Metrics on Technical Risks, Clinical Development Times, and Approval Times for Cancer Drugs

Joseph A. DiMasi, Ph.D.
Director of Economic Analysis
Tufts Center for the Study of Drug Development
Tufts University

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Tufts Center for the Study of Drug Development
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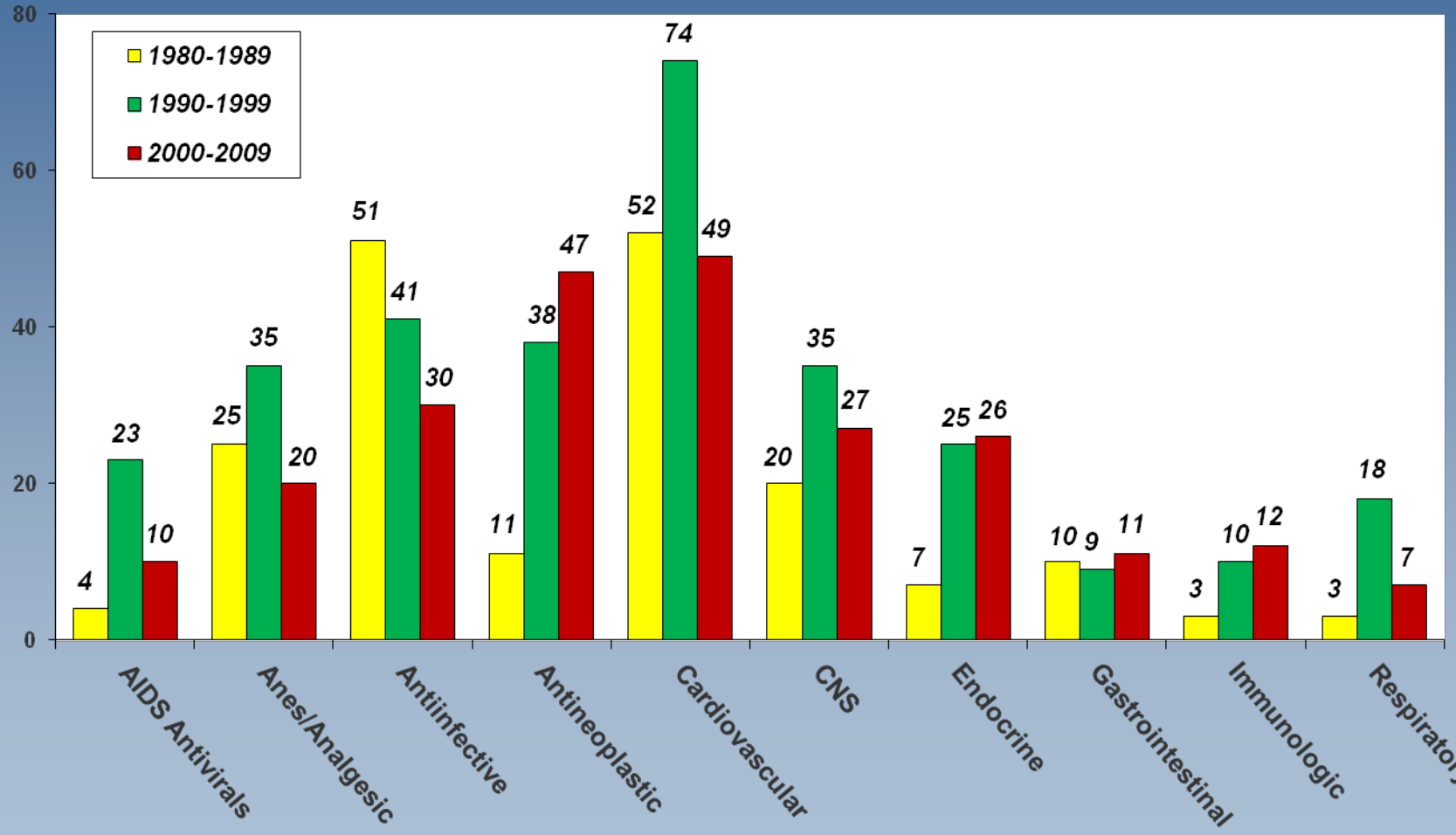
Agenda

- Cancer drug development approval trends
- Cancer drug development risk: probability of obtaining regulatory marketing approval
- The clinical development phase for cancer drugs
- The regulatory approval phase for cancer drugs

