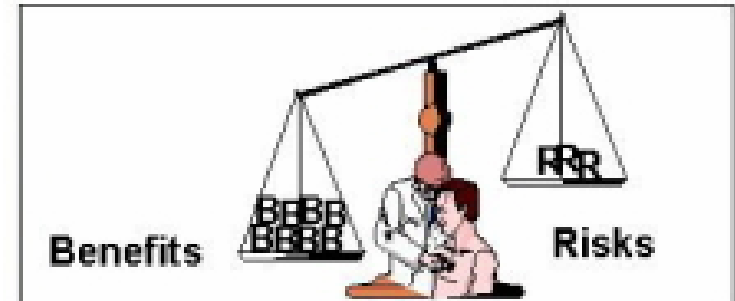
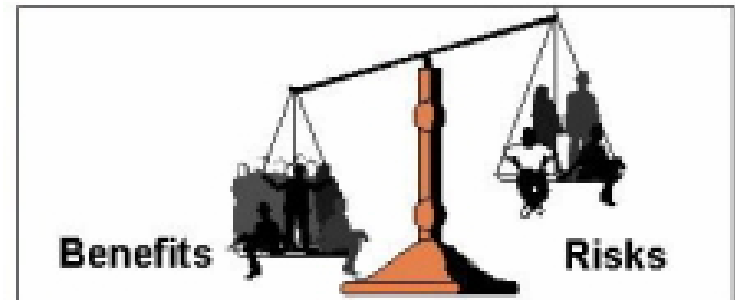
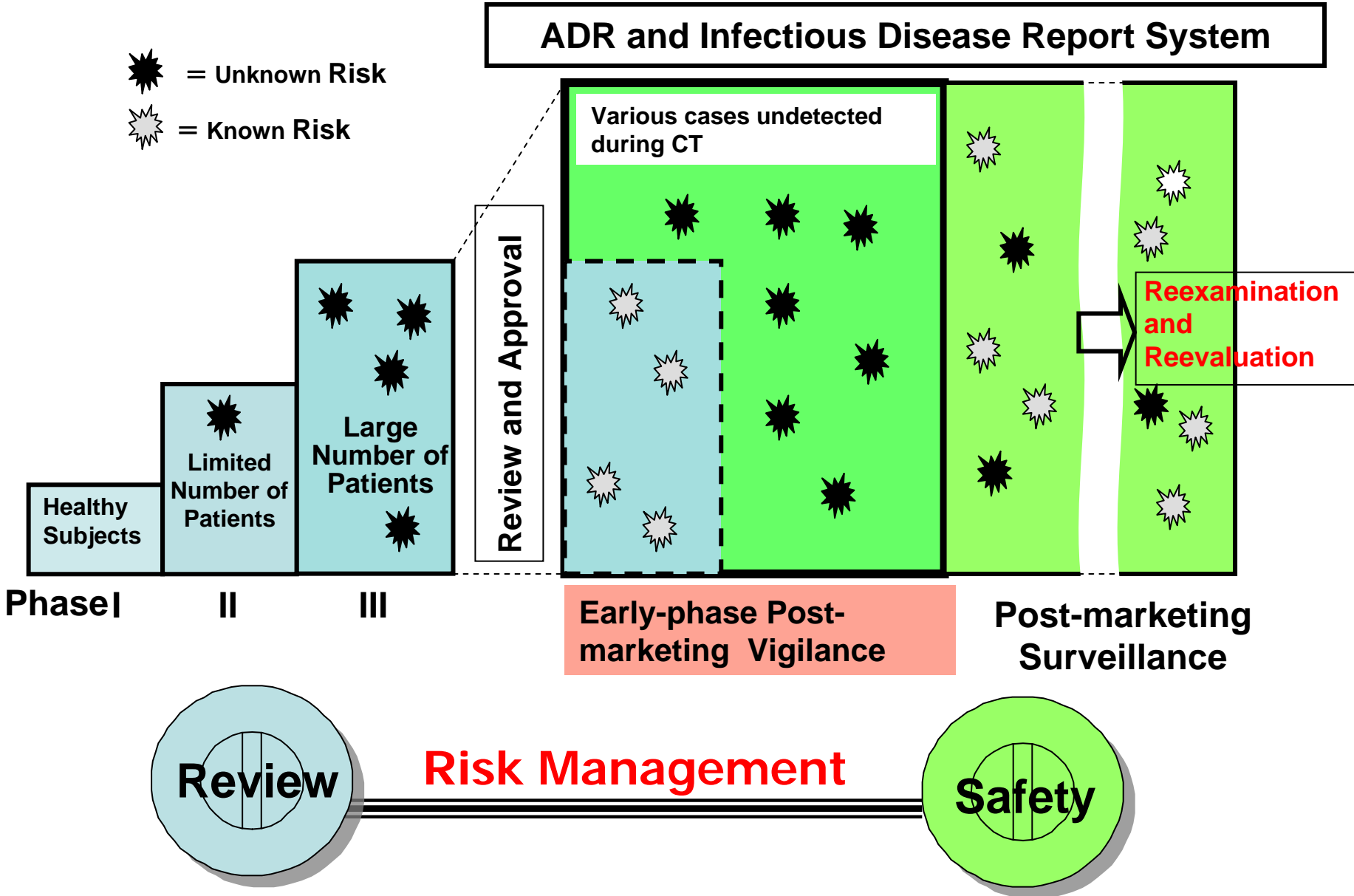


Benefits/Risks Safety Decision Makers

- **Regulatory Agency**
 - evaluates benefits/risks for the population.
- **Health Care Provider**
 - evaluates benefits/risks for a patient
- **Patient**
 - evaluates benefits/risks in terms of personal value.



Known and Unknown Risks and their Detection



Risk Management Cycle



Collaboration among Regulatory Agencies, Health Care Professionals, Patients and Industry

Discussions

- What do you expect from industry to ensure the effectiveness of drug safety measures?
- How can we help each other to improve drug safety system in each country?
- What should be done to meet the challenge of progress of simultaneous global drug development and the emergence of innovative pharmaceuticals?