

The logo for PhAMA, featuring the word "PhAMA" in white, bold, sans-serif font. The "Ph" is on a dark blue background, and "AMA" is on a red background.

**PhAMA**

Innovative Medicines for Malaysia

# 1ST NATIONAL BIO-THERAPEUTICS CONGRESS – PUTTING PATIENT FIRST

**22 NOVEMBER 2014**

# Pharmaceutical Biotechnology – The Needs and Challenges of Innovation

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**PhA MA**

**1ST NATIONAL BIO-THERAPEUTICS**

# Innovation for unmet medical needs – The center of our attention

**32,6**

million people live with cancer

**130+**

million people have hepatitis C

**24**

million cases of schizophrenia

***Two-thirds of all diseases are either still not treated adequately or not treated at all***

**235**

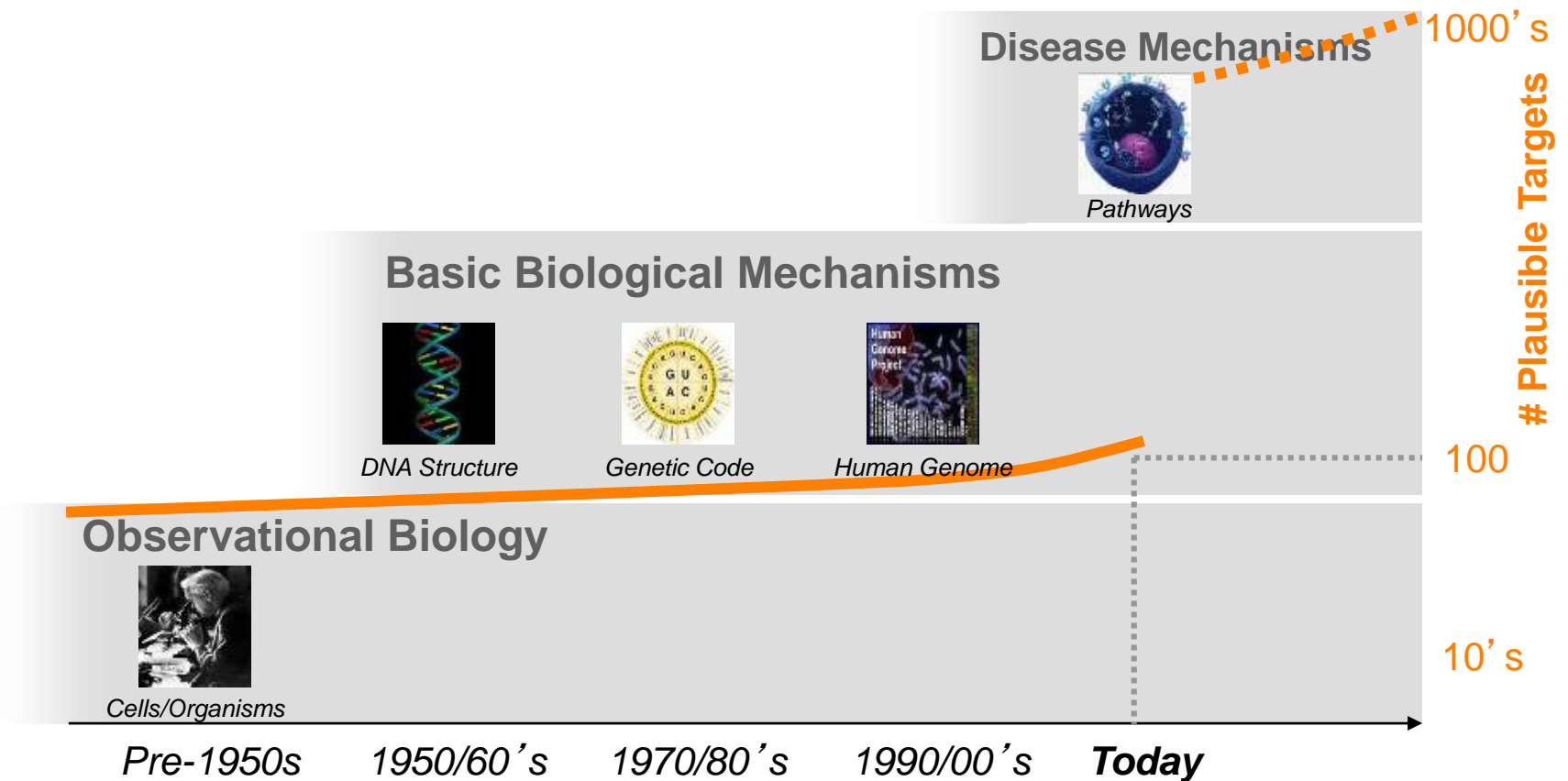
million cases of asthma

**347**

million people live with diabetes

# Understanding Disease Mechanisms

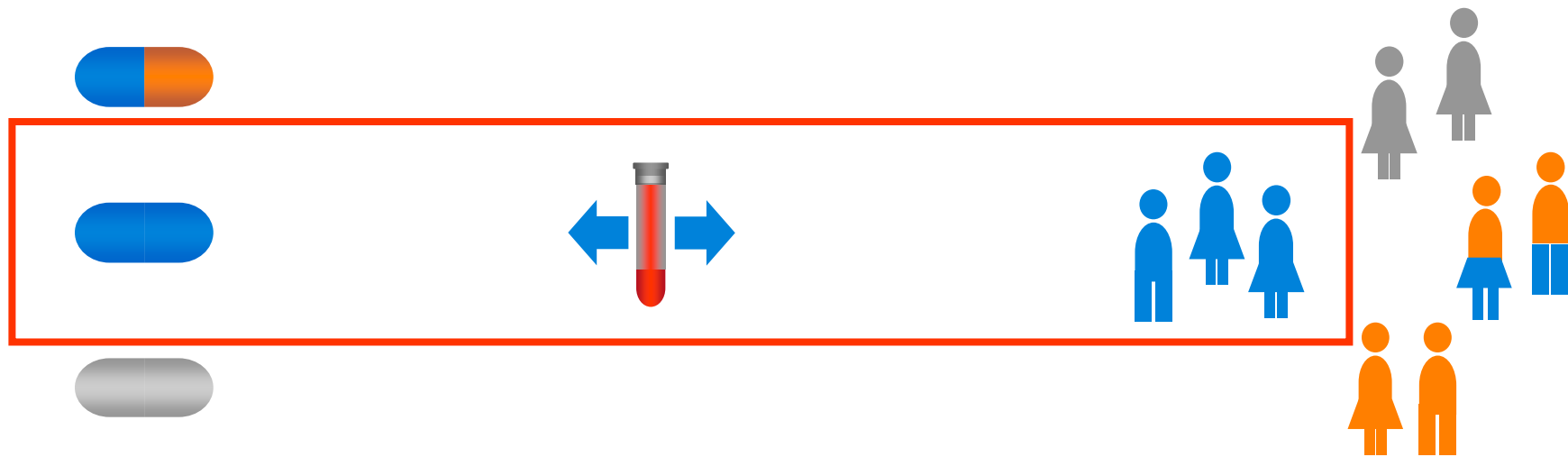
*Where did we come from, where are we going?*



# Understanding the disease is one thing - Fitting treatments to patients another

## Effectiveness of treatment can be improved . . .

- 20-75% of patients do not receive effective treatment<sup>1</sup>
- Thousands of deaths/yr from adverse drug reactions (e.g. US<sup>2</sup>)



