

# SPONSOR'S GUIDE TO CLINICAL TRIALS



[sidra.org](http://sidra.org)

سدرة للطب  
Sidra Medicine



## Welcome To Sidra Medicine Clinical Trials Collaboration

Sidra Medicine represents the vision of Her Highness Sheikha Moza bint Nasser who serves as its chairperson. This high-tech facility is home to world-class patient care, scientific expertise and educational resources.

Sidra Medicine is part of a dynamic research and education environment in Qatar and through strong partnerships with leading institutions around the world, we are creating an intellectual ecosystem to help advance scientific discovery through investment in medical research.

Based in Education City and as an entity of the Qatar Foundation for Education, Science and Community Development, Sidra Research feeds into Qatar Foundation's educational strategies. Education City includes leading international institutions such as Weill Cornell Medicine-Qatar, Georgetown University,

Carnegie Mellon University, and HEC Paris as well as recently established national research centers like Qatar Biomedical Research Institute and Qatar Environment and Energy Research Institute.

We work closely with academic partners like Weill-Cornell Medicine in Qatar (WCM-Q) and Qatar University (QU) as well as other health and research institutions like Hamad Medical Corporation (HMC), Primary Health Care Corporation (PHCC) and Qatar Biobank – raising the standard of healthcare throughout the country and providing valuable opportunities for research and learning.

Our distinguished children's specialist services encompasses the following areas:

## Children & Young People's Services

|                          |                                  |                         |
|--------------------------|----------------------------------|-------------------------|
| Adolescent Medicine      | Genetic and Genomic Medicine     | Qatar Poison Center     |
| Allergy and Immunology   | Hematology and Oncology          | Rehabilitation Medicine |
| Cardiology               | Infectious Diseases              | Rheumatology            |
| Dental                   | Intensive Care                   | Sidra Child Advocacy    |
| Developmental Pediatrics | Mental Health                    | Program (SCAP)          |
| Ear, Nose and Throat     | Neonatology                      | Sleep Lab               |
| Emergency                | Nephrology                       | Urology                 |
| Endocrinology            | Neurology                        | Wellness Clinic         |
| Eye Care                 | Neurosurgery                     |                         |
| Gastroenterology         | Orthopedic                       |                         |
| General Pediatrics       | Plastic and Craniofacial Surgery |                         |
| General Surgery          | Pulmonology                      |                         |

## Women's Services

|                                   |                         |                                                  |
|-----------------------------------|-------------------------|--------------------------------------------------|
| Cord Blood Banking                | Lactation Support       | Physiotherapy                                    |
| Emergency                         | Maternal Fetal Medicine | Reproductive Medicine and In Vitro Fertilization |
| Endocrinology                     | Menopause               | Sleep Lab                                        |
| Fetal Diagnostics and Imaging     | Mental Health           | Ultrasound                                       |
| Gynecology                        | Obstetrics              | Urology                                          |
| Internal Medicine and Pulmonology | Pain Management         | Weight Management                                |

Moreover, it stands as the sole specialist center in the region offering comprehensive care for children with rare disease and pregnant women facing fetal complications. Through its state-of-the-art facilities and services, Sidra Medicine reflects Qatar's pioneering ethos and unwavering dedication to human and social advancement.

Thank you for considering a collaboration with Sidra Medicine for your Clinical Trials. This document outlines the steps and requirements for partnering with us to conduct Clinical Trials.



# Clinical Trials Office (CTO) Scope



## CTO Services Provided

- 1 Study Start up, Activation & Conduct
- 2 Compliance and Quality Assurance
- 3 Training and Mentoring
- 4 Regulatory Support
- 5 Clinical Trials Unit (CTU) a dedicated ward for clinical conduct of clinical trials at Sidra.
- 6 Study Closure
- 7 Study Support Activities
  - Project Management
  - Data Entry and Quality
  - Participant Recruitment
  - Clinical Monitoring
  - Safety Monitoring
  - Logistical Support
- 8 Grant funded academic research studies

# CTO Scope and Services



## Operational Support

Providing Sidra's Investigators support to ensure seamless clinical trial operations both for academic and industry sponsored clinical trials - Covering project management, quality control, participant recruitment, site monitoring and logistical coordination to maintain efficiency, compliance and data integrity.



## Capacity Building

Enhancing research capabilities through structured training programs, personalized mentoring, and ongoing regulatory guidance-empowering teams with the skills and knowledge required to maintain compliance and deliver high-quality clinical research. CTO operates in accordance with policies and SOPs governed by Sidra's Governance structure.



