

The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS

CANCER CENTER



March 2021

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 and obesity rates and increase HPV vaccinations
- Extend the highest level of 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 close to home
- Recruit and retain the best physician scientists
- Leverage partnerships for further innovation in drug discovery and development

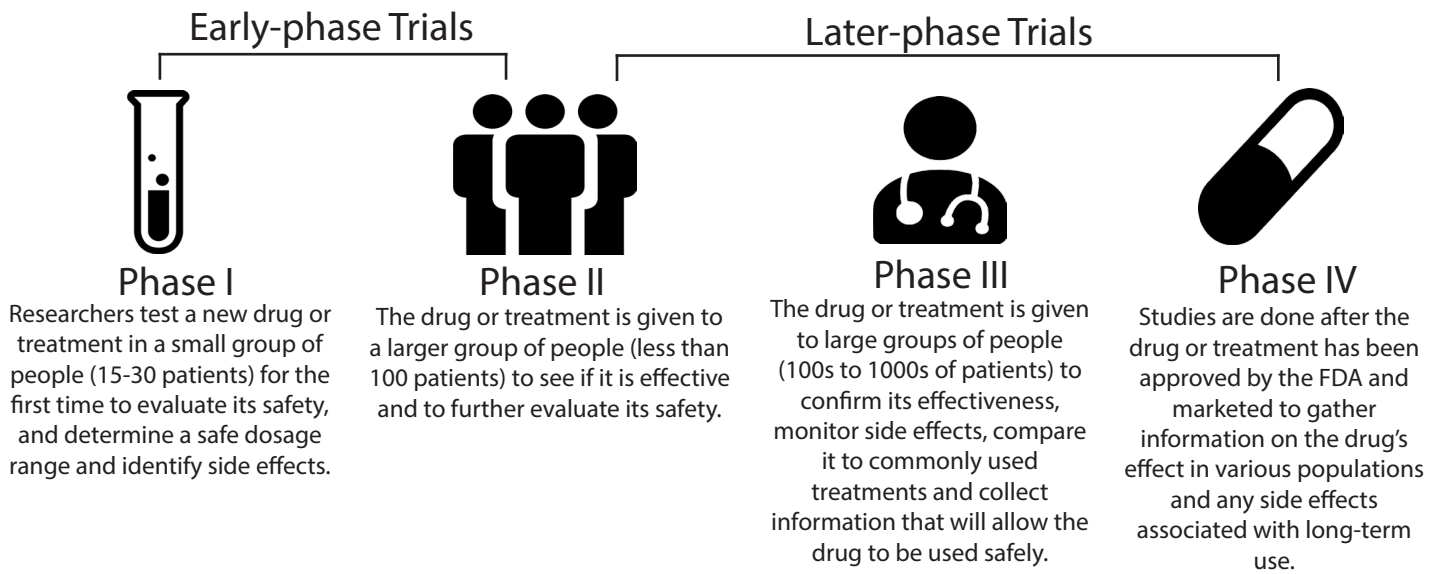
KU Cancer Center aims to do nothing less than fundamentally transform the cancer experience – to give all people in our region greater access to breakthrough ideas and novel treatments.



