United States Food and Drug Administration

Emerging Drug Safety Technology Program

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

**Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 355) and section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). FDA has a longstanding commitment to ensure medicines marketed in the United States are safe through continued surveillance and research following approval. In the postmarket setting, regulated industry (per 21 CFR 314.80, 314.98, and 600.80) is obligated to review all adverse drug experience information received or otherwise obtained and submit reports to FDA. Both industry and regulatory authorities face challenges with timely and efficient collection, processing, and evaluation of single and aggregate patient safety data compounded by ever-increasing case volumes. Advances in emerging technology have the potential to address some of these challenges by creating more efficiencies within a pharmacovigilance (PV) surveillance system. The pharmaceutical industry is expanding its use of artificial intelligence (AI) and other emerging technologies across the drug product lifecycle, including PV.

FDA is interested in accelerating its understanding of how AI-enabled tools and other emerging technologies are being used for PV, their associated risks and benefits, model evaluation processes (including performance characteristics), and barriers to implementation. The Emerging Drug Safety Technology Program (EDSTP) is a means by which applicants and/or other relevant parties who meet the eligibility and selection criteria for participation can meet with the Center for Drug Evaluation and Research (CDER), through Emerging Drug Safety Technology Meetings (EDSTMs), to share information about their use of AI and other emerging technologies, and their potential applications in post-market PV.

The initial phase of the EDSTP was announced in the *Federal Register* on June 11, 2024 (89 FR 49179). Since then, CDER has received numerous meeting requests and inquiries from the pharmaceutical industry and other relevant parties, seeking to discuss their latest applications of emerging technologies in PV. The requests represent a diverse set of use cases that are of interest to the Agency. Given the current level of interest in the program expressed by respondents, FDA anticipates an increase in the number of meetings granted to expand the Agency's understanding of how AI-enabled tools and other emerging technologies are being used in PV.

The purpose of the EDSTMs is to facilitate discussion and mutual learning of the pharmaceutical industry's application of these technologies in PV. EDSTMs can be requested by applicants with at least one approved application regulated by CDER and/or other relevant parties supporting industry's PV activities (e.g., academia, contract research organizations (CROs), PV vendors,

software developers) who develop, leverage, or intend to leverage AI or other emerging technologies that can be used to satisfy the postmarketing reporting requirements in 21 CFR 314.80, 314.98, and 600.80. If selected for a meeting, participants will meet with CDER staff to discuss their research, development, and/or use of AI and other emerging technologies in PV. FDA plans to leverage these learnings to help inform potential regulatory and policy approaches around the use of AI and other emerging technologies in PV.

2. Purpose and Use of the Information Collection

The EDSTP will collect information for the following purposes: (1) serve as the central point of contact for dialogue between industry and CDER on the use of AI and other emerging technologies in PV; (2) enable knowledge management and transfer within FDA specific to the context of use for AI and other emerging technologies in PV; and (3) further thinking about policy and application of potential regulatory approaches within the landscape of AI and other emerging technologies.

3. Use of Improved Information Technology and Burden Reduction

Sponsors will access information concerning the EDSTP through the official website, www.fda.gov/drugs/science-and-research-drugs/cder-emerging-drug-safety-technology-program-edstp. Submissions will be made and communication with industry will be conducted through email. Collected information will be stored in an internal FDA SharePoint library.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. We assist small businesses through resources available on our website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

There is no set schedule for participation or collection of information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No exemption is being sought.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of July 3, 2025 [90 FR 29561]. FDA received one comment. The submitter provided supportive comments of the FDA's EDSTP. However, the one comment was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via program email is applicant/requester attendees name, email address, and position/title. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA limited the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Respondents will provide an initial submission to FDA detailing their meeting proposal. We estimate this will require 10 hours to prepare. If selected for participation in an EDSTM, the respondent will then need to prepare and deliver a 20-50 minute presentation, which will require an additional burden of 30 hours. FDA estimates 25 organizations will submit requests to present at EDSTMs per year, and 12 meetings will be held per year.

Table 1 – Estimated Annual Reporting Burden

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Industry request to give presentation at EDSTM | 25 | 1 | 25 | 10 | 250 |
| Industry preparing and delivering presentation at EDSTM after request has been granted | 12 | 1 | 12 | 30 | 360 |
| TOTAL | | | 37 | | 610 |

12b. Annualized Cost Burden Estimate

We estimate half of the total hours required for preparing and submitting the information collection requirements under the EDSTP will be provided by a professional in computer and information systems (Bureau of Labor Statistics (BLS) Occupation code 11-3021) with an

average AI industry wage of $91.25 per hour assisted by an executive administrative assistant (BLS 43-6011) at an average wage of $39.51 per hour for the remaining half of the total hours required. The cost to respondents is estimated to be $39,881.80.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Computer and Information Systems Managers (BLS 11-3021) - Management, Scientific, and Technical Consulting Services | 305 | $91.25 | $27,831.25 |
| Executive Administrative Assistants (BLS 43-6011) – Management of Companies and Enterprises | 305 | $39.51 | $12,050.55 |
| Total | | | $39,881.80 |

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no other annual or capital costs to respondents.

14. Annualized Cost to the Federal Government

| Activity | Frequency (per year) | Burden Hours | No. of FTEs | Total Hours |
|---|---|---|---|---|
| EDSTM | 12 | 1.5 | 20 | 360 |
| EDSTM Pre-meeting | 12 | 1 | 20 | 240 |
| EDSTP Meetings (Program) | 12 | 1 | 14 | 168 |
| EDSTM Decisional Meetings | 4 | 1 | 14 | 56 |
| Email Communication – Eligibility | 24 | 0.125 | 1 | 3 |
| Email Communication – Selection | 12 | 0.125 | 1 | 1.5 |
| Email Communication – Inquiries | 24 | 0.25 | 4 | 24 |
| Email Communication – Scheduling | 12 | 1 | 1 | 12 |
| EDSTM Documentation – Meeting Summaries | 12 | 2 | 1 | 24 |
| EDSTM Documentation – Meeting request tracking | 12 | 0.5 | 1 | 6 |

| | | | | |
|---|---|---|---|---|
| OSE Working Group quarterly meeting | 4 | 1 | 2 | 8 |
| OSE Working Group ad hoc meeting | 6 | 1 | 2 | 12 |
| Total | | | | 914.5 |

FDA estimates the EDSTP will require 914.5 federal employee hours per year, or 0.44 FTE. We estimate that the responsibilities will be performed by a GS-13 level federal employee at a cost of $58,080 ($132,000/FTE * 0.44 FTE). The source of funding for this program will be PDUFA.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with the EDSTP and will display in that notice both the OMB control number and its current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.