WIN

2011–2012 REPORT

WORLDWIDE INNOVATIVE NETWORKING
IN PERSONALIZED CANCER MEDICINE

www.winconsortium.org

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Making an impact on cancer care across the globe by bringing ground-breaking discoveries in personalized cancer medicine from the bench to the bedside at an accelerated pace.

WIN represents a global collaboration of cancer centers, life science and biotech organizations, pharmaceutical and technology companies, and patient advocacy groups. These stakeholders have come together from all parts of the world to address the challenge of increasing the efficacy of cancer diagnostics and therapeutics by understanding the genetics and biology of each individual's tumor and accounting for genetic differences across diverse populations—from North and South America, Europe, Asia, and the Middle East.

Institut de cancérologie GUSTAVE ROUSSY VILLEJUIF - www.igr.fr

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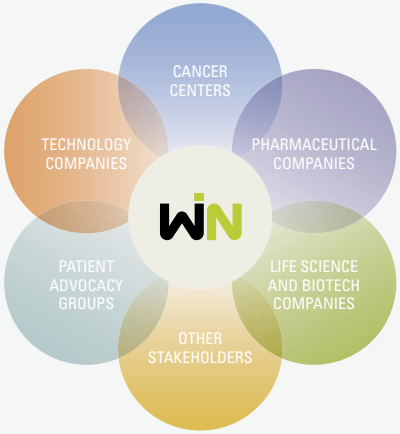

THE WIN STORY

Global diversity and inclusion of all stakeholders is WIN's most important and differentiating asset.

The Worldwide Innovative Networking (WIN) Consortium in personalized cancer medicine was initiated in 2010 with leadership from the Institut Gustave Roussy (France) and The University of Texas MD Anderson Cancer Center (USA). WIN is a first-of-it's-kind, non-profit, non-governmental organization headquartered in Paris.

WIN was created to *accelerate the pace and reduce the cost of* translating novel cancer treatments to the bedside by developing and applying, through worldwide clinical trials and research projects, the most promising advances in genomic-based cancer research.

WIN aims to initiate research projects each year in a global consortium guided by an independent scientific advisory board. Our goal is to make an impact on personalized cancer therapy around the globe by increasing the number of patients having access to innovative, global clinical trials in the area of genomic-based cancer therapeutics. Global diversity and inclusion of all stakeholders is WIN's most important and differentiating asset.

WHAT MAKES WIN UNIQUE

Worldwide Scope of Clinical Research

With member cancer centers in 13 countries on four continents, the WIN Consortium has a unique global scope that enables its clinical trials to encompass a diverse patient population. Individual patients around the world differ due to ethnicity and environment, and these differences may affect the response to therapies that target genetic aberrations in their cancers. WIN's global scope allows for the identification of genome-based cancer therapies that may vary in effectiveness across populations. WIN's capacity to simultaneously enroll patients from diverse populations into the same clinical trial should be beneficial for all stakeholders to more rapidly develop selective biomarkers and drugs that impact clinical care not only in the Western, but also the non-Western world.

Cross-Sector Collaboration of All Stakeholders in Genomic-Targeted Cancer Treatment

WIN is unique structurally in that it brings together organizations from academia, business and not-for-profit organizations to focus on translating the latest advances in personalized cancer medicine into the standard of care. WIN is built on the recognition that all stakeholders in personalized cancer therapy must collaborate and share information in order to most effectively bring the latest innovations in personalized cancer care to the patient.

Focus on Clinical Innovation, Efficacy, and Implementation

WIN's primary focus is on conducting clinical trials and projects that validate and use genetic biomarkers to select appropriate targeted therapies for individual patients, thus enhancing the efficacy of personalized cancer treatments. WIN moves beyond identifying the genetic abnormalities present in different types of cancers to the clinical application of ground-breaking advances in early diagnostic tools and personalized cancer therapies in the care of each individual patient.

Annual WIN Symposium

The WIN Symposium brings together hundreds of leaders and practitioners from academia, pharma, biotech/life science companies, regulatory authorities, and patient advocacy from around the world each year. Symposium sessions are split evenly between speakers from academia and speakers from industry and other sectors who discuss their findings, tactics, and objectives in personalized cancer medicine. The Symposium provides a unique forum for these various stakeholders to assemble on an annual basis to exchange knowledge, approaches, and advances in personalized cancer therapies in a non-siloed setting.

STRUCTURE AND GOVERNANCE

WIN is a non-profit organization incorporated in France, and is funded in part through membership dues paid by WIN member organizations. Each WIN clinical trial and scientific project has its own principal investigator and independent funding, project-specific agreements (including intellectual property provisions) between participating members with funding sources such as grant-making bodies, private funders, and philanthropy.

WIN governing bodies include its Directorate and its General Assembly. WIN Consortium projects and clinical trials are evaluated by WIN's independent Scientific Advisory Board (SAB), which is comprised of a global cross-section of prominent leaders in the area of genomic-based cancer therapeutics. Members of the SAB are drawn both from WIN member organizations as well as from organizations that are not members of the Consortium.

