

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

	Approved FY20 Budget			Actual FY20 as of 6/30/2020		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 6,200,000		\$ 6,200,000	6,128,475		\$ 6,128,475
Clinical Trial Collection		6,000,000	6,000,000		7,675,082	7,675,082
Cancer Research Center Clinical Services		2,500,000	2,500,000		3,049,951	3,049,951
Cancer Center Support Grants for NCI-designated Cancer Centers		400,000	400,000		644,586	644,586
University of Kansas Hospital Community Support		1,182,100	1,182,100		1,020,555	1,020,555
KU Cancer Center Support		1,000,000	1,000,000		288,619	288,619
Facility Rent Collection		383,124	383,124		383,124	383,124
Common Area Maintenance Fee	-	336,822	336,822		336,822	336,822
Interest Earnings			-	64,777		64,777
Build America Bond Interest Subsidy	164,000	-	164,000	147,188	-	147,188
Total Revenue	6,364,000	11,802,046	18,166,046	6,340,440	13,398,739	19,739,179
Expenditures						
Payroll						
Director, Phase I Program & startup	71,901	206,288	278,189	71,957	197,916	269,873
Physician Positions	129,263	57,738	187,001	148,736	60,370	209,106
Research Leadership	109,150	203,590	312,740	243,799	376,958	620,757
Business Development	-	237,319	237,319	-	171,807	171,807
Research Scientists	135,333	85,277	220,610	115,115	47,160	162,275
Research Laboratory Staff	182,301	355,352	537,653	357,129	301,327	658,456
Research Nursing, Study Coordination & Regulatory	2,897,515	6,104,350	9,001,865	2,420,583	5,636,020	8,056,603
Administration	-	780,166	780,166	-	746,061	746,061
Budget & Finance Support	182,406	516,098	698,504	229,167	408,155	637,322
Total Payroll	3,707,869	8,546,178	12,254,047	3,586,486	7,945,774	11,532,260
Other Operating Expense						
Operating Expenses	300,000	500,000	800,000	82,015	807,106	889,121
Remodeling for Additional Space	-	200,000	200,000		98,510	98,510
Telephone & Networking	34,000	-	34,000	31,365	-	31,365
Mass Spec Lease	81,048		81,048	78,540	-	78,540
Clinical Trial Research Initiatives for Comprehensive Status	440,151	155,760	595,911	368,777	438,168	806,945
KUH Clinical Services Settlement Cost - Operations	-	2,500,000	2,500,000	-	2,908,809	2,908,809
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		336,822	336,822
Total Other Operating Expense	855,199	4,075,706	4,930,905	560,697	4,972,539	5,533,236
Facility Expense						
Facility Operations	962,270	-	962,270	775,327	-	775,327
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,465	-	1,222,465	1,184,990	-	1,184,990
Total Facility Expense	2,184,735	-	2,184,735	1,960,317	-	1,960,317
Total Expenditures	\$ 6,747,803	\$ 12,621,884	\$ 19,369,687	\$ 6,107,500	\$ 12,918,313	\$ 19,025,813
Revenue less Expenditures	(383,803)	(819,838)	(1,203,641)	232,940	480,426	713,366
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	2,600,000	2,800,000
Operating Account - Beginning Balance	3,142,143	4,733,106	7,875,249	2,939,631	3,916,678	6,856,309
Operating Account - Ending Balance	\$ 2,158,340	\$ 3,513,268	\$ 5,671,608	\$ 2,572,571	\$ 1,797,104	\$ 4,369,675

The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS

CANCER CENTER



October 2020

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.

Masonic Cancer Alliance (MCA) is the outreach network of The University of Kansas Cancer Center. 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 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

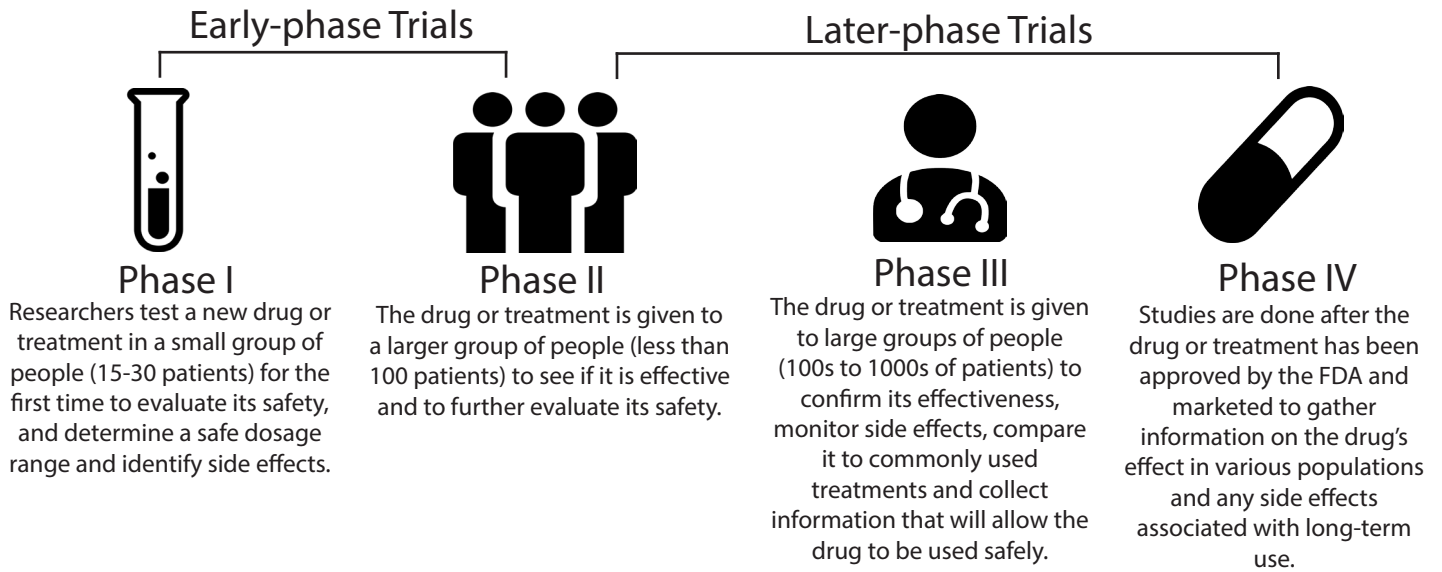
KU Cancer Center aims to do nothing less than fundamentally transform the cancer experience – to give all people in our region greater access to breakthrough ideas and novel treatments.



