Exhibit 10.13  
 SERVICES AGREEMENT  
 This Services Agreement (this “Agreement”) is made and entered into as of July 15, 2020, (the “Effective Date”), by and between Worldwide Clinical Trials, Inc., with offices at 0000 Xxxxxxxxx Xxxxxxx, Xxxxx 000, 00000, Xxxxxxxxxxx, XX, Xxxxxx Xxxxxx, (together with its Affiliates, “Worldwide) and Neurotrope Bioscience, Inc., with offices at 1185 Avenue of the Xxxxxxxx, 0xx Xxxxx, Xxx Xxxx, XX 00000 (“Sponsor”). Worldwide and Sponsor are sometimes individually referred to herein as a “Party” and collectively as the “Parties”.  
 For purposes of this Agreement, “Affiliates” means any entity that controls, is controlled by or is under common control with, that Party. “Control” means the possession, directly or indirectly, of at least 50% of the share capital or voting rights or of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise.  
 WHEREAS, Sponsor is engaged in the research and development of pharmaceutical products;  
 WHEREAS, Worldwide is engaged in providing services to pharmaceutical manufacturers in support of their clinical research and product development activities;  
 WHEREAS, Worldwide and Sponsor desire that Worldwide provide certain services with respect to Sponsor’s clinical study, NTRP-101-204 entitled “A Randomized, Double-Blind, Xxxxxxx-Xxxxxxxxxx, Xxxxx 0 Study Assessing Safety, Tolerability and Long-term Efficacy of Bryostatin in the Treatment of Moderately Severe Alzheimer’s Disease Subjects Not Receiving Memantine Treatment” (the "Study") for the study of Sponsor’s drug Bryostatin 1 ("Study Drug"); and  
 WHEREAS, Sponsor and Worldwide desire to enter into this Agreement in order to set forth definitively their respective rights and obligations with respect to the conduct of the Study.  
 NOW THEREFORE, in consideration of the premises and the mutual promises and undertakings herein contained, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:  
 1.0 SERVICES  
 Worldwide, itself or through one of its Affiliates (if applicable) hereby agrees to perform the services (the “Services”) in accordance with the terms of the scope of Services attached hereto as Exhibit A, incorporated herein by reference (the “Scope of Services”), and this Agreement.  
 1.1 Performance  
 Worldwide shall perform the Services and shall use its commercially reasonable efforts to complete the Services within the estimated time frame as set forth in the timeline attached hereto as Exhibit B and incorporated herein by reference (“Timeline”). Such time estimate assumes, however, the full cooperation of Sponsor, Regulatory Authorities, Ethics Committees and investigators and other third parties not under Worldwide’s control, and shall be subject to adjustment (including costs) if the work for the Services is delayed due to circumstances outside the reasonable control of Worldwide, including, but not limited to:  
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 · failure of Sponsor to deliver clinical supplies in due time, provided such failure is the actual cause of the delay;  
 · amendments to previously agreed upon protocols, procedures or documents required for the Services at the request of Sponsor or Sponsor’s (or its advisors’);  
 · significant delays in pre-Study meetings or in other tasks to be performed by Worldwide caused by Sponsor;  
 · delays in obtaining or subsequent withdrawal of regulatory or ethical review approvals concerning the Services;  
 · death or disability of any investigator or other research specialist on the Study;  
 · higher ratio of drop-outs among trial subjects than anticipated in this Agreement;  
 · lower enrollment rates than expected and agreed to by Worldwide and Sponsor; or  
 · unforeseen changes in the relevant medical practice.  
 1.2 Compliance with Laws/Agreements  
 Worldwide shall perform Services under this Agreement in accordance with the terms of this Agreement, the Protocol for the Study, the Sponsor approved standard operating procedures for the Study (the “Standard Operating Procedures”), the current Guidelines for Good Clinical Practice promulgated by the FDA ("GCP Guidelines"), the Declaration of Helsinki of the 41st World Medical Assembly, South Africa 1996 as amended, and all other applicable laws and regulations, including the following as applicable, 21 CFR Part 11, 312, 50, 54, 56, the Health Information Portability and Accountability Act of 1996 and all regulations and official guidelines promulgated thereunder and the Health Information Technology for Economic and Clinical Health Act (the “Applicable Laws”).  
 The Parties and their respective owners, officers, directors, employees or agents have not and shall not pay, give, offer or promise to pay or give, or authorize the payment, directly or indirectly, of any money or anything of value to any foreign government official or employee (including employees of state-owned institutions), for the purpose of (i) influencing any act or decision of such official or of such government, (ii) inducing that person to do or omit doing any act in violation of his or her lawful duty, (iii) securing an improper advantage, or (iv) influencing such official to use his influence with the government to effect or influence the decision of such government, in order to assist Sponsor or Worldwide in obtaining or retaining business for or with or directing business to any person.  
 Each Party agrees to comply with all applicable anticorruption laws, rules and regulations. The Parties agree to reasonably cooperate with each other’s diligence efforts in order to satisfy each Party’s obligations under the United States Foreign Corrupt Practices Act, as amended (“FCPA”), the UK Bribery Act and any implementing legislation under the OECD Convention Against Bribery of Foreign Government Officials in International Business Transactions.  
 1.3 Transfer of Obligations  
 Pursuant to Title 21 CFR Part 312.52, Sponsor hereby transfers to Worldwide all of the obligations identified in Exhibit A attached hereto and incorporated by reference herein. Notwithstanding the foregoing, Sponsor will retain the ultimate authority and control over and responsibility for the Study. The Parties acknowledge and agree that Sponsor shall at all times be deemed to be the “sponsor” of the Study pursuant to the terms of the Federal Food, Drug and Cosmetic Act, as from time to time amended, and the regulations of the U.S. Food and Drug Administration (“FDA”), as promulgated in Title 21 of U.S. Code of Federal Regulations.  
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 1.4 Changes  
 The Parties may make changes in or additions to the Scope of Services, provided, however, that, subject to the terms of this Section 1.4, no such changes or additions shall be implemented prior to the execution by the Parties of a change order (a “Change Order”), the form of which is attached hereto and incorporated herein as Exhibit E. The Change Order shall include detailed information on the changes to the Scope of Services and any associated changes to the Timeline, Budget and/or payment schedule. Sponsor acknowledges that Worldwide is not obligated to perform any out-of-scope work described in a Change Order until the Change Order is signed by both Parties. Provided, however, in the event that Worldwide provides additional Services or expends additional resources, at Sponsor’s written request and in strict accordance with Sponsor’s written requirements, in the absence of a Change Order, Sponsor will compensate and/or reimburse Worldwide for all pre-approved reasonable and necessary fees and reasonable and necessary out-of-pocket costs actually incurred. For any Change Order that affects the scope of the regulatory obligations that have been transferred to Worldwide, Worldwide and Sponsor shall execute a corresponding amendment to Exhibit A. Sponsor shall file such amendment where appropriate, or as required by applicable law.  
 2.0 WORK PRODUCT  
 During the term of this Agreement, Worldwide shall maintain all materials and all other data or documents included in the Trial Master File obtained or generated by Worldwide in the course of providing the relevant Services in accordance with Worldwide’s standard operating procedures, including all computerized records and files (“Work Product”), in a secure area reasonably protected from fire, theft and destruction with duplicate copies retained with the same care as the original Work Product. All Work Product shall be the Confidential Information and the exclusive property of Sponsor. At the expiration or termination of this Agreement, and subject to satisfaction of the Parties’ obligations thereunder, Sponsor shall provide Worldwide with written instructions as to the disposition of the Work Product created under this Agreement. Such written instructions will provide that Worldwide (a) deliver the Work Product, in the form in which Worldwide currently holds them, to a designated Sponsor location or to such other entity or at such other address as Sponsor may specify, (b) retain the materials for the period of time specified in this Agreement, or (c) destroy all such materials except for those which Worldwide is required by law or regulation to store or maintain. Upon expiration or termination of this Agreement, any storage, destruction or shipping costs or services relating to such disposition of the Work Product will be billed by Worldwide to Sponsor as Pass-through Expenses (as defined below) in accordance with the terms of this Agreement. Notwithstanding the foregoing, Worldwide may retain one electronic archival backup copy of such Work Product in accordance with Worldwide’s Data Retention Policy, subject to its ongoing obligation to maintain the confidentiality of such materials.  
 3.0 PAYMENT AND COMPENSATION  
 The Parties agree that the fees and other reimbursements that Worldwide will receive for performing the Services hereunder are subject to the following terms and conditions.  
 3.1 Compensation for Services  
 This Agreement includes a budget for the Services (the, “Budget”) to be performed by Worldwide, which is attached hereto as Exhibit C, and is incorporated herein by reference. Sponsor shall pay to Worldwide such amounts as set forth and more fully described in the Budget until such time as Worldwide and Sponsor agree that the Sponsor’s monetary obligations to Worldwide are fully satisfied. Worldwide agrees that it shall not incur any cost or expense in excess of the amounts set forth in the Budget for any item, without the prior written approval of Sponsor (in accordance with Section 1.4). Worldwide will use its commercially reasonable efforts to control and limit the costs and expenses, including Pass-through Expenses (as defined below), associated with this Agreement and to obtain and pass along to Sponsor all available discounts and allowances.  
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 3.2 Pass-through Expenses  
 Sponsor will reimburse Worldwide for travel and other reasonable and necessary out-of-pocket expenses, exclusive of grant payments (described below), actually incurred by Worldwide as agreed to by Sponsor and identified in the Budget or otherwise pre-approved in writing by the Sponsor, which Worldwide will invoice to Sponsor without xxxx-up (“Pass-through Expenses”). All reimbursement of Pass-through Expenses hereunder must be supported by receipts provided by Worldwide. Pass-through Expenses may include, but shall not be limited to lodging, travel, third party vendor costs, and other reasonable and necessary costs.  
 In order to facilitate payment of invoices for Worldwide’s pre-approved travel expenses incurred during the performance of Services, Worldwide will submit to Sponsor a report containing at least the following details: (i) photocopies of receipts greater than Two Hundred Fifty ($250.00) USD for Study-related travel expenses, including lodging, air travel, ground transportation, meals and other miscellaneous expenses, such as overnight courier charges and photocopying, (ii) date and travel destination, (iii) employee name, and (iv) purpose of trip/expense. In addition to copies of all receipts over Two Hundred Fifty ($250.00) USD, Sponsor shall have the right to obtain additional backing documentation for any line item which requires further clarifications. Such requests shall be made in good faith and where there is a specific concern with the line item(s) in question. All expenses, discounts, rebates and allowances obtained under Section 3.2 will be passed through and properly reflected in invoices to Sponsor and shall be without xxxx up. Worldwide will use economy class airfare for all domestic flights and all international flights which are less than eight (8) hours in flight duration, and business class airfare for all international fights which are eight (8) hours or more in flight duration. For the avoidance of doubt, calculations of flight duration should not include layover time between flights.  
 3.3 Invoices;  
 Worldwide shall submit a reasonably detailed invoice by email to Sponsor (xxxxxxxxxx@xxxxxxxxxxxxxxxxxxxx.xxx) on a monthly basis in accordance with the Payment Schedule with appropriate supporting documentation, including those set forth in Section 3.2.  
 3.4 Payment Terms  
 Sponsor agrees to pay for Services and Pass-through Expenses in accordance with the Payment Schedule, the (“Payment Schedule”) attached hereto as Exhibit D and incorporated herein by reference. Sponsor will pay for all Services, Pass-through Expenses and other invoiced items within forty five (45) days of receipt of invoice. All payments will be made in the currency noted in the Payment Schedule. All fees for Services and Pass-through Expenses under this Agreement are stated exclusive of any local, state, federal or foreign sales and use taxes, VAT, if any, as any such taxes shall be paid by Sponsor. If such taxes are applicable under local regulations, Worldwide will add these taxes to the invoices at the relevant rate. For the avoidance of doubt, the requirements of this provision shall not apply to any employment-related taxes, income taxes, duties, or withholding and shall only apply to taxes applicable to the Services.  
 Payments shall be made by Sponsor via wire transfer of immediately available funds to Worldwide’s account set forth below:  
 Account Holder: Worldwide Clinical Trials, Inc.  
 Bank Name: HSBC Bank USA, NA  
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 Bank Address: 000 Xxxxx Xxxxxxx Xx.  
 Xxxxxxx Xxxxx, XX 00000  
 ABA Routing No.: 000000000  
 Bank Account No.: 000-00000-0  
 Swift Code: XXXXXX00  
 Taxpayer ID#: 00-0000000  
 3.5 Project Delays  
 In the event Sponsor delays, suspends or places a hold on the Study for any reason, Sponsor shall promptly provide Worldwide with written notice of such delay, hold or suspension, and Sponsor and Worldwide will, within 30 days of such notice, agree on appropriate revisions to this Agreement and each Party will complete its respective duties and obligations as described in any resulting Change Order. During the period following Worldwide’s receipt of Sponsor’s notice of delay, hold or suspension, if Sponsor desires Worldwide to continue the assignment of certain Worldwide Study personnel to the Study, in addition to any other payments due to Worldwide hereunder, Sponsor agrees that it shall pay for such special personnel fees associated with such continued assignment at a negotiated rate, such negotiated rate to be agreed upon by the Parties prior to commencement of the delay, as evidenced by a Change Order. Said personnel fees shall be invoiced by Worldwide on a monthly basis and shall be due and payable by Sponsor within forty-five (45) days of Sponsor’s receipt of Worldwide’s invoice. If Sponsor does not wish to retain certain Worldwide Study personnel for the duration of the delay or on hold period, Worldwide shall have the right to reallocate any and all such staff after such thirty (30) calendar day period. If the delay or on-hold period continues for ninety (90) days either Party may, by provision of written notice, terminate this Agreement without penalty.  
 3.6 Currency Management  
 All invoices and amounts to be paid under this Agreement shall be in US currency.  
