

Implementing Broadly Engaged Team Science at Academic Health Centers

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This report summarizes QE Philanthropic Advisors' work on the Clinical Research Forum's Broadly Engaged Team Science project led by Harry Selker. It is meant to serve a basis for discussions at the April 2018 CR Forum Leadership meeting and to inform selection of speakers at a panel at the concurrent ACTS meeting.

CONTENTS

SUMMARY	2
SECTION I. BACKGROUND	2
SECTION II. TERMINOLOGY	4
SECTION III. CHALLENGES TO IMPLEMENTING BROADLY ENGAGED TEAM SCIENCE	5
SECTION IV. EXAMPLES OF BROADLY ENGAGED TEAM SCIENCE	10
SECTION V. CONCLUSIONS	15
APPENDIX I: Expert Interviews	17
APPENDIX II: Helpful Resources	18

SUMMARY

The purpose of this project is to identify barriers at Academic Health Centers (AHCs) to implementing “broadly engaged team science” and suggest activities that the Clinical Research Forum (CR Forum) can undertake to foster its adoption at AHCs. Broadly engaged team science is defined as “*the meaningful involvement of relevant stakeholders including patients, caregivers, clinicians and other healthcare stakeholders from both nonprofit and for-profit sectors in the research process—from topic selection through design and conduct of research to dissemination of results.*”¹ Information was gathered from interviews with AHC leaders, clinical researchers, and representatives of government funding agencies, private non-profit and for-profit organizations, as well as the review of pertinent websites and publications.

The challenges to implementing broadly engaged team science at AHCs include recognizing the contributions of team members and promoting them, inadequate resources and infrastructure to train and support team participants, and institutional policies that erect barriers to meaningful stakeholder engagement. The following are six possible future activities that the CR Forum leadership might consider supporting. The first four suggestions fit within ongoing CR Forum activities or build on an existing activity. In contrast, suggestions five and six would represent new directions for the CR Forum.

1. Advocate for the funds, particularly for PCORI, as well as policy changes needed to better support broadly engaged team science at AHCs.
2. Identify successful broadly engaged team science projects and highlight them at meetings and workshops to identify the best practices and build its value proposition.
3. Endorse and advocate for the implementation of the recommendations, tools and guidelines relating to patient engagement, stakeholder identification, and other issues impacting broadly engaged team science that have been developed by PCORI and others.
4. Each year, recognize an outstanding broadly engaged team science project that has engaged patients and changed clinical practice and/or added special value to the clinical enterprise.
5. Work with the American Association of Medical Colleges and other organizations to examine how AHC promotion and tenure policies deter or reward faculty participating in broadly engaged team science.
6. Host a meeting with representatives of large health systems to explore how health systems might work with AHCs to improve the infrastructure and training needed to engage patients and advance broadly engaged team science projects integral to learning health systems.

SECTION I. BACKGROUND

As noted in a recent National Academy of Sciences (NAS) consensus report (2015), “Over the past six decades, as scientific and social challenges have become more complex and scientific knowledge and methods have advanced, scientists have increasingly joined with colleagues to conduct collaborative

¹ Selker, H.P. and Wilkins, C.H., [From Community Engagement, To Community Engaged Research, To Broadly Engaged Team Science](https://doi.org/10.1017/cts.2017.1), Journal of Clinical and Translational Science, Vol.1, February 2017, <https://doi.org/10.1017/cts.2017.1>

research often referred to as ‘team science’.” The National Cancer Institute’s website toolkit on team science defines team science as a “collaborative effort to address a scientific challenge that leverages the strengths and expertise of professionals trained in different fields.”² While scientists whose research is conducted solely within their own independent laboratories continue to make important contributions, the model of team science involving researchers collaborating across departments and even different institutions is now a well-accepted research paradigm at AHCs. In response to this shift, AHCs have revamped promotion and tenure policies to recognize members of scientific teams and added new personnel tracks. Nonetheless, challenges remain at many AHCs in aligning institutional policies and infrastructure to facilitate the team approach, and a plethora of papers and studies on how to establish, manage and evaluate scientific teams has yielded a new discipline- “the science of team science.”^{3,4}

Similarly, the view that research on human diseases, and, in particular, projects involving human subjects, should incorporate input from patients and their communities, which was galvanized by AIDS activists in the 1990’s, is now widely accepted with more funding organizations mandating some level of patient and community input. However, requirements for and/or approaches to how patients should be engaged can differ considerably, varying not only with the funding source but also with the research questions being investigated.

The trend towards increased patient engagement has been accelerated by the Patient Centered Outcomes Research Institute (PCORI), which supports outcomes research “that can help patients and those who care for them make better-informed decisions about healthcare choices.” PCORI supported projects require “meaningful involvement of patients, caregivers, clinicians and other healthcare stakeholders throughout the research process—from topic selection through design and conduct of research to dissemination of results” (www.pcori.org). This type of engagement, which goes beyond team science or community engaged research, has been referred to by Selker and Wilkens (2017) as “**broadly engaged team science.**”⁵ It requires adopting an inclusive and participatory framework to help build trust and engage diverse stakeholders.

The rationale for conducting broadly engaged team science rests not only on the ethical and moral obligation that research about patients should engage patients and their communities, but the need to include experts from different disciplines to answer complex research questions, and the view that when patients and their communities are engaged, patient recruitment will be faster, the outcome

² <https://www.scienceofteams-science.org/scits-a-team-science-resources>

³ <https://www.nap.edu/catalog/9942/bridging-disciplines-in-the-brain-behavioral-and-clinical-sciences>

⁴ <https://www.scienceofteams-science.org/>

⁵ Selker, H.P. and Wilkins, C.H., From Community Engagement, To Community Engaged Research, To Broadly Engaged Team Science, Journal of Clinical and Translational Science, Vol.1, February 2017, <https://doi.org/10.1017/cts.2017.1>

measures chosen will be more appropriate, and the uptake of research findings will probably be more efficient with input from patients and health care providers.⁶

For these reasons, CR Forum, under the leadership of Harry Selker, is working to highlight the importance of broadly engaged research teams in translational and clinical research and the need for AHCs to do more to encourage meaningful engagement of patients and other stakeholders. In that context, QE Philanthropic Advisors was retained to work with a small committee of CR Forum leaders⁷ to review useful resources; identify the barriers to implementing broadly engaged team science at AHCs; and provide examples of clinical research projects that have successfully utilized this model.

