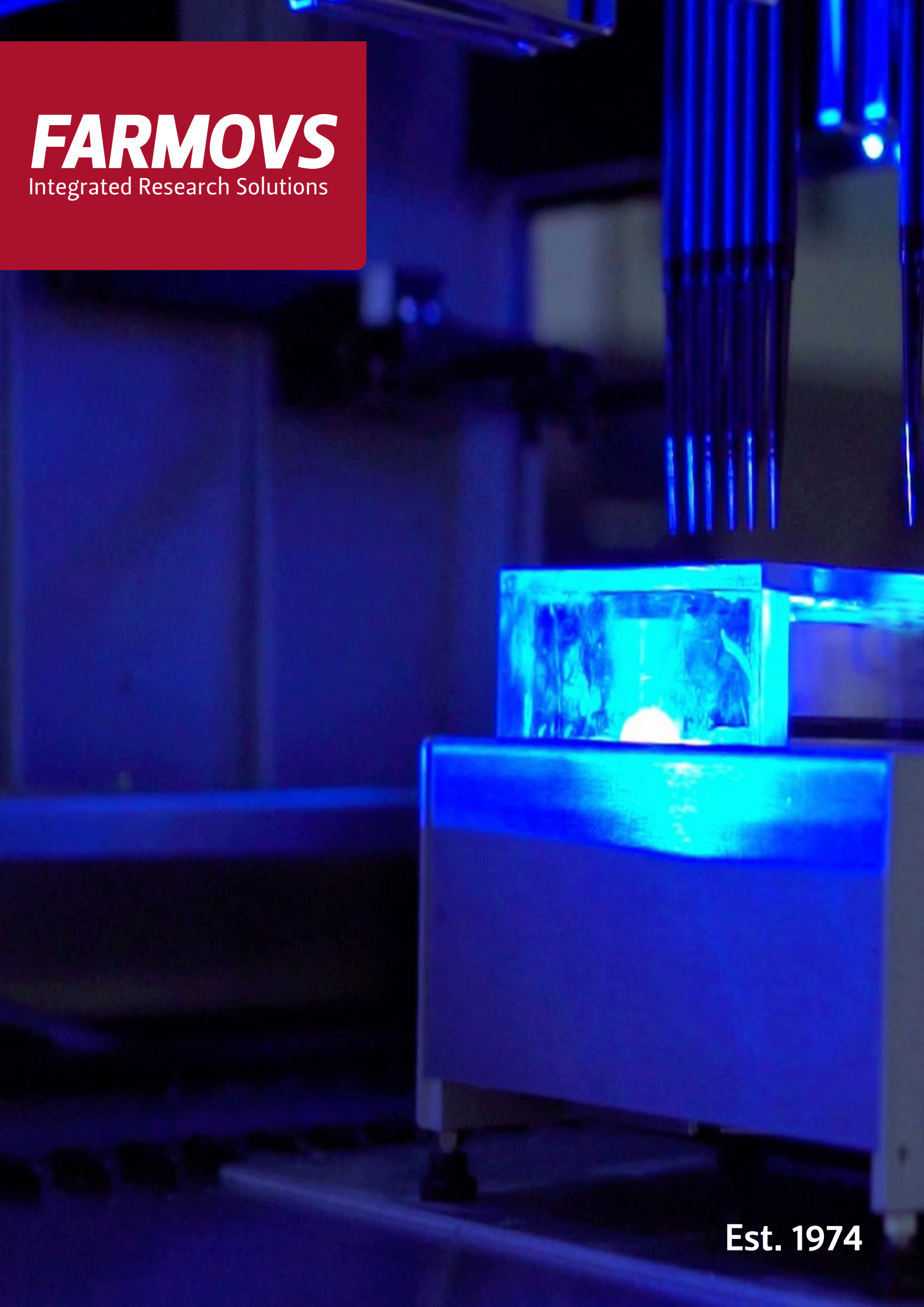
FARMOVS
Integrated Research Solutions
Est. 1974

Content

Overview

Est. 1974

FARMOVS is a South African specialty, full-service clinical research organisation that conducts ICH-GCP compliant Phase I to III clinical trials.

