CHeT

CHeT/CTCC/CMSU Overview

SCORE

21 AUG 2024

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CHeT Overview

The Center for Health + Technology is an academic research organization within the University of Rochester Medical Center. For more than three decades, CHeT has served as a worldwide leader in the conduct, planning, management, implementation, analysis, and rescuing of large multi-center clinical research studies. Over the past generation, CHeT has re-shaped the conduct of clinical research and advanced knowledge to improve health for thousands, if not millions, of individuals.

Simultaneously, our innovative and novel technologies and outcome measures have shaped and improved how research is conducted and how therapies are evaluated. Our skilled team of consultants are readily available to provide guidance to academic institutions, pharmaceutical companies, technology firms, not-for-profit foundations, advocacy groups, and the federal government.

- CHeT Director: Chad Heatwole, MD, MS-CI

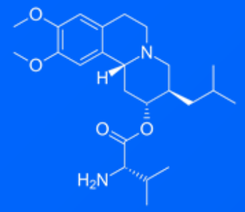
Our Mission

To advance ***human therapeutics, health, and knowledge*** through exceptional people, skillful research, and partnerships.

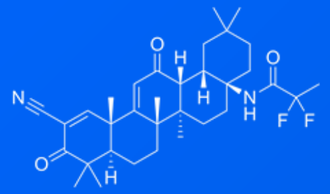
Our Story

- 135+ Clinical Studies
- 40,000 Research Participants
- 10 FDA Approvals

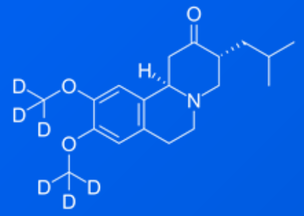
10 FDA Approvals



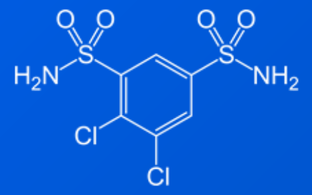
Valbenazine
2023
Sponsor: Neurocrine Biosciences
Disease: Chorea for Huntington's disease
Brand Name: Ingrezza



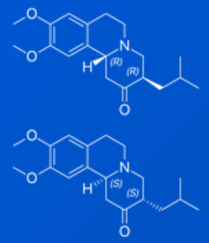
Omaveloxolone
2023
Sponsor: Reata Pharmaceuticals
Disease: Friedreich's Ataxia
Brand Name: Skyclarys



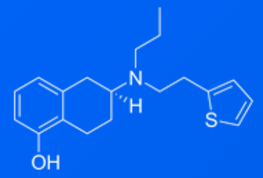
Deutetrabenazine
2017
Sponsor: Teva Pharmaceuticals
Disease: Huntington's disease
Brand Name: Austedo



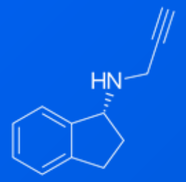
Dichlorphenamide
2015
Sponsor: Taro Pharma
Disease: Primary Hypokalemic & Primary Hyperkalemic Periodic Paralysis
Brand Name: Keveyis



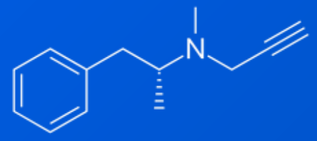
Tetrabenazine
2008
Sponsor: Prestwick Pharmaceuticals
Disease: Huntington's disease
Brand Name: Xenazine



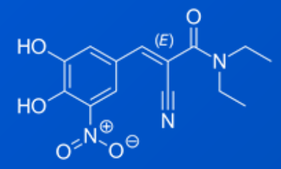
Rotigotine
2007
Sponsor: Schwarz Pharma
Disease: Parkinson's disease
Brand Name: Neupro



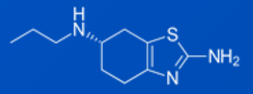
Rasagiline
2006
Sponsor: Teva Pharmaceuticals
Disease: Parkinson's disease
Brand Name: Azilect



Selegiline
2006
Sponsor: Somerset Pharmaceuticals
Disease: Parkinson's disease
Brand Name: Emsam



Entacapone
2003
Sponsor: Orion Corporation
Disease: Parkinson's disease
Brand Name: Comtan



Pramipexole
1997
Sponsor: Pharmacia & Upjohn
Disease: Parkinson's disease
Brand Name: Mirapex

CHeT

CHeT Health

CHeT Outcomes

CHeT Analytics

CHeT Innovation

Clinical Trials Coordination Center

Clinical Materials Services Unit

CHeT Health

CHeT Health aims to advance evidence-based health policies to help all individuals, reduce health disparities, inform government regulatory agencies, and augment the involvement of diverse populations during therapeutic trials.

CHeT Health is:

Improving Diversity in Clinical Trials

Improving understanding of barriers to participation in clinical trials in underrepresented communities and to improve the representation of participants across CHeT clinical research studies.

Generating Evidence

Exploring the role of evidence-based health policy in shaping health outcomes and reducing health disparities through primary and secondary data.

Informing Action

Leveraging knowledge within and outside of CHeT in the areas of health policy, equity, government regulation, and regulatory science to inform meaningful change and advance health equity.

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CHeT Outcomes

CHeT Outcomes specializes in the development and validation of highly sensitive disease-specific, patient-reported and caregiver-reported outcome measures for use in therapeutic trials and FDA drug-labeling claims.

- CHeT Outcomes has developed and individually validated more than 160 disease-specific instruments and over 1,000 subscales that quantify symptomatic disease burden during clinical trials.
- Our instruments are capable of reliably measuring how a patient feels and functions, can reduce sample size requirements, are highly recommended by the NIH's common data elements initiative, and are designed to detect meaningful changes in health prior to traditional and generic outcome measures.
- CHeT Outcomes will collaborate with you to develop and fully validate a disease-specific outcome measure for any disease, and we provide consultation regarding outcome measure selection, use, optimization, and analysis.

Our Instruments

Our instruments measure the multifaceted, patient-perceived disease burden in individual diseases. Our team of epidemiologists, biostatisticians, qualitative researchers, patient advocates, linguists, computer programmers, outcomes researchers, and physicians has developed patient-reported and caregiver-reported outcome measures for adult and pediatric populations, including instruments for the following diseases:

- Alzheimer's disease (AD)
- Adrenomyeloneuropathy (AMN)
- Amyotrophic lateral sclerosis (ALS)
- Cerebral cavernous malformation (CCM)
- Charcot Marie Tooth (CMT)
- Crohn's disease (CD)
- Dementia
- Drenoleukodystophy (ALD)
- Duchenne muscular dystrophy (DMD)
- Facioscapulohumeral muscular dystrophy (FSHD)
- Fibromyalgia (FM)
- Friedreich's ataxia (FA)
- Huntington's disease (HD)
- Inclusion body myositis (IBM)
- Lung cancer (LC)
- Mild Cognitive Impairment (MCI)
- Myasthenia gravis (MG)
- Myotonic dystrophy Type 1 (DM-1)
- Myotonic dystrophy Type 2 (DM-2)
- Parkinson's disease (PD)
- Spinal-bulbar muscular atrophy (SBMA)
- Spinal muscular atrophy (SMA)

5 Pivotal Studies

Our disease-specific instruments were shown to be more responsive in detecting clinically-relevant changes compared to traditional functional measures.

