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growth analysis

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by funding *needs-driven research*
and developing *effective innovation systems*.

Through its activities in this field, VINNOVA aims to make a significant contribution to Sweden´s development into a leading centre of economic growth.

In December 2006, VINNOVA was commissioned by the Swedish Government to perform an international study to shed light on the competitiveness of the Swedish sectorial innovation systems of pharmaceuticals, biotechnology and medical technology in international comparison. The study will include analyses in three main focus areas in an innovation system perspective:

- The key players in the Swedish innovation system, who they are and their position in an international comparison
- Trends, initiatives and commitments in other countries/regions
- Comparative case studies to investigate the competitiveness of the Swedish innovation system

The main question being "What structure, growth and development capacity does the Swedish pharmaceuticals, biotechnology and medical technology industry have compared to other countries/ regions excelling in this field?"

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Two of the ”new” Sciences - Nanomedicine and Systems Biology in the United States

by

Martin A. Wikström

growth analysis

Washington D.C.

Preface

In December 2006, VINNOVA was assigned by the Swedish government to conduct an international benchmarking of the Swedish sectorial innovation systems in pharmaceuticals, biotechnology and medical technology. Case studies and international comparisons of activities in different countries are important in assessing and understanding the Swedish conditions and challenges with regard to life science research and innovation. The by far most influential country globally is the United States considering the size of the science base, R&D-investments and industry. The trends in the U.S. therefore tend to have a strong influence on the global development. VINNOVA has thus commissioned ITPS (today the Swedish Agency for Growth Policy Analysis) to analyse and describe the situation for a number of life science areas in the U.S.

This study which is one of the above mentioned studies is based on data and information concerning primarily policy trends in Nanomedicine and Systems biology.

The report is based on published studies and information, searches in databases, interviews as well as analysis of the gathered materials. The report was written by Martin A. Wikström, Swedish Agency for Growth Policy Analysis, Washington D.C. The Project Manager for the international benchmarking project is Anna Sandström, VINNOVA.

VINNOVA in June 2009

Gunnel Dreborg
Acting Director and Head, Strategy Development Division

Contents

Abbreviations of Agencies and Departments

ANH – Alliance for NanoHealth

BIS – Bureau of Industry and Securities (DOC)

CPSC – Consumer Product Safety Commission

CSREES – Cooperative State research, Education, and Extension Service (USDA)

DHS — Department of Homeland Security

DOC — Department of Commerce

DOD — Department of Defense

DOE — Department of Energy

DOEd – Department of Education

DHHS/HHS — Department of Health and Human Services

DOJ — Department of Justice

DOL – Department of Labor

DOS – Department of State

DOT — Department of Transportation

DOTreas – Department of the Treasury

EPA — Environmental Protection Agency

FDA – Food and Drug Administration (HHS)

FS – Forest Service (USDA)

FHWA — Federal Highway Administration

IARPA – Intelligence Advanced Research Project Agency

ITC – International trade Commission

NASA— National Aeronautics and Space Administration

NBA – NanoBusiness Alliance

NCI – National Cancer Institute

NIGMS – National Institute of General Medical Sciences

NIH — National Institutes of Health (HHS)

NIOSH – National Institute for Occupational Safety and Health (HHS)

NIST— National Institute of Standards and Technology (DOC)

NHLBI – National Heart, Lung and Blood Institute

NNI – National Nanotechnology Initiative

NRC – National Research Council

NSF — National Science Foundation

TSA — Transportation Security Administration

USDA — U.S. Department of Agriculture

USPTO – U.S. Patents and Trademark Office

1 Sammanfattning

Nanomedicin och systembiologi är två vetenskapsområden som växt fram under de senaste decennierna och som visar stor potential till vetenskapliga framsteg, innovationer och nya produkter. Nanomedicin kan sägas vara den biomedicinska grenen av nanoteknologi. Nnanomaterial och produkter kan i framtiden komma att användas i vitt skilda applikationsområden som exempelvis ”targeted drug delivery”, visualisering av cancertumörer och som forskningsverktyg. Systembiologi är av stort intresse bland annat då området använder sig av ett integrerat synsätt där det studerade *systemet* är i fokus. Detta skiljer det från de mer reduktioniska tillvägagångssätt som ofta används. Både systembiologi och nanomedicin är interdisciplinära och kräver kompetens inom ett flertal områden inklusive biomedicin, fysik, kemi och beräkningsvetenskaper. Den interdisciplinära karaktären demonstreras också av att ett stort antal myndigheter och organisationer finansierar forskning och utveckling (FoU) inom båda områdena.

”The National Nanotechnology Initiative” (NNI) är en ”flermyndighetsorganisation” som har uppdraget att koordinera de federala myndigheternas investeringar i nanoteknologisk FoU. Totalt består NNI av 25 myndigheter och departement varav 13 investerar i nanoteknologisk FoU. Den i särklass största federala finansiären av nanomedicin är ”National Institutes of Health” (NIH) vars investeringar görs både genom individuella institut (totalt 27 institut och centra finns inom NIH) och genom det strategiska ”NIH Roadmap”-initiativet. Allteftersom nanomedicin utvecklats som vetenskapsområde har inte bara nya vetenskapliga frågeställningar och resultat framkommit utan även frågor som rör exempelvis regleringar. Aktuella frågeställningar rör bland annat möjlig toxicitet av nanomaterial på arbetsplatser och för patienter, hur nanomaterial transporteras i kroppen och framtagandet av standarder. ”Food and Drug Administration” (FDA) och andra myndigheter som ”National Institute of Standards and Technology” (NIST) arbetar med framtagandet av regleringar och nya standarder. ”National Institute for Occupational Safety and Health” (NIOSH) arbetar med hälsa på framför allt arbetsplatser. Ett partnerskap mellan privata och offentliga aktörer för att lösa kritiska frågor för nanomedicin har föreslagits. I partnerskapet skulle bland annat FDA och andra offentliga och privata aktörer ingå. Ett stort antal FoU-initiativ inom nanomedicin föreligger vid såväl universitet som inom industrin.

FoU inom systembiologi stöds av ett antal federala myndigheter inklusive NIH, ”National Science Foundation” (NSF), ”Department of Energy” (DOE) och enheter/myndigheter under ”Department of Defense” (DOD).

Anledningen till att finansieringsbilden är så bred är bland annat att systembiologiska studier inte bara rör biomedicinska frågeställningar utan exempelvis också energiproduktion. Ett antal olika institut vid NIH och även åtskilliga initiativ inom ”NIH Roadmap” stödjer systembiologisk FoU. Ett stort antal satsningar föreligger vid olika universitet och intresset från industrin är substantiellt.

Sammantaget anses båda vetenskapsområdena ha stor nationell betydelse och det finns ett relativt starkt ekonomiskt federalt stöd för forskning och utveckling inom fälten. För nanomedicin föreligger dock ett antal frågor som behöver få sin lösning för att fältet skall kunna utvecklas väl framöver.

2 Abstract

Nanomedicine and Systems Biology are two scientific fields that have emerged during the last decades. Both field show a strong potential for scientific leaps and for new innovations and products. Nanomedicine is the biomedical branch of Nanotechnology and nanomedical products may in the future be used for many applications including drug delivery, imaging and as research tools. Systems Biology is interesting not least as it demonstrates an integrative approach to science in which studies concerns the *system.* This set is apart from the more reductionist approach. Both fields require a diverse workforce with expertise in many fields such as biomedicine, chemistry, physics and computational biology. The interdisciplinary character is also demonstrated by the large number of agencies and organizations that support research and development (R&D) in the two fields.

The National Nanotechnology Initiative coordinates the federal investments in Nanotechnology and consists of 25 agencies and departments of which 13 have a Nanotechnology R&D budget. The National Institutes for Health (NIH) is the largest federal sponsor of Nanomedicine. NIH investments are made both through individual institutes (NIH consists of 27 individual institutes and centers) and through the strategic NIH Roadmap initiative. While Nanomedicine as a scientific field is evolving, new research questions as well as regulatory issues arise. These concern for instance potential toxicity of nanomaterials for workers and patients, mass transport of nanoparticles in the body, and standards. The Food of Drug Administration (FDA) and other agencies such as the National Institutes of Standards and Technology (NIST) are involved in many regulatory issues and standards settings while the National institute for Occupational Safety and Health (NIOSH) deals with health issues in the workplace. A public-private partnership involving the FDA and other stakeholders has been suggested to identify and resolve critical outstanding questions. Many R&D initiatives at universities as well as in industry exist across the nation.