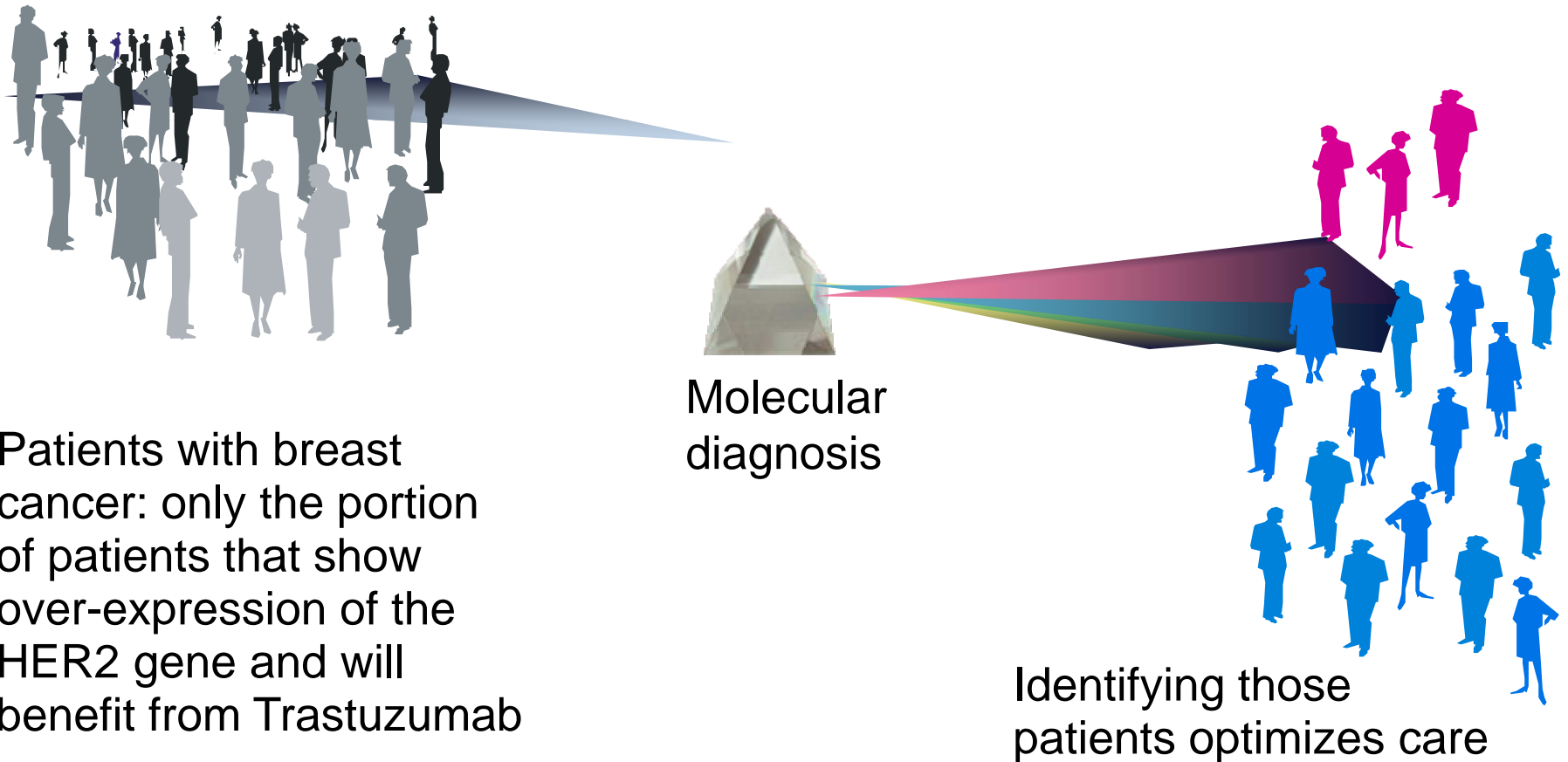
. . . by tailoring treatments to **selected patient groups** defined by **biomarkers**

<sup>1</sup> Spears et