



! "

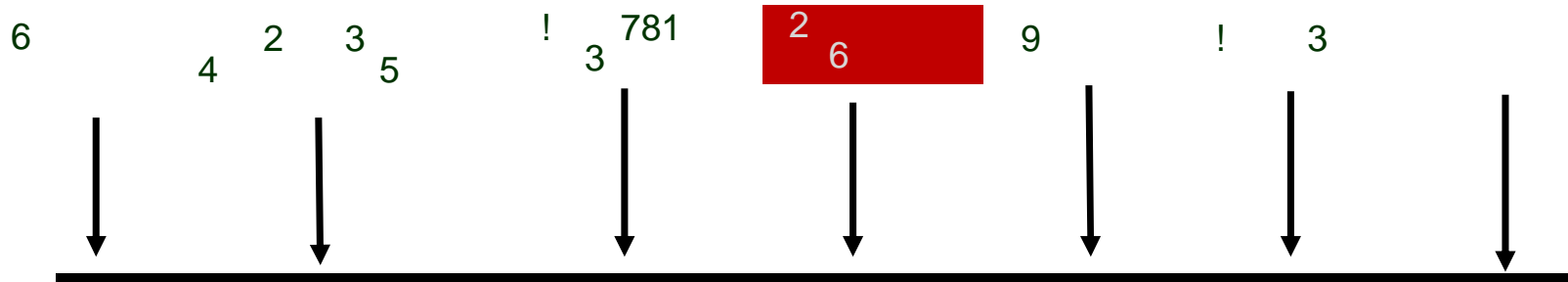
" #

	\$%&'()	%*&%++	,\$-&-'%
.	*&-, -	%&++'	'*&,(%
	\$&-%*	'%+	,\$&\$(%
/	\$&,\$\$,&(00	-&'\$'
1	*&,* ,	%&+\$\$'	\$+&*\$(



!"

> ?



$\frac{6}{6} \frac{8}{8} ;$

$\frac{1}{2} \frac{3}{3}$

$! \therefore$

$6 : 3$

$/ \begin{matrix} 3 < \\ = \\ \therefore \end{matrix} !$

$\frac{2}{6}$

$=$
 $=$

3 B D : 3 =B

B "

6. ' ') * ! % ## !
C!2 % +++,+ - ." / 0! *
&/ %&

: 3			
	@ *,	*\$1*0	A'+
!	%+&')& ,	(&'

!"#\$%& ' (



! "

```
* , : ,++( ,+%'  
6 $+&** -E ,++( %(%&%*%E ,+%'  
" 2! B !
```

```
!" #  
$" " % % "" #  
$"!$" &" "" "" "" #
```

0 % &1 ' (

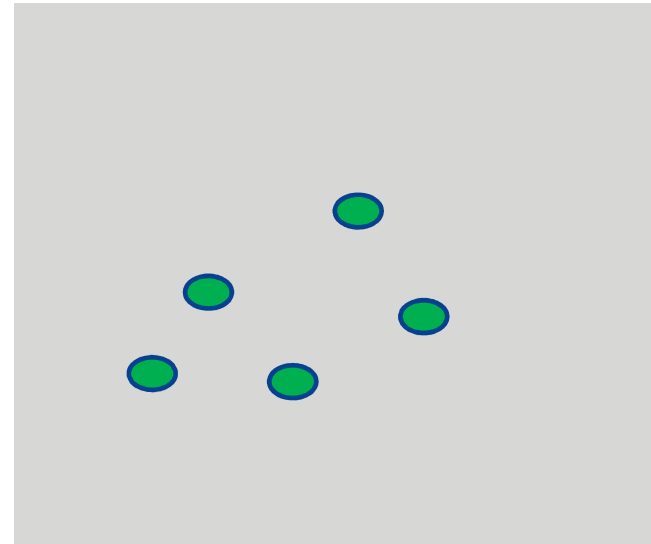
#

+ & # 2 3 4 ! 5 & 0 & ,+(- %0&%%&,+%\$
6 2# &,\$ %-&\$&,+% (0 - * # / 6 ! / 0 !
0 # # - + - +066% #* !78 # 4 ! !
9 7 ! !7 -