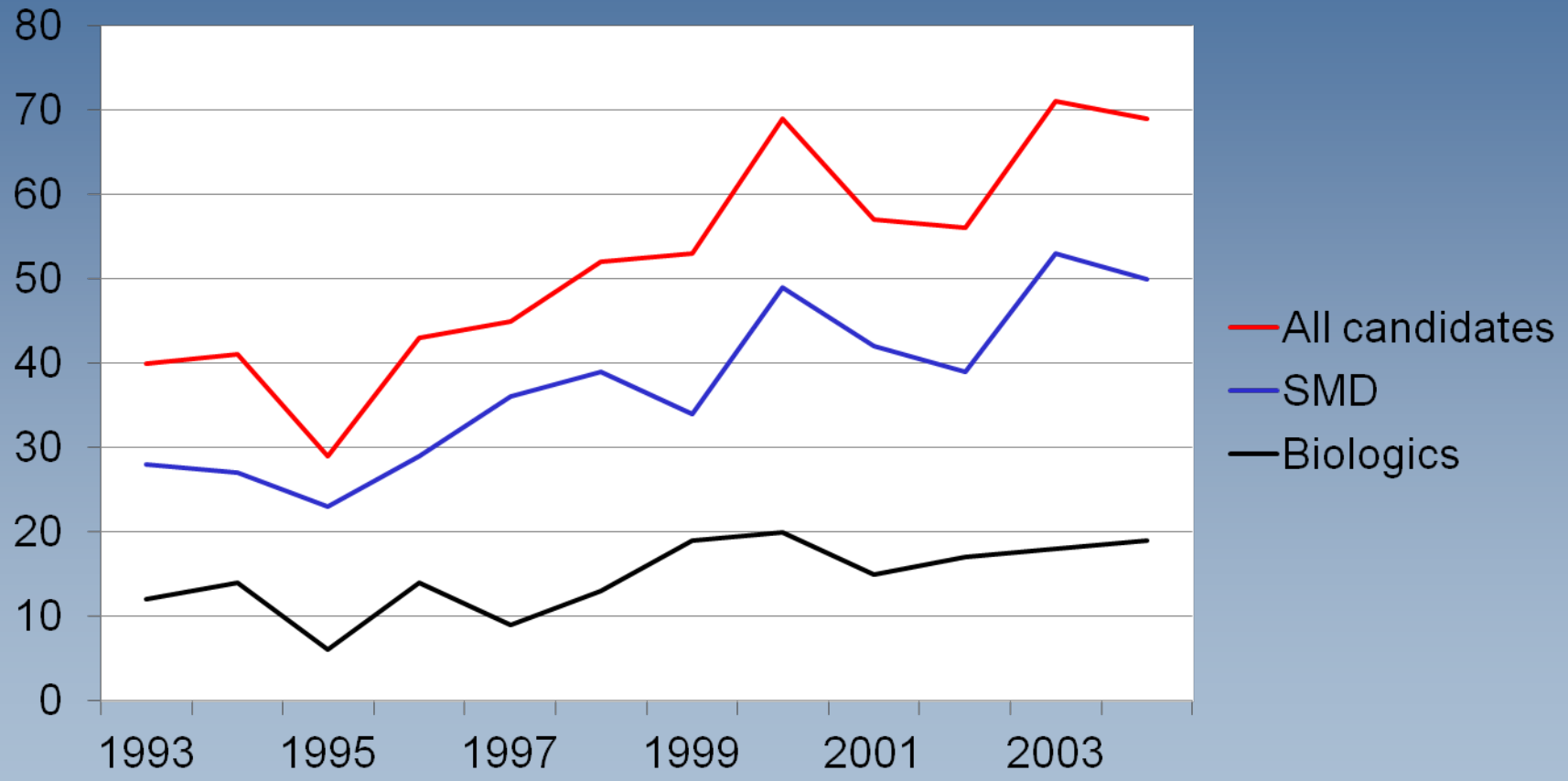
Cancer Drug Development Trends

Number of U.S. New Drug Approvals by Therapeutic Class and Decade



Source: Kaitin and DiMasi, Clin Pharmacol Ther 2011;89(2):183-188

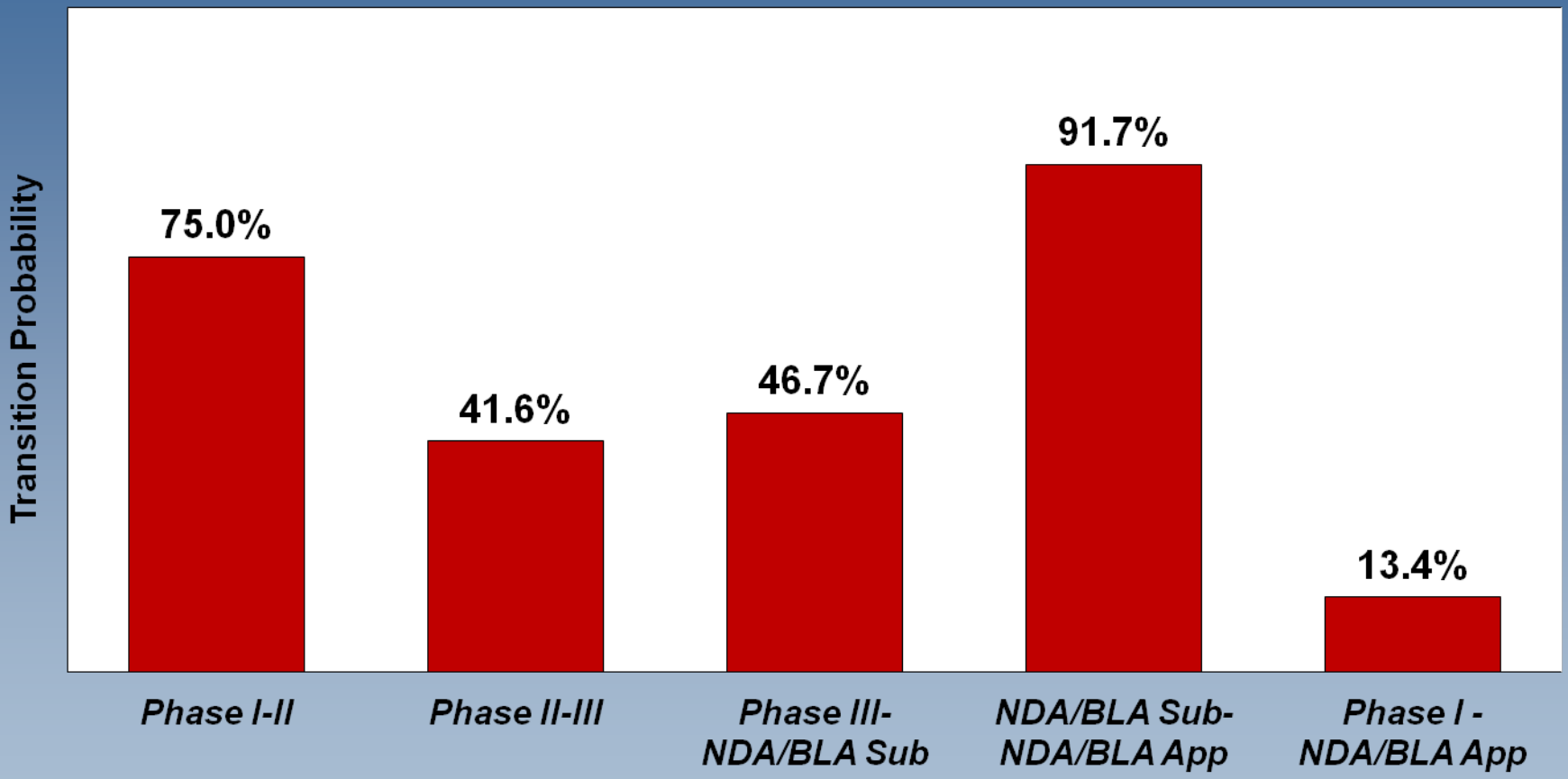
Number of New Cancer Drugs Entering Clinical Testing Per Year From 1993 to 2004



