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Ricerca, innovazione, assistenza

Il nuovo scenario all'orizzonte in oncologia, tra cronicizzazione della malattia e sostenibilità

Alberto Bortolami

Coordinamento Scientifico Rete Oncologica del Veneto

Istituto Oncologico Veneto

SFIDA IN ONCOLOGIA

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Invecchiamento della popolazione

Aumento incidenza malattia tumorale

+ MALATI

+ 4 % annuo dal 2003 al 2017 nuove diagnosi
+ 24% dal 2010 proiezioni 2017 pazienti vivi dopo una diagnosi di tumore

Nuove opzioni terapeutiche

COSTI UNITARI ELEVATI E CRESCENTI

Cronicizzazione della malattia oncologica metastatica

PER PIU' TEMPO

Aumento dei costi per il Sistema Sanitario

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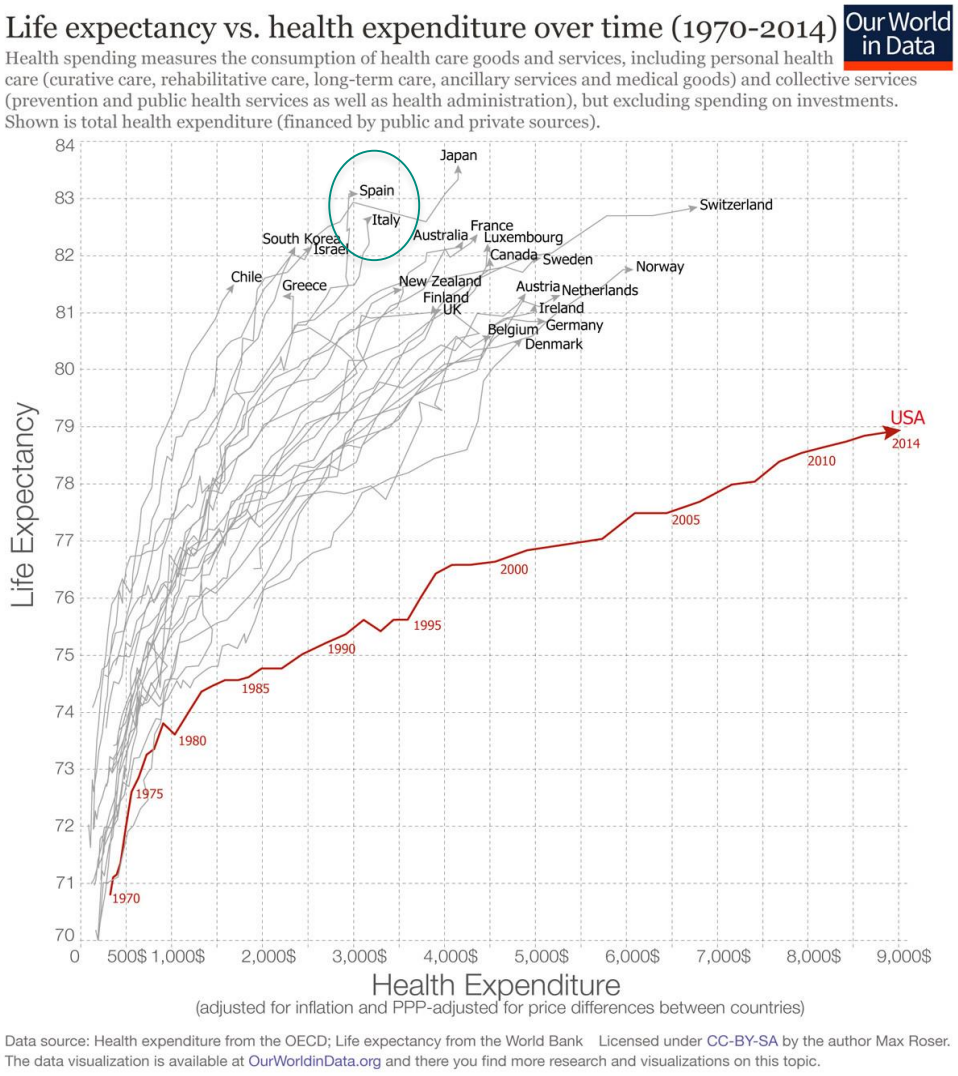
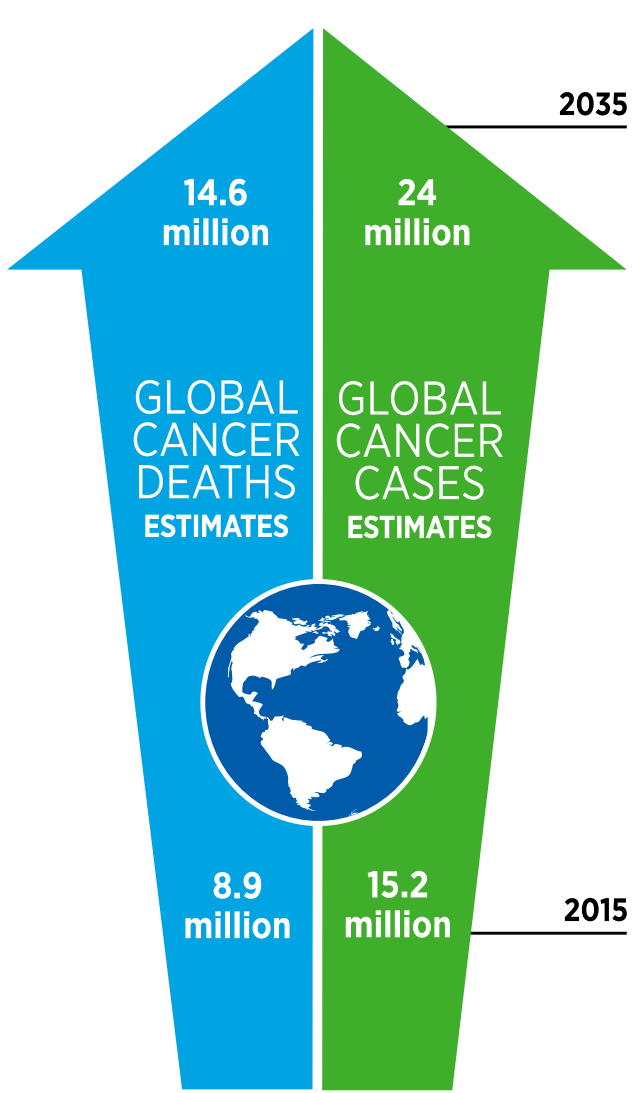
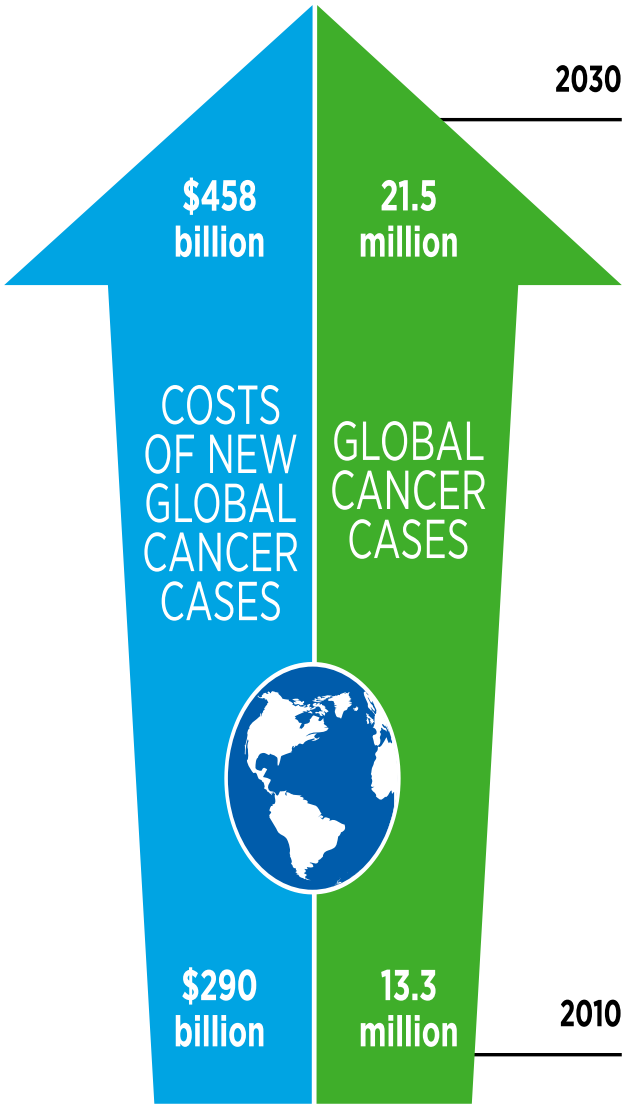
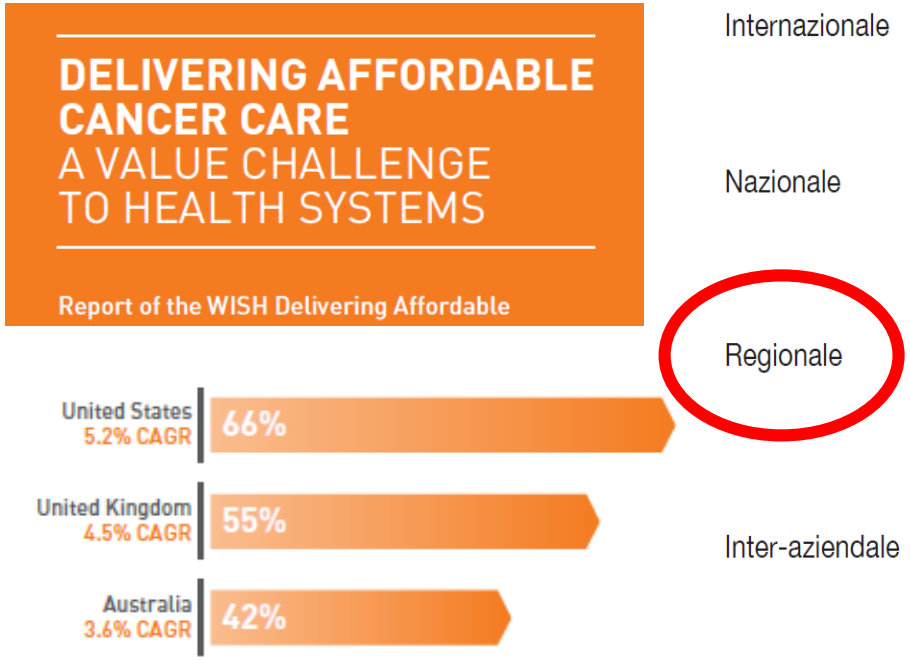






