

Positivism: An Approach to Develop Indigenous Medicine



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Present Scenario in Drug Development

From Idea to Market :

- Time span > 15 years
- Cost > US \$ 1.5 billion
- Inputs from different disciplines
- Regulations

Paradox

- **Resource Crunch**
- **Lack of Co-ordination**

Way Out ?

- **Need Based Research**
- **Solutions from within:**
 - **Different System of Medicines**
 - **Rich Experience**
 - **Peoples Faith**
 - **Government Patronage**

POSITIVISM

(a scientific model)

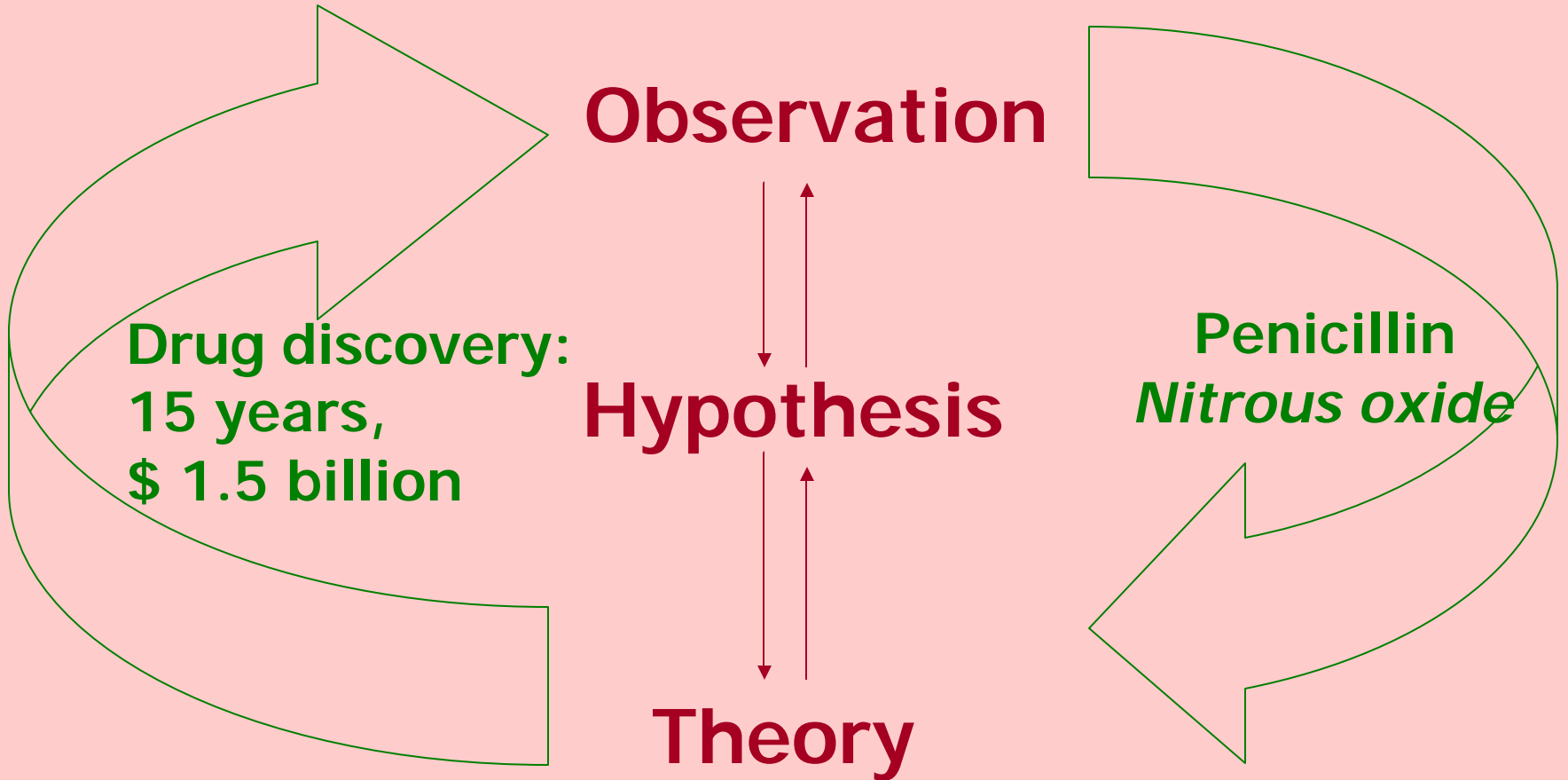
Observation

Hypothesis

Theory

**Drug discovery:
15 years,
\$ 1.5 billion**

**Penicillin
*Nitrous oxide***



Positivism : An Example

Observation

Preliminary study:

