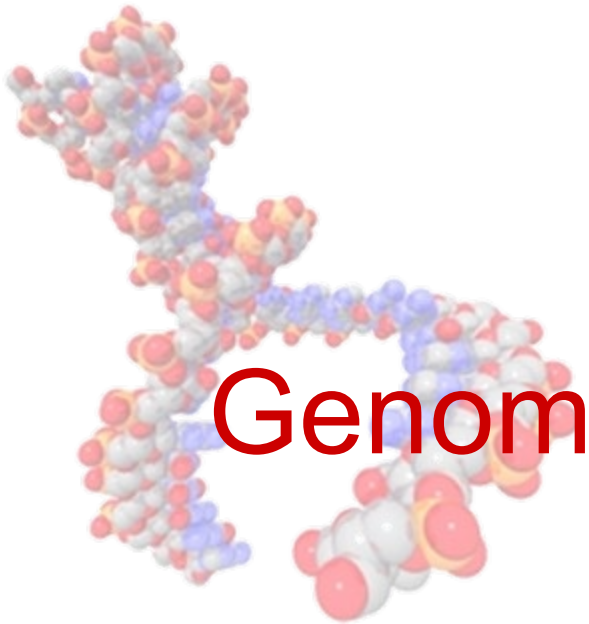

Genomics and Privacy

Privacy Symposium / HIPAA Summit
August 20, 2008

Stan Crosley (Eli Lilly)
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International Pharmaceutical PRIVACY CONSORTIUM

