United States Food and Drug Administration

Surveys and Interviews with Investigational New Drug Sponsors to Assess Current Communication Practices with FDA Review Staff under the Sixth Authorization of the Prescription Drug User Fee Act

OMB Control No. 0910-NEW

SUPPORTING STATEMENT **Part A. Justification**

1. Circumstances Making the Collection of Information Necessary

Pursuant to the requirements of the Paperwork Reduction Act (44 USC 35) and Public Law, No. 115-52, 131 Stat. 1005 (also known as the Food and Drug Administration Reauthorization Act of 2017, or FDARA), the U.S. Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information collection that FDA committed to in Section I.I.1.a of the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 letter ("PDUFA VI Commitment Letter"). Section I.I.1.a of the PDUFA VI Commitment Letter states that an independent third party will assess current practices of FDA and sponsors in communicating during drug development, and that the contractor "will be expected to separately engage both FDA staff and individual sponsors through contractor-led interviews as part of the assessment".

The Investigational New Drug (IND) phase of drug development is the time during which human trials of investigational drugs are conducted. This phase spans from the first IND-related submission (including a pre-IND meeting request) until the submission of a marketing application. During this time span, sponsors and FDA engage in many types of communications and submissions, including meetings, teleconferences, emails, phone calls, information requests (IRs), written responses, etc., with the intent to share information and provide critical advice (e.g., trial design, dose selection, nonclinical study requirements, manufacturing, and facility issues). To ensure the effectiveness of human drug review programs, it is critical that these communications be conducted in a timely and efficient manner.

Congress first enacted PDUFA in 1992 to ensure the timely review of new drugs and biologics by FDA. Since the initial five-year term of PDUFA, it has been reauthorized every five years. In PDUFA V, FDA committed to publish a guidance that describes best practices and procedures for timely, transparent, and effective communications between IND sponsors and the FDA at critical junctures in drug development. Additionally, FDA has published other guidances, Manuals of Policies and Procedures (MAPPs), and Standard Operating Procedures and Policies (SOPPs) that discuss policies and procedures for communications between FDA and sponsors. FDA's commitments for PDUFA VI include contracting with an independent third party to assess current practices of FDA and sponsors in communicating during IND drug development and identify best practices and areas of improvement. Due to the significant volume of FDA-sponsor

interactions in a given year, the assessment will be based on a random subset of drug development programs identified by IND number.

The purpose of the independent assessment of IND communication practices required under PDUFA VI is to answer the following questions:

- What are current FDA review staff and sponsor IND communication practices?
- To what extent do current IND communications incorporate recommended practices, guidances, and standard operating procedures?
- How do communication practices vary by IND characteristics such as sponsor size, special designations, review office, meeting type, and IND phase?
- How do FDA review staff and sponsors characterize IND communications during drug development?
- What practices help optimize IND communications, what challenges hinder optimum communications, and what steps can FDA review staff and sponsors take to improve communications moving forward?

To answer these questions, the third-party contractor, Eastern Research Group, Inc. (ERG), will separately engage both FDA staff and individual sponsors through contractor-led interviews. Additionally, the contractor will collect data from IND documentation and FDA and sponsor surveys. For a sample of up to 150 active commercial INDs that have activity during a one-year period, the contractor plans to collect information as follows:

- For each formal meeting between FDA review staff and sponsors, send a survey to the sponsor to solicit specific feedback about communication practices employed for that meeting.
  For the purpose of this assessment, formal meetings are Type A, B, B (End of Phase), and C meetings during the IND phase of drug development. Meetings may be in-person, telephone or videoconference, or Written Response Only (WRO).
- For each IND, conduct an interview with the sponsor to obtain broader feedback about all communications with FDA review staff during the study period, including telephone and email interactions in addition to meetings.

The contractor, ERG, will keep individual information collected private; ERG will not disclose personally identifying information to FDA or any other party. ERG will develop anonymized aggregated summaries of survey and interview responses, analyze this information to identify common themes, consider these results along with IND data and feedback from FDA review staff to develop a set of findings and recommendations, and prepare a report and presentation. FDA will publish the report on the Agency's public website and hold a public meeting about the assessment.

This assessment, utilizing information collected through surveys and interviews with IND sponsors, will be of great interest to FDA's stakeholders, including the regulated industry, patient and consumer groups, healthcare professionals, and Congress. Equally important, the assessment will be critical in helping FDA understand IND sponsor perspectives on what is working well, ongoing challenges and pain points, lessons learned, and opportunities for improvement.

