PDUFA VI
Communications
Assessment
Request for Task Order Proposal (RTOP)

"PDUFA VI commitment to assess current practices of FDA and sponsors in communicating during IND drug development"

1. Background

The timely review of the safety and effectiveness of new drugs and biologics is central to FDA's mission to protect and promote the public health. Prior to enactment of the Prescription Drug User Fee Act (PDUFA) in 1992, FDA's drug review process was relatively slow and not very predictable compared to other countries. As a result of concerns expressed by both industry and patients at the time, Congress enacted PDUFA, which provided the added funds through user fees that enabled FDA to hire additional reviewers and support staff and upgrade its information technology systems. In return for additional resources, FDA agreed to certain review performance goals, such as completing reviews of New Drug Applications (NDAs) and Biologics License Applications (BLAs) and taking regulatory actions on them in predictable timeframes. These changes revolutionized the drug approval process in the United States and enabled FDA to speed the application review process for new drugs and biologics without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of new drugs and biologics prior to approval.

PDUFA provides FDA with a source of stable, consistent funding that has made it possible for it to focus on promoting innovative therapies and help bring to market critical products for patients. When PDUFA was originally authorized in 1992, it had a five-year term. The program has been subsequently reauthorized every five years with the most recent reauthorization occurring in 2012 for fiscal years 2013-2017. To prepare for reauthorization of PDUFA for a new five-year period, FDA conducted negotiations with the regulated industry and held regular consultations with public stakeholders including patient advocates, consumer advocates, and healthcare professionals between September 2015 and February 2016. Following these discussions, related public meetings, and agency requests for public comment, FDA published proposed recommendations for PDUFA VI for fiscal years 2018-2022. The proposed recommendations include an FDA commitment to continue to enhance timely interactive communication with sponsors during drug development and assess current practices of FDA and sponsors in communicating during drug development.

Enhanced Communication Practices between FDA and Sponsors during Drug Development

The Investigative 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. 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[1][2]. Additionally, FDA has published other guidances, MAPPs and SOPPs that discuss policies and procedures for communications between FDA and sponsors[3].

The proposed recommendations for PDUFA VI include an FDA commitment to contract 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 third-party contractor will be expected to separately engage both FDA staff and individual sponsors through contractor-led interviews as part of the assessment. Additionally, the contractor will be expected to collect data from IND documentation and FDA and sponsor surveys as part of the overall assessment. This assessment is the subject of this task order.

2. Objectives

The primary objective of this assessment task order is to assess current communication practices between the FDA and sponsors during IND drug development. This includes assessing the timeliness, quality, and methods of communication practices between FDA review teams and sponsors and identifying best practices.

Key Objectives

[1] PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017

[2] Best practices for communication between IND sponsors and FDA during drug development

[3] Draft guidance for industry investigational new drug applications prepared and submitted by sponsor-investigators
Guidance for industry Expedited Programs for Serious Conditions — Drugs and Biologics
Guidance for industry Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants
Guidance for industry Formal Meetings Between the FDA and Sponsors or Applicants
Guidance for review staff and industry Good Review Management Principles and Practices for PDUFA Products
MAPP 4515.1 Email Best Practices
MAPP 6025.1 Good Review Practices
MAPP 6025.6 Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics
MAPP 6030.9 Good Review Practice: Good Review Management Principles and Practices for Effective IND Drug Development and Review
SOPP 8101.1 Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants
SOPP 8104 Documentation of Telephone Contacts with Regulated Industry
SOPP 8113 Handling of Regulatory Faxes in CBER
SOPP 8119 Use of Email for Regulatory Communications

1. Using information from FDA's corporate databases as well as other databases (e.g., database or other tracking mechanism developed by contractor), assess current state of FDA and sponsor IND communication practices.

2. Collect and analyze qualitative feedback from FDA review staff and sponsors on what is working well and what is not; identify best practices; and major pain points for sponsors and FDA in communicating during IND drug development.

