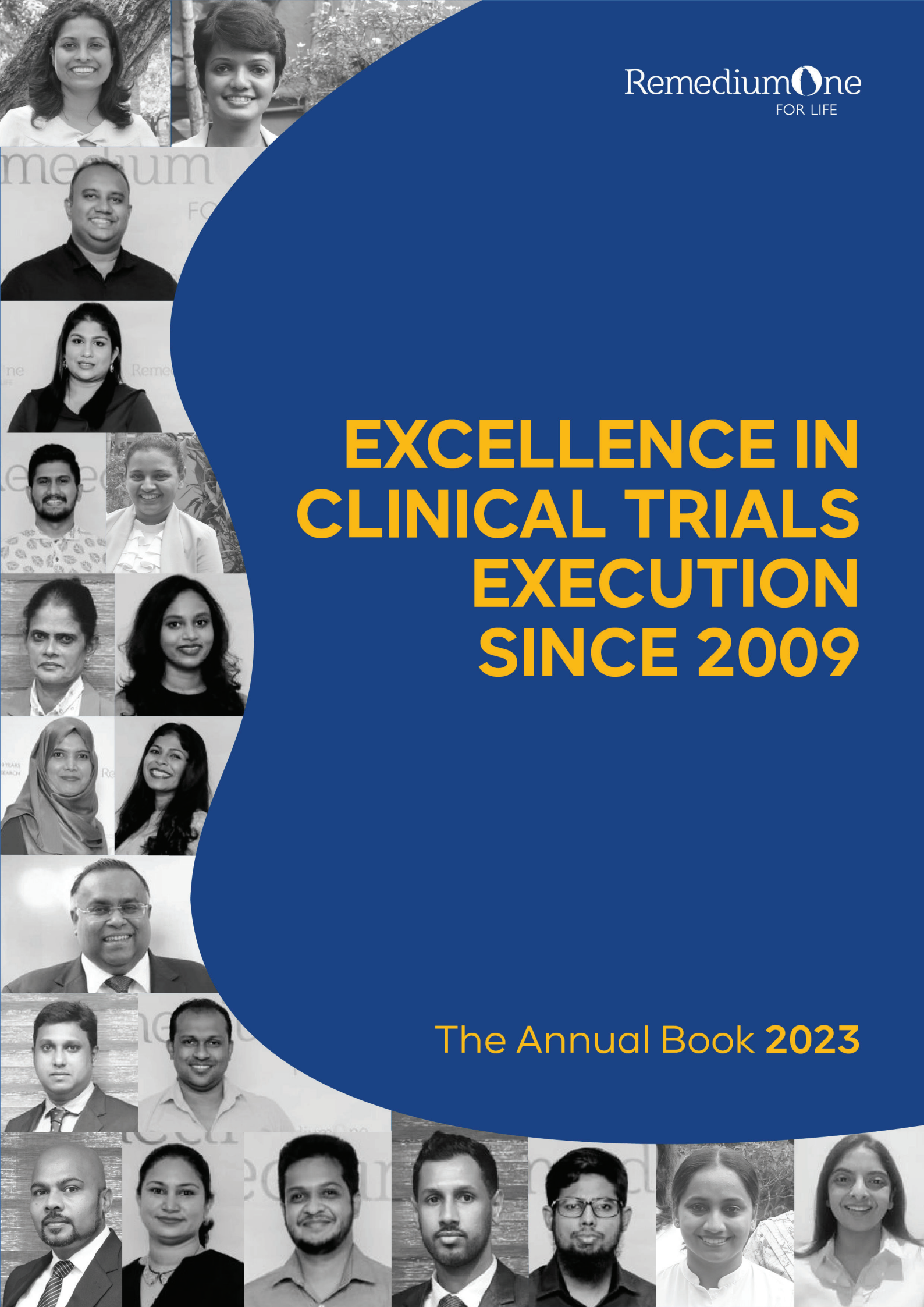


# EXCELLENCE IN CLINICAL TRIALS EXECUTION SINCE 2009

The Annual Book 2023



## Vision Our Aspiration

To become the most valued partner to our clinical development and life sciences clients and a role model to the industry.

Est.  
**2009**

**13+**  
Years of Experience

**40+**  
Pivotal Clinical Trials

**10,000+**  
Volunteers

**40+**  
Audits With No Critical Finding

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# Anuradha Dahanayake

## Head-Clinical Development



As we reflect on the past year, I am proud of all that we have achieved together at RemediumOne. Our journey began 14 years ago with a high-impact, policy-challenging investigator-initiated trial on snakebite. Today, we have grown into a clinical research organization that is making a significant impact on the health of communities around the world. Our commitment to rigorous scientific methodology and ethical principles has enabled us to successfully conduct numerous clinical trials, each providing valuable insights into the prevention, diagnosis, and treatment of a wide range of medical conditions.

***I strongly believe that clinical research should focus on advancing the practice of medicine and improving the quality of patient care.***

Through collaboration with leading academic institutions, industry partners, regulatory bodies and most importantly our investigators, we have fostered a culture of excellence and innovation within our organization.

More than ever before, we are part of a worldwide effort to create new tools, therapeutics, and treatments to solve global health challenges. We are immensely proud of the experienced teams of investigators, clinicians and young and dynamic staff whose tireless efforts to fulfill missions ensure our communities stay healthy and safe.

Of course, the past year has been particularly challenging, as we have steered through the COVID-19 pandemic and its impact on our work. However, our work on non-communicable diseases has taken on even greater importance in the context of the pandemic and economic crisis. We have seen how these have disproportionately impacted those with underlying health conditions. We recognize the urgent need to develop new therapies and interventions that can help prevent and manage these conditions. And we have committed to doing our part to address these issues.

Another key areas of focus in recent years has been on the prevention and management of Dengue, a mosquito-borne disease that possess a significant threat to public health. In the past years, we became a part of the AEGIS (Advancing Evidence for the Global Implementation of Spatial Repellents) program with the aim of broadening our expertise in this specific domain.

We are also proud to be managing clinical trials for rare diseases such as Immunoglobulin A nephropathy. This disease affects a small population, but its impact on patients and their families is significant.

***"Globally, more than 1 billion people suffer from high blood pressure. The George Institute for Global Health (TGI) has trialed a new dose pill for hypertension, that combines three medications in one (Triple Pill), which would change the way high blood pressure is treated around the world."***

***"In 2016, Triple pill vs usual care management for patients with mild-to-moderate hypertension (TRIUMPH) study was initiated in Sri Lanka to evaluate whether a triple low-dose pill would reduce blood pressure quickly and more effectively than standard case."***

*Study Results can be read through:*

*Lifestyle modification for resistant hypertension: The TRIUMPH randomized clinical trial - ScienceDirect*

*Study Identifier NCT02342808*

*Lifestyle Interventions in Treatment-Resistant Hypertension - Full Text View - ClinicalTrials.gov*



## Dilini Karunarathna

### Head- Quality Assurance & Quality Control



I am incredibly proud of the progress in our journey towards the total quality focused culture. Our commitment to excellence is evident in every aspect of our services, from our diligent approach to work to the exceptional services we extend to our valued clients. In recent years, we have made significant progress towards our vision of becoming Integral part in global clinical research. Our team has grown in both size and expertise, and we have expanded our services to meet the evolving needs of the industry.

Over the past year, we have managed to meet and exceeded our customer expectations. **No major or critical findings were observed during audits.** This is a tribute to our dedication to quality and our ability to deliver on our promises. It also demonstrates the trust and confidence that our clients have in us, which is something that we value greatly.

Our key focus lies on three fundamental pillars: quality, growth, and innovation. We remain committed to maintaining the highest standards of quality in everything we do, and we will continue to invest in our team's education and training to ensure that we stay at the forefront of the industry.

At the same time, we are committed to driving sustainable growth through expanding our services, developing new partnerships, and exploring new markets. Finally, we believe that innovation will be a key driver of success in the years to come, and we are committed to investing in cutting-edge technologies and approaches that can help us to improve the efficiency and effectiveness of clinical research.

I am excited about the future of RemediumOne, and I am confident that we will continue to make a positive impact in the world of clinical research.

**"Our team has grown in both size and expertise, and we have expanded our services to meet the evolving needs of the industry."**

ISO 9001:2015

**BUREAU VERITAS**  
Certification



ISO/IEC 27001:2013

**BUREAU VERITAS**  
Certification



0008

**"FDA Audit readiness program is arranged at constant intervals for the investigators and the research teams. Last program was arranged by Madeline Ducate, Consultant & Clinical Research Expert with Over 30 Years of Industry Experience."**

[Madeline Ducate | LinkedIn](#)

Senior Trainer-Regulatory Audit

# Isuru Edirisinghe

## Head- Human Capital

I am pleased to announce that we have achieved outstanding results in the previous year, despite facing difficulties caused by the pandemic and the economy.

Our accomplishments are a testament to the outstanding teamwork and culture of execution that define our organization, and we are proud of the exceptional results we have achieved together. The team's commitment to learning and development, executing tasks with precision, meeting deadlines, and exceeding expectations has been exemplary, resulting in successful outcomes that have surpassed our targets.

Looking ahead, we remain excited about the opportunities and challenges that the future holds. We are confident in our ability to meet these challenges head-on and deliver outstanding results for our clients and patients. Our commitment to execution excellence is unwavering, and we will continue to strive for excellence in everything we do.

Our exceptional accomplishments in numerous clinical trials have garnered recognition, highlighting the outstanding outcomes we have attained. Repeatedly surpassing customer expectations has become a hallmark of our unwavering commitment to excellence. Our track record of excellence is a source of pride for us, and we are committed to maintaining this standard in all our future endeavors.

Despite the obstacles presented by the pandemic and economic crisis, we have continued to manage our trials with the utmost care and attention to detail. Our staff has worked tirelessly to ensure that every trial we manage is executed flawlessly, with no compromise on quality or safety.

We are grateful to all our partners and stakeholders who have supported us in our efforts to foster innovation and improve patient outcomes. Our vision is to continue working collaboratively with our partners to deliver impactful results that positively impact the world of clinical research.

**"Our track record of excellence is a source of pride for us, and we are committed to maintaining this standard in all our future endeavors."**

In conclusion, I would like to extend my gratitude to all our stakeholders for their unwavering support. Our shared commitment to execution excellence is what makes us stand out in the world of clinical research. We are excited about the future and look forward to continuing to work together with our partners to achieve our shared goals.

**"Each RemediumOne staff member receives an average of more than 30 hours of training annually, which is above the industry standards."**







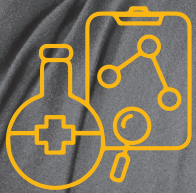
"The team's commitment to executing tasks with precision, meeting deadlines, and exceeding expectations has been exemplary, resulting in successful outcomes that have surpassed our targets. Training and development has played a big part."

**Dr. Namal Wijesinghe**  
Partnerships & Alliances



# AT A GLANCE

From the Inception



**40+**  
Successful Delivery of Trials



**10,000+**  
Participants



**300+**  
Investigators



**50+**  
Trial Centres



**30+**  
Clients



**ZERO**  
Major or Critical Findings

## **New Initiatives**



- Real World Evidence and Late Phase Trials
- Drug Safety and Pharmacovigilance
- Medical Writing
- Market Authorization and Commercialization





# RECAP 2022

## March

A sponsor for ISCR 2022  
15<sup>th</sup> Annual Conference



## April

President's award for research to  
Prof. Asita de Silva for TRIUMPH  
trial scientific publication



## June

Sri Lanka Diabetes and  
Cardiovascular Initiative End Term  
Evaluation – Report produced by  
RemediumOne



## June

RemediumOne is a proud  
partner of **Academic  
Sessions of the Sri Lanka  
Association of Clinical  
Pharmacology &  
Therapeutics**



## July

Appreciation by Chairman &  
CEO of PPD for commendable  
work by RemediumOne despite  
COVID pandemic



**David Simmons**  
Chairman & CEO  
PPD

"Dear RemediumOne Team, During these unprecedented and disruptive times, knowing that we can count on each other is now more important than ever. That's why i am writing to you today on behalf of our entire PPD team, we want to express our appreciation to you and all members of the RemediumOne team for all you do in partnering with us to help pharmaceutical, biotechnology, medical device, academic and government organizations bring life-changing therapies to patients- at the best of times and especially now."

