ESMO MEETING REPORT

CANCER PATIENT ADVOCACY NETWORKS DRIVING RESEARCH

ESMO WORKSHOP

Dr Bettina Ryll, Chair of the ESMO Patient Advocates Working Group (PAWG)

5 to 7 February 2016, Brussels, Belgium

The **Cancer Patient Advocacy Networks Driving Research** Workshop (1) took place from 5 to 7 February 2016 in Brussels, Belgium.

The workshop was hosted by ESMO's Patient Advocate Working Group (PAWG), whose mission is to optimise patient care in Europe; to assist continuous improvement of cancer specific information and education; to strengthen patient autonomy and support patient's rights.

Cancer care has come a long way, but not for all cancers, and there are still critical issues to be addressed in Europe and elsewhere. Not all cancer patients are equal. For some cancers there is a high rate of survival, whilst for other rarer cancers, there is no treatment available, so little hope. Research often comes short of patients' needs. Patients, who are the only ones to know "what it is really like to be a patient," have a unique perspective and role to play in determining priorities and driving research. They are experts in their own right. Although the ultimate purpose of healthcare is to benefit patients, they are the largest underused resource of our health systems.

Sustainability of care is a key issue today. Involving patients in research (from clinical trial design to market authorisation) can help make the process faster and more effective. New technologies allow patient organisations to collect quality, real-world data on treatments and outcomes.

Background

Cancer Patient Networks

Patient Networks often begin as small support groups started by patients and their carers when receiving a cancer diagnosis and finding themselves baffled by healthcare systems, treatment options (or lack of them), medical vocabulary, available information (or lack of it) and in need of support. These informal groups often grow into associations and networks as more patients join and see the urgency of making their knowledge and experience available to others in their own language.

Cancer Patient Networks aim to empower patients by enabling them to access the best treatment, to make the best choices, to be active in their own care as well as getting together to advocate for better care and quality of life. When little or no therapies are available, such as in rare cancers, patients have had a fundamental role in making society aware of the urgent need for action and in driving research.

Patient networks provide information and support and are increasingly demanding to be seen not as passive recipients of medicine, but as full and valid stakeholders in health systems, involved in the whole therapeutic process, including clinical research.

Patients are experts in their own right and have particular needs and interests. They are ready to collaborate with other stakeholders (researchers, clinicians, industry, regulatory bodies, etc.) to ensure that the best treatments are available in a timely manner to all cancer patients.

Clinical Research

Medical research entails the gathering of data to develop new treatments or adjust existing ones. Patients have a valuable contribution to make to the development of new therapies including identifying needs; setting priorities; participating in the designing of clinical trials; gathering data about effects and side effects; contributing to or even creating biobanks and funding research.

Developing medicines is a long, expensive and complex process. To be able to contribute to it, patients need to understand how it works. Research is about more than just making new drugs, it entails understanding the needs, working on diagnostics, medical devices and also non pharmaceutical therapies.

Patients are the ones experiencing disease and the effects and side effects of treatments. No one knows better than they do what is valuable to them. The information they hold can help medical research to progress in a way no other stakeholder can.

Recognising the unique role of patients in developing new strategies, ESMO hosted the "Cancer Patient Networks Driving Research Workshop" in Brussels on February 4 to 2016.

35 participants, from 21 countries, gathered to discuss ways patients can drive research successfully and efficiently. A wide range of speakers from pharmacovigilance, regulatory and health technology assessment agencies, professional societies and IT companies, among others, helped patient advocates reflect on the best ways to generate evidence for policy makers and researchers.

After a first session where participants introduced themselves and the work of the groups and institutions they represented, the workshop focused on how patient networks could leverage their research potential.

See slides http://oncologypro.esmo.org/Meeting-Resources/ESMO-Patient-Advocate-Workshop

SESSION 1: DIRECT PATIENT REPORTING IN PHARMACOVIGILANCE

Pharmacovigilance: patient reporting, why it matters

Florence Van Hunsel, Pharma Epidemiologist working for the Netherlands Pharmacovigilance Centre (3), Lareb, explained the evolution of patient reporting of adverse drug reactions (ADRs). Despite debate regarding the value of patient reports, since 2012 the EU has made it mandatory to receive reports from patients regarding ADRs. The challenge is to implement efficient patient reporting systems that capture their uniqueness. Guidelines are being developed for patient reporting in pharmacovigilance. Patient involvement has prompted a culture change: from drug oriented organisation to patient oriented organisation. Lareb has seen a steep rise in patient reports. Patients appear to be motivated mainly by altruism ("I don't want this to happen to others").

