

## Polipíldora como estrategia para reducir el riesgo cardiovascular

# Polipíldora: una realidad en el presente, una esperanza de futuro.

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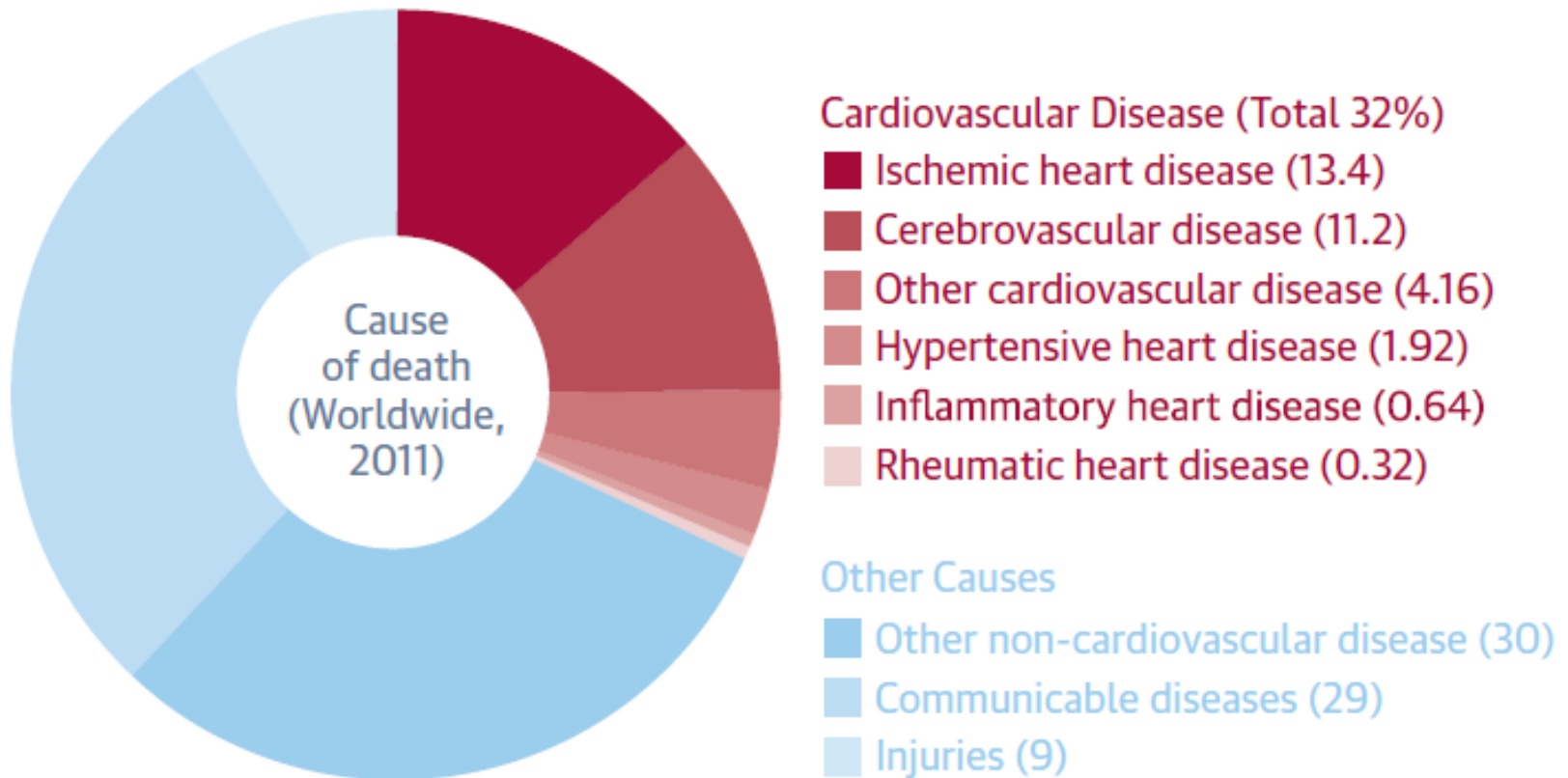
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2. El fenómeno de la adherencia terapéutica: causas, impacto clínico y económico y estrategias para mejorar la adherencia.
3. Trinomía: del debate conceptual a la práctica clínica.
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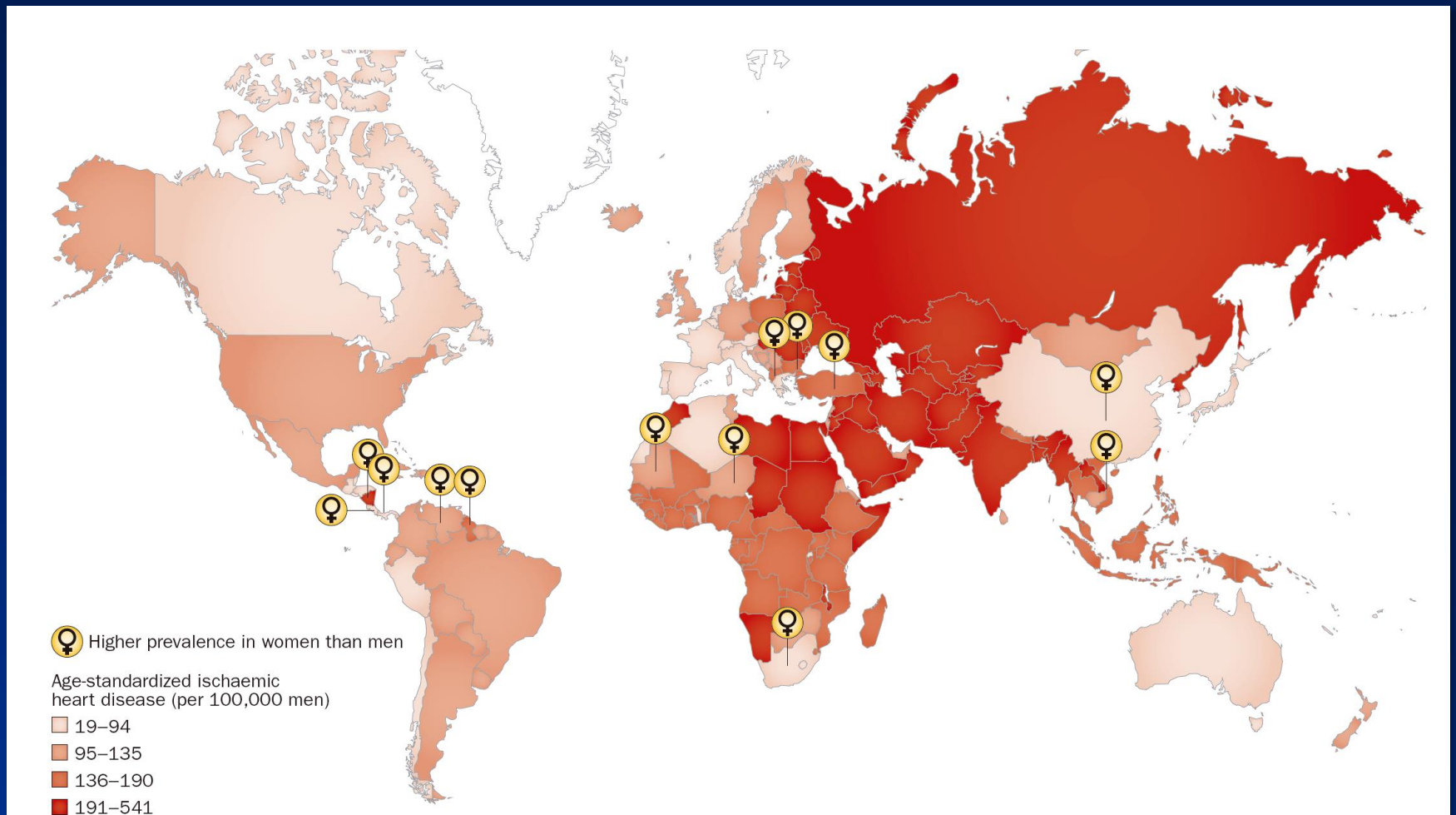
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# CARDIOVASCULAR DISEASE IN 2011



