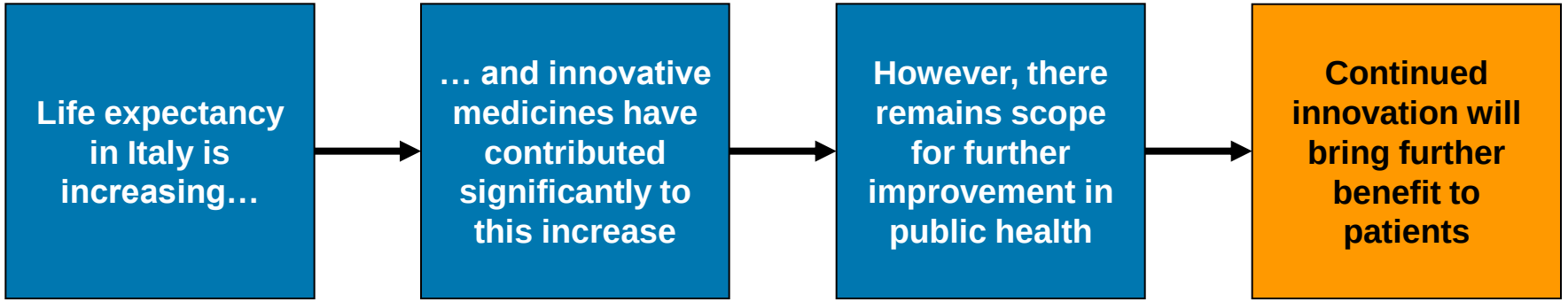
Assessing the benefit of medicine in Italy

May 2010



Pfizer

Innovative medicines are having a significant impact on public health in Italy



Cardiovascular disease

Diabetes

Cancer

Infectious disease

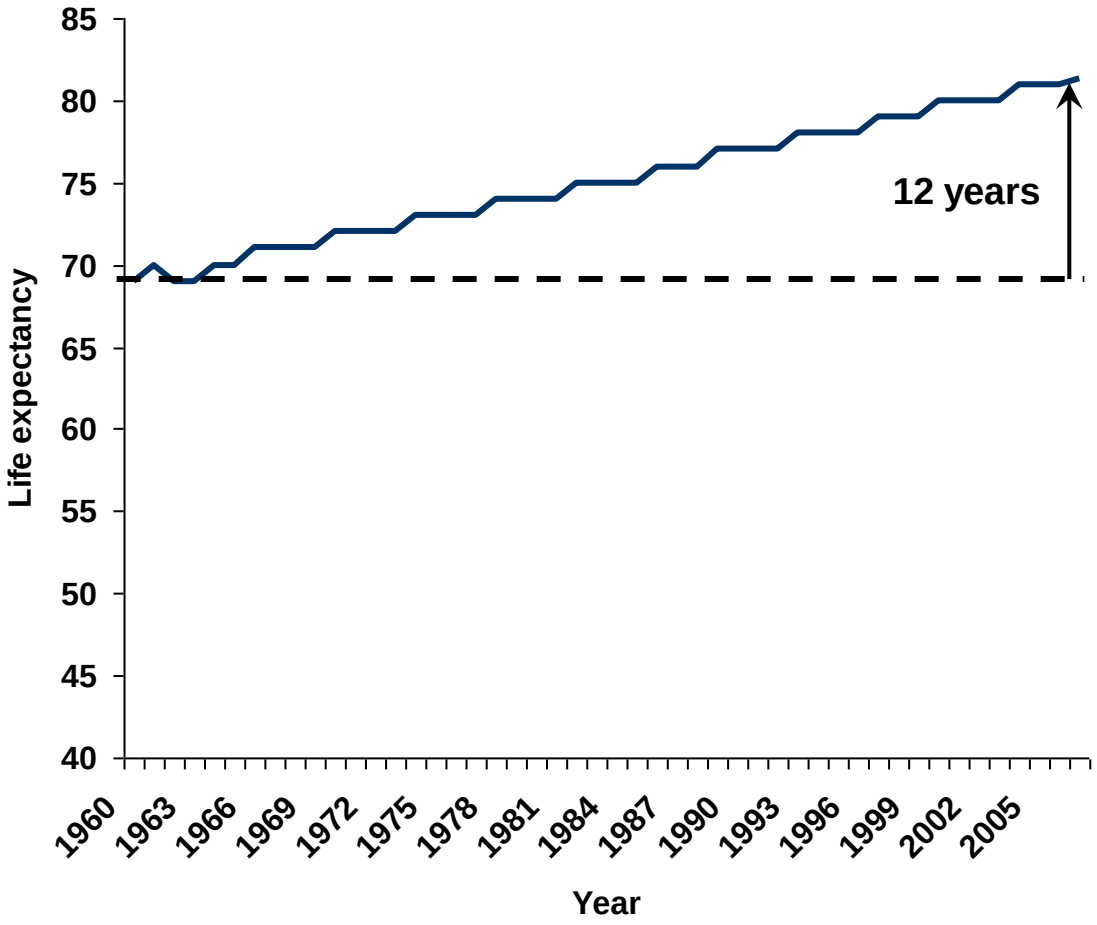
Rheumatoid arthritis

Orphan disease

Schizophrenia

However, further emphasis on innovation in Italy is needed – the proportion of GDP spent on R&D is much lower than the European average

Life expectancy in Italy is increasing



Life expectancy at birth crossed the threshold of 80 years for the population as a whole in 2000

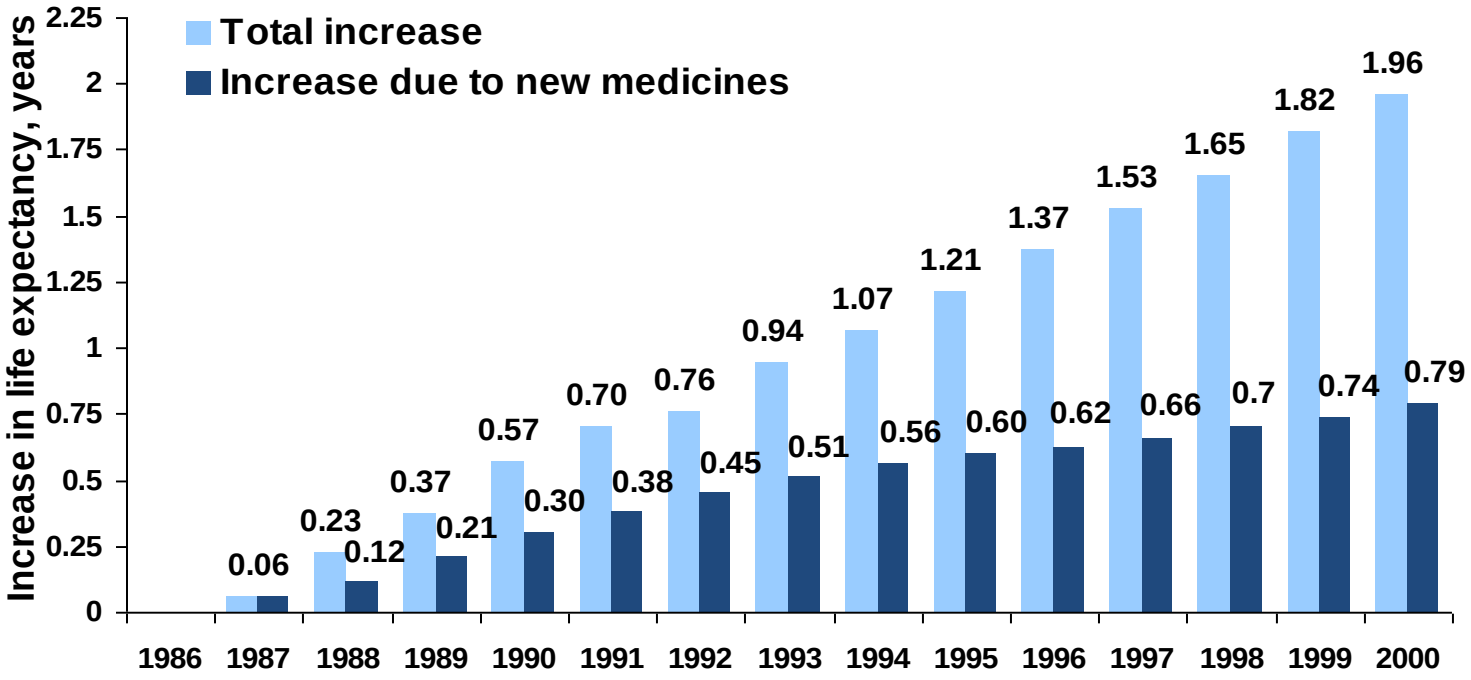
It is estimated that a male born in 2008 can expect to live 79 years, and a female can expect to live 84 years.

