

**A Community Pathologist–Driven Approach to the Implementation of Best Practices in Immuno-oncology [IO] Across the Multidisciplinary Cancer Care Team [COMPATH-IO]**

**Grant ID: 34604349**

**Submitted by:  
American Society for Clinical Pathology  
and  
Q Synthesis LLC**

**Abstract:**

As key members of the multidisciplinary immuno-oncology (IO) team, pathologists and laboratory professionals can effectively shape IO policies and procedures in their institutions by shortening the timeframe from IO research to practice and improving the quality of patient care. However, there is significant lack of awareness and confusion about fundamental IO science and diagnostics, and suboptimal integration of pathologists and laboratory professionals in multidisciplinary and interprofessional IO cancer care teams. The American Society for Clinical Pathology (ASCP), in collaboration with Q Synthesis LLC, seeks funding for COMPATH-IO, a comprehensive two-year learning and practice-change educational program, designed to (1) increase the knowledge, skills, and competence of pathologists and laboratory professionals involved in cancer diagnosis and management of IO-related cancers; (2) empower community laboratory teams to play a greater role in institutional IO policies/protocols within community cancer centers; (3) promote pathologists and laboratory professionals as members of the multidisciplinary and interprofessional IO cancer care team; and (4) disseminate best practices and lessons learned from the program among the broader IO multidisciplinary patient care team. Proposed activities include (1) practice survey, (2) online scientific modules, (3) group leadership discussions, (4) multidisciplinary QI initiatives, and (5) problem-based learning panel discussions. Online continuing medical education/ continuing medical laboratory education (CME/CMLE) activities will be made available at no cost to more than 100,000 learners in the United States and Europe. ASCP is committed to advancing its full IO Education Strategy with its target audiences; additional components not included in this proposal include tactics to enhance communication of rapidly developing IO science. Results from COMPATH-IO will shape future learning and change-based initiatives designed to enhance patient care across the IO diagnosis and treatment cycle.

**Key Words:** Immuno-oncology (IO), pathology, laboratory professional, quality improvement, multidisciplinary team, IO diagnosis, immunotherapies, pan-tumor immuno-oncology.

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## Overall Goal and Objectives

The American Society for Clinical Pathology (ASCP), in collaboration with Q Synthesis LLC,<sup>i</sup> seeks funding for COMPATH-IO, a comprehensive pan-tumor<sup>ii</sup> immuno-oncology (IO) education and quality improvement (QI) program. Pathologists and laboratory professionals (e.g., clinical laboratory scientists, administrators, and laboratory technicians) are key members of the multidisciplinary team<sup>iii</sup> with roles in the diagnosis, testing, and management of IO-related cancers. As key health care providers responsible for the testing and identification of biomarkers and immune checkpoints, the laboratory team must understand the scientific foundations and procedural considerations of IO diagnostics and treatment. However, there remains significant lack of awareness and confusion among the laboratory team about IO testing and diagnosis; if left unaddressed, this gap could lead to significant loss of patient lives.

The COMPATH-IO program is designed to (1) increase the knowledge, skills, and competence of pathologists and laboratory professionals responsible for cancer diagnosis and management using pan-tumor IO; (2) empower community pathology teams to play a greater role in shaping and implementing institutional IO policies/protocols within cancer centers; (3) promote pathologists and laboratory professionals as leaders in the multidisciplinary team who can guide medical oncologists and other team members in the safe and effective implementation and delivery of IO; and (4) disseminate best practices and lessons learned to enhance capacity to ensure proper diagnosis and inform therapeutic decisions among the broader IO multidisciplinary patient care team.

COMPATH-IO activities are a component of ASCP's IO Education Strategy, which is designed to address educational needs and drive implementation science and evidence-based practice change. As part of the IO Education Strategy, the program will support learning of foundational IO scientific concepts and promote integration of the learning into practice among the cancer care team. The program employs a learning and change-based approach to education and patient care throughout the IO diagnosis and treatment cycle. In addition, COMPATH-IO aims to increase the laboratory team's critical scientific knowledge and leadership skills to build capacity and drive systems-based change in community cancer care. Tools and enduring materials will be distributed to domestic and international learners for a period of three years.