Background on Genomics

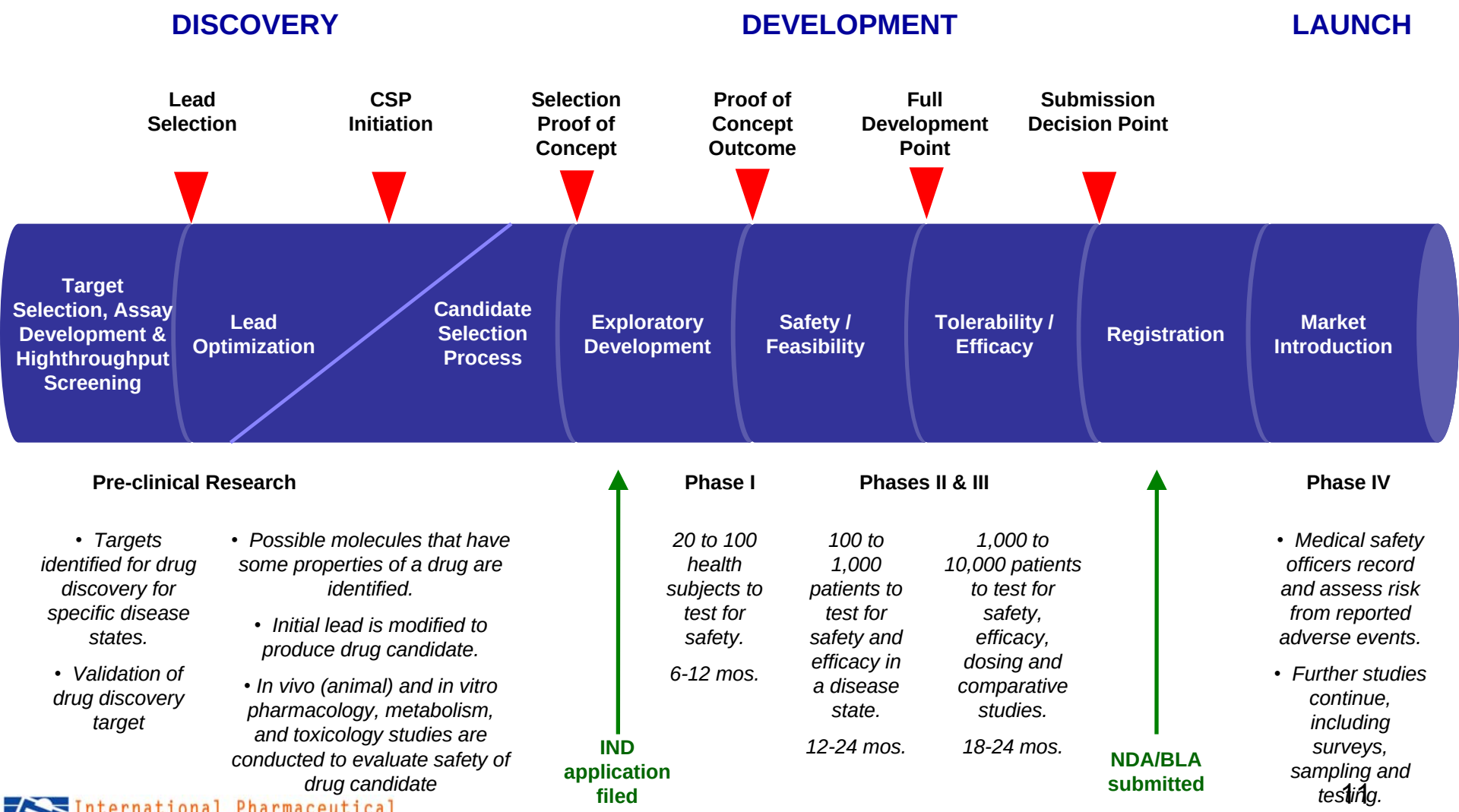
Blockbuster Business Model

- Future success of a pharmaceutical company depends heavily on the number and quality of drugs in the pipeline
- The industry has traditionally relied primarily on the "blockbuster model", where a few key drugs make up the majority of the company's revenue
- Challenges presented by the blockbuster model
  - Industry has fully exploited "low hanging fruit"
  - Expiration of patent terms
  - Pricing/reimbursement pressures