Country-level data

World Bank (2010), Istat (2009)

Innovative medicines have contributed to this increase in life expectancy

40-59% of the total increase in life expectancy across 52 countries including Italy is attributable to innovative medicine launches. Life expectancy is continuing to increase as a result of progress in the treatment and prevention of cardiovascular disease and cancer



40-59% of the increase in life expectancy is due to innovative medicine

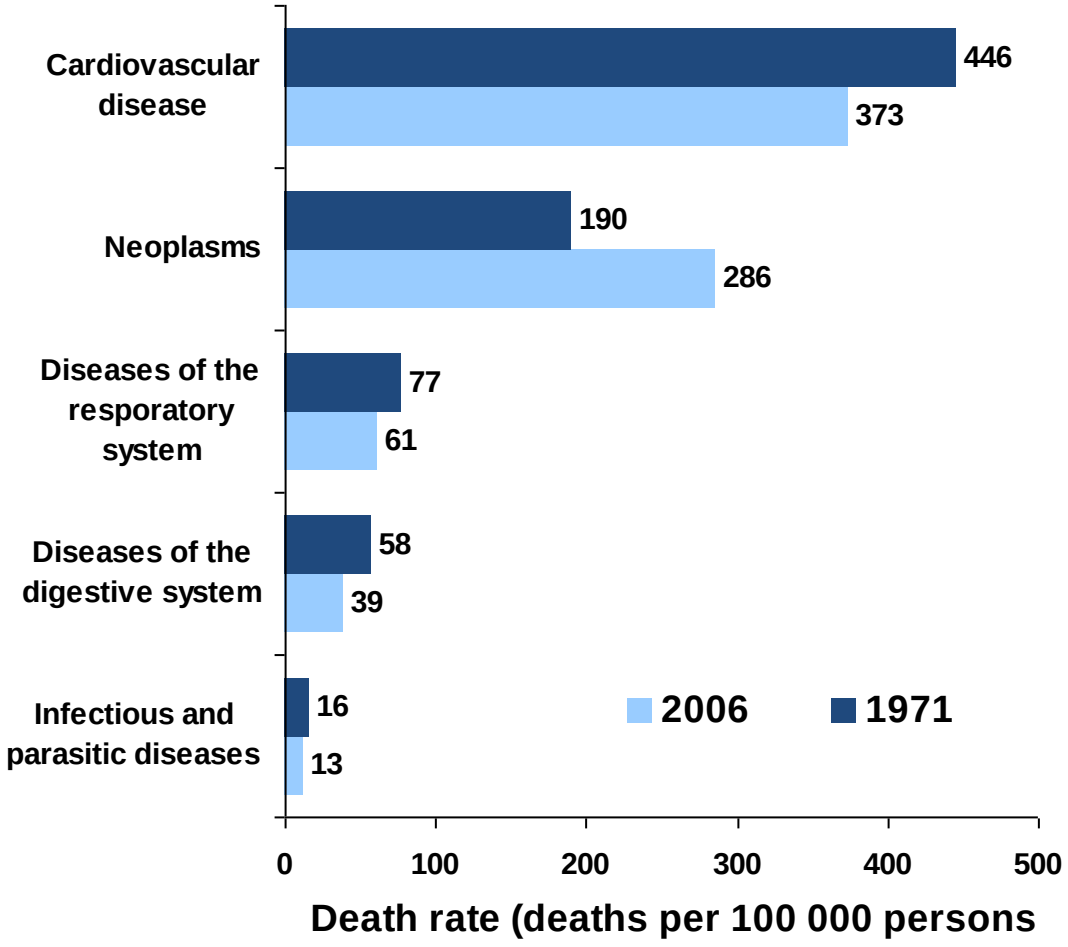
Global-level data

Lichtenberg (2005)

However, there remains scope for further improvement in public health

Even though death rates for most categories are falling, mortality rates due to disease are still high. The leading cause of death in Italy in 2009 was cardiovascular disease (39% of all deaths), followed by cancer (30% of all deaths)

Unlike other disease specific death rates, death due to cancer has increased over the last 30 years

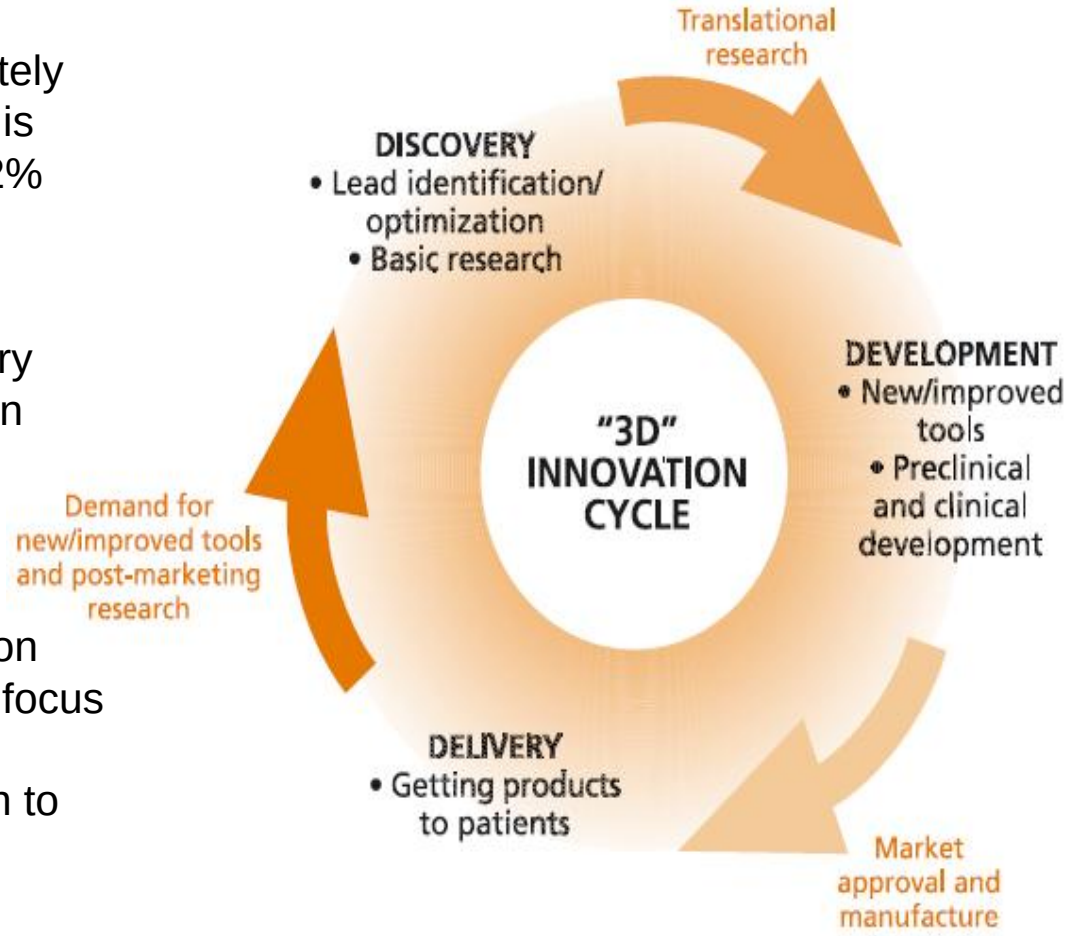


Country-level data

Istat (2009)