## Study Life Cycle Management

Overseeing the entire clinical trial life cycle, from initiation to completion, including study start-up activities such as feasibility assessments, site selection, and regulatory submissions; managing day-to-day conduct through participant enrollment, data collection, and monitoring support; and ensuring proper study close-out with final data reconciliation, reporting, and archiving-all in compliance with regulatory and ethical standards.

**CTO serves as a centralized governing office and the primary point of contact for investigators, academia, Sponsors, Pharma companies and Contract Research Organization (CROs).**

# Teams providing Clinical Trial Support



At Sidra, clinical trials are conducted with the collaboration of a dedicated team of professionals, ensuring the highest standards of research and patient care. The Clinical Trials Team work collaboratively to

oversee trial operations, ensure regulatory compliance, coordinate research activities, and provide essential support for the effective conduct of clinical trials

## Core Clinical Trial Team

The core team responsible for conducting and managing clinical trials includes:

**1** Chief Research Officer

**2** Executive Director

**3** Managers

**4** Leads

**5** Research Nurses

**6** Research Coordinators

**7** Officers

# Teams Providing Clinical Trial Support

In addition to the core team, several support functions play a crucial role in providing clinical support for the conduct of trials. These include:

- Principal Investigators and their clinical teams
- Research Nurses
- Research Pharmacists
- Research Laboratory
- Sidra Logistics and supplies
- IT and EMR services



## Chief Research Officer

Sets research direction and goals



## Executive Director

Manages overall trial strategy and resources



## Management

Managers and leads overseeing trials



## Research Team

Principal Investigators, Nurses, Pharmacists and laboratory team conducting research



## Functional Management

Coordinators and officers aiding trials





## Research Pharmacy

At Sidra, all clinical trials investigational product is managed by dedicated research pharmacy team within the main pharmacy. The Research Pharmacy team includes both research pharmacists and pharmacy technicians. The research pharmacy works as per ICH GCP and ensures all trial medication is prepared, dispensed and maintained in the inventory as per protocol.

The research pharmacy team is responsible for secure storage of IMP, temperature monitoring, maintaining accountability and inventory and supplying of IMP as per protocol. The research pharmacy has dedicated and trained staff, a controlled secure space and specific policies and procedure to run a smooth clinical trial service.



## Research Laboratory

The Research laboratory at Sidra has been established as a dedicated lab to cater to clinical trial activities. This space is controlled by the research staff at Sidra who support sample collections, processing, analysis and shipments specifically for clinical trials. This space is dedicated to organizing and complying to central lab requirements for shipments as frequently as required on global trials.



## IT and EMR (Electronic Medical Records) services

The IT and EMR services at Sidra are inherent parts of the CTO procedures where IT systems are used to automate, control and maintain quality of source documents as required by ICH- GCP for Clinical trials. Each Clinical Trial at Sidra is set up as a new project within the EMR system to mimic the schedule of events per specific protocol to ensure high standards and compliance tracking.

# Clinical Trials Unit (CTU)

The Clinical Trial Unit (CTU), established in 2025, is a specialized clinical ward facility dedicated to the patients on clinical trials at Sidra. . Our unit supports a broad spectrum of clinical trials by providing specialized dedicated research space — from trial visits planning and conduct of trial activities in a dedicated space equipped for trial oversight — all while upholding the highest ethical and safety standards.

With its cutting-edge medical facilities and skilled research staff, the CTU facilitates both interventional and non-interventional trials in outpatient and day care settings. Data integrity, participant safety, and confidentiality are our top priorities in every study. By creating a collaborative, creative atmosphere that enables physicians to easily incorporate research into their practice. Our main objective is to support Sidra's overarching vision through the Research Core and turn new scientific discoveries into real health benefits for the communities we serve.



## Key Facility Features

- Adjustable hospital beds and reclining chairs: allowing patients to rest comfortably during observation and recovery periods.
- Continuous vital sign monitoring: including automated equipment for heart rate, blood pressure, oxygen saturation, and respiratory rate, ensuring that any adverse events are quickly detected.
- Emergency response equipment: crash carts, resuscitation equipment, oxygen supply, and suction machines readily available.
- IV therapy capability: infusion pumps and IV poles to administer study drugs, fluids, or supportive treatments as per protocol.
- Privacy Rooms: ensuring each participant has a secure and dignified space for rest and observation.
- Comfort amenities: Pillows, entertainment (e.g. Wi-Fi), and call bells so participants can easily contact staff if needed.
- Clean facility for drug dispensation
- Dedicated Consultation and family rooms for consenting procedures
- Child Friendly waiting areas and registration desks
- Dedicated research nurse



## Dedicated Nursing & Clinical Staff

- Research nurses and trial coordinators monitor patients closely during observation periods.
- The clinical Trials Unit is integrated with the clinical fellowship program at Sidra making clinical trials a hub of capacity building and development in the region. The clinical fellows are an integral part of trial conduct at Sidra paving the way for future researchers.
- Rapid access to physician support and consultation if any safety concerns arise.



