

# The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS  

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CANCER CENTER



March 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.

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

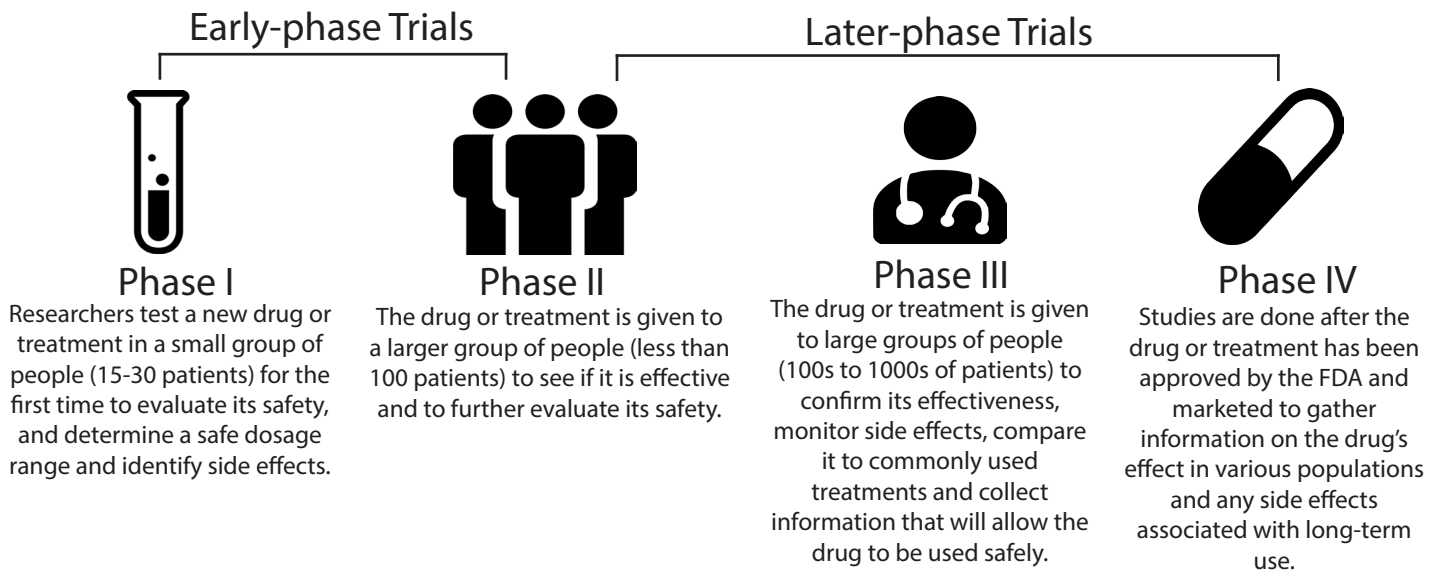
KU Cancer Center aims to do nothing less than fundamentally transform the cancer experience – to give all people in our region greater access to breakthrough ideas and novel treatments.



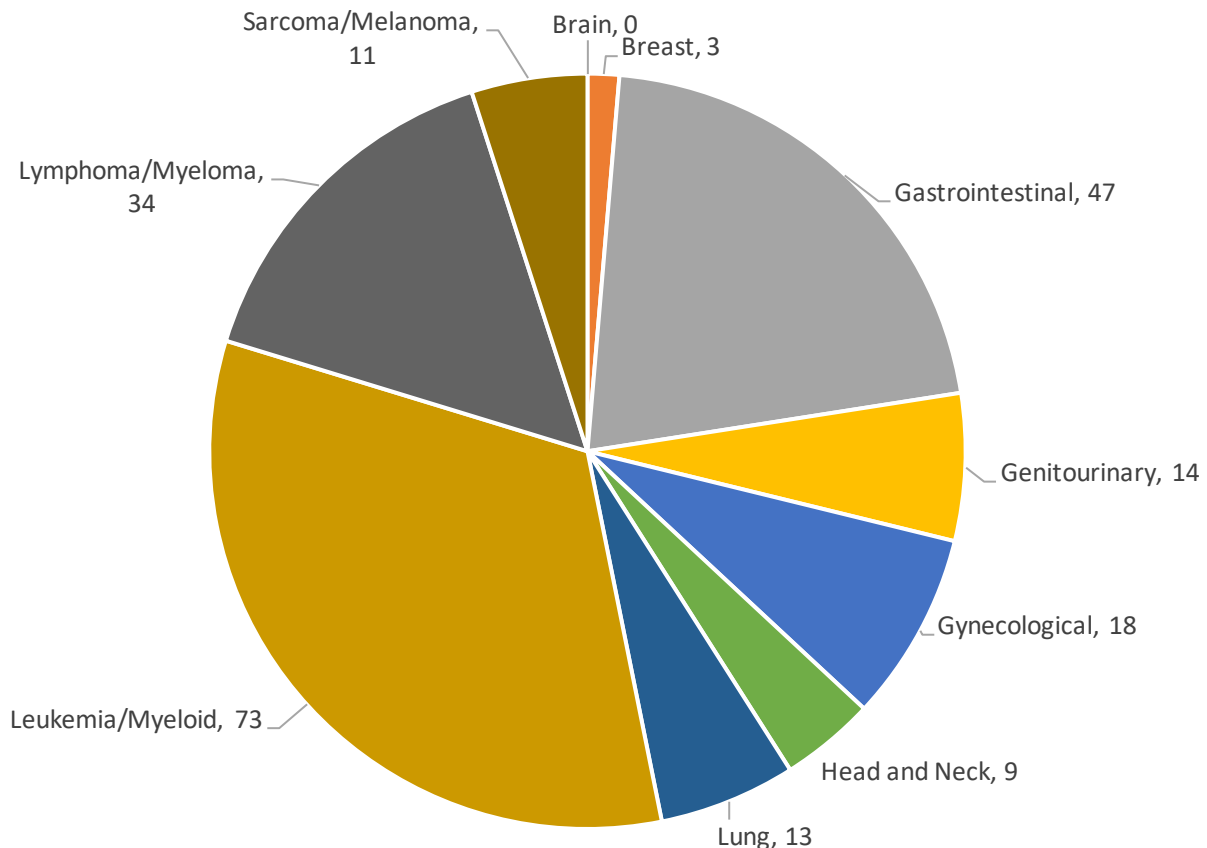
A Cancer Center Designated by the  
National Cancer Institute

