

Capturing Added Value in immuno-oncology

Balancing rapid access and new metrics for valuation

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Disclosures: Patrick Hopkinson

- Employment: currently employed by Bristol-Myers Squibb as head of Worldwide Health Economics and Outcomes Research, Markets
- The views expressed in this presentation are personal based on my experience and do not necessarily reflect the views of Bristol-Myers Squibb

Topics

1. Cancer: still a high burden
2. The potential for immuno-oncology treatments to reduce the burden of cancer
3. Challenges and solutions to demonstrating the value of immuno-oncology treatments in oncology

1. Cancer: still a high burden

Despite considerable improvements in outcomes, 1 in 3 people with cancer will not survive more than 5 years.

Cancer in the EU – still the unbeaten disease¹

2.45 million
new cases
per year

1.23 million
deaths
per year

126 billion
Euros in
total costs

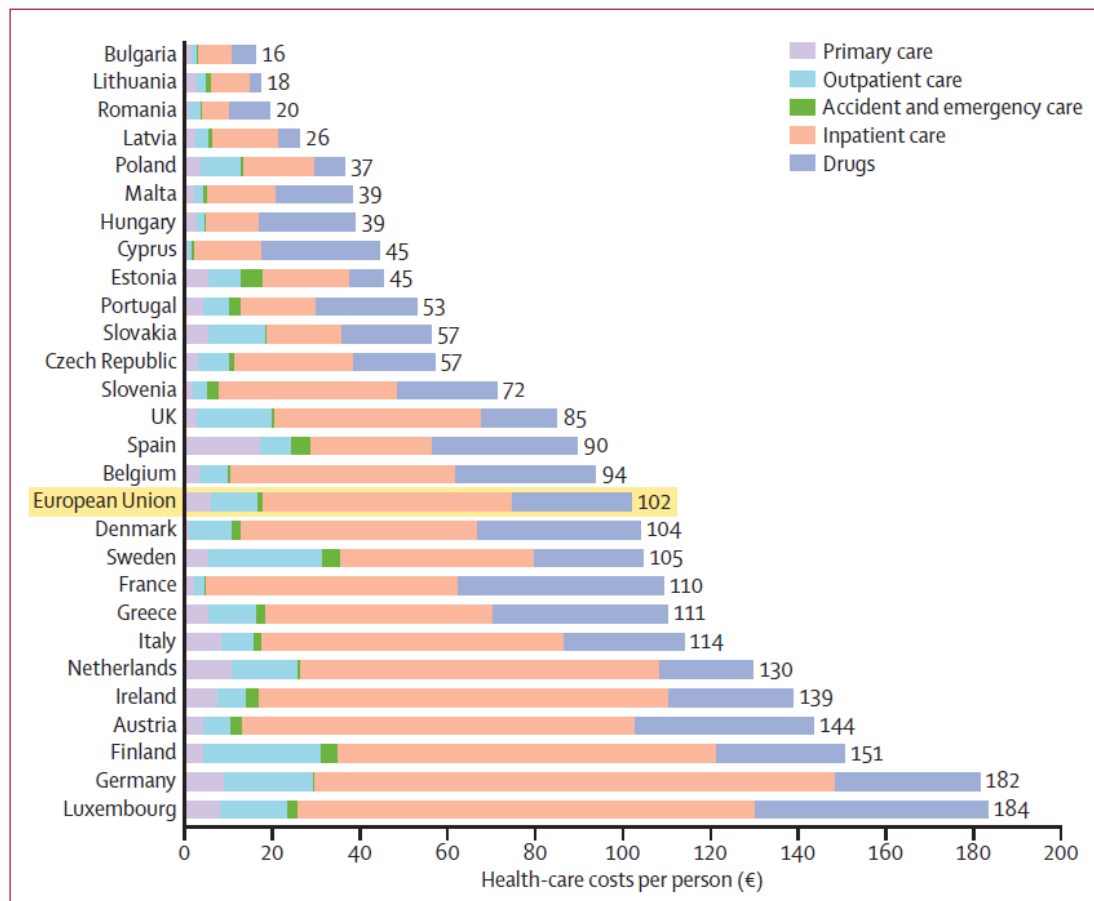
75 billion
Euros in
indirect
costs

1 in 3 people with cancer today will not survive more than 5 years²

Note: all figures above are for all types and stages of cancer

1. Luengo-Fernandez 2013
2. SEER Cancer Statistics 2014.

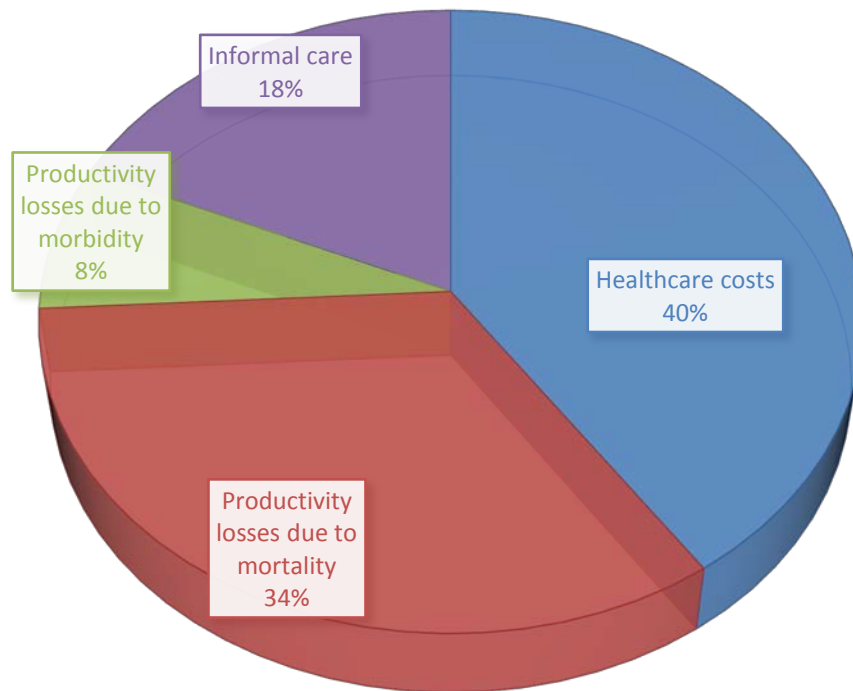
A considerable burden to our health care systems



Source: Luengo-Fernandez, Lancet Oncol 2013

- Cancer care accounts for 4% of overall health expenditure in EU27
- Hospitalisations are the main cost driver in all EU countries

A substantial cost to society

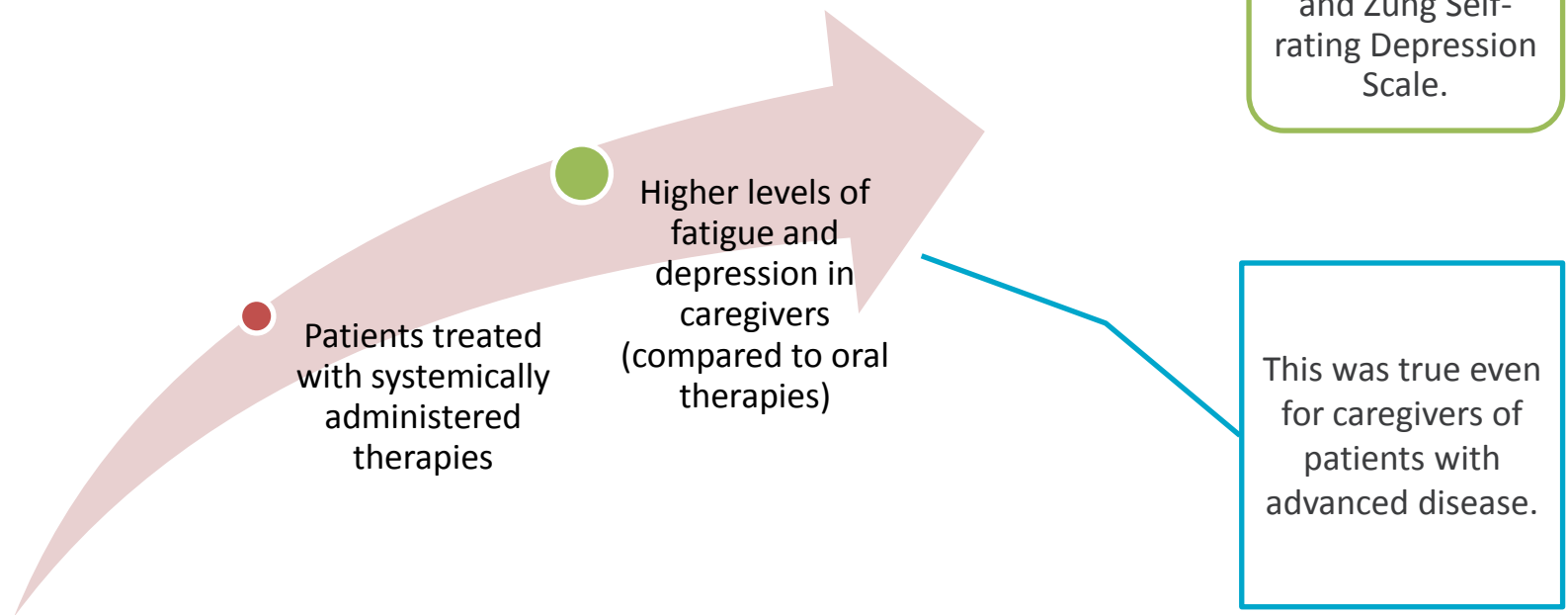


- **Productivity losses because of early death: €42.6 billion**
- **Lost working days: €9.43 billion**
- **Informal care: €23.2 billion**

