



Survey results: Unmet needs of Non-Small Cell Lung Cancer patients with brain metastases

Kathy Oliver

Co-Chair, Patient Advisory Committee

Chair and Co-Director, International Brain Tumour Alliance

Hampton Shaddock

Head, Global Affairs

Sanofi Genzyme

Jemma Reast

Research Manager and Advocate for Patient Voices

Ipsos

NSCLC with brain metastases

Roundtable Presentation

DATE: 27th October 2021

Methodology and Sample

Methodology

10 minutes online survey with selected oncologists and 25 respiratory specialists

Participation criteria

- Must be within at least 1 of the 5 roles listed in sample plan
- Qualified in their specialty for between 3 and 30 years
- Treat NSCLC patients with brain metastases
- At least one patient with NSCLC with brain metastases for the last 6 months

Dates

Field work : August – September 2021
Analysis: October 2021

Quoted Sample



	US	EU	UK	DE	FR	IT	ES	Total
Medical Oncologist	55	162	27	25	33	40	37	217
Clinical Oncologist	2	43	13	5	5	8	12	45
Radiation Oncologist	30	6	3	1	1	0	1	36
Haem-Oncologist	13	14	0	12	0	2	0	27
Respiratory Specialist	0	25	7	7	11	0	0	25
Total	100	250	50	50	50	50	50	350

Initiative

Ipsos Mori on behalf of Sanofi and Regeneron Alliance, GCIH and the European Cancer Organisation (ECO)

Challenges of care NSCLC with brain mets

Patients suffer an array of symptoms linked to both NSCLC and brain metastasis

On average specialists identify a range of **17 different symptoms** that NSCLC patients with brain metastases might experience



Base: All Respondents Total (n=350)

T1. In your experience, what proportion of your NSCLC patients with brain metastases experience the following symptoms?

T1b. And which of these symptoms do you perceive to be a symptom that is unique to their brain metastases and not symptoms relating to their NSCLC in general?

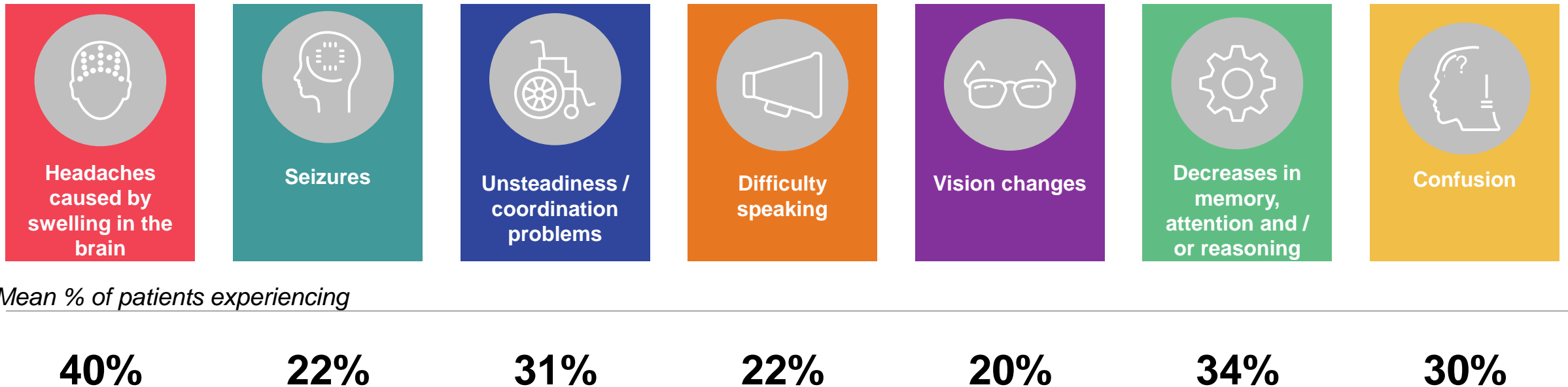
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Cancer symptoms are compounded by brain mets symptoms affecting coordination, speech, memory loss and confusion

7 most frequently selected as unique to brain metastases patients (cognitive functioning)



Mean % of patients experiencing

T1. In your experience, what proportion of your NSCLC patients with brain metastases experience the following symptoms?

T1b. And which of these symptoms do you perceive to be a symptom that is unique to their brain metastases and not symptoms relating to their NSCLC in general?

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Coordination of medical care is acknowledged as a particular challenge for NSCLC patients with brain metastases by specialists



3 in 4 agree

coordination of medical care is more challenging for NSCLC patients with brain metastases

73% agreeing with the statement:

“It is more challenging to coordinate the medical care of a NSCLC patient with brain metastases compared to NSCLC patients (without brain metastases)”

**compared to caregivers to patients without brain metastases*

Base: All Respondents Total (n=350), US (n=100), EU (n=250)

P1 Considering your NSCLC patients with brain metastases to what extent do you agree or disagree with each of the statements below?

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When treating NSCLC patients with brain metastases, challenges experienced by specialists are vast and varied

Little consensus on the core challenges when treating NSCLC patients brain metastases

On average specialists select

7 activities within the management of NSCLC patients with brain metastases to be challenging

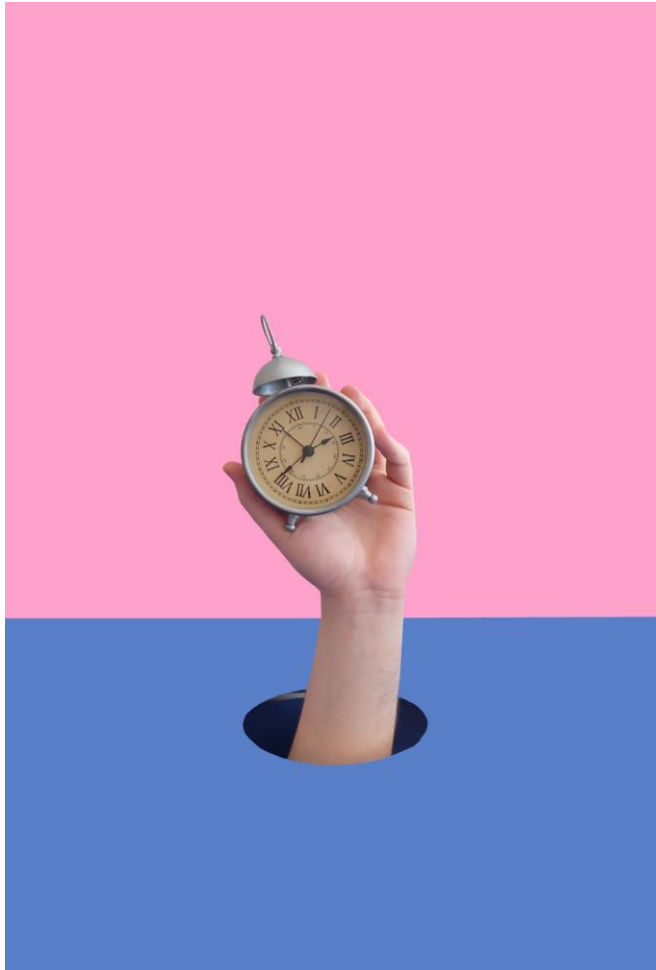


Of the 18 possible challenges, all were stated to be a challenge (Very challenging / fairly challenging / somewhat challenging) by around of 3 in 10, showing the complexity of the condition and the issues that HCPs and their patients are facing.

Base: All Respondents Total (n=350)

P3 When treating NSCLC patients with brain metastases how challenging or not are each of the following roles/activities to you personally?

The official allotted time for appointments is challenging for over half of respondents



Half of HCPs

Report “*Having a detailed conversation with a patient in the official time allotted for appointments*” as a challenge, making it the top challenge amongst oncologists we spoke to

Very challenging / fairly challenging / somewhat challenging

Base: All Respondents Total (n=350), US (n=100), EU (n=250)

P3 When treating NSCLC patients with brain metastases how challenging or not are each of the following roles/activities to you personally?

More than 2 in 5 specialists find providing quality information to their NSCLC patients with brain metastases to be a particular challenge



44% of HCPs

Find “*providing quality information to them about their condition (e.g. printed, online or video information)*” challenging

Very challenging / fairly challenging / somewhat challenging

Weighted Base: All Respondents Total (n=300) US (n=100), EU (n=250)

P3 When treating NSCLC patients with brain metastases how challenging or not are each of the following roles/activities to you personally?

Access to a survivorship plan comes after access to a variety of support groups in terms of priority support services

When asked to choose top 5 important support services

5% believe a survivorship plan is the top support service in terms of importance

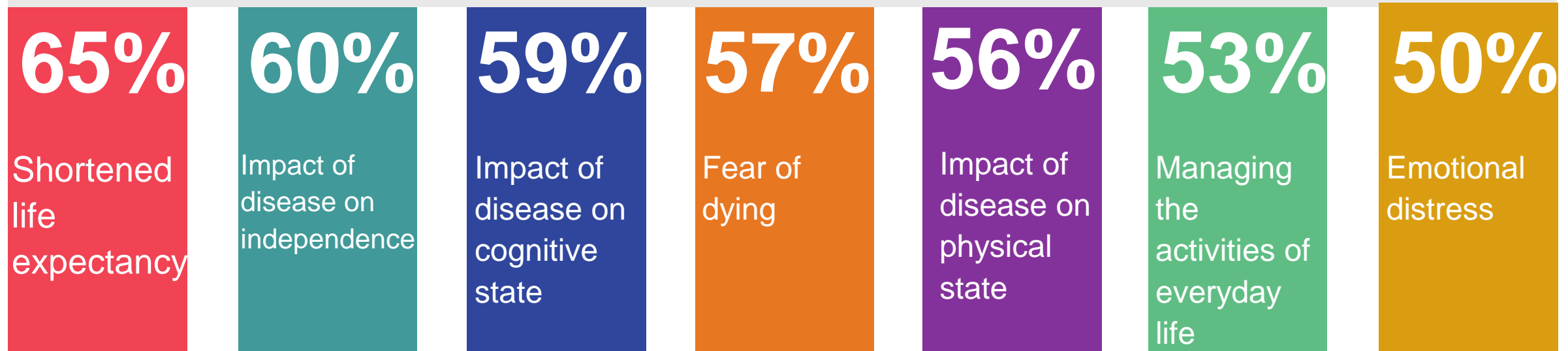


The emotional side NSCLC with brain mets

In addition to physical and mental impairment, emotional distress is a key challenge for many patients according to specialists

We asked oncologists to select the top 7 challenges to patients, though we expected the vast majority to select 'shortened life expectancy' and 'fear of dying' that was not the case. Impact on QoL is a focus for patients.

Top 7 challenges amongst patients – HCP perceptions



Base: All Respondents Total (n=350), US (n=100), EU (n=250)

T4. In your experience, what do you think patients find most challenging about having NSCLC with brain metastases?

However, some specialists recognise providing emotional/moral support is challenging



Half of HCPs

Report “*Providing emotional and/or moral support to the patient and their caregivers and family*” as a challenge, making it another top challenge amongst oncologists we spoke to

Very challenging / fairly challenging / somewhat challenging

Base: All Respondents Total (n=350), US (n=100), EU (n=250)

P3 When treating NSCLC patients with brain metastases how challenging or not are each of the following roles/activities to you personally?

Specialists view themselves as the most useful resource to patients and their caregivers

2 in 3

Ranked 'face-to-face support with oncologist' or 'online support with oncologist' in 1st, 2nd or 3rd place as most useful in accessing the information about patients' condition



Base: All Respondents Total (n=350), US (n=100), EU (n=250)

13 Which of the following sources, if any, do you think your NSCLC patients with brain metastases (and/ or their caregivers) find most useful in accessing information about their condition? (Top 5 support services, placing them in order of importance)

However... many report challenges with having open conversations with patients and caregivers

2 in 5 physicians

(41%) find it challenging “being open and honest with the patient if asked difficult questions (e.g. on prognosis, likelihood of recurrence, etc)”

(Very challenging / fairly challenging / somewhat challenging)



Base: All Respondents Total (n=350), US (n=100), EU (n=250)

I3 Which of the following sources, if any, do you think your NSCLC patients with brain metastases (and/ or their caregivers) find most useful in accessing information about their condition?

P3 When treating NSCLC patients with brain metastases how challenging or not are each of the following roles/activities to you personally?

40% feeling less than well equipped to managing NSCLC patients with brain metastases

40%

Admit to feeling only 'somewhat equipped', 'fairly poorly equipped' or 'very poorly equipped' to manage NSCLC patients with brain metastases.

60% state they feel fairly well equipped or very well equipped

Base: All Respondents Total (n=350), US (n=100), EU (n=250)

T2. How well or poorly equipped do you feel managing patient care for your NSCLC patients with brain metastases compared to those without brain metastases?

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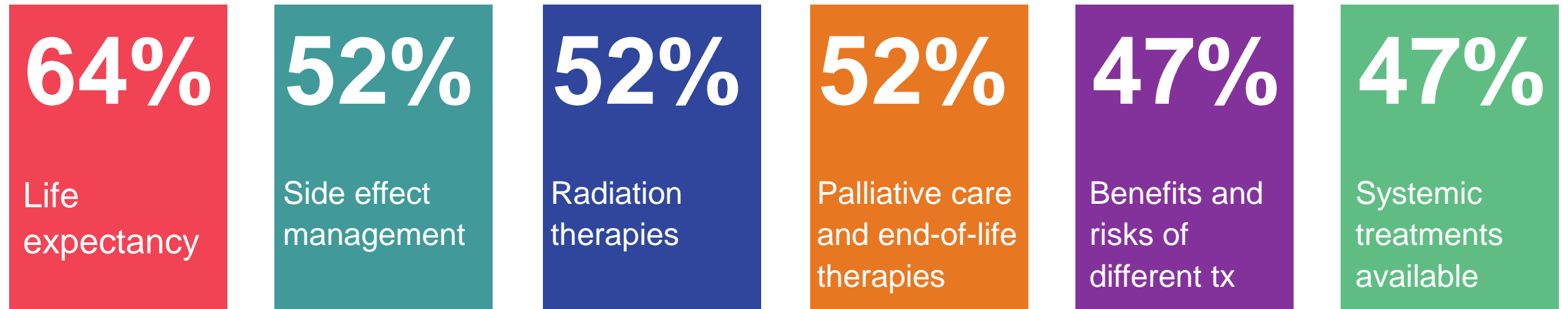
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Support needs NSCLC with brain mets

Some specialists acknowledge patients require more information on life expectancy, treatment or end of life care

6 most frequently selected topics that HCPs think NSCLC patients with brain metastases might want to know more about their condition



Base: All Respondents Total (n=350), US (n=100), EU (n=250)

11 Thinking of your NSCLC patients with brain metastases, which areas, if any, do you think they want to know more about their condition?

Caregivers to those with brain metastases become even more involved in their care management* and also require support

**compared to caregivers to patients without brain metastases*

82% agree that the “supportive role of caregivers of NSCLC patients with brain metastases becomes more all-encompassing”



Strongly agree / tend to agree

72% agree that “Caregivers of NSCLC patients with brain metastases are more stressed than caregivers of NSCLC patients without brain mets”



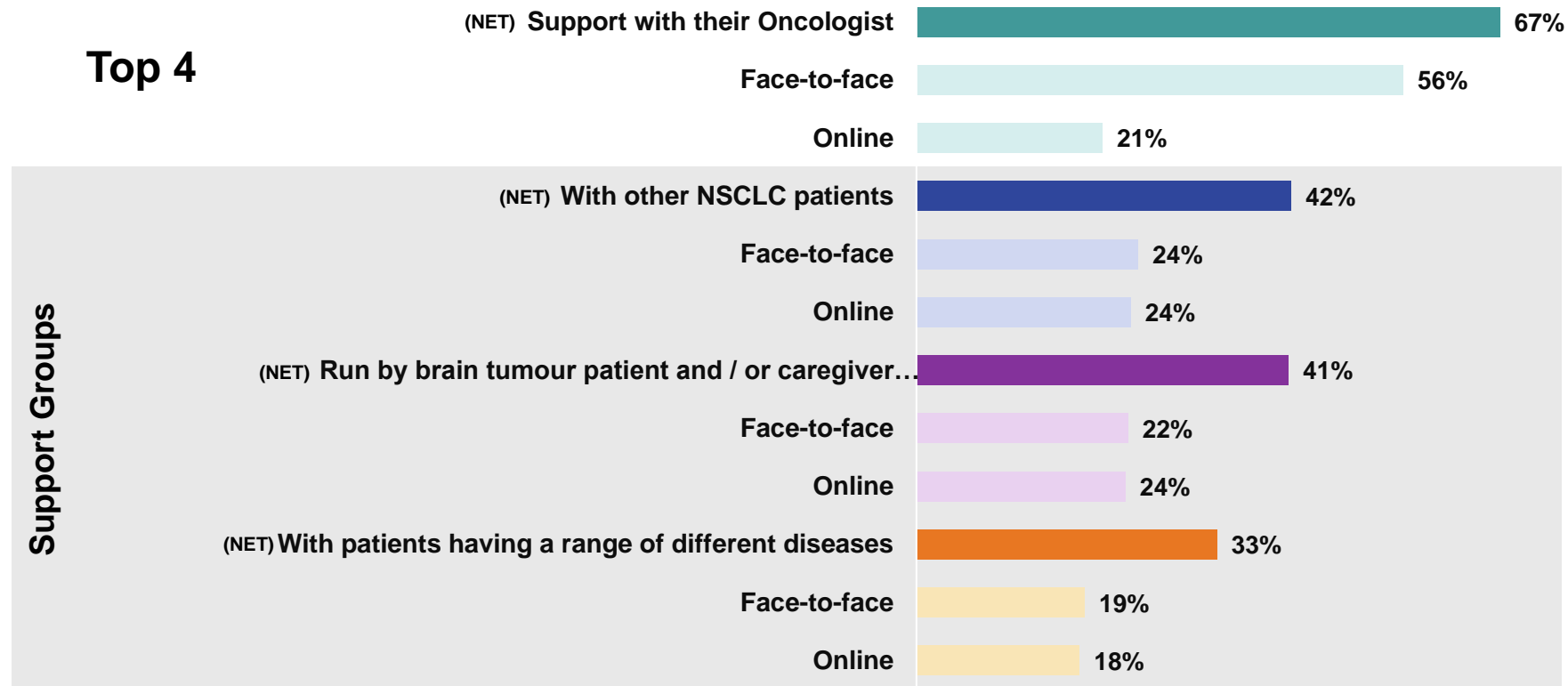
Strongly agree / tend to agree

Base: All Respondents Total (n=350), US (n=100), EU (n=250)

P1 Considering your NSCLC patients with brain metastases to what extent do you agree or disagree with each of the statements below?

Oncologists and support groups with other patients with NSCLC and/or brain mets are important in providing information

Ranked 1st / 2nd / 3rd



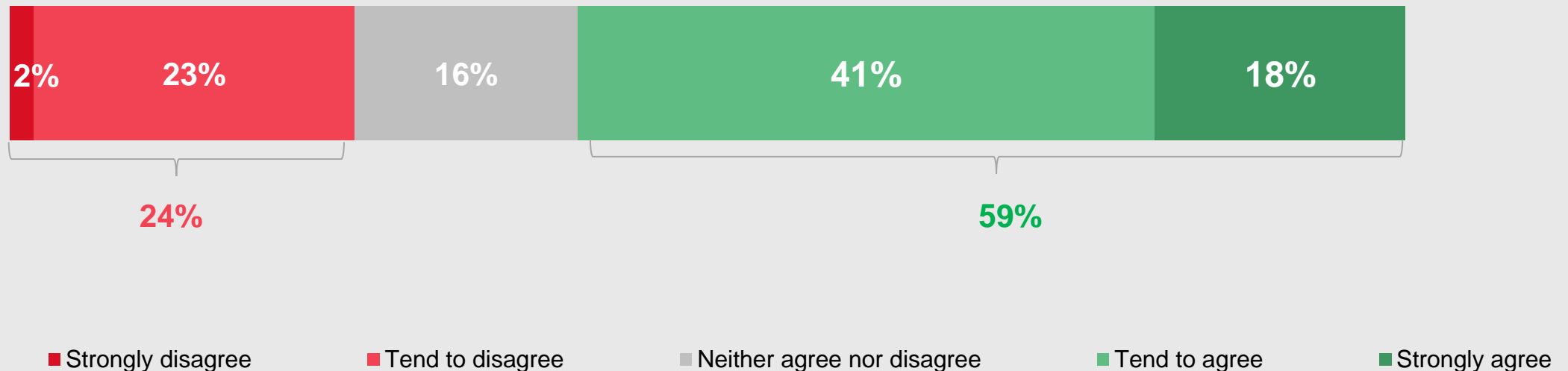
Base: All Respondents Total (n=350), US (n=100), EU (n=250),

13 Which of the following sources, if any, do you think your NSCLC patients with brain metastases (and/ or their caregivers) find most useful in accessing information about their condition?

