Over-the-Counter Drugs Modernizing Communications Between CDER and Industry

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Who has bought an Over the Counter product?

- It is estimated that here in the United States, on average there are 2.9 billion trips taken annually to purchase an OTC product
- U.S. consumers make 26 trips a year to purchase OTC products. They only visit doctors, on average, three times a year.
- The average household will spend approximately $338 per year on OTC drugs.

https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics

Over-The-Counter Monographs

- The OTC drug review was established to evaluate the safety and effectiveness of OTC drug products marketed in the United States before May 11, 1972
- The monographs are ‘recipe books’ that establishes the conditions, under which an OTC drug is generally recognized as safe and effective (GRASE)
  - Their benefits outweigh their risks
  - The potential for misuse and abuse is low
  - Consumer can use them for self-diagnosed conditions
  - They can be adequately labeled
  - Health practitioners are not needed for the safe and effective use of the product

Over-the-Counter Monograph User Fee Agreement (OMUFA) & OTC Monograph Order Request (OMOR)

Infrastructure

- Build a basic infrastructure (IT and training) to meet the goals of monograph reform

Communication

- Enhance communication and transparency

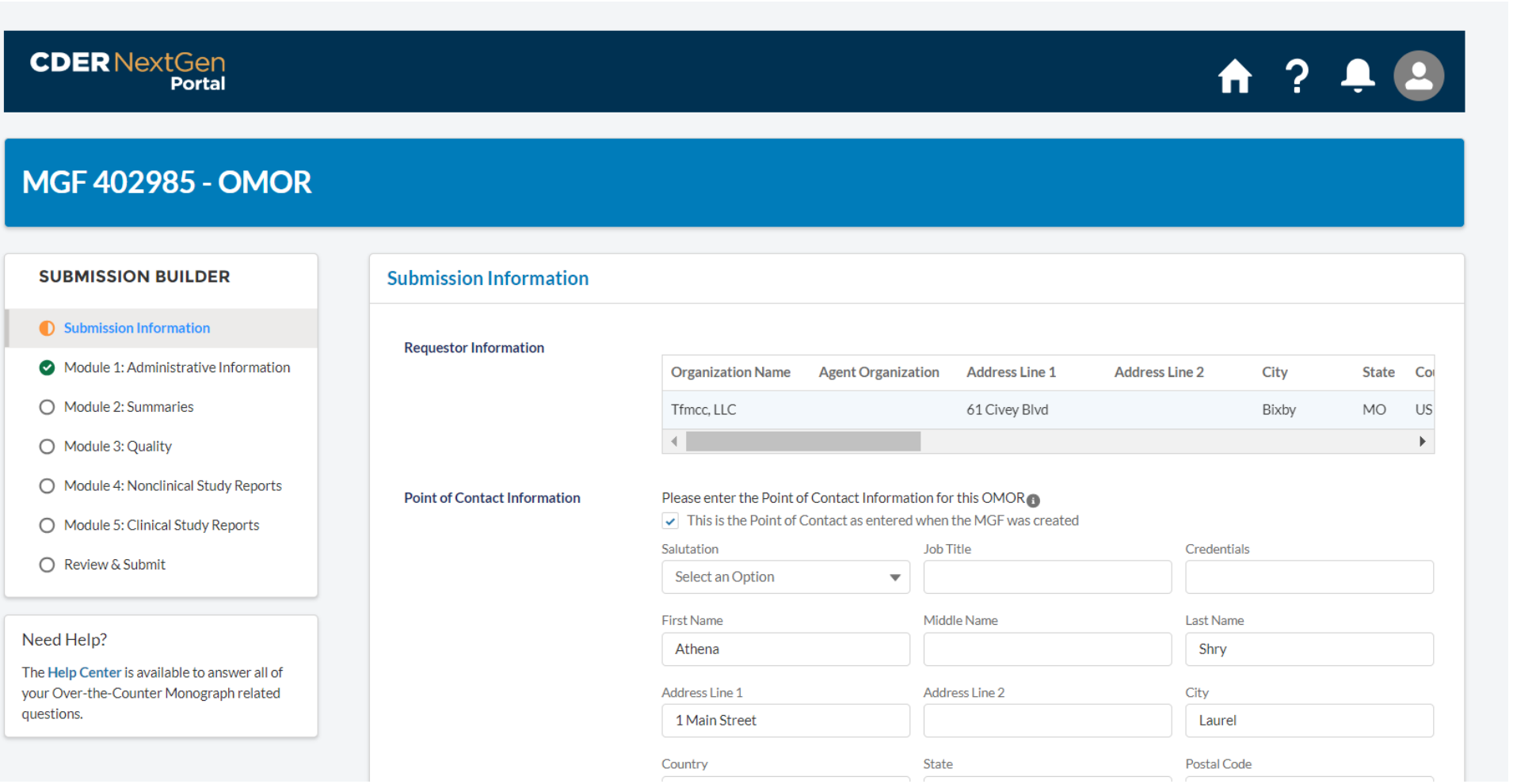
Tracking

- Develop and incorporate measures to track successes and Agency accountability

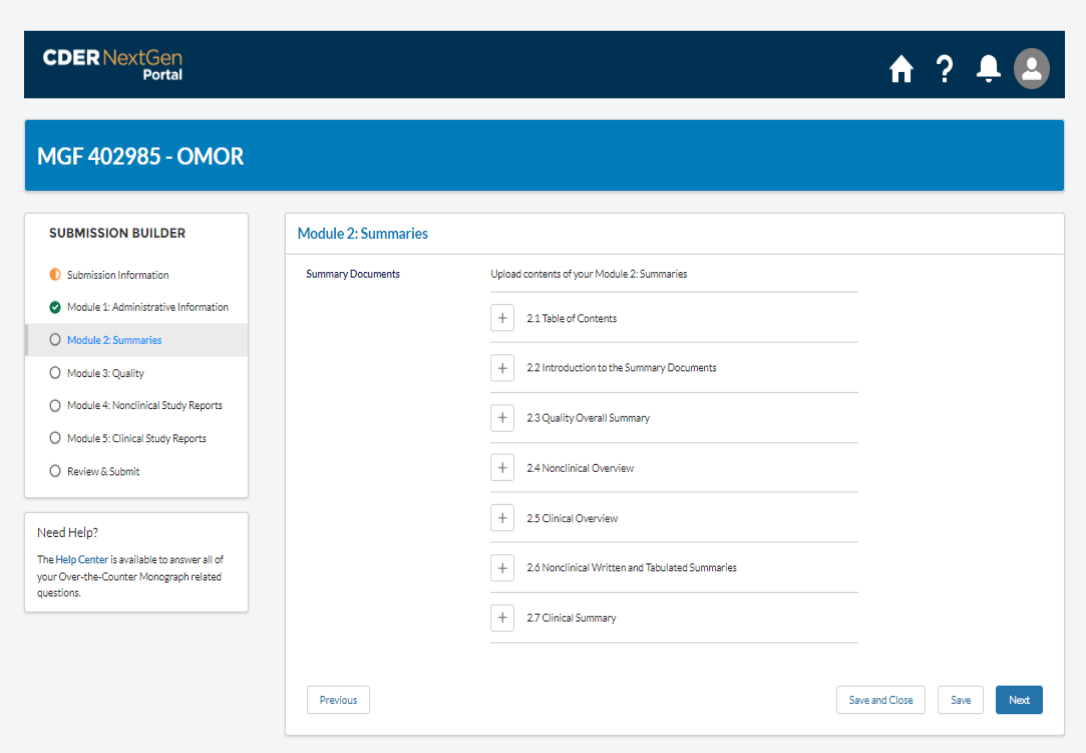
CDER NextGen Portal Overview

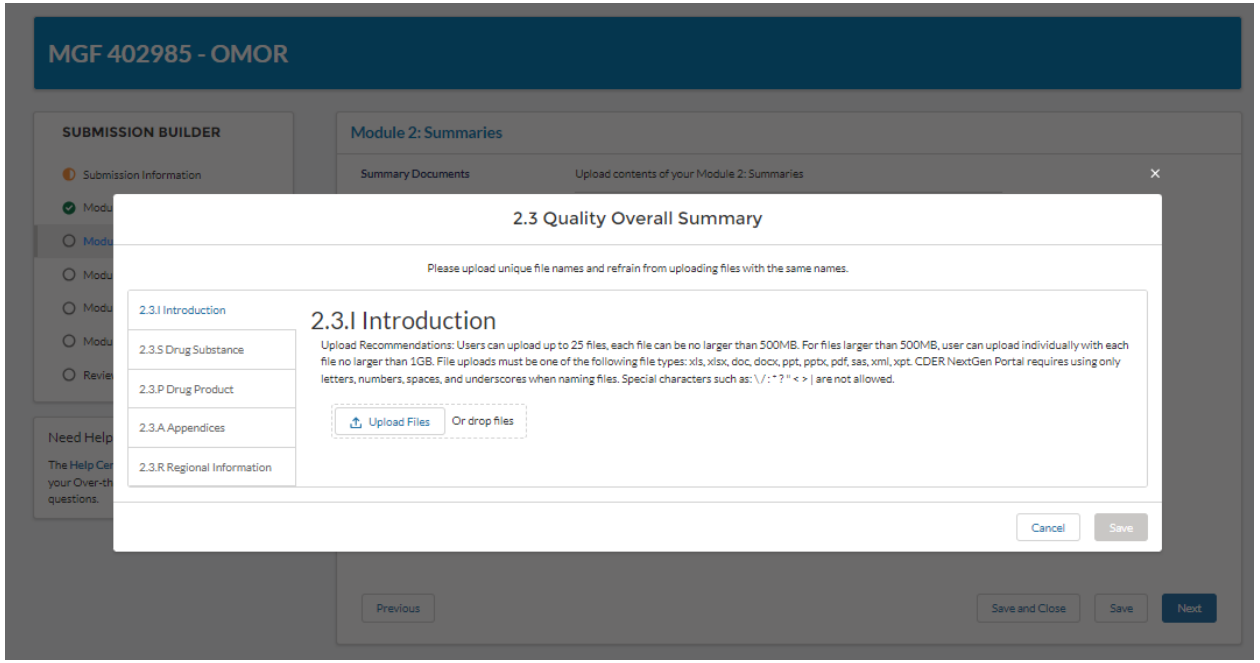
- ✓ Singular Point of entry for industry
- ✓ Accessibility provided at no cost to industry
- ✓ Leverage Salesforce for enhanced user interface and robust capabilities

