

The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS

CANCER CENTER



October 2018

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 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 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 pioneers 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
- 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

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

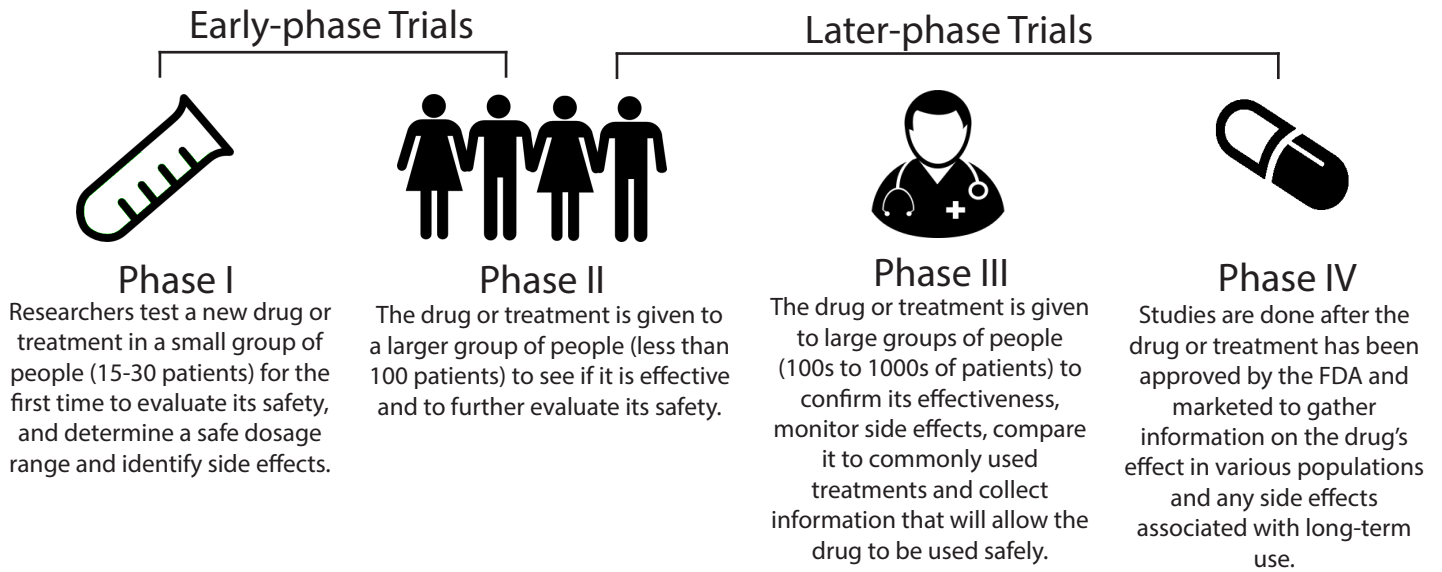
- Develop highly personalized cancer treatments for each unique patient
- Offer state-of-the-art cancer treatments here at home
- Recruit the best physician scientists



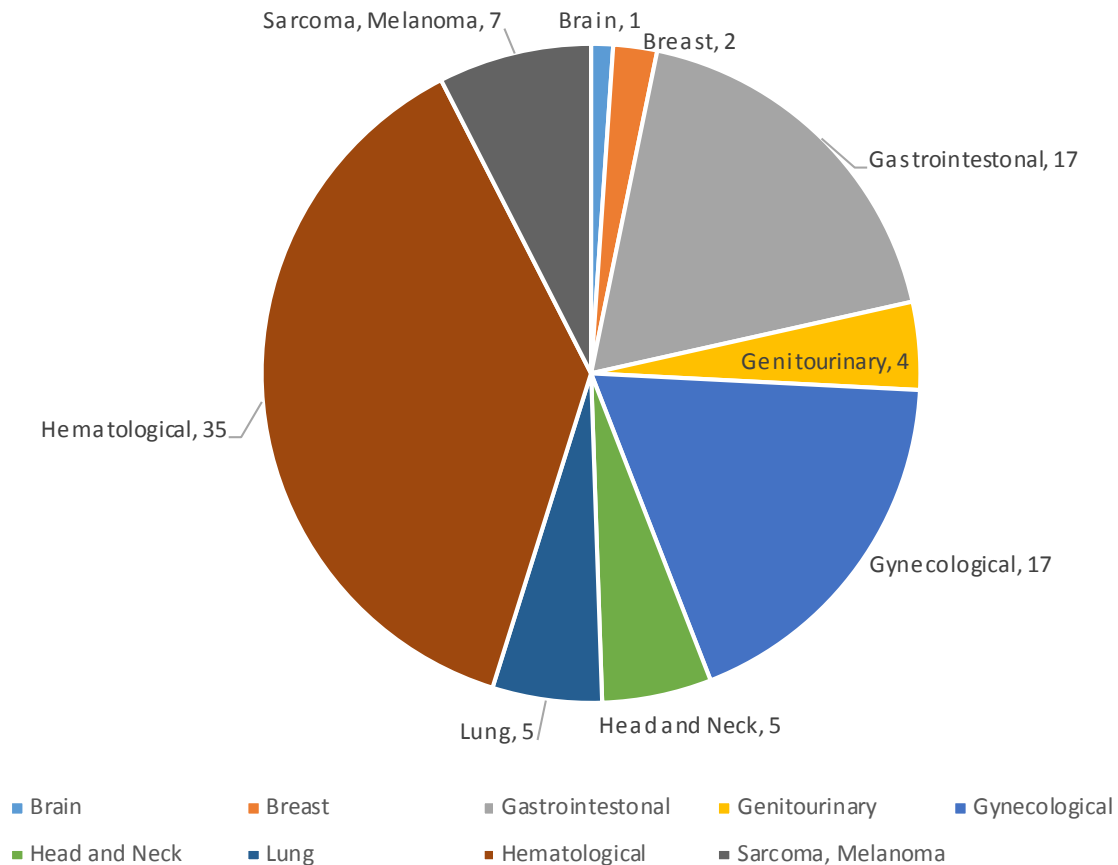
A Cancer Center Designated by the
National Cancer Institute

