

Nanotherapeutics for patients

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ETP
Nanomedicine



COCIR's Objectives

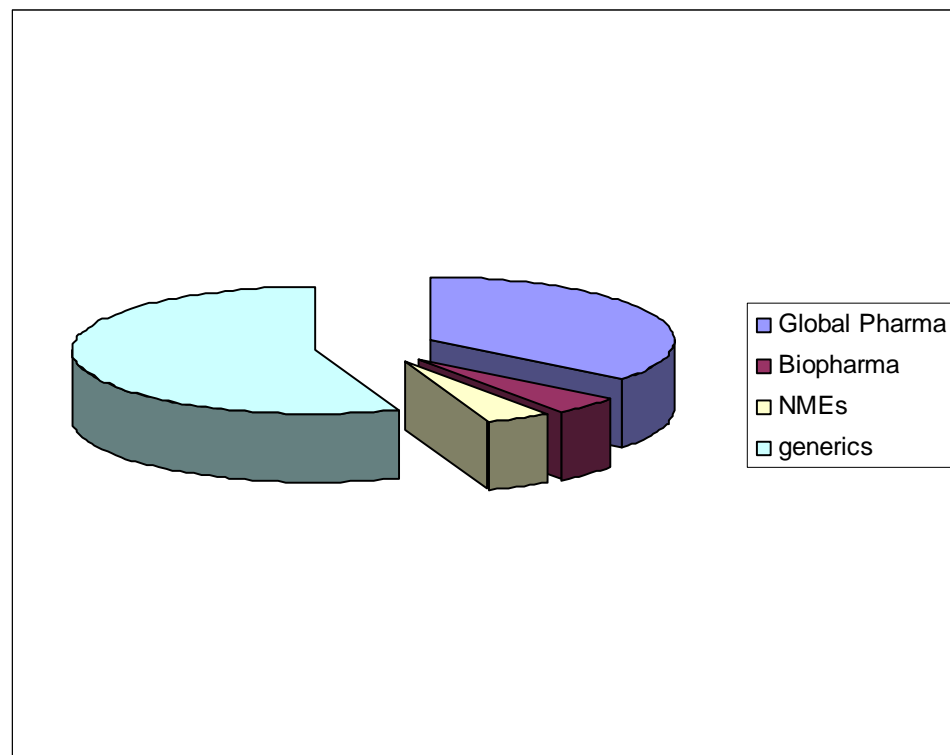
- Disease Prevention - Vaccines
- Patient Focused processes – Patient centricity
- Leverage IT – Structure prediction software
- Accelerate medical methods & Technologies –



- Exploiting advances in flow synthesis and biology at the microfluidic scale
- Funded by Pfizer, UCB and Technology Strategy Board (UK Government)
- Value based outcome focused reimbursement –

This has accelerated drug innovation in the sector including
Nanomedicine

Value based outcome focused reimbursement



- 2008 Global Market \$820bn Scrip
- 2009 Generic sales \$270bn → \$500bn 2015 Scrip 3439

Radical Innovation is good for patients

*When the promise of the opportunity is very large, and the concomitant risk and uncertainty of the opportunity are high, this is **radical innovation***

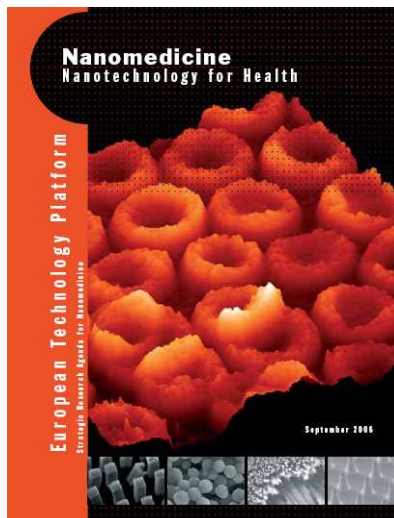
- There is more pressure for Pharma to adopt radical innovation – balanced by regulation
- Radical Innovation has come in in the past from SMEs and academia e.g. the Biotech revolution
- The Biotech Industrial model is being replaced by Open Innovation
 - It is essential than Academics and SMEs understand the change

Improving knowledge and communication

- An understanding of the implications of Open Innovation
- Each applied academic department developing an industrial liaison & two-way communication policy
- For more thoughts join the ETP

Nanotechnology applications for sustainable health care— latest progress and future of drug delivery

2006



2009

Selection of
Translatable
Technologies to
Help Patients ...and
the industrial
Sector

The Consequences of *Laissez faire* for the EU? 2006-2009

- Much Nanomedicine research has not been translated to benefit patients and industry
- European Industry is not able to take advantage of the academic sector
- Translatable areas are likely to be championed elsewhere.