Since 1974, FARMOVS has successfully managed and conducted more than 3,000 clinical trials for clients across the globe, ranging from small biotech firms to the largest pharmaceutical companies.

The FARMOVS competitive advantage is our wealth of bioequivalence and Phase I experience, clinical trial expertise and patient recruitment success through our Site Management Organisation (SMO) division.

We, furthermore, have a large clinical research facility with an on-site ISO 15189 accredited clinical laboratory and a Good Laboratory Practice (GLP) certified bioanalytical laboratory.

Our excellent regulatory inspection history, long-standing relationships with our clients and extensive experience within the South African and international GCP and GLP environment offer our clients additional value.

Although most of our clients make use of our holistic clinical research solution, we can also offer standalone services that can be integrated into your existing service solution.

Our responsive and flexible approach to research, enables our clients accomplish their goals much faster than anticipated.

Our clinical research services includes bioanalytical research, clinical research, an in-house pharmacy, a depot, a logistical and international sample handling unit, site management organisation (SMO), recruitment of study participants, project management, medical writing, quality assurance, a regulatory service, quality management, a logistical and international sample handling unit, on-site archiving and secure document destruction.

Click HERE to visit our world class facilities.

Our Facilities

FARMOVS offers a full-service clinical research site, conveniently situated on the campus of the University of the Free State (UFS).

Our research partners and subject matter experts (SMEs) from the UFS are located within a 10 km radius, enabling cost-effective research collaboration.

Important facts about our clinical research site and its facilities:

- GLP certified bioanalytical laboratory.
- ISO 15189 accredited clinical laboratory.
- Research clinic with 90 beds.
- Pharmacy and pharmacy depot.
- Manual glucose clamp unit.
- On-site spirometry unit.
- On-site archive and secure document destruction.
- Transit laboratory for the handling of PK/PD sample processing and shipment.
- Emergency medical equipment and qualified staff present to assist.
- Equipped kitchen for food-drug interaction studies.
- 1.7 km from hospitals; emergency response unit arrives in ~ 5 minutes.

An early phase clinical unit with a bioanalytical laboratory located on the same research site.

Research Experience

Over the past 48 years we have gained extensive experience in the following therapeutic areas:

- Auto immune
- Cardiovascular
- Central nervous system
- Dermatology
- Gastrointestinal tract
- Gynaecology
- GIT
- Haematology
- Infectious diseases
- Metabolic and endocrine
- Oncology
- Psychiatry
- Respiratory
- Tuberculosis

Types of clinical trials performed:

- First in human (FIH)
- Abbreviated new drug applications
- BE studies
- Biosimilar studies
- Drug-drug interaction
- Food effect studies
- Manual glucose clamps
- Inhalation generic
- Pain modelling
- Plethysmography and respiratory challenge studies
- Recombinant vaccines
- Renal and hepatic impairment (plus matching healthy volunteers)
- SAD/MAD
- Specialised PK/PD and biomarker
- Spiro-ergometry
- Telemetry
- Telemetry (+ stomach pH)
- Thorough corrected QT interval (Healthy volunteers and patients)
- 505 b2 strategic and regulatory support

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Unique Study Population

FARMOVS is located in Bloemfontein, which is a medical hub that serves a population rich in ethnic diversity. Our SMO network further extends our reach to the rest of South Africa and most rural areas. This gives us potential access to over 58 million people.

South Africa's diverse population consists of 80% African, 8.3% Caucasian, 2.5% Indian or Asian and 8.8% smaller ethnic groups.

The current FARMOVS study population closely resembles the South African population demographics. It includes healthy volunteers, treatment naive patients and individuals with different medical conditions.

