TREAT TB | Technology, Research, Education and Technical Assistance for Tuberculosis

PRACTICAL RECOMMENDATIONS
FROM THE STREAM CLINICAL TRIAL

Pharmacy and Supply Chains

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STREAM is a multi-country clinical trial evaluating shorter, more tolerable multidrug resistant tuberculosis (MDR-TB) regimens, carried out over more than 10 years.

The trial offered an exceptional opportunity for pharmacists to participate in ground-breaking research. This guide provides practical recommendations on six key areas designed to improve pharmacy operations in future clinical trials.

Companion documents covering community engagement and implementing clinical trials can be found here.

LEFT

The pharmacy team at AHRI, one of two sites in Addis Ababa, Ethiopia fill a prescription for a STREAM trial participant

About STREAM

STREAM is the first large-scale, multi-country clinical trial to examine shortened regimens for MDR-TB. It is also the first phase III registration trial to test the efficacy and safety of bedaquiline in a shorter regimen. STREAM began in 2012 as a pragmatic trial (Stage 1) funded by the United States Agency for International Development (USAID). Stage 2, which added two bedaquiline-containing arms, resulted in additional funding from Janssen Pharmaceuticals and STREAM becoming a US FDA-regulated registration trial. The two stages of the trial recruited more than 1,000 participants at sites in Ethiopia, Georgia, India, Moldova, Mongolia, South Africa, Uganda, and Vietnam, making STREAM the world's largest recruited clinical trial for MDR-TB.

STREAM Stage 1 compared a 9–11-month MDR-TB regimen to the 20–24-month regimen previously recommended by the World Health Organization (WHO). Results from Stage 1 were published in the *New England Journal of Medicine* and demonstrated that favorable outcomes for participants on the control (20–24-month regimen) and intervention (9–11-month) regimens were very similar under trial conditions. The STREAM Stage 1 results, which also showed that the shorter regimen can reduce costs to the health system and patients, played a key role in the development of the WHO recommendations on the use of shorter regimens to treat MDR-TB.

STREAM Stage 2, which is ongoing, is evaluating an all oral, bedaquiline-containing regimen that is potentially as effective as and more tolerable than the injectable-containing regimens currently in use. It is also evaluating the comparative cost of the two regimens, for both the patient and the health system. Stage 2 is expected to contribute important evidence for future policy decisions about injectable-free MDR-TB regimens. Recruitment to Stage 2 of the trial was completed in January 2020 and results are expected in 2022.

Successful implementation of the STREAM clinical trial required sufficient quantities of clinical supplies to be available at the trial sites for participants recruited into the trial. Treatment interruptions due to medicine shortages or stock outs would be detrimental for participants and for trial outcomes. A team of pharmacists made sure all investigational medicinal products (IMPs) (i.e., medicines administered to participants in the trial) were available for timely dispensing to participants. IMP flow from manufacturers to participants (Figure 1) had to be carefully planned and executed throughout the trial. Despite many challenges in managing IMPs, none of the recruited participants had to interrupt their treatment due to IMP shortages or stock outs.

Figure 1: Clinical Supply Chain

In addition to supply of IMPs, other supplies including laboratory supplies, medical consumables and test kits were made available to trial sites under the supervision of the Sponsor pharmacists. For Stage 2, clinical supplies were secured via multiple providers, including Vital Strategies (the trial Sponsor), the trial sites, and IQVIA, the trial's contract research organization (CRO). Sponsor pharmacists ensured all clinical supplies met minimum quality requirements to ensure consistency across all trial sites.

Vital Strategies was specifically responsible for the supply of: IMPs for three of the four regimens evaluated in Stage 2, medical consumables, pharmacy auxiliaries (e.g., counting trays, pill cutters, label printers, labels, and plastic bags), laboratory reagents and consumables that could not be sourced locally, small laboratory equipment (e.g., centrifuges and microscopes), tests (e.g., visual acuity tests, microbiology test kits), export packaging for samples, and any other supplies that could not be sourced locally. Portable hearing tests were also procured which provided sites tablet based audiometry for the detection of hearing loss among participants.