(Top 5 support services, placing them in order of importance)

The majority of specialists claim to be satisfied with the amount of information available to patients and caregivers, however a quarter are dissatisfied

“I am satisfied with the amount of information available to my NSCLC patients with brain metastases and their caregivers about their condition”

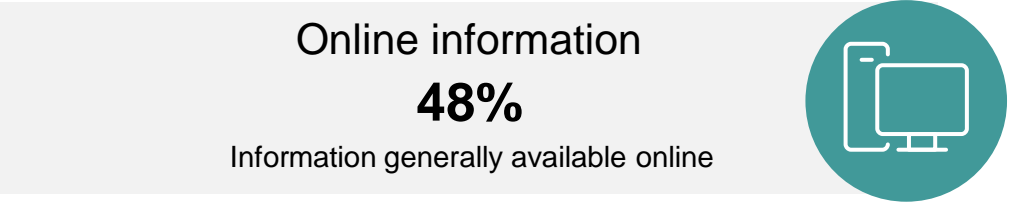
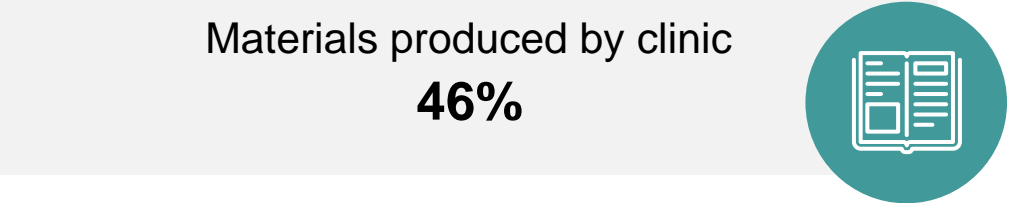


Base: All Respondents Total (n=350), US (n=100), EU (n=250)

12 Please select to what extent you agree / disagree with the following statement.

Many specialists have access to general online information or materials produced by their clinic

Top 3 information and materials available to offer for NSCLC patients with brain mets



However...

18% report to either have none available or don't know

Base: All Respondents Total (n=350), US (n=100), EU (n=250)
14 What, if any, information and materials do you have at your disposal to offer your NSCLC patients with brain metastases.
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THANK YOU.

Emma
Middleton

Details:

emma.middleton@ipsos.com

Jemma
Reast

Details:

jemma.reast@ipsos.com

Csaba Dégi

Co-Chair, Survivorship and Quality of Life Network,
European Cancer Organisation

Director, International Psycho-Oncology Society (IPOS)

Kathy Oliver

Co-Chair, Patient Advisory Committee, European Cancer
Organisation

Chair and Co-Director, International Brain Tumour Alliance



The treatment challenges of metastatic lung cancer

Rudolf Huber

Past-Chair, Lung Cancer Group, Thoracic Oncology Assembly
European Respiratory Society (ERS)

Klaus Feldmann

Vice President and Head of Marketing Oncology, Europe and
Canada
MSD

Metastatic Lung Cancer

TNM classification stage IV

SCLC

about 80 % stage IV at time of diagnosis

NSCLC

about 50 % stage IV at time of diagnosis

- M1a (intrathoracic spread)
- M1b (single extrathoracic spread)
- M1c (multiple extrathoracic spread)

M1a/b: stage IVA – MST 11.5 months, 5-Y-S 10 %

M1c: stage IVB – MST 6 months, 5-Y-S 0 %*

* IASLC database

Metastatic Lung Cancer – NSCLC Treatment Options



Systemic therapy

- Immuno-Chemotherapy
- Immuno-monotherapy
- Targeted therapy
- Chemotherapy

Local therapy

- palliative
- radical (oligometastatic disease)

Best supportive care

Thank You!

Diagnosed but not treated: The case of advanced NSCLC in Europe

Dr. Thomas Hofmarcher (IHE – The Swedish Institute for Health Economics)
and co-authors Prof. Nils Wilking (Karolinska Institutet), Prof. Peter Lindgren (IHE)

27 October 2021

*Disclosures by TH: Institutional speaker fees from MSD International Business GmbH
The research study was commissioned and funded by Merck Sharp & Dohme (MSD) and based on independent research delivered by IHE. MSD has had no influence or editorial control over the content of this study, and the views and opinions presented in the study are not necessarily those of MSD.*



Method

Part 1: How many diagnosed patients are receiving drug treatment?

$$\text{Treatment rate (\%)} = \frac{\text{Number of patients on drug treatment}}{\text{Number of potentially eligible patients}}$$

Based on IQVIA volume (milligram sold) and info on reimbursement, treatment duration, etc.

Based on information from national cancer registries

Registry-based studies often only look at this group



NSCLC patients, stage IIIB/C + IV		
1st line	2nd line	3rd line
<ul style="list-style-type: none"> Newly diagnosed cases Recurrent cases from earlier stages 	Progressors from 1 st to 2 nd line	Progressors from 2 nd to 3 rd line

Scope of research:

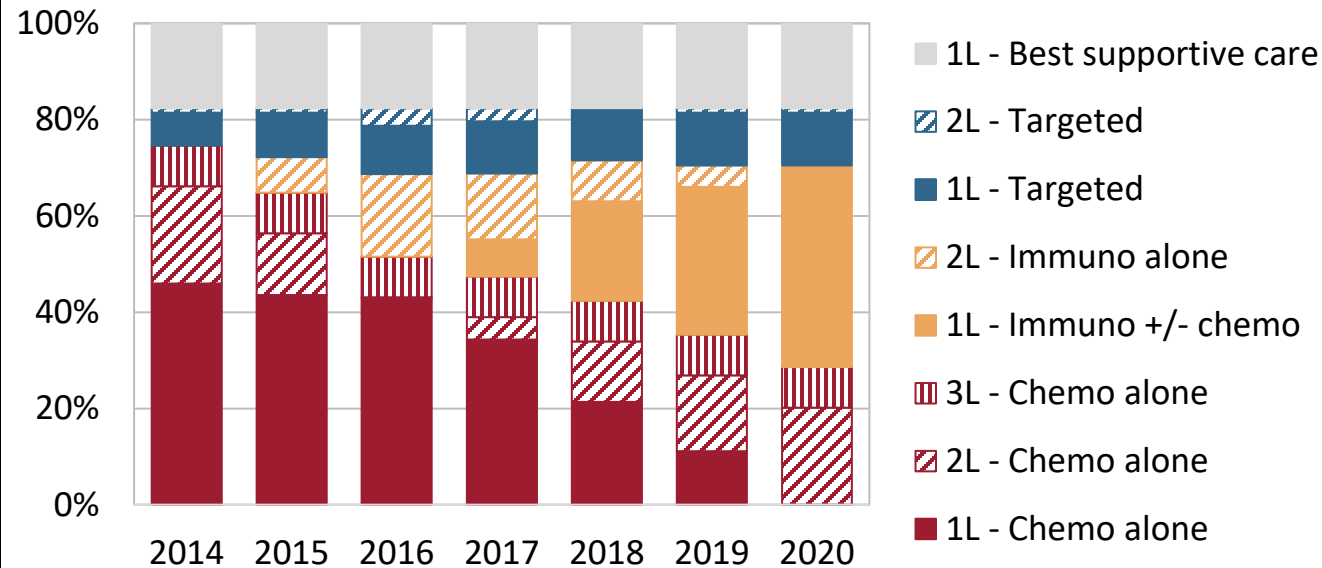
- 11 countries
- 2014 to 2020
- Drug treatment = all EMA-approved drugs in advanced NSCLC + older chemo-drugs

Part 2: Why are patients not receiving any drug treatment? Why do they receive outdated treatment options?

- Two-step approach:
- Crude assessment of treatment barriers via online survey of 1 clinical representative and 1 industry representative in every country
 - Validation and identification of additional barriers with clinical representatives (and patient representatives) in local workshops

Drug treatment rates based on ESMO guidelines and EMA approvals

Optimal drug treatment rate in advanced NSCLC
 (disaggregated proportions by line of therapy)



A 100% treatment rate is a hypothetical situation

- ESMO recommends systemic therapy to all 1st line patients with ECOG PS 0-2 (not PS 3-4)
- A proportion of patients will only receive “best supportive care” as 1L treatment, because of factors such as poor PS and co-morbidities

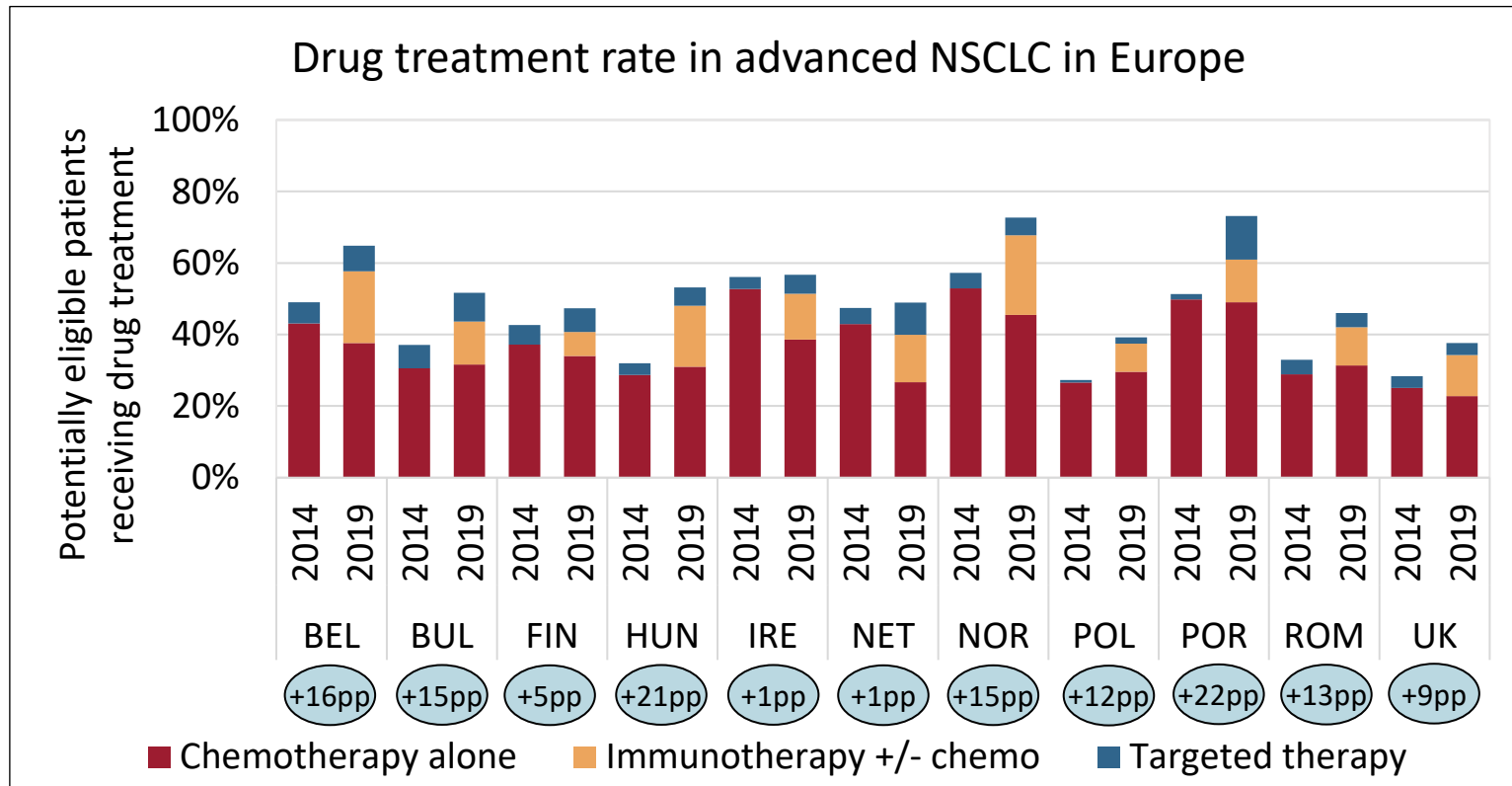
Aims for drug treatment rates:

- (1) High overall treatment rate
- (2) Right mix of chemo-IO-targeted

Assumptions for the optimal drug treatment rate:

- 25% of both newly diagnosed patients and recurrent patients from earlier stages were assumed to receive only best supportive care as first-line therapy in all years, translating into 18% of total patients.
- 20% of patients in first-line therapy were assumed to have an ECOG PS of 2 and 55% an ECOG PS of 0-1 and all of them receive drug treatment.
- 40% of patients with active 1st line treatment continue to active 2nd line treatment, and another 40% of those continue to active 3rd line treatment.
- Share of mutations (same in 1L and 2L): EGFR 13%, ALK 4.5%, ROS1.5%, BRAF-V600E 1.5%, NTRK 0.3%
- PD-L1 expression (same in NSQ (excl. mutations) and SQ, and in 1L and 2L): PD-L1 \geq 1% 54%, PD-L1 \geq 50% 25%.
- Histology (same in 1L and 2L): NSQ 65% (including all mutations), SQ 35%.

Treatment rates by type of therapy in Europe – 2014 vs. 2019 (preliminary results)



Notes: pp = percentage points.

Hungary: The comparatively high number of death-certificate-only cases among the incidence numbers introduces a downward bias to the treatment rates.

(1) Overall treatment rates have improved in all countries, but most miss the ESMO-benchmark

(2) Very large differences in treatment rates across countries:

Top = BEL, NOR, POR

Mid = BUL, FIN, HUN, IRE, NET, ROM

Low = POL, UK

(3) No correlation between wealthy and less wealthy countries in overall treatment rates

(4) Composition of the treatment rates has changed profoundly, usually according to:

- Targeted therapy ↑
- IO+/-chemo ↑
- Chemotherapy ↓

... but are far away from the ESMO-benchmark

Main barriers of treatment rates in Europe

Patients remain untreated
because of ...

**Poor performance
status at diagnosis**

High prevalence
of co-morbidities

Clinical guidelines

Narrow clinical eligibility
criteria (stage IIIB/C and
ECOG PS 2 are excluded)

Treatment refusal
by patients

Financial resources,
human resources,
infrastructure

**Long delays in
time to treatment**

Country-specific
barriers

Patients receive outdated
treatment options
because of

**Low use of modern
cancer drugs due to
slow reimbursement**

Financial resources,
human resources,
infrastructure

**Limited continuing
medical education**

Clinical guidelines

Country-specific
barriers

Thank You!

Contact information: thomas.hofmarcher@ihe.se

IHE – The Swedish Institute for Health Economics (<https://ihe.se/en/>)

Anne-Marie Baird

Member, Patient Advisory Committee, European Cancer
Organisation

President, Lung Cancer Europe



The potential of biomarkers and testing for improvement

Aleš Ryška

President

European Society of Pathology (ESP)

Rodney Smith

Head of Medical Affairs

Daiichii Sankyo

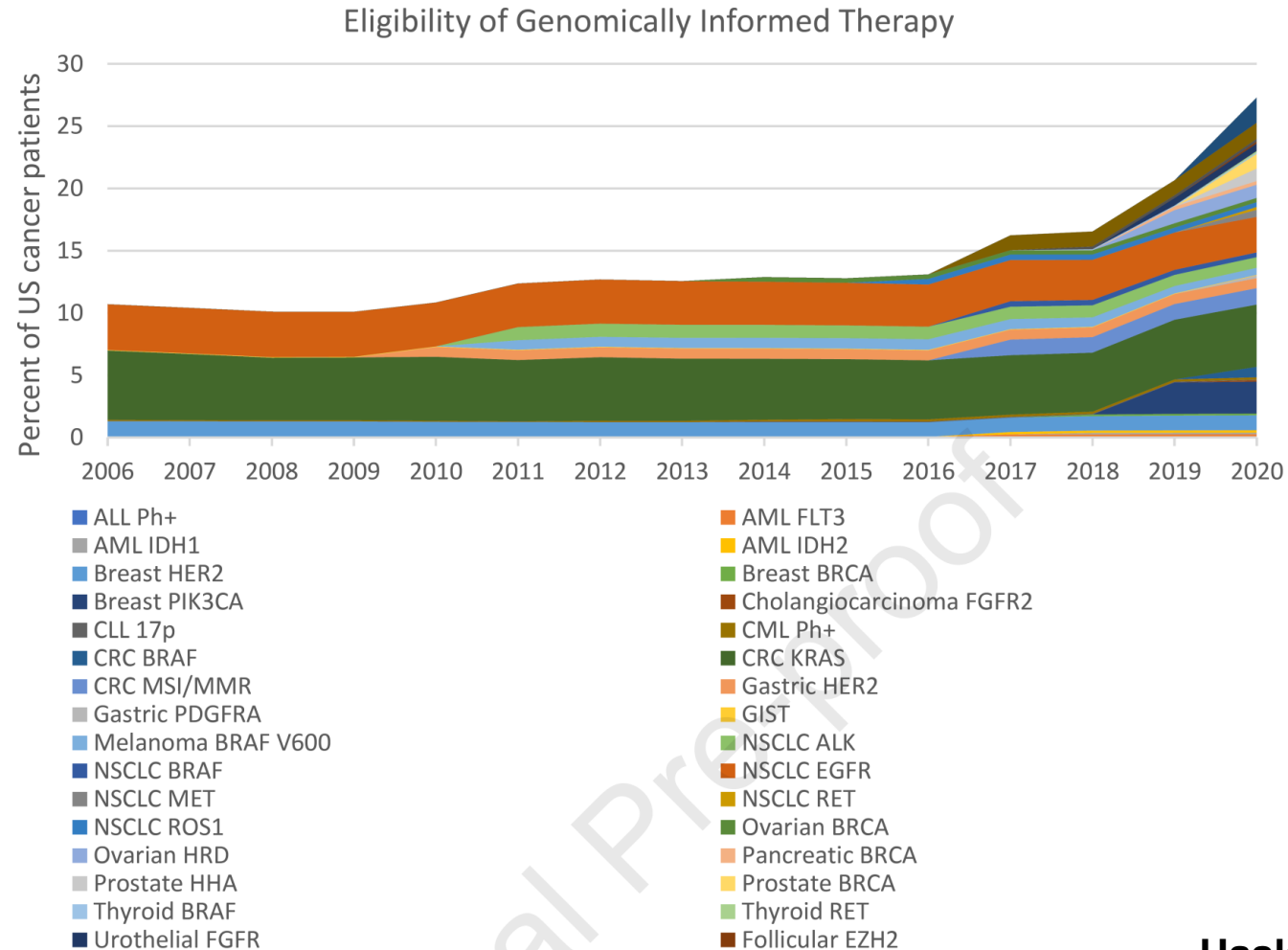


Biomarker testing of cancer – what are the major challenges?

