Developing the Translational Research Workforce: A Pilot Study of Common Metrics for Evaluating the Clinical and Translational Award KL2 Program

Margaret Schneider, Ph.D.[1], Lourdes Guerrero, Ed.D., M.S.W.[2], Lisa B. Jones, M.A.[3], Greg Tong, M.P.H.[4], Christine Ireland, M.A., M.P.H.[4], Jill Dumbauld, M.P.H.[5], and Julie Rainwater, Ph.D.[6]

Abstract

Purpose: This pilot study describes the career development programs (i.e., NIH KL2 awards) across five Clinical and Translational Science Award (CTSA) institutions within the University of California (UC) system, and examines the feasibility of a set of common metrics for evaluating early outcomes.

Methods: A survey of program administrators provided data related to the institutional environment within which each KL2 program was implemented. Application and progress report data yielded a combined data set that characterized KL2 awardees, their initial productivity, and early career outcomes.

Results: The pilot project demonstrated the feasibility of aggregating common metrics data across multiple institutions. The data indicated that KL2 awardees were an accomplished set of investigators, both before and after the award period, representing a wide variety of disciplines. Awardees that had completed their trainee period overwhelmingly remained active in translational research conducted within an academic setting. Early indications also suggest high rates of success with obtaining research funding subsequent to the KL2 award.

Conclusion: This project offers a model for how to collect and analyze common metrics related to the education and training function of the CTSA Consortium. Next steps call for expanding participation to other CTSA sites outside of the University of California system.
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Introduction

Since the inception of the Clinical and Translational Science Award (CTSA) program in 2006, mentored career development awards have been a key component of the NIH strategy to build the translational research workforce.[1] Recently, there has been increased attention to weaknesses in the pipeline for clinical and translational researchers.[2–5] The KL2 mentored career development program was a required component of the overall CTSA award since its inception. The CTSA KL2 programs typically provide scholars (MD, MD/PhD, or PhD) with 3–5 years of support for a career development experience at a critical early career stage under the mentorship of experienced investigators. The KL2 provides salary support and limited research funds with the goal of transitioning participant careers to independent status through attainment of other individual NIH awards such as K08 (Mentored Clinical Scientist Research Career Development Award), K23 (Mentored Patient-Oriented Research Career Development Award) or R01 (Research Project Grant).

As stated on the website for the National Center for Advancing Translational Science (the NIH component under which the CTSAs reside), "providing the resources to train, cultivate and sustain future leaders of the biomedical research workforce is a key CTSA program goal."[6] In 2014, the most recent year for which data are available, the NIH distributed over 45 million dollars to support KL2 awardees at 50 CTSAs nationally. Despite the substantial investment in training by NIH and CTSAs, no systematic, comprehensive evaluation of the research career development program has been conducted thus far. After exhaustively examining the available data, the Biomedical Research Workforce Working Group[2] stated that "The working group was frustrated and sometimes stymied throughout its study by the lack of comprehensive data regarding biomedical researchers" (p. 11). A descriptive study was conducted by an external evaluation consultant[7] but it did not include career outcomes that institutions would use to benchmark performance.

There are several reasons why an overall evaluation of the CTSA mentored career training grant program has not been conducted. Relatively speaking, the CTSA program is still rather young, with the first round of 12 centers funded in 2006 and additional centers phased in until the year 2011 when the maximum 62 centers were funded. Accordingly, until recently, it was too early to expect to be able to detect an impact of the KL2 program on investigators' productivity. Another barrier to conducting an overall evaluation has been the absence of a nationally coordinated plan for common metrics. For the most part, individual CTSAs have determined what and how to document the impact of the program on trainees. Even the standard outcomes typically utilized to track academic productivity—grants and publications—while universally tracked across CTSAs, have not been tracked in a standardized method or using shared definitions. Moreover, each CTSA has independently developed tracking processes and tools that make cross-CTSA comparisons challenging.[8]

In 2010, the five University of California CTSAs (located at UC San Diego, UC Irvine, UC Los Angeles, UC Davis, and UC

[1]School of Social Ecology, and Institute for Clinical and Translational Science, University of California, Irvine, California, USA; [2]David Geffen School of Medicine at UCLA, General Internal Medicine and Health Services Research, UCLA Clinical and Translational Science Institute, Los Angeles, California, USA; [3]Institute for Clinical and Translational Science, University of California, Irvine, California, USA; [4]School of Medicine, University of California, San Francisco, California, USA; [5]Clinical and Translational Research Institute, University of California, San Diego, California, USA; [6]Schools of Health and Clinical and Translational Science Center, University of California, Davis, California, USA.

