WHO e-Prequalification System (ePQS)

Learning materials

WHO Immunization Devices (IMD-PQS)

2025

Prequalification Applicants
Prequalification Holders

World Health Organization

Vaccines & Immunization Devices Assessment Team (VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

UPDATED: 19/09/2025

Key access links (for reference)

WHO ePQS Portal landing page:

https://extranet.who.int/prequal/epqs-portal

ePQS login link:

https://who.lightning.force.com/lightning

Intended audiences of these learning materials

AUDIENCES

1. ***Primarily:*** IMD-PQS **Prequalification Holders** (manufacturers and resellers of WHO prequalified immunization devices) and **first-time applicants** for WHO Immunization devices prequalification.

2. These learning materials may also be of interest to: IMD-PQS external experts engaged in the evaluation of application dossiers, as a complement to the dedicated materials provided for that group.

Purposes of these learning materials

Learning materials are intended as comprehensive resources to support users gain necessary competence and autonomy in using the features and functions of ePQS. **These learning materials concern Immunization Devices (IMD-PQS) users. The deck:**

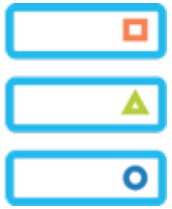
1. Explains the role(s) of ePQS in the IMD-PQS prequalification process
2. Introduces the ePQS navigation
3. Guides PQ Holders and new applicants through the ePQS prequalification and post-prequalification applications
4. Introduces key concepts and terminology
5. Provides links to all detailed technical guidance

ePQS Portal

Q&A / coaching sessions with the IMD-PQS ePQS support team may be scheduled subsequent to this self-training.

Overview of these learning materials

ePQS Portal



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- Introduction
- Pilot
- Registration
- Terminology

SECTION B – DISCOVERY

- Navigating ePQS features & functions

SECTION C – PROCEDURES

- Step-by-step instructions of the application procedures

SECTION D – SUPPORT

- Additional and forthcoming technical support

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SECTION A – SET-UP

1

ePQS Portal Introduction

January 2025

1. ePQS Introduction – What is ePQS?

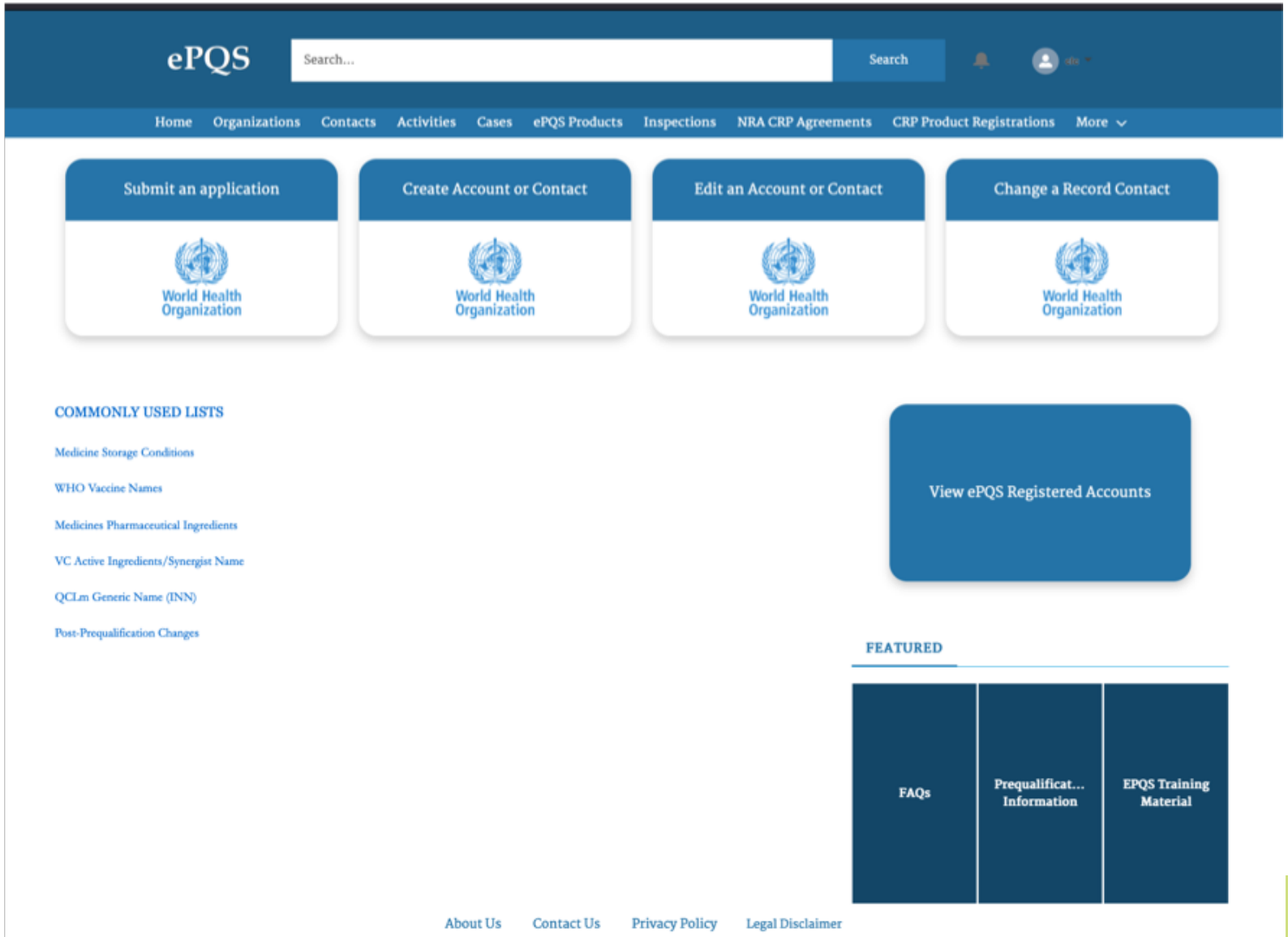
The ePQS "e-**P**re**Q**ualification **S**ystem" platform provides prequalification applicants and PQ Holders (product manufacturers and resellers) a one-stop online portal to:

- submit & manage prequalification applications & post-PQ variations
- follow the site inspections process
- view records relevant to them
- submit required changes to account, contact & product information
- upload and download documents securely
- view and monitor notifications for pending activities

Product annual reassessment (the IMD-PQS Annual Review) will be included in the ePQS system in future (2026/7).

In additional to these processes, the ePQS platform **supports all communication between applicants, PQ Holders and the WHO PQ** and external experts related to the workflows via a cloud file-sharing system integrated into ePQS system.

1. ePQS Introduction – Home page appearance



1. ePQS Introduction
Communication with IMD-PQS

First contact with IMD-PQS – “offline”

- The first contact with the Immunization Devices (IMD-PQS) Secretariat for a new application for prequalification remains by email (application pre-submission & fees).
- If the Secretariat deems that an application is warranted, the Secretariat will direct the applicant to register on the ePQS platform.
- Hereafter, all communication related to the prequalification application, up to and including the final decision, will pass through the ePQS platform.

Applications and post-PQ processes

- Communication between applicants / Prequalification Holders and the IMD-PQS Secretariat will take place via:
  - the ePQS application wizard,
  - the ePQS integrated email agent & file-sharing (cloud)
  - the downloadable request forms on the ePQS home page, and
  - the up/download of documents to the relevant “External Communications” folder within each user’s account, or the users ePQS personal folder.

1. ePQS Introduction
Key components of the ePQS platform

The two key components of the WHO ePQS platform

The “application wizard”

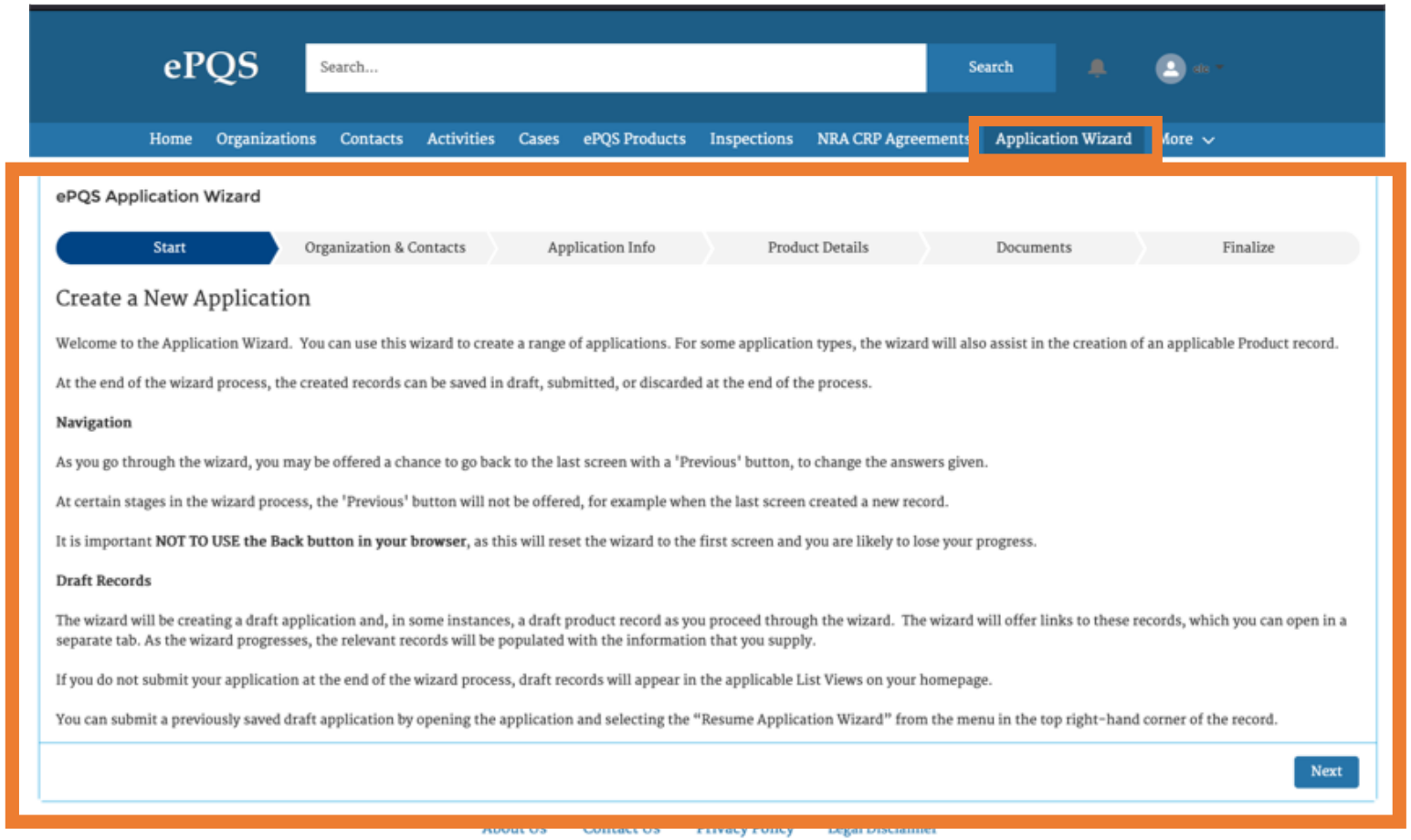
Applications for prequalification, as well as submissions for post-prequalification product variations, take place via the “Application Wizard” tool.

Cloud file-sharing facility (“Box”)

A cloud file-sharing facility manages the uploading, storage and sharing of documents between external applicants, WHO prequalification divisions and external experts. (The name of this cloud file-sharing facility is “Box”.) File-sharing takes place via an “External Correspondence” folder, accessible via document tabs within each ePQS *Account*, *Case Record* or *Product Record,* or the users Personal folder in ePQS.

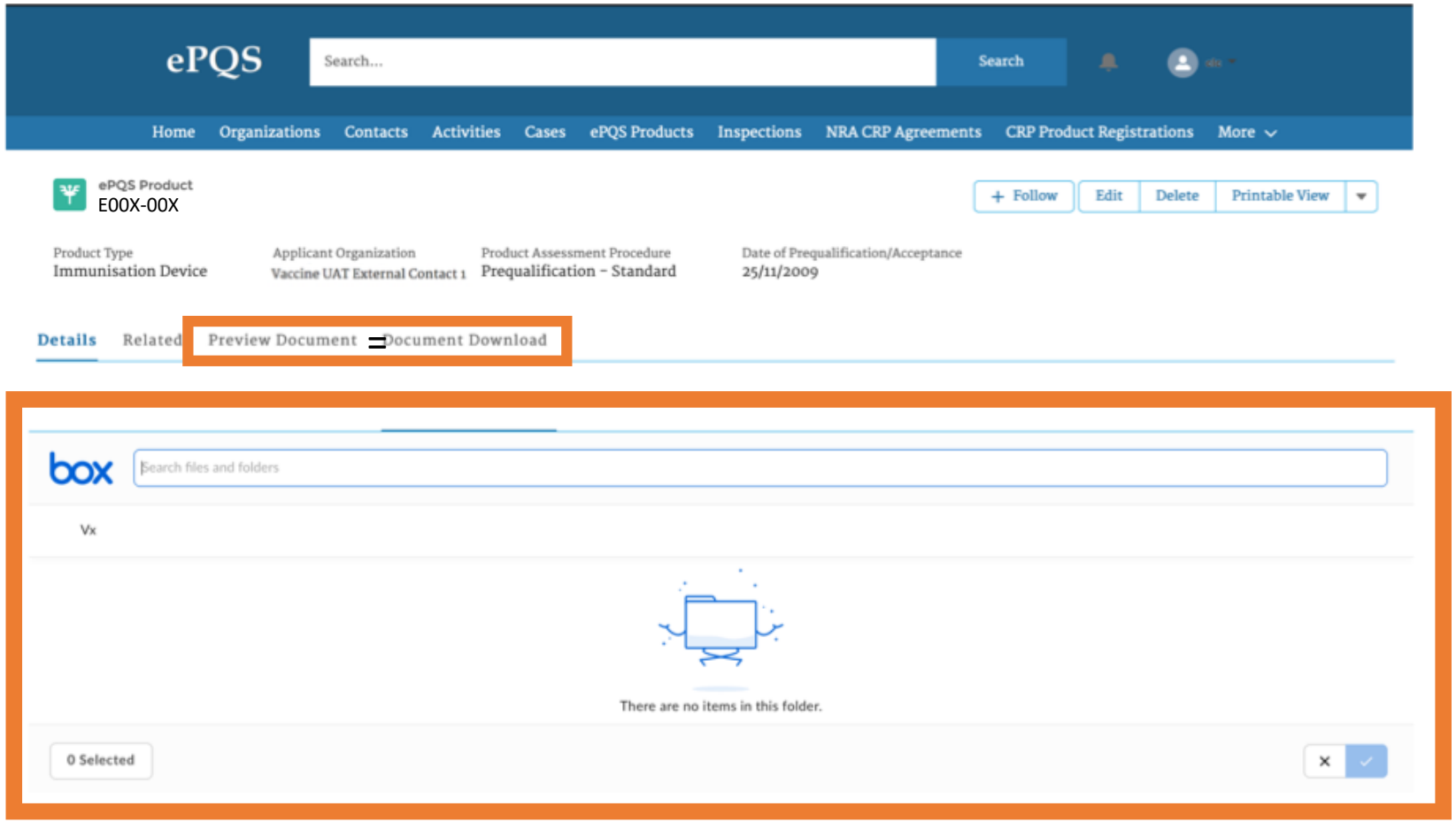
1. ePQS Introduction

Quick view - Application Wizard



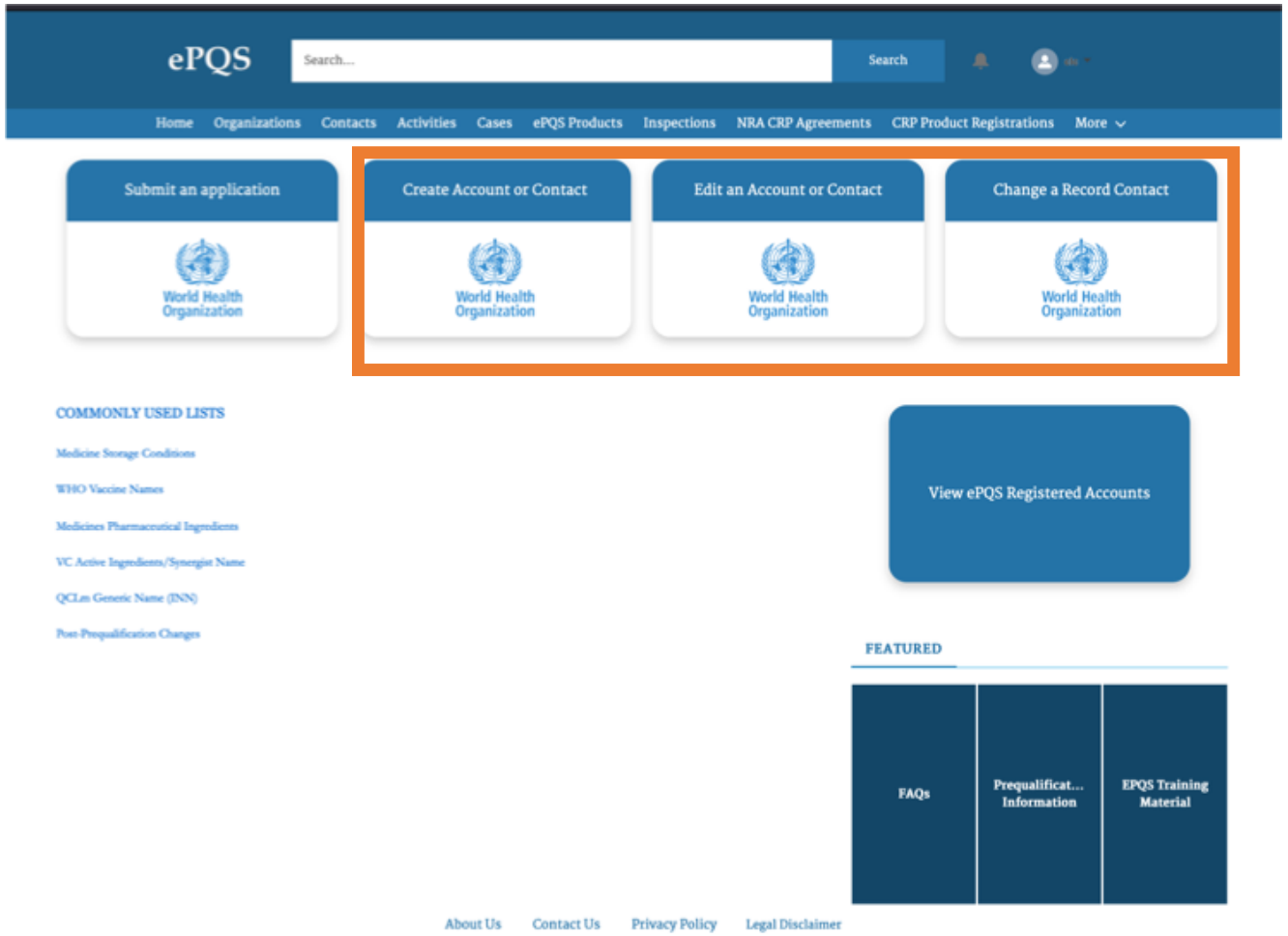
1. ePQS Introduction

Quick view - Document up/download



1. ePQS Introduction

Quick view - Data change request forms



1. ePQS Introduction - ALL Features & functions overview

The ePQS platform offers the following features and functionalities to facilitate the prequalification-related processes:

❖ Global search facility	❖ Outstanding/pending activities tab
❖ Notification “Bell” icon	❖ Document submission, preview & download
❖ Menu bar for major record types	❖ Contacts & accounts
❖ List views	❖ Personalized commonly-used lists
❖ Application Wizard	❖ FAQs and training materials

2

Registration & Access

3. Registration

1. Account contacts have already been created for all IMD-PQS Prequalification Holders

2. Prequalification Holders must **verify their account and contact** details prior to registration. The IMD-PQS Secretariat will reach out individually to users with the required forms for this stage.

3. Contacts need to “register” to gain access to the the system.

   Registration is via the:
   “External Form – New ePQS User” linked here:
   https://who.my.salesforce.com/sfc/p/#3X000005AZtm/a/NN000001rmcH/.Kqqi2wVzq1TIiizyfrvIoi_0D5v_7CmXUozH01_Ke0

   Each new user / registration request must complete:
   - **Section 1 (Declaration),**
   - **Section 3 (New User) and**
   - **Section 4 (New Account)**

5. **Return the form to vaccprequalification@who.int, with the IMD-PQS Secretariat in copy.**

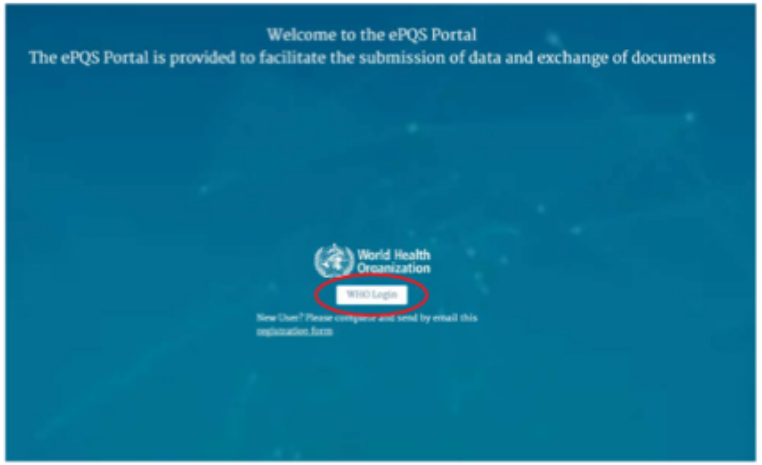
2. Access

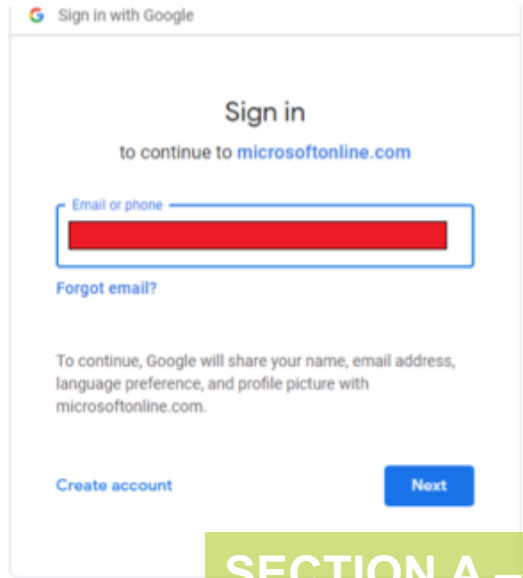
Once the registration is successfully completed, access to the ePQS portal can be obtained by:

1. Accessing the link: https://who.my.site.com/ePQS/s/login/

2. **EITHER** - clicking the “WHO Login” button. The user will be directed to WHO Microsoft identity platform where they will be required to enter their username and click on the “Next” button.

3. **OR -** depending on which authentication mechanism is being used by their email address service, WHO’s identity platform will direct the user to provide the password the user uses for the email service.





3

Concepts & terminology

3. Concepts & terminology

This section of the learning materials provides key terms that users will encounter whilst using ePQS.

It is intended as an ongoing reference guide throughout the training and your ePQS use.

3. Concepts & terminology – two critical terms

“Records” and “Cases”

Record

A single instance of object data. Records types include:

- **Product record** (basic information about a product),
- **Product Variant r**ecord (detailed product specification data),
- **Contact record** (individual user),
- **Account record** (PQ Holder organisation),
- **Case record** (record of a prequalification-related application in ePQS).

Case

Every prequalification (or associated) application (E.g. Inspection, post-prequalification product variant) begins with the creation of a *case*.

3. Concepts & terminology – other key terms

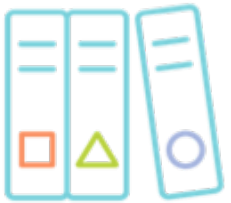
“Records” and “Cases”

Activity	Any system activity taken in relation to an ePQS *case*.
Case record type	For each case, the record type will be either “*Vx IMD Applicatio*n”, or “*Vx IMD Post-PQ change*” or *“Vx IMD Reassessment”.* These terms are defined below.
ePQS Case ID	Once opened, each case will be assigned an ID in the format “PQ-IMD-YEAR-XXXX”.

3. Concepts & terminology – other key terms

Terms related to applications

Application	New application for product prequalification, post-PQ change (variation) or Reassessment. Submitted via the Application Wizard.
Applicant organization	The legal entity submitting a prequalification application or post-prequalification change.
Application number	Unique code assigned to each new application in ePQS, in the format “PQ-IMD-202X-XXXX”. Identical to the “ePQS Case ID”.
Application wizard	ePQS process assistant: a user interface that leads users through each ePQS process via a sequence of prompted, guided steps.



3. Concepts & terminology – other key terms

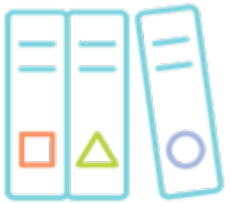
IMD-PQS-specific application processes on ePQS

Vx IMD Application	IMD-PQS ePQS Application type meaning: “New application for product prequalification”.
Vx IMD Post-PQ change	IMD-PQS ePQS Application type meaning: “Post-prequalification variation, a change to product or manufacturing process”.
Vx IMD Reassessment	IMD-PQS ePQS Application type meaning: “IMD Annual Review of prequalified products”.

3. Concepts & terminology – other key terms

Terms related to products

IMD Product	Section of the application/case/product record that contains the basic information about a product submitted for review. For example, the product name, description, type and applicant organization.
IMD Product Variant	Sub-section of the unique product application/case/product record that contains the record of all of the detailed product technical specifications.
(WHO) Product ID number	Once a prequalification application is completed and submitted in the application wizard, the product will be assigned an ID number in the format: “P-XXXXX”.
External ID	Subsequent to a successful application for prequalification, WHO IMD-PQS will assign an External ID in the traditional format of the “PQS Product number”: “E0XX-XXX”.
Product Site	Location and facility at which a product is manufactured.



SECTION B – DISCOVERY

ePQS navigation & features - Discovery

This “discovery” section of the learning materials guides users through the different features and functions of ePQS and where they can be found.

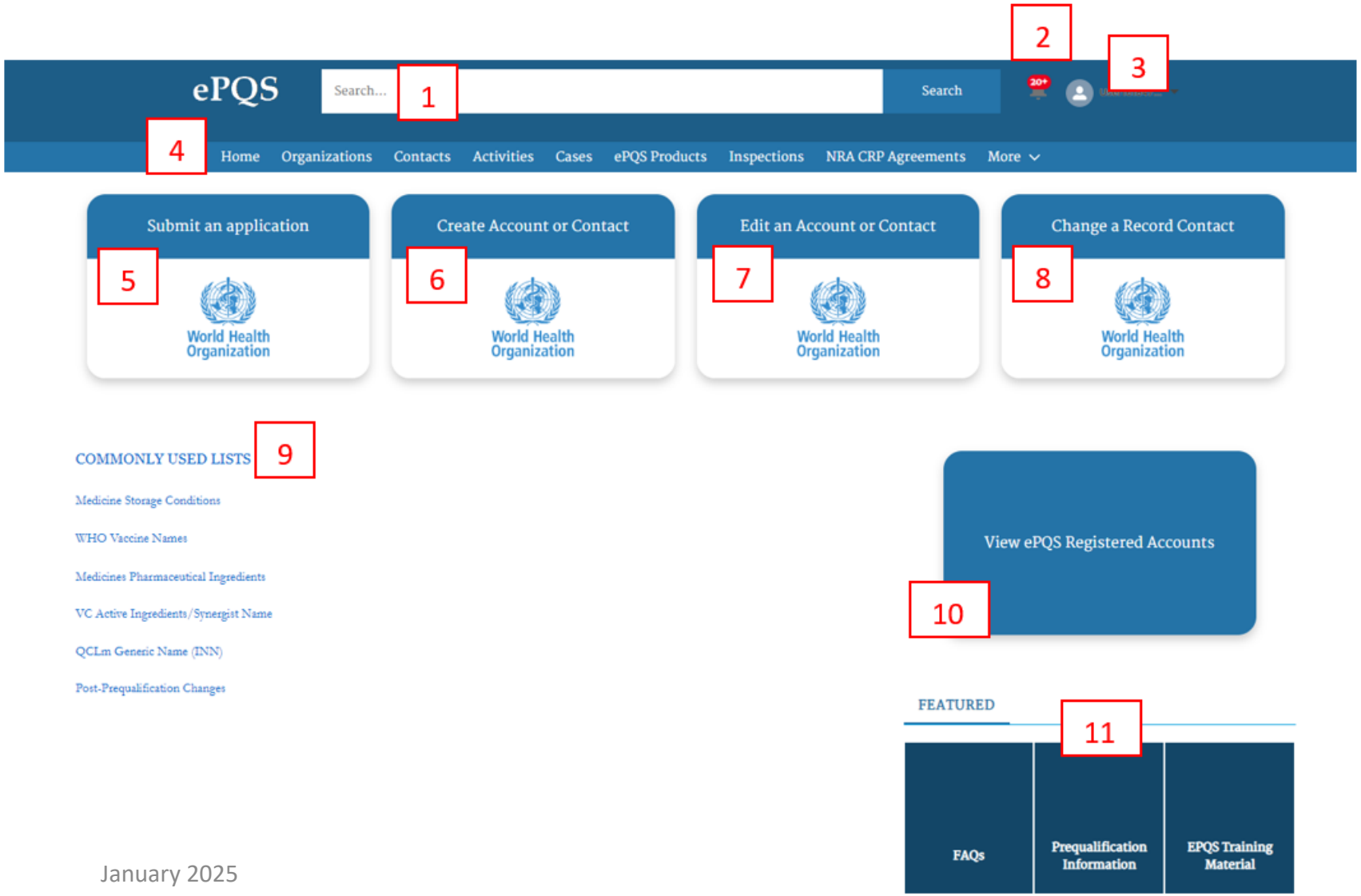
It is intended as a learning aid and ongoing reference guide.

4

Navigating ePQS – General guide

January 2025

4. ePQS navigation – Homepage map



1) Global search facility

Key word searches will retrieve any record matching the entered criteria, provided the user has access to the record.

2) Notification "Bell" Icon

System generated notifications will be recorded here.

3) Personal Settings and Profile

Using this menu you can access your personal user details and log out of the system.

4) Object Menu Bar

List views of the major record types can be accessed from this menu. The menu items will vary depending on the type of external user.

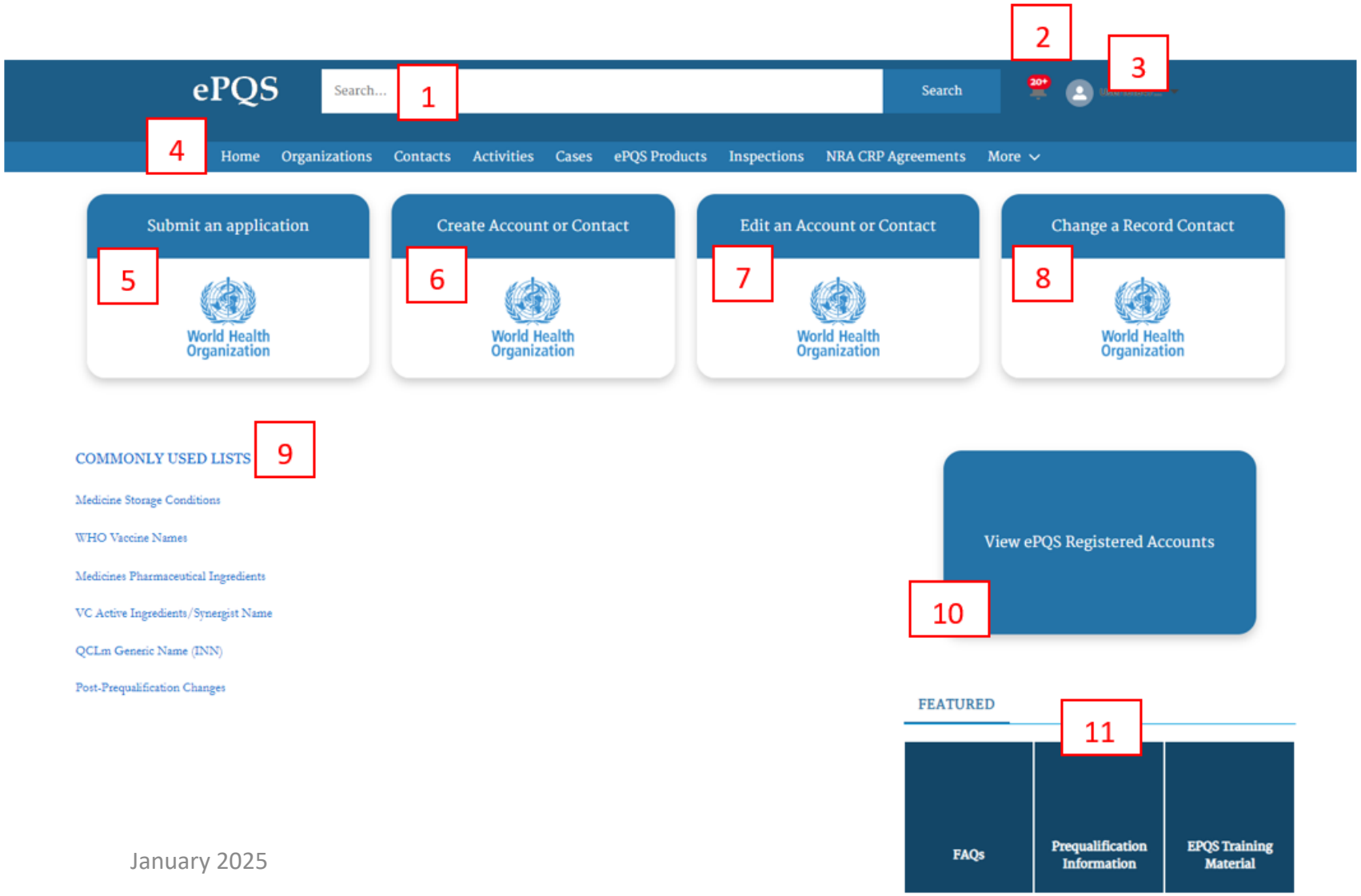
5) Application wizard

This initiates the creation of a new application

6 to 8) Contacts and Accounts

These menu items download the relevant forms for completion.

