Industry Practices that Benefit/Will Benefit by Patient Engagement

Ken Getz, MBA

Director of Sponsored Programs, Associate Professor

Tufts CSDD, Tufts University School of Medicine

Founder and Board Chair, CISCRP

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Drug Development Operating Conditions

	2005	2015
Number of Drugs in R&D Globally	**6,465**	**10,686**
Clinical Development Cycle Time *(IND Filing to NDA/BLA Submission)*	**6.3 years**	**6.8 years**
Regulatory Cycle Time *(NDA/BLA Submission to Approval)*	**1.6 years**	**1.6 years**
Approval Rate for All Drugs Entering Clinical Testing	**16.4%**	**11.3%**
Total Capitalized Cost to Develop a Single Successful Drug	**$1.04 Billion ($US)**	**$2.56 Billion ($US)**

DiMasi JA, Grabowski HG, Hansen RW. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. *Journal of Health Economics*. 2016; 47:20-33

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A Fundamental Challenge: Protocol Design Complexity

A Typical Phase III Protocol	2001 - 2005	2011-2015
Total Number of Endpoints	7	13
Total Primary and Key Secondary Endpoints	*4*	*5*
Total Number of Eligibility Criteria	31	50
Total Number of Procedures	110	187
Total Planned Volunteer Visits	12	15
Total Data Points Collected	494,236	929,203
Proportion of Data 'Non-Core'	18%	32%

Getz KA, Campo. Trends in Clinical Trial Design Complexity. *Nature Reviews Drug Discovery*. May 2017; 16:5

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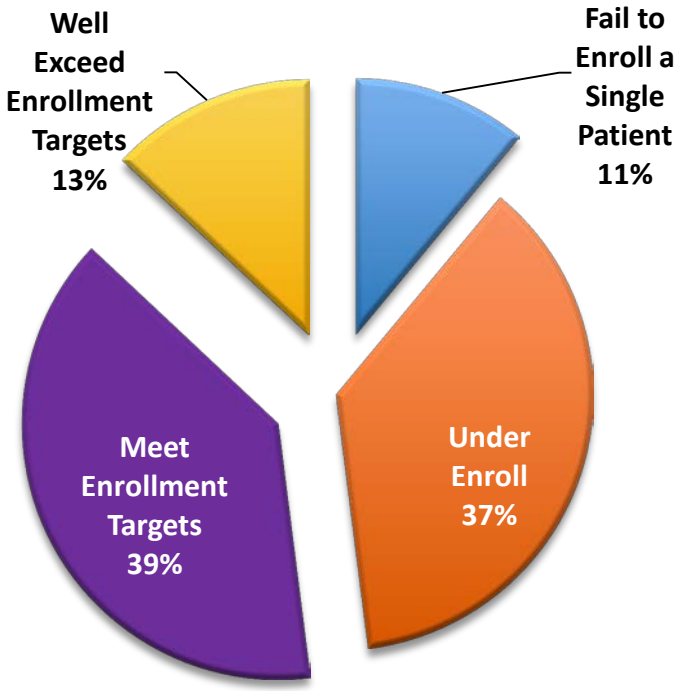
Impact on Patient Recruitment and Retention

Doubling Planned Timelines

	Increase in Planned Study Duration to Reach Target Enrollment
Overall	94%
Cardiovascular	99%
CNS	116%
Endocrine/Metabolic	113%
Oncology	71%
Respiratory	95%

Enrollment Activation and Achievement



Getz K. Improving Protocol Design Feasibility to Drive Drug Development Economics and Performance. *International Journal of Environmental Research and Public Health*. 2014;11(5):5069-5080.

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Impact on Study Execution

Typical Phase III Protocol (means)	2001-2005	2011-2015
Number of Investigative Sites	40	65
Number of Countries	5	10
Number of Patients Randomized	729	597
Proportion of Sites Using Mass & Social Media for Recruitment	41%	63%
Total Study Start-up Cycle Time *(Site Identification to First Patient In the Study)*	25.6 weeks (CoV .61)	29.1 weeks (CoV .87)
Number of Protocol Amendments	1.4	2.3
Time from Each Patient Visit to Data Entry	6.9 days (CoV .66)	8.1 days (CoV .89)
Last Patient Last Visit to Data Base Lock	33.4 days (CoV .75)	36.1 days (CoV .93)

Lamberti MJ, Chakravarthy R, Getz K. New Benchmarks for Study Conduct. *Applied Clinical Trials*. January 2017;25(12): 28-32.