Aleš Ryška

European Society of Pathology

Estimated eligibility of genome informed therapy in US cancer patients, 2006-2020



Non-Small Cell Lung Cancer in Countries of Central and Southeastern Europe: Diagnostic Procedures and Treatment Reimbursement Surveyed by the Central European Cooperative Oncology Group

ALES RYSKA,^a RARES BUIGA,^b ALBENA FAKIROVA,^c IZIDOR KERN,^d WŁODZIMIERZ OLSZEWSKI,^e LUKAS PLANK,^f SVEN SEIWERTH,^g ERIKA TOTH,^h ERI ZIVKA,ⁱ CHRISTIANE THALLINGER,^{j,l} CHRISTOPH ZIELINSKI,^{k,l} LUKA BRCIC^m

- survey conducted by the Central European Cooperative Oncology Group (CECOG)
- availability and reimbursement of molecular testing in NSCLC

europaean
cancer
ORGANISATION

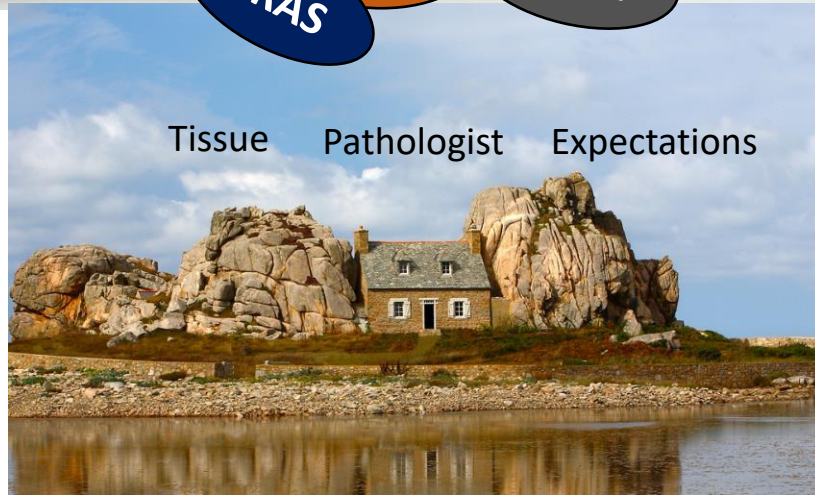
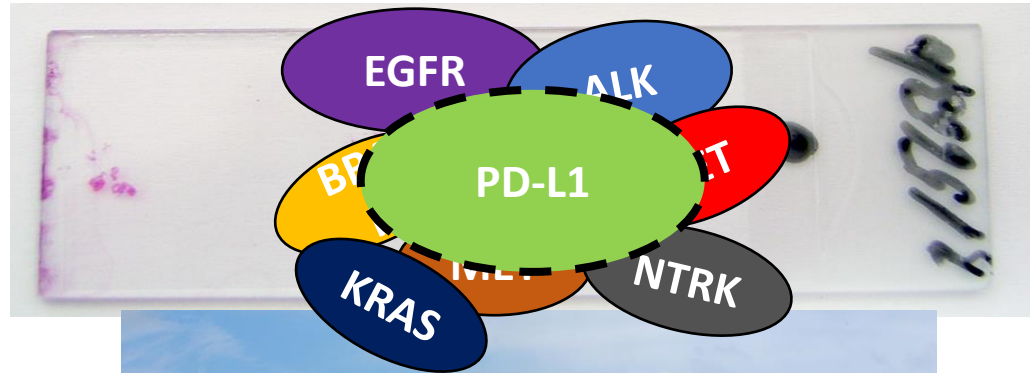


Testing reimbursement

	EGFR	ALK	ROS1	BRAF	PD-L1
Austria	Green	Green	Green	Green	Green
Bulgaria	Red	Red	Blue	Grey	Red
Croatia	Red	Red	Blue	Blue	Red
Czechia	Yellow	Yellow	Blue	Grey	Yellow
Hungary	Yellow	Yellow	Yellow	Yellow	Yellow
Poland	Yellow	Yellow	Blue	Blue	Red
Romania	Red	Red	Blue	Yellow	Grey
Serbia	Red	Grey	Blue	Yellow	Grey
Slovakia	Yellow	Yellow	Yellow	Grey	Yellow
Slovenia	Green	Green	Blue	Blue	Red

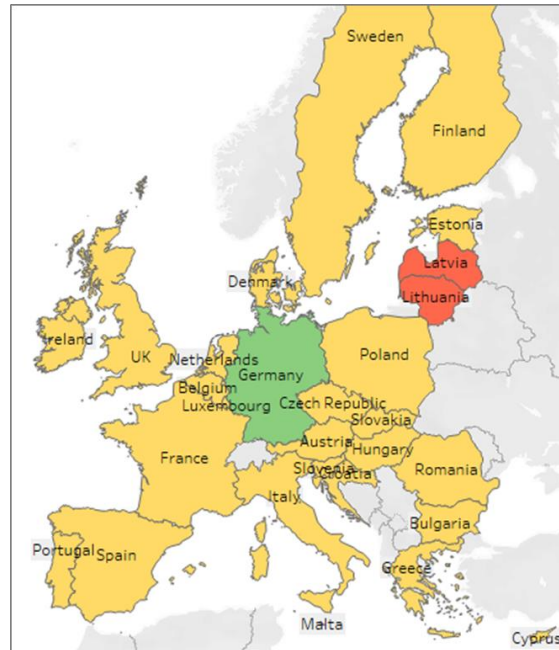


Single gene vs. multigene (NGS) approach



Significant variations in drug and test access as well as test quality across Europe

Medicines access



Single biomarker test access



Multi-biomarker test access



Thank You!

Rodney Smith

Head of Medical Affairs
Daiichii Sankyo

DESTINY-Gastric02 Study Design

- An open-label, multicenter phase 2 study in Western patients with HER2+ gastric or GEJ cancer (NCT04014075)

Key eligibility criteria

- Pathologically documented, unresectable or metastatic gastric or GEJ cancer
- Centrally confirmed HER2 positive disease (defined as IHC 3+ or IHC 2+/ISH+) on biopsy after progression on first-line trastuzumab-containing regimen
- ECOG PS 0 or 1

T-DXd
6.4 mg/kg Q3W
N = 79^a

Primary endpoint

- Confirmed ORR by ICR

Secondary endpoints^b

- PFS by ICR
- OS
- DOR by ICR
- Safety and tolerability

- DESTINY-Gastric02 is the first study focused only on second-line T-DXd monotherapy in Western patients with HER2+ gastric/GEJ cancer who have progressed on a trastuzumab-containing regimen
- It is the follow-on study to DESTINY-Gastric01, which evaluated T-DXd third-line or later in Asian patients¹
- Patients were enrolled in Europe (Belgium, Great Britain, Italy, Spain) and the United States (data cutoff: April 9, 2021)

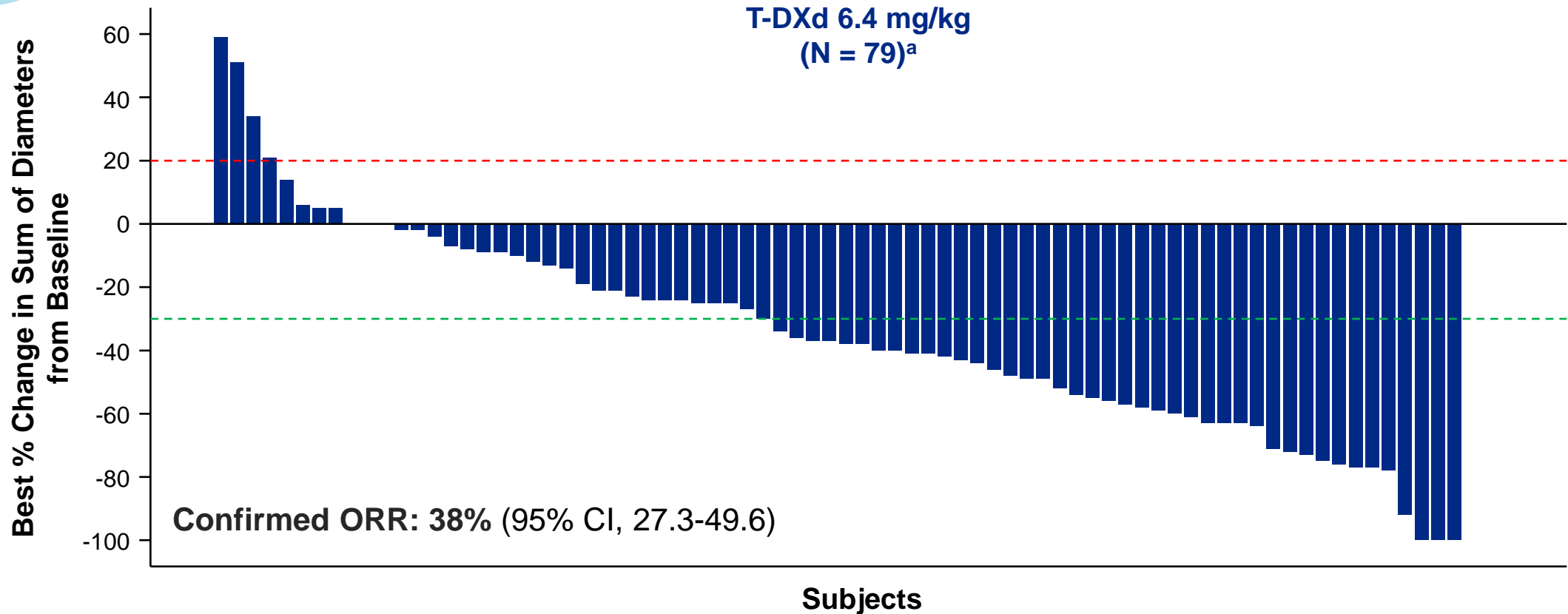
^aEnrollment of 80 patients was planned; actual enrollment was 79 patients.

^bOther secondary endpoints were ORR, PFS, and DOR by investigator assessment, pharmacokinetics, anti-drug antibodies, and patient-reported outcomes.

1. Shitara K et al. *N Engl J Med.* 2020;382:2419-30.

DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; GEJ, gastroesophageal junction; HER2, human epidermal growth factor receptor 2; ICR, independent central review; IHC, immunohistochemistry; ISH, in situ hybridization; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; T-DXd, trastuzumab deruxtecan; Q3W, every 3 weeks.

Best Percentage Change of Tumor Size from Baseline



^a3 patients were missing baseline or post-baseline target lesion assessment.
Red line at 20% indicates progressive disease; green line at -30% indicates partial response.
Analysis conducted in the full analysis set.

DESTINY-Lung01 Study Design

Multicenter, international, 2-cohort phase 2 trial (NCT03505710)

Cohort 1: HER2-overexpressing^c
(IHC 3+ or IHC 2+)
T-DXd 6.4 mg/kg q3w
N = 49

Cohort 1a: HER2-overexpressing^c
(IHC 3+ or IHC 2+)
T-DXd 5.4 mg/kg q3w
N = 41

Cohort 2:
***HER2*-mutated**
T-DXd 6.4 mg/kg q3w
N = 42

Cohort 2 expansion:
***HER2*-mutated**
T-DXd 6.4 mg/kg q3w
N = 49

Primary end point

- Confirmed ORR by ICR^d

Secondary end points

- DOR
- PFS
- OS
- DCR
- Safety

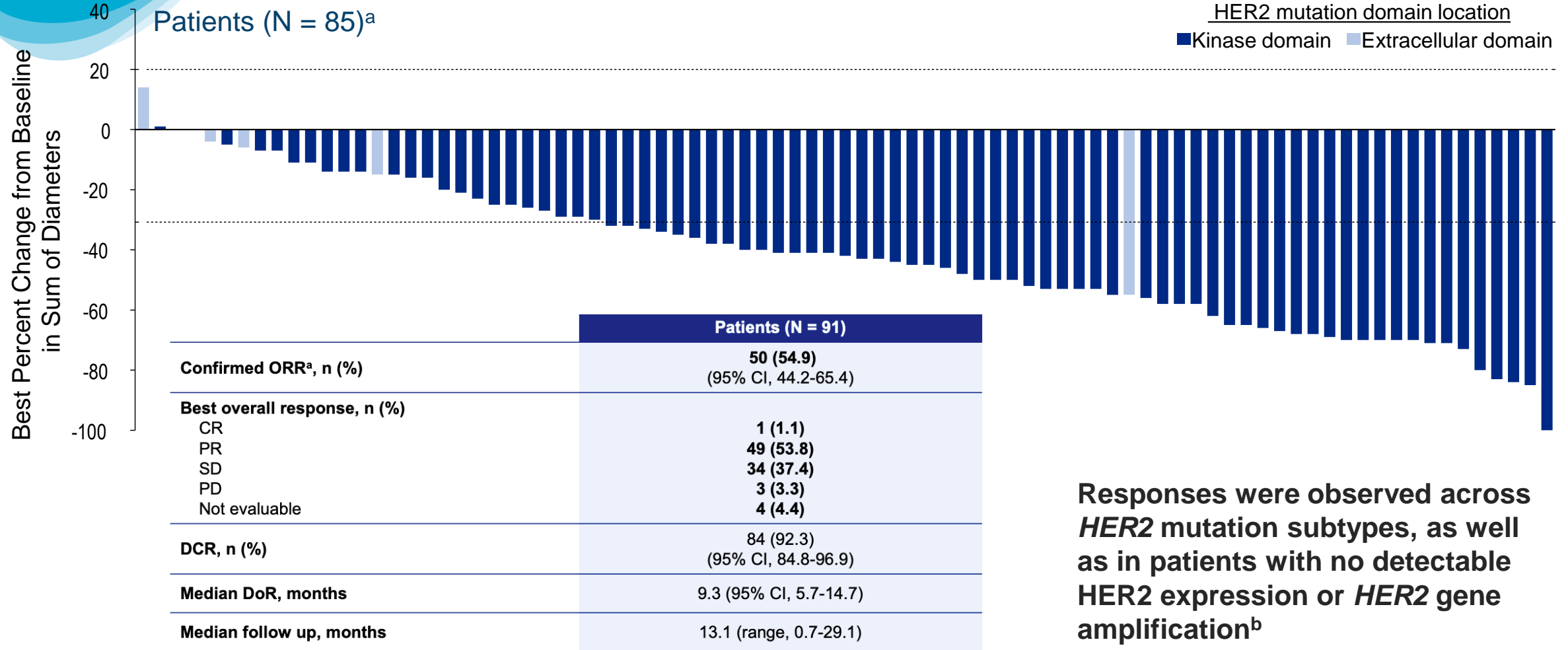
Exploratory end point

- Biomarkers of response

^aPatients with asymptomatic brain metastases not requiring ongoing steroid or anticonvulsant therapy were allowed to enroll ^bHER2 mutation documented solely from a liquid biopsy could not be used for enrolment ^cHER2 overexpression without known HER2 mutation was assessed by local assessment of archival tissue and centrally confirmed ^dPer RECIST v1.1

DCR, disease control rate; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; ICR, independent central review; IHC, immunohistochemistry; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PS, performance status; q3w, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.

Best Percentage Change of Tumor Size From Baseline



^aPrimary endpoint
 CR, complete response; DoR, duration of response; PD, progressive disease; PR, partial response; SD, stable disease.

^bBest change in tumor size by ICR for 85 of 91 patients for whom baseline and postbaseline data were available. Baseline is last measurement taken before enrollment. ^bThe OncoPrint™ Dx Target Test (Thermo Fisher Scientific) was used to confirm local *HER2* mutation status and to determine *HER2* amplification status. *HER2* protein expression status was determined by immunohistochemistry using a modified PATHWAY anti-*HER2* (4B5) (Ventana Medical Systems, Inc.) assay. Shown is best (minimum) percentage change from baseline in the sum of diameters for all target lesions; (-), negative; (+), positive; I, insertion; N, no; S, substitution; Y, yes. Blank cells (except for the prior *HER2* TKI therapy row) indicate patients whose tumor samples were not evaluable or assessed. The upper dashed horizontal line indicates a 20% increase in tumor size in the patients who had disease progression and the lower dashed line indicates a 30% decrease in tumor size (partial response).

Thank You!

Zorana Maravic

Chief Executive

Digestive Cancers Europe



Biomarker testing – challenges in gastrointestinal cancers

Patrick Michl

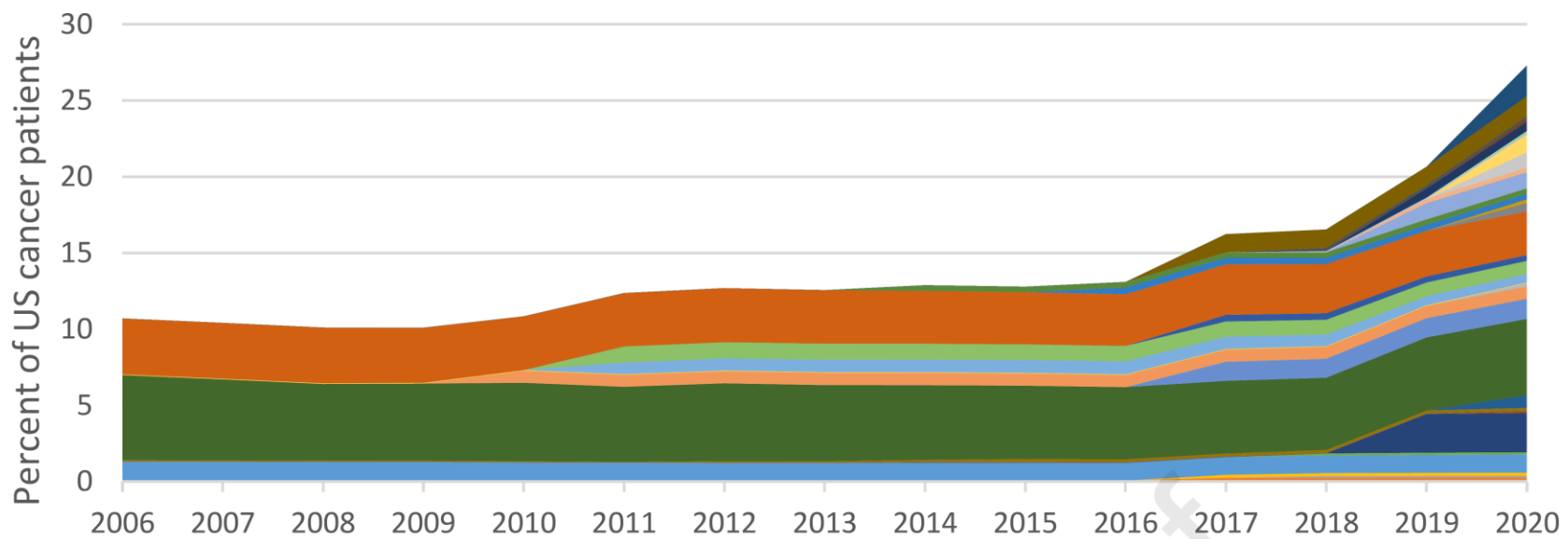
European Pancreatic Club

UEG Public Affairs Committee



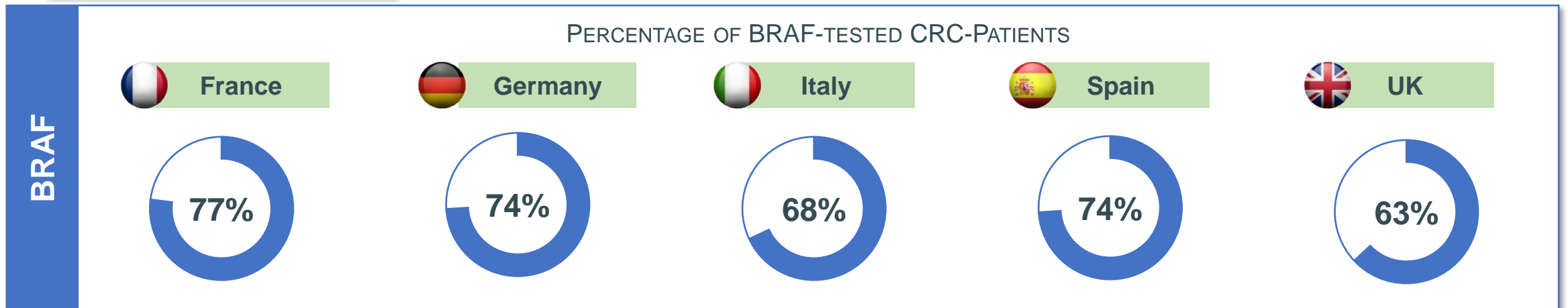
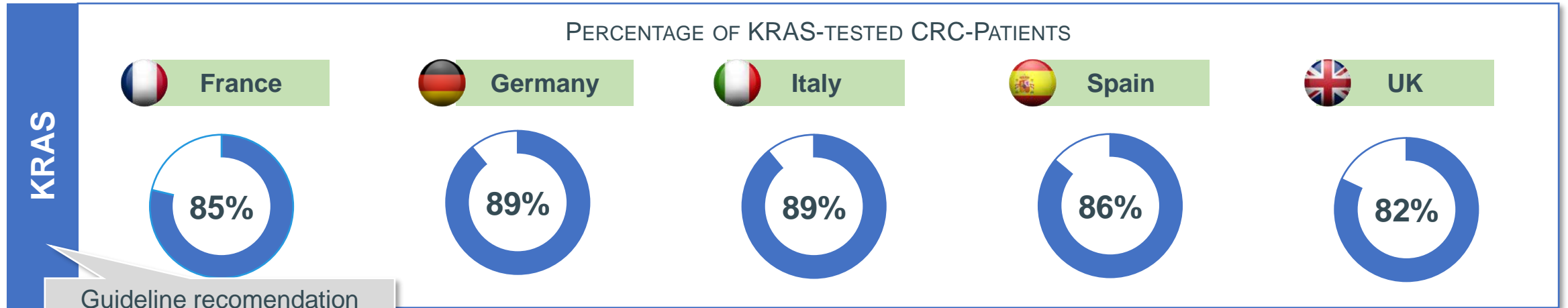
Estimated eligibility of genome informed therapy in cancer patients

