



# Comparison of Intravesical Therapy and Surgery as Treatment Options for Bladder Cancer (CISTO) Study Engagement Plan



## 1. Background Information

**Principal Investigator:** John L. Gore, MD, MS; University of Washington  
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**Project Title:** Comparison of Intravesical Therapy and Surgery as Treatment Options for Bladder Cancer (CISTO)

**Contract ID Number:** PCS-2017C3-9380

**Groups Engaged** (check all that apply):

- Patients/Consumers
- Family Caregivers
- Patients/Caregivers/Advocacy Organizations
- Community-Based Organizations
- Clinicians
- Clinics/Hospitals/Health System Representatives
- Purchasers
- Payers
- Life Sciences Industries
- Policy Makers
- Training Institutions
- Subject Matter Experts
- Other, please specify:

**NOTE:** the CISTO Bladder Cancer Study Engagement Plan was submitted to PCORI in July 2019. This publicly available plan has been edited slightly from its original form to protect advisor privacy and private details of the ongoing CISTO Bladder Cancer Study. For questions or to request additional information about our engagement approach, visit our website at [CISTOStudy.org](http://CISTOStudy.org) or contact our team at [advisoryboards@uw.edu](mailto:advisoryboards@uw.edu).



## 2. Goals

The CISTO Bladder Cancer Study was developed as a result of long-term partnership with patients, family members, caregivers, and patient advocates through the Bladder Cancer Advocacy Network (BCAN). Funded by two Eugene Washington PCORI Engagement Awards (1089-BCAN, 6148-BCAN), engaged patients, family members, and caregivers contributed through the BCAN Patient Survey Network to the identification, refinement, and prioritization of patient-centered research questions. That engagement resulted in the research question that the CISTO Bladder Cancer Study seeks to answer – how do bladder removal and additional medical therapy compare among patients who have a recurrence of non-muscle invasive bladder cancer?

As we conduct the CISTO Bladder Cancer Study, continued meaningful engagement of patients, family members, caregivers, and patient advocates is vital, to ensure that we continue to focus on the outcomes that are important to patients and their families and caregivers. Additionally, as the CISTO Bladder Cancer Study launches recruitment and data collection efforts and looks ahead to dissemination and translation of results, our team is engaging an External Advisory Board composed of clinicians and other healthcare representatives, including payers, industry, and professional societies, including a representative from a guidelines committee. Engagement of these stakeholders will be key to ensuring that the results of the CISTO study are adopted by the urologic community.

Table 1 below outlines our broad goals for engagement in the CISTO Bladder Cancer Study, along with key activities that inform each goal.

Table 1. CISTO Bladder Cancer Study Engagement Goals		
Engagement Goal	Key Activities	Measurement
<p><b>1</b> Following our engagement practices in the study design phase, continue to incorporate stakeholder voices in all aspects of study conduct. Fully employ the patient and caregiver perspectives via the Advocate Advisory Board to maintain the study’s commitment to a patient-centered approach through all phases of research.</p>	<ul style="list-style-type: none"> <li>• Monthly Advocate Advisory Board meetings</li> <li>• Quarterly External Advisory Board meetings</li> <li>• Interim outreach between meetings to provide study updates and request feedback</li> <li>• Bi-annual combined Advocate Advisory Board and External Advisory Board meetings (i.e., Study Advisory Committee) to promote co-learning and relationship building</li> <li>• Dissemination of regular newsletters to ensure that all stakeholders are aware of</li> </ul>	<ul style="list-style-type: none"> <li>• Description of feedback from stakeholder advisors and how that information has informed various facets of the research study</li> <li>• Results of formal evaluation process (numeric scores, narrative comments) relating to engagement methods, tactics, and outreach.</li> </ul>

