

Overview on National Guidelines for Ayurveda and Traditional Medicines Research in Nepal 2026

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Section I: Background & Scope

Ayurveda and Traditional Medicine (ATM) are among the **oldest healthcare systems**, practiced for thousands of years.

- Widely used globally, especially in **Asia, Africa, and Latin America**, and increasingly as **Complementary and Alternative Medicine (CAM)** in developed countries.
- **Nepal has rich diversity** in traditional practices including Ayurveda, Yoga, Naturopathy, Sowa-Rigpa, and folk medicine.
- Strong cultural beliefs and **time-tested remedies** make ATM popular in both rural and urban populations.
- Recognized by **National Health Policy (2019)** as a component of the national healthcare system.
- Government promotes **research, integration, and scientific validation** of traditional medicine.

Need and Development of ATM Research Guidelines

- Growing global use demands **systematic, scientific, and ethical research frameworks.**
- **Traditional medicine research faces challenges due to:**
 - Holistic and personalized treatment approaches
 - Multi-component therapies (polyherbal, mineral-based)
- **Establishment of institutions like:**
 - National Ayurveda Research and Training Centre (NARTC)
 - Nepal Health Research Council (NHRC)

Need and Development of ATM Research Guidelines

- NHRC developed “**National Guidelines of Ayurveda and Traditional Medicines Research 2026**”.
- **Focus areas:**
 - Standardization, safety, efficacy, and quality control
 - Integration of traditional concepts (Prakriti, Dosha, Agni) with modern research
 - Ethical practices, GCP, and evidence-based validation
- **Aim:** Bridge traditional knowledge with modern science for global acceptance and improved healthcare.

Scope of these guidelines (1)

- To establish research guidelines for developing proposals to conduct ATM research in Nepal in accordance with scientific methods and ethical standards.
- To promote evidence-based research in ATM systems by integrating classical principles with contemporary scientific research methodologies.
- To ensure the **quality, safety, and efficacy evaluation of ATM drugs, therapies, and practices** through suitable research designs and regulatory frameworks.

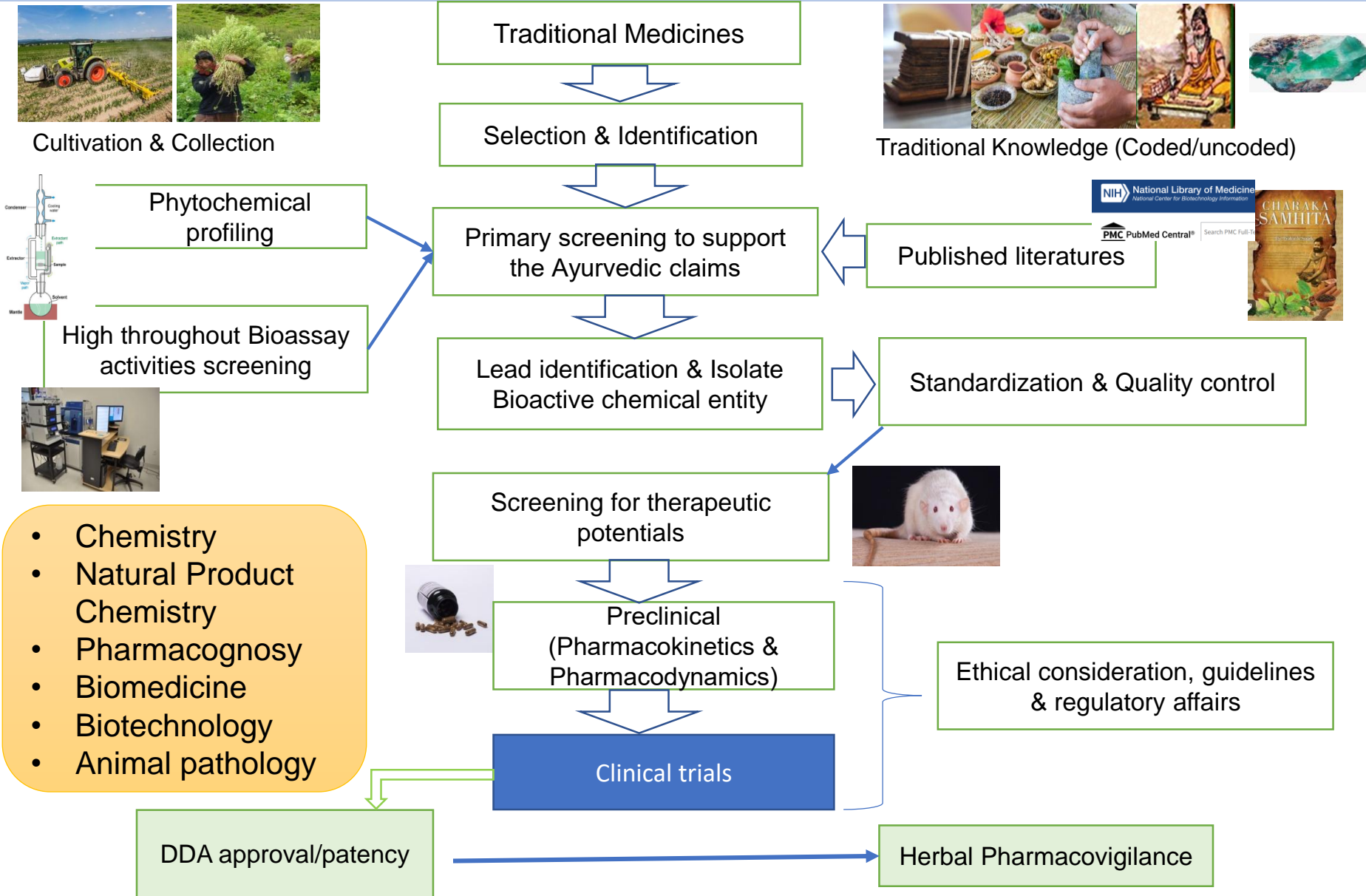
Scope of these guidelines (2)

