RARE CANCERS EUROPE

JARC
JOINT ACTION ON RARE CANCERS

EURACAN
ERN on adult cancers
(solid tumours)
(ERN EURACAN)

Tumori rari

FONDAZIONE IRCCS
ISTITUTO NAZIONALE
DEI TUMORI

UNIVERSITÀ
DEGLI STUDI
DI MILANO

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Rare cancers are not so rare: The rare cancer burden in Europe

Gemma Gatta [a,], Jan Maarten van der Zwan [b], Paolo G. Casali [c], Sabine Siesling [b], Angelo Paolo Dei Tos [d], Ian Kunkler [e], Renée Otter [b], Lisa Licitra [f], Sandra Mallone [g], Andrea Tavilla [g], Annalisa Trama [a], Riccardo Capocaccia [g], The RARECARE working group*

Eur J Cancer 2011;47:2493

Table 3 - Data quality indicators and other characteristics of malignant cancers diagnosed in European cancer registries 1995-2002 and included in the analyses.

Country	Registry	Number of malignant cancers	Data quality indicators					
			Death certificate only (%)	Autopsy (%)	Microscopic verification (%)	Cases 1995-1998 censored before 5 years (%)	Morphology code NOS* (%)	Topography code NOS* (%)
Austria	Austria	306,498	8.9	0.0	85.2	5.9	10.1	0.6
Belgium	Flanders	144,715	0.0	0.2	89.8	0.0	7.3	0.5
France	Bas Rhin	13,113	0.0	0.0	95.8	3.3	3.9	0.2
	Calvados	5895	0.0	0.0	98.1	6.1	2.5	0.3
	Calvados digestive	2801	0.0	0.0	87.0	4.4	10.5	0.3
	Côte d'Or digestive	4376	0.0	0.0	82.8	0.5	17.5	0.2
	Côte d'Or haematol.	1884	0.0	0.0	100.0	7.2	0.0	0.5
	Doubs	5782	0.0	0.0	95.8	2.1	3.2	0.3
	Haut Rhin	9073	0.0	0.0	96.4	5.8	2.9	0.1
	Hérault	10,505	0.0	0.0	0.0	6.4	1.5	0.1
	Isère	12,526	0.0	0.0	94.1	4.6	4.1	0.1
	Loire Atlantique	3746	0.0	0.0	100.0	6.8	0.0	0.0
	Manche	6267	0.0	0.0	96.5	2.7	3.4	0.3
	Marne and Ardennes	168	0.0	0.0	100.0	3.6	0.0	0.0
	Somme	6481	0.0	0.0	94.2	6.6	5.5	0.8
	Tarn	4935	0.0	0.0	93.8	2.0	5.9	1.3
Germany	Saarland	54,132	3.9	0.0	91.8	5.8	8.0	0.5
Iceland	Iceland	8854	0.1	1.4	96.6	0.0	3.5	0.0
Ireland	Ireland	156,529	2.0	0.3	86.7	0.0	11.0	0.7
Italy	Alto Adige	18,676	0.7	0.0	89.5	0.0	9.2	0.5
	Biella	11,770	1.3	0.4	87.0	0.0	12.5	0.3
	Ferrara	23,760	1.1	0.0	88.1	0.4	9.7	0.6
	Firenze	66,097	0.9	0.1	80.4	0.4	17.7	0.8
	Friuli VG	78,882	0.6	1.9	91.0	0.3	9.8	2.1
	Genova	44,207	1.8	0.0	81.4	0.0	16.6	0.9
	Macerata	10,396	1.3	0.0	87.4	0.2	13.1	0.6
	Modena	34,947	0.5	0.0	88.6	0.4	11.8	0.5
	Napoli	8165	3.9	0.0	73.0	1.9	17.6	1.4
	Palermo	581	2.2	0.0	92.6	0.0	7.2	0.0
	Parma	23,836	1.0	0.0	86.0	0.3	13.1	0.7
	Ragusa	10,687	1.9	0.8	80.9	0.1	24.6	0.6
	Reggio Emilia	22,152	0.2	0.0	88.1	0.0	13.8	0.5
	Romagna	60,667	2.4	0.0	87.9	0.1	12.3	0.5
	Salerno	26,917	2.5	0.0	77.5	4.0	23.7	1.1
	Sassari	18,084	2.9	0.2	84.4	0.0	16.4	0.7
	Trento	17,798	2.0	0.0	85.0	0.3	27.8	3.8
	Umbria	45,221	0.7	0.0	84.0	0.1	12.6	0.6
	Varese	24,728	1.1	0.0	89.0	11.5	10.8	0.4
	Veneto	84,528	1.5	0.2	87.5	0.8	13.7	1.7

- **Pediatric cancers**
- **Haematologic rare neoplasms**
- **Sarcomas**
- **Rare thoracic cancers**
- **Neuroendocrine tumours**
- **Head & neck cancers**
- **Central nervous system tumours**
- **Rare female genital cancers**
- **Rare urological and male genital tumours**
- **Endocrine gland tumours**
- **Digestive rare cancers**
- **Rare skin cancers & non-cutaneous melanoma**

original article

Annals of Oncology
doi:10.1093/annonc/mdr610

Sarcoma: concordance between initial diagnosis and centralized expert review in a population-based study within three European regions

I. Ray-Coquard[1,2], M. C. Montesco[3], J. M. Coindre[4,5], A. P. Dei Tos[6], A. Lurkin[1,2], D. Ranchère-Vince[2], A. Vecchiato[3], A. V. Decouvelaere[2], S. Mathoulin-Pélissier[4,5,7], S. Albert[7], P. Cousin[2], D. Cellier[8], L. Toffolatti[6], C. R. Rossi[3,9] & J. Y. Blay[2,10] for the Conticanet group

[1]University Lyon, EAM 4129 Health Individual Society, Hôtel Dieu, Lyon; [2]Centre Léon Bérard, Lyon, France; [3]Veneto Institute of Oncology (IOV), IRCCS, Padova, Italy; [4]University Bordeaux Segalen; [5]INSERM U916, Bordeaux, France; [6]General Hospital of Treviso, Italy; [7]INSERM CIC-EC7 and Clinical and Epidemiological Research Unit, Institut Bergonié, Bordeaux; [8]Merck Serono, Lyon, France; [9]University of Padova, Italy; [10]NSERM U590 Cytokine and Cancer, Centre Léon Bérard, Lyon, France

Background: Sarcomas represent a heterogeneous group of tumors. Accurate determination of histological diagnosis and prognostic factors is critical for the delineation of treatment strategies. The contribution of second opinion (SO) to improve diagnostic accuracy has been suggested for sarcoma but has never been established in population-based studies.