	<ul style="list-style-type: none"> <li>activities with opportunity to comment</li> <li>Conduct formal evaluation activities at key study points to assess engagement within the study and identify any areas for improvement and/or change</li> </ul>	
<p><b>2</b> Recruit and engage with a diverse range of stakeholders representing the community of patients, caregivers, and other stakeholders affected by and working in bladder cancer.</p>	<ul style="list-style-type: none"> <li>Continually assess Advisory Board membership to include a range of professional and personal backgrounds</li> <li>Work with BCAN leadership to ensure Advocate Advisory Board remains reflective of the enrolled study population</li> <li>Engage all study clinical site investigators through the CISTO newsletter and regular site-wide calls</li> <li>Continually assess clinician site leads and External Advisory Board members to ensure we are engaging with clinicians reflective of the population of providers who treat bladder cancer patients.</li> <li>Manage meeting discussions by calling on advisors in turn to share feedback, to ensure everyone is given an opportunity to speak and to foster a supportive format for sharing opinions and perspectives of all stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>Demographic characteristics of advisors (e.g., geographic location, health experience, professional experience/clinical specialties, degrees, stakeholder perspective, etc.)</li> <li>Results of formal evaluation process (numeric scores, narrative comments) with stakeholder advisors to assess engagement within the study and identify any areas for improvement and/or change</li> </ul>
<p><b>3</b> Optimize study recruitment and retention</p>	<ul style="list-style-type: none"> <li>Involve Study Advisory Committee members in development of patient-facing materials.</li> <li>Involve Study Advisory Committee members in troubleshooting recruitment and retention issues as they arise.</li> </ul>	<ul style="list-style-type: none"> <li>Description of Advisor input that resulted in changes to materials, approach, or retention activities.</li> <li>Case studies of specific recruitment or retention issues brought to advisors for</li> </ul>

	<ul style="list-style-type: none"> <li>Leverage ongoing communications avenues (e.g., newsletter, site-wide calls) to share best practices for supporting recruitment and retention with sites</li> </ul>	<p>troubleshooting and how advisor input was put into practice to resolve issues</p> <ul style="list-style-type: none"> <li>Description of recruitment and retention best practices shared with sites.</li> </ul>
<p><b>4</b> Identify innovative ways to disseminate study results to patients, caregivers, clinicians, and other stakeholders that are making treatment decisions relating to non-muscle invasive bladder cancer recurrence.</p>	<ul style="list-style-type: none"> <li>Share study results as they are available at Advocate and External Advisory Board meetings, to discuss key messages and potential venues for communicating.</li> <li>Involve stakeholder advisors in study results review meetings and dissemination planning meetings to identify key messages and avenues for communication.</li> <li>Open all publication writing groups to involve at least one advocate advisor and at least one other stakeholder advisor per group</li> </ul>	<ul style="list-style-type: none"> <li>List of key messages and venues identified by stakeholder advisors.</li> <li>Documentation of process and outcomes of dissemination along channels identified by stakeholder advisors.</li> <li>Publication list with stakeholder advisor authorship identified.</li> </ul>

Table 2 identifies engagement goals related to each stakeholder group involved in the project. The goals highlight the particular expertise embodied by each group, and the role that group plays in strengthening the project.

Table 2. Stakeholder Advisor Goals for Engagement		
Stakeholder Group	Group for Engagement	Goals
<p><b>Patients</b> <b>Caregivers</b> <b>Advocacy Organizations</b></p>	<p>Advocate Advisory Board</p>	<ul style="list-style-type: none"> <li>Keep patient experience at the forefront of the CISTO Bladder Cancer Study to ensure the research conducted is patient-centered</li> <li>Improve outcomes and experiences for future patients and caregivers</li> <li>Apply professional areas of expertise to assist the CISTO stakeholder engagement activities and improve the study as a whole</li> </ul>
<p><b>Advocacy Organizations</b> <b>Clinicians</b> <b>Healthcare Payer</b> <b>Life Science Industry</b></p>	<p>External Advisory Board</p>	<ul style="list-style-type: none"> <li>Improve outcomes and experiences for future patients and caregivers</li> <li>Optimize the CISTO Bladder Cancer Study design and execution to ensure the applicability of study results across</li> </ul>

**Professional Societies  
(including guidelines  
committees)**

stakeholder groups, including clinicians, payers, life sciences industry, and professional societies.

- Support the national outreach profile of the CISTO Bladder Cancer Study, to ensure that quality research results are made available to all necessary stakeholders
- Support dissemination and implementation of study results by providing relevant stakeholder perspective on approaches, materials, messages, and metrics for communication.
- Incorporate CISTO Bladder Cancer Study findings into future guidelines to guide clinical practice and healthcare delivery.