Patient reports often focus on the severity of adverse reactions and effects on quality of life. Patients also report ADRs (such as sexual dysfunctions), which do not appear in notices and highlight blind spots of pharmacovigilance systems (herbal remedies).

The current challenge is to promote patient reporting. In some countries less that 1% of patients know they can report and how they can. A promising tool is being developed by the Innovative Medicines Initiative (IMI). WEB RADR (4) is a mobile app for patients and healthcare professionals to report ADRs to national competent authorities.

VigiAccess: WHO international database of suspected side effects

Rebecca Chandler, from the Uppsala Monitoring Centre (UMC) in Sweden spoke about VigiAccess, the WHO user-friendly interface that allows patients and healthcare professionals (HCPs) to search VigiBase (WHO international database of ADRs) to find data on medicine side effects. Over 12 million adverse events reports from 120 countries are included in VigiBase.

UMC has built a global pharmacovigliance system, encouraging local initiatives, with the aim of providing independent, high quality medical reference to ensure medicine safety and best practice. Patient reports are included in VigiBase. No causality is required to be proven to be included in the database. Individual case safety reports (ICSRs) are on the rise with a 20% growth over the past year. As of 1 January 2016, over 2.9 million reports came from consumers, not HCPs. Some side effects reported are already in the label leaflets, but the severity of ADRs may be underestimated. VigiBase contains all reported ADRs so it is a useful resource for HCPs patients and advocates.

Information goes out via the WHO Pharmaceuticals Newsletter (6), which is available to the public. VigiBase is currently focusing on drug interactions. The main challenge today is making patients and HCPs aware that VigiBase and VigiAccess exist and finding ways to make it easier to use them. A useful tool is the free *Take and Tell App* (7), which links to VigiAccess. The EMA website (8) should also be checked for links to national authorities in charge of pharmacovigilance.

SESSION 2: MAPPING ACCESS TO TREATMENT FOR ADVOCACY

Mapping Access: The Myeloma Patients Europe (MPE) *example*

Ananda Plate, (role) from MPE Spain, presented their mapping project. Seeing that access to proper treatment remains a challenge in many European countries and that advocacy efforts so far had not had the desired impact, MPE decided that mapping the challenges would be a good starting point to understand the complex issues regarding access by gathering evidence, which in turn would be useful for education, information, best practice exchange and advocacy.

The MEP ATLAS (9) of access to myeloma treatment measured (among others): existing treatments; current clinical trials; time gap between discovery of drug and clinical access; access to available treatments; drug approval in various countries (differences and similarities); barriers to access perceived by clinicians and patient organisations across countries in relation to self declared needs and health expenditure (health systems, budgets, etc).

As expected, the Atlas confirmed that more research is needed into myeloma and new strategies are needed to ensure equal access to treatment for patients. The MPE ATLAS provides essential evidence to advocate for access. Issues of unequal access also require EU strategies and MPE will continue to strive to help organisations join forces to advocate for *"the right treatment to be available to the right patient at the right time."*

ESMO assessment of patient access to cancer medications in Europe

Prof Rolf Stahel, Past President of ESMO, spoke about two of the society's initiatives to assess access to cancer medication in Europe. ESMO strives to reduce the disparities in cancer outcomes (survival) across Europe. Among many reasons for these disparities: general health and lifestyle issues; system infrastructure; timely diagnosis; access to treatments; pricing of innovative drugs; incoherent reimbursement strategies, etc.

In 2015, the WHO published a *List of Essential Medicines for Cancer* (10) to which ESMO contributed.

ESMO is working on an *Anti Neoplastic Medicines Survey* (11) measuring access to cancer medicines, including those on the WHO essential cancer medicines list. The survey will report on the approval status of drugs, reimbursement issues and actual availability of both old and new drugs.