28 GLOBAL CANCER CENTERS AND INDUSTRY PARTNERS

4 CONTINENTS

13 COUNTRIES

WIN was formed on the premise that Consortium members can accomplish together what no single institution or group of patients can do alone.

WIN CONSORTIUM 2012 ACHIEVEMENTS

In 2012, the WIN Consortium reached a number of significant milestones in its development and in the fulfillment of its mission.

WIN was designed to address obstacles to the discovery, development and application of biomarker-driven cancer therapies. Conducting global, biomarker-driven clinical trials that test the most innovative advances in personalized cancer medicine in a worldwide patient population is the focus of the Consortium and a primary reason the Consortium was created. In 2012, the WIN Scientific Advisory Board approved the WINTHER trial, the Universal Biomarker Project, and the Biomarker Database and work began on initiating these projects. In 2013, the WIN Consortium will launch this first round of clinical trials and projects. A new call for research proposals is planned for submittal and review in 2013.

WIN was formed on the premise that Consortium members can accomplish together what no single institution can do alone. It was initiated by the Institut Gustave Roussy and The University of Texas MD Anderson Cancer Center, and today has 19 member cancer centers representing four continents, five major technology partners, two pharmaceutical partners and two patient advocacy partners.

The 4th annual WIN Symposium took place in Paris on June 28–29, 2012. The Symposium was a resounding success with over 400 delegates and more than fifty distinguished speakers, panelists, and session chairs from world-leading institutions, businesses, and not-for-profit organizations coming together from around the world to share and collaborate on the latest innovations in personalized cancer care. The WIN Symposium is key to WIN's strategic objectives.

We are excited about what the Consortium and its members have accomplished over the past year: the planning of WIN's first round of global clinical trials, the addition of high-profile Consortium members from new sectors, and the continued success of the WIN Symposium in driving collaboration around the globe.

We want to thank the distinguished group of scientists who serve on WIN's independent Scientific Advisory Board, without whom WIN could not have made such tremendous strides forward. And, special thanks to Richard L. Schilsky, Chairman, who also serves on WIN's Executive Committee and plays a major role in decisions about our clinical trials and Symposium.

We look forward to building on this progress in 2013, bringing us closer to translating the latest and most innovative discoveries in personalized cancer medicine into the standard of care for each patient.

John Mendelsohn, MD, Chair

Alexander Eggermont, MD, PhD, Vice Chair


Carrying out global
clinical trials based on
the most innovative
advances in personalized
cancer medicine.

WIN 2012 CLINICAL TRIALS

WIN's structure allows for and encourages each member of the WIN Consortium to submit proposals for biomarker-driven clinical trials and projects to be carried out by the Consortium. WIN's independent Scientific Advisory Board then reviews these proposals, suggests revisions and makes recommendations to the WIN leadership. We are pleased to announce that three studies, representing WIN's first round of global clinical trials and projects, have been approved by the Scientific Advisory Board and are being initiated. Each of these three studies seeks to overcome a key obstacle to the implementation of the latest innovations in personalized cancer medicine into the standard of care:

The WINTHER Trial (WIN THERapeutics) is an academic and international clinical trial that applies a systems biology concept to achieve a fundamental change in the standard of care for cancer patients. It is the first clinical trial offering a choice of therapy guided by each patient's individual biology for 100% of patients included in the study, with the goal of accurately predicting the most effective targeted experimental therapy or standard chemotherapy for each patient. WINTHER conducts comprehensive DNA, RNA, and microRNA investigations using multiple advanced sequencing techniques, including next generation sequencing. For cancers that lack a targetable genetic aberration, expression arrays will be performed on biopsies of matched tumor and normal tissue from each patient, thus eliminating "noise" due to variability of expression in different tissues. The resulting data are interpreted with a bioinformatics program based on an extensive assembled database of drugs and gene expression data, producing an individualized predictive score of the efficacy of existing drugs for each patient, irrespective of cancer type.

WINTHER represents a breakthrough compared to current personalized medicine approaches, which offer, at best, genomic-guided therapy for up to 40% of patients involved whose cancers have actionable genetic aberrations. The European Health Directorate independently evaluated the project and awarded WINTHER a grant of three million Euros, representing an important endorsement from Europe's highest health research governing body. Due to its complexity, the WINTHER trial pilot starts in five cancer centers: MD Anderson (USA), IGR (France), Segal Cancer Center (Canada), Vall d'Hebron Institute of Oncology (Spain) and Chaim Sheba (Israel). Once launched, the trial will be extended to other members.

The Universal Biomarker Study (UBM), based on a breakthrough technology from Life Technologies, seeks to validate a commercial technology that identifies the 384 most frequent cancer mutations in circulating DNA through a non-invasive, blood-based test. While circulating DNA in individuals with cancer is known to contain tumoral DNA released from tumors, serum DNA markers are not currently used for the detection of relapse or response to therapy in cancer patients. Applications of the UBM study, which is open to all WIN members, include efficient and non-invasive patient monitoring and follow up; the creation of a universal pharmacodynamic test for use in clinical trials; quick tumor genotyping; and serum genotyping when a biopsy is not available. A second stage of UBM application could include the early detection of tumors.

