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Jewel City 2023

# The tripartite Agreement between Pharma manufacturing, Research and Politics that is pivotal for the continue survival of the Nigeria Pharmaceutical Landscape


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# Précis/Outline


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- **What is a tripartite agreement?**
- Historical perspective of tripartite agreement
- **How do you write an agreement between three parties?**
- Uses of the Tripartite Agreement
- **How do we use it to achieve our objectives in the pharmaceutical landscape?**
- Recommendations

# Questions?

- What is the current state of Local drugs manufacturing?
- What are the challenges  and what are the solutions?
- Are there Research and Development Gap?
- What can we do to bridge this gap?
- What is happening in Nigeria now?
- Can the tripartite model of agreement solve this problem?

# What is a tripartite agreement?

- A tripartite agreement is an important document specifying the details of an agreement between **three separate parties**
  - for example in a transaction between two parties where a bank is acting as a guarantor for one of the parties.

- is a contract that legally binds three separate parties.

  - In this context, the politician standing as a guarantor/link between the researcher and Pharmaceutical Industry

- The **tripartite agreement** clarifies the status of all the parties involved in the transaction.

- The tripartite agreement also includes the legal process which defines how, when and to whom various agreements in the property are transferred between the parties.

- It consists of the **rights** and **obligations** from the perspective of each party involved.

- It drafts the responsibilities of each party throughout the different phases of the business/transaction.

- The most important aspect of a tri-party agreement is the part where the **legal consequences** of a non-compliant activity are defined.

# Historical perspective

- It started when the “Tripartite Agreement” was initiated as an international monetary agreement that was entered into by the United States, France, and Great Britain in September 1936.

# Pharmaceutical Example

TRIPARTITE COOPERATION AGREEMENT

By and Between

NOVARTIS PHARMA AG

GENENTECH, INC.

AND

TANOX, INC.

Dated as of February 25, 2004

# Example: Model Industry Collaborative Research Agreement (mICRA)

- The model Industry Collaborative Research Agreement is designed to support clinical research collaborations involving the pharmaceutical and biotechnology industries, academia and NHS organisations across the UK.

- It is supported by a comprehensive guidance document which sets out its background and aims and details how the agreement should be used in the development of contracts for specific clinical research collaborations.
  - https://innovations.hscni.net/library/model-agreements-library/

Representatives from **industry**, universities and the NHS, and the Intellectual Property Office, were brought together with expert legal opinion to develop a model Agreement that can be used to support all collaborative research scenarios

# How do you write an agreement between three parties?

- The draft agreement must use **clear** and **clear-cut** language.

- It must specify each party's rights and obligations in detail, including remedies for breaching the agreement.

- It must include all necessary legal clauses in the agreement, such as indemnification and dispute resolution clauses.

# What should you look for in a Tri-party Agreement?

- The detailed contents of a tripartite agreement heavily depend on the business/transaction you are dealing with.

- the general items that must be included in a tri-party agreement.
  - Name of the parties involved
  - Objectives of the agreement
  - Perspectives of all three parties
  - Obligations and responsibilities of every party
  - Consequences of non-compliance

# Format of a Memorandum of Agreement

- Title
- Authority
- Purpose of the Agreement. Name of parties involved. ...
- Detailed Description of Roles and Responsibilities.
- Duration of the Agreement.
- Modification or Termination.
- Signatures of Parties' Principals

# Advantages of a strong Tri-party Agreement

- Some of the advantages that a tri-party agreement brings to the table are:
  - **Transparency:** It clearly states the responsibilities and obligations of all three parties involved in the agreement. It systematically decodes the interests and liabilities of each party.
  - **Eliminates fraudulent practices:** Once the three parties enter into an agreement, each party becomes responsible for the other two. Hence, any fraudulent activities or non-compliant actions will hold legal consequences. These consequences will only hold true for the fraudulent party as the other two parties will be protected via the agreement.
  - **Increases ease of doing business:** Once the parties enter into a strong, detailed contract, it creates a safety net for all three parties and ensures that all transactions are well monitored.

# Pharmaceutical Researcher

- professional who performs research to drive drug discovery, development, and testing and their work is Multidisciplinary in nature.
  - Drug discovery and development involves the collective contributions of many scientific specialists including:
    - Chemists , biochemists, physiologists, pharmacologists, toxicologists, pathologists, physicians, biostatisticians and computer scientists among others.

- These professionals are typically bench-level scientists who are charged with executing experiments as part of a team-based research project aimed at introducing new drugs to the marketplace.