Types of Clinical Trials

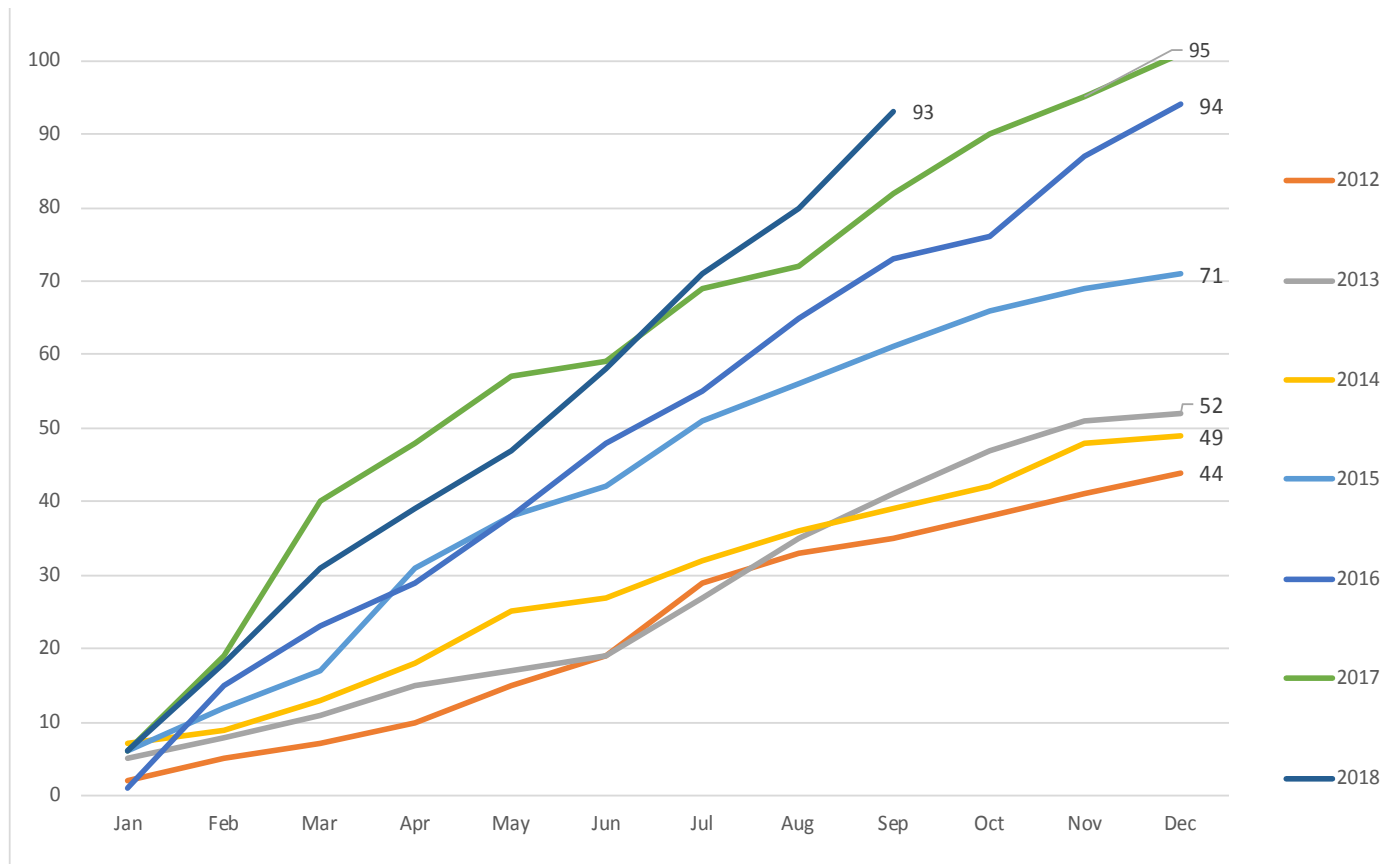
Cancer clinical trials provide access to potential advancement in care and lead to innovations in cancer prevention. Clinical trials are conducted in four phases:



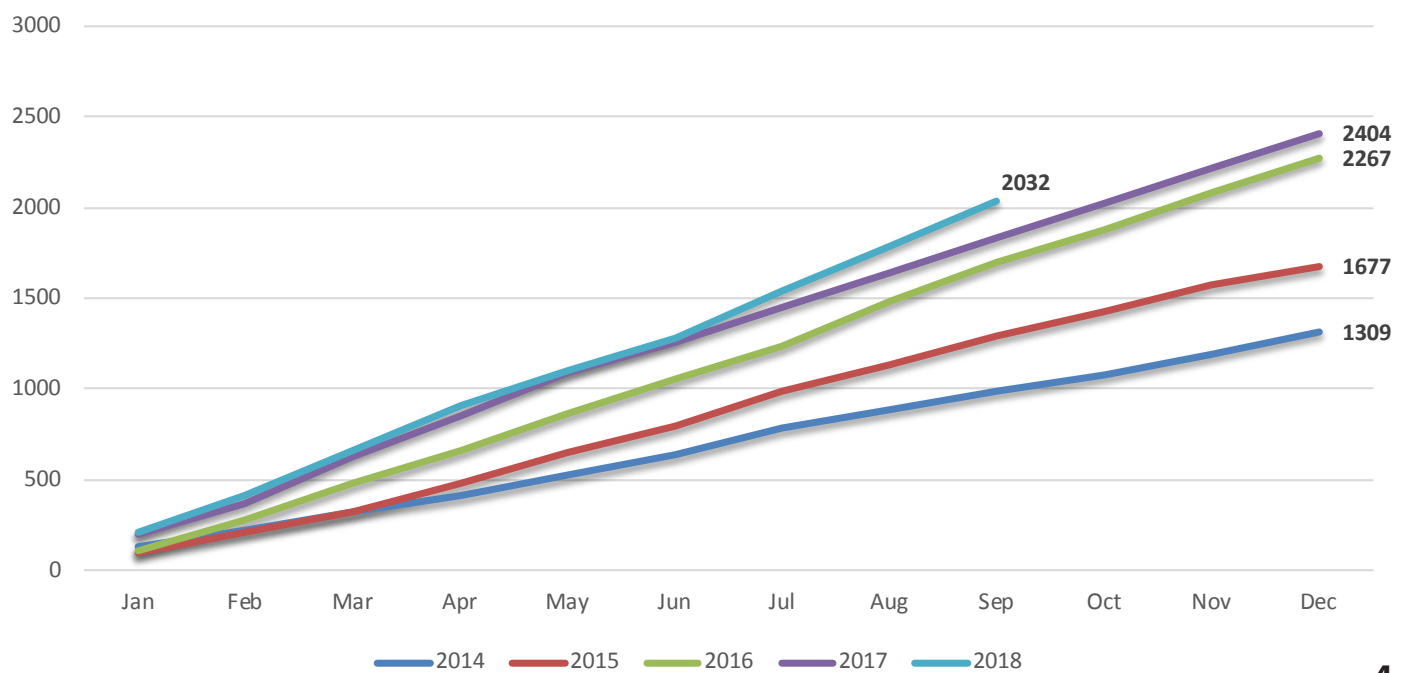
Early-phase Clinical Trials



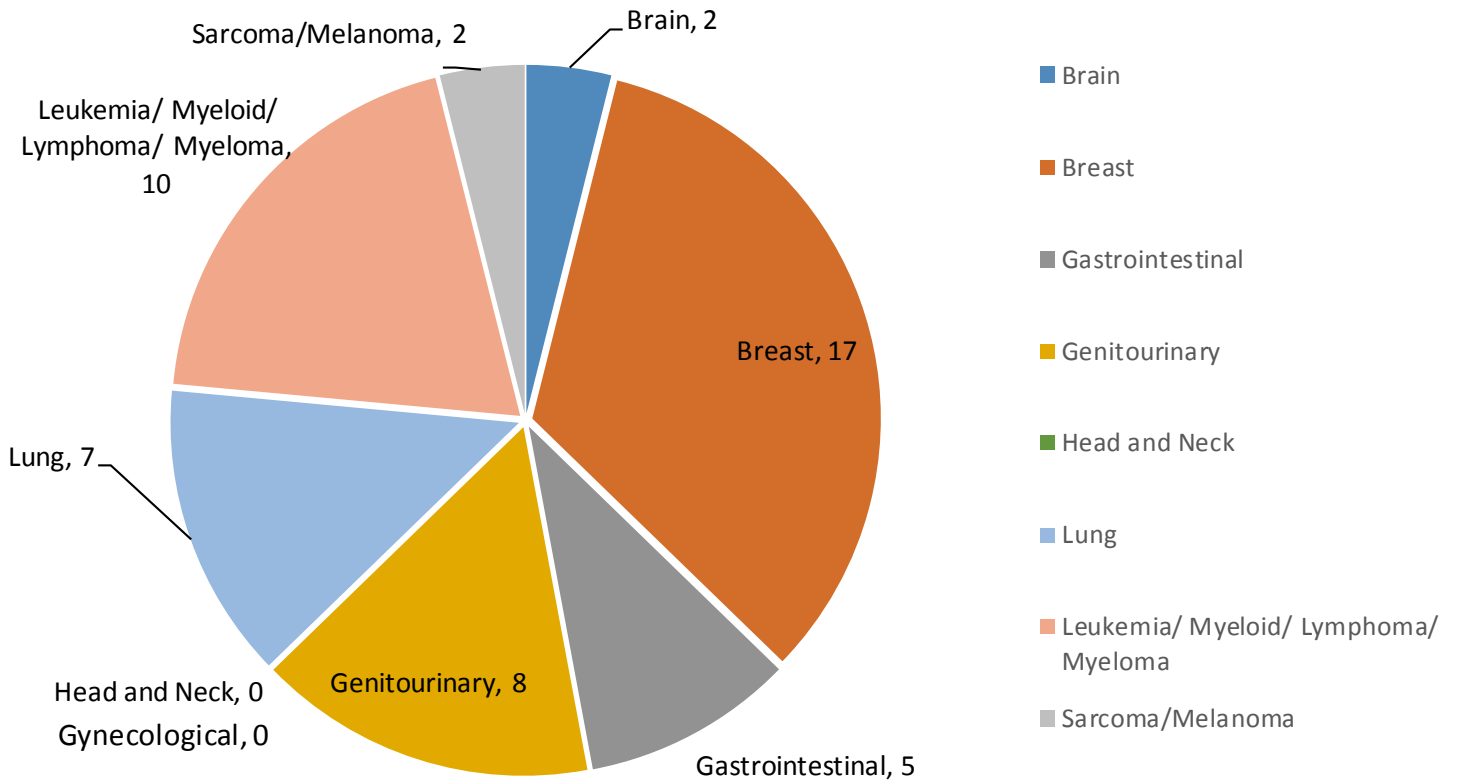
Early-phase Clinical Trial Accrual



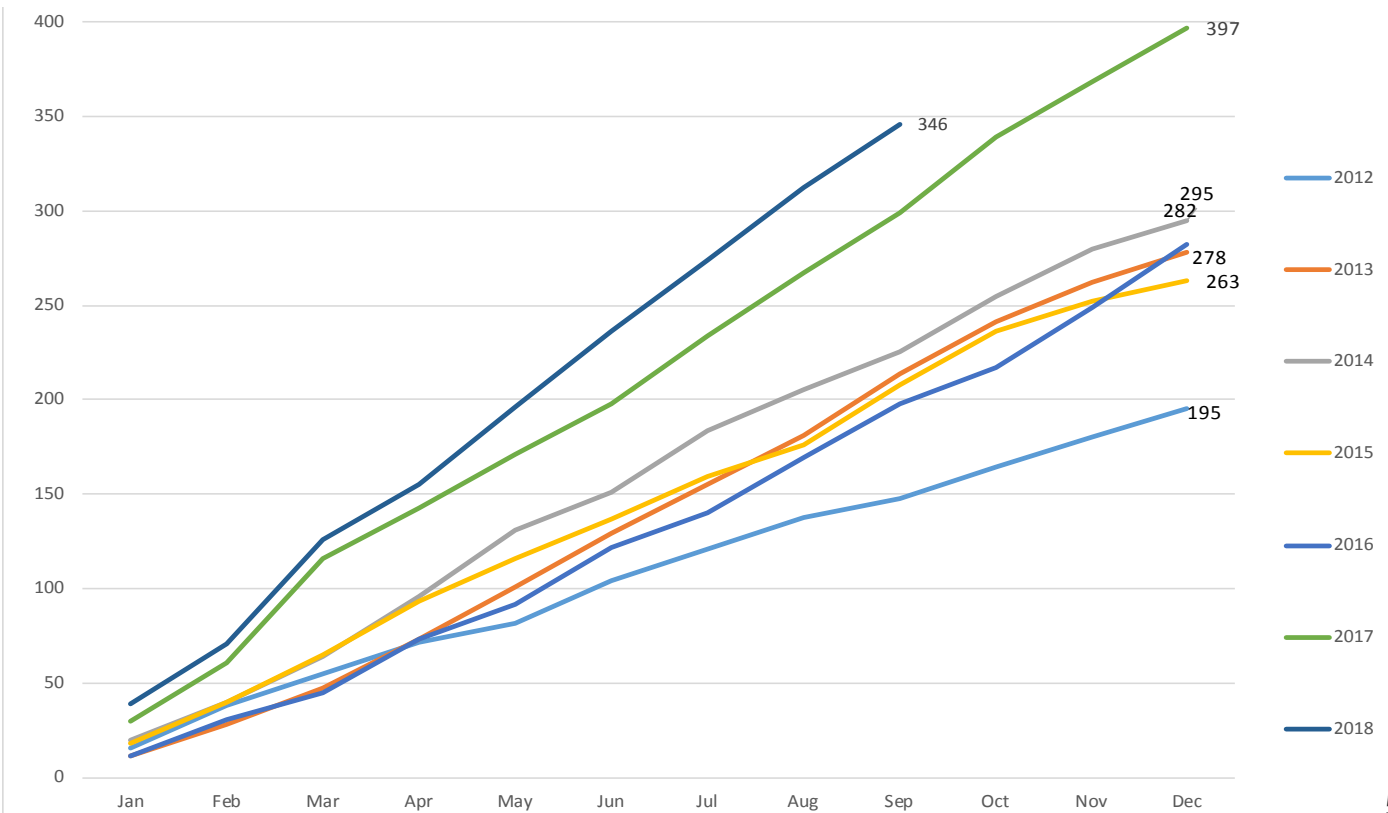
Early-phase KU CRC Patient Visits



Later-phase Clinical Trials



Later-phase Clinical Trial Accrual



Clinical Trials Patient Total By Location

Site Location	Patient Total
KU Clinical Research Center (early phase)	93
KU Cancer Center Main Outpatient site	310
KU Cancer Center Community sites	47
Midwest Cancer Alliance sites	21
Other sites	37

Top Five Counties for KU CRC Patient Visits

	County	Unique Patients
1	Johnson County (KS)	537
2	Jackson County (KS)	356
3	Clay County (MO)	160
4	Leavenworth County (KS)	93
5	Wyandotte, KS	86

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.

