ONCOLOGY RECOGNITION DAY

On September 26th, faculty, staff and leadership across Fred Hutch, UW Medicine and Seattle Cancer Care Alliance came together to support our collaborative Cancer Consortium partnership. The event started with an interactive poster session, which displayed important contributions made by over 250 people in an effort to improve a process or system within the network. All were inspired by the hard work and dedication demonstrated by each team to help speed research and improve health care delivery to our patients.

At the award ceremony, Drs. Gary Gilliland, Paul Ramsey and Fred Appelbaum each presented an unsuspecting employee with a wonderful list of accolades and appreciation on behalf of our entire community. STTR would like to thank everyone for the hard work demonstrated daily in support of one another and our mission.

Congratulations!!

PROCESS/SYSTEMS IMPROVEMENT AWARDS

SCCA Employee Health & Safety Committee Staff Injury Reduction – Co-Chairs Kathleen Hite & Pam Gregory [SCCA]
Institution-Sponsored IND Program – Lacey Hedin [Fred Hutch]
Leveraging SharePoint as a Tool to Manage National Clinical Trials Network (NCTN) Studies: A Regulatory Perspective – Claire Rein-Weston [ITHS]
AML/MDS Therapy Plans and Research Sample Acquisition – Taylor Sekizaki [UW Medicine]
Sarcoma Intake Algorithm – Cindy Gist [People’s Choice]

EMPLOYEE RECOGNITION AWARDS

Kiranjit Dhillon [Fred Hutch]
Sandra Olson [UW Medicine]
Christy Satterlee [SCCA]

STTR SPIRIT AWARD

sRAMP Team – for joint efforts to improve clinical trial startup across the Cancer Consortium

Photo credits: Fred Hutch/Robert Hood
ONCOSCAPE UPDATE

Oncoscape is a collaborative platform and community that unites the clinical, genetic and computational fields in an effort to advance the understanding of cancer biology and improve patient care. [https://oncoscape.sttrcancer.org](https://oncoscape.sttrcancer.org)

CREATE, STORE & TRANSFER COHORTS

Using the Cohorts and Collections feature, users can select patients of interest in one analysis tool and seamlessly view or compare their molecular or clinical results in another. There is the ability to retain these cohorts for future analysis.

NEW DATA ANALYSIS TOOLS

Follow the progress of new beta tools on the development site.

With the Sunburst tool, users can explore flow data and visualize relative percentages of cells for each biomarker, viewing tumor and normal cell population stratified by tissue, cell and marker type. In the Clusters tool, users can simultaneously view multiple layouts of patient similarity plots and discover how a selected group is distributed. Heatmap provides a selectable grid of molecular values shaded according to a color scale.

USER & API DOCUMENTATION

Oncoscape now provides resources to address user questions! Tool documentation provides navigational guides, methods and data along with video tutorials of general use cases. If users want to explore our data structures and perform simple queries from the collections, our API documentation guide has simplified the process with easily clickable menus.

To learn more visit: [http://resources.sttrcancer.org/oncoscape](http://resources.sttrcancer.org/oncoscape)
INCREASED TOOL CAPACITY

User feedback sessions spurred many new interactive features. Users can now specify color-coding options for patients based on either molecular or clinical data. A retractable menu bar of cohort plots provides users with relevant data on selections, such as age of diagnosis, vital status and more including an interactive Kaplan-Meier survival curve. Our spreadsheet now includes all clinical fields from multiple demographics and treatment tables and supports the annotation of values.

