Exploring the quantitative dimensions of the economic impact of nanomedicine

International Symposium on Assessing the Economic Impact of Nanotechnology

OECD
&
U.S. National Nanotechnology Initiative

Hosted by
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The ETPN

- The European Technology Platform (ETP) is an “instrument” initiated by the European Commission to foster strategic initiatives and networking of European industrial companies and other actors in specific fields of technology.

- Core activities of ETPs consist of creating visions, setting-up strategic research agendas, initiating new projects and incorporating their member’s interests in political processes.

The ETP members

Institutions

EUROPEAN COMMISSION

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The ETP Public members

The ETP Public members

… and many more!

ETP Organization:
3 technical working groups / 3 joint advisory groups

Nano Diagnostics
Nanotechnology based diagnostics and imaging

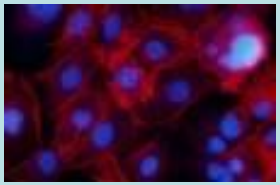
Nano Pharmaceutics
Nanotech for drug delivery, Nanodevices

Regenerative Medicine
Nanotechnology for regenerative medicine

Ethical and Social Aspects of Nanomedicine

Regulatory Framework

Intellectual Property Rights



Economic Impact of Nanomedicine

➢ Challenges

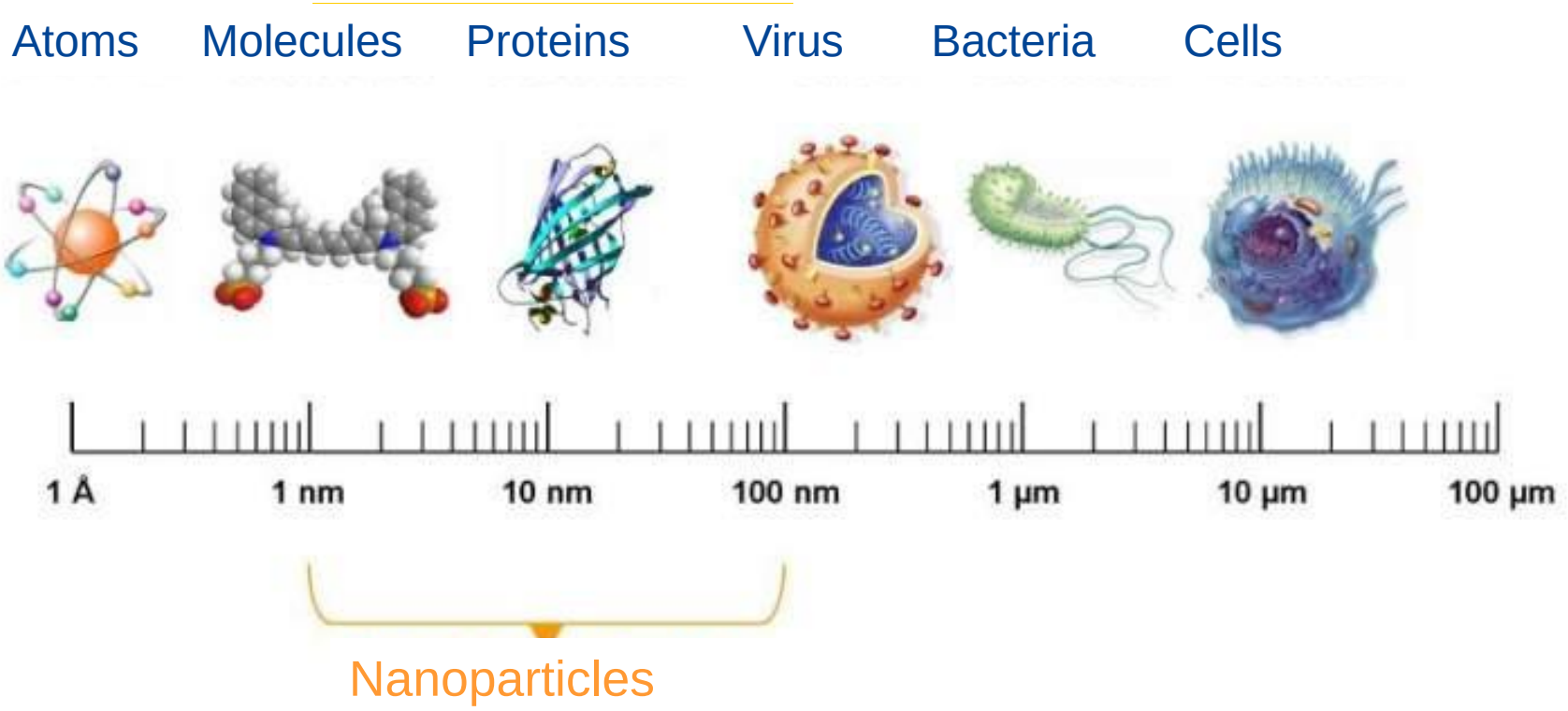
- ✓ **Lack of data:** Medico-ecomomic studies; R&D public investment contribution to the production of marketed products; comparative studies between differents healtcare models, …
- ✓ **The term Nanomedicine:** is not always mentionned, doesn't cover clearly the field of Nano applied to health: Diag & Treatment; In-vivo & In-vitro; Nanomedicine & Nano in converging technologies ….. But also Nano associated to existing solution (eg: implant coating) .
- ✓ Assessing economic impact impose to embrace the **complexity of forces that drive economic growth** and the inherent uncertainty surrounding outcomes observed at a particular point in time.
- ✓ In Healthcare, **time scale** from research to marketed products is very long , the **risk of failure** is very high, and innovation can be limited by ethic, medical practice and reimbursement issues.