Eligibility of Genomically Informed Therapy



- ▶▶▶ ALL Ph+
- ▶▶▶ AML FLT3
- ▶▶▶ AML IDH1
- ▶▶▶ AML IDH2
- ▶▶▶ Breast HER2
- ▶▶▶ Breast BRCA
- ▶▶▶ Breast PIK3CA
- ▶▶▶ Cholangiocarcinoma FGFR2
- ▶▶▶ CLL 17p
- ▶▶▶ CML Ph+
- ▶▶▶ CRC BRAF
- ▶▶▶ CRC KRAS
- ▶▶▶ CRC MSI/MMR
- ▶▶▶ Gastric HER2
- ▶▶▶ Gastric PDGFRA
- ▶▶▶ GIST
- ▶▶▶ Melanoma BRAF V600
- ▶▶▶ NSCLC ALK
- ▶▶▶ NSCLC BRAF
- ▶▶▶ NSCLC EGFR
- ▶▶▶ NSCLC MET
- ▶▶▶ NSCLC RET
- ▶▶▶ NSCLC ROS1
- ▶▶▶ Ovarian BRCA
- ▶▶▶ Ovarian HRD
- ▶▶▶ Pancreatic BRCA
- ▶▶▶ Prostate HHA
- ▶▶▶ Prostate BRCA
- ▶▶▶ Thyroid BRAF
- ▶▶▶ Thyroid RET
- ▶▶▶ Urothelial FGFR
- ▶▶▶ Follicular EZH2

Current disparities across Europe: KRAS- and BRAF testing for colorectal cancer



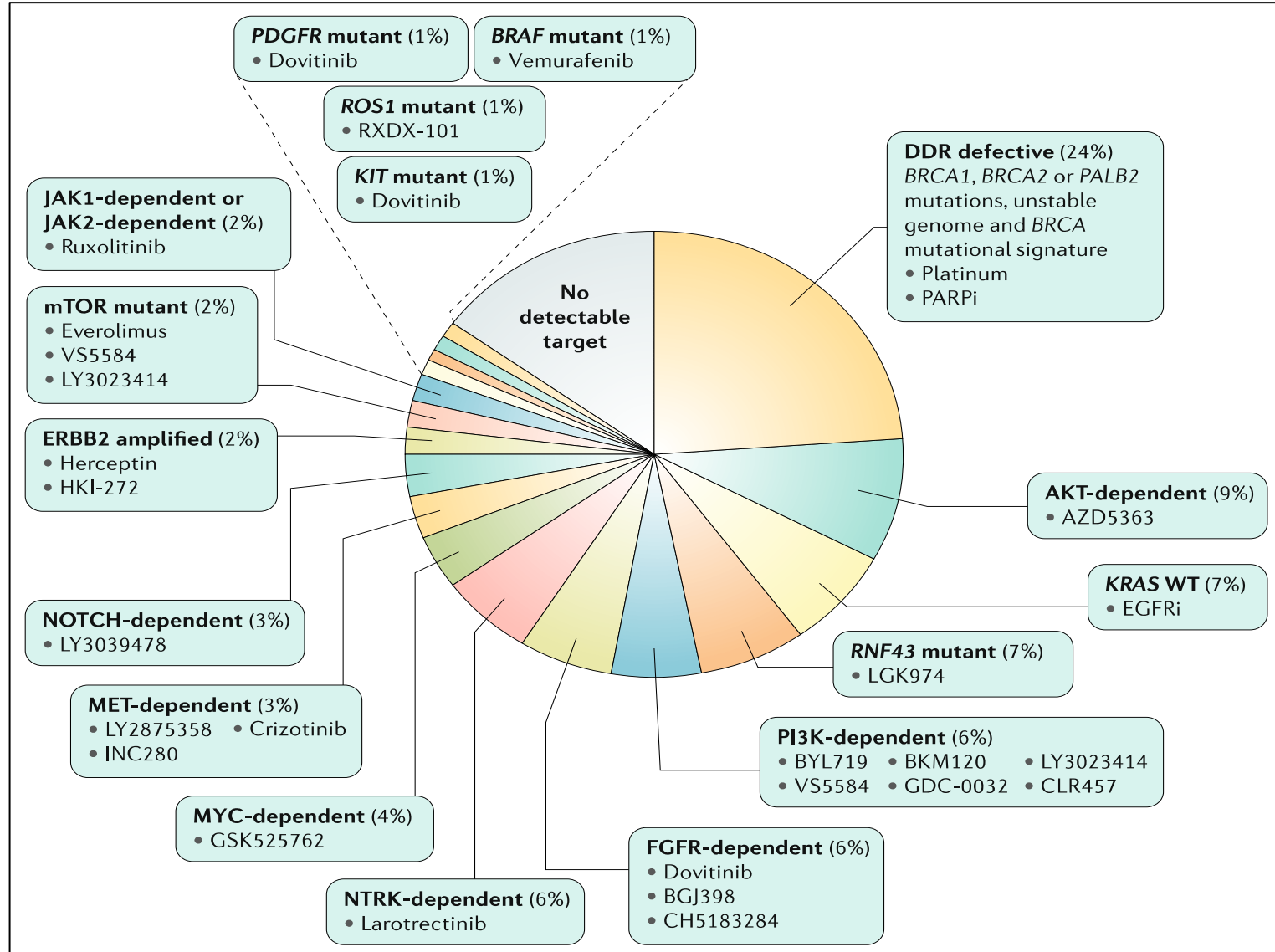
COLORECTAL: Actual availability		
Country:	Cetuximab	Panitumumab
Austria	Always	Always
Belgium	Always	Always
Cyprus	Always	Never
Denmark	Always	Always
Finland	Usually	Usually
France	Always	Always
Germany	Always	Always
Greece	Not available	Usually
Holland	Always	Always
Iceland	Always	Always
Ireland	Always	Always
Israel	Always	Always
Italy	Always	Always
Luxembourg	Always	Always
Norway	Always	Always
Portugal	Usually	Always
Spain	Always	Always
Sweden	Usually	Usually
Switzerland	Always	Always
Turkey	Always	Always
United Kingdom	Always	Always
Albania	Never	Not available
Armenia	Half the time	Half the time
Belarus	Usually	Not available
Bosnia and Herzegovina	Occasionally	Always
Bulgaria	Occasionally	Occasionally
Croatia	Always	Not available
Czech Republic	Always	Always
Estonia	Always	Always
Georgia	Occasionally	Never
Hungary	Always	Never
Kazakhstan	Always	Occasionally
Kosovo, Republic of	Not available	Not available
Kyrgyzstan	Occasionally	Occasionally
Latvia	Always	Always
Lithuania	Always	Occasionally
Macedonia	Not available	Not available
Malta	Always	Usually
Montenegro	Always	Half the time
Poland	Always	Always
Romania	Always	Never
Russian Federation	Occasionally	Occasionally
Serbia	Always	Not available
Slovenia	Usually	Occasionally
Slovakia	Usually	Always
Turkmenistan	Not available	Not available
Ukraine	Usually	Usually
Uzbekistan	Not available	Not available

Always
Usually
Half the time
Occasionally
Never
Not available
Missing data

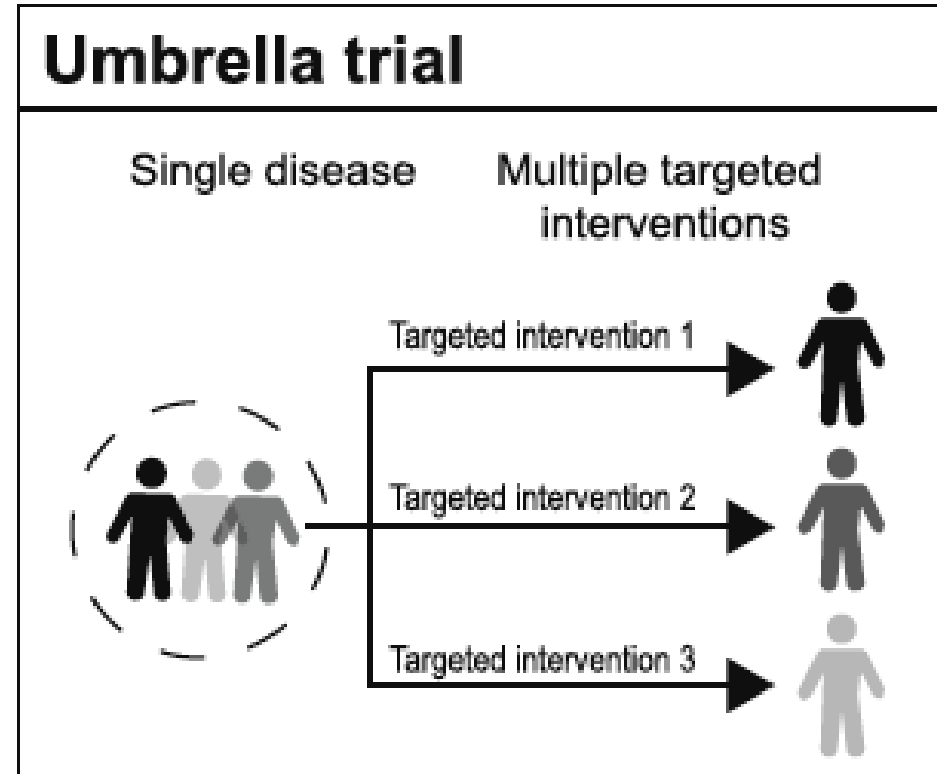
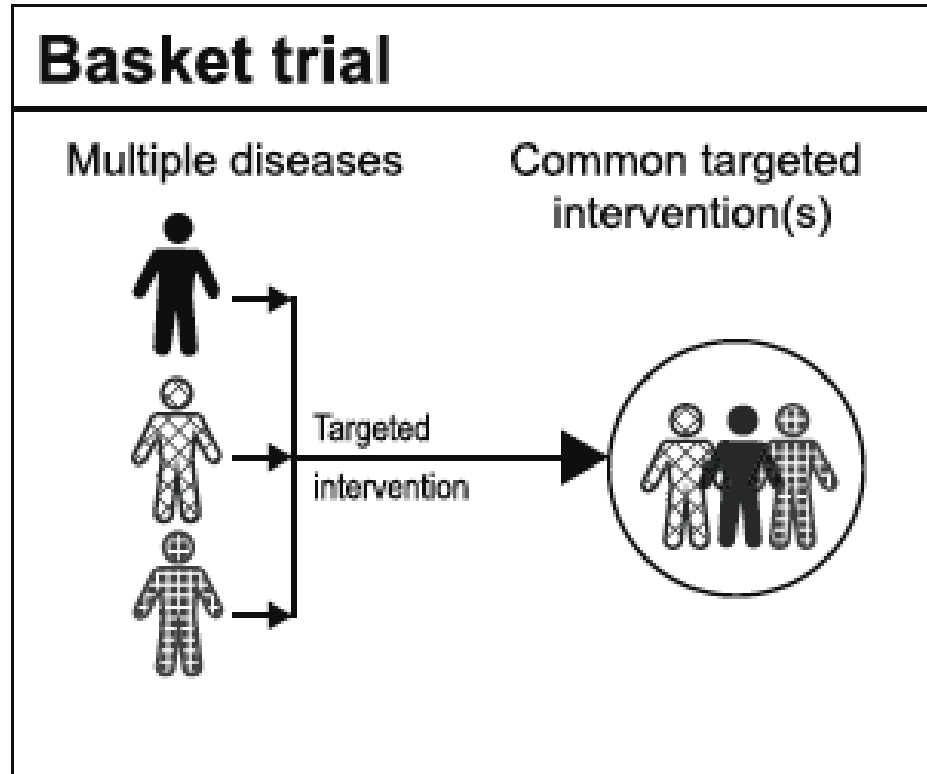
Colorectal Cancer: Disparities in availability of EGFR- antibodies across Europe



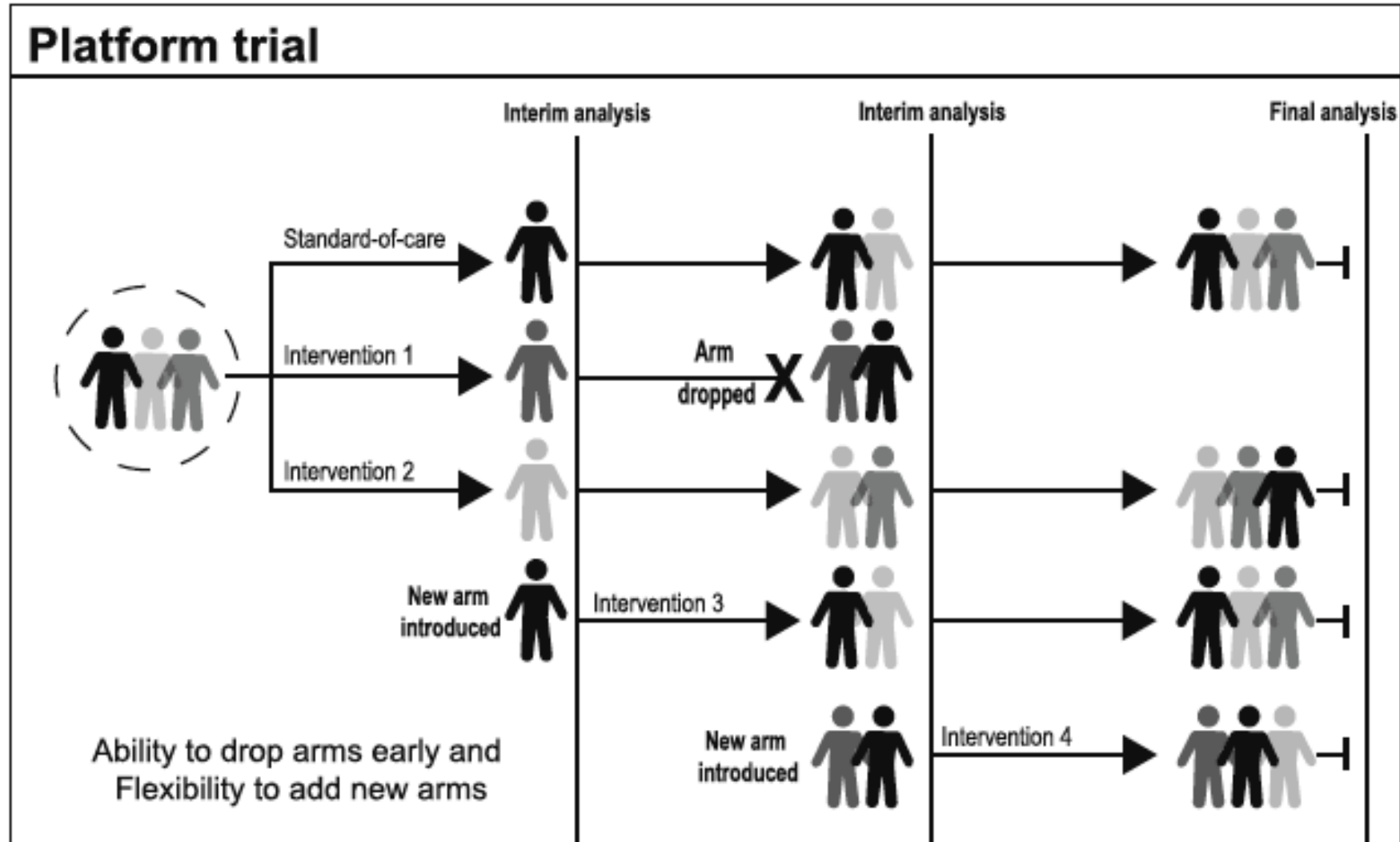
Challenge genetic heterogeneity in GI cancers: Pancreatic cancer as example



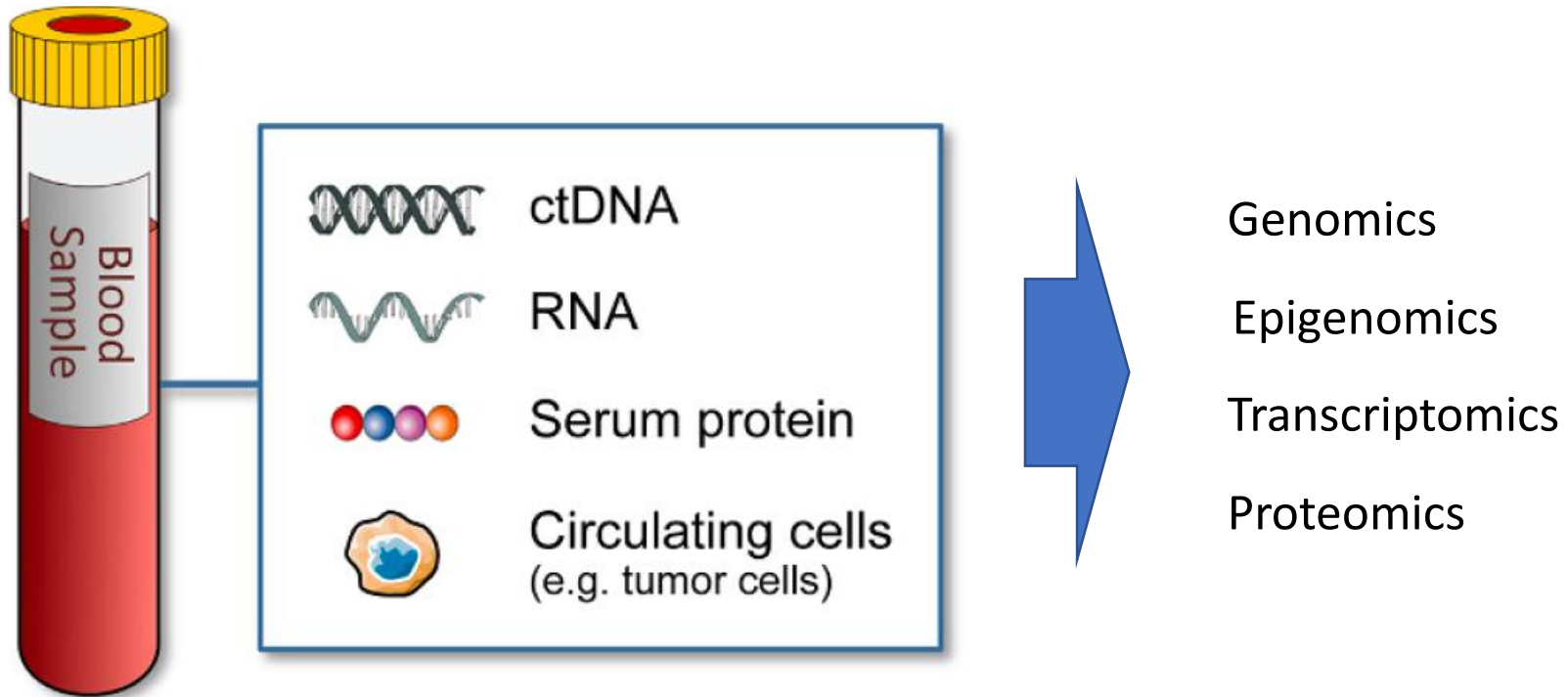
Novel trial designs for evaluation of multiple biomarkers: „Basket“ versus „Umbrella“ trials



Adaptive platform trial design



Challenge: complexity of –omics biomarkers



Challenges for biomarker-driven therapies across Europe

- Increasing availability of current standard biomarker testing across Europe
- Combining suitable panels of multi -omics biomarkers (protein, miRNA, lncRNA, ctDNA, circulating tumor cells) to increase predictive accuracy
- Integrating artificial intelligence in better defining discriminative biomarker combinations
- Validation of promising candidate biomarkers in large multinational platform trials with adaptive design

Multi-stakeholder partnerships from industry, academia and politics on a European level required!

Thank You!



