Work Order

Title of Project: Biostatistics and Programming Services for {{study\_number}} Study

Work Order: #{{wo\_number}}

This Work Order #{{wo\_number}} (“Work Order”) is made effective as of {{wo\_date}} (“Work Order Effective Date”) and is executed pursuant to and is governed by the terms and conditions of that certain Master Services Agreement, dated as of May 11th, 2020 (the “Master Services

Agreement”), by and between **{{sponsor}}** (“Customer”), and **EDETEK, Inc.**

(“EDETEK”). To the extent that there is any conflict between the terms and conditions of the Master Services Agreement and this Work Order, the Master Services Agreement shall control. All capitalized terms in this Work Order are used as defined in the Master Services Agreement. The following terms and conditions apply solely to work performed under this Work Order and do not apply to any other Work Orders.

Time shall be of the essence in connection with any deadlines set forth in this Work Order.

1. Project Summary:

EDETEK shall provide {{services}} services for the Customer’s studies {{study\_number}} (the “Services”), as described in detail in EDETEK’s Proposal for Biostatistics and Programming Services for {{study\_number}} Study, dated {{wo\_date}}, incorporated herein by this reference and attached hereto as Attachment 1 (the “Proposal”).

2. Deliverables:

The Services and Deliverables are as described in detail in EDETEK’s Proposal.

3. Budget:

The maximum amount due under this Work Order shall not exceed ${{budget}}USD. Breakdown of costs is as described in detail in EDETEK’s Proposal.

4. Term:

The term of this Work Order will commence on the Work Order Effective Date set forth above and will continue until the earlier of (i){{end\_date}}, (ii) the Services described are complete or (iii) this Work Order is terminated in accordance with the Agreement.

5. Approved Subcontractors:

Provider shall notify the Customer in writing if it intends to use a subcontractor, in part or in full. Mirum, at its own discretion, shall have the right to refuse the use of a particular subcontractor.

6. Fees and Payment Schedule:

Invoices shall be e-mailed to Customer at {{customer\_email}}, (Attn: Accounts Payable) on a monthly basis upon completion of the Services and Customer’s receipt and acceptance of the Deliverables.

Payments will be made within thirty (30) days of Customer’s receipt of invoice from EDETEK, except for any amounts that Customer disputes in good faith, and cumulative charges will not exceed the amount shown above without prior written approval by both parties in the form of an Amendment. Payee information is as follows:

**Payee**: EDETEK, Inc. **Name of Bank**: JPMorgan Chase Bank, N.A.

**Attn**: Wei Kong **Swift code**: CHASUS33

**Phone**: (609) 720-0888 **ABA** #: 021202337

**E-Mail**: [ar.team@edetek.com](mailto:ar.team@edetek.com) **Account #**: 834543977

**Address**: 101 College Road East, Floor 2 **Account** **name**: EDETEK, Inc.

Princeton, NJ 08540

7. Facilities:

All Services will be performed at EDETEK locations.

8. Key Personnel:

All Services will be performed by EDETEK project team.

ACCEPTED AND AGREED by their duly authorized representatives.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **{{sponsor}}.** | |  | **EDETEK, Inc** | |
| By: |  |  | By: |  |
| Name: |  |  | Name: |  |
| Title: |  |  | Title: |  |
| Date: |  |  | Date: |  |

**ATTACHMENT 1**

Proposal

|  |  |
| --- | --- |
|  | |
|  | Biostatistics and Programming  Services for ENV-202 Study |
|  |  |
| {{wo\_date}} | |  | | --- | | **EDETEK Inc.**  101 College Road East, 2nd Floor  Princeton, NJ 08540  (609) 720-0888  www.EDETEK.com | |  | | **Jian Chen**  President  (609) 720-0888  jian.chen@EDETEK.com | |  | | © EDETEK Inc. 2025  *This document is the property of EDETEK Inc., and the information contained herein is confidential. This document, either in whole or in part, must not be reproduced or disclosed to others or used for purposes other than that for which it has been supplied, without EDETEK Inc.’s prior written permission, or, if any part hereof is furnished by virtue of a contract between EDETEK Inc. and a third party, as expressly authorized under that contract.* | |

## Request for Proposal from the Customer

EDETEK has been asked by the Customer to provide biostatistics and programming services to support the ENV-202 study.

