A perspective on nanotechnology policy in the U.S.

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MIT
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MARBLE CENTER FOR CANCER NANOMEDICINE
Small technologies, **BIG** impact

KOCH INSTITUTE
for Integrative Cancer Research at MIT

Disclaimer

The opinions expressed in this presentation are my own and do not reflect the position of the U.S. government or my home institution.

The National Nanotechnology Initiative (NNI)

"Just imagine, materials with 10 times the strength of steel and only a fraction of the weight; shrinking all the information at the Library of Congress into a device the size of a sugar cube; **detecting cancerous tumors that are only a few cells in size**. Some of these research goals will take 20 or more years to achieve. But that is why—precisely why there is such a critical role for the Federal Government."

President Clinton, California Institute of Technology, January 21, 2000

Vision of the NNI

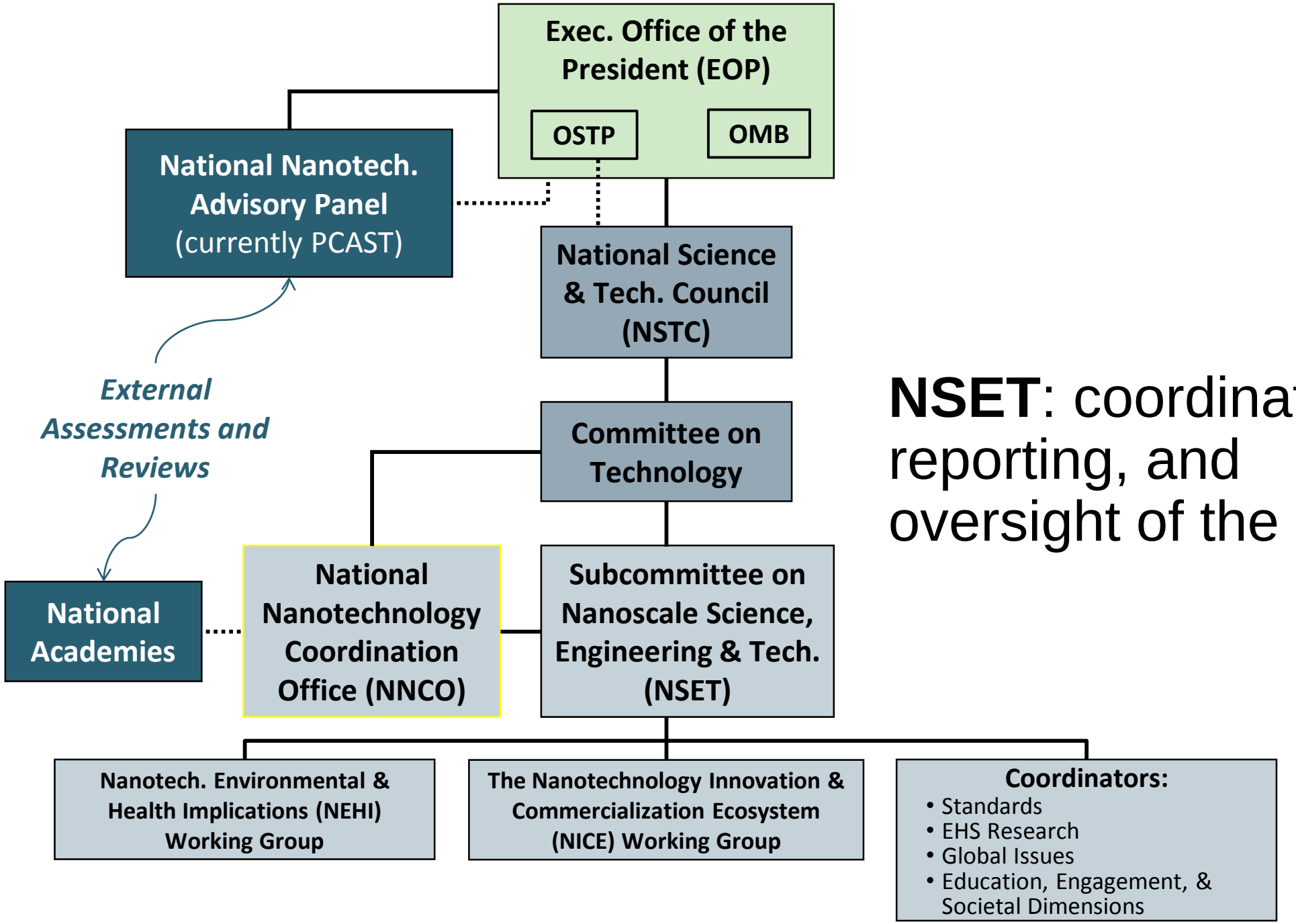
A U.S. Government research and development (R&D) initiative involving 20 Federal department, independent agencies, or commissions working together toward the shared and challenging vision of "*a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society*."

