

AHA 2020

GALACTIC-HF: INVESTOR & MEDIA EVENT

NOVEMBER 13, 2020 1:00 PM ET

Forward-Looking Statements

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Guest Speakers



John Teerlink, MD

Professor of Medicine, University of California San Francisco, Director of Heart Failure, San Francisco Veterans Affairs Medical Center and Executive Committee Chair, GALACTIC-HF

**GALACTIC-HF
Results**



Scott Solomon, MD

Edward D. Frohlich Distinguished Chair, Professor of Medicine, Harvard Medical School and Director of Noninvasive Cardiology, Brigham and Women's Hospital

**Making Sense
of Subgroups**



G. Michael Felker, MD, MHS

Professor of Medicine, Vice-Chief of Cardiology for Clinical Research, Duke University School of Medicine and Director of Cardiovascular Research, Duke Clinical Research Institute

**Unmet Need
in Advanced HF**



Nihar R. Desai, MD, MPH

Associate Professor of Medicine, Associate Chief, Cardiovascular Medicine, Yale School of Medicine, Center for Outcomes Research and Evaluation

**Economic
Burden of HF**

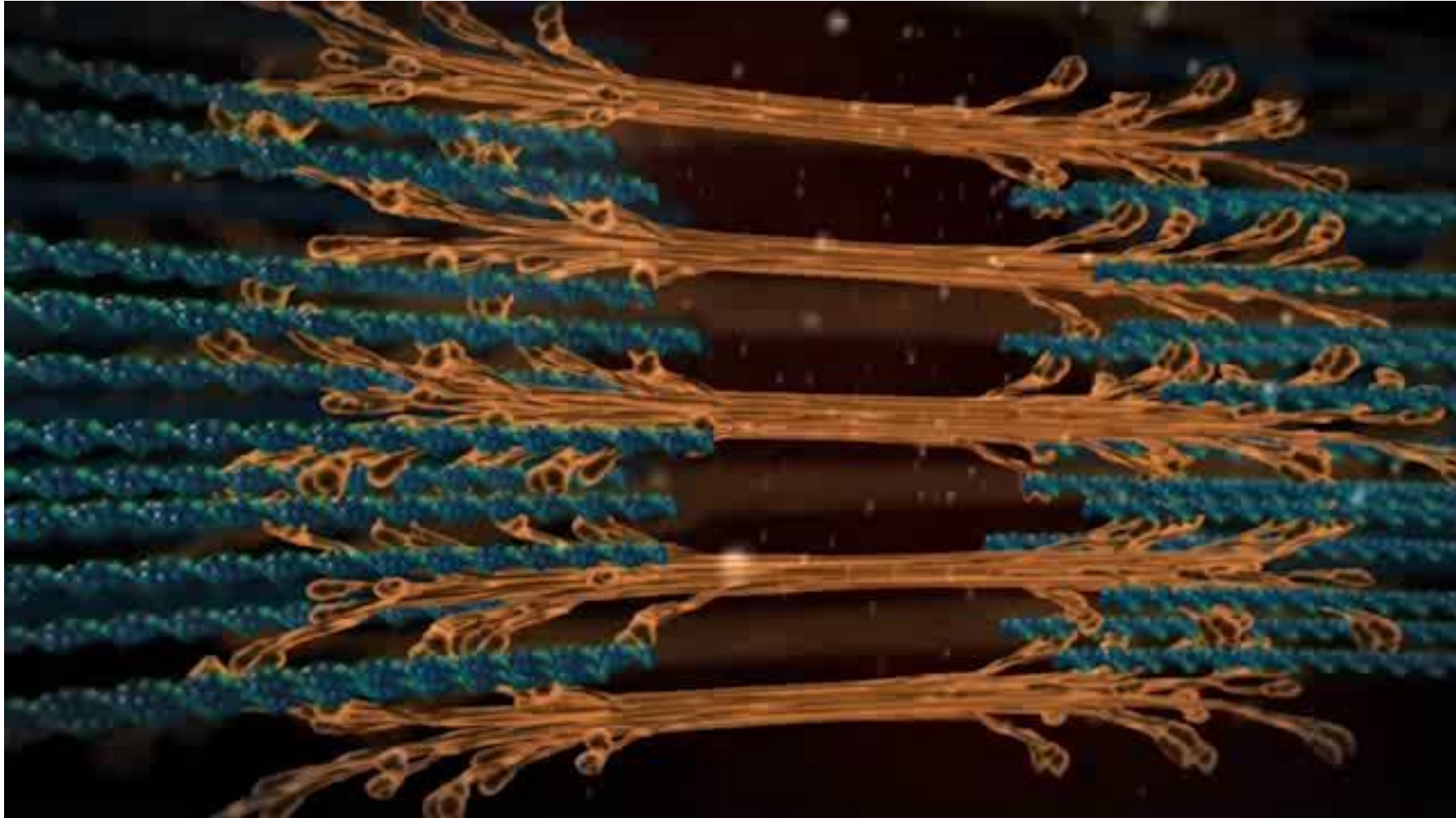
INTRODUCTION

Robert Blum, President & CEO

A BIOLOGICALLY-DRIVEN APPROACH

Fady Malik, M.D., Ph.D., Executive Vice President, R&D

The Sarcomere: The Engine of Muscle Contractility

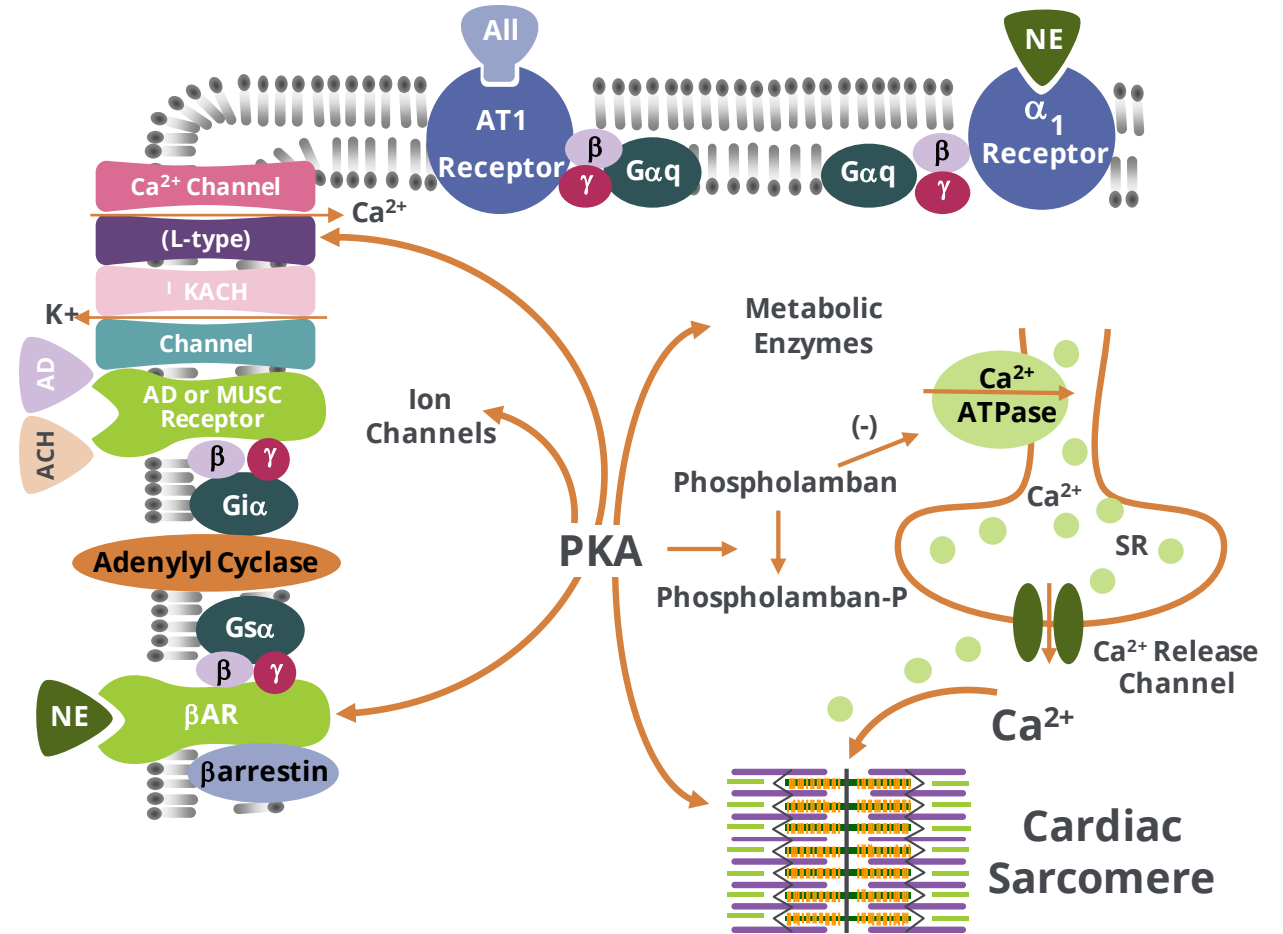


Small Molecules Can Improve Cardiac Function...

Indirect Mechanisms

PKA phosphorylates proteins throughout the myocyte

Intracellular $[Ca^{2+}]$ **increases**



PKA = Protein Kinase A

3

Potential Advantages of Targeting the Sarcomere

Therapeutic Hypothesis

Directly target the sarcomere

Ø PKA activation

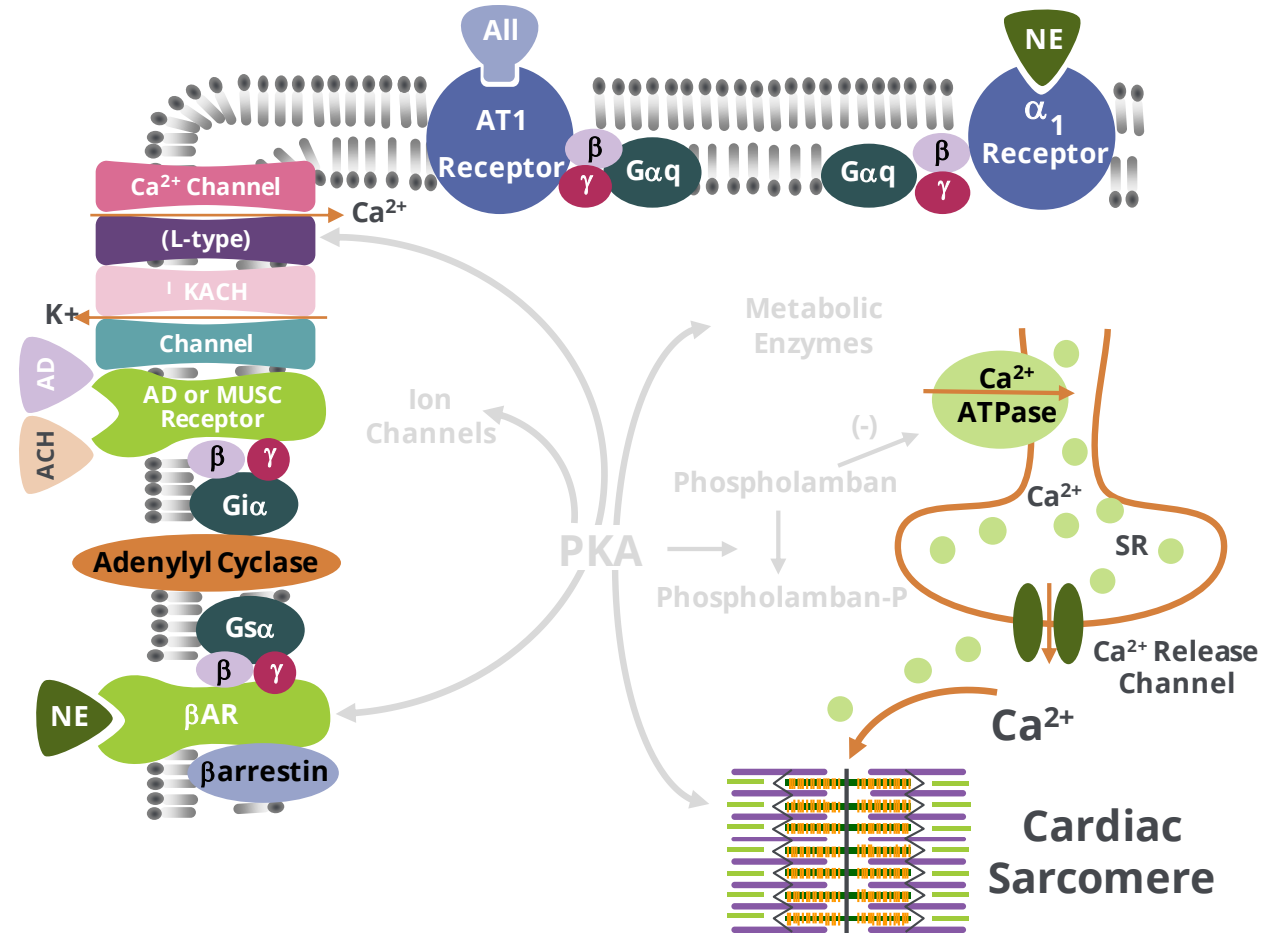


Intracellular $[Ca^{2+}]$ **unchanged**



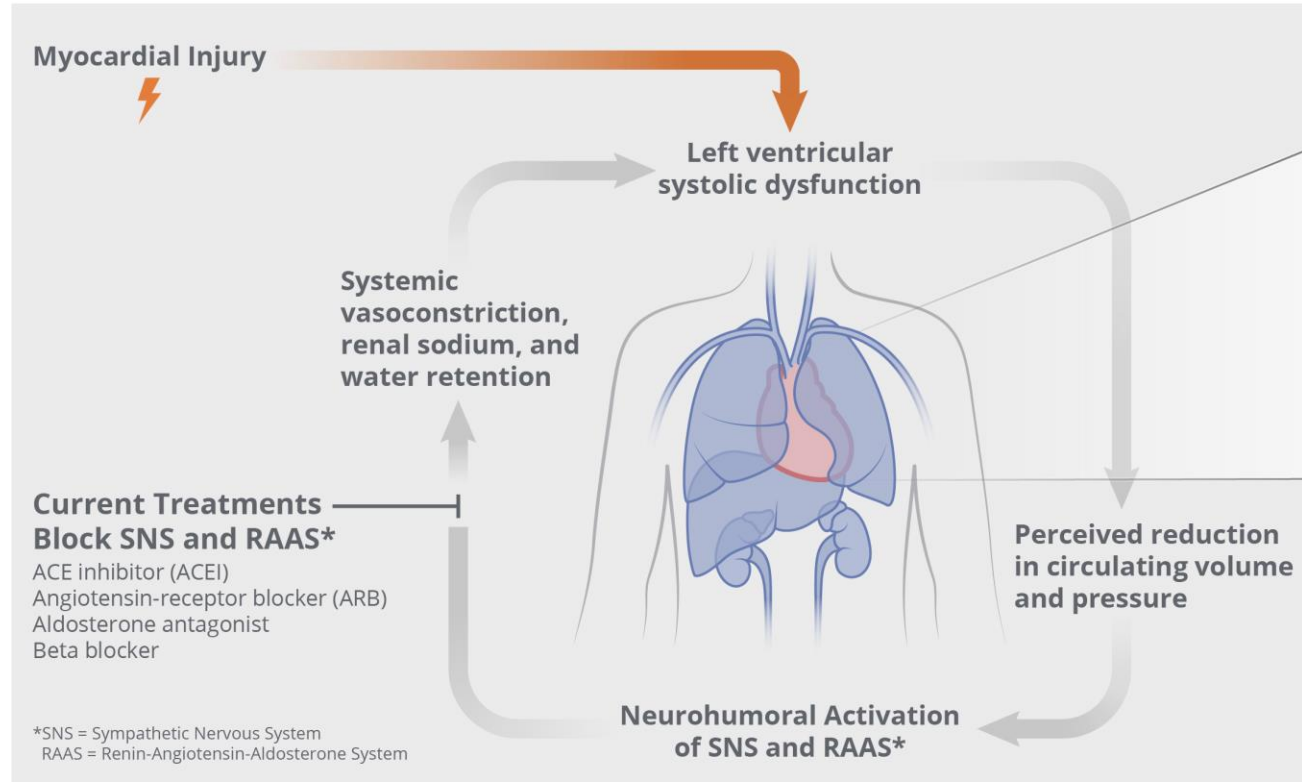
- ↑ Contractility
- ↔ Heart rate
- ↔ Blood Pressure
- ↔ O_2 Demand
- ↑ Efficiency
- ↓ Arrhythmias