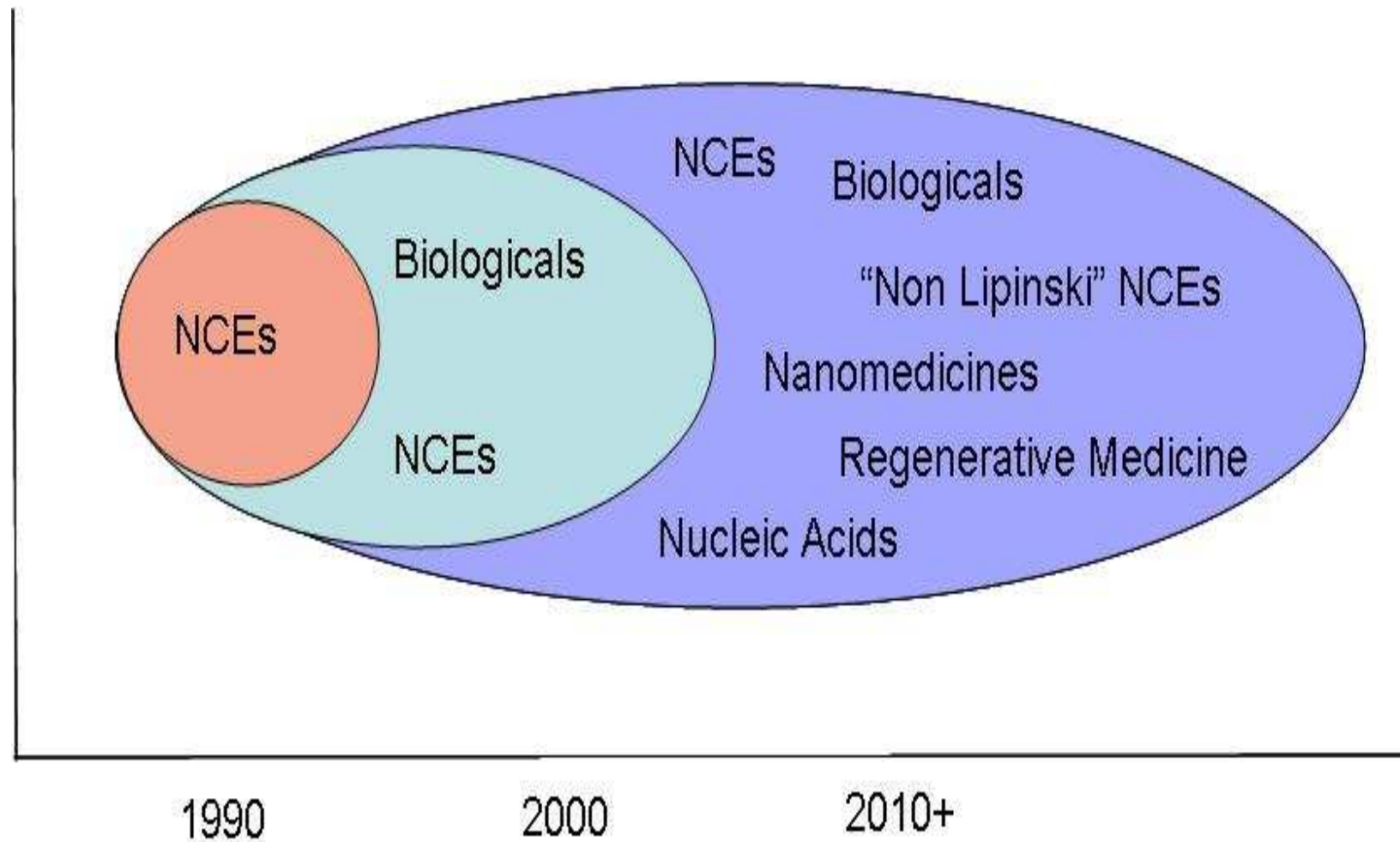
Funding the right translatable nanomedicine programmes

- Many options were identified in the SRA
- With the passage of time it is clear that some are more industrially favoured over others
- It is hoped that the winners and losers with the rationale will be identified in a detailed update to the SRA later in 2009

Field needs to.....

