

The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS
CANCER CENTER



September 2016

KU Clinical Research Center Overview

Designed unlike any other clinical research facility in the country, the 82,400-square-foot **KU Clinical Research Center** (KU CRC) is equipped with state-of-the-art features and efficient use of space, resources and manpower to best accommodate patients and researchers. The building was donated by the Hall Family Foundation, totally renovated by the JCERT Authority, and features:

- Cutting-edge cancer trials, easily accessible outpatient rooms, office space and specimen collection labs
- Clinical research functions combined into one location
- Pharmacy to dispense and monitor medications along with pharmacy patient advocates to help with insurance billing questions and issues
- Clinical lab for performing complete blood counts, blood chemistry analysis, urinalysis and preparation of bone marrow biopsies
- A pavilion for gatherings and community events

At the KU CRC, clinical trials are designed to identify safer and more effective approaches to prevention, screening, diagnosis and treatment of cancer. Cancer clinical trials provide access to potential advancements in care and lead to medical innovations in cancer prevention and treatment. These trials may be a patient's best chance for increased survival.

Through the **Phase I Oncology Unit**, the KU CRC strives to:

- Introduce new cancer drugs to the market that are more effective and less toxic
- Offer more options to patients
- Develop strong partnerships with referring physicians
- Gain national program recognition

The **Clinical Trials Office (CTO)** provides comprehensive, centralized support services that span the life cycle of cancer clinical trials from concept through manuscript and assures that the patient population and resources needed to successfully conduct these trials is in compliance with all federal, state and local regulations. The CTO has facilitated significant growth of investigator-initiated clinical research at the KU Cancer Center while implementing and administering cost-effective processes to ensure the research activities have scientific merit, protect patient safety, maintain scientific integrity and are fiscally sound.

The **Midwest Cancer Alliance (MCA)** is the outreach arm of the University of Kansas Cancer Center. The MCA is a membership-based organization that brings together cancer research, care and support professionals to advance the quality and reach of cancer prevention, early detection, treatment and survivorship. It links member hospitals, medical professionals and their patients with KU Cancer Center research and clinical trials. The administrative offices for the MCA are housed in the KU CRC.

The KU CRC is an important piece of the pie for KU Cancer Center's efforts to achieve Comprehensive Cancer Center designation from the National Cancer Center Institute, which would further position KU and its partners at the forefront of cancer research, treatment and possible cures.

What Our Clinical Trial Patients Have to Say



"If I could help someone else avoid some of what I went through during treatment, then a clinical trial is the right thing to do. I wanted to help make a difference for another person."

-Michael Farmer, KU CRC Clinical Trial Patient

Countdown to NCI Comprehensive Cancer Center Status

We reached a significant milestone in 2012 by achieving National Cancer Institute (NCI) *Cancer Center* designation, but our journey is not over. We have embarked on a goal to attain the most elite designation available to a cancer center: NCI *Comprehensive Cancer Center* designation. Achieving comprehensive designation will enable us to offer the highest level of research, prevention, treatment and survivorship available. Of more than 5,000 cancer centers in the U.S., just 69, or 1.3 percent, are NCI-designated. Of those, only 47 have achieved comprehensive designation. Comprehensive designation is awarded after a rigorous evaluation process that shows the center pursues scientific excellence and has the capability to integrate diverse research approaches to cancer. Comprehensive Cancer Centers are expected to initiate and conduct early phase, innovative clinical trials and to participate in the NCI's cooperative groups by providing leadership and recruiting patients for trials. Comprehensive Cancer Centers must also conduct activities in outreach and education, and provide information on advances in healthcare for both healthcare professionals and the public.

NCI designation is transforming our region

- Patients treated at NCI centers have a 25 percent greater chance of survival
- Expanded access to innovative treatments by opening 209 treatment trials
- 90 percent of Kansas City patients now receive life-saving cancer treatments in their own backyard
- Economic driver-- 3,600 jobs created and \$2.5 billion in economic development by 2018

Our journey needs to continue

- Exponential growth in cancer cases-- 45 percent increase projected by 2030
- Cancer is the #1 cause of death in Kansas and second cause in Missouri
- 1 in 2 men and 1 in 3 women will be diagnosed with cancer in their lifetime

Comprehensive designation takes us farther

- Cancer is becoming a disease of disparity
- Focuses on cancer prevention, early detection and improved health outcomes
- Advances translational research

Comprehensive designation delivers community benefits

- Improves access to prevention services and cancer treatment for underserved and minority communities
- Aims to decrease smoking rates, increase HPV vaccinations and reduce obesity rates
- Extends the highest level of research, prevention, treatment and survivorship available

Accelerating progress: Because cancer does not wait

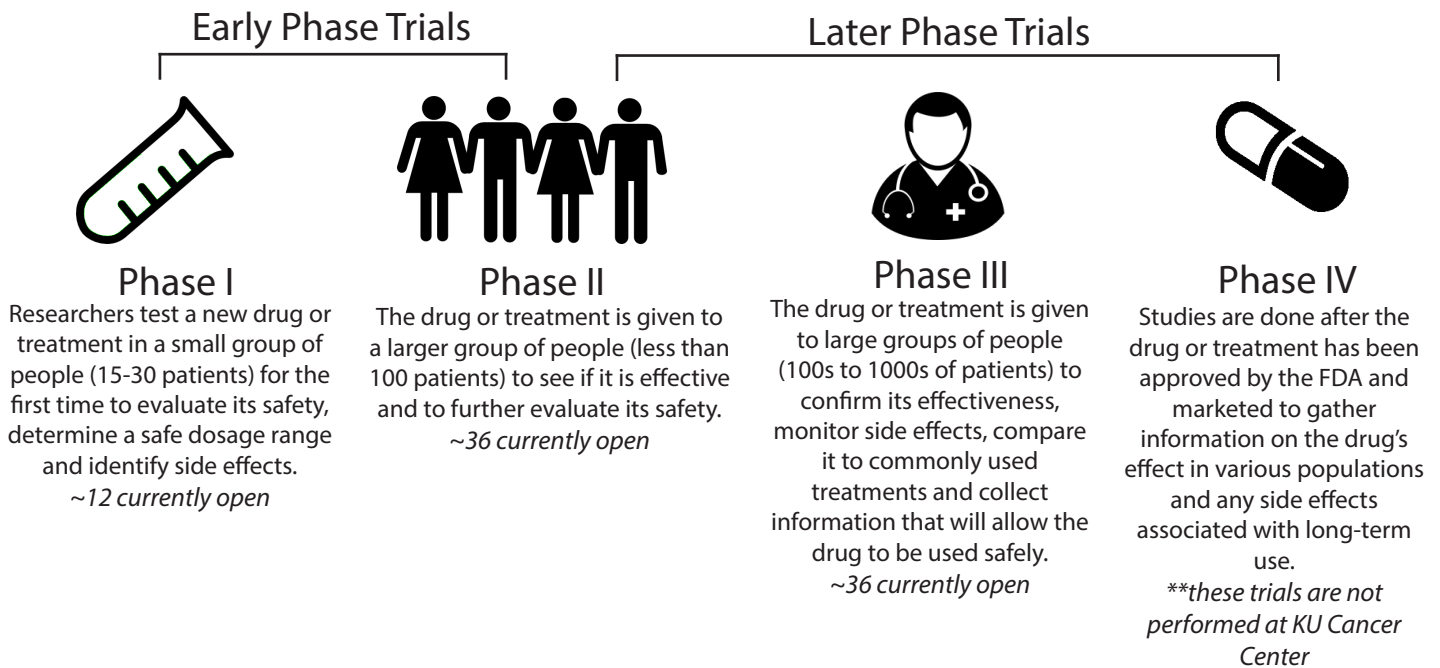
- Develop highly personalized cancer treatments for each unique patient
- Offer state-of-the-art cancer treatments here at home
- Recruit the best physician scientists
- Leverage partnerships for further innovation in drug discovery and development



