

Implementation Strategies to Increase Clinical Trial Enrollment in a Community-Academic Partnership and Impact on Hispanic Representation: An Interrupted Time Series Analysis

Nahomy Ledesma Vicioso, BS¹; Diana Lin, BA¹; Daniel R. Gomez, MD, MBA¹; Jonathan T. Yang, MD, PhD¹; Nancy Y. Lee, MD¹; Andreas Rimner, MD¹; Yoshiya Yamada, MD¹; Michael J. Zelefsky, MD¹; Noah S. Kalman, MD²; Charles E. Rutter, MD³; Rupesh R. Kotecha, MD²; Minesh P. Mehta, MD²; Joseph E. Panoff, MD²; Michael D. Chuong, MD²; Andrew L. Salner, MD³; Jamie S. Ostroff, PhD⁴; Lisa C. Diamond, MD, MPH⁵; Noah J. Mathis, BS¹; Oren Cahlon, MD¹; David G. Pfister, MD⁶; Zhigang Zhang, PhD⁷; Fumiko Chino, MD¹; Jillian Tsai, MD¹; and Erin F. Gillespie, MD¹

QUESTION ASKED: Can a set of implementation strategies within a community-academic partnership facilitate clinical trial accrual in radiation oncology? If so, do these efforts improve representation of diverse patient populations on clinical trials?

SUMMARY ANSWER: Implementation of a combination of targeted practice-level and physician-level strategies significantly increased clinical trial enrollments at community-based partner sites, which translated to improved Hispanic representation compared with matched trials open only at the main academic center.

WHAT WE DID: Within the Memorial Sloan Kettering Cancer Alliance, we implemented a set of strategies that consisted of (1) altered financial incentives at the practice level, (2) building a coalition of physicians treating metastatic disease, and (3) practice facilitation to promote physician-physician communication regarding clinical trial enrollment issues. We collected patient-level and trial-level enrollment data for radiation oncology investigator-initiated therapeutic clinical trials at community-based partner sites before and after implementation and then conducted an interrupted time series analysis. To assess the proportion of Hispanic patients enrolled on trials with and without participation from partner sites, a subset of trials were selected in which a matched trial was conducted only at the main academic center and pooled proportions were reported descriptively.

WHAT WE FOUND: Mean quarterly patient enrollments pre- versus postimplementation increased from 1 to 11 ($P < .002$). Among three investigator-initiated randomized therapeutic radiation trials open in community-based partner sites, the proportion of Hispanic patients was 21% compared with 5.1% on matched trials open only at the main academic center.

BIAS, CONFOUNDING FACTORS: The simultaneous implementation of multiple strategies limits the ability to identify the key driver of practice change, whereas the lack of a control group does not rule out the existence of secular trends. The selected matched trials were open for variable lengths of time in the partner sites (generally shorter than the main academic center), which we did not adjust to preserve the real-world nature of the analysis.

REAL-LIFE IMPLICATIONS: A combination of implementation strategies that include practice-level and physician-level incentives facilitated radiation oncology clinical trial enrollment within a targeted community-academic partnership. A positive consequence of community-based clinical trial enrollment is to reduce disparities in representation of minority populations. Major academic institutions have a responsibility to advance efforts to increase participant diversity in clinical trials. Targeted partnerships with hospitals that serve under-represented populations appear to be an efficient strategy that may warrant being prioritized.

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CORRESPONDING AUTHOR

Erin F. Gillespie, MD, Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, 1275 York Ave, Box 22, New York, NY 10065; e-mail: efgillespie@ucsd.edu.

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abstract

PURPOSE Community-academic partnerships have the potential to improve access to clinical trials for under-represented minority patients who more often receive cancer treatment in community settings. In 2017, the Memorial Sloan Kettering (MSK) Cancer Center began opening investigator-initiated clinical trials in radiation oncology in targeted community-based partner sites with a high potential to improve diverse population accrual. This study evaluates the effectiveness of a set of implementation strategies for increasing overall community-based enrollment and the resulting proportional enrollment of Hispanic patients on trials on the basis of availability in community-based partner sites.

METHODS An interrupted time series analysis evaluating implementation strategies was conducted from April 2018 to September 2021. Descriptive analysis of Hispanic enrollment on investigator-initiated randomized therapeutic radiation trials open at community-based sites was compared with those open only at the main academic center.

