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Milan Italy

16-17 FEBRUARY 2016

The 6th ESMO Conference on Sarcoma & GIST features a multidisciplinary update of the current medical therapy of these diseases, with emphasis on the clinical approach.

Conference Co-Chairs
Paolo G. Casali, Italy, A. Paolo Dei Tos, Italy, and Jean-Yves Blay, France

State of the art

The GIST model

The STS closest to the GIST model
The STS farthest from the GIST model

The model of druggable STS with a known driver
The model of druggable STS with an uncertain driver

Diverse histologies, diverse models
The model of localised STS

Building a STS model for immune therapy

Monday, 15 February 2016
ESMO Preceptorship: Soft tissue sarcoma (STS) & Gastrointestinal stromal tumours (GIST): The basics

A one-day meeting designed to provide young oncologists with a brief outline of both STS & GIST. It could be a first contact with these diseases for oncologists who are interested to know more about them and to have an introduction to the high-profile conference in the two days afterwards.

09:30-11:00 90'	**Session 1 The diseases**	**Chair: Paolo G. Casali, IT**
30'	The natural history of STS & GIST	Paolo G. Casali, IT
30'	The pathology of STS & GIST	A.Paolo Dei Tos, IT
30'	The molecular biology of GIST	Maria Debiec-Rychter, BE

11:00-11:30	Coffee Break

11:30-13:00 90'	**Session 2 Principles of local treatment**	**Chair: Piotr Rutkowski, PL**
30'	Surgical margins in STS & GIST	Peter Hohenberger, DE
30'	Principles of radiation therapy in STS	Rick L. Haas, NL
30'	Surgical challenges across primary sites of STS	Sylvie Bonvalot, FR

13:00-14:00	Lunch

14:00-15:30 90'	**Session 3 Multidisciplinary treatment in the localised-disease setting**	**Chair: Javier Martin-Broto, ES**
30'	Adjuvant chemotherapy of STS	Jean-Yves Blay, FR
30'	Adjuvant therapy of GIST	Heikki Joensuu, FI
30'	Multidisciplinary challenges in STS and GIST	Peter Hohenberger, DE

15:30-16:00	Coffee Break

16:00-17:30 90'	**Session 4 The medical approach in the advanced-disease setting**	**Chair: Mikael Eriksson, SE**
30'	Principles of systemic therapy of STS	Ian Judson, UK
30'	Histology- and molecularly-driven medical therapy of STS	Silvia Stacchiotti, IT
30'	Targeted therapy of metastatic GIST	Peter Reichardt, DE