- To strengthen research capacity and coordination among researchers, institutions, and regulatory bodies involved in ATM research in Nepal.
- To provide policymakers with scientific and evidence-based findings in ATMs in Nepal for improvement in healthcare policy and public health outcomes.

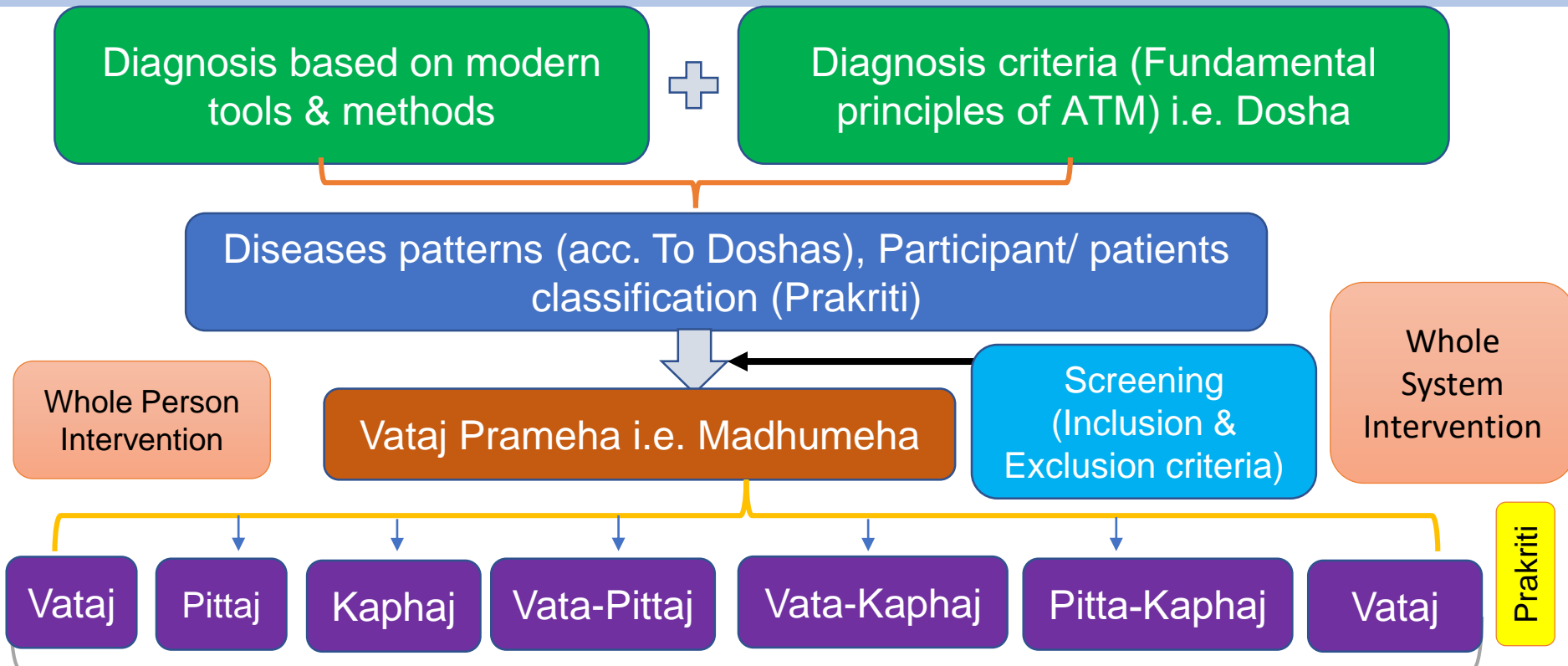
Section II: Integrative Research Approach

- Integrative Research Approaches in Ayurveda & Traditional Medicine
- **Bridging Traditional Knowledge (TK) & Modern Science**
- Multidisciplinary, Interdisciplinary & Transdisciplinary Models
- Holistic Solutions for Complex Health Problems

Bridging TK & Modern Science



TK Integration into Research Methods



Groups	Intervention
Groups	Outcomes analysis
Standard	FBS, PPBS, RBS, Hb1Ac, Sign and symptoms of T2DM & Madhumeha
Whole components test plus standards	FBS, PPBS, RBS, Hb1Ac, Sign and symptoms of T2DM & Madhumeha
Whole components test	FBS, PPBS, RBS, Hb1Ac, Sign and symptoms of T2DM & Madhumeha

