

# Clinical Research Destination India

April 23<sup>rd</sup> 2005

Bangalore Bio 2005

**D A Prasanna**  
**Vice Chairman and MD**

***Manipal Acunova***

Manipal Towers, 14 Airport Road  
Bangalore. India

- A clinical trial is a research study to answer specific questions about drugs, new therapies or new ways of using known treatments.
- Clinical Trials and Research are used to determine whether new drugs or treatments are both safe and effective.
- Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

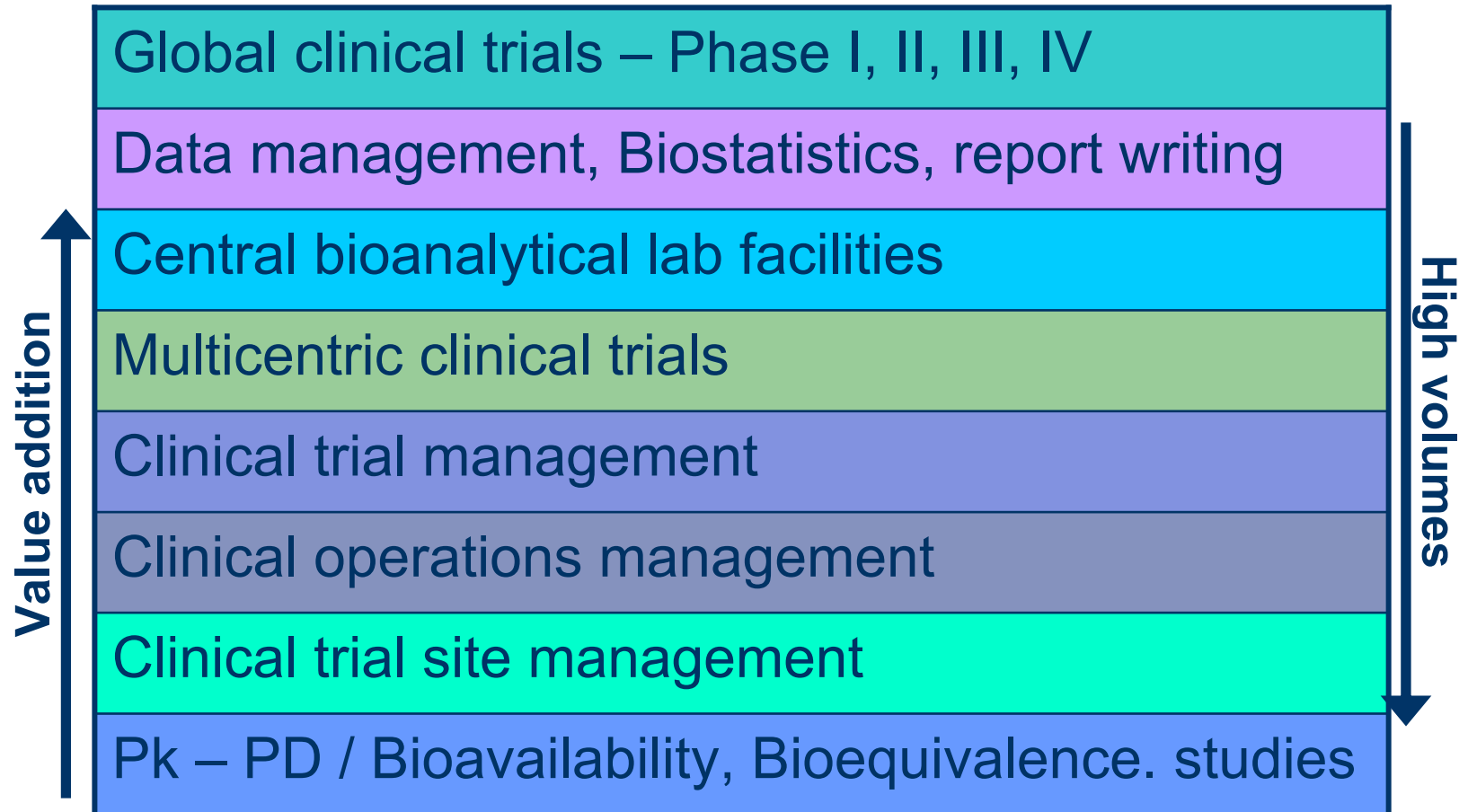
***Research Data on Effectiveness & Safety  
Credible with Regulators***

- > **Treatment trials** - test new treatment, new combinations of drugs, or new approaches to surgery or radiation therapy. Well equipped Hospital with Research Oriented Clinicians
- > **Prevention trials** - look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals or lifestyle changes. Multi Disciplinary Teaching Hospitals with 'Community Medicine Departments' who have public health transformation track record & who have registries & longitudinal record.
- > **Screening trials** – test the best way to detect certain diseases or health conditions. Centres with diagnostic facilities, where Doctors and Scientists collaborate.
- > **'Quality of life' trials** ( or supportive care trials) – explore ways to improve comfort and the quality of life for individuals with a chronic illness. Sites which have stable Doctor-Patient relationships and which maintain longitudinal patient records.

