

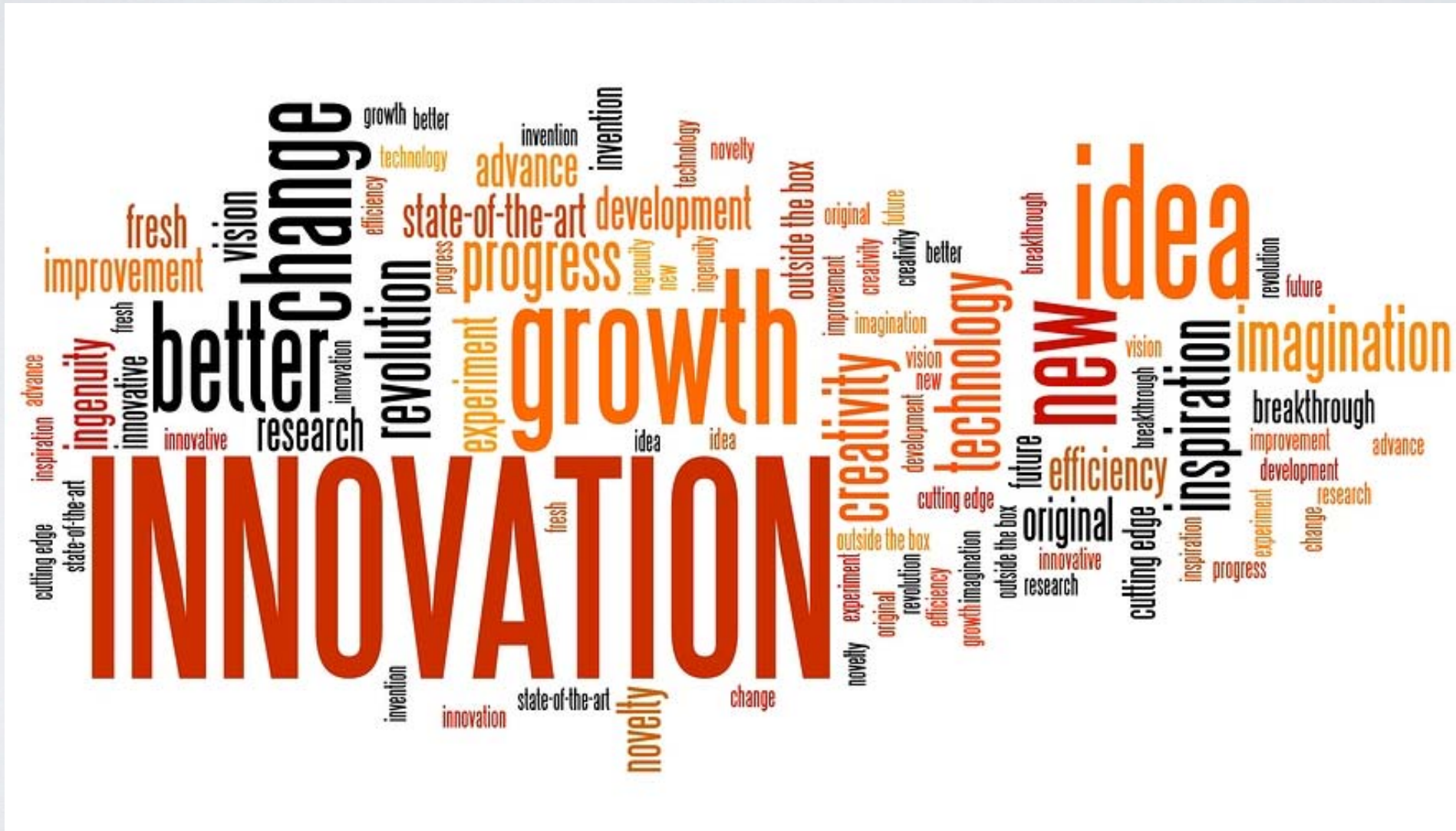
INNOVATION IN CANCER CLINICAL TRIALS

SWOG Fall Meeting October 2017

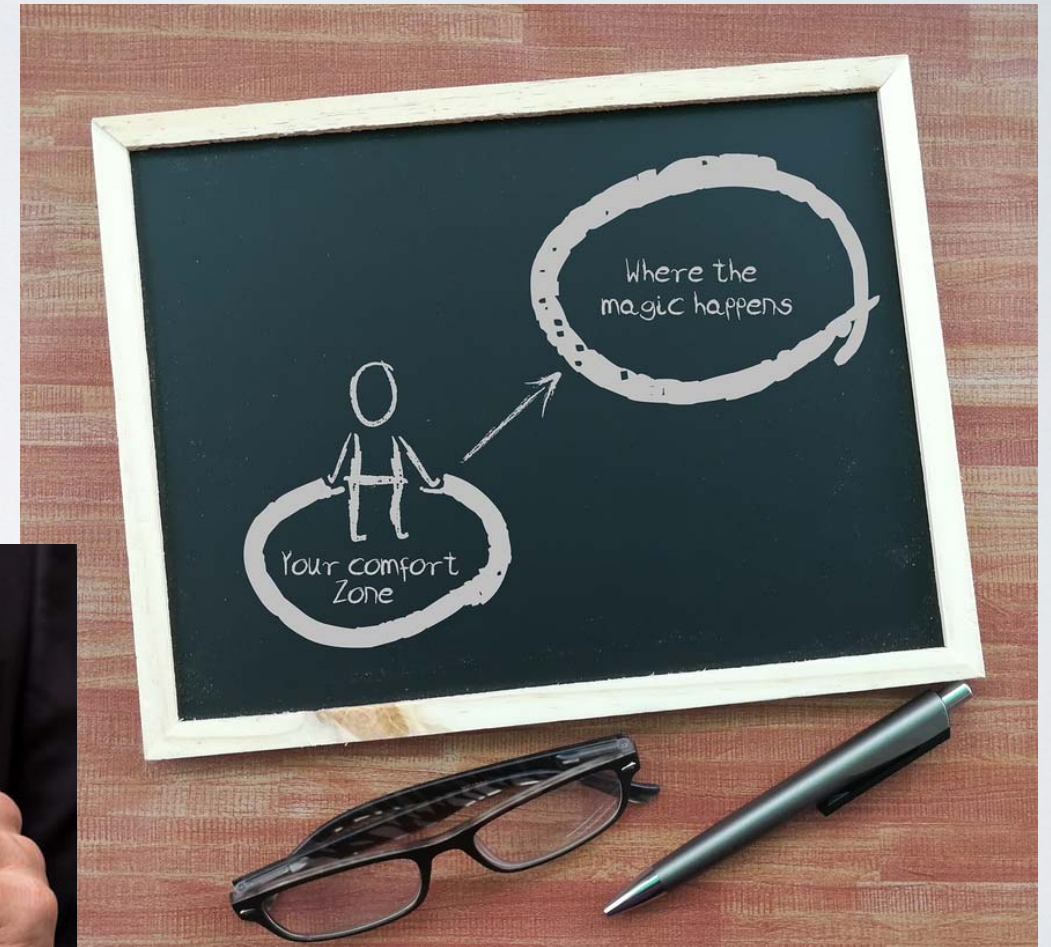
Dr. Larry Chu

Alicia C. Staley

WHAT IS INNOVATION?



WHAT INSPIRES INNOVATION?



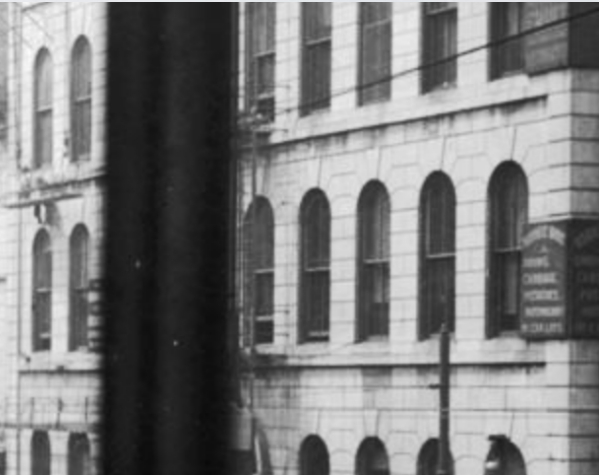
WHAT CAN INSPIRE INNOVATION IN CLINICAL TRIALS?



The Model T

Yes, it might be as simple as that.

CHICAGO 1912 = INNOVATION



INNOVATION IS A CHANGE OF STATE



- Static Assembly to
- **Dynamic Assembly**
- *Ford found inspiration outside his core industry,*
- *developed new way*

CHICAGO 2017 - #SWOGONC

Innovation in Cancer Clinical Trials? Is it really possible?

The Model T Clinical Trial

**** no, not a patient assembly line ****

From a static to DYNAMIC process

What happens if we encourage the 'Patient' to become dynamic?

WHAT IF?