# Steps for Collaboration

## Step 1: Contact Us

If you represent a sponsor or a CRO interested in collaborating with Sidra Medicine, reach out to our Clinical Trials team using the following contact details:

- **Email:** [clinicaltrials@sidra.org](mailto:clinicaltrials@sidra.org)
- **Phone:** +974 4003 3333

## Step 2: Sign Confidentiality Agreement

Before sharing any confidential information (such as study protocols, feasibility questionnaires, or investigator brochures), a Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) must be established. Our team will assist you in setting up this agreement.

## Step 3: Site Selection Visit

Once the CDA/NDA is in place, you can schedule a site selection visit. Our Clinical Trials team will provide all necessary support and facilities tours. You may also share the study synopsis at this stage.

## Step 4: Send Protocol for Review

If Sidra Medicine is selected as a site, submit the study protocol and study related documents, our team will assess the internal feasibility of the protocol. At this stage, the sponsor should consider setting up a Data Safety Monitoring Board (DSMB) (if required) as this is required for Ministry of Public Health submission.

## Step 5: Internal Feasibility Assessment

The Clinical Trials team will conduct a thorough internal feasibility assessment based on the protocol specifics, which may involve departments such as Pharmacy, Radiology, Imaging, Cardiology, Pathology, Laboratory, IT etc. Once the internal feasibility is completed and satisfactory capacity is confirmed, the next step is Internal Research Committee approval.

Furthermore, we have a dedicated research pharmacy and a dedicated research laboratory, designed to meet the highest standards of clinical research. These facilities strictly adhere to ICH-GCP (International Council for Harmonization - Good Clinical Practice), GMP (Good Manufacturing Practices), Good Laboratory Practices (GLP) and ISO (International Organization for Standardization) standards.

## Step 6: Authorization to Proceed with IRC (Internal Research Committee)

After the feasibility assessment, the Internal Research Committee (IRC) will review the proposal. This is our internal process. The required documents, listed in the IRC checklist, must be submitted by the sponsor to the CTO. The IRC will schedule a meeting within three weeks of receiving the documents, and a decision will be made within 15 days after the meeting. At the IRC meeting, the trial feasibility assessment, the Clinical Research Risk Assessment and Categorization Tool (CRRACT) and the department chief approval letter will be presented by CTO. Additionally, clinical trial insurance coverage and indemnity will be established based on the risk assessment. Once the IRC approval is granted, the study IRB submission may proceed.



### Step 7: Negotiate Budget/Contract

Simultaneously with the IRC submission, the CTO will support budget set up and contracts negotiation by liaising with the Sidra Contracts, Legal, and Finance teams.

### Step 8: IRB Approval

At Sidra Medicine, we use the IRBNet system for Institutional Review Board (IRB) submissions. The study team at Sidra Medicine will manage the submission process to seek approval, with the sponsor providing the necessary IRB documents as part of the IRB package. The IRB at Sidra convenes monthly for a full board review, and the decision will be released within 14 days after the meeting. To be considered for the full board committee review, IRB documents must be submitted at least three weeks prior to the meeting date. Once the IRB approval is granted, the MoPH submission (if applicable) may proceed. After obtaining IRB approval, a DSMB meeting should be conducted before submitting the study for review by the Ministry of Public Health (MoPH). It is essential to secure a favorable opinion from the DSMB and ensure that this opinion is included in the submission to the MoPH.

### Step 9: Ministry of Public Health (MoPH) Approval

The sponsor/CRO/Delegated personnel must submit a Clinical Trial Application (CTA) form, along with supporting documents, to the MoPH in Qatar. This includes a completed and signed Clinical Trial Authorization form and supporting documents, which can be sent to MoPH after securing Sidra Medicine IRB approval. The submitting personnel will receive an email notification of the MoPH approval, which should then be shared with the CTO.

