

Multicancer Early Detection Consortium Initiative

September 2021

MCED

SUMMARY OF THEMES

Establishing the foundation for a multicancer early detection consortium

Multicancer early detection (MCED) is an emerging set of technologies that—with a blood, breath, urine, saliva, or stool sample—can enable clinicians to rapidly screen for multiple cancer types at once. These technologies could potentially be used in clinical care to screen asymptomatic individuals for signals of cancer, detect cancer earlier in symptomatic patients, and monitor cancer patients or survivors for residual or new signals of cancer.

Conversations around MCED technologies tend to center on their perceived ability to be used as a screen for early signals of cancer, when treatments are more likely to lead to better outcomes.¹ However, the introduction of MCED technologies will require careful risk-benefit analyses. While there are likely benefits to screening and diagnostic programs, these can also introduce patient harms (e.g., in leading to potential false-positive results). Additionally, many stakeholders in the healthcare community recall past medical innovations with troubled introductions into clinical care that led to public confusion.² Stakeholders fear that if the technologies are not properly evaluated for their clinical applicability—and clinicians and health systems do not proactively prepare for their implementation—the public will lose confidence in the technologies before they are optimized.

With the above challenges in mind, a group of leading public and private healthcare stakeholders recommended forming a consortium to evaluate the clinical and public health value of MCED.³ Subsequently, during the first half of 2021, a voluntary group of steering committee members and advisers representing a range of perspectives across the healthcare sector—including primary-care, population-health, and oncology clinicians and academics; payers; not-for-profit/patient-advocacy organizations; and industry representatives—initiated work to design this consortium. The MCED Consortium would help establish standards and implementation guidance for using MCED technologies in clinical care and seek to understand and address the impact of these technologies, especially on health equity.

This *Summary of Themes* synthesizes the MCED Consortium design effort, which built upon work in 2020, ran for the first half of 2021, and concluded with the creation of the MCED Consortium Blueprint, a consensus document that lays out the mission, scope, objectives, governance, work plans, and operating model for the group. The blueprint lays the foundation for a public-private collaborative that will be formalized as a not-for-profit organization. *For a*

list of steering committee members and advisers as well as additional contributors to the consortium's design, please see Appendix 1, on page 13.

Consortium design integrates takeaways from the MCED Forum

Efforts to design the MCED Consortium began in mid-2020, when Tapestry Networks engaged various stakeholders from the US and UK healthcare sectors to discuss key challenges and concerns regarding MCED technologies in oncology treatment and management.⁴ Discussions culminated in the December 2020 MCED Forum, where participants laid the groundwork to form the consortium, with the following key takeaways:

- **There is a need for a public-private consortium dedicated to MCED that encompasses the spectrum of healthcare stakeholders engaged in the potential use of these technologies.** MCED technologies, if successful, could usher in a paradigm shift in cancer detection; therefore, the healthcare community should proactively evaluate the potential hurdles and barriers to acceptance of these technologies. The work of this novel MCED Consortium would complement the efforts of ongoing consortia, such as BloodPAC, the International Alliance for Cancer Early Detection, and the Early Detection Research Networks,⁵ which do not specifically address the broader MCED concerns from an integrative health system view, inclusive of both public and cancer-patient needs. As one stakeholder emphasized, the MCED Consortium is not *“an oncology-only enterprise; it is a population-health enterprise.”*
- **The consortium should prioritize evaluating clinical utility and establishing care pathways, while also educating clinicians, patients, and the public and promoting health equity.** Forum participants recognized the 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.”* While they identified evaluating clinical utility and establishing care pathways for clinical implementation as the two most pressing challenges gating MCED technologies, they also noted an urgent need to ensure that these technologies do not exacerbate health disparities and that communication and 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 need to address concerns regarding the consortium's ability to succeed, including questions on credibility.** A *“tightly defined mission statement”* is required to guide the consortium's actions, ensure clear focus and action orientation, and delineate it from other efforts in the space. Guiding principles should prioritize integrity, health equity, objectivity, inclusivity, transparency, simplicity, and productivity. *The consortium's initial mission statement and guiding principles can be found in Appendix 2, on page 17.*

- **The consortium design process must move quickly while ensuring inclusivity.**

Participants supported initiating the consortium design work with a “*small, agile, and ambitious*” steering committee that would address key questions on the consortium’s work plans, governance, and operating structure. However, participants also stressed that the consortium would need to grow quickly and be inclusive of all relevant stakeholders to truly address critical challenges in the MCED space.

