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DUTCH MEDICINES DAYS

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The impact and use of quality registries

Can real-world data complement post-approval clinical trials?

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Today's Topics

I. What is the DMTR?
II. How can real-world data improve healthcare?
III. Can quality registries complement post-approval trials?

I. What is the DMTR?

- 14 hospitals in NL are *melanoma centers*
- All patients are registered in the Dutch Melanoma Treatment Registry (DMTR)
- Inclusion in the DMTR:

  Unresectable stage IIIC and stage IV melanoma (since 2012)

  Adjuvant treated stage III and IV melanoma (since dec 2018)
- Data are registered by trained data-managers
- Medical-oncologists supervise and approve data
- Data are used for quality assurance, benchmarking and scientific research

II. How can real-world data improve healthcare?

1) Monitoring real-world clinical practice
   - Guideline adherence
   - Quality standards
   - Learning from heterogeneity
   - Impact of COVID-19

2) Benchmarking results
   - Quality indicators
   - Dynamic dashboards
   - Scientific committee discussions

3) Scientific research
   - Subgroup analysis
   - Health outcomes in real-world
   - Economic research
   - Miscellaneous

MDPI

Article

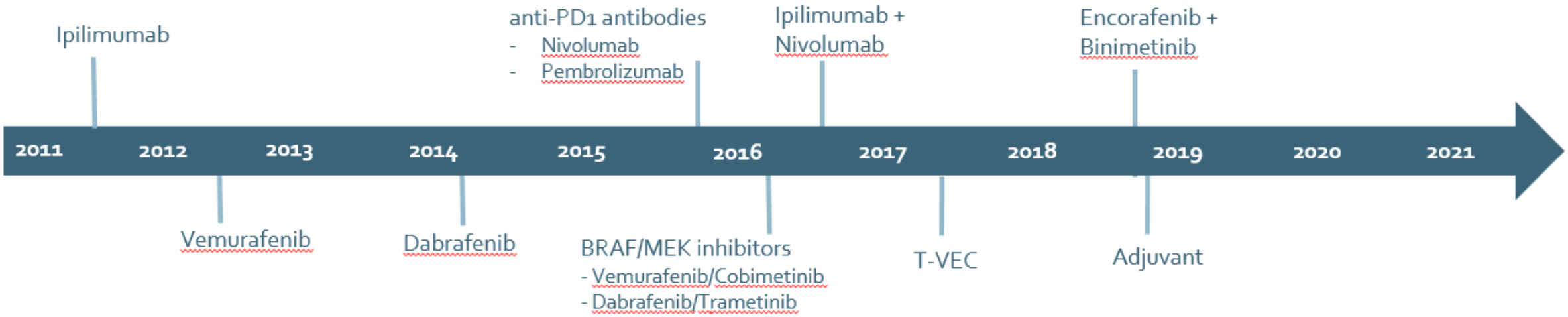
Healthcare Costs of Metastatic Cutaneous Melanoma in the Era of Immunotherapeutic and Targeted Drugs

Brenda Leeneman [1,*], Carin A. Uyl-de Groot [1,2], Maureen J. B. Aarts [3], Alexander C. J. van Akkooi [4], Franchette W. P. J. van den Berkmortel [5], Alfons J. M. van den Eertwegh [6], Jan Willem B. de Groot [7], Karin H. Herbschleb [8], Jacobus J. M. van der Hoeven [8], Geke A. P. Hospers [9], Ellen Kapiteijn [10], Djura Piersma [11], Rozemarijn S. van Rijn [12], Karijn P. M. Suijkerbuijk [13], Albert J. ten Tije [14], Astrid A. M. van der Veldt [15], Gerard Vreugdenhil [16], Michel W. J. M. Wouters [4,17], John B. A. G. Haanen [18] and Margreet G. Franken [1,2]

*"....mean total / monthly costs **€ 105,078/€ 7652** for patients who received systemic therapy (n = 4022)...."*

