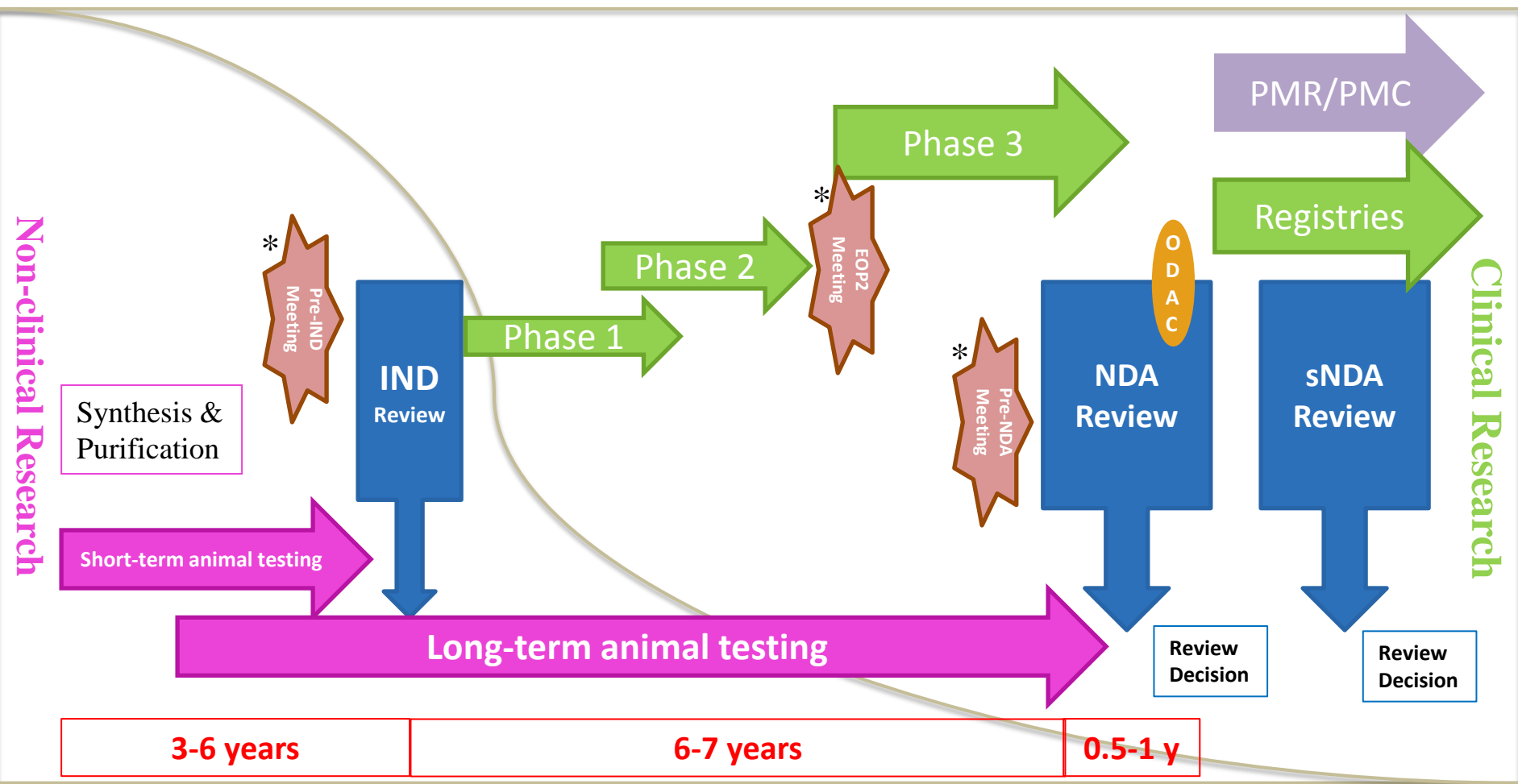


FDA Workshop Cardiovascular Toxicity Assessment In Oncology Trials

with support from
AACR, ACC, AHA & ASCO

Co Chairs: Laleh Amiri-Kordestani, MD & Ana Barac, MD

FDA & Drug Development



