Board of Governors Meeting
via Teleconference/Webinar

September 27, 2016

12:00-1:30 p.m. ET

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors

Joe Selby, MD, MPH
Executive Director

Agenda

Time	Agenda Item
12:00	Call to Order, Roll Call, and Welcome
12:00 – 12:10	**Consent Agenda:** Minutes of the August 16, 2016 Board Meeting, Committee Nominations, and PEAP Chairs
12:10 – 12:40	**Consider for Approval:** FY2017 Budget
12:40 – 12:50	**Consider for Approval:** Sunset of Record Retention Policies and Revised Delegation of Authority
12:50 – 1:00	**Consider for Approval:** Addition to the 2015 Cycle 3 New Oral Anticoagulants (NOACs) PFA Award Slate
1:00 – 1:30	Update on the STRIDE Falls Prevention Trial
1:30	Wrap up and Adjournment

Welcome to PCORI's Newest Board Members

- We are honored to welcome two new Board members
  - Russell Howerton, MD, Chief Medical Officer and Vice President of Clinical Operations at Wake Forest Baptist Medical Center
  - Kathleen Troeger, MPH, Director of Outcomes Research at Hologic, Inc., a global healthcare and diagnostics company

Consent Agenda Items

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Nominations for EDIC, RTC, SOC, FAC Chairs, Vice Chairs

The Governance Committee is making the following nominations for approval by the Board:

- EDIC – Chair, Debra Barksdale (Reappointment for 2nd term)
  Vice Chair, Robert Jesse (Reappointment for 2nd term)
- RTC – Chair, Freda Lewis-Hall (Reappointment for 2nd term)
  Vice Chair, Allen Douma (Nominated for 1st term – no previous Vice Chair served)
- SOC – Chair, Robert Zwolak* (Nominated for 1st term)
  Vice Chair, Alicia Fernandez* (Nominated for 1st term)
- FAC – Chair, Larry Becker* (Nominated for 1st term)

*previously appointed to serve remaining term of previous Chair, Vice Chair

New Patient Engagement Advisory Panel Chair

Name	Stakeholder Group	Primary Affiliation	Term of Chair position (In Years)
Jane Perlmutter	Patients, Caregivers, Patient Advocates	Self-employed (Gemini Group)	1

Motion for Consent Agenda Items

That the Board approve:

- Minutes from the August 16, 2016 Board meeting
- Nominations for Chairs, Vice Chairs for the Engagement, Dissemination and Implementation Committee (EDIC), Research Transformation Committee (RTC), Science Oversight Committee (SOC), and the Finance and Administration Committee (FAC)
- Nomination for Chair of the Patient Engagement Advisory Panel (PEAP)

Board Vote

Call for a Motion to:	• **Approve** each of the Motions on the Consent Agenda
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Proposed FY2017 Budget
(October 1, 2016 – September 30, 2017)

Larry Becker

Chair, Finance and Administration Committee

Regina Yan, MA

Chief Operating Officer

Agenda

- Key Definitions
- Funding Commitment Plan
  - PCORI Estimated Revenue and Expenditures
  - Funding Commitment Plan through FY2017: By Funding Category
  - Cumulative Award Commitments vs. Award Payments
  - Total Revenue vs. Total Expenditures per Year
- Cash Balances
  - Projected FY2016
  - Projected FY2017
- FY2017 Budget Overview
  - Budget Development Process
  - Key Budget Themes
  - Major Components
  - FY2017 Proposed vs. FY2016 Projection
  - Key Drivers of Increase
- Motion to Approve

Key Definitions

Award Commitments – the amount of funding PCORI intends to award or has awarded, most in the form of multi-year contracts for research, infrastructure, engagement, and dissemination awards

Award Payments – the amount PCORI pays to research, infrastructure, and engagement/dissemination awardees in response to invoices received for costs incurred under awarded contracts

- Note: Award commitments occur earlier than award payments. Award payments lag award commitments and the associated payments are spread over multiple years

Program Expenses – all program award payments as well as all direct operating costs (including personnel), associated with Science, Infrastructure, Engagement, and Dissemination departments and the Methodology Committee

Program Support – all operating costs, including personnel, associated with Evaluation & Analysis, Contract Management Administration, and Communications departments

Administrative Support – all operating costs, including personnel, associated with Board of Governors/Governance, Office of the Executive Director, General Counsel, Chief Operating Officer, which also includes Information Technology, Finance, Procurement, Human Resources, and Administrative Services

PCORI Estimated Revenue and Expenditures

	In Millions	% of Total Expenditures
Revenue (thru FY2019)	$3,469	
Program Expenses (thru FY2024)	**$3,108**	**90%**
Award Payments (Research/Infrastructure/Engagement)	$2,681	78%
Dissemination	$103	3% (or 4% of Awards)
Other Program Expenses	$324	9%
Program Support (thru FY2024)	**$113**	**3%**
General Admin (thru FY2024)	**$248**	**7%**
Total Expenditures*	**$3,469**	**100%**

* $2.7 billion expected to be committed by FY2019. Expenses will continue through FY2024 until all research projects are completed.