Source: Luengo-Fernandez, Lancet Oncol 2013

Caregiver fatigue and depression are also affected by patient's systemic therapies

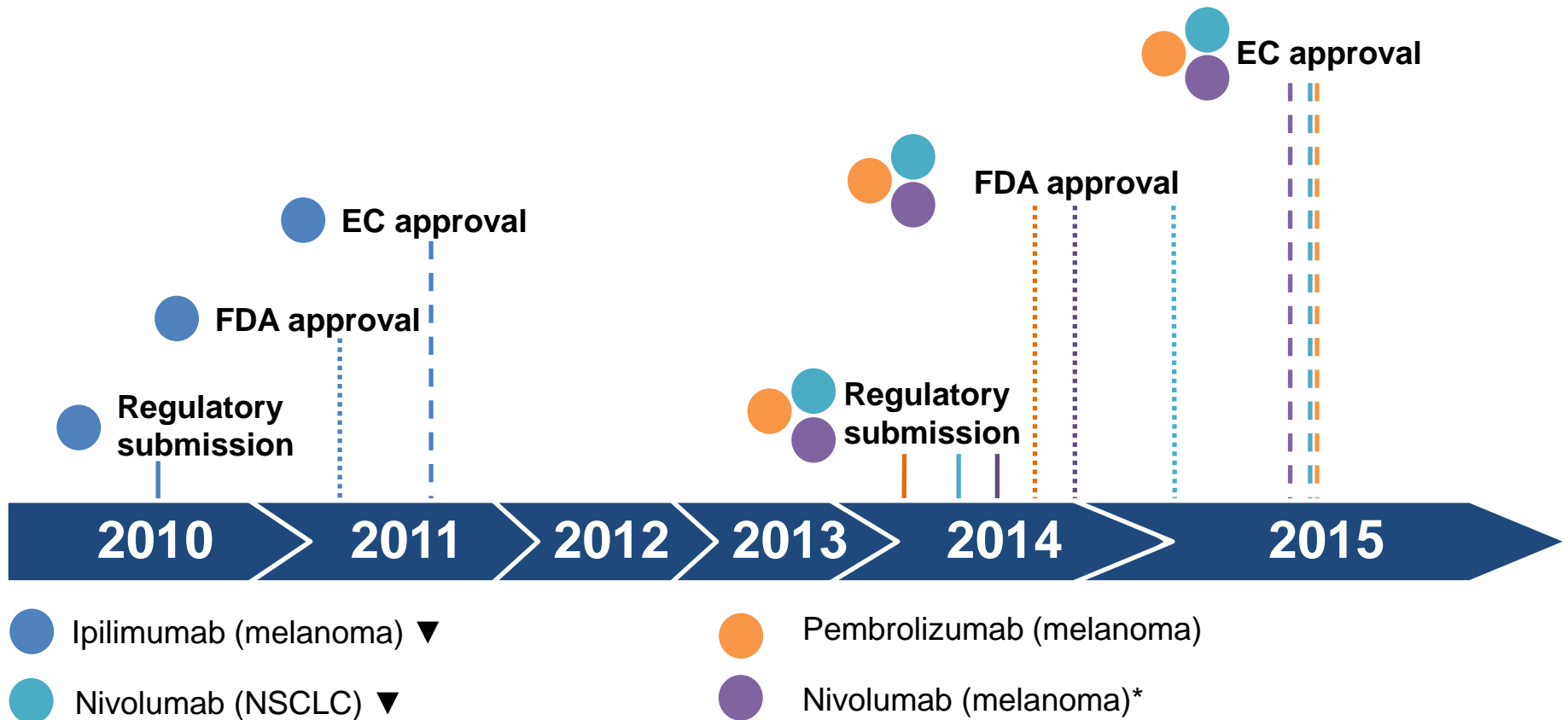
- > Barzelloni *et al.* presented data on fatigue and depression in family caregiver of patients with lung, breast and colorectal cancer.
- > Fatigue and depression were compared between caregivers of patients treated with oral versus systemically administered therapies.



FACT-F: Functional assessment of cancer therapy – fatigue, SDS: self-rating depression scale,

2. Potential for immuno-oncology treatments to reduce the burden of cancer

A rapid pace of progress, making treatments available to patients with many different forms of cancer

