# Request Overview

We request a line-item quote for IND writing and formatting support for a new molecular entity with a target filing in 2021. Details of responsibilities, documents within scope, and estimated timelines are below.

Please provide an estimated number of resources (eg, single or multiple contributors). Due to the training requirement for our document management system, we prefer a consistent 1-2 resources. Sponsor has annual IND targets which will require the same support with a different timeline. Thus, a master service agreement with option to extend the SOW is desired.

# Responsibilities

* Writing support for Module 2.4, 2.6.1, 2.6.2, 2.6.3, 2.6.4, 2.6.5, 2.6.6,2.6.7 (PK, Toxicology and Pharmacology sections of IND) such as collating info from vendor reports and internal reports, populating tabulated summary documents.
* Module 4 reference management. Ordering references from RightFind, collating documents and loading them into our document management system.
* Formatting support of Module 2 section (listed below) of regulatory documents
* Formatting support of Module 3
* Formatting and pre-publishing of internal Module 4 reports (approximately 5-10 reports)

Documents will be prepared and archived in a document management system, a customized system based on Documentum . Access to this system will require 9 e-learning modules of with an estimated time to completion of ~6 hours.

* Module 2 and 3 documents will be authored, reviewed, and approved in EDMS.
* Module 4 reports will be formatted and finalized outside of the document management system and archived in EDMS for submission.

# Estimated Project Plan and Timelines for Work

Number of drafts and estimated timelines may be estimated from this section. Detailed timeline is subject to change based on data availability.

## High Level Writing Timelines for Module 2 Documents

|  |  |  |  |
| --- | --- | --- | --- |
| Task Name | Duration | Start | Finish |
| **Module 2** | **114 days** | **Thu 5/20/21** | **Tue 10/26/21** |
| **2.2 CTD Introduction** | **30 days** | **Thu 5/20/21** | **Wed 6/30/21** |
| **2.3 Quality Overall Summary (introduction doc only)** | **30 days** | **Wed 7/21/21** | **Tue 8/31/21** |
| **2.4 Nonclinical Overview** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| **2.6.1 Introduction** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| **2.6.2 Pharmacology written summary** | **44 days** | **Tue 6/1/21** | **Fri 7/30/21** |
| **2.6.3 Pharmacology tabulated summary** | **44 days** | **Tue 6/1/21** | **Fri 7/30/21** |
| **2.6.4 Pharmacokinetic written summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| **2.6.5 Pharmacokinetic tabulated summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| **2.6.6 Toxicology written summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| **2.6.7 Toxicology tabulated summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |

## Detailed Module 2 Writing Timelines

The timelines below are approximations and may be shifted as appropriate by the availability of data. Note: “final edits” indicate the addition and/or confirmation of the final NOAEL, as reported by the Toxicology Study Director.