Our database of healthy volunteers include individuals from various ethnic groups, namely 72% African, 23.5% Caucasian and 4.4% other smaller ethnic groups.

We have a well-established network and can offer our clients access to patients in various therapeutic fields. These include auto immune, cardiology, infectious diseases, oncology, and women's health.

For a full list of our therapeutic areas, click HERE.

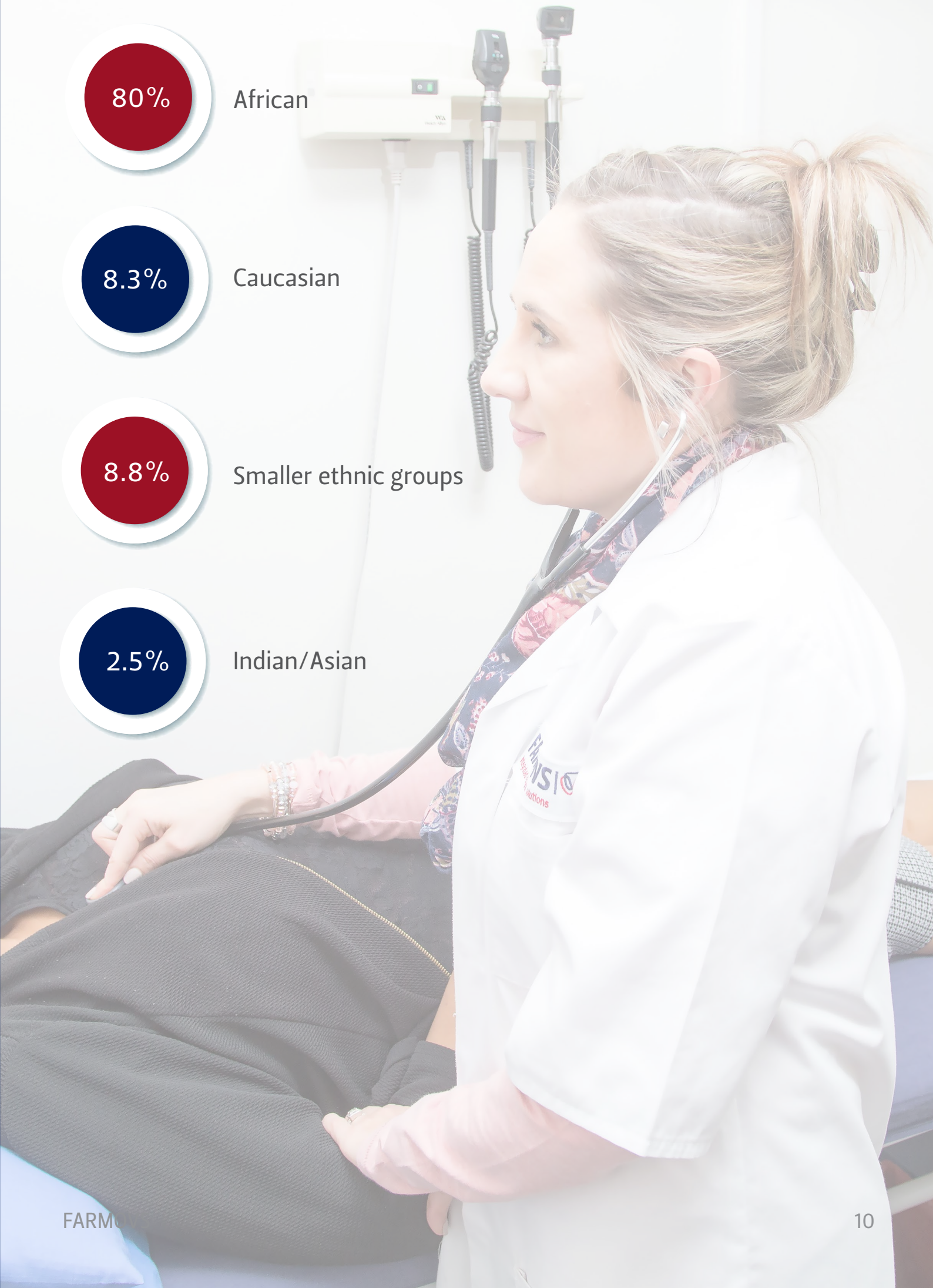
Click **HERE** for an introduction to our study population