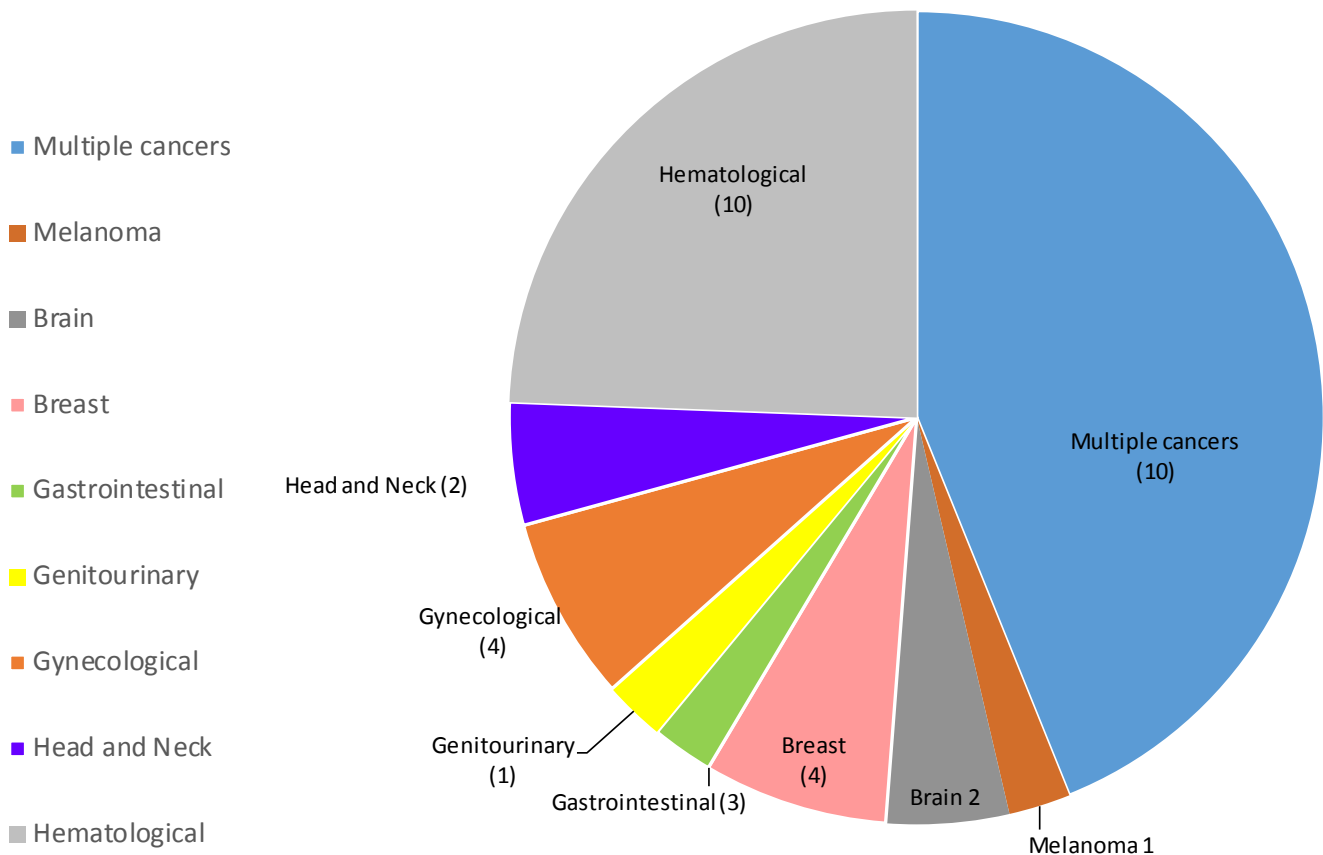
A Cancer Center Designated by the
National Cancer Institute