➢ Assumptions

1. **Nanomedicine development is "surfing" on the transformation (on-going revolution) of medical practice and is contributing to the development of the new Healthcare Market Model**
2. Def nanotechnology: 1 nm to 100 nm*, **but some nanomedicine are up to "1,000 nm"**

***surface effects such as Van der Waals force attraction, hydrogen bonding, electronic charge, ionic bonding, covalent bonding, hydrophobicity, hydrophilicity, and quantum mechanical tunneling. At this level,**

Nano - In the molecular range……



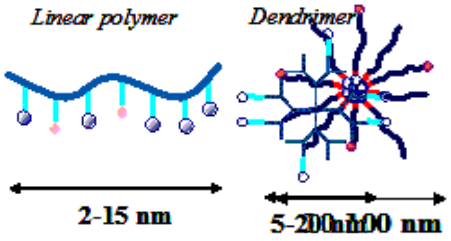
….. But

Different types of nanoparticles

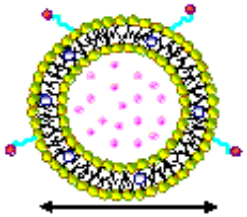
1 — 1000 Taille (nm)

Nanocarriers (for drug or contrast agent)

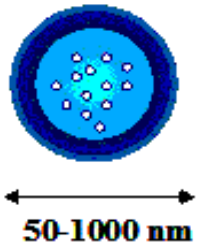
Macromolecular assemblies:



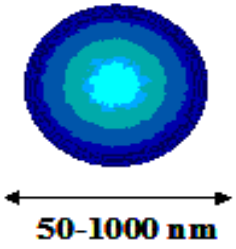
Micelles:



Liposomes:

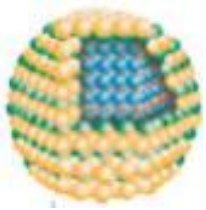


Nanospheres / Nanocapsules:

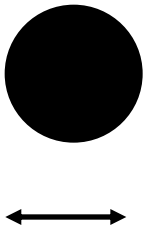


Nanoparticulate Contrast Agents

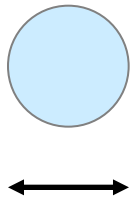
Quantum Dots (Fluorescence):



Paramagnetic and Superparamagnetic Metal Oxide Nanoparticles (IRM):

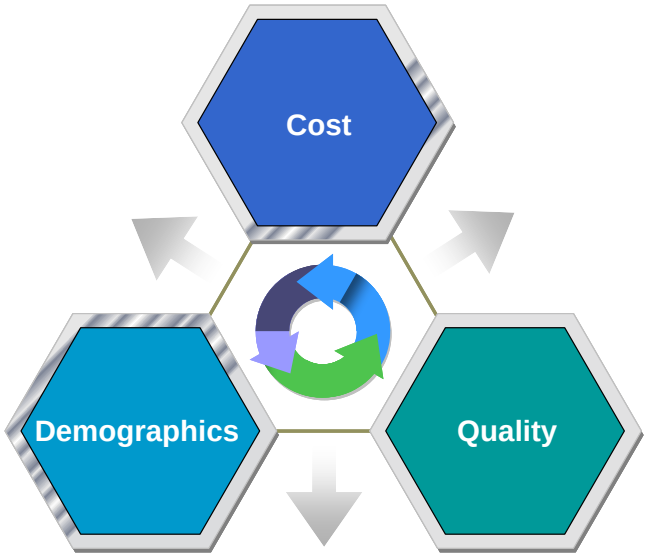


Gas Bubbles (echography):



Healthcare Is Challenged By Three Interlocking Crises That Make Present Healthcare Systems Unsustainable

- Healthcare is challenged by three interlocking crises that make present healthcare systems unsustainable:
  - ☑ **Rising costs**
  - ☑ **Changing demographics**
  - ☑ **Quality**



The Size of the Problem – Quality

- **15%** of patients admitted to hospital suffer an adverse event.
- **8%** of adverse events result in death.
- **6%** of adverse events result in permanent disability.
- **10-20%** of all adverse events are caused by medication errors.
- **10-15%** of hospital admissions occur because providers do not have access to previous care records.
- **20%** of laboratory tests are requested because the results of previous investigations are not accessible.

