Grant ID 34709947

Improving Health Care Capacity in Immuno-Oncology: A Global Quality Collaborative

A collaboration between prIME Oncology and RealCME

Abstract:
The key goals of this global Immuno-Oncology Quality Collaborative (IOQC) are to 1) provide education that closes professional practice gaps aligned with key quality measures in immuno-oncology, enable and support clinicians as they implement the quality strategies within their own institutions, and assess the real-world impact of the initiative at the practice and health system levels, and 2) provide, for the first time, evidence of the impact of a scalable, immersive, online simulation-based QI solution on a specific set of quality measures which can address the enormous workforce retraining challenge facing oncology practices in their transition to value-based care. The target audience for the IOQC initiative is physicians, PAs, NPs, nurses and other clinicians who provide care for patients with cancer in North America, the European Union, Switzerland and Israel. A *Virtual Quality Improvement (vQI) Curriculum* will deliver the education, and participants will be supported to implement practice changes through IOQC regularly scheduled conference calls, organized by region. This curriculum's activities are supported by the RealCME analytic platform, RealMeasure®, a patented, highly dynamic, comprehensive, and reliable program assessment platform. Learners participating in the IOQC in the US will be assessed using claims data to demonstrate the impact of participation in the Collaborative on their real-world patient-level outcomes. Additionally, through predictive modeling, the educational impact on specific learner profiles (based on location, practice type, years in practice, affiliations, types of contracts, etc.) will be analyzed, and the aspects of the intervention that had the greatest impact will be identified.

Keywords: *cancer immunotherapy, immune-related adverse events, quality improvement, checkpoint inhibitors, biomarker testing, checkpoint inhibitor therapy, PD-L1*

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Overall Goals and Objective

The global Immuno-Oncology Quality Collaborative (IOQC) has two key goals, including 1) provide education that closes professional practice gaps aligned with key quality measures in immuno-oncology, enable and support clinicians as they implement the quality strategies within their own institutions, and assess the real-world impact of the initiative at the practice and health system levels, and 2) provide, for the first time, evidence of the impact of a scalable, immersive online simulation-based QI solution and peer-to-peer support on a specific set of quality measures which can address the enormous workforce retraining challenge facing oncology practices in their transition to value-based care. The analysis of the initiative will, through advanced analytics, link curriculum data with real world data, confirming that participants have extended the educational impact into their practice and system. It will therefore be important to broadly share the results and applicability of the program on a greater scale through publication and outreach to global cancer institutions, societies and hematology/oncology practices that are planning or initiating QI projects.

Current Assessment of Need in Targeted Area

The introduction of immune checkpoint inhibitors has resulted in a sea change for the management of many historically difficult-to-treat malignancies.[1] However, though these agents are improving outcomes for patients, their incorporation into the standard of care is slowed by a set of unique practical challenges, such as effective patient selection, assessment of response, and management of immune-related adverse events (irAEs).[2–4] Moreover, clinicians' lack of knowledge about the unique and complex mechanisms of action of these agents can increase the challenge of addressing these practical challenges. As the aggressive exploration of immune checkpoint inhibitors continues into their risks/benefits, either alone or in combinations with traditional targeted agents, chemotherapy, and other, novel agents, clinicians need to be educated further on the real-world use of these agents.

Learner data from several prIME Oncology activities illustrate educational needs regarding these practical challenges.[5–8] For example, several baseline, pre-activity questions asked at a recent CME-certified activity (presented at ASCO 2017 and developed by prIME Oncology and SITC) found that a multidisciplinary group of clinicians (both from the US and from outside of the US) were unclear about how to approach the initiation of checkpoint inhibitors and how/whether biomarker testing is needed to be done first, to determine whether or not checkpoint inhibitor therapy would be appropriate.[9] For a question about treating NSCLC, only 57% of learners (N = 69) recognized the appropriate use of PD-L1 testing (and the levels required) before initiating checkpoint inhibitor therapy. Approximately 7% of learners indicated they would use a checkpoint inhibitor combination that is not currently approved for the treatment of NSCLC. Similarly, for questions evaluating the use of these agents in head and

