# Designing a public-private consortium to address the challenges of multicancer early detection

## Executive summary

A new frontier in cancer screening is leveraging liquid-based detection, which look for signals of cancer in blood, urine, or stool samples, to create multi- rather than single-cancer screens. For those organizations focused on advancing multicancer early detection (MCED), the ambition is to develop blood tests, that could potentially be ordered annually, to screen healthy individuals for early signals of cancer, catch cancer earlier, and ultimately save more lives.[1]

This emerging technology represents a paradigm shift in cancer detection: moving from screening select individuals at higher risk of developing specific cancers to screening the broader population for 10–50 possible cancers at once. MCED has the potential to reduce mortality through earlier detection and treatment of cancer and its advocates believe the technology has the potential to significantly improve public health. However, this shift is not without challenges—namely, defining the clinical utility, value, and efficacy of MCED and preparing health systems for the systematic changes in cancer-care workflow.

Throughout the second half of 2020, Tapestry Networks engaged primary care and oncology healthcare stakeholders in discussions to understand the key concerns facing the adoption of MCED and established the need for a focused and inclusive consortium to address these issues. This work culminated in the December 2020 MCED Forum, where participants coalesced around what approaches could be taken by a multistakeholder, public-private consortium to address MCED challenges and laid the groundwork for such a consortium to take shape.

Key takeaways from the MCED Forum are as follows:

- **There is a need for a public-private consortium dedicated to MCED.** Participants overwhelmingly agreed that MCED represents a paradigm shift in cancer detection and that for the broader healthcare community to accept these technologies, it will require a proactive—rather than reactive—review of potential hurdles.

- **The consortium should prioritize the dual challenges of defining and evaluating clinical utility and establishing care pathways for clinical implementation, keeping in mind the need to educate clinicians and the public on MCED.** Focus areas for the clinical utility workstream could include defining pragmatic endpoints, modeling the consequences of MCED, and using real-world evidence to evaluate MCED's clinical utility. Focus areas for the care pathway workstream could include developing a stepwise approach to disseminating care pathway guidance, exploring the link between pathways and reimbursement, and evaluating existing roadblocks to current screening recommendations. Participants continued to debate the appropriate value message of MCED but agreed that education should be included in the consortium's work to ensure there is a *"common language"* and better understanding of MCED across stakeholders.
- **The mission statement and guiding principles should address concerns regarding the consortium's ability to succeed, including key questions on credibility.** The consortium's credibility—or potential lack thereof—is a source of many risks and challenges facing its work. Defining a mandate too broadly could also reduce the likelihood of the consortium's success. Participants suggested developing a *"tightly defined mission statement"* to guide the consortium's actions and delineate it from other efforts in the space. They also indicated that prioritizing the guiding principles of integrity, health equity, objectivity, inclusivity, transparency, simplicity, and productivity would provide the consortium with the tools needed to proactively address success risks.
- **The consortium should launch with a small and agile steering committee tasked with further defining the consortium's structure and laying the groundwork for an inclusive membership.** Specifically, this steering committee will be tasked with refining the consortium's mission, guiding principles, and end goals; designing initial workstreams and identifying the projects within them; identifying an institutional home for the consortium; establishing additional governing bodies; securing sufficient seed funding and developing approaches for longer-term support; and exploring the creation of a public advisory group.

Participants recognized that there is currently an *"enormous opportunity for us to do something that really could reshape how cancer prevention is defined and delivered,"* and they look forward to launching an MCED consortium in 2021.

# Introduction

"Detecting cancer early can be the difference between life and death. When cancer is caught early, it is often easier and less costly to treat, and patients are more likely to survive. The importance of early detection has been made clear with widespread adoption of screenings like mammograms and colonoscopies, leading to a substantial reduction in mortality."[2]

—Lisa Lacasse, President of the American Cancer Society Action Network

*"MCED is a paradigm shift. It has the components of a technology advance plus the complexity of entering the spectrum of cancer workflows. We will have enormous evaluation and implementation challenges, and a lot of unanswered questions. No one group makes the decision about how to move forward. Having a consortium with a broad perspective of very different stakeholders and viewpoints is going to be critical."*

—MCED Forum participant

It is well known that detecting cancer in earlier stages is linked to more effective treatments and a better chance of long-term survival.[3] However, early cancer screens are only available in the United States for five types of common cancers—colon, breast, prostate, lung, and cervical—while the United Kingdom offers three—bowel, breast, and cervical. Other cancers are detected only after symptoms arise, arguably when it is already too late for effective treatment.[4] In response, organizations are investigating novel ways to screen for cancers earlier and to screen for multiple cancers simultaneously. Liquid-based detection, which looks for signals of cancer in blood, urine, or stool samples, are gaining traction in the research community as they are a less invasive cancer-detection approach and have the ability to detect multiple cancers at once, including those cancers that are typically diagnosed at later stages.[5] For those organizations focused on advancing multicancer early detection (MCED), the ambition is to develop blood tests, that could potentially be ordered annually, to screen healthy individuals for early signals of cancer, catch cancer earlier, and ultimately save more lives.[6]