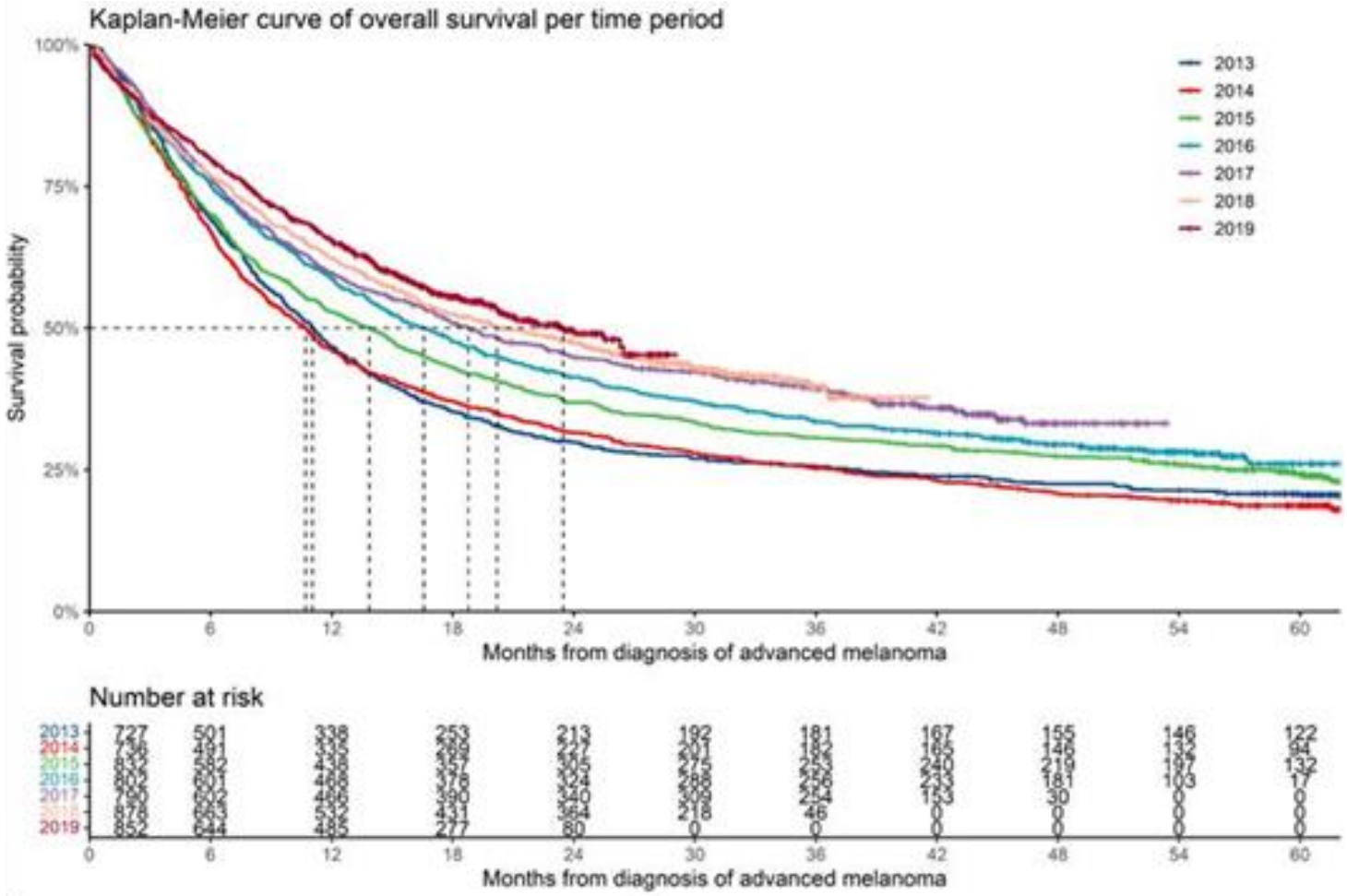
II. How can real-world data improve healthcare?

Monitoring real-world treatment



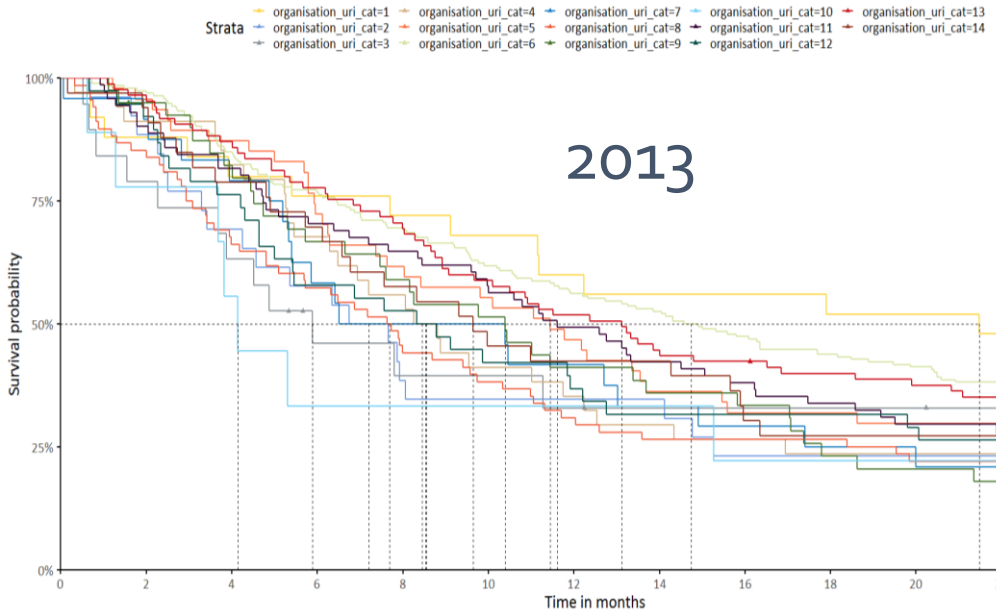
II. How can real-world data improve healthcare?

