UNIVERSITY OF
SOUTH CAROLINA

School of Medicine
Greenville

Blueprint for Academic Excellence in the University of South Carolina School of Medicine – Greenville (USCSOM-G)

18 April 2012

Mission

Improve the health of the people and diverse communities we serve by educating health professionals who will care compassionately, teach innovatively, and improve constantly.

Vision

Transform health care for the benefit of the people and communities we serve.

Guiding Principles

1. USCSOM-Greenville will be responsive to the changing health care needs of our society.
2. USCSOM-Greenville will strive to consider the needs of the students, faculty, and administration in a manner which enhances the stature of both USC and GHS.
3. USCSOM-Greenville understands that health care delivery is constantly evolving and that its physician graduates should facilitate and advocate transformation that improves care provision.
4. USCSOM-Greenville will be integrated with all aspects of the GHS delivery system.
5. USCSOM-Greenville will graduate physicians who understand and participate in research that compares the relative clinical effectiveness and outcomes of various treatments.
6. USCSOM-Greenville supports development of a health care workforce that reflects future societal needs and the diversity of the communities served.
7. USCSOM-Greenville will educate physicians to be champions for patient safety, standardization, evidenced based care, and quality; responsible to the medical needs of their community; sensitive to the societal cost of medicine; activists for the education of the future health care workforce; and practitioners that care for all patients regardless of race, social stature, or ability to pay.
8. USCSOM-Greenville students will practice patient centered care that values the interdependent roles of health care providers and facilities in service to their patients.
9. USCSOM-Greenville will produce physicians competent not only in medical knowledge, technical skill, and patient care, but also in compassion, collaborative interpersonal communication, professional responsibility and ethical behavior.
10. USCSOM-Greenville believes that candidates for medical school who value professionalism and possess exceptional interpersonal communication skills can be prepared, identified, and selected to become successful practicing physicians.
11. USCSOM-Greenville will establish a learning environment that emphasizes the relationship between undergraduate medical education and the real world of patient care.
12. USCSOM-Greenville strives to alleviate the cost of medical education as a significant barrier to student matriculation and graduation, or as a factor in the selection of a career specialty.
13. USCSOM-Greenville utilizes policies and procedures that synergistically combine the academic virtues of USC with the operational efficiencies of the GHS health system to the benefit of its students, faculty and staff.
14. USCSOM-Greenville faculty will emphasize and demonstrate the clinical import of the materials that they teach.
15. USCSOM-Greenville faculty selection, development, and promotion processes will favor those committed to their profession as a calling; who view their teaching ability as a gift and privilege.
16. USCSOM-Greenville graduates will be fully prepared and highly competitive to enter graduate medical education.

17. USCSOM-Greenville appreciates that access to medical information is constantly changing and that educational focus must continually emphasize methods to optimally acquire the most current knowledge.
18. USCSOM-Greenville will utilize educational resources, infrastructure and technology in a fiscally responsible manner, incorporating external resources in the education of health care students when advantageous.

Institutional Comparisons

Top 10 Public Medical Schools ***(Primary Care) 2012 US News & World Report:*** University of Washington, University of North Carolina-Chapel Hill, Oregon Health and Science Center, University of California-San Francisco, University of Colorado – Denver, University of Nebraska Medical Center, University of Massachusetts-Worcester, University of Michigan, University of Minnesota, University of California – Los Angeles.

5 Peer Institutions: Our peer group is called the Macy Schools. These are the schools initiated in this century and currently under study by the AAMC through a grant from the Macy Foundation. Of the 19 Macy Schools, the five listed below are most similar to USCSOM – G in both the stage of their development and in their focus on innovative curriculum design based upon a close working relationship between the parent university and its affiliated delivery system.

- Oakland University William Beaumont School of Medicine
- Cooper Medical School of Rowan University
- Hofstra North Shore – Long Island Jewish School of Medicine at Hofstra University
- Virginia Tech Carilion School of Medicine
- Western Michigan University School of Medicine

Goals

Five-Year Goals

Goal 1: Recruit a full contingent of Biomedical Sciences Faculty (24) and transition four Clinical Department Chairs (Family Medicine, Internal Medicine, Orthopaedics and Pediatrics).

Goal 2: Graduate the first class in 2016 and achieve 95% residency placement in the National Residency Match Program.