The National Nanotechnology Initiative

Collaborative research and development that will advance understanding and control of matter at the nanoscale for:

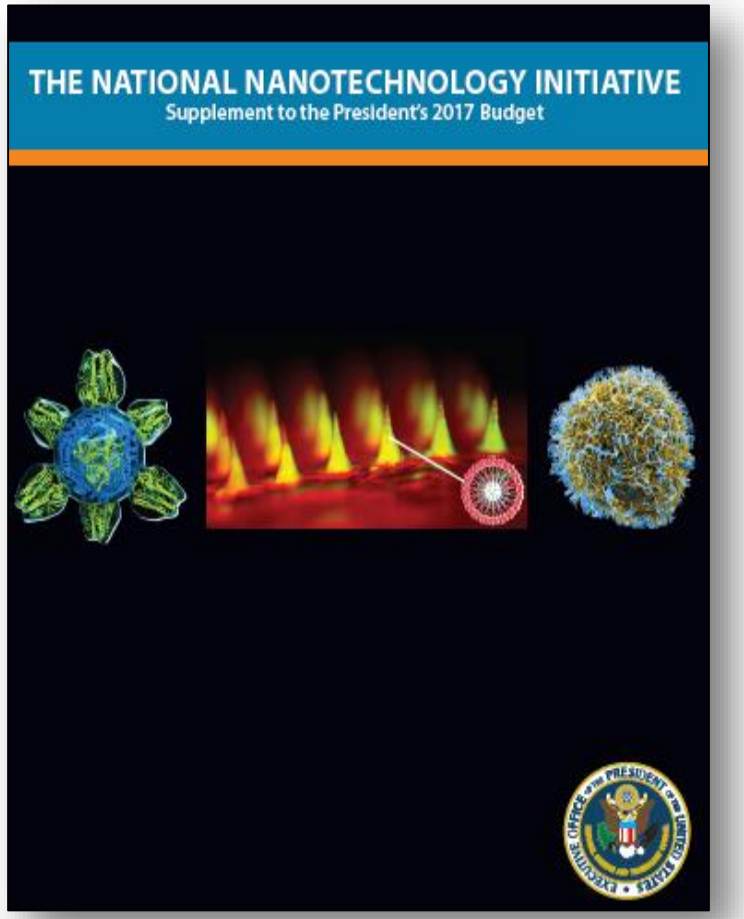
- National economic benefit
- National security
- Improved quality of life

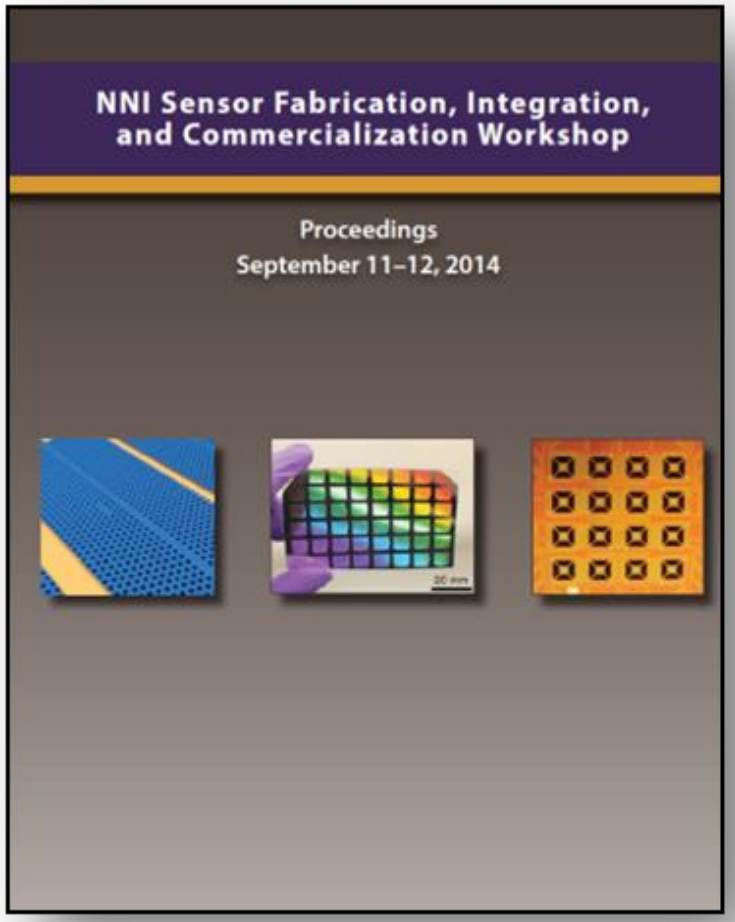
DOE
HHS/NIH
OSTP
OMB
NSF
DOD
DOC/NIST
HHS/FDA
NASA
USDA/NIFA
USDA/ARS
HHS/CDC/
NIOSH
USDA/FS
DOS
EPA
DOTr
NRC
DOT
DOC/
USPTO
IC/DNI
DOI/
USGS
DOJ
DOL
DOC/EDA
DOC/BIS
DHS
CPSC
ITC
DOEd