Blueprint focuses on action-oriented work plans, balanced governance, and a sustainable operating model

Over the course of six months, a volunteer group of steering committee members and advisers explored various approaches and key questions related to the design of an MCED consortium. Following an iterative process—including individual interviews to understand initial perspectives, group calls to debate various approaches, additional feedback interviews with a broad range of external stakeholders outside the group to challenge and test the design, and meetings to confirm the ideal strategy—the steering committee members and advisers drafted a consensus design document, the MCED Consortium Blueprint. This document will serve as a foundation for formalizing the MCED Consortium as a not-for-profit organization. Key aspects of the blueprint are summarized in the following sections.

The consortium will be a stand-alone nonprofit dedicated to evaluating MCED technologies

“This has been said many times, but our central value is to be guided by evidence, wherever that evidence leads—whether it leads to demonstration of benefit, lack of benefit, or even harm.”

—Primary care/public health representative

The MCED Consortium will be an independent, nonprofit, US-UK public-private consortium. Directed by its mission statement and guiding principles, the consortium aims to evaluate emerging data from MCED studies and establish standards in MCED technology by defining the clinical and public-health value of the technology, providing guidance for its use in clinical practice, and developing a public-outreach approach that identifies and mitigates potential health inequities that could arise from the use of MCED technology.

The consortium will operate at a precompetitive level and will not endorse or promote any specific MCED technology. As such, the consortium will not pursue the topics of clinical validity or reimbursement, although the consortium will be cognizant of ongoing work in this space, understanding that these may impact its work. Additionally, the consortium will seek to avoid duplicating the efforts of other groups by recognizing that regulatory- and coverage-related topics are being addressed through other organizations, and it acknowledges the need to ensure connectivity to the work of those groups as relevant.

Funding and membership options focus on driving work and sustainability

Consortium membership will be open to all US and UK organizations with an interest in advancing the consortium's work plan, the ability to meet membership resource requirements, and the willingness to affirm the consortium's disclosure and prohibition requirements—namely, a prohibition on having financial or business relationships with any tobacco, e-cigarette, or associated pass-through entity.

For organizations that meet the consortium's membership requirements, there will be two membership options: (1) enterprise membership, which allows companies and nonprofit organizations to participate in all the consortium's workgroups, and (2) per-workgroup membership, which allows for-profit companies meeting budget and revenue requirements to join specific workgroups. Individuals unaffiliated with a participating organization may also join the consortium as a volunteer at the workgroup level. Dedicated seed money provides for administrative operating costs, with membership and grant resources intended to support work streams.

Governance structure ensures independence and credibility

The consortium's governance structure will be streamlined to ensure the independence of the workgroups and expedite decision-making. The governance hierarchy will include an executive committee that acts as the face of the consortium, a collaborative steering committee to address project concerns, and individual workgroup leadership. Additional details on the functions of each group are as follows:

- **The executive committee will be the consortium's governing body.** The executive committee will be responsible for general oversight of the consortium. Oversight activities include fostering adherence to the consortium's mission and guiding principles, determining each workgroup's project funding, approving new members, and serving as the public face of the consortium. The committee will consist of 17 total seats, with three seats each assigned to representatives from industry, oncologists/specialists, payers, primary care/prevention, and public/patient advocacy. Government and public-sector representatives may also serve as executive committee liaisons in the future.
- **The steering committee will act as an oversight body for individual workgroup projects.** The steering committee will consist of the workgroup chairs and deputy chairs and be a collaborative body. It will have oversight of individual workgroup projects, troubleshoot potential roadblocks, and identify paths to move projects forward. The steering committee will elevate issues with individual projects, as needed, to the executive committee.
- **Workgroup chairs and deputy chairs will lead individual workgroup efforts.** Workgroup chairs and deputy chairs will be responsible for leading each workgroup and guiding project completion. Specific tasks will include overseeing and executing the project plan, monitoring progress against work-plan objectives and outcomes, ensuring scientific quality

and credibility of projects, and communicating with other workgroups, as relevant, to advance projects.