Opportunities for progress in metastatic breast cancer

Matti Aapro

President, European Cancer Organisation

Fatima Cardoso

President, ABC Global Alliance

Tanja Spanic

President, Europa Donna

Community 365 Roundtable Meeting on Metastatic Cancer

Overview of current issues in METASTATIC BREAST CANCER

F. Cardoso, MD

Director, Breast Unit, Champalimaud Clinical Center, Lisbon, Portugal

Chair, ABC Global Alliance and ABC Guidelines

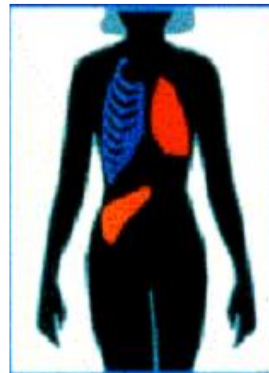
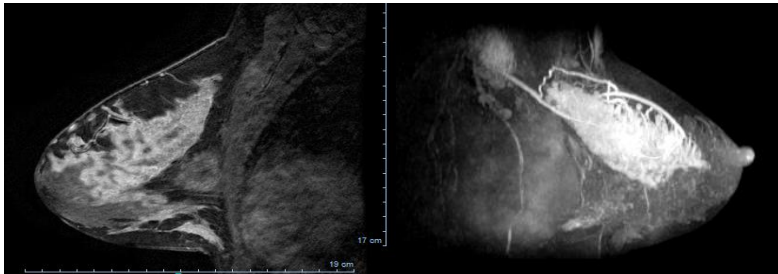
ESO Scientific Committee



DEFINITION OF ABC and MBC

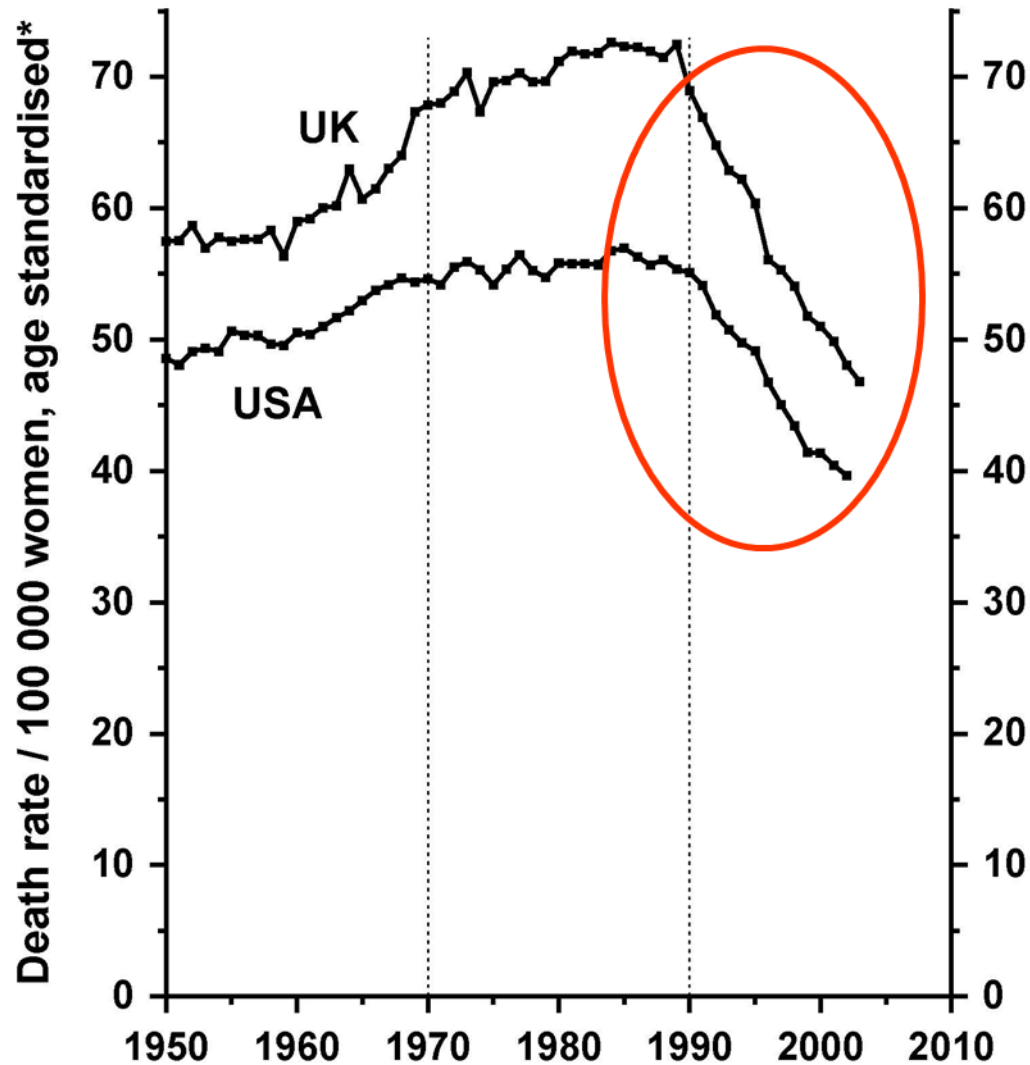
Includes 2 clinical situations:

1. **Inoperable Locally Advanced Breast Cancer (LABC)**, that has not yet spread to distant sites
2. **Metastatic Breast Cancer**, that has spread to distant sites (most common are bone, liver, lung, brain, lymph nodes); also called Stage IV breast cancer.



WHY DO WE NEED TO FOCUS ON ABC/MBC?

UK and USA 1950–2003/2: Females Breast cancer mortality at ages 35–69



*Mean of annual rates in the seven component 5-year age groups

Source: WHO mortality & UN population estimates

EBC OUTCOME EVOLUTION

Breast Cancer

Despite ↑ incidence - ↓ mortality

* Screening & early diagnosis
(introduced in the late 70's/80's)

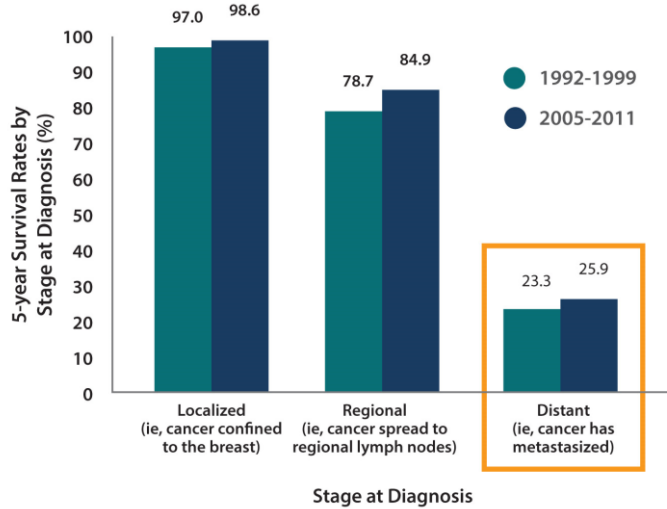
* Education & advocacy

but also

- Better treatment options/strategies
(adjuvant CT and tamoxifen developed in the late 70's/80's)

5 year survival rates for mBC still around 25%

5-year Survival Rates by Stage at Diagnosis (Female Breast Cancer, US SEER), 1992-1999 Compared with 2005-2011^{1,2}



- American Cancer Society. Breast Cancer Facts & Figures 2003-2004. Atlanta, GA: American Cancer Society; 2003.
- National Cancer Institute. SEER stat fact sheets: breast cancer. <http://seer.cancer.gov/statfacts/html/breast.html>. Accessed July 31, 2015.



Cardoso et al. Global Analysis of Advanced/Metastatic Breast Cancer: Decade Report (2005–2015). *The Breast* 39: 131-138, 2018.

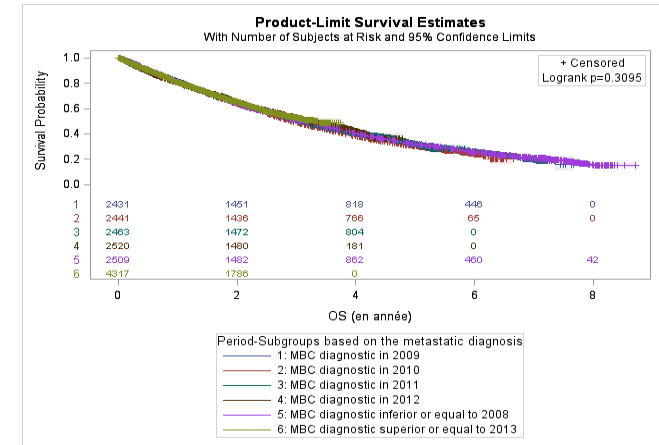
ABC OUTCOME EVOLUTION



Delaloge et al, ASCO 2017, Gobbini et al, EJC 2018

Evolution of OS over time

Observed Overall Survival From Diagnosis of Metastatic Disease
All Patients



Median FU for the whole cohort is 4.05 yrs [95 CI: 3.98-4.12]

Period	2008	2009	2010	2011	2012	2013
Median OS (95% CI)(yrs)	3.12 [2.92-3.31]	2.94 [2.78-3.09]	3.09 [2.94-3.24]	3.23 [3.02-3.48]	3.09 [2.89-3.25]	3.29 [3.09-ND]

Prognosis of de novo & recurrent MBC diverges over time

Breast Cancer Res Treat
DOI 10.1007/s10549-017-4529-5

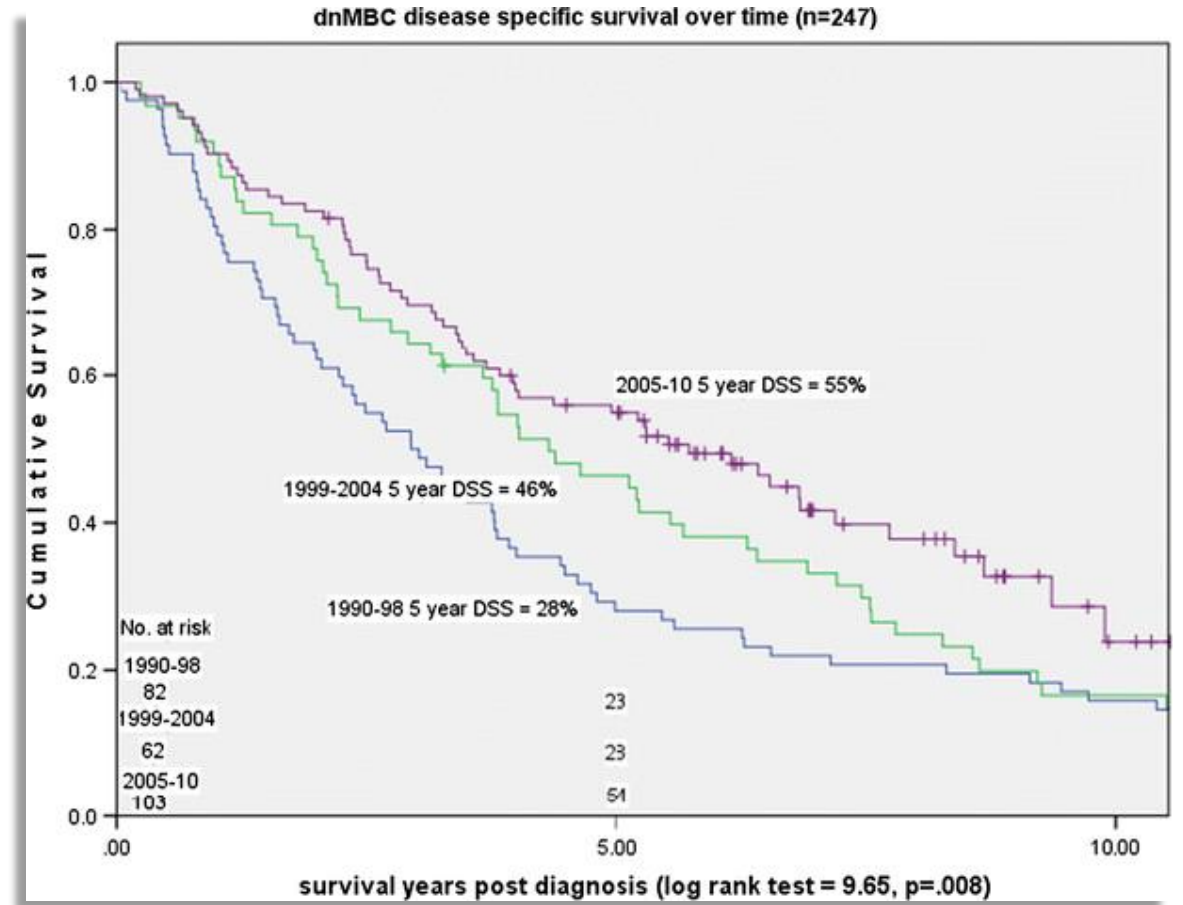
CrossMark

EPIDEMIOLOGY

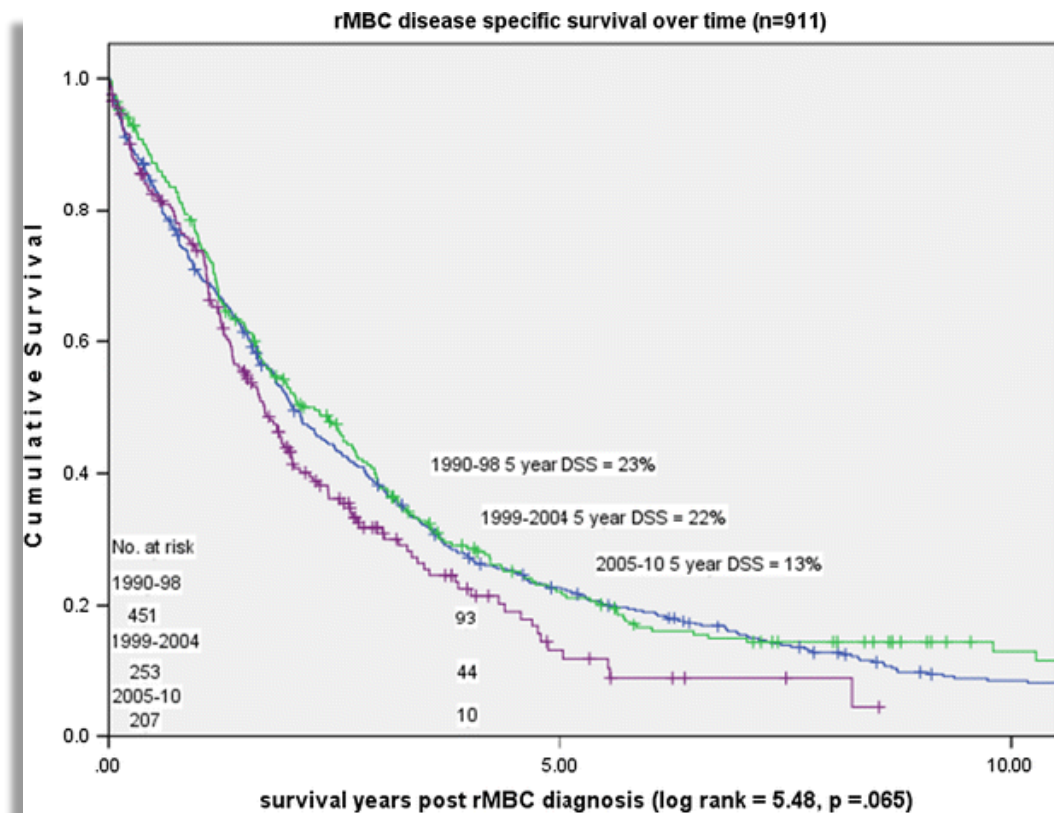
Differential presentation and survival of de novo and recurrent metastatic breast cancer over time: 1990–2010

Judith A. Malmgren^{1,2} · Musa Mayer³ · Mary K. Atwood⁴ · Henry G. Kaplan⁴

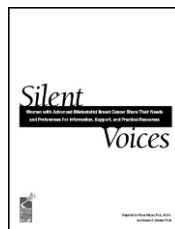
de novo MBC
mean survival = 5.03 yrs



Recurrent MBC
mean survival = 2.81 yrs



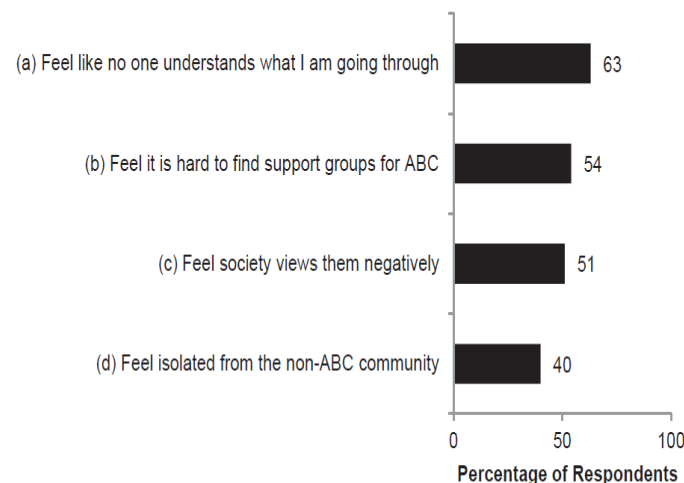
THE PSYCHOLOGICAL SUFFERING OF HAVING AN UNCURABLE AND OFTEN FORGOTTEN DISEASE...



- Most women do not feel that healthcare professionals, researchers, the media, women with EBC, and the governments pay enough attention to MBC.
- Throughout the survey there is a worrying picture of feelings of guilt, abandonment, isolation, and loneliness during the hard journey through MBC..
- 44% of respondents reported being afraid to talk open about their disease and 52% said their friends and family were uneasy talking about the disease.

Seminars in Oncology Nursing (26) 3, 2010; Community Oncology, Sep. 2010

Women with ABC feel isolated



B How women with ABC feel about their lives

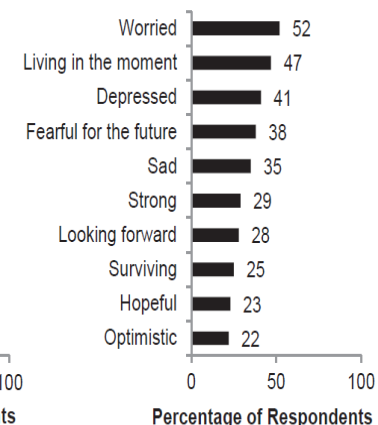


Fig. 1. Emotional needs of patients with ABC. (A) Percentages of respondents who strongly agreed or agreed somewhat with the statements. Statements (a), (b), and (d) refer to the Count Us, Know Us, Join Us survey (women with ABC, weighted base $n = 1065$), whereas statement (c) refers to the Here & Now (H&N) survey (women with ABC and their caregivers, $N = 304$). (B) How respondents (women with ABC and their caregivers, $N = 304$) in the H&N survey viewed their life after diagnosis of ABC. Abbreviation: ABC, advanced breast cancer.

HOW CAN WE CHANGE THIS?

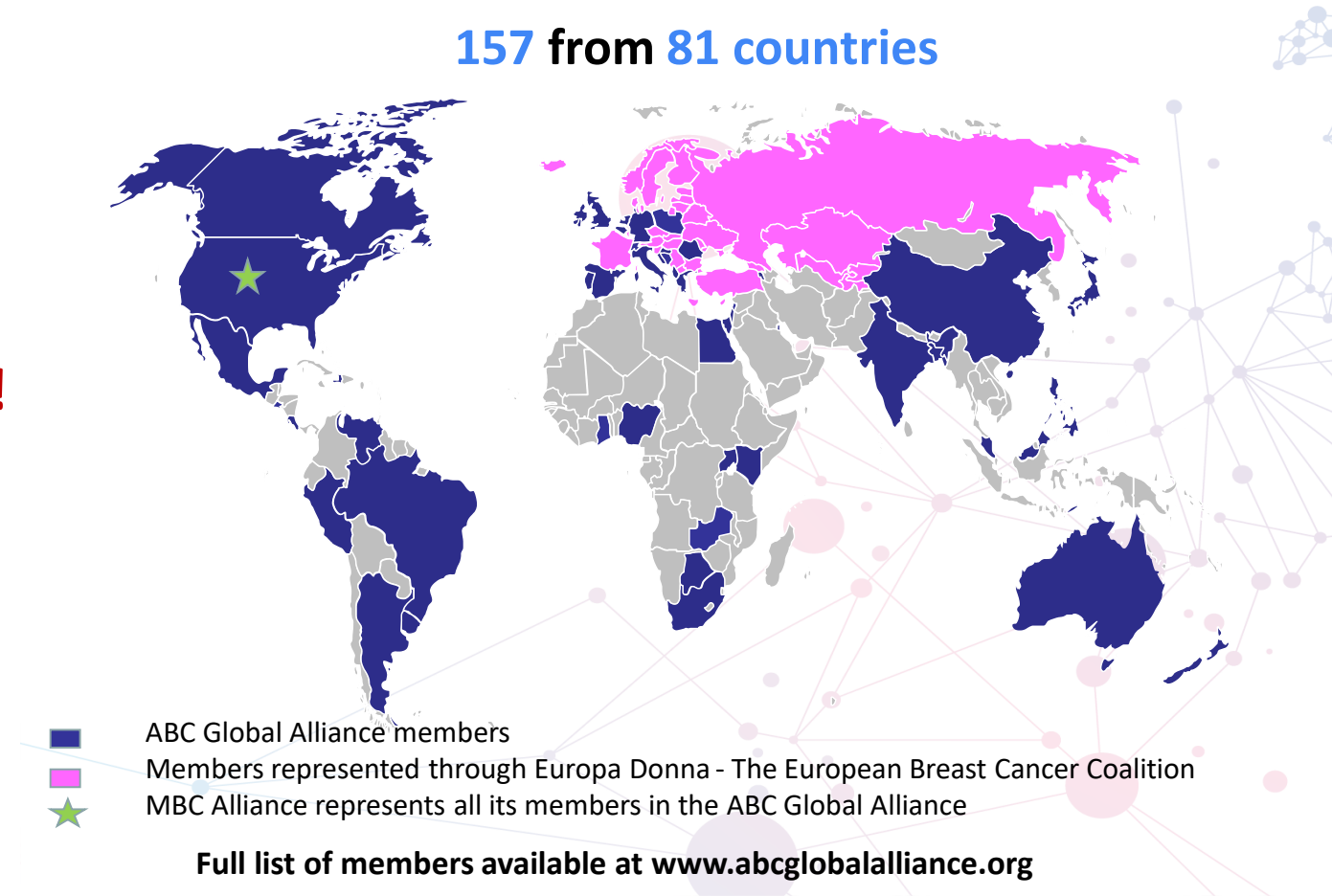


The ABC Global Alliance
Continuing the work of the ABC Consensus
Conference and Guidelines

Members as of March 2021

157 from 81 countries

GET TOGETHER!
COLLABORATE!
SHARE RESOURCES AND KNOWLEDGE!