Partnering with patients speeds innovation in research

Partnering with patients will improve data sharing

Partnering with patients makes research more accessible

Partnering with patients in cancer clinical trials will
change the culture of medicine

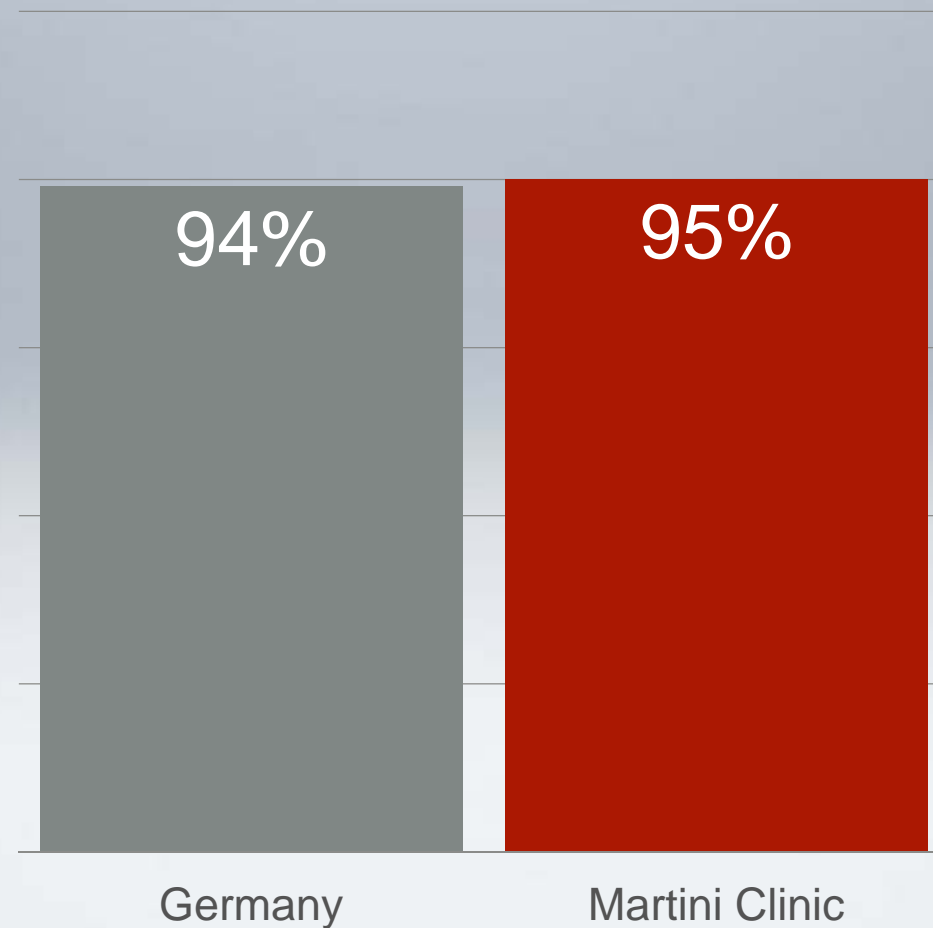


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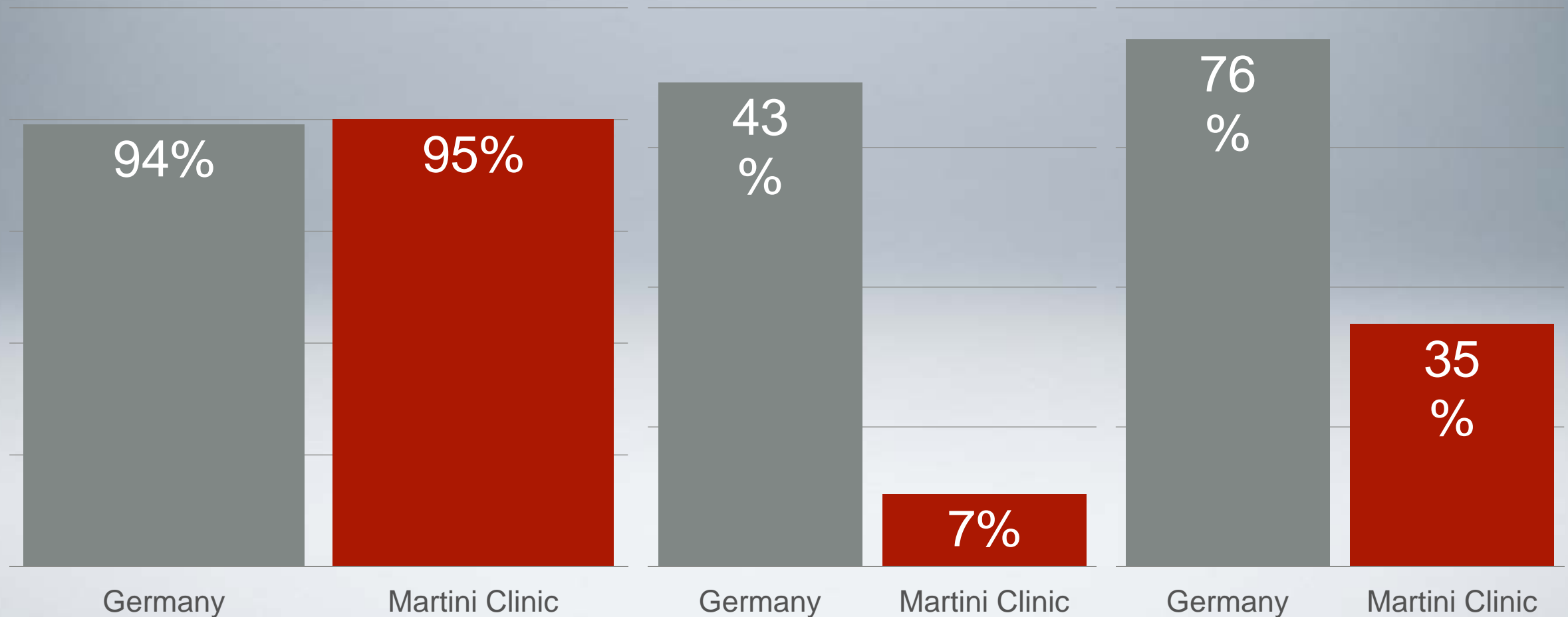
Partnering with patients speeds innovation in research

5 year Prostate Cancer Survival Rates



Partnering with patients speeds innovation in research

5 year Prostate Cancer Survival Rates 1 yr Incontinence 1 yr Severe Erectile Dysfunction



Source: Martini Klinik, BARMER, GEK: Report Krankenhaus 2012, Patient-reported outcomes (EORTC=PSM), 1 year after treatment, 2010



Perspective

DECEMBER 23, 2010

What Is Value in Health Care?

Michael E. Porter, Ph.D.

In any field, improving performance and accountability depends on having a shared goal that unites the interests and activities of all stakeholders. In health care, however, stakeholders have

myriad, often conflicting goals, including access to services, profitability, high quality, cost containment, safety, convenience, patient-centeredness, and satisfaction. Lack of clarity about goals has led to divergent approaches, gaming of the system, and slow progress in performance improvement.

Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent.¹ This goal is what matters for patients and unites the interests of all actors in the system. If value improves, patients,

Value — neither an abstract ideal nor a code word for cost reduction — should define the framework for performance improvement in health care. Rigorous, disciplined measurement and improvement of value is the best way to drive system progress. Yet value in health care remains largely unmeasured and misunderstood.

Value should always be defined around the customer, and in a well-functioning health care system, the creation of value for patients should determine the rewards for all other actors in the system. Since value depends on results, not inputs, value in our context⁸ is not inputs⁹ as things are done, but rather the results achieved by doing things. Thus, we define value as the difference between what the patient would have experienced without the intervention and what he or she actually experiences with it.

