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# 11TH WORLD DRUG DELIVERY SUMMIT

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## Challenges in evaluation of nanomedicine pharmacokinetics and generic bioequivalence

The success of nanomedicine (NM) drug delivery platforms relies upon their ability to influence drug disposition. Therefore, pharmacokinetic evaluation of NM is crucial to optimizing formulation properties and understanding how these properties result in therapeutic benefit. Comprehensive pharmacokinetic evaluation of NM requires quantification of several drug species, including NM encapsulated and encapsulated drug, and in some cases free and protein bound forms of the encapsulated drug as well. Indeed, the pharmacokinetic complexity of NM adds substantial difficulties to traditional pharmacokinetic and bioequivalence studies. This presentation will address the importance and challenges of monitoring the disposition and *in vivo* integrity of nanotechnology platforms, highlighting potential problems with current bioanalytical techniques, and introducing a new stable isotope tracer methodology currently under evaluation through a partnership between the FDA and NCI.

### Biography

Stephan T Stern is Acting Deputy Director and Senior Principal Scientist at the National Cancer Institute's Nanotechnology Characterization Laboratory (NCL), located at the Frederick National Laboratory for Cancer Research in Frederick, Maryland. The NCL assists in all phases of the nanomedicine drug development process, from early preclinical to late stage clinical trials, working with academic laboratories and the pharmaceutical industry. At the NCL, he oversees nanomedicine pharmacology and toxicology. Data generated from these studies support formulation optimization, regulatory filings, and environmental risk assessment. His research interests include novel drug formulation, bioanalytical method development, and pharmacokinetic modeling. Prior experience includes a postdoctoral fellowship at the University of North Carolina - Chapel Hill in the division of drug delivery and disposition, and curriculum in toxicology, and work within regulated areas of the pharmaceutical industry. He received his BS degree in biochemistry from the University of Rochester and his PhD in toxicology from the University of Connecticut at Storrs. He is a Diplomate of the American Board of Toxicology.

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