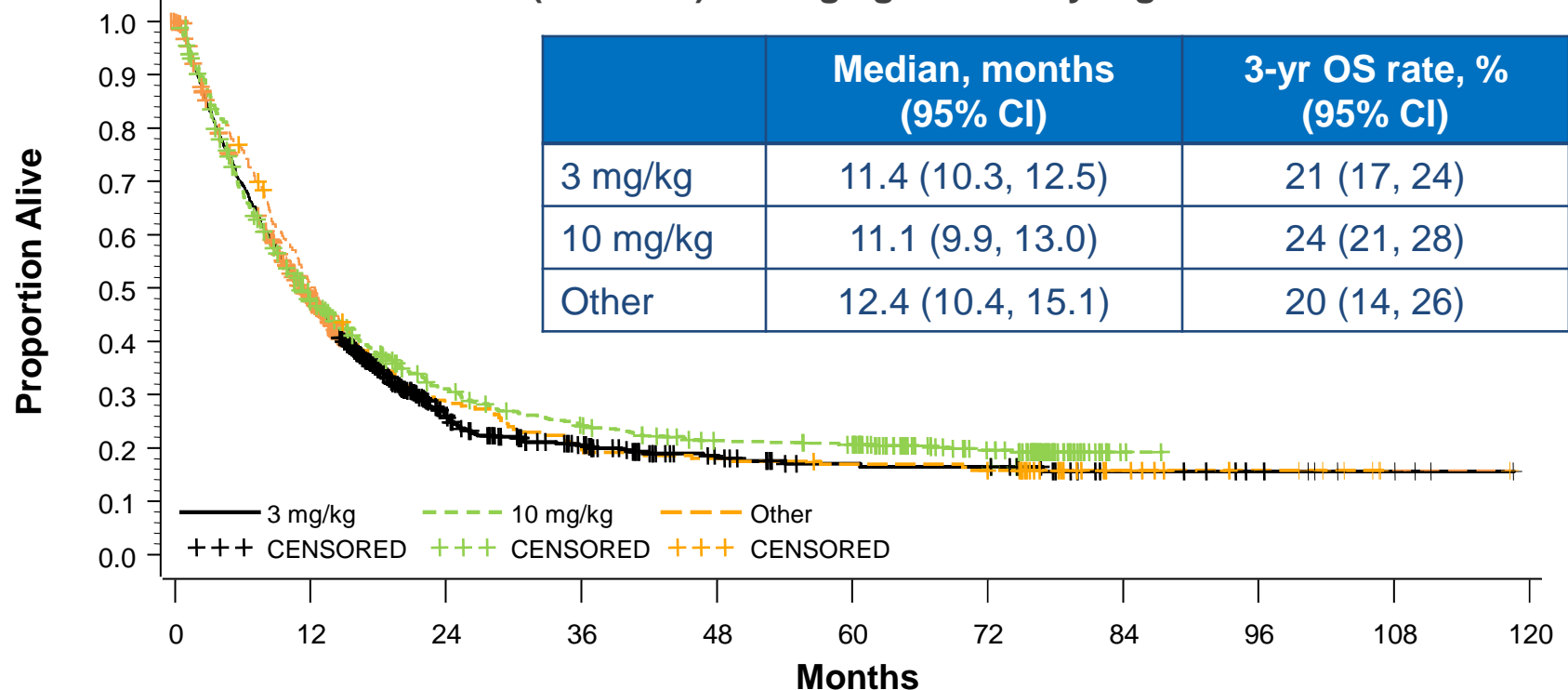


EC, European Commission; FDA, Food and Drug Administration

**Nivolumab received Japan approval July 2014*

Potential long-term survival for advanced cancer patients who previously had very few treatment options available

Long term survival from pooled prospective and retrospective ipilimumab studies in advanced melanoma (N = 1861)* - 3 mg/kg is the only registered dose



Patients at Risk

3 mg/kg	965	429	127	73	41	29	28	12	8	4	0
10 mg/kg	706	316	191	145	118	111	64	2	0	0	0
Other	190	94	52	36	33	30	28	12	7	1	0