Types of Clinical Trials

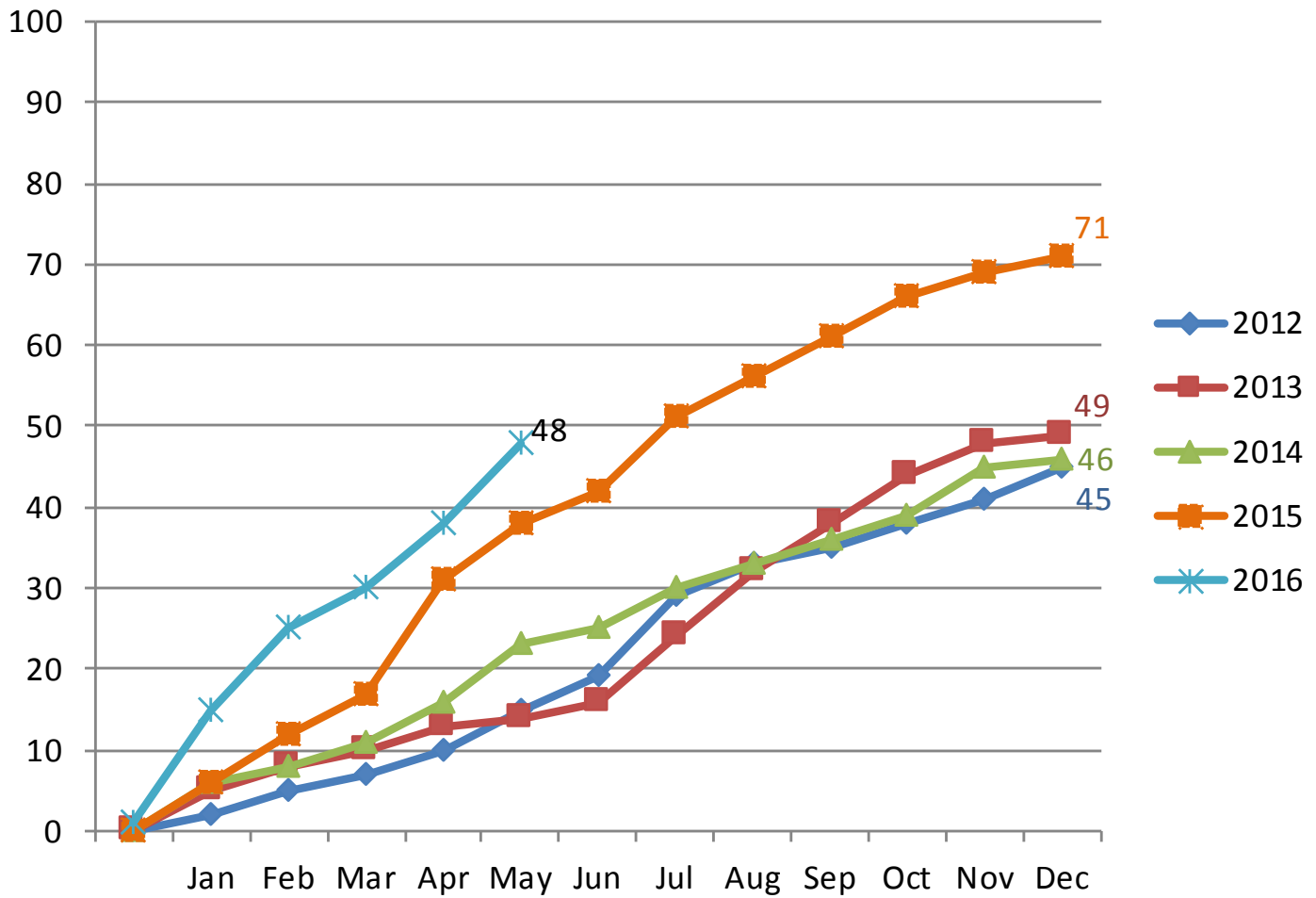
Cancer clinical trials provide access to potential advancement in care and lead to innovations in cancer prevention. Clinical trials are conducted in four phases:



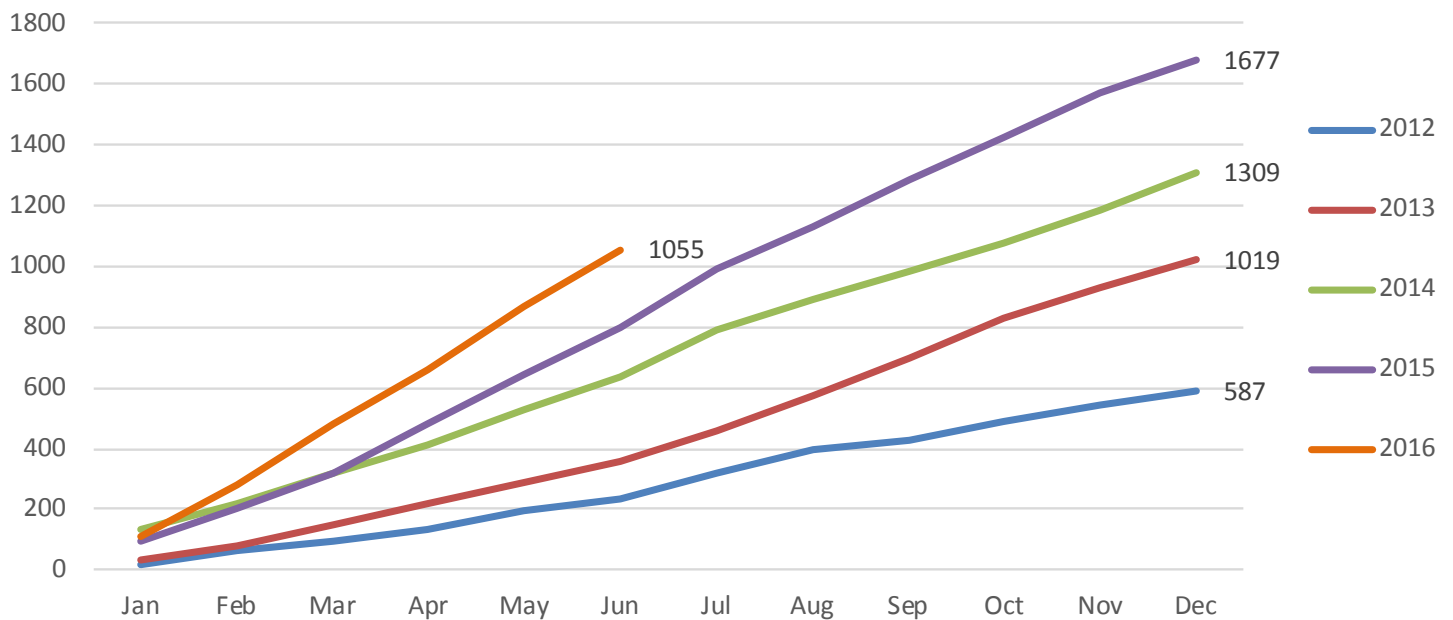
Early-Phase Clinical Trials through 2016



