Clinical Trial Services

Drug and Device Discovery Collaboration

Does Cincinnati Children's support collaborative efforts with industry?

Yes, we believe that partnerships between industry and our top tier researchers can lead to new discoveries that can improve outcomes for pediatric populations. Cincinnati Children's has more than 1,100 investigators pursuing studies in most of the major pediatric sub-specialties.

Protocol Development

Are Cincinnati Children's specialists available to collaborate with pharmaceutical sponsors to develop new pediatric protocols?

Yes. As a large academic medical and research center, we have staff with expertise and extensive experience with developing early phase pediatric protocols for clinical trials. Sponsors may contact the OCTR if they would like to partner with an investigator for science/medical input and and haven't identified one.

Do your services include study design optimization?

Yes, our pediatric-specific insight and experience can lead to the most effective study design and optimize time-to-market for pediatric drug development, which reduces overall cost.

Do you provide pharmacokinetic modeling/simulation?

Yes. We have extensive experience in pediatric pharmacokinetic modeling and simulation to support pediatric study plans.

Why should I partner with Cincinnati Children's for pharmacometric services?

The pharmacometric services at Cincinnati Children's offer extensive expertise in quantitative pharmacology and population pharmacokinetic/pharmacodynamic (PK/PD) modeling. Our sophisticated modeling and simulation software enables more effective trial design and helps meet the challenges of a limited patient population.

The lead for our pharmacometric services, Alexander Vinks, PharmD, PhD, director of the Division of Clinical Pharmacology, has more than 20 years in the field of therapeutic drug monitoring and applied pharmacokinetics, both in the research aspects of population pharmacokinetic studies, as well as in the clinical application of these approaches to clinical patient care. Also, because Dr. Vinks serves as an advisor on an FDA pediatric sub-committee, we offer clients extensive knowledge of the FDA review process. Our team can coordinate the entire process, from developing the study design and writing the pediatric-specific clinical protocol to implementing the protocol and analyzing data. This gives sponsors one-stop convenience and provides the cost efficiencies of a single location.

Does Cincinnati Children's have research connections with other pediatric and adult networks?

Not only can Cincinnati Children's provide expertise in the protocol development, it may provide access to pediatric and adult research networks to conduct the trial. In addition, Cincinnati Children's has the ability to function as the lead site for your study.

Biostatistics and Data Management Clinical Trial Support

Can you provide clinical data management support for clinical trials?

Yes. We have clinical data managers with more than 10 years of industry experience in supporting clinical trials including managers certified by the Society of Clinical Data Management.

Do you have a clinical data management system?

Yes. Cincinnati Children's has licensed Medidata Rave®, which is an industry-leader in electronic data capture and is a 21 CFR Part 11 compliant system. We have certified Rave builders on staff.

Do you provide statistical support for clinical trials?

Yes. We have statisticians with more than 20 years of experience supporting pharmaceutical trials. The statisticians are available to participate in study design, development and execution of statistical analysis plans.

Is statistical programming support for clinical study reports available through Cincinnati Children's Clinical Trial Services?

Yes. We have certified SAS programmers who will provide tables, figures, and listings for incorporation into clinical study reports.

Regulatory Affairs and Trial Operations

Does Cincinnati Children's have regulatory professionals on staff?

Yes, our regulatory affairs professionals with pharmaceutical and medical device experience manage IRB and FDA submissions, regulatory files, SAE/AE reporting, FDA/NIH reports and DSMB reports. In addition, the regulatory affairs specialists provide training, quality review and audit preparation.

Are there staff members who have multi-site experience?

Yes, the experienced regulatory, operations, and management teams have a successful track record of operationalizing and managing multi-site trials. Experienced teams serve as central coordinating and regulatory coordinating centers for multisite trials.

Does Cincinnati Children's have experienced clinical research associates on staff?

Yes, experienced monitors well versed in FDA regulations, monitoring visits, creation and execution of monitoring plans, ICH guidelines and GCP provide training, study start-up and SIVs. They are on staff to ensure investigators meet regulatory requirements and obligations.

Investigators

How many potential investigators?

