

# New Global Cancer Coalition Calls for a "Reimagining" of Patient-Centric Clinical Trials



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## **New Consensus Paper Published in *Nature Medicine* by 35 Members of Bloomberg New Economy International Cancer Coalition**

### **East-West collaboration argues that post-pandemic, telemedicine and remote monitoring can deliver better cancer treatment and care to underserved populations**

NEW YORK, April 19, 2022 /PRNewswire/ -- The Bloomberg New Economy International Cancer Coalition (the "Coalition") today called for a permanent paradigm change in the way cancer patients are diagnosed, treated and cared for across the globe. In a commentary piece published today in *Nature Medicine*, the Coalition demonstrates that the COVID-19 pandemic upended the infrastructure and delivery of oncology clinical trials worldwide and that technologies such as telemedicine, improved diagnostic capabilities, and remote monitoring have huge potential and should be better harnessed to become more broadly used for clinical trials in the future.

In an effort to allow potentially lifesaving experimental therapies for patients to continue during the pandemic, government regulators, medical centers, and clinical trial sponsors implemented unprecedented flexibilities in clinical trial conduct. The U.S. Food and Drug Administration (FDA) along with regulatory agencies from China, Russia, the European Union, Brazil, Australia and Nigeria separately issued guidance that was adopted by their respective regions which provided new opportunities to optimize the patient experience, and, illuminated how digital technology and collaboration may improve access, alleviate patient burden, and increase the diversity of participants, including those in remote and disadvantaged communities.

"With a coordinated, global multi-stakeholder effort, we absolutely can convert these improvements to a permanent paradigm change in cancer patient medicine post-pandemic," said **Richard Pazdur**, Director of the U.S. Food and Drug Administration's (FDA) Oncology Center of Excellence (OCE), a member of the Coalition and an author on the new *Nature Medicine* piece. "Achieving broader diversity across clinical trials is a key priority for the FDA and finding ways to lower barriers for patients to benefit from trials is necessary both here and abroad."

The Coalition was formed explicitly to explore ways to drive better access and international collaboration to clinical trials, while also encouraging regulatory harmonization that would accelerate the development of novel cancer treatments, screening, and prevention. The Coalition is comprised of leaders from academic medical centers, government regulatory agencies, the pharmaceutical and biotechnology industry, contract research organizations, patient advocacy groups and policy think tanks. It launched virtually in Spring 2021 and in-person at the Bloomberg New Economy Forum in Singapore with founding partners including Asia Society and Memorial Sloan Kettering Cancer Center (MSK). In the Commentary piece, the Coalition recommends three areas of focus to move forward a new model of cancer care.

### **Patient identification and enrollment: leveraging hub and spoke networks**

The Coalition highlights some of the barriers facing patient enrollment including: healthcare providers lacking sufficient information and the time to identify, evaluate, and confidentially discuss clinical trial options with their patients; inequitable access to biomarker testing and

next generation sequencing (NGS), including liquid biopsy and overly restrictive upfront inclusion/exclusion criteria.

Limited trial availability in a patient's local area is also a major stumbling block. Many trials are only limited to academic medical centers. In the U.S. 74% of patients receive treatment in their communities, and for many patients to participate in a trial, their local oncologist must advise and refer them to trials conducted at other institutions, of which the physician might have minimal knowledge.

The Coalition argues that information technology tools should be part of the solution to overcoming many of these barriers. It envisions building towards an interactive international database in which patients with cancer may elect to enter at diagnosis and data may be added over time, including digital pathology and molecular profile. Maintaining data provenance across multiple care sites could be achieved if each patient receives a global ID.

Once patients are matched to trials, enrollment could be managed by a hub-and-spoke network where academic or large community cancer centers serve as a hub for distributed clinical research sites in the wider community. A hub-and-spoke network is widely implemented in the management of acute stroke and myocardial infarction and could be further facilitated in accrual efforts through technological innovations such as remote consent.

"The goal is to bring the trial to the patient, maintaining established clinician-patient relationships of trust," said **Bob Li**, Medical Oncologist and Physician Ambassador to China and Asia-Pacific at MSK, and lead author on the new *Nature Medicine* piece.

"Promoting the concept of patient-centric care, this network model would ensure that trials are being offered to patients regardless of where they live. It has been demonstrated that when eligible patients are offered a trial, they consent more than 50% of the time. We must do better by improving patients' access to potentially lifesaving clinical trials."