4. ePQS navigation – Homepage map



9) Commonly Used Lists

These links provide access to a series of reference lists that are referred to at various points of some application wizards.

For instance, as part of the FVP application wizard the applicant will be asked to nominate a WHO Vaccine Name. If the applicant is unfamiliar with the possible WHO Vaccine Names, they can review these from this list.

10) View ePQS Registered Accounts

Account (Organisation) records are important records referred to on product, application, inspection and product site records.

During the wizard process, if an account is not present in the ePQS database, it will not be possible, for instance, to create a manufacturing site (Product Site) for a product.

11) FAQ and training materials

Relevant reference materials and information will be made available via these links.

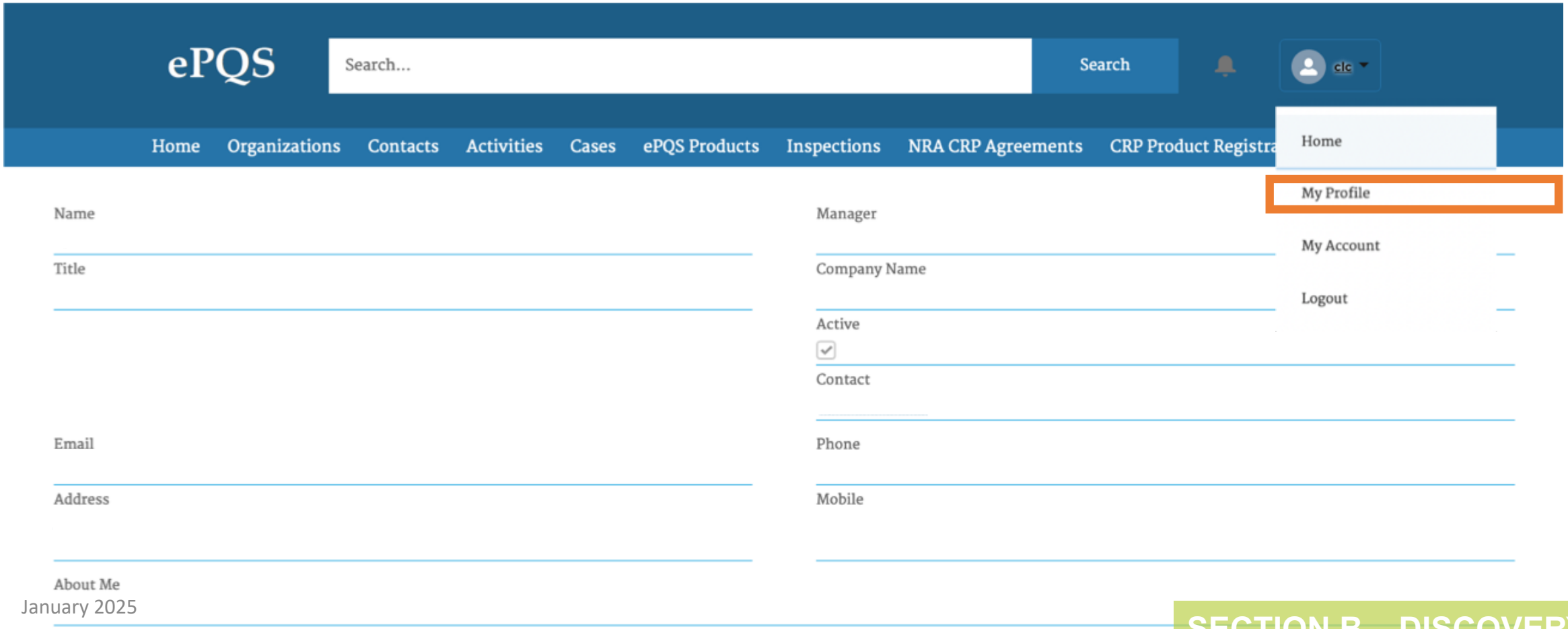
4. ePQS navigation – My profile

The “My Profile” icon is an important tool on the platform.

Select “My profile” to refer to the information that is stored in ePQS about your contact account.

4. ePQS navigation – My profile

“My profile” appearance.



4. ePQS navigation – My account

The “My account” icon provides users with access to most actions.

Select “My account” to access all related products and documents, as well as available actions.

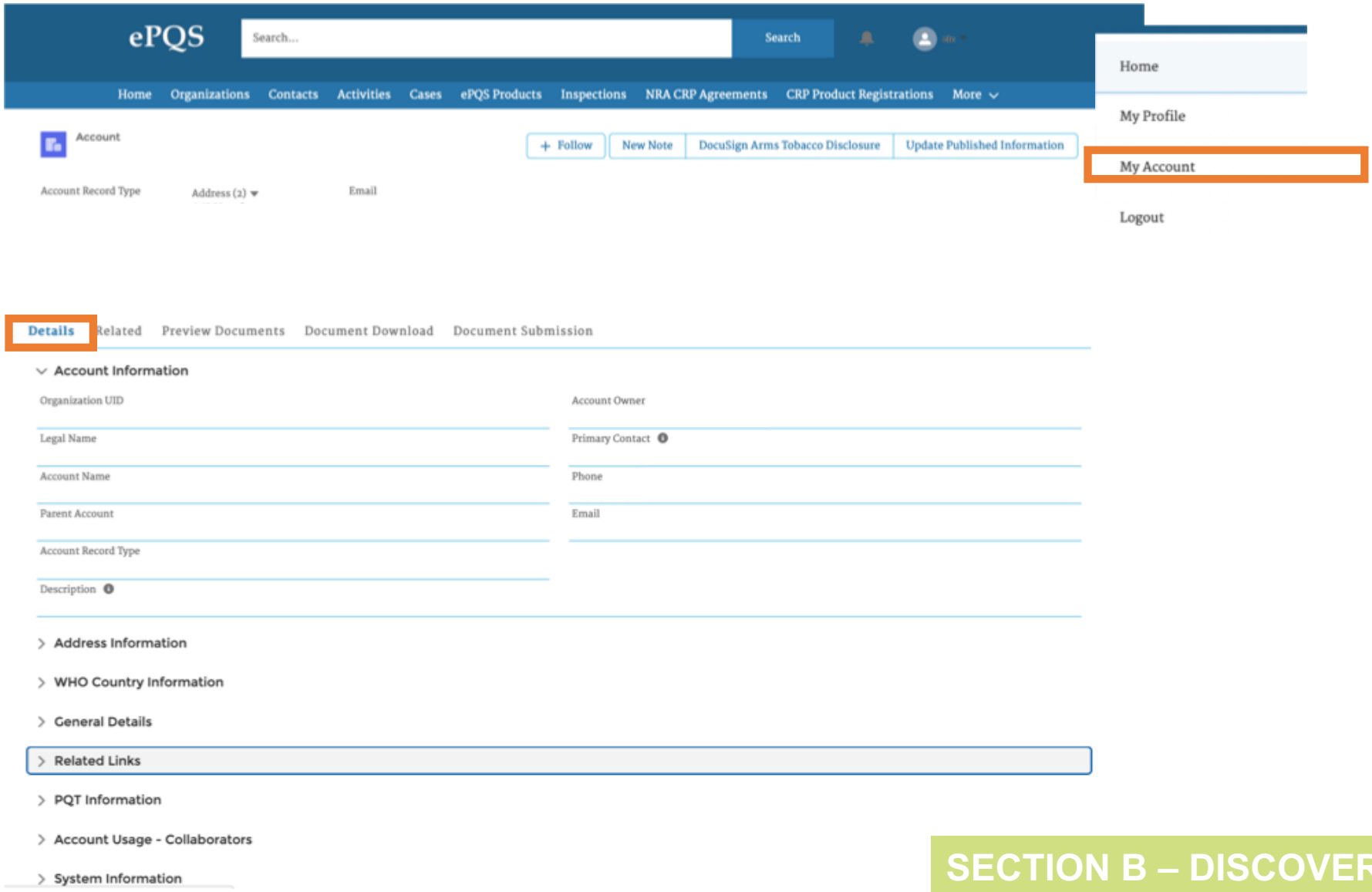
4. ePQS navigation – My account

“My account” appearance.

5 sub-tabs appear:

- Details;
- Related;
- Preview documents;
- Document download;
- Download submission.

”Details” displays the information that is stored in ePQS related to the PQ Holder (or other supplier entity) that a user is linked to**.**

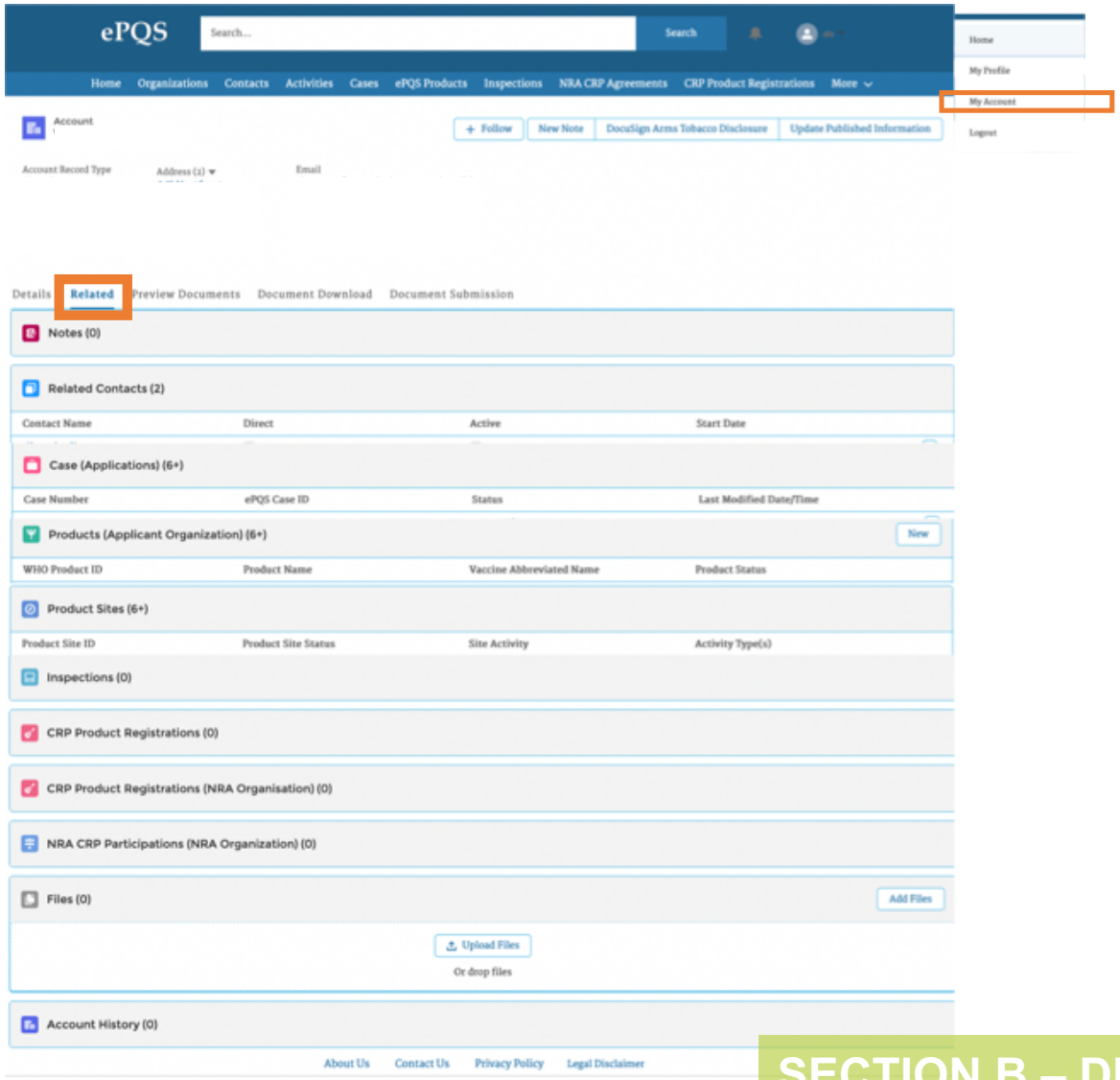


4. ePQS navigation – Related

”Related” provides a list of all records in ePQS related to a user’s account.

This includes:

- contacts;
- accounts;
- products;
- product sites;
- inspections;
- files; and
- account history**.**

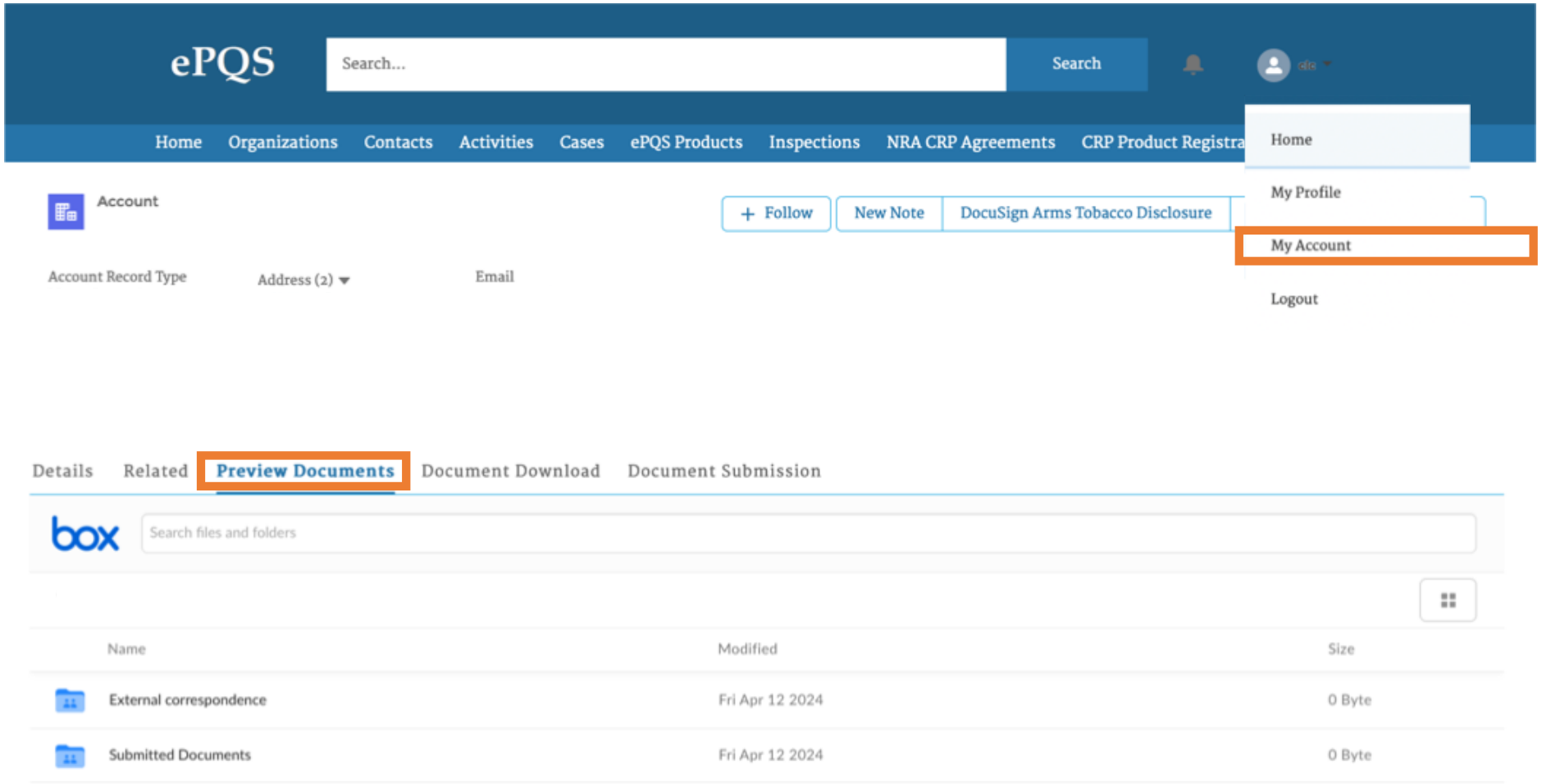


4. ePQS navigation – Documents

”Preview documents” is a reference library of all documents related to a user’s account.

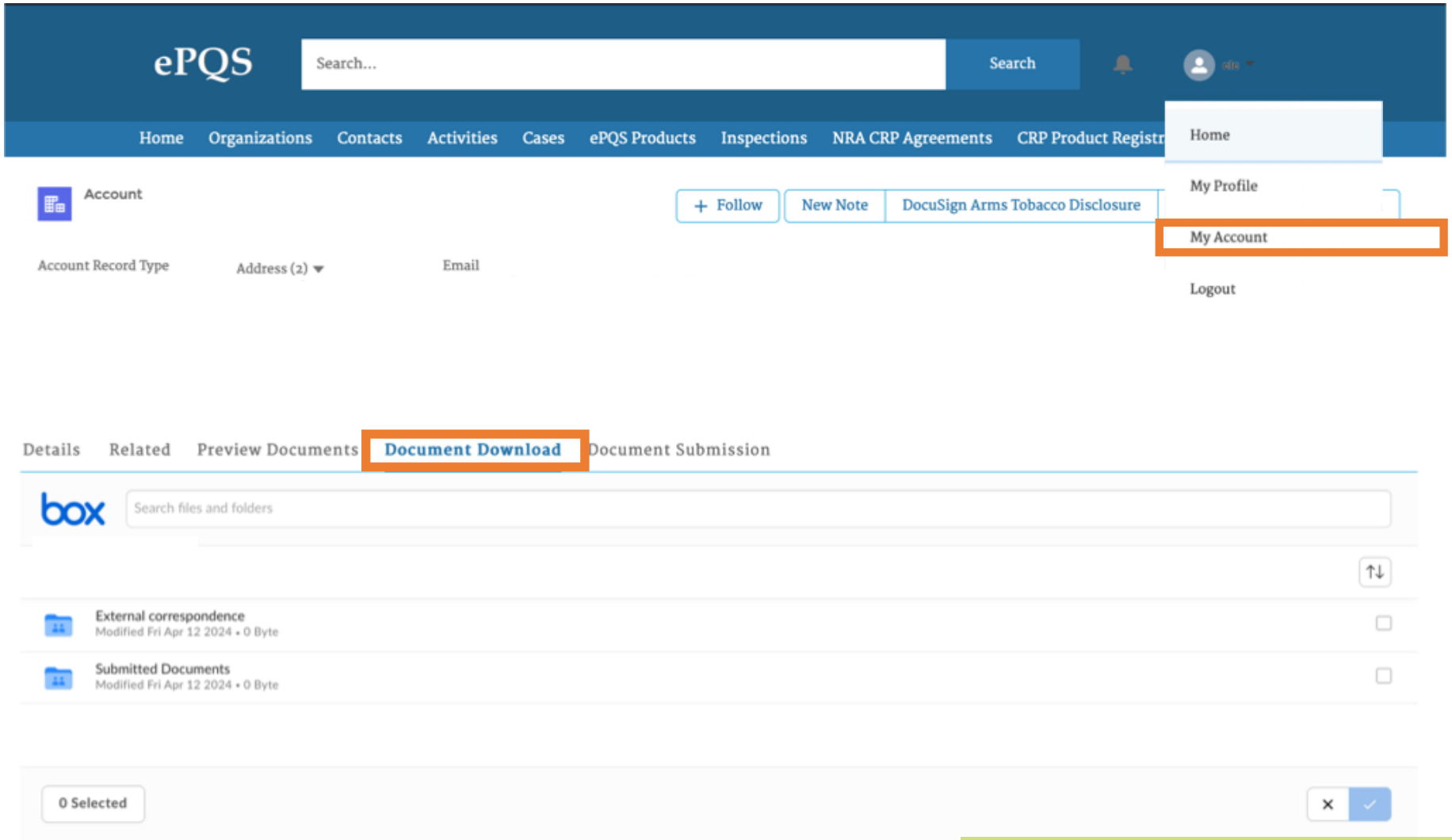
“External correspondence” contains the documents users have submitted as correspondence with the IMD-PQS Secretariat.

“Submitted documents” contains the documents uploaded to the account, or as part of an application wizard process.



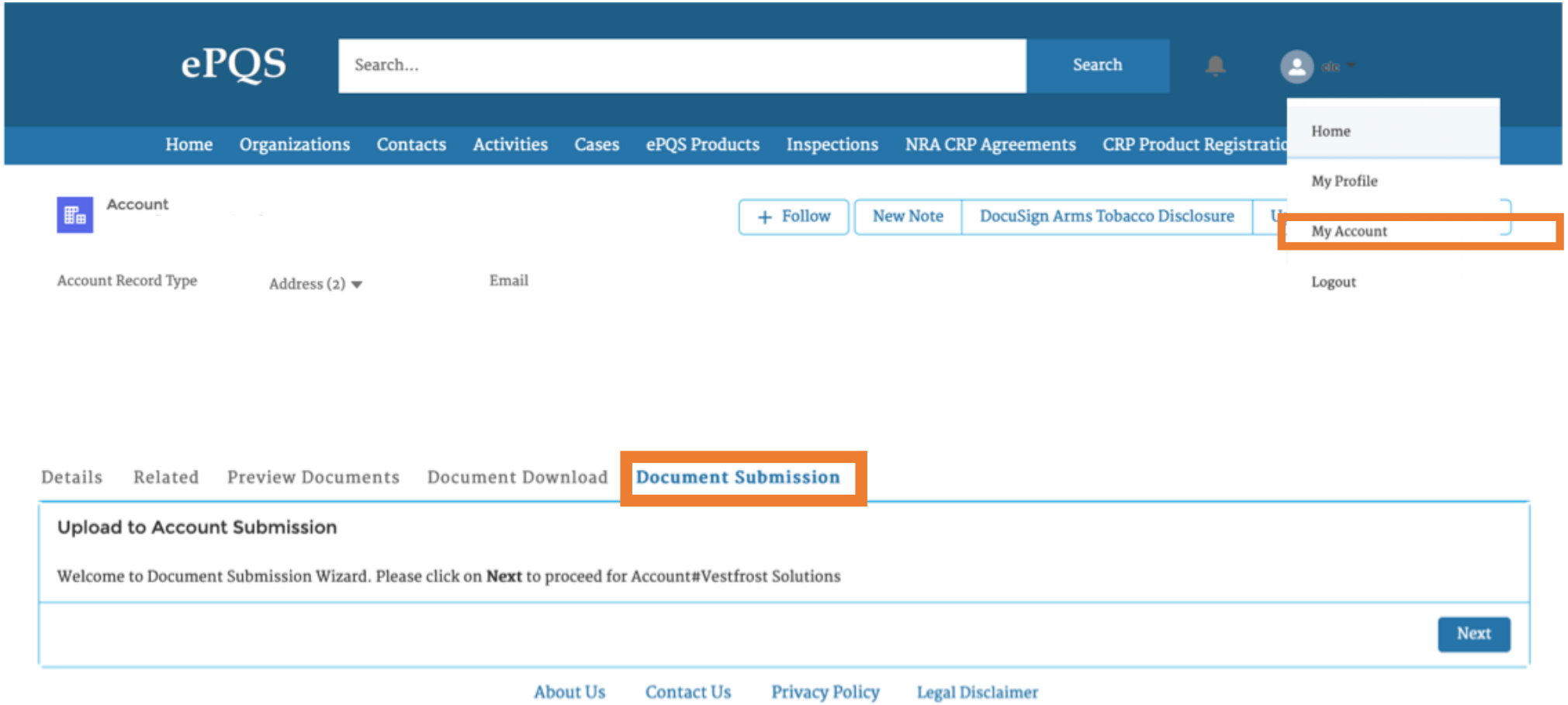
4. ePQS navigation – Documents

”Download documents” allows users to download and save locally all the documents related to their account.



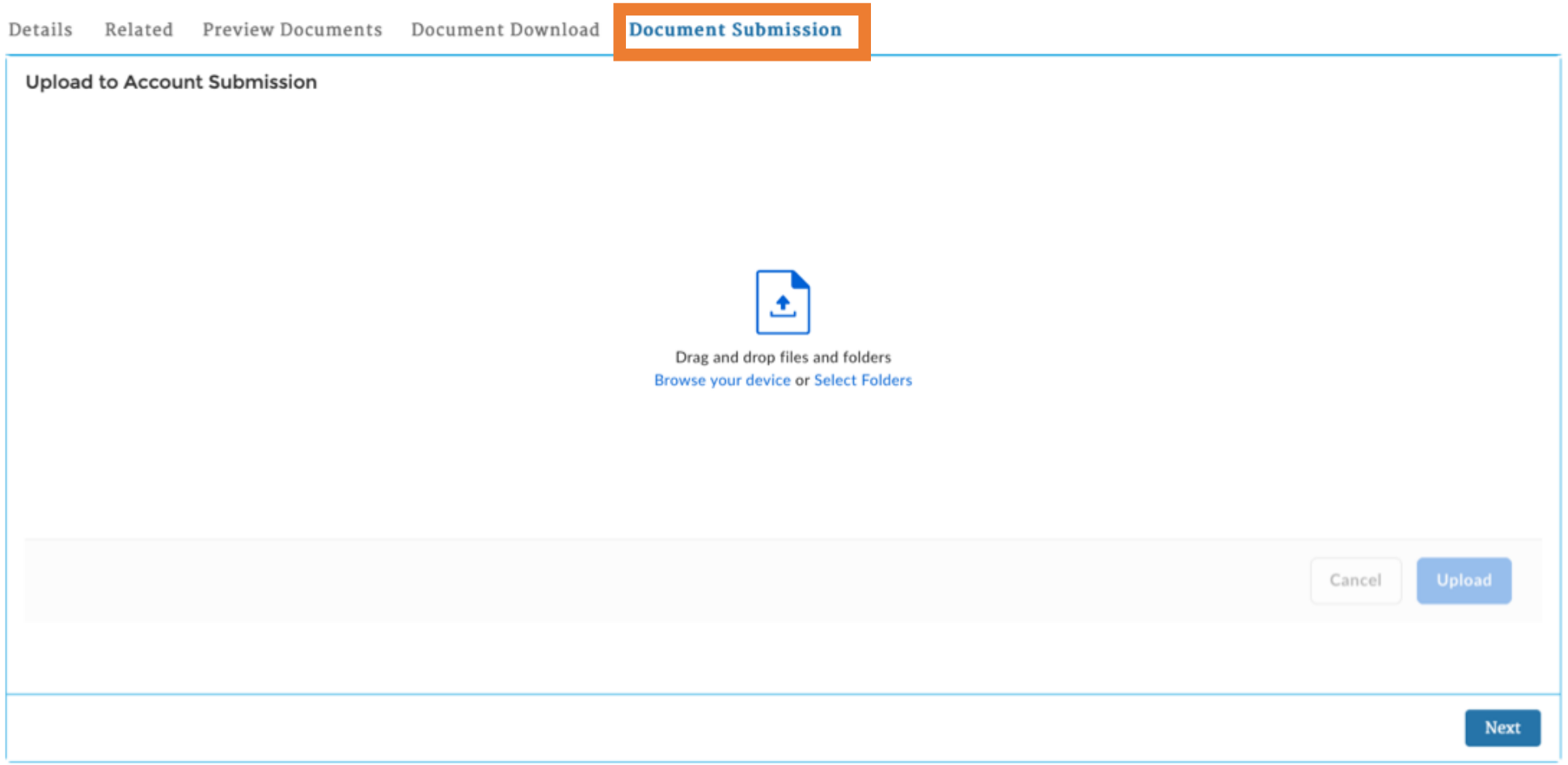
4. ePQS navigation – Documents

”Document submission” enables users to upload documents to their account.



4. ePQS navigation – Documents

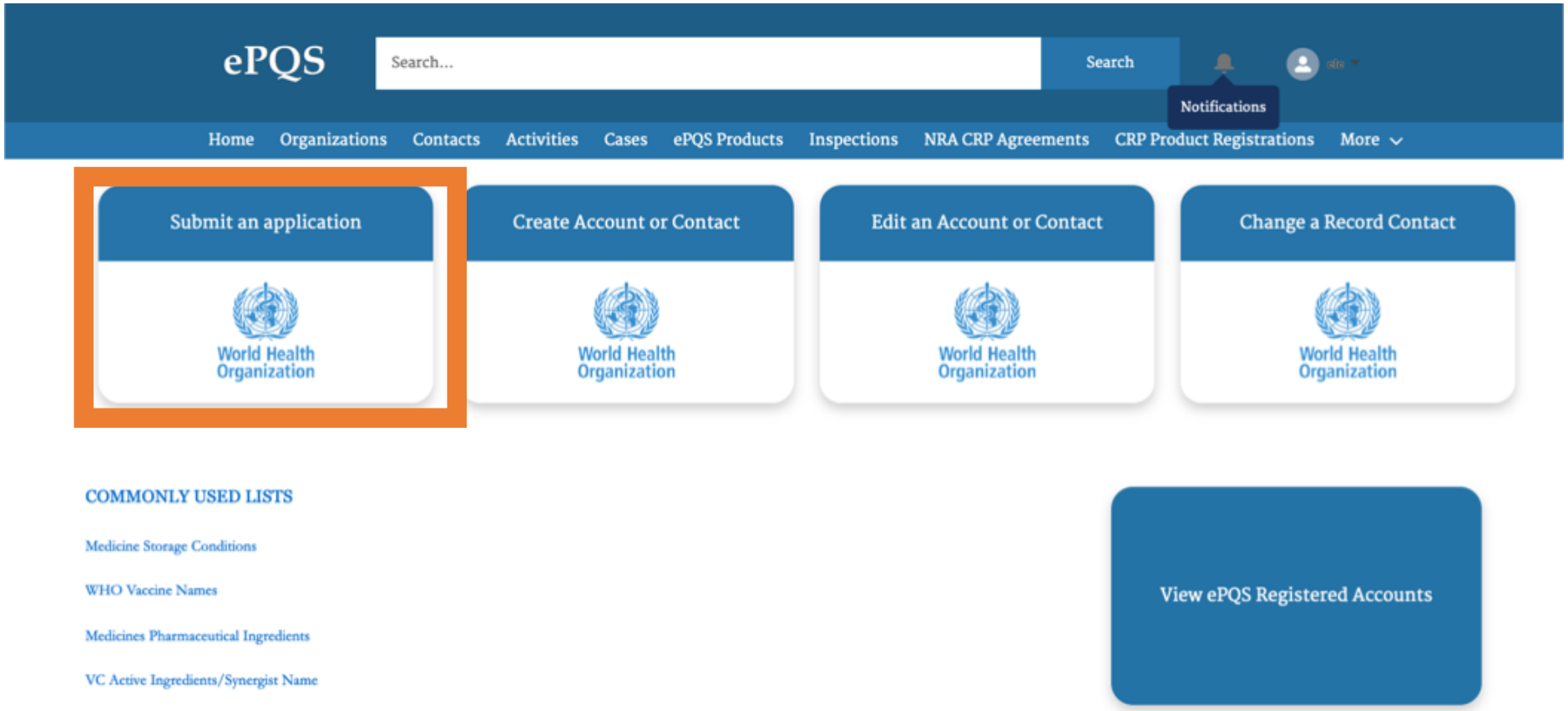
”Document submission” interface allow users to upload documents by drag-and)drop or browsing their device.



4. ePQS navigation – Wizard

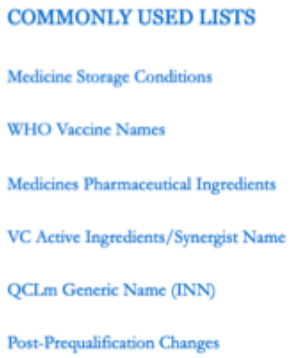
“Submit an application” tab provides access to the **“Application Wizard”** for prequalification applications and post-PQ variation submissions.

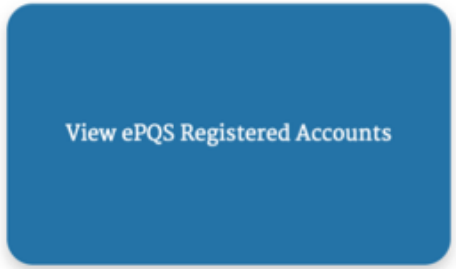
It is **MANDATORY** to complete the Application Wizard **IN FULL**, including all product specification data, before submitting the applications.



4. ePQS navigation – Forms

The three other tabs on the homepage provide access to application forms to request the creation or editing of your account or associated contact details.

