

# Serenus Biotherapeutics – Bridging the Gap between Science and Need

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IPNET

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**Bridging the gap between science and need**

“In the future, regional and global power and national stability will be determined not by who controls arms, but by who controls access to medicines”

Michel Sidibe – UNAIDS Executive Director (June 2012)

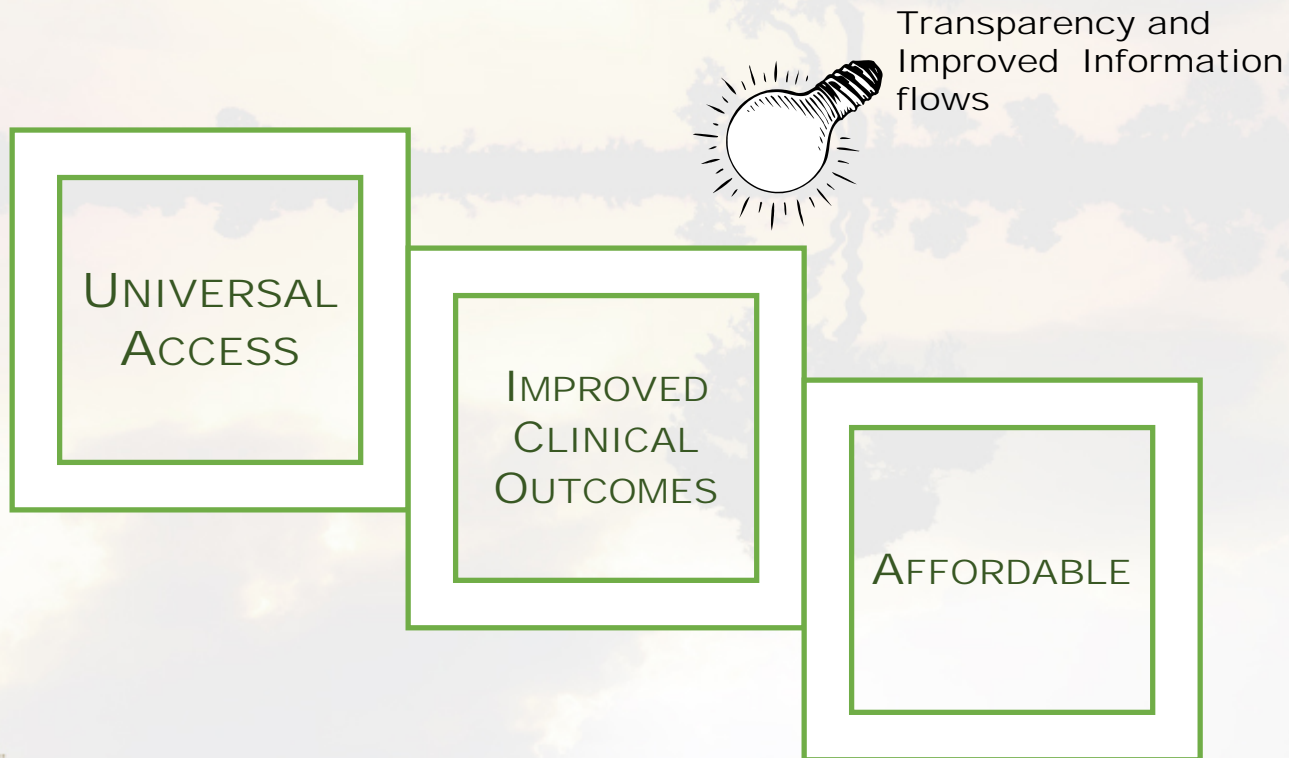


# Outline

- ❖ The Holy Grail of Healthcare
- ❖ The Current Status of Healthcare in Africa
- ❖ Key Transitions in (African) Healthcare
- ❖ About Serenus
  - Vision & Mission
  - Strategy
  - Disease Management Approach



