

Pre-Clinical Breakout session

Presenter

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**Project 1: Nano-Periodic
Patterns for Predicting
Risk/Benefit Boundaries**

Issue to be Solved

- **Issue Category:** Development of predictive nano-periodic risk/benefit parameters for two major “well defined” nano particle categories;
- **Soft Matter Nanomaterial:**
 - Dendrimers; 0-D/1-D
- **Hard Matter Nanomaterial:**
 - Silica Nanoparticles; 0-D/!-D

Project Description

- *Determine nano-periodic behavior patterns for*
- *Solubility Enhancement (Nano-Excipient Properties)*
- *Aggregation Propensity*
- *Membrane Transport:*
- Oral (Caco-2 cells); Gut
- Topical (Keratinocytes); Skin
- *Physiological Retention/Excretion*
- Oral
- IV
- **As a function of “critical nanomaterial design parameters”(CNDP);**
- (a) Size,(b) Shape, (c) Surface Chemistry, (d)Flexibility

Expected Results (applicability)

- **Output**

- Develop critical nano periodic patterns that will guide; (a) benefit optimization and (b) risk avoidance for two major “well defined” nanomaterial categories
- **How the outputs will address the issue**
- *Manufacturers:* Allow better pre-clinical nano prototype design to avoid later consequences
- *FDA:* Cost-effective and efficient review turnaround

Critical Study Design Elements and Data Output Elements

- **Design**

- Systematic examination of structure controlled nanomaterials :
 - Sizes: 1-100 nm
 - Shapes: 0-D/1-D
 - Surface Chemistries: (a) Hydrophilic/Hydrophobic (b) Anionic, © Cationic
 - Flexibility: Soft Matter vs. Hard Matter Nanomaterials
 - **Analytical Monitoring:** Micro-PET , radio-labels, fluorescence, confocal microscopy, electrophoresis, ,HPLC/SEC chromatographies, etc.
 - **Output**
 - Broad spectrum of size, shape and surface chemistry measurements carried through to open literature access associated with important nano material performance features.
 - Quantitative models

Timeline/ Level of Effort

- **Timeline** (roughly: initiation to completion)
 - ~3 years
- **Level of effort** (roughly: \$250k/year)

Project 2:

Issue to be Solved

- **Issue Category:** Uncertainty reduction
- (narrative)

Expected Results (applicability)

- Output
- How the outputs will address the issue

Critical Study Design Elements and Data Output Elements and

- Design
- Output

Timeline/ Level of Effort

- **Timeline** (roughly: initiation to completion)
- **Level of effort** (roughly: \$200k increments)

Project 3:

Issue to be Solved

- **Issue Category:** Uncertainty reduction
- (narrative)

Expected Results (applicability)

- Output
- How the outputs will address the issue

Critical Study Design Elements and Data Output Elements and

- Design

- Output

Timeline/ Level of Effort

- **Timeline** (roughly: initiation to completion)
- **Level of effort** (roughly: \$200k increments)

Project 4:

Issue to be Solved

- **Issue Category:** Uncertainty reduction
- (narrative)

Expected Results (applicability)

- Output
- How the outputs will address the issue

Critical Study Design Elements and Data Output Elements and

- Design
- Output

Timeline/ Level of Effort

- **Timeline** (roughly: initiation to completion)
- **Level of effort** (roughly: \$200k increments)