



Inventions  Public Health

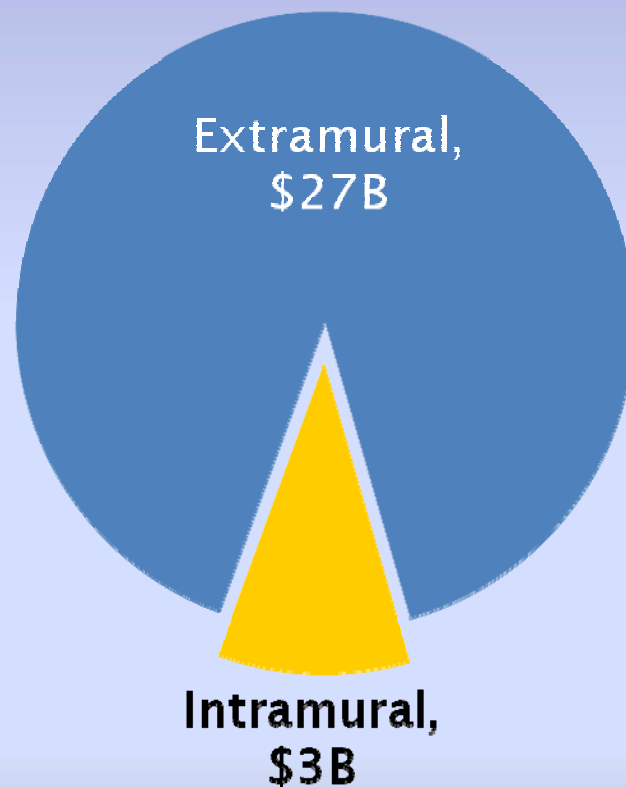
# The NIH Experience

Ajoy Prabhu, M.S., M.B.A.  
Head, Marketing and Operations  
Office of Technology Transfer  
National Institutes of Health  
U.S. Department of Health & Human Services





# FY10 NIH Budget





# Intramural Technologies in Numbers

- 353 invention disclosures
- 110 U.S. patents issued
- 215 licenses executed
- 1,400+ active licenses
- \$91.2 million in royalties collected
- 77 CRADAs executed
- 365 active CRADAs
- ~ 600 products developed
- 22 drugs and biologics
- Licensees: Total Sales ~\$6B





# NIH Licensed Products

## Therapeutics

- Didanosine
- Fludara<sup>®</sup>
- Hivid<sup>®</sup>
- Kepivance<sup>®</sup>
- NeuTrexin<sup>®</sup>
- Prezista<sup>®</sup>
- Sporanax<sup>®</sup>



- Synagis<sup>®</sup>
- Taxol<sup>®</sup>
- Velcade<sup>®</sup>
- Videx<sup>®</sup>
- Vitravene<sup>®</sup>
- Zenapax<sup>®</sup>
- Zevalin<sup>®</sup>

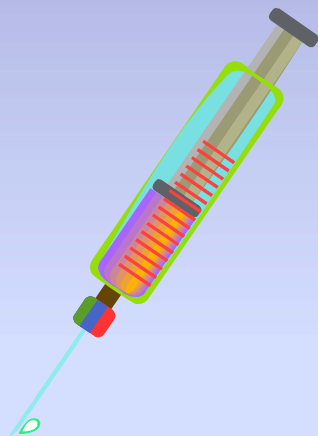




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## Vaccines

- Certiva<sup>®</sup>
- Cervarix<sup>®</sup>
- Gardasil<sup>®</sup>
- Havrix<sup>®</sup>



- Hepatyrix<sup>®</sup>
- LYMERix<sup>™</sup>
- RotaShield<sup>®</sup>
- Twinrix<sup>®</sup>





# NIH Licensed Products

## Diagnostics

- AcuTect®
- BRACAnalysis®
- HIV Test Kits
- NeoTect®
- Parvovirus B19 Immunoassay
- PathVysion® HER-2 DNA Probe Kit
- Pathway® Her-2/neu (4B5)
- Thyrogen®