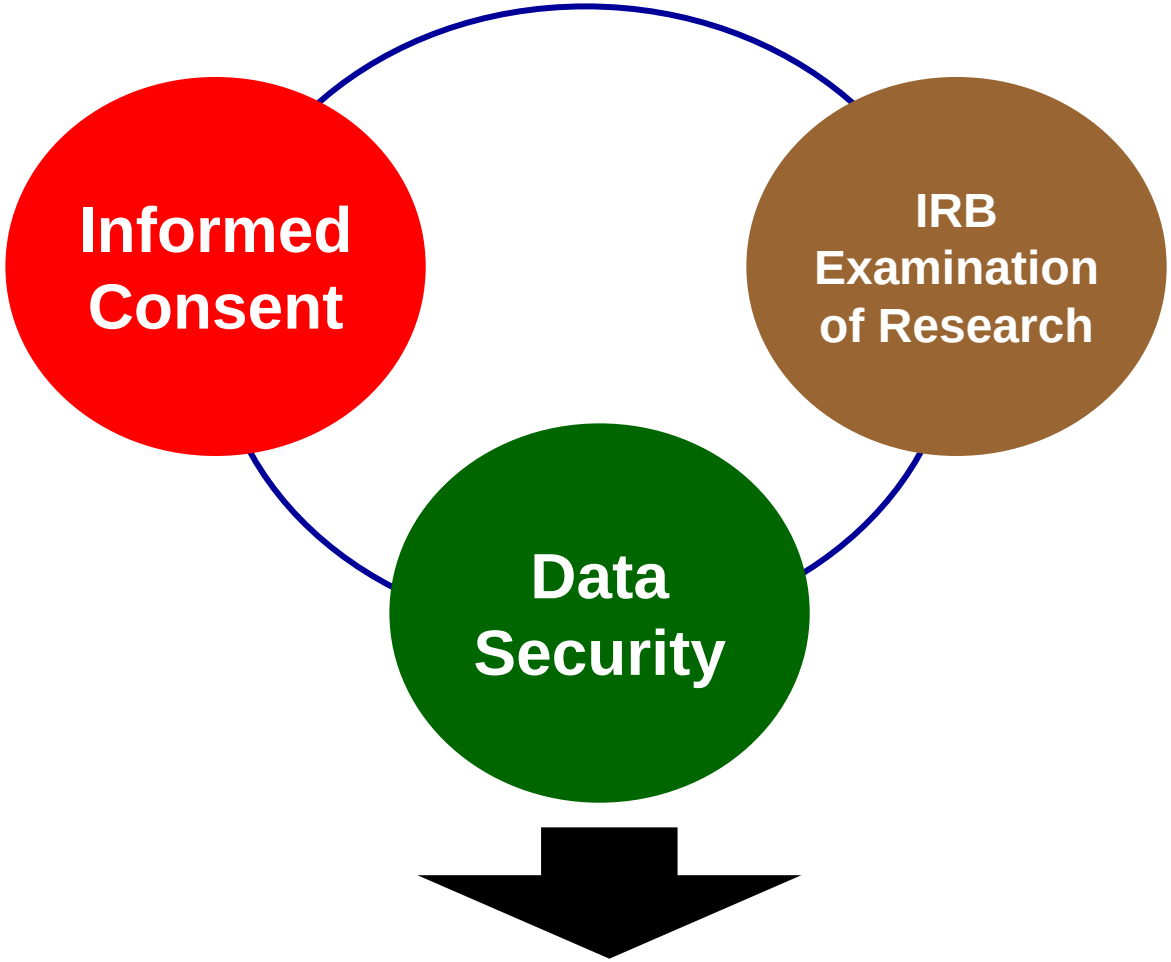
Personalized Medicine Business Model

- Utilizes pharmacogenomics, which benefits from the recent advances of genomics/proteomics technology
- *Potentially*, reduced development costs; shorter development time from discovery to launch
- *Potentially*, smaller clinical trials required to prove efficacy in target population (depends on regulatory requirements)
- Greater probability of clinical compounds reaching market
- Better safety profile
- Treat specific populations based on biomarkers or molecular diagnostics/imaging results
- ► Should not require blockbuster-sized sales to generate attractive returns on investment