MCED represents an evolution in cancer-detection technologies and its advocates note that it is an enormous opportunity to improve public health.[7] By screening for exponentially more cancers and before symptoms arise, MCED technologies could dramatically increase early cancer detection rates, reducing mortality and the burden of cancer while improving patients' lives. However, MCED faces some skepticism from the broader medical community, given ongoing debates regarding the clinical utility (the usefulness of a test for clinical practice[8]) and effectiveness of single-cancer screens. They fear potential overtreatment of slow-growing

Designing a public-private consortium to address the challenges of multicancer early detection

cancers, which may be best approached with a "watch and wait" strategy, or invasive diagnostic procedures for false-positive results, both of which can have harmful repercussions for patients.[9] This caution is also held by guideline agencies such as the US Preventive Services Task Force and the UK National Institute for Health and Care Excellence, which do not recommend early screening for asymptomatic adults for many cancers.[10] The debate about weighing the harms versus the benefits of cancer screens is magnified with the introduction of MCED because the value calculation becomes incredibly complex, simultaneously evaluating multiple patient populations and cancers.

Despite these concerns about MCED's application, the field continues to make progress. Clinical trial results suggest that MCED tests are technically sound in successfully identifying multiple cancer signals.[11] Innovators in this space are expected to release additional trial results in 2021, and some are working with health systems—most recently, the UK National Health Service announced a pilot with GRAIL—to launch pilots exploring the real-world applications of these technologies,[12] prompting some to expect that the technology will be available on the market sooner rather than later.[13] Given that MCED represents a significant departure from current single-cancer screening approaches, its anticipated arrival has prompted many stakeholders in the oncology community to ask how they can prepare for these tests. They noted that understanding what this technology can and cannot do is critical to ensure value to patients and the public.

Throughout the second half of 2020, Tapestry Networks engaged primary care and oncology healthcare stakeholders in discussions to understand the key challenges and concerns facing the adoption of MCED and what approaches could be taken by a multistakeholder, public-private consortium to address these gaps. Discussions culminated in the MCED Forum held on December 4, 2020. *For a list of all discussion contributors, please see Appendix 1, on page 16.*

Across conversations, participants considered the following questions:

- Where is there a need for a public-private consortium focused on MCED?
- What focus areas should this consortium address?
- How can this consortium proactively address risks and ensure success?
- What is the optimal design for this consortium?

This *ViewPoints* synthesizes the views that arose during the MCED Forum and in the conversations with a broader group of stakeholders that preceded it, along with additional external analysis when relevant.

## Affirming the need for an MCED public-private consortium

> *"It's a good opportunity to have conversations about MCED in advance and address not only the challenges we know about but identify the challenges we haven't yet realized will be there."*
>
> —Clinician representative

Many consortia, such as BloodPAC, the International Alliance for Cancer Early Detection, and the Early Detection Research Networks[14] are already advancing various topics linked to liquid-based and early cancer detection, generally focused on early-detection research and the analytical and clinical validity of these technologies. However, given that MCED marks a major shift in thinking from a single-cancer to a multicancer detection paradigm, participants agreed that for the broader healthcare community to be accepting of these technologies, there needs to be a proactive focus—*"ahead of time rather than just in time,"* as one participant said—on the wider challenges facing their clinical adoption. All participants acknowledged that the challenges are beyond any one organization to address and a broad range of public- and private-sector entities need to be engaged. They affirmed that creating a public-private consortium dedicated to addressing the challenges of MCED posed an exciting opportunity to advance public health. As one participant voiced, *"The science is fascinating and there is a real opportunity here. The question is how do we accelerate MCED so it improves patients' lives and aligns with patient values?"*

### Proactive preparation is critical to build on lessons learned from the introduction of past screens

When MCED technology launches on the market, it will not be introduced into a vacuum. Participants noted that MCED technologies can learn from the past introductions—and mistakes—of previous screens, highlighting lessons from the prostate specific antigen (PSA) screen for prostate cancer and 23andMe's direct-to-consumer genetic-risk screening. In the 1990's PSA screening became widespread and led to the overdiagnosis and harmful overtreatment of men who had non-life-threatening cancer.[15] Participants recommended that MCED evidence receive careful consideration to proactively identify which populations and/or cancers will be helped by the technology. As one payer stated, *"I would hate to relive the lessons of prostate cancer with this technology. When PSA screening came out, we all thought it was great—we penalized providers for not using it! As more evidence came out, we took away PSA screening and now we say there is value in the screen when it is used in a nuanced way."* Additionally, participants pointed to 23andMe, and its lack of clinical utility and guidance that left clinicians unprepared or unable to respond to results,[16] as a reason to proactively educate clinicians on the technology and prepare them with clinically appropriate workflows. One said, *"23andMe came out with great fanfare—but what were we supposed to do with these patients? It created a whole generation of really anxious patients and proved that using molecular tests to do mass screening can do harm. It was an abject disaster."* Moreover, as another participant noted, MCED is *"different than anything we've experienced in the past—it*

*is multicancer,"* yet stakeholders are accustomed to exploring the value of cancer screens on a cancer-by-cancer basis. Participants agreed that having a consortium of leading relevant stakeholders would demonstrate to the broader medical community that leaders have *"coalesced around the issues and been thoughtful in addressing them"* and, as such, would help pave the way for a paradigm shift from single to multicancer detection.