# Examples of Products Developed Under NIH CRADAs

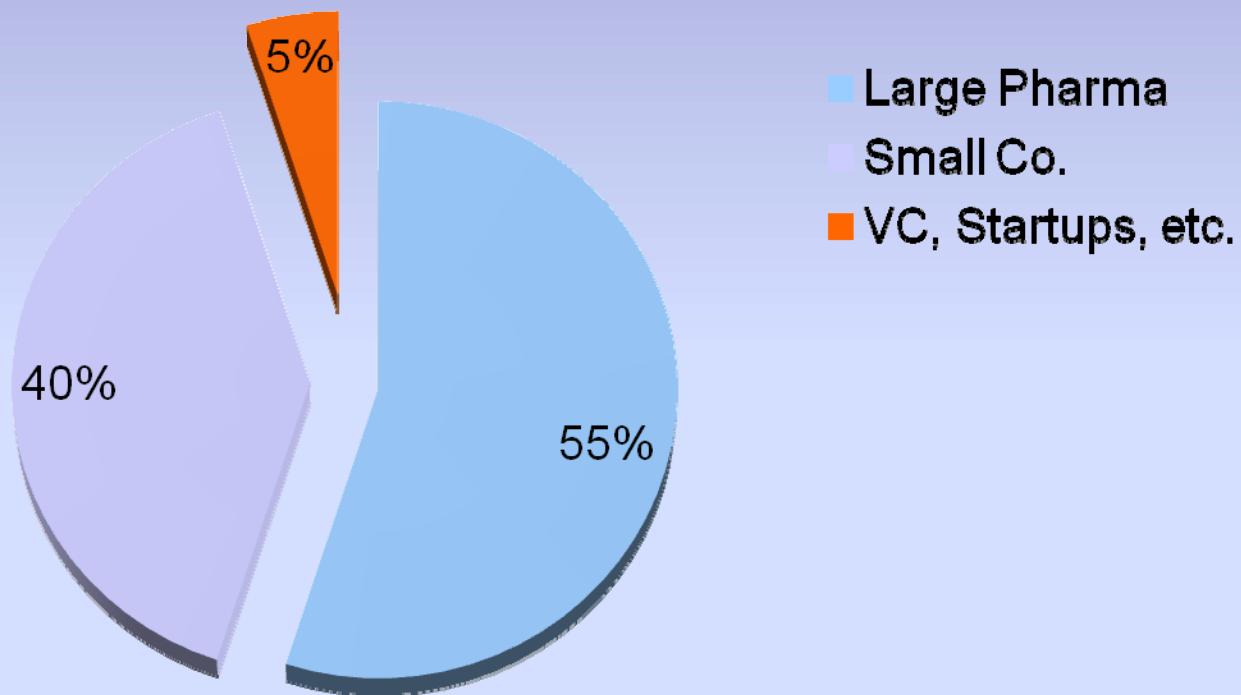
Product	Company	Use
FluMist®*	MedImmune	Influenza vaccine
Havrix®	GlaxoSmithKline	Vaccine against hepatitis A
Taxol®	Bristol-Myers Squibb	Treatment of solid tumors and Kaposi's cancer
Taxus® Express	Boston Scientific	Treatment of coronary artery disease (drug-eluting stent)
Thyrogen®	Genzyme Therapeutics	Adjunct to thyroid cancer treatment
Velcade®	Millennium Pharmaceuticals Inc.	Treatment of multiple melanoma

\*Not based on NIH IP





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#### Dental Technology



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### [Identification of Colorectal Cancer Biomarkers by Serum Protein Profiling](#)

Tuesday, December 01, 2009 7:00 PM

This invention describes serum features that distinguish colorectal carcinoma malignant patient samples versus healthy samples using surface-enhanced laser desorption ionization time-of-flight (SELDI-TOF) mass spectrometry. By comparing healthy versus malignant samples, the investigators were able to identify thirteen (13) serum features that have been validated using an independently collected, blinded validation set of 55 sera samples. The features are characterized by the mass to charge ratio (m/z ratio). The investigators have shown that SELDI-TOF based serum marker protein profiling enables minimally invasive detection of colon cancer with 96.7 percent sensitivity and 100 percent specificity. Colorectal cancer is the third most common cancer and the third leading cause of cancer-related mortality in the United States. Current diagnostic methods for colorectal cancer have a large non-compliance rate because of discomfort, e.g., sigmoidoscopy or colonoscopy, or have a high rate of false positive results, e.g., fecal occult blood tests. The claimed invention has the potential to be a widely used, easy-to-use, and inexpensive diagnostic.