# Global Burden of Cardiovascular Disease



**8 out of 10 cardiovascular deaths occur in LMIC**

# Global treatment rates with antiplatelet, statin and BP lowering

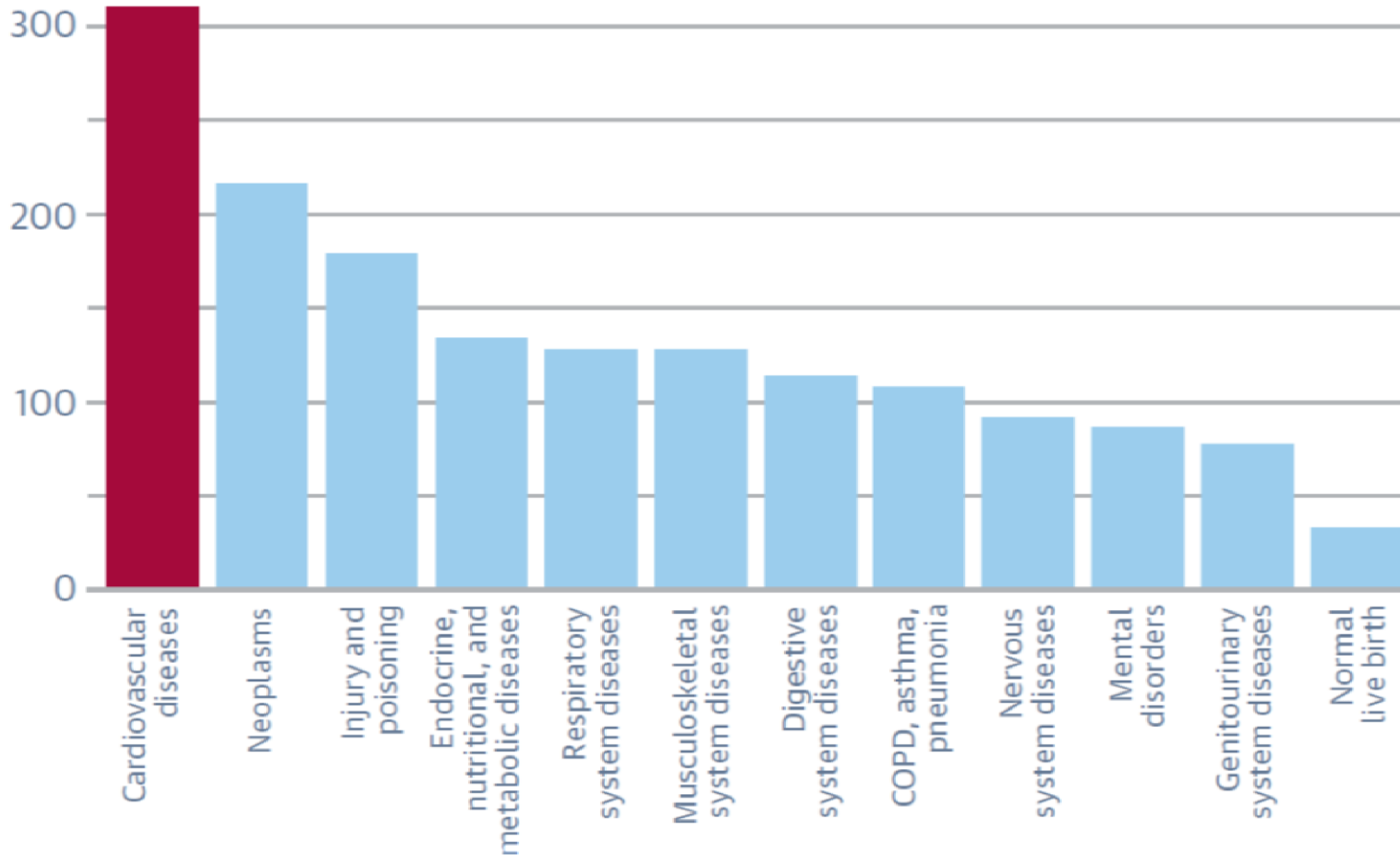
Previous MI: 8%

Previous Stroke: 14%



# CARDIOVASCULAR DISEASE IN 2011

Total Cost of Illness by Major Diagnosis, in US, 2009 (billions of US dollars)