## Multiple challenges to MCED present opportunities for a consortium

Participants pointed to four core challenges to the application of MCED technology that a consortium could seek to address:

- **Defining the clinical utility, value, and efficacy of MCED.** The largest concern among participants was the possibility for patient harm—physically, mentally, and financially—due to overdiagnosis, overtreatment, or being diagnosed with a cancer for which there are few treatment options. One participant noted, *"It will be easier to perform the test than the treatment. What will happen to these patients?"* Many had concerns that MCED would simply introduce new costs to the healthcare system without producing additional value associated with early clinical interventions. One participant expressed the need to discern, *"When is the test truly a value-add from both a clinical and cost perspective?"*

> *"This whole business of finding cancer early doesn't always work out. We've tried it before, and it led to all these invasive procedures when there was no cancer."*
>
> —Payer representative

- **Equipping clinicians and health systems for the systematic changes in cancer care associated with MCED.** Participants wondered how MCED would fit in the current screening and diagnosis landscape and feared that clinicians and health systems are not ready for the resulting workflow changes. They highlighted that there are many stakeholders—primary care, diagnostic and other specialists, navigators, and oncologists—who help diagnose and care for a cancer patient. Moreover, these stakeholders may operate across a range of healthcare organizations, making education as well as the coordination and optimization of the workflows difficult. *"This is the hard part,"* one participant said. *"How do you orchestrate a market reaction among primary-care providers and the universe of specialists that could be called upon? I'm assuming the 99% won't be ready for the first case and their practice pattern will not be informed by evidence. I worry a lot about adoption and real-world use without the mapping of what the follow-on should be."*

- **Responding to the lack of adequate research investment in both early cancer detection and early cancer treatments.** The great majority of cancer research is focused on treating end-stage disease while historically less than 15% of national research funding goes to early detection.[17] Participants highlighted this outsized investment and agreed that for MCED to make an impact on health, there needs to be a shift in investment dollars to support both

early cancer research and research on clinically relevant treatment options for these cancers. Otherwise, there could be patients diagnosed with early cancers without any optimal treatment options, as one participant noted: *"Surgery will be the answer in a lot of cases, but it's not always."*

- **Concern about patient protections if/when MCED is broadly adopted.** Presently, MCED technology is being presented as a cancer screen that will require follow-up confirmatory diagnostics. Nevertheless, participants worry that MCED results could be used to establish a preexisting condition for patients even if they do not explicitly confirm a cancer diagnosis. Participants fear the technology could unintentionally lead to widespread discriminatory practices—potentially for health insurance, depending on the future legal standing of the Affordable Care Act, and certainly for life, long-term, and disability insurance, for which there is no preexisting condition protection.

Recognizing there is a need *"to define the level of evidence to make MCED worthwhile for everyone"* and *"to figure out how to implement this technology to the betterment of all we serve,"* participants prioritized the first two areas, as these are the most pressing challenges gating MCED technologies.

## Clarifying the consortium's initial focus areas: defining and evaluating clinical utility, preparing new care pathways for clinical implementation, and educating the public

> *"The test is a static moment in time; the value is what comes after. Establishing the follow-up workflows and addressing barriers will be absolutely critical to demonstrating value."*
>
> —Payer representative

According to a participant, *"defining clinical utility for multicancer early detection tests, understanding where there is utility because the benefits outweigh the harms, and drafting conceptual guidance on implications for care pathways and interactions with individuals"* are the utmost priorities for an MCED consortium. Participants affirmed that defining clinical utility and establishing associated care pathways for MCED technology are inextricably linked issues and therefore should be addressed in tandem. Additionally, they recognized that educating clinicians, patients, and the general public will be a cross-cutting issue for the consortium that cannot be overlooked.

### Addressing MCED's clinical utility includes the need to establish interim usage guidelines

In healthcare, clinicians typically rely on guidance from official bodies, such as the US Preventive Services Task Force or the UK National Institute for Health and Care Excellence, as gold-standard guidance that can help define clinical utility. However, in the case of MCED, participants acknowledged that guidance from official entities *"will require a greater body of evidence than what we have now or are likely to have in the future."* As such, participants

acknowledged the need to think both carefully and creatively about the guidance and evidence required for clinical usage, given the potential value of MCED. *"The conundrum is that it takes so much time to show differences in mortality, but if you're short of that, there is so much skepticism from the physician community,"* one participant said.