Check out these features and more at: https://dev.oncoscape.sttrcancer.io

DEVELOPER CORNER

Onocoscape is evolving from a data visualization tool to a general-purpose data and compute platform. This quarter, MongoDB was implemented and over 2,600 collections of TCGA data were added. Authorization and authentication for private data were implemented using Kong and Nginx. To leverage R, openCPU was incorporated. To maximize the reach and utility of Onocoscape’s data infrastructure we have made all of this functionality available via REST APIs.

http://resources.sttrcancer.org/api
http://resources.sttrcancer.org/api/data-explorer

Have additional feedback or questions? Please email us at: contact@oncoscape.org
CLINICAL RESEARCH UPDATE

Anogenital Cancers

THERAPEUTIC USE OF HPV L1 VACCINE IN ANOGENITAL NEOPLASIA: THE VIVA TRIAL

Drs. Margaret Madeleine & Anna Wald

This investigator-initiated trial, called the HPV Vaccine to Interrupt Progression of Vulvar and Anus Neoplasia (VIVA) Trial, will enroll 345 individuals starting in March 2017. It is a double-blind, randomized, placebo-controlled trial which will test the therapeutic impact of the approved HPV vaccine (Gardasil 9, Merck) as an adjunct to surgery for high-grade intraepithelial anal or vulvar neoplasia (AIN3/VIN3).

Bladder Cancer

A PHASE III, OPEN-LABEL, MULTICENTER, RANDOMIZED STUDY OF ATEZOLIZUMAB [ANTI-PD-L1 ANTIBODY] VERSUS OBSERVATION AS ADJUVANT THERAPY IN PATIENTS WITH PD-L1−SELECTED, HIGH-RISK MUSCLE-INVASIVE BLADDER CANCER AFTER CYSTECTOMY

Dr. Michael Schweizer

This is a randomized Phase II study testing atezolizumab vs. observation in patients that have undergone cystectomy for muscle invasive bladder cancer (upper tract disease is excluded). Patients that have received prior neoadjuvant therapy are eligible if they have ≥pT2 disease or N+ disease; those not receiving adjuvant therapy are required to have ≥pT3 disease or N+ disease. Patient must randomize within 12 weeks of cystectomy.

Brain Cancer

PHASE I/II STUDY OF ADOPTIVE IMMUNOTHERAPY FOR ROR1+ GLIOBLASTOMA WITH DEFINED SUBSETS OF AUTOLOGOUS T CELLS ENGINEERED TO EXPRESS A ROR1-SPECIFIC CHIMERIC ANTIGEN RECEPTOR

PHASE I/II STUDY OF ADOPTIVE IMMUNOTHERAPY FOR IL13Rα2+ GLIOBLASTOMA WITH DEFINED SUBSETS OF AUTOLOGOUS T CELLS ENGINEERED TO EXPRESS AN IL13Rα2+SPECIFIC CHIMERIC ANTIGEN RECEPTOR

Drs. Hans-Peter Kiem & Eric Holland

Two investigator-initiated CAR T cell trials will be opening in early 2017 for glioblastoma patients using defined subsets of autologous T cells engineered to either target ROR1+ or IL13Rα2+ glioblastoma. These are Phase I/II, open-label, nonrandomized studies that will evaluate the safety and potential antitumor activity of adoptively transferring autologous ROR1 CAR-T cells for patients with ROR1+ glioblastoma or IL13Rα2+ CAR T cells for patients with IL13Rα2+ glioblastoma. The primary endpoint of the trial will be to determine the safety of these CAR-T cells using a dose escalation/de-escalation design to define a cell dose that has acceptable toxicity, and might be used for a future larger phase II trial to evaluate efficacy.
Breast Cancer

**WOKVAC - VACCINE THERAPY IN PREVENTING CANCER RECURRENCE IN PATIENTS WITH NON-METASTATIC, NODE POSITIVE, HER2 NEGATIVE BREAST CANCER THAT IS IN REMISSION**

**DR. NORA DISIS**

This phase I investigator-initiated trial, in partnership with Wings of Karen, studies the side effects and best dose of a vaccine therapy in preventing cancer from coming back in patients with non-metastatic, node positive, human epidermal growth factor receptor (HER)2 negative breast cancer in which all signs and symptoms have disappeared. Vaccines made from deoxyribonucleic acid (DNA) may help the body build an effective immune response to kill tumor cells. Giving multiple vaccinations may make a stronger immune response and prevent or delay the return of cancer.