Monitoring real-world treatment

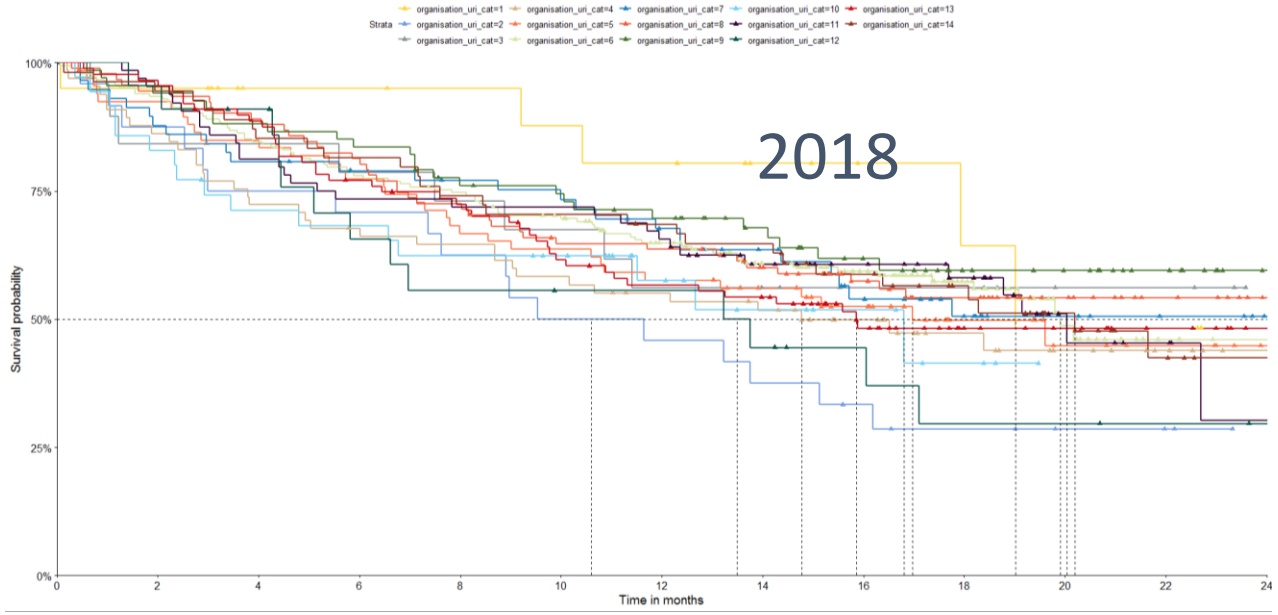


II. How can real-world data improve healthcare?

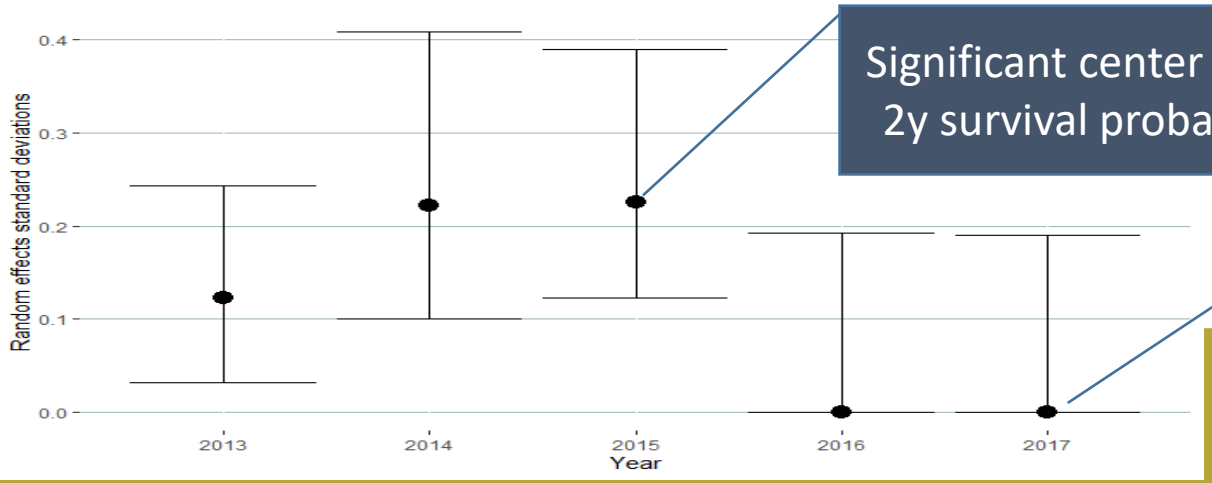
Benchmarking results



2013



2018



Significant center effect
2y survival probability

No center effect

Van Breeschoten et al, Submitted

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II. How can real-world data improve healthcare?
Scientific research