neck and bladder cancers, learners showed uncertainty about optimal use of these agents. About 36% (N= 72) of learners indicated they would not initiate checkpoint inhibitor therapy for a qualified patient with head and neck cancer unless their tumor was above a certain level of PD-L1 expression, although that is not required in this setting; about the same number of learners (ie, 29%; N = 70) indicated the same treatment practice for a qualified patient with bladder cancer; again, this is not indicated in this setting.[9] Baseline, pre-activity data from a recent program developed for US-based hematology/oncology fellows found that learners were divided on the appropriate response to relapse in a patient with NSCLC and no actionable driver mutations, with low/no PD-L1 expression.[5] Only about 59% of learners (N = 27) selected a best answer choice of initiating an anti-PD1 antibody and 33% suggested they would enroll the patient in a clinical trial of an anti-PD-L1 + anti-CTLA-4 antibodies instead of using an approved checkpoint inhibitor. Baseline, pre-activity data from a program presented to a multidisciplinary audience (both US and OUS) at the 2017 ASCO GU conference also found that clinicians are uncertain about how best to implement the use of checkpoint inhibitors, in this case for the treatment of advanced bladder cancer.[7] Only 39% of respondents (N = 36) correctly answered a question on this topic before participating in the activity. Discussions between participants and faculty during this program indicated significant interest and uncertainty surrounding the use of biomarkers in bladder cancer immunotherapy.

The identification and management of immune-related adverse events (irAEs) associated with checkpoint inhibitors was also educational gap identified by recent learner data. At the prIME/SITC symposium presented at ASCO 2017 11% of learners (N = 82) indicated that they would treat grade 3 immune-related adverse events using NSAIDS and only 79% of learners would correctly use high-dose steroids.[9] At another activity on this topic learners indicated in their evaluation comments that they needed more education on the practical challenges associated with immunotherapy use, including the treatment of irAEs.[10] Discussions between participants and faculty during an activity presented at the 2017 ASCO GU conference indicated significant interest in learning more about how to optimally identify and manage the adverse events associated with checkpoint inhibitors.[7] All together, these data indicate that clinicians from both inside and outside of the US have several educational gaps that need to be addressed regarding the use of checkpoint inhibitors in oncology. Clinicians have demonstrated that they are not optimally integrating biomarker testing into their clinical practice; have some uncertainty as to which are the best treatment strategies for using checkpoint inhibitors; and do not consistently know how to identify and manage the irAEs associated with checkpoint inhibitors.

Ideally, clinicians should be using biomarker testing appropriately, initiating checkpoint inhibitor therapy (in both treatment-naïve and treatment experienced settings, depending on the approved indications of each agent), and identifying and managing irAEs in an optimal

manner, and consistent with evidence-based recommendations and guidelines. Systems-based educational gaps impacting the use of immunotherapy, such as care coordination, communication between oncologist and pathologists, and communication and shared decision making between clinicians and patients, also suggest needed education. A quality improvement (QI) approach would be well suited to address these gaps and consistent with the transition occurring in the US and European healthcare system to a value-based approach. However, effective participation in QI requires a significant re-training of the healthcare workforce involving the upgrading and re-alignment of skills beyond clinical knowledge that have not been a focus of the traditional educational curricula through which oncologists earned their degrees and in the programs in which they trained. Thus, the burden of training their current and incoming workforce falls on healthcare organizations that will need to invest in team-based training based on the new paradigm of QI and on delivering quality-focused healthcare. The following set of skills are considered essential for achieving desired quality-related results and should be cultivated at an early stage:

- Analytic Skills – developing an organizational capability to collect, organize and analyze large volumes of healthcare data (clinical, cost, claims, customer experience, etc.) and deriving insights around gaps and breaks in quality. ASCO encourages oncology practices to prioritize the continuous collection of high quality data and participate in an oncology-specific learning health system in which collected data is retrospectively and prospectively analyzed to generate evidence, and applying these new insights to clinical care and research.
- Clinical Discipline – to minimize variation in quality of care. It has been estimated that clinical care variation alone accounts for approximately US $355 billion in excess spending and that 40% of hospital costs could be reduced by clinical standardization. The skills required include disciplined reporting (EHR), improved clinical competency for better adherence to treatment guidelines, establishment of a systematic and disciplined referral system, and better and more efficient resource utilization. In oncology, a number of value-based frameworks have been developed (e.g., ASCO, NICE) that include the assessment of clinical benefits, toxicity, and direct costs. ASCO urges the continuous refinement of these frameworks to assess the comparative value of treatment options and to support decision making processes.
- Customer Focus - to support the shift to patient-centered care. A key goal of QI is to improve the patient experience, which requires better patient communication, learning and implementation of patient-centered measures of performance, and incorporation of empathy into day-to-day practice. ASCO strongly urges the incorporation of the patient perspective in developing and implementing value-based frameworks for oncology practices.
- Interpersonal Skills - to improve organization-wide performance and efficiency through leadership, problem-solving, team-building and communication skills. *This issue is striking for oncologists*, since their patients, depending on the type and stage of cancer at diagnosis, may be seen by gynecologic oncologists, hematologists, medical

