



*Globalization of Clinical  
Trials: And Need For  
African Clinical Trial  
Consortium*

*AT THE (SCSSN)SICKLE  
CELL SUPPORT SOCIETY  
OF NIGERIA 2017  
CONFERENCE  
(24-08-17*



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- Chairperson, 'Breast Without Spot' Initiative | <http://www.breastwithoutspotng.org>
- Co-Director Bone Marrow Registry, Nigeria | <http://www.bonemarrownigeria.org>
- Past Observer to The Board of Union for International Cancer Control (UICC)
- President International Cancer Week Initiative In Nigeria (ICW)
- Consultant to NAFDAC on Clinical Trials & Co-Chair Nigerian Clinical Trials Technical Working Group
- **Member National Health Research Committee of the National Health Act**
- **Member National Cancer Control Steering Committee**
- **Board Member Pink Oak**

# Outline



## ■ The Globalization Process

### ■ THE AFRICAN CLINICAL TRIAL CONSORTIUM

- Global Pharma at a Glance
- Trends in Global Clinical Trial
- What is Driving this Trend?
- Why Should Africa Seek to Participate?
- Who are our Competitors? What are they doing?
- Can Africa Leverage the Opportunity?
- Conclusions

# ***Globalization is essentially about economics***

## ■ What is Globalization?

- Process of integration of global economy
- Process of interaction and integration among the people, companies and governments of different nations
- It is not a new phenomenon
  - began 5 centuries ago with European colonization

## ■ Drivers of Globalization

- Specific policies on international trade and investment
- Explosion of information and computer technology
- Dismantling of trade barriers
- Expanded economic power of global transnational companies

# *Globalization*

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“The landscape is changing and clinical trials starting now are becoming more and more global with increased activities in the new emerging economies.”

-- Getz, K.A., Applied Clinical Trials, December 1, 2005

“A truly global company will be one that uses the intellect and resources of every corner of the world.”

-- John F. Welch, General Electric

“Globalization has shrunk the world and enlarged the R&D process to multinational dimensions”

-- Dr Margaret Hamburg, FDA Commissioner

# THE BIRTH OF THE AFRICAN CLINICAL TRIAL CONSORTIUM

- Africa's Triple Burden of Disease
- Need To Diversify Africa's economy
- Improve The HealthCare Indices and Reverse Health Tourism
- Birth of **Clinical Trial Africa Vision 2020 Initiative** (June 2016)
- Birth of Clinical Trial Consortium (CTC)(September 2016)
- 1<sup>st</sup> All Africa Clinical Trial Summit (ACTC) (June 2017)

# THE BIRTH OF THE AFRICAN CLINICAL TRIAL CONSORTIUM

- A Multidisciplinary, Multi-Institutional, Pan-African Network of Clinical Trialists & African Regulatory Authorities
- Membership, will be organization, Individual and Stakeholder
- our mandate to build a robust Clinical Trial sector in Africa
- It is one of the major decisions taken at the 1<sup>st</sup> All Africa Clinical Trial Summit, and we have commenced the preliminary framework for the establishment of the Africa Clinical Trial Consortium to drive and fast-track the Clinical Trial Africa Vision 2020 Initiative.
- Already enjoying a Robust membership from several African Countries

# THE BIRTH OF THE AFRICAN CLINICAL TRIAL CONSORTIUM

- it was a majority opinion that the African clinical trial sector should seek a coordinated and collaborative continent-wide strategy that mirrors the African Union Vision for a developed and economically integrated Africa.
- This means that we should seek to stoke the embers of strength wherever we find them in Africa, such that these strengthened nodes of clinical trial expense will then become sources of inspiration and mentors to the rest of Africa

# THE BIRTH OF THE AFRICAN CLINICAL TRIAL CONSORTIUM

- ☐ ACTC to promote Regional Centers of excellence and
- ☐ Conduct Training/ training/ training
- ☐ The Institutions will be Tiered, based on Institutional Readiness data acquired through a Questionnaire: Tier
- ☐ system - Level 1/11/111 Institutions for Clinical Trials
- ☐ Subsequently, Capacity building will be top priority
- ☐ Followed by aggressive marketing of Tiered Institutions
- ☐ Special interest in Graduate students

