



Approaches to Assessing the Impact of Biomedical Research: Examples from the National Cancer Institute

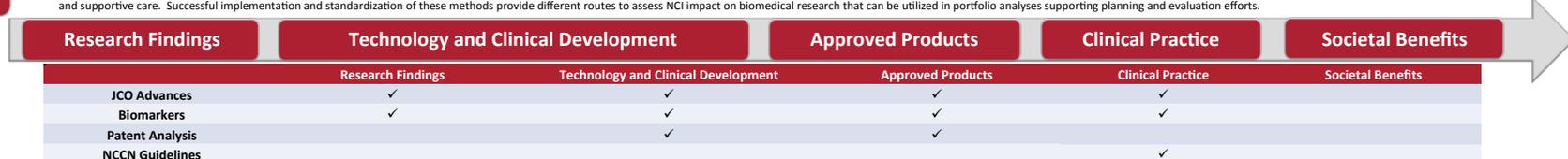


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Background

In the course of conducting a portfolio analysis, there is often interest in going beyond just assessing the scope of the projects to also linking outputs and outcomes to the projects comprising the portfolio. Given lags from basic discovery to translation into interventions, multiple converging approaches need to be used in order to assess impact. A research portfolio can be linked to key advances in multiple ways, both by tracing forward from the original project and tracking its outputs and by tracing backward from an output to its funding origins. Using backward tracing methods, the National (NCI) explored a variety of downstream products as indicators of the impact of NCI funding on public health. The methods described here assess the NCI's role in expert-identified basic and clinical scientific advances, biomarkers, FDA-approved drugs, and guidelines for cancer treatment, screening and detection, and supportive care. Successful implementation and standardization of these methods provide different routes to assess NCI impact on biomedical research that can be utilized in portfolio analyses supporting planning and evaluation efforts.



	Research Findings	Technology and Clinical Development	Approved Products	Clinical Practice	Societal Benefits
JCO Advances	✓		✓		
Biomarkers	✓	✓	✓	✓	
Patent Analysis		✓	✓		
NCCN Guidelines				✓	

Methods

JCO Advances

- Articles classify advances by type/area (e.g., Breast Cancer; Survivorship)
- Articles use expert judgment to identify key research advances and source publications for each advance
- Advances and cited publications are the source material for the analysis

Biomarkers

- Web of Science articles are automatically scanned for mention of biomarkers
- Scientists review and classify articles relative to development stage, disease area and biomarker use
- Articles marking advances in biomarker development are searched for in databases of NCI-funded publications

Patent Analysis

- Patent and citation information obtained from the USPTO patent database
- Non-patent reference data obtained from the US Patent Board; Thomson Reuters ScienceWire databases now also offer links between patents and non-patent literature references

NCCN Guidelines

- When references were publications, automated searches of NIH databases (SPIRES, MEDLINE) used to find NIH and NCI award numbers

	Final Product Analyzed	Data Source(s)	Linkages to NCI Support
JCO Advances	"Major" and "notable" advances from Journal of Clinical Oncology (JCO) "Clinical Cancer Advances" series (2005-2012)	Journal articles Conference presentations FDA press releases and underlying clinical trials	Funding acknowledgement, intramural author affiliation Funding acknowledgement, intramural author affiliation Journal article reporting trial results • Funding acknowledgement • Intramural author affiliation Clinical trial sponsor
Biomarkers	Breast cancer biomarkers curated by scientists and integrated into the Thomson Reuters Integrity databases	Journal articles	Funding acknowledgement
Patent Analysis	FDA-approved drugs indexed in FDA orange book	Journal articles (non-patent references) Patents listed in new drug application (NDA) Cited patents	Funding acknowledgement Funding acknowledgement in government interest section Funding acknowledgement in government interest section
NCCN Guidelines	56 guidelines published by National Comprehensive Cancer Network (NCCN) in 2012 (40 treatment, 9 supportive care, 7 risk/screening)	Journal articles	Funding acknowledgement
Strengths	<ul style="list-style-type: none"> Annual document summarizing recent advances from the past year Represents consensus judgments of leaders in field Identifies publications and presentations that represent source of each advance Small number of advances facilitate detailed analysis 	<ul style="list-style-type: none"> Quantitative measure useful as one indicator of the development of biomarker funding contributions Manually curated robust categorization allows multiple layers of analysis Automated component enables scanning through large publication datasets 	<ul style="list-style-type: none"> Fully automated process provides fast and objective insight into potential links of basic research to downstream outputs Analysis of metadata (e.g., persistence of researchers and institutions) allows an additional layer of automated vetting
Limitations	<ul style="list-style-type: none"> Does not identify which advances build on underlying base of NCI-supported research Relies on judgment of expert panel who shift from year to year Publications may not list all sources of support Where multiple sources of support are listed, not feasible to determine relative contribution of each source 	<ul style="list-style-type: none"> Additional manual curation needed to identify-development process stage at which NIH/NCI-funded research contributed Analysis limited to references appearing in MEDLINE-indexed journals Proprietary data source 	<ul style="list-style-type: none"> Additional analysis still required to qualify the nature of the contribution of the basic research to the drug development process Generational citation methods require additional scrutiny due to indirect linkages
Future Approaches	<ul style="list-style-type: none"> Integrate the four methods shown to provide richer information regarding NCI impact Trace backward to underlying basic research Trace forward – accuracy of JCO expert predictions; impact of clinical practice changes resulting from NCCN guidelines; broader societal impacts such as improved public health or economic benefits (e.g., actual clinical practice by oncologists) Expand approaches beyond NCI/NIH funding as additional funders acknowledge support in a standardized fashion Explore integrating information into analyses that could support NCI decision making process 		