Note: Reports combined and individual results of T2DM & Madhumeha

Core Elements: Whole System Research Protocol

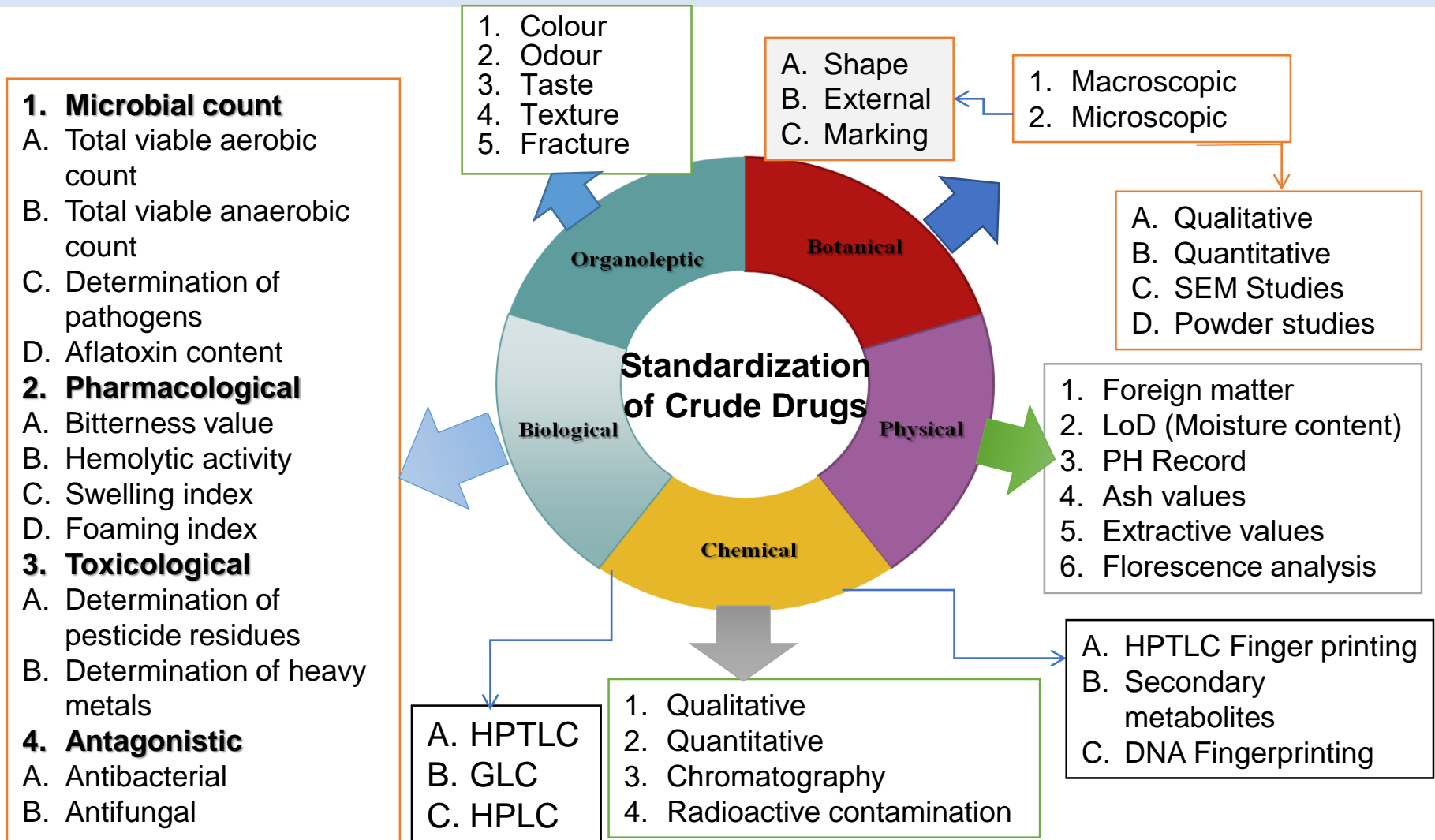
- Research Question
- ↓
- Population/Participants (Prakriti, Dosha-based)
- ↓
- Intervention (Holistic Ayurveda Care)
- ↓
- Comparison (Standard / Usual Care)
- ↓
- Outcomes (Biomedical + Ayurvedic + PROs & CONS)
- ↓
- Study Design (Pragmatic, Mixed)
- ↓
- Reporting (Structured & Transparent)

Section III: Drugs Standardization

Definition

- Process of ensuring **uniformity in identity, purity & quality**
- Applies to single, polyherbal & polyherbal-mineral formulations
- Uses **pharmacognostical, phytochemical & physicochemical parameters**
- **Ayurvedic formulations must undergo drug standardization before biological activity, preclinical & safety studies**
- Aims for **global acceptance** & integration into mainstream healthcare

WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues



Components of Drug Standardization

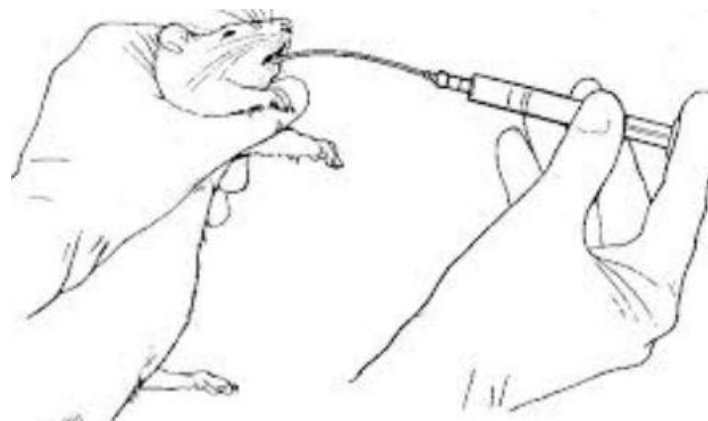
SOPs for:

- Preparation of investigational product/formulation/composition
- **Standardization of finished AYUSH formulations** (follow GMP of Ayurveda)
- Targeted biological activities / diseases / pharmacotherapeutic uses
- Safety & toxicity (follow OECD guidelines)
- Preservation, packing & storage
- Regulatory approval (for new drugs)
- Clinical evaluation & trial protocol

Section IV: Safety and Toxicity Evaluation

Guidelines for safe and ethical research practices

- Quality specifications ensure **standardization of products and procedures**
- **Two categories:**
 - Pharmacological (herbal, mineral, herbo-mineral)
 - Non-pharmacological (procedure-based therapies)
- **Types of toxicity evaluation:**
 - Acute toxicity (<14 days)
 - Sub chronic toxicity (1-3 months)
 - Long-term toxicity (6-12⁺ months)
 - Local toxicity
- **Methods:**
 - In vitro (cell-line studies)
 - In vivo (animal studies) as per recommended OECD guidelines
- **Applicable to clinical, preclinical, and experimental studies**



Quality Specifications for Investigational Products

Quality specifications ensure **standardization of products and procedures**

- **Two categories:**

- Pharmacological (herbal, mineral, herbo-mineral)
- Non-pharmacological (procedure-based therapies)

- **Must follow:**

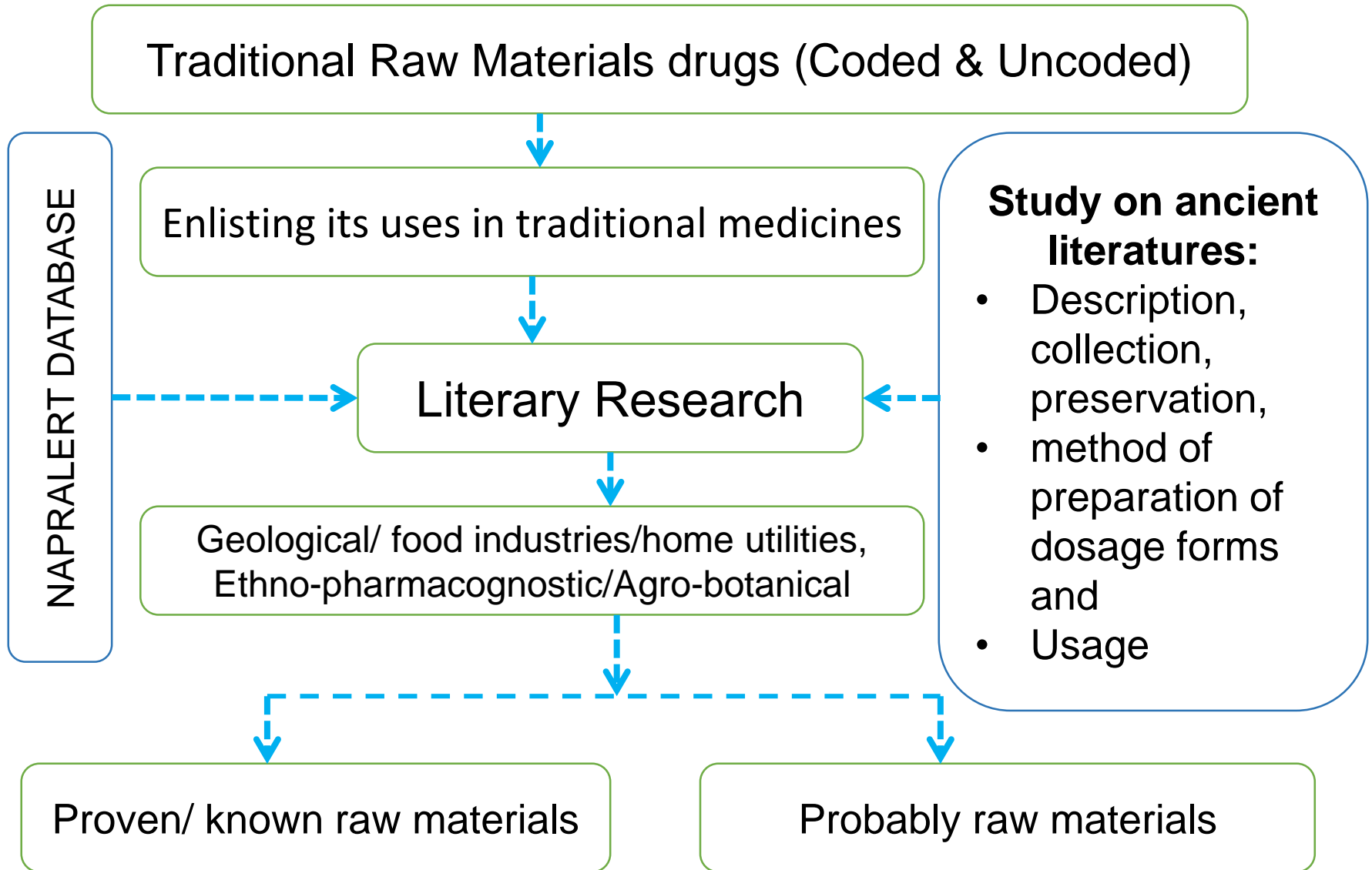
- Ayurvedic Pharmacopoeia of India (API)
- WHO QC guidelines
- Ayurvedic Formulary of India (AFI)
- Required before **Ethical Review Board (ERB) approval**

