

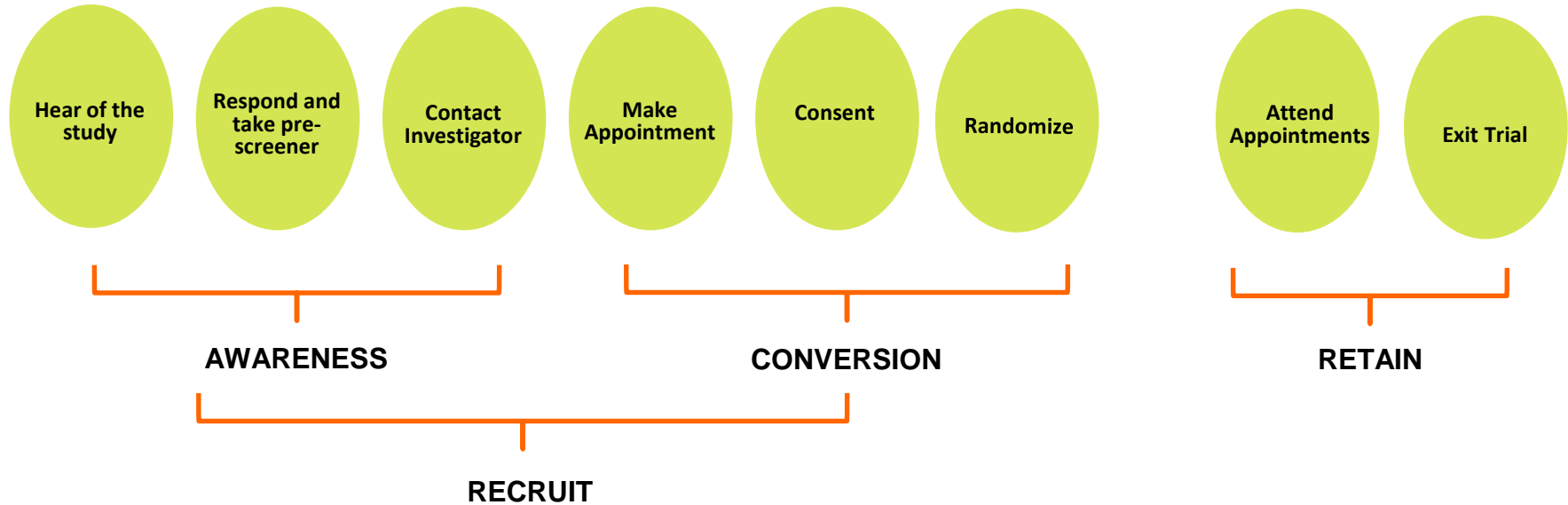
A Critical Need to Support Patient Centricity in Clinical Research

Ken Getz, MBA

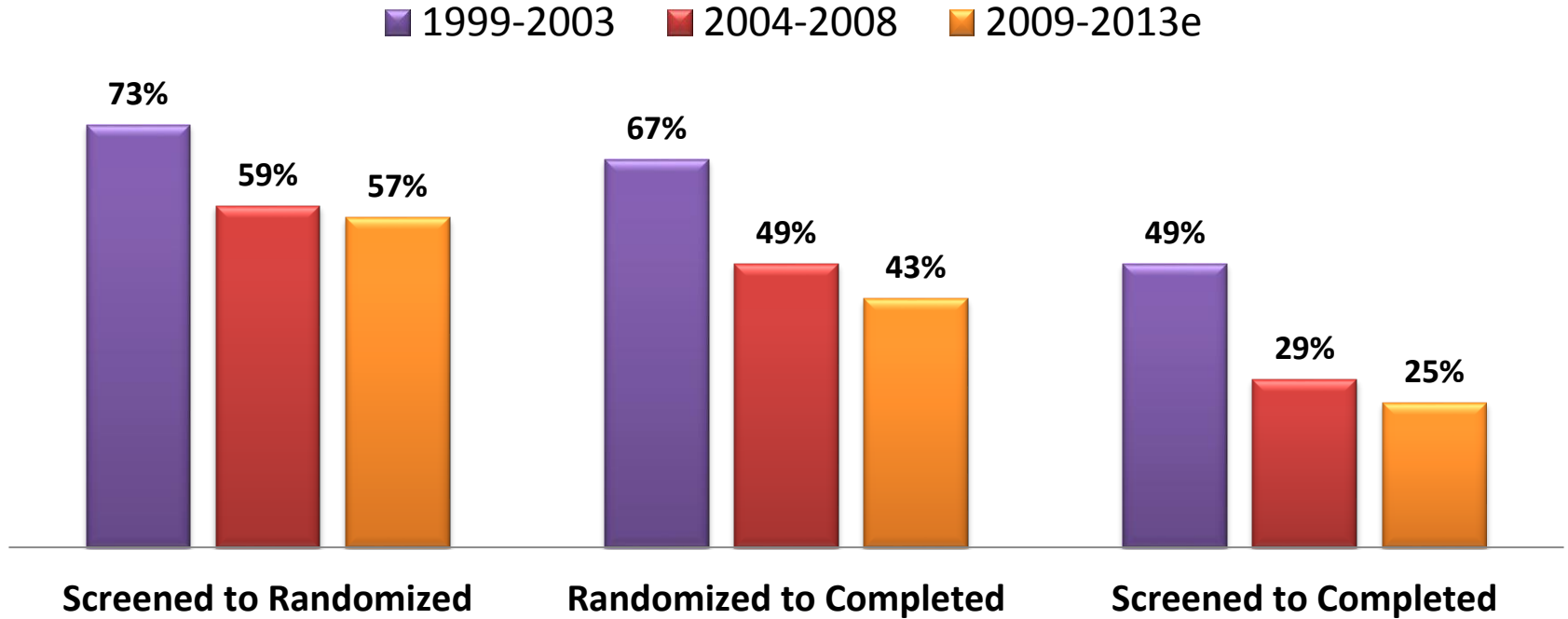
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The 'Trial Centric' Process