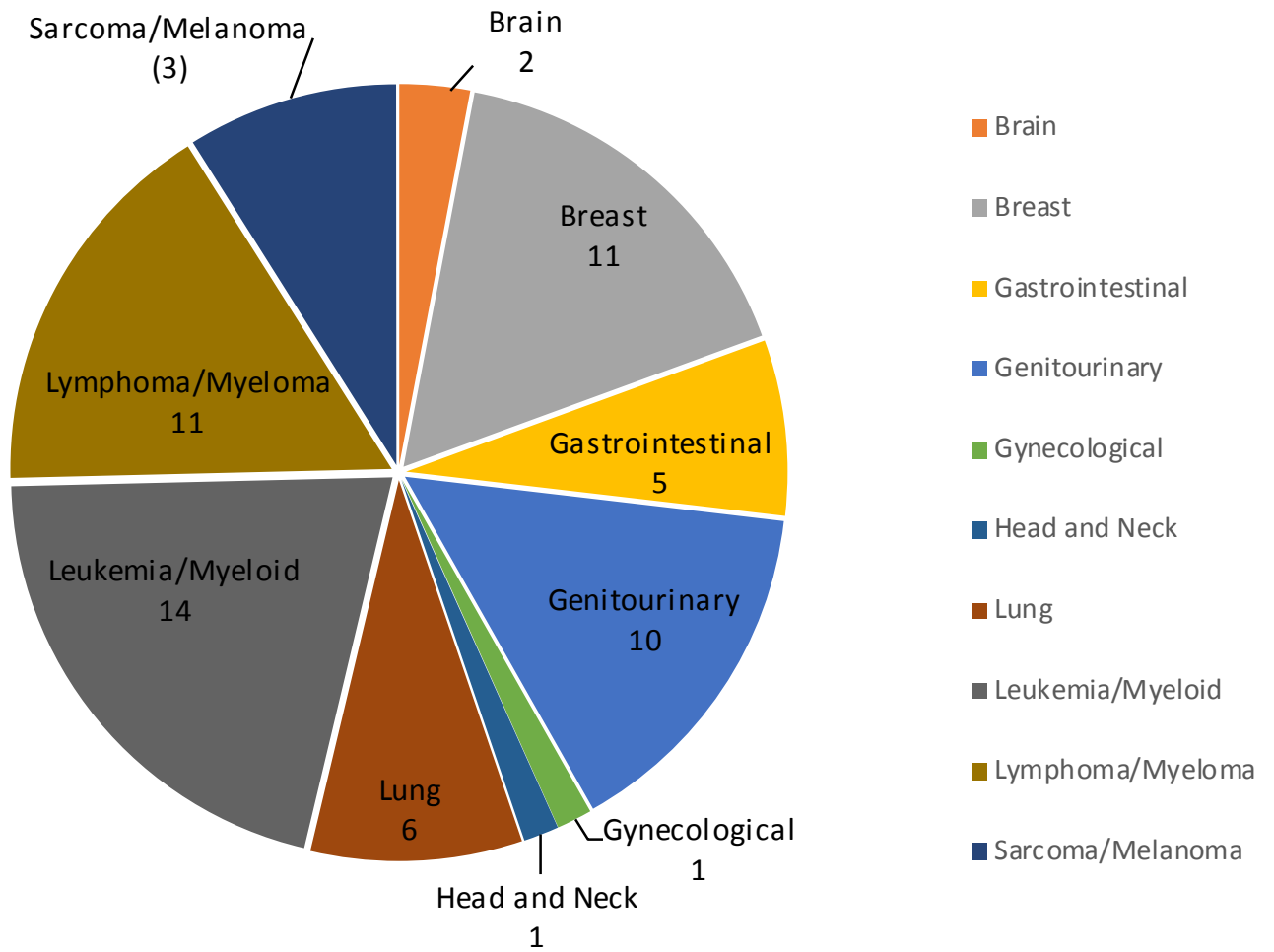
Early-Phase Clinical Trial Accrual



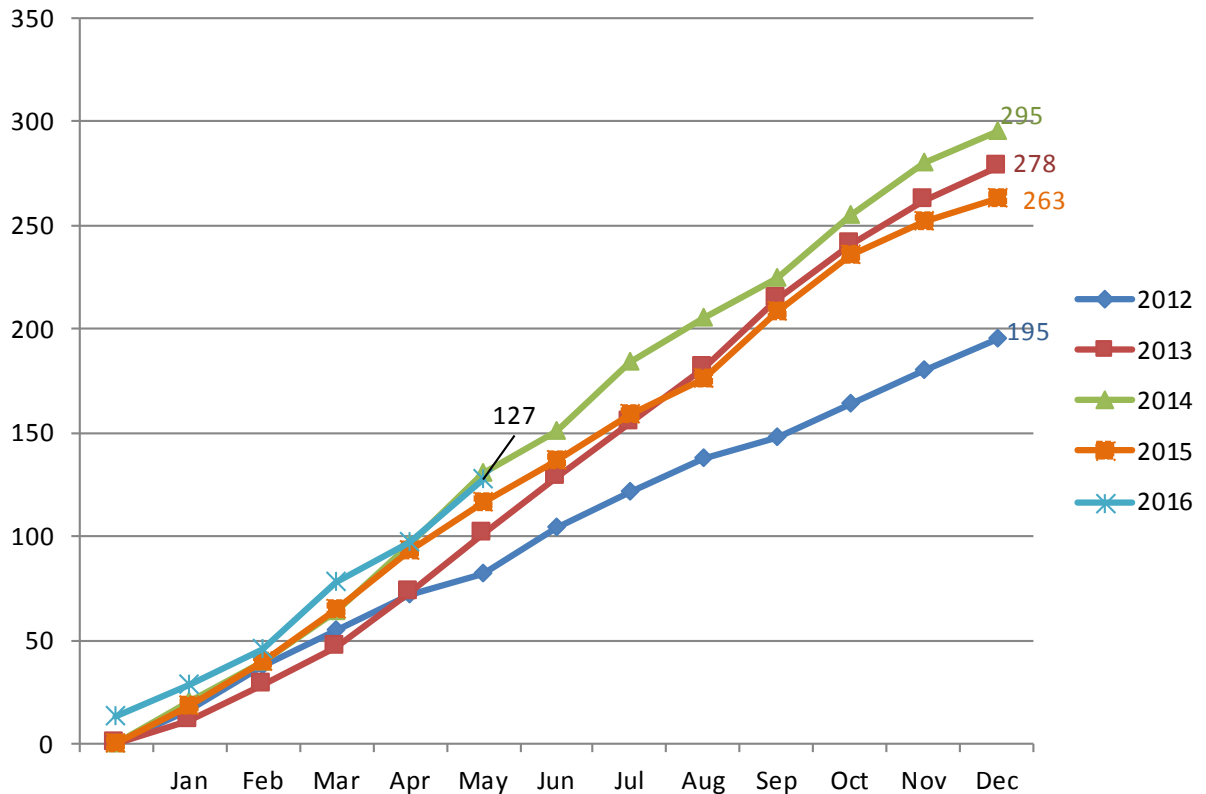
Early-Phase KU CRC Patient Visits



Later-Phase Clinical Trials through 2016



Later-Phase Clinical Trial Accrual



Clinical Trials Open By Location

Site Location	Patient Total
KU Clinical Research Center (early phase)	48
KU Cancer Center Main Outpatient site	127
KU Cancer Center Community sites	55
Midwest Cancer Alliance sites	15
Other sites	2