## August

**BEAT C Sri Lanka's  
response to COVID 19.**  
Report by RemediumOne



## September

Saumiyah Ajanthan  
won global award for  
abstract submission.  
Held in Singapore.



22 Early Career Researchers-  
ICE 2022 Abstract Award for  
"Glucose tolerance status at 3  
to 18 months postpartum of Sri  
Lankan women with a history of  
Gestational Diabetes Mellitus"



## October

A donation of a -50°C freezer  
to the Infectious Diseases  
Hospital (IDH)





## October

Felicitation for one of our Nephrology KOLs, **Dr. Chula Herath, Consultant Nephrologist**



## November

RemediumOne celebrated **13<sup>th</sup> Anniversary**



**Prof. Asita de Silva** selected as **world's top 2% of scientists** by Stanford – Elsevier



Takeda dengue vaccine received first marketing authorization from Indonesia. RemediumOne is managing this trial in Sri Lanka from 2016



RemediumOne partnered with John Hopkins Bloomberg School of Public Health first time for a social sciences program implementation in Sri Lanka



## December

ENRICH-AF Investigators' meeting in Delhi, India



Investigators engagement program at Kandy National Hospital



## November

Prof. Craig Anderson, Chief Principal Investigator of TRIDENT clinical trial visited Sri Lanka for an Investigators' discussion



RemediumOne joins in the Advancing Evidence for the Global Implementation of Spatial Repellents (AEGIS) program by University of Notre Dame and UNITAID



# International Clinical Trials Day

## 20 May 2022

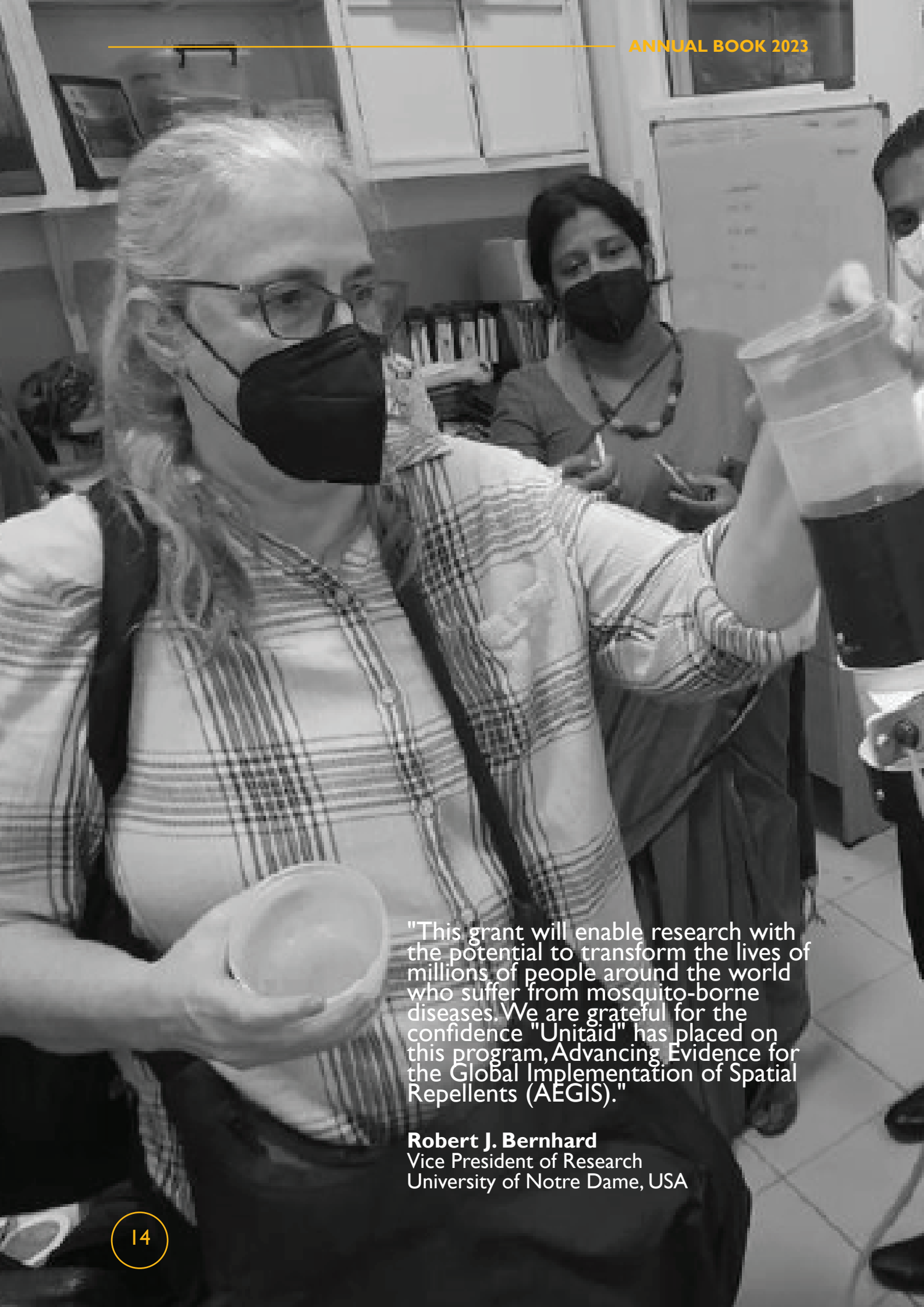
A message from  
Prof. Asita de Silva,  
Senior Professor of Pharmacology  
Director, Clinical Trials Unit  
Faculty of Medicine,  
University of Kelaniya

As we celebrate International Clinical Trials Day, it is essential that we take a moment to reflect on the significance of this day. Clinical trials have been used for the development of therapeutic interventions for centuries and we should be extremely proud for our involvement in this field. The evidence we generate through our day-to-day assessment of interventions is crucial for establishing the safety and efficacy of new therapeutic interventions, including medicines, devices, diets, or physiotherapy. Without this evidence, medicine cannot advance. Thus, by generating evidence through clinical trials, we make a significant effort towards the benefit of patients.









"This grant will enable research with the potential to transform the lives of millions of people around the world who suffer from mosquito-borne diseases. We are grateful for the confidence "Unitaid" has placed on this program, Advancing Evidence for the Global Implementation of Spatial Repellents (AEGIS)."

**Robert J. Bernhard**  
Vice President of Research  
University of Notre Dame, USA

# Initiation of Spatial Repellent Study in Sri Lanka



Managed by

Funded by



We are excited to announce that Sri Lanka has joined the global initiative, Advancing Evidence for the Global Implementation of Spatial Repellents (AEGIS) in 2022. And the aim of the program is to generate further evidence about an innovative new tool, spatial repellents, to help prevent vector-borne diseases like dengue. The project is managed by the University of Notre Dame, USA, and monitored by FHI Clinical, global clinical research organisation, with funding from Unitaid. It is significant to note that the socio-logical impact of this project is handled through a study conducted by Johns Hopkins University, Bloomberg School of Public Health. This is a significant milestone in our ongoing efforts to combat the spread of Dengue, a disease that affects many people in Sri Lanka. This is the first ever, community based large-scale clinical trial in Asia to quantify the protective efficacy of a Spatial Repellent product.

As a member of this program, Sri Lanka will gain access to the latest research and technology in mosquito control, and we will be able to share our own experiences and expertise with the global community. We hope that our participation in this program will contribute towards achieving our goal of eradicating dengue from our country. Sri Lanka has successfully eradicated malaria in 2016.

***We at RemediumOne are committed to working with our partners to find solutions to public health challenges, and we look forward to continuing our efforts to improve the lives of people in Sri Lanka and around the world.***

Read More: [AEGIS](#)



Unitaid is a global health agency engaged in finding innovative solutions to prevent, diagnose and treat diseases more quickly, effectively and for affordable prices, in low and middle income countries.

# Hope for Cure 1<sup>st</sup> Edition

RemediumOne is proud to have launched "Hope for Cure" in 2022, a quarterly bulletin that focuses on rare diseases in Sri Lanka. Through this magazine, we aim to raise awareness about the challenges faced by patients with rare diseases and the efforts being made to find cures. We also hope to showcase Sri Lanka's capacity in contributing to the clinical trials on rare diseases and to provide a platform for sharing information with the international research community and we hope to encourage investigators to highlight rare disease research interests and the opportunities of their interests. We believe that this magazine will be an important resource for patients, healthcare providers, and researchers alike, and we look forward to continuing our work in this area.



**Saumiyah Ajanthan**  
Research & Insights



**Read or Download :**

[https://www.remEDIUMone.com/ro\\_resources/rare-diseases-bulletin-v-1-0-i-1-0/](https://www.remEDIUMone.com/ro_resources/rare-diseases-bulletin-v-1-0-i-1-0/)

**Read the latest editions through our LinkedIn profile :**

<https://www.linkedin.com/company/remEDIUMone/>

**Write to us :** [inquiries@remEDIUMone.com](mailto:inquiries@remEDIUMone.com)



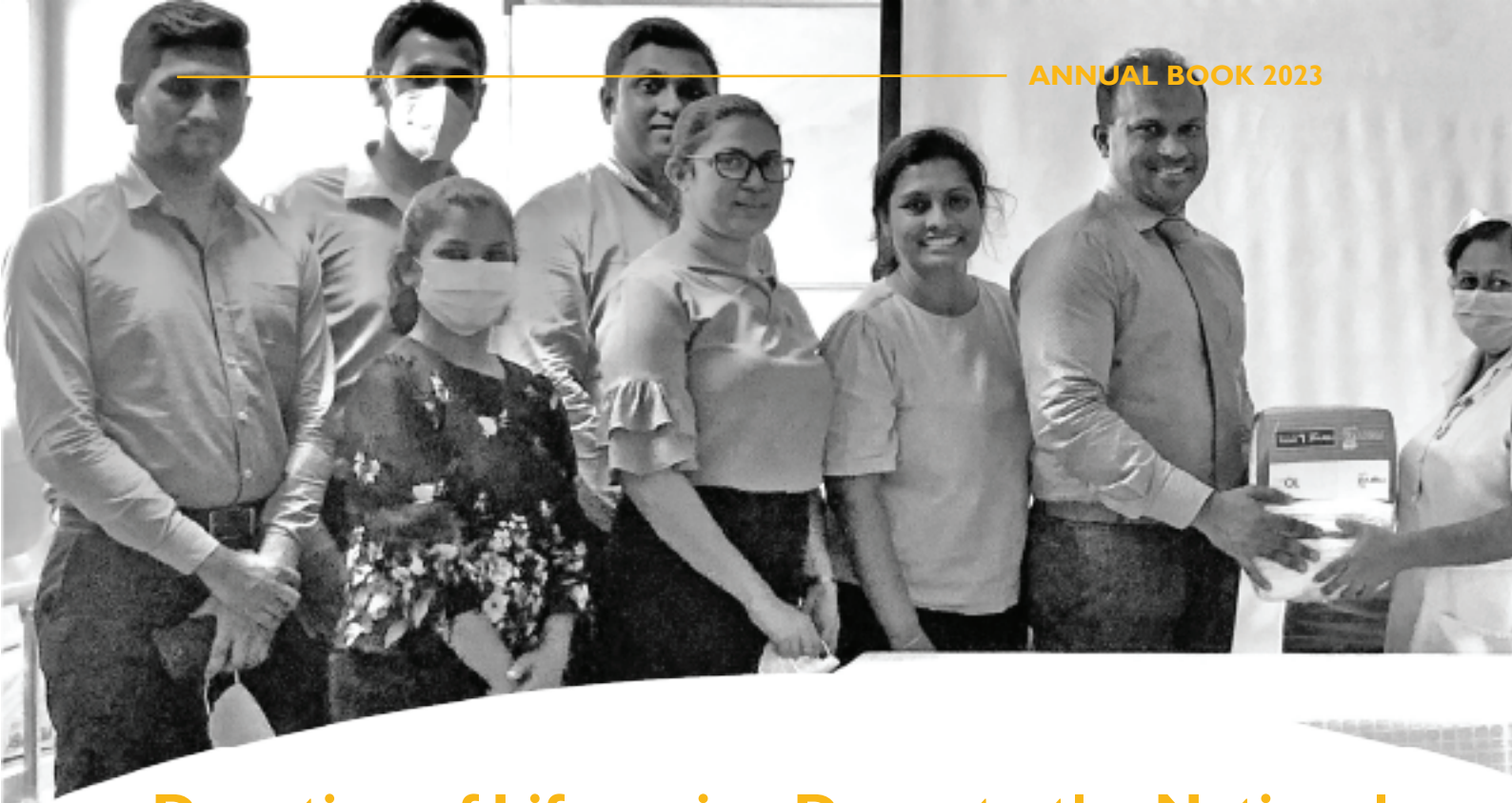
## Enhancing infrastructure capacity of our partnering institutes