- The researchers are made of multidisciplinary scientists

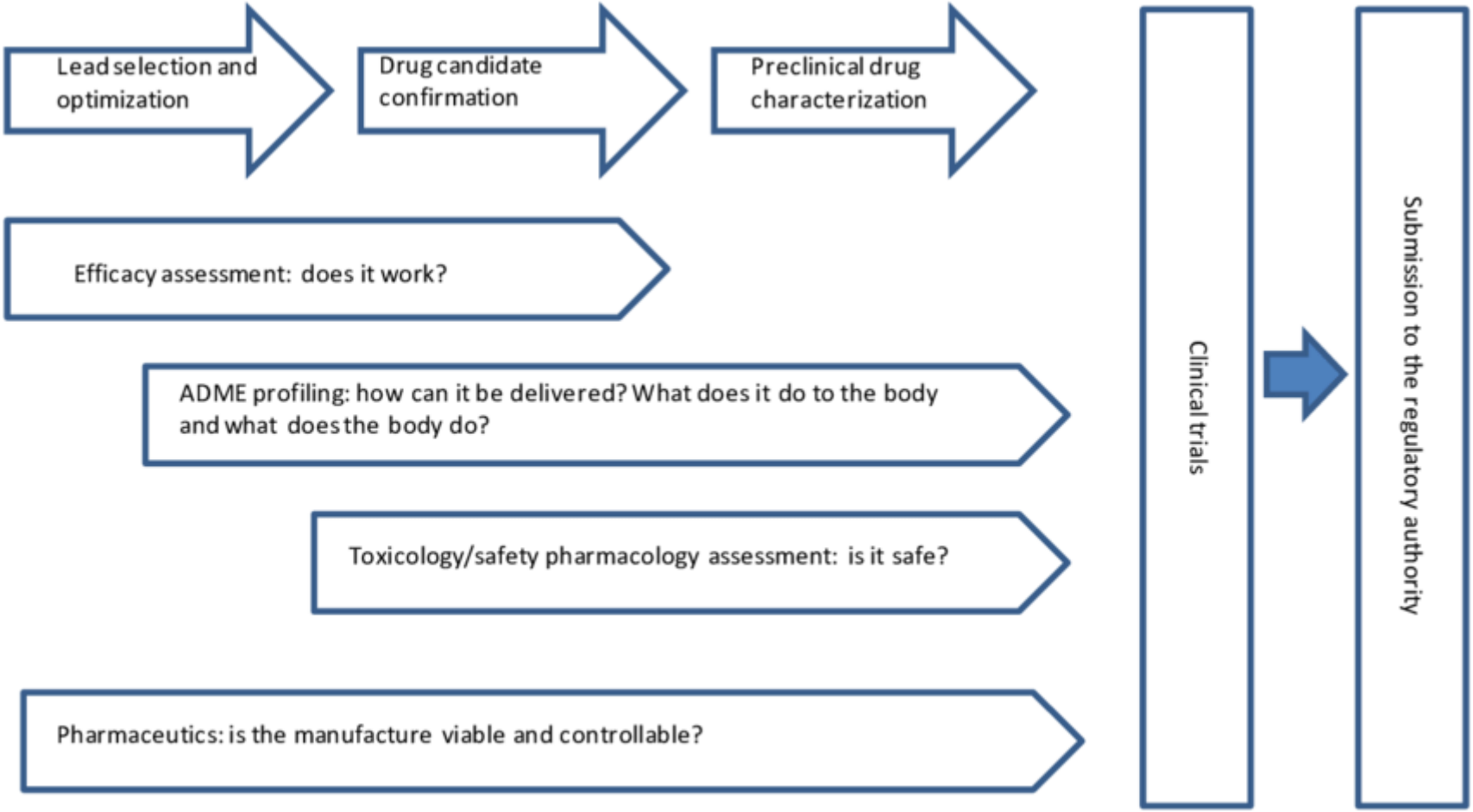
## Challenges confronting the Pharmaceutical Landscape

no synergy between the researchers and Pharmaceutical Industries/weak research-industry interactions.