Full list of members available at www.abcgloballiance.org

Website www.abcgloballiance.org

Email rventura@abcgloballiance.org

Social media [@ABCGlobalAll](https://twitter.com/ABCGlobalAll)

What has changed the outcome of Early BC leading to important decreased mortality, and that must also be applied in Advanced BC:

GUIDELINES



1500 participants
from 90 countries



www.abc-lisbon.org

MULTIDISCIPLINARY CARE



MULTIDISCIPLINARY TEAM

Indispensable for

EBC
LABC
MBC

In **CLINICAL PRACTICE & RESEARCH**

**TREATMENT ACCORDING TO GUIDELINES
IMPROVES SURVIVAL AND QoL**





Bridging the Gap

PLEASE JOIN US!!!

Sixth International Consensus Conference

4-6 November 2021

VIRTUAL MEETING

Advanced Breast Cancer

Chair: F. Cardoso, PT

Co- Chair: R. Haidinger, DE

Honorary Chairs: E.P. Winer, US

L. Norton, US – A. Costa, CH/IT

Scientific Committee: N. El Saghir, LB - A. Eniu, CH

S. Paluch-Shimon, IL - F. Penault-Llorca, FR

H. Rugo, US - T. Wiseman, UK

recommended by



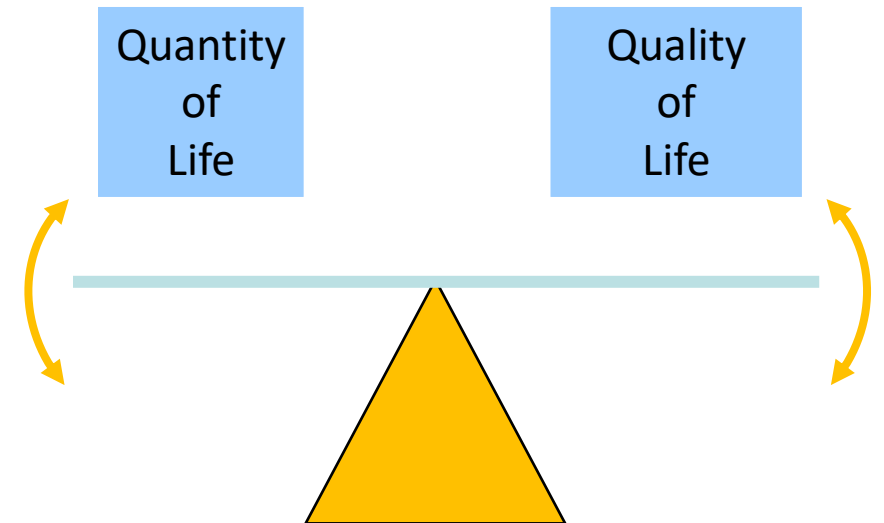
Reveive updates on
www.abc-lisbon.org
#ABClisbon

INTEGRATING PATIENTS' PERSPECTIVE

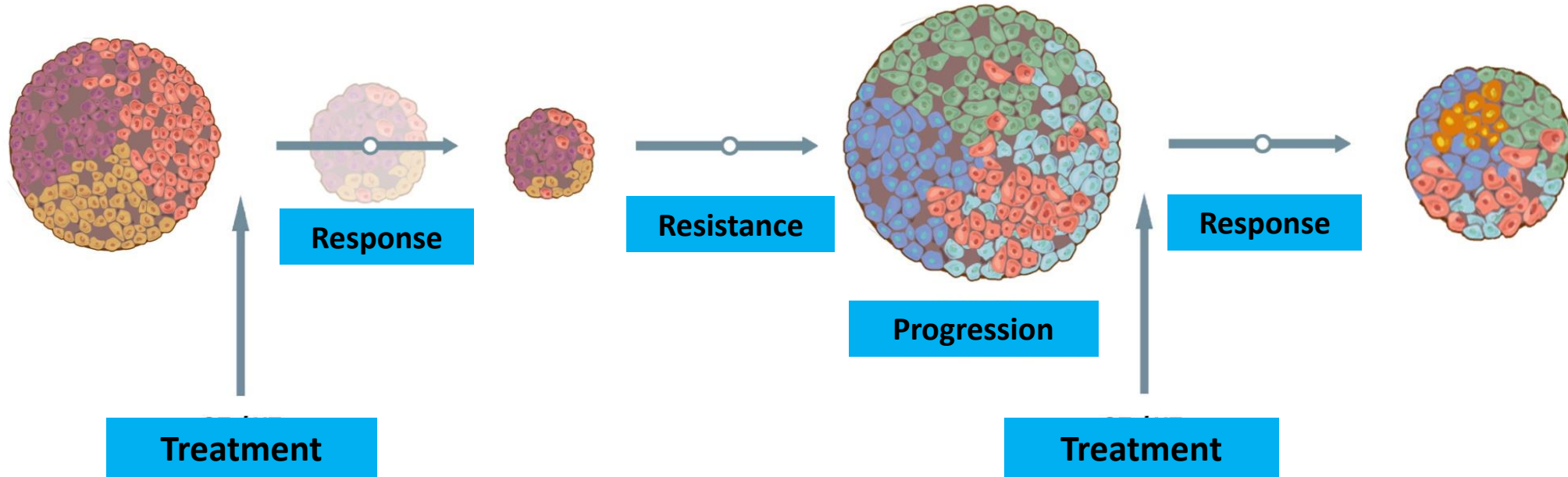
- DEFINE PRIORITIES TOGETHER
- DEFINE GOALS OF TREATMENT: DELICATE BALANCE BETWEEN QUANTITY AND QUALITY OF LIFE IN METASTATIC DISEASE – very personal
- ACCEPTABLE TOXICITY SHOULD BE DEFINED BY THE PATIENT
- DEFINE TOGETHER WHICH ENDPOINTS TRULY MATTER
- DEFINE TOGETHER WHAT IS “MEANINGFUL BENEFIT”
- COMMUNICATION
- AWARENESS/EDUCATION/FIGHT STIGMA

Goals of PATIENT-CENTERED treatment in ABC

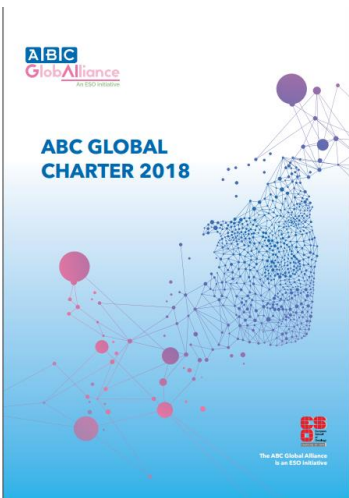
- **Balancing treatment efficacy and toxicity is the main objective**
- **Goals of treatment:**
 - **Improve survival**
 - **Delay disease progression**
 - **Prolong duration of response**
 - **Palliate symptoms**
 - **Improve or maintain quality of life**
 - **In the near future, transform into a chronic disease**



THE MAJOR PROBLEM OF TUMOR RESISTANCE TO THERAPY



**CRUCIAL IMPORTANCE OF HAVING ACCESS TO
SEVERAL TYPES/LINES OF TREATMENT**



ABC Global Charter

10 goals for the next 10 years

DEFINE PRIORITIES TOGETHER

COMPREHENSIVE NEEDS ASSESSMENT

DEFINES MOST URGENT AND ACTIONABLE GOALS

Done with (almost) all different stakeholders involved in ABC

1 HELP PATIENTS WITH ABC LIVE LONGER BY DOUBLING ABC MEDIAN OVERALL SURVIVAL BY 2025

2 ENHANCE OUR UNDERSTANDING ABOUT ABC BY INCREASING THE COLLECTION OF HIGH QUALITY DATA

3 IMPROVE THE QUALITY OF LIFE (QOL) OF PATIENTS WITH ABC

4 ENSURE THAT ALL PATIENTS WITH ABC RECEIVE THE BEST POSSIBLE TREATMENT AND CARE BY INCREASING AVAILABILITY OF ACCESS TO CARE FROM A MULTIDISCIPLINARY TEAM

5 IMPROVE COMMUNICATION BETWEEN HEALTHCARE PROFESSIONALS (HCP) AND PATIENTS WITH ABC THROUGH THE PROVISION OF COMMUNICATION SKILLS TRAINING FOR HCPS

6 MEET THE INFORMATIONAL NEEDS OF PATIENTS WITH ABC BY USING EASY TO UNDERSTAND, ACCURATE AND UP-TO-DATE INFORMATION MATERIALS AND RESOURCES

7 ENSURE THAT PATIENTS WITH ABC ARE MADE AWARE OF AND ARE REFERRED TO NON-CLINICAL SUPPORT SERVICES

8 COUNTERACT THE STIGMA AND ISOLATION ASSOCIATED WITH LIVING WITH ABC BY INCREASING PUBLIC UNDERSTANDING OF THE CONDITION

9 ENSURE THAT PATIENTS WITH ABC HAVE ACCESS TO TREATMENT REGARDLESS OF THEIR ABILITY TO PAY

10 HELP PATIENTS WITH ABC CONTINUE TO WORK BY IMPLEMENTING LEGISLATION THAT PROTECTS THEIR RIGHTS TO WORK AND ENSURE FLEXIBLE AND ACCOMMODATING WORKPLACE ENVIRONMENTS



International Agency
Research on Cancer



2 ENHANCE OUR UNDERSTANDING
ABOUT ABC BY INCREASING THE
COLLECTION OF HIGH QUALITY DATA
(Goal n° 2)

MAIN GOALS

- 1) How to track the ABC patient
- 2) Minimum set of data to collect
- 3) Harmonize definitions
- 4) Determine the PREVALENCE OF ABC

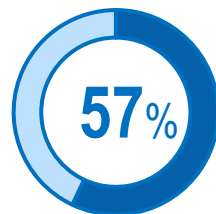
PROBLEM:

**CANCER REGISTRIES DO NOT
REGISTER RELAPSES!**

(Goal n° 10)

- 10 HELP PATIENTS WITH ABC CONTINUE TO WORK BY IMPLEMENTING LEGISLATION THAT PROTECTS THEIR RIGHTS TO WORK AND ENSURE FLEXIBLE AND ACCOMMODATING WORKPLACE ENVIRONMENTS

ECONOMIC IMPACT



Patients in paid employment

75%

Had to make changes to employment post diagnosis

Suffered income decline

70%

Suffered stress due to changes in financial situations

The Invisible Woman 2.0 report - Five years on
<https://www.wearehereandnow.com/invisible-woman.html>

PROBLEM:

**INDIRECT COSTS OF CANCER:
LOSS OF PRODUCTIVITY!
FINANCIAL BURDEN PTS & FAMILIES
PSYCHOLOGICAL BURDEN!**

I have cancer but I want to work

MARC BEISHON



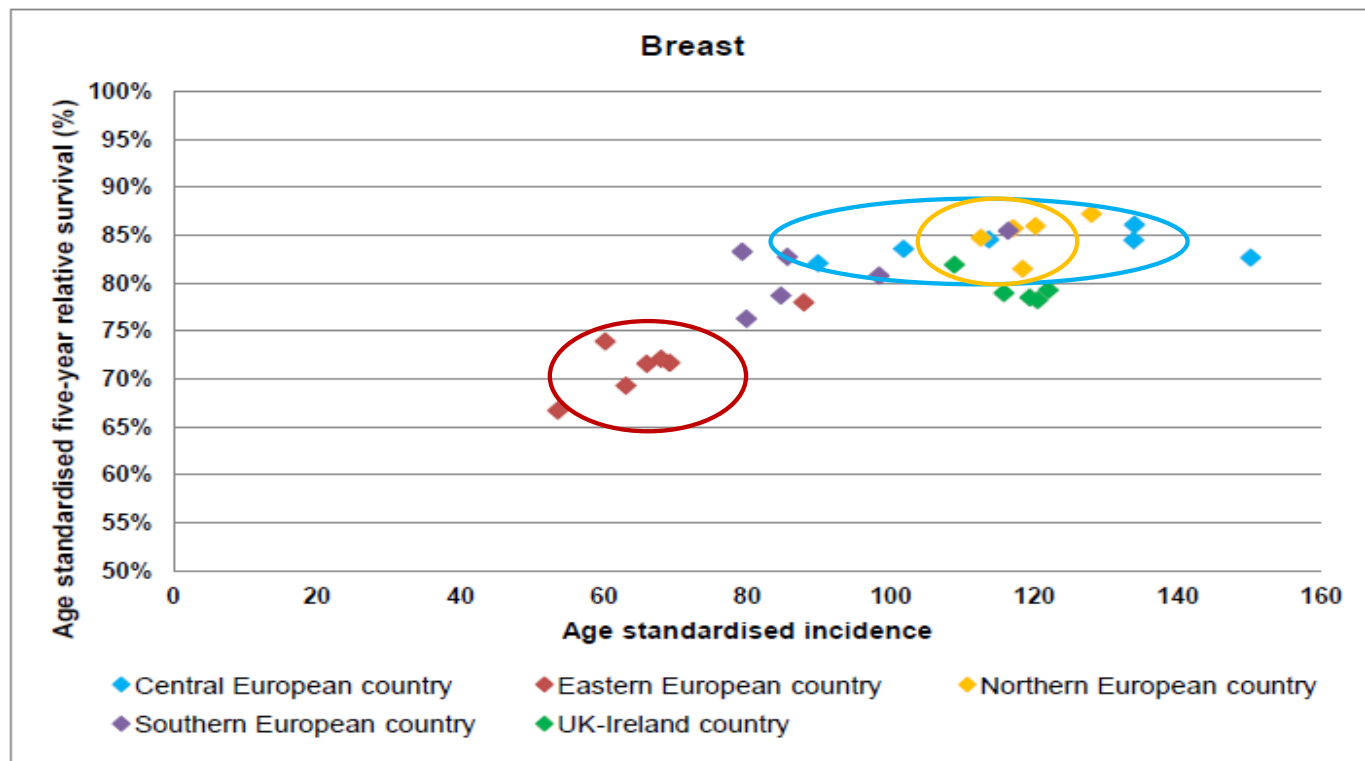
CHANGE WORK-RELATED LAWS
Ability to work part-time, flexible timetables, work from home, fight stigma and prejudice at work...

Brussels organised last November by the ABC Global Alliance, the multistakeholder organisation for tackling the many issues faced by people with advanced breast cancer.

A TREATMENT CAN ONLY BE EFFICACIOUS IF IT IS ACCESSIBLE!

Disparities in cancer outcomes (survival) across Europe

Figures 2: Age-standardised incidence (rates per 100,000 person-year) vs. age-standardised five-year relative survival (%) for cancers of breast (women), prostate, skin melanoma by European region. Period of diagnosis 2000-2007. Countries represented by dots.



INEQUALITIES IN ACCESS TO CARE exist between countries but also within each country

INEQUALITIES IN ACCESS TO CARE are directly LINKED TO OUTCOME

DEFINE TOGETHER WHAT IS “MEANINGFUL BENEFIT”

- **Not everything that is approved has meaningful benefit**
- **Not every “positive” trial is a true step forward**
- **Not always the new therapy is better than the old one**
- **Cost should be linked to benefit**
- **We should all be responsible in our decisions**



European Society for Medical Oncology

ESMO Magnitude of Clinical Benefit Scale

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

American Society of Clinical Oncology Statement:
A Conceptual Framework to Assess the Value of Cancer
Treatment Options

Lowell E. Schipper, Nancy E. Davidson, Dana S. Wollins, Courtney Tyme, Douglas W. Blayney, Diane Blum, Adam P. Dickler, Patricia A. Ganz, J. Russell Hoverman, Robert Langdon, Gary H. Lyman, Neal J. Meropol, Therese Mulvey, Lee Newcomer, Jeffrey Peppercorn, Blaise Polite, Derek Raghavan, Gregory Rossi, Leonard Saltz, Deborah Schrag, Thomas J. Smith, Peter P. Yu, Clifford A. Hudis, and Richard L. Schilsky



Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst



Editorial: Why are guidelines not followed in clinical practice?



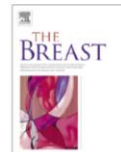
NEED FOR CHANGE IN REIMBURSEMENT RULES
In many countries, current rules do not facilitate oral, less toxic treatments, nor shorter treatments of radiotherapy



Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst



Viewpoints and debate

Why is appropriate healthcare inaccessible for many European breast cancer patients? – The EBCC 12 manifesto



Fatima Cardoso ^{a,*}, Fiona MacNeill ^b, Frederique Penault-Llorca ^c, Alexandru Eniu ^{d,e},
Francesco Sardanelli ^{f,g}, Elizabeth Bergsten Nordström ^h,
Philip Poortmans ⁱ, on behalf of the EBCC12-Faculty

Thank You!

Olivia Pagani

Breast Cancer Programme Coordinator, European School Of
Oncology (ESO)

Breast Cancer Consultant, Hopital Riviera-Chablais, Rennaz,
Vaud

Anything different in young women?