Section V: Clinical Evaluation

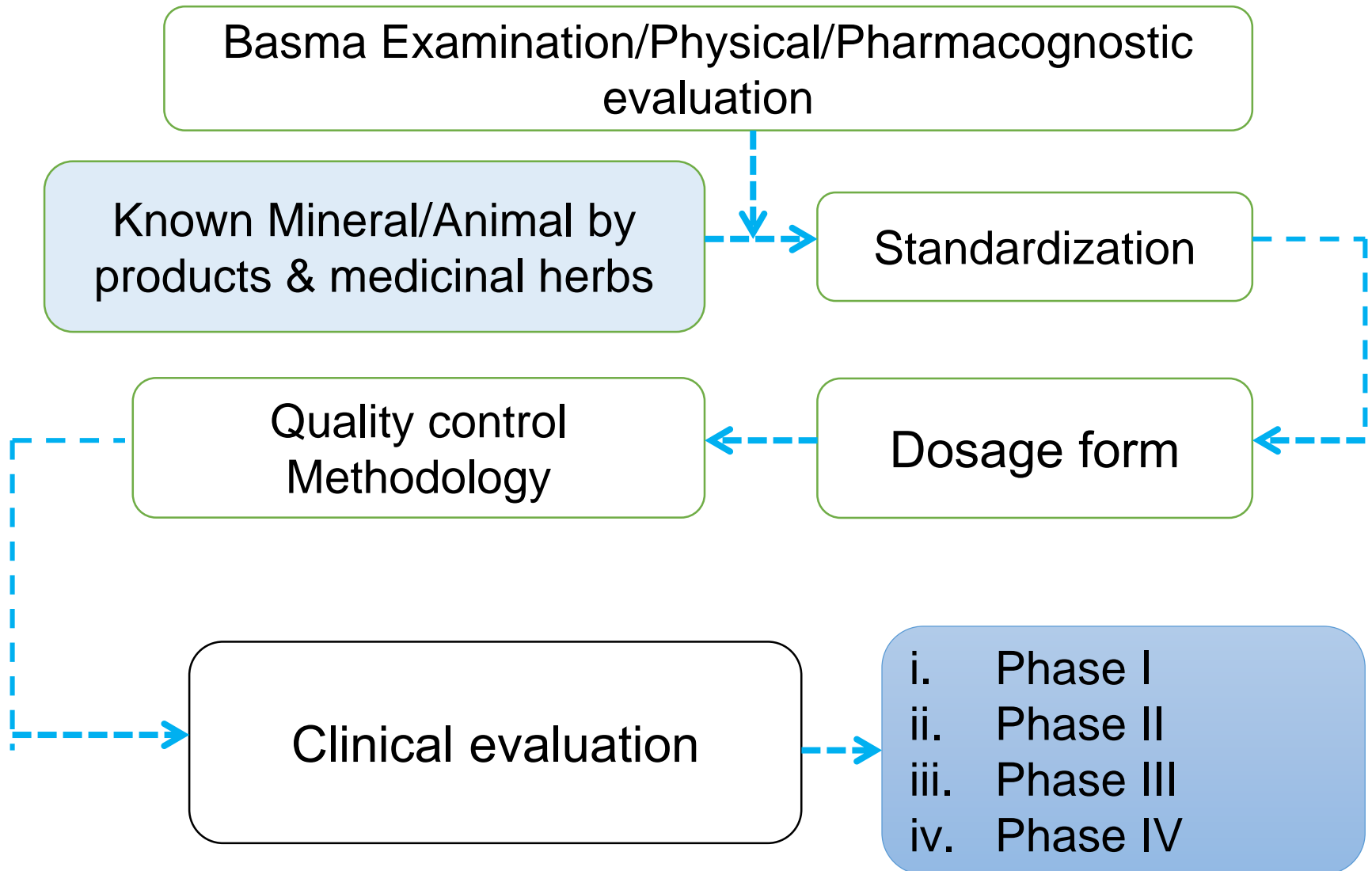
Introduction

- Systematic assessment of safety and efficacy
- Focus on therapeutic outcomes in humans
- **Integrates:**
 - **Ayurvedic principles (Prakriti, Dosha, Dhatu, Agni)**
 - **Modern clinical research methods**
- Includes observational and experimental studies
- Ensures evidence-based validation

Research on Raw Materials



Proven/Known Raw Materials (Non-toxic)