80% African

8.3% Caucasian

8.8% Smaller ethnic groups

2.5% Indian/Asian



Bioanalytical Research

FARMOVS offers the highest quality bioanalytical services for qualitative and quantitative drug, metabolite and biomarker analysis in a variety of matrices.

With 48 years of experience, we have developed an extensive database with more than 580 internally developed and validated analytical methods that adhere to ICH and US Food and Drug Administration guidelines. Our methods have been used in more than 3,000 pre-clinical and clinical trials.

We continuously develop new analytical methods for our clients. The laboratory routinely performs safety testing for clinical chemistry and haematology analysis amongst others.

We have the largest GLP certified bioanalytical laboratory in Africa and we are geared for world-class drug development. Our team of extraordinary bioanalytical experts thrive on the excitement generated by new discoveries.

They view their daily routine as a world filled with novel methods of analysis and subsequent technological integration that expands the horizons of clinical research. They feel that their work forms an important part of the discovery and production of new life-saving medicines that are constantly improving the quality of life of people all over the world.

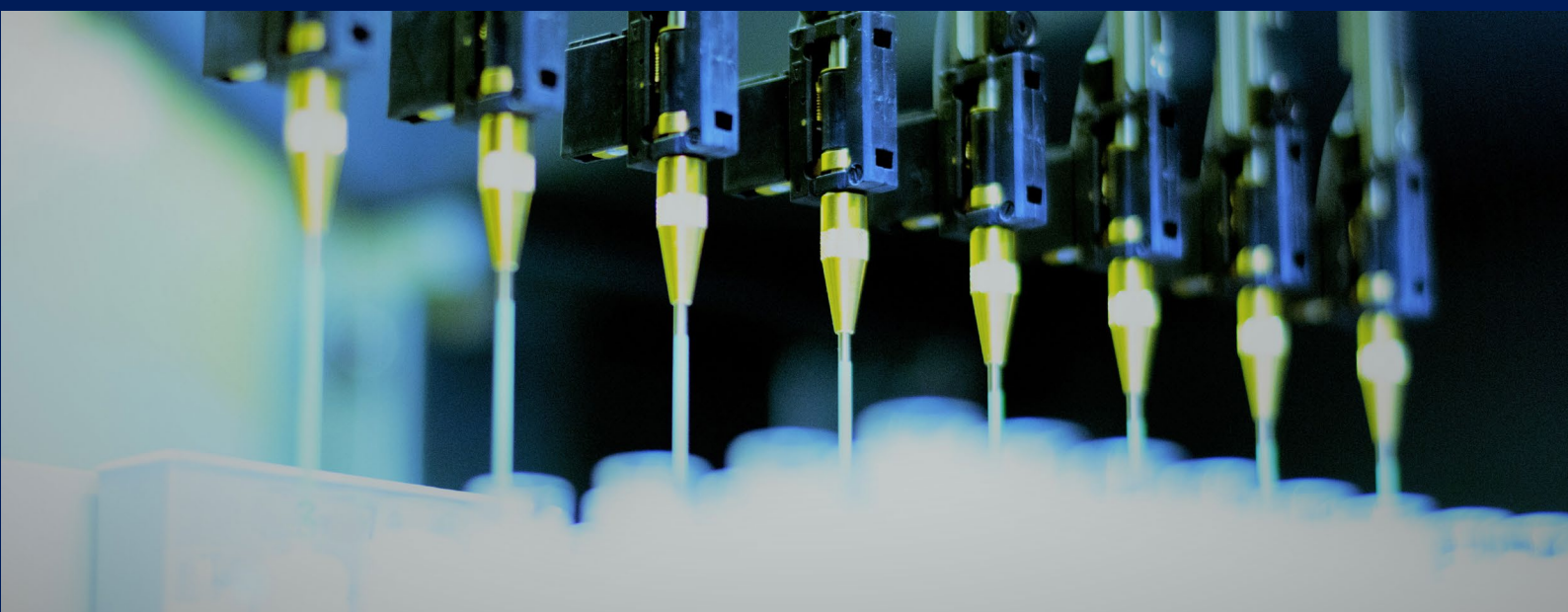
You can download our list of Validated Assay Methods here: www.farmovs.com