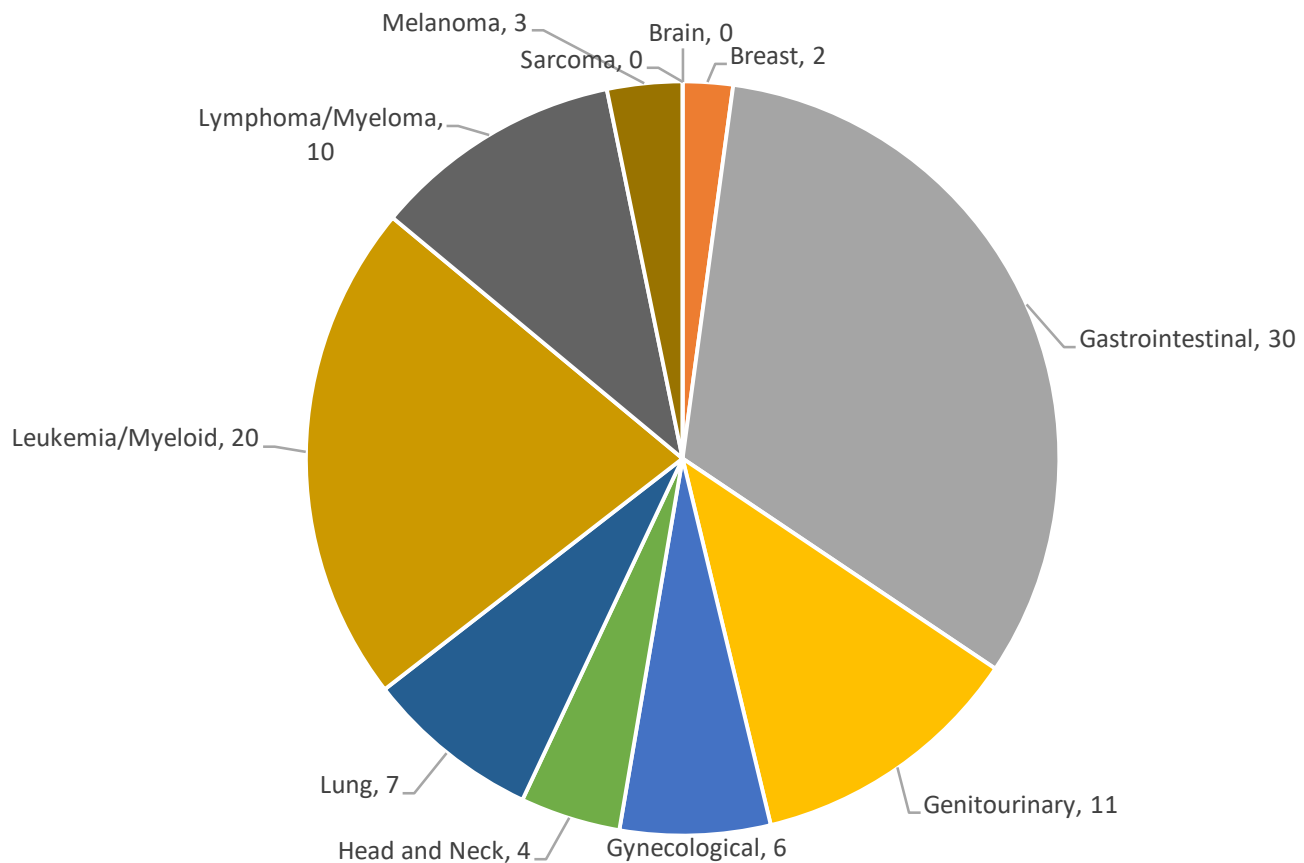
A Cancer Center Designated by the
National Cancer Institute

