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# Conducting Health Economics Research to Enhance Cancer Equity: Clinical Trials

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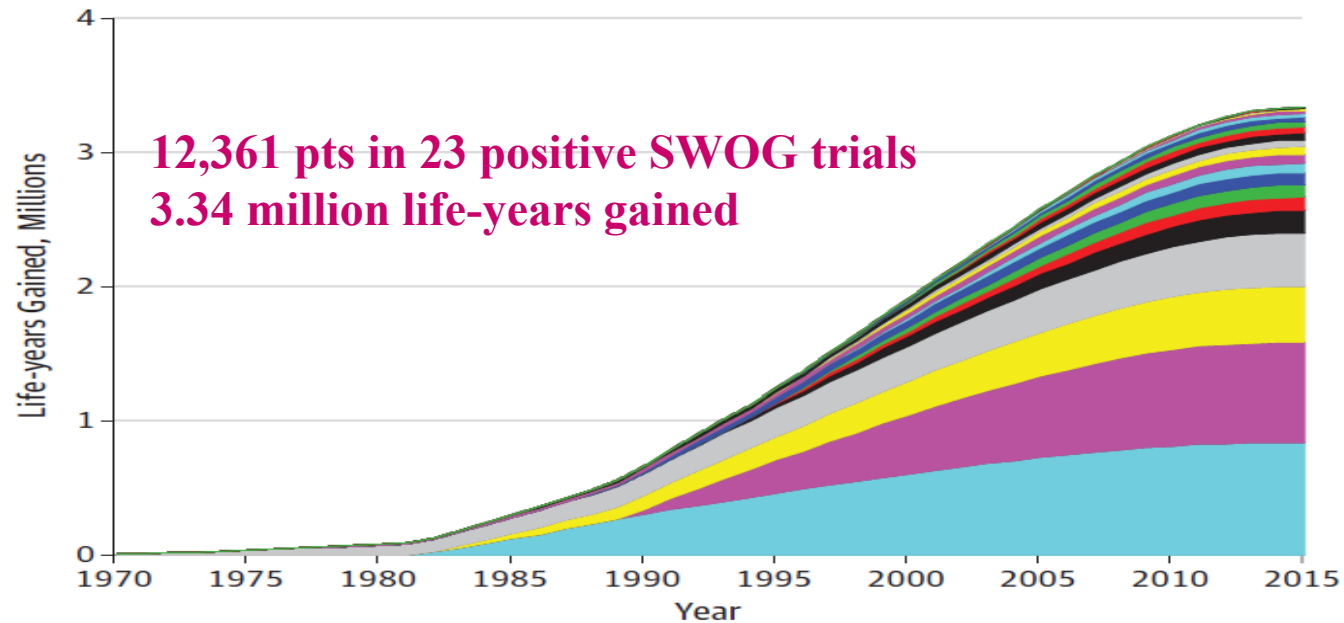


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# Clinical trials are critical for advancement of cancer care



Unger, J et al. JAMA Oncol 2017;3:1345-51



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# BUT...

- Adult cancer clinical trial participation is **suboptimal**
  - 5% of all adult cancer patients in the United States
  - Less than 2% on cooperative group trials
- Older patients, minorities, women, lower SES, and rural pts are underrepresented
  - *Results less generalizable*
  - *Social justice: deprived of some of the best therapies*
- While Black people are ~20% of Boston's population, they are underrepresented (3.3%) among those accrued to clinical trials.

**We have to do better!**

Boston Public Health Commission Health of Boston report (2015)



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# What leads to disparities in trial participation?

- Protocol requirements – *age limits, strict exclusion criteria (e.g. labs, co-morbidities, brain mets, HIV+)*
- Attitudinal – *lack of knowledge, fear of side effects, ‘guinea-pig’ perception*
- Access – *insurance coverage, slow financial clearance process, trial availability at community cancer centers*
- Other Financial – *out-of-pocket \$, travel, housing/food, lost income*

Beaver, J et al. NEJM. 2017 376(16): 1504-5.  
Meropol, N et al. J Clin Oncol. 2016 34(5): 469-78.  
Nipp R,...Moy B. Oncologist 2016;20:572-5



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# Coverage of clinical trials under ACA

- ACA Section 2709 – Required coverage of routine health care costs for patients participating in clinical trials
  - ‘Grandfathered plans’ – existing health plans as of 3/23/10
  - Covers out-of-state but not necessarily out-of-network
- Medicare National Coverage Determination (Sept 2000)
- No requirement for Medicaid coverage of routine patient costs on clinical trial – *ASCO Policy Statement on Medicaid Reform*