Systems Biology R&D is supported by a number of agencies including the NIH, the National Science Foundation (NSF), the Department of Energy (DOE) as well as agencies within the Department of Defense (DOD). The reason for this broad funding picture is largely that Systems Biology research does not only deal with biomedical questions but for instance also with energy production. A number of NIH institutes support Systems Biology R&D and the field is also heavily sponsored by initiatives within

the NIH Roadmap. A large number of initiatives are present at universities and institutes and there is also a substantial interest from industry.

In all, both scientific areas are seen as being of national importance and there is a strong federal support for R&D in the fields. There are, however, a number of issues that needs to be resolved for Nanomedicine if the field is going to evolve rapidly in the future. There is also a clear interest from industry for both areas.

3 Nanomedicine

3.1 Introduction to Nanotechnology

Nanotechnology[1] deals with matters and materials on the molecular scale. Normally this means smaller than 100 nanometers (1 nm = $1*10^{-9}$m). The scientific/technological area is broad and includes the creation of new materials and devices with potential applications in for instance energy production, electronics and medicine.

The origin of the term "Nano-technology" can be traced to a talk[2] given by Dr. Richard Feynman at the American physical Society in 1959 that was entitled "There´s plenty of Room at the Bottom". Feynman noted that different physical properties could be expected due to scale. As an example, gravitation would become less pronounced while Van der Waals attractions would become more important on the molecular level. The term "Nanotechnology" was defined by Dr. Norio Taniguchi from the Tokyo Science University as, "mainly consisting of the processing of, separation, consolidation, and deformation of materials by one atom or by one molecule", in a paper published in 1974 [1]. The technological significance of Nanotechnology and Nanoscience was promoted by Dr K.E. Drexler in the 1980's and 1990's [2,3] and his book entitled "Engines of Creation: The Coming Era of Nanotechnology (1986, [2]) is often considered to be the first book on Nanotechnology. Nanoscience and Nanotechnology started to take of as a scientific field during the 1980's partly due to the development of the scanning tunneling microscope (STM)[3] and the birth of cluster science[4]. Furthermore, the development of the STM led to the Nobel Prize for Drs. Heinrich Rohrer and Gerd Binnig in 1986.

Nanomedicine[5] can be seen as the biomedical branch of Nanotechnology [4]. There are large numbers of potential applications of nanosize particles in both biomedical research and development (R&D), and in the clinic. A few, such as Albumin nanoparticles are already in use. Potential applications include the medical use of nanoparticles for drug delivery and imaging (e.g. of cancer tumors), nanoelectronic interfaces (e.g. in neuroscience), biosensors, applications of molecular nanotechnology and more. Current issues of very high importance include the potential toxicity

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[1] http://en.wikipedia.org/wiki/Nanotechnology
[2] http://www.zyvex.com/nanotech/feynman.html
[3] http://nobelprize.org/educational_games/physics/microscopes/scanning/index.html
[4] http://physchem.ox.ac.uk/~doye/jon/PhD2/node3.html
[5] http://en.wikipedia.org/wiki/Nanomedicine

for workers and patients of nanoscale materials, as well as the environmental impact of nanomaterials.

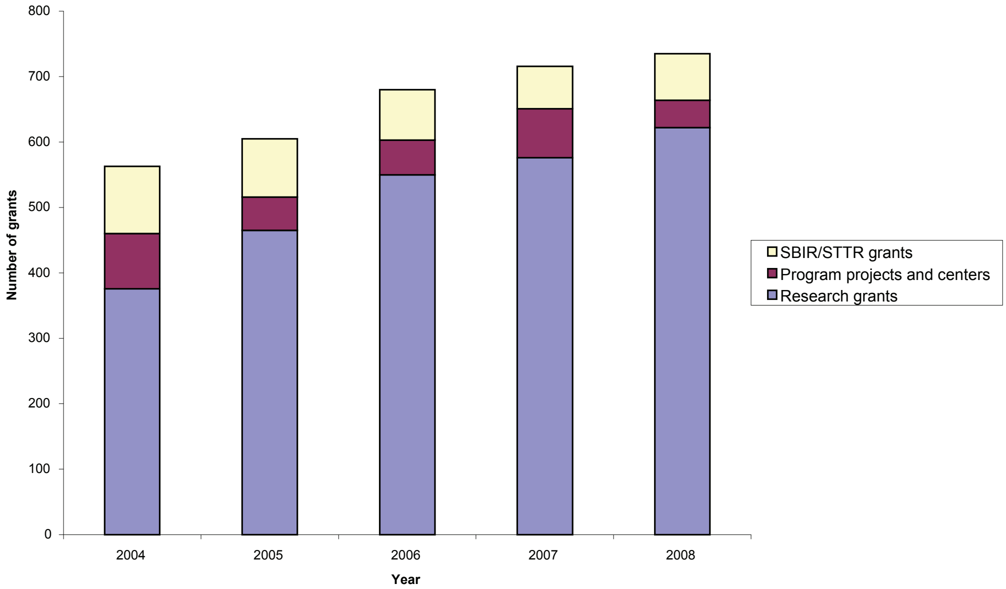
3.2 Federal Nanomedicine Research and Development

Nanotechnology is multidisciplinary and contains knowledge from, and activities in, many scientific fields including physics, chemistry, biology, medicine, IT, material sciences and engineering. Studies in areas such as molecular biology, demonstrates that biomedical studies at the nanoscale have been conducted for many years. However, Nanotechnology, formally seen, came to medicine relatively late although activities have expanded rapidly in recent years. Nanotechnology efforts in the biomedical field show new and interesting ideas with regard to nanosize designs and technologies.

One way to look at federal Nanomedicine efforts is to look at the number of grants awarded by Department of Health and Human Services (HHS) agencies. In figure 1 is depicted the situation with regard to research grants, program projects and centers awards, and Small Business Innovation research (SBIR) and Small business Technology Transfer (STTR) grants based on a search in the CRISP[6] database (Computer retrieval of Information of Scientific Projects). It is interesting to note that while the number of Nanomedicine research grants has grown steadily for a long time, this is not the case for the business-oriented SBIR and STTR grants or the program projects and centers category.

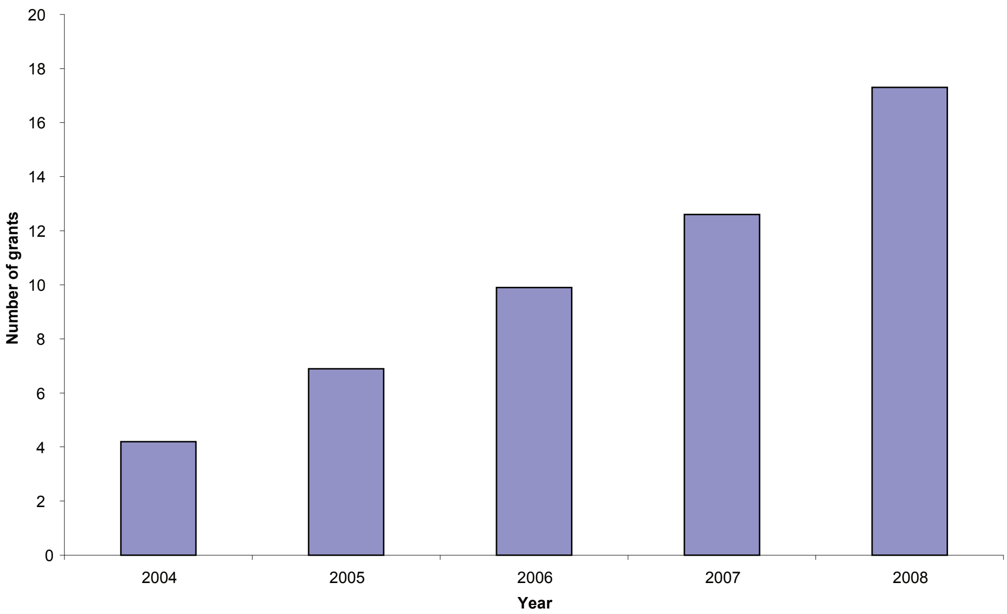
[6] http://crisp.cit.nih.gov/

Figure 1 Nanomedicine-related grants awarded by HHS agencies. The graph is based on searches in the CRISP database using the search terms: nanoparticle, nanocrystals, nanoscale, nanotechnology, nanoscience, nanostructure, nanopore, nanomaterials, nanomedicine, nanofabrication, nanosensors and nanowires



The National Cancer Institute (NCI) is one of the major players with regard to efforts in Nanomedicine and has established a number of research centers (see also NIH Roadmap, chapter 4.2.2). The results from a search of Nanomedicine-related research grants at NCI can be seen in figure 2. It should be kept in mind that additional grant types exist.