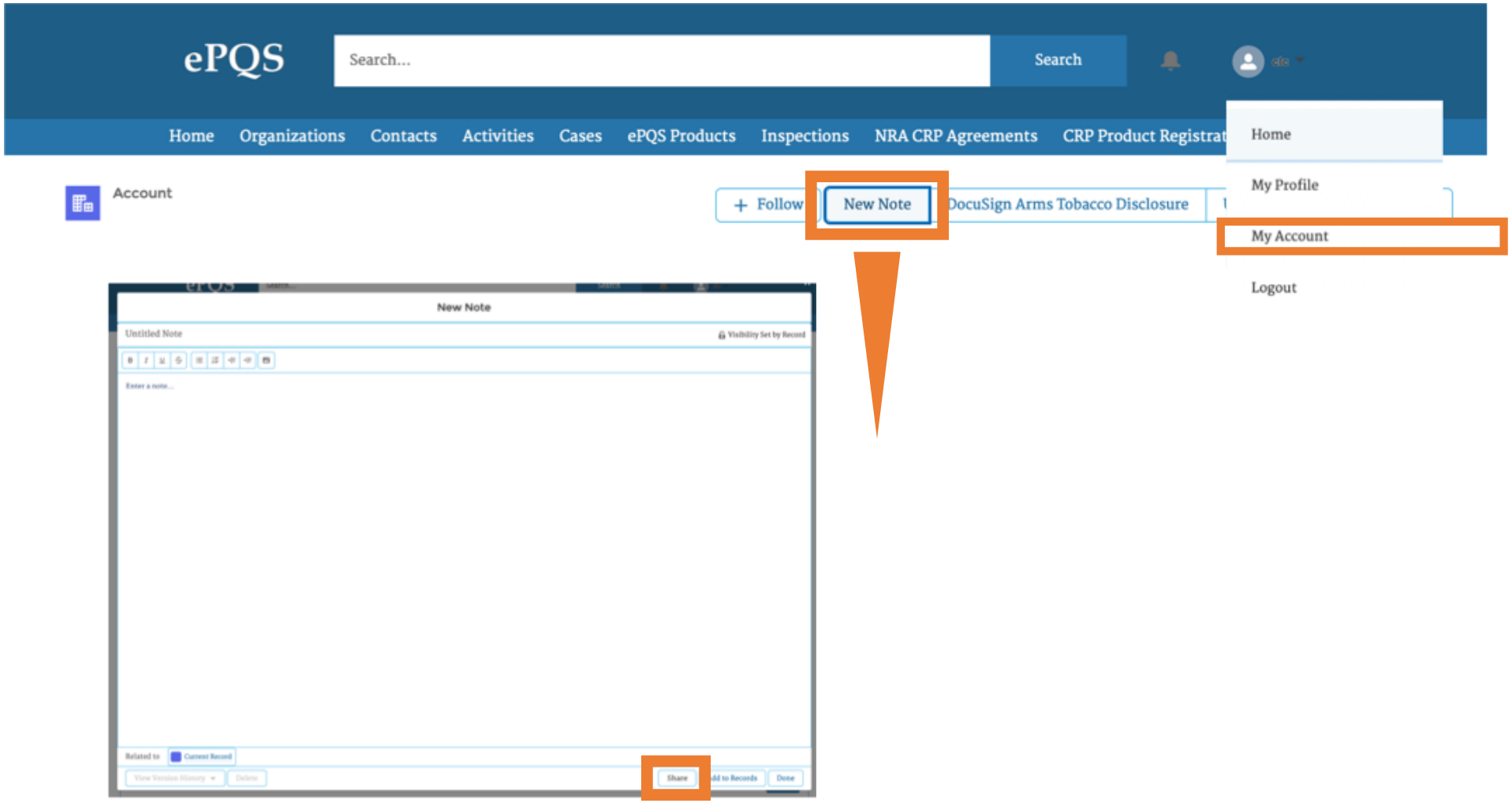




4. ePQS navigation – Notes

Under the users **“account”** interface, users may also create **“notes”.**

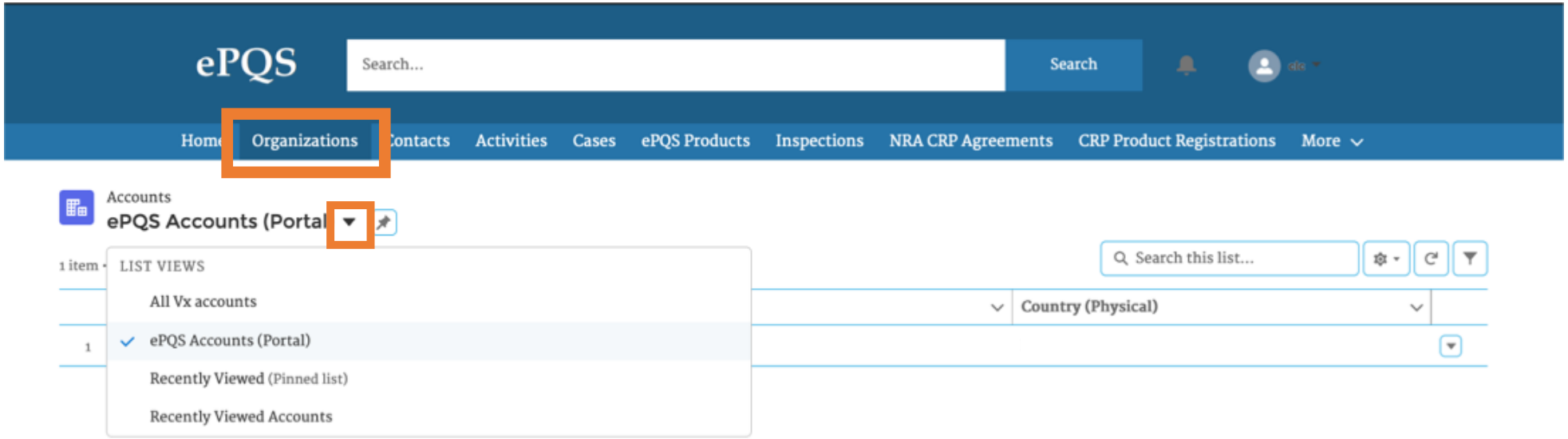
Notes may also be shared with others (users’ contacts or internal / WHO users).



4. ePQS navigation – Organisations

Via the **“Organisations”** tab users can access a list of all organisation accounts associated with their own.

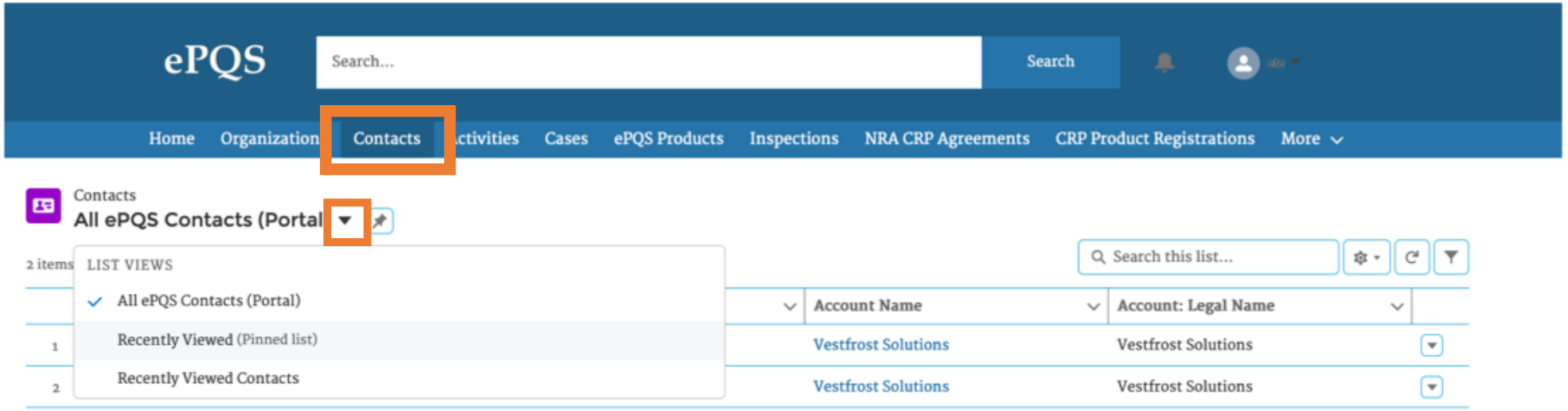
Various **list views** are available using the inverted arrow; including “all” and “recently viewed”



4. ePQS navigation – Contacts

Via the main **“Contacts”** tab, users can access a list of all organisation accounts associated with their own.

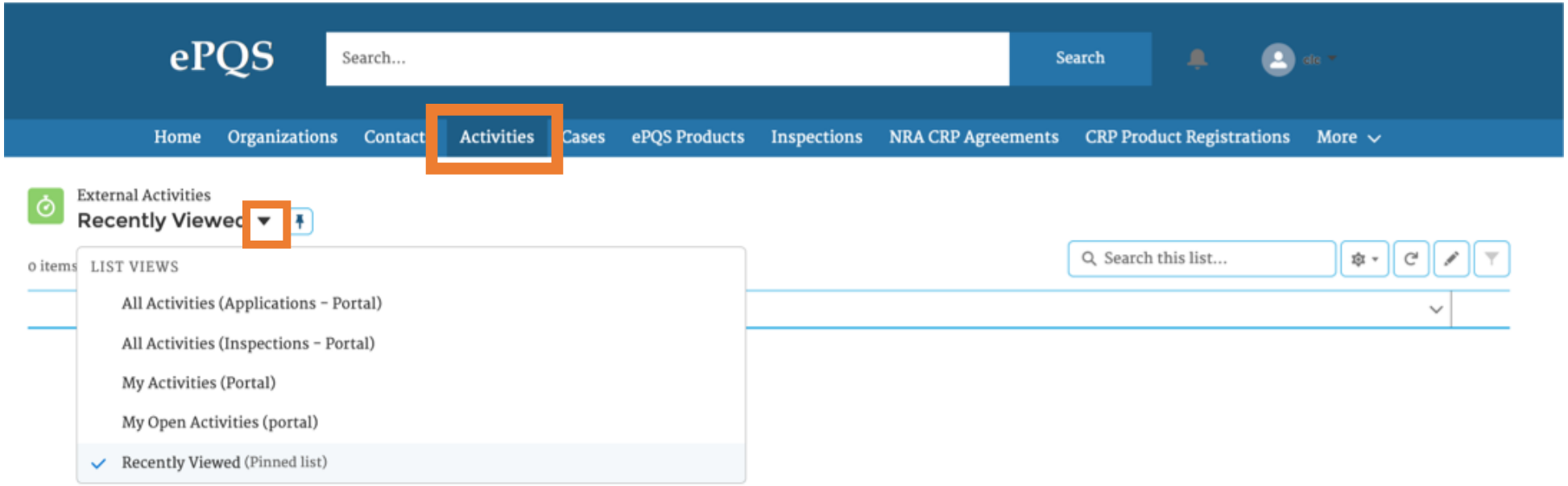
Various **list views** are available; including “all” and “recently viewed”



4. ePQS navigation – Activities

Via the **“Activities”** tab, users can access a list of all the **“external activities”** related to their account. This includes applications, post-PQ variants and inspections.

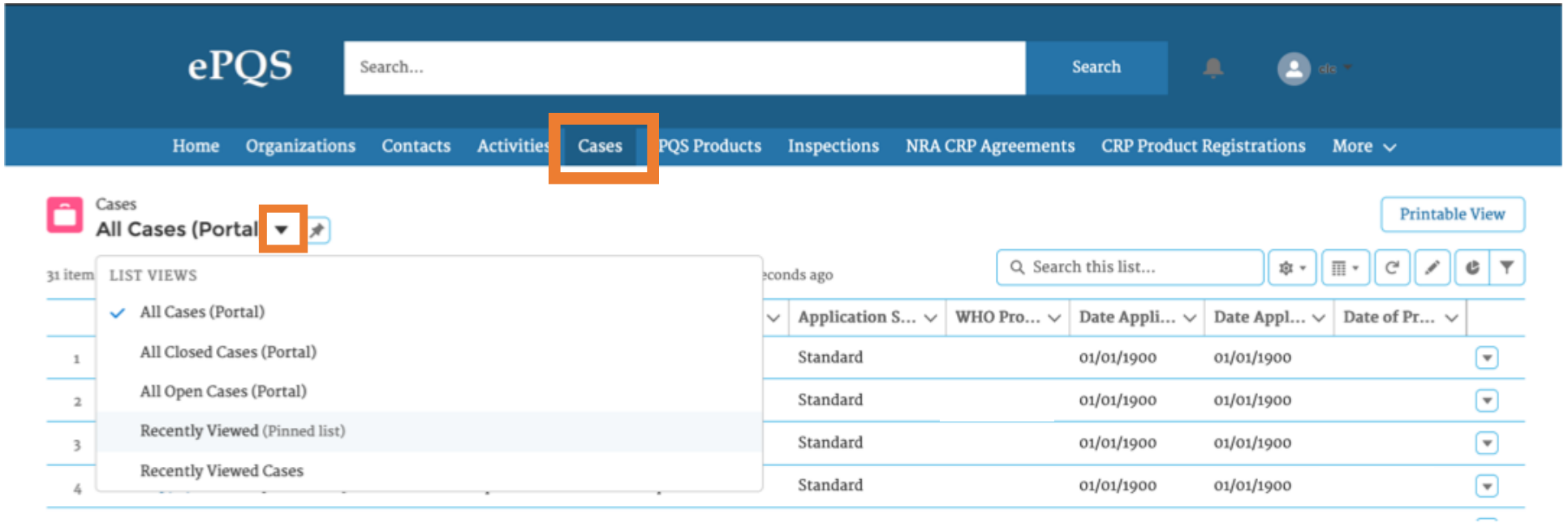
Various **list views** are available; including “My activities” and “recently viewed”



4. ePQS navigation – Cases

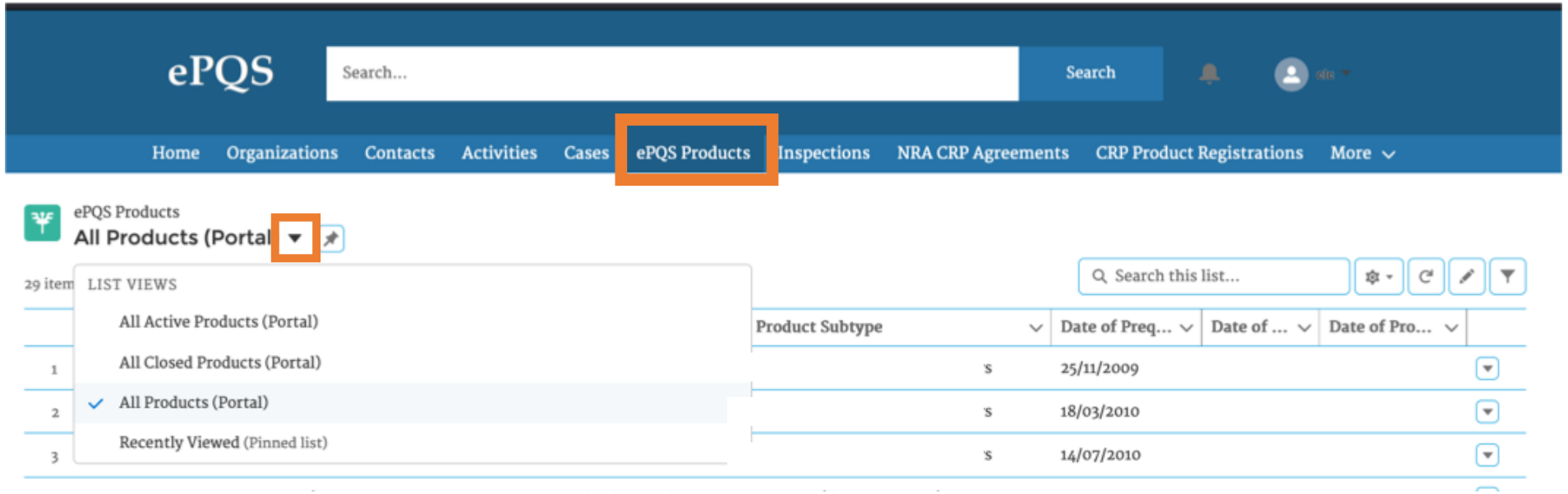
Likewise, a list of all **“cases”** relevant to a user’s account is available via the main tab.

Available **list views** include “Open cases”, ”Closed cases”, “All” and “Recently viewed”.



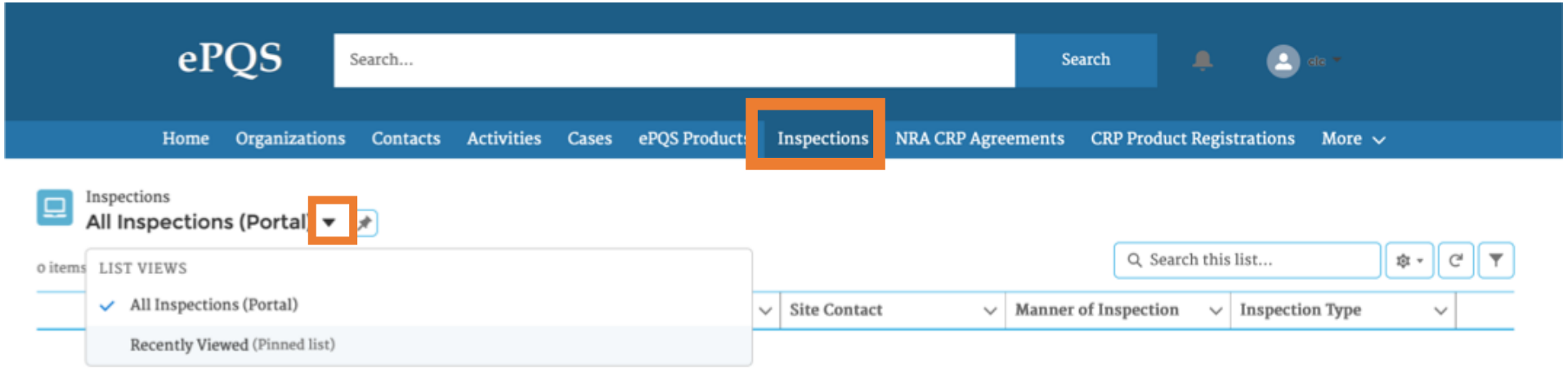
4. ePQS navigation – Products

Likewise, a list of all **“products”** related to a user’s account is available via the main tab.



4. ePQS navigation – Inspections

And a list of all **“Inspections”** related to a user’s product sites is available via the main tab.



4. ePQS navigation – Bell

The **bell notification** provides an overview of all the outstanding notifications and actions relevant to a user's account.

SECTION C
– APPLICATION PROCEDURES

5

Step-by-step guide

5. Step-by-step guide

ePQS activities required of a user to set-up their account and to process applications and associated processes include:

a. Verifying product data records
b. Verifying access, accounts and contact details
c. Verifying correct record visibility and correct product list visibility
d. Accessing and verifying functionality of personal user folder
e. Submitting applications (if applicable)
f. Submitting post-PQ variation submission (if applicable)
g. Uploading documents (related to the submission)
h. Downloading documents shared with the applicant
i. Assigning activities to applicants
j. Verifying bell and email notifications associated with actions

5a

Verification of product data sheets

5a. Verification of product records

TASK

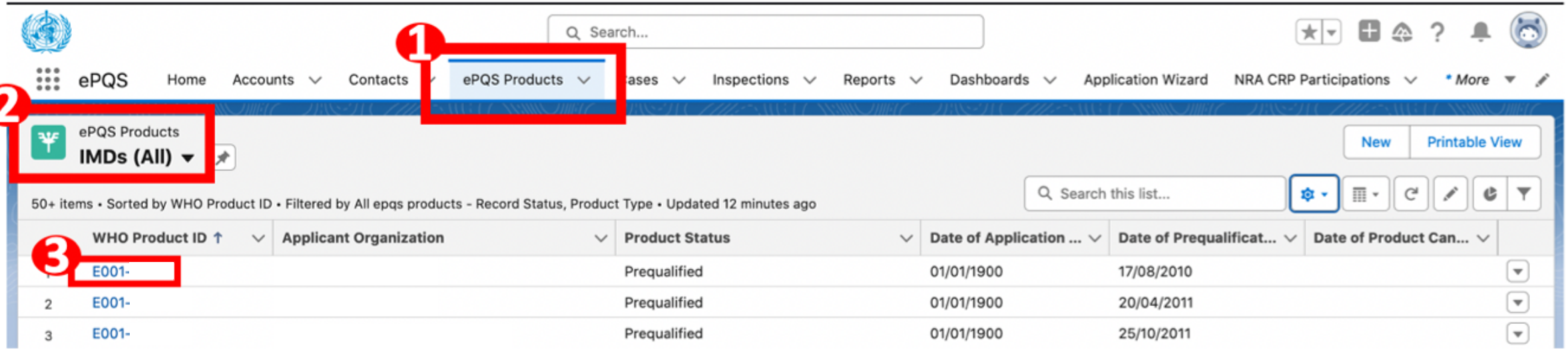
Once registraton and access is obtained, existing PQ Holders and new applicants must first verify that all data is correct on each of their product pages.

@ Communicate any omissions or errors to: pqsinfo@who.int & huckerbyg@who.int using the relevant change request form linked on slide 60 of this deck.

5a. Verification of product data records

Registered users may find their product data records for verification:

1. On the ePQS homepage, select the **“ePQS Products”** tab.
2. In **“list view”** select **“IMDs (All)”**
3. In this view users can select individual prequalified products



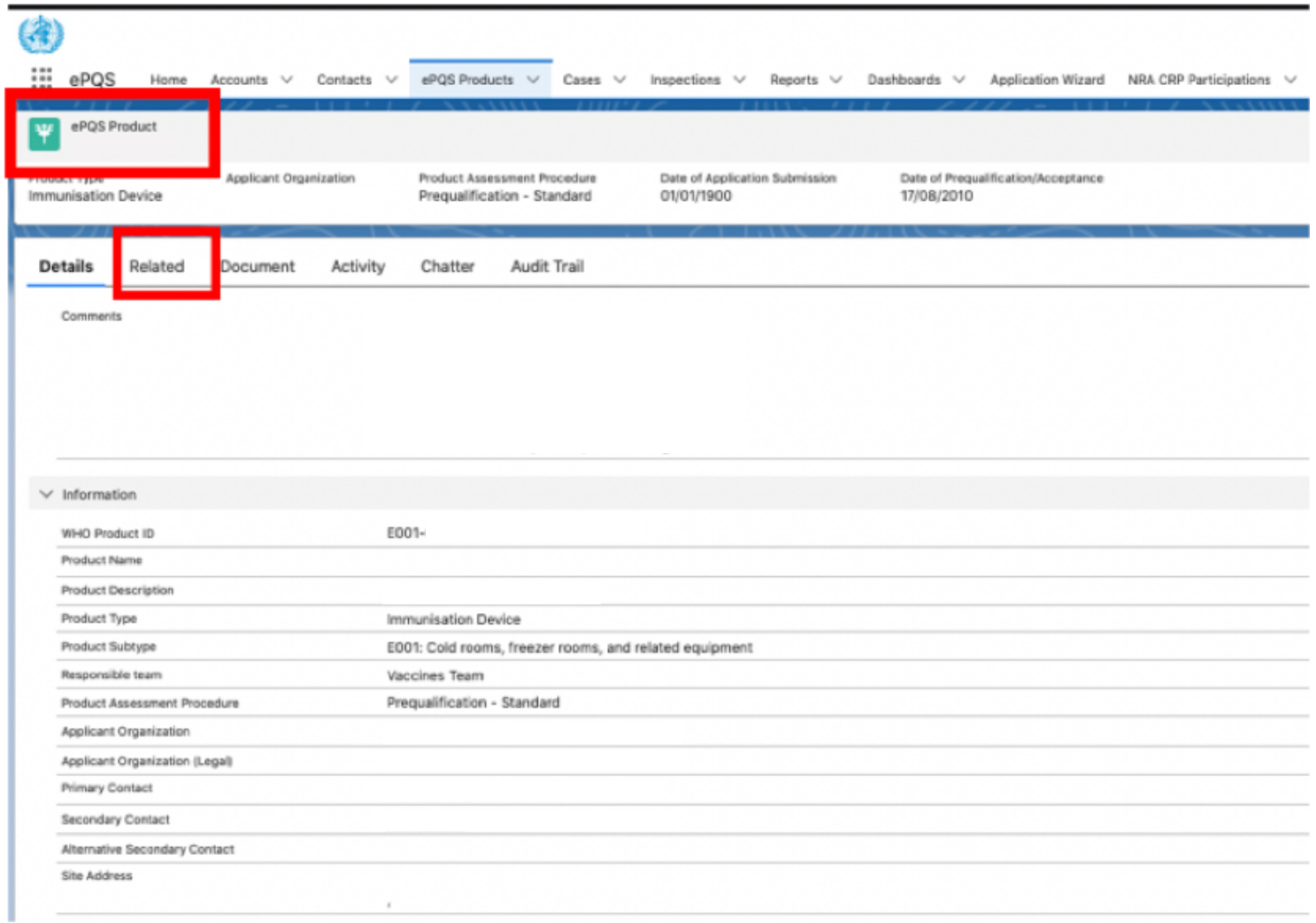
5a. Verification of product data records

Users should click on the product code **“E00X-XXX”** to view the relevant “Product page”.

Important: users need to progress further to the “**Product Variant page**” to see product’s technical specifications.

Users should click on the

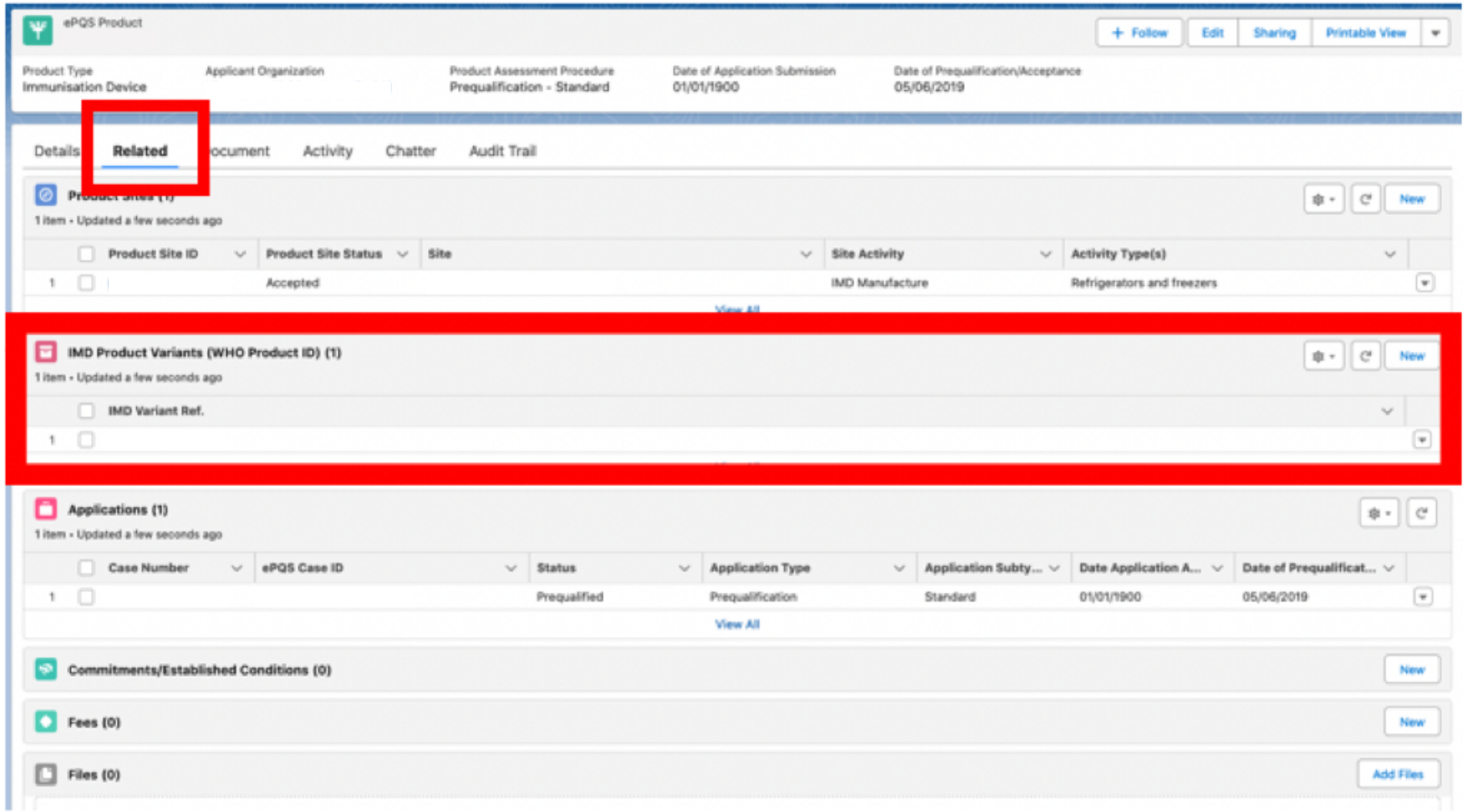
“Related” sub-tab.



5a. Verification of product data records

“Related” brings up a list of the record-types related to this specific product.

Select the record displayed under **“IMD Product Variant”**



5a. Verification of product data records

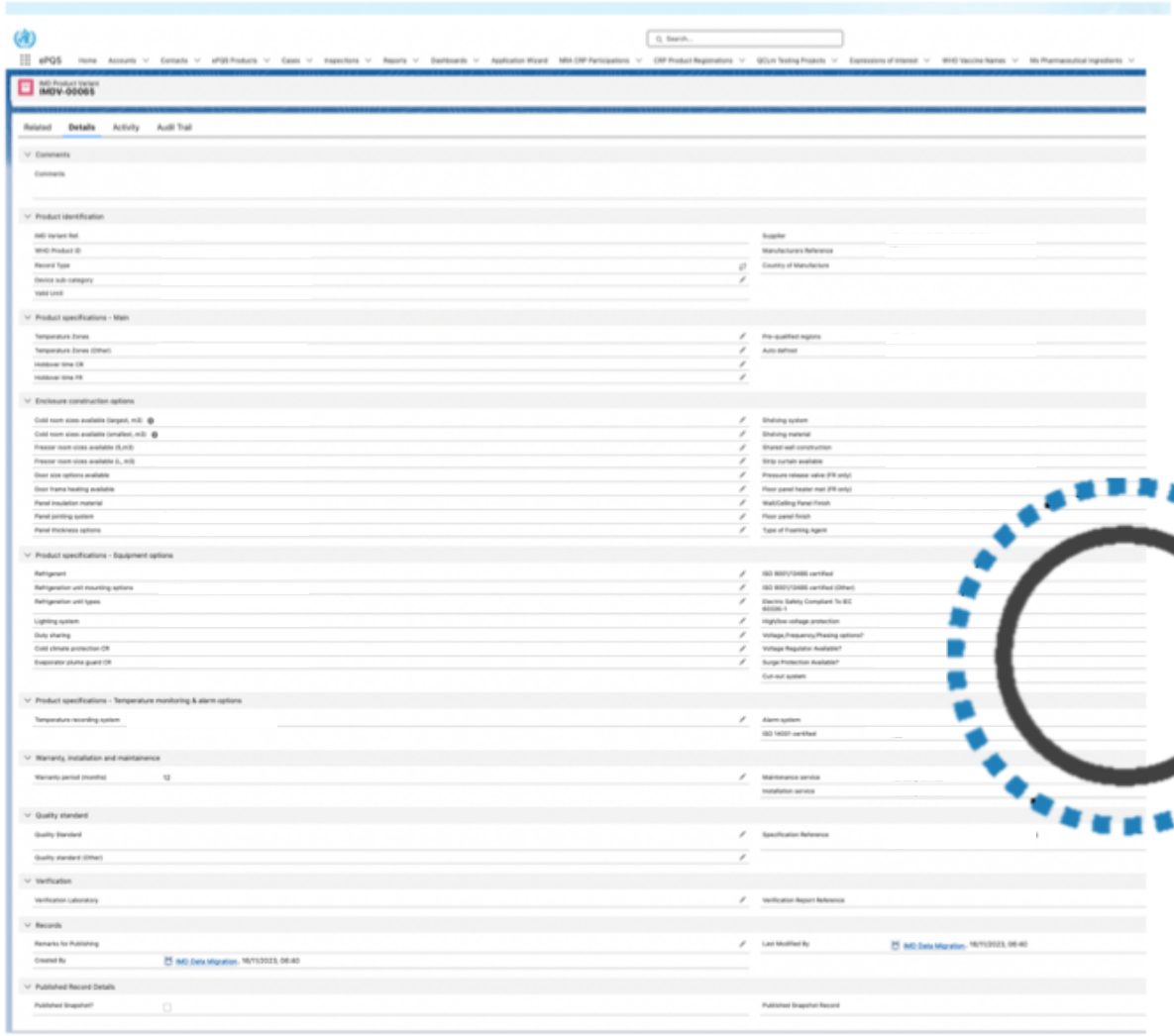
This brings the user to the "**product variant page**" (e.g. here for E001)

USER TASK →

- Review all data fields

- Report any errors or issues to the IMD-PQS Secretariat: pqsinfo@who.int & huckerbyg@who.int

- To report issues please use the templates on the following slide.