### [Human Renal Cell Carcinoma \(RCC\) Cell Lines Derived from Surgically Removed Tumors](#)

Tuesday, December 01, 2009 7:00 PM

Scientists at the National Institutes of Health (NIH) have developed three cell lines obtained from renal cell carcinoma (RCC) patients. The cell lines, designated 1581 RCC, 1764 RCC, and 2194 RCC, were derived from human tumor samples surgically resected from patients in the inventors' clinic. Each cell line is human leukocyte antigen-A2 (HLA-A2) negative and expresses a variety of known tumor antigens. The 1764 RCC cell line is known to express the HLA-A3 antigen and high levels of nonmutated fibroblast growth factor 5 (FGF-5). These cell lines can be widely used in molecular biology for various assays and to screen for potential therapeutics with activity against RCC. The RCC cell lines can also serve as negative control samples for HLA-A2 expression.

### [Methods and Compositions for the Diagnosis of Neuroendocrine Lung Cancer](#)

Tuesday, November 03, 2009 7:00 PM

The technology relates to the use of cDNA microarrays to facilitate the identification of pulmonary neuroendocrine tumors. In order to identify molecular markers that could be used to classify pulmonary tumors, the inventors examined the gene expression profiles of clinical samples from patients with small cell lung cancer (SCLC), large cell neuroendocrine carcinoma (LCNEC), and typical carcinoma (TC) tumors by cDNA microarray analysis to detect hybridization between cDNA from tumor cells and DNA from a panel of 8,897 human genes. Gene expression was found to be nonrandom and to exhibit highly significant clustering that divided the tumors into their assigned World Health Organization (WHO) classification with 100% accuracy. The inventors concluded that pulmonary neuroendocrine tumors could be classified based on the genome-wide expression profile of the clinical samples without further manipulations.

### [Prediction of Immune Response Outcomes to Keyhole Limpet Hemocyanin \(KLH\) Treatment](#)

Monday, October 26, 2009 8:00 PM

Keyhole limpet hemocyanin (KLH) is a large, heterogeneous glycosylated protein that is being tested as an immunotherapeutic agent to treat bladder cancer. KLH is approved for use in parts of Europe and Asia and is in late stage clinical trials in the U.S. KLH immunotherapy however only produces a clinical response in approximately 40-50% of patients, and currently there is no good method to select the subset of patients that will respond best to this treatment. This invention revealed that levels of certain serum antibodies can be used as biomarkers to predict the magnitude of the antibody response to the glycoprotein KLH. The best correlations are obtained by using a combination of markers. Since the size of the antibody response correlates with the clinical response, the invention provides a method to select the subset of patients that may benefit most from this form of treatment.

### [Identification of Persons Likely to Benefit from Statin Mediated Cancer Prevention by Pharmacogenetics](#)

Sunday, October 11, 2009 8:00 PM

Inhibitors of 3-hydroxy-3-methylglutaryl (HMG) coenzyme A reductase (statins) are a class of well-tolerated compounds that are the most widely used cholesterol-lowering drugs in the United States. Reduced cancer risk among statin users has also been observed as a secondary outcome in randomized controlled clinical trials evaluating effects of statins on cardiovascular outcomes. However the observed cancer risk reduction varied with different clinical studies. Thus there is a need to identify individuals who would benefit from treatment with statins. The current invention describes a pharmacogenetic method to identify candidates who are most likely to benefit from treatment with statins to reduce cancer risk, and consequently minimizing any unnecessary cost and side effects in individuals who do not benefit. Specifically, we discovered that an HMGCR genetic variant rs12654264 is associated with significantly lower colorectal cancer risk, with most of the benefit seen in HMGCoA reductase inhibitor (statin) users. We also discovered that this same HMGCR genetic variant is associated with significantly higher serum cholesterol levels in Israeli colorectal cancer patients. The same HMGCR genetic variant has also been associated with significantly higher serum cholesterol levels in two independent groups of individuals of mixed European descent ([<http://www.broad.mit.edu/diabetes/scandinavians/index.html>] and *N Engl J Med*.2008 March 20;358(12):1240-1249 (<http://www.ncbi.nlm.nih.gov/pubmed/18354102?dopt>]). These data suggest that the same genetic variant modifies cholesterol metabolism in a manner that affects both colorectal cancer risk and cardiovascular risk.