Types of Clinical Trials

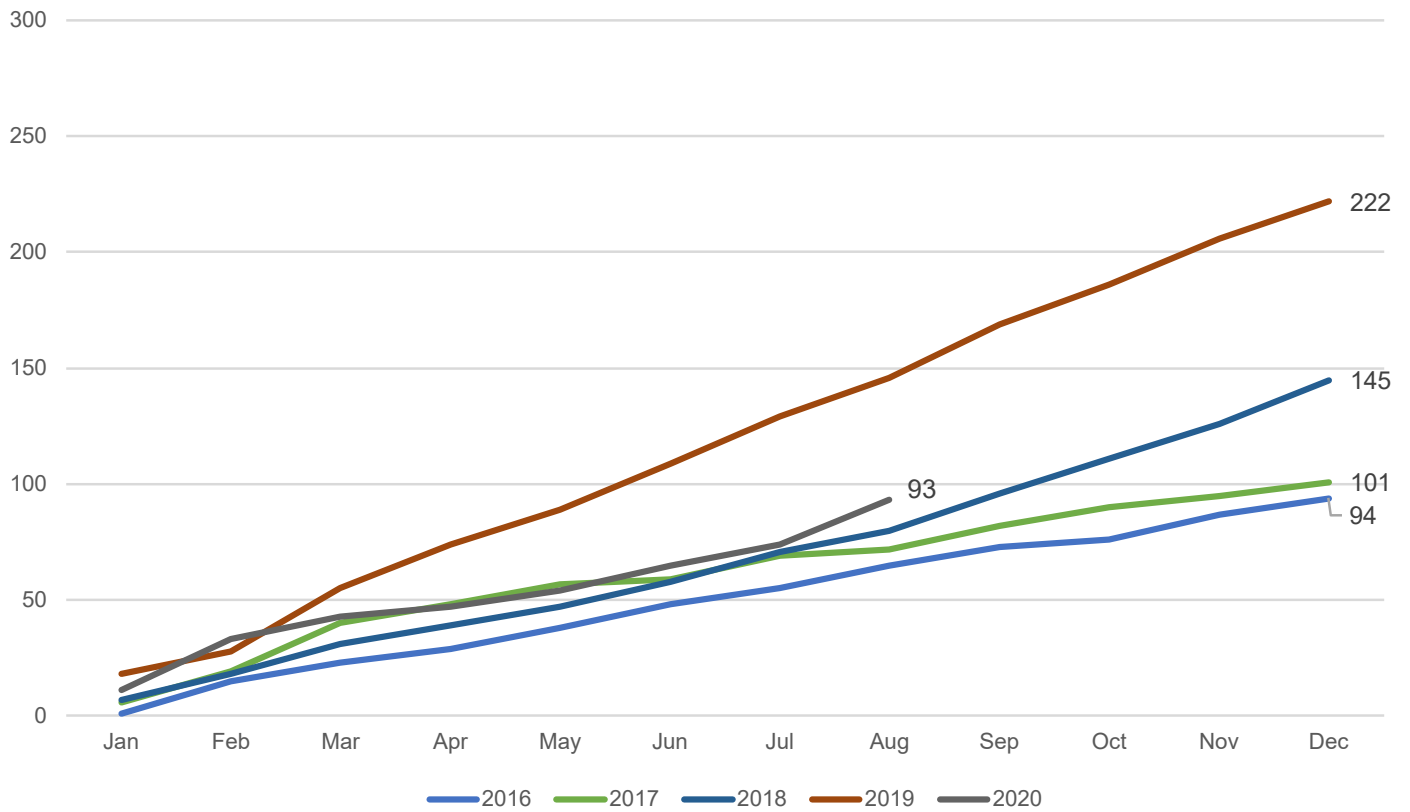
Cancer clinical trials provide access to potential advancement in care and lead to innovations in cancer prevention. Clinical trials are conducted in four phases:



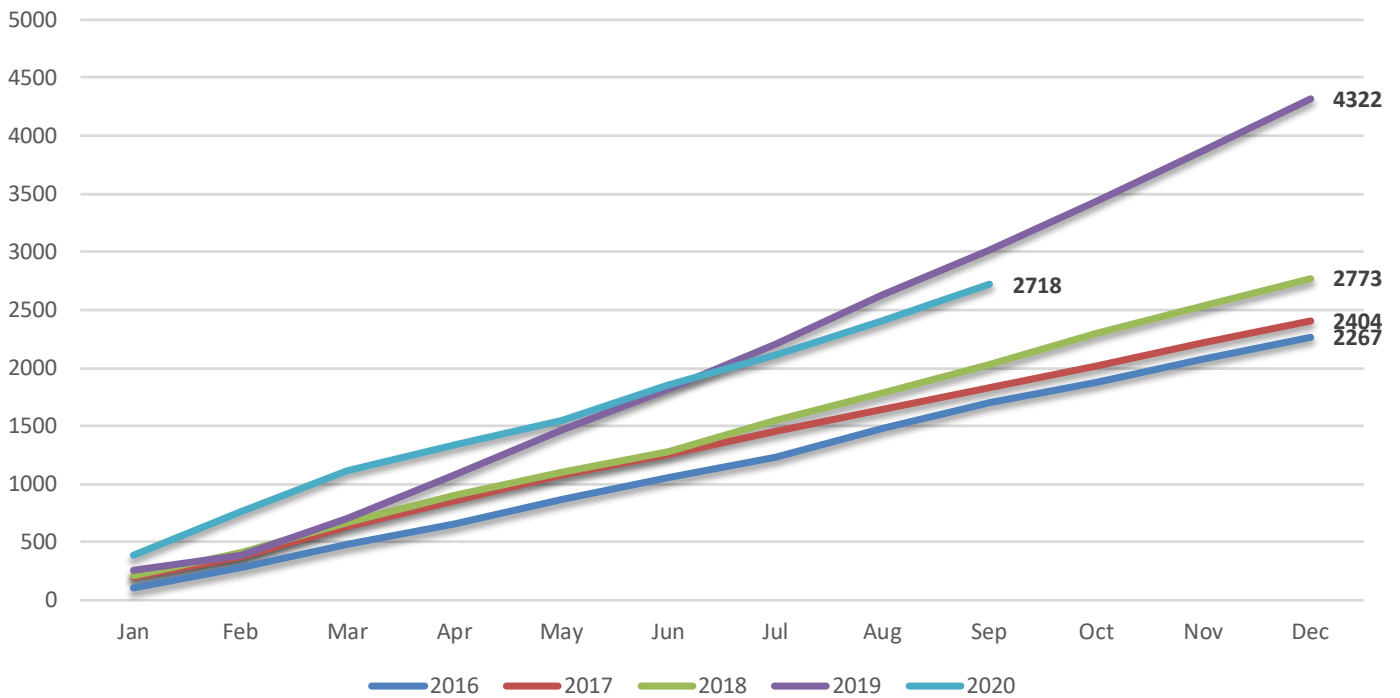
Early-phase Clinical Trial Accrual by Disease Group