al., Trends Mol Med, 2001

<sup>2</sup> Lazarou et al., JAMA, 1998

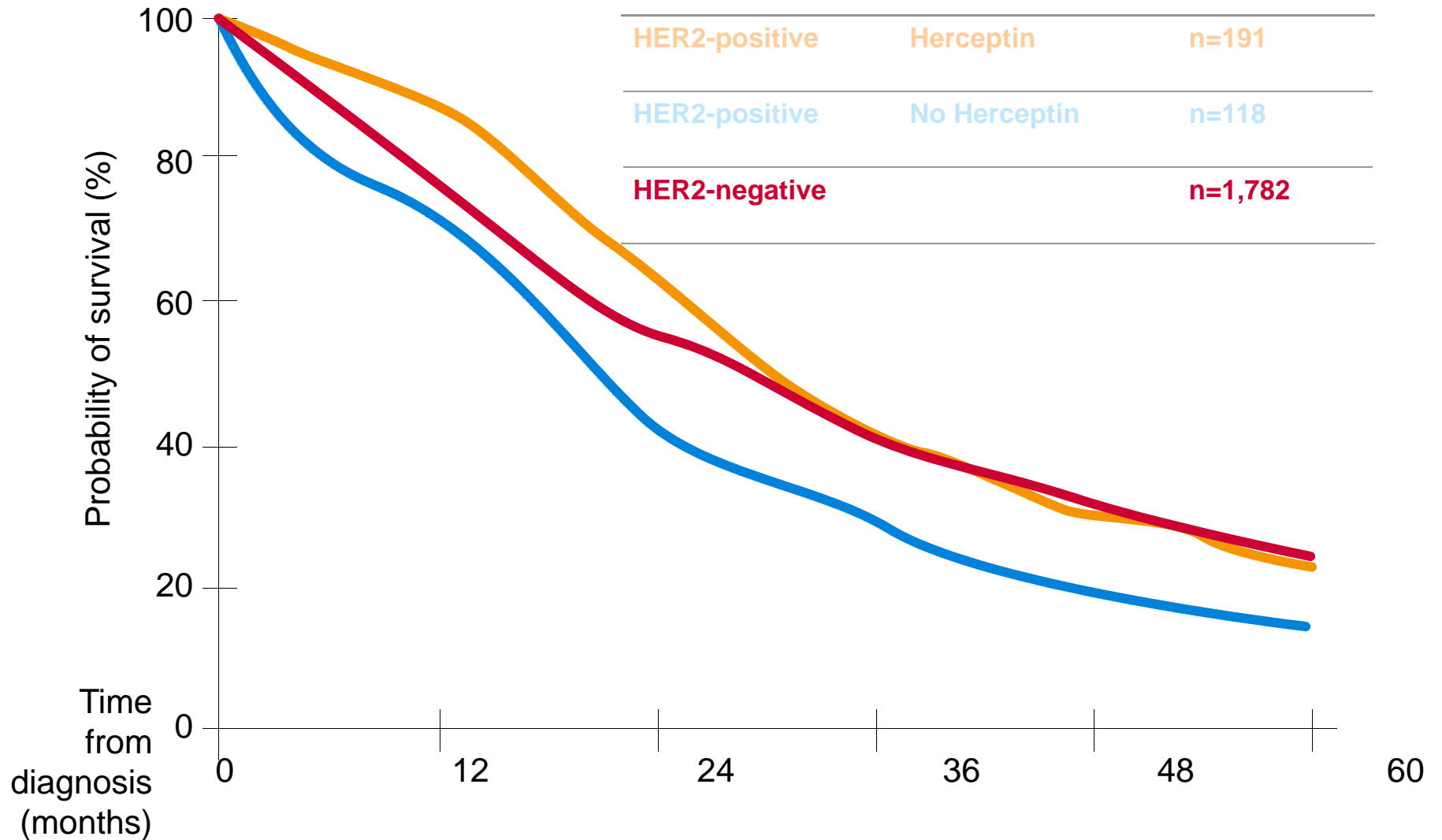
# Personalised Healthcare is becoming a reality

