

New Drug Application(NDA)

Abbreviated New Drug Application (ANDA)

and

Investigational New Drug Application(IND)

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**This is a vast topic and a short
overview is given
and
in no way complete justice
can be done for this**



Dedicated to my son Lionel Crasto,

He was only in first standard in school (dec2007)
when I was Paralysed head to toe.

His smiling face sees me through day in and day out.

Vast readership from academia and industry motivates me, and keeps me going.

I am helping millions with free websites and has 7 million hits on google

Thanks for helping me to keep lionel smiling

Contents

1. New Drug Application(NDA)

- a) Introduction.
- b) Goal of NDA
- c) Classification of NDA
- d) New drug development review
- e) The NDA in CTD Format

2. Abbreviated new drug application(ANDA)

- a) Introduction
- b) Goal of ANDA
- c)Patent certification condition

3. Conclusion.

4. References.

*DRUG DEVELOPMENT

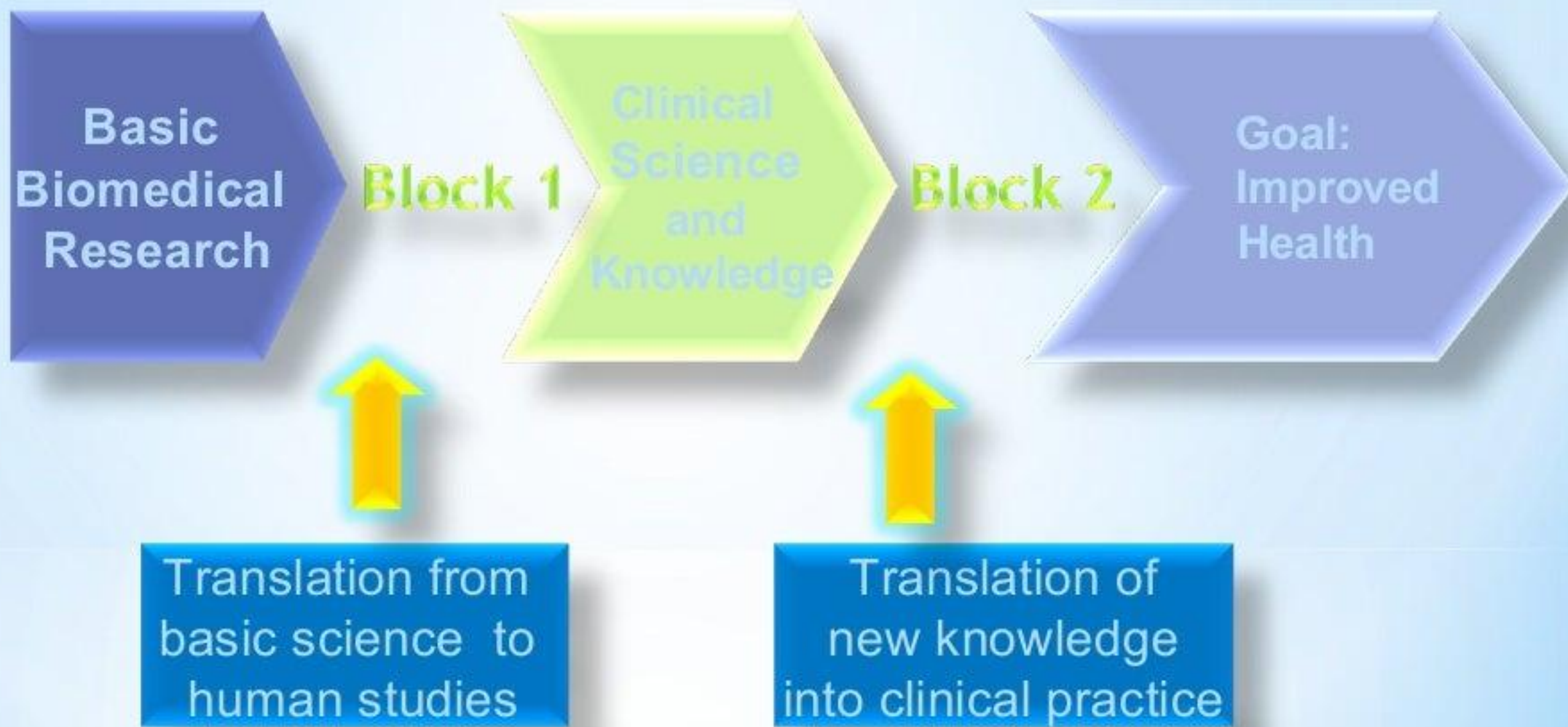


- ✓ Development of a new therapeutic drug is a complex, lengthy and expensive process