Methods: Histological data of patients diagnosed with sarcoma in Rhone-Alpes (France), Veneto (Italy) and Aquitaine (France) over a 2-year period were collected. Initial diagnoses were systematically compared with SO from regional and national experts.

Results: Of 2016 selected patients, 1463 (73%) matched the inclusion criteria and were analyzed. Full concordance between primary diagnosis and SO (the first pathologist and the expert reached identical conclusions) was observed in 824 (56%) cases, partial concordance (identical diagnosis of connective tumor but different grade or histological subtype) in 518 (35%) cases and complete discordance (benign versus malignant, different histological type or invalidation of the diagnosis of sarcoma) in 121 (8%) cases. The major discrepancies were related to histological grade (n = 274, 43%), histological type (n = 144, 24%), subtype (n = 18, 3%) and grade plus subtype or grade plus histological type (n = 178, 29%).

Conclusion: More than 40% of first histological diagnoses were modified at second reading, possibly resulting in different treatment decisions.

Concordance	Zero	Partial	Full	*P*
Included tumors[a]	104	515	814	
Type of laboratory				
Public	40 (5%)	241 (32%)	477 (63%)	**<0.001**
Private	64 (9%)	274 (41%)	337 (50%)	
Included tumors[b]	119	518	820	
Type of tumor sample				
Biopsy	26 (9%)	110 (38%)	154 (53%)	0.47
Surgical specimen	93 (8%)	408 (35%)	666 (57%)	
Included tumors	51	409	449	
Grade				
I	18 (7%)	77 (30%)	164 (63%)	**<0.001**
II–III	33 (5%)	332 (51%)	285 (44%)	
Included tumors[c]	116	515	821	
Type of sarcoma				
Soft tissue	82 (9%)	323 (36%)	502 (55%)	**0.004**
Visceral	34 (6%)	192 (35%)	319 (59%)	
Included tumors	121	518	824	
Region				
Aquitaine	34 (10%)	148 (42%)	170 (48%)	**<0.001**
Rhone-Alpes	65 (10%)	252 (38%)	345 (52%)	
Veneto	22 (5%)	118 (26%)	309 (69%)	
Included tumors	121	518	824	
Subgroup analysis				
SO requested	71 (13%)	263 (47%)	230 (40%)	**<0.001**
No SO requested	50 (6%)	255 (28%)	594 (66%)	

Ann Oncol 2012;23:2442

RARE CANCERS EUROPE

Rare Cancers Consensus Meeting: Pathology in Rare Cancers

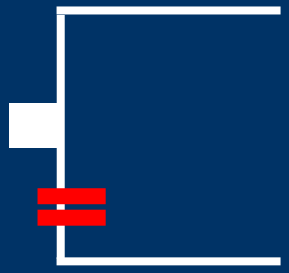
10 – 11 February 2014, Brussels

- **Referral to expert rare cancer pathologists is crucial for appropriateness**
- **Networks are the best tool for proper referral**
- **Multidisciplinarity is the best environment for rare cancer patient healthcare**

ESMO

European Society of Pathology

Treatment «phases»



cancer

localized disease

metastases (1st CT)

(2st CT)