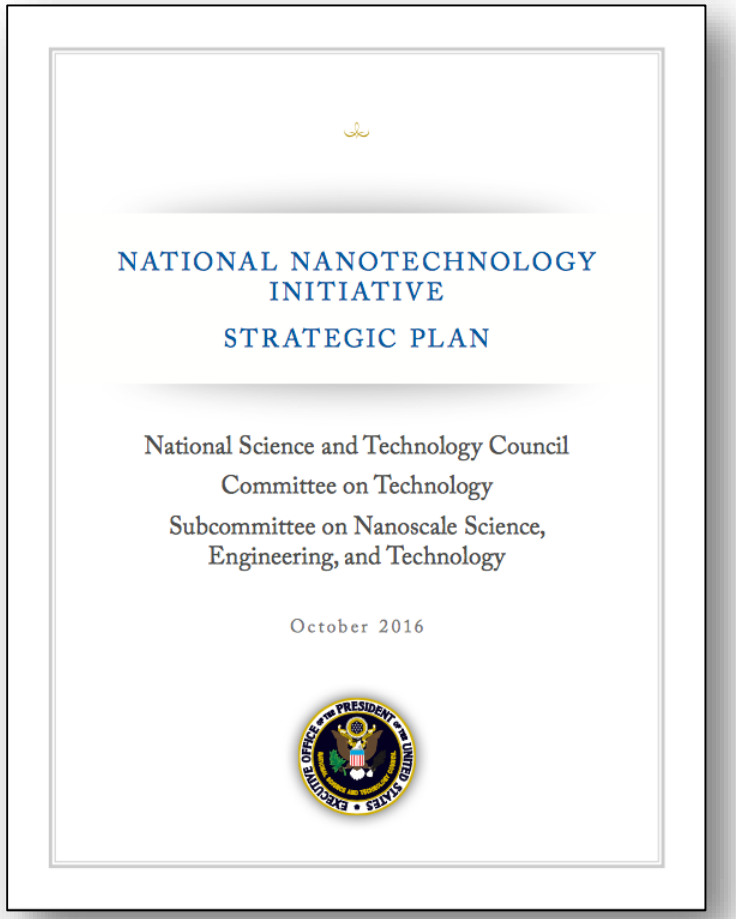


NSET: coordination, reporting, and oversight of the NNI

Reporting NNI Activities and Progress







Reports can be accessed at www.nano.gov

Examples of Federal Activities in Nanomedicine

NIH

NCL Nanotechnology Characterization Laboratory

NCI Alliance for Nanotechnology in Cancer

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA FDA

DEPARTMENT OF DEFENSE • UNITED STATES OF AMERICA

CANCER MOONSHOT