Olivia Pagani



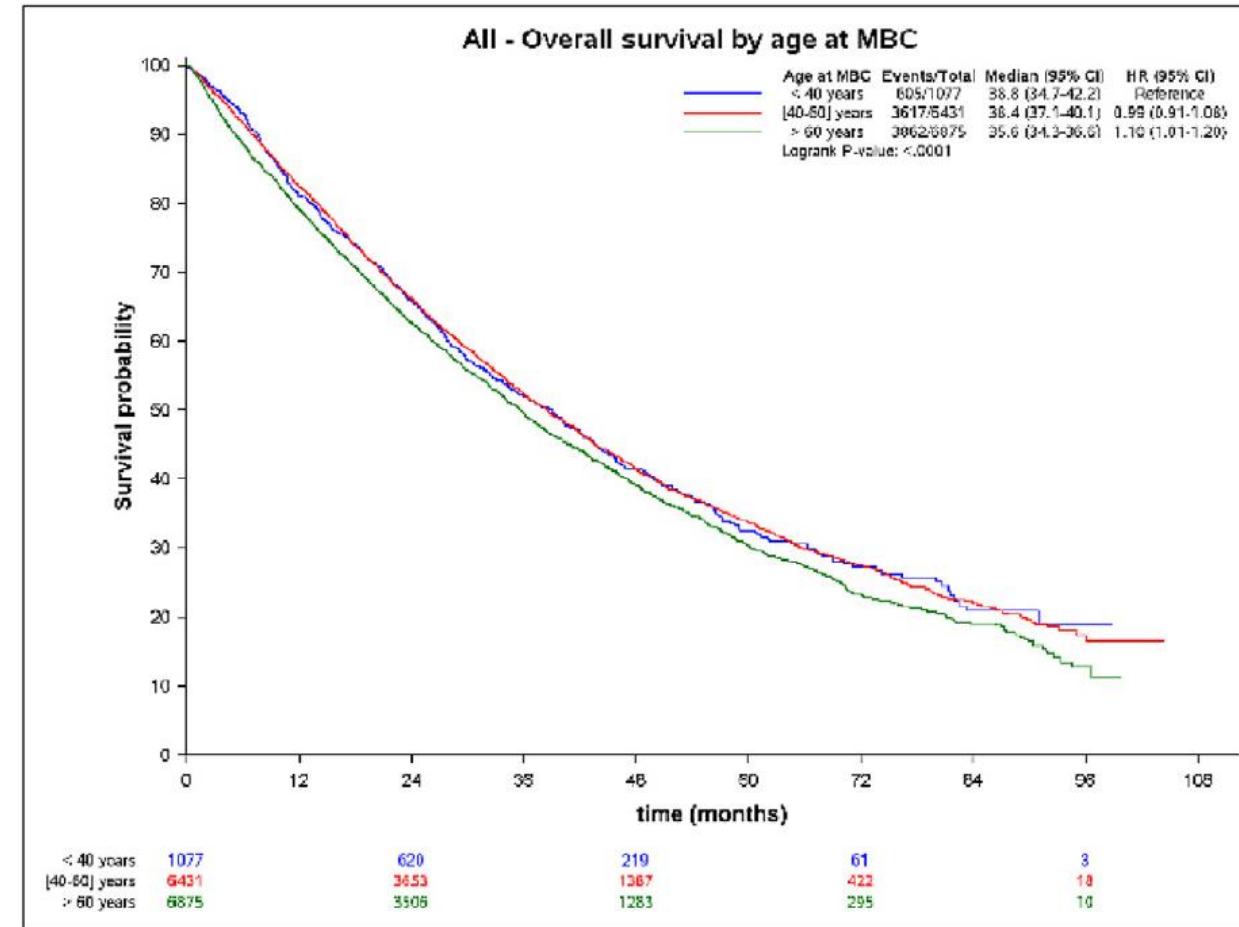
Impact of age at diagnosis of metastatic breast cancer on overall survival in the real-life ESME metastatic breast cancer cohort

Sophie Frank ^{a,*}, Matthieu Carton ^a, Coraline Dubot ^a, Mario Campone ^b, Barbara Pistilli ^c, Florence Dalenc ^d, Audrey Mailliez ^e, Christelle Levy ^f, Véronique D'Hondt ^g, Marc Debled ^h, Thomas Vermeulin ⁱ, Bruno Coudert ^j, Christophe Perrin ^k, Anthony Gonçalves ^l, Lionel Uwer ^m, Jean-Marc Ferrero ⁿ, Jean-Christophe Eymard ^o, Thierry Petit ^p, Marie-Ange Mouret-Reynier ^q, Anne Patsouris ^r, Tahar Guesmia ^s, Thomas Bachelot ^t, Mathieu Robain ^s, Paul Cottu ^a

14.403 women included

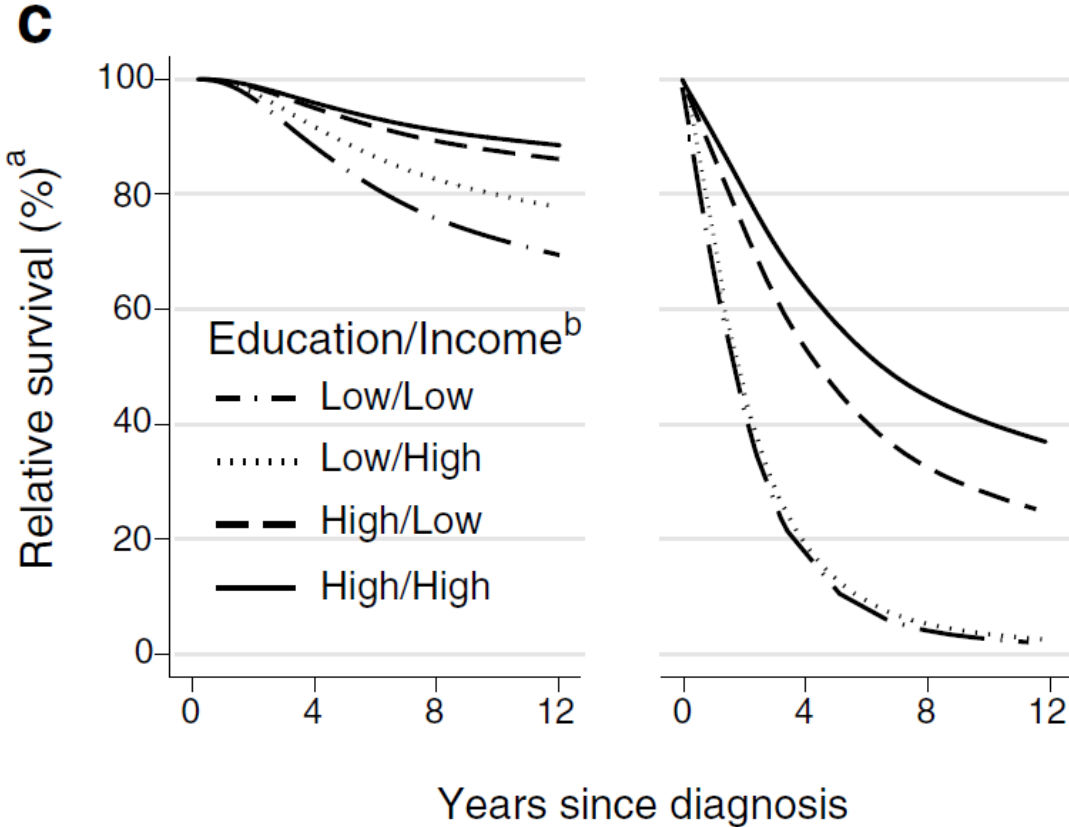
1077 (7.5%) <40 years at MBC diagnosis

Although young age is associated with more aggressive presentations at diagnosis of MBC, it has no deleterious effect on OS in this large series, at a median follow-up of 48 months



Stage-specific survival has improved for young breast cancer patients since 2000: but not equally

Cassia Bree Trewin^{1,2,3} · Anna Louise Viktoria Johansson^{4,5} · Kirsti Vik Hjerkind² · Bjørn Heine Strand^{6,7,8} · Cecilie Essholt Kiserud⁹ · Giske Ursin^{5,10,11}



General recommendations

Overall, the stage-specific outcome of young BC patients has improved over the years due to diagnostic and treatment advances.

Nonetheless, even in countries with universal health care, these improvements are significantly lower for women with low socio-economic status (SES) compared to those with high SES.

Every young BC patient must have access to optimal cancer treatment and supportive care according to the highest standards of patient centered care, irrespective of her social status.

(LoE: Expert opinion)

Advanced breast cancer

Very little is known about psycho-social challenges and dying concerns in young parents with ABC. Most of the data refer to Caucasian, upper, middle-class women within nuclear families.

In general, patients express concerns for their children and their co-parent, and personal concerns which impact their QoL, contribute to the emotional and psychological distress, and increase family dysfunction.

Further research in this setting is needed on patients from diverse backgrounds, non-nuclear families, on the co-parent, parents and caregivers.

(LoE: Expert opinion)



Bridging the Gap

Advanced Breast Cancer

Sixth International Consensus Conference

4-6 November 2021

VIRTUAL MEETING

Chair: F. Cardoso, PT

Co- Chair: R. Haidinger, DE

Honorary Chairs: E.P. Winer, US

L. Norton, US – A. Costa, CH/IT

Scientific Committee: N. El Saghir, LB - A. Eniu, CH

S. Paluch-Shimon, IL - F. Penault-Llorca, FR

H. Rugo, US - T. Wiseman, UK

recommended by



Reveive updates on
www.abc-lisbon.org
#ABClisbon

EM-71707

Thank You!

Isabelle Soerjomataram

Deputy Branch Head, Cancer Surveillance

International Agency for Research on Cancer (IARC)

Breast cancer in Europe in 2020

0.5 million

Breast cancer
cases

142,000

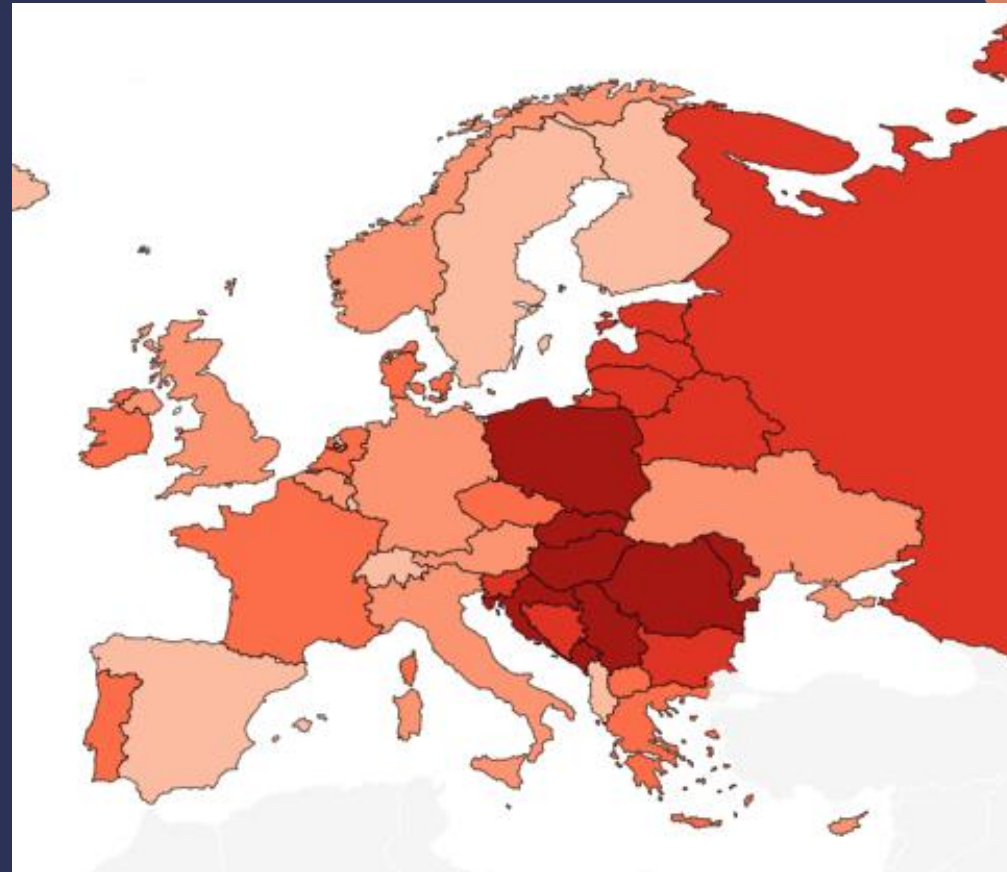
Breast cancer
deaths

NO: 2.8%

DK: 7.7%

UK: 5.4%

Ukr: 8.9%



Swiss: 6.5%

Breast cancer in Europe in 2020

0.5 million

Breast cancer
cases

142,000

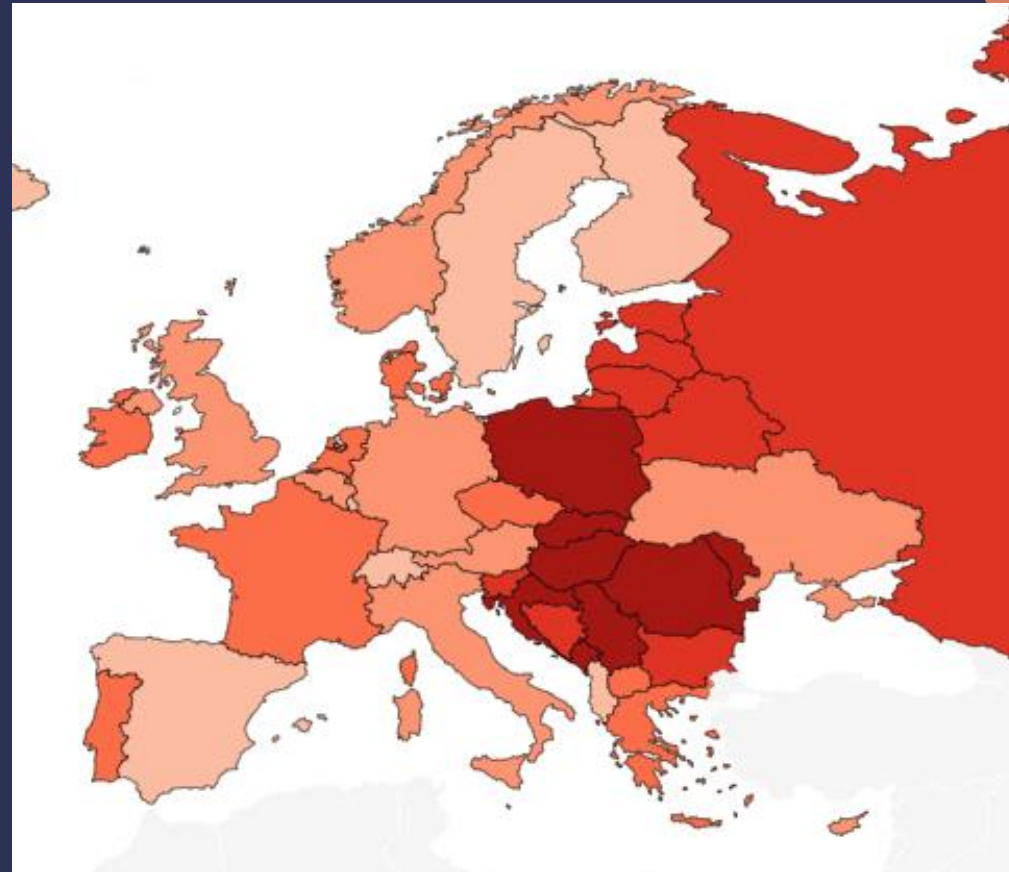
Breast cancer
deaths

ICE: 16%

NO: 7.1%

DK: 0%

UK: 8%



Breast cancer in Europe in 2020

0.5 million

Breast cancer
cases

142,000

Breast cancer
deaths

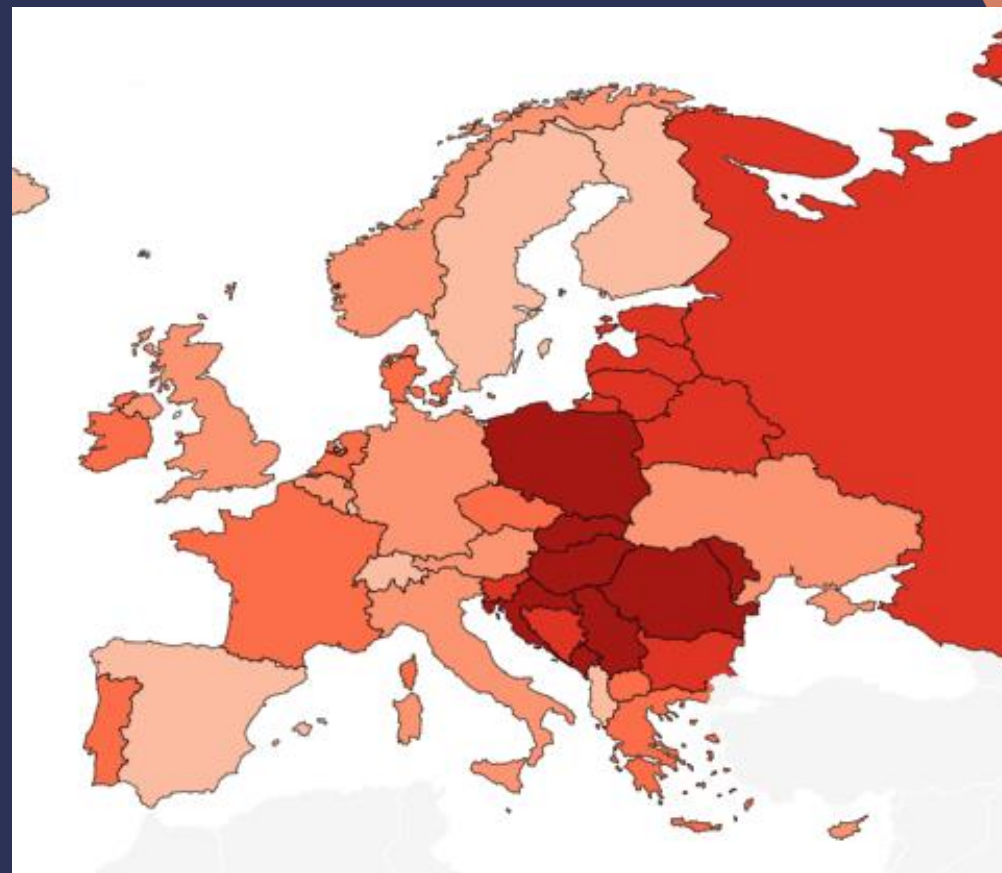
NO: 7.1%

DK: 0%

ICE: 16%

UK: 53%
~2003

UK: 8%
~2018



Metastatic breast cancer data in Europe

Most countries: **No**
(population-based) data

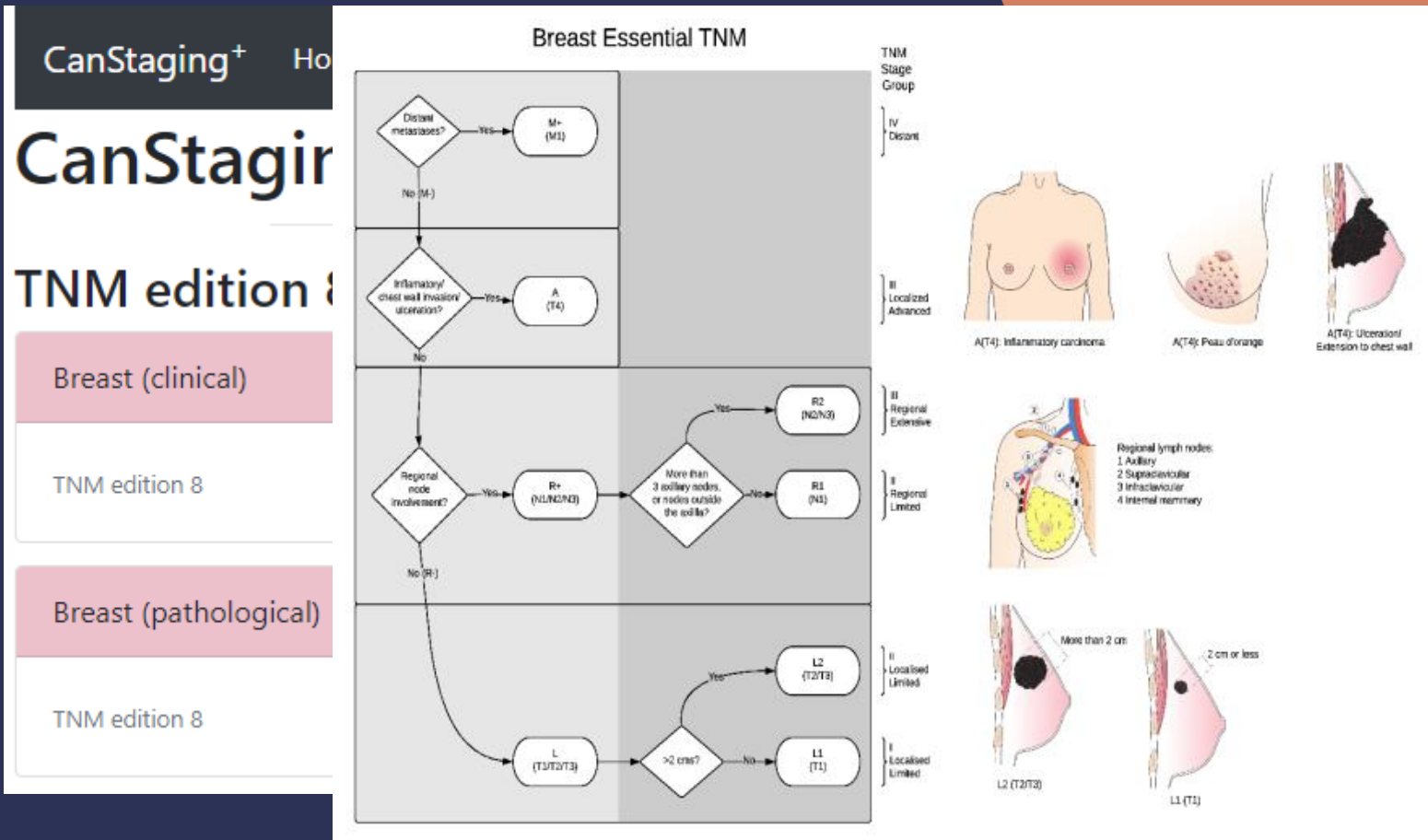
- Completeness

Different systems

- TNM, editions
- SEER

→ CanStaging⁺ tool

→ Essential TNM



<https://canstaging.org/tool>

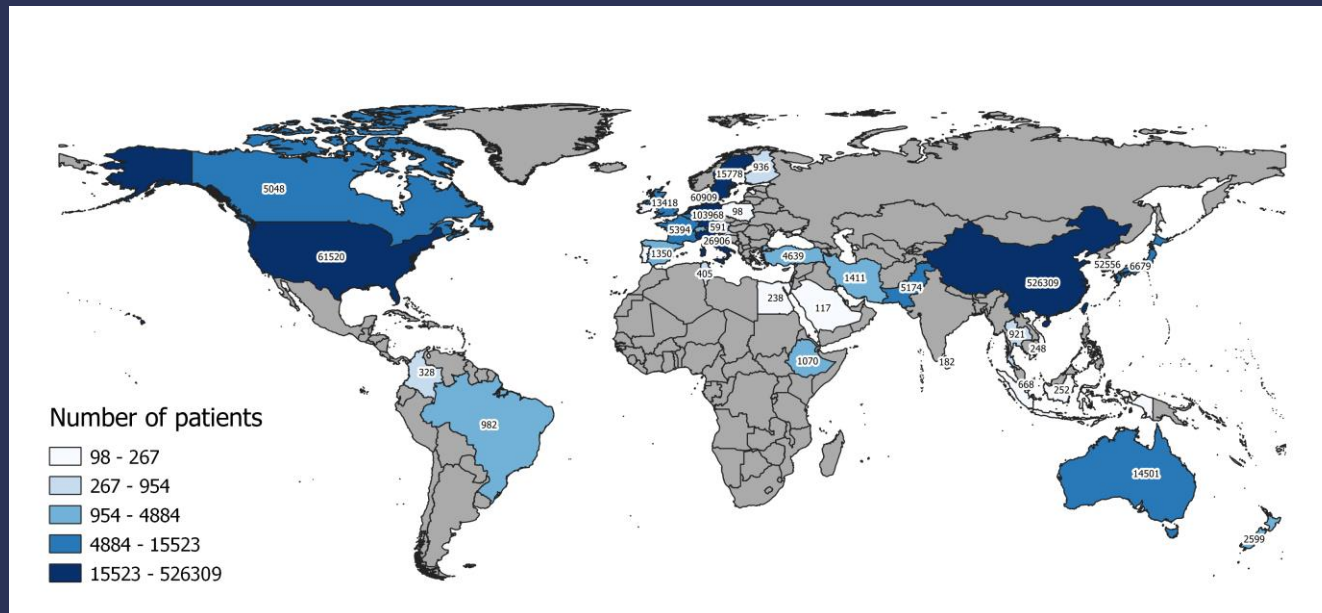
Soerjomataram LO 2021

Piñeros M et al, LO 2019

Metastatic Breast Cancer

Data on MBC: « de novo » (distant at initial diagnosis)

- a **systematic review** and meta-analysis of **distant recurrence rates** in women with early (M0) breast cancer
- **definitions** of and **methods** to collect recurrent breast cancer in routine health care / cancer registry



Morgan E ongoing

Moving forward: Metastatic breast cancer

No DATA → No ACTION

Improving data, hence action for better outcome:

- (Inter)national projects and collaborations
- Setting standards
- Provision of tools
- Implementation

Monitor, measure and report progress to adapt and evaluate

Thank You!