2. Purpose and Use of the Information Collection

FDA's contractor for the IND communications assessment has prepared draft protocols and scripts for administering surveys, and scheduling and conducting interviews with sponsors of active commercial INDs (sample of up to 150) that have activity during a one-year period. Most of these respondents to the information collection are private-sector companies; some are education, nonprofit, or government organizations. The protocols ensure that ERG is aware of all entities who are candidates for surveys and interviews and administers surveys or schedules and conducts interviews in a timely, consistent manner using good practices. The survey includes statements that respondents will rate on their level of agreement or disagreement with opportunities for comments, and the interview script includes open-ended questions aimed at obtaining a thorough understanding of sponsor experiences and insights about IND communication practices for their products.

The purpose of the information collection is to help fulfill FDA's commitment to the regulated community under PDUFA VI to conduct an independent assessment of FDA-sponsor communication practices during the IND stage of drug development. The contractor will analyze survey and interview responses to identify practices that sponsors perceive as helpful to the IND review process as well as practices that might benefit from improvement. The survey and interview information collected from IND sponsors will help FDA understand sponsor perspectives on IND-stage communication practices that are working well, ongoing challenges and pain points, lessons learned, and opportunities for improvement.

In turn, FDA will use this information, along with internal FDA review staff perspectives, to:

- Determine the current state of IND communication practices.
- Determine how (if at all) to revise IND communication practices between FDA review staff and industry during drug development.
- Demonstrate compliance with the commitment to conduct and publish an independent assessment.
- Share information about FDA communication practices with IND sponsors with the regulated community, the public health community, Congress, and the general public.

3. Use of Improved Information Technology and Burden Reduction

Overall, FDA estimates that 98% of respondents will use electronic means to fulfill the agency's information request. Specifically, FDA estimates that 100% of survey respondents will use electronic means to complete surveys; the survey is fillable and can be submitted electronically. FDA estimates that 95% of interview participants will participate via teleconference; using teleconference technology such as WebEx will enable interviewees to eliminate any travel-related burden for participation. FDA estimates that 5% of interview participants will participate in person because of their proximity to an interview location. These estimates are based on experiences with past PDUFA-related assessments.

4. Efforts to Identify Duplication and Use of Similar Information

The information from IND sponsors that FDA seeks is unique to this assessment and does not currently exist. FDA's contractor will request sponsor feedback immediately after each IND-stage meeting and broader feedback on all types of IND communications between the sponsor and FDA review staff during the data collection period. No other known entities are collecting IND-specific feedback on FDA-sponsor communication practices during the IND stage of drug development. Furthermore, FDA is conducting this information collection in support of a commitment made to industry for PDUFA VI.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that approximately 39% of survey and interview respondents (about 235 individuals) will be employed by sponsors that are small businesses (where small business is defined as having fewer than 500 employees). The information being requested has been held to the absolute minimum required for the intended use of the data. In addition, FDA's contractor for the independent assessment will not ask small businesses or entities to travel, pay for telephone charges, or incur other unusual expenses. To avoid such expenses and minimize burden, ERG will conduct interviews by telephone if the sponsor will not be in or chooses not to be in Silver Spring, MD during the desired interview timeframe.

6. Consequences of Collecting the Information Less Frequently

FDA's contractor will ask survey respondents to participate in one survey per IND-stage formal meeting. FDA will ask interview respondents to participate in one interview per IND. This is the minimum frequency possible to obtain the required feedback from IND sponsors on meetings and other communications with FDA review staff during drug development.

To maximize respondent recall and minimize burden, FDA will ask survey respondents to respond to surveys within one week of the meeting. FDA will ask interviewees to discuss their experiences with IND-stage communication practices during the second half of the data collection period, after they have had sufficient experience with these communication practices.

There would be several consequences of not collecting the data as proposed. First, FDA would not fulfill its PDUFA VI commitment to conduct an assessment of FDA-sponsor communication practices during the IND stage of drug development. Second, FDA would lack sponsor perspectives on best practices and potential improvements for IND communications between FDA and sponsors. Finally, sponsors would not have the opportunities they expect to share their opinions about FDA-sponsor IND communication practices.

The proposed data collection is one-time only.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *FEDERAL REGISTER* of 8/16/2018 (83 FR 40771). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No incentives are being offered to respondents to participate in this information collection.

10. Assurance of Confidentiality Provided to Respondents

FDA has enlisted an independent contractor, ERG, to conduct the surveys and interviews that comprise this data collection. FDA staff will not participate in any surveys or interviews with IND sponsors. In addition, ERG will keep individual respondent information private by: (1) handling all information processing internally; (2) securely storing raw survey and interview information; and (3) sharing only anonymized aggregated summaries of results with FDA and the public.

FDA maintains its own data on INDs and IND sponsors. Therefore, the agency will know what sponsor organizations will be asked to participate in surveys and interviews for this project. FDA will not know which sponsor organizations—or which individuals employed by these organizations—accepted and responded to survey and interview requests.