Poor Funding/Weak Financial Base

Poor Infrastructure/Research Tools

In Nigeria , we remain heavily dependent on imported pharmaceuticals



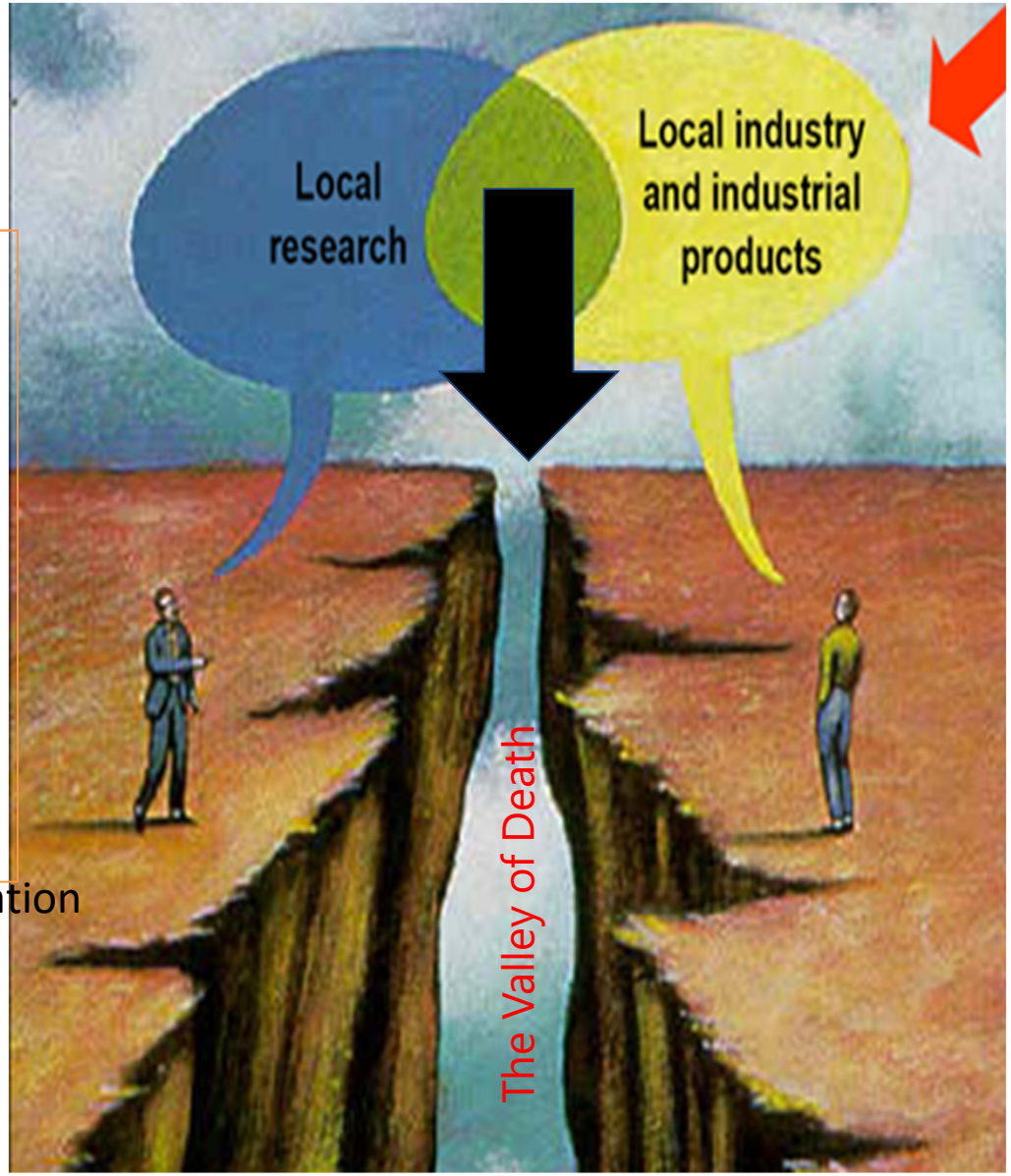

Source: Simon (2009)

Tasks performed in the phases of discovery and preclinical development.

# The Valley Death

- The Valley of Death is the depth of loss of:
  - Research Outcomes
  - Products Development insights

- Largely due to lack of Synergy between the Researching body (Institutions), the Products development body (Industry) and the Policy body (Government/politicians).

