

Agency Mission-Specific Metrics for Technology Transfer

Ansalan E. Stewart, Ph.D.
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Background

History

- The technology transfer activities of NIH are of interest to congress, governmental agencies and academicians
- Traditional technology transfer metrics are outputs that include the number of licenses held and the income generated from royalties
- These measures do not address the outcomes of licensing biotechnologies
- NIH established the FY 2001 GPRA Goal of developing new metrics

NIH OTT Mission and Activities

- Mission - link science and the marketplace to improve public health
 - Movement of information & technologies from research findings in NIH intramural labs to practical application in general research use or to benefit health
 - largely accomplished through overseeing patent prosecution, negotiating and monitoring licensing agreements

Measures of Program Success

Traditional

- Employee Invention Reports
- Patents
- Licenses
- Earned Royalties

Mission-specific

- Hospitalization rates
- Orphan Drug status
- 1st of its kind
- Mortality rates
- Improves research efficiency

Evolution of Study

Project Progression: early 2002

- Formed a working group
- Identified potential metrics
- Reviewed potential methodologies
- Identified model studies
- Reviewed potential sources of reliable data
- Selected methodology and metrics

Methodology & Metrics Selected

Methodology

Case study approach utilizing secondary epidemiological data to highlight individual therapeutic drugs or vaccines resulting from NIH-licensed technologies

Metrics

Health-related metrics were selected based upon the epidemiology of the disease for which product incorporating NIH technology(s) is indicated

Sample Metrics of Public Health Effect

- First-in-kind drugs and vaccines
- Doses of drug prescribed
- Effect of treatment on
 - hospitalization, mortality and incidence rates
 - number of disease-related morbidity
 - patients' quality of life
 - e.g. Ease of administration, Dosing schedule

Sample Data Sources

- Clinical and Scientific publications
- Pharmaceutical companies (Licensee)
e.g. websites; marketing, R&D and pharmacoeconomic branches
- Product inserts
- User pool e.g. M.D.s
- Inventors
- OTT licensing records
- Food and Drug Administration
- Centers for Disease Control
- World Health Organization
- Health-related NGOs

Project Progression: 2002-2003

- **2002**

OTT conducted two case studies with the guidance of an NIH working group to test the methodology and metrics selected

- **2003**

- OTT refined methodology
- OTT conducted three additional case studies

Uses of Case Studies

- Provided to Congressional and NIH staff (e.g. NIH Director & Communications Office) to demonstrate
 - value of technology transfer in achieving NIH mission
 - public benefit of technology transfer
 - outcomes of NIH research
- Market program to potential partners (e.g. licensees)

Sample Case Study: Synagis[®]

Questions Addressed

- What is the epidemiology of the disease for which Synagis[®] is indicated?
- What was/were the standards treatment/s available to patients before this product hit the market?
- What was NIH's role in the R&D for Synagis[®]?
- What was the licensee's role in the R&D of Synagis[®]?
- If and how has Synagis[®] affected public health?

Metrics

Health-related metrics were selected based upon the epidemiology of the disease for which Synagis[®] is indicated (RSV)

RSV-Related Epidemiology

- Linked to Seasonal Epidemics
- Primarily manifests as bronchiolitis or pneumonia (morbidity)
- Risk factors for severe infection and hospitalization are premature birth and chronic lung disease
- May result in death

Table 1. Epidemiological Features of RSV

Epidemiological measure	Statistics
Hospitalization (U.S.)	90,000 – 100,000 admissions/year
Prevalence*	95% seropositive by 2 years old
Mortality (worldwide)	400,000 – 1,000,000
Morbidity (during RSV season)	50 – 80% bronchiolitis hospitalizations 30 - 60% pneumonia hospitalizations
Demographics	Time of RSV season differs geographically 30% > males vs. females

Metrics Selected

- # patients treated
- Novelty of drug
- Incidence of hospitalization
- Duration of hospitalization
- Duration of RSV outbreaks
- Infection rate during outbreak
- Mortality
- Quality of life
 - administration route
 - dosing schedule

Results

- > 100,000 patients treated
- 1st monoclonal antibody approved by the FDA to treat an infectious disease
- Reduction in incidence and duration of hospitalization as well as in infection rate during and duration of RSV outbreaks
- No significant change in mortality rates
- Administered intramuscularly vs. IV, and on outpatient basis vs. in hospital
- Full course of treatment necessary to attain maximum benefit
- Eliminates risk of exposure to blood-borne pathogens

Table 2. Synagis[®] -Related Epidemiology

Epidemiological measure	Non-prophylaxed	Synagis[®]-prophylaxed
<i>Hospitalization</i>		
- CLD* patients >2 yrs old	18.4%	5.6%
- 29-32 wG** no CLD	10.3%	2.0%
- 22-35 wG no CLD	9.8%	1.5%
<i>RSV outbreak</i>		
(Infection rate)	32%	7.6%
(Duration)	7 weeks	7 days
<i># Patients Treated</i>		
(2000)		>100,000

Public Health Effect

Synagis[®]:

- reduces the incidence of RSV hospitalization
- eliminates the risk of nosocomial infections or blood borne pathogens
- improves the patients' quality of life because it is less invasive, and can be administered on an outpatient basis

Web Addresses for Case Studies

- <http://ott.od.nih.gov/NewPages/SynagisCS.pdf>
- <http://ott.od.nih.gov/NewPages/HavrixCS.pdf>
- <http://ott.od.nih.gov/NewPages/VidexCS.pdf>
- <http://ott.od.nih.gov/NewPages/VitraveneCS.pdf>
- <http://ott.od.nih.gov/NewPages/FludaraCS.pdf>

Current Direction

Need to Expand Approach

- Approach not practical for evaluating ~200 technologies within NIH portfolio with earned royalties
- Highly dependent upon the cooperation of the licensee and archival data
- Less effective for technologies for which there is little published
- Desire uniform, rigorous and quantitative means of measuring outcomes
- Need to capture the outcomes of research tools, research reagents, diagnostics and medical devices.

Role of Contractor

Hired RTI International using OE funds to

- expand methodology
- identify universal metrics
- pilot-test the metrics
- develop a template for applying metrics to NIH portfolio

Not Seeking information about

- technology transfer procedures
- economic impact
- how to alter OTT's business practices

Objectives for Contractor

- Locate existing metrics, tools and data sources for determining the effect of a product upon the public health or research enterprise
- Recommend whether or not new metrics need to be developed to make determination
- Categorize metrics, tools and data sources as to the product type for which they are relevant
e.g. hospitalization rates under drug/vaccine category
- Test relevant metrics on subset of products (pilot tests)

Final Report

- Literature Review and summary of expert interviews
- Menu of metrics and tools that can be used to measure the health and/or research outcomes of four broad categories of products

Categories of products in NIH portfolio

- Drugs and Vaccines
 - Medical Devices
 - Research Tools and Reagents
 - Diagnostics
- Pilot Tests

Contact Information

Ansalan Stewart, Ph.D.

Technology Transfer Policy Specialist

NIH Office of Technology Transfer

6011 Executive Boulevard, Suite 325

Rockville, Maryland 20852-3804 USA

Telephone: (301) 435-5146

Fax: (301) 402-0220

Stewart@od.nih.gov