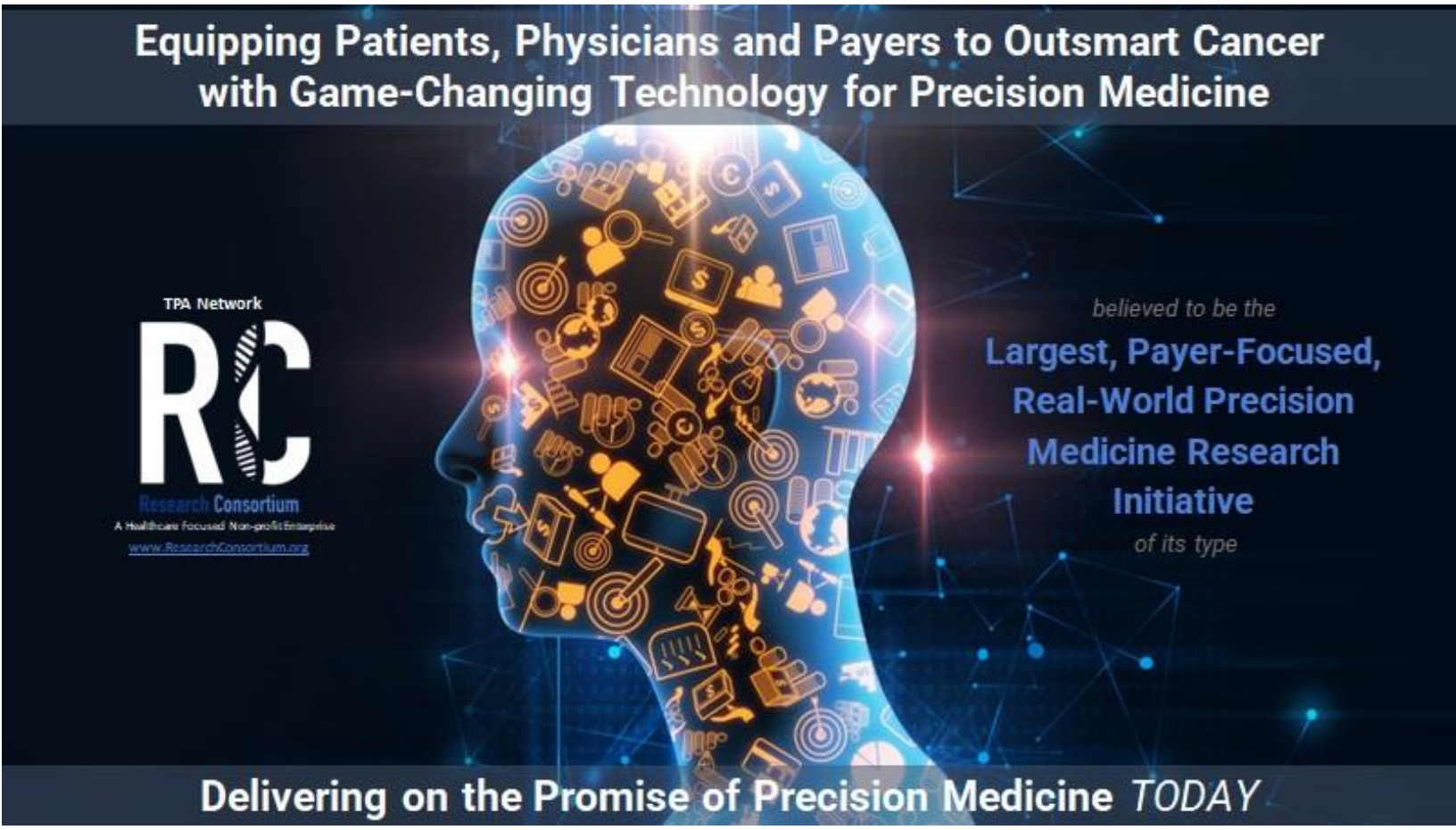

Owing exclusively to the generosity of a unique collaboration of world-renowned cancer researchers, oncologists, scientists, economists and academic genomic labs…

TPA Network
Research Consortium
a Healthcare-Focused Non-Profit Enterprise

– 1,000 cancer patients will benefit from free advanced diagnostic testing.

Overview

This real-world, payer-focused research initiative is believed to be the largest precision medicine study of its type ever undertaken. It seeks to demonstrate the clinical utility of recent advancements in precision medicine technologies that help oncologists to scientifically match cancer drugs to a patient's unique genomic profile … understanding that without translational research of this type, it may take more than 15 years to get these lifesaving technologies covered by insurers and into widespread clinical use.