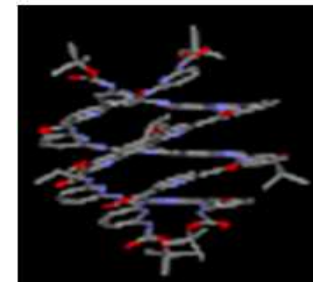
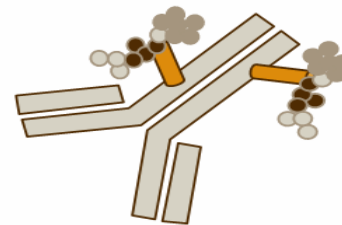
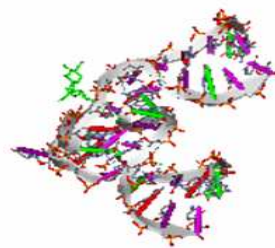
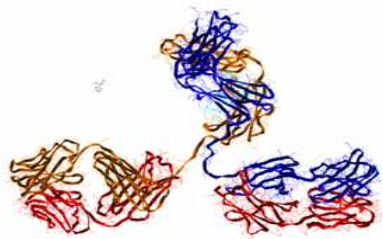
- To improve knowledge and communication between stakeholders
- Fund the right translatable nanomedicine programmes
- Improve the Review of Proposals
- Improve the design of European and National calls

Diversification of "Drug Space" after Biotech



Nanodelivery Vectors for Large Molecules

- Pressure is on to increase market for Biologicals
- DNA/RNA therapeutics will not impact patients without delivery tools
- There are many macromolecular “non-Lipinski” – chemical entities being researched which need delivery



Example 1 - Industrial Need for Macromolecule Delivery

- **Nanoencapsulation technologies which have a significant payload and capable of transport through biological barriers.** Such particles to be biocompatible and acceptable to regulatory agencies i.e. not retained in the body even if inert. Particles should be relatively inexpensive, manufacturable and although stable capable of delivering a therapeutic effect.
- **Transporters or technologies capable of moving nanoparticles across biological membranes, tissues or organs** at a capacity such that therapy can be effective. For proteins this could be 10mgs per day orally for example.
- **Choice of delivery route or barriers to be crossed.** Oral, Pulmonary, Blood Brain Barrier
- **High bioavailability of macromolecule** >>10%.
- **Choice of therapeutic modality.** This could include small molecules, proteins, antibodies, nucleic acids, peptide mimetics, PNAs, foldamers, “non-Lipinski” molecules and possibly materials that require some external activation such as ultrasound. Small molecules have normally good bioavailability and expensive delivery technologies may not be reimbursed making them probably a lower priority?
- **Theranostics - to do or not to do?**

Prognosis

- Nanopharmaceuticals is/will be an important growing industrial sector
- Current value difficult but ~€10bn