RESULTS Overall, 84 patients were enrolled in clinical trials in the MSK Alliance, of which 48 (56%) identified as Hispanic. The quarterly patient enrollment pre- vs postimplementation increased from 1.39 (95% CI, -3.67 to 6.46) to 9.42 (95% CI, 2.05 to 16.78; $P = .017$). In the investigator-initiated randomized therapeutic radiation trials open in the MSK Alliance, Hispanic representation was 11.5% and 35.9% in two metastatic trials and 14.2% in a proton versus photon trial. In matched trials open only at the main academic center, Hispanic representation was 5.6%, 6.0%, and 4.0%, respectively.

CONCLUSION A combination of practice-level and physician-level strategies implemented at community-based partner sites was associated with increased clinical trial enrollment, which translated to improved Hispanic representation. This supports the role of strategic community-academic partnerships in addressing disparities in clinical trial enrollment.

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INTRODUCTION

The National Institutes of Health Revitalization Act of 1993 established guidelines for inclusion of women and minorities in National Institutes of Health-funded clinical trials.¹ A subsequent study of nonsurgical National Cancer Institute Clinical Trial Cooperative Group trials in breast, colorectal, lung, and prostate cancers showed that Hispanic patients were 28% less likely to enroll on clinical trials than White patients.² Between 1996-1998 and 2000-2002, Hispanic enrollment remained unchanged, and then more recent data through 2016 showed that it may even be decreasing.³ Within radiation oncology, a study of prospective trials conducted from 1996 to 2019 found that only 10% of

all participants identified as Hispanic, which the authors noted to be lower than their proportional in the US population according to the 2018 census.⁴ Hispanic representation is even lower among trials testing more advanced technologies, such as proton therapy.⁴

Community-academic partnerships could potentially improve patient access to clinical trials by bringing trials to the community, where under-represented patients are more often treated for cancer.⁵ Facilitators in the community include cultural and linguistic competence among staff who are embedded in the community and a greater level of trust.⁶ However, barriers to enrollment in this setting include inadequate research budgets and support staff (including review boards), inadequate

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administrative support (including legal), and lack of trial availability (which is related to strict eligibility criteria).⁷

In 2017, our tertiary cancer center (Memorial Sloan Kettering [MSK]) began opening investigator-initiated clinical trials in radiation oncology at MSK Cancer Alliance community-based partner hospitals.

In the current study, we evaluate and report (1) the effectiveness of select implementation strategies in facilitating general community-based clinical trial accrual in radiation oncology and (2) the impact of enhanced multicenter trial enrollment on Hispanic representation on investigator-initiated randomized trials compared with enrollment only at a main academic center.

METHODS

Data Collection

We included all patients enrolled in radiation oncology investigator-initiated therapeutic clinical trials at the MSK Alliance partner sites from April 2018 to September 2021. Patient-level data included age, self-reported race and ethnicity, trial protocol number, consenting physician, and institution (MSK vMSK Alliance partner). Clinical trial-level data collected included date opened at MSK, date opened in the MSK Alliance site (if applicable), and disease site (ie, genitourinary, breast, thoracic/lung, head and neck, and metastatic). Physician years of experience was estimated from the medical school graduation year, which is publicly available.

In addition, patients enrolled at MSK on select matched investigator-initiated randomized therapeutic radiation trials open during the study period were included. This study was approved by the IRB of MSK.

Implementation Strategies

Strategies to promote general clinical trial enrollment within the MSK Alliance were guided by Expert Recommendation for Implementing Change⁸ and were implemented in March 2020. They included the following:

1. *altered financial incentives* at the practice level (70% per-patient cost paid to the partner site);
2. *building a coalition* of physicians treating metastatic disease (defined as recruiting and cultivating relationships with partners, in this case, through an externally funded grant for practice improvement in radiation therapy for bone metastases);
3. *practice facilitation* including sharing contact information to promote physician-physician communication regarding clinical trial issues (ie, patient eligibility, clinical decision making, radiation treatment planning, etc).