Colorectal Cancer

**PROSPECT: CHEMOTHERAPY ALONE OR CHEMOTHERAPY PLUS RADIATION THERAPY IN TREATING PATIENTS WITH LOCALLY ADVANCED RECTAL CANCER UNDERGOING SURGERY (PHASE III)**

**DRS. ALESSANDRO FICHERA (NATIONAL PI) & GABI CHIOREAN (SEATTLE PI)**

The PROSPECT trial, by randomizing patients to either preoperative radiation or selective preoperative radiation and evaluation before chemotherapy and TME, provides an opportunity to reduce the use of pelvic radiation in patients who might not benefit from it. In this phase II/III multicenter trial, neoadjuvant FOLFOX (Oxaliplatin, Leucovorin, and 5-Fluorouracil) with selective use of chemoradiation (5-fluourouracil and pelvic radiation), is being tested against the current standard of preoperative chemoradiation (5-flourouracil and pelvic radiation) for rectal cancer patients undergoing low anterior resection with TME. The primary endpoint for the phase II portion of the trial is R0 resection rate. If the trial achieves an equally high R0 resection rate in the intervention arm as in the control arm, the study will proceed to phase III. The Phase III will evaluate time to local recurrence and disease-free survival.

Head & Neck Cancer

**WEE1 INHIBITOR AZD1775, DOCETAXEL, AND CISPLATIN BEFORE SURGERY IN TREATING PATIENTS WITH BORDERLINE RESECTABLE STAGE III-IVB SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK**

**DR. EDUARDO MENDEZ**

This investigator-initiated trial is the first trial aimed at targeting head and neck cancer’s most common genetic driver – TP53. This represents a true “bench-to-bedside” pipeline from collaborative work by basic and clinician-scientists at the Fred Hutch, UW Medicine and Seattle Cancer Care Alliance. This trial is aimed at an intensification strategy for advanced head and neck squamous cell carcinoma (HNSCC) targeting WEE1, a gene product relied upon by p53 mutant tumors to maintain viability. This phase I trial studies the side effects and the best dose of WEE1 inhibitor MK-1775 [AZD1775] when given together with docetaxel and cisplatin in treating patients with stage III-IVB squamous cell carcinoma of the head and neck that may or may not be able to be removed by surgery (borderline resectable).
Leukemia

A FEASIBILITY STUDY OF “EARLY” ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION FOR RELAPSED OR REFRACTORY AML

DR. MARY-ELIZABETH PERCIVAL
In this investigator-initiated trial patients will receive re-induction with a standard high-dose cytarabine-containing regimen followed by a reduced-intensity conditioning regimen of fludarabine and melphalan 21 to 60 days later. We have solicited input from multiple leukemia and transplant team members to streamline rapid donor identification and subsequent HCT. This novel, multifaceted project will bring together collaborators from the leukemia and transplant community within the Cancer Consortium. The goal of this study is to characterize the feasibility of implementing a practice-changing approach of early allogeneic HCT through a single-center clinical trial conducted at UW/FHCRC.

Lung Cancer

A PILOT STUDY OF MPDL3280A (PD-L1 ANTIBODY THERAPY AND HYPOFRACTIONATED IMAGE-GUIDED RADIOTHERAPY [HIGRT]) IN PATIENTS WITH METASTATIC NON–SMALL CELL LUNG CANCER

DR. RAMESH RENGAN
The purpose of this investigator-initiated study is to find out whether a brief course of radiation therapy given to one area affected by the cancer will improve the chances of responding to immunotherapy in the form of a medicine called MPDL3280A, an antibody against PD-L1. PD-L1 is expressed on lung cancers and is known to block the effects of the body's immune system in attacking the cancer. Blocking this PD-L1 has been shown to improve the body’s immune cells to attack and kill the cancer cells in non-small cell lung cancer. The goal of this study is to see if prior treatment with radiation will allow improved recognition of the cancer by the body’s immune cells in the presence of MPDL3280A.