3. Scope of Work:

This project will assess the timeliness, quality, and methods of current communication practices between FDA review teams and sponsors and identify best practices. The scope of this contract will cover all aspects of data collection, analysis, assessment, interviewing of key FDA staff and sponsors, reporting, documentation, and other tasks deemed necessary to conduct a thorough assessment of current communication practices during IND drug development. The standards for scientific review and regulatory decision-making are not the subject of this assessment.

The assessment will cover a prospective randomly-selected cohort of 100 - 150 commercial IND drug development programs that are active within CDER and CBER between April 1, 2018 and April 30, 2019[4]. NDA and BLA applications will not be included in the study cohort.

Within the selected cohort, the following characteristics should be represented:

1. Large and small sponsors
2. INDs with and without Breakthrough Designation(BTDs) or INDs with or without Regenerative Medicine Advanced Therapies(RMATs)
3. 17 CDER clinical review divisions and three CBER product offices and OCBQ
4. Type A, B, B (EOP), C meeting types
5. All IND phases (e.g. Pre-IND and Phase, 1, 2, 3,)

A prospective study design will allow for a more reliable recall of communication practices from FDA staff and sponsors due to the nature and frequency of contact during IND drug development. IND communications and submissions occurring during the study period for the selected INDs will be assessed quantitatively. However, IND communication practices will be assessed more broadly through qualitative methods. The contractor will use the sample characteristics noted above, as well as any others that the Project Advisory Group

[4] This range in cohort size was derived by analyzing the last two fiscal years of commercial IND communication records between FDA and sponsors. The total number of unique INDs is based on CDERs public report located here: https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/indactivityreports/ucm373554.htm. The total unique active commercial INDs for FY15 and FY16 were approximately 7000 for each year. When applying a confidence level of 95% together with a confidence interval of 10 to this average population of INDs, approximately 95 INDs would need to be included in a sample cohort. To account for the various characteristics that need to be considered (e.g. IND phases, large/small sponsor), a sample cohort range of 100-150 INDs was selected.

(PAG) may recommend, to design the study's cohort.

The contractor will collect quantitative and qualitative data on communication practices of both the FDA and sponsor for the INDs in the selected cohort using a mixed method approach. This will include analyzing IND documents housed in corporate databases; conducting contractor-led interviews and surveys with FDA review staff and sponsors; and attending FDA/sponsor meetings if and when they occur for the designated study cohort during the study period.

The contractor will be responsible for developing interview guides, surveys, and document data collection tools to collect qualitative data and quantitative metrics on key communication practices. The specific metrics and survey questions should be developed by the contractor using the aforementioned guidances, MAPPs, and SOPPs as source documents to assess timeliness, quality, and methods used in IND communications, and the FDA Technical Advisory Group (TAG). In some cases, the contractor may want to use IND meeting performance metrics that are concurrently collected (and subsequently published) by FDA to augment their own analyses. The contractor should consider, but not be limited to, the following communication practices to inform interview and survey questions and quantitative metrics:

1. Completeness of sponsor meeting requests and briefing, meeting, or background packages
2. Resolvability of sponsor meeting questions in pre-meeting packages, by published guidance
3. Organization and adequacy (in terms of information FDA needs to provide adequate answers) of sponsor meeting packages
4. Completeness and adequacy of preliminary meeting responses by FDA
5. Utilization of meeting minutes/WRO templates by FDA RPM
6. Suitability of sponsor milestone meeting requests to the drug's stage of development
7. Appropriate usage of language (e.g. shall, critical) when FDA conveys statutory or advisory responses
8. Timeliness of sponsor submissions and FDA responses that are not already tracked PDUFA goals (using suggested performance metrics and timelines in the Formal Meetings Guidance and Good Review Practice MAPP[5][6])
9. Timeliness of sponsor responses to IRs
10. Overall sponsor, review team and RPM perspectives (pain points, best practices) on current communication practices, considering timeliness, quality, and methods
11. Frequency of and details regarding direct contact between review team members and sponsors outside of meetings(the Best Practices for

[5] Guidance for industry Formal Meetings Between the FDA and Sponsors or Applicants

[6] Good Review Practice: Good Review Management Principles and Practices for Effective IND Drug Development and Review

Communications Guidance specifies this is a rare practice and must be pre-approved)