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**Identification of Colorectal Cancer Biomarkers by Serum Protein Profiling**

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Posted On: Tue 12/1/2009 7:00 PM

This invention describes serum features that distinguish colorectal carcinoma malignant patient samples versus healthy samples using surface-enhanced laser desorption ionization time-of-flight (SELDI-TOF) mass spectrometry. By comparing healthy versus malignant samples, the investigators were able to identify thirteen (13) serum features that have been validated using an independently collected, blinded validation set of 55 sera samples. The features are characterized by the mass to charge ratio (m/z ratio). The investigators have shown that SELDI-TOF based serum marker protein profiling enables minimally invasive detection of colon cancer with 96.7 percent sensitivity and 100 percent specificity. Colorectal cancer is the third most common cancer and the third leading cause of cancer-related mortality in the United States. Current diagnostic methods for colorectal cancer have a large non-compliance rate because of discomfort, e.g., sigmoidoscopy or colonoscopy, or have a high rate of false positive results, e.g., fecal occult blood tests. The claimed invention has the potential to be a widely used, easy-to-use, and inexpensive diagnostic.

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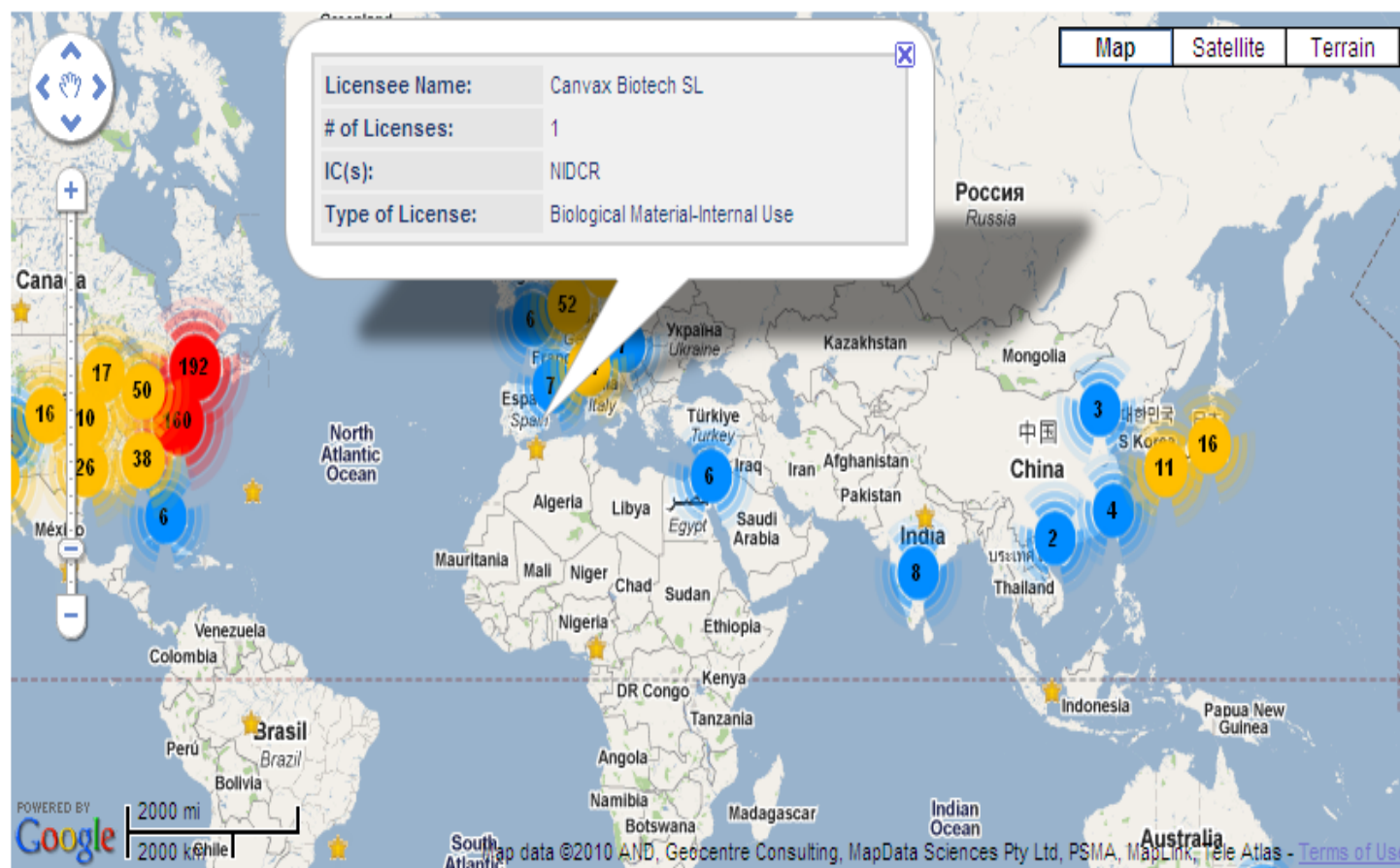
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Country:  Institute/Center:  FY Executed:

The impact of NIH and FDA Intramural Research Programs is truly global. The stars on the map represent locations where a commercial entity has completed a license with the NIH Office of Technology Transfer for an NIH or FDA intramural invention. These licenses allow for the transfer of inventions and discoveries from the NIH/FDA Intramural Research Programs to biotechnology companies for commercial development or use in research.

The licenses on this map can be filtered by country of licensee, NIH Institute, and fiscal years that the license has been active. Densely populated areas are represented in clusters rather than stars. To view these areas, please zoom further into the map.







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Product Type:

-- All --

Launched FY:

-- All --

Approval:

-- All --

SUBMIT

CLEAR

Product:  
Cervarix®

Use:  
Vaccine for human papilloma virus (HPV) to protect from cancers

NIH Contribution:  
Non-infectious HPV-like particles for immunization

Features:  
First EU approved vaccine against cervical cancer and genital warts

Inventors:  
D. Lowy, et al

Institutes/ Centers:  
National Cancer Institute

Licensee:  
GlaxoSmithKline

Market Launch:  
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## Product Development Pipeline

The NIH Intramural Research Program is exceptionally innovative as exemplified by the many products currently on the market that benefit the public everyday (see [Product Showcase](#)). There are also almost 1,400 inventions from the Intramural Program that are currently available for licensing to companies for commercial development (see [Licensing Opportunities](#)). Many inventions, however, have been licensed and are now in clinical development with the hope of eventually reaching the market. These inventions are shown below as a development pipeline and illustrate the valuable synergy between NIH and industry as well as the depth and richness of the science conducted at NIH.

### PRODUCT DEVELOPMENT » THERAPEUTICS

Indication	IC	Licensee	Product	Phase I	Phase II	Phase III	NDA	Market
Cancer	NCI	Schering AG	Fludara®	█	█	█	█	█
Cancer	NCI	Bristol-Myers Squibb	Taxol®	█	█	█	█	█
HIV	NCI	Barr Laboratories	Didanosine Delayed-Release Capsules	█	█	█	█	█
HIV	NCI	Roche Laboratories	Hivid®	█	█	█	█	█
HIV	NCI	Tibotec Pharmaceuticals	Prezista®	█	█	█	█	█
HIV	NCI	Bristol-Myers Squibb	Videx®	█	█	█	█	█
Multiple myeloma	NCI	Millennium Pharmaceuticals	Velcade®	█	█	█	█	█
Non-Hodgkin's lymphoma	NCI	Coulter Corporation	Zevalin®	█	█	█	█	█
Respiratory syncytial virus	NIAID	MedImmune	Synagis®	█	█	█	█	█
Glioblastoma	NCI FDA	Neo-Pharm	Cintredekin Besudotox (IL13-PE38QQR)	█	█	█		
Metastatic melanoma	NCI	Medarex	MDX-010 (gp100 peptide used in conjunction with Ipilimumab)	█	█	█		
Multiple myeloma	NCI	KOSAN Biosciences	KOS-953 [17-AAG (tanespimycin)]	█	█	█		
Acute radiation syndrome	NCI	Humanetics	BIO 300	█	█			
Anemia associated	NICHD	Repros	Proellex®	█	█			





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## Technology Specific Brochures

The marketing group has created several technology-specific brochures that list technologies. Please check with the Technology Licensing Specialist (contact information available below the technology abstract) for current availability.

If you need other disease-specific brochures, please email Ajoy Prabhu, Head of Marketing Operation at [aprabhu@mail.nih.gov](mailto:aprabhu@mail.nih.gov).

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**Neurotrophic Component**

**Description of Invention:**  
Neuronal cell death has been associated with neurodegenerative conditions, including Alzheimer's, AIDS-related dementia, Huntington's disease, and Parkinson's disease. ADNF-1 complex polypeptides have also been associated with developmental retardation and learning disabilities.