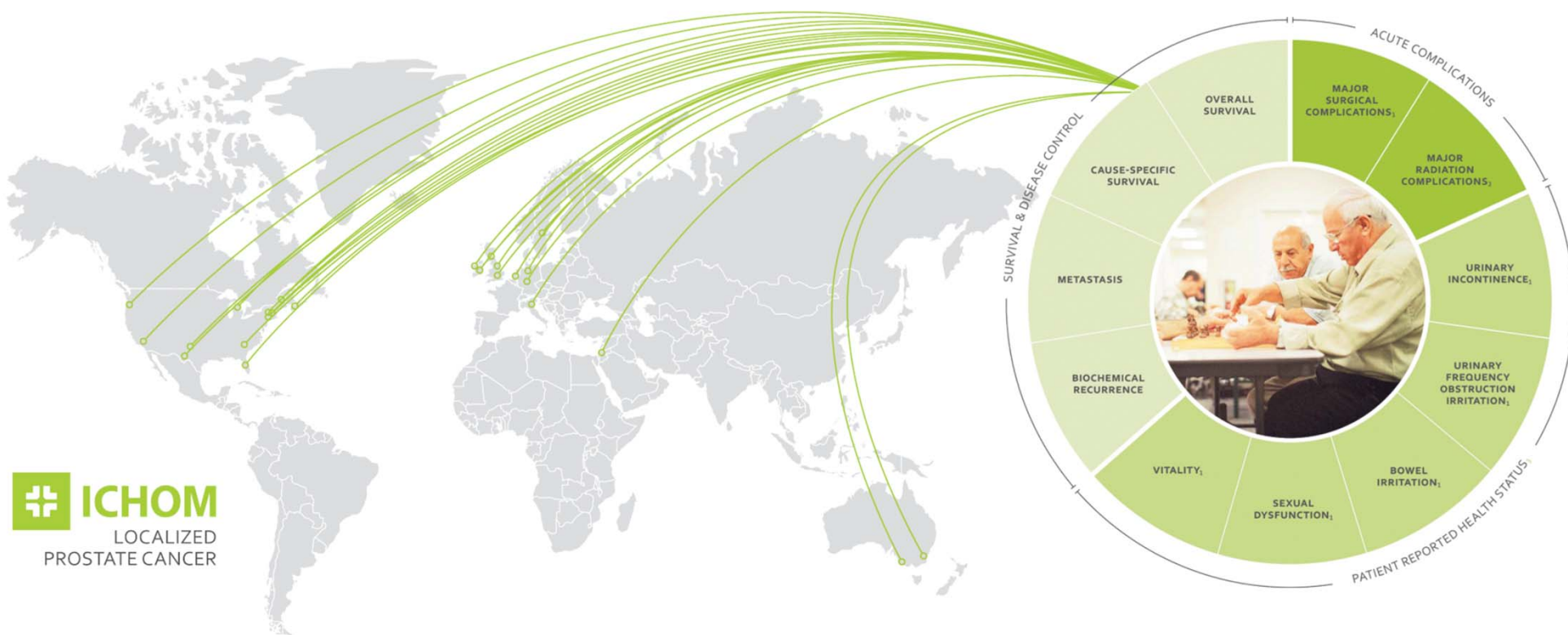
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շորս:

value is a central challenge. Nor is value measured by the process of care used; process measurement and improvement are important tactics but are no substitutes for measuring outcomes and costs.

Since value is defined as outcomes relative to costs, it encompasses efficiency. Cost reduction without regard to the outcomes achieved is dangerous and self-defeating, leading to false "savings" and potentially limiting effective care.

Outcomes, the numerator of the value equation, are inherently condition-specific and multidimensional. For any medical condition, no single outcome captures the results of care. Cost, the equation's denominator, refers to the total costs of the full cycle of care for the patient's medical condition, not the cost

THE GLOBAL STANDARD – INTERNATIONAL COLLABORATION IS IN OUR DNA





Colorectal Cancer
Malignant Neoplasms



Breast Cancer
Malignant Neoplasms



Localized Prostate Cancer
Malignant neoplasms



Advanced Prostate Cancer
Malignant neoplasms



Lung Cancer
Malignant neoplasms

Malignant neoplasms

Lung Cancer

Partnering with patients speeds innovation in research

Partnering with patients, literally speeds research.

Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project

Bennett Levitan, MD, PhD¹, Kenneth Getz, MBA²,
Eric L. Eisenstein, DBA³, Michelle Goldberg, MBA⁴,
Matthew Harker, MPH, MBA⁵, Sharon Hesterlee, PhD⁶,
Bray Patrick-Lake, MFS⁷, Jamie N. Roberts, MPH, MA⁷,
and Joseph DiMasi, PhD²

Abstract

Background: While patient groups, regulators, and sponsors are increasingly considering engaging with patients in the design and conduct of clinical development programs, sponsors are often reluctant to go beyond pilot programs because of uncertainty in the return on investment. We developed an approach to estimate the financial value of patient engagement. **Methods:** Expected net present value (ENPV) is a common technique that integrates the key business drivers of cost, time, revenue, and risk into a summary metric for project strategy and portfolio decisions. We assessed the impact of patient engagement on ENPV for a typical oncology development program entering phase 2 or phase 3. **Results:** For a pre-phase 2 project, the cumulative impact of a patient engagement activity that avoids one protocol amendment and improves enrollment, adherence, and retention is an increase in net present value (NPV) of \$62MM (\$65MM for pre-phase 3) and an increase in ENPV of \$35MM (\$75MM for pre-phase 3). Compared with an investment of \$100,000 in patient engagement, the NPV and ENPV increases can exceed 500-fold the investment. This ENPV increase is the equivalent of accelerating a pre-phase 2 product launch by 2½ years (1½ years for pre-phase 3). **Conclusions:** Risk-adjusted financial models can assess the impact of patient engagement. A combination of empirical data and subjective parameter estimates shows that engagement activities with the potential to avoid protocol amendments and/or improve enrollment, adherence, and retention may add considerable financial value. This approach can help sponsors assess patient engagement investment decisions.

