Health Economics – Oncology – Immuno-Therapy

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IHE FORUM

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My employer:

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Introduction

Launches in the past seven years

- *E*
- *O*
- *D*
- *E*
- *N*
- *E*
- *(O)*
- *(KO)*

ONCO ACTIVE

- 2L advanced melanoma
- 1L advanced melanoma
- 1L advanced melanoma (combination)
- 3-4L Hodgkin's lymphoma
- 2L Head and Neck Carcinoma
- 2L squamous NSCLC
- 2L non-squamous NSCLC
- 2L renal cell cancer
- 2L urothelial cancer

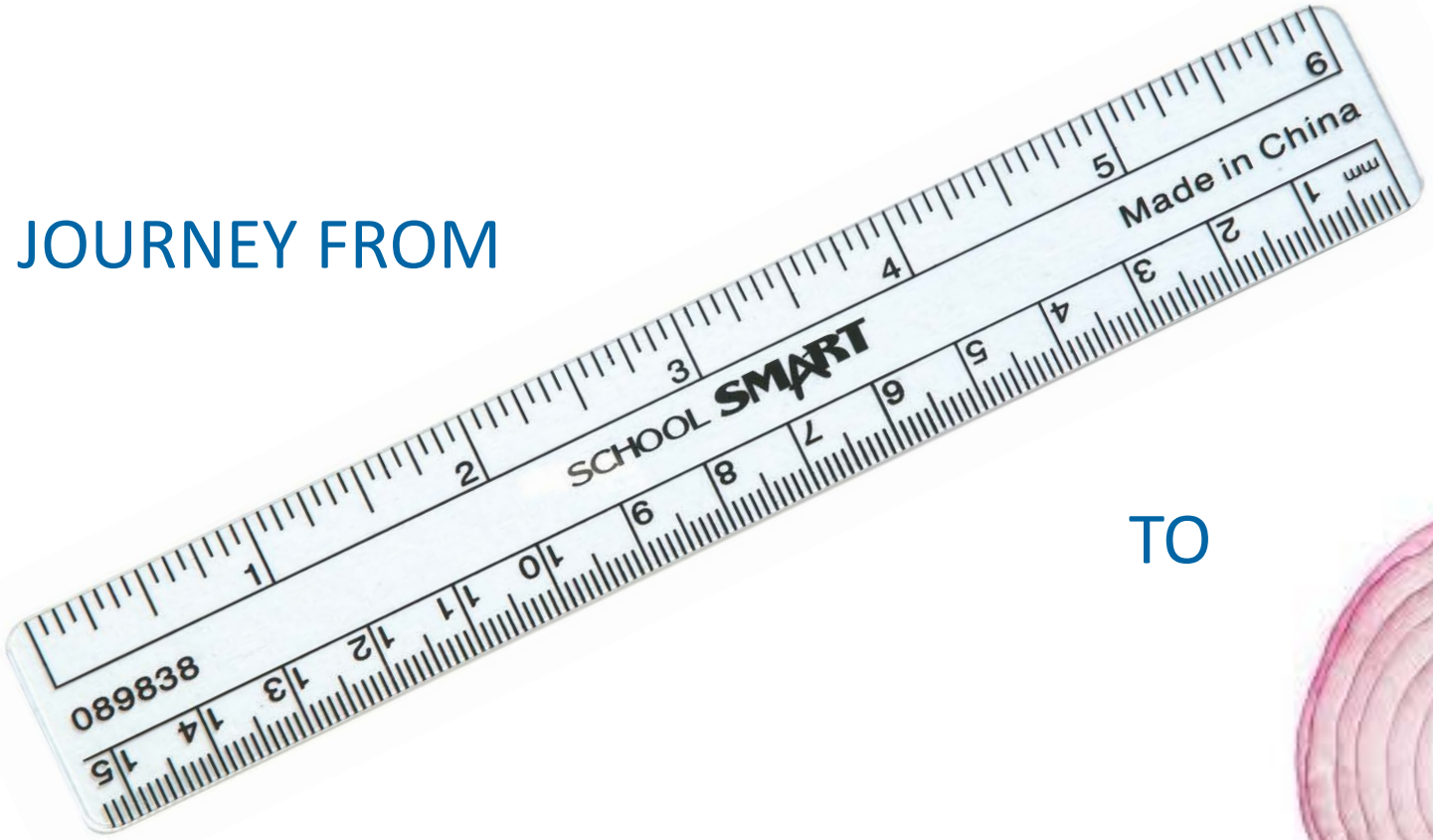
ONCO JUPP

- 2L advanced melanoma
- 1L advanced melanoma

~25 interactions with reimbursement agencies per Nordic country

Managed introductions

THE JOURNEY FROM



TO

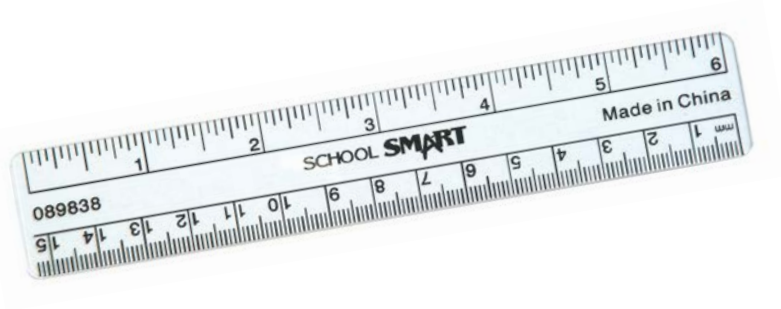
Managed introductions – ”the ruler” – clear steps leading to access

Before there was nothing – but let’s start with something

The ruler processes were introduced around 2005-2007

Step 1 – 2 – 3 etc.

- Keeping track of where resources are spent
- Lack of resources
