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CenterWatch Weekly

November 11, 2019

Use Commonly Available Data Early to Inform Eligibility and Recruitment, Experts Say

By Colin Stoecker

Getting study teams to consider using readily available data to help design and enroll clinical trials can be more difficult than it should be.

To encourage using real-world data, managers should start as early as possible in the design of a trial and use case studies to help staff understand what options are available. Creating a pilot for early phase or feasibility trials or using case studies where the data have worked are good techniques to help, said Sudha Raman, an assistant professor in the department of population health sciences at Duke University.

Raman, speaking at a Clinical Trials Transformation Initiative (CTTI) webinar, suggests asking three questions when considering using commonly available data like electronic health records and insurance claims in a clinical trial design:

- Are the eligibility criteria of interest identifiable in the data?
- Are the data relevant and of enough quality?
- Is the data analysis cost-effective?

"Once you have identified what kind of commonly available data to use, you then need to set up a discussion about how to use it concerning the scientific objectives, the endpoints, and the operational considerations," said Raman.

Using commonly available data early on in a trial might actually replace current recruiting methods, said Jack Sheehan, Janssen

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CROs Moving to Electronics, But Paper Still Prevalent, Survey Shows

By Colin Stoecker

While CROs are gung-ho on some new technologies to manage trials, they still rely heavily on paper-based systems, a new survey shows.

Electronic data capture (EDC), electronic trial master files (eTMF) and clinical trial management systems (CTMS) are increasingly in use, but half of CROs responding to the survey said they still use paper to manage information exchange with sites.

Because most sites still store their trial data in regulatory binders rather than electronic systems, CROs' ability to share information with their sites electronically is limited, the survey says. Most respondents, 96 percent, said they experience significant challenges with exchanging information with sites, according to Veeva's 2019 Unified Clinical Operations Survey Report.

Seventy-one percent of respondents had issues with tracking and reporting paper documents, 59 percent with misfiled or missing documents and 48 percent with manual document exchange.

Attempting to overcome these hurdles, 93 percent of respondents said they use a standalone EDC system, 77 percent use an eTMF system, 71 percent a randomization and trial supply management (RTSM) system, and 70 percent a clinical trial management system (CTMS).

The number of CRO respondents using an eTMF has tripled since 2014, with 60 percent of CROs now using a purpose-built

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Industry Briefs

U.S. Gears Up Against Potential Biomedical Research Theft

The NIH and FBI are continuing to root out scientists from China and other countries who are accused of stealing biomedical research from U.S. institutions.

Twenty-four of more than 180 cases have already been referred to the Health and Human Services Department's Office of the Inspector General at 71 U.S. institutions, including many of the country's largest medical schools, says NIH.

The White House Office of Science and Technology Policy (OSTP) sent a letter in September to 18,000 members of the U.S. research community saying that "over the past several years, some nations have exhibited increasingly sophisticated efforts to exploit, influence, and undermine our research."

OSTP Director Kelvin Droegemeier added that his office will hold meetings at a number of U.S. academic institutions to discuss the issue over the next few months.

ACRO, Congress Begin Work on New Cures Act

The Association of Clinical Research Organizations (ACRO) is working with the Congressional Research and Development Caucus (CRDC) and others on new legislation that would address recent innovations in clinical research.

Billed as a second 21st Century Cures Act, the legislation would focus on developments in patient engagement, use of real-world data and digital technologies.

ACRO and CRDC, chaired by Rep. Bill Foster (D-IL) and Rep. Jim Baird (R-IN), met in late October to discuss plans for the new bill.

The draft legislation, to be sponsored by Rep. Diana DeGette (D-CO) and Rep. Fred Upton (R-MI), is expected early next year.

Senate HELP Committee Schedules Nov. 20 Confirmation Hearing for Stephen Hahn

The Senate's committee on Health, Education, Labor and Pensions will hold a confirmation hearing for Stephen Hahn as FDA Commissioner on Wednesday, Nov. 20.

The committee's chair, Sen. Lamar Alexander (R-Tenn.), following a meeting this week with Hahn, said he believes he is "well-qualified to lead the agency" and brings "a crucial perspective" as a chief executive. Hahn currently is chief medical executive of the MD Anderson Center in Houston.

