API Assessment Update &

ePQS update

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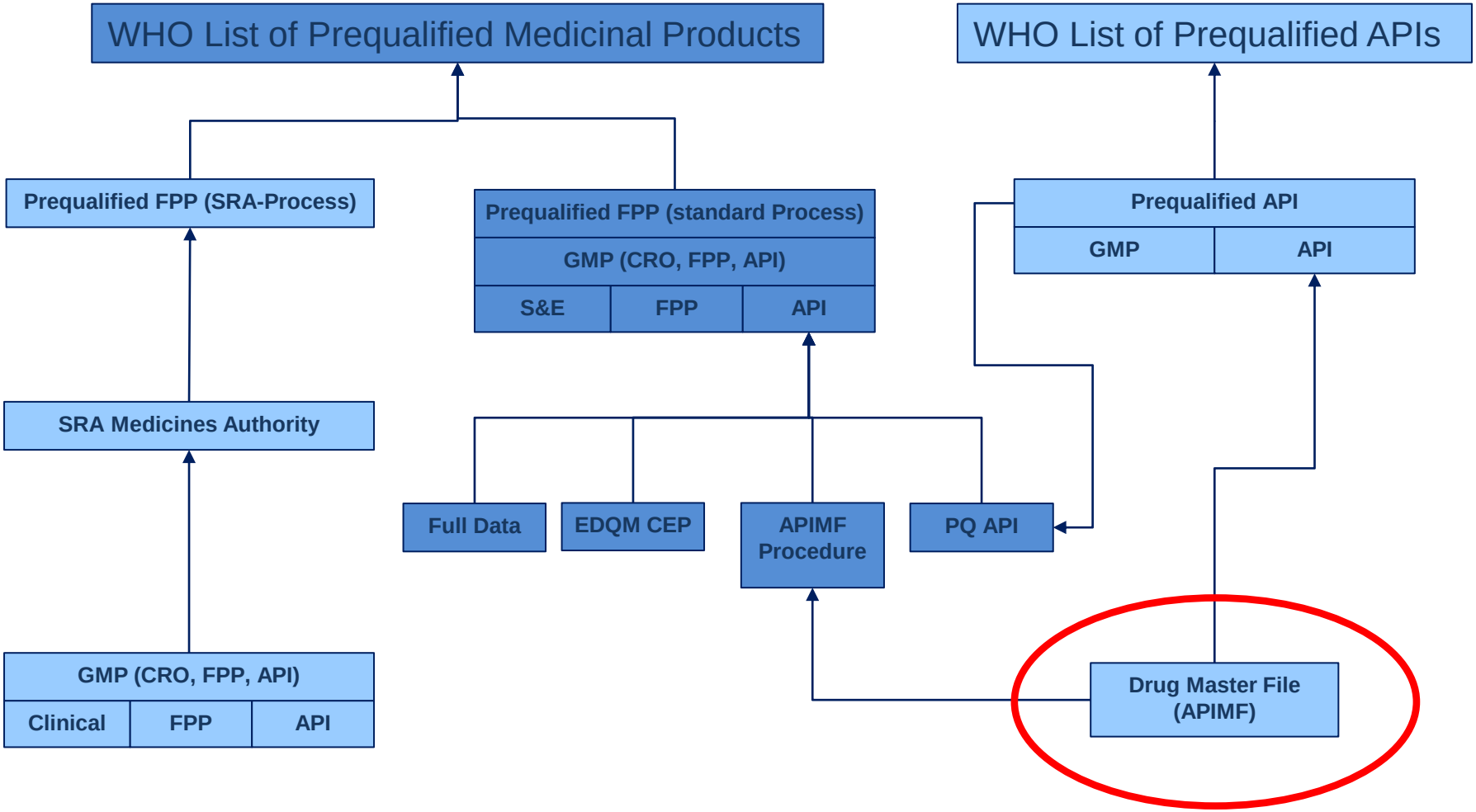
API assessment within PQT Medicines