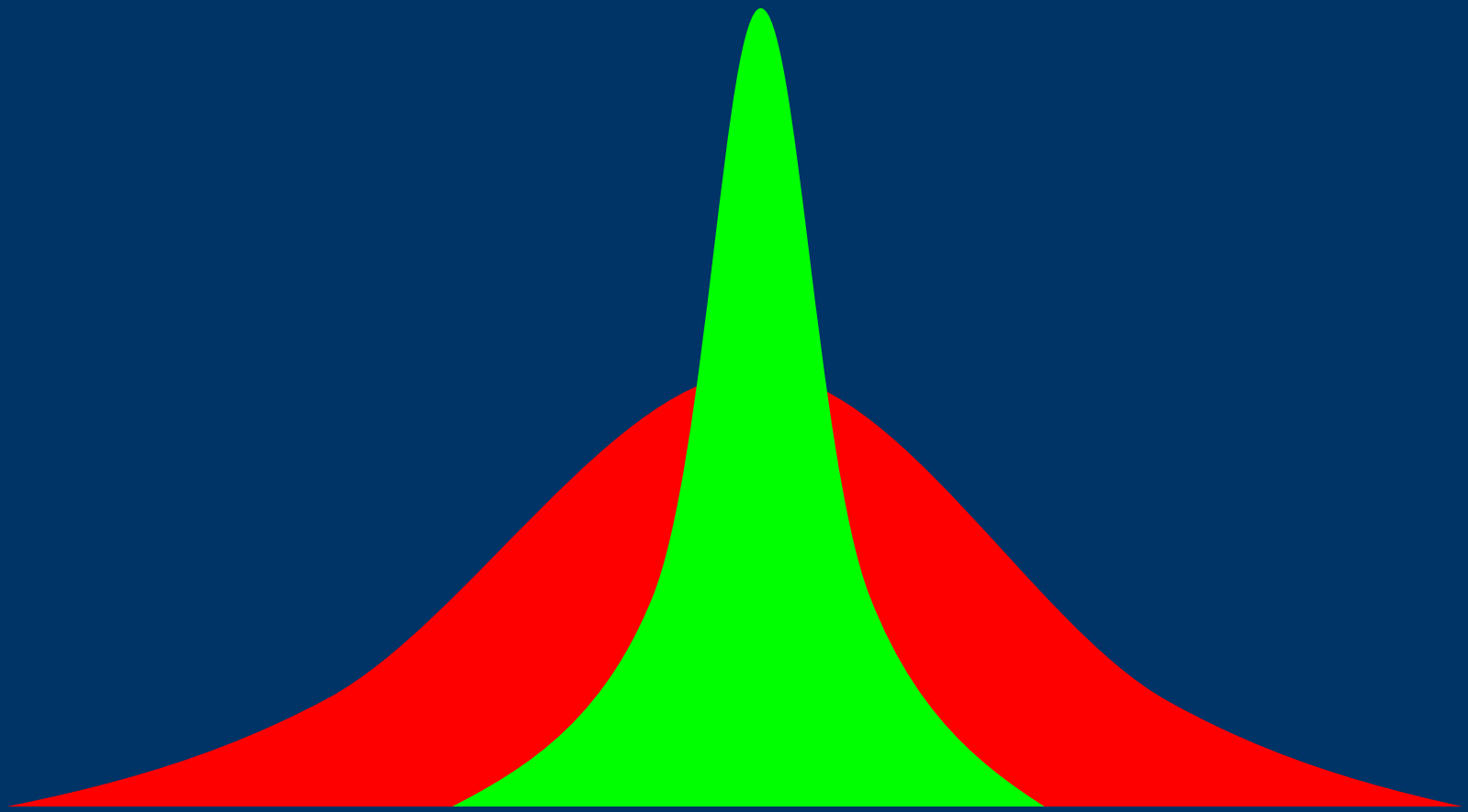
terminal disease

European Action Against Rare Cancers

Recommendations Addressing Regulatory Barriers in Rare Cancer Care

We:

1. Acknowledge that while the process for establishing the efficacy of new medicines is in principle the same for all cancers, the strength of the evidence – intended as level and quality of evidence and statistical precision – that is achievable in common cancers is difficult to achieve in rare conditions and, therefore, a higher degree of uncertainty should be accepted for regulatory as well as clinically informed decision-making.



review

Annals of Oncology 00: 1–7, 2014
doi:10.1093/annonc/mdu459

Rare Cancers Europe (RCE) methodological recommendations for clinical studies in rare cancers: a European consensus position paper

P. G. Casali[1]*, P. Bruzzi[2], J. Bogaerts[3] & J.-Y. Blay[4] on behalf of the Rare Cancers Europe (RCE) Consensus Panel

[1]*Adult Mesenchymal Tumour Medical Oncology Unit, Fondazione IRCCS Istituto Nazionale Tumori, Milan;* [2]*Clinical Epidemiology Unit, National Institute for Cancer Research, Genova, Italy;* [3]*European Organization for Research and Treatment of Cancer (EORTC), Brussels, Belgium;* [4]*Department of Medical Oncology, Centre Léon Bérard, Centre de Recherche en Cancérologie, Université de Lyon, Lyon, France*

Received 29 July 2014; revised 18 September 2014; accepted 19 September 2014

While they account for one-fifth of new cancer cases, rare cancers are difficult to study. A higher than average degree of uncertainty should be accommodated for clinical as well as for population-based decision making. Rules of rational decision making in conditions of uncertainty should be rigorously followed and would need widely informative clinical trials. In principle, any piece of new evidence would need to be exploited in rare cancers. Methodologies to explicitly weigh and combine all the available evidence should be refined, and the Bayesian logic can be instrumental to this end. Likewise, Bayesian-design trials may help optimize the low number of patients liable to be enrolled in clinical studies on rare cancers, as well as adaptive trials in general, with their inherent potential of flexibility when properly applied. While clinical studies are the mainstay to test hypotheses, the potential of electronic patient records should be exploited to generate new hypotheses, to create external controls for future studies (when internal controls are unpractical), to study effectiveness of new treatments in real conditions. Framework study protocols in specific rare cancers to sequentially test sets of new agents, as from the early post-phase I development stage, should be encouraged. Also the compassionate and the off-label settings should be exploited to generate new evidence, and flexible regulatory innovations such as adaptive licensing could convey new agents early to rare cancer patients, while generating evidence. Though validation of surrogate end points is problematic in rare cancers, the use of an updated notion of tumor response may be of great value in the single patient to optimize the use of therapies, all the more the new ones. Disease-based communities, involving clinicians and patients, should be regularly consulted by regulatory bodies when setting their policies on drug approval and reimbursement in specific rare cancers.

Key words: rare cancers, clinical trials, research methodology

- **Clinical decision-making**
- **Methods to combine evidence**
- **New study designs**
- **Surrogate end points**
- **Organization of studies**

REPORTS FROM PAST EVENTS / Rare Cancers Conference 2012

Rare Cancers Conference 2012

Exploring ways to improve clinical research on rare cancers

Date : 01 Mar 2012

Organised by the European Society for Medical Oncology (ESMO) and Rare Cancers Europe, the Rare Cancers Conference, held on 10 February 2012 in Brussels, provided a multi-stakeholder platform for rare cancer and rare disease experts from across Europe to exchange views and share insights into what can be done to improve the methodology of clinical research on rare cancers.

The first two conference sessions offered an overview of rare cancers and associated challenges for clinical research and drug development and also presented a variety of (potential) solutions as well as best practice examples. Where traditional frequent clinical research approaches are not possible, due to the small numbers of patients, it is particularly challenging to make sure that rare cancer patients are not being left without appropriate clinical research and therapeutic progress.

The third session of the conference therefore also highlighted the need for reaching a broad multi-stakeholder consensus on a set of recommendations on improving the methodology of clinical research on rare cancers. These recommendations will be the product of an ongoing multidisciplinary and multi-stakeholder online consensus discussion, promoted by Rare Cancers Europe. They will focus on best methods, including innovative ones, for clinical research on rare cancers, and rare subgroups of frequent cancers, with the goal of encouraging:

- clinical researchers to exploit innovative solutions for the design and analysis of clinical studies;
- clinicians to exploit innovative solutions for the combination of all available knowledge;
- regulators to accept evidence built through these solutions;
- clinicians' and patients' communities to exploit all forms of collaboration to put together as large series as possible for prospective and retrospective clinical and translational research;
- methodologists to advance research into new methodological solutions better fitting the needs of studies on small series

All interested stakeholder groups are encouraged to actively participate in this open discussion, the result of which will be a consensus paper to be publicly presented in autumn 2012. This paper could then be used for related advocacy efforts. All parties interested in joining this discussion are invited to contact Rare Cancers Europe.