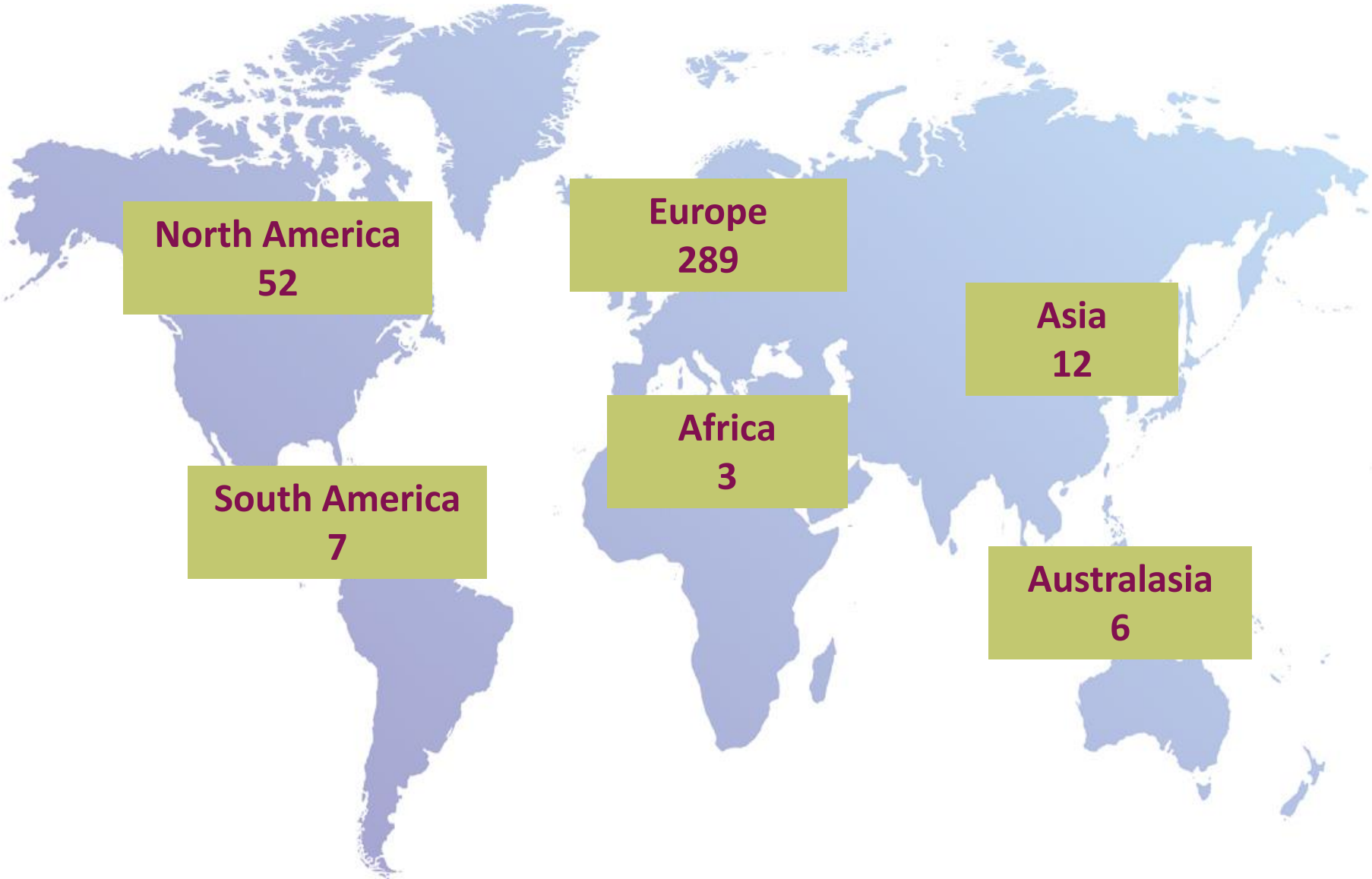
ESMO

Monday, 15 February 2016
ESMO Advanced course: Soft tissue sarcoma (STS) & Gastrointestinal stromal tumours (GIST): Advanced

Created for professionals who are already familiar with these diseases, this one-day event offers intensive discussions on STS & GIST clinical cases. Attendees will benefit from discussions about challenging clinical cases with specialists from both the EU and USA, leveraging the different perspectives and expertise across continents.

09:30-11:00 90'	**Session 1 Localised GIST: Case discussions**	**Moderator: Jean-Yves Blay, FR**
	Case(s) presenter: Alessandro Gronchi, IT	Panelists : Ronald P. DeMatteo, US; Mikael Eriksson, SE; Xavier Garcia del Muro, ES; Giovanni Grignani, IT, Peter Hohenberger, DE, Heikki Joensuu, FI; Toshirou Nishida, JP; Piotr Rutkowski, PL. Jonathan C. Trent, US
11:00-11:30	Break	
11:30-13:00 90'	**Session 2 Metastatic GIST: Case discussions**	**Moderator: A.Paolo Del Tos, IT**
	Case(s) presenter: Alessandro Gronchi, IT	Panelists : Massimo Aglietta, IT; Sebastian Bauer, DE; Jean-Yves Blay, FR; George S. Demetri, US; Lee Helman, US; Ian Judson, UK; Javier Martin Broto, ES; Michael Montemurro, CH; Peter Reichardt, DE
13:00-14:00	Lunch	
14:00-15:30 90'	**Session 3 Localised STS: Case discussions**	**Moderator: Piero Picci, IT**
	Case(s) presenter: Alessandro Gronchi, IT	Panelists: Larry Baker, US; Sylvie Bonvalot, FR; Alexander Fedenko, RU; Stefano Ferrari, IT; Rick L. Haas, NL; Kirsten Sundby Hall, NO; Antoine Italiano, FR; Piero Picci, IT; Raphael Pollock, US; Silvia Stacchiotti, IT; Dirk Strauss, UK
15:30-16:00	Break	
16:00-17:30 90'	**Session 4 Metastatic STS: Case discussions**	**Moderator: Paolo G. Casali, IT**
	Case(s) presenter: Alessandro Gronchi, IT	Panelists: Robert S. Benjamin, US; Paolo G. Casali, IT; Alessandro Comandone, IT; Bass Hassan, UK; Robin Jones, UK; Robert Maki, US; Shreyas Patel, US; Chandrajit Raut, US; Scott Schütze, US; William D. Tap, US; David Thomas, AU; Winette van der Graaf, UK; Andrew Wagner, US