Outcome of the old model of R&D

Patient response rates to majors drug therapies

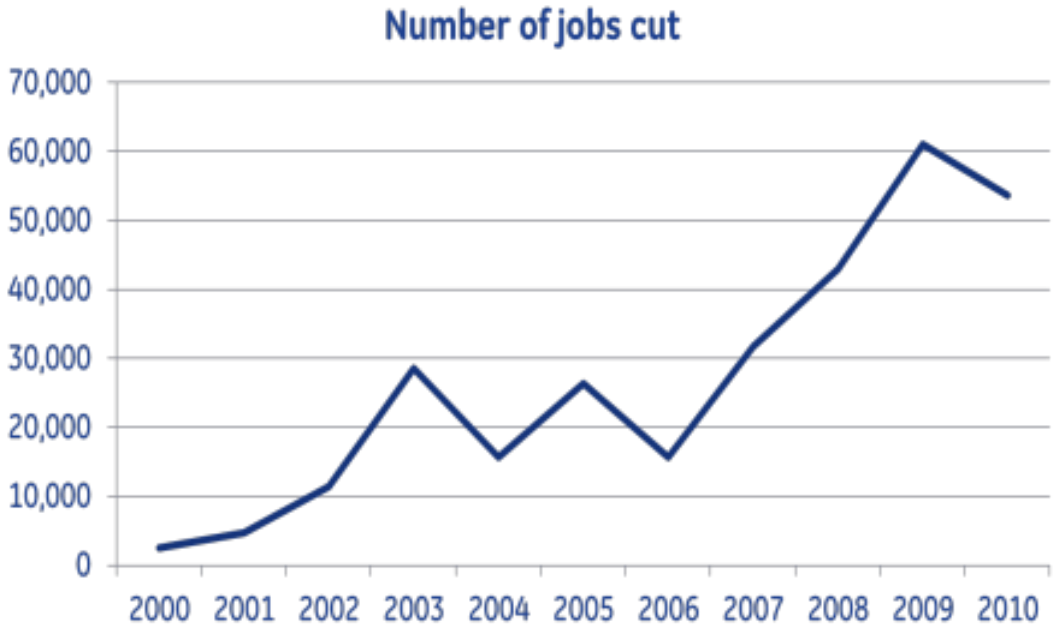
Category of Disease	% who respond to therapy
Analgesics for pain (Cox-2 inhibitors)	80%
Asthma	60%
Cardiac Arrythmias	60%
Schizophrenia	60%
Migraine (acute)	52%
Migraine (prophylaxis)	50%
Rheumatoid Arthritis	50%
Osteoporosis	48%
HCV	47%
Alzheimer's Disease	30%
Oncology	25%

The fundamental driver of high costs & quality issues is the inconsistency of healthcare delivery & outcomes from region to region, state to state, & even hospital to hospital. Such variance is bad for your health & the healthcare system as a whole

Source: Physicians' Desk Reference

A Decade In Drug Industry Layoffs

Since 2000, the pharmaceutical industry has cut ~ 300.000 jobs
(eq. Pfizer, Merck & GSK combined).*



- *Of course:*
  - *some hired back by other Pharma*
  - *also big mergers are one reason for the cuts.*

The Health industry search a new business model or even more lay offs will occur

→ Personalized Medicine & Targeted Therapy
→ From Blockbuster to Niche Buster
→ Nanomedicine is part of this model

***Source: Challenger, Gray & Christmas, Inc. ©**

Healthcare Trends: 'Early Health'

Clinical Convergence: Personalized Medicine/Targeted Therapy

- Diagnostic tests (in-vivo and in-vitro)
- Diagnosis linked to therapy
- Convergence of pharma and diagnostic industries

Toward Patients

- Increased patient responsibility and power

Toward Prediction

- From post-symptomatic diagnosis to pre-symptomatic screening
- Genomic revolution and molecular imaging

Productivity Driven

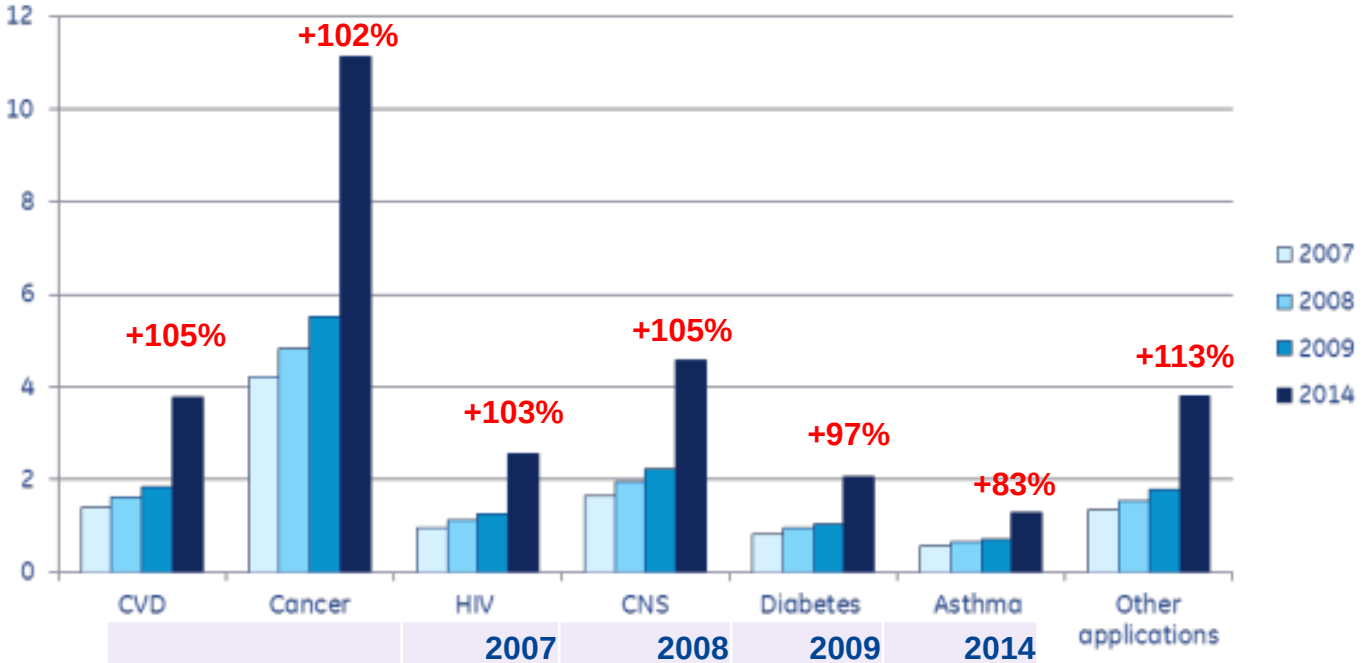
- Payors demand rigorous cost/benefit analysis and health technology assessments

