

# The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS  

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CANCER CENTER



October 2019

# 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 **Early-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 treatment 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 lifecycle 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 **Masonic Cancer Alliance (MCA)** is the outreach network 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 component of KU Cancer Center's efforts to achieve Comprehensive Cancer Center designation from the National Cancer Center Institute, which would further position KU Cancer Center and its partners at the forefront of cancer research, treatment and possible cures.



## What Our Clinical Trial Patients Say

*"Because of a clinical trial,  
I have a life with my children."*

*- Corina Ramirez, Clinical Trial Patient*

# Transforming Cancer Care in Our Region

At The University of Kansas Cancer Center, we are on an urgent journey to break the devastating grip of cancer. Our first step on this journey was to achieve National Cancer Institute Cancer Center designation in 2012. We are the only cancer center in the region, and one of only 71 in the nation, to receive this distinction, a symbol of research and clinical excellence. KU Cancer Center's NCI designation allows patients to stay close to home while still receiving the most advanced cancer care from a deep bench of specialists. NCI-designated Cancer Centers are trailblazers in cancer research, recognized for their scientific leadership, resources and depth of their research in basic, clinical and population science.

## **NCI designation is transforming our region**

- Patients treated at NCI centers have a 25 percent greater chance of survival
- More Kansas City patients receive life-saving cancer treatments close to home

**But there is more to do!** Over the next 10 years, the number of cancer diagnoses are predicted to increase 45 to 50 percent: 1 in 2 men and 1 in 3 women will be diagnosed with cancer in their lifetime.

This is why we must achieve NCI Comprehensive Cancer Center status, the next step in our quest to conquer cancer. Comprehensive Cancer Center designation is the premier ranking awarded by the National Cancer Institute. It is the gold standard, awarded to cancer centers that are recognized for their trailblazing research and leadership in developing cutting-edge treatments.

Comprehensive cancer centers attain this elite distinction by demonstrating significant depth and breadth in basic, clinical and translational research, with a clear focus on the cancers most affecting their communities. This requires a deep understanding of the cancer issues faced by those we serve and responding with tailored solutions. To move from NCI Designation to NCI Comprehensive, we must demonstrate solid basic research discoveries that build on our collective knowledge of cancer's biology, and apply these findings to advance new therapies; identify cancer risk factors and develop actionable cancer prevention strategies; and create more clinical trial opportunities for patients, including underserved populations.

## **Benefiting our community through focused treatment and prevention efforts**

- Improve access to prevention services and cancer treatment for underserved and minority communities
- Decrease smoking rates, increase HPV vaccinations and reduce obesity rates
- Extend 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

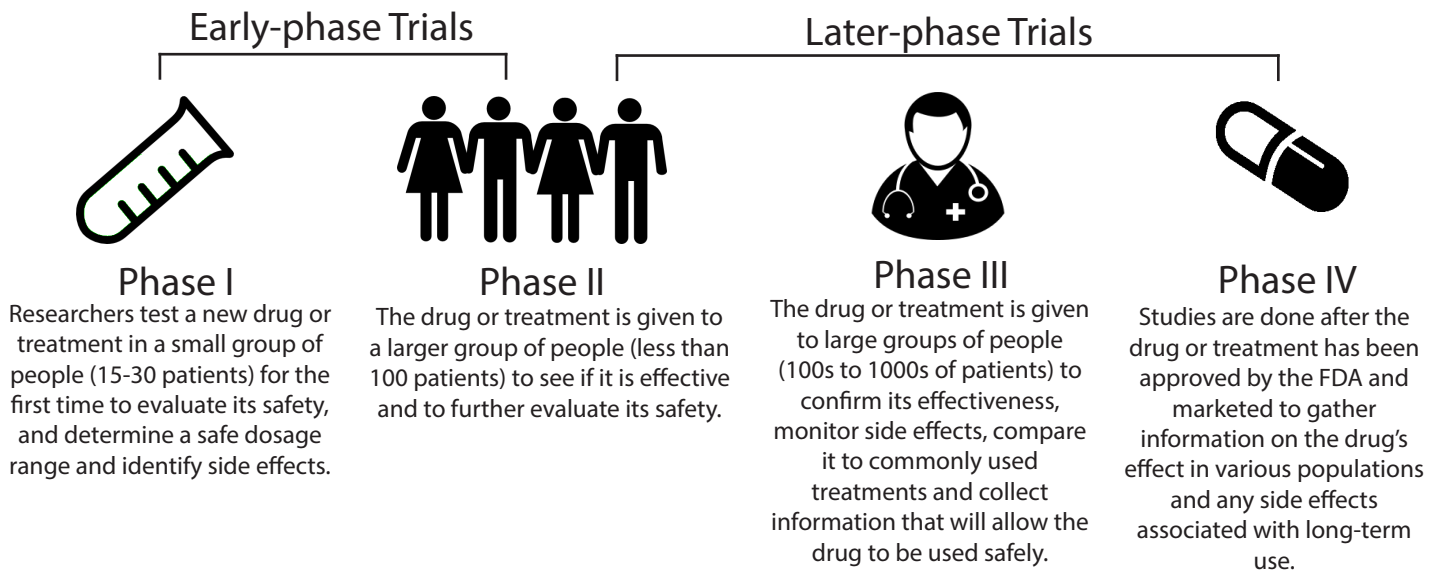
KU Cancer Center aims to do nothing less than fundamentally transform the cancer experience – to give all people in our region greater access to breakthrough ideas and novel treatments.



