Consultation on the Advisory group report for the Horizon 2020 Societal Challenge on Health, Demographic Change and Well-being

WHO YOU ARE:		
Pse describe in the box briefly the organisation replying to the consultation (Number and type of Members, Legal status, Sectors of activity…)	**European CanCer Organisation (ECCO).** Through its 24 Member Societies - representing over 80 000 professionals - ECCO is the only multidisciplinary organisation that connects and responds to all stakeholders in oncology Europe-wide. ECCO is a not-for-profit federation (AISBL) that exists to uphold the right of all European cancer patients to the best possible treatment and care, promoting interaction between all organisations involved in cancer at European level. It does this by creating awareness of patients' needs and wishes, encouraging progressive thinking in cancer policy, training and education and promoting European cancer research, prevention, diagnosis, treatment and care through the organisation of international multidisciplinary meetings.	

Vertical Themes	**YOUR OPINION** (on the proposed theme)	**YOUR RATIONALE** (i.e. The expected impact of your proposed changes on Health, Demographic Change or the Well-being of European Citizens; the possible impact on businesses - in particular SMEs - on economic growth and job creation; the potential socio-economic outcome or contribution to the definition or the implementation of health policies...)
1. Personalised medicine	1. ECCO welcomes the focus on Personalised Medicine (PM), which is of critical relevance to cancer - indeed, individualised approaches are increasingly called for in oncology to foster positive outcomes across the patient pathway. ECCO would like to highlight the importance of involving multi-disciplinary cancer professionals and patients in decision-making processes regarding PM at all levels. It is also critical that PM initiatives take accessibility and affordability issues into account so as to enable patients across all of Europe to benefit from the best possible treatment and care. 2. ECCO invites the Commission to consider using the term "personalised medicine" (without 's') as opposed to "medicines" as indeed, it is essential that the entire treatment is personalised, not only drug therapies. In cancer many examples can be given around the personalisation of radiation oncology or surgery or the entire multi-modality treatment strategies. It is essential that such key non-drug assets have equal chances to benefit from EU grants. In general, ECCO invites the Commission to use 'treatment' or 'care' rather than 'drugs' or 'medicines' as the latter are too limiting and leave important treatment/care options out of scope. 3. ECCO would also like to emphasize the importance of integration of clinical care with research within the Personalised Medicine concept. Indeed, basic research through translation to clinical research and implementation is a continuous and increasingly overlapping process, with considerable shorter time lines than before. Integration of these elements is therefore of the utmost importance. 4. ECCO would also welcome a broader wording regarding the categories of actors considered in this section especially to ensure that academia and SMEs are considered alongside bigger corporations. 5. Under 4.1, instead of using 'widening participation', ECCO suggests to use 'widening access', so the perspective of the patient is mirrored and the concept of inequality is included. 6. ECCO suggests expanding the scope of treatment options considered throughout the chapter to also include radiomics – the high-throughput extraction of large amounts of image features from radiographic images. 7. ECCO would welcome the inclusion of a paragraph about the role of education and learning in supporting the medical community in personalised clinical decision making.	1. Academic publications in oncology (incl. Annals of Oncology, The Lancet Oncology, etc.) overwhelmingly indicate that PM holds the potential to address more efficiently and effectively the treatment of cancer as a leading cause of European citizens' death in the EU (as of 2013 Eurostat data published in 2016). A European Commission report on a PM Workshop that it organised in 2010 also states "some diseases, e.g. the stratified treatment of some cancers has delivered major health gains." PM could thus help bring down the important socio-economic costs associated with cancer, including productivity losses due to early death (estimated to cost EUR 42,6 billion in Europe alone, lost working days (EUR 9,43 billion) and informal care costs (EUR 23,2 billion) (indicators as per European Commission COM(2014) 584 final). 2. As for many other diseases, optimal cancer care requires treatment and care from a wide range of disciplines (for which true and equal multidisciplinarity is the key factor). 3. Basic research including translation to clinical research and practical implementation is a continuous and increasingly overlapping process, with considerable shorter time lines than before. Integration of these elements is therefore of the utmost importance. 6. Radiomics is one of the answers to the need of tailoring treatments, adding to the increasing wealth of tumour-, patient and treatment related data that are made available to personalise treatment approaches (BIG DATA).