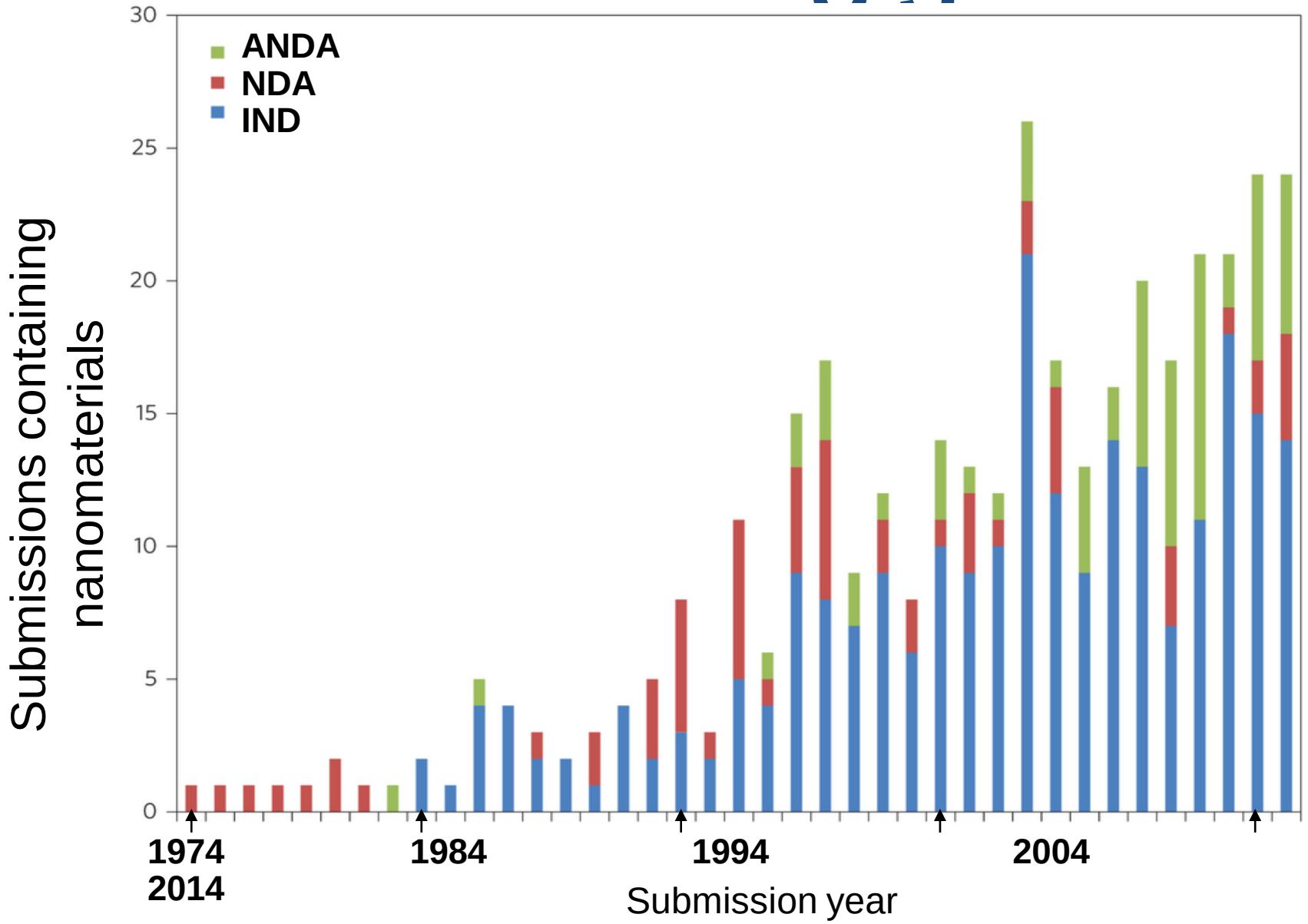
us-eu bridging nanoEHS research efforts

http://us-eu.org

ISO International Organization for Standardization

ASTM INTERNATIONAL Standards Worldwide

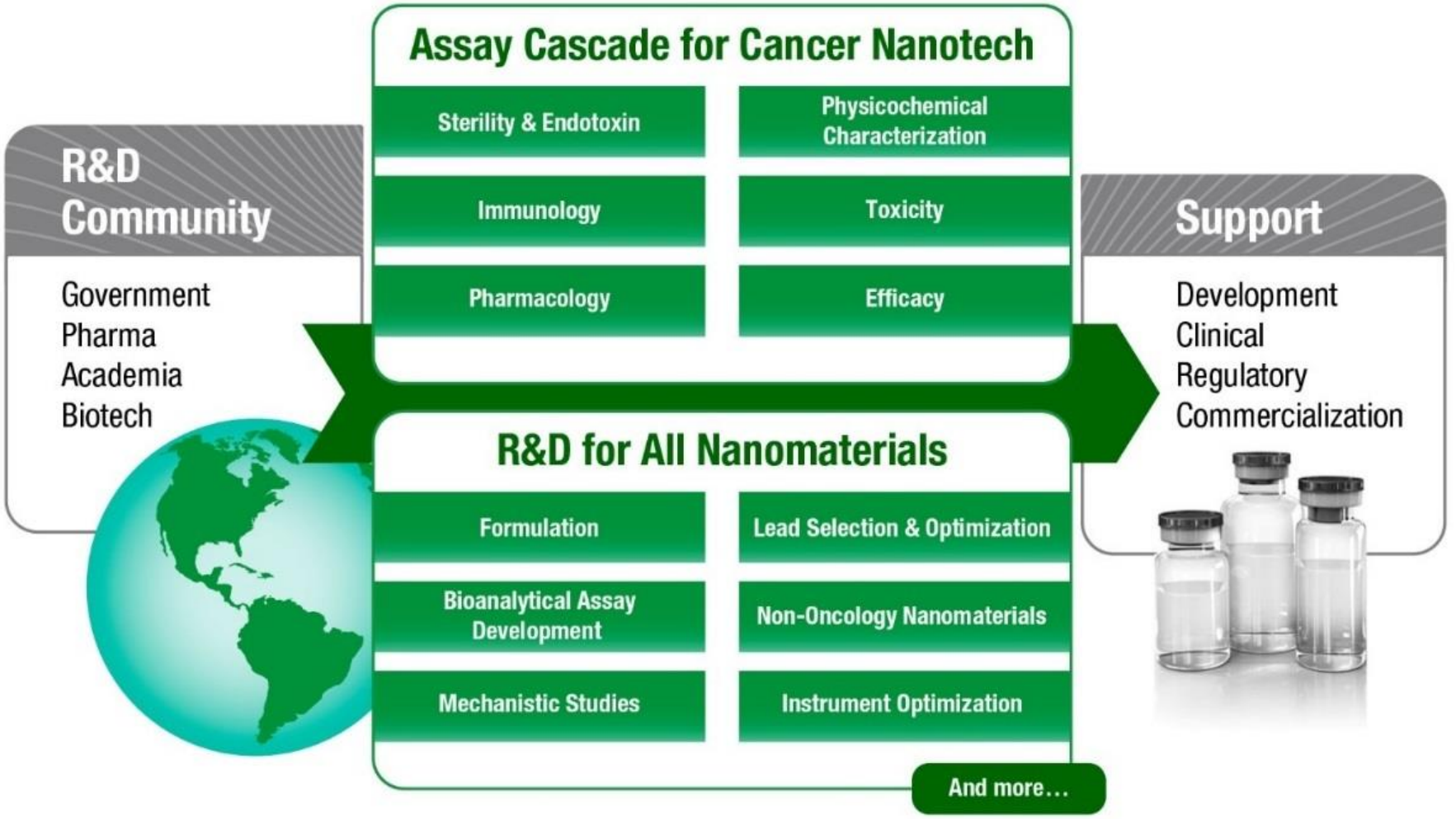
Evolving Nanomedicine Landscape in U.S



- Increase in the submissions of drug products containing nanomaterials over the last two decades
- Most products focused on cancer treatment (35%)
- **15% approval rate of NDAs from the submitted 234 INDs**

