



THIEVON-WRIGHT

C O N S U L T I N G G R O U P ®

February 21, 2017

Dr. Oscar A. Colon-Acosta, MD
Founder/CEO
In Situ Global Clinical Trials Network, LLC
Metro Office Park
Metro Parque 7, Street 1, Suite 204
Guaynabo, PR 00968

Dear Dr. Colon-Acosta:

This document will serve as a Letter of Agreement (the “Agreement”) between In-Situ Global Clinical Trials, LLC (SITE) and Thievon-Wright Consulting Group LLC (TWCG), a subsidiary of Evolution Research Group, LLC (Collectively referred to herein as the “Parties”) for General Business Development Consulting Services and inclusion in the ERG Affiliate Network.

The parties agree to the following:

1. TWCG agrees to provide the following services in support of the SITE’s ongoing business development efforts as outlined below:
 - **TWCG’s Business Development Team:** The team is comprised of the Senior Vice President of Business Development, Director of Business Development Operations and Executive Assistant; as well as 5 full-time Business Development professionals who work on behalf of SITE to procure new business;
 - **Market research and pipeline verification:** The team utilizes various industry resources including, but not limited to, BioPharm Insight, NeuroPerspectives, Neurograms, CenterWatch weekly & monthly, FiercePharma, BIO SmartBrief, Clinical Trials.gov, PharmaTimes, and Pharmaceutical Online News. The team also follows several aspects of social media including Linked In, Facebook, etc. and constantly conducts internet searches to track sponsor pipeline updates;
 - **Marketing and Promotion:** TWCG’s marketing team regularly updates marketing information on the network which includes, managing and updating the cnssites.com website; Site Summary Sheets, posting SITE news and accomplishments when applicable, alerting industry of the TWCG conference schedule, developing case studies, writing periodic newsletters, updating CRO databases and running advertisements in various publications such as CenterWatch online. TWCG also attends numerous conferences and sponsors both the conference itself and special events and develops all marketing materials to be utilized and/or presented at the conferences.
 - **Site Opportunity Information managed through Salesforce:** TWCG manages a Salesforce database which requires continuous data entry, updating and maintenance. A team approach identifies account activity by tiers and documents qualified contacts, leads and projects. The team tracks all opportunities for SITE in real time.

- **Client Engagement Activities Daily (non-facing):** TWCG’s internal team is in **constant contact** with CROs and Sponsors, working to identify new leads. The team also assists SITE with the management of study start-up activities through telephone contact, emails, on-line presentations, organizing teleconferences, etc.
- **Client Engagement (Face-to-Face):** TWCG’s team will strive to schedule and attend client presentations/meetings to “pitch” SITE’s services and to prepare capabilities presentations relevant to the project opportunity. These slide decks are routinely updated with sites’ and PIs’ most recent information on capabilities, experience, recent performance metrics, patient population data, specialized procedures, etc. TWCG’s team will work closely with SITE to ensure accurate data is included.
- **Budgets and Contracts:** TWCG will work closely with SITE to negotiate budgets for studies procured through the team’s efforts. The SITE will be responsible for all legal language, but assistance will be provided and feedback will be shared during the process with regards to pricing, payment schedules, pass-through costs and additional budget related items.
- **Conference Support:** TWCG establishes an annual “Conference Schedule” which typically includes 10-20 conferences. The schedule is distributed to the Network Sites as early as possible in the calendar year. Past conferences chosen have included those in the following areas: Neurology, Psychiatry, Early Clinical Development, Addiction, Sleep Disorders, Pain, Alzheimer’s disease, and other therapeutic areas. All site personnel are invited to attend these conferences at their own expense. TWCG promotes all sites at all relevant conferences with the focus being on the gathering of strategic/competitive information and to meet with potential new clients and also with current clients. Clients are entertained, and at key conferences, a private suite may be provided to host meetings. As the network remains heavily focused in neuroscience, TWCG holds an annual Dessert Reception at ASCP to highlight all the sites in our Network, and all sites are expected to contribute to this expense.
- **Site pipeline reports:** The SITE will receive monthly pipeline reports which are reviewed during a monthly call. This call is designed to review all open opportunities and to discuss how to progress them to a “Closed Win.” The SITE is also required to share the progress of all ongoing studies and share any other pertinent information that may be helpful to the TWCG team. Examples include new staff, new capabilities, successful patient recruitment efforts, challenges with any current studies, key information gained through client contact, etc.
- **Conduct Compliance Training:** ERG’s Quality Assurance Group will conduct in-person Compliance Training annually, or as needed, and SITE will reimburse for related Travel and Expenses. The training is included in the start-up fees for the first year. Subsequent Annual Training will be charged at a fee of \$3,000/day plus travel expenses. If TWCG determines there are quality issues at SITE and a QA visit/audit is required, SITE will pay \$2500/day for on-site audits up to 3 days and include a CAPA report. SITE may also request support from the QA team and such projects/training/auditing will be charged based upon the needs, and discussed and approved by both parties in advance.

OPTIONAL SERVICES AVAILABLE FOR ADDITIONAL CHARGE:

- **PI Training Program** – SITE may wish to have a PI visit another SITE within the network. Depending upon the project, parties will negotiate the fees in advance of the visit. If SITE wishes to send a PI to an ERG site for on-site training and PI shadowing, there will be no charge for this, but SITE will bear all costs related to travel, lodging, etc.
- **CRC Training Rotation** – SITE may benefit from an experienced ERG CRC rotating through SITE’s various locations. If ERG can accommodate a request for support, the cost and logistics will be agreed upon in advance and in writing by both parties.
- **Client On-Site Visits:** If the sponsor or SITE requests that a TWCG attendee be present at a pre-study or site assessment visit, the SITE will only pay for travel expenses related to that visit. No daily fee will be charged.

- Rater Training: SITE agrees to pay all fees related to rater training services provided by ERG or CNS Ratings, LLC (collaborator of ERG) for any requested rater training services.
2. Services will begin on March 1st and will continue there for a period of twelve (12) consecutive calendar months, contingent upon successful completion of a QA assessment visit. After twelve (12) months both parties will discuss renewal or revision of these terms, unless otherwise terminated pursuant to Paragraph 8 of this Agreement.
 3. SITE Agrees to pay TWCG a \$15,000.00 non-refundable, start-up fee for the services described herein. This is a one-time start-up fee and is due within thirty (30) days upon acceptance of this Agreement. In addition, SITE agrees to pay reasonable travel and related expenses for an initial QA site inspection and possible Compliance Training by ERG's Quality Assurance Group.
 4. SITE is required to keep the following documents up to date and submit copies to TWCG: GCP training, SOPs, medical licenses, annual CVs.
 5. TWCG is waiving the monthly fee for this Agreement. If SITE should begin to offer inpatient Phase 1 services, the parties agree to negotiate a monthly fee related to promoting these services.
 6. SITE agrees to pay 8% of collected revenue on all studies placed with all clients brought to SITE through TWCG/ERG. SITE agrees to pay five percent (5%) of the collected revenue for open-label extension studies. Commissions are due monthly based upon collected revenue from the prior month. SITE shall report the prior month's collected revenue by study to TWCG by the 5th of each month. Payment for the prior month's collected revenue is due by the 20th of each month. Collected revenue includes revenue for all direct and indirect fees including bed fees, overhead, PI and CRC fees, start-up fees, pharmacy fees, etc. It does not include revenue for pass-through costs such as IRB fees, advertising, patient stipends, or fees associated with outside medical services such as imaging services, provided there is no mark-up.
 7. Thievon-Wright Consulting Group, LLC (TWCG) will have the right of first refusal to make an offer to acquire the SITE under the terms negotiated by the parties if SITE is considering a transaction.
 8. SITE agrees to share all information regarding study opportunities not brought to the site by TWCG unless CDA with sponsor prohibits such activity. SITE agrees to make every effort to implore the sponsor, under such circumstances, to allow TWCG to join the CDA or enter into a separate one. At a minimum, SITE will refer the Sponsor to TWCG for direct discussions.
 9. SITE agrees to immediately alert TWCG when the following events occur: scheduling of a PSV, scheduling of a Sponsor, CRO or FDA Audit; SAEs; enrollment or screening holds; dosing errors; laboratory process errors; scope changes or amendments to CTAs; and any other issues requiring the attention of the TWCG Account Director. SITE agrees to immediately notify TWCG of receipt of contract and budget materials and also to forward copies of original and executed contracts for any studies procured through TWCG/ERG.

10. SITE Agrees to pay TWCG a \$1,500 fee for any study that SITE declines AFTER the budget and contract negotiations have been completed. Unless the sponsor is unreasonable and TWCG agrees declining the study is a sound decision, SITE agrees to the fee for the time and effort expended by TWCG.
11. TWCG will devote considerable resources to launching SITE as a member of an elite and well-established network. SITE understands that the arrangement is exclusive and agrees not to enter into an oral or written agreement or arrangement with other independent business development representatives. SITE agrees to notify TWCG of any other consulting arrangements SITE enters into related to clinical research activities **that are not** related to business development activities.
12. Either party may terminate this Agreement for any reason in writing upon thirty (30) days written notice. Any commissions earned after the date of termination will continue to be paid monthly until all subjects are enrolled and completed in each study. This includes studies that are listed on the pipeline report, but are not yet contracted.
13. The Parties agree to maintain confidentiality of the Sponsors, protocols, protocol synopses, investigator brochures, and all other “confidential information” as identified by a Sponsor or SITE. This includes information related to all studies even after certain information is disclosed at Scientific Meetings, in scientific publications and other venues. Opinions, medical or otherwise, related to ongoing or recently completed trials, shall not be shared with any outside party. Site also agrees to keep confidential all compliance training materials, pipeline reports, and other information provided to SITE by TWCG that is considered proprietary in nature. TWCG and SITE agree to keep confidential the terms of this Agreement in so far as it does not limit the ability of TWCG to provide services under this Agreement or SITE to enter into agreements for business.
14. This agreement shall be governed by the laws of New Jersey, without regard to conflicts of law principles.
15. This agreement may be amended only in writing signed by both parties. This agreement may not be assigned without the consent of the other party.

Please indicate your acceptance of this Letter of Agreement by signing below and returning to my attention.

We look forward to working with you and your team and anticipate a mutually beneficial relationship.

Sincerely,

AGREED AND ACCEPTED

Lori T. Wright
Chief Executive Officer

Oscar Colon-Acosta, MD
Founder/CEO