5a. Verification of product data records

Product Data Sheet feedback forms are available on the IMD-PQS website here:

https://extranet.who.int/prequal/immunization-devices/prequalification-guidance-applicants-prequalification-holders

There, users will find a feedback form for each category:

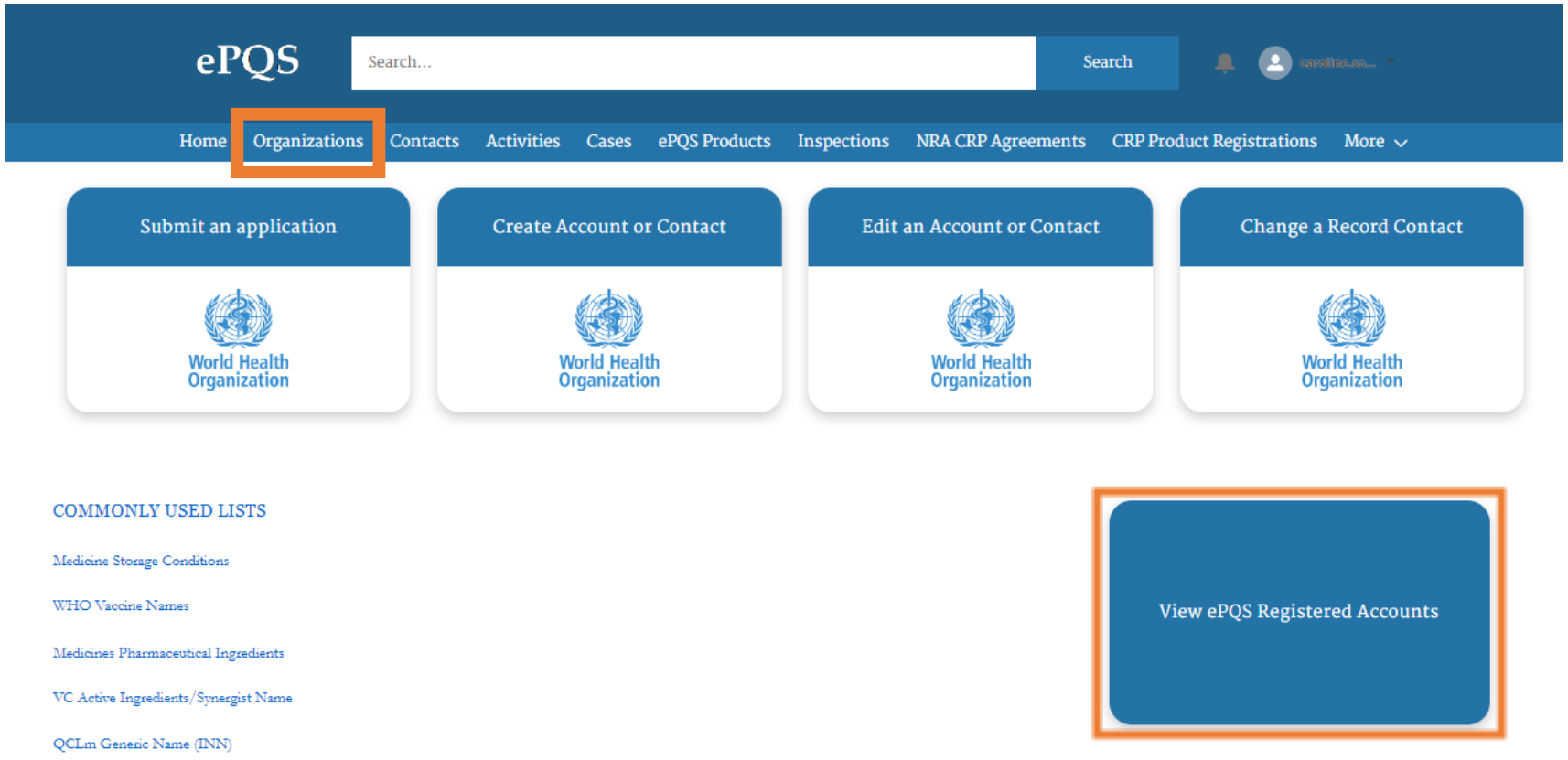
- IMD-PQS Data Sheet feedback form E001
- IMD-PQS Data Sheet feedback form E002
- IMD-PQS Data Sheet feedback form E003
- IMD-PQS Data Sheet feedback form E004
- IMD-PQS Data Sheet feedback form E005
- IMD-PQS Data Sheet feedback form E006
- IMD-PQS Data Sheet feedback form E007 Energy Harvest Control
- IMD-PQS Data Sheet feedback form E007 Voltage Stabilisers
- IMD-PQS Data Sheet feedback form E008
- IMD-PQS Data Sheet feedback form E010
- IMD-PQS Data Sheet feedback form E013

5b

Accessing registered accounts

5b. Accessing registered accounts

To access a list of all accounts related to their own account, users should click either on **“Organisations”** or **“View ePQS Registered Accounts”.**



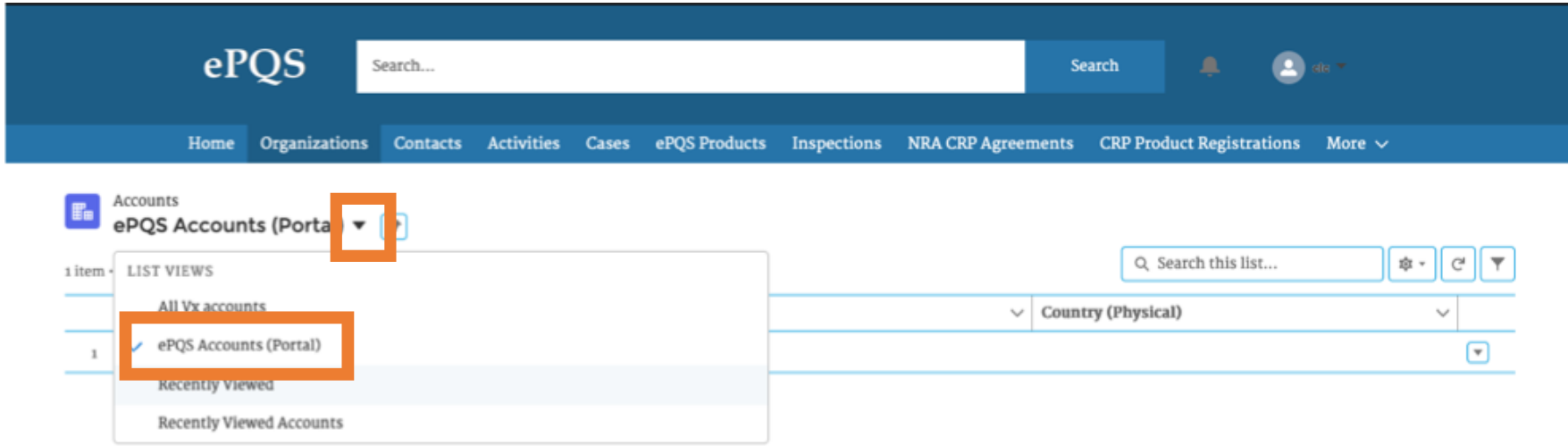
5b. Accessing registered accounts

Users may select different **list views**.

Recommended: **“ePQS Accounts”**.

Users should **review each record** that appears in the list:

Account types include:
- Non-State actors (private sector)
- Government institutions
- Institution
- Committee

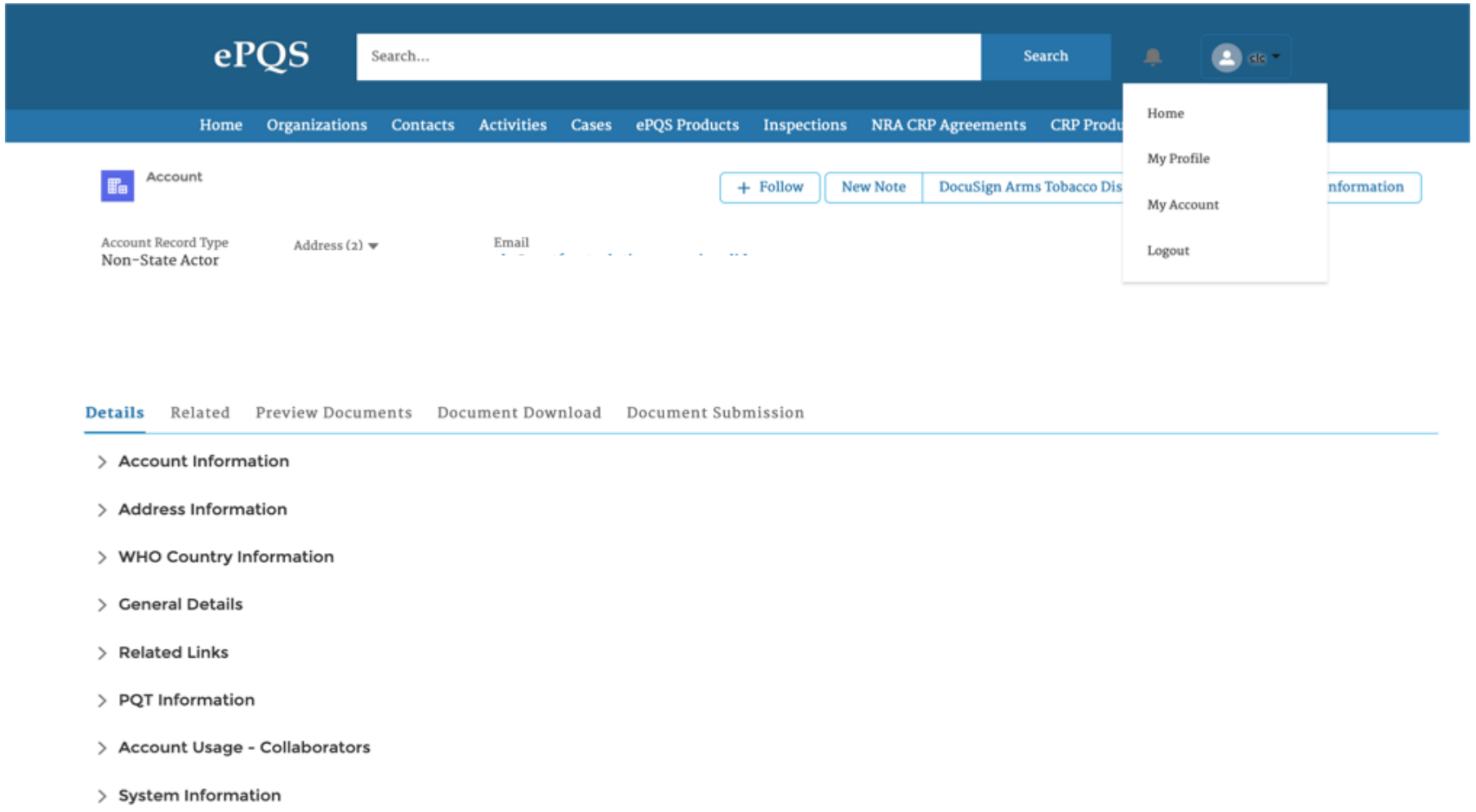


*** As an IMD-PQS prequalified manufacturer or reseller, the only account to which a user is associated is their own company.

5b. Accessing registered accounts

Inside each account record, users should **open each drop down section** (“Account information”, “Address information” etc.) and **verify that the data** and information contained inside each is correct.

- Report any errors or issues to the IMD-PQS Secretariat: pqsinfo@who.int & huckerbyg@who.int



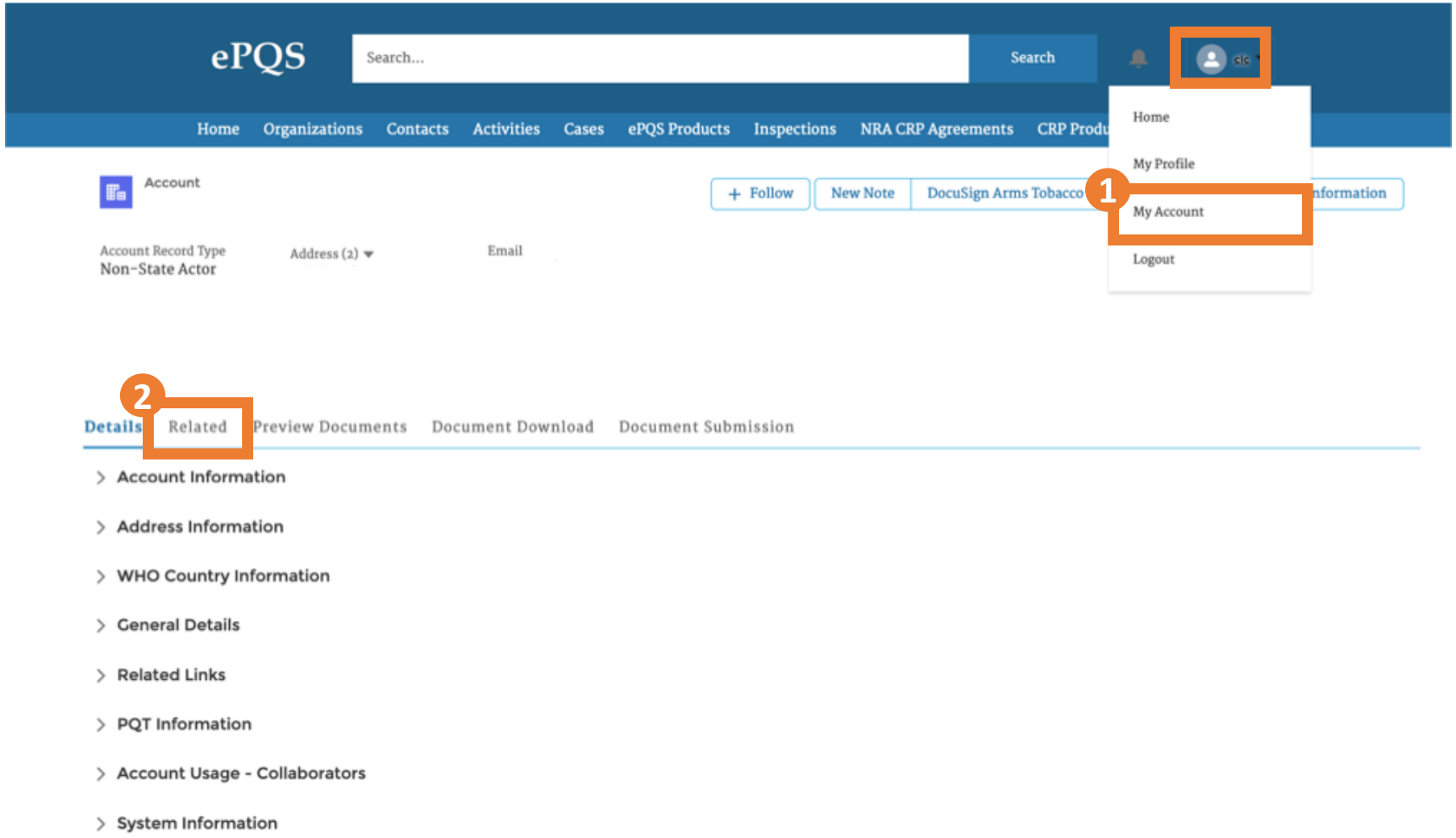
5c

Correct record visibility

5ci. Correct record visibility

1. Users should click on their profile icon, and select **“My Account”**.

2. Then, click on the sub-tab **“Related”**.



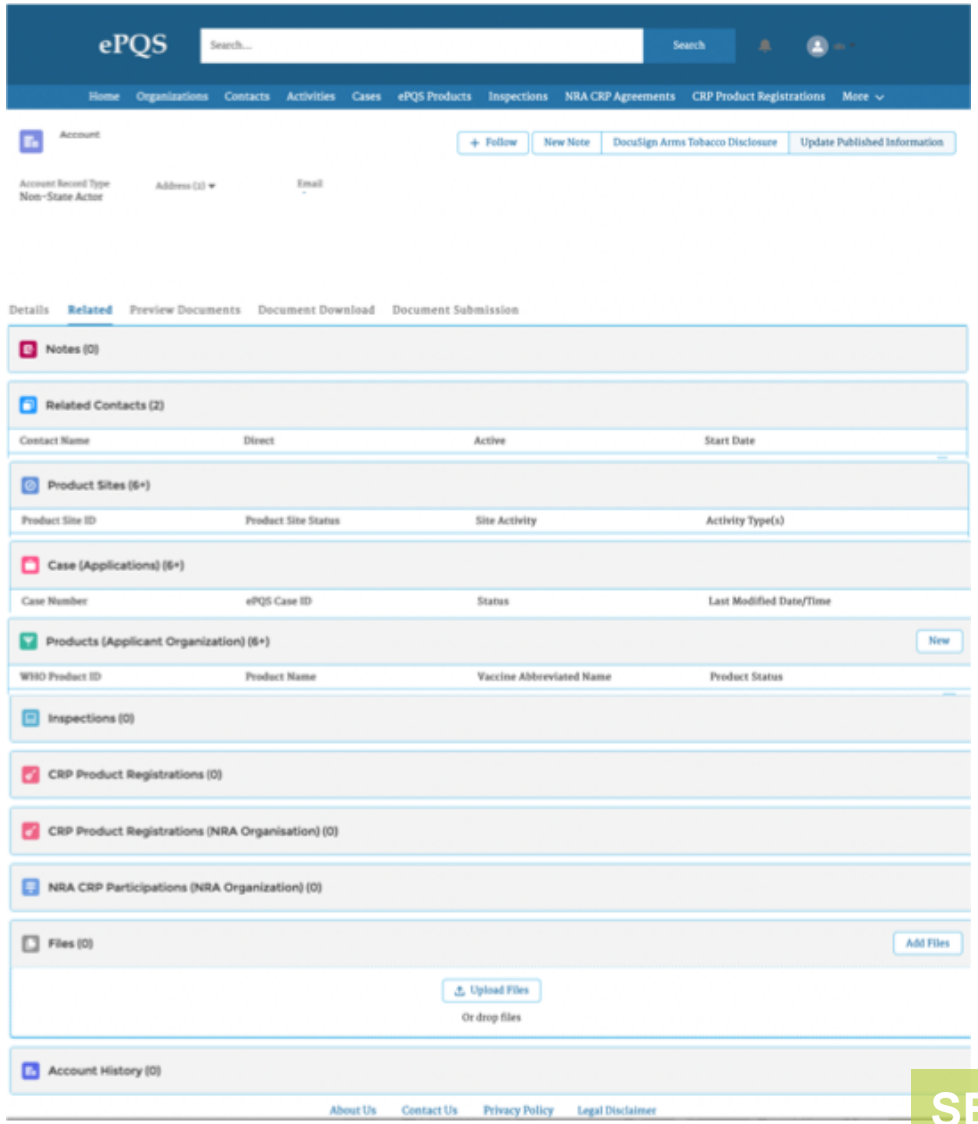
5ci. Correct record visibility

The **“Related”** sub-tab displays all records, of all types, related to a user’s account.

Users should **open and view** each type of record.

Ensure that each of the following types of records are visible:

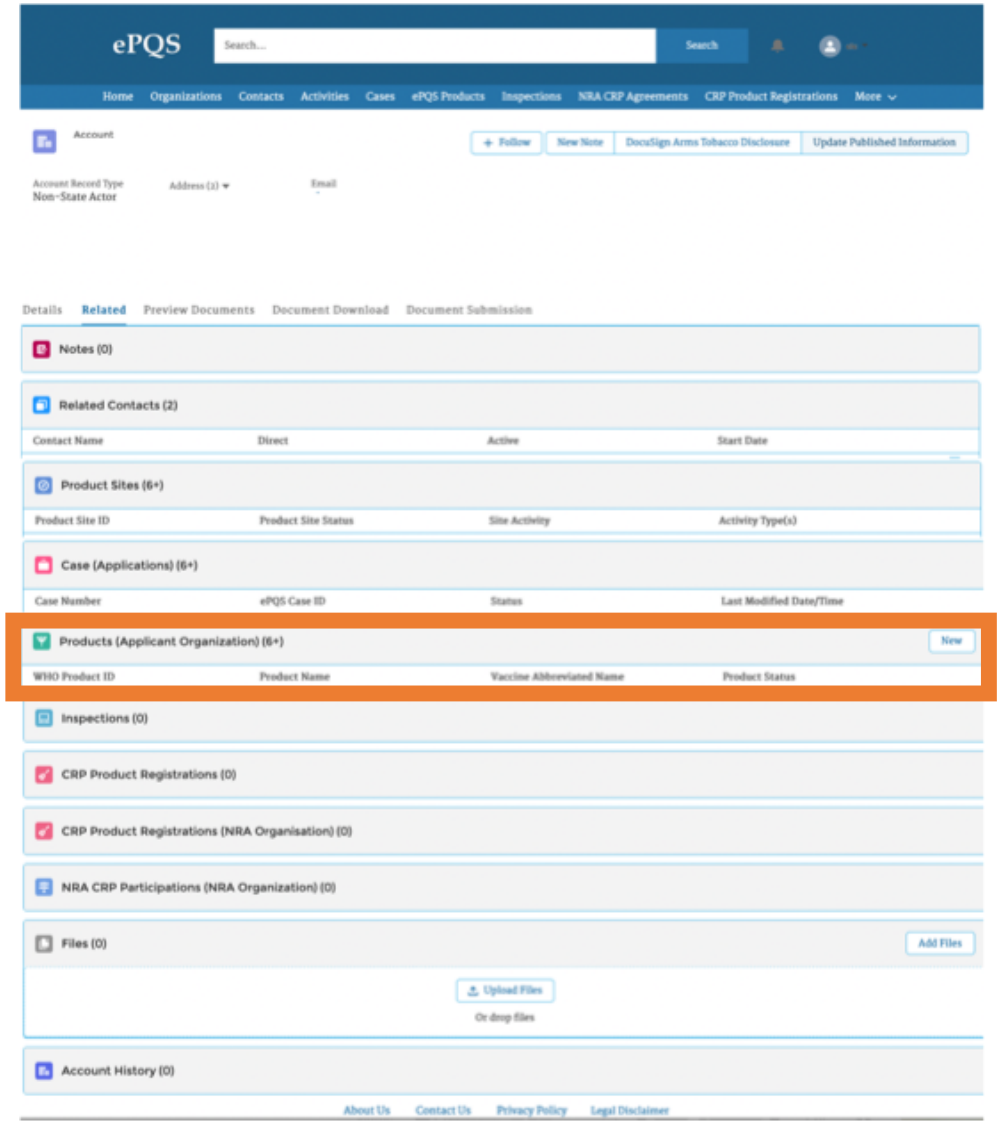
- Notes
- Related contacts
- Product sites
- Case
- Products
- Files
- Account history



5cii. Correct record visibility - Products

Products

Expand or click directly on the Products sub-tab.

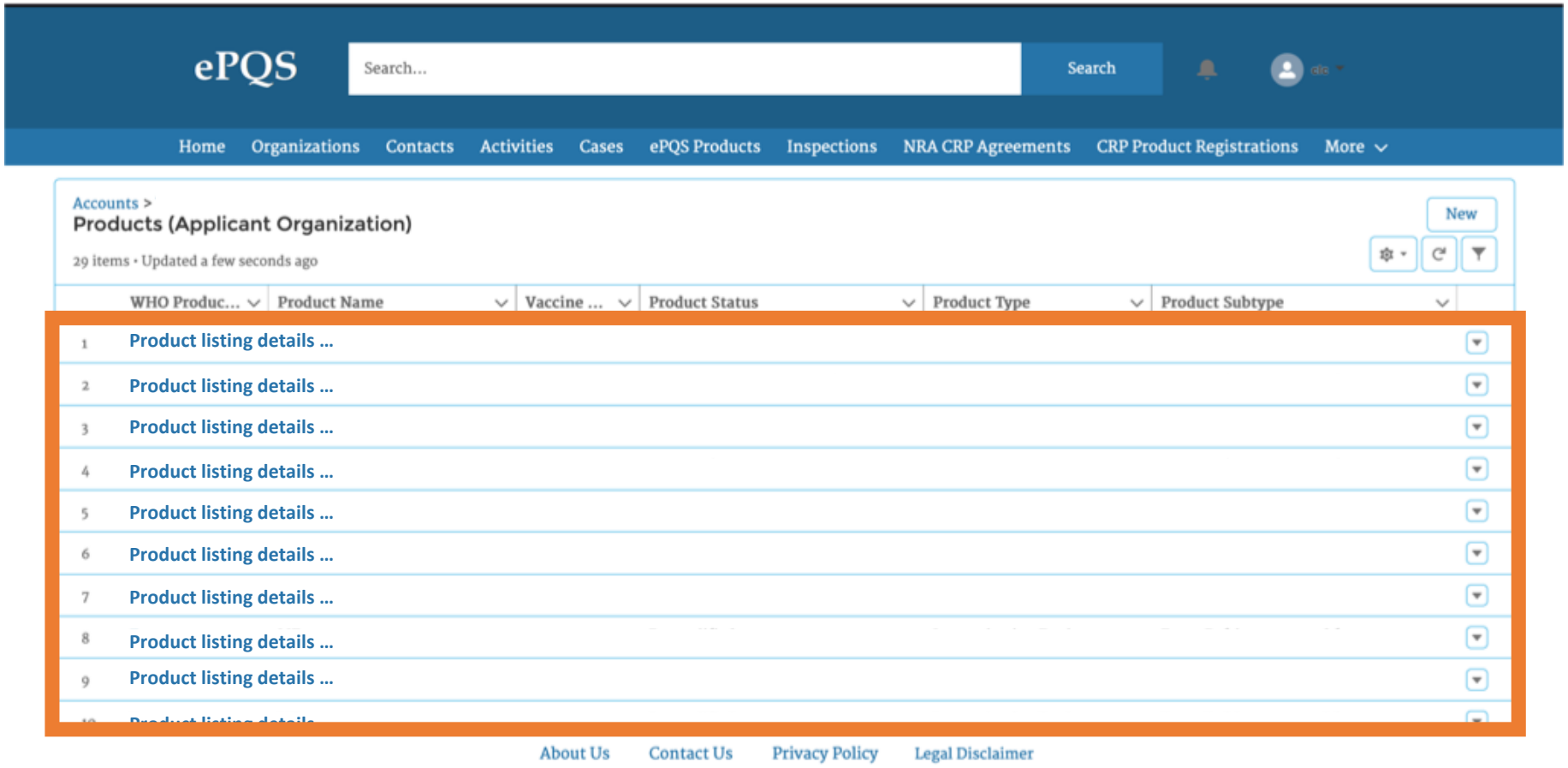


5cii. Correct record visibility - Products

Products

Users should **review the list of products** that is displayed:

1. Users should **verify** that ALL of their previously and currently prequalified products, and/or products currently under review are visible in the list.
2. Users should also **verify** that their account displays ONLY products from their organisation and NOT products of any other organisation.



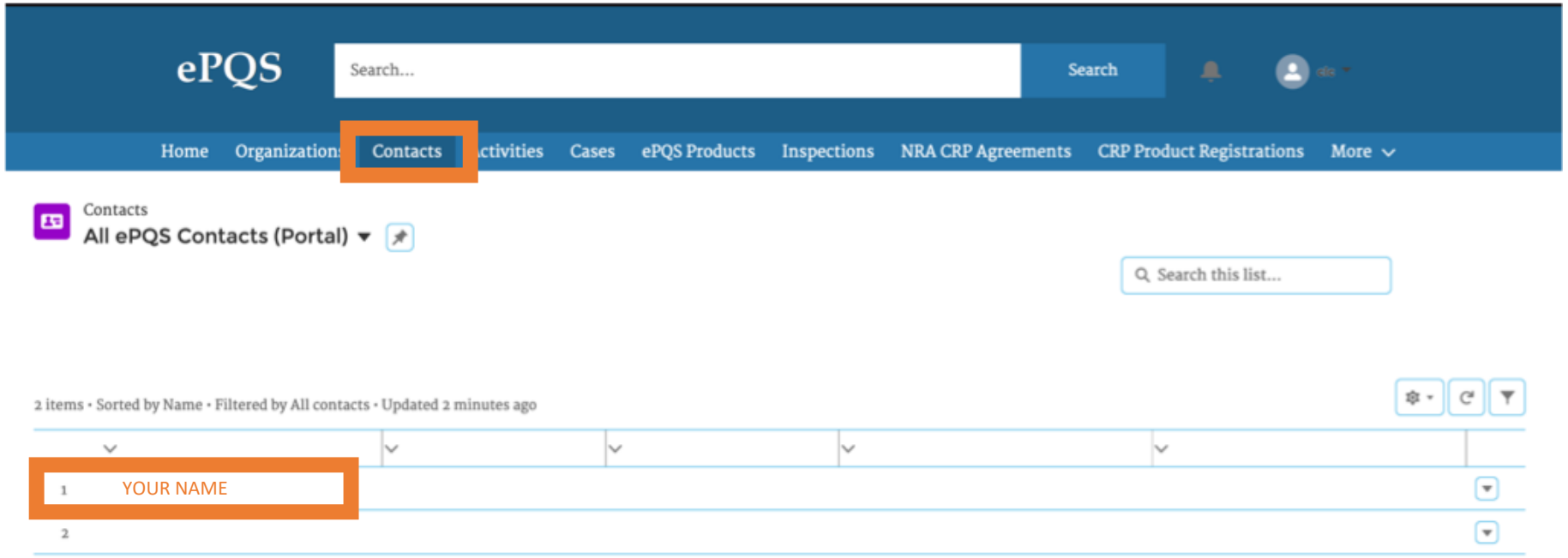
5d

Personal use folder

5d. Personal use folder

ePQS provides external users a **“Personal folder”**, in which they may upload/store documents they are working on, before submitting them or sharing them with IMD-PQS.

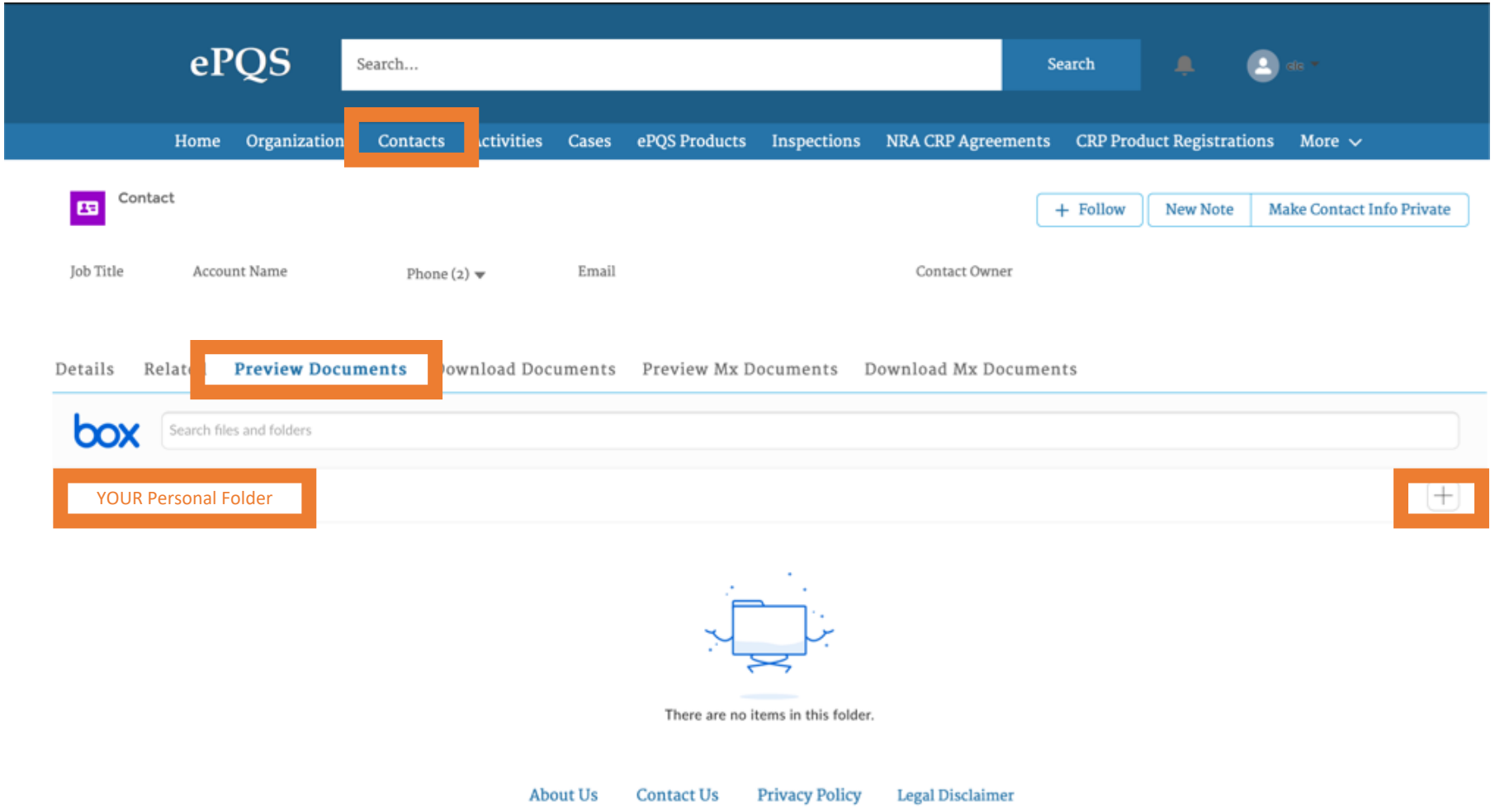
To access the personal use folder, users should go to **“Contacts”** and **choose themselves** from the list of contacts.



5d. Personal use folder

Once inside their own contact record, users should click the **“Preview Documents”** tab. Users will see a folder: **(YourName) “PersonalFolder”**. Upload documents by clicking on the **“+”** icon.

IMPORTANT – personal folders are **not private**. Internal users (IMD-PQS) can view all external user Personal Folders.



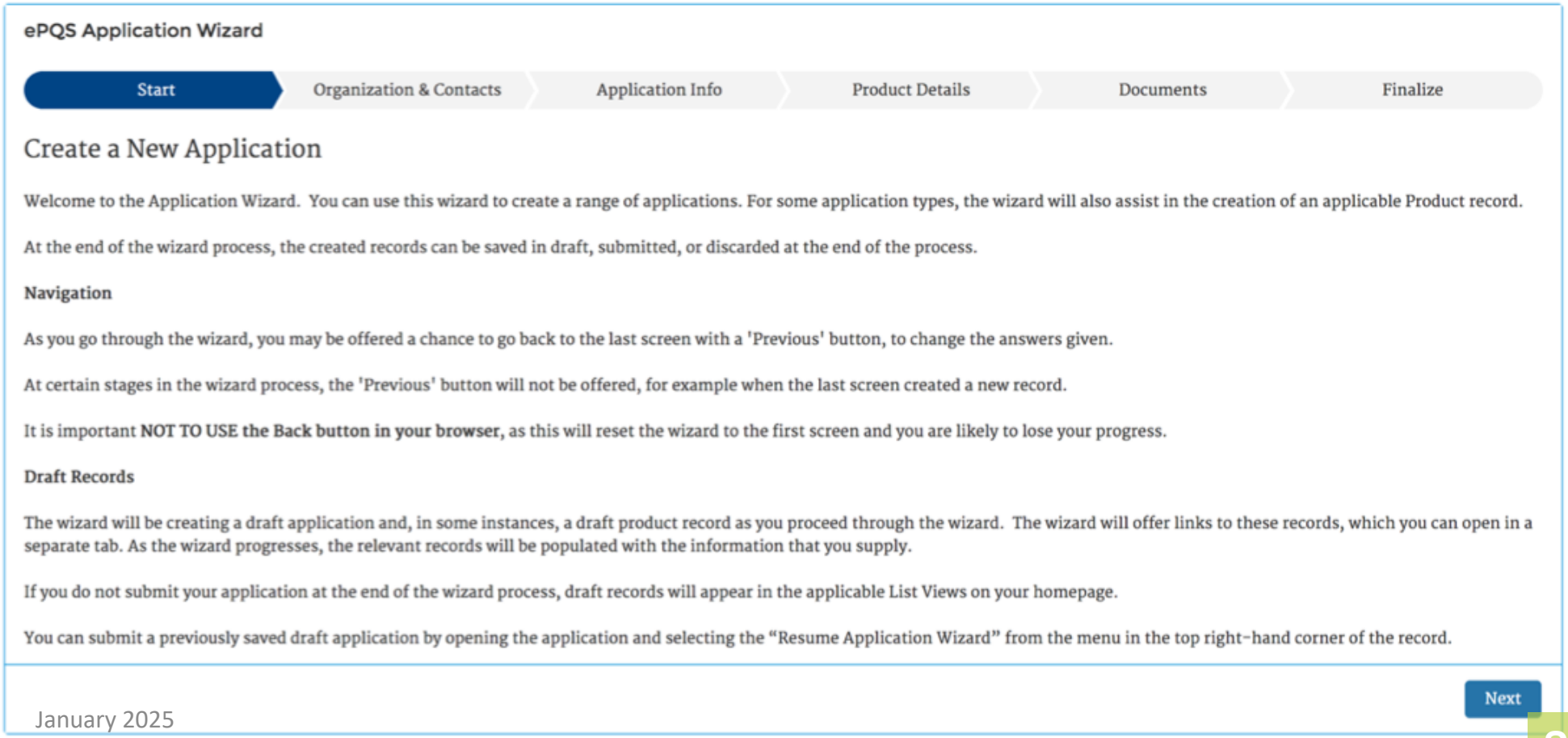
SECTION C – PILOT

5e

Application submission procedure

5e. Application submission procedure

The **“Application Wizard”** tool provides step-by-step instructions for how to complete the application. The wizard welcome page provides an overview of the process:



5e. Application submission procedure

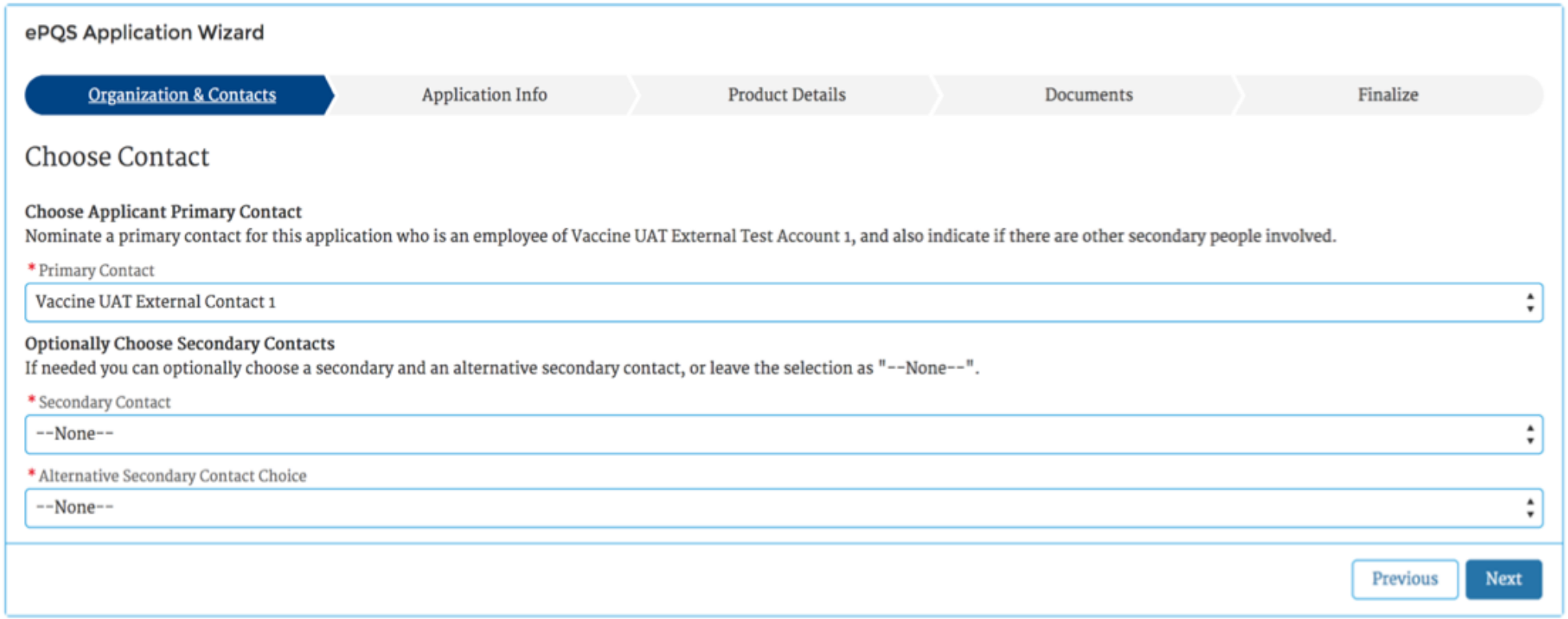
VERY IMPORTANT INFORMATION:

- You MUST complete the full Application Wizard, **including the "PRODUCT VARIANT" section**, for your application to be considered by the WHO IMD team. Please do not click "submit" on your application until you have completed the full Application Wizard, including the "PRODUCT VARIANT" section.
    - It is NOT possible to return to a submitted application to complete the **Application Wizard**.
    - If you submit an application *without* completing the Application Wizard, the application will be **discarded** and you will need to submit a new application.
    - (You CAN return to an already-submitted application to submit **documents** or additional documents however, using the "Additional Documents Wizard" tool.)

