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Academic-Industrial Partnerships for Translation of Cancer Technologies

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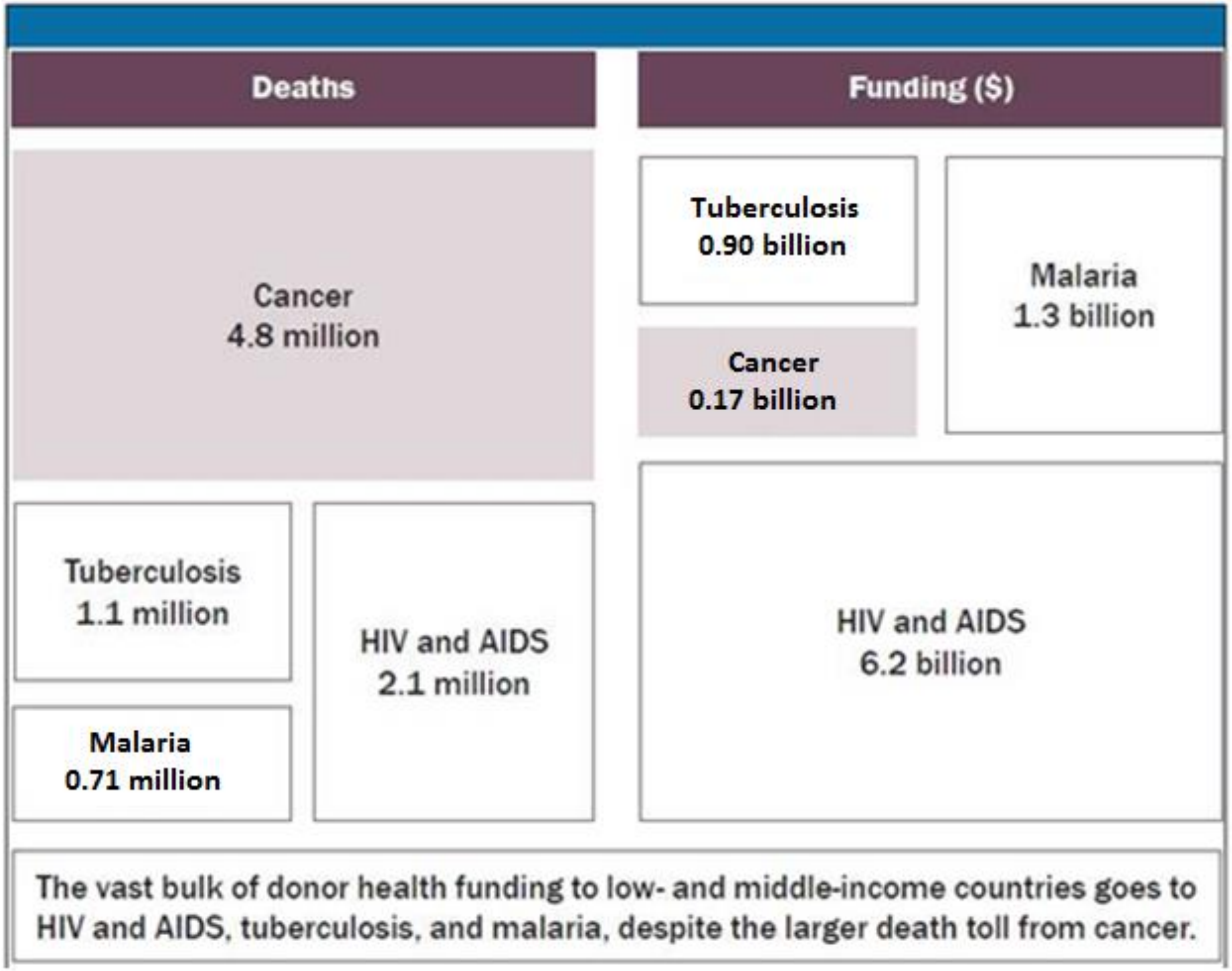
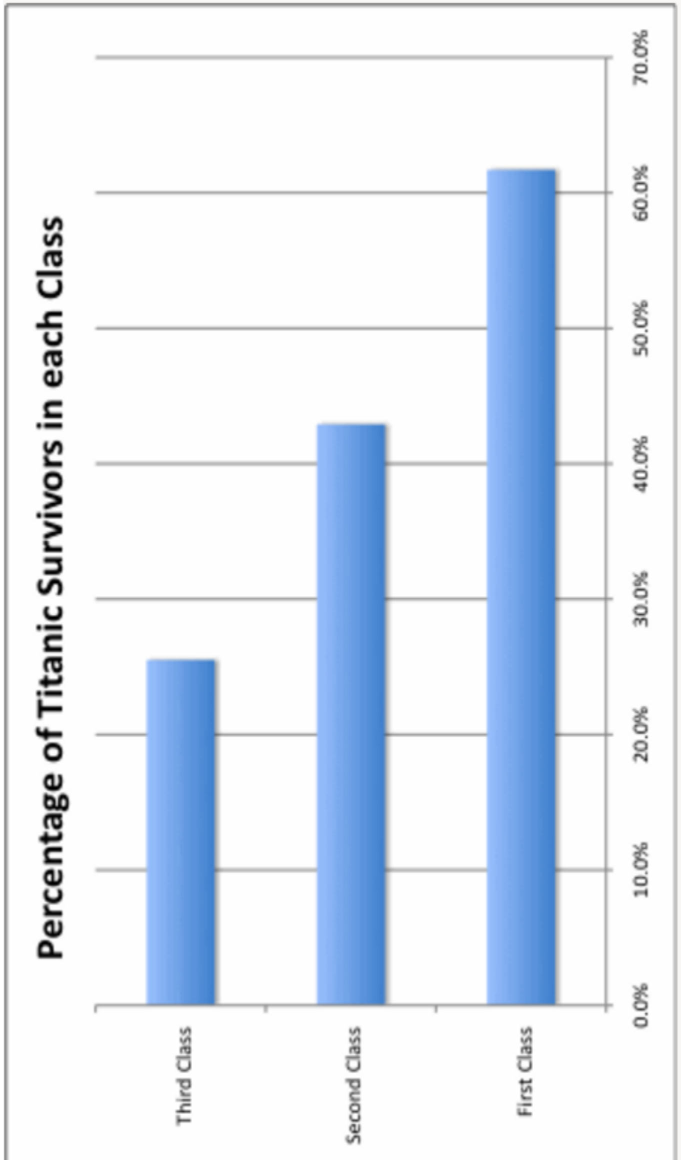
The Issue of Cancer Health Disparity