Instrument Translations

- Chinese
- Czech
- Danish
- Dutch (NL)
- Dutch (Belgium)
- English (UK/Ireland)
- English (Australia/New Zealand)
- French (France)
- French (Canada)
- French (Belgium)
- German (Germany)
- German (Belgium)
- Greek
- Hindi
- Italian
- Japanese
- Korean
- Portuguese (Brazil)
- Serbian
- Slovak
- Spanish (Latin America)
- Spanish (Spain)
- Spanish (US)
- Swedish
- Thai
- Turkish

CHeT

CHeT Health

CHeT Outcomes

CHeT Analytics

CHeT Innovation

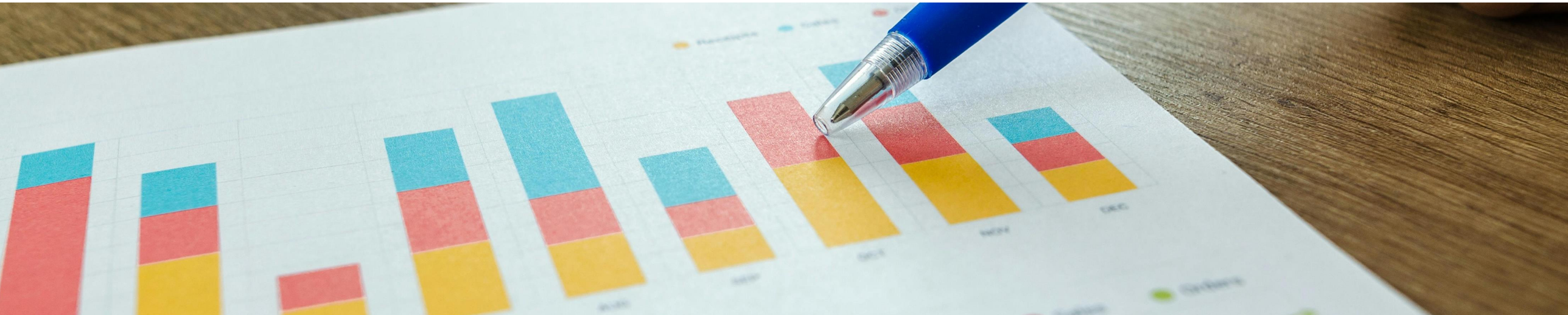
Clinical Trials Coordination Center

Clinical Materials Services Unit

CHeT Analytics

Goals

1. **Reduce costs** of drug development in clinical research.
2. **Support research initiatives** to facilitate efficient trial design and answer research questions.
3. **Enhance clinical care** for those living with neurodegenerative disorders (e.g., PD, HD) and other disease states.



Resources

Understanding every trial has unique needs, CHeT maximizes effectiveness with experienced resources to deliver customized biostatistics and data mining efforts.

Access to clinical trial and observational study data from over 100 studies.

Extensive knowledge of **developing clinical disease progression models**

Expertise in **statistical methodology** for clinical research

Existing Study Highlights for Collaborative Research

Parkinson's Disease

- 75 Studies
  - 55 Interventional
  - 20 Observational

Huntington's Disease

- 37 Studies
  - 31 Interventional
  - 6 Observational

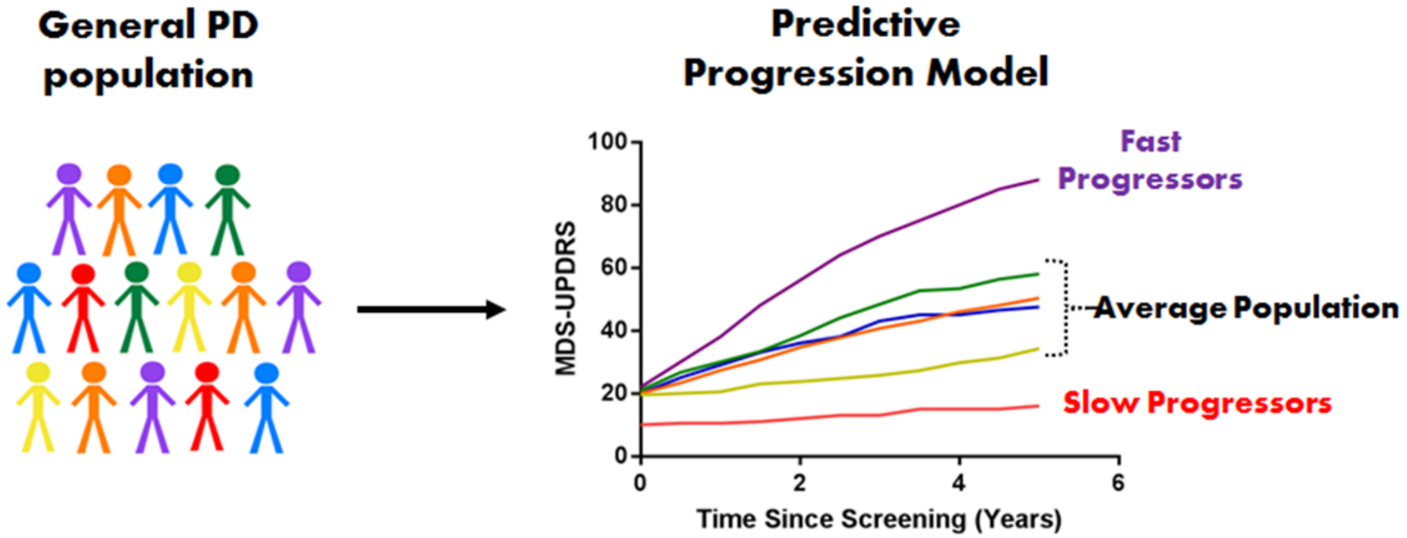
Others

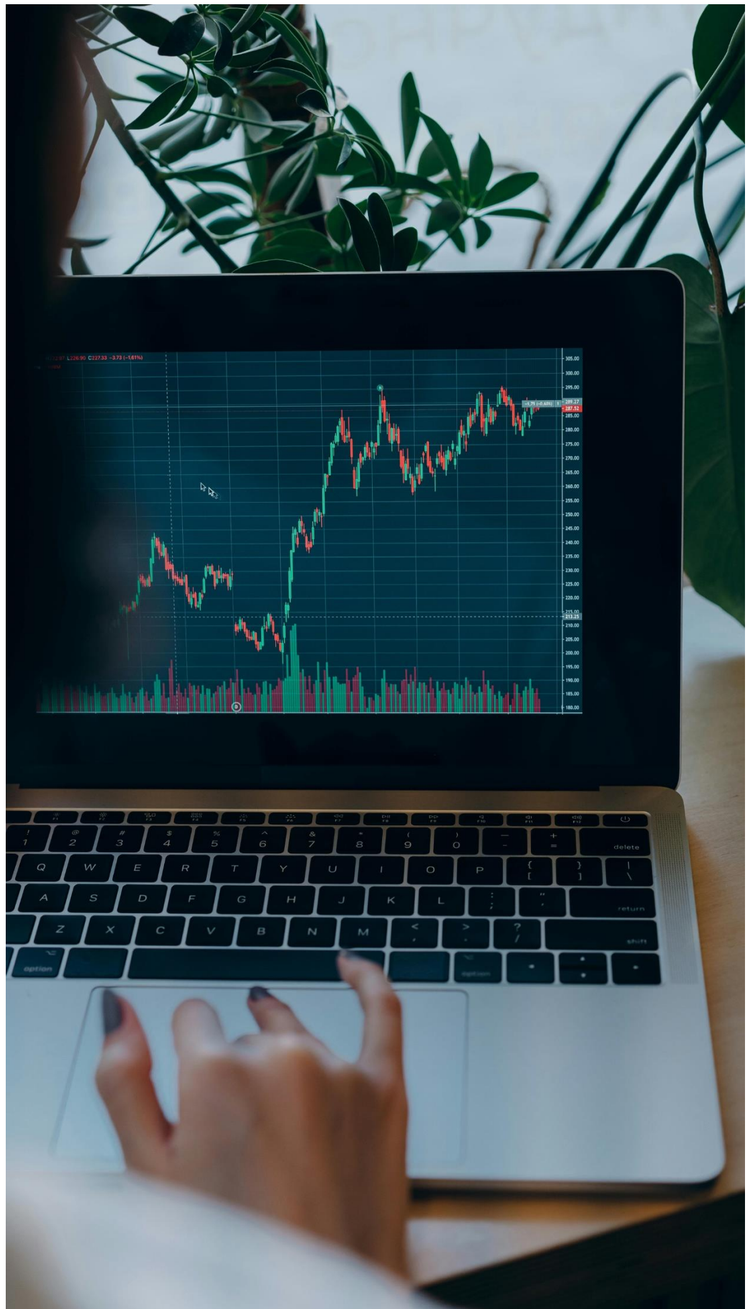
- Friedreich's Ataxia – 6 Studies
- HIV/AIDS – 8 Studies