Top Five Counties for KU CRC Patient Visits

	County	Unique Patients
1	Johnson County (KS)	254
2	Jackson County (KS)	235
3	Wyandotte County (KS)	73
4	Leavenworth County (KS)	61
5	Clay County (MO)	48

Services to Support Clinical Trials

Correlative Laboratories

The correlative laboratory is staffed and operated by the Clinical Pharmacology division of KU Cancer Center. This lab provides trained staff and equipment for the acquisition, processing, storage, and shipment of biological samples generated from clinical studies including blood, urine, ascites fluid, and tissue samples. The Correlative Laboratories provide critical support for more than 130 cancer clinical trials and approximately 10 non-cancer trials.

Bioanalytical Laboratory

The Bioanalytical Laboratory at KU CRC is a state-of-the-art facility for the support of clinical and translational studies. The Bioanalytical Lab develops, optimizes, validates, and applies various methods to the identification and quantitation of drugs, drug metabolites, and other small molecules from clinical samples to generate data for assessment of either pharmacokinetics or for examination of biomarkers of effect.

Pharmacokinetic/Pharmacodynamic Services (PK/PD)

The mission of the PK/PD unit is to advise investigators on the incorporation of PK/PD to add value to clinical studies and to guide the experimental design to maximize this value. This includes the optimization of dosing and sampling protocols. Data generated by the Bioanalytical Laboratory or by third parties are used for pharmacokinetic calculations.



Summary of Economic Impact of NCI Designation Pursuit

REGIONAL ECONOMIC IMPACT BY CLINICAL TRIAL RESEARCH	ACTUALS 2007-2014	PROJECTED 2015-2020	TOTAL
<u>Economic Impact</u>			
JCERT Operations & Research Investments	15,001,698	30,948,016	45,949,714
Clinical Trial Revenues from Federal Grants & Private Sector	7,601,938	20,815,076	28,417,014
Additional Regional Economic Impact ¹	11,146,291	27,394,072	38,540,363
	38,505,436	84,567,989	123,073,425
JCERT building Renovation	19,352,640	-	19,352,640
Additional Regional Economic Impact of Renovation ³	20,016,436	-	20,016,436
	39,369,076	-	39,369,076
<u>Total Economic Impact</u>	77,874,512	84,567,989	\$162,442,501
<u>Jobs Creation Impact</u>			
New Jobs Created by Operations & Research Investment	82	22	104
Additional Regional Jobs Created ²	177	26	203
	259	48	307
New Jobs Created by Construction Investments	162	-	162
New Regional Jobs Created by Construction Investments ³	123	-	123
	285	-	285
<u>Incremental Jobs Created</u>	545	48	592

Assumptions

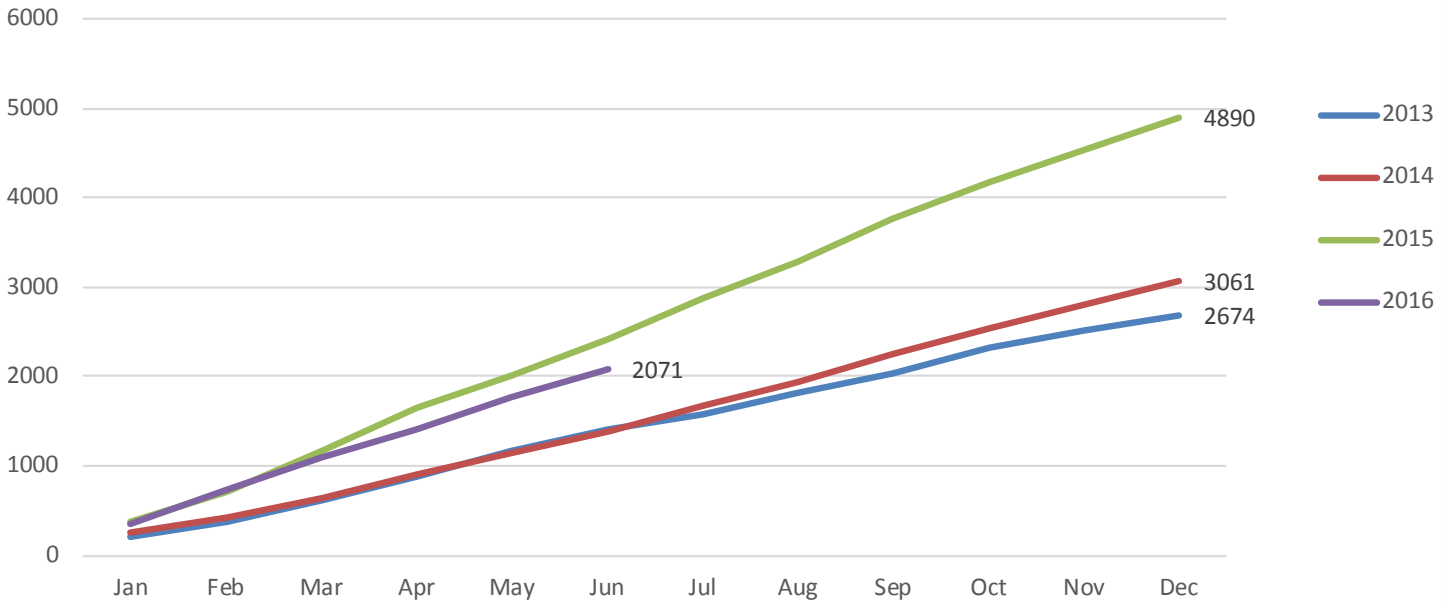
- 1- Financial Economic Impact: using business activity multiplier for state of Kansas of 2.06 per \$1 in NIH awards (per "How NIH Funding Helps Your State's Economy, Families USA" - June 2008)
- 2- Jobs Creation Impact: per "Battelle/BIO State Bioscience" reports circa 2010 and 2012, using employment multiplier for Kansas of 3.19 (2007-2012) and 2.20 (2013-2018) total jobs created for each new biotech job
- 3- For capital investment, using business activity multiplier for Kansas of 2.0343 per \$1 spend in construction; employment multiplier for state of Kansas of 1.76 total jobs created for each construction job (per 2010 annual Input-Output Table of Regional Input-Output Modeling System (RIM II), Bureau of Economic Analysis) The impact lasts only for the duration of the construction.
- 4- Excludes clinical revenue and job growth.