These supplies were managed through a complex supply chain which consisted of:

- Sourcing
- Procurement
- Shipping from suppliers to an intermediary warehouse
- Receipt in the intermediary warehouse
- Relabeling (one IMP needed an additional label)
- Inventory management at the intermediary warehouse
- Consolidation and preparation for onward shipping to the trial sites
- Shipping to the trial sites

Pharmacists played a key role in the STREAM clinical trial. Vital Strategies pharmacists ensured:

- A functioning clinical supply chain was in place
- Only IMPs manufactured per Good Manufacturing Practices (GMP) and Good Clinical Practice (GCP) were used in the trial
- All IMPs were purchased, transported, and stored according to regulations and guidelines and in compliance with standard operating procedures (SOPs)
- IMP storage conditions set by the manufacturers were respected and documented throughout the supply chain
- All quantities of purchased IMPs were accounted for and any unused IMPs were properly disposed
- All site pharmacies were regularly monitored and their compliance with GCP guidelines, the trial protocol, and the trial's Pharmacy Plan was evaluated
- All records related to IMPs were maintained

Vital Strategies pharmacists worked closely with site pharmacists who were responsible for ensuring:

- All IMPs received at the sites were securely stored in accordance with manufacturers' storage requirements
- IMPs were only used as indicated in the protocol and any deviations were documented
- Only eligible participants received prescribed IMPs
- Prescribed IMPs were repacked and labeled as per the trial's Pharmacy Plan
- Participants were properly counseled about the use of prescribed IMPs and need to return any unused IMPs
- Proper stock keeping and reconciliation for each IMP batch received
- All study files and prescriptions related to STREAM were properly filed and securely stored

Pharmacy and Clinical Supplies

Designing, implementing, and monitoring pharmacy operations and clinical supplies for the STREAM clinical trial was essential but complex. At its core, a well-functioning supply chain for clinical supplies was key for maintaining their quality, preventing stock outs and subsequently avoiding treatment interruptions. When planning for a trial, the elements that need to be in place to achieve this should not be underestimated. An overarching consideration is the need for sufficient numbers of staff with appropriate qualifications and experience and ensuring detailed monitoring and standardization procedures are in place to meet the needs of a clinical trial.

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Pharmacists' Input on Trial Design

Solicit pharmacists' input during the pre-trial strategy and planning phase

STREAM was implemented at trial sites across eight countries in Africa, Asia and Europe, each with vastly different experience and specific constraints requiring careful tailoring of how clinical supplies were delivered, documented, and monitored. This made the development of supply chain processes extremely complicated. The level of detail required was, however, not fully anticipated in the design phase of the trial. The trial would have benefited from greater input from Sponsor pharmacists in the design of the protocol and implementation strategy. Pharmacists are uniquely placed to inform the development of effective supply chains and if considered in this planning phase, potential inefficiencies could have been addressed rather than confronting them as they emerged. This is particularly important for regulatory trials.

One instance where earlier planning would have been beneficial was the development of a contingency strategy for local sourcing of supplies to avoid stock-outs. Minimizing potential disruptions is foundational to an agile clinical trial supply chain enabling a more rapid response to disruptions. Had the complexity of the supply needs been better anticipated, then relationships and arrangements for contingency plans could have been put in place in advance. For example, to lessen the impact of supply blockades caused by recalls, back orders, or stock outs, having existing contractual relationships with local vendors and suppliers directly would have been valuable in securing safe multisource supplies.

In addition to being included in planning to support the establishment of efficient supply chains, the involvement of pharmacists at this stage could also have supported site selection. In STREAM, site selection began with a desk-top analysis of recruitment potential based on burden of disease and competing trials and did not necessarily include an assessment of local pharmacy capacity and experience. At some sites, Sponsor pharmacists did conduct initial pharmacy assessments, and this proved to be extremely beneficial. This allowed the Sponsor to better understand the local pharmacy context and decide if more start-up capital would be required to ensure adequate systems were in place prior to trial implementation. The pharmacy assessments became more comprehensive over time taking into consideration themes, including infrastructure needs, identified from prior assessments. However, incorporating detailed, standardized pharmacy assessments from the outset at all sites would have informed the selection process with a clearer understanding of the requirements to ensure sites were prepared for trial implementation.