# The Holy Grail of Healthcare



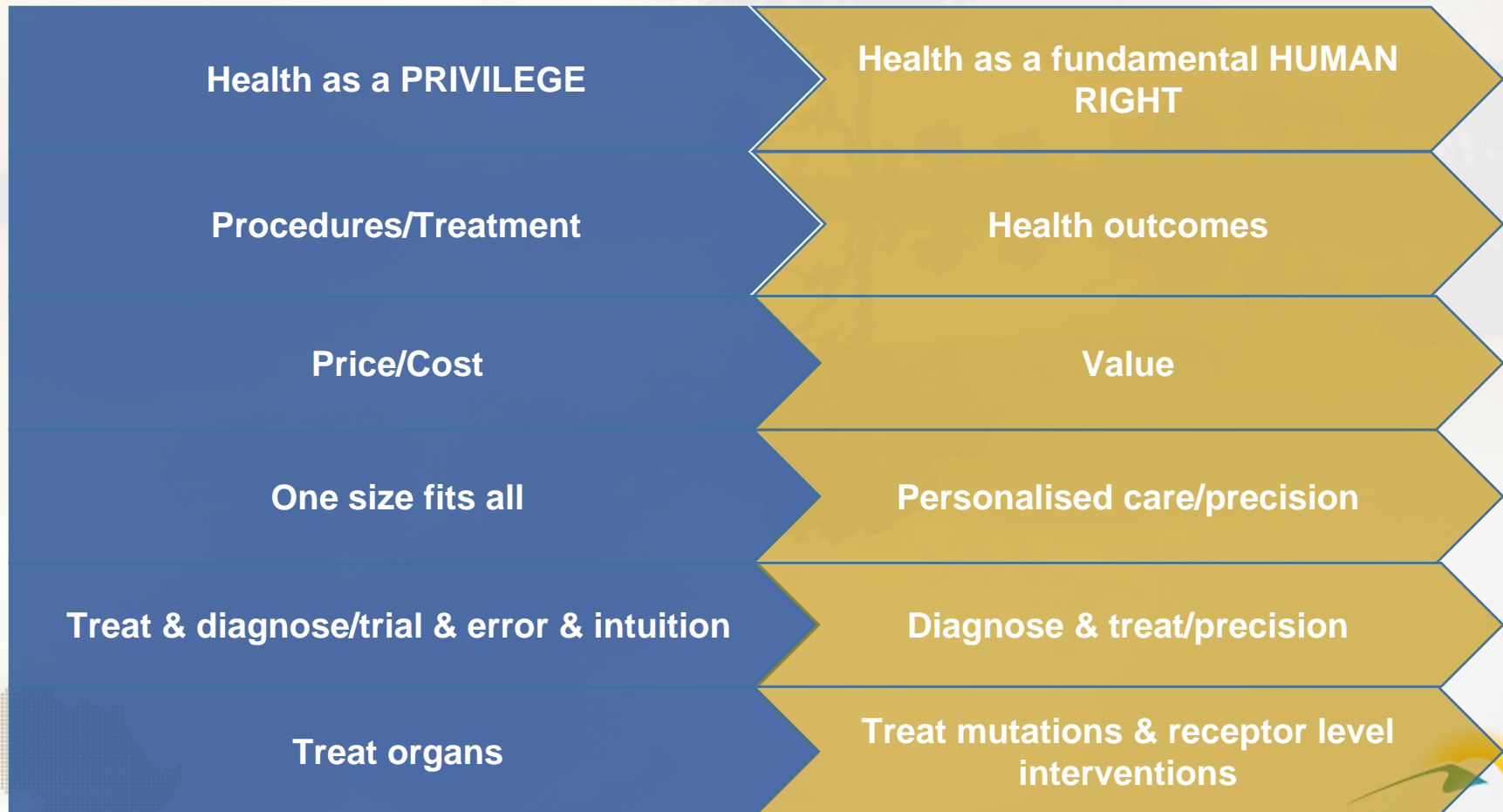
# Key Transitions in (African) Healthcare