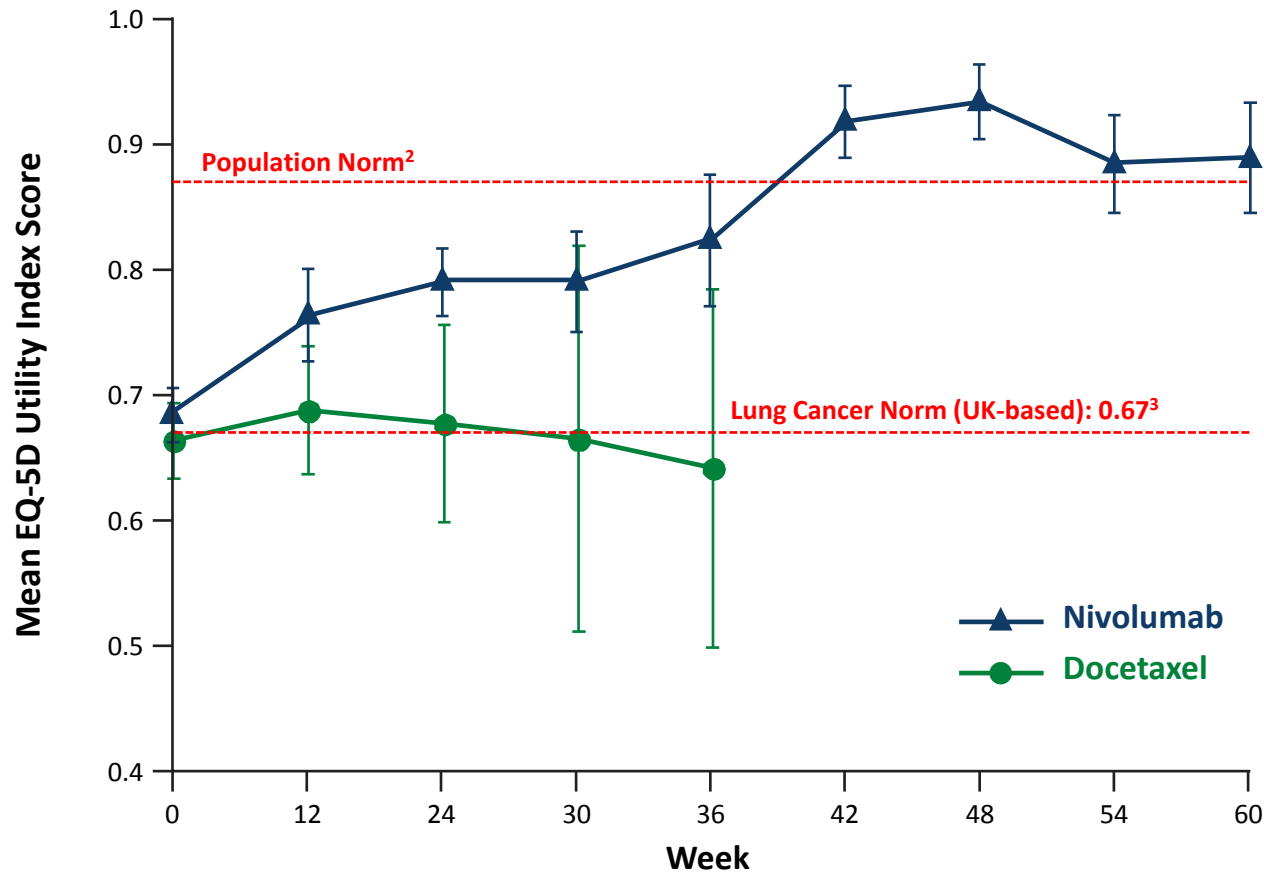
*Non-randomized subset analyses.

Schadendorf D, et al. *J Clin Oncol*. 2015.

This improvement in survival is also considered in the context of safety outcomes

- Yervoy is associated with side effects resulting from excessive activity of the immune system, including severe reactions and inflammation.
- Most will resolve following appropriate treatment and/or stopping on Yervoy
- The most common individual side effects (affecting > 10% of patients), are
 - diarrhoea
 - rash
 - pruritus (itching)
 - fatigue (tiredness)
 - nausea (feeling sick)
 - vomiting
 - decreased appetite and
 - abdominal pain (stomach ache).
- The full list of all side effects reported with Yervoy is accessible at http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002213/human_med_001465.jsp&mid=WC0b01ac058001d124, under the tab entitled "What is the risk associated with Yervoy?"

Quality of survival: immuno-oncology treatment shows a positive impact on quality of life