IO diagnostics will revolutionize cancer therapy, with high-quality and accurate diagnoses at the center of the cancer care cycle. COMPATH-IO goals and activities were designed to address four critical gaps identified by the ASCP IO Workgroup and existing literature. Alignment of the clinical gaps, program goals, activities, and measurements are depicted in the Logic Model in Figure 1.

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<sup>i</sup> Q Synthesis, LLC, (details on p. 14) is an independent health care education and quality improvement company focusing on the practice-based applications of implementation science to advance health services research.

<sup>ii</sup> Per the Pfizer-Merck RFP, pan-tumor IO is defined as being applicable across the entire field of IO, inclusive of multiple disease states (e.g. lung cancer, melanoma, colorectal cancer, etc.)

<sup>iii</sup> Multidisciplinary refers to physicians from multiple specialties (e.g. pathologists and oncologists).

## Immuno-oncology Project Logic Model

This logic model visually depicts desired outcomes, clinical gaps, learning objectives, activities, and measurements.

Outcome	Clinical Performance Gaps	Learning Objectives	Activities	Measurement/Outcomes
<b>Reducing specified clinical gaps in the diagnosis and treatment of IO to improve patient care and outcomes.</b>	Lack of awareness of the scientific considerations and implications of IO biomarkers, checkpoints, and clinical pathways in the identification, diagnosis, and treatment of multiple cancers. Lack of understanding of how complex combinations of various therapeutic agents, disease states, and thresholds impact IO diagnostics and treatment plans.	Describe US and European IO laboratory practice patterns for benchmarking  Guide the appropriate selection of IO treatment for cancers based on complex combination of therapeutic agents, disease states, and thresholds	<u><b>Activity 1</b></u> IO Practice Survey	Statistical analysis of practice patterns
	Suboptimal use of IO testing and reporting guidelines as well as emerging protocols among the laboratory team. This includes understanding clinical indications for and analytical processes related to biomarker and pathway testing.	Enhance knowledge, skills, and competence of pathologists in IO, including immune biomarkers, checkpoint, and pathway testing and interpretation  Improve practice patterns related to IO diagnostics and therapy via the use of multidisciplinary teams.	<u><b>Activity 2</b></u> IO Scientific Core Online Modules  <u><b>Activity 3</b></u> IO <u>ChangeMakers</u> : Virtual Leadership Discussions	Participation records Session and module evaluations Multiple-choice questionnaire for pre/post-course medical knowledge Intent-to-change questions Passing of CME post-test Qualitative analysis of QI change plans  <u><b>Moore's Levels (1-6)</b></u> Participation Satisfaction Knowledge Change Confidence Performance Patient Health
	There is suboptimal integration of pathologists and laboratory professionals in the multidisciplinary cancer care team, which negatively affects patient care and safety.	Increase implementation of best practices in IO clinical care by enhancing data-driven multidisciplinary quality improvement at selected US partner sites	<u><b>Activity 4</b></u> Multidisciplinary Live QI Initiatives	
	Lack of development of and support for pathology and laboratory leadership on the multidisciplinary and inter-professional cancer care team.	Increase pathology leadership on multidisciplinary teams by enhancing communication and change management skills of the laboratory team	<u><b>Activity 5</b></u> IO Implementation PBL and Enduring Panel Discussions	

**Figure 1: COMPATH-IO Logic Model**

## Assessment of Need

Immuno-oncology engages the body's natural defenses to fight cancer. Some IO treatments improve or restore immune system function.<sup>1</sup> Others use drugs that target checkpoint inhibitors to enhance immune function and target tumor cells.<sup>2</sup>

Immuno-oncology breakthroughs are shifting paradigms and methods in cancer care. Dr. Christoph Huber, President of the Board of Directors of the Association for Cancer Immunotherapies (CIMT), stated in the CIMT 2014 Annual Report that rapid breakthroughs in immunotherapy require new models for scientific exchange, collaboration, and education. The report also highlighted significant diagnostic and clinical knowledge gaps about immunotherapeutic antibodies and treatments currently approved by the FDA.<sup>3</sup> To fill this gap, ASCP formed its IO Workgroup in 2016 and developed a comprehensive IO Education Strategy designed to bridge IO-related clinical gaps in the pathology and laboratory medicine communities.<sup>4</sup> As there is little baseline data about emerging practice patterns for IO diagnostics in the US and Europe, COMPATH-IO will establish baseline data about practice and address the following clinical gaps for the laboratory team.