President Trump announced his intention to nominate Hahn to the agency's leadership role on Nov. 1, and the nomination was officially sent to the Senate on Tuesday (*CenterWatch Weekly*, Nov. 4, 2019).

NCI Designates University of Wisconsin as National Coordinating Center

The University of Wisconsin has been selected as the national coordinating center for NCI's Cancer Prevention Clinical Trials Network.

The $11.8 million grant places UW at the forefront of a research network consisting of three leading medical research centers in the U.S., including Northwestern University, the University of Arizona and the University of Texas.

The New Data Management, Auditing and Coordinating Center will coordinate activities across the network, including centralized data management and reporting, clinical trials auditing, and administrative and logistical coordination.

Takeda Gets Rights to MD Anderson Cancer Therapies

Takeda will collaborate with the University of Texas MD Anderson Cancer Center to develop and test innovative oncology therapies.

Under the arrangement, Takeda will have rights to up to four of the center's natural killer (NK) cell therapies, derived from umbilical cord blood cells. The partners will collaborate on the development of a CAR NK-cell therapy platform in a trial starting in 2021.

New ALS App Set for Trial Use This Month

A new app for tracking progression of Amyotrophic Lateral Sclerosis (ALS) will be tested in clinical trials beginning this month, thanks to a $300,000 grant from the ALS Foundation.

The ALS iNVOLVE/eNGAGE app captures 80 patient data points a day using patients' phones to measure movement and vocal strength.

The first clinical trial to use the app will enroll 50 patients across five ALS medical research sites, including Harvard, Massachusetts General Hospital, Duke University, Barrow Neurological Institute, University of California-San Diego and the University of Colorado.

T3D Therapeutics Gets Funding from NIA for Alzheimer's Hopeful

In a field that has stumped scientists for nearly two decades, another hopeful Alzheimer's compound has received a $15 million grant from a private investor to take its study into phase 2.

T3D Therapeutics out of North Carolina will begin phase 2 of its trial on drug T3D-959 in patients with mild-to-moderate Alzheimer's. The drug targets folded proteins in the brain and works to combat sugars and fats that

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Up and Coming

This feature highlights changes in clinical research organizations' personnel.

ACADIA Pharmaceuticals, Inc.

ACADIA Pharmaceuticals, Inc. has named **Ponni Subbiah** senior vice president, global head of medical affairs and chief medical officer. Subbiah recently served as CMO at Indivior.

Aeglea BioTherapeutics

Aeglea BioTherapeutics has expanded its senior management team with the appointment of **Ravi M. Rao** as chief medical officer and **Michael C. Hanley** as chief commercial officer. Rao was most recently vice president and head of global medical affairs at GlaxoSmithKline. Hanley was previously vice president and U.S. chief commercial officer for Esteve Pharamceuticals.

Albireo Pharma

Michelle Graham has been appointed chief human resources officer at Albireo Pharma. Graham was most recently senior vice president and chief human resources officer with TESARO.

Arecor Limited

Arecor Limited has named **Jim MacDonald-Clink** vice president of business development. MacDonald-Clink was previously head of business development for Munipharma.

Biodesix

Biodesix has expanded its leadership team with the addition of **Scott Hutton** as chief executive officer. Hutton previously served as chief operating officer with the company.

BioDuro

Jeffery Blazevich has been named chief financial officer at BioDuro. Blazevich's most recent appointment was CFO at Zest Dental Solutions.

Cerecin

Cerecin has named **Bruce Morimoto** vice president of drug development. Morimoto previously served as the vice president of drug development operation with Alkahest, Inc.

Cognition Therapeutics

James O'Brien has been appointed chief financial officer at Cognition Therapeutics. O'Brien was most recently executive vice president of finance at Enzo Biochem.