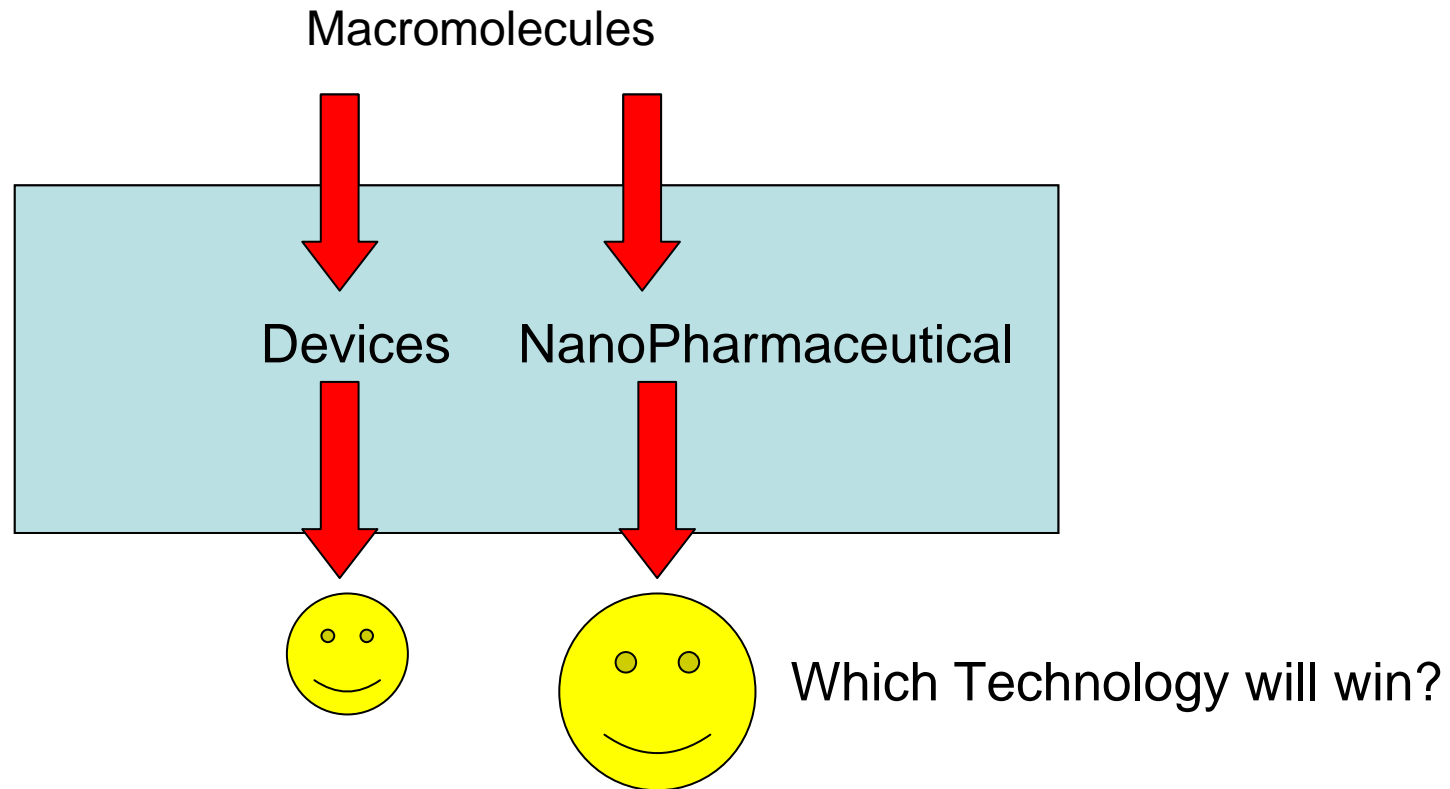


Terry,
living with Parkinson's disease

What about other Delivery Systems – Blue Sky?

- Such systems must have a likelihood of being accepted by regulators and not introducing new barriers (DMPK/toxicity/Pharmacology) without clear advantages.
- Not simply a case of toxicity but analytical & DMPK
- TiO₂, Silica, Cadmium, Cobalt, CNT, Gold
Polymers are they translatable to the market
- The key questions need to be answered early and not at the end of expensive research. Otherwise not translatable or **fundable**.

Example 2 - Devices for Macromolecule Delivery



Devices

- **Technology Breakthrough Areas**
- low cost nano hollow needle arrays
- metering systems for drug delivery
- Stability of drug payload
- Immunogenicity/ biocompatibility of device and contents
- Micro/nano electronic devices for disease control e.g. CNS
- Sophisticated external positioning and activation devices MRI/FU which also produce regulatory challenges - device and drug
- No pain and perhaps needle less
- Devices with internal or external monitoring of therapy
- **Clinical Benefit**
These systems could offer pain-free safe delivery of macromolecules at home provided the **device costs are low (<2€)**

Example 3 - Industrial need for better *in silico* predictions

- Computation tools. Our current software are not adequate. At stake here are faster drug design and less animal testing.



Sten,
living with restless legs syndrome

© UCB

The Opportunities

- To produce a win – win symbiotic culture which can show the world how it should be done
- To target really original research areas leveraging industrial know-how



Frieda,
living with diabetic neuropathic pain

Thank You for your attention

