



Nirosha Sithirapathy

ASSOCIATE

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Industry Experience

Legal Counsel

PSI CRO UK Ltd.

Global Contract Lead

INC Research LLC (now Syneos Health LLC)

Contracts Associate

PRA Health Sciences

As a seasoned in-house lawyer, Nirosha's background has provided her with the business orientated skillset to provide pragmatic commercial legal advice on a wide range of clinical trial procedures and matters. She has assisted numerous clients and stakeholders in the creation of policies and procedures that address various compliance challenges, including contract management flows, anti-bribery, global spend transparency initiatives (such as EFPIA), and data protection requirements.

Nirosha has focused much of her practice in support of global clinical contracting. Her experience managing biopharmaceutical contracting activities includes creating specialized templates and negotiating bespoke clinical trial agreements spanning more than 50 countries.

Nirosha has experience working with clients in the drug and device spaces in a range of therapeutic areas including neurology, oncology, cardiovascular, urology, dermatology, immunotherapy, autoimmune diseases, gene therapy, women's health and neuroendocrine disorders, age related disorders, hemoglobinopathies, rare diseases, metabolic, neurodegenerative, and musculoskeletal diseases, antiviral, blood-related disorders, diabetic and other peripheral neuropathies.

EXPERIENCE

PSI CRO UK Ltd.

Legal Counsel

- Worked on clinical trial related agreements spanning over 50 countries
- Advised on the legal implications of day to day business operations
- Supported creation of policies, procedures and processes
- Lead Attorney resolving various issues arising during the conduct of global clinical studies
- Experience across various therapeutic and phase areas, including oncology, medical devices, gene therapy, novel antibiotics. hemophilia,

Bar Admissions

- New York

Education

- School of Oriental and African Studies, University of London LLB (Hons.)
- London School of Economics, University of London LLB



Nirosha Sithirapathy (continued)

kidney disease, immune disorders and other chronic and acute medical conditions

INC Research LLC (now Syneos Health LLC)

Global Contract Lead

- Worked on site and vendor related clinical trial agreements across an international geographical mix, with specialization in Belgium, Germany and the UK
- Contract Lead providing support for the resolution of issues arising during the conduct of global clinical studies
- Experience across various therapeutic and phase areas, including oncology, neurology, hemophilia, kidney disease, immune disorders and other chronic and acute medical conditions, design and development of novel antibiotics

PRA Health Sciences

Contracts Associate

- Worked on site level clinical trial agreements across a European and Middle Eastern geomix
- Assisted with the resolution of issues arising during the conduct of clinical studies
- Experience across various therapeutic and phase areas, including acting as a dedicated resource for neurology and antiviral focused biotechnology companies

RECENT CLIENT WORK

Supported several clients with bespoke template development in global Phase I-IV drug and device trials and studies, including:

- Pre-screening observational study and Phase 2 study work for studies sponsored by Jounce Therapeutics, Inc.
- Multiple Phase 1, 2 and 3 global clinical trials across several compounds sponsored by HUTCHMED (China) Limited and affiliates
- Phase 2 and 3 clinical trials sponsored by Puma Biotechnology, Inc. across Europe, Asia and the Americas, including observational study work
- Several Phase 1 clinical trials and studies sponsored by various clients including Aduro Biotech, Inc., Epizyme, Inc. and Teneobio, Inc and affiliates
- Several Phase 2 clinical trials sponsored by various clients, including Regenacy Pharmaceuticals Inc., Tesaro Inc. and Sojournix, Inc.
- Several Phase 3 trials sponsored by Tesaro, Inc in collaboration with European Network of Gynaecological Oncological Trial Groups
- Phase 4 global clinical trial sponsored by Portola Pharmaceuticals, Inc.
- Multiple global clinical trials across various phases sponsored by Deciphera Pharmaceuticals, LLC, including multinational Phase 3 trial involving 100 sites in Americas, Europe and Asia Pacific regions
- Medical device study work for Palette Life Sciences-AB

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COMMUNITY

Nirosha supports a range of children's services in the UK, acting as an independent volunteer, return interviewer and children's advocate for the National Youth Advocacy Service (NYAS) and Reconstruct. She also supports the England Korfball Association as the child protection officer for Oxfordshire Korfball Association.

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