2. Rare diseases	1. ECCO welcomes the focus on Rare Diseases as an area of high relevance to cancer. Indeed, rare cancers represent a significant share of rare diseases in Europe (WHO estimates that some 30 million people are affected by rare disease in the region, and project RARECARE counts some 4 million rare cancer patients in the EU). Furthermore, multiple academic resources point to an advance of Personalised Medicine (PM) for all cancer types, which implies that all cancers are unique and thereby have the potential to be treated as rare and in any case be approached on an increasingly individual basis in the future. 2. Enabling research and development of innovative therapies, collaborative working, and access to expertise and quality care are key issues for rare cancers. 3. The involvement of patients and a multi-disciplinary approach remain of central importance. Accessibility and affordability are also essential and indeed present more complex issues in the rare cancers field, as development of innovation may be hindered by a limited degree of commercial attractiveness. It is therefore imperative that academia is sufficiently resourced to undertake research. It is furthermore critical to capitalise on the concentration of patients in expert treatment centres, such as the European Reference Networks (ERNs), for research purposes. Sustainability of research structures for rare cancers, including through ERNs, needs to be secured. 4. Under 1.1, ECCO invites the Commission not to restrict the role of industry to pharmaceutical companies only. In general, ECCO would welcome a wider scope when it comes to companies to ensure that medical devices are also clearly in scope.	Based on the RARECARE (EU Health Programme project) findings, more than 4 million people in the EU are affected by rare cancers, which represent in total about 22% of all cancer cases. Rare cancers are furthermore characterised by particularly high mortality rates, which makes their human and socio-economic cost considerable despite being qualified as 'rare'.
3. Research and innovation for infectious diseases	-	-

4. Non-communicable diseases	1. ECCO welcomes the focus on non-communicable diseases (NCDs). ECCO sees value in focusing on the NCD cluster rather than on specific NCDs especially in the area of prevention given that many of the NCDs share common risk factors. This approach is nevertheless limited as it tends to put too much focus on prevention on one hand and not enough on screening/early diagnosis and improving quality of care/treatment. There is still important progress to be made in the area of cancer screening, diagnosis and treatment and research plays a pivotal role in this area. ECCO would therefore welcome a more balanced content of the NCDs section that reflects the importance of all three dimensions. 2. ECCO welcomes the focus on multidisciplinarity but calls for more systematic reference to multidisciplinarity across the section and in the document. 3. ECCO would welcome a greater focus on improving quality of care looking not only at treatments per se but also into more comprehensive issues related to the organisation of care, pathways and performance measurement. Regarding the latter there is an important need for more research in the area of standardisation of outcomes measures, including Patient Reported Outcome Measures (PROMs), and data collection and sharing. 4. ECCO would like to emphasise the need for more health economic evidence in the area of cancer/NCDs especially when it comes to cost-effectiveness of multidisciplinarity and combined therapies/interventions. 5. Given the importance of health workforce in ensuring delivery of quality care, ECCO feels that the topic of health workforce should be mentioned in this section and/or in other relevant sections 6. On page 42, ECCO believes that it would be appropriate to list cancer as a separate disease like the other NCDs and not just list it under item 8. 7. ECCO believes that it would be appropriate to align the phrasing of the section with the phrasing of the section on infectious diseases. 8. ECCO would like to underline the importance of supportive care which is needed both as a result of cancer or a result of its treatment(s). More emphasis would be needed on innovative approaches (e.g. immersive VR, ICT) to facilitate supportive care (including but not limited to) advance symptom management) but also interventions that promote patient empowerment.	1. Cancer is the second cause of mortality in Europe as a whole (being already the leading causes in several European countries) and will likely become the first cause within the next 20 years. NCDs share common risk factors. That makes it relevant to use a cluster approach when looking into prevention. But the picture is quite different when it comes to early detection (still some room for joint screening programmes between CVDs and diabetes, less evident for cancer) and treatment, two areas for which research can make a huge difference but that necessitate a disease-specific approach. 2. There is a large consensus and a growing evidence supporting the fact that multidisciplinarity is a critical success factor to ensure quality cancer care (also true for other NCDs) and the best possible patient outcomes. 3. Standardisation of health outcome measures, PROMs and systematic collection of data are among the most recurrent topics discussed at the different cancer expert meetings. 4. There are important data gaps in Europe when it comes to both costs and clinical outcomes (benefits) making health economic evaluation difficult to perform. In addition, the design of national Health Technology Assessment (HTA) evaluations makes it difficult to focus on combinations of health interventions as many HTA evaluations focus merely on individual drugs. This approach does not reflect the reality of patients and healthcare teams with most patients now being treated with a combination of drugs and other interventions (radiation therapy, surgery, etc). 5. As acknowledged by the existence of the EU Joint Action on Health Workforce Planning & Forecasting, the topic of the health workforce is of central importance to ensure European citizens benefit from the best available care, live longer and enjoy more productive lives.