Through the continued process of innovation, further benefits can be brought to patients

- In 2008, Italy invested approximately 1% GDP in R&D activities, which is half of the European average of 2% and almost 4 times less then the European leader Sweden
- The Italian pharmaceutical industry was ranked 5th globally for sales in 1999. However, this high level of production and distribution is not matched by research activities
- Therefore, investment in innovation and R&D should be an important focus for Italy in the future in order to improve the countries contribution to the industry and ultimately the contribution to reducing disease-related morbidity and mortality

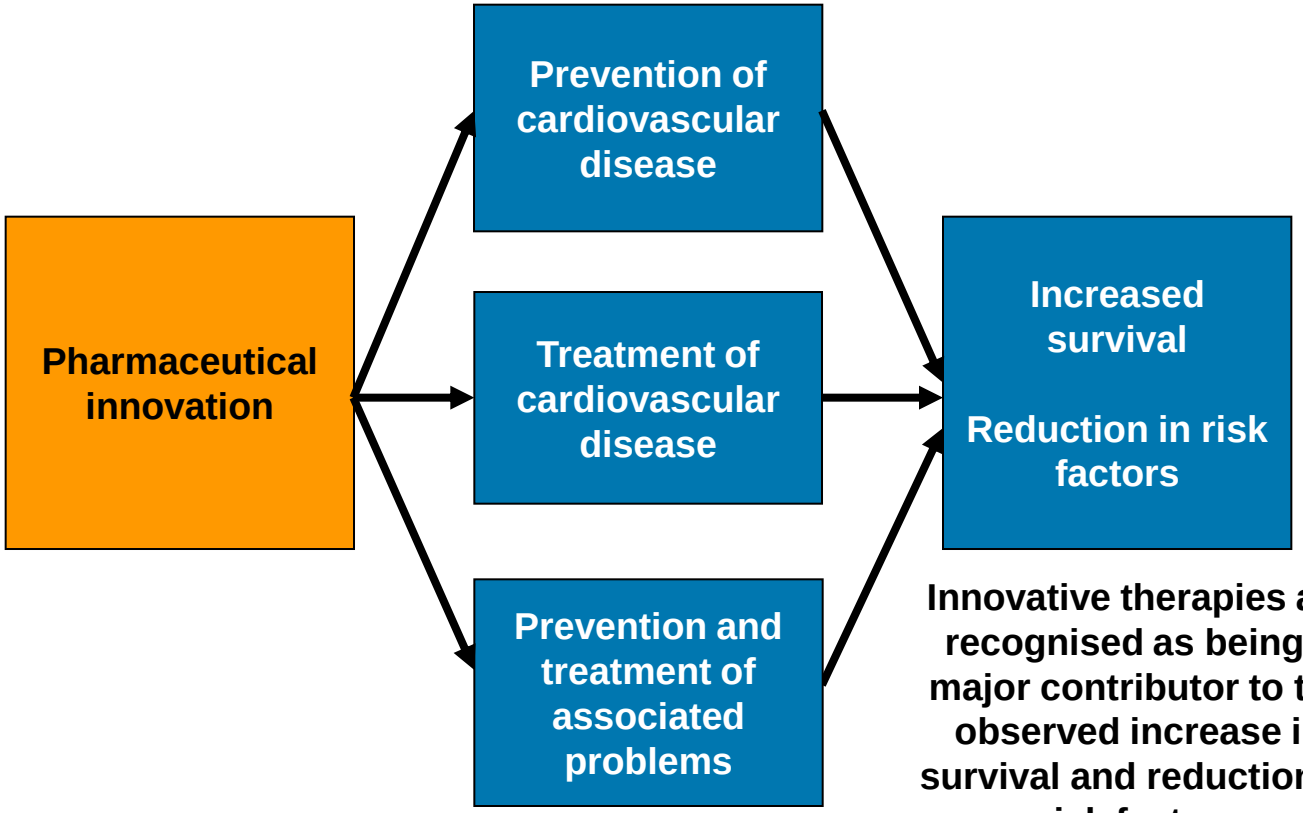


WHO (2006), Modena (2001), Eurostat (2010)

CHAPTER 1: Innovation is significantly benefiting patients with…

Cardiovascular disease

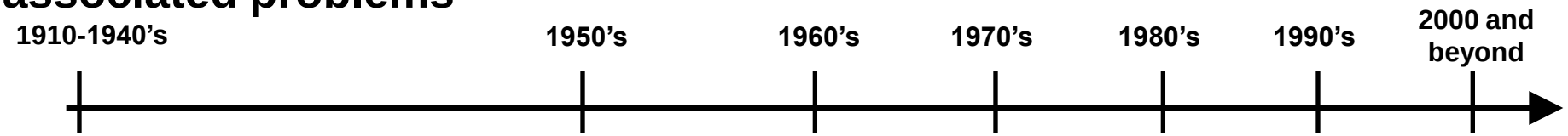
Pharmaceutical innovation has reduced cardiovascular-related mortality



Innovative therapies are recognised as being a major contributor to the observed increase in survival and reduction in risk factors

However, cardiovascular disease remains the leading cause of death in Italy and there remains a significant need for innovation in the treatment of this problem

Pharmaceutical innovation has resulted in significant progress in both the prevention and the treatment of cardiovascular disease and its associated problems



1919 Organic mercury causes diuresis and is beneficial in oedema associated with heart failure

1913 Adrenaline found to be able to relax and constrict vessels – alpha and beta receptors identified

1949 Sulfa drug used to treat oedema due to heart failure. However, long term toxicity a problem

Identification of **Chlorthiazide** – improved reduction of oedema and high blood pressure with a safer profile

1950 Acetazolamide identified – 300 times more potent.

1958 First **Beta-blocker** identified, but initial compound has low potency

Propanalol identified soon after – **revolutionary as it offers for the first time preventative therapy for asymptomatic patients**

Early 1960s Loop diuretics discovered (new mechanism of action) followed shortly by the potassium sparing diuretics **Spironolactone** and **Amiloride**

1971 Start of research into **Statin** therapy by inhibiting the enzyme associated with synthesis of cholesterol

Mevastatin identified followed by the isolation of the more effective inhibitor **Lovastatin**

1980s Angiotensin converting enzymes investigated for heart disease. **ACE inhibitors** used to control high blood pressure – the active compound **Captopril** discovered with further developments with pro-drugs such as **Quinapril**

As a result further research leads to the discovery of the angiotensin II receptor with medicines developed to block it such as **Losartan**

Today – Six statins are available in Italy: **Atorvastatin, Fluvastatin, Lovastatin, Pravastatin, Rosuvastatin and Simvastatin.**

1950's-60's Medicines to treat high cholesterol first identified but there were many unwanted side effects