Kindly also avoid pausing your application during the creation of the "product record" and/or the "product variant record" at the current time, as there is a risk of subsequent Wizard sections being omitted once you restart the application. You may however safely pause before or after these stages in the wizard.

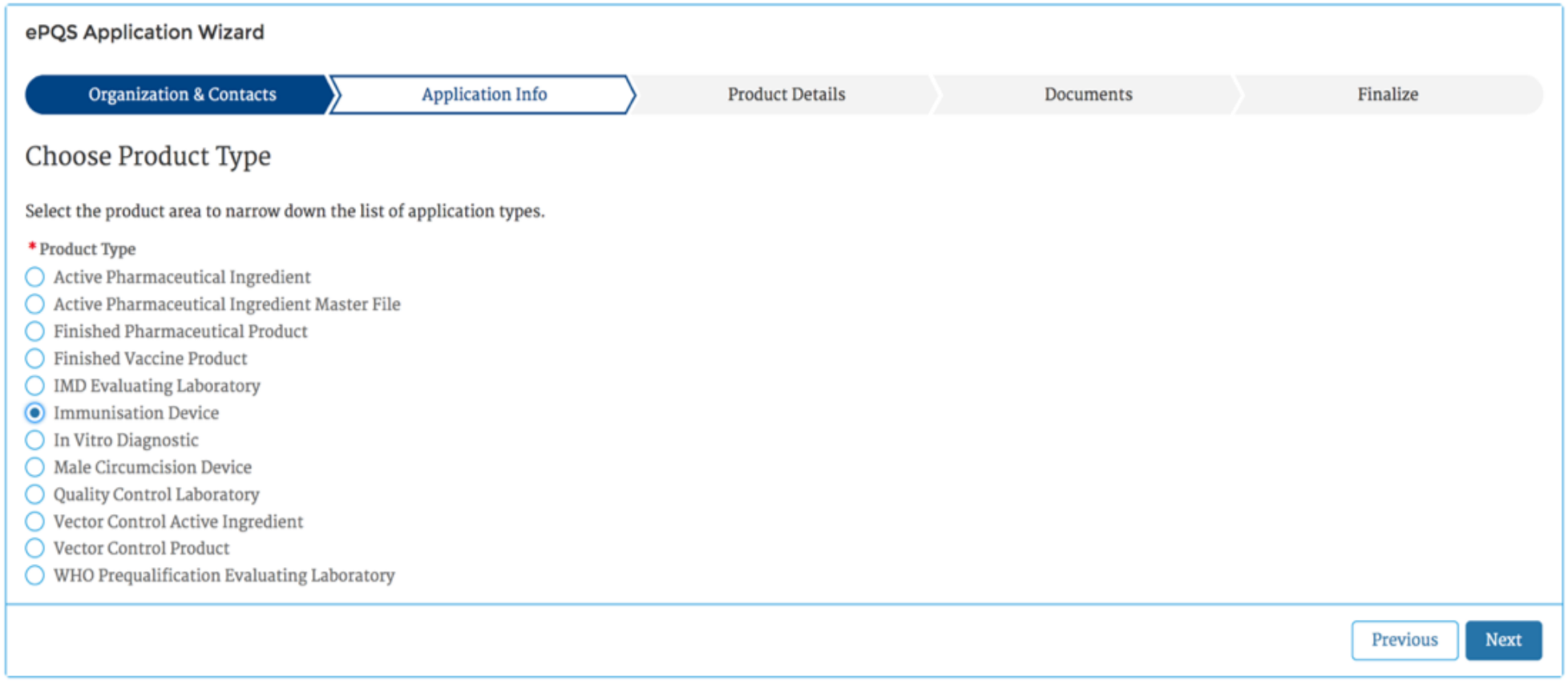
5e. Application submission procedure

Applicants will first be prompted to select the relevant **contacts** (themselves, their colleagues):



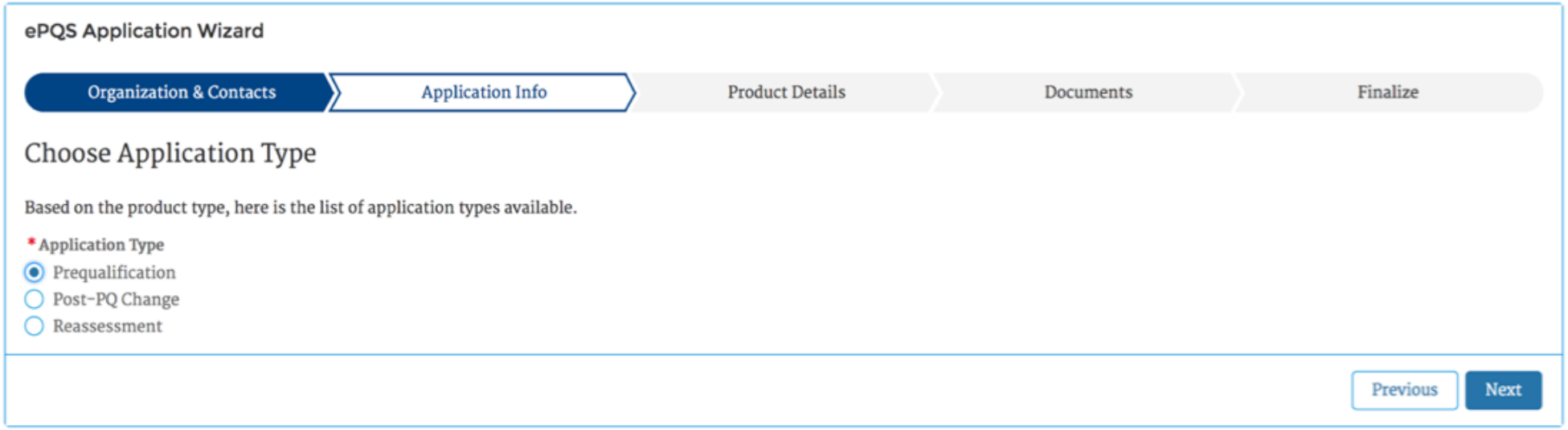
5e. Application submission procedure

Next, select **“Immunization Device”** as the product type:



5e. Application submission procedure

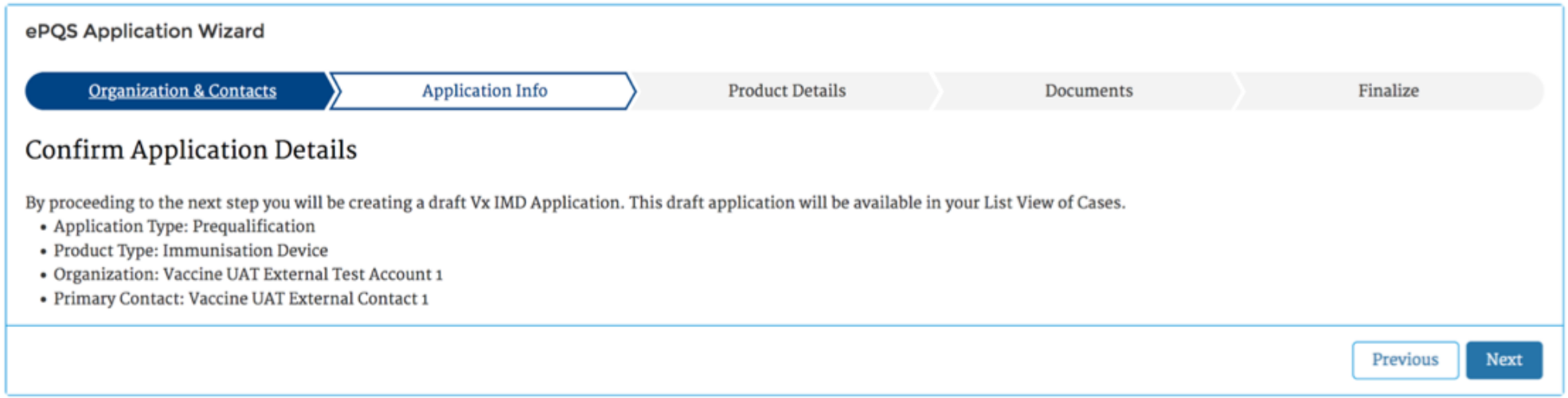
Next, select **“Prequalification”** as the application type:



5e. Application submission procedure

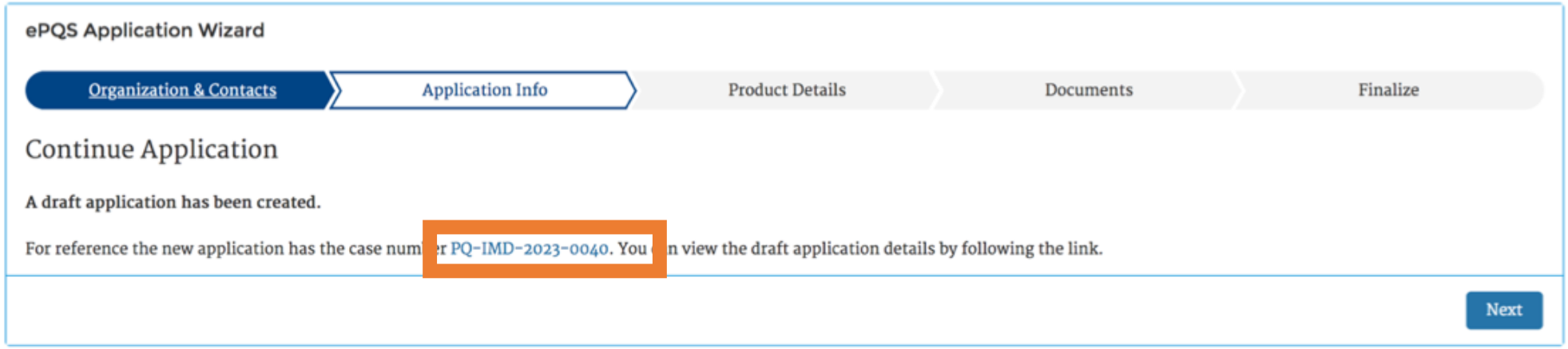
The Wizard will ask for confirmation of the application details:

Note: WHO-IMD applications are classified as **“Vx IMD”** (Vaccines – Immunization Devices) within the ePQS system.



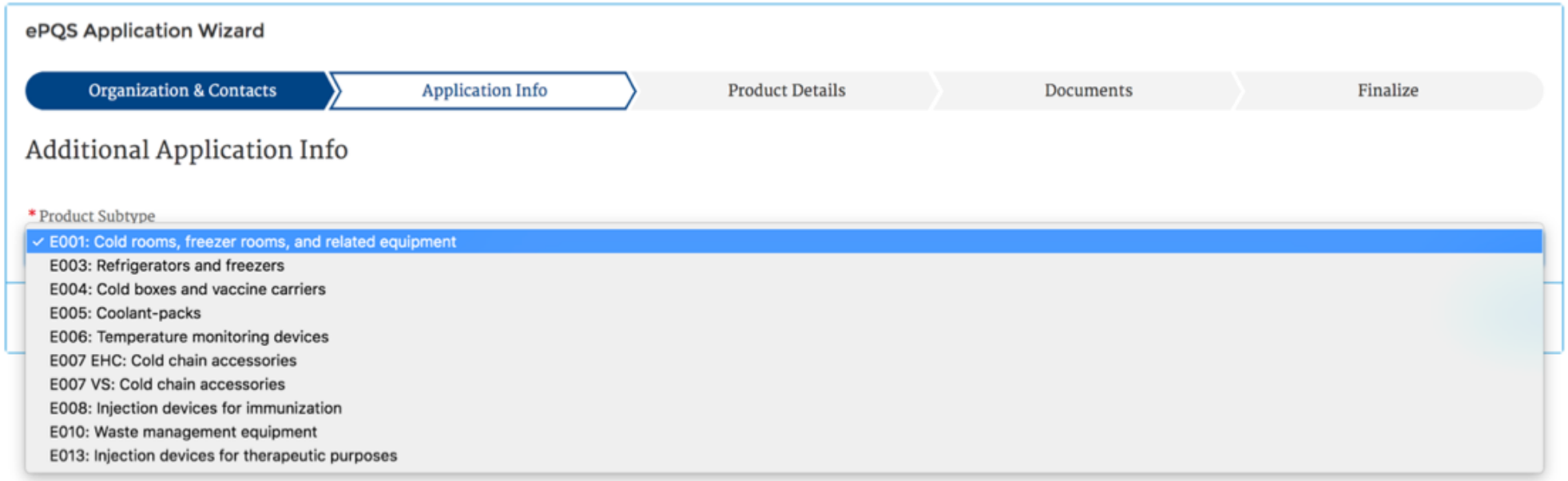
5e. Application submission procedure

The Wizard will provide the your **case number**.
Make a physical note of this reference number:



5e. Application submission procedure

Next, select the **“Product Subtype”** (the IMD-PQS Product Category):

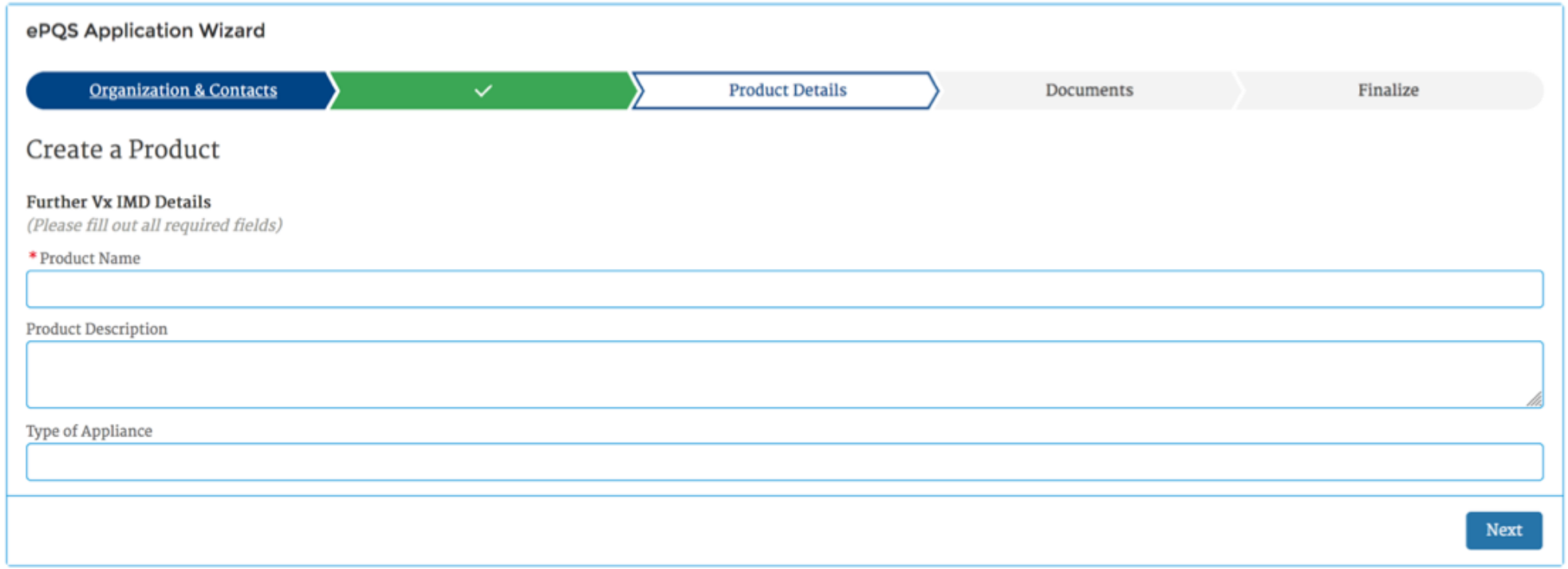


5e. Application submission procedure

The Wizard will provide the **application number** (which is the same as the case number shown previously):

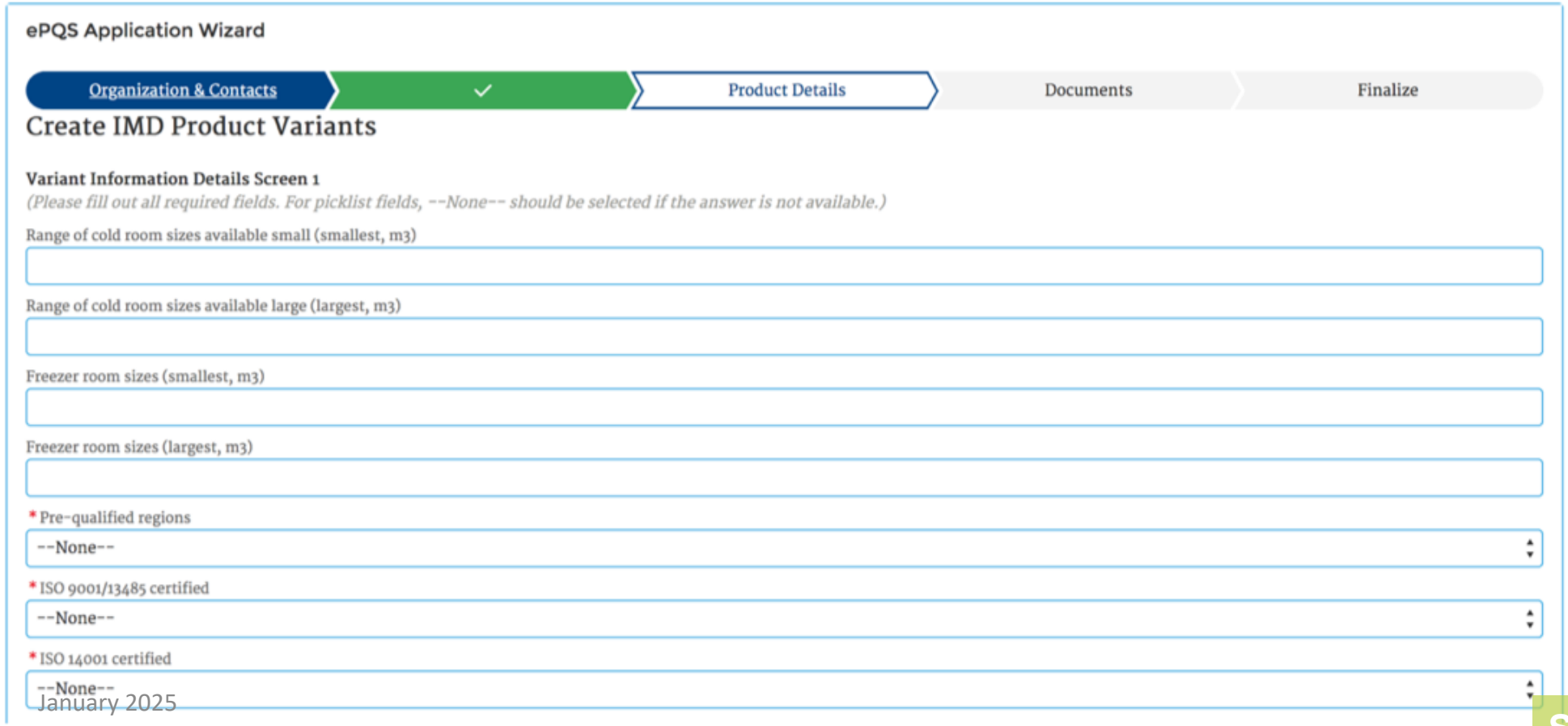
5e. Application submission procedure

Input a **product name –** the manufacturer product reference**.** A **description**, and the **type of appliance** (free text) are also useful, but not mandatory:



5e. Application submission procedure

The following section of the application requires the input of **the full product specifications** (called the “IMD Product Variant” page).



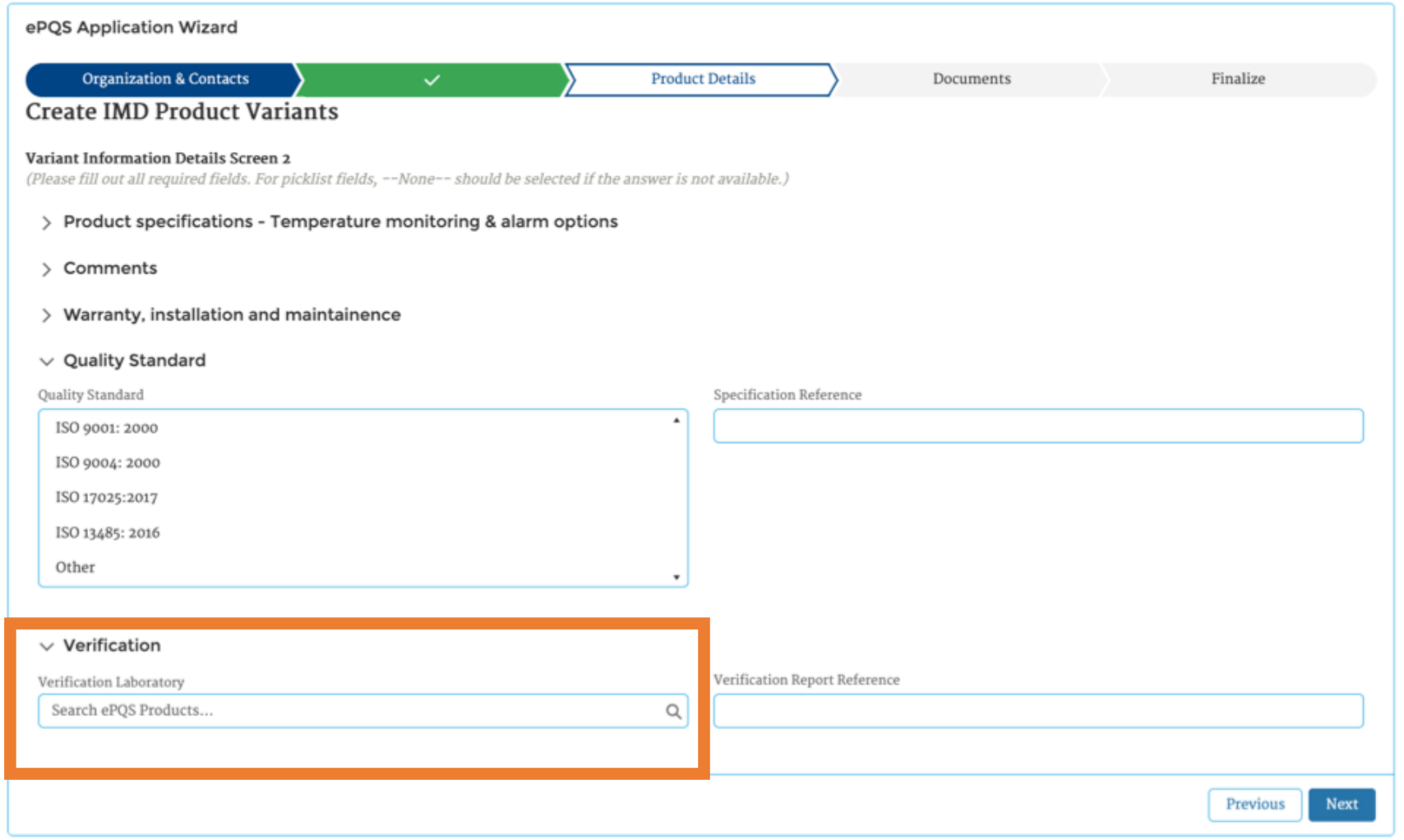
****All fields are required** unless not applicable for a product. There are multiple such pages to complete for each category of product.

5e. Application submission procedure

IMPORTANT INFORMATION REGARDING VERIFICATION LABORATORIES:

At the present time the ePQS data field for Verification Laboratory selection does not function.

Kindly submit this information to the IMD-PQS team by email, copying huckerbyg@who.int.



5e. Application submission procedure

IMPORTANT REMINDER:

- You MUST complete the **"PRODUCT VARIANT" section** of the "Application Wizard", for your application to be considered by the WHO IMD team. Please do not click "submit" on your application until you have completed the full Application Wizard, including the "PRODUCT VARIANT" section.
    - It is NOT possible to return to a submitted application to complete the **Application Wizard**.
    - If you submit an application *without* completing the Application Wizard, the application will be **discarded** and you will need to submit a new application.

Kindly also avoid pausing your application during the creation of the "product record" and/or the "product variant record" at the current time, as there is a risk of subsequent Wizard sections being omitted once you restart the application. You may however safely pause before or after these stages in the wizard.

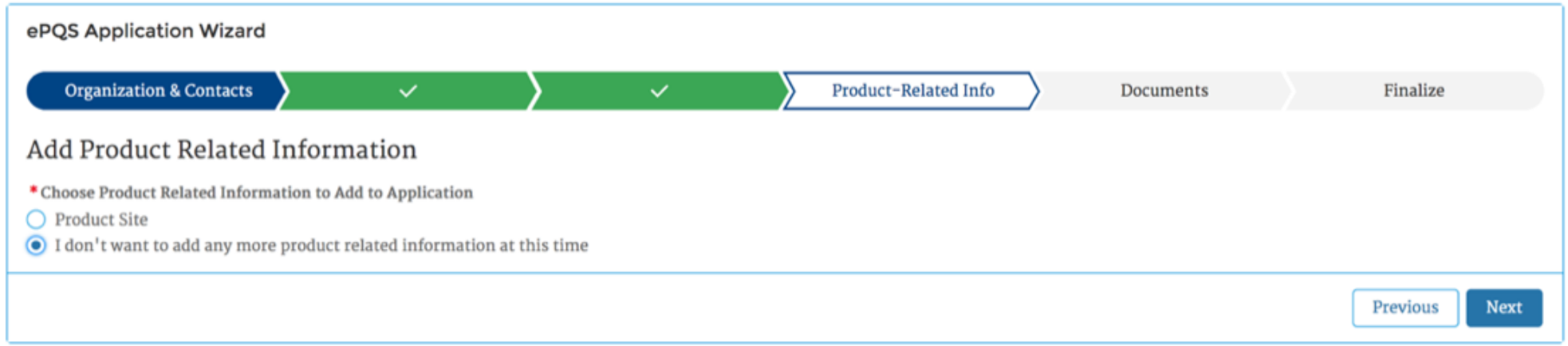
5e. Application submission procedure

Once the Variant Information Detail pages are completed, the wizard will provide the **“IMD Product Variant Ref.”**. Make a physical note of this reference number:

5e. Application submission procedure

Next, please provide information about the **“product site”** (the actual site of product manufacture). This information is for the WHO Inspections team. Click on “Product Site” and select the product site option provided (which is related to your company).

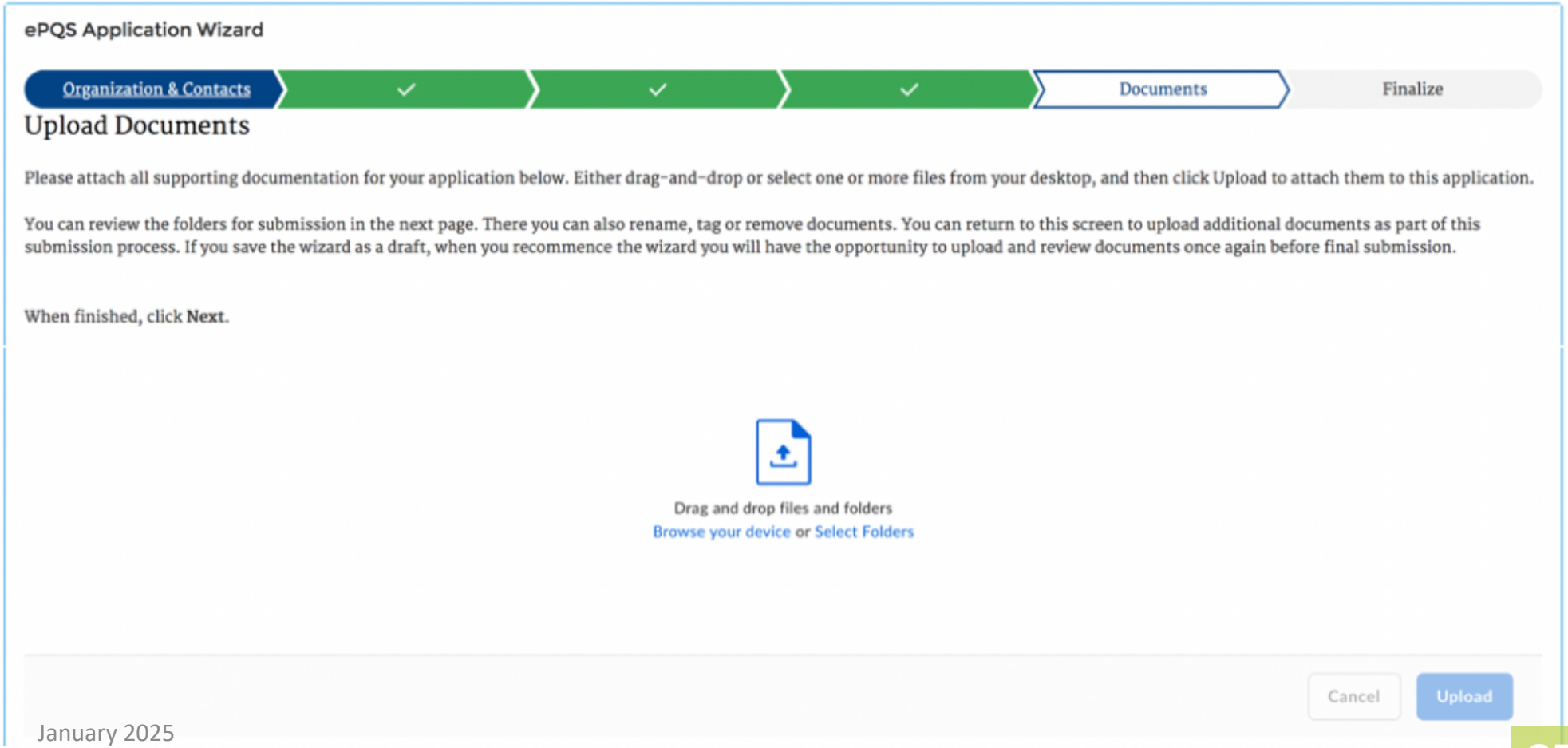
- If the product site option provided is your office address and NOT the manufacturing site please contact Huckerbyg@who.int and provide the manufacturing site address. The addresses will then be correctly assigned in ePQS.
- If your prequalified products are manufactured at MORE THAN ONE site, please contact Huckerbyg@who.int and provide the additional manufacturing site address. A new product site will be created and assigned to this product.



Updated: September 2025

5e. Application submission procedure

The final stage of the Wizard allows applicants to upload the (mandatory) documents.



See next slide for information related to what documents to submit:

5e. Application submission procedure

List of mandatory documents.

The IMD-PQS Secretariat has provided a detailed list of application requirements, including mandatory documents, in their email response to your "Pre-submission" form.

In addition, users may refer to Section 3.4.3 of the ***IMD-PQS Prequalfication Holder Guidelines*** for a generic list of the documentation that must be provided for a complete application for each product category.

