EUROPEAN CANCER PATIENT COALITION

Nothing About Us **Without Us!**

Patients associations: the collaboration is on going

Francesco De Lorenzo
ECPC President

27th October 2014

ECPC: "Nothing about us, without us"

- **Representing 349 cancer patient groups in 46 countries**
- **All cancers** – common and rare
- **Run and governed by patients**
- Promoting **timely access** to appropriate prevention, screening, early diagnosis, treatment and care for all cancer patients
- **Reducing disparity** and inequity across the EU
- Encouraging the **advance of cancer research & innovation**
- Increasing cancer patients' **influence** over European health and **research policy**
- Members of the **European Commission Expert Group on Cancer Control**

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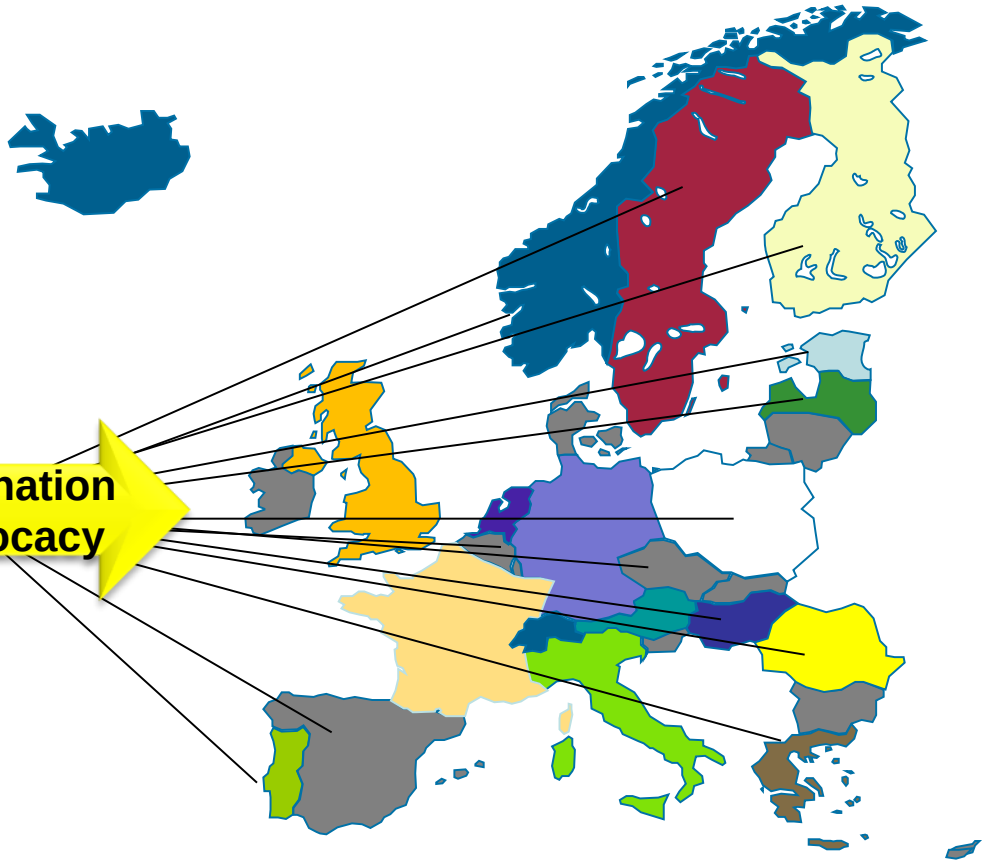
ECPC Advocacy : bridging diversity to support cancer survivors

- Empowerment of survivors and communities
- Stating the case to better support cancer survivors
- Advancing and disseminating activities through collaboration and networking
- Providing voice of consensus to communicate to stakeholders
- Promoting multidisciplinary advocacy at the EU/National level