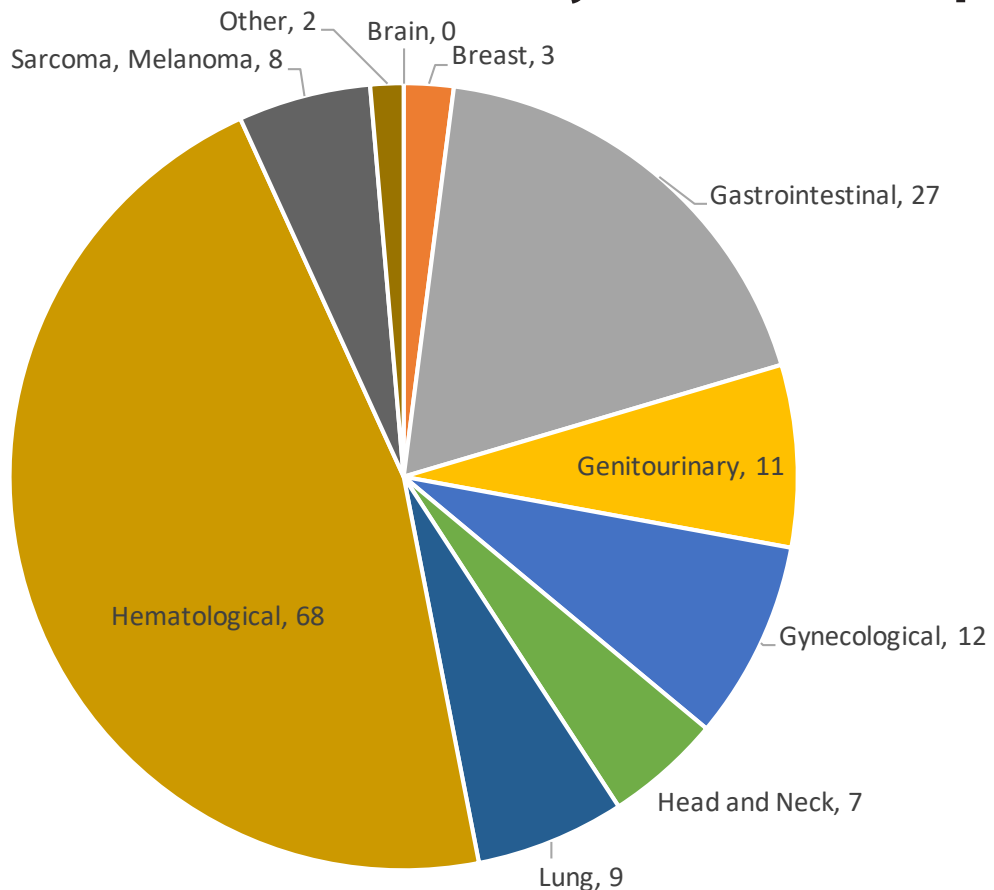
A Cancer Center Designated by the  
National Cancer Institute

# Types of Clinical Trials

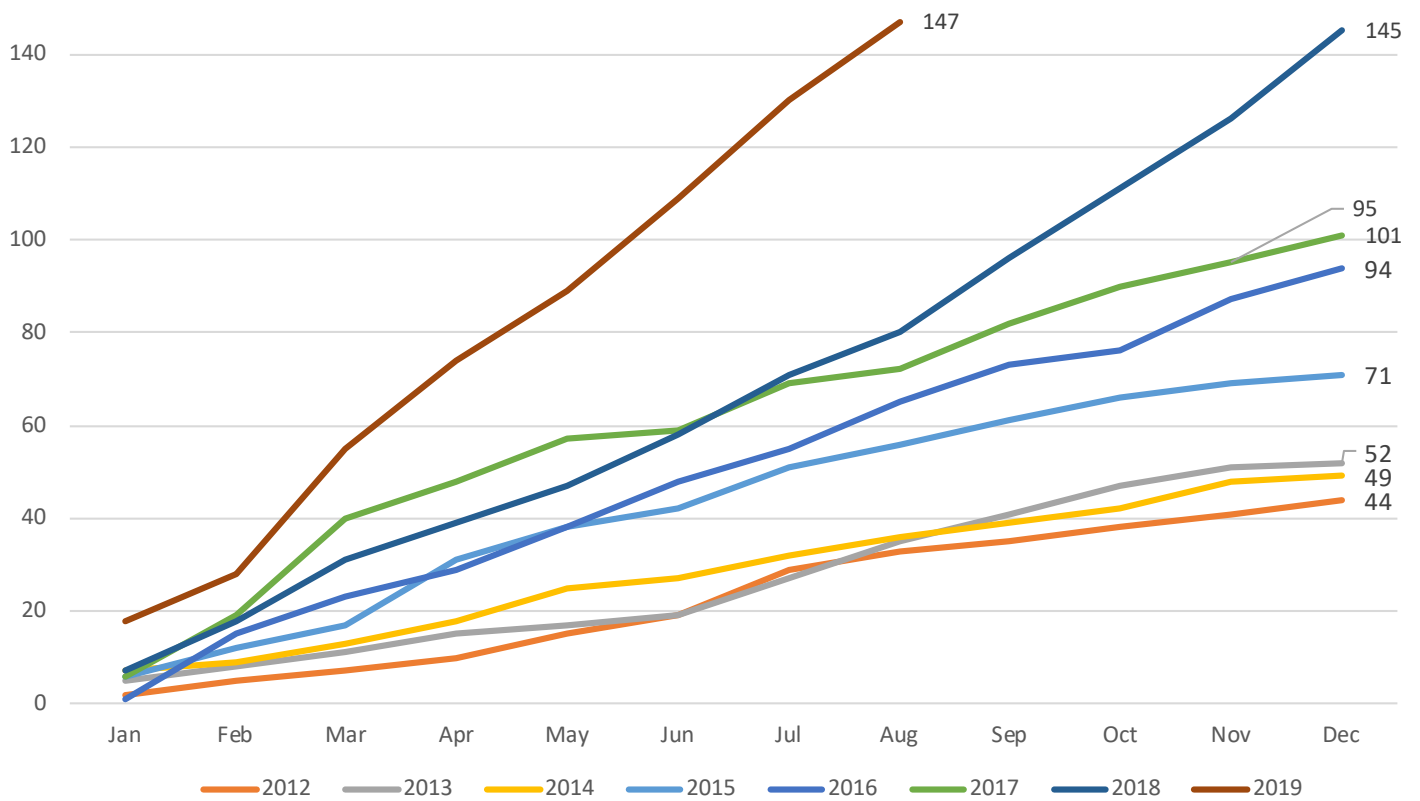
Cancer clinical trials provide access to potential advancement in care and lead to innovations in cancer prevention. Clinical trials are conducted in four phases:



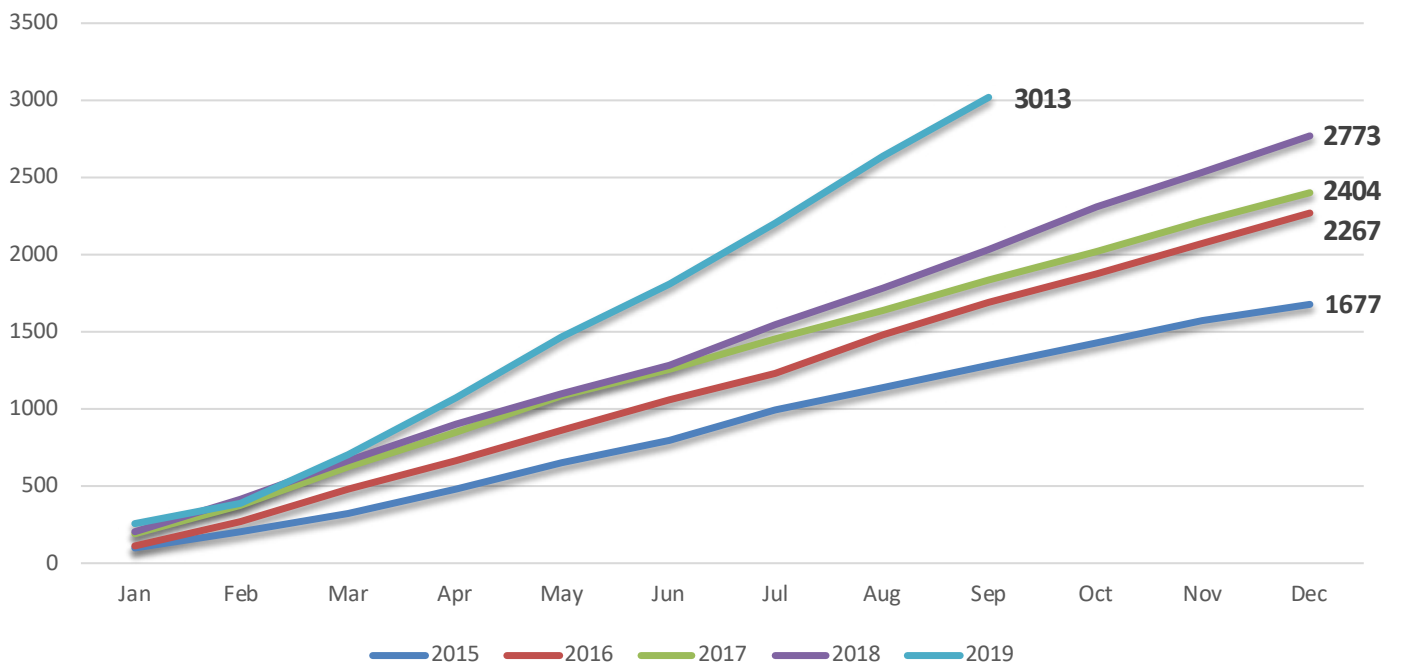
## Early-phase Clinical Trial Accrual by Disease Group