RECOMMENDED BEST PRACTICES

Increase efficiencies by including pharmacists' input in the following areas:

- The pharmacists' input is needed from the beginning of the trial design and planning phase to determine possible sourcing, procurement, and supply strategies in line with the trial objectives
- Considerations for regulatory trial requirements should be made during the trial design and protocol development phase
- Considerations for regulatory trial requirements should be made during supply chain design to inform sourcing, procurement, and supply chain management strategy
- Pharmacists should be included in site assessments to ensure sites have required infrastructure to meet regulatory requirements and anticipate potential infrastructure investments

Supply Chain Resources

Ensure the supply chain management system has adequate resources and procedures in place

The Sponsor did not have extensive experience in procurement and clinical supply chain management for clinical trials and considered outsourcing of procurement to external parties, as is often done for clinical trials. However, after taking into account the time commitments and budget required for outsourcing, a pragmatic clinical supply chain management approach was adopted. The Sponsor undertook procurement and subsequent supply chain activities internally with a team of pharmacists (one pharmacist for Stage 1 and an additional pharmacist for Stage 2). The experience of managing the trial's complex supply chain highlighted that it is crucial for the management system to be well resourced with documented and detailed SOPs.

In Stage 1 of the trial, a strategy document – the Pharmacy Plan – was written and distributed to trial sites to serve as a guide for IMP management. Although the Pharmacy Plan provided an overview of what was needed, it did not provide enough detail to meet the complex needs of the trial. As the trial progressed, it was apparent that separate Sponsor and site pharmacy SOPs were needed to document IMP flow from manufacturers to trial participants. Development of these SOPs during Stage 2 ensured standardization of supply chain management across sites.

The SOPs required an appropriate level of detail to ensure a standardized system across the sites, and that resources were in place to ensure the SOPs could be followed. For example, GCP requires temperature monitoring for IMP storage. This was outlined in the Pharmacy Plan and site pharmacists were requested to maintain daily temperature monitoring logs. However, during site monitoring visits conducted by Sponsor pharmacists, challenges with temperature monitoring were identified and highlighted that the guidance in the Pharmacy Plan was not sufficient. At some sites, the temperature was recorded once per day (at noon), but it was recorded twice (at the beginning and at the end of the shift) at other sitesDifferent thermometers were also used by sites. Different thermometers were also used by sites, ranging from simple alcohol filled thermometers to more advanced digital thermometers, and some pharmacies had continuous temperature monitoring systems in place. Thus, data from different sites did not provide a uniform picture or ensure the recommended IMP storage conditions were maintained. To address this gap, Vital Strategies identified calibrated digital thermometers and all site pharmacies were equipped with these thermometers. An SOP on how to use them, and how to monitor and record the temperature was provided to sites. This ensured that temperature monitoring and recording was done consistently across all STREAM site pharmacies.

"Time spent on developing detailed SOPs paid off by providing reassurance that even simple tasks were performed by the pharmacists in a uniform manner resulting in the same level of care for trial participants regardless of their location."

STREAM SPONSOR PHARMACIST

RECOMMENDED BEST PRACTICES

The supply chain management system should have adequate resources and procedures in place in the following areas:

- Sufficient resources should be made available to ensure the site pharmacies have adequate and appropriate infrastructure, including systems for temperature monitoring and recording, to manage clinical supply chains
- Sufficient time should be allowed for identification and procurement of tools for supply chain management and record-keeping
- Standard operating procedures should be in place to ensure consistent trial implementation across site pharmacies and in accordance with trial requirements

Forecasting

Robust forecasting is needed to ensure continuous availability of clinical supplies while preventing waste

The STREAM trial included complex study regimens – recruited participants could be assigned to any of the 13 treatment combinations with eight IMPs typically prescribed during the intensive phase and four IMPs during the continuation phase. In total, 13 IMPs had to be available at each site to allow recruitment and uninterrupted treatment for participants.

In order to avoid treatment interruptions, there was a need for sufficient stocks of IMPs to be available while minimizing costs of inventory, storage, and waste due to expiry. Additionally, long supplier lead times and relatively short IMP expiry (typically less than one year for one of the IMPs) had to be taken into consideration. Moreover, delays in recruitment of participants due to strict inclusion and exclusion criteria made desired stock level calculations challenging.

These complex circumstances required the development of a robust forecasting system to continuously monitor risks of supply chain disruptions including timing of recruitment at each site; the estimated number of participants to be recruited monthly; typical participant's weight; and the estimated number of participants who may be lost to follow up.

The supply chain strategy implemented for the trial relied on a number of forward planning elements including pre–positioning medicines at regional depots for onward shipping to the sites, regular monitoring of stock levels, and continuously reforecasting IMP needs based on the latest recruitment data and trends to mitigate the risk of supply chain disruptions.

Our initial forecasting was based on optimistic scenarios of rapid recruitment of up to 50 participants per month per site. This resulted in an oversupply of IMPs and subsequent expiry and need for disposal and replenishment. However, once recruitment started, monthly recruitment reports were generated which were used to calculate expected recruitment for the upcoming period and enabled realistic forecast calculations.