CytoSorbents Corporation

CytoSorbents Corporation has appointed **Zsolt Molnár** medical director, **Albert T. Leung** as senior director of clinical affairs and **Peter J. Nelson** senior director of clinical affairs on the U.S. team. Molnár last served as head of the department of anesthesiology and intensive therapy at the University of Szeged in Hungary. Leung recently served as the chief medical officer for GlySure Ltd in the UK. Nelson was formerly an associate professor of medicine and regional clinical center principal investigator at the University of Washington Medical Center in Seattle.

Elysium Health

Elysium Health, Inc. named **Morgan Levine** as head of Bioinformatics. Levine is currently a professor and aging researcher at the Yale School of Medicine.

Entasis Therapeutics

Entasis Therapeutics has named **David Altarac** chief medical officer. Altarac was previously senior vice president and head of global regulatory affairs, global drug safety and research and development quality and compliance at Shire.

Entrada Therapeutics

Nathan Dowden has been appointed chief operating officer at Entrada Therapeutics. Dowden previously served as senior vice president of strategy and corporate development at Rubius Therapeutics.

Experic

Niyati Patel has been appointed director of quality assurance and compliance at Experic. Patel was formerly the associate director of quality assurance at Extremity Medical, LLC.

Glympse Bio

Glympse Bio has appointed **Tracey Dawson** chief commercial officer and head of strategy. Dawson was most recently vice president of global product development and commercialization for the multiple sclerosis franchise at Biogen.

Imago BioSciences

Imago BioSciences has named **James D. Watson** chief business officer. Watson formerly served as CBO at Sigilon Therapeutics and Alvine Pharmaceuticals.

Jopari Solutions

Tom McCarthy has been named vice president of sales at Jopari Solutions. McCarthy was previously vice president of business development at One Call Care Management.

Kura Oncology

James Basta has been named chief legal officer and corporate secretary, as well as chief compliance officer at Kura Oncology. Basta was previously senior vice president and chief corporation counsel at Biogen.

Laboratory for Advanced Medicine

Kenneth Chahine has been named chief executive officer at Laboratory for Advanced Medicine. Chahine formerly served as executive vice president and general manager of AncestryDNA.

Lifescience Dynamics

Alfred Reszka has been appointed chief business officer at Lifescience Dynamics.

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Industry Briefs

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cause the plagues, tangles and inflammations seen in AD patients.

The trial, which also has support from the National Institute on Aging, expects to begin enrolling patients in the first quarter of 2020.

Grants Awarded to Reanalyze Suspect Trial Data

An organization that advocates for reanalyzing data from questionable past trials is awarding grants to researchers to look for flawed data and conclusions.

The Restoring Invisible and Abandoned Trials (RIAT) project has awarded three grants of $150,000 each this year to mine unpublished clinical trial information, including de-identified patient data, for details that could call into question the results of the trials.

The first study funded by RIAT began in January 2019. Researchers from the University of Adelaide are examining data from an influential study of the effectiveness and safety of Prozac and counseling for depressed adolescents.

More recent grants went to a psychologist in private practice for a study of unreported protocol deviations and findings in an often-cited trial to test alternative treatments for depression, and an Indiana University School of Public Health's re-examination of a trial of a neuropathic pain drug in which the manufacturer allegedly cherry-picked results to obscure unfavorable findings.

RIAT plans to award three more grants in 2020.

Up and Coming

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Reszka previously held the position of executive director and head of strategic business intelligence at Merck & Co.

Minnetronix Medical, Inc.

Minnetronix Medical, Inc. has named **Jeremy Maniak** chief executive officer. Maniak was most recently chief operating officer at Minnetronix.

NiKang Therapeutics

Peter Li has been named chief executive officer at NiKang Therapeutics. Li was previously co-founder and founding CEO and chairman for Turning Point Therapeutics, Inc.

Odylia Therapeutics

Ashley Winslow has been named chief scientific officer at Odylia Therapeutics. Winslow comes to Odylia from the Orphan Disease Center at the University of Pennsylvania where she was senior director of portfolio development and translational research.

PyschoGenics

Mark Varney has been named chief scientific officer at PsychoGenics. Varney previously served as CEO at Neurolixis.

Santhera

Dario Eklund was named chief executive officer at Santhera. Eklund previously held the position of chief commercial officer with Vifor Pharma.