PKA = Protein Kinase A

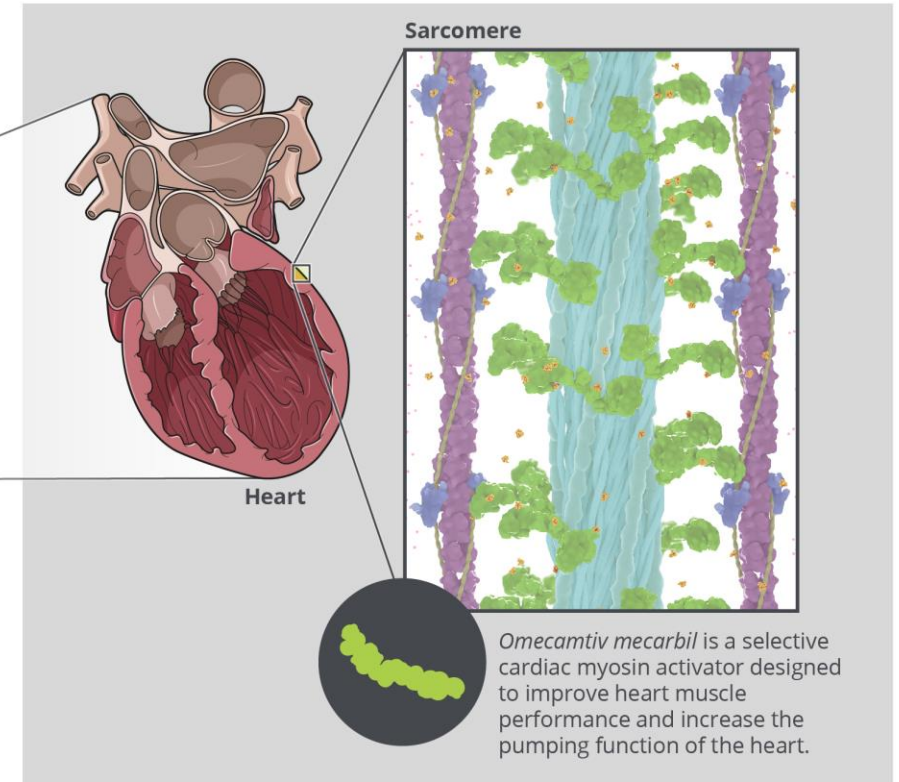


Omecamtiv Mecarbil: Novel Mechanism Approach

Current Treatments

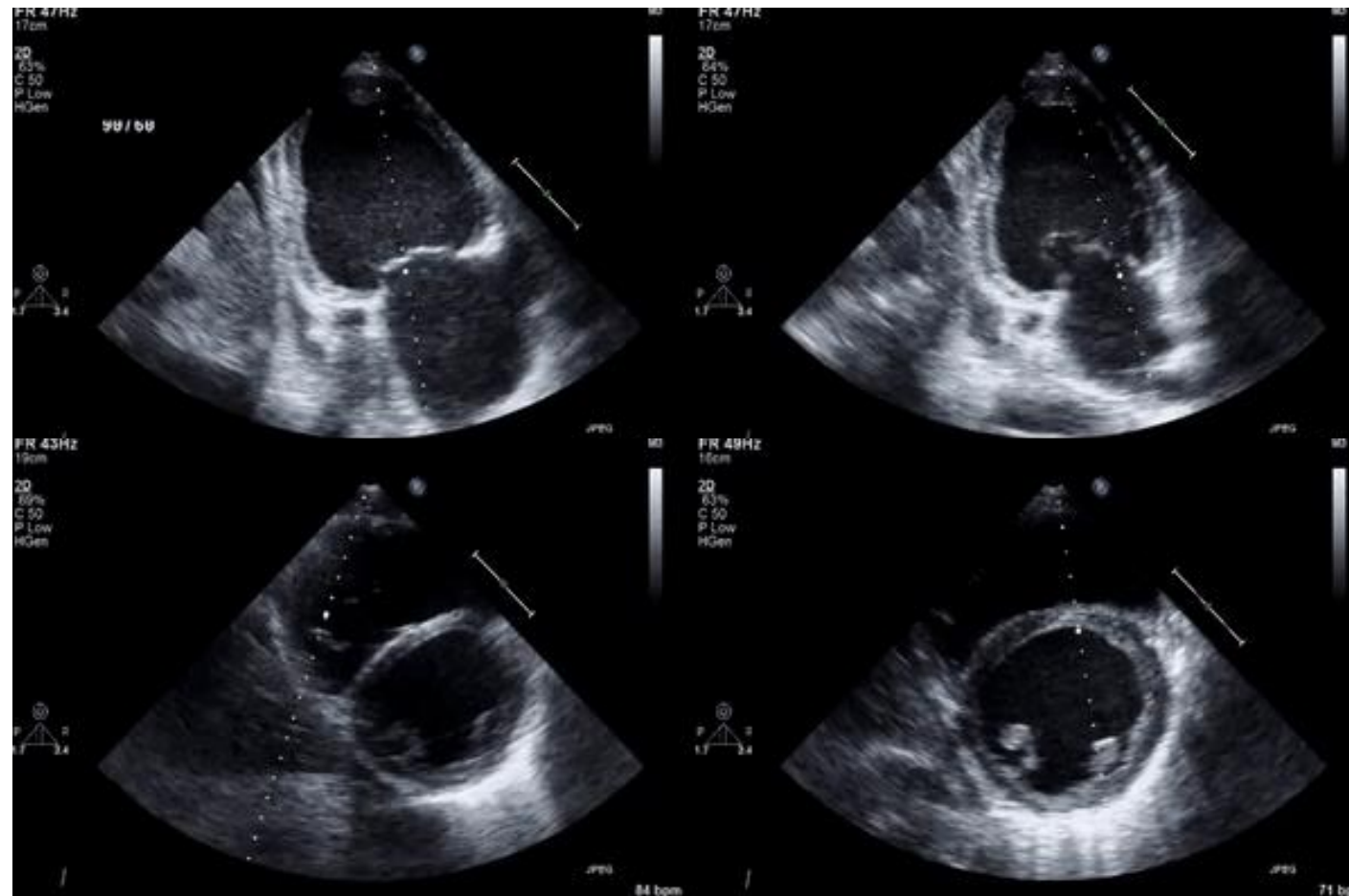


Omecamtiv mecarbil



Omecamtiv Mecarbil: Effects on Cardiac Function

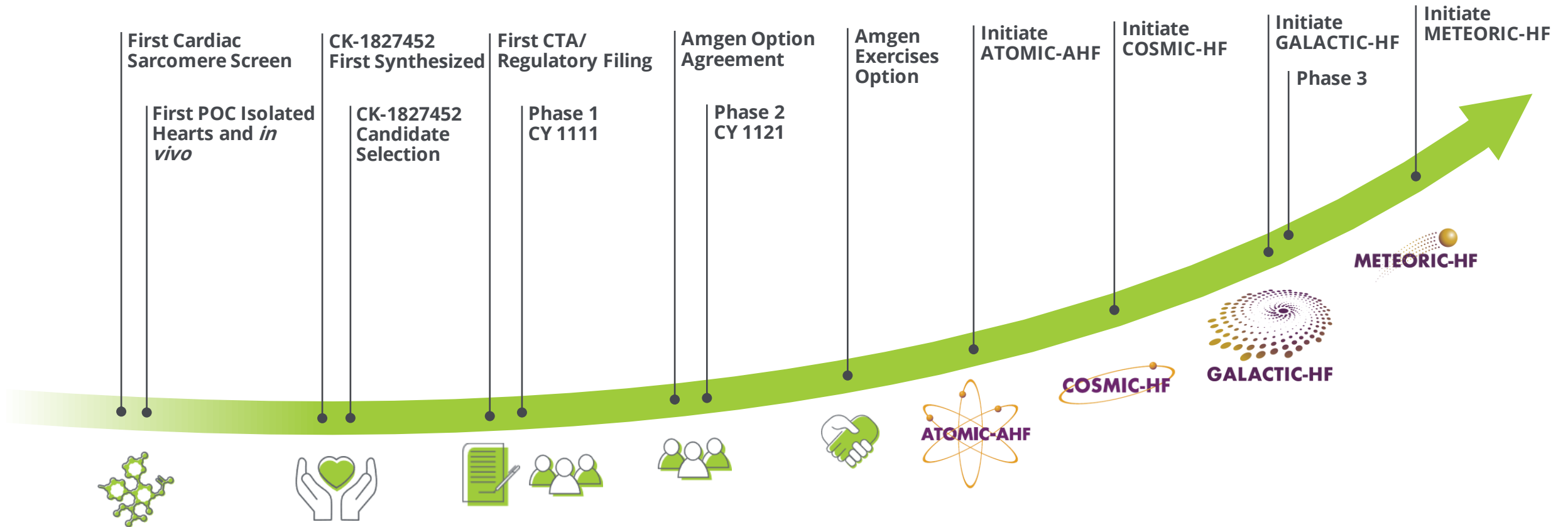
Human Translation



Images and data from patient
enrolled in CY 1121

Omecamtiv Mecarbil: The Journey

11 Phase 1 studies with over 300 patients, 7 Phase 2 trials with over 1,400 patients



GALACTIC-HF RESULTS

John Teerlink, M.D., Professor of Medicine, University of California San Francisco, Director of Heart Failure, San Francisco Veterans Affairs Medical Center and Executive Committee Chair, GALACTIC-HF

Omecamtiv Mecarbil In Chronic Heart Failure With Reduced Ejection Fraction:

The Global Approach To Lowering Adverse Cardiac Outcomes Through Improving Contractility In Heart Failure (GALACTIC-HF) Trial

John R Teerlink,¹ Rafael Diaz,² G. Michael Felker,³ Marco Metra,⁴
John JV McMurray,⁵ Scott D Solomon,⁶ Lucie A Sharpsten,⁷ Jason C Legg,⁷
Claire Varin,⁸ Siddique A Abbasi,⁷ Fady I Malik,⁹ Christopher E Kurtz⁷
on behalf of the GALACTIC-HF Investigators

¹San Francisco VAMC/ UCSF, San Francisco, CA; ²Rosario Inst of Cardiology,
Rosario, Argentina; ³Duke Clinical Res Inst, Durham, NC; ⁴Univ of Brescia,
Brescia, Italy; ⁵BHF Cardiovascular Res Ctr, Glasgow, United Kingdom;

⁶Brigham and Women's Hosp, Boston, MA; ⁷Amgen Inc.,
Thousand Oaks, CA; ⁸Servier, Suresnes, France;

⁹Cytokinetics Inc., South San Francisco, CA.



Disclosures

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- Funded by Amgen, Inc., Cytokinetics, Inc., and Servier Laboratories
- Lead author disclosures:
 - **J.R. Teerlink:** Research Grant/ Consultant: Abbott, **Amgen**, Astra Zeneca, Bayer, Boehringer-Ingelheim, Bristol-Myers Squibb, **Cytokinetics**, Medtronic, Merck, Novartis, **Servier**

Background

- No therapies for chronic HFrEF that directly target systolic dysfunction have improved patient outcomes
- Omecamtiv mecarbil (OM)¹ is a novel, selective cardiac myosin activator ("myotrope"²) that improves cardiac structure/function and decreases heart rate and NT-proBNP in patients with HFrEF^{3,4}
- The GALACTIC-HF trial (clinicaltrials.gov NCT02929329) enrolled inpatients and outpatients with HFrEF to evaluate the effect of omecamtiv mecarbil treatment on cardiovascular outcomes and safety

¹Malik FI, et al. *Science* 2011;331:1439–43; ²Psotka MA, et al. *J Am Coll Cardiol* 2019;73:2345–53;

³Teerlink JR, et al. *Lancet* 2016;388:2895–2903; ⁴Teerlink JR, et al. *JACC Heart Fail* 2020;8:329–40.