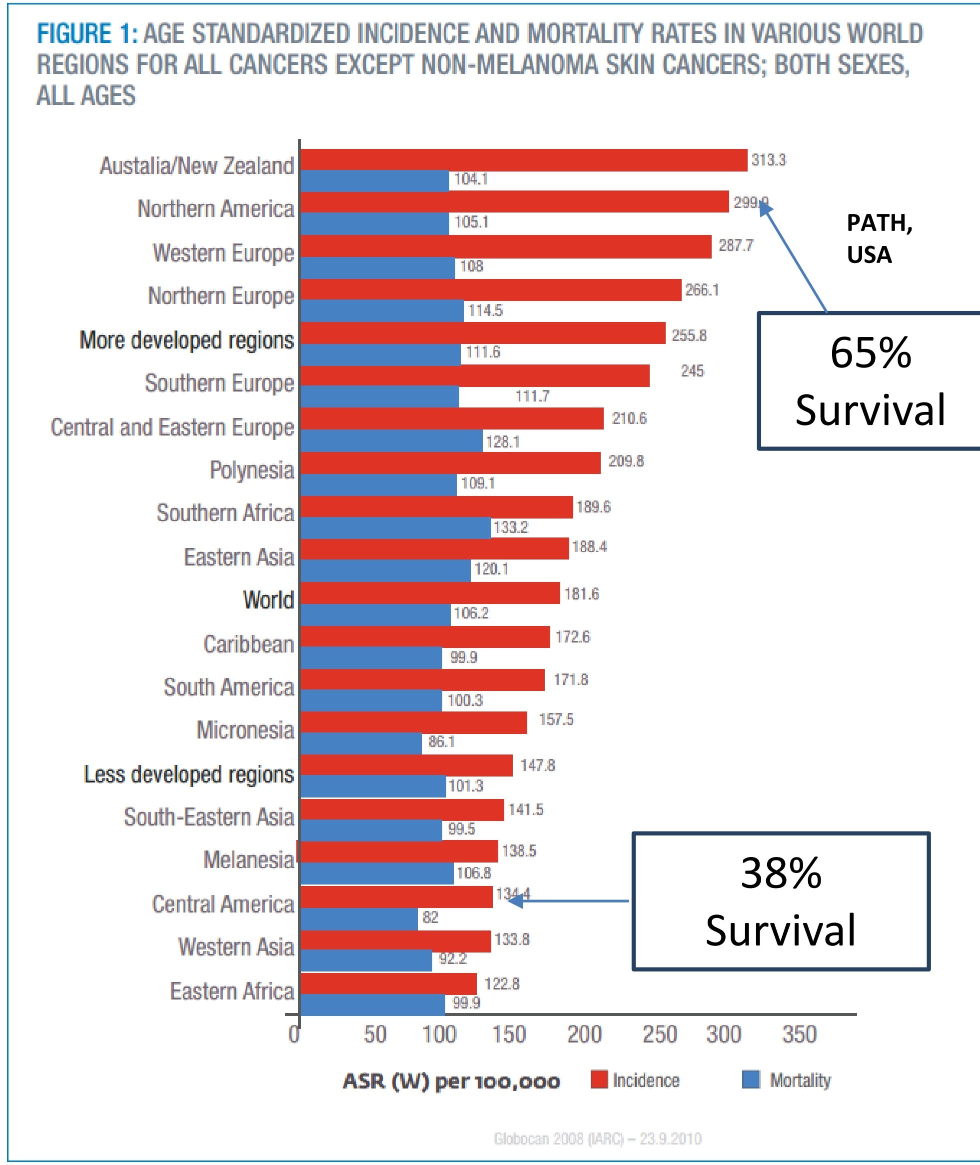
Money driven research?