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# Barriers to clinical trial participation



Characteristic	OR (95% CI)	P value
Age $\geq$ 65	0.79 (0.58-1.08)	0.14
Female gender	0.93 (0.58-1.49)	0.75
African American race	1.31 (0.74-2.33)	0.35
Income $<$ \$50,000	0.73 (0.57-0.94)	0.01
Education $<$ college	0.92 (0.73-1.16)	0.49
Comorbidity score $\geq$ 2	0.81 (0.65-1.02)	0.07
Distance to clinic $\geq$ 13 mi	0.66 (0.54-0.81)	$<$ 0.001

Unger, J et al. 2016. JAMA Oncol. 2(1): 137-9.

## Other financial barriers to clinical trial participation

- Out-of-pocket spending – deductibles, copayments, coinsurance ‘ routine care’ is \$\$
- Travel to clinical trial center
- Housing / Meals
- Lost work / income

Patients may be considering trial enrollment in the context of significant previous cancer-related spending



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# MGH Cancer Care Equity Program



## Patient Selection:

- enrolled in or being screened for a clinical trial
- referred to CCEP by their cancer team

## Patient Referral

Oncology provider • Social work • New patient access nurse • Research nurse

## Lazarex Foundation

- Determines need for assistance
- Reimburses patients monthly

## CCEP

- Liaise with Lazarex Foundation, patient & team
- Track patient outcomes and collect data