The Prequalification Guidelines can be downloaded from: https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-applicants-prequalification-holders

5e. Application submission procedure MANDATORY folder structure

IMD PQS requires applicants to upload the application documents under the following folder structure.

- **A. INITIAL APPLICATION ROUND 1**
  - A1. DOSSIER SUBMISSION INFORMATION
    - A1i. PRE-SUBMISSION APPLICATION
    - A2ii. DEVICE TECHNICAL SPECIFICATION
    - A3iii. LABORATORY/MANUFACTURER QUALITY CERTIFICATION(S)
    - A4iv. DEVICE MARKETING APPROVAL(S)
  - A2. COMPLETED APPLICATION REVIEW TEMPLATE
  - A3. SUBMISSION DATA
    - A3i. TEST REPORTS
    - A3ii. INSPECTION REPORTS
    - A4iii. USER-TESTING REPORTS
    - A5iv. RISK ANALYSIS
  - A4. EQUIPMENT CALIBRATION CERTIFICATES
  - A5. TEST PROTOCOLS
- **B. APPLICATION REVIEW ROUND 2**
- **C. APPLICATION REVIEW ROUND 3**

Upload the pre-submission you submitted previously to the IMD-PQS Secretariat (if relevant).

This is the Application Review Template provided to you in the application guidance from the IMD-PQS Secretariat.

*** Include the up-to-date, most recent version of the Application Review Template in every round of review.*

- **This folder structure is mandatory.**
- **However, applicants are only required to create & upload the folders & subfolders that are relevant & required for their application.**
- **Refer to the detailed list of application requirements provided to you by the WHO IMD-PQS Secretariat.**

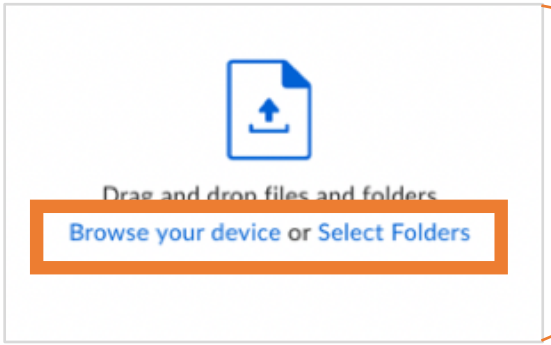
- **CLICK HERE TO DOWNLOAD THIS FOLDER STRUCTURE IN PRE-FORMATTED .ZIP FORMAT: https://extranet.who.int/prequal/key-resources/documents/imd-pqs-epqs-mandatory-folder-structure**

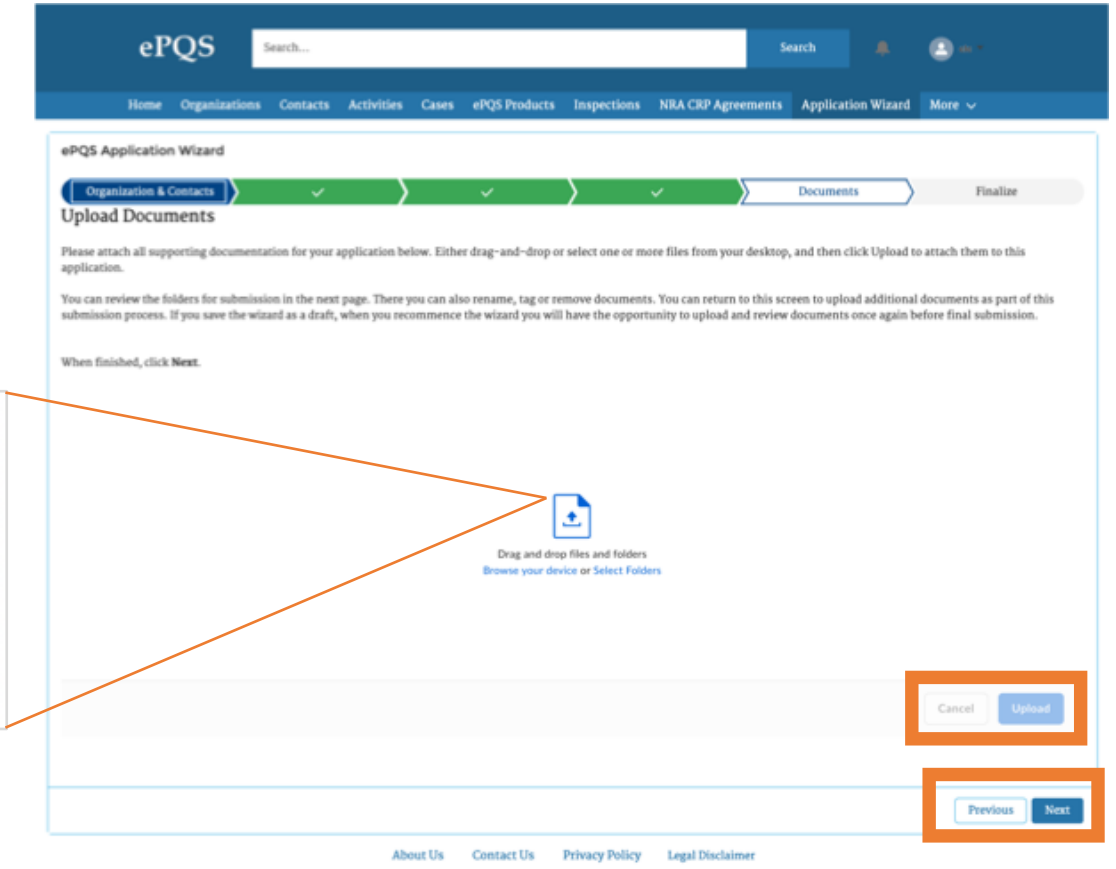
5e. Application submission procedure
MANDATORY folder structure

1 **Create the folder structure locally on your computer.**

- A. INITIAL APPLICATION ROUND 1
  - A1. DOSSIER SUBMISSION INFORMATION
    - A1i. PRE-SUBMISSION APPLICATION
    - A2ii. DEVICE TECHNICAL SPECIFICATION
    - A3iii. LABORATORY/MANUFACTURER QUALITY CERTIFICATION(S)
    - A4iv. DEVICE MARKETING APPROVAL(S)
  - A2. COMPLETED APPLICATION REVIEW TEMPLATE
  - A3. SUBMISSION DATA
    - A3i. TEST REPORTS
    - A3ii. INSPECTION REPORTS
    - A4iii. USER-TESTING REPORTS
    - A5iv. RISK ANALYSIS
  - A4. EQUIPMENT CALIBRATION CERTIFICATES
  - A5. TEST PROTOCOLS
- B. APPLICATION REVIEW ROUND 2
- C. APPLICATION REVIEW ROUND 3

2 **Then, upload each folder and sub-folder to ePQS on the "Upload Documents" page. Keep the names and numeration as shown on this slide (even if not all folders are relevant).**



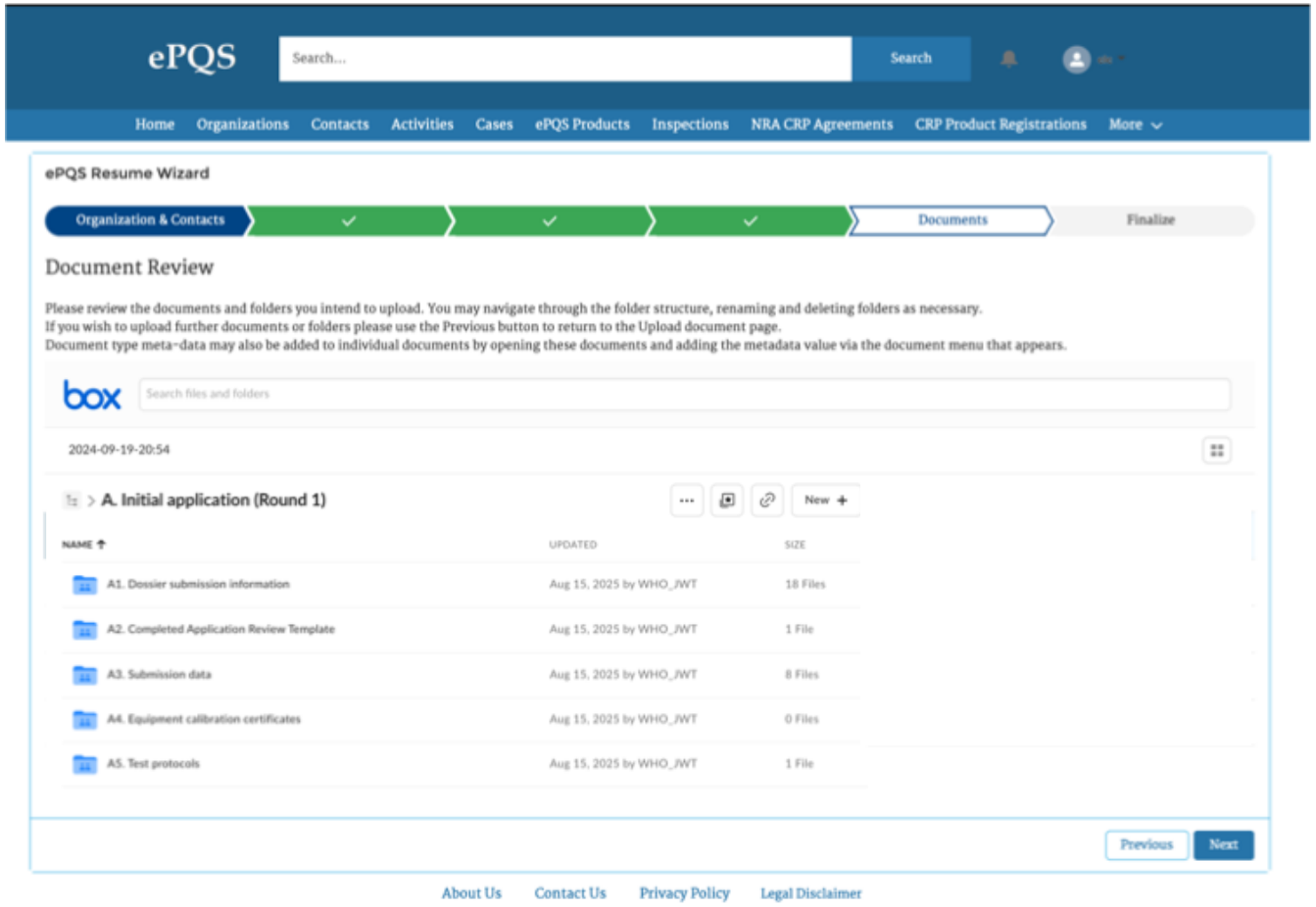


5e. Application submission procedure MANDATORY folder structure

3 **Once uploaded, Box will display the folder structure as shown here.**

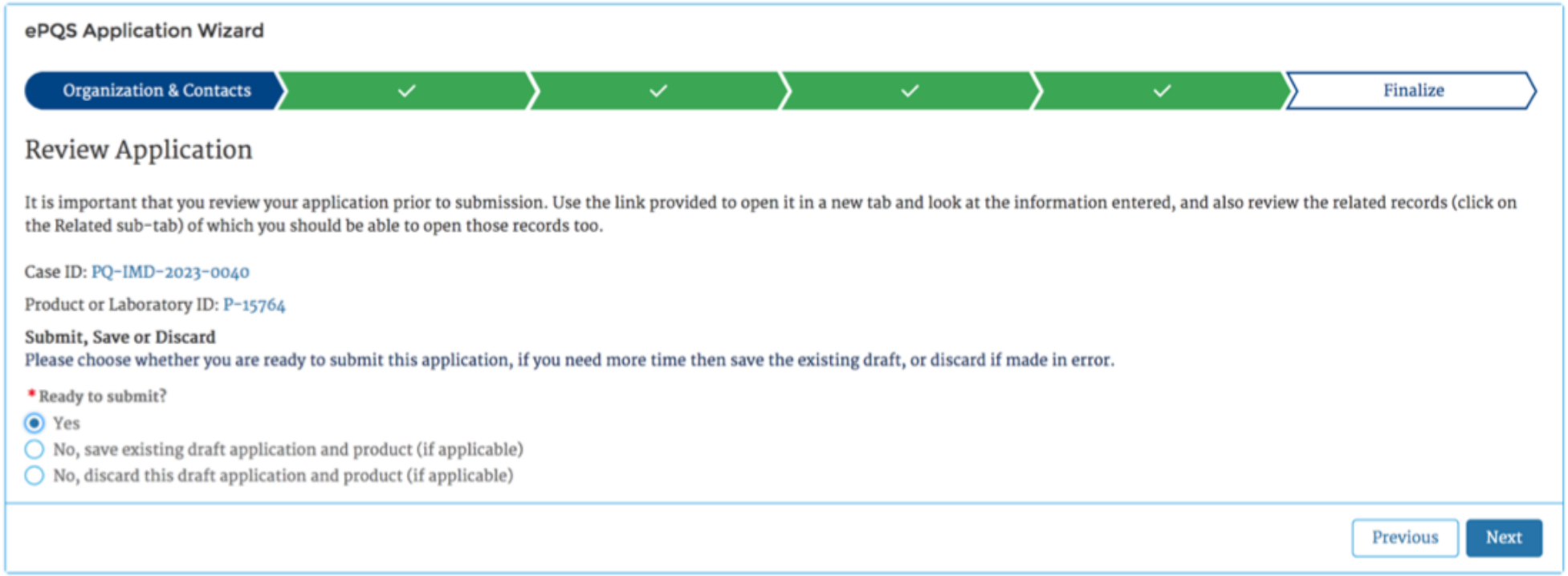
Once all documents are uploaded, click “next”.

IMPORTANT: A folder will **not** upload if it does not contain a document. Only upload the folders / sub-folders if they contain at least one document.



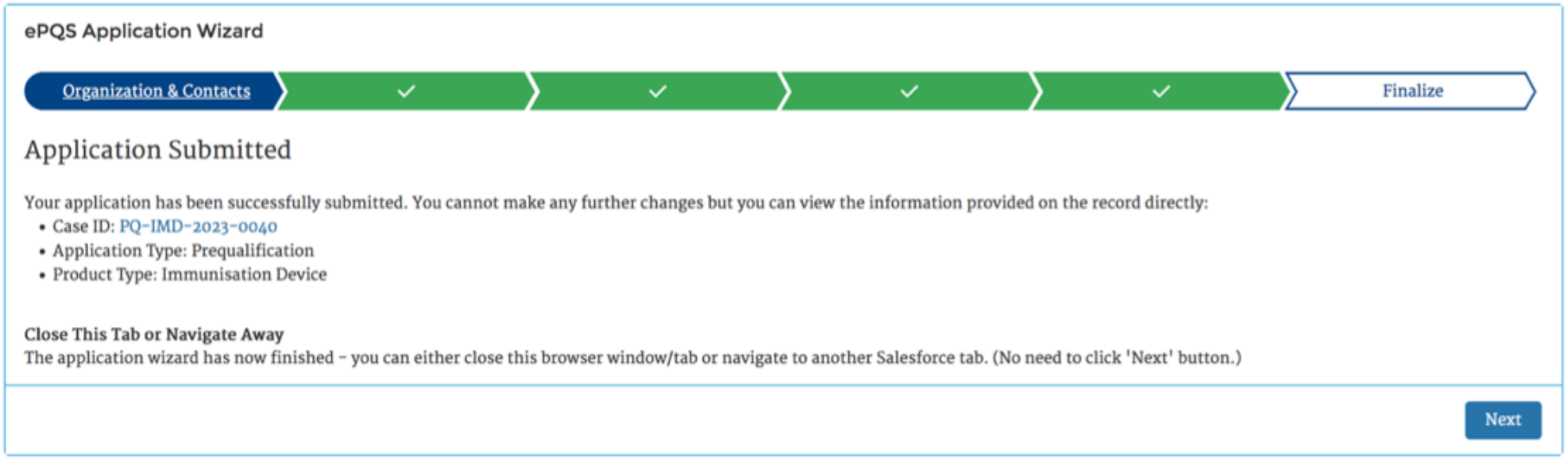
5e. Application submission procedure

Once the complete documentation has been uploaded to the submission, the Wizard will provide the option to **submit**, **save draft** or **discard draft**:



5e. Application submission procedure

Once **“submit”** has been selected, the Wizard will confirm the Case ID. **The application is complete.** The IMD-PQS Secretariat will contact the applicant via the ePQS email agent and/or “Box” cloud file-sharing system with any further requests for information and with information about next steps.

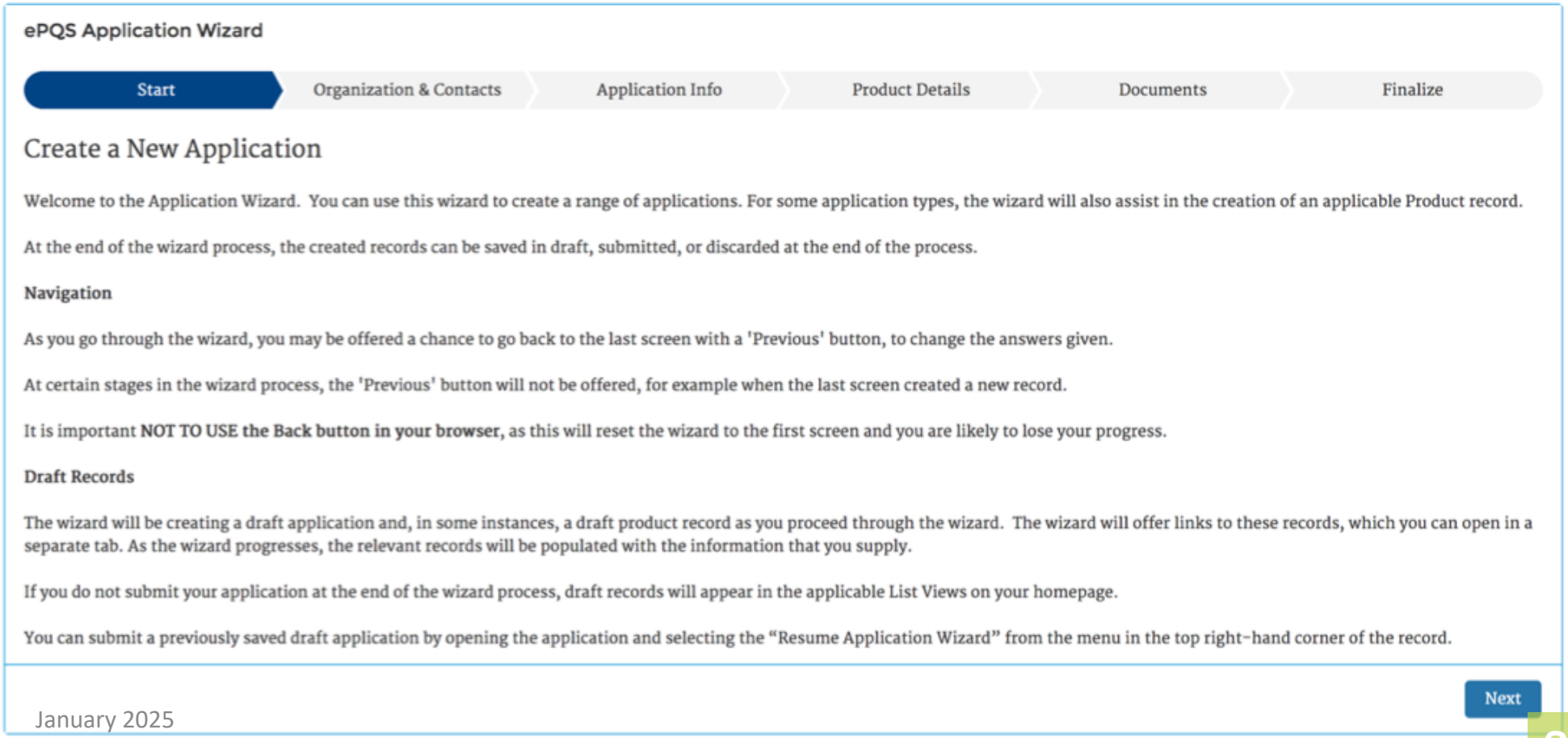


6f

Post-PQ variation submission

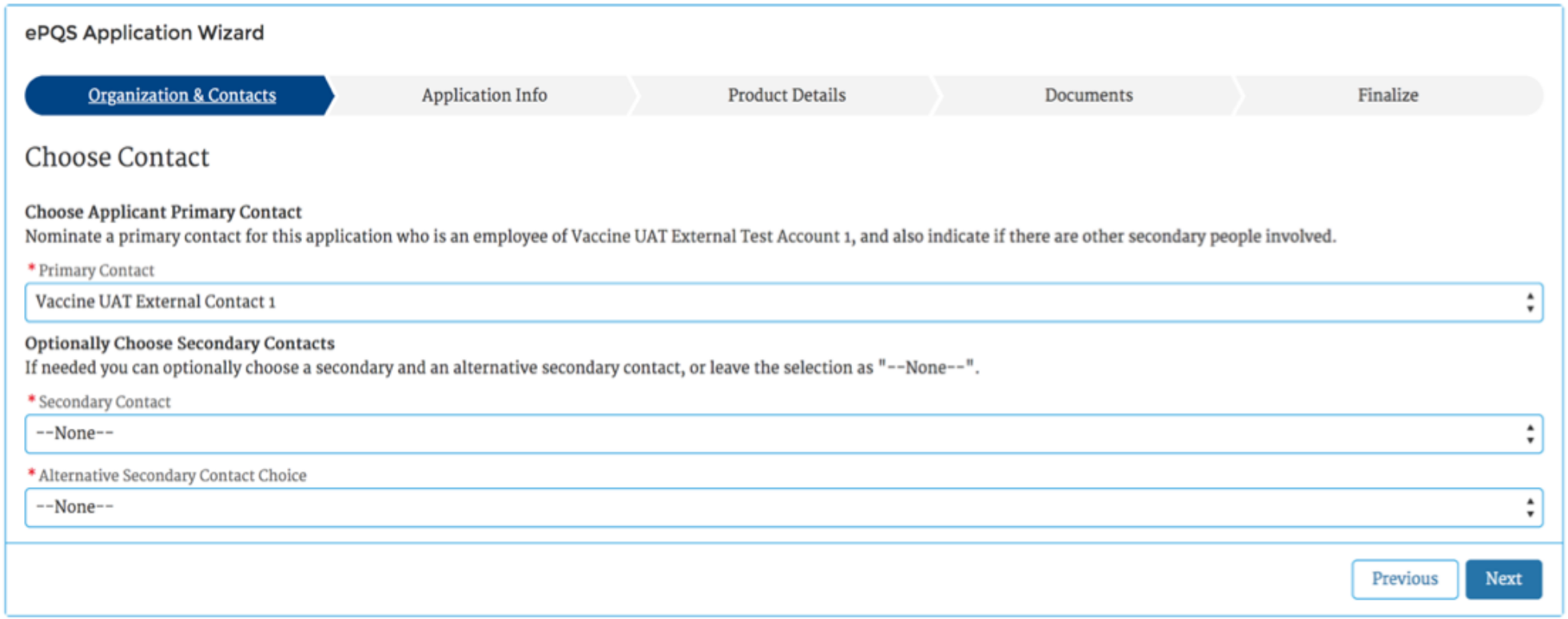
5f. Post-PQ variation submission procedure

The **“Application Wizard”** tool provides step-by-step instructions for how to complete the application. The wizard welcome page provides an overview of the process:



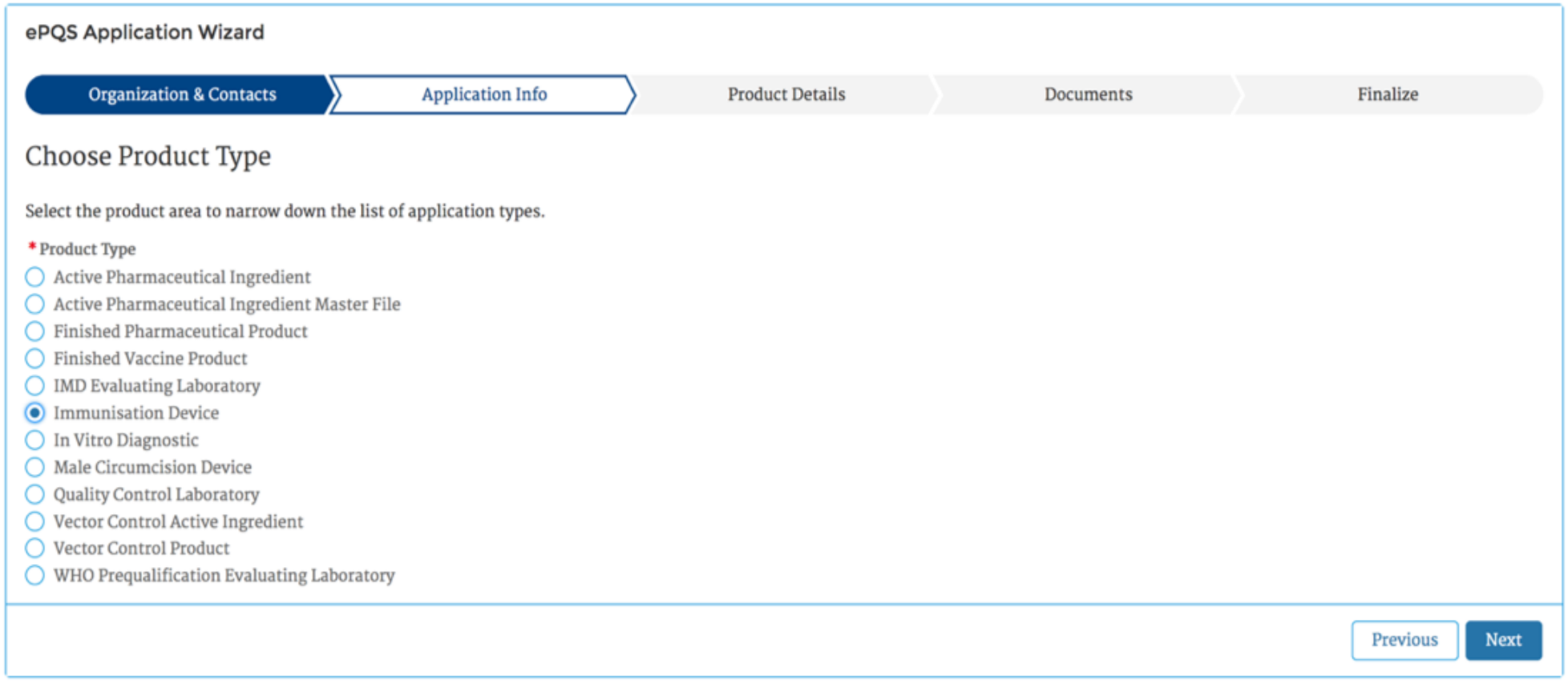
5f. Post-PQ variation submission procedure

Applicants will first be prompted to select the relevant contacts:



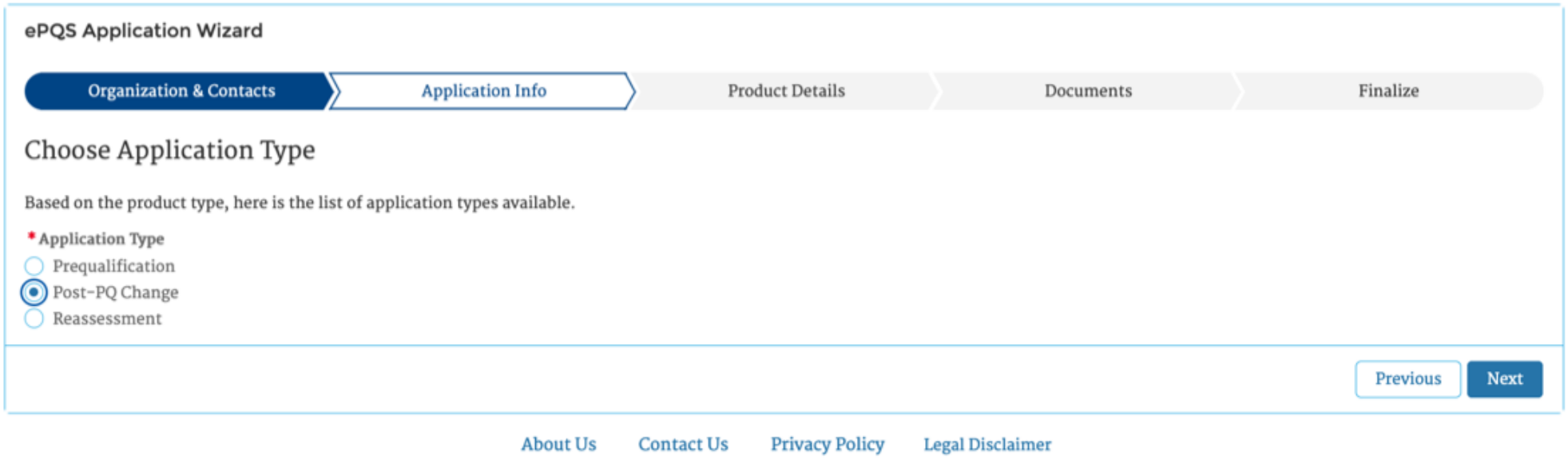
5f. Post-PQ variation submission procedure

Next, select **“Immunization Device”** as the product type:



5f. Post-PQ variation submission procedure

Select **“Post-PQ Change”** as the application type:

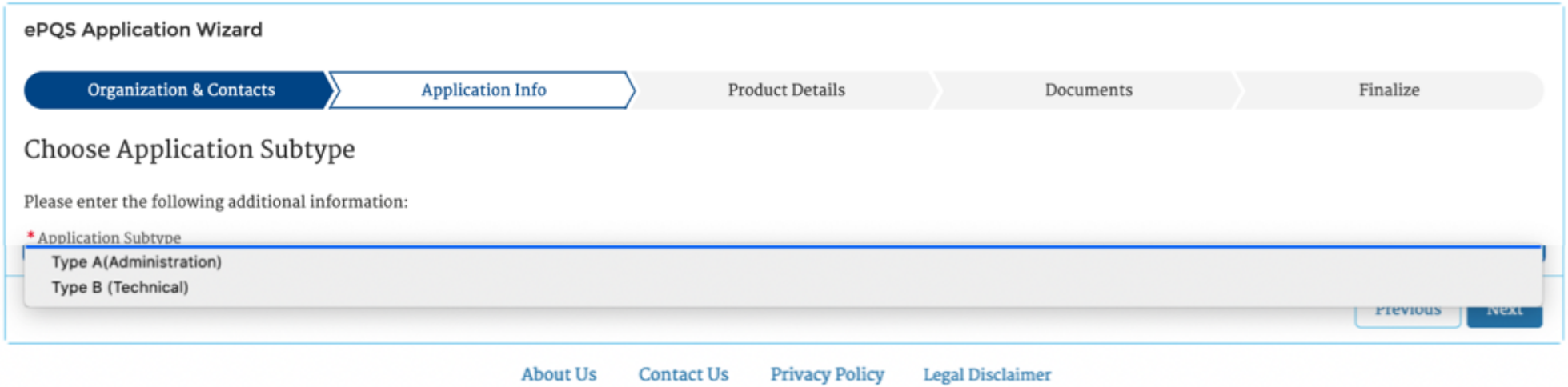


5f. Post-PQ variation submission procedure

Next, users have a choice between two types of post-PQ variations:

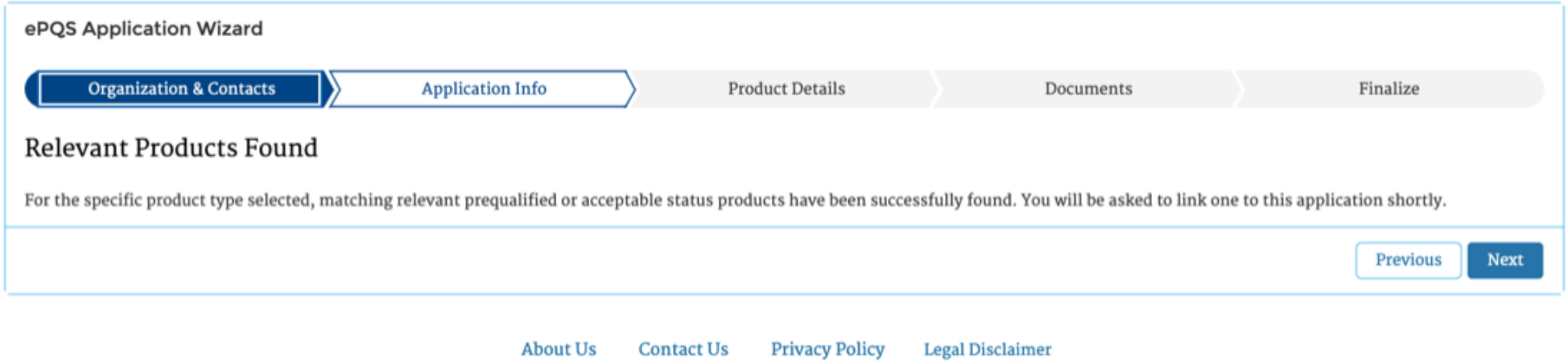
- **Type A - Administration** → Select for ADMINISTRATIVE data changes.
- **Type B – Technical** → Select for TECHNICAL variations that conncern product specifications

NOTE – the following sequence of screens are the same for both of these options.



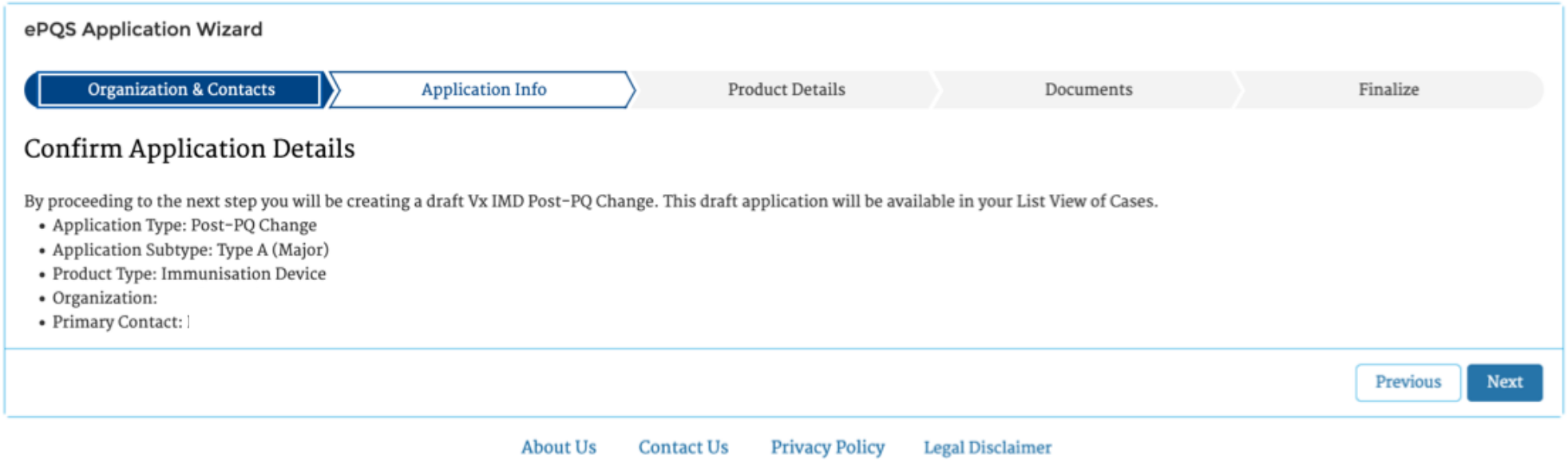
5f. Post-PQ variation submission procedure

The next screen advises that users will be asked to select the product for which they wish to report the variation. The selection happens on the later screen.



