

The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS

CANCER CENTER



April 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 **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 component of 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



"I'm not here for myself. I want to make memories every day for other folks and let my experience be a learning tool for them."

- Nedra Bonds, KU CRC Clinical Trial Patient

Transforming Cancer Care in Our Region

In 2012, The University of Kansas Cancer Center achieved National Cancer Institute (NCI) Cancer Center designation, a significant accomplishment. Our designation was renewed in 2017. Of more than 5,000 cancer centers in the U.S., just 70 are NCI-designated. 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. We are already working towards the next goal: achieving NCI Comprehensive designation.

Achieving Comprehensive Cancer Center designation will enable us to offer the highest level of research, prevention, treatment and survivorship available. 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
- More Kansas City patients receive life-saving cancer treatments close to home

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

NCI Designation brings a tailored approach to fighting cancer

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

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

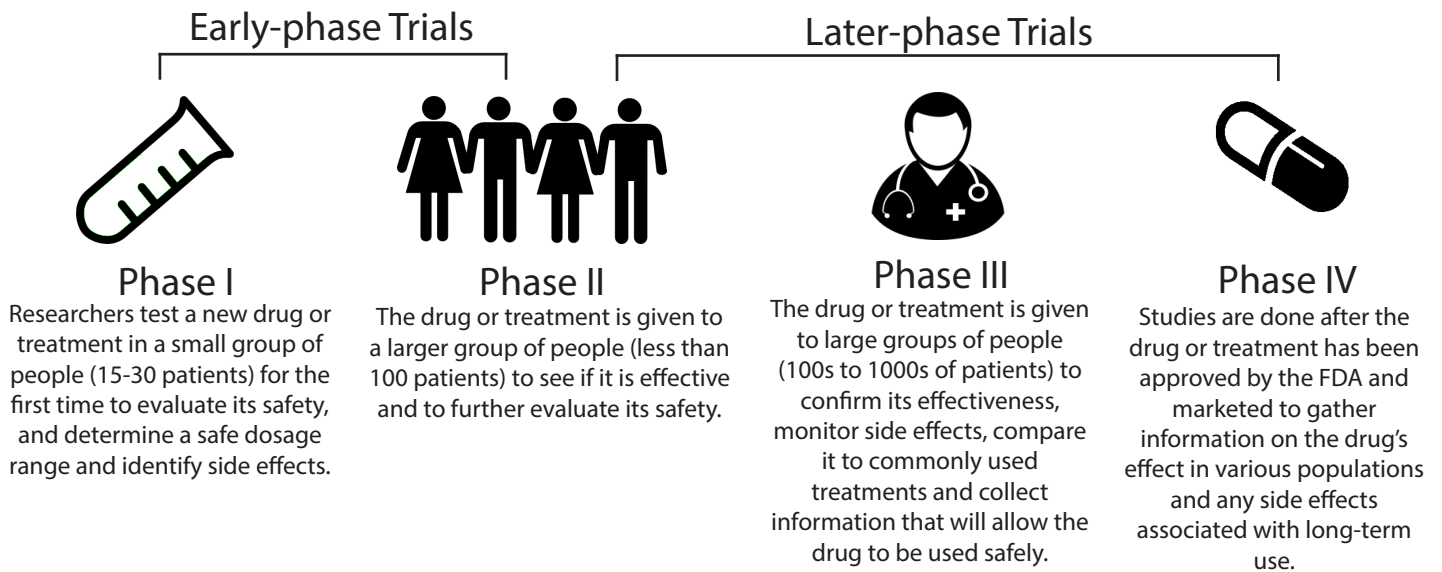
- Develop highly personalized cancer treatments for each unique patient
- Offer state-of-the-art cancer treatments here at home
- Recruit the best physician scientists
- Leverage partnerships for further innovation in drug discovery and development