12. Utilization by sponsors of RPMs as main point of contact
13. Development of mutually agreeable communication strategies between FDA and sponsors
14. Frequency of changes in review team membership and rationale
15. Frequency of overall changes in FDA advice to sponsors and rationale
16. Extent to which FDA's advice impacted sponsors' drug development strategies
17. Frequency and assessment of initial comprehensive multidisciplinary breakthrough therapy meetings held for INDs with indications designated as BTD/RMAT
18. Frequency and assessment of communications for INDs with indications designated as BTD/RMAT

As specified in the PDUFA VI commitment letter, the contractor will describe their findings in a final report by March 2020, as will be detailed in task section 4, below.

The contractor will present, by the end of March 2021, the findings of their independent assessment at a public workshop to be scheduled and organized by FDA. The presentation will include but not be limited to, anonymized, aggregated feedback from sponsors and FDA review teams that resulted from the contractor interviews as well as publically shareable quantitative metrics. The contractor will work with the FDA project manager and PAG in preparing for this public meeting.

4. <u>Description of Tasks:</u>

<u>Project initiation:</u>

1. The contractor shall participate in a project kick-off meeting to review the task order, including the project timeline, scope, and schedule of deliverables. At this meeting, the contractor shall present its proposed overall approach and work plan to FDA. The contractor shall revise the proposed approach based on FDA feedback.

2. The contractor shall participate in an orientation period to become familiar with the details of FDA's IND review process, relevant guidances/MAPPs/SOPPs, obtain access to all necessary IT systems (e.g. DARRTS and CRMTS), and attend any necessary and relevant FDA trainings. This period will last not more than two weeks and will take place at FDA's headquarters at White Oak, MD.

3. The contractor shall develop a detailed work plan to assess FDA-sponsor current communications and interactions in the IND drug development phase. This shall include:

a. A quantitative and qualitative approach to prospectively assess active IND programs in the study period; the qualitative approach will also include inquiries on best practices and pain points gleaned from review team experiences prior to the study period.
b. Sample size and cohort details
c. Detailed list of developed metrics on key communication practices to assess timeliness, quality, and methods used in IND communications as listed in Section 3.

The contractor shall present the detailed proposed approach, sample cohort, and list of metrics to FDA and subsequently revise it based on any FDA feedback. The detailed assessment plan shall be modified as necessary throughout the assessment based on accumulated experience and agreement by FDA.

4. The contractor shall develop the necessary tools (e.g. data collection instruments, interview guides, survey questions, database) for capturing and analyzing information collected in accordance with the assessment approach. The data collection instruments, interview guides, and other tracking tools shall be modified as necessary throughout the assessment based on accumulated experience. The qualitative data collection tools should include inquiries that elicit current and prior best practices in communication between sponsors and FDA.

5. The contractor shall develop a proposed approach to the quantitative and qualitative analysis of all data collected for the assessment. The contractor shall present the proposed approach to FDA and subsequently revise it based on any FDA feedback.

6. The contractor will prepare all necessary materials for the Office of Management and Budget (OMB) approval for data collection materials that will be facilitated by the FDA project manager and staff. The Paperwork Reduction Act (PRA) requires the FDA to follow and complete HHS and OMB approval processes and procedures for federally sponsored data collections[7].

Project execution

7. The contractor shall assess the timeliness, quality, and methods used in IND communications between FDA and sponsors by executing, applying, and collecting the finalized evaluation plan, methods and metrics, including:
   a. Retrieving and reviewing all relevant IND formal documentation in corporate databases (e.g. IRs, memorandums, meeting requests, meeting minutes, meeting packages, study protocols, written response only (WROs) responses) for the designated study cohort during the study period.
   b. Conducting independent interviews of FDA review staff and sponsors for the designated study cohort during the study period. The total number of interviewees will be based on the final number of INDs selected as part of the study cohort. The contractor will conduct interviews with each selected IND's review team and