Sorting out of patients of APML

Pilot Study: (Cancer Research Committee under CCRAS. Duration 3 Years)

1. Bone marrow aspiration & peripheral blood smear measurement
2. Liver & Kidney function test for toxicology evaluation



Hypothesis

Can silver based compound be effective for treating the APML patients ? 'Yes'

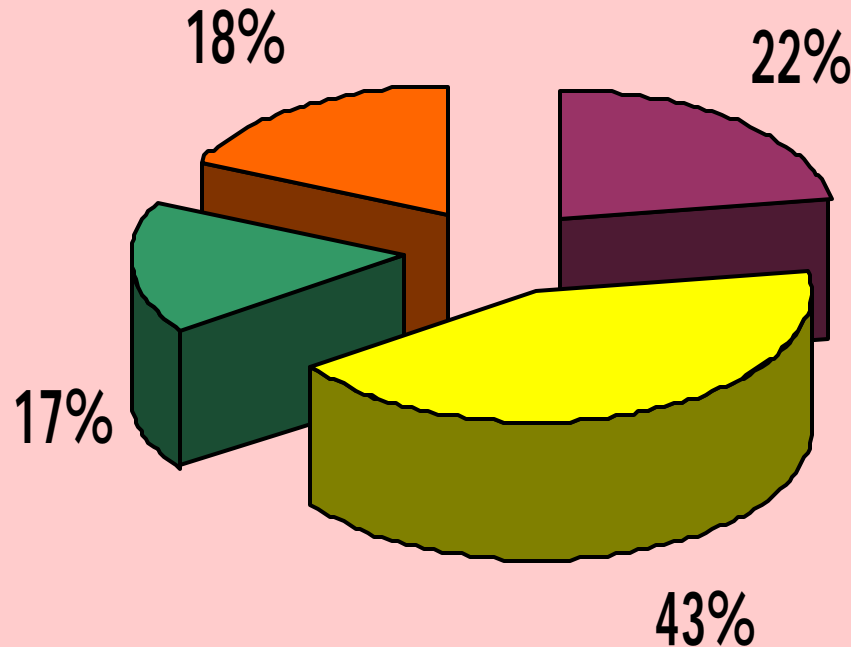


Theory

1. Standardization of raw material
2. Development of in-process quality control technique
3. Standardization of finished product
4. Toxicological studies
5. Effective Dose studies
6. Human trials
7. Pharmacological explanations

Summarized Details of treated patients of APML

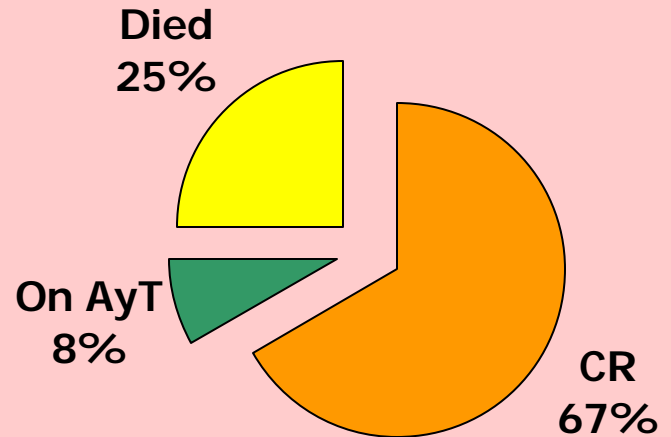
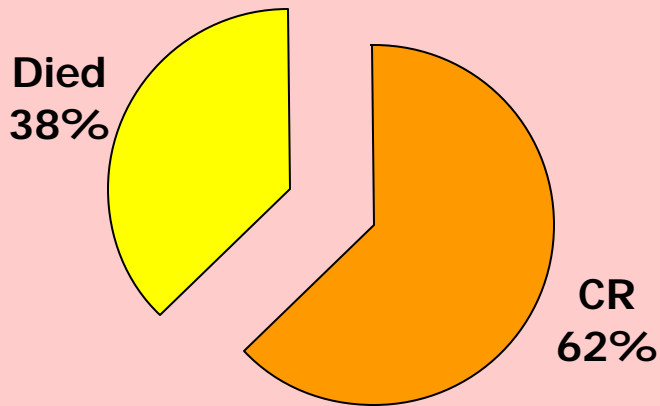
n = 73