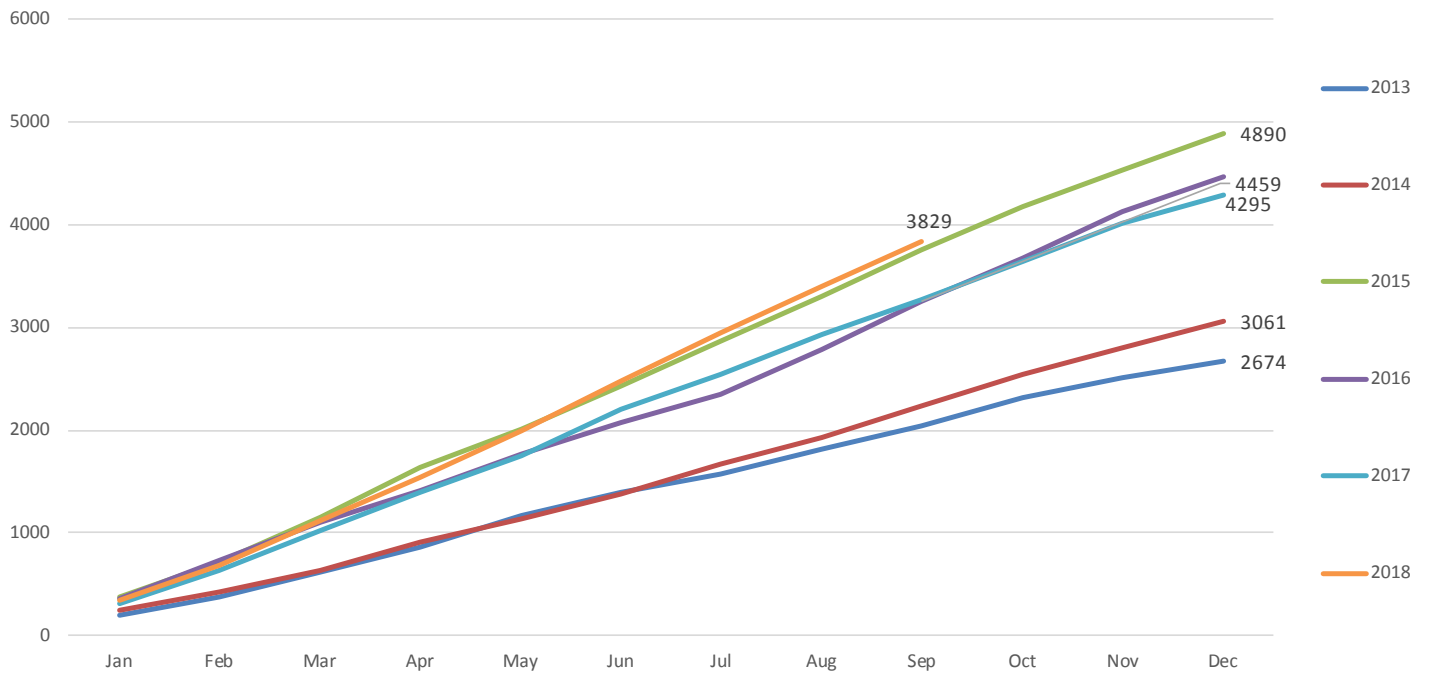


Other Organizations Conducting Research at the KU Clinical Research Center

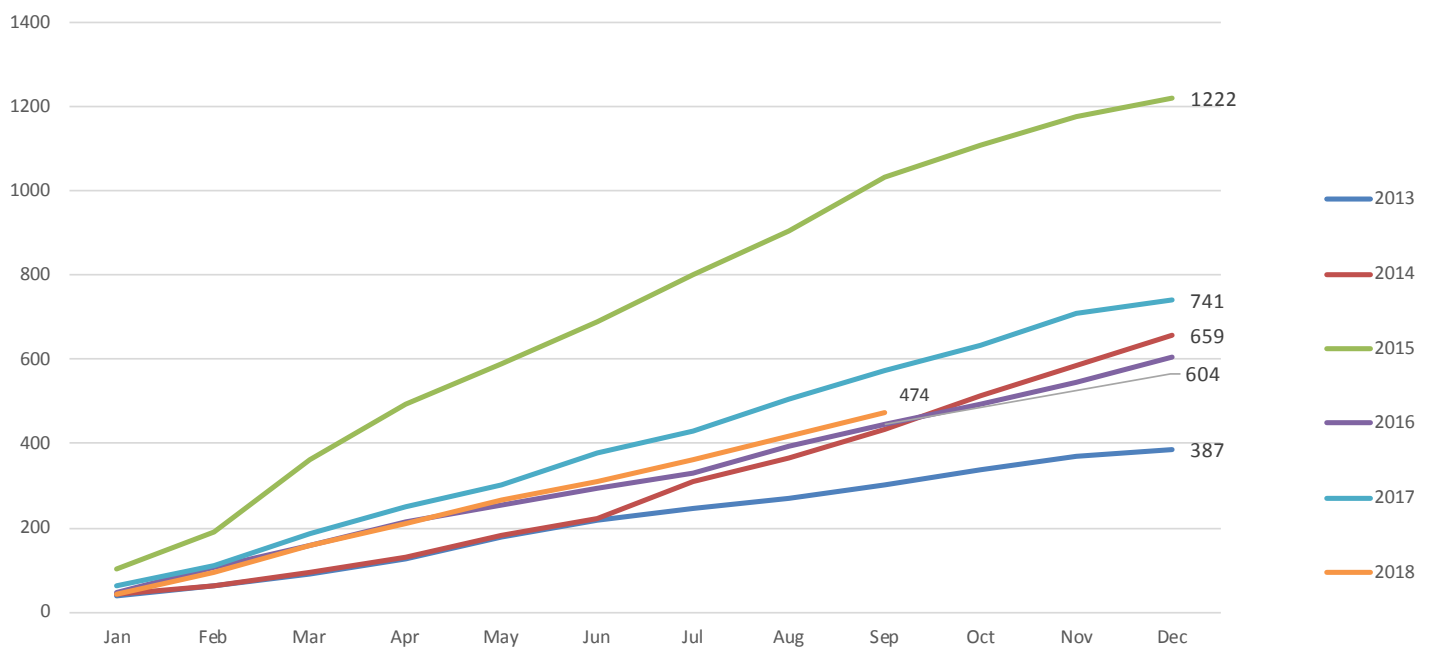
Clinical and Translational Science Unit (CTSU)

