

ARTICLE

Going beyond bibliometrics: A system to track the progress and impact of biomedical research funded by Susan G. Komen

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Abstract

Traditional metrics used to assess the outcomes and impact of biomedical research, such as publications, citations, and follow-up grant funding, do not measure the impact on changes in health practice (standard of care), policy, guidelines, or other societal outcomes and may not be meaningful to stakeholders, such as patients, donors, or the public. Susan G. Komen has developed a research product tracking system to monitor the progress of Komen-funded research products along the research pipeline and to measure the potential impact on patients more directly. In the Komen Product Tracking System, each funded grant is classified by product potential (e.g., treatment, biomarker, etc.) and by stage in the research pipeline (e.g., basic research, preclinical research, clinical trials, and regulatory approval/commercialization). Progress through the research pipeline is updated each year while the grant is active. The Komen Product Tracking System can be used to assess outcomes and the impact of Komen-funded research in several ways: by viewing snapshots at a given time to understand what research products are in the pipeline at that time and what stages they are in, viewing new products added during a defined funding period and, most importantly, assessing how many products have progressed in the research pipeline and have contributed to, or have potential to contribute to, practice changes that result in direct impacts on patients. The tracking system enables us to communicate the impact of our research to our donors, patients, the public, and other stakeholders in a more meaningful way.

Study Highlights**WHAT IS THE CURRENT KNOWLEDGE ON THE TOPIC?**

Metrics, such as publications, citations, and follow-up grant funding, are typically used to assess the outcomes and impact of biomedical research. However, they do not translate to how research progress leads to changes in health outcomes, or changes in paradigms (knowledge), practice (standard of care), and policy. Tracking grant support and publications does not directly indicate how research may have led to real-world benefits. In addition, these metrics may not

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be meaningful to stakeholders, such as donors, board members, patients, or the public.

WHAT QUESTION DID THIS STUDY ADDRESS?

How can we move beyond traditional metrics, such as publications, citations, and follow-up grant funding, to measure the potential impact of research outcomes?

WHAT DOES THIS STUDY ADD TO OUR KNOWLEDGE?

The Komen Product Tracking System was developed to assess outcomes and impact of Komen-funded research. It demonstrated the progress of Komen-funded research and the products resulting from this research entering the research pipeline. It determined if Komen-funded products are in clinical use and could be contributing to clinical practice changes.

HOW MIGHT THIS CHANGE CLINICAL PHARMACOLOGY OR TRANSLATIONAL SCIENCE?

The Komen Product Tracking System could be adapted for other health research organizations to assess how their research is contributing to progress at various stages in the research pipeline, and whether it has led to practice or policy changes and is contributing to real-world benefits for patients. We believe tracking research products reflects more meaningful metrics of biomedical research impact than traditional bibliometrics.

INTRODUCTION

The goal of biomedical research is to understand the causes of human disease and develop effective diagnostics, therapeutics, or preventions. Yet, traditional metrics used to assess the outcomes and impact of biomedical research do not measure the impact on scientific progress or societal outcomes. They focus on outcomes that are mainly of interest to the academic community. The most common approaches for evaluating research success continue to utilize proxy measures, such as publications, citations, and follow-on grant funding. Although insightful, these metrics do not necessarily translate to how research progress leads to changes in health outcomes, or changes in paradigms (knowledge), practice or guidelines (standard of care), and policy. Tracking grant support and publications does not directly indicate how research may have led to real-world benefits. In addition, these types of metrics may not be meaningful to various stakeholders, such as donors, board members, patients, or the public.

The landscape for evaluating the impact of scientific research is rapidly evolving. Focus is increasingly shifting from whether a researcher has published their research to the impact that piece of research has had on the scientific community and the world at large.¹⁻⁴ As a result, alternative methods of tracking research impact have been developed. For example, alternative impact metrics, known as “altmetrics,” are nontraditional bibliometrics that complement more traditional citation impact metrics. They incorporate “use” of a research item by tracking views and downloads, discussions (journal comments, blogs,

mentions on social media and mainstream media, and public policy papers), and saves (Mendeley, etc.), among others.⁵⁻⁷ Although altmetrics incorporate components that are of interest to a broad range of stakeholders, this type of metric is primarily a measure of the researcher, or the contribution to the field, and may not assess the impact of a study on patient care.