AI Analytical Services

Provide analytical modeling, consulting and support to drive clinical research efficiency & effectiveness

- Develop clinical disease progression models that predict meaningful clinical outcomes to patients, caregivers, and researchers.
- Apply learnings from models to develop strategies to reduce drug development costs through efficient clinical trial designs.
- Visualize complex data to identify patterns and drive strategic analysis.
- Harmonize distinct sources of data to increase sample size and generate more robust findings.





Biostatistical Services

Provide biostatistical support for new clinical trials, other interventional studies, and observational studies.

- Knowledgeable in study processes from the planning phase to presentation of results.
  - Contribute to **protocol development**
  - Develop a **statistical analysis plan**
  - Provide Data Safety Monitoring Board support (i.e. **unblinded statistician**)
  - Perform **statistical analyses**
  - Promote standardized data collection based on **CDISC standards**
  - Contribute to **preparation of manuscripts**
  - Pharmacokinetic (PK) & Pharmacodynamic (PD) analysis

Provide consulting to assess relevant existing studies to answer research questions.

- Develop and evaluate new outcome measures to quantify disease progression (e.g. composite scores).
- Utilize lab data and biospecimens to identify potential biomarkers to quantify disease progression.
- Provide replication of analyses in independent studies as well as new exploratory analyses on existing study data.

Model-Based Clinical Trial Enrichment

Case Study: Predicting Fast Progressors in Parkinson's disease

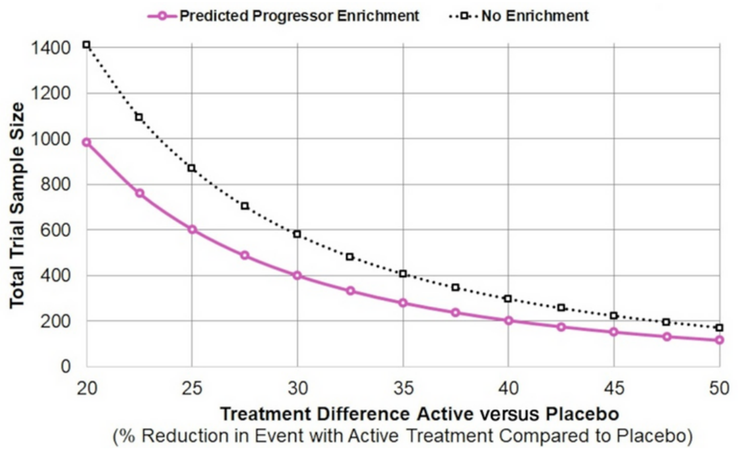
Problem: Clinical trials in Parkinson's Disease often face challenges with large sample sizes and lengthy durations to detect meaningful changes.

CHET Value Add

Using our predictive models, we can significantly **reduce the required sample size and reduce follow-up times** for clinical trials by enriching the enrollment with patients likely to experience rapid disease progression.

Model Predictions

- **15% to 30% Reduction in Sample Size** by focusing on patients more likely to reach meaningful endpoints.
- **Patient Enrollment Savings** resulting in dozens to 100s of fewer participants compared to the traditional target enrollment in most clinical trials.



Example

30% treatment difference requires 400participants instead of 600

33.33% Reduction in Sample Size!

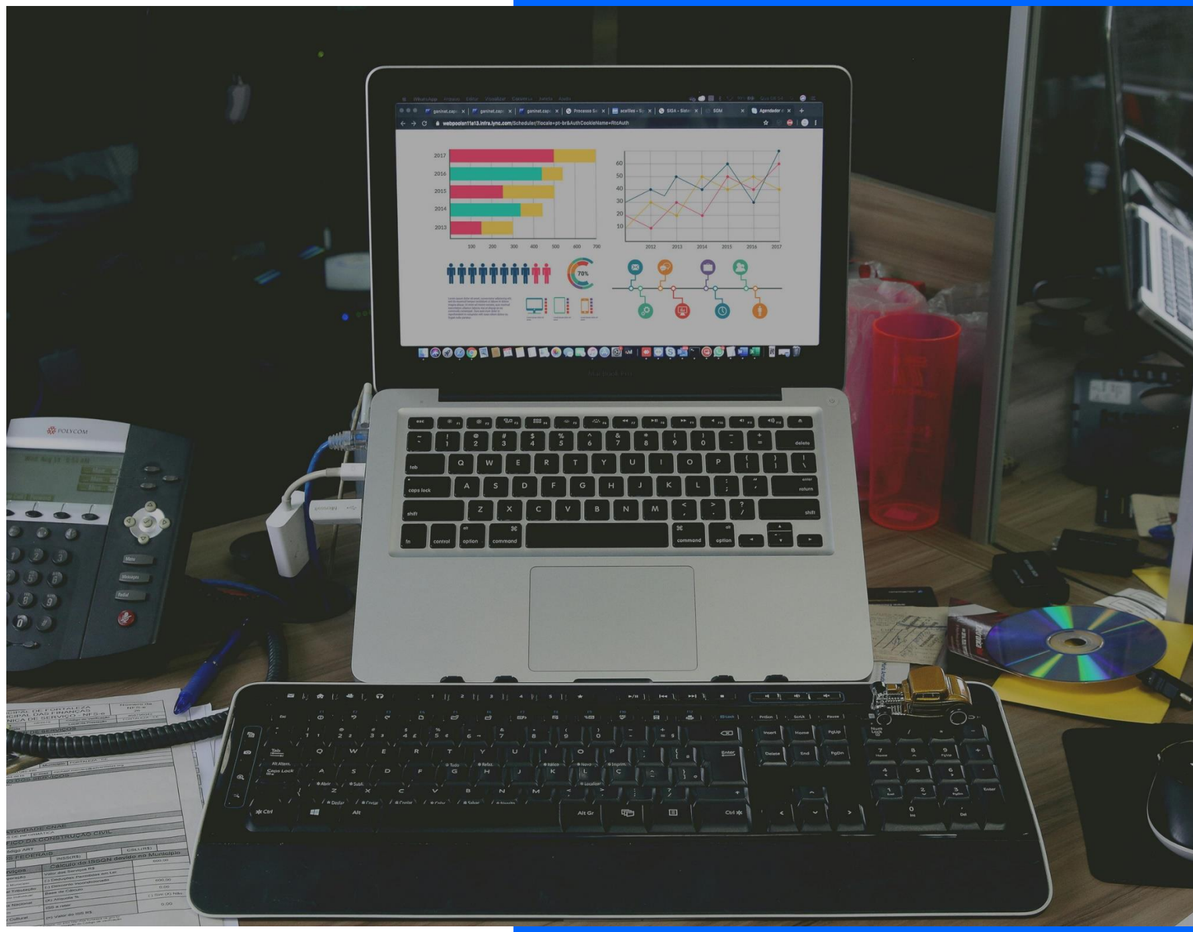
Enrollment Savings Example

Save $thousands in operating costs by reducing sample size requirements

Pharmacometrics Expertise

Provide pharmacokinetic and pharmacodynamic modeling and simulation capabilities to guide pre-clinical and clinical drug development programs.