DIURETICS

BETA-BLOCKERS, ACE INHIBITORS, ANGIOTENSIN II ANTAGONISTS

STATINS

Global- and Country-level data

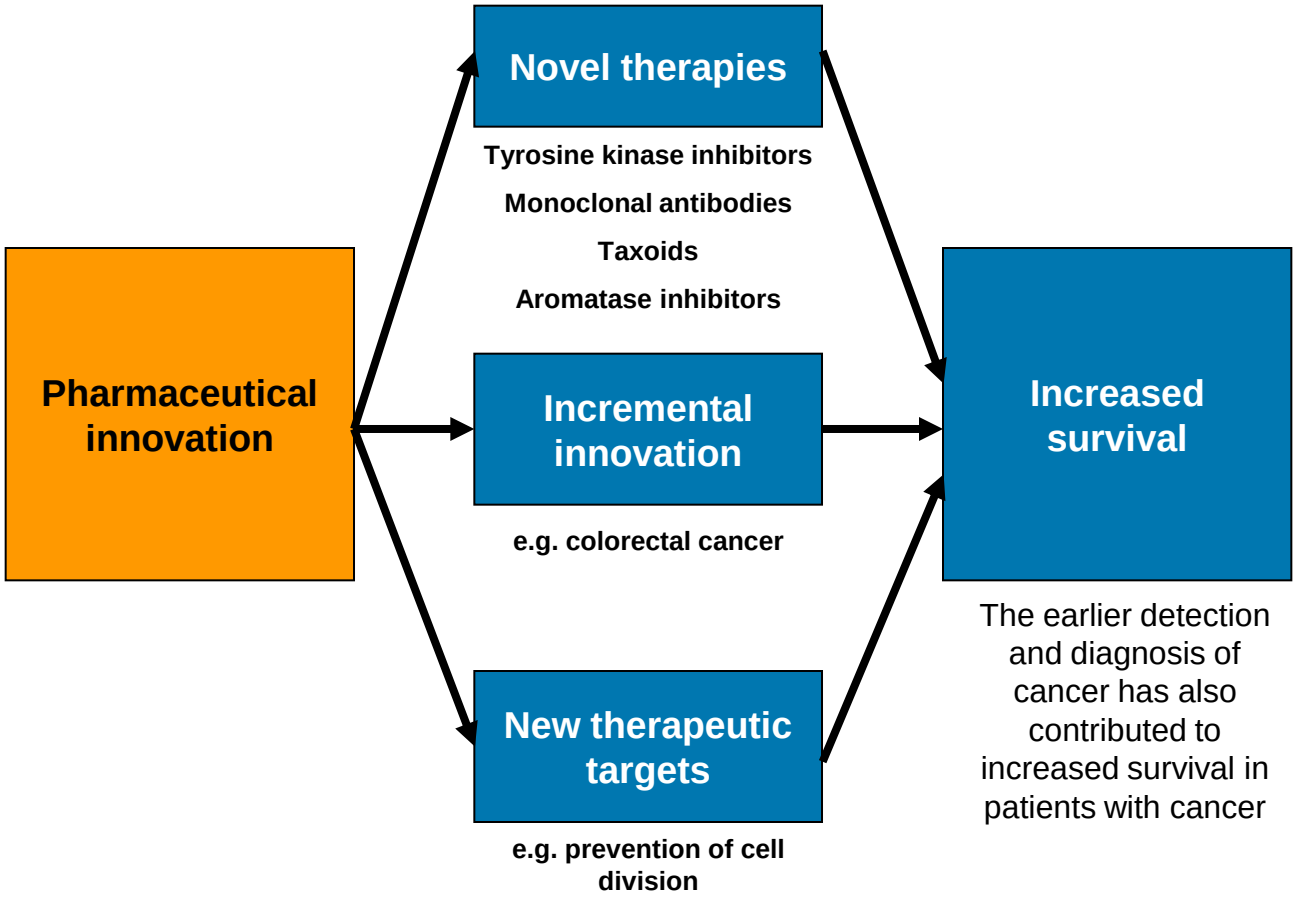
"The fundamental mechanisms of disease are being explored for future novel innovative treatments to offer further patient benefits"

ABPI (2004), OsMed (2009)

CHAPTER 3: Innovation is significantly benefiting patients with…

Cancer

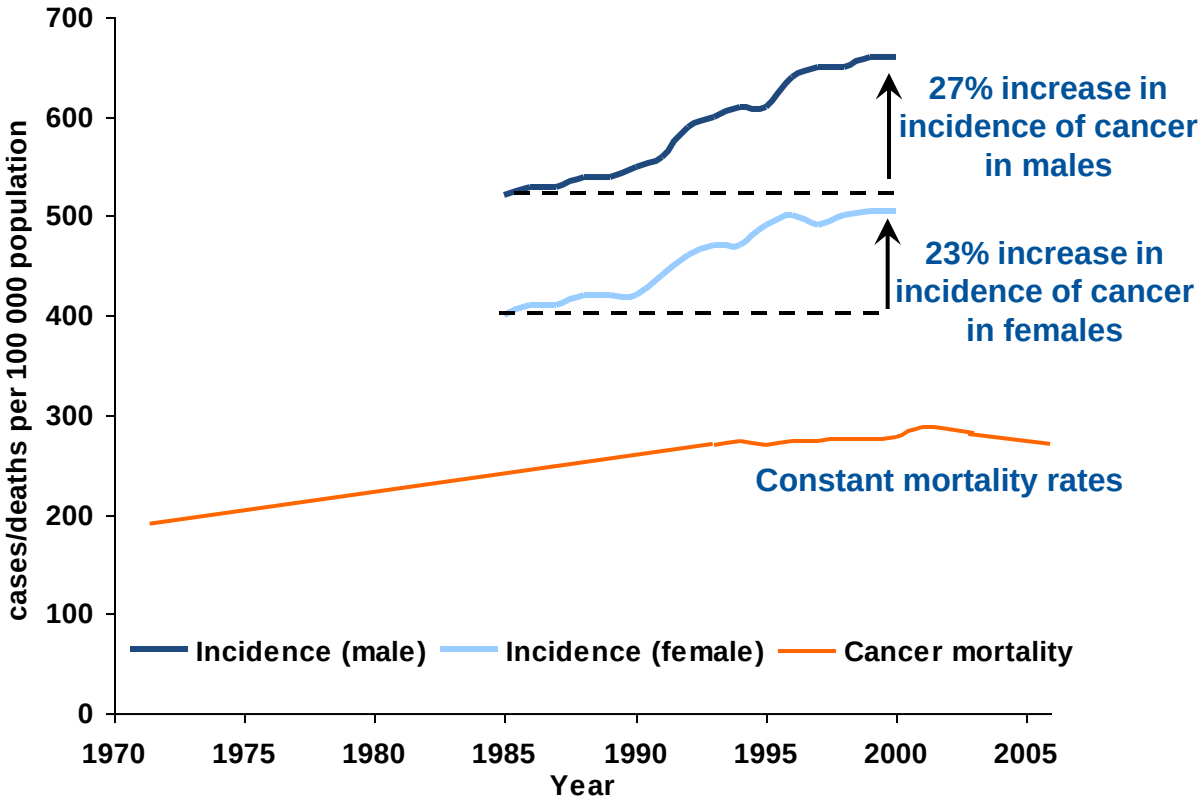
Pharmaceutical innovation has increased the likelihood of survival for patients with cancer



However, cancer remains one of the leading causes of death in Italy and survival is varied across different cancer sites; there remains a significant need for innovation in the treatment of this disease

Cancer mortality in Italy has stabilised despite a 25% increase in the incidence of cancer

- Over the past 30 years, the mortality rates for all malignant neoplasms have increased by 50%
- However, over the last decade mortality rates have been constant despite rising incidence rates