oncologists, pediatric oncologists, hematologists/oncologists, radiation oncologists, surgical oncologists, or urologists. Care may be provided by PCPs, surgeons, pathologists, emergency medicine physicians, nurses, NPs, PAs, medical technicians, genetic counselors, MSWs, mental health specialists, pharmacists, pain and palliative care specialists. All of these groups are facing staffing and resource challenges, making the need to improve interdisciplinary efficiency and coordination of paramount importance.

QI training programs exist for health care professionals (HCPs), and the landscape is fragmented with sources including government, academic centers, profit and non-profit organizations. The majority of training programs are on-site mentoring programs that are often expensive to implement, not scalable, reduce work time, and lack the ability to have learners review and repeat the training. Furthermore, administrative time requirements represent a growing burden and consistently rate as one of the top concerns in research across medical specialties including the ASCO Practice Census survey. Therefore, there is a need for scalable, convenient, highly efficient continuous QI training programs that will not add to the administrative burdens on clinicians, addresses both theoretical and practical aspects of QI, does not require missed work time, and focuses on all domains of QI education including leadership, analytics, clinical, teamwork, and empathy.

TARGET AUDIENCE

The target audience for the IOQC initiative is physicians, PAs, NPs, nurses and other healthcare providers who provide care for patients with cancer in **North America and the European Union, including Switzerland and Israel**. The initiative will be promoted heavily, using various modalities, to the global prIME Oncology membership of 50,000 clinicians. Faculty will also play a key role in encouraging global participation in the initiative. Clinician interest will be maximized by aligning the initiative with key priorities of the target audience who are motivated to make changes in their practices due to a variety of factors including budget constraints, patient and health system demands, and compensation incentives. This will ensure that the two primary goals of the initiative are met (see Overall Goals and Objectives section). Along with the target audience of participants, this initiative has the potential to benefit healthcare organizations, government agencies, institutions, practices, medical educators, payers, and other individuals and entities globally who may wish to replicate this model.

PROJECT DESIGN AND METHODS

prIME Oncology and RealCME will work with expert faculty to address these issues in the context of a quality focused, educational experience that will immerse learners in a **functional simulation** of participating in a Quality Improvement initiative within an integrated health system. The faculty will construct a virtual oncology practice within a health system with the staffing, volume, affiliations, patient demographics, payer profiles, and baseline quality

measures representing an authentic, representative center. The faculty will select appropriate quality measures and baseline values to be utilized in the simulated Quality Improvement initiative, which will be constructed from a number of publicly available sources and organizations as well as data from recently concluded prIME Oncology programs.

Potential quality measures that can be utilized to reflect improved capacity in immuno-oncology include the following: 1) utilization of biomarker testing, based on evidence-based guidelines and recommendations; 2) initiation of checkpoint inhibitor therapy in both treatment-naïve and treatment experienced settings, depending on the approved indications of each agent, and 3) identification and management of irAEs consistent with evidence-based guidelines and recommendations, measured by reduced ER visits, reduced irAE-related hospitalizations, and reduced interruptions of therapy, 4) use of patient-directed decision support tools. Throughout the period of participation in the simulated QI initiative, clinicians will be invited to collaborate with their peers through the Immuno-Oncology Quality Collaborative Regional Support Calls. These QI thought leader-moderated conference calls will provide an informal way for oncologists and practice members to support each other's efforts as they implement quality strategies in their own institutions.