Cancer Deaths Versus Funding in Low- and Middle-Income Countries
Note. All amounts are in U.S. dollars.
Note. From Public Radio International's (PRI's) The World (http://www.pri.org/programs/the-world). Copyright 2012 PRI. Used with permission from PRI® (http://www.pri.org).



Class Travelled



The Cancer Epidemic in Central Appalachia

Tech & Science, (Nov 7, 2017)

http://www.newsweek.com/2015/07/31/cancer-epidemic-central-appalachia-354857.html

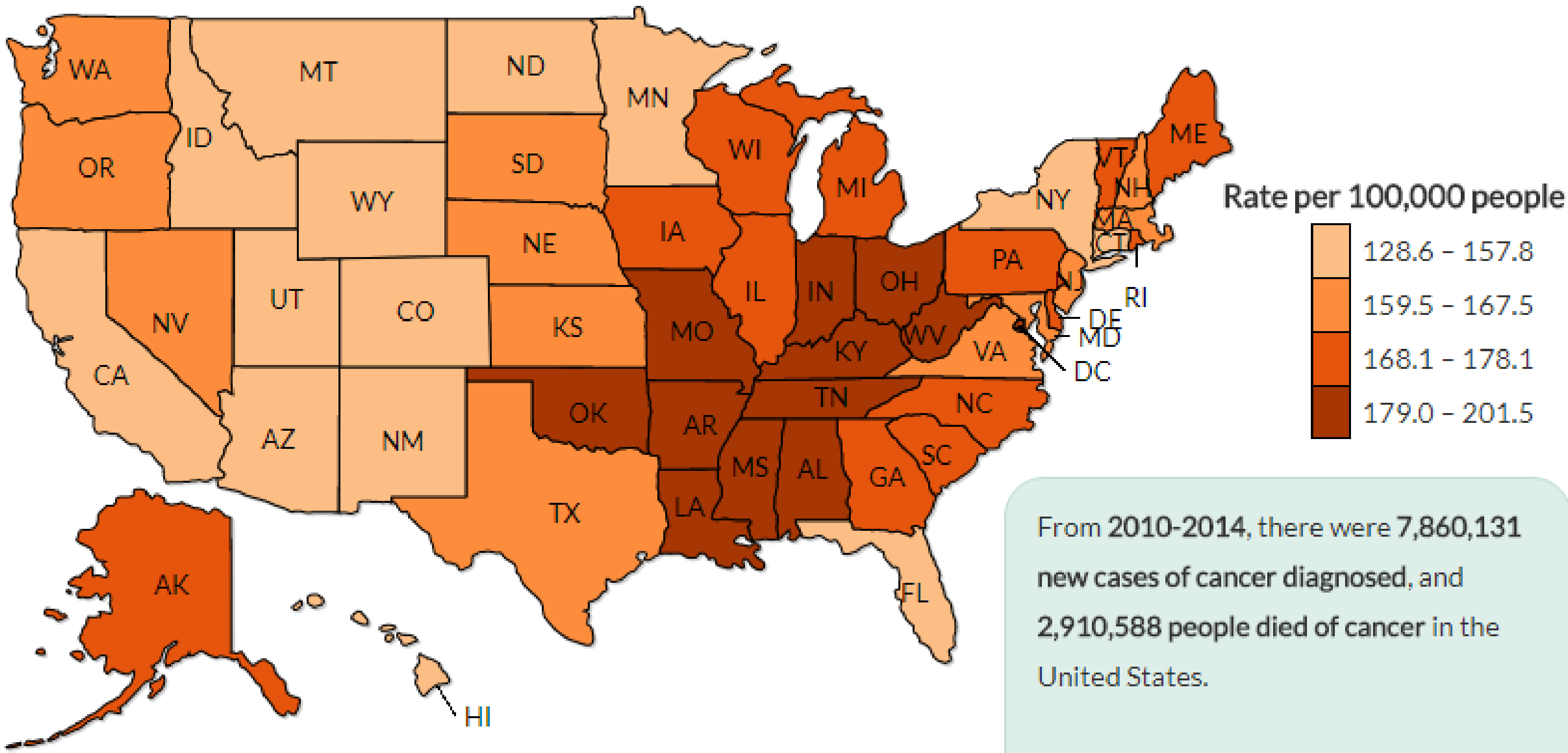
Newsweek

A mural of a coal miner is visible in an empty storefront as signs advertising vacant apartments and stores hang in the windows along the main business street in Cumberland, Kentucky in October 2014. Kentucky has more cancer than any other state in the country, with cases heavily concentrated in the Appalachian counties.