The Biomarker Registry Project is a project that seeks to create a web-based database open to the entire scientific community on negative and unpublished biomarker studies. While many thousands of biomarker studies have been and continue to be conducted, a limited number of biomarkers are currently used widely in the clinic, and significant obstacles exist to more rapidly translating biomarker investigations into standards of care. Biomarker studies with negative outcomes are rarely published, and the access of the scientific community to these study results is limited. Moreover, increased standardization and consistency in biomarker studies is needed to increase the usefulness of biomarker study results within the scientific community. The Registry creates a resource open to the entire scientific community on negative and unpublished randomized biomarker investigations, and also provides a venue for investigators to pre-register the hypothesis of planned tumor biomarker studies, thus ensuring the veracity of biomarker studies by assuring against post-hoc statistical analyses.

These three studies represent some of the most innovative approaches to personalized cancer medicine. With its global scope and collaborative, cross-sector structure, we believe that the WIN Consortium is uniquely positioned to carry out trials—that drive the latest advances in genome-based cancer medicine—more quickly and effectively than existing approaches. A new round of WIN global clinical trials is planned for submission and review in 2013.

Richard L. Schilsky, MD, Chair, SAB

Vladimir Lazar, MD, PhD, COO

Photo 1: (from left to right) J. Jack Lee, PhD, DDS, University of Texas MD Anderson Cancer Center; Vladimir Lazar, MD, PhD, Institut Gustave Roussy; Eitan Rubin, PhD, Ben Gurion University; Amir Onn, MD, Chiam Sheba Medical Center; Gary Palmer, MD, JD, Foundation Medicine; Philippe Viehl, MD, PhD, Institut Gustave Roussy; Josep Taberno, MD, Vall d'Hebron University Hospital

Photo 2: Vladimir Lazar, MD, PhD; Alexander Eggermont, MD, PhD; John Mendelsohn, MD

Photo 3: Richard Schilsky, MD; John Mendelsohn, MD

"The WIN Symposium reflects the vision and goals of ASCO's blueprint for transforming cancer research (www.ASCO.org/Blueprint) and the potential that molecularly-driven therapies have to transform clinical research. ASCO is pleased to endorse the 2012 meeting because of the opportunities it provides for international collaboration." – Sandra Swain, MD, President of ASCO

WIN 2012 SYMPOSIUM

The WIN 2012 Symposium, held on June 28–29 in Paris, was the fourth in a successful series of annual meetings dedicated to the latest advances in personalized cancer medicine. The Symposium attracted more than 400 delegates from over 30 countries who came together to discuss, share, and collaborate on how to most effectively translate the latest advances in biomarker-driven, personalized cancer research into the standards of clinical care. This unique, cross-sector effort featured distinguished global leaders speaking on topics centered on the theme of WIN 2012: *The Efficacy of Biomarkers and Personalized Cancer Therapeutics*.

Day one of the Symposium focused on areas that included the fundamental concepts and strategies needed to improve the efficacy of therapeutics; WIN Consortium's newly initiated global clinical trials and projects; advances in the use of biomarkers in diagnostics and drug development; systems biology and bioinformatics; and patient advocacy. Day two focused on innovative targets of biomarker research and new drug discoveries; innovative therapeutics and clinical trials; combinatorial biomarkers and the efficacy of therapeutics; and the future of genomic medical care, and potential contributions of biointelligence and systems biology modeling.

The information presented at WIN 2012 showcased both the tremendous opportunities and challenges of personalized cancer medicine. Today, molecular profiling of each individual's tumor has been shown to improve patient outcomes, even in early phase clinical trials. And, profiling patients to search for actionable genetic mutations has become far more widespread. Hundreds of potential new biomarkers are being discovered and the development of biomarker-targeted therapies and diagnostics are increasingly prioritized in pharmaceutical and life sciences companies' R&D.

However, speakers noted that the current knowledge of genomic-based cancer care is insufficient to explain disease progression and resistance to therapies. Many new genetically-targeted drug compounds currently fail at proof of concept, and there is much we need to learn about understanding perturbations to individuals' biological systems and how to optimally combine therapeutic agents. Much still needs to be done to efficiently integrate multiple genomic data sets and effectively translate genetic profiles from the lab into a format usable by a physician.

A great deal of information was shared at the Symposium about how to meet these challenges. You can see this information on our website.

The main theme of the 2013 WIN Symposium, to be held on July 10–12 in Paris, will be: *Personalized Cancer Therapy: From Innovation to Implementation*. We invite all interested researchers to join the distinguished speakers, panelists, and delegates from around the world in examining the clinical applications of the latest developments and most innovative approaches to personalized cancer care.

The WIN 2012 Symposium attracted more than 400 delegates from over 30 countries who came together to discuss, share, and collaborate on how to most effectively translate the latest advances in biomarker-driven, personalized cancer research into the standards of clinical care.

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