Prof Stahel referred to the current "nightmare of the cancer patient road" due to the time lapse between the approvals of new drugs by the EMA until they are available in each country (anything between two to ten years).

Recognising the need for clear and unbiased information regarding the clinical benefit of new therapeutic approaches, supported by credible research, ESMO is developing a *Magnitude of Clinical Benefit Scale*, (ESMO MCBS) (12). It aims to highlight treatments that bring substantial improvement to the duration of survival or the quality of life (QoL) of cancer patients.

Prof Stahel concluded by saying that while inequalities in access and costs to patients, especially for newer more expensive drugs need addressing, the current shortages affecting old and inexpensive drugs are unacceptable and should be tackled urgently.

Turning mapping into advocacy

Dr Ana Maria Forsea from *Melanoma Patient Network Europe* (MPNE) and the Carol Davila University of Medicine and Pharmacy in Bucharest, Romania, introduced participants to various relevant sources of information about the burden of cancer in Europe. Among them:

- The European Cancer Observatory (EUCAN) country factsheets (13), which show the incidence, mortality and prevalence data for 24 different cancer types in the EU. Data shows huge disparities in the cancer care spectrum from prevention, diagnosis, treatment availability, multidisciplinary care, care for survivors, to registration and reporting.
- In 2014, the European Commission (EC) published a European Code Against Cancer (14), listing 12 actions citizens can take to reduce cancer risk
- The European Network for Indicators on Cancer (EUNICE) (15) by the International Agency for Research on Cancer (IARC) and the WHO aimed to provide additional new indicators of cancer survival (not covered by EUROCARE) of value to health services and clinical management.
- EUROCOURSE (Europe against cancer: Optimisation of the use of registries for scientific excellence in research) is another EC funded project aiming to improve the use of cancer registries in Europe through researchers networking, information exchange and benchmarking of best practice. EUROCOURSE explores five domains: cancer burden, prognosis, quality of care and quality of life, public health and aetiology.
- Another essential resource for advocacy is the ESMO drug availability map already referred to by Prof Stahel.
- The EUROSTAT (statistical office of the EC) data regarding annual average net earnings across the EU are a useful tool for advocates, for example to compare to the cost of a melanoma drug.

- The OECD Cancer Care has issued a policy document "Cancer Care: Assuring Quality to Improve Survival" (17) calling for policy actions to ensure resource allocation to cancer care, to assure quality and improve survival after cancer.
- The European guide for quality national cancer control programmes (NCCPs) (18) published by the National Institute of Public Health as part of the European Partnership Action Against Cancer (EPAAC) with funding from the EU, gives background and practical advice on developing efficient national control plans and refers to prevention, integrated care and supportive functions within the health system (including governance and financing, epidemiology and research). The guide gives a useful list of indicators to monitor progress.
- EUROCHIP (10), the European Cancer Health Indicator Project, funded by DG Sanco, focuses on fighting inequalities in cancer by improving information and knowledge by using unique tools of comparison and solidarity. EUROCHIP 1 delivered indicators in the domains of prevention, screening and care. EUROCHIP 2 aimed to reduce inequality gaps in cancer information by acting as a network of networks to promote common actions. EUROCHIP 3 investigated four areas in particular (cervical cancer screening in Eastern Europe, EU cancer registration, information on survivorship and on cancer costs and outcome). The final EUROCHIP report (20) contains a list of proposed health indicators for cancer, including operational definition, information on possible sources and methodological issues as well as availability in different countries.
- The Cancer Control Joint Action (CANCON), a network of cancer control stakeholders, issued recommendations in a European Guide on Quality Improvement in Comprehensive Cancer Control (21). The Guide is meant to give governments, policy makers, health care providers and funders and cancer care professionals guidelines to: reduce inequalities at various levels; to improve cancer care and the quality of life of patients and survivors. CANCON calls for the integration of medical services and the creation of comprehensive cancer centres (CCC) linked to others by comprehensive cancer care networks (CCCN), for the effective use of available resources.
- The need for a specific information system for cancer in order to facilitate the use of available data for cancer research and control, lead to the proposal for a European Cancer Information System (ECIS) (22). ECIS should centralise all European data on cancer and allow open access to its resources. Proposed indicators lie in the domains identified by EUROCHIP (prevention, epidemiology and cancer registration, screening, treatment and clinical aspects, macro social and economic variables).
- The 2012 edition of the National Cancer Control Planning (NCCP) Toolkit for Civil Society, (23) is a joint effort between UICC and the European Cancer Leagues (ECL) to support advocates and policy makers. The toolkit is detailed and easy to use, including chapters on how to assess the situation, how to implement action and how to measure progress.