Our findings, summarized below, are based on interviews with AHC leaders, clinical investigators, representatives of government funding agencies, private, nonprofit and for-profit groups and patient advocacy organizations, as well as a review of pertinent websites and publications. Some of the points made by individual interviewees are presented in bulleted italics for emphasis. Appendix I lists the individuals interviewed for this project.

SECTION II. TERMINOLOGY

As noted above, the term “team science” refers to scientific efforts that involve professionals from varying disciplines. Building on language on PCORI’s website, Selker and Wilkins coined the term **broadly engaged team science**, which we use here to refer to science that includes:

“...the meaningful involvement of relevant stakeholders including patients, caregivers, clinicians and other healthcare stakeholders from both nonprofit and for-profit sectors in the research process—from topic selection through design and conduct of research to dissemination of results.”

The “meaningful involvement of stakeholders,” while critical, is variable depending on the research project. This is an evolving area with few hard definitions or rules. This ambiguity can cause confusion and sometimes makes it difficult to differentiate it from “team science.” For example, PCORI supported outcomes research requires the engagement of patients and their communities as major stakeholders, but not all outcomes research may necessitate patient stakeholder involvement. One example is the investigation of the role of computerized physician order entry systems for prescribing drugs in decreasing medical errors, which was conducted by an interdisciplinary team at the University of Pennsylvania that did not involve patients.⁸ The PCORI website⁹ has a comprehensive chart that identifies stakeholders, defines them and gives examples useful in identifying relevant members of research teams. However, as noted above this is an evolving area with a framework of principles and guidelines, but few, if any, firm definitions or rules. Discussing which stakeholders should be part of a

⁶ Cornerstones of Collaboration: Foundation-led Partnerships to Accelerate R&D, 2017; <http://www.fastercures.org/reports/view/69>

⁷ Committee members include Rob Califf, Pamela Davis, Rebecca Jackson, and Harry Selker.

⁸ Koppel, *The Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors*, JAMA, 293,10, (pp1197-1203) 2005

⁹ <https://www.pcori.org/engagement/what-we-mean-engagement/pcoris-stakeholders>

team in a given research project or how they should be meaningfully engaged is beyond the scope of this paper. Rather, this paper's focus is on identifying the barriers to implementing broadly engaged team science at AHCs and providing a few examples of individual research projects and/or programs that have employed this model.

Appendix II contains short descriptions of websites of selected organizations or institutes, which have useful resource materials, tools and papers about team science and/or broadly engaged team science.

SECTION III. CHALLENGES TO IMPLEMENTING BROADLY ENGAGED TEAM SCIENCE

While AHCs are critical players in medical research, their structure, processes and culture have not always been conducive to either team science or broadly engaged team science. The tremendous growth in biomedical research at AHCs in the twentieth century was driven predominantly by the growth of NIH and its investigator-initiated research project grants (R01s). Thus, the organization and promotion policies established by AHCs during this period were aligned with R01 recipients in mind. Today, the situation is rapidly evolving with AHCs adapting their policies and structure to a new reality - more cross-disciplinary team science projects, global research networks that share and mine large databases, and patient groups and venture philanthropy that fund more milestone-driven research.

Nonetheless, impediments to team science still exist at AHCs and also impede broadly engaged team science, although additional barriers and/or issues may add to the difficulty of engaging multiple stakeholders. The discussion below groups these barriers into four overlapping categories. No attempt is made to provide a comprehensive review of the issues, but rather to reflect the issues emphasized by those we interviewed. More comprehensive discussion of the challenges to conducting interdisciplinary team science have been well described in numerous publications including in an National Academy of Sciences study published in 2000 on bridging disciplines in the brain, behavior and clinical sciences.¹⁰

1. AHC Infrastructure

Centers of excellence, interdepartmental core facilities and graduate training programs, as well as other approaches have diminished the vertical silos that a department structure creates at many AHCs, and, thus, have given researchers more flexibility to participate in cross-disciplinary research. In terms of clinical research, the CTSA program has provided critical funding that has strengthened the infrastructure needed to train clinical investigators, support clinical research protocols, and engage patient communities at many institutions. Moreover, CTSA grants have helped AHCs restructure their organizations so that the various staff engaged in these clinical research activities no longer work isolated in silos within their institutions, but are located in integrated core facilities.¹¹ Despite these positive changes, feedback from those interviewed indicated that conducting broadly engaged team

¹⁰ www.nap.edu/catalog/9942/bridging-disciplines-in-the-brain-behavioral-and-clinical-sciences

¹¹ Brassil, D., et.al., The Rockefeller University Navigation Program: A Structured Multidisciplinary Protocol Development and Educational Program to Advance Translational Research, CTS Journal, 2014: 7 (1) 12-19.

science on human subjects can be challenging and the infrastructure at AHCs is often inadequate and/or fragmented.¹² In general, outreach to identify patient stakeholders at AHCs is often inefficient, although some institutions have successfully used CTSA resources to provide a central mechanism to help investigators identify and accrue trained patient stakeholders.¹³

- *An interviewee noted that without a robust infrastructure focused on stakeholder engagement, the burden of finding effective patient stakeholders often falls on the shoulders of physician-scientists who already are over-committed.*
- *Several of those involved in CTSA programs reported the reduced CTSA grant levels available today are not adequate to maintain the infrastructure they built with earlier CTSA grants and expressed concerns about obtaining the funds needed to sustain their programs.*

Recommendation:

- ❖ ***Successful models for supporting broadly engaged team research have included infrastructure such as centralized hubs containing trained “facilitators” that coordinate input of various experts, and help build trust and provide training for patients, partners and other stakeholders. Establishing such an infrastructure and maintaining it can be relatively costly. While disease specific patient groups, industry and PCORI frequently provide these resources in-house or fund them externally, recovering the cost of these activities from some NIH grant mechanisms is more difficult. This is a potential area of advocacy for CR Forum.***

2. AHC Policies and Processes

Career Tracks and Promotion Policies: Much has been written about the misalignment of incentives between career advancement and participation in team science. In response to this issue, many AHCs have added new career tracks and/or revised promotion criteria for existing career tracks. However, the senior faculty implementing the revised promotion criteria can be slow to recognize the need to change, suggesting it is a cultural issue as well as a policy issue. It is unclear if the AHCs that revised their career tracks and/or promotion criteria to better align with the rise in team science have been successful in providing the appropriate incentives to attract and retain the needed staff.