*Molecular insights allow better treatment decisions*



# Trastuzumab Changed the Natural History of HER2+mBC

*HER2-positive status has almost become a favourable prognostic factor*



**Many steps to explore the full potential of a new drug**  
*Benefits are greater the earlier the drug is used*

**Adjuvant therapy**

Benefit = months, years,  
potential for cure (long-term remission)

**Earlier stages of cancer**

Benefit = many, many months

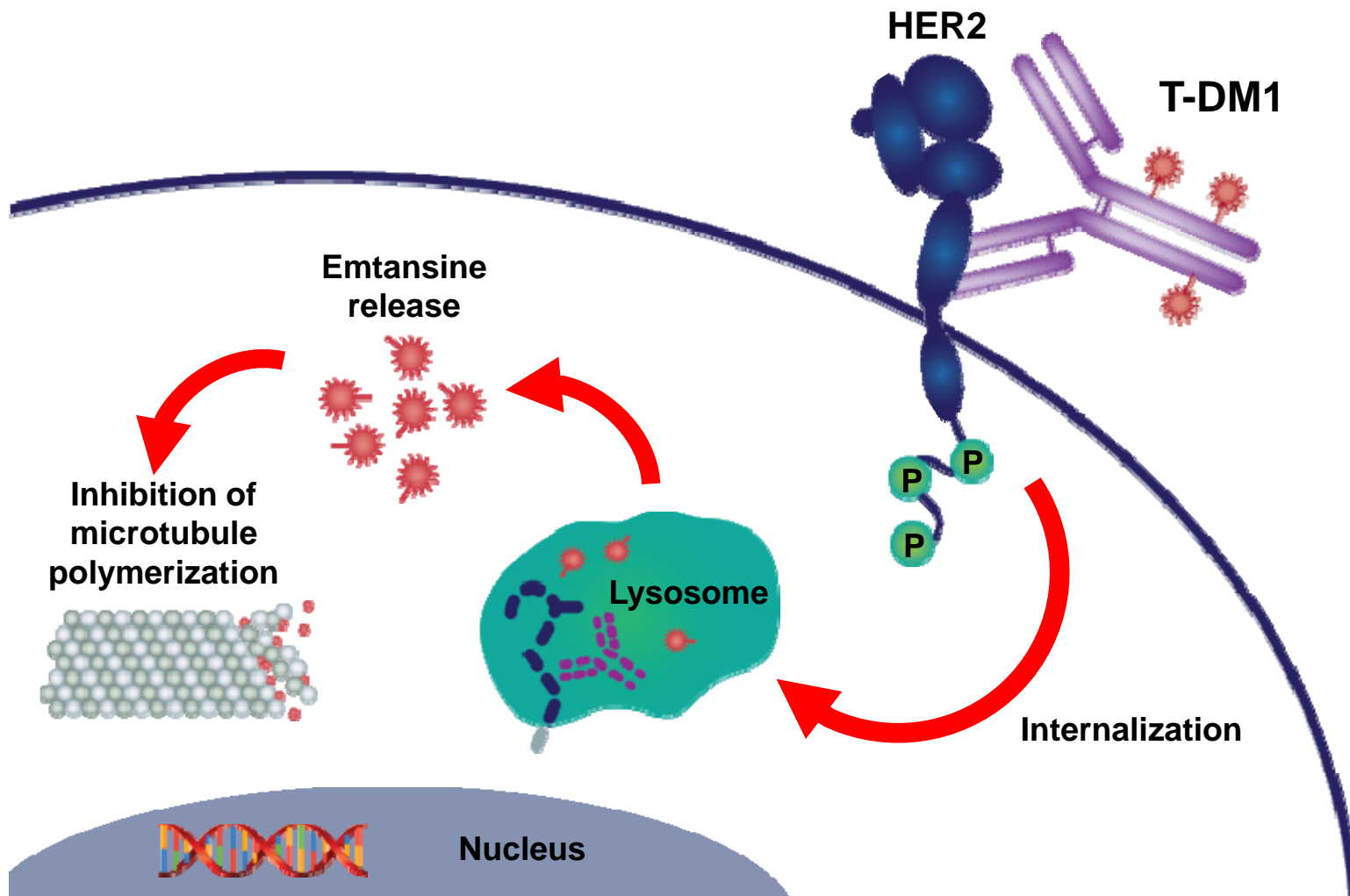
**Late stage disease**

Benefit = weeks, a few  
months



# Trastuzumab emtansine ADC

14 CT performed/ongoing

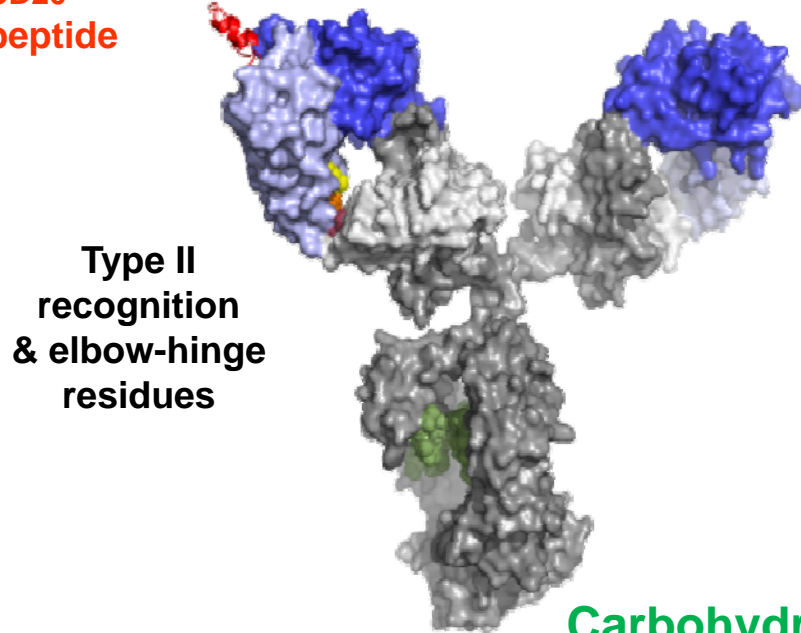


Adapted from LoRusso PM, et al. *Clin Cancer Res* 2011.

# Obinutuzumab: glycoengineered, anti-CD20 mAb

## 10 CT performed/ongoing

CD20  
peptide



- Increased direct cell-death induction
- Enhanced antibody-dependent cell-mediated cytotoxicity (ADCC)
- Lower complement-dependent cytotoxicity (CDC) activity