The MCED consortium could fill the gap by developing interim value analyses and guidelines or guardrails for MCED usage, knowing these might be more restrictive at the start but could broaden over time as more data is accumulated. Specific suggestions for the focus of this work include the following:

- **Thinking creatively to define endpoints that expedite the evaluation and adoption of MCED.** It will be essential to ensure that these endpoints are rigorous enough to convince physicians of the technology's utility. Endpoints will also be important for comparing MCED technologies with one another. Some agreed with the suggestion that the consortium's first output should be *"a white paper that looks at the endpoints and evidence that are warranted for widespread adoption."*
- **Modeling the consequences of MCED by cancer types and/or use cases.** Participants noted that an analysis of *"the trade-off between helping people versus harm of false positives"* could be a quick win, but that additional, real-world data studies would be critical.
- **Using real-world evidence to evaluate MCED's clinical utility.** Participants expressed broad support and excitement for a pilot project that could compare early MCED adopters–categorized by state, region, health system, or high-risk patient population—with appropriate control groups. Some noted this approach could study the clinical benefits and economic value of the technology.

## Defining MCED's application in clinical practice will require establishing care pathways that address existing care challenges

> *"How do we implement MCED so that patients will be better off than they are now? If you screen, then there should be a course of action with the results."*
>
> —Payer representative

One patient advocate noted, *"Three of the scariest words someone can hear are 'you have cancer,' but perhaps the four scariest words are 'you may have cancer.'"* Participants believed strongly that clinicians would need to be equipped with detailed care pathways—whether newly designed, or existing pathways adapted to the new technology—to properly work up a positive MCED result and determine if the patient has cancer as well as to decide the most appropriate treatment (which could include active surveillance). Anything short of that was equated to *"unleashing a tempest in the health system."* They also acknowledged care pathways would need to consider the current state of cancer care diagnosis and delivery in the United States, which varies widely because of local care availability and access.

The MCED consortium could develop, evaluate, and recommend care pathways for positive MCED results, though participants recognized this effort would take time as more data from ongoing clinical trials are needed to guide decision-making. Specific suggestions for the focus of this work include the following:

- **Taking a stepwise approach to defining and disseminating care pathways.** Participants noted that *"working up these tests is completely new and different"* and would require—at least initially—dedicated expertise to interpret results, consider current guidelines, and decide on what is needed and next steps. Some participants suggested that creating, evaluating, and disseminating care pathways should happen in a progressive fashion. In this example, the work would initially be focused on the academic researchers following clinical-trial patients. Once their workflow is established and validated, it could be transitioned to high-risk centers of care run by diagnostic specialists, and eventually to primary care. One clinician mused, *"There is a way forward to democratize the work-up of the patient, but my instinct is to go slow and allow time for the medical community to learn and disseminate the knowledge."*
- **Exploring the link between pathway adoption and reimbursement incentives.** Multiple participants pointed to the role of reimbursement in physician behavior and pathways adoption. One participant gave the example of primary-care clinicians in a capitated-care environment who *"won't be paid more to manage early cancer detection"* as a potential barrier to getting primary-care clinicians involved. Another noted that if payers decided to reimburse all follow-up care resulting from a positive MCED test, *"then you will see specialty diagnostic clinics popping up because it will result in downstream revenue."*
- **Addressing existing roadblocks to current screening recommendations and compliance.** Participants were quick to note that *"the transition [from primary care to oncology] is not smooth on the best of days"* and that current cancer screening pathways already face a litany of barriers that will not disappear just *"because it is easier to perform a simple blood draw."* The consortium will need to explore how MCED care pathways can address health disparities and care barriers such as lack of care coordination, access to diagnostics and follow-up care, and patient compliance.

## Public education and communication cannot be overlooked

Participants agreed that educating clinicians, patients, and the general public should be included in the consortium's work so that everyone can *"speak to the patient with a common voice and a common understanding of what we know and what we don't know yet [about MCED]."* However, the debate remains around what value message should be communicated and when to begin that communication.

While many participants emphasized MCED's value message for individual patients, some suggested the consortium consider alternative messages focused on the value more broadly.

Designing a public-private consortium to address the challenges of multicancer early detection

One suggested the messaging goal be *"reducing aggressive or bad cancers in the population"* while another stressed the value in identifying patients with cancers that were previously undetectable in the early stages and funneling them into research efforts.

Generally, participants agreed that *"it is premature to get into patient education"* because comprehensive patient-education strategies are dependent on clinical-trial results. However, a few dissented, instead advocating for educating potential patients and the public as clinical utility work is better understood.