Coordination & Advocacy



European level

National level

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The problem

Estimated number of cases, all cancer combined, both sexes, Europe

GLOBOCAN 2008

2,445,000

1,234,000

6,617,411

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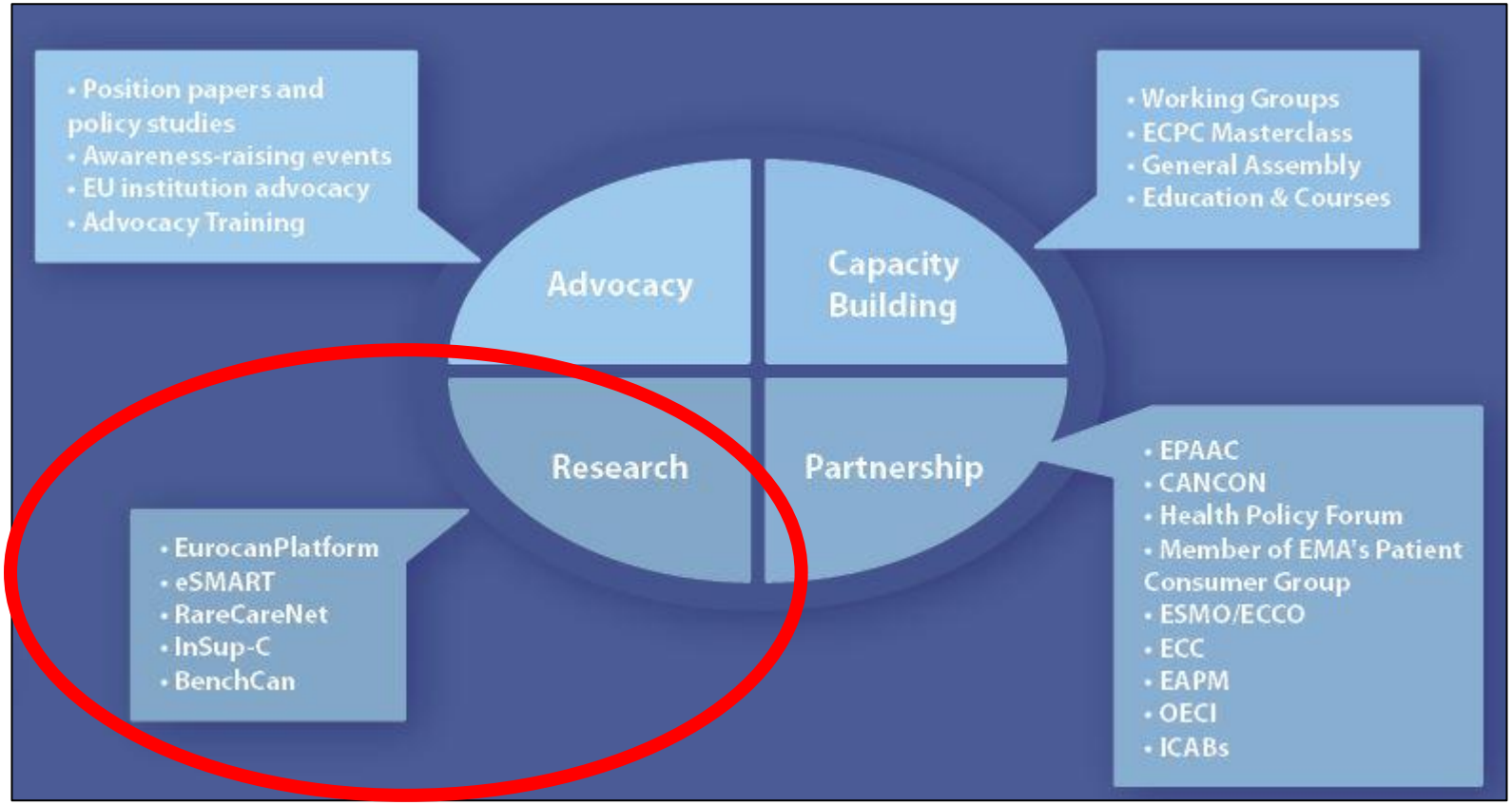
European Cancer Patient Coalition's Activities

ECPC & Research: Credibility comes from expertise



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RARECARENet

Problem: few countries (e.g France) have recognised specialised centres for rare cancers

- **The Project**
  - **EAHC** financed project
  - **Consortium** of 11 partners

- **ECPC Deliverables**
  - A list of **144 Rare Cancer patient organisations** across Europe
  - An **online library** with information on rare cancers:
    - diagnosis, treatment and follow-up
  - The identification of **Centres of Excelence for rare cancers in Europe** (ongoing)

