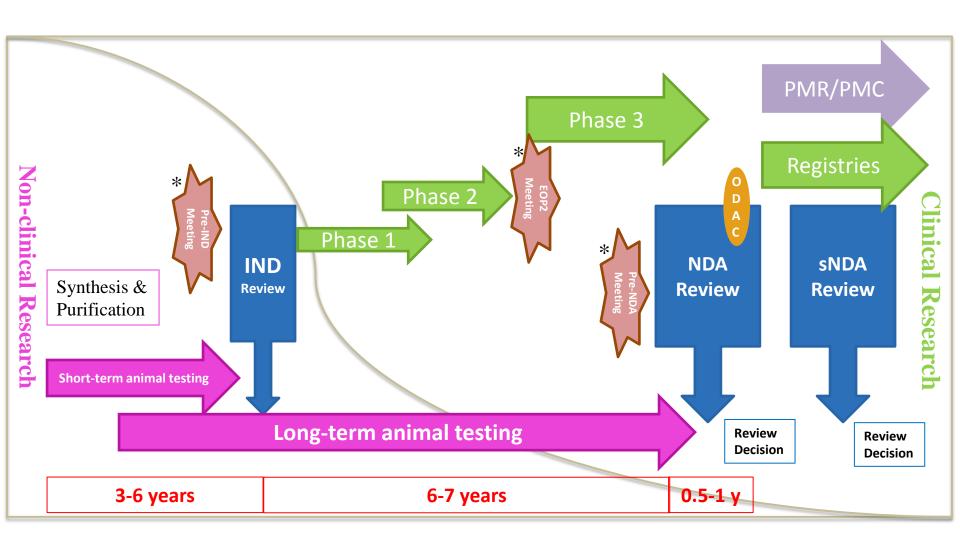






FDA & Drug Development





FDA Expedited Programs

Four programs

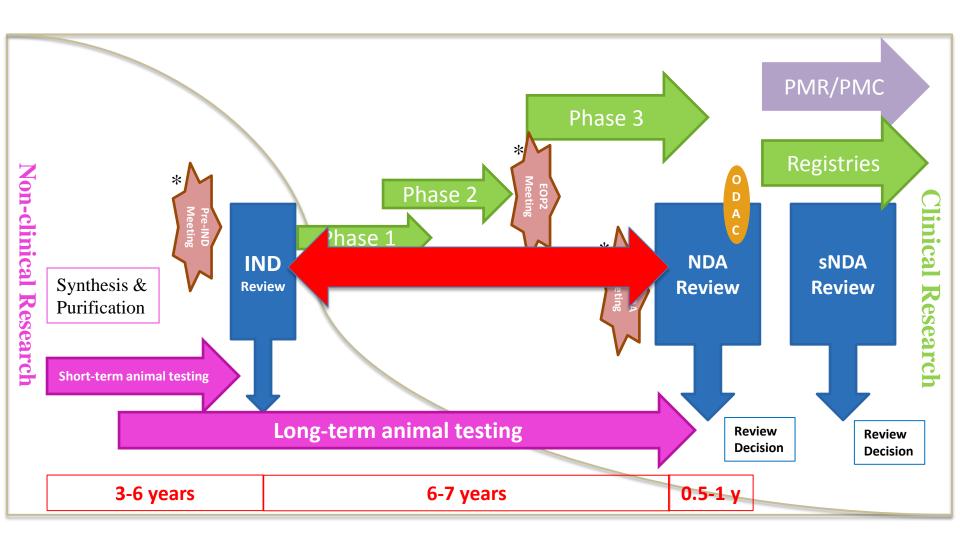
- Fast Track Designation
- Priority Review Designation
- Breakthrough Therapy Designation
- Accelerated Approval Pathway

One goal

 To hasten the approval of safe and effective therapies to treat serious conditions