RARE CANCERS EUROPE

review

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Key words: rare cancers, clinical trials, research methodology

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

London, October 3rd 2014

RARE CANCERS EUROPE

Workshop on single-arm trials (SAT) in oncology

30th June 2016, 9:30-16:30 Participation by invitation only

EMA is pleased to announce the Joint EMA-ESMO Workshop on: "Single arm trials on oncology clinical development". The Workshop will debate the strengths and weaknesses of single-arm trials in marketing authorizations for oncology drugs. The views of different stakeholders including clinicians, patients, developers, regulators and HTAs will be explored, discussing different clinical scenarios and development approaches

Charis: F. Pignatti (EMA) and P. Casali (ESMO)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE
European Society for Medical Oncology

London, June 30th 2016

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

single-arm trials for cancer drug approval and patient access

J Martinalbo, J Camarero, B Delgado-Charro, P Démolis, J Ersbøll, P Foggi, B Jonsson, D O'Connor, F Pignatti

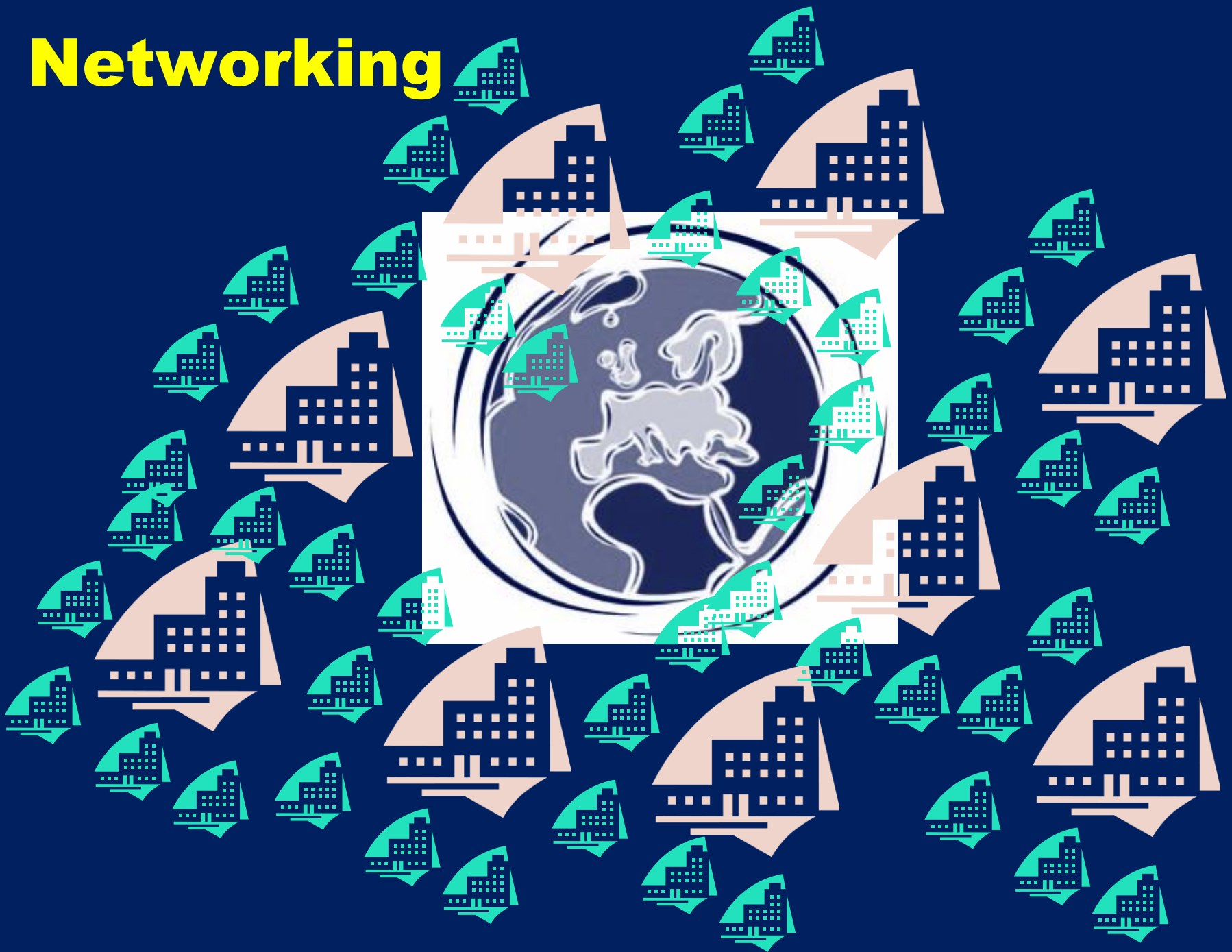
ESMO Annual Congress 2016, Copenhagen

the views expressed are the personal views of the presenter and may not be understood or quoted as being made on behalf of or reflecting the position of EMA or its committees or working parties.
I have no conflicts of interest