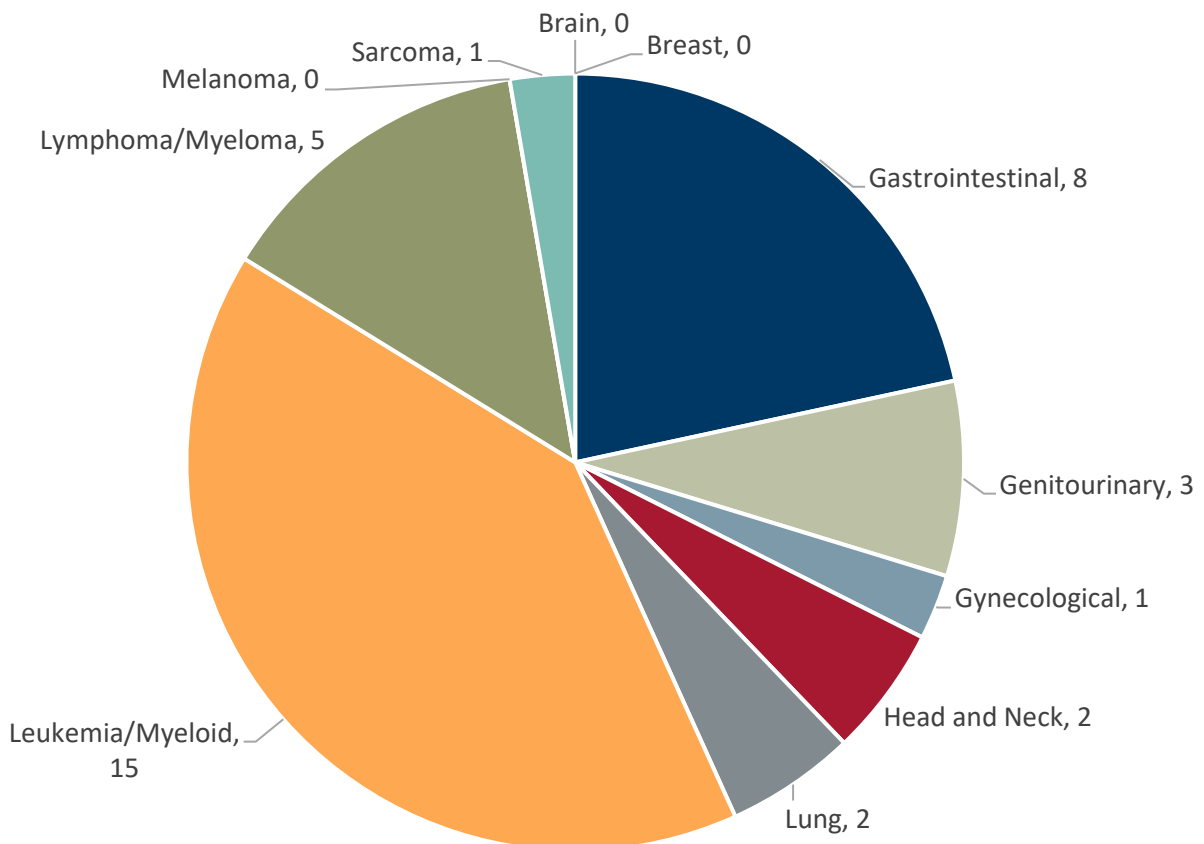
A Cancer Center Designated by the
National Cancer Institute