- *One interviewee estimated that only about 15% of AHCs have promotion and tenure language relating to team science, although this may be underestimated, and more information needs to be collected about the revised policies at AHCs. Nonetheless, the consensus view of those interviewed was more efforts are needed to ensure that those contributing to scientific teams are recognized and have rewarding career tracks.*

A critical issue is that evaluating a team member’s contributions and their overall productivity can be challenging.¹⁴ In many cases, the prevalent standard for judging an individual’s research productivity

¹² Smith, S.K., Patient Engagement Practices in Clinical Research Among Patient Groups, Industry and Academia in the U.S: A survey, PLOS, DOI:10.1371/journal/pone.0140232, October 2015.

¹³ <https://vict.vanderbilt.edu/pub/resources/upload/files/CES%20Toolkit.pdf>

¹⁴ Mazunde, et al., Evaluating Academic Scientists Collaborating in Team-Based Research: A Proposed Framework, Academic Medicine, 90:10, October 2015.

based on their first and last author placement on papers is no longer valid. Likewise researchers may be penalized for not being a PI on NIH grants, despite being essential members of well-funded interdisciplinary research teams.

In that context, the Multi-Regional Clinical Trial Center at Brigham and Women's Hospital and Harvard (MRCT) has begun to address the issue of giving credit for the contributions of team scientists. Working with the New England Journal of Medicine and the Association of American Medical Colleges, MRCT has begun to establish guidelines and criteria for crediting researchers for their work in generating, curating and making datasets available, and for acknowledging the work of authors in publications.¹⁵

Participation in broadly engaged team science adds another layer of complexity to evaluation because it requires time to communicate and build trust in a broad team. Thus members of large team science projects may require more protected time or support for longer time frames and they may have fewer results in the short term than solo researchers. All of these issues need to be taken into account by AHC promotion committees.

- *One interviewee emphasized that while the issues around tenure and team science had been discussed and written about by many, they are not easily resolved and simply waiting for AHCs to change organically is inadequate. Thus, CR Forum should consider how they might take a leadership role in bringing about change.*

Data Sharing and Intellectual Property Policies: A growing number of government agencies, funding organizations, and publishers are endorsing the call for increased data sharing, many with the ultimate goal of open data in the place of managed access mechanisms, which typically have terms of use and in some cases oversight by the data generators themselves. Patients groups such as the Cystic Fibrosis Foundation and the Multiple Myeloma Research Foundation have funded milestone-driven research networks for several decades that require data sharing, and have helped break down these barriers. Despite the fact that NIH and PCORI now have policies mandating and/or encouraging data sharing,¹⁶ barriers to open access to data still remain and the RO1 culture where data collected by an investigator belong to that investigator is still prevalent at AHCs. Additional efforts are needed to facilitate sharing de-identified patient data between and among stakeholders, AHCs and health systems. A noteworthy project launched by academia that can serve as a model of data sharing is the Metastatic Breast Cancer Project (described in Section IV), which has created a fully accessible open database of de-identified genomic, clinical and self-reported data from metastatic breast cancer patients.

- *Several of those interviewed felt access to data across networks is often limited, even in cases where participants within a network are mandated to share data internally. NIH's All of Us program and the open access platform and ecosystem it is creating was identified as an important activity with the potential of influencing how researchers access and share clinical information.*

¹⁵ Bierer, B.E., Crosas, M, Pierce, H.H., Data Authorship as an Incentive to Data Sharing, New England Journal of Medicine, 376; 17, April 2017.

¹⁶ https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html and <https://www.pcori.org/get-involved/provide-input/data-access-and-data-sharing-policy-public-comment>

Policies for data sharing, open access, and intellectual property often differ at different AHCs, health systems and other institutions. This can present a serious barrier to broadly engaged team science, which often requires access to patient data from large cohorts. Negotiating open access to data and harmonizing legal agreements across all the stakeholder institutions in complex multi-site studies can be costly unless institutions have quick acting, informed staff and flexible policies.

Recognizing this has been a barrier, FasterCures, the Clinical Trials Transformation Institute (CTTI), MRCT, and other organizations have posted examples of templates and other materials to facilitate the process of finalizing legal agreements needed to support team science and increase transparency and data sharing.¹⁷ All these issues, which should be negotiated with team members, their institutions and stakeholders during early phases of a project, have the potential for causing serious delays.

Inflexible, Slow Bureaucracies: Like many large, complex organizations, AHCs can have cumbersome, entrenched business processes and administrators who resist policy modifications that they view as unproven or too risky. For example, the use of central IRBs for multisite clinical studies has been promoted for many years as a way to help accelerate clinical research studies, but their use was resisted by many AHCs and it took considerable efforts from patient organizations and other groups to overcome their resistance.¹⁸ Several interviewees noted that internal bureaucratic process, which might seem minor, can lead to serious delays or even permanent roadblocks.

- *One interviewee observed that the allowable level of patient stipends at her AHC was not aligned with the meaningful participation of patients in broadly engaged teams. This self-imposed AHC rule along with the cumbersome paperwork required of patients if their stipends were increased presented a significant barrier to recruiting patient stakeholders at the respondent's institution.*

In addition, many AHCs are now part of large health systems that are continuing to expand in an increasingly challenging health care environment. Moreover, other health systems not affiliated with medical schools are starting their own schools. Integrating and streamlining these complex organizations to ensure they are “learning health systems,” able to deliver high quality care efficiently, will require flexible business processes and administrators who support broadly engaged team science projects that improve health services and enable their organizations to quickly adopt new therapeutic approaches.

Recommendations:

- ❖ ***Institutions need to carefully review their policies to determine if and how they can adjust them to reduce barriers to attracting and retaining scientists working on broadly engaged science teams, as well as to meaningfully engage patients and other stakeholders.***

¹⁷ FasterCures Toolkit; <http://train.fastercures.org/toolkits/>

¹⁸ New NIH guidelines require that for applications with due dates on or after January 25, 2018 all sites participating in multi-site studies, which involved non-exempt human subject research funded by the NIH, will use a single Institutional Review Board to conduct the ethical review requires for the protection of human subjects.