5f. Post-PQ variation submission procedure

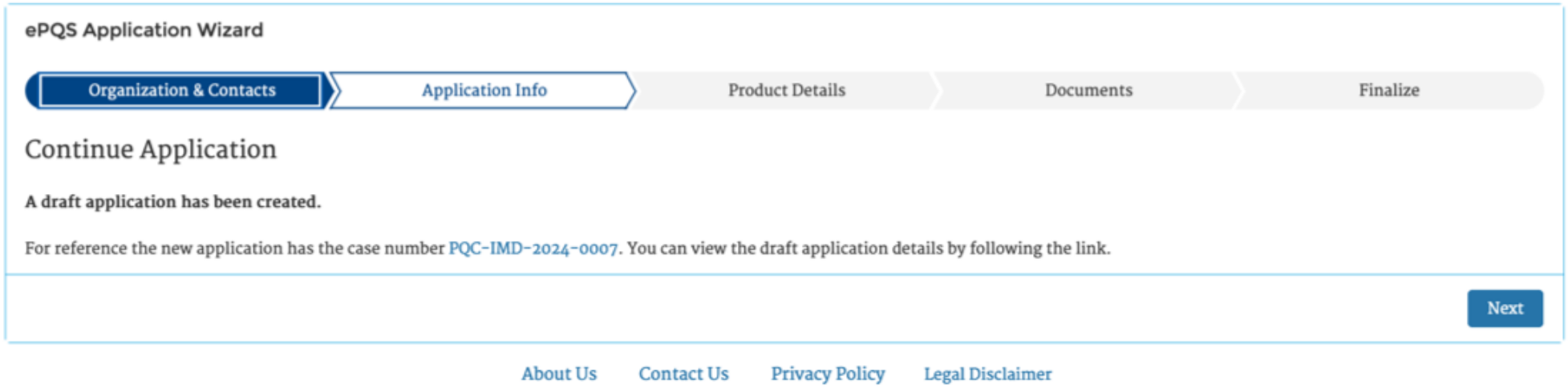
The next screen summarizes the application details that the user has inputted so far, and asks for confirmation.



5f. Post-PQ variation submission procedure

The draft application has now been created. This screen asks the user to confirm their wish to continue.

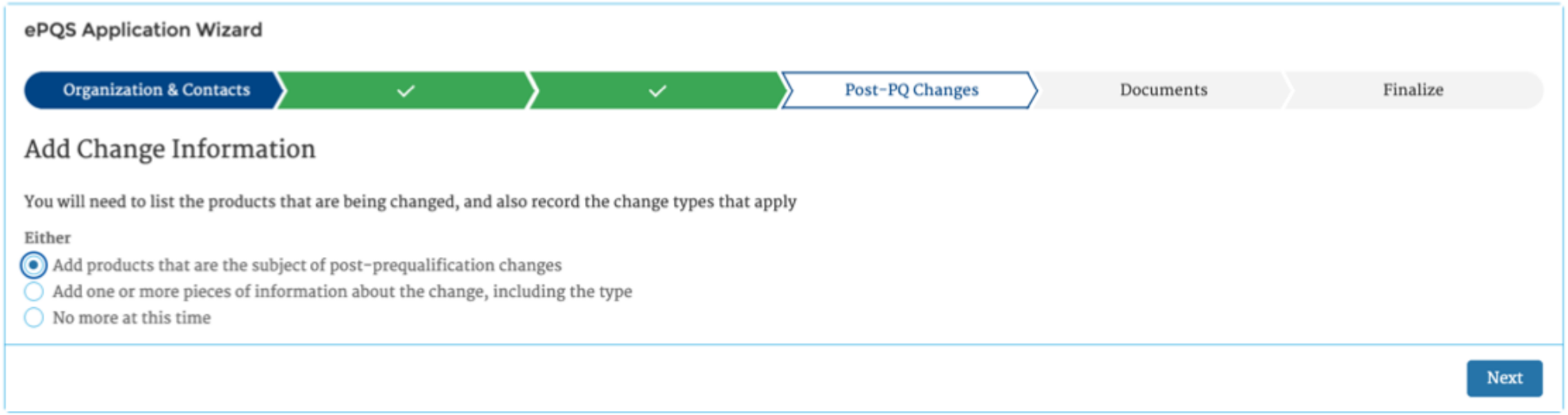
It provides an **application case number**. It is recommended to make a physical note of this number.



5f. Post-PQ variation submission procedure

The next screen, **“Add Change Information”** is a recurring screen in the remaining part of the application. It reappears until the user has selected each of these options in sequence, starting here with **“Add products…”**. (Later, the application will loop back and users will need to select “Add one or more pieces of information…”, and finally “No more at this time”.)

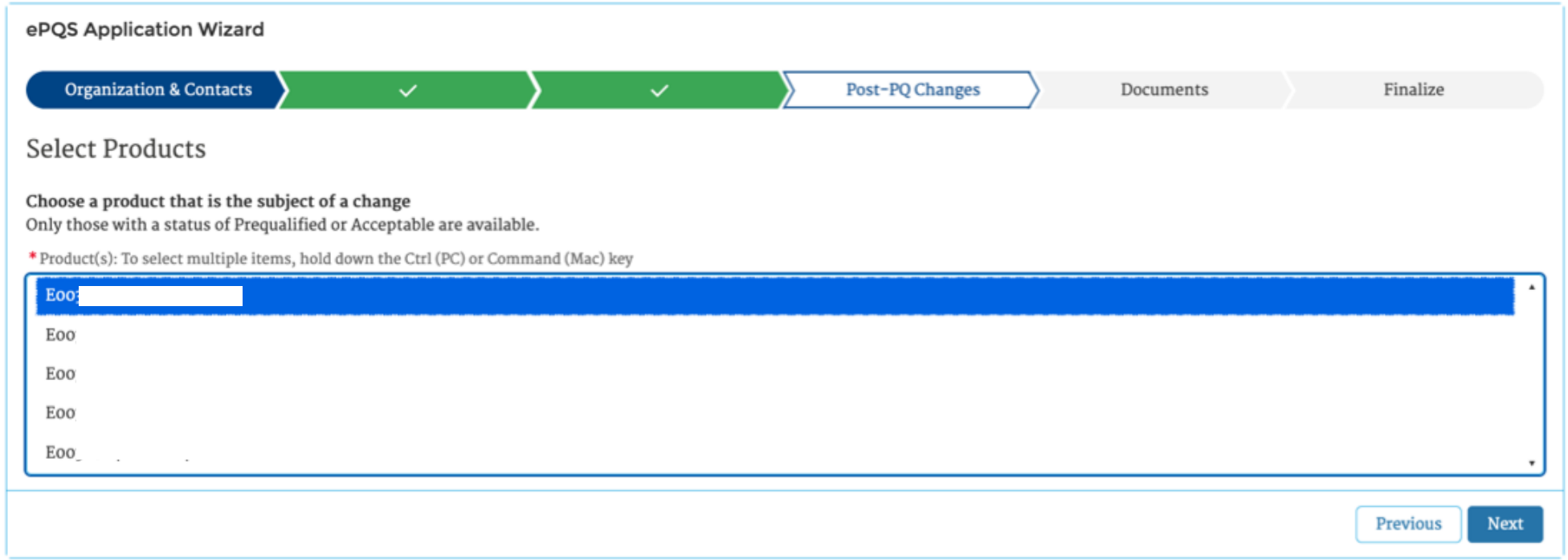
At this stage, select **“Add products…”**



5f. Post-PQ variation submission procedure

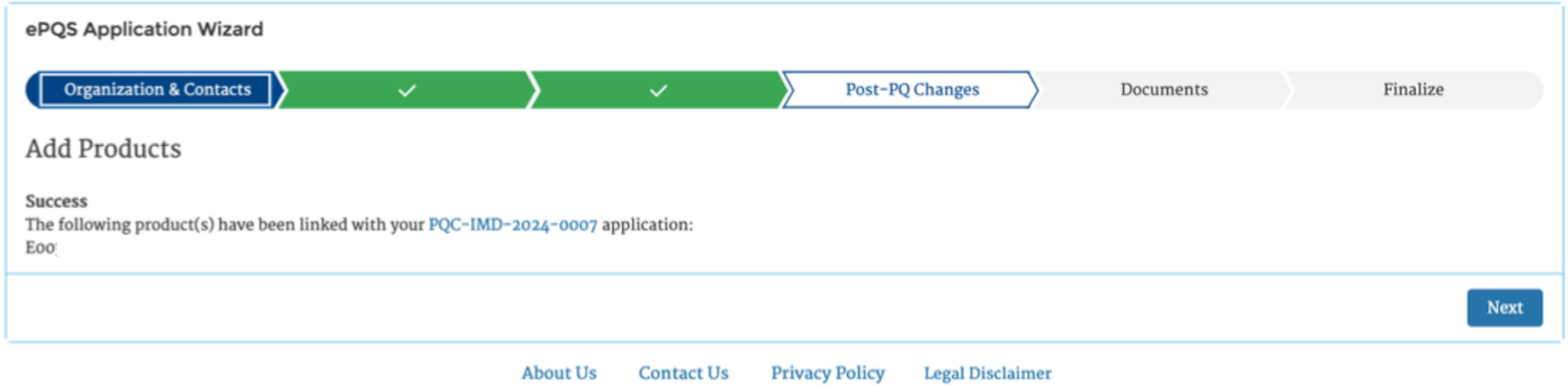
The Wizard will provide a list of products currently related to the user's account.
Users should **select the product** for which they wish to submit a post-PQ variation.

Note – users may only select one product for each round on this screen. If they wish to submit a variation for multiple products, they may add other products the next time this screen appears.



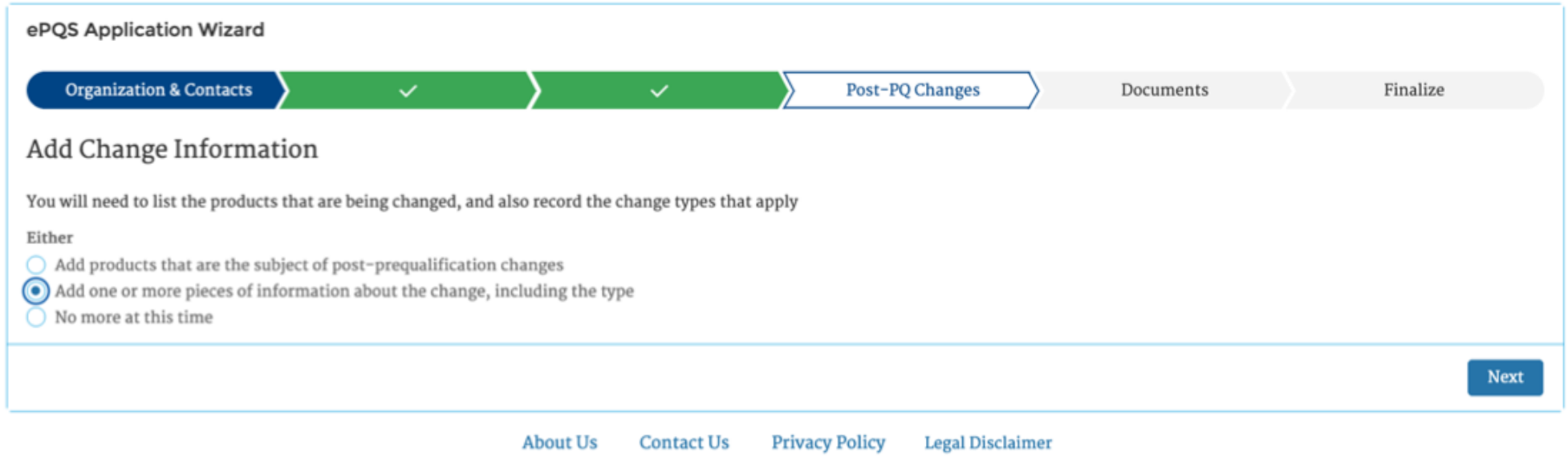
5f. Post-PQ variation submission procedure

The next slide confirms the product selection.



5f. Post-PQ variation submission procedure

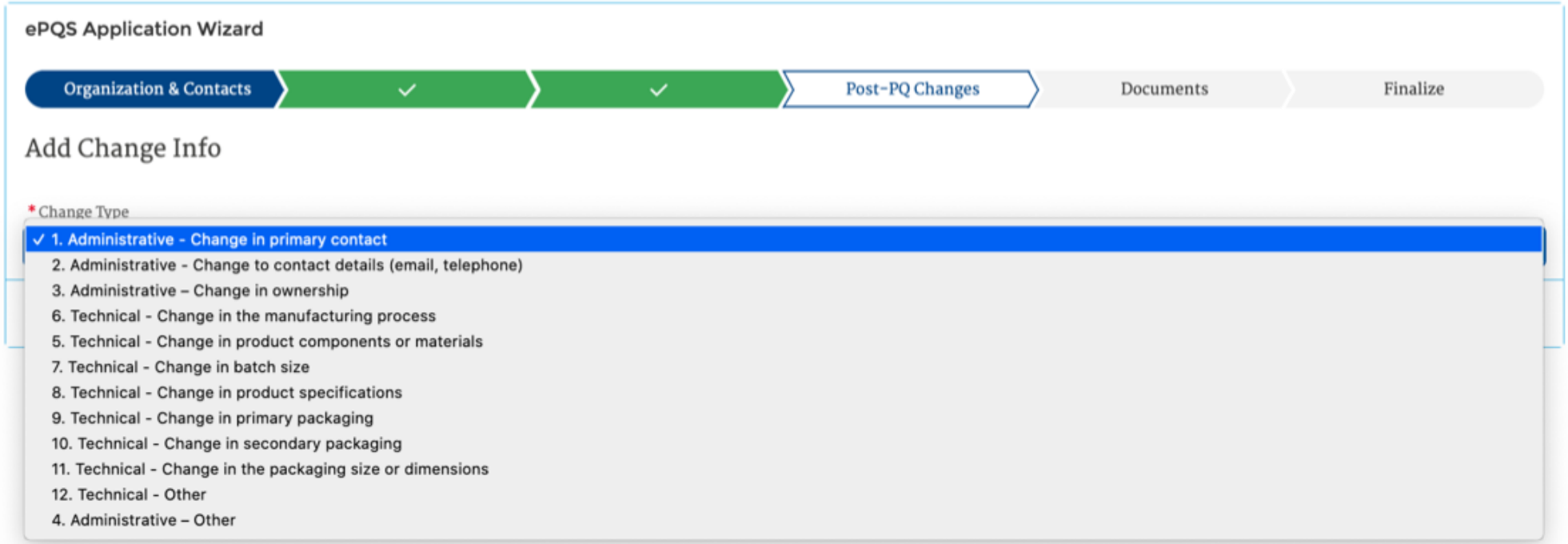
Next, users are presented for a second time the **“Add Change Information”** screen.
This time, select **“Add one or more pieces of information…”**.



5f. Post-PQ variation submission procedure

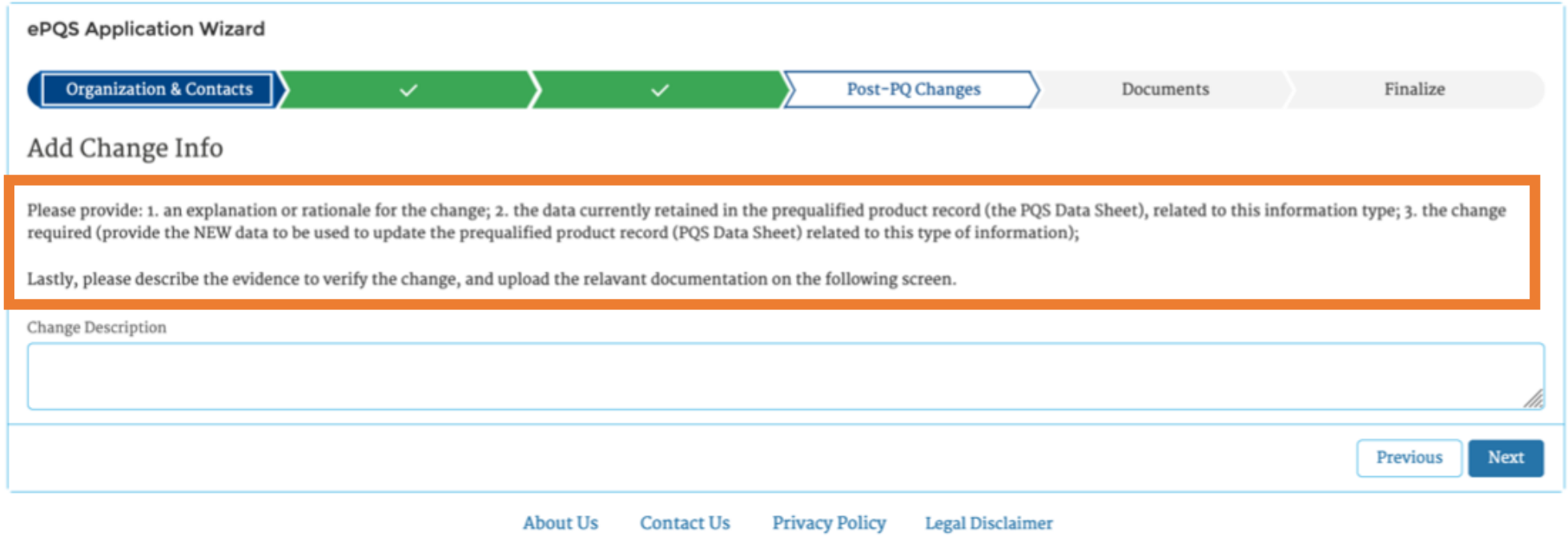
Here users are asked to select the **precise type of variation** (change) they wish to submit. Select one type of change (variation) from the list.

Note – This same list will appear irrespective of whether “Type A Administrative” or “Type B Technical” change types was selected at the start.



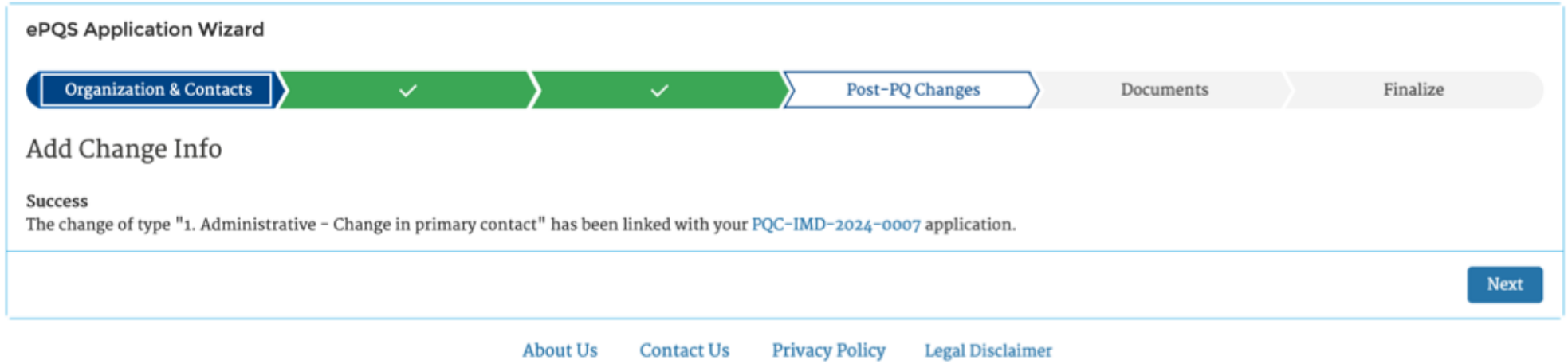
5f. Post-PQ variation submission procedure

Here users are asked to provide the detailed information related to the change. **It is very important to provide the complete set of information here, as described in the text on the screen.** If complete information is not provided, the application will be returned to the user for further input.



5f. Post-PQ variation submission procedure

On this screen, the Wizard confirms that the change information has been linked with the product you selected.

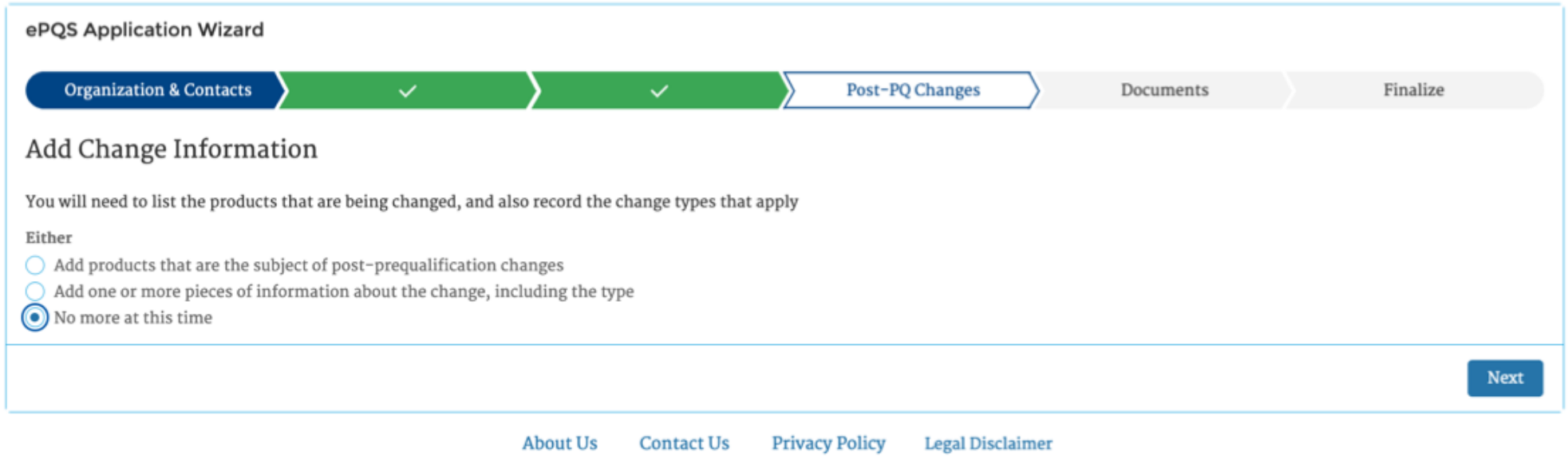


5f. Post-PQ variation submission procedure

Next the **“Add change information”** screen displays for a third time.

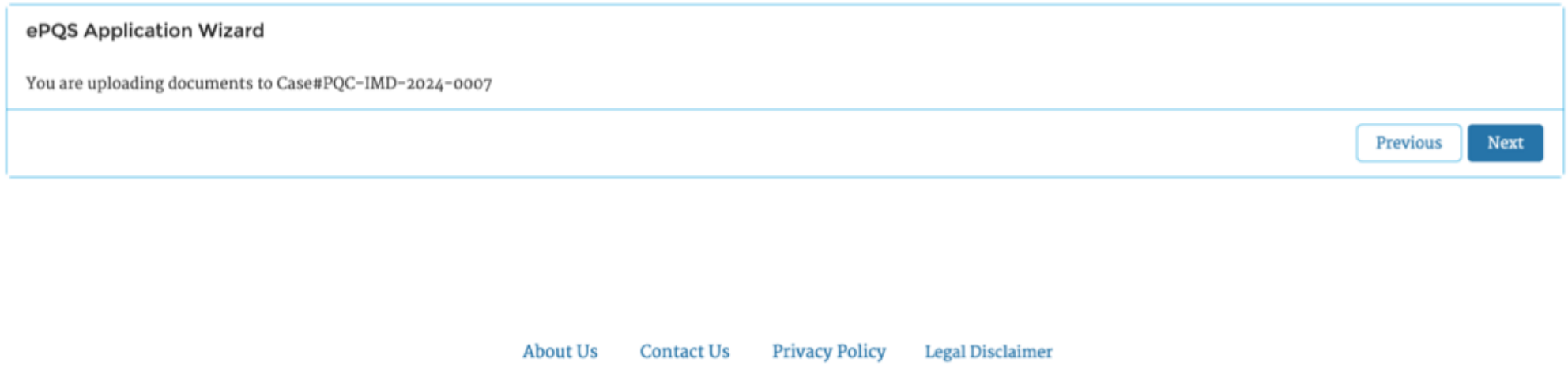
Note - If is wished to report changes to additional products, the user may begin to add the additional or next product(s) here by re-selecting the second option. The user will be prompted to add the change details for that additional product on the screen that follows.

If it NOT wished to add additional products, select **“No more at this time”**.



5f. Post-PQ variation submission procedure

Assuming that “No more at this time” has been selected, the user will be moved onto the start of the document upload procedure. Click “Next”.

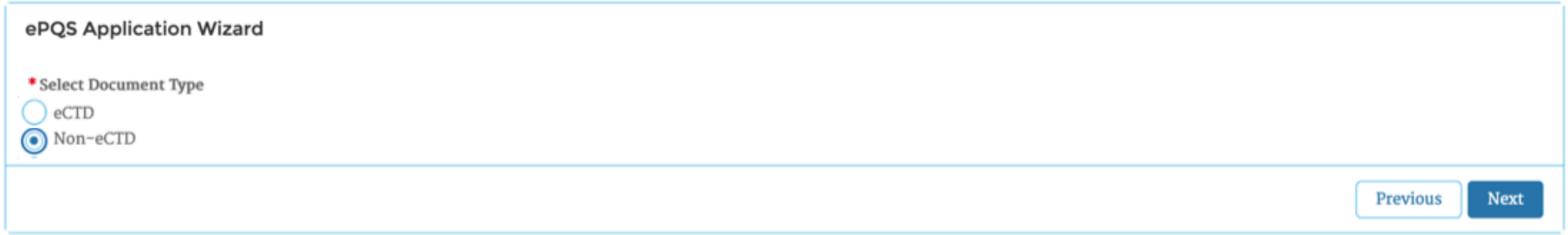


5f. Post-PQ variation submission procedure

The user should select the type of document you will upload (CTD or eCTD).

WHO requirements and guidance on eCTD documents can be found here: https://extranet.who.int/prequal/ectd-portal

IMPORTANT – WHO IMD-PQS does NOT currently require eCTD documents. IMD-PQS PQ Holders should select **"Non-eCTD".**



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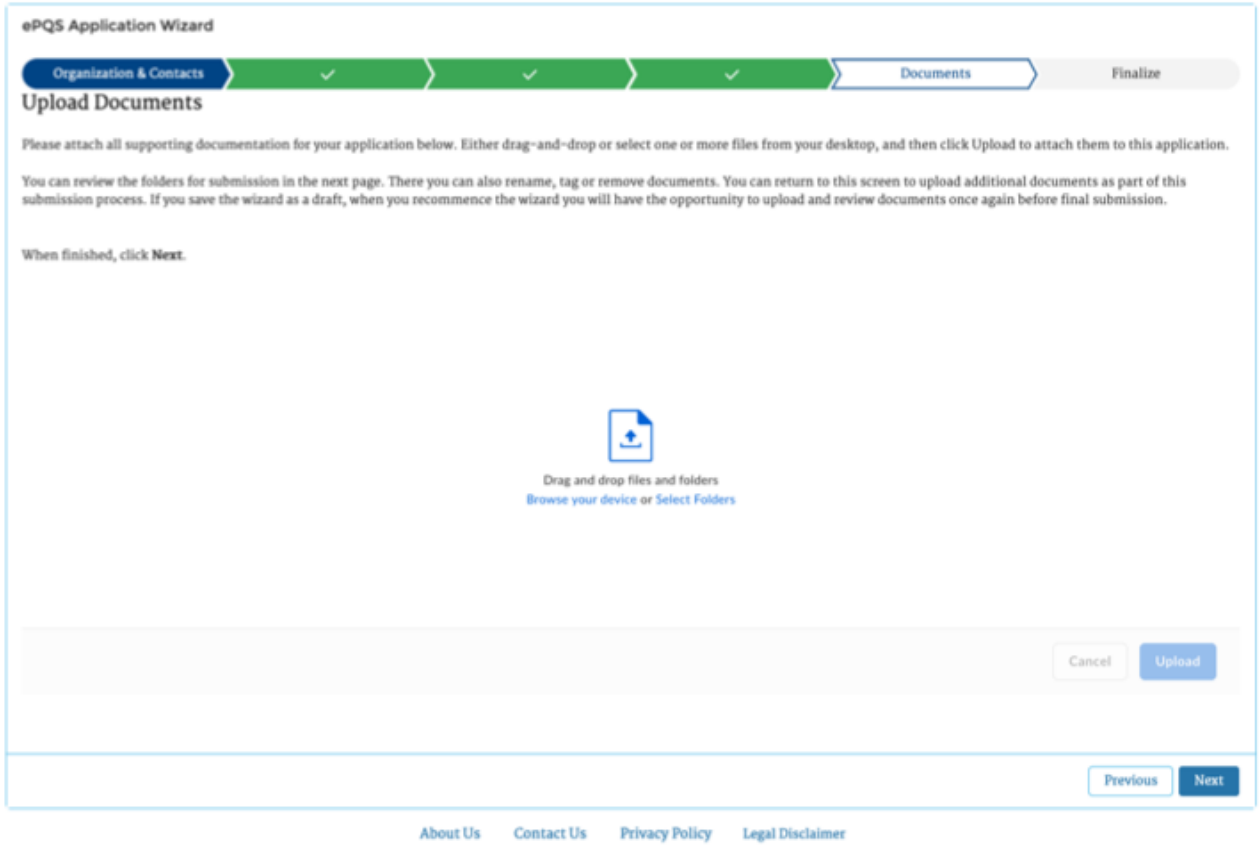
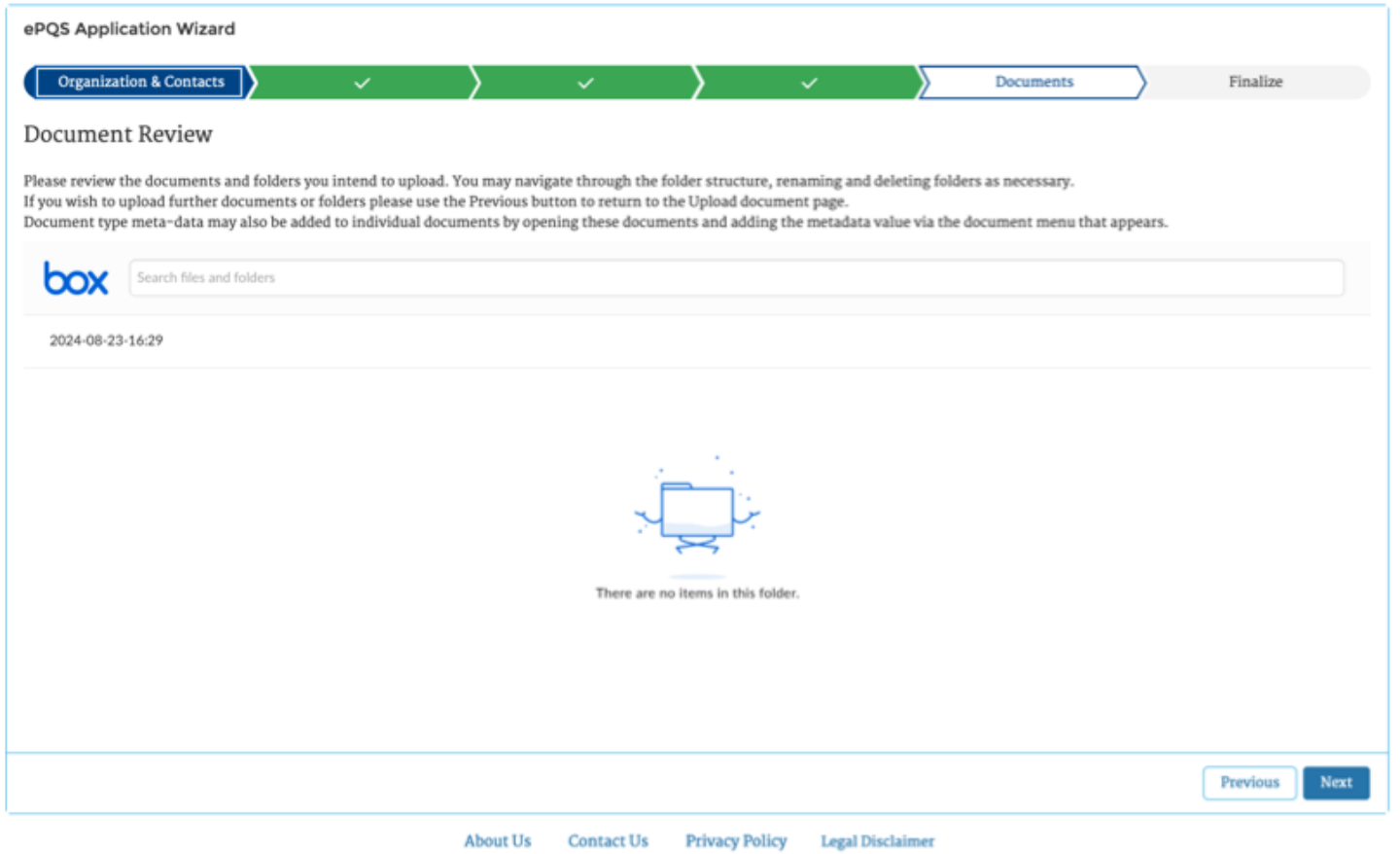
5f. Post-PQ variation submission procedure

On this screen, users should upload ALL the documents related to the change (variation) request, **specifically the evidence required for IMD-PQS to verify the change requested**.