Types of Clinical Trials

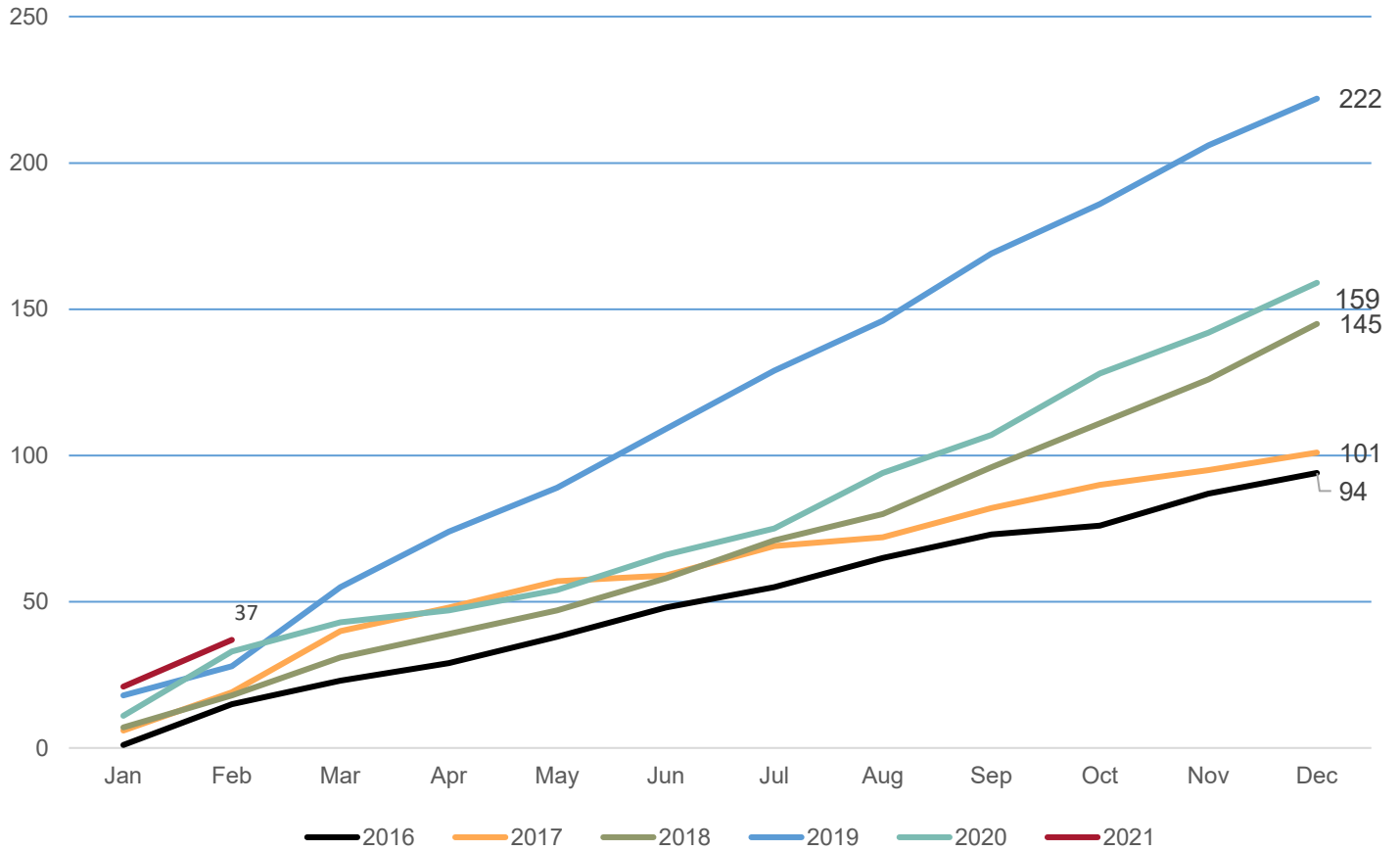
Cancer clinical trials provide access to potential advancement in care and lead to innovations in