Other systems that aim to capture research impact beyond bibliometrics include the High Impacts Tracking System (HITS) developed at the National Institute of Environmental Health Sciences (NIEHS), which documents the outputs and impacts of National Institutes of Health (NIH)-funded grants,⁸ and the Translational Science Benefits Model developed at Washington University (St. Louis, MO) to understand the impact of translational science on health care outcomes.⁹ However, these systems tend to focus on a particular part of the research pipeline, not the continuum. Although the field is advancing in terms of how to measure research impact, gaps remain, and a more systematic method is needed to measure the impacts of research endeavors from basic through translational and clinical research that eventually result in health benefits.

Susan G. Komen has sustained a strong commitment to supporting research that will identify and deliver cures for breast cancer. Komen is the world's largest breast cancer organization, funding more breast cancer research than any other nonprofit outside the federal government. Since its founding in 1982 with a single research grant, Komen's research investment now exceeds \$1 billion, funding more than 2700 research grants and over 500 clinical trials.

Komen's research focus has evolved over the years. In the beginning, Komen focused on understanding the basic biology of breast cancer. As we learned about more factors that make cancer cells grow and spread, we invested more in the translation of this knowledge into better approaches for early detection and diagnosis, understanding metastasis and recurrence, and developing novel therapies for all stages of breast cancer, with the goal of accelerating scientific discoveries to acquire new knowledge and advance personalized care for all. Our goal is to understand how our research may be contributing to changes in paradigms (knowledge), breast cancer care and practice changes (standard of care), and policy. Over the past 5 years, we have used several approaches to assess impact in these areas, including bibliometric analysis and case studies, as well as development of a robust research product tracking system, described herein.

Research progresses along a pipeline, moving from basic research to preclinical or translational research to clinical research before it reaches patients.¹⁰⁻¹³ To evaluate the impact of Komen-funded research and measure progress toward our mission and research goals, Komen developed a robust coding schema and tracking system, called the Komen Product Tracking System. Using this system, we can identify and monitor the potential products of Komen-funded research and monitor how these products progress along the research pipeline to measure the potential impact on patients more directly. The data presented in this paper represent a subset of products from Komen-funded research grants that were active in 2016 (awarded in previous years) or newly awarded from 2016 to 2021. It should be noted that Komen has been funding research since 1982 and has been contributing impactful products to the research pipeline since that time.

METHODS

Komen's Product Tracking System was created over several iterations and includes two classification components. The first component classifies research products. We developed a list of potential products of research comprised of broad, high-level product categories of research outputs, impacts, and process, which informed the basis of our framework (Table 1). More detailed subcategories of potential products resulting from Komen-funded research were curated using Komen's already existing topic coding systems, as well as the Common Scientific Outline,¹⁴ as a guide. The product list includes high-level product categories, such as treatments, devices, or healthcare delivery methods, etc. (Table 1). Products can be further categorized by more detailed subcategories where appropriate (e.g., combination treatment versus single agent, etc.).

TABLE 1 High level representation of the framework for Komen's Product Tracking System: Examples of product categories

High Level Product Categories

Behavioral Intervention
Biomarker
Community Education Material
Database/Registry/Repository
Device/Technologies
Drug Target
Guidelines or Frameworks
Healthcare Delivery Tool or Method
Novel Therapy (preventive or treatment)
Nutritional Supplement/Diet/Intervention
Risk factors (endogenous/exogenous)
Software/Analytical Tool

A product may be considered “hard” or “soft.” Hard products consist of tangible products, such as a new drug, device, or diagnostic test. Soft products are the outcomes of a grant that may not be a tangible product but rather are knowledge building with the potential for a hard product. Soft products include items such as genes or proteins that could serve as a potential target for a new therapy or biomarker test.

The second component of the Product Tracking System classifies the stage of a product in the research pipeline, which was developed based on an amalgamation of acknowledged and accepted phases in the research pipeline.¹⁰⁻¹³ For the purposes of this classification system, we used four broad categories: basic research, preclinical research, clinical testing, and regulatory review and approval by a governing body (e.g., US Food and Drug Administration [FDA], European Medicines Agency [EMA], and Canadian Food Inspection Agency [CFIA])/commercialization (Table 2). For basic and preclinical research, products are subcategorized as discovery, validation, and prototype development and drug design. Clinical research is subcategorized according to clinical trial phase (0–III), observational trial, or repository.