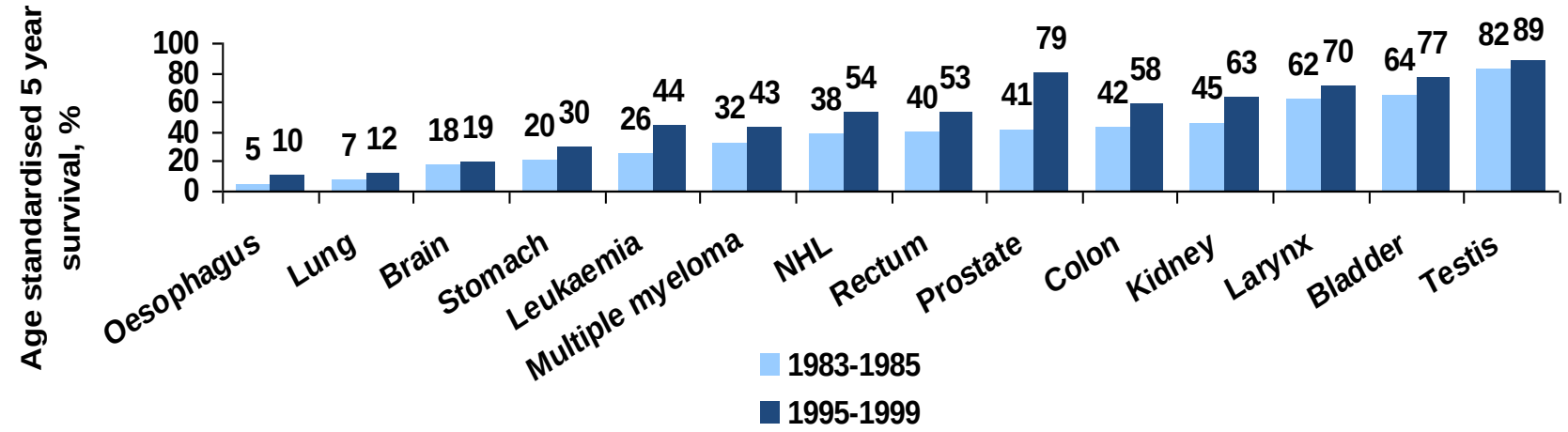


Country-level data

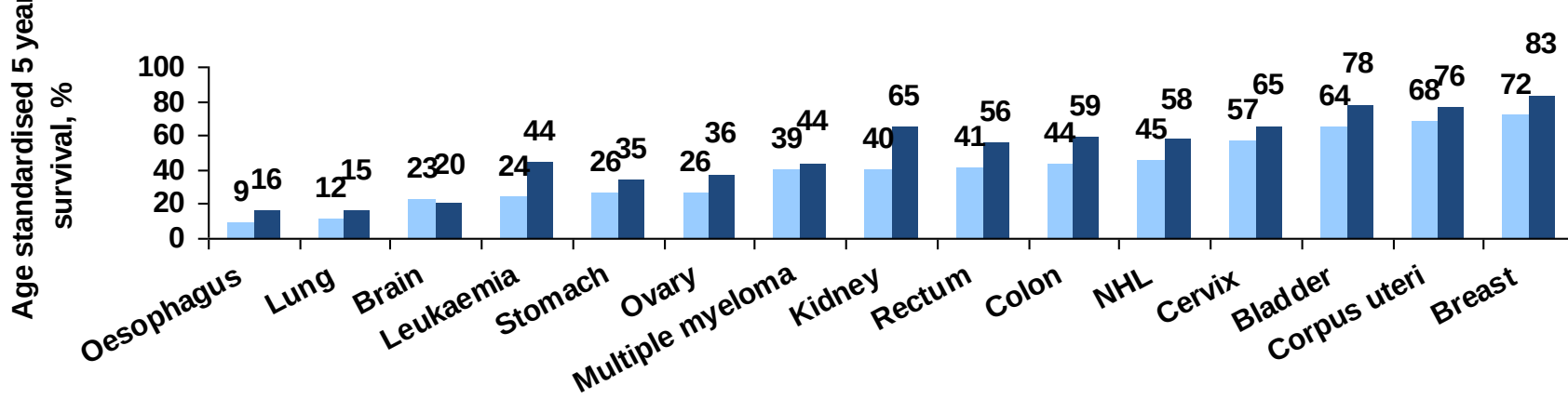
Capocaccia (2007), Istat (2009)

And increasing survival rates can be seen across a wide range of cancers in Italy

MALES



FEMALES



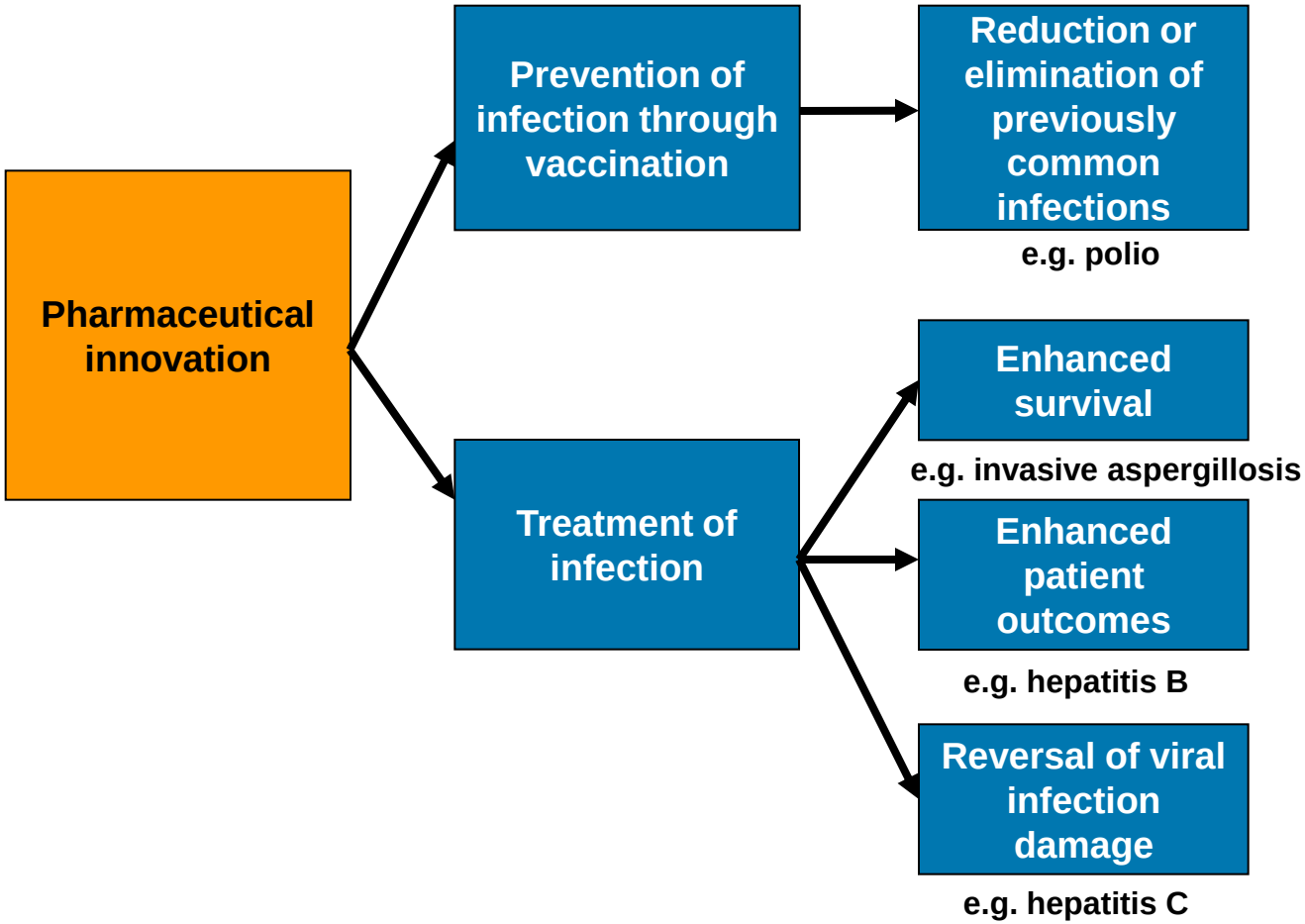
Country-level data

EUROCARE (2009)