"& 7 ! 3 0::: "6 < 5+6
& %()0 ,(&%+&,+% (

7 4 ! & /! 44 7 > F
! 4 7 ! & = ' F
F 7 ! =+ & # # - >+ -? @+066% =

(' () * + ,
(- . -

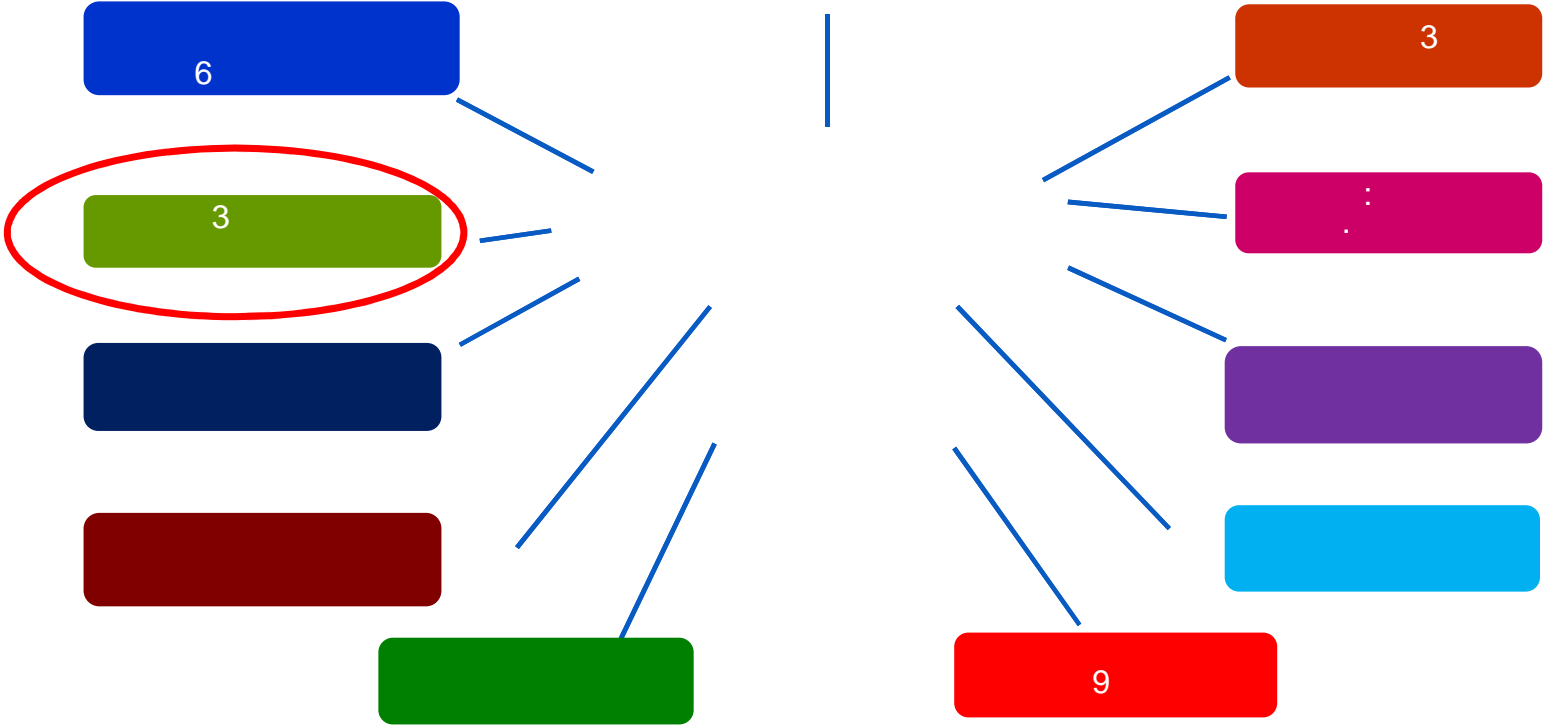


\$ 1 /) 0
\$ 33 2 ' (2
\$ 4 5 + () 1

=C.B! 3 '=C.
" %&+++&+++ D
1 :
1 >2 4# F 5
16
1 # F
1 2 C# #

0) 4 3 6 , 5

G.



