JOB DESCRIPTION

Job Title:	Director Clinical Development
Job Code:	
Reports To (Title):	Senior Vice President of Clinical Development
Department Name:	Clinical Development
Revision Date:	October 2, 2020
FLSA:	Exempt

I. JOB SUMMARY:

Directs clinical operations and provides oversight of clinical trials for the use of ^{186}RNL and other drugs in Plus Therapeutics' clinical development pipeline. Implements and executes clinical trials through all phases of the study. Ensures all study procedures occur in accordance with agreed clinical development plans and regulatory requirements. Keeps executive-level management informed of progress and problems. Responsible for resource allocation, including budget and personnel.

II. REQUIREMENTS:

EDUCATION:

- Bachelor's degree in Biological Science or a related field.

KNOWLEDGE AND EXPERIENCE:

- Minimum 10 years' experience in a management role running industry-sponsored clinical trials in oncology and, preferably, with experience in glioblastoma and with medical devices.
- Knowledge of pharmaceutical industry, terminology and practices.
- Knowledge of early- to mid-phase clinical program operations strategy and planning
- Knowledge of FDA regulations and their practical implementation.
- Knowledge of GCP guidelines.

LICENSES AND CERTIFICATIONS:

- Professional licenses/ certifications preferred but not required.

ADDITIONAL DESIRABLE QUALIFICATIONS:

- Advanced degree applicable to the health sciences is highly preferred.

SKILLS AND ABILITIES:

- Expertise with clinical site management, CRO/Vendor management and logistical execution of clinical trials required.
- Proficient with Microsoft Office Word, Excel Power Point, and Project.
- Ability to manage and prioritize workload effectively.
- Ability to exercise independent judgment.

- Ability to communicate effectively both orally and in writing and to establish and maintain cooperative working relationships with persons contacted in the course of performing assigned duties including Company management and outside business associates.
- Strong attention to details.
- Ability to interact with senior management on a regular basis.
- Available to travel on short notice to clinical sites throughout the US and ability to manage travel schedules, such as flight schedules.

PROBLEM SOLVING AND DECISION MAKING:
- Develops solutions to a variety of complex problems; ensures solutions are consistent with organization objectives.

PHYSICAL REQUIREMENTS:
- Ability to hear and speak to employees and business associates on the phone and in person.
- Regularly required to sit, stand, bend, reach and move about the facility.
- Work performed in an office setting, ability to sit for long hours at a time.
- Ability to see the letters and numbers on a personal computer screen and on memos, reports and other documents (near vision).

SUPERVISORY RESPONSIBILITY:
- Clinical trial team within the United States and as assigned.

TRAVEL REQUIREMENTS:
- Valid driver's license, proficient driving skills, and up-to-date car insurance.
- Substantial travel required to clinical trial sites across the US.

III. RESPONSIBILITIES:

- Directs the execution of clinical trials to support company objectives.
- Directs the oversight of the design, preparation and initiation of study protocols and other required documentation in compliance with project plans, federal regulations, GCP, and good medical practice, and will interpret clinical data.
- Supports clinical development strategies such that clinical trials achieve objectives in an efficient and cost-effective manner.
- Collaborates with other internal partners to ensure that study designs are appropriate with respect to available time, resources, and local and national regulations.
- Ensures that regulatory documentation pertaining to clinical trials is accurate and meets regulatory timelines.
- Provides leadership and oversight for vendor management. Oversees the selection and use of clinical trial management systems as needed (such as data management, Electronic Data Capture (EDC), and Electronic Patient Reported Outcomes (ePRO)).
- Directs the clinical team (i.e. training, performance planning and evaluation).
- Works closely with upper-level executives in establishing the company's long-range clinical research and/or product development goals and objectives.
- Working with senior management, interacting with and selecting investigators for clinical studies, and post approval support (US and globally) as required.
- Contributes to company strategy and evaluation of Investigator-Initiated Trials.
- Accepts additional work-related projects and assignments as required.