cancer prevention. Clinical trials are conducted in four phases:



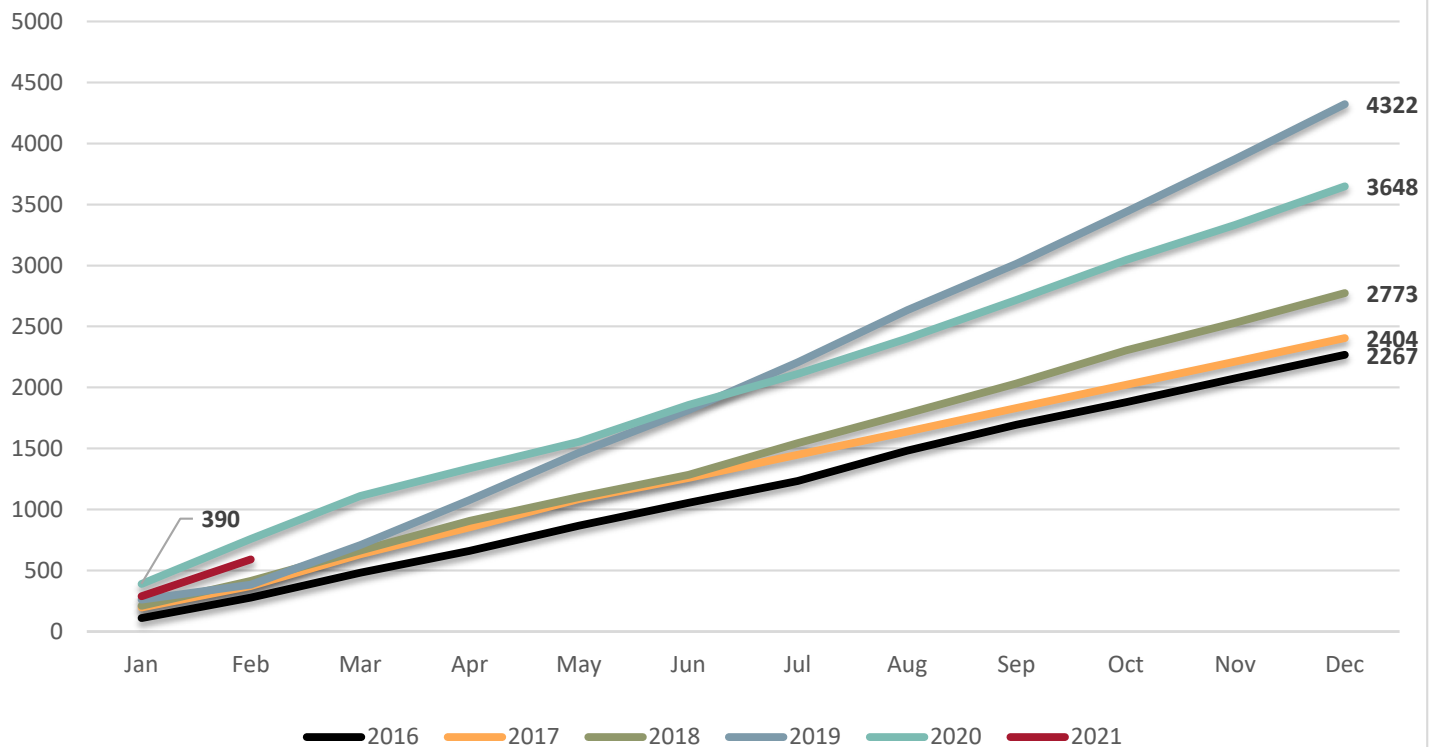
Early-phase Clinical Trial Accrual by Disease Group