Other Organizations Conducting Research at the KU Clinical Research Center

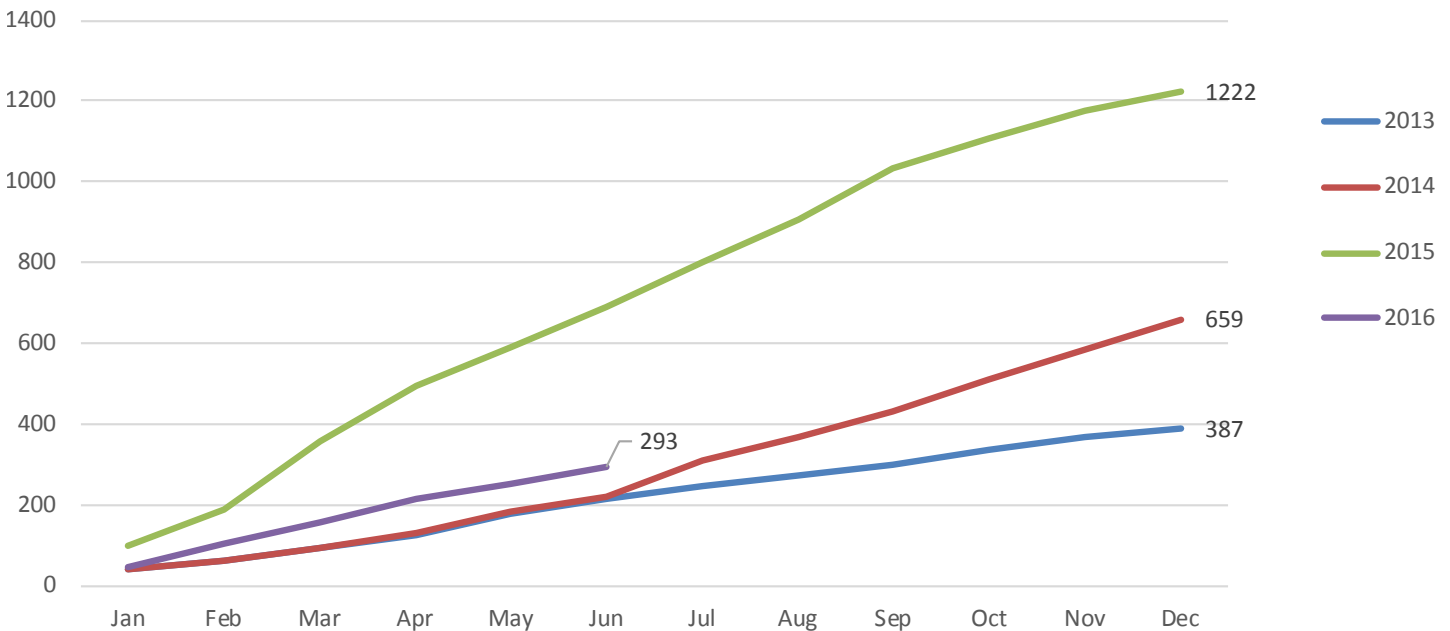
Clinical and Translational Science Unit (CTSU)

The CTSU provides the Kansas City region with a centralized resource for supporting clinical and translational research. The clinic and staff support both pharmaceutical trials and investigator-initiated studies for researchers mostly outside the oncology area.

Total CTSU Patient Visits through 2016



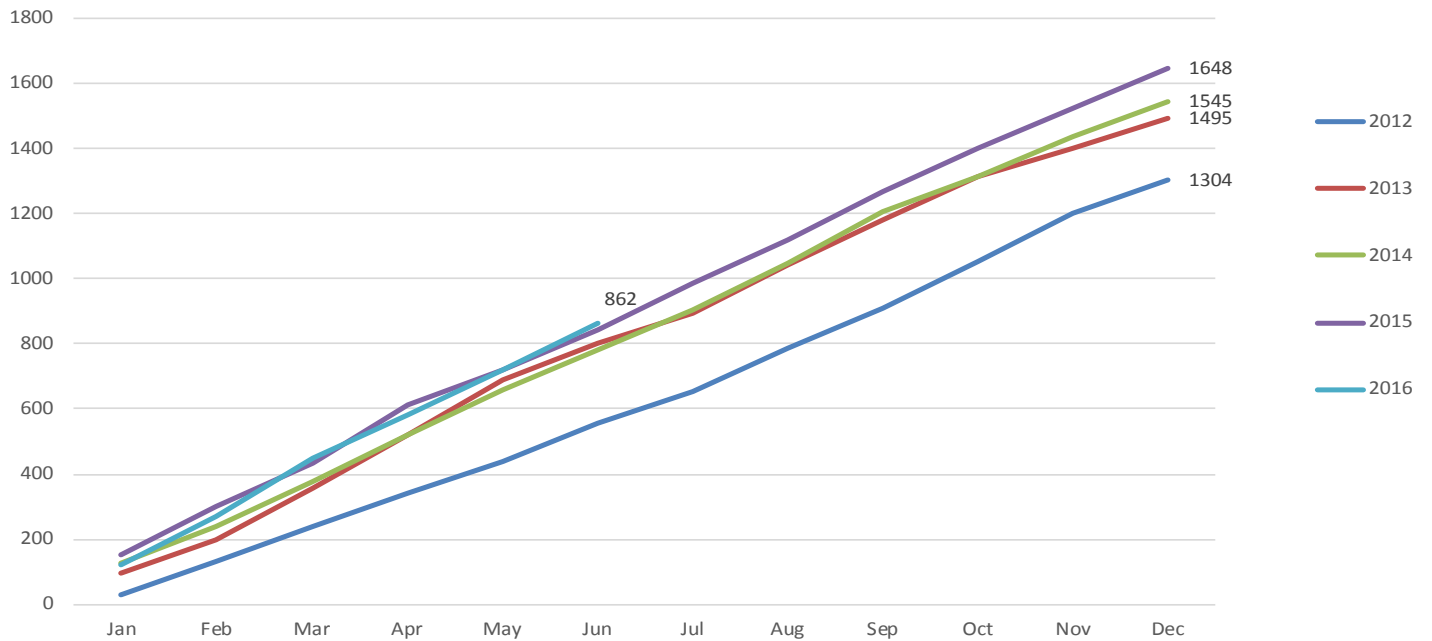
Total CTSU New Patient Accrual through 2016



Alzheimer's Disease Center

The University of Kansas Alzheimer's Disease Center's (KU ADC) mission is to improve the lives of patients and families with Alzheimer's disease by eliminating the disease through research into its treatment and prevention. The clinical operations of the KU ADC include both research and outpatient clinics.