Goal 3: Achieve provisional LCME accreditation in 2014 and full accreditation in 2016.

Goal 4: Achieve 95% three year pass rate for eligible students on the USMLE.

Goal 5: Complete $80 million capital campaign.

2012-2013 Academic Year Goals

Goal 1: Complete recruitment of 75% of Biomedical Sciences faculty (18).

Goal 2: Matriculate highly qualified inaugural class in accord with USCSOM-G admissions standards.

Goal 3: Develop and deliver year one integrated, modular curriculum; develop year two curriculum.

Goal 4: Establish USCSOM – G policies, procedures, handbooks and unit criteria.

Goal 5: Recruit USC IAHC Director and SmartState Chairs in Reconstruction and Rehabilitative Sciences (CRRS) and Childhood Translational Neurotherapeutics.

Proposed Academic Dashboard Measures for USCSOM - G

1. Matriculate 50 students (+/- 10%) in July 2012
2. Maintain 350 clinical faculty in seven clinical departments
3. Biomedical Sciences Faculty:

Brian Tobin, PhD	Department Chair; Professor	Physiology
Robert Best, PhD	Professor	Cytogenetics
James Buggy, PhD	Associate Professor	Neuroscience
Andrea Deyrup, MD, PhD	Clinical Assistant Professor	Pathology
Thomas Nathaniel, PhD	Clinical Assistant Professor	Neuroscience
Jayne Reuben, PhD	Clinical Associate Professor	Pharmacology
William Roudebush, PhD	Clinical Associate Professor	Physiology
Jennifer Trilk, PhD	Clinical Assistant Professor	Physiology
Shanna Williams, PhD	Clinical Assistant Professor	Anatomy
William Wright, PhD	Clinical Assistant Professor	Physiology

4. Clinical Faculty:

Clinical Professor	Clinical Professor of Practice	Clinical Associate Professor	Clinical Assistant Professor	Clinical Instructor	Emeritus Clinical Professor	Emeritus Clinical Associate Professor
33	1	42	348	12	3	1

5. Contract Faculty:

Peggy Wagner, PhD	USC IAHC Director, Research Development	Research
Neena L. Champaigne, MD	Greenwood Genetics	Clinical Faculty
Barbara DuPont, PhD	Greenwood Genetics	Cytogentics
Michael J. Friez, PhD	Greenwood Genetics	Director, Diagnostic Laboratory
Leta M. Tribble, PhD	Greenwood Genetics	Education
Tim Wood, PhD	Greenwood Genetics	Biochemical Laboratory

Scholarship, Research, and Creative Accomplishments

- USCSOM-G became the 137th accredited medical school in North America on October 4, 2011.
- USCSOM-G was the only applicant medical school to achieve preliminary accreditation in 2011.
- The $39.5 million Health Sciences Education Building was designed to facilitate curriculum and promote inter-professional education. The facility includes a state of the art simulation center and simulated patient education areas which will allow it to serve as a regional health science education resource. The building will be finished on budget and ahead of schedule in May 2012.
- The first USCSOM-G/Greenville Hospital System (GHS) grant was submitted through the USC Sponsored Programs Office on February 24, 2012. The $7 million NIH grant was submitted by Mitzi Nagarkatti, PhD, and Bruce Lessey, MD, PhD, for 3-D modeling of the endometrium. If funded, work on the project will be done in association with ITOR Innovation Zone Biotech partner, Kiyatek. The intent is to create and connect additional 3-D tissue models and study immune modulation.

Academic Health Center (USCSOM-G and GHS) CME/CE Report (Fiscal Year Ended September 30, 2011):

	Activities	Hours of Instruction	Physician Participants	Non-Physician Participants
Directly Sponsored	76	855.5	7,265	1,990
Jointly Sponsored	1	6.0	20	65
Total, All Activities	77	861.5	7,285	2,055

Academic Year 2013 Budget:

The proposed budget is included as **attachment 1** and includes $2.0 million in tuition funding and $14.2 million in funding support from GHS.

Research Plan:

GHS is actively involved in a collaborative strategic planning process for academics that includes education and research. As a part of the GHS Academic Health System, USCSOM-G is party to that process. It is anticipated that there will emerge five research cluster areas consonant with the overall direction of the Academic Health System. USCSOM-G faculty will be encouraged to align their research interests and initiatives with one or more of the following clusters.