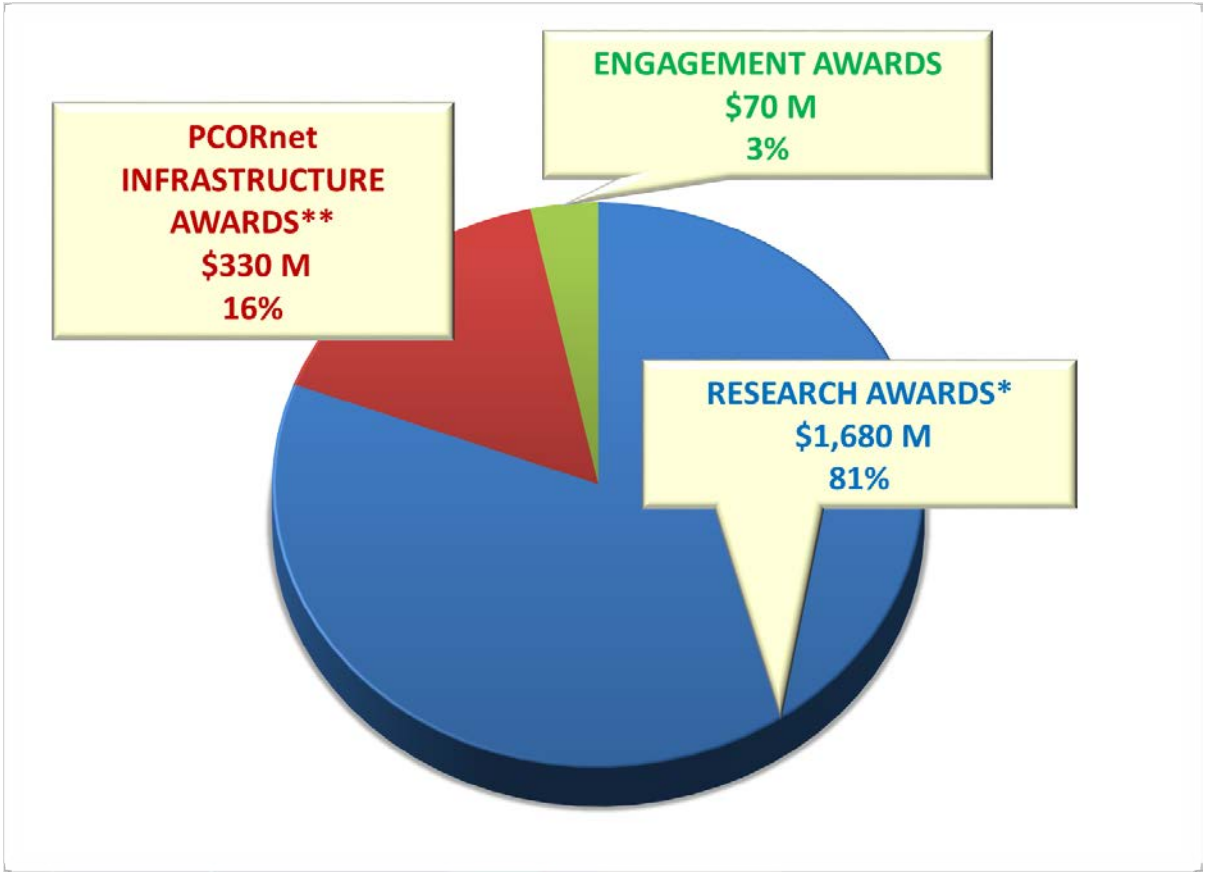
Dissemination:	Includes all PCORI dissemination activities, plus funds PCORI provides to awardees to conduct dissemination.
Other Program Expenses:	Includes all direct operating costs (including personnel), associated with Science, Infrastructure, Engagement, and Dissemination departments and the Methodology Committee.
Program Support:	Includes all operating costs, including personnel, associated with Evaluation & Analysis, Contract Management Administration, and Communications departments.
General Admin:	Includes costs related to the Board, administrative staff, rent, IT system infrastructure, etc.

Funding Commitment Plan (through FY2017)

At the end of FY2017, PCORI plans to have committed 78% of its total award commitments funds of $2.681 billion

COMMITMENTS ($ in millions)	**Prior**	**FY2016 Projection**	**FY2017 Proposed**	**Cumulative as of Sep 30, 2017**
Research Awards (includes PCORnet Research)	$ 952	$ 306	$ 422	$ 1,680
PCORnet Awards (Infrastructure)	252	44	34	330
Engagement and Pipeline to Proposal Awards	19	24	27	70
Total Commitments	**$ 1,223**	**$ 374**	**$ 483**	**$ 2,080**

Cumulative Funding Commitment Plan:
By Funding Category (FY2012 – FY2017)