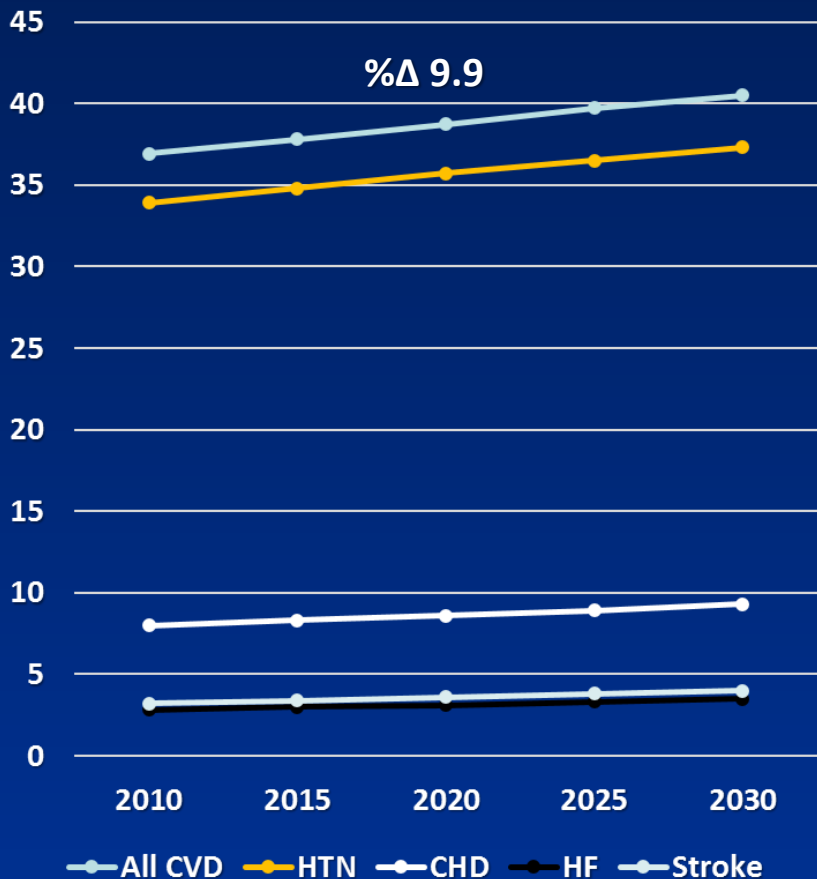


# AHA Policy Statement

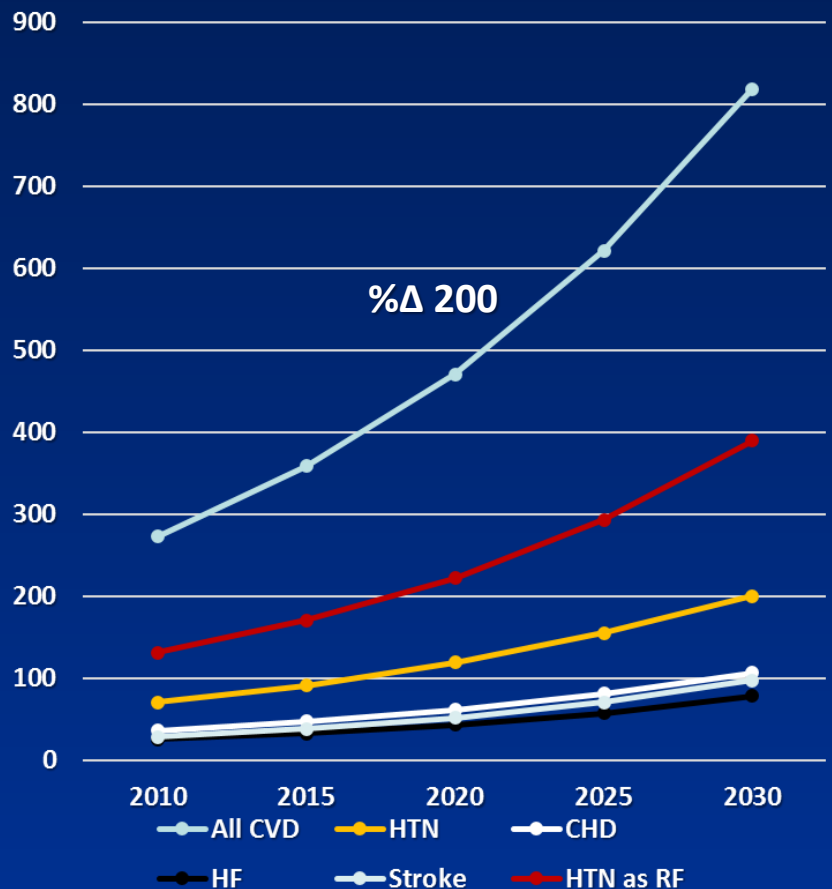
## Forecasting the Future of Cardiovascular Disease in the United States

A Policy Statement From the American Heart Association

### Projections of Prevalence

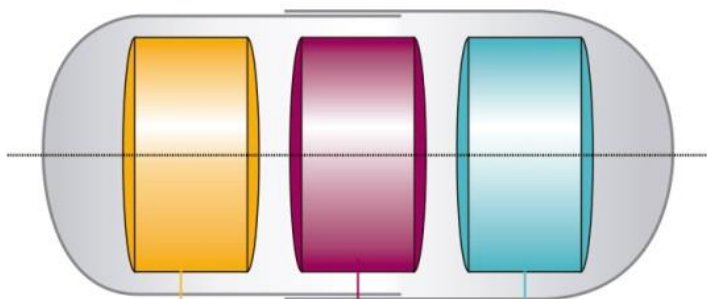


### Projections of Direct Cost (Billions USD)





# A Polypill Strategy for Secondary Cardiovascular Prevention: from concept to reality



**Acetylsalicylic acid**  
Platelet  
antiaggregation

**Atorvastatin**  
Plaque  
stabilisation

**Ramipril**  
Myocardial  
remodelling



Fuster *cnïc* ferrer



Reduces the number of components to simplify treatment regimen:  
**Improves adherence**

Cost Effective Strategy  
**Improves affordability**

Favors global **accessibility** to pharmacologic treatment

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# Medication Non-Adherence

...America's other drug problem



AMERICAN COLLEGE of CARDIOLOGY

MED ADHERENCE



Nearly **3 out of 4** Americans admit that they **do not always take their medication** as directed

This **problem** causes...

**1/3**



of medicine-related **hospitalizations**

Nearly

**1,250,000**

**deaths** in the U.S. each year

Almost

**\$300 billion**

in **avoidable costs** to the health care system annually

Number of Americans **affected by a chronic condition** requiring **medication therapy**

is expected to grow



from **133 million**



to **157 million** by 2020

# Medication Non-Adherence

## The Five Dimensions of Non Adherence

<b>Social/ Economic</b>	<b>Health Care System</b>	<b>Condition- Related</b>	<b>Therapy- related</b>	<b>Patient- related</b>
Age and race Family size Marital status	Patient Provider relationship	Comorbidities (depression)	Polypharmacy Side effects	Cognitive impairment
Socio economic status Education Employment Income	Overworked HCP  Communication	Asymptomatic condition	Complexity of treatment Lack of immediate benefit of therapy	Assumption once person feels better: discontinuation
Health Illiteracy	Lack of incentives	Long duration, chronic disease	Social stigma	Media influence
Cost of medication	Lack of empathy	Frequent changes of treatment	Duration	Fear of side effects