### State of the art -50°C freezer to the Infectious Diseases Hospital (IDH) in Sri Lanka

As a part of the program in enhancing capacity of our partners, RemediumOne has donated a -50°C freezer to the Infectious Diseases Hospital, Angoda in Sri Lanka. This equipment was purchased and utilized for a clinical trial and in which the institution has made an immense involvement. This contribution will have a significant impact on the capacity of the hospital to store and manage temperature-sensitive vaccines, medications, and samples, thereby enhancing the quality of care provided to patients, fostering a more efficient healthcare system and future research. Together, we will work towards a healthier future for the people of Sri Lanka and the world at large.

Infectious Diseases Hospital was primarily established to provide treatment for Dengue. During the pandemic, this hospital with over 500 beds functioned as primary centre for COVID treatment & research. IDH is one of the oldest healthcare institutes in Sri Lanka.





## Donation of Life-saving Drugs to the National Hospital of Sri Lanka and "The National Institute for Nephrology, Dialysis & Transplantation (NINDT), Maligawatte

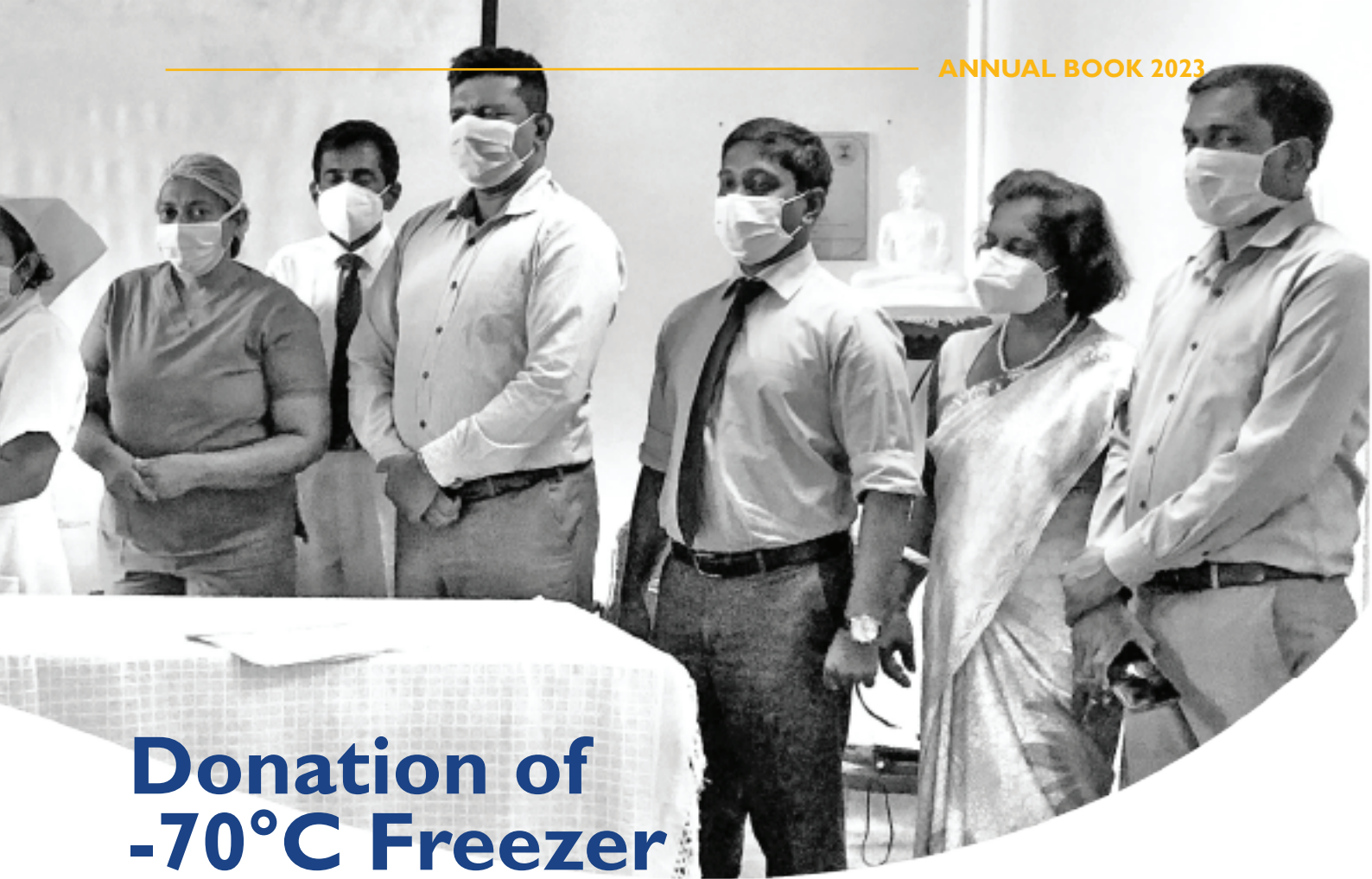
At RemediumOne, we believe that giving back to the community is an essential part of our social responsibility. In line with this belief, we donated life-saving cardiology and nephrology drugs to the National Hospital of Sri Lanka and NINDT during the economic crisis.

As part of our initiative, we identified the critical need for these drugs and took immediate action to provide them to the respective hospitals. We understand the importance of access to essential medicines in saving lives and improving the quality of life of the patients, especially during challenging times.

National Hospital of Sri Lanka (NHSL) founded in 1864, is the leading hospital in Sri Lanka. This hospital has 18 intensive care units, 21 operating theaters and more than 4,000 beds.

# Giving Back to the Society





## Donation of -70°C Freezer

We were able to donate a -70°C Freezer to the Faculty of Medicine, University of Kelaniya. This donation was made possible through our collaborative research work on a COVID control program in Sri Lanka, where RemediumOne and the Clinical Trials Unit (CTU), University of Kelaniya played a vital role.

The -70°C Freezer will be used for academic purposes at the faculty, which will benefit the students and the teaching staff in their research activities. We recognize the importance of supporting academic institutions in their research efforts, and we are committed to contributing to their success.



**Rajeewa Perera**  
Site Infrastructure & Instrumentation





## Enhancing Competencies: Empowering growth through active learning methods

RemediumOne arranged an outbound training program for its staff in May 2022. The program was conducted by [Wild-Drift](#) and was focused on team building and self-leadership. The two-day program was held in a scenic hill station, providing an ideal setting for staff members to engage in team-building activities, develop their leadership skills, and foster a sense of unity and collaboration among themselves.

The program was structured in a way that encouraged staff members to step outside their comfort zones and engage in activities that challenged their physical and mental abilities. The team-building exercises included hiking, rock climbing, and river crossing, among others, which required the staff members to work together, communicate effectively, and support one another.

Moreover, the self-leadership sessions were designed to help staff members to identify their strengths and weaknesses, set personal and professional goals, and develop effective strategies to achieve them. A 100 day program with clear measures of success was set out after the training and we are proud to say that all the goals set out were exceeded.

Overall, the outbound training program was a tremendous success, and the staff members returned to work with renewed energy, motivation, and a stronger sense of teamwork. At RemediumOne, we believe that investing in our staff's development and well-being is crucial to our success, and we look forward to organizing more such training programs in the future.

***"RemediumOne is a collection of the brightest minds from various fields of disciplines including medicine, biology, microbiology, genetics and pharmacology. From the time of joining the company, an employee is carefully nurtured to strive for excellence. A dedicated human resources management team ensures that our team is not only client-focused and quality conscious but also focused on individual personal development."***



**Samantha Ranathunga**  
Director/ CEO



One Team. One Dream.







# Execution Excellence during COVID 19 Pandemic: Two Case Studies



**Samantha Ranathunga**  
Director/ CEO



# Execution Excellence during COVID 19 Pandemic: Two Case Studies

The COVID-19 pandemic has posed numerous challenges to the clinical research industry worldwide, including in Sri Lanka. Nevertheless, even amidst the challenges posed by the pandemic, RemediumOne has successfully upheld its exceptional track record in the proficient management of clinical trials. The case studies examine how RemediumOne achieved execution excellence in its clinical trial management amidst the pandemic.

Sri Lanka is considered a favorable destination for conducting clinical trials due to its comprehensive primary, secondary and tertiary health care coverage, educated and literate patient population, freely accessible standard of care in the state sector and an experienced medical fraternity with exposure in centres of excellence in the UK, Australia, USA, etc.

The combination of these factors supported by experienced leadership, an efficient and well-equipped work force comprising of science graduates that are trained in executing complex clinical research projects was the essence of success achieved in the two case studies described in this report, that resulted in Sri Lanka being ranked as the number one recruiter in the world.

In Sri Lanka, from 3 January 2020 to, 31 May 2023, there have been 672,449 confirmed cases of COVID-19 with 16,872 deaths, reported to WHO. As of 29 October 2022, a total of 40,116,590 vaccine doses have been administered.

**Source :**

<https://covid19.who.int/region/searo/country/lk>

RemediumOne is a leading clinical research organization in Sri Lanka which is having an on-going partnership with Clinical Trials Unit (CTU), University of Kelaniya that specializes in conducting Phase II to Phase IV clinical trials across a wide range of therapeutic areas and performing value added services to the clinical development. The organization has a team of experienced professionals who are well-versed in handling various aspects of clinical trial management.

Such successes were achieved amidst the COVID-19 pandemic and the socio-economic and political crisis that derailed a nation and led many people towards abject poverty. The Clinical Trials Unit, University of Kelaniya and its private partner RemediumOne, the premier clinical research organization in Sri Lanka (herein referred to as the clinical trial project leadership team) were executing clinical trials at the best during the turmoil. The direction taken by this collaborative partnership to ensure project success was inspired by the **VUCA** model, developed by U.S. army war college in 1987 (*Volatility, Uncertainty, Complexity and Ambiguity*) and its adaptation **TUNA**, Which is a newer complexity model developed during COVID (*Turbulence, Uncertainty, Novel, and Ambiguity*) with an emphasis on the strategic decisions taken to overcome adversity and lessons learnt during execution.