New technology and innovation should be the building blocks of any laboratory. We believe that technological collaboration is the key to optimisation. Thus, we selected the best technology to support our bioanalysis team.

Amongst these are, the Microlab® STARLet and the SCIEX 7500®. The Microlab® STARLet apparatus by Hamilton was specifically selected for its ability to perform sample analysis in large quantities at a greater speed by means of robotic pipetting and robotic automated microplate reading, which is a semi-automated process.

Secondly, we acquired Aurora, the SCIEX Triple Quad™ 7500 LC-MS/MS mass analyser, which is marketed as one of the most sensitive triple quadrupole mass spectrometers available, allowing for sub-picogram/ml quantification. This apparatus has many advantages, given that our clients can access unprecedented analytical sensitivity, which enables the quantification of PK profiles of drugs that have a very low systemic absorption.

Aurora, the STARlet and our other analysis aparatus sets FARMOVS apart from other CROs, creating an exciting and favourable landscape for clients to explore FARMOVS as their new partner in bioanalytical research.



Clinical Research

FARMOVS has access to one of the most diverse study populations. This enables us to access patients across different ethnic groups.

A close collaborator network that includes the Medical School of the UFS gives us access to research experts in a variety of therapeutic ares.

Our database of over 4000 healthy volunteers and established SMO function extends our recruitment activities to rural areas. As a result, patient recruitment activities can reach treatment naive participants and patients with various medical conditions.

Clinical research takes place in our state of the art Clinic with 90 beds and 8 private rooms for long-term studies.

Our on-site ISO 15189 accredited clinical laboratory enables us to decrease analysis turn-around time to approximately 2-4 hours. Our medical technicians and technologists ensure that this service is always available.

We offer the following:

- Clinical chemistry.
- Haematology and ex-vivo coagulation.
- Rapid SARS-CoV-2 antigen testing.
- Serology.
- Urinary analysis (including point of care drugs-of-abuse, pregnancy, cotinine and urinalysis).
- A variety of electrochemiluminescence methods.

In response to the Covid-19 pandemic, we adapted our research clinic with medical grade HEPA filters to ensure that patients are protected against virusses when they participate in clincial trials.

We are ready to facilitate your next study!

4000+ healthy volunteers and access to treatment naive patients

On-site ISO 15189 accredited clinical laboratory

Pharmacy and Depot

The FARMOVS in-house pharmacy is registered with the South African Pharmacy Council (SAPC) as an Institutional Pharmacy. Two pharmacists and two pharmacist assistants, who are also registered with the SAPC, offer clients world class service standards.

Access to the pharmacy is restricted and study medication is stored and/or prepared in a automated temperature controlled environment with REES Scientific technology. Monitored temperature levels include room temperature (15–25 °C), refrigerated (2–8 °C) or freezing (-20 °C), depending on the storage conditions required for the specific study medication.

Dispensing and compounding activities are strictly guided by study-specific requirements. A Class II bio-safety cabinet is used for aseptic preparation of study medication, and we use monochromatic lights when handling light sensitive medication.

The FARMOVS pharmacy has a depot service, which entails the storage, distribution, and destruction of study medication for multi-centre late phase studies in South Africa.