1. Health Services Research under the aegis of the Institute for Advancement of Heath Care (IAHC) portfolio areas:
    a. Compare effectiveness of interventions and inform policy.
    b. Investigate patient centered models of care.
    c. Study methods to build workforce capacity.

    See **attachment 2** for a list of IAHC scholars and programs/projects.
2. Oncology translational research within the following four programmatic pillars of ITOR:
    a. Phase I Clinical Research Unit with 20 clinical trials open at any given time (see **attachment 3**).
    b. Biorepository as a component of the USC Cancer Center Tissue Bank (see **attachment 4**).
    c. Innovation Zone and research laboratories (Lab21, Kyatek, and NuBad).
    d. Clinical Genomics Center in association with Lab21 and anchored by a Life Technologies Ion Torrent next generation gene sequencer; GHS ITOR has been selected as one of the 10 initial global network partners to participate in Life Technologies' Genetic Care Interchange (GCI).

    Additional GHS oncology translation research opportunities are found in the 270 active oncology clinical trials at GHS; the Integrative Cancer Therapy Rehabilitative Science Program with active research proceeding in collaboration with Mark Davis, PhD; and the FACT-accredited Bone Marrow Transplant Program.

3. Education research to be developed as a collaborative initiative between USCSOM-G, the GHS Center for Teaching and Learning, and the USC College of Education.
4. Orthopaedic and cardiovascular translational research in collaboration with the Clemson University BioEngineering Department on the GHS Patewood Campus (CUBEInc).
5. Health Care Information Technology Cluster; to be developed.

University of South Carolina School of Medicine - Greenville
Academic Year 2012 - 2013
Proposed Budget
Attachment 1

Revenues:		
Tuition	$	1,958,000
Deductions from Revenues:		
Financial Aid	$	195,800
Bad Debt		3,916
Total Deductions from Revenues:	$	199,716
Total Operating Revenues	**$**	**1,758,284**
Operating Expenses:		
Salaries and Wages	$	6,453,302
Employee Benefits		1,806,925
Supplies		603,780
Purchased Services and Other Costs		7,074,178
Total Operating Expenses	**$**	**15,938,185**
Net Gain/(Loss) before GHS Subsidy	**$**	**(14,179,901)**
Subsidy from GHS	$	14,179,901
Net Gain/(Loss)	**$**	**-**

Attachment 2:

GREENVILLE HOSPITAL SYSTEM
UNIVERSITY MEDICAL CENTER

Institute for Advancement of Health Care (IAHC)

Focus: Health Services and Patient-Centered Research

Purpose

Building on a rich history of research, the Institute for Advancement of Health Care (IAHC) was established by GHS in 2008 in partnership with University of South Carolina (USC) to facilitate and support health services research. The IAHC provides an inter-institutional organizational framework designed to integrate USC, public health practitioners, health services researchers and GHS clinicians to address population health and health care issues related to *access, quality, and cost*. The IAHC facilitates initiatives coordinating USC and other academic institutions' research and education with GHS clinical programs; supporting workforce development; leveraging the resources of the respective parties; and enhancing the reputation of institutions involved. *Modeled after AHRQ, the IAHC has 3 interactive Portfolio Areas with goals as follows.*

IAHC Strategic Research Portfolio Areas

The following portfolio areas will guide the development, implementation and evaluation of initiatives aligned with the IAHC.

- **Compare Effectiveness of Interventions and Inform Policy**
  The goal is to identify and support Comparative Effectiveness Research (CER) and outcomes research as defined by the Institute of Medicine (IOM) "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care."

- **Investigate Patient Centered Models of Care**
  The goal is to develop, implement and evaluate new care models that improve patient outcomes through emphasis on care management including such topics as patient-centered team-based care, patient self-management support, and models that stimulate innovation in care delivery and practice change. This portfolio parallels elements of the agenda of the Agency for Healthcare Research and Quality including the use of health information technology to improve outcomes, quality and safety initiatives, and innovation. Practice Based Research Network (PBRN) will be explored for implementation.

- **Study Methods to Build Workforce Capacity**
  The goal is to identify and support research and scholarly activities designed to inform innovative education and training (quality and quantity) of health and healthcare professionals. This portfolio will facilitate and support research activities for IAHC Scholars and trainees.