RESULTS

The system works as follows (Figure 1). First, grants are classified by product potential, which captures the product(s) that could result from the research study. Every grant must be coded to at least one product. Grants may have more than one product. For example, a grant studying the efficacy of a new treatment and developing a biomarker to test whether a patient will respond to that treatment would be coded to both a treatment product, as well as a

clinical biomarker product. Individual examples could include a grant studying detection of metastases, which may be coded to a clinical biomarker product, or a grant

TABLE 2 High level representation of the framework for Komen's Product Tracking System: Stages in the research pipeline

Stages
Stage 1a: Basic Research – Discovery/Target Identification
Stage 1b: Basic Research – Validation
Stage 1c: Basic Research –Prototype Development and Drug Design
Stage 2a: Preclinical Testing – Discovery
Stage 2b: Preclinical Testing – Validation
Stage 2c: Prototype Development and Drug Design
Stage 3a: Phase 0 Clinical Trial (pilot)
Stage 3b: Phase I Clinical Trial
Stage 3c: Phase II Clinical Trial
Stage 3d: Phase III Clinical Trial
Stage 3e: Observational Trial, Repository or Data Gathering through interviews, focus groups or patient databases
Stage 4: Regulatory Review/Commercialization

studying how to improve inclusion and representation of diverse patient populations in clinical research, which may be coded to a preclinical guideline/framework product.

Second, after the product(s) of the grant are identified, each product is coded to a stage in the research pipeline (Figure 1). Each product is coded to up to two stages in the research pipeline; for example, a product may be studied at both the basic and preclinical research stages simultaneously. Product stage is updated annually when the progress report from the grant's principal investigator is reviewed by Komen. Movement from one stage to the next in the pipeline is then assessed, which allows monitoring of progress for all research products along the pipeline during the funding period. Of course, the research process is more complicated than this linear, progressive schema, and products in each phase can circle back to the previous phase and then move forward again. These movements can be noted by our system; however, for simplicity and ease of reporting these metrics to multistakeholder audiences, we use common high-level definitions and report progress in a linear fashion.

Each year, new grants are coded with the system and codes for existing, active grants are updated to reflect the