While there is no express assurance of confidentiality that can be supported by law, the design of the data collection will allow responses to be anonymous. Interviewees will be assured of the privacy, to the extent available under law, of their responses through language placed prominently on all interview materials as well as introductory comments made by the interviewer. ERG will assure respondents of the privacy of their information by incorporating the following text into survey instruments and interview scripts:

> "Your participation/nonparticipation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-

respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law."

Interviewers will be trained on the privacy of responses and will be prepared to describe the policy in detail, provide examples, and respond to any related questions from participants. For example, the interviewer will explain that each individual's answers will be combined with those of others and presented in summary form only, and that FDA will not have access to the names of participants.

This information collection does not involve collection of personally identifiable information (PII). This project does not require Institutional Review Board (IRB) review because this assessment does not constitute biomedical research on human subjects.

11. Justification for Sensitive Questions

No sensitive questions will be asked of respondents during this information collection. Some questions ask sponsors for frank assessments of interactions and communications with FDA during the IND stage, which might be perceived as sensitive to some sponsors. This information is crucial to understanding the current state of FDA and sponsor communication practices in IND development and review, what practices contribute to valuable communications, and what practices can be refined to improve communication. The contractor will keep private the identity of individual sponsor representatives, as well as each person's responses to survey and interview questions; all survey and interview materials will emphasize this. ERG will not identify any individual as an interviewee to FDA.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

This information collection will take place over a two-year period. Estimated participation times are based on experience with similar surveys and interviews for similar types of assessment projects:

- IND sponsors will respond to surveys by completing a fillable form online; a text version of the form is attached. The time required to complete a survey is estimated to be 10 minutes or less. FDA's contractor will manage the survey using Qualtrics or a similar tool.

- IND sponsors will participate in interviews via teleconference or, if convenient, face-to-face meeting; interview questions are attached. One to three sponsor representatives may participate in each interview. The time required to respond to requests for an interview and participate in the interview is estimated to be up to 90 minutes.

Table 1: Estimated Annual Reporting Burden[1]

Portion of Study	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
IND sponsors: Surveys	150	1	150	0.17 (10 minutes)	25
IND sponsors: Interviews	450	1	450	90	675
Total					700

[1]There are no capital costs or operating costs associated with this collection of information.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized cost to respondents to be the burden hours estimate multiplied by the median hourly wage estimate (Source: Occupational Employment Statistics, Bureau of Labor Statistics). FDA used the median wage estimate ($90.00) for Physicians and Surgeons, All Others, Standard Occupational Code (SOC) 29-1069, because this wage falls in the middle of the range of wages for NDA/BLA managers in the pharmaceutical industry. FDA multiplied this median wage by 1.4 to capture benefits, resulting in a loaded hourly median wage rate of $126.00.

Table 2. Annualized Cost to Respondents.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
IND sponsor	675	$126.00	$85,050.00

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

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

This independent assessment of IND communication practices encompasses several evaluation methodologies, including surveys and interviews with IND sponsors. The survey and interview effort involves development of protocols and scripts, implementation of the surveys and interviews, and analysis of results to develop findings and recommendations about FDA-sponsor IND communication practices. The annualized cost to the Federal government is estimated to be

$150,000, which is the total contractor cost and FDA oversight cost of the interview portion of the independent assessment project: approximately $10,000 is for survey and interview development costs (e.g., instrument development, implementation design, etc.), $130,000 is for survey and interview implementation and analysis, and $10,000 is for FDA oversight of contractor activities. There are no other costs to the Federal government for implementation.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The following table outlines the project schedule for data collection, report preparation, report publication, and public presentation.

Table 3. Project Time Schedule

Tasks	Estimated Number of Weeks After OMB Approval
Interview and survey information collected	68 weeks
Assessment report completed	76 weeks
Assessment report published	90 weeks
Conduct public presentation	120 weeks

The data analysis plan describes how ERG will analyze the data collected in order to generate meaningful assessment results. Broadly, ERG will conduct quantitative and qualitative analyses to produce three types of results for the PDUFA VI IND communications assessment:

- **Profiles of types of PDUFA VI IND communications.** To develop a profile of each major type of PDUFA VI IND communication, ERG will calculate relevant metrics, analyze related quantitative data, and analyze related qualitative information to describe current practices.
- **Answers to evaluation questions.** To answer each evaluation question, ERG will synthesize metrics values, related quantitative data, and qualitative information to develop evidence-based explanations.
- **Findings and recommendations.** ERG will synthesize quantitative and qualitative data across all communication topics to develop an integrated set of findings and actionable recommendations related to PDUFA VI IND communication practices.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.