- Develop protocols for pre-clinical and clinical testing of small molecule compounds and protein-based therapeutics to evaluate drug safety and pharmacodynamic effects
- Conduct non-compartment and compartmental modeling to characterize pharmacokinetics of therapeutics
- Provide population pharmacokinetic modeling services to understand patient factors that influence drug exposures and responses
- Design and conduct of drug-drug interaction studies for ensuring optimal safety of drugs
- Concomitant medication monitoring and coding for clinical trials



By the Numbers

>12

Lead Protocol Pharmacologist for > 12 clinical trials conducted by industry, consortium, and academic investigators.

16

PK/PD modeling and simulation of 16 unique therapeutic compounds.

>40

Pharmacology findings reported in the **> 40 peer-reviewed publications and abstract presentations.**

Case Study #1: 2CARE Study

Coenzyme Q10 in Huntington Disease

The largest therapeutic clinical trial to date in Huntington disease.

Problem: A pharmaceutical company wanted to identify **an improved measure of clinical progression** in early Huntington disease (HD) using existing observational & interventional clinical trial data.

- 608 research participants
- 46 clinical sites in the US, Canada and Australia
- (Date of study – published)

CHET Value Add

Leveraging our experience with existing HD studies and statistical expertise:

- **A composite measure was identified that characterized clinical progression better than individual symptom domain outcomes.**

Results & Impact

- This measure has been used as an outcome in clinical trials investigating potentially disease-modifying therapies, allowing a more sensitive measure of clinical change over current outcomes.
- Use of this measure in clinical trials results in smaller sample size estimates

Case Study #2: ACTG Study A5386

Broadly Neutralizing Antibody Therapy for HIV Treatment and Cure

Phase 1 clinical trial to induce HIV-1 control

Problem: Unknown exposure-response profile of investigational agents required advanced translational PK/PD modeling and simulation to **determine appropriate timing of antiretroviral treatment interruption.**

- Up to 46 research participants living with HIV-1
- Two novel antibody drugs with long half-lives given in combination for the first time to adults living with HIV
- Goal is to stop antiretroviral therapy and test whether study compounds can control HIV infection.
- NCT04340596

CHET Value Add

Leveraging data from animal studies and healthy human subject studies to predict PK/PD profiles of two novel broadly neutralizing antibodies:

- **PK profiles were modeled and used to predict appropriate timing of antiretroviral treatment interruptions to maximize safety and potential to see efficacy.**

Results & Impact

- This measure has been used as an outcome in clinical trials investigating potentially disease-modifying therapies, allowing a more sensitive measure of clinical change over current outcomes.
- Use of this measure in clinical trials results in smaller sample size estimates

ACTG

Advancing Clinical Therapeutics Globally
(formerly AIDS Clinical Trials Group)

Make the Most of Your Data With Us

Model-Based Drug Development

CHeT drives clinical trial effectiveness by determining a targeted sub-population to more accurately delineate the effects of the drug vs. the underlying condition.

Data Visualization

CHeT uses a number of visualization tools to share and explore information, providing researchers and decision makers a means to insights.

Disease Modeling Collaboration

CHeT is at the forefront of neurological disease research and analytics. We work with a number of other data science organizations, providing guidance and working through new ideas. This provides both scalability and a constant stream of new ideas and opportunities.

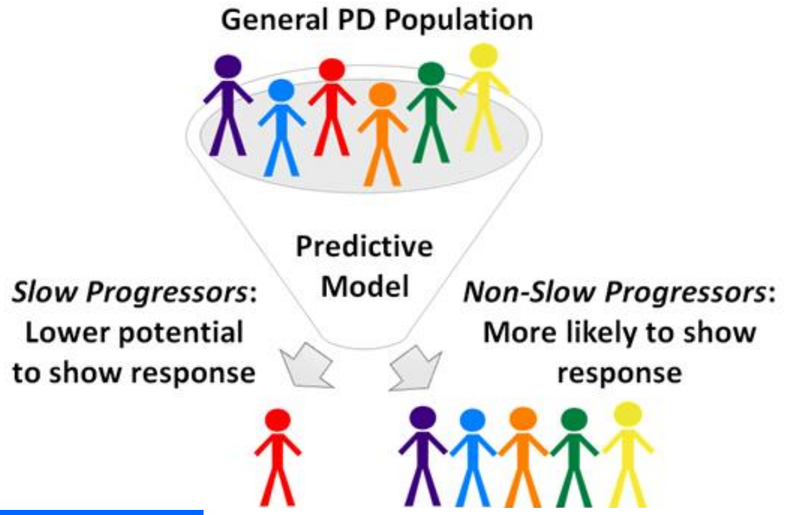
Clinical Pharmacology Services

Pharmacokinetics(PK)/Pharmaco-dynamics(PD)
Study design /Modeling and analysis

- Non-compartmental/compartmental
- Population (NONMEM software)

Pharmacogenomics – NYS COE

- DNA/RNA isolation and cloning
- DNA hybridization assays
- RT-PCR



Sample Collaborations

- Clinical Trial Simulation
- Prediction of Disease Progression

- DaTscan Imaging and Progression

- Identification of Patient Groups with Evolution of Key Symptoms

- Data platform to test and develop disease progression model

- Machine Learning / Artificial Intelligence / Deep Learning

Other Collaborators/Clients

CHeT

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CHeT Outcomes

CHeT Analytics

CHeT Innovation

Clinical Trials Coordination Center

Clinical Materials Services Unit

CHeT Innovation

Over the last decade, CHeT Innovation has pioneered new technologies, tools and approaches in clinical trials to transform design, assessment, and evaluation of novel therapies for neurological disorders.

- CHeT Innovation has conducted a dozen studies with virtual visits that have reached more than 1500 participants throughout the country. We have recruited and retained a national cohort of clinical trial-ready participants in a longitudinal natural history study.
- CHeT Innovation has amassed a local and national registry of highly engaged participants known as project:brain health. You can visit projectbrain.org to learn more.
- CHeT Innovation has extensive experience in applying smartphones, wearable sensors, video analytics, and invisible sensors that collect data inside and outside the clinic.

WATCH-PD

Evaluate the ability of sensors to assess features and progression of symptoms in early, untreated Parkinson's disease. Sensor assessments at home and in the clinic are compared to the traditional in-person assessments.

132 Participants (82 PD, 50 Control)

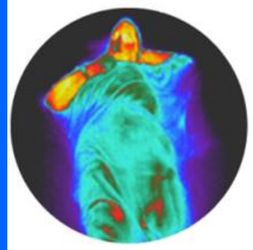
Collaborators: Biogen, Takeda

AT-HOME PD

Evaluate clinical outcomes using video visits in a virtual national observational study. Capture real-world data using a Parkinson's disease-specific smartphone application.

220 Participants

Collaborators: Massachusetts General Hospital, Northwestern University, Sage Bionetworks, NIH



SQUAD

Assess the use of wearable devices, sensors, polysomnography, and video to detect and quantify scratching. Evaluate the relationship between patient-reported outcomes and scratching and sleep metrics from wearable sensors.

45 Participants

Collaborators: Pfizer

VALOR-PD

Use video visits to evaluate the longitudinal change in individuals at genetic risk (due to mutations in the LRRK2 gene) of Parkinson's disease. Develop a cohort of participants ready for clinical trials of gene-directed therapies.