# Types of Clinical Trials

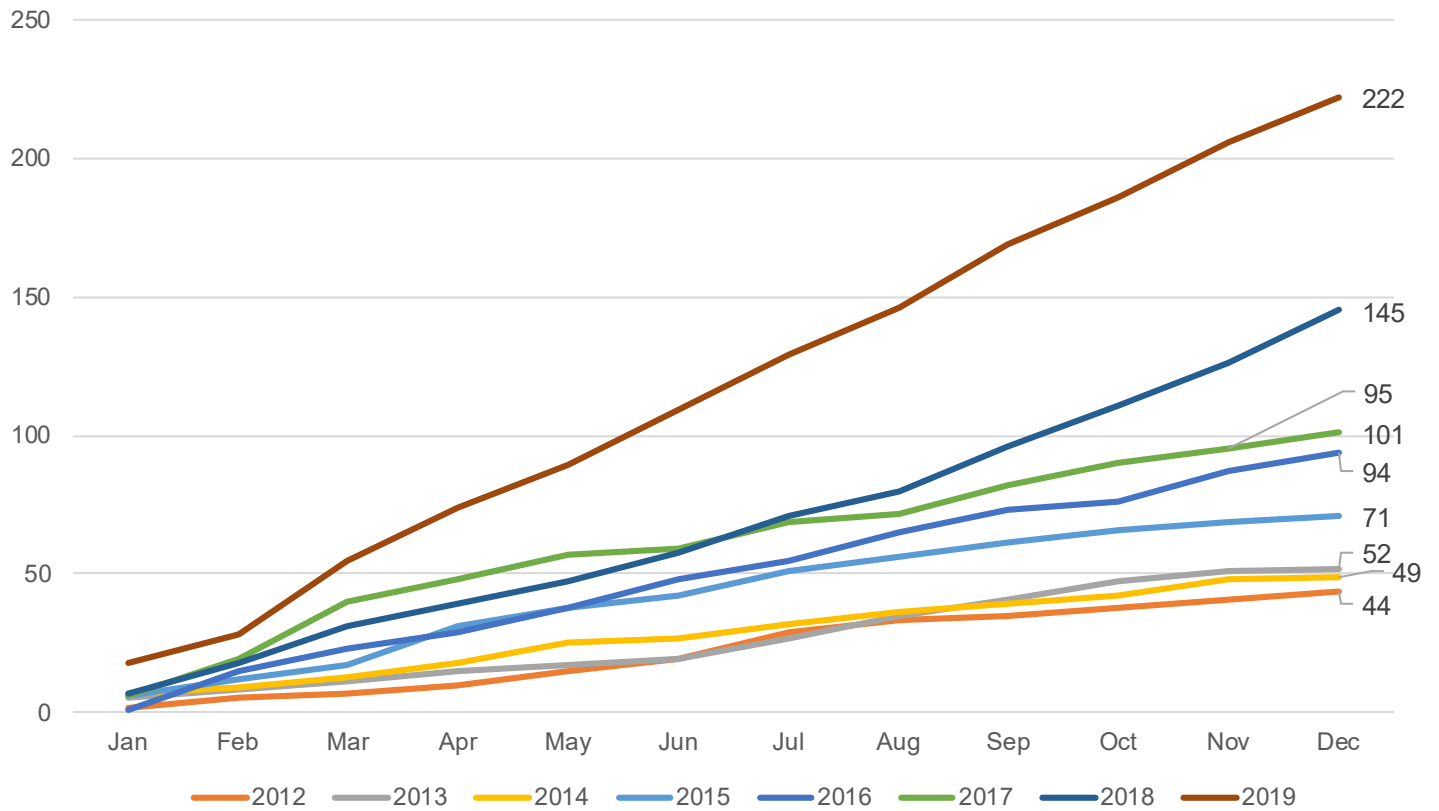
Cancer clinical trials provide access to potential advancement in care and lead to innovations in cancer prevention. Clinical trials are conducted in four phases:



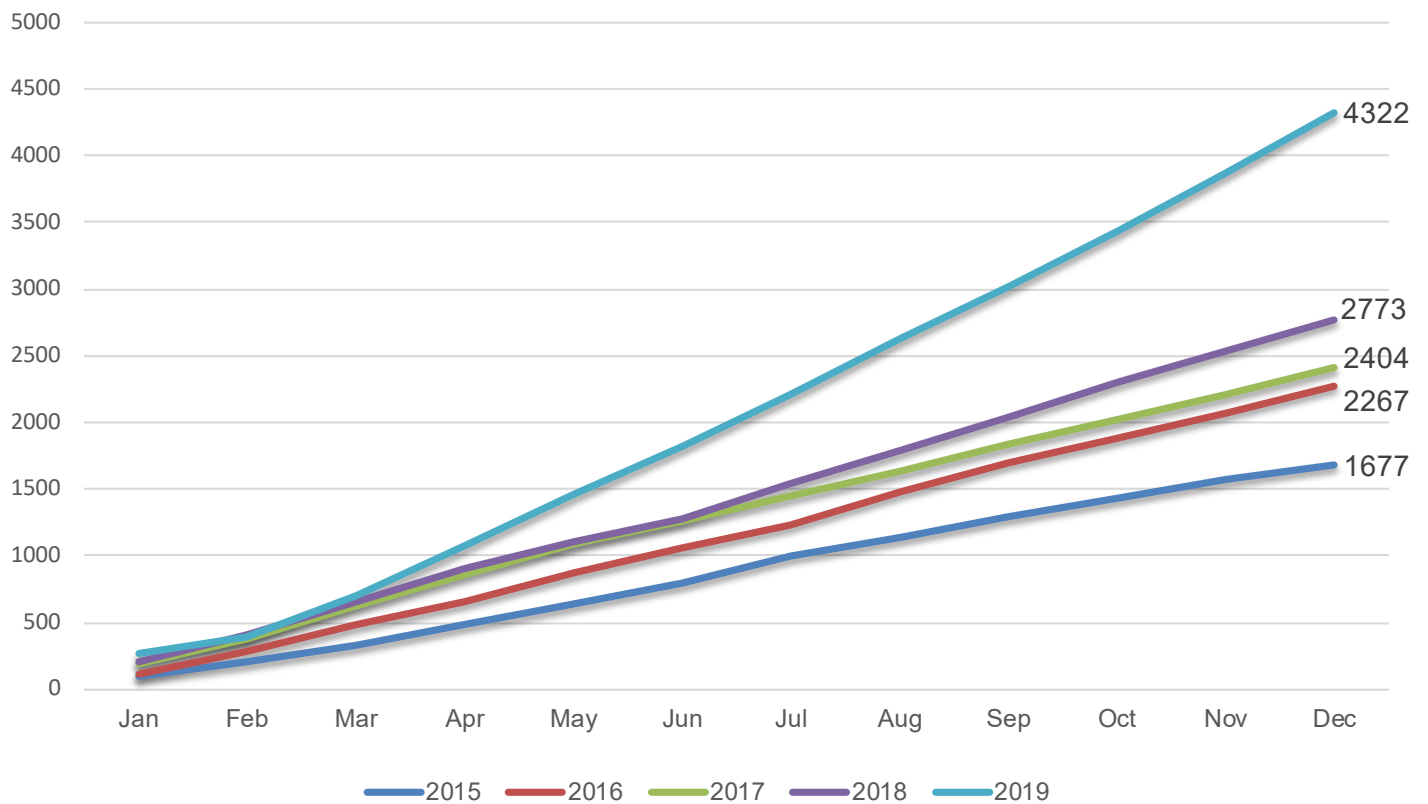
## Early-phase Clinical Trial Accrual by Disease Group