Inclusion and Exclusion Criteria

Key inclusion criteria

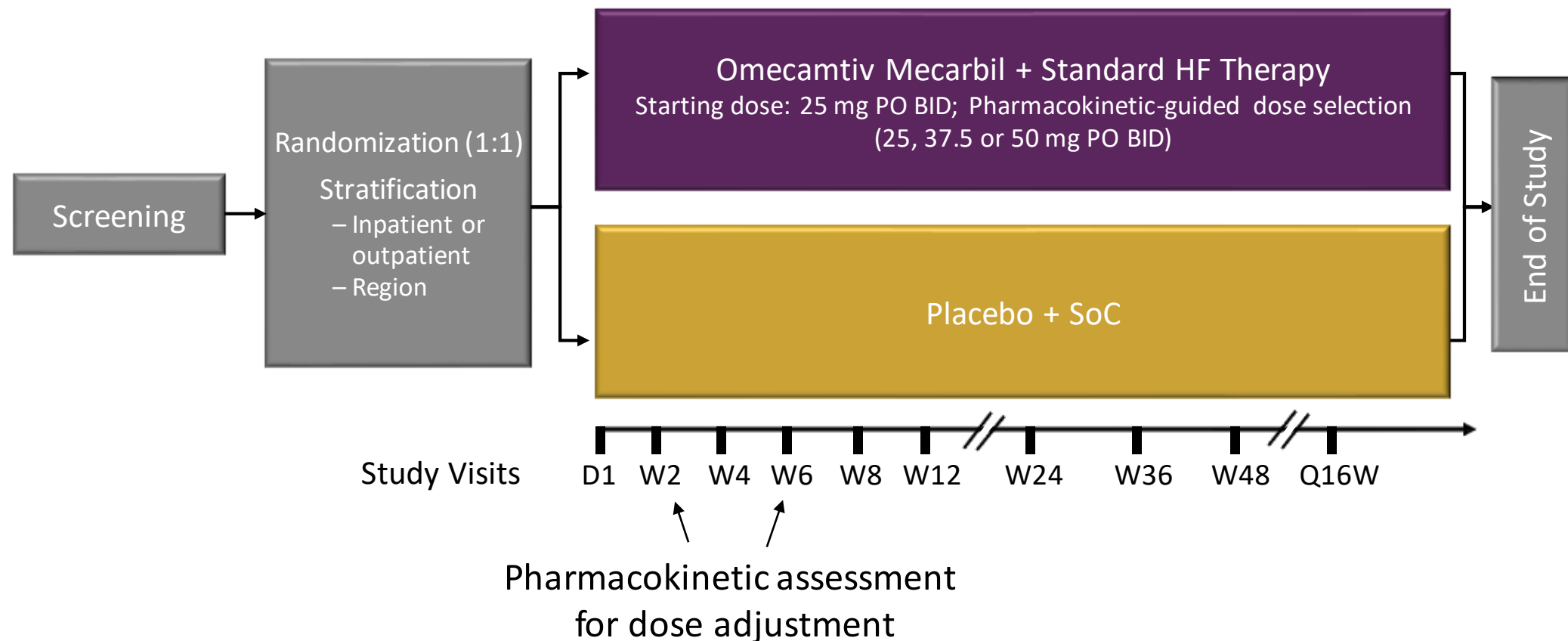
- Male or female, ≥ 18 to ≤ 85 years of age
 - New York Heart Association class II to IV
 - History of chronic heart failure (HF)
 - LVEF $\leq 35\%$
 - BNP ≥ 125 pg/mL or NT-proBNP ≥ 400 pg/mL (atrial fibrillation/flutter: BNP ≥ 375 pg/mL or NT-proBNP ≥ 1200 pg/mL)
 - Managed with standard HF therapies
 - Currently hospitalized for HF (Inpatients)
- OR
- Urgent ED visit or hospitalization for HF within 1 year prior to screening (Outpatients)

Key exclusion criteria

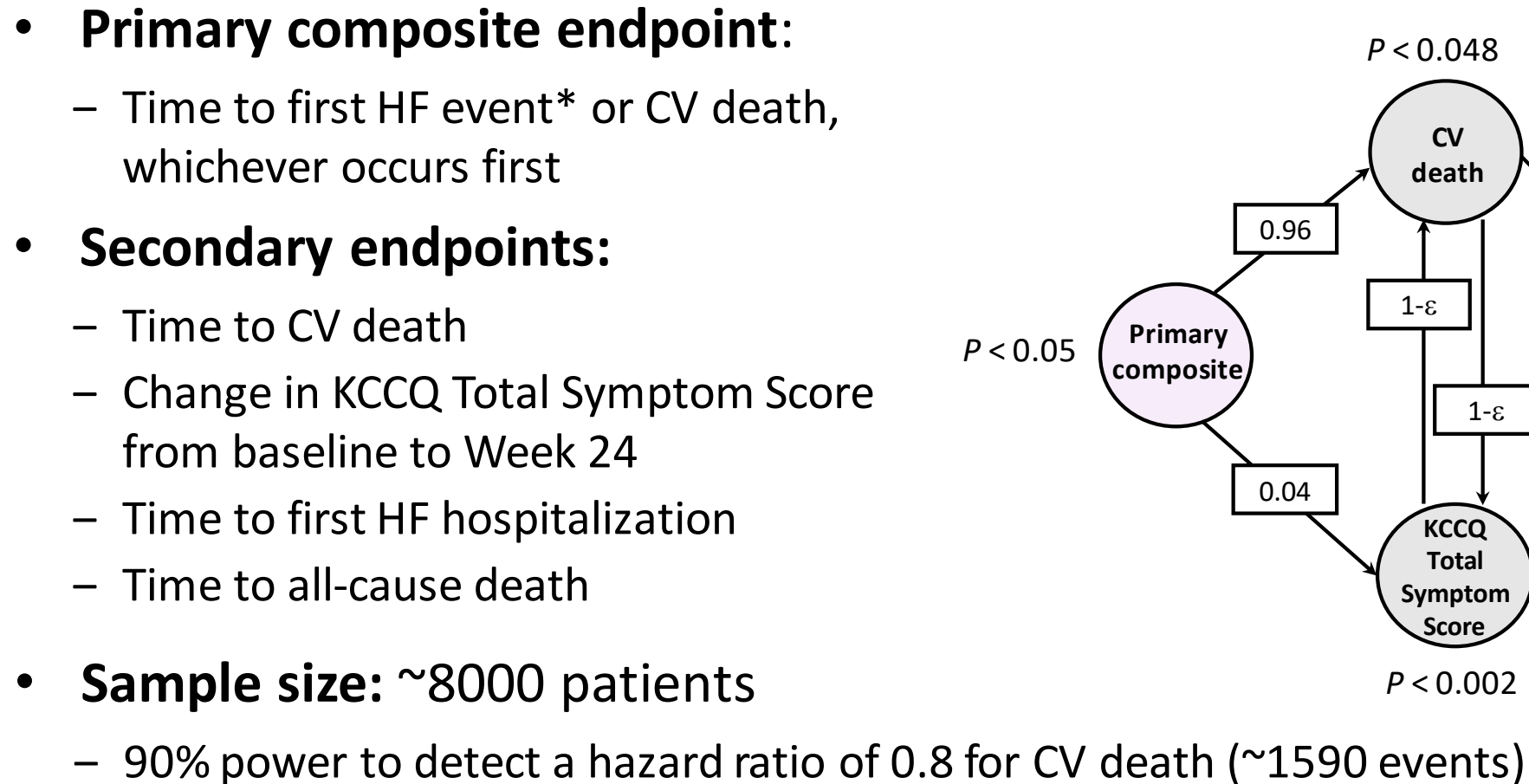
- Hemodynamic or clinical instability requiring mechanical support or intravenous medication (within last 12 hours)
- Systolic blood pressure < 85 mmHg
- Estimated GFR < 20 mL/min/1.73 m²
- Recent ACS events or CV procedures (including planned procedures) within last 3 months
- Other conditions that would adversely affect participation in the trial

Trial Design

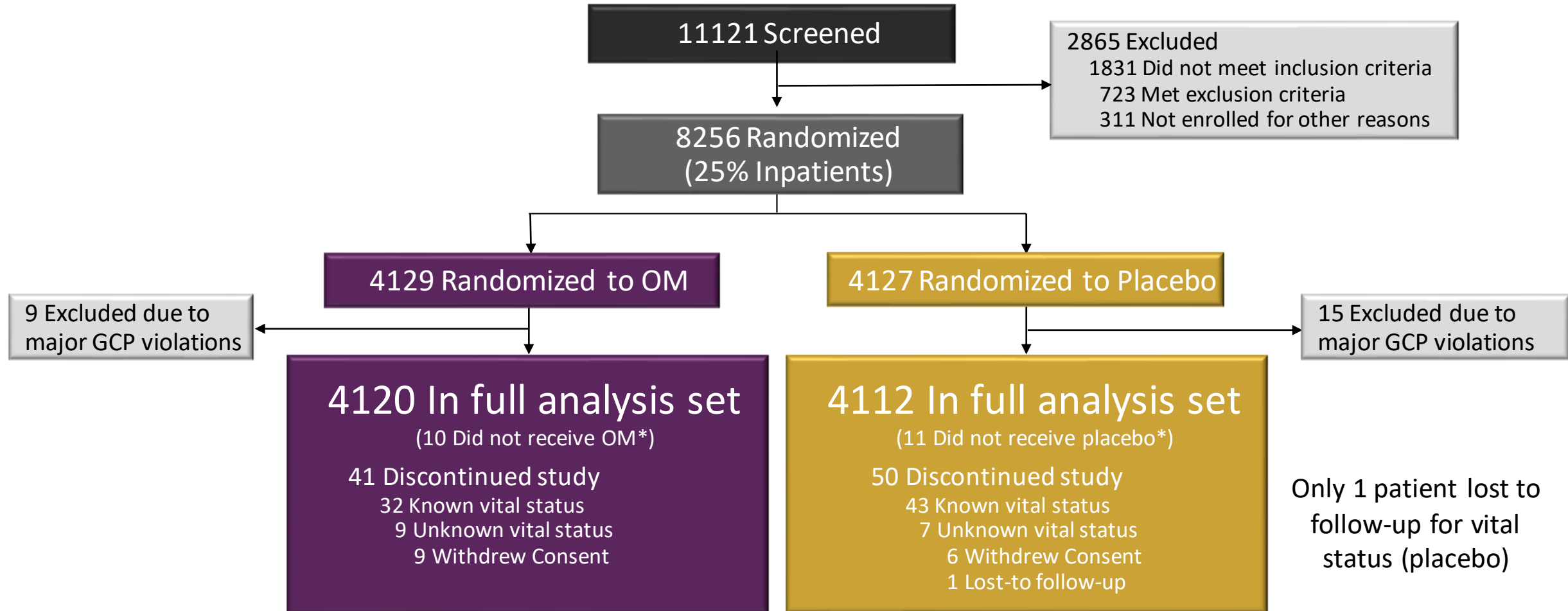
Multicenter, international, randomized, double-blind, placebo-controlled, event-driven Phase 3 study



Outcomes and Statistical Analysis



Patient Disposition



Overall median study exposure was 21.8 months

*Not included in safety analysis set.

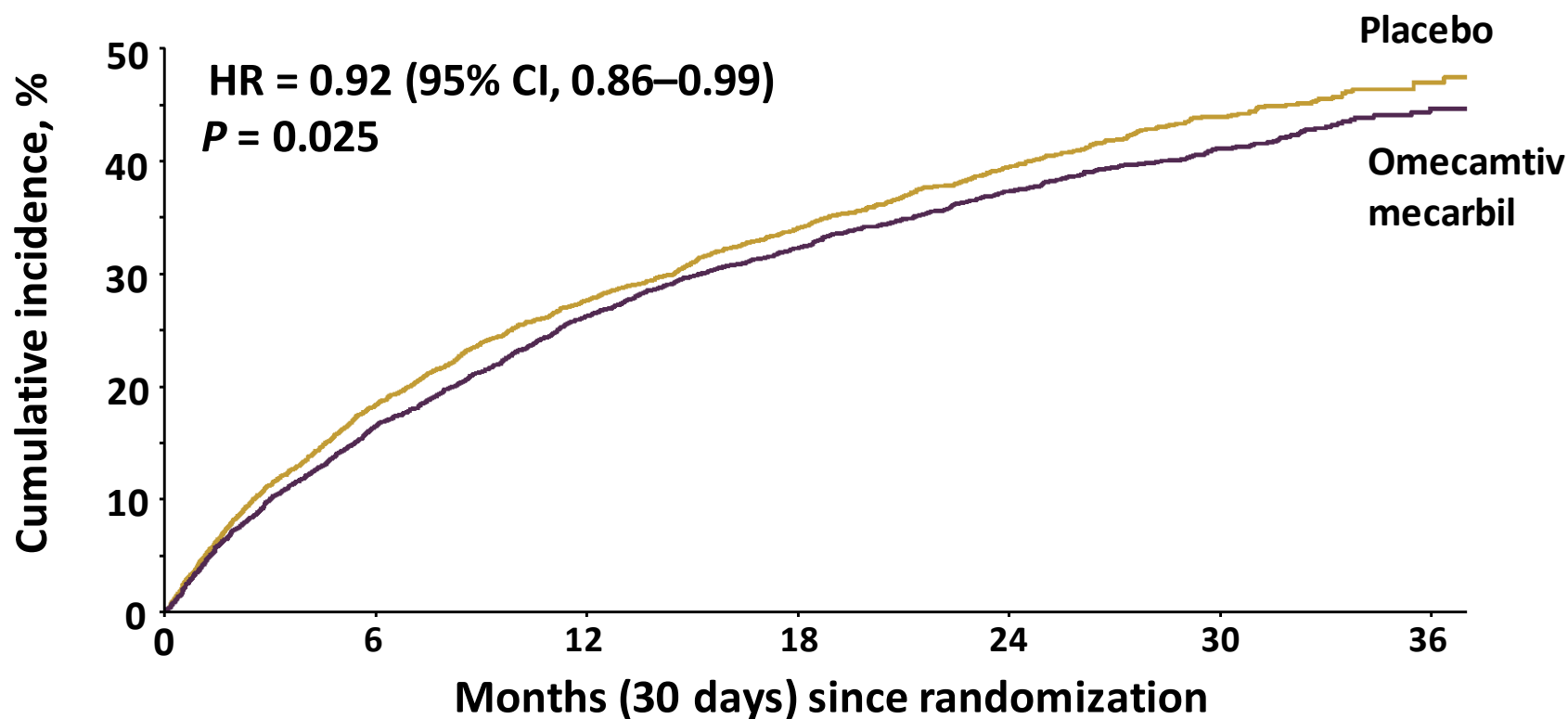
Baseline Characteristics

Characteristic	OM (N=4120)	Placebo (N=4112)
<i>Demographics</i>		
Age (years), median (Q1, Q3)	66 (58, 73)	66 (58, 73)
Sex, female, %	21	21
White/Asian/Black/other, %	78/9/7/7	78/9/7/7
<i>Heart Failure History and Medical Conditions</i>		
HF event prior to randomization (outpatients), median (months)	3.2	3.1
LVEF (%), mean (SD)	27 (6)	27 (6)
NYHA class, II/III/IV, %	53/44/3	53/44/3
Ischemic etiology, %	53	54
Atrial fib/flutter at screening, %	28	27
Type 2 diabetes, %	40	40

Characteristic	OM (N=4120)	Placebo (N=4112)
<i>Vital signs and Laboratory Parameters</i>		
SBP (mmHg), mean (SD)	116 (15)	117 (15)
Heart rate, mean (SD)	72 (12)	72 (12)
eGFR (mL/min/1.73m ²), median (Q1, Q3)	59 (44, 74)	59 (44, 74)
NT-proBNP (pg/mL), median (Q1, Q3)	1977 (980, 4061)	2025 (1000, 4105)
Cardiac TnI (ng/mL), median (Q3)	0.027 (0.052)	0.027 (0.052)
<i>Medications and Cardiac Devices</i>		
ACEI/ARB/ARNi, %	87	87
ARNi, %	20	19
BB, %	94	94
MRA, %	78	78
SGLT2i, %	2.5	2.8
CRT, %	14	14
ICD, %	32	31

