ePQS & eCTD

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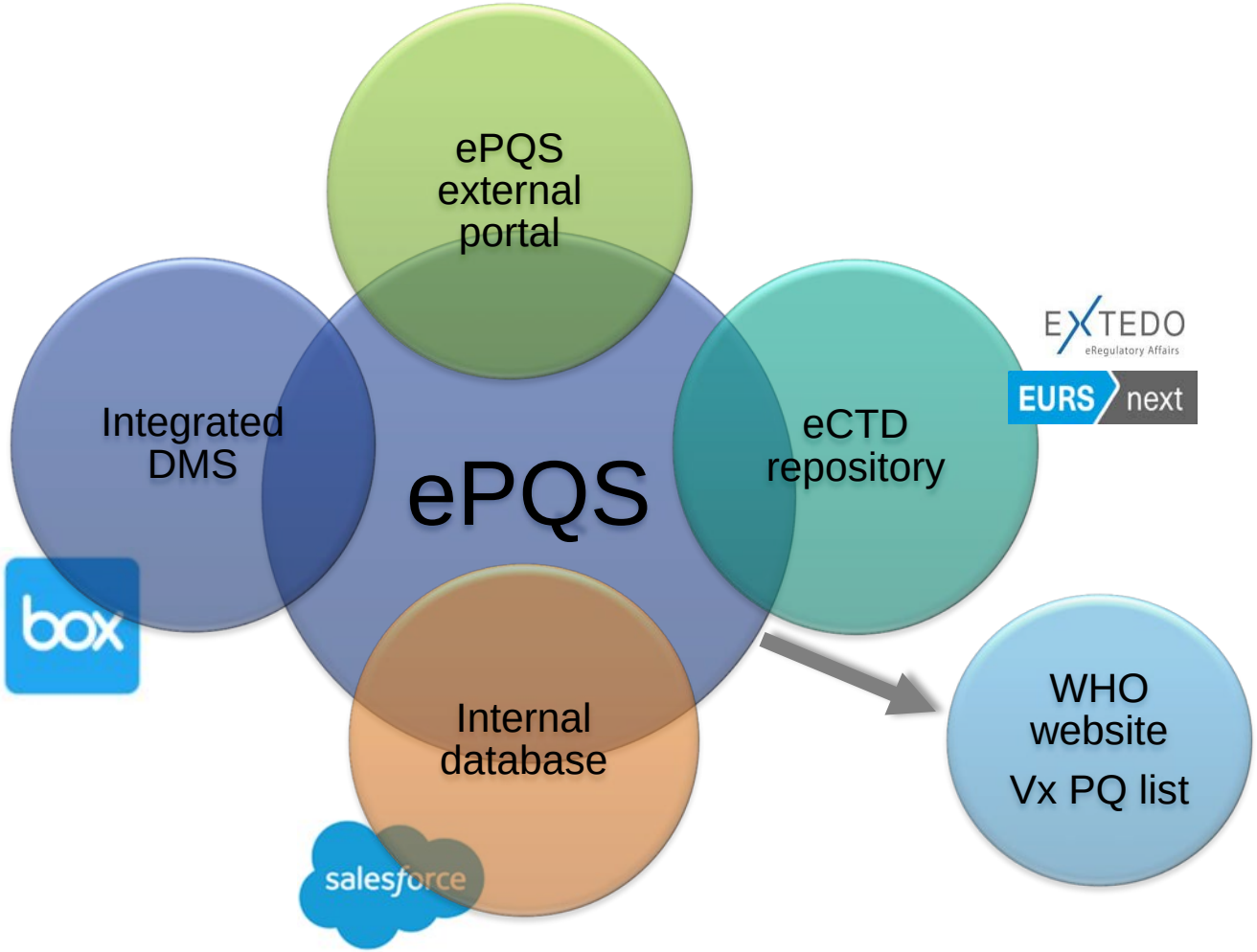
What is ePQS?