Source: Tufts CSDD

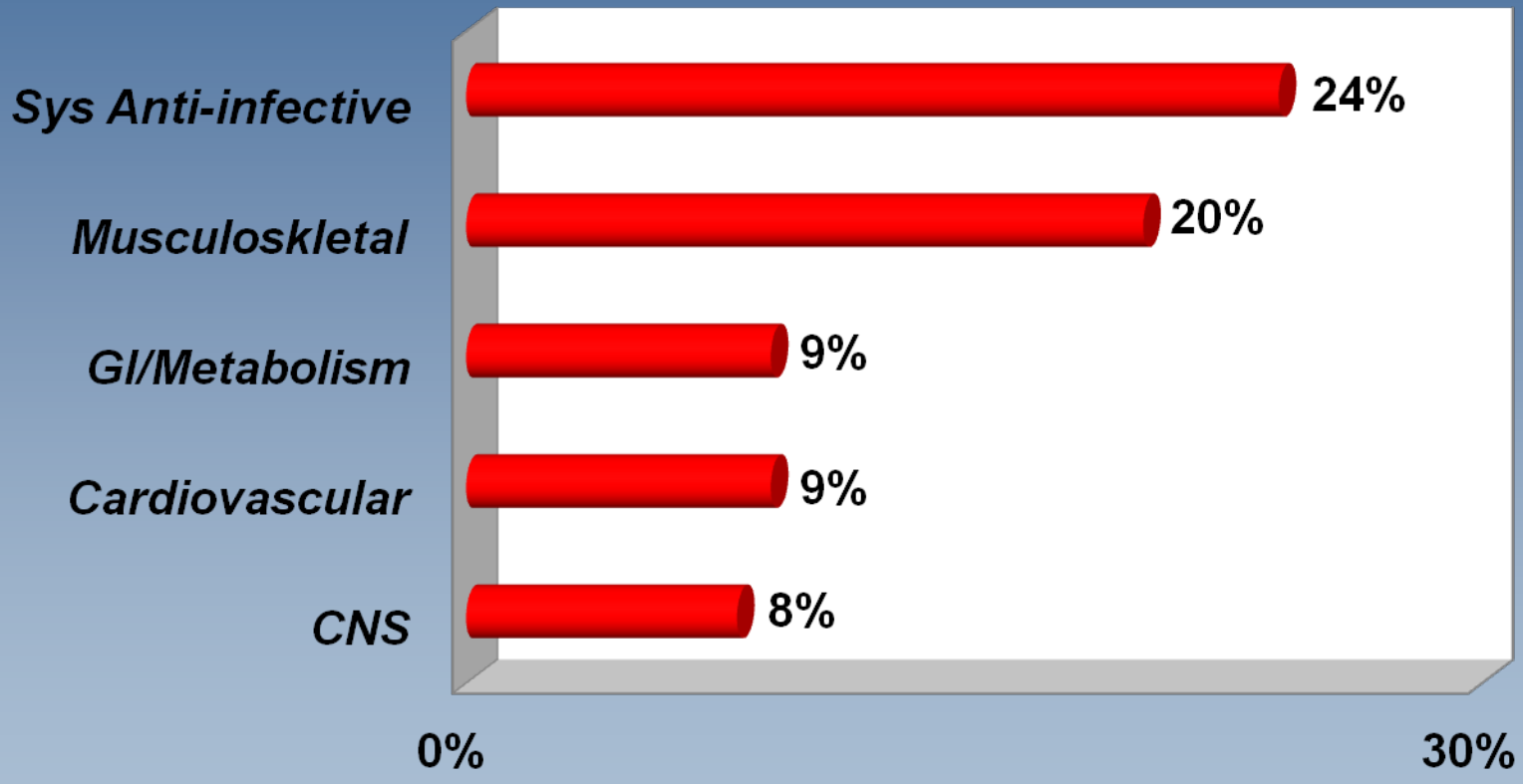
Risks in Cancer Drug Development

Phase Transition Probabilities for Cancer Drugs First Entering Clinical Pipeline, 1993-2004