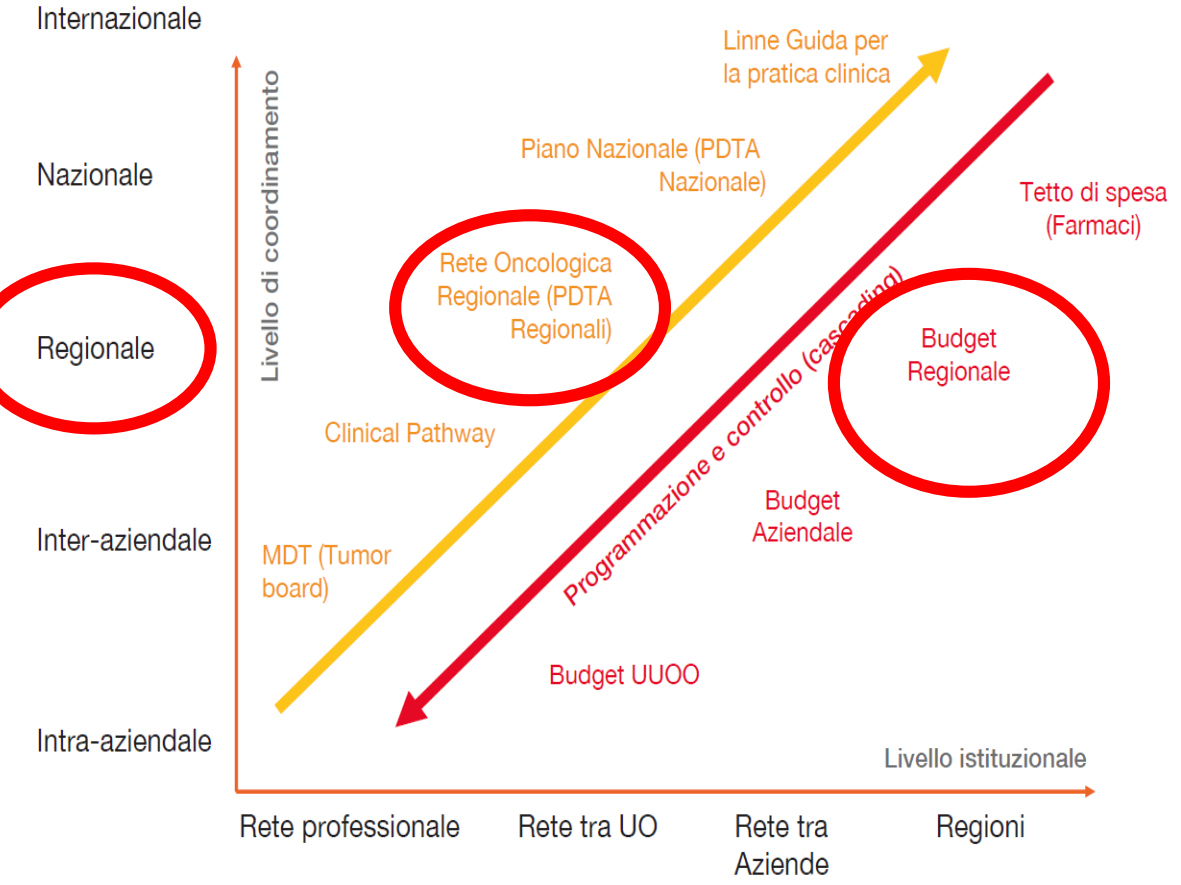
Slide courtesy of Dr Massuti * AACR report 2017 and 2018



"The expectation is that cancer care costs will rise dramatically"

FAVO 10° Rapporto sulla condizione assistenziale dei malati oncologici

FIGURA 1: LIVELLI E FORME DI COORDINAMENTO DELLE CURE ONCOLOGICHE



Fonte: Elaborazione dell'autore

Courtesy of Alessandra Buya

Le dimensioni di governo clinico della Rete

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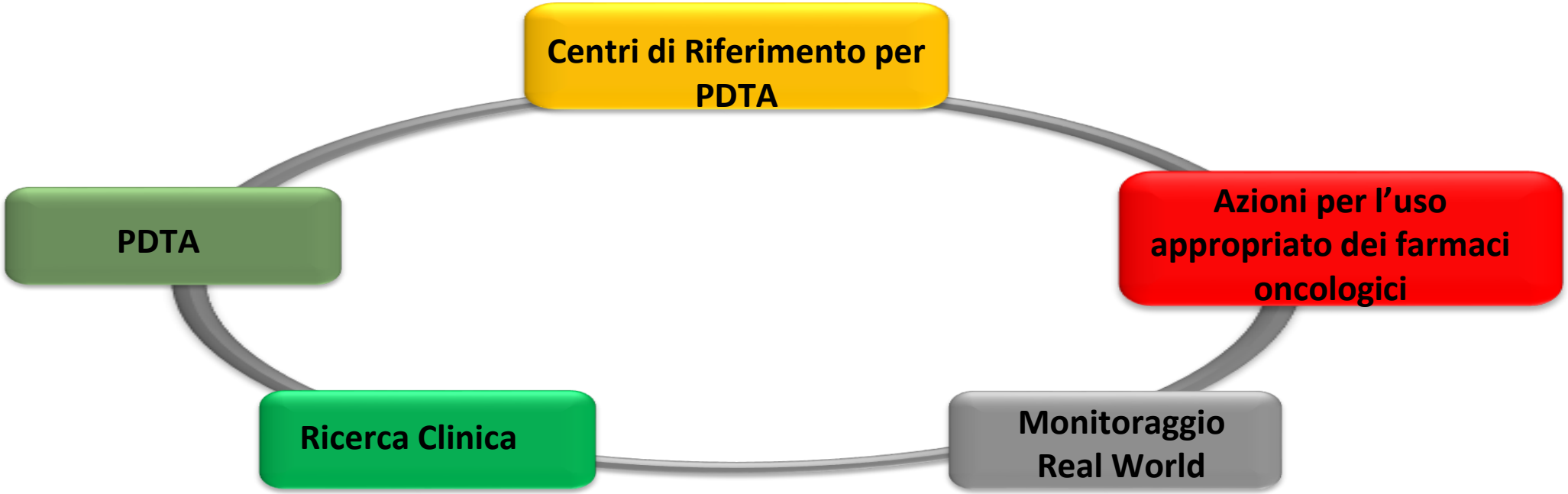
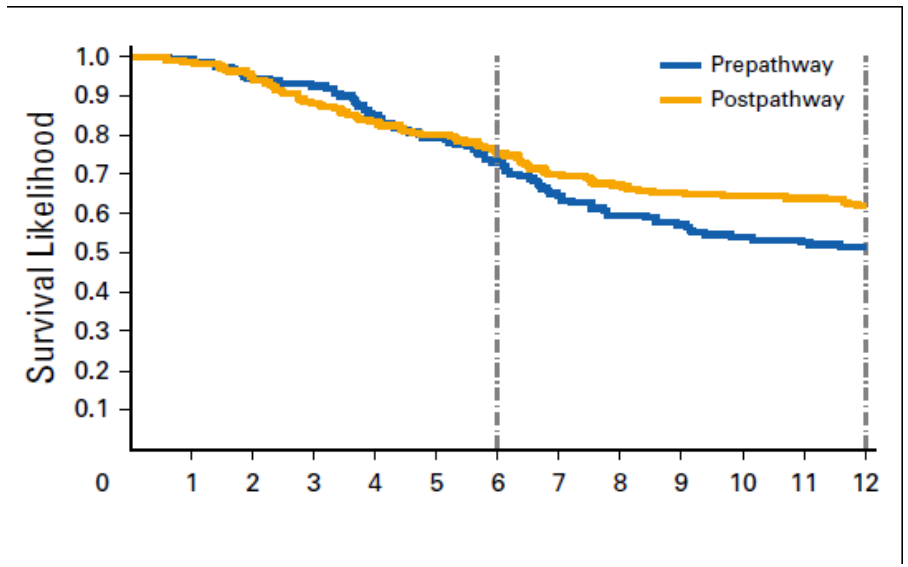