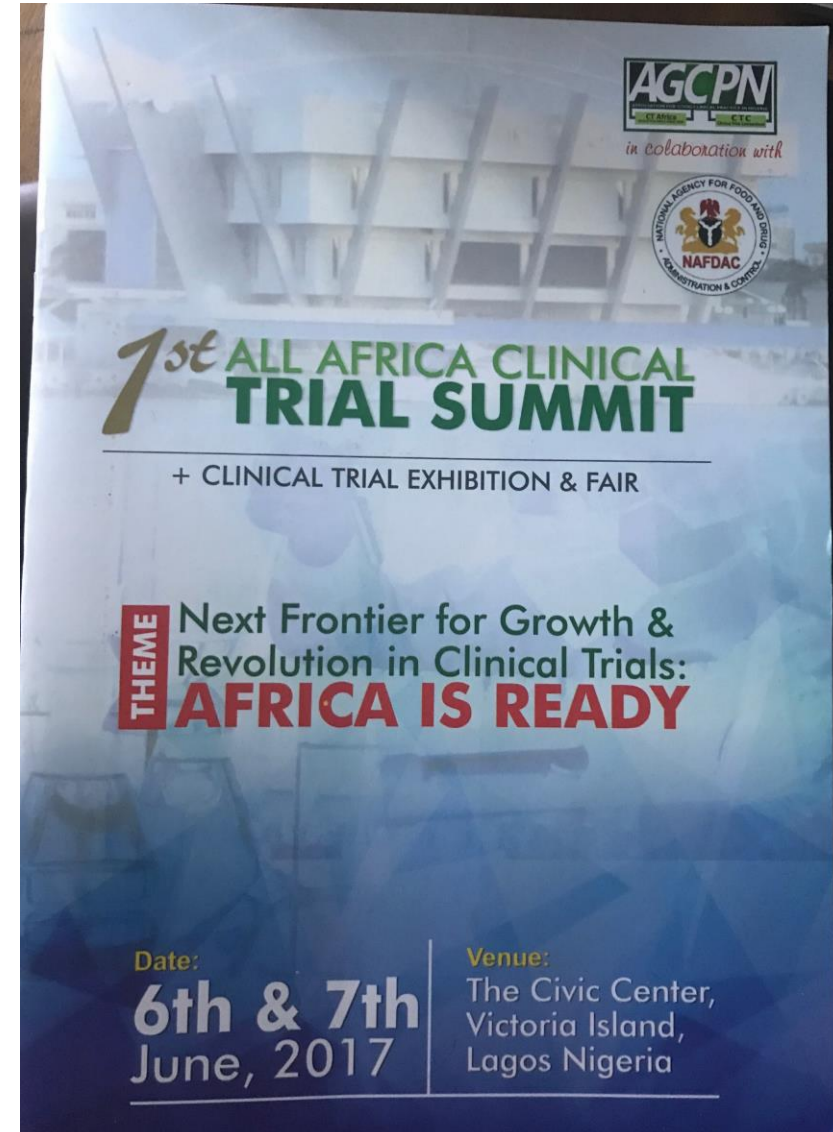
# NEED FOR COLLABORATION BETWEEN ACTC & SCSSN

- SCSSN shares the passion and vision for building sustainable Research Networks and collaborative multi-institutional platforms for health innovation within Africa
- ACTC desires to foster and enhance a relationship between the SCSSN and ACTC, and formalize a vehicle for supporting her goals and vision
- Discuss ways in which ACTC /AGCPN's International team of experts can be deployed to the benefit of SCSSN

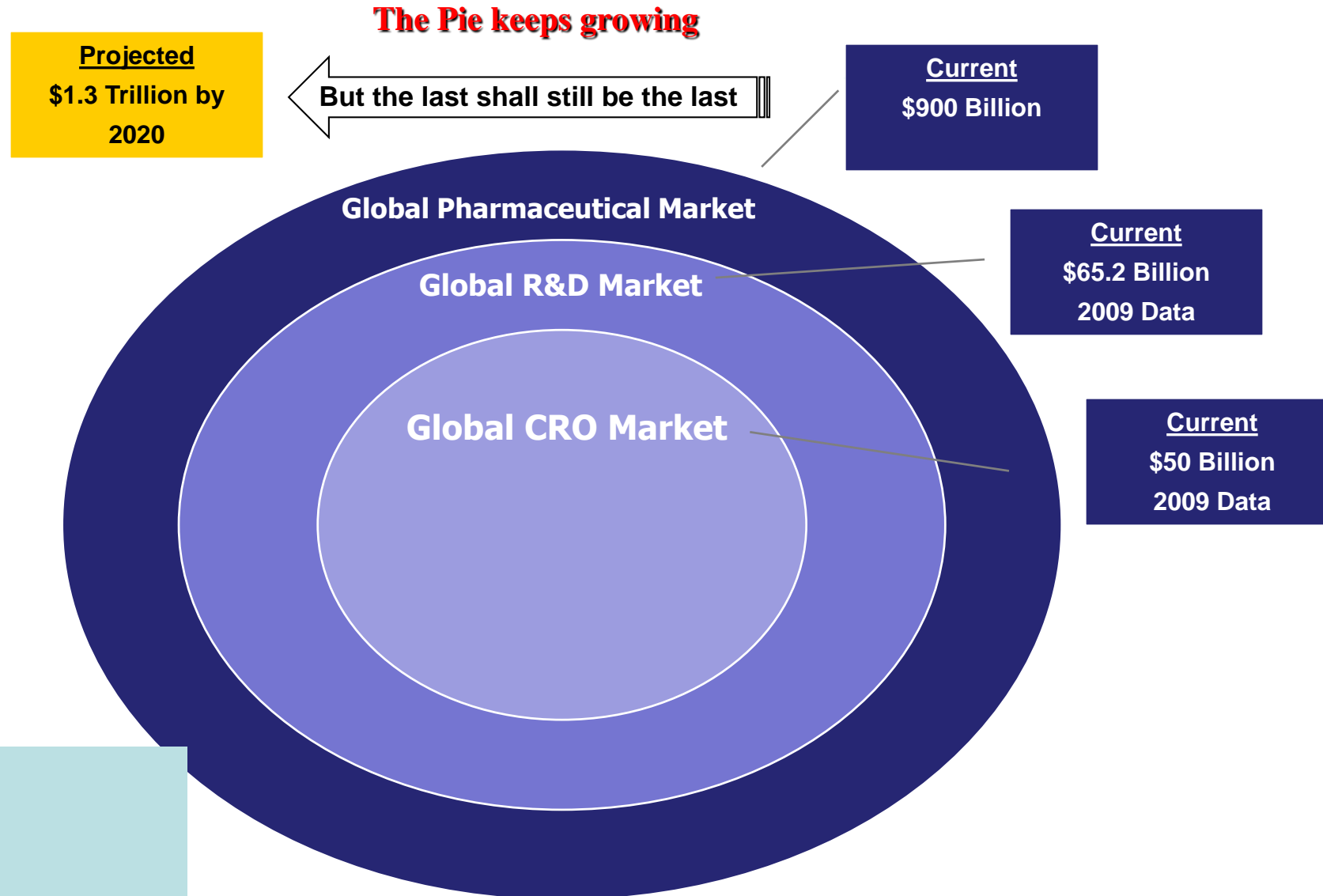
# 1<sup>st</sup> ALL AFRICA CLINICAL TRIAL SUMMIT