5. Paediatrics	1. ECCO welcomes the focus on the paediatric population including teenagers and young adults in contrast to limiting to childhood cancers. As childhood cancers are rare diseases, the considerations mentioned for that vertical theme also apply here. 2. SIOPE - the European Society for Paediatric Oncology supported by the FP7 project ENCCA produced a multi-stakeholder endorsed Long-Term Strategy that largely reflects the AG Report focus areas. 3. The following topics mentioned in the Report are of particular relevance - Innovative treatments with new mechanisms of action (MOA), addressing disparities in access to standard care and highly specialised treatment interventions as well as in access to clinical research and innovation in a timely fashion, and participatory continuity of care for survivors, including through Health Care Surveillance passports (end of treatment summaries) and Patient Reported Outcome Measures (PROMs) and associated research platforms. With regards to highly specialised treatment interventions, research should also be an integral part of the picture in a collaborative setting, and sustainability of both research and care structures is key. ECCO also fully endorses the involvement and empowerment of patients and their families at multiple levels as mentioned in the Report. 4. ECCO would like to underline the need for more efficient and systematic outcome research to monitor the introduction of innovative therapies and diagnostic approaches from effectiveness, social and health economic viewpoints as well as from both the individual patient and society point of views.	As the AG Report states, results of existing therapies for childhood cancers clearly fall short of society's expectations with 6,000 children still dying from cancer each year in the EU and around 70% of the survivors suffering serious long-term side effects due to treatment. Associated socio-economic challenges pertain among others to informal caring costs and challenges faced by survivors in integrating into normal life including the workforce while co-existing with post-treatment effects.
6. Public health and prevention including migration	ECCO welcomes the focus on public health and prevention given the importance of these areas to tackle the pandemic of NCDs including cancer in Europe. ECCO also welcomes the emphasis put on evidence-based prevention and the importance of demonstrating through research the effectiveness of different public health and prevention programmes. Given the strong focus on prevention in the NCDs section ECCO would welcome efforts to ensure that links between the two sections are more clearly acknowledged and to ensure that more focus is put on screening/early detection and treatment/quality of care in the NCDs section (4).	Prevention is key to stop the progression of NCDs including cancer in Europe. There is little evidence on which prevention programmes are most efficient Hence more research in this area is needed.

7. Active and healthy ageing	1. ECCO welcomes the focus on Ageing due to the high incidence of cancer in the older sub-groups of the European population. Whereas a multi-disciplinary approach and patient-centricity remain key, the following topic mentioned in the AG Report is of particular relevance as per conclusions of the ECCO Oncopolicy Forum 2015 - 'Active participation of elderly citizens in research'. Indeed, there is a lack of evidence about relevant outcomes of different types of treatment in older patients, including those who are frail or suffer comorbid conditions. The reason is that older patients are often excluded from clinical trials, and also that clinical trials rarely gather data on aspects like functional and cognitive status, which are seen as priorities by many older patients. 2. In addition to clinical trials, more academic prospective studies are needed to learn about real-life results for patients with different treatments and different levels of frailty. It is about building evidence that doctors and patients need to make informed decisions about which treatment options offer the best chance for people with their particular level of frailty and comorbidities to achieve their preferred outcomes. ECCO would thus like to strongly stress the importance of including geriatric oncology research in Horizon 2020 to accumulate evidence-based data on older patients with cancer, including Patient Reported Outcomes (PROMs). 3. There could also be an argument for suggesting that payments should be linked to providing PROMs, assessed either by a test, or asking the patient. Professional and patient groups could jointly define which PROMs should be part of the reimbursement criterion. 4. Under 1.2, ECCO invites the Commission to consider including the study of survivorship and follow-up in the research orientations.	Europe faces a rapidly rising demand for cancer care among older people, because many more people are living to an older age, and cancer is more common in elderly people. As highlighted by the ECCO Oncopolicy Forum 2015 (report available), there is a general shift towards sponsors requiring to provide “real world” registry-based data, driven in particular by the requirement of health technology assessors who want to evaluate the true value of a new drug in a general population. At the same time, governments and insurance companies are starting to insist that PROMs should be reported, which may help get them incorporated into routine practice. Cancer is creating a new generation of survivors, needing special attention in social inclusion.