The STREAM trial was implemented at 15 trial sites, across eight countries with site pharmacists with various levels of experience in forecasting. In order to facilitate their tasks, a simple quantification tool was developed to help with calculating needed quantities of IMPs. This was disseminated to each site pharmacist along with training by the Sponsor pharmacists.

"Analyses of delivery lead time data and stock levels provided important performance benchmarks and enabled us to respond more quickly to delays and potential disruptions."

STREAM SPONSOR PHARMACIST

RECOMMENDED BEST PRACTICES

Robust forecasting is needed to ensure continuous availability of clinical supplies while preventing waste in the following areas:

- Ensuring accurate forecasting is essential to secure sufficient quantities of IMPs for each site
- IMP forecasting must be conducted taking into consideration participant recruitment forecasting. Forecasting needs to be regularly conducted and readjusted as needed to avoid waste
- The supply chain strategy must take into consideration recruitment challenges to be able to respond to increases and decreases in IMP demand
- Forecasting and quantification tools can facilitate the forecasting process and should be used to ensure accurate forecasting

Trial Documentation Systems

Designing efficient record keeping systems facilitates documentation of trial related activities and improves readiness for audits and inspections

Accurate and timely documentation of trial processes is critical for managing clinical supply chains. This also ensures that the records are available for audits and inspections. Since Vital Strategies managed the trial supply chain, all records related to procurement, shipment, storage, relabeling, dispensing, returns, and disposal of IMPs had to be maintained in the Trial Master File (TMF) and site pharmacists maintained records in Pharmacy Site Files. Regular filing of documents in the TMF and Pharmacy Site Files by Sponsor pharmacists and site pharmacists, respectively, should be part of daily routine despite the fact that it is time-consuming and tedious. As the TMF requires documentation for all sites, having a dedicated staff member to manage the TMF can also help ensure that it is accurately maintained.

The most efficient process for maintaining the TMF emerged as the trial progressed. Records were generated by Sponsor pharmacists, the site pharmacists, or they were received from suppliers as required. World Courier, the logistics organization we partnered with, stored substantial quantities of IMPs and provided access to their stock management database so the status of incoming shipments, stock levels at the intermediary storage depots, and status of outgoing shipments could be documented in real time. All purchases and shipments were recorded in an electronic tracking sheet and electronic and hard copies of the files were maintained in the TMF. However, early in the trial, these processes were not in place. For example, not all IMPs were transported via intermediary storage depots, especially in Stage 1. Additionally, during Stage 1, a consolidated database of purchases and shipments was not maintained and only electronic records for individual purchases and shipments were created. It meant that the system was not as efficient as it needed to be, and previous records had to reconstructed and filed.

RECOMMENDED BEST PRACTICES

Efficient record keeping systems should be put in place with the following measures:

- Records on movement of IMPs from suppliers to participants should be maintained throughout the trial
- Validated and secure electronic systems to document the supply chain from procurement to dispensation of IMP to trial participants should be available
- All documents should be filed in the TMF and Pharmacy Site Files on an ongoing basis to ensure the trial is ready for any audits or inspections
- Have a dedicated staff member to maintain the TMF

Capacity Building

Provide comprehensive guidance and support for site pharmacists to build their capacity to implement research

The traditional pharmacist's role in a community or hospital setting is often restricted to dispensing medications; however, there is a shift towards clinical pharmacy, where pharmacists play a more active role in direct patient care and medication therapy management. This particularly becomes the case in a clinical trial, where pharmacists need to not only have experience with dispensing medications and providing clinical pharmacy services but also in understanding concepts of research and clinical trial management. Yet the lack of clinical research experience at many of the sites meant that the site pharmacists and trial administrators lacked understanding of the breadth of responsibilities and expectations placed on the site pharmacists. It is therefore important that capacity building support is provided for site pharmacists. Given the diversity of site pharmacists and their varying levels of experience, creating a detailed step-by-step guide outlining the roles and responsibilities of the pharmacist would have been extremely beneficial at the start of the trial.