Lymphoma

EVALUATION OF PRETARGETED ANTI-CD20 RADIOIMMUNOTHERAPY COMBINED WITH BEAM CHEMOTHERAPY AND AUTOLOGOUS STEM CELL TRANSPLANTATION FOR HIGH-RISK B-CELL MALIGNANCIES

DR. AJAY GOPAL
This investigator-initiated study is looking at a way of giving radiation to lymphoma patients before they have a stem cell transplant. Radioimmunotherapy (RIT) is a combination of radiation therapy and immunotherapy. In immunotherapy, a laboratory-produced molecule called a monoclonal antibody is designed to recognize and attach to the surface of cancer cells. In RIT, a monoclonal antibody is paired with a radioactive material, or radiotracer. When injected into the patient’s bloodstream, the radiation-linked monoclonal antibody, or agent, travels to and binds to cancer cells, allowing a high dose of radiation to be delivered directly to the tumor cells while limiting damage to normal tissues.
MDS/MPN

INITIAL CYTOREDUCTIVE THERAPY FOR MYELODYSPLASTIC SYNDROME PRIOR TO ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION (ICT-HCT STUDY)

DR. BART SCOTT

This is a prospective investigator-initiated trial randomizing patients with intermediate and high-risk MDS who are allogeneic hematopoietic cell transplantation (HCT) candidates to receive pre-HCT therapy with induction chemotherapy (IC) versus hypomethylation. The primary aim is to prospectively assess the impact of hypomethylating agents versus induction chemotherapy as initial therapy on survival in the study population. We will also assess transplant frequency, relapse and quality of life. Results from this study will provide controlled, prospective data on the impact of pre-HCT IC versus hypomethylating therapy on transplantability and transplant outcome, thereby guiding clinical practice. Although there is a growing body of retrospective literature, no randomized prospective trials comparing IC with hypomethylation have been performed.

Myeloma

PHASE 1 STUDY OF SGN-CD352A IN PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA

DR. DAMIAN GREEN

Multiple Myeloma is considered an incurable disease with standard treatments. Recent data demonstrates that naked monoclonal antibodies directed to CS-1 and CD38, antigens expressed on myeloma cells, have antitumor activity. The development of an antibody drug conjugate that is targeted to a highly expressed myeloma antigen, and that can deliver a potent DNA damaging agent, is a rational approach to the treatment of Multiple Myeloma. This study is designed to evaluate the safety, tolerability and antitumor activity of SNG-CD352A. The trial is set to open in November 2016.

Ovarian Cancer

OLAPARIB OR CEDIRANIB MALEATE AND OLAPARIB COMPARED WITH STANDARD CHEMOTHERAPY FOR OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER (NRG GY004)

DR. HEIDI GRAY

This randomized Phase III trial studies olaparib or cediranib maleate and olaparib to see how well they work compared with standard platinum-based chemotherapy in treating patients with platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer that has come back. Olaparib and cediranib maleate may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Cediranib maleate may stop the growth of ovarian, fallopian tube or primary peritoneal cancer by blocking the growth of new blood vessels necessary for tumor growth. Drugs used in chemotherapy, such as carboplatin, paclitaxel, gemcitabine hydrochloride and pegylated liposomal doxorubicin hydrochloride work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing or by stopping them from spreading. It is not yet known whether olaparib, or cediranib maleate and olaparib is more effective than standard platinum-based chemotherapy in treating patients with platinum-sensitive ovarian, fallopian tube or primary peritoneal cancer.
Pancreatic Cancer

**PEGPH20 + NAB-PACLITAXEL PLUS GEMCITABINE FOR STAGE IV PREVIOUSLY UNTREATED PANCREATIC DUCTAL ADENOCARCINOMA**

DR. ANDREW COVELER

This Phase III, randomized, double-blind, placebo-controlled, multicenter study is based on science developed at Fred Hutch. The trial will test the efficacy and safety of PEGylated Recombinant Human Hyaluronidase (PEGPH20) combined with nab-paclitaxel plus gemcitabine (PAG treatment), compared with placebo combined with nab-paclitaxel plus gemcitabine (AG treatment), in participants with hyaluronan (HA)-high Stage IV previously untreated pancreatic ductal adenocarcinoma (PDA). Patients will be randomized in a 2:1 ratio to PAG or AG treatment.

