The Cost of Clinical Trial Delays

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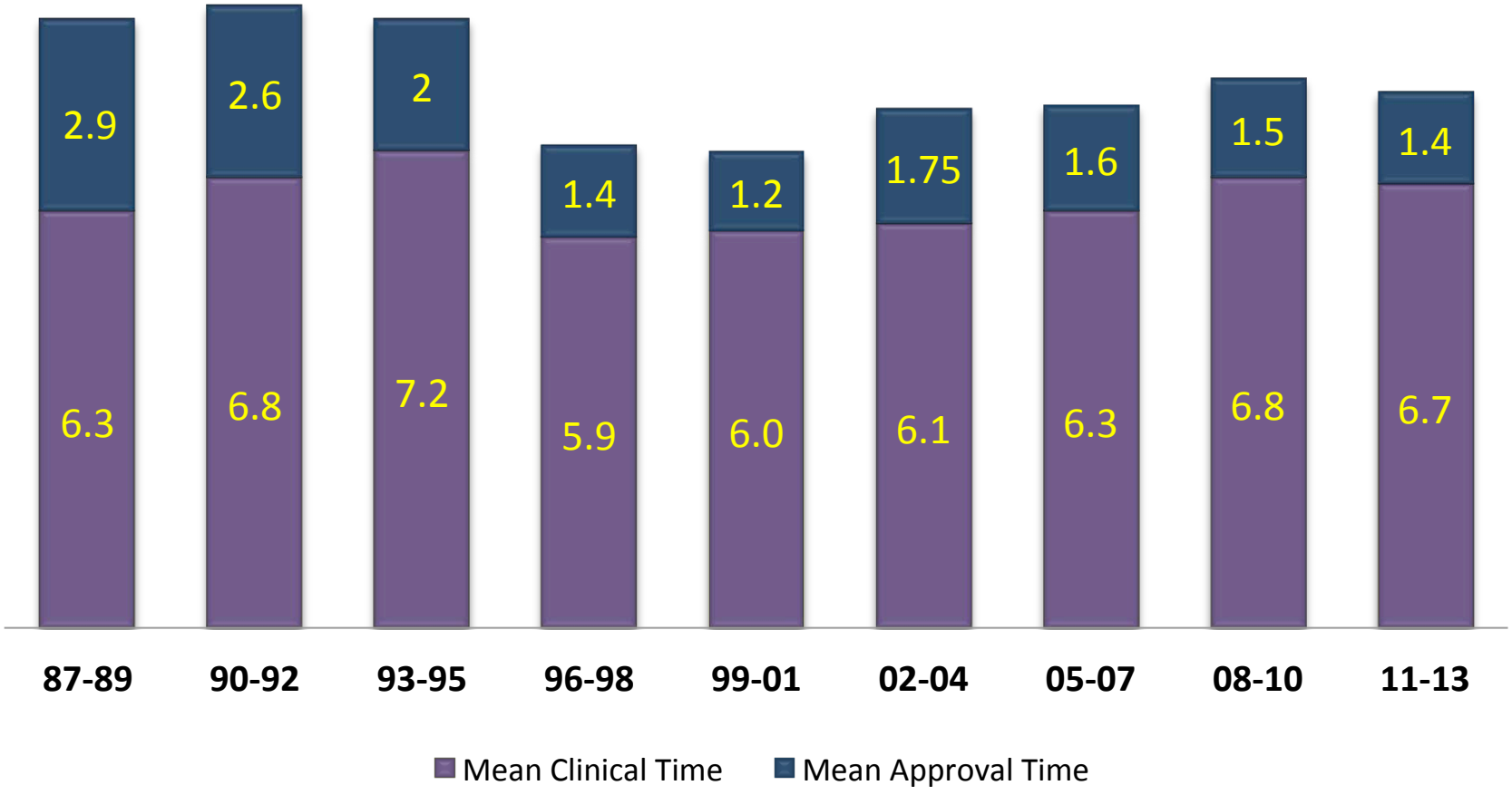
Agenda

- Incidence and causes of delays
- Quantifying the cost of delays
- Anticipating the impact of patient centric initiatives on reducing the cost of delays