Forsea concluded that there are many resources (although not all available to the public) and actions going on.

The important thing for patient advocates is to look at existing data and identify current gaps in their local systems. If the data is not there, it needs to be mapped. Then a decision needs to be made on priorities and measurable objectives: Which are the meaningful gaps? What is the minimum acceptable now?

SESSION 3: CIVIC KNOWLEDGE

Patient knowledge contribution to society

Giovanni Moro, Past President of *Cittadinanzattiva* (25), a Roman think tank dedicated to promote active citizenship, introduced participants to basic concepts of advocacy and politics.

Although citizen's competence in public affairs is often questioned, people everywhere invest a lot of time and energy engaging in public policy making and producing knowledge.

The citizen's standpoint (not the same as point of view) is valuable, since people live conditions, situations, places, and services directly and individually, giving them a unique and specific knowledge that official "experts" do not have. For example, disabled people have a personal experience of architectural barriers, which should influence public policy on mobility. People want things to change "so that others don't suffer what I suffered."

Citizens should be involved and exercise power in the whole policy making cycle: agenda, planning, decision, implementation and evaluation. It is especially important to foster "meaningful engagement" by providing tools to engage in effective ways. Signing a petition a day does not necessarily bring about meaningful change.

SESSION 4: GENERATING EVIDENCE FOR REGULATORY AND HTA BODIES

What evidence is useful for regulators?

Francesco Pignatti, from the European Medicines Agency (EMA) explained how patient involvement with the EMA had evolved over time. The first patients to be included in discussions and committees came from the HIV community in the 90s. Slowly interaction with patients became routine. Today patient experience is embedded into most EMA output. Nevertheless, the EMA would like to do more.

Currently the EMA is looking to find out what individual patients think. How do they value benefits and risks? How do these values distribute across the patient population? Are there groups of patients with similar values?

Regarding which type of evidence is useful for regulators Pignatti said that assessing benefits and risks involves studying probabilities and utilities. This is where patient input is necessary since regulators tend to be more risk averse than patients, especially those with rare cancer types.

Recently EMA has worked with Melanoma and Myeloma patient groups to see how to reflect individual preferences (Overall survival? Decreasing toxicity?). Good studies are needed on distribution of individual preference and comparison across sub groups.

Many additional research questions remain, such as: how to deal with complex endpoints; which are the best sampling mechanisms; how to approach bias; how and when to conduct patient preference studies; how to use results; can results be used for regulatory, HTA, patient and physician decisions? Patients have their word to say on all of them.

Collaborating with EMA on risk/benefit assessment: the MPNE experience

Dr Bettina Ryll, from the *Melanoma Patient Network Europe* explained that trying out new drugs entails risks. Access to experimental treatments is highly regulated, but melanoma patients often have no alternative but to try drugs in development.

An EMA survey showed that regulators were more risk averse than patients. Carers and advocates also tend to be more risk averse than patients. So, if regulators and advocates are risk averse, how can things change for patients?

Patients' attitudes to risk depend on many factors, including the stage of the disease and availability of alternative treatments.

In general patients want their drugs to be safe, but when there are no available treatments, patients are willing to try innovative drugs and demand access to clinical trials. This is of course an individual decision, which is why the system should not serve the average, but each individual patient.

MPE experience of generating evidence for the EMA

Ananda Plate, from Myeloma Patients Europe (MPE) spoke about their experience in the EMA pilot study on risk and benefits (26), aiming to evaluate new methodology for collecting data from patients. She highlighted EMA's genuine desire to innovate and the complementary role between EMA and Patient Organisations.