Perspectives in metastatic prostate cancer

Arnulf Stenzl

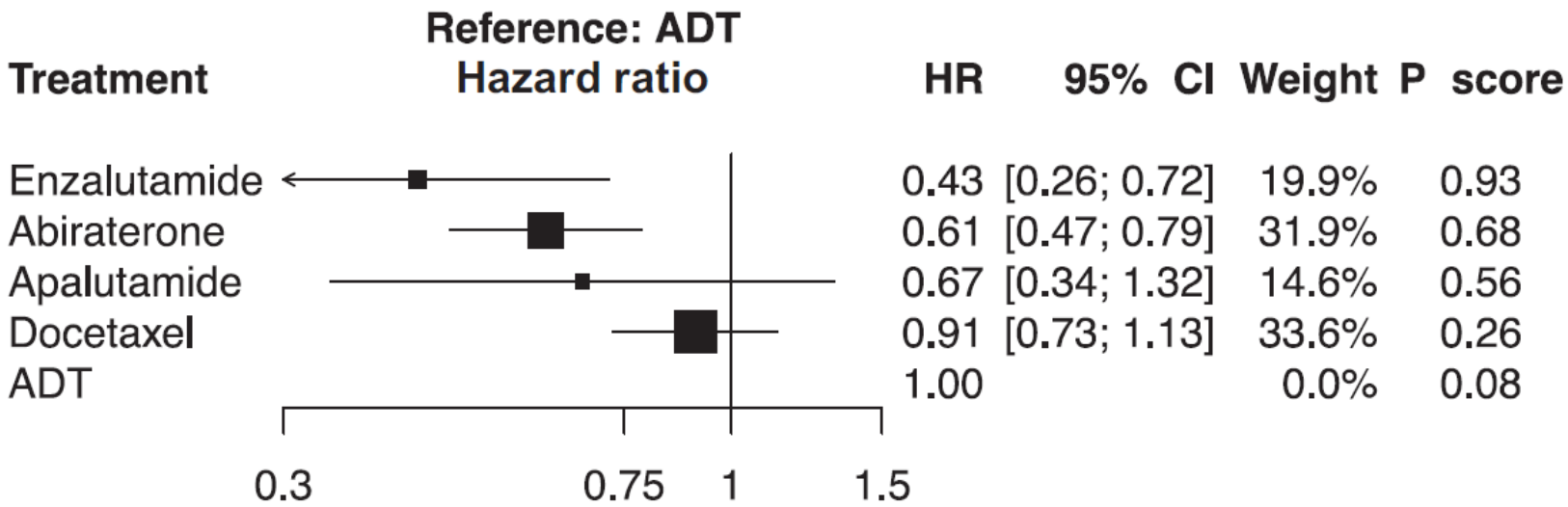
Adjunct Secretary General
European Association of Urology (EAU)

Andrew Cavey

Global Program Head, Prostate Cancer
Novartis



Association between systemic therapy and overall survival in early detected, low-volume mHSPC



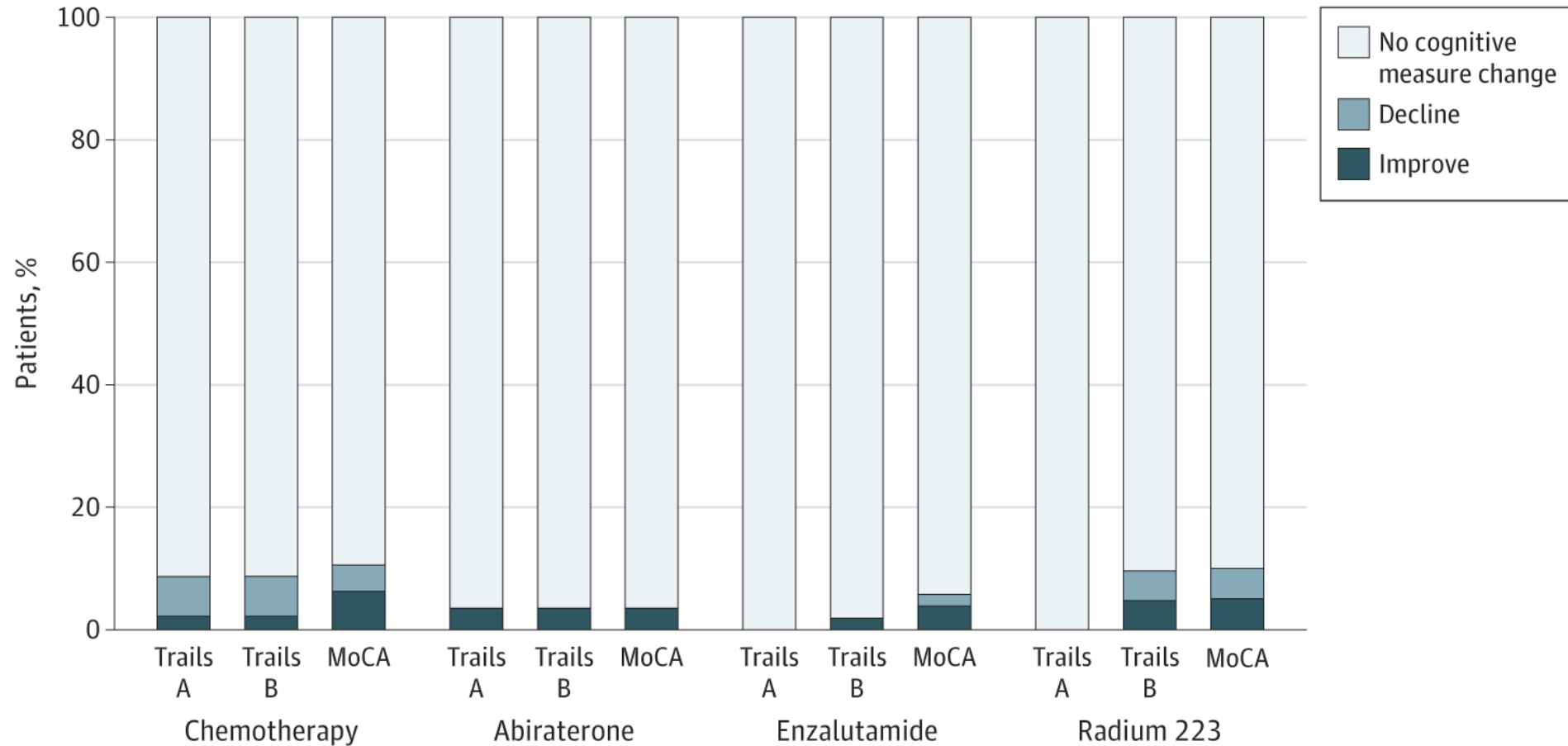
Association of Chemotherapy, Enzalutamide, Abiraterone, and Radium 223 With Cognitive Function in Older Men With Metastatic Castration-Resistant Prostate Cancer

Shabbir M. H. Alibhai, MD, MSc¹; Henriette Breunis, CCRP¹; Gregory Feng, HBSc¹; et al

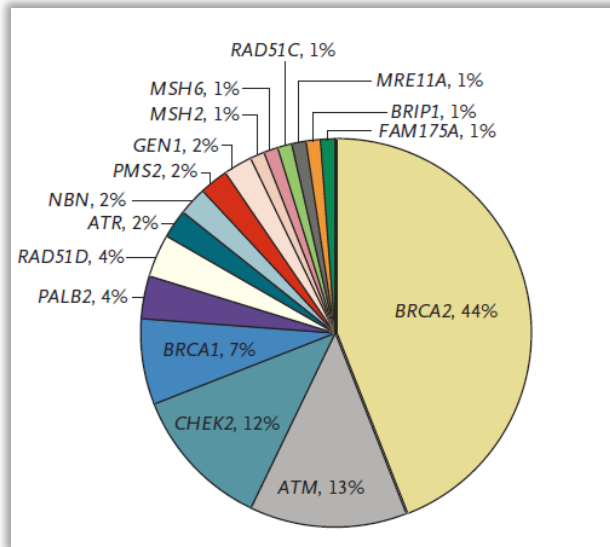
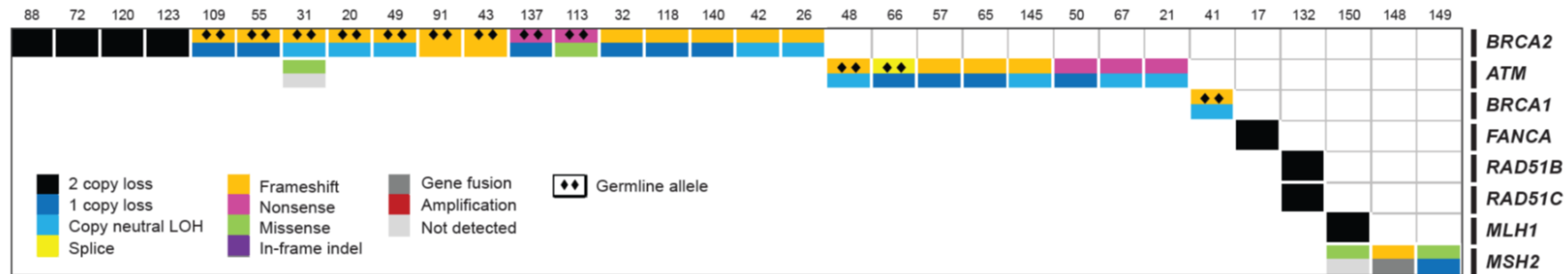
[Author Affiliations](#) | [Article Information](#)

JAMA Netw Open. 2021;4(7):e2114694. doi:10.1001/jamanetworkopen.2021.14694

Change in Cognitive Assessment ?



DNA repair pathway aberrations (23%) → the solution for a personalized approach



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Inherited DNA-Repair Gene Mutations in Men with Metastatic Prostate Cancer

C.C. Pritchard, J. Mateo, M.F. Walsh, N. De Sarkar, W. Abida, H. Beltran, A. Garofalo, R. Gulati, S. Carreira, R. Eeles, O. Elemento, M.A. Rubin, D. Robinson, R. Lonigro, M. Hussain, A. Chinnaiyan, J. Vinson, J. Filipenko, L. Garraway, M.-E. Taplin, S. AlDubayan, G.C. Han, M. Beightol, C. Morrissey, B. Nghiem, H.H. Cheng, B. Montgomery, T. Walsh, S. Casadei, M. Berger, L. Zhang, A. Zehir, J. Vijai, H.I. Scher, C. Sawyers, N. Schultz, P.W. Kantoff, D. Solit, M. Robson, E.M. Van Allen, K. Offit, J. de Bono, and P.S. Nelson



Discuss with us

Earlier/better imaging improves outcome of metastatic disease?

Maximal treatment in Hormone Sensitive Prostate Cancer (HSPC) improves outcome. But also Quality of Life?

Has personalized – genetic classification and adjusted treatment - arrived with metastatic prostate cancer?

Thank You!

Hendriquer Reinders-Huisman

Urology Nurse Practitioner, Groningen, the Netherlands

Scientific Congress Office Member, European Association of
Urology Nurses (EAUN)

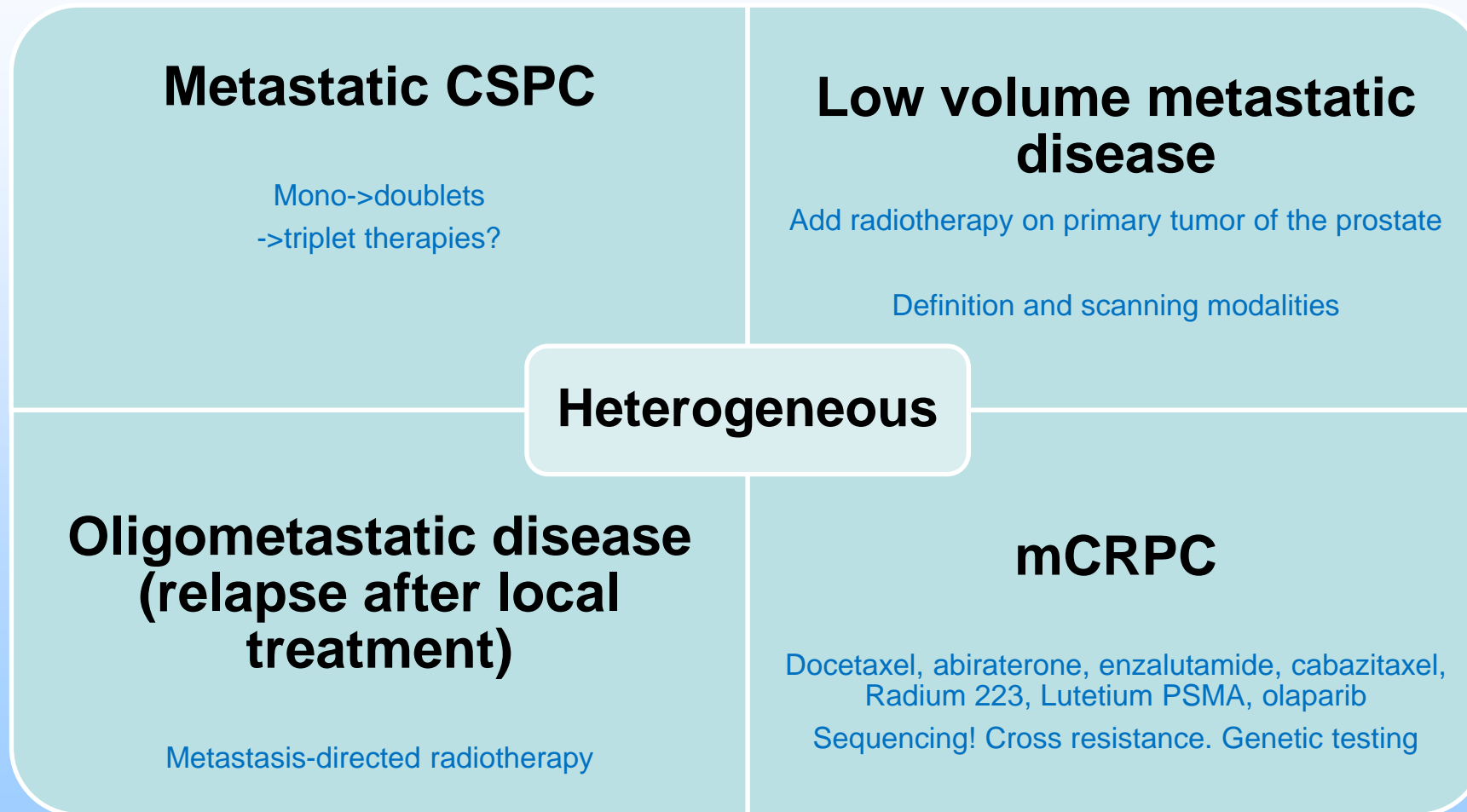


Urology nursing perspective on metastatic prostate cancer

Hendrique Reinders-Huisman, MSc, RN

Urology nurse practitioner at Martini Hospital, The Netherlands

Member of the Scientific Committee of the EAUN



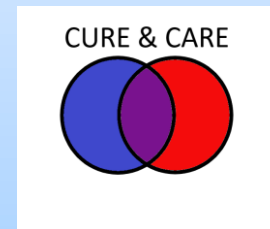
More:

- Treatments. Shift towards upfront.
- Complexity
- Personalized treatment plan/Shared decision making
- Information
- Patient dilemma's
- Departments: urology, oncology, radiology, radiotherapy

A patient centered approach

Nurses: holistic approach

Nurse practitioners: interprofessional role -> combining care and cure



Coordination/liaison/casemanager

Information

PROMS

To foster the highest standards of urological nursing care throughout Europe and to facilitate the continued development of urological nursing in all its aspects.

Thank You!

Ken Mastris

President, European Cancer Patient Coalition

Past-President, Europa Uomo

Who we are?

- **Largest** European cancer patients' umbrella organisation established in 2003
- **+450 member organizations** in 47 Countries globally
- Advocate for patients to be acknowledged as **equal partners & co-creators of their own health**
- We work for a **Europe of equality**, where all Europeans with cancer have **timely & affordable access to the best treatment and care** available, throughout their life



The European Cancer Patient Coalition Board's 2019-2022 strategy is based upon five pillars:

Policy



To influence the EU legal framework and the European and national political agenda

Research



To increase the role of patients in cancer research as co-researchers

Education and capacity building



To empower members to shape national cancer policy and strengthen their abilities to better serve cancer patients

Communication



To raise awareness on main challenges faced by patients to access innovations and other resources available for cancer patients

Governance



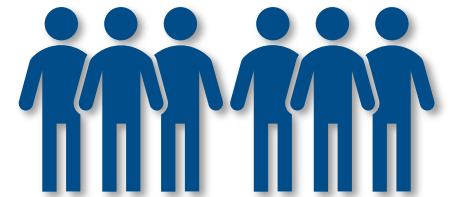
To build a sustainable model for governance and cooperation with its Members



Prostate Cancer is the most diagnosed male cancer

Every year, around **450.000** European men are diagnosed with prostate cancer.

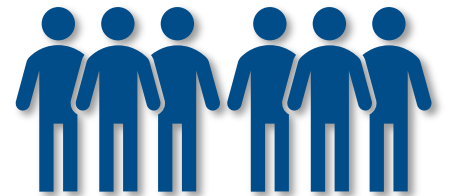
With over **2 million** men across the EU now living with the disease.





- The incidence of advanced prostate cancer in some countries is likely a reflection of the **late detection** because of the lack of awareness of the necessity of early detection or the lack of proper diagnostic tools.

COVID-19 pandemic
increased the
disparities



Patients, general practitioners and the broader public should be better informed



early diagnosis



early screenings



access to affordable care



access to medicine



access to trials



survivorship care



patient-centred approach

Thank you!



Ken.mastris@ecpc.org

European Cancer Patient Coalition

Avenue des Arts 6
1210 Brussels, Belgium

www.ecpc.org | info@ecpc.org | + 32 (0) 2 721 41 14