



KONGELIG NORSK AMBASSADE

On behalf of the Norwegian Embassy, **LINK Medical** invites you to: “Risk Management in Early Phase Clinical Trials - Practical Implication”

When: March 5th • **Time:** 13:00-17:30 • **Where:** Norwegian Embassy, Skarpögatan 4, Stockholm

Don't let regulatory requirements stall your company's innovation, instead embrace the changing regulatory landscape to further develop your clinical plans, especially in the early strategic plans for prime clinical candidates.

At this meeting, you will learn from our team of experts and clinicians who will simplify what you need to know to get your drug to proof of concept as quickly and efficiently as possible. You will learn about concepts of early-stage development, the regulatory framework including key changes and, how to identify and mitigate risks in early clinical trials.

Speakers:

Gunnar Danielsson, former GCP inspector has traveled the world performing GCP inspections for the Swedish Medical Product Agency for over 10 years. He has 40 years' experience in Clinical Research and has a wealth of experience from the Pharmaceutical industry in terms of quality management, electronic systems, data management, and clinical design and conduct. Gunnar today is a key advisory resource and helps to design studies in the most effective way, meeting regulatory requirements.

Austin Smith received his medical degree from the Royal College of Physicians in Ireland in 1993. He spent the following 14 years working within the health-care system with extensive time training and working at the internationally renowned Hammersmith Hospital and The Royal Marsden Trust, rising to a position as Resident Oncologist at The London Clinic, one of the UK's largest private hospitals. From there he transitioned into the CRO industry, and for the past decade he has held a position as Medical Director, Early and Experimental Oncology Clinical Development at Theradex Oncology.

Agenda

13:30 – Registration

14:00 – Start and Welcome by Ambassador Christian Syse

14:05 – Welcome by Ola Gudmundsen

14:10 – Gunnar Danielson – Regulatory landscape overview and practical implications for conducting early clinical development

14:50 – Austin Smith – Drug Dev. Strategy & Changing Landscape for Biotech

15:30 – Break Coffee and refreshments

15:45 – Jeffery Yachnin: Investigator – Feedback from collective studies on what makes a study good and how to get the most out of patients

16:15 – Q/A

16:35 – Dinner

17:30 – ends

Jeffrey Yachnin MD, PhD Originally from Montreal, Canada Jeffrey is a medical oncologist who took an early interest in clinical research and has been working with clinical trials since 1995. He has worked as head of the cancer trials unit at the University Hospital in Uppsala from 2006 until 2011. Since then, he has been head of the Center for Clinical Cancer Studies at Karolinska University Hospital. Mr. Yachnin works primarily with early clinical trials both in academic and industry-sponsored studies.

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