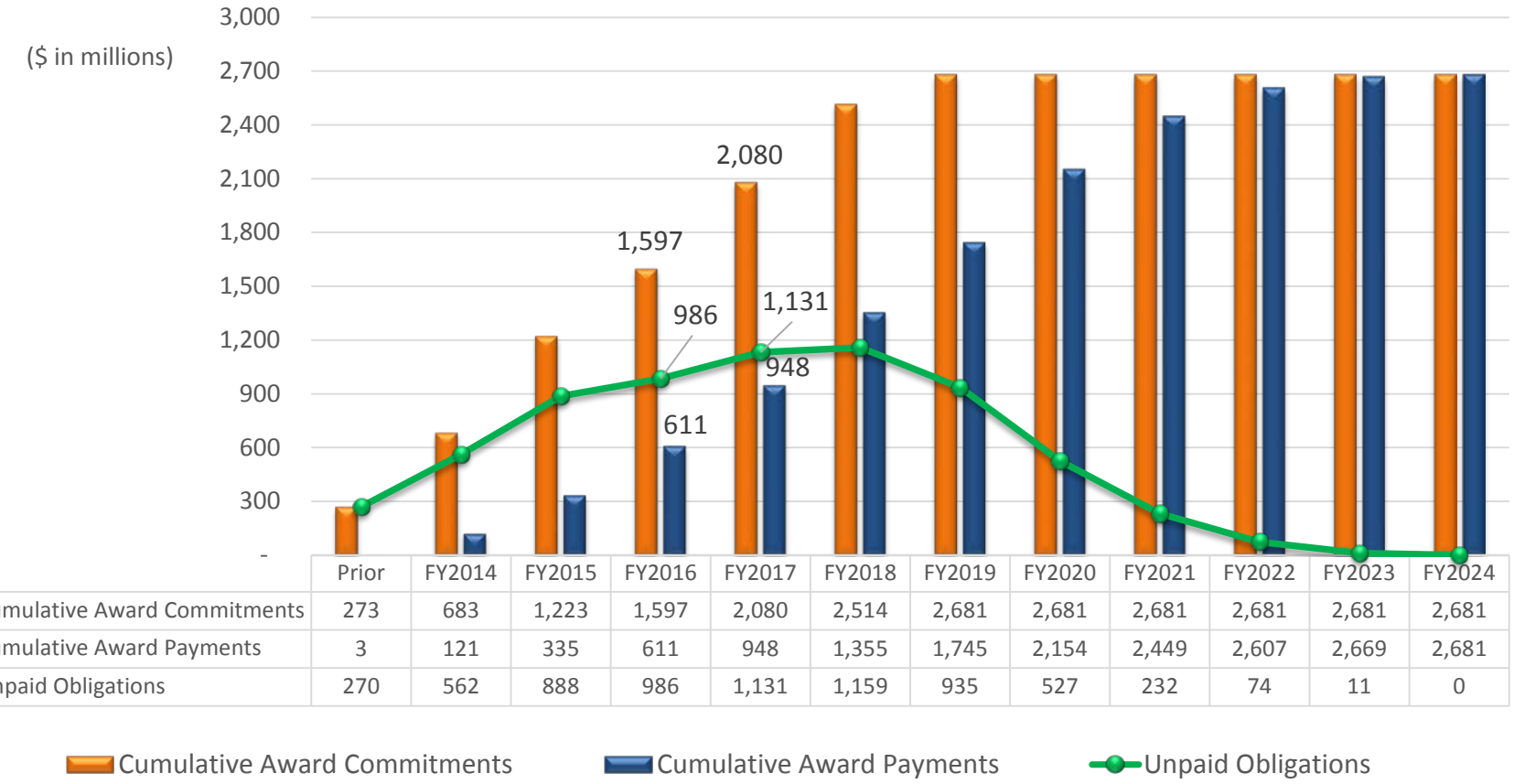


* Research funding commitments include projects conducted within PCORnet.

** PCORnet Infrastructure funding commitments are CER capacity building investments that make the data and partnerships with patients, clinicians and researchers available to CER researchers, but does not actually invest in Research that uses this infrastructure, as does the Research funding.