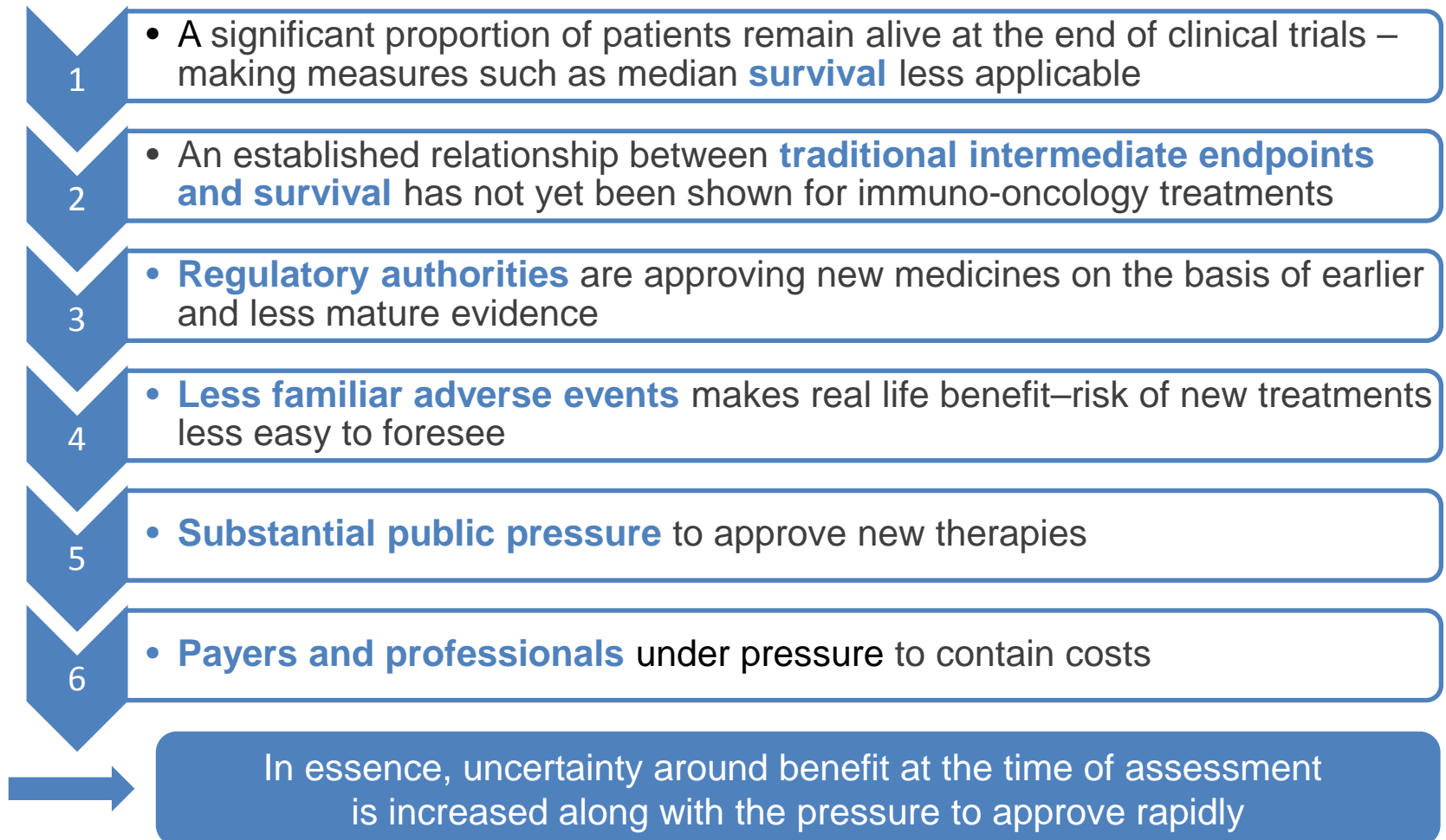


NSCLC patients returned to population norms of QoL at 36-42 weeks

Nivolumab (n = 97)	97	50	32	32	21	18	13	13	8
Docetaxel (n = 89)	88	32	9	5	5	4	4	2	1

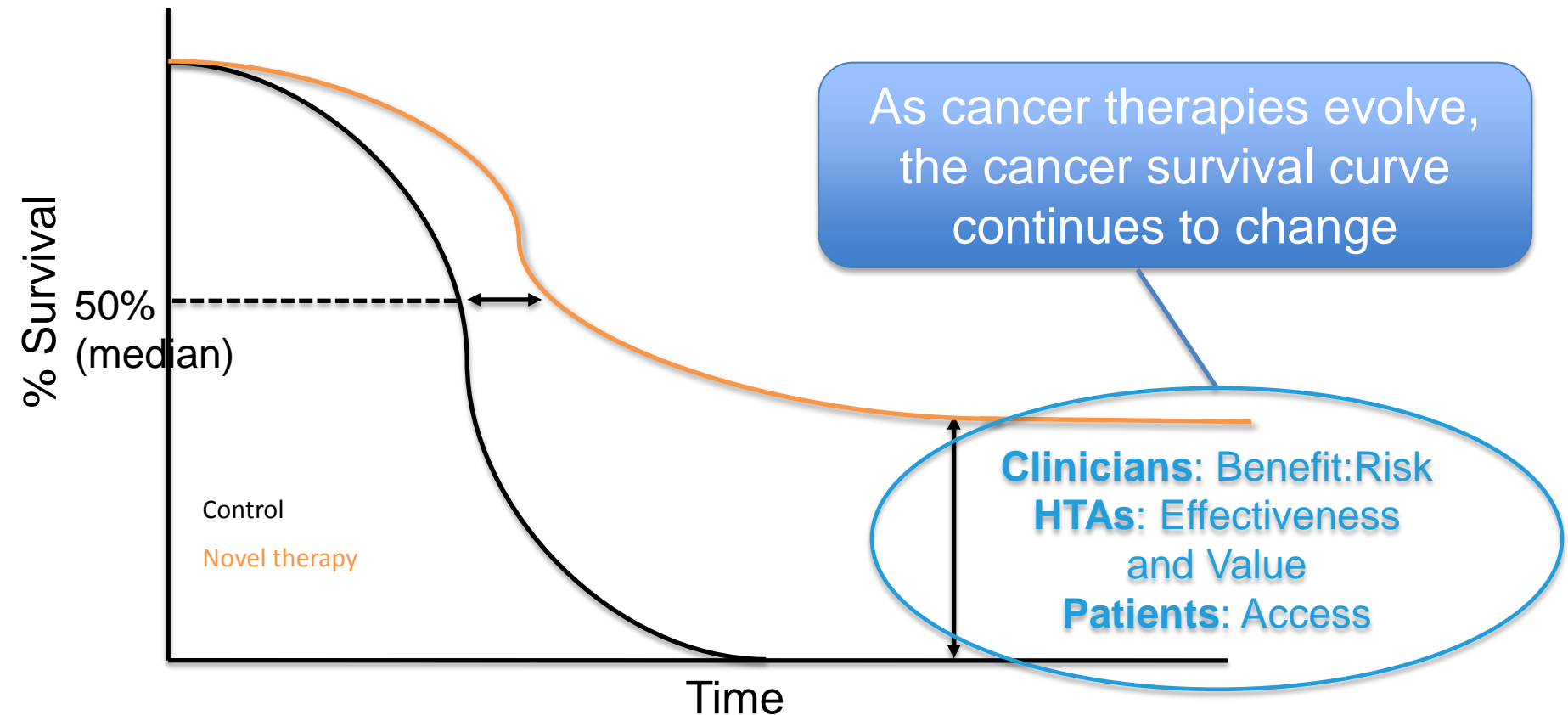
3. Challenges and solutions to demonstrating the value of immuno-oncology treatments