While the consortium’s executive committee may offer input and guidance for projects, day-to-day project oversight is the responsibility of each workgroup chair. The executive committee has the right to review a workgroup’s outputs/findings but cannot refuse to release conclusions. One exception to this principal is the Communications Workgroup, which will publish the consortium’s official positions and strategies, which must be approved by the executive committee.

Initial workgroups will focus on clinical utility, care delivery, health equity, and communications

The four initial workgroups—Clinical Utility, Care Delivery, Health Equity, and Communications—will execute projects to achieve the consortium’s work plan. Each workgroup will work independently but with close collaboration on shared topics, while soliciting feedback and suggestions from the executive committee and public representatives as appropriate. Workgroups will have designated consortium-funded chairs and be supported by the third-party institution’s administrative staff. The following sections provide further details on the focus of each workgroup.

Clinical Utility Workgroup will develop interim frameworks

Since a clinical utility framework for MCED technologies does not yet exist, the Clinical Utility Workgroup will engage and leverage the knowledge of the broader healthcare community—including regulators, guidelines developers, clinicians and academics, payers, and patients, as well as public-health, health-economics, and other subject-matter experts—to design interim clinical utility frameworks for using MCED technologies as a screen for asymptomatic individuals and a diagnostic for symptomatic patients. These frameworks will identify the specific cancers and populations for which the benefits of the tests outweigh the harms and propose pragmatic approaches for evidence generation. The frameworks will segment the cancers included in MCED tests into manageable groups, consider currently established endpoints and measurements, and be updated as further evidence related to MCED technologies is generated and published.

“One of the very important roles of this group is to understand the evidence base and to be able to use it in a way that’s productive. We have to base everything we do on evidence that is rapidly developing and going to be incomplete even when we want to make some recommendations.”

—Primary care/public health representative

Care Delivery Workgroup will create a library of associated care pathways

While the clinical utility of MCED technologies is being evaluated, the Care Delivery Workgroup will proactively develop guidance and associated clinical workflows for the technologies' introduction into clinical care as both a screen and a diagnostic test. Specifically, the workgroup will create a library of diagnostic and care pathways related to MCED technologies and test adjustments to these pathways in real-world clinical settings. It will also identify and propose workable approaches to infrastructure and workflow changes associated with the technologies' implementation. The workgroup will continuously study and adapt the diagnostic and cancer-care pathways and operational challenges associated with MCED tests as new data become available.

“Workflows are not crystal clear by any stretch. What happens after those tests come back? How do we go about counseling patients appropriately? How do we responsibly address the next steps? These are really important issues for the consortium to explore.”

—Payer representative

Health Equity Workgroup will address disparity issues

“We all know that as new technologies get introduced, they theoretically have the potential to sustain health disparities, enhance them, or reduce them—but most often they end up enhancing disparities.”

—Primary care/public health representative

The Health Equity Workgroup will evaluate and develop guidance on how the implementation of MCED technologies could be used to reduce healthcare disparities and advance health equity. This workgroup will include representatives from organizations focused on serving minority and underserved populations in their local communities. Members of the workgroup will be embedded in the Clinical Utility, Care Delivery, and Communications workgroups. The workgroup will proactively elevate and address disparities and health-equity issues within other workgroups as well as advance its own stand-alone efforts.

Communications Workgroup will design educational materials and promote the consortium's work

If MCED technologies ultimately demonstrate clinical utility, it will be critical to educate clinicians and the public about MCED so that everyone has a common understanding of what these technologies are, how they work, and their known risks and benefits. The Communications Workgroup will share and promote the consortium's lessons with a wider audience, design educational materials that prepare clinicians and healthcare professionals for the potential implementation of MCED technologies in clinical care, and develop communications and educational materials that foster better understanding of MCED technologies among the general public.

“MCED could reset the way we practice medicine. If it does, there's a huge opportunity and need to educate primary care, specialists, and the public on the underlying science.”