|  |  |  |  |
| --- | --- | --- | --- |
| Task Name | Duration | Start | Finish |
| **Module 2** | **114 days** | **Thu 5/20/21** | **Tue 10/26/21** |
| **2.2 CTD Introduction** | **30 days** | **Thu 5/20/21** | **Wed 6/30/21** |
| Draft 1 writing | 5 days | Thu 5/20/21 | Wed 5/26/21 |
| Draft 1 review | 5 days | Thu 5/27/21 | Wed 6/2/21 |
| Draft 2 writing | 5 days | Thu 6/3/21 | Wed 6/9/21 |
| Draft 2 review | 5 days | Thu 6/10/21 | Wed 6/16/21 |
| Final draft edits | 2 days | Thu 6/17/21 | Fri 6/18/21 |
| QC | 5 days | Mon 6/21/21 | Fri 6/25/21 |
| Approval | 2 days | Mon 6/28/21 | Tue 6/29/21 |
| Pre-publish | 1 day | Wed 6/30/21 | Wed 6/30/21 |
| **2.3 Quality Overall Summary (introduction doc only)** | **30 days** | **Wed 7/21/21** | **Tue 8/31/21** |
| Draft 1 writing | 5 days | Wed 7/21/21 | Tue 7/27/21 |
| Draft 1 review | 5 days | Wed 7/28/21 | Tue 8/3/21 |
| Draft 2 writing | 5 days | Wed 8/4/21 | Tue 8/10/21 |
| Draft 2 review | 5 days | Wed 8/11/21 | Tue 8/17/21 |
| Final draft edits | 2 days | Wed 8/18/21 | Thu 8/19/21 |
| QC | 5 days | Fri 8/20/21 | Thu 8/26/21 |
| Approval | 2 days | Fri 8/27/21 | Mon 8/30/21 |
| Pre-publish | 1 day | Tue 8/31/21 | Tue 8/31/21 |
| **2.4 Nonclinical Overview** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| Draft 1 writing | 10 days | Mon 6/7/21 | Fri 6/18/21 |
| Draft 1 review | 10 days | Mon 6/21/21 | Fri 7/2/21 |
| Draft 2 writing | 10 days | Mon 7/5/21 | Fri 7/16/21 |
| Draft 2 review | 10 days | Mon 7/19/21 | Fri 7/30/21 |
| Final draft edits | 5 days | Thu 10/7/21 | Wed 10/13/21 |
| QC | 5 days | Thu 10/14/21 | Wed 10/20/21 |
| Approval | 2 days | Thu 10/21/21 | Fri 10/22/21 |
| Pre-publish | 2 days | Mon 10/25/21 | Tue 10/26/21 |
| **2.6.1 Introduction** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| Draft 1 writing | 10 days | Mon 6/7/21 | Fri 6/18/21 |
| Draft 1 review | 10 days | Mon 6/21/21 | Fri 7/2/21 |
| Draft 2 writing | 10 days | Mon 7/5/21 | Fri 7/16/21 |
| Draft 2 review | 10 days | Mon 7/19/21 | Fri 7/30/21 |
| Final draft edits | 5 days | Thu 10/7/21 | Wed 10/13/21 |
| QC | 5 days | Thu 10/14/21 | Wed 10/20/21 |
| Approval | 2 days | Thu 10/21/21 | Fri 10/22/21 |
| Pre-publish | 2 days | Mon 10/25/21 | Tue 10/26/21 |
| **2.6.2 Pharmacology written summary** | **44 days** | **Tue 6/1/21** | **Fri 7/30/21** |
| Draft 1 writing | 10 days | Tue 6/1/21 | Mon 6/14/21 |
| Draft 1 review | 10 days | Tue 6/15/21 | Mon 6/28/21 |
| Draft 2 writing | 10 days | Tue 6/29/21 | Mon 7/12/21 |
| Draft 2 review | 10 days | Tue 7/13/21 | Mon 7/26/21 |
| Final draft edits | 1 day | Tue 7/27/21 | Tue 7/27/21 |
| QC | 1 day | Wed 7/28/21 | Wed 7/28/21 |
| Approval | 1 day | Thu 7/29/21 | Thu 7/29/21 |
| Pre-publish | 1 day | Fri 7/30/21 | Fri 7/30/21 |
| **2.6.3 Pharmacology tabulated summary** | **44 days** | **Tue 6/1/21** | **Fri 7/30/21** |
| Draft 1 writing | 10 days | Tue 6/1/21 | Mon 6/14/21 |
| Draft 1 review | 10 days | Tue 6/15/21 | Mon 6/28/21 |
| Draft 2 writing | 10 days | Tue 6/29/21 | Mon 7/12/21 |
| Draft 2 review | 10 days | Tue 7/13/21 | Mon 7/26/21 |
| Final draft edits | 1 day | Tue 7/27/21 | Tue 7/27/21 |
| QC | 1 day | Wed 7/28/21 | Wed 7/28/21 |
| Approval | 1 day | Thu 7/29/21 | Thu 7/29/21 |
| Pre-publish | 1 day | Fri 7/30/21 | Fri 7/30/21 |
| **2.6.4 Pharmacokinetic written summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| Draft 1 writing | 10 days | Mon 6/7/21 | Fri 6/18/21 |
| Draft 1 review | 10 days | Mon 6/21/21 | Fri 7/2/21 |
| Draft 2 writing | 10 days | Mon 7/5/21 | Fri 7/16/21 |
| Draft 2 review | 10 days | Mon 7/19/21 | Fri 7/30/21 |
| Final draft edits | 5 days | Thu 10/7/21 | Wed 10/13/21 |
| QC | 5 days | Thu 10/14/21 | Wed 10/20/21 |
| Approval | 2 days | Thu 10/21/21 | Fri 10/22/21 |
| Pre-publish | 2 days | Mon 10/25/21 | Tue 10/26/21 |
| **2.6.5 Pharmacokinetic tabulated summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| Draft 1 writing | 10 days | Mon 6/7/21 | Fri 6/18/21 |
| Draft 1 review | 10 days | Mon 6/21/21 | Fri 7/2/21 |
| Draft 2 writing | 10 days | Mon 7/5/21 | Fri 7/16/21 |
| Draft 2 review | 10 days | Mon 7/19/21 | Fri 7/30/21 |
| Final draft edits | 5 days | Thu 10/7/21 | Wed 10/13/21 |
| QC | 5 days | Thu 10/14/21 | Wed 10/20/21 |
| Approval | 2 days | Thu 10/21/21 | Fri 10/22/21 |
| Pre-publish | 2 days | Mon 10/25/21 | Tue 10/26/21 |
| **2.6.6 Toxicology written summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| Draft 1 writing | 10 days | Mon 6/7/21 | Fri 6/18/21 |
| Draft 1 review | 10 days | Mon 6/21/21 | Fri 7/2/21 |
| Draft 2 writing | 10 days | Mon 7/5/21 | Fri 7/16/21 |
| Draft 2 review | 10 days | Mon 7/19/21 | Fri 7/30/21 |
| Final draft edits | 5 days | Thu 10/7/21 | Wed 10/13/21 |
| QC | 5 days | Thu 10/14/21 | Wed 10/20/21 |
| Approval | 2 days | Thu 10/21/21 | Fri 10/22/21 |
| Pre-publish | 2 days | Mon 10/25/21 | Tue 10/26/21 |
| **2.6.7 Toxicology tabulated summary** | **102 days** | **Mon 6/7/21** | **Tue 10/26/21** |
| Draft 1 writing | 10 days | Mon 6/7/21 | Fri 6/18/21 |
| Draft 1 review | 10 days | Mon 6/21/21 | Fri 7/2/21 |
| Draft 2 writing | 10 days | Mon 7/5/21 | Fri 7/16/21 |
| Draft 2 review | 10 days | Mon 7/19/21 | Fri 7/30/21 |
| Final draft edits | 5 days | Thu 10/7/21 | Wed 10/13/21 |
| QC | 5 days | Thu 10/14/21 | Wed 10/20/21 |
| Approval | 2 days | Thu 10/21/21 | Fri 10/22/21 |
| Pre-publish | 2 days | Mon 10/25/21 | Tue 10/26/21 |