277 Participants

Collaborators: 23andMe, NIH

Innovation Timeline

2012

1ST VIRTUAL RESEARCH STUDY FOR PARKINSON'S DISEASE

2014

1ST VIRTUAL RESEARCH STUDY FOR HUNTINGTON'S DISEASE

mPower

2015

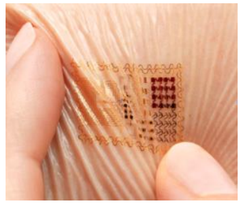
1ST APPLE RESEARCHKIT APP FOR A NEUROLOGICAL DISORDER

2017

1ST MOBILE APP FOR HUNTINGTON'S DISEASE

2018

1ST LONGITUDINAL WEARABLE SENSOR STUDY FOR HUNTINGTON'S DISEASE



2019

1ST BIO-SENSOR USE IN PHASE III DRUG TRIAL FOR HUNTINGTON'S DISEASE

WATCH-PD

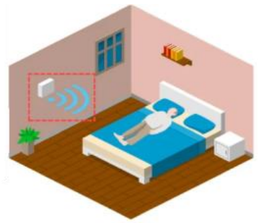
2020

1ST LONGITUDINAL MULTI-SITE DIGITAL TECHNOLOGY STUDY IN EARLY PARKINSON'S DISEASE

UR-Udall

2021

1ST MULTI-FACETED STUDY ON PARKINSON'S DISEASE PROGRESSION, REMOTE ASSESSMENT, AND DIGITAL TOOLS FOR REAL WORLD ASSESSMENTS



2022

1ST STUDY TO IDENTIFY PARKINSON'S DISEASE SIGNALS AT HOME USING ARTIFICIAL INTELLIGENCE-ENABLED DETECTION

Novel Digital Studies

WATCH-PD

132 Participants
Evaluate the ability of sensors to assess features and progression of symptoms in early, untreated Parkinson's disease. Sensor assessments at home and in the clinic are compared to traditional in-person assessments.

IN COLLABORATION WITH

Biogen

Takeda

Scratch and Sleep Quantification in Atopic Dermatitis (SQUAD)

45 Participants
Assess the use of wearable devices, sensors, polysomnography, and video to detect and quantify scratching. Evaluate the relationship between patient-reported outcomes and scratching and sleep metrics from wearable devices and sensors.

IN COLLABORATION WITH

Pfizer

AT-HOME PD

220 Participants
Evaluate clinical outcomes using video visits in a virtual national observation study. Capture real-world data using a Parkinson's disease-specific smartphone application.

IN COLLABORATION WITH

NIH National Institutes of Health

MGH 1811 MASSACHUSETTS GENERAL HOSPITAL

SageBionetworks

NORTHWESTERN UNIVERSITY

Virtual Cohort of LRRK2 Carriers

277 Participants
Recruit and retain a national cohort of LRRK2 carriers with and without PD in collaboration with 23andMe. Follow cohort via video visits and prospectively characterize cohort and compare it to those of traditionally-established LRRK2 cohorts.

IN COLLABORATION WITH

23andMe

NIH National Institutes of Health

“I like to compare our understanding of Parkinson’s to a street lamp in the night; we only get a glimpse of the disease when patients visit clinic. Moreover, the methods we use to track the disease over time are subjective. As a result, we have a very limited insight into how Parkinson's disease impacts people's daily lives. This study shows that remote monitoring has the potential to identify individuals with Parkinson’s and create an objective measure of severity and progression. This could be a powerful tool to detect the disease early and conduct research more efficiently.”

— Ray Dorsey, M.D., a professor of Neurology at the University of Rochester Medical Center (URMC)

Current approach to measuring Parkinson disease outcomes

We are in the dark

Proportion of day with tremor

Variability in motor function

Number of words spoken

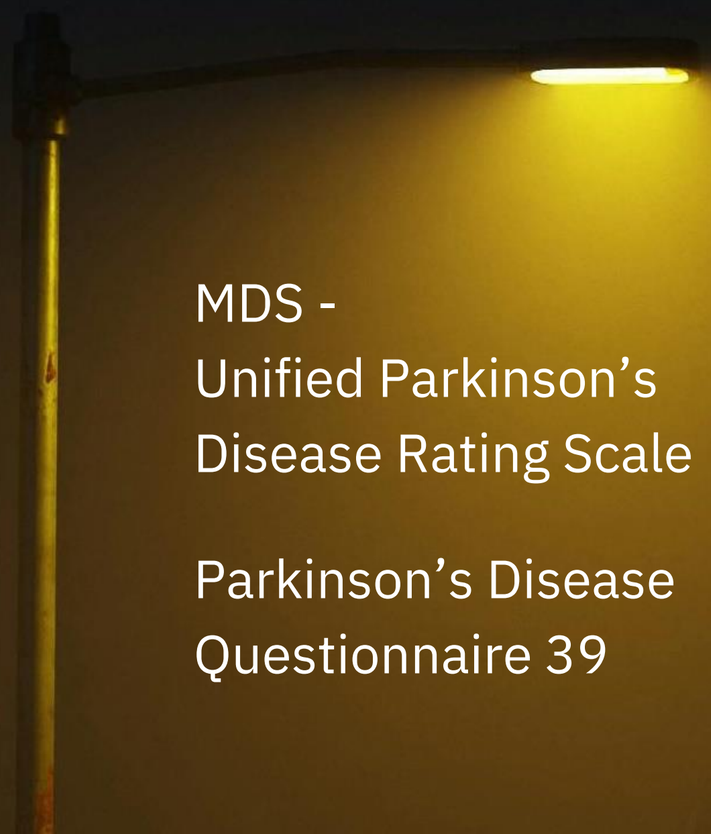
Proportion of day spent sedentary

Time spent alone

Number of steps taken

Time spent outside the home

Autonomic function at home



MDS - Unified Parkinson's Disease Rating Scale

Montreal Cognitive Assessment

Parkinson's Disease Questionnaire 39

Timed Up and Go

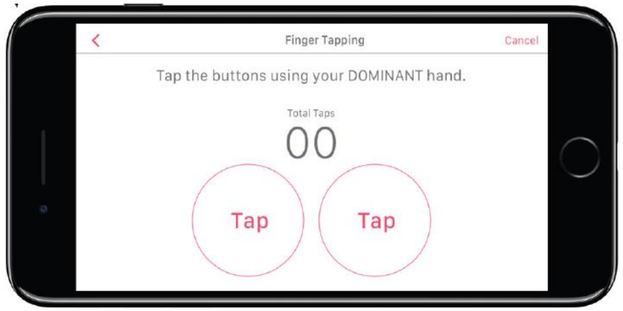
Three Technologies Utilized in WATCH-PD

Smart Watch

The Watch has sensors that detect tremor, gait, balance, and other features of movement. Participants completed a set of motor activities while wearing the watch.

Smart Phone

A customized app provided a convenient way to collect frequent, objective data. Participants perform a set of motor and cognitive assessments on the phone.