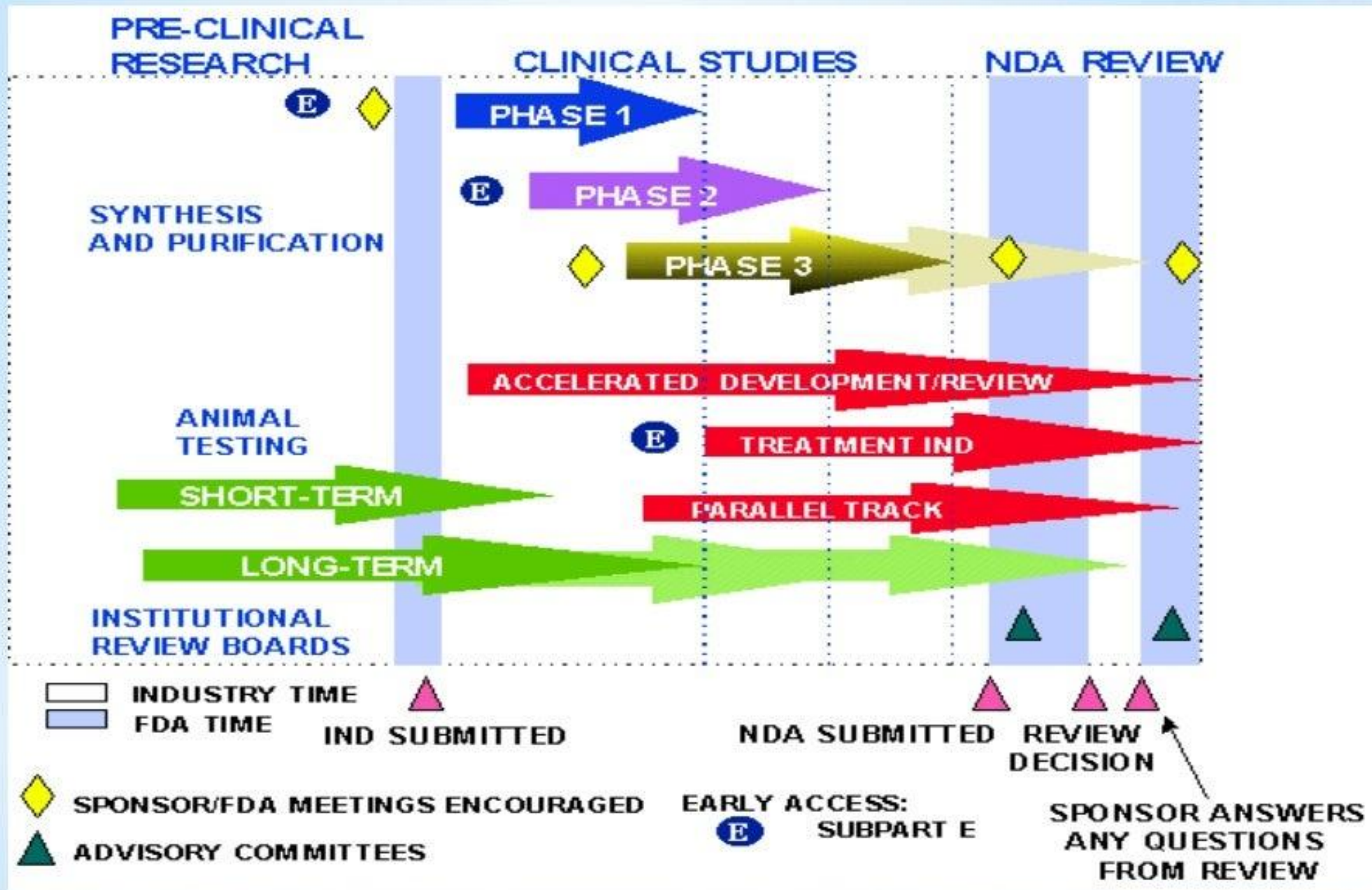


- ✓ costs nearly 900 million dollars and an average of 15 years.

* THE TWO TRANSLATIONAL BLOCKS



DRUG DEVELOPMENT PROCESS



New Drug Application

- Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization
- The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.
- The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA

New Drug Application

***Introduction**

Critical component for drug approval process which required to submit to USFDA before drug commercialization.

The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

***Goal**

The NDA provide enough information to permit FDA reviewer to reach safety, efficacy and quality for pharmaceutical production

NDA Classifications

- ✓ New Molecular Entity
- ✓ New Salt of Previously Approved Drug (not a new molecular entity)
- ✓ New Formulation of Previously Approved Drug (not a new salt OR a new molecular entity)
- ✓ New Combination of Two or More Drugs
- ✓ Already Marketed Drug Product - Duplication (i.e., new manufacturer)
- ✓ New Indication (claim) for Already Marketed Drug (includes switch in marketing status from prescription to OTC)

- ✓ Already Marketed Drug Product - No Previously Approved NDA

* *The Federal Food, Drug, and Cosmetic Act* is the basic food and drug law of the U.S. The law is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

* **LAWS, REGULATIONS,
POLICIES, PROCEDURES**

* *Code Of Federal Regulations (CFR)*

- The final regulations published in the *Federal Register* (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the *CFR*.
- The *CFR* is divided into 50 titles that represent broad areas subject to Federal regulations.
- The FDA's portion of the *CFR* interprets the *The Federal Food, Drug, and Cosmetic Act* and related statutes. *Section 21 of the CFR* contains most regulations pertaining to food and drugs.

21CFR Part 312

Investigational New Drug Application

21CFR Part 314

INDA and NDA Applications for FDA Approval to Market a New Drug (New Drug Approval)

21CFR Part 316

Orphan Drugs

21CFR Part 58

Good Lab Practice for Nonclinical Laboratory [Animal] Studies

21CFR Part 50

Protection of Human Subjects

21CFR Part 56

Institutional Review Boards

21CFR Part 201

Drug Labeling

21CFR Part 54

Financial Disclosure by Clinical Investigators

* **LAWS, REGULATIONS, POLICIES, PROCEDURES**
Cont.....

*CDER's Manual of Policies and Procedures (MaPPs)

MaPPS are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities.