Statistical Analysis

A Wilcoxon rank-sum test was used to compare the absolute number of trial enrollments per quarter. In addition, an interrupted time series analysis was conducted to evaluate changes pre- and postimplementation on the basis of both the change in intercept and slope. Descriptive

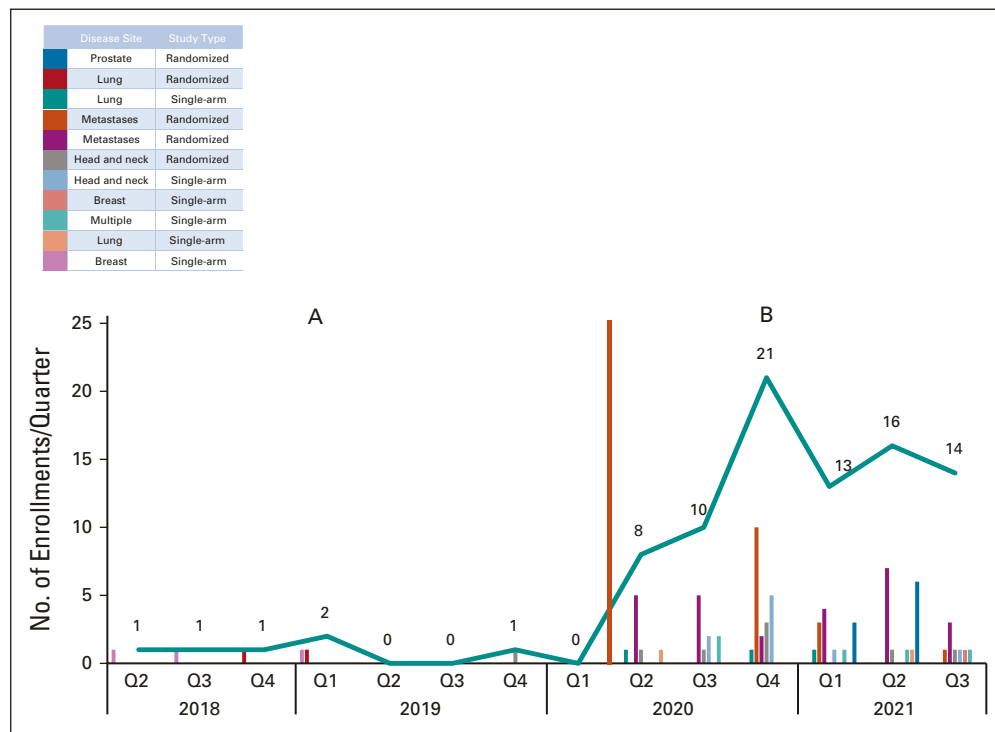


FIG 1. Community-based clinical trial enrollment per quarter (A) before and (B) after implementation (orange line) of altered financial incentives, building a coalition (for metastatic disease) and practice facilitation from April 2018 (Q2) to September 2021 (Q3). Q, quarter.

statistics were used to report the pooled proportion of patients reporting Hispanic ethnicity enrolled in each randomized clinical trial.

RESULTS

Participant Characteristics

Overall, 84 patients were enrolled in the Alliance trials during the study period. Participants had a median age of 67 (range 44-89) years. Forty-eight (56%) participants self-identified as Hispanic.

Evaluation of Implementation Strategies' Impact

Patient enrollment in the MSK Alliance increased from a mean of 1 per quarter (preimplementation) to 11 per quarter (postimplementation; $P = .002$; Fig 1). In the interrupted time series analysis, the *intercept* increased from 1.39 (95% CI, -3.67 to 6.46) before to 9.42 (95% CI, 2.05 to 16.78; $P = .017$) after implementation. The *slope* (rate of change in patient enrollments) was not significantly different from zero before the intervention (coefficient -0.14; 95% CI, -1.15 to 0.86; $P = .76$) or afterward (coefficient 1.29; 95% CI, -0.56 to 3.14; $P = .15$). The total number of therapeutic clinical trials open in the MSK Alliance before vs after implementation was similar (5 v 8), and patients were enrolled on a diversity of trials (Fig 1).

Among 41 radiation oncologists eligible to enroll patients in the Alliance, 9 (22%) accrued at least one patient at any time during the study period. Among enrolling physicians,

the total number of patients enrolled per physician ranged from 1 to 36. Physician enrollers had a median of 14 years of experience (interquartile range 9.25-24.25) compared with 28.5 years of experience (interquartile range 13-37.5) for nonenrollers.