Information Driven

- Integrated, accessible, personalized and actionable patient information

PERSONALIZED MEDICINE,

Global Sales by Therapeutic Area Through 2014 ($ BILLIONS)



	2007	2008	2009	2014	
CVD	1.39	1.61	1.84	3.78	
Cancer	4.23	4.82	5.53	11.12	
HIV	0.96	1.11	1.26	2.57	
CNS	1.66	1.95	2.23	4.57	
Diabetes	0.83	0.95	1.05	2.07	
Asthma	0.56	0.64	0.71	1.3	
Other applications	1.34	1.53	1.78	3.79	
Total	10.97	12.61	14.4	29.2	+103%

Source: BCC Research

The ROI for Targeted Therapies
Personalized Medicine Clinical Case Study Examples

Literature Clinical Case Studies	Action	Costs	Outcomes
Personalized Medicine Adverse Event Avoidance: Warfarin An anticoagulant long used in treating blood-clotting problems in cardiovascular disease, cancer, and some surgical procedures. Difficult to dose due to great variation in individual responses to the drug (effective doses range from 0.5mg to 60 mg/day).	Prior to genetic testing, trial-and-error dosing was the norm, sometimes with serious consequences; under-dosing of Warfarin could lead to strokes, and over-dosing could lead to severe and even fatal hemorrhages.	**Genetic testing** to guide Warfarin dosing could avoid 85,000 serious bleeding events and 17,000 strokes annually in the U.S. Treatment cost estimates in 2006 were as follows: Cost per severe bleeding event is approximately $13,500. Cost per stroke is $39,500	**The estimated potential annual health care cost savings** from individual dosing of Warfarin based on genetic testing are **$1.1 billion with a range of $100 million – $2 billion for the U.S. health care system.**
Personalized Medicine Decreases Costs Associated with the Life Course of a Disease – Gleevec (Imatinib) A molecularly targeted drug approved in 2001 for the treatment of chronic myeloid leukemia (CML). Each year, 4,500 Americans are diagnosed with CML.	Targets tumor protein in cancer cells, avoids damage to healthy tissue	Treatment Cost of CML **disease progression** is as follows: Chronic phase inpatient: $998/day Accelerated phase inpatient: $1,400/day Blast crisis: $1,433/day.	Although long-term outcomes for control of CML are not known, **Gleevec** prevents progression of CML, **prevents future treatment costs, and improves quality of life** for affected individuals.
Personalized Medicine Impacts the Cost of Care: HIV/AIDS – Genotype Analysis Resistance Testing (GART) For individuals with HIV/AIDS, resistance to highly active antiretroviral therapy (HAART), the current standard of care for HIV, is associated with disease progression and death.	GART results allow physicians to determine the ideal regimen of therapy, based on an individual drug resistance profile. GART is a personalized medicine diagnostic that determines how an individual will respond to drugs used in HAART.	**Cost of care** (physician visits, diagnostic tests, treatments, and inpatient care) for individual with HIV is $8,427/6 months; costs for an individual who has AIDS is $10,893/6 months – a greater than $2,000 savings over six months for every person with HIV whose disease does not progress to AIDS.	Employing **GART in HIV improves life expectancy**, reduces the number of cases that progress to AIDS, and also increases life expectancy by nine months **compared** to HAART therapy **without resistance testing**.

Source: Deloitte Center for Health Solutions

Nanomedicine Represent a Huge Promise for Health Care & is part of the Personalized Medicine

Earlier diagnosis increases chances of survival. By the time some symptoms are evident to either the doctor or the patient, it may be already too late.

- Conventional medicine is reactive to tissue-level problems that are happening at the symptomatic level. Nanomedicine can diagnose and treat problems at the molecular level inside single-cells, prior to traditional symptoms.

- Conventional medicine is not readily available to much of humanity because it is labor-intensive and that labor is sophisticated and expensive. Nanomedicine can be much more preventive, comparatively inexpensive because it will minimize use of expensive human experts, and can be more readily mass produced and distributed.

Some ways that nanotechnologies will impact on healthcare

- Greatly improved "directed therapies" for treating cancer & CardioVascular diseases using new nano- drug/gene delivery systems
- Tiny implantable devices to monitor health.
- Tiny implantable devices with nanobiosensors to treat chronic diseases *(diabetes, cardiovascular, arthritis, Parkinson's disease, Alzheimer's disease,…)* with fewer side-effects.
- New point-of-care and home healthcare devices.

MARKET POTENTIAL

- **The nanomedicine market is in early growth.**
  - ✓ While nano-enhanced drug delivery products are already a commercial reality
  - ✓ more advanced nanotech-based medical devices are still in development, although some are at the clinical testing stage.