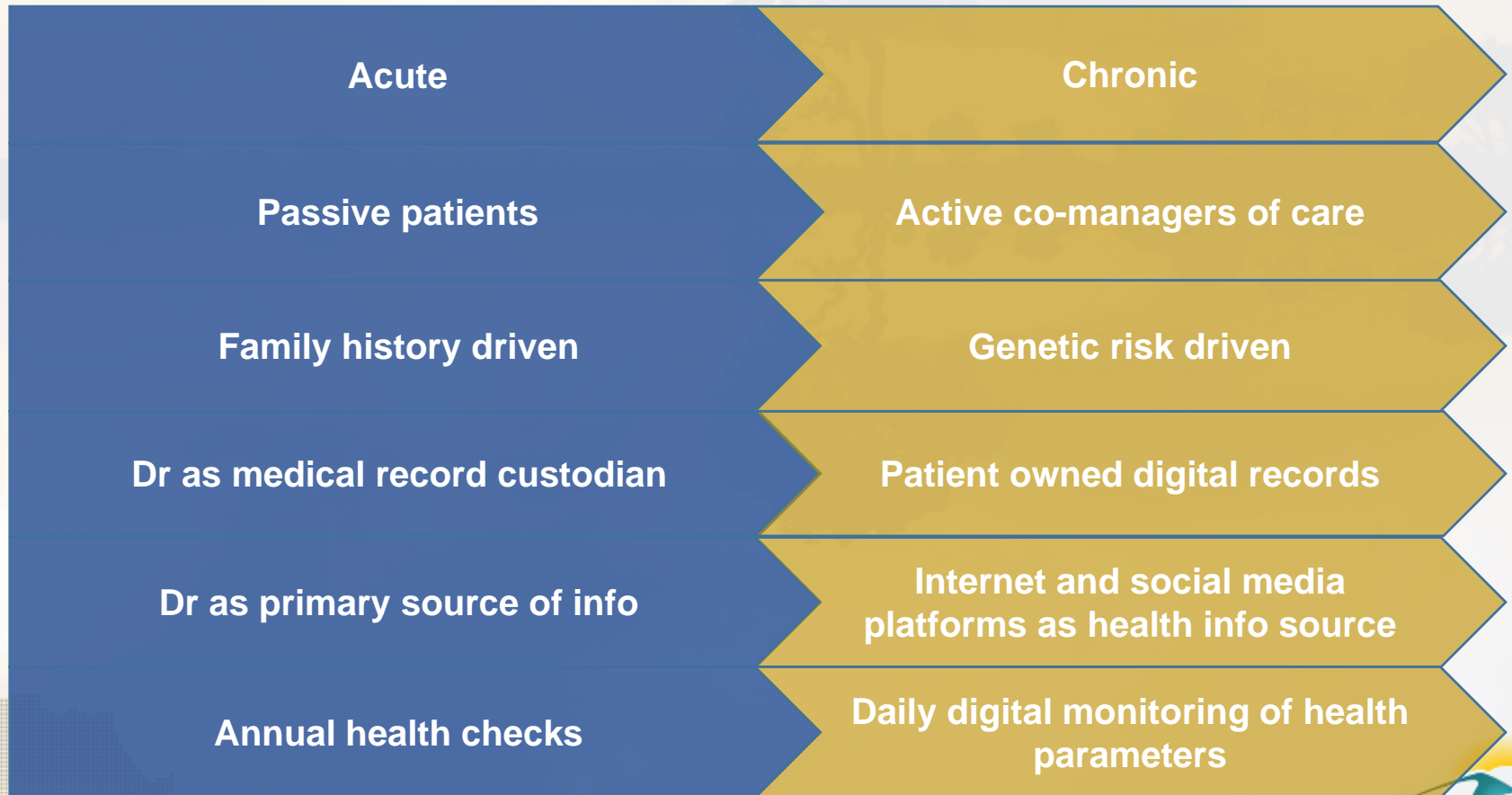
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