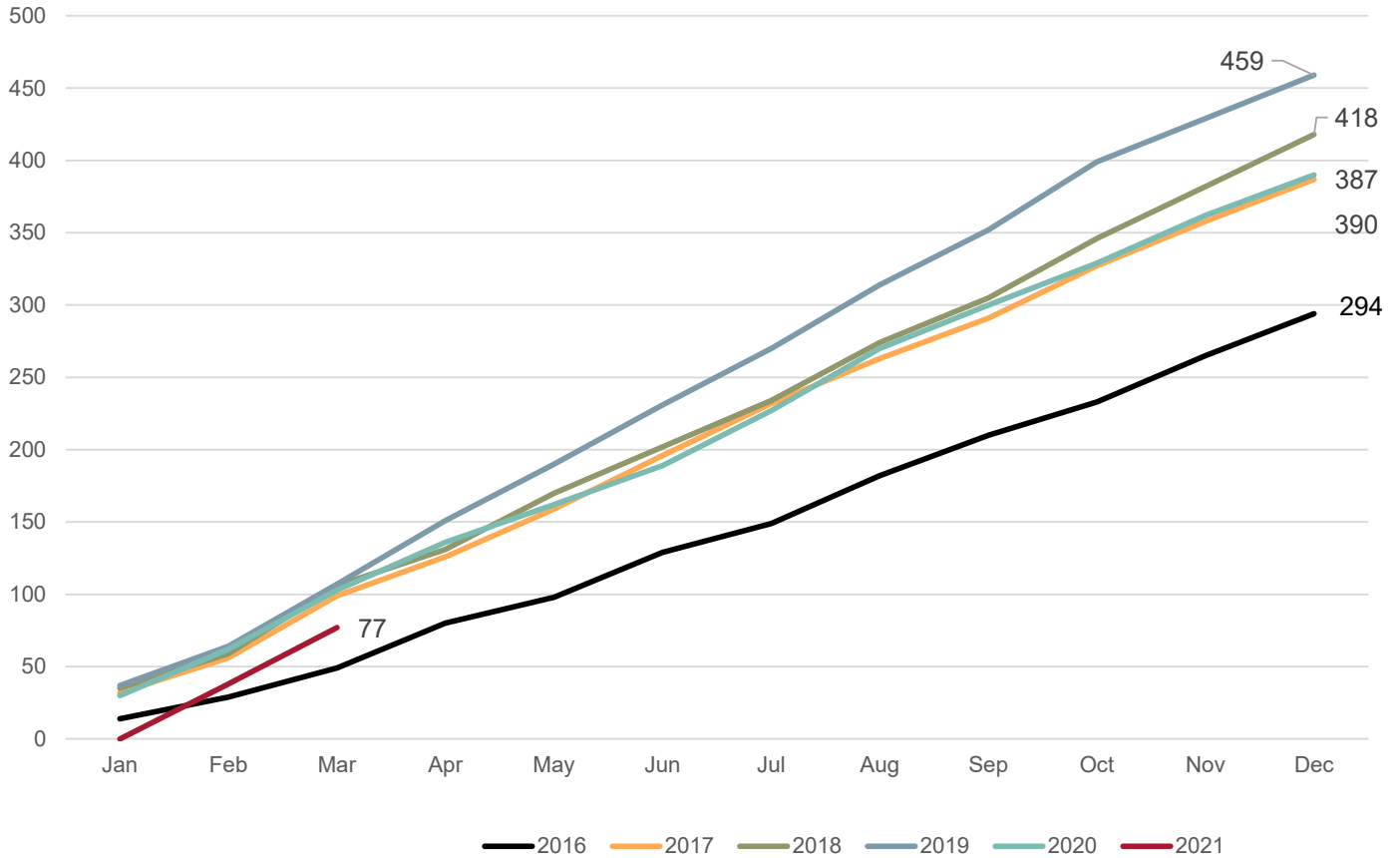
Early-phase Clinical Trial Accrual



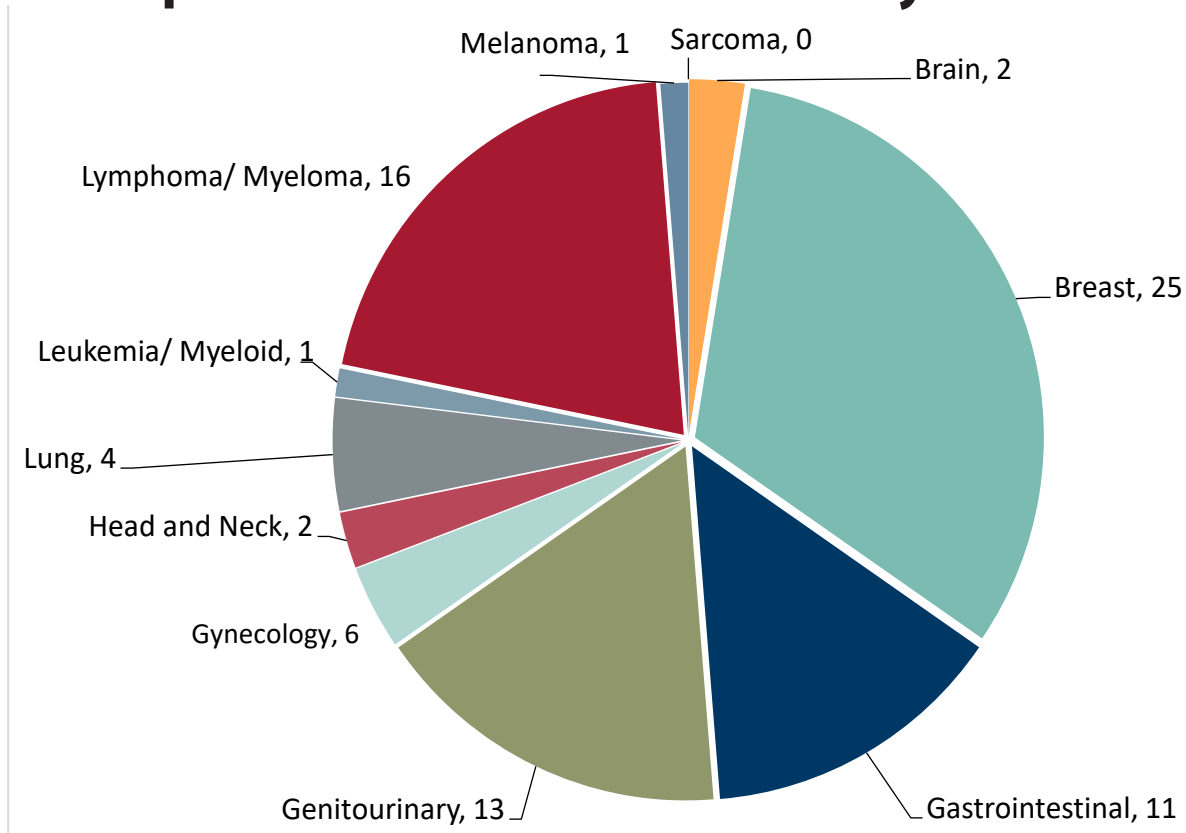
Early-phase KU CRC Patient Visits



Later-phase Clinical Trial Accruals



Later-phase Clinical Trial Accrual by Disease Group



Clinical Trials Patient Total By Location

Interventional treatments

Site Location	Patient Total
KU Clinical Research Center (early phase)	37
KU Cancer Center Community sites	74
Masonic Cancer Alliance sites	3
Children's Mercy	4
Other sites	1