Figure 2 NCI research grants related to Nanomedicine. The graph is based on a search in the CRISP database using the search term: nanoparticle, nanocrystals, nanoscale, nanotechnology, nanoscience, nanostructure, nanopore, nanomaterials, nanomedicine, nanofabrication, nanosensors and nanowires



3.2.1 National Nanotechnology Initiative (NNI)

Introduction and budget

The NNI was established in fiscal year (FY) 2001 to coordinate the federal agencies R&D efforts in Nanotechnology and Nanoscience. NNI works as the central point for communication, collaboration and cooperation and, at present, consists of the Nanotechnology-related activities at 25 agencies with R&D and/or other (e.g. regulatory) roles. 13 of the agencies have R&D budgets relating to Nanotechnology and the reported NNI budget represents the collective sum of these. The NNI in itself does not fund R&D. The agencies with R&D budgets in the area are:

- Cooperative State Research Education and Extension Service, U.S. Department of Agriculture (CSREES, USDA)
- Department of Defense (DOD)
- Department of Energy (DOE)
- Department of Homeland Security (DHS)
- Department of Justice (DOJ)
- Department of Transportation (DOT)
- Environmental Protection Agency (EPA)
- Forest Service (FS, USDA)

- National Aeronautics and Space Administration (NASA)
- National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS)
- National Institute of Standards and Technology (NIST), Department of Commerce (DOC)
- National Institutes of Health (NIH, HHS)
- National Science Foundation (NSF)

In tables 1 and 2 is shown the R&D budget levels for Nanotechnology initiatives at the agencies over time. It should however be remarked that the new President as well as Congress has increased science-related spending significantly through the American Recovery and Reinvestment Act (ARRA)[7] and by supporting funding in line with the America COMPETES Act[8] [cf 5]. This suggests that the table shows somewhat lower figures compared to the final funding level for 2009.

Table 1 Nanotechnology funding levels for NNI agencies. * 2008 and 2009 funding levels for DOE include the Offices of Science, Fossil Energy, and Energy Efficiency and Renewable Energy

NNI Budget, 2007 - 2009 (USD in millions)

	2007 Actual	2008 Estimate	2009 Proposed
DOD	450	487	431
NSF	389	389	397
DOE*	236	251	311
HHS (NIH)	215	226	226
DOC (NIST)	88	89	110
NASA	20	18	19
EPA	8	10	15
HHS (NIOSH)	7	6	6
USDA (FS)	3	5	5
USDA (CSREES)	4	6	3
DOJ	2	2	2
DHS	2	1	1
DOT (FHWA)	1	1	1
TOTAL	**1,425**	**1,491**	**1,527**

Source: The National Nanotechnology Initiative

[7] http://www.recovery.gov/
[8] http://thomas.loc.gov/cgi-bin/bdquery/z?d110:SN00761:@@@D&summ2=m&

Table 2 Time series of Nanotechnology funding levels at different federal agencies.

NNI Budget History by Agency (USD in millions)

Agency	2001 Actual	2002 Actual	2003 Actual	2004 Actual	2005 Actual	2006 Actual
DOD	125	224	220	291	352	424
NSF	150	204	221	256	335	360
DOE	88	89	134	202	208	231
DHHS (NIH)	40	59	78	106	165	192
DOC(NIST)	33	77	64	77	79	78
NASA	22	35	36	47	45	50
EPA	5	6	5	5	7	5
USDA (CREES)			1	2	3	4
DHHS (NIOSH)					3	4
USDA (FS)						2
DOJ	1	1	1	2	2	.3
DHS		2	1	1	1	2
DOT(FHWA)						1

Source: The National Nanotechnology Initiative

Agencies or departments that are NNI members but does not have a specific Nanotechnology R&D budget includes the Department of Education, the Department of State, the Department of Labor, the Department of the Treasury, the U.S. Patents and Trademark Office (DOC), the Food and Drug Administration (HHS), the International Trade Commission, the Nuclear Regulatory Commission, the U.S. Geological Survey (Department of the Interior), the Bureau of Industry and Security (DOC) and the intelligence community.

Agenda and mission

NNI has defined a number of official goals that are:

- to advance a world-class Nanotechnology R&D program
- to foster the transfer of new technologies into products for commercial and public benefit
- to develop and sustain educational resources, a skilled workforce, and the supporting infrastructure and tools to advance Nanotechnology
- to support responsible development of Nanotechnology

As mentioned above, NNI does not fund R&D directly but informs and influences the federal budget and planning processes by itself and through its member agencies. The NNI and its agencies have defined 8 program component areas (PCA's) that are major subject areas consisting of projects and activities. The PCA's are:

- *Fundamental Nanoscale Phenomena and Processes*

  Discovery and development of fundamental knowledge pertaining to new phenomena in the physical, biological and engineering sciences occurring at the nanoscale. Elucidation of scientific and engineering principles related to nanoscale structures, processes and mechanisms.
- *Nanomaterials*

  Research aimed at the discovery of new nanoscale and nanostructured materials and at a comprehensive understanding of the properties of nanomaterials. R&D leading to the ability to design and synthesize nanostructured materials with specific properties in a controlled manner.
- *Nanoscale Devices and Systems*

  R&D that applies the principles of nanoscale science and engineering to create new, or to improve existing, devices or systems. The PCA includes the incorporation of nanoscale and nanostructured materials to achieve improved performance or new functionality.
- *Instrumentation Research, Metrology and Standards for Nanotechnology*

  R&D pertaining to the tools needed to advance Nanotechnology research and commercialization, including next-generation instrumentation for characterization, measurement, synthesis and design of materials, structures, devices and systems. The PCA also includes R&D and other activities related to the development of standards.
- *Nanomanufacturing*

  R&D aimed at enabling scaled-up, reliable and cost-effective manufacturing of nanoscale materials, structures, devices and systems.
- *Major Research Facilities and Instrumentation Acquisition*

  Establishment of user facilities and acquisition of major instrumentation and alike, to develop the nations infrastructure for the conduct of nanoscale science, engineering and technology R&D.
- *Environment Health and Safety*

  Research primarily directed at understanding the environmental, health and safety impacts of Nanotechnology development and corresponding risk assessment, management as well as methods for risk mitigation.
- *Education and Societal Dimensions*

  Education-related activities such as for instance development of materials for schools and university programs, technical training, public outreach and engagement. The PCA also contains research to identify and quantify the broad societal implications of nanotechnology.

The relationships between the PCA's and the agencies missions and interest can be seen in table 3.