### 3. Engagement Structure

The overall governance of the CISTO Bladder Cancer Study falls under the purview of the Executive Committee, composed of CISTO Co-PIs John Gore and Angela Smith, along with directors and key staff of each of the three study Coordinating Centers – the Data, Clinical, and Stakeholder Coordinating Centers (Figure 1). Each of these Coordinating Centers owns a specific study area, overseeing operations in each area and reporting back up through the Executive Committee to coordinate operations across Centers.

Co-PI Angela Smith serves as the director of the Stakeholder Coordinating Center (SCC), which functions as the central hub for all engagement and stakeholder activities. The Stakeholder Coordinating Center’s primary goal is to ensure that stakeholder perspectives are solicited, heard, and implemented across the CISTO Bladder Cancer Study. To accomplish that goal, multiple members of the Executive Committee (bolded names in Figure 1 below) serve as members of the Stakeholder Coordinating Center (SCC), providing multiple avenues for sharing stakeholder perspectives with the Executive Committee and across the Data and Clinical Coordinating Centers, as well as the opportunity for Executive Committee decisions and activities within the Data and Clinical Coordinating Centers to be communicated back to members of the SCC for action. In addition, CISTO co-PI Angela Smith, Project Director Erika Wolff, and Senior Project Manager On Ho serve across all three Coordinating Centers and the Executive Committee, allowing for dissemination of information and decisions across all Coordinating Centers and committees. This ensures that the stakeholder voice is represented beyond the SCC into all operational facets of the study.

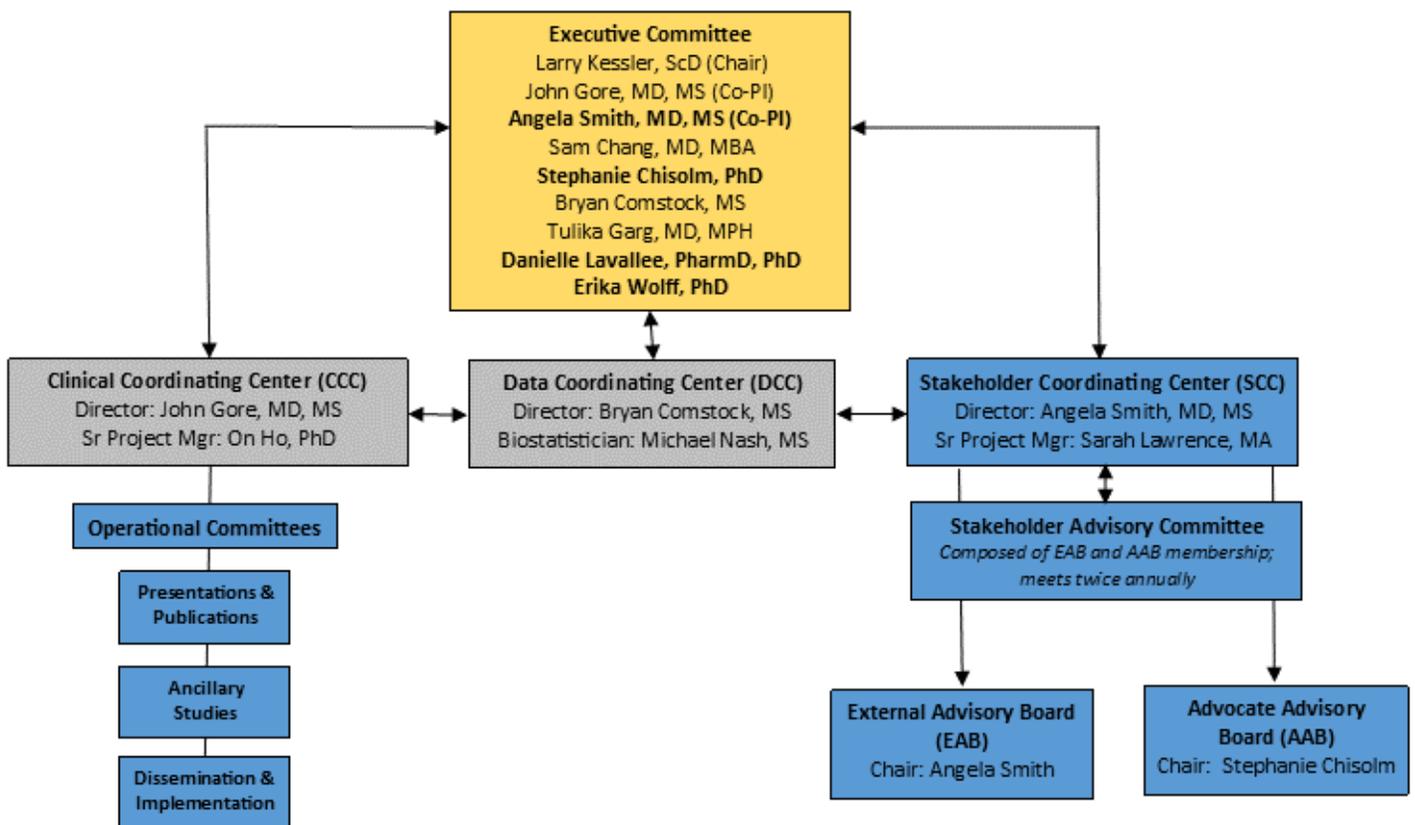
The SCC includes a Study Advisory Committee, composed of two stakeholder advisory boards representing a broad range of perspectives – the Advocate Advisory Board and the External Advisory Board.