Top Five Counties for KU CRC Patient Visits

	County	Unique Patients
1	Johnson County (KS)	161
2	Jackson County (MO)	107
3	Clay County (MO)	43
4	Platte County (MO)	43
5	Wyandotte County (KS)	30

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 200 cancer clinical trials and approximately 8 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.

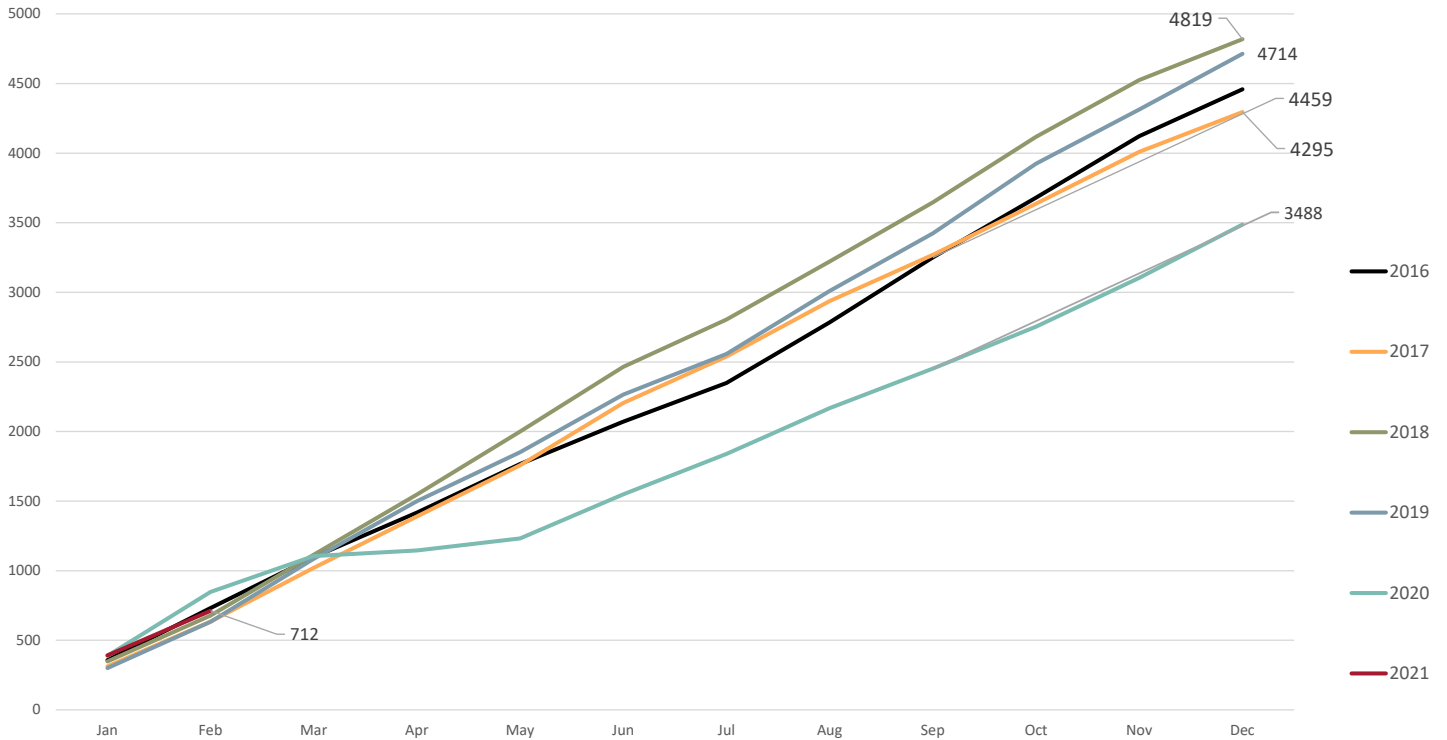


Other Organizations Conducting Research at the KU Clinical Research Center

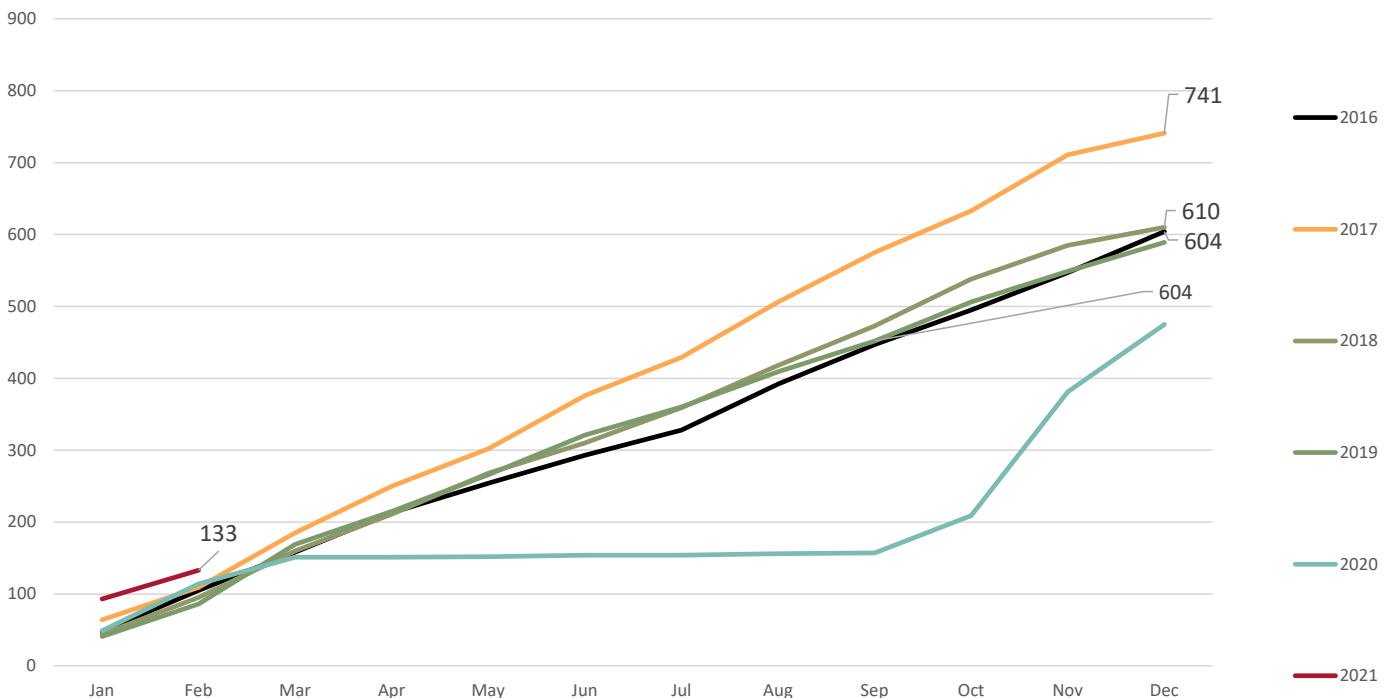
Clinical and Translational Science Unit (CTSU)