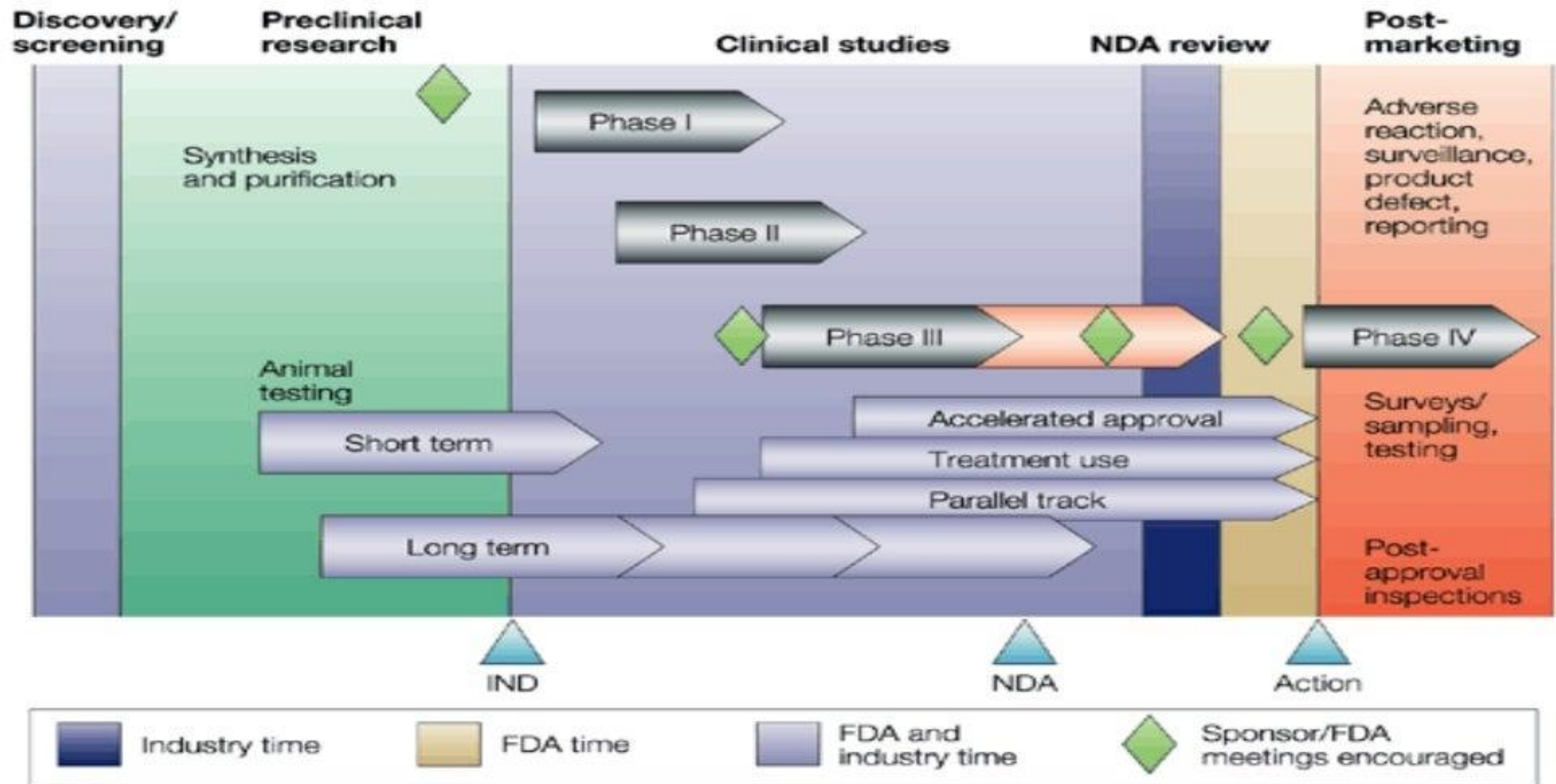
***LAWS, REGULATIONS,
POLICIES, PROCEDURES
Cont.....**

Flow of Presentation

- What is NDA
- Goals of NDA
- When will we go for NDA
- NDA Forms
- Contents of NDA
- Guidance document for submission of NDA
- Submission of NDA
- Review & Approval of NDA