Interventions & Procedures

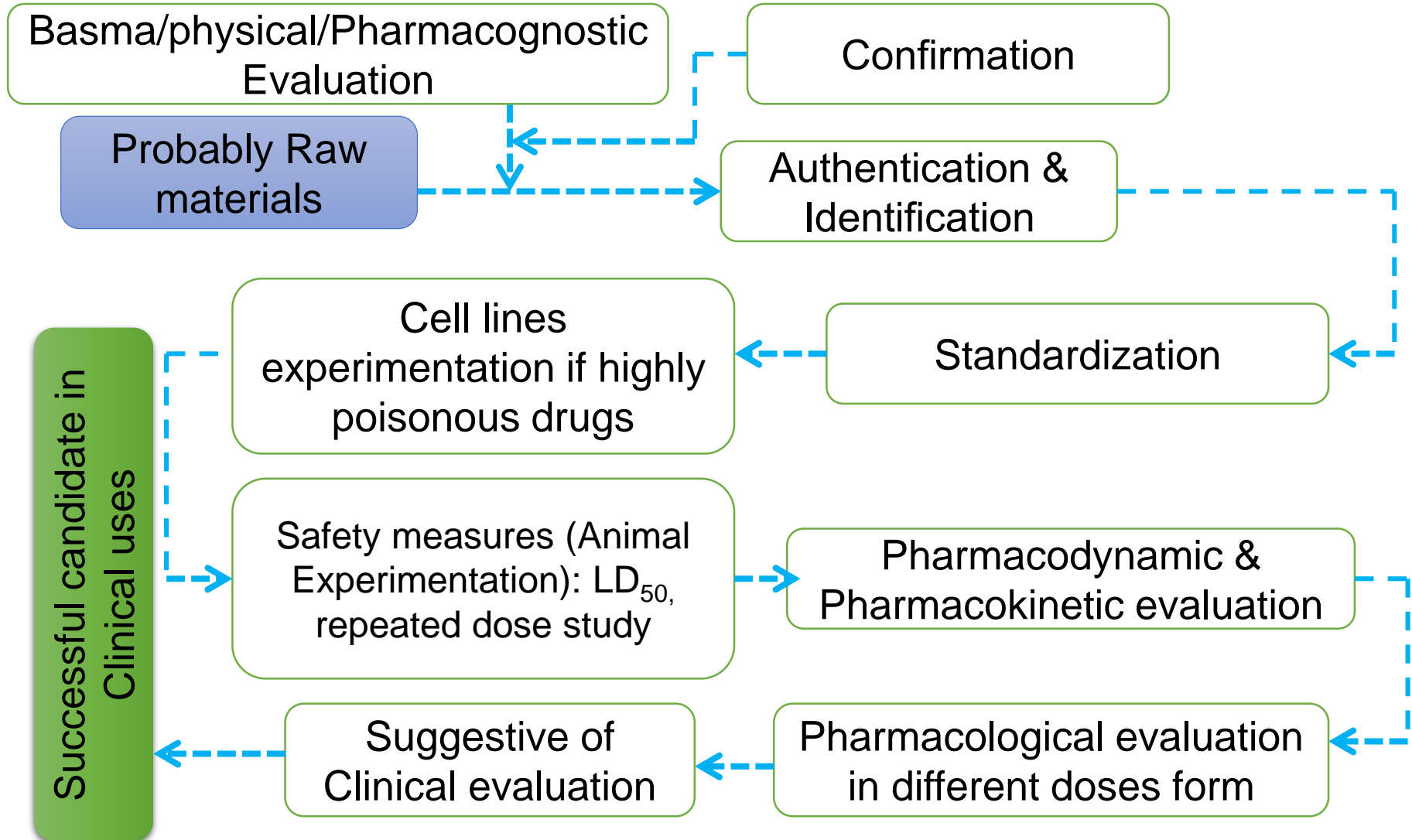
- **Types:**

- Drug-based
- Therapy-based (Panchakarma, Yoga, Meditation, Counselling)

- **Requirements:**

- Standardization
- SOPs
- Dose and duration
- Includes pre-, intra (Main) and post-therapy care

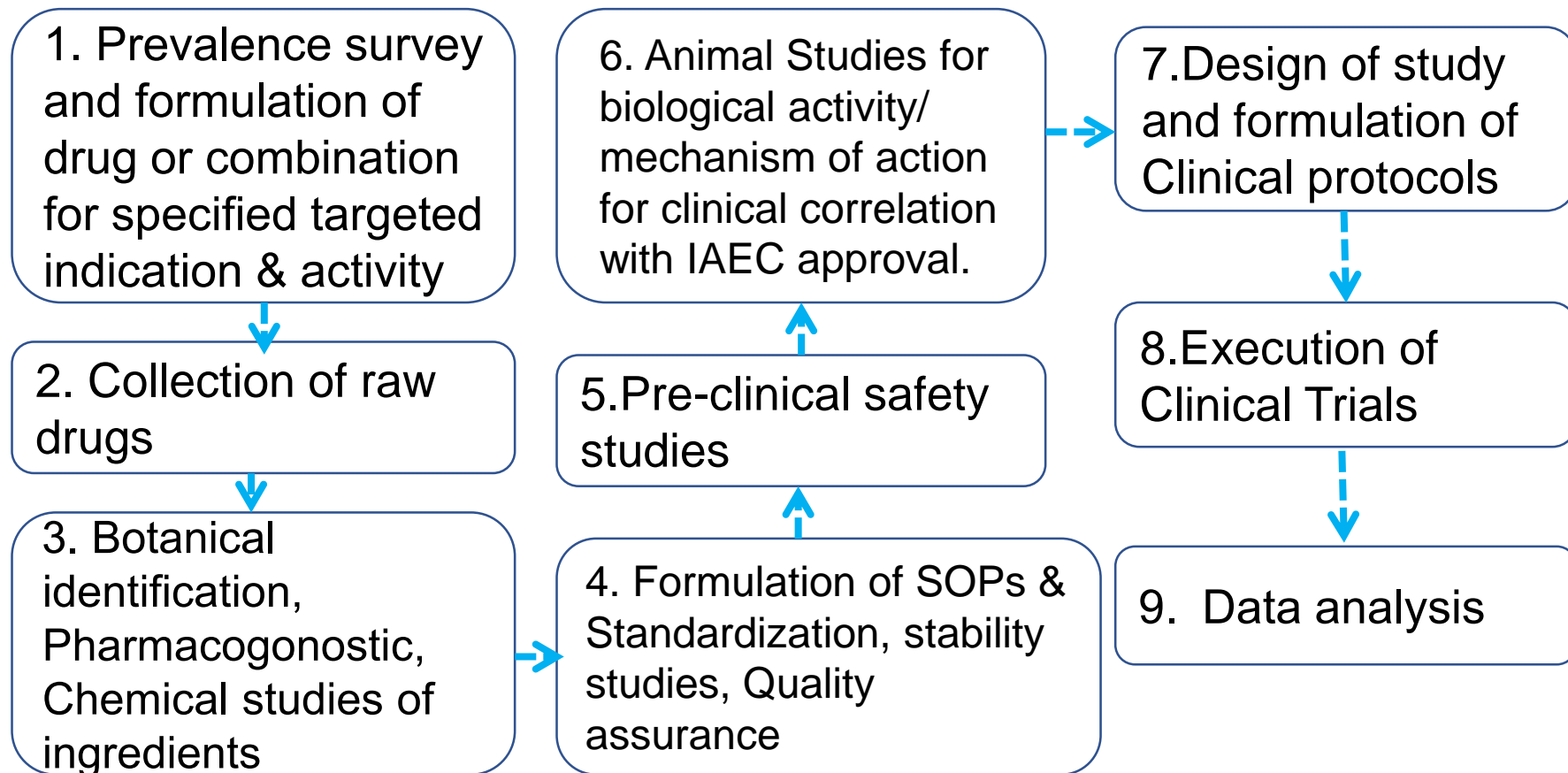
Probably Known Raw Materials Evaluation (Suspected harmful)