**Carbohydrate glycoengineered (GlycoMab™ technology):**

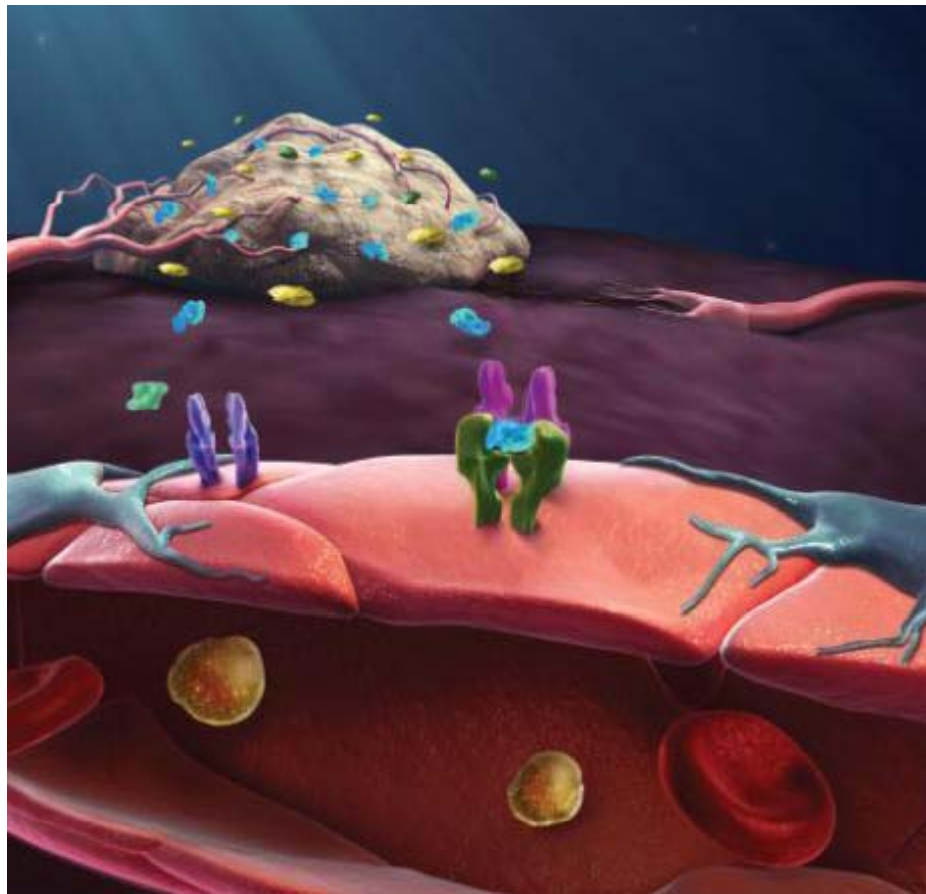
Overexpression of GnTIII and ManII glycosylation genes in Ab production cell lines leads to Ab glycoforms bearing bisected, complex afucosylated oligosaccharides in Fc region

In collaboration with Biogen Idec

Umaña et al, Blood 2006; 108, abstract 229, Umaña et al, Ann Oncology 2008, 19 (suppl 4), abstract 098

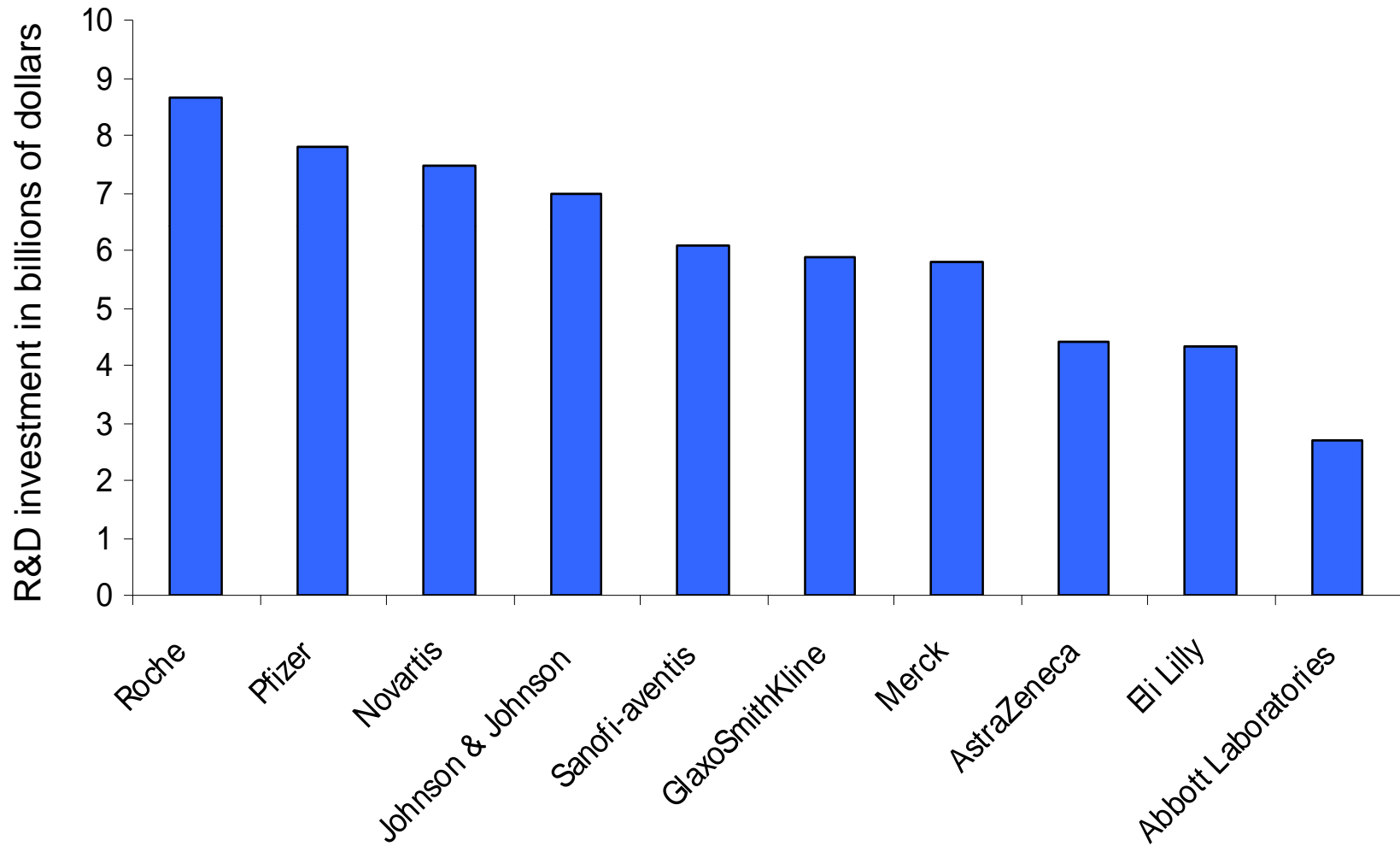
**More than 500 clinical trials in over 50 cancers  
investigating the use of Bevacizumab\***