Component Descriptions

1) The Virtual Quality Improvement (vQI) Curriculum: This three-activity instructional design engages learners through the construct of participating in a QI initiative, focused on clinical decision-making, leadership training, data analysis, and team interactions, and following IHI's "Model for Improvement.". The premise of the curriculum is that learners play multiple roles within an oncology practice of a heath system that is initiating a QI initiative focused on specific quality issues reflecting increased immuno-oncology related capacity. Learners are made aware of the nature and magnitude of the quality issues at the health system and its impact on patient care. The baseline Quality Measure (QM) scores for the practice will be presented in the initial activity and the decisions learners make as they play the role of clinicians, quality officers, care managers, etc., throughout various scenarios within the activities will impact the results of the QI initiative and the improvement measured on the selected QMs. Specifically, algorithms will be created that adjust the selected QMs based on learner scores on challenge questions tagged to each quality measure. The activities of the curriculum are launched in a staggered fashion so that the responses from the previous activity and the advancements made to date on the quality measures are presented and discussed.

The curriculum offers multiple points of reflection, each providing participants the opportunity to consider what clinical, process, or behavior changes resulted in the changes to the QMs and how these findings relate to their own center. Learners will have the opportunity to visit their initiative Dashboard where they can view their own curriculum data to date, with peer

benchmarking, and the virtual health system's current progress on the selected quality measures. The key advantage of this model is that changes to the QM benchmarks are based on actual participant responses to interactive challenges throughout the activities, a powerful tool to motivate learners to implement these changes in their own practice to achieve similar results, and to put them on a track for continuous professional development and improvement.

a) Initial Module

The first activity sets the stage for the initiative. Learners will be presented with a full background of the oncology practice and health system, including its pertinent baseline quality measure scores. Benchmarks for these measures will also be provided when available or applicable. Participants then meet key decision makers and practitioners, help build the optimal QI team, and proceed to engage with approximately three-to-four patient or practice scenarios, each with multiple quality challenges. Challenges are followed by peer benchmarking, and faculty commentary and guidance. An intervention plan to improve the selected QMs is a key component of faculty discussions and is determined at the conclusion of the activity.

b) Interim Module

The interim module will be launched 60-90 days after the initial activity. The distribution of responses from the previous module will be reviewed and applied to the interim results of the QI initiative. At the beginning of each interim module, the learner will view the updated quality measure scores. The QI team will discuss current achievements, and determine needed changes in the QI interventions per the PDSA (Plan Do Study Act) approach. The interim module will consist of multiple PDSA cycles. In each cycle, the QI team will review the latest quality measure scores, further analyze practice data, discuss necessary refinements to the intervention plan, and identify strategies to implement them. Throughout each PDSA cycle, learners are challenged to interpret data, identify barriers to improvement through a variety of patient or practice scenarios, and prioritize changes to be made in the current intervention plan.

c) Final Module

The final module will launch 60-90 days after the interim module. Participants will be presented with the final results from this initiative. These results will be based on the distribution of all participant responses to the challenges in the previous activities. Baseline vs. final quality measure scores of the practice will be shared with participants along with appropriate benchmarks. Faculty will discuss the advancements made and their impact on patient care, review persistent management challenges, and detail how the knowledge and skills gained during the training can be applied to real-world practice.

2) The Immuno-Oncology Quality Collaborative Regional Support Calls: Participants in the vQI Curriculum will be invited to join the Immuno-Oncology Quality Collaborative support calls, focused on helping members implement the quality strategies discussed in the vQI Curriculum within their organization. Collaboratives Support Calls will be organized by region, with the EU and US separated, and led by a QI thought leader who will moderate three conference calls over a twelve-month period. Each call will focus on an issue related to successful implementation of an immune-oncology related QI initiative. Joining the Collaborative calls will be voluntary but highly encouraged throughout the intervention period as extremely unique venues to exchange best practices with their peers. Summaries of each Collaborative discussion will be shared with all participants in order to demonstrate the value of participation.