Among the challenges faced, Plate included the insufficient time to recruit patients; the difficulty of recruiting patients; difficulties in communicating the objectives and relevance of the study to member groups and the technicality of questions that made it difficult for patients to answer.

Among the lessons learned, Plate said that the pilot study served as a model of collaboration between regulators and patient advocacy groups to develop new methodology and tools to collect patient input. It also provided unique insights into patient preferences. Plate recommended that Pan European recruitment be improved in order to unveil potential regional differences in preferences and that patients with specific disease stage be enrolled in order to answer specific benefit/risk questions.

Generating data is a complex and time consuming process. For patient organisations it is a big commitment, so they should be clear from the start what they want out of it.

Decision Making in Health Technology Assessment (HTA) processes

Jacoline Bouvy, Scientific Advisor from the *National Institute for Health and Care Excellence* (NICE), UK explained the role of the Institute in developing national clinical guidelines to secure consistent, high quality, evidence based care for patients. NICE advises the *National Health Service* (NHS) and plays a role in the HTA decision- making process.

Reliable data is needed for marketing authorisation, pricing and reimbursement. Each nation state in Europe has different processes. The EU is currently working on a convergence of methods to assess the best treatments. EUnetHTA is an example of a network of HTA across Europe to develop reliable and transferable information to contribute to local *health technology assessment* (HTA). NICE advises the NHS based on reviews of clinical and economic evidence. It aims to find the best medicines available. They study efficacy (does it work?) and effectiveness (how well does it work?). NICE uses an economic model where *quality adjusted life year* (QALY) is an important tool for decision-making. One QALY equals a year of life with full health. QALYs combine the effect of treatment on quality of life (QoL) and life expectancy, and are used to determine the value for money of medical interventions. QoL data is important in decision-making and patients have an important role in defining it.

In order to study disease progression with old and new medicines and the *incremental cost effectiveness ratio* (ICER) of treatments NICE uses *health related quality of life* (HRQL) criteria that include self-reported measures of physical and mental health. HRQLs are essential in NICE's decision making, so it is vital they capture what they are supposed to. The role of patient reporting and real world evidence is key. Today most HRQL comes from clinical trials and registries.

NICE recognises the value of reaching out to more and different patients and to including patient representatives in committees. NICE needs better methods for collecting objective and reliable data and patients have an important role to play.

Experience of the Lymphoma Coalition (LC Europe) Patient Survey

Charlotte Roffiaen, Regional Director of Lymphoma Coalition Europe (30) spoke about their Global Patient Survey (GPS). Lymphoma is a cancer of lymphatic system that has over 60 subtypes (including Hodgkin and non Hodgkin lymphomas). Understanding subtypes is essential as treatments are specific to each one.

The GPS has been carried out online every two years since 2008. The 2016 version will be in 14 languages. The GPS measures patient experience on barriers to access, physical, psychological and social issues resulting from the disease or treatment and patient communication with physicians.

The challenge is to reach patients who are not involved in organisations. How to find them? If they have a rare cancer, why are they not participating in our groups and surveys? What is the reality of their treatment? Many patients are being treated by doctors who are not experts in lymphoma. Last year 10% of respondents said they consulted patient organisations for information. Social networks can help reaching out.

Chronic Myeloid Leukemia (CML) Adherence Study

Jan Geissler from the CML advocates network (31) presented their research on adherence to oral cancer therapy that is of key importance to maximise treatment effectiveness in CML patients.

With the advance of molecular target therapies, cancer has become a chronic disease but patients are required to take their drugs indefinitely on a daily basis. Studies previously demonstrated that non-adherence was a problem, so the CML Advocates Network decided to conduct a large international study in order to understand motivations and behavioural patterns of adherence, in order to improve adherence by developing innovative tools.

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CML Advocates Network conducted a full scientific study, with a validated adherence scale (used for other diseases) in 79 countries and in 12 languages. They reached 2546 CML adult patients.

Results showed that only 21 % of patients take their medication as prescribed. Physicians should not take patients adherence assessment for granted. Those with lower adherence tended to be younger, on treatment for a longer time or using the twice-daily regimen and experiencing strong side effects.

Conclusions were that adherence in the long term is poor in a cancer where disease control is clearly linked to adherence. Results are available online (32) and were presented at meeting and publications.