- **Most of the nanotechnology R&D investment comes from government and established corporations.**
  - ✓ US ~33% of all publications & ~ 50% of patent filings.
  - ✓ Europe VS the US: while Europe is at the forefront of research, the US leads in the number of patent filings.
  - ✓ The strong patenting activity of U.S. leads more advanced commercialization status than elsewhere.

convergence of nano & biotechnology

The convergence of nanotechnology, biotechnology & many new technologies are in progress with a high potential impact on future health and health care system on:

- Early diagnosis
- Healthcare IT
- Nanomedicine
- Smart implants
- Non invasive surgery
- System biology

Convergence is also happening in areas such as:

- scientific instruments *(nanosensors for biomarkers)*
- analytical methodologies *(quantum dot fluorescence, DNA/proteomic arrays)*
- new material systems *(biomimic materials, self assembling materials)*
- New pharma systems *(nanomedicine, nanoparticle labeled drugs, theranostics)*

44 marketed Nano-delivry products

Product	Generic	Formulation	Indication	Manufacturer
Abraxane	Paclitaxel	Polymeric nanoparticles	Cancer chemotherapy	Celgene
Abelcet	Amphotericin B	Liposomal formulation	Fungal infections	Elan/Alkermes, Enzon, Cephalon
Adagen	Adenosine deaminase	PEGylation	Enzyme replacement therapy	Enzon, Sigma-Tau
AmBisome	Amphotericin B	Liposomal formulation	Oral and perioral infections	Astellas/Gilead Sciences
Amphotec	Amphotericin B	Liposomal formulation	Oral and perioral infections	Three Rivers Pharmaceuticals/ALZA
Avinza	Morphine sulphate	nanocrystal formulation	Moderate to severe pain	Elan/Alkermes, Pfizer
Copaxone	Glatiramer acetate	Copolymer of l-glutamic acid, l-alanine, l-tyrosine and l-lysine)	Multiple sclerosis	Teva Pharmaceuticals
Curosurf	Poractant alfa	Liposome	Neonatal respiratory distress	Chiesi Farmaceutici SpA
DaunoXome	Daunorubicin	PEGylated liposome formulation	Cancer chemotherapy	Gilead Sciences
DepoCyt	Cytarabine	Sustained-release liposomes	Cancer chemotherapy	SkyePharma/Enzon
Depodur	Morphine sulphate	Liposome	Postop pain relief	Pacira Pharmaceuticals
Diprivan	Propofol	Liposomes	Induction of anesthesia	AstraZeneca
Doxil/CaelyX	Doxorubicin	PEGylated liposome formulation	Cancer chemotherapy	ALZA/ OrthoBiotech/ Schering Plough
Elestrin	Estradiol gel	Phosphate nanoparticles	Menopausal symptoms	BioSante
Elyzol	Metronidazole	Dental gel	Parodontitis	Camurus
Emend	Aprepitant	Nanocrystal formulation	Anti-emetic	Merck & Co+ Elan/Alkermes
Epaxal	Hepatitis A vaccine	Virosome technology	Prevention of Hepatitis A infection	Berna Biotech
Episil	Bioadhesive barrier	Fluidcrystal	Oral pain	Sinclair/Teva
Estrasorb	Estradiol gel	Micellar nanoparticles	Menopausal symptoms	Novavax/Espirit Pharma
Focalin XR	Dexmethylphenidate hcl	Nanocrystals	ADHD	Novartis Elan/Alkermes
Fosrenol	Lanthanum carbonate	Inorganic nanoparticles	End-stage renal disease	Shire
Genexol PM	Paclitaxel	Polymeric micelles	Cancers	Samyang

Product	Generic	Formulation	Indication	Manufacturer
Indaflex	Indomethacin	Solid lipid nanoparticles	Osteoarthritis	AlphaRx
Inflexal V	Subunit influenza vaccine	Virosome	Influenza prophylaxis	Crucell
Invega Sustenna	Paliperidone	Nanocrystal	Antipsychotic	Janssen
Macugen	Pegaptanib	Pegylated anti-vegf aptamer	Age-related macular degeneration	OSI Pharmaceuticals/ Pfizer
Myocet	Doxorubicin citrate complex	Liposome encapsulated	Cancer chemotherapy	Cephalon/Zeneus Pharma/ Sopherion Therapeutics
Megace ES	Megestrol acetate	Nanocrystal formulation	Cancer therapy	Elan/Alkermes+Pfizer+Bristol-Myers Squibb
MuGard	Hydrogel mouth rinse	Nanogel	Head and neck cancers	Access Pharma
Naprelan	Naproxen	Nanocrystal formulation	Arthritis, gout	Elan/Alkermes
Nanotax	Paclitaxel	Polymeric nanoparticles	Cancer chemotherapy	Dabur Pharma
Neulasta	Filgrastim	Pegylation	Neutropenia	Amgen
Oncospar	PEG-L-asparaginase	Pegylation	Cancers	Enzon/Scherine-Plough
Pegasys	Peginterferon alfa 2a	Pegylation	Hepatitis B, hepatitis C	Roche/Nektar
PegIntron	Peginterferon alfa 2b	Pegylation	Chronic hepatitis C	Schering-Plough
Rapamune	Sirolimus	Nanocrystal formulation	Immunosuppresion	Wyeth Elan/Alkermes
Renagel	Sevelamer hcl	Poly (allylamine) resin	Hyperphosphatemia in hemodialysis	Genzyme
Salinum	Potassium, magnesium, chlorine	Oral liquid	Xerostomia	
Somavert	Pegvisomant	Polymer protein conjugate	Acromegaly	Pfizer
Ritalin LA	Methylphenidate hcl	Pulsatile release nanocrystal formulation	ADHD	Elan/Novartis
Survanta	Beractant	Liposome encapsulated	Neonatal respiratory distress	Abbott
Tricor	Fenofibrate	Nanocrystal formulation	Lipid reduction	Abbott Elan/Alkermes
Triglide		Fenofibrate nanocrystal formulation	Lipid reduction	SkyePharma/ First Horizon Pharmaceuticals/Sciele Pharma
Verelan/ Verelan PM	Verapamil	Elan's SODAS multiparticulate technology	Hypertension	Elan/Alkermes Schwarz