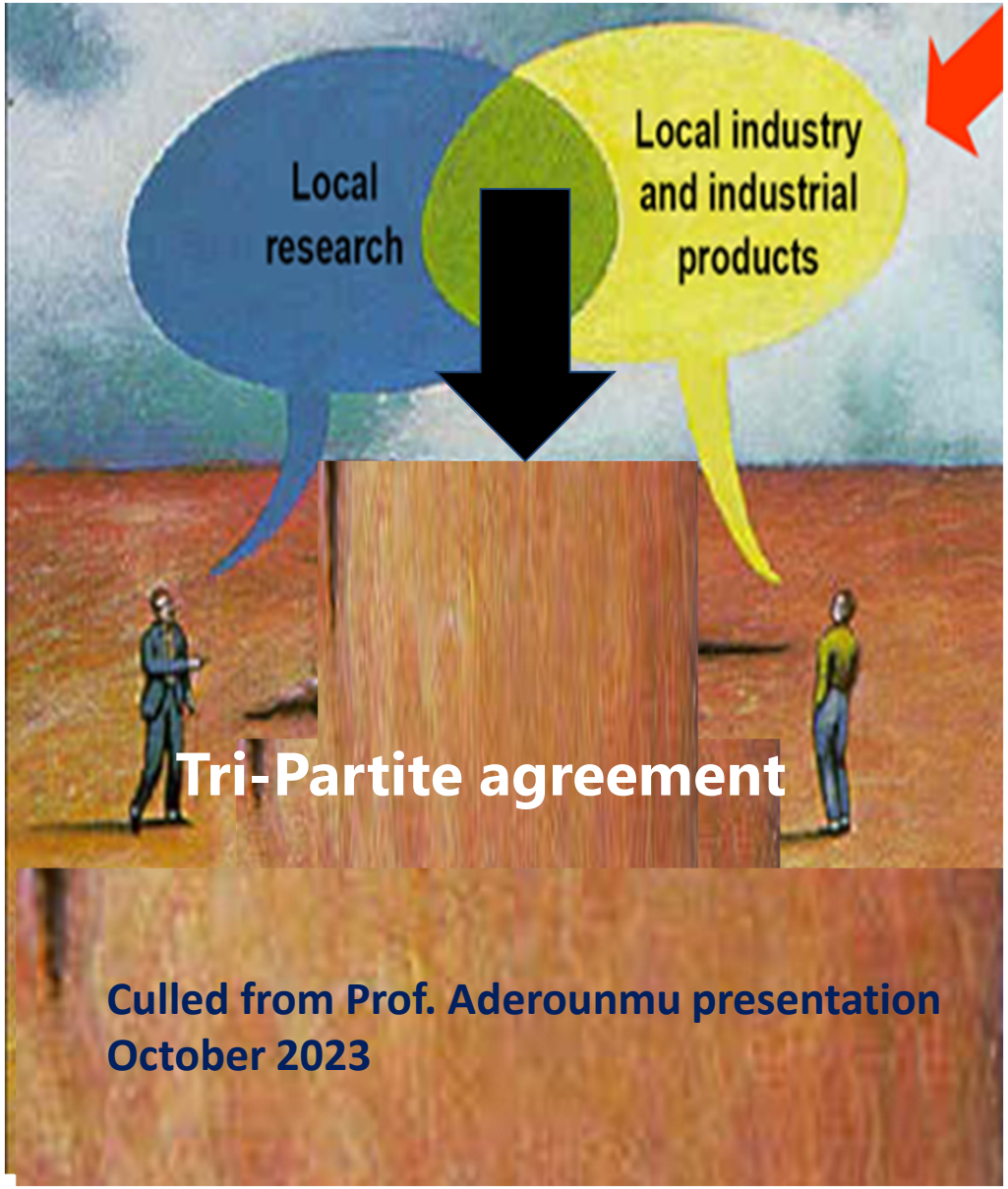



Culled from Prof. G. A. Aderounmu presentation October 2023

# SOLUTIONS

# The Valley Death

- Can the the problem(s) associated with the "Valley of Death" be solved through
  - Partnership
    (Tri-Partite agreement)



# Funding-Challenges

- Solutions:
  - Need to Increase investment in basic research
  - Expansion of funding sources
  - Encourage collaboration with private and the government sectors for research

(**Through the politicians**)

- It is of great importance to note that promotion of pharmaceutical research and development is very critical for health intervention and therefore, there is need for **synergistic** action between the **researcher** and the **Pharmaceutical Industries** in order to meet the healthcare needs of this nation.

  - This can be achieved by the government (politicians) by encouraging conducive atmosphere for achieving this in the current dispensation –possibly also through funding.

  - The politician can facilitate the tripartite agreement

- There is need to facilitate close Academia-Industry Interactions in Nigeria Pharmaceutical Innovation System.
  - Siyanbola *et al.* (2012) reported that the intensity of interactions (academic-Pharmaceutical Industry) is limited as only 20% of pharmaceutical researchers from Universities and 7% from Research Institutes had strong interactions with Pharmaceutical firms, while only 4 firms have strong interactions with the researchers. **However,** I strongly believe there is a strong relationship now as observed with the MoU signed by NAPA and NAIP.

