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### Three Federal Agencies Embark Upon New Initiative

The National Cancer Institute (NCI), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS) recently announced a new initiative aimed at better understanding the function of biomarkers in cancer research, diagnosis, and treatment. The Oncology Biomarker Qualification Initiative (OBQI) will bring these three agencies together to collaborate and share resources to examine and identify the vital role that biomarkers - the biological indicators of disease - play in a variety of cancers.

Biomarkers can be analyzed through a patient's blood, tissue samples, or with imaging scans, potentially allowing researchers and physicians to individualize treatment based on a clearer understanding of how those biomarkers impact a patient's cancer. For example, one well-known biomarker that affects approximately 25% of the women diagnosed with breast cancer is the HER2 gene. Women whose cancer over-expresses this gene are considered "HER2 positive" and are given a therapy specifically designed to counteract the over-expression of this biomarker. Ultimately, if the OBQI is successful, physicians will be able to match other therapies to patients based on biomarker research, so that more patients are treated only with the therapies from which they are likely to derive a significant benefit.

In order to achieve this goal, the OBQI will try to determine whether particular biomarkers can help researchers:

- Evaluate whether a patient's tumor is responding to treatment, after just one or two courses of therapy
- Demonstrate that a tumor is dying, even if it is not shrinking
- Indicate which patients are at higher risk for disease recurrence
- Predict whether a tumor will respond to a specific treatment
- Quickly determine whether an investigational therapy is effectively treating the tumor

The first OBQI project will evaluate a scanning method called Fluorodeoxyglucose-Positron Emission Tomography - or FDG-PET - which is used to detect non-Hodgkin's lymphoma. In this study, researchers will use the FDG-PET scanning technology on patients currently being treated for non-Hodgkin's lymphoma to see if the FDG-PET can predict whether the tumor will respond to the therapy.

According to officials at NCI, FDA and CMS, this and other research produced by the initiative could help patients by reducing the time and resources needed to conduct clinical trials, which in turn would speed drug development by honing in on effective tumor targets. Additionally, Medicare may be more willing to cover the cost of therapies developed through biomarker research because there would be scientific evidence pointing to which patients are most likely to benefit from the treatment.

While the OBQI research is promising for researchers, physicians, and patients and their families, some advocates have voiced concern that the initiative may be perceived as negative by the drug industry. Although these companies could benefit by shortened timelines for drug discovery, clinical research, and the FDA approval process, they may fear that biomarker research will eventually narrow the population of patients using their treatments. And if the OBQI does help researchers link the presence of certain biomarkers to specific therapies, it is likely that future treatments will be designed to benefit segments of the patient population rather than treating patients with a "one size fits all" approach.

In spite of these concerns, the OBQI does have the potential to bring about major change in the way that cancers are diagnosed and treated, which ultimately is good news for the entire cancer community.

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### **Gastrointestinal Cancers Symposium News of Colorectal Cancer Treatments**

This year the annual Gastrointestinal Cancers Symposium was held at the end of January and was co-sponsored by the American Society of Clinical Oncology, The American Gastrointestinal Association, the Society of Surgical Oncology and the American Society for Therapeutic Radiology and Oncology.

#### **Addition of Oxaliplatin to Treatment Increases Survival**

For many years almost all colorectal cancer (CRC) patients received 5-FU and leucovorin for chemotherapy treatment. When irinotecan was approved for use with CRC patients, it was paired with 5-FU and leucovorin and referred to as FOLFIRI. Somewhat later, when oxaliplatin was approved, it too was paired with 5-FU and leucovorin and referred to as FOLFOX. FOLFOX and FOLFIRI became the mainstays of CRC chemotherapy treatment.

Doctors in the Gruppo Oncologico Nord Ovest (GONO) in Italy reported on a phase III study that compared FOLFIRI (Arm A) to FOLFOXIRI (Arm B: 5-FU, leucovorin, irinotecan and oxaliplatin) as first line treatment for patients with metastatic CRC. The 244 patients enrolled were well matched and

treatment was received every two weeks. The results for the primary endpoint, response rate, showed that overall RR (complete + partial) was significantly higher in the FOLFOXIRI (66% vs 41%, p=0.0002). Another result reported at a median follow-up of 14 months was that the average progression free survival was greater in the FOLFOXIRI arm, 9.8 vs 6.9 months (p=0.0006). Overall survival at 30 months was 34% in the FOLFOXIRI arm vs 21% in the FOLFIRI arm (p=0.032)

The toxicities reported showed that all measures were higher in the FOLFOXIRI arm but the most significant difference was in grade 2-3 peripheral neurotoxicity, which was (arm A/arm B) 0% vs 18%. (See report below.)

*Biweekly irinotecan, oxaliplatin, and infusional 5FU/LV (FOLFOXIRI) versus FOLFIRI as first-line treatment of metastatic colorectal cancer (MCRC): Results of a randomized, phase III trial by the Gruppo Oncologico Nord Ovest (GONO).*

For more info link here to ASCO's [2006 Gastrointestinal Cancers Symposium](#) site.