DAVID GOLDMAN/AP

Rates of Cancer Deaths in the United States, 2010-2014 (CDC)

https://nccd.cdc.gov/USCSDataViz/rdPage.aspx



From **2010-2014**, there were **7,860,131 new cases of cancer diagnosed**, and **2,910,588 people died of cancer** in the United States.

Cancer is the second leading cause of death in the United States, exceeded only by heart disease. **One of every four deaths in the United States is due to cancer.**

Distance as a Barrier to Cancer Diagnosis and Treatment

In almost all the studies analyzed, patients who lived far from hospitals and had to travel more than 50 miles had a more advanced stage at diagnosis, lower adherence to encoded treatments, a worse prognosis, and a worse QoL.
(Ambroggi, Oncologist, 2015)

Authors	Type of study	Patients (*n*)	Cancer type	Place and country	Results
Scoggins et al. [1]	Retrospective	3,917	Breast, colorectal, and lung cancer	Washington, USA	One hour more in driving time or 100 miles more in driving distance associated with more advanced disease at diagnosis
Stitzenberg et al. [9]	Retrospective	615	Melanoma	North Carolina, USA	For each 1-mile increase in distance, Breslow thickness increased by 0.6%
Parsons et al. [14]	Retrospective	3,286	Colorectal cancer	Maine, USA	Increasing distance to primary care provider associated with late-stage for colorectal cancer
Huang et al. [17]	Retrospective	12,322	Breast cancer	Kentucky, USA	Advanced diagnosis associated with longer average travel distances than early-stage diagnoses ($p < .01$)

Technology Development in Cancer Research and the Current Funding Paradigm

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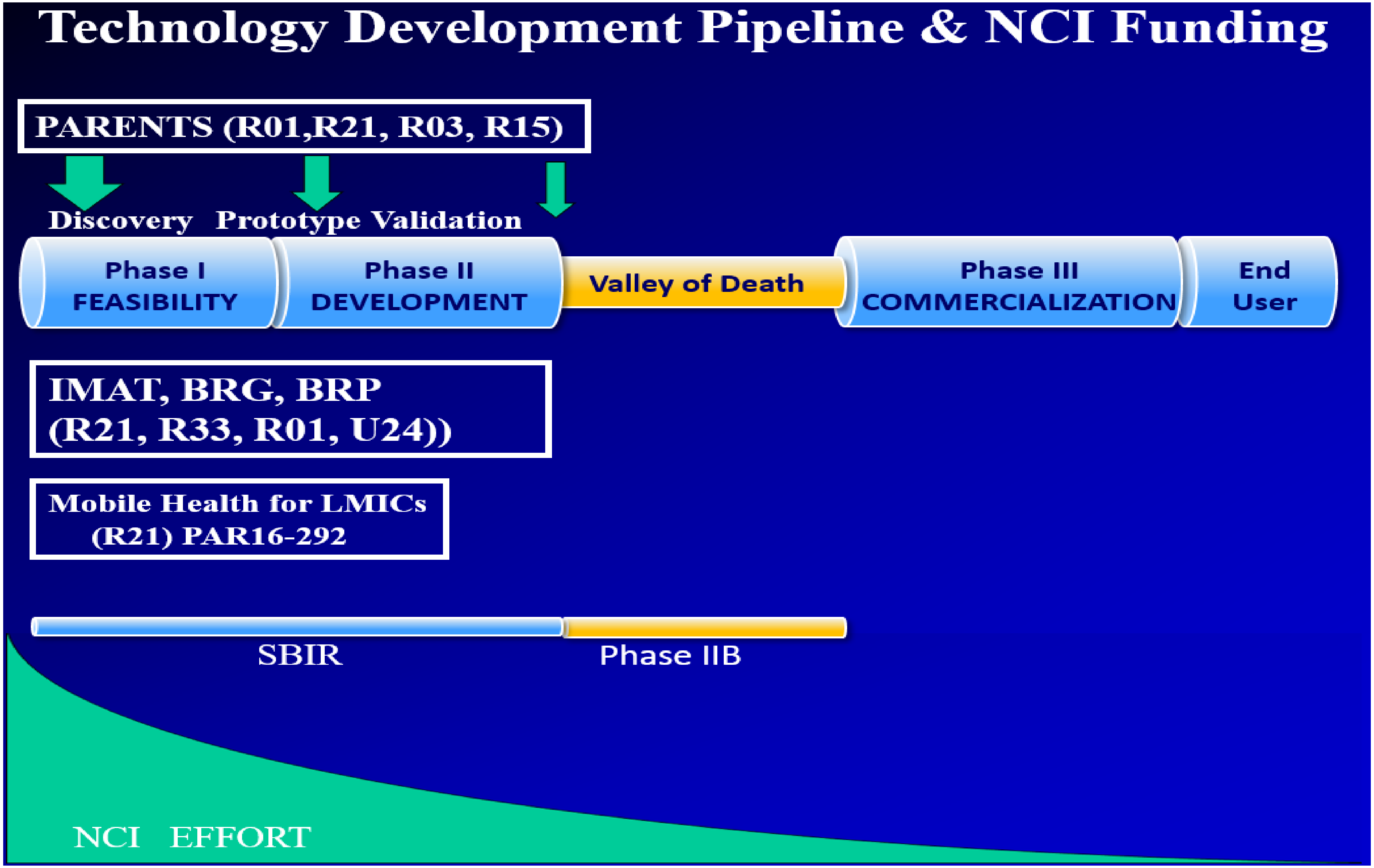