EVALUATION DESIGN

The analysis of the initiative will provide, for the **first time, evidence of the impact of a scalable digital solution on a specific set of quality measures**. Curriculum activities are supported by the RealCME analytic platform, RealMeasure®, a patented, highly dynamic, comprehensive, and reliable program assessment platform. The activities, along with a Post Curriculum Assessments (PCA), will integrate the RealMeasure testing design. The platform collects a rich data set seamlessly and in real-time for analysis at the curriculum and individual activity level
In addition to the outcomes analysis using curriculum data, participants in the US will be assessed through the use of claims data that will be measured at baseline and an appropriate interval after the initiation of the intervention to demonstrate the impact of participation on their real-world patient-level outcomes (Moore's objective Level 5 and Level 6). **This analysis will confirm that participants have extended the educational impact into their practice and network**. (See Real World Data section below). RealMeasure® methodology enables objective and quantitative measurement of the effectiveness of the curriculum and its impact on learners' clinical practice. Assessment includes the RealIndex®, a multidimensional situation-based question that evaluates learners' performance of evidence-based best practices, as well as paired-question sets related to specific learning domains. The model employs a rigorous experimental design for accurate and reliable analysis and interpretation by experienced RealCME research associates. Data will be analyzed using statistical procedures intended to evaluate both the magnitude and significance of changes across the curriculum and in each activity. Analysis will be conducted using a matched-pair item methodology. **This evaluation design allows for participants to serve as their own control group, thus eliminating intersample variability and ensuring the accurate measurement of change over the course of the curriculum through follow-up**. Since the launch of the RealMeasure® platform in 2009, over 520,000 learners have participated in evaluated activities. This high volume of participants ensures that the psychometric properties of RealMeasure® are continuously evaluated, which affirms the reliability and validity of the platform.

1. Performance Measurement: The RealIndex® Model

The RealIndex model was developed in collaboration with New York University's Consortium for Research and Evaluation of Advanced Technologies in Education and is designed to provide meaningful insight into the effect of the curriculum on a learner's clinical practice.

A. Methodology: The RealIndex is a composite score based on a multidimensional question that addresses the learning objectives identified in the curriculum. Participants will be presented with a real-life clinical scenario, followed by a series of statements to be assessed as either consistent with or inconsistent with evidence-based best practice and with actions they would take in their own practice. The RealIndex is administered prior to the first activity of the curriculum (baseline), after the completion of each activity, and finally in a post-curriculum follow-up assessment (PCA). A schematic of the assessment design is provided in Figure 2.

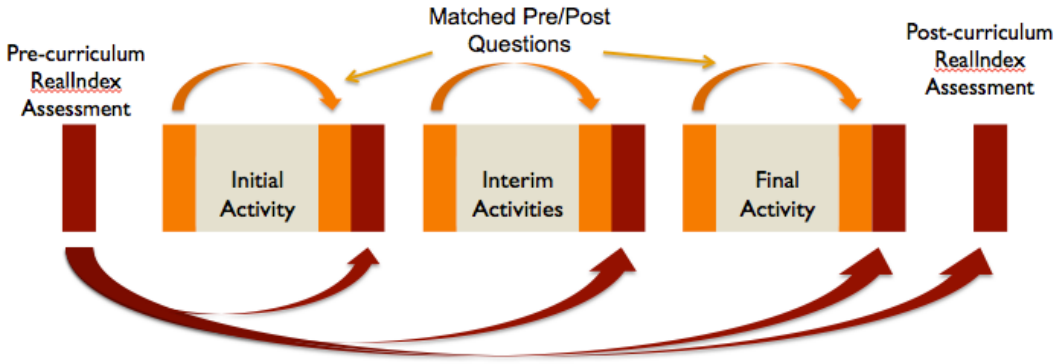

Figure 2. Schematic of Learner Data Collection Pathway

B. Learner-Pathway Analysis: Performance analysis will include the measurement of change in the RealIndex from baseline to the final intervention. It will also measure the impact of participation in multiple activities, of different types of activities, and the cumulative effect of each additional activity on the change in RealIndex from baseline.

C. Reliability and Validity: Reliability has been established through over 400,000 learner interactions with the RealIndex. Internal reliability (Cronbach's alpha) was conducted, and results indicated a high level of consistency in the measure with alpha coefficients ranging from .715 to .838. The progression of a learner's RealIndex score from baseline correlates positively with self-reported behavioral changes in their practice (measured at follow-up). Construct validity was substantiated through confirming the positive convergent relationship between learner domains and the RealIndex across curricula.

II. Evaluation by Learner Domain

Each activity in the RealMeasure platform contains a variety of question types that focus on specific learner domains: knowledge, competence, confidence, and practice strategy. Learning

objectives and subject areas identified in the needs assessment will be assigned to specific questions. In addition to the clinically-focused domains, questions will also be tied to specific QI-related domains, and improvement in each of these domains will be tracked and reported, including assessment skills, leadership skills, problem solving, empathy, and communication.