<https://www.clinicaltrials Summit.org/agcpncts17>

Password: contact us at [agcpng@gmail.com](mailto:agcpng@gmail.com) and [okoyeij@unncolmed.org](mailto:okoyeij@unncolmed.org) or call 08033314449 (To ask for training Calendar)



# Global Pharma at a Glance



# *Trends in Global Clinical Trials*

## **Traditional Clinical Trial Regions**

- North America
- Western Europe
- Oceania

## **Emerging Regions**

- Asia (*China and India*)
- Latin America (*Mexico, Brazil*)
- Eastern Europe (*Russia*)
- Africa (*South Africa*)

# Snapshot of Global CT Distribution

## By Number of CT Sites

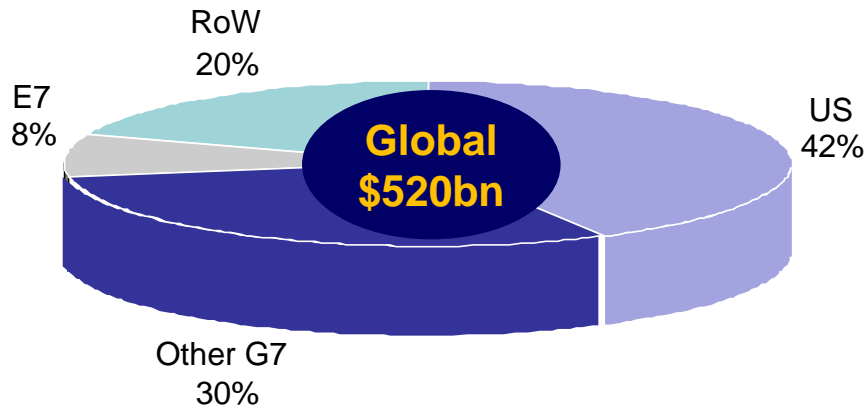
Region	# of Countries	# of sites	Shares (%)
North America	2	39313	53
Western Europe	15	18896	25.5
Oceania	3	3271	4.4
Developed Economies	20	61480	82.9
Eastern Europe	11	5578	7.5
Asia	9	2845	4
Latin America	7	2784	3.8
Middle East	2	642	1
Africa	1	553	0.8
Emerging Market	30	12402	17.1
Total	50	73882	182.9