Table 3 Relationships between the program component areas and the agencies missions and interests

■ – Primary □ – Secondary

Agency* \ PCA	Fundamental Nanoscale Phenomena & Processes	Nanomaterials	Nanoscale Devices & Systems	Instrumentation Research, Metrology, & Standards	Nanomanufacturing	Major Research Facilities & Instrumentation Acquisition	Environment, Health, & Safety	Education & Societal Dimensions
BIS (DOC)	□	■	■	■	□			
CPSC	□	□	■	■	□		■	□
CSREES (USDA)	□	■	■	□	□		□	■
DOD	■	■	■	□	■	□	□	□
DOEd							□	■
DOE	■	■	□	□	□	■	□	□
DHS	■		■	■		□		
DOJ			■					
DOL		□			□		■	■
DOS	□	□	□	□	□	□	■	■
DOT	■	□	■		■		■	
DOTreas		■	■					
EPA	□	■	■	□	■		■	□
FDA (HHS)	□	□	■	□	□		■	
FS (USDA)	□	■	■	□	■		□	
IARPA	□	■	■		□			
ITC		■	■		■			
NASA	□	■	■		□	□		
NIH (HHS)	■	□	■	□			■	□
NIOSH (HHS)		□			□		■	□
NIST (DOC)	■	■	□	■	■	□	□	
NRC				■				
NSF	■	■	□	□	■	■	■	■
USGS (DOI)	■			■			■	
USPTO (DOC)		■	■	■	■			

Source: National Nanotechnology Initiative strategic plan

The NNI has also defined a number of application areas. NIH (HHS) together with the Department of Labor, the Environmental Protection Agency and the Food and Drug Administration (HHS) have leading roles for the Medicine and Health area while other agencies and departments have lesser roles. The involvement of the different agencies and offices in relation to the application areas can be seen in table 4.

Table 4 NNI Agency contributions to selected Nanotechnology application areas

Application area \ Agency	CPSC	CSRES	DOD	DOE	DHS	DOJ	DOL	DOT	EPA	FDA	FS	IARPA	ITC	NASA	NIH	NIOSH	NIST	NSF
Aerospace			X	0	0			0				0	0	X			0	0
Agriculture & Food		X	0	0	0	0			0	X	0							0
National Defense & Homeland Security		0	X	0	X	0			0	0		X	0	0	0	0	0	0
Energy		0	X	X	0				0		0	0	0	0			0	0
Environmental Applications	0	0	0	0	0		X		X	0	0				0	0	0	X
Information Tehnology			X	0	0							0	0	0	0		0	X
Medicine & Health	0	0	0	0			X		X	X				0	X	0	0	0
Transportation & Civil Infrastructure			0	0	0			X	0		0						0	0

X=Central role, 0=Supporting role

Source: The National Nanotechnology Initiative

NNI Research Centers

The NNI, through its members, has made investments in the establishment of more than 60 research and development centers dedicated to Nanoscience and Nanotechnology. Agencies that have established centers[9] with various missions include the National Science Foundation, the Department of Energy, the Department of Defense, NASA, the National Institute for Occupational Safety and Health, the National Institute of Standards and Technology, and the National Institutes of Health. The NIH and NIOSH centers are:

- Nanotechnology Characterization Laboratory, NCI-Frederick
- Integrated Nanosystems for Diagnosis and Therapy , Washington University
- Nanotechnology: Detection & Analysis of Plaque Formation Emory University and Georgia Tech
- Nanotherapy for Vulnerable Plaque , Burnham Institute
- Translational Program of Excellence in Nanotechnology, Massachusetts General Hospital
- *Center for the Optical Control of Biological Functions, University of California—Berkeley
- *Center for Cell Control, University of California—Los Angeles

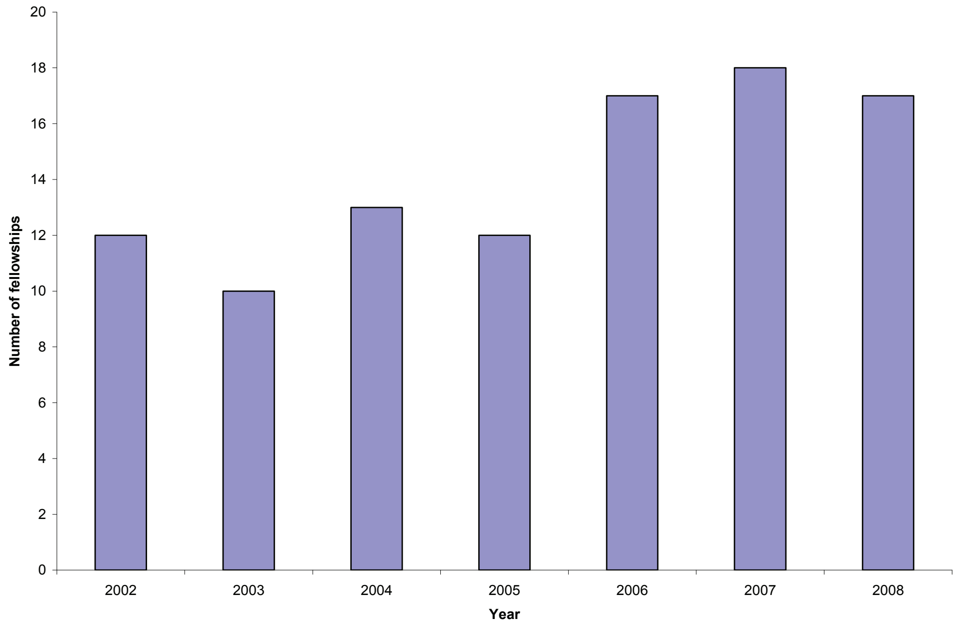
[9] http://www.nano.gov/html/centers/nnicenters.html

- *Phi29 DNA-Packing Motor for Nanomedicine, Purdue University, University of Cincinatti
- *Nanomedicine Center for Nucleoprotein Machines, Georgia Institute of Technology
- *National Center for Design of Biomimetic Nanconductors, University of Illinois—Urbana-Champaign
- *Center for Protein Folding Machinery, Baylor University
- *Nanomedicine Center for Mechanical Biology, Columbia University
- *Engineering Cellular Control: Synthetic Signaling and Motility Systems, University of California—San Francisco
- The Siteman Center of Cancer Nanotechnology Excellence, Washington University
- Center of Nanotechnology for Treatment, Understanding, and Monitoring of Cancer (NANO-TUMOR), University of California, San Diego
- Carolina Center of Cancer Nanotechnology Excellence, University of North Carolina
- Center for Cancer Nanotechnology Excellence Focused on Therapy Response, Stanford University
- MIT-Harvard Center of Cancer Nanotechnology Excellence, Massachusetts Institute of Technology
- Nanotechnology Center for Personalized and Predictive Oncology, Emory University and Georgia Institute of Technology
- Center for Cancer Nanotechnology Excellence, Northwestern University
- Nanosystems Biology Cancer Center, California Institute of Technology
- Nanotechnology Research Center, Robert A. Taft Lab (NIOSH)

[*] *= Nanomedicine Development Center Awards (NIH Roadmap, See chapter 4.2.2)*

The NIH centers are funded both by individual NIH institutes such as the National Cancer Institute (NCI) and by the NIH Nanomedicine Roadmap Initiative. A number of centers are collaborative efforts. NSF is in the process of establishing a new center for environmental health and safety.

Figure 3 Nanomedicine-related postdoctoral fellowships (F32) awarded by the NIH. The graph is based on a search in the CRISP database using the search term: nanoparticle, nanocrystals, nanoscale, nanotechnology, nanoscience, nanostructure, nanopore, nanomaterials, nanomedicine, nanofabrication, nanosensors and nanowires



3.2.2 The National Institute for Occupational Safety and Health (NIOSH) – Safety and Health in the workplace

Considering the rapid development of Nanoscience with a number of new Nanotechnology products every week, it is crucial to understand the health effects and hazards posed by nanosize materials. NIOSH works to raise the awareness of health and occupational issues related to Nanotechnology and to make recommendations on best practices in the production and use of nanomaterials. The agency states that research clearly indicates that the physicochemical properties of materials can affect their biological effects and that many such properties differ for nanosize particles compared to particles of the same materials but with a larger size.

Examples of potential health concerns include ways of materials to enter the body through the airways or through dermal exposure, deposition in the respiratory tract and blood, as well as secondary translocation to other organs. According to NIOSH, experimental studies in rats suggest that nanosize particles may be more potent than larger particles in causing pulmonary inflammations and lung tumors. Adverse effects on lung function have been reported in studies of workers exposed to aerosols of some manufactured or incidental microscopic and nanoscale particles. In addition, there is insufficient information regarding fire and explosion risks associated with nanomaterial powders. The chemical (e.g. catalytic) properties of nanoscale particles may also differ from those of larger scale materials.