SESSION 5: SUBJECTS NO MORE, PATIENT NETWORKS AND CLINICAL RESEARCH

Research priority setting: the James Lind Alliance *experience*

Kathy Oliver, Chair of the *International Brain Tumour Alliance,* IBTA (32), spoke about her experience working with the *James Lind Alliance* (34) to set priorities in neuro-oncology. When patient groups want to be involved in research it is difficult to know exactly what to study and how to get started.

The James Lind Alliance (JLA) brings together patients, carers and clinicians in Priority Setting Partnerships (PSPs) to prioritise the top 10 uncertainties about the effect of treatments. The aim is to help those who fund health research to be aware

of what matters to patients and clinicians. People who are directly affected by the disease have unique priorities. Physicians often overlook things that are essential to patients and caregivers. Participants can submit various priorities, ranging from prevention, diagnosis, surgery, radiotherapy, chemotherapy, palliative care, to side effects.

The *James Lind Alliance Priority Setting Partnership in Neuro-Oncology* (JLA PSP NO) (35) defined the survey question as: "which is the most important research priority for brain and spinal cord tumours?"

In a final workshop that took place in November 2014, stakeholders met to choose the final top ten questions/uncertainties (38) ranging from the influence of lifestyle factors on tumour growth to the effect of resection on survival in people with a suspected glioma of the brain or spinal cord. These Top Ten uncertainties are now being made known to research institutions (NHS, MRC, Cancer UK, etc.) and promoted through presentation of abstracts to medical congresses and publications.

IBTA is also participating in the JLA PSP learning group, together with other organisations (Parkinson, Alzheimers, etc.) in order to discuss processes and how to work better together.

Big Data: What patient advocates should know

Dr. Scott Wagers, from the eTRIKS consortium (17 partners) in Belgium, spoke about managing data. The eTRIKS project is funded to support other projects, by providing advice, open source platforms and training to translation research projects.

In today's world, the challenges are not to miss valuable information within the data overload and keeping all the data together and accessible in a common platform. The risk, after conducting research, is that all the information ends up stored in a single computer and lost to future research. Integrated and explorable data, are valuable data.

Wagers shared examples of projects using central platforms to increase value through data sharing, such as the collaboration with OncoTrack looking at data sets to discover new markers for colon cancer. Medical research data sets almost always have relevance beyond the initial study they were collected for. eTRIKS help interrogate complexity. Sometimes people who had nothing to do with a clinical study re-examine results and find previously unseen valuable information.

Regarding the evolution of patient involvement in research, Wagers said things have changed slowly, but there are now many ways to involve patients thanks to increased patient education and online resources. Patients should not have a token participation, but be meaningfully engaged in research projects since they provide unique insight, feedback and passion that drive projects forward.

Building your own biobank

Ulla Ohlms, from the *PATH (Patients' Tumour Bank of Hope) biobank* (41) a non-profit foundation in Germany started by breast cancer survivors, spoke about her journey from cancer patient in 2000 to Chair of PATH today.

Ohlms explained that cancer care has come a long way, with molecular biology and personalised medicine. Modern patients are educated thanks to the democratisation of knowledge via Internet and highly demanding. Thanks to advances in treatment and information, patients and professionals can make better decisions.

The PATH biobank was founded with the intention of supporting breast cancer research by providing fresh tumour tissue samples and data. The biobank operates with high ethical and technical standards and is non-profit: free for patient wanting to contribute biomaterials, but a cost recovery fee is charged to researchers for samples. Today it is the largest biobank of fresh frozen biomaterials in Europe and the first patient driven biobank in the world.

SESSION 6: CLINICAL RESEARCH

Optimal patient access to clinical trials by molecular screening platforms: the EORTC-SPECTA platform example

Stefanie Broes, from EORTC and PhD fellow at KU Leuven in Belgium, explained how patients can drive their own trials and how molecular screening platforms might help them by creating bridges between cancer patients and clinical research.