**Clinical Gap #1: Pathologists and laboratory professionals lack awareness about the core science of IO and the implications of biomarkers, checkpoints, and clinical pathways in the identification, diagnosis, and treatment of pan-tumor cancer. There is also a lack of understanding of how complex combinations of various therapeutic agents, disease states, and thresholds affect diagnostics and treatment plans.**

Advancements in IO have created new—and nonintuitive—diagnostic paradigms and testing protocols for cancer. ASCP Chief Medical Officer Dan Milner, MD, reports that there is considerable confusion in the broader pathology and laboratory medicine community about the basic science of IO, as well as a lack of skill in testing and diagnostics associated with IO and immunotherapeutics (oral communication, May 27, 2017). Pathologists and laboratory professionals must develop their basic scientific knowledge as well as the testing and diagnostic skill sets associated with IO and immuno-therapeutics. Pathologists must understand the science of immune biomarkers, checkpoint molecules and their pathways, and their implication on the identification, diagnosis, and treatment of multiple cancers. Specific consideration must be given to understanding complex combinations of therapeutic agents, disease states, and thresholds affecting IO diagnostics. This suboptimal knowledge also hinders multidisciplinary communication between the pathologist and oncologist, affecting patient care.<sup>5,6</sup>

Pathologists and other members of the laboratory team have suboptimal understanding of pre-analytic considerations, such as tissue requirements, for testing of immune biomarkers, checkpoints, and pathways in various cancers and tumors. In addition, private-practice and community pathologists may find it challenging to keep up-to-date on rapidly changing knowledge in the management and treatment of multiple cancers and the complex combination of therapeutic agents, disease states, and thresholds affecting IO diagnostics. This

suboptimal knowledge hinders the multidisciplinary communication and teamwork that advances appropriate patient care.<sup>6</sup>

**Clinical Gap #2: There is suboptimal awareness among laboratory team members about current IO testing and reporting guidelines as well as emerging protocols. This includes understanding clinical indications for and analytical processes related to biomarker and pathway testing.**

Current practice guidelines that include IO diagnostics tend to focus on specific disease states. There is currently no established guideline for immunotherapy testing and diagnostics, and pathologists and other members of the laboratory team lack the knowledge and skills necessary to implement appropriate disease-specific guidelines, such as *EGFR* biomarker testing guidelines for colorectal cancer or tissue requirements for *ROS1* biomarker testing in non-small cell lung cancer, and testing protocols for immune biomarkers, checkpoints, and pathways. There is a profound need in pathology for IO diagnostic approaches that extend beyond traditional evidence-based guidelines requiring published literature reviews and years to develop.

Dr. Michael Feldman, chair of the ASCP IO Workgroup and Professor of Pathology at the University of Pennsylvania, predicts that IO will change diagnostic paradigms and current workflows in the laboratory. “Pathologists and laboratory professionals lack a core foundation on both the basics of IO therapies and the rapid scientific advancements in the field. IO transcends, as well as changes, the traditional way in which the laboratory diagnoses and communicates about cancer” (oral communication, May 24, 2017). Furthermore, Feldman and other members of the ASCP IO Workgroup have found that there are currently few widely accepted evidence-based practice resources available for testing protocols, laboratory workflows, and diagnostic best practices in IO.

**Clinical Gap #3: There is suboptimal integration of pathologists and laboratory professionals in the multidisciplinary team, which adversely affects patient care and safety.**

Pathologists and laboratory professionals are critical members of the IO care team, involved in diagnosis and the management of adverse reactions in IO care. In clinical settings, pathologists and laboratorians are often underutilized as members of the tumor board or cancer care teams. “There is no set method for engagement of community pathologists in tumor boards or on cancer care teams—some centers completely engage pathologists, some centers partially engage them, and some do not engage them at all. There are great opportunities to enhance the quality of care by effectively engaging pathologists and the lab in care teams,” states a QI expert on the ASCP IO Workgroup (oral communication, June 2, 2017).