Cost and Survival Analysis Before and After Implementation of Dana-Farber Clinical Pathways for Patients With Stage IV Non–Small-Cell Lung Cancer

David M. Jackman, Yichen Zhang, Carole Dalby, Tom Nguyen, Julia Nagle, Christine A. Lydon, Michael S. Rabin, Kristen K. McNiff, Belen Fraile, and Joseph O. Jacobson

Table 2. Cost Analysis for Patients With Stage IV Non–Small-Cell Lung Cancer Before and After Pathways

Pathways Cohort	Mean Cost ($)	95% CI ($)	*P*
Unadjusted cost			.03
Prepathway	64,508	53,140 to 75,876	
Postpathway	48,515	41,421 to 55,608	
Adjusted cost			.01
Prepathway	69,122	33,242 to 105,001	
Postpathway	52,037	25,200 to 48,849	



Conclusion

After introduction of a clinical pathway in metastatic NSCLC, cost of care decreased significantly, with no compromise in survival. In an era where comparative outcomes analysis and value assessment are increasingly important, the implementation of clinical pathways may provide a means to coalesce and disseminate institutional expertise and track and learn from care decisions.

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Oncology Pathways & Outcome: MTB for Breast Cancer Patients

Country	Population & Nb	Primary Endpoint	Results
Scottish study[1]	14,000 women with breast cancer	BC-specific mortality and all-cause mortality	**18% reduction in BC mortality at 5 years** with multidisciplinary care
Belgian study[2]	25,178 women with breast cancer	Survival for BC by hospital volume	**Improved 5-year survival rates** in high-volume versus low-volume hospitals (**83.9% vs 78.8%,** respectively)

1. Kesson EM, et al. *BMJ*. 2012;26;344:e2718; 2. Vrijens F, et al. *Breast*. 2012;21(3):261-266.

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PDTA Mammella
(Decreto Regionale: n. 114 del 24/10/2016)

Coordinatori Scientifici

NICOLA BALESTRIERI, PIERFRANCO CONTE, ANNAMARIA MOLINO

Componenti Gruppo di lavoro PDTA DELLA RETE ONCOLOGICA VENETA PER I PAZIENTI AFFETTI DA TUMORE DELLA MAMMELLA

ALBERTO AMADORI, GIORGIO BERNA, NICOLA BALESTRIERI, FERNANDO BOZZA, PAOLO BURELLI, PIERFRANCO CONTE, LAURA EVANGELISTA, ALESSANDRO GAVA, MASSIMO GION, STEFANIA GORI, MAURIZIO GOVERNA, VALENTINA GUARNERI, LICIA LAURINO, MARCO LORENZINI, GRAZIANO MENEGHINI, ANNAMARIA MOLINO, ENRICO ORVIETO, GUIDO PAPACCIO, LUIGI PESCARINI, GIOVANNI PAOLO POLLINI, ANTONIO RIZZO, PAOLO SARTORI, SAMANTHA SERPENTINI, GIAMPIETRO STEFANI, ALESSANDRO TESTOLIN, LEONARDO TRENTIN, VINCENZO VINDIGNI, LIA ZANETTI, MANUEL ZORZI