- Most of the NCI funding effort in in technology development for cancer research is allocated in early development and validation (not much funding in translation). This results mostly in excellent publications in high impact journals, but how many of these great ideas become something that can be used in the clinic and actually help people?

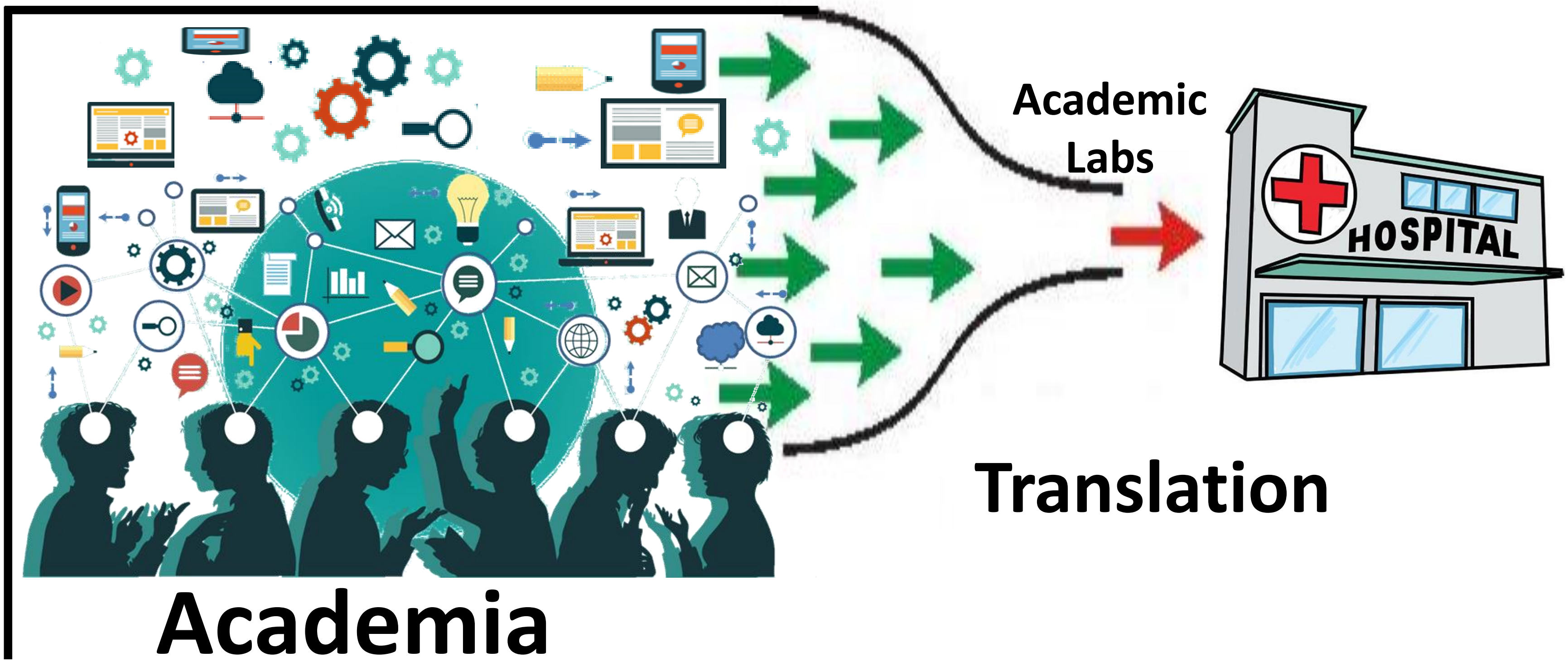
What is Technology Translation?