Hispanic Representation on Randomized Trials

Three investigator-initiated randomized therapeutic radiation clinical trials were open in the Alliance during the study period. The proportion of patients self-identifying as Hispanic was 11.5% (9 of 78) and 35.9% (28 of 78) in two metastatic trials and 14.2% (8 of 56) in a proton vs photon randomized trial for a pooled proportion of 21.2% (45 of 212).

Among three matched randomized trials open only at MSK (non-Alliance), the proportion of patients self-identifying as Hispanic was 5.6% (6 of 107) and 6.0% (4 of 65) in two metastatic trials and 4.0% (4 of 101) in a proton versus photon randomized trial for a pooled proportion of 5.1% (14 of 273; Fig 2).

DISCUSSION

This study demonstrates that a combination of implementation strategies at the practice and physician level is associated with clinical trial enrollment within a targeted community-academic partnership. A positive consequence of increased community-based clinical trial enrollment was to reduce disparities in representation of minority populations, including Hispanic patients in this study. Such efforts improve access to trials for patients while increasing

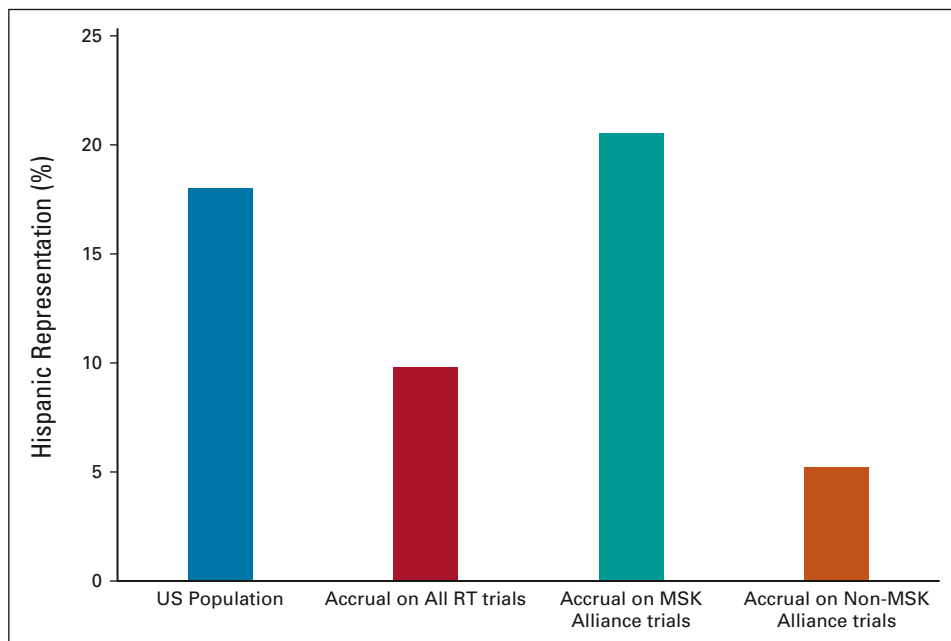


FIG 2. Hispanic patient representation in randomized investigator-initiated radiation oncology clinical trials opened in the MSK Cancer Alliance ($n = 3$) compared with those open only at MSK (non-Alliance, $n = 3$). Proportions of Hispanic representation in the US population (on the basis of the 2018 US Census) and on all radiation trials ($n = 71$)⁴ are included for reference. MSK, Memorial Sloan Kettering; RT, radiation therapy.

generalizability of trial results for real-life practice environments.⁹

Practice-level incentives alone have been shown in a previous randomized study to be ineffective at promoting clinical trial accrual.¹⁰ This, combined with large variations in individual physician accrual in our study, leads us to hypothesize that physician-level engagement is critical in enhancing enrollment. For this study, a coalition of physicians treating metastatic disease was convened as part of a National Comprehensive Cancer Network grant.¹¹ Although trial accrual is not an aim of the grant, such structured efforts likely contribute to enhancing trial enrollment. The relatively high accrual on metastatic trials, observed after the creation of the metastases physician coalition, further supports this hypothesis.

