are ready to submit, need more time to save a draft, or want to discard the draft. Three radio buttons are provided: 'Yes', 'No, save existing draft application and product (if applicable)', and 'No, discard this draft application and product (if applicable)'. At the bottom right, there are 'Previous' and 'Next' buttons.

When the user is ready to submit they can do so. The ownership of the record reverts to PQT and therefore the records become non-editable. An email notification will be sent to the Applicant's primary contact.

### Note

It can be observed via the portal that the status of the records will have also changed, normally to Under Screening.

## Deleting unwanted records

In case a draft application is no longer wanted, or if other interventions are needed then the ePQS manager should be contacted at [ePQS@who.int](mailto:ePQS@who.int) for assistance.

## Post-submission

Notifications for requests for information, submission of documents is covered in other guidance.