The Advocate Advisory Board is chaired by Stephanie Chisolm, Director of Education and Research at the Bladder Cancer Advocacy Network and includes 8 additional members – 6 representing the patient perspective, 1 the caregiver perspective, and 1 advisor who has experience both as a patient and a caregiver. The External Advisory Board is chaired by Angela Smith, Director of the SCC and CISTO co-PI. Six additional advisors serve on the External Advisory Board, representing clinician (3), industry (1), payer (1) and policy maker (1) perspectives.

Dr. Chisolm and Dr. Smith both report regularly to the full SCC team and the Executive Committee, sharing input from the Advisory Groups and proposing adjustments to study materials, approaches, and other elements based on advisor feedback through the Executive Committee or study investigators and staff serving across Coordinating Centers. The Study Advisory Committee brings together these two boards bi-annually, once in-person at the annual CISTO study meeting and once virtually, to encourage cross-collaboration and relationship building. Key Clinical Coordinating Center operational committees (e.g., presentations and publications, ancillary studies, dissemination and implementation) will also have stakeholder advisor involvement as relevant and timely issues arise. For example, we plan to hold space for at least one stakeholder advisor to join the authorship group for each study publication.

**Figure 1. Engagement Structure in CISTO Bladder Cancer Study**



**Note: Members of the Executive Committee listed in bold font are also members of the Stakeholder Coordinating Center.**



### Experience with Engagement

Our team has extensive experience engaging multiple stakeholder groups, as well as a long track record of collaborating together to facilitate stakeholder engagement in research. Co-PIs John Gore and Angela Smith and Advocate Advisory Board Chair Stephanie Chisolm have collaborated on two PCORI-funded engagement awards (1089-BCAN, 6148-BCAN) – the first to develop and implement the BCAN Patient Survey Network, creating a sustainable infrastructure for patient prioritization of research questions, and the second to develop and implement research training for patients and stakeholders, to facilitate nationwide patient engagement in bladder cancer research. Both of these projects entailed extensive engagement of patients, caregivers, and other stakeholders to meet the goals of the projects. The current membership of the Advocate Advisory Board for the CISTO Bladder Cancer Study was developed through previous engagement efforts as part of these two funded projects. Details of the partnership are highlighted in recent publications, including:

1. Smith AB, Chisolm S, Deal A, Spangler A, Quale DZ, Bangs R, Jones JM, Gore JL. Patient-centered prioritization of bladder cancer research. *Cancer*. 2018 Aug 1;124(15):3136-3144. PMID: 29727033
2. Raskolnikov D, Brown B, Holt SK, Ball AL, Lotan Y, Strobe S, Schroeck F, Ullman R, Lipman R, Smith AB, Gore JL. Reduction of Pain During Flexible Cystoscopy: A Systematic Review and Meta-Analysis. *J Urol*. 2019 Jun 20:101097JU00000000000000399. doi: 10.1097/JU.0000000000000399. [Epub ahead of print]. PMID: 31219763

Additionally, SCC co-investigator Danielle Lavalley, along with SCC Senior Project Manager Sarah Lawrence, developed the CERTAIN Patient Advisory Network, a network of over 100 patients and researchers partnering together in research. Dr. Lavalley and Ms. Lawrence have also partnered with Dr. Gore to develop the INSPIRE Research Portal, which supports active patient and stakeholder engagement in research by providing one-stop access to tools and resources to support engagement partnerships. Dr. Lavalley and Ms. Lawrence also have experience leading similar engagement efforts through two PCORI-funded pragmatic clinical trials, Comparing Surgery versus Antibiotics to Treat Appendicitis (CODA) and Comparison of Surgery and Medicine on the Impact of Diverticulitis (COSMID).