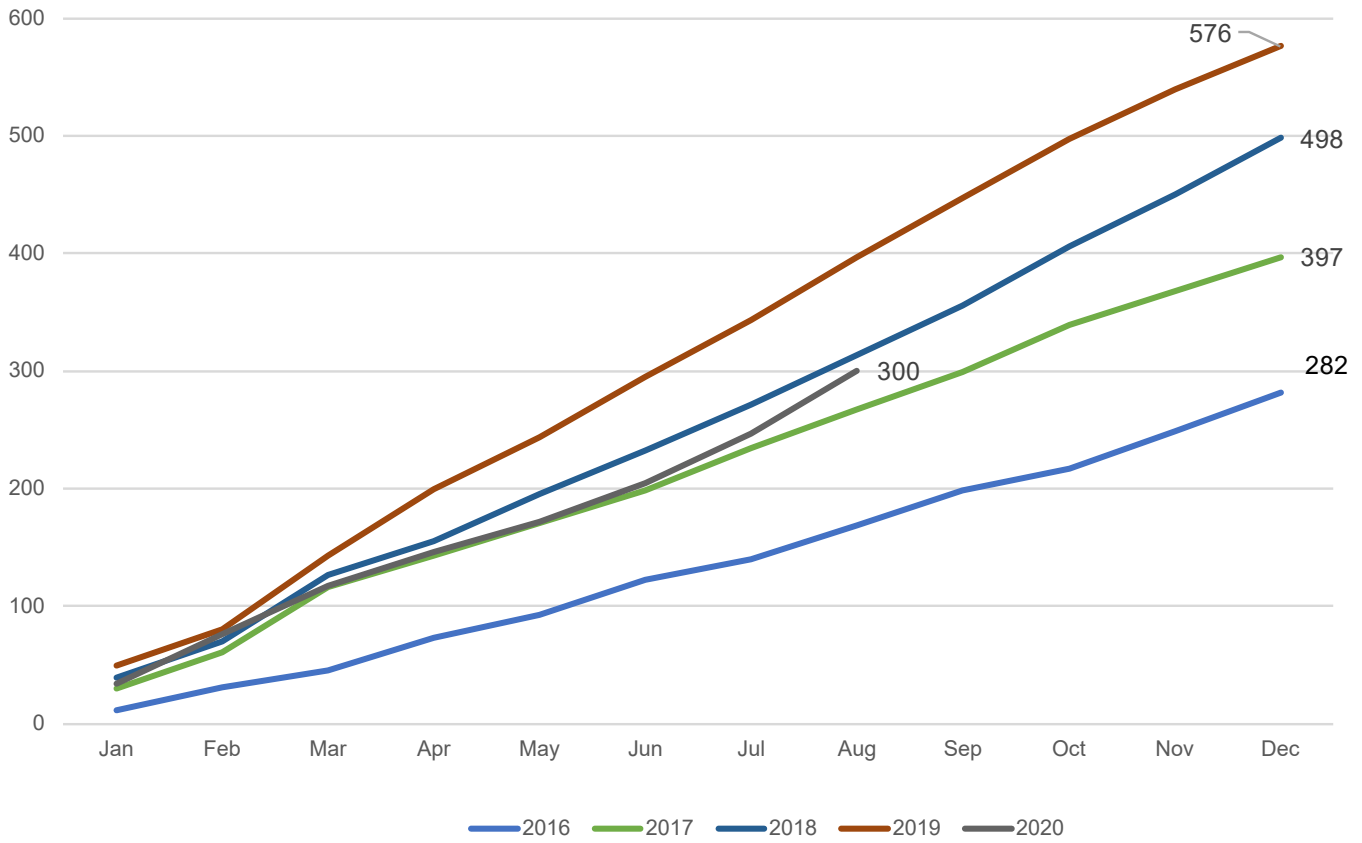
Early-phase Clinical Trial Accrual



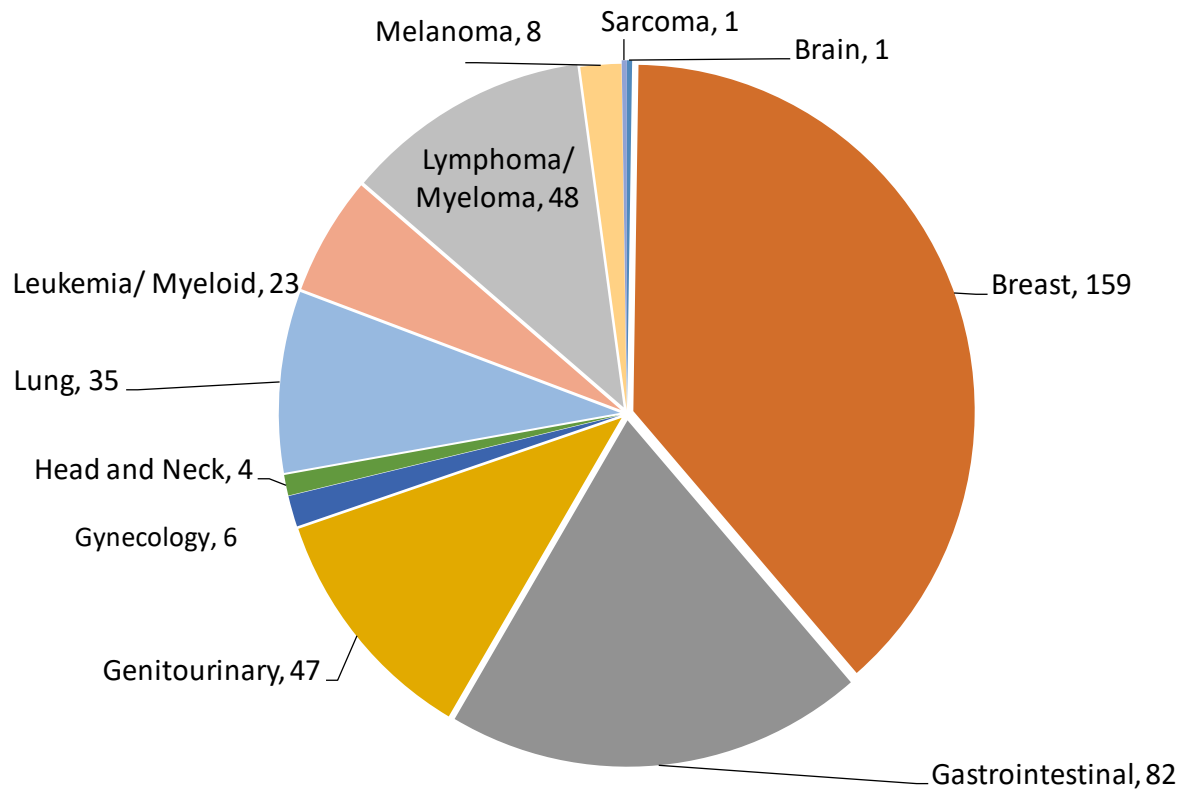
Early-phase KU CRC Patient Visits



Later-phase Clinical Trials



Later-phase Clinical Trial Accrual by Disease Group



Clinical Trials Patient Total By Location

Site Location	Patient Total
KU Clinical Research Center (early phase)	93
KU Cancer Center Main Outpatient sites	292
KU Cancer Center Community sites	85
Masonic Cancer Alliance sites	27
Children's Mercy	14
Other sites	10

Top Five Counties for KU CRC Patient Visits

	County	Unique Patients
1	Johnson County (KS)	618
2	Jackson County (MO)	523
3	Clay County (MO)	213
4	Platte County (MO)	142
5	Wyandotte County (KS)	121

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.