The first case of COVID 19 in Sri Lanka was detected on 27th Jan 2020, in a Chinese citizen, and on 20th March 2020, a nationwide curfew was implemented as the number of cases started to increase. Since then, there have been three major waves that swept across the nation, with the third wave lasting from 15th April 2021 to 30th June 2022, claiming over 16,000 lives and 574,000 cases. The vaccination drive by the Ministry of Health, however, curtailed the development of severe disease in many individuals, with more than 14 million receiving at least 2 doses of an approved vaccine. Mandatory masking, extensive hygiene practices such as hand-washing, nationwide lock-downs and social distancing have brought the caseload down to single digits in November 2022, symbolizing the hard work carried out by the Sri Lankan healthcare system to overcome this disease.

## Challenges faced during COVID-19 pandemic:

The COVID-19 pandemic posed several challenges to health care sector and the clinical research industry globally, including in Sri Lanka. Some of the significant challenges faced by health care sector in Sri Lanka and RemediumOne during the pandemic were:

1. Restrictions on movement and transportation, which made it difficult to conduct site visits and monitoring of trials..
2. Delays in obtaining necessary regulatory approvals due to the pandemic-induced slowdowns in government offices.
3. Limited availability of clinical trial supplies and equipment due to global disruptions in supply chains.
4. Safety concerns for clinical trial participants and staff due to the risk of contracting COVID-19.





## Execution excellence in managing clinical trials during the pandemic:

The COVID-19 pandemic and socio-economic and political crisis although resulted in many adverse effects, the impact it had on the clinical trial industry in Sri Lanka was minimal. Many clinical trials that were ongoing when these crises hit, continued to perform well despite the adversity and in some cases, were able to outperform many other countries in recruiting patients delighting our sponsors and global clinical research organisations. Two such case studies where projects exceeded the expectations of the sponsors and reached number one status globally are detailed below.

**Project X** is a global multi-center clinical trial conducted by a global research organisation in Australia, New Zealand, India, and Sri Lanka for COPD patients. The study was initiated in 2020 and had recruited 25 patients in Australia and New Zealand by Jan 2022. The Sri Lankan sites were activated in February 2022, and since then have surpassed other countries to be the global leader in recruitment within a short span of 9 months, recruiting 140 subjects. Although the country was severely impacted by the political and socio-economic crisis with shortages of fuel, food, gas, and medicines the recruitment across 4 centres in Sri Lanka was not impacted. Due to strategies implemented through TUNA /VUCA model by the clinical trial project leadership team.

**Project Y** is a global multi-center trial in hypertension initiated in USA, Australia, New Zealand, Poland, and UK, in the year 2020 by an Industry partner. The recruitment was carried out at a very slow pace initially with a high global screen failure rate of around 60-65%. However, with the activation of the Sri Lankan sites in Aug 2020, the global study recruitment received a much-needed boost, with Sri Lanka managing to rise to the number one position globally in recruitment by recruiting 650 subjects in 2 years. The key determinant here is the low screen failure rate in Sri Lankan subjects, which stood at a below par average of 20-25%. This symbolizes the compliance and careful selection of the patients recruited to the trial in Sri Lanka, the rapport built between the study team and the participants, and the overall quality of the project delivery by the clinical trial project leadership team.

## VUCA and TUNA Models

The way the aforementioned case studies were able to successfully deliver record-breaking recruitment and generate high-quality data, all amidst the COVID-19 pandemic and the political and socio-economic crisis could be attributed to the operational excellence of the clinical trial project leadership team.

The well-known VUCA model, which is the acronym for Volatility, Uncertainty, Complexity and Ambiguity first introduced in 1987 by the U.S. Army War College and published by Herbert Barber in 1991 could be used to describe how these projects were able to successfully deliver amidst a VUCA environment.

Despite the VUCA model been effectively used in handling the crises and challenges faced by it, the proposed TUNA model (Turbulence, Uncertainty, Novel, and Ambiguity) could also be used to address two other major facts not directly addressed in the VUCA model. They are Turbulence and Novel nature of the challenges faced.

Turbulence could be defined as a highly unstable scenario, much like the chaos that unraveled with the COVID-19 pandemic and the political and socio-economic crisis. All stakeholders of the clinical trial industry were impacted by these crises, with difficulties faced in sourcing the essentials for survival. Effective communication, addressing the risks through effective mitigation strategies and compensation of the employees during these turbulent times were some effective strategies implemented to ensure maximum productivity and efficiency in delivering project success.

Novelty is the quality of being new, and the COVID-19 pandemic was a clear example of a novel challenge faced by the Sri Lankan clinical trial industry as well as the globe in general. The methods used to overcome this novel challenge reflects the use technology for work, such as the boom of virtual audio / video conferencing applications such as Zoom that forced many sponsors to conduct their routine project visits / meetings / monitoring and evaluation visits virtually ensuring smooth flow of work and significantly cutting down expenses. Various other global meetings with key project stakeholders were conducted via zoom ensuring effective participation of the Sri Lankan contingent in various high-level discussions despite the chaotic environment that existed within the country.



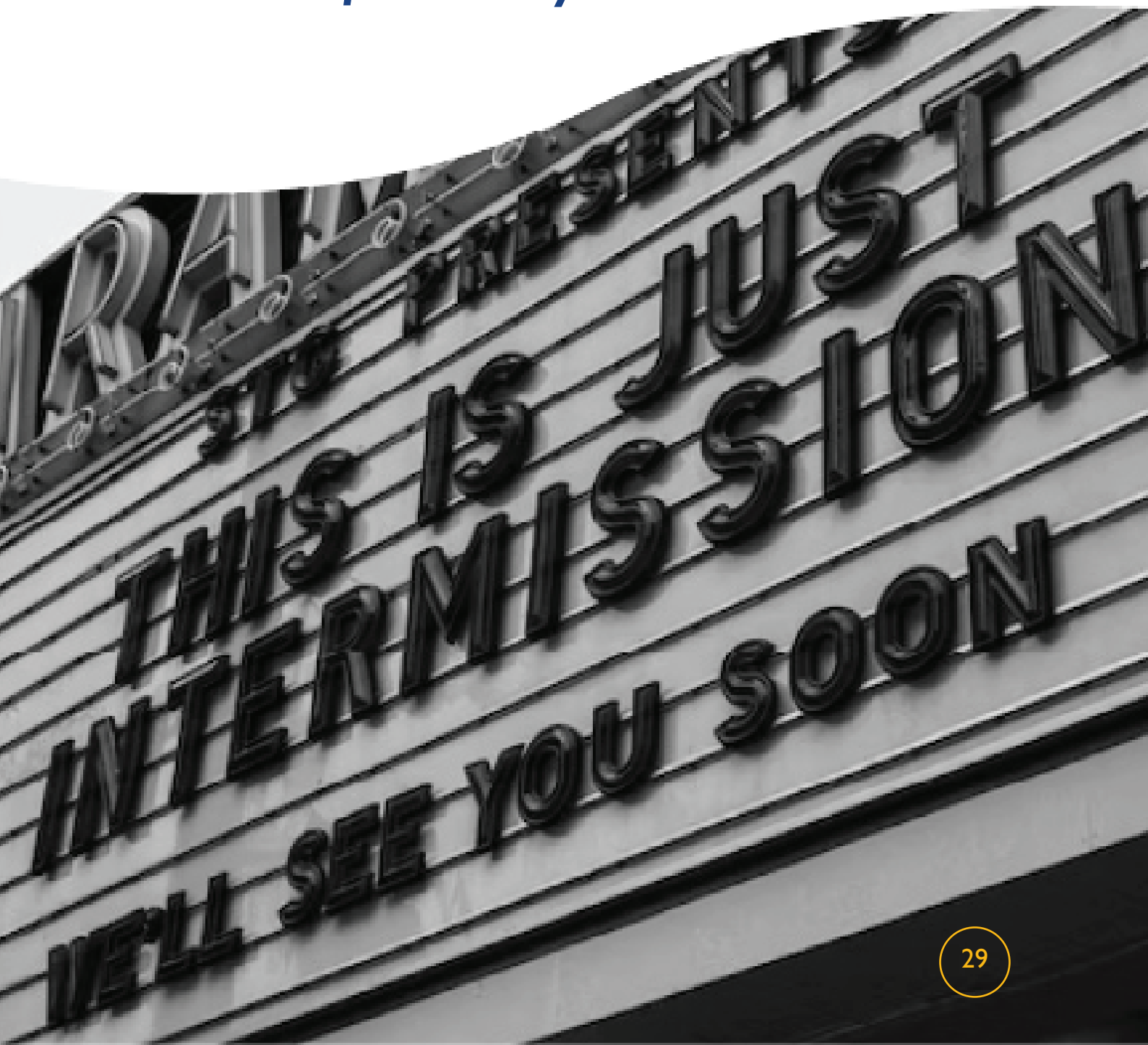
We would like to highlight some of the key steps taken by us to make sure that the trials executed by us exceeded the Sponsor expectations.

1. **Remote monitoring:** RemediumOne utilized remote monitoring technology to monitor clinical trial sites remotely. This technology enabled the organization to collect and analyze data without physically visiting the site, reducing the risk of exposure to COVID-19.
2. **Streamlined regulatory approvals:** RemediumOne worked closely with regulatory authorities to streamline the approval process, ensuring that the necessary approvals were obtained promptly to minimize delays.
3. **Alternative supply chain management:** RemediumOne worked with alternative suppliers and vendors to obtain necessary supplies and equipment, minimizing the impact of disruptions in global supply chains.
4. **Strict safety protocols:** RemediumOne implemented strict safety protocols for clinical trial participants and staff, including regular COVID-19 testing, temperature checks, and social distancing measures.

## **THE KEY LESSONS LEARNED** to effectively and successfully conducting clinical trials amidst the **COVID-19** pandemic and socio-economic and political crisis are as follows.

- I. Always **keep your customer informed**. When adversity hits, that is when the customer needs to be provided with on-time information on the situation.
- II. **Frequent risk analysis** and implementing **practical and actionable mitigating strategies** are vital in addressing potential issues in a proactive manner.
- III. **Constant communication** with both internal and external stakeholders is critical in rapport building and instilling confidence that the situation can be overcome with persistence and perseverance.
- IV. Always **have a fall-back option** when planning contingencies as there is a high probability that the first plan would fail during a crisis.
- V. Always **plan for the worst** possible outcome when planning work packages during a crisis.
- VI. **Compensating employees** financially and providing extensive psychological support during a crisis is vital in boosting employee morale, productivity and securing loyalty.
- VII. **Explore business diversification** to ensure business continuity.

***"Therefore, this would further encourage sponsors and global clinical research organisations to consider Sri Lanka as an ideal destination for clinical trials, as there are much greater thresholds to be reached when executing projects in the absence of adversity."***





# Dr. Cyril Fernando Memorial Oration (1900 -1955)

Combating burden of CVD through innovative strategies to improve blood pressure control.

**Prof. Asita de Silva - Founder, RemediumOne**

High blood pressure is a leading cause of global mortality, resulting in 18 million deaths annually, with 80% occurring in low- and middle-income countries (LMICs). In South Asia, hypertension is also the primary cause of disability-adjusted life years (DALYs) and premature deaths, particularly affecting younger age groups and leading to significant economic consequences<sup>1</sup>. In Sri Lanka, hypertension prevalence ranges from 20% to 30%, affecting approximately 1 in every 4 or 5 individuals<sup>2,3</sup>.

Meta-analyses of prospective studies done in Europe and the Asia-Pacific region have highlighted the strong correlation between blood pressure indices and cardiovascular mortality, stroke, and ischemic heart disease, emphasizing the risk posed even by moderately high systolic blood pressure<sup>4,5</sup>.