Keywords

patient engagement, therapeutic development, expected net present value, risk-adjusted financial model

Therapeutic Innovation
& Regulatory Science
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DOI: 10.1177/2168479017716715
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The ENPV increase from the combined amendment/patient experience impact is equivalent to reducing time to launch by 30 months for the pre-phase 2 case and by 17 months for the pre-phase 3 case.

”

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Partnering with patients will improve data sharing



LARRY CHU, MD
PROFESSOR, EXECUTIVE DIRECTOR MEDICINE X
STANFORD UNIVERSITY SCHOOL OF MEDICINE

WE'VE MAPPED THE WORLD. NOW LET'S MAP HUMAN HEALTH.

MY MOOD TODAY



Enthusiastic
80%

Scared
20%

MY SLEEP LAST NIGHT



Times awakened
2

Sleep duration
7.5 hr

MY HEARING TEST



Left ear
Normal

Right ear
Normal

MY ECG TODAY



Heart rate
72 bpm

PR Interval
0.17

MY DIET TODAY



Coffee
2 cups

Water
8 oz

MY IMMUNIZATION RECORD



Tetanus
Yes

Pertussis
Yes

MY MOVEMENT TODAY



Strenuous activity
Often

Minutes walked
45 min



Partnering with patients will improve data sharing



Partnering with patients makes research more accessible

Patients are powerful at spreading information at medical meetings and engaging in meaningful conversations.

Original Paper

Patient Participation at Health Care Conferences: Engaged Patients Increase Information Flow, Expand Propagation, and Deepen Engagement in the Conversation of Tweets Compared to Physicians or Researchers

Audun Utengen^{1*}, MBA; Dara Rouholiman^{2*}, BS; Jamison G Gamble^{2*}, MPH; Francisco Jose Grajales III^{3*}, MS, CD, R Kin; Nisha Pradhan^{4*}, BA; Alicia C Staley^{2*}, MBA, MS; Liza Bernstein^{2*}; Sean D Young^{5*}, MS, PhD; Kevin A Clauson^{6*}, PharmD; Larry F Chu^{2*}, MS, MD

¹Symplr, Los Angeles, CA, United States

²Stanford Medicine X, Stanford University School of Medicine, Stanford, CA, United States

³Center for Social Innovation and Impact Investing, Sauder School of Business, University of British Columbia, Vancouver, BC, Canada

⁴Clinical Genetics Service, Memorial Sloan Kettering Cancer Center, New York, NY, United States

⁵University of California Institute for Prediction Technology, Department of Family Medicine, University of California, Los Angeles, Los Angeles, CA, United States

⁶College of Pharmacy, Lipscomb University, Nashville, TN, United States

*all authors contributed equally

Corresponding Author:

Larry F Chu, MS, MD
Stanford Medicine X
Stanford University School of Medicine
300 Pasteur Drive
Stanford, CA, 94305
United States
Phone: 1 (650) 723 6632
Fax: 1 (650) 497 9335
Email: lchu@stanford.edu

Abstract

Background: Health care conferences present a unique opportunity to network, spark innovation, and disseminate novel information to a large audience, but the dissemination of information typically stays within very specific networks. Social network analysis can be adopted to understand the flow of information between virtual social communities and the role of patients within the network.

Objective: The purpose of this study is to examine the impact engaged patients bring to health care conference social media information flow and how they expand dissemination and distribution of tweets compared to other health care conference stakeholders such as physicians and researchers.

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information to a large audience, but the dissemination of information typically stays within very specific networks. Social network

“

Health care conferences that fail to engage patients in their proceedings may risk limiting their engagement with the public, disseminating scientific information to a narrow community and slowing flow of information across social media channels.

”

Partnering with patients makes research more accessible

	Patients	HCP	Researchers
Tweet Volume	309	118	138
Engagement (replies)	25	5	6
Composition	1.5%	6.6%	21.1%

Maarten P.T. de Wit, Tineke A. Abma, Marije S. Koelewijn-van Loon, Sarah Collins and John Kirwan
The Journal of Rheumatology January 2014, 41 (1) 177-184; DOI: <https://doi.org/10.3899/jrheum.130816>

eLetters

Next ➔

Abstract

and conduct of phenomenology research'. It has enriched the research agenda by identifying
 parts of the conference in 2015. Long-term engagement has made a significant change in the scope
Results. The role of patients has evolved from a single focus group in 2005 to full integration in all
 subjected to an inductive content analysis.