Primary Composite Endpoint

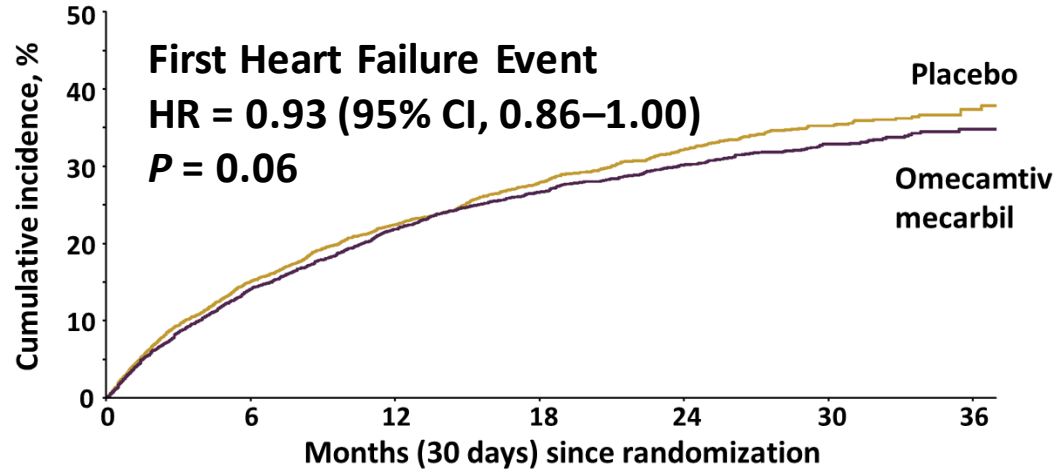
Time to First Heart Failure Event or Cardiovascular Death



Patients at risk, n

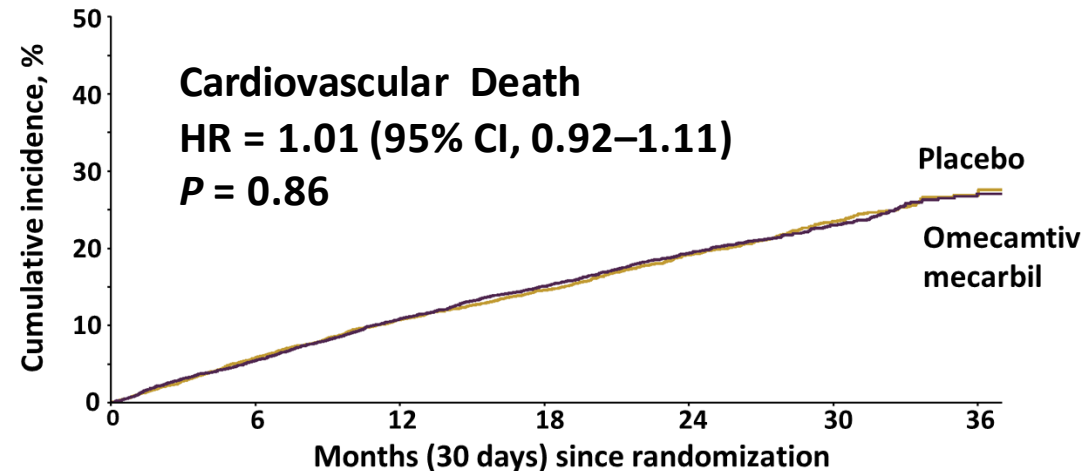
Placebo	4112	3310	2889	2102	1349	647	141
Omecamtiv mecarbil	4120	3391	2953	2158	1430	700	164

Primary Composite Components and KCCQ TSS



Patients at risk, n

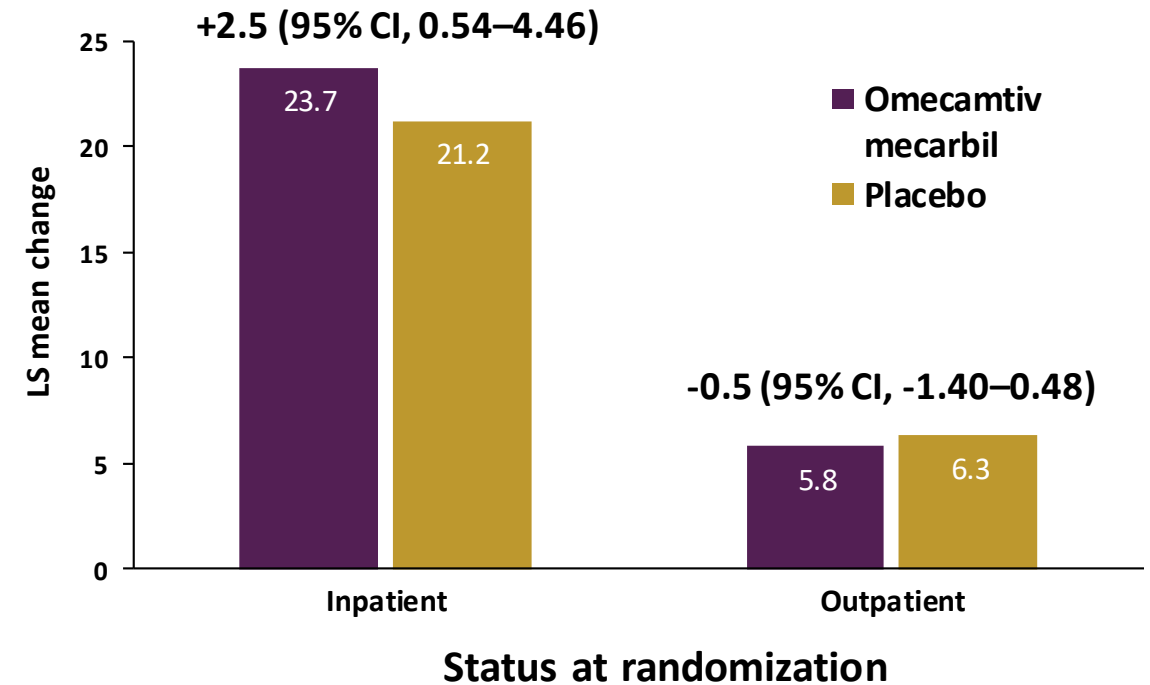
Placebo	4112	3309	2889	2102	1348	647	141
OM	4120	3391	2953	2156	1430	699	164



Patients at risk, n

Placebo	4112	3821	3560	2722	1788	885	201
OM	4120	3838	3556	2710	1838	903	224

**Change in Kansas City Cardiomyopathy Questionnaire
Total Symptom Score from Baseline to Week 24**
Joint test P = 0.028





Primary Outcome: Subgroup Results

Subgroup

Overall

Randomization Setting

Inpatient

Outpatient

Region

Asia

E. Europe with Russia

Latin America

US and Canada

W. Europe, South Africa, and AUS

Age

< 65

≥ 65

Sex

Female

Male

Race

Asian

Black or African American

White

Other

Baseline NYHA Class

II

III/IV

Diabetes at baseline

No

Yes

Primary cause of HF

Ischemic

Non-ischemic

History of MI

No

Yes

Presence of Atrial fib/flutter

No

Yes

Hazard Ratio (95% CI)

0.92 (0.86, 0.99)

0.89 (0.78, 1.01)

0.94 (0.86, 1.02)

0.80 (0.61, 1.05)

0.90 (0.80, 1.02)

0.90 (0.75, 1.07)

0.85 (0.73, 0.99)

1.07 (0.93, 1.23)

0.91 (0.82, 1.02)

0.94 (0.86, 1.03)

0.95 (0.81, 1.12)

0.92 (0.85, 0.99)

0.79 (0.61, 1.02)

0.82 (0.64, 1.04)

0.95 (0.88, 1.03)

0.91 (0.69, 1.21)

0.97 (0.87, 1.08)

0.88 (0.80, 0.97)

0.91 (0.83, 1.01)

0.93 (0.84, 1.03)

0.90 (0.82, 0.98)

0.96 (0.86, 1.07)

0.93 (0.85, 1.03)

0.91 (0.83, 1.01)

0.86 (0.79, 0.94)

1.05 (0.93, 1.18)

Subgroup

Baseline LVEF

≤ median (28%)

> median (28%)

Baseline NT-proBNP (excl. Afib)

Inpatient + ≤ Median

Inpatient + > Median

Outpatient + ≤ Median

Outpatient + > Median

Baseline HR

≤ Median (71 bpm)

> Median (71 bpm)

Baseline SBP

≤ Median (116 mmHg)

> Median (116 mmHg)

Baseline eGFR

≤ 60 mL/min/1.73m²

> 60 mL/min/1.73m²

Baseline use of ACEi

No

Yes

Baseline use of ARB

No

Yes

Baseline use of MRA

No

Yes

Baseline use of ARNi

No

Yes

Baseline presence of CRT

No

Yes

Baseline presence of ICD

No

Yes

Hazard Ratio (95% CI)

0.84 (0.77, 0.92)

1.04 (0.94, 1.16)

0.97 (0.74, 1.28)

0.75 (0.61, 0.92)

0.88 (0.73, 1.05)

0.85 (0.75, 0.97)

0.91 (0.82, 1.01)

0.93 (0.85, 1.03)

0.90 (0.82, 0.99)

0.95 (0.85, 1.05)

0.98 (0.89, 1.07)

0.84 (0.75, 0.94)

0.94 (0.85, 1.03)

0.90 (0.81, 1.00)

0.91 (0.85, 0.99)

0.97 (0.83, 1.15)

0.98 (0.85, 1.12)

0.91 (0.83, 0.98)

0.91 (0.84, 0.99)

0.97 (0.83, 1.13)

0.93 (0.86, 1.01)

0.84 (0.72, 0.99)

0.94 (0.86, 1.03)

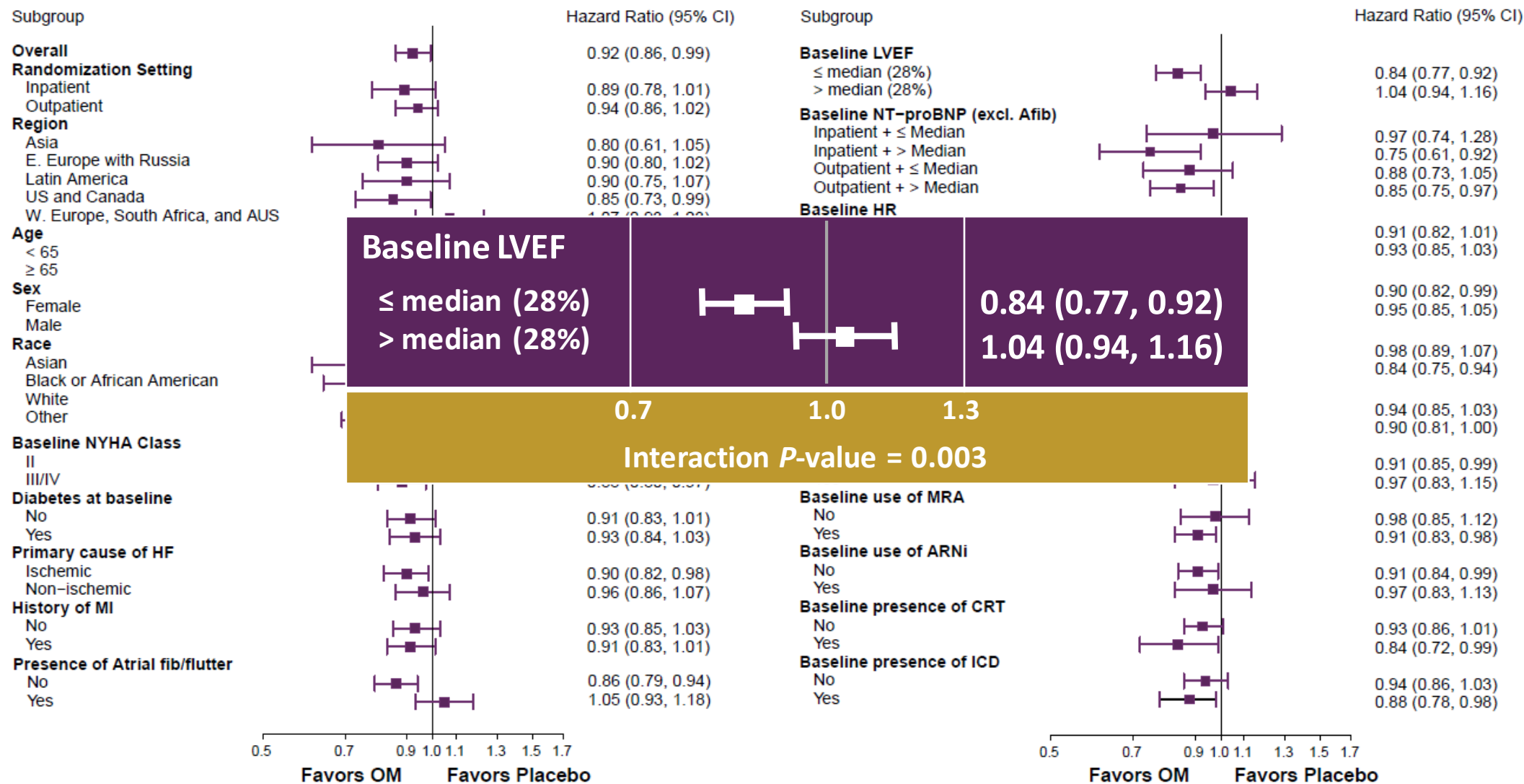
0.88 (0.78, 0.98)

0.5 0.7 0.9 1.0 1.1 1.3 1.5 1.7
Favors OM Favors Placebo

0.5 0.7 0.9 1.0 1.1 1.3 1.5 1.7
Favors OM Favors Placebo



Primary Outcome: Subgroup Results



Vital Signs and Laboratory Results

Variable	Omecamtiv Mecarbil (N=4110)	Placebo (N=4101)	Relative Risk or Difference (95% CI)
Vital signs, laboratory values: change from baseline to Week 24			
Systolic BP, mmHg, mean (SD)	1.4 (15.3)	1.5 (15.6)	-0.1 (-0.9, 0.6)
Heart rate, bpm, mean (SD)	-2.1 (12.6)	-0.5 (12.8)	-1.6 (-2.2, -1.0)
Potassium, mmol/L, mean (SD)	-0.01 ± 0.57	-0.01 ± 0.57	0.00 (-0.03, 0.03)
Creatinine, mg/dL, mean (SD)	0.03 ± 0.33	0.02 ± 0.32	0.01 (-0.01, 0.02)
NT-proBNP, pg/mL, median (Q1, Q3)	-251 (-1180, 295)	-180 (-915, 441)	0.90 (0.86, 0.94)
Cardiac troponin I, ng/mL, median (Q1, Q3)	0.004 (-0.002, 0.021)	0.000 (-0.009, 0.008)	0.004 (0.003, 0.005)

No reduction in blood pressure
No negative impact on renal function or potassium

Adverse Events

Adverse event	Omecamtiv Mecarbil (N=4110)	Placebo (N=4101)	Relative Risk (95% CI)
Any serious AE, n (%)	2373 (57.7)	2435 (59.4)	0.97 (0.94, 1.01)
Drug discontinuation due to AE, n (%)	371 (9.0)	382 (9.3)	0.97 (0.85, 1.11)
Adverse events of interest			
Ventricular tachyarrhythmias	290 (7.1)	304 (7.4)	0.95 (0.82, 1.11)
Torsade de pointes/QT prolongation	176 (4.3)	195 (4.8)	0.90 (0.74, 1.10)
SAE of ventricular arrhythmia requiring treatment	119 (2.9)	127 (3.1)	0.93 (0.73, 1.20)
Adjudicated major cardiac ischemic events, n (%)	200 (4.9)	188 (4.6)	1.06 (0.87, 1.29)
Myocardial infarction	122 (3.0)	118 (2.9)	--
Hospitalized for unstable angina	25 (0.6)	12 (0.3)	--
Coronary revascularization	115 (2.8)	117 (2.9)	--
Adjudicated Strokes	76 (1.8)	112 (2.7)	0.68 (0.51, 0.91)

No imbalance of AEs/SAEs (including cardiac ischemia and arrhythmias)

Conclusions

- In patients with HFrEF, omecamtiv mecarbil statistically significantly reduced the risk of the primary composite outcome (first HF event or CV death)
- The pattern of adverse events, including myocardial ischemia and ventricular arrhythmias, were similar in the omecamtiv mecarbil and placebo groups
- Selectively targeting the cardiac sarcomere with omecamtiv mecarbil, the first-in-class myotrope, is a novel approach to improving cardiac function
- Further analyses of GALACTIC-HF will provide greater insight into subgroups who may demonstrate greater benefit, such as patients with lower ejection fraction in whom improving cardiac function may have a greater role

For full details,
please see:

ORIGINAL ARTICLE

Cardiac Myosin Activation with Omecamtiv Mecarbil in Systolic Heart Failure

J.R. Teerlink, R. Diaz, G.M. Felker, J.J.V. McMurray, M. Metra, S.D. Solomon, K.F. Adams, I. Anand, A. Arias-Mendoza, T. Biering-Sørensen, M. Böhm, D. Bonderman, J.G.F. Cleland, R. Corbalan, M.G. Crespo-Leiro, U. Dahlström, L.E. Echeverria, J.C. Fang, G. Filippatos, C. Fonseca, E. Goncalvesova, A.R. Goudev, J.G. Howlett, D.E. Lanfear, J. Li, M. Lund, P. Macdonald, V. Mareev, S. Momomura, E. O'Meara, A. Parkhomenko, P. Ponikowski, F.J.A. Ramires, P. Serpytis, K. Sliwa, J. Spinar, T.M. Suter, J. Tomcsanyi, H. Vandekerckhove, D. Vinereanu, A.A. Voors, M.B. Yilmaz, F. Zannad, L. Sharpsten, J.C. Legg, C. Varin, N. Honarpour, S.A. Abbasi, F.I. Malik, and C.E. Kurtz, for the GALACTIC-HF Investigators*

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945 Site Investigators in 35 Countries!!