- **Totally different systems for hospital and open care medicines**
  - Harsh control of open care medicines
  - In some systems no control at all of hospital medicines
- Rapidly growing number of novel hospital medicines – e.g. oncology



Managed introductions – ”the onion” – continuous access processes

The onion processes were introduced around 2011 and onwards

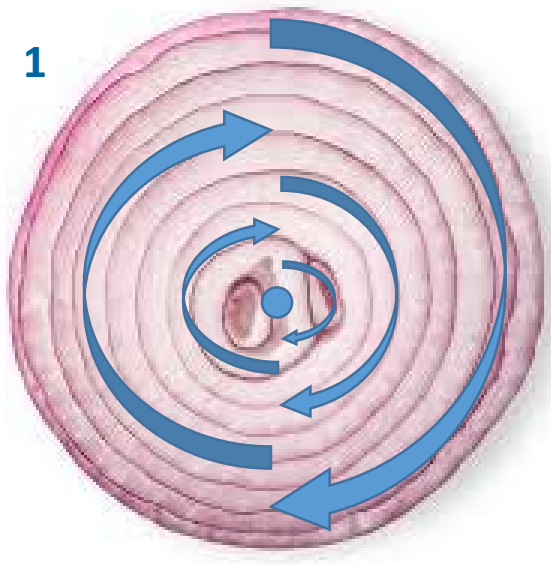
- Lack of flexibility in ruler processes
- Increased pressure on affordability
- Exponential increase in number of hospital medicines launched
- Payers successful in reaching favourable agreements with companies
- Very often connected to tenders/contracts

Work your way into the core

- Steps not clear
- Process evolving while ongoing
- Multiple/unclear stakeholders
- Several processes per product – at the same time

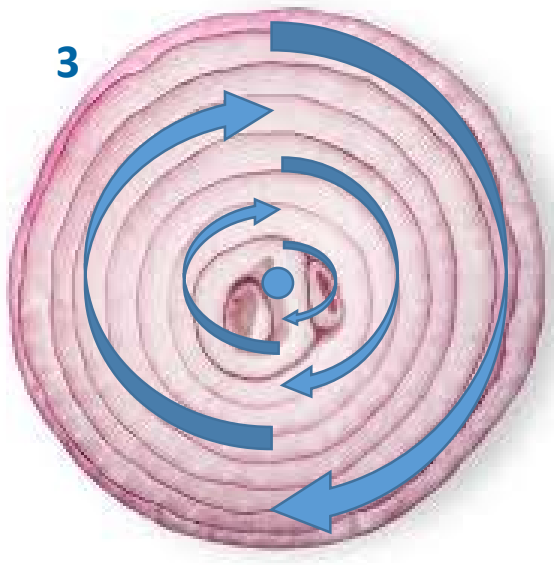
Managed introductions – ”the onion” – continuous access processes

The biggest difference compared to the old ruler process is the continuity of the onion process – it never stops



moves towards the core

new competitor, indication, new tender, other change etc.