As the knowledge currently is incomplete with regards to health effects, NIOSH has published a precautionary document [7]. NIOSH present recommendations and guidelines are largely intended to minimize workers exposure to nanoparticles. Engineering solutions similar to those for work with aerosols (e.g. filters, ventilation systems, respirators, physical separation of workers from materials etc.), educational efforts as well as assessments of work places are stressed in the efforts to establish good work practices. NIOSH has formulated interim guidance for medical screening of nanotechnology workers[10]. The agency stresses that there is insufficient data on health effects to make recommendations on medical screening and that further research is needed.

3.3 The food and Drug Administration and the Alliance for Nanohealth

A large number of agencies are involved in Nanotechnology initiatives. The FDA named Nanomedicine a priority in the 2006 report "The Critical Path Opportunities list and report" (cf [5]) and has initiated collaborations with other agencies including NCI and NIST. NIST is largely involved in research and the development of standards. The FDA initiative includes the FDA Nanotechnology Task Force charged with determining regulatory approaches to encourage the development of innovative, safe, and effective FDA-regulated products with Nanotechnology materials. The mission is in line with the health concerns for Nanotechnology workers and patients using Nanotechnology products. New methods must be developed to ensure safety and efficacy of nanoscale medical devices and therapies.

The Alliance for NanoHealth[11] (ANH) is an organization primarily based in Texas that aims to take an interdisciplinary approach to develop Nanotechnology-based solutions to unresolved problems in medicine. Its principal goal is to provide new clinical approaches to saving lives through better diagnosis, treatment, and prevention and to develop and apply Nanotechnology tools to counter diseases such as heart disease, cancer, diabetes, stroke, and infection. The ANH contains eight major research and education institutions, scientists and clinicians (located within a number of healthcare facilities in Texas). Member institutions include the Baylor College of Medicine, The University of Texas M.D. Anderson Cancer

[10] http://www.cdc.gov/niosh/docs/2009-116/
[11] http://www.nanohealthalliance.org/

Center, Rice University, the University of Houston, The University of Texas Health Science Center at Houston, Texas A&M Health Science Center, University of Texas Medical Branch and The Methodist Hospital Research Institute. The ANH plans to introduce a corporate membership to facilitate exchanges with industry and to improve the efficiency of clinical translation.

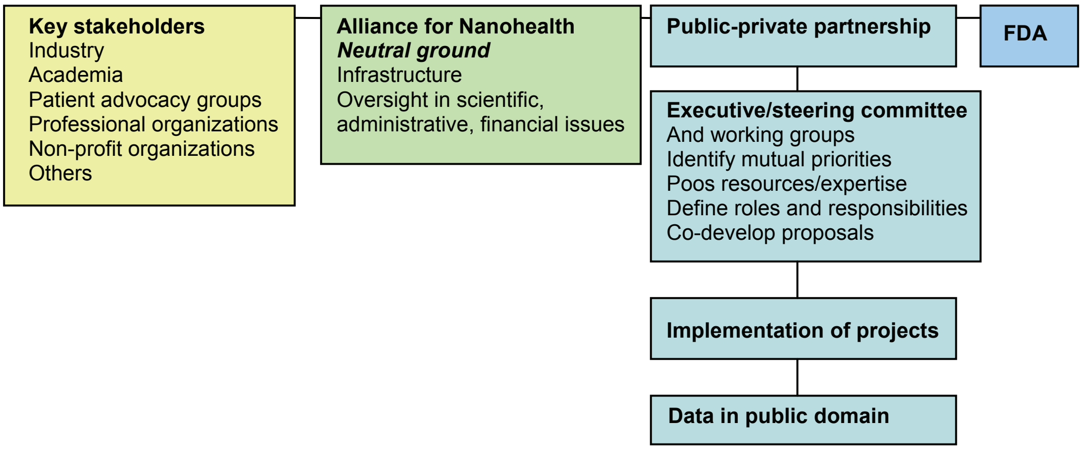
In order to identify and discuss top scientific hurdles for the introduction of nanoproducts to patients, the FDA and the ANH organized a workshop in March 2008 with participants from industry, academia and government [9]. The workshop identified the following key issues that need to be resolved:

- To determine the distribution of nanoparticulate carriers in the body following systemic administration through any route
- To develop imaging modalities for visualization of nanoparticle biodistribution over time
- To study mass transport across compartmental boundaries in the body
- To develop new mathematical and computational models in order to create a "periodic table" of nanoparticles
- To establish standards and reference materials as well as consensus testing protocols, in order to provide benchmarks for the development of novel classes of materials
- To realize an analytical toolkit for nanopharmaceutical manufacturing accompanied by specification sheets with toxicological safety and biodistribution properties

Private-public partnerships such as the SEMATECH[12] consortium have been successful in the past. One additional major outcome from the meeting was that a partnership between private and public stakeholder including the FDA and the ANH was proposed. The organization of the proposed partnership can be seen in fig 4.

[12] http://www.sematech.org/

Figure 4 Outline of the proposed private-public partnership for Nanomedicine



Sources: The Food and Drug Administration and Nature Nanotechnology

3.4 The NanoBusiness Alliance

The NanoBusiness Alliance (NBA) association is an active industry organization that aims to promote innovation in and commercialization of Nanotechnology. The organization has a network of leading startups, Fortune 500 companies, research institutions, non-governmental organizations and public-private partnerships.

NBA claims that Nanotechnology will be incorporated in 15% of global manufacturing during the coming 10 years and that the technology is of importance for many areas including electronics, health, energy, and homeland security. The organization is concerned about issues such as the "slow growth of seed-stage capital for innovators", patent and regulatory issues and the increasing investments in Nanotechnology by foreign competitors. NBA is strongly for a reauthorization of the 21st Century Nanotechnology Research and Development Act[13]. In February 2009, the House of Representatives passed the National Nanotechnology Initiative Amendments Act of 2009 (H.R. 554). The bill reauthorizes and updates the federal interagency Nanotechnology research and development program. However, the Senate has note voted on the issue yet (mid-April 2009). NBA also wants legislators to help small businesses more by providing access to more early-stage capital for innovation and by attracting foreign investments.

[13] http://thomas.loc.gov/cgi-bin/bdquery/z?d108:SN00189:

The organization runs the annual NanoBusiness Alliance Public Policy Tour and has contacts with policymakers, press and interest groups.

3.5 Scientific journals in Nanotechnology, Nanoscience and Nanomedicine

The use of scientific articles to measure the impact of a research field is complicated by many factors including that research results may be published in a multitude of journals and may not be clearly tagged with "nano". However, the presence of specialized journals may give some idea of the impact of the field. Below are a number of journals in Nanoscience listed together with their impact factor[14] for 2007. In a number of cases, no impact factor could be found (NF). One of the most common reasons for this is that journal was started during the last three years and that the factor could not be calculated as a result of this.