## Addressing concerns about the consortium's ability to succeed

Participants repeatedly noted potential concerns about the consortium's credibility—specifically, the fear of being perceived as favoring one specific company rather than working precompetitively with a variety of MCED innovators or as potentially excluding, and offending, necessary stakeholders relevant to the application of MCED. Participants also expressed fears that the consortium may not be successful because of either an inability to focus—*"going so broad you can't get things done,"* as one said—or wasting time and energy on reinventing the wheel. Participants proposed a mission statement and guiding principles to address concerns regarding the consortium's credibility and, ultimately, its success. *For a full list of considerations of consortium risks and amelioration approaches, please see Appendix 2 on page 19.*

Participants emphasized the need for *"tightly defined mission specification"* to guide the consortium's actions and delineate it from other efforts in the space. There was strong consensus that *"the consortium's mission is different from industry's"* and could be loosely drafted *"to define what clinical utility would look like, what adoption would look like, and what it would require to get the technology into the community at large."*

Participants prioritized the following principles to guide the consortium's work and address credibility and action concerns:

- **Integrity and health equity.** Overwhelmingly, participants agreed that *"the principle of 'do no harm' weighed above all else."* Also, recognizing that underserved communities already lack equal access to cancer care, participants stressed the need to make reducing disparities in care a *"front-and-center priority."*

- **Objectivity.** The consortium must not appear to further a specific organization's agenda, especially for nonprofits and clinicians to participate. *"There is a need to ensure this is an honest, objective broker of utility and value as opposed to a commercial aspiration,"* one participant said.
- **Inclusivity.** Recognizing the need for collective rather than individual efforts, participants stressed the need for the consortium to be inclusive. *"The more a group like this can make an effort to collectively answer questions, as opposed to going off on our own or have multiple small groups cropping up, is a good investment,"* one said.
- **Transparency.** Acknowledging the current atmosphere of highly variable public trust of science, some urged the consortium to *"appreciate people's general skepticism and lack of trust in new technology"* and to counter it with transparency, clearly sharing and articulating all evidence so that *"if we say MCED is high value, people can see exactly why."*
- **Simplicity and productivity.** Participants suggested keeping initial consortium tasks simple—and building upon them incrementally—to ensure immediate productivity and successful progress to outcomes. *"If a barrier is hit, we need to identify why and how to get over it. What needs to happen to keep actions moving forward so an effort of this magnitude doesn't get wrapped up in its own complexity?"* one said.

*"We will need to ensure access to underserved communities, not just for the test but for the follow-on care. We must ensure a continuum of care for underserved cancer patients and that we are not part of the problem in terms of widening the gap between the haves and the have-nots."*

—Patient advocate

*"We would not be comfortable being part of something that was feathering the nest of a single commercial entity. We would want to see equitable representation from all major companies in the space."*

—Patient advocate

*"An important principle is sustaining momentum. With other consortia, I feel like we read chapter one but don't get to chapter two in time, so we have to go back to chapter one. We need to avoid that here."*

—Clinician representative

## Building the MCED consortium: starting small and agile and expanding to be inclusive

Throughout the meeting, participants debated the value of launching a consortium quickly with a small and agile membership versus taking the time to build membership that is representative of all MCED stakeholders. Participants agreed that a more focused steering committee would be initially necessary to finalize the consortium's governance and operating structure. However, to truly address the challenges in the MCED space, this group would need to quickly grow to be inclusive of all relevant stakeholders required to shift the current single-cancer detection paradigm. They outlined specific suggestions for how to initiate the process.

## Steering committee tasked with laying the consortium's foundation

Recognizing that *"unless we move quickly, we will fall behind and our value will be diminished,"* participants supported launching the consortium with an initial small steering committee or *"central brain"* of 12–15 individuals. Membership of the steering committee is to be determined, but participants underscored that members need to have strong institutional backing behind them and should be deemed formal representatives of their employer organizations. Participants also strongly agreed that the steering committee should include an impartial chair who is knowledgeable about the landscape, *"can work effectively across all these stakeholders,"* and is familiar with underrepresented and underserved communities.

> *"The 'central brain' is not the full public-private consortium; it's just the start. Then we will build. Once we have clarity on the workstreams and these questions on structure, funding, and setup, then we begin to morph into the full, inclusive consortium."*
>
> — Industry representative

The intention is for this group to be *"small, agile, and ambitious,"* and its role will be to finalize key questions on the consortium's governance and operating structure. The steering committee's next steps include the following:

