

Human Health & Medicine Breakout Session 2

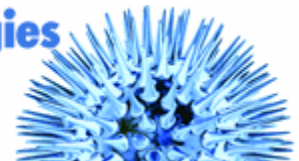
Scott McNeil, Laurie Locascio, Dae Won Moon, Mr. Park, Marty Fritts, Alan Steele, Tom Campbell, John Lang, John Garrett, Daniele Gerundino, Kenneth Dawson, Peter Hatto



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Existing documentary standards

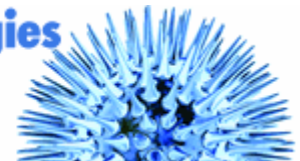
- USP, ISO, ASTM, OECD, ISO 10993 series (18-19)
- Not documentary standards but may be leveraged to develop standards - NCI/NCL (ncl.cancer.gov), ILS (Interlaboratory standardization) methods
 - NCI/NCL assay cascade includes methods for physical characterization, in vitro characterization and in vivo characterization



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Scope

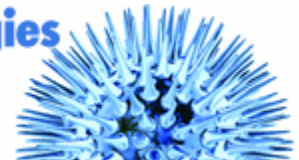
- Nanomaterials in medicine (nanomedicine, nanotherapeutics, nano in medical devices)
- In the standards arena, there are many shared issues between nanomaterials deliberately delivered to the body and nanomaterials to which one is accidentally exposed



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Framework

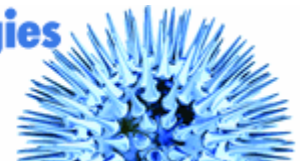
- Tiered approach - different levels of standards should be considered depending on exposure route and exposure level (incidental, medical)
- Obviously, nanomedicines must go through very rigorous processes and regulatory procedures that are dictated by country



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Documentary Standards Needs

- Short term (less than 2 years)

WHAT DO WE NEED?

- Protocols for pharmacokinetics - ADME Tox (absorption, distribution, metabolism, excretion) - high priority in OECD
- Define a minimum set of measurements - size, zeta potential (surface charge), solubility - predictor of toxicity?
- Particle characterization protocols for nanohealth - ones that take into account the biological coating (MALDI, SIMS)
 - Methods for analysis of surface conjugated layers
- Toxicology screening tests - good or bad for human health
- Methods to determine NM stability in biological matrices
- Standards for delivery for NMs - route of exposure

HOW CAN THIS BE ACCOMPLISHED?

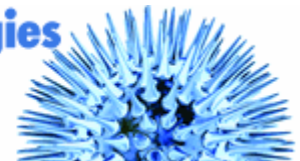
- Most should be Publicly available standard or technical report in short term to support community with best practices



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Documentary Standards Needs

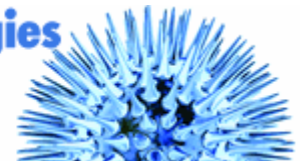
- Medium term (2-5 years)
 - More protocols for pharmacokinetics- ADME Tox
 - Methods for in vitro/in vivo measurement of nanomaterials and cell interaction
 - Define a minimum set of measurements - size, zeta potential (surface charge), solubility - predictor of toxicity?
 - Standards for bioconjugated surface layers



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Documentary Standards Needs

- Longer term (> 5 years)

currently lacking in empirical data to support these

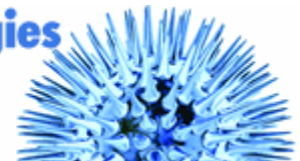
- Methods to determine efficacy
- Methods to determine pharmacokinetics of particle (particokinetics or toxicokinetics)- stability and fate in vivo
- Methods to evaluate intracellular or extracellular trafficking
- Protocols to measure stability of NMs in vitro and in vivo
- Methods for NM analysis in cells and tissues
- Methods to determine response of biosystems to NMs (identify endpoints-imaging, biomarkers)



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Measurement Needs

Existing methods/tools

- Many disparate efforts, NCI-NCL laboratory specifically for nanohealth applications (from characterization through in vivo)

New methods/tools needed for:

- Surface stoichiometry (ratio of proteins adsorbed)
- Surface biofunctionality (bioactivity)
- Epitope map (mapping small units of peptides with bio activity)
- In vivo imaging of NMs
- In vivo measurements of distribution
- Cross imaging modalities (modeling)

New Tools needed in:

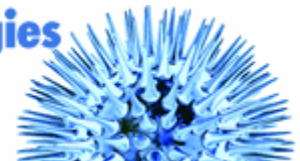
- Separation science
- Modeling
- Imaging (CARS, Neutron imaging, attosecond science for tomography at nm scale)



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Barriers

Need for

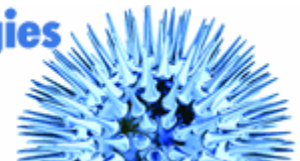
- Basic research and validation of ADME Tox protocols for use in nanohealth
- In vivo characterization methods to track unlabeled materials
- Regulator adoption of standards



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Resources

- Existing resources
 - Oodles but never enough and not here
- Resource challenges
 - Strategic coordination for documentary standards, materials, and validation
 - Funding that spans globe/ international funding for standards & validation efforts
 - Who pays?



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