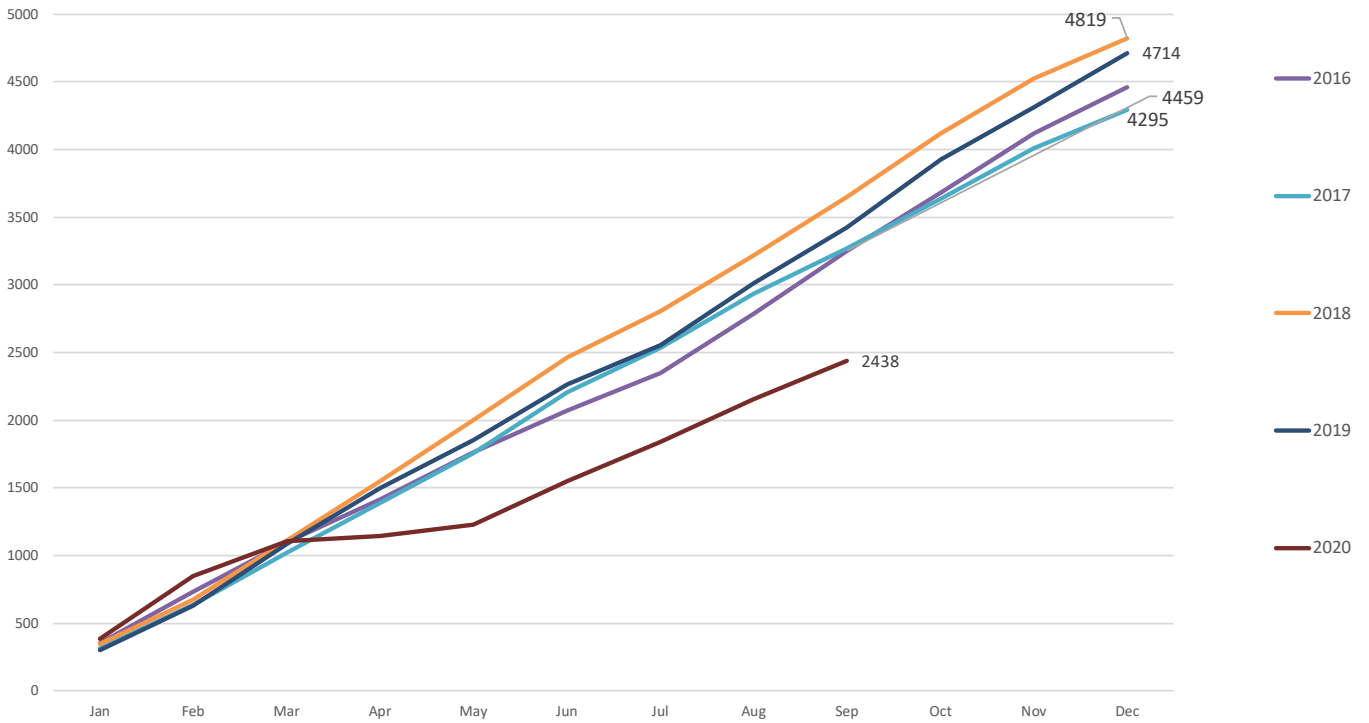


Other Organizations Conducting Research at the KU Clinical Research Center

Clinical and Translational Science Unit (CTSU)

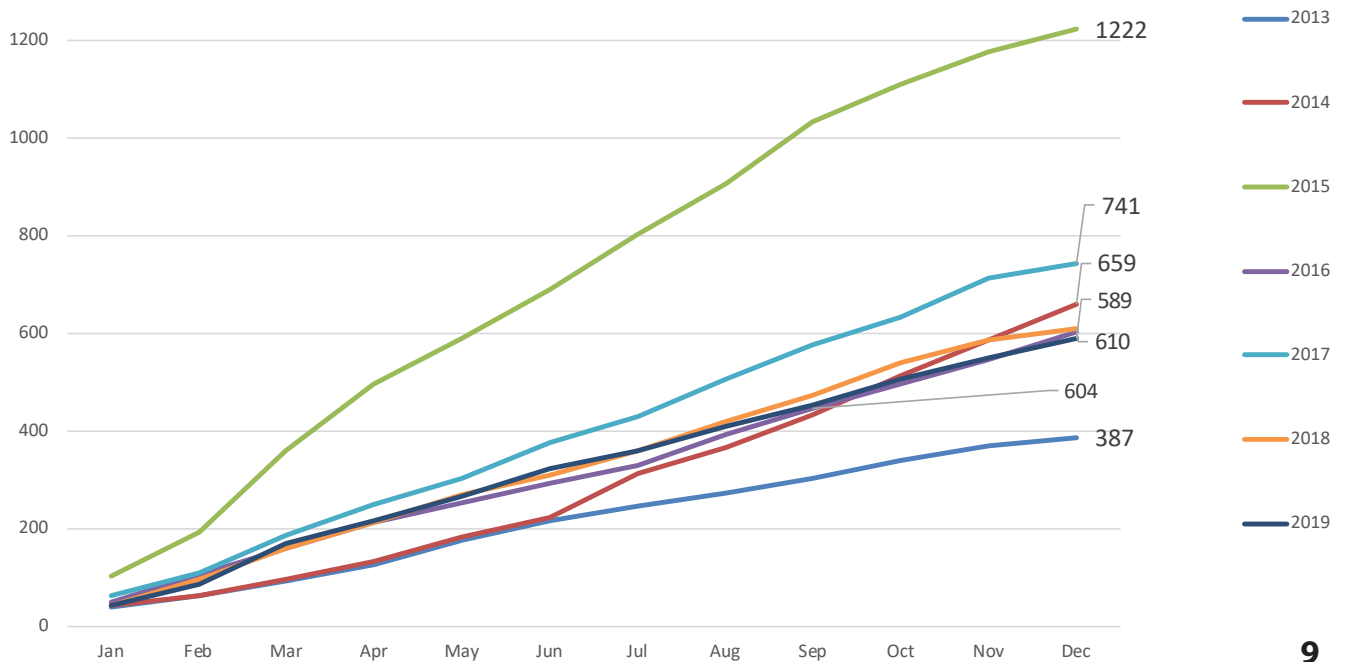
The CTSU provides the Kansas City region with a centralized resource for supporting clinical and translational research. The clinic and staff support both pharmaceutical trials and investigator-initiated trials for researchers mostly outside the oncology area, but some trials do support cancer and cancer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