Continued medical innovation is needed to improve patient outcomes, but today the current model of drug development is not sustainable. Drug development is long and costly and carried mostly by society and patients. Most importantly, large numbers of patients continue to being treated with ineffective or insufficient regimens. Precision medicine brings new promise of effectiveness, but the discovery of rarer subtypes of cancer means it is difficult to recruit sufficient numbers of patients in traditional clinical trials for these mutations. Disease fragmentation is a challenge but it can be overcome.

As a proposed solution, the EORTC (42) developed its SPECTA (Screening Patients for Efficient Clinical Trial Access) molecular screening platform initiative.

Participating patients are screened prospectively, meaning independent of a particular trial protocol. Patients' tumour tissue is categorised at a molecular level and together with patients' clinical data it is kept in a central database. Using a single entry point, trials can then be proposed to the platform and the right patients are matched to the appropriate trial on the basis of their molecular characterization.

The SPECTA infrastructure is public, but requires collaboration between industry and academia to ensure that new treatments can be proposed to the appropriate patients. It is also important to reach a critical mass of patients. Challenges include: the need for standards and quality assurance that are essential to ensure that pathology and molecular testing are done in the same way in different laboratories; the setting up of the infrastructure and logistics of the Platform and, most importantly, data sharing and privacy issues.

SPECTA platforms are already running for colorectal cancer and lung cancer, with others in advanced development for brain, melanoma, and rare and prostate cancers. They aim to break the current silo approach to precision medicine by helping run innovative trials in multinational settings.

In conclusion, SPECTA benefits patients directly by providing access to treatments as well as indirectly by its neutral governance of samples and data provided to researchers, thereby propelling scientific knowledge and therapeutic progress. Simultaneously SPECTA helps to reduce the cost and accelerate the process of drug development, by allowing industry fast access to their patient population of interest.

The follow-up of patients through various stages of disease represents a live database of patient information, which is valuable for HTA, payers and regulators for example to support decision making such as in the adaptive licensing program currently being discussed with the EMA.

Lastly, the initiative allows establishing new collaborative models. These aspects are great advantages for health-care providers and most importantly they serve the patients' best interests.

The ECAB example of patient involvement in clinical trial design

Svilen Konov, HIV activist residing in the UK, explained the history of European Community Advisory Boards (ECAB) of the European AIDS Treatment Group (EATG)(43).

ECAB was created in 1997 as a forum for collaboration with industry and other institutions to encourage R&D in HIV/AIDS and related co infections. ECAB is a pan European organisation with headquarters in Brussels, with around 100 expert patient and treatment advocates in 40 countries.

ECAB is currently contributes to: HIV protocols, informed consent forms, patient leaflets, giving feedback to companies and the EMA, clinical trial management committees, clinical guidelines writing committees, EMA committees and the organising committees of conferences.

Fostering academic clinical research in Europe: the CAREFOR initiative

Prof Rolf Stahel, ESMO Past President, presented the CAREFOR initiative (44) for fostering and safeguarding independent academic cancer research in Europe hosted jointly by EORTC, ESMO and the European Association for Cancer Research, EACR.

Most drug and device development is carried out by industry (61%). Academia faces many difficulties in running clinical trials. In general research is highly fragmented and independent research is endangered today in Europe.

Academic sponsors (universities and hospitals, networks of investigators and networks of networks) usually work on new indications (such as for rare cancers) and on treatment optimisation (such as for immunotherapy).

CAREFOR has three strategic axes:

- Unite & educate: structure the role of academic groups in Europe, reach out to more professional societies, illustrate lifesaving achievements of academia
- Facilitate: assess impact of legal frameworks on independent clinical research in the EU; map needs of cross border collaboration and share existing solutions
- Involve patients: ensure systematic integration of patient perspective into CAREFOR activities

Stahel used examples relating to breast cancer and lung cancer to illustrate the value of independent academic research and the role CAREFOR can play.