- Journal of Nanoscience and Nanotechnology[15] 1.987
- International Journal of Nanotechnology (IJNT)[16] 0.750
- Nanotechnology[17] 3.310
- Nature nanotechnology[18] 14.917
- Journal of Nanotechnology[19] NF
- Journal of Biomedical Nanotechnology[20] NF
- Nanomedicine[21] NF
- International Journal of Nanomedicine[22] 0.618
- The Open Nanomedicine Journal[23] NF
- The Open Nanoscience Journal[24] NF
- International Journal of Nanoscience[25] NF
- Journal of Experimental Nanoscience[26] 0.875

[14] http://thomsonreuters.com/products_services/scientific/Science_Citation_Index_Expanded
[15] http://www.aspbs.com/jnn/
[16] http://www.inderscience.com/browse/index.php?journalID=54&year=2004&vol=1&issue=1/2
[17] http://www.iop.org/EJ/journal/0957-4484
[18] http://www.nature.com/nnano/index.html
[19] http://www.hindawi.com/journals/jnt/
[20] http://www.aspbs.com/jbn/
[21] http://www.nanomedjournal.com/
[22] http://www.dovepress.com/international-journal-of-nanomedicine-journal
[23] http://www.bentham.org/open/tonmj/index.htm
[24] http://www.bentham.org/open/tonanoj/
[25] http://www.worldscinet.com/ijn/ijn.shtml
[26] http://www.nanoscienceworks.org/publications/journals/journal-of-experimental-nanoscience

3.6 Summary

Nanotechnology and not least the biomedical branch, Nanomedicine, is by many seen as one of the most important scientific and technological areas that has developed during the last decades. The interest is strong in both the public and private sectors and many universities have introduced centers or other strategic initiatives in Nanomedicine. However, few universities have specific degrees in Nanotechnology. The NNI is a federal collaborative effort involving agencies that fund Nanotechnology R&D and/or have other intererests (e.g. regulatory) in the field. Out of the 25 member agencies in the NNI, 13 have R&D budgets for Nanotechnology. DOD followed by NSF, DOE and the NIH are the largest federal funders of Nanotechnology R&D with the NIH being in particular important for Nanomedicine. The NCI and other NIH institutes make significant contributions to Nanomedicine as does the NIH Common fund (NIH Roadmap Initiative). While the number of federal Nanomedicine research grants have increased in recent years the situation is mixed with regard to, for instance, business-oriented SBIR/STTR awards. The FDA has named Nanomedicine a priority and collaborates with other agencies as well as with organizations such as the Alliance for Nanohealth. FDA priorities include to resolve regulatory approaches and scientific hurdles to the introduction of medical nanoproducts. An important issue is the potential toxicity of nanoproducts for workers and patients. NIOSH has published preliminary guidelines for the use and/or production of nanomaterials in the workplace. However, much further research is needed and many issues are unresolved.

4 Systems Biology

4.1 Introduction

The Systems Biology field has developed strongly during the last 5 to 10 years. Systems Biology is an interdisciplinary science that focuses on the systematic study of complex interactions in biological systems. The definition of what Systems Biology "is", is somewhat mixed. One definition is that it is a scientific field where the interactions in a biological system are studied. Another definition states that it primarily is an integrative approach to science in contrast to reductionism [10]. Yet again another definition is that it uses operational protocols to perform research consisting of cycles of theory, modeling, experimental validation and refinement of theories etc[27]. These definitions are overlapping and additional ones exist. However, the most correct one most likely comprises all aspects mentioned above.

Systems Biology as a discipline was introduced by Dr. Mihajlo Mesarovic in 1966 at a seminar entitled "Systems Theory and Biology" [11]. Important stepping stones was the birth of functional genomics, the mapping of the human genome in the 1990's and the build-up of computational power. The development of genomic mapping, proteomics, high-throughput screening (HTS) techniques and bioinformatics has contributed strongly to the success of the field.

During the last decades, Systems Biology has started to appear as a scientific discipline in its own right. Research in the field may concern many different questions such as the integrated cellular signaling system in individual cells or the whole nervous system of a species. Systems Biology R&D does not only concern biomedicine but also, for instance, research on new methods for energy production. Systems Biology uses many different techniques including genomics, proteomics, physiological techniques and computational approaches. There are many federal initiatives that concern Systems Biology R&D. However, not all of these use the actual term "Systems Biology". Many different institutes and centers, not least within the NIH, are involved.

Many countries including the U.S, Japan, Switzerland and the countries of the European Union have funding initiatives relating to Systems Biology. The U.S. and Japan are often seen as forerunners due to early recognition of the field and thereby early investments. The founding of the Molecular

[27] http://www.bbsrc.ac.uk/science/areas/ebs/themes/main_sysbio.html

Sciences Institute[28] at University of California at Berkeley in 2006, and the Institute of Systems Biology[29] in Seattle, Washington (state) in 2000, were important initiatives for the development of the field.

Industry interest in Systems Biology R&D appears to be substantial and concerns, for instance, the pharmaceutical industry, the biotechnology industry as well other bioprocess industries [12]. One area of interest to companies is modeling which may concern drug target identifications, models of intracellular biochemical networks and clinical trials designs. Biological systems modeling for different purposes is used by large companies such as AstraZeneca, Johnson & Johnson, Novartis and Pfizer as well as smaller companies such as Gene Network Sciences[30], Genomatica[31] and many others.

4.2 What makes System Biology different?

In some ways Systems Biology may be viewed as an approach to science rather than a ”classic” scientific field [13, 14]. In Systems Biology the focus is on the complex networks of biological interactions and the field complements “classical” reductionist approaches in biological research. An example - researchers have since long worked to identify bioactive molecules and components such as enzymes, second messengers, neurotransmitters and membrane proteins in different types of cells in controlled environments. Systems Biology looks at how the biological system functions as a whole, and thereby complements the reductionist studies by revealing how higher-level functionality emerge from interactions between the building blocks identified. Biological systems are often extremely complex and research in the field brings together components from biology, engineering, mathematics and computation. Therefore, it is crucial that experts from different areas come together. Among the expertise most needed are computational scientists that can construct quantitative and qualitative models, experts in high-throughput screening (HTS) that can measure the expression of many genes simultaneously, and skilled engineers to create the necessary equipment and meet the technical challenges (e.g. in robotics, miniaturization, sensors etc.). Biological or biomedical knowledgeable researchers are obviously important to understand the research questions at hand. In principle, Systems Biology can be said to often work in an iterative cycle in which model-driven experimentation and experiment-driven modeling alternate.

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[28] http://www.molsci.org/
[29] http://www.systemsbiology.org/
[30] http://www.gnsbiotech.com/static_content/
[31] http://www.genomatica.com/

4.3 Support for Systems Biology

The U.S. federal government, non-profit organizations and major universities are making substantial investments into systems-oriented and integrative research. Examples of initiatives include the Institute for Systems Biology[32] in Seattle, the Computational and Systems Biology initiative at the Massachusetts Institute of Technology (MIT)[33], the Bio-X project[34] at Stanford University and many others. The Broad institute (cf. [8]), a joint venture between MIT and Harvard University, as well as the Whitehead Institute (Cambridge, Massachusetts, next door to the Broad Institute) are initiatives that aim to bridge the gap between genomics and medicine and that work in areas such as cancer, medical and population genetics, genome biology and cell circuits, chemical biology, metabolic diseases, computational biology and bioinformatics.

Federal support for the above and many other Systems Biology initiatives are coming from NIH, NSF, DOD including the Army Research Office and DARPA, DOE and other agencies. It is again important to remember that Systems Biology R&D does not only concern biomedical questions.

4.3.1 The National Institutes of Health

The trans-institute NIH Roadmap program contains a number of initiatives that support Systems Biology research and development. Among these are the Molecular libraries initiative[35] (300 million USD) which includes Chemical Genomics centers[36], National Network of Molecular Screening Centers[37] and the National Technology Centers for Networks and Pathways[38] [cf. 8]. The Roadmap efforts within computational biology and modeling including the establishment of 7 National Centers for Biomedical Computing[39] are of great importance for R&D in Systems Biology. In figure 5 is depicted the number of “Systems Biology-labeled” research grants, program projects and centers awards as well as SBIR/STTR grants, awarded by HHS agencies over time. It is interesting to note that the number of research grants and program projects and center awards are increasing while the situation is mixed for the business-oriented SBIR/STTR awards.