7 3 5 -) 8 (+

!
1 & ! #
A:B
A0 6 .6 //&



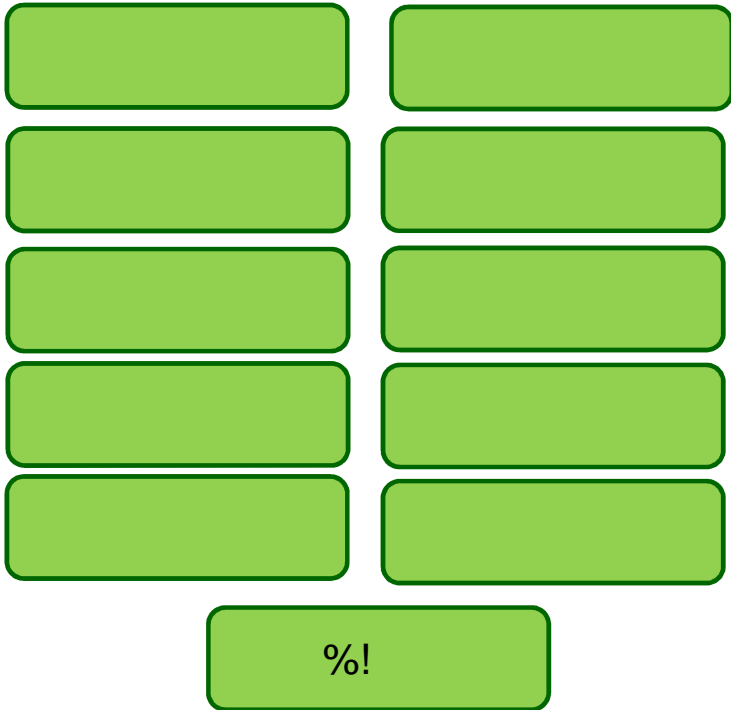
*) !. ! #& ! &3 #
) * \$* !
>* * !/ !7## & ?