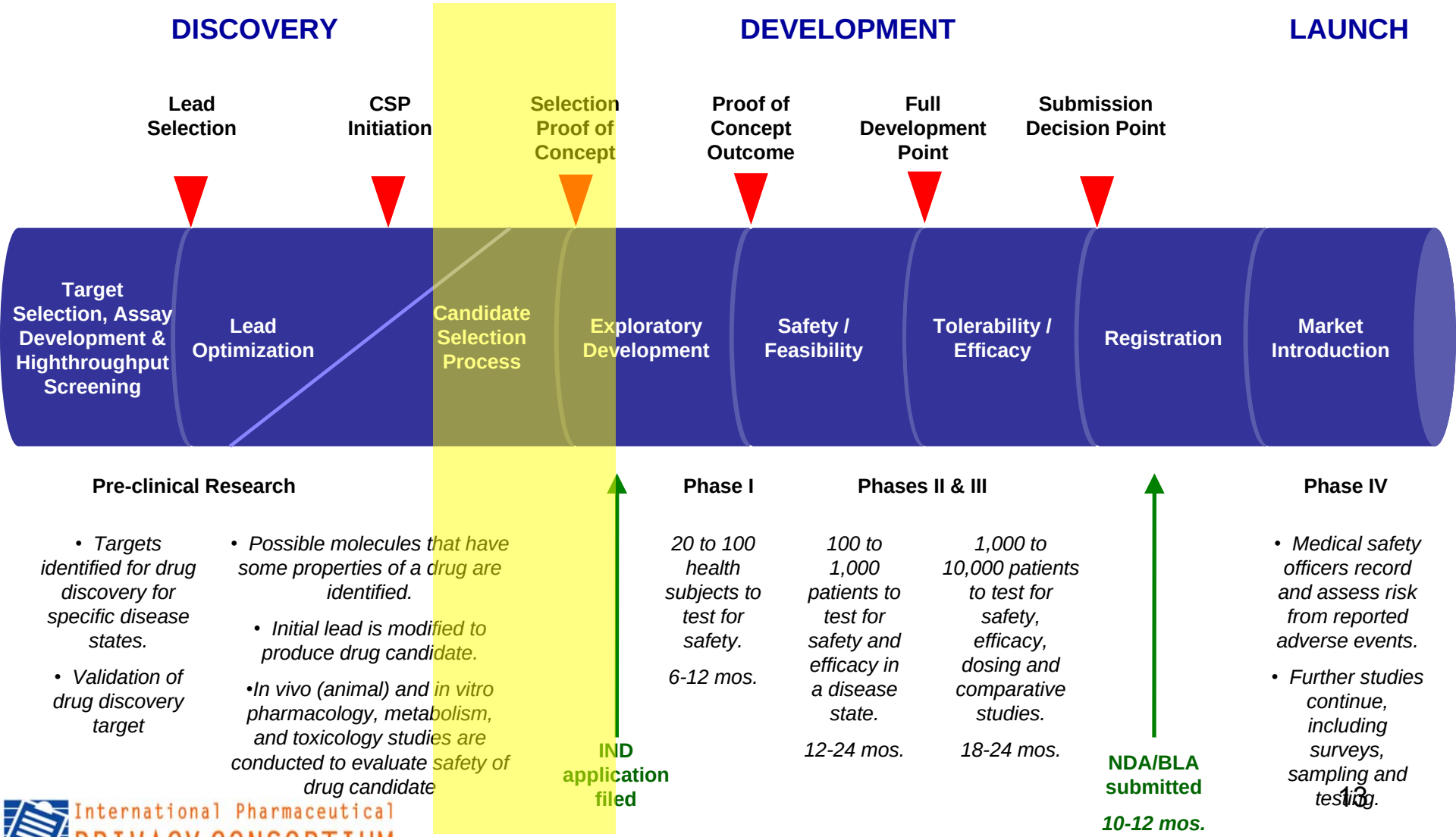
Drug Discovery and Development