**Bevacizumab has the largest clinical trial program  
ever initiated in oncology**



# Innovation is the result of an immense R&D effort

*Roche for example has spent more than 9.8 billion CHF in R&D in 2009*



# R&D in the pharmaceutical industry



- **4500 new molecules** (900 in oncology) are being developed around the world
- Every year **~30 new molecules** are approved by health authorities
- Attrition rate of **95 percent**
- R&D investment has **tripled during the past 15 years**

# How regulatory systems should evolve globally ?

- **Greater regulatory convergence of pharmaceutical regulations is necessary facilitating R&D investment and to increase and expedite patient access to new and innovative medicines**
  - Remove duplicative/different requirements between agencies, which hinder global drug development and supply
  - Develop a more innovative evaluation framework
    - adaptive licensing / breakthrough
    - inter agency reviews
  - Mutually recognize GMP inspections

# IMS Health Study Identifies \$200+ Billion Annual Opportunity in the US from Using Medicines More Responsibly

The report – *Avoidable Costs in U.S. Healthcare: The \$200 Billion Opportunity from Using Medicines More Responsibly* – examines six areas that contribute to unnecessary costs: **medication non-adherence, delayed evidence-based treatment practice, misuse of antibiotics, medication errors, suboptimal use of generics and mismanaged poly-pharmacy** in older adults. Together, these areas lead to unnecessary utilization of healthcare resources involving an estimated 10 million hospital admissions, 78 million outpatient treatments, 246 million prescriptions and four million emergency room visits annually. The study found significant opportunities for improvement – to ensure that patients receive the right medicines at the right time, and take them in the right way.

**On a global basis the opportunity is estimated \$500+ Billion**

# Access to Healthcare

## *Comprehensive and holistic approaches are required to improve health outcomes*

### **Improve affordability** *(Value-based pricing)*

- Differential pricing
- Patient assistance programs
- Health insurance
- No-patents in LDCs



### **Strengthen infrastructure** *(Facilities, healthcare workers)*

- Train healthcare professionals
- Invest in health facilities
- Supply chain management

**Improved  
health  
outcomes**

### **Deliver innovation** *(Investment in R&D)*

- Advance standard-of-care
- Personalised Healthcare
- Off-patent innovation



### **Increase awareness** *(Education, screening, support)*

- Health and disease awareness
- Screening programs
- Patient support services
- Treatment compliance



# Roche Egypt: Second brand of Hepatitis treatment

## *Enabling access for public sector*

### Challenges:

- High prevalence of HCV infection
- Treatment not reimbursed

### Our approach:

- Locally packaged 2<sup>nd</sup> brand with different name and formulation
- Reduced pricing to MoH for public market
- Sales of Pegasys continue in private market
- Provides local employment & builds capacity