X4 Pharmaceuticals

X4 Pharmaceuticals, Inc. has named **Derek Meisner** general counsel. Meisner most recently served as general counsel at Genocea Biosciences in Cambridge, Mass.

Zyla Life Sciences

Todd N. Smith has been appointed president, chief executive officer and director at Zyla Life Sciences, effective immediately. Smith previously served as CEO and director of Iroko Pharmaceuticals, Inc.

Features

Use Commonly Available Data

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Scientific Affairs director of real-world value and evidence in neuroscience, who also spoke at the webinar.

"Janssen recently needed patients on a specific background medication and were unsure how common that would be worldwide," said Sheehan. The clinical team "looked at databases in the U.S. and Europe to get a better handle on that."

But using medical records and insurance claims to support recruitment is not always perfect, said Sheehan. Claims and electronic health records data are often incomplete and not filed in a timely manner. "The level of recency of data is very different in HIV than it is for flu," said Sheehan.

"Sometimes flu inclusion criteria specify having the virus within the last month" and claims data won't be up to date.

CROs Moving to Electronics

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eTMF application. Over the past five years, eTMF has steadily replaced CTMS, according to the survey.

EDC, RTSM, and CTMS systems in use by CROs are all up from 2017, with EDC, which is the most heavily used, showing a 7 percentage point increase.

Since 2017, RTSM saw a 19 percentage point increase due to the complexity of protocol design, according to the survey, and CTMS use increased 12 percentage points as CROs aimed to reduce costs and improve study quality, the survey said.

Although new types of software can be used for many different parts of trials, they are particularly effective in study startup.

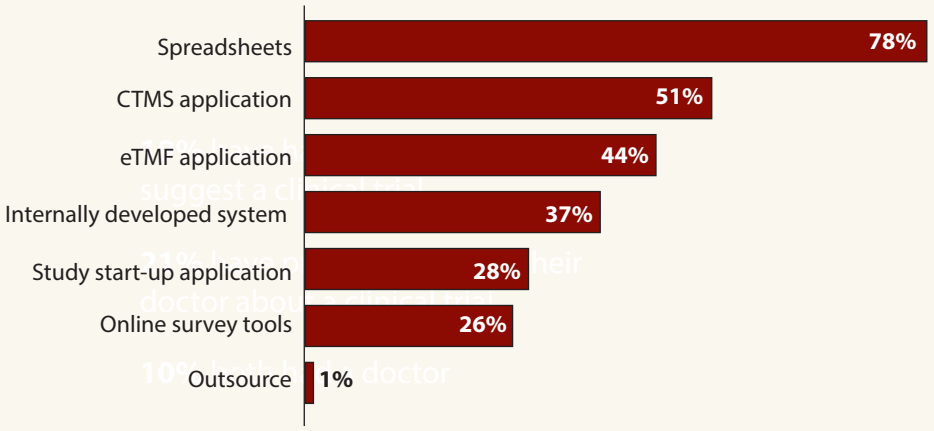
Study startup is actually slower today than it was a decade ago, and CROs are working hard to develop apps and purpose-built software to expedite the time that it takes to bring a drug to market. According to the survey, 86 percent of trials experience a study startup delay.

Only about half of CROs surveyed use CTMS, eTMF, or internally developed applications for study startup. For example, 28 percent of CROs use custom study startup applications, more than twice as many as sponsors.

Tools used to manage study startup processes are still dominated by Excel, at 78 percent. A close second to manage study startup was CTMS at 51 percent, followed by using eTMF applications at 44 percent.