Overall Drug Development Durations

(Cycle Time in Years from IND Approval to NDA Approval)



Source: Tufts, CSDD

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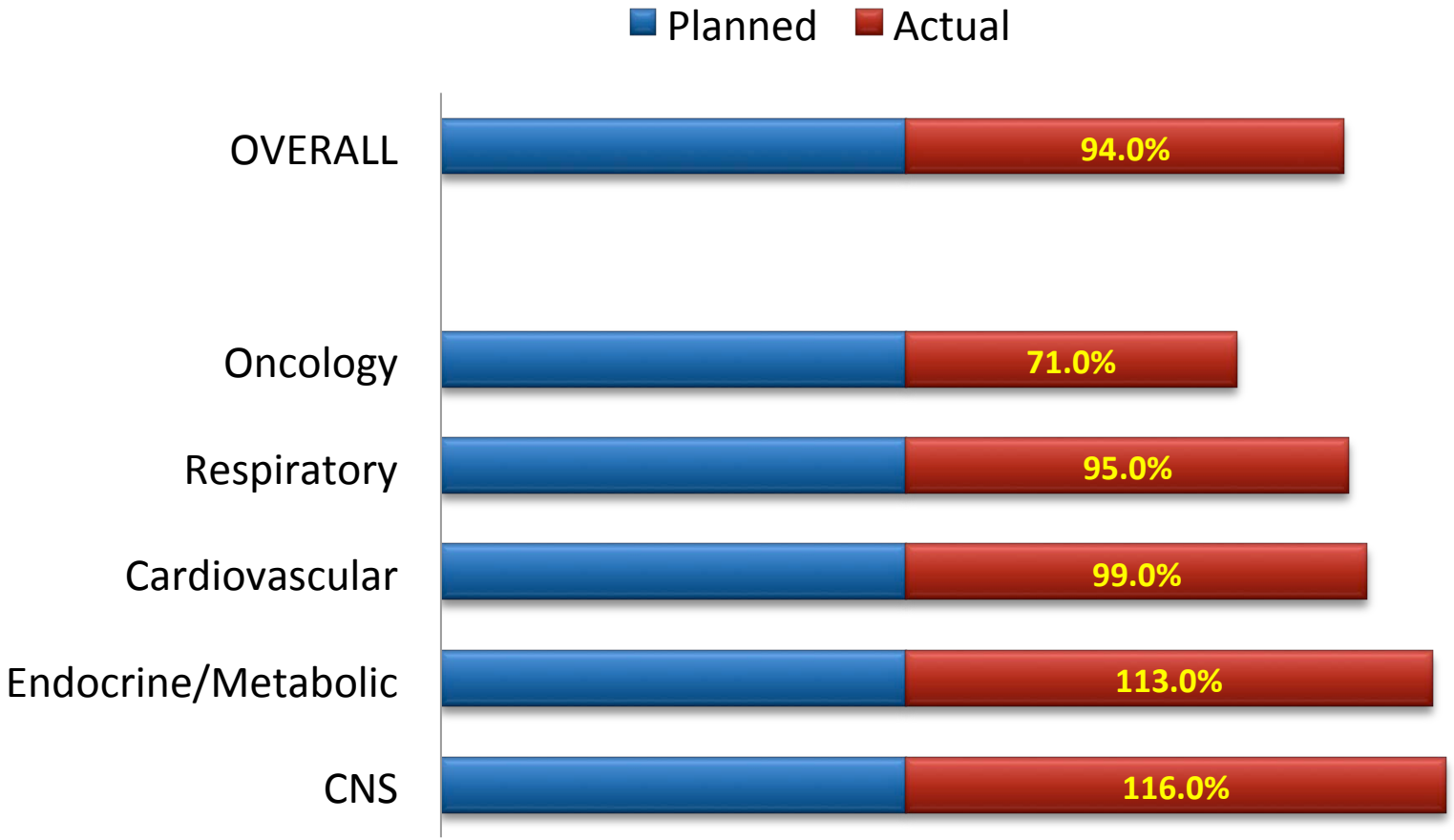
Actual Enrollment Timelines Typically Double Planned Timelines