### Step 10: Final Steps Before Site Initiation

Once all approvals are secured—including those from the IRC, IRB, and MoPH, as well as all contracts in place—the finalization and execution of Clinical Trial Agreements with the sponsor and any involved third parties can proceed, as well as the budget finalization for the trial. After obtaining these approvals, the sponsor can schedule a Site Initiation Visit.

## Step 11: Initiate Trial

The sponsor can schedule a Site Initiation Visit (SIV) to provide investigators and study teams training on the study protocol and related procedures. After successfully completing the SIV, the sponsor can issue a site activation letter, officially allowing the study to begin and patient recruitment to start. The Clinical Trial can commence at Sidra Medicine once the following conditions are met:

1. Provision of training to investigators and study teams on GCP, the study protocol, and other pertinent areas.
2. Conducting a Site Initiation Visit.
3. Ensuring availability of Investigational Product (IP) and study supplies onsite.

Our Clinical Trials team will support you throughout the study start-up to close-out, ensuring a smooth and compliant process.

## Step 12: Conduct of Trial

- Dedicated Research Coordinators from the CTO will be assigned to work closely with the Principal Investigator (PI) to ensure smooth trial operations.
- A dedicated research-trained nurse and pharmacist will also be assigned to manage patient care and IP handling.
- All research coordinators are ACRP (Association of Clinical Research Professionals) certified with a minimum of 3+ years of experience in clinical trials, ensuring expertise and compliance.
- Clinical trials will be listed on the Sidra Referral Program and featured on the Sidra website to enhance visibility and patient recruitment.
- We will leverage Sidra's dedicated research strategy programs and registries to facilitate feasibility assessments and boost patient recruitment.





## Main Focal Points and Contact Information

### Clinical Trials Office

clinicaltrials@sidra.org  
+974 4003 3333

### IRB Related Queries

irb@sidra.org  
+974 4403 7496

### Logistics Related Queries

logistics@sidra.org  
+974 4003 9204

### Budget/Contract Related Queries

clinicaltrials@sidra.org  
+974 4003 3333

### MoPH Submission

clinicaltrial@moph.gov.qa

### Pharmacy Related Queries

PharmacyResearchTeam@sidra.org

### Lab Related Queries

gmp@sidra.org

## Delivery Address for Study Related consumable Supplies

### Sidra Medicine

Education City, Al Luqta Street,  
PO Box: 26999/North Campus Doha, Qatar  
Attention: Sidra Custom and Logistics  
Tel: +974 4003 9204  
Mob: +974 3123 4286  
Email: logistics@sidra.org



## Shipping and Documentation Process for Sidra

To ensure smooth shipment delivery process and Customs clearance, provide the following documents mentioned below. The sponsor/ delegate must provide these documents to the site logistic team prior to the shipment process. This is the minimum list required but not limited to:

- Original commercial invoice (signed and wet stamped by supplier & attested by the Chamber of Commerce)
- The invoice must have:
  - A proper description of the item
  - Harmonized System Code (H.S Code) against each line item
  - Unit and gross price for each item
  - Incoterm
- Certificate of origin issued and attested by the Chamber of Commerce.
- Detailed packing list:
  - Must show exact packing details (batch and expiry where applicable)
  - Number of pieces, net weight, and gross weight

Note: Above requirements are based on the current Customs regulations and may be subject to change.

- Sidra Logistics team will provide shipping instructions to the vendor/supplier only when Sidra or our freight forwarder is involved (eg: Geodis, DHL).
- If the order is Delivered Duty Paid – the complete shipping and clearance will be handled by the freight forwarder appointed by the supplier. The supplier must coordinate with their freight forwarder for any special shipping requirements.

To support document verification, the vendor must follow these steps to ensure compliance with regulatory and logistical requirements, reduce the risk of delays or errors during customs clearance, and confirm that all shipping details align with Sidra's policies and standards:

- Send the draft invoice to Sidra Logistics team for verification to check the details and HS code. Once confirmed, the vendor can proceed with packing and shipping.
- Notify the Sidra Logistics Team as soon as the shipping method (Normal Air Freight, Express Courier, or Sea Freight) is decided.
- Based on the shipping method, the Sidra Logistics team advise whether Chamber of Commerce-attested originals are required.
- A pre-alert must be sent to the Sidra Logistics team before the shipment departs from the origin.

Note: Before dispatching the items, the Sponsor/CRO must inform the Sidra logistics team and submit the necessary documentation for review.

Send the documents to **[logistics@sidra.org](mailto:logistics@sidra.org)**.