DR. SUNIL HINGORANI

Pancreatic Cancer Action Network (PANCAN) Precision Promise is a flexible, precision-medicine clinical trials consortium available at a select number of institutions that is ‘driven by doing what is best for the individual patient’. Precision Promise clinical trials allow participants to transition in and out of numerous substudies of various experimental treatment approaches, depending on their tumor’s unique and shifting biology.

Prostate Cancer

**A PHASE I/II TRIAL OF CONCURRENT CHEMOHORMONAL THERAPY USING ENZALUTAMIDE (MDV-3100) AND CABAZITAXEL IN PATIENTS WITH METASTATIC CASTRATION RESISTANT PROSTATE CANCER**

DR. HEATHER CHENG

This investigator-initiated Phase I/II trial aims to determine if there is therapeutic synergy between combining a newer, more potent anti-androgen [enzalutamide] with a more potent taxane chemotherapy [cabazitaxel] for men with metastatic hormone-resistant prostate cancer. The study will also include obtaining metastatic biopsies and correlative biological specimens to be analyzed in the laboratories of Dr. Elahe Mostaghel (Hutch CRD Division), and will offer the opportunity to better understand the biological and molecular response and resistance of this combination.

Sarcoma

**A TRIAL OF PEMBROLIZUMAB IN COMBINATION WITH DOXORUBICIN AS TREATMENT FOR PATIENTS WITH ADVANCED SARCOMAS**

DRS. ROBIN JONES AND SETH POLLACK

Immunotherapies may work better when combined with chemotherapy that leads to tumor breakdown and subsequent presentation of tumor specific antigens to T cells. Single agent doxorubicin is considered the standard front-line chemotherapy for most patients with advanced soft tissue sarcoma. Although doxorubicin may kill myeloid cells that frequently interfere with immunotherapy, it tends to spare T cells which are critical for checkpoint inhibition.

Our new STTR-supported, investigator-initiated trial of doxorubicin combined with pembrolizumab will be the first trial ever combining doxorubicin with a checkpoint inhibitor and the first trial combining a checkpoint inhibitor with cytotoxic chemotherapy for sarcoma patients. While the trial is open to anthracycline naïve patients in any line of therapy, this will be the first checkpoint inhibitor trial open to sarcoma patients in the front-line.
CANCER RESOURCES DATABASE

A comprehensive database of no- and low-cost resources for patients, caregivers, friends and family

In the age of social media, it’s not uncommon to see posts in our feeds of a friend, family member or acquaintance diagnosed with cancer. We recognize that as patients or loved ones of those with cancer, it’s easy to feel overwhelmed and knowing where to go for resources can be challenging. Knowing this, our interns saw an opportunity to help and began thinking of ways in which STTR could make it easier for patients to get the support they need.

There are a tremendous number of wonderful organizations who seek to aid and support those dealing with cancer. However they can often be difficult and time-consuming to find. Our hope was that as an organization with time and resources, we were in a unique position to create something that would be able to serve cancer patients both locally and nationally.

http://resources.sttrcancer.org/resources-connect

Examples of resources found in our database

**24 Hour Peer Support** - American Childhood Cancer Organization: in partnership with Inspire, a company that builds and manages online healthcare communities, we’ve created a place where you can connect with others who know what you are going through.

**A Camp to Remember** - Tamarack Grief Resource Center: a fun, supportive and healing summer camp for kids ages 8 to 14 who are grieving the death of a loved one.

**PICC Line Cover** - Care + Wear: a functional and fashionable PICC line cover that aims to improve the quality of life for those living with PICC lines.