Is an IT solution that brings all core areas of WHO PQ Unit into a centralized platform, that will allows the processing of information for:

- Vaccines
- Immunization devices
- Medicines
- Diagnostics
- Vector control
- Quality control laboratory
- Inspections

ePQS consist of several integrated packages



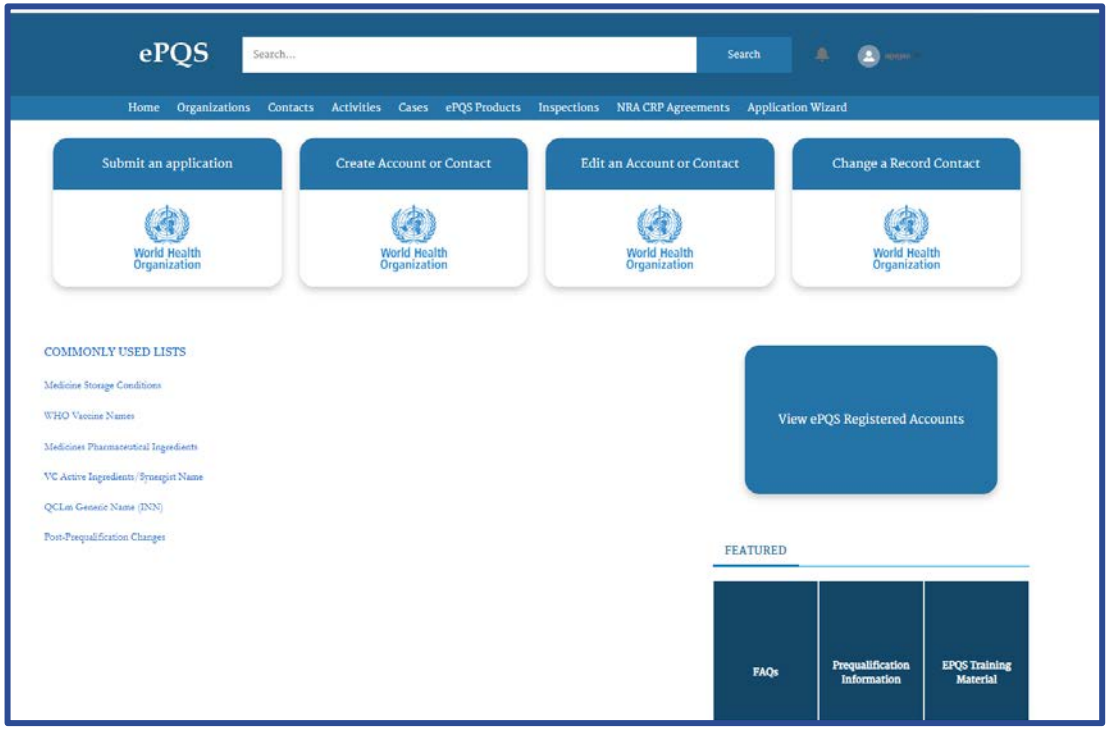
Current status implementation

- ✓ All PQ teams are now using ePQS and IMD migrated recently
- ✓ The DMS is being finalized and Document migration will follow
- ✓ Web Publishing: medicines, quality control labs., vector control, WPEL PQ lists, FPP Pipeline are now coming from ePQS (10 mins refresh)
- ✓ Document migration will be the last step, after which all teams will work exclusively in ePQS

ePQS – external portal

Designed to:

- ✓ Submit applications
- ✓ View records related to their application/product/site
- ✓ Upload and download documents in as secured environment
- ✓ View and monitor notifications for pending activities



Contacts and Accounts access

Access to records will be based upon the user's relationship to an Organization (Account).