EDETEK resources will act as the Customer’s extended team members, providing stable and scalable services based on the Customer’s analytical needs. Quality services provided by EDETEK will allow the Customer’s resources to focus on strategic activities while having the flexibility to handle dynamic needs.

## Materials to Be Provided by the Customer

The Customer will provide to EDETEK the following Materials for Services:

* Study Protocols
* Study Raw Data
* Annotated CRFs
* External Data Transfer Agreement (DTA)

EDETEK resources will work in EDETEK’s own validated SAS environment. All file transfers will be through 21 CFR Part 11 compliant and validated ShareFile services.

## EDETEK Resources

EDETEK will employ the resources best fit for the tasks, including technical skills, industry experience, communication effectiveness, and overall project management and delivery capabilities.

All the programming specs will be clear, complete, accurate, and up to date.

All production and validation programs will be delivered as part of the delivery package.

## EDETEK Contacts

Project Leader: Jing Liu, Senior Director, Biometrics

Administration Contact: Jian Chen, President

Payment Contact: Wei Kong, VP Accounting

Contracts: Kevin Prizeman, Business Development

## {{sponsor}} Contact

{{representative\_name}}, {{title}}, {{sponsor}}

## Study Maintenance

Initiation of live studies often comes with changes to the casebook and database. If during the study, significant changes are requested by the Customer are not the results of EDETEK’s performance, the out-of-scope work will be invoiced on hourly basis, after acquiring written approval from Mirum Pharmaceuticals. EDETEK will work with Mirum Pharmaceuticals to identify the most cost-effective approach for each study.

## Pricing

The following table summarizes the pricing for each group of activities, as well as the total budget.