Source: Tufts CSDD

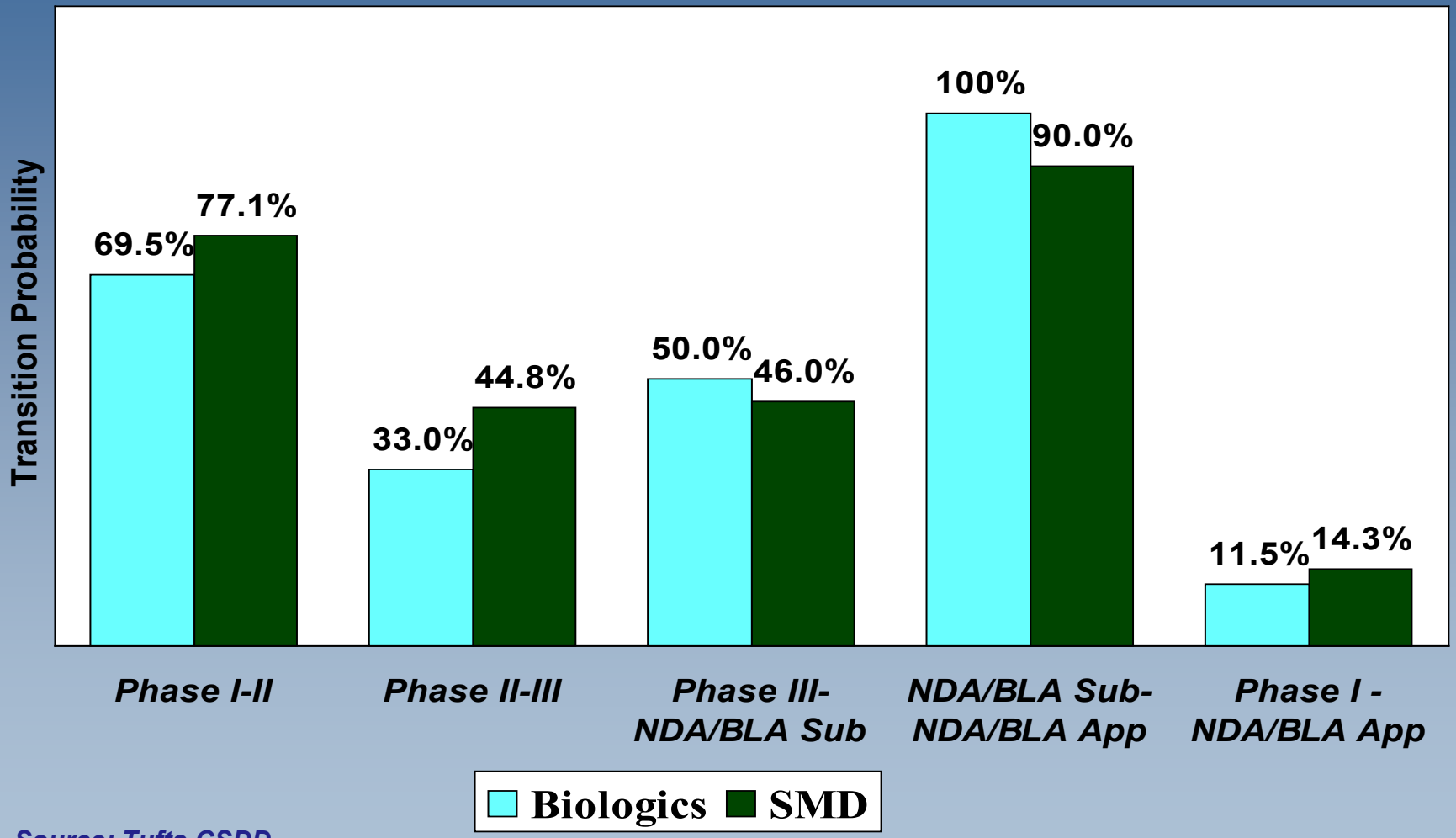
Clinical Approval Success Rates by Therapeutic Class



Data from top 50 firms

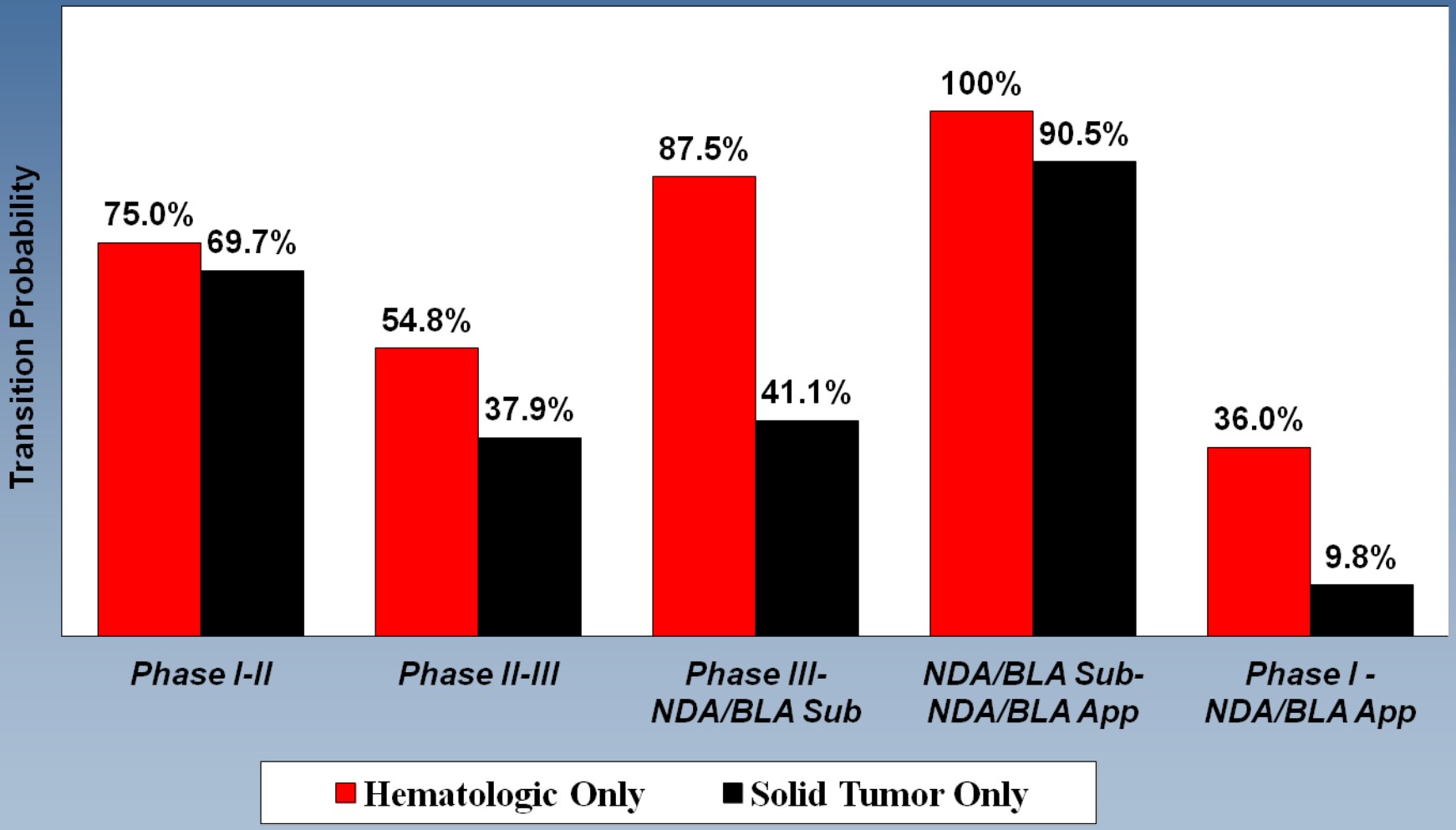
Source: DiMasi et al., Clin Pharmacol Ther 2010;87(3):272-277