Based on Berndt et al, 2008

## *Also Manifesting within the Pharma industry*

### *New opportunities emerging within the E7 economies*

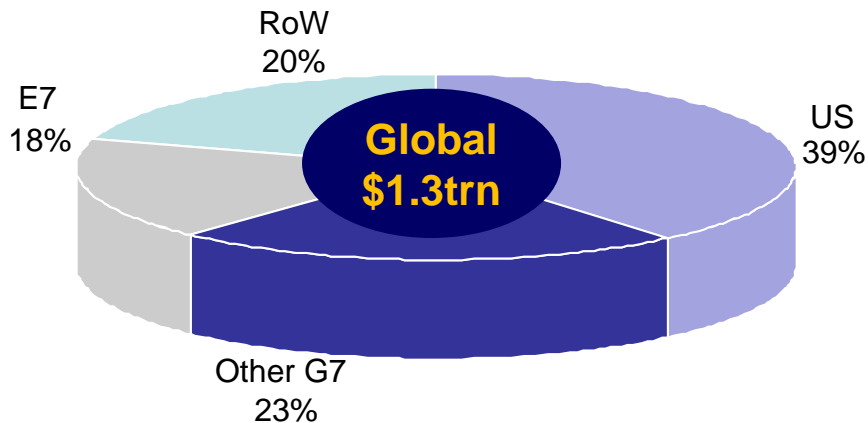
**Breakdown of global market 2005**



□ By 2020 ~20% global sales from E7\*\* countries

□ China possibly the biggest market in the world, Turkey and India possibly in the top ten

**Breakdown of global market 2020\***

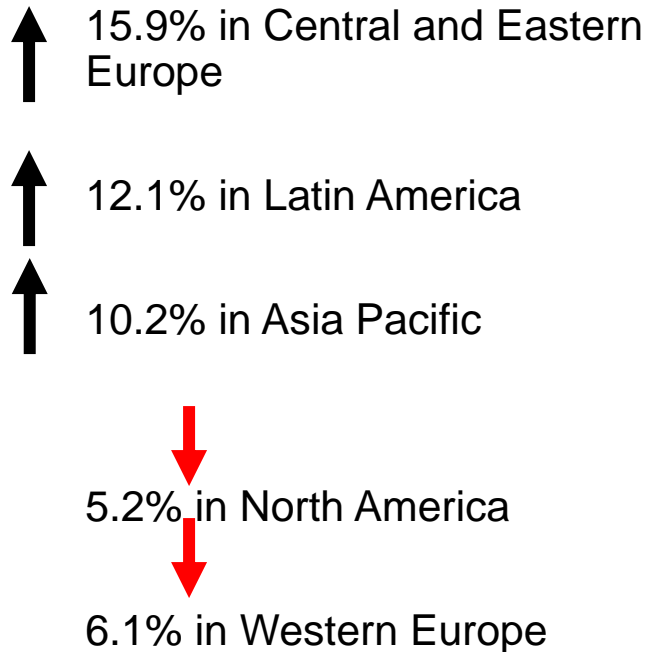


■ \*\*E7 nations = Brazil, China, India, Indonesia, Mexico, Russia and Turkey

\* Assumes G7 grow at mid-single digits, E7 grow low- to mid-double digits

# Trends in Global Clinical Trials Are Changing

Mix of FDA-regulated investigators is changing:  
Between 2004 and Now



**Half of all  
pivotal  
studies  
submitted  
to the  
FDA  
contain  
foreign  
data**

# *The Future of Global CT*

The more relevant question for Africa may not be where things are now, but.....

Where are we heading?



# *Key Reasons for Globalization*

## **Push Factors**

- Access to larger market
- Saturation of traditional locations - **Increasing competition for limited subjects**
- Access to naïve subjects
- Reduce Operational costs
- Reduce Development time
- Global companies have global sourcing mindset
- Decreasing R&D Productivity with huge impact on cost

# *Key Reasons for Globalization*

## **Pull Factors**

- Cost advantages of new locations
- Improving regulatory environment in emerging regions
- Improvements in infrastructure and CT facilities in EC
- Response to regulatory requirements in EC
- Stronger IPRs in new markets
- Future size of non-traditional markets

# *Why should Africa seek to participate?*

## **Economic benefits**

- Foreign revenue
  - Corporate tax to the government from Clinical Research-based corporations
  - Payments to Investigators, Labs, IRBs, etc
- Infusion of Capital
  - Investments by Global CROs opening up business in Africa
- Create employment
  - Emergence of CROs and ancilliary CT organizations with capacity to employ
  - Employment for Scientists, Researchers, Medical Professionals
  - Revitalize science based businesses
- Reversal of the Brain Drain Phenomenon
- Improve National Reputation

# *Why should Africa seek to participate?*

**This is more than economic benefits...It is about life**

## **Benefits to Public Health and Pharmaceutical Sectors**

- Access to medical care and subsidized medical treatment
- Access to novel drugs
- Bring attention of researchers to national health priorities
- Improvements in medical infrastructure and CT facilities
- Bring New Therapies into the country
- Better Capacity to address local neglected diseases
- Improved standards of medical practice
- Knowledge Transfer and Skill Development
- Growth of Indigenous Pharmaceuticals
- Opportunities for Indigenous pharmaceuticals to be part of global pharmaceutical continuum.
- Many more.....