In many community cancer centers, pathologists work off-site and spend very little time directly interacting with members of the clinical care team. Given that some cancer centers hold several tumor boards each week, it may be difficult for pathologists to attend every meeting.

Pathologists who do not regularly attend tumor boards may miss key opportunities to provide valuable input regarding the pathologic features that are characteristic of cancers, extending beyond their basic gross and histomorphologic aspects. This valuable information may impact how clinicians develop treatment plans and monitor care for cancer patients.<sup>7</sup>

**Clinical Gap #4: Development of and support for pathology and laboratory leadership on the multidisciplinary and interprofessional<sup>iv</sup> cancer care team.**

The emerging science of IO provides an opportunity to strengthen pathologist and laboratory leadership on multidisciplinary clinical care teams. Physician leadership is an important component of the delivery of modern health care. The American Hospital Association has identified several emerging competencies for physicians in the next generation of health care delivery, including leadership, systems theory and analysis, cross-disciplinary cooperation and interpersonal and communication skills. Engaging health care providers such as pathologists and laboratory professionals in leadership training can improve the quality and delivery of health care services, reduce costs, and improve health outcomes.<sup>8</sup>

Due to the growing complexity of biomarker testing and interpretation, the role of pathologists is becoming more central to safe and effective delivery in precision medicine in cancer care. Their unique perspective on disease processes and access to tissue specimens allow pathologists to guide cancer clinicians who are developing treatment plans and monitoring response to therapies.<sup>9</sup>

The ASCP IO Workgroup advocates that pathologists and laboratory team members work hand in hand with other members of the multidisciplinary team to improve the quality of IO diagnostics and appropriate use of immunotherapy for cancer care. The ASCP IO Workgroup, carrying out the mandate to provide “the right test for the right patient at the right time” to enhance quality in IO patient care, has identified areas for pathology leadership support for QI, including evidence-based QI planning for disease-specific IO procedures and protocols and developing consistent protocols and workflows related to IO diagnosis and treatment.

**Target Audience**

The primary target audiences for this program are pathologists, laboratory professionals, and community pathology teams. Secondary audiences include oncologists and other multidisciplinary team members (e.g., pulmonologists, urologists, surgeons, radiologists, radiation oncologists, nurses, navigators, pharmacists, and administrators) at community cancer centers. Because of distinct differences in US and international health care delivery and

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<sup>iv</sup> The term “interprofessional” in this document refers to teams of advanced practitioners (e.g. physicians and clinical laboratory scientists), other cancer care providers (e.g. nurses, laboratory professionals) and/or support staff (quality improvement data specialists, etc.) on the cancer care team.

practices, the IO ChangeMakers: Virtual Leadership Discussions and Multidisciplinary Live QI Initiatives will focus on US practices.<sup>v</sup>

**Table 1: COMPATH-IO Program Overview**

	<b>Educational Activities</b>	<b>Primary Audience</b>	<b>Secondary Audience</b>	<b>Scope</b>	<b>Estimated 2-yr Direct Impact</b>
<b>1</b>	IO Practice Survey	Pathologists, laboratory professionals	Individual multidisciplinary team members	US+EU	500+ respondents
<b>2</b>	IO Scientific Core Online Modules	Pathologists, laboratory professionals	Individual multidisciplinary team members	US+EU	2,000 learners
<b>3</b>	IO ChangeMakers: Virtual Leadership Discussions	Community pathologists, senior lab professionals, lab administrators	N/A	US only	40 direct learners
<b>4</b>	Multidisciplinary Live QI Initiatives	Multidisciplinary IO teams at Community Cancer Centers		US only	40+ direct learners, 200+ in-direct learners
<b>5</b>	IO Implementation PBL Live/ Enduring Panel Discussions	Multidisciplinary teams	N/A	US+EU	2,000 learners

Activities 1, 2, and 5 will be made available to more than 100,000 pathologist and laboratory professional ASCP members, 5,000 European Society of Pathology (ESP) and International Liaison of Pathology Presidents (ILPP) members, and others. COMPATH-IO will leverage these connections, along with those of Q Synthesis, to recruit participants for the Virtual Leadership Discussions and Multidisciplinary Live QI Initiatives.