new process starting

Real life case

Case: Oncology

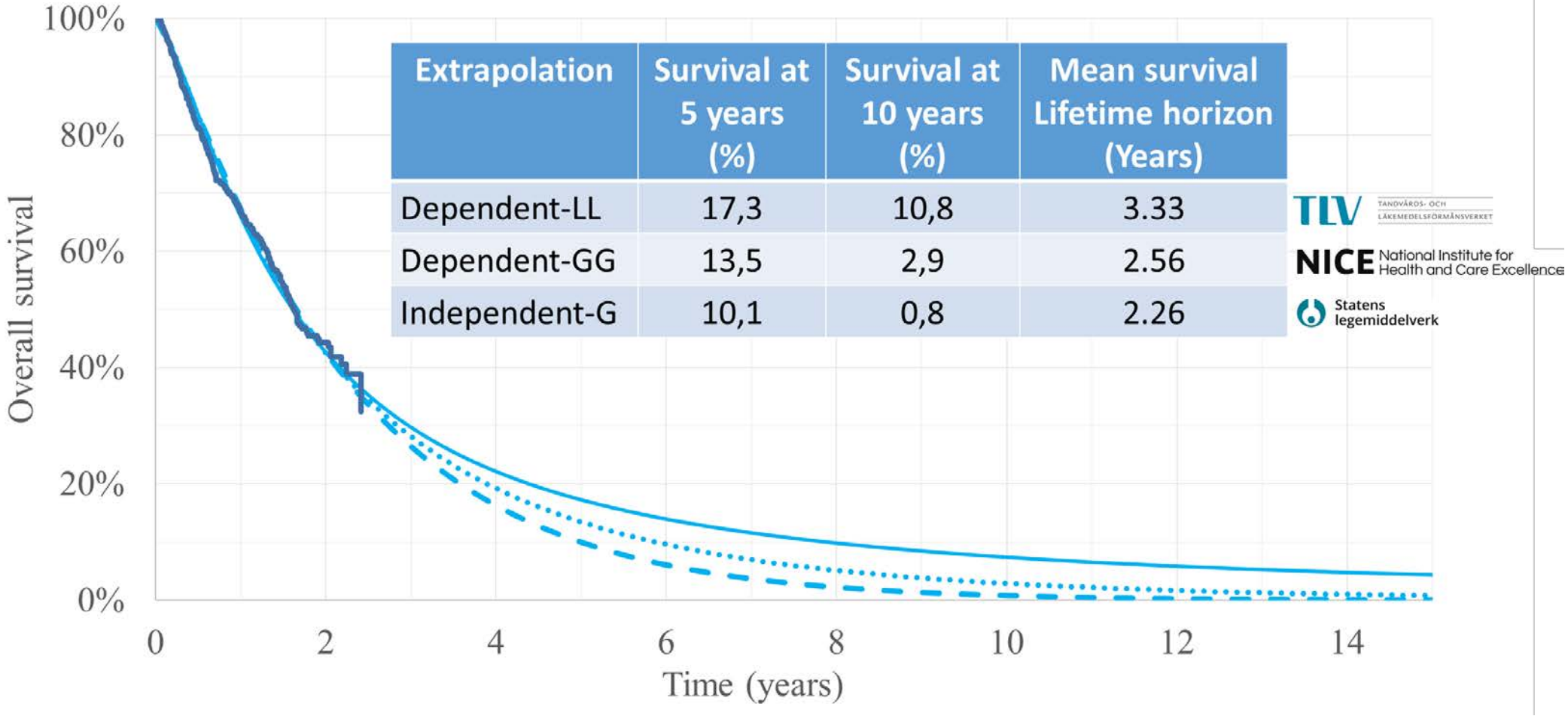
Recommendations

- Important to collect and use external data - RWE
- Later data-cuts and other studies with longer follow-up are important
- Find evidence against poorly fitting extrapolation models
- Leverage inter- and intra-country experience

Case: Oncology

ONCO COMP

Extrapolation	Survival at 5 years (%)	Survival at 10 years (%)	Mean survival Lifetime horizon (Years)
Dependent-LL	17,3	10,8	3.33
Dependent-GG	13,5	2,9	2.56
Independent-G	10,1	0,8	2.26



