

# Nanomedicine & Healthcare

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## Biomarkers evaluation in clinical trials: Important factors for success

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**B**iomarkers translational research in clinical trials that lead to potential diagnostic and/or prognostic applications require the implementation of certain key factors that will be discussed and illustrated with concrete examples.

### Speaker Biography

Miriam Moscovitch-Lopatin, PhD, PMP: NCRI Biorepository Lab Supervisor, Neurology at Massachusetts General Hospital Assistant; Instructor in Neuroscience at Harvard Medical School. Dr. Moscovitch-Lopatin was the Program Manager for the Huntington's Disease (HD) Biomarkers Program and directed proteomic biomarkers translational research, validation, and GLP deployment in clinical studies, as well as major aspects of the MGH' HD biorepository. Her major focus has been measuring different species of mutant and normal Htt proteins in tissues and biofluids from

preclinical and multicenter clinical trials. She has demonstrated the feasibility of using huntingtin (including the novel detection of oligomeric mutant huntingtin -mHtt) as a pharmacodynamic marker and showed that CSF and plasma levels of several mHtt species are highly correlated with each other and with some clinical outcomes. She recently co-developed with scientists at Quanterix the first ultra-sensitive Simoa assay for quantifying low levels of BDNF in CSF samples from HD patients for use in BDNF stem cell repletion therapy. Prior to her current position, Dr. Lopatin directed the development of qualification and release of personalized vaccines against Follicular Non-Hodgkin's Lymphoma at Biovest/BioVax and conducted pre-clinical research in transplantation immunology as an Instructor in Medicine at Harvard Medical School/BIDMC. Dr. Moscovitch-Lopatin holds a Ph.D. in Immunology from the Weizmann Institute, Rehovot, and a BSc and MSc in Life Sciences and Microbiology/Immunology from the Hebrew University, Jerusalem, Israel and she has a Project Management Profesional (PMP) certification..

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