Attention will be given to the development of educational research designed to examine inter-professional education; innovative teaching and learning; and life-long learning strategies. Outcomes will inform training for future health and health care professionals.

IAHC Scholars Program

Clinicians and researchers will have access to an IAHC Scholars Program designed to foster and support collaborative research and scholarly activities as well as facilitate mentoring relationships for junior faculty and students. The program has been established to facilitate identification of research expertise aligned with the three research portfolio areas of the Institute. The program will provide a conduit for aligning collaborative research opportunities among clinical, academic and industry partners. Scholars will address a health care "theme" that contributes to one or more of the three strategic research portfolio area; and will be supported in their research development, implementation and dissemination activities. Scholars will complete the IAHC Scholars Interest Form that will capture their research expertise/interest. This information will be captured in a database and posted on the following IAHC website www.ghs.org/IAHC to facilitate collaborative research and support mentoring for faculty and students. Additionally, Scholars will be invited to participate in the University of South Carolina School of Medicine-Greenville education and thus be eligible for an adjunct faculty appointment.

To foster networking, IAHC Scholars' roles and responsibilities include but are not limited to the following:

- Lead programs and initiatives consistent with each scholar's area of expertise
- Represent the IAHC in their respective communities and broader constituencies
- Attend periodic meetings to evaluate projects, assist in developing new initiatives, and provide input to the IAHC Administrator and Directors upon request
- Leverage resources to facilitate applications for external funding to support projects consistent with the IAHC portfolios
- Participate in conferences and meetings as appropriate to foster networking and share best practices

IAHC – Catalog of Programs/Projects

GHS has a long history of collaboration with academic institutions and it continues to evolve. While not an exhaustive list, the following programs/projects are in various stages of their development with potential for growth. The following programs/projects have been aligned with the strategic direction of the Greenville academic campus and the IAHC. This list is dynamic and reflective of research and education initiatives aligned with the three (3) portfolio areas of the IAHC.

IAHC Supported Programs/Projects

PROGRAM/PROJECT	KEY LEADERS	FUNDING
Portfolio Area: STUDY METHODS TO BUILD WORKFORCE CAPACITY		
Education & Workforce Development Health Care Workforce Direction Model Workforce Capacity Pipeline Program: Medical Experience (MedEx) Academy	Brenda Thames, EdD – GHS Al Squire – GHS Doug Dorman – GHS George Maynard – GHS Academic Partners	**Funding support in progress** **$540,000+ Pledged**
University of South Carolina School of Medicine - Greenville Expansion to a 4 Year Medical School to address physician shortage	Jerry Youkey, MD – GHS Spence Taylor, MD – GHS Team of GHS and USC Faculty and Staff	
Building Training Capacity for Physicians – A Faculty Development Model Medical Education Day	Michael Fuller, MD – GHS **Peggy Wagner, PhD – USC** Matthew Hudson, PhD – GHS **Robert McKeown, PhD – USC** Angelo Sinopoli, MD – GHS Brenda Thames, EdD – GHS	**$1,203,500 (5 years) HRSA Proposal Not Funded Note: Good Score**
Vascular Surgery and Bioengineering Research and Education (Patewood C) Cardiovascular Imaging Leadership Concentration and Research Opportunities	Eugene Langan, MD – GHS **Martine LaBerge, PhD – Clemson** **Lee Crandall, PhD – Clemson** Eric Walker – GHS	Industry partnerships and funding to support research
Student Research Assisted Reproductive Technology (Data Related)	William Boone, PhD – GHS Lee Higdon, PhD – GHS **Herman Senter, PhD – Clemson**	Training grant opportunities
Electrophysiology Simulation Training Center (Advanced cardiac electrophysiology training center to meet the workforce need and study the effects on delivery of care)	Donald Rubenstein, MD – GHS Glenn Wert – GHS **Martine Laberge, PhD – Clemson** Fred Baus, PhD – University Center	Industry partnerships and funding
Nurse Practitioner Training Program A Partnership with Greenville Community Foundation (A study to examine workforce capacity building in collaboration with a community partner)	Suzanne White – GHS Angelo Sinopoli, MD – GHS Hiep Pham, MD – GHS Susan Bethel – GHS **Peggy Hewlett, PhD – USC**	$500,000 RWJ Proposal (not funded – will resubmit)
Health and Health Disparities Initiatives Minority Health Summit Annual community-wide education event with over 1200 participants annually	Robyn Zimmerman – GHS Melinda Hudson – GHS **Veronica Parker, PhD – Clemson** **Saundra Glover, PhD – USC**	**$12,900 - USC** **$26,000 DHEC grant**
MedEx Academy Tier I Research Project Hand Hygiene Research, Policy and Practice program to supplement student health care learning activities	Brenda Thames, EdD – GHS Tom Diller, MD – GHS Alfred Squire – GHS Matthew Hudson, PhD – GHS Lee Higdon, PhD – GHS Stephanie Tanner – GHS Connie Steed – GHS	NIH National Institute of Allergy and Infectious Disease Proposal (May 2011 submission) $175,000 annual for 5 years