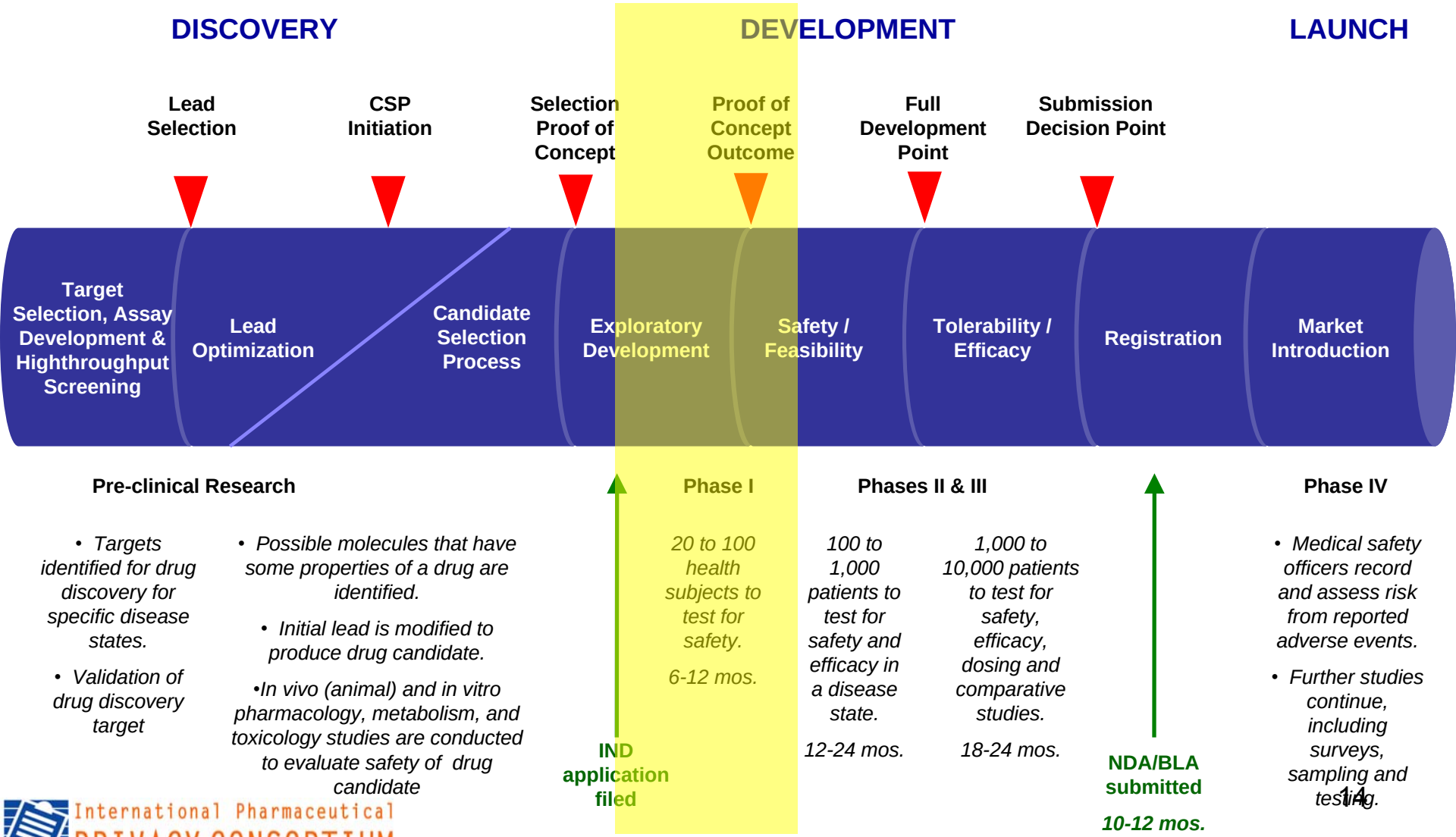
Protections Built into Biomedical Research