# Database non-concurrent cohort study



*cnïc*

**aetna**<sup>SM</sup>

 **ferrer**

## Assessing the Impact of Medication Adherence on Long-term Outcomes Post Myocardial Infarction

S. Bansilal, JM. Castellano, HG. Wei, EG. Vinado, A. Freeman, CM. Spettell, FG. Alonso, G. Steinberg, G. Sanz, V. Fuster

European Society Of Cardiology Congress 2014

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Mount  
Sinai

**aetna**  Healthagen

ESC CONGRESS  
BARCELONA 2014



#esccongress

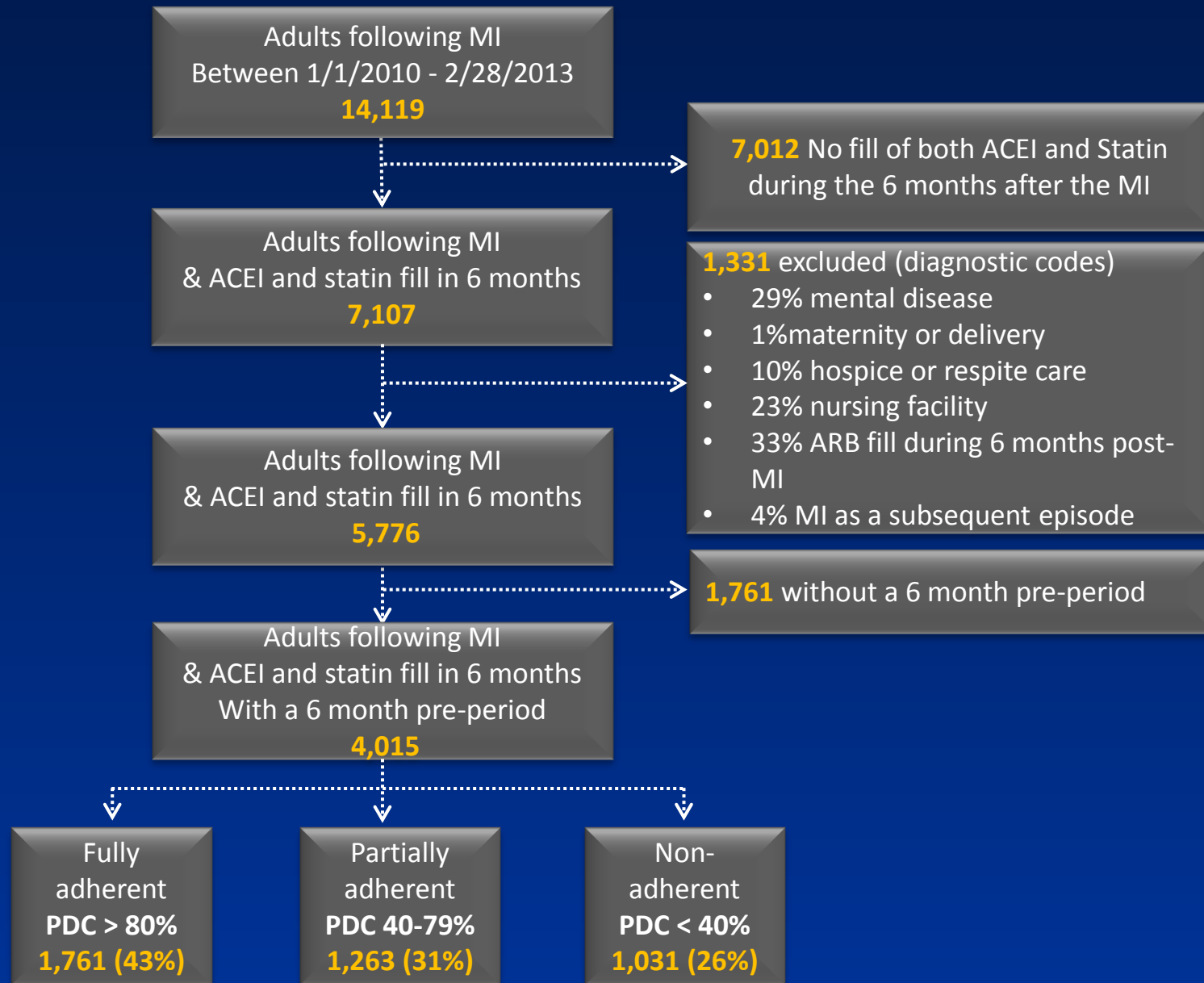
[www.escardio.org/esc2014](http://www.escardio.org/esc2014)

Presented ESC 2014 Registry Hotline Aug 31, 2014



*cnic*

*aetna*<sup>SM</sup>



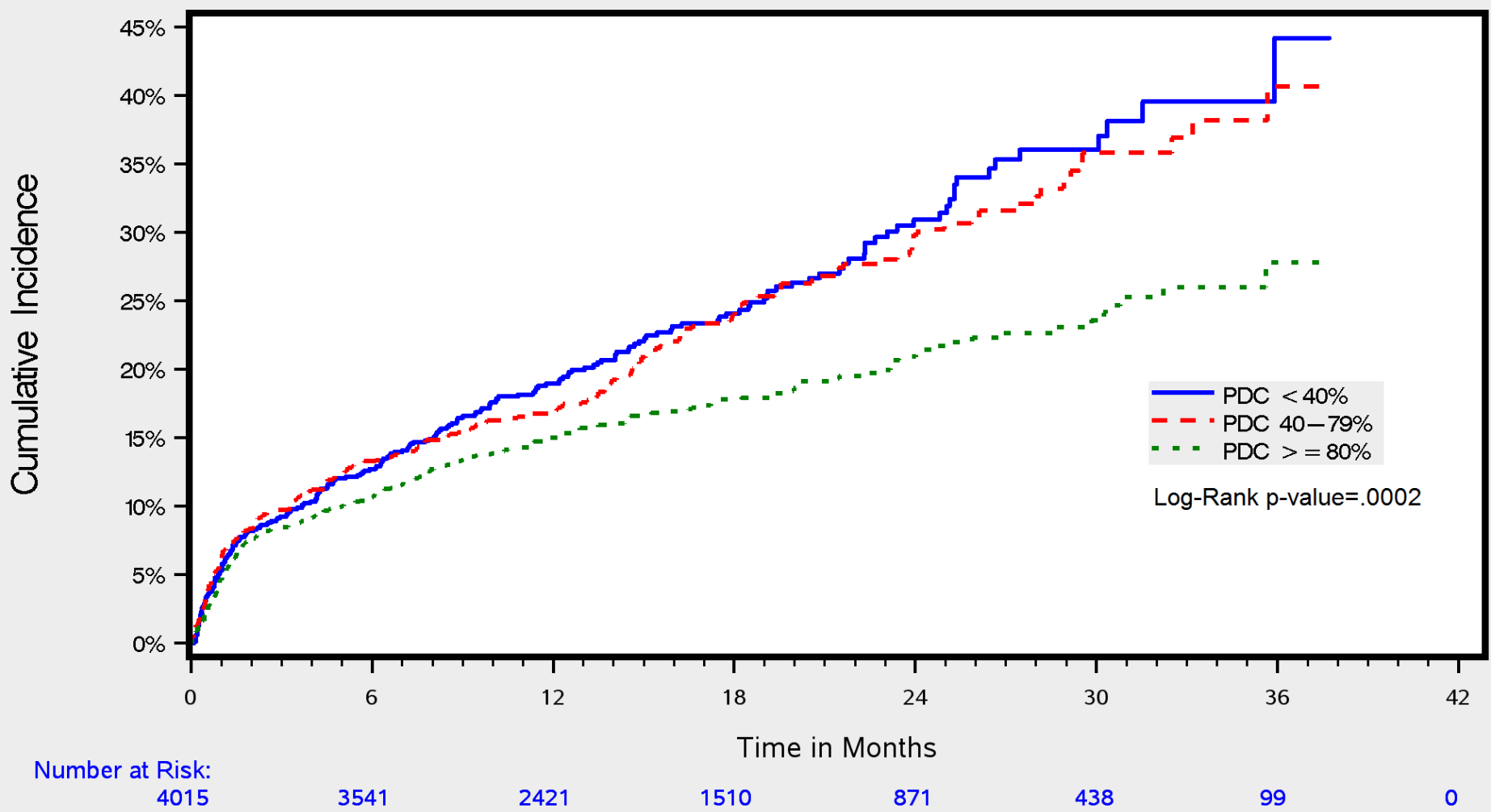


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# Time to Major cardiac Event by Adherence Levels