<b>Drugs for treating colon cancer</b>	
<b>Generic Name</b>	<b>Brand Name</b>
Fluorouracil (5FU)	Adrucil
Leucovorin	Wellcovorin
Irinotecan (CPT-11)	Camptosar
Capecitabine	Xeloda
Oxaliplatin	Eloxatin
Bevacizumab	Avastin
Cetuximab (C225)	Erbitux

<b>Combinations of drugs to treat colon cancer</b>	
FOLFIRI	Infusional 5FU, Leucovorin, Irinotecan
FOLFOX	5FU, Leucovorin, Oxaliplatin
IFL	Irinotecan, bolus 5FU, Leucovorin
FOLFOXIRI	Infusional 5FU, Leucovorin, Irinotecan, Oxaliplatin
XELIRI/CAPEIRI	Xeloda, Irinotecan/Capecitabine, Irinotecan
XELOX/ CAPEOX	Xeloda, Oxaliplatin/Capecitabine, Oxaliplatin

### **Neuroprotective Agent Shows Promise**

When peripheral neuropathy becomes severe enough, doses of oxaliplatin are reduced. However, a reduction in dose or delay in treatment often results in suboptimal outcomes. Therefore, preventing side effects or reducing their severity is critical to optimal treatment delivery and improved long-term outcomes. Furthermore, peripheral neuropathy may become a persistent condition, affecting the quality of life for long-term survivors.

Xaliproden (SR57746A), which is not FDA approved for any indication, showed evidence of reducing dose-limiting neurotoxicity in patients being treated for metastatic CRC with oxaliplatin. Six hundred forty nine patients receiving FOLFOX4 participated in a phase III randomized placebo controlled study conducted by researchers from Glasgow University, Glasgow, Scotland. Xaliproden was given from the first day of chemotherapy until 15 days past the last FOLFOX cycle.

The primary endpoints were reduction in the risk of occurrence of grade 3-4 peripheral sensory neuropathy (PSN) and non-inferiority in response rate (RR). Results reported showed a 39% ( $p=0.0203$ ) reduction in the risk of grade 3-4 PSN for patients receiving Xaliproden. In addition, Xaliproden showed no detrimental impact on outcomes in those patients receiving the drug.

Xaliproden is an oral non-peptide compound which has shown to exhibit a wide range of neurotrophic effects. Neurotrophic factors are substances that are responsible for the growth and survival of neurons during development, and for maintaining adult neurons. Neurotrophic factors also are capable of making damaged neurons regrow their processes in a test tube and in animal models.

Most recently Xaliproden has shown modest effects in amyotrophic lateral sclerosis (ALS) and Alzheimer disease.

*Randomized double blind (DB) placebo (Plcb) controlled phase III study assessing the efficacy of Xaliproden (X) in reducing the cumulative peripheral sensory neuropathy (PSN) induced by the oxaliplatin (Ox) and 5-FU/LV combination (FOLFOX4) in first line treatment of patients (pts) with metastatic colorectal cancer (MCRC).*

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### **ADVOCATE LECTURE SERIES ON GENOMICS, PHARMACOGENETICS AND TISSUE COLLECTION, STORAGE AND ACCESS**

The Indiana University Department of Defense Breast Cancer Center of Excellence and the Research Advocacy Network are co-sponsoring an Advocate Lecture Series in March. The lecture series is to inform advocates about the importance of genomics, pharmacogenetics and biospecimen collection and storage in making targeted treatments available to patients. The faculty is composed of the researchers who are part of the IU/DOD Breast Cancer Center of Excellence. The lecture series will be conducted as webinar meetings where participants use a toll free conference number and view the slides on their computer screens. There is no charge to the participants and it is not necessary to download additional software. The series will include three 1 hour presentations starting at 11 am Central, 12 noon Eastern and 9 am Pacific.

- On March 16th, George W. Sledge, Jr. MD, the Director of the Center, will present an overview of the IU/DOD grant, the "omics" involved in the research, the desired outcomes and how advocates can support this research.
- On March 23rd, Jenny Chang, MD will give an overview of genomics in cancer and David Flockhart, MD, PhD will provide an overview of pharmacogenetics.
- On March 30th, Ann Thor, MD will discuss the operational issues in collecting and storing biospecimens, especially in multi-centered, multi-country research.

If you are interested in participating, please visit

<http://www.linkconferencecall.com/reg/researchadvocacy/> to register. The sessions will be archived for later playback for those that are unable to attend the live sessions. Funding for the lecture series was provided by the DOD Breast Cancer Center of Excellence and Eli Lilly and Company.

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### **What It Means For Me™: Fact Sheets**

Two fact sheets have been added to the "What it Means for Me" Fact Sheet Series. These fact sheet topics are on the results of the Avastin and Herceptin studies in breast cancer. These are available for download on the [Research Advocacy Network Publications](#) area of the website.