Academic grade prototype

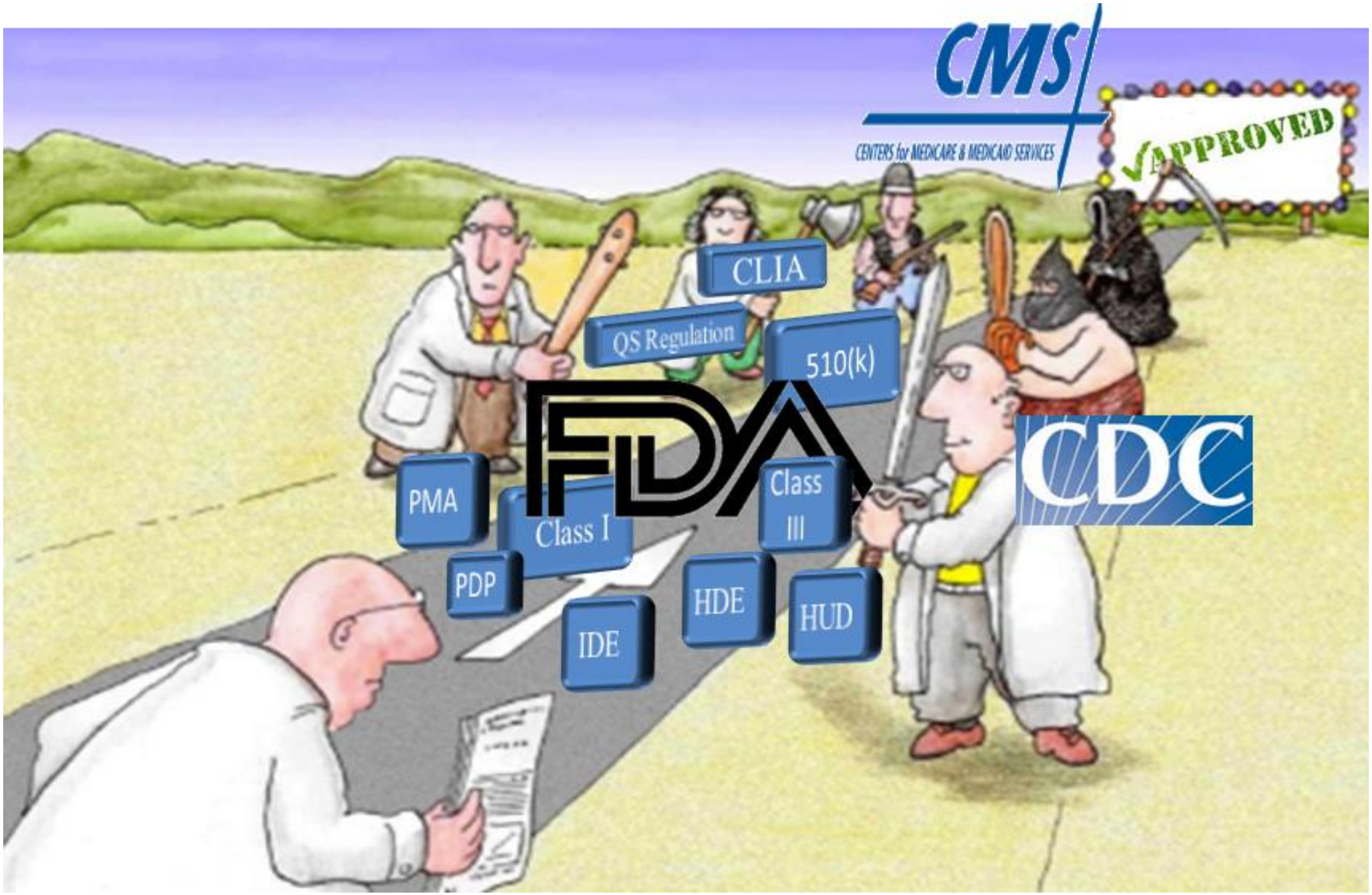
Commercial device

Side effects of the current funding paradigm

- Traditional funding mechanisms produce publications, but are much less effective in producing pre-commercial prototypes or commercial products.
- Pile up of inventions at the laboratory door of academic institutions (from IMAT, BRP, BRG and others).
- Most of the academic researchers may decide to focus on basic research rather than translational research.



Even if academics would like to work in translational research, most academics don’t know much about how to make their prototype technology into a commercial product



https://www.fda.gov/MedicalDevices/ucm187277.htm
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm

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Academic-Industrial Partnerships for Translation of Cancer Technologies (AIP)