TLV Tandvårds- och läkemedelsförmånsverket

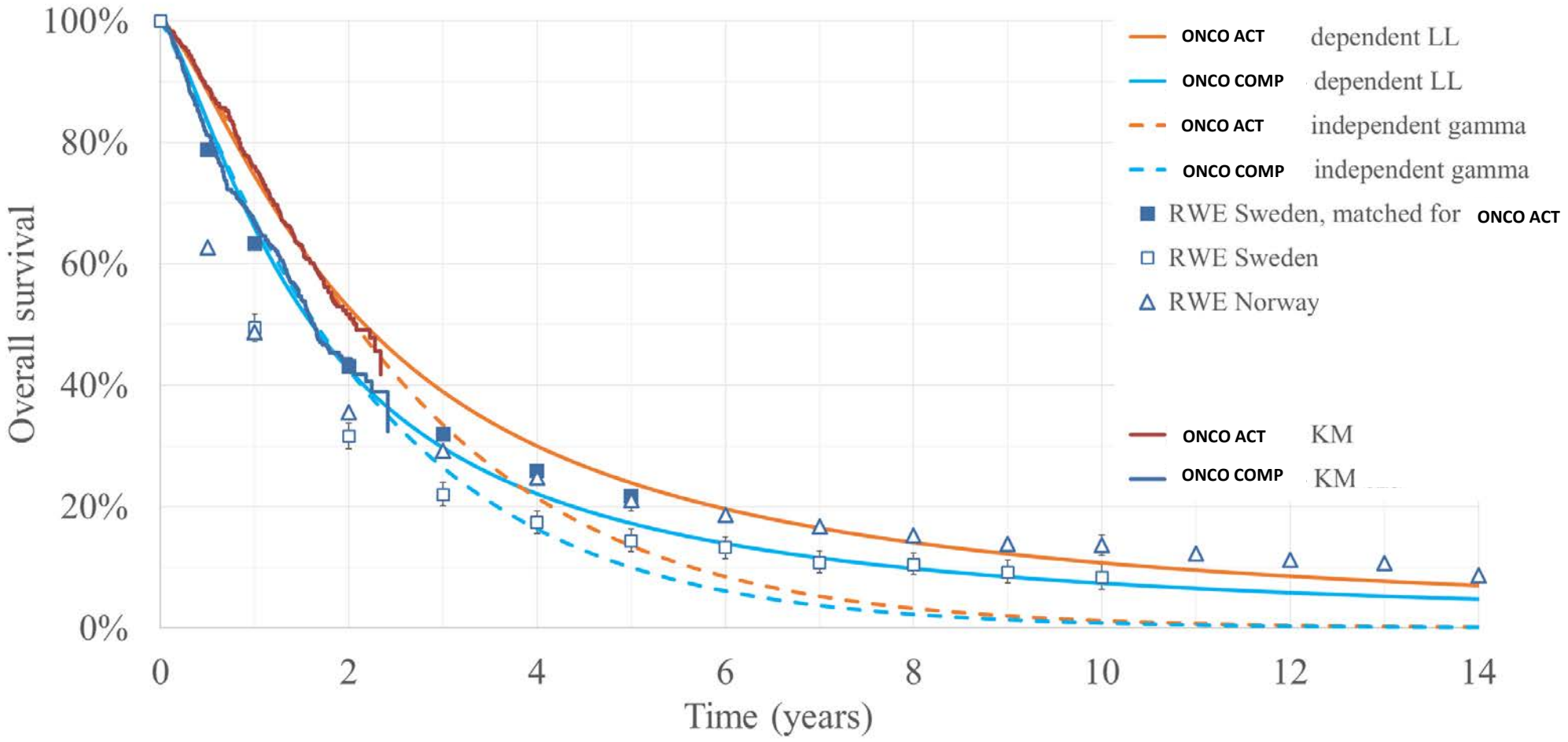
NICE National Institute for Health and Care Excellence