Sponsor pharmacists strengthened capacity of site pharmacists through numerous methods. For example, to strengthen their capacity and ensure site pharmacists could meet the needs of the trial, we provided supportive supervision to STREAM sites through onsite visits and regular communication to ensure the Pharmacy Plan and trial protocol were adhered to. The collection of monthly stock reports, and regular CRO visits to site pharmacies in Stage 2 also ensured that pharmacy staff were adept and prepared for regulatory inspections. Sponsor pharmacists also instituted continuing education activities by providing monthly scientific articles with topics ranging from pharmacist roles within global health to advances in MDR-TB treatment. We also developed a GCP course, available online, specifically geared toward pharmacy practice to make sure site pharmacists were educated on the biomedical ethics within clinical trials of investigational drugs. The benefits of these capacity building activities were seen in more efficient and reliable supply chain management and pharmacy operations.

"Vital Strategies Sponsor pharmacists provided us monthly Pharmacy Continuing Education resources. These resources were very useful for my professional development. I even shared them with my colleagues."

STREAM PHARMACIST, STAGE 2 SITE

RECOMMENDED BEST PRACTICES

Build the capacity of site pharmacists in implementing research through the following measures:

- Create a comprehensive pharmacy guide that provides concrete steps each pharmacy staff member must undertake to succeed in the role, including supply chain management, pharmacy operations, data collection, and reporting
- Create electronic training materials which cover important topics, including GCP and common medication and dispensing errors, for pharmacy staff
- Incorporate online refresher training to ensure staff are abreast of any trial developments that impact pharmacy operations
- Create audit and inspection readiness training for pharmacy staff to ensure they are prepared for any drug regulatory body or sponsor audit
- In addition to onsite monitoring, consider remote monitoring options to ensure adequate oversight
- SOPs should be agreed upon and provided to outline roles and responsibilities for trial pharmacists
- Provide access to professional and local pharmacy training to increase staff knowledge and skills and promote continuous learning

Valuing Local Expertise

Deep local knowledge needs to be valued when designing new data management tools and pharmacy plans

STREAM was implemented across eight countries, all with vastly different experiences with clinical trial implementation. Given the wealth of knowledge required to work and operate in various countries worldwide, in-depth conversations with local pharmacy organizations, drug regulatory authorities, and trial pharmacists would have been useful in order to adapt the implementation strategy, and particularly data management systems, to fit the local context.

At one of the trial sites in South Africa, we found that one of the STREAM pharmacy logs designed for trial implementation was duplicative and ineffective. Given the robust pharmacy operations that already existed within the hospital at the trial site along with experienced clinical trial staff, we were able to adopt the existing system and apply it to the STREAM trial. However, for our trial sites in India, additional STREAM pharmacy logs were designed to more effectively document IMP dispensing to participants via field workers.

There is a great deal of reliance on the site pharmacists to not only gather accurate data, but also to be able to review and interpret the data. The most effective data collection systems were in place when the site pharmacists understood exactly why the data were needed and they felt motivated and empowered as important members of the research team. Having a clear understanding of how data will be captured and utilized is critical to gain buy-in and establish trust amongst site pharmacists. In contrast, there was reluctance from site pharmacy staff when the Sponsor requested collection of data they felt were useless or redundant. Creating a collaborative environment amongst all site pharmacists and ensuring systems and processes are designed taking into consideration feedback from site pharmacists would benefit trial implementation and add tremendous value.

"The Sponsor pharmacists worked very closely with site pharmacists. Close working relationships amongst team members was very important for the trial."

STREAM STAGE 2 PHARMACIST

RECOMMENDED BEST PRACTICES

Value local knowledge when designing new data management tools and pharmacy plans through the following measures:

- Allow site pharmacists sufficient time to provide comments and recommendations before pharmacy plans are finalized
- Interview local pharmacists and professional pharmacy organizations to understand the scope of pharmacists' practice and landscape within the country
- Develop an electronic data management system in collaboration with local pharmacists to ensure efficiencies and leverage existing systems

CASE STUDY

Pharmacy operations and clinical supply chain management in Kampala, Uganda: A commitment to capacity building

In 2017, the Makerere University Lung Institute (MLI) situated in the Mulago National Referral Hospital became a STREAM trial site for STREAM Stage 2. MLI is globally recognized as an essential TB treatment facility, but had limited experience with complex, multi-country phase III TB trials. This would bring complexities that had not been encountered at the site before and highlights the commitment from the MLI staff and the Sponsor to strengthen pharmacy operations and clinical supply chain management.

STREAM required a wide variety of supplies and Investigational Medicinal Products (IMPs) to be available at trial sites during the trial. Therefore, the first priority was to ensure that MLI had the proper pharmacy infrastructure and capacity to receive, store, dispense and maintain IMP accountability. This meant preventing stockouts or oversupply that could put a strain on IMP availability or cause IMP wastage due to expiry, or inappropriate storage respectively. With support of the STREAM Sponsor, Vital Strategies, MLI was able to modify one of its office spaces into a pharmacy and obtain necessary approvals for its function.