- **Refine the consortium's mission, guiding principles, and end goals.** The steering committee will iterate and finalize the concepts discussed during the MCED Forum to prepare for the official consortium launch.
- **Further design initial workstreams and identify projects within them.** While there was agreement that the consortium should focus on the topics of clinical utility and care pathways, specific approaches need to be detailed. The steering committee will define the initial priorities and projects for each workstream.
- **Establish governing bodies within the consortium.** Participants agreed that governance structures will depend on the selected workstream projects and required support. They made various suggestions for what that structure could look like, from funneled leadership to concentric circles of decision-making authority. The steering committee will establish a blueprint for how the consortium's governance model will evolve with membership growth and complexity.
- **Identify an institutional home for the consortium.** While there was strong support for creating an independent entity to house the consortium, participants agreed the process for establishing a 501(c)(3) organization is lengthy and cumbersome. Recognizing the need for speed, participants suggested the consortium be embedded or affiliated with an existing nonpartisan nonprofit with capabilities to support the science-driven goals of the effort, such as Cancer Research UK, Friends of Cancer Research, StandUp2Cancer, or the Foundation for the National Institutes of Health, initially. A few participants highly

encouraged an affiliation, with one noting, *"It creates an easier pathway to get people involved because the organization is known, plus you can be folded into existing infrastructure."* Additionally, this organization may be able to supply the impartial chair for the consortium.

- **Create a plan to secure funding that retains the consortium's independence and integrity.** Participants recognized that the scope of the consortium's actions and impact will be directly related to its fees or funding structure. One noted, *"If you go big in terms of size or projects, that means more staff, support, and therefore resourcing."* The steering committee will draft consortium revenue targets for potential projects and create plans to gather funds, whether through membership dues, sponsorship, or philanthropy.
- **Explore the creation of a public advisory group.** The importance of *"keeping public health at the center"* and creating a *"participatory role for patients to inform decision-making"* were consistent points of discussion. Participants suggested developing a public advocacy group comprised of 8–12 individuals from diverse backgrounds to *"offer their views on MCED and codesign the consortium."* Some expressed skepticism not of the idea but of how to find individuals who are representative of the public because *"everyone is a member of the general population, but individuals don't represent the general public—they represent themselves."* The steering committee will continue to explore whether such a group can be created and what their role will be within the consortium.

## Additional design recommendations for consideration

While participants agreed that the steering committee would finalize the consortium's structure, they also arrived at specific recommendations, including the following:

- The consortium will follow an "implementor model," where it will define, initiate, fund, monitor, and evaluate work that meets the consortium's objectives.
- The consortium will launch as a transatlantic organization focused on the United Kingdom and the United States, with the possibility to expand to additional countries over time.
- The consortium will hire dedicated staff members, rather than rely on volunteers, to provide support and ensure the consortium's speed and productivity.
- Representation on governance committees *"should be elected and rotating, with the opportunity for a variety of folks to serve."*
- As the consortium matures, it will be inclusive of all stakeholders relevant to the application of MCED in clinical practice, potentially including representatives from industry, clinicians (e.g., primary- and specialty-care clinicians, epidemiologists, care navigators, and radiologists), patient advocacy groups, payers, public- and community-health groups, pharmaceutical developers, additional subject matter

> *"We will need dedicated staff. They are the glue that holds consortia together; you cannot get anything done without them."*
>
> —Clinician representative

Designing a public-private consortium to address the challenges of multicancer early detection

experts, and other industry players interested in long-term health (e.g., life insurance companies).

## Conclusion

Participants repeatedly expressed their excitement to form a multistakeholder consortium that drives and informs the research, guidance, and education to improve MCED, with the goal of reducing the burden of cancer and improving patients' lives. One forum participant said, *"I think my enthusiasm that we can accomplish meaningful things together only increased based on the discussions and the engagement we had today. I think we all realize that there is such enormous opportunity for us to do something that really could reshape how cancer prevention is defined and delivered."*

Recognizing that, as one said, *"we'll get further together than we would independently,"* participants called for increased momentum to launch a multistakeholder MCED consortium. Next steps aiding the launch include finalizing initial organizational commitments for involvement in the steering committee, sharing broader communications about the consortium to both get the word out to potential stakeholders and avoid duplicating efforts, and a parallel search for the third-party home for this effort.

## About this document

*ViewPoints* reflects the use of a modified version of the Chatham House Rule whereby comments are not attributed to individuals, corporations, or institutions. Italicized quotations reflect comments made by participants before and during the meeting.

Tapestry Networks is a privately held professional-services firm. Its mission is to advance society's ability to govern and lead across the borders of sector, geography, and constituency. To do this, Tapestry forms multistakeholder collaborations that embrace the public and private sector, as well as civil society. The participants in these initiatives are leaders drawn from key stakeholder organizations who realize the status quo is neither desirable nor sustainable and are seeking a goal that transcends their own interests and benefits everyone. Tapestry has used this approach to address critical and complex challenges in corporate governance, financial services, and healthcare.