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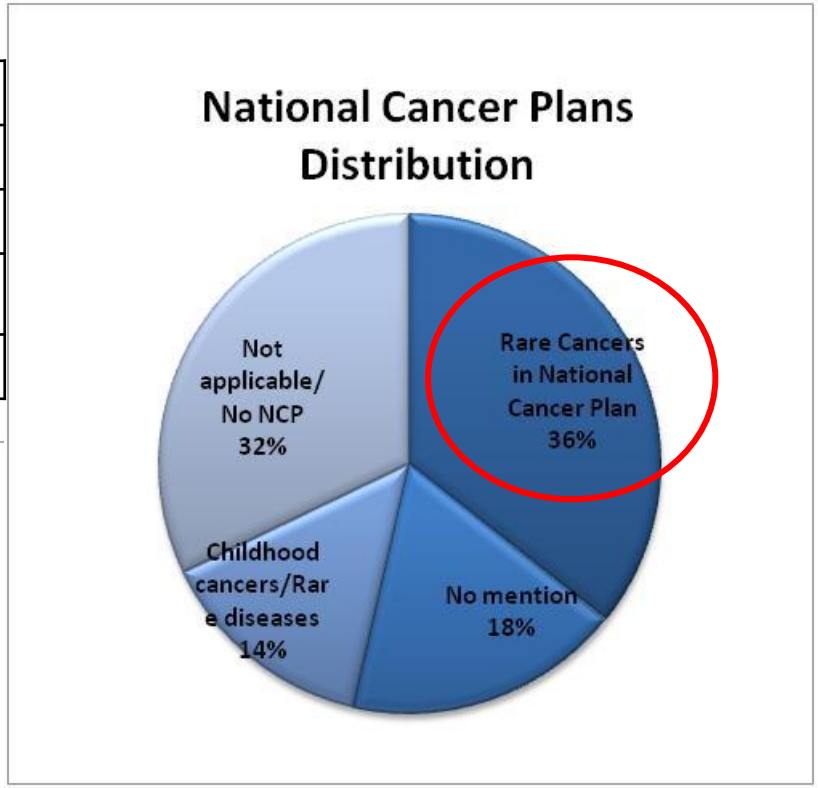
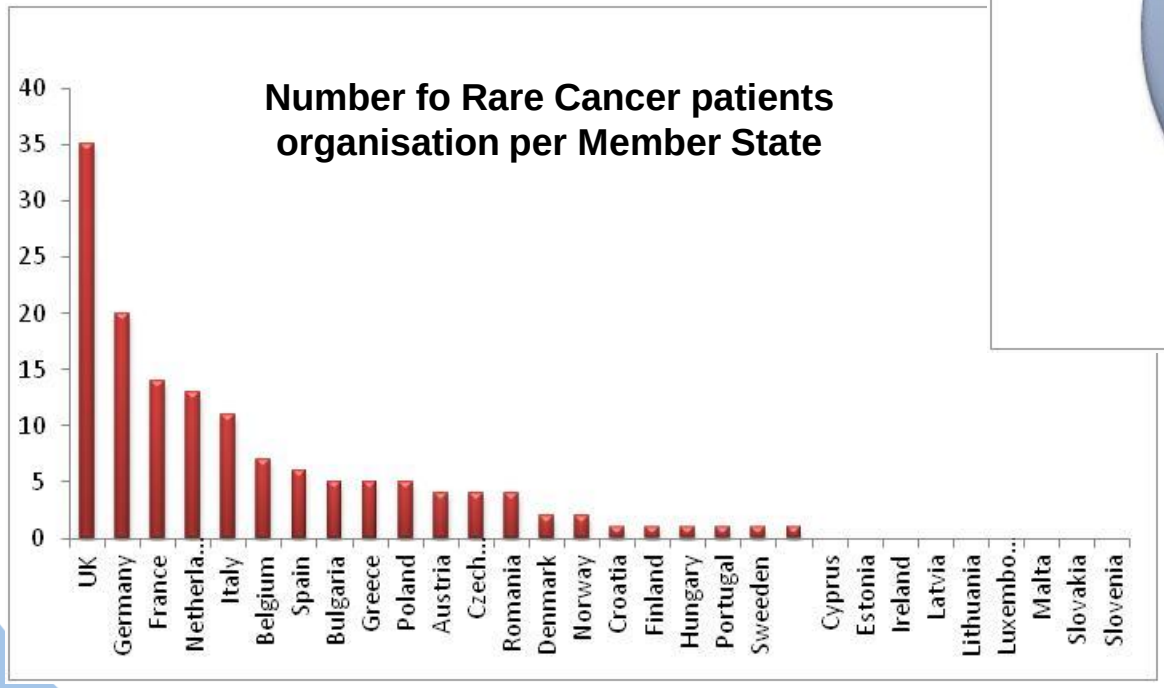
RARECARENet

FINDINGS

Are rare cancers mentioned in NCPs?	
Yes	10
No mention	5
Only Childhood cancers/Rare diseases	4
Not applicable/ No NCP	9





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eSMART

- **Objectives:**
  - demonstrate the effects of a real-time, mobile phone based, remote patient monitoring intervention on key patient outcomes and delivery of care provided to people with cancer during and after chemotherapy
- **Outcome:**
  - Creation of areal-time, mobile phone based remote patient monitoring system, the Advanced Symptom Management System (ASyMS)
  - Test of the ASyMS
- **ECPC's role:**
  - Provide guidance from the patient perspective;
  - Dissemination

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Empowerment through projects

: prevention, early detection, improved treatments through translational research

ECPC's role: dissemination - from the lab to the patient

in collaboration with eCancer

- **BIOBANKING**
  - Biobanking glossary and Frequently Asked Question
  - Publication launched this week – AVAILABLE NOW
- **BIOMARKERS**
  - Video on importance of biomarkers for cancer patients AVAILABLE ON ECPC.ORG
  - Empowering patients through PERSONALISED MEDICINE