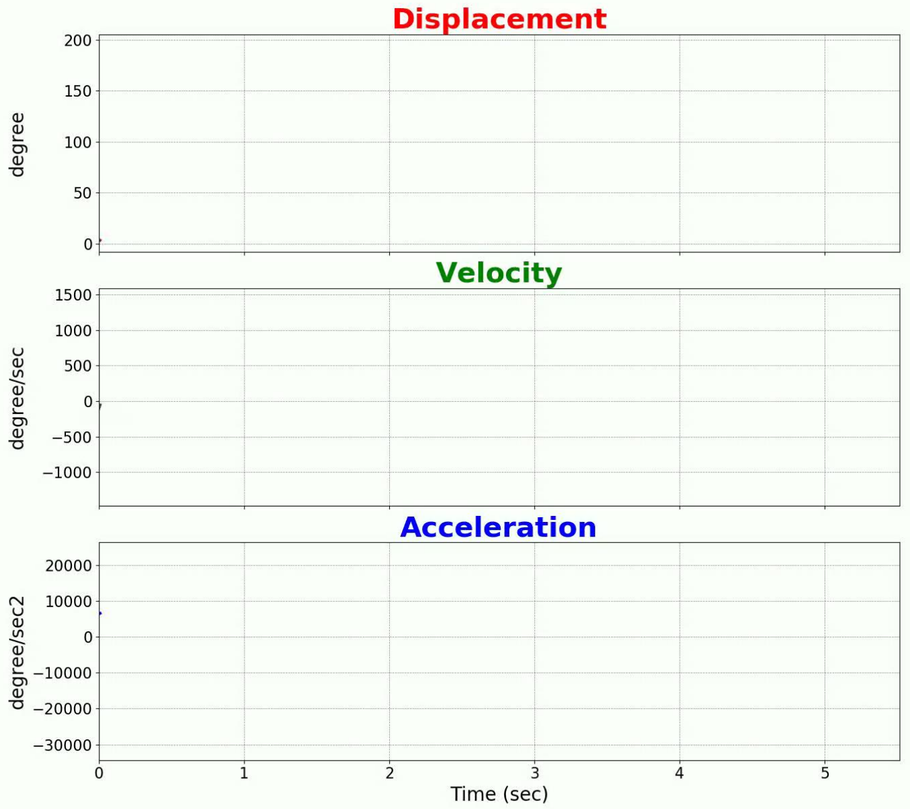


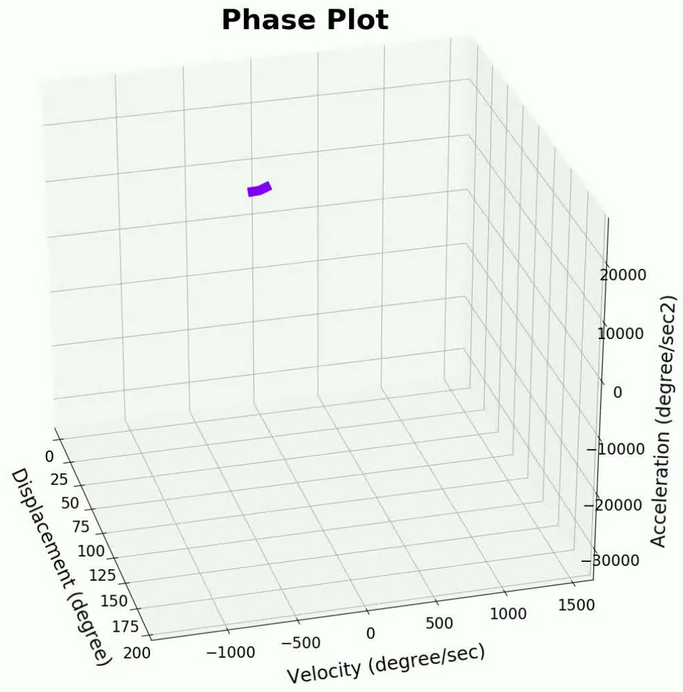
Sensors

Sensors make up a state-of-the-art system for measuring many aspects of movement.

Visualizing Movement Data: Wrist Rotations

Pronation-Supination Task

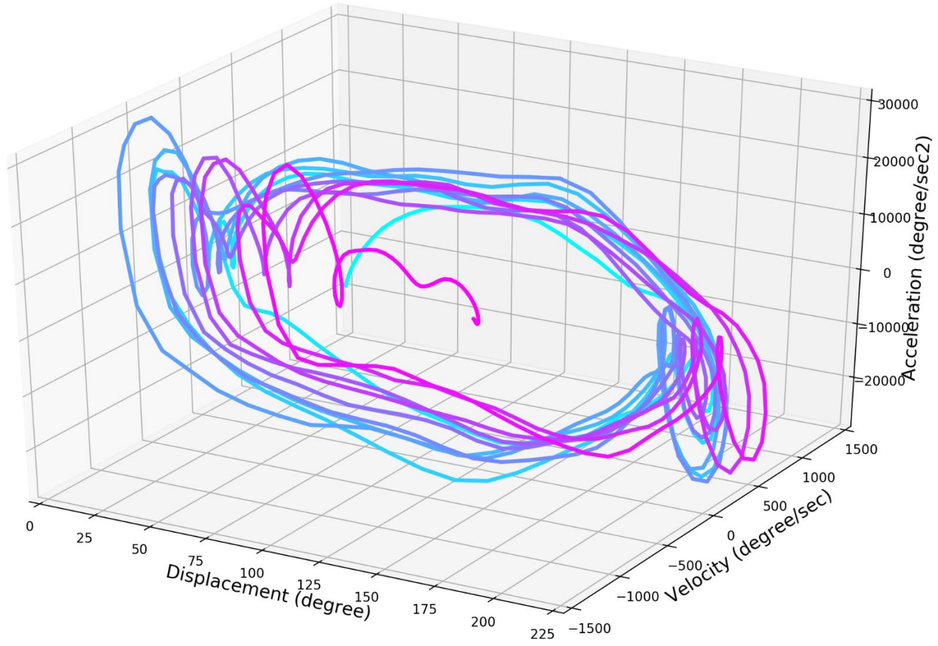




Wrist Pronation/Supination: Control vs. Parkinson’s

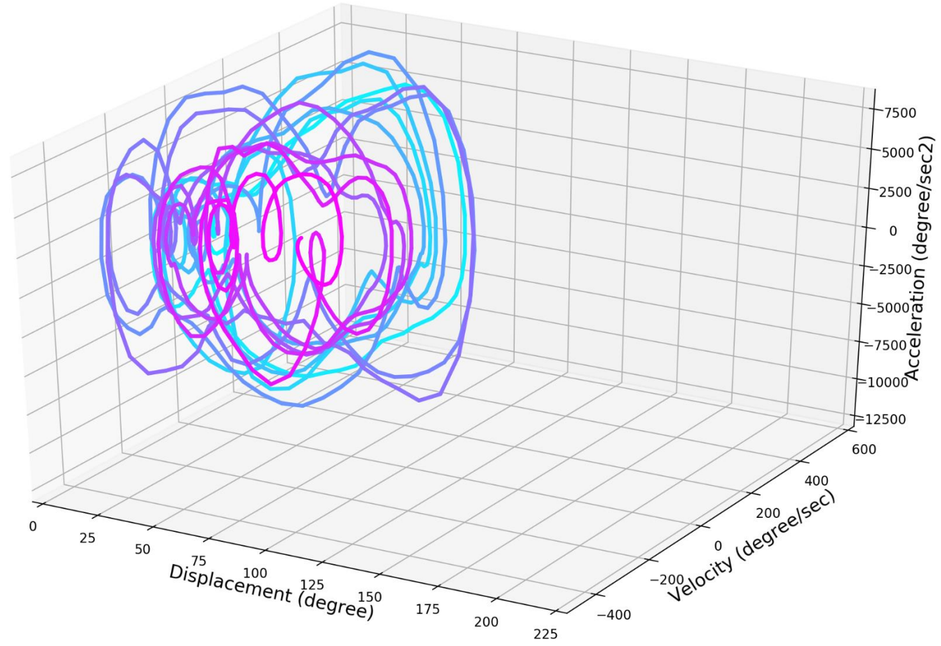
Control Participant

Subject: S136-7281, Visit: V01, Task: left_wrist_rotations, Tpt: 1, Segmenter: mtruskin