## Appendix 1: Contributors

The following stakeholders participated in discussions with Tapestry Networks; an asterisk denotes MCED Forum participants:

- **American Cancer Society:** Robert Smith, Senior VP, Cancer Screening*
- **American Society of Clinical Oncology:** Stephen Grubbs, VP, Clinical Affairs
- **Blue Cross Blue Shield Association:** Naomi Aronson, Executive Director, Clinical Evaluation, Innovation, and Policy; Lea Drye, Director of Clinical Science Services*
- **Broad Institute:** Viktor Adalsteinsson, Associate Director, Gerstner Center for Cancer Diagnostics
- **Cancer Research UK:** David Crosby, Head of Early Detection Research*
- **Cancer Research UK Manchester Institute**: Caroline Dive, Deputy Director*
- **Cancer Support Community:** Kim Thibodeaux, CEO*
- **Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy, Tufts Medical Center:** Tara Lavelle, Assistant Professor and Investigator*; Peter Neumann, Director
- **Columbia University:** Azra Raza, Professor of Medicine, Director of the MDS Center
- **CVS Health:** Roger Brito, Division Head, Enterprise Oncology
- **Early Disease Detection Research Project UK:** Saskia Sanderson, Chief Behavioral Scientist*
- **Exact Sciences:** Paul Limburg, CMO for Screening*
- **Freenome:** Girish Putcha, CMO and Clinical Laboratory Director; Valerie Veitengruber, Senior Director, Reimbursement & Health Policy
- **Foundation Medicine:** Jen Mills, Vice President, Patient and Professional Partnerships
- **Friends of Cancer Research:** Jeff Allen, President and CEO*
- **Georgetown University School of Medicine:** Kenny Lin, Professor of Clinical Family Medicine and Deputy Editor, *American Family Physician*
- **GRAIL:** Heather Braun, Director of Stakeholder Engagement*; Sara Hiom, Director of Cancer Intelligence, GRAIL Europe*; Sir Harpal Kumar, President, GRAIL Europe*; Joan Malcolm, Director of External Affairs*; Joshua Ofman, Chief of Corporate Strategy and External Affairs*
- **Guardant:** Kathryn Lang, VP, Outcomes and Evidence

- **Humana:** Bryan Loy, Corporate Medical Director, Oncology, Laboratory, and Personalized Medicine Strategies*
- **Intermountain Healthcare:** Lincoln Nadauld, Vice President, Chief Precision Health/Genomics*
- **Kaiser Permanente:** Daniel Jacobs, Reconstructive Surgeon
- **King's College London:** Peter Sasieni, Academic Director of King's Clinical Trials Unit and Professor of Cancer Prevention
- **Johnson & Johnson:** Avrum Spira, Global Head of JJ Innovation, Lung Cancer Center
- **Mass General Cancer Center/Harvard Medical School:** Keith Flaherty, Director of Clinical Research, Professor of Medicine; Josh Metlay, Chief, Division of General Internal Medicine; Lecia Sequist, Director of Center for Innovation in Early Cancer Detection, Professor of Medicine
- **Memorial Sloan Kettering's Center for Health Policy and Outcomes:** Peter Bach, Director
- **Milken Institute:** Ed Greissing, Executive Director, Milken Institute Center for Public Health*; Esther Krofah, Executive Director, FasterCures
- **Milliman:** Gabriela Dieguez, Consulting Actuary*
- **NHS England:** Sir Mike Richards, Chair, Independent Review of Diagnostic Services, and former National Cancer Director*
- **Ochsner Health System:** Phil Oravetz, Chief Population Health Officer*
- **Oregon Health and Science University School of Medicine, Knight Cancer Institute:** Tom Beer, Professor of Medicine and Deputy Director*; Brian Druker, Associate Dean for Oncology and Director*
- **Pacific Business Group on Health:** Emma Hoo, Director, Pay for Value*
- **Providence Cancer Center:** Walter Urba, Director, Cancer Research
- **Sarah Cannon:** Howard "Skip" Burris, President and Chief Medical Officer, and Executive Director of Drug Development, Sarah Cannon Research Institute; former American Society of Clinical Oncology president*
- **Stand Up to Cancer:** David Bernstein, Senior Director, Science & Strategy*; Jim O'Sullivan, Director, Philanthropy and Corporate Relations; Sung Poblete, CEO
- **University College of London:** Mark Emberton, Professor of Intervention Oncology and Dean of Faculty of Medical Sciences*; Yoryos Lyratzopoulos, Professor of Clinical Epidemiology, lead for Epidemiology of Cancer Healthcare and Outcomes Group, and

Senior Cancer Epidemiologist for the National Cancer Registration and Analysis Services of Public Health England

- **University of Cambridge:** Rebecca Fitzgerald, Interim Director of MRC Cancer Unit; Fiona Walter, Reader in Primary Care Cancer Research, Primary Care Unit, Department of Public Health and Primary Care, and Consultant GP at School of Clinical Medicine*
- **University of Michigan:** Daniel F. Hayes, Professor of Breast Cancer Research
- **University of Pennsylvania, Abramson Cancer Center at the Perelman School of Medicine:** Carmen Guerra, Ruth C. and Raymond G. Perelman Associate Professor of Medicine, Vice Chair of Diversity and Inclusion, and Associate Director of Diversity and Outreach*
- **West Yorkshire and Harrogate Cancer Alliance:** Sean Duffy, Clinical Director and Alliance Lead and Strategic Clinical Lead with Leeds Cancer Centre