- ❖ ***If new career tracks and revised promotion criteria have been adopted, AHCs need to assess their impact on members of research teams and disseminate that information to the broader AHC community. CR Forum could work with other professional organizations to ensure that this information is collected and shared.***

3. People

Broadly engaged team research requires a diverse workforce with a range of expertise and training. Establishing and maintaining an adequate workforce requires providing: (a) training for clinical investigators and other staff on leading complex teams and engaging stakeholders; (b) ensuring that they have protected time to engage in these activities and access to needed experts (IT specialists, ethicists, statisticians, social workers, regulatory experts, etc.); and, (c) career paths that value and retain members of the teams. The culture of AHCs and the diversity of broadly engaged teams also can pose barriers and special efforts may be needed to ensure that team members share a common vocabulary and work together effectively. Identifying and engaging patients and/or their families as part of teams requires staff with time and the ability to build bridges in the patient community and to provide the training to optimize their contributions to research teams.

PCORI and other organizations have provided numerous examples of ways to engage such outside stakeholders. A number of training modules are available on the web. These include PCORI tools, the Team Science Toolkit of the NCI, COALESCE (CTSA Online Assistance for Leveraging the Science of Collaborative Efforts), a CTSA supported project of Northwestern University.¹⁹ Patient advocacy groups, particularly rare disease patient groups, have been instrumental in helping to identify and train patients to participate as engaged stakeholders in research teams.

Recommendation:

- ❖ ***AHCs need to ensure that the leaders and other members of broadly engaged teams, including all stakeholders, receive appropriate training and that the AHC staff participating in these teams has sufficient protected time to engage in this training and carry out their work.***

4. Funding

As already noted, broadly engaged team science often requires more time and staff, making it more costly. Patient-driven organizations that raise their own research funds to support their research agenda have long embraced the broadly engaged team research model. A significant number of patient groups have excelled at providing the “glue” (funds, staff, and set requirements) that effectively bind different sectors together in broadly engaged team science collaborations. Independent and family foundations also have supported this type of engagement for some of their programs. In contrast, the added expenses incurred by AHCs conducting broadly engaged team science have been harder to recoup from government grants. With the exception of programs like PCORI, the NIH CTSA program and

¹⁹ PCORI.org; www.teamsciencetoolkit.cancer.gov/Public/Home.aspx; www.nucats.northwestern.edu/resources/team-science-resources.html

clinical trial networks, most other federal grant mechanisms are not structured to provide the needed resources to engage patients and other stakeholders. In contrast, PCORI not only provides funds for these types of activities, but it requires grant proposals to explicitly address stakeholder membership and planning in investigator teams and provides guidance and examples to assist the investigators.

- *Several CR Forum members remarked that other government funding agencies should adopt the PCORI requirements for stakeholder engagement for the translational and clinical research, but those agencies also will need to fund the additional staff required to support broadly engaged research teams.*
- *Two interviewees noted that the for-profit sector has recognized the value of patient engagement and many companies are now moving quickly to invest in the needed infrastructure to include patients at all stages of drug development.*

Today, about sixty percent of AHCs' academic budgets are generated from patient care.²⁰ Moreover, as more AHCs morph into or are being integrated into large learning health systems, the funding model is likely to continue to shift as health systems, competing in the healthcare marketplace, are more willing to invest additional resources into patient engagement and staff development activities, which support broadly engage team science that improves the quality of their care. The pharmaceutical industry also has recognized the need to engage patients “early and often” and, thus, they might be potential partners in training and other activities designed to enhance patient engagement.

Recommendations:

- ❖ ***Stable funding is needed to support the staff and infrastructure to conduct broadly engage team science and to evaluate its impact or return on investment.***
- ❖ ***AHCs should explore the potential role of their affiliated health systems in helping to support the needed infrastructure for engaging patients and other stakeholders, particularly for health services and outcomes research.***

SECTION IV. EXAMPLES OF BROADLY ENGAGED TEAM SCIENCE

1. Measuring Success

Despite the growing consensus that broadly engaged team science is valuable, most information supporting its value is anecdotal. Many prominent examples of successful broadly engaged team science efforts have been led by disease-specific patient groups such as the Cystic Fibrosis Foundation, the Multiple Myeloma Research Foundation, and Parent Project Muscular Dystrophy. These organizations have worked for decades with their patient communities and scientific advisors to set their research goals, identify expert researchers to participate in studies they fund, specify the parameters for data sharing and IP, recruit patients in studies, and provide the critical funds to support much of the early

²⁰ Revenue of U.S. Medical Schools by Source, Fiscal Year 2016; <https://www.aamc.org/data/finance/480314/figures1-2.html>

stage proof-of-concept research that helps attract industry partners. More recently, PCORI has supported numerous grants that require stakeholder involvement and these too should yield a number of useful examples that can be used by AHCs in their own efforts.

- *Rob Califf, a member of the CR Forum committee advising this project, has observed that when specific disease communities use this “team ecosystem,” research progress often moves faster than for diseases that do not engage in this model.*

The assumptions are that when specific disease communities and others engage in this sort of team ecosystem progress improves because research design and implementation are responsive to patients’ and stakeholders’ needs, more patients will agree to be research participants, and research results are more likely to be translated into actionable improvements in patient care.²¹ Importantly, it also serves democratic ideals of accountability and transparency.

While the examples presented in the next section support these assumptions, they do not provide concrete measurements of the value (return on investment) of broadly engaged team science compared to other research models. Additional work is needed to clarify when and how to implement broadly engaged team science, and approaches to measure its success and its value or return on investment.²² In that context, a recent publication by Barry Levitan and his colleagues describes the use of a risk adjusted financial model to estimate the expected net present value (NVP) of patient engagement.²³ Using this model, the authors estimated the NVP for an oncology development program entering Phase 2 trials, (assuming the cumulative impact of patient engagement resulted in one less protocol amendment and improvements in enrollment, adherence and retention) would be an increase in NPV of \$62 million.

2. Noteworthy Examples of Broadly Engaged Team Science

As noted, the value proposition for broadly engaged team science still needs more evidence as well as guidance on the best methods to employ. Furthermore, broadly engaged team science projects vary considerably in the type of research questions being addressed and how stakeholders are engaged. The following examples include a project initiated by a disease-focused patient group, a project launched by two academic institutions, and several activities supported by PCORI. The examples were chosen merely to stimulate dialogue on the applicability of the term “broadly engaged team science” and the diversity of projects that have benefited from engagement of patients and other stakeholders.

Parent Project Muscular Dystrophy’s Project Quantifying Caregiver Preferences for the Benefits and Risks of Emerging Therapies (PPMD; parentprojectmd.org). PPMD’s mission is to end Duchenne’s

²¹ Laura Esmail, Emily Moore and Alison Rein. Evaluating Patient and Stakeholder Engagement in Research: Moving from Theory to Practice. J Comp Eff Res (2015) 4(2); 133-145.