CHAPTER 4: Innovation is significantly benefiting patients with…

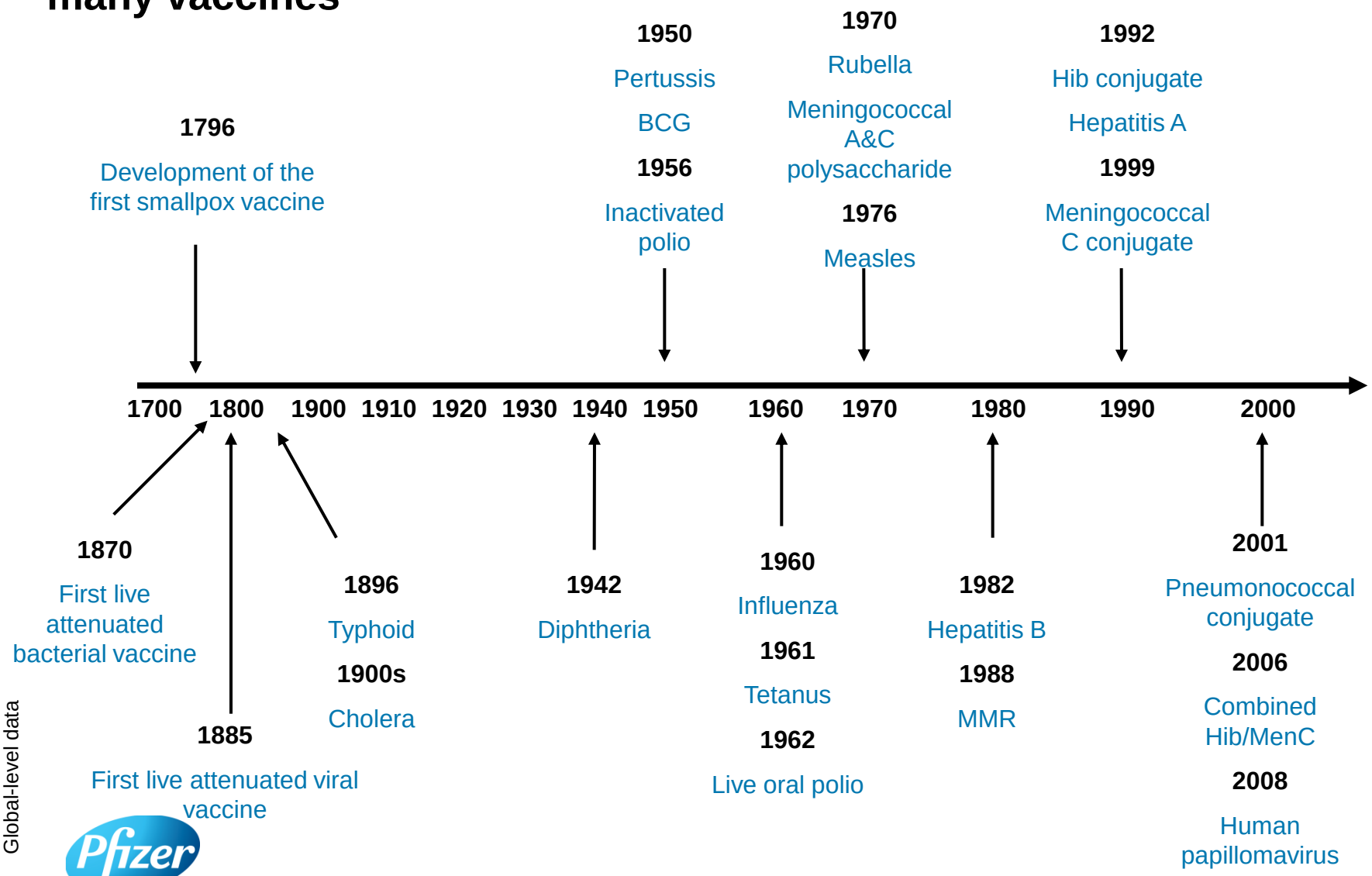
Infectious Disease

Pharmaceutical innovation has enhanced the prevention and treatment of infectious disease



However, severe infectious disease remains a significant problem, requiring innovation in both the development of effective treatments and preventative vaccines

Pharmaceutical innovation has enabled the development of many vaccines

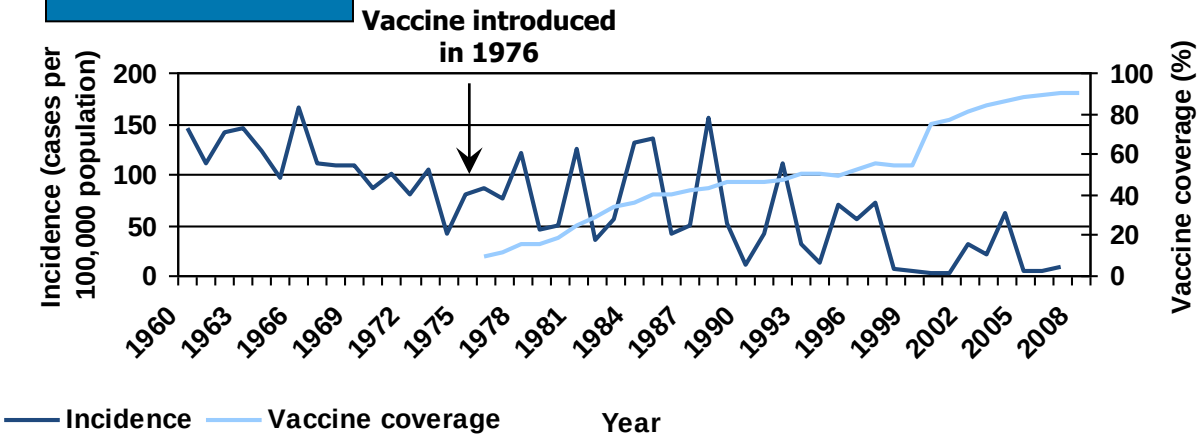


Global-level data

Adapted from NHS (2008)

And vaccination has reduced the incidence of many previously common infectious diseases

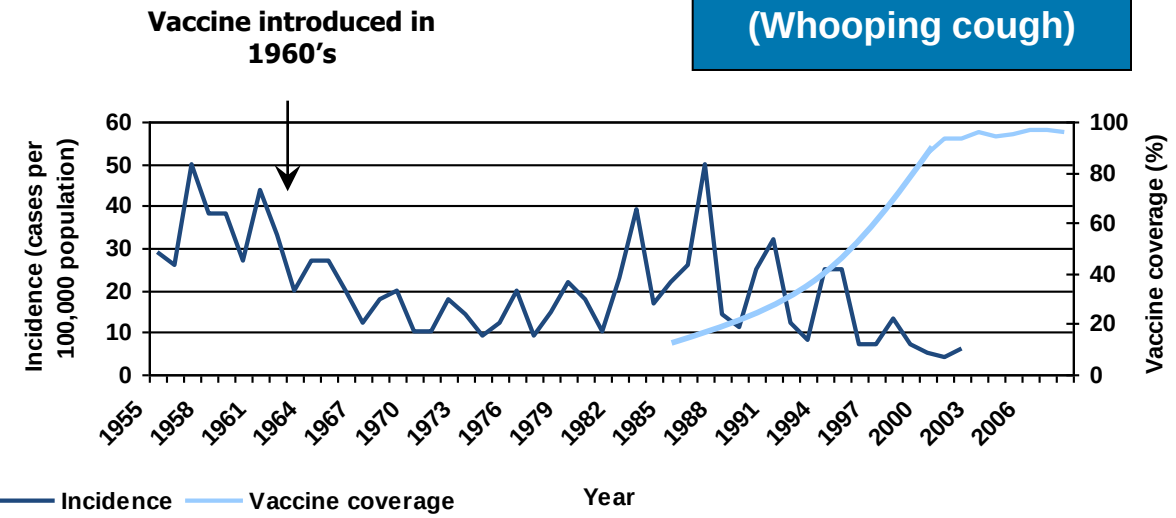
Measles



"Although childhood vaccination coverage has increased in recent years, reaching the national average of 88% in 2006, it is still below the target of 95%, and outbreaks continue to occur."