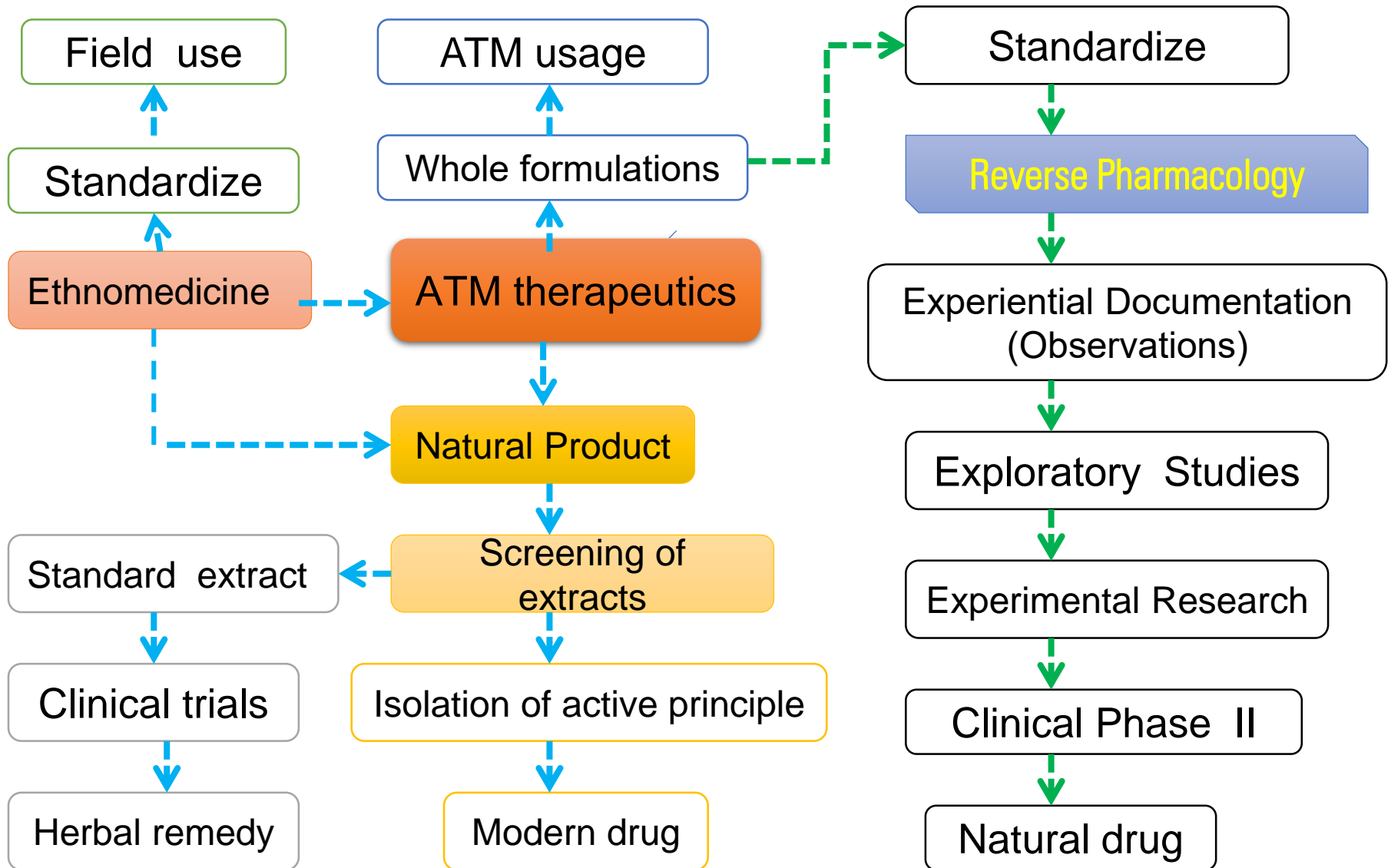
General Methodologies & Guidelines of Drug Development

IPR Protection and issues of filing of patent to be addressed at suitable stage.