## 4. Proposed Meeting and Key Activity Timeline

Table 4. CISTO Engagement Activities			
Meeting Type	Frequency	Setting	Purpose/Intent
Executive Committee	Monthly	In-person, virtual as needed	To provide oversight to the study overall, as well as individually to advisory and working groups/committees. The Executive Committee ensures that the stakeholder voice is being represented across the study. Membership of Executive Committee includes stakeholder representatives (patient advocate, clinician, professional society).
Stakeholder Coordinating Center	Minimum of monthly, with increased frequency as	In-person, virtual as needed	To serve as a weekly to monthly check-in for all activities related to stakeholder engagement. Provides an opportunity for all SCC-involved investigators, advisors, and staff

	needed to coordinate AAB involvement and stakeholder outreach.		to come together to report on engagement activities and coordinate efforts across groups, as well as plan for communications and presentations of advisor input to Executive Committee and other Coordinating Centers. Membership of Stakeholder Coordinating Center includes stakeholder representatives (patient advocates).
Study Advisory Committee	Minimum of two meetings annually, one of which occurs at the annual meeting.	In-person, virtual as needed	To provide an opportunity for the Advocate and External Advisory Boards to meet as one stakeholder committee and ensure goals of each group are aligned, providing consistency across stakeholder boards.
Advocate Advisory Board	Minimum of quarterly, with increased frequency as needed (e.g., twice monthly in project start-up, monthly during recruitment ramp up)	In-person, virtual as needed	To serve as a primary venue to present study progress and updates, as well as study-related questions and topics to advisors for feedback. Examples of items discussed so far include the participant informational video script, elements of the study protocol, and surveys that study participants will be asked to complete.
External Advisory Board	Minimum of bi-annually, with increased frequency as needed	In-person, virtual as needed	To support the national outreach, dissemination and implementation of the results from the CISTO Study.
Annual Meeting	Annually	Primarily in-person at BCAN Think Tank, virtual option provided as needed	To provide an in-person platform for all stakeholder advisors and study collaborators to come together and collaborate once yearly. The Annual Meeting will serve as a venue for recognizing contributions to overall study progress, and to facilitate team-building and co-learning across stakeholders.
Newsletter	Bi-monthly to quarterly. Frequency will change as deemed necessary.	Newsletter	To disseminate study information, progress, and updates to all stakeholders including, but not limited to, patient/caregiver/advocate advisors, clinicians, other stakeholder partners, site PIs and other research collaborators, etc.



## 5. Partner Preparation

Our team recognizes the importance of thoroughly preparing stakeholder partners to participate in research partnerships and frequently poll advisors for additional information or resources they need to successfully contribute to the CISTO Bladder Cancer Study. We developed orientation plans for all stakeholder partners and launched the orientation activities at meetings of our Advocate and External Advisory Boards. The initial in-person meeting of the combined Advocate and External Advisory Boards, the Study Advisory Committee, served as a venue to reinforce previous advisor orientation and provided a venue for in-person relationship building. We will continue to offer this in-person opportunity for the Study Advisory Committee to convene at the annual CISTO Study meeting, along with a second virtual opportunity on a yearly basis.

### **Advocate Advisory Board**

Advocate advisors, encompassing people representing patient, caregiver, and patient advocate perspectives, were emailed an orientation materials package, which included key contacts; background reading, including the final study research plan and the milestone list with the role/relevance to the Advocate Advisory Board noted; a role description for advisors, adapted from other studies for which our team has managed engagement; and administrative set-up documents, such as a privacy agreement and information needed to pay advisors. The Advocate Advisory Board conducted a virtual kickoff meeting on March 1, 2019, in which orientation materials were covered, the advisor role description was discussed and agreed to, and group expectations and values were set. A selection of advisor onboarding materials can be found on the CISTO Study website, [CISTOStudy.org](http://CISTOStudy.org).