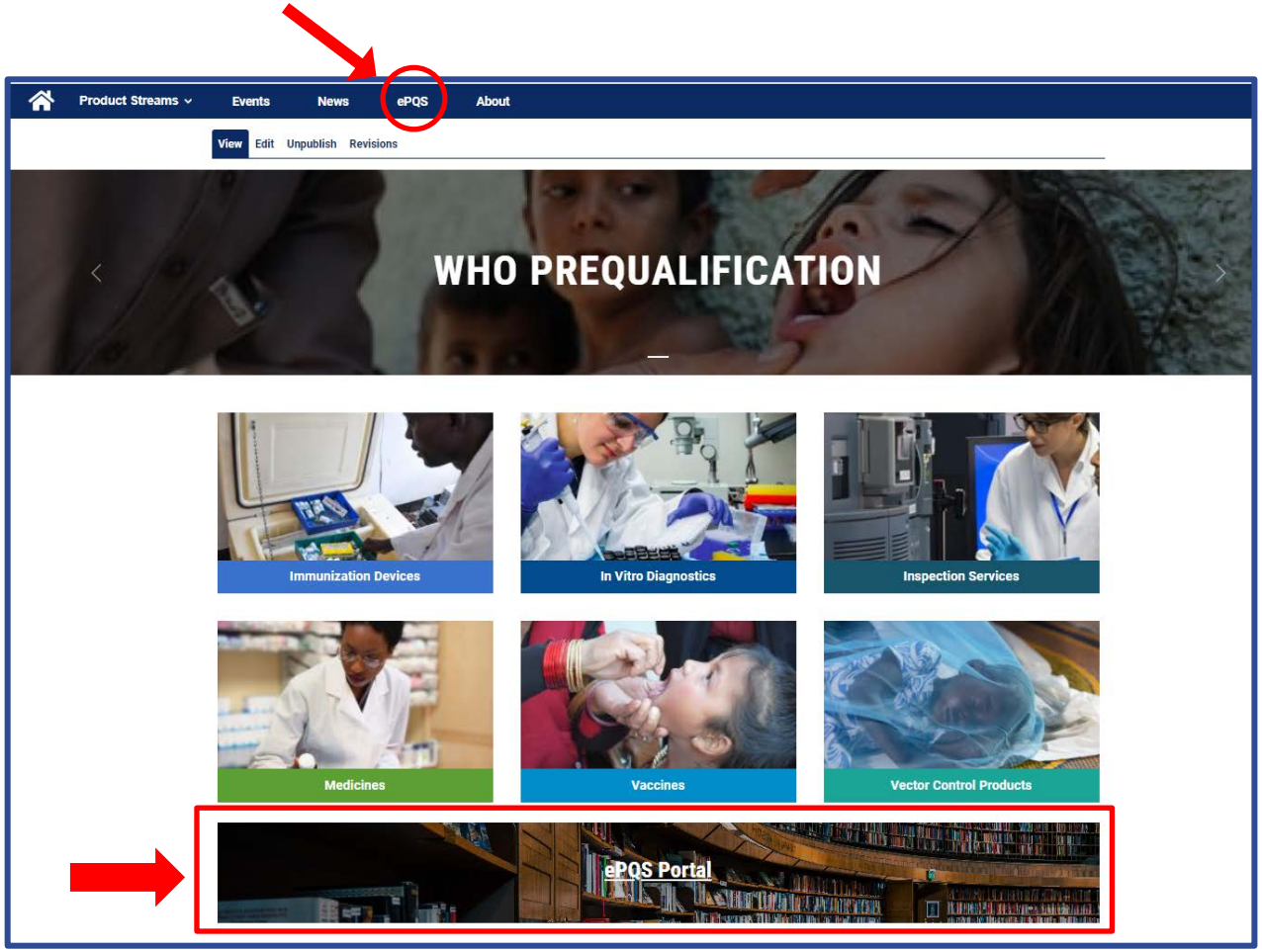
- *e.g., users belonging to 'Vaccines Biotech Int.', will only be able to see 'Vaccines Biotech Int.' records.*

The relationship between the contact and the account will determine access to the records.

As part of the registration process, the manufacturer will have to select 2 official contacts for the account they belong to.