To enhance interest among target audiences, the COMPATH-IO Program will be featured on ASCP's website and social media outlets such as Facebook and Twitter. In addition, a core group of ASCP leaders and workgroup members will promote the program through their own social media outlets. In addition, after program completion, educational and scientific findings from the COMPATH-IO Program will be distributed to the broader community of pathology, laboratory science, and CME professionals through press releases, presentations, and publications. As ASCP implements its full IO Education Strategy, results from COMPATH-IO will be used to shape future education and change-based initiatives designed to enhance patient care throughout the IO diagnosis and treatment cycle.

<sup>v</sup> Based on the results of this program, future iterations of the IO ChangeMakers activity may be expanded to include additional laboratory-based groups (e.g., technicians, quality improvement specialists) and international learners to develop ChangeMaker tools for pathology.



## **Project Design and Methods**

ASCP, in partnership with Q Synthesis, requests \$450,000 to support the implementation of continuing education and QI activities associated with the ASCP IO Education Strategy. This program will bridge the described clinical gaps in IO-related cancer diagnosis in the pathology and laboratory medicine communities.

## **Learning Objectives**

On completion of the program, COMPATH-IO primary target audiences will be able to:

- Describe US and European IO laboratory practice patterns for learner benchmarking;
- Enhance IO skills, and competence, including immune biomarker, checkpoint, and pathway testing and interpretation;
- Guide the selection of appropriate IO cancer treatment based on complex combinations of therapeutic agents, disease states, and thresholds;
- Improve practice patterns related to IO diagnostics and therapy by engaging multidisciplinary teams;
- Increase implementation of best practices in IO clinical care by enhancing data-driven multidisciplinary QI programs at selected US partner sites; and
- Increase pathology leadership on multidisciplinary teams by enhancing communication and change management skills of the laboratory team.

These learning objectives will be addressed by the following activities, selected from ASCP's IO Education Strategy:

- Activity 1: IO Practice Survey
- Activity 2: IO Scientific Core Online Modules
- Activity 3: IO ChangeMakers: Virtual Leadership Discussions
- Activity 4: Multidisciplinary Live QI Initiatives
- Activity 5: IO Implementation Problem-Based Learning (PBL) Live/Enduring Panel Discussions

A description of each activity follows below.

### **Activity 1: IO Practice Survey**

ASCP will develop a practice survey to assess the state of IO testing, reporting, and associated performance gaps among laboratory team members. In accordance with survey research literature, the 20-minute survey will gather data about relevant variations in local practice patterns and system capabilities for IO testing, including patient identification, referral patterns, collection and analysis of specimens, and composition of the clinical team involved in IO management. In addition, variation among current testing patterns and self-reported comfort with IO testing, interpretation, and reporting will be assessed.

ASCP's seven-stage survey development process, based on Don Dillman's survey research principles.<sup>10</sup> will be utilized to develop and disseminate the surveys. Questions will be

customized to respondents and written to address both pathology and laboratory medicine staff perspectives. Furthermore, the survey will be distributed to ASCP and European pathology society membership, which includes pathologists and laboratory professionals involved in cancer diagnosis across the United States and Europe.

Immuno-oncology practice patterns are still emerging, especially in community care settings. The IO program Steering Committee will utilize the survey results to better understand laboratory-based IO practice patterns and challenges, and data will be used to benchmark learner and practice changes in the program. Although survey respondents do not earn CME/CMLE credit, the survey will inform program content development and design for COMPATH-IO credit-bearing activities and will be utilized for post-activity evaluation follow-up.

### **Activity 2: IO Scientific Core Online Modules**

ASCP will develop three one-hour interactive online CME modules—segmented into shorter just-in-time learning “lessons”—designed to increase pathologists and laboratory professionals’ core scientific knowledge and skills in IO. The program will promote learner gains in knowledge and skills through authentic, engaging patient cases and scenarios. Potential module topics for pathologists and laboratory professionals include the foundational science of IO (immunology, pathways, and mechanisms of action), IO testing methodologies, communication of results to the team, and the clinical use of FDA-approved IO agents (both in combination and in multimodal strategies). The final module topics will be subject to evidence-based review by the Steering Committee. Leveraging its existing relationships with international pathology organizations such as ESP and ILPP, ASCP will expand the reach of this project component to European pathologists and laboratory professionals to enhance their knowledge of foundational IO science and FDA-approved therapies. The educational activities will be hosted in ASCP's Learning Management System and made available for registration to both US and European participants. Furthermore, images used in this program will be added to ASCPedia, ASCP's cloud-based digital repository and archive, which can be utilized by registered pathologists and laboratory professionals.<sup>vi</sup>

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<sup>vi</sup> ASCPedia is ASCP's Alfresco™-based digital image repository and archive. ASCPedia images are available for viewing by registered ASCP members and stored for future education programs.