## Pharmacy Shipments Address for IP shipments

### Sidra Medicine

PO BOX 26999

OPP Qatar Foundation

CSB Delivery area, AL Luqta Area

Email: [PharmacyResearchTeam@sidra.org](mailto:PharmacyResearchTeam@sidra.org)

The Path for Ordering, Importing and Receiving Investigational Products for Clinical Trials at Sidra has been outlined on page 18.

## Import Process for Investigational Products (IP) at Sidra Medicine

The import process for Investigational Products (IP) at Sidra follows established procedures outlined in Sidra's Policies (POL) and Procedures (PRO) as per the MoPH guidelines, like the process for any medicine imported or received at Sidra.

However, it is important to note that ALL IPs require an Import Permit issued by the MoPH, which does not use the term 'Import License.' The import license is obtained by the site pharmacy team.

## A. Steps for Obtaining an Import Permit

### 1. Site Activation

Upon site activation, the first IP shipment will be triggered by the sponsor. The sponsor must liaise with the pharmacy team.

### 2. Shipment Preparation

Once the shipment is ready from the supplier/sponsor, the pharmacy team will contact the CTO for the required documents to obtain the import permit.

### 3. Document Preparation

The CTO will provide the following documents to the research pharmacy team to apply for an Import permit. Upon receipt of first three documents below, the pharmacy will prepare document No. 4 and provide all documents to SDS.

- Approved Study Protocol
- Sidra IRB approval for the Study
- MoPH approval for the Study
- An official letter addressed to Dr. Aisha AL-Ansari, Director, pharmacy & drug control dept, from MoPH requesting the approval of the Import Permit for the specific Study

### 4. Submitting Documents

The research pharmacy team will provide the documents to the Sidra Drug Supply (SDS) team.

### 5. Import Permit Application

SDS will apply for the import permit through the MoPH Portal.

### 6. Approval and Receipt

Once approved, SDS will send the import permit to the research pharmacy team.

## B. Timeline for Approval

Once the application is submitted, the Import Permit is typically issued within 4-5 working days.

## C. Issue of Import Permit

The Import Permits are issued per shipment, rather than for the entire duration of the study. These permits are necessary for customs clearance and to facilitate the receipt of shipments. Once the permit is approved, SDS will send it to the Site Pharmacy Team, who will then share it with the sponsor and CTO team. The Site Pharmacy Team will maintain the records of all import permits.