Editorial support provided by Ellen Stoltzfus, PhD, and Maya Shehayeb, PharmD, MS (Amgen, Inc.)

MAKING SENSE OF SUBGROUPS

Scott Solomon, M.D., Edward D. Frohlich Distinguished Chair,
Professor of Medicine, Harvard Medical School and Director of
Noninvasive Cardiology, Brigham and Women's Hospital



Putting GALACTIC-HF in Context: Understanding Subgroups

Scott D. Solomon, MD
The Edward D. Frohlich Distinguished Chair
Professor of Medicine
Harvard Medical School
Brigham and Women's Hospital

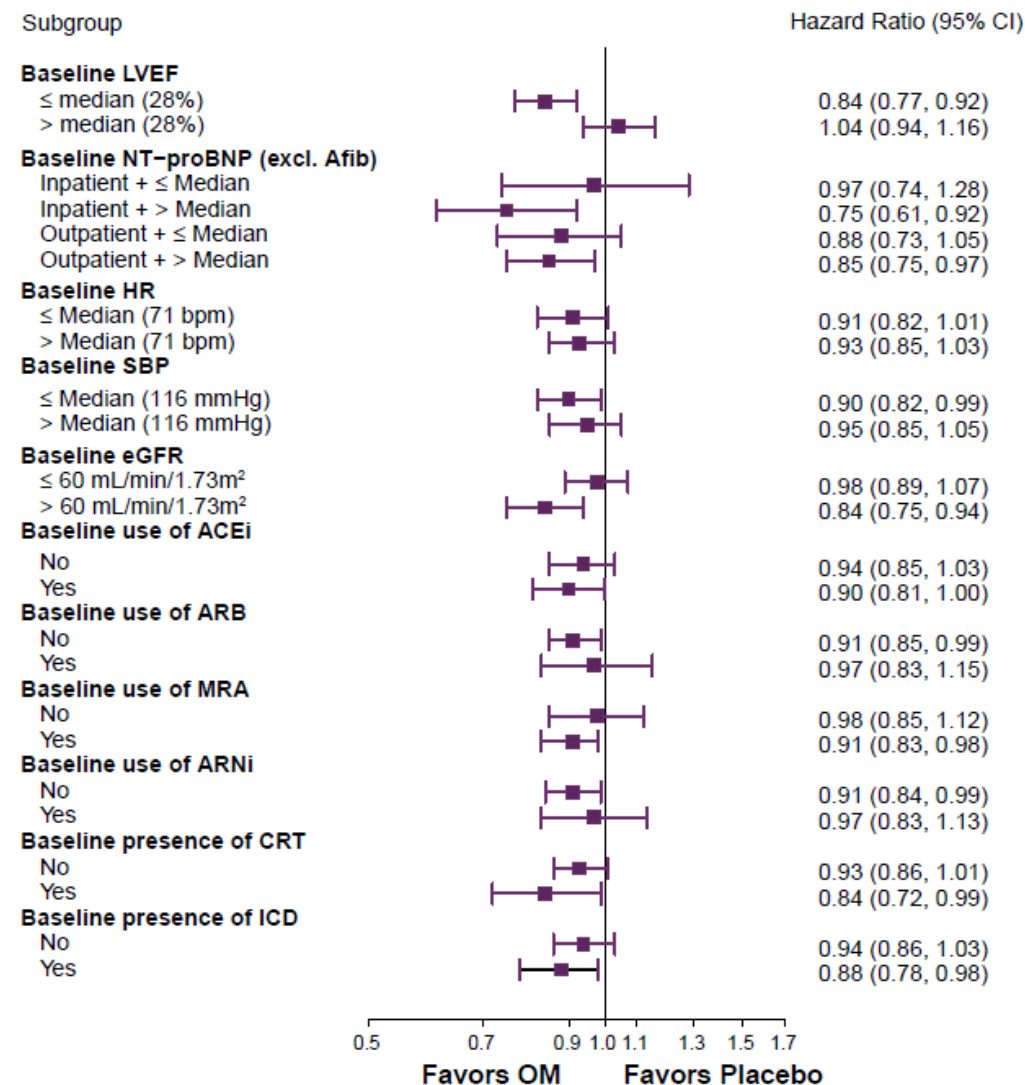
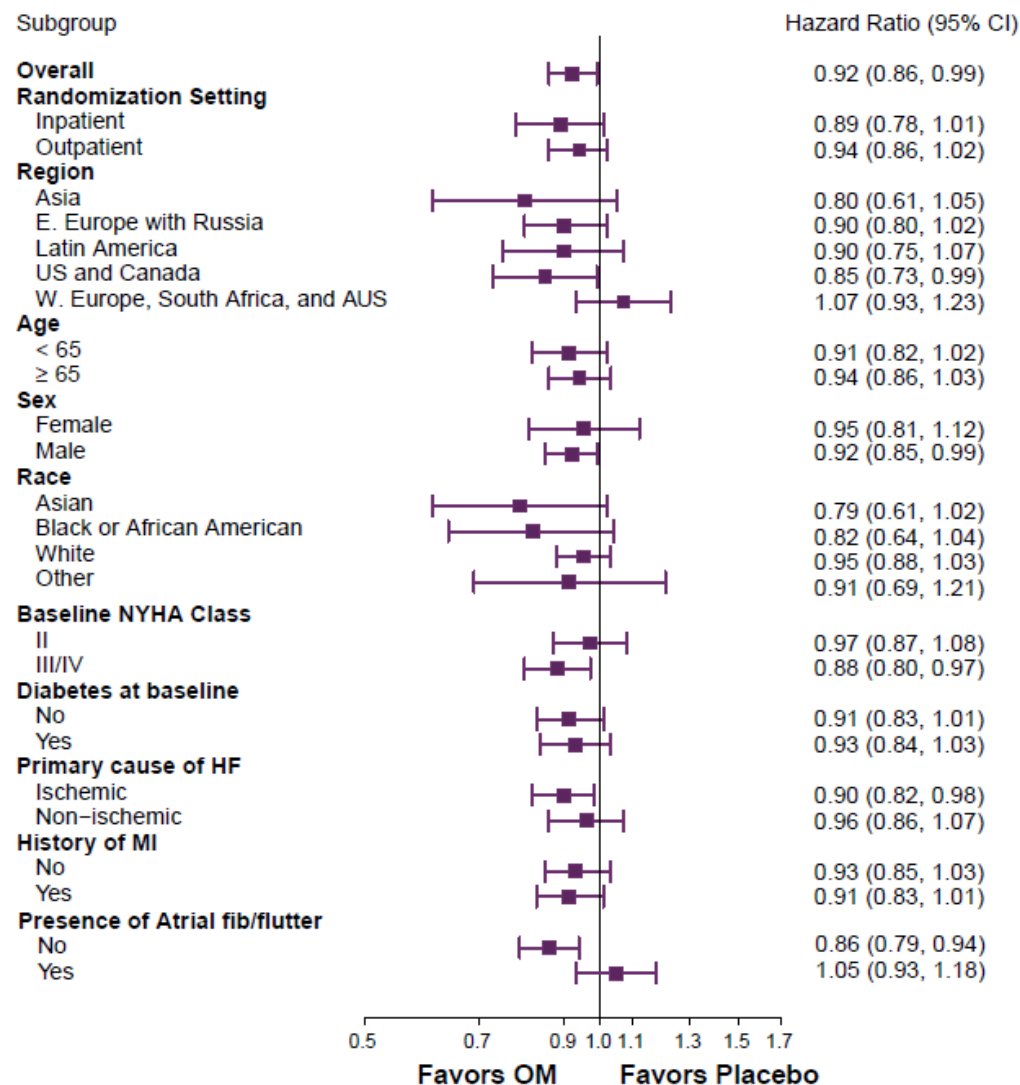
Disclosures

- Dr. Solomon has received research grants from Alnylam, Amgen, AstraZeneca, Bellerophon, Bayer, BMS, Celladon, Cytokinetics, Eidos, Gilead, GSK, Ionis, Lone Star Heart, Mesoblast, MyoKardia, NIH/NHLBI, Neurotronik, Novartis, Respicardia, Sanofi Pasteur, Theracos, and has consulted for Akros, Alnylam, Amgen, Arena, AstraZeneca, Bayer, BMS, Cardior, Cardurion, Corvia, Cytokinetics, Daiichi-Sankyo, Gilead, GSK, Ironwood, Merck, Myokardia, Novartis, Roche, Takeda, Theracos, Quantum Genetics, Cardurion, AoBiome, Janssen, Cardiac Dimensions, Tenaya, Sanofi-Pasteur, Dinaqor, Tremeau, Moderna, CellProThera

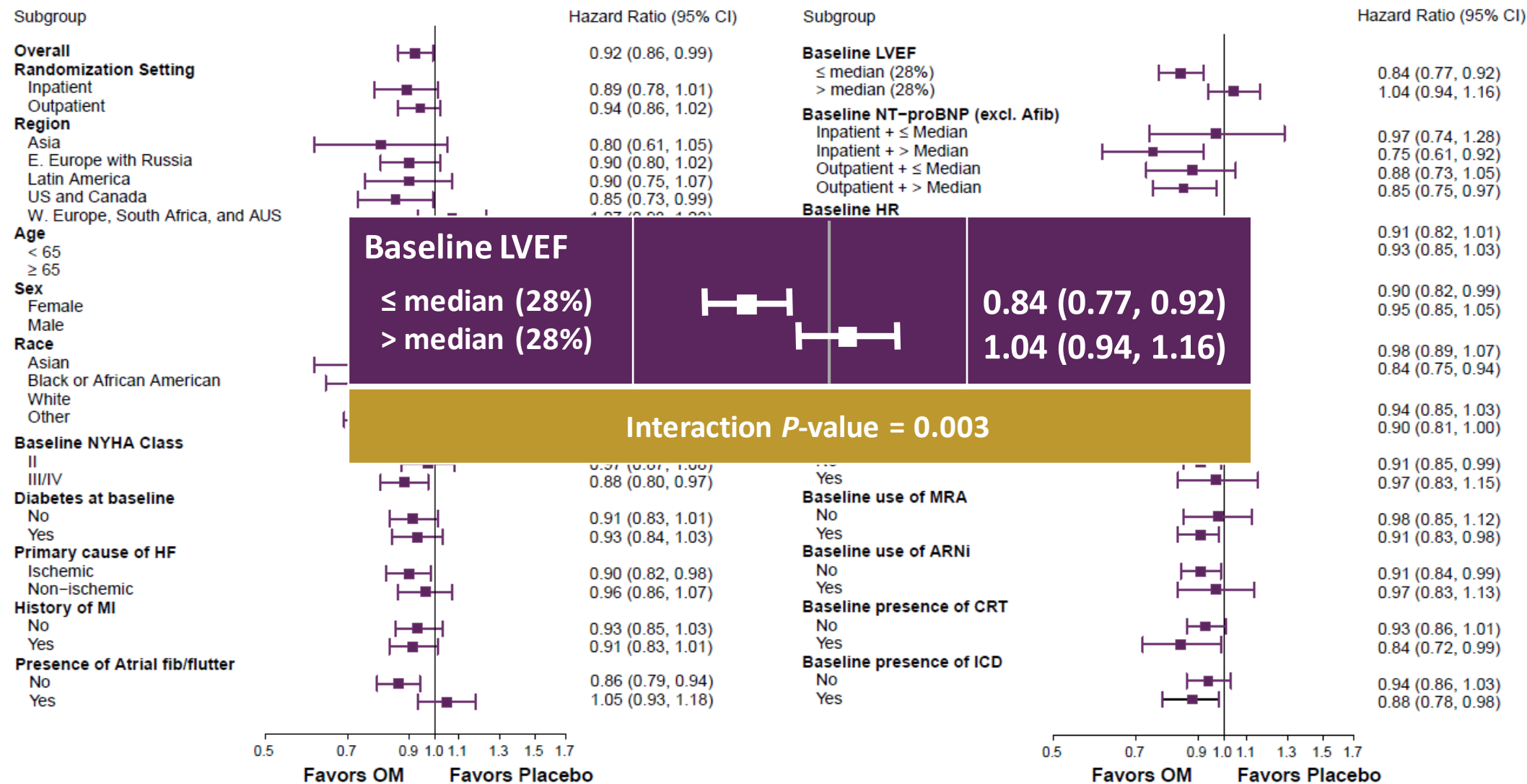
GALACTIC HEADLINE RESULTS

- Significant albeit modest overall treatment effect
- Greater benefit in patients with lower LVEF

Primary Outcome: Subgroup Results



Primary Outcome: Subgroup Results



On Looking at Subgroups

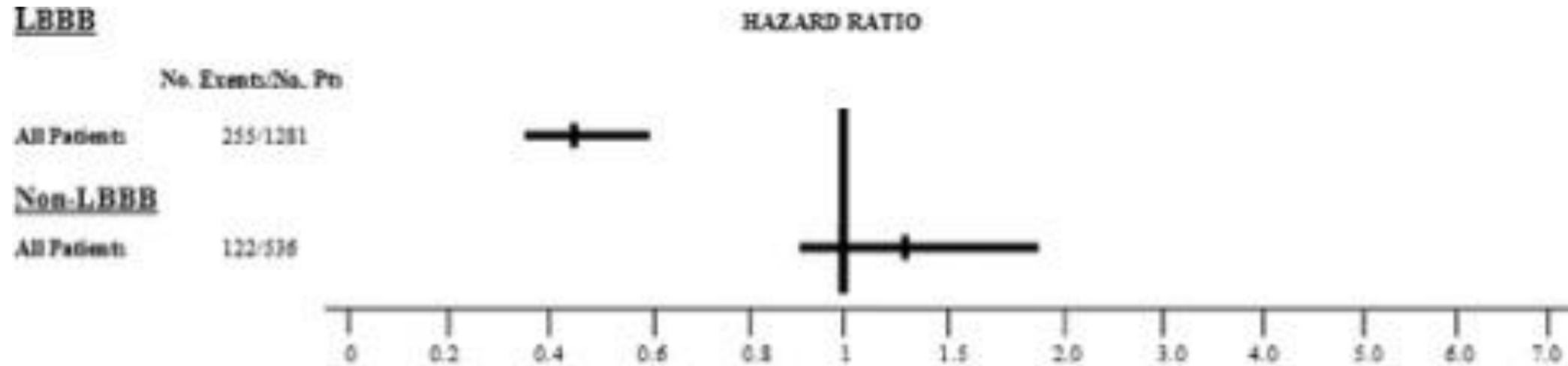
Janet Wittes, PhD

- Subgroups are generally assessed to test for consistency of results, *not* heterogeneity
- ...If we are lucky, all the reported subgroups will show essentially the same thing, and the summary of results will include a statement that “the findings were consistent across subgroups of interest.”