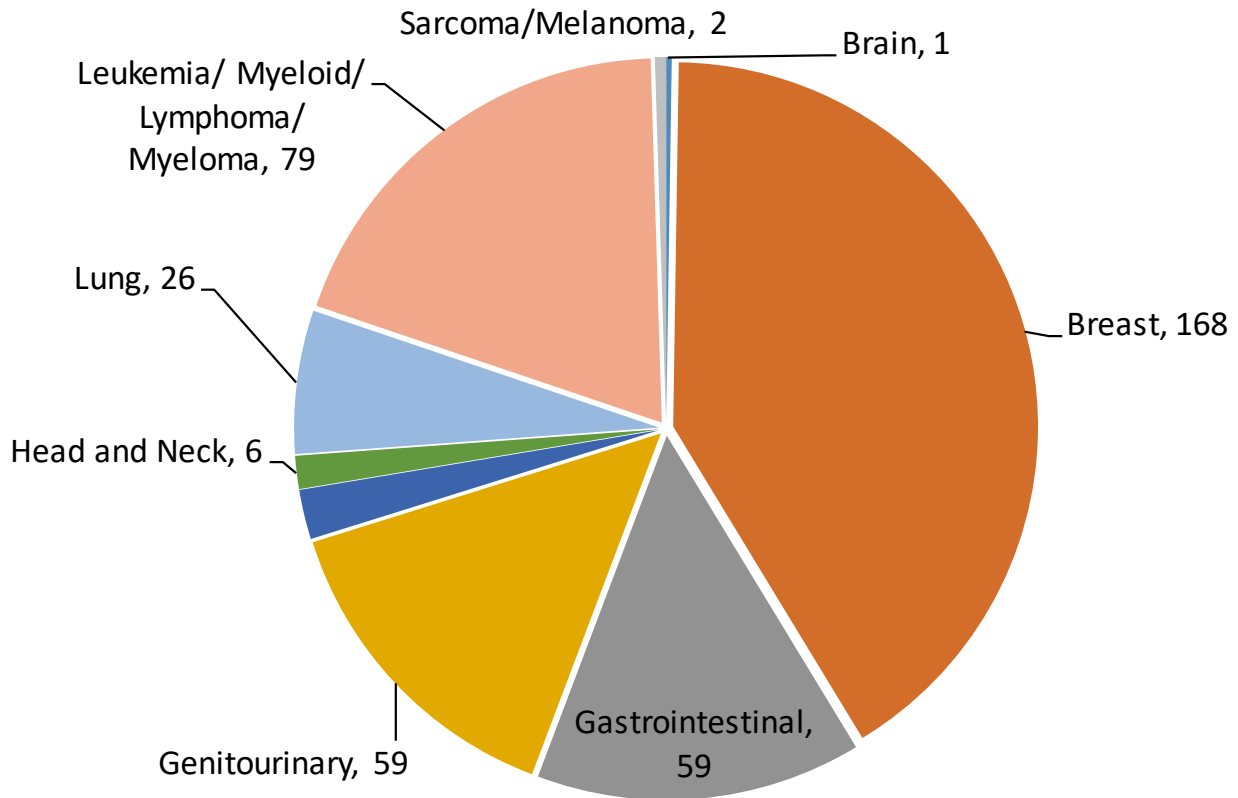
# Early-phase Clinical Trial Accrual



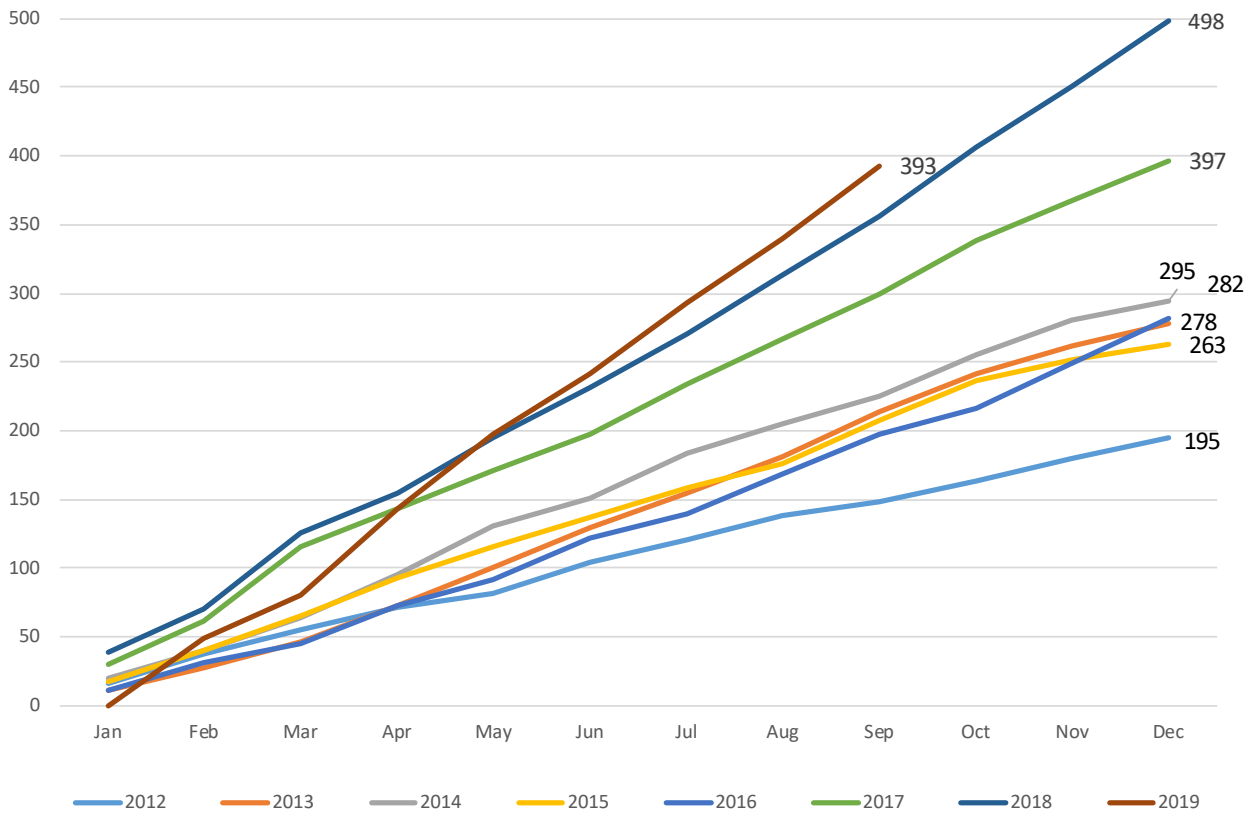
# Early-phase KU CRC Patient Visits



# Later-phase Clinical Trials



# Later-phase Clinical Trial Accrual by Disease Group



# Clinical Trials Patient Total By Location

January-August 2019

Site Location	Patient Total
KU Clinical Research Center (early phase)	147
KU Cancer Center Main Outpatient sites	308
KU Cancer Center Community sites	62
Masonic Cancer Alliance sites	38
Other sites	3

## Top Five Counties for KU CRC Patient Visits

1st Quarter 2019

	County	Unique Patients
1	Jackson County (KS)	159
2	Johnson County (KS)	164
3	Wyandotte County (MO)	62
4	Clay County (MO)	43
5	Platte County (MO)	19