# *Why should Africa seek to participate?*

**This is more than economic benefits...It is about life**

## **Benefits to Educational Sectors**

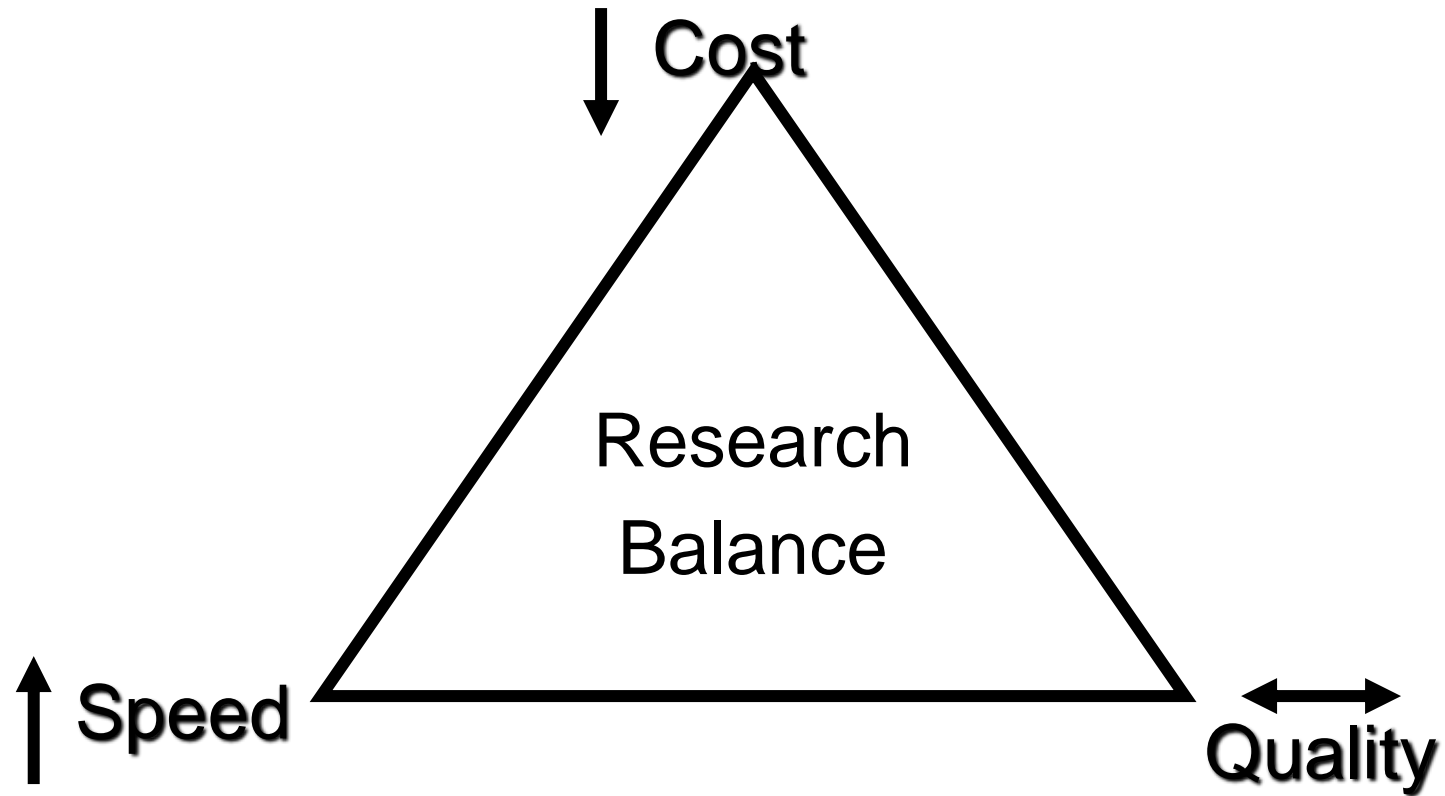
- Fuel the development of the knowledge-based economy
- Researchers are abreast with Cutting edge research in the medical and pharmaceutical science discipline
- Favorable atmosphere that could inspire the imagination of researchers in the science discipline
- Avenues for researchers in the field to attain professional satisfaction
- Opportunities for Investigators and Key Opinion Leaders with interest in Investigator-initiated clinical research