369 PARTICIPANTS FROM 41 COUNTRIES



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North America 9%

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Africa 6%

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134 COUNTRIES

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ESMO Asia 2016 Congress

Singapore - 16 Dec - 19 Dec 2016

The second ESMO Asia 2016 will take place in Singapore 16-19 December 2016. This scientific and educational congress is led by an international scientific committee and promotes the sharing of expertise and interaction between regional and international experts in oncology. The programme will offer state of the art science and the current standard across all major tumour types.

Mark your calendars for the second ESMO Asia 2016 Congress!

» Important deadlines

Deadline	Date
Abstract submission	17 August 2016
Early registration	21 September 2016
Late-breaking abstracts	2 November 2016
Late registration	9 November 2016

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1 January 2016 (Vol 1 Issue 1) Table of Contents

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ESMO Open—Cancer Horizons and the future of oncology

Christoph C Zielinski

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► Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/esmoopen-2015-000008).

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In recent years we have witnessed an almost complete repositioning of oncology. Our understanding of the basic biology of the disease has evolved,[1] as has our view of cancers that were once considered as a single entity and are now known to be composed of a wide variety of molecular subgroups.[2] In tandem, the landscape of cancer therapy has also changed, with cancer treatment shifting from largely non-specific cytotoxic procedures to sophisticated treatment options targeting selected signal transduction pathways or single driver mutations, facilitating precision therapies and their use in specific, clearly characterised molecular situations.[3] The recent introduction of immunological treatment modalities aimed at modulating and neutralising tumour-induced suppression of immunocompetent cells in the tumour microenvironment is also heralding a potent new approach in the treatment of cancer.[4] The enormous progress in drug development[5] can be attributed to a range of aspects: results from the Cancer Genome Project;[6] expectation of the public for swift access to new efficacious drugs for ever more diversified patient populations; and steps taken by regulatory authorities to make such access possible under the proviso of appropriate evidence supporting postulated mechanisms of action and target selection.[7] This is further complemented by the impressive development pipelines for new and upcoming immuno-oncology treatment modalities, involving the identification of new indications and new receptors which are amenable to therapeutic interventions, and studies to understand the dynamics in treatment responses.[4]

As a consequence of our exponentially increasing knowledge in diagnostics, treatment and available technology, oncology has become an interdisciplinary medical science. This is structurally relevant for individual institutions and is reflected by the establishment of comprehensive cancer centres, uniting diagnostic and clinical disciplines with translational research, basic science and epidemiology.[8] It has also resulted in the establishment of interdisciplinary tumour boards, constructed to provide individual patients with the entire wealth of knowledge of various medical specialties dealing with malignant diseases. This encompasses diagnostics, including the assessment of molecular tumour characteristics; radiological assessments, utilising the vast potential of functional scintigraphy; and the direct clinical input of surgical, radiotherapeutic and medical oncology specialists. This approach also allows input from translational research and provides an opportunity for recruitment of patients into appropriately designed clinical trials of novel therapies.