■ Relapse ■ De novo ■ Refractory / Defaulter ■ Post Remission

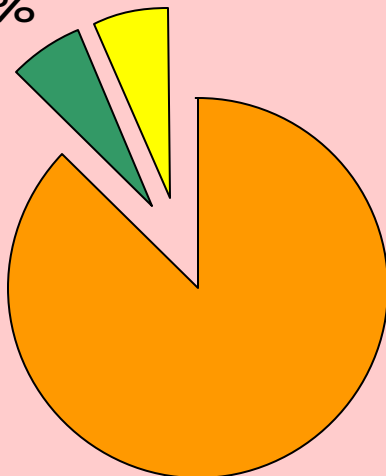
December 1982 - December 2004

Distribution of APML Patients



Relapse

On Died
AyT 6%
6%

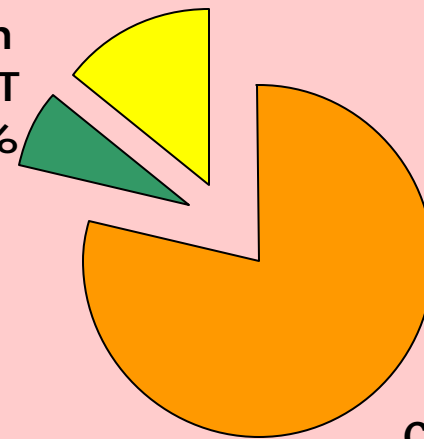


De novo

CR
88%

Defaulter / Refractory

Died
14%
On
AyT
7%



Post Remission

CR
79%

Current Scenario of Ay. Treatment for APML

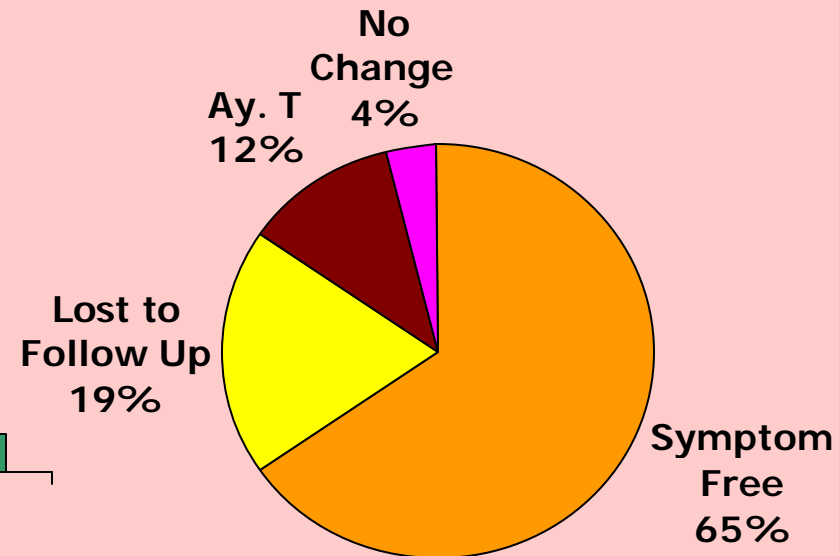
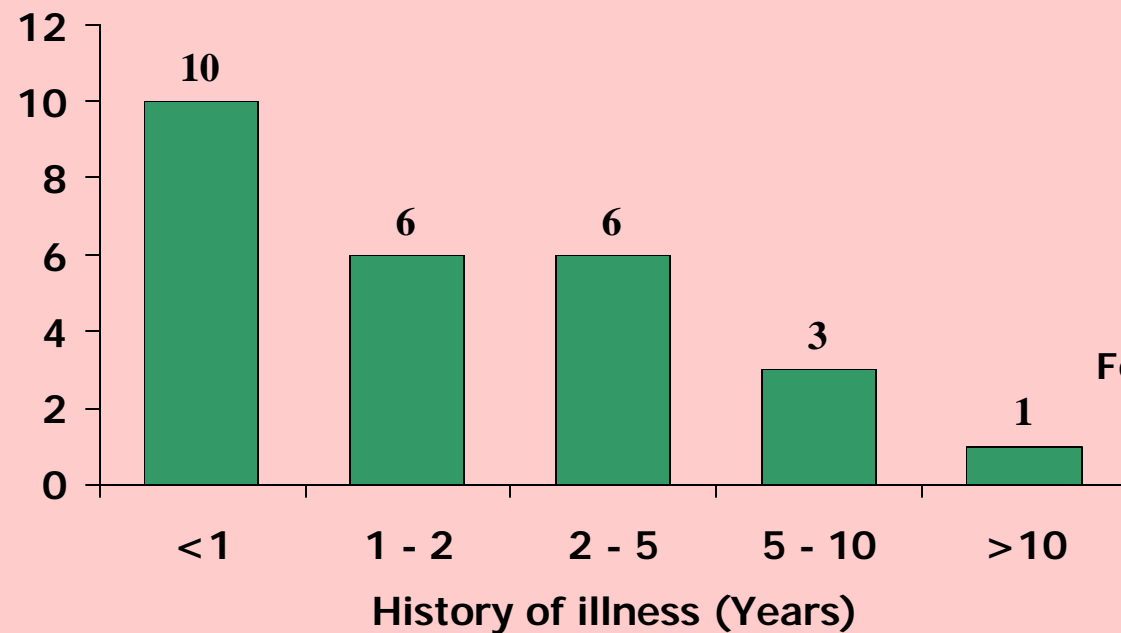
- **Product Availability & Indoor Treatment at VCPCRF, Dehradun**