# 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.



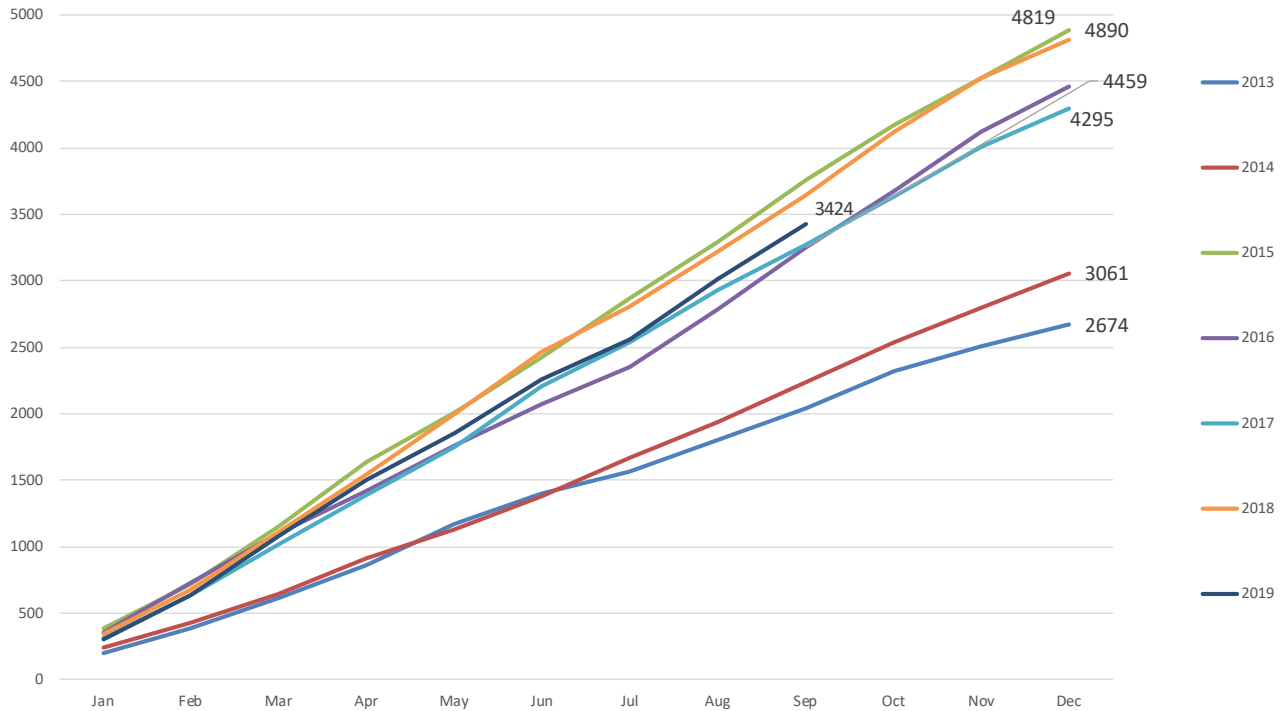


# Other Organizations Conducting Research at the KU Clinical Research Center

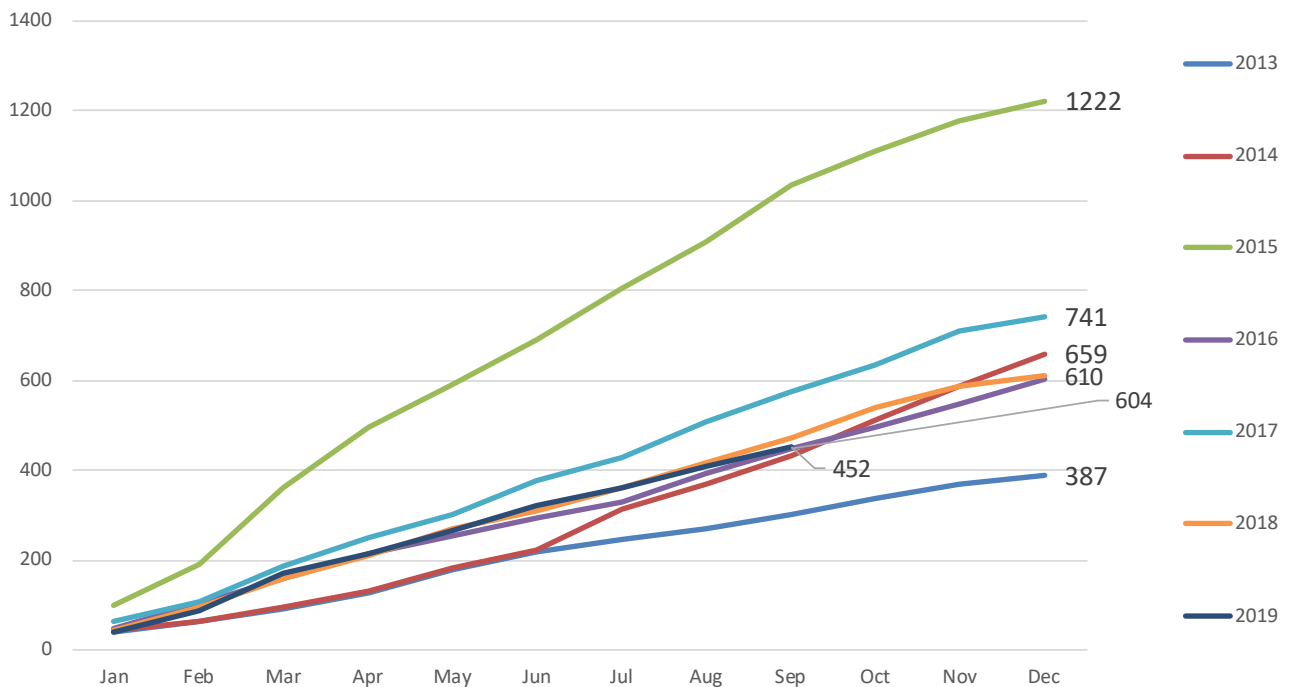
# Clinical and Translational Science Unit (CTSU)

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 trials for researchers mostly outside the oncology area, but some trials do support cancer and cancer survival.