A Cancer Center Designated by the
National Cancer Institute

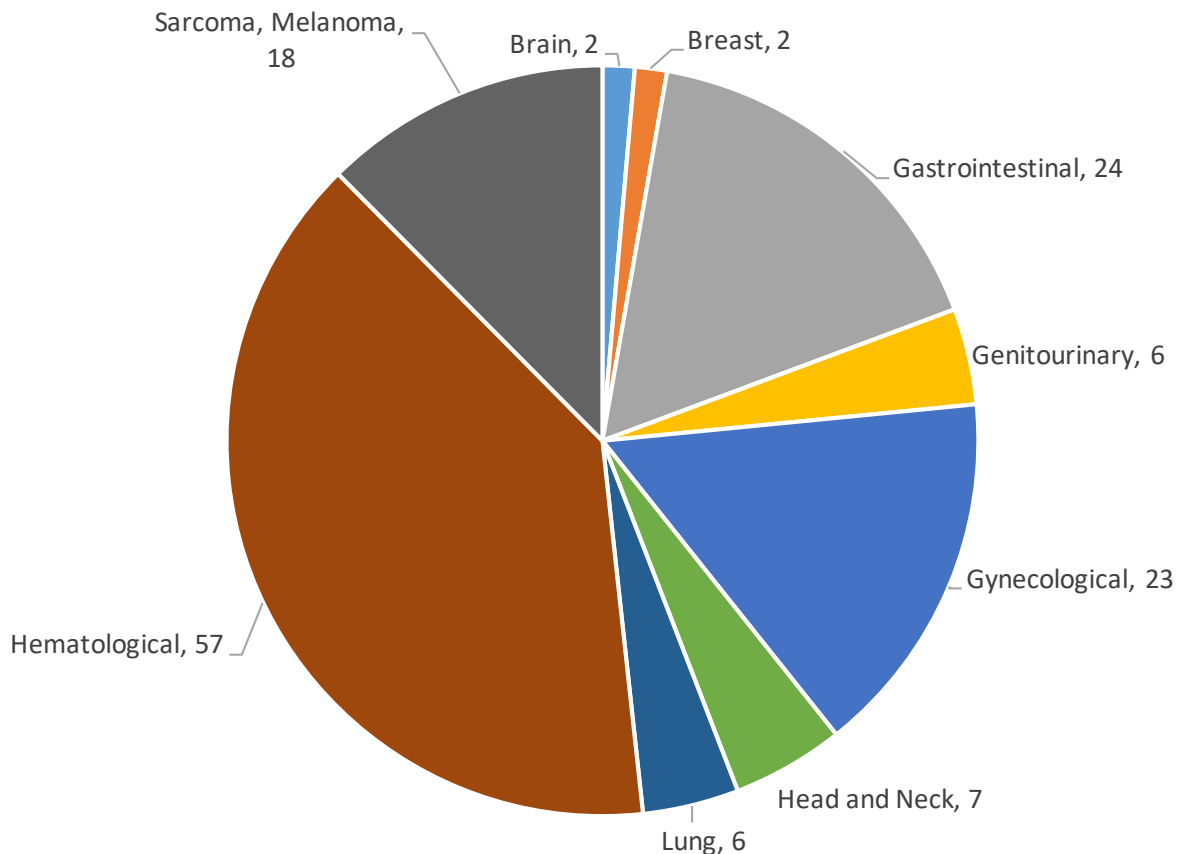
Types of Clinical Trials

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

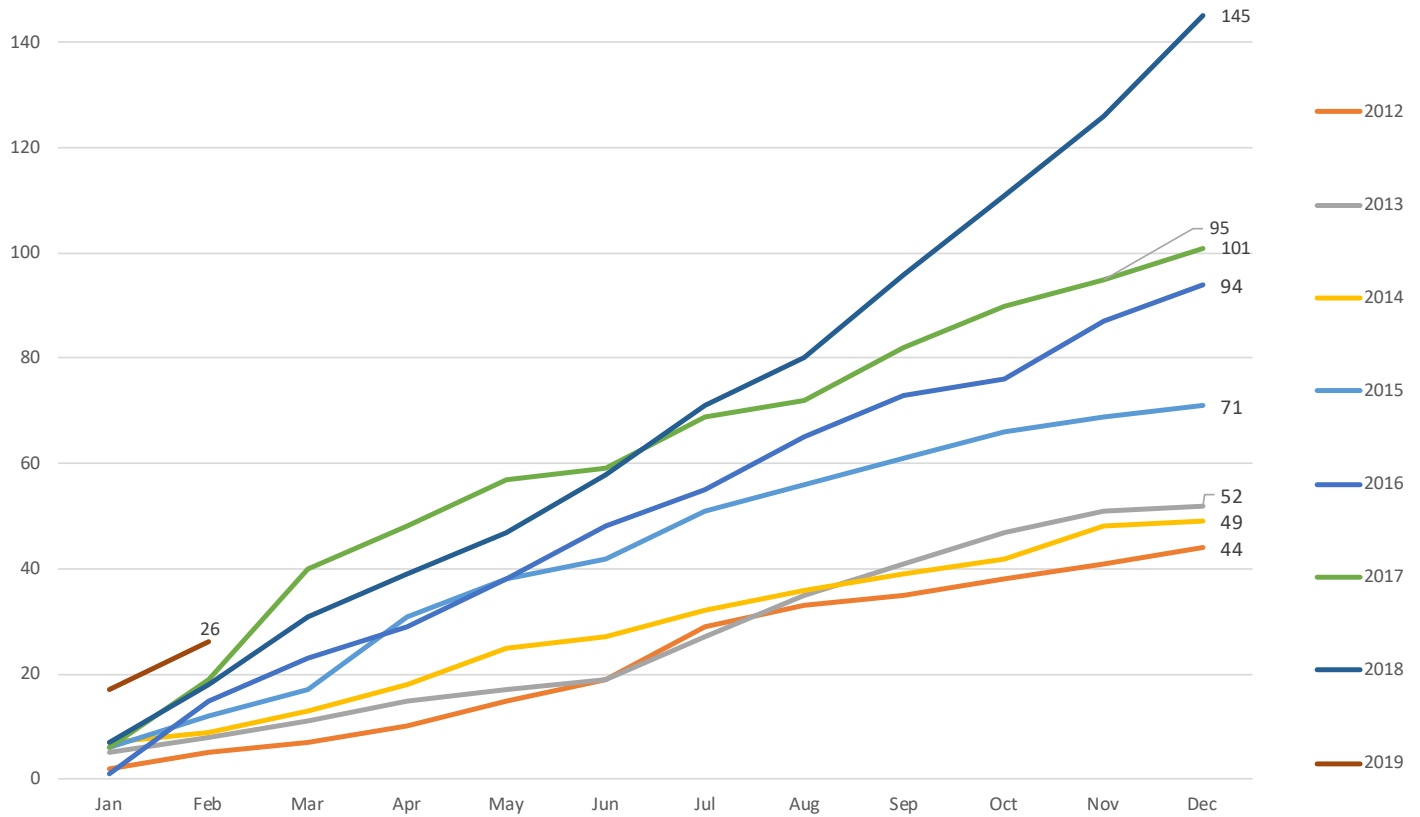


Early-phase Clinical Trial Accrual by Disease Group