Cumulative Award Commitments vs. Award Payments

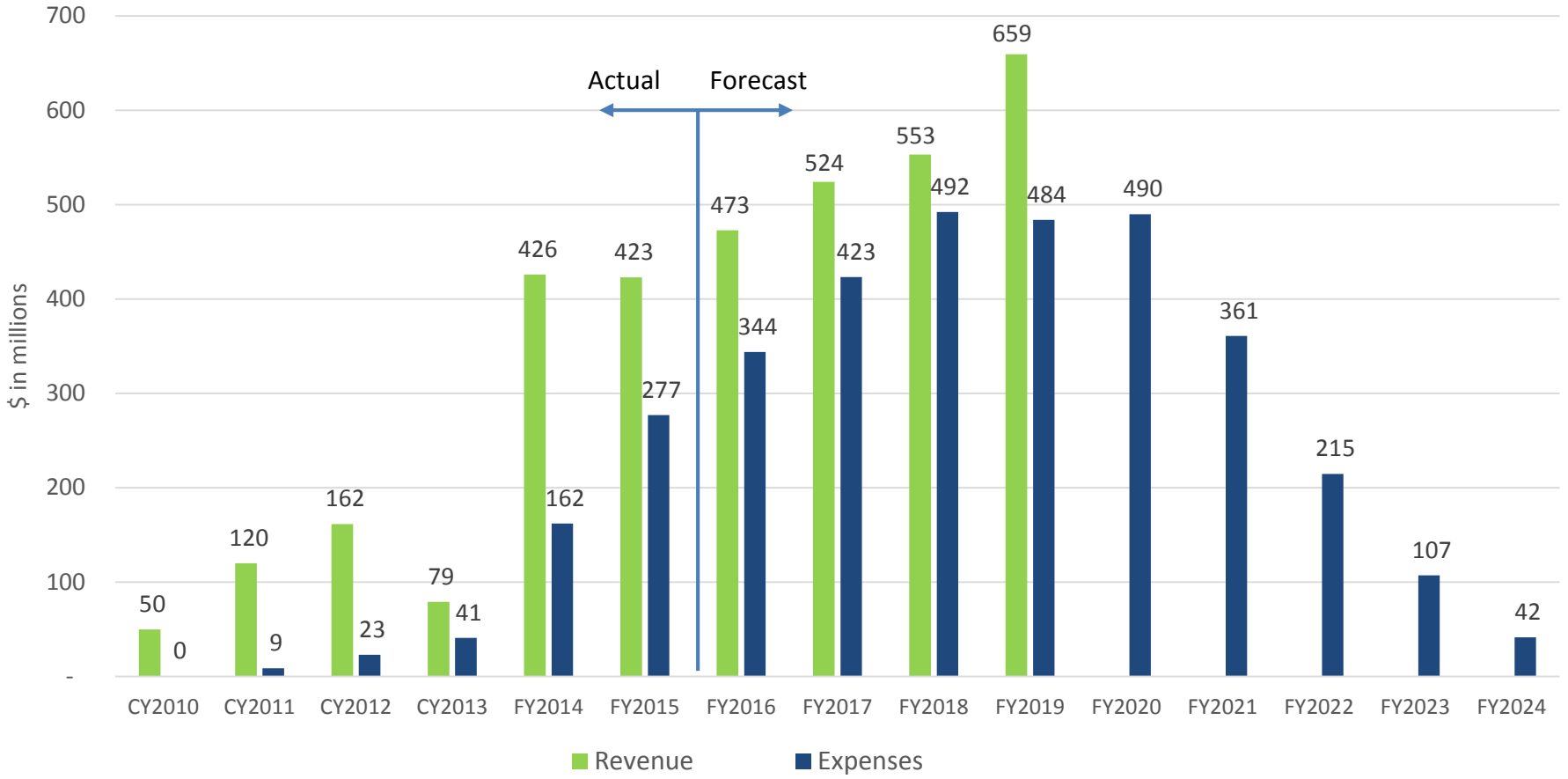
$2.7 billion will be committed by 2019 (excluding Dissemination Awards). Award Payments are anticipated to continue through 2024



	Prior	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Cumulative Award Commitments	273	683	1,223	1,597	2,080	2,514	2,681	2,681	2,681	2,681	2,681	2,681
Cumulative Award Payments	3	121	335	611	948	1,355	1,745	2,154	2,449	2,607	2,669	2,681
Unpaid Obligations	270	562	888	986	1,131	1,159	935	527	232	74	11	0

Total Revenue vs. Total Expenditures Per Year

PCORI has modeled its cash flow to ensure proper management and closing out of research obligations and operations expected to occur through 2024 based on revenue received through 2019



Note: In calendar year 2013, the Board of Governors voted to change the financial reporting period for PCORI to a fiscal year that begins on October 1 and ends on September 30 of each year. Total revenues and expenses for the nine-month fiscal year January 1, through September 30, 2013, are presented for illustration purposes.

Projected FY2016 Cash Balances

CASH FLOW ($ in Millions)	
Cash balance on September 30, 2015	**$748**
Cash receipts (FY2016)	473
Cash disbursements (FY2016)	(344)
Projected cash balance on September 30, 2016 [1]	**$877**
Outstanding Award Obligation – September 30, 2016	**$986**

[1] Includes funds in the operating accounts and PCORTF.