- The researcher must know the needs of the pharmaceutical industries in order to find a way to meet the healthcare needs of the nation and improve the quality of life of its populace.

- Research on the basic ingredients that will be needed in the production of quality pharmaceutical products should also be encouraged.

- Notably, policy-makers (Politicians) need to encourage universities and Pharmaceutical firms to engage in partnerships (**Collaboration**).

- **Tripartite agreement** can facilitate joint research and development on pharmaceutical products.
  - The **politician** can bridge the perceived gap between **Researchers** and the **Pharmaceutical sector** (productive sector) that would allow the rapid transformation of known knowledge into innovation.

  - The facilitated collaborative engagement with industry may be of great benefit to academics' research activities by establishing relationships with knowledge users and mobilizing resources that will complement public research funding.

# General Recommendations

- **Tripartite agreement** should be encouraged in order to fast track drug development
- **Develop more effective and diverse funding sources to spur local and international investment**:
- it is necessary to expand funding sources available to local manufacturers

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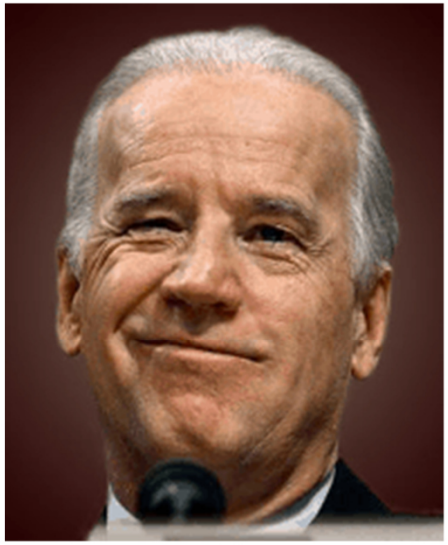
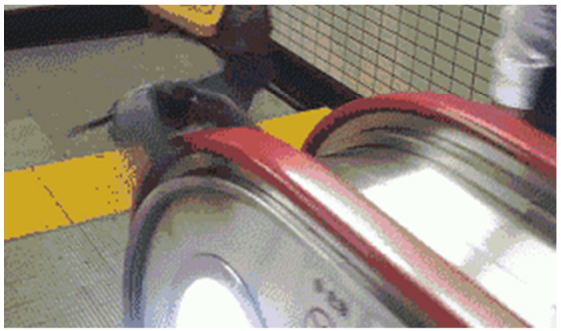
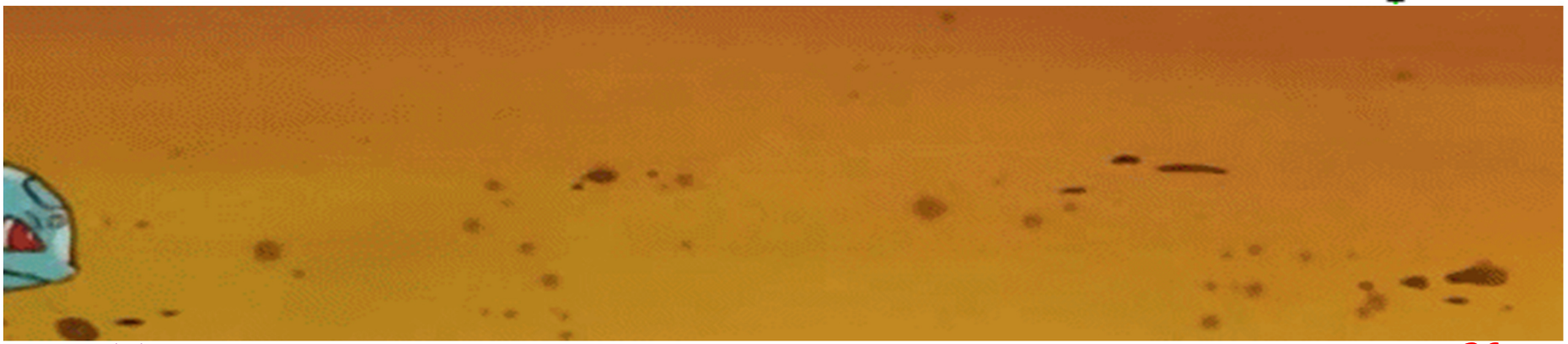




**Arigato**

**gozaimasu**




Thank You!