FDA Communication Log

**Purpose:** This log can be used to maintain a chronology of interactions, communications and submissions between the FDA and the Sponsor (or Sponsor-Investigator) for the referenced IND/IDE. This log is intended to provide a general overview of the flow and events for the project. The detailed communications and documents are maintained and available in the regulatory binder.

**Name and brief description of the Investigational Product:**

**Indication for Use:**

**SNOMED CT Indication Disease Term:**

**IND/IDE Number:**

**Sponsor-Investigator:**

**Contact for FDA Submissions:**

**Date Submitted to FDA:**

**Date Received by FDA:**

**Effective Date:** **Last Annual Report Submitted to FDA:**

**FDA Regulatory Project/Program Manager:**

**Cost Recovery Approved by FDA on:** xx/xx/xxxx, **Expires:** xx/xx/xxxx+1

**Studies under this IND**

* **IRB#:**
* **Title:**
* **ClinicalTrials.gov Identifier:** NCT

If This IND/IDE relies on or provides a cross-reference, include details of these references here, IND # of LOA, when it was obtained what it refers to.

| **Submission Serial # or Reference #** | **Date (and time) of Communication or Submission** | **Type of Interaction** | **Description of Interaction** |  |
| --- | --- | --- | --- | --- |
| 0000 |  | Initial IND Submission | Serial # 0000, Initial IND Submission, included Cover Letter, 3926, 1571, 1572, 3674, IND Packet (Protocol, Consent, CMC, Previous Human Experience, Pharm/Tox, and LOA for Cross Reference.(insert cover letter or key document) |  |
| 0000.1 |  | Email from NextGen | Confirmation email received from NextGen Portal assigning the Unique Event ID: RI-(insert/embed submission confirmation) |  |
| 0000.2 |  |  |  |  |
| 0000.3 |  |  |  |  |
| 0001 |  |  | Serial #0001, Formal submission of  |  |
| 0001.1 |  | Email from NextGen | Confirmation email received from NextGen Portal assigning the Unique Event ID: (insert/embed submission confirmation) |  |
| 0002 |  |  | Serial #0002, Formal submission of  |  |
| 0002.1 |  | Email from NextGen | Confirmation email received from NextGen Portal assigning the Unique Event ID: (insert/embed submission confirmation) |  |
| 0002.2 |  |  |  |  |
| For interactions between formal communications, use previous formal submission serial number and follow that with either a decimal increment or alphabetical increment. | For submissions where the time is relevant, email, ESG, NextGen, include a time with the date | EmailNextGenIND AmendmentIND Annual Report | Include a general description of the submission.For completeness, the actual file submission may be embedded as a PDF into the word document, these files are active and can be opened and viewed while in the word version of the log. This allows for a very complete single document of the FDA activity.Save emails as PDF to allow for better functionality.Insert or embed the actual submission document or a key document (cover letter) for quick reference. If review of actual documents should be necessary, go to actual folder to access these. |  |
|  |  |  |  |  |
|  |  |  |  |  |

***Cost Recovery Tracking Template – For INDs where cost recovery requests have been submitted to the FDA the table below can be used to track these as they may have a different, review and approval cycle than the IND.***

**Cost Recovery Tracking (21 CFR 312.8(b))**

*Typically, valid for one year, recommendation from FDA to submit reauthorization request at* ***least 60 days prior*** *to the end of the authorization period. There are separate fields in OnCore to Track Cost Recovery Submissions and Reminders*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study IRB#** | **Submission Date** | **Approval Date** | **Expiration Date** | **Notes****(enter Serial #)** |
|  |  |  |  |  |
|  |  |  |  | Serial #0000; Cost Recovery Submitted |
|  |  |  |  |  |
|  |  |  |  | Cost Recovery Approved |
|  |  |  |  |  |
|  |  |  |  |  |

**References**

| **Submission Serial # or Reference #** | **Date (and time) of Communication or Submission** | **Type of Interaction** | **Description of Interaction** |  |
| --- | --- | --- | --- | --- |
| 0000 |  | Initial IND Submission | Note that if Form FDA 3926 is being used for submissions there are no references to Serial Numbers on this form so only a sequence reference number should be used  |  |
| 0000.1 |  | Email from NextGen |  |  |
| 0000.2 |  |  |  |  |
| 0000.3 |  |  |  |  |
| 0001 |  |  | Serial #0001, Formal submission of  |  |
| 0001.1 |  | Email from NextGen | Confirmation email received from NextGen Portal assigning the Unique Event ID: (insert/embed submission confirmation) |  |
| 0002 |  |  | Serial #0002, Formal submission of  |  |
| 0002.1 |  | Email from NextGen | Confirmation email received from NextGen Portal assigning the Unique Event ID: (insert/embed submission confirmation) |  |
| 0002.2 |  |  |  |  |
| For interactions between formal communications, use previous formal submission serial number and follow that with either a decimal increment or alphabetical increment. | For submissions where the time is relevant, email, ESG, NextGen, include a time with the date | EmailNextGenIND AmendmentIND Annual Report | Include a general description of the submission.For completeness, the actual file submission may be embedded as a PDF into the word document, these files are active and can be opened and viewed while in the word version of the log. This allows for a very complete single document of the FDA activity.Save emails as PDF to allow for better functionality.Insert or embed the actual submission document or a key document (cover letter) for quick reference. If review of actual documents should be necessary, go to actual folder to access these. |  |
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