Source: Tufts CSDD, 2012

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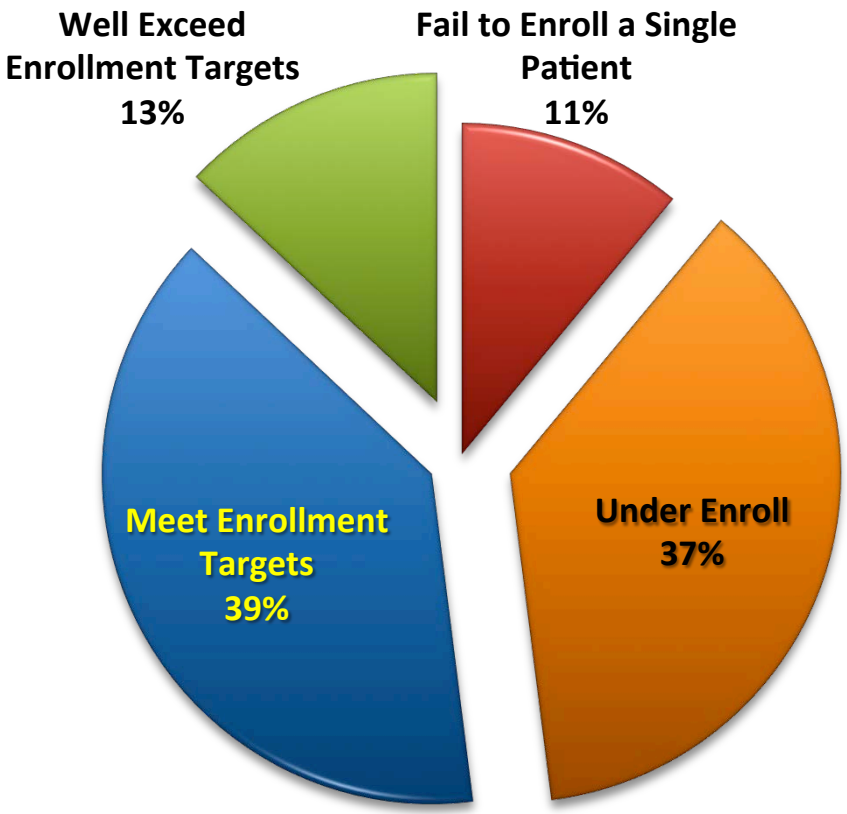
Investigative Site Enrollment Achievement



(N= 15,965 sites participating in 153 global phase II and III clinical trials)

Source: Tufts CSDD, 2012

Increasing Protocol Complexity

	A Typical Phase III Protocol	2002	2012
Scientific	Total Number of Endpoints	7	13
	Total Number of Procedures	106	167
	Proportion of Procedures that are 'Non Core'	18%	31%
	Total Number of Eligibility Criteria	31	50
Operating	Total Number of Countries	11	34
	Total Number of Investigative sites	124	196