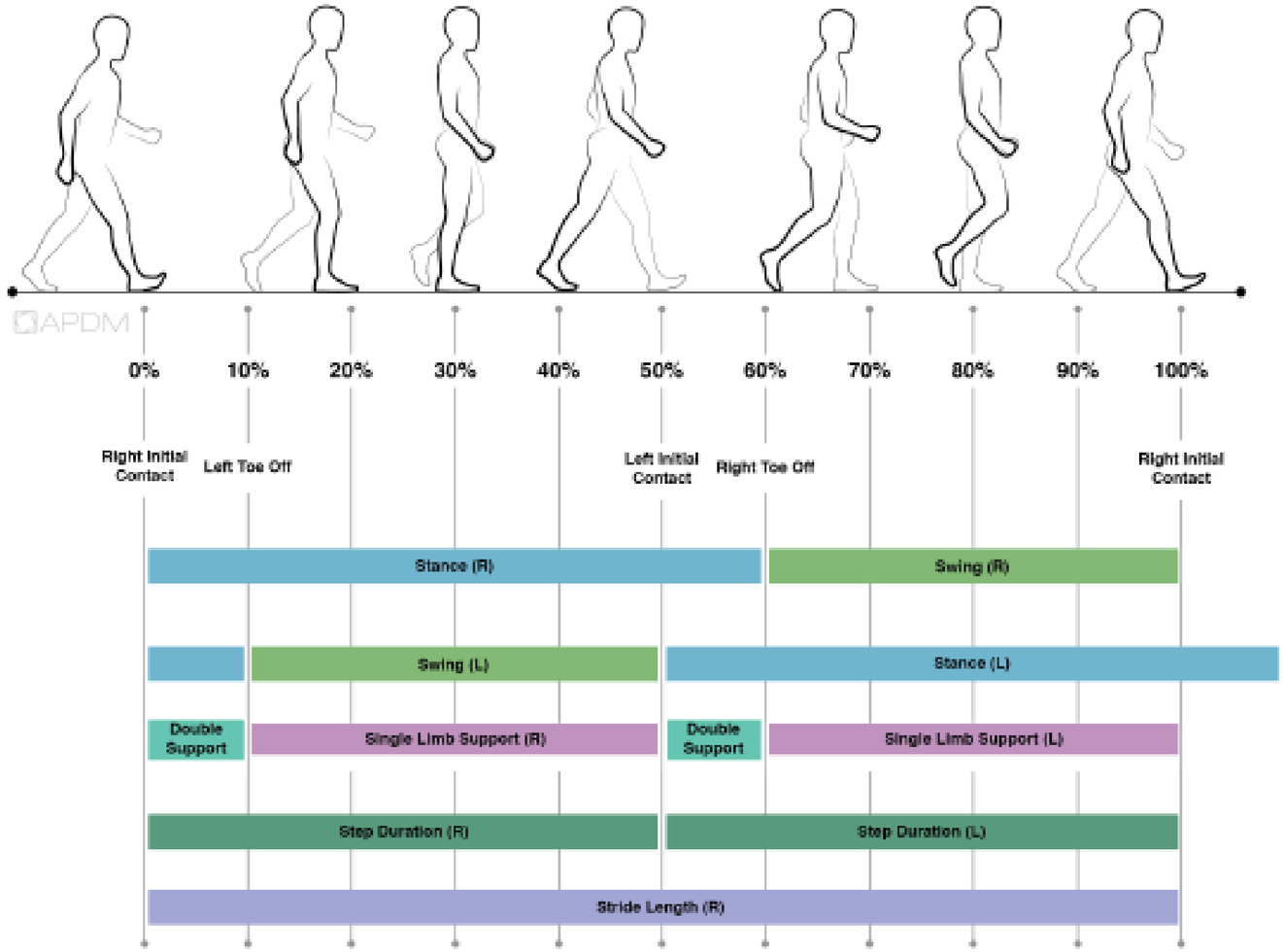


Parkinson’s Disease Participant

Subject: S001-7004, Visit: V02, Task: left_wrist_rotations, Tpt: 1, Segmenter: eremingt



Gait Outcome Measures



- Stride Length
- Gait Speed
- Foot Strike Angle
- Arm Swing Range of Motion
- Double Support
- Arm-Swing Velocity
- Lateral Step Variability
- Lumbar Range of Motion

Passive Data Collection

- Steps Taken
- Heart Rate
- Sleep history
- Presence of Tremor, Severity, and Fraction of time with Tremor
- Time spent horizontal vs. sitting vs. standing
- Falls
- Noise levels

CHeT

CHeT Health

CHeT Outcomes

CHeT Analytics

CHeT Innovation

Clinical Trials Coordination Center

Clinical Materials Services Unit

Clinical Trials Coordination Center (CTCC)

The Clinical Trials Coordination Center (CTCC) specializes in the development, management, and conduct of clinical research studies.

- Provides a full range of research and clinical trial management support services that facilitate the conduct of clinical research from study concept through data analysis, publication, and FDA approval.
- Over the past **30 years**, the CTCC has managed the conduct of over **135 clinical research studies with 50 sponsors** (government, industry, & private) that enrolled **over 40,000 research participants spanning over 200+ sites** in Australia, Austria, Canada, France, Germany, Italy, New Zealand, Norway, Poland, Spain, Sweden, United States, Netherlands, and the United Kingdom.

200+
Credentialed Investigators

14
Countries Where We've Conducted Trials

30
Years of Experience

Clinical Trials Coordination Center

Study Start-Up (including but not limited to the following): Novel and adaptive trial design; Protocol development and training; Contract facilitation and negotiation; Site selection based on key performance indications and research study datasets

Monitoring: Remote, risk-based quality management, and on-site

Data Management: Clinical Data Management System (21 CFR part 11 compliant); Data sharing, Visualization, and Data standards (CDISC, STDM, CDASH, CDE)

Clinical Trial Rescue and Recovery: Provide services to revamp, refocus, and revitalize your clinical trial

Investigational New Drug/Device Exemption support

Statistical analysis, modeling, and data mining

CTCC has the infrastructure to conduct worldwide, high quality, regulatory-compliant, and multi-center clinical research:

- 200+ credentialed investigators and coordinators
- Direct web-based data entry and ePRO
- Access to 100+ research study datasets
- Data visualization tools and templates
- Clinical Trial Management Systems (21 CFR part 11 compliant)
- 60+ SOPs and guidelines for audit readiness

CTCC Infrastructure

- Project Management
- Data Management
- Quality Management
- Site Monitoring
- Risk-Based Monitoring
- Medical/Safety Monitoring
- Analytic Database Integration
- Data Mining
- Biostatistics/Data Modeling
- Adjudication Committees
- Finance/Contract Administration
- Vendor Management