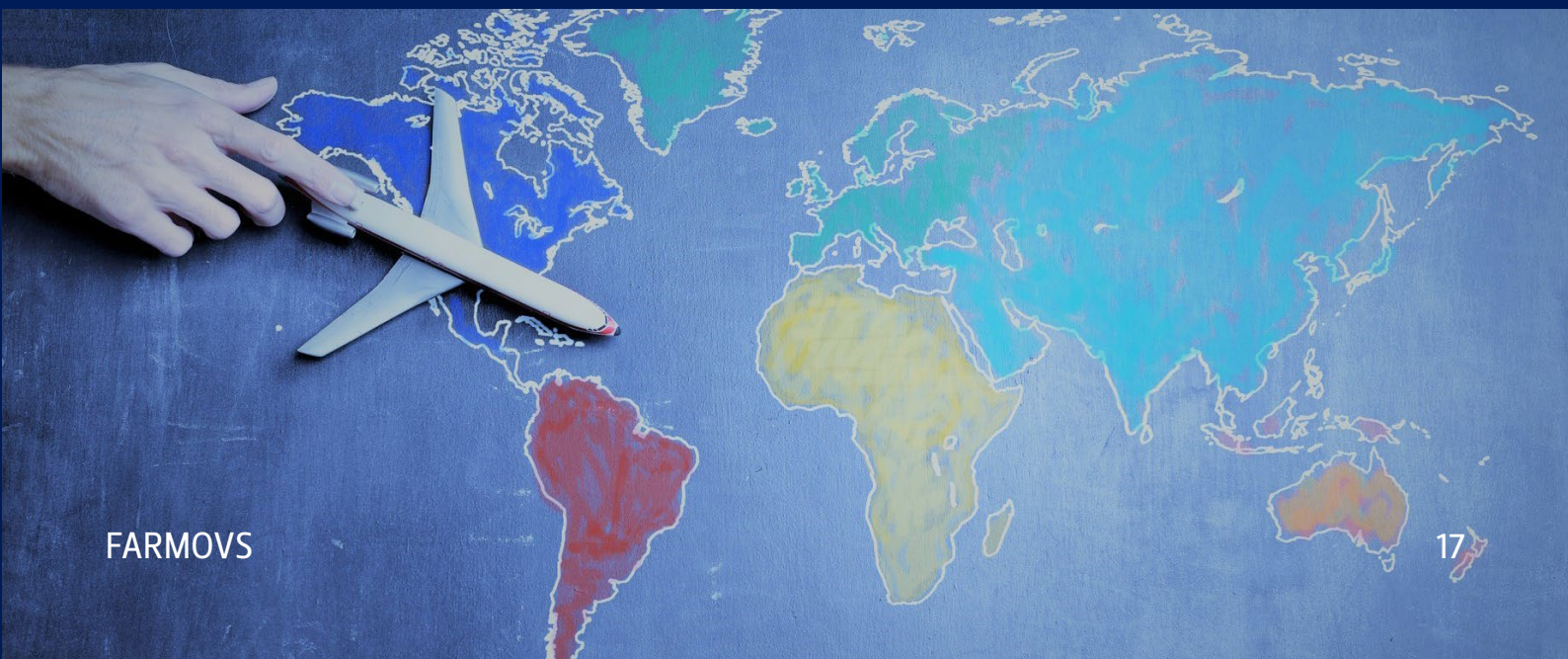
Close collaboration with our international logistical and sample handling division adds value and leads to synergy between our laboratories and research clinic.

Logistics & Sample Handling

We are favourably equipped to manage import or export services to and from South Africa. FARMOVS sample logistics coordinators are experienced and are IATA certified. We use our on-site ISO accredited clinical laboratory, GLP certified bioanalytical laboratory and state of the art pharmacy to our advantage to import, receive, handle, store, and export items for our clients. Any sample or other clinical trial supplies are included.