Click **HERE** to view a ***3-minute video*** that describes this vitally important research initiative.

WHAT IS THE CONTEXT OF THIS RESEARCH INITIATIVE?

Today, we know that no two cancers are alike, that people process drugs differently, that cancer is best defeated by genomic-based therapies, and that the hundreds of FDA-approved cancer drugs are routinely prescribed together. With thousands of genomic variants, and millions of possible drug combinations, literally billions of treatment possibilities exist: making evaluating each beyond human capability. Much like GPS helps navigate through traffic and unfamiliar territory, precision medicine addresses this complexity with technology that helps physicians with their complex treatment decision-making by identifying science-based therapies. This initiative will demonstrate the clinical utility of these innovations and accelerate their coverage and adoption. Click **HERE** to see the supporting Research Studies.

WHAT IS THE SIGNIFICANCE OF THIS INITIATIVE?

Unfortunately, the scientific research that proves that a new medical intervention works does not include the measures that enables payers to assess their "clinical utility", a term used to describe their relevance, usefulness or value of an intervention in practice. As a result, sadly, only a small portion of the 2 million Americans diagnosed with cancer this year will have access to precision medicine technology. This vital translational research seeks to demonstrate the clinical utility of these technologies to patients, physicians, health systems and insurers (in real world settings and scenarios) to accelerate their coverage by insurers, speed their adoption by physicians and increase access to them to every cancer patient.

WHAT ARE THE GOALS OF THIS RESEARCH INITIATIVE?

Advanced precision medicine diagnostic tests will be provided free to 1,000 cancer patients to study patient, caregiver, physician and payer behavior with respect to their clinical utility. The funds raised here will be used to retain world-renowned researchers, oncologists, scientists and healthcare economists — from America's leading universities — to develop study protocols, conduct, manage and publish the study. A seasoned grant writer will pursue an added ~$1.25 million in public, corporate and foundational funding* to cover the cost of DNA sequencing by two top university genomic labs (that are being provided for ~10% of the cost paid by insurers (avoiding millions of dollars in expense).

* e.g., NGS equipment manufacturers, health systems, insurers, the NIH, etc.

WHAT IS TRANSLATIONAL RESEARCH AND WHY IS IT SO VITALLY IMPORTANT?

Unlike traditional scientific research that proves the clinical efficacy of a medical intervention, translational research is intended to (translate) move basic science discoveries quickly and efficiently into practice by enhancing the adoption, uptake and use of best practices. The clinical efficacy of these technologies has been demonstrated through numerous peer-reviewed studies. This “T3” translational research is intended to improve the efficient use of precision medicine technologies and the way they are provided and employed, for system-wide change, understanding that the movement of evidence-based clinical interventions into routine practice doesn't typically occur without a focused effort. T3 research often includes “dissemination research” that looks to address the deficiencies in the distribution of research-based knowledge and “implementation research” to enhance its uptake into routine practice to improve patient outcomes and benefit population health.

WHAT IS CLINICAL UTILITY AND HOW IS IT DEMONSTRATED?

All payers have finite financial resources with which to satisfy their plan participants' needs. To manage their limited funds, payers justifiably cover only those treatments that have been proven to be useful in clinical practice, by requiring evidence of their clinical utility: a term used to describe the relevance, usefulness or value of an intervention in medical care. We have expanded the scope of the outdated, narrow, provider-focused clinical utility construct to recognize the patient-centric reality of precision medicine, by incorporating dimensions of value that encompass a patient's well-being, sense of personal control, and preferences with respect to health system options. As such, we will study the use of these technologies by the full spectrum of healthcare stakeholders in real world settings outside the formalism of a randomized controlled study. Click **HERE** to view our short presentation of our expanded version of Clinical Utility.

RESEARCH TEAM AND COLLABORATORS

Complex by nature, translational research is a bidirectional process that involves multidisciplinary integration of basic, clinical, practice, population and policy-based research and requires a multi-method inquiry that employs quantitative and qualitative data assessment. To assist with this undertaking, the **Research Consortium** is enlisting world-renown cancer researchers, oncologists, scientists, healthcare economists, oncology pharmacists and other subject-matter experts from America's leading universities and academic genomic laboratories to assist with study design, protocols, data collection and results assessment. We also have a seasoned grant writing professional on our team who will solicit $1+ million in additional public, corporate and foundational funding (e.g., from NGS equipment makers, health systems/insurers, the NIH, etc.)

HOW WILL STUDY PARTICIPANTS BE SOURCED?