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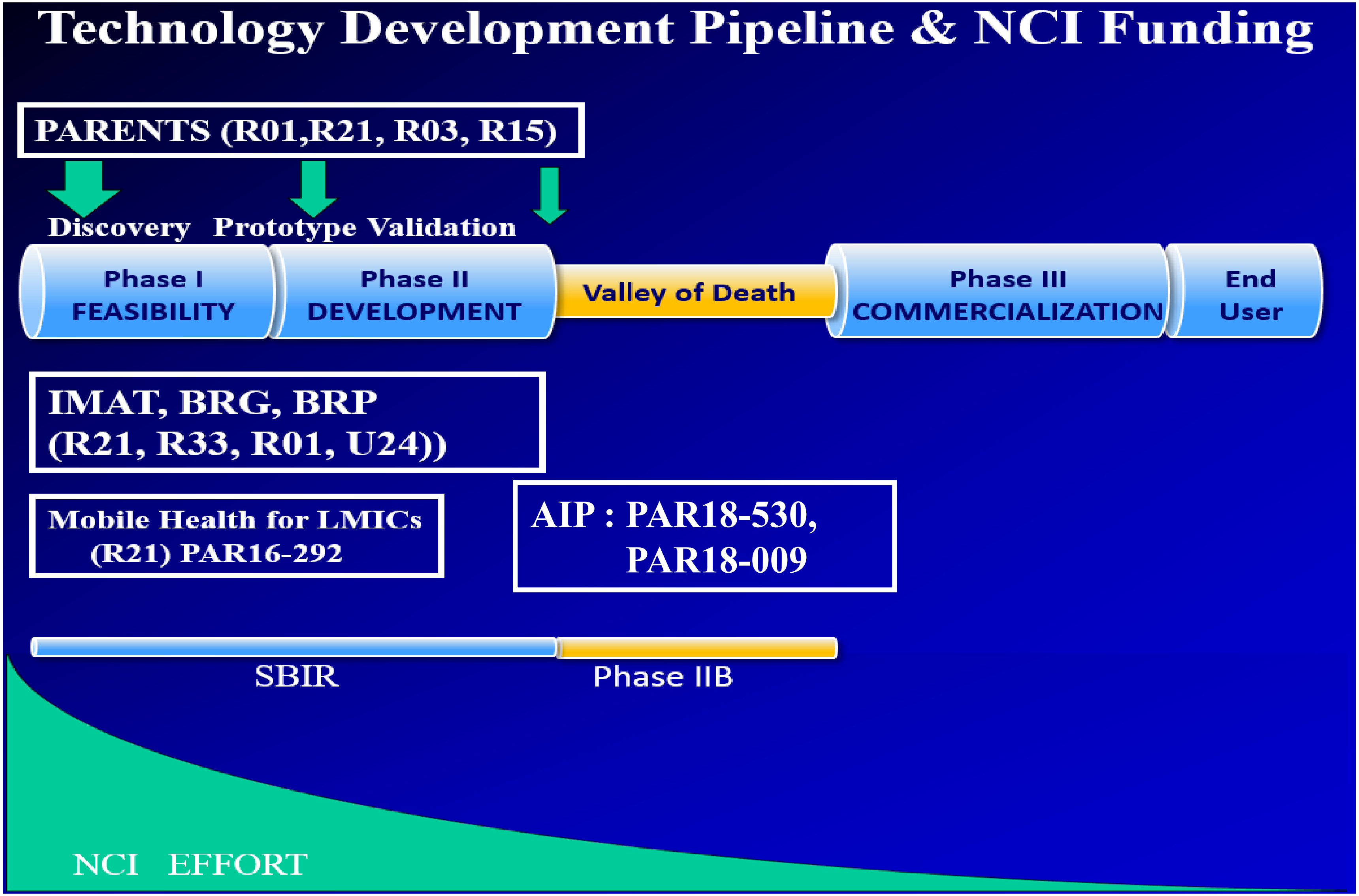

We developed the Academic-Industrial Partnerships (AIP)initiative to address the issue of translation

Rationale for Academic-Industrial Partnerships for Translational Research

How to break the bottleneck that piles up inventions at the lab of academic institutions, which don't reach the clinic?

A strategic alliance between academia and industry is necessary to provide critical mass and broad expertise required for transition to the clinic

Business partner provides complementary expertise in the following:

- Pre-commercial engineering, business, marketing, fabrication and regulatory knowhow
- Convert a feasibility prototype into one with industrial specifications
- Validation to satisfy regulatory approvals and deliver a pre-commercial prototype

Note a new flavor of innovation in the AIP announcement

- This FOA defines innovation as likelihood to deliver a new capability to end users.
- Is it likely to deliver a capability that is new to a high, intermediate, or low resource setting or in a well-, moderately- or underserved population?

WHY FOCUS IN INNOVATION?

Because review values innovation!

- Traditional definition
  "Something new, I have never seen before"

- AIP definition:

  Innovation as likelihood to deliver a new capability to end users. This definition of innovation is deliberately broad to accommodate a wide range of projects and their problems in need of solutions. For example, objectives may include adaptations of existing or new technologies or methods affordable for use in any setting, including those with low resources or underserved populations.

Academic-Industrial Partnerships for Translation of Technologies for Cancer Diagnosis and Treatment (PAR8-009, PAR18-530, R01)

https://grants.nih.gov/grants/guide/pa-files/PAR-18-530.html.

Encourages applications from research partnerships formed by academic and industrial investigators, to accelerate the translation of technologies, methods, assays or devices, and/or systems for preclinical or clinical molecular diagnosis or in vitro imaging that are designed to solve a targeted cancer problem.