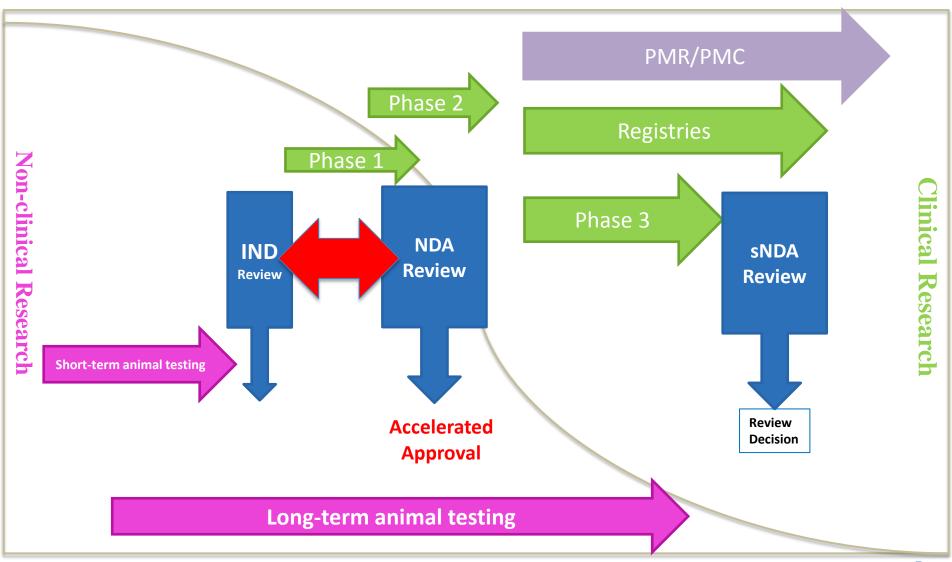


Old Paradigm: Drug Development





New paradigm: Drug Development



Hematology/Oncology (CDER) NME NDAs/BLAs Drug Approvals 2014 to Sep 2015

Name	Fast Track	Breakthrough Therapy	Priority Review	Accelerated Approval
RAMUCIRUMAB	•		•	
SILTUXIMAB			•	
CERITINIB		•	•	•
BELINOSTAT	•		•	•
IDELALISIB*	•	•	•	
PEMBROLIZUMAB		•	•	•
BLINATUMOMAB		•	•	•
OLAPARIB			•	•
NIVOLUMAB	•	•	•	•
PALBOCICLIB		•	•	•
LENVATINIB			•	
PANOBINOSTAT			•	•
SONIDEGIB			•	



Cancer Survivors Statistics

As of January 1, 2014

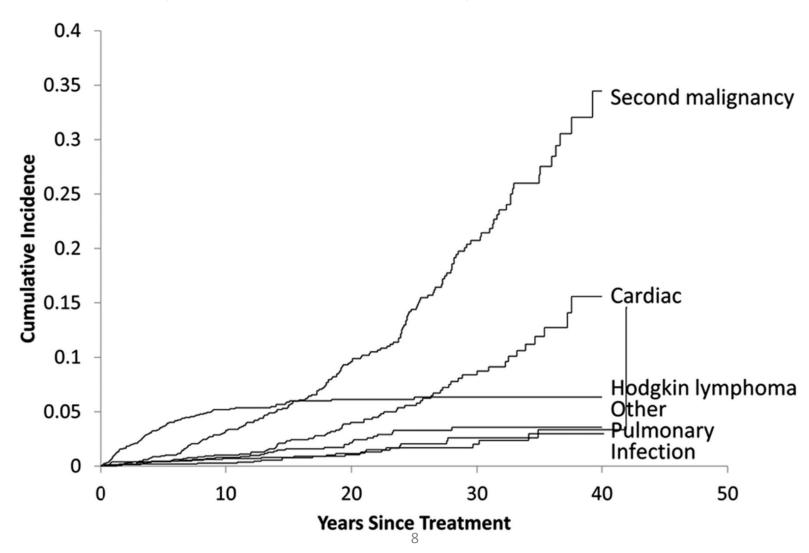
Male **Female** Prostate Breast 2,975,970 (43%) 3,131,440 (41%) Colon & rectum Uterine corpus 621,430 (9%) 624,890 (8%) Melanoma Colon & rectum 516,570 (8%) 624,340 (8%) Urinary bladder Melanoma 455,520 (7%) 528,860 (7%) Non-Hodgkin lymphoma **Thyroid** 297,820 (4%) 470,020 (6%) Non-Hodgkin lymphoma Testis 244,110 (4%) 272,000 (4%) Kidney Uterine cervix 229,790 (3%) 244,180 (3%) Lung & bronchus Lung & bronchus 196,580 (3%) 233,510 (3%) Oral cavity & pharynx Ovary 194,140 (3%) 199,900 (3%) Leukemia Kidney 159,280 (2%) 177,940 (3%) All sites All sites 6,876,600 7,607,230

As of January 1, 2024

Male			Female			
Prostate			Breast			
4,194,190 (45%))	3,951,930 (41%)			
Colon & rectum			Colon & rectum			
789,950 (8%)			771,070 (8%)			
Melanoma			Uterine corpus			
698,040 (7%)			756,980 (8%)			
Urinary bladder			Melanoma			
577,780 (6%)				696,280 (7%)		
Non-Hodgkin lymphoma		oma		Thyroid		
3	390,170 (4%)			645,330 (7%)		
	Kidney		Non-Hodgkin lymphoma			
3	318,990 (3%)			360,220 (4%)		
	Testis		L	ung & bronchus		
308,000 (3%)				289,400 (3%)		
Oral cavity & pharynx		/nx		Cervix		
	241,920 (3%)			244,840 (3%)		
Lung & bronchus		5		Ovary		
2	240,530 (3%)			236,320 (2%)		
Leukemia			Kidney			
230,590 (2%)				221,260 (2%)		
All sites			All sites			
9,312,080				9,602,590		



Cause-Specific Mortality of HL Survivors





FDA Mission

- FDA is responsible for:
 - promote the public health by reviewing clinical research and taking appropriate action on the marketing of regulated products, and
 - 2. protect the public health by ensuring that human drugs are **safe** and **effective**.



Goals of the Workshop

- Provide a forum for discussion of cardiovascular toxicity assessment within oncology clinical trials
 - in vitro and in vivo nonclinical models to assess cardiovascular toxicity.
 - best practices for identifying cardiovascular safety signals within oncology clinical trials.
 - the role of imaging and biomarkers to predict and monitor cardiovascular toxicities.
 - what cardiovascular risk factors need to be captured at baseline and throughout the study.
 - how to improve the cardiovascular Adverse Events reporting within oncology clinical trials beyond CTCAE.
 - Review the evidence available regarding implementation of cardiovascular prevention strategies.
 - how to design and implement cardiovascular safety registries.