—Oncology representative

Workgroups will incorporate public representation

The consortium's work will have an impact on public health; therefore, public representation and/or public opinion must be incorporated into each workgroup. Broadly, there are three approaches the workgroups could employ—or blend—to incorporate public representation and/or feedback into their work:

- Partnering with an academic or medical institution to bring together relevant leaders that represent the public (e.g., schools of public health that focus on implementation science or health disparities), medical institutions researching MCED and working with existing patients, or an academic institution exploring the ethics of novel technologies
- Partnering with nonprofit organizations that focus on understanding consumer preferences to solicit public opinion (e.g., the National Consumer League, Consumer Reports, or existing nonprofits dedicated to understanding patient preferences)
- Creating a platform within the workgroup/consortium to solicit direct feedback from the public (e.g., focus groups, citizen juries, digital ethnography, or virtual platforms for public interactions)

“The patient’s voice is very important. If patients do not accept MCED, there’s no use in any one of us developing these innovations.”

—Patient advocacy

A third-party administrative body will support governance and operations

The consortium will rely upon its selected administrative body, Healthspieren, to provide the dedicated staff to support the consortium's operations, member relations, external stakeholder engagement, research/science expertise, and public-policy education and engagement. Healthspieren will also work with the consortium's leadership to establish the consortium as a separate 501(c)(3) organization and develop its multistakeholder funding model.

Rigorous testing and broad stakeholder consultation informed the blueprint, highlighting risks and measures of success

Designing the MCED Consortium did not occur in a vacuum. While steering committee members and advisers acted as the main architects of the consortium's design, they also tested various approaches and ideas with a wide range of outside stakeholders, whose feedback was actively incorporated into the final MCED Consortium Blueprint. Steering committee members and advisers also proactively shared drafts of the full blueprint with select stakeholders to act as independent reviewers. In July 2021, most of these outside reviewers joined the Final Design and Pre-Launch of the MCED Consortium meeting, where they discussed the blueprint, identified additional risks to the consortium, and collectively defined success for the consortium with steering committee members and advisers.

Stakeholder validation for the consortium and its focus areas

Stakeholders who contributed to the design effort expressed varying perspectives on MCED technologies. Some representatives of the primary-care, public-health, and payer communities expressed reservations. One reviewer warned, *“There’s a tacit assumption here that the technologies will prove valuable, but I’ve seen plenty of technologies that were promising and ultimately didn’t work out.”* On the other end, industry representatives and those who work closely with cancer patients were more optimistic, highlighting that *“the tests are ready, and their promise is huge.”* Others fell in the middle, believing the technologies are encouraging but that *“it’s absolutely critical for evidence to be generated”* to understand their clinical applicability. All agreed that much work needs to be done collaboratively across the healthcare system to ensure that these technologies, when ready, are implemented responsibly and effectively.

“A consortium of academia, industry, payers, healthcare providers makes a lot of sense. It is the right group of people to think through how we can best translate exciting technology into helping as many human beings as we can.”

—Patient advocacy representative

“There is a huge need for what the consortium is trying to do.”

—Oncology representative

Overall, stakeholders emphasized the need to proactively prepare for a future with MCED technology and embraced the MCED Consortium concept. They agreed that the work plans and consortium design proposed in the blueprint were *“thoughtful, transparent, explicit, very compelling,”* and complementary to existing efforts and groups in this space.

Considerations on health equity, data, and public representation

Stakeholders who reviewed the MCED Consortium Blueprint encouraged the steering committee members and advisers shaping the consortium design and work plan to integrate and address the following considerations:

- **The need to address health-equity challenges.** Stakeholders consistently noted that reducing disparities in care would be essential to the consortium’s work, with some underscoring that their main goal was *“to support the introduction of this technology in a way that will intentionally and very purposely reduce health disparities.”* Stakeholders suggested three core considerations for the Health Equity Workgroup. First, the workgroup should consist of representatives from organizations that are actively serving underserved populations in their communities. Many agreed that *“while traditional approaches from academia are very relevant, without community organizations, items will be missed.”* Second, the consortium should recognize that achieving equity is about not only addressing technology-access barriers but also *“ensuring that there is knowledge about the tests available in medically underserved communities.”* Finally, stakeholders highlighted the opportunity for the consortium to promote diversity in ongoing studies and *“target efforts in populations that have not been included in any of these studies.”* One clinician noted, *“We still do not fully understand the disparities or performance of PSA [prostate-*

specific antigen] screening in all populations. Without inclusion of diverse populations in trials, that mistake could be repeated in MCED.”