CTCC Singular Services

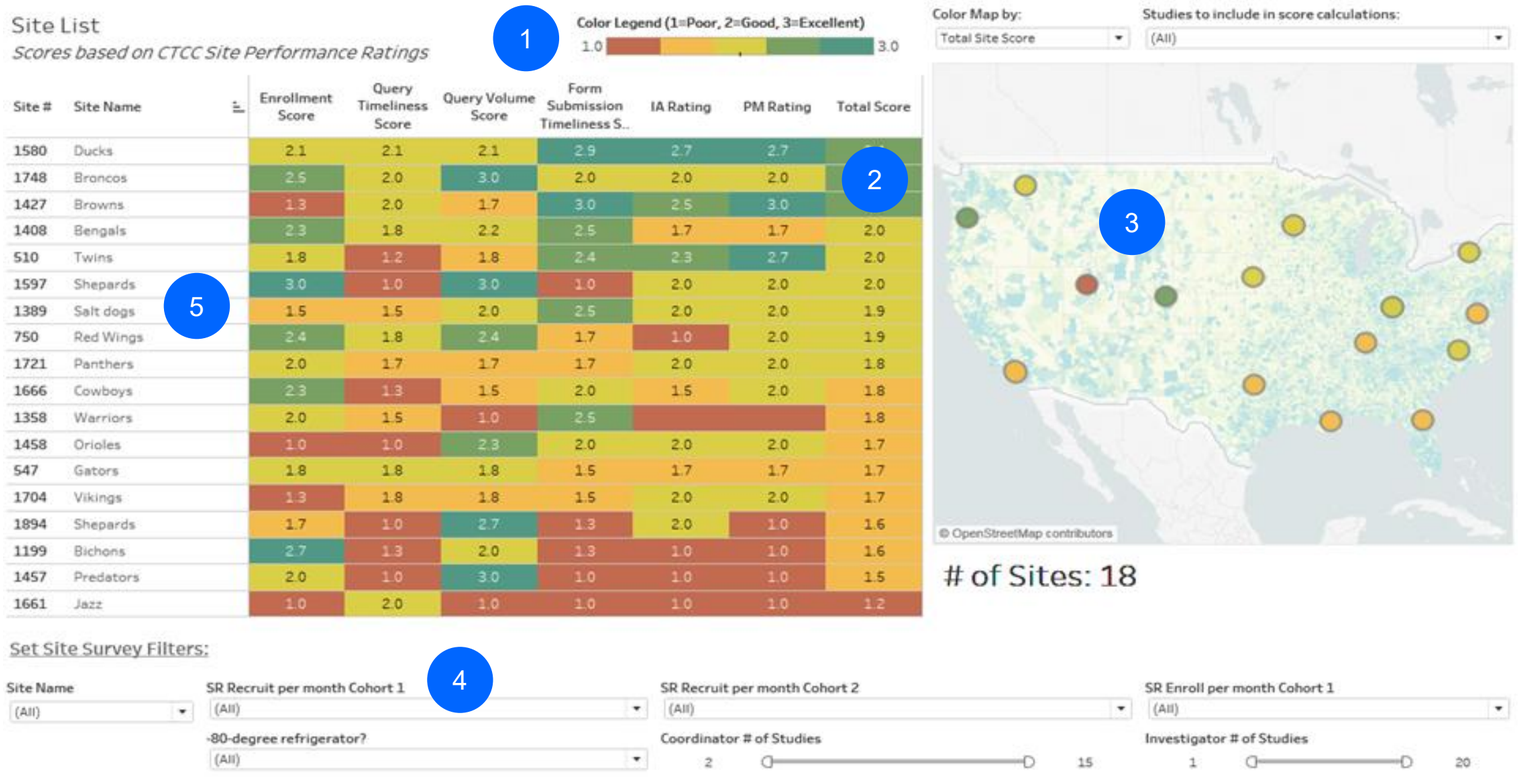
- **Study Documentation Writing**
  - INDs
  - Protocols
  - Consent Forms
- **Database Build**
  - RedCap
  - TrialMaster (21 CFR Part 11 Compliant)
- **Database/Study Reports**
- **Data Review and Cleaning**
- **Monitoring Services**
  - On-Site Monitoring
  - Remote Monitoring
  - Risk Based Monitoring Services
- **Regulatory Support Services**
- **Development of Recruitment Materials**
- **Data Visualization**

Data Visualization Tools for Efficient, Comprehensive Site Selection in a Multi-Center Clinical Trial

Cindy Casaceli[1], David Penz[1], and Melissa Kostrzebski[1]

1.Center for Health + Technology, University of Rochester

Visualization of Performance Metrics



1. Metrics from multiple data sources were combined onto one view.
2. Sites can be sorted by a total rating score that factors in multiple metrics.
3. Maps can be used to view sites that are in close geographic proximity.
4. Filters can be used to include sites based on survey answers.
5. Clicking a site opens a display containing more information about that site.

Objective

To pilot the use of the Tableau© data visualization tool to facilitate and reduce the time required to complete site selection for the NILO-PD study.

Background

Traditional approach to selection process has been a challenge due to:

- Difficulty comparing multiple documents
- Decision making based on data silos
- Limited data visualization in Excel

Site selection meetings would typically take over 2.5 hours due to these challenges

Methods

Data was collected and merged from survey responses from potential sites, historical performance ratings, and participation in other CTCC studies. The site selection tool was built using Tableau software to integrate this data and facilitate the site selection conversation.

Conclusion

Dynamic interactivity of the tool allowed for ‘what if’ scenarios to be explored and presented, leading to a 40 % decrease in time (1hr Meeting) to select final sites with quality metrics driving conversation.

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CLINICAL MATERIALS SERVICES UNIT [CMSU]

CHET CMSU
CENTER FOR HEALTH + TECHNOLOGY

FDA DRUG APPROVALS

CMSU played a pivotal role in obtaining FDA approval for these drugs by providing comprehensive secondary packaging, labeling, storage, and distribution services for the pivotal studies leading to approval.

APPROVED
2015

KEVEYIS®

KEVEYIS®
dichlorphenamide 50 mg tablets

An oral carbonic anhydrase inhibitor indicated for the treatment of primary hyperkalemic and hypokalemic periodic paralysis

TARO

APPROVED
2020

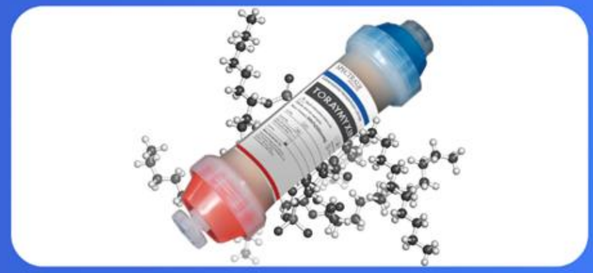
WYNZORA®

A once-daily, topical, fixed-dose combination cream for plaque psoriasis in adults

mc2 therapeutics

GRANTED BREAKTHROUGH DEVICE DESIGNATION
2022

PMX
(TORAYMYXIN™ PMX-20R)



A Polymyxin B extracorporeal direct hemoadsorption column which is highly effective in removing endotoxin in the bloodstream

SPECTRAL INC Medical

Clinical Materials Services Unit (CMSU)

The Clinical Materials Services Unit (CMSU) offers comprehensive clinical trial supply services including:

- Secondary packaging and labeling of clinical trial materials (drugs and devices)
- Package development, integrity, & performance testing
- Label design and printing using ClinPro LBL™ (21 CFR part 11 compliant)
- Storage options (room temperature and 2-8ºC)
- Clinical supply chain strategy & management
- Secure environment
- Returns management/destruction
- Kit design to align with dispensing visits
- Creation of drug accountability logs and operations/pharmacy manuals
- Presentation of drug/device supplies at Investigator Meetings
- Management of expiration/retest dates

CMSU vs. IDS Services

CMSU (Think Wholesale/Bulk)

- Multi-center studies (2 or more sites) requiring shipments across State lines
- Large single center (U of R) studies requiring significant volumes of drug and larger kit configurations
- Contact:
  - Eileen Fannon, Sr. Director CMSU
  - Christopher Mark, Director Operations CMSU
- Main phone number: 350-3838
- Email: cmsu-BD@cmsu.rochester.edu

IDS (Think Pharmacy - Rx)

- Per-subject dispensing
- Provide service for single center U of R run studies
- Same range of services as have always been provided, including over encapsulation, compounding etc.
- Contact Kyle Richards: 275-6275

CHET

Contact Us:

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