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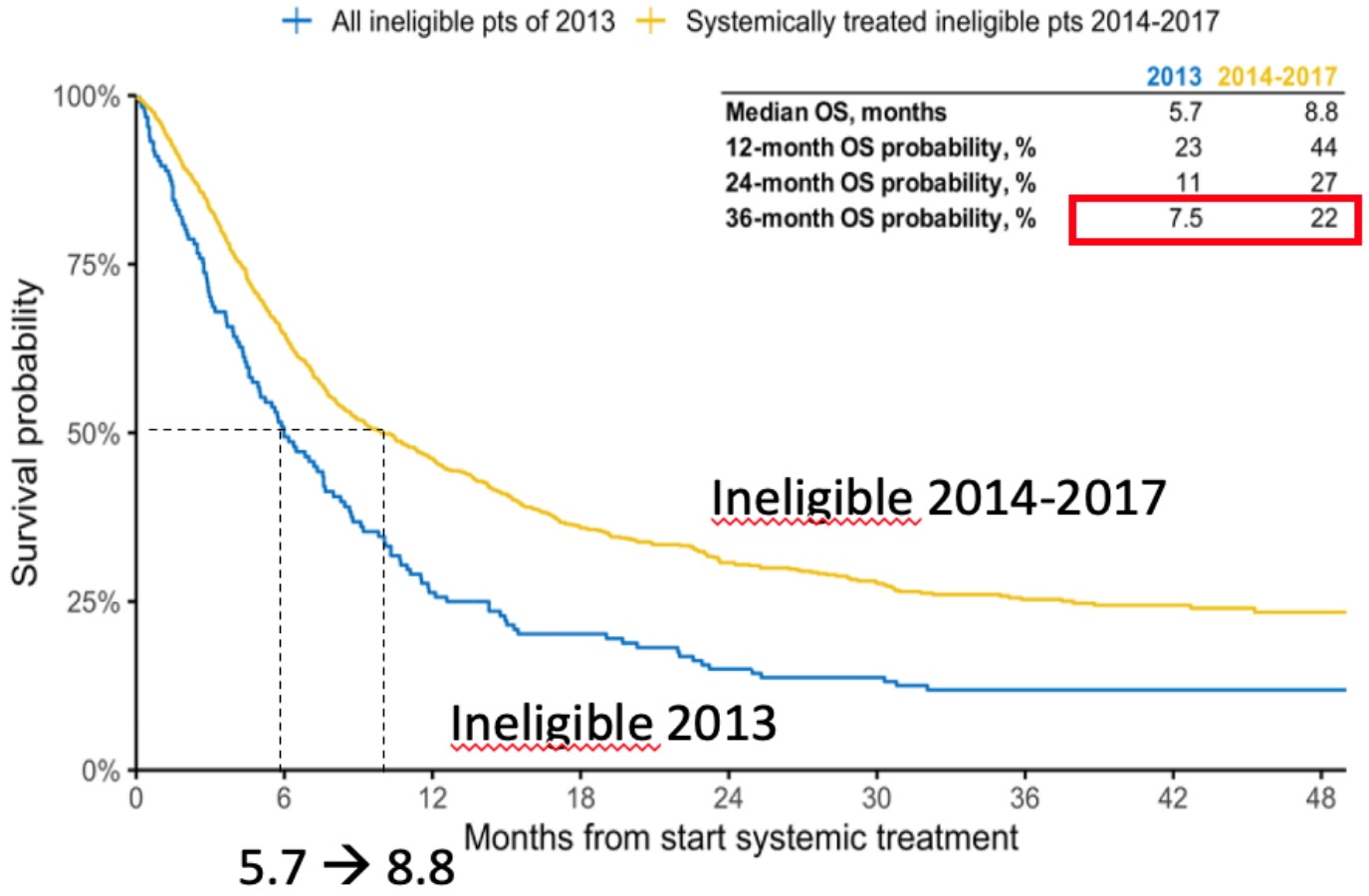
CANCER THERAPY AND PREVENTION

IJC

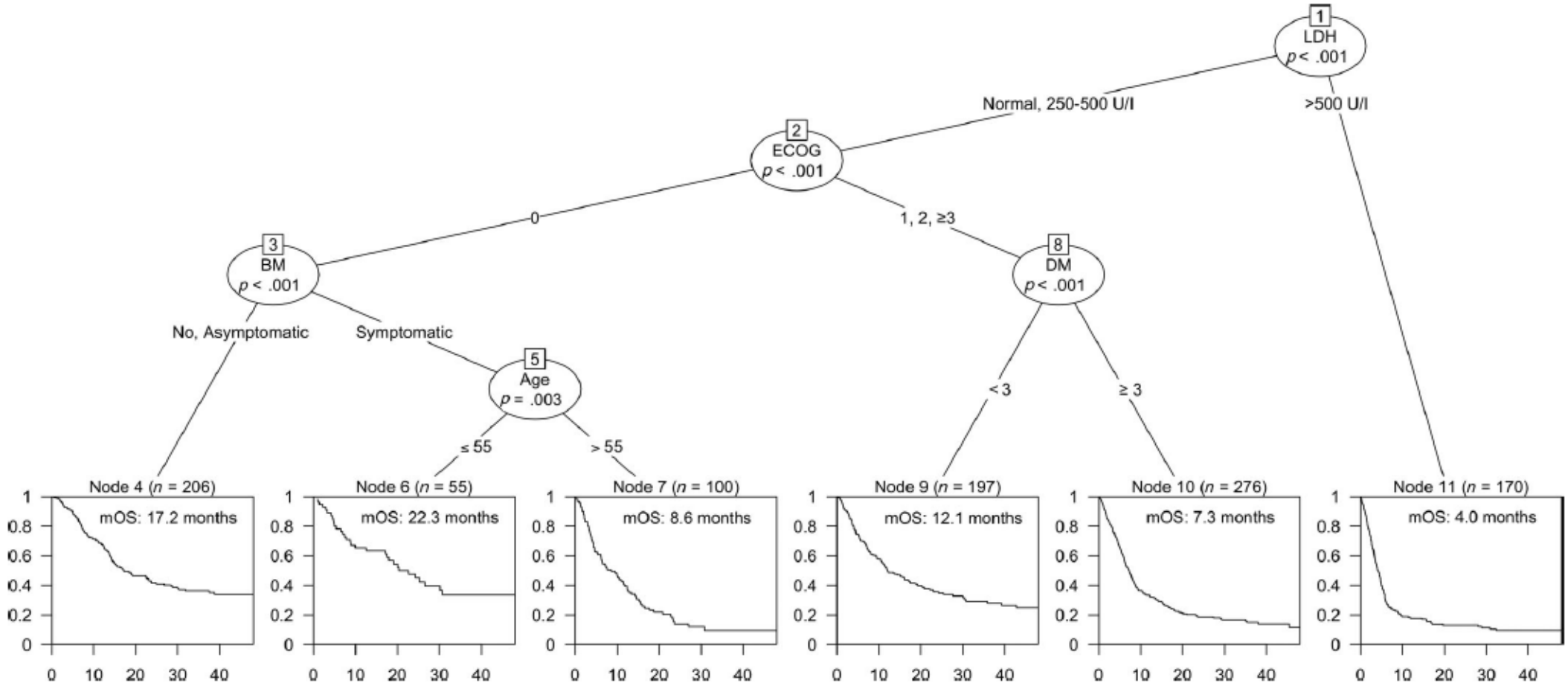
Real-world outcomes of advanced melanoma patients not represented in phase III trials