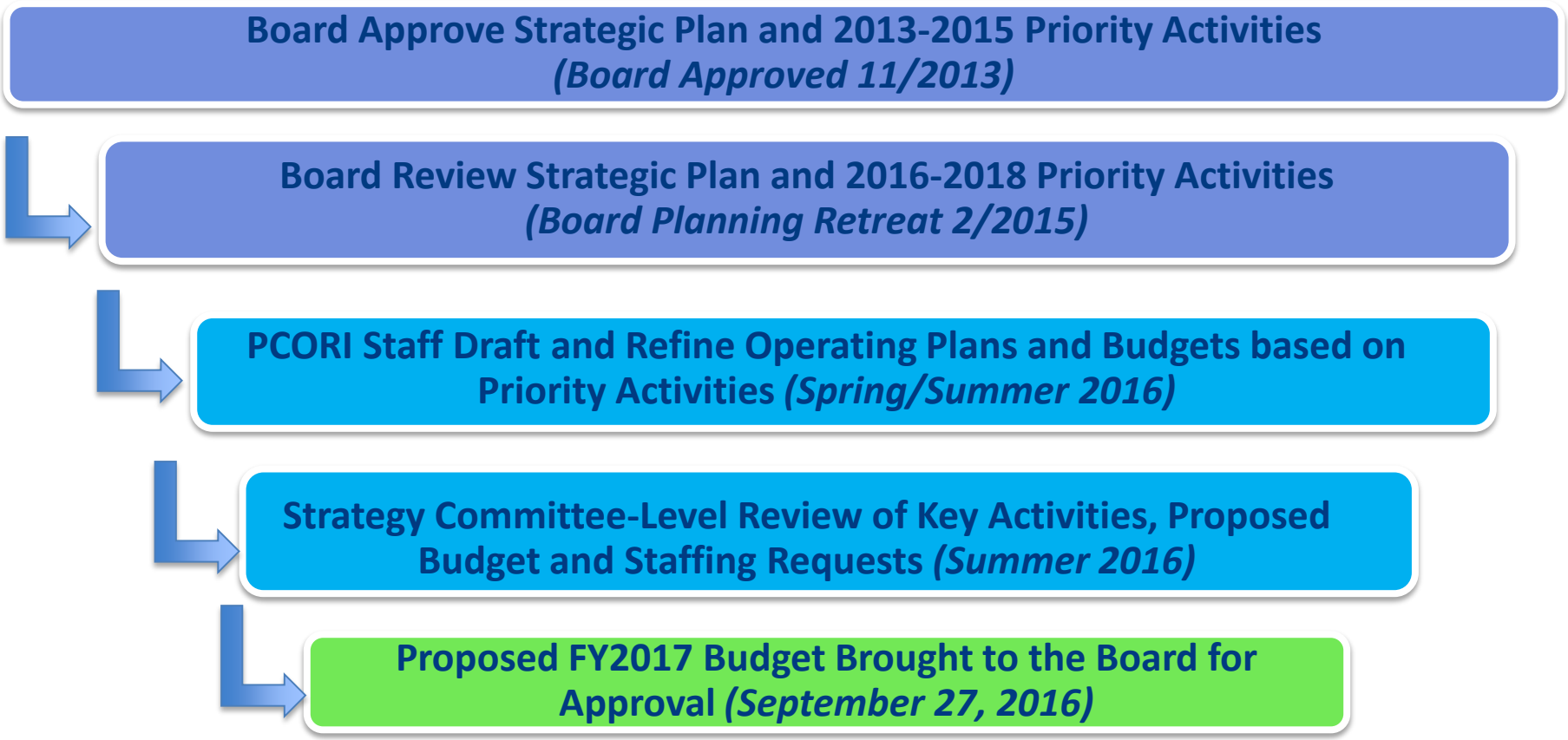
Projected FY2017 Cash Balances

CASH FLOW ($ in Millions)	
Projected cash balance on September 30, 2016	**$877**
Cash receipts (FY2017)	524
Cash disbursements (FY2017)	(423)
Projected cash balance on September 30, 2017 [1]	**$977**
Outstanding Award Obligation – September 30, 2017	**$1,131**

[1] Includes funds in the operating accounts and PCORTF.

Budget Development Process

PCORI's budget is developed through a comprehensive process grounded in its strategic plan



FY2017 Budget Overview

Key 2017 Budget Themes

- **Increase in payments for Research Awards**
  - *$1.5 billion awarded in research projects (as of July 31, 2016)*
- **Launch of Peer Review Process of PCORI-Funded Research**
  - *Expect $9.4 million of activities over 6 years*
- **Initiation of Dissemination and Implementation Program**
  - *Lay translation of results of PCORI funded projects; Implementation of legislative mandate of public reporting; Dissemination & Implementation awards; and publication of PCORI findings in peer-review Journals*

FY2017 Budget Overview: Major Components

Financial Presentation	2017 Budget	
REVENUE	$ 523,985,819	
EXPENSES		
PROGRAM EXPENSES (Award Payments & Program Expenses)		
Research	262,819,126	
Infrastructure (PCORnet)	78,548,284	
Engagement	32,147,465	
Dissemination	5,638,679	
	379,153,554	90%
PROGRAM SUPPORT		
Evaluation & Analysis	3,190,342	
Contracts Management & Administration	5,929,619	
Communications	5,395,250	
	14,515,211	3%
ADMINISTRATIVE SUPPORT		
Board of Governors/Governance	743,000	
Management and General	28,664,689	
	29,407,689	7%
TOTAL EXPENSES	$ 423,076,454	100%
NET CHANGE IN ASSETS	$ 100,909,365	

FY2017 Budget vs. FY2016 Projection

EXPENDITURES	2017 Budget		2016 Projection		FY '17 Budget vs. FY '16 Projection $ Var	% Var
REVENUE	$ 523,985,819		$ 472,664,219		$ 51,321,600	11%
EXPENSES						
PROGRAM EXPENSES						
(Award Payments & Program Expenses)						
Research	262,819,126		226,764,154		36,054,972	16%
Infrastructure (PCORnet)	78,548,284		59,461,589		19,086,695	32%
Engagement	32,147,465		20,174,218		11,973,247	59%
Dissemination	5,638,679		-		5,638,679	100%
TOTAL PROGRAM EXPENSES	379,153,554	90%	306,399,961	89%	72,753,593	24%
PROGRAM SUPPORT						
Evaluation & Analysis	3,190,342		1,336,681		1,853,661	139%
Contracts Management & Administration	5,929,619		5,500,967		428,652	8%
Communications	5,395,250		3,698,721		1,696,529	46%
TOTAL PROGRAM SUPPORT	14,515,211	3%	10,536,369	3%	3,978,842	38%
ADMINISTRATIVE SUPPORT						
Board of Governors/Governance	743,000		949,914		(206,914)	(22%)
Management and General	28,664,689		25,853,509		2,811,180	11%
TOTAL ADMINISTRATIVE SUPPORT	29,407,689	7%	26,803,423	8%	2,604,266	10%
TOTAL EXPENSES	$ 423,076,454	100%	$ 343,739,753	100%	$ 79,336,701	23%

