Enhancing Diversity and Inclusion in Rare Disease Clinical Trials: The Role of Sri Lanka

The need for diverse participation in clinical trials cannot be overstated, especially when it comes to rare diseases. Historically, racial and ethnic minorities have been underrepresented in clinical trials, which has resulted in significant health disparities among underrepresented populations. In fact, the Federal Drug Administration (FDA) issued draft guidance (April 2022) outlining the need for the development of race and ethnicity diversity plans for products under the FDA's remit, recommending that all products include a diversity plan. This guidance is a result of 30 years of policy priority and heroic efforts by healthcare advocates to improve clinical trial diversity.

South Asia, a melting pot of genetic diversity, is home to thousands of ethnically and culturally diverse populations (Tätte et al., 2019). While consanguineous marriages are nearly uncommon or prohibited by societal pressure in Western societies, in many parts of Africa and Asia, including South Asia, approximately 20–50% of marriages are consanguineous (Mobarak et al., 2019). In Sri Lanka a study by Premawardhena et al., 2020 reveals that the overall national consanguinity rate is 7.4%. This contributes to an increased risk of rare diseases by facilitating the inheritance of recessive genetic variants within families.

A survey analyzing gene therapy clinical trials listed on ClinicalTrials.gov found that the majority of these trials were conducted in high-income countries and upper middle-income countries, with very limited representation from lower-middle-income and low-income countries (Cornetta et al., 2022). Specifically, when examining trials for diseases like Duchenne muscular dystrophy (DMD), spinal muscular atrophy (SMA), and Huntington's disease (HD), the overwhelming majority (99%) of trials were concentrated in HICs and UMICs, excluding South Asian countries (Wijekoon et al., 2023). This exclusion is particularly striking, considering that South Asians constitute a significant portion (40%) of the Asian population and 25% of the global population.

Including Sri Lanka in rare disease clinical trials can contribute to addressing issues of underrepresentation and improve the generalizability of the trial results.

Advantages of Sri Lanka for Rare Disease Clinical Trials:

1. **Diverse Patient Population**: Sri Lanka's diverse patient population ensures a broader representation of ethnic and genetic backgrounds. By including patients from different racial and ethnic groups, the trials can better understand the impact of treatments on diverse populations.
2. **Disease Registries:** Clinician researchers in Sri Lanka have established disease registries for rare diseases such as lupus nephritis, chronic obstructive pulmonary disease (COPD), and IgA nephropathy. These registries enable trial sponsors to identify suitable patients, track their outcomes, and gather valuable data on disease progression and potential treatments.
3. **Healthcare Infrastructure**: Sri Lanka possesses a robust healthcare infrastructure, including universal state-funded health coverage, dedicated specialty hospitals, and investigators with clinical trial experience. This infrastructure supports the execution of rare disease projects in line with international standards.
4. **Regulatory Framework**: Sri Lanka has a well-defined regulatory framework for clinical trials, ensuring compliance with ethical and safety standards. This regulatory support facilitates efficient and streamlined trial initiation and execution.

5. **Advanced Facilities**: Sri Lanka offers CAP-accredited central laboratories, long-term document archival and retrieval facilities, drug destruction facilities for used and unused investigational medical products (IMPs), accredited calibration services, and temperature-controlled specimen and drug transport facilities. These advanced facilities contribute to reliable data collection, storage, and transportation throughout the clinical trial process.

Sri Lanka's potential as a location for rare disease clinical trials lies in its diverse patient population, disease registries, robust healthcare infrastructure, supportive regulatory framework, and advanced facilities. By conducting inclusive and equitable trials in Sri Lanka, sponsors can enhance diversity, improve the generalizability of trial results, and address historical underrepresentation.

To discover how RemediumOne can optimize participant engagement and enrollment in rare disease clinical trials in Sri Lanka, we invite you to connect with our Leadership Team.

References:

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