Edizione 1:2016

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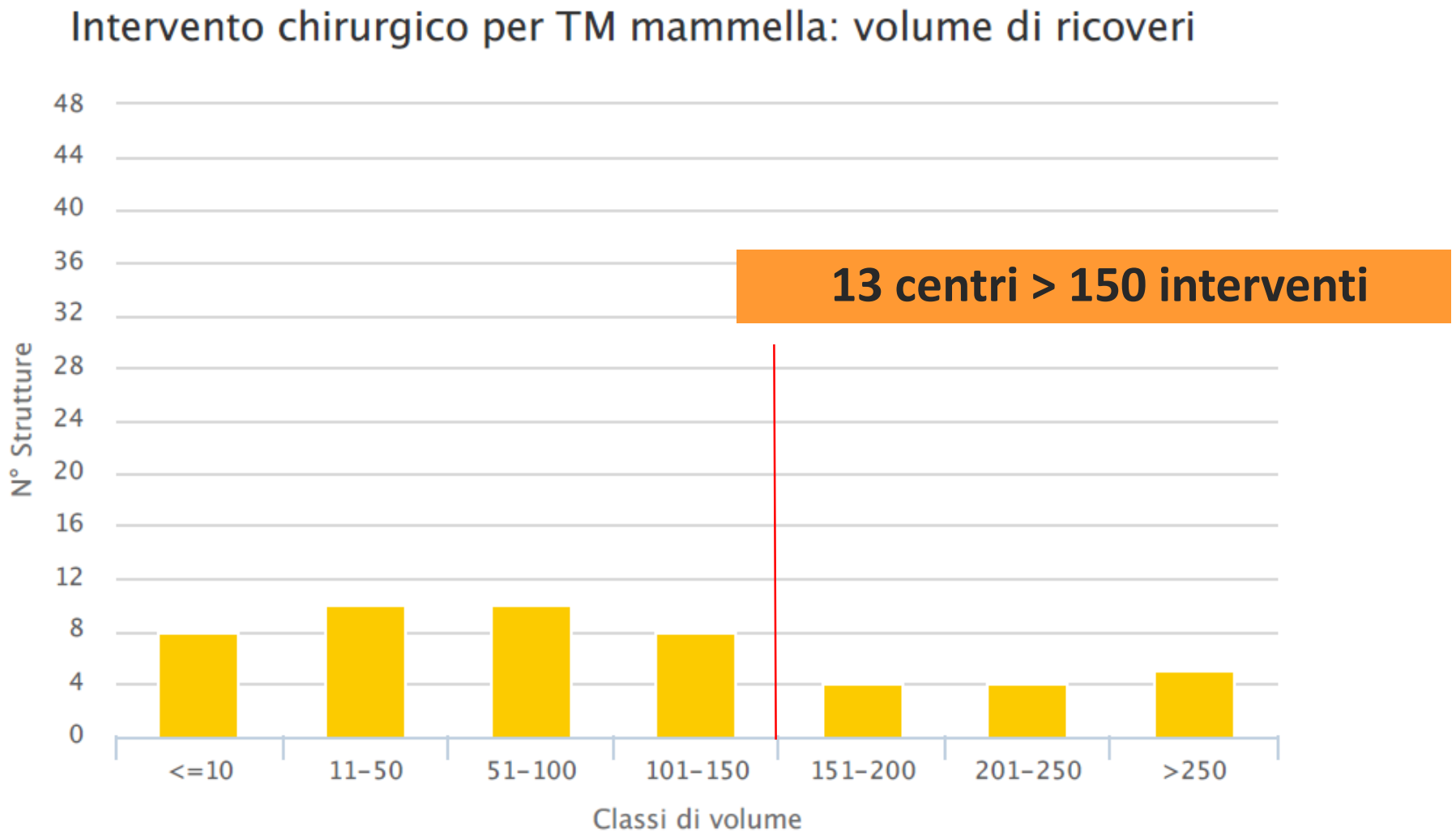
CENTRI DI RIFERIMENTO
PDTA DEL CARCINOMA MAMMARIO