The SCC team maintains ongoing contact with advisors and is continually striving to build rapport so that advisors are comfortable expressing their opinions, sharing differing points of view, and voicing any concerns. For further information on how conflicts and concerns have been handled within the CISTO Study SCC and associated advisory boards, contact our team at [advisoryboards@uw.edu](mailto:advisoryboards@uw.edu).

### **External Advisory Board**

As part of the first External Advisory Board meeting on June 7<sup>th</sup>, 2019, the stakeholder advisors were provided an overview of the CISTO Bladder Cancer Study and reviewed and commented on a draft charter to guide the Board's activities, which included a description of the External Advisory Board's role and expectations for meeting frequency. External Advisory Board members agreed to the charter, which is available on the CISTO Study website, [CISTOStudy.org](http://CISTOStudy.org).

### **Study Advisory Committee**

With support from our PCORI Program and Engagement Officers, the first Study Advisory Committee meeting was incorporated into the CISTO Kickoff Meeting held on August 8, 2019. This served as an excellent opportunity to bring together the Advocate and External Advisory Boards and launch their engagement. The meeting was well-attended, including four patient advisors, a representative advocate advisor, and two external advisors. A third external advisor who was unable to attend in-person reached out for a separate debrief with Dr. Gore.

The goals of the first Study Advisory Committee meeting were to:

1. Provide a team-building opportunity



2. Orient the committee about the study organization in order to better understand how the study components fit together
3. Discuss key areas that are critical across the stakeholder groups

Toward these goals, the meeting accomplished the following:

1. We provided a networking lunch opportunity to allow Study Advisory Committee members to socialize and get to know each other in a relaxed atmosphere, just prior to the CISTO Kickoff Meeting.
2. We presented the study organization and introduced each advisor to the team, to help the Study Advisory Committee understand how they will continue to contribute to the study.
3. We coordinated breakout group discussions to have representation from the advocate and external advisors, including having an external advisor lead and facilitate one of the group discussions. The discussions covered three areas that will impact all stakeholder groups and the breadth of the study:
  - a. Recruitment and retention strategies
  - b. How to convey information – dissemination tactics
  - c. Strategies for site-wide communications – best practices

The informative discussions and feedback are being distilled down to actionable strategies that will be the basis for future discussion and operational development among the Study Advisory Committee, SCC, and study team. Looking ahead, we anticipate that one of the bi-annual Study Advisory Committee meetings will occur adjacent to the CISTO Annual Meeting in order to take advantage of the advisory boards in attendance. Therefore, the first Study Advisory Committee meeting held in conjunction with the Kickoff Meeting sets the tone for effective stakeholder engagement to encourage ideas that will contribute to the downstream success of the study.

### **Advisor Training and Education**

Many of CISTO's stakeholders come to the table with a wealth of previous advisor experience and both personal and professional knowledge. For example, members of our Advocate Advisory Board have all completed the BCAN PEER training, developed as part of a previously funded PCORI Engagement Award, of which Dr. Smith was PI. Additionally, many External Advisory Board members were collaborators in the work that was done prior to the CISTO Bladder Cancer Study and bring a wealth of knowledge about the research question and our goals for engagement. As we conduct evaluation of advisor experiences throughout the study, we will identify any new topics that advisors need additional training on and will design training sessions or materials based on those needs.

### **Research Team Member Preparation**

Our engagement team has extensive experience in engaging diverse stakeholders and working with partners with limited research knowledge. Study Co-PI and SCC Director Angela Smith has co-led two PCORI-funded Engagement Awards with Study Co-PI John Gore and the Bladder Cancer Advocacy Network. The first, "Engaging Patients in Bladder Cancer Research Prioritization" (1089-BCAN) involved patients to prioritize research questions important to bladder cancer patients and caregivers. The second, "Patient Empowerment through Engagement Research Training in Bladder Cancer PCOR" (6148-BCAN) created the PEER research training program, to provide research training to patient advocates in bladder cancer, with the goal of facilitating nationwide patient engagement efforts in bladder cancer research. In both, she gained significant experience engaging diverse stakeholders. The first engagement



award established a community of trust within the bladder cancer patient advocate community. Trust and co-learning were then applied to the second engagement award, which brought together researchers and patient advocates on research teams, to address questions emanating directly from the prioritized research questions from the first engagement award. This second engagement award was critical, as it focused on education of patient advocates in the research process. Through education, patient advocates gained confidence. Simultaneously, researchers began to understand the value added through patient partnership. Through this engagement award focused on education of our patient partners, we were able to capitalize on the knowledge gained to create the current Advocate Advisory Board. This established infrastructure was critical to “hit the ground running” as we began study activities.