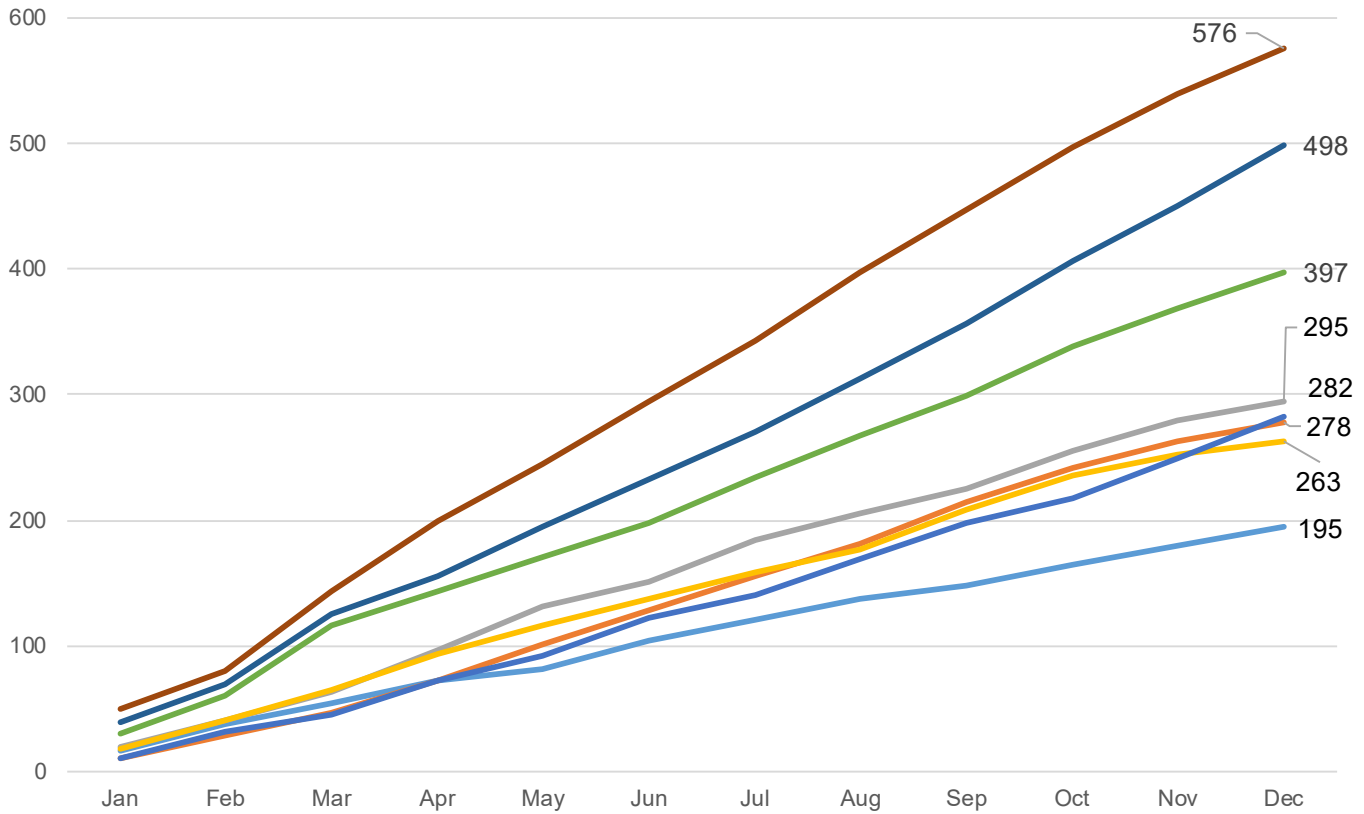
# Early-phase Clinical Trial Accrual



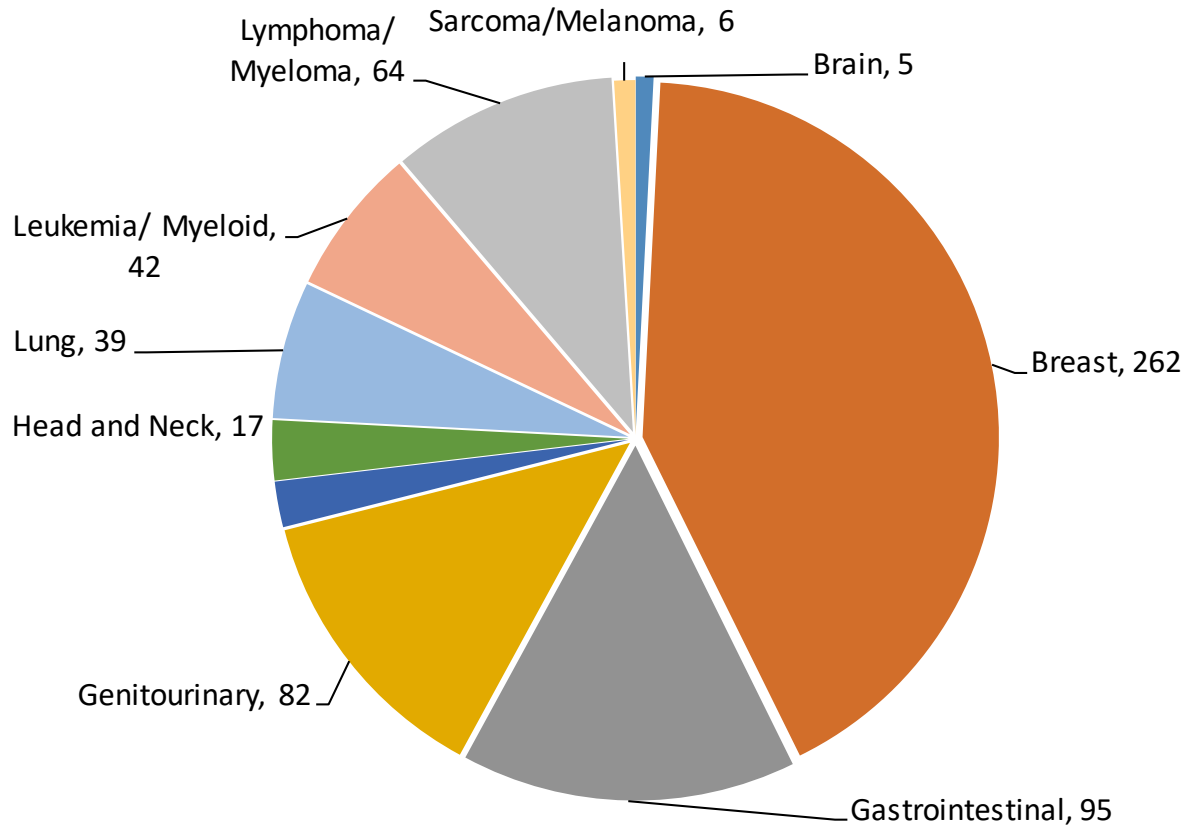
# Early-phase KU CRC Patient Visits



# Later-phase Clinical Trials



# Later-phase Clinical Trial Accrual by Disease Group



## Clinical Trials Patient Total By Location

Site Location	Patient Total
KU Clinical Research Center (early phase)	222
KU Cancer Center Main Outpatient sites	1204
KU Cancer Center Community sites	140
Masonic Cancer Alliance sites	70
Children's Mercy	101
Other sites	73

## Top Five Counties for KU CRC Patient Visits

	County	Unique Patients
1	Johnson County (KS)	1065
2	Jackson County (MO)	808
3	Wyandotte County (KS)	330
4	Clay County (MO)	301
5	Platte County (MO)	147