Please check portal webpage for more information.
https://extranet.who.int/prequal/epqs-portal

Access to the ePQS portal



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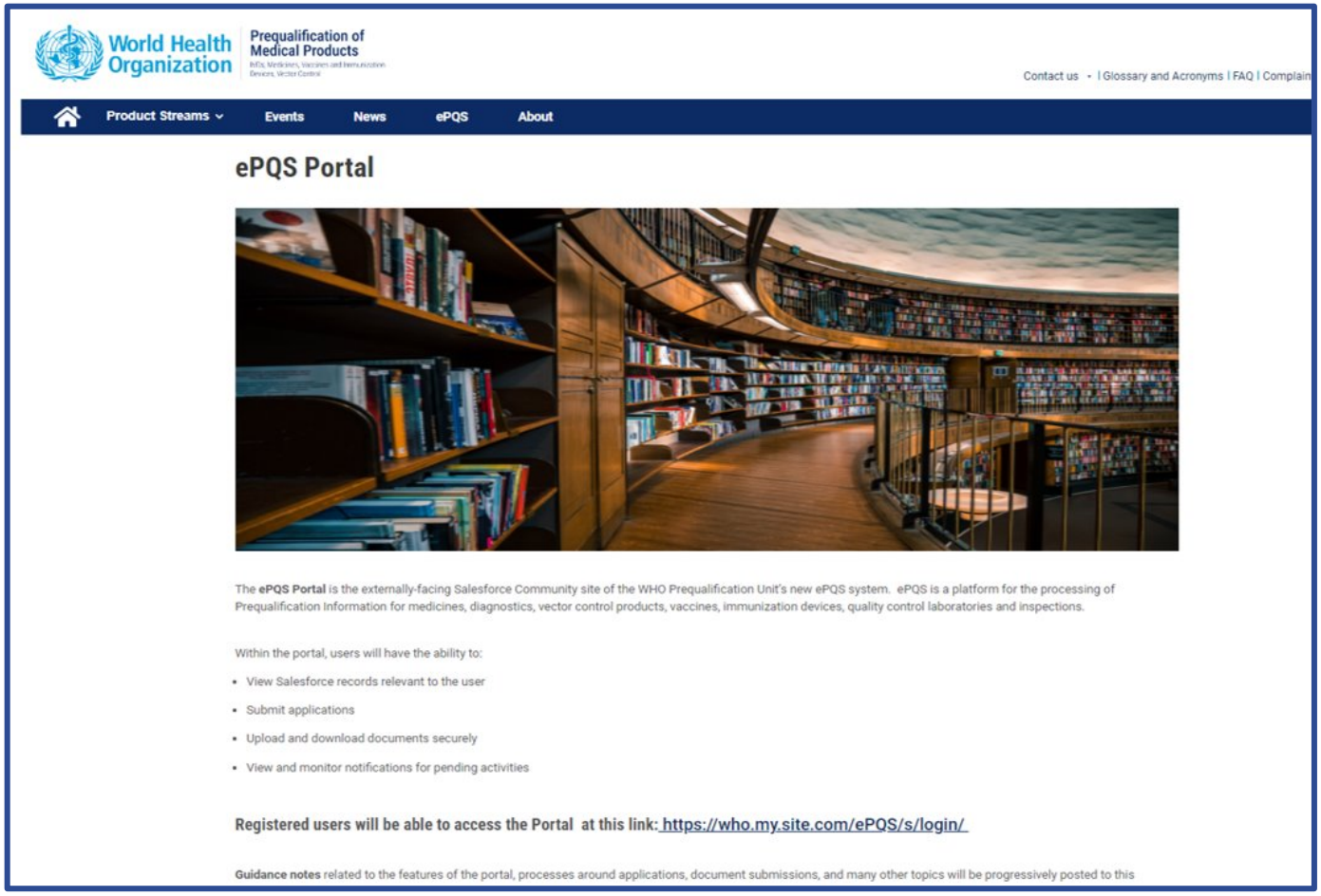
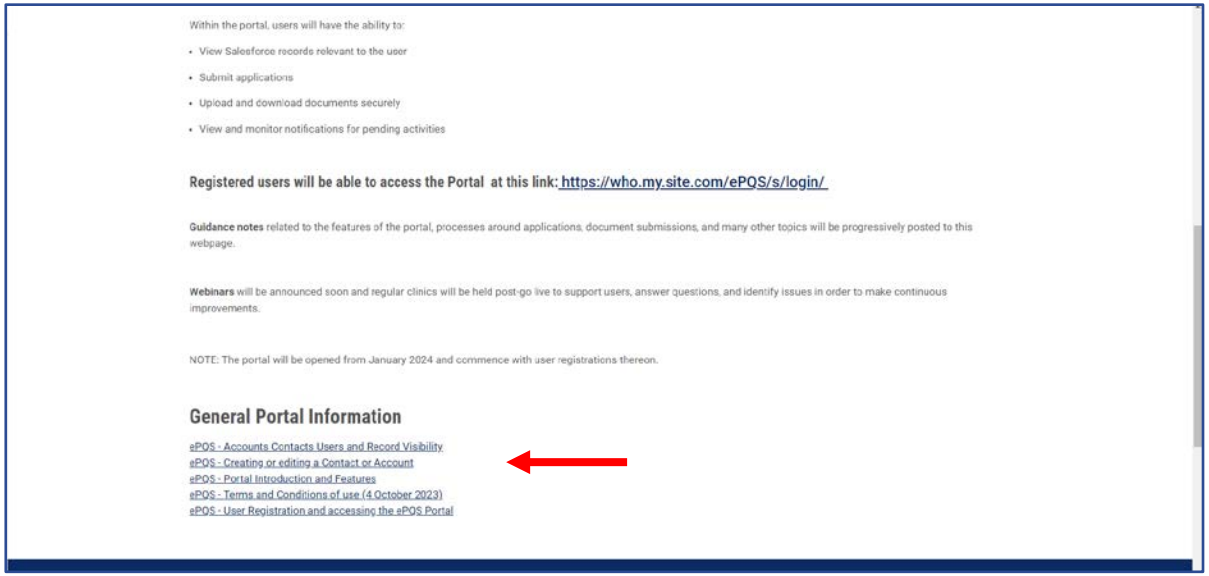