**Budget Summary**

**Biostatics and Programming Services**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activities** | **Unit** | **Unit Cost ($)** | **Units** | **Budget** |
| **Task 1. Project Management and Statistician Support** |  |  |  | **$30,500** |
| Project Management, Resource Coordination, Communication | Hours | $150 | 10 | $1,500 |
| Unblinded Senior Statistician Support | Hours | $200 | 70 | $14,000 |
| Unblinded Statistical Team Support | Hours | $150 | 100 | $15,000 |
|  |  |  |  |  |
| **Task 2. Creation of SDTM Package** |  |  |  | **$60,200** |
| **SDTM Base Development** |  |  |  | **$31,500** |
| SDTM Spec | Domain | $200 | 25 | $5,000 |
| SDTM Trial Design | Domain | $500 | 5 | $2,500 |
| SDTM Subject Level | Domain | $1,200 | 20 | $24,000 |
| Basic Data Refresh | Per Refresh | $800 | 25 | $20,000 |
| Fully QC'd Data Refresh | Per Refresh | $1,350 | 2 | $2,700 |
| aCRF, Define, & SDRG | Study | $6,000 | 1 | $6,000 |
|  |  |  |  |  |
| **Task 3. Creation of ADaM Datasets** |  |  |  | **$60,300** |
| **ADaM Base Development** |  |  |  | **$39,800** |
| ADaM Spec | Dataset | $600 | 13 | $7,800 |
| ADaM Simple | Dataset | $2,000 | 7 | $14,000 |
| ADaM Complex (ADSL, ADLB, ADEXSUM, etc.) | Dataset | $3,000 | 6 | $18,000 |
| Basic Data Refresh | Per Refresh | $1,000 | 10 | $10,000 |
| Fully QC'd Data Refresh | Per Refresh | $2,250 | 2 | $4,500 |
| Define & ADRG | Study | $6,000 | 1 | $6,000 |
|  |  |  |  |  |
| **Task 4. Creation of SRC (Safety Review Committee) TLFs** | |  |  | **$43,838** |
| **SRC TLF Base (Production & Validation)** |  |  | **35** | **$13,838** |
| Unique Tables | Table | $450 | 15 | $6,750 |
| Repeat Tables | Table | $183 | 10 | $1,825 |
| Unique Figures | Figure | $500 | 5 | $2,500 |
| Repeat Figures | Figure | $203 | 5 | $1,013 |
| Unique Listings | Listing | $350 | 5 | $1,750 |
| Repeat Listings | Listing | $165 | 0 | $0 |
| SRC Data Refresh Package (SDTM, ADAM, TLF) | Per Refresh | $5,000 | 6 | $30,000 |
| Unit price is half of CSR considering reuse |  |  |  |  |
| Only if modification from CSR TLF is needed |  |  |  |  |
| The refresh unit price already includes the (partial) refresh of SDTM and ADaM. So, no extra refresh costs for these. |  |  |  |  |
|  |  |  |  |  |
| **Task 5. Interim Analysis TLFs** |  |  |  | **$49,425** |
| **Interim Analysis TLF Base** |  |  | **145** | **$44,425** |
| Unique Tables | Table | $450 | 35 | $15,750 |
| Repeat Tables | Table | $183 | 50 | $9,125 |
| Unique Figures | Figure | $500 | 10 | $5,000 |
| Repeat Figures | Figure | $203 | 20 | $4,050 |
| Unique Listings | Listing | $350 | 30 | $10,500 |
| Repeat Listings | Listing | $165 | 0 | $0 |
| IA Data Refresh Package | Per Refresh | $5,000 | 1 | $5,000 |
| Unit prices and counts are half of CSR considering reuse, including creation of unblinded package |  |  |  |  |
| Only if modification from CSR TLF is needed |  |  |  |  |
|  |  |  |  |  |
| **Task 6. Creation of Final TLFs** |  |  |  | **$81,775** |
| **Final CSR TLF Base (Production & Validation)** |  |  | **118** | **$76,775** |
| Unique Tables | Table | $900 | 35 | $31,500 |
| Repeat Tables | Table | $365 | 30 | $10,950 |
| Unique Figures | Figure | $1,000 | 8 | $8,000 |
| Repeat Figures | Figure | $405 | 5 | $2,025 |
| Unique Listings | Listing | $700 | 30 | $21,000 |
| Repeat Listings | Listing | $330 | 10 | $3,300 |
| CSR Data Refresh Package | Per Refresh | $5,000 | 1 | $5,000 |
|  |  |  |  |  |
| **Task 7. Ad Hoc Support (Pre-allocated)** |  |  |  | **$34,500** |
| Ad hoc support billed by the number of outputs, e.g., datasets and TFLs (Senior Programmer) | Hours | $135 | 100 | $13,500 |
| Ad hoc support billed by the number of outputs, e.g., datasets and TFLs (Programming) | Hours | $105 | 200 | $21,000 |
| Pre-allocated |  |  |  |  |
|  |  |  |  |  |
| **Task 8. Meetings** |  |  |  | **$8,750** |
| One study kick-off meeting Several planned or ad hoc project management meetings during study on-going | Meeting | $350 | 25 | $8,750 |
|  |  |  |  |  |
| **Total Budget** |  |  |  | **$369,288** |

The total budget for Tasks 1 – 8 of {{services}} for {{study\_number}} is **${{budget}}**