Source: Tufts CSDD

Delays Associated with Complexity

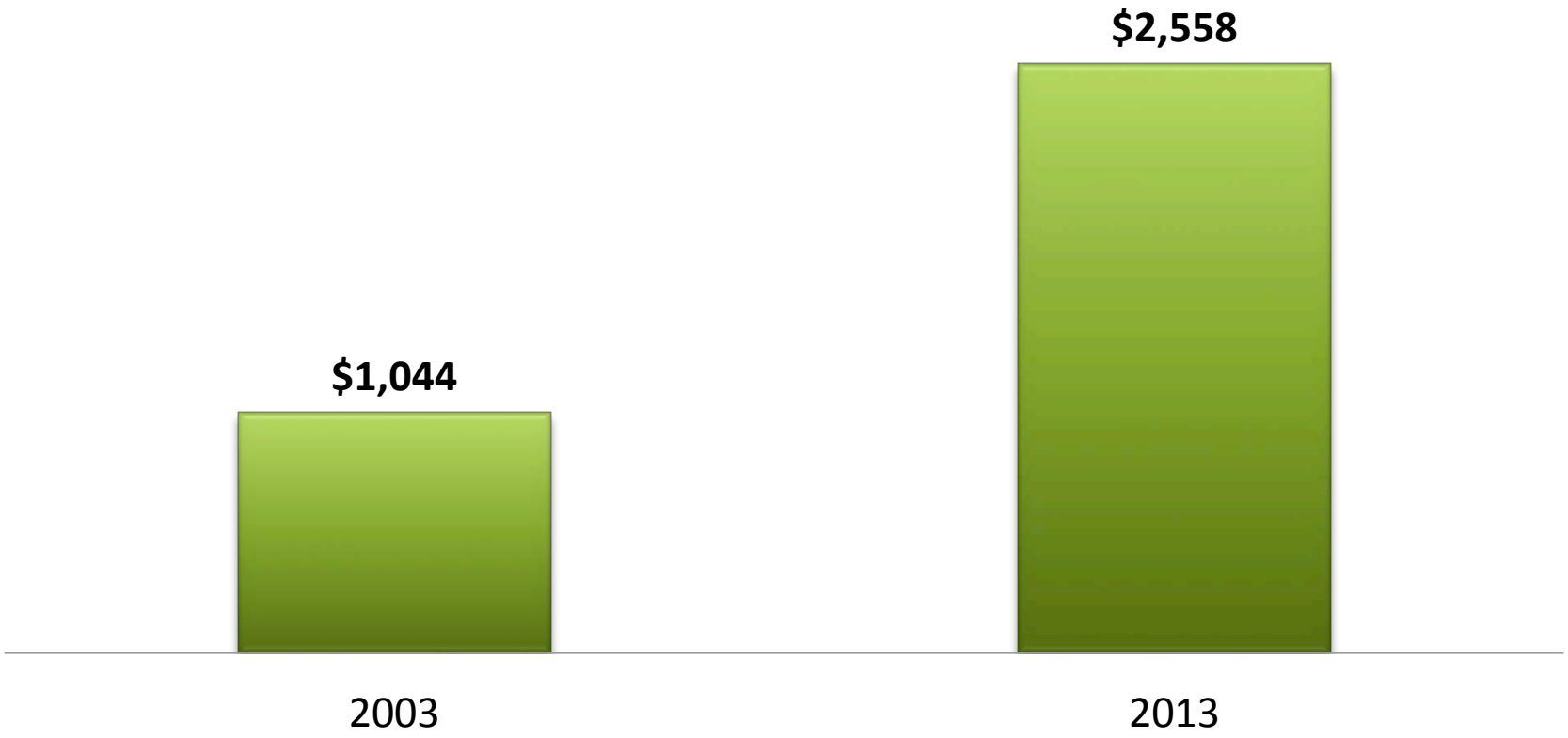
(All TAs, Phases II-III)

	Most Complex Protocols
Study volunteer screen to completion rate	-50%
Time from Protocol Ready to FPFV (median)	+12%
Time from Protocol Ready to LPLV (median)	+73%
Number of Amendments	+68%

Source: Tufts CSDD, 2013

Capitalized Cost to Develop an Approved New Drug has More than Doubled

($US millions expressed in 2013 dollars)



Source: Tufts CSDD

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Peeling Apart Direct and Capitalized Costs

	DIRECT COSTS	CAPITALIZED COSTS	Difference
Basic Research through Preclinical	$237 million	$358 million	51%
Clinical through Regulatory Approval	$474 million	$560 million	18%
Allocated Failures	$684 million	$1.6 billion	134%
TOTAL per APPROVED DRUG	$1.4 billion	$2.6 billion	

Source: Tufts CSDD

Assessing the Impact of Patient Centric Initiatives

Engagement Objective
1. Improved Feasibility
2. Enhanced Convenience
3. Greater Relevance
4. Higher Ownership and Participation

The Impact of Patient Centric Initiatives

Engagement Objective	Outcome
Feasibility	Speed and Efficiency; Success Rates
Convenience	Speed and Efficiency
Relevance	Speed and Efficiency; Success Rates
Ownership and Participation	Speed and Efficiency

Quantifying Impact

(Savings on Capitalized Costs in 2013 $s)

Level of Improvement	Cycle Time	Success Rate
5%	$102 million	$153 million
10%	$250 million	$384 million
25%	$390 million	$486 million

Source: Tufts CSDD

Q&A and Thank You!

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