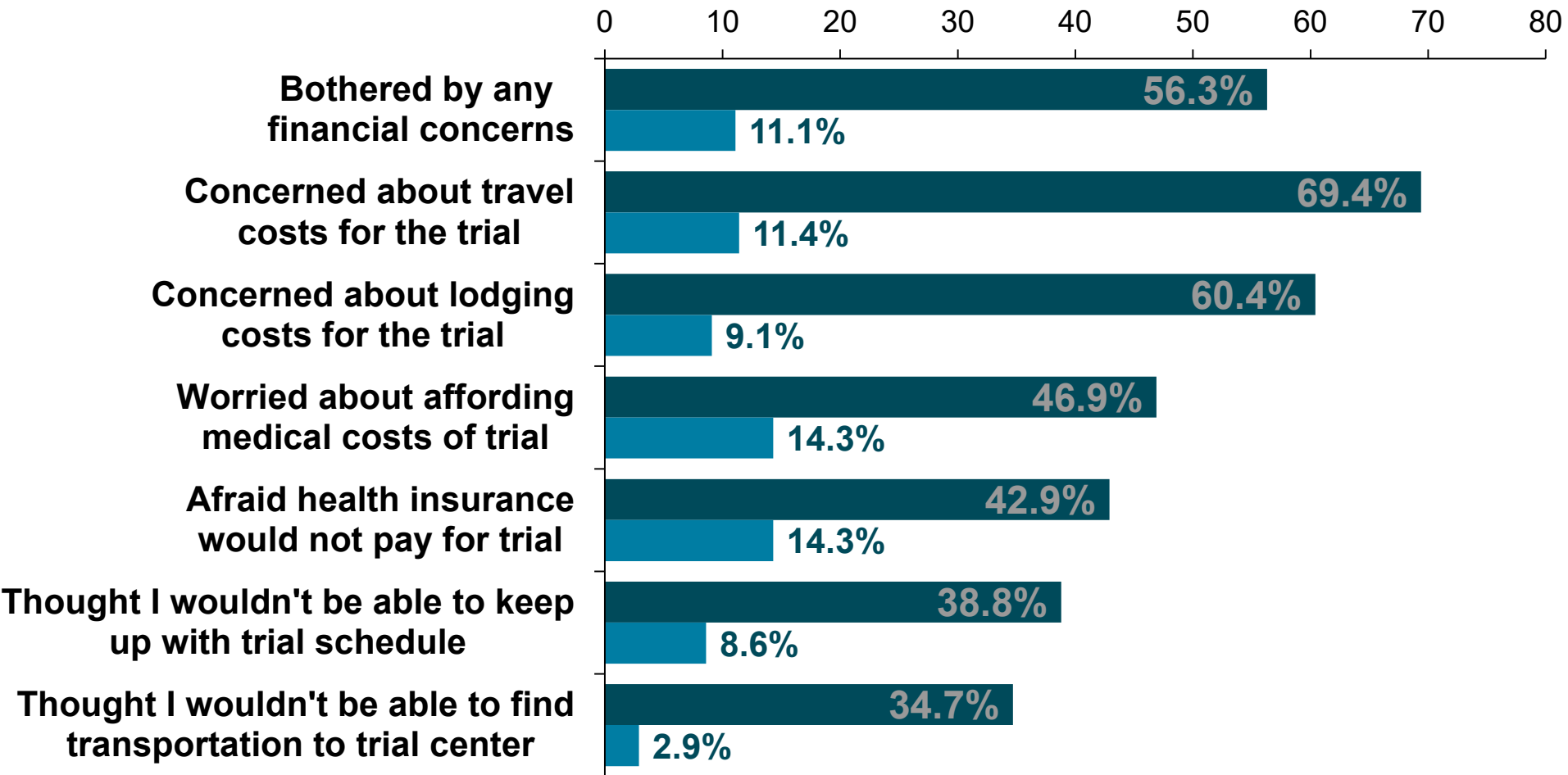


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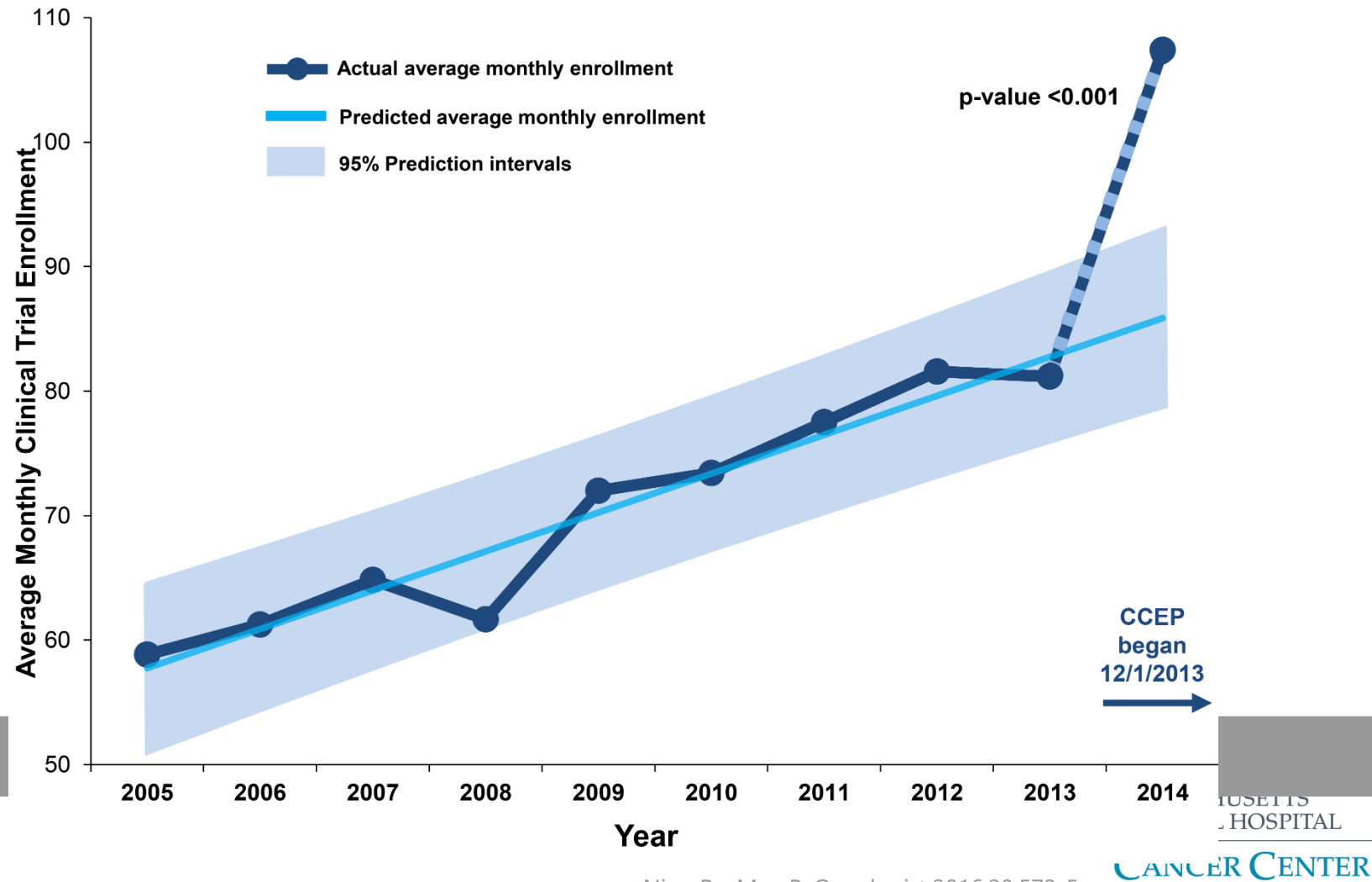
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# Baseline Financial Barriers