What are the key HTA challenges in immuno-oncology?

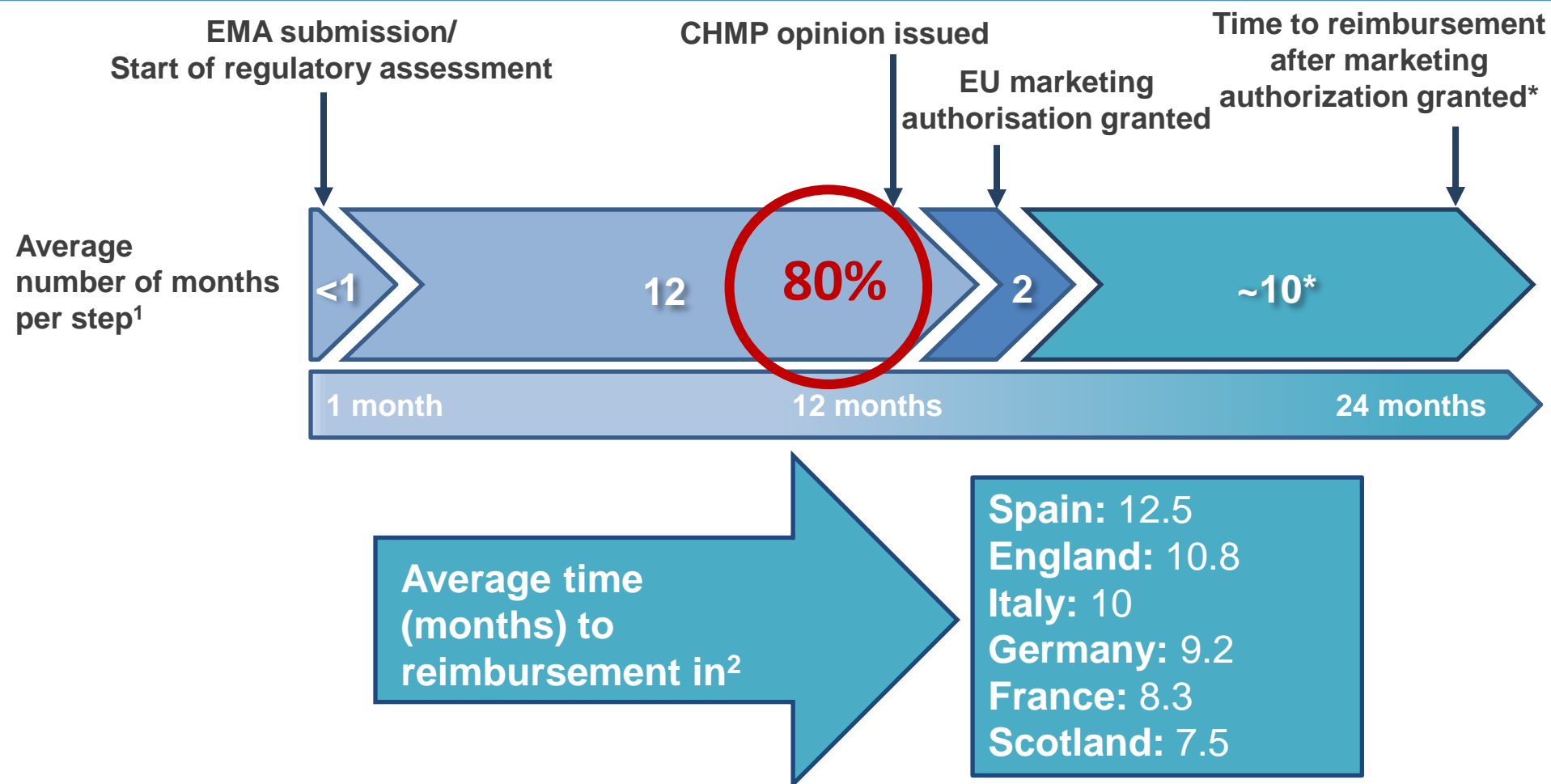


Shifting the survival curve for advanced cancers: the need for new approaches to assessing survival

