New Drug Application(NDA)

Abbreviated New Drug Application *(ANDA)*

and

Investigational New Drug Application(*IND*}

BY DR ANTHONY CRASTO

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

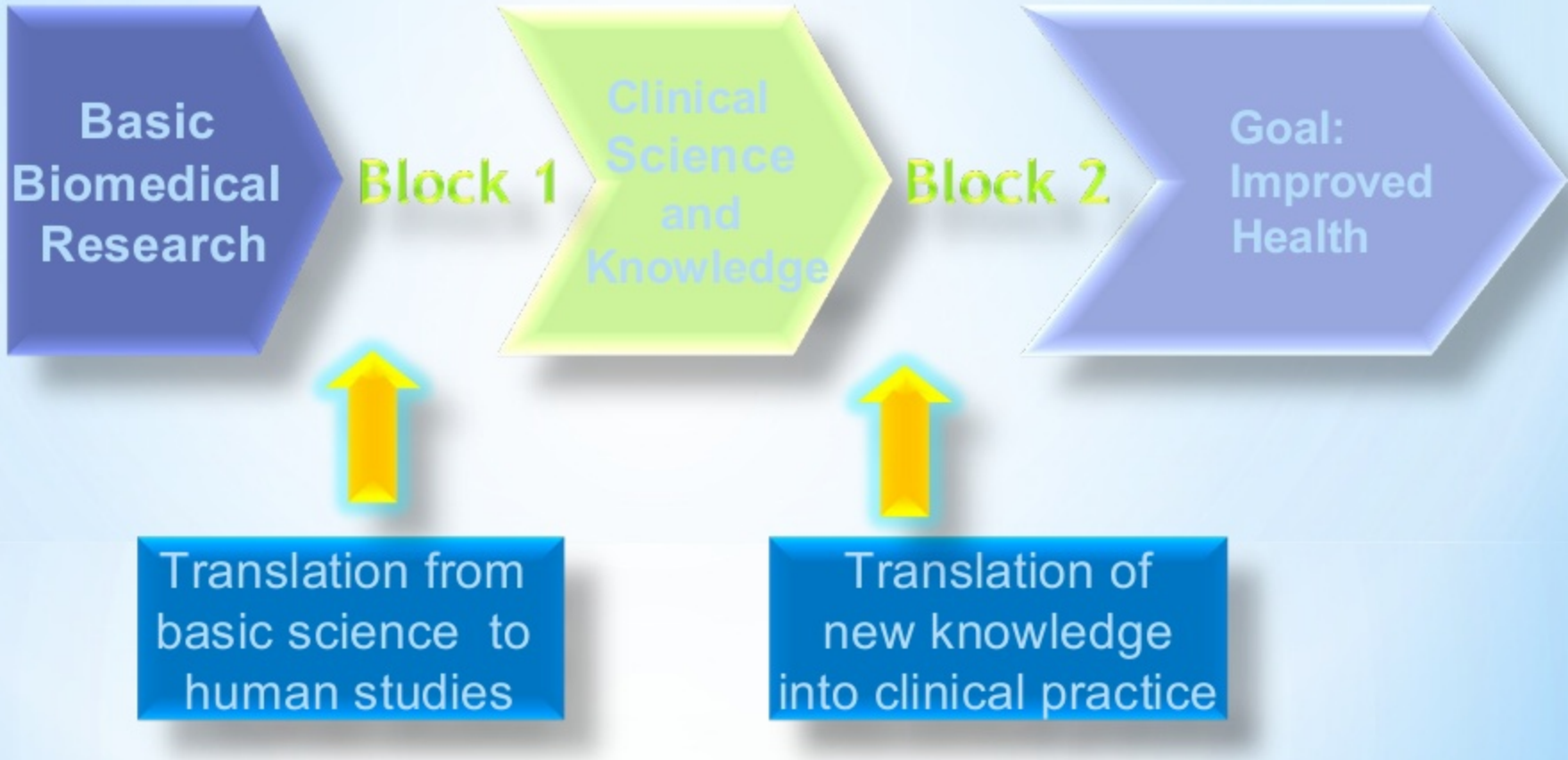
Thanks for helping me to keep lionel smiling