# Average Monthly Clinical Trial Enrollment by Year



# Monthly Reimbursement per Participant

Local	Regional	National
<b>\$185</b>	<b>\$300</b>	<b>\$900</b>



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# ASCO Roundtable on Addressing Financial Barriers to Clinical Trials: July 2017

- Goal: to better define the scope of financial burdens on clinical trials and identify solutions both at the policy and clinical level
- Participants: Clinicians, researchers, NCI, payers, industry, Biden Moonshot Initiative, FDA,



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# Recommendations (1)

- **Improve payer clinical trial coverage policies**
  - **Clinical trial cost payment policies should be revised so that they are made consistent, streamlined, and transparent to all stakeholders**
- **During the clinical trials development and enrollment process, provide patients with clear, transparent information about potential trial-related patient out-of-pocket costs, and include mechanisms to support patient financial/health literacy.**

Winkfield K...Moy B. J Clin Oncol 2018



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## Recommendations (2)

- **Remove impediments to ethically appropriate financial compensation for trial-related out-of-pocket costs. Provision of such financial support should not be considered undue inducement**
- **Incentivize research that will better characterize patient costs incurred for participating in cancer clinical trials and support the longer-term development of tools to identify and mitigate the risk of trial-associated financial hardship.**

# Policy: Massachusetts state legislature

## ★ BILL H.4211 *191st (Current)*

### AN ACT TO IMPROVE PATIENT ACCESS TO CANCER CLINICAL TRIAL PROGRAMS

 View Text

**Sponsor:** Joint Committee on Public Health

 Print Preview

**Status:** Referred to Joint Committee on Health Care Financing

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#### Bill History

Displaying 8 actions for Bill H.4211

Date	Branch	Action
11/19/2019	House	Reported from the committee on <a href="#">Public Health</a>
11/19/2019	House	New draft of <a href="#">H1933</a>
11/19/2019	House	Reported favorably by committee and referred to the committee on <a href="#">Health Care Financing</a>
3/23/2020	House	Reporting date extended to Friday May 1, 2020, pending concurrence
3/26/2020	Senate	Senate concurred
4/29/2020	House	Reporting date extended to Friday June 19, 2020, pending concurrence
4/30/2020	Senate	Senate concurred
6/22/2020	House	Reporting date extended to Thursday December 31, 2020, pending concurrence



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# Federal Policy: CLINICAL TREATMENT Act: H.R. 913 and S. 4742

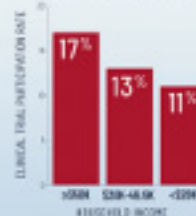
## CLINICAL TREATMENT ACT MEDICAID ENROLLEES NEED CLINICAL TRIAL ACCESS

Clinical trials often provide the best treatment options for patients with life-threatening conditions. But many can't enroll because federal law doesn't require Medicaid to cover the routine costs of participating.

Only 12 states require this coverage—leaving 42.2 million people on Medicaid in 38 states potentially without clinical trial coverage.<sup>1</sup>



Cost is one of the biggest barriers to clinical trial participation—particularly for low-income patients.<sup>2</sup>



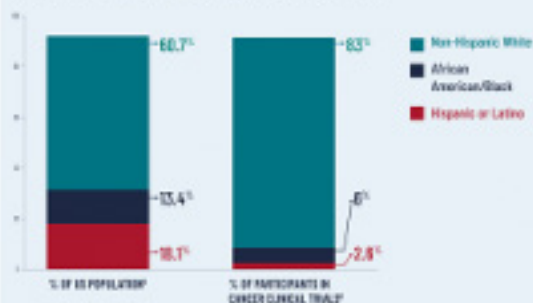
Medicaid is the only major payer that doesn't guarantee coverage of routine care costs for trial participants.



All other major payers—including Medicare—cover these costs. Covering routine costs would have a minimal impact on overall Medicaid spending: Medicaid covers these costs for patients who do not enroll in trials.<sup>3,4</sup>

Closing this coverage gap would reduce racial/ethnic disparities and improve the validity of data and the quality of new treatments.

Minorities are underrepresented in clinical research.



Passage of the bipartisan CLINICAL TREATMENT ACT (H.R. 913) would put clinical trials within reach of millions more patients—including children, people with disabilities, and rural Americans.

CONGRESS:

Pass the CLINICAL TREATMENT Act and give every patient on Medicaid the opportunity to access new treatments and participate in research. #ClinicalTrialAccess



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