[7] More information for the PRA and data collection procedures can be found here: https://www.hhs.gov/ocio/policy/collection/infocollectfaq.html

sponsor. The contractor will manage the process of inviting and scheduling all interviews. These discussions may occur in person at FDA's headquarters in White Oak, MD or through teleconference or web-based technologies. The contractor will use the Applicant interview guide(s) developed in task 4. The information collected shall be aggregated and made anonymous prior to inclusion in the assessment or any report.

c. Attending FDA/sponsor meetings, if and when they occur, for the designated study cohort during the study period. Generally, face-to-face meetings are conducted at FDA Headquarters in White Oak, MD. The contractor shall be physically present for all face-to-face FDA-applicant meetings or participate by telephone for all meetings held by telephone. The length of these meetings is estimated to be 1-2 hours each.
d. The contractor may conduct their own secondary analysis of IND PDUFA performance metrics, already tracked, collected (and subsequently published) by the FDA. This option will be discussed with the FDA during the project initiation phase and agreed upon in the final assessment plan.

8. Using quantitative and qualitative data collected the contractor shall conduct an analysis, in accordance with the work plan, to assess the timeliness, quality, and methods used in IND communications between FDA and sponsors. The conduct of the analysis shall be ongoing, culminating in a final assessment of the study cohort. Analysis of communication practices should include but not be limited to:
   a. Descriptive analysis of the quantitative data collected
   b. Comparisons by small and large sponsors
   c. Comparisons by BTD/RMAT and non-BTD/RMAT INDs
   d. Comparisons by meeting format (e.g. WROs vs. In-person vs. TCON)
   e. Comparisons by IND drug development phase
   f. Comparisons by INDs with or without RMATs
   g. Qualitative analysis of FDA and sponsor interviews
   h. Recommendations to improve and/or modify IND communication practices

<u>Project reporting</u>

9. The contractor shall brief the FDA Project Manager and the FDA TAG at regular intervals throughout data collection and analysis.
10. The contractor will prepare and present project updates and findings to the FDA Program Advisory Group (PAG) quarterly throughout the project timeframe.
11. The contractor shall complete a final analysis and develop a final report summarizing the assessment methodology, data, analysis, key learnings, and recommendations.
12. The contractor will submit to FDA a draft of the final evaluation report by Feb 2020 and subsequently revise based on FDA feedback by March 2020.
13. The contractor will develop presentation slides for a public meeting to be held by the end of March 2021. Included in the presentation of the assessment will be anonymized, aggregated feedback from sponsors and FDA review teams resulting from the contractor interviews as well as publically shareable quantitative metrics.

14. The contractor will present the assessment findings, including the anonymized, aggregated feedback from sponsors and FDA review teams resulting from the contractor interviews, at a public meeting to be held by the end of March 2021.

General administrative tasks

15. The contractor will take meeting minutes at all project-related updates and meetings with the PAG (e.g. kickoff meeting, quarterly updates) and provide final meeting minutes to the project manager within 2 business days.
16. The contractor will schedule and develop all FDA and sponsor interviews and/or survey deliverables
17. The contractor will develop and send all project-related slides or other documents pertinent to any project meeting, including but not limited to, project updates or final briefings, to the FDA PM 2 days in advance.

In addition to the deliverable formats described in section 5, the final report shall be submitted in Adobe Acrobat portable document format, compliant with Sec. 508 of the Rehabilitation Act and suitable for posting on FDA's website. The posted versions of these assessments shall be redacted as appropriate to protect commercial confidential information.

5. Deliverables and Milestones

The scope of work forms the basis for the following proposed schedule of deliverables. The actual schedule of deliverables may vary based on the final agreed-upon work plan, which should conform to the PDUFA VI commitment of FDA publishing a final report by the end FY2020 and presenting the findings at a public meeting by March 2021. All documents, plans, diagrams, presentations, etc., are to be submitted solely in electronic form and in the native file format of Microsoft Word 2003, Excel 2003, or Power Point 2003, or later versions. The Contractor shall provide the following, as a result of specific tasking in performance of the activities in this SOW:

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
Project Initiation Phase				

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
1	Initiate project in kick-off meeting with FDA; present proposed project approach and work plan	1	Presentation to FDA of the proposed overall approach and work plan that describes the key project milestones, project schedule and proposed staffing	1 week after initiation
2	Revise overall approach and work plan based on FDA feedback	2	Revised overall approach and work plan	2 weeks after initiation
3	Participate in an orientation to review IND review process, relevant guidance/MAPPs/SOPPs, and the implementation details of the IND drug development phase.	3	Completion of orientation program	3 weeks after initiation

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
4	Develop detailed proposed assessment approach, including the sample cohort size and details. Develop list of metrics	4	Presentation to FDA on: • Detailed proposed assessment approach, including the sample cohort size and details • Full list of metrics	4 weeks after initiation
5	Revise detailed proposed assessment approach, including the sample cohort details. Revise list of metrics	5	Revised: • Detailed proposed assessment approach, including the sample cohort details • Full list of metrics	5 weeks after initiation

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
6	Develop the necessary tools (e.g. data collection instruments, interview guides, survey questions, database) for capturing and analyzing information collected in accordance with the assessment approach.	6	Presentation to FDA on: • Tools to capture and analyze data	8 weeks after initiation
7	Develop a proposed approach to the quantitative and qualitative analysis of all data collected on the INDs reviewed	7	Presentation to FDA on: Proposed approach to the quantitative and qualitative analysis of all data collected on the INDs reviewed	8 weeks after initiation
8	Revise tools (e.g. data collection instruments, interview guides, survey questions, database) for capturing and analyzing information collected in accordance with the assessment approach	8	Revise: • Tools to capture and analyze data	9 weeks after initiation
9	Preparation of all necessary materials for the office of management and budget (OMB) approval for data collection materials	9	Prepare all necessary materials for OMB approval	9 weeks after initiation

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
10	Revise approach to the quantitative and qualitative analysis of all data collected on the INDs reviewed	10	Revise approach to the quantitative and qualitative analysis of all data collected on the INDs reviewed	9 weeks after initiation
Project execution phase				
11	Quarterly update to the PAG	11	Quarterly updates with the FDA PAG including findings to date (face-to-face meeting)	June 2018
12	Quarterly update to the PAG	12	Quarterly updates with the FDA PAG including findings to date (face-to-face meeting)	September 2018
13	Quarterly update to the PAG	13	Quarterly updates with the FDA PAG including findings to date (face-to-face meeting)	December 2018
14	Quarterly update to the PAG	14	Quarterly updates with the FDA PAG including findings to date (face-to-face meeting)	March 2019
15	Quarterly update to the PAG	15	Quarterly updates with the FDA PAG including findings to date (face-to-face meeting)	June 2019

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
16	Quarterly update to the PAG	16	Quarterly updates with the FDA PAG including findings to date (face-to-face meeting)	September 2019
17	Quarterly update to the PAG	17	Quarterly updates with the FDA PAG including findings to date (face-to-face meeting)	December 2019
18	Collect and analyze quantitative and qualitative data using approved instruments, surveys, and interview guides on a rolling basis beginning in April 2018	18	Collect and analyze quantitative and qualitative data using approved instruments, surveys, and interview guides on a rolling basis beginning in April 2018	December 2019
19	Develop draft report of communication practices between FDA and sponsors that includes quantitative and qualitative data analyses of all INDs studied between April 2018 to April 2019	19	Presentation to PAG and submission of draft assessment	Feb 2020

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
20	Revise report of communication practices between FDA and sponsors that includes quantitative and qualitative data analyses of all INDs studied between April 2018 to April 2019 based on FDA feedback	20	Revised draft assessment	Mar 2020
21	Submit Final report of communication practices between FDA and sponsors that includes quantitative and qualitative data analyses of all INDs studied between April 2018 to April 2019	21	Final report	Apr 2020
22	Develop draft presentation materials for public meeting	22	Draft presentation slides for public meeting	May 2020
23	Revise presentation materials for public meeting	23	Revise presentation materials for public meeting	February 2021
24	Present run-through of public meeting to the PAG	24	Present run-through of public meeting to the PAG	February 2021