MoH = Ministry of Health

\* local IFN manufacturer entered market

Private market  
1<sup>st</sup> brand Pegasys  
pre-filled syringe

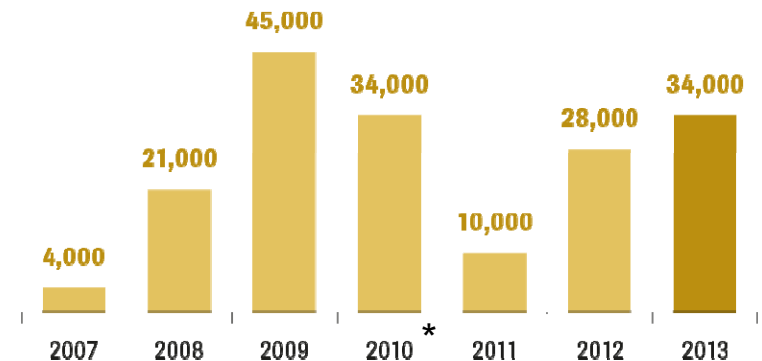


Public market  
2<sup>nd</sup> brand Pegferon  
vial



### Results:

Patients on treatment  
Over 170,000 people treated to date



# Roche Philippines: Socialised pricing

## *Linked to patients' ability to pay*

### Challenges:

- National funding limited (biologics not covered)
- Limited insurance; ~80% patients pay out-of-pocket
- <10% HER2 +ve patients on Herceptin; most cannot adhere to recommended therapy duration

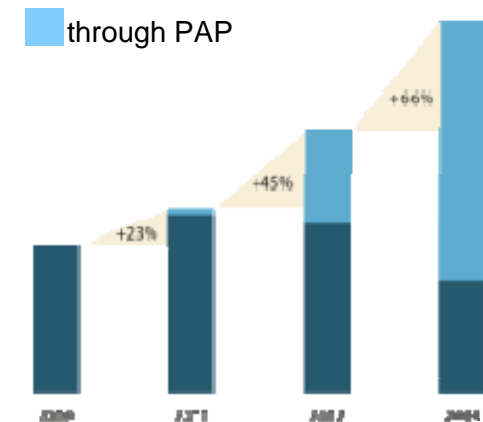
### Our approach:

- Roche Patient Access Program (PAP) provides discounts to patients based on financial status\*
- Programs to improve HER2 test accuracy
- Partnered with Philam Life Insurance, Pru Life Insurance and 5 HMO's to develop health insurance policies

### Results:

- >60% of patients receive Herceptin through PAP
- Lowers cost barrier in mind of physicians

### Patients on Herceptin



\* assessed by an independent third party  
HMO = Health Maintenance Organisation

# Roche China: Improving health insurance coverage

## *Working with insurance companies to develop policies*



### Data

- Roche provides data on treatment algorithms, epidemiology, etc...
- Education on cancer for insurance sales-force
- Public cancer awareness and prevention programmes



### Policy

- Companies use data to develop affordable cancer insurance policies which provide appropriate cancer care



### Access

- Patients gain access to hospitals, doctors and best available treatment
- Funds to cover adequate treatment and care
- Cancer education and support

- Cancer is a major killer in China
- Current insurance provides limited coverage for cancer treatment



- Contracts with ten local Chinese insurance companies
- Around 20 million policies sold since 2011

# Roche Asia: Improving quality of HER2 testing

## *Educational initiative for lab technicians, pathologists, surgeons and oncologists*



### Training: sample collection → treatment

- **Surgeons** on excision and handling of tissue biopsy
- **Lab technicians** in performing tests, **pathologists** in scoring and interpreting results
- **Oncologists** on need for reliable HER2 test and link to treatment decision
  
- **13,475 healthcare professionals reached** in 2013 in 11 markets\*

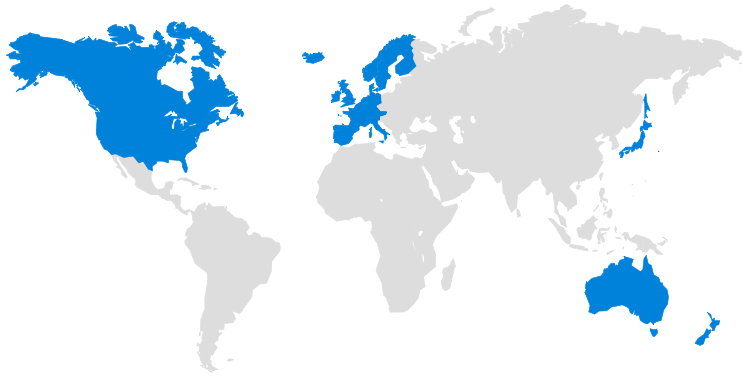
**Enable people to receive an accurate and timely diagnosis of disease and appropriate selection for treatment**

\* China, Hong Kong, Indonesia, Malaysia, Philippines, South Korea, Taiwan, Thailand, Vietnam

# Access to Healthcare

## *Tailored solutions for each market*

### Established Markets



### General access and healthcare coverage

Negotiate with payers on reimbursement

- *Commercial arrangements*
- *Personalised reimbursement models*

### Emerging Markets



### Limited healthcare coverage and/or infrastructure

Enable access to public funding

- *Differential pricing*
- *Patient assistance programs*
- *Private health insurance*

Healthcare systems support



**Thank you**



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