

NIA Open Webinar Nanomedicine: Diagnostics and therapeutics advancing through nanotechnology

7 March 2018 1500 CET

The webinar will start at 1500 CET and we will keep participants on mute during the presentations



Welcome



- Focus on a key aspect of nanotechnology
- Combining science, business and regulatory aspects
- Today's focus on nanomedicine:
 - Diagnostics
 - Therapeutics

Agenda

- Introduction to nanomedicine
- Endomag
- Senolytic Therapeutics
- Regulatory overview

Participation

• Welcome to ask questions through chat function and we will unmute after each presentation for verbal questions, audio quality permitting



Before we start....

NIA priorities and actions for 2018

- Global Regulatory Working Group
- Nanotechnology Innovation Council
- <u>New website</u>
- Annual symposium April 10
- Expanded news open newsletter, projects newsletter
- However, always more fun as a Member.....



Devices and therapeutics

Devices:

- Any technology used to diagnose, investigate or monitor disease, handicap, injury, including non-pharmacological/immune contraception.
- Spans diverse technologies, plasters, MRI machines, lab-based diagnostics, injectable imaging materials.
- Can be mechanical or biological, implantable, *in vitro* etc.
- Very often used internally, giving strong focus on human interaction and crossing over into need to assess like a therapeutic.

Therapeutics:

- Preventing or treating diseases in humans
- Substance or combination of substances which may be used in or administered to humans to restore, correct, maintain or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.



Role of nanotechnology

- Extremely broad applications, for same reason as nanomaterials are used everywhere
- Aim not to provide exhaustive list but look at examples of nanomaterials and their ability to advance medicine
- Healthcare is a good target sector for nanomaterials:
 - High cost of products/therapeutics, thus high early stage investment and long development times
 - Positive response to advanced technologies from patients
 - Complex regulatory pathways
 - Introduction of nanomaterials does not distort development pathway and actively adds value to evidence-based assessments
- Approved products still low yet to reach full potential



The case for nano within diagnostics and therapeutics

Nanomaterial characteristics allow significant advances for products where improvements are often incremental for performance or clinical benefit: Biological perspectives:

- Access through challenging biological barriers (blood brain)
- Altered characteristics of a therapeutic (reduced toxicity, increased solubility, faster and longer biological action)
- Smaller to interact with DNA/RNA levels
- Many therapeutics are large, complex molecules, slow to reach target, too fast/too slow for metabolism or excretion, nanotechnology can alter this
- Result improved performance of existing technologies very attractive for faster time to clinic, longer life for patent-end products, new value to off patent medicines - WINNER

Materials performance perspectives:

 Faster, improved, smaller device performances – as nanomaterials add in any sector



Drug formulation

Paclitaxel (1971) chemotherapy for breast, pancreas, lung

- Abraxane is approved product
- Paclitaxel delivered in spherical nanoform.
- Resolves solubility (insoluble in water), significant reduction in side effects over previous formulations

Doxorubicin (1974) chemotherapy for breast, ovarian bladder, leukaemia, often in combination

- Caelyx is approved product
- Pegylated Liposomal delivery
- Liposomes with nanostructure allow better delivery and can be tagged to be tumour-specific. Better accumulation at tumour and reduced cardio-toxic side effects



Formulation (2)

Sirolimus (1999) Immunosuppressive agent for post transplant organs

- Rapamune is approved product
- Nanocrystal colloidal nanodispersion with reduced particle size
- Greater stability of product plus improved bioavailability

• Contrast reagents for imaging

Industries Association

- Materials for implants smaller, more durable
- Improved delivery of insulin and protection of pancreatic islets
- Delivery to previously unreachable parts of the eye, potential clinical impact in retinitis pigmentosa
- Enhanced formulation of anti-bacterials to increase efficacy and reduce development of resistance
- Tissue engineering nano-porous scaffolds for biologized implants



The future is bright

Healthcare is a significant target application for nanomaterials and nanotech:

- Many patent-end technologies can be re-invigorated without full development costs of novel therapeutics
- Better diagnostics has impact on therapeutics efficacy and clinical impact
- Successful products where clinical unmet need OR significant advances over current gold standards
- For human assessment, already processes in place
- Nanomaterials can advance where interventions can take place diagnostics and treatments outside hospital setting
- Costs can be saved throughout healthcare pathway: earlier diagnosis, better disease management, fewer side effects, less invasive surgery, fewer sick days, less hospital time
- Many existing nanomaterials could be applied into healthcare not about novel materials into novel medicines



Useful resources

- European Medicines Agency
- US Food and Drug Administration
- EU Observatory for Nanomaterials
- European Technology Platform for Nanomedicine





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