 3.7 Disputed Invoices  
 In the event Sponsor disputes one or more items in an invoice, Sponsor will notify Worldwide in writing within thirty (30) business days of receipt of the invoice and such notice shall contain a reasonably detailed description of the item(s) being disputed and the basis therefor. Worldwide will respond to Sponsor within ten (10) business days of receipt of the notification. This written communication pattern will continue until Worldwide has provided Sponsor with sufficient justification for the disputed item(s) or until the Parties agree to a resolution of the disputed amount. Sponsor shall pay the undisputed portion of the invoice within forty-five (45) days of receipt of invoice and shall use its reasonable efforts to pay the disputed amount within fifteen (15) days of resolution of the dispute pursuant to Section 17.12. In the event the Parties are unable to reach a satisfactory resolution within sixty (60) days of the original invoice, either Party may pursue alternative remedies in accordance with this Agreement.  
 4.0 THIRD PARTY AGREEMENTS  
 Worldwide may contract with various third parties to perform part of the Services, with the prior written consent of the Sponsor, provided that (i) the subcontractor agrees in writing to be bound by terms consistent with this Agreement, including without limitation, regarding maintaining the confidentiality of proprietary information, and regarding ownership of intellectual property in connection with the Services, assignment to Sponsor of any intellectual property in connection with the Services; (ii) Worldwide shall use its best efforts to ensure that any subcontractor has the capability to perform the subcontracted services to the standards required under this Agreement and in compliance with Applicable Laws, (iii) Worldwide shall remain primarily responsible to Sponsor for the performance of such subcontracted Services, and (iv) any subcontracting shall not relieve Worldwide of its obligations hereunder and Worldwide hereby agrees to manage the performance of any permitted subcontractor.  
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 For purposes of this Agreement, subcontractors do not include third party vendors providing ancillary services on the Study, provided that Worldwide’s agreement with any such third-party vendor includes a provision making Sponsor an intended third-party beneficiary of the agreement with a right to enforce Worldwide’s rights under the agreement. Liability of Worldwide to Sponsor with respect to such third-party vendors shall be limited to the extent Worldwide is negligent in the performance of its obligations under this Agreement; however, Worldwide shall provide to Sponsor any amounts that Worldwide may recover from such third party vendors as a result of any error or service failure on the part of such vendors in connection with Services under this Agreement.  
 If Sponsor requests that Worldwide use a particular third party and Worldwide does not wish to contract with that third party based upon commercially reasonable reasons (such as the inability to agree with such provider upon mutually acceptable terms or a negative assessment of such provider’s performance or abilities), then Sponsor shall contract directly with such provider (a “Sponsor Designated Vendor”) and, unless otherwise agreed in writing, Worldwide will have no responsibility for the selection, instruction or supervision of such Sponsor Designated Vendor.  
 4.1 Institutions/Investigators  
 Worldwide’s Services under this Agreement may include identifying potential medical institutions (“Institutions”) or clinical investigators (“Investigators”) and/or negotiating, executing and/or administering contracts with such parties which will govern their participation in the Study (“Clinical Trial Agreements”). If, pursuant to the Scope of Services, Sponsor delegates to Worldwide the responsibility for negotiating and/or executing Clinical Trial Agreements, the following provisions will apply:  
 (a) Sponsor may provide Worldwide with a list of suggested Institutions and/or Investigators to be recruited by Worldwide for a Study. Worldwide shall notify Sponsor in writing as to any listed Institution/Investigator with which Worldwide does not wish to contract.  
 (b) Selection of all Institutions or Investigators will be subject to approval by Sponsor prior to initiation of any Study-related activities involving that Institution/Investigator or the start of any negotiations with such Institution/Investigator.  
 (c) Each Clinical Trial Agreement shall be consistent with this Agreement. The Clinical Trial Agreement used with each Institution and Investigator will be in a form approved in advance by Sponsor. Any material changes to the form Clinical Trial Agreement shall be replaced with fall-back language that has been pre-approved by Sponsor. If outside of the fall-back language, the change shall require the prior written approval of the Sponsor.  
 (d) In the event that local law prohibits Sponsor from being a party to a Clinical Trial Agreement, Sponsor (a) shall have the right to approve the Clinical Trial Agreement template; (b) shall be a named third-party beneficiary to each Clinical Trial Agreement if possible; and, (c) shall have the right but no obligation to approve all finalized Clinical Trial Agreements prior to execution by Worldwide.  
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 (e) If an Institution/Investigator requests indemnification from Sponsor, standard indemnification language, generated by the Sponsor, will be provided to the Institution/Investigator. If the Institution/Investigator requests changes to the standard language, Sponsor will negotiate with the Institution/Investigator, if agreed, Sponsor will issue a letter of indemnification directly to the Institution/Investigator. Sponsor acknowledges that Worldwide shall have no indemnification obligation to any Institution/Investigator relative to the Study Drug or the applicable Study protocol. In addition, Worldwide shall not be deemed to have failed to perform under this Agreement in the event an Institution/Investigator declines participation in a Study as a result of Sponsor’s refusal to indemnify such Institution/Investigator.  
 (f) The Sponsor may elect that grant payments to Institutions/Investigators be administered on its behalf by Worldwide, acting solely as payment agent unless otherwise agreed to by Worldwide in writing. Worldwide shall distribute all payments to Institutions/Investigators according to the provisions of the applicable Clinical Trial Agreement and this Agreement. Sponsor acknowledges and agrees that Worldwide will manage all administration of payments or other obligations to Investigators/Institutions for Services rendered in connection with relevant Studies solely out of funds provided to Worldwide from Sponsor for this specific purpose. Furthermore, Sponsor acknowledges and agrees that Worldwide intends to maintain a cash neutral policy with regard to Institutions/Investigators payments. In the event Worldwide or the Institutions/Investigators incur bank fees with respect to the remittance of these grant payments, such fees will be borne by Sponsor. All payments to Institutions/Investigators and any associated bank fees will be made by Worldwide solely from the funds that have been specifically provided by Sponsor to Worldwide for this purpose and not from Worldwide funds. Worldwide will not be liable for payments not made on a timely basis to any Institution/Investigator as a result of Sponsor’s failure to provide, in advance, sufficient funds for such payments.  
 The Parties acknowledge and agree that, for the purposes of this Agreement, Institutions/Investigators shall not be considered as employees, agents or subcontractors of Worldwide and that Investigators will be required to exercise their own independent medical judgement. Worldwide’s responsibilities with respect to Institutions/Investigators shall be limited to those specifically set forth in this Agreement.  
 5.0 CONFIDENTIAL INFORMATION  
 The Parties acknowledge and agree that in the course of performing Services hereunder, either Party may be exposed to or be given confidential or proprietary information of the other Party (“Confidential Information”). The Parties agree to hold all Confidential Information in secrecy for a period of ten (10) years from the effective date of the expiration or earlier termination of this Agreement and shall disclose Confidential Information to third parties only on a need-to-know basis. Without limiting the generality of the foregoing, Confidential Information shall include, without limitation, financial information, protocols, brochures, formulations, research and development programs, methodology, testing techniques, analytical test method, test samples and prototypes, information gathered or viewed during a site visit, audit or inspection of a Party, analyses, software, source codes and technological or other know-how. Confidential Information shall be deemed to be all such information given by the disclosing party to the receiving party except for information which is (i) publicly available or later becomes publicly available through no fault of the receiving party; (ii) obtained by the receiving party from a third party entitled to disclose it; (iii) already in possession of the receiving party as indicated in its written records; (iv) independently developed by the receiving party without use of the Confidential Information; or (v) required by any law, rule, regulation, order, decision, decree, or subpoena or other judicial, administrative, or legal process to be disclosed.  
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 Both Parties shall ensure that all of its officers, employees, consultants, agents, investigators or contractors who receive such Confidential Information understand and shall be bound by the confidentiality provisions of this Agreement.  
 Unless otherwise agreed in writing, within thirty (30) days after the termination of the Agreement or the written request by the disclosing party, the receiving party shall return to the disclosing party all Confidential Information in documentary or permanent form including any and all copies thereof, except for one archival copy that the receiving party can keep for its records (which may be electronic). The Parties agree that each party is and shall remain the exclusive owner of its own Confidential Information and all patent, copyright, trade secret and other intellectual property rights therein unless and until a further agreement is executed.  
 The Parties acknowledge that any violation of the terms of this Section 5.0 may result in irreparable injury and damage to disclosing party that is not adequately compensable in money damages, and for which disclosing party may have no adequate remedy at law. Accordingly, the receiving party agrees that the disclosing party shall be entitled to seek (without waiving any additional rights or remedies, including monetary damages, otherwise available to the disclosing party at law, in equity, or by statute) preliminary and permanent injunctive relief in the event of a breach or intended or threatened breach by the receiving party.  
 6.0 OWNERSHIP OF DATA AND INTELLECTUAL PROPERTY  
 Any invention, discovery, processes, know-how, trade secrets, data, copyrights, trademarks, improvements, or any other intellectual property right related to Sponsor’s products or technology, including the Study Drug, the Protocol, Sponsor’s Confidential Information, which is conceived or reduced to practice as a result of the performance of the Services hereunder (the “Inventions”) shall become Sponsor property and shall be used by Sponsor as Sponsor deems appropriate. Worldwide agrees to, and shall contractually require and use reasonable efforts to cause Institutions and Investigators to execute and have executed assignments of the Inventions to Sponsor, along with other documents that be necessary or helpful to Sponsor in filing patent applications, or which may relate to any litigation or interference and/or controversy in connection therewith. The entire control, prosecution, and conduct of any patent application filed by Sponsor shall be outside the jurisdiction of and without expense to Worldwide and its officers, employees, representatives and agents. Worldwide acknowledges that Sponsor has the exclusive right to file patent applications in connection with the Inventions. Worldwide warrants that neither it, nor its employees, agents and representatives, will prevent Sponsor from filing patent applications for, or from applying the results of the research carried out for Sponsor hereunder.  
 All reports, data, technical information, original works of authorship and all other information, furnished by or on behalf of Sponsor, or created specifically for Sponsor as a deliverable under a this Agreement, shall be the sole property of Sponsor. Nothing under this Section or any other Section of this Agreement shall be construed as (i) granting to any Party any rights under any patent, copyright or other intellectual property right of the other Party (ii) granting to any Party any rights in or to the Confidential Information of the other Party other than the limited right to use such Confidential Information solely for the purposes expressly permitted by Section 5.0 of this Agreement.  
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 Sponsor acknowledges that Worldwide possesses certain computer programs, applications, algorithms, databases, methods, techniques, processes and other materials and ideas independently developed by Worldwide which do not rely upon, reference, or inextricably incorporate Sponsor Confidential Information or Study Drug and which relate to Worldwide’s business or operations (“Worldwide Works”). All Worldwide Works, and all revisions, improvements and enhancements thereto, are the exclusive property of Worldwide or its licensors. Sponsor agrees that any improvements, alterations or enhancements to the Worldwide Works during the term of this Agreement or the Study shall be the sole property of Worldwide. Subject to Section 5.0 hereof, in no event shall Worldwide be precluded from use of its general knowledge, skills and experience, and any of its ideas, concepts, know-how and techniques used or developed by it in the course of providing Services under this Agreement. Worldwide represents and warrants that it is entitled to deliver Worldwide Works where the same is delivered as part of the Services hereunder for Sponsor and its Affiliates’ use, and Worldwide further represents and warrants that use by Sponsor and its Affiliates’ of any such Worldwide Works is properly authorized and will not constitute an infringement or other violation of any rights of any third party.  
 7.0 TERM AND TERMINATION  
 7.1 Term  
 Unless earlier terminated according to Sections 7.2-7.5 below, this Agreement will remain in effect from the date first written above until Worldwide has completed performance of all Services (including delivery of all deliverables) and Worldwide has received from Sponsor all of the payments due hereunder.  
 7.2 Termination for Material Breach  
 In the event that either Party commits a material breach in any of the terms or conditions of this Agreement, and that Party fails to cure the breach within thirty (30) days after receipt of notice of the default or breach from the other Party, the Party giving notice may, at its option, immediately terminate this Agreement at the end of the 30-day period. For the avoidance of doubt, non-payment of undisputed invoices by Sponsor or non-payment by Worldwide to Institutions/Investigators under Section 4.1(f) shall automatically be deemed a material breach.  
 7.3 Termination by Sponsor without Cause  
 Sponsor shall have the right to terminate this Agreement (for other than breach by Worldwide) at any time by giving appropriate written notice at least sixty (60) days prior to the desired termination date.  
 7.4 Termination for Other Reasons  
 Sponsor shall have the right to terminate this Agreement due to patient safety at any time by giving appropriate written notice. Either Party shall have the right to terminate this Agreement at any time upon receipt of written notice to the other Party, if the other Party shall be adjudicated insolvent or shall petition for or consent to any relief under any insolvency, re-organization, receivership, liquidation, compromise, or any moratorium statute, whether now or hereafter in effect, or shall make an assignment for the benefit of its creditors, or shall petition for the appointment of a receiver, liquidator, trustee, or custodian for all or a substantial part of its assets, or if a receiver, liquidator, trustee or custodian is appointed for all or a substantial part of its assets and is not discharged within thirty (30) days after the date of such appointment. In the event that any of the above events occur, that Party shall immediately notify the other, in writing, of its occurrence.  
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 7.5 Termination Procedures  
 Upon termination of this Agreement, the Parties will reasonably cooperate with each other to provide for an orderly cessation of Worldwide’s Services. Worldwide shall use its commercially reasonable efforts to minimize costs associated with the cessation of the Services. In the event Sponsor terminates only part of the Services, the Parties will cooperate in good faith to enter into a Change Order amending the terms of this Agreement accordingly. In the event the Agreement or any of the Services is terminated, Worldwide will be entitled to receive payment for Services performed (based on units completed) and pre-approved expenses actually incurred or irrevocably committed to third parties (excluding salary and overhead) up to the effective date of termination. In addition, Sponsor shall pay all reasonable fees and expenses incurred by Worldwide that are necessary or reasonably required in connection with the orderly cessation of the Services. If a Study or the Agreement is cancelled or terminated before the Services have been performed completely, Worldwide shall refund to Sponsor any funds advanced to Worldwide for fees and costs not yet incurred or due to the extent that the payments for the liabilities associated with such fees or costs can reasonably be avoided in whole or in part.  