< 3 " 3 3 6 3 ! = 3
6 =

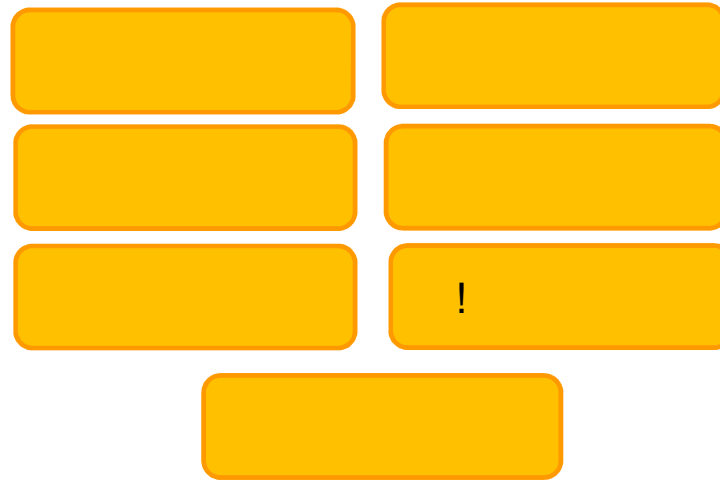
3 4 6:25 1 ,+%0

2

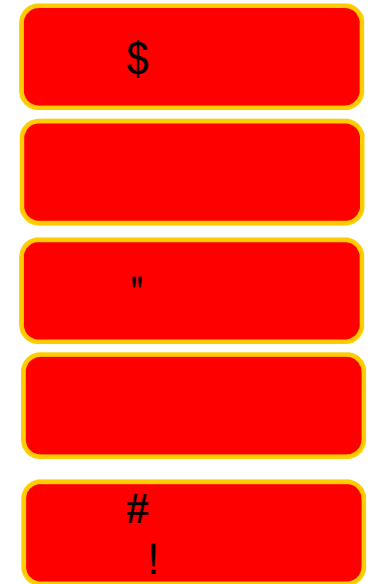


4

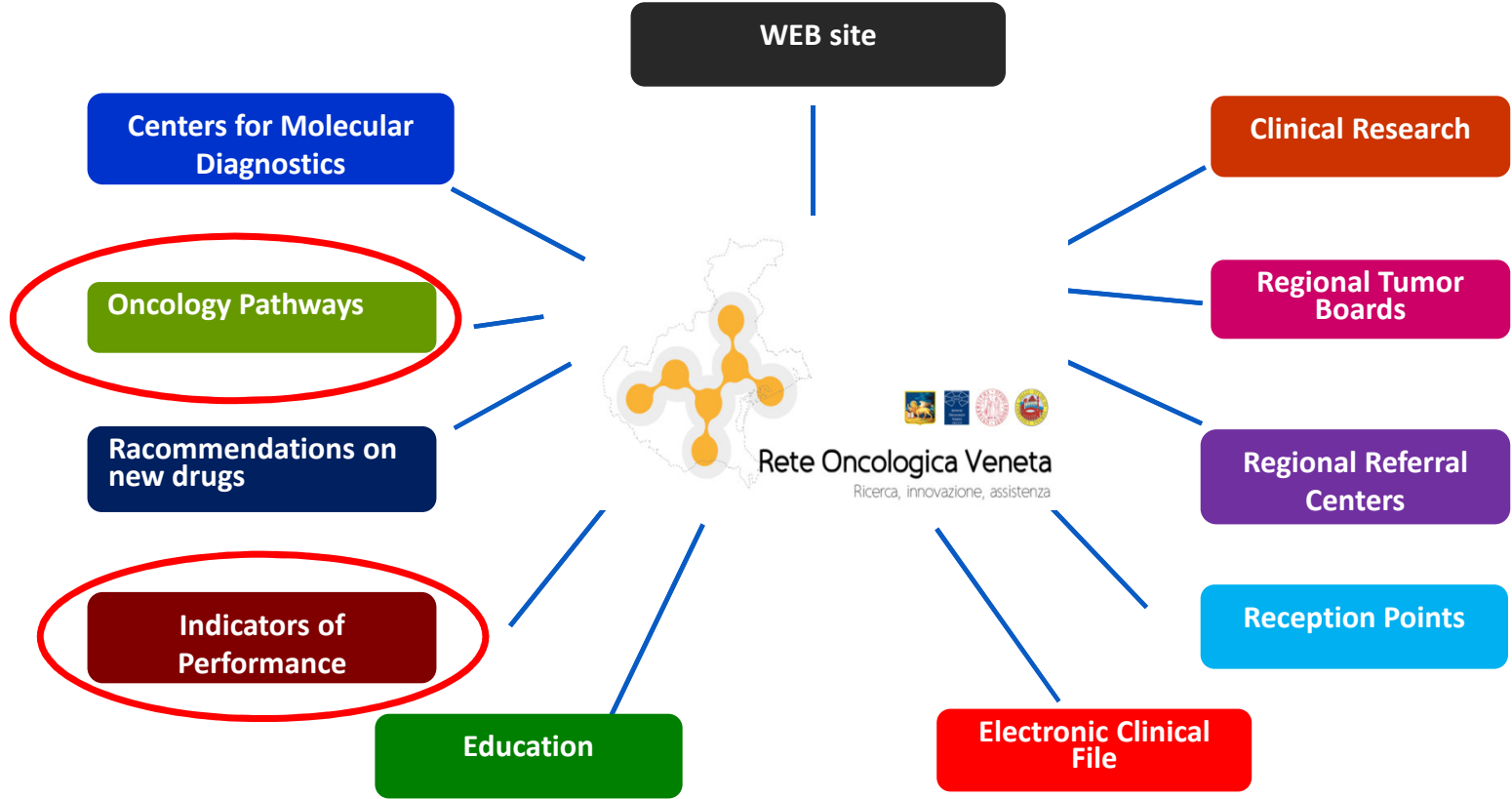
5



G



ROV: Aims & Working Groups