Correspondence: Margaret Schneider (mls@uci.edu)

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San Francisco) formed the UC BRAID (Biomedical Research Acceleration and Development) to leverage the combined resources of all five institutions. Originally formed to facilitate system-wide harmonization of the Electronic Medical Records at all five Academic Medical Centers, the partnership has since opened the door to a number of UC collaborations. The present project emerged from UC BRAID and brought the five evaluation functions from the UC CTSAs together with the intention of identifying and piloting common metrics for the mentored career training programs supported by the CTSA program. The goal was to demonstrate the feasibility of a cross-CTSA evaluation, including identification of common metrics, sharing of data, and preliminary analysis with the expectation that lessons from this exercise could inform future national efforts to evaluate the CTSA-supported training programs.

Common metrics across a large and ambitious program such as the CTSA Consortium can meet several critical needs, as succinctly described in a recent publication by Rubio et al.,[8] describing an effort to pilot common metrics in several areas, including Institutional Review Board functioning. These investigators point to three main functions that common metrics can serve: (1) establishing benchmarks that give individual CTSAs some standard against which to evaluate their accomplishments; (2) facilitating process improvement efforts by identifying best practices; and (3) enabling an overall evaluation of the impact of the CTSA Consortium as a whole. Absent common metrics, each CTSA continues to function in isolation, and fails to benefit from the wealth of experience and knowledge that is being accumulated by the Consortium as a whole.

This pilot study provides a description of the career development programs and their participants across five CTSA institutions within the University of California system, as well as an analysis of early outcomes. Descriptive data include trainee attributes such as gender, race/ethnicity, degree, prior research productivity, and field of study. Outcome data were collected in three main areas including subsequent research funding, publication activity, and career outcomes (i.e., academic appointments and continued involvement in the translational research enterprise).

The basic logic model for the CTSA training program is shown in *Figure 1*. Others have begun to articulate complex conceptual models of the path to success for translational scientists.[9] Our project, however, aims to provide a more fundamental examination of the relationship between the training investment and outputs and outcomes. At the outset, the five collaborating institutions agreed to pursue this analysis using only the data routinely available at our institutions, which varied as to whether it contained information necessary to test a more elaborate model of career success.

Methods

Program evaluators at each of the five UC CTSAs collaborated to identify a set of common data elements that were being collected about their individual KL2 participants. For the purposes of this pilot study, we were interested in the feasibility of developing common metrics at the trainee level using each institution's routinely collected data. Thus, while substantial data management and recoding were assumed to be necessary, the intention was to avoid any new data collection. Ultimately, this restriction was modified to permit conducting web-based searches for grant and publication information for one site that was able to provide only aggregate data. The publicly available databases PubMed and NIH RePORT were utilized for these searches.

Since no prior effort had developed tools for placing the KL2 programs in an institutional context, we developed a web-based survey of CTSA Education Core program administrators. The survey, sent via email in April 2014, asked about institutional and program characteristics, such as the amount of CTSA funding devoted to the program, number of KL2 slots available, selection processes, prerequisites, and required activities and coursework. Each institution then completed a spreadsheet that collected information about all their individual KL2 trainees supported at their site from the inception of their CTSA award up to January 1, 2014. One set of information reflected the