# 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.



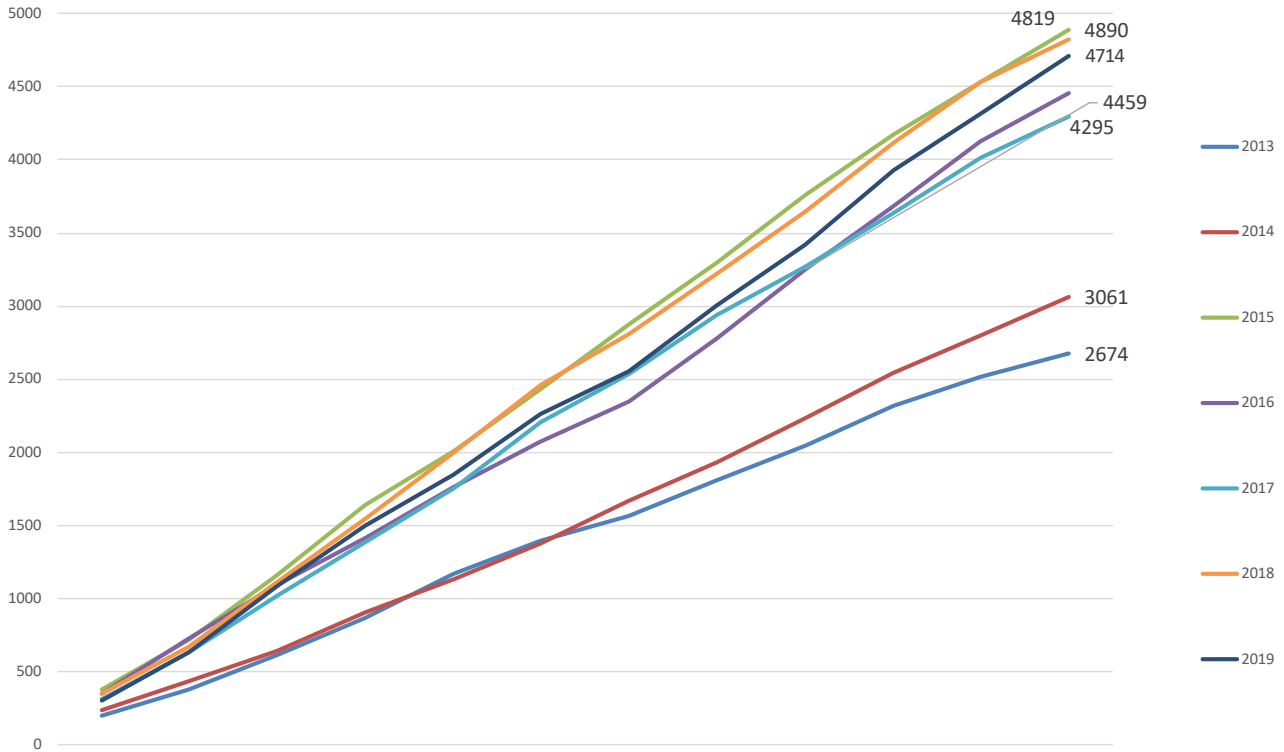


# Other Organizations Conducting Research at the KU Clinical Research Center

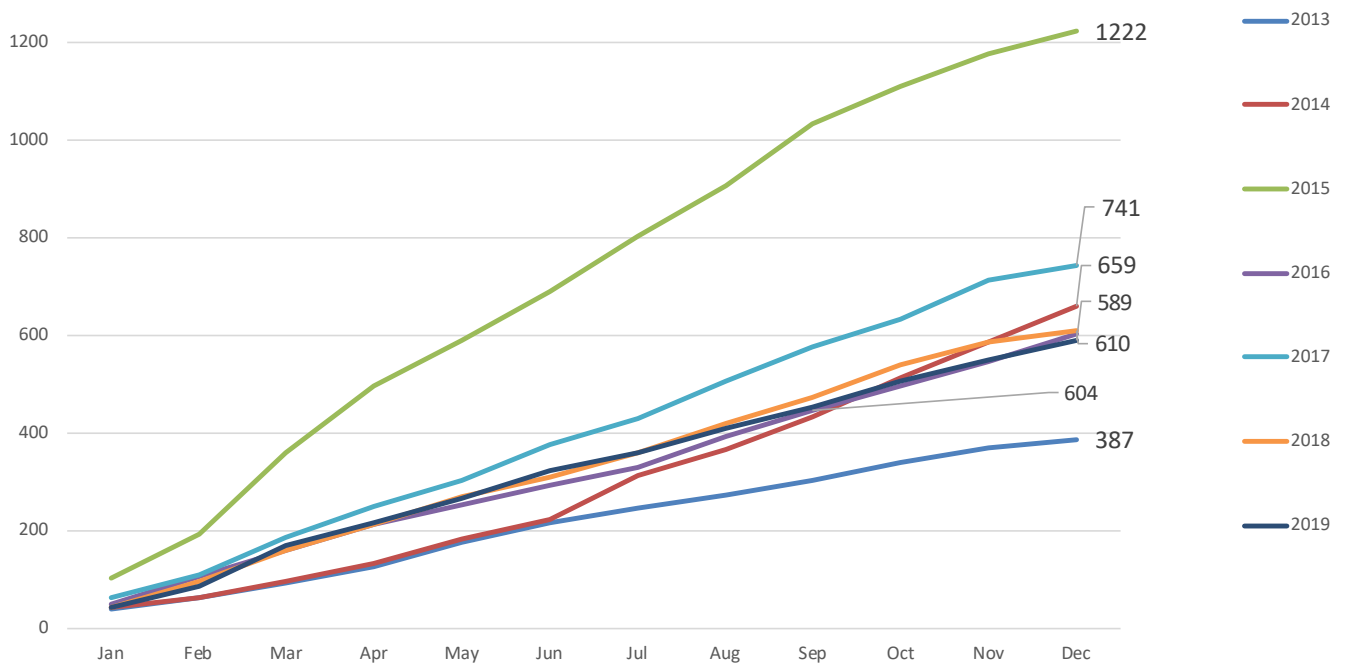
# Clinical and Translational Science Unit (CTSU)