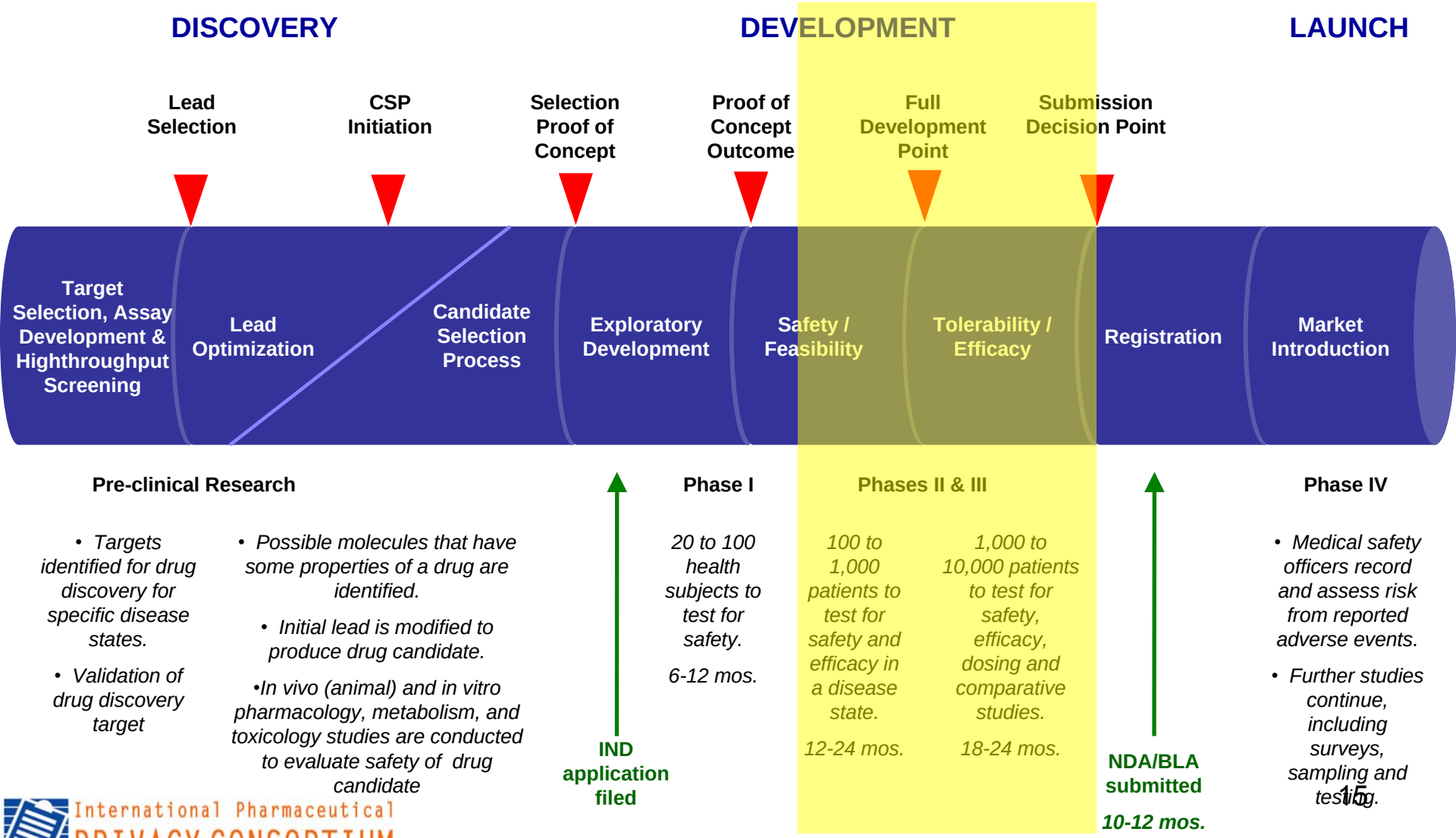
Pre-Clinical Testing



Phase I


DISCOVERY
DEVELOPMENT
LAUNCH
Lead Selection
CSP Initiation
Selection Proof of Concept
Proof of Concept Outcome
Full Development Point
Submission Decision Point
Target Selection, Assay Development & Highthroughput Screening
Lead Optimization
Candidate Selection Process
Exploratory Development
Safety / Feasibility
Tolerability / Efficacy
Registration
Market Introduction
Pre-clinical Research
Phase I
Phases II & III
Phase IV
• Targets identified for drug discovery for specific disease states.
• Validation of drug discovery target
• Possible molecules that have some properties of a drug are identified.
• Initial lead is modified to produce drug candidate.
•In vivo (animal) and in vitro pharmacology, metabolism, and toxicology studies are conducted to evaluate safety of drug candidate
IND application filed
20 to 100 health subjects to test for safety.
6-12 mos.
100 to 1,000 patients to test for safety and efficacy in a disease state.
12-24 mos.
1,000 to 10,000 patients to test for safety, efficacy, dosing and comparative studies.
18-24 mos.
NDA/BLA submitted
10-12 mos.
• Medical safety officers record and assess risk from reported adverse events.
• Further studies continue, including surveys, sampling and testing.

Phase II/III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Post-Approval

- Need to identify patient populations for whom drug is indicated (and ensure that drug not taken by populations for whom contraindicated)
  - Development of companion diagnostics
- Pharmacovigilance
- Phase IV studies

Challenges of ‘Information Based Medicine’

Key Privacy Issues

- What's 'identifiable'?
  - Current law
  - Developments in technology
  - Reference databases
- Notice, choice, access & amendment, confidentiality, anonymization
- Secondary research, biobanking
  - Specific vs. general consent
- Risks of unauthorized disclosure
  - Potential for discrimination in employment and insurance (elsewhere?)
  - Psychological impact - stigmatization

Questions

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