## Appendix 2: Considerations of consortium risks and amelioration approaches

Participants discussed potential risks to the success of an MCED consortium and outlined possible amelioration approaches.

| Consortium risk | Amelioration approach |
|---|---|
| **Mission creep and consortia fatigue** | Set clear and attainable goals and timelines, demonstrate early value or quick wins, and ensure commitment for the long haul. |
| **Lack of credibility** | Establish partnerships with recognized nonpartisan groups, as well as a clear set of governing principles, prioritizing inclusivity and integrity. Include an impartial chair on governing structure. |
| **Lack of quality and progress of individual projects** | Develop a system to qualify and monitor projects in an unbiased way, allowing and supporting fast failure and retailoring of projects as needed. |
| **Inadvertently reinventing the wheel** | First step of each workgroup is to sort out what work and learning have already been done (published and unpublished). |
| **Lack of stakeholder engagement** | Clarify upfront what each stakeholder will get in return for their engagement and what the consortium can accomplish collectively that a single organization could not on its own. |
| **Reduced stakeholder engagement due to overlapping consortia** | Publicly communicate goals and ongoing outputs of the consortium and ensure dialogue, with complementary efforts to reduce duplication and amplify impact. |
| **Limited resourcing due to external economic and/or pandemic issues** | Reconsider the timing and focus of workstreams, and prioritize some over others if resources are temporarily limited. |
| **Unanticipated data challenges** | Shift focus to accomplish goals in alternative ways (e.g., if data necessary to inform the MCED modelling does not exist in the form or quality needed, shifting to planning for inputs from prospective real-world evidence designs to inform models). |

## Endnotes

[1] Organizational mission statements supporting this ambition include "What We Do: The Earlier the Better," Thrive Exact Sciences, accessed January 18, 2021, and "It Is Our Capability and Our Commitment That Make Us GRAIL," GRAIL, accessed January 18, 2021.

[2] American Cancer Society Cancer Action Network, "New Legislation Aims to Increase Early Cancer Detection in Medicare," press release, December 3, 2020.

[3] "Cancer," World Health Organization, September 12, 2018.

[4] M.A. Richards, "The Size of the Prize for Earlier Diagnosis of Cancer in England," *British Journal of Cancer* 101, suppl. 2 (December 3, 2009), S125-S129.

[5] "Liquid Biopsy for Early Cancer Detection," Canadian Cancer Society, November 15, 2017.

[6] "What We Do: The Earlier the Better," Thrive Exact Sciences, and "It Is Our Capability and Our Commitment That Make Us GRAIL," GRAIL.

[7] "New Research Suggests Multi-Cancer Early Detection Blood Test Could Reduce Late-Stage Cancer Diagnoses by More Than Half,"*Businesswire,* December 16, 2020.

[8] John W. Peabody, et al., "New Thinking on Clinical Utility: Hard Lessons for Molecular Diagnostics," *American Journal of Managed Care* 20, no. 9 (September 2014).

[9] Keren Landman, "The Hidden Problems of Early Cancer Detection," *Elemental,* January 6, 2020.

[10] See US Preventive Services Task Force negative recommendations for Pancreatic Cancer Screening, Ovarian Cancer Screening, Thyroid Cancer Screening, and Testicular Cancer Screening in asymptomatic adults.

[11] Ben Fidler, "Thrive, Chasing Grail with a Cancer Blood Test, Finds Tumors in Seemingly Healthy Women," *BioPharma Dive*, April 28, 2020.

[12] Conor Hale, "NHS to Pilot Grail's Cancer-Spotting Blood Test in 165,000 Patients," *Fierce Biotech,* November 30, 2020.

[13] "GRAIL Confirms Q2 2021 Introduction of Galleri, First-of-Kind Multi-Cancer Early Detection Blood Test," *Businesswire,* January 11, 2021.

[14] For more information on these consortia, see "International Alliance for Cancer Early Detection," Cancer Research UK, accessed December 2020; "About Us," BloodPAC, accessed January 18, 2021; "Objectives: The Intents of the Early Detection Research Network," National Cancer Institute, accessed December 2020. For information about recent and upcoming meetings, see "36th EDRN Steering Committee Meeting - Tuesday 27 October Agenda," National Cancer Institute, accessed January 18, 2021, and "The Early Detection of Cancer Conference," OHSU Knight Cancer Institute, Canary Center at Stanford, and Cancer Research UK, accessed January 18, 2021.

[15] "Confronting A Controversy- The PSA Question," Premier Medical Group, May 14, 2020.

[16] Megan A. Allyse, et al., "Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing," *Mayo Clinic Proceedings* 93, no. 1 (January 2018), 113-120.

[17] Susan J. Curry, et al., *Fulfilling the Potential for Cancer Prevention and Early Detection* (Washington DC: National Academies Press, 2003). 398-399.