Contents

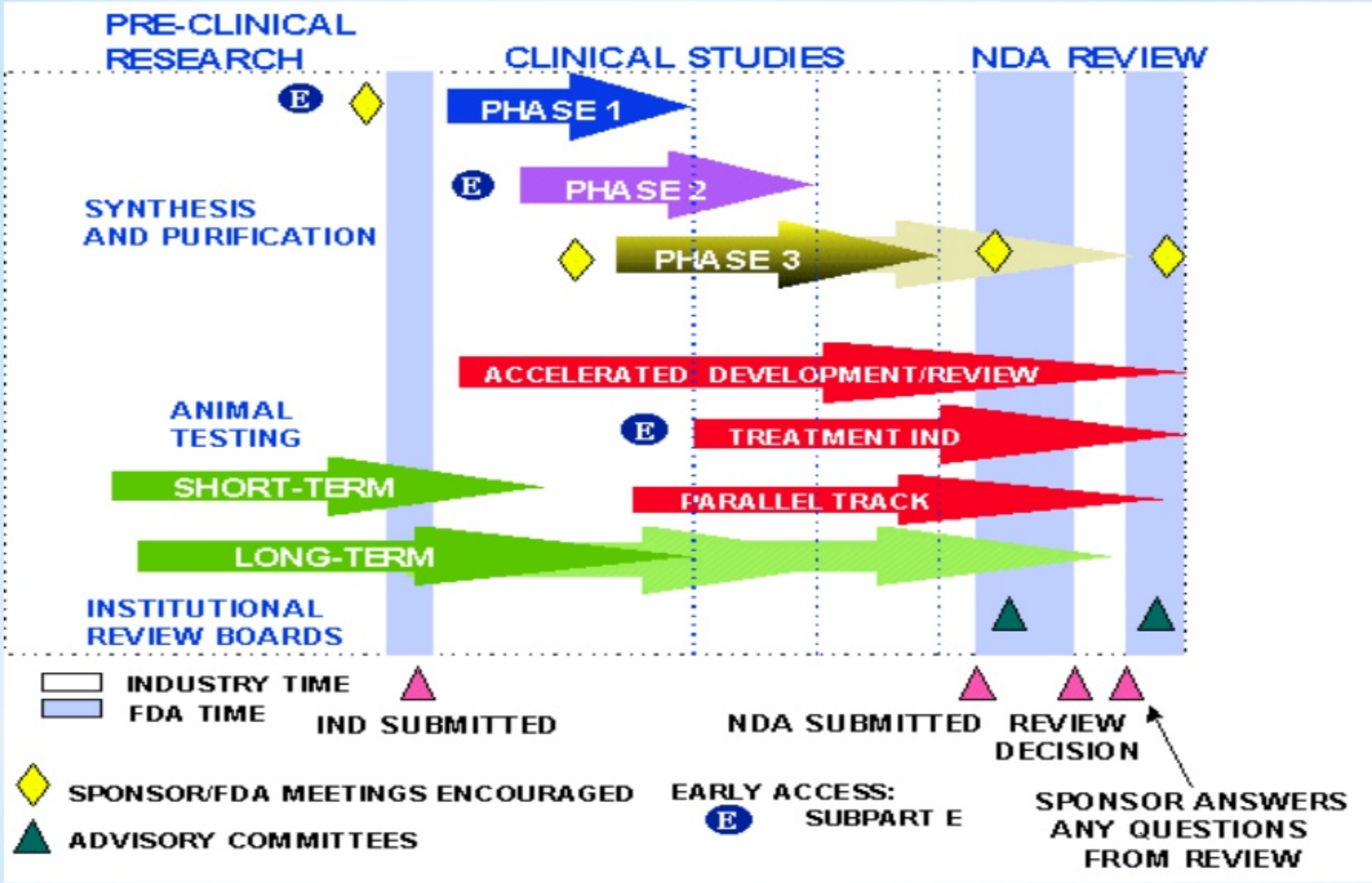
*DRUG DEVELOPMENT

- ✓ 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

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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

LAWS, REGULATIONS, POLICIES, PROCEDURES

* *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.