Martinalbo J et al
ESMO 2016

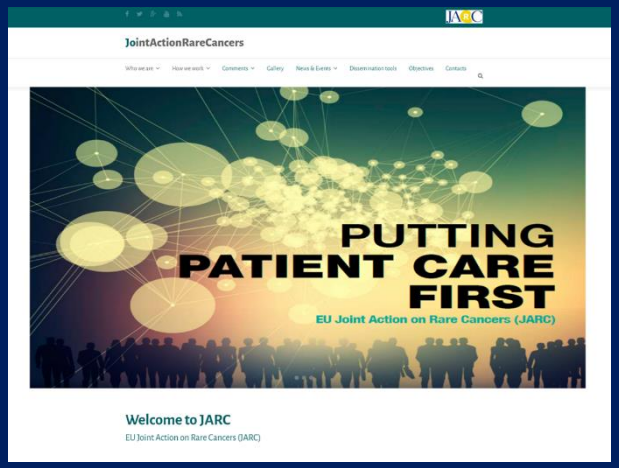
Pros/retrospective clinical DBs

Networking



ERN BOND	European Reference Network on bone disorders
ERN CRANIO	European Reference Network on craniofacial anomalies and ear, nose and throat (ENT) disorders
Endo-ERN	European Reference Network on endocrine conditions
ERN EpiCARE	European Reference Network on epilepsies
ERKNet	European Reference Network on kidney diseases
ERN-RND	European Reference Network on neurological disease
ERNICA	European Reference Network on inherited and congenital anomalies
ERN LUNG	European Reference Network on respiratory diseases
ERN Skin	European Reference Network on skin disorders
ERN EURACAN	European Reference Network on adult cancers (solid tumours)
ERN EuroBloodNet	European Reference Network on haematological diseases
ERN eUROGEN	European Reference Network on urogenital diseases and conditions
ERN EURO-NMD	European Reference Network on neuromuscular diseases
ERN EYE	European Reference Network on eye diseases
ERN GENTURIS	European Reference Network on genetic tumour risk syndromes
ERN GUARD-HEART	European Reference Network on diseases of the heart
ERN ITHACA	European Reference Network on congenital malformations and rare intellectual disability
MetabERN	European Reference Network on hereditary metabolic disorders
ERN PaedCan	European Reference Network on paediatric cancer (haemato-oncology)
ERN RARE-LIVER	European Reference Network on hepatological diseases
ERN ReCONNET	European Reference Network on connective tissue and musculoskeletal diseases
ERN RITA	European Reference Network on immunodeficiency, autoinflammatory and autoimmune diseases
ERN TRANSPLANT-CHILD	European Reference Network on Transplantation in Children
VASCERN	European Reference Network on Rare Multisystemic Vascular Diseases

JOINT ACTION ON RARE CANCERS



FONDAZIONE IRCCS
ISTITUTO NAZIONALE
DEI TUMORI

www.jointactionrarecancers.eu

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Society for Medical Oncology (ESMO),

Joint Action on Rare Cancers (JARC),

Rare Cancers Europe (RCE)

&

Oncology Working Party (ONCWP)

Licensing in rare cancers: a role for ERNs?

Programme

16 April 2018
European Medicines Agency, London, United Kingdom
Meeting room 2F

Innovative trial designs

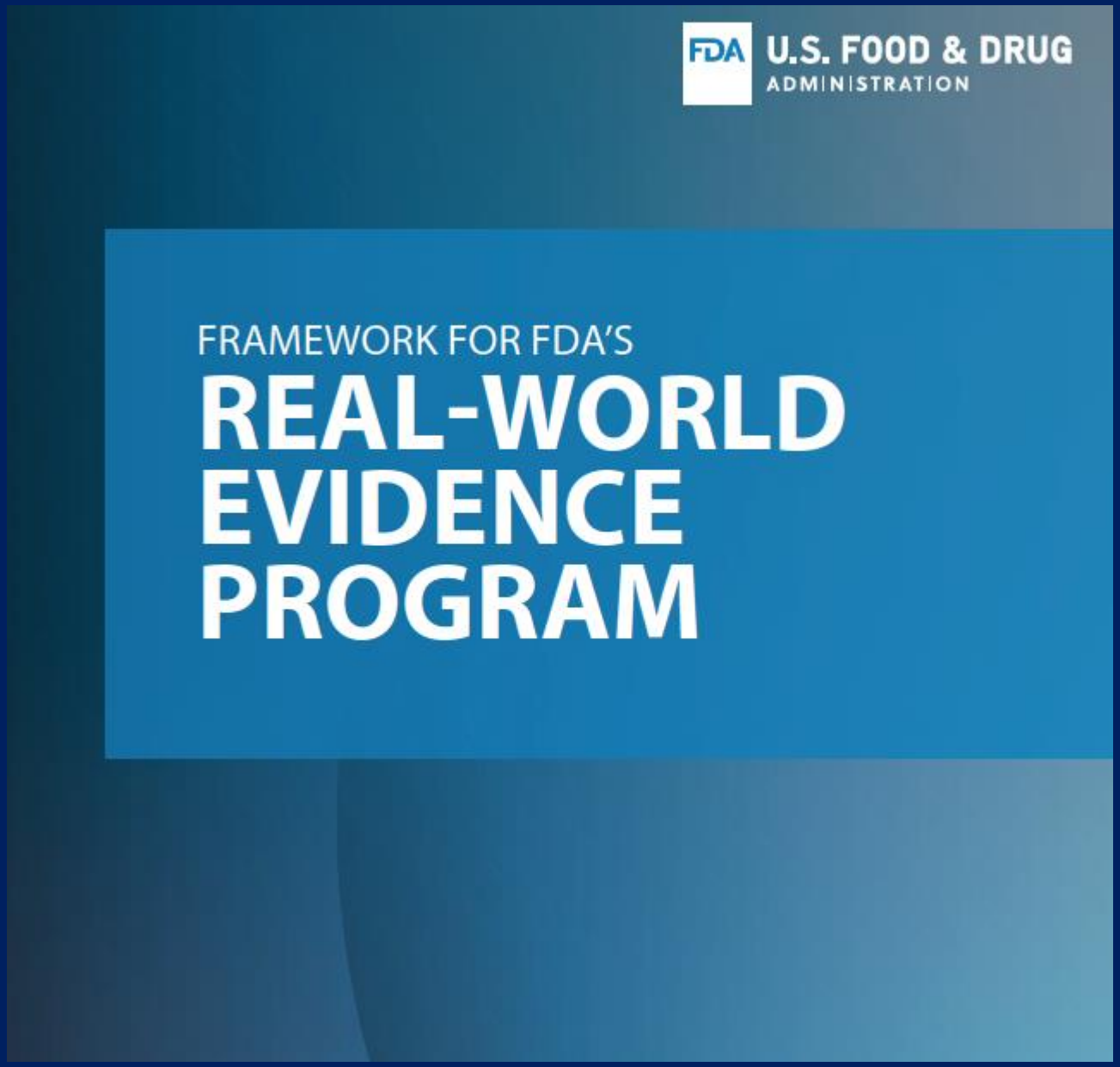
- Biomarker led designs (umbrella, basket): predictive, prognostic enrichment
- Adaptive design: trial strategy modification pre-defined rules
- Cohort led design & use of RWD: pragmatic trials, hybrid, observational

CLINICAL RESEARCH

OUTCOME RESEARCH

Pro & Cons of generating RWE from RWD

- Low validity
- Quality control
- Collection bias
- Multiple sources > closer to causality
- Closer but unstructured


FDA
U.S. FOOD & DRUG
ADMINISTRATION
FRAMEWORK FOR FDA'S
REAL-WORLD
EVIDENCE
PROGRAM

Dec 2018

Scope of RWE Program Under 21st Century Cures Act

Under the Cures Act, FDA's RWE Program must evaluate the potential use of RWD to generate RWE of product effectiveness to help support approval of new indications for drugs approved under FD&C Act Section 505(c) or to help to support or satisfy postapproval study requirements. FDA's RWE Program will also apply to biological products licensed under section 351 of the Public Health Service Act.