- **Capacity Building - Training of Ayurvedic Graduates**
- **Collaborative Clinical Units at Bangalore, Chandigarh, Delhi, Mumbai, Trivandrum, Pune & United Arab Emirates**

Drug Development for APML

Proposed Collaborators:

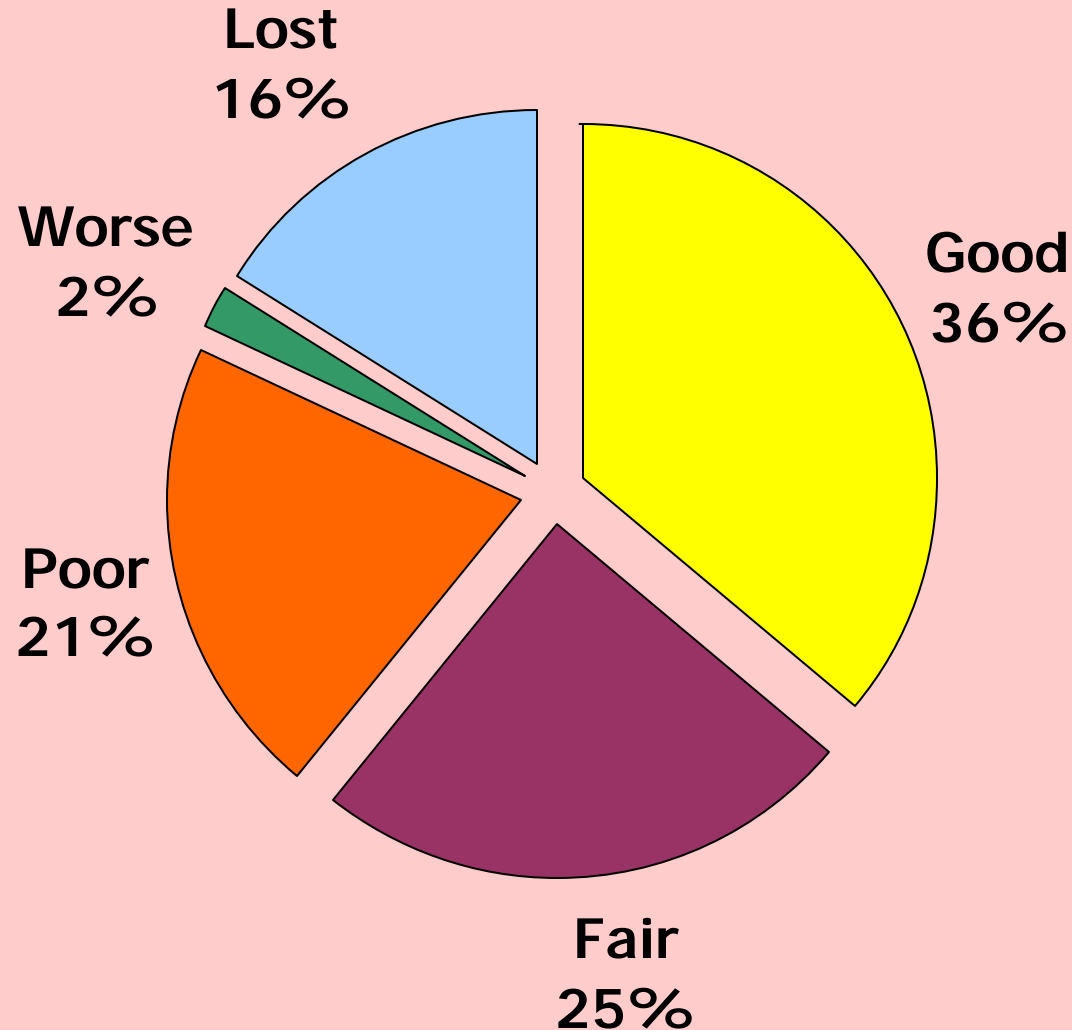
- Product & Process Patent - NRDC
- Multicentre Phase II Clinical Study- ICON
- Physico-Chemical Structure Analysis- NCL
- Toxicological Study - RRL
- Pharmacological Study -CDRI
- Commercial Production-IPCA Laboratories