Portal OMOR Submission Builder

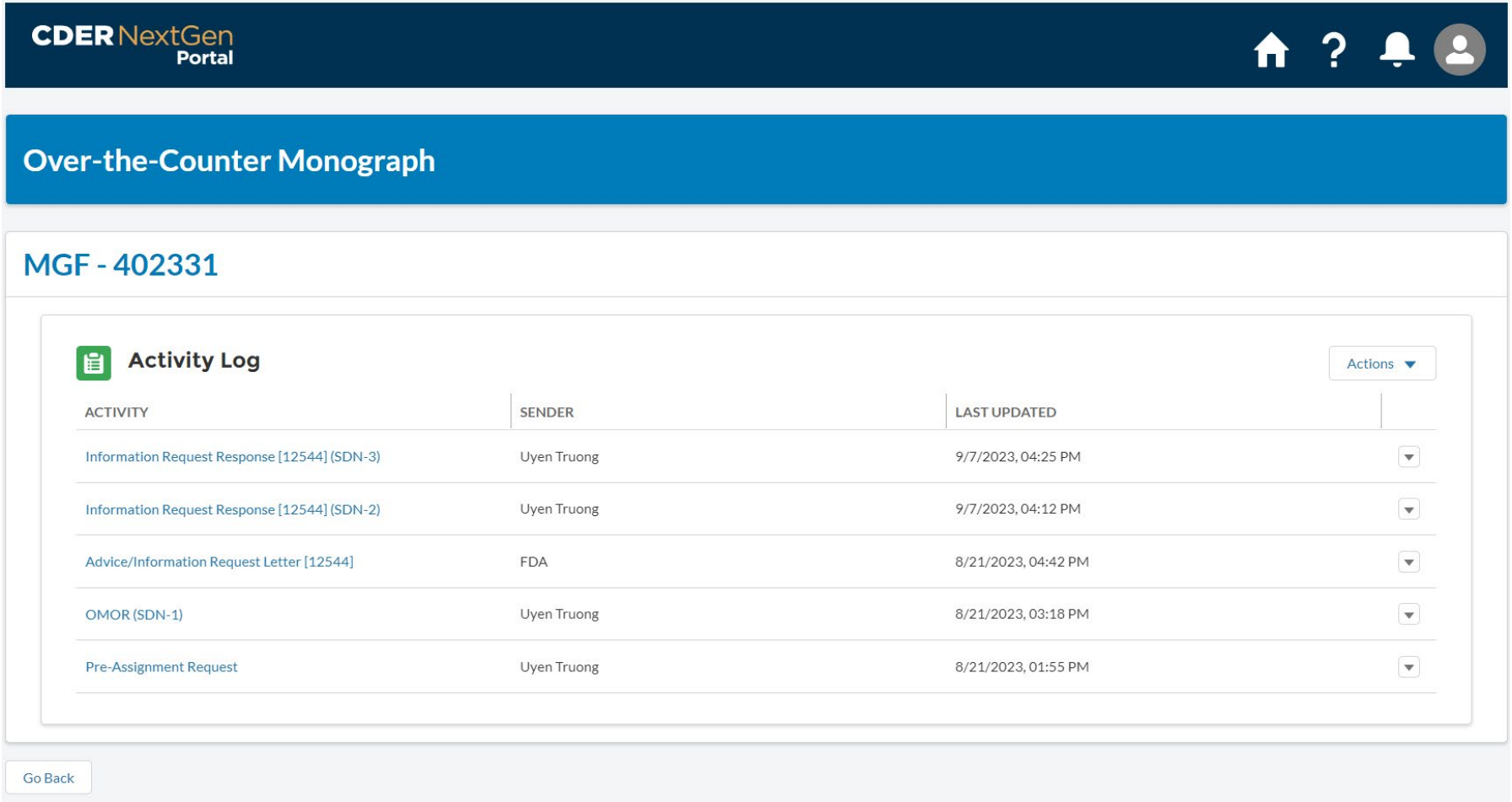


Portal OMOR Submission Builder (cont'd)

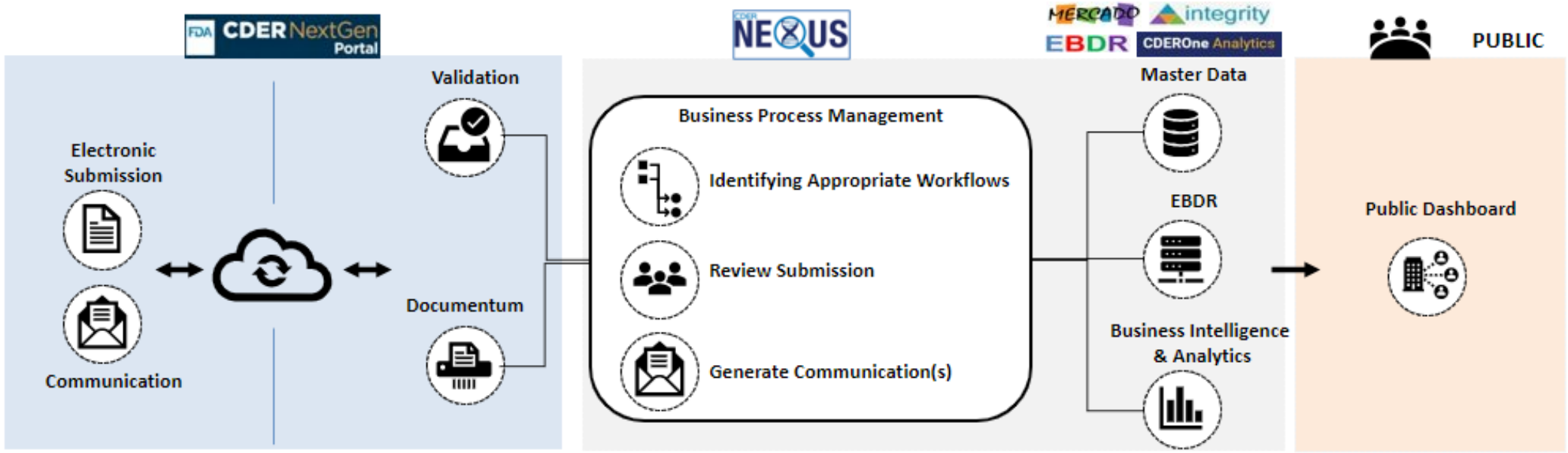




Portal OTC Activity Log



OTC Flow of Information



https://dps.fda.gov/omuf

Summary Of Benefits

Efficiency: All information regarding meeting requests, OMORS and other correspondences are stored in one place. Requestors can view all transactions at any time.

Timeliness: Electronic Meeting Requests, OMORs, and Amendments can be delivered immediately. FDA communications including Advice/ Information Requests are also delivered immediately.

Automation: Requestors can log in, initiate a submission, and receive an automated confirmation of a transaction. FDA also received automated confirmation of new submissions and assignments.

Knowledge Management: Data is created, captured, received and stored in structured format

Instruction: References guides, and step-by-step instructions are available at any time. Helpful hints and resource information is also available throughout the Portal screens

The Future of OMUFA

Questions?

Thank you!

We are on break and will reconvene shortly.