* *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

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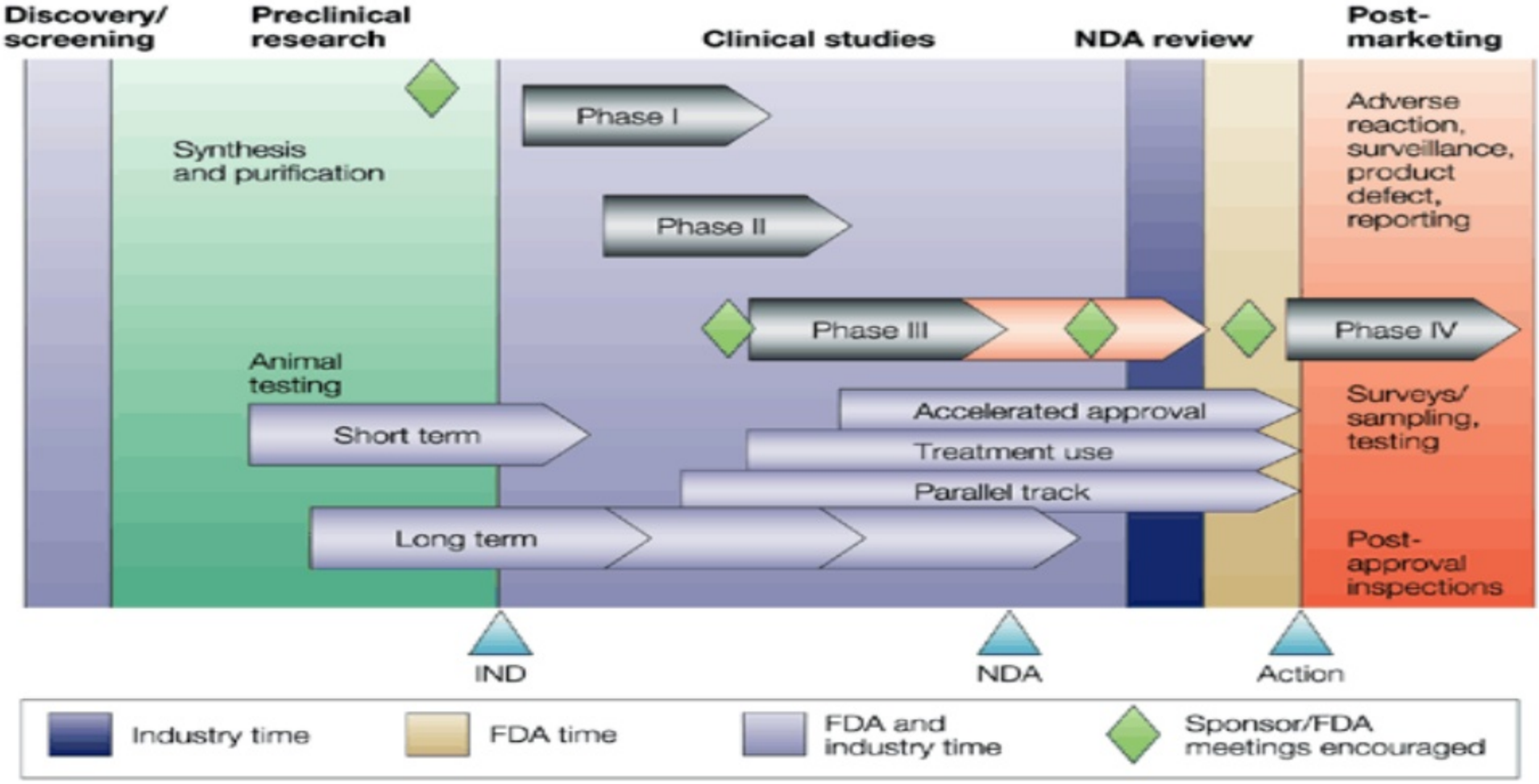
New Drug Development and Review Process