## Total CTSU Patient Visits



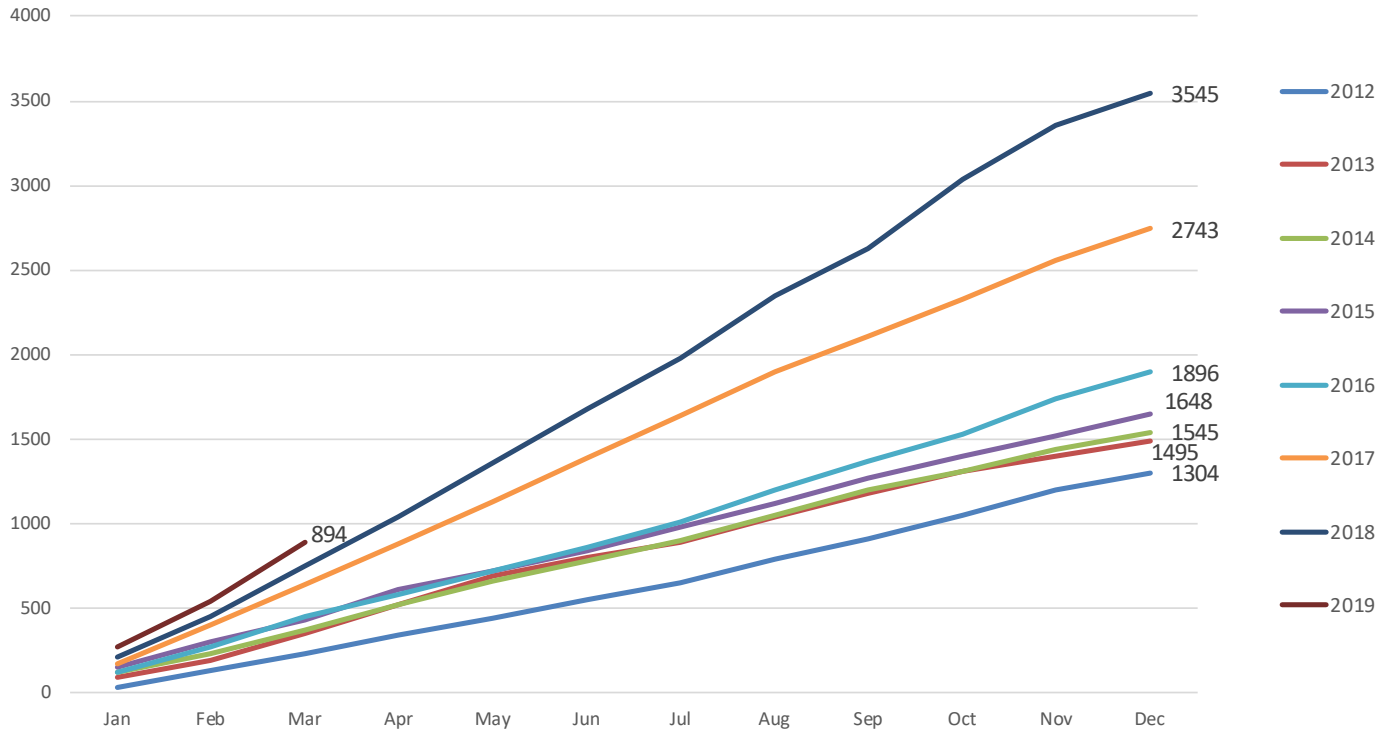
## Total CTSU Patient Accrual



# Alzheimer's Disease Center

The KU 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. It is one of only 31 NIH-funded Alzheimer Disease Centers. The clinical operations of the KU ADC include both research and outpatient clinics which take place at the Clinical Research Center (CRC).

## Alzheimer's Disease Center Patient Visits



# Alzheimer's Disease Center

Since NIA funding began in 2011, the KU ADC has supported 31 national and international pharmaceutical trials. In first quarter 2020, the KU ADC will start 2 Alzheimer's prevention studies and 2 Alzheimer's treatment studies.

## International/Pharmaceutical Trials

Study	Sponsor	Enrollment to Date
A4*	NIH/Eli Lilly	20
ADNI3*	NIH /ATRI	16
DAPA*	AstraZeneca LP	8
LEARN*	NIH/Eli Lilly	14
PEGASUS*	Amylyx	4
Generation 1	Novartis	13
Generation 2	Novartis	3
Graduate II	Genetech Inc	0
AbbVie	AbbVie	8
Trailblazer	Eli Lilly	5
ASPREE	NIH/Berman Center	41
Daybreak	Eli Lilly	3
EARLY	Janssen	1
ENGAGE	Biogen	8
TTP Open-label	vTv Therapeutics	4
TTP	vTv Therapeutics	14
LZAX	Eli Lilly	8
NEUROTROPE	Neurotrope	4
MK-8931	Merck	19
TCAD	NIH/Toyama	13
Elan 201	Janssen	3
IGIV	NIH/Baxter	11
Janssen 301	Janssen	2
Janssen 302	Janssen	5
Janssen 351	Janssen	6
Resveratrol	NIH	1
SNIFF	NIH /National Institute of Aging	2
SUMMIT AD	Janssen	11
Wyeth-3001	Wyeth	2
Exelon Patch	Novartis	8
Exelon Patch-open label	Novartis	6
	<b>TOTALS</b>	<b>263</b>

\*Currently enrolling studies

NIH=National Institutes of Health

# Alzheimer's Disease Center

The KU ADC has supported 39 investigator-initiated studies resulting in 2,172 enrollments to date.

Study	Sponsor	Enrollment to Date
ADC Clinical Cohort*	NIH	433
ADMIT*	NIH	53
DYNAMIC*	NIH	2
EXERT*	NIH	10
GEM*	NIH	8
IGNITE*	NIH	138
LEAP! Rx*	NIH	0
NICE*	NIH	57
rrAD*	NIH	119
REACT*	NIH	61
SEAD2*	KUMC/Ausio	29
SIESTA*	NIH	9
STATINS*	NIH	10
TOAD*	Alzheimer's Association	31
ACCEL	KU ADC Pilot	87
ADEPT	NIH	77
APEX	NIH	118
APP PET-Disclosure	NIH	315
Diabetes and EF	KPP	8
EECP	Internal Medicine	7
FamTechCare	NIH	41
FRITO	KU Endowment	61
INFORM	NIH	52
KDRAFT	CTSA	15
Mediterranean Diet	Frontiers/KU ADC Pilot	26
MILK	KU ADC Pilot	3
MPA/ACCEL	KU ADC Pilot	14
PACER	Ziegler Award	3
PACER 2	Foundation for Physical Therapy	24
POX	CTSA	6
Remote Monitoring	CTSA	6
REST	KU ADC Pilot	3
RetinaAD	St. Luke's Hospital Foundation	36
SBIR	NICHHD	33
SEAD	KUMC/Ausio	16
SPA	ADDF	20
TEAM	NIH	102
TORTIAS	NIH	14
TrACR	KU ADC Pilot/AHA	125
<b>TOTAL</b>		<b>2172</b>

## Investigator-initiated Trials

\*Currently enrolling studies

ADDF=Alzheimer's Drug Discovery Foundation  
 AHA=American Heart Association  
 CTSA=Clinical Translational Science Award  
 NIH=National Institutes of Health  
 NICHHD=National Institute of Child and Health Development  
 KPP=Kansas Partners in Progress

