Important Resources

Resources Available at the University of Southern California

TriNetX

Accelerate the Clinical Trial Design and Recruitment Process

https://sc-ctsi.org/resources/trinetx

Service description: Available to USC researchers is the web-based application TriNetX, a real-world data network of providers and pharma companies that enhances clinical trial design and accelerates patient, site and principal investigator recruitment.

How to get access: For access to TriNetX please email cri@usc.edu including the subject line "TriNetX Account Request".

Cerner Health Facts

Multi-Site Electronic Health Records for Data Mining and Health Economics

https://sc-ctsi.org/resources/cerner-health-facts

Service description: Available to members of the USC community, the CERNER Health Facts® database captures and stores de-identified, longitudinal electronic health record (EHR) patient data, and then aggregates and organizes these data into consumable data sets to facilitate analysis and reporting. The data are generated from Cerner and non-Cerner participating contributing facilities and go back as far as 2000.

Currently Cerner Health Facts contains data from:

- Over 158,300,000 patients
- Over 1.3 billion laboratory results
- Over 84 million acute admissions, emergency and ambulatory visits
- Over nine years of detailed pharmacy, laboratory, billing and registration data
- More than 151 million orders for nearly 4,500 drugs by name and brand, and
- 100% of Patients in Orchid, Keck Care and KIDS.

How to access: If you are a member of the USC community, please contact cri@usc.edu to request access.

Access Los Angeles Countywide Patient Data

https://sc-ctsi.org/resources/access-los-angeles-countywide-patient-data

Service description: The Los Angeles Data Resource (LADR) is a joint project of major Los Angeles health care provider organizations aimed at enabling implementation studies as well as patient-oriented research collaborations. LADR is an integration of medical records and clinical research data across all participating networks. Investigators are able to find sets of aggregated patient information through a web-based application all while preserving patient privacy.

How to get access: Please email cri@usc.edu requesting account access to LADR.

The Voice of the Patient: A Series of Reports from FDA's Patient-Focused Drug Development Initiative

Under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V), the US Food and Drug Administration conducted 24 disease-specific Patient-Focused Drug Development (PFDD) meetings to more systematically gather patients' perspectives on their condition and available therapies to treat their condition. The Voice of the Patient Reports summarize the input provided by patients and patient representatives at each of these public meetings.

These reports can be found on the FDA website -

https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm368342.htm

Diseases/conditions with The Voice of the Patient Reports: Opioid Use disorder, Hereditary Angioedema, Alopecia Areata, Autism, Sarcopenia, Organ Transplant, Neuropathic Pain Associated with Peripheral Neuropathy, Psoriasis, Hemophilia A, Hemophilia B, von Willebrand Disease and Other Heritable Bleeding Disorders, Parkinson's Disease, Non-Tuberculous Mycobacterial (NTM) Lung Infection, Huntington's Disease, Functional Gastrointestinal Disorders, Chagas Disease, Breast Cancer, Female Sexual Dysfunction, Idiopathic Pulmonary Fibrosis, Neurological Manifestations of Inborn Errors of Metabolism, Pulmonary Arterial Hypertension, Fibromyalgia, Cell Report, Narcolepsy, Human Immunodeficiency Virus (HIV) Patient-Focused Drug Development & HIV Cure Research, Chronic Fatigue Syndrome and Myalgic Encephalomyelitis

How Patient Experience Data Could Enhance Medical Product Development and Decision Making

Type of Patient Experience Data	Type of Stakeholder		
	Patient Stakeholders*	**Medical Product Developers/Researchers**	**Regulators**
Patient registry or natural history study data	• Inform communications, education and outreach efforts for the patient community • Inform future research • Provide basis for recruitment in clinical trials	• Help identify biomarkers and clinical outcome measures that will show how well a patient responds to a treatment in clinical trials • Inform clinical trial design • Support clinical trial recruitment	• Enhance the understanding of the course of disease over time, identifying demographic, genetic, environmental, and other factors that correlate with its development and outcomes in the absence of treatment (or while on available therapies)
Study report or survey data on the therapeutic context (severity of condition and unmet medical need), including perspectives on disease background, severity of condition and available treatment options	• Identify burden of disease and unmet medical needs that warrant further scientific discussion • Identify opportunities and gaps where further development and research may be needed • Identify considerations for clinical endpoints and clinically meaningful outcomes • Inform patients on possibilities to participate in development and validation of clinical trial endpoints and patient-reported outcomes	• Informs Target Product Profile • Identify clinical domains (e.g., most bothersome symptoms) of the condition that could be targeted for new treatment development • Identify how the condition may vary by sociodemographic factors, subgroups, culture, and disease severity • Inform the selection, development and modification of meaningful clinical endpoints and outcomes, and tools that measure what matter most to patients • Inform clinical trial design, including appropriate inclusion and exclusion criteria	• Inform FDA decision-making throughout medical product lifecycle • Enhance the understanding of the therapeutic context for benefit-risk assessments • Enhance understanding of meaningful endpoints and outcomes to patients to appropriately advise sponsors on a medical product development plan in early phases of development • Inform FDA guidance on disease-specific clinical, scientific and regulatory matters • Inform FDA assessments of medical product development programs
Clinical trial experience data, including perspectives on trial visits and assessments	• Help clinical trial participants better prepare for the trial, including the informed consent process • Inform patients on opportunities to participate in clinical trials and improve overall recruitment • Help individual decision making on whether to enroll in a trial	• Enhance recruitment and retention for clinical trials • Inform development of informed consent documents • Provide insight into clinical trial participant burden, including frequency and conduct of trial visits and assessments	• Enhance understanding of patient's experience with clinical trial design and inclusion/exclusion criteria to better advise sponsors
Patient input on benefits and risks	• Inform future research • Identify unmet medical needs that warrant further scientific discussion • Enhance the understanding of benefits and risks for patients	• Enhance the understanding of patient input on benefits and risks to inform benefit-risk assessment	• Enhance the understanding of patient input on benefits and risks to inform benefit-risk assessment
Perspectives on ways to communicate information to patients and prescribers	• Inform communications and education for the patient community to enhance shared decision-making between patients and prescribers	• Improve the overall communication of information to patients and prescribers	• Inform how to convey key information that helps facilitate patients' informed decision-making

*Patient stakeholders include patients, caregivers and patient advocates. To provide standardized nomenclature and terminologies related to patient-centered medical product development, these terms are defined in FDA's Patient-Focused Drug Development Glossary: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm610317.htm

Draft Guidance: Developing & Submitting Proposed Draft Guidance Relating to Patient Experience Data Guidance for Industry and Other Stakeholders https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm628903.pdf

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