EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1st International Workshop on Nanomedicines

Way forward

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What we learned

- The current regulatory framework based on benefit/risk approach and including risk management plan and environmental risk assessment, is adequate for the development and evaluation of current "nano" applications in pharmaceuticals.
- New methods are accepted to complement the relevant existing guidelines and new features will be assessed as they emerge.
- Nanomedicines are not a homogenous group, but specialised functional systems engineered at a nano-scale with variable complexity
- Current regulatory experience allows the assessment of many aspects of nanomedicines, but there is a scientific gap between the current knowledge and the more advanced and emerging nanomedicines: gaps for scientific research to fill.

Challenges (1/2)

- Scientific understanding of the interaction between cells and nanomedicines in biological systems is rapidly evolving: immunological, metabolic and pharmacological activity enriched by novel and additional physical/chemical dimensions is linked to how cells "see" and respond to "nano" properties.

- The ways we look at and act on health and disease may change due to emerging and advanced applications of nanotechnology: so might the ways we develop, approve and use medicines.

Challenges (2/2)

- Previously un-attainable effects impacting on the paradigm of future medicines: requirements underpinning the established benefit/risk methodology need to adapt and evolve accordingly.

- Nanotechnology is developing globally, quickly and across many applications: continued dialogue is essential for regulatory scientists to keep pace with innovation and relevant new assessment methods.

Way Forward (1/2)

1. Facilitate early scientific dialogue and knowledge transfer among Regulatory, Academic and Industrial innovators

2. Dedicate international workshops to:
    a) monitor the scientific progress of emerging nanomedicines
    b) engage civil society
    c) anticipate needs for patients and society
    d) create a common language to communicate complex science

3. Extend the expertise available to regulators to
    a) identify risks and opportunities early
    b) support novel methods qualification
    c) provide high quality scientific advice
    d) support MAA data evaluation
    e) develop tools for risk assessment and minimization

Way forward (2/2)

4. Expand multidisciplinary regulatory platforms to
   a) share regulatory understanding and activities
   b) learn from neighbouring frameworks
   c) promote convergence on requirements
   d) master borderline aspects

5. International focus groups to share experience and debate regulatory science with the community

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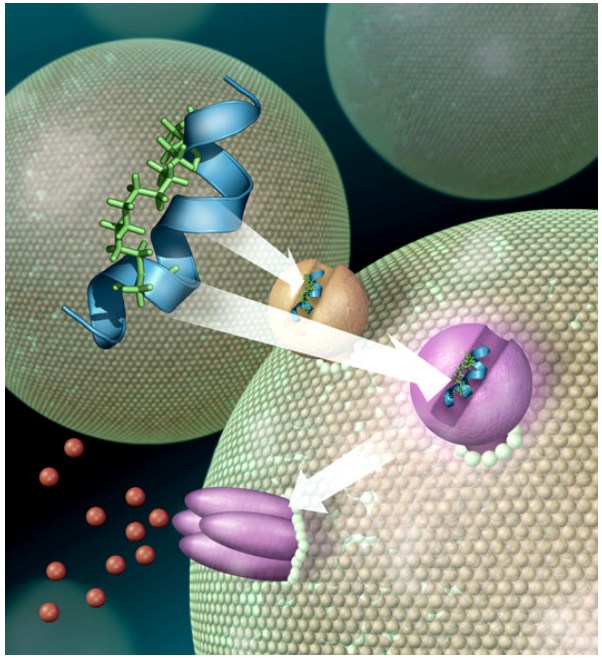
- To the Speakers & Chairs
- To the Participants
- To the Workshop organising team



"Stapled peptides selectively bind targets and trigger liposomal release." Eric D. Smith

Dana-Farber Cancer Institute