Despite the scientific evidence, more than a billion people worldwide still have uncontrolled or non-optimal blood pressure. The global rate of blood pressure control among individuals with hypertension is approximately 14%, and in LMICs, this rate is even lower at around 8.0%. This has probably resulted in an estimated 20% of global deaths attributable to non-optimal blood pressure. Particularly, blood pressure control rate among those who are treated is less than 40% globally and in LMICs this rate is much lower at around 26%<sup>6</sup>.

There is a need to challenge the traditional paradigms that are unlikely to effectively address the cardiovascular disease crisis and to develop innovative solutions both in terms of clinical care as well as health system delivery to improve overall outcome for our patients. We conducted two large control randomized trials using innovative approaches. One in the tertiary care setting and other in the community to try and improve blood pressure control among hypertensives in Sri Lanka.

The most recent WHO Guideline of 2022 in the pharmacological management of hypertension recommends two-drug combination therapy, preferably in a single-pill combination as initial treatment for adults with hypertension requiring drug therapy. However, no trial has evaluated the use of triple therapy with fixed dose combinations at low doses for early or initial treatment of hypertension. This gap led to the initiation of the TRIUMPH trial, conducted in collaboration with the George Institute for Global Health in Australia and funded by National Health and Medical Research Council (NHMRC), Australia, and Global Alliance for Chronic Diseases (GACD).

***TRIUMPH was a randomised, open label trial of low-dose triple blood pressure-lowering therapy versus usual care. The study enrolled 700 participants from Sri Lanka with an average age of 56 and blood pressure of 154/90 mm Hg. Around half the participants were randomly chosen to take the Triple Pill, receiving a fixed-dose combination pill containing telmisartan 20mg, amlodipine 2.5mg and chlorthalidone 12.5mg, with the option to use a double-dose version after six weeks. The remaining half of the participants were given usual care.***

***The research team evaluated whether clinicians and patients would be likely to adopt the Triple Pill concept, alongside an economic evaluation to determine its cost effectiveness, which will be important for governments and other funders to consider. Further opportunities to implement the Triple Pill in a wider setting are also being explored in Sri Lanka.***

A meta-analysis conducted by Salim Yusuf et al<sup>8</sup>. revealed that the highest risk for cardiovascular disease exists in high-income countries. However, the biggest burden of cardiovascular diseases and highest case fatality rates are in low-income countries. Also, the event rates of cardiovascular events and case fatality rates are higher in rural communities, indicating that current risk mitigation strategies may not effectively reach rural populations.

***COBRA-BPS trial concluded that in rural communities in Bangladesh, Pakistan, and Sri Lanka, a multicomponent intervention that was centered on proactive home visits by trained government community health workers who were linked with existing public health care infrastructure led to a greater reduction in blood pressure than usual care among adults with hypertension. This trial was managed by RemediumOne in Sri Lanka.***

Publication can be read at <https://www.nejm.org/doi/full/10.1056/NEJMoa1911965>

COBRA-BPS trial was conducted in Sri Lanka, specifically in the Puttalam district, with 870 participants recruited and over 90% retention at the end of the two-year follow-up. Baseline characteristics showed that the Sri Lankan population was relatively older, had a higher literacy rate, and a higher prevalence of chronic comorbidities such as diabetes and chronic kidney disease compared to Bangladesh and India. While Sri Lankan participants had free access to medicines such as Angiotensin receptor blockers (ARBs) and calcium channel blockers, a significant proportion still had uncontrolled or poorly controlled blood pressure, indicating that access to medication alone is insufficient.

The results of the trial demonstrated that the Multi Component Intervention (MCI) led to a significant reduction in blood pressure. At 24 months, the mean reduction in systolic blood pressure was 5.2 mmHg greater in the intervention group compared to the control group, and the mean reduction in diastolic blood pressure was 2.8 mmHg greater. Blood pressure control was achieved in 53.2% of the participants in the intervention group compared to 43.7% in the control group. The study concluded that the MCI, delivered through existing primary health-care infrastructure and utilizing Community Healthcare Workers (CHWs), improved blood pressure control in rural communities at a low cost<sup>9</sup>.

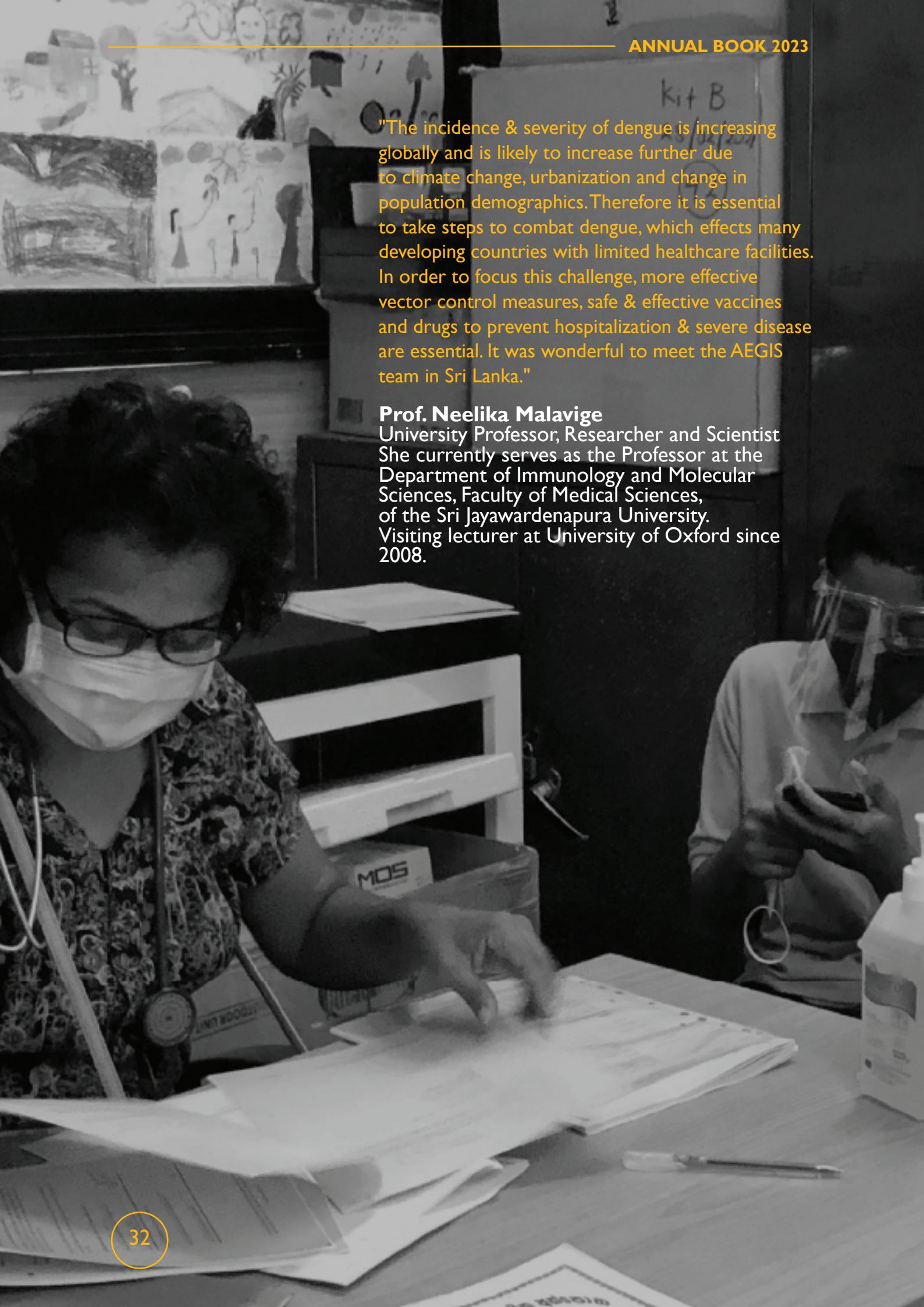
The findings of the study highlight the importance of CHWs in managing high blood pressure and emphasize that a proactive approach with home visits and interventions can lead to a meaningful reduction in blood pressure in rural areas. The results were published in the New England Journal of Medicine, supporting the implementation of MCI for hypertension care in rural communities.

It is crucial to urgently implement and scale up these interventions in LMICs to achieve the global action plan of reducing high blood pressure prevalence by 25% by 2025 and reducing premature deaths.

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"The incidence & severity of dengue is increasing globally and is likely to increase further due to climate change, urbanization and change in population demographics. Therefore it is essential to take steps to combat dengue, which effects many developing countries with limited healthcare facilities. In order to focus this challenge, more effective vector control measures, safe & effective vaccines and drugs to prevent hospitalization & severe disease are essential. It was wonderful to meet the AEGIS team in Sri Lanka."

**Prof. Neelika Malavige**

University Professor, Researcher and Scientist  
She currently serves as the Professor at the Department of Immunology and Molecular Sciences, Faculty of Medical Sciences, of the Sri Jayawardenapura University. Visiting lecturer at University of Oxford since 2008.

## RemediumOne Solving Health Care Problems At Community Level

Sri Lanka is facing a double burden of diseases - communicable and non-communicable. While the country has been successful in curbing communicable diseases like Malaria, vector-borne diseases like Dengue are still posing a serious threat to the economy and healthcare system. On the other hand, non-communicable diseases are on the rise in Sri Lanka due to factors like an aging population, dietary habits, and lifestyle changes.

RemediumOne has been contributing significantly to solving healthcare problems in the community since its inception. The COBRA-BPS trial focused on multifactorial intervention for hypertension control in the rural set up. The trial was conducted in rural Sri Lanka, Bangladesh and Pakistan. Sri Lankan arm of the study was managed by RemediumOne, in coordination with Duke NUS Medical School, Singapore. The study found that a multicomponent intervention focused on proactive home visits by trained government community health workers in rural communities in Bangladesh, Pakistan, and Sri Lanka resulted in a significant reduction in blood pressure among adults with hypertension, compared to usual care.

RemediumOne is also conducting a dengue vaccine trial for an industry partner. The trial started in 2015, and in just six months, 2100 children were enrolled in the program and put on active surveillance to detect febrile illness. Active surveillance was conducted through telephonic contacts, with each child being contacted on a weekly basis. Currently, after 2 boosters, the study is successfully maintaining the retention rate above 98%.

In addition to the dengue vaccine trial, the Notre Dame University and John Hopkins Bloomberg School of Public Health in the USA have collaborated with RemediumOne and have initiated a Dengue vector control program in Sri Lanka, which is a part of the AEGIS global initiatives. The program's objective is to manage vector-borne diseases with spatial repellents and is being executed in the Western province of Sri Lanka, where the Dengue disease prevalence is high. The program is community-based, large-scale, and innovative, and is being carried out under the supervision of the Epidemiology Unit and National Dengue Control Unit, Ministry of Health. Spatial repellents, according to the WHO, are an effective means of mosquito control in the environment.

Over the years, RemediumOne has evolved its operational model to tackle healthcare interventions at the community level. This has included the incorporation of various healthcare professionals, such as community nursing officers, phlebotomists, social science workers, vector control officers, and staff with expertise in performing complex community-level interventions.



**Dr. Chamini Kanatiwela de Silva**  
Project Manager -Dengue SR  
Lead -Decentralized Clinical Trials



Our state of the art telephonic surveillance system and the well experienced surveillance team makes weekly contacts with all participants and their parents where communication on health issues along with febrile surveillance is carried out.

To further enhance our community-level programs, we have established a pharmacovigilance center in collaboration with the Clinical Trials Unit at the University of Kelaniya. This center will carry out post-authorization campaigns effectively for existing and future drugs or interventions at the highest international standards.

