

# RemediumOne Perspectives

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## INSIDE

### INSIGHT

Operational lessons learned from successfully managing a clinical trial on hypertension management

### INFORMATION

New study reveals Sri Lanka as a global hotspot for diabetes.



## Insights

### Operational Lessons Learned from Successfully Managing a Clinical Trial on Hypertension Management

High blood pressure (BP) is the leading cause of preventable morbidity and mortality globally. The benefits of BP lowering in reducing cardiovascular (CV) events are well established and there is clear evidence that greater BP lowering confers a greater reduction in CV events 1-3.

Unfortunately, however, despite the availability of safe, well-tolerated, and relatively in-expensive BP-lowering therapies, <14% of adults with hypertension have BP controlled to a systolic/diastolic BP <140/90 mmHg 4. The COBRA-BPS study highlighted the magnitude of uncontrolled hypertension in rural Sri Lanka, with approximately 64% having uncontrolled BP 5.

Combination therapy has the potential to address the aforementioned barrier of under treatment of hypertension with monotherapy as well as physician inertia 6.

RemediumOne is currently managing the Sri Lankan component of a multi-country trial that is evaluating the safety and efficacy of a unique, three-in-one pill for treatment of hypertension. With 8 participating countries, Sri Lanka has contributed to over 40% of global recruitment.

Here are the key operational lessons learned from the successful progress of this trial.

### **Selecting the right sites:**

Sri Lanka's healthcare system, which provides free healthcare to all citizens, is a significant advantage when it comes to selecting appropriate sites for clinical trials.

- The system ensures that there is a well-established healthcare infrastructure across the country, making it easier to identify and select suitable trial sites.
- As healthcare is free and accessible to all citizens, there is a higher likelihood of individuals seeking medical attention for a variety of conditions, including those targeted by the clinical trial. This leads to a larger pool of potential trial participants and facilitates recruitment efforts.
- As the healthcare system is well-integrated and well-regulated, there is a high level of expertise among healthcare professionals, providing the necessary medical oversight for clinical trials.

### **Participants with a high literacy rate, which enables them to follow instructions and adhere to the study protocol:**

Each participant was provided with a digital BP monitor for home monitoring of BP for the entire duration of the trial. BP readings were encrypted and transferred automatically to the trial database via SIM connection. 97% of BP monitors returned were in good condition and participants were capable of measuring their BP as per the instructions given.

## **Qualified and experienced investigators with an appetite for research:**

The investigators are board certified medical specialists who have undergone mandatory overseas training and are exposed to clinical trial conduct during their training. Thus, the benefits included:

- Investigators can analyze the target population for a clinical trial and identify appropriate channels to reach potential participants. For this trial, the investigators were a combination of Cardiologists and General Physicians. Considering the target population, they identified the Visiting physician Out-Patient Department as a suitable channel for recruiting participants at most sites.
- Investigators helped to streamline the recruitment process by screening potential participants to ensure that they meet the study criteria before they are referred to the clinical trial site. This helped to increase the efficiency of the recruitment process and reduced the burden on site staff.

## **Early site engagement through pre-screening activities:**

Having a defined pre-screening procedure presented a valuable opportunity to streamline clinical trial

screening and enrollment processes, inform recruiting approaches, and maximize the success of trial enrollment.

## **Enroll the right participants:**

The team continuously monitored recruitment rates and adjusted the recruitment strategy as needed to ensure that enrollment targets are met. Engagements with the trial Investigators on eligibility discussions helped in minimizing screen failures, run-in failures and enrollment of ineligible patients.

## **Participant retention through a telephone surveillance system:**

Apart from the measures outlined in the protocol, the operational team in Sri Lanka set up a telephone surveillance system to ensure that participants were adhering to the blood pressure measurement schedule specified in the protocol. This system allowed the team to monitor participants remotely and ensure that they were complying with the study requirements, which is critical to obtaining accurate and reliable data. The implementation of this system highlights the team's commitment to ensuring the success of the trial and their resourcefulness in finding innovative solutions to potential issues. It also demonstrates the importance of proactive measures to monitor and support participants



in clinical trials, which can help to ensure that the trial produces high-quality and useful data.

To explore how RemediumOne can enhance participant engagement and enrollment for clinical trials, get in touch with our Leadership Team or peruse our capabilities in further detail.

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# Information

## New Study Reveals Sri Lanka as Global Hotspot for Diabetes

According to a recent study published in BMJ Open Diabetes Research and Care, Sri Lanka is now considered a global hotspot for diabetes, with a higher prevalence of the condition compared to other countries in the region.

The study used data from the Sri Lanka Health and Ageing Survey 2018/2019 and found that approximately 1 in 8 adults aged 18 years and older in Sri Lanka have diabetes, while nearly a quarter of the population has pre-diabetes. These figures are concerning, as diabetes is a chronic disease that can lead to serious complications, such as heart disease, stroke, kidney disease, and blindness.

According to the International Diabetes Federation (IDF), the burden of diabetes is high in Sri Lanka when compared to other Asian countries. In 2019, the IDF estimated that the prevalence of diabetes among adults aged 20-79 years in Sri Lanka was 8.5%, higher than the average prevalence of 8.1% in the South-East Asian region. Furthermore, the number of adults with diabetes in Sri Lanka is projected to increase to 1.9 million by 2045, representing a significant health and economic burden. These statistics highlight the urgent need for effective prevention and management strategies to address diabetes in Sri Lanka.

The study's findings highlight the urgent need for effective prevention and management strategies to address the growing burden of diabetes in Sri Lanka. These strategies may include lifestyle interventions, such as promoting healthy eating habits, increasing physical activity, and reducing tobacco use, as well as targeted screening and treatment programs for people with diabetes and pre-diabetes.

Overall, the study provides important insights into the prevalence and burden of diabetes and pre-diabetes in Sri Lanka and underscores the importance of continued research and interventions to address this significant public health challenge.

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