IL MODELLO ORGANIZZATIVO INTEGRATO

Prevenzione-diagnosi precoce- trattamento del carcinoma della mammella

DGR n.1693/2017

Volumi di ricoveri intervento chirurgico per TM Mammella dati 2015



Volumi di ricoveri intervento chirurgico per TM Mammella Dati 2017

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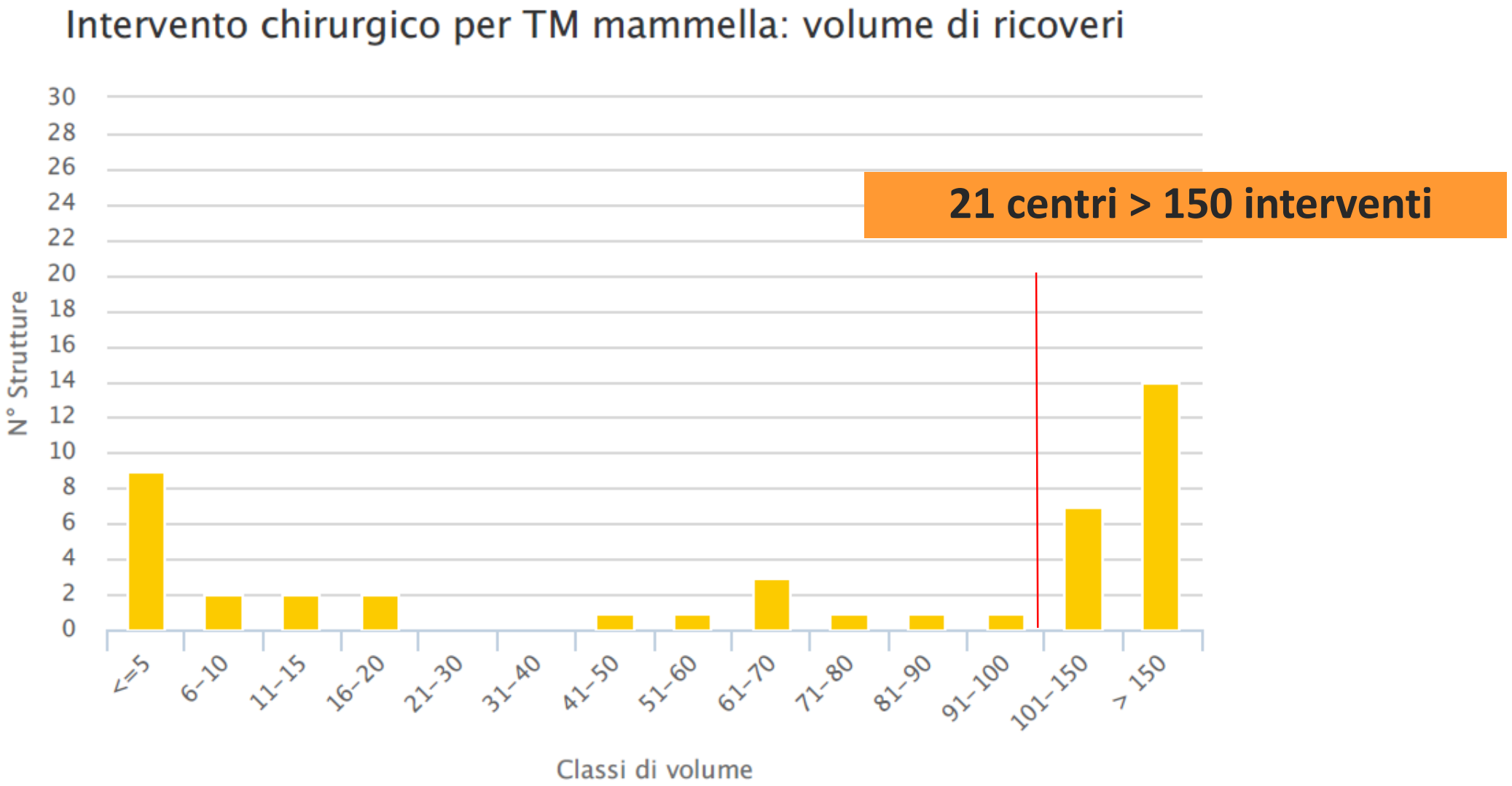

ONCOLOGY PATHWAYS & OUTCOME: TIME TO RADIOTHERAPY FOR H&N PATIENTS

Country	Population & Nb	Primary Endpoint
NCDB USA[1]	**25,216** patients with stage III/IV H&N tumors	Median OS according to time to Radiotherapy after Surgery

	Time to Radiotherapy		
	≤ 42 days	**43-49 days**	**≥ 50 days**
# of pts	9,765	4,735	10,716
Median OS yrs	**10.5**	**8.2**	**6.5**

1. Harris JP et al. JAMA Otolaryngol Head Neck Surg, 2018

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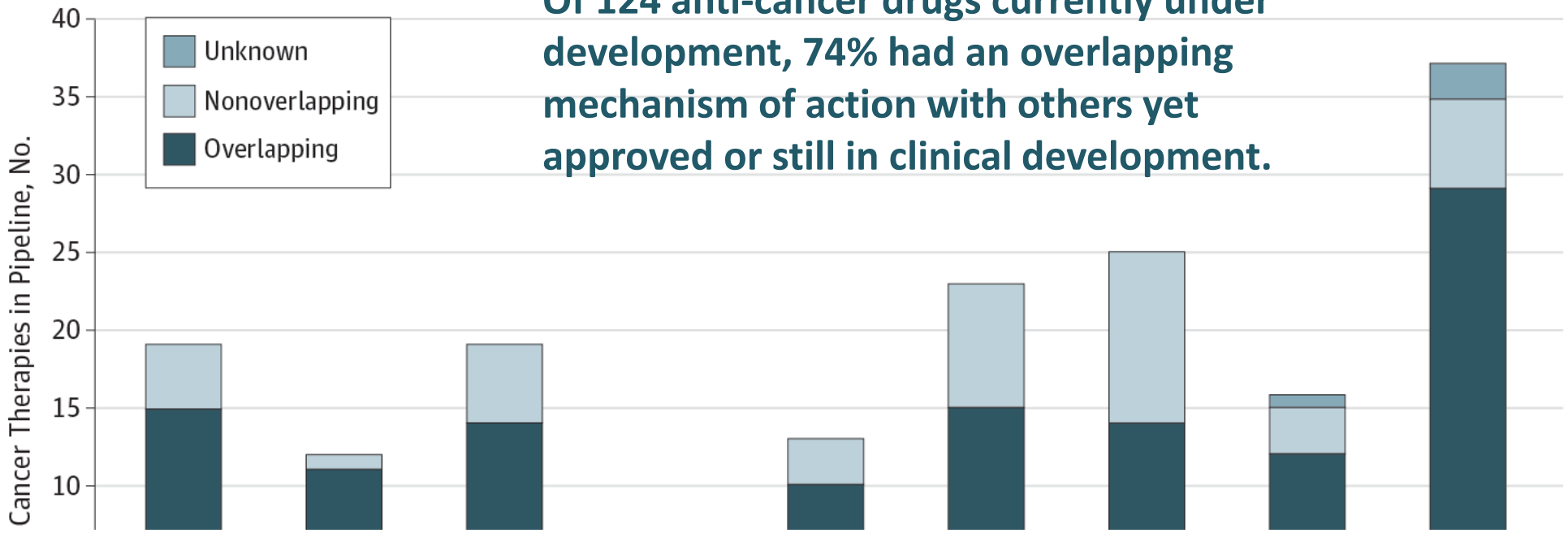
COSTO FARMACI ONCOLOGICI

- **Continue nuove indicazioni in oncologia (fase avanzata ≈20 nuovi farmaci + di 30 indicazioni 2017-2019)**
- **Nuovi farmaci a prezzi molto elevati *(terapie croniche al costo delle terapie in acuto)***
- **Durata nuovi trattamenti……lunghe durate costi elevati (costo medio mensile dai 2.000 ai 5.000 €)**
- **Terapie in combinazione ……costi aumentano**
- **Difficoltà nel fare una budget impact**

Costs of “me too” drugs



Of 124 anti-cancer drugs currently under development, 74% had an overlapping mechanism of action with others yet approved or still in clinical development.