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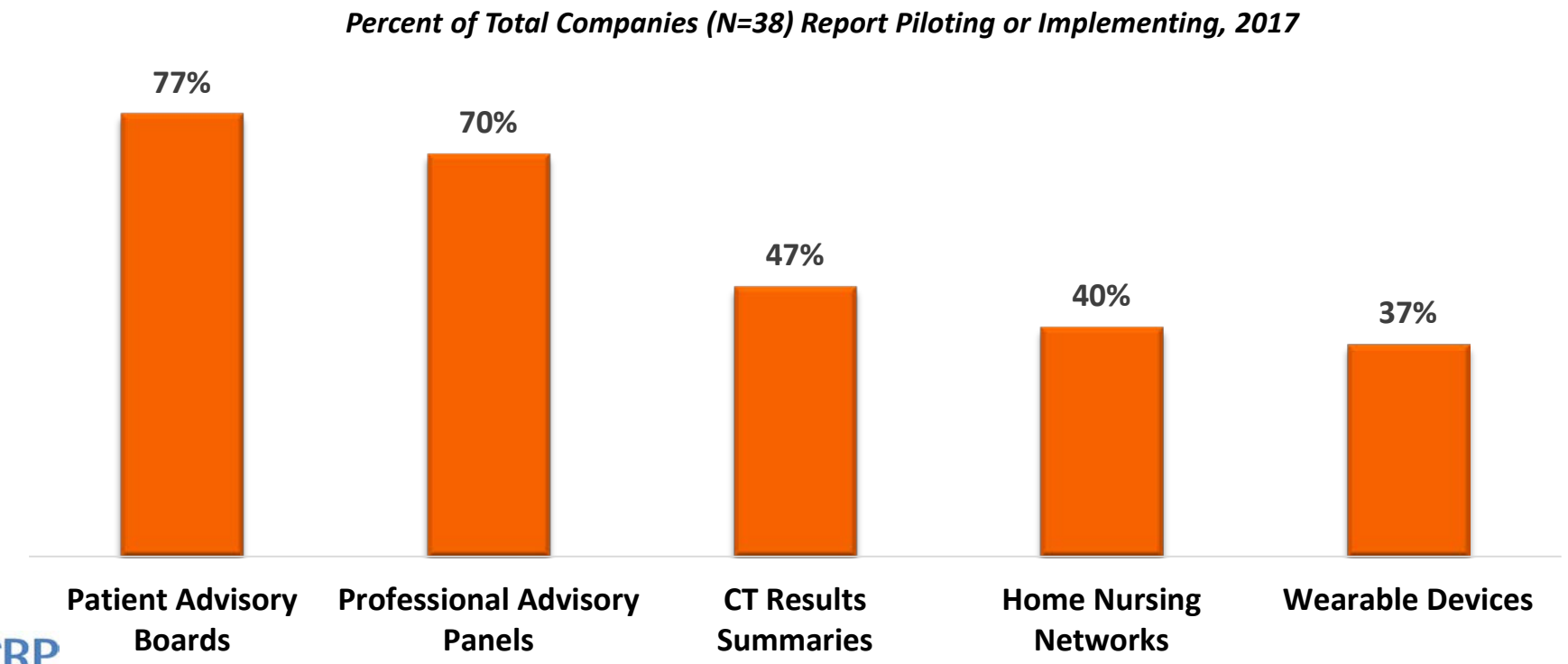
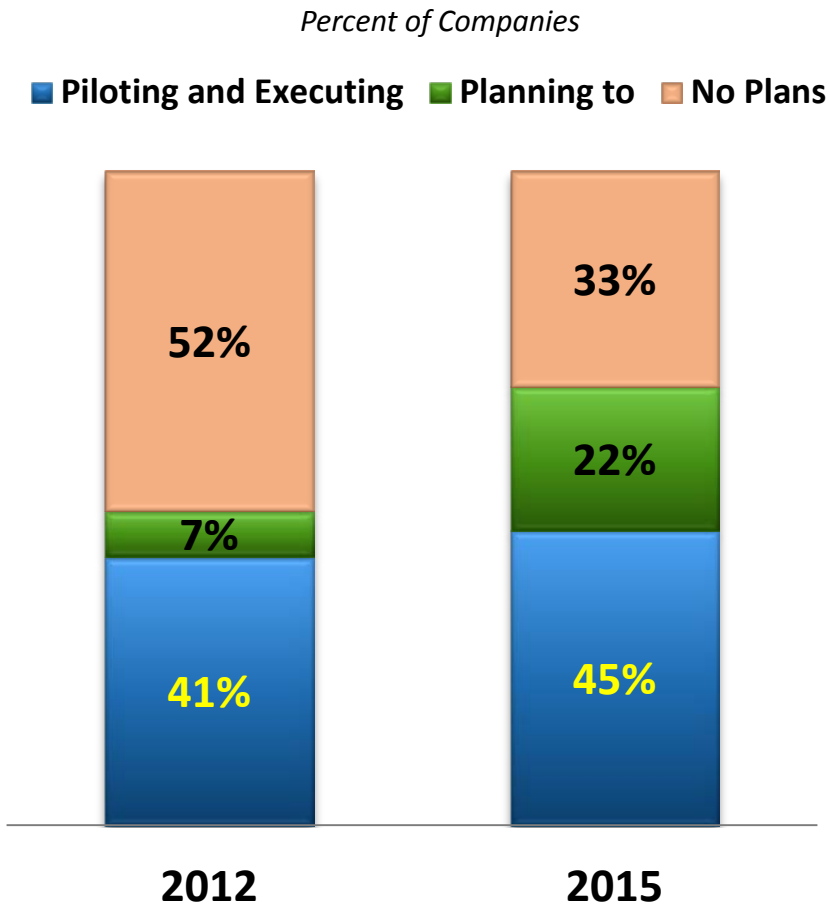
Primary Benefits of Patient Engagement