## D. Shipment and Delivery Process

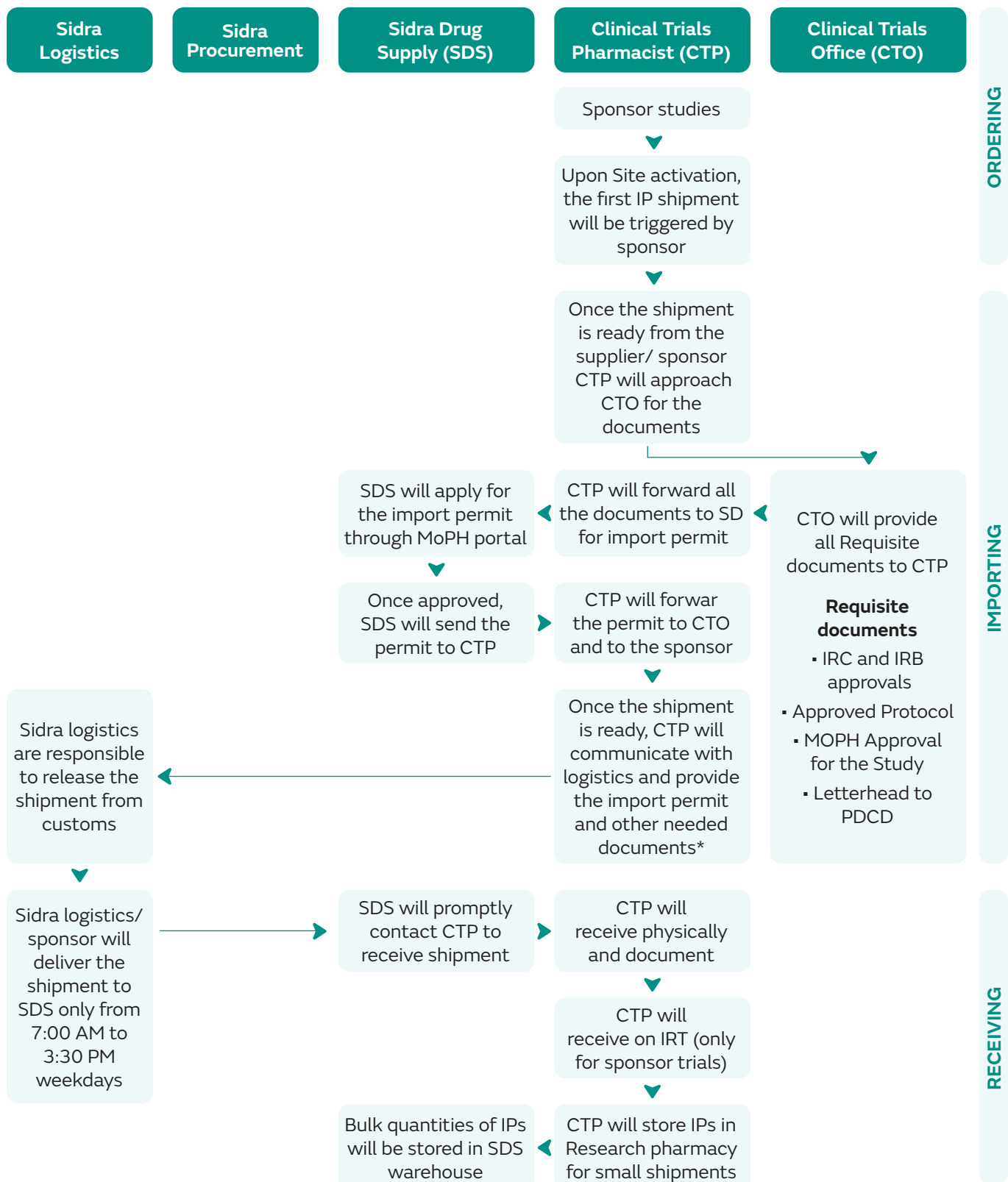
- The shipment delivery process will only begin once the import permit is issued.
- The Sponsor contracted shipment vendor will handle the release of the IP shipment from customs upon receipt of the Import Permit from the Research Pharmacy team.
- The shipment will be delivered to the SDS mall level store, only between 7 am – 3:30 pm on weekdays (Sunday to Thursday only).
- SDS focal points will ensure the prompt delivery of the IP to the Research Pharmacy team.

## E. Receiving of IP at Site

- The Research Pharmacy team will physically receive the shipment, document it, and ensure it is recorded in interactive response technology (IRT). The team will then store the IP in the Research Satellite Pharmacy room (HB-4E 235B).
- The temperature monitoring process begins once the shipment is received by the research pharmacy team. Temperature is monitored centrally by Biomedical engineering (BME) department, and monthly reports are autogenerated.

## The Path for Ordering

# Importing and Receiving Investigational Products for Clinical Trials at Sidra (for Sponsor-Studies)



Abbreviations: IP: Investigational Product, PDCD: Pharmacy drug and control department, MoPH: Ministry of Public Health, IRT: Interactive Response Technology \* Examples of other documents Invoice (Value of each items must be mentioned separately, Incoterms, HS code, Country of origin & Quantity), detailed packing list & Certificate of origin (COO)



## Partner with Sidra Medicine to Advance Clinical Research

At Sidra Medicine, our Clinical Trials Office is dedicated to transforming the landscape of children and women's health through cutting-edge clinical research. As a leading academic medical center in Qatar, we combine world-class infrastructure with regionally unmatched expertise in pediatric care and research.

We recognize that children are not just small adults—and their care requires tailored, evidence-based solutions. That's why we work closely with sponsors to design and conduct trials that are safe, ethical, and impactful.

### By choosing Sidra Medicine as your clinical research partner, you benefit from:

- Deep expertise in pediatric clinical trials, across a wide range of therapeutic areas
- A state-of-the-art research infrastructure embedded within a premier children's hospital

- Access to diverse patient populations in Qatar and the wider MENA region
- Efficient study start-up timelines and regulatory navigation support
- Multilingual, family-focused clinical teams trained in pediatric-specific care and communication

Located in the heart of the Middle East, Sidra Medicine serves as a hub for global pediatric research collaboration.

Join us in shaping the future of pediatric healthcare—locally and globally.

Contact our Clinical Trial's Office to explore how we can support your next pediatric study.

 Sidra Medicine, Qatar

 <https://www.sidra.org/>

 [ClinicalTrialsOffice@sidra.org](mailto:ClinicalTrialsOffice@sidra.org)