- **The role the consortium could play in the collection, harmonization, and standardization of MCED-related data.** Reviewers recognized that data reconciliation and analysis is going to play a key role in all the consortium’s workgroups and work plans. One public-health expert emphasized, *“There’s a lot of work that needs to go into thinking about how to unify and harmonize data across institutions and countries.”* While some proposed that the consortium consider tackling data-related issues directly, others noted that groups such as BloodPac may already be addressing data-standardization topics; therefore, the consortium might instead focus on ways to integrate data precompetitively to inform the workstream efforts.
- **The need for strong public representation and patient orientation within the consortium.** Although reviewers acknowledged that the focus of the consortium’s evaluations will be on MCED technologies, all agreed that patients and the public must be kept at the center of the work. As one stakeholder noted, *“We don’t take care of lab test results or even cancers; we take care of patients.”*

Potential consortium risks that leaders should manage

The steering committee and advisers proactively identified many risks to the consortium’s work and potential amelioration tactics. *See Appendix 3, on page 18, for this list.* However, blueprint reviewers highlighted additional caveats and complexities to consider:

- **The broader healthcare community may be skeptical of the consortium’s premise and composition.** Some stakeholders acknowledged initial hesitations about engaging in efforts to design the MCED Consortium, as they did not want to appear to be an industry agent. However, after reviewing the blueprint and seeing the proactive attempts to ensure the consortium’s credibility (e.g., impartial executive committee chairs, balanced stakeholder representation in the executive committee, and the autonomy of individual workgroups) all stakeholders expressed an interest in supporting the work of the consortium and remaining engaged with its efforts.

“I don’t want to be in a group to just rubber-stamp the technologies, but the intentions of this group are spot on.”

—Oncology representative

- **The consortium may feel compelled to make suggestions and/or draft guidance with limited evidence.** Some stakeholders feared that without robust evidence—especially from

“It is absolutely crucial that the evidence is generated in primary-care settings with nonspecific presentations in a range of ages; otherwise, this evidence is just not going to be useful.”

—Primary care/public health representative

primary-care settings, where the majority of MCED technologies are intended to be delivered—and with only limited understanding of an identified cancer’s natural history, such as whether a particular cancer tends to progress aggressively, the consortium could potentially move too quickly to make clinical utility and care delivery recommendations. This could, in turn, inadvertently promote access to *“unproven technology.”* Reviewers stressed that the consortium must be *“very, very mindful about what kind of actions we take and the responsibility we have in managing our momentum.”*

- **The consortium could exacerbate existing disparities by failing to account for clinical heterogeneity.** As mentioned above, stakeholders encouraged the consortium and the Health Equity Workgroup to pursue opportunities to promote diversity in ongoing MCED studies to better understand how these technologies perform in varying populations. They warned that *“one-size-fits-all guidelines are problematic”* and that the consortium could potentially *“run the risk of taking that pathway,”* inadvertently exacerbating disparities.
- **The consortium could hinder the understanding of MCED technologies with educational materials that are not adequately tailored to distinct populations.** Stakeholders reiterated that genomic literacy and knowledge of next-generation sequencing’s capabilities are not prevalent in the medical community or the general public. They worried that MCED technologies, if not explained well, could fail to be understood by primary-care clinicians and/or the public. They appreciated that the Communications Workgroup intends to conduct a landscape assessment to understand what the public knows and thinks about MCED technologies and stressed the necessity of considering the needs and preferences of various end users and populations—including underserved communities, both clinical and nonclinical—in communications materials.

“Clinicians, the public, and patient communities vary in their preferences across these complex areas of risk, benefit, and utility. It will be important to collect and integrate data to better understand their values.”

—Primary care/public health representative

- **Landscape changes in regulation or policy could potentially impact the consortium’s work.** Participants discussed at length whether it was wise to consider certain topics related to regulation (i.e., clinical validity and legislative policies regarding coverage and reimbursement) as outside the consortium’s scope. While participants ultimately agreed

“If the consortium is not going to address these [regulatory and legislative] issues directly, they need to at least set up the conversations because these are going to be significant debates.”