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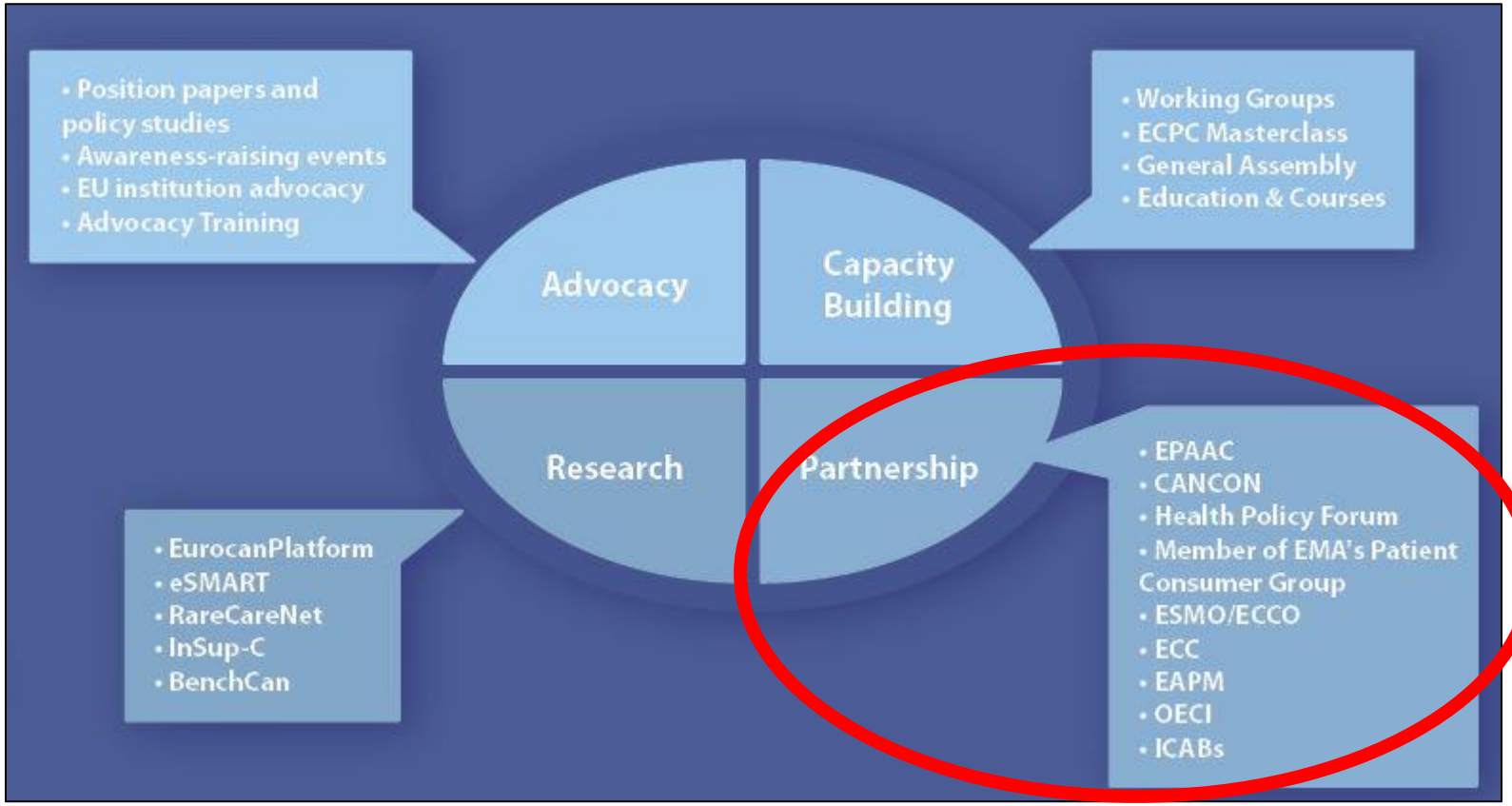
European Cancer Patient Coalition's Activities