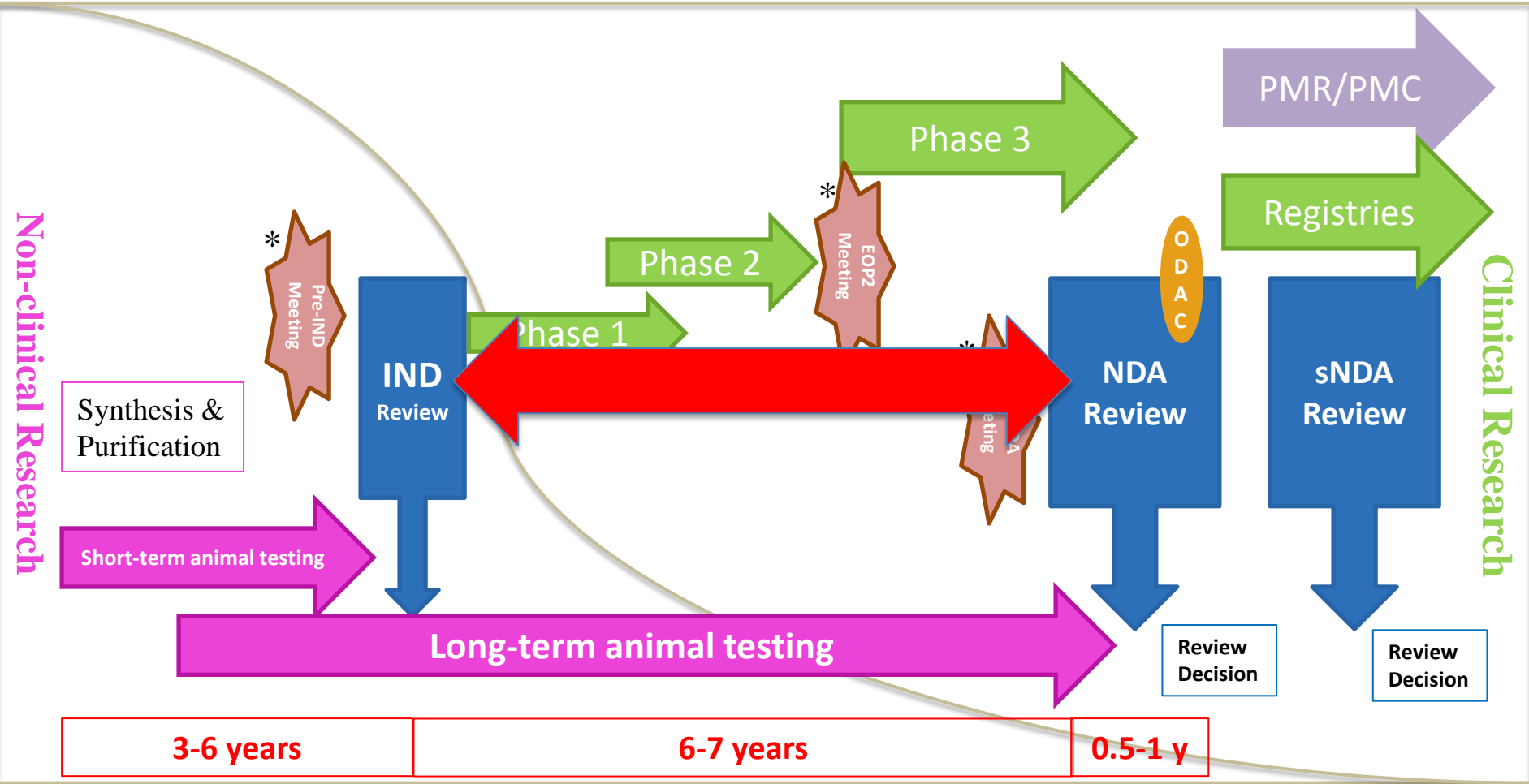
*Sponsor meetings

FDA Expedited Programs

- **Four programs**
 - Fast Track Designation
 - Priority Review Designation
 - Breakthrough Therapy Designation
 - Accelerated Approval Pathway