FY2017 Budget: Key Drivers of Increase

- **$423 million** draft FY2017 operating budget
  - **$79.3 million (23%)** over FY2016 projection
- Key Drivers of Increase over FY2016 Projection:
  - $65 M in award payments for the following areas:
    - *Research*
    - *Infrastructure*
    - *Engagement*
    - *Dissemination*
  - $5 M in personnel costs
    - *Represents additional 30 funded positions in FY2017 (an average of 250 funded FTEs in FY2017 versus 220 funded FTEs in FY2016)*
  - $4 M in Peer Review costs, Training Initiatives *(Research 101 and Team Science),* Research Evidence Mapping costs, and topic brief development costs

Board Vote

Call for a Motion to:	• **Approve** the Proposed FY2017 Budget
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Updated Delegation of Authority and Record Retention Policies

Larry Becker
Chair of the Finance and Administration Committee

Mary Hennessey, Esq.
General Counsel

Regina Yan, MA
Chief Operating Officer

Updated Delegation of Authority and Expenditure Approval Policy

- Addresses the circumstances under which an officer, director, employee, or other representative of PCORI may legally bind PCORI, authorize payments, and/or commit to expenditures on behalf of PCORI
- Originally approved by the Board in 2011. Many of the 2011 provisions are outdated, conflict with other Board-approved policies, or could be improved, streamlined, and/or clarified
- The revised policy addresses substantive areas that were addressed in the original 2011 policy as well as parts of the *Decision Making Matrix* approved by the Board in 2013
- Some provisions of the 2013 *Decision Making Matrix* are duplicative of the revised policy, some are outdated, and others can be addressed in other policies or procedures

Updated Delegation of Authority and Expenditure Approval Policy

- The Finance and Administration Committee (FAC) recommends that the Board:
  - Approve the proposed revised Delegation of Authority and Expenditure Approval Policy
  - Sunset the 2011 Delegation of Authority Policy
  - Sunset the 2013 Decision-Making Matrix

Updated Record Retention Policy

- Establishes standards for the retention and destruction of core corporate and governance records of PCORI
- Originally approved by the Board in 2011. Since that time, PCORI has matured and become a more complex organization
- Revised policy reflects applicable legal requirements and core governance and operational needs
- The FAC recommends that the Board:
  - Sunset the 2011 Record Retention Policy
  - Affirm that Executive Staff have authority to approve updated and future versions of the Policy, keeping the FAC informed to ensure that PCORI can update the revised Policy as needed to comply with legal requirements and meet governance and operational needs

Board Vote

Call for a Motion to:

- **Sunset** the following Board-approved policies:
  - ***Record Retention Policy*** (approved 01.20.11) and affirm that Executive Staff have authority to approve revised versions, keeping the FAC informed
  - ***Delegation of Authority Policy*** (approved 03.08.11)
  - ***PCORI Decision Making Matrix – Responsibility by Functional Area*** (approved 11.18.2013)

Call for the Motion to Be Seconded:

- **Second** the Motion
  - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

- Vote to **Approve** the **Final** Motion
  - Ask for votes in favor, opposed, and abstentions

Board Vote

Call for a Motion to:	• **Approve** the proposed revised ***Delegation of Authority and Expenditure Approval Policy***
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Addition to the 2015 Cycle 3
New Oral Anticoagulants (NOACs) in the Extended Treatment of Venous Thromboembolic Disease
Targeted PFA Award Slate

Christine Goertz, DC, PhD

Chair, Selection Committee

Evelyn P. Whitlock, MD, MPH

Chief Science Officer

Objective of the Targeted PFA

- This initiative addresses important questions for comparing alternatives for extended treatment with anti-coagulants (blood thinners) in patients with deep vein thrombosis or pulmonary embolism (types of blood clots) and addresses gaps in high-quality information on the risks and benefits of extending blood thinner treatment beyond three months
- Priority Research Question:
  - How do different strategies for extended anticoagulation (blood thinning) treatment compare for patients who have completed a course of treatment after an initial episode of blood clot in the leg (deep vein thrombosis) or lung (pulmonary embolism)?
- Funds Available: up to $30M
- In July, 2016 the Board approved funding two research projects for a total of $6.5M
- We propose to fund a 3rd application today

Cycle 3, 2015 Slate Overview – An Update

- 12 Letters of Intent (LOIs) submitted
- 9 LOIs invited to submit a full application (75%)
- 8 applications were received (89% of invited LOIs)
- In July 2016, Board funded 2 applications* out of 8 received applications (25%)
- The Selection Committee approved one RCT for further programmatic review
  - *Warfarin vs Direct Oral Anticoagulants for Secondary Prevention of Recurrent Venous Thromboembolism: a randomized comparative effectiveness trial*
- Staff have worked extensively with the investigator and research team to ensure that the RCT study design is robust and the project plan is feasible
- We propose funding this RCT using the remaining allocated funds from the targeted PFA