Total CTSU Patient Visits



Total CTSU Patient Accrual

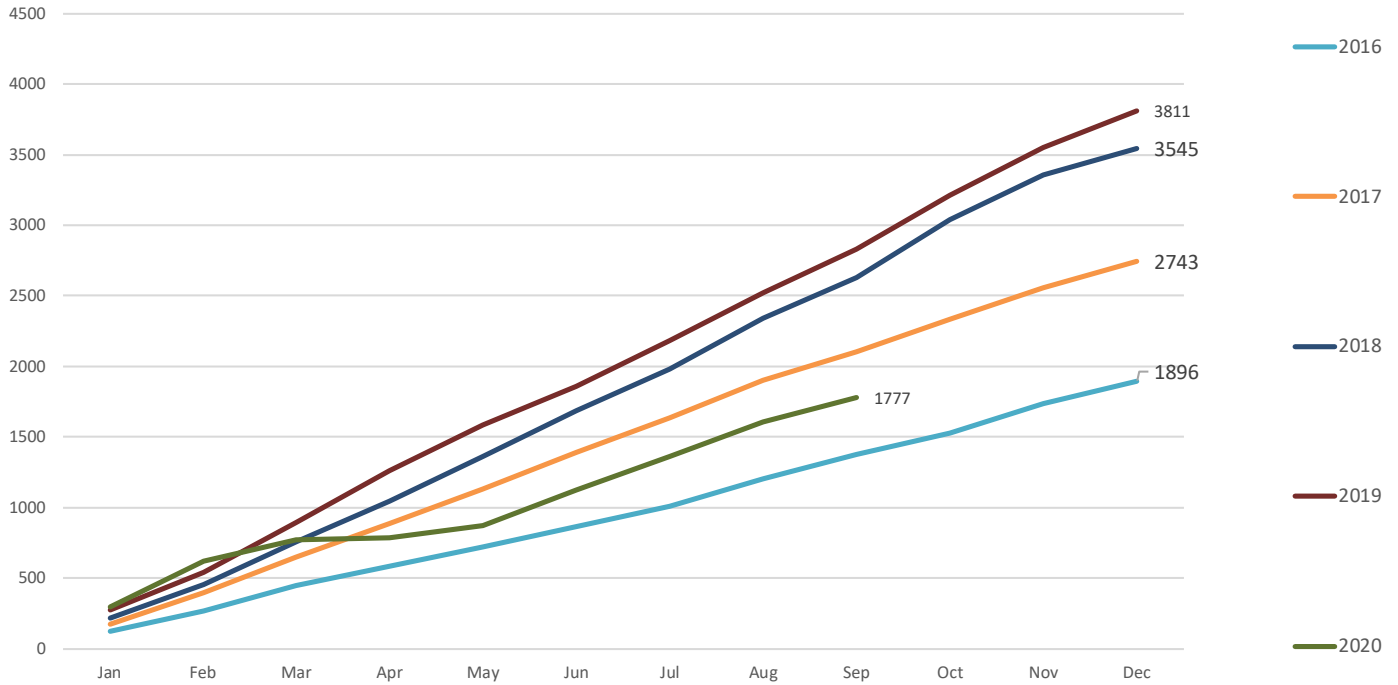
*data through 2019



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 38 national and international pharmaceutical trials. The Center has started 2 Alzheimer's prevention studies and 2 Alzheimer's treatment studies this past quarter.

International/Pharmaceutical Trials

Study	Sponsor	Enrollment to Date
A4*	NIH/Eli Lilly	20
A3-45*	NIH/Eli Lilly	0
AbbVie Open-label*	AbbVie	5
ADNI3*	NIH/ATRI	16
Alector*	Alector	0
Clarity*	Eisai	0
DAPA*	AstraZeneca LP	18
Embark	Biogen	0
LEARN*	NIH/Eli Lilly	15
LIFE-DSR*	LuMind/ATRI	0
PEGASUS*	Amylyx	9
TRC PAD*	NIH	0
Vaccinex*	IQVIA	0
Generation 1	Novartis	13
Generation 2	Novartis	3
AbbVie	AbbVie	9
Trailblazer	Eli Lilly	5
ASPREE	NIH/Berman Center	41
Daybreak	Eli Lilly	3
EARLY	Janssen	1
ENGAGE	Biogen	8

Study	Sponsor	Enrollment to Date
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
	TOTAL	285

*Currently enrolling studies

NIH=National Institutes of Health

Alzheimer's Disease Center

The KU ADC has supported 47 investigator-initiated studies resulting in 2,548 enrollments to date.

Investigator-Initiated Trials

Study	Sponsor	Enrollment to date
ADC Clinical Cohort*	NIH	427
ADMIT*	NIH	52
AEROBIC*	NIH	0
AMIE*	KU Endowment	4
AROMA*	NIH	43
BB8-AD*	NIH	33
Brain Healthy Diet*	NIH	8
C-NAP*	NIH	25
DYNAMIC*	NIH	24
EXERT*	NIH	10
GEM*	NIH	22
IGNITE*	NIH	180
LEAP! Rx*	NIH	60
MOVER*	KU Endowment	45
NICE*	NIH	101
REACT*	NIH	65
SEAD2*	KUMC/Ausio	38
SIESTA*	NIH	15
STATINS*	NIH	19
TDAD*	NIH	7
TOAD*	Alzheimer's Association	32
ACCEL	KU ADC Pilot	87
ADEPT	NIH	77

Study	Sponsor	Enrollment to date
APEX	NIH	118
APP PET-Disclosure	NIH	315
Diabetes and EF	KPP	8
ECEP	Internal Medicine	7
FamTechCare	NIH	41
FRITO	KU Endowment	61
INFORM	NIH	52
KDRAFT	CTSA	15
	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
rrAD	NIH	126
SBIR	NICHD	33
SEAD	KUMC/Ausio	16
SPA	Alzheimer's Drug Discovery Association	20
TEAM	NIH	102
TORTIAS	NIH	14
TrACR	KU ADC Pilot/AHA	125
	TOTAL	2,548