Horizontal Themes	**YOUR OPINION** (on the proposed theme)	**YOUR RATIONALE** (i.e. The expected impact of your proposed changes on Health, Demographic Change or the Well-being of European Citizens; the possible impact on businesses - in particular SMEs - on economic growth and job creation; the potential socio-economic outcome or contribution to the definition or the implementation of health policies...)
I. Big data	ECCO recognises the importance of big data for oncology and stresses the need to meaningfully involve multi-disciplinary cancer professionals and patient advocates in all relevant decision-making as key stakeholders. Furthermore, the ECCO Patient Advisory Committee puts forward the following more specific recommendations (in reference to Study on Big Data in Health, Telemedicine and Public Health Contract No 20157305 under Framework contract № EAHC/2013/Health/01 Lot 1 ‘Health reports on a specific topic – analysis and forecasting’): 1. In the development of regulations on privacy and data protection, reference should be made to the jurisprudence of the European Court of Justice (ECJ) on the definition of “data concerning health”. By doing so, coherence is enhanced regarding the nature of the data to be protected. 2. There needs to be a profound discussion involving patients in a systematic and meaningful manner on how the existing conflict between the sharing of data and patient security can be balanced in an appropriate way. 3. Patient consent forms with a standard structure across Europe can be helpful in the context of securing patients’ rights. 4. A mapping of existing data sources for well-defined categories of data/research questions is a useful starting point for obtaining quality big data in health. 5. Activities to increase digital health literacy and the awareness of the added-value of Big Data should be done coordinated manner with maximum benefit and minimalised risk to patients. 6. ECCO invites the Commission to consider including under 1 the new developments in prediction of response, such as the use of patient specific tumor/normal tissue organoids, gene profiling of tumor (organoids), radiomics, as well as the contribution of big data research in terms of cost effectiveness of treatments.	1-6. Cancer is identified by the AG Report as an area where the EU has demonstrated research leadership and can achieve further strides with big data. One case in point is Personalised Medicine (PM), which holds a huge potential for cancer according to a multitude of academic studies. PM could thus help bring down the important socio-economic costs associated with cancer, including productivity losses due to early death (estimated to cost EUR 42,6 billion), lost working days (EUR 9,43 billion) and informal care costs (EUR 23,2 billion) (indicators as per European Commission report on COM(2014) 584 final). To ensure that that big data developments can be exploited to achieve improved health outcomes in cancer, multidisciplinary healthcare professionals and patient advocates should be closely involved in all relevant developments to ensure buy-in and respond to real needs and concerns. 6. The new developments in prediction of response have the potential to revolutionise cancer treatment, hence having a great impact on society, on the wellbeing of citizens. Similarly, bringing attention and facilitating research in the field of sustainability of health care, linking cost of treatments and outcome, is a major contribution to better health for everybody, for informed choices when it comes to investments and a reply to the impact of the ageing population on the sustainability and organization of health care services
II. eHealth, mHealth, ICT	Please see the input in the I. Big data section. In addition, the ECCO Patient Advisory Committee puts forward the following more specific recommendations for e/mHealth: 1. To accept telehealth, patients and health professionals want it to be user-centric as opposed to technology-driven; 2. Telehealth should not negatively affect the patient–health professional relationship, but rather aim to increase mutual trust; 3. Telehealth needs to deliver real benefits and add value to users in relation to solely conventional healthcare; 4. Health professionals and patients will accept telehealth services only as long as they have at least the same safety and reliability standard as conventional health services; 5. Workforce and training/education initiatives will need to embrace the patient advocate input as to what resources are indeed needed to enhance the quality of health care. 6. Please refer to the “Chain of trust project” which stipulated that Self-confidence and competence in using telehealth services and mutual confidence between users are crucial and should not be underestimated.	E/mHealth could help address the important healthcare costs associated with cancer in the EU - €126 billion in 2009, with healthcare accounting for €51,0 billion (40%) as per European Commission COM(2014) 584 final.