The CERTAIN Patient Advisory Network, led by SCC Co-Investigator Danielle Lavalley and Senior Project Manager Sarah Lawrence, was developed in 2012 to support active patient and stakeholder engagement in research. Since its founding, the CERTAIN Patient Advisory Network has supported engagement efforts on over 10 research studies, encompassing a range of clinical and research topics, and involving partners who range from completely unexperienced with research to seasoned research partners working across multiple research studies.

The CERTAIN Patient Advisory Network developed the Inspire Research Portal ([www.InspireResearch.org](http://www.InspireResearch.org)), which offers one-stop access to tools and resources on a variety of topics to support patient-researcher partnerships. The Inspire Research Portal currently houses over 150 tools, resources, and trainings focused on supporting partnerships, from both the researcher and the patient/caregiver/advocate perspective. SCC team members have ready access to resources on the Inspire Portal supporting diversity in engagement, relationship-building, managing conflicts, training and educating advisors on research topics, and strategically planning for engagement to inform study efforts.

## **6. Recruitment and Retention**

CISTO’s study design includes the incorporation of the stakeholder’s voice in all phases of research. At the outset of CISTO activities, the SCC team reviewed the study milestone list and identified anticipated stakeholder advisor roles for each milestone. For the Advocate Advisory Board in particular, an intense focus on recruitment and retention will be a recurring theme of engagement. Table 5 below outlines the input and outcomes of input on recruitment- and retention-related issues to date, as preparation for recruitment was underway. Moving forward, as recruitment begins, the Advocate and External Advisory Boards will receive updates at each meeting on recruitment progress, and time will be allotted for the study recruitment team to share challenges in recruitment for discussion and problem-solving with the advisors.

<b>Table 5. Advocate Advisor Feedback on Recruitment and Retention-Related Issues to Date</b>		
<b>Item for Feedback</b>	<b>Type of Feedback Received</b>	<b>(Expected) Outcome/Impact on Study</b>
<b>Informational Video</b>	<ul style="list-style-type: none"> <li>Terminology and phrasing</li> <li>Patient representation</li> <li>Formatting</li> <li>Disease characteristics</li> </ul>	<ul style="list-style-type: none"> <li>Simplified language that improves clarity of video. Produced a video that was more informative to participants</li> <li>Identified real patients with real life experience to star in the video, rather than actors, to improve personal connection between video and study participants</li> </ul>
<b>Patient Baseline/Follow-Up Surveys</b>	<ul style="list-style-type: none"> <li>Terminology and phrasing</li> <li>Formatting</li> <li>Information flow</li> <li>Additional clarification and information</li> <li>Length of time to complete survey</li> <li>Frequency of baseline outreach</li> </ul>	<ul style="list-style-type: none"> <li>Improved patient user experience of surveys</li> <li>Added overall clarity</li> <li>Incorporated patient and caregiver perspective into surveys making them more user-friendly specifically for their intended population</li> <li>Improved rate of completion of baseline survey</li> </ul>
<b>Study Protocol</b>	<ul style="list-style-type: none"> <li>Terminology and phrasing</li> <li>Avoid approach of patients on day of surgery</li> <li>Methods to approach caregivers for interview consent</li> <li>Set expectations for types of survey questions</li> <li>Provide support for completion of TTO survey</li> </ul>	<ul style="list-style-type: none"> <li>Clarity of study procedures</li> <li>Improved likelihood of recruitment</li> <li>Avoidance of negative psychological impact of questionnaires (by thoughtful timing with regard to disease state)</li> <li>Improved experience with sensitive survey questions</li> </ul>
<b>Patient Handout</b>	<ul style="list-style-type: none"> <li>Terminology and phrasing</li> <li>Patient representation</li> <li>Formatting</li> <li>Disease characteristics</li> </ul>	<ul style="list-style-type: none"> <li>Improved content of handout to accurately reflect the video in an alternate written format</li> </ul>
<b>Promotional Materials</b>	<ul style="list-style-type: none"> <li>Study slogan</li> </ul>	<ul style="list-style-type: none"> <li>Helped convey the study purpose and made the study more approachable to different audiences</li> </ul>