D'Mello, S. R. et al. Nature Nanotechnology (2017)

Nanotechnology Characterization Laboratory

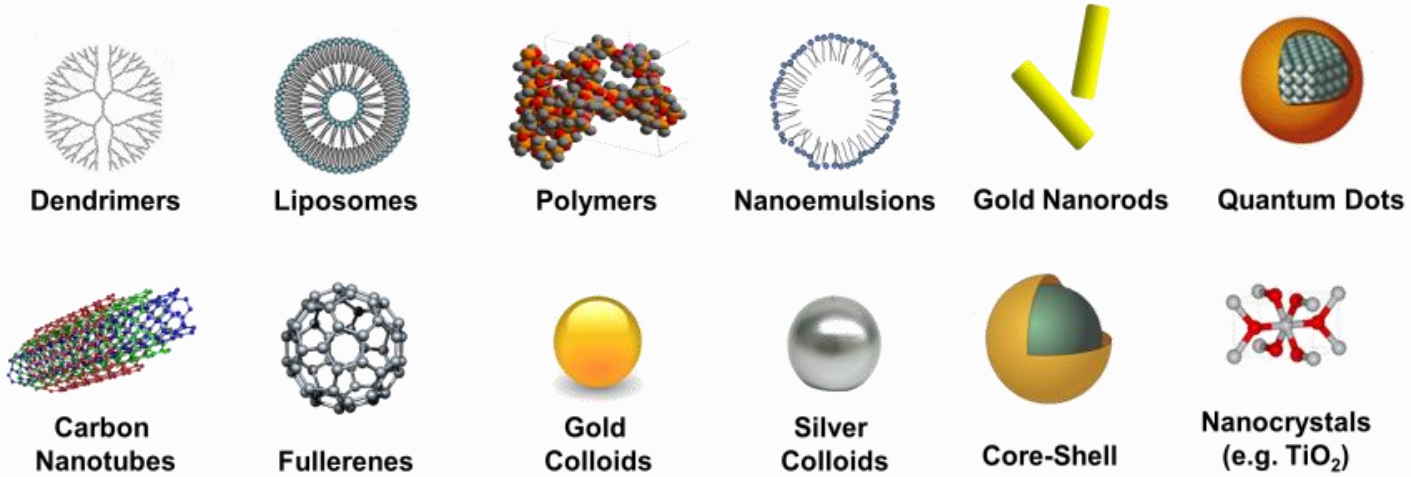


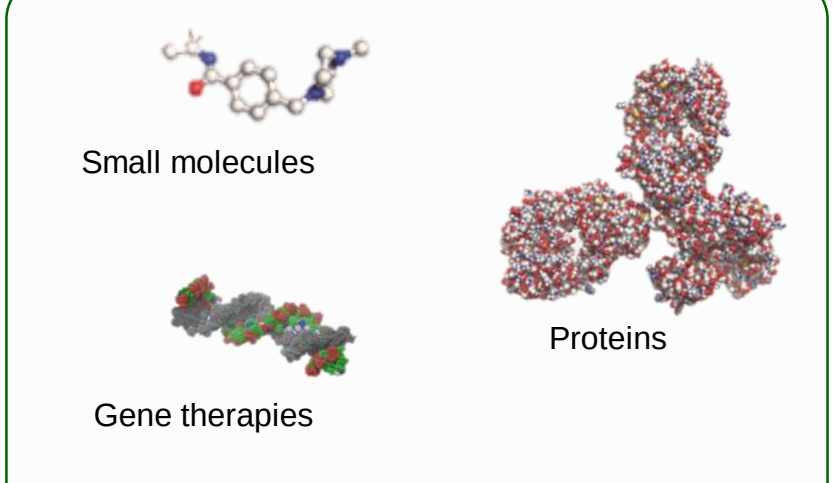
NCL encompasses nanotech expertise & resources from multiple disciplines all in one location. NCL has 10+ years of knowledge and expertise in nanoparticle characterization.