Phase Transition Probabilities for Cancer Drugs by Molecule Type (First Human Testing, 1993-2004)



Source: Tufts CSDD

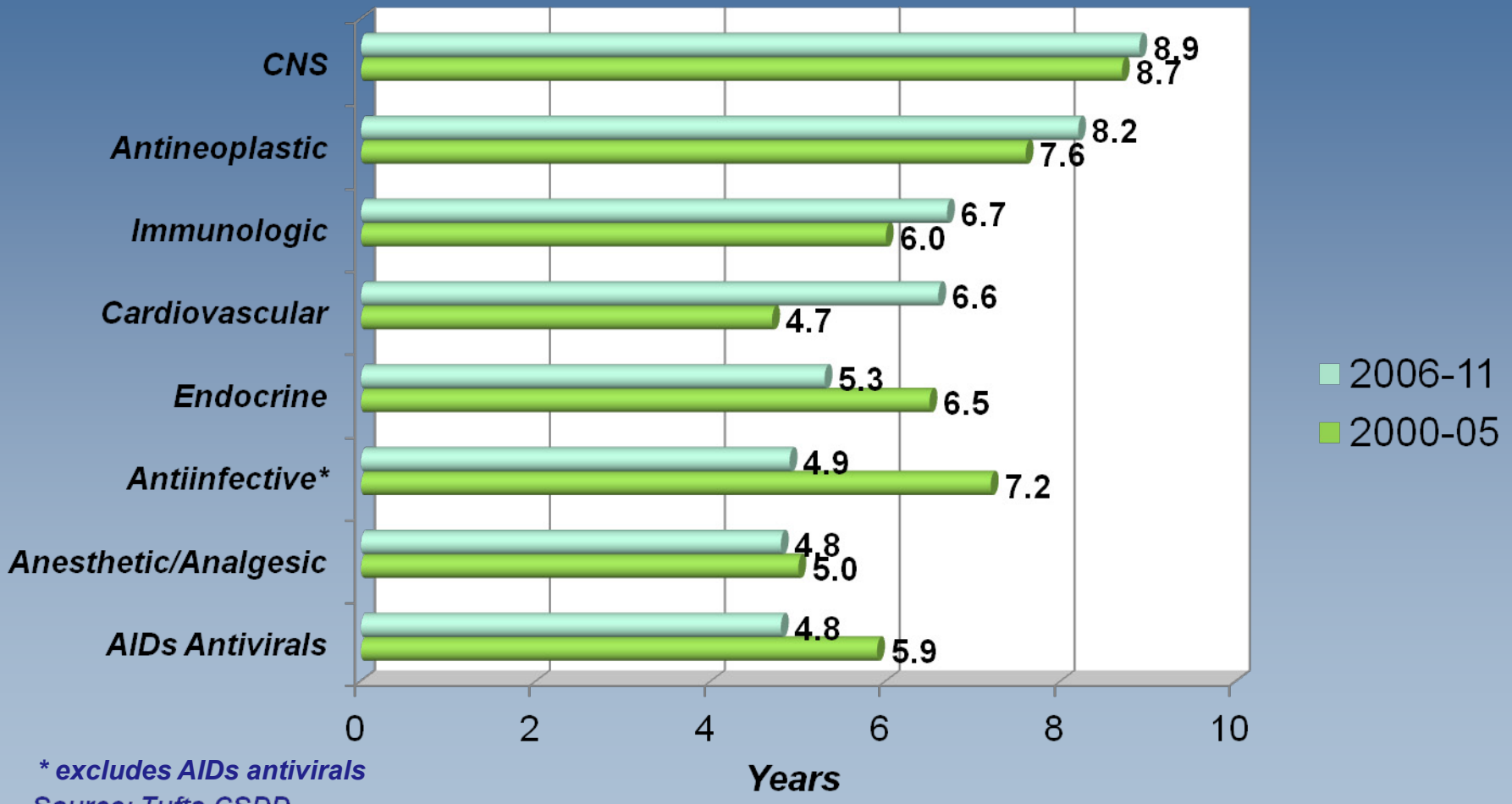
Phase Transition Probabilities for Cancer Drugs by Cancer Type (First Human Testing, 1993-2004)