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



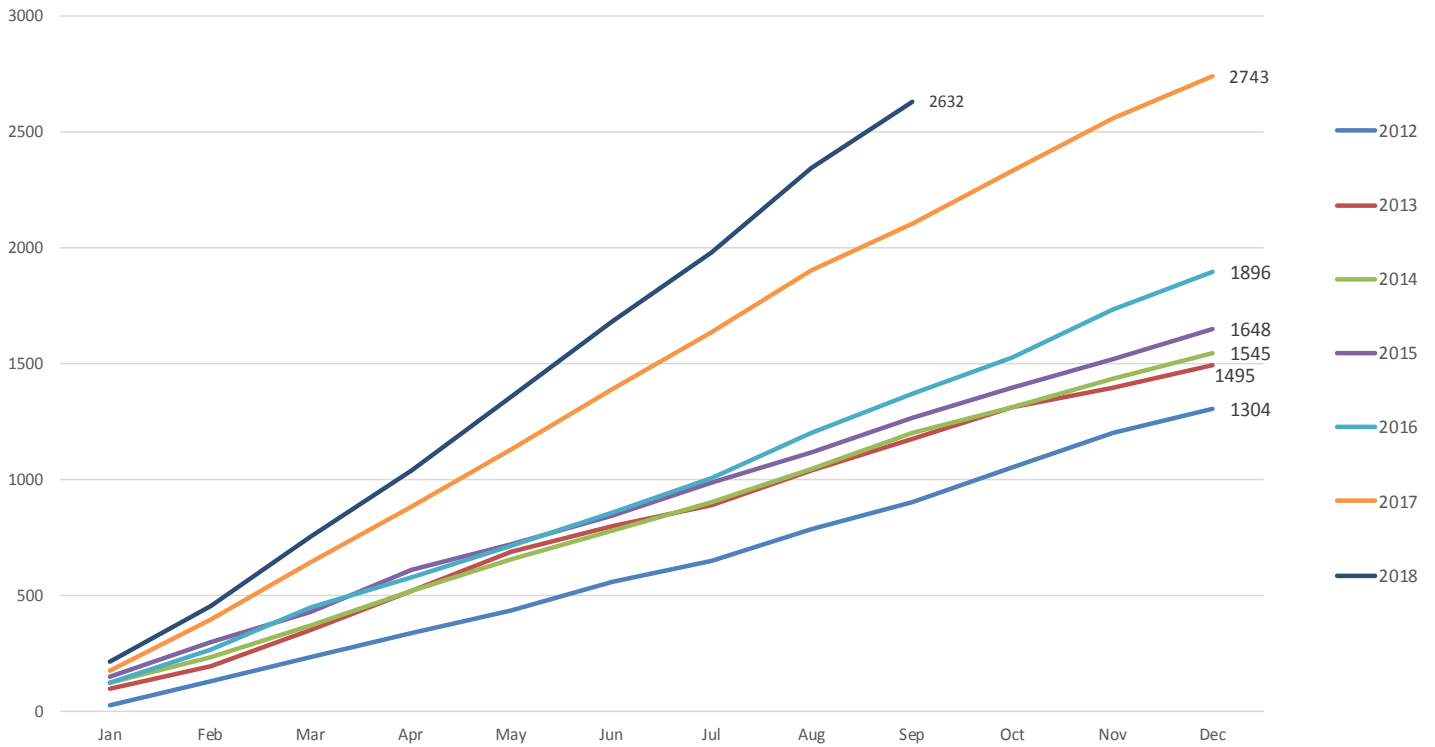
Total CTSU Patient Accrual



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 28 national and international pharmaceutical Trials. Two of the recently added studies are focused on Alzheimer's treatment.

International/Pharmaceutical Trials

Study	Sponsor	Enrollment to Date
A4*	NIH/Eli Lilly	20
AbbVie*	AbbVie	7
ADNI3*	NIH/ATRI	13
Daybreak*	Eli Lilly	3
EARLY*	Janssen	1
ENGAGE*	Biogen	8
Generation 1*	Novartis	9
Generation 2*	Novartis	0
LEARN*	NIH/Eli Lilly	14
PEGASUS*	Amylyx	0
Trailblazer*	Eli Lilly	0
ASPREE	NIH/Berman Center	41
TTP Open-label	vTv Therapeutics	4
TTP	vTv Therapeutics	14
LZAX	Eli Lilly	8
NEUROTROPE	Neurotrope	4
TCAD	National Institutes of Health/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
SMIFF	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		216

*Currently enrolling studies

NIH=National Institutes of Health

Alzheimer's Disease Center

The KU ADC has supported 33 investigator-initiated studies resulting in 1,876 enrollments to date.