Michiel C. T. van Zeijl[1,2] | Rawa K. Ismail[1,3,4] | Liesbeth C. de Wreede[5] | Alfonsus J. M. van den Eertwegh[6] | Anthonius de Boer[3,4] | Maaike van Dartel[4] | Doranne L. Hilarius[7] | Maureen J. B. Aarts[8] | Franchette W. P. J. van den Berkmortel[9] | Marye J. Boers-Sonderen[10] | Jan-Willem B. de Groot[11] | Geke A. P. Hospers[12] | Ellen Kapiteijn[2] | Djura Piersma[13] | Rozemarijn S. van Rijn[14] | Karijn P. M. Suijkerbuijk[15] | Albert J. ten Tije[16] | Astrid A. M. van der Veldt[17] | Gerard Vreugdenhil[18] | John B. A. G. Haanen[19] | Michel W. J. M Wouters[1,20]

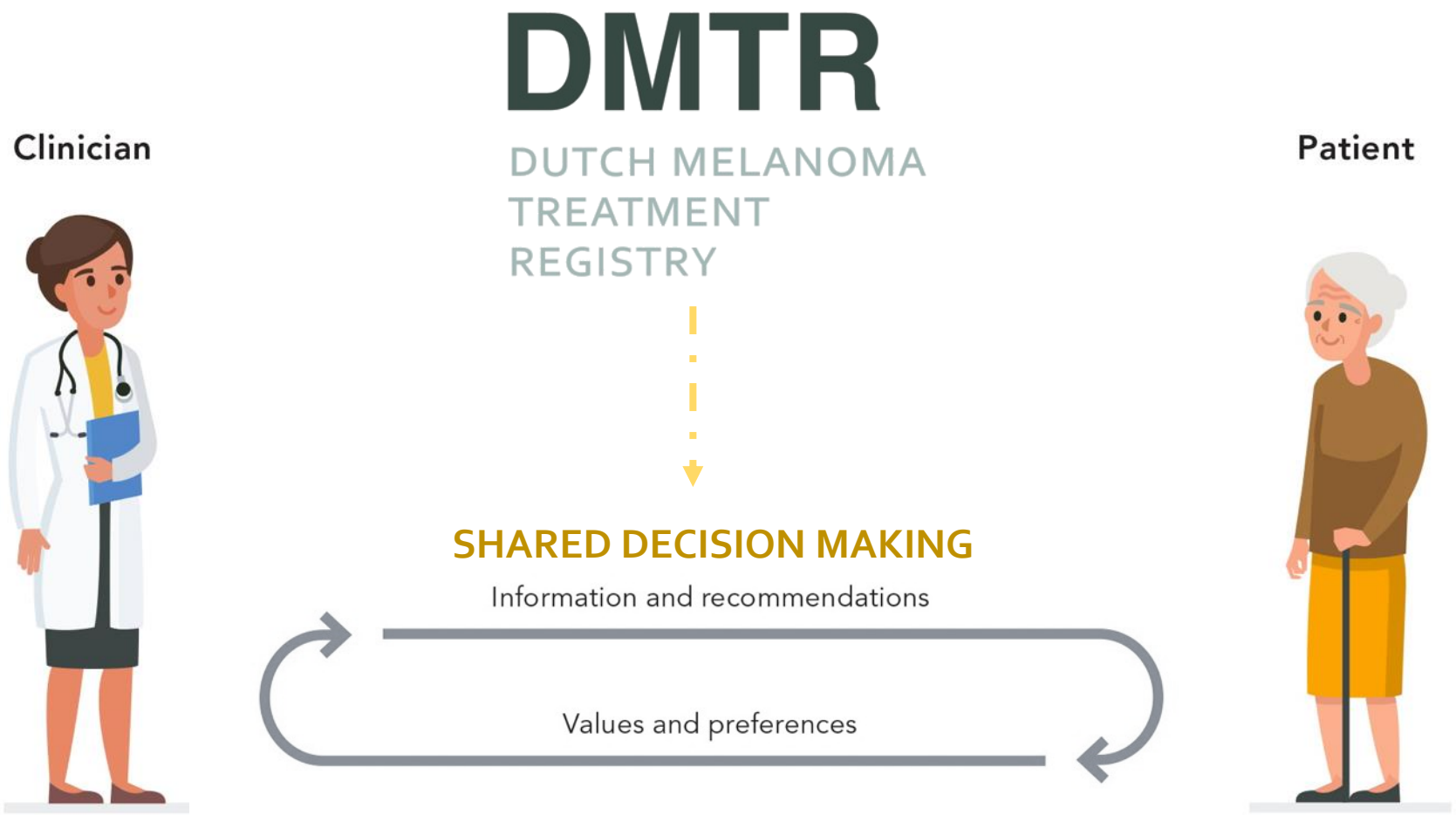


	2013	2014-2017
Median OS, months	5.7	8.8
12-month OS probability, %	23	44
24-month OS probability, %	11	27
36-month OS probability, %	7.5	22