Preliminary Results with Metal Based Ayurvedic Treatment (MBAT) in the patients of Chronic Pancreatitis (n=26)



Preliminary Results in the Patients of Common Migraine (n=105)

June 2002 - December 2004



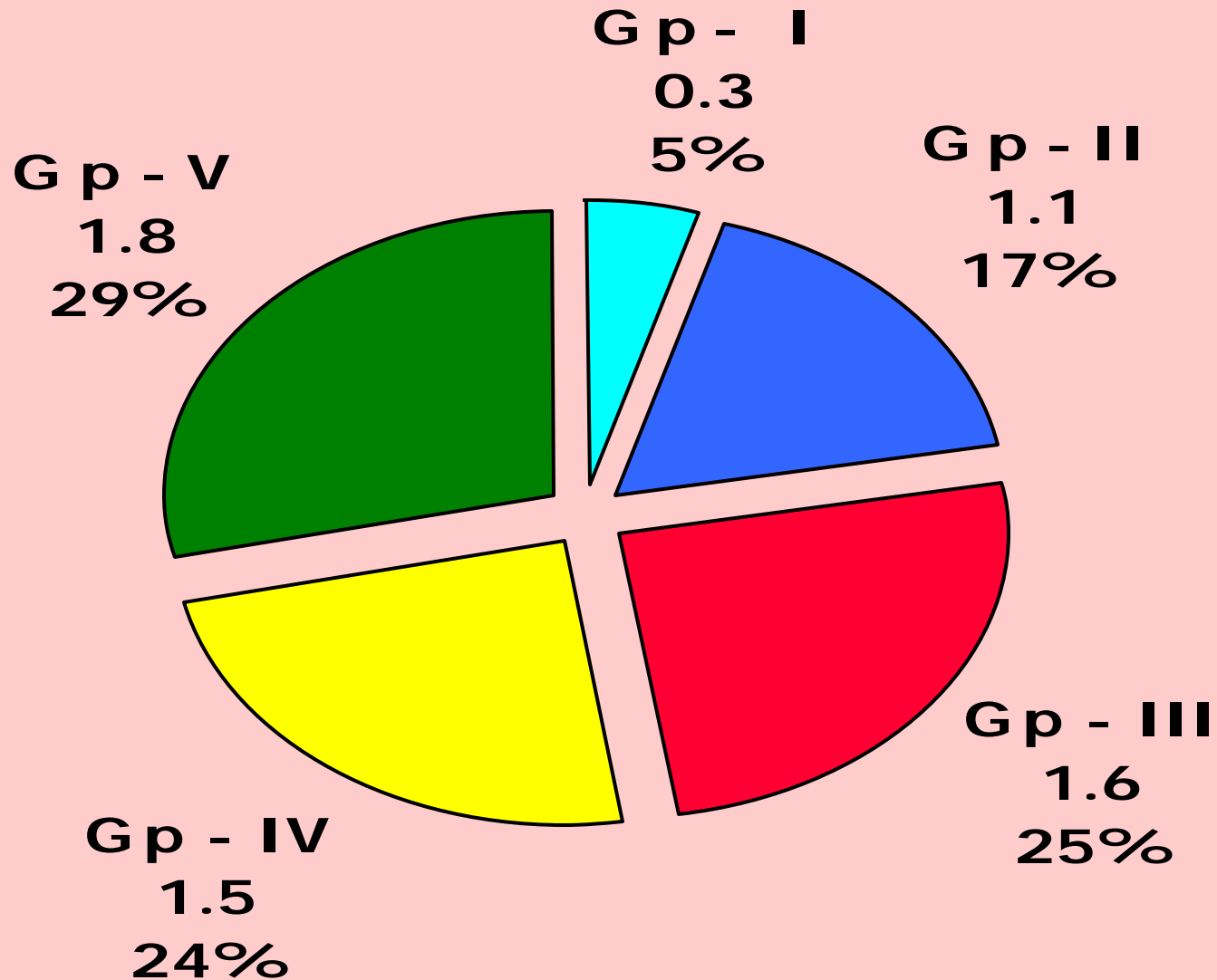
Controlled Study on Anemia

Subject= 600 NPG Women (11- 45 years)

Group -I	Control	120
Group -II	Diet + IFA	120
Group -III	Diet + AYAS	120
Group -IV	Diet + SS	120
Group -V	Diet + AYAS + SS	120

- Filter paper method used
- 90 days study
- QAP carried out

Gain in Hb. gm% among various groups