Study	Sponsor	Enrollment to Date
ADC Clinical Cohort*	NIH	402
ADMIT*	NIH	37
APEX*	NIH	105
APP PET-Disclosure*	NIH	315
EXERT*	NIH	5
FamTechCare*	NIH	41
FRITO*	KU Endowment	61
IGNITE*	NIH	56
Mediterranean Diet*	Frontiers/KU ADC Pilot	26
MILK*	KU ADC Pilot	4
rrAD*	NIH	74
REACT*	NIH	52
REST*	KU ADC Pilot	3
SEAD2*	KUMC/Ausio	19
TOAD*	Alzheimer's Association	32
TrACR	KU ADC Pilot/AHA	125
ACCEL	KU ADC Pilot	87
ADEPT	NIH	77
Diabetes and EF	KPP	8
EECP	Internal Medicine	7
INFORM	NIH	52
KDRAFT	CTSA	15
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	NICHHD	33
SEAD	KUMC/Ausio	16
SPA	Alzheimer's Drug Discovery Association	20
TEAM	NIH	102
TORTIAS	NIH	14
	TOTAL	1876

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 FY18 Budget			Actual FY18 as of 06/30/2018		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 5,900,000		\$ 5,900,000	6,010,400		\$ 6,010,400
Clinical Trial Collection		3,300,000	3,300,000		5,748,131	5,748,131
Cancer Research Center Clinical Services		1,560,000	1,560,000		2,378,235	2,378,235
Cancer Center Support Grants for NCI-designated Cancer Centers		208,364	208,364		1,415,345	1,415,345
KU Cancer Center Support		2,440,436	2,440,436		562,158	562,158
Facility Rent Collection		402,617	402,617		383,124	383,124
Common Area Maintenance Fee	-	317,328	317,328		336,822	336,822
Interest Earnings			-	48,781		48,781
Build America Bond Interest Subsidy	162,600	-	162,600	160,572	-	160,572
Total Revenue	6,062,600	8,228,745	14,291,345	6,219,753	10,823,815	17,043,568
Expenditures						
Payroll						
Director, Phase I Program & startup	322,617	68,669	391,286	70,394	217,940	288,334
2 Physician Positions	678,939	64,236	743,175	371,784	75,667	447,451
Research Leadership	216,549	201,414	417,963	332,670	215,737	548,407
Business Development	159,788		159,788	160,237	-	160,237
Research Scientists	328,713	71,528	400,241	161,965	60,145	222,110
Research Laboratory Staff	65,796	266,584	332,380	11,668	311,980	323,648
Research Nursing, Study Coordination & Regulatory	1,325,016	5,313,424	6,638,440	2,822,142	3,679,842	6,501,984
Budget & Finance Support	332,307	125,037	457,344	112,654	409,314	521,968
Total Payroll	3,429,725	6,110,892	9,540,617	4,043,514	4,970,625	9,014,139
Other Operating Expense						
Operating Expenses	200,000	250,000	450,000	160,284	752,081	912,365
Telephone & Networking	45,000		45,000	35,848	-	35,848
Mass Spec Lease	160,963		160,963	-	-	-
Clinical Trial Research Initiatives for Comprehensive Status	300,000	500,000	800,000	155,247	224,400	379,647
KUH Clinical Services Settlement Cost - Operations	800,000	1,760,000	2,560,000	-	2,258,996	2,258,996
KUH Clinical Services Settlement Cost - Facility Rent	-	219,862	219,862	-	383,124	383,124
KUH Clinical Services Settlement Cost - Common Area Maintenance		500,083	500,083	-	336,822	336,822
Total Other Operating Expense	1,505,963	3,229,945	4,735,908	351,379	3,955,423	4,306,802
Facility Expense						
Facility Operations	890,413		890,413	846,477	-	846,477
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,464	-	1,222,464	1,221,132	-	1,221,132
Total Facility Expense	2,112,877	-	2,112,877	2,067,609	-	2,067,609
Total Expenditures	\$ 7,048,565	\$ 9,340,837	\$ 16,389,402	\$ 6,462,502	\$ 8,926,048	\$ 15,388,550
Revenue less Expenditures	(985,965)	(1,112,092)	(2,098,057)	(242,749)	1,897,767	1,655,018
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	3,349,356	3,440,291	6,789,647	4,014,896	4,774,889	8,789,785
Operating Account - Ending Balance	\$ 1,863,391	\$ 2,328,199	\$ 4,191,590	\$ 3,272,147	\$ 6,672,656	\$ 9,944,803