Portfolio Area: COMPARE EFFECTIVENESS OF INTERVENTIONS AND INFORM POLICY		
"Power to Prevent – A Family Lifestyle Approach to Diabetes Prevention" Recruitment and Retention of African Americans for Power to prevent – A Type II Diabetes Education Program	Melinda Hudson – GHS Matthew Hudson, PhD – GHS DHEC Staff	**DHEC subcontract to GHS $27,000**
Consumer Engagement and Quality Health Care Encouraging consumer engagement through a consumer-initiated quality discussion	**Matthew Hudson, PhD – GHS** **Peggy Wagner, PhD – USC**	Robert Wood Johnson Foundation Pre-proposal submission
Quality and Patient Safety Program Focus: To improve quality outcomes and processes to optimize the delivery of health care through research and education. - Hand Hygiene - Human Factors Analysis Classification System - Data Mining of Adverse Events - Medication Events with Coumadin - Use of Eye Movements to Improve Training - Development of Communication Review of Systems - Evaluation and Implementation of Lean Six Sigma Training - Evaluation of the Efficacy of Influenza - Vaccine on Absenteeism	Tom Diller, MD – GHS **Anand Gramopadhye, PhD – Clemson** Matthew Hudson, PhD – GHS Lynn Crespo, PhD – GHS Michael Fuller, MD – GHS **Peggy Wagner, PhD – USC**	Joint strategic research and education External funding opportunities
Portfolio Area: INVESTIGATE PATIENT CENTERED MODELS OF CARE		
Total Health **Duke Endowment Grant**	Angelo Sinopoli, MD – GHS Nancy Proffitt, RN - GHS **Dennis Poole, PhD – USC**	**$2.6 million**
Childhood Obesity Development of comprehensive treatment for pediatric obesity	Kerry Sease, MD – GHS Cara Reeves - GHS **Russ Pate, PhD – USC**	
Pediatric Clinic An approach to care for pediatric patients from underrepresented populations	Bill Schmidt, MD – GHS Tom Moran – GHS **Bob Moran, PhD – USC** **Pam Gilliam, PhD – USC** **Other USC Faculty**	
Promoting Resources in Developmental Education (PRIDE) Program Duke Endowment Grant ***CoEE Approved*** Process for hiring Endowed Chair underway	Desmond Kelly, MD – GHS William Schmidt, MD – GHS **Robert McKeown, PhD – USC** **Christine Curtis, PhD – USC**	**$673,100** **Endowed Chair $2 million Secured and Chair recruited**
Neuroscience Research - Headache (Migraine) Intervention Project - Primary Care in Multiple Sclerosis	Mary Hughes, MD – GHS Matt Hudson, PhD – GHS **Peggy Wagner, PhD – USC** **Jun Wu, PhD - USC**	
Practice Based Research Network (Primary Care Physician Practices)	Pat Marshall, MD – GHS **Peggy Wagner, PhD – USC**	