Cincinnati Children's has more than 1,100 investigators in most of the major pediatric sub-specialty areas.

Is additional investigator background available on request?

Yes, more information may be obtained once an investigator has been identified including:

- The patient population to which the investigator has access
- The investigator's research study experience
- The number of research studies the investigator has conducted and in which specific disease(s)/condition(s)

Will one PI and/or study coordinator be able to attend the investigator meeting?

Yes

Will the PI be available during the monitoring visit to meet with the CRA (with advance notice)?

Yes

Site Management

Is Cincinnati Children's part of a site management organization (SMO)?

No

Institutional Review Board

Is the use of a central Institutional Review Board/Ethics Committee (IRB/EC) permitted?

Depends on the circumstances. In most instances, we use our own local IRB, but there are instances where we will rely on an outside IRB.

How often does the local IRB meet?

Weekly, every Tuesday.

What is the submission time prior to a meeting?

There is no submission deadline. Submissions are reviewed on a first come, first serve basis.

Are there internal committees that must approve the study prior to final IRB approval?

Yes, additional ancillary reviews (such as division, radiology, etc.) are required for certain projects. All of these reviews are embedded within the IRB application process.

What is the turnaround time for written approval documentation?

For a full board, new study submissions are typically 6 to 8 weeks from the time the submission is made. Additional submissions vary based on type of submission and level of review required.

Has the FDA, EMEA, or other regulatory authority audited Cincinnati Children's?

Yes, as a large research institution, we have experience with various inspections by regulating agencies. The PI can provide specific details regarding their personal experiences.

When?

Specific audit results are available from the department or division where applicable.

What is the IRB complete name and address?

Cincinnati Children's Hospital Medical Center
Institutional Review Board
3333 Burnet Avenue, MLC 5020
Cincinnati, OH 45229-3039

Is there a need to have informed consent forms translated into other languages?

Occasionally, based on study population, translated documents may be needed. Verbal translation services during visits are available.

Do you use off-site storage?

Yes

Access Document Management
690 Crescentville Road
Cincinnati, OH 45246-1314
513-671-7717

Contracts and Budgets

Will Cincinnati Children's accept a unilateral CDA?

No, Cincinnati Children's requires a mutual CDA prior to sharing confidential information.

Do you require the contract and budget to be finalized before submitting to the IRB?

The contract and budget process can occur in parallel with the regulatory processes. However, this is a division/PI level decision.

Is the division or PI responsible for budget negotiations?

All industry sponsored budgets are negotiated and approved through the Sponsored Research Service (SRS) in collaboration with the division.

Can budget negotiations start with a draft protocol?

The final protocol, CTA and proposed budget must be received prior to initiating any budget or contract negotiations.

Payment Information:

Checks should be made payable to:

Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Research Billing, MLC 4900
Cincinnati, OH 45229-3039

Please reference PI name and protocol number.
Tax ID # 31-0833936

Research Facilities

Is there designated research space?

Cincinnati Children's has approximately 1,425,000 square feet of research facilities. This includes monitor rooms, pediatric- and adult-friendly exam/treatment rooms, and waiting areas.

Are there onsite investigational pharmacies with locked storage?

Yes

Are there onsite laboratory facilities?

Yes

- Central Laboratory
- Multiple specialty laboratories

The Clinical and Translational Research Center (CTRC) and the Schubert Research Clinic

The CTRC, as part of the Center for Clinical & Translational Science & Training (CCTST), provides resources that enable investigators to perform high-quality, patient-oriented research at various venues across the Academic Health Center and the community.

The CTRC outpatient service is operated inside the Schubert Research Clinic, which is located on the first floor of the Clinical Sciences Pavilion (aka "Location T") on the Cincinnati Children's main campus. It includes 28 exam rooms, one preparatory lab with equipment for processing samples, a packaging and shipping room for clinical research samples, a metabolic kitchen for nutritional studies and teaching, body composition laboratory with DXA scanners, a vascular research laboratory, and 3T magnetic resonance imaging.