ncl.cancer.gov

Nanotechnology Characterization Laboratory

400 Different nanomaterials characterized with a wide range of nanotechnologies and APIs





50 Protocols harmonized for various nanoparticles

14 NCL collaborators in clinical trials

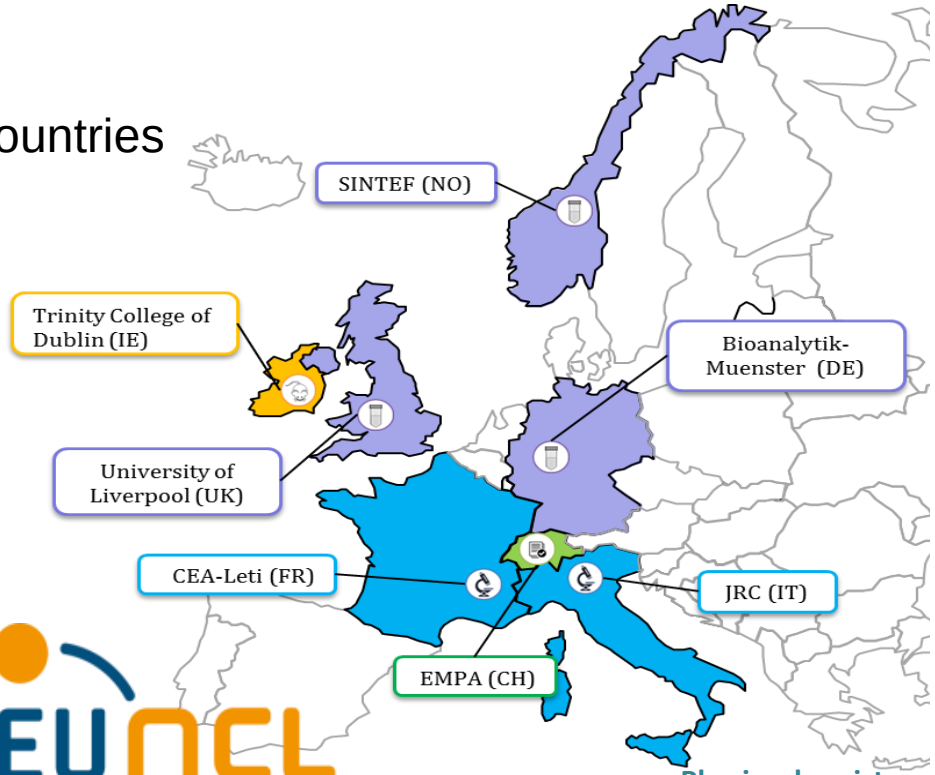
150 Extensive pharmacokinetic and toxicological preclinical studies

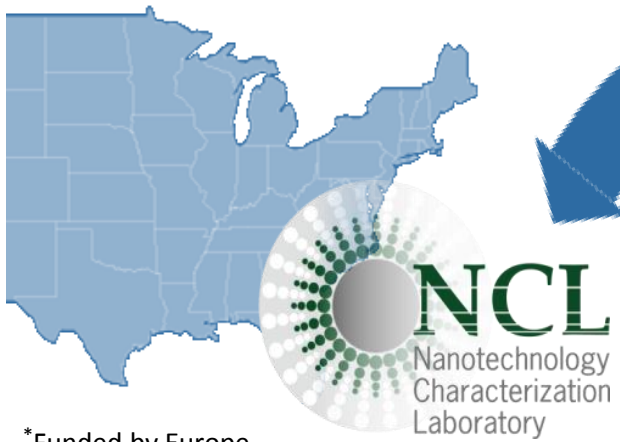
200 Peer-reviewed publications

Transnational Collaboration in Nanomedicine

NCL is a partner in the establishment of a multinational NCL-like entity in Europe

- EU NCL is consortia of 8 labs across 7 countries
- US-EU collaboration aimed at facilitating regulatory convergence for nanomedicine, FDA, EU National Authorities, & EMA
- Collaboration expands much-needed access to nanomaterial characterization for developers





*Funded by Europe

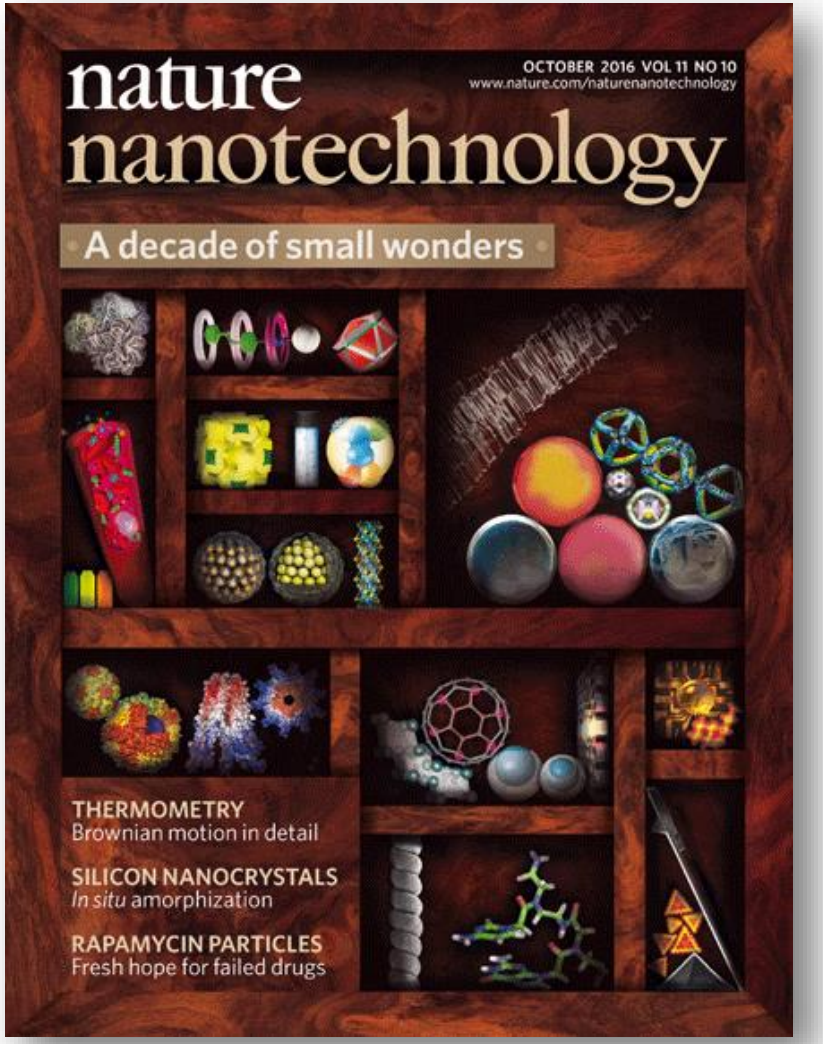
EU NCL Nanomedicine Characterisation Laboratory