Temperature excursions can impact the stability, safety, and quality of IMPs, which could reduce their effectiveness; thus, IMPs must be stored in a temperature-controlled environment to preserve the pharmacological effects. When creating a sustainable pharmacy within MLI, a fully insulated and temperature-controlled storage unit was needed to achieve the required storage conditions for IMPs. Before the STREAM trial, storing IMPs for participants enrolled in clinical trials treated at the MDR-TB ward was not possible. Physicians and pharmacists had to walk from one end of the hospital to the other to drop-off prescriptions and bring IMPs back for administration. Therefore, STREAM provided temperature-controlled storage units in the TB ward, to make IMPs available closer to the participants and the time between participant prescription and the administration of their IMPs was reduced, and as well as the waiting time for participants and providers.

Another area of capacity building was establishing a pharmacy team able to manage the complexity of the trial. STREAM trial participants received different combinations of up to 13 medicines during the 9-month minimum treatment period and MLI received 36 different batches of IMPs throughout the trial. The site hired a dedicated pharmacist to manage IMPs for STREAM which helped ensure adequate supplies and medications were available for trial participants.

To implement STREAM, the MLI pharmacy team had to address levels of complexity they had not experienced before and take on responsibilities specific to the trial which were new to them. The pharmacists' activities involved managing import permits for incoming IMP shipments, stock management, repacking and dispensing prescribed IMPs for participants during their hospital stay and home treatment. The Sponsor pharmacists and the MLI team worked together to build systems that did not exist before as required. For example, to prevent any stockouts of IMPs which could interrupt treatment for participants, pharmacists at MLI created a robust database for trial drug management. Unfortunately, due to challenges with stable internet availability this system could not be used and a paper-based system had to be followed. The STREAM Sponsor pharmacists and MLI team also worked together to create a well-designed strategy to continuously monitor for risks that could cause such disruptions.

At the heart of the team's success when faced with significant challenges was their resilience and agility. This was seen when building relationships with the National Drug Authority (NDA), which oversees the import of medicines, including IMPs, for clinical trials, to ensure succinct supply chains. The country of Uganda prides itself on its well established drug regulatory system overseen by the NDA and the pharmacy team quickly discovered that the importation of clinical supplies was lengthy and challenging resulting in long lead times for import permits and initial shipment licenses taking an average 69 days and 227 days, respectively. STREAM pharmacists fostered strong relationships with NDA representatives subsequently to better understand the process and regulatory agency requirements to mitigate potential bottlenecks and to ensure the site had the most up-to-date information regarding changes to the regulatory process. In doing so, turnaround times for permits and shipments decreased to 53 days in 2018 and further down to 36 in 2019.

The pharmacy team at MLI took on the STREAM clinical trial with expertise in pharmacy operations, but not necessarily experience with pharmacy needs for phase III TB trials. Through collaboration and an open commitment to strengthening capacity, the team built excellent and sustainable pharmacy operations and supply chain management systems. It is testament to this commitment that meant MLI avoided major stockouts and ensured all trial participants could continue their treatment without any interruptions.

"STREAM was the first trial I've ever participated in as a pharmacist. My standards and practice have enormously improved with the help of the STREAM trial management team. I really appreciate their efforts in lifting the standards for clinical trial pharmacists at all STREAM sites."

IVAN SEGAWA, STREAM PHARMACIST IN KAMPALA, UGANDA

GLOSSARY

Good Clinical Practice (GCP) is the international ethical, scientific, and quality standard for clinical trials.

Good Manufacturing Practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards.

Investigational Medicinal Product (IMP) is a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial.

Medication is a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Pharmacy Plan is a supply chain and pharmacy operations guide used for the STREAM trial.

Site Pharmacists are responsible for providing pharmaceutical management for participants at STREAM trial sites.

Sponsor Pharmacists are responsible for the clinical trial supply chain and pharmacy operations for the STREAM trial.

Standard Operating Procedure (SOP) is an established or prescribed method to be followed routinely for the performance of designated operations or in designated situations.

Supply Chain is the management of the flow of goods and services and includes all processes that transform raw materials into final products.

Trial Master File (TMF) is a collection of the important content for clinical trials that are overseen by a regulatory agency.

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