*Recommended by the Selection Committee

Warfarin vs Direct Oral Anticoagulants for Secondary Prevention of Recurrent Venous Thromboembolism: a randomized comparative effectiveness trial

- **Research Question:**
  - Are all direct oral anticoagulants/regimens equivalent for efficacy and safety for long term treatment of venous thromboembolism (VTE)?
- **Population:**
  - Adults with confirmed acute symptomatic and unprovoked deep vein thrombosis/pulmonary embolism, previously treated with oral anticoagulation for 3-6 months, and at high risk for recurrent VTE
- **Intervention:** Rivaroxaban or apixaban
- **Comparator(s):** Warfarin
- **Outcomes of Interest:** Safety (major and clinically-relevant non-major bleeding); Effectiveness (VTE recurrence)
- **Study Design:** Pragmatic prospective, randomized, open-label, blinded endpoint three-arm clinical trial
  - Sample Size: 3,165 (60 sites est.)
- **Length of Follow-up:** 12 months
- **Budget:** $14.8M

Warfarin vs Direct Oral Anticoagulants for Secondary Prevention of Recurrent Venous Thromboembolism: a randomized comparative effectiveness trial (cont.)

- **Engagement:**
  - Key partners include the national blood clot organization, clinical societies, payers, purchasers, and industry; all will participate in the study advisory committee which will provide feedback to the scientific steering committee throughout the study; a patient representative will serve on both committees

- **Potential Impact:**
  - Patients and clinicians must consider the balance of recurrent venous thromboembolism with major bleeding events—study results will offer insight into the risks and benefits of common alternatives: rivaroxaban, apixaban, and warfarin

New Oral Anticoagulants (NOACs) in the Extended Treatment of Venous Thromboembolic Disease

*1 New Recommended Project**

Approved 2 Projects

Proposed 2 + 1 = 3 Projects

PFA	Allotted	Previously Awarded Budget	Proposed Total Budget*
New Oral Anticoagulants (NOACs) in the Extended Treatment of Venous Thromboembolic Disease	**$30M**	**$6.5M**	**$21.3M**

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.

*Total budget = direct + indirect costs

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended additional award from the Cycle 3, 2015 New Oral Anticoagulants (NOACs) in the Extended Treatment of Venous Thromboembolic Disease Targeted PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

STrategies to
Reduce
Injuries and
Develop confidence in
Elders

STRIDE: A Multisite Pragmatic Trial to Reduce Serious Falls-related Injuries

Shalender Bhasin, MD
Thomas Gill, MD
David B. Reuben, MD

© 2014 STRIDE

Background

- 1/3 of older Americans fall each year
  - 20-30% of these have moderate to severe injuries (e.g., hip fractures, head trauma)
  - Leading cause of fatal and nonfatal injuries
  - < 50% discuss their falls with PCP
- Despite evidence that falls can be prevented by multifactorial intervention, the quality of care for falls remains poor

The STRIDE Study

- Funders: Patient-Centered Outcomes Research Institute (PCORI) and National Institute on Aging
- Joint Principal Investigators
  - Shalender Bhasin (Harvard/Partners HealthCare)
  - Tom Gill (Yale)
  - David Reuben (UCLA)
- 14 Pepper Centers
- Data Coordinating Center: Yale

The Research Question

What is the **comparative effectiveness** of:

- Nurse co-management of falls risk factors
- Enhanced physician management of falls risk factors