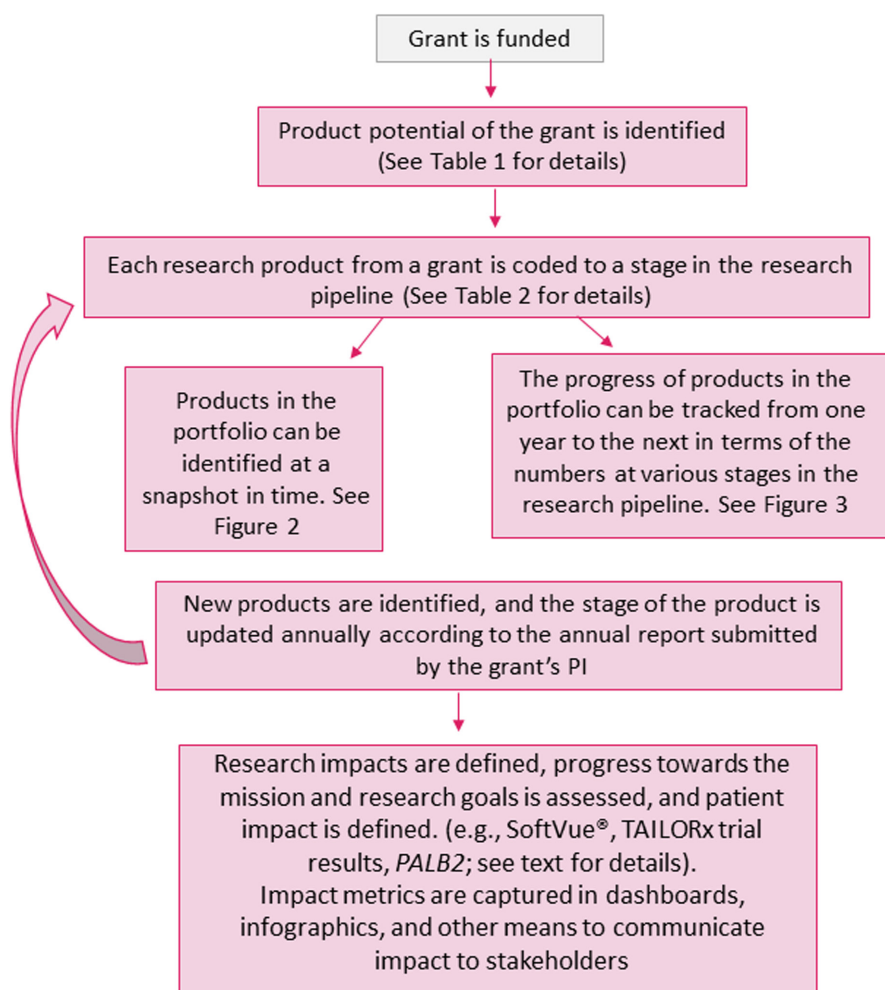


FIGURE 1 Flowchart showing how grants are coded with the Komen Product Tracking System. PI, principal investigator.

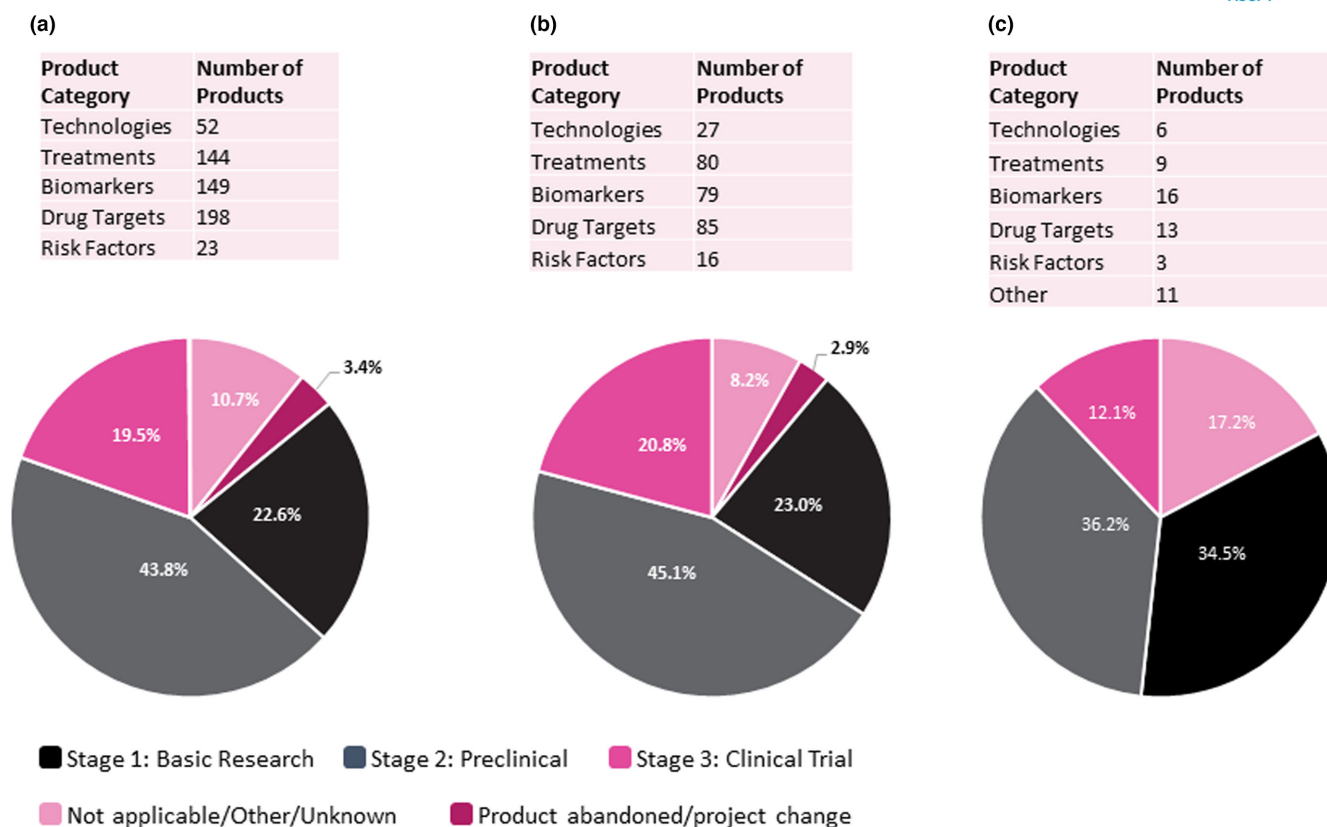


FIGURE 2 Products can be viewed as a snapshot in time with the Komen Product Tracking System. (a) Cumulative number of products funded during defined period of time by product category and the percentages of the products in each phase of the research pipeline. (b) Products associated with active grants by product category and phase. (c) New products added in a fiscal year by product category and phase. Note that product types and stages are not inclusive of all categories. This is a high-level representation of multiple coding categories and is intended to demonstrate how the coding system works and can be used.