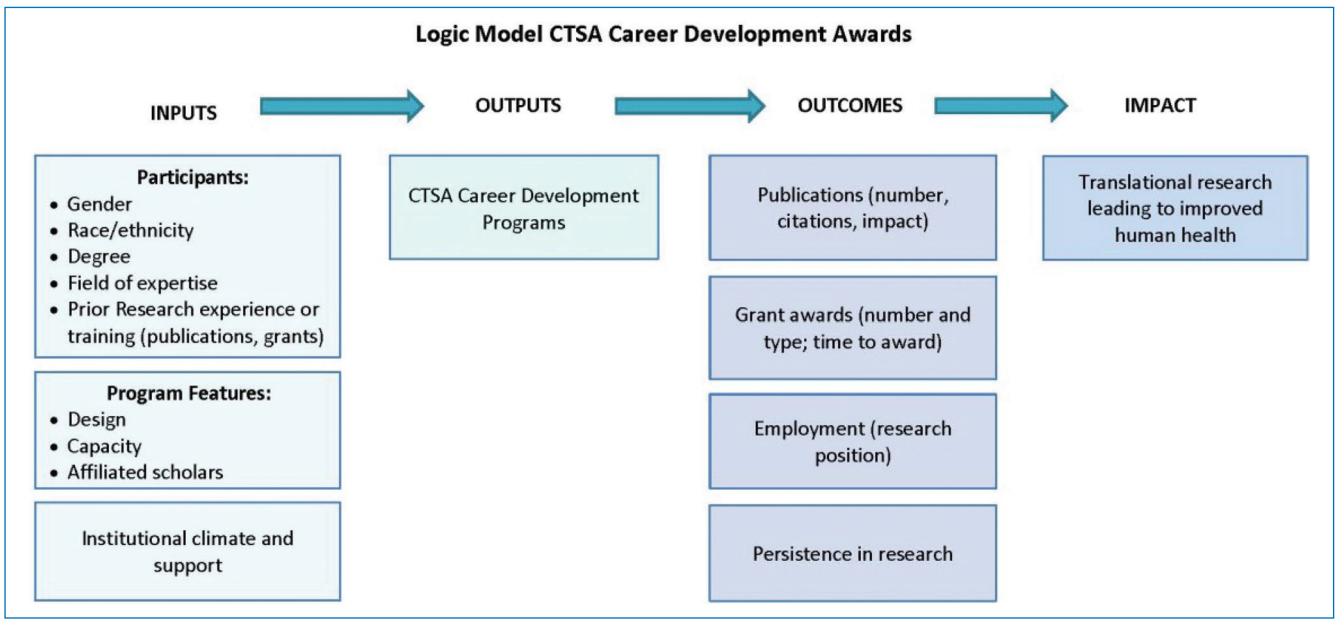

Figure 1. Logic model of CTSA KL2 career development awards.

characteristics and status of each KL2 awardee at the time of applying for the award. Characteristics reported for each trainee included degree held (MD, PhD or equivalent, MD/PhD), race/ethnicity, gender, home department, and professional status (i.e., rank on the academic promotions ladder), as well as the number of publications and grants received prior to the KL2. Data from the progress reports required at each site were obtained to add the following information about each awardee's experience during and after the award: number of years in the program, number of publications and grants generated during and after the award, and continued engagement in translational research and/or academics after completing the program. Grant awards were coded as NIH, industry, foundation, or non-NIH government. For NIH awards the data included the type of NIH grant received (i.e., RO1, K08, etc.).

We analyzed the aggregated data to examine:

1. variations in the design and structure of KL2 programs across the five UC CTSA institutions;
2. the demographic and academic profile of CTSA KL2 trainees, including their diversity in ethnicity, gender, discipline, and prior research training and productivity;
3. the postaward research productivity of UC CTSA KL2 trainees in terms of publications and grants;
4. the extent to which UC CTSA KL2 trainees were employed in research careers subsequent to their training.

Results

Characteristics of the training programs and trainees

Environment and context of KL2 training programs at the UC CTSAs

The five programs varied in terms of number of years in operation, amount of NIH funding available to support the KL2 programs, amount of local institutional support, number of trainees supported at any one time, and required elements for participation in the KL2 training program (see *Table 1*). NIH funds earmarked to support each KL2 program ranged from a low of $370,000 to a high of $3,000,000, and the number of trainees supported by the CTSA funding at any one time ranged from a low of 3 to a high of 19. None of the CTSAs required specific courses as part of the K program. One site required that the awardees already hold a Master's degree in clinical research, public health or the equivalent, while another site required that awardees earn a Master's in Clinical Research as part of their training.

Number and training time of KL2 awardees

A total of 126 scholars participated in one of the five UC CTSA KL2 programs between 2006 and 2014, as shown in *Table 2*. For all five programs combined, there were 47 scholars still funded as of January 1, 2014, and 79 who had completed their KL2. It is important to recognize that scholars were at different points in their careers as regards to the KL2 award when the data were collected and that the number of years of support provided to the KL2 awardees also varied. Among those who had completed their award, the average duration of support was 2.96 years (SD = 1.43). The majority (72%) of the still-funded scholars had been in the program for 2 years or less. For most of the KL2 awardees that had completed the award (67%), it had been 2 years or less since they completed the award.

Demographic characteristics of KL2 awardees

As shown in *Table 3*, overall, there were more females (55%) than males (45%) in the programs, and the majority of awardees (65%) were white. Racial/ethnic diversity was introduced by Asian (25%), Hispanic/Latino (7%) and African American (2%) awardees. Most of the award recipients held an MD degree (77%), followed by recipients with PhDs or equivalent (12%) and those with combined MD/PhDs (11%). The majority of the 126 KL2 scholars ($N = 81$, 64%) were faculty at the Assistant Professor level at the time of the award. The UC CTSA KL2 programs support investigators from a wide variety of disciplines.

