SACRA
SOUTH AFRICAN CLINICAL RESEARCH ASSOCIATION

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Key to Transformation and Capacity Building in the Clinical Trial Industry in South Africa

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MEDINOVA
Improving Treatments

TRANSFORMATION & CAPACITY BUILDING
(T's & C's Apply)

"What counts in life is not the mere fact that we have lived. It is what difference we have made to the lives of others that will determine the significance of the life we lead."

— Dr. Nelson R Mandela

AGENDA

- WHY
- HOW
- WHO
- Introduce new concepts:
  "ROPE", "QRS", "CTWB" & "Reform SA"

WHY

What are the Imperatives?

- Moral
- Social
- Political
- The PATIENT

MORAL

- Obligation to “Give-Back”
- Rural development – represent demographics & diversity of clinical trial participants;
- Benefit the public sector patients – ***poorest of the poor.***

SOCIAL

- Employment Equity – Designated groups

  Develop Capacity – In a rapidly growing Industry we need to increase the pool of knowledge to stay globally competitive
- Create Jobs (not transfer jobs) – **new entrants** in the job market

SOCIAL

"Investing in young people's health and education is the best way for a country to unlock productivity and innovation, cut poverty, create opportunities, and generate prosperity." - *Goalkeeper Report – Bill & Melinda Gates Foundation*

POLITICAL

"…we need to reform, not merely transform, our economy.

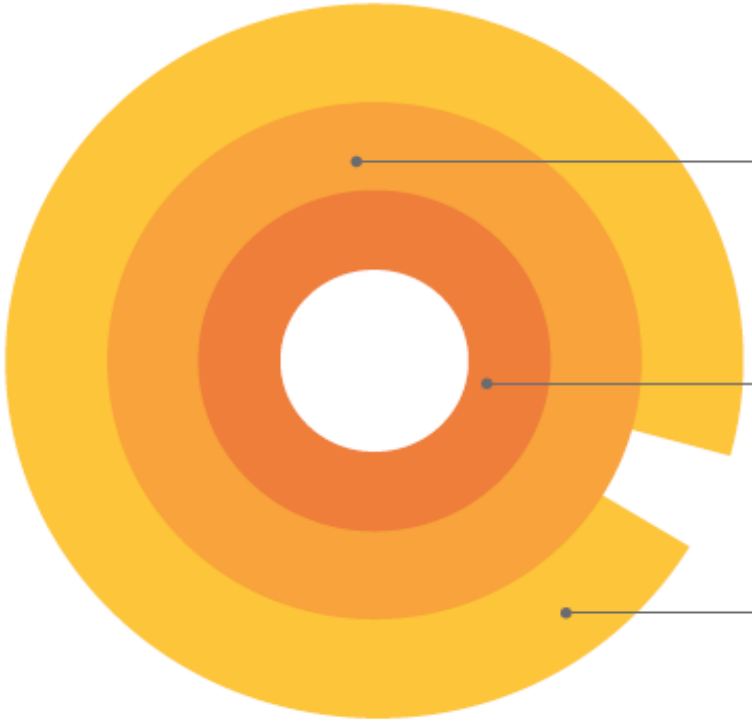
Transformation swaps out power relations in the way we create wealth.

Reform breaks the way we create wealth."

- Peter Bruce – Business Times

THE PATIENT

Figure 3: Benefits of clinical trial participation



100% agree that participating in clinical research has **reduced their overall cost** of healthcare

Reduced cost of care

100% agree that participating in clinical research has **improved their interest/ involvement** in their overall healthcare

Improved patient engagement

95% agree that adding clinical research has **significantly or somewhat improved their overall quality of care**

Improved quality of care

THE PATIENT

PATIENT COMMENTARY:

- *"They even include my spouse into the meetings and care plans."*

- *"What it's done is it's made me much more regimented. I was never near as regimented. It keeps me engaged"*

- *"Clinical research participation definitely makes me more aware."*

THE PATIENT

Interesting dispensing stats in the USA:

- 40% of prescriptions are not filled;
- 60% of the balance of 60% - meds not take correctly = poor compliance;
- Therefore: Only 24% of prescriptions = desired compliance;
- Compare this with the CT Industry = >90% desired compliance.