Source: BCC Research

18 marketed Pharmaceutical products

Product	Composition	Indication	Company	Annual Sales ($ Millions)
Abelcet	Amphotericin B/lipid	Fungal infections	Enzon	23
Ambisome	Liposomal amphotericin B	Fungal infections	Gilead	350
Doxil, Caelyx	Liposomal doxorubicin	Kaposi's sarcoma	Ortho, Schering-Plough	360
Depocyt	Liposomal cytarabine	Cancer	Skyepharma	170
Visudyne	Liposomal verteporfin	Age-related macular degeneration	QLT, Novartis	150
Estrasorb	Estradiol in micelles	Menopause	Novavax	130
Adagen	PEG-adenosine deaminase	Immunodeficiency	Enzon	33
Neulasta	PEG-GCSF	Neutropenia	Amgen	500
Oncospar	PEG-asparaginase	Leukemia	Enzon	65
Pegasys	PEG-α-interferon 2a	Hepatitis C	Nektar, Roche	1,650
PEG-Intron	PEG-α-interferon 2b	Hepatitis C	Enzon, Schering-Plough	975
Macugen	Pegylated anti-VEGF aptamer	Age-related macular degeneration	OSI Pharmaceuticals, Pfizer	175
Somavert	PEG-HGH	Acromegaly	Nektar, Pfizer	325
Copaxone	Copolymer of amino-acids	Multiple sclerosis	TEVA	3,250
Renagel	Crosslinked poly(allylamine) resin	Chronic kidney disease	Genzyme	575
Megace ES	Nanocrystalline megestrol acetate	Eating disorders	Elan, Par	55
Rapamune	Nanocrystalline sirolimus	Immunosuppression	Elan, Wyeth	340
Abraxane	Paclitaxel protein-bound nanoparticles	Cancer	Abraxis, AstraZeneca	675

15 marketed Imaging/diagnostic & biomaterial

Product	Composition	Indication	Company
		***In vivo* Imaging**	
Resovist	Iron nanoparticles	Liver tumors	Schering, Berlin
Feridex/Endorem	Iron nanoparticles	Liver tumors	Advanced Magnetics, Guerbet
Gastromark/Lumirem	Iron nanoparticles	Imaging abdominal structures	Advanced Magnetics, Guerbet
		***In Vitro* Diagnostics**	
Lateral flow tests	Colloidal gold	Pregnancy, ovulation, HIV etc	British Biocell, Amersham/GE, Nymox
Clinical cell separation	Magnetic nanoparticles	Immunodiagnostics	Dynal/InVitrogen, Miltenyl Biotec, Immunicon
		Biomaterials	
Ceram X duo	Nanoparticle composite	Dental filling Material	Dentspley
Filtek Supreme	Nanoparticle composite	Dental filling material	3M Espe
Mondial	Nanoparticle-containing dental prosthesis	Dental restoration	Heraeus Kulzer
Premise	Nanoparticle composite	Dental repair	Sybron Dental Specialities
Tetric Evoceram	Nanoparticle composite	Dental Repair	Ivoclar Vivadent
Ostim	Nano-hydroxy apatite	Bone defects	Osartis
Perossal	Nano-hydroxy apatite	Bone defects	Aap implantate
Vitoss	Nano-hydroxy apatite	Bone defects	Orthovita
Acticoat	Silver nanoparticles	Antimicrobial wound care	Nucryst
		Active Implants	
Pacemaker	Fractal electrodes	Heart failure	Biotronik

Source: Company websites, *Nature Biotechnology* October 2006, 24:10

>70 Nanomedical Products in Clinical trials

Cardiology/Vascular Diseases

11 NCE Juvisync (sitagliptin and simvastatin); Merck; For the treatment of type II diabetes, Approved October 2011

12 NCE Sutent (sunitinib malate); Pfizer ; For the treatment of pancreatic neuroendocrine tumors, Approved May 2011

13 NCE Tradjenta (linagliptin); Boehringer Ingelheim; For the treatment of type II diabetes, Approved May 2011

Gastroenterology

14 NCE Afinitor (everolimus); Novartis; For the treatment of advanced pancreatic neuroendocrine tumors, Approved May 2011

Hematology

Neurology

Otolaryngology

31 Peptide Firazyr (icatibant); Shire; For the tre

onatology

32 NCE Gralise (gabapentin); Abbott; For the t

y/Toxicology

33 NCE Incivek (telaprevir); Vertex; For the tre

sychology

34 NBE Nulojix (belatacept); Bristol-Myers Squ

espiratory Diseases

35 NCE Victrelis (boceprevir); Merck; For the t

Musculoskele

35 NCE Victrelis (boceprevir); Merck; For the treatment of chronic hepatitis C genotype 1, Approved May 2011

14 NCE Afinitor (everolimus); Novartis; For the treatment of advanced pancreatic neuroendocrine tumors, Approved May 2011

15 NCE Dificid (fidaxomicin); Optimer Pharmaceuticals; For the treatment of Clostridium difficile-associated diarrhea, Approved May 2011

16 NCE Duexis (ibuprofen and famotidine); Horizon Pharma; For the relief of rheumatoid arthritis and osteoarthritis and prevention of gastric ulcers, Approved April 2011