- [Avastin Studies: What It Means For Me](#)
- [Herceptin Studies: What It Means for Me](#)

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**Reporting on some of our activities:**

***Advocate Institute adds playbacks from "Research Into Practice" Lecture Series***

The Advocate Institute has added three session playbacks from the NCCN / RAN Advocate Lecture Series on "Research Into Practice." This series is an excellent way for advocates to better understand the influencers and barriers to advancing research results into clinical practice. The one hour sessions can be accessed at: <http://www.researchadvocacy.org/advocateInstitute/>

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**Research Advocacy Network Activities**

- March 6-7 Data Sharing and Intellectual Capital Working Group
- March 8-12 National Comprehensive Cancer Network 11th Annual Conference Roundtable panel *"Oncology Practice Today" Quality Evaluation, Coverage and Reimbursement*
- March 16-Indiana University Dept of Defense (DoD) Breast Cancer Center of Excellence Advocate Lecture Series. Click here to register
- March 23-Indiana University Dept of Defense (DoD) Breast Cancer Center of Excellence Advocate Lecture Series Click here to register
- March 30 - Indiana University Dept of Defense (DoD) Breast Cancer Center of Excellence Advocate Lecture Series Click here to register
- April 1-5 AACR Annual Meeting
- April 9 - 11 caBIG Annual Meeting
- April 10-13 NCCTG Spring Meeting
- April 19-23 Tenth Intercultural Cancer Council Biennial Symposium, Washington DC
- May-June Focus on Research Webconferences
- June 1 Women Against Lung Cancer Annual Meeting, Atlanta, GA
- June 2-6 American Society of Clinical Oncology (ASCO) Annual Meeting, Atlanta, GA

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<b>Awareness Events</b>	
<b>January</b>	<b>July</b>
Cervical Cancer Screening Month	<b>August</b>
<b>February</b>	Multiple Myeloma Awareness Week
National Donor Day (14 <sup>th</sup> )	National Minority Donor Awareness Day(1 <sup>st</sup> )
Wise Health Consumer Month	National Lesbians Cancer Awareness Day (24 <sup>th</sup> )
<b>March</b>	<b>September</b>
Kidney Cancer Awareness Month	Childhood Cancer Month

Lymphedema "D" Day (6 <sup>th</sup> )	Gynecological Cancer Awareness Month
National Colorectal Cancer Awareness Month	Leukemia & Lymphoma Awareness Month
National Nutrition Month	National Ovarian Cancer Awareness Month
<b>April</b>	National Thyroid Cancer Awareness Month
Cancer Control Month	Prostate Cancer Awareness Month
Cancer Detection & Early Awareness Month	Pain Awareness Month
Cancer Fatigue Awareness Month	<b>October</b>
Head & Neck Cancer Awareness Month	National Breast Cancer Awareness Month
Lymphoma Awareness Month	National Mammography Day(21 <sup>st</sup> )
National Young Adult Cancer Awareness Week - April 3-9	<b>November</b>
Oral Cancer Awareness Week - April 11 – 17	Brain Tumor Awareness Day
Testicular Cancer Awareness Week - April 1-7	Lung Cancer Awareness Month
<b>May</b>	National Hospice & Palliative Care Month
Brain Tumor Action Week - May 1-7	National Pancreatic Cancer Awareness Month
Cover the Uninsured Week – May 1-7	National Family Caregivers Month
Melanoma Monday(2 <sup>nd</sup> )	National Caregivers Month
National Melanoma/Skin Cancer Detection & Prevention Month	National Bone Marrow Donor Awareness Month
Skin Cancer Awareness Month	Smoking Cessation Awareness Month
<b>June</b>	<b>December</b>
National Cancer Survivors Day (4 <sup>th</sup> )	National Aplastic Anemia Awareness Month
Sarcoma Awareness Month	

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**We need your help!** Your Donation Makes a Difference! If you believe in the hope of research and the power of advocacy, you can help the Research Advocacy Network by sending a donation. RAN is an exempt 501 c 3 organization and dependent on your support to keep going. Our mailing address is: East Rand Rd, Suite 175, Arlington Heights, IL 60004. Thanks! Another way to donate is just by shopping! Buy your office supplies, books, sporting gear, CDs and everyday items at the iGive Mall at [www.iGive.com/ResearchAdvocacyNetwork](http://www.iGive.com/ResearchAdvocacyNetwork). You can shop at 500 stores and without even knowing it, you'll be helping Research Advocacy Network at the same time. A check was just received from this program and we want to say thank you for supporting Research Advocacy Network in this way!

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### Research Advocacy Network Welcomes New Members!!!

Thanks to all of you who have recently joined the Network. For those that have not yet please go to <http://www.researchadvocacy.org/> and click on "Join". There are no dues for Network membership and this will assure that you receive all notices and have access to Network programs.

Network News is currently published 10 times per year and includes articles on advocacy, research results and activities. Please share Network News with your friends with the link above. However, we ask when using information from Network News that you give attribution, and keep the subscription and copyright information intact.

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