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

	Approved FY19 Budget			Actual FY19 as of 06/30/2019		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
<b>Revenue</b>						
JCERT Sales Tax	\$ 6,000,000		\$ 6,000,000	5,981,600		\$ 5,981,600
Clinical Trial Collection		4,500,000	4,500,000		6,218,498	6,218,498
Cancer Research Center Clinical Services		2,500,000	2,500,000		2,236,274	2,236,274
Cancer Center Support Grants for NCI-designated Cancer Centers		263,609	263,609		342,793	342,793
University of Kansas Hospital Community Support					1,083,057	1,083,057
KU Cancer Center Support		2,500,000	2,500,000		471,020	471,020
Facility Rent Collection		383,124	383,124		383,124	383,124
Common Area Maintenance Fee	-	336,822	336,822		327,075	327,075
Interest Earnings			-	78,462		78,462
Build America Bond Interest Subsidy	164,000	-	164,000	154,448	-	154,448
<b>Total Revenue</b>	<b>6,164,000</b>	<b>10,483,555</b>	<b>16,647,555</b>	<b>6,214,510</b>	<b>11,061,841</b>	<b>17,276,351</b>
<b>Expenditures</b>						
<b>Payroll</b>						
Director, Phase I Program & startup		277,809	277,809	269,496	-	269,496
Physician Positions	163,079	313,000	476,079	196,454	254,802	451,256
Research Leadership	255,101	118,310	373,411	143,503	537,825	681,328
Business Development	230,393	-	230,393	160,954	39,244	200,198
Research Scientists	130,984	90,317	221,301	130,778	82,527	213,305
Research Laboratory Staff	198,282	341,524	539,806	238,101	327,552	565,653
Research Nursing, Study Coordination & Regulatory Administration	2,105,520	5,594,508	7,700,028	2,319,559	4,954,294	7,273,853
Budget & Finance Support	243,627	330,608	574,235	119,818	471,868	591,686
<b>Total Payroll</b>	<b>3,326,986</b>	<b>7,066,076</b>	<b>10,393,062</b>	<b>3,578,663</b>	<b>6,668,112</b>	<b>10,246,775</b>
<b>Other Operating Expense</b>						
Operating Expenses	145,000	374,000	519,000	84,994	852,032	937,026
Remodeling for Additional Space	-	150,000	150,000			
Telephone & Networking	35,000	-	35,000	34,837	-	34,837
Mass Spec Lease	80,000		80,000	80,000	-	80,000
Clinical Trial Research Initiatives for Comprehensive Status	380,837	234,750	615,587	113,801	291,651	405,452
KUH Clinical Services Settlement Cost - Operations	500,000	2,500,000	3,000,000	-	2,595,823	2,595,823
KUH Clinical Services Settlement Cost - Facility Rent	-	383,124	383,124	-	383,124	383,124
KUH Clinical Services Settlement Cost - Common Area Maintenance		336,822	336,822		327,075	327,075
<b>Total Other Operating Expense</b>	<b>1,140,837</b>	<b>3,978,696</b>	<b>5,119,533</b>	<b>313,632</b>	<b>4,449,705</b>	<b>4,763,337</b>
<b>Facility Expense</b>						
Facility Operations	952,350	-	952,350	952,772	-	952,772
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,465	-	1,222,465	1,201,146	-	1,201,146
<b>Total Facility Expense</b>	<b>2,174,815</b>	<b>-</b>	<b>2,174,815</b>	<b>2,153,918</b>	<b>-</b>	<b>2,153,918</b>
<b>Total Expenditures</b>	<b>\$ 6,642,638</b>	<b>\$ 11,044,772</b>	<b>\$ 17,687,410</b>	<b>\$ 6,046,213</b>	<b>\$ 11,117,817</b>	<b>\$ 17,164,030</b>
<b>Revenue less Expenditures</b>	<b>(478,638)</b>	<b>(561,217)</b>	<b>(1,039,855)</b>	<b>168,297</b>	<b>(55,976)</b>	<b>112,321</b>
Less Current Amount Set aside for Capital Reserve	400,000	-	400,000	400,000	-	400,000
Less Current Amount Set aside for Operations	200,000	400,000	600,000	200,000	2,700,000	2,900,000
Operating Account - Beginning Balance	2,835,227	3,332,667	6,167,894	3,272,146	6,672,656	9,944,802
<b>Operating Account - Ending Balance</b>	<b>\$ 2,956,589</b>	<b>\$ 3,171,450</b>	<b>\$ 6,128,039</b>	<b>\$ 2,840,443</b>	<b>\$ 3,916,680</b>	<b>\$ 6,757,123</b>