²² Juan Pablo Domecq, et.al., Patient engagement in research: a systemic review, BMC Health Services Research, 2014;14:89

²³ Levitan, B, et. Al., Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI’s Patient Groups and Clinical Trials Project, Therapeutic Innovation & Regulatory Science, 1-10, 2017: DOI:101177/2168479017716715.

Muscular Dystrophy. Its board, made up of families and friends of Duchenne patients, oversees a variety of activities including advocating for and directly supporting research to develop drugs to treat Duchenne's Muscular Dystrophy. In that context, PPMD funded and led a quantitative preference study surveying caregivers on their preferences regarding potential benefits and risks of emerging therapies for Duchenne's Muscular Dystrophy.²⁴ An advocacy oversight team worked with caregivers, drug developers from industry and clinicians to identify the various benefits and risks of the emerging therapies to include in the survey instrument using a best worst scaling model. The survey results showed caregivers scored stopping or slowing the progression of muscle weakness more highly than changes in life span, supporting the view that parents of affected children valued the quality of their children's lives more than extending their lives. PPMD reported the outcome of this study to the FDA and it led to the first patient advocacy-initiated draft guidance for a rare disease, which was issued by the U.S. FDA in 2015.

WISDOM Study (PCORI.org). Led by Dr. Laura Esserman at UCSF, WISDOM is a pragmatic, adaptive, randomized multicenter clinical trial that began in 2016. It is part of the PCORI funded Pragmatic Clinical Studies initiative. WISDOM is designed to compare risk-based screening to annual screening in 100,000 women age 40 to 74. The project is a product of an extensive multi-year stakeholder engagement process that brought together consumers, advocates, primary care physicians, specialists, policy makers, technology companies and payers to help resolve the long debated issue of how and when to screen women for breast cancer. The trial's primary endpoint is to determine whether risk-based screening is non-inferior to annual screening for how many late-stage cancers are detected. In addition, the morbidity of risk-based versus annual screening will also be assessed in terms of biopsies performed. A noteworthy aspect of WISDOM is that health insurers were engaged early and that after extensive negotiations all the insurers in California agreed to cover the cost of the trial-related genetic tests for their members.²⁵

Metastatic Breast Cancer Project (MBCP; mbcproject.org). MBCP was launched by the Broad Institute and Harvard in collaboration with the Dana Farber Cancer Institute and was initially funded by a philanthropic gift to the Broad Institute. Nikhil Wagle, M.D., a breast cancer oncologist and researcher at the Dana Farber Cancer Center leads the project along with Corrie Painter, Ph.D., a cancer researcher, cancer patient, and patient advocate. The project partners researchers directly with patients to collect tumor samples and clinical data in the U.S. and Canada to create a database of genomic data, clinical data and patient reported information on women with metastatic breast cancer. Importantly all the pre-publication data (in de-identified format) entered into the MBCP database is fully accessible to the research community as well as to patients with no restrictions. Patients have been involved since the early planning of the project. Currently, MBCP's partner organizations also include many of the breast

²⁴ Holly L. Pealy, et al., 2014, [A Community-Engaged Approach to Quantifying Caregiver Preferences for the Benefits and Risks of Emerging Therapies for Duchenne Muscular Dystrophy](http://dx.doi.org/10.1016/j.clinthera), *Clinical Therapeutics*, 36,5. <http://dx.doi.org/10.1016/j.clinthera>. 2014.04.011

²⁵ Laura Esserman, the WISDOM Study and Athena Investigators, [The WISDOM Study: breaking the deadlock in breast cancer screening debate](https://doi.org/10.1038/s41523-017-0035-5), *Nature*, 2017;_doi:10.1038/s41523-017-0035-5

cancer patient organizations such as the Breast Cancer Research Foundation, the Triple Negative Breast Cancer Foundation, and the Inflammatory Breast Cancer Network Foundation.

Improve Care Now: Involving Patients in Research on Inflammatory Bowel Disease (ICN;

www.improvecarenow.org). ICN is one of 29 PCORI funded health networks in PCORnet (the National Patient-Centered Clinical Research Network) whose mission is to transform the health care, and costs for children and adolescents with inflammatory bowel disease (IBD) - Crohn's disease and ulcerative colitis. Led by Peter Margolis, MD, PhD, Professor of Pediatrics and Director of Research at the Center for Health System Excellence at Cincinnati Children's Hospital Medical Center, ICN is a scalable and sustainable peer-production Learning Health System²⁶ that not only provides children with IBD outstanding health care, but also serves as a platform for conducting health outcomes research. More than 70 pediatric gastroenterology care centers in the U.S. and the United Kingdom participate in ICN, which serves 45% of all US children with inflammatory bowel disease. Remarkably, since ICN's establishment in 2007, the proportion of patients in remission (with inactive disease) increased from 55 percent to 77 percent, primarily through greater standardization procedures making care more proactive and reliable.

The Research Action for Health Network (REACHnet: reachnet.org). REACHnet is one of 13 Clinical Data Research Networks based in health care systems that have been established by PCORI. Funded in 2014, REACHnet is a partnership between the Louisiana Public Health Institute, Ochsner Health System, Partnership for Achieving Total Health (PATH), Louisiana State University, Pennington Biomedical Research Center, Tulane University and Baylor Scott & White Health. It has established a health information technology platform, which provides access to longitudinal clinical data on more than 3 million patients across Louisiana and Texas, engages patients and providers in patient centered research, and fosters multi-stakeholder group collaborations to drive research agendas, develop projects and conduct collaborative comparative effectiveness research. REACHnet's PI is Rebekah Angove, PhD. REACHnet's platform has supported a continually expanding list of research projects including studies on diabetes, weight management, and care for patients with chronic obstructive pulmonary disease and heart failure.

As is the case for other PCORI funded activities, patient engagement is an integral part of REACHnet. An example of a study that benefited from patient engagement is a REACHnet obesity research study in which patient partners informed researchers that study participants became anxious when they were weighed and that blood pressures should be measured before patients were weighed, rather than after. This small, simple change improved the quality of the data and the validity of the study results.