◀ Periplo

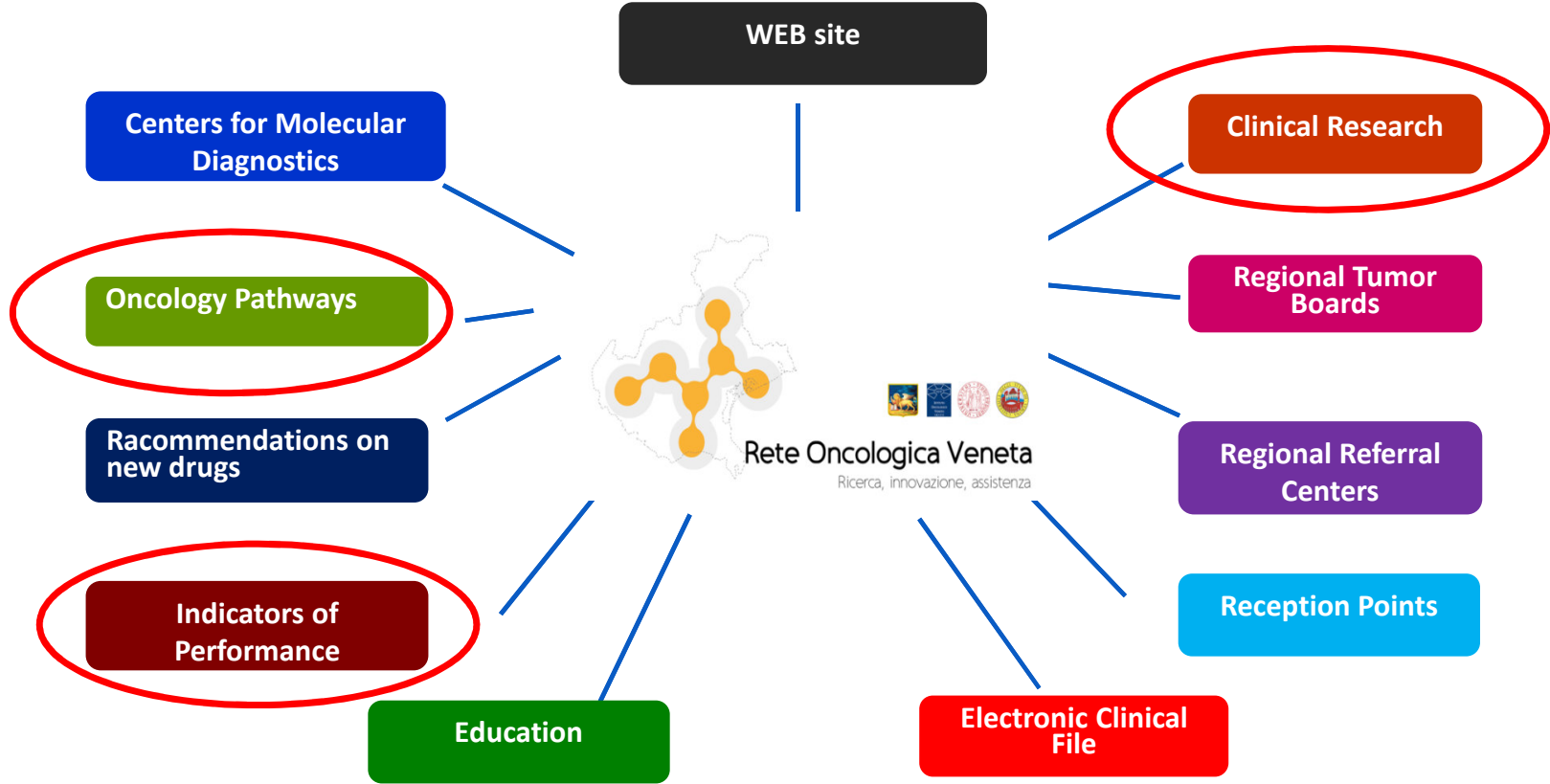


Indicators of Lung Cancer Pathway			
	Clinicians	Its & statisticians	Available & Extractable from Data Bases
Facilities	1	1	1
Procedures	19	11	11
TOTAL	20	12	??