We postulate that an efficient strategy for reducing disparities in trial representation is to prioritize targeted partnerships with hospitals that serve under-represented populations, are embedded in underserved communities, and have developed strong relationships on the basis of mutual respect and trust. A majority of accruals of Hispanic patients in the current study originated from our partner site in Miami, FL, which serves a higher proportion of Hispanic patients. Such sites are more likely to have clinicians and research staff who can best deliver culturally appropriate health education and recommendations, perhaps even in their preferred language, particularly benefiting Hispanic patients with limited English proficiency.¹²

Major academic institutions, which often treat a less diverse patient population, including higher educational level, White, non-Hispanic, and higher socioeconomic status, have a responsibility to advance efforts to increase participant diversity in clinical trials. Such efforts should be supported with tailored and targeted external support grant mechanisms. Funding agencies should prioritize promotion of minority representation in

research¹³ by developing mechanisms that hold grant recipients accountable and encourage minimal goals for diverse study participation. Although reporting requirements already exist, only 10%-30% of cancer trials report ethnicity, specifically Hispanic.^{3,14,15} In the study by Bero et al⁴ evaluating representation in radiation oncology, Hispanic ethnicity was reported in 58% trials, which is encouraging.

This study has several limitations. First, the implementation of multiple strategies simultaneously and the lack of a control group limit our ability to identify the key factor driver of practice change and to control for secular trends, respectively. Second, sensitivity analysis of our interrupted time series suggests that the nonzero slope post-implementation was sensitive to the value in quarter 4 2020, which was just before the placement of enrollment caps (January 2021) because of COVID-19–related staffing shortages. In addition, the evaluated randomized trials were open for variable lengths of time, which we did not adjust for. However, such adjustments would increase the effect of accruing patients from community-based sites. We instead opted for a realistic snapshot given the reality of delays associated with opening trials at multiple institutions.

In conclusion, our findings highlight the value in working with and supporting targeted community sites that serve a greater proportion of Hispanic patients to increase representation and reduce disparities in oncology clinical trials. The combination of practice-level financial support, physician-level engagement, and practice facilitation encouraged enrollment generally in clinical trials at partner sites, which positively affected equity in clinical trial accrual. This study adds to a growing body of literature, suggesting that the road to a sustainable solution requires multifaceted approaches, thoughtfully designed academic-community partnerships, and dedicated and funded programs that leverage the capabilities of appropriately targeted competent community partner sites.

AFFILIATIONS

¹Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY

²Department of Radiation Oncology, Miami Cancer Institute, Baptist Health South Florida, Miami, FL

³Hartford HealthCare Cancer Institute, Hartford, CT

⁴Department of Psychiatry and Behavioral Sciences, Memorial Sloan Kettering Cancer Center, New York, NY

⁵Immigrant Health and Cancer Disparities Service, Memorial Sloan Kettering Cancer Center, New York, NY

⁶Department of Medical Oncology, Memorial Sloan Kettering Cancer Center, New York, NY

⁷Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY

CORRESPONDING AUTHOR

Erin F. Gillespie, MD, Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, 1275 York Ave, Box 22, New York, NY 10065; e-mail: efgillespie@ucsd.edu.

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AUTHOR CONTRIBUTIONS

Conception and design: Diana Lin, Minesh P. Mehta, Joseph E. Panoff, Andrew L. Salner, Jamie S. Ostroff, Oren Cahlon, David G. Pfister, Fumiko Chino, Jillian Tsai

Administrative support: Minesh P. Mehta

Provision of study materials or patients: Nancy Y. Lee, Minesh P. Mehta, Andrew L. Salner

Collection and assembly of data: Nahomy Ledesma Vicioso, Diana Lin, Jonathan T. Yang, Erin F. Gillespie

Data analysis and interpretation: Nahomy Ledesma Vicioso, Diana Lin, Daniel R. Gomez, Jonathan T. Yang, Nancy Y. Lee, Andreas Rimner, Yoshiya Yamada, Michael J. Zelefsky, Noah S. Kalman, Charles E. Rutter,

Rupesh R. Kotecha, Minesh P. Mehta, Michael D. Chuong, Lisa C. Diamond, Noah J. Mathis, Oren Cahlon, David G. Pfister, Zhigang Zhang, Fumiko Chino, Jillian Tsai, Erin F. Gillespie

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Daniel R. Gomez

Honoraria: Varian Medical Systems, Merck, Bristol Myers Squibb, AstraZeneca, RefleXion Medical, Vindico Medical Education, US Oncology, GRAIL