Our international logistical and sample handling services include:

- Import/export management of clinical trial supplies (e.g., PK collection kits and intellectual property and PK sample storage).
- Pre-arrival customs clearance.
- In-transit temperature monitoring with TempTales®.
- Validated REES Scientific for on-site storage.
- -20 ˚C / -80 ˚C storage capacity.
- Transport between the clinic and the laboratory in under three minutes, while samples are safeguarded in thermo-isolated trolleys.
- We use World Courier®.



SMO

Site Management Organisation (SMO) is managed by a group of highly skilled individuals. They focus on multi-site clinical trials, for patient studies in Phase II-III of the clinical research cycle.

We have extensive project management, regulatory, site management and monitoring experience within the South African and International Good Clinical Practice environment.

You can enhance your results by collaborating with our network of over 35 sites. SMO site selection and site qualification include criteria such as therapeutic experience and study population access, while ensuring that trained staff and adequate site facilities are available.

Some of our specialist investigator sites are linked to SMEs in a variety of rare disease therapeutic areas, adding to our existing portfolio of therapeutic areas that our clients can access.

We constantly expand our network by investing in new research naïve sites. This initiative is a tailor-made development and site readiness programme. We also approach research naive investigators who have an interest in clinical research and include them in our research projects.

These capacity building initiatives are aimed at developing the Southern African clinical research landscape and is fully supported by SAHPRA. When developing new network sites, we provide SOP templates and facilitate data standardisation and increase the recruitment capacity of each new research site by including them in our established network.

This unlocks new possibilities for the entire collaborator network. As a result, our clients receive the best service with the highest quality research results in the shortest possible time.

Access the following services through our SMO division:

- Institutional Pharmacy
- Pharmacy depot
- Logistical service and international sample handling
- Quality assurance (QA)
- Quality management (QM)
- Project management and site management
- Monitoring services
- Pharmacovigilance
- Medical writing
- Regulatory services

Project Management

An experienced team of project managers oversee Phase I clinical studies for local and international clients. We build lasting relationship with our clients and service providers by valuing each role-player, firmly believing that the contribution of the entire team leads to the success of a study.

The project management team ensure open and timeous communication regarding the milestones and status of each project and deliverable and we strive to achieve the highest level of client satisfaction.

Expand your research capabilities and entrust the FARMOVS project management team to:

- Manage Phase I studies, from initiation to close-out, including FIH and Healthy Volunteer Bioequivalence and Bioavailability studies, in close collaboration with the principal investigator and clinical team.
- Engage in full-service project management, including oversight of the study across all phases; i.e., from protocol preparation and submission to Regulatory Authorities, clinical conduct, bioanalysis, data management and biostatistics to report writing, in close collaboration with all role-players and service providers.
- File essential documents and maintain the investigator site file, support you with the compilation and maintenance of your trial master files (including on-site archiving after study close-out)
- Provide after study support, such as assistance with regulatory queries related to dossier submissions.

Medical Writing

Benefit from more than 18 years of medical writing experience:

Our team of regulatory medical writers draws on many years of experience in the development of a variety of clinical study documents. These documents are created following global, regional, and country-specific guidelines, tailored to client needs. The team makes use of either FARMOVS document templates or client templates, as preferred by the client and/or as required by the research. FARMOVS subject matter experts or external consultants provide input and advice as required. Quality control forms an integral part of the document development process to ensure only the highest quality deliverables.

Translation of documents to local language(s) is performed in-house by mother-tongue speakers of the target language or is outsourced to external, qualified translation services.

Our medical writing services Include:

- Clinical study protocols and amendments (Phase I–III) according to ICH E6.
- Clinical study reports (Phase I–III) (integrated, full, abbreviated, synoptic and addenda) according to ICH E3 and in eCTD format.
- Subject information sheets and informed consent forms (such as main, serology, genetic, biobanking for future research).
- Subject directed documents (including pamphlets, questionnaires, and subject diaries).
- Adverse events and case narratives
- Investigator's brochures.
- Articles and abstracts for scientific publication.
- Translation of documents.