Unlike many other research studies, this initiative will involve the exclusive use of real-world evidence: observational data gathered in real life situations, in real-world settings with real patients. The study's primary participants (cancer patients and their oncologists) will be sourced from health systems, union- and employer-sponsored healthplans and health insurers. To enroll 1,000 cancer patients, we anticipate the need for a recruitment pool of 250,000+ adult plan participants. The Research Consortium team members have decades of experience working with healthplans and longstanding relationships with C-suite decision-makers at the nation's largest third party benefits administrators, labor unions, MCOs and health insurers (as well as the benefits brokers and consultants with whom they collaborate).

WHAT RESEARCH METHODS WILL BE EMPLOYED?

Complex by nature, translational research is a bidirectional process that involves multidisciplinary integration of basic, clinical, practice, population and policy-based research that requires a multi-method inquiry employing both quantitative and qualitative data assessment. This initiative will involve real-world people, in real-life scenarios in real-world settings. It will evaluate the use of precision medicine tools by oncologists to improve medical outcomes, as well as pre-authorization and UR nurses to help them identify and avoid wasteful low-clinical-value cancer treatments. The tools that will be employed will include interviews, focus group discussions, observation, surveys, questionnaires and case studies (administered formally or informally) conducted face-to-face or via remote media — collected from patients, physicians, caregivers and payers. For these reasons, this initiative requires the enlistment of a broad and diverse research team of subject-matter experts.

DESCRIBE THE STUDY PATIENT JOURNEY

This real-world, payer-focused research initiative will involve real cancer patients and their oncologists. To ensure that patients, caregivers, physicians and payers like fully understand the get the most from what the subject advanced precision medicine technologies have to offer, we are incorporating the use of patient care navigators, provider sherpas and board certified oncology pharmacists to assist oncologists with their complex treatment dosing decision-making. Click **HERE** to see a graphic depiction of the Patient Journey

WHAT ARE THE STUDY CHALLENGES?

The only material challenge that we can identify relates to our ability to recruit patient - MD pairings as many research endeavors fail because they are underpowered. Understanding this, our goal is to keep attrition rates low so that 1,000 cancer patients complete the entire study. We do not envision this being a problem as NGS testing is only available to a small portion of cancer patients and the AI-supported, biomarker-based tool that scores and ranks possible cancer therapies is such a new tool that the AMA just recently (01/01/23) issued a new Category III CPT Code (0794T) to cover this groundbreaking innovation. The treatment data generated by these tools is of great value to patients and physicians alike — especially patients with metastatic cancer where multiple lines of therapy have been unsuccessful — as this is when novel combination therapies are more likely considered.

WHAT IS THE PROJECT'S BUDGET?

This study will cost ~$1.5 million. The universe of study participants will include 1,000 cancer patients, ~300 oncologists and 40+ healthplan sponsors (from which study patients will be recruited). The funds raised here will fully fund the initial study planning, design and set-up expenses and costs related to (patient/physician/payer) participant contracting, regulatory compliance, grant writing, research platform and travel. An additional $150,000 will be raised to cover the study's fixed costs.

This study's largest cost ($1 million) is for NGS tests, PGx tests and AI-based drug treatment analysis. While insurers pay up to $10,000/patient for these tests, as a non-profit, our cost from two university labs is only $1,000. These funds will come from public, corporate and foundational donors (e.g., NGS equipment makers, health systems/insurers, NIH). These per capita costs can be funded, on a rolling basis, as study participants are recruited.

WHAT IS THE PROJECT TIMELINE?

This research initiative will study the behavior of 1,000 cancer patients, their physicians, caregivers and payers (e.g., health plans, insurers) as they learn about, employ and evaluate new precision medicine technologies used in the diagnosis, testing and treatment of real advanced cancer patients ... in real-world scenarios. Although the patient - physician observation period is fairly brief, it may take two years to complete the study and publish the results.

We welcome your support and participation.

To support this effort, corporate and foundational research sponsors are invited to click **HERE**.

Individuals, patient advocacy and support groups wanting to link to, promote or help sponsor the participation of a cancer patient/oncologist pair in this study are invited to click **HERE**.

TPA NETWORK Research Consortium, Ltd.

An emerging non-profit, industry-wide healthcare research initiative that helps

Providers evaluate new medical technologies and healthcare innovations,
Plan Participants obtain leading-edge health care,
Scientists advance medical research, and
Payers / **Health Systems** reduce risk.

TPA NETWORK Research Consortium
a Healthcare-Focused Non-Profit Enterprise

Richard L. Nicholas, FOUNDER
Richard@ResearchConsortium.org
www.ResearchConsortium.org
(858) 395-4114