**Overall Budget Summary**

|  |  |
| --- | --- |
| \*Preferred Vendor Discount: | 10% |
|  |  |
| **Part 1 - Biostatistics & Programming Activities** |  |
|  |  |
| **Biostats & Programming Activities** | **Budget** |
| Task 1. Project Management and Statistician Support | $30,500 |
| Task 2. Creation of SDTM Package | $60,200 |
| Task 3. Creation of ADaM Datasets | $60,300 |
| Task 4. Creation of SRC (Safety Review Committee) TLFs | $43,838 |
| Task 5. Interim Analysis TLFs | $49,425 |
| Task 6. Creation of Final TLFs | $81,775 |
| Task 7. Ad Hoc Support (Pre-allocated) | $34,500 |
| Task 8. Meetings | $8,750 |
| **Total of Pre-Defined Activities** | **$369,288** |
| P.V. Discount | -$36,929 |
| **Final Budget After P.V. Discount** | **$332,359** |
|  |  |
|  |  |

The grand total budget of study {{study\_no}} after discount is **${{budget}}.**

The units of deliveries for SDTM and analysis datasets, TLFs, and documents have been estimated for purposes of this proposal. {{sponsor}} will only be billed for the actual number of units that are requested and delivered.

EDETEK’s resources can travel on an as-needed basis. The travel and accommodation expenses will be invoiced accordingly.

**Rates for Additional Deliverables**

For in-study changes, EDETEK will submit a change request, and only proceed after approval.

|  |  |
| --- | --- |
| **Resource** | **Hourly Rate** |
| Project Management | $150 |
| System Builder | $100 |
| Senior Clinical Data Manager | $135 |
| Clinical Data Manager | $100 |
| Senior Statistician | $200 |
| Statistician | $150 |
| Senior Programmer | $135 |
| Programmer | $105 |

## Completion Schedule

Services will be completed in accordance with the following schedule. All deliverables will be posted to a designated area of a 21 CFR Part 11 compliant file exchange portal. The access will only be provided to the appropriate personnel of {{sponsor}}.

|  |  |  |
| --- | --- | --- |
| Deliverables | Required Time | Comments |
| SDTM |  |  |
| SDTM First Draft | 5 weeks | The deliverables include production SDTM datasets, mapping spec, SDTM aCRF, P21 validation report |
| SDTM Validated Package | 7 – 8 weeks | The deliverables include validation logs, validation summary, Define draft, cSDRG draft, in addition to production package. |
| Monthly Data Refresh | 48 hours | SDTM datasets, mapping spec, SDTM aCRF, P21 validation report |
| Fully QC’d Data Refresh | 96 hours | The deliverables include validation logs, validation summary, in addition to production package. |
| Define and cSDRG | Various | Will be provided along with the first validated package, as well as the final package. Interim versions are available upon request. |
| ADaM |  |  |
| ADaM First Draft | 5 weeks after SDTM 1st draft | The deliverables include production ADaM datasets, mapping spec, P21 validation report |
| ADaM Validated Package | 7 – 8 weeks after SDTM 1st draft | The deliverables include validation logs, validation summary, Define, ADRG, in addition to production package. |
| Monthly Data Refresh | 24 hours after SDTM delivery | ADaM datasets, mapping spec, P21 validation report |
| Fully QC’d Data Refresh | 72 hours after SDTM delivery | The deliverables include validation logs, validation summary, in addition to production package. |
| Define and ADRG | Various | Will be provided along with the first validated package, as well as the final package. Interim versions are available upon request. |
| TLF |  |  |
| TLF First Draft | 4 weeks after ADaM 1st draft | The deliverables include production TLF in individual RTFs, as well as PDF with TOC. |
| TLF Validated Package | 6 - 7 weeks after ADaM 1st draft | The deliverables include validation logs, validation summary, in addition to production package. |
| Fully QC’d TLF Refresh | 72 hours after ADaM delivery | The deliverables include validation logs, validation summary, in addition to production package. |
| Topline | 5 days after DBL | Will provide validated SDTM, ADaM, and topline TLFs identified by Mirum Pharmaceuticals, validated by statistician. |
| Final TLF Package | 4 – 5 weeks after DBL | Will provide validated SDTM, ADaM, and complete TLF packages, as well as Define (with ARM if requested), cSDRG/ADRG, and all validation documents. |

## Terms

The customer will be invoiced monthly for work performed.