### **Activity 3: IO ChangeMakers: Virtual Leadership Discussions**

ASCP, in collaboration with Q Synthesis LLC, will develop four virtual CME credit-bearing group leadership discussions. This program component aims to educate and empower community pathologists, senior laboratory professionals, and laboratory administrators to serve as effective change agents. ASCP will recruit a cohort of up to 40 learners with a strong interest in leading IO initiatives at their respective organizations. Via case-based scenarios, the IO ChangeMakers will discuss techniques to guide the delivery of IO among their interprofessional and multidisciplinary teams. The virtual session will be led by an expert facilitator and will consist of a combination of pre-course work, a virtual small-group discussion of team-based case studies, and post-course work. These activities will engage participants in interactive sessions about the role of physician leadership, the application of change management strategies, and the leadership skills needed for the navigation of IO care delivery in community settings. IO ChangeMakers will have access to an online discussion site to facilitate communication with peers and IO experts.

### **Activity 4: Multidisciplinary Live QI Initiatives**

Q Synthesis LLC, in collaboration with ASCP, will recruit three US community cancer centers accredited by the American College of Surgeons Commission on Cancer to engage in intensive QI initiatives.<sup>11</sup> The QI initiatives will be centered on implementation science principles and the critical role of pathology in IO-based patient care. Furthermore, the QI initiatives will help the centers implement process and care improvements, as well as incorporate new scientific knowledge about the utility of IO agents for solid tumors and hematologic malignancies. This will be accomplished by operationalizing new workflow policies and procedures that will lead to measurable improvement in patient care and health care quality.

Through a series of live CME initiatives with follow-up activities, each cancer center will use QI methods and implementation science to improve their IO processes and assess the impact on patient care. The IO Scientific Core Online Modules and ChangeMakers: Virtual Leadership Discussions will be available to participants in the initiatives to promote IO knowledge and related skills.

The QI Initiative will utilize the Active Implementation Framework to help define "what needs to be done, who will do the work and when, and establish hospitable environments for the work to accomplish positive outcomes."<sup>12</sup> This framework incorporates the Plan-Do-Study-Act cycles for quality improvement.<sup>13</sup> QI performance improvement plans, outlining site-specific IO improvement strategies and measurements, will be implemented using Q Synthesis' QI Implementation Process as described in Figure 2.



**Figure 2: Quality Improvement [QI] Project Implementation**

**Activity 5: IO Implementation PBL Live/Enduring Panel Discussions**

Two live 1.5-hour CME multidisciplinary panel discussions will be developed to extend the program’s reach. The first interactive problem-based learning session, to be presented at the 2018 ASCP Annual Meeting, will focus on overcoming common barriers to implementing and delivering IO in community pathology settings. The second will be presented at the 2019 ASCP Annual Meeting by faculty and members of the multidisciplinary teams involved in the QI initiatives, who will share best practices and lessons learned. Both sessions will be recorded and offered as enduring materials at no cost to registered users to extend the reach of the sessions to other learners. To encourage further dissemination of the IO-related learning, ASCP will support the submission of up to two posters/panel discussions by faculty and Multidisciplinary Live QI Initiative participants to other academic and scientific association annual meetings.

**An Innovative Approach:** As the only organization representing the entire laboratory team, ASCP has long-standing experience developing and disseminating interactive multidisciplinary case-based educational initiatives to improve pathology practice, communication, and teamwork. Q Synthesis has extensive experience in the design and implementation of QI initiatives focused on multidisciplinary health care teams. This pan-tumor project builds on

experience in previous multidisciplinary ASCP projects designed to improve delivery of cancer care in community settings, including NSCLC (GAIN, EMPOWER) and colorectal cancer (EMBARC). Although IO-related educational initiatives are becoming more prevalent, the COMPATH-IO project uniquely focuses on laboratory team foundational learning and leadership in multidisciplinary collaboration to deliver pan-tumor IO in community settings.