THE PATIENT

Today, less than 1% of the U.S. population participates in clinical trials, yet 72% say they would participate if recommended to do so by their doctor

- Patients would see improved access to care, better care, decreased cost and increased engagement
- Return on Patient Experience -***"ROPE"*** vs ROI

HOW

1. <u>Training Academies in South Africa:</u>

- ***Doctors & Nurses:***

  Theoretical & Practical training (Internships) programmes are currently available in South Africa (SA) – some pro bono

- ***CRA's & SSC's:***

  "Graduate Programmes" offered in SA & with MEDICAL Universities in the UK & USA – discussions at an advanced stage

- Data Capturers, Recruiters, Quality Control & Admin:
  New entrants – even without any prior qualification

HOW

2. **<u>Rural State Hospital Development Programme:</u>**
    - CT Centres owned & operated by the state
    - Centres of excellence
    - Rural Hubs for T's & C's
    - Acquire RTI for future planning healthcare planning

3. **<u>Co-Principal Investigators:</u>**
    - Nurses as Co-PI's – think out of the box
    - Rural development programme

HOW

4. SAHPRA

- T's & C's is mission critical
- Increase protocol reviewers – China from 50 to 600 in 1 year
- Decrease approval timelines for CT's
- China and India our biggest competitors outside of the USA

HOW

5. **<u>Foreign Skills:</u>**
   - Exchange programmes between countries
   - “BRICS” (Russia, India & China)
   - SA an advantage to punch above its weight within “BRICS”s
   - GME (Global Medical Exchange)

HOW

6. <u>Reshaping the Value Proposition of Clinical Trials:</u>

- Integrate with governments national healthcare strategies
- Part of the continuum of healthcare
- In the USA - Cost of Health Care ↓ by 60% over 12 months

CT's must be a **"Care Option"** to every patient

Moving from disease-focused treatment to personalised and more patient-centred care

WHO

1. Government

- DoH + other departments
- SAHPRA
- HPCSA
- Hospitals – Rural State Hospitals

WHO

2. Pharmaceutical Companies

- Support CT centre's in state hospital
- Equipment or other resources – Witbank Hospital – ECG & LFT
- Mutually beneficial relationships are necessary

WHO

3. QRS's 

QRS = **Q**uality **R**esearch **S**ites = *Heartbeat* of CT's

- *Customized, integrated, end to end operations quality solutions*
- A unified clinical environment with a seamless flow of content and data versus a series of singular solutions – CLINICAL TRIALS WITHOUT BORDERS "***CTWB***"
- Tracking all performance metrics to help cut cycle times, increase efficiency & Quality

WHO

4. **SACRA**
   - Coordinate these complex relationships on behalf of the multiple stakeholders
   - Harmonise long-term sustainable solutions

5. **Private Clinincal Trial Sites**
   - Learnerships / Internships
   - Succession planning for ageing PI's

WHO

6. **<u>Academia / Medical Schools</u>**
   - Dedicated CT training programmes

7. **<u>Media & NGO's</u>**
   - Public awareness about CT's

WHO

8. Traditional Healers

- Most underutilised resource in the CT industry
- Probably the ***KEY*** to unlocking the potential benefit of the CT industry to ALL stakeholders
- Progress has been made in establishing a working relationship with Traditional Healers in Mpumalanga

TO DO LIST

1. Transformation and Capacity Building Task Team for the Medical Research Industry of South Africa

"REFORM SA" – Task Team

- Responsible to move the Needle "Fast & Furious"

2. KOL's & KDM's of each stakeholder

3. DoH officials – Training of National, Provisional & Local officials in the benefits and for CT's

TO DO LIST

4. **SAHPRA** – We welcome the change of strategy from

   "Red-Tape" to "Red-Carpet"

5. **Export skills:** in fact we are already doing it, need to scale up "GME"

6. **Hospital CEO's** – need their buy-in to **ALLOW** pro bono training programmes. Good buy-in from from Mpumalanga DoH

THANK YOU

"Work, work, and work to obtain education. Later, your education will work for you"

— Dr Dorah Diale

"LEGACY should be fundamental to all what we do as humans. Clinical Research provides us the platform to leave a great legacy for mankind with new treatments, whilst helping global health systems and governments manage healthcare provision effectively."

— Mr. Kumar Muthalagappan, OBE. CEO: MeDiNova Global