The clinic can accommodate visits of less than 30 minutes to greater than 10 hours and is equipped for all participants from infants to seniors. It is fully staffed with 42 highly trained and skilled nurses, dietitians, medical assistants, research assistants, study coordinators and registration staff. The CTRC also has admission privileges for a dedicated 12-bed inpatient unit located on the main campus for overnight (23-hour short stays and sleep studies) and inpatient research admissions.

Access to the clinic is open to any Cincinnati Children's clinical researcher with a currently approved IRB study. This new clinical sciences building makes Cincinnati Children's the nation's largest pediatric research center.

Investigational Drug Service

Does CCH have access to a pharmacy for research?

Yes, the CCH Investigational Drug Service (IDS) provides services customized to each research protocol conducted at CCHMC. These services include randomization, inventory maintenance, all aspects of drug accountability, compounding and preparation of blinded dosage forms, developing pre-printed order forms, and dispensing investigational drugs according to protocol. The IDS is responsible for both inpatient and outpatient investigational medication dispensing for industry sponsored, grant funded and investigator-initiated protocols.

The current IDS staff includes 4 pharmacists, as well as one pharmacy technician. The IDS is located on the CCHMC Burnet Campus, location T, room T2.600, directly above the Schubert Research Clinic. The pharmacy occupies 1800 square feet of space for drug storage, preparation and office space for the staff. A satellite IDS pharmacy is also operated at the CCHMC Oak campus serving as the pharmacy for the Gamble Program/Vaccine and Treatment Evaluation Unit. The IDS is responsible for the pharmacy activities for all clinical trials conducted at CCHMC and currently manages drug inventory and dispensing for over 300 active protocols.

Are IDS and SRC staff considered research study staff?

No, the policy at CCH is that all IDS and SRC staff are working within the limits of their job description and responsibilities. As such, they are not considered study staff and are not listed on the Delegation of Authority log. Please note that there may be other hospital staff that are covered under this category.

Does IDS have a drug accountability system?

Yes, they use the Vestigo system.

Vestigo is an application to support investigational drug services for the management of the drug therapy used as part of a research protocol. Vestigo features tools to assist with the protocol management, full electronic virtual inventories with drug accountability, dispensing and labeling of prescriptions, protocol billing management and reporting.

What is the IDS shipping address?

Cincinnati Children's
Investigational Drug Service
3333 Burnet Avenue, MLC 1011
Cincinnati, Ohio 45229

Do monitors have access to the IDS for on-site visits?

Yes, the IDS is located at T2.600, and monitors are allowed access to the area. However, monitors should work with each study team (i.e. investigator, study coordinator, etc.) to schedule all visits to the IDS. Monitors should not contact pharmacy staff to schedule IDS monitoring directly. All visitors must adhere to all CCH policies governing institutional access and badging requirements.

Can the IDS manage the destruction of drug at study closure?

Yes, the IDS has a policy about drug destruction that is available upon request and can manage the process. Alternatively, drug can be shipped back to the sponsor for destruction.

Does the IDS have temperature monitoring capabilities?

Yes, room temperature is monitored via a min/max thermometer and is logged daily Monday through Friday. Refrigerators/freezers are monitored electronically via a RMMS system. Staff are notified of any alarms after hours via page/text. All equipment is on back-up power.

Electronic Medical Records (EMR)

Is the EMR validated or is it certified by the Office for the National Coordinator for Health Information Technology (ONC)?

Yes. The EMR is validated, meaning documentation exists to verify that the system was installed correctly and that all functions have been tested to ensure they accurately, reliably, and consistently perform as intended. The EMR is certified and system certifications are available on the ONC website.

Is the EMR used for research purposes?

No, the EMR is not Part 11 compliant for use in research. Research documentation is stored in paper format or within a Part 11 compliant system.

Are unique user IDs and confidential passwords required to access the EMR and are regular password changes required?

Yes. Password updates are required at a regular frequency established by organizational policy.

Does the EMR have an audit trail to track entry of and changes to data, including recording date/time/author of data creation, change, or deletion? Can audit trail information be made available for review upon request?

Yes and yes.

Is there documented training for persons that use and maintain the EMR?

Yes

Are written procedures in place for the use/operations/maintenance of the EMR system?

Yes

Will external study monitors have direct read only access to the EMR? If so, will the access be limited to study participants and require a unique user ID and password?