Pertussis (Whooping cough)

"Since the introduction of the pertussis vaccine in 1962, epidemic peaks have regularly occurred every 3–4 years… [with] decreasing incidence and decreasing peak height… Since 1998 no further epidemics have been observed although a slight increase in incidence was reported in 2002."



Country-level data

Salmaso (2001), Istat (1999,2001, 2002, 2005), Sorvelianza Pediatri Sentinella (2010), Rota (2005), WHO (2010), Manfredi (2005), MdS (2008)

But prevention through vaccination is still needed for many serious infections

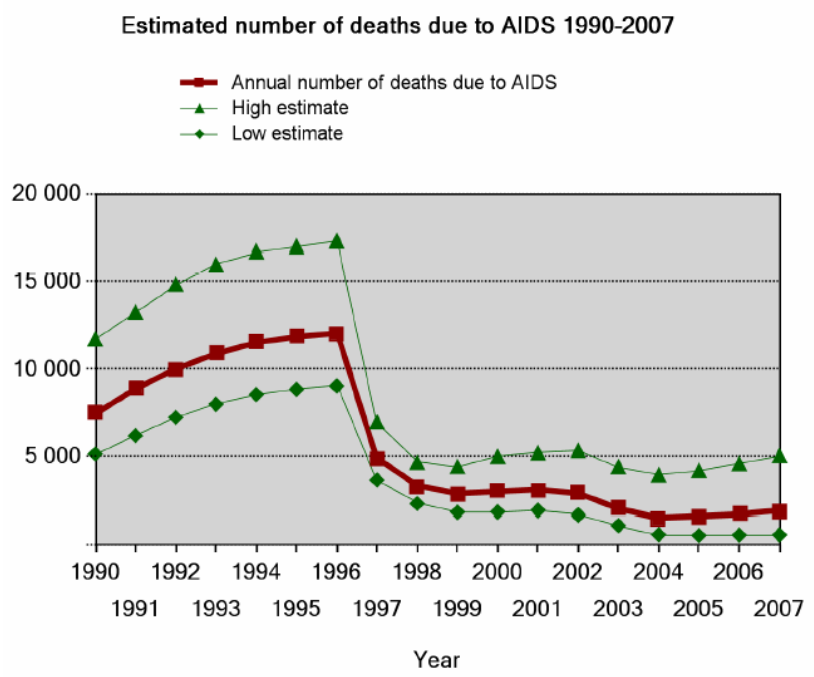
Meningitis



- Around 900 people in Italy are affected by bacterial Meningitis each year, associated with a 14% mortality rate
- In survivors, one in seven people will be left with a permanent disability
- In the past 20 years vaccines have been developed against Haemophilus influenzae type B (Hib) (1992), Meningitis C (1999), and Pneumococcal Meningitis (2006), **but there is no vaccine for Meningitis B – the strain accounting for 66% of all cases in Italy**

HIV/AIDs

- Around 150 000 people in Italy are estimated to be living with HIV, up from 140 000 in 2001
- The annual number of deaths due to HIV has fallen dramatically since the introduction of HAART in 1996
- In September 2009 **the discovery of a breakthrough new vaccine was reported which may reduce the risk of HIV by a third, however, no cure or vaccine is currently available to treat HIV/AIDS**



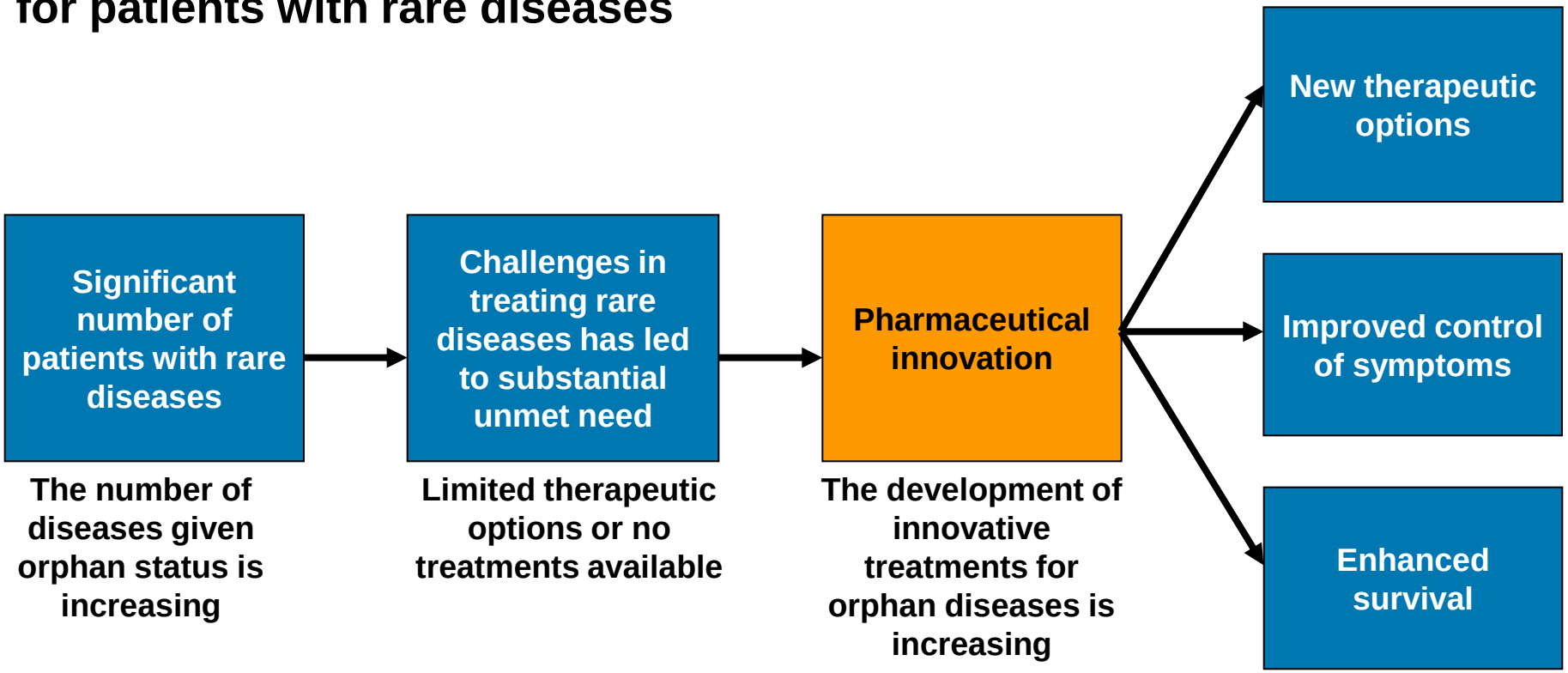
Istituto Superiore di Sanità (2007), WHO (2008), EU-IBIS Network (2007)