PRELIMINARY RESULTS – ROV 2017

	INDICATORS		N
1	Percentage of patients staged with PET-TC before surgery	37,3%	212/568
2	Percentage of patients treated with antitumor drugs 30 days or less before death	10,8 %	271/2505

ROV: Aims & Working Groups





✓ Studi clinici in corso

Tumori Ematologici

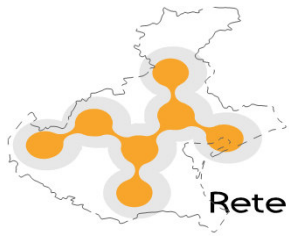
Tumori Solidi

- Cerebrali
- Esofago
- Gastroenterici
 - Colon-retto
 - Fegato
 - Pancreas
 - Adiuvante
 - Metastatico
 - Stomaco
 - Vie Biliari

- 142 Clinical trials
- 18 tumor types
- 9 regional participating sites

- Ginecologici
 - Cervice uterina
 - Endometrio
 - Utero
 - Ovaio
 - Vulva
- Mammari
 - Adiuvante
 - BRCA Mutati
 - Metastatico
 - Neo-Adiuvante
- Melanoma
- Neuroendocrini
- Polmonari
 - Mesotelioma
 - Microcitoma
 - Tumore polmonare non a piccole cellule (NSCLC)
- Sarcomi
- Testa-Collo
- Uro-Genitali
 - Prostata
 - Rene

<https://salute.regione.veneto.it/web/rov/studi-clinici-in-corso>



Rete Oncologica Veneta
Ricerca, innovazione, assistenza



The Veneto Oncology Network: choice of excellence for every patient



Olaparib in Advanced
BRCAm breast cancer

Assessment of the Efficacy and Safety of Olaparib Monotherapy versus Physicians Choice Chemotherapy in the Treatment of Metastatic Breast Cancer Patients With Germline BRCA1/2 Mutations.

First patient worldwide

- 1 IRCCS
- 2 Universities
- 2 Teaching Hospitals
- 21 Community Hospitals
- 8 Advocacy Groups

I3Y-MC-JPBL monarch 2 

A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Fulvestrant with or without LY2835219, a CDK4/6 Inhibitor, for Women with Hormone Receptor Positive, HER2 Negative Locally Advanced or Metastatic Breast Cancer

First patient in Europe

Development and Validation of a High-Quality Composite Real-World Mortality Endpoint

Melissa D. Curtis, Sandra D. Griffith, Melisa Tucker, Michael D. Taylor, William B. Capra, Gillis Carrigan, Ron Holzman, Aracelis Z. Torres, Paul You, Brandon Arniere, and

Are clinical trial eligibility criteria an accurate reflection of a real-world population of advanced non-small-cell lung cancer patients?

K. Al-Baimani MD,* H. Jonker MSc,* T. Zhang PhD,† G.D. Goss MD,*† S.A. Laurie MD,*† G. Nicholas MD,*† and P. Wheatley-Price MBChB MD*†

VIEWPOINT

years. A PubMed search on the terms “real world data,” “real world evidence,” and “registry” showed a 600% increase in citations during the period 2002 to 2016 (from 2,435 citations per year to 14,956 citations per year). RWD have historically been used to answer

y:
ence

ven
nce

in Use of the Electronic Medical Record

Sarah S. Kadish, Erica L. Mayer, David M. Jackman, Mark Pomerantz, Lauren Brady, Audra Dimitriadis, Jessica L.F. Cleveland, and Andrew J. Wagner

VIEWPOINT

Real-World Evidence and Real-World Data for Evaluating Drug Safety and Effectiveness

By Vineeta Aggarwal, Vincent Miller, et al.

Real-World Evidence in Clinical Trials: As A

Position Paper

The use of real-world data in cancer drug development

E. Skovlund^{a,b,*}, H.G.M. Leufkens^c, J.F. Smyth^d

Why Real World Data?

