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Lessons from the Field

Strategic establishment of an International Pharmacology Specialty Laboratory in a resource-limited setting

Background: A growing number of drug development studies that include pharmacokinetic evaluations are conducted in regions lacking a specialised pharmacology laboratory. This necessitated the development of an International Pharmacology Specialty Laboratory (IPSL) in Zimbabwe.

Objectives: The aim of this article is to describe the development of an IPSL in Zimbabwe.

Methods: The IPSL was developed collaboratively by the University of Zimbabwe and the University at Buffalo Center for Integrated Global Biomedical Sciences. Key stages included infrastructure development, establishment of quality management systems and collaborative mentorship in clinical pharmacology study design and chromatographic assay development and validation.

Results: Two high performance liquid chromatography instruments were donated by an instrument manufacturer and a contract research organisation. Laboratory space was acquired through association with the Zimbabwe national drug regulatory authority. Operational policies, standard operating procedures and a document control system were established. Scientists and technicians were trained in aspects relevant to IPSL operations. A high-performance liquid chromatography method for nevirapine was developed with the guidance of the Clinical Pharmacology Quality Assurance programme and approved by the assay method review programme. The University of Zimbabwe IPSL is engaged with the United States National Institute of Allergy and Infectious Diseases Division of AIDS research networks and is poised to begin drug assays and pharmacokinetic analyses.

Conclusions: An IPSL has been successfully established in a resource-limited setting through the efforts of an external partnership providing technical guidance and motivated internal faculty and staff. Strategic partnerships were beneficial in navigating challenges leading to laboratory development and training new investigators. The IPSL is now engaged in clinical pharmacology research.

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