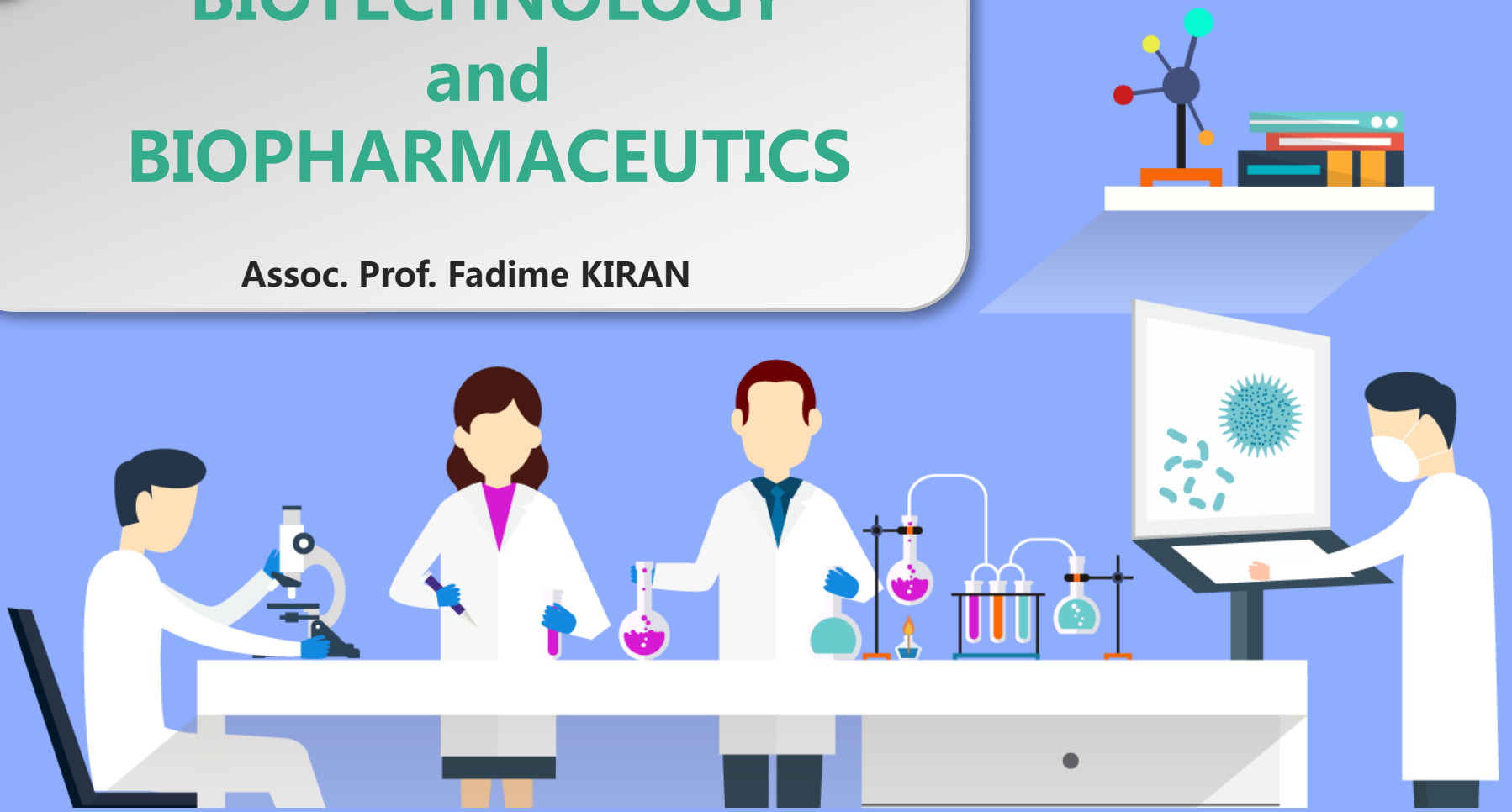
BIOTECHNOLOGY and BIOPHARMACEUTICS

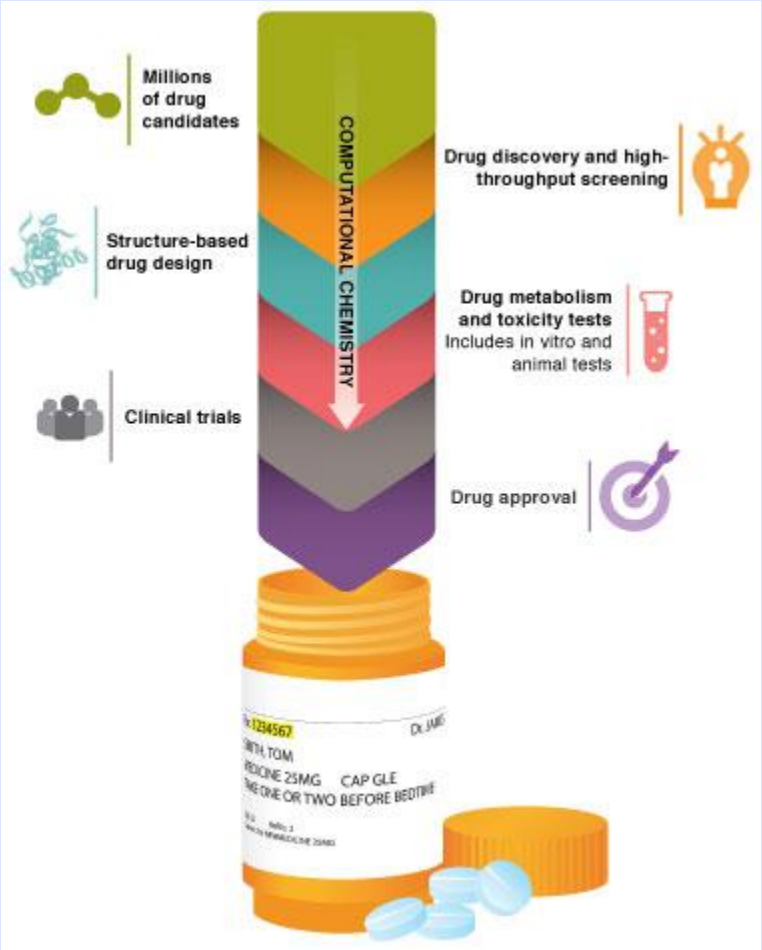
Assoc. Prof. Fadime KIRAN



04

- Biopharmaceuticals: From Idea to Industry

DRUG DEVELOPMENT




Drug Development Process
Discovery and Development
Preclinical Research
Clinical Research
Review
Post-Market Safety Monitoring

Step 1: Discovery & Development

Phase	Target Discovery	Target Validation	Lead Generation & Refinement	Preclinical Development	
Goal	Find All Targets	Eliminate Wrong Targets	Generate Molecules	Eliminate Molecules	Advance Molecules
					

Step 2: Preclinical Research

Researchers determine the following about the drug:

✓Absorption, distribution, metabolization, and excretion information

✓Potential benefits and mechanisms of action

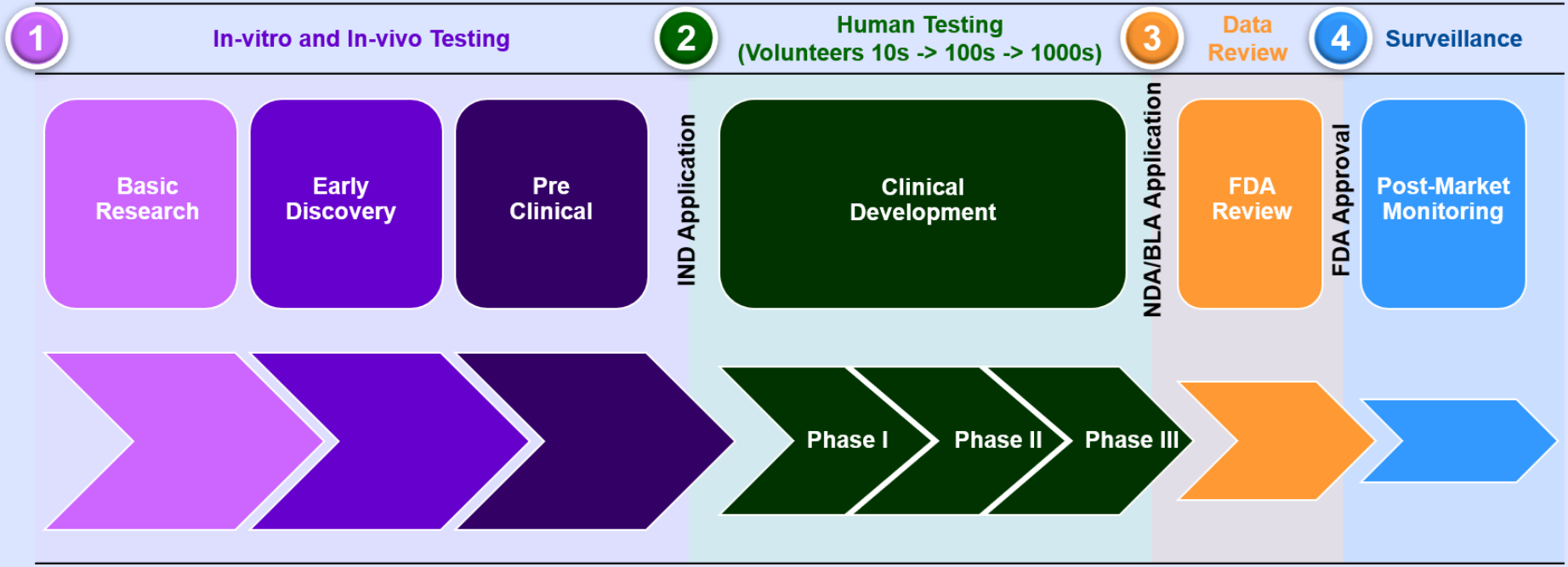
✓Best dosage, and administration route

✓Side effects/adverse events

✓Effects on gender, race, or ethnicity groups

✓Interaction with other treatments

✓Effectiveness compared to similar drugs


1
In-vitro and In-vivo Testing
2
Human Testing
(Volunteers 10s -> 100s -> 1000s)
3
Data
Review
4
Surveillance
Basic
Research
Early
Discovery
Pre
Clinical
IND Application
Clinical
Development
NDA/BLA Application
FDA
Review
FDA Approval
Post-Market
Monitoring
Phase I
Phase II
Phase III