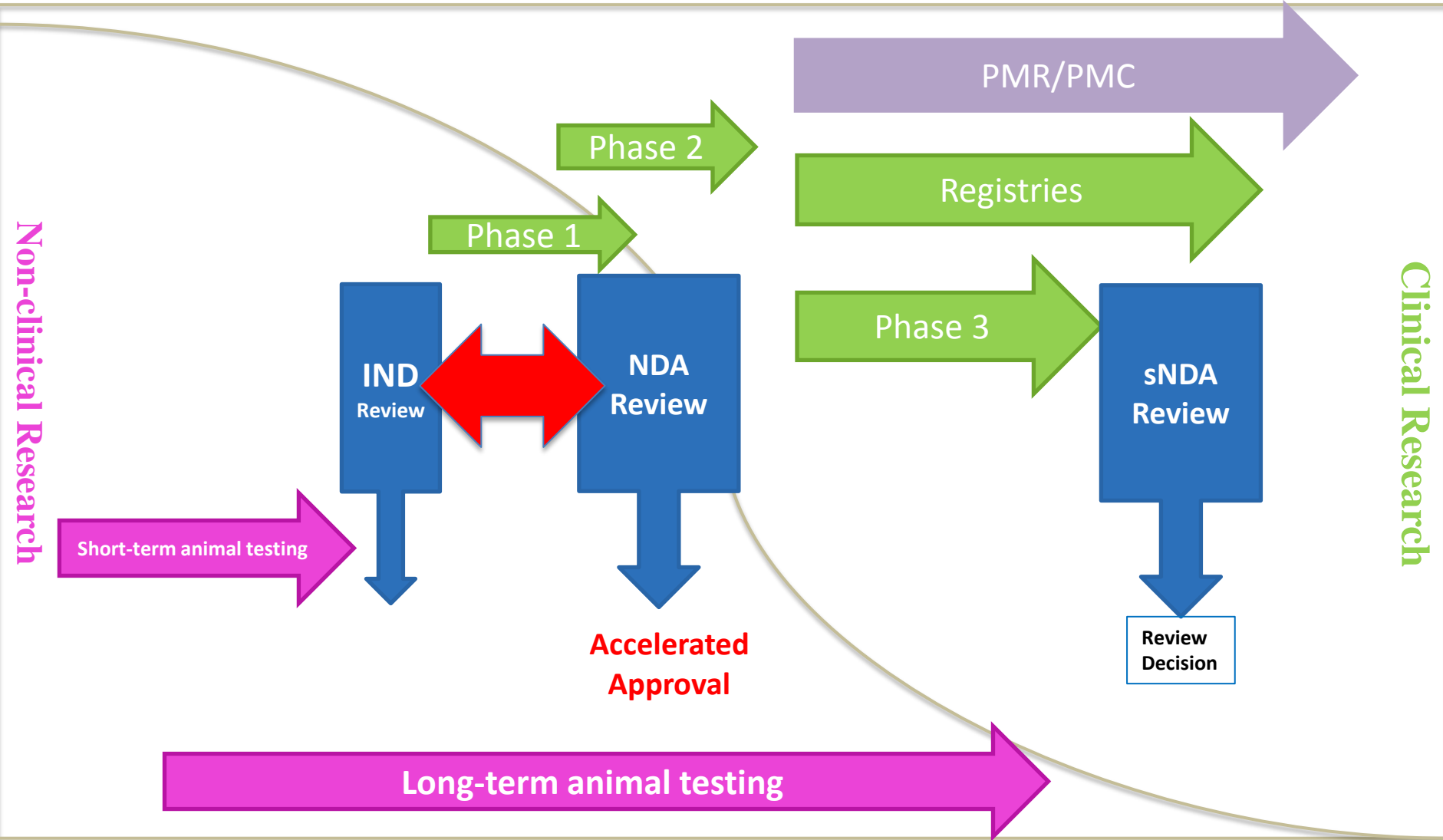
- **One goal**
 - To hasten the approval of safe and effective therapies to treat serious conditions