—Patient advocacy representative

that these topics are not precompetitive and acknowledged that other groups are addressing them (e.g., Early Detection Research Networks’ clinical validity work, International Liquid Biopsy Standardization Alliance’s regulatory efforts, and Prevent Cancer Foundation legislative efforts⁶), they stressed that the consortium should be aware of these efforts and understand how they

may impact the consortium’s work.

Proposed measures of success

Finally, reviewers discussed various measures by which to judge the consortium’s success, including the following achievements:

- **Creating consensus and consensus-based documents that move research forward.** Multiple stakeholders noted it would be extremely beneficial if the consortium could create MCED evidence standards that are utilized broadly in the community and scientific literature. Clinicians and researchers could cite these similarly to how, for example, they currently use the Consolidated Standards of Reporting Trials Statement and/or the Standards for Reporting of Diagnostic Accuracy Studies statements.
- **Creating solutions for a diversity of patients that help close the health-equity gap.** Many stakeholders believe that reducing gaps in health equity would be the most significant measure of success for the consortium. They noted that success would entail not only expanding access to high-quality screening and diagnostics to populations that have traditionally been marginalized from such access, but also continuing to prioritize health equity as a consortium priority and *“proposing solutions to these [issues] and approaches that get ahead of the game.”*
- **Being viewed as a credible leader on MCED technologies.** Part of the consortium’s success will be reflected in ongoing, long-term engagement by key thought leaders and organizations. *“We’ll know that we are successful if people stay involved and we are viewed as the trusted group on MCED,”* a participant noted.

Conclusion

Stakeholders involved in drafting or reviewing the MCED Consortium Blueprint expressed diverse viewpoints and perspectives regarding the technology and its future clinical applicability. Nevertheless, all acknowledged that the establishment and design of the consortium to date reflected a tremendous accomplishment in and of itself. They also

recognized its outsized potential to impact public health with the technology. One stakeholder summarized, *“I am enormously excited by the consortium’s mission and the blueprint. I’m also quite frankly terrified. These technologies provide an impressive opportunity to reshape how cancer prevention and early detection is delivered and, importantly, to democratize these efforts. MCED is going to be paradigm shifting, and it’s essential that clinicians and the public don’t lose confidence in these technologies before they’re optimized. The stakes are too high to not do this well.”*

In this spirit, as a next step, the consortium’s administration will be transferred to the third-party institution referenced above to begin the formal process of establishment as a 501(c)(3) organization. Simultaneously, leadership for the executive committee and workgroup chairs and deputy chairs will be retained, and the consortium’s general membership recruitment will begin.

About this document

This *Summary of Themes* reflects the use of a modified version of the Chatham House Rule whereby names of participants and their affiliations are a matter of public record, but comments are not attributed to individuals, corporations, or institutions. Italicized quotations reflect comments made by participants during MCED Consortium design meetings and discussions.

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.

The views expressed in this document represent consolidated views of those who contributed to the design phase of the of the Multicancer Early Detection Initiative, which ran from January to July 2021 and integrates broader landscape analyses and previous discussions from the December 2020 Multicancer Early Detection Forum. This document is not intended to represent the policies or positions of the individual participants or their affiliated organizations.

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Appendix 1: Contributors

The following stakeholders contributed to the design phase of the of the Multicancer Early Detection Initiative, which ran from January to July 2021 and provided significant feedback and inputs that helped develop the MCED Consortium Blueprint. Note that this list includes a variety of contributors; an asterisk (*) denotes a participant in the July 21 Final Design and Pre-Launch of the MCED Consortium meeting, and a dagger (†) denotes an MCED steering committee member or adviser.

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- National Comprehensive Cancer Network: Bob Carlson, Chief Executive Officer
- National Society of Genetic Counselors: Sara Riordan, President
- National Minority Quality Forum: Gary Puckrein,* Founding President and Chief Executive Officer
- Ochsner Health System: Phil Oravetz, Chief Population Health Officer
- Oncology Nursing Society: Brenda Nevidjon, CEO
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- WebMD: John Whyte, CMO

Appendix 2: Consortium's mission and guiding principles

The MCED Consortium's steering committee member and adviser group drafted the following initial mission statement and guiding principles.

Mission

To reduce the burden of cancer by evaluating how MCED technologies may improve cancer detection, treatment, and care to benefit all people.