Alzheimer's Center Patient Visits through 2016



Alzheimer's Disease Center

Since NIA funding began in 2011, the KU ADC has supported 19 National and **international pharmaceutical trials** (see table to right) Two additional clinical trials started enrolling participants in 2016.

Study	Sponsor	Enrollment Date
Neurotrope	Neurotrope	0
ENGAGE*	Biogen	3
STEADFAST*	vTv Therapeutics	5
A4 LEARN*	NIH/Lilly	13
TCAD*	NIH/Toyama	13
A4*	NIH/Lilly	16
SNIFF	NIH	2
Solanezumab-LZAX	Lilly	8
Merck	Merck	19
Resveratrol	NIH	1
ADNI 2--rollover	NIH	10
ADNI 2—new	NIH	11
ASPREE	NIH	41
Summit	Janssen	3
Exelon Patch-open label	Novartis	4
Elan 301/302	Janssen	6
Wyeth 3001	Wyeth	2
IGIV	Baxter/NIH	11
Exelon Patch	Novartis	8
	TOTAL	160

The KU ADC has supported 24 **investigator-initiated** studies (see table to right) resulting in 1123 enrollments. Two new studies (Med Diet and REACT) started enrolling participants in 2016.

Study	Sponsor	Enrollment Date
ADC Clinical Cohort	NIH	404
Med Diet*	Frontiers/KU ADC Pilot	2
REACT*	NIH	1
TOAD*	Alzheimer's Association	7
FamTechCare*	NIH	12
APP*	NIH	141
APEX*	NIH	30
KDRAFT*	Frontiers Pilot	14
SEAD	KUMC/Ausio	16
EECP	Internal Med	8
INFORM	NIH	52
MPA/ACCEL	KU ADC Pilot	101
ADEPT	NIH	79
PACER	Ziegler Award	3
PACER 2	Foundation for Physical Therapy	24
POX	Frontiers Pilot	6
TEAM	NIH	101
Diabetes and EF	KPP	8
SBIR	NICHD	33
Remote Monitoring	CTSA	6
TORTIAS	NIH	14
POX	CTSA	6
Retina study	St. Luke's Hospital Foundation	35
SPA	ADDF	20
	TOTAL	1123

**Johnson County Education Research Triangle
KUMC Clinicial Research Center
Statement of Net Assets**

	July 31, 2016	June 30, 2016	June 30, 2015	June 30, 2014
ASSETS				
Cash and Cash Equivalents (Unencumbered)				
UMB Trustee Accounts (Bond Reserve /P&I)	\$ 1,756,914.40	\$ 1,756,900.60	\$ 2,004,496.35	\$ 1,998,870.42
KUMC JCERT Operations	3,808,806.00	3,881,175.00	4,363,737.00	3,390,176.00
KUMC JCERT Capital Reserve	950,000.00	550,000.00	150,000.00	100,000.00
KUMC JCERT Operating Reserve	1,100,000.00	1,000,000.00	400,000.00	400,000.00
Total Cash and Cash Equivalents (Unencumbered)	7,615,720.40	7,188,075.60	6,918,233.35	5,889,046.42
UMB Trustee Accounts Market Value Change	-	-	862.40	1,793.40
Capital Assets				
Land 4350 Shawnee Mission Parkway				
	1,421,810.00	1,421,810.00	1,421,810.00	1,421,810.00
Clinical Research Center Building & Improvements				
Accumulated Depreciation Building & Improvements	(3,659,318.41)	(3,586,121.18)	(2,707,755.92)	(1,829,563.87)
Total Buildings & Improvements	16,558,752.75	16,631,949.98	17,489,194.08	18,367,386.13
Furniture & Equipment				
Accumulated Depreciation Furniture & Equipment	(858,349.09)	(844,134.80)	(747,171.69)	(481,353.93)
Total Furniture & Equipment	669,983.76	684,198.05	770,055.49	1,035,873.25
Vehicles				
Accumulated Depreciation Vehicles	(21,436.09)	(21,436.09)	(18,756.69)	(13,397.55)
Total Vehicles	-	-	2,679.40	8,038.54
Total Capital Assets	18,650,546.51	18,737,958.03	19,683,738.97	20,833,107.92
TOTAL ASSETS	\$ 26,266,266.91	\$ 25,926,033.63	\$ 26,602,834.72	\$ 26,723,947.74
LIABILITIES & NET ASSETS				
Liabilities				
Bonds Payable				
KUMC 2010P-1 Bond	\$ 705,000.00	\$ 705,000.00	\$ 1,390,000.00	\$ 2,055,000.00
KUMC 2010P-2 Build America Bond	11,980,000.00	11,980,000.00	11,980,000.00	11,980,000.00
Total Bonds Payable	12,685,000.00	12,685,000.00	13,370,000.00	14,035,000.00
Total Liabilities	12,685,000.00	12,685,000.00	13,370,000.00	14,035,000.00
Net Assets	13,581,266.91	13,241,033.63	13,232,834.72	12,688,947.74
TOTAL LIABILITIES & NET ASSETS	\$ 26,266,266.91	\$ 25,926,033.63	\$ 26,602,834.72	\$ 26,723,947.74