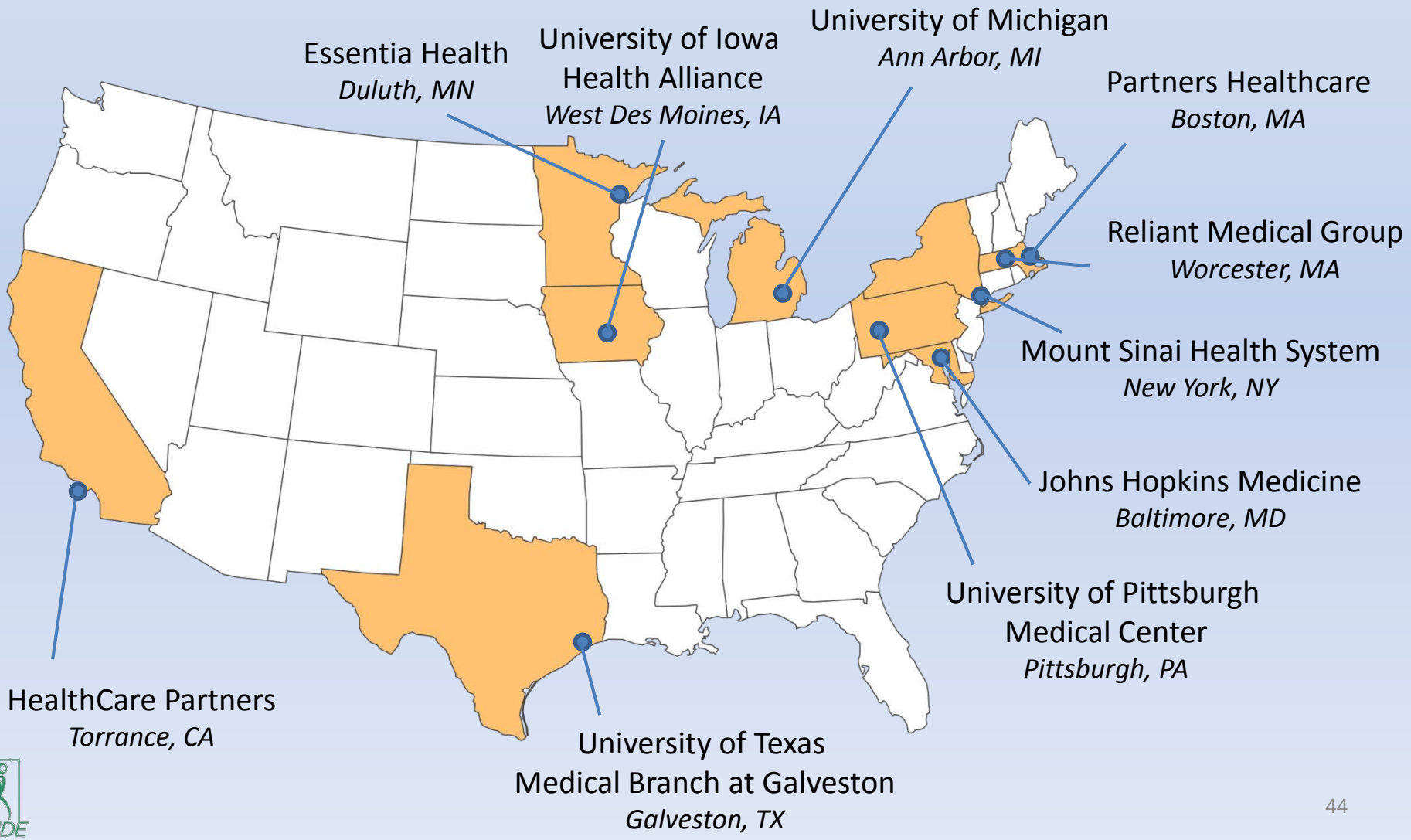
in reducing **serious falls-related injuries** and improving other outcomes (all falls-related injuries, falls efficacy, physical function and disability, anxiety) among **elders at risk** of falls-related injuries?

Study Design

- Trial conducted in clinical care settings
- Practices randomly assigned to receiving intervention or enhanced usual care
- 10 sites, 86 practices, 707 primary care physicians
- Up to 6000 community-dwelling participants ≥70 years (and their caregivers) who have one or more risk factors for serious falls-related injuries
    - Fallen and hurt self in the past year
    - Fallen 2 or more times in the past year
    - Fear of falling because of balance or gait
- Follow-up 20-40 months

STRIDE

Clinical Trial Sites



Patient and Stakeholder Collaboration

- National Patient and Stakeholder Committee (NPSC) meets bi-weekly
  - Representation from all 10 clinical trial sites
  - Patients, caregivers, clinicians, community providers
  - NPSC has representatives on all study committees
  - NPSC members review all study materials and provide input into study issues
- Local Patient and Stakeholder Committees formed at each clinical trial site (10 in total)
  - Meet at least quarterly to address local study issues such as identifying community fall prevention resources
  - NPSC provided structured training of each LPSC and ongoing support

STRIDE

The Interventions

- Nurse co-management of falls risk factors
  - Decision support (algorithms)
  - Information systems (software)
  - Patient/caregiver engagement and activation
  - Linkage to community-based resources
- Enhanced physician management of falls
  - Patients are given 2-page CDC Stay Independent falls informational pamphlet and are encouraged to discuss fall prevention with their PCP
  - Physicians are offered an educational webinar about falls prevention based on CDC STEADI

Falls Care Manager's Co-management Role

With patient/caregiver, collaborate in:

- Assessing risks of falling
- Creating a risk-reduction care plan
- Implementing the plan
- Coordinating multiple providers
- Promoting patient self-management
- Facilitating access to community-based resources
- Monitoring the patient's progress
- Helping the patient/caregiver overcome obstacles (using motivational interviewing)

STRIDE

Risk Factors addressed

- Leg strength, mobility, and balance
- Osteoporosis, including Vitamin D
- Medications that increase the risk of falling
  - alcohol use
- Home safety
- Blood pressure drops when standing
- Visual impairment
- Foot problems and footwear

Outcomes

- Primary:
  - Serious falls injuries requiring medical attention
- Secondary:
  - All falls-related injuries
  - Well-being
    - Physical function and disability
    - Anxiety and depression
    - Falls efficacy

STRIDE Progress to Date and Future Plans

- Start Date: 6/1/2014
- Intervention implemented at all 10 sites
- Completed pilot study of recruitment and intervention
- 15 Falls Care Managers trained and providing care
- 3322 Participants recruited (9/10/2016)
- Projected recruitment completion date: March 31, 2017
- Interim report: after 50% of primary outcomes reached
- Projected final follow-up date: November 30, 2018
- Final report: June 2, 2019

STRIDE

Challenges and barriers

- Screening and recruitment
- Standardizing the intervention
- Integration into practices
- Conducting pragmatic trials in diverse community settings
- Oversight by two funders

Questions

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chairperson, Board of Directors