- **Randomized clinical trials frequently lack of external validity**, because they usually include selected patients who account for 2% to 4% of the overall cancer population; indeed, these trials are under-representative of some patients categories
- These critical issues might be solved by **real-world studies, where data collection from medical records reflects the experience of most cancer patients.**
- Recently, both the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) have promoted the **collection of real-world data in the future post-marketing drug monitoring**, regulatory and approval flow

ROV and RWE

Study	Description	Study type	Sponsor	PI	Current status
MOST	Multicenter prospective observational study on EGFR TKIs as first-line treatment of EGFR positive Non-Small Cell Lung Cancer	Prospective multicenter	ROV c/o IOV	Pasello	Published
MAP	Monitoring of the adherence to PDTA in breast and lung cancer in Italy	Retrospective multicenter	PERIPLO Onlus	Guarneri	EC approval pending
RENEW	Real life prospective observational study assessing treatment outcomes and the budget impact of newly approved drugs in a regional Italian oncology network	Prospective multicenter	ROV c/o IOV	Guarneri	EC submission
ARGO-Lung	Adherence to PDTA as appropriateness, affordability and quality of care in breast and lung cancer – Retrospective substudy on nivolumab use in NSCLC	Retrospective multicenter	ROV c/o IOV	Conte (ARGO) Pasello (ARGO-Lung)	EC submission



The
Oncologist®

Health Outcomes and Economics of Cancer Care

From Diagnostic-Therapeutic Pathways to Real-World Data: A Multicenter Prospective Study on Upfront Treatment for *EGFR*-Positive Non-Small Cell Lung Cancer (MOST Study)

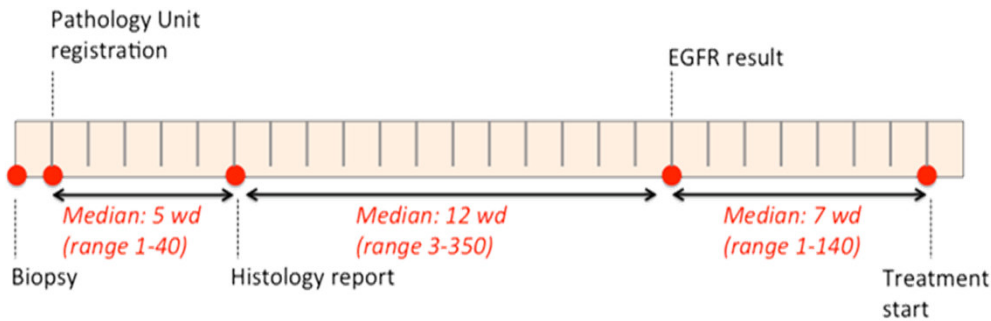
GIULIA PASELLO,^a GIOVANNI VICARIO,^b FABLE ZUSTOVICH,^c FRANCESCO ONIGA,^d STEFANIA GORI,^e FRANCESCO ROSETTI,^f ANDREA BONETTI,^g
ADOLFO FAVARETTO,^h SILVIA TOSO,ⁱ ROBERTA REDELLOTTI,^j ANTONIO SANTO,^k DANIELE BERNARDI,^l PETROS GIOVANIS,^m CRISTINA OLIANI,ⁿ
LORENZO CALVETTI,^o CARLO GATTI,^p GIOVANNI PALAZZOLO,^q ZORA BARETTA,ⁿ ALBERTO BORTOLAMI,^a LAURA BONANNO,^a MARCO BASSO,^b
JESSICA MENIS,^{a,r} DONATELLA DA CORTE,^c STEFANO FREGA,^a VALENTINA GUARNERI,^{a,r} PIERFRANCO CONTE,^{a,r} ON BEHALF OF VENETO
ONCOLOGY NETWORK