17 NCE Incivek (telaprevir); Vertex; For the treatment of genotype 1 chronic hepatitis C, Approved May 2011

18 NCE Recto (nitroglycerin) ointment 0.4%; ProStrakan; For the treatment of chronic anal fissure, Approved June 2011

19 NCE Sutent (sunitinib malate); Pfizer; For the treatment of pancreatic neuroendocrine tumors, Approved May 2011

20 NCE Victrelis (boceprevir); Merck; For the treatment of chronic hepatitis C genotype 1, Approved May 2011

Musculoskeletal

36 AB Actemra (tocilizumab); Genentech; For the treatment of systemic juvenile idiopathic arthritis, Approved April 2011

37 NCE Duexis (ibuprofen and famotidine); Horizon Pharma; For the relief of rheumatoid arthritis and osteoarthritis and prevention of gastric ulcers, Approved April 2011

Nephrology/Urology

38 NBE Nulojix (belatacept); Bristol-Myers Squibb; For the prevention of organ rejection following kidney transplant, Approved June 2011

39 AB Soliris (eculizumab); Alexion; For the treatment of atypical hemolytic uremic syndrome, Approved September 2011

54 NANO Sylatron (peginterferon alfa-2b); Merck; For the treatment of melanoma, Approved April 2011

55 NCE Vandetanib (vandetanib); Astra Zeneca; For the treatment of thyroid cancer, Approved April 2011

56 NCE Xalkori (crizotinib); Pfizer; For the treatment of ALK+ non-small cell lung cancer, Approved August of 2011

57 AB Yervoy (ipilimumab); Bristol-Myers Squibb; For the treatment of metastatic melanoma, Approved March 2011

58 NCE Zelboraf (vemurafenib); Roche; For the treatment of BRAF + melanoma, Approved August of 2011

59 NCE Zytiga (abiraterone acetate); Centocor Ortho Biotech; For the treatment of prostate cancer, Approved May 2011

69 AB Actemra (tocilizumab); Genentech; For the treatment of systemic juvenile idiopathic arthritis, Approved April 2011

70 NCE Duexis (ibuprofen and famotidine); Horizon Pharma; For the relief of rheumatoid arthritis and osteoarthritis and prevention of gastric ulcers, Approved April 2011

http://www.centerwatch.com/drug-information/fda-approvals/drug-areas.aspx?mp=empty

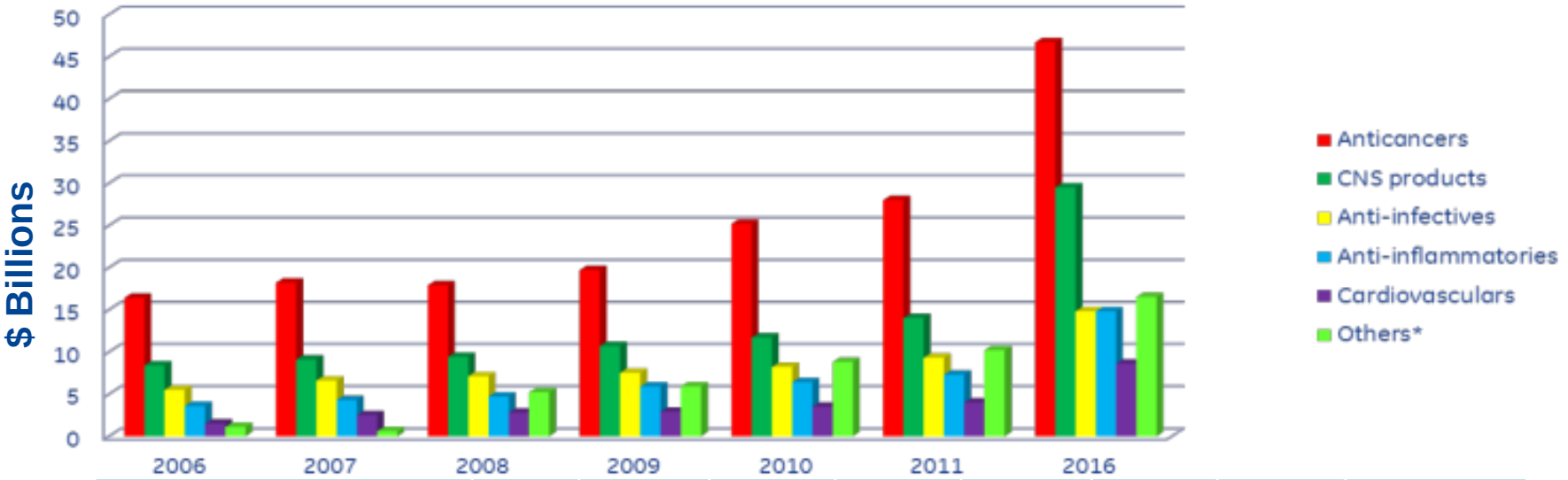
Global NanoMedicine Market, Through 2016 ($Billions)

	2008	2009	2010	2011	2016	CAGR*% 2011-2016
Global Pharmaceuticals	323.7	346.4	370.6	402.2	630.7	9.4
Total Nanomedicine market	51.1	57.8	63.8	72.8	130.9	12.5
Total nanopharmaceuticals sales	*47.1*	*53.3*	*58.6*	*66.8*	*123.0*	*13.0*
Total Nano-diagnostic sales	*4.0*	*4.5*	*5.2*	*6.0*	*7.9*	*5.7*
NanoMedicine as % of all Pharmaceuticals	15.8	15.4	15.8	16.6	19.5	