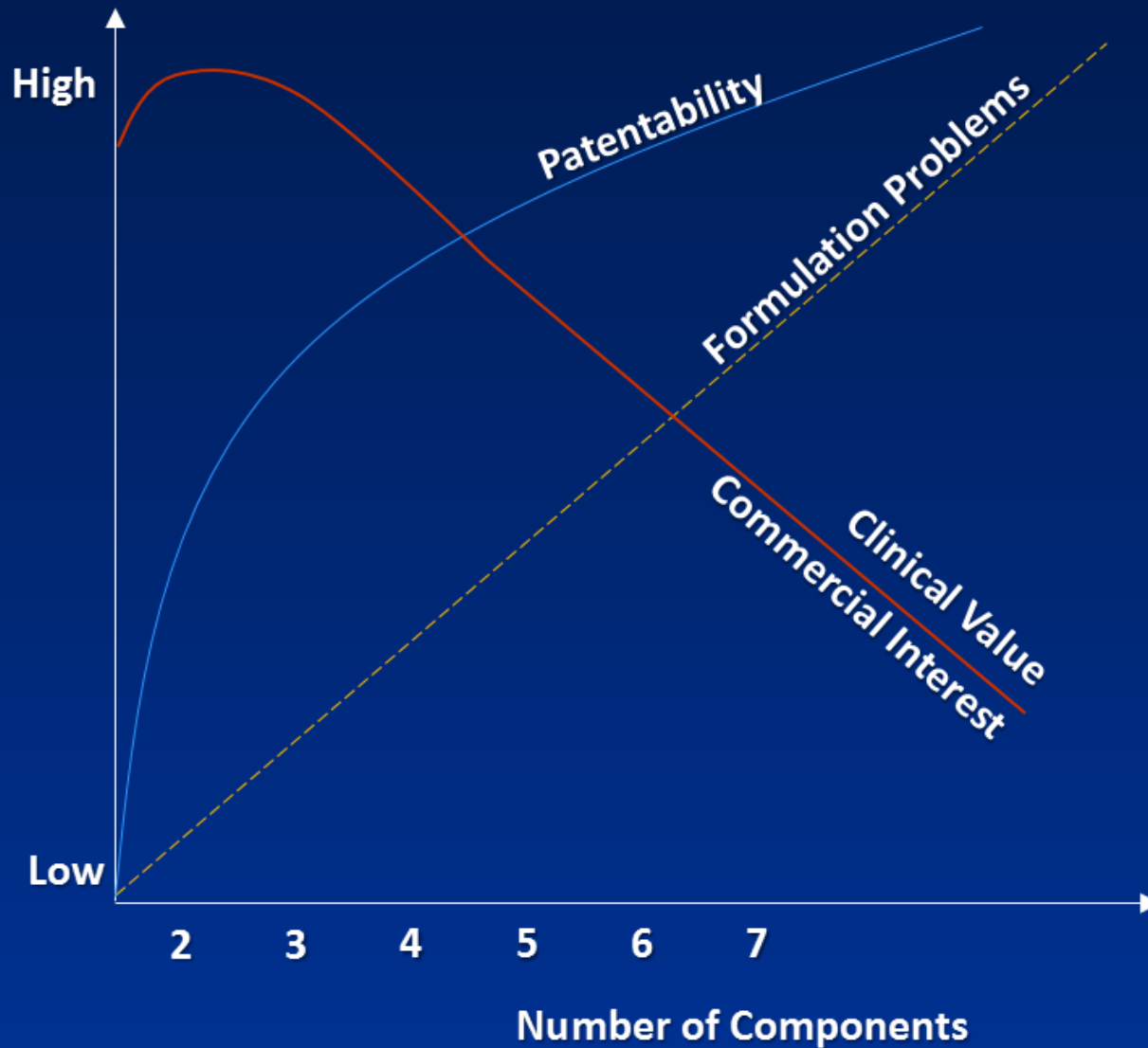


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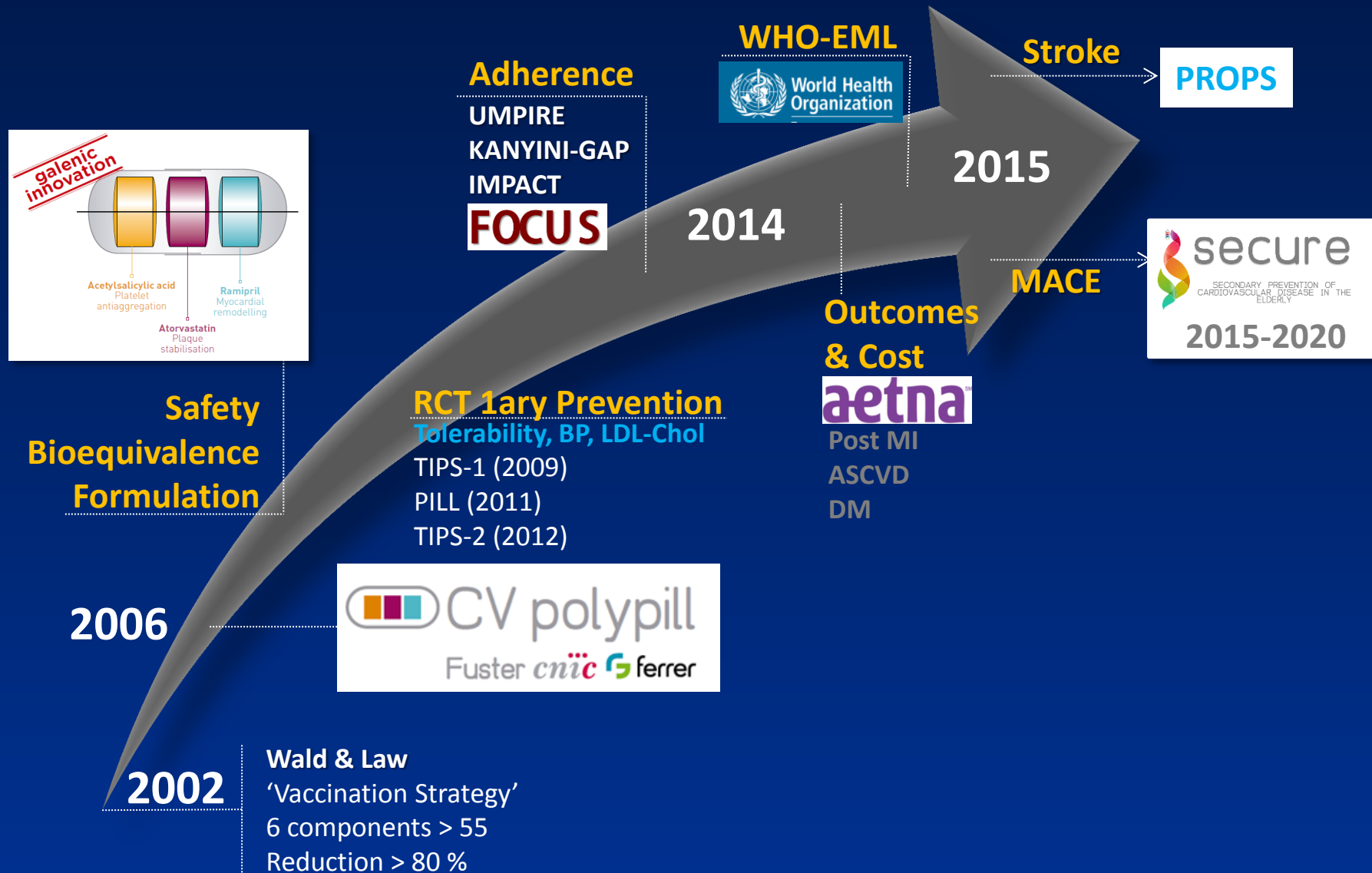
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# Challenges in the Pharmaceutical Development of a CV Polypill:



# EVOLUTION OF THE POLYPILL CONCEPT



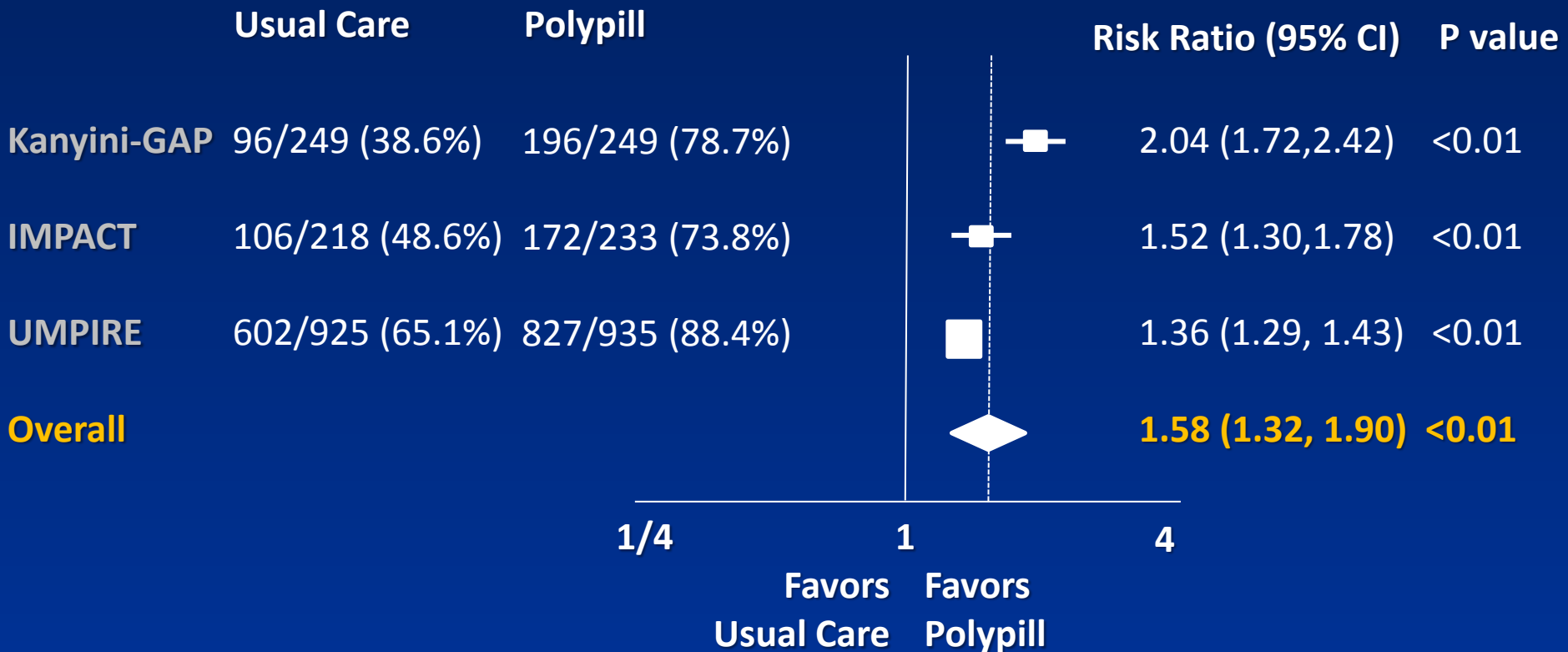
# SPACE Program Results

## Primary Outcomes – Adherence at 12 months

UMPIRE: n= 2002, India & W. Europe

Kanyini-GAP: n=623 in Australia, half indigenous

IMPACT: n=513 in NZ, half indigenous



## ORIGINAL INVESTIGATIONS

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## EDITORIAL COMMENT

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# Polypill Opens a Path for Improving Adherence\*

K. Srinath Reddy, MSc, MD, DM



**I**n September 2011, the United Nations called for concerted efforts to reduce global mortality from chronic noncommunicable diseases (NCDs) (1). In the hopes of achieving this goal, the World Health Organization adopted a strategy in May 2012

This message is especially pertinent for low- and middle-income countries (LMICs), which contribute to 80% of all NCD-related deaths and 90% of NCD-related deaths that occur in those younger than 60 years of age. Addressing this global burden



# secure

SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN THE ELDERLY

## Primary Objective:

To compare the efficacy of **Trinomia** with taking several drugs separately, in patients **over 65** with a diagnosis of an **AMI** in the prevention of CV events (**death from CV causes, nonfatal MI, stroke, and hospitalization requiring revascularisation**).

# SECURE | Consortium



Centro Nacional de Investigaciones Cardiovasculares Carlos III (CNIC) | **SPAIN**  
| Valentin Fuster, MD, PhD (PI) Jose M. Castellano MD, PhD (Co-PI)



Istituto di Ricerche Farmacologiche "Mario Negri" (IRFMN) | **ITALY**  
| Maria Carla Roncaglioni, Biol Sci Dr



Charité, Universitätsmedizin Berlin | **GERMANY** | Wolfram Döhner, MD, PhD



University Hospital of Besançon | **FRANCE** | François Schiele, MD



Wroclaw Medical University | **POLAND** | Piotr Ponikowski, MD, PhD



Semmelweis University | **HUNGARY** | Matyas Keltai, MD, PhD



General University Hospital in Prague | **CZECH REPUBLIC** | Aleš Linhart, MD, PhD



Fundación Investigación Biomédica Hospital Clínico San Carlos | **SPAIN**  
| Antonio Fernandez Ortiz MD, PhD