Lung-MAP (lung-map.org). Lung-MAP is a biomarker-driven, squamous cell lung cancer clinical trial that uses state-of-the-art genomic profiling to match patients to sub-studies testing investigational treatments that may target the genomic alterations, or mutations, found to drive growth of their cancer. This adaptive clinical trial is a public-private collaboration involving stakeholders and funders including the National Cancer Institute (NCI), NCI's National Clinical Trials Network, SWOG Cancer Research,

²⁶ <https://www.pcori.org/research-results/2013/improvecarenow-learning-health-system-children-crohns-disease-and-ulcerative>

Friends of Cancer Research, the Foundation for the National Institutes of Health, several pharmaceutical companies (Amgen, Bristol-Myers Squibb, Genentech, Pfizer, AstraZeneca, and AstraZeneca's global biologics R&D arm, MedImmune), Foundation Medicine and several lung cancer advocacy organizations. Instead of patients having to undergo multiple diagnostic tests to determine eligibility for many different studies, enrollees will be tested just once according to a "master protocol" and assigned to one of multiple trial sub-studies, each testing a different drug from a different developer. The approach should improve access for patients to promising drugs, improve access for researchers to relevant enrollees based on their genomic profiles, and reduce the cost and time needed to develop new therapeutics.

PROSPER Study for Stroke Survivors and Their Families (PCORI.org). The PROSPER (Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research) is a PCORI funded project, which supports multiple research studies designed to help patients, doctors, and other healthcare professionals make informed decisions about how to treat patients after a stroke. PROSPER stakeholders include clinicians, health systems, the American Heart Association and the American Stroke Association and most importantly patients. For example, in a study of the use of anticoagulants post stroke, a query of patients with a mean of age of 80 about the most important outcome to them was not survival time but the days they spent in a hospital. This outcome was not originally identified as critical to monitor, but an analysis of the data to address the patients' primary concern demonstrated that anticoagulants not only improved clinical outcomes but also resulted in 47 fewer days in hospital.²⁷ Adrian Hernandez, M.D., M.H.S, Associate Director of the Duke Clinical Research Institute, is the principle investigator.

The Learn About My Pain Study (LAMP)

(<http://journals.sagepub.com/doi/abs/10.1177/1359105315570985>). This PCORI-funded randomized clinical trial, which targeted hard to reach low income patients, evaluated the efficacy of literacy-adapted and simplified cognitive behavioral therapy versus usual care in managing chronic pain. The social and educational vulnerabilities of the study participants shaped the development and delivery of both bio and psychosocial interventions. Participants who did not read at the fifth grade level or higher received oral assistance in understanding the intervention materials and completing surveys. As described in an *Annals of Internal Medicine* paper, members of the cognitive behavioral and education groups had larger decreases in pain intensity scores and improved physical function between baseline and post-treatment than participants receiving usual care.²⁸ An accompanying editorial by Robert Kerns noted that an engaged health care organization and staff, small financial incentives for patient travel and a patient-centered approach to service delivery can lower barriers to participating in research.²⁹ Mary Janevic is the lead author of the study.

²⁷ Ying Xian, et.al. Real World Effectiveness of Warfarin Among Ischemic Stroke Patients with Atrial Fibrillation: Observational Analysis from Patient-centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER) Study. *BMJ*, 2015; 350:h3786|doi:10.1136/bmj.h3786.indd

²⁸ Beverly E Thorn, et.al., Literacy-Adopted Cognitive Behavioral Therapy Versus Education for Chronic Pain at Low-Income Clinics. *Ann Intern Med*. Doc: 107326/M17-0972

²⁹ Robert D. Kerns. Shining a LAMP on Efforts to Transform Pain Care in America. *Ann Intern Med*. Doi:10.7326/M18-0061

SECTION V. CONCLUSIONS

CR Forum represents leading research AHCs and serves its member organizations through convening and advocacy functions. While AHCs have been key research engines since the middle of the twentieth century, the advent of big data, crowd sourcing, engaged patient communities, interdisciplinary team science, and global connectivity is altering the way research is conducted at these institutions. Moreover, AHCs are often associated with health systems, which now are part of a rapid restructuring of US healthcare into fewer, larger “learning health systems” competing to provide the best quality care to patients. These changes impact both the research questions being asked and the way research is being conducted.

Two trends have been the growth in team science and increased support for the meaningful engagement of patients and other stakeholders in translational and clinical research projects. We refer to the research model that encompassed both these trends as “broadly engaged team science.” Despite increasing support for this research model, significant barriers to implementing broadly engaged team science exist at AHCs and more work is needed to lower those barriers and to examine the value proposition of when and how to implement this research model.

To summarize, the following observations were gleaned from interviews and publications:

- Whenever possible, clinical and translational research should engage patients and other stakeholders in meaningful ways. Nonetheless, because engaging stakeholders in broadly engaged team science adds complexity, time and cost, its application and implementation should be guided by its value to a given endeavor.
- The lack of a stable source of adequate funding for the infrastructure required to support broadly engaged team research at AHCs was identified by the AHC researchers interviewed as a major barrier. For example, without dedicated staff to identify and train patient stakeholders, already overcommitted physician-scientists often shoulder the burden of engaging patient stakeholders in their research.
- Health services research, clinical trials, and quality improvement activities provide examples of areas where broadly engaged team science has clear value. As health systems expand and compete in a challenging healthcare market, this type of research will be increasingly important. Health systems and their affiliated AHCs should collaborate to better support the infrastructure and staff required to engage patients in health services research.
- AHCs policies on reimbursement of stakeholders, data sharing and transparency, etc. must continue to evolve to facilitate instead of hamper broadly engaged team science.
- Promotion and tenure policies for AHC faculty, while evolving at some institutions to recognize team science contributions, remain major barriers to broadly engaged team science. Additional analysis of AHC promotion policies is needed to determine how they affect the advancement of faculty members participating in broadly engaged team science.
- PCORI funding has been key to transforming the research community to embrace the concept that the engagement of patients and other stakeholders is beneficial and a worthwhile goal for most

studies. However, cultural barriers still need to be overcome. Overcoming these barriers and building trust among stakeholders takes time.

- Many best practice examples of broadly engaged team science are not currently driven by AHCs, but by patient groups, foundations, industry, funding agencies such as PCORI, and to a smaller degree the NIH CTSA program.
- The recent FDA guidance on patient focused drug development is a major step in ensuring that the patients' voice is heard. It is resulting in increased commitments by the pharmaceutical industry to engage patients at all stages of its work, from identifying relevant outcome measures, to designing patient friendly trials and marketing products.
- The challenge now is to decrease the barriers to conducting broadly engaged team science in academia and to promote this research model at AHCs.