Too many ‘me too’ drugs→ current health budget burden

- Are we pooling **too many resources**, money, and time into therapeutic indications **with relatively little gain**?
- From the **patient** perspective, are we delivering on their **expectations**?
- How can we best **avoid duplication** in drug discovery efforts?

Fojo T et al, JAMA Otolaryngol Head Neck Surg 2014
Tabernero J, Ann Oncol 2015

Stima del numero di nuovi pazienti potenzialmente eleggibili ALK+ ogni anno in Regione Veneto (N: 103)

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Categoria di pazienti	%	n	Fonte
N.casi incidenti di tumore al polmone in Veneto		3153	Registro Tumori Veneto (stima per l'anno 2018, applicando i tassi di incidenza osservati nel 2013 alla popolazione 2018
Casi caratterizzati istologicamente	76%	2396	Registro Tumori Veneto, stima per il 2016
NSCLC in Veneto	88%	2109	Rapporto AIOM AIRTUM 2018
NSCLC istologia non squamosa	70%	1476	Stima del Clinico
NSCLC ALK+	**7%**	**103**	**Linee Guida AIOM 2018 sul tumore al polmone**
NSCLC ALK+ stadio IIIb-IV	80%	83	Stima dei Clinici
NSCLC ALK+, n da trattare	90%	74	Stima dei Clinici
NSCLC ALK+, n da trattare con ECOG 0,1,2, %	90%	67	Stima dei Clinici

The importance of an alk inhibitor in ALK+ patient journey

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1L-CHEMOTHERAPY + 2L-CHEMOTHERAPY

mPFS 10 months

1L-CHEMOTHERAPY + CRIZOTINIB + 2L-CHEMOTHERAPY

mPFS 16.3 months

CRIZOTINIB + 1L-CHEMOTHERAPY+ 2L-CHEMOTHERAPY

mPFS 19.5 months

1L-CHEMOTHERAPY + CRIZOTINIB + CERITINIB+2L-CHEMOTHERAPY

mPFS 21.7 months

CRIZOTINIB + 1L-CHEMOTHERAPY+ CERITINIB+2L-CHEMOTHERAPY

mPFS 24.9 months

ALECTINIB……

mPFS 34 months

Durata della Immunoterapia nel NSCLC

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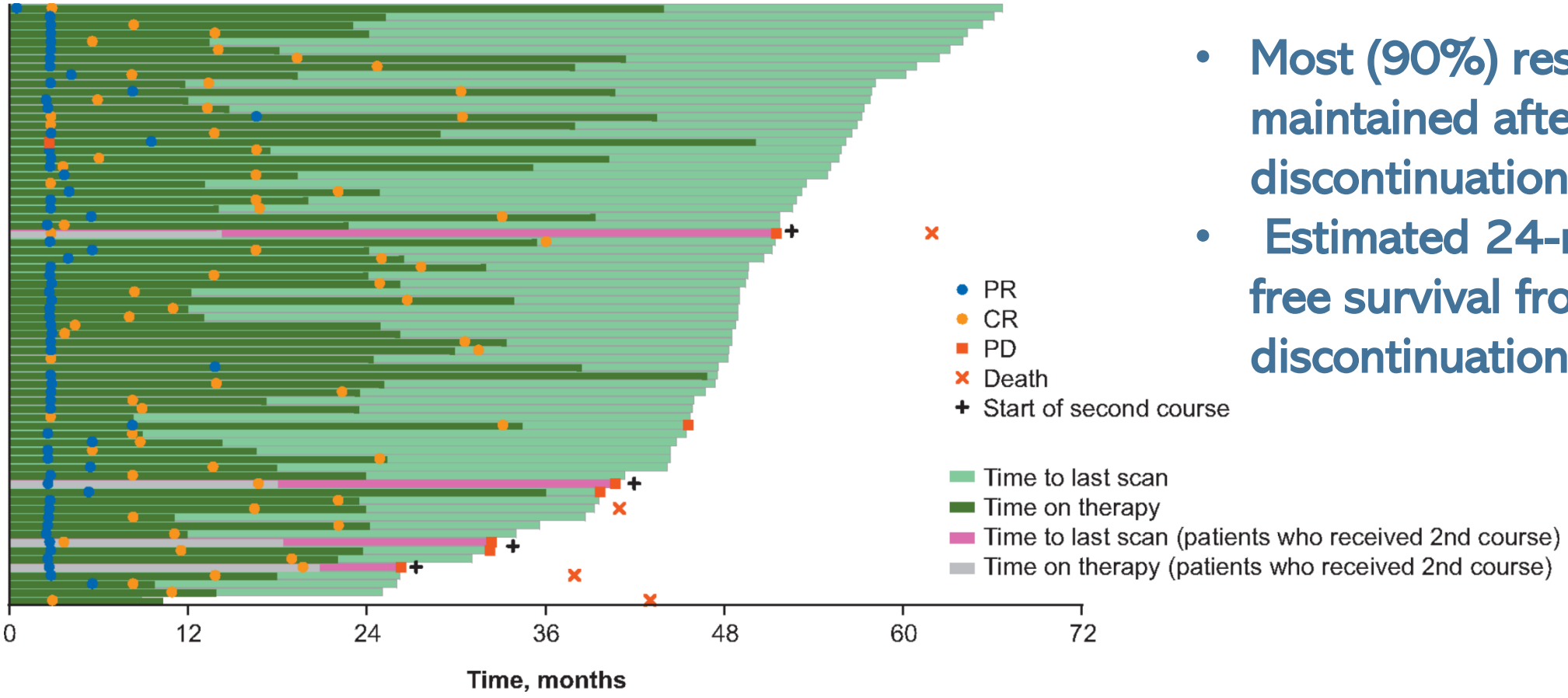
First Line Advanced	
KN-024	*2 yrs (35 cycles)*
KN-189	*2 yrs*
KN-407	*2 yrs*
KN-042	*2 yrs*
CM 227	*2 yrs*
IM150	*Indefinite*
IM132	*Indefinite*