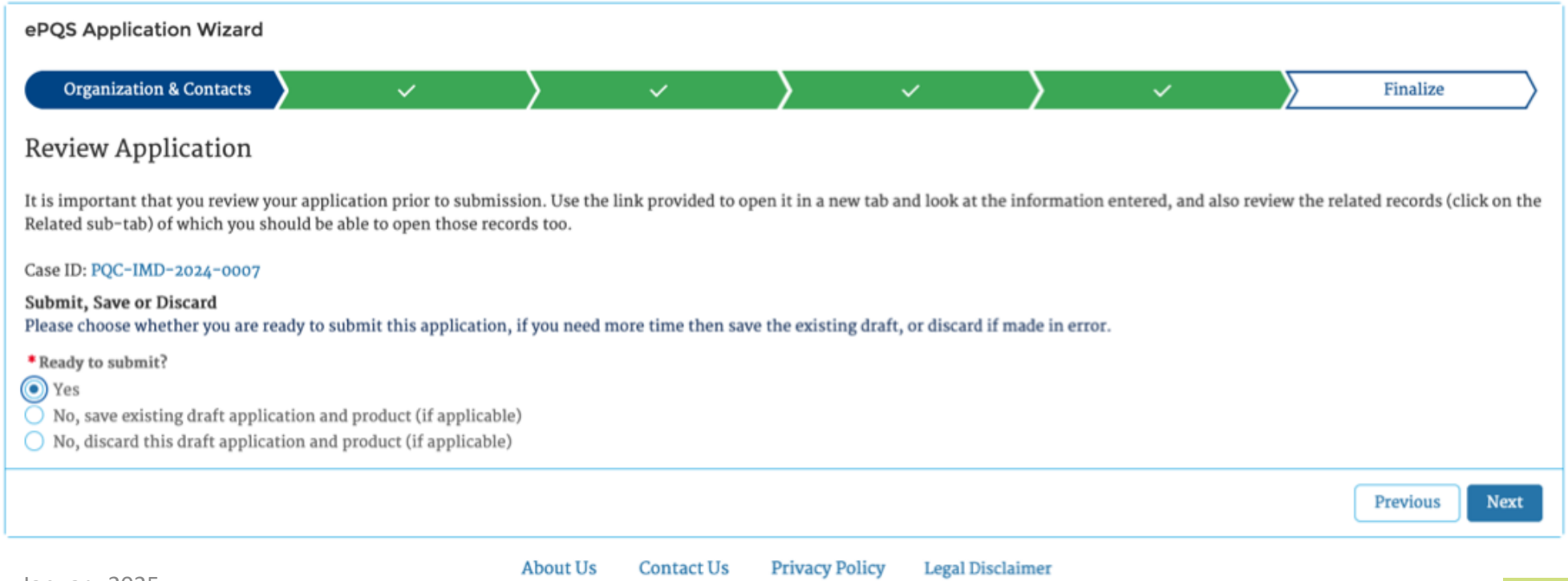
5f. Post-PQ variation submission procedure

On the subsequent screen, users will see a display list of all the documents that have been uploaded.



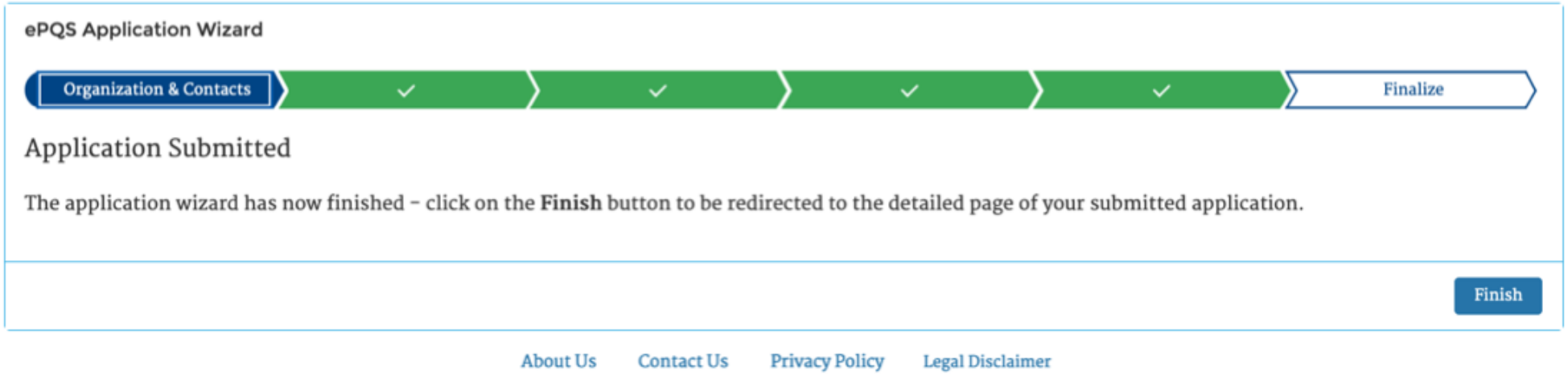
5f. Post-PQ variation submission procedure

Users are now at the **review and submit stage**. On this screen, users may opt to use the generated ePQS case number or link provided earlier to review the application. Otherwise, select **“Yes”** to submit, or else **“No, save draft”** if it is wished to come back later to complete or update the submissions, or **“No, discard”**.



5f. Post-PQ variation submission procedure

The Wizard will confirm that the application has been submitted.
Click **“Finish”** to be taken to an overview of your change application.

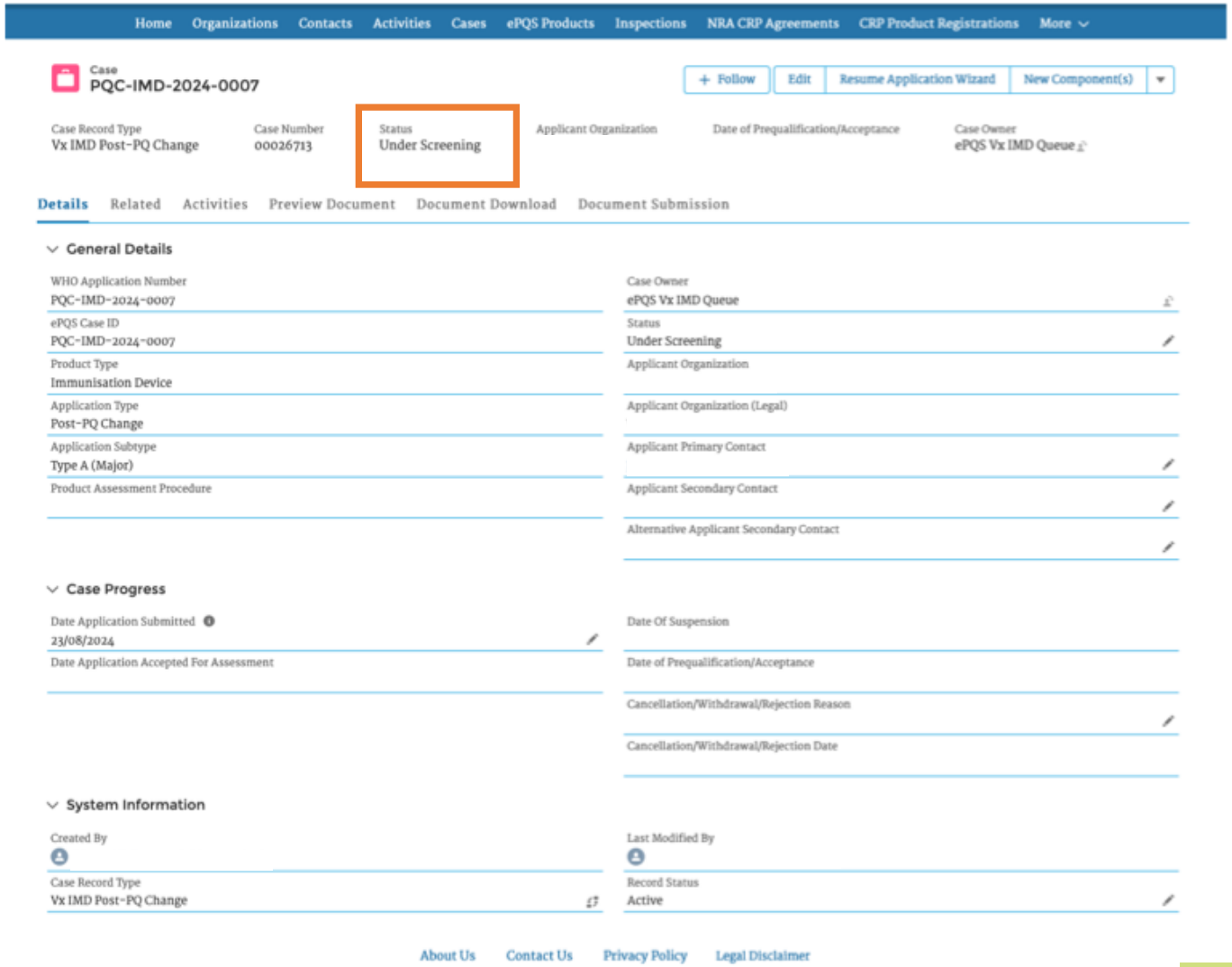


5f. Post-PQ variation submission procedure

This screen displays the case information related to the change (variation) submission.

The status will be listed as **“Under Screening”**.

A **“Required action”** notification will be delivered to the IMD-PQS Secretariat and Technical Specialists responsible for reviewing the change request and information submitted.



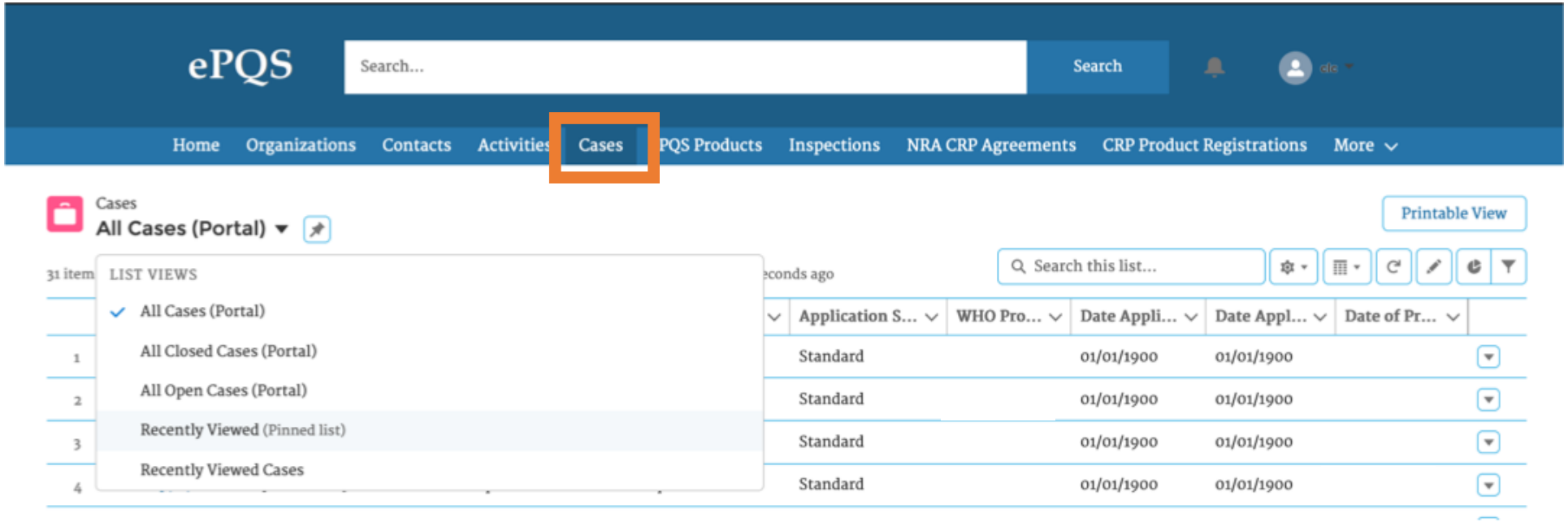
SECTION C – PILOT

5g

Up/downloading of documents

5g. Up/downloading of documents – Related to a PQ application (a “CASE”)

Documents related to a “case” record - i.e. product applications - are available under the “**Cases”** tab.

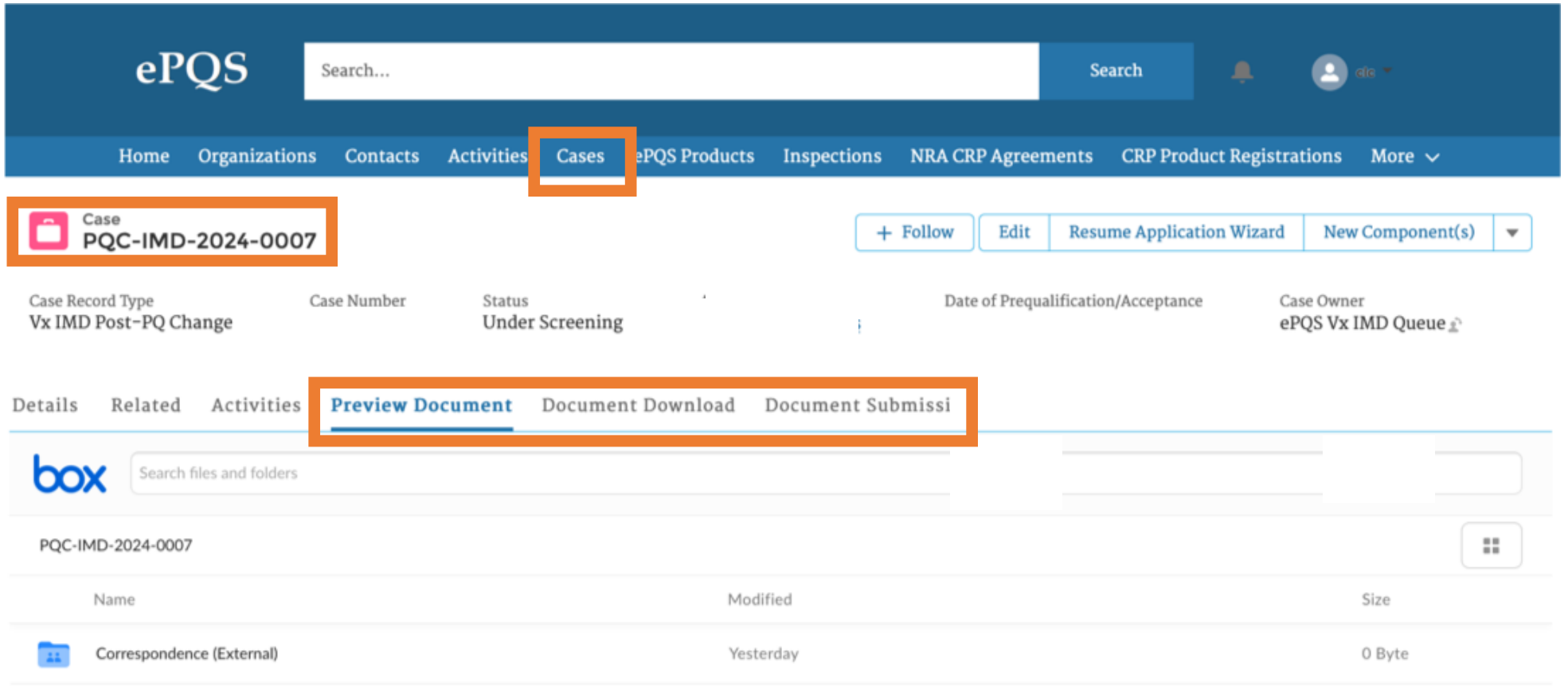


5g. Up/downloading of documents – Related to a PQ application (a “CASE”)

Only an **“External correspondence”** folder is available for cases.

The **“Preview”**, **“Download”** and **“Submission”** functions are available.

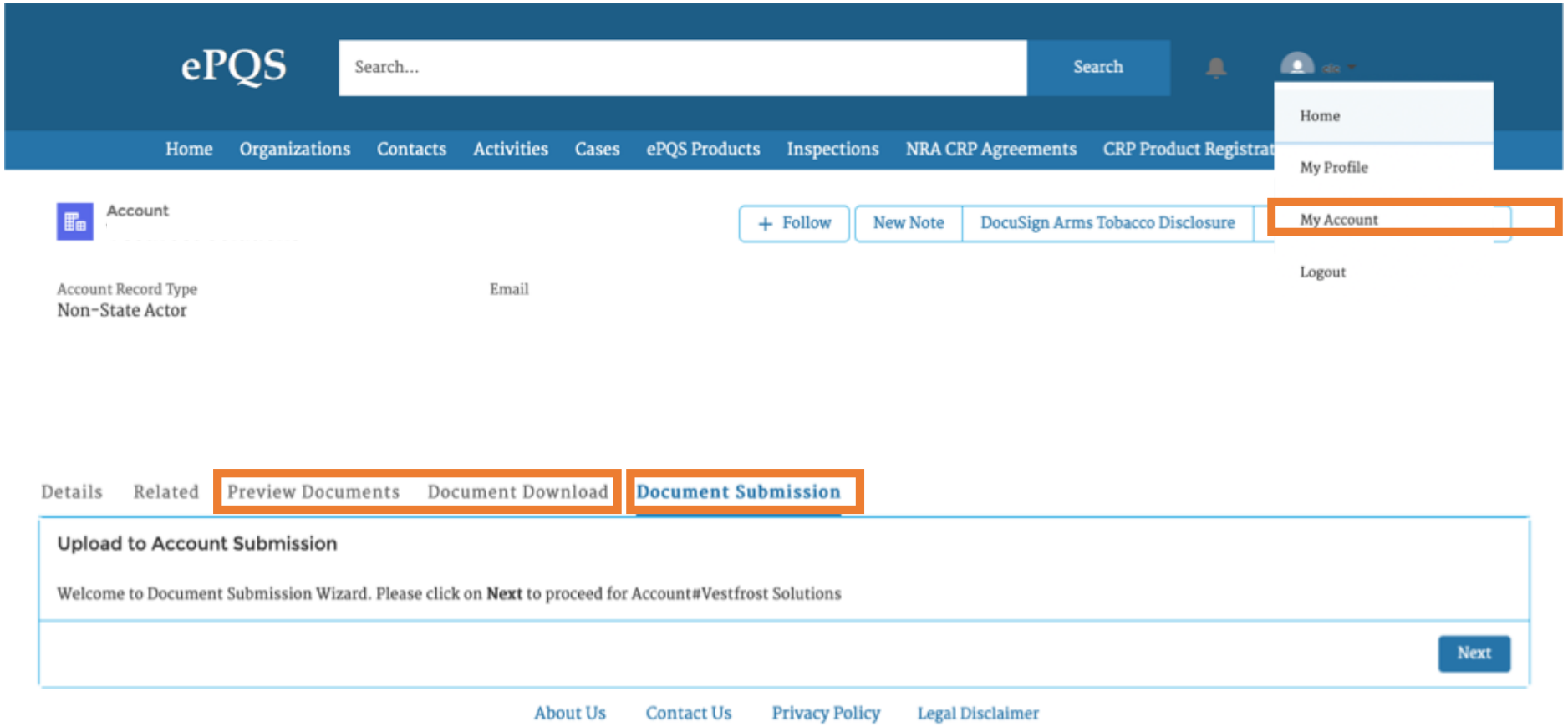
Users should ensure that they are able to upload documents & visualise them.



SECTION C – PILOT

5g. Up/downloading of documents – Related to organisation ACCOUNT

Under **“My Account”** or **“Document Submission”,** users may upload, preview and download documents related to their account or organisation (for example, certification and licencing).

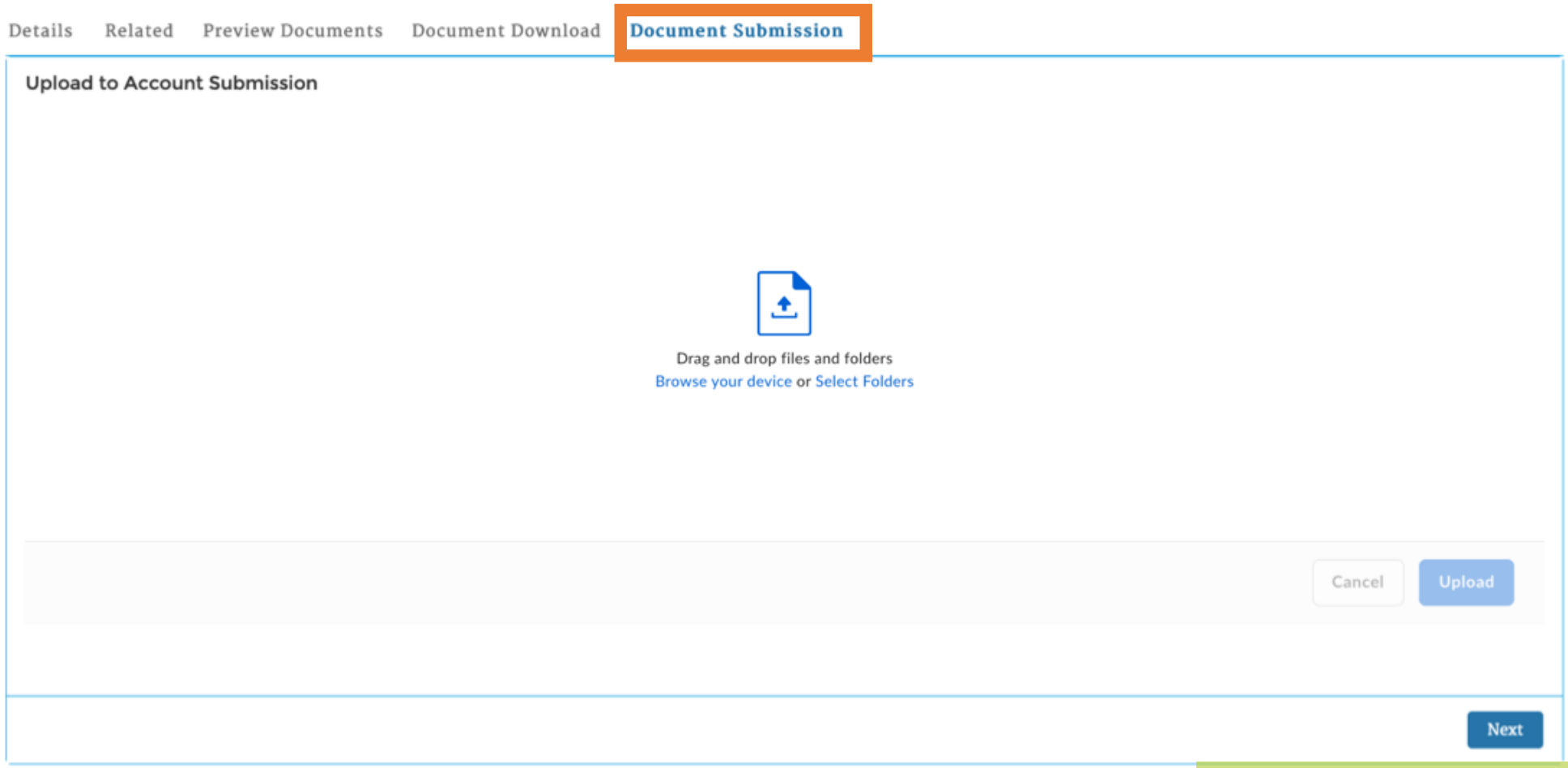


SECTION C – PILOT

5g. Up/downloading of documents – Related to organisation ACCOUNT

Document submission interface →

Once documents are uploaded, users can view them in **“Preview”.**



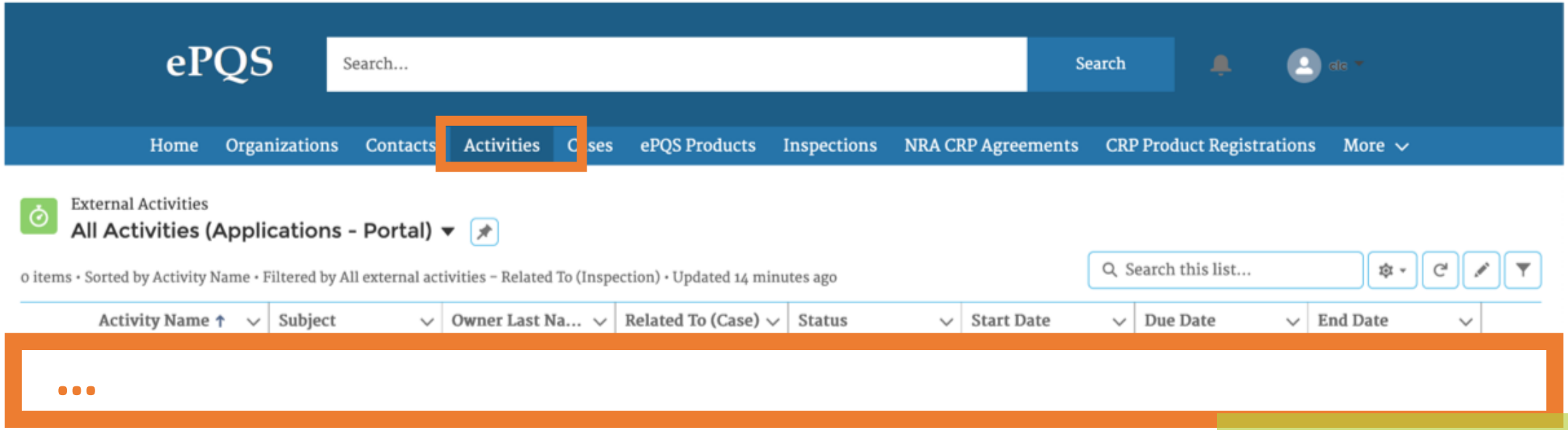
5h

Viewing assigned activities

5i. Viewing of assigned activities

Clicking on the **“Activities”** tab will display a list of all pending activities related to your account. Clicking on each list item will take you to the detailed instructions / requirements of each task. **Users should note that they will automatically receive an email (via the contact-registered email address) each time a new activity is assigned.**

Tasks might include the upload/transmission of further information, providing a response to a specific question, or a request to schedule a meeting.

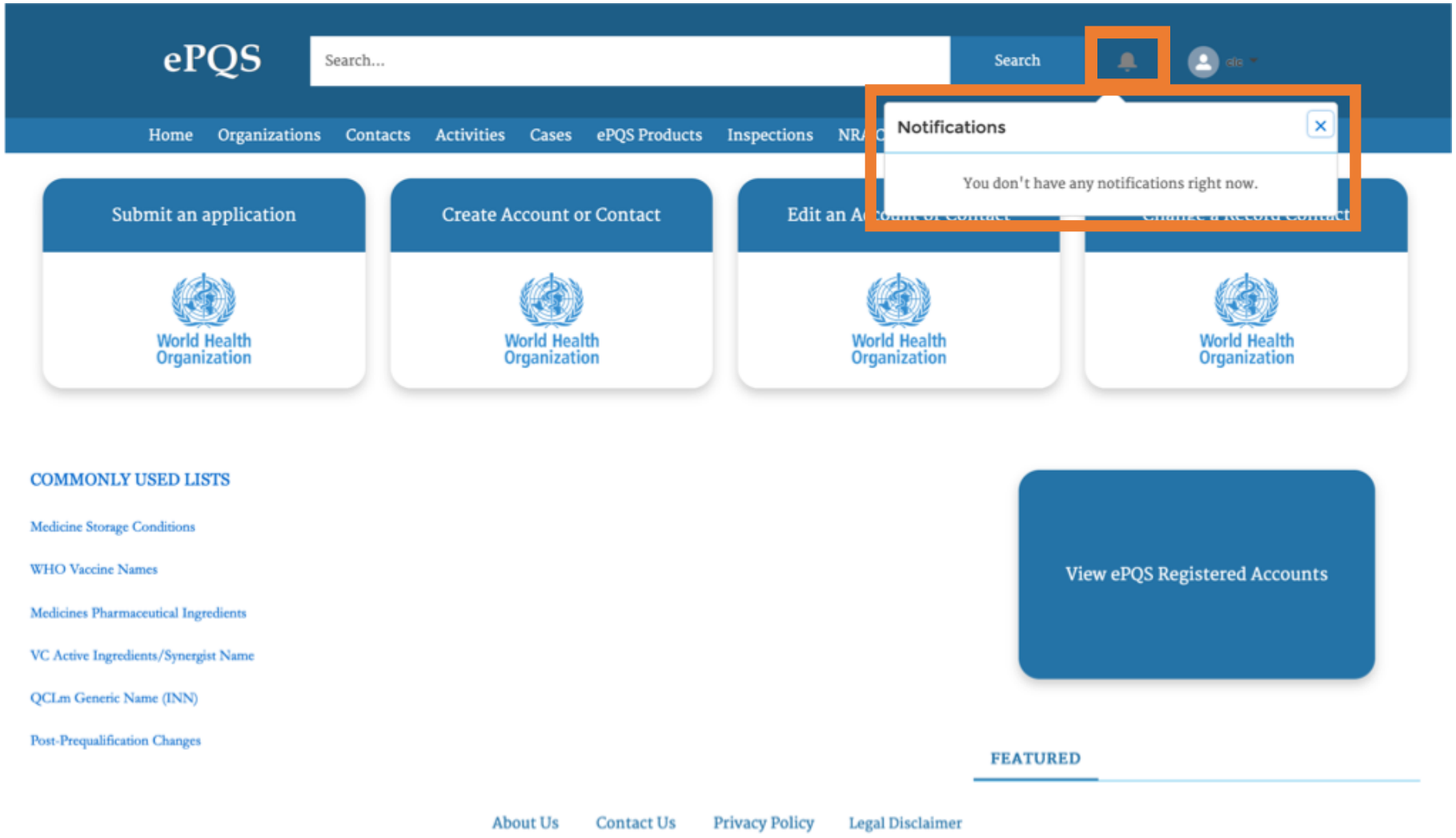


5i

Bell and email notifications & associations with actions

5j. Assignment of activities to applicants

Users will find a list of any pending activities via the **bell notification**.



SECTION C – PILOT

SECTION D – TECHNICAL SUPPORT

6

Additional technical support

6i. IMD-PQS Technical support

IMD-PQS will provide the following additional support to new users over 2025/6.

ePQS Portal

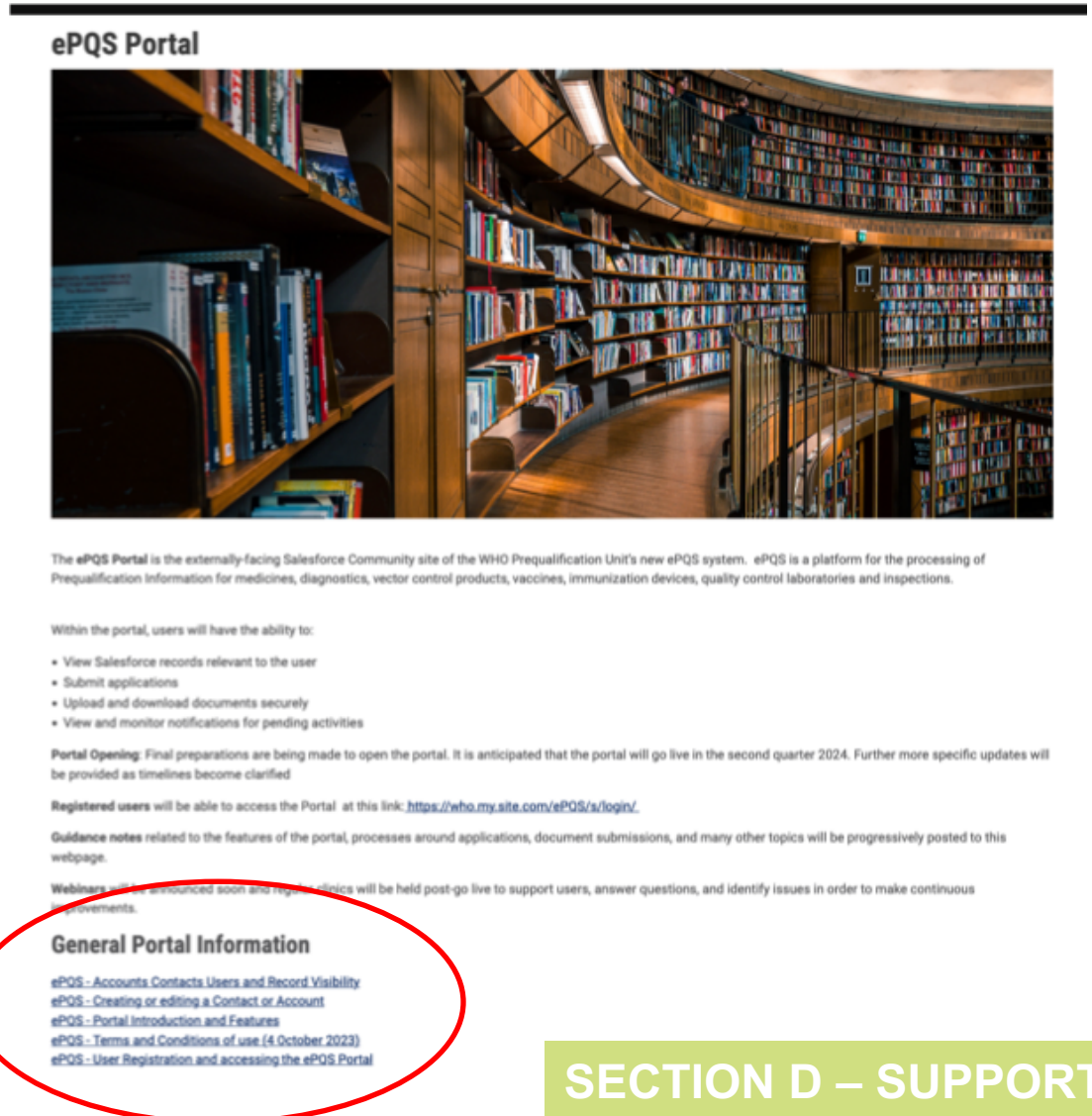
- ePQS Personalised Coaching, Q&A Guide
- Email support
- PQ Holder Guidelines* Annex 7

* LINK: https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-applicants-prequalification-holders

6ii. General user guidance – specific training

General guidance is available on the ePQS landing page:

Link: https://extranet.who.int/prequal/epqs-portal

General Portal Information

ePQS - Accounts Contacts Users and Record Visibility
ePQS - Creating or editing a Contact or Account
ePQS - Portal Introduction and Features
ePQS - Terms and Conditions of use (4 October 2023)
ePQS - User Registration and accessing the ePQS Portal