Old Paradigm : Drug Development



*Sponsor meetings

New paradigm: Drug Development

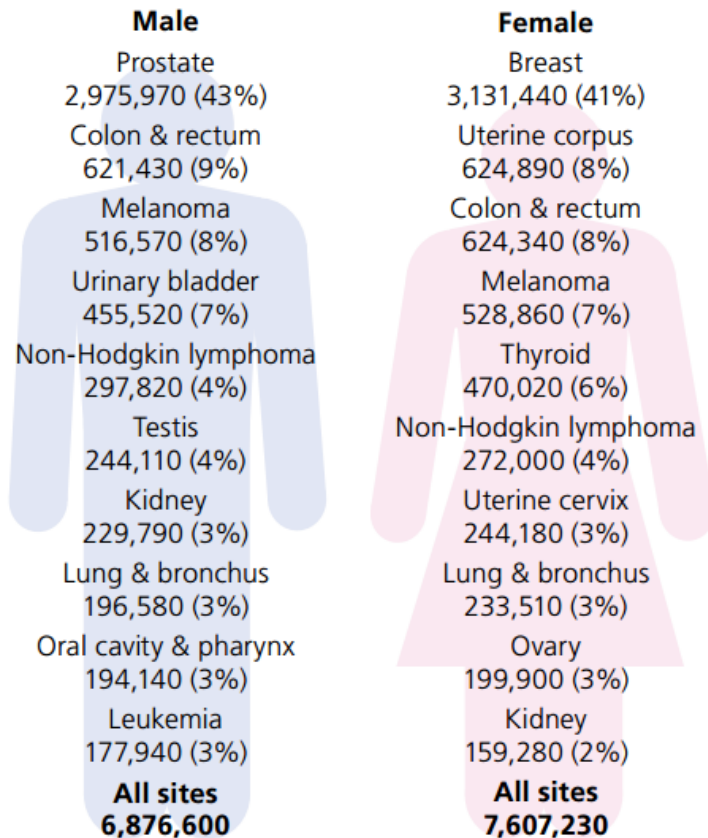


Hematology/Oncology (CDER) NME NDAs/BLAs Drug Approvals 2014 to Sep 2015

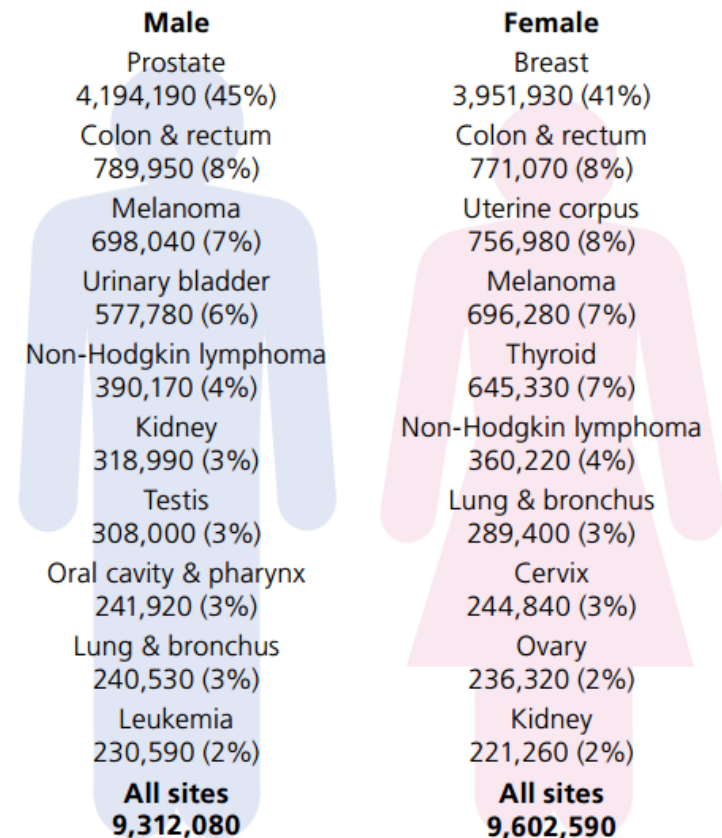
Name	Fast Track	Breakthrough Therapy	Priority Review	Accelerated Approval
RAMUCIRUMAB	●		●	
SILTUXIMAB			●	
CERITINIB		●	●	●
BELINOSTAT	●		●	●
IDELALISIB*	●	●	●	
PEMBROLIZUMAB		●	●	●
BLINATUMOMAB		●	●	●
OLAPARIB			●	●
NIVOLUMAB	●	●	●	●
PALBOCICLIB		●	●	●
LENVATINIB			●	
PANOBINOSTAT			●	●
SONIDEGIB	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