 8.0 DEBARMENT CERTIFICATION  
 Worldwide and its Affiliates represent and certify that neither they, nor any of their respective employees or Study personnel have ever been (a) debarred or voluntarily excluded or convicted of a crime for which a person can be debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §335a(a) , as amended, or any equivalent local law, regulation or guidelines thereof, in any country in which any portion of the Study is conducted (“§335a”); nor (b) threatened to be debarred or voluntarily excluded or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under § 335a, or subject to any governmental sanction that would prevent the rendering of Services hereunder in any jurisdiction in which the Study is to be conducted, nor (c) excluded from participation in any federally-funded health-care program. Worldwide agrees that it shall notify Sponsor in writing within 2 days in the event of any debarment, voluntary exclusion, conviction, threat, indictment or exclusion prohibited by this Section occurring during the Term of this Agreement and will suspend all activity of such individual immediately upon notification of investigation or debarment.  
 Worldwide represents and certifies that it has not and will not knowingly use in any capacity the services of any individual, corporation, partnership, or association which has been (a) debarred or voluntarily excluded or convicted of a crime for which a person can be debarred under § 335a; (b) threatened to be debarred or voluntarily excluded or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under § 335a, or subject to any governmental sanction that would prevent the rendering of Services hereunder in any jurisdiction in which the Study is to be conducted or (c) excluded from participation in any federally funded health care program.  
 9.0 RECORDS, AUDITS AND INSPECTIONS  
 9.1 Records  
 Worldwide shall keep full and accurate records and accounts of all its activities in connection with this Agreement, including reasonable substantiation of all Services provided, expenses incurred. Additionally, Worldwide shall maintain a system of internal controls sufficient to provide reasonable assurance that all transactions related to this Agreement are executed and are properly recorded in Worldwide’s books and records. All records relating to this Agreement including, but not limited to, Worldwide’s invoices shall be available for inspection and audit by Sponsor as set forth in Section 9.2, or any independent auditors designated by Sponsor, upon ten business days prior written notice, and for a period of four (4) years following the completion of the Study, unless a longer retention period is required by Applicable Laws. Sponsor agrees that its independent auditors may be required to execute a reasonable confidentiality agreement with Worldwide or Worldwide’s Affiliate or subsidiary, as the case may be, which contains mutually agreed-upon terms. Further, Sponsor’s financial audit of Worldwide or any Worldwide Affiliate or subsidiary hereunder shall be subject to the confidentiality obligations set forth herein.  
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 9.2 Audits by Sponsor  
 During the term of this Agreement, Worldwide will permit representatives of Sponsor who are not competitors of Worldwide to examine, at reasonable times during normal business hours, subject to at least ten (10) business days prior written notice to Worldwide (except in the case of “for cause” audits where Sponsor will provide three (3) business days prior written notice to Worldwide), and at Sponsor’s sole cost and expense: (i) the facilities where the Services are being, will be or have been conducted; (ii) related Study documentation; and (iii) any other relevant information necessary for Sponsor to confirm that the Services are being or will be or have been conducted in conformance with applicable standard operating procedures, this Agreement and in compliance with Applicable Laws and regulations, including related financial information relating to Worldwide service fees, Pass-through Expenses and grant payments to Investigators. Worldwide will provide copies of any materials reasonably requested by Sponsor during such inspection.  
 9.3 Inspection by Regulatory Authorities  
 During the term of this Agreement, Worldwide will permit regulatory authorities to examine, (i) the facilities where the Services are being conducted; (ii) study documentation; and (iii) any other relevant information, including information that may be designated by Worldwide as confidential, reasonably necessary for regulatory authorities to confirm that the Services are being conducted in compliance with Applicable Laws and regulations. Worldwide will immediately notify Sponsor if any regulatory authority schedules, or without scheduling, begins an inspection that relates to the Services, and, unless expressly prohibited by such regulatory authority, permit Sponsor to attend such inspection.  
 9.4 Inspections of Investigator Site(s) by Worldwide  
 In connection with Worldwide’s provision of Services as specified in this Agreement, Worldwide may conduct monitoring visits and/or inspections of Investigator Sites. Based on Worldwide’s observations during such Investigator Site visits and inspections, Worldwide may decide: i) that enrollment should be suspended at the Investigator Site; ii) that an Investigator Site’s non-compliance needs to be reported to Sponsor and/or regulatory authorities; and/or (iii) Investigator Site’s participation in a Study needs to be terminated. Upon such a determination, Worldwide will present to Sponsor a basis for its decision. If Sponsor disagrees with the basis for Worldwide’s decision, Worldwide will assign its contract with the Investigator Site to Sponsor and Sponsor agrees to accept such assignment and to be responsible for all contractual duties and obligations to the Investigator Site.  
 10.0 INDEMNIFICATION  
 10.1 Indemnification by Worldwide  
 Worldwide shall indemnify, defend and hold harmless Sponsor and its Affiliates and their respective officers, directors, employees and agents from any loss, damage, cost or expense (including reasonable attorney’s fees) (“Losses”) arising from any third party claim, demand, assessment, action, suit or proceeding (a “Claim”) arising out of (i) any material breach by Worldwide Group of any material obligations under this Agreement or the Protocol, (ii) any Worldwide Group’s negligence or intentional misconduct; or (iii) any Worldwide Group’s material failure to comply with any applicable law for FDA regulations, except to the extent such Losses are caused by Sponsor’s negligence or willful misconduct.  
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 10.2 Indemnification by Sponsor  
 Sponsor shall indemnify, defend and hold harmless Worldwide and its Affiliates and their respective officers, directors, employees and agents (the “Worldwide Group”) from any Losses arising from any Claim arising out of (i) Worldwide’s adherence to written instructions provided by Sponsor to Worldwide, including adherence to the Protocol and proper performance of the Services in accordance with this Agreement and the Protocol; (ii) the Study drug’s harmful or otherwise adverse effect, including, without limitation, a Claim based upon the consumption, sale, distribution or marketing of any substance, including the Study drug, (iii)any breach by Sponsor of any material obligations under this Agreement, or (iv) the negligence or intentional misconduct of Sponsor, except to the extent such Losses are caused by Worldwide Group’s negligence or wilful misconduct.  
 In the event Worldwide incurs reasonable and necessary costs or out-of-pocket expenses as a result of it becoming involved in, or being required to appear or otherwise participate in, a matter (i) relating to the Study that is the subject of a claim or any proceeding, litigation, arbitration or some other dispute resolution mechanism, and (ii) where Worldwide’s performance of the Services in a manner other than in compliance with this Agreement is not at issue in such claim, then Sponsor shall reimburse Worldwide for pre-approved reasonable and necessary costs or out-of-pocket expenses. The Parties agree to cooperate with each other and to use commercially reasonable best efforts in good faith to minimize Worldwide’s participation in and the costs or out-of-pocket expenses relating to such disputes.  
 10.3 Indemnification Procedures  
 Upon receipt of written notice of any Claim which may give rise to a right of indemnity from the other Party hereto, the Party seeking indemnification (the “Indemnified Party”) shall give written notice thereof to the other Party, (the “Indemnifying Party”). The Indemnified Party shall permit the Indemnifying Party, at its own option and expense, to assume the complete defense of such Claim, provided that the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense. As to those Claims with respect to which the Indemnifying Party does not elect to assume control, the Indemnified Party will afford the Indemnifying Party an opportunity to participate in such defense, at the Indemnifying Party’s own cost and expense.  
 11.0 LIMITATION OF LIABILITY  
 Under no circumstances shall either Party be liable under this Agreement for any indirect, incidental, special or consequential damages of the other Party resulting from such Party’s performance or failure to perform under this Agreement. In addition and except for the confidentiality and indemnification obligations of Worldwide under Sections 5 and 10.1, respectively, in no event shall the collective, aggregate liability of the Worldwide Group to Sponsor exceed one and one-half times the amount of fees due or actually paid by Sponsor to Worldwide pursuant to this Agreement.  
 12.0 INSURANCE  
 Sponsor hereby represents and warrants that it shall maintain adequate clinical trial and product liability insurance coverage, with insurance companies having an A. M. Best Rating of "A-, VII" or better, consistent with industry standards to cover all personal injury, death or loss suffered as a result of the Study Drug, participation in the trial or the trial screening process. Sponsor shall provide Worldwide with a copy of Sponsor’s effective Certificate of Insurance or such other documented evidence to confirm that it has such coverage. Sponsor shall maintain such insurance for the entire duration of the Study and shall notify Worldwide of any changes in coverage which impact the coverage requirements set forth above.  
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 Prior to commencement of any work under this Agreement, Worldwide shall, at its sole expense, maintain the following insurance on its own behalf, with insurance companies having an A. M. Best Rating of "A-, VII", or better:  
 (1) Commercial General Liability (including Premises Operations). The policy must be on an occurrence form and include the following limits: Each Occurrence: $1,000,000; General Aggregate: $2,000,000.  
 (2) Commercial Umbrella Liability. This policy must include the following limits: Occurrence Limit: $4,000,000; Aggregate Limit (where applicable); $4,000,000 Policy to be excess of the Commercial General Liability, Commercial Automobile Liability and Employers Liability.  
 (3) Product/Professional Liability Coverage (Errors & Omissions): Each Claim Limit: $ 10,000,000; Aggregate Limit: $10,000,000. Throughout the term of this Agreement, the Errors & Omissions Liability insurance's retroactive date will be no later than the effective date of this agreement. Upon expiration or termination of this Agreement, Worldwide will either continue to maintain an active insurance policy, or purchase an extended reporting period coverage for claims first made and reported to the insurance company within sixty (60) months after the end of the Agreement.  
 Upon request, Worldwide shall provide Sponsor with a copy of Worldwide’s Certificates of Insurance or such other documented evidence to confirm that it has all of the foregoing coverage. Worldwide shall maintain such insurance for the entire duration of the Study and shall notify Sponsor of any reduction in coverage which impact the coverage requirements set forth above.  
 13.0 REPRESENTATIONS AND WARRANTIES  
 13.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.  
 13.2 Each Party represents that it has all qualifications, authorizations, licenses or permits which are necessary for performance of its obligations under this Agreement.  
 13.3 Worldwide represents and warrants to Sponsor that:  
 (a) Worldwide is a duly incorporated and validly existing corporation under the laws of the Delaware;  
 (b) Worldwide represents that taken together with its Affiliates it has personnel, equipment, experience and expertise sufficient in quality and quantity to provide all comprehensive Services requested by Sponsor hereunder and agreed to by Worldwide and its Affiliates and that any and all such Services will be performed commensurate with the commercially reasonable standards generally applicable to the conduct and management of clinical drug studies by a clinical research organization throughout the world;  
 (c) upon execution and delivery of this Agreement, this Agreement shall constitute a legal, valid and binding agreement of Worldwide and its Affiliates, as applicable, enforceable in accordance with its terms, except to the extent enforceability may be affected by applicable bankruptcy, reorganization, insolvency, and moratorium laws and other laws applicable generally to creditors’ rights and debtors’ remedies from time to time in effect;  
 Page 13 of 47  
 (d) neither the execution and delivery of this Agreement nor Worldwide’s performance of its obligations hereunder will violate or breach, or otherwise constitute or give rise to a default under, the terms or provisions of Worldwide’s registration documents or its By-Laws or any equivalent document or of any material contract, commitment or other obligation to which Worldwide is a party, or violate or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or governmental agency to which Worldwide is subject; and  
 (e) Worldwide has developed a business interruption and disaster recovery program and is executing such program to assess and reduce the extent to which Worldwide’s hardware, software and embedded systems may be susceptible to errors or failures in various crisis (or force majeure) situations. In the event that any data, reports or materials that are delivered by Worldwide to Sponsor are inaccurate, and Worldwide does not reasonably dispute such inaccuracy, and such inaccuracy is caused by errors or failures of Worldwide’s personnel, hardware, software or embedded systems then Worldwide will, to the extent possible, fix, or if necessary, re-perform the deliverables at its own expense within mutually agreeable time frames. If Sponsor and Worldwide mutually agree that Worldwide is not capable of timely or satisfactory re-performance and Worldwide has been paid for such Services, then Worldwide will reimburse Sponsor for the reasonable costs related to a third party’s re-performance of such services or reimburse Sponsor for the reasonable internal costs allocated for the re-performance of such services; provided, however, such reimbursement shall not exceed the amount of money Worldwide received for the performance the inaccurate Services.  
 (f) Worldwide will employ commercially reasonable efforts to ensure that all data collected and stored by it pursuant to this Agreement will be safeguarded against loss, damage and destruction arising from any cause including, but not limited to, theft, fire, flood, earthquake, lightning, and electrical disruption. Such measures and processes will include, but not be limited to, (a) storage of hard-copy documents and computer storage disks in locked, fireproof containers, and (b) back-up and recovery systems (which are periodically tested) for computer-based systems. Sponsor has the right, but not the obligation, subject to at least ten (10) business days prior written notice to Worldwide, during normal business hours and at mutually agreed upon dates and times, to periodically inspect Worldwide’s premises to determine whether the foregoing measures and processes are in effect and being implemented. Such inspections shall be subject to the confidentiality obligations set forth herein.  
 14.0 DISCLAIMER  
 Sponsor acknowledges that the results of the Studies for which the Services are to be provided hereunder are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by Worldwide that the product covered by this Agreement can, either during the term of this Agreement or thereafter, be successfully developed or receive the required approval by the regulatory authorities.  
 Sponsor acknowledges that the development of the protocol concept and scientific rationale shall be the sole responsibility of Sponsor regardless of Worldwide’s involvement in Study design or protocol-writing (or lack thereof).  