## *A Practical Example*

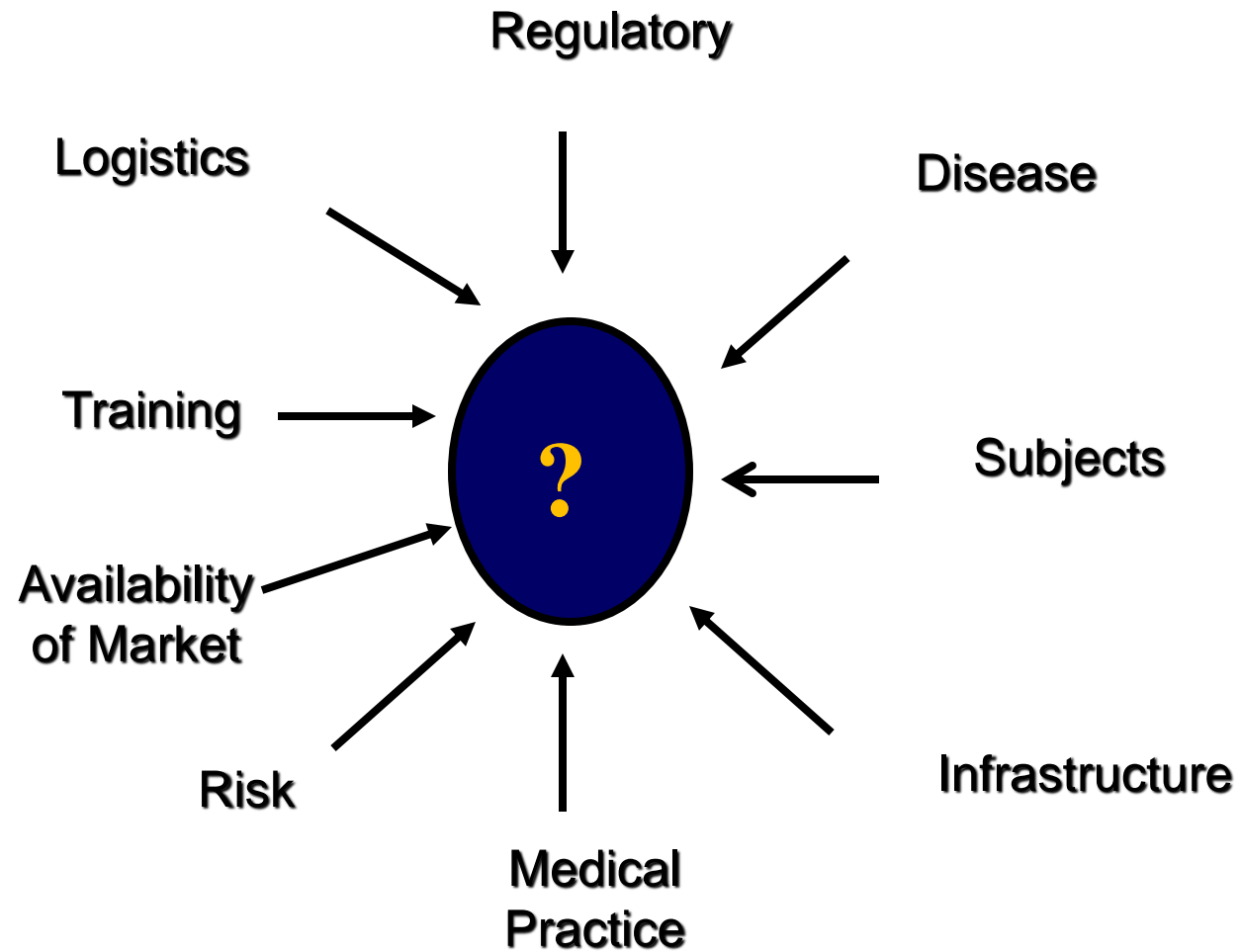
### **Poland**

30% of hospital cancer therapy  
is funded by clinical trial  
sponsors

# *Decision to place a clinical trial*



# Global Trial Placement Decision Making



*A Stake in your Success*

# *Competition Among Emerging Regions*

Nations are focused on out-thinking and out-strategizing each other in the scramble for the global market



*A Stake in your Success*

## **What of Africa?**

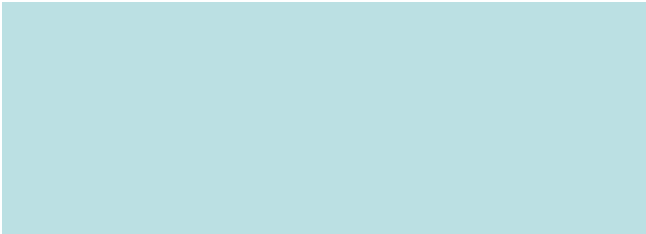
# Do we have the enabling environment for rewarding innovation?

***“if Canada is not successful in rewarding innovation, that innovation will be developed elsewhere”***

*(Russell Williams, President of Canada's Research Based Pharmaceutical Companies (Rx&D), Statement – PMPRB Report 2005, Canada NewsWire, 23 June 2006)*

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***Are we prepared to do what is  
required to Prepare Africa?***



# *Can Africa Deliver on these?*

## **Innovation System**

- Integrate CT regulation with overall Healthcare delivery strategy
- Harmonize policies among various ministries/agencies with impact on healthcare and CT

## **Data Privacy**

- Increase commitment to uphold and enforce international property Rights protection as per international standards

# *Can Africa Deliver on these?*

## Regulatory

- Streamline regulatory approval process
- Study start up 12 weeks from regulatory submission
- Create effective monitoring and tracking tools for all clinical trials in Africa
- Synchronize national regulatory requirements with global regulatory guidelines (GCP, GLP, GMP, safety Reporting, etc)
- Regulations must have sufficient legal authority
- GCP Certification