II. How can real-world data improve healthcare?
Scientific research (2)

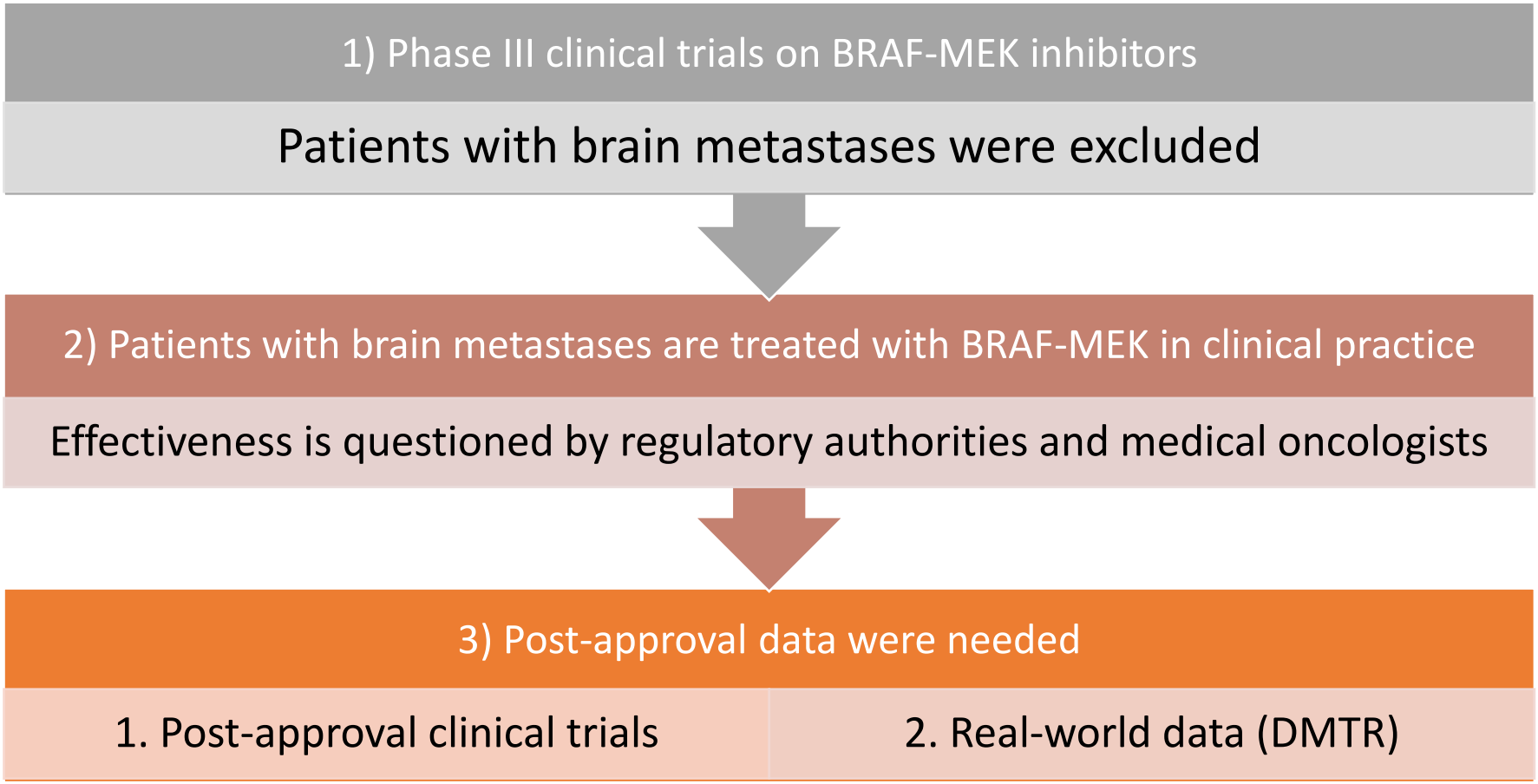


II. How can real-world data improve healthcare?

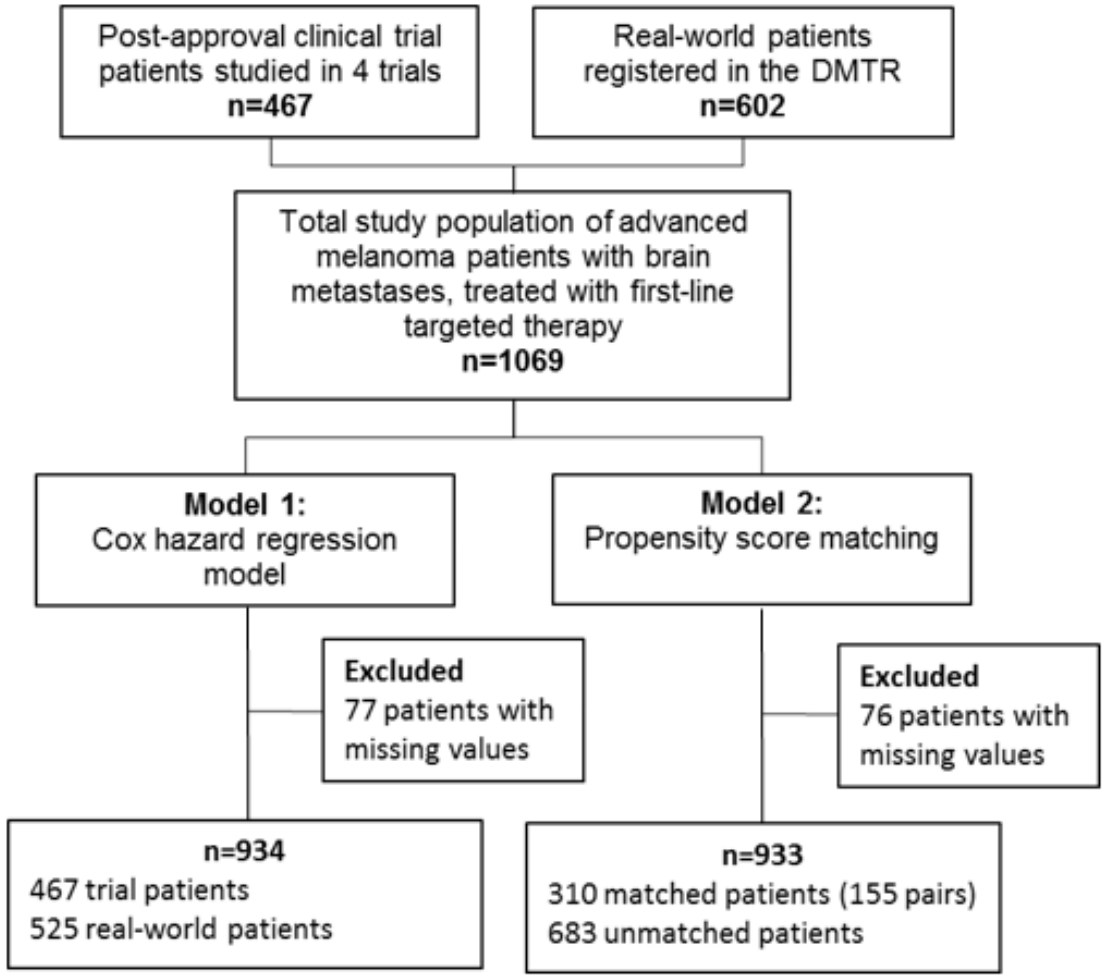


Schrager S et al. Fam Pract Manag. 2017

III. Can quality registries replace the need for post-approval trials? Comparison of trial and real-world data

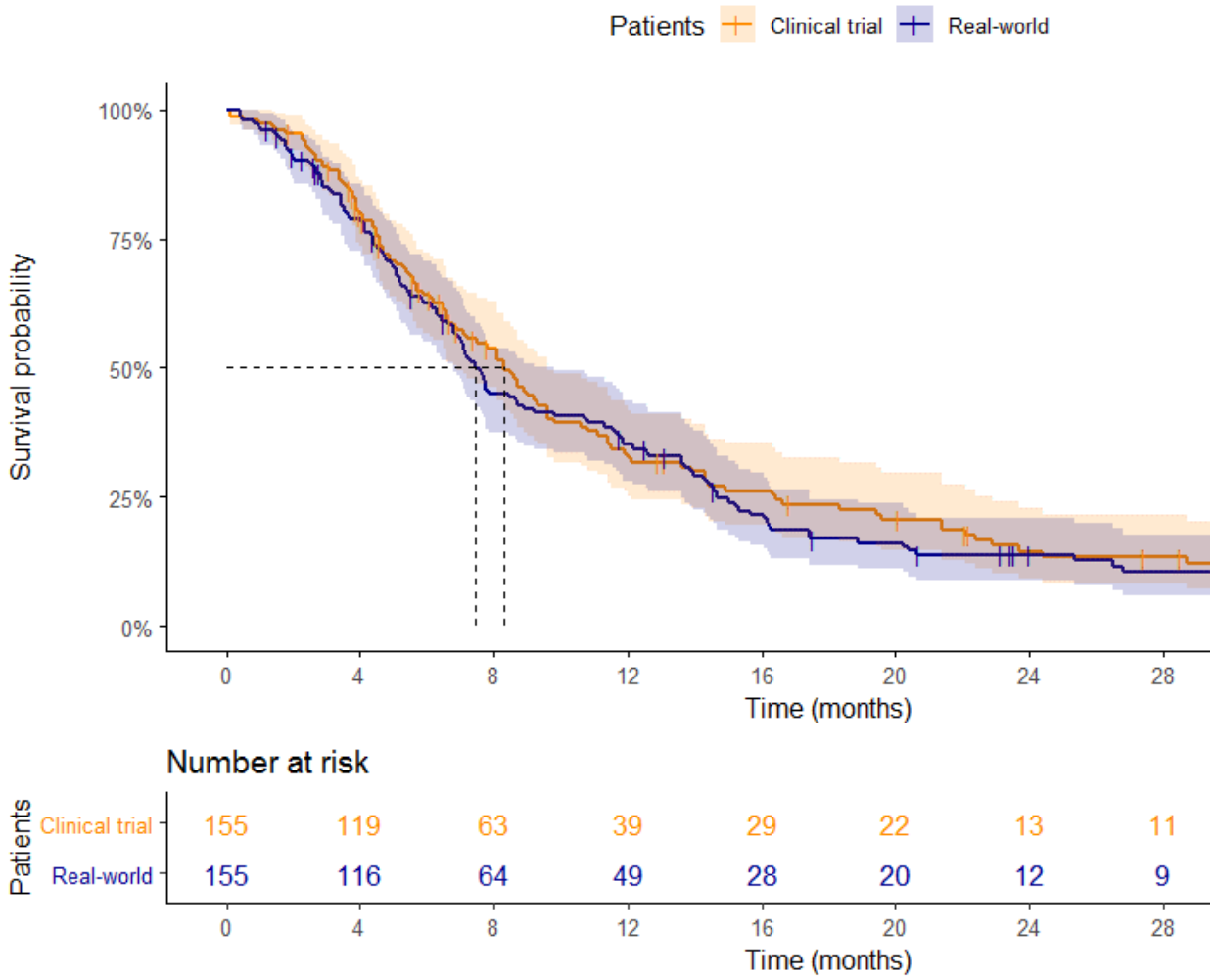


Comparison of trial and real-world data



- Real-world data from the DMTR
- Post-approval clinical trial data from the MEB

Comparison of trial and real-world data



Variable		N	Events	Hazard Ratio (HR)	HR (CI)	P-value
Database						
	Clinical trial	467	305		Reference	
	Real-world	525	421		1.19 (0.93, 1.51)	0.165
Age						
	<50 years	321	230		Reference	
	50-59 years	263	186		1.11 (0.92, 1.36)	0.281
	60-69 years	232	171		1.20 (0.98, 1.47)	0.079
	>70 years	176	139		1.37 (1.10, 1.70)	0.005
Gender						
	Male	589	433		Reference	