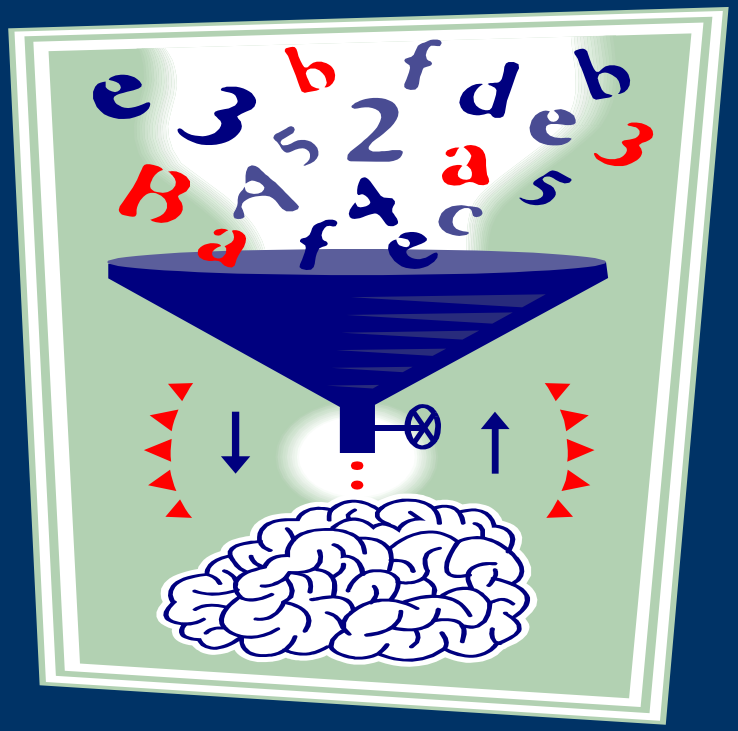
RWD can also be used to improve the efficiency of clinical trials, even if not used to generate RWE regarding product effectiveness. For example, RWD can help with:

- Generating hypotheses for testing in randomized controlled trials
- Identifying drug development tools (including biomarker identification)
- Assessing trial feasibility by examining the impact of planned inclusion/exclusion criteria in the relevant population, both within a geographical area or at a particular trial site
- Informing prior probability distributions in Bayesian statistical models
- Identifying prognostic indicators or patient baseline characteristics for enrichment or stratification
- Assembling geographically distributed research cohorts (e.g., in drug development for rare diseases or targeted therapeutics)

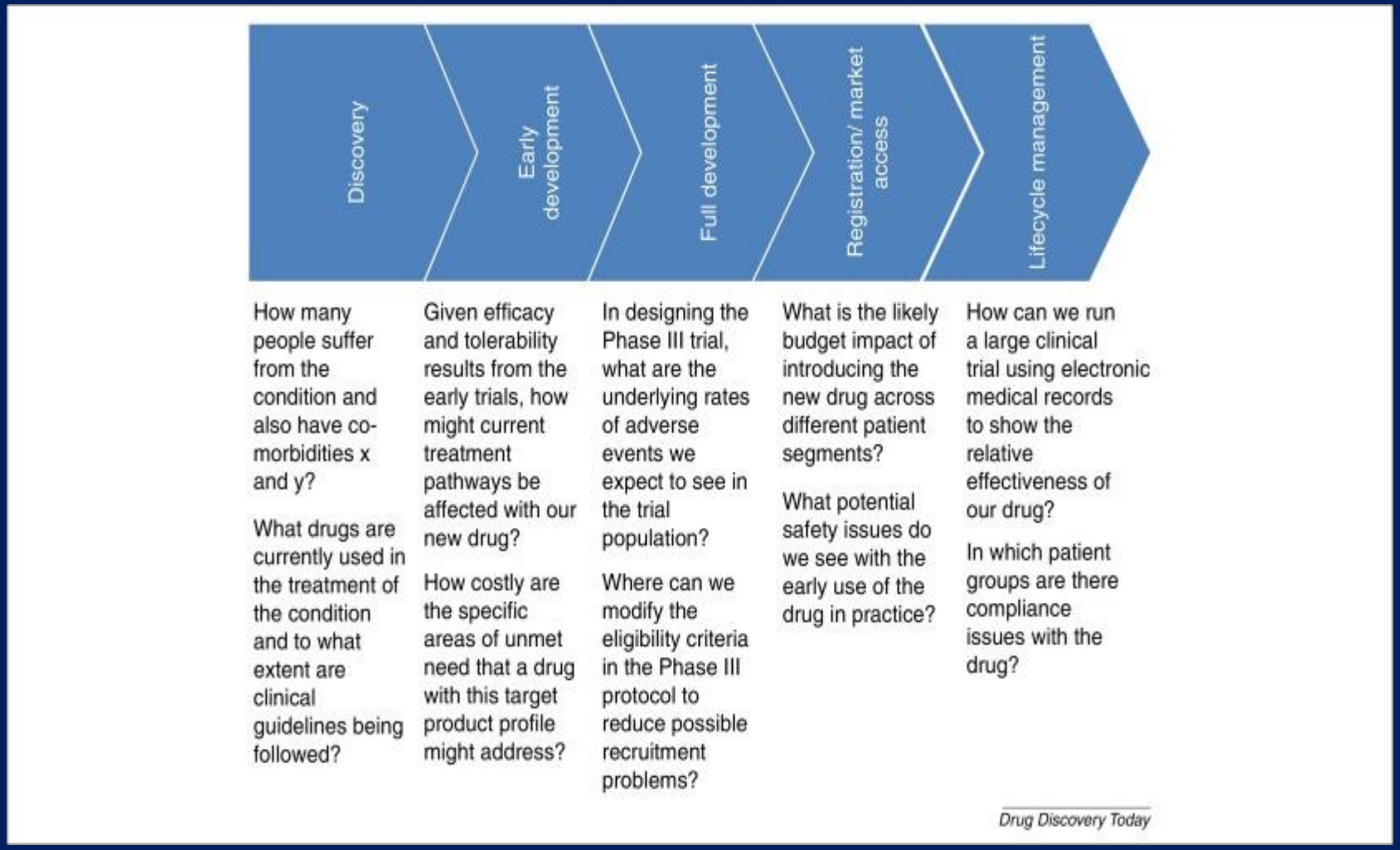
1. *A priori*, determine and declare that a study is a Hypothesis Evaluation Treatment Effectiveness (HETE) study or an Exploratory study based on conditions outlined below
2. Post a HETE study protocol and analysis plan on a public study registration site prior to conducting the study analysis.
3. Publish HETE study results with attestation to conformance and/or deviation from the study protocol and original analysis plan. Possible publication sites include a medical journal, or a publicly available web-site.
4. Enable opportunities to replicate HETE studies (i.e., for other researchers to be able to reproduce the same findings using the same data set and analytic approach). The ISPE companion paper lists information that should be reported in order to make the operational and design decisions behind a RWD study transparent enough for other researchers to reproduce the conduct of the study.
5. Perform HETE studies on a different data source and population than the one used to generate the hypotheses to be tested unless it is not feasible (e.g., another data set is not available)
6. Authors of the original study should work to publicly address methodological criticisms of their study once it is published.
7. Include key stakeholders (patients, caregivers, clinicians, clinical administrators, HTA/payers, regulators, manufacturers) in designing, conducting, and disseminating HETE studies.