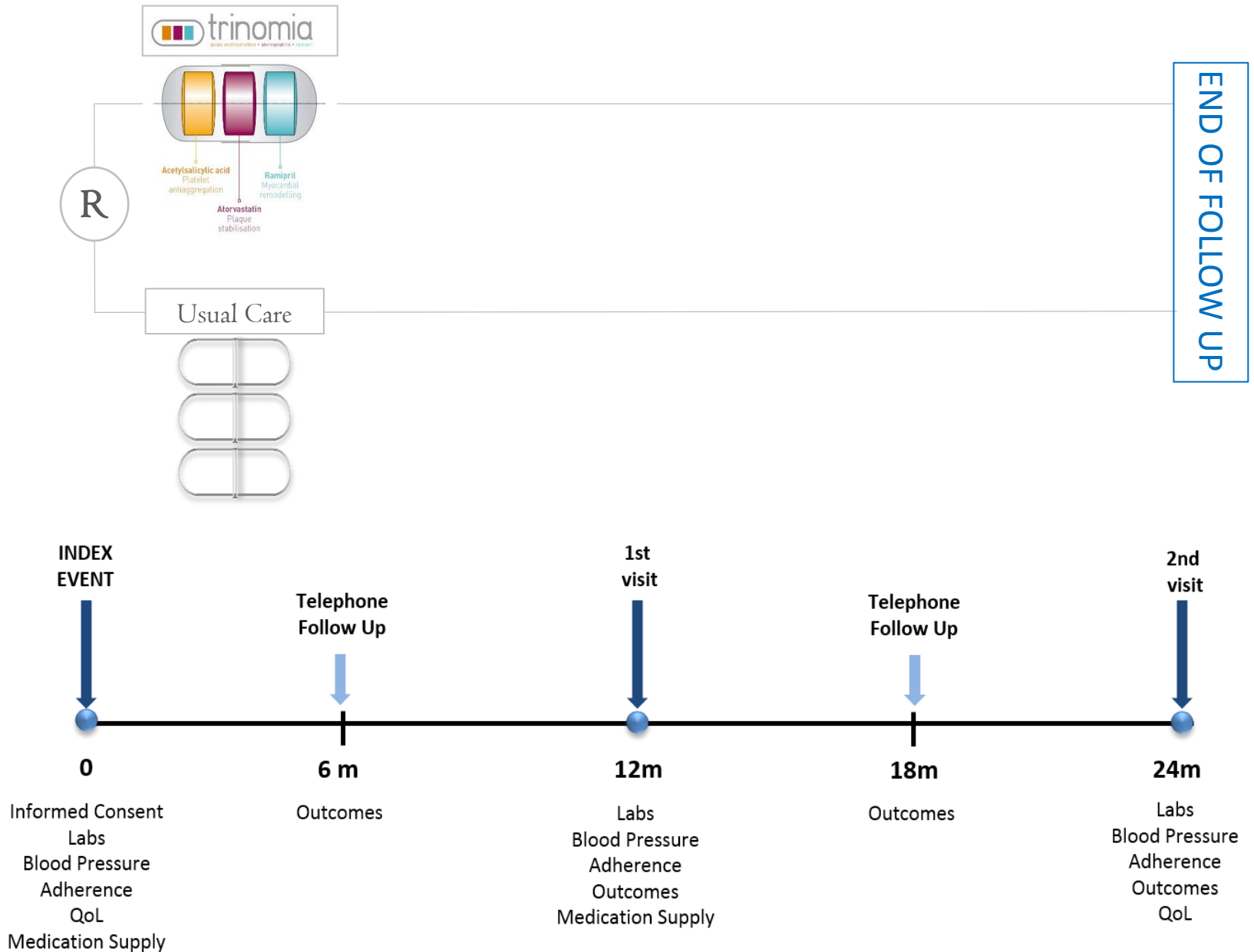


London School of Hygiene and Tropical Medicine (LSHTM) | **UK** |  
Stuart Pocock, BSc MSc PhD