Preparatory phase (1) and Drug development phases (2-9)



Reverse Pharmacology Pathways



Section VI: Research in Folkloric/Ethno Medicines

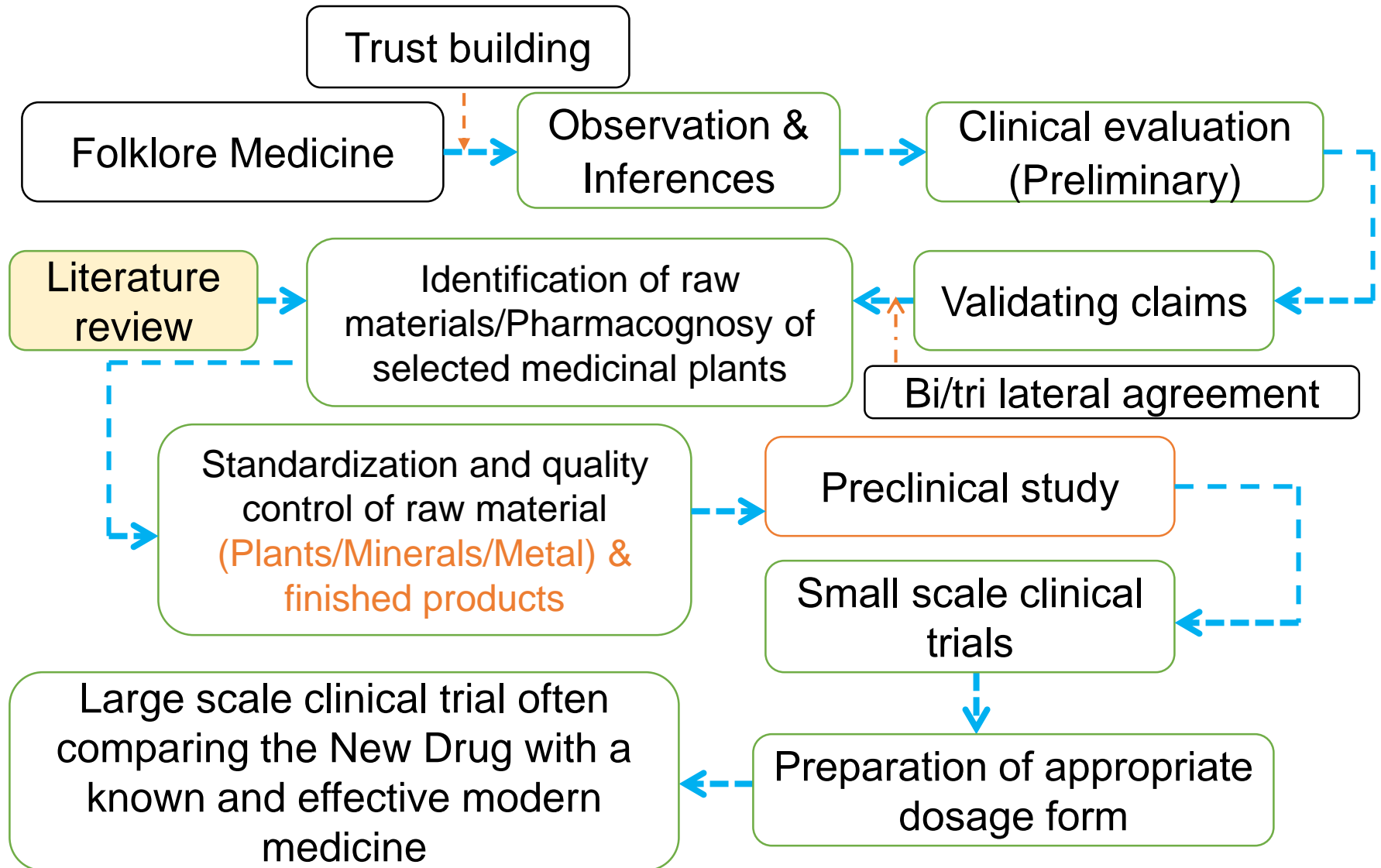
- **Introduction**

- Definition of folkloric/ethnomedicine
- Based on traditional, cultural knowledge
- Passed through generations
- Need for scientific validation

- **Objectives of Research**

- Documentation of traditional practices
- Scientific validation of claims
- Generation of baseline data
- Leads for preclinical and clinical studies

Suggested Approach for Folkloric Claims



Ethical Considerations

- Mandatory ethical approval (IRC/ERB)
- Informed consent required
- Monitoring & auditing
- DSMB oversight
- Compliance with GCP guidelines

Summary

- **Clinical evaluation is essential for:**
 - Scientific validation
 - Safety assurance
 - Global acceptance of Ayurveda
- Integrates traditional knowledge with modern research
- Supports evidence-based healthcare

Queries Please ???

Thank You for Your Kind
Attention