### Evaluation Design

The COMPATH-IO evaluation employs a formative and summative approach, with interim and final program reporting. The evaluation is anticipated to demonstrate Moore’s Levels 1-6 (Table 2).

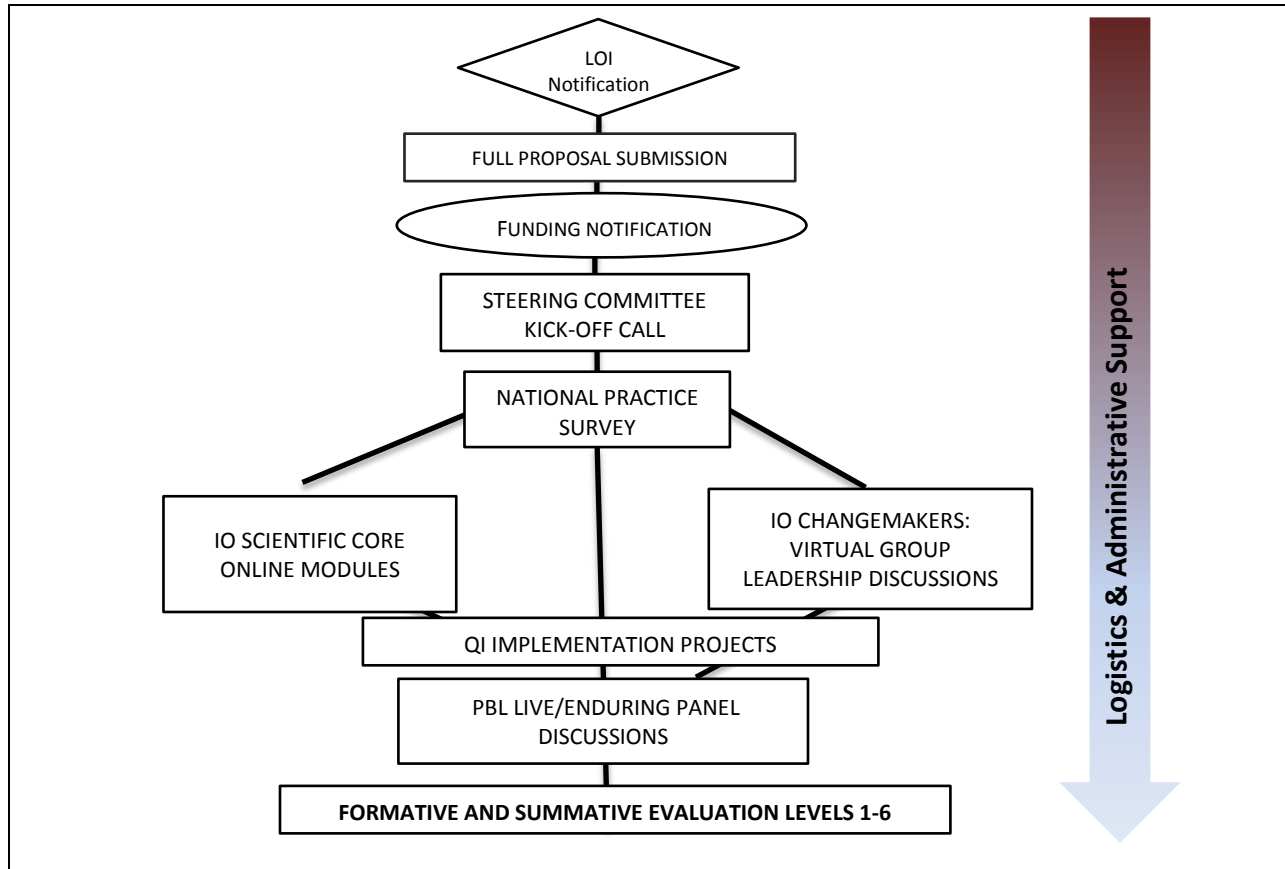
**Table 2: Project Outcomes and Measurement Tools**