Worsening Patient Enrollment Rates



Source: Tufts CSDD; N=3,534 phase II-IV protocols

Primary Characteristics of ‘Trial Centricity’

**DO YOU HAVE ... YOU MAY
QUALIFY FOR A RESEARCH
STUDY.**

**...Announcing a new
breakthrough treatment for...**



- Focus on Filling Trials
- No Response to Negative Portrayals
- Resting on Our Laurels
- Ineffective and Misaligned Messages from the research community
- Failure to Customize Messages
- Failure to Engage the Public’s Network of Support

'Patient Centric' Clinical Trials Process

- Patient-driven research agendas, funding and participation
- Use of wide variety of channels (including social and digital media) to educate, reach and engage study volunteers
- Crowdsourced input into program planning and protocol design
- Direct-to-Patient Clinical Trial Participation for relevant studies
- Mobile health-based collection of vital signs and patient reported outcomes
- Shared findings and disseminating trial results to study volunteers
- Integrated and coordinated site and HCP participation

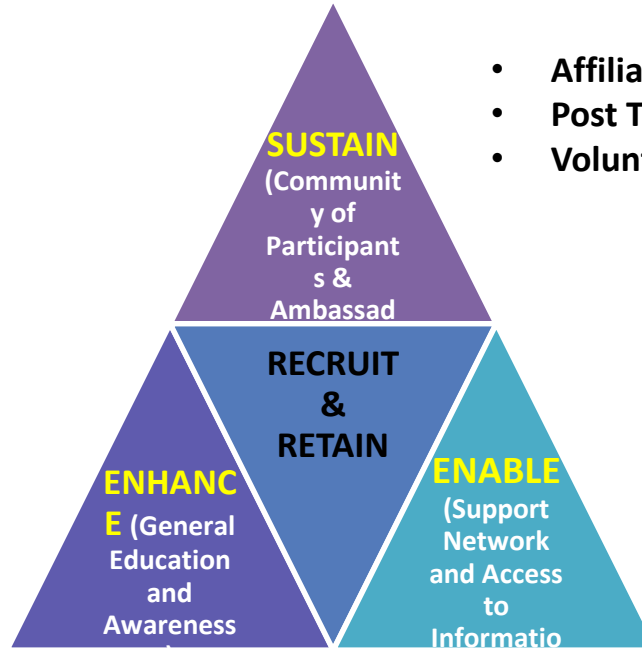
***It's Not About Bringing Patients to Trials;
It's About Bringing Trials to Patients***

Public and Patients Engaging the Research Enterprise

General Education	Development Planning and Fundraising	Study Design	Recruitment and Retention	Monitor and Analyze Data	Regulatory Review and Approval	Disseminate and Communicate Results	Education Ambassadors
Ongoing messages positioning participation and the Enterprise	Collaboration with patients and patient communities	Solicited input into design and feasibility from patients and patient communities	Awareness and encouragement from patient communities	Patient membership on DSMBs	Patient participation on advisory committees and post-market surveillance initiatives	Distribution & ongoing discussion through patients and patient communities	Interactions at community centers, the media, classrooms

- Supported by, and Coordinated with, enabled investigative sites
- Built on a foundation of engaged stakeholders including health care professionals and health educators

A Comprehensive Model of Engagement



- **AWARE for All**
- **‘Medical Heroes’ PSA**
- **Media Outreach**
- **Science Museum Exhibit**
- **Speakers Bureau**
- **Search Clinical Trials**
- **Legislation**
- **Gift of Participation**

- **Affiliation initiatives**
- **Post Trial Communication**
- **Volunteer Ambassadors**

- **Site/CTSA Support**
- **HC Provider Education**
- **Pharmacy-directed education**
- **‘Voice of the Patient’**
- **Medical Community Outreach**

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THANK YOU and Q&A

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