Source: Tufts CSDD

Cancer Drug Development and Approval Times

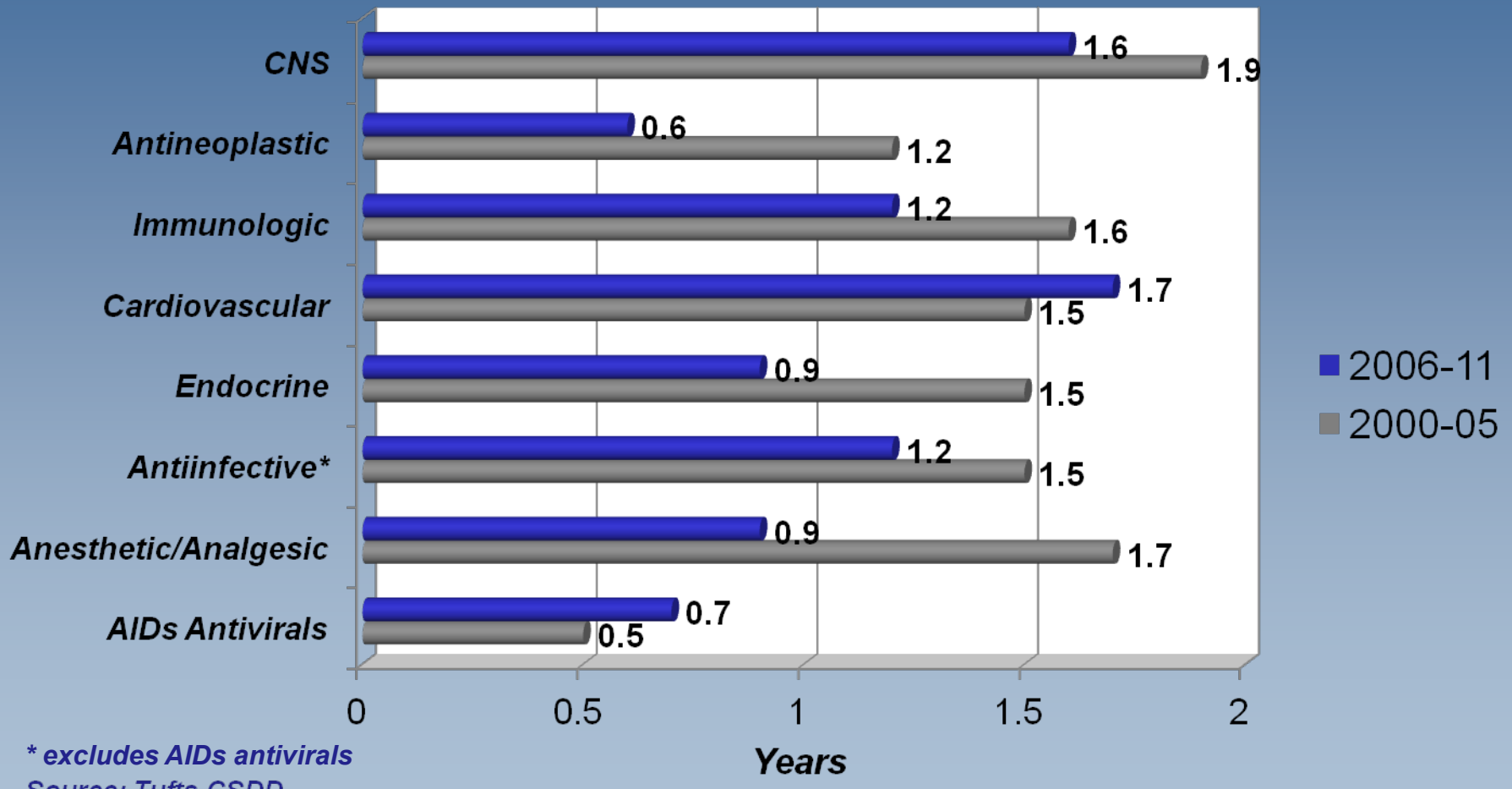
Clinical Development Times Vary by Period and Across Therapeutic Classes, 2000-2011



** excludes AIDs antivirals*

Source: Tufts CSDD

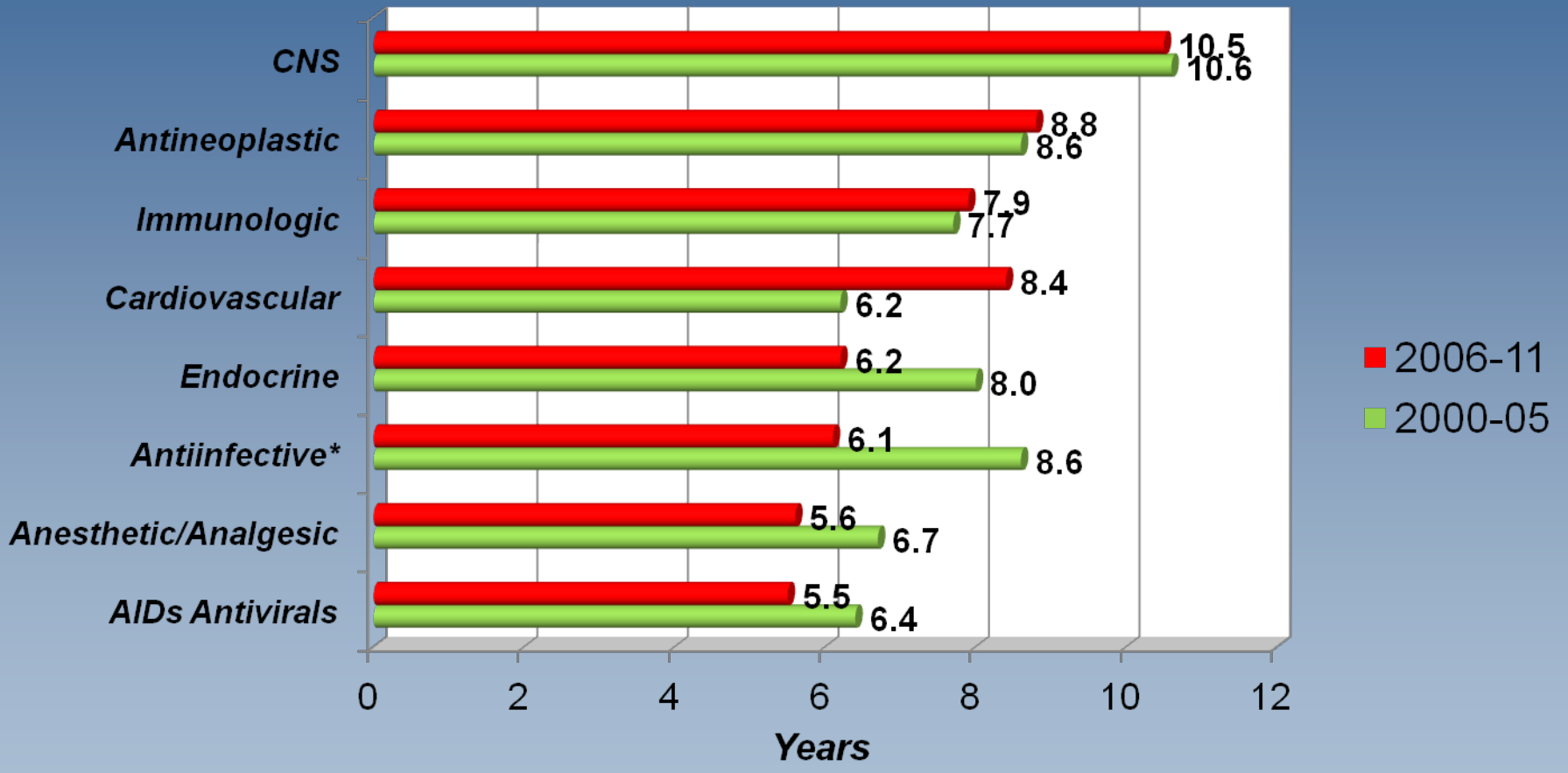
U.S. Approval Times by Period and Therapeutic Class, 2000-2011