*Currently enrolling studies

AHA=American Heart Association

CTSA=Clinical Translational Science Award

NIH=National Institutes of Health

NICHD=National Institute of Child and Health Development

KPP=Kansas Partners in Progress

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

	Approved FY21 Budget			Actual FY21 as of 9/30/2020		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 6,300,000		\$ 6,300,000	1,589,995		\$ 1,589,995
Clinical Trial Collection		6,500,000	6,500,000		1,246,904	1,246,904
Cancer Research Center Clinical Services		2,750,000	2,750,000		365,486	365,486
Cancer Center Support Grants for NCI-designated Cancer Centers		400,000	400,000		46,256	46,256
University of Kansas Hospital Community Support		1,182,100	1,182,100		288,361	288,361
KU Cancer Center Support		1,500,000	1,500,000		26,928	26,928
Facility Rent Collection		383,124	383,124		63,954	63,954
Common Area Maintenance Fee	-	336,822	336,822		56,137	56,137
Interest Earnings			-	2,988		2,988
Build America Bond Interest Subsidy	147,329	-	147,329	71,616	-	71,616
Total Revenue	6,447,329	13,052,046	19,499,375	1,664,599	2,094,026	3,758,625
Expenditures						
Payroll						
Director, Phase I Program & startup	72,151	198,465	270,616	16,235	52,329	68,564
Physician Positions	147,894	59,450	207,344	34,483	42,853	77,336
Research Leadership	166,782	380,375	547,157	37,138	101,220	138,358
Business Development	-	389,847	389,847	-	65,473	65,473
Research Scientists	116,184	45,500	161,684	18,678	-	18,678
Investigator Initiated Trial Staff	353,017	228,023	581,040	81,261	47,871	129,132
Research Laboratory Staff	208,464	372,832	581,296	69,684	58,597	128,281
Research Nursing, Study Coordination & Regulatory	2,900,083	6,385,447	9,285,530	533,845	1,164,859	1,698,704
Administration	61,250	1,240,807	1,302,057	-	200,144	200,144
Budget & Finance Support	272,398	727,080	999,478	43,221	126,919	170,140
Total Payroll	4,298,223	10,027,826	14,326,049	834,545	1,860,265	2,694,810
Other Operating Expense						
Operating Expenses	125,000	875,000	1,000,000	20,813	184,885	205,698
Telephone & Networking	61,139	-	61,139	1,217	-	1,217
Mass Spec Lease	81,048		81,048	-	-	-
Clinical Trial Research Initiatives for Comprehensive Status	-	250,000	250,000	-	-	-
KUH Clinical Services Settlement Cost - Operations	-	2,750,000	2,750,000	-	633,471	633,471
KUH Clinical Services Settlement Cost - Facility Rent	-	383,124	383,124	-	63,954	63,954
KUH Clinical Services Settlement Cost - Common Area Maintenance		336,822	336,822		56,137	56,137
Total Other Operating Expense	267,187	4,594,946	4,862,133	22,030	938,447	960,477
Facility Expense						
Facility Operations	856,900	-	856,900	178,164	-	178,164
Withheld by Trustee for Debt Service & Trustee Expenses	1,190,940	-	1,190,940	149,623	-	149,623
Total Facility Expense	2,047,840	-	2,047,840	327,787	-	327,787
Total Expenditures	\$ 6,613,250	\$ 14,622,772	\$ 21,236,022	\$ 1,184,362	\$ 2,798,712	\$ 3,983,074
Revenue less Expenditures	(165,921)	(1,570,726)	(1,736,647)	480,237	(704,686)	(224,449)
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	(2,000,000)	(1,800,000)	50,000	-	50,000
Operating Account - Beginning Balance	2,692,578	526,685	3,219,263	2,572,572	2,049,103	4,621,675
Operating Account - Ending Balance	\$ 1,926,657	\$ 955,959	\$ 2,882,616	\$ 2,902,809	\$ 1,344,417	\$ 4,247,226

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

	Sept. 30, 2020	June 30, 2020	June 30, 2019
ASSETS			
Cash and Cash Equivalents (Unencumbered)			
UMB Trustee Accounts (Bond Reserve /P&I)	\$ 1,940,334.66	\$ 1,940,334.66	\$ 1,783,355.81
KUMC JCERT Operations	2,902,809.00	2,572,571.00	2,840,443.00
KUMC JCERT Capital Reserve	1,395,296.00	1,386,261.00	1,060,481.00
KUMC JCERT Operating Reserve	1,650,000.00	1,600,000.00	1,400,000.00
Total Cash and Cash Equivalents (Unencumbered)	7,888,439.66	7,499,166.66	7,084,279.81
UMB Trustee Accounts Market Value Change	-	-	-
Capital Assets			
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	(7,350,014.80)	(7,129,870.24)	(6,249,292.00)
Total Buildings & Improvements	12,897,756.74	13,117,901.30	13,998,479.54
Furniture & Equipment	1,528,332.85	1,528,332.85	1,528,332.85
Accumulated Depreciation Furniture & Equipment	(1,528,332.85)	(1,538,286.36)	(1,364,748.48)
Total Furniture & Equipment	-	(9,953.51)	163,584.37
Vehicles	21,436.09	21,436.09	21,436.09
Accumulated Depreciation Vehicles	(21,436.09)	(21,436.09)	(21,436.09)
Total Vehicles	-	-	-
Total Capital Assets	14,319,566.74	14,529,757.79	15,583,873.91
TOTAL ASSETS	\$ 22,208,006.40	\$ 22,028,924.45	\$ 22,668,153.72
LIABILITIES & NET ASSETS			
Liabilities			
Bonds Payable			
KUMC 2010P-1 Bond	\$ -	\$ -	\$ -
KUMC 2010P-2 Build America Bond	8,990,000.00	9,760,000.00	10,515,000.00
Total Bonds Payable	8,990,000.00	9,760,000.00	10,515,000.00
Total Liabilities	8,990,000.00	9,760,000.00	10,515,000.00
Net Assets	13,218,006.40	12,268,924.45	12,153,153.72
TOTAL LIABILITIES & NET ASSETS	\$ 22,208,006.40	\$ 22,028,924.45	\$ 22,668,153.72