A. Methodology: All questions presented to the learner in the Pre-Test of an activity are paired with the identical question in the Post-Test and follow-up (PCA). Changes in learner domains will be evaluated cumulatively across a curriculum, as well as by activity.

Question Type	Point of Administration	Question Format	Assessment
Knowledge	Pre-test, Post-test, PCA	Multiple Choice, True/False	Scored
Competence	Pre-test, Post-test, PCA	Multiple Choice, True/False (case-based)	Scored
Confidence	Pre-test, Post-test, PCA	Likert Scale	Self-report (non-scored)
Practice	Pre-test, Post-test, PCA	Likert Scale	Self-report (non-scored)
RealIndex®	Presented prior to initial curriculum activity, after each activity, and PCA	Clinical vignette, multiple statement, drag-and-drop categorization	Scored

B. Reliability: RealMeasure assessment of learning domains has shown consistent performance across curricula. Global improvement across learning domains averages 30 percent from cumulative Pre-Test to Post-Test. These global gains also translate to a 30 percent average improvement in the learning objectives and subject areas scores identified across curricula.

III. Retention Analysis

The Post Curriculum Assessment (PCA) will measure learners' retention across all domains. The PCA includes the RealIndex® and a selection of questions previously presented in the curriculum, which cover all learning objectives and question types.

A. Methodology: The PCA is delivered to learners six to eight weeks after the completion of their final curriculum intervention. To ensure accurate measurement and analysis, the PCA is individualized, based on the time of a learner's curriculum completion and the specific items they completed within the previous activities.
B. Reliability: The PCA has shown consistency across multiple RealCME curricula. Global net increases in the RealIndex, measured from baseline to the PCA, average 11 percent. Net changes in learner domains demonstrate increases that average from 6 percent to 30 percent across question types.

Real World Data

Learners participating in the vQI curriculum in the US will be assessed using claims data, to demonstrate the impact of participation in the vQI curriculum and the Collaborative on their real-world patient-level outcomes. Real world data will be measured at baseline and an appropriate interval after curriculum participation. Additionally, predictive modeling will allow

us to profile the educational impact on specific learner profiles, (based on location, practice type, years in practice, affiliations, types of contracts, etc.), and identify which aspects of the intervention had the greatest impact on learners' real-world practice behavior, such as the incremental impact of participation in the Collaborative Support Calls. **Claims data measures will be selected by faculty and may include**: 1) utilization of biomarker testing, based on evidence-based guidelines and expert recommendations, 2) initiation of checkpoint inhibitor therapy in both treatment-naïve and treatment experienced settings, depending on the approved indications of each agent, 3) identification and management of irAEs consistent with evidence-based guidelines and expert recommendations and measured by reduced ER visits, reduced irAE-related hospitalizations, and reduced interruptions of therapy, and 4) use of patient/family-directed decision support tools. The source of the claims data will be Decisions Resources Group (DRG), a provider of healthcare analytics. DRG has a database of 280 million unique U.S. patients with over 5 years of historical data, including 1,100 cancer centers, 6.6 billion medical and pharmacy claims, and EHR data for over 46 million patients. This depth of data enables analysis of care across all therapeutic areas, including referral and treatment patterns. Lastly, 1.6 million U.S. healthcare providers are represented in their provider databases allowing for detailed profiling and cohort analysis of healthcare providers**. Key evaluation metrics include** engagement, which includes total participation, activity engagement levels, multi-activity participation, and pre/post curriculum improvement across all learning objectives and all domains (clinical and QI); final QM scores of virtual oncology practice (driven by learner responses); participation numbers in Immuno-Oncology Quality Collaborative Support Calls; and pre/post intervention real world data extractions (claims data in US)

DETAILED WORKPLAN AND DELIVERABLES SCHEDULE

Task	Timing
Faculty recruitment and briefing	October - November 2017
Content development Activity 1	November 2017-January 2018
Launch of Activity 1	January 2018
Content development of Activity 2	February 2018-March 2018
Launch for Activity 2	April 2018
First Set of Collaboratives: May	June 2018
Content development for Activity 3	May 2018 - June 2018
Launch for Activity 3	July 2018
Interim Outcomes Report	August 2018
Second Set of Collaboratives	September - October 2018
Third Set of Collaboratives	November - December 2018
Final Outcomes Report	June 2019

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