Task #	Requirement	Deliverable #	Description	Target completion date, frequency of deliverable, or number of weeks after project initiation for completion
25	Present findings of final report at public meeting	25	Public meeting presentation	March 2021
Status Updates				
26	Progress updates with the FDA Project Manager (phone)	--	Progress updates	Biweekly from project initiation

6. Staffing

The contractor shall staff the project with one project manager who shall be responsible for participating in kick-off/closing meetings, ensuring that personnel are making necessary progress in meeting deliverable deadlines, holding regular progress updates with FDA, resolving any performance issues with personnel, and contributing to the qualitative and quantitative data gathering and analysis, among other duties. FDA expects that this task order will require contribution by at least one senior program evaluation subject matter expert with expert knowledge of INDs, qualitative and qualitative research and analysis, and program evaluation. In addition, FDA expects the project to be staffed with at least two entry-level or junior program evaluation subject matter experts with experience in qualitative and quantitative data gathering and analysis.

7. Government Furnished Property

The FDA will provide laptops, tokens, badges, network access, necessary software, and access to relevant FDA data systems to all contractors. FDA badges and government furnished equipment will be provided to the contractor within one month following the date of award. Immediately after award of the contract, the contractor will provide a complete list of all personnel to FDA. For status updates with the FDA that can occur by teleconference, FDA will provide the teleconference information.

8. Period of Performance

Performance of this task order shall commence on the task order execution date and shall not extend beyond April 30, 2021. Once the final report is submitted by April 2020 (Task 14), the contractor will engage in any project related work associated in refining the presentation materials that they will present at a public workshop by March 2021 (Task 15 – 17). The estimated period of performance is 38 months.

9. Security and Privacy

The contractor agrees that contractor personnel will not divulge or release data or information developed or obtained in connection with the performance of the resulting contract, unless made public by FDA or upon written approval of the Government.

Except as may otherwise be permitted by a data owner, the contractor personnel agrees not to use, disclose or reproduce proprietary data, other than as required in performance of the contact; provided, however, that nothing herein shall be construed as precluding the use of any data independently acquired by the contractor without such limitation.

Due to the sensitive nature of the information involved, all contractor personnel will be required to sign a non-disclosure agreement before data and information otherwise exempt from public disclosure (e.g. Privacy Act or Data Collected Under an assurance of Confidentiality) may be disclosed to them.

The contractor shall submit a roster, by name, position and responsibility, of all staff (including subcontractor staff) working under the contract that will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change.

Each contractor/subcontractor employee who may have access to non-public Department information under this contract shall complete and submit the FDA Form 3398: Contractor's Commitment to Protect Non-Public Information (NPI) Agreement available upon request from the FDA Intranet site. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer or designee prior to performing any work under the contract. The Project officer or designee will inform the contractor of any additional forms and training that are required.

10. Place of Performance and Equipment

The contractor will be expected to attend in person at FDA's White Oak Headquarters orientation sessions, FDA PAG quarterly progress updates, interviews with FDA staff, any interviews with applicants conducted in person, sponsor meetings, and other activities that can't be conducted virtually.

Other contract-related technical work may be performed off-site via Virtual Private Network (VPN) using FDA-issued laptops/computer equipment with tokens, personal identity verification (PIV) cards (badges) and appropriate network accounts. The contractor shall be responsible for providing internet access so contractor-assigned computers are able to connect to the FDA network via VPN.

FDA provides laptops, printers, scanners, badges, as necessary for access to relevant FDA data systems. These materials and resources shall remain the property of the US Government and shall be returned in good condition to the COR at the conclusion of the period of performance.

Otherwise the contractor will be responsible for providing their own equipment. FDA badges and Government furnished equipment will be provided to the contractor within one month following the date of award. For activities requiring on-site participation, FDA will provide the contractor with work space as necessary on the White Oak campus. The contractor may be required to utilize hoteling space, existing offices, or other shared space at the campus and move frequently while working at the White Oak Campus.

11. Evaluation Criteria

The following evaluation criteria will be used in assessing the technical proposals for the work specified in this statement of work:

1. Technical understanding of the work described in this statement of work
2. Approach to conducting the work and meeting requirements
3. Qualification of key personnel