Cancer Survivors Statistics

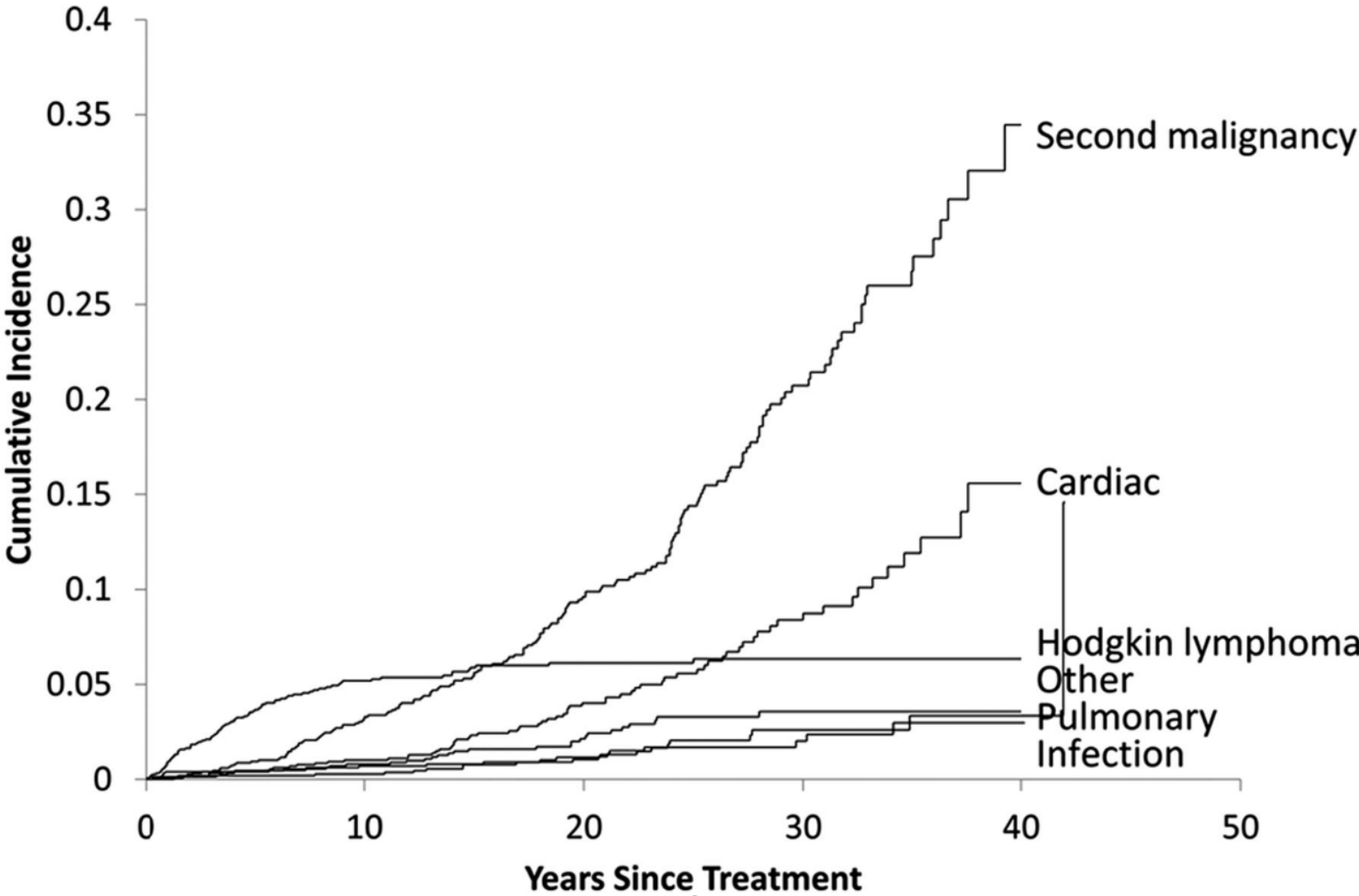
As of January 1, 2014



As of January 1, 2024



Cause-Specific Mortality of HL Survivors





FDA Mission

- FDA is responsible for:
 1. 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.