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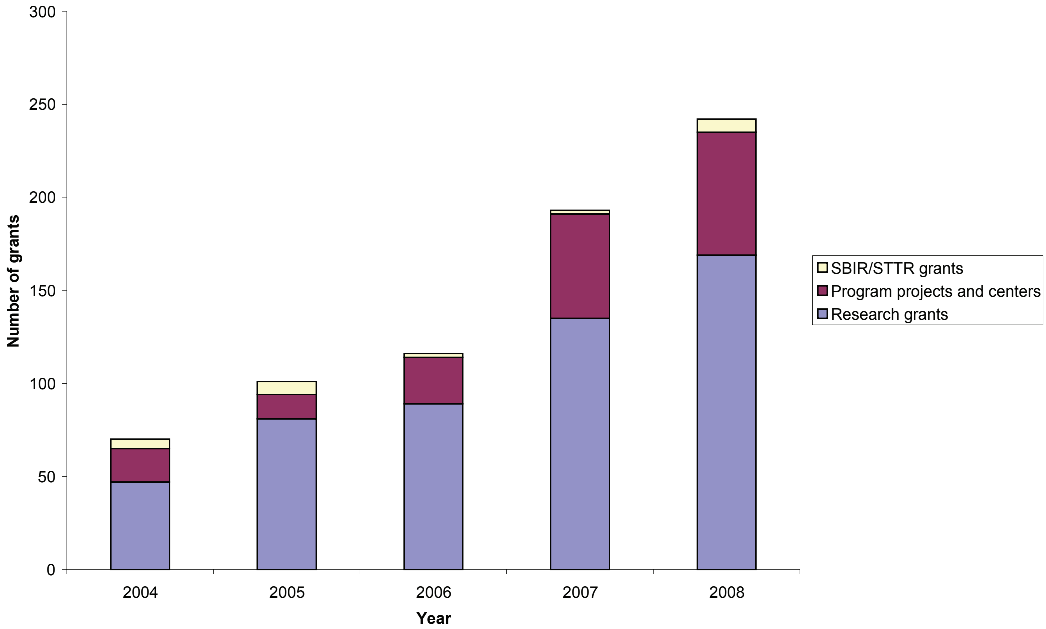
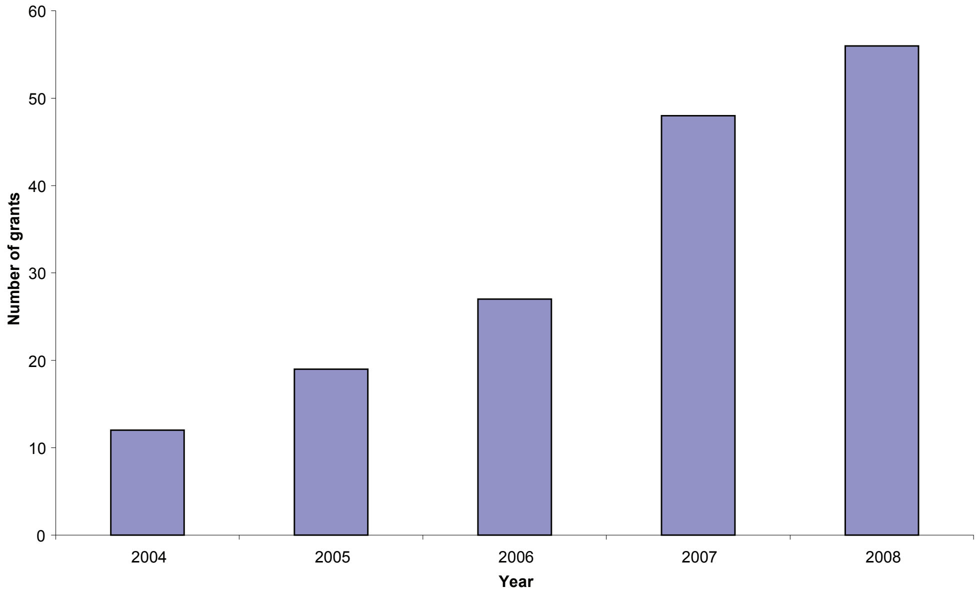
32 http://www.systemsbiology.org/
33 http://csbi.mit.edu/
34 http://biox.stanford.edu/
35 http://mli.nih.gov/mli/
36 http://www.ncgc.nih.gov/
37 http://nihroadmap.nih.gov/molecularlibraries/
38 http://nihroadmap.nih.gov/buildingblocks/technologycenters/
39 http://www.ncbcs.org/index.html

Figure 5 Systems Biology grants by HHS agencies. The graph is based searches in the CRISP database using the search term "Systems Biology"



The first official federal support for "Systems Biology"-labeled research started in 1998 by the National Institute of General Medical Sciences (NIGMS) [13] and the institute is still a large R&D sponsor of the field. However, other NIH institutes including the National Cancer Institute (NCI) and the National Heart, Lung and Blood Institute (NHLBI) make large investments as well. The number of "Systems Biology-labeled grants awarded by NIGMS can be seen in figure 6.

Figure 6 Systems Biology research grants by NIGMS. The graph is based searches in the CRISP database using the search term "Systems Biology"



The NIGMS National Centers for Systems Biology

As mentioned above the NIGMS is a large sponsor of Systems Biology and the institute has introduced a number of National Centers for Systems Biology[40]. The primary mission of the centers is to promote institutional development of multidisciplinary research, training, and outreach programs that focus on systems-level studies of biomedical phenomena. One additional objective is to increase the number of mathematicians that study biomedical problems. The current centers are:

- *Center for Cell Decision Processes at the Massachusetts Institute of Technology*. The center focuses on "developing numerical models of the mammalian signal transduction networks that regulate cell death and proliferation and on testing these models experimentally. A significant effort is devoted to systematizing and automating biological measurements."
- *Center for Complex Biological Systems at University of California at Irvine*. The center focuses on "how biological systems in model organisms process spatial information during development, intracellular signaling, and cell proliferation. Other efforts include the development

[40] http://www.nigms.nih.gov/Initiatives/SysBio/Centers/

of computational and optical tools needed for measuring and modeling spatially dynamic systems."

- *Center for Genome Dynamics at the Jackson Laboratory (Maine)*. The center focuses on "how patterns of genetic variation emerge and persist over time. By creating a collection of genetic information from a set of more than 200 inbred strains of mice, the research team studies expression patterns to identify co-expressed genes, examine how these patterns evolved, and investigate how the overall genome organization affects phenotype."
- *Center for Modular Biology at Harvard University (MA)*. The center investigates "how well the idea of "functional modules" (sets of molecules) helps us understand the organization, behavior, and evolution of cells and organisms. Combining computational and experimental approaches, the center studies how modules allow long-term evolvability to coexist with short-term robustness, asks how modules affect interactions among mutations in evolution, and examines the role of modules in the interplay between social behavior and gene expression."
- *Center for Quantitative Biology at Princeton university (NJ)* that "uses advanced computational methods to understand how biological molecules interact with and respond to their environment. The center facilitates systems biology research by providing its participants and other Princeton labs access to state-of-the-art-technologies for computation, DNA microarray, advanced imaging, and mass spectrometry. Education at the undergraduate and graduate level is a key activity."
- *Center for Systems Biology in Seattle (WA).* The center is "designing and developing novel tools for microfluidic measurement, molecular imaging, and computational modeling to better understand how cells differentiate and respond to environmental changes, to identify diagnostic markers of prostate cancer, and to model cell dynamics and signaling networks."
- *Chicago Center for Systems Biology at the University of Chicago*. The center focuses on "modeling the dynamic behavior of transcriptional regulatory networks as they respond to physiological, developmental, and evolutionary inputs and pressures. The research in the center is expected to reveal structure-function relationships in networks that lead to robustness of cells and organisms in response to environmental and genetic change."
- *Duke (University) Center for Systems Biology (NC)* which "employs a systems biology approach to address the orchestrated processes of the cell cycle, development and differentiation, and population variation in model organisms."
- *New York Center for Systems Biology at the Mount Sinai School of Medicine.* The center focuses on "the systems-level study of medicine and therapeutics. The team integrates theoretical and experimental

approaches to understand how drugs—both therapeutic and abused—affect the organization and physiology of cells, tissues, and organs. The researchers will concentrate on interactions occurring in the heart and brain."

4.3.2 Other federal support for Systems Biology

The NSF has taken a number of initiatives that relate to Systems Biology including, for example, the Quantitative Systems Biotechnology[41] and Frontiers in Integrative Biological Research[42] programs. NSF also supports Systems Biology research by supporting R&D in for instance molecular biology, computational bioscience and synthetic biology.

The Defense Advanced Research Projects Agency (DARPA) supports Systems Biology R&D, not least the Stanford University Bio-X[43] interdisciplinary program and computational programs. The Army Research Office funds various System Biology initiatives such as the Institute of Collaborative Biotechnology (ICB)[44] which is a partnership between Massachusetts Institute of Technology (MIT), the University of California at St. Barbara, the California Institute of Technology and industries such as SAIC, Nanex, the Aerospace Corporation and others. ICB research concerns technological innovations in bio-inspired materials and energy, biomolecular sensors, bio-inspired network science, and biotechnological tools.