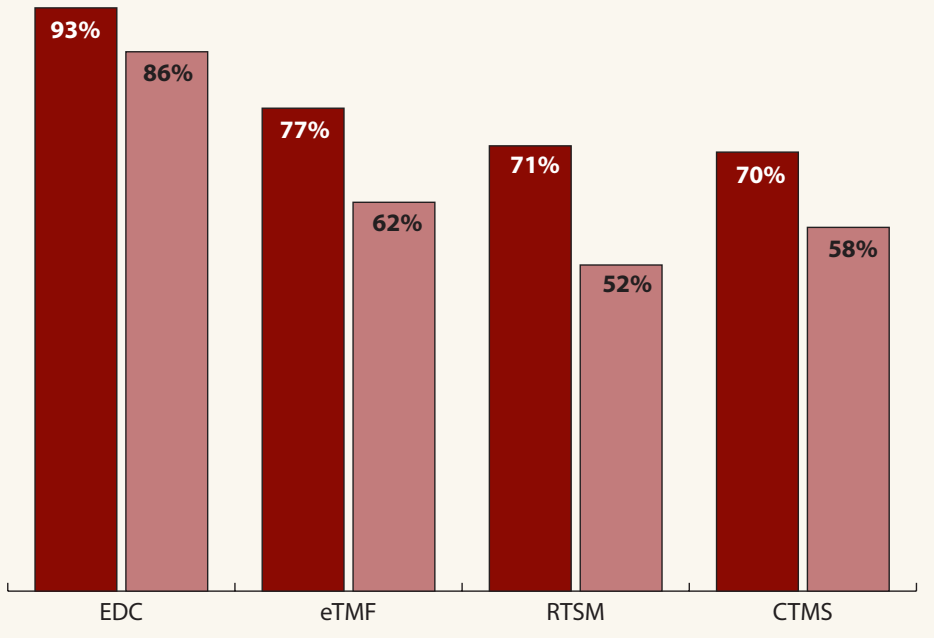
To improve study startup, 60 percent of CROs say it would be best to reduce the use of spreadsheets and manual processes.

Tools CROs Use to Manage Study Startup



Source: Veeva 2019 Unified Clinical Operations Survey

Applications CROs Use Most Often



Source: Veeva 2019 Unified Clinical Operations Survey

Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
BioCryst Pharmaceuticals, Inc.	BCX9250	fibrodysplasia ossificans progressive (FOP)	Phase 1 trial initiated enrolling healthy subjects	biocryst.com
Revolution Medicines, Inc. Amgen	RMC-4630 in combination with AMG 510	advanced solid tumors	Phase 1b trial initiated enrolling subjects with advanced solid tumors harboring the KRASG12C mutation	revmed.com amgen.com
X4 Pharmaceuticals, Inc.	X4P-001	Severe Congenital Neutropenia (SCN)	Phase 1b trial initiated enrolling 45 subjects with SCN and other selected congenital neutropenia disorders	x4pharma.com
CohBar, Inc.	CB4211	nonalcoholic steatohepatitis (NASH), NAFLD and obesity	Phase 1b trial initiated enrolling 20 obese subjects with NAFLD	cohbar.com
Cartesian Therapeutics	Descartes-08	generalized myasthenia gravis (GMG)	Phase 1/2 trial initiated	cartesiantherapeutics.com
Ichnos Sciences	ISC 27864	osteoarthritic pain	Phase 2b trial initiated enrolling 624 adult subjects with moderate osteoarthritic pain of the knee and/or hip at sites in India.	ichnossciences.com
Ichnos Sciences	ISB 830	atopic dermatitis	Phase 2b trial initiated enrolling 312 adult subjects with moderate to severe atopic dermatitis at sites in the U.S., Canada and Europe	ichnossciences.com
RhoVac AB	RV001	prostate cancer	Phase 2b trial initiated enrolling 175 subjects at multiple centers in Denmark, Finland, Sweden, United Kingdom, Belgium, Germany and the U.S.	rhovac.com
Biohaven Pharma Holding Company Ltd.	troriluzole	Alzheimer's disease	Phase 2/3 trial initiated enrolling subjects with mild to moderate Alzheimer's disease	biohavenpharma.com
CymaBay Therapeutics, Inc.	seladelpar	Primary Biliary Cholangitis (PBC)	Phase 3 trial initiated enrolling 240 subjects in over 20 countries	cymabay.com
Revance Therapeutics, Inc.	DaxibotulinumtoxinA for Injection (DAXI)	isolated cervical dystonia (CD)	Phase 3 trial initiated enrolling 301 subjects at 60 sites in the U.S., Canada and Europe	revance.com
EpicentRX, Inc.	RRx-001	small cell lung cancer	Phase 3 trial initiated enrolling 126 subjects with third-line and beyond small cell lung cancer	epicentrx.com
Okami Medical Inc.	LOBO Vascular Occlusion System	occlusion of peripheral blood vessels	510(k) approval granted by the FDA	okamimedical.com
Autolus Therapeutics plc	AUTO1	acute lymphoblastic leukemia (ALL)	Orphan drug designation granted by the FDA	autolus.com