### **Treatment and monitoring: enhancing remote and hybrid models**

Given the often arduous on-study visits required by oncology clinical trials, sometimes involving procedures such as imaging and biopsies, on-protocol treatment is inconvenient, costly and time-consuming, creating a barrier for patients who lack the time and means necessary to participate. This is especially true for patients who live at a distance from the large medical centers that conduct most such protocols. In the U.S., nearly half of patients with metastatic breast, prostate, colorectal, and non-small cell lung cancers need to drive more than 60 minutes each way to access a clinical trial site. Such geographic disparities are seen globally.

The COVID-19 pandemic has led research teams to re-examine the need for in-person visits and significantly accelerated the adoption of remote and hybrid trials. Clinical trials have adopted telemedicine technology for remote consent, toxicity monitoring and follow up, local laboratory and imaging studies and remote shipment of oral medicines to patients' homes.

With effective coordination, clinical trials could be broadened to engage local physicians' practices, pharmacies, or patients' homes for mobile phlebotomy where data could be transmitted online.

"To accelerate the eradication of cancer, we need multi-stakeholder, multi-regional collaboration, to promote both patient-centric clinical trials and international regulatory harmonization," said **Kevin Rudd**, President and CEO of the Asia Society and former Prime Minister of Australia. "This would not only provide global public goods by building the policy, scientific, and technological infrastructure for international public health collaboration, but could also become the new ping-pong diplomacy between the U.S. and China."

### **Regulatory harmonization: lowering barriers to patient-centric care across the globe**

The Coalition concludes that the lack of harmonization among international regulatory policies is the most consequential barrier in worldwide efforts to develop novel strategies for cancer treatment and prevention. Currently there is currently no international diagnostics standard for cancer molecular profiling, regulatory restrictions on international cancer genetics data sharing may also prevent translational science discoveries and impede early-phase novel drug development and there is a lack of legal and regulatory policy to guide telemedicine and remote monitoring both in the U.S., and internationally.

The Coalition cites three examples that demonstrate the potential benefits of international collaboration and regulatory harmonization:

- **The U.S. FDA-initiated *Project Orbis*** - an international collaboration among government regulatory agencies for simultaneous submission and review of new oncology products, currently consisting of the U.S., Canada, Australia, Singapore, Switzerland, Brazil, the United Kingdom, and Israel.
- **China's NMPA** has approved several oncology products based on foreign data after joining the *International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use* (ICH) in 2017, including the 9-valent HPV vaccine against cervical cancer after only 9 days of review
- **The European Union Clinical Trials Regulation** came into effect on 31 January 2022 in an effort to harmonize submissions in a single application instead of applying to each European Union member

"Cancer's toll knows no borders, and when it comes to fighting it, neither can we," said **Michael R. Bloomberg**, founder of Bloomberg LP and Bloomberg Philanthropies. "We're making important strides in prevention and treatment, and the more partners we can bring together from around the world, the more lives we can save."

The following Coalition members authored the paper:

- Memorial Sloan Kettering Cancer Center, Weill Cornell Medicine, New York, USA
- Princess Margaret Cancer Center, University of Toronto, Toronto, Ontario, Canada
- Dana-Farber Cancer Institute, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA
- Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA
- Massachusetts General Hospital Cancer Center, Boston, MA, USA
- Society for Translational Oncology, USA
- Oncology Center of Excellence, Food and Drug Administration, Silver Spring, MD, USA
- Cancer Support Community, USA
- Foundation Medicine, MA, USA
- Novartis, Switzerland
- PPD, Inc, USA
- Resolution Bioscience, Agilent Technologies, USA
- McKinsey Cancer Center, McKinsey & Company
- Bloomberg New Economy Forum, New York, NY, USA
- Asia Society, New York, NY, USA
- Daiichi Sankyo, Japan
- Innovent Biologics, China
- Janssen, Johnson and Johnson, USA
- BeiGene, China
- Zai Lab, China
- Amgen, USA
- Genentech, USA
- Yale Cancer Center, Yale School of Medicine, New Haven, CT, USA
- Jiangsu Hengrui Medicine, China
- Bayer AG, Germany
- Shanghai TuoXin Health Promotion Center, China
- CEO Roundtable on Cancer, USA
- Guangdong Lung Cancer Institute, Guangdong Provincial People's Hospital, Guangdong Academy of Medical Sciences, Chinese Thoracic Oncology Group, Guangzhou, China

## **About The Bloomberg New Economy International Cancer Coalition**

Co-chaired by Kevin Rudd, President and CEO of the Asia Society and former Prime Minister of Australia and Stefan Oelrich, Member of the Board of Management of Bayer AG and President Pharmaceuticals, The International Cancer Coalition is composed of CEOs and senior representatives from the leading global pharmaceutical, biotech and diagnostic companies, senior representatives from regulatory bodies, and researchers and academics from major cancer centers and universities worldwide.

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