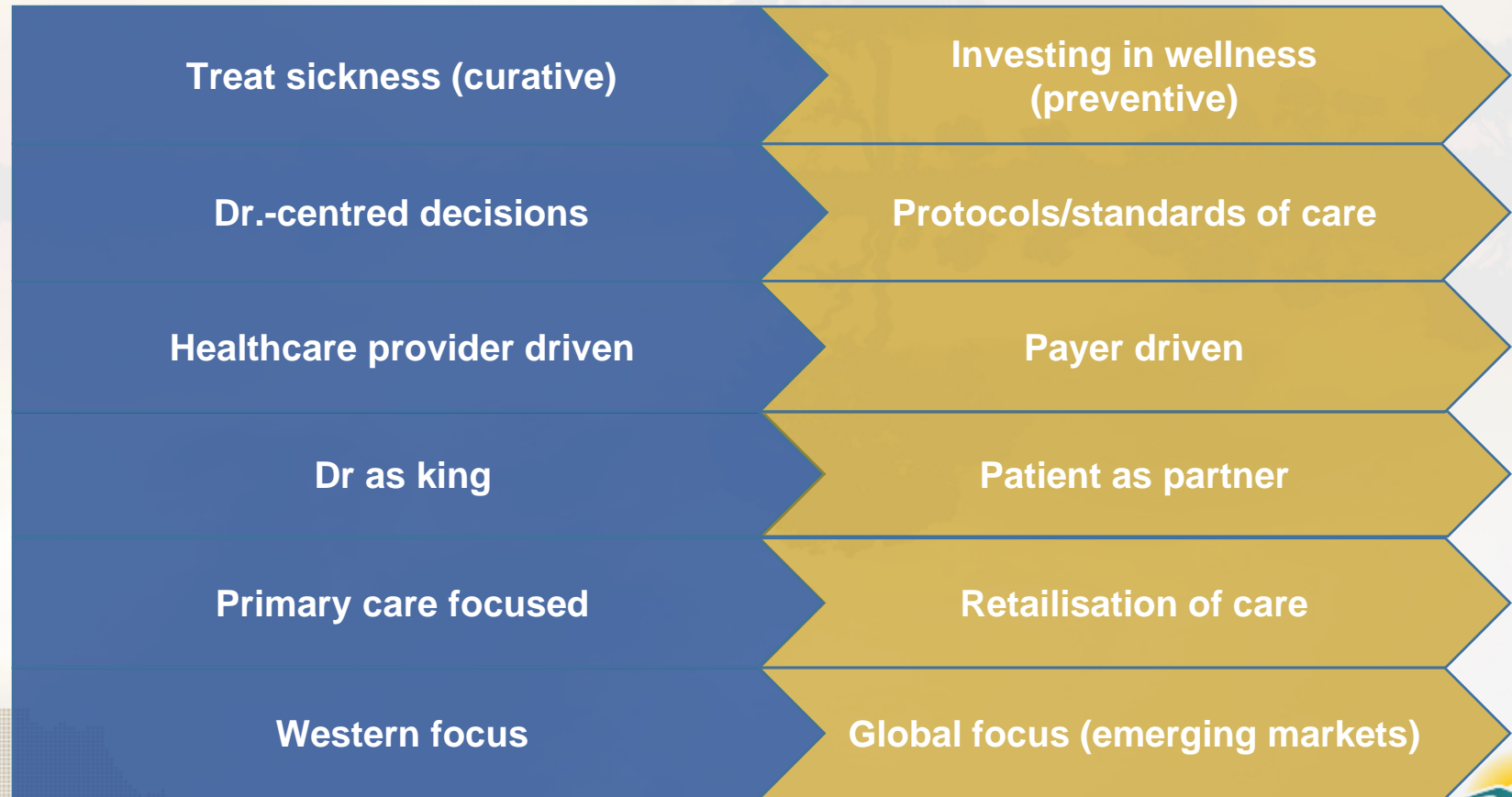
# Key Transitions in Healthcare (1)