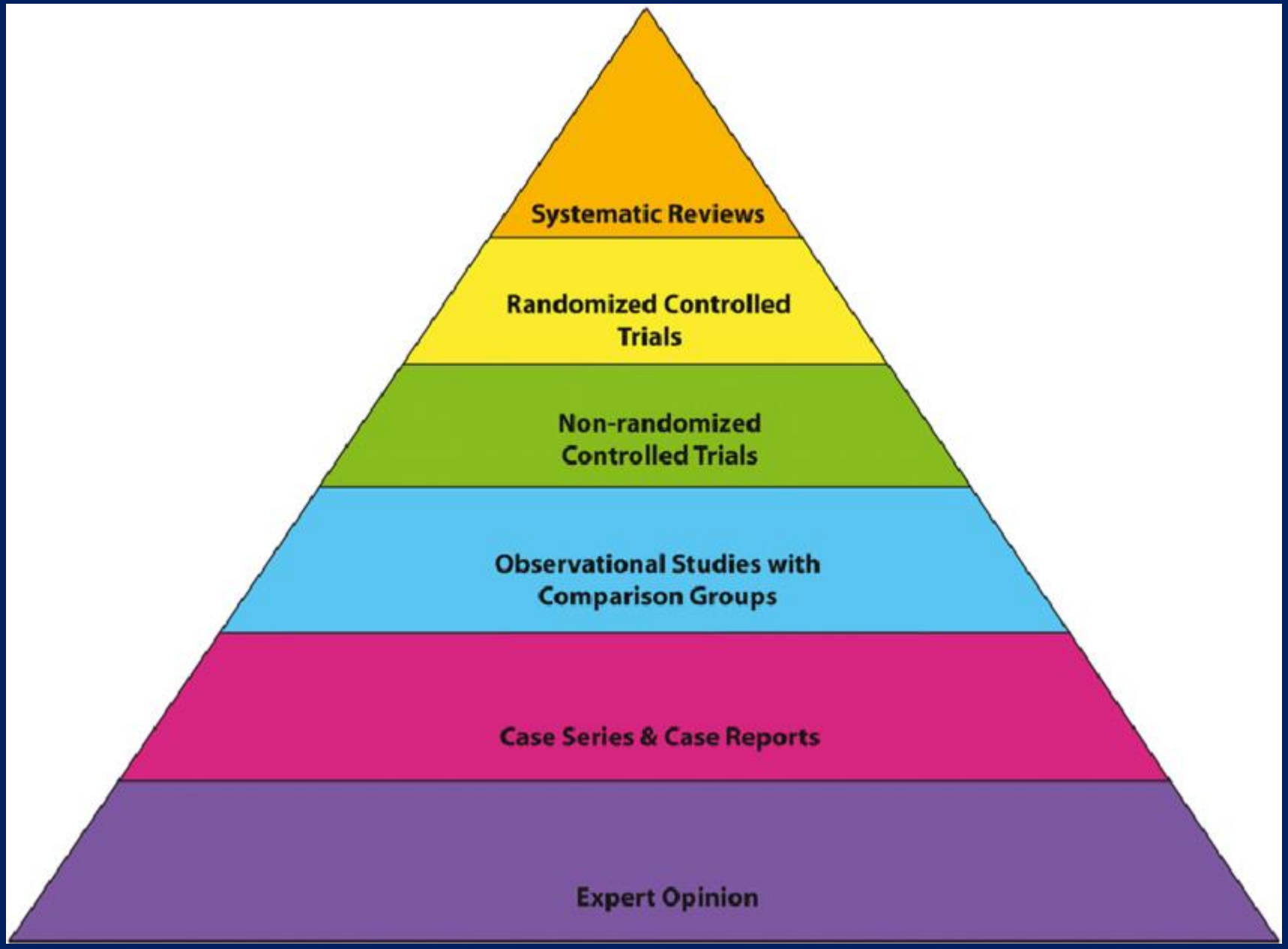
Pharmacoepidemiology and Drug Safety **and** ***Value in Health*****. Berger 2017**

«Big data»...