On the global scale, the burden of cancer as a social challenge has been recognised,[9] but access to innovative and often prohibitively expensive cancer drugs for even high-income countries is a widely discussed and relevant topic.[10] The financial burden that now accompanies many novel cancer agents, an issue which is also relevant for high-income countries, has prompted the European Society for Medical Oncology[11] and the American Society of Clinical Oncology[12] to generate measures for the containment of expenditure on various pharmaceutical products. This has resulted in the first definition of a Magnitude of Clinical Benefit in an ESMO-initiated Scale.[13]

It seems likely that these wide-reaching and varied developments in oncology over the last decade are not only going to last but will probably continue to develop at an increasing pace. Therefore, it can definitely be considered timely for ESMO to launch *ESMO Open—Cancer Horizons*: an open access online-only journal which is presenting its first publications here. While *Annals of Oncology* will continue to be ESMO's flagship journal, *ESMO Open—Cancer Horizons* has been designed to offer a very broad, easily accessible format, facilitating rapid publication of data and direct access to information on important ESMO policies, original publications and both scientific and clinical

Risks of the new EU Data protection regulation: an ESMO position paper endorsed by the European oncology community

recommendations

In summary, patients should have the right to 'donate' their data and tissues to health research. Patient consent for use of data or tissue for health research should be a fully informed, withdrawable, more or less broad, 'one-time' process, which truly implements the patients' rights, rather than creating burdensome, possibly harmful consequences to the patients' community. The patient shall retain access to the tissue and data donated, hence ensuring him/her to obtain relevant information related to his/her condition. On the contrary, denial of this right would make patients less free, because they would be denied a civil right, i.e. to contribute to research, which advances knowledge and leads to new ways of improving their health and that of other patients. There need to be put in place legal provisions to protect data confidentiality, reviewing mechanisms to oversee retrospective researches and biobanks, and a system allowing full transparency of research processes and storage of patient tissue in biobanks. Cancer registries should be able to register cancer cases and patient data without the requirement of patient consent, in order to provide society and health administrators with exhaustive health data for public health policy decisions.

The European cancer community urges all EU decision makers to save research, as well as to protect the right of patients to donate their data and tissues to advance research and find cures. EU decision makers are urged to change the European Parliament Amendments 191 and 194 to Articles 81 and 83, as they would impair public health research within and across EU Member States. A balance between the right to privacy and the right to health can be achieved by reasonably addressing all concerns, while fully complying with those relating to confidentiality and ethical use of personal health data.

endorsements

This ESMO position paper on the EU General Data Protection Regulation is endorsed by the following organisations, and under review for endorsement by additional organisations:

European Organization for Research and Treatment of Cancer

European, Middle Eastern & African Society for Biopreservation and Biobanking

Eurocan Platform

European Society of Surgical Oncology

European Society of Pediatric Oncology

European CanCer Organisation

European Cancer Patient Coalition

European SocieTy for Radiotherapy & Oncology

Association of European Cancer Leagues (ECL)

Show your support and sign the
Call to Action Against Rare Cancers:

www.rarecancerseurope.org

Rare Cancers Europe is a joint initiative based on a partnership between the European Society for Medical Oncology (ESMO), the European Organisation for Rare Diseases (EURORDIS), the European Cancer Patient Coalition (ECPC), the European Organisation for Research and Treatment of Cancer (EORTC), Conticanet, EuroBoNeT, the World Sarcoma Network (WSN), the Association of European Cancer Leagues (ECL), the Chronic Myeloid Leukaemia Support Group, the International Brain Tumour Alliance (IBTA), Orphanet, the Chronic Myeloid Leukaemia Advocates Network, the Sarcoma Patients EuroNet Association (SPAEN), GIST Support UK & PAWS-GIST, Cancer 52, the International Kidney Cancer Coalition (IKCC), the Chordoma Foundation, the Fondazione IRCCS Istituto Nazionale dei Tumori, the European Institute of Oncology (IEO), the European Society for Paediatric Oncology (SIOP Europe), the European Society of Surgical Oncology (ESSO), the Grupo Español de Tumores Huérfanos e Infrecuentes (GETHI), the European School of Oncology (ESO), the European Oncology Nursing Society (EONS), ecancer, the European Society of Pathology (ESP), the European, Middle Eastern and African Society for Biopreservation and Biobanking (ESBB). Novartis Oncology (initiating sponsor and industry partner), Pfizer Oncology (industry partner), and Sanofi (industry partner). The campaign is moreover supported by additional corporate supporters, including Amgen (silver industry supporter) and Takeda Pharmaceuticals Europe (silver industry supporter).