Statens legemiddelverk

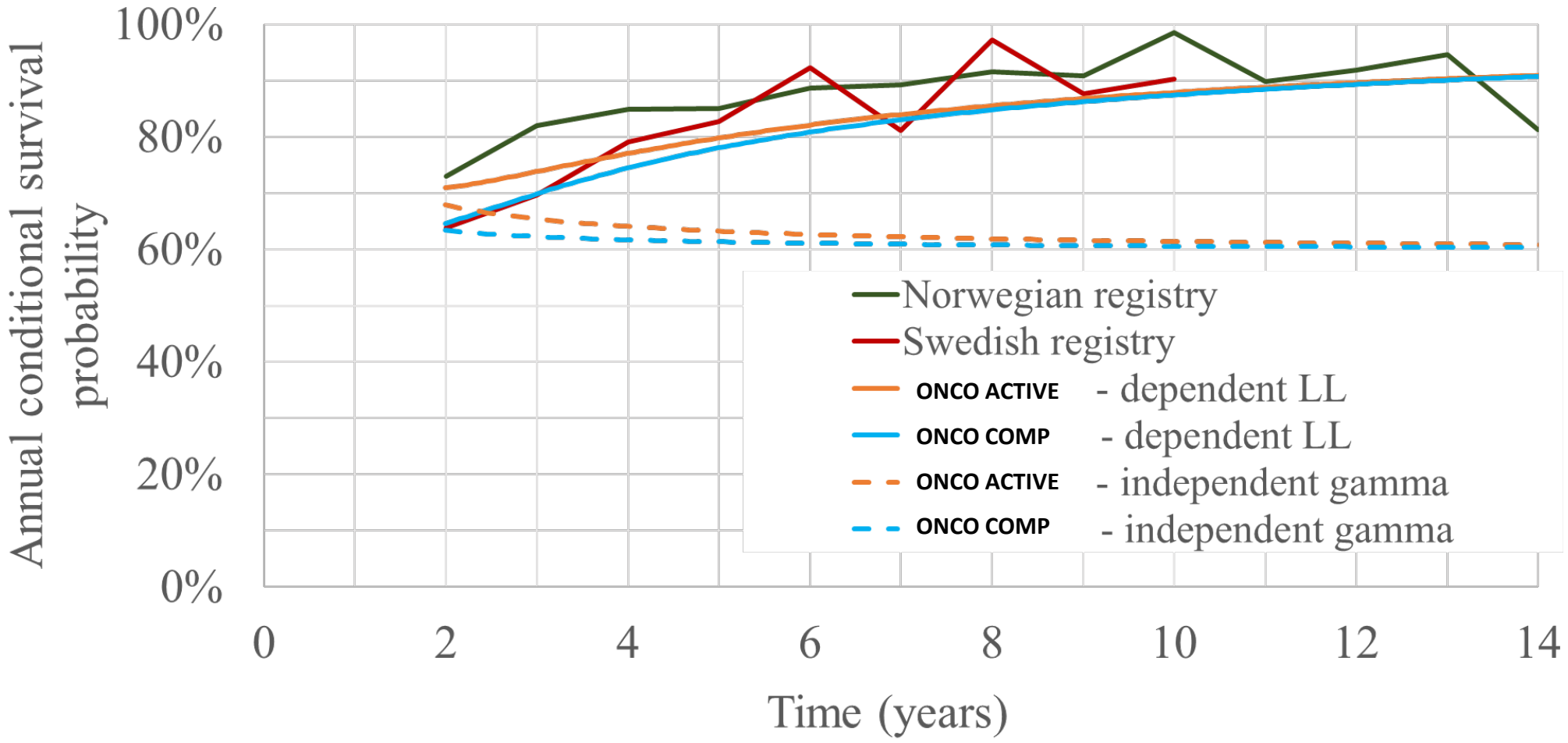
Case: Oncology

Distribution	Mean lifetime survival (14-months dataset)	Mean lifetime survival (26-months dataset)	Delta (26 vs 14 months)
Mean estimated survival gain of ONCO ACTICVE **versus** ONCO COMP			
Single-LL	11.0 months	11.3 months	+0.3 months (+3.2%)
Single-GG	9.9 months	10.5 months	+0.5 months (+5.4%)
Indep-G	4.9 months	6.5 months	+1.6 months (+32.5%)

Case: Oncology



Case: Oncology Survival



Case: Oncology – final remarks slide 6/6

A few personal thoughts on Immuno-Therapies and how they affect health economics compared to yesterday's cancer care

- ✓ Different effect on end-points (e.g. affects OS but not PFS or vice versa)
- ✓ Different effect on outcome parameters (e.g. improved HRQL)
- ✓ Different AE profiles (important in HE-models?)
- ✓ Will be combined with both old and "new" treatments
- ✓ Often very different mode-of-action
- ✓ No classical dose-response curve
- ✓ Role of bio-markers (disease & effect modifiers)

- Triggers new type of modelling? – response based survival, cure fraction modelling
- Raises the question of classical Markov models vs. Partitioned Survival models
- Triggers research into relationship of PFS and OS in different indications

- Important to collect and use external data - RWE
- Later data-cuts and other studies with longer follow-up are important

Changed and increased formal competency required in both companies but also HTAs

We are only in the very beginning – The journey will continue for a long time…

A few final thoughts

Final thoughts

- Once a therapeutic areas gets crowded with several therapies working across treatment lines of treatment OS gets more and more difficult to measure. How to deal with trials or treatments where OS is not feasible?

- Sometimes a trial allows for several statistical distributions to be fitted quite nicely to the trial data. Could depend on curve shape, rather short follow-up within the trial etc. How do we handle this?

- Uncertainty is perhaps the most fashionable word used today in health economics. Is uncertainty referred to too much?

    - ✓ in results from health economic model
    - ✓ in (clinical) data informing the health economic model
    - ✓ in decision making

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