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



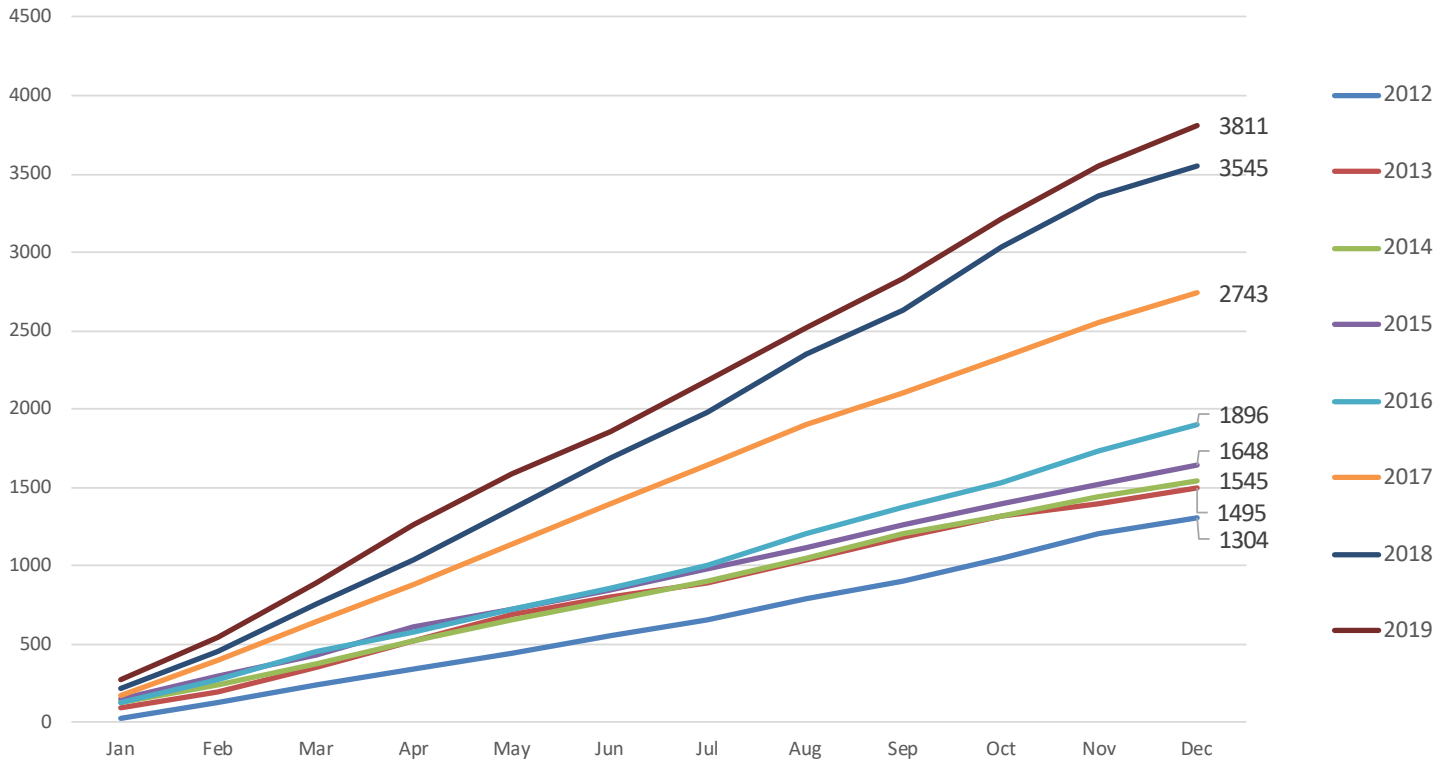
## Total CTSU Patient Accrual



# 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	13
LEARN*	NIH/Eli Lilly	14
PEGASUS*	Amylyx	8
Generation 1	Novartis	13
Generation 2	Novartis	3
Graduate II	Genetech Inc	0
AbbVie	AbbVie	9
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>TOTAL</b>	<b>273</b>

\*Currently enrolling studies

NIH=National Institutes of Health

# Alzheimer's Disease Center

The KU ADC has supported 45 investigator-initiated studies resulting in 2,463 enrollments to date.

## Investigator-Initiated Trials

Study	Sponsor	Enrollment to date
ADC Clinical Cohort*	NIH	427
ADMIT*	NIH	53
AMIE*	KU Endowment	2
AROMA*	NIH	43
BB8-AD*	NIH	13
C-NAP*	NIH	25
DYNAMIC*	NIH	8
EXERT*	NIH	10
GEM*	NIH	21
IGNITE*	NIH	172
LEAP! Rx*	NIH	60
MOVER*	KU Endowment	76
NICE*	NIH	57
rrAD*	NIH	126
REACT*	NIH	65
SEAD2*	KUMC/Ausio	32
SIESTA*	NIH	14
STATINS*	NIH	14
TDAD*	NIH	1
TOAD*	Alzheimer's Association	32
ACCEL	KU ADC Pilot	87
ADEPT	NIH	77
APEX	NIH	118
APP PET-Disclosure	NIH	315