Country-level data

CHAPTER 6: Innovation is significantly benefiting patients with…

Orphan Diseases

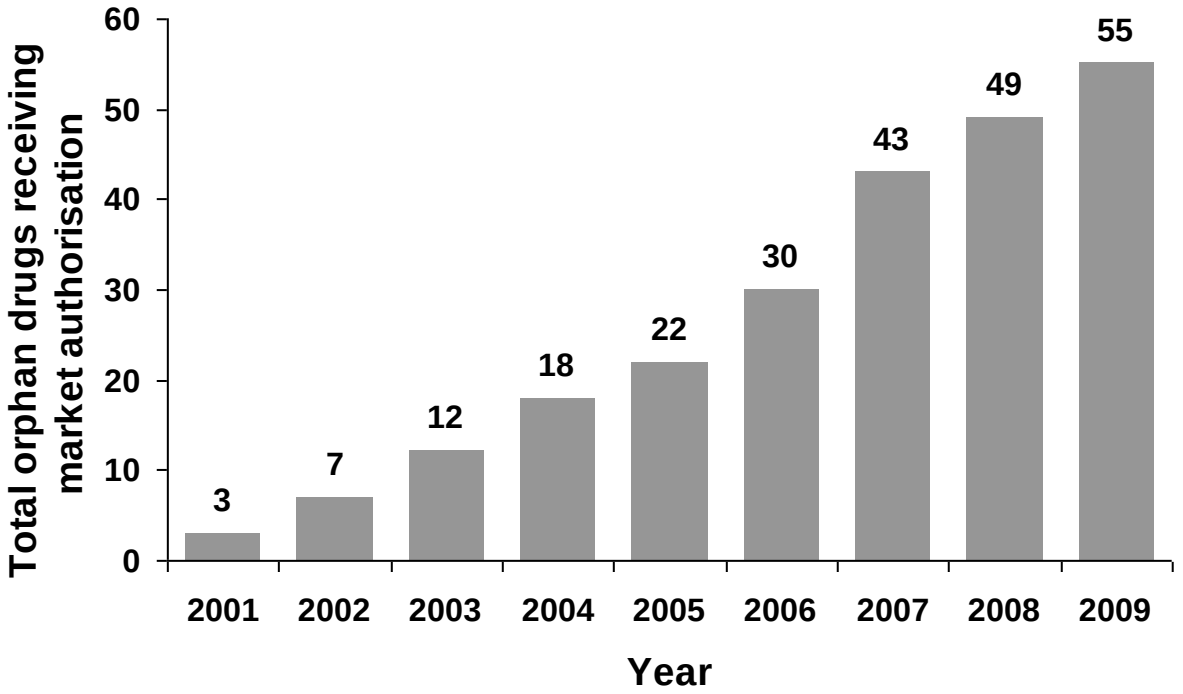
Pharmaceutical innovation has led to significant benefits for patients with rare diseases



However, there remains a significant unmet need for innovation in the development of therapies for orphan diseases with limited therapy options in order to improve symptom control and survival

The number of diseases given orphan status is expanding, but the number of treatments available is also increasing

- The definition of an orphan or rare disease in Europe is a disease that affects 5 in 10 000 people
- Rare diseases are often severe, chronic, progressive, and life-threatening
- The number of rare diseases around the world with no treatment currently available is estimated to be between 4000 to 5000 and still increasing
- 27 to 36 million people are estimated to be affected by rare diseases in the EU



The development of innovative orphan drugs to treat rare diseases has increased, offering patients new options or treatments that were previously unavailable

EU- level data

Orphanet (2009), EMEA (2007), EURORDIS (2005)

With regional strategies in place to prioritise the diagnosis and treatment of rare disease in Italy

The Ministry of Health published a decree in 2001 that aimed at improving the prevention, diagnosis, and treatment of rare diseases

The Italian National Centre for Rare Diseases (Istituto Superiore di Sanità) is the leading organization in EUROPLAN, an EU-wide initiative to develop national strategic plans for rare diseases

Orphan drugs are a research priority for the Italian National Medicines Agency (AIFA), with 20 independent research proposals funded in 2005, and 24 funded in 2006

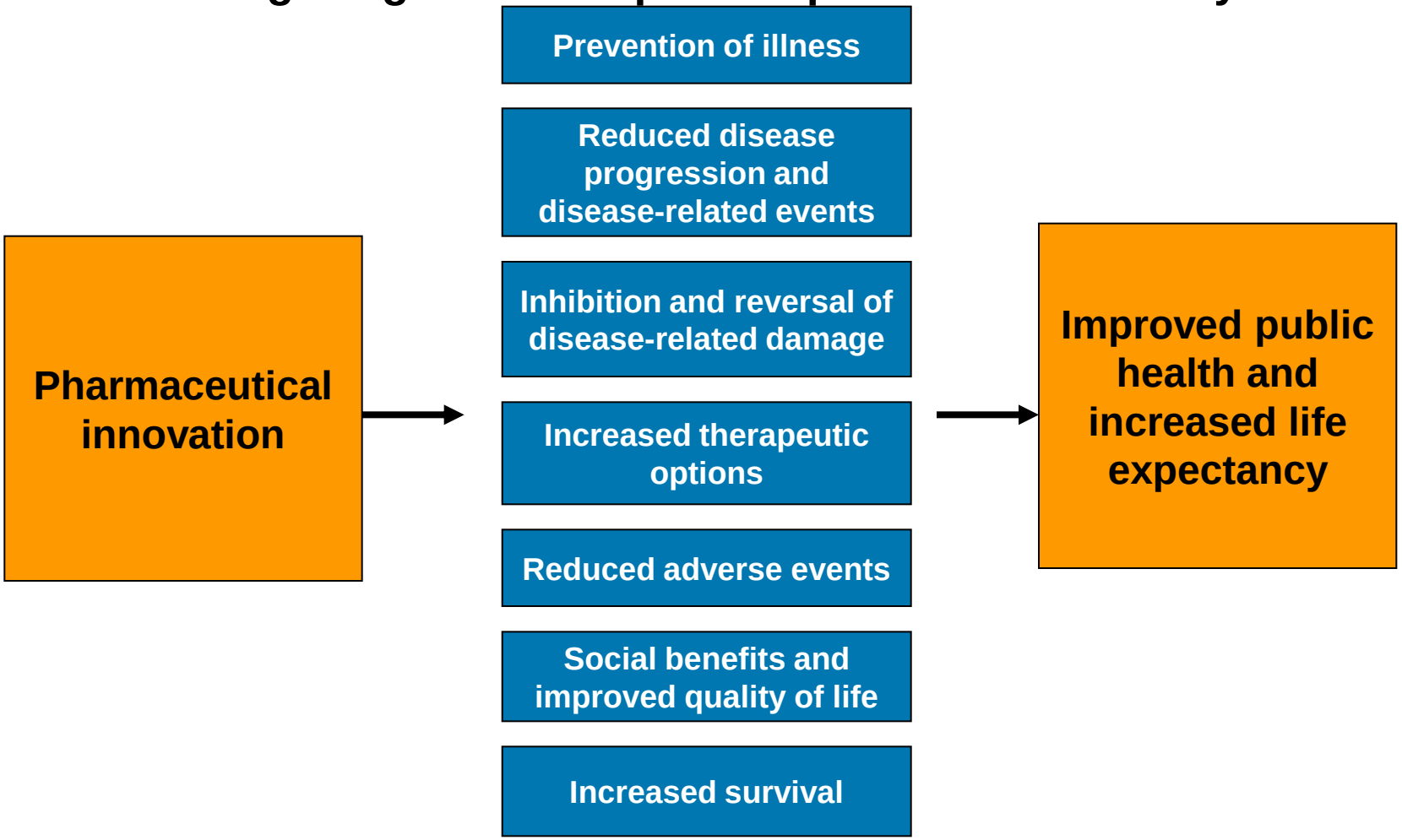
- Rare diseases have been a priority topic in Italy since 1998
- Since 2001, rare diseases have been a priority in all Italian National Health Plans (2003-2005, 2006-2008)
- Although there is not a single overarching national plan, there are a series of regional plans designed to emphasise the diagnosis and treatment of rare diseases
- A national registry of rare diseases has been established and there is a national research programme
- Italy is one of only four countries (Denmark, France, Sweden) that has dedicated centres of expertise for rare diseases
- 36 of the 46 authorized orphan drugs are now available for patients in Italy:

"Funding research programmes will lead to discovery of new drugs"

Country-level data

Taruscio (2008), EUROPLAN (2008), ECRD (2007)

Pharmaceutical innovation provides many patient benefits and are having a significant impact on public health in Italy



Continued pharmaceutical innovation is vital for the continued improvement of public health