The Oncologist 2019;24:1–9

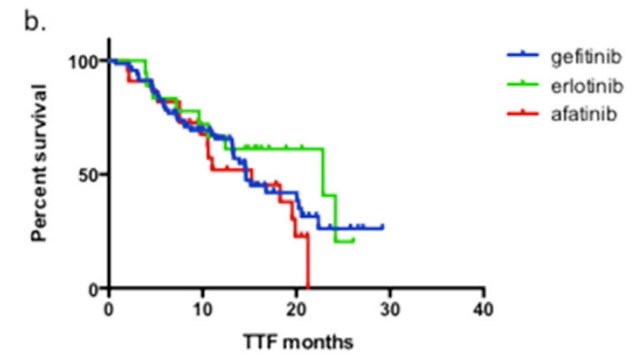
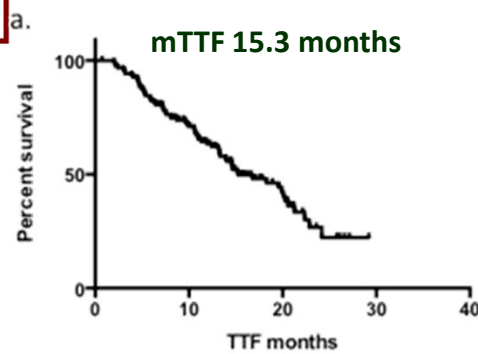
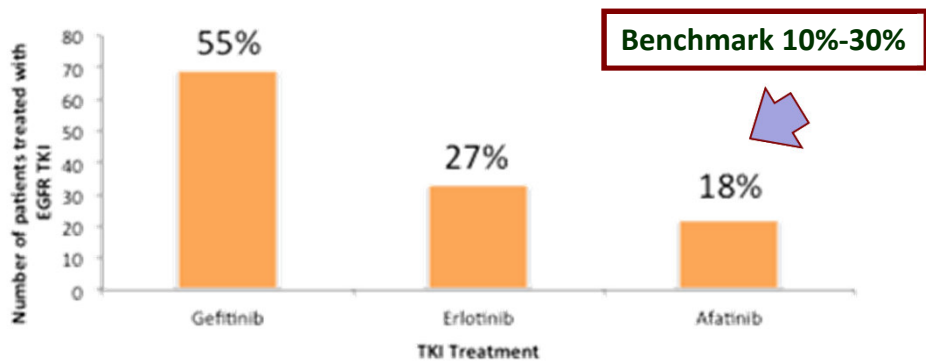
Diagnostic pathway: results

N=447 enrolled patients:

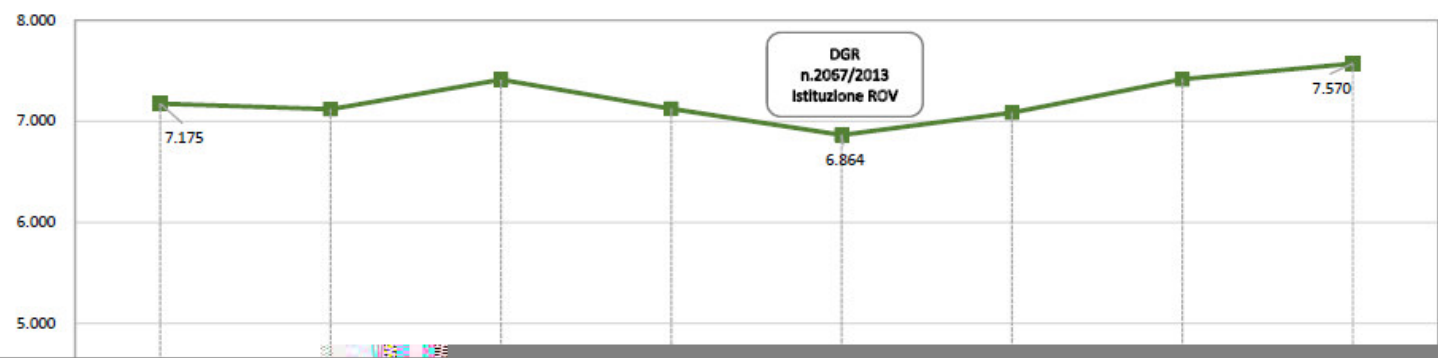
Available EGFR mutation status in 447 pts



- Reflex test was performed in 60% of cases.
- More than 50% of EGFR mutation tests not performed *in house* in 7 Centers
- **Benchmark: 10 working days**
- **EGFRm+ cases treated first line with TKIs: 98% (benchmark: $\geq 90\%$)**



Mobilità Veneto - Numero di pazienti ricoverati per neoplasia maligna



THE NET TO PROTECT THE CANCER PATIENT

- **Technical Scientific Activity**
(Dr. Alberto Bortolami)
- **Logistics and Educational Activity**
(Dr.ssa Fortunata Marchese)
- **Clinical Trials and Research Projects**
(Dr.ssa Laura McMahon; Dr.ssa Claudia Pupo)
- **Reception and orientation**
(Dr.ssa Virginia Pozza)
- **Statistic backing**
(Dr. Sandro Tognazzo)

*Technical, scientific and organisational support
to all working groups and activities*