How Do We Interpret Subgroups?

- Subgroup must be prespecified (not *post hoc*) ✓
- Should be large – patients and events (smaller less reliable – subgroups are always underpowered) ✓ - 4000+ patients!
- Use a test for interaction and ideally adjust for multiplicity (ideally a multivariable analysis) ✓ - significant interaction test
- Examine the architecture of the total data and adjacent subgroups (internal consistency) ✓ - other way around would have not made sense
- Biological coherence/plausibility ✓ - makes sense that a drug that makes heart contract better will work better in lower EF patients

MADIT-CRT: Subgroup dictated therapy



Benefit only in patients with LBBB despite overall benefit

Summary

- Patients in GALACTIC-HF with lowest EF benefit to a greater extent than do patients with higher EF
- This benefit occurred on top of *very* good background therapy
- This subgroup finding, in light of a significant albeit modest overall benefit, provides a clear roadmap for OM becoming standard of care in patients with advanced heart failure and low EF – a group with great unmet need

UNMET NEED IN ADVANCED HF

G. Michael Felker, M.D., M.H.S., Professor of Medicine, Vice-Chief of Cardiology for Clinical Research, Duke University School of Medicine and Director of Cardiovascular Research, Duke Clinical Research Institute

Unmet Needs in Advanced Heart Failure

G. Michael Felker, MD, MHS, FACC, FAHA, FHFSA
Professor of Medicine
Vice-Chief for Clinical Research, Duke Cardiology
Director of Cardiovascular Research, DCRI
Duke University School of Medicine



Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE



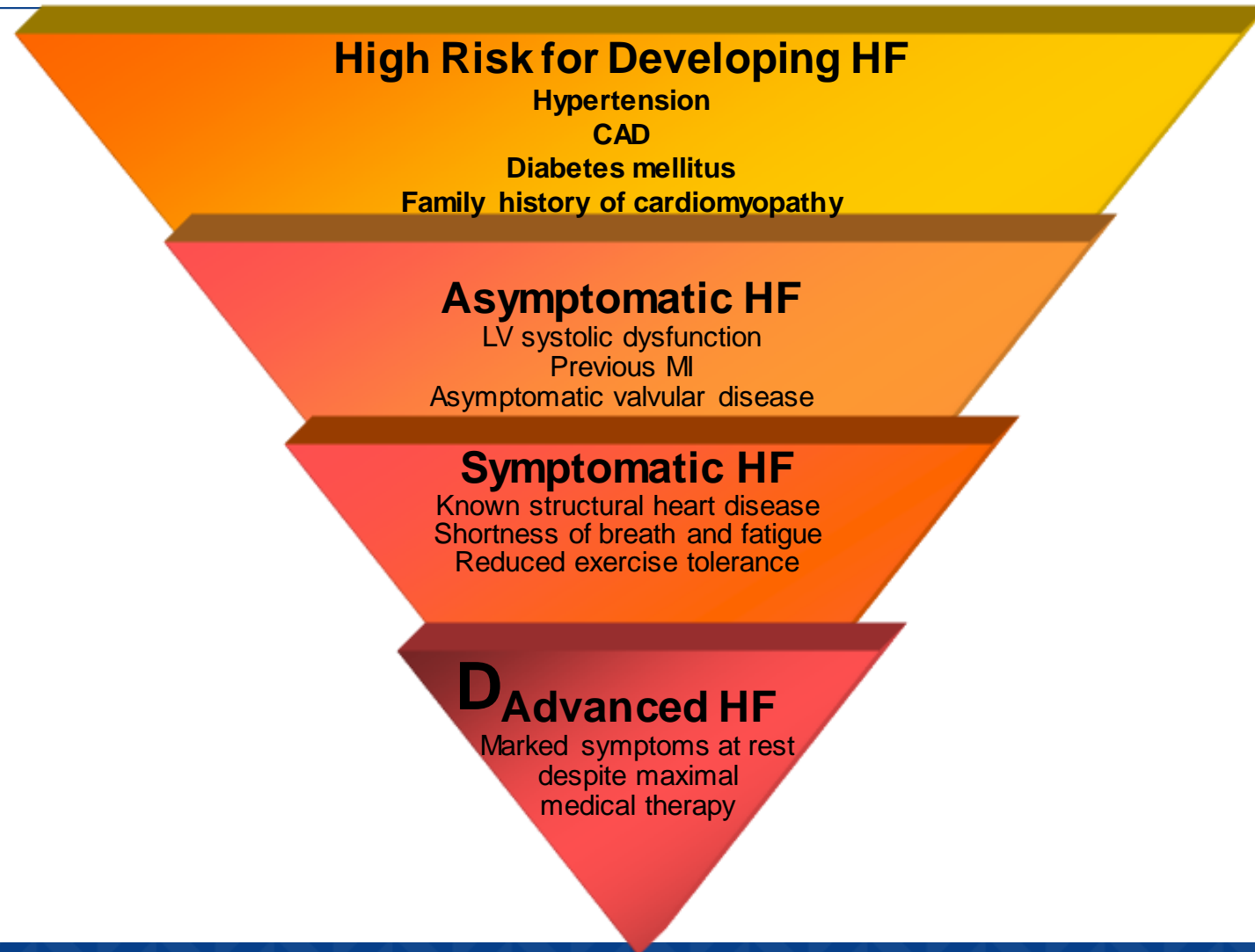
Duke Heart

What is “Advanced Heart Failure”?

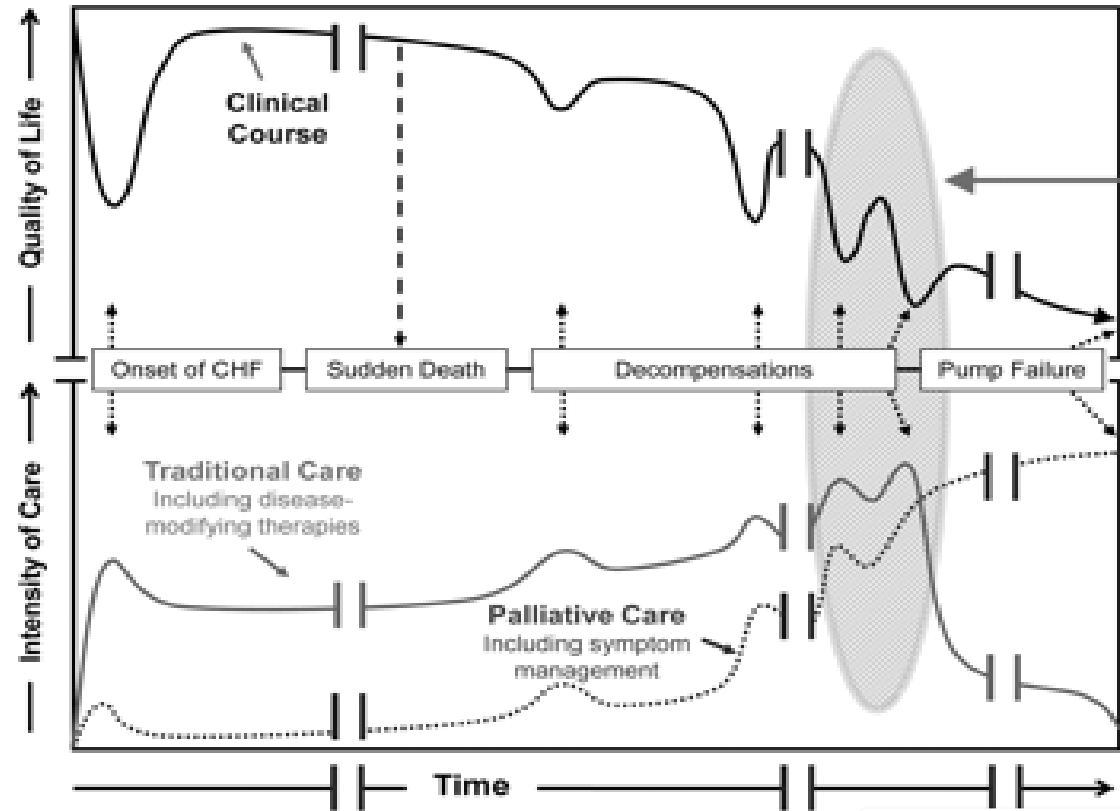
- **Despite optimal medical and device treatment, the presence of:**
 - Significant persistent symptoms
 - Objective evidence of severe impairment of cardiac performance
 - $EF < 30\%$
 - Impaired invasive or non-invasive hemodynamics
 - Recurrent hospitalizations
 - Severe impairment of functional capacity ($6MWD < 300$ m, $peak\ V_{O2} < 12$ mg/kg/min)



Defining the Heart Failure Population: AHA/ACC Staging



The Natural History of Heart Failure



Neurohormonal
abnormalities
predominate



Low output
symptoms
predominate

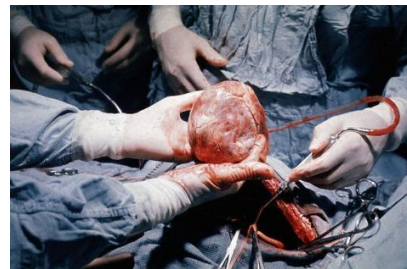
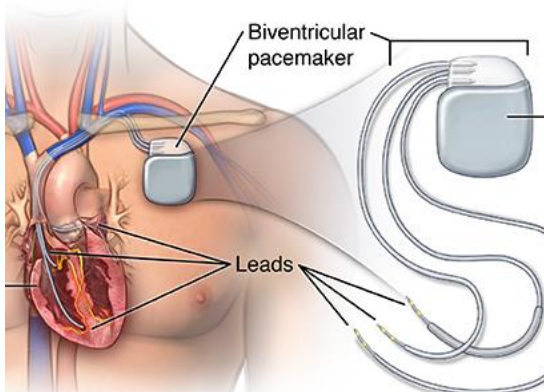


Warning Signs from the Bedside:

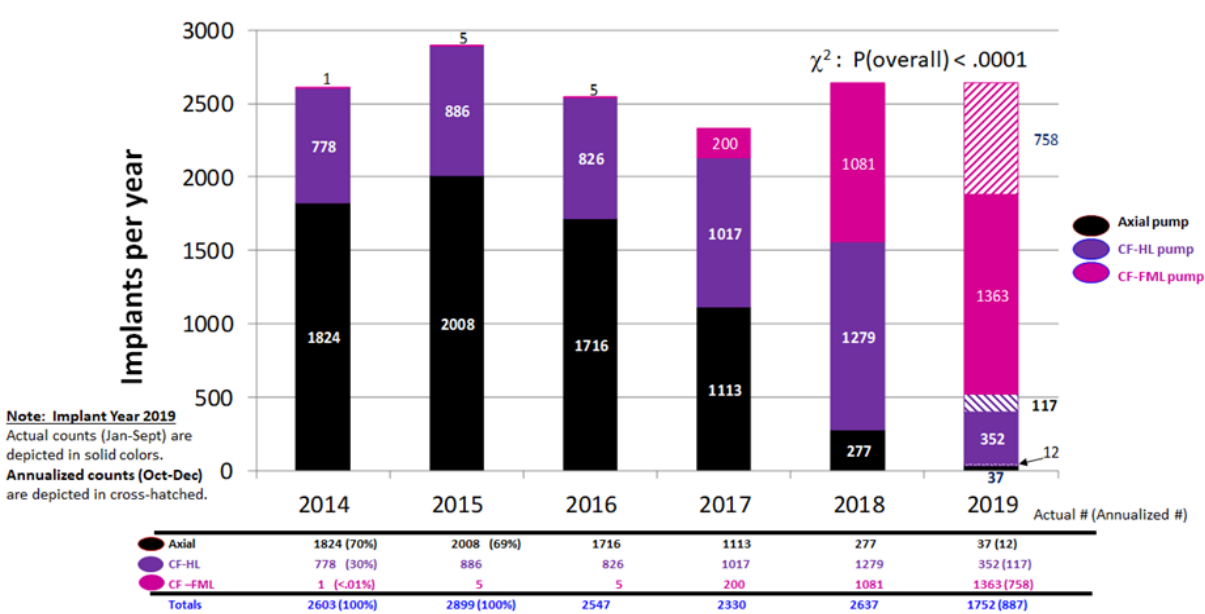
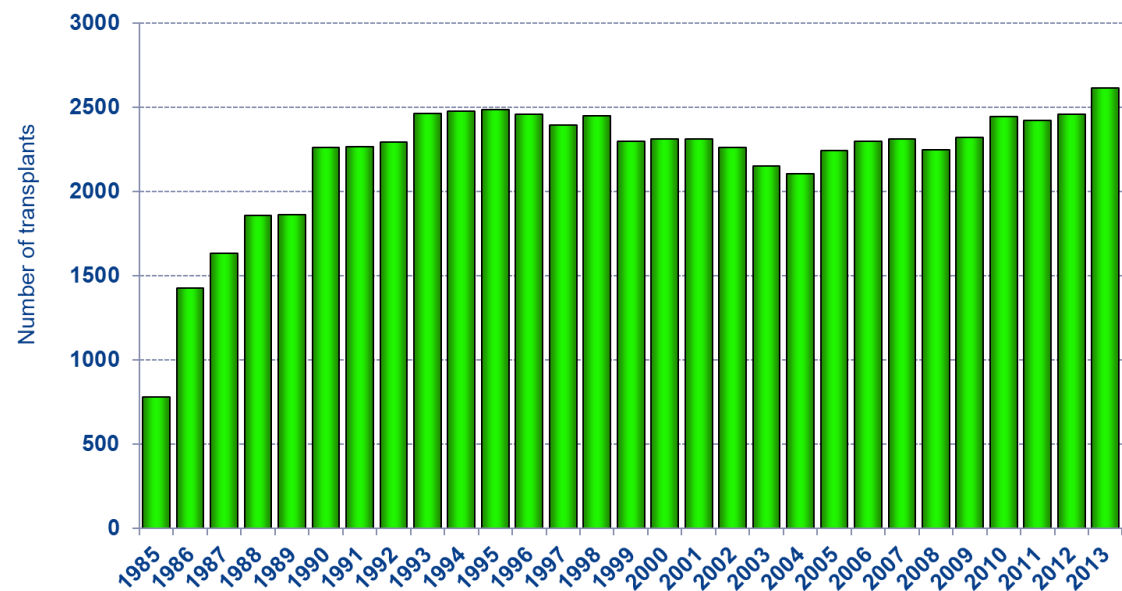
- Recurrent heart failure hospitalizations
- “Baseline” is deteriorating
- Worsening hypotension leading to dose reduction or stopping of BB/ACE/ARB/ARNi
- Worsening azotemia leading to dose reduction or stopping of ACE/ARB/ARNi/MRA
- Worsening diuretic resistance (increased doses required to maintain euvolemia)