current stage of the product(s) in the research pipeline. New products for existing active grants may also be identified if the research aims have been updated. The tracking system allows us to monitor progress of all research products along the pipeline during the funding period. Thus, we can track a product derived from the grant as it moves through the various stages, from basic research through clinical testing, regulatory approval, and practice changes.

Since it was developed, we have used the Komen Product Tracking system to assess and report the outcomes and impact of Komen-funded research. The data presented in this paper represent a subset of products from Komen-funded research grants that were active in 2016 (awarded in previous years) or newly awarded from 2016 to 2021.

There are multiple ways this system is used to assess the outcomes and impact of Komen-funded research. Snapshots can be taken at a given time to understand what research products are in the pipeline at that time. Figure 2 shows snapshots of Komen's research grant portfolio by product and pipeline stage. We can track the cumulative number of products funded by Komen during a defined period (i.e., active grants [currently funded] and closed

grants; Figure 2a). At the time point shown in Figure 2a, Komen had a total of 566 products in the research pipeline, including 198 new drug targets, 144 treatments, 149 biomarkers, and 52 technologies. We can also report the products associated with active, currently funded grants (Figure 2b) and new products added during a defined funding period (Figure 2c). Likewise, we can assess where each product is in the research pipeline. For example, at the time point shown in Figure 2a, of the 566 products, 22.6% were at the basic research stage, 43.8% were at the preclinical research stage, and 19.5% were at the clinical research stage.

The system can also be used to track how many products progressed through the research pipeline during a given period. In the example shown in Figure 3, eight products progressed from basic to preclinical research, and three products progressed from preclinical to clinical research. Products can also make intermittent steps within one of the broad categories, for example, from discovery to validation while remaining in basic research. Products can also circle backward in the pipeline as results from new studies are found and refinement of studies occurs. Products can then move forward again.