Examples of issues that real world data (RWD) can address at the different stages of the drug development lifecycle




Systematic Reviews
Randomized Controlled Trials
Non-randomized Controlled Trials
Observational Studies with Comparison Groups
Case Series & Case Reports
Expert Opinion

R $p \leq 0.05$

The good clinical decision…

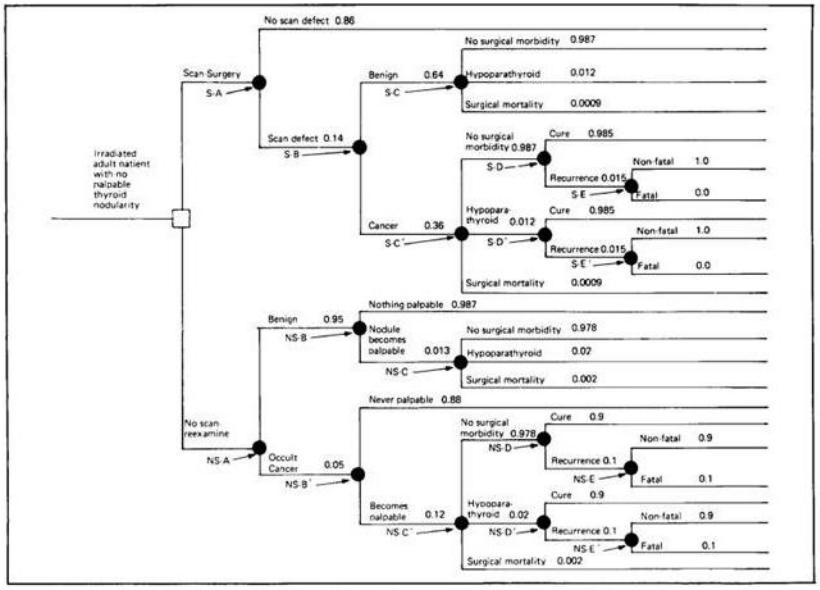
…is a patient-physician shared decision in conditions of uncertainty!

MEDICAL PROGRESS

DECISION ANALYSIS

STEPHEN G. PAUKER, M.D., AND JEROME P. KASSIRER, M.D.

$$* \quad P_{dis|find} = \frac{P_{dis} \times P_{find|dis}}{\sum_{i=1}^{n} P_{dis\ i} \times P_{find|dis\ i}},$$



N Engl J Med 1987;316:250

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Big Data and models for personalized Head and Neck Cancer Decision support

Workshop_All_Prese....pdf | Workshop_All_Prese....pdf | Workshop_All_Prese....pdf | Workshop_All_Prese....pdf | Mostra tutto

Start 18:26 22/01/2019

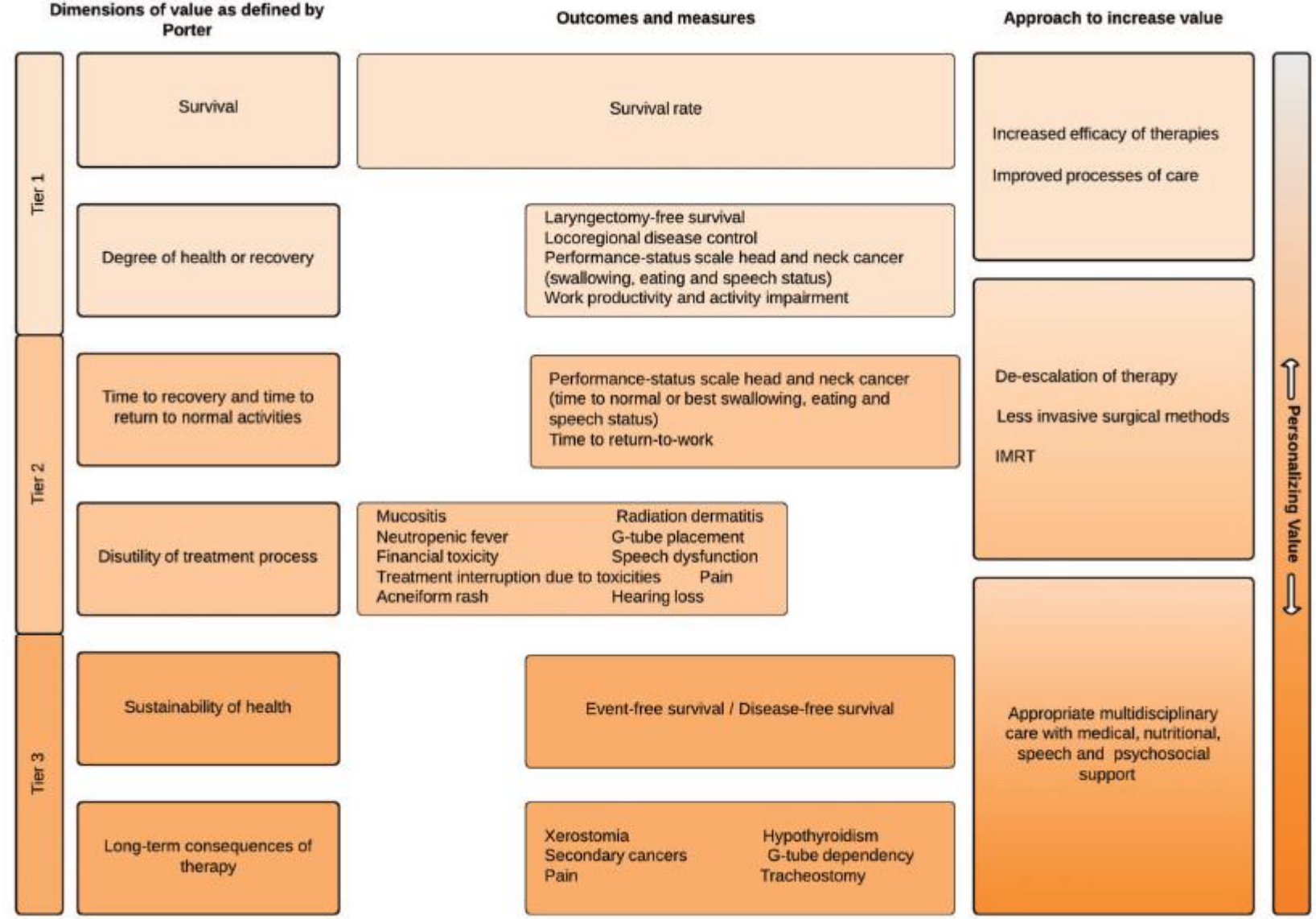

FIG 1. Application of the dimensions of value (adapted from Porter et al.[8]) to head and neck cancer care.

RARE CANCERS EUROPE

JARC
JOINT ACTION ON RARE CANCERS

EURACAN
ERN on adult cancers
(solid tumours)
(ERN EURACAN)

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