Site research staff will review access options and choose the method best suited to the study. Monitors may be provided with print outs from the EMR which meet the criteria for certified copies, can complete an assisted review by spot checking EMR records in the presence of site research staff, or can be granted access to review EMR records for specific research participants via the EpicCare Link web platform. If the EpicCare Link review option is chosen, the monitor will be asked to complete an electronic agreement and assigned a unique user ID and password. Monitor access is read only, limited to research study participant records, and can occur onsite or remotely.

Is the EMR system periodically backed up? Are data retention periods compliant with local regulations?

Yes and yes.

Equipment for Research Trials

Is a -70°C/-20° C specimen storage freezer available? If so, are the freezers alarmed and monitored?

Yes. Freezers are available and monitored 24/7 by an automated centralized electronic system.

What other equipment is available?

Other available equipment includes (but not limited to):

- 12-Lead ECG
- Refrigerator
- Treadmill
- Pulse Oximeter
- Ultra-sonic Nebulizer
- Metabolic Cart for CPET
- Body Plethysmograph (Body Box)
- Non-Refrigerated Centrifuge
- Refrigerated Centrifuge
- Cycle Ergometer
- Access to dry ice

Participant Recruitment and Retention Tactics

The Office for Clinical and Translational Research (OCTR) marketing staff works with Cincinnati Children's researchers to assess recruitment needs of research studies, construct plans, and implement actions that ensure targeted and effective recruitment and retention efforts. The OCTR marketing staff have marketing and communications degrees, as well as extensive professional experience in health care marketing, advertising, public relations and communications.

Recruitment

Depending on the individual recruitment and retention needs of the study (and the extent of the recruitment budget), a participant recruitment plan is customized using various appropriate strategies and tactics. Some of the recruitment tactics include:

- Printed materials including flyers, posters, brochures, postcards, etc.
- 80-plus recruitment stations (within Cincinnati Children's facilities and in the community), each displaying 10–36 branded individual clinical study flyers (specifically targeted to that location's demographics, when possible). Study information from recruitment stations has been very effective with minority population recruitment.
- Internet and intranet—using the Cincinnati Children's web site, local and national support association web sites, targeted web advertising
- Email—using Cincinnati Children's internal email system (Outlook) to more than 18,000 email boxes. Study information is frequently forwarded to family and friends in the community.
- Social media organic posts on Facebook (facebook.com/cincinnatichildrensstudies), and Pinterest (pinterest.com/cincykidstrials)
- E-newsletter/updates sent to database of interested potential participants/households
- Paid advertising through work with our Cincinnati Children's approved marketing agency; includes Facebook and other social media ads, TV, radio and print ads
- Community events such as school and community health fairs where face-to-face contact may be made and study materials distributed
- Public relations activities through collaborations with Cincinnati Children's Marketing and Communications Department including local and national television, radio, internet, print and other media opportunities
- Support groups—partnering with community support groups (locally and nationally) to disseminate study information through group web sites, networks, newsletters, special events/meetings and in-person presentations

Retention

Participant retention tactics are tailored to the individual needs of each study. Some of the retention tactics include:

- Creating branded participant reminder notes, birthday cards, magnets, stickers, appointment cards, post cards, mugs and many more appropriate promotional items
- Developing special promotions to encourage/remind participants of required compliance, an appointment or other study related activity
- Facilitating the creation of study specific web sites to communicate/interact with the study population
- Coordinating, writing and publishing study newsletters—both electronic and hard-copy versions
- Cultivating relations with internal and community support groups to pursue joint ventures in order to reach their constituents (and families) via their communication tools, networks and special events
- Planning special events and group activities for study participants
- Identifying and branding appropriate small recognition gifts and certificates for participants to foster a sense of accomplishment and recognition for reaching study goals

Race and Gender of Cincinnati Children's Patients

Race	
White	67.4%
Black	18.9%
Other	8.1%
Asian/Pacific	2.3%
American Indian or Alaskan Native	0.13%
Native Hawaiian/Other Pacific Islander	0.16%
Unknown	0.15%

Gender	
Female	50.5%
Black	49.1%