** excludes AIDs antivirals*

Source: Tufts CSDD

Clinical Development Plus Approval Phase Times by Period and Therapeutic Class, 2000-2011



** excludes AIDs antivirals*
Source: Tufts CSDD

Number of FDA Review Cycles (FY96-06) for Approved Drugs by Therapeutic Class

	1 CYCLE	2 CYCLES	3 CYCLES	4 CYCLES	5 CYCLES
Analg/Anesth n=24	**62.5% n=15**	**25.0% n=6**	**12.5% n=3**	--	--
Anti-infective n=55	**69.1% n=38**	**27.3% n=15**	**3.6% n=2**	--	--
Anti-neoplastic n=43	**67.4% n=29**	**23.3% n=10**	**9.3% n=4**	--	--
Cardiovascular n=58	**39.9% n=22**	**46.6% n=27**	**8.6% n=5**	**6.9% n=4**	--
CNS n=29	**17.2% n=5**	**62.1% n=18**	**20.7% n=6**	--	--
Endocrine n=33	**66.7% n=22**	**18.2% n=6**	**15.2% n=5**	--	--
Gastrointestinal n=12	**25.0% n=3**	**41.7% n=5**	**33.3% n=4**	--	--
Immunologic n=15	**60.0% n=9**	**20.0% n=3**	**13.3% n=2**	--	**6.7% n=1**
Respiratory n=9	**33.3% n=3**	**44.4% n=4**	**22.2% n=2**	--	--
Miscellaneous n=20	**30.0% n=6**	**60.0% n=12**	**10.0% n=2**	--	--

Source: DiMasi and Faden, Drug Information Journal 2009;43(2):201-225

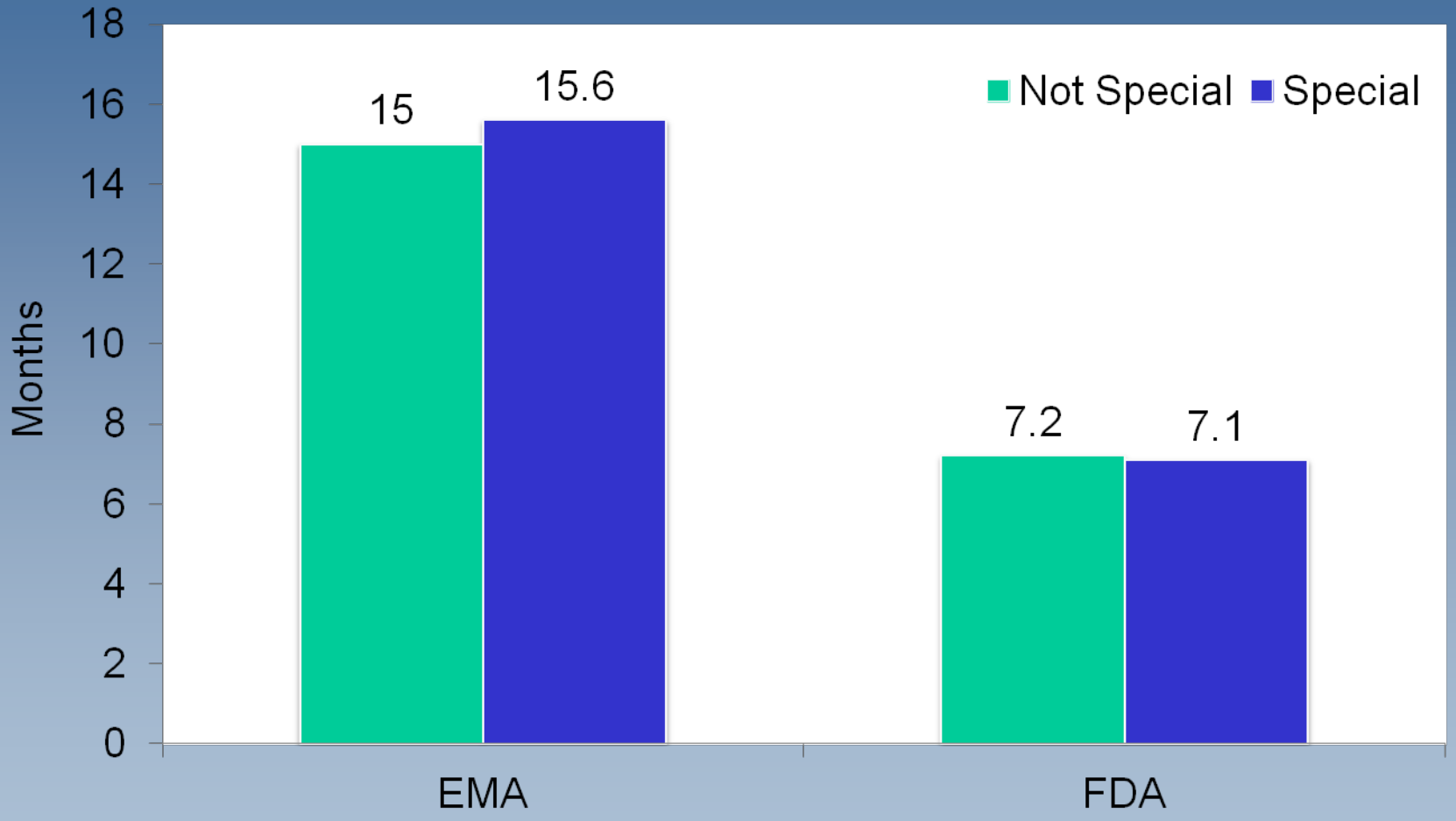
FDA Special Designation Trends

	Oncology 2002-2006	Oncology 2007-2011	Non-Oncology 2002-2006	Non-Oncology 2007-2011
Orphan	42%	57%	21%	22%
FT	73%	38%	15%	9%
AA	46%	17%	7%	5%
Any	77%	67%	29%	29%