## Module 3 Document List

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| --- |
| Task Name |
| **Module 3** |
| **3.2.S.1 General Information** |
| **3.2.S.2.1 Manufacturer** |
| **3.2.S.2.2 Description of Manufacturing Process and Process Controls** |
| **3.2.S.2.3 Control of Materials** |
| **3.2.S.2.4 Controls of Critical Steps and Intermediates** |
| **3.2.S.2.5 Process Validation and/or Evaluation** |
| **3.2.S.2.6 Manufacturing Process Development** |
| **3.2.S.3.1 Elucidation of Structure and other Characteristics** |
| **3.2.S.3.2 Impurities** |
| **3.2.S.4.1 Specification** |
| **3.2.S.4.2 Analytical Procedures** |
| **3.2.S.4.3 Validation of Analytical Procedures** |
| **3.2.S.4.4 Batch Analyses** |
| **3.2.S.4.5 Justification of Specification** |
| **3.2.S.5 Reference Standards or Materials** |
| **3.2.S.6 Container Closure Systems** |
| **3.2.S.7.1 Stability Summary and Conclusions** |
| **3.2.S.7.2 Post Approval Stability Protocol and Stability Commitment** |
| **3.2.S.7.3 Stability Data** |
| **3.2.P.1 Description and Composition of the Drug Product** |
| **3.2.P.2 Pharmaceutical Development** |
| **3.2.P.3.1 Manufacturer(s)** |
| **3.2.P.3.2 Batch Formula** |
| **3.2.P.3.3 Description of Manufacturing Process and Process Controls** |
| **3.2.P.3.4 Controls of Critical Steps and Intermediates** |
| **3.2.P.3.5 Process Validation and/or Evaluation** |
| **3.2.P.4 Control of Excipients** |
| **3.2.P.5.1 Specifications** |
| **3.2.P.5.2 Analytical Procedures** |
| **3.2.P.5.3 Validation of Analytical Procedures** |
| **3.2.P.5.4 Batch Analyses** |
| **3.2.P.5.5 Characterization of Impurities** |
| **3.2.P.5.6 Justification of Specification(s)** |
| **3.2.P.6 Reference Standards or Materials** |
| **3.2.P.7 Container Closure System** |
| **3.2.P.8.1 Stability Summary and Conclusion** |
| **3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment** |
| **3.2.P.8.3 Stability Data** |
| **3.2.A.1 Facilities and Equipment Report** |
| **3.2.A.2 Adventitious Agents Report** |