Advanced Heart Failure: Therapeutic Options

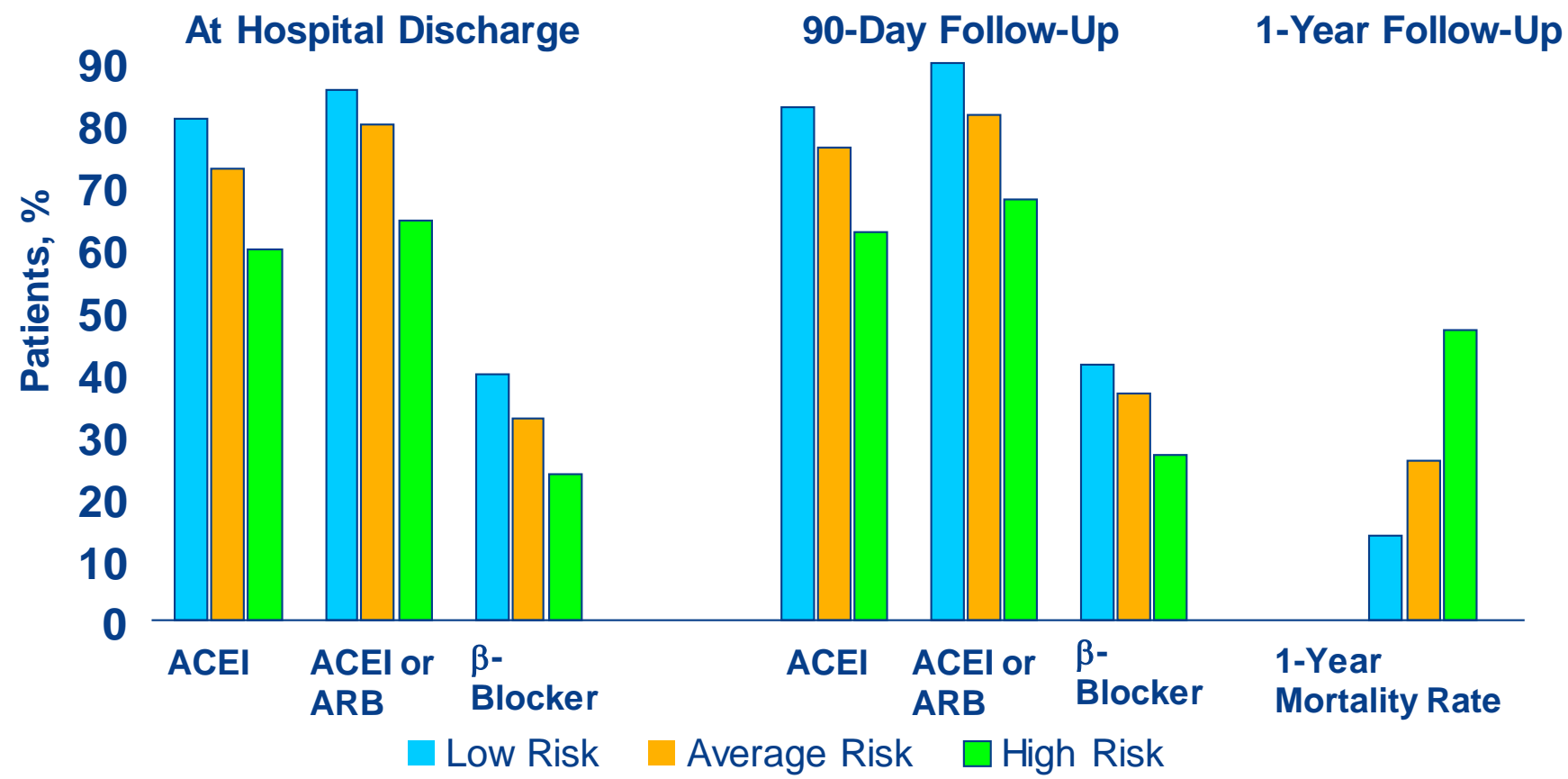


Transplant and Mechanical Cardiac Support Volumes



< 6000 pts annually treated with transplant or durable MCS

Risk-Treatment Mismatch in HF: Canadian EFFECT Study



The sickest patients are the most difficult to treat with GDMT

Drug Intolerance to GDMT in HFrEF

Hypotension

- Diuretics
- ACE-inhibitors
 - ARBs
 - ARNIs
- Beta-blockers
- MRA

Azotemia/Renal/K

- Diuretics
- ACE-inhibitors
 - ARBs
 - ARNIs
- MRA

Angioedema

- ACE-inhibitors
 - ARBs
 - ARNIs

Bradycardia/Fatigue

- Beta-blockers



Persistent Unmet Need for Therapies That:

- Do not have overlapping side effect profile with other aspects of GDMT
- Can be used in advanced patients despite relative hypotension and azotemia
- Directly address impaired cardiac performance that is central to pathophysiology of more advanced heart failure
- Affect symptoms, functional capacity, recurrent hospitalizations



Paradigms of Chronic Disease Management

- Option 1. Many available meds, tailored to pt characteristics and response

- Hypertension
- Diabetes
- Atrial fibrillation
- Cancer chemotherapy
- HIV
- Hyperlipidemia

- Option 2. Give all the proven meds at once to all pts

- Heart failure

Over time Option 2 is unsustainable and there will be increasing need to target specific groups of patients with specific therapies



ECONOMIC BURDEN OF HF

Nihar R. Desai, M.D., MPH, Associate Professor of Medicine,
Associate Chief, Cardiovascular Medicine, Yale School of
Medicine, Center for Outcomes Research and Evaluation

The Heart Failure Landscape and the Move to Value

Nihar R. Desai, MD, MPH

Associate Professor of Medicine, Yale School of Medicine

Associate Chief, Section of Cardiovascular Medicine

Medical Director, Value Based Programs

Investigator, Center for Outcomes Research and Evaluation



Heart Failure Landscape

HF is the
**#1 cause of
hospitalization and 30-
day readmission** among
Medicare beneficiaries

5-year mortality rate of
≈75%
for patients hospitalized for HF

**127% projected
increase** in the total cost
of HF from 2012-2030, now
nearly \$80 billion

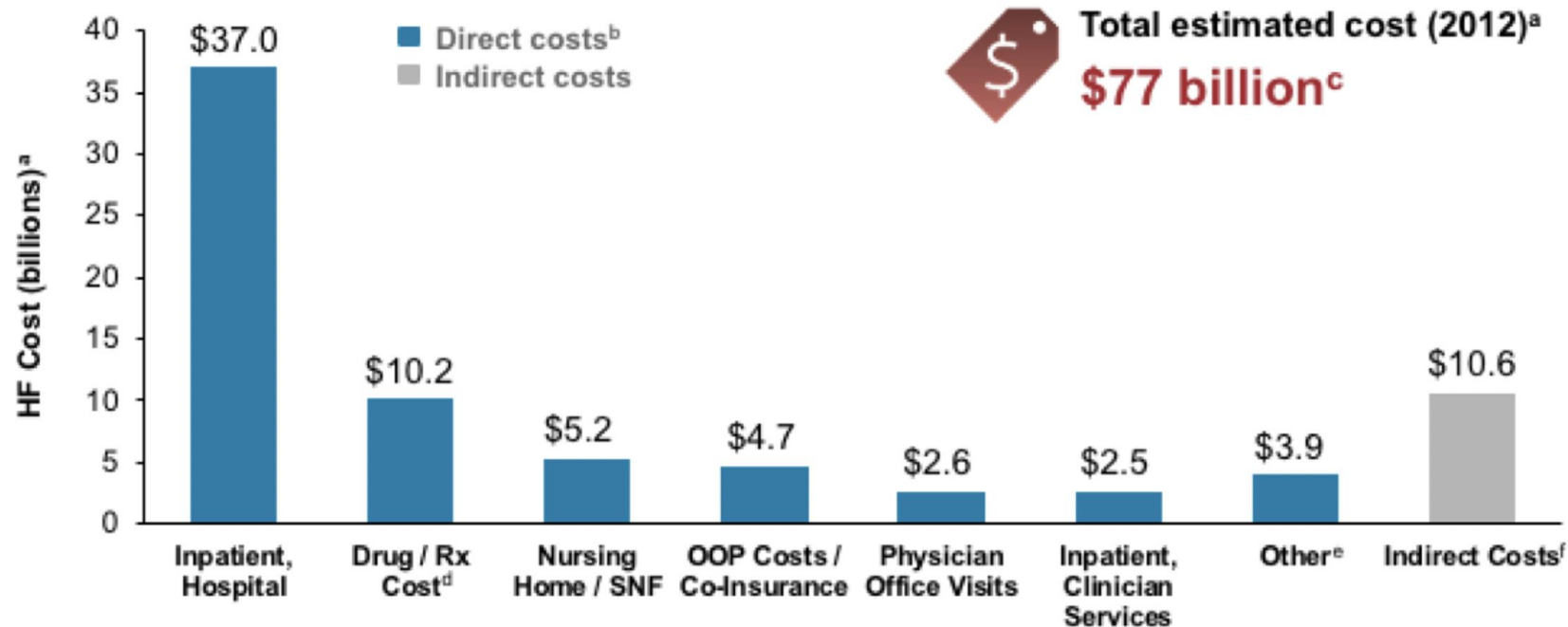
Substantial variation in
quality, outcomes, and
payments
(Value Opportunity)

New therapies do not enter a vacuum but rather a complex and dynamic ecosystem that will favor strategies that create value.

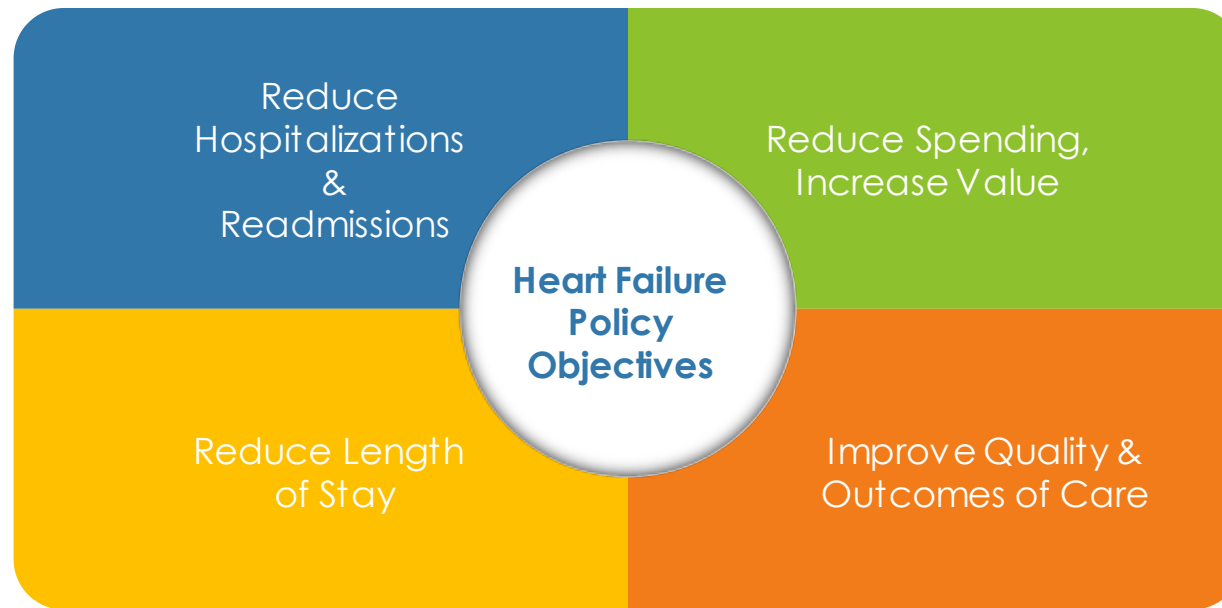


Staggering Economic Burden

Hospitalizations Represent ~50% of the Total Cost of Care for HF in the US



We Are In the Midst of Climate Change



Payment Models...They Are A Changin'

Medicare Payment Policy

IPPS/FFS

P4P

HRRP
HVBP
MIPS

Bundled
Payments

BPCI
BPCI-Advanced

Accountable Care
Organizations

MSSP
NextGen ACO



Srinivasan D et al. *J Card Fail.* 2017;23:615-620; Burwell SM. *N Engl J Med.* 2015;372:897-899.