III. Integration of care	1. ECCO welcomes the focus on the theme of integration of care. At the same time, ECCO feels that current priorities largely relate to health ICT while research could also focus on care processes and coordination between healthcare professionals to overcome fragmentation in cancer care delivery and to take better into consideration patient needs. 2. The incidence of cancer is increasing as well as five-year survival. An increasing number of people will live with the consequences of cancer and its treatment and will usually also experience one or more co-morbidities, often not related to the cancer/treatment. It is acknowledged that primary care will have an expanding role in cancer management. Therefore ECCO believes that attention should be given to models of interactions between different healthcare professions (within secondary care professions as well as from primary care to secondary care and vice versa) involved in the cancer management and between healthcare facilities. 3. Given the existing evidence supporting the benefits for patients of embedding research in routine care (not only for patients enrolled in trials), ECCO invites the Commission to consider the relationship between research and routine care in the section on integration of care. 4. ECCO would welcome a stronger emphasis on the role of patients as active players in the organisation and delivery of care.	1. Feedback from patients indicates that information, timely referral and continuity of care are important issues. Apart from anticancer treatment and during the entire disease trajectory, patients often need symptom management and psychological care to achieve the best possible quality of life. Primary care professionals (including supportive care) can play an important role in providing care in these areas throughout the cancer care pathway. 2. Healthcare professionals (both in secondary care and primary care) acknowledge the need to work together in multidisciplinary teams to provide the best care to patients and to cope with the demands of providing care for people with cancer. Structured care management and communication processes can reduce costs.
IV. Environment and health, green solutions and sustainability including climate change	-	-
Cross-cutting Issues	**YOUR OPINION** (on the proposed theme)	**YOUR RATIONALE** (i.e. The expected impact of your proposed changes on Health, Demographic Change or the Well-being of European Citizens; the possible impact on businesses - in particular SMEs - on economic growth and job creation; the potential socio-economic outcome or contribution to the definition or the implementation of health policies...)
A. Social Sciences and Humanities, integration, inequalities, migration and ethics	1. ECCO welcomes the focus on inequalities in this section. 2. ECCO would like to emphasise even more the need for more health economic evidence in the area of cancer/NCDs especially when it comes to cost-effectiveness of multidisciplinarity and combined therapies/interventions, without forgetting the importance of the right utilisation of diagnostic tools and options. 3. Given the importance of survivorship and rehabilitation in cancer care (and similarly for many other diseases), ECCO would welcome that a stronger emphasis is put on these issues in this section.	1. Important inequalities in terms of access to care (incl. treatment) and in terms of quality cancer care are observed in Europe but more evidence about the scope of the issue and potential solutions is needed. 2. There are important data gaps in Europe when it comes to both costs and clinical outcomes (benefits) making health economic evaluation difficult to perform. In addition, the design of national HTA evaluations makes it difficult to focus on combinations of health interventions as HTA evaluations focus on individual drugs. This approach does not reflect the reality of patients and healthcare teams with most patients now being treated through a combination of drugs and other interventions (radiotherapy, surgery, etc). At the same time inequalities between availability and use of diagnostic options lead to a broad range of inefficient utilisation of therapeutic procedures, from a lack of personalised adaptation of treatment in some cases and over-diagnosis on other circumstances.
B. Sex and gender differences in medicine	ECCO welcomes the focus on sex and gender differences in medicine. The organisation believes that there is a need for a broad base of reporting involving both sexes and all parts of society to make informed decisions. ECCO also believes that people should be encouraged to report adverse effects/ adverse drug reactions and take part in clinical trials and that allowing the collection and use of Big Data is key to addressing this issue	Classically, drugs are tested in young fit healthy men while many drugs are taken by elderly women with a number of long term medical conditions. As women and men are metabolically different in many ways when it comes to drugs (and disease) many assumptions are made which can endanger health as a result. Low income group men (often recruited for trials to earn some money) are notorious for not reporting adverse effects/ adverse drug reactions. The safety of a drug is in question from lack of reporting. This not only impacts on patient safety it also reduces concