POSITION DESCRIPTION AND CANDIDATE SPECIFICATIONS

COMPANY: **SanBio, Ltd.**

POSITION: **Sr. Clinical Research Associate/Clinical Trial Manager**

LOCATION: **Mountain View, CA**

REPORTING RELATIONSHIP: **Global Director of Clinical Operations**

THE COMPANY

SanBio is a global regenerative medicine company with cell-based products in various stages of research, development and clinical trial testing. The Company's vision is to create and lead the field of regenerative medicine and the Company is currently one of the leading companies in the CNS therapeutic area.

SanBio, Inc. owns and has licensed various technologies related to regenerative medicine. Its current product portfolio consists of three bone marrow derived stem cell products: SB623 for neural cell regeneration, SB618 for myelination and SB308 for muscle regeneration.

SanBio has successfully conducted a Phase 1/2A clinical trial for chronic stroke with SB623 and achieved human proof of concept (POC), a major milestone. SanBio is now proceeding with its next P2B study (ACTIsSIMA) for this indication. Additionally, SB623 is proceeding with a P2 study in a second indication (Traumatic Brain Injury) under the same IND.

Preclinical studies of SB623 in ophthalmological / retinal indications such as dry AMD (Age-related Macular Degeneration) and spinal cord injury are being completed to enable additional IND submissions. SanBio's allogeneic cell-based platform gives the company a competitive advantage versus autologous-based approaches with respect to product consistency and scale up. In addition to large-scale production, SanBio stores and transports these stem cells in the vapor phase of liquid nitrogen thereby facilitating global distribution of a multi-year shelf life product.

The Company estimates over $3B in potential annual revenue from its first indication of chronic stroke alone. SanBio is well positioned for late stage product development and commercialization with a key corporate partnership, Sumitomo Dainippon Pharm and its wholly owned US subsidiary, Sunovion Pharmaceuticals, currently in place. The Company raised significant capital via a very successful initial public offering (TYO: 4592) in April of 2015.

The new Clinical Trial Manager joining the Company in this role will make significant contribution to the ongoing clinical programs at SanBio. In doing so, s/he will work at the

leading edge of translational regenerative medicine which witnesses the convergence of scientific understanding with industrial application.

Located in Mountain View, California, SanBio is headquartered in the heart of Silicon Valley with proximity to leading universities and institutes and numerous innovative life science and technology companies.

Information and details can be found on the Company website and via the following link to scientific publications:
http://www.san-bio.com

EXECUTIVE TEAM

SanBio is led by a team of dedicated and experienced executives who contribute their significant expertise to leading the preclinical, clinical and commercial activities of the Company. The Company has engaged a scientific advisory board comprised of leading scientific and medical experts in the field.

THE POSITION

SanBio is seeking an exceptional experienced Clinical Trial Manager to play a key role in the execution of its clinical programs. This role offers an exciting opportunity for a talented professional to contribute their clinical trial expertise as well as develop significant career experience in the emerging field of regenerative medicine.

The Clinical Trial Manager is responsible for the day-to-day operations of 1-4 clinical trials commensurate with complexity including start-up, conduct, close-out activities.

PRIMARY POSITION RESPONSIBILITIES

- Provide the day to day operational management of CROs and/or vendors to ensure delivery against scope of work.
- Lead the development, review and finalization of study related documents for trial execution.
- Collaborate with internal and external partners to facilitate operational execution of study tasks.
- Ensure all operational tracking needs are identified, including systems and tools to meet the needs of the team and to facilitate reporting to the study/program leader.
- Provides operational input to the core study documents including the protocol, informed consent, clinical study report, and CRF.
- Oversees the collation of feedback on study level documentation and ensures appropriate updates are made.
- Ensures accuracy of vendor invoices and site payments. Communicate variance and action to resolution to program leader.
- Oversee forecasting and ordering of clinical/non-clinical supplies.

- Oversee data management processes including collection and cleaning of clinical database, reconciliation of clinical and safety databases, and data interpretation and evaluation.
- Manage and oversee site management activities in accordance to the monitoring plan: including review monitoring reports, trending errors or other indicators of site difficulties, identification of potential problem sites and development of corrective action plans as required. As needed, provide oversight of CRO and maintain site relationship, this can include booster visits, SIV, or KOL interactions.
- Provides input into, and implementation of, the study level audit plan, quality, risk management and contingency plans.
- Actively track progress and completion of study milestones accordingly. Ensure maintenance, tracking and reporting of operational metrics/updates.
- Identify and participate in creation of clinical operations SOPs, best practice and standards across study team and organization as needed.
- Monitor safety surveillance and reporting activities.
- Organize and manages Investigator Meeting, DSMB/Safety meetings, Site/Monitoring meetings, and other study related meetings.
- Establishes the set-up of archives for essential documents including trial master file.
- Provide support and direction to clinical team members as assigned.
- Ensure adherence to ICH/GCP/local regulations, and SOPs.

QUALIFICATIONS & KEY ATTRIBUTES

- BA/BS degree in Biological Science or Nursing required with advanced degree preferred. Potential candidates with equivalent experience and accomplishments will be considered.
- 5+ years of clinical research experience in the biotechnology/pharmaceutical industry. Experienced with multi-center international studies is preferred.
- Experience managing CROs, central laboratories, and other clinical study vendors.
- Experience as a clinical trial monitor is a plus. Experience with surgical studies is a plus.
- Experience preparing clinical trial timelines, budgets and contracts.
- Knowledge of GCP and ICH guidelines, and local regulations.
- Proficient computer skills with MS Office (Word, Excel, Access, Outlook, Explorer and PowerPoint) is required.
- Ability and willingness to travel up to 15% of the time (international and domestic).

INTERPERSONAL CHARACTERISTICS:

- Demonstrated energy and passion. A commitment to helping deliver clinical trial achievements pertinent to SanBio's mission.
- Autonomous, self-starter with sense of ownership and interest ingrowth and progress in their career via delivering results; comfortable working in a changing environment.

- Strong interpersonal, communication and leadership skills, including the ability to build relationships both internal and external. Ability to work in an international environment with internal and/or external partners.
- A quick study with excellent written and verbal communications and professional presentation skills and demeanor.
- Key attributes: problem solver, creative, positive mental attitude, direct, take-charge, good sense of humor.
- Enjoy collegial open discussions; able to thrive in the absence of egotism.
- An outstanding work ethic, high-integrity, team player attitude.

ENVIRONMENT:

The Company is driven in its mission to advance the field of regenerative medicine. The Clinical professional joining in this role will work closely with a small team of dedicated professionals and will bring substantial impact. The culture is collaborative and one where team members are expected to be proactive and objective-driven - delivering results in line with respective responsibilities. The SanBio corporate culture calls for career development and advancement to optimally motivate the team.

COMPENSATION:

SanBio offers a competitive base and incentive compensation package. The Company provides an array of benefits to promote a healthy and creative work environment for its team members.