Publication and grant history of KL2 awardees

Many KL2 recipients were fairly accomplished early-stage researchers prior to entering the KL2 programs. The vast majority (96%, $N = 121$) had authored or coauthored at least one publication prior to receiving the KL2 award and almost as many of the awardees (91%, $N = 116$) were the first-author on at least one publication. Almost one-third (29%, $N = 37$) had received at least one research grant prior to the beginning their KL2.

	CTSA1	CTSA2	CTSA3	CTSA4	CTSA5
CTSA start date year	2006	2006	2010	2011	2010
CTSA size*	Small	Large	Small	Large	Medium
KL2 funding as percentage of total CTSA award	10%	16%	11%	8%	8%
Maximum number of training slots†	6	19	3	9	3
Applicant pool‡	8	40	18	33	25
Master's degree available	Yes	Yes	Yes	Yes	Yes
Required coursework	No	No	No	No	No

*Size of CTSA defined by size of the CTSA grant as follows: <$6 m annual in 2014 = small; $6–$8 m annual = medium; >$8 m annual = large.
†Maximum number of slots available as reported in the training report portion of the Annual Progress Report.
‡Number of applicants for available slots in the 2014 call for applications.

Table 1. Program and institutional characteristics of five UC CTSAs.

	Current scholars (*N* = 47)	Alumni scholars (*N* = 79)
Years of KL2 support		
1 year or less	22	14
2 years	12	19
3 years	9	20
4 years	3	11
5 or 6 years	1	15
Years since terminating KL2		
1 year or less	–	35
2 years	–	18
3 years	–	8
4 years or more	–	18

Table 2. Years of KL2 support and years since terminating the K award in five CTSAs as of 2014 (*n* = 126).

Productivity of the KL2 awardees

Publications and grants

Information on postaward publications was available for 71% (*N* = 90) of the KL2 scholars (missing data were the result of nonrespondents on follow-up surveys). Out of these 90 current and former KL2 scholars, 93% (*N* = 84) had published at least one paper since receiving the training award, and 72% (*N* = 65) had published at least one paper as first author. As a group, the 90 KL2 awardees generated 1,424 publications in the period after receiving the KL2 award, for a mean of 15.82 per awardee (range = 0–98, median = 10). Out of these 1,424 publications, 345 were first-authored by the KL2 awardee. The average number of first-authored publications was 3.79 per awardee (range = 0–36, median = 3).

When all NIH funding types were considered simultaneously, 62 (49%) of the pool of 126 KL2 awardees had received at least one NIH award since entering the training program. Out of these grants, 9 were KO8 Mentored Career Development Awards, and 36 were K23 Mentored Career Development Awards. Taking into account the extended time frame for applying for and receiving an NIH RO1 award, our analysis of the rate at which KL2 awardees received RO1 funding from the NIH examines the data by year of entry into the program, and does not include scholars who entered the program after 2010 (see *Table 4*). Overall, 23% of the 66 KL2 awardees in this analysis had received at least one RO1 by January of 2014 (two investigators had received two RO1s). In general, proportions are lower for those investigators who had less time subsequent to receiving their award. Among investigators for whom at least 6 years had elapsed since their award, 34% had obtained RO1 funding.

Four of the five sites maintained tracking that documented grants from all sources in addition to NIH, such as foundation or nonprofit, industry or other government grants. These four sites accounted for 55 of the scholars in the total combined data set. Among the 38 scholars from these sites who began their appointment in 2012 or earlier, a total of 60 non-NIH awards had been received by 16 investigators since commencing their KL2 training grant (35 foundation-supported, 22 industry-funded, and 3 non-NIH government).