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

	Approved FY20 Budget			Actual FY20 as of 09/30/2019		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
<b>Revenue</b>						
JCERT Sales Tax	\$ 6,200,000		\$ 6,200,000	1,594,000		\$ 1,594,000
Clinical Trial Collection		6,000,000	6,000,000		1,171,579	1,171,579
Cancer Research Center Clinical Services		2,500,000	2,500,000		403,805	403,805
Cancer Center Support Grants for NCI-designated Cancer Centers		400,000	400,000		70,001	70,001
University of Kansas Hospital Community Support		1,182,100	1,182,100		205,507	205,507
KU Cancer Center Support		1,000,000	1,000,000		41,874	41,874
Facility Rent Collection		383,124	383,124		95,781	95,781
Common Area Maintenance Fee	-	336,822	336,822		84,205	84,205
Interest Earnings			-	28,369		28,369
Build America Bond Interest Subsidy	164,000	-	164,000	75,571	-	75,571
<b>Total Revenue</b>	<b>6,364,000</b>	<b>11,802,046</b>	<b>18,166,046</b>	<b>1,697,940</b>	<b>2,072,752</b>	<b>3,770,692</b>
<b>Expenditures</b>						
<b>Payroll</b>						
Director, Phase I Program & startup	71,901	206,288	278,189	16,487	45,338	61,825
Physician Positions	129,263	57,738	187,001	35,205	14,276	49,481
Research Leadership	109,150	203,590	312,740	37,755	131,835	169,590
Business Development	-	237,319	237,319	-	44,402	44,402
Research Scientists	135,333	85,277	220,610	40,474	10,706	51,180
Research Laboratory Staff	182,301	355,352	537,653	53,720	106,330	160,050
Research Nursing, Study Coordination & Regulatory	2,897,515	6,104,350	9,001,865	630,994	1,114,894	1,745,888
Administration	-	780,166	780,166	-	136,976	136,976
Budget & Finance Support	182,406	516,098	698,504	42,425	123,837	166,262
<b>Total Payroll</b>	<b>3,707,869</b>	<b>8,546,178</b>	<b>12,254,047</b>	<b>857,060</b>	<b>1,728,594</b>	<b>2,585,654</b>
<b>Other Operating Expense</b>						
Operating Expenses	300,000	500,000	800,000	24,616	259,080	283,696
Remodeling for Additional Space	-	200,000	200,000			
Telephone & Networking	34,000	-	34,000	8,073	-	8,073
Mass Spec Lease	81,048		81,048	-	-	-
Clinical Trial Research Initiatives for Comprehensive Status	440,151	155,760	595,911	63,991	63,234	127,225
KUH Clinical Services Settlement Cost - Operations	-	2,500,000	2,500,000	-	489,326	489,326
KUH Clinical Services Settlement Cost - Facility Rent	-	383,124	383,124	-	95,781	95,781
KUH Clinical Services Settlement Cost - Common Area Maintenance		336,822	336,822		84,205	84,205
<b>Total Other Operating Expense</b>	<b>855,199</b>	<b>4,075,706</b>	<b>4,930,905</b>	<b>96,680</b>	<b>991,626</b>	<b>1,088,306</b>
<b>Facility Expense</b>						
Facility Operations	962,270	-	962,270	216,800	-	216,800
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,465	-	1,222,465	301,224	-	301,224
<b>Total Facility Expense</b>	<b>2,184,735</b>	<b>-</b>	<b>2,184,735</b>	<b>518,024</b>	<b>-</b>	<b>518,024</b>
<b>Total Expenditures</b>	<b>\$ 6,747,803</b>	<b>\$ 12,621,884</b>	<b>\$ 19,369,687</b>	<b>\$ 1,471,764</b>	<b>\$ 2,720,220</b>	<b>\$ 4,191,984</b>
<b>Revenue less Expenditures</b>	<b>(383,803)</b>	<b>(819,838)</b>	<b>(1,203,641)</b>	<b>226,176</b>	<b>(647,468)</b>	<b>(421,292)</b>
Less Current Amount Set aside for Capital Reserve	400,000	-	400,000	100,000	-	100,000
Less Current Amount Set aside for Operations	200,000	400,000	600,000	50,000	2,700,000	2,750,000
Operating Account - Beginning Balance	3,142,143	4,733,106	7,875,249	2,840,445	3,916,678	6,757,123
<b>Operating Account - Ending Balance</b>	<b>\$ 2,158,340</b>	<b>\$ 3,513,268</b>	<b>\$ 5,671,608</b>	<b>\$ 2,916,621</b>	<b>\$ 569,210</b>	<b>\$ 3,485,831</b>

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

	Sept 30, 2019	June 30, 2019	June 30, 2018
<b>ASSETS</b>			
Cash and Cash Equivalents (Unencumbered)			
UMB Trustee Accounts (Bond Reserve /P&I)	\$ 956,478.76	\$ 1,783,355.81	\$ 1,773,178.80
KUMC JCERT Operations	2,916,621.00	2,840,443.00	3,351,024.00
KUMC JCERT Capital Reserve	1,160,481.00	1,060,481.00	950,423.00
KUMC JCERT Operating Reserve	1,450,000.00	1,400,000.00	1,200,000.00
Total Cash and Cash Equivalents (Unencumbered)	6,483,580.76	7,084,279.81	7,274,625.80
UMB Trustee Accounts Market Value Change	-	-	-
<b>Capital Assets</b>			
Land 4350 Shawnee Mission Parkway	1,421,810.00	1,421,810.00	1,421,810.00
Clinical Research Center Building & Improvements	20,247,771.54	20,247,771.54	20,247,771.54
Accumulated Depreciation Building & Improvements	(6,469,436.56)	(6,249,292.00)	(5,368,713.76)
Total Buildings & Improvements	13,778,334.98	13,998,479.54	14,879,057.78
Furniture & Equipment	1,528,332.85	1,528,332.85	1,528,332.85
Accumulated Depreciation Furniture & Equipment	(1,408,132.95)	(1,364,748.48)	(1,191,210.60)
Total Furniture & Equipment	120,199.90	163,584.37	337,122.25
Vehicles	21,436.09	21,436.09	21,436.09
Accumulated Depreciation Vehicles	(21,436.09)	(21,436.09)	(21,436.09)
Total Vehicles	-	-	-
<b>Total Capital Assets</b>	15,320,344.88	15,583,873.91	16,637,990.03
<b>TOTAL ASSETS</b>	<b>\$ 21,803,925.64</b>	<b>\$ 22,668,153.72</b>	<b>\$ 23,912,615.83</b>
<b>LIABILITIES &amp; NET ASSETS</b>			
<b>Liabilities</b>			
Bonds Payable			
KUMC 2010P-1 Bond	\$ -	\$ -	\$ -
KUMC 2010P-2 Build America Bond	9,760,000.00	10,515,000.00	11,255,000.00
Total Bonds Payable	9,760,000.00	10,515,000.00	11,255,000.00
Total Liabilities	9,760,000.00	10,515,000.00	11,255,000.00
Net Assets	12,043,925.64	12,153,153.72	12,657,615.83
<b>TOTAL LIABILITIES &amp; NET ASSETS</b>	<b>\$ 21,803,925.64</b>	<b>\$ 22,668,153.72</b>	<b>\$ 23,912,615.83</b>