Aging Driver Innovation Initiative - Project A – Home Lab - Project B – Driving Health Inventory - Project C – Clinical Driving Simulator and Drive Safety - Project D – Instrumented Vehicle - Project E – Aging Motorcyclists - Project F – Smart Nightstands - Project G – 360 Degree Driving Simulator	Angelo Sinopoli, MD – GHS Kevin Kopera, MD – GHS Stan Healy – GHS **Paul Eleazer, MD – USC** **Johnell Brooks, PhD – Clemson** **Paul Venhovens, PhD – Clemson (CU-ICAR)** **Sue Levkoff, PhD – USC**	**Fullerton Foundation: $49,959 funded for pilot** **$300,000 implementation grant – Aug submission** **Endowed Chairs**
Cancer Research - Oncology Rehabilitation Program - Institute for Translational Oncology Research (ITOR) ITOR will integrate GHS, research university partners and biotech partners	Larry Gluck, MD – GHS Joe Stephenson, MD – GHS **Mark Davis, PhD – USC** **Frank Berger, PhD – USC**	University-wide discussions with faculty interested in cancer research
Other Broad Initiatives Aligned with the IAHC		
Health Sciences Collaboration (HSSC) HSSC is a state-wide biomedical research collaborative and is committed to transforming South Carolina's public health and economic wellbeing through research.	Jerry Youkey, MD – GHS Tom Diller, MD – GHS **Clemson Faculty and Endowed Chairs** **USC Faculty and Endowed Chairs** **MUSC Faculty and Endowed Chairs**	**A statewide opportunity for collaborative research and scholarship**
SC Medical Translational Technology Program (Agreement between the Stryker Corporation and 6 hospitals to support research)	Jerry Youkey, MD – GHS John Mateka – GHS **Martine Laberge, PhD - Clemson**	**Estimated $2 million/year to support bioengineering research**

External funding (public/private) sought to support the Program/Project. Blue denotes funds received or pending.

Attachment 3

ITOR Clinical Research Unit

OVERVIEW

Agility & Speed – Ability to launch a clinical trial within 8 weeks

- ***Demonstrated Track Record / Performance – 13 First in Human Studies***
- ***Reputation / Established Sponsors/Clients – Over 35 Pharmaceutical Partners***
- ***Nationally Prominent – In Operation Since 2004***

- **12 full-time, expert staff members**
- **1 Director of Clinical Operations**
- **1 RN research manager**
- **2 research infusion, oncology certified RNs**
- **2 registered nurses who serve as clinical research coordinators**
- **2 data coordinators**
- **1 regulatory specialist**
- **1 lab technician**
- **1 dedicated Pharm D**
- **1 pharmacy technician**

Highlighted ACTIVE TRIALS

- Sponsor: **Ardea Biosciences** – USO 10-022 RDEA119 MEKi + Sorafenib – HCC
- Sponsor: **Amgen**- Denosumab in Giant Cell Tumorof Bone
- Sponsor: **Amgen 534** - Cisplatin, Etoposide, AMG479/AMG102 – Extensive Small Cell Lung Ca
- Sponsor: **Amgen 257** - Carboplatin, Paclitaxel, AMG479 – Advanced Squamous Cell Lung Ca
- Sponsor: Biovex - Oncovex / GMCSF – Unresectable, Metastatic Melanoma
- Sponsor: **Cylene** - USO 10-139 CX4945 Multiple Myeloma
- Sponsor: **Eisai** - Temozolomide, E7016 – Solid Tumors
- Sponsor: **Eisai** - USO 09-014 – E6201 – BRaf + Metastatic Melanoma
- Sponsor: **Eisai** - USO 09-191 – Dacarbazine + E7080 – Metastatic Melanoma
- Sponsor: **Eli Lilly** - USO 08-008 – LY573636 + single agent chemo – Solid Tumors
- Sponsor: **GSK** - USO 09-249 Eltrombopag TPO R + Gemcitabine – thrombocytopenia
- Sponsor: **GSK** - Lapatanib – HER2 + Solid Tumors
- Sponsor: **GSK** - Pazopanib Solids Study
- Sponsor: **Infinity** - USO 10-004 – Gemcitabine + IPI-926 – Metastatic Pancreatic Ca
- Sponsor: **NovaRx** - Lucanix Vaccine – Maintenance Tx for Non Small Cell Lung Ca
- Sponsor: **Progen** - USO 05-033 – PG11047 + single agent chemo – Solid Tumors
- Sponsor: **Threshold Pharmaceuticals** (PCRT) – TH302 metastatic pancreatic
- Sponsor: **Tokai** - TOK-001 – Chemo Naïve Castration Resistant Prostate Cancer
- Sponsor: **Allos** – PDX019 in solids, lymphoma, myeloma with renal impairment

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Highlighted ACTIVE TRIALS cont...