New Drug Development and Review Process

Steps from Test Tube to New Drug Application Review



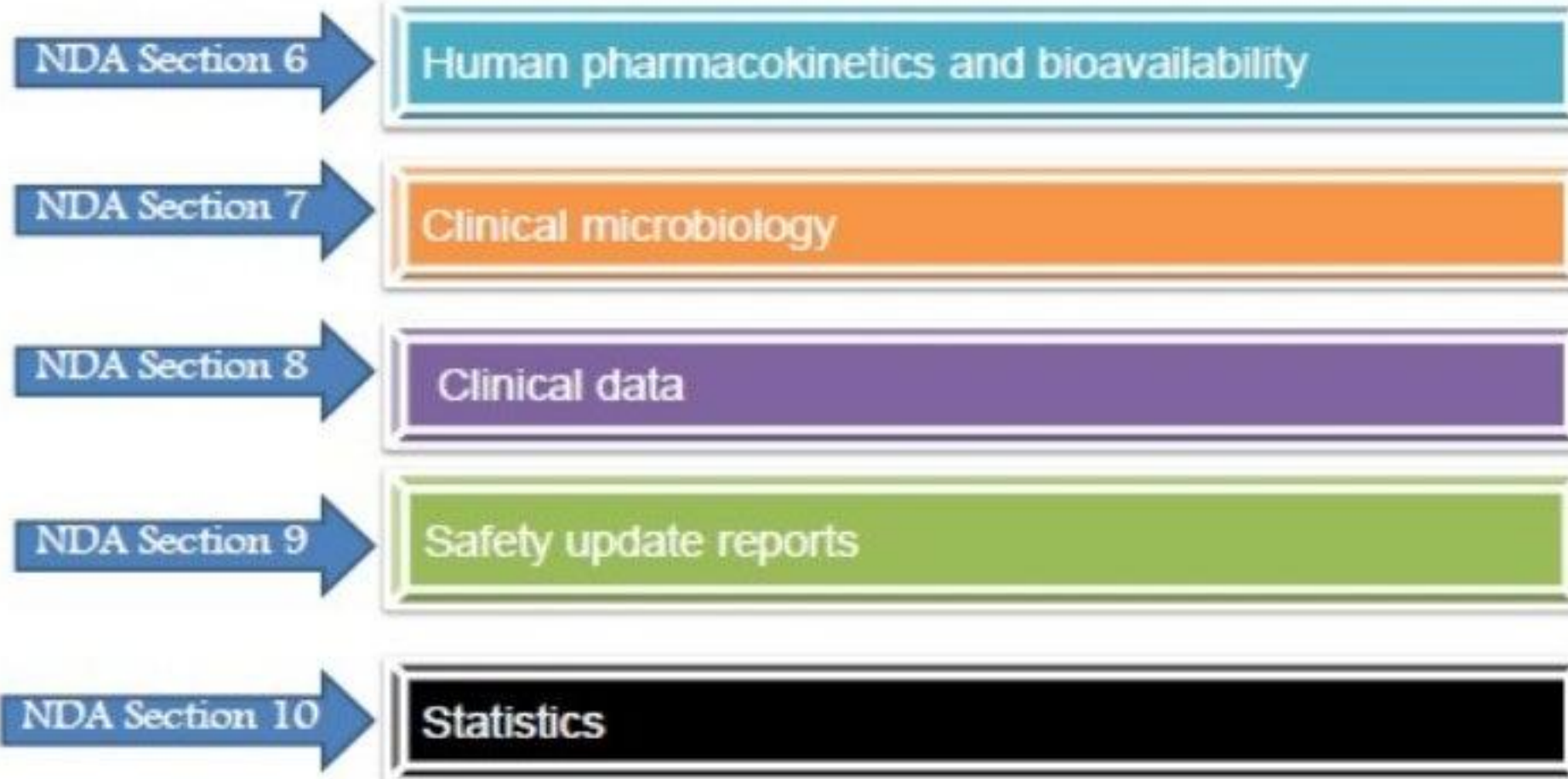
NDA Contents

Contd...



NDA Contents

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NDA Contents

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NDA Contents

Contd...

NDA Section 16

Debarment certificate

NDA Section 17

Field copy certification

NDA Section 18

User fee coversheet

NDA Section 19

Financial disclosure

NDA Section 20

Other

Phases of clinical testing

Phase	Number of patients	Length	Purpose	Percent successfully completing
Phase1	20-100	Several months	Mainly safety	67
Phase2	Up to several hundred	Several months to two years	Some short-term safety but mainly effectiveness	45
Phase3	Several hundred to several thousand	1-4 years	Safety, effectiveness, dosage	5-10