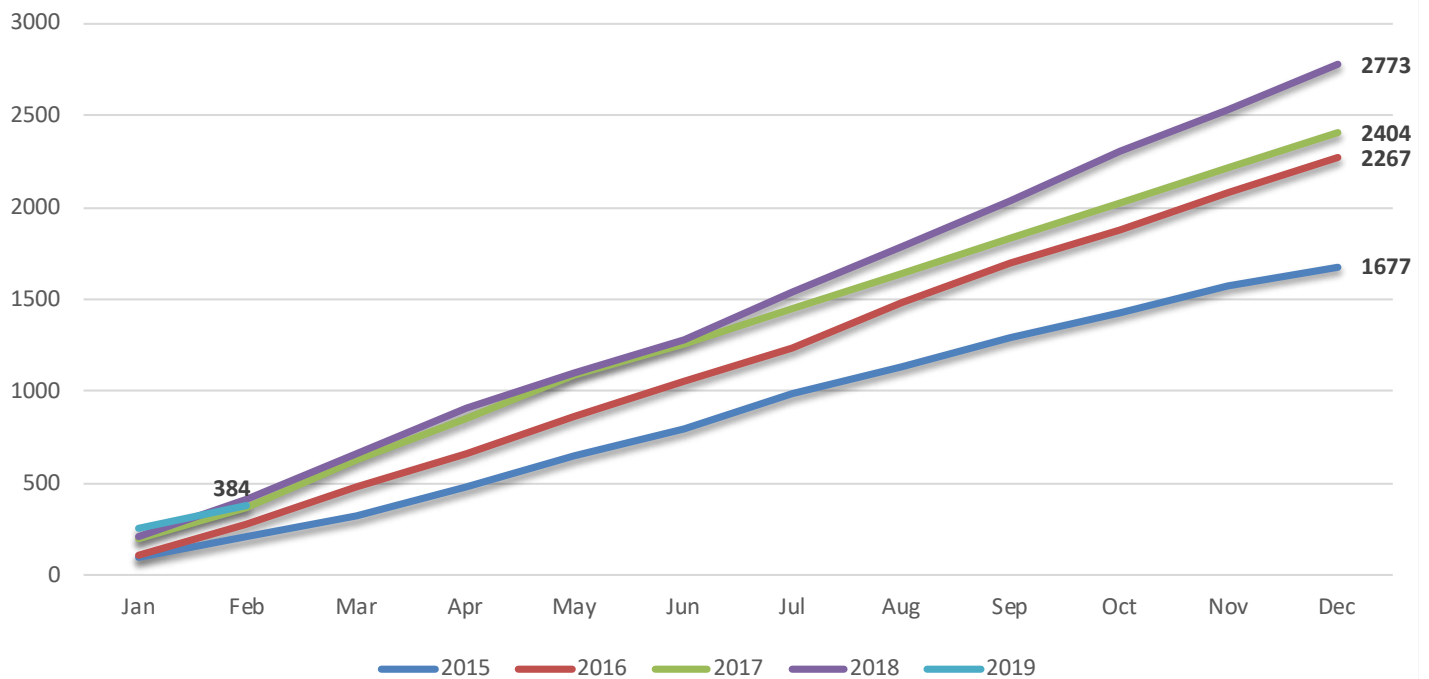
January-December 2018



Early-phase Clinical Trial Accrual

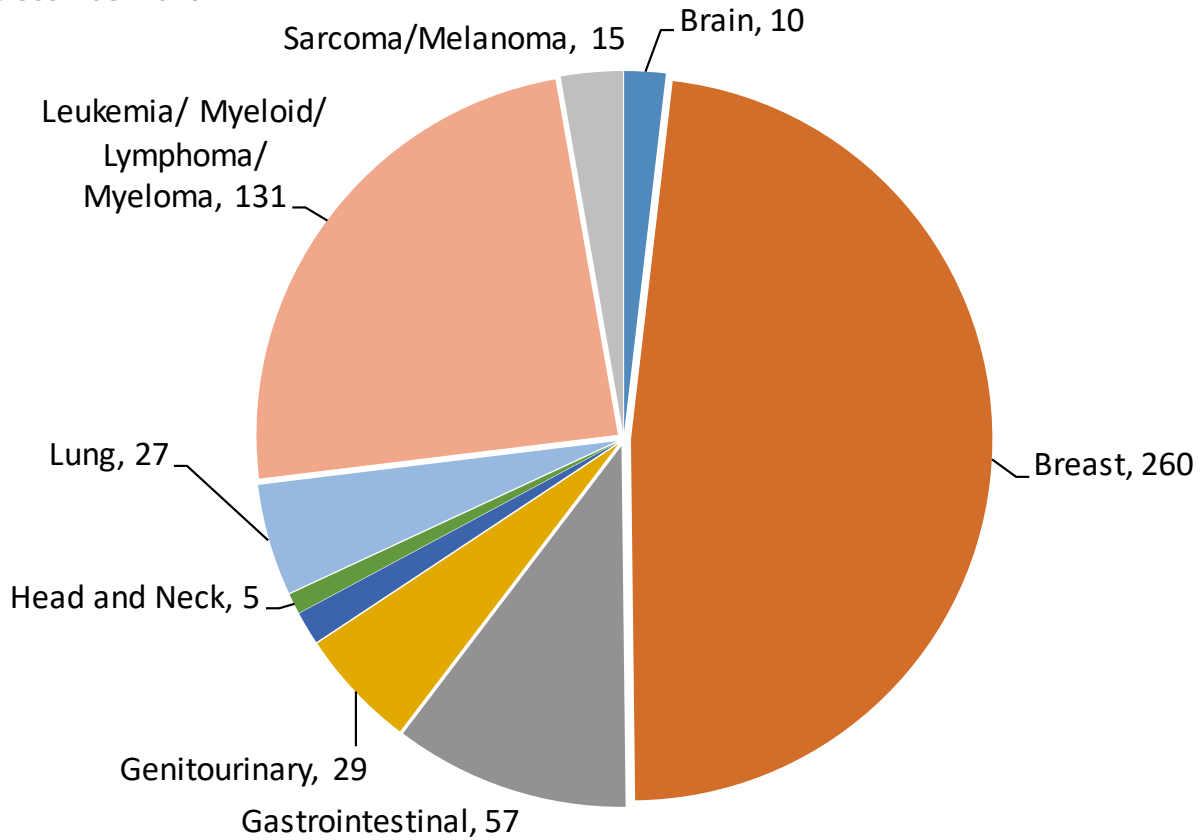


Early-phase KU CRC Patient Visits

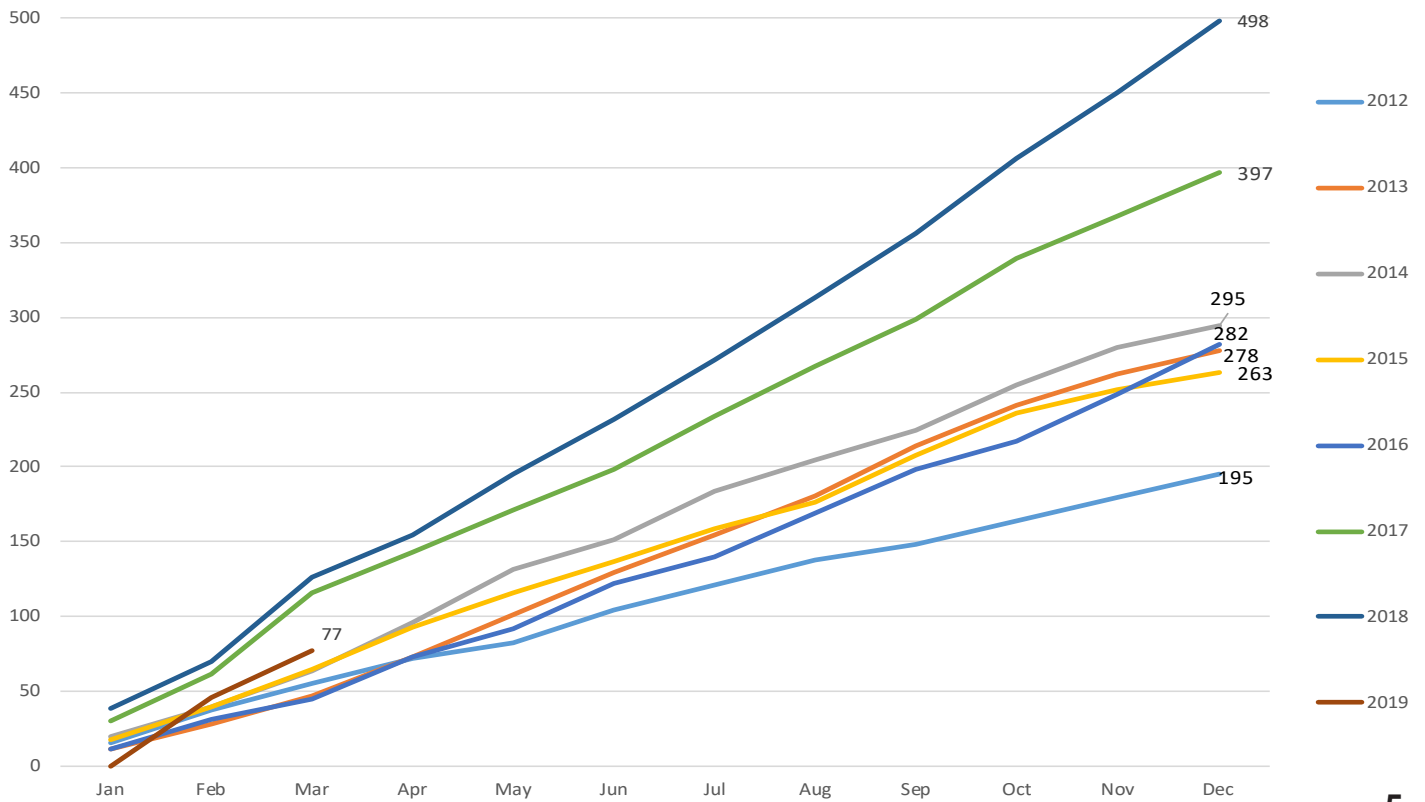


Later-phase Clinical Trials

January-December 2018



Later-phase Clinical Trial Accrual by Disease Group



Clinical Trials Patient Total By Location

January-December 2018

Site Location	Patient Total
KU Clinical Research Center (early phase)	145
KU Cancer Center Main Outpatient sites	418
KU Cancer Center Community sites	65
Midwest Cancer Alliance sites	29
Other sites	59

Top Five Counties for KU CRC Patient Visits

January-December 2018

	County	Unique Patients
1	Johnson County (KS)	746
2	Jackson County (KS)	508
3	Clay County (MO)	197
4	Wyandotte County (MO)	167
5	Leavenworth County (KS)	102

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.