Steps from Test Tube to New Drug Application Review



NDA Contents

Contd…

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NDA Contents

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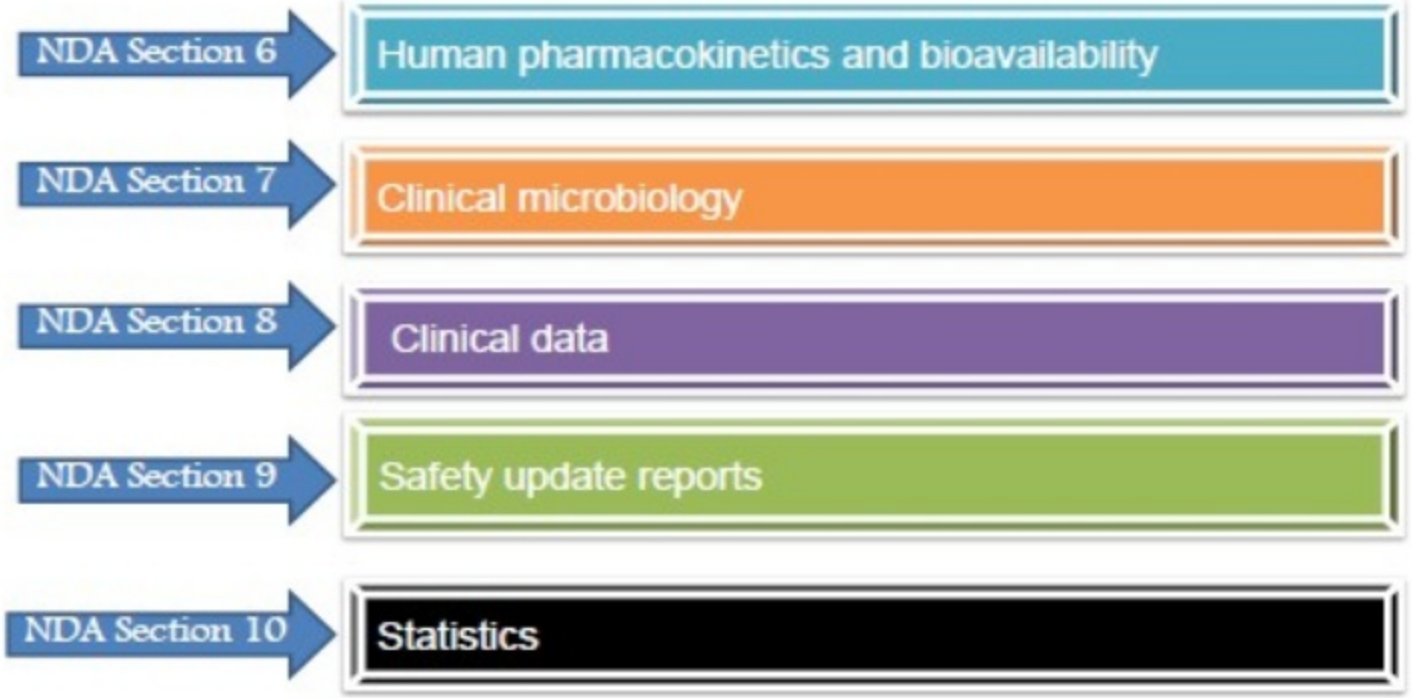