# *Can Africa Deliver on these?*

## **Ethics**

- Government initiatives to strengthen ethics committee approval process
- Recognition of critical importance of informed consent
- Overall benefit to healthcare delivery in Africa

## **Quality**

- Data of pivotal studies acceptable across borders
- Availability of sites that can meet international standards **(INSTITUTIONAL READINESS QUESTIONNAIRE)**
- Necessary investment in education and training: public & private

## **Logistics**

- More labs set up
- Diagnostics and imaging facilities
- CT materials shipment and transport system put in place

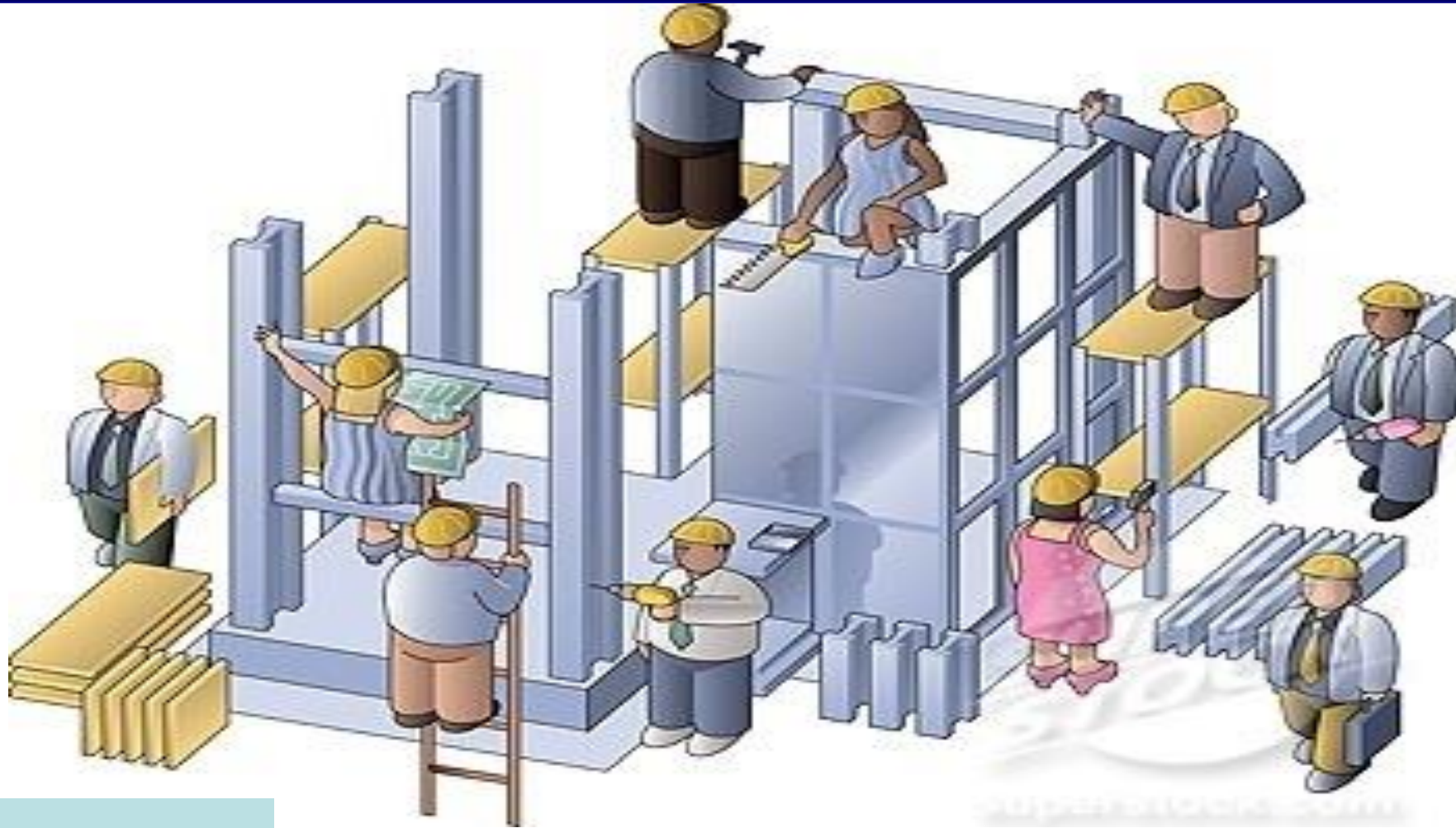
***My Answer is.....***

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***Yes We Can!!!***

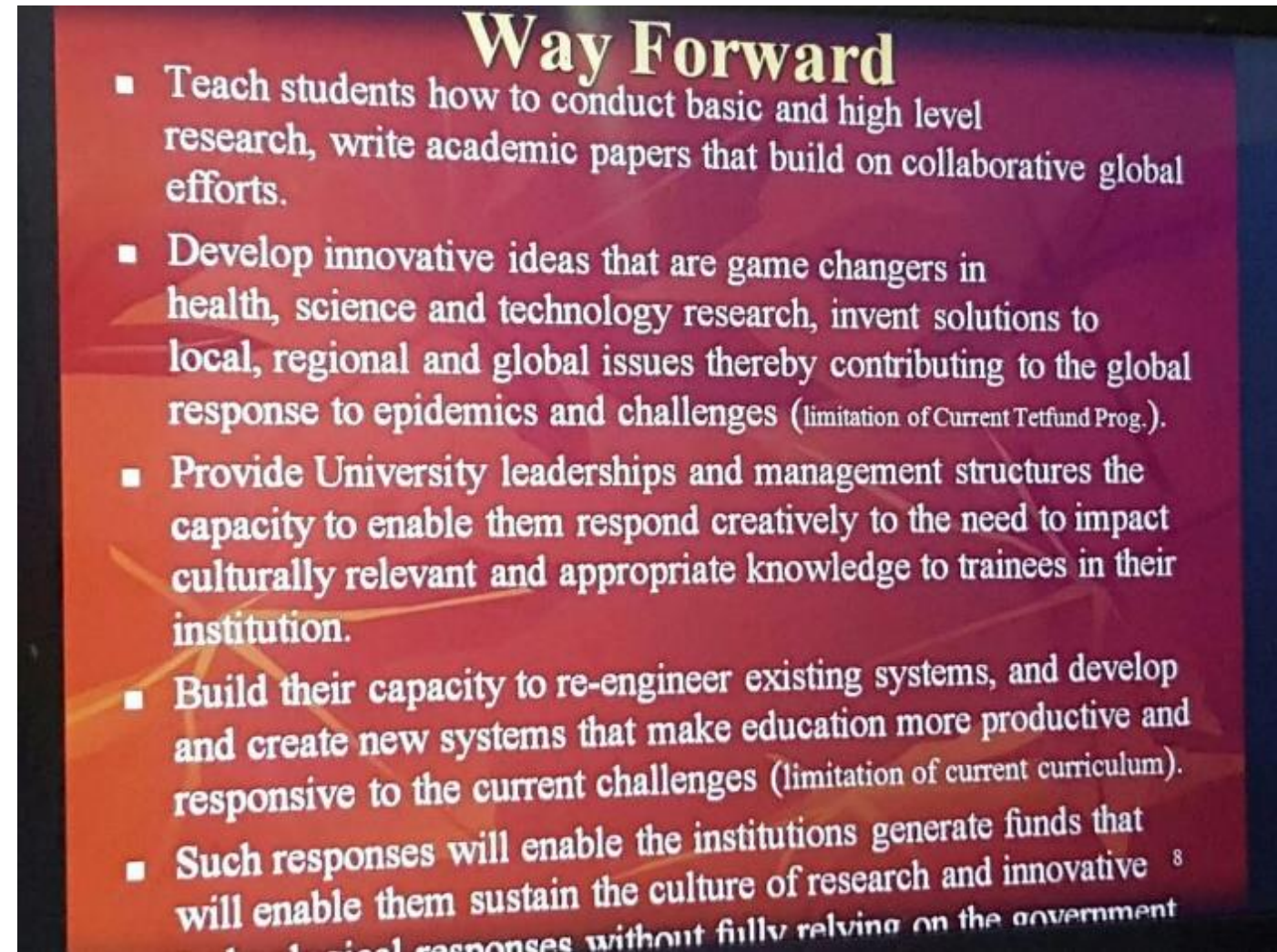
***IF.....***

# *If We Invest and Build*



# ACKNOWLEDGEMENT

- DR TONY IKEME/CLINTRIAD/ DR SIMON AGWALE



## Way Forward

- Teach students how to conduct basic and high level research, write academic papers that build on collaborative global efforts.
- Develop innovative ideas that are game changers in health, science and technology research, invent solutions to local, regional and global issues thereby contributing to the global response to epidemics and challenges (limitation of Current Tetfund Prog.).
- Provide University leaderships and management structures the capacity to enable them respond creatively to the need to impact culturally relevant and appropriate knowledge to trainees in their institution.
- Build their capacity to re-engineer existing systems, and develop and create new systems that make education more productive and responsive to the current challenges (limitation of current curriculum).
- Such responses will enable the institutions generate funds that will enable them sustain the culture of research and innovative<sup>8</sup> responses without fully relying on the government

*Theme:*

*Next frontier for Growth &  
Revolution in Clinical Trials*

**AFRICA IS READY**

## AGCPN CHARTS NEW FRONTIER FOR GROWTH AND REVOLUTION IN CLINICAL TRIALS IN AFRICA

**REQUEST FOR PARTNERSHIP AND INVITATION**



***DAAU  
ADUPE  
NAGUDE  
I THANK YOU***