Outcome	Activity	Data Collected	Measurement Tools
Level 1: Participation	2,3,4,5	<ul style="list-style-type: none"> <li>Total number of participants</li> <li>Demographic info</li> </ul>	<ul style="list-style-type: none"> <li>Participation records</li> <li>Evaluation surveys</li> </ul>
Level 2: Satisfaction	2,3,4,5	<ul style="list-style-type: none"> <li>% of participants indicating the content level was appropriate</li> <li>% of participants indicating the learning objectives were met</li> </ul>	<ul style="list-style-type: none"> <li>Session and module evaluation surveys</li> </ul>
Level 3a: Declarative Learning	2,3,4,5	Improvement in procedural knowledge over baseline in post program activity	<ul style="list-style-type: none"> <li>Multiple-choice questionnaire for pre-course/post-course medical content</li> </ul>
Level 3b: Procedural Learning	2,3,4,5	Documentation of intent to change clinical practice	<ul style="list-style-type: none"> <li>Intent-to-change questions</li> </ul>
Level 4: Competence	2,3,4,5	Documentation of specific aspects of practice change	<ul style="list-style-type: none"> <li>CME post-test</li> </ul>
Level 5: Performance	3,5	Changes to institutional policies or protocols	<ul style="list-style-type: none"> <li>Post-course evaluations and post-tests</li> <li>Analysis of improvement plans</li> </ul>
Level 6: Patient Health	3,5	Documented clinical management of patients treated with immunotherapy	<ul style="list-style-type: none"> <li>Interviews and focus groups</li> <li>Electronic health record / chart reviews</li> </ul>

Baseline data (and projected change) will be assessed using quantitative analysis of the IO Practice Survey. Evaluation results will assess satisfaction with the project (Levels 1/2) and changes in learning and competence (Levels 3a/3b/4) due to education content. The Multidisciplinary QI Initiatives will provide data for changes in performance (Level 5) and patient health (Level 6). A mixed-methods approach will be used to assess the impact of the QI Initiatives on change across the sites.

**Detailed Work Plan and Deliverables Schedule**

COMPATH-IO implementation will be overseen by a Steering Committee of ASCP’s IO Workgroup members over a period of two years (Figure 3 and Table 3).



**Figure 3: COMPATH-IO Workflow Diagram**

**Table 3: Deliverables Schedule**

Year	Activity Duration	Education Activity	Key Deliverables	Proposed Completion Dates
<b>2017</b>	9/23-11/1	Award notification & project launch	Letter of agreement	11/1/2017
	12/1-12/15	Project oversight kickoff with Steering Committee	Project blueprint	12/15/2017
			Evaluation plan	12/15/2017
<b>2018</b>	1/5- 3/15	Activity 1: IO Practice Survey	Survey launch	2/1/2018
			Survey end date	3/1/2018
			Executive briefing	3/15/2018
	3/15-6/30	Activity 2: IO Scientific Core Online Modules (3 modules)	Faculty kickoff meeting	3/15/2018
			Curriculum development	5/1/2018
			Module development	5/31/2018
			Module launch	6/1-6/30/2018
	3/15-8/31	Activity 3: IO ChangeMakers: Virtual Leadership Discussions (4 discussion groups of 10 each)	Recruitment	Fall 2017
			Pre-course work/launch of groups	3/15- 4/30/2018
			Post-course work	3/16- 5/30/2018
10/3-10/5	Activity 5: ASCP 2018 Live/Enduring Panel	2018 ASCP Annual Meeting Live Panel	10/3- 10/5/2018	
12/1	Discussion	Enduring education launch	12/1/2018	
<b>2018- 2019</b>	8/1/2018-7/31/2019	Activity 4: Multidisciplinary Live QI Initiatives (3 sites)	Site 1	8/1/2018-6/30/2019
			Site 2	8/15/2018-7/15/2019
			Site 3	8/31/2018-7/31/2019
<b>2019</b>	9/11-13	Activity 5: ASCP 2019 Live /Enduring Panel	2019 ASCP Annual Meeting Live Panel Discussion	9/11-9/13/2019

12/1	Discussion	Enduring education launch	12/1/2019
12/31	Project wrap-up	Financial reconciliation	1/30/2020

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