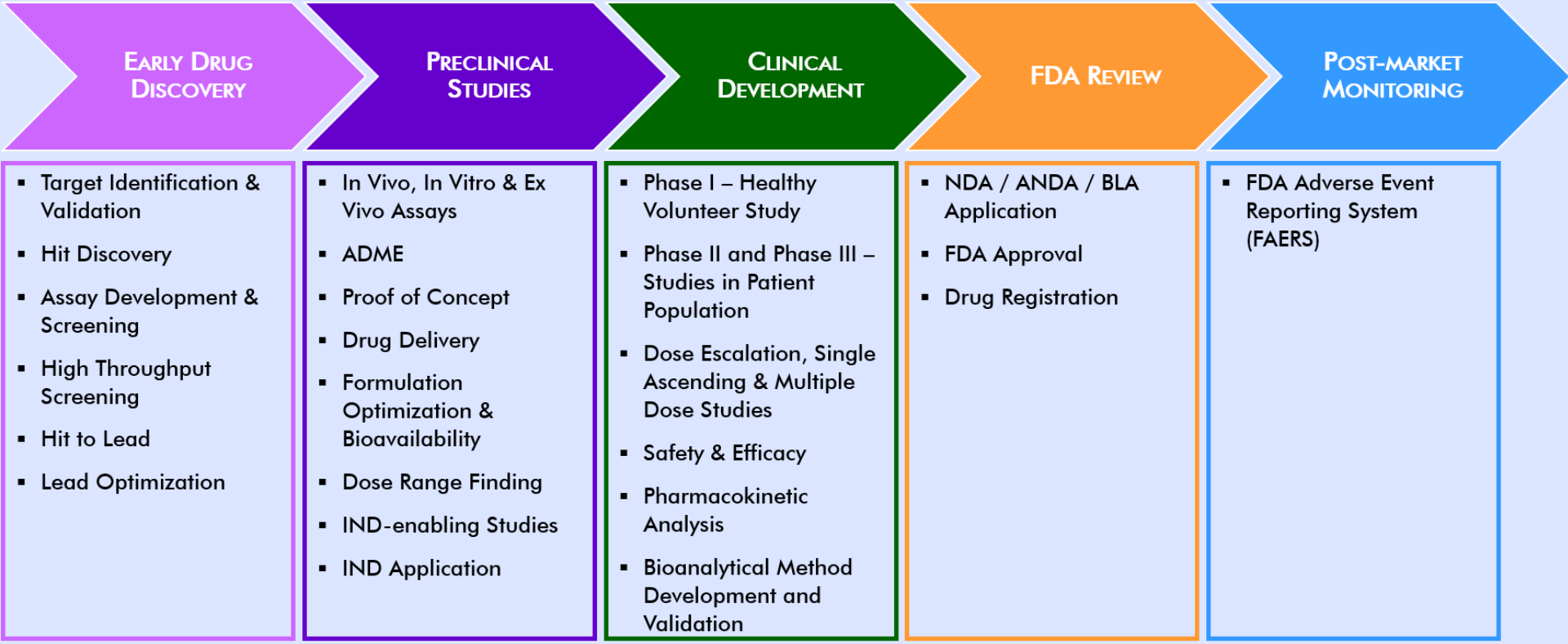
Step 3: Clinical Development

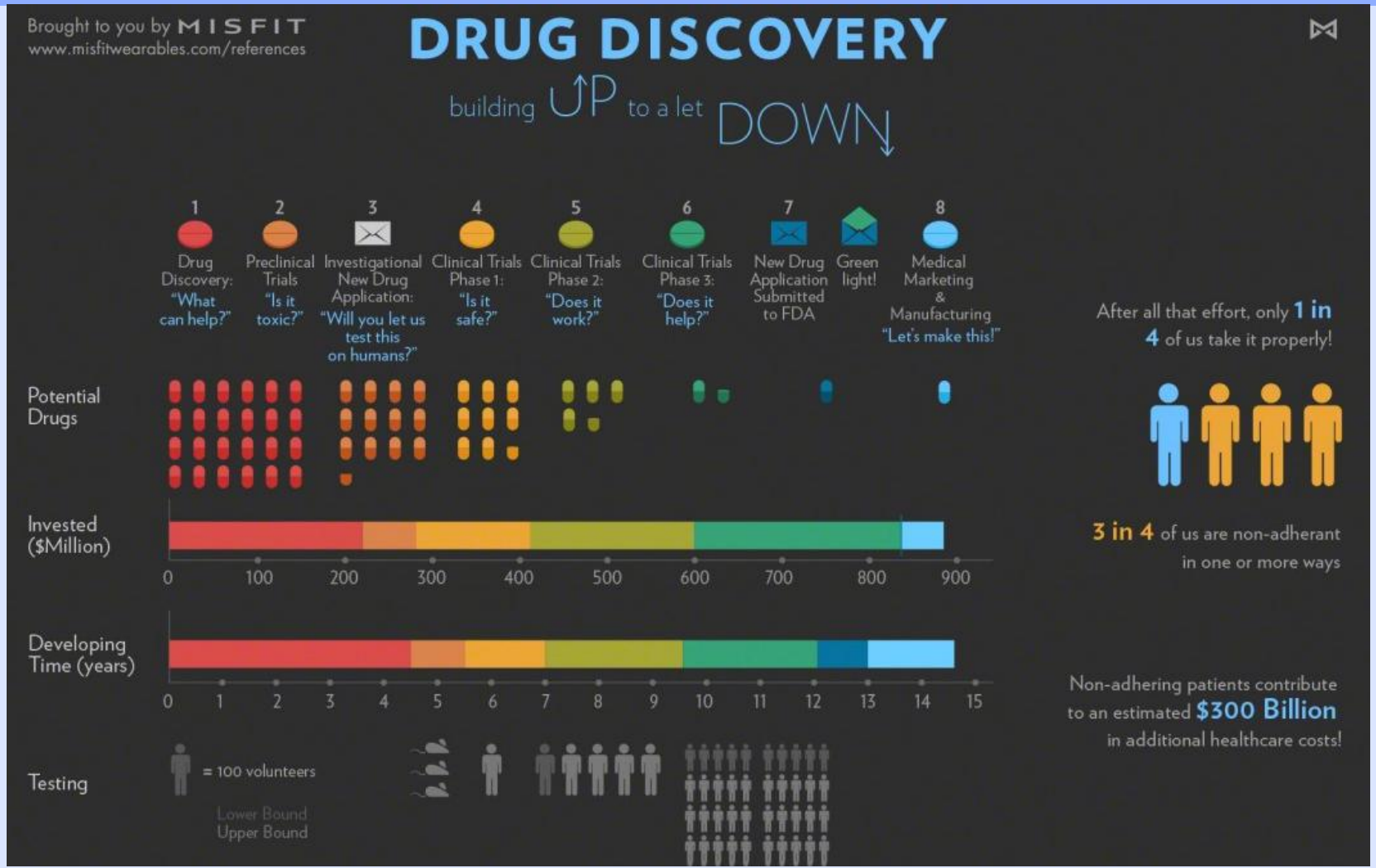
Step 4: FDA Review

New drug applications may fail for a variety of reasons…

- **Toxicity**
- **Efficacy**
- **PK Properties or Bioavailability**
- **Inadequate Drug Performance**

Step 5: Post-market Monitoring




Brought to you by MISFIT
www.misfitwearables.com/references
DRUG DISCOVERY
building UP to a let DOWN
1
Drug Discovery: "What can help?"
2
Preclinical Trials "Is it toxic?"
3
Investigational New Drug Application: "Will you let us test this on humans?"
4
Clinical Trials Phase 1: "Is it safe?"
5
Clinical Trials Phase 2: "Does it work?"
6
Clinical Trials Phase 3: "Does it help?"
7
New Drug Application Submitted to FDA
Green light!
8
Medical Marketing & Manufacturing "Let's make this!"
Potential Drugs
Invested ($Million)
0 100 200 300 400 500 600 700 800 900
Developing Time (years)
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Testing
= 100 volunteers
Lower Bound
Upper Bound
After all that effort, only 1 in 4 of us take it properly!
3 in 4 of us are non-adherant in one or more ways
Non-adhering patients contribute to an estimated $300 Billion in additional healthcare costs!

ANY QUESTION?


Thank you