https://extranet.who.int/prequal/epqs-portal

Opening of the ePQS portal

- ✓ Registration for Portal access will open early 2024
- ✓ Guidance information will continue to be added to this page.
- ✓ Webinars and clinics for users are planned to assist applicants.



Within the portal, users will have the ability to:

- View Salesforce records relevant to the user
- Submit applications
- Upload and download documents securely
- View and monitor notifications for pending activities

Registered users will be able to access the Portal at this link: https://who.my.site.com/ePQS/s/login/

Guidance notes related to the features of the portal, processes around applications, document submissions, and many other topics will be progressively posted to this webpage.

Webinars will be announced soon and regular clinics will be held post-go live to support users, answer questions, and identify issues in order to make continuous improvements.

NOTE: The portal will be opened from January 2024 and commence with user registrations thereon.

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

eCTD - electronic Common Technical Document

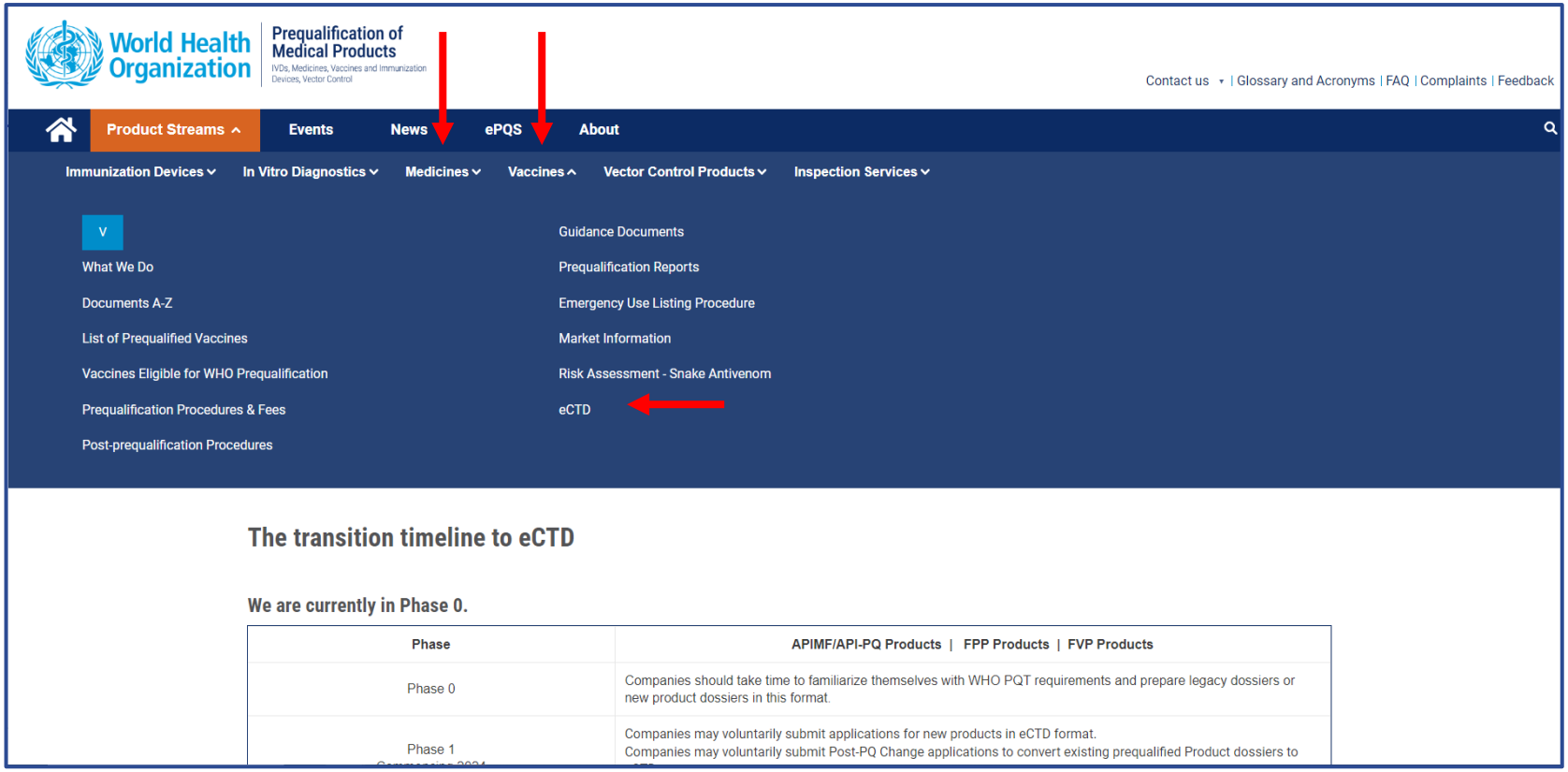
- ✓ Provides a harmonized technical solution to implementing the CTD electronically
- ✓ The purpose is to reduce burden of document lifecycle and facilitate document review by the assessors
- ✓ Module 1 requirements have been posted to the PQT webpage
- ✓ The first webinar has occurred, and further webinars and industry clinics are planned for 2024
- ✓ Expected opening early 2024

eCTD Transition phases

- Phase 1 (2024): optional eCTD submissions.
- Phase 2 (+1 year): Mandatory for new product applications.
- Phase 3 (+2 years): Mandatory all applications in eCTD.

eCTD Portal

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



eCTD - 2023 10 18 PQT Validation Criteria v 1.0

eCTD - FAQ WHO PQT

eCTD - WHO eCTD guidance for Industry

eCTD - WHO PQT eCTD checksums

eCTD - WHO PQT Technical Files

eCTD - WHO PQT Valid Values XML

eCTD - WHOPQT eCTD M1 Specification (Files-Elements-Folders)

THANK YOU