P4P: Pay For Performance; FFS: Fee-For-Service; IPPS: Inpatient Prospective Payment System; BPCI: Bundled Payment for Care Improvement;

MSSP: Medicare Shared Savings Program; ACO: Accountable Care Organization; HRRP: Hospital Readmission Reduction Program; HVBP:

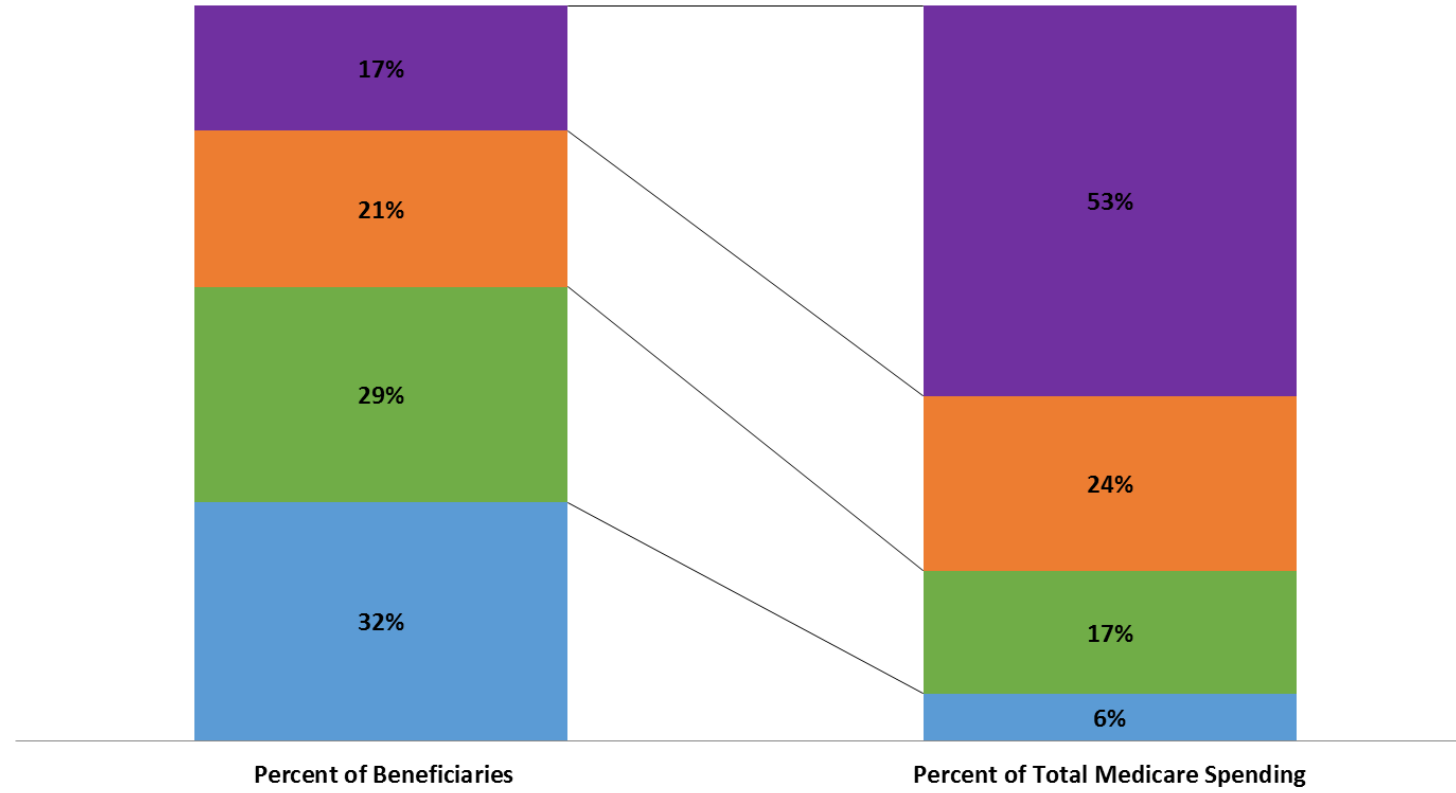
Hospital Value Based Purchasing Program; MIPS: Merit Based Incentive Payment System



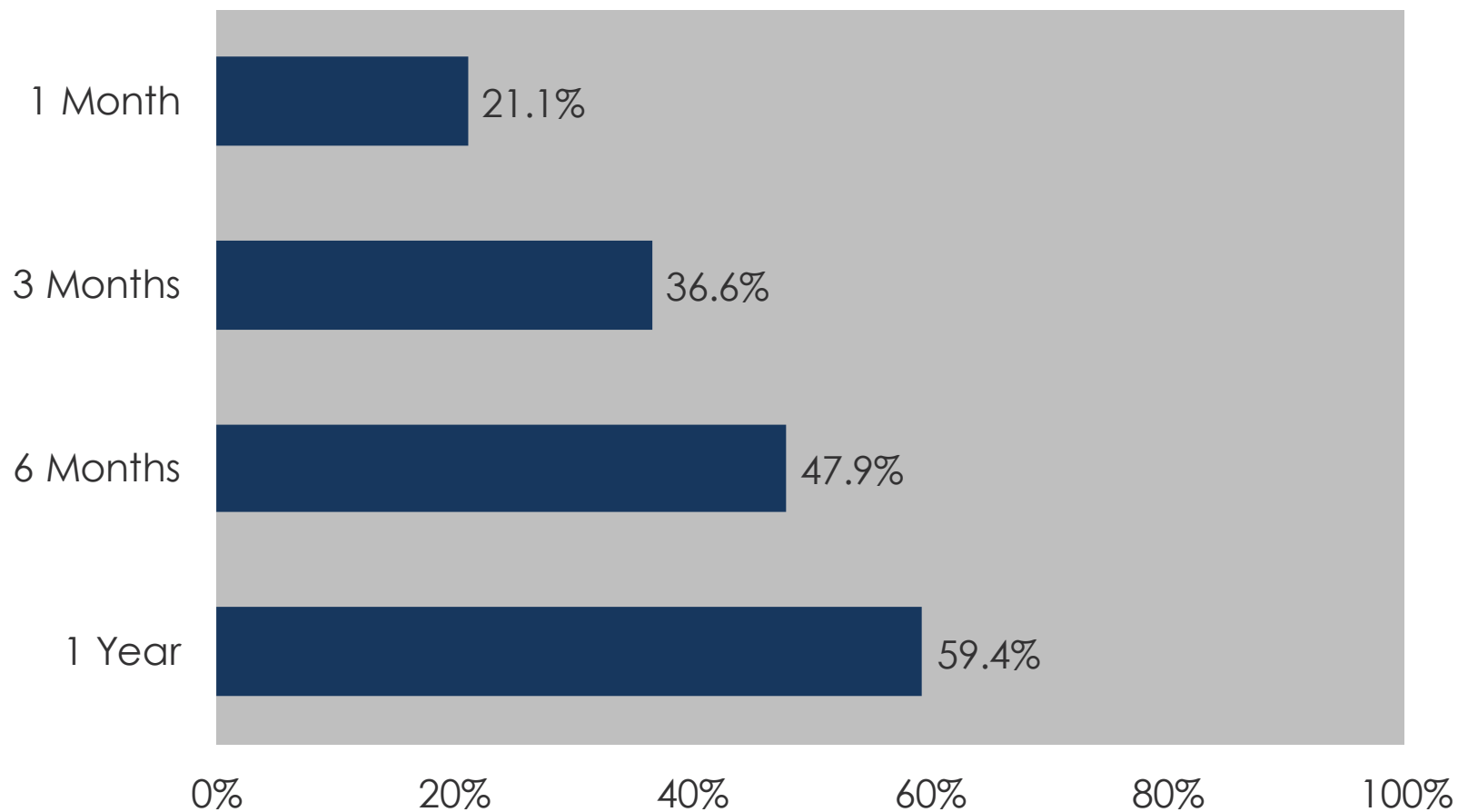
Patients, Populations, and Policy

Figure 13: Distribution of Medicare Fee-for-Service Beneficiaries and Medicare Spending by Number of Chronic Conditions: 2017

■ 0 to 1 condition ■ 2 to 3 conditions ■ 4 to 5 conditions ■ 6+ conditions



Readmissions: Prevalent, Costly, (Preventable)



Cumulative Percentage of Patients Rehospitalized



Jencks SF, Williams MV, Coleman EA. *N Engl J Med* 2009;360:1418-28.



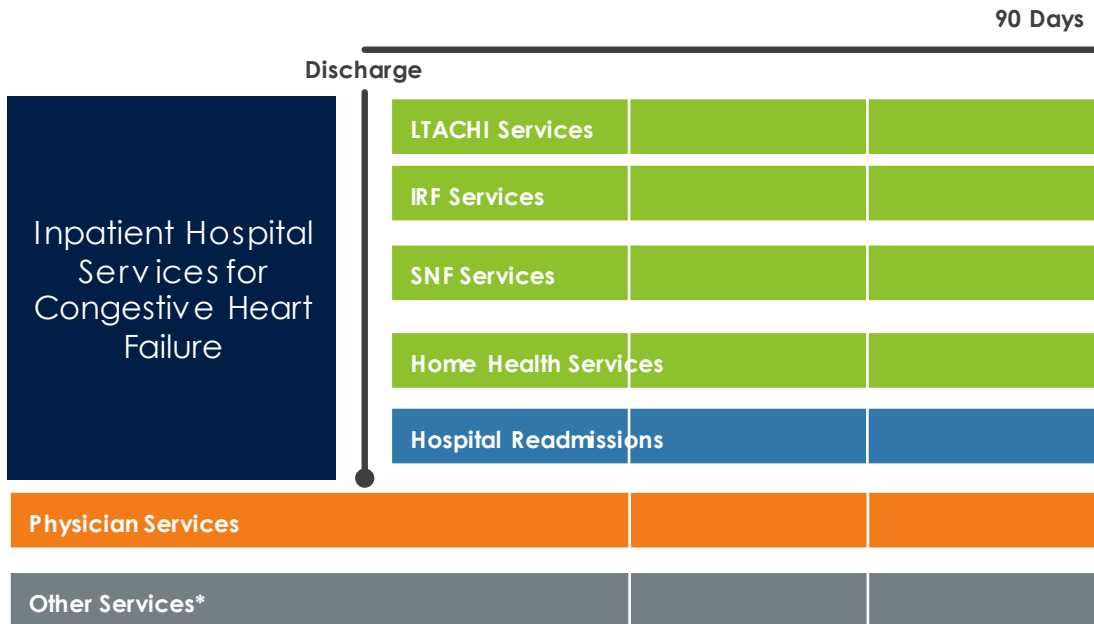
The Hospital Readmission Reduction Program

Year penalties applied	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Performance (measurement) period	June 2008 – July 2011	June 2009 – July 2012	June 2010 – July 2013	June 2011 – July 2014	June 2012 – July 2015	June 2013 – July 2016
Diagnosis of initial hospitalization	Heart attack Heart failure Pneumonia	Heart attack Heart failure Pneumonia	Heart attack, Heart failure, Pneumonia COPD, hip or knee replacement	Heart attack, Heart failure, Pneumonia COPD, hip or knee replacement	Heart attack, Heart failure Pneumonia COPD, hip or knee replacement, CABG	Heart attack, Heart failure Pneumonia COPD, hip or knee replacement, CABG
Penalties: percentage reduction in base payments on all Medicare inpatient admissions						
Maximum rate of penalty	1%	2%	3%	3%	3%	3%
Average hospital penalty (among penalized hospitals only)	-0.42%	-0.38%	-0.63%	-0.61%	-0.74%	-0.79%
Percent of hospitals penalized	64%	66%	78%	78%	79%	82%
CMS estimate of total penalties	\$290 million	\$227 million	\$428 million	\$420 million	\$528 million	\$574 million



BPCI-Advanced Nuts & Bolts

Hospitals are financially accountable for the cost and quality of care provided to Medicare fee-for-service beneficiaries for the inpatient stay through to 90-days post discharge



*Hospital outpatient services, Part B drugs, durable medical equipment (DME), clinical laboratory services, hospital and independent outpatient therapy services. LTACH, Long-term acute care hospital; IRF, Independent rehabilitation facility; SNF, skilled nursing facility.



90-Day, Retrospective Bundled Payment

- FFS payments continue to be made for individual healthcare services
- Total FFS payments for clinical episode are then retrospectively reconciled against a predetermined Target Price
- Depending on the result of the reconciliation, each participant will receive a Net Payment Reconciliation Amount (NPRA) or must make a payment to CMS (Repayment Amount)

Keys to Success:

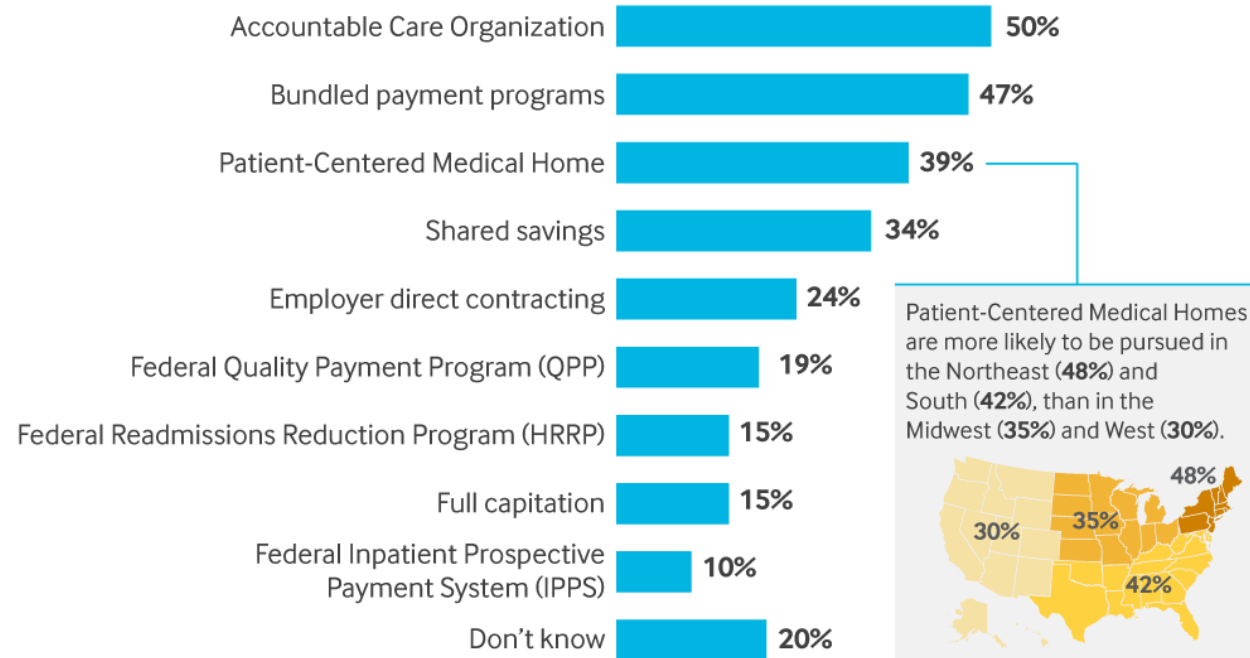
- Ensure efficiency and high quality of inpatient care
- Reduce avoidable readmissions,
- Reduce unnecessary post-acute care services,
- Optimize post-acute care use, and
- Perform well on pre-specified outcome measures



Providers and Systems Are Preparing For the Value Based World

Health Care Organizations Are Pursuing a Range of Value-Based Care Models

Which value-based care models is your organization actively pursuing?



Base: 552 (multiple responses)
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society



A Glimpse Into the Future

Secretary Azar Points to Significant Bundled Payments Expansion Including Both Voluntary and Mandatory Models



"We need results, American patients need change, and when we need mandatory models to deliver it, **mandatory models are going to see a comeback**"

"I want to share with all of you for the first time today: We intend to revisit some of the episodic cardiac models that we pulled back, and **are actively exploring new and improved episode-based models** in other areas, including radiation oncology. We're also actively looking at ways to build on the lessons and successes of the Comprehensive Care for Joint Replacement model."

"We're not going to stop there: We will use all avenues available to us—including **mandatory and voluntary episode-based payment models.**"

Secretary Azar
November 8, 2018



Azar speech at Patient-Centered Primary Care Collaborative Conference.
<https://www.advisory.com/daily-briefing/2018/11/09/payment-models>



Summary and A Look Ahead

- The pressure to move to a value based model of health care delivery and financing is intense and will only further intensify.
- There is an urgent need to reimagine heart failure care with this push to value.
- Therapies and strategies that deliver value to patients, providers, and payers (improved outcomes, better QoL, reduced costs) will thrive in this evolving ecosystem.



Q&A

Type your question into the box below the webcast window

CLOSING REMARKS

Robert Blum, President & CEO