The Journal of Rheumatology
Vol. 41, Issue 1
1 Jan 2014
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Involving patient research partners has a significant impact on outcomes research: a responsive evaluation of the international OMERACT conferences

Maarten de Wit,¹ Tineke Abma,¹ Marije Koelewijn-van Loon,² Sarah Collins,³ John Kirwan⁴

To cite: de Wit M, Abma T, Koelewijn-van Loon M, *et al*. Involving patient research partners has a significant impact on outcomes research: a responsive evaluation of the international OMERACT conferences. *BMJ Open* 2013;3:e002241. doi:10.1136/bmjopen-2012-002241

► Prepublication history for this paper are available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2012-002241>).

Received 20 October 2012
Revised 2 April 2013
Accepted 3 April 2013

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ABSTRACT

Objective: To assess the inclusion of patients as international research partners in Outcome Measures in Rheumatology (OMERACT) conferences and how this has influenced the scope and conduct of outcomes research in rheumatology.

Design: A thematic content analysis of OMERACT internal documents, publications and conference proceedings, followed by a responsive evaluation including 32 qualitative semistructured interviews.

Setting: The international, biannual research conference OMERACT 10 (Malaysia, 2010).

Participants: Senior researchers (n=10), junior researchers (n=2), representatives of the pharmaceutical industry and regulators (n=2), conference staff (n=2), new patient delegates (n=8) and experienced patient delegates (n=8).

Results: The role of patients evolved over 10 years from a single patient focus group to full participation in all areas of the meeting and inclusion in research group meetings between conferences. Five main categories of impact emerged: widening the research agenda; including patient relevant outcomes in core sets; enhancing patient reported instruments; changing the culture of OMERACT and consequences outside OMERACT. Patient participants identified previously neglected outcome domains such as fatigue, sleep and quality of life. These domains were included in the research agenda and core sets. The role of patients evolved over 10 years from a single patient focus group to full participation in all areas of the meeting and inclusion in research group meetings between conferences. Five main categories of impact emerged: widening the research agenda; including patient relevant outcomes in core sets; enhancing patient reported instruments; changing the culture of OMERACT and consequences outside OMERACT. Patient participants identified previously neglected outcome domains such as fatigue, sleep and quality of life. These domains were included in the research agenda and core sets.

ARTICLE SUMMARY

Article focus

- Since 2002, patients have participated as collaborative partners in the biannual conference on Outcome Measures in Rheumatology (OMERACT).
- Although the contribution of patients has been praised and there is a widespread call for scientific publications on the impact of engaging with patients, no systematically obtained evidence has been published to support the idea that the structural involvement of patients in research conferences is beneficial.
- Our qualitative study reports the combined results of a thematic document analysis and 32 semistructured interviews with all stakeholders including researchers, patient participants and representatives from the pharmaceutical industry and international regulators.

Key messages

- Long-term engagement with arthritis patients in OMERACT conferences has significantly influenced outcome research in the field of rheumatology.
- Patients have successfully contributed to the research agenda of OMERACT by identifying new domains that are important for patients, and promoting their inclusion in the research agenda and core sets.
- Long-term engagement with arthritis patients in OMERACT conferences has significantly influenced outcome research in the field of rheumatology.

“ Including patients as partners in OMERACT conferences has widened its focus and adjusted the way of working. It has resulted in new developments in the research agenda and the use of more patient-relevant outcomes in clinical trials. These collaborations have influenced perceptions and beliefs among many patients and researchers, and led to wider patient involvement as partners in research. ”