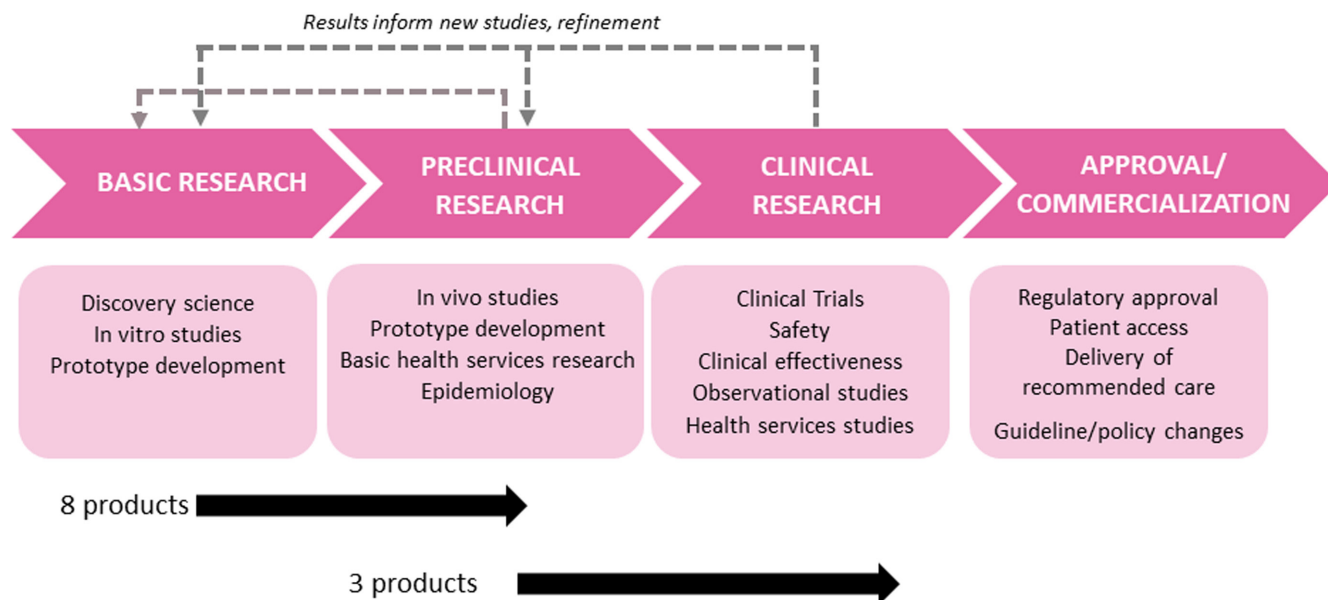


FIGURE 3 Products progressing through the research pipeline in a 1-year period. This figure demonstrates how the Komen Product Tracking System can be used to track how many products progress through the different stages of the research pipeline over a given time period. In this 1-year period, 6% of the total products progressed a stage, including eight products that progressed from Basic Research to Preclinical Research and three products that progressed from Preclinical Research to Clinical Research. Note that products can also circle backward in the pipeline (gray line). In addition, we can track progression within a stage (e.g., progressing from basic research discovery to basic research validation).

Another application of this system is to quantitatively track the impact of funded research against specific research goals or focus areas. For example, Komen has two primary research priorities: conquering metastatic and aggressive breast cancers and eliminating breast cancer disparities. The product tracking system gives us the ability to quantify the impact of our research portfolio that is tied to the goal of targeting and treating metastatic and aggressive breast cancers, and approaches for reducing breast cancer disparities. In this instance, we can calculate the percentage of our products that are focused on metastatic disease or health disparities and have moved from preclinical to clinical studies, putting them closer to our goal. We can use this system to drill down further to quantitatively look at specific products related to these focus areas. For example, we can quantify new treatments or biomarkers for metastasis or new healthcare delivery methods to improve health equity that have arisen from research funding at a given time, or over a period of time.

Ultimately, Komen's Product Tracking System has allowed us to demonstrate how Komen-funded research has led to practice changes and resulted in direct impact for patients. For example, Komen-funded research led to the FDA approval of SoftVue,¹⁵ an ultrasound-based alternative to mammography that is more effective for women with dense breasts and is now available commercially. After the grant was funded, we identified one product for the grant, a device that was being studied at stage 2a:

preclinical discovery. By year 3 of the grant, it progressed through the research pipeline, reaching stage 2b: preclinical validation. That project received a subsequent grant from Komen and the product continued to be tracked, progressing to stage 3b: phase I clinical trial. At the end of the grant term, the product was in the process of commercialization. Consequently, we kept in regular contact with the principal investigator on the progress of the product and learned it was being tested in clinical trials in several hospital systems and being used in conjunction with mammography. Using the Komen Product Tracking System, we were able to track this device through the research pipeline starting at preclinical studies to commercial use of a product. A second example is a biomarker assay, which we tracked from preclinical to patient impact. The biomarker assay was looking at banked biospecimens from the TAILORx trial, which showed that many women with ER+, HER2- breast cancer, and a low recurrence score can safely skip chemotherapy after surgery.¹⁶ The Komen Product Tracking System was used to track the biomarker assay test from preclinical to clinical use. A third example is the identification of a new breast cancer susceptibility gene called *PALB2*, which is now included in genetic testing for breast cancer risk.¹⁷ The Komen Product Tracking System was used to track identification of the risk gene from basic research to clinical application. These are just three examples of products that were coded at the award of the grant and tracked through the research pipeline

during and after the award period until they were adapted into clinical use.

DISCUSSION

We developed the Komen Product Tracking System to move beyond bibliometrics and other metrics that assess the researcher, and to provide metrics that more directly reflect the potential of Komen-funded research to advance our knowledge about breast cancer, impact patient care, and ultimately save lives.

As with all systems that aim to assess the impact of biomedical research, the Komen Product Tracking System has some limitations. Although the system provides great insight into the research impact of the grant portfolio, particularly active grants, tracking products beyond the grant funding term is challenging. Once a grant term ends, the ability to track the products associated with that grant through the pipeline becomes limited, as the principal investigator is no longer required to report on research progress. Although we cannot systematically follow products that are no longer funded by Komen, these products continue to progress along the research pipeline due to funding from other sources. We use a few approaches to follow discoveries beyond the funding term. We can do this through bibliometric analysis, by identifying publications that may have resulted from Komen funding or that are related to the Komen-funded product. We also may actively reach out to the investigator, as in the case of SoftVue, to ask for updates on products that have reached an advanced stage in the pipeline. Most often, investigators voluntarily reach out to Komen with updates from their Komen-funded research. We are also evaluating whether it would be beneficial to survey past grantees on updates about their projects after funding is complete. Such follow-up could be targeted, focusing on those products identified through the tracking system as promising, or at advanced stages, and provide us with valuable information on whether those products have progressed further in the pipeline after the Komen grant.