Study	Sponsor	Enrollment to date
Diabetes and EF	KPP	8
EACP	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	FPTR	24
POX	CTSA	6
Remote Monitoring	CTSA	6
REST	KU ADC Pilot	3
RetinaAD	St. Luke's Hospital Foundation	36
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
	<b>TOTAL</b>	<b>2,463</b>

\*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

FPTR=Foundation for Physical Therapy Research

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

	Approved FY20 Budget			Actual FY20 as of 03/31/2020		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
<b>Revenue</b>						
JCERT Sales Tax	\$ 6,200,000		\$ 6,200,000	4,285,475		\$ 4,285,475
Clinical Trial Collection		6,000,000	6,000,000		5,449,321	5,449,321
Cancer Research Center Clinical Services		2,500,000	2,500,000		2,197,228	2,197,228
Cancer Center Support Grants for NCI-designated Cancer Centers		400,000	400,000		434,285	434,285
University of Kansas Hospital Community Support		1,182,100	1,182,100		725,890	725,890
KU Cancer Center Support		1,000,000	1,000,000		207,819	207,819
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			-	54,988		54,988
Build America Bond Interest Subsidy	164,000	-	164,000	147,188	-	147,188
<b>Total Revenue</b>	<b>6,364,000</b>	<b>11,802,046</b>	<b>18,166,046</b>	<b>4,487,651</b>	<b>9,554,502</b>	<b>14,042,153</b>
<b>Expenditures</b>						
<b>Payroll</b>						
Director, Phase I Program & startup	71,901	206,288	278,189	52,233	143,662	195,895
Physician Positions	129,263	57,738	187,001	108,983	44,228	153,211
Research Leadership	109,150	203,590	312,740	117,824	345,126	462,950
Business Development	-	237,319	237,319	-	120,915	120,915
Research Scientists	135,333	85,277	220,610	127,446	34,754	162,200
Research Laboratory Staff	182,301	355,352	537,653	278,263	216,005	494,268
Research Nursing, Study Coordination & Regulatory	2,897,515	6,104,350	9,001,865	1,820,197	4,051,299	5,871,496
Administration	-	780,166	780,166	-	520,274	520,274
Budget & Finance Support	182,406	516,098	698,504	133,582	332,826	466,408
<b>Total Payroll</b>	<b>3,707,869</b>	<b>8,546,178</b>	<b>12,254,047</b>	<b>2,638,528</b>	<b>5,809,089</b>	<b>8,447,617</b>
<b>Other Operating Expense</b>						
Operating Expenses	300,000	500,000	800,000	78,115	879,751	957,866
Remodeling for Additional Space	-	200,000	200,000			
Telephone & Networking	34,000	-	34,000	24,138	-	24,138
Mass Spec Lease	81,048		81,048	-	-	-
Clinical Trial Research Initiatives for Comprehensive Status	440,151	155,760	595,911	211,938	397,537	609,475
KUH Clinical Services Settlement Cost - Operations	-	2,500,000	2,500,000	-	2,141,360	2,141,360
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
<b>Total Other Operating Expense</b>	<b>855,199</b>	<b>4,075,706</b>	<b>4,930,905</b>	<b>314,191</b>	<b>3,958,607</b>	<b>4,272,798</b>
<b>Facility Expense</b>						
Facility Operations	962,270	-	962,270	577,117	-	577,117
Withheld by Trustee for Debt Service & Trustee Expenses	1,222,465	-	1,222,465	1,005,483	-	1,005,483
<b>Total Facility Expense</b>	<b>2,184,735</b>	<b>-</b>	<b>2,184,735</b>	<b>1,582,600</b>	<b>-</b>	<b>1,582,600</b>
<b>Total Expenditures</b>	<b>\$ 6,747,803</b>	<b>\$ 12,621,884</b>	<b>\$ 19,369,687</b>	<b>\$ 4,535,319</b>	<b>\$ 9,767,696</b>	<b>\$ 14,303,015</b>
<b>Revenue less Expenditures</b>	<b>(383,803)</b>	<b>(819,838)</b>	<b>(1,203,641)</b>	<b>(47,668)</b>	<b>(213,194)</b>	<b>(260,862)</b>
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	2,600,000	2,750,000
Operating Account - Beginning Balance	3,142,143	4,733,106	7,875,249	2,939,631	3,916,678	6,856,309
<b>Operating Account - Ending Balance</b>	<b>\$ 2,158,340</b>	<b>\$ 3,513,268</b>	<b>\$ 5,671,608</b>	<b>\$ 2,441,964</b>	<b>\$ 1,103,484</b>	<b>\$ 3,545,447</b>