Second+ Line	
KN-010	*2 yrs*
CM-057	*Indefinite*
CM-017	*Indefinite*
OAK	*Indefinite*

- Time to generate a response?
- Time to maintain a response?

Reck, NEJM 2016, Herbst, Lancet 2015, Paz-Ares, ASCO 2018, Brahmer, NEJM 2015, Hellman, NEJM 2018, Socinski, NEJM 2018

KEYNOTE001
Lesson from melanoma 5Y-FU



N=67, pts discontinued pembro after CR for observation

- Most (90%) responses were maintained after discontinuation
- Estimated 24-month disease-free survival from treatment discontinuation was 89.9%.

Hamid O, Ann Oncol 2019

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Real-World Study on EGFR+ NSCLC

The MOST study is a real-world data collection reporting a multicenter adherence and compliance to diagnostic-therapeutic pathways defined for patients with epidermal growth factor receptor-mutant non-small cell lung cancer. This represents an essential element of evidence-based medicine, providing information on patients and situations that may be challenging to assess using only data from randomized controlled trials.

This study may be of interest to various stakeholders (patients, clinicians, and payers), providing a meaningful picture of the value of a given therapy in routine clinical practice.

Drug cost and time on treatment

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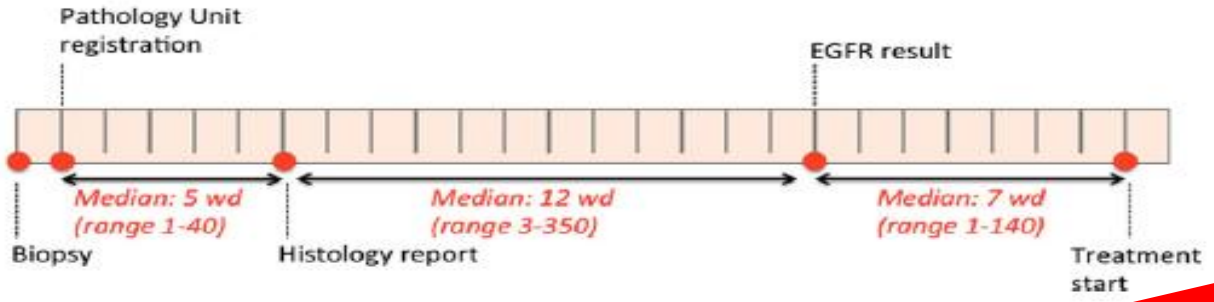
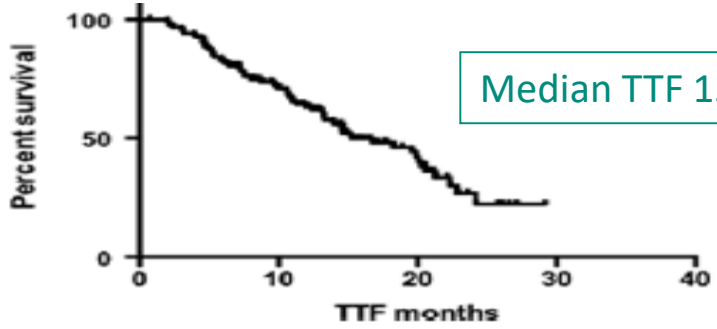
MOST Study 109 *EGFR*-mutant patients treated with gefitinib, erlotinib and afatinib





Median TTF 15.25 mo.

Oncologists treat beyond RECIST-PD

Drug	Reimbursement method			trials)	MOST, mo	pivotal trials, mo	Monthly price, €	Cost/patient based on mTTF (MOST, PBR excluded), €	Real BI based on mTTF (MOST,PBR excluded), €	Cost/patient based on mPFS (pivotal trials, PBR excluded), €	Theoretical BI based on mPFS (pivotal trials, PBR included), €	BI gap (real-theoretical), €
Gefitinib	3 mo PBR		9	14	14.6	9.5	2,190	27,474.43	2,007,949.98	20,808.14	1,234,754.73	773,195.25
Erlotinib	50% CS (first two packs)	18	NA	NA	22.9	9.7	1,865	40,834.08	735,013.49	16,221.76	291,991.66	443,021.83
Afatinib	6 mo PBR	22	18	34	15.3	11	1,796	31,978.82	495,638.69	19,752.86	286,811.49	208,827.21
Total		109							3,238,602.17		1,813,557.88	1,425,044.29

Abbreviations: BI, budget impact; CS, cost sharing; mPFS, progression-free survival; mTTF, time to treatment failure; NA, XXXX; PBR, payment by result; pts, patients.

Pasello – The Oncologist 2019