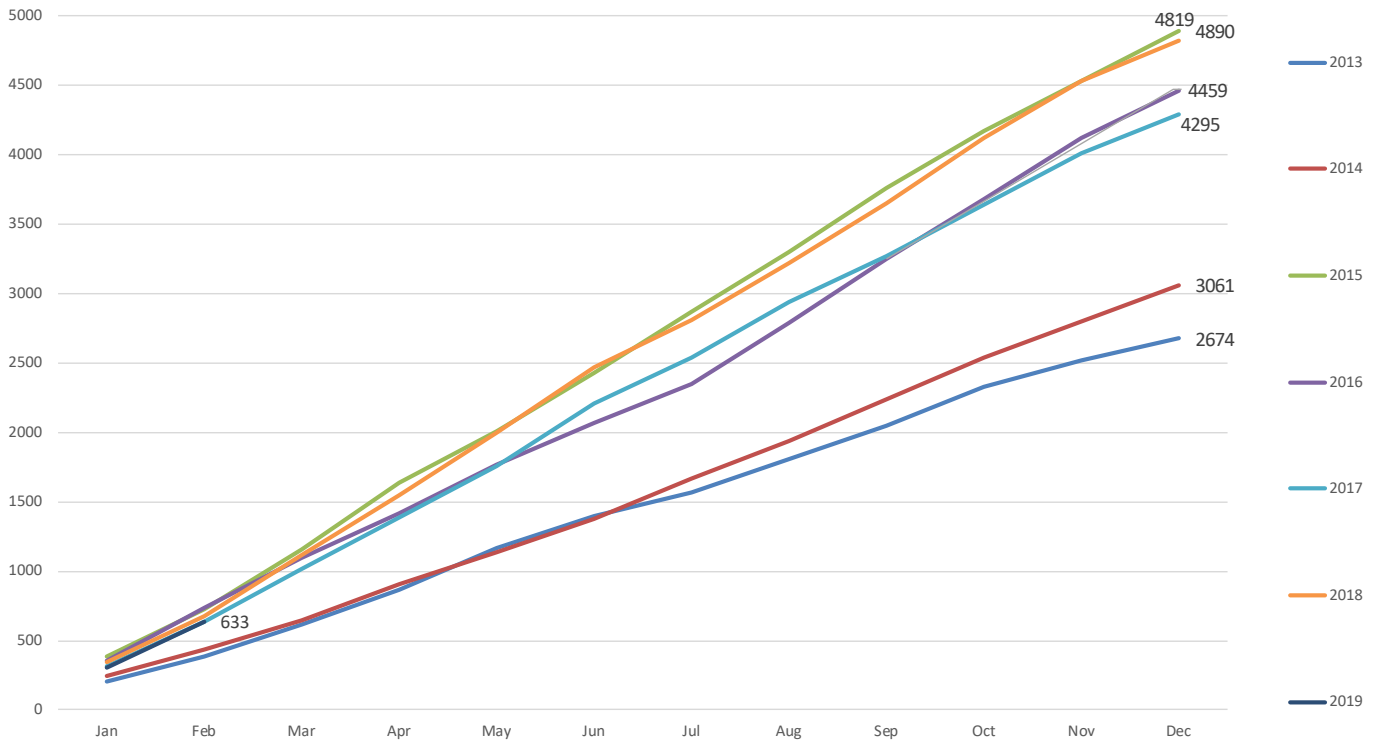


Other Organizations Conducting Research at the KU Clinical Research Center

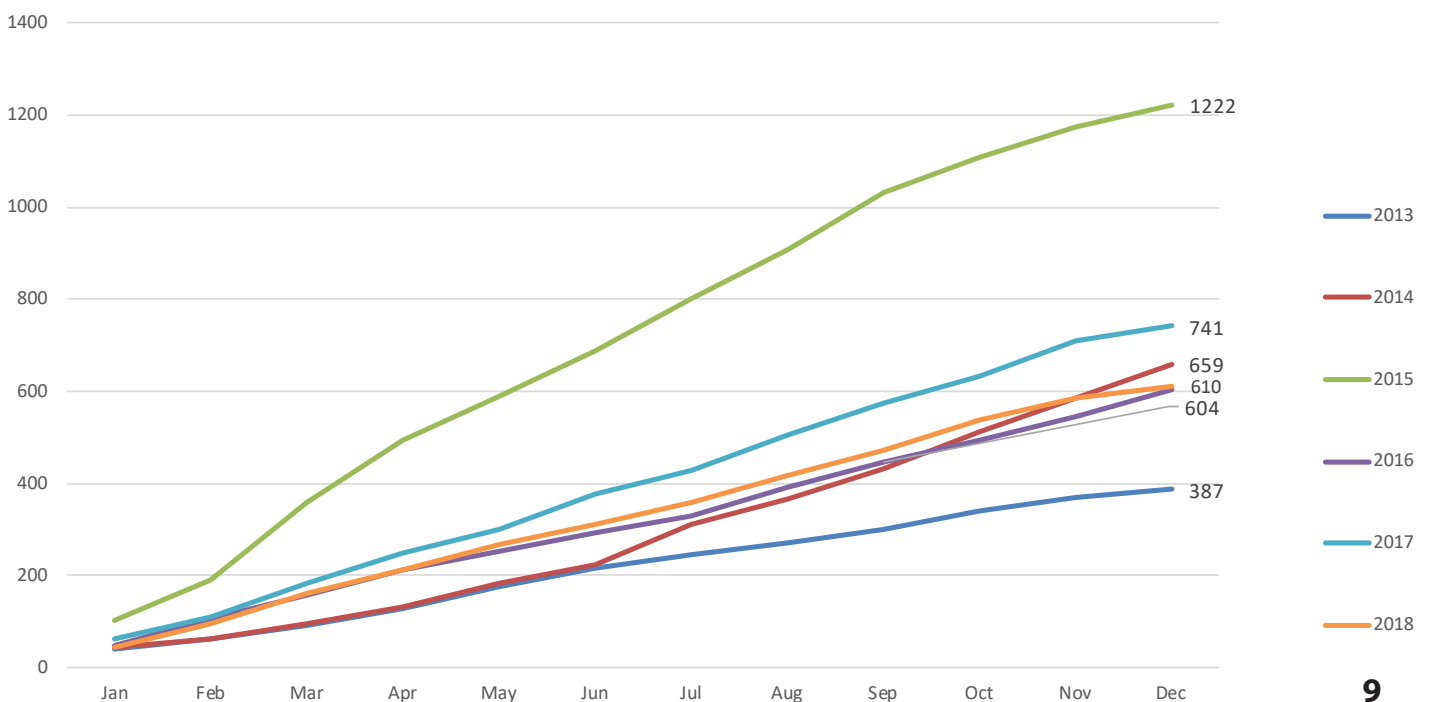
Clinical and Translational Science Unit (CTSU)