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Drug & Device Pipeline News

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Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Sanofi	Fluzone High-Dose Quadrivalent (Influenza Vaccine)	prevention of influenza disease caused by influenza A and B strains contained in the vaccine in subjects 65 years of age and older	sBLA approval granted by the FDA	sanofi.us
RedHill Biopharma Ltd.	Talicia (omeprazole magnesium, amoxicillin and rifabutin) delayed-release capsules 10 mg1/250 mg/12.5 mg	*Helicobacter pylori* (*H. pylori*) infection in adults	Approval granted by the FDA	redhillbio.com
GE Healthcare	Clariscan	intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity	Approval granted by the FDA	gehealthcare.com
Crescita Therapeutics Inc.	Pliaglis (enhanced formulation)	superficial dermatological procedures	Approval granted by the FDA	crescitatherapeutics.com
Sandoz	Ziextenzo (pegfilgrastim)	infection in cancer patients	Approval granted by the FDA	sandoz.com

Research Center Spotlight

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Clinical Trial Center, Loma Linda University Health

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Loma Linda University Medical Center, and its affiliate entities, operates some of the largest clinical programs in the U.S. in areas such as neonatal care and outpatient surgery and is recognized as the international leader in infant heart transplantation and proton treatments for cancer.

Coastal Carolina Research Center

Mount Pleasant, SC
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Coastal Carolina Research Center is a dedicated research facility that provides area residents the opportunity to volunteer and participate in clinical trials and research that focus on primarily "outpatient" studies in multiple therapeutic areas and diseases.

MDFirst Research

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(704) 491-1102
akumar@mdfirstresearch.com

MDFirst Research is a clinical research center committed to helping sponsors meet and exceed patient recruitment, quality assurance and data integrity goals efficiently. It has extensive experience conducting Phase II-IV clinical trials of drugs and devices.

NeuroStudies.net, LLC

Decatur, GA
(404) 475-0552
jcavin@neurostudies.net

NeuroStudies.net is a clinical research group dedicated to improving treatment options for neurological conditions (including Alzheimer's Dementia, Parkinson's, Multiple Sclerosis). It grew from Dr. Marshall L. Nash's medical practice, Dekalb Neurology Associates, LLC.

Northwell Health Clinical Trials Office

Lake Success, NY
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Northwell Health strives to improve the health of the communities it serves and is committed to providing the highest quality clinical care. It is one of the nation's largest health care systems with 23 hospitals and over 650 outpatient facilities.

Oregon Urology Institute

Springfield, OR
(541) 284-5508
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Oregon Urology Institute's primary objective is to offer the finest urologic care for adult and pediatric patients, and give patients access to the latest pharmaceutical developments through clinical trial participation.

Palm Research Center

Las Vegas, NV
(702) 736-5161
eneylon@palmresearchcenter.com

Palm Research Center is a private research company established in 2008 to implement clinical trials in the Las Vegas area. It has a strong focus on clinical trials involved in Endocrinology, Diabetes, and Metabolism.

Quality Medical Research

Nashville, TN
(615) 835-4750
cstahl@qualitymedicalresearch.com

Quality Medical Research is a dedicated research facility with over 30 years of research experience that handles all phases of research studies from Phase I, II, III and IV clinical trials. Quality Medical Research has successfully completed over 200 Phase I-IV clinical trials.

University of Louisville Department of Cardiovascular Medicine Research Division

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The department is nationally recognized for its cardiac stem cell research and focus on treating heart failure. It's a member of the Cardiovascular Cell Therapy Research Network, which has seven U.S. stem cell centers that conduct clinical trials on heart/vascular disease treatments.