This invention discloses new ADNF-1 complex polypeptides. Previously, Activity Dependent Neurotrophic Factor (ADNF) polypeptides have been shown to be effective for reducing neuronal cell death, for reducing oxidative stress, for reducing condition(s) associated with neurodegenerative disorders, and for enhancing learning and memory, both pre- and post-natally, and for other conditions.

With these additional ADNF-1 complex polypeptides it will be easier to target specific receptors in different cell types and to individually tailor drug treatment regimes to those afflicted with neurodegenerative disorders.

**Inventors:**  
Douglas E Brenneman (NICHD)

**Patent Status:**  
HHS, Reference No. E-209-2001/0  
HHS, Reference No. E-209-2001/1  
HHS, Reference No. E-209-2001/2  
US, Patent No. 7,427,590, Issued 23 Sep 2008  
US, Application No. 12/197,915 filed 25 Aug 2008

**Portfolios:**  
Central Nervous System  
Central Nervous System - Diagnostics  
Central Nervous System - Therapeutics

**For Licensing Information Please Contact:**  
[Samuel Bish Ph.D.](#)  
NIH Office of Technology Transfer  
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Rockville, MD 20852  
United States  
Email: [bishse@mail.nih.gov](mailto:bishse@mail.nih.gov)  
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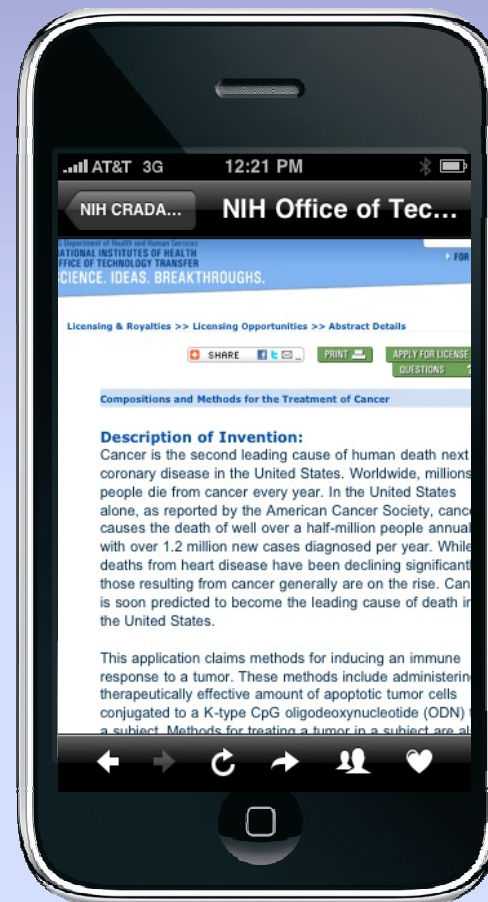
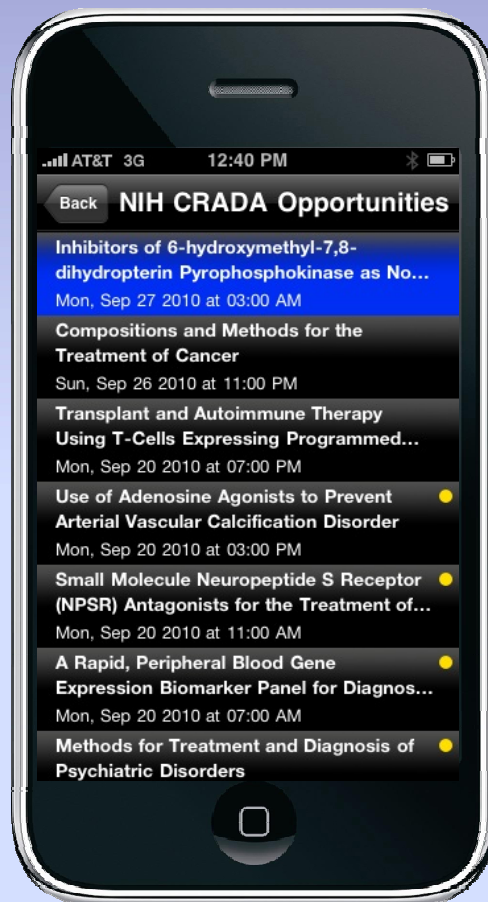
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