	Female	403	293		0.94 (0.80, 1.09)	0.406
ECOG						
	0-1	856	605		Reference	
	2-4	136	121		1.45 (1.16, 1.81)	0.001
LDH						
	Normal	489	323		Reference	
	250-500 U/l	298	230		1.46 (1.22, 1.75)	<0.001
	>500 U/l	205	173		2.02 (1.64, 2.47)	<0.001
Organsites						
	<3	347	227		Reference	
	>2	645	499		1.25 (1.05, 1.48)	0.012
Brainmetastasis						
	Asymptomatic	597	408		Reference	
	Symptomatic	395	318		1.34 (1.11, 1.61)	0.002
Therapy						
	Mono	577	436		Reference	
	Combination	415	290		0.67 (0.54, 0.84)	<0.001
Surgery						
	No	855	647		Reference	
	Yes	137	79		0.68 (0.53, 0.87)	0.002
Radiotherapy						
	No	843	633		Reference	
	Yes	149	93		1.08 (0.83, 1.40)	0.578
Year						
	2010-2011	219	111		Reference	
	2012-2013-2014	356	313		0.74 (0.57, 0.97)	0.030
	2015-2016	207	172		0.61 (0.42, 0.86)	0.006
	2017-2018-2019	210	130		0.59 (0.38, 0.91)	0.018

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III. Can quality registries replace the need for post-approval trials? Comparison of trial and real-world data

	Post-approval clinical trials	Real-world data
1) Research question	Clinical benefit	Specific subpopulations
	Treatment strategies	Treatment duration
		Treatment strategies (LDH normalizing)
2) Available data/resources	Resources are limiting factor	Outcomes (intracranial response) should be integrated in the registry
	Time-consuming	High-quality data (validated, complete)
3) Patient population	Patients included in the phase III trials	Rare populations (children, elderly) not included in trials

Today's Topics

I. What is the DMTR?
   - Population-based quality registry including melanoma patients

II. How can real-world data improve healthcare?
   - Through benchmarking and scientific research

III. Can quality registries complement post-approval trials?
   - Yes, if requirements for the registry are met

Thank you!

For more information:
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