- Sponsor: **Merrimack** - USO 10-190 MM-111 in Her 2+ solid tumor
- Sponsor: **Lilly** - USO 08-029 LY573636 and Sutent in mRCC
- Sponsor: **Novartis** - MEK162 in melanoma
- Sponsor: **Novartis** - BKM120 in solids
- Sponsor: **Pfizer** - Crizotinib (Alk Inhib) in solids (exc lung) and lymphoma
- Sponsor: **Celgene** - USO 10-270 Oral Azacitidine in MDS/CMML/AML
- Sponsor: **GSK** - NYESO1 in melanoma
- Sponsor: **GSK** - USO 09-115 MEK Inh CP1b
- Sponsor: **Mersana** - USO 06-146 XMT-1001 in NSCLC and Gastroesophageal

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ITOR Clinical Research Unit

Compound, Vaccine, and Virus Experience

Monoclonal antibodies targeting:

- **CD33**
- **CD40**
- **Prostate stem cell antigen**
- **IGFR**
- **Program death receptor-1**
- **VEGFR-2**
- **CTLA-4**
- **EGFR**
- **TRAIL-2**

Compounds that inhibit:

- **XIAP**
- **Scatter factor from binding c-met**
- **Eg5 protein**
- **PI3K pathway**
- **Multi-tyrosine kinases**
- **Thioredoxin-1**
- **CDK**
- **Polo-like kinase**

Vaccines:

- **Antigenic vaccine in NSCLC**
- **Whole cell vaccine for prostate cancer**
- **Dendritic vaccine for RCC and melanoma**

Viruses:

➢Adenovirus that targets Rb pathway defective cancer cells

➢Adenovirus that is transfected with the TNF gene Vaccina Virus

➢Seneca Valley Virus

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ITOR Clinical Research Unit
First in Man Trial Experience

- **CG0070** is a conditionally replicating oncolytic adenovirus regulated by a promoter upregulated in Rb pathway defective tumor cells. It selectively expresses GM-CSF
- **SVV-001** is a replication competent picornavirus
- **AZD4877** is an Eg5 inhibitor
- **CG53135** is a fibroblast growth factor that induces proliferation of epithelial and mesenchymal cells
- **Dendrivax** Vaccine created by fusing autologous dendritic cells with irradiated tumor cells and given in conjunction with IL-2
- **Melanix® Vaccine** Dendritic cells fused with irradiated tumor cells as a cancer vaccine in conjunction with BCG
- **JX594** is a replication-competent, GM-CSF transgene-expressing therapeutic vaccinia virus
- **Tokai-001** inhibits CYP17, an enzyme that controls androgen production in the adrenals, testes and prostate
- **E7016** is PARP inhibitor

Attachment 4:

Institute for Translational Oncology Research (ITOR)
Status Report – March 13, 2012
FY12 thru 2/29/12

PATIENT ENROLLMENT SUMMARY

Clinical Research Unit (08-7167):

Trial Sponsor	New Accruals Oct	New Accruals Nov	New Accruals Dec	New Accruals Jan	New Accruals Feb	FY12 Accruals to Date
Independent Industry	1	1	1	9	1	13
TOP (US Oncology)	1	4	3	1	1	10
Totals	2	5	4	10	2	23

MONTHLY TRIAL AND PATIENT AVERAGES:

Sponsor	Trials Open to Accrual	Trials Open to Follow-Up	Patients on Treatment	Patients in Follow-Up
Independent	20	5	15	8
USO TOP	6	3	9	1
Total:	26	8	24	9

Biorepository Services (08-7166):

Sponsor	Patient Consents Oct	New Accruals Nov	New Accruals Dec	New Accruals Jan	Patient Consents Feb	FY12	Total Overall
Total Cancer Care (TCC)	36	38	35	NA	NA	109	2353
TCC Daily Path Prep	33	35	31	NA	NA	99	374
TCC Weekly Tissue Shipment	28	14	22	10	All tissue has been shipped	74	245
ITOR-USC Biorepository	Initiate Jan 2012	NA	NA	NA	Pending consent approval	0	0
Target Now Surgeries/ Tissue Blocks	6 / 1	11 / 5	6 / 0	6 / 4	2 / 5	31 / 15	346
Caris Registry	0	0	4	0	6	10	137
Intervention Insights	4	2	1	0	0	7	7
Totals	108	105	99	20	13	345	3462