ECPC's partnerships: the importance of teaming up



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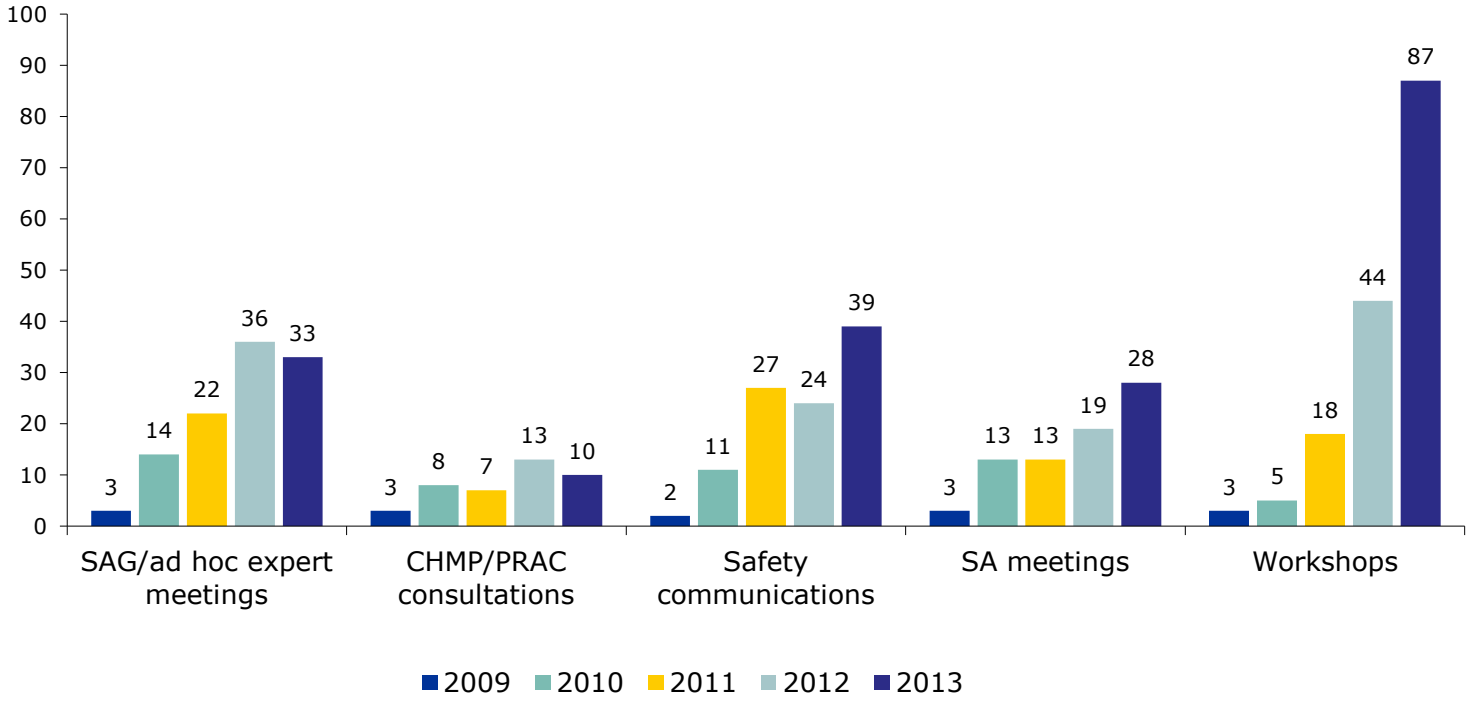
Some of the organisations working with the EMA

EMA's activities involving patients
A rising role

Comparison of patients involvement in EMA strategic activities
2009–2013



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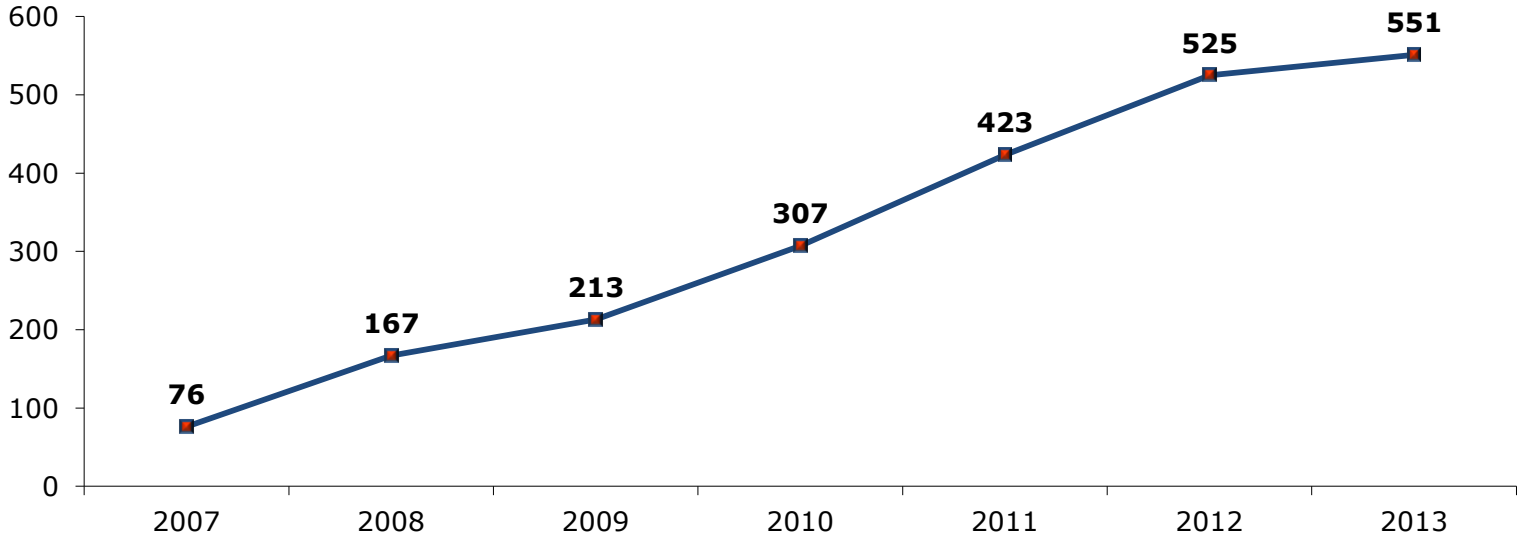
The number of patients involved in EMA's activities is on the rise