***"In conclusion, RemediumOne's initiatives in Sri Lanka are commendable and demonstrates the organization's commitment to solving healthcare problems at the community level. By addressing the challenges of vector-borne diseases and non-communicable diseases, RemediumOne is making a significant contribution to improving the health of the Sri Lankan population."***



# Driving towards Patient Safety (Real World Evidence and Pharmacovigilance)

Patient safety is a key concern for all stakeholders in the healthcare industry. As healthcare becomes more complex, and treatments become more advanced, ensuring patient safety has become an even more important issue. Real world evidence (RWE) and pharmacovigilance (PV) programs are two areas where RemediumOne is actively driving towards improving patient safety.

We are actively working to expand the capabilities in this area. The company is investing in new technology and data analysis tools to help gather and analyze real-world data. RemediumOne is also building partnerships with healthcare providers, and other organizations to gain access to the data needed to conduct RWE studies. Currently databases are built in diabetology, nephrology and oncology at key national level clinics.

Our expanded focus on RWE studies reflects the changing landscape of healthcare and the increasing importance of real-world data in medical research. By leveraging our expertise in clinical trials and investing in new technologies and partnerships, RemediumOne is well-positioned to help advance the field of RWE studies and provide valuable insights into the safety and effectiveness of drugs, devices, and other medical interventions.

RWE effectiveness programs are important to Sri Lanka for several reasons. Firstly, RWE allows for the evaluation of the effectiveness and safety of healthcare interventions in real-world settings.

***"This is particularly important in Sri Lanka, where healthcare interventions may not always have the same efficacy and safety as they do in clinical trial settings due to differences in patient populations, disease burdens, and healthcare systems."***

Secondly, RWE initiatives have the potential to provide valuable insights in shaping healthcare decision making in Sri Lanka. By analyzing real-world data on healthcare interventions and outcomes, RWE programs can identify areas where improvements can be made to ensure that patients receive the best possible care.

Thirdly, RWE programs can help to inform healthcare policy in Sri Lanka. By providing policymakers with real-world evidence on the effectiveness and safety of healthcare interventions, RWE programs can help to shape policies that improve patient outcomes and optimize the use of healthcare resources.

We have now started working on designing and delivering RWE trials. These trials are designed to collect data from patients in real-world settings, including their homes, workplaces, and communities. The data collected is used to identify patterns and trends that can help to improve patient safety. For example, if a drug is found to have unexpected side effects in the real world, this information can be used to modify treatment protocols and reduce the risk of harm to patients.

Our recent collaboration with a global leader in statin manufacturing involves exploring the prescription patterns of statins in Sri Lanka. Through real-world data analysis on statin prescriptions, we will gain a deeper understanding of how these drugs are prescribed in Sri Lanka, enabling identification of areas for improvement. The trial's outcomes will offer significant insights to the medical community locally and internationally, assisting in informed decision-making on statin prescription in their practice. Moreover, the insights from this trial will contribute to the broader literature on statin prescription patterns, benefiting researchers and policymakers globally.

We are committed to conducting high-quality RWE studies that are both rigorous and transparent. The company follows established best practices for RWE study design and analysis and works closely with multiple stakeholders to ensure that its studies meet their standards for quality and reliability.

**Pharmacovigilance** is another important area where RemediumOne is working to improve patient safety. While Sri Lanka has a well-established regulatory environment for pharmacovigilance, the active involvement of stakeholders in this area is poor. This gap is particularly concerning when it comes to ensuring the safe use of medications in real-world settings. In response, RemediumOne through its partner University of Kelaniya has taken the initiative to establish a pharmacovigilance center that will actively monitor safety signals and generate safety narratives for clinical trials for regulatory submissions. This initiative will play a crucial role in improving patient safety by ensuring timely identification, assessment, and management of adverse drug reactions, contributing to the overall safety and effectiveness of medications used in clinical practice.

The new center will utilize state-of-the-art technology for active monitoring of safety signals in Sri Lanka, as well as established collaborations with international centers of excellence. This will ensure that the latest best practices and techniques are used in all aspects of the center's operations. Case processing and other related pharmacovigilance segments will be handled according to international standards, and global directories will be used for coding.

Through this initiative, RemediumOne aims to enhance the safety of medication use in Sri Lanka and contributes to improving the health of the people in the country and around the world. We believe that this is a critical area of focus, given the role that medication plays in the treatment and management of many health conditions.




**Thanush Jeevarajah**  
Real World Evidence & Late Phase Trials



The establishment of this new pharmacovigilance centre which is housed at University of Kelaniya is an important milestone for RemediumOne and reflects our commitment to advancing healthcare through rigorous scientific research and ethical practices. By collaborating with the Clinical Trials Unit at the University of Kelaniya, we can draw on the expertise of leading researchers and clinicians in the field of pharmacovigilance and ensure that our efforts are grounded in the latest scientific knowledge.

At the same time, the center will also serve as a platform for training and education in pharmacovigilance. We recognize that building capacity in this area is essential for the long-term success of pharmacovigilance efforts in Sri Lanka and beyond. Through partnerships with department of pharmacology, University of Kelaniya, local healthcare providers, regulatory agencies, and other stakeholders, we aim to build awareness and understanding of the importance of pharmacovigilance and promote the adoption of best practices in this area.

***"Overall, we are excited about the potential of this new pharmacovigilance center to make a real difference in the health and well-being of people in Sri Lanka and beyond. We believe that by investing in this area, we can contribute to improving the safety and efficacy of medications, and ultimately help to save lives and improve health outcomes."***



"Advances in technology and access to information have lead to increased demand for evidence of benefits and risks in real world setting by all relevant stakeholders including regulator, healthcare providers and patients."  
FDA, 2022

# Partnerships and Alliances

## New Collaboration with



## Population Health Research Institute

HEALTH THROUGH KNOWLEDGE

We are proud to announce the new partnership in 2022 with the Population Health Research Institute (PHRI) in Canada, one of the leading institutions for global health research. This partnership is an exciting development that will help to advance healthcare through cutting-edge research in multiple areas.

The partnership between RemediumOne and PHRI will leverage the strengths of both organizations to address important healthcare challenges and improve the health outcomes of people in Sri Lanka and around the world. By combining our expertise in clinical research and global health, we can work together to develop innovative solutions to some of the most pressing health issues of our time.

One area where our partnership is already making a difference is in the assessment of a medical intervention to improve the clinical outcome of patients with atrial fibrillation who have had a stroke. This is a critical area of focus, given the significant burden of stroke on global health and the need for effective treatments to improve outcomes for patients.

Read More about "Atrial Fibrillation" on PHRI:  
<https://www.phri.ca/?s=Atrial+fibrillation>

***"At RemediumOne, we are excited about the potential of this partnership to make a real difference in the health of people in Sri Lanka and beyond. We believe that by collaborating with leading institutions like PHRI, we can help to advance healthcare research and innovation, and ultimately improve health outcomes for patients around the world."***



**Dr. Namal Wijesinghe**  
Partnerships & Alliances

## About PHRI

PARTICIPANTS **1,500,000**

STAFF **300**

CONTINENTS **6**

YEARS OF STUDIES **29**

COUNTRIES **102**

ONGOING STUDIES **100**

SITES **1,600**

COMPLETED STUDIES **153**

SCIENTISTS, INVESTIGATORS AND FELLOWS **70**

## ENRICH-AF

Edoxaban for Intra-Cranial Hemorrhage Survivors with Atrial Fibrillation

The objective of this is to evaluate whether Edoxaban is superior to standard medical therapy in reducing the risk of stroke in high-risk atrial fibrillation patients with previous intracranial hemorrhage.

Type of study **Interventional - Drug**

Study Design **Randomized, open, blinded end-point**

Number of Countries **18**

Number of Sites **155**

Number of Participants, globally **1,200**

Study Duration **2019-2024**

**Read more:**

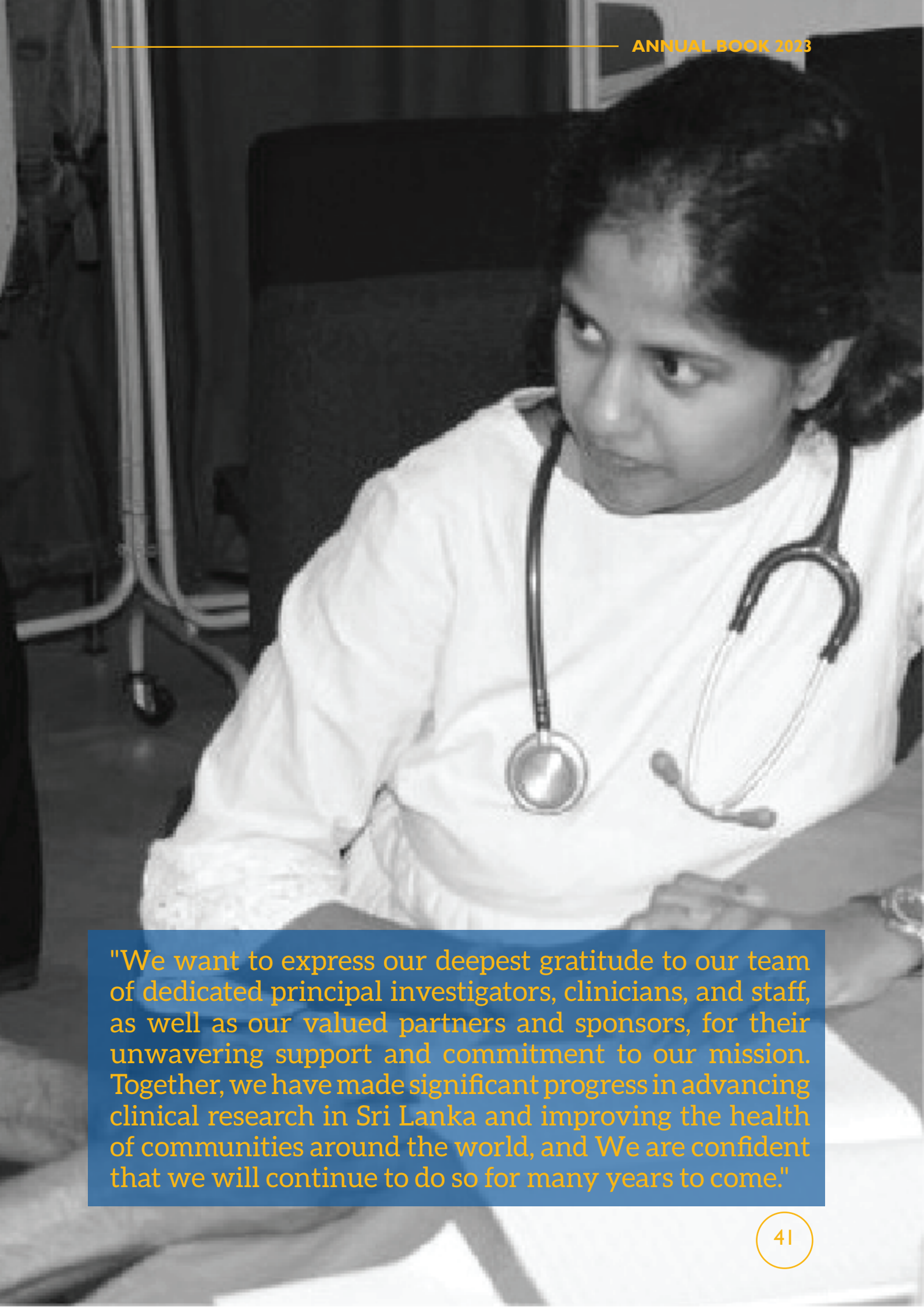
[ENRICH-AF - Research Studies - PHRI - Population Health Research Institute of Canada](#)



"At RemediumOne,  
we believe  
that giving  
back to the  
community  
is an essential  
part of our  
social  
responsibility."