Another caveat of Komen's Product Tracking System is that the cumulative number of products increases every year, both because new products are added, and because products that are no longer funded by Komen remain in the pipeline and remain in the database. One way we manage this in reporting is to report only the active portfolio. In addition, if funding for research grants were to decrease, the number of new products added to the pipeline would also decrease over time. However, using the system, we can still assess impact and progress by looking at the percent of a particular product in the total active portfolio. For example, of our active products, we can report what percentage are focused on metastasis, disparities, treatments, etc. Focusing

on the active grant products provides a better reflection of what is currently funded by Komen in the pipeline. Given these challenges and caveats, we are continuously working to improve Komen's Product Tracking System and view it as an evolving system. We anticipate future iterations will allow improved tracking and reporting.

How we assess the impact of research needs to evolve so that we can more easily communicate this impact with metrics that resonate with a variety of stakeholders. To do this, innovation in research evaluation and improved metrics are needed to demonstrate research impact. Our system moves beyond traditional metrics to show the potential research has to impact knowledge, clinical practice, and policy. This system is unique because it tracks products in an organization's research portfolio as well as progress along the research pipeline.

The information generated with this system can be used in a variety of ways. The data can be organized into dashboards and infographics to show the impact of our research investments to various stakeholders. To date, most dashboards and infographics generated from these data have been used internally, to inform decision making about our research programs and keep Komen leadership apprised of our research impact. One externally facing example can be found on Komen's website: Komen's Research Fast Facts Overview (<https://www.komen.org/wp-content/uploads/Research-Fast-Facts-Overview-4final.pdf>). More public facing infographics that share these data are planned for future iterations.

The data generated from the tracking system can also be used to assess the health impacts of Komen's funded research. We can determine if Komen-funded products are adopted into clinical use or resulting in practice changes, as shown by the SoftVue and other examples, noted previously. As noted, many outcomes/impacts occur outside the life cycle of the Komen grant and have been identified through follow-up with and voluntary reporting by the primary investigator.

In addition to demonstrating impact, the data can also be used to identify promising products to follow (i.e., those close to the end of the pipeline to see if they changed practice, policy, etc.) and research projects to continue funding and consider for further development and commercialization. The data generated with this system can be used to develop a plan for potentially working with other organizations and institutional intellectual property offices to facilitate further product development or provide funding to move discoveries through the "Valley of Death"^{18,19} and into clinical trials. Funding mechanisms can be identified to support research at the early commercialization stage, which provides early-stage funding for future commercialization of products.

Although this system was tailored specifically for Komen and breast cancer research, this framework could be

adapted to work within a variety of institutional structures, missions, and disciplines. For example, the high-level product categories are not specific to cancer research and could be applicable to any health research area. Different health research funders could use the high-level categories in this system, generally, or could customize them to be more specific to their type of research, regardless of disease focus. We believe the Komen Product Tracking System could also be used to create a more generalizable system that could easily be adopted by other health research funders. Research alliances already exist that could further these efforts, including the Health Research Alliance (HRA)²⁰ and the International Cancer Research Partnership (ICRP).¹⁴ Of note, the Komen tracking system already incorporates common classification systems used by these organizations, such as the Common Scientific Outline (CSO). Tracking these metrics has been impactful to Komen, and other organizations could similarly track their own products to measure impact in their specific field or therapeutic area.

We believe the Komen Product Tracking System may offer a new way for research funders to systematically track the impact of their research beyond bibliometrics, with a focus on direct impact on patients as research outcomes are translated to changes in paradigms (knowledge), practice or guidelines (standard of care), and policy. We hope that other organizations will adapt this system to their own needs to better measure their impact so that, as a research community, we are all better able to communicate how we are impacting people's lives in a meaningful way.

AUTHOR CONTRIBUTIONS

A.M.D., S.R., and K.W. designed the research. A.M.D. and K.W. performed the research and wrote the manuscript. A.M.D. analyzed the data.

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CONFLICT OF INTEREST

The authors declared no competing interests for this work.

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