RARE CANCERS

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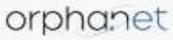
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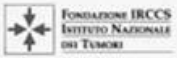
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EJC

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	304,498	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	5742	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	3766	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	23,740	1.1	0.0	88.1	0.4	9.7	0.6
	Firenze	66,087	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	8145	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	17,788	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

1. Pediatric cancers
2. Haematologic rare neoplasms
3. Sarcomas
4. Rare thoracic cancers
5. Neuroendocrine tumours
6. Head & neck cancers
7. Central nervous system tumours
8. Rare female genital cancers
9. Rare urological and male genital tumours
10. Endocrine gland tumours
11. Digestive rare cancers
12. Rare skin cancers & non-cutaneous melanoma

RARE CANCERS EUROPE

Joining forces for action

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*

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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

Joining forces for action

review

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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

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

RARE CANCERS EUROPE

Joining forces for action

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

RARE CANCERS EUROPE

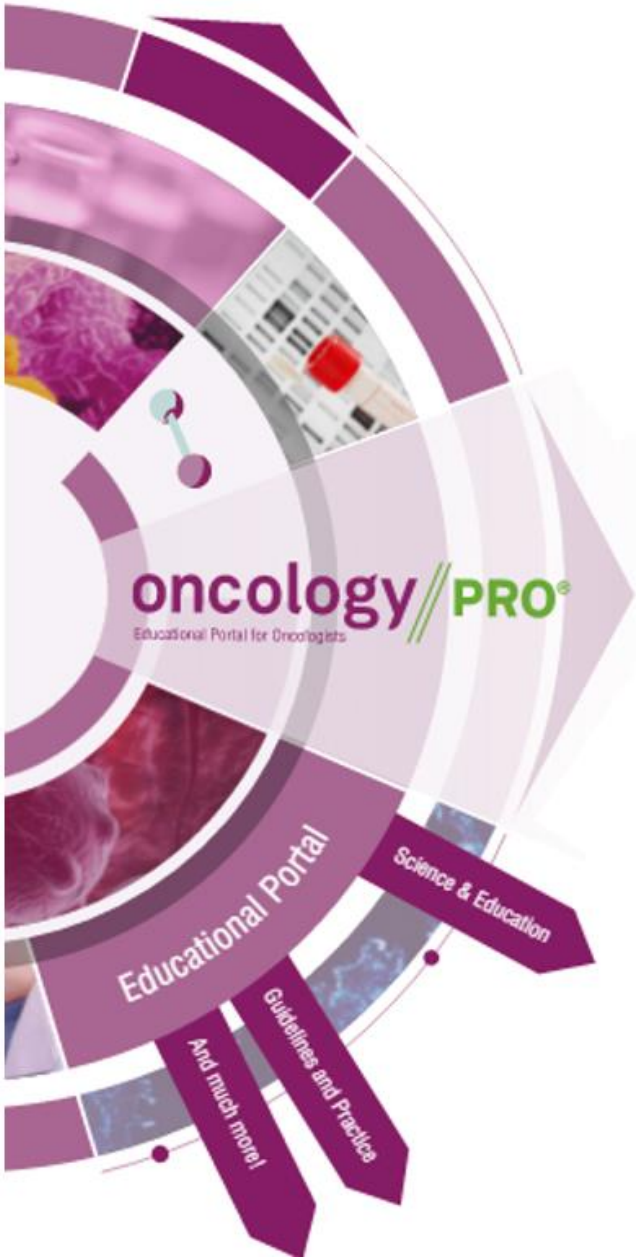
Joining forces for action

European Reference Networks

- promote good quality and safe care to patients by fostering proper diagnosis, treatment, follow-up and **management of patients across the Network**
- empower and **involve patients**
- offer and promote **multi-disciplinary advice** for complex cases
- develop and implement **clinical guidelines** and cross-border patient pathways
- exchange, gather and **disseminate knowledge**, evidence and expertise within and outside the Network
- promote **collaborative research** within the Network
- reinforce research and **epidemiological surveillance**, through setting up of shared registries
- exchange and disseminate knowledge and best practices, in particular by **supporting national centres and networks**

Clinical Practice Guidelines

- Soft tissue sarcomas
- Gastrointestinal Stromal Tumours
- Bone Sarcomas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7-11 OCTOBER 2016

IMPORTANT DEADLINES

11 May 2016	Abstract submission
30 June 2016	Early registration
23 August 2016	Late breaking abstracts
31 August 2016	Late registration

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