BBC Research

NANOMEDICAL:

Global Sales by Therapeutic Area, 2006-2016 ($Billions)



Therapeutic Area	2006	2007	2008	2009	2010	2011	2016	CAGR% 2011-2016
Anticancer	16.4	18.2	17.9	19.7	25.2	28	46.7	10.8
CNS product	8.4	9.1	9.4	10.7	11.7	14	29.5	16.1
Anti-infective	5.5	6.6	7.1	7.5	8.2	9.3	14.8	9.7
Anti-inflammatorie	3.6	4.3	4.7	5.9	6.4	7.3	14.8	15.2
Cardiovascular	1.5	2.5	2.8	2.9	3.5	4	8.6	16.5
Others*	1.1	0.6	5.2	5.9	8.8	10.2	16.5	10.1
Total nanomedicine sales **	36.5	41.3	47.1	52.6	63.8	72.8	130.9	12.5

*** includes: Orthopedic, wound mgt, dental, cardiac implants, …..** **** without diag**

Source BCC Research

MARKET POTENTIAL

- **Drug delivery has been the main near-term opportunity for the nanomedicine.**
  - ✓ Sales of drugs with poor solubility and low bioavailability totaled some $90 billion in 2010 *(up from $75 billion in 2008).*
  - ✓ The total estimated "nano-delivery" market already exceeded $16 billion.
- **Molecular diagnostics is the 2nd opportunity for nanotechnology.**
  - ✓ In 2010, the global market for molecular diagnostics was worth $8 billion
    - ~3% of the total diag. market
    - ~15% of the in vitro diag. market.
  - ✓ in 2010 the estimated "nano-diagnostic" market was at $5 billion.
    - significant contribution: Biochip developments and nanobiotechnology

Impact on Employment

- Of the ~ 200 companies identified being active in nanomedicine worldwide, 159 are start-ups and SMEs
- 41 major pharmaceutical and medical device corporations have nanomedicine products on the market or run development projects in which nanotechnology plays a role

Source: BBC Report

Nanomedicine: Cost Considerations

For the major cost-causing disease *(cancer, cardiovascular, neurodegenerative and musculo-skeletal diseases)*, **technology dependent costs account for a maximum of 20% of the total costs***

→ **Thus nanomedicine is likely to have a strong impact on healthcare costs:**

- **Nanomedicine can reduce future health care costs if they**
  - Aim at major cost-causing diseases
  - Reduce treatment cost, by better efficiency lower side effect *(Targeted Therapy)*
  - Reduce personnel costs ei: reduction inpatient care days
  - Contribute to "healthy ageing".

- **Nanomedicine can even increase health care costs if they**
  - Aim at diseases of minor cost relevance ei: infections
  - Come as add-on technology with an unfavorable cost-benefit-ratio

***source Farkas et al, 2004**

Cost Considerations per application

examples of Personalized medicine where in the nanomedicine can impact health expenditures

I. CV disease

- With 30% of the projected deaths the leading cause of death worldwide, *even small cost effects (positive or negative) will have a large cost impacts.*.

- Main cost drivers are intensive care for chronic patients and rehabilitation for stroke patients.
  - Potential nanotechnology innovations which may offer a cost reduction:
    - ✓ detection of unstable plaques to early identify those patients at high risk of heart attack for effective prevention strategies.
    - ✓ Or even more simultaneous detection and treatment of unstable plaques *(ETPN contribution to FP7)*

Cost Considerations per application

examples of Personalized medicine where in the nanomedicine can impact health expenditures:

II. Diseases of the nervous system:

- "nano-in vivo-diagnostic" & "nano-therapy" *(all in development)*
  - Nano-diagnostic based on NDDS can transport drugs across the BBB*.
  - Nano-Therapy can be stronger antioxidant drugs than any of the traditionally drugs.

- It's difficult to estimate the cost impact,
  - Because none of these products are marketed yet,
  - But the hope is to prolong the period without the need for expensive care and that the savings in care exceed the costs for additional diagnostics and medication.

Cost Considerations per application

examples of Personalized medicine where in the nanomedicine can impact health expenditures:

III. Cancer

- requires an average stay in hospital of 10 days in Europe.

- For cancer diagnostics and treatment, in vivo diagnostic & DDS nanotechnology can ei:
  - Reduce treatment cost: Monitor the therapeutic effects of drugs, to improve the efficiency of expensive treatments (several 1.000€/month).
  - Reduce side effects and relate cost. NDDS* can improve drug accumulation at the tumour site and in that way reduce side effects (eg: liposomal doxorubicin).
  - Improve treatment and cost such as iron nanoparticle-based hyperthermia *(significantly lower costs at equivalent efficacy)*

- However all life prolonging anticancer medicines can result in higher cost due to the occurrence of secondary tumours.

*** nanotechnology-based drug delivery systems**

European Opportunity

Building a full "Integrated European GxP Infrastructure" on an Open Innovation Model to efficiently handle the translational activity *(Academia to Industry)*

Real R&D infrastructure with trained team and facilities working according to the highest standard

- Characterization Lab *(equivalent to the NCL in the US)* open to Public and private
- Industrial prototype
- Industrialization, early manufacturing
- Tox package
- Pre-clinical development
- Regulatory
- QC
- Business development
- Research to sustain development
- Market access

From early non clinical proof of concept to end of Phase 1/Pilot Study

Thank you!