Consulting or Advisory Role: Olympus Medical Systems, Medtronic, Johnson & Johnson/Janssen

Research Funding: Merck, Varian Medical Systems, AstraZeneca, Bristol Myers Squibb

Travel, Accommodations, Expenses: Varian Medical Systems, AstraZeneca, Merck, Vindico Medical Education, US Oncology, Driver Inc

Jonathan T. Yang

Stock and Other Ownership Interests: Nanocan Therapeutics

Consulting or Advisory Role: Debiopharm Group, Galera Therapeutics, AstraZeneca, Nanocan Therapeutics

Research Funding: AstraZeneca, Kazia Therapeutics, X-RAD Therapeutics

Nancy Y. Lee

Consulting or Advisory Role: Merck, Pfizer, Merck Serono, Sanofi, Mirati Therapeutics, Roche/Genentech

Research Funding: AstraZeneca, Pfizer (Inst)

Andreas Rimner

Honoraria: More Health

Consulting or Advisory Role: AstraZeneca, Merck, Boehringer Ingelheim

Research Funding: Varian Medical Systems (Inst), Boehringer Ingelheim (Inst), Pfizer (Inst), AstraZeneca (Inst), Merck (Inst)

Yoshiya Yamada

Employment: Memorial Sloan-Kettering Cancer Center

Leadership: Chordoma Foundation

Honoraria: Varian Medical Systems, BrainLAB, Vision RT

Speakers' Bureau: BrainLAB, Vision RT, Varian Medical Systems

Research Funding: Varian Medical Systems

Travel, Accommodations, Expenses: Philips Healthcare

Other Relationship: University of Wollongong

Michael J. Zelefsky

Honoraria: Accuray

Consulting or Advisory Role: Alpha Tau, Boston Scientific

Patents, Royalties, Other Intellectual Property: Ferring provided partial funding for a clinical trial (Inst)

Other Relationship: Editor in Chief for Brachytherapy

Noah S. Kalman

Consulting or Advisory Role: Naveris

Rupesh R. Kotecha

Honoraria: Accuray, Novocure, Elekta, BrainLAB, Elsevier, ViewRay, PeerView

Consulting or Advisory Role: ViewRay, Novocure

Speakers' Bureau: Novocure

Research Funding: Medtronic (Inst), Blue Earth Diagnostics (Inst), Novocure (Inst), GT Medical Technologies (Inst), AstraZeneca (Inst), Exelixis (Inst), ViewRay (Inst), BrainLAB (Inst)

Travel, Accommodations, Expenses: PeerView

Minesh P. Mehta

Leadership: Oncoceutics

Stock and Other Ownership Interests: Chimerix

Consulting or Advisory Role: Karyopharm Therapeutics, Mevion Medical Systems, ZappRx, Sapience Therapeutics, Xoft

Patents, Royalties, Other Intellectual Property: WARF patent 14/934,27, Topical vasoconstrictor preparations and methods for protecting cells during cancer chemotherapy and radiotherapy

Uncompensated Relationships: Xcision Medical Systems, ViewRay

Michael D. Chuong

Employment: Fertility and IVF Center of Miami

Honoraria: ViewRay, Sirtex Medical

Consulting or Advisory Role: ViewRay, Advanced Accelerator Applications

Speakers' Bureau: ViewRay, Sirtex Medical

Research Funding: AstraZeneca/MedImmune, ViewRay

Travel, Accommodations, Expenses: ViewRay

Andrew L. Salner

Consulting or Advisory Role: Best Doctors Inc

Jamie S. Ostroff

Patents, Royalties, Other Intellectual Property: UptoDate

David G. Pfister

Consulting or Advisory Role: Boehringer Ingelheim, Incyte

Research Funding: Boehringer Ingelheim (Inst), AstraZeneca (Inst), Exelixis (Inst), Novartis (Inst), MedImmune (Inst), Merck (Inst), Genentech/Roche (Inst), Lilly (Inst), Bayer (Inst), Eisai (Inst), Regeneron (Inst), Atara Biotherapeutics (Inst), MeiraGTX (Inst), Hookipa Pharma (Inst)

Fumiko Chino

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Jillian Tsai

Honoraria: Varian Medical Inc

Consulting or Advisory Role: Varian Medical Systems

Erin F. Gillespie

Other Relationship: eContour

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