CR Forum could undertake six possible activities to foster broadly engaged team science at AHCs. These suggestions are meant to be starting points for discussions among the CR Forum leadership, and were developed recognizing CR Forum's organizational capacity. The first four suggestions either fit within ongoing CR Forum activities or build on an existing activity. In contrast, suggestions five and six represent new directions for the CRF Forum.

1. Advocate for the funds, particularly for PCORI, as well as policy changes needed to better support broadly engaged team science at AHCs.
2. Identify successful broadly engaged team science projects and highlight them at meetings and workshops to identify the best practices and build its value proposition.
3. Endorse and advocate for the implementation of the recommendations, tools and guidelines relating to patient engagement, stakeholder identification, and other issues impacting broadly engaged team science that have been developed by PCORI and others.
4. Each year, recognize an outstanding broadly engaged team science project that has engaged patients and changed clinical practice and/or added special value to the clinical enterprise.
5. Work with the American Association of Medical Colleges and other organizations to examine how AHC promotion and tenure policies deter or reward faculty participating in broadly engaged team science.
6. Host a meeting with representatives of large health systems to explore how health systems might partner with AHCs to support and improve the infrastructure and training needed to engage patient stakeholders and advance broadly engaged team science projects integral to learning health systems.

APPENDIX I: EXPERT INTERVIEWS

Elaine Gallin and Queta Bond conducted phone interviews with the following individuals as part of the consultation on this paper.

Team Lead and Project Director: Harry Selker, MD, MSPH, Executive Director, Institute for Clinical Research and Health Policy Studies; Dean, Clinical and Translational Science Institute; Professor of Medicine, Tufts University Medical School; Chair, Clinical Research Forum

Interviews

1. Lars Berglund, MD, PhD, Interim Dean of the School of Medicine, Associate Vice Chancellor for Biomedicine, University of California Davis
2. Rob Califf, MD, Vice Chancellor for Health Data and Science at Duke Health; Director of Integrated Health Data Science; Senior Manager at Verily Life Science
3. Maria Carrillo, PhD, Chief Science Officer, Alzheimer's Association
4. Barry S. Collier, MD, Physician-in-Chief of The Rockefeller University Hospital; VP of Medical Affairs and Director for Clinical and Translational Science, The Rockefeller University
5. Pamela Davis, MD, PhD, Dean of The School of Medicine, Case Western Reserve University
6. Maryrose Franko, PhD, Executive Director, Health Research Alliance
7. Cynthia Grossman, Associate Director, Science of Patient Input, Faster Cures
8. Steve Heinig, Director Science Policy, AAMC
9. Sharon E. Hesterlee, PhD, Research Project Lead Gene Therapy, Bamboo Therapeutics, a subsidiary of Pfizer, Inc.
10. Marc Hurlbert, PhD, Chief Mission Officer, Breast Cancer Research Foundation
11. Rebecca Jackson, MD, Associate Dean For Clinical Research, Director of Center for Clinical And Translational Research, The Ohio State University Medical College
12. Alex Ommaya, DSc, Senior Director, Clinical And Translational Research and Policy, AAMC
13. Bray Patrick-Lake, MFS, Director of Stakeholder Engagement, Duke Clinical Research Institute, Duke University
14. Phillip Rak, MBA, Project Manager- NUCATS, Northwestern Feinberg School of Medicine
15. Amy Comstock Rick, JD, President and CEO, Food and Drug Law Institute
16. Joe Selby, MD, MPH, Executive Director, Patient Centered Outcomes Research Institute
17. Lana Skirboll, PhD, Vice President, Academic and Scientific Affairs, SANOFI US
18. Thomas O. Staiger, MD, Medical Director, University of Washington Medical Center, Seattle
19. Brian Strom, MD, MPH, Inaugural Chancellor of Rutgers Biomedical and Health Sciences, and Executive VP for Health Affairs, Rutgers University
20. Sharon Terry, MA, President and CEO, Genetic Alliance
21. Nikhil Wagle, MD, Assistant Professor in Medicine, Harvard Medical School; Deputy Director, Center for Cancer Precision Medicine, Dana Farber Cancer Institute; Associate Member, Broad Institute
22. A. Eugene Washington, MD, MSc., Chancellor for Health Affairs, Duke University

APPENDIX II: HELPFUL RESOURCES

The following are selected web-based resources that provide useful information, guidelines and tools for those planning and participating in translational and clinical broadly engaged team science projects.

PATIENT CENTERED OUTCOMES RESEARCH INSTITUTE: PCORI

As noted on their website (<https://www.pcori.org/about-us>), “PCORI was established to fund research that can help patients and those who care for them make better-informed decisions about the healthcare choices they face very day, guided by those who will use that information. “

The PCORi website is an excellent resource for those interested in conducting broadly engaged science, which is defined as “meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders (includes patients, clinicians, researchers, purchasers, payers industry, hospitals, policy makers and training institutions) throughout the research process—from topic selection through design and conduct of research to dissemination of results.” The PCORI website provides methodology standards, an engagement rubric, sample engagement plans, a chart identifying the different stakeholders with examples, and a framework for compensating patient partners to help those applying for PCORI awards. Importantly, the sample engagement plans provide *real life applications* of broadly engaged stakeholder participation in research.

There are “engagement” blogs where PCORI staff and guest authors share thoughts about PCORI’S engagement initiatives and about engagement in research. Literature on engagement can also be found at <https://www.pcori.org/literature/engagement-literature>.

CME credit can be earned for the course “Engaging patients and other stakeholders: guidance from the PCORI engagement rubric” at <https://www.pcori.org/research-results/putting-evidence-work/cmece-activities#content-2006>.

THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD PROGRAM

The CTSA Program (www.ncats.nih.gov), established in 2006, has funded a national consortium of research institutions that work together to strengthen translational and clinical research. Currently overseen by NIH’s National Center for Advancing Translational Science (NCATS), the program is designed to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public. The program goals are to:

- Train and cultivate the translational science workforce;
- Engage patients and communities in every phase of the translational process;
- Promote the integration of special and underserved populations;
- Innovate processes to increase the quality and efficiency of translational research, particularly of multisite trials; and
- Advance cutting edge informatics.