Foreign Institutions are eligible to apply
Foreign components are allowed

Budget: Not limited but must reflect the needs of the project (talk to program before submitting a budget that exceeds $500,000)

The total project period request may not exceed 5 years

Examples of funded projects

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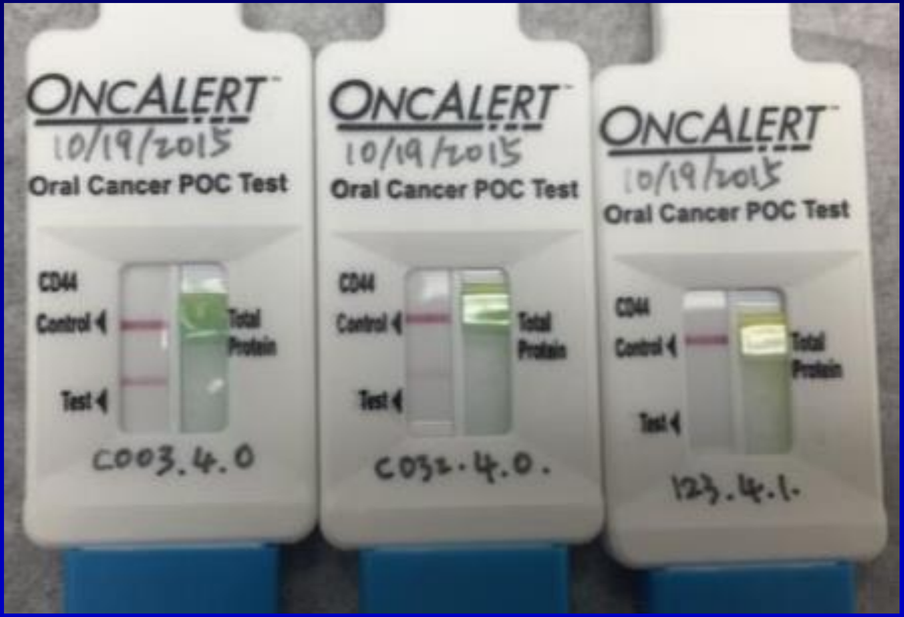
A novel point of care test for oral and oropharyngeal cancer risk
Joseph Califano, University of California San Diego/Vigilant Biosciences

The previously developed ELISA system has been converted to an economical ($25) lateral flow system, similar to that used in commercial pregnancy tests



https://projectreporter.nih.gov/project_info_details.cfm?aid=9239502&icde=36821361

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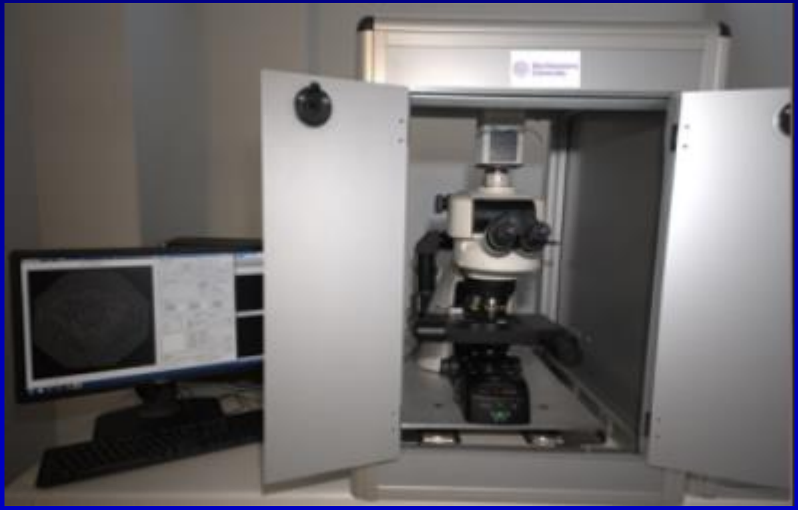
Translating buccal nanocytology for lung cancer screening into clinical practice

Vadim Backman, Northwestern University/NanoCytomics

Minimal invasive, cost-effective method based on biphotonic technology, partial wave spectroscopy (PWS). Analyzing chromatin alterations, PWS can be used for lung cancer screening to identify the subset of patients who are likely to harbor lung cancer and would benefit from low-dose CT



https://projectreporter.nih.gov/project_info_description.cfm?aid=9539327&icde=40413592

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Computerized histologic image predictor of cancer outcome

Anant Madabhushi, Case Western Reserve University/Inspirata, Inc

Development and validation of a computerized histologic image-based predictor (CHIP) to identify which early-stage, estrogen receptor positive (ER+) breast cancer patients are candidates for hormonal therapy alone and which women are candidates for adjuvant chemotherapy based on analysis of the pathology slides derived from biopsy and surgical specimens.

https://projectreporter.nih.gov/project_info_description.cfm?aid=9512832&icde=40413655

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Development of an LMIC-adapted Thermocoagulation Prototype for the Treatment of Cervical Pre-cancer.

Miriam Cremer, Cleveland Clinic CWRU/WISPA Medical technology GMBH

The adapted thermoablation device enables use by non-physician health providers. Nurses and midwives increasingly provide clinical services in areas that are otherwise medically underserved and they have strong potential to provide thermoablation treatment in areas with the highest need

Work to be done in Mexico and El Salvador

* Courtesy of Dr. Miriam Cremer

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