Theoretical Survival with Various Cancer Treatments^{1,2}

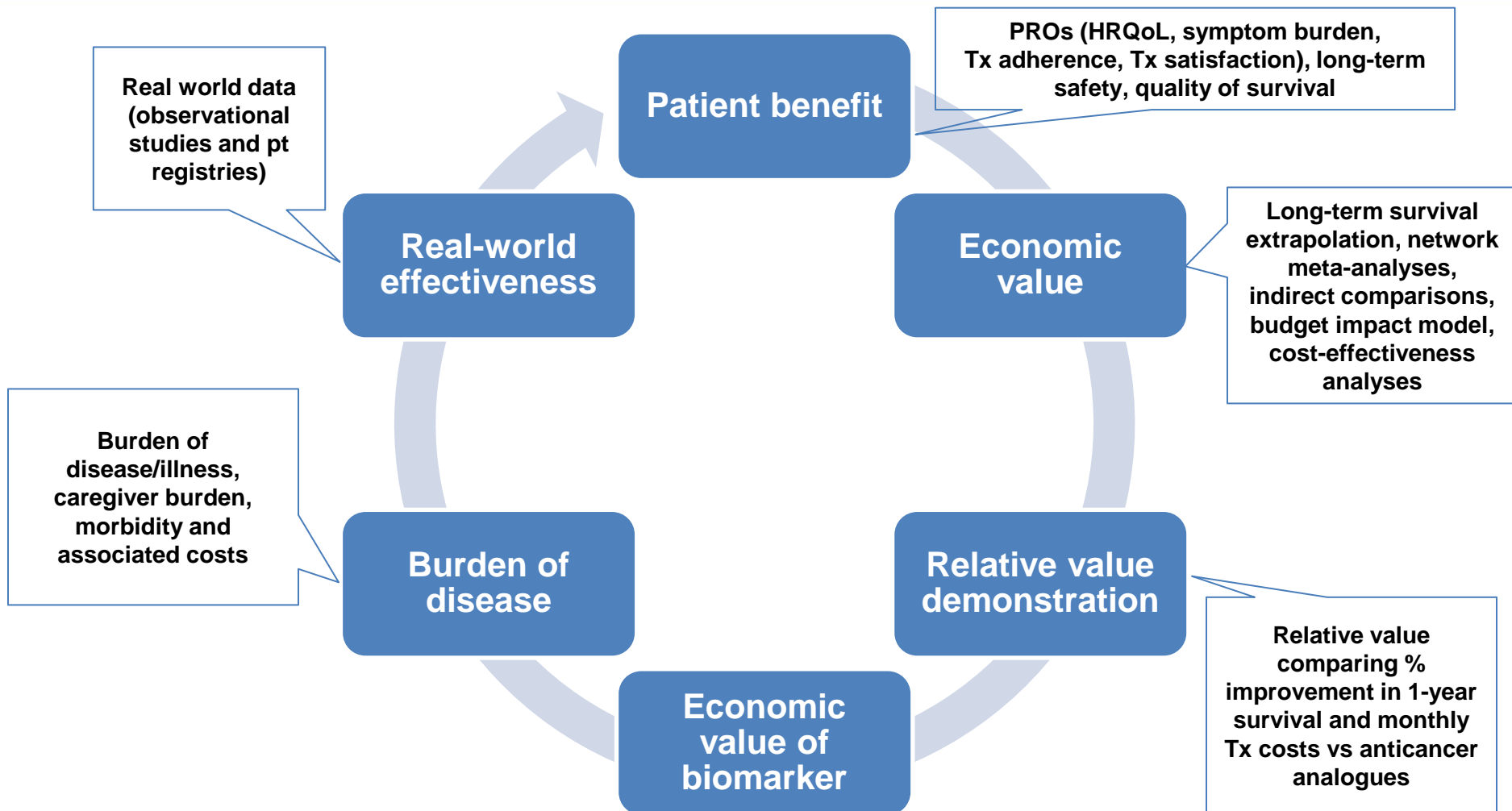


The need for accelerated approval and access decisions: patients lose treatment opportunity during approval process



*Average for EU5: Spain, England, Italy, Germany, France and Scotland

Categories of value demonstration needed to fully capture benefit



A broader range of outcomes will need to be given more weight and uncertainty needs to be managed more effectively

- HTA traditionally puts more emphasis on efficacy/effectiveness and safety than on societal or other outcomes – **broader societal outcomes should be also used**
- It is also necessary to move beyond median overall survival and **assess mean overall survival – area under the survival curve – as well as landmark survival**
- Uncertainty around efficacy/effectiveness and safety, particularly in the medium to long-term, can be addressed by **longer follow up after approval**
- Health-related quality of life is often inferred from individual symptoms as these offer a more complete data set – **holistic measures of QoL should be used**
- There are fewer randomised controlled trials (RCTs) and more real-world data and modelling – **this needs to be embraced by decision makers.**

THANK YOU