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



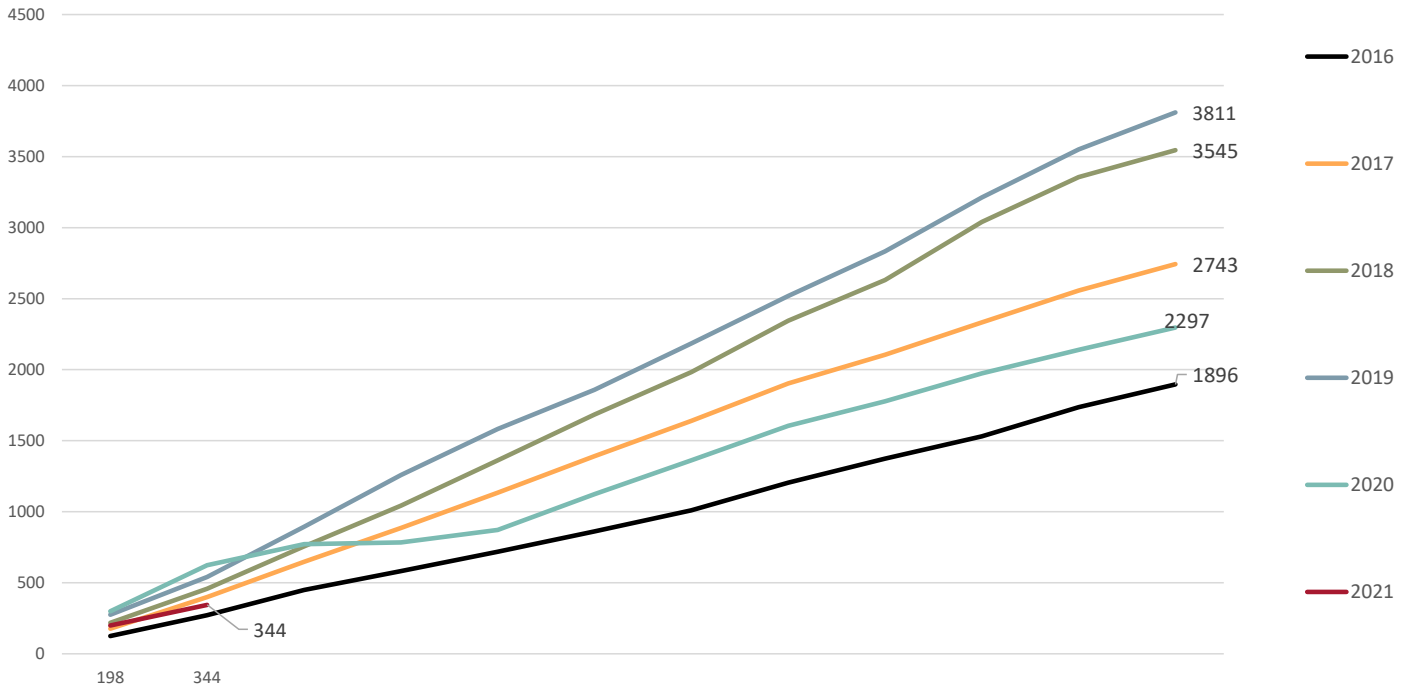
Total CTSU Patient Accrual



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 39 national and international pharmaceutical trials. The Center plans to begin 4 new studies in early 2021.

International/Pharmaceutical Trials

Study	Sponsor	Enrollment to Date
A3-45*	NIH/Eli Lilly	1
ADNI3*	NIH/ATRI	17
Alector*	Alector	0
DAPA*	AstraZeneca LP	21
LIFE-DSR*	LuMind/ATRI	0
TRC PAD*	NIH	9
Vaccinex*	IQVIA	0
vCCC*	NIH	0
A4	NIH/Eli Lilly	20
AbbVie Open-label	AbbVie	6
LEARN	NIH/Eli Lilly	15
Embark	Biogen	4
PEGASUS	Amylyx	9
Clarity	Eisai	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

Study	Sponsor	Enrollment to Date
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
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
TOTAL		304

*Currently enrolling studies

NIH=National Institutes of Health

Alzheimer's Disease Center

The KU ADC has supported 48 investigator-initiated studies resulting in 2,627 enrollments to date.

Investigator-Initiated Trials

Study	Sponsor	Enrollment to date
ADC Clinical Cohort*	NIH	427
ADMIT*	NIH	52
AEROBIC*	NIH	8
AMIE*	KU Endowment	2
AROMA*	NIH	43
BB8-AD*	NIH	36
Brain Healthy Diet*	NIH	8
C-NAP*	NIH	25
DYNAMIC*	NIH	48
EXERT*	NIH	10
GEM*	NIH	23
GETActive*	KUMC Pilot	3
IGNITE*	NIH	182
LEAP! Rx*	NIH	60
MOVER*	KU Endowment	45
NICE*	NIH	124
REACT*	NIH	68
SEAD2*	KUMC/Ausio	40
SIESTA*	NIH	23
STATINS*	NIH	20
TDAD*	NIH	10
TOAD*	Alzheimer's Association	32
ACCEL	KU ADC Pilot	87
ADEPT	NIH	77

*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

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	2,627