Guiding principles

- **Health equity:** Consortium will recognize the needs of underserved communities and develop an approach for MCED technology that proactively addresses gaps in health disparities.
- **Inclusivity:** Consortium will ensure that all stakeholder perspectives are heard and considered.
- **Integrity:** Consortium will pursue a pace that promotes innovation in the field without endangering patients, i.e., exposing them to potential harm.
- **Longevity:** Consortium efforts will focus on identifying solutions for not only the status quo but also future innovation in MCED.
- **Objectivity:** Consortium efforts will maintain strategies independent from any sponsoring companies and will be led by a governance body working at a precompetitive level. Consortium will not promote, endorse, or favor any specific product or pipeline.
- **Practicality:** Consortium will leverage existing channels and partner with organizations with relevant capabilities rather than “reinvent the wheel.”
- **Simplicity:** Consortium will commit to an action-oriented approach that prioritizes specific, tangible barriers to momentum, while keeping patient and public interests at the forefront.
- **Sustainability:** Consortium will focus on advancing quality and improving public health while considering the available resources and limitations of stakeholders across the health system (including patients, clinicians, payers, developers, etc.)
- **Transparency:** Consortium will commit to communicating shared lessons to advance progress in the field.



Appendix 3: Consortium risks and amelioration approaches

Risk	Amelioration approach
Lack of credibility (viewed as industry or advocacy group agent)	Establish partnerships with recognized nonpartisan groups, set clear governing principles that prioritize inclusivity and integrity, and ensure an impartial chair.
Mission creep and fatigue	Set clear and attainable goals and timelines, demonstrate early value or quick wins, and ensure commitment for the long haul.
Lack of quality and/or progress of projects	Develop a system to qualify and monitor projects in an unbiased way, allowing and supporting fast failure and retailoring of projects as needed.
Reinventing the wheel	The first step of each workgroup is to map what work and learning have already been done or are ongoing (published and unpublished).
Lack of stakeholder engagement	Clarify what each stakeholder will get in return for their engagement and what the consortium can accomplish collectively that an organization could not on its own.
Reduced engagement due to overlapping consortia (e.g., policy and advocacy consortia)	Publicly communicate goals and ongoing outputs of the consortium and ensure dialogue, with complementary efforts to reduce duplication and amplify impact.
Limited resourcing	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 modelling doesn't exist, shift to planning for inputs from real-world evidence to inform models).
Landscape shifts in regulation or reimbursement	Ensure that feedback and outputs from other efforts addressing these issues (e.g., BloodPac) are integrated into this effort.

Endnotes

¹ [Cancer](#),” World Health Organization, March 3, 2020.

² Stakeholders typically referred to lessons from prostate-specific antigen screening, 23andMe’s direct-to-consumer genetic-risk screening, and Theranos’s fraud case and ultimate closing. For more information on these topics see [“Confronting A Controversy—The PSA Question,”](#) Premier Medical Group, May 14, 2020; 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; and Lydia Ramsey Pflanzler, [“The Rise and Fall of Theranos, the Blood-Testing Startup That Went from Silicon Valley Darling to Facing Fraud Charges,”](#) *Business Insider*, April 11, 2019.

³ Multicancer Early Detection Forum, [“Designing a Public-Private Consortium to Address the Challenges of Multicancer Early Detection,”](#) ViewPoints (Waltham, MA: Tapestry Networks, 2021), 5–7.

⁴ Multicancer Early Detection Forum, [“Designing a Public-Private Consortium to Address the Challenges of Multicancer Early Detection,”](#) 1–2.

⁵ For more information on these consortia, see [“International Alliance for Cancer Early Detection,”](#) Cancer Research UK, accessed August 25, 2021; [BloodPAC](#) website, accessed August 25, 2021; [“Objectives: The Intents of the Early Detection Research Network,”](#) National Cancer Institute, accessed August 25, 2021. 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, October 6–8, 2021.

⁶ For more information on these efforts, see [“Mission and Structure,”](#) National Cancer Institute Early Detection Research Network, accessed August 25, 2021; [“International Liquid Biopsy Standardization Alliance \(ILSA\),”](#) Foundation for the National Institutes of Health, accessed August 25, 2021; [“Re: Essential Legislation in Our Battle against Cancer,”](#) Prevent Cancer Foundation, March 16, 2021.