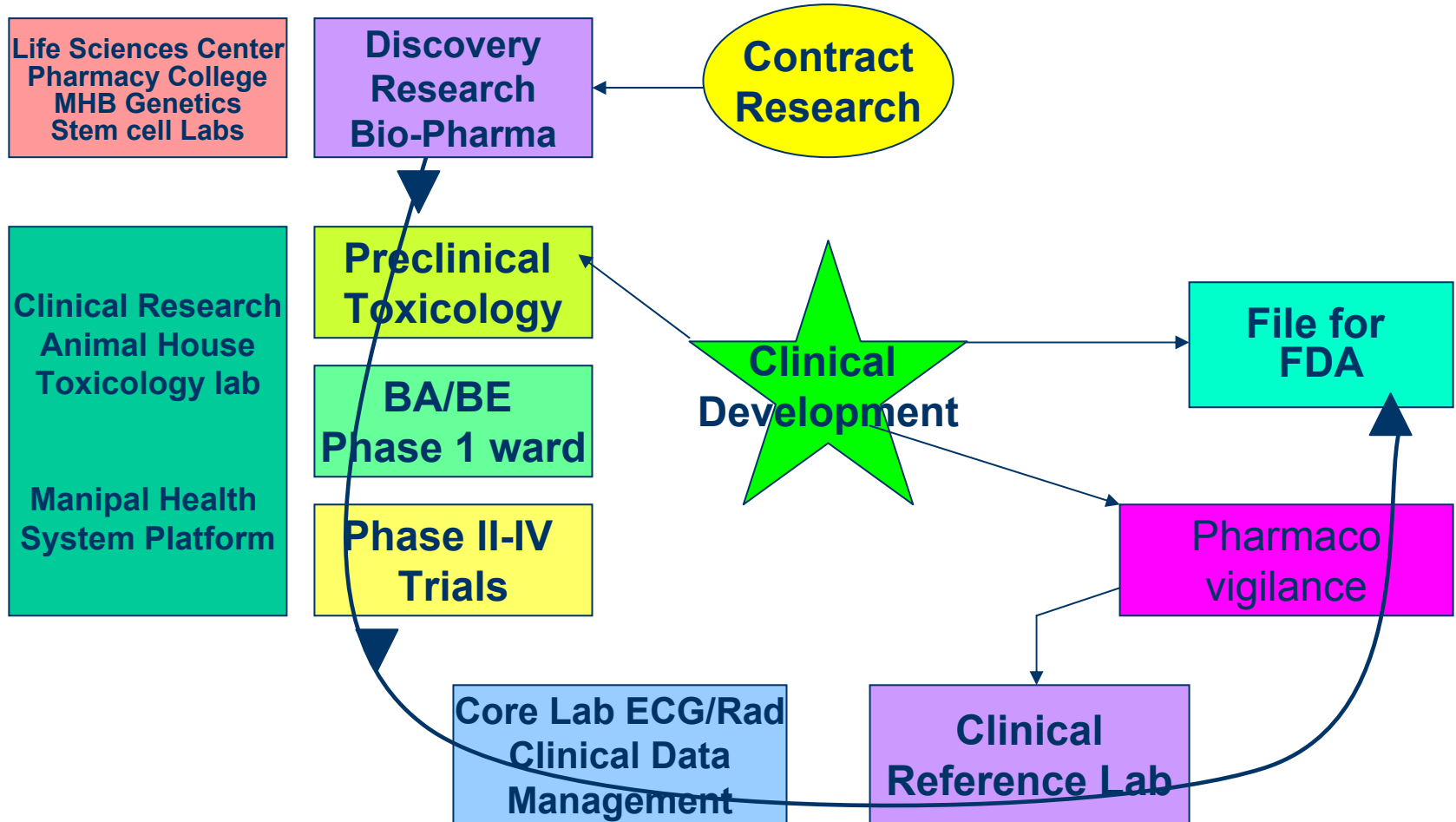
***Clinical Research Sites need  
Clinical and Scientific Infrastructure***

## *Phases of Research & Where to do?*

- In **Phase I** trials, researchers test a new drug or treatment in a small group of healthy people ( 20 -80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Little information on Human Safety. Conduct only under highly experienced Investigators. Site should have highest readiness for adverse event management. Ethics committee needs scientific experts.**
- In **Phase II** trials, the study drug or treatment is given to a selected group of patients (100 – 300) to see if it is effective and to further evaluate its safety.
- **Need Therapeutic Specialists with experience. Ideally conducted under special clinical research wards under controlled conditions.**
- In **Phase III** trials, the study drug or treatment is given to a large group of patients ( 1000 – 3000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Ideally conducted in teaching hospital ward**
- In **Phase IV** trials, post marketing studies delineate additional information including the drug's risks, benefits and optimal use.
- **Lowest risk. Can be done in non teaching sites and clinics.**



***India should differentiate with High Value Addition vs. East Europe, South Africa...***



## *What We need to do in India...*

- Rapid build up required infrastructure and implementation competencies
- Meet ICH, GCP, GLP ( GXP) guidelines
- Attain recognition as quality clinical trial destination – data to be trustworthy and reliable
- generated data to be accepted to global regulatory authorities, medical fraternity, patients etc.,
- Train ourselves to attain global recognition through accreditations & certifications

[da.prasanna@acunovalife.com](mailto:da.prasanna@acunovalife.com)

[www.acunovalife.com](http://www.acunovalife.com)

Manipal  
**ACUNIOVA**  
DISCOVERY • DEVELOPMENT • THERAPEUTICS