**Ingrid de Silva**  
Procurement & Logistics



"We want to express our deepest gratitude to our team of dedicated principal investigators, clinicians, and staff, as well as our valued partners and sponsors, for their unwavering support and commitment to our mission. Together, we have made significant progress in advancing clinical research in Sri Lanka and improving the health of communities around the world, and We are confident that we will continue to do so for many years to come."

# Why Sri Lanka is a preferred destination for Clinical Research



**Chanaka Fernando**  
Head- Business Assurance

- Large, literate patient pool
- Excellent hospital network & healthcare structure
- Well defined regulatory framework
- Predictable startup timeline spans between 16-18 weeks
- GMK, UK recognized highly qualified medical specialists
- Common use of English
- Treatment protocols in line with latest guidelines
- Good support infrastructure – courier facilities, IT

## *Sri Lanka Statistics*

**Population**

**21,893,579**

**GDP per Capita**

**USD 4,560**

**Literacy rate, adult total (%)**  
of people ages 15 and above)

**92%**

**Global Knowledge Index 2022**

**79th** (out of 132)

**High in Human Development**

**16th** (out of 28)

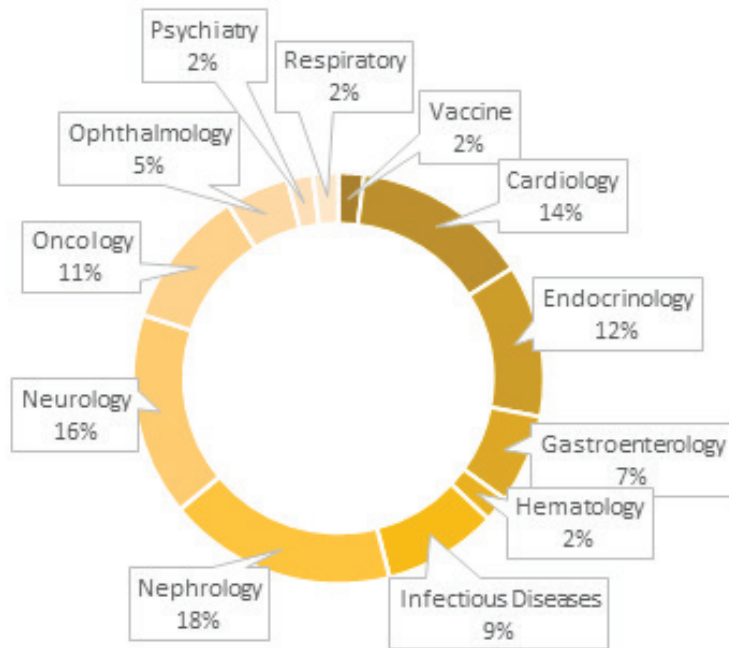
**Source-**

<https://www.knowledge4all.com/country-profile?CountryId=1101>

<https://data.worldbank.org/country/sri-lanka>



# Therapeutic Areas

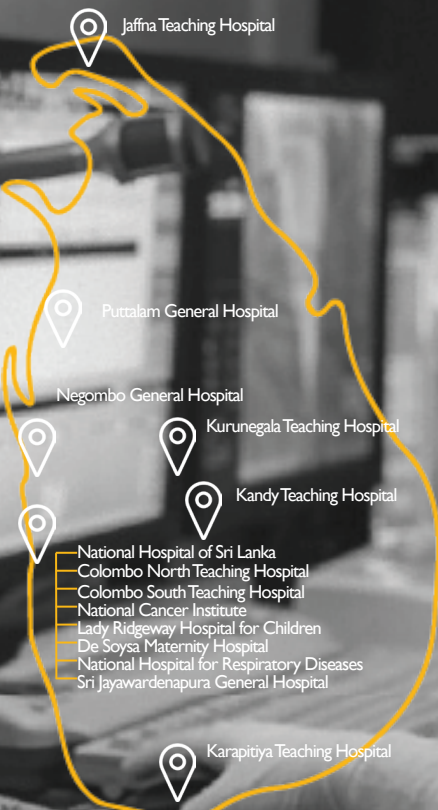


Area	Trials Completed	Trials Ongoing
Cardiology	5	2
Endocrinology	5	1
Gastroenterology	2	1
Hematology		1
Infectious Diseases		4
Nephrology	4	5
Neurology	5	3
Oncology	4	1
Ophthalmology	1	1
Psychiatry		1
Respiratory		1
Vaccines		1

Clinical trial expertise of RemediumOne spans across wider therapeutic areas

- **26** clinical trials were completed **without any major or critical audit findings**
- **22** ongoing clinical trials

## Partnerships with institutions throughout Sri Lanka



# WOMEN AT REMEDIUUMONE



**Anuradha Dahanayake**  
Head- Clinical Development

"We are a clinical research organization collaborating with international universities and research centers. In our organization, 80% of employees are young female science graduates. They all have a positive attitude towards their work and the work environment. They prioritize patient care and are deeply concerned about patient safety.

Personally, I have over 12 years of experience in clinical research, working on numerous projects across different therapeutic areas. As a team lead, I am dedicated to sharing my knowledge and experience with my team members. I consistently provide guidance and mentorship to support their personal and professional development."

"As an organization, we excel in most of our trials, becoming global leaders in many of our projects. Currently, we are conducting clinical trials in hypertension, neurology, nephrology, and rare diseases. Our expertise extends beyond patient recruitment; we are also recognized for maintaining high data quality. Today, as we celebrate International Women's Day, we, as female leaders, acknowledge our responsibility to contribute more to society."

**Watch full video :**

<https://www.linkedin.com/feed/update/urn:li:activity:7041007499499503617/>

## **Dr. Chamini Kanatiwela de Silva**

Project Manager- Dengue SR  
Lead- Decentralized Clinical Trials

"I am primarily involved in managing community-based clinical trials at RemediumOne. As a clinical trials manager, it is my responsibility to ensure the smooth progress of these crucial trials. I oversee the day-to-day operations of the projects, ensuring that targets are met and meaningful outcomes are produced."



"At present, I am leading a young and dynamic research team comprising of multidisciplinary professionals, with 50% of them being females. I work closely with investigators from renowned universities worldwide. Being a leader in community-based clinical research, I collaborate with national and regional-level policymakers, healthcare professionals, community leaders, and various other community members. Maintaining strong relationships with these stakeholders is crucial in successfully managing community-based clinical trials. It is fulfilling to know that the work I do has a significant impact on people's lives."

"Moreover, I am passionate about engaging with science as it provides a means for me to contribute to addressing some of the pressing challenges we face. The contribution of women in science is not only essential for enriching their own lives but also for promoting the well-being of communities worldwide through effective participation in the field."

44

**Watch full video :**

<https://www.linkedin.com/feed/update/urn:li:activity:7043535723806789632/>

# OUR PARTNERS

## WHOM WE ARE WORKING WITH



**Shehan Gnanapragasam**  
Project Acquisition

RemediumOne places significant emphasis on collaboration with a diverse range of international research partners. These partners span across three key categories, namely academic institutions, industry organizations, and clinical research organizations. Each of these categories represents a center of excellence in their respective domains.

By fostering close relationships and working hand-in-hand with our esteemed partners, RemediumOne aims to tackle healthcare challenges and unlock novel solutions. We recognize the immense value that these partnerships bring to our organization. They serve as the vital driving force behind our ability to thrive in the healthcare industry.

Through collaborative efforts, knowledge sharing, and leveraging the expertise of our partners, RemediumOne continuously endeavors to innovate and make meaningful contributions to the field of healthcare. We understand that our success is intricately linked to the strength of these partnerships, and we remain dedicated to nurturing and expanding them for the benefit of patients and healthcare advancement.



## Global Sponsors

## Global Academic Research Organisations (AROs)



## Partner Organizations



## Global Clinical Research Organisations (CROs)



## Key Collaborators visited RemediumOne in 2022



Dr. Karl Roberts, Chief Operating Officer of The George Medicines, and Ardian Latifi, Head of Clinical Operations at The George Medicines, visited Sri Lanka to personally engage with investigators and show appreciation for their efforts in study recruitment.

Professor Antony Rodgers, Professor of Global Health at the Faculty of Medicine at UNSW Sydney and Chair of Clinical Epidemiology at the Faculty of Medicine at Imperial College London, visited Sri Lanka to meet the clinical team involved in one of his clinical trials. Sri Lanka has contributed over 80% of the trial's power.



Professor Craig Anderson, who holds positions as Professor of Neurology and Epidemiology in the Faculty of Medicine at the University of New South Wales and clinical academic neurologist at Royal Prince Alfred Hospital in Sydney, Australia, recently engaged in a series of discussions with neurologists working as Principal Investigators on one of his landmark stroke trials. Additionally, Professor Anderson serves as the Executive Director of The George Institute China at Peking University Health Science Center in Beijing, China.

Professor Hilali Noordeen, an Associate Professor at UCL in London and a Consultant Orthopaedic & Spinal Surgeon, visited RemediumOne to finalize the signing of a contract for an exciting clinical trial.



Prior to the launch of the Dengue Spatial Repellent Study in Sri Lanka, a delegation comprising Prof. John Grieco - Lead Principal Investigator of the AEGIS program, Prof. Nicole Achee- Scientific Director of the AEGIS program, Prof. Steven Harvey from John Hopkins University- Principal Investigator of the Social Science component, and the team paid a visit to the country. During this visit, they had the opportunity to engage with policymakers at the national and regional levels within the healthcare sector, engaging in fruitful discussions pertaining to the project.



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SCAN & READ MORE  
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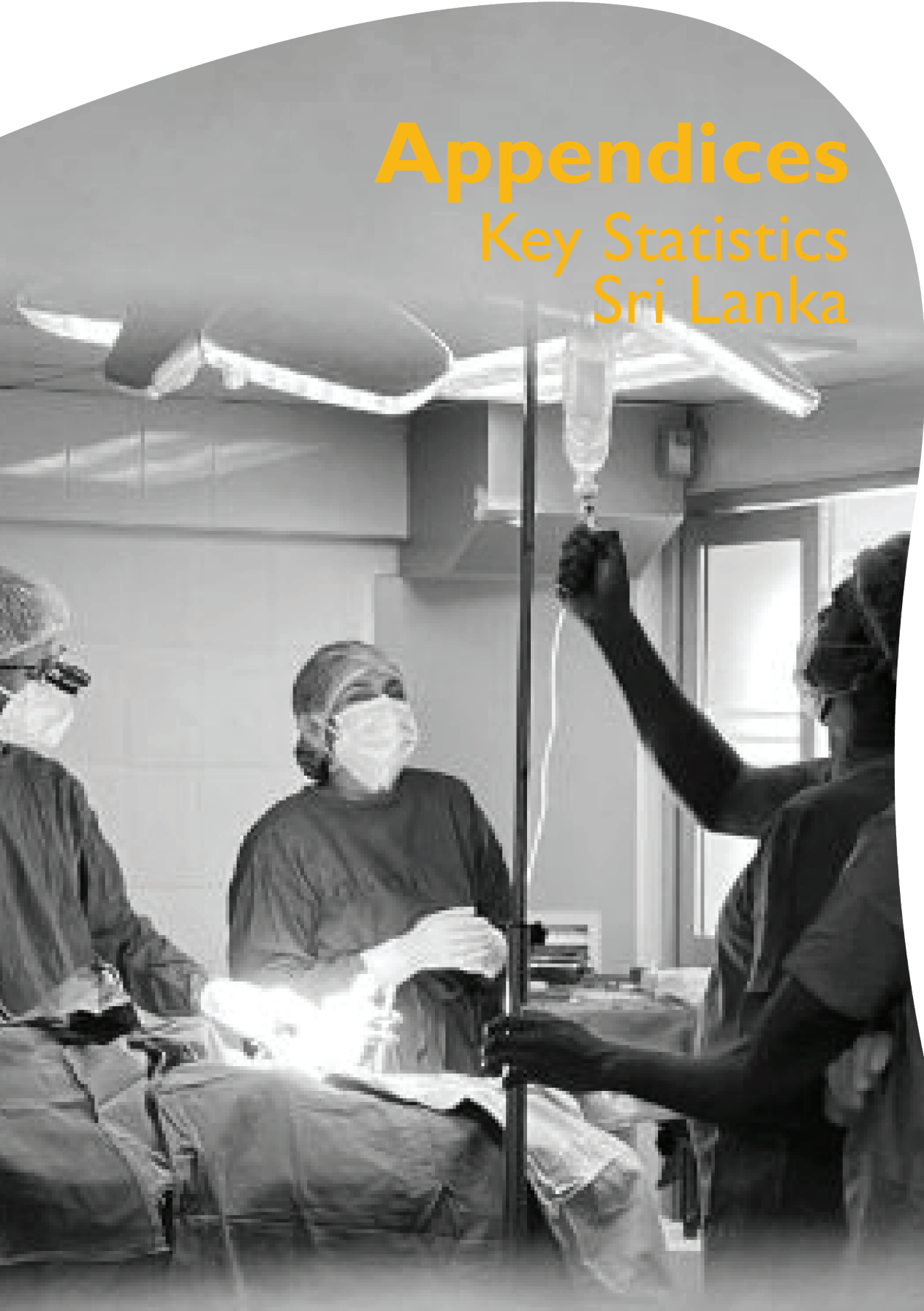




# Appendices

## Key Statistics

### Sri Lanka



# Healthcare Structure of Sri Lanka

Sri Lanka's healthcare system is a mix of public and private healthcare facilities. The government of Sri Lanka provides free healthcare services to its citizens through a network of government hospitals and clinics, while the private sector provides healthcare services to those who can afford it.

