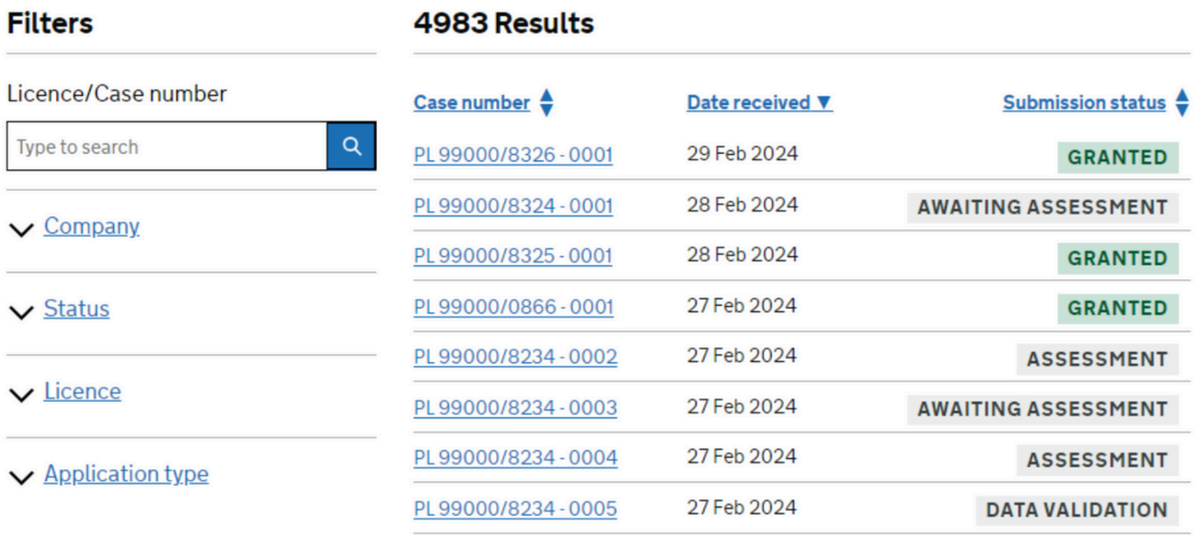
eSubmissions highlights

ASPHALION
Knowledge from experience

MHRA RegulatoryConnect Portal

- Log in from your existing MHRA Submissions Portal credentials.
- **Track the status of applications** and view live **authorisation details**.
- Show the status of any pending submissions (excluding information updates and Periodic Safety Update Reports (PSUR)).