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



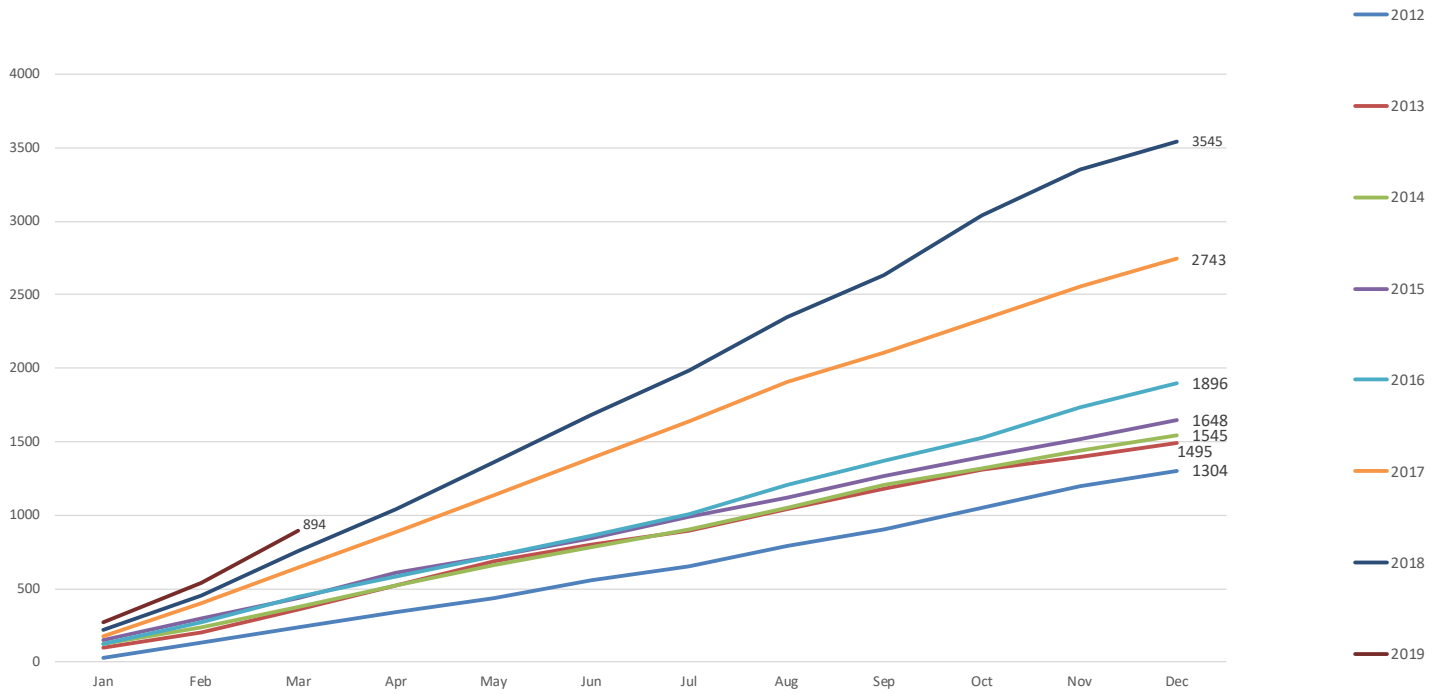
Total CTSU Patient Accrual



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. Two of the three recently added studies are focused on Alzheimer's treatment.

International/Pharmaceutical Trials

Study	Sponsor	Enrollment to Date
A4*	NIH/Eli Lilly	20
AbbVie*	AbbVie	8
ADN13*	NIH/ATRI	14
DAPA*	AstraZeneca LP	1
Generation 1*	Novartis	13
Generation 2*	Novartis	1
Graduate II*	Genetech Inc	0
LEARN*	NIH/Eli Lilly	14
PEGASUS*	Amylyx	1
Trailblazer*	Eli Lilly	2
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
	TOTALS	246

*Currently enrolling studies
NIH=National Institutes of Health

Alzheimer's Disease Center

The KU ADC has supported 36 investigator-initiated studies resulting in 1,995 enrollments to date.

Study	Sponsor	Enrollment to Date
ADC Clinical Cohort*	NIH	402
ADMIT*	NIH	46
APEX*	NIH	117
APP PET-Disclosure*	NIH	315
EXERT*	NIH	8
FRITO*	KU Endowment	61
IGNITE*	NIH	88
LEAP! Rx*	NIH	0
MILK*	KU ADC Pilot	4
NICE*	NIH	20
rrAD*	NIH	103
REACT*	NIH	57
REST*	KU ADC Pilot	3
SEAD2*	KUMC/Ausio	28
STATINS*	NIH	1
TOAD*	Alzheimer's Association	31
TrACR	KU ADC Pilot/AHA	125
ACCEL	KU ADC Pilot	87
ADEPT	NIH	77
Diabetes and EF	KPP	8
EECP	Internal Medicine	7
FamTechCare	NIH	41
INFORM	NIH	52
KDRAFT	CTSA	15
Mediterranean Diet	Frontiers/KU ADC Pilot	26
MPA/ACCEL	KU ADC Pilot	14
PACER	Ziegler Award	3
PACER 2	Foundation for Physical Therapy	24
POX	CTSA	6
Remote Monitoring	CTSA	6
RetinaAD	St. Luke's Hospital Foundation	35
SBIR	NICHD	33
SEAD	KUMC/Ausio	16
SPA	Alzheimer's Drug Discovery Association	20
TEAM	NIH	102
TORTIAS	NIH	14
	TOTAL	1995

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
 NICHD=National Institute of Child and Health Development
 KPP=Kansas Partners in Progress