Total number of patients and consumers involved in EMA's activities
2007–2013



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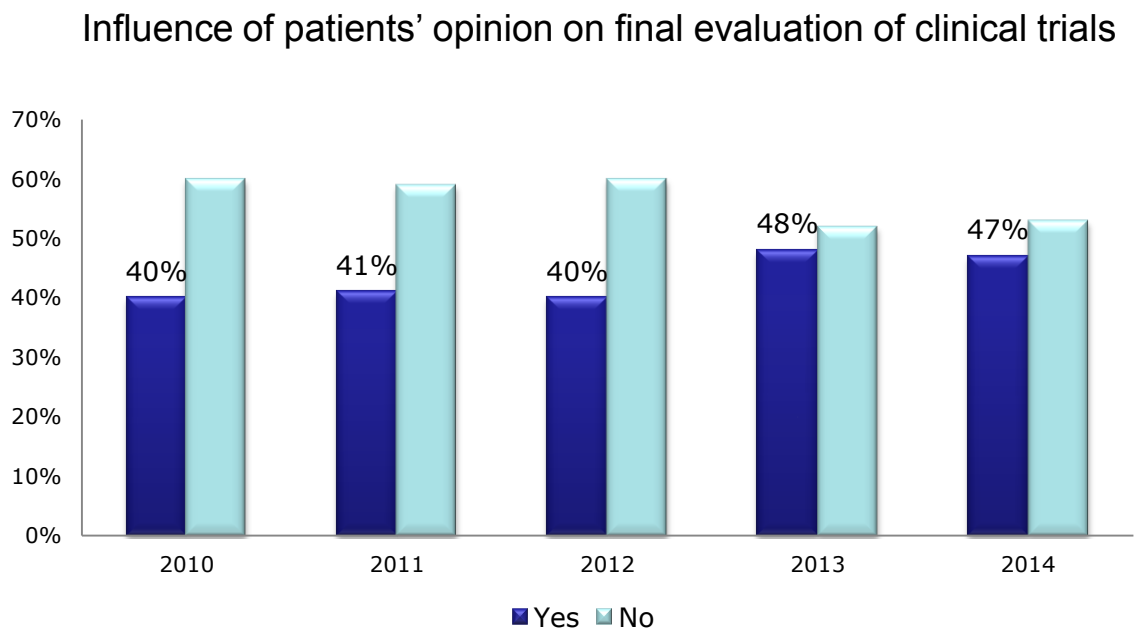
Patients' critical role in evaluating clinical trials



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ECPC & EMA

- **ECPC collaborates with the EMA since 2013.**
- **Rigid eligibility criteria, in particular:**
  - Legitimity and representativeness;
  - Trasparenza finanziaria e decisionale
- Our representatives are:

- **Kathi Apostolidisi, ECPC Vice President**

- **PhD Rafal Swierzewski, ECPC Board Member**

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ECPC & EMA – Our contribution

- ECPC representatives' activites within the second semester 2013:

  - Revision of 12 drugs' informative sheets
  - 6 documents approved with the support of patients (EPAR summaries; EMA general communications; PRAC communications and reports);
  - Participation to 3 meetings for the definition of:
    - Implementation of directive on falsification of medicines;
    - Implementation of directive on pharmacovigilance;
  - Promotion of regulation on public hearings as a new instrument to involve individual patients within the pre and post autorisation processes and pharmacovigilance;
  - Participation to Scientific Advice Groups meeting to bring patients' perspective to the discussion table of researchers and doctors
  - Cooperation between HTAs and EMA enhanced and matured;
  - Implementation of regulation on Clinical Trials

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Inequalities in cancer care in EU
The Joint Actions – EU Added value

EPAAC

- **European Guide for Quality National Cancer Control programmes**
  Basic document depicting the state of art of cancer care and providing fundamental suggestions to promote convergence in national approaches to cancer plans

- **ECPC Role: patients' voice through all WP**
  - Voicing the need for an **European Cancer Information System**;
  - Stressing the importance of an **EU strategy on rare tumours** (in collaboration with **ESMO – RARECARENet**)