Physicochemistry
Biological, in vivo
Biological, in vitro
Quality

EU NCL fully operational March 2017

www.euncl.eu

Nanomedicine: An Evolution or Revolution?



thesis

The long way to the market

Nanotechnology is starting to play a role in a number of commercial products, though in an evolutionary, rather than revolutionary way, says Peter Dobson.

In the 1990s, some of us were convinced that nanotechnology was going to be a transformative technology that would have major impacts on many sectors, would spawn a new generation of electronic and optical devices, change healthcare and give rise to many new materials. After over 20 years, it is interesting to reflect on whether and in what way the field has delivered on its potential.

I have to confess to being one of those who initially showed a degree of optimism

the titanium dioxide with manganese to transform the material from an n-type semiconductor to a slightly p-type one. So, from the initial idea we succeeded to make a material that blocked ultraviolet light but also prevented the formation of $OH^{\bullet}$ free radicals. We filed a patent and this was licensed to Oxonica and it very quickly attracted the attention of the pharmaceutical and healthcare company Boots, who incorporated it in its Soltan sunscreen product, and it is available to this day, in the

with the Stagecoach bus company being one of their largest customers.

These examples as well as my experience more generally have taught me that attempts to create new companies by simply concentrating on a 'technology push' seldom works. In pushing a particular technology, the engineer or scientist begins to believe in their own idea so much that they become blind to the needs of the users or customers. In fact, it is difficult to think of any such approaches that have been successful. On the other hand,

Nature Nanotechnology, 2016 Volume 11 No 10
Dobson, P. Nature Nanotechnology, November 2016 Volume 11 No 11

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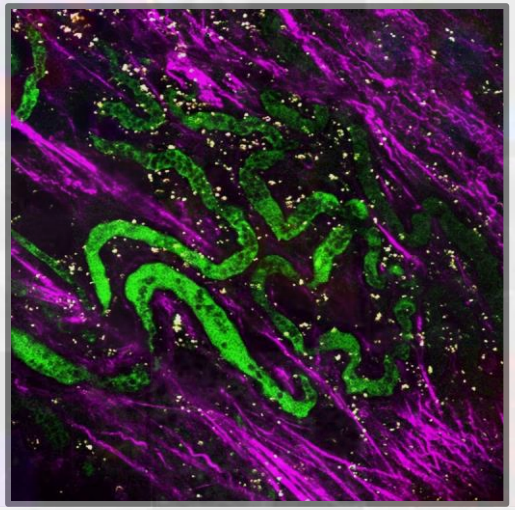
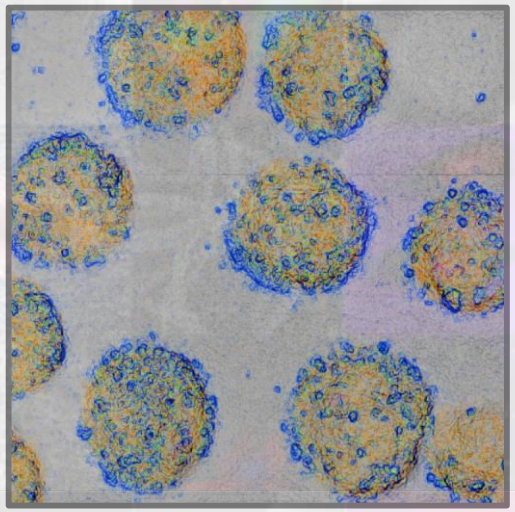
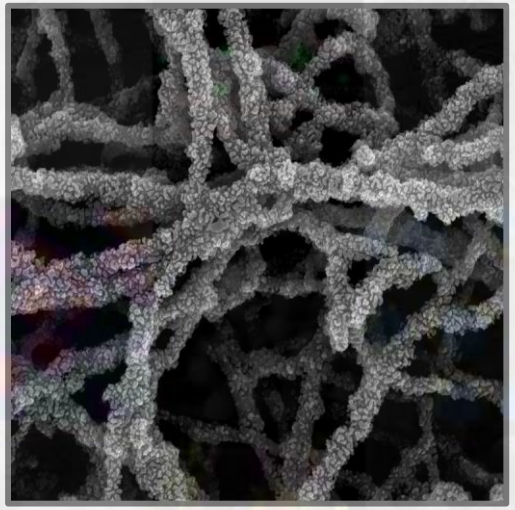