Focus/Relevance | **Feasibility** | **Convenience**



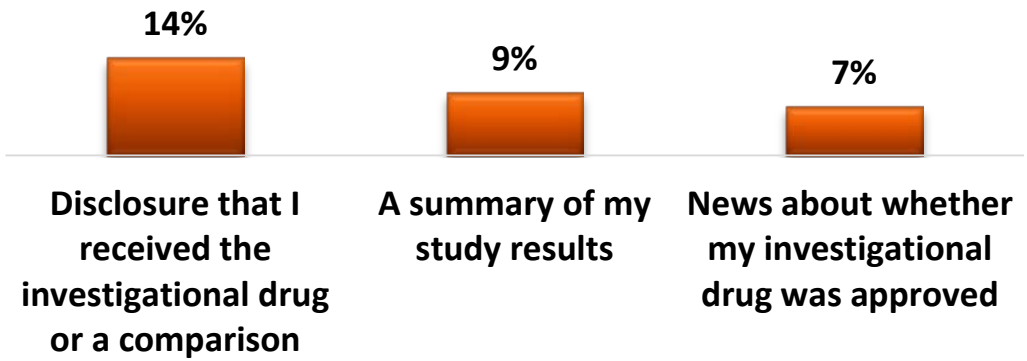
Getz K. Measuring Adoption and Value of Patient Engagement. *Applied Clinical Trials*. Feb 2017; 26:2.

Intent and Patient Centric Practice



Example: Plain Language Summaries

91% of patients feel that it is important to receive a summary of their clinical trial results… 30% report personally receiving some information about their study:



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Patient-Engaged Clinical Trials: Looking Ahead

- Ongoing, routine, broadly-supported public outreach and education raising overall literacy
- Customizable, flexible, intimate engagement with patients; enabled by and incorporated into their community of care
- Highly fluid and integrated infrastructure, systems and personnel supporting open, multi-party collaborations
- Continuous structured and unstructured data mining, analysis, and adaptation
- Remote quality, risk and performance oversight and management
- Personalized, plain language clinical trial results summaries as a standard practice

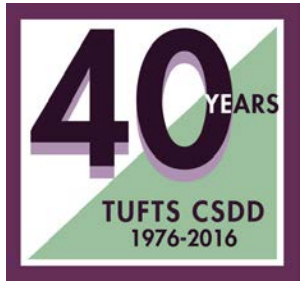
Thank You!

Ken Getz

Director, Sponsored Research Programs, Associate Professor

Tufts CSDD, Tufts University School of Medicine

617-636-3487, Kenneth.getz@tufts.edu



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