	Number	Percentage
Male	57	45%
Female	69	55%
Race		
White	82	65%
Asian	31	25%
Black	3	2%
Unknown/not reported/other	10	8%
Ethnicity		
Hispanic/Latino	9	7%
Unknown/not reported/other	118	93%
Degree		
MD	97	77%
PhD or equivalent*	15	12%
MD/PhD	14	11%
Discipline		
Medicine	38	30%
Pediatrics	20	16%
Internal Medicine	16	13%
Surgery	8	6%
Neurology/Neurosciences	7	5%
Nursing	7	5%
Infectious Disease	5	4%
Psychiatry/Behavioral	5	4%
Dermatology	5	4%
Emergency Medicine	4	3%
Radiation Oncology	3	2%
Biostatistics or Informatics	3	2%
Pharmacy	3	2%
Dentistry	3	2%
Pathology	2	1%
Other†	7	5%
Professional status		
Assistant Professor	81	64%
Associate Professor	37	29%
Other‡	6	5%
Not reported	2	1%

*Includes DSc, DDS, PhD, PharmD, ScD.
†Includes Biological Sciences, Cardiac Electrophysiology and Arrhythmia Services, Opthalmology, Hospital Care, Biochemistry and Biophysics, Division of Research, Clinical Addiction Research & Education Unit.
‡Includes "Clinical Professor," "Physician," "Volunteer."

Table 3. Characteristics of KL2 awardees at five CTSA institutions, 2006–2014 (*n* = 126).

Persistence in research and academia

The overarching goal of the CTSA KL2 workforce development effort is to facilitate sustainable careers in translational science. The majority (98%) of the 79 UC CTSA KL2 scholars who had completed the award by the end of 2014 continued to conduct

Year	Number of new KL2 awardees	Number (%) receiving an RO1 by January 2014	NIH success rate for new RO1 awards*
2006	10	3 (30%)	16.3%
2007	10	4 (40%)	19.2%
2008	12	4 (33%)	19%
2009	15	1 (7%)	18%
2010	19	3 (16%)	18%

*Source: NIH RePORT (http://report.nih.gov/success_rates/index.aspx).

Table 4. RO1 awards received over time among KL2 awardees who received their training award before 2011 ($N = 66$).

research after their KL2 award and an identical proportion was employed in an academic environment.

Discussion

Our pilot project experience convinced us that developing an initial set of common metrics using data elements which are routinely collected at our CTSA institutions is feasible. This finding sets the stage for potentially expanding our metrics to more sophisticated indicators of translational research career success attributable to the CTSA program. The need to do so is increasingly critical because NCATS, like other NIH institutes, is evolving its view of career trajectories and workforce development beyond the academic/independent scientist goal. Robust data on career choices of KL2 alumni will be necessary to properly align training programs within the CTSA Consortium.

It should be noted that, other than posttraining employment of the KL2 scholar, we essentially abstracted and combined data that are already routinely reported to NIH. We did not have access to the NIH Information for Management, Planning, Analysis, and Coordination (IMPAC II) database which is the primary source through which information about career development award applicants is stored, including basic demographic information and data regarding prior and subsequent NIH grant applications. Consequently, we had to rely on record keeping systems within each institution which may not be of comparable quality and completeness. Moreover, determining program effects without a comparison cohort is impossible. Comparing CTSA KL2 scholars to others on NIH-wide measures of application quality would also be informative. Nevertheless, the fact that we were able to combine data and develop some comparisons implies that benchmarks and a set of common metrics may be quite feasible if NCATS makes available the data already residing at NIH.

Despite the limitations of our study in terms of sample size (i.e., five sites), variability in data collection and recording methods, and nonstandard definitions, the results do provide a window into the characteristics of the CTSA KL2 award program. Demographic data for the five sites indicate that the programs are diverse in terms of gender, with over half of the scholars being female. The racial/ethnic diversity was similar to that present among medical school graduates in California as reported by The Henry J. Kaiser family Foundation for 2014 (i.e., 40% White, 4% Black, 31% Asian, and 9% Hispanic).[10] A majority of the award recipients had medical training, which is consistent with the stated mission of the CTSAs to "enhance the transit of therapeutics, diagnostics, and preventive interventions along the developmental pipeline."[1] The broad representation across multiple health-related disciplines indicates that the KL2 programs are aligned with the CTSA intention of remaining disease-agnostic.

In terms of the early indications of program outcomes, our data suggest that recipients of the KL2 awards are succeeding in traditional terms of obtaining grant funding and publishing in peer-reviewed journals. The proportion receiving NIH funding is lower than that reported by Mason et al.[11] in their evaluation of the NCI K award program. They report that 56% of the NCI awardees were awarded NIH funding after receiving a K award. However, there are several contextual issues that must be considered in comparing these studies. First, the time period included in the NCI study was 1980–2008. In comparison to the time frame of the present study, the NCI study covered a much longer period (i.e., 28 years vs. 8 years) and an era during which the average success rate for NIH applications was much higher (i.e., 28% vs. 18%). Thus, the K awardees evaluated in the NCI study had a much longer period of time over which to obtain NIH funding and did so in less competitive climate. Relative to the overall NIH success rate in the years 2010–2014 (18%), the CTSA KL2 awardees in this study appear to be doing quite well, especially given the fact that the proportions presented here are not "success rates" in the same way as computed by NIH, since we do not know the proportion of trainees who submitted RO1 proposals. Also, given that few NIH applications are funded on the first try in the current climate, and that the review process typically spans almost a full year, we expect that the success rate of the KL2 awardees will rise exponentially over time.