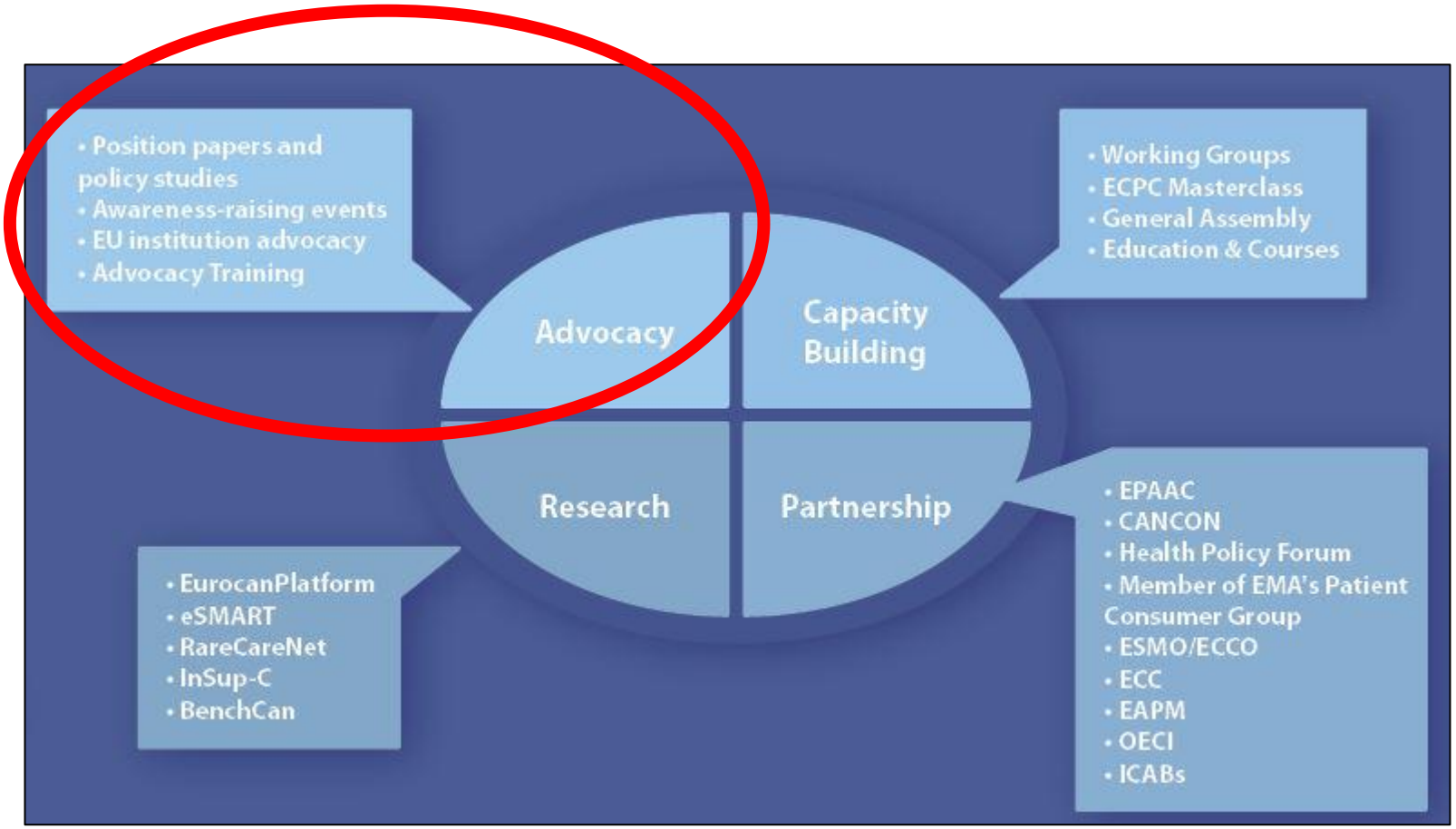
Concluded

Inequalities in cancer care in EU
The Joint Actions
CANCON

- **European Guide for Quality Improvement in Comprehensive Cancer Control**
  - Joint Action between the European Commission and 17 Member States (voluntary base)
  - Co financed by the Commission (Health Programme) and Member States
  - Joint activities are foreseen by the 3rd Health Programme
  - Duration: 3 years
- **Expected outcome:**
  - **Member State Platform** dedicated on cancer;
  - **European Guide on Quality Improvement in Comprehensive Cancer Control:** guidelines for Member States to ameliorate their national cancer plans.
- **ECPC Role**
  - **Work Package 2: Dissemination**
  - **Work Package 4: Coordination of the Guide drafting**
  - **Work Package 5: Member States Platform**
  - **Work Package 7: Community Cancer Care**
  - **Work Package 8: Survivorship and Rehabilitation**
  - **Work Package 9: Screening**

European Cancer Patient Coalition's Activities

ECPC: cancer patients' credible voice in Europe



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European Cancer Patient's Bill of Right & Call to Action

- **The Bill of Rights:**
  - **A catalyst for change:** to provide every European citizen with the right to the optimum standard of care;
  - Basic tool for all EU cancer patients
  - Wide political support

- **ECPC Call to Action**
  - First **action point** derived from the Bill of Rights
  - A **political manifesto** for the **new MEPs**, engaging them in fighting cancer;
  - More than **30 supporting MEPs**, from all groups
  - **Objective: creation of health intergroup**

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Health for Citizens – H4C
Intergroup of the European Parliament

- **What is an Intergroup?**
  - A group of MEPs, **recognised by the European Parliament** (but not EP bodies), aiming at:
    - Holding exchanges of views on **particular subjects**
    - **Promoting contact between MEPs and civil society.**
- **What is H4C?**
  - An Intergroup promoted by most political groups, interlinking EU health policies with all other EU policieis (social, labour, economic, justice etc etc)
  - Aims at bringing “Health in all policies”
- **ECPC within the H4C intergroup**
  - Provides the Secretariat;
  - Chairs the workstream on cancer
  - All Call to Action MEPs endorsed H4C!