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 15.0 EMPLOYEES; NON-SOLICITATION  
 Worldwide’s staff is not, nor shall they be deemed to be at any time during the term of this Agreement, the employees of Sponsor. In consideration of the fees and benefits provided in this Agreement, Sponsor agrees that, without Worldwide’s prior written consent, during the term of this Agreement and for a period of twelve (12) months following its expiration or other termination, neither Sponsor nor any of its Affiliates shall directly or indirectly solicit for employment or contract, attempt to employ or contract with, or assist any other entity in employing, contracting with or soliciting for employment or contract any employee who is at that time employed/contracted by Worldwide and who had been employed/contracted by Worldwide in connection with this Agreement issued hereunder. In the event that legal action becomes necessary for the enforcement of all or any part of this provision, the prevailing party shall receive in addition to any other damages or relief awarded, its reasonable attorneys’ fees, together with appropriate costs and interest. Sponsor acknowledges that in the event of a breach of this Section 15.0, Worldwide shall be entitled to seek injunctive relief for any such breach.  
 16.0 NOTICES  
 All notices provided for in this Agreement shall be in English and shall be sent by registered first class mail, postage prepaid, return receipt requested, addressed to the respective Parties as follows:  
 If to Sponsor:  
 Neurotrope Bioscience, Inc.  
000 Xxxx 00xx Xxxxxx, Xxx Xxxx, XX 00000  
ATTN: Xxxxxx Xxxxxxxxx  
Chief Financial Officer  
Via email: xxxxxxxxxx@xxxxxxxxxxxxxxxxxxxx.xxx  
 If to Worldwide:  
 c/o Worldwide Clinical Trials, Inc.  
0000 Xxxxxxxxx Xxxxxxx, Xxxxx 000, 00000  
Xxxxxxxxxxx, XX, Xxxxxx Xxxxxx  
ATTN: Legal Counsel  
 17.0 MISCELLANEOUS  
 17.1 Modification  
 This Agreement may be supplemented, amended or modified only by mutual agreement of the Parties. No supplement, modification or amendment of this Agreement will be binding unless it is in writing and signed by both Parties.  
 17.2 Assignment  
 Neither Party shall have the right to assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party, except that either Party may assign this Agreement to an Affiliate, any purchaser of or successor to that area of its business to which this Agreement is related, any purchaser of all or substantially all of such Party’s assets or in excess of 50% of such Party’s voting securities, and any successor corporation resulting from any merger, consolidation, reorganization, business organization, joint venture or similar transaction of such Party with or into such corporation. Worldwide assignment, delegation or subcontracting to any third parties shall be in accordance with the terms of this Agreement. Any permitted assignment by either party will not relieve such Party of its obligations or liability incurred prior to assignment. Any assignment not in compliance with the terms of this provision shall be void.  
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 17.3 Force Majeure  
 Neither Sponsor nor Worldwide shall be liable for delays in performing or any failure to perform any of the terms of this Agreement caused by the effects of fire, strike, war (declared or undeclared), insurrection, acts of terror, government restriction or prohibition, or other causes reasonably beyond its control and without its fault, but the Party failing to perform shall use all commercially reasonable efforts to resume performance of this Agreement as soon as feasible. Any episode of force majeure which continues for 30 days from the date of notification of its existence shall give the non-affected Party the right to terminate this Agreement upon 30 days additional notice.  
 17.4 Severability  
 If any provision of this Agreement is found by a court to be void, invalid or unenforceable, the same shall either be reformed to comply with applicable laws and regulations or stricken if not so conformable, so as not to affect the validity or enforceability of the remaining provisions of this Agreement, except if the principal intent of this Agreement is frustrated by such reformation or deletion in which case this Agreement shall terminate.  
 17.5 English Language  
 Unless the Parties otherwise agree, any document that is provided in connection with this Agreement must be (a) in English, or (b) accompanied by a certified English translation, in which case the English translation shall prevail unless the document is a statutory or other official document.  
 17.6 Entire Agreement  
 The Parties hereto acknowledge that each has read this Agreement, understands it and agrees to be bound by its terms. The Parties agree that this Agreement is the complete agreement between the Parties on the subject matter and supersedes all proposals (oral or written), letters of intent, understandings, representations, conditions, warranties, covenants and other communications between the Parties relating to the same subject matter.  
 17.7 Survival  
 The terms, contained in Section 3, Sections 6.0, 7.6, 8.0, 10.0, 11.0, and 17.0 of this Agreement shall survive the completion of performance, expiration or termination of this Agreement. Sections 5.0, and 15.0 shall survive for the period expressly set forth in such Section or, if none, the applicable statute of limitations period applicable to a claim for breach of such provision.  
 17.8 Governing Law  
 This Agreement shall be interpreted and enforced in accordance with the laws of the State of Delaware and each Party hereby specifically consents to the personal jurisdiction thereof.  
 17.9 Waiver  
 No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances will be deemed to be construed as a further or continuing waiver of such term, provision or condition or of any other term, provision or condition of this Agreement.  
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 17.10 Independent Contractors  
 The Parties’ relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Subject to Section 10.0 and/or as may be expressly agreed otherwise in the case of legal representation in the EU, neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.  
 17.11 Counterparts  
 This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission, by e-mail delivery of a “.pdf” format data file or other electronic means, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original thereof.  
 17.12 Arbitration  
 In the event a dispute relating to this Agreement arises between the Parties, the Parties shall confer in good faith to resolve the dispute through negotiations between respective senior executives of the Parties. In the event that the Parties are unable to resolve the dispute, the Parties will attempt to resolve the dispute in good faith through mediation. If the dispute has not been resolved by mediation within sixty (60) days of the initiation of the procedure, the dispute shall be settled by arbitration administered by the American Arbitration Association under its Commercial Arbitration Rules in Delaware. Judgment shall be rendered by a mutually agreed upon single arbitrator. The provisions of this Section may be enforced by any court of competent jurisdiction, and the Party seeking enforcement shall be entitled to an award of all costs, fees and expenses, including reasonable attorneys’ fees, to be paid by the Party against whom enforcement is ordered.  
 IN WITNESS WHEREOF, the undersigned have caused this Agreement to be executed by their respective duly authorized representatives effective as of the Effective Date.  
 NEUROTROPE BIOSCIENCES, INC. WORLDWIDE CLINICAL TRIALS, INC.  
 By: /s/Xxxxxx Xxxxxxxxx By: /s/ Xxxxxxx Xxxxxx  
 Name: Xxxxxx Xxxxxxxxx Name: Xxxxxxx Xxxxxx  
 Title: CFO Title: Legal Counsel  
 Date: July 23, 2020 Date: July 23, 2020  
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 LIST OF EXHIBITS:  
 EXHIBIT A: Scope of Services   
EXHIBIT B: Timeline   
EXHIBIT C: Budget   
EXHIBIT D: Payment Schedule   
EXHIBIT E: Form of Change Order   
 Page 18 of 47  
 EXHIBIT A  
SCOPE OF SERVICES  
 Assumptions:  
 Study Assumptions and Specifications  
General Study Information   
Drug/Compound Bryostatin  
Indication Alzheimer's Disease  
Study Phase Phase II  
Bid Currency USD  
 Study Sites   
Number of Countries 1  
Number of Sites 20  
North America 20  
USA 20  
Patients   
Number of Screened Patients 220  
Number of Enrolled Patients 100  
Number of Drop Outs 15  
Number of Completed Patients 85  
Site Monitoring and Site Management   
Number of CRAs (Headcount Based) 3  
Monitoring Visits   
Number of Phone Qualification Visits 10  
Number of Site Qualification Visits 10  
Number of Site Initiation Visits 20  
Number of Remote Monitoring Visits 140  
Number of Interim Monitoring Visits 140  
Pool of Additional Visits 80  
Number of Close-outs Visits 20  
Site Maintenance Months 530  
Remote Data Review 390  
Meetings   
Internal Alignment (KO) Meeting Yes  
Sponsor Alignment (KO) Meeting Yes  
Project team teleconferences Yes  
Number of internal teleconferences 82  
Number of sponsor teleconferences 82  
Site Activation   
Feasibility/ Site Identification 15  
Essential Documents & Review 20  
Investigator Agreements 20  
Central Institutional Review Board (IRB) Site Submissions 20  
Medical Affairs   
Number of Months for Medical Planning 1  
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 Study Assumptions and Specifications  
Eligibility Review 220 Screened Subjects  
Listings Reviews 100 Enrolled Subjects  
Coded Data Review 100 Enrolled Subjects  
Ongoing Safety Reviews of Labs and ECG alerts 318 Alerts  
Pharmacovigilance   
Estimated Number of SAE(s) 11  
Estimated Number of Expedited SUSAR(s) 1  
Safety Database Setup and Maintenance Argus Database  
Number of Follow-up Reports per Event 2  
Data Management   
CRF Pages   
Number of Pages/Enrolled Patient 225 Total per Patient  
 (30 Unique)  
Number of Pages/Screen Fail Patient 23  
Clinical Data Management System IBMCD  
Randomization System IBMCD  
Number of Edit Checks 240  
Number of Dictionary Coding Terms (AEs, MedHistory, Medications) 2,500  
MedDRA Coding 1,000  
WHODRUG Coding 1,500  
Number of External Vendor Data Loads 26  
Data Cleaning 23565 Pages  
Manual Listings 780  
Reconciliation of SAE(s) 11  
Number and Type of Database Transfers 9 Total Transfers  
Biometrics   
Statistical Analysis Plan Yes  
Randomization Schedule Yes  
Number and Type of Analyses:   
Dry Runs Yes  
Full Analysis 1  
PK Analysis Not Included  
Final Analysis Data Displays:   
Number of Tables 25 Unique / 50 Repeat  
Number of Listings 25 Unique  
Number of Figures/Graphs 10 Unique / 10 Repeat  
Datasets:   
Data sets SDTM 25 Datasets  
Data sets XXxX 15 Datasets  
Ongoing CDISC Transfers 5  
Medical Writing   
Informed Consent Form 3  
Clinical Study Report (Shell and body text) Not Included  
CSR Published Not Included  
Data Safety Monitoring Board (DSMB)   
Number of Meetings 2  
DSMB Data Displays   
 Page 20 of 47  
 Study Assumptions and Specifications  
Number of Tables 5 Unique / 18 Repeat  
Number of Listings 11 Unique  
Number of Figures/Graphs 5 Unique / 5 Repeat  
 Responsibilities:  
 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Feasibility/ Site Identification X  
Identify Sites X  
Unblinded Feasibility under Confidentiality Disclosure Agreement X  
Site Activation Lead Planning Per Country X  
Liaise with Global Project Lead, Regional Project Manager, Lead Clinical Research Associate and Site Activation Lead to Develop a Site Activation Strategy X  
Communicate Start-up Timelines X  
Develop a Risk Log and Priority Action Items X  
Provide Strategic Input to Site Selection X  
Develop Site Activation Tracker Template X  
Trial Master File (TMF) Filing & QC X  
Regulatory Project Plan X  
Regulatory Set-up X  
Set Up Electronic and Hardcopy Files X  
Familiarize with Protocol, Investigator Brochure and Investigational Medicinal Product Dossier (IMPD) X  
Set Up Trackers or Databases, Including Country Requirements X  
Core Documents Master Templates X  
Develop Master Templates for Core Documents X  
Essential Documents & Review (US) X  
Prepare and Distribute Essential Documents Templates X  
Customize Essential Document Templates with Site Specific Information X  
Collect Essential Document from Sites X  
Provide First Review of Essential Documents for Compliance X  
Provide Second Review of Essential Documents for Compliance X  
Communicate Deficiencies to First Reviewer X  
Sign Off Essential Documents Package X  
Answer Questions or Provide Clarification and Training to Project Team on Process or Requirements X  
Provide Weekly Tracking and Progress Reports X  
File Essential Documents and Checklist (Electronic Trial Master File/ Trial Master File, Internal Filing) X  
Essential Documents Review Plan X  
Essential Documents Checklist X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Investigator Agreements X  
Prepare Template X  
Negotiate Site Contracts to Execution X  
Ensure the Completion of Site Indemnification Letters X  
Administrative Quality Control all Investigator Agreements X  
Track Status of Investigator Agreements X  
Coordinate all Required Translations X  
Investigator Agreements Country Specific Templates X  
Customize Master Template with Country, Project and Sponsor-specific Requirements X  
Arrange Translation into Local Languages X  
Perform Final Review and Formatting X  
Contract and Budget Plan (CBP) X  
Prepare Contract and Budget Plan for Initial Strategy. Any Substantial Amendments to the Contract and Budget Plan will Require a Contract Amendment X  
Investigator Grant Build X  
Build Grant Plan for the Study. Any Substantial Amendments to the Country and Site Strategy will Require a New Build and Contract Amendment X  
Submission Strategy & Risk Assessment X  
Develop Submission Strategy and Perform a Risk Assessment X  
Central Institutional Review Board (IRB) Site Submissions (US) X  
Prepare Regulatory Packages for Initial Submission X  
Complete Application Forms X  
Quality Control all Packages Prior to Submission X  
Submit Regulatory Packages to Central Institutional Review Board (IRB) X  
Track Regulatory Package/ Submission Status X  
Review & Customize Informed Consent Form X  
Maintain Informed Consent Form Tracking Log X  
Central Institutional Review Board (IRB) Submission, Study Level (US) X  
Preparation of Package, Quality Control, Submission, Response to Queries at Study Level to the Central Institutional Review Board (IRB) X  
Master Informed Consent Form (ICF) Review X  
TMF Management Plan & TMF Risk Assessment X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Draft, Review and Update Trial Master File Management Plan which Includes but is not Limited to:  
- Project Timelines and Deliverables, i.e., Target Date of Submission of Trial Master File Documents to the Electronic Trial Master File Inbox by Submitters  
- Define Electronic Trial Master File Configuration Requirements  
- Delivery Intervals of Wet-ink Documents to Sponsor, if Required, (Quarterly, End of Study, etc.)  
- Final Shipment of Trial Master File to Sponsor  
- Forwarding applicable Records Management Compliance Standard Operating Procedures to sponsor, if needed.  
- Listing of each wet-ink document required to be maintained during the course of the study  
- Description of Quality Control/file reviews conducted by the project team  
- Description of the Trial Master File close-out process X  
Approve Trial Master File Management Plan X  
Worldwide TMF: TMF Set-up: Pre Site Activation Activities X  
Determine Trial Master File Filing Structure X  
Review Trial Master File Management Plan for Sponsor-hosted Trial Master Files. Check for Alignment with Worldwide's Record Management Compliance Standard Operating Procedures X  
Provide Sponsor with Worldwide's Standard Operating Procedures Describing Trial Master File Document Protection (Scanning for Disaster Recovery), Secure File Area Conditions (Protection Against Fire/ Environmental Factors), and Secure Access to File Area Locations (Controlled and Restricted Access) X  
Provide Detailed Expectations Regarding Type of Access Requirements of Sponsor and Worldwide's Project Team Including Timeframes for Access and Review X  
Prepare Annotated Trial Master File Structure X  
Prepare/ Configure the Trial Master File According to Worldwide's Standard Operating Procedures and Trial Master File Management Plan or Sponsor Plans if Sponsor-hosted Electronic Trial Master File. X  
Agree Trial Master File Compliance Reporting Needs with the Sponsor X  
Design Periodic Trial Master File Quality Control Process X  
Facilitate Electronic Trial Master File System Training of all Users; Provide Project-specific Training Tools to Project Management X  
Worldwide TMF: TMF Final Reconciliation & Transfer X  
Complete Final Quality Control and Reconciliation of the Trial Master File X  
Generate Trial Master File Gap Analysis for Review with Sponsor X  
Complete a Final Review of the Trial Master File Data Due for Transfer X  
Transfer Trial Master File Data to Sponsor X  
Obtain Signed Transfer of Ownership Form from Sponsor X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Internal Alignment (KO) Meeting X  
Prepare for Internal Alignment Meeting X  
Attend and Participate in Meeting X  
Sponsor Alignment (KO) Meeting X  
Prepare for Sponsor Alignment Meeting X  
Attend and Participate in Meeting X  
Sponsor Teleconferences X  
Prepare for Teleconference - Gather Metrics, Issues and Any Action Item Updates X  
Attend and Participate in Meeting X  
Internal Teleconferences X  
Prepare for Teleconference - Gather Metrics, Issues and Any Action Item Updates X  
Attend and Participate in Meeting X  
Lead Clinical Research Associate Support X  
Communicate with Sponsor, Project Team and Vendors X  
Attend and Participate in the Internal Project Clinical Research Associate (CRA) Training X  
Provide Project Oversight X  
Create and Disseminate Project Metrics X  
Create Study Monitoring Manuals, Plans and Tools X  
Review Vendor Portals (Not in Preparation for Site Visit or Meetings) X  
Provide Ongoing Review of and Updates to Study tools, Trackers, Reports and Metrics X  
Provide Ongoing Trial Master File Review X  
Organizes, Tracks and Ensures the Clinical Study Report is Delivered to All Sites, Institutional Review Boards, and Competent Authorities (In Countries Where Applicable). Ensures Acknowledgment of Receipts are Available/ Filed. X  
Site Management X  
Communicate with Sites During Start-up, Conduct and Closure and Resolve Site Issues Throughout the Study X  
Support Sites During Start-up, Sites Set-up (Includes Back-up Sites), Conduct and Closure X  
Update Clinical Trial Management System as Needed X  
Write Telephone Contact Reports X  
Communicate with the Project Team Regarding Site Issues X  
General Site Contact and Communication X  
Provide Remote Monitoring X  
Follow Up with Sites on Protocol Violations/ Deviations and Queries/ Data Management Issues X  
Provide Assistance with Investigational Medicinal Product (IMP) Site Issues (i.e. Shipment, Acknowledgement, Interactive Response Technologies Site Entry and Review review) X  
Send/ Deliver Safety Information to Sites (if not performed by the Pharmacovigilance Team) X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Communicate with Sites Regarding any Serious Adverse Events (SAE) Issues X  
Provide Electronic Trial Master File Updates on an Ongoing Basis and Quality Control of Site Documents Collected in-between Site Visits X  
Internal Clinical Research Associate Calls & Project Communication X  
Clinical Research Associate Training (not at Investigator Meeting) X  
Remote Pre-site Selection Visits X  
Prepare for Visit X  
Perform Visit (Remote) X  
Write Visit Report X  
Complete Visit Follow-up X  
Review and Approve Visit Report X  
On-site Pre-site Selection Visits X  
Prepare for Visit X  
Travel to and from Location X  
Perform Visit X  
Write Visit Report X  
Complete Visit Follow-up X  
Review and Approve Visit Report X  
On-site Site Initiation Visits X  
Prepare for Visit X  
Travel to and from Location X  
Perform Visit X  
Write Visit Report X  
Complete Visit follow-up X  
Review and Approve Visit Report X  
Remote Monitoring Visits Conduct X  
Prepare for Visit X  
Perform Visit (Remote) X  
Write Visit Report X  
Complete Visit Follow-up X  
Review and Approve Visit Report X  
On-Site Monitoring Visits Conduct X  
Prepare for Visit X  
Travel to and from Location X  
Perform Visit X  
Write Visit Report X  
Complete Visit Follow-up X  
Review and Approve Visit Report X  
Additional Time On-site X  
On-site Close-out Visits X  
Prepare for Visit X  
Travel to and from Location X  
Perform Visit X  
Write Visit Report X  
 Page 25 of 47  
 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Complete Visit Follow-up X  
Review and Approve Visit Report X  
Reconcile Final Trial Master File X  
Remote Electronic Data Capture (EDC) Review Conduct X  
Set-up Grant Payments X  
Enter New Payees into the Finance System X  
Acquire and Save all W-9's (US Sites Only) X  
Process Grant Payments X  
Initiate and Print Purchase Orders X  
Process Check or Wire X  
Enter Voucher and Payment Transactions into the Finance System X  
Provide Status Updates X  
Track and Record all Payments X  
Process Site Cost Payments X  
Set-up Vendor Payments X  
Enter New Payees into the Finance System X  
Acquire and Save all W-9's (US Sites Only) X  
Process Vendor Payments X  
Process Check or Wire upon Project Management Approval X  
Enter Voucher and Payment Transactions into the Finance System X  
Risk Based Quality Management X  
Protocol Risk Assessment X  
Database Set-up & Configuration X  
Define Argus Database Specifications X  
Build Database X  
Test Database X  
Validate Database X  
Safety Management Plan Development X  
Write Safety Management Plan to Define Roles and Responsibilities of the Sponsor and Worldwide and Describe the Procedures for the Management, Processing, and Reporting of Serious Adverse Events (SAE) and Pregnancies X  
Arrange for Review and Incorporation of Comments X  
Obtain Approval from All Relevant Parties X  
Safety Training (Sites, Clinical Research Associates, Project Team) X  
Develop Training Materials X  
Train All Relevant Worldwide/ Sponsor/ Site Staff of Pharmacovigilance Requirements and Obligations X  
Provide Follow-up Training as Required X  
Serious Adverse Events (SAE) Processing, Investigation, Narrative, Approval & Query Generation X  
Assess Each Serious Adverse Event (SAE) for Seriousness, Listedness and Causality X  
Review Coding, Querying and Narratives and Analyze Similar Events X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Provide Approval and Follow-up on each Serious Adverse Event (SAE) X  
Analysis of Similar Events (AOSE) (US SUSARs only) X  
Safety Management Maintenance X  
Maintain and Update the Safety Management Plan as Necessary to Define Roles and Responsibilities of the Sponsor and Worldwide and Describe the Procedures for the Management, Processing, and Reporting of Serious Adverse Events (SAE) and Pregnancies X  
 Review and Incorporate Updated Comments X  
Approve Updates X  
Preparation of Line Listings (LL) X  
Prepare and Write the Line Listings and Annual Safety Reports X  
Review and Incorporate Comments X  
Approve Updates X  
Suspected Unexpected Serious Adverse Reaction (SUSAR)/ Annual Safety Reports (ASR)/ Line Listings (LL) submission to Investigators X  
Arrange for the Timely Submission of Pharmacovigilance Documents to Relevant Investigators to Ensure Regulatory Compliance X  
DSUR Preparation (Writing and Compiling) X  
Pharmacovigilance Closeout X  
Arrange for the Preparation of Pharmacovigilance Data Stored in Argus to be Transferred to the Sponsor X  
Deliver Data Safety Monitoring Board (DSMB) Database & Tables, Figures & Listings (TFLs) X  
DSMB Statistical Analysis Plan (SAP) X  
DSMB Unique Tables X  
Create Unique Study Tables (One Draft) X  
Validate Unique Study Tables X  
Finalize Unique Study Tables After Sponsor Review X  
Validate Final Unique Study Tables X  
DSMB Repeat Tables X  
Create Repeat Study Tables (One Draft Post Database Lock) X  
Validate Repeat Study Tables X  
Finalize Repeat Study Tables After Sponsor Review X  
Validate Final Repeat Study Tables X  
DSMB Unique Listings X  
Create Unique Study Listings (One Draft Post Database Lock) X  
Validate Unique Study Tables X  
Finalize Unique Study Listings After Sponsor Review X  
Validate Final Unique Study Listings X  
DSMB Unique Figures X  
Create Unique Study Figures (One Draft Post Database Lock) X  
Validate Unique Study Figures X  
Finalize Unique Study Figures After Sponsor Review X  
Validate Final Unique Study Figures X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
DSMB Repeat Figures X  
Create Repeat Study Figures (One Draft Post Database Lock) X  
Validate Repeat Study Figures X  
Finalize Repeat Study Figures After Sponsor Review X  
Validate Final Repeat Study Figures X  
Medical Planning X  
Review the Protocol and Investigator Brochure to Gain an Understanding of the Trial X  
Prepare Medical Monitoring Plan X  
Provide Additional Study Document Review and Comment X  
Prepare and Conduct Clinical Research Associates (CRA) Training X  
Communicate with Vendors to Determine Specifications Documents (Normal Ranges, Alerts Set-up, etc.) X  
Medical Management X  
Communicate with Sites/ Clinical Research Associates/ Project Team/ Sponsor on Protocol-medical Issues X  
Document and Log Discussions X  
Review Protocol Deviation Log X  
Eligibility Review X  
Review Selected Screening Datasets for Prospective Assessment of Eligibility X  
Develop Subject Eligibility Form X  
Discuss Process Design X  
Listings Reviews X  
Provide Adverse Events (AE), Serious Adverse Events (SAE), Medical History, Concomitant Medications, Xxxxx Xxxxx, Demographics Listings Review. Assumes One Cycle. X  
Coded Data Review X  
Provide Medical Review of Non-direct Hits for Medical Coding of Adverse Events, Concomitant Medications and Medical History X  
Ongoing Safety Reviews of Labs and ECG Alerts X  
Review Predefined Lab and Electrocardiogram Alerts X  
Follow Up with Sites as Needed X  
Maintain Medical Monitor Log X  
Data Management Plan X  
Prepare Data Management File and Filing of Trial Master File Documents X  
Draft Data Management Plan for Sponsor Approval X  
Training X  
Electronic Case Report Form (eCRF) Development X  
Create Database/ Electronic Data Capture (EDC)/ Electronic Case Report Form (eCRF)Specifications X  
Electronic Case Report Form (eCRF) Completion Guidelines X  
Draft Electronic Case Report Form Completion Guidelines and Electronic Data Capture Training Manuals for Sponsor Approval X  
Edit Check Specifications X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Specify Electronic, Manual and Statistical Analysis Software (SAS) Data Validation Checks X  
Manual Listings Creation X  
User Acceptance Testing X  
Define Electronic Data Capture (EDC) Roles and Responsibilities (Study Attributes) X  
Build and Validate Data Management Database X  
Conduct User Acceptance Testing of Database X  
Program and Validate Electronic, Manual and SAS Data Validation Checks X  
Set-up of Standard Reports X  
Provide Specification, Creation and Running of Data Management Reports X  
User Manual Development X  
Electronic Data Capture (EDC) Support X  
Manage Access to Study-specific Electronic Data Capture (EDC) X  
Train Users on EDC X  
Provide Site Support (Access and eCRF Questions) X  
Serious Adverse Event (SAE) Reconciliation X  
Program and Validate SAE Reconciliation Program X  
Serious Adverse Event (SAE) Reconciliation Maintenance X  
Run SAE Reconciliation Program X  
Resolve Issues that Arise from SAE Reconciliation X  
Data Cleaning X  
Provide Data Cleaning and Listing Review X  
Reconcile Database and Clean Local Lab Normal Ranges X  
Manual Listing Review X  
Vendor Reconciliation Set-up X  
Draft Data Transfer Agreement X  
Programming and Validation of Reconciliation Program X  
User Acceptance Testing of Reconciliation Process X  
Vendor Reconciliation Maintenance X  
Upon Receipt of Data for Reconciliation, Run Reconciliation Programs X  
Resolve Issues that Arise from Reconciliation with Vendors X  
Vendor Integration Set-up X  
Draft Data Transfer Agreement X  
Program and Validate Integration Program X  
Conduct User Acceptance Testing of Integration Process X  
Upon Receipt of Data for Integration, Run Integration Programs X  
Resolve Issues that Arise from Integration with Vendors X  
Vendor Integration Maintenance X  
Upon Receipt of Data for Reconciliation, Run Reconciliation Programs X  
Resolve Issues that Arise from Integrations X  
MedDRA Coding (via Coding Tool within EDC) X  
Provide Medical Coding and Raise Appropriate Queries X  
Manage Dictionary X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
WHODRUG Coding (via Coding Tool within EDC) X  
Provide Medical Coding and Raise Appropriate Queries X  
Manage Dictionary X  
Coding Dictionary Updates X  
Data Transfer Set-up X  
Create Data Transfer Programs and Transfer of Data During the Course of the Study X  
Data Transfers X  
Database Lock X  
Conduct Database Quality Assessments X  
Provide Data Report X  
Create Database Lock Authorization Form X  
Lock Database X  
Provide Database Lock Report X  
Conduct Final Data Transfer of Raw Data X  
Distribute PDFs of Electronic Case Report Forms (eCRF) to the Sites and Sponsor for Archiving X  
Archive CDs X  
Randomization/ Kit list/ Interactive Response Technologies Review X  
Create Randomization Specification X  
Create and Validate One Dummy Randomization X  
Create and Validate One Final Randomization X  
Data Management Specifications X  
Review One Draft of the Data Management Deliverables (eCRFs, Edit Checks, Database Set-up) for Appropriate and Necessary Data Collection with a Focus Towards Study Objectives and Endpoints X  
Statistical Analysis Plan & Mock Shells X  
Create One Draft Statistical Analysis Plan (SAP), Formatted, to be Inserted Directly into the Methods Section of an ICH-E3 Compliant Clinical Study Report X  
Create One Draft of Table and Listing Shells for Each Unique Table and Listing X  
Quality Control Draft Statistical Analysis Plan (SAP) and Table and Listing shells X  
Create Final Statistical Analysis Plan (SAP) and Final Table and Listing Shells X  
Study Data Tabulation Model (SDTM) Datasets X  
Provide Study Data Tabulation Model (SDTM) Datasets from Raw Data Files Provided by the Data Management Team in Accordance with the Clinical Data Interchange Standards Consortium (CDISC) Implementation Guide and Worldwide's Standards (If Sponsor-specific Standards are Required Information Should be Provided at the Beginning of the Project) X  
Create Dataset Specifications Document X  
Create One Draft Version of SDTM Datasets X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Validate Draft Version of SDTM Datasets via Independent Quality Control and Open CDISC X  
Create One Final Version of SDTM Datasets X  
Validate Final Version of SDTM Datasets via Independent Quality Control and Open CDISC X  
Analysis Datasets X  
Provide Analysis Data Model (XXxX) Datasets (Or Derived Datasets) Based on SDTM Data, Implementation Guide and Worldwide's Standards (If Sponsor-specific Standards are Required Information Should be Provided at Project Outset) X  
Create Dataset Specifications Document X  
Create One Draft Version of XXxX Datasets X  
Validate Draft Version of XXxX Datasets via Independent Quality Control X  
Create One Final Version of XXxX Datasets X  
Validate Final Version of XXxX Datasets via Independent Quality Control X  
Define.xml and Data Reviewers Guide for SDTM, Annotated CRF X  
Create One Draft and One Final “Define.xml” Document for SDTM Datasets X  
Create One Draft and One Final “Define.xml” Document for XXxX Datasets X  
Create One Draft and One Final Annotated CRF, Annotated with the Variables in the SDTM Datasets X  
Create One Draft and One Final Study Data Reviewers Guide, Adding Further Detail to the SDTM Datasets X  
Create One Draft and One Final Analysis Data Reviewers Guide, Adding Further Detail to the XXxX Datasets X  
Deliver Final Database & Table, Figures & Listings X  
Final Unique Study Tables X  
Create Unique Study Tables (One Draft Post Database Lock) X  
Validate Unique Study Tables X  
Finalize Unique Study Tables After Sponsor Review X  
Validate Final Unique Study Tables X  
Final Repeat Study Tables X  
Create Repeat Study Tables (One Draft Post Database Lock) X  
Validate Repeat Study Tables X  
Finalize Repeat Study Tables After Sponsor Review X  
Validate Final Repeat Study Tables X  
Final Unique Study Listings X  
Create Unique Study Listings (One Draft Post Database Lock) X  
Validate Unique Study Listings X  
Finalize Unique Study Listings After Sponsor Review X  
Validate Final Unique Study Listings X  
Final Unique Study Figures X  
Create Unique Study Figures (One Draft Post Database Lock) X  
Validate Unique Study Figures X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Finalize Unique Study Figures After Sponsor Review X  
Validate Final Unique Study Figures X  
Final Repeat Study Figures X  
Create Repeat Study Figures (One Draft Post Database Lock) X  
Validate Repeat Study Figures X  
Finalize Repeat Study Figures After Sponsor Review X  
Validate Final Repeat Study Figures X  
Statistical Input to Clinical Study Report (CSR) X  
Delivery Dry Run Database & Table, Figures & Listings X  
Model Inform Consent Form(s) (ICF(s)) X  
Obtain Final Protocol X  
Establish Template to be Utilized X  
Generate First Draft for Sponsor Review X  
Generate Second Draft for Sponsor Approval X  
Deliver Final Model Informed Consent Form X  
Scale Identification and Acquisition X  
Contact Copyright Holder to Identify/ Acquire Scales (Including Translated Versions as Applicable) X  
Approve Correct Scales Acquired X  
Coordinate with Contracts to Obtain Scales X  
Creation of Source Documents X  
Apply Header/ Footer to Scales X  
Coordinate with Regulatory for Ethics Committees/ Institutional Review Board Submission X  
Approve Source Documents X  
Make Scales Available for Use by Sites X  
Approve Scales X  
Rater Training Plan X  
Develop Rater Training Plan (Methodology, Experience Requirements) X  
Approve Rater Training Plan X  
File Rater Training Plan into Trial Master File X  
Develop Rater Training Database/ Tracker X  
Create Rater Experience Qualification (Survey) X  
Rater Experience Verification X  
Work with Project Team to Develop Process for Obtaining Potential Site Raters to Complete Rater Experience Qualification (Survey) X  
Distribute Rater Experience Qualification (Survey) X  
Collect Rater Experience Qualification (Survey) from Sites X  
Review Rater Experience against Rater Training Plan X  
Recommend Next Steps for Proposed Raters Who do Not Meet Sponsor-agreed-Qualifications X  
Approve Raters for Study Who do Not Meet Sponsor-agreed Qualifications (Overrides) X  
File Rater Experience Qualification (Survey) Forms into the Trial Master File X  
Rater Training and Certification X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Track/ Manage Raters at Each Site X  
Process Investigator Meeting Raters for Training/ Certification X  
Process New Raters for Training/ Certification throughout the study X  
Follow Up with Raters to Complete Training/ Certification X  
Issue Training/ Certification Certificates X  
File Training/ Certification Certificates into the Trial Master File X  
Applied Skill Assessment (ASA) not at Investigator Meeting X  
Instructions for Site Raters on How to Submit Applied Skills Assessment (ASA) to Worldwide X  
Clinical Review and Feedback for Applied Skills Assessment (ASA) X  
Complete Applied Skills Assessment Form (For Each Rater's ASA) X  
File Applied Skills Assessment Form into the Trial Master File X  
Coordinate Next Steps with Sponsor when Rater Fails the Applied Skills Assessment X  
Didactic Presentation X  
Develop Didactics for the Study X  
Approve Didactics X  
Web Portal X  
Define Requirements for Study Web Portal X  
Provide Training Materials to be Uploaded to the Web Portal X  
Develop/ Configure Study Web Portal X  
User Acceptance Test Study Web Portal X  
Data Surveillance Plan X  
Develop Data Surveillance Plan (Methodology) X  
Approve Data Surveillance Plan X  
Develop Source Document Review Database/ Tracker X  
Develop EDC Monitoring Database/ Tracker X  
Set-up of Clinical Assessment Technologies EDC Data Monitoring System X  
Provide Data Management with Flags to be Programmed into EDC/ SAS X  
Develop and Test EDC/ SAS Flags X  
Define Requirements for EDC Monitoring Reports X  
Develop and Test EDC Monitoring Reports X  
Clinical Assessment Technologies Data Management Reports X  
Electronic Data Capture (EDC) Flag Clinical Review X  
Provide Clinical Review of Flagged Subject Visits X  
Collection & Review of Source Documents X  
Document Interactive Response Technology Notifications in Source Document Database/ Tracker X  
Collect Source Documents from Sites for Clinical Review X  
Follow Up with Sites for Missing (Not Submitted) Source Documents X  
Review Clinical Source Documents X  
Clinical Assessment Start-up & Planning X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Clinical Assessment Maintenance & Reporting X  
Clinical Assessment Technologies Virtual Training Session X  
Confirm Attendees and Communication Details X  
Create and Distribute Invitation to Attend Training Sessions X  
Conduct Virtual Training Sessions X  
Close Out Virtual Training Sessions (Document Attendees, Distribute Training Certificates) X  
Pre go-live Project Management, Requirements Gathering & Design (SaaS) X  
Lead Interactive Response Technology-focused Gathering Meetings X  
Write User Requirements Specifications According to Protocol Design X  
Write Interactive Response Technology Project Plan X  
Configuration/Coding (SaaS) X  
Configure Interactive Response Technology System for Study According to Specifications X  
Write Custom Code if Required X  
Validation (SaaS) X  
Develop Test Plan X  
Perform Testing of System Against Specifications X  
Review testing materials X  
Review and Sign Test Plan X  
Review and Sign Test Summary Report (Including a Review of any Defects) X  
Systems Integrations (SaaS) X  
Manage the Set-up of Any Integrations Between Interactive Response Technology and Other Systems X  
Coordinate Data Transfers X  
Configure and Test Integration X  
Sponsor User Acceptance Testing (SaaS) X  
Set Up Data for User Acceptance Testing X  
Facilitate the Performance of User Acceptance Testing for the Sponsor X  
Interactive Response Technologies Inventory Implementation and Review X  
Interactive Response Technology Project Management (SaaS) X  
Oversight and Accountability for the Project X  
Act as Point of Escalation for Any Interactive Response Technology-related Issues for the Study X  
Production Support (SaaS) X  
Daily Support of Interactive Response Technology X  
Production Randomization Monitoring and Audit X  
Monitoring Patient and Material Randomization to Ensure Correct Execution in Production X  
Decommissioning (SaaS) X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Coordinate Decommissioning of the System and Data Archiving at End of Study X  
Clinical Trial Management System (CTMS) Set-up X  
Develop User Requirement Specifications X  
Monitoring Visit Report (MVR) Review and Configuration X  
CTMS OnPoint and SharePoint Build/ Configuration X  
CTMS OnPoint and SharePoint User Acceptance Testing X  
Create Study-specific Guides X  
Create System Alerts X  
Develop Sponsor Training Slides X  
Create Study Specific Access Form X  
Submit Documents to the eTMF as required X  
Conduct Study Team Q&A Session X  
Conduct Sponsor Training X  
Clinical Trial Management System Helpdesk/ Maintenance X  
Administer Required Training X  
Grant CTMS User and Study Access X  
Respond to CTMS service desk requests X  
Support MVR Issues and Changes X  
Edge Payments Customization X  
Edge Payments Maintenance, Support, Changes X  
Grant System Access X  
Respond to Helpdesk Queries X  
Add Sites X  
Edge Payments Maintenance, Support, Changes X  
Rater Web Portal Set-up X  
Rater Web Portal Maintenance, Support, Changes X  
Create Study Specific Integration documents for Interactive Response Technologies to EDC X  
Create Study Specific Integration documents for EDC to OnPoint CTMS X  
Integration Set-up X  
Project Management - Start-up X  
Identify Sites/ Principal Investigators X  
Create or Review Project Plans X  
Execute Project Plans X  
Prepare for and Plan Site Training X  
Provide and Receive Project-specific Training (Develop Training, Presenting, Receive Training, Includes Protocol Review Time) X  
Set Up Internal/ External Systems X  
Review Sponsor Standard Operating Procedures X  
Review Scope of Work and Finalize Study Specifications X  
Develop Project Timelines X  
Prepare for and Attend Internal and External Meetings and Calls Including Agenda/ Minute Preparation X  
Prepare and Distribute Study Newsletters and Other Site Communications X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Maintain and Quality Control Trial Master File (Including Response to Internal or Sponsor Audits) and Deliver to Sponsor X  
Manage Study Vendors (Includes Identification, Selection, Contract Negotiation and Management) X  
Complete all Project-related Internal System Data Entry such as Time Entry, Monthly Operational Reviews, Resource Planning, Financial Tracking or Other Internal Systems X  
Prepare Site/ Study Documents (Site Reference Material, Study Binders, Recruitment Tools) X  
Manage Site Supplies X  
Manage Site Grant and Principal Investigator Reimbursement Payments (Includes Initiating Grant Fund Replenishment Invoicing Requests and Approval of Payments) X  
Complete Revenue Reporting and Projections X  
Manage Changes to Contracts X  
Procure Invoice Approval (Includes Follow-up Internally or with Sponsor X  
Manage Vendor Payments X  
Complete Financial Reconciliation X  
Monitor, Evaluate and Adjust Key Performance Indicators X  
Generate Status Reports X  
Track Project-related Data to Facilitate and Inform Status Reporting and Study Management X  
Project Management - Conduct X  
Oversee Patient Recruitment X  
Prepare for and Plan Investigator Meeting (For Those Occurring after Start-up) X  
Participate in and Present at Investigator Meeting (For Those Occurring after Start-up) X  
Oversee the Management, Monitoring, Adjustment and Ongoing Revision of Project Plans (Updates to Study Plans, Review of Risks and Identification of New Mitigation Strategies) X  
Provide and Receive Project-specific Training (Develop Training, Presenting, Receive Training, Includes Protocol Review Time) X  
Oversee Changes to Internal/ External Systems X  
Revise Project Timelines X  
Prepare for and Attend Internal and External Meetings and Calls including Agenda/ Minute Preparation X  
Prepare and Distribute Study Newsletters and Other Site Communications X  
Maintain and Quality Control Trial Master File (Including Response to Internal or Sponsor Audits) and Deliver to Sponsor X  
Manage Study Vendors (Includes Identification, Selection, Contract Negotiation and Management) X  
Complete all Project-related Internal System Data Entry such as Time Entry, Monthly Operational Reviews, Resource Planning, Financial Tracking or Other Internal Systems X  
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 Worldwide Clinical Trials Responsibility Matrix  
Task Worldwide's  
Responsibility  
Prepare Site/ Study Documents (Site Reference Material, Study Binders, Recruitment Tools) X  
Manage Site Supplies X  
Manage Site Grant and Principal Investigator Reimbursement Payments (Includes Initiating Grant Fund Replenishment Invoicing Requests and Approval of Payments) X  
Complete Revenue Reporting and Projections X  
Manage Changes to Contracts X  
Procure Invoice Approval (Includes Follow-up Internally or with Sponsor X  
Manage Vendor Payments X  
Complete Financial Reconciliation X  
Monitor, Evaluate and Adjust Key Performance Indicators X  
Generate Status Reports X  
Track Project-related Data to Facilitate and Inform Status Reporting and Study Management X  
Project Management - Close-out X  
Oversee the final management, monitoring, adjustment and ongoing revision of project plans X  
Provide and receive Project Specific Training (develop training, presenting, receive training) X  
Revise Project Timelines X  
Prepare for and attend Internal and External Meetings and Calls including Agenda/Minute Preparation X  
Prepare and Distribute Site Communications X  
Maintain and Quality Control Trial Master File (Including Response to Internal or Sponsor Audits) and Deliver to Sponsor X  
Manage Study Vendors X  
Complete all Project-related Internal System Data Entry X  
Prepare Site/ Study Documents X  
Manage Site Supplies X  
Manage Site Grant and Principal Investigator Reimbursement Payments X  
Complete Revenue Reporting and Projections X  
Manage Changes to Contracts X  
Procure Invoice Approval (Includes Follow-up Internally or with Sponsor X  
Manage Vendor Payments X  
Complete Financial Reconciliation X  
Monitor, Evaluate and Adjust Key Performance Indicators X  
Generate Status Reports X  
Track Project-related Data to Facilitate and Inform Status Reporting and Study Management X  
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 EXHIBIT B  
TIMELINE  
 Study Timeline Estimated Start Date Estimated End Date Duration (Months)  
Commencement of Work (Start Date) 20-Apr-2020   
Protocol Finalized 1-Jun-2020   
Study Start-up 20-Apr-2020 27-Sep-2020 5.3  
Patient Enrollment Period 28-Sep-2020 14-Sep-2021 11.6  
Patient Active Treatment 15-Sep-2021 3-Oct-2022 12.6  
Patient Follow-up Phase 4-Oct-2022 4-Oct-2022 0.0  
Last eCRF Submitted to Data Management 5-Oct-2022 2-Nov-2022 1.0  
Database Lock 3-Nov-2022 15-Nov-2022 0.4  
Final Tables, Listings, Figures/Graphs 16-Nov-2022 5-Jan-2023 1.7  
Final Clinical Study Report 6-Jan-2023 13-Mar-2023 2.2  
Total Study Duration (Months) 34.6  
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 EXHIBIT C  
BUDGET  
 Service Agreement Budget  
Services Unit # Units Unit Cost  
USD Total Cost USD  
Site Activation   
o Feasibility/ Site Identification Site 15.00 784.00 11,760.00  
o Site Activation Lead Planning Per Country Country 1.00 2,268.00 2,268.00  
o Site Activation Lead Oversight - Start Up Phase Site Months 106.00 226.80 24,040.80  
o Site Activation Lead Oversight - Conduct Phase Site Months 510.00 98.60 50,286.24  
o Trial Master File (TMF) Filing & QC Site/Quarter 196.00 311.24 61,002.86  
o Regulatory Project Plan Plan 1.00 2,270.00 2,270.00  
o Regulatory Set-up Study 1.00 3,450.00 3,450.00  
o Regulatory Tracking & Follow-up Country/Month 31.00 151.55 4,698.05  
o Core Documents Master Templates Study 1.00 3,995.00 3,995.00  
o Essential Documents & Review (US) Site 20.00 2,513.50 50,270.00  
o Essential Documents Review Plan Plan 1.00 2,334.00 2,334.00  
o Essential Documents Checklist Country 1.00 131.50 131.50  
o Investigator Agreements CTA 20.00 1,644.75 32,895.00  
o Investigator Agreements Country Specific Templates Country Template 1.00 1,352.00 1,352.00  
o Contract and Budget Plan (CBP) Plan 1.00 985.00 985.00  
o Investigator Grant Build Build 1.00 2,750.00 2,750.00  
o Submission Strategy & Risk Assessment Country 1.00 1,393.00 1,393.00  
o Central Institutional Review Board (IRB) Site Submissions (US) Site 20.00 667.00 13,340.00  
o Central Institutional Review Board (IRB) Submission, Study Level (US) Study 1.00 944.00 944.00  
o Central IRB Site Submissions (US)- Yearly Maintenance Site/Year 58.00 314.00 18,212.00  
o Central IRB Submissions (Study Level)- Yearly Maintenance Study/Year 3.00 236.00 708.00  
o Central IRB Site Submissions (US)- End of Trial Notifications Site 20.00 157.00 3,140.00  
o Central IRB Submissions (Study Level)- End of Trial Notifications Study 1.00 59.00 59.00  
o Master Informed Consent Form (ICF) Review ICF 3.00 1,816.00 5,448.00  
o Translation Coordination Language 1.00 1,416.00 1,416.00  
 Sub-Total Study Site Activation 299,148.45  
Trial Master File   
o TMF Management Plan & TMF Risk Assessment Plan 1.00 700.00 700.00  
o Worldwide TMF: TMF Set-up: Pre Site Activation Activities Sites 20.00 525.00 10,500.00  
o Worldwide TMF: TMF Maintenance & QC Site Months 623.00 56.49 35,192.66  
o Worldwide TMF: TMF Final Reconciliation & Transfer Sites 20.00 379.57 7,591.32  
 Sub-Total Trial Master File 53,983.98  
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 Service Agreement Budget  
 Services Unit # Units Unit Cost  
USD Total Cost USD  
Project Meetings   
o Internal Alignment (KO) Meeting Meeting 1.00 14,628.00 14,628.00  
o Sponsor Alignment (KO) Meeting Meeting 1.00 15,681.00 15,681.00  
o Webex Trainings Meeting 2.00 1,385.00 2,770.00  
o Sponsor Teleconferences Teleconferences 82.00 1,098.17 90,050.02  
o Internal Teleconferences Teleconferences 82.00 1,098.17 90,050.02  
 Sub-Total Project Meetings 213,179.04  
Clinical Monitoring   
o Lead Clinical Research Associate Support Month 33.00 12,101.75 399,357.69  
o Site Management Site Months 530.00 595.19 315,451.58  
o Internal Clinical Research Associate Calls & Project Communication Month 28.00 1,013.20 28,369.62  
o Clinical Research Associate Training (not at Investigator Meeting) Attendee 4.00 1,478.00 5,912.00  
o Remote Pre-site Selection Visits Visit 10.00 1,013.00 10,130.00  
o On-site Pre-site Selection Visits Visit 10.00 3,283.50 32,835.00  
o On-site Site Initiation Visits Visit 20.00 3,675.50 73,510.00  
o Remote Monitoring Visits Conduct Visit 140.00 950.92 133,129.10  
o On-Site Monitoring Visits Conduct Visit 140.00 4,257.43 596,040.30  
o Additional Time On-site Visit 80.00 820.61 65,648.69  
o On-site Close-out Visits Visit 20.00 4,216.46 84,329.15  
o Remote Electronic Data Capture (EDC) Review Conduct Site Months 390.00 181.60 70,824.60  
 Sub Total Clinical Monitoring 1,815,537.73  
Grant & Vendor Payments   
o Set-up Grant Payments Contract 20.00 110.00 2,200.00  
o Process Grant Payments Payment 480.00 66.39 31,866.78  
o Process Site Cost Payments Site 20.00 55.00 1,100.00  
o Set-up Vendor Payments Vendor 3.00 102.00 306.00  
o Process Vendor Payments Month 57.00 54.34 3,097.20  
 Sub-Total Grant & Vendor Payments 38,569.98  
Risk Based Quality Management   
o Protocol Risk Assessment Risk Assessment 1.00 14,224.58 14,224.58  
 Sub Total Quality Assurance Audits 14,224.58  
Drug Safety   
o Database Set-up & Configuration Database 1.00 3,640.00 3,640.00  
o Safety Management Plan Development Plan 1.00 3,957.00 3,957.00  
o Safety Training (Sites, Clinical Research Associates, Project Team) Training 1.00 1,039.50 1,039.50  
o Serious Adverse Events (SAE) Processing, Investigation, Narrative, Approval & Query Generation SAE 11.00 1,693.39 18,627.29  
o Analysis of Similar Events (AOSE) (US SUSARs only) SUSAR Report 1.00 496.12 496.12  
o Safety Management Maintenance Month 32.00 1,530.63 48,980.30  
o Preparation of Line Listings (LL) Report 1.00 650.02 650.02  
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 Service Agreement Budget  
 Services Unit # Units Unit Cost  
USD Total Cost USD  
o Suspected Unexpected Serious Adverse Reaction (SUSAR)/ Annual Safety Reports (ASR)/ Line Listings (LL) submission to Investigators Country \* Submissions 3.00 160.63 481.88  
o DSUR Preparation (Writing and Compiling) DSUR 3.00 12,577.16 37,731.48  
o Pharmacovigilance Closeout Transfer 1.00 3,336.17 3,336.17  
 Sub-Total Drug Safety 118,939.76  
Data Safety Monitoring Board (DSMB)   
o Deliver Data Safety Monitoring Board (DSMB) Database & Tables, Figures & Listings (TFLs) Delivery 2.00 22,667.24 45,334.48  
 DSMB Statistical Analysis Plan (SAP) Plan 1.00 11,770.88 11,698.28  
 DSMB Unique Tables Unique Table 5.00 1,534.49 7,672.43  
 DSMB Repeat Tables Repeat Table 18.00 604.87 10,887.73  
 DSMB Unique Listings Unique Listing 11.00 938.77 10,326.51  
 DSMB Unique Figures Unique Figure 5.00 2,816.32 14,081.61  
 DSMB Repeat Figures Repeat Figure 5.00 930.77 4,653.86  
 Sub-Total Data Safety Monitoring Board 104,654.90  
Medical Monitoring   
o Medical Planning Month 1.00 23,050.00 23,050.00  
o Medical Management Screened Subject 220.00 215.88 47,492.90  
o Eligibility Review Screened Subject 220.00 479.73 105,539.78  
o Listings Reviews Enrolled Subject 100.00 119.93 11,993.16  
o Coded Data Review Enrolled Subject 100.00 19.19 1,919.11  
o Ongoing Safety Reviews of Labs and ECG Alerts Alert 318.00 167.91 53,396.71  
o Maintain Medical Monitor Log Month 24.00 1,144.69 27,472.66  
 Sub-Total Medical Monitoring 270,864.32  
Data Management   
o Data Management Plan Plan 1.00 3,474.00 3,474.00  
o Training Study 1.00 3,264.00 3,264.00  
o Electronic Case Report Form (eCRF) Development Unique Pages 30.00 601.65 18,049.50  
o Electronic Case Report Form (eCRF) Completion Guidelines Database 1.00 3,088.00 3,088.00  
o Edit Check Specifications Edit Check 240.00 80.31 19,274.40  
o Manual Listings Creation Listing 30.00 959.00 28,770.00  
o User Acceptance Testing Database 1.00 7,720.00 7,720.00  
o Set-up of Standard Reports Study 1.00 7,672.00 7,672.00  
o User Manual Development Study 1.00 1,544.00 1,544.00  
o Electronic Data Capture (EDC) Support Users 60.00 128.33 7,699.86  
o Serious Adverse Event (SAE) Reconciliation SAE 11.00 193.00 2,123.00  
o Serious Adverse Event (SAE) Reconciliation Maintenance Months 26.00 99.64 2,590.65  
o Data Cleaning Total Pages 23,565.00 1.24 29,204.50  
o Manual Listing Review Listings 780.00 100.69 78,538.32  
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 Service Agreement Budget  
 Services Unit # Units Unit Cost  
USD Total Cost USD  
o Vendor Reconciliation Set-up Vendor 2.00 3,072.00 6,144.00  
o Vendor Reconciliation Maintenance Upload 51.00 586.90 29,931.82  
o Vendor Integration Set-up Integration 1.00 3,446.00 3,446.00  
o Vendor Integration Maintenance Upload 26.00 586.90 15,259.37  
o MedDRA Coding (via Coding Tool within EDC) Terms 1,000.00 4.03 4,032.41  
o WHODRUG Coding (via Coding Tool within EDC) Meds 1,500.00 8.05 12,082.22  
o Coding Dictionary Updates Year 2.00 1,610.97 3,221.93  
o Data Transfer Set-up Database 1.00 384.00 384.00  
o Data Transfers Transfer 9.00 400.66 3,605.90  
o Database Lock Database Lock 1.00 7,801.85 7,801.85  
o Archive CDs Site 20.00 86.13 1,722.51  
o Data Management Coordination Month 31.00 1,610.97 49,940.15  
 Sub-Total Data Management 350,584.39  
Biostatistics   
o Randomization/ Kit list/ Interactive Response Technologies Review List 2.00 6,024.00 12,048.00  
o Data Management Specifications Protocol 1.00 6,574.55 6,574.55  
o Statistical Analysis Plan & Mock Shells Plan 1.00 17,893.58 17,893.58  
o Study Data Tabulation Model (SDTM) Datasets Dataset 25.00 2,688.39 67,209.84  
o Analysis Datasets Dataset 15.00 3,353.40 50,300.93  
o Define.xml and Data Reviewers Guide for SDTM, Annotated CRF Specification 5.00 5,084.93 25,424.65  
o Deliver Final Database & Table, Figures & Listings Delivery 1.00 7,643.93 7,643.93  
 Final Unique Study Tables Unique Table 25.00 1,544.01 38,600.23  
 Final Repeat Study Tables Repeat Table 50.00 608.63 30,431.36  
 Final Unique Study Listings Unique Listing 25.00 944.60 23,614.97  
 Final Unique Study Figures Unique Figure 10.00 2,833.80 28,337.97  
 Final Repeat Study Figures Repeat Figure 10.00 936.55 9,365.46  
o Statistical Input to Clinical Study Report (CSR) CSR 1.00 6,425.06 6,425.06  
o Delivery Dry Run Database & Table, Figures & Listings Delivery 1.00 15,315.15 15,315.15  
 Sub-Total Biostatistics 339,185.68  
Medical Writing   
o Model Inform Consent Form(s) (ICF(s)) ICF(s) 3.00 8,204.00 24,612.00  
 Sub-Total Medical Writing 24,612.00  
Clinical Assessment Technologies   
o Scale Identification and Acquisition Scale 6.00 1,029.00 6,174.00  
o Creation of Source Documents Language\* Scale 12.00 429.63 5,155.50  
o Rater Training Plan Plan 1.00 2,805.00 2,805.00  
o Rater Experience Verification Rater 43.00 96.75 4,160.25  
o Rater Training and Certification Rater 34.00 182.50 6,205.00  
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 Service Agreement Budget  
 Services Unit # Units Unit Cost  
USD Total Cost USD  
o Applied Skill Assessment (ASA) not at Investigator Meeting ASA\*Rater 34.00 275.88 9,379.75  
o Didactic Presentation Presentation 1.00 1,438.38 1,438.38  
o Web Portal Portal 1.00 6,043.10 6,043.10  
o Data Surveillance Plan Plan 1.00 13,985.50 13,985.50  
o Set-up of Clinical Assessment Technologies EDC Data Monitoring System System 1.00 9,837.50 9,837.50  
o Clinical Assessment Technologies Data Management Reports Month 24.00 398.57 9,565.71  
o Electronic Data Capture (EDC) Flag Clinical Review Visit 384.00 215.41 82,715.84  
o Collection & Review of Source Documents Visit \* Scale 244.00 151.25 36,905.00  
o Clinical Assessment Start-up & Planning Month 5.00 1,798.25 8,991.25  
o Clinical Assessment Maintenance & Reporting Month 24.00 938.13 22,515.01  
o Clinical Assessment Technologies Virtual Training Session WebEx 2.00 6,306.00 12,612.00  
 Sub-Total Clinical Assessment Technologies 238,488.79  
Interactive Response Technology   
o Pre go-live Project Management, Requirements Gathering & Design (SaaS) Build 1.00 15,484.00 15,484.00  
o Configuration/Coding (SaaS) Build 1.00 5,856.00 5,856.00  
o Validation (SaaS) Build 1.00 8,928.00 8,928.00  
o Review testing materials Build 1.00 996.00 996.00  
o Systems Integrations (SaaS) Build 1.00 15,680.50 15,680.50  
o Sponsor User Acceptance Testing (SaaS) Build 1.00 10,368.00 10,368.00  
o Interactive Response Technologies Inventory Implementation and Review Build 1.00 1,732.00 1,732.00  
o Interactive Response Technology Project Management (SaaS) Month 26.00 3,443.50 89,530.88  
o Production Support (SaaS) Month 26.00 4,732.71 123,050.37  
o Production Randomization Monitoring and Audit System 1.00 3,662.73 3,662.73  
o Decommissioning (SaaS) System 1.00 2,197.64 2,197.64  
 Sub-Total Interactive Response Technology 277,486.12  
Technology   
o Clinical Trial Management System (CTMS) Set-up System 1.00 10,927.00 10,927.00  
o Clinical Trial Management System Helpdesk/ Maintenance Month 35.00 892.08 31,222.89  
o Edge Payments Set-up: Grant Payments System 1.00 2,848.00 2,848.00  
o Edge Payments Customization System 1.00 4,895.00 4,895.00  
o Edge Payments Maintenance, Support, Changes Month 24.00 278.58 6,685.89  
o Rater Web Portal Set-up System 1.00 19,353.00 19,353.00  
o Rater Web Portal Maintenance, Support, Changes Month 29.00 536.29 15,552.44  
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 Service Agreement Budget  
 Services Unit # Units Unit Cost  
USD Total Cost USD  
o Integration Set-up System 1.00 36,093.00 36,093.00  
o Integration Maintenance, Support, Changes Month 29.00 406.92 11,800.68  
 Sub-Total Technology 139,377.90  
Project Management   
o Project Management - Start-up Month 5.00 22,531.57 112,657.83  
o Project Management - Conduct Month 24.00 19,571.52 469,716.40  
o Project Management - Close-out Month 5.00 16,116.23 80,581.15  
 Sub-Total Project Management 662,955.38  
 Total Estimated Service Fees 4,961,793.00  
 Discount -372,134.48  
 Total Estimated Service Fees including Discount 4,589,658.53  
 System & General Expenses   
o IBMCD Electronic Data Capture (EDC) Maintenance & Hosting Month 29.00 6,000.00 174,000.00  
o Argus Safety Database Set-up & Configuration System 1.00 15,000.00 15,000.00  
o Argus Safety Database Hosting Month 25.51 2,116.82 54,000.00  
o Clinical Trial Management System User Access System 1.00 3,000.00 3,000.00  
o IBMCD IRT System Fees System 1.00 14,500.00 14,500.00  
o Electronic Trial Master File (eTMF) Monthly Hosting Fees Site months 733.00 35.00 25,655.00  
o Regulatory System Fees Site 31.00 387.10 12,000.00  
Total System & General Expenses 298,155.00  
 Estimated Pass-through Costs   
 Study Start-up Pass-through Costs   
o Print and Ship Investigator Site File to Sites Site 20.00 300.00 6,000.00  
o Institutional Review Board (IRB) Site Regulatory Documents (includes preparation, collection, annual renewals if needed)   
 North America - Central IRB Site 20.00 1,500.00 30,000.00  
 Sub-Total Start-up Pass-through Costs 36,000.00  
Clinical Monitoring Pass-through Costs   
o Pre-site Selection Visits Visit 10.00 700.00 7,000.00  
o Site Initiation Visits Visit 20.00 700.00 14,000.00  
o Interim Monitoring Visits Visit 140.00 700.00 98,000.00  
o Additional Time on Site Visit 80.00 700.00 56,000.00  
o Close-Out Visits Visit 20.00 700.00 14,000.00  
o Site Management Site Months 530.00 10.00 5,300.00  
 Sub Total Study Conduct Pass-through Costs 194,300.00  
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 Services Unit # Units Unit Cost  
USD Total Cost USD  
Clinical Assessment Technologies Pass-through Costs   
o Scale Licenses License 6.00 7,567.50 45,405.00  
o Scale Translations Scales\* Languages 1.00 2,500.00 2,500.00  
o Rater Experience Surveys/Trial Interactive Raters\*Surveys 10.00 10.00 100.00  
 Sub-Total Clinical Assessment Technologies Pass-through Costs 48,005.00  
Archiving Pass-through Costs   
o Shipment of Completed Case Report Forms (CRF) Back to Sites (archive copy, disc for EDC) Shipment 20.00 50.00 1,000.00  
o Shipment of Completed electronic Case Report Forms (eCRF)Back to Sponsor (disc ) Shipment 1.00 50.00 50.00  
 Sub-Total Archiving Pass-through Costs 1,050.00  
Trial Master File Pass-through Costs   
o Final Transfer of Study Records to Sponsor (Disk) Transfer 1.00 150.00 150.00  
 Sub-Total Project Management Pass-through Costs 150.00  
Project Management Pass-through Costs   
o Project Management Passthrough Costs Month 35.00 100.00 3,500.00  
 Sub-Total Project Management Pass-through Costs 3,500.00  
Third Party Vendor Costs   
o Central Lab: ACM Study 1.00 248,814.00 248,814.00  
o ECG Provider: ERT Study 1.00 114,000.00 114,000.00  
o Avantor Sciences (ballpark) Study 1.00 40,000.00 40,000.00  
 Sub-Total Third Party Vendors 402,814.00  
PI Fees   
o Investigator Grants- Completed patients Patient 85.00 37,304.00 3,170,840.00  
o Investigator Grants- Screen failure patients Patient 120.00 3,645.50 437,460.00  
o Investigator Grants- Dropped patients Patient 15.00 21,548.40 323,226.00  
o Site Costs Site 20.00 13,032.00 260,640.00  
 Sub-Total PI Fees 4,192,166.00  
Total Estimated Pass-Through Costs 4,877,985.00  
 Total Estimated Budget 9,765,798.53  
Note that the unit costs are derived from the total cost after regional & annual rates have been applied and therefore result in a blended rate.   
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 EXHIBIT D  
PAYMENT SCHEDULE  
 1. Service Fees:  
 1.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, upon signature of this Work Order, Sponsor will pay Worldwide an advance payment of $488,781.35 due upon ten (10) days of receipt, (advance payment represents 10% of the Service Fee and System and General Expenses total). All subsequent invoices will be submitted to Sponsor by email monthly based on units completed in the preceding month according to the Budget above, with each subsequent invoice for Service Fees and System and General Expenses reduced by 10% until the advance payment is exhausted. With the exception of the first payment described above in the amount of $488,781.35, payment terms shall be as defined in this Agreement. Any outstanding balances will be reconciled at the end of the Study.  
 1.2. The bottom line discount (“Discount”) shall be defined as a one-time discount applied to the service fees of this study budget, based on the current scope and specifications detailed within this Work Order. Should these parameters vary from what is presented within, Worldwide reserves the right to adjust any discounts or commercial incentives based on the revised scope and budget values.  
 1.3. Payment shall be issued by check or wire transfer at Sponsor’s option. Wiring instructions are as follows:  
 Account Holder: Worldwide Clinical Trials, Inc.  
 Bank Name: HSBC Bank USA, NA  
 Bank Address: 000 Xxxxx Xxxxxxx Xx.  
 Xxxxxxx Xxxxx, XX 00000  
 ABA Routing No.: 000000000  
 Bank Account No.: 000-00000-0  
 Swift Code: XXXXXX00  
 Taxpayer ID#: 00-0000000  
 2. Pass-through Expenses:  
 2.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, Worldwide shall invoice Sponsor an advance payment of $137,163.80 due upon ten (10) days of receipt (advance payment represents 20% of the anticipated Pass-through Expenses). Worldwide will submit subsequent monthly invoices by email for incurred Pass-through Expenses based on actuals, with each subsequent invoice for Pass-through Expenses reduced by 20% until the advance payment is exhausted. With the exception of the first payment described above in the amount of $137,163.80 payment terms shall be as defined in this Agreement. Any outstanding balances will be reconciled at the end of the Study.  
 3. Investigator/Institution Fees:  
 3.1. Notwithstanding the payment terms in Section 3.4 of the Agreement, Worldwide shall invoice Sponsor an advance payment of $314,412.45 due upon ten (10) days of receipt (advance payment represents 7.5% of the anticipated Investigator/Institution grants). Periodically, Worldwide will invoice Sponsor by email to replenish this advance back-up to an amount equivalent to 7.5% of the anticipated Investigator/Institution grants or such other amount of funds needed to bring the balance to the sufficient amount to ensure that payments are made to sites in a timely manner. The invoice will be accompanied by a report which itemizes the Investigator/Institution grants that have been paid in the period, and will reconcile the use of funds received from Sponsor. If an increase in the amount of anticipated Investigator/Institution grants is necessary, Worldwide will provide appropriate support justifying such increase. Any outstanding balances will be reconciled and provided no earlier than 30 days after at the end of the Study. For avoidance of doubt, Worldwide will make all grant payments only from funds received from Sponsor specifically for this purpose. Worldwide shall not be liable for any payments delays due to the delay in receipt of funds from Sponsor.  
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 EXHIBIT E  
FORM OF CHANGE ORDER  
 Client: Worldwide Project Manager:  
Protocol Number: Worldwide ID:  
Change Order #: Date:  
 Worldwide Clinical Trials, Inc. (“Worldwide”) and Neurotrope Bioscience, Inc. (“Sponsor”) entered into an agreement dated [effective date] (“Agreement”) [as amended by Change Order # 1 effective [effective date]] [and further amended by Change Order # 2 effective [effective date]] in which Worldwide was to provide certain Services to Sponsor in connection with Study [insert Protocol number] (“Study”). Worldwide and Sponsor wish to amend the Agreement as follows:  
 1. Revisions to the Scope of Services. The Scope of Services has been revised as described below, and Worldwide will provide the following additional services [will not provide the following services initially contracted]:  
 Description of Service Cost  
 2. Revisions to the Study Budget. As a result of the changes to the Services and Scope of Services, this Change Order # [Insert] [increases] [decreases] the Service fees as shown above. A revised total budget value is below.  
 Services Fees Estimated Pass Through Costs Total  
Original Agreement Value:   
Change Order #1 Value:   
[Add additional Change Orders as necessary]   
Revised Contract Value:   
 3. Revisions to the Payment Schedule. A revised and restated payment schedule, as amended by Change Order # [Insert#] is detailed below.  
 Payment Schedule, as amended by Change Order # [Insert]  
 Except to the extent specifically modified by this Change Order # [Insert], the provisions of the Agreement remain unmodified and the Agreement as amended by this Change Order # [Insert] is confirmed as being in full force and effect. All defined terms within the Agreement shall have the same meaning when used herein.  
 Authorized representatives of the Parties have executed this Change Order # [insert] effective as of the Effective Date written above.  
 Worldwide Clinical Trials, Inc. Neurotrope Bioscience, Inc.  
 By: Sample By: Sample  
 Name: Name:   
 Title: Title:   
 Date: Date:   
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