Interestingly, the productivity of the CTSA KL2 awardees in terms of publications in peer-reviewed journals compares quite favorably to that reported in the prior evaluation of NCI K awardees. In the Mason et al. report,[11] 89% of awardees had published in the years subsequent to their award. Among the KL2 recipients in our sample, the proportion was even higher (94%). Moreover, two-thirds of the CTSA KL2 awardees was featured as first author on a publication in the years since the award, even though the window of time included in the analysis was only 5 years. Some of this productivity may be a function of selection, since 100% of the CTSA KL2 awardees had published at least one article prior to the award. A portion of this difference may also reflect generally shorter times to publication resulting from the efficiencies of the electronic management of publishing.

Our data suggest that the CTSA KL2 award shows early signs of success in growing the translational workforce, as the vast majority of the awardees who had completed their KL2 award still remained active in translational research and within an academic venue. It remains to be seen, however, how active these individuals will be over time. In particular it will be interesting to observe whether

those with clinical training are able to remain as productive in the research realm as those who pursue a career path of pure research. Concern has been expressed in various quarters concerning the viability of the physician–scientist career path,[12] which points to a need to track the long-term trajectories of clinically trained KL2 awardees separate from those without clinical training.

There are additional metrics of training program success that were not addressed in this pilot project. There has been much discussion, for example, of using bibliometrics to measure research impact.[13] The most common metric used is number of citations, which is often proposed as a proxy for the impact of a single publication on the scientific field. In practice, however, deriving meaningful metrics from the data surrounding publications is complex and challenging. Rather than tackle the many issues related to bibliometrics in this feasibility project, a separate project is under way (involving the five UC CTSAs and the CTSA at Weill-Cornell Medical College) to carefully and thoroughly examine the utility of bibliometrics for evaluating the impact of the CTSA enterprise. Another indicator of training program success that has been suggested is the "K2R" transition time; that is, the number of years it takes for a K awardee to procure an RO1 or equivalent award. Prior examinations of training programs have indicated that K2R peaks at about 8 years.[3] Because the CTSA program is so young and our sample size relatively small, our dataset would not support an analysis of K2R with any robustness. No doubt, the K2R transition time will be a focus of future cross-CTSA analyses. In terms of the impact of the training program on individual career trajectories and success, our pilot project was limited in scope to examining the proportion of trainees who remained engaged in translational research and who retained a position in an academic environment. Many other metrics of career success have been proposed, including metrics of extrinsic success (e.g., financial success, promotions, and leadership positions) and metrics of intrinsic success (e.g., life satisfaction, job satisfaction).[14] Because we agreed *a priori* to confine the current study to data already collected by all of our members, we were unable to include these more specific metrics of professional success in this analysis. Some of these indicators would not be difficult to track, and would simply require modifying existing data collection tools (e.g., promotions). Others, however, pose challenges in terms of establishing common definitions and assessment procedures (e.g., life satisfaction). This study, then, offers a framework for embarking on the journey toward common metrics, and opens the door to more elaborate projects that may incorporate these additional metrics of program success.

Common metrics are time consuming, resource intensive, and challenging, but their pursuit is worthwhile since they have considerable value for evaluating the national investment in translational research training. Metrics that link back to program elements and processes that can be altered to improve program quality and strategically manage the future of CTSA will be especially salient in the future. Thus, future efforts that build on this pilot study may seek to include more elaborate analyses of the different training programs across the CTSA sites, for the purpose of identifying and disseminating best practices.

Conclusions

This project demonstrates the feasibility of combining data from multiple CTSA sites to document and evaluate the KL2 training programs administered within these centers. Although the program is still quite young, early indications suggest that several objectives of the program are being met. Trainees are broadly representative of a wide range of health-related disciplines, and equally distributed between males and females. The quality of the awardees is high, as illustrated by their record of publishing and obtaining grant funding prior to receiving the KL2 award. Moreover, among those trainees who have exited the program, rates of publishing and obtaining grant funding are indicative of success, while the near-100% retention of trainees in the translational science career path provides a strong endorsement of the KL2 programs.

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