Quality Assurance

We realise how important the quality assurance (QA) function is in the clinical research process. Thus, our team of dedicated experts ensures that our clients receive the best service.

The FARMOVS QA team is independent of our service units that conduct regulated activities. Our mission is to assess the compliance of clinical research activities proactively and independently, according to current local and international standards of good practice (GxP) and other relevant laws and regulations.

As an independent function, QA identifies and highlights risks and risk trends through audit and inspection activities, and consultancy. We facilitate informed decisions to safeguard regulatory compliance and protect subject safety, data integrity and company reputation.

We focus on conducting GCP audits across all research phases, conducting specialised GxP audits and facilitating and hosting sponsor audit and regulatory inspection activities.

We conduct a full range of audits, covering all aspects of clinical research. For example, project specific process-based audits comprising protocol, informed consent, study conduct, case report forms, clinical study reports, trial master files/investigator site files, investigator site audits, data management databases, system audits including safety reporting, and third-party supplier audits.

Allow FARMOVS QA to facilitate the following for your next study:

- Independent audits.
- ISO and GLP audits that include study based audits or facility and process based audits.
- Consulting.
- Training.

Reap the benefits of more than 30 years clinical research QA experience.

Over 30 years of QA experience at your disposal

Regulatory Service

The diversity of the South African study population has multiple benefits. However, regulatory submission and approval may become cumbersome if you are not well acquainted with the regulatory landscape.

The FARMOVS Regulatory team is experienced, and routinely prepares clinical trial application packages for SAHPRA and research ethics comittee submissions. We ensure that regulatory submissions are of the highest quality to secure favourable outcomes for our clients in the shortest possible time.

Timelines for regulatory approval:

- Bioequivalence / bioavailability studies in healthy volunteers, including generic product development, takes approximately eight weeks from submission to approval. Applications can be submitted at any time.
- Other studies are reviewed by the SAHPRA Clinical Trials Committee (CTC). Meetings take place every eight weeks. Approval of a successful submission is typically received within 12 to 14 weeks.

Timelines for research ethics approval:

- Clinical trial applications are submitted to the Health Sciences Research Ethics Committee (HSREC) of the UFS, for research ethics review.
- Applications are reviewed on a monthly basis and submissions have to be presented at least two weeks prior to a scheduled meeting date.
- Possible required modifications are communicated shortly after a meeting. Conditional approval (pending SAHPRA approval) is obtained within ten working days after submission of our responses to said modifications.

Decrease your study timeline and allow the FARMOVS regulatory specialists to manage the regulatory aspects on your behalf.

On-Site Archiving

FARMOVS offers on-site archiving services which are managed according to existing regulations.

Restricted access is monitored closely and designated trained personnel ensure that archiving operations are in line with the requirements of the Organisation for Economic Co-operation and Development Good Laboratory Practice, International Organization for Standardisation and the GCP.

Our archive facilities are equipped with temperature and humidity monitoring and fire-suppression systems to ensure that documents are always kept safe.

Once the retention period expires, we also offer secure document destruction services to our clients.

Quality Management

Continuous quality management (QM) optimises the quality of all our deliverables to our clients. The FARMOVS QM service portfolio includes:

- Management of the Controlled Documents System.
- Risk assessments during the entire life-cycle of each study.
- Collaboration with the study team to address any risks and issues that could potentially hamper the optimal performance of each study.
- Collection of quality metrics that determine areas for improvement.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Inspection History

Our first successful regulatory inspection took place in 1997. Since then we have maintained our successful inspection history with the most prominent regulatory authorities in the world.

During the last 25 years, we have gained valuable experience and have built a stellar reputation. Our clients can rest assured that their clinical trials are conducted by the oldest and most experienced CRO in Africa.

* We have a successful inspection history with these regulatory authorities.

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