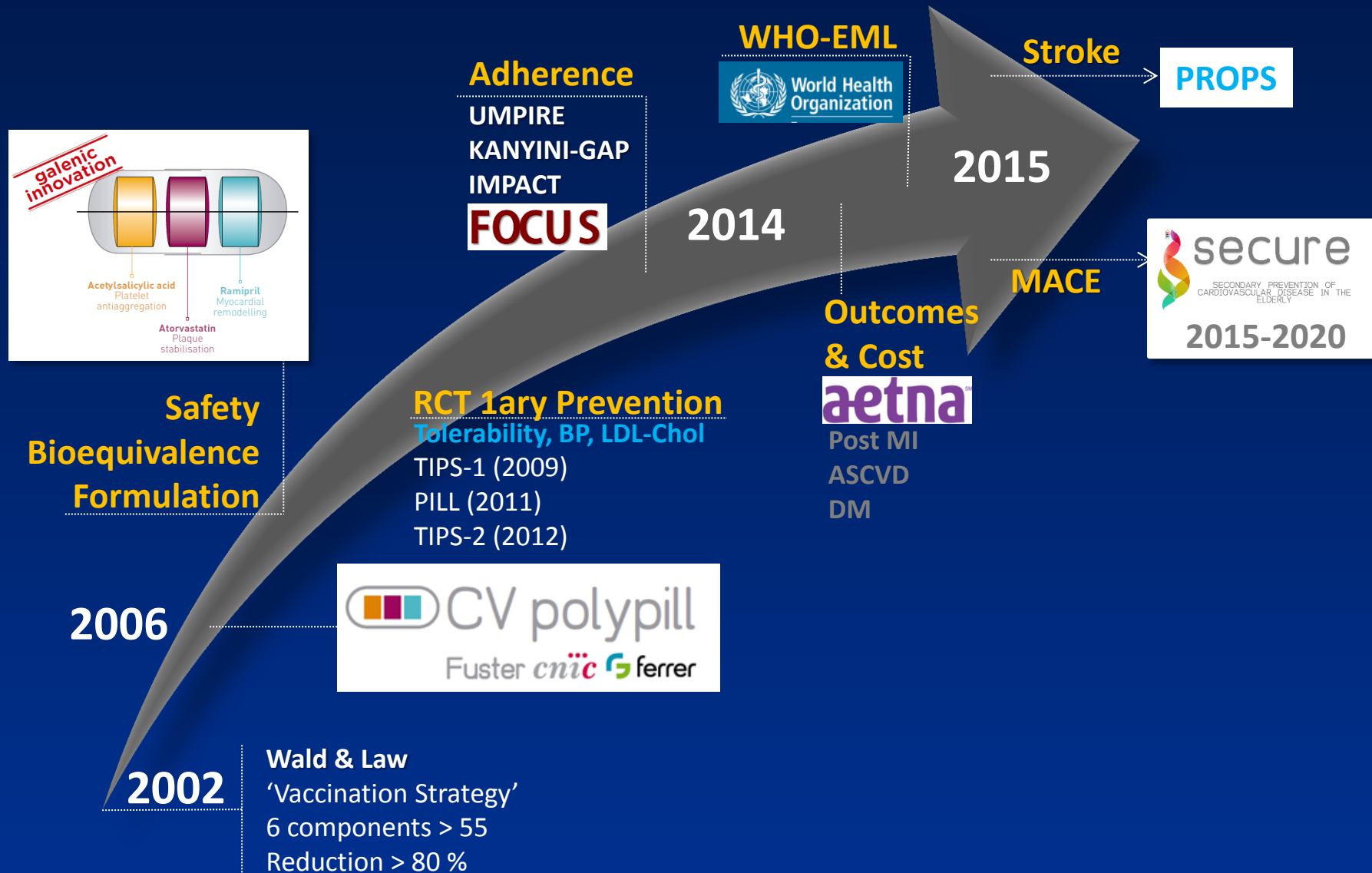


Ferrer | **SPAIN** | Fabiana d'Aniello, PhD

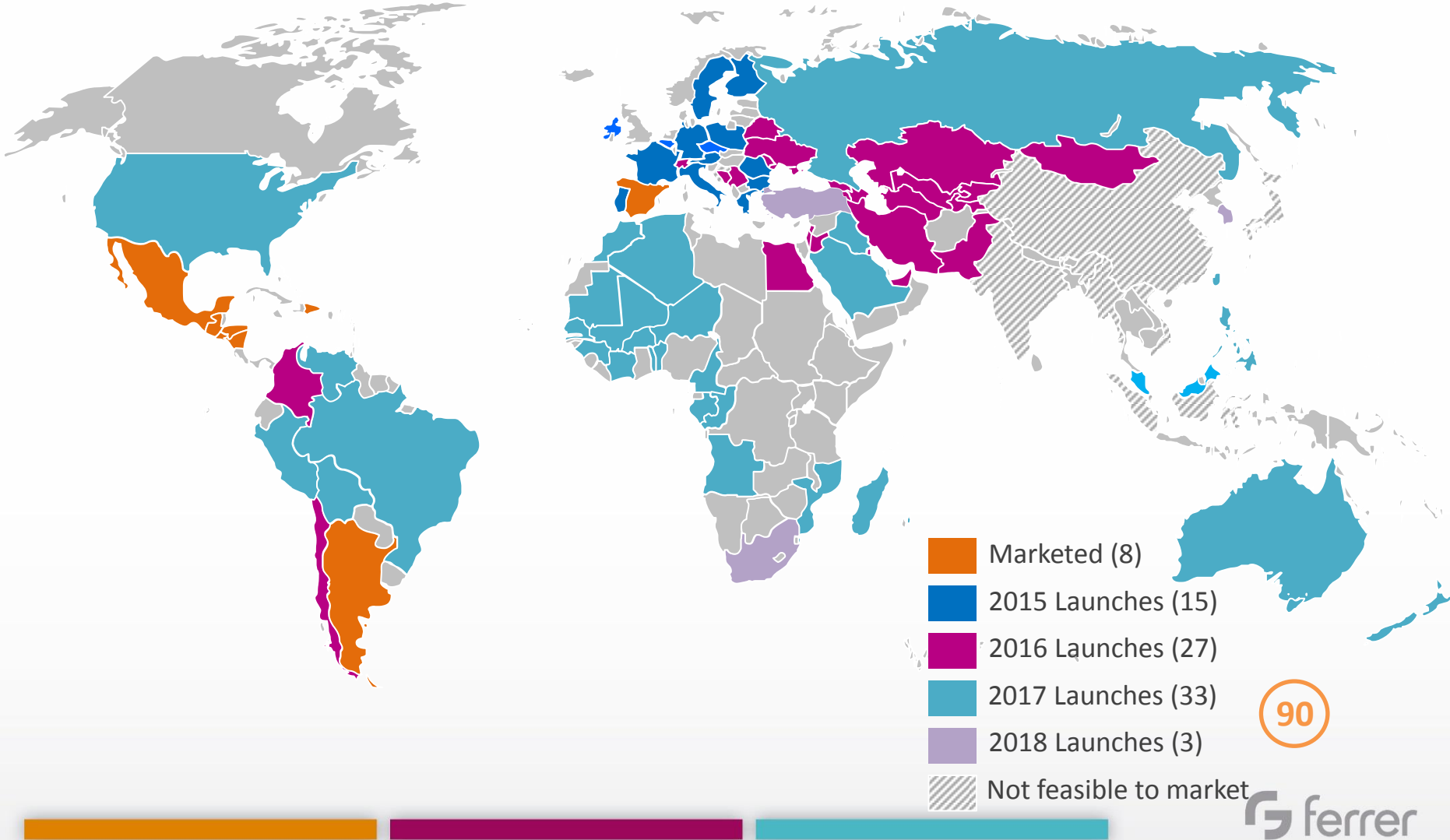
# SECURE | Visiting Schema



# EVOLUTION OF THE POLYPILL CONCEPT







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## Trinomia: Indicaciones

Indicación de sustitución tras evento cardiovascular  
(prevención secundaria)

1. Pacientes controlados con los tres fármacos
2. No cumplidores o que han abandonado uno de los fármacos
3. Pacientes que no toleran dosis altas de atorvastatina
4. Pacientes con AAS + atorvastatina + ARA-II

# Clinical Inertia: The Gap between Guidelines and Clinical Reality

Gérard Reach

## Clinical Inertia

A Critique of  
Medical Reason

 Springer

**Management of Risk Factors (2001):**  
“recognition of a problem but failure to act”  
Health care provider does not initiate or intensify therapy

**Providers:** Disagreement with guidelines, soft reasons, patient perception, overestimating care, training...

**Patients:** perspectives and demands

**Patient-Doctor:** caregivers inertia/patients adherence

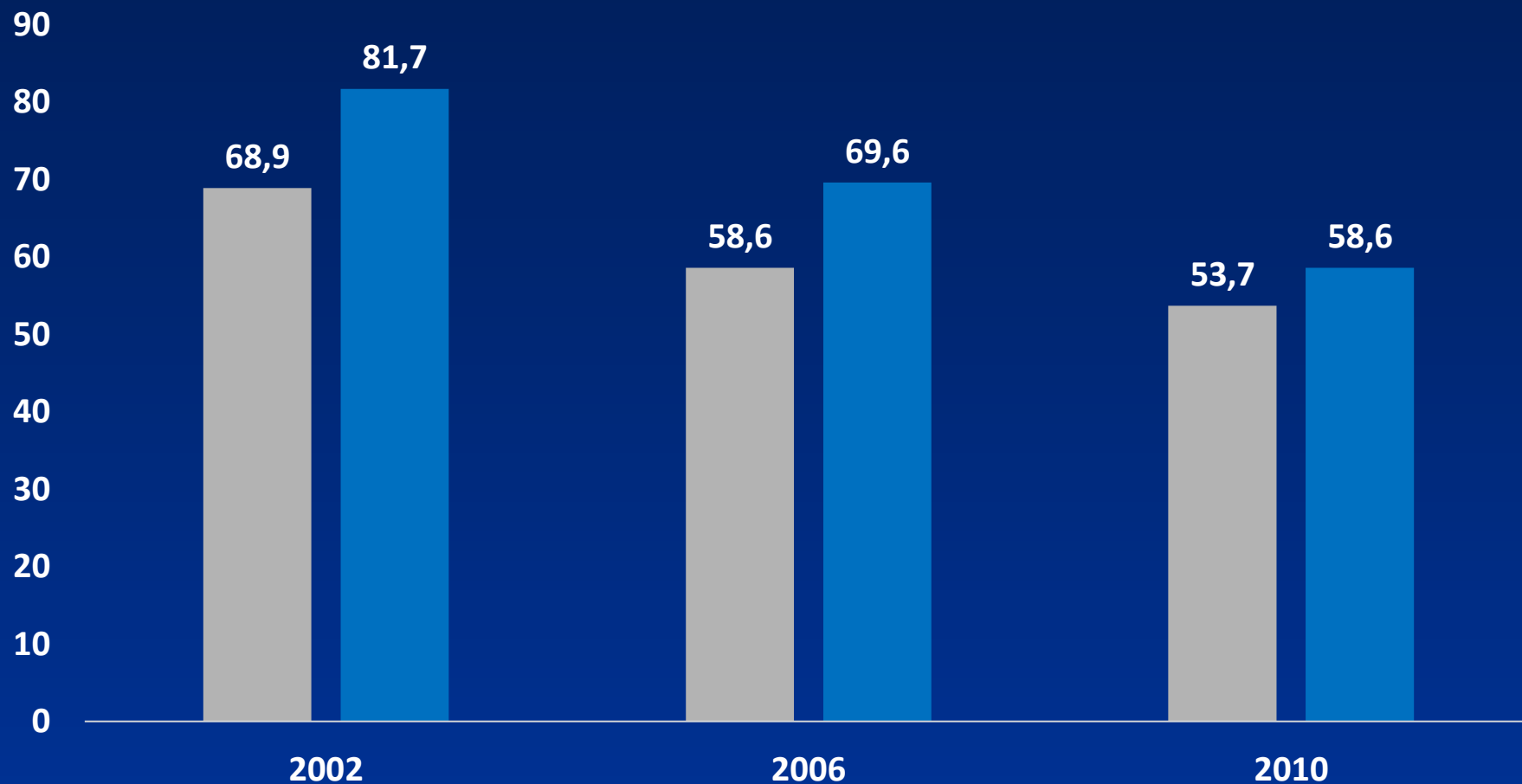
**System:** modified threshold/modified goals

**Combination** is always more effective than **titration**

# Evolution of therapy inertia in primary care setting in Spain during 2002-2010

PRESion arterial en la población Española en los Centros de Atención Primaria (PRESCAP)

■ Uncontrolled BP (%) ■ No Modification



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**1.**

Permite realizar un **abordaje más global** de la **prevención secundaria** cardiovascular, aportando en una sola capsula 3 principio activos de elevada eficacia en la **reducción del riesgo cardiovascular y la mortalidad**

**2.**

**Facilita el cumplimiento terapéutico.**

**3.**

**Simplifica la pauta posológica**, con una sola cápsula al día, **umentando la adherencia** al tratamiento por parte del paciente en comparación con la toma de sus 3 componentes por separado.

# Medication Non-Adherence

ADHERENCE TO LONG-TERM THERAPIES

Evidence for action



World Health Organization 2003

*“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments”*