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

	March 31, 2018	June 30, 2018	June 30, 2017
ASSETS			
Cash and Cash Equivalents (Unencumbered)			
UMB Trustee Accounts (Bond Reserve /P&I)	\$ 1,822,640.35	\$ 1,773,178.80	\$ 1,763,142.56
KUMC JCERT Operations	2,986,428.00	3,351,024.00	4,014,896.00
KUMC JCERT Capital Reserve	965,127.00	950,423.00	809,755.00
KUMC JCERT Operating Reserve	1,350,000.00	1,200,000.00	1,100,000.00
Total Cash and Cash Equivalents (Unencumbered)	7,124,195.35	7,274,625.80	7,687,793.56
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	(6,029,147.44)	(5,368,713.76)	(4,488,135.52)
Total Buildings & Improvements	14,218,624.10	14,879,057.78	15,759,636.02
Furniture & Equipment	1,528,332.85	1,528,332.85	1,528,332.85
Accumulated Depreciation Furniture & Equipment	(1,321,364.01)	(1,191,210.60)	(1,017,672.72)
Total Furniture & Equipment	206,968.84	337,122.25	510,660.13
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	15,847,402.94	16,637,990.03	17,692,106.15
TOTAL ASSETS	\$ 22,971,598.29	\$ 23,912,615.83	\$ 25,379,899.71
LIABILITIES & NET ASSETS			
Liabilities			
Bonds Payable			
KUMC 2010P-1 Bond	\$ -	\$ -	\$ -
KUMC 2010P-2 Build America Bond	10,515,000.00	11,255,000.00	11,980,000.00
Total Bonds Payable	10,515,000.00	11,255,000.00	11,980,000.00
Total Liabilities	10,515,000.00	11,255,000.00	11,980,000.00
Net Assets	12,456,598.29	12,657,615.83	13,399,899.71
TOTAL LIABILITIES & NET ASSETS	\$ 22,971,598.29	\$ 23,912,615.83	\$ 25,379,899.71

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

	Approved FY19 Budget			Actual FY19 as of 03/31/2019		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 6,000,000		\$ 6,000,000	4,567,000		\$ 4,567,000
Clinical Trial Collection		4,500,000	4,500,000		4,744,321	4,744,321
Cancer Research Center Clinical Services		2,500,000	2,500,000		1,291,314	1,291,314
Cancer Center Support Grants for NCI-designated Cancer Centers		263,609	263,609		263,388	263,388
University of Kansas Hospital Community Support					773,876	773,876
KU Cancer Center Support		2,500,000	2,500,000		577,706	577,706
Facility Rent Collection		383,124	383,124		287,343	287,343
Common Area Maintenance Fee	-	336,822	336,822		252,616	252,616
Interest Earnings			-	56,952		56,952
Build America Bond Interest Subsidy	164,000	-	164,000	154,448	-	154,448
Total Revenue	6,164,000	10,483,555	16,647,555	4,778,400	8,190,564	12,968,964
Expenditures						
Payroll						
Director, Phase I Program & startup		277,809	277,809	195,527	-	195,527
Physician Positions	163,079	313,000	476,079	143,331	184,706	328,037
Research Leadership	255,101	118,310	373,411	161,415	540,297	701,712
Business Development	230,393	-	230,393	117,745	21,858	139,603
Research Scientists	130,984	90,317	221,301	95,735	60,361	156,096
Research Laboratory Staff	198,282	341,524	539,806	160,062	226,514	386,576
Research Nursing, Study Coordination & Regulatory Administration	2,105,520	5,594,508	7,700,028	1,627,336	3,346,260	4,973,596
Budget & Finance Support	243,627	330,608	574,235	88,377	335,193	423,570
Total Payroll	3,326,986	7,066,076	10,393,062	2,589,528	4,715,189	7,304,717
Other Operating Expense						
Operating Expenses	145,000	374,000	519,000	74,035	590,085	664,120
Remodeling for Additional Space	-	150,000	150,000			
Telephone & Networking	35,000	-	35,000	26,270	-	26,270
Mass Spec Lease	80,000		80,000	80,000	-	80,000
Clinical Trial Research Initiatives for Comprehensive Status	380,837	234,750	615,587	69,785	224,791	294,576
KUH Clinical Services Settlement Cost - Operations	500,000	2,500,000	3,000,000	-	1,752,797	1,752,797
KUH Clinical Services Settlement Cost - Facility Rent	-	383,124	383,124	-	287,343	287,343
KUH Clinical Services Settlement Cost - Common Area Maintenance		336,822	336,822		252,616	252,616
Total Other Operating Expense	1,140,837	3,978,696	5,119,533	250,090	3,107,632	3,357,722
Facility Expense						
Facility Operations	952,350	-	952,350	686,981	-	686,981
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,465	-	1,222,465	1,087,519	-	1,087,519
Total Facility Expense	2,174,815	-	2,174,815	1,774,500	-	1,774,500
Total Expenditures	\$ 6,642,638	\$ 11,044,772	\$ 17,687,410	\$ 4,614,118	\$ 7,822,821	\$ 12,436,939
Revenue less Expenditures	(478,638)	(561,217)	(1,039,855)	164,282	367,743	532,025
Less Current Amount Set aside for Capital Reserve	400,000	-	400,000	300,000	-	300,000
Less Current Amount Set aside for Operations	200,000	400,000	600,000	150,000	2,700,000	2,850,000
Operating Account - Beginning Balance	2,835,227	3,332,667	6,167,894	3,272,146	6,672,656	9,944,802
Operating Account - Ending Balance	\$ 2,956,589	\$ 3,171,450	\$ 6,128,039	\$ 2,986,428	\$ 4,340,399	\$ 7,326,827