FT = Fast Track
AA = Accelerated Approval
Any = FT, AA, and/or Orphan

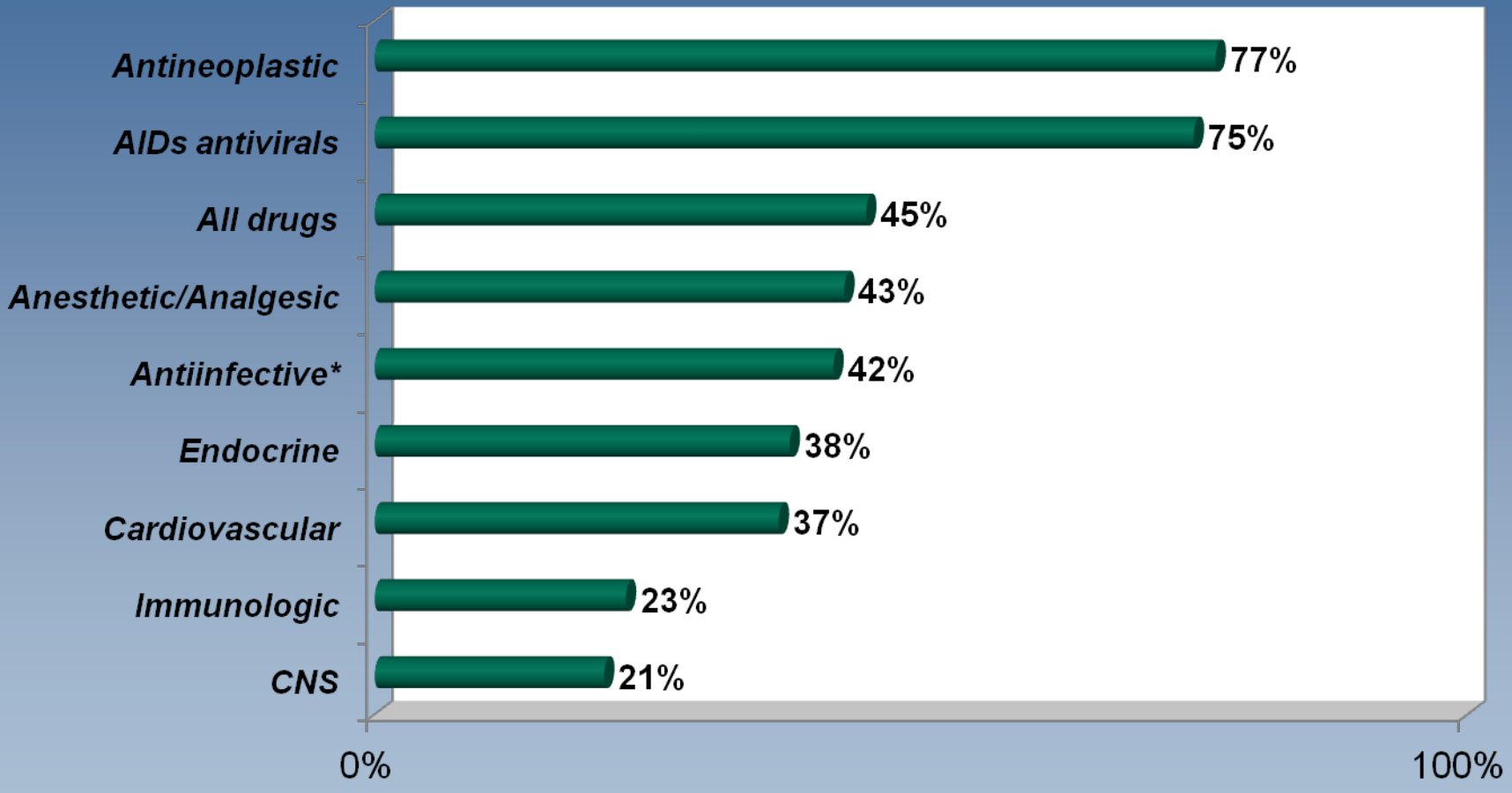
Source: Tufts CSDD Impact Report, vol 14, no 5, Sept/Oct 2012

Special Designation Status (FT, AA, EC & Orphan) Had Little Impact on Oncology Drug Approval Times in the U.S. and EU (2007-2011 approvals)



Source: Tufts CSDD Impact Report, vol 14, no 5, Sept/Oct 2012

Share of Approvals with FDA Priority Rating by Therapeutic Class, 2000-2011



** excludes AIDs antivirals*
Source: Tufts CSDD

Conclusions

- Technical risk in cancer drug development is very high, although the risk in some therapeutic classes is greater
- Cancer drug development risks vary significantly by cancer type, but not molecule size
- Clinical development times for cancer drugs are relatively high
- Approval phase times for cancer drugs, though, are relatively low
- Cancer drugs are much more likely to be included in special FDA programs designed to speed development and/or review
- Special FDA program status, however, is not associated with shorter approval times for cancer drugs

Tufts Center for the Study of Drug Development

Tufts University, Boston, Massachusetts, USA

Joseph A. DiMasi, Ph.D.
Director of Economic Analysis

Website
http://csdd.tufts.edu

Email
joseph.dimasi@tufts.edu

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