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European Commission's Expert Group on Cancer Control

- **Group of cancer experts**
  - **Patients**
  - **Doctors**
  - **Researchers**
  - **Civil society working on prevention**

- **Objectives**
  - Assist the Commission with drawing up legal instruments, policy documents, guidelines and recommendations on cancer control
- **ECPC represents patients within the Expert Group**
  - Policy makers recognise role of patients
  - Important multistakeholder platform!

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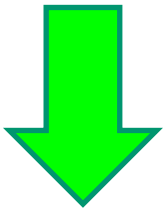
General Data Protection Regulation

- **Threatens to limit bio-banks and retrospective clinical research in ways that could be detrimental to health**
- **The regulatory frameworks for medicinal products and in-vitro diagnostics are insufficiently connected, leading to missed opportunities. Predictive assays to personalize treatment are currently insufficient**



Data protection rules should facilitate access to medical data that is crucial for both prospective and retrospective medical research

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General Data Protection Regulation
Patients advocacy's role

ECPC supported **ESMO** and the oncology community

VS

Risks derived from GDPR (articles 81 & 83)

Main consequence: slowing down or total block of research based on population-based disease registries

Patients believe in science!

Cancer patients advocates are fundamental partners (civil society) to achieve results both in the lab and within parliamentary assemblies (national and Europeans)

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EU'S CROSS-BORDER HEALTHCARE DIRECTIVE

Highlights inequalities in patient access from country to country as a result of inadequate national budgets

Member States:

- **<u>sometimes</u> do not reimburse duly authorised drugs**
- **<u>sometimes</u> discourage their prescription in first-line therapy or exclud them from regional formularies**
- **<u>frequently</u> take longer than permitted by EU legislation to make decisions on pricing and reimbursement – from a few months to several years**

THE IMPACT OF CURRENT ECONOMIC CRISIS IS INTENSIFYING THE TREND

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NEED FOR EQUAL ACCESS TO TREATMENT

Effective treatments are lacking but even where they exist, access is often prevented for a number of reasons (regulatory issues, delays in reimbursement, inequalities between member states, etc.).

At the same time as the EU is developing its cross-border healthcare directive, more and more obstacles are raised to prevent patients from crossing borders to take part in clinical trials. That is unacceptable

Action is required quickly because for the thousands of melanoma patients who will die unnecessarily if it is not taken, this is really a matter of life or death

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NEED FOR EASIER ACCESS TO NOVEL TREATMENTS

Insufficient coordination with the processes for authorising, pricing or reimbursing diagnostics further complicates access to molecular testing and innovative treatments

The diverse methods of deciding prices and reimbursement across the Member States often fail to capture or reward appropriately the potential value of a new medicine. This may lead to underestimate the true value of a melanoma treatment package, for instance to ignore the impact of non-treatment, or the benefits of shortened hospitalisation or reduced side-effects

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Access to innovative treatment
The Italian best Practice

- **The issue:**
  - **EMA newly authorised drugs are not timely adopted by Member States;**
  - **Reimbursements arrive with huge delays.**
- **The solution:**

Translation of Article 44, paragraph 3, 5bis and 5ter of law n. 98, 9th August 2013

Article 44, paragraph 5bis

AIFA is obliged to prioritise the classification of the new drugs falling within the categories expressed in paragraph Art. 44 paragraph 3 over any other pending classification process, given that the request for classification from the pharmaceutical company has been correctly submitted, including all the necessary supporting documents.

AIFA can schedule extraordinary meetings of its Commissions responsible for the classification of the aforementioned new drugs, in order to ensure the smooth and quick categorisation.

AIFA is obliged to finalise the process fo categorisation of the aforementioned drugs within the limit of 100 days.

Article 44, paragraph 5ter

Pharmaceutical companies in process of receiving a market authorisation from the EMA for new drugs falling within the domain of Article 44 paragraph 3 are obliged to submit to AIFA a request for categorisation of the mentioned new drug within 30 days after having being granted the market authorisation from the EMA.

In case the pharmaceutical company would fail to submit the due categorisation request, AIFA will solicit prompt action, requesting the company to react within the successive 30 days.

ECPC's role in M-ICAB

ECPC Achievements:

- Produced by ECPC in February 2010
- **3 European Conferences** organised by ECPC with recommedations to policy makers
- Over the last years, ECPC has built a community of stakeholders to support patients.
- MICAB paper published in September 2013 on ecancer

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The future of M-ICAB

- Renewed dedicated webpage within ECPC new Website
- Updated of the White Paper on Melanoma
- Creation of a dedicated ECPC Working Group on Melanoma to support the update of the White Paper

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Thank you very much!

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Nothing about us – without us!

Please get in touch!

Francesco De Lorenzo

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ECPC- Melanoma Independent Community Advisory Board (MICAB)

CHAMPIONING THE INTERESTS OF EUROPEAN CANCER PATIENTS