Development of Indigenous Medicine

- Leap from Tradition to Technology
- Documentation of Clinical Experiences
- Pilot Studies
- *Prima facie* evidence for *New Treatment Protocols - NTP*

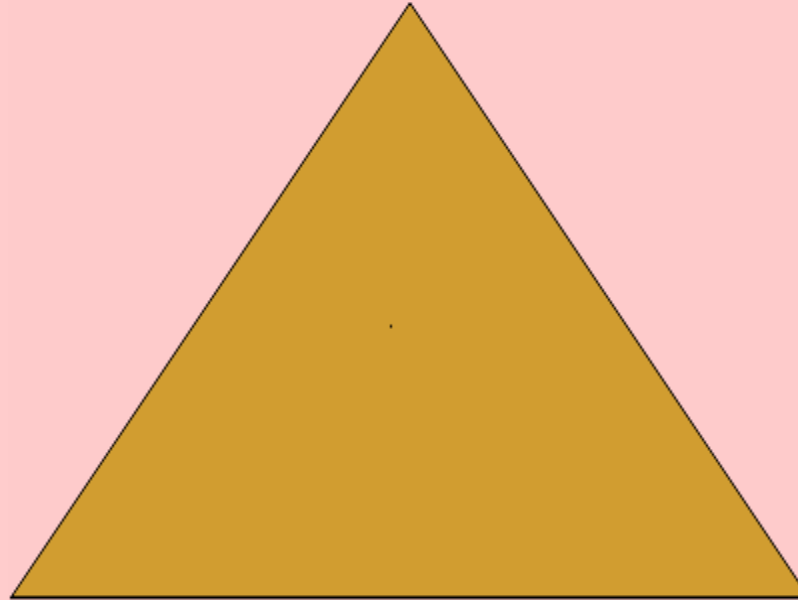
Essential Requisite

- **Reproducibility**
- **Safety**
- **Efficacy**
- **Availability**
- **Pharmacological Explanations**

Future Directions

Modern Science

Traditional
Medicine



Modern
Medicine

Principle of Golden Triangle

Outcome

- **Data Generation**
- **Credibility**
- **Authenticity**
- **Partnership**
- **Reward**

Thank You