To coordinate and provide resources to facilitate the work of the consortium of CTSA grantees, NCATS established a coordinating center - the Center for Leading Innovation and Collaboration (CLIC) <http://clic-ctsa.org>. Hosted at the University of Rochester, [the CLIC](#) facilitates inter-site communications enabling the development of collaborations and access to training materials, research tools, and data sets. Its website is a useful resource and includes an event site that connects CTSA to meetings such as the Translational Science Meeting and the Science of Team Science Annual Meeting. The Science of Team Science (SciTs) field is building the evidence base for how to conduct, manage, and support effective and efficient team-based research and ultimately enhance the science it produces.

CLIC is developing useful tools including a common metrics program to assess clinical and translational science research workforce development and to measure excellence in clinical and translational science research. CLIC also has curated a list of tools and resources covering education, best practices, and job and sabbatical opportunities, communicating research findings, and model research agreements to speed the process of establishing research collaborations. Other activities help researchers find collaborators and develop a common informatics ecosystem. The CTSA program stipulates that “research institutions must collaborate with community organizations to identify and understand public health needs” and the report, *Principles of Community Engagement*, provides a comprehensive guide to the core principles for engaging diverse communities in clinical research activities.

NATIONAL CANCER INSTITUTE TEAM SCIENCE TOOLKIT: SCIENCE OF TEAM SCIENCE (SciTs)

The Team Science Toolkit (<http://cancercontrol.cancer.gov/brp/SciTS>) is a user-generated collection of information and resources that support the practice and study of team science. The toolkit connects professionals from many disciplines, providing a forum for sharing knowledge and tools to maximize the efficiency and effectiveness of team science initiatives. The toolkit was developed and is maintained by the Science of Team Science Team at the National Cancer Institute, Division of Cancer Control and Populations Science, Behavioral Research Program.

This website identifies team science as a “collaborative effort to address a scientific challenge that leverages the strengths and expertise of professionals trained in different fields,” provides a list of key publications and links to other activities, and identifies factors that influence the conduct of team science. These include the following.

- Funding Trends
- Institutional infrastructure and resources for communication and data sharing

- Organizational policies—such as promotion and tenure policies—that impact team-based endeavors
- Team processes, including the existence of agreements related to proprietary rights to data and discovery, as well as mechanisms for feedback and reflection
- Interpersonal dynamics among team members
- Team members’ collaborative skills and experiences

A variety of resources are provided such as model agreements to support new collaborations, syllabi and training materials, information about communications and data management systems to support collaboration, and ways to find and connect with collaborators and other resources. There are also measures and methods for evaluating team science outcomes. There are tips on ways to use the toolkit and communication materials that describe the Toolkit and how to use it.

FASTERCURES

FasterCures (Fastercures.org), a non-profit Center of the Milliken Institute, has a mission to “save lives by speeding up and improving the medical research system.” Useful publications downloadable from their website include *Principals for Responsible Negotiation, Key Research Agreement Terms and Definitions*, and *University-foundation Relations: From Transactional to Transformative Partnerships*. Their initiative *Patients Count* aims to advance the science of patient input by hosting workshops of key opinion leaders and creating one-stop shop of resources for stakeholders across the R&D ecosystem. The following two initiatives provide useful information for those interested in establishing new collaborations and networks:

- **Consortia-pedia** is a searchable catalogue of nearly 500 cross-sector consortia in R&D that analyzes how consortia have brought together partners with a shared R&D goal. Based on this analysis, a framework report presents a series of questions for those seeking to create new collaborative efforts, expand existing ones, or re-orient early-stage programs. In addition, an article, *Consortium Sandbox: Building and Sharing Results* by Mark D. Lim (*Science Translational Medicine*, 26 June 2014, Vol 6, Issue 242, pp242cm6) surveys the landscape of 369 consortia.
- *The Research Acceleration and Innovation Network (TRAIN)* is a venue for foundations that fund research to share best practices. The has a variety of tools to facilitate patient foundation/university partnerships including model agreements, templates for annual reports, and consortium master technology transfer agreements are provided at <http://train.fastercures.org/toolkits/foundation-university-partnerships/>. A recent report *Cornerstones of Collaboration: Foundation-led Partnerships to Accelerate R&D*, examines different types of relationships and agreement structures, how agreements originate and what is necessary to sustain them, and how partners are addressing legal and cultural challenges that can divide them. The report is written as a guide for foundation leaders rather than academic health leaders focusing on the challenges that disease-oriented foundations have faced in starting research consortia.

CLINICAL TRIALS TRANSFORMATION INITIATIVE

CTTI's (Ctti-clinicaltrials.org) mission is to develop and drive adoption of practice that will increase the quality and efficiency of clinical trials. Comprised of over 80 member organizations from across the clinical trial enterprise, they work to impact clinical trials policy and practice, by convening stakeholders, issuing reports, making recommendations and developing implementation tools. CTTI's project Patient Groups & Clinical Trials released a useful report in October 2015 entitled, *Effective Engagement with Patient Groups Around Clinical Trials*. The report provides specific recommendations for all the stakeholders, describes patient engagement across the spectrum of research, and offers tools to assess patient engagement. A paper based on this report, *The Rules of Engagement: CTTI Recommendations for Successful Collaborations Between Sponsor and Patient Groups Around Clinical Trials*, by Bloom, D, et al., has been published in the journal, *Therapeutic Innovation and Regulatory Science* 1-8, 2017. Both of these items are posted on the CTTI website. Other useful reports and tools available on the CTTI website include: a tool to assist in decision-making when engaging stakeholders in study design, and a tool to assist in how to monitor recruitment process and performance as well as recommendations for informed consent. Most recently, CTTI has been engaged by the U.S. FDA to support its Patient Engagement Collaborative (PEC), which will be composed of a group of patient advocates that will advise the FDA about engaging patients in its regulatory decision-making process.

MULTI-REGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD (MRCT)

MRCT (mrctcenter.org) was founded in 2009 and engages expert stakeholders from industry, academia, advocacy groups, nonprofits and regulatory agencies to take on critical issues in the conduct and oversight of clinical trials. As a neutral convening organization they aim to identify regulatory, oversight, and ethics issues and facilitate solutions in clinical trials around the world, resolve regulatory and ethical issues to improve the clinical trial enterprise, foster respect for clinical trial participants; and promote regulatory convergence within multiple regions to accelerate innovation and improve health care around the world. MRCT's efforts on data transparency include recommendations on academic credit for data sharing, and harmonized governance for data sharing return of individual and aggregate results to clinical trial participants. MRCT's Ethical Framework activities include harmonizing terminology and educational materials on informed consent and the development of a Post-Trial Responsibilities Document and Toolkit.