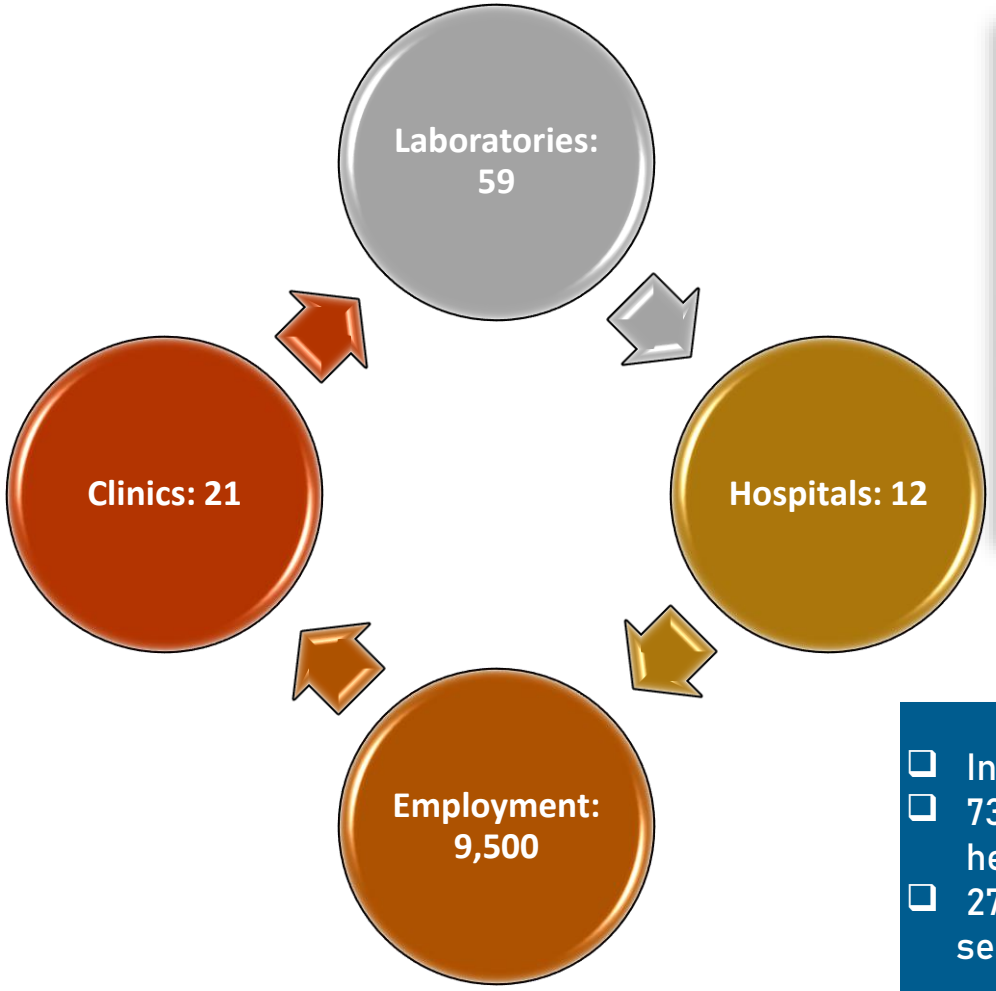
ECONOMIC DEVELOPMENT BOARD MAURITIUS

MAURITIUS as a clinical trial destination

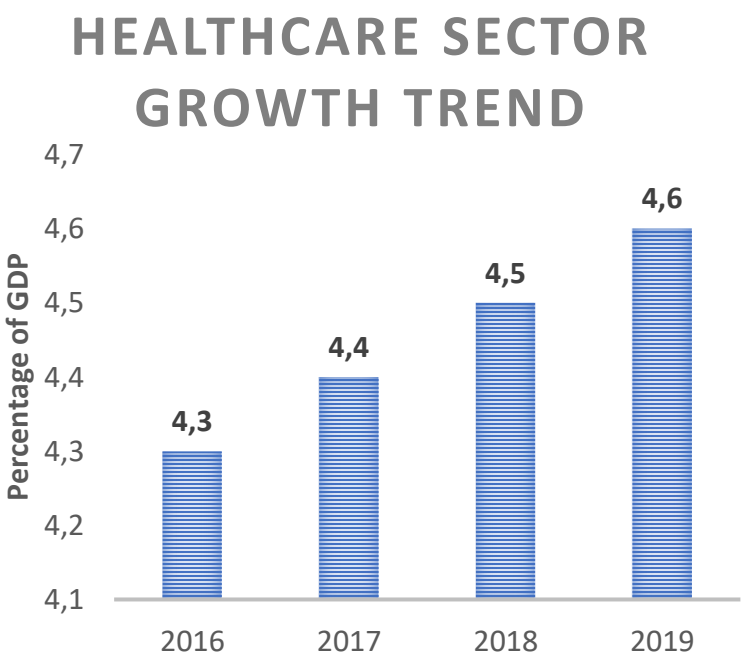
An Overview of the Healthcare Sector



GDP Contribution: 5.6% (2021 est.)