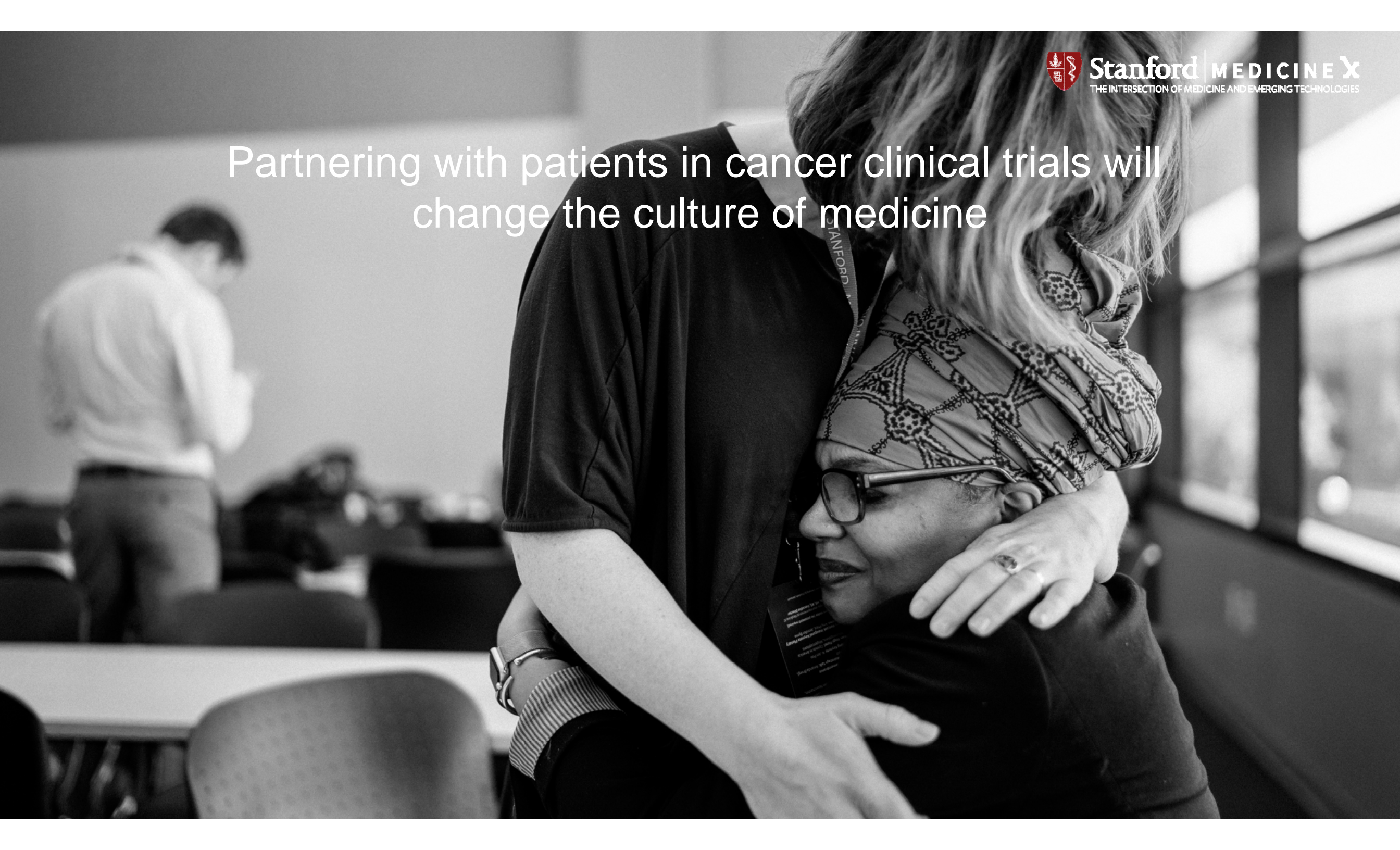
Partnering with patients in cancer clinical trials will change the culture of medicine

Everyone IncludedTM is a framework for healthcare innovation, implementation and transformation based on principles of mutual respect and inclusivity. It is the culmination of six years of co-creation with patients, caregivers, providers, technologists, and researchers at Stanford Medicine X that has resulted in a series of design and leadership principles intended to drive collaborative healthcare innovation efforts. It helps bring groups of diverse stakeholders together on equal footing work together to collaboratively co-produce the future of health care.

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Partnering with patients in cancer clinical trials will
change the culture of medicine



Partnering with patients in cancer clinical trials will change the culture of medicine







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is a year round program that focuses on:
people + technology + design

LESSONS LEARNED

Partnering with patients speeds innovation in research

Partnering with patients will improve data sharing

Partnering with patients makes research more accessible

Partnering with patients in cancer clinical trials will
change the culture of medicine

INNOVATION IN CANCER CLINICAL TRIALS

- Clinical Research as a Care Option
- Simplified Consent Process
- Inclusion/Exclusion Criteria is more attainable
- Value exchange for all involved
- Patients don't look for trials, trials come to the Patient

**Clinical Research delivered to the right patient, at the right time,
at the right place, in the right dose.**

THANK YOU