Next steps:

- Patient Track at ESMO 2016 from 7 to 11 October in Denmark, input from patients is welcome
- Find ways to collaborate, share information and pool our resources
- Produce a toolkit on how to drive research, find public support and navigate problems
- Find an alternative word to "patient" which has passive undertones
- Put mentoring in place so that more experienced patient groups can guide new ones
- Use the example of "We Can" network that pools information

Annexes

- Photo Gallery (courtesy of ECL): link http://bit.ly/20MAHQo

Links

1) Workshop Programme: http://www.esmo.org/content/download/74015/1338464/file/ESMO-Workshop-Cancer-Patient-Advocacy-Networks-Driving-Research.pdf

2) ESMP PAWG: http://www.esmo.org/About-Us/Who-We-Are/EU-Policy-Committee/Patient-Advocates-Working-Group

3) Lareb: http://www.lareb.nl

4) WEB RADR: http://web-radr.eu/about-us/

5) VigiAccess: http://www.vigiaccess.org

6) WHO Pharmaceuticals Newsletter: http://www.who.int/medicines/publications/newsletter/en/

Patient involvement in EMA regulatory committees: https://www.eupati.eu/ema-regulatory-committees/

7) Take and Tell App: http://takeandtell.org

8) National pharmacovigilance authorities: https://eudravigilance.ema.europa.eu/human/websites02.asp

9) MPE Atlas on access to treatment: http://www.mpeurope.org/news/european-atlas-on-access-to-myeloma-treatment-survey

10) WHO Essential Medicines List: http://www.esmo.org/Oncology-News/WHO-Model-List-of-Essential-Medicines-Revised and www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf

11) ESMO Anti Neoplastic Drug Survey: http://www.esmo.org/Policy/Anti-Cancer-Medicines-Availability

12) ESMO Magnitude of Clinical Benefit Scale: http://www.esmo.org/Policy/Magnitude-of-Clinical-Benefit-Scale

13) EUCAN 2012 country factsheets: www.eco.iarc/eucan

14) European Code Against Cancer 2014: http://cancer-code-europe.iarc.fr/index.php/en/

15) EUNICE 2007: http://ec.europa.eu/health/ph_projects/2004/action1/docs/2004_1_33_inter_en.pdf

16) EUROCOURSE: www.eurocourse.org

17) OECD Cancer Care document: http://www.oecd.org/els/health-systems/Focus-on-Health_Cancer-Care-2013.pdf

18) European Guide for Quality National Cancer Control Programmes: www.cancercontrol.eu

19) EUROCHIP: http://www.tumori.net/eurochip/

20) EUROCHIP final report: http://www.tumori.net/eurochip/report_3.php

21) CANCON: www.cancercontrol.eu

22) ECIS: http://www.epaac.eu/news/149-the-proposal-for-european-cancer-information-system-ecis

23) UICC- ECL toolkit supporting NCCP: http://www.uicc.org/advocacy/advocacy-resources/cancer-planning

24) ESMO 2016 sessions: http://www.esmo.org/Conferences/ESMO-2016-Congress

25) Cittadinanzattiva: www.cittadinanzattiva.it, and www.fondaca.org

26) EMA MPE pilot study: www.mpeurope.org

27) EMA Criteria for patient and consumer organisations involvement in EMA: http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/q_and_a/q_and_a_detail_000082.jsp and http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2016/02/WC500200850.pdf

28) NICE: www.nice.org.uk

29) EUnetHTA: www.eunethta.eu

30) LC Europe: www.lymphomacoalition.org

31) CML Advocates Network: www.cmladvocates.net

32) CML Advocates Network survey: http://www.cmladvocates.net/education

33) IBTA: www.theibta.org

34) James Lind Alliance: www.jla.nihr.ac.uk

35) JMS PSP NO: http://www.jla.nihr.ac.uk/priority-setting-partnerships/neuro-oncology

36) UK DUET: www.library.nhs.uk/duets

37) PICO format: www.researchguides.uic.edu

38) Top 10 JLS PSP uncertainties: http://www.jla.nihr.ac.uk/priority-setting-partnerships/neuro-oncology

39) eTRICKS consortium: www.etricks.org, www.assembledchaos.com

40) Play Decide: www.playdecide.eu

41) PATH biobank: www.path-biobank.org

42) EORTC SPECTA platform: http://www.eortc.org/wp-content/uploads/2015/08/SPECTA-flyer-2015.pdf

43) ECAB: http://www.eatg.org/scientific_research

44) CAREFOR: www.eortc.org/carefor

45) EU Clinical Trial Regulation: http://ec.europa.eu/health/human-use/clinical-trials/regulation/index_en.htm