Master Services Agreement
SPONSOR Day Month 2018

I. Description of Services:

Provide medical writing, document processing, bibliography management, clinical research and clinical consulting services as described in project-specific attachments.

- Medical Writing may include (but not be limited to) preparation, revision or formatting of documents such as clinical protocols and related documents, clinical and preclinical study reports, investigational drug brochures, briefing documents, white papers, specialized analyses and position papers, clinical trial summaries, literature surveys, manuscripts for publication, meeting compendia, posters, and slide presentations, or other documents as requested by SPONSOR.
- Regulatory writing may include preparation, review, QA or editing of components of regulatory submissions, as requested.
- IND/IMPD/NDA/BLA/MAA Documents may include (but not be limited to) Module 1 Product labeling following SPL format (created in Word), annotated product labeling following SPL format (created in Word); Module 2, CTD Introduction, Quality Overall Summary, Nonclinical Overview, Clinical Overview, Nonclinical Written and Tabulated Summaries, and Clinical Summary; Module 3, Quality; Module 4, assembly on Nonclinical Study Reports, and Module 5, Clinical Study Reports.
- Regulatory submission support services may include (but not be limited to) the following: development of company-specific style guides; development of document templates and Work Practice Guidelines (WPG), and formatting SOPs to support SPONSOR CTD activities; and provision/review of applicable guidances and regulatory statutes.
- Electronic document processing, if requested, may include (but not be limited to) rendering of Word documents to PDF, scanning of documents to PDF, bookmarking and hyperlinking, or evaluation of existing PDF documents for submission suitability.
- Bibliography management, if requested, may include (but not be limited to) product-specific or general literature searches, acquisition and maintenance of product-specific publication archives, management of copyright clearance permissions and licenses, and other related activities as requested, all on behalf of SPONSOR or its clients.
- Clinical research services, if requested, may include (but not be limited to) evaluation and summarization of client protocols and development plans, case report form development or assessment, and data quality assurance.
- Clinical Consulting may include other activities in relation to clinical drug or device development not listed above, as requested.

II. Terms and Conditions

Good-faith estimates of projected charges will be provided on a per-project basis as individual Work Order attachments to this Master Services Agreement (MSA).

- Should the nature, scope, or assumptions upon which that good faith estimate was based change after initiation of the project, the Work Order will be adjusted accordingly to cover all submitted invoices and accrued charges within 30 days of the change.
- All services to be provides on a time and materials (hourly) basis as described in the Work Order. Cayuga will invoice only for those hours, fees and expenses actually accrued.
- Activity on project-related tasks will be accrued on a half-hourly basis and charges will be submitted in the form of a project-specific invoice at the end of each month.
- Project-related travel will be kept to the minimum practical for each project. Travel time for Cayuga Consulting staff will be billed door to door, including delays, at 75% of the standard hourly rate for that person or activity as specified in the MSA, unless otherwise agreed to in the project-specific Work Orders.
- Expenses incurred while carrying out authorized project tasks will be passed through to SPONSOR. Expenses will be broken out by travel-related expenses, copying and printing charges, cost of materials to prepare archive versions of QA documentation, shipping charges, and other miscellaneous project-related expenses as applicable. Original receipts or scanned versions or receipts will be provided as attachments to a project-specific invoice.
- All hourly charges and expenses incurred while carrying out project-related tasks will be submitted to SPONSOR on a monthly or twice-monthly basis as described in the specific Work Order.
- A 10% Administrative Service Fee will be applied to all Invoices.
- All invoices are to be paid by SPONSOR within 30 days of receipt unless otherwise specified in the Work Order.

III. Hourly Rates

Cayuga will provide summaries of qualifications for all staff proposed for project-specific activity, for SPONSOR review and approval prior to initiation of activity. The following hourly rates will apply to all activities carried out under this MSA unless otherwise specified in a project-specific Work Order:

- Clinical/Regulatory Consultant: $175/hr
- Senior Medical Writer: $175/hr
- Medical Writer: $150 /hr
- Safety Narrative Writer: $150/hr
- Project Manager: $175/hr
- Quality-assurance Auditor: $150/hr
- Electronic Document/Scanning Specialist: $125/hr plus $1/page scanned

- Bibliographic and Literature Search Services: $175/hr

IV. Modification, Renewal, and Termination of this Agreement

This MSA will be in effect for a period not to exceed two years; renewals and or modifications of the MSA may be made in writing with the mutual agreement of both Cayuga Consulting and SPONSOR as an addendum to the MSA.

- Individual Projects described in Work Orders attached to this MSA may be terminated at any time upon 30 days written notification by either party. Expenses and hourly charges incurred by Cayuga Consulting up to the termination date of the Work Order.
- This MSA may be terminated in its entirety, and all related project activity terminated, by either party upon written notification, provided 30 days before the desired termination date. All project charges and expenses accrued by Cayuga Consulting up to the termination date, plus the Early Termination Fee (if applicable) must be paid within 30 days upon submission of a final invoice.
- In the event the MSA or a specific Work Order is terminated, both SPONSOR and Cayuga will make good faith efforts to close out project activities within 30 days in a manner consistent with good business practices, good clinical practices, and applicable law.

V. Signatures

This MSA will be in effect from the date shown below, as indicated by signatures of authorized representatives of both parties.

Cayuga Consulting
20 Dewey St.,
Providence, RI 02909

_____
Donna D. Walczak, PhD
President
Date: _____

SPONSOR
Street Address
City, State

_____
Name
Title
Date: _____