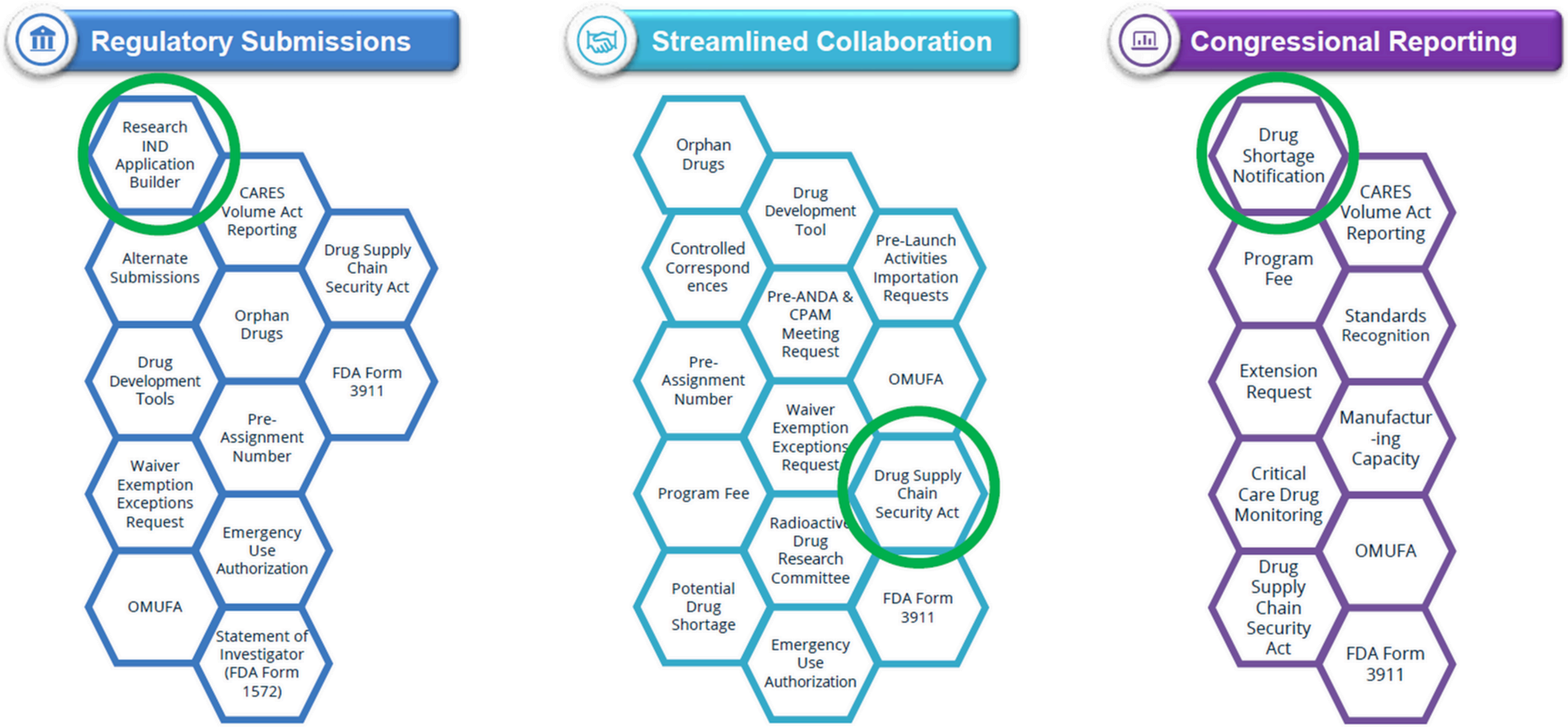
FDA - CDER NextGen Portal

ASPHALION
Knowledge from experience

- **CDER Standards Recognition:** Request to informally recognize voluntary consensus standards related to quality.
- **DSCSA (Drug Supply Chain Security Act) Waiver, Exception, and Exemption Request:** Submit a request for a waiver, exception, or exemption from requirements related to product tracing, product identifier, authorized trading partners and verification.
- **EUA (Emergency Use Authorization):** Submit questions or an EUA submission when a drug product may be considered for emergency use to diagnose, cure, mitigate, treat, or prevent a disease caused by a threat agent in or during a declared public health emergency. Do NOT use to request an Emergency IND.
- **Over-the-Counter (OTC) Monograph:** Submit certain OTC Monograph submissions.
- **RDRC (Radioactive Drug Research Committee):** Submit RDRC submissions (e.g., Annual Reports, Special Summary Reports, Membership Summary Reports).
- **Statement of Investigator (Form FDA 1572):** Prepare, sign, and download Form FDA 1572.
- **Drug Notifications (3911 Platform):** Submit, review or terminate a 3911 submission. Notify FDA of illegitimate drug products (within 24 hours after determining a product is illegitimate).

FDA - CDER NextGen Portal

ASPHALION
Knowledge from experience



FDA - FAERS (Adverse Event Reporting System)

- **FAERS** is a database that contains information on submitted adverse event and medication error reports.
- On **April 1st, 2026, ICH E2B (R3) will be mandatory for safety reporting electronic transmission.** Optional since April 1st, 2024.
- **Submissions** either through FDA ESG (using Database-to-Database E2B transmission) or SRP (Safety Reporting Portal).

	Current	Future
PRE-Marketing (IND)	eCTD	ICH E2B (R3)
POST-Marketing (NDA, BLA, ANDA)	ICH E2B (R2)	ICH E2B (R3)

EU - PIP IRIS Portal Submissions

Starting from **4th June 2024**, the EMA will transition **from the current EMA Gateway to the IRIS portal** for submissions related to paediatric procedures.

New Paediatric submissions are mandatory via IRIS platform from 4 June 2024

Please note that from 4 June 2024, the following types of **new** paediatric submissions must be carried out via IRIS:

- Initial paediatric investigation plan (PIP)
- Modification of an agreed PIP
- Product-specific waiver
- Compliance check
- Annual report on paediatric deferred measures
- Confirmation of applicability of a class waiver, or inclusion of an indication within a condition
- Discontinuation of paediatric development.

To ensure a smooth transition to using the IRIS platform, it is essential that applicants prepare well in advance, including registering for IRIS, as described in the following

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-and-rpis_en.pdf

The gateway is open for ongoing paediatric procedures only.

RoW - New eCTD Regions & Upcoming Changes

World Health Organization: From 2024, voluntary for new products and post-PQ changes conversion. Submissions through ePQS Portal.

Singapore: From Q4-2024. Submissions through HSA eCTD Portal (sign in with CorpPass).

Economic Community of West African States: From Nov 1st, 2023, for centralised procedures. eCTD from May 1st, 2026. Submissions through ECOWAS eCTD Portal.

Ukraine: From January, 2025, voluntary for variations and from August 18th, 2025, mandatory for all applications.

RoW - New eCTD Regions & Upcoming Changes

South Africa: New M1 v3.0 will be released by October 1st, 2024, with an automatic mandatory use, including updates on current eCTD guidelines and validation criteria. Developing a new eCTD submission portal

Australia: New M1 v3.2 release by July-2024 (voluntary), mandatory by (Q1-2025). This will include updates also on validation criteria.

Europe: New eCTD EU M1 3.1 specification and Validation Criteria v8.0 has already been published.