**Johnson County Education Research Triangle
KUMC Clinical Research Center Budget Report**

	Approved FY16 Budget			Actual FY16 as of 06/30/2016		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 5,600,000		\$ 5,600,000	\$ 5,653,000		\$ 5,653,000
Clinical Trial Collection		580,000	580,000		3,536,203	3,536,203
Cancer Research Center Clinical Services					3,452,128	3,452,128
Cancer Center Support Grants for NCI-designated Cancer Centers					164,353	164,353
KUCC Support					1,875,209	1,875,209
Facility Rent Collection		500,080	500,080		500,084	500,084
Common Area Maintenance Fee	-	137,713	137,713		219,862	219,862
Interest Earnings			-	18,324		18,324
Build America Bond Interest Subsidy	162,600	-	162,600	163,127	-	163,127
Total Revenue	5,762,600	1,217,793	6,980,393	5,834,451	9,747,839	15,582,290
Expenditures						
Payroll						
Director, Phase I Program & startup	379,306		379,306	143,046	307,398	450,444
2 Physician Positions	448,955		448,955	182,790	63,963	246,753
Research Leadership	321,255	54,993	376,248	220,056	115,459	335,515
Business Development	194,450		194,450	159,240		159,240
Research Scientists	201,500		201,500	180,278	152,891	333,169
Research Laboratory Staff	143,640	59,584	203,224	171,610	249,999	421,609
Research Nursing, Study Coordination & Regulatory	420,204	565,423	985,627	1,512,915	2,631,816	4,144,731
Budget & Finance Support	326,067	-	326,067	273,491	183,740	457,231
Total Payroll	2,435,377	680,000	3,115,377	2,843,426	3,705,266	6,548,692
Other Operating Expense						
Operating Expenses	141,300	75,700	217,000	84,126	471,767	555,893
Telephone & Networking	15,000		15,000	27,915		27,915
Mass Spec Lease	160,963		160,963	160,963		160,963
KUH Clinical Services Settlement Cost - Operations	1,350,000		1,350,000	-	2,250,266	2,250,266
KUH Clinical Services Settlement Cost - Common Area Maintenance		137,713	137,713		219,862	219,862
KUH Clinical Services Settlement Cost - Facility Rent	-	500,080	500,080	-	500,084	500,084
Total Other Operating Expense	1,667,263	713,493	2,380,756	273,004	3,441,979	3,714,983
Facility Expense						
Facility Operations	869,920		869,920	826,043	-	826,043
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,465	-	1,222,465	1,374,540	-	1,374,540
Total Facility Expense	2,092,385	-	2,092,385	2,200,583	-	2,200,583
Total Expenditures	\$ 6,195,025	\$ 1,393,493	\$ 7,588,518	\$ 5,317,013	\$ 7,147,245	\$ 12,464,258
Revenue less Expenditures	(432,425)	(175,700)	(608,125)	517,438	2,600,594	3,118,032
Less Current Amount Set aside for Capital Reserve	50,000	-	50,000	400,000	-	400,000
Less Current Amount Set aside for Operations	600,000		600,000	600,000		600,000
Operating Account - Beginning Balance	4,105,746	522,732	4,628,478	4,363,737	568,157	4,931,894
Operating Account - Ending Balance	\$ 3,023,321	\$ 347,032	\$ 3,370,353	\$ 3,881,175	\$ 3,168,751	\$ 7,049,926

**Johnson County Education Research Triangle
KUMC Clinical Research Center Budget Report**

	Approved FY17 Budget			Actual FY17 as of 07/31/2016		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 5,800,000		\$ 5,800,000	\$ 919,500		\$ 919,500
Clinical Trial Collection		2,600,000	2,600,000		102,158	102,158
Cancer Research Center Clinical Services		1,560,000	1,560,000		203,155	203,155
Cancer Center Support Grants for NCI-designated Cancer Centers		174,200	174,200		3,054	3,054
KU Cancer Center Support		2,693,494	2,693,494		147,588	147,588
Facility Rent Collection		500,084	500,084		41,674	41,674
Common Area Maintenance Fee	-	219,862	219,862		18,322	18,322
Interest Earnings			-	2,188		2,188
Build America Bond Interest Subsidy	162,600	-	162,600	-	-	-
Total Revenue	5,962,600	7,747,640	13,710,240	921,688	515,951	1,437,639
Expenditures						
Payroll						
Director, Phase I Program & startup	424,801	68,669	493,470	7,987	33,956	41,943
2 Physician Positions	375,172	238,669	613,841	21,010	27,063	48,073
Research Leadership	225,003	177,054	402,057	9,934	29,862	39,796
Business Development	179,788		179,788	18,791		18,791
Research Scientists	117,000		117,000	41,168	30,943	72,111
Research Laboratory Staff	226,700	180,276	406,976	22,721	24,273	46,994
Research Nursing, Study Coordination & Regulatory	1,346,208	4,173,602	5,519,810	195,446	268,767	464,213
Budget & Finance Support	241,750	281,579	523,329	39,185	7,551	46,736
Total Payroll	3,136,422	5,119,849	8,256,271	356,242	422,415	778,657
Other Operating Expense						
Operating Expenses	200,000	125,700	325,700	2,090	63,774	65,864
Telephone & Networking	25,000		25,000	3,781		3,781
Mass Spec Lease	160,963		160,963	-		-
Clinical Trial Research Initiatives for Comprehensive Status	500,000	328,300	828,300		12,368	12,368
KUH Clinical Services Settlement Cost - Operations	800,000	1,560,000	2,360,000	-	167,165	167,165
KUH Clinical Services Settlement Cost - Common Area Maintenance		219,862	219,862		41,674	41,674
KUH Clinical Services Settlement Cost - Facility Rent	-	500,084	500,084	-	18,322	18,322
Total Other Operating Expense	1,685,963	2,733,946	4,419,909	5,871	303,303	309,174
Facility Expense						
Facility Operations	880,569		880,569	66,631	-	66,631
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,465	-	1,222,465	65,313	-	65,313
Total Facility Expense	2,103,034	-	2,103,034	131,944	-	131,944
Total Expenditures	\$ 6,925,419	\$ 7,853,795	\$ 14,779,214	\$ 494,057	\$ 725,718	\$ 1,219,775
Revenue less Expenditures	(962,819)	(106,155)	(1,068,974)	427,631	(209,767)	217,864
Less Current Amount Set aside for Capital Reserve	400,000	-	400,000	400,000	-	400,000
Less Current Amount Set aside for Operations	100,000		100,000	100,000		100,000
Operating Account - Beginning Balance	3,424,181	173,011	3,597,192	3,881,175	3,168,750	7,049,925
Operating Account - Ending Balance	\$ 1,961,362	\$ 66,856	\$ 2,028,218	\$ 3,808,806	\$ 2,958,983	\$ 6,767,789