

Re.: NutriLeads is looking for senior clinical research manager (0.8 - 1 Fte)

NutriLeads

NutriLeads ([www.nutrileads.com](http://www.nutrileads.com)) is a dynamic clinical-stage Health Ingredients company that develops crop-derived food ingredients with clinically proven health benefits for specific patient and consumer groups. Our proprietary ingredients support human physiology, beneficially modulate the gut microbiome, and are naturally sustainable.

The Company's most advanced ingredient, NL-01, supports immune function and increases resistance to respiratory infections. Whilst project NL-02 provides protection against intestinal infections. Project NL-03 improves metabolic health by supporting the gut microbiome. NutriLeads is constantly looking for new leads to add to its portfolio.

All of NutriLeads' proprietary ingredients undergo clinical trials to demonstrate their efficacy in improving human health and are taken through regulatory approval for market access before being licensed out to partner companies who will incorporate the ingredients in their finished (food) products.

Following a successful proof of concept study, we currently have two trials ongoing; a trial involving an experimental common cold infection in 158 subjects is approaching the end of the clinical phase, a large multi-centre trial (Ireland, Scotland, France) involving 600 older adults will start enrolling in October. A third, smaller trial focussed on effects on the microbiota will be initiated later this year. **In this context we are looking for an experienced Clinical Research Manager to initiate, monitor and coordinate (multi-centre) clinical trials with (medical) food products in patients and healthy volunteers. You will report to the management team and work closely with others in the company, with CRO's and leading experts in the field.**

NutriLeads has currently a team of 7 based in Wageningen consisting of the 3 co-founders and 4 employees (4 PhD, 2 MSc, 1 MBA) working with numerous collaborators throughout Europe.

Responsibilities and tasks (working closely with the other team members):

- You initiate, monitor and coordinate (multi-center) clinical trials with (medical) food products in patients and healthy volunteers.
- You act as the lead function between NutriLeads, as sponsor, and the CRO's, the sites and other related parties making sure we leverage all capabilities and build/maintain the momentum to execute the clinical program within time and budget according to the appropriate quality standards.
- You coordinate protocol and CRF writing.
- You coordinate CRO and site selection
- You coordinate contract management with CROs and other vendors.
- You set up and maintain the internal documentation.
- You work and interact across functions within the NutriLeads team core team and with its consultants.

Skills and capabilities:

- You are action oriented, have a can-do mentality and can work effectively in a small cross-functional team and with many external collaborators.
- You have a scientific background (MSc / PhD) in the life sciences and at least 5-year (preferably 10 years) experience in clinical trial management.
- You have broad experience in clinical trial management and are able to maintain the overview, proactively identify and manage risks, switching easily from strategic decisions and overall supervision to action-oriented troubleshooting.
- You have a track record and strong capabilities to build and manage effective collaborations and vendor relations.
- You have experience with all phases of a clinical trial including initial design, CRO and site selection, protocol and CSR writing, monitoring and final reporting.
- You have been involved in the production of food or food additives/ingredients.
- You have experience in developing and implementing GCP documentation systems and are up to date on the pertinent regulatory requirements.
- You are experienced in project management and proficient in English.
- NutriLeads is based in Wageningen, The Netherlands and the currently ongoing trials are run in Amsterdam, France, Ireland and Scotland, which will require travelling.
- Affinity with the science underpinning the preventative health impact of nutrition and experience with working within a pharmaceutical/ Nutritional company is a pre.
- Starting date no later than September 1<sup>st</sup>, 2018 is a pre.

If you are interested in this position, please forward a letter indicating specifically your experience related to the above “responsibilities and tasks” as well as your CV to: Erik Dam ([erik.dam@nutrileads.com](mailto:erik.dam@nutrileads.com)).