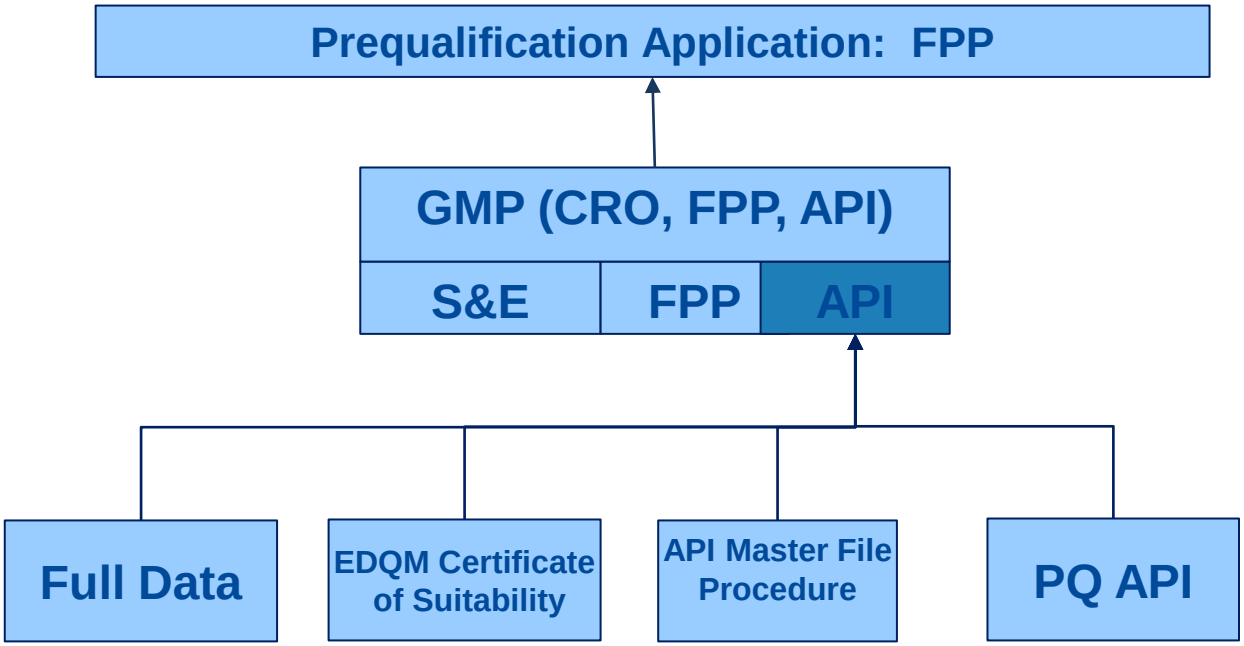
API manufacturers may be involved in two ways.

- Seeking prequalification of their own API.
- In support of a finished pharmaceutical product (FPP) seeking prequalification (4 options).