DOE has invested large funds into Systems Biology initiatives including research on microbes and plants, with the goal of harnessing mechanisms for producing energy from sunlight. DOE launched the Genomics to Life (Genomics:GTL) program[45] in 2002 which is planned to last for 25 years. The program consists of different phases and will facilitate and accelerate the transition from genomics to Systems Biology with an emphasis on microbiology. GTL sponsors three bioenergy centers[46] as well as several other major research initiatives. In 2007, approximately 160 million USD was spent on the program by DOE.

[41] http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=5495
[42] http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=6188
[43] http://biox.stanford.edu/
[44] http://www.icb.ucsb.edu/
[45] http://genomicsgtl.energy.gov/
[46] http://genomicsgtl.energy.gov/centers/index.shtml

4.4 The Integrative BioSystems Institute at Georgia Tech

Systems Biology initiatives are now relatively common and are, as mentioned above, present at many universities. An example of an initiative is the "Integrative BioSystems Institute[47] (IBSI) at Georgia Tech. Georgia Tech created the institute to enable the faculty to explore the intersection of traditional engineering and science disciplines and the life sciences. Of high importance is the development of new better pharmaceutics and better therapies to fight serious diseases, and to find ways to deal with environmental challenges that threaten human health. IBSI aims to "understand complex biological systems in which molecules, cells, organs, organisms, populations and communities interact", and brings together researchers from many fields such as:

- Biologists that develop and design strategies for studies and perform experiments
- Engineers that design new advanced instrumentation for, for instance, molecular localizations
- Computational experts that manage, analyze and integrate the experimental data and that create dynamic models

Information regarding the human and others genome is now available and, together with the advancement of HTS enables scientists to measure large numbers of cellular components simultaneously, and thereby perform systems level studies on the molecular level. A large number of studies are being performed at IBSI, by IBSI scientists as well as by scientists from other departments and institutions. Studies concern a number of disease areas including cancer and neurodegenerative diseases. Methods in - for instance - genomics, proteomics, measurement technologies and computational biology are developed and used.

Biomedical questions including the improvement of drug discovery processes and treatments are important. However, as mentioned above, Systems Biology does not always concern medical questions and some laboratories active at IBSI study for instance environmental decontamination processes. One example concerns the binding of Uranium. External funding to projects at IBSI comes from a large number of federal sources including NIH, NSF, DARPA, DOE, and the DOD Strategic Environmental Research and Developmental Programs as well as from industry (e.g. DuPont).

[47] http://www.ibsi.gatech.edu/

4.5 Scientific journals in Systems Biology

A number of journals in Systems Biology are listed below together with their impact factor[48] for 2007. It should however be kept in mind that additional journals exist and that many articles are published in journal with a broader scope.

BMC Systems Biology[49]	NF
Molecular Systems Biology[50]	9.954
EURASIP Journal on Bioinformatics and Systems Biology[51]	NF
The Open Systems Biology Journal[52]	NF

NF=Not found, usually younger journals for which the impact factor has not yet been determined.

4.6 Summary

Systems Biology is a relatively "new" scientific discipline that has emerged during the last decades as a field in its own right. The U.S. and Japan often are seen as forerunners due to early recognition of the field. One of the unique features of the area is that research in Systems Biology usually uses an integrative approach in which a whole biological system is studied. This suggests that the field complements "classical reductionist" approaches. Furthermore, Systems Biology research may concern many systems and levels of systems from single cells to whole organism. A number of methods are used including classical experimental approaches, computational studies and HTS. The many methods used require that experts from many fields come together in collaborations.

Systems Biology studies concern a large number of purposes including basic and applied biomedical questions and energy production. As a result, many different R&D funders are interested in the area including federal agencies such as NIH, NSF, DOE and DOD. The NIGMS at NIH is a prominent sponsor of R&D in the field and has established a number of research centers across the nation. Other NIH institutes also sponsor Systems Biology activities and the NIH Roadmap contains a number of initiatives relevant for the area. The interest from agencies such as DOE largely concerns energy production in biological systems. Other potential

[48] http://thomsonreuters.com/products_services/scientific/Science_Citation_Index_Expanded
[49] http://www.biomedcentral.com/bmcsystbiol/
[50] http://www.nature.com/msb/index.html
[51] http://www.hindawi.com/journals/bsb/
[52] http://www.bentham.org/open/tosysbj/

application areas exist as well and activities are widespread at universities. Furthermore, the interest from industry is substantial.

5 Discussion

Nanomedicine, the biomedical application of Nanotechnology, and Systems Biology are both relatively “new” disciplines that have evolved during the last decades. This report briefly describes initiatives in the United States that are related to the two fields, with an emphasis on the federal level. Although some non-federal activities are described, there are many more initiatives being taken on local and state levels by both public and private entities (including universities and companies). The federal level is however crucial for R&D in the U.S. and federal agencies are the largest sponsors of R&D at universities and colleges [5].

Systems Biology and Nanomedicine are in some aspects connected and it is likely that Nanomedicine will provide many of the tools necessary for Systems Biology R&D. This is particularly likely for studies dealing with subcellular and molecular interactions. Vice versa, Systems Biology will provide knowledge necessary for the development of Nanomedicine. Some nanomedical products are already used and nanomaterials may in the future be important for, for instance, targeted drug delivery and imaging. Both fields are strongly multidisciplinary and require that experts from many scientific fields come together in close collaborations. R&D in both areas is strongly supported by multiple federal agencies and a number of NIH institutes support both fields. Both research fields also receive strong support from the strategic NIH Roadmap initiative located within the NIH Office of the Director. Although the NIH Roadmap contains a Nanomedicine program, there is no specific program labeled “Systems Biology”. However, the NIH institute that first started to officially support Systems Biology was NIGMS and the institute is still a strong supporter of the field. Systems Biology is in some ways more of an approach to science and research rather than a “classical scientific field”. In contrast to more “classical reductionist” approaches to research, Systems Biology is integrative and looks on a system as a whole. The system studied can however in principle be anything from a cell to a whole organism. Systems Biology research does not only deal with biomedical question but also with areas such as energy production by microbes and plants. This is demonstrated by the substantial support from DOE. Industry interest in Systems Biology is substantial, not least with regard to computational modeling which is used for many purposes.

Nanotechnology is highly prioritized by many federal agencies and the National Nanotechnology Initiative (NNI) is an interagency organization charged with the coordination of federal Nanotechnology R&D. The NNI has, in total, 25 member agencies and departments of which 13 have specific Nanotechnology R&D budgets. The NNI does not have an R&D budget in itself but has formulated a number of application areas including Medicine and Health as well as 8 Program Component Areas (PCA's). The member agencies that do not have R&D budgets have other interests in Nanotechnology. An example is the FDA which is heavily involved in regulatory questions for Nanotechnology and that collaborates with other federal agencies, universities and private entities. A public-private partnership between the FDA, the NanoHealth Alliance and other groups has been suggested to tackle scientific and regulatory questions. Other agencies that are involved in different aspects of Nanomedicine include NIH and NIOSH. NIH is the fourth largest federal sponsor of Nanotechnology research and the main federal funder of Nanomedicine R&D. NNI, though NIH and NIOSH, has established a number of Nanomedicine research centers. NCI is highly supportive of Nanomedicine and a number of the NIH research centers are focusing on Nanomedicine coupled to cancer.

Important current issues in Nanomedicine and in which NIOSH is heavily involved, include health concerns for Nanotechnology workers as well as the potential toxicity of nanoproducts. Research questions including how nanoparticles are transported in the body are high up on the agenda. Industry interest for Nanotechnology products is strong and the NanoBusiness Alliance is a relatively influential organization in Washington D.C.

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09 Forskning och innovation för hållbar tillväxt

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VINNOVA´s mission is to promote sustainable growth
by funding needs-driven research
and developing effective innovation systems

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