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NDA Contents

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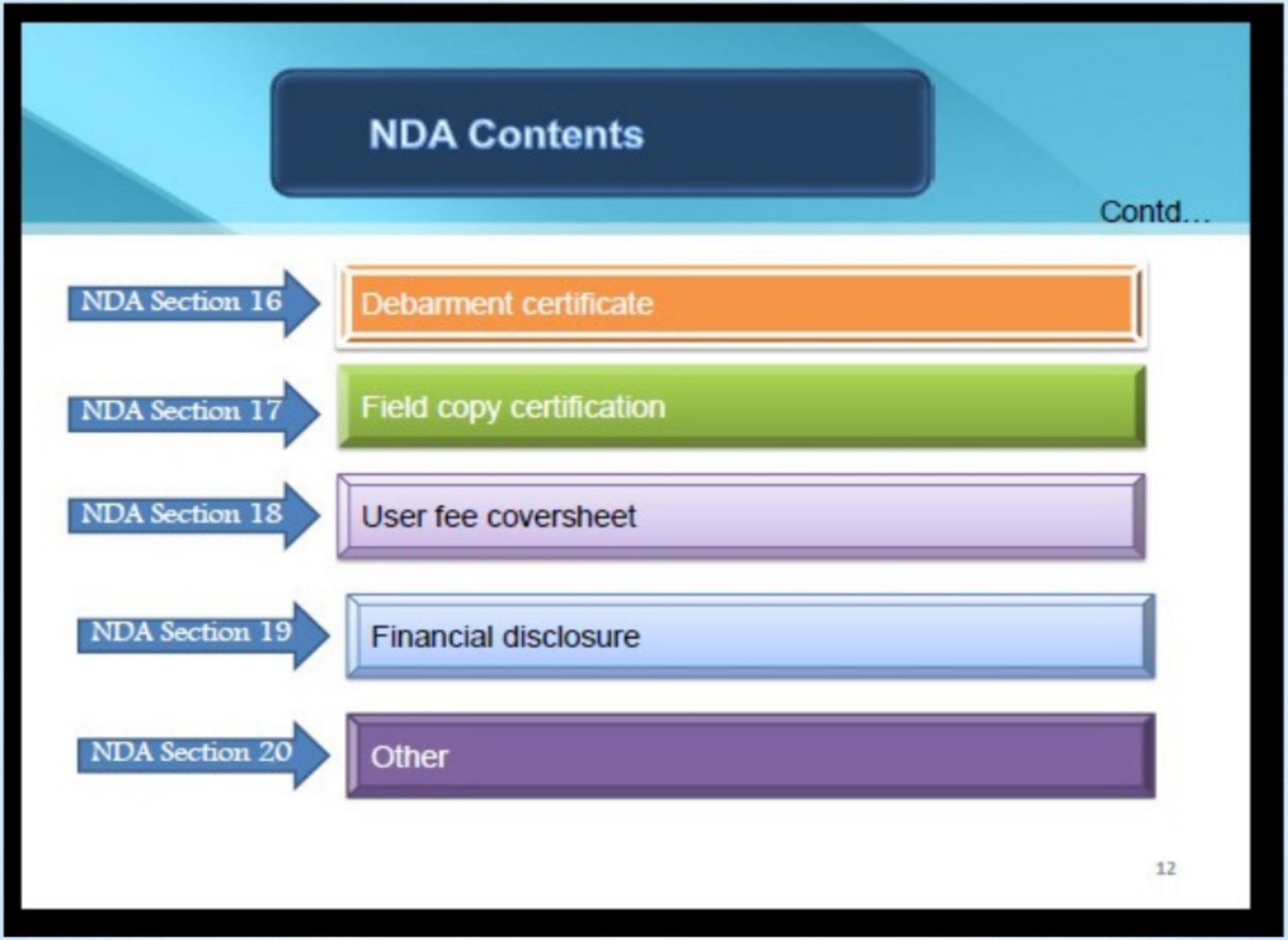
NDA Contents
Contd…
NDA Section 16
Debarment certificate
NDA Section 17
Field copy certification
NDA Section 18
User fee coversheet
NDA Section 19
Financial disclosure
NDA Section 20
Other
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Phases of clinical testing

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