Bed capacity: > 5,500 (public & private sector)

Doctors	3,210
Dentists	411
Pharmacists	536
Qualified nurses	4,400



- Increase in expenditure and infrastructure
- 73% of healthcare needs catered by public healthcare institutions
- 27% of healthcare needs catered by private sector

Mauritius : Clinical Research

- Regulatory framework for Clinical Trial
- Clinical Research Regulatory Council (CRRC) for clinical trial applications
- Presence of reputed CROS

Opportunities

- Dermatology
- High Blood Pressure
- Lupus
- Cardiac
- Endocrinology
- Heart disease

5 Contract Research Organisations

Engage in pharmaceutical and cosmetic research and development

Multi-ethnic population

Wide array of patients

Infectious diseases affecting population

Used by leading laboratories and cosmetic brands

SANOFI

Pierre Fabre

L'OCCITANE EN PROVENCE

NAOS

L'ORÉAL

CIDP NATURALLY INNOVATIVE

CAP RESEARCH

WHY MAURITIUS

INCENTIVES

- 8-year tax holiday
- Exemption from payment of Registration Duty
- Vat Exemption on construction of purpose-built building/ facility for healthcare, biotechnology and life sciences
- VAT exemption on plants and equipment
- No Land Conversion tax

Human Capital

Presence of international Contract Research Organisations

Ideal Regional Hub for sub Saharan region

Innovative and latest technology

- Over 80 approved clinical trials
- Around 15,000 volunteers
- Inspection by sponsors

Examples of key studies conducted / in progress:

- Sleep Apnea
- Meningitis
- Lupus
- Cardiovascular disease
- Diabetes
- High Blood Pressure
- Cosmetics

Legal framework

Clinical Research Regulatory Council (CRRC)

- Operates under the Clinical Trial Act
- Qualified members under the Council
- Mandated to licence applications for clinical trial

Registration of CRO: MUR 50,000

Clinical Trial Act caters for:

- Clinical Research Regulatory Council (CRRC) responsible for registration of CROs the regulation and control of trial licenses being issued.
- Ethics Committee (EC) to advise the CRRC regarding welfare, safety, health and protection of human subjects participating in clinical trials.
- Pharmacovigilance Committee (PC) to monitor all clinical trials being performed and ensure Good Clinical Practice (GCP)

Registration of CRO

- No CRO shall conduct, or assist in, a clinical trial in Mauritius unless it is registered with the Council.
- A CRO seeking registration with the Council shall make an application at least 2 months before beginning of operations.
- Application form and supporting documents should be submitted.
- The CRO shall ensure that trials are adequately monitored.
- The CRO shall implement quality assurance and quality control as per standard operating procedures designed for the purpose.

Application Process for Clinical Trial Licence

Application	Application with the CRRC (accompanied with fee and documents)
Evaluation	Evaluation by the CRRC
Submission	Submission of application and documents to Ethics committee and further assessment by pharmacovigilance committee (if required)
Payment of fees and issue of licence	Payment of fees and application issued by CRRC

Clinical Trials on Medical Devices

- Registration with CRRC for clinical trial of medical devices
- Submission of Application Form and documents
- Issuance of Licence

Governed under Clinical Trials (Medical Devices Trials) Regulations 2021

Classification of Medical Devices

- Non-Invasive
- Invasive
- Surgically Invasive
- Surgically Invasive (Short-Term)
- Surgically Invasive (Short-Term)
- Active Devices

Fees

	Rs	PILOT STUDY	PIVOTAL STUDY	POST APPROVAL STUDY
Issue of trial license	10,000			
Issue of amended trial license	20,000			
Issue of duplicate license	10,000			
Annual service fee	20,000			
Class I medical device with low risk		10,000	20,000	10,000
Class IIa medical device		20,000	40,000	20,000
Class IIb medical device with moderate risk		40,000	80,000	40,000
Class III medical device with high risk		100,000	200,000	75,000