Sangeeta N. Bhatia

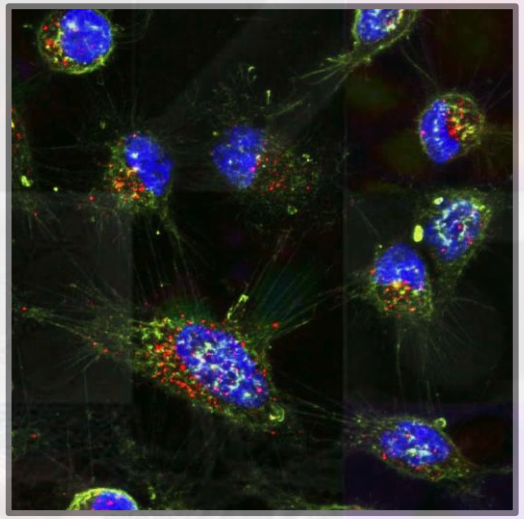
Daniel G. Anderson



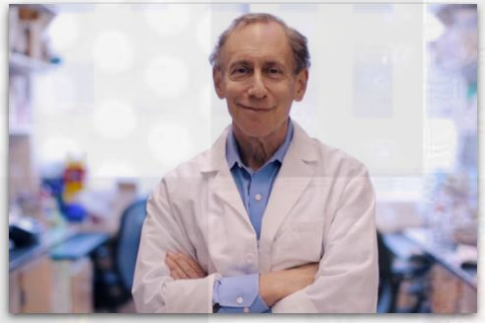


Angela M. Belcher

Paula T. Hammond

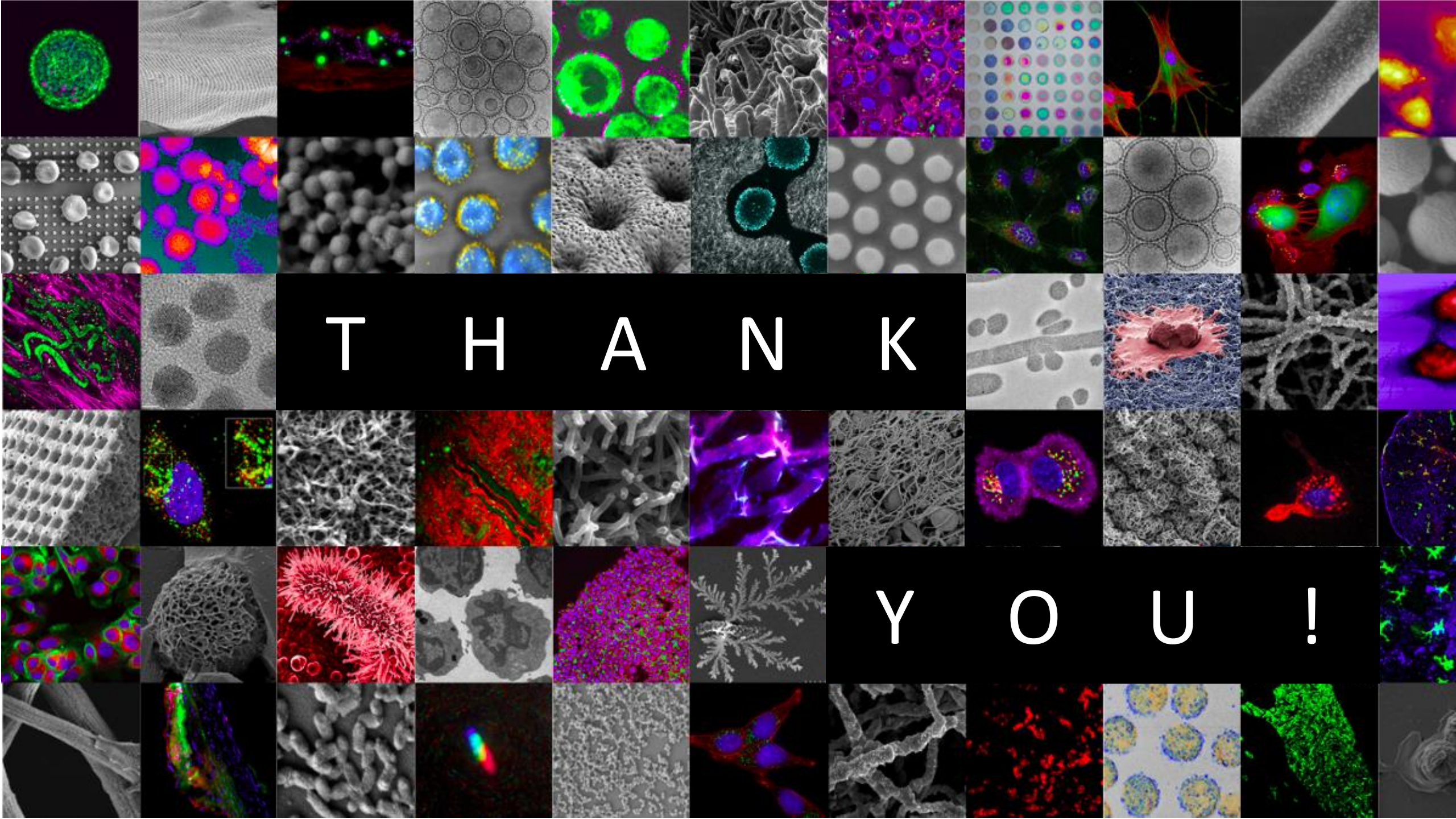


Darrell J. Irvine



Robert S. Langer

http://nanomedicine.mit.edu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Y O U !