The Ministry of Health is responsible for the management of the public healthcare system, which includes the provision of preventive, curative, and rehabilitative services. There are three levels of healthcare facilities in Sri Lanka, which are the primary, secondary, and tertiary levels.

Primary healthcare services are provided through a network of public health clinics, medical officer of health (MOH) offices, and rural hospitals. The secondary level of healthcare is provided through district hospitals and base hospitals, while the tertiary level of healthcare is provided through teaching hospitals and specialized hospitals.

In addition to the public healthcare system, Sri Lanka also has a private healthcare sector. The private sector includes private hospitals, clinics, and laboratories, which provide medical services to those who can afford them.

Overall, the healthcare system in Sri Lanka is considered to be relatively well developed, with a high level of access to basic healthcare services. However, there are still challenges in providing adequate healthcare services to all citizens, particularly in rural areas, where access to healthcare facilities is limited.



# Disease Burden

## Communicable Diseases

Sri Lanka has made significant progress in controlling communicable diseases over the past few decades, thanks to a strong public health system and effective disease control programs. Here are some of the key communicable diseases and their prevalence in Sri Lanka:

<b>Malaria</b>	Sri Lanka was declared malaria-free in 2016, after a successful campaign to eliminate the disease. The last case of indigenous malaria was reported in 2012.
<b>Dengue</b>	Health authorities have reported elevated dengue fever activity nationwide in Sri Lanka in May 2023, with more than 33,000 suspected cases reported Jan. 1-May 14. This is 1.7 times higher than the 19,908 cases reported over a similar period in 2022.
<b>Tuberculosis (TB)</b>	Health authorities have reported elevated dengue fever activity nationwide in Sri Lanka in May 2023, with more than 33,000 suspected cases reported Jan. 1-May 14. This is 1.7 times higher than the 19,908 cases reported over a similar period in 2022.
<b>Hepatitis</b>	Viral hepatitis is a significant public health issue in Sri Lanka, with a high prevalence of hepatitis B and C. In 2022, there were 1,408 cases of hepatitis B reported in Sri Lanka, and 3,281 cases of hepatitis C.
<b>Influenza</b>	Influenza is a seasonal respiratory illness that is prevalent in Sri Lanka. In 2022, there were over 15,000 cases of influenza reported in Sri Lanka, with a mortality rate of 0.2%.

Overall, Sri Lanka has been successful in controlling many communicable diseases, but efforts are ongoing to address persistent challenges, such as dengue, tuberculosis, and viral hepatitis.



## Non Communicable Diseases

Non-communicable diseases (NCDs) are a significant public health concern in Sri Lanka, with high rates of prevalence and mortality. Here are some of the key NCDs and their prevalence in Sri Lanka:

<b>Cardiovascular Diseases</b>	Cardiovascular diseases (CVDs), such as heart disease and stroke, are the leading cause of death in Sri Lanka, accounting for more than 30% of all deaths. In 2022, there were 62,666 deaths due to CVDs in Sri Lanka. The prevalence of hypertension, a major risk factor for CVDs, is estimated to be around 26% in Sri Lanka.
<b>Diabetes</b>	Diabetes is a growing concern in Sri Lanka, with an estimated prevalence rate of 9.2%. In 2022, there were 26,482 deaths due to diabetes in Sri Lanka.
<b>Cancer</b>	Cancer is a significant cause of morbidity and mortality in Sri Lanka, with an estimated 23,000 new cases diagnosed annually. The most common types of cancer in Sri Lanka are breast, colorectal, and lung cancer.
<b>Chronic Respiratory Diseases</b>	Chronic respiratory diseases, such as chronic obstructive pulmonary disease (COPD) and asthma, are a significant burden in Sri Lanka, with an estimated prevalence rate of 3-5%. In 2022, there were 9,691 deaths due to chronic respiratory diseases in Sri Lanka.
<b>Chronic Kidney Disease</b>	Chronic kidney disease (CKD) is a growing problem in Sri Lanka, particularly in rural areas. The prevalence of CKD is estimated to be around 15-20%, and it is a leading cause of death in some parts of the country.

Overall, NCDs are a major public health concern in Sri Lanka, and efforts are ongoing to address the high prevalence rates of these diseases. Prevention and management strategies, such as lifestyle modifications and early detection and treatment, are important for reducing the burden of NCDs in Sri Lanka.



# OUR WORK

## Past & Current Clinical Trials

Indication / Disease Area	Brief Description
Snakebite	A study to increase the safety of polyvalent antivenom available in South Asia.
Stroke	A study to of a Chinese traditional medicine to improve outcomes after stroke.
Rheumatoid Arthritis	A study on rheumatoid arthritis in patients with refractory disease to currently available treatment.
Diabetes Mellitus	A study to improve diabetes control in patients with high risk of cardiovascular disease.
Breast Cancer	A study to improve survival in patients with breast cancer.
High blood cholesterol and heart disease	A study on high blood pressure control.
Adenoviral conjunctivitis	A study to improve symptoms and reduce duration of illness in patients with viral conjunctivitis.
Blepharospasm	A study to treat a painful eye condition in patients previously treated with Botulinum toxin.
Colorectal cancer	A study to reduce relapses in patients with cancer in the large intestine.
Head and neck cancer	A study to increase the overall survival of patients with previously untreated cancer in the mouth or soft palate.
Diabetes mellitus in children	A study to improve control of diabetes in children with type I diabetes
Stroke	A study to determine the best head position in patients after an acute stroke.
High blood pressure	A study to improve treatment of high blood pressure.
Systemic Lupus Erythematosus (SLE)	A study to reduce disease activity in patients with SLE.
Kidney disease	A study to achieve complete disease remission in patients with lupus kidney disease.
Gastrointestinal disease	A study to improve treatment of Crohn's disease, an inflammatory disease in the intestines.
Dengue	A study to develop a vaccine to prevent dengue.
High blood pressure	A study to improve control of high blood pressure in patients living in very rural areas in South Asia through primary healthcare intervention.
Stroke / Bleeding in the brain	A study to find out whether intensive blood pressure lowering can prevent recurrent stroke in patients with a history of brain haemorrhage.
Diabetes in pregnancy	A study to find out whether appropriate lifestyle changes in pregnant South Asian women with diabetes will prevent type II diabetes later in life.
Cardiovascular disease	A study to reduce risk of cardiovascular disease in high-risk patients with diabetes, high cholesterol and high blood pressure.

Blood disorder	A study to improve outcomes in patients with breakdown of red cells in the blood.
Chronic kidney disease (CKD)	A study to improve anaemia in patients with CKD.
Kidney disease	A study to improve treatment options in patients with a type of kidney disease
Chronic lung disease	A study to reduce death in patients with chronic lung disease and heart disease.
High blood pressure	A study to assess a novel approach to control blood pressure in patients with high blood pressure.
High blood cholesterol	A study to find out whether cinnamon can reduce LDL cholesterol in the blood.
COVID 19	A study to assess a treatment for COVID-19 delivered as a nasal spray.
Brain haemorrhage	A study to improve outcomes in patients who have had a bleeding episode in the brain.
Kidney disease	A study to improve treatment options in patients with a type of kidney disease
Dengue	A study to reduce dengue in children with the use of a novel mosquito repellent device.





## Publications of trials we have contributed to

1. PLoS Medicine 2011; 8(5): e1000435. DOI:10.1371/journal.pmed.1000435
2. International Journal of Stroke 2013; 8: 491-94
3. Cerebrovascular Diseases 2013; 35: 18-22
4. Stroke 2013; 44: 2093-2100
5. Stroke 2013; 44: 3580-3.
6. The Lancet 2015; 385: 617-28
7. Cerebrovascular Disease 2015; 39: 309-18
8. Stroke 2016; 47: 44-52
9. Journal of Hypertension 2016; 34: 1872-81
10. Journal of the Neurological Sciences 2016; 371: 126–130
11. Cerebrovascular Disease 2017; 43: 36-42
12. New England Journal of Medicine, 2017: 2017;376:2437-47. DOI: 10.1056/NEJMoa1615715
13. Trials, 2017: DOI 10.1186/s13063-017-2018-0
14. Translational Stroke Research, 2017: DOI 10.1007/s12975-017-0548-0
15. American Journal of Hypertension 2018; <https://doi.org/10.1093/ajh/hpy071>
16. Journal of the American Medical Association 2018; 320(6): 566-579. doi:10.1001/jama.2018.10359
17. Nephrology Dialysis Transplantation 2018: 1-8 doi: 10.1093/ndt/gfy184
18. Diabetic Medicine 2018: doi: 10.1111/dme.13850
19. BMJ Open 2018; 8:e022317. doi:10.1136/bmjopen-2018-022317
20. Journal of Human Hypertension 2019; 33(5): 411-418. doi: 10.1038/s41371-019-0193-z
21. Journal of the American College of Cardiology 2019; 73(9): DOI: 10.1016/S0735-1097(19)32640-3
22. Journal of the American College of Cardiology 2019;74(9):1167-1176. 10.1016/j.jacc.2019.03.013
23. The Lancet Diabetes & endocrinology 2019; 7(8): 618-628
24. Journal of Obesity 2019; Article ID 4914158, 11 pages <https://doi.org/10.1155/2019/4914158>
25. PLoS One 2019; <https://doi.org/10.1371/journal.pone.0211100>
26. BMJ Open 2019;9:e030584. doi: 10.1136/bmjopen-2019-030584
27. BMJ Open 2019 Oct 7;9(10):e031773. doi: 10.1136/bmjopen-2019-031773.
28. Lancet Global Health 2019; 7: e1359-66.
29. New England Journal of Medicine 2020; 382:717-726
30. JAMA Cardiology 2020; 5(11): 1219-1226
31. Lancet Global Health March 19, 2021 [https://doi.org/10.1016/S2214-109X\(21\)00033-4](https://doi.org/10.1016/S2214-109X(21)00033-4)
32. Trials 2021; 22, 943: <https://doi.org/10.1186/s13063-021-05881-7>
33. Nature Medicine 2021: Accepted for publication