## 7. Process and Outcomes Monitoring

We plan to conduct regular evaluation of engagement activities, in alignment with the phases of the research process and anticipated shift in activities and type of input solicited during each phase. Table 6 outlines the anticipated shifts in advisory activities related to shifts in phases of research, and we will design evaluation activities to reflect these changes. As the research phases outlined below will overlap in conduct, we will plan to conduct evaluations at 6 month intervals and will aim to conduct an



evaluation at the close of each research phase, to adequately capture activities conducted within that period.

<b>Table 6. Phases of Research and Associated Advisory Activities.</b>		
<b>Phase of Research</b>	<b>Approximate Length of Research Phase</b>	<b>Anticipated Advisory Activities</b>
Study start-up	6 months	<ul style="list-style-type: none"> <li>• Review of study protocol and participant outreach materials.</li> <li>• Partnership relationship building</li> <li>• Communication planning</li> <li>• Partner education and relationship building</li> </ul>
Recruitment start-up	1 year	<ul style="list-style-type: none"> <li>• Troubleshooting recruitment and retention issues</li> <li>• Review of staff recruitment training materials</li> <li>• Reporting of recruitment updates and milestones</li> <li>• Partner education and relationship building</li> </ul>
Recruitment maintenance and retention	2 years	<ul style="list-style-type: none"> <li>• Reporting of recruitment updates and milestones</li> <li>• Troubleshooting retention-related issues</li> <li>• Partner education and relationship building</li> <li>• Involvement in communications, dissemination, and publication planning</li> </ul>
Data analysis and interpretation	3 years	<ul style="list-style-type: none"> <li>• Review of study results as available</li> <li>• Involvement in communications and dissemination planning</li> <li>• Involvement in publication and other dissemination development</li> <li>• Partner education and relationship building</li> </ul>
Dissemination and implementation	4-5 years	<ul style="list-style-type: none"> <li>• Involvement in communications and dissemination planning, development, and implementation</li> <li>• Partner education and relationship building</li> </ul>

Evaluations will focus on soliciting detailed feedback on the engagement activities that occurred during the evaluation period and will also include evaluation around standard domains (Table 7).

<b>Table 7. Domains of Evaluation</b>
<p><b>Knowledge and understanding, as well as additional training or information needed</b></p> <ul style="list-style-type: none"> <li>• Of the research process</li> <li>• Of the CISTO Bladder Cancer Study</li> <li>• Of the advisor role</li> </ul> <p><b>Competency of research team in engaging with advisors</b></p> <ul style="list-style-type: none"> <li>• Communication between study team and advisors (frequency and type)</li> <li>• Respect for advisor input</li> <li>• Meeting facilitation/discussion</li> <li>• Managing diverse viewpoints</li> <li>• Conflict resolution</li> </ul> <p><b>Advisor satisfaction</b></p>

- With contributions made
- With how the study team uses advisor input
- With communication between study team and advisors

In addition to a review of the results of the formal evaluation process (e.g., numeric scores, narrative comments, etc.), our team will also review quarterly a number of metrics relating to our engagement goals, and put plans into place as necessary to improve performance (Table 8).

#### **Table 8. Engagement Metrics**

- Count and description of meetings with Advisory Boards (dates, agenda items, attendance)
- Count and description of feedback from stakeholder advisors and how that information has informed the research study
- Description of engagement that has occurred outside of meetings (e.g., newsletters sent, feedback solicited via survey, email with study updates, etc.)
- Advisor retention rate for reporting period
- Count and demographic characteristics of advisors (e.g., geographic location, health experience, professional experience/clinical specialties, degrees, etc.)
- Case studies of specific recruitment or retention issues brought to advisors for troubleshooting and how advisor input was put into practice to resolve issues
- Publication list with stakeholder advisor authorship identified.
- Description of advisor participation in communication and dissemination planning.