Prequalification of APIs



API Manufacturers supporting an FPP

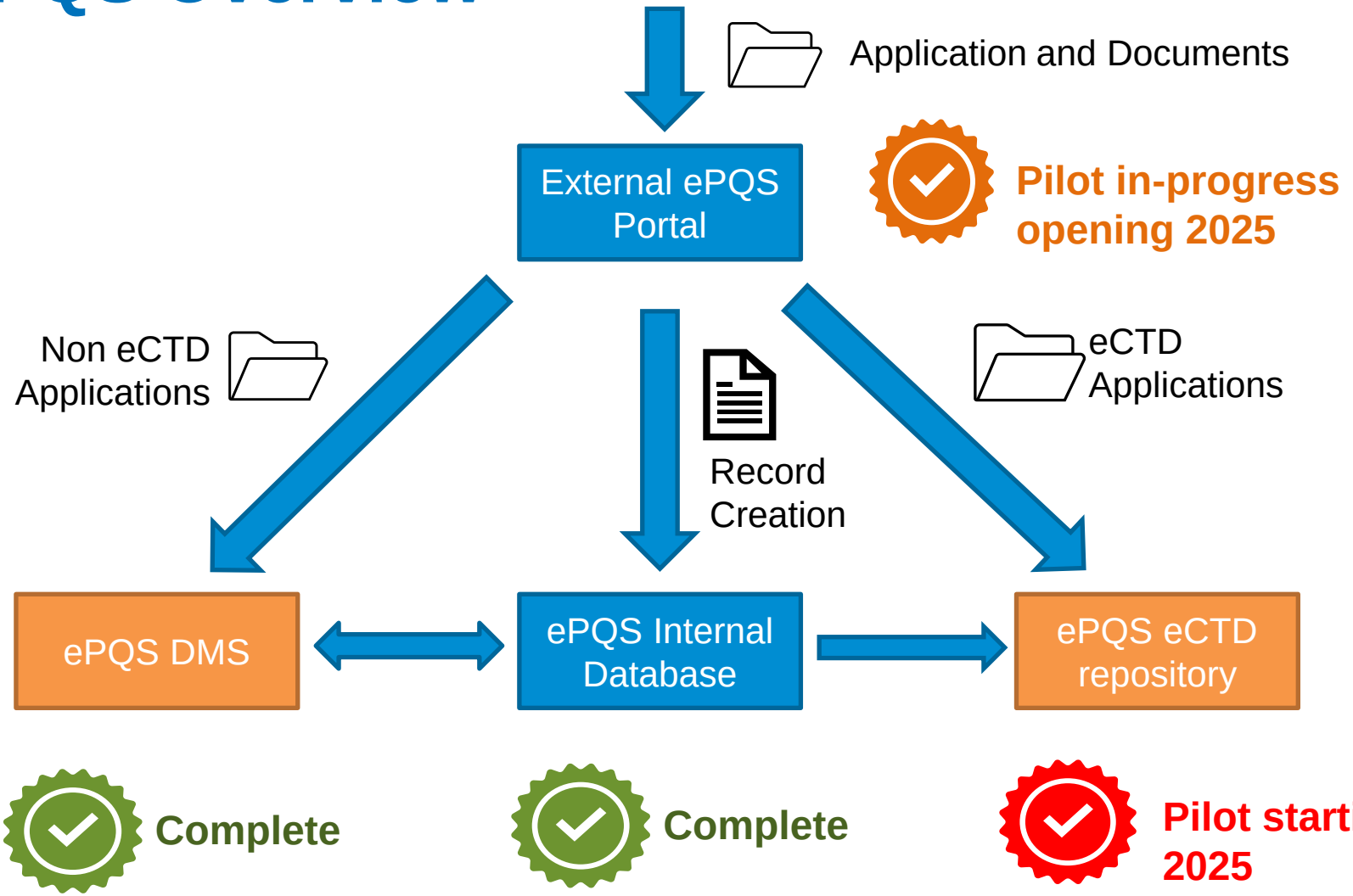


API assessment by the numbers

- 180 Prequalified APIs and 93 APIMFs accepted only via APIMF Procedure.
- 49 APIs under assessment for Prequalification and 12 APIMFs for the APIMF procedure only.
- 120 amendment applications received in 2024 to-date.
- 20 APIs PQd in 2024 to-date: median WHO time (<250 days), Manuf time (<289 days).
- This includes the first prequalified Tranexamic acid API.
- Priority given to rifampicin-related applications given world-wide shortage.

ePQS update

ePQS Overview



ePQS Portal

- A secure platform for external users.
- It uses WHO's Microsoft Azure Active Directory, which ensures only authorized users with the right username and password are granted access to the ePQS portal and all related systems
- Applicants, NRAs, External experts each have different visibility of records
- Permits filing of applications, responses and general tracking of applications
- Secure document transfer to and from WHO
- See dedicated page: https://extranet.who.int/prequal/epqs-portal
- **Pilot has commenced. Opening Q1 2025**

eCTD

- Integration is being developed to allow submission of eCTD formatted documents via the portal into an eCTD repository.
- This will greatly improve applicants' ability to manage their documents, and our ability to follow changes.
- See dedicated page: https://extranet.who.int/prequal/ectd-portal
- Mod 1 structure has been developed and finalized.
- **Pilot commencing early 2025**
- Submissions in eCTD format for APIs and FPPs will not be compulsory immediately. See webpage for timeline.
- Conversion of an existing accepted or prequalified product will be initiated by filing an eCTD Baseline variation or amendment.

eCTD Baseline

- It is intended to be a “light” process, relying on company declarations regarding similarity of details to those prequalified.
- On-going applications must be completed first.
- No changes should be made within the Baseline application. Submit changes before or after the conversion.

eCTD Baseline

The documentation provided with an eCTD baseline submission, would include as a minimum:

For APIMFs:

- Mod 1 documents: cover letter, application form and summary of changes.

- Module 2 and 3 sections reflecting the currently accepted product details.

For FPPs:

- Mod 1 documents: cover letter, application form, QIS, and a revised version of the SMPC, PIL and/or labels if these are affected

- Module 2 and 3 sections reflecting the currently accepted product details.

Questions?