# Key Transitions in Healthcare (2)

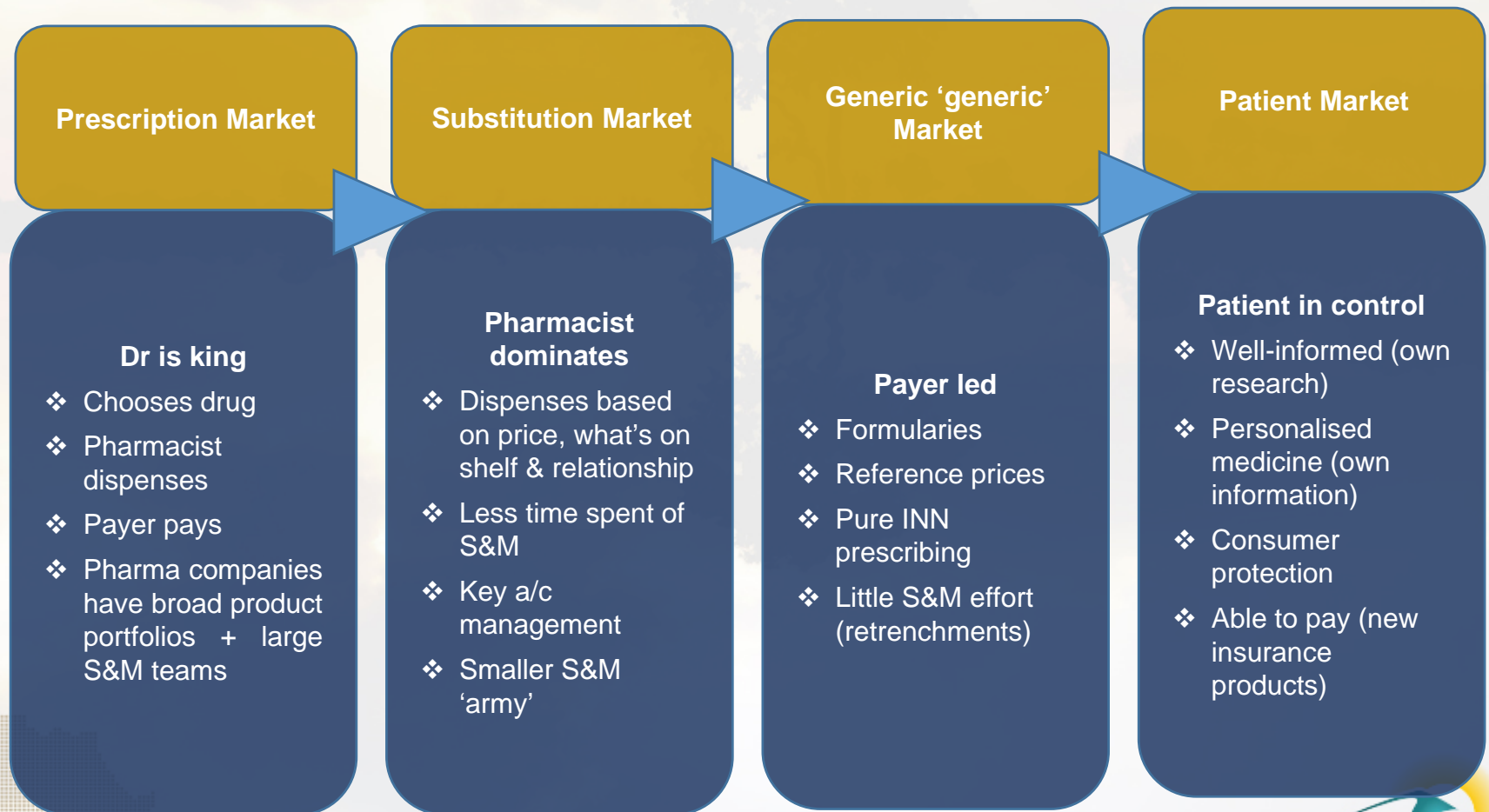



# Key Transitions in Healthcare (3)





# Key Transitions in Healthcare (4)





*The Current  
Status of  
Healthcare in  
Africa*



# Changing Disease Landscape

- ❖ Shift in burden of illness from communicable to non-communicable diseases (NCDs) across the region
  - NCD's will have surpassed infectious diseases as the leading cause of death in Africa by 2030
- ❖ The proportional contribution of NCDs to the region's healthcare burden is expected to rise to 21% by 2030
- ❖ Africa is forecasted to experience the largest increase in death rates from cardiovascular disease, cancer, respiratory disease and diabetes during the next decade
  - 60 million people with hypertension by 2020
  - 1 million cases of cancer annually
  - 18.6 million people with diabetes by 2020
  - Chronic respiratory diseases (COPD / asthma) and neuro-psychiatric conditions
- ❖ This will result in greater demand for healthcare and best in class chronic therapies

# Significant Health Challenges

## ❖ Inadequate healthcare infrastructure

- Software – Shortage of healthcare HR
- Hard ware – clinics, hospitals, labs, Supply chain inadequate
- Inadequate quality systems and limited access
- Inadequate Supply Chain systems
- Limited use of technology

## ❖ Limited healthcare funding

- Limited National budgets
- Donor dependence (? fatigue)
- Significant OOP expenditure

## ❖ Limited access to quality assured products and technologies

- Sub-standard / counterfeits
- Supply chain inadequacies
- Competencies in forecasting & quantification

# About Serenus



# The Rationale for the Founding of Serenus

## ❖ Address specific challenges

- Sourcing of products & promotion of research into products & technologies that meet an unmet need
- Delayed introduction of new and best in class health Technologies, that normally take 8 – 10 years after introduction in the developed world
- Quality-assured products (role of technology)
- ADR & lack of clinical response due to poor Rx choice / genetics

## ❖ Old model not sustainable

- More HCP engagement (CME's, journal support etc.)
- Patient Assistance Programmes, education / awareness & adherence programmes (m-Health)
- better HCP / KOL collaboration and sharing of best practices both on the continent and internationally;

## ❖ Promotion of medical congresses on the continent

# The Rationale for the Founding of Serenus

## ❖ Need to

- engage & integrate HCP's on the continent into global focus groups e.g. International Primary Care Respiratory Group (IPCRG); Oncology focus groups; Cardio-metabolic Syndrome focus groups; Paediatric Management Group (PMG) etc.
- coordinated response to the challenges that we face
  - e.g strengthening or setting up Antibiotic Stewardship Collaborations with key stakeholders on the continent
- Promoting R&D and promoting continental clinical trial collaborations
- Form Strategic partnerships with governments / health funders (PPP's, Health outcomes focus)

Serenus Biotherapeutics' mission is to transform lives through accelerated access to quality and affordable novel medicines in Africa





Our  
Vision is to build a Pan  
African Pharmaceutical  
company renowned for  
innovation, exceptional  
customer service, and  
the provision of high  
quality, safe, and  
efficacious medication  
to the people of the  
African continent

# About Serenus Biotherapeutics

- ❖ Pan- African, privately owned specialty biopharmaceutical company
- ❖ Strategic Intent – to address unmet medical needs of diseases with high regional prevalence in Africa
- ❖ Capabilities in R&D – will partner to bring Phase II and III opportunities to market
  - CRO, clinical trial site & investigator identification, regulatory and ethics committee approvals)
- ❖ Serenus is involved in the in-licensing, registering and commercialization of FDA, EMA and Japanese PMDA approved therapeutics for the African market
- ❖ We are experts in managing product approvals, pricing, reimbursement, distribution, compliancy, and marketing practices on the African regional and national levels



# About Serenus Biotherapeutics

- ❖ Diversified portfolio of innovative NCE, OTC, OTX and novel Generic medicines across multiple therapeutic areas
- ❖ Aim to become an African based R&D company delivering medical solutions responsive to Africa's needs
- ❖ Aspires to be a the leader in the African pharmaceutical sector:
  - presence in various regional economic and trade hubs
  - excellent customer service,
  - good Corporate Governance and being a responsible corporate citizen



# International Scientific Advisory Board



**Michael Makanga MD  
PhD**

- EDCTP Director of South-South Cooperation and Head of Africa Office
- International experience in conducting and management of health research programmes, emphasis in conduct of clinical trials
- Strong Liaisons with African political leadership, policy makers and the scientific community with the purpose of ensuring a genuine African ownership



**Richard Chin, MD**

- Founder and CEO of Kindred Biosciences
- Previous Head of Clinical Research for the Biotherapeutics Unit at Genentech
- Served as CEO of OneWorld Health, a Gates Foundation-funded nonprofit organization developing drugs for impoverished patients in developing countries
- Serves on the board of directors of several biotechnology companies, including Immunocellular Therapeutics



**Solomzi Makohliso  
B.Sc M.Sc Ph.D**

- Founder & Chief Executive Officer, Ayanda Biosystems S.A., Switzerland
- Founder and Director, NanoBioInnovations South Africa, Developing affordable biopharmaceuticals particularly tailored for and focused on African markets
- Resident Entrepreneur at the Council for Scientific & Industrial Research, South Africa



**Eliangiringa Amos  
Kaale, B.Pharm Ph.D**

- Expert on drug quality assurance and regulatory affairs
- Member of Technical Committee for Registration of Human Medicine in Tanzania
- Awardee of Alexander von Humboldt Fellowship for Experienced Senior Scientist



**Karniyus Shingu  
Gamaniel (OON),  
PhD, FCCP, FPSN**

- Outstanding achievements in R & D on Phyto Medicines, authored several books.
- Holds three US patents on Phytomedicines
- Currently a member of the Scientific Advisory Committee (SAC) of the International Foundation for Science (IFS).
- Audit person and Scientific Advisor on the MacArthur Foundation, Rockefeller Foundation



**Keertan Dheda  
MBBCh (Wits), FCP  
(SA), FCCP, PhD (Lond)**

- Professor of Respiratory Medicine and Head of the Lung Infection and Immunity Unit at The University of Cape Town Lung Institute
- Associate member at the IIDMM, UCT
- Attending Consultant GP and Pulmonologist at Groote Schuur Hospital and UCT Hospital in Observatory in Cape Town
- South African Department of Science and Technology - National Research Foundation Chair

# Our Guiding Principles



## Sustainability

- Build local healthcare capacity
- Continued growth and strengthen stakeholder relationships
- Best African Pharma legacy
- Disruptive business models



## Responsibility

- Ethical Corporate citizen
- Partner IP protection and management
- Improving health outcomes of patients
- Risk management



## Innovation

- Situational adaptability – market specific
- Harnessing mHealth technologies
- Patient-Centric solutions
- Entrepreneurship



## Diversity

- Africa is not a one size fits all
- Culturally sensitive
- Differences in medical need



# Our Strategy

## Differentiation

- Patient Focus
- Service Offering
- m-Health
- Public Private Partnerships / Mix

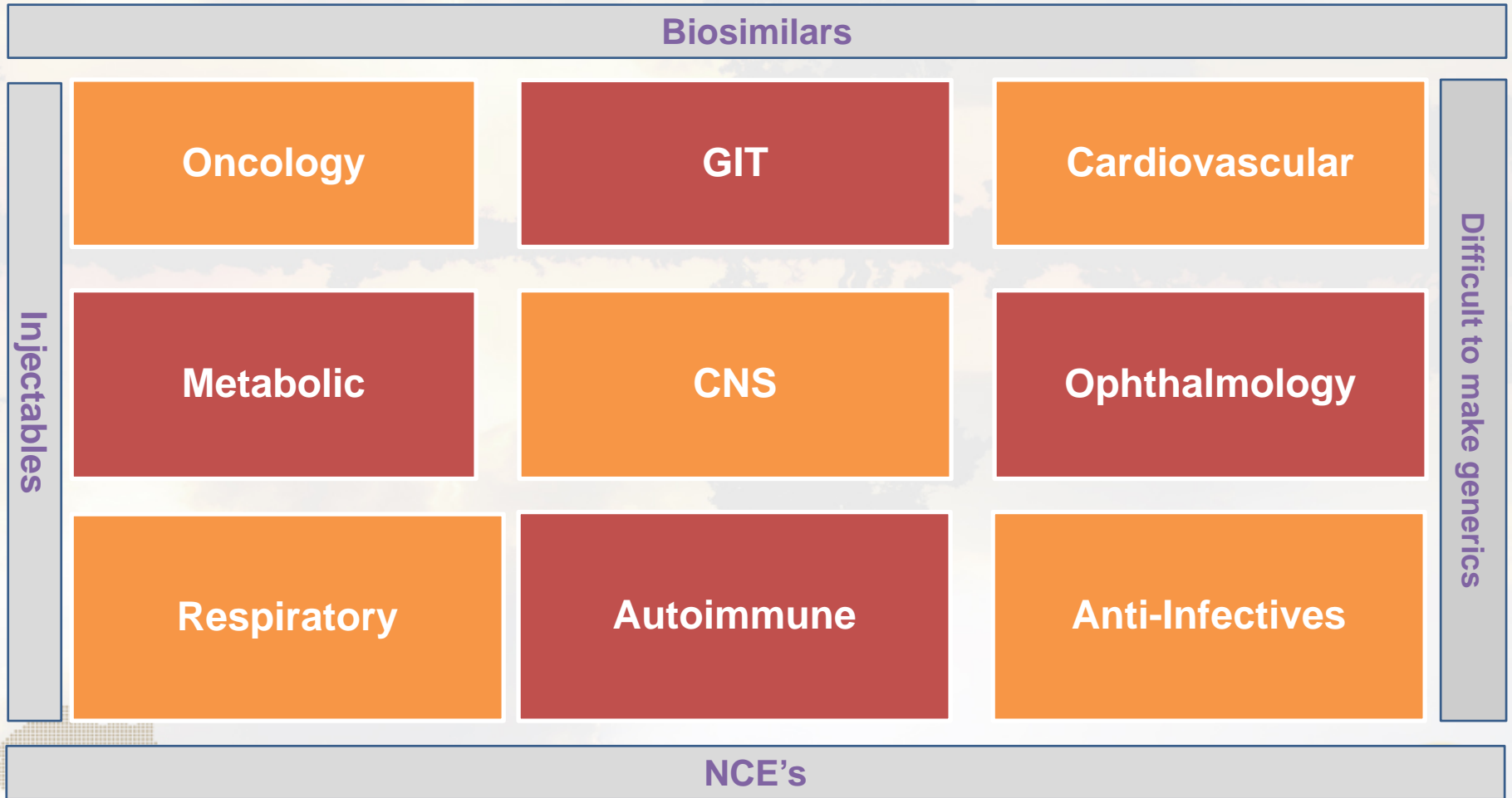
## OUR TWIN STRATEGY

## Diversification

- NCE (e.g novel 4<sup>th</sup> Gen Quinolone)
- Difficult to make generics (Injectable suite)
- Innovative Health Technologies (Xenex)
- Improved Dx (Genomic & NGS testing, POC)



# Therapeutic Area Focus



“It’s far more important to know what person the disease has than what disease the person has”

Hippocrates



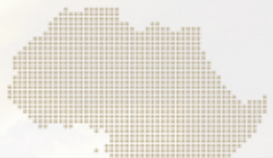
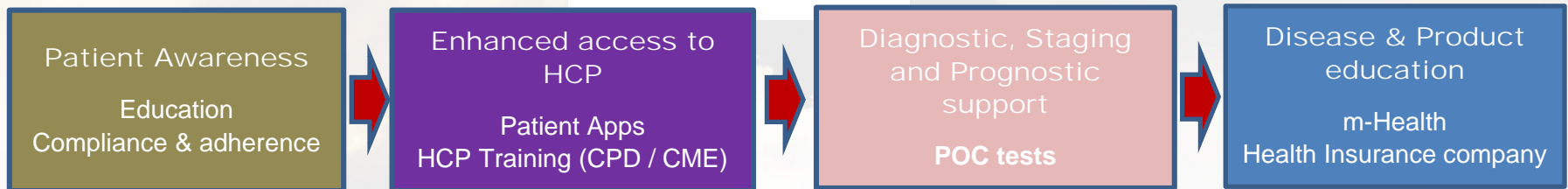


# Shortening Path to Patient

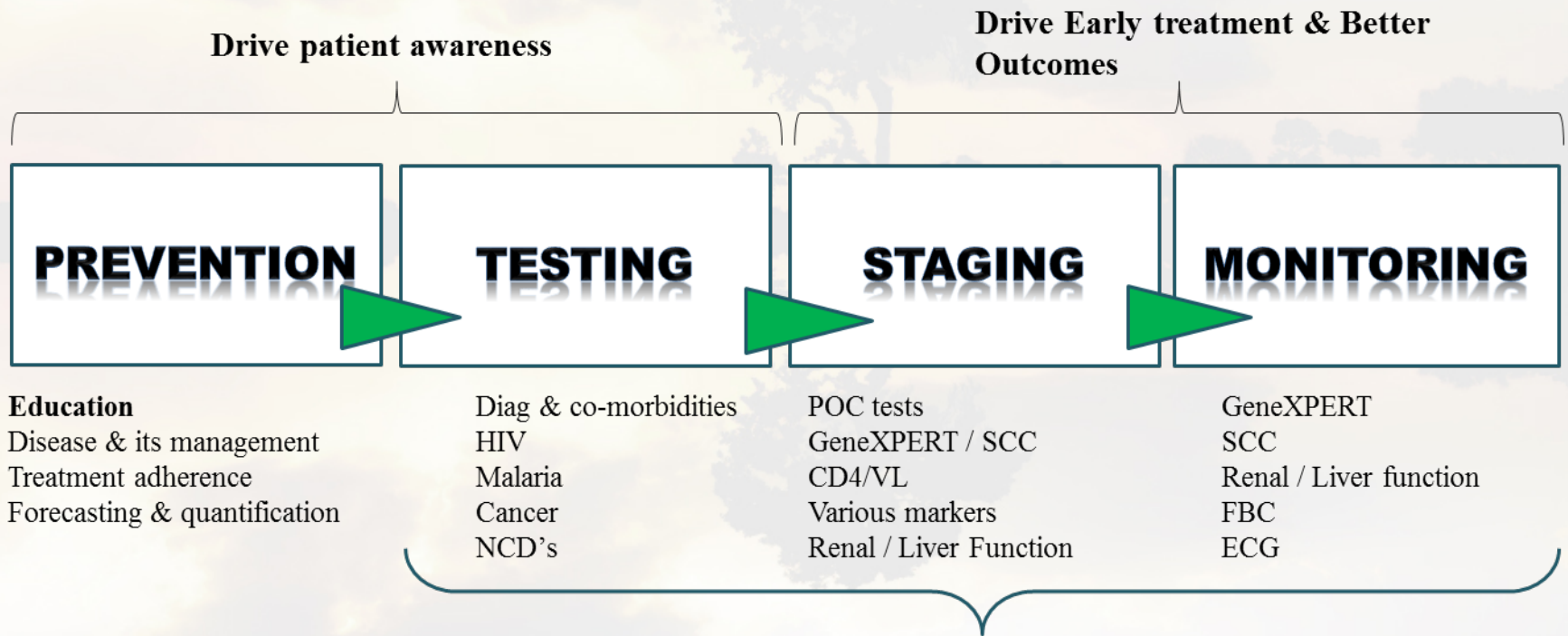
## Path to Market



## Path to Patient




# Integrated Disease Intervention Pathway



SCC - Sputum culture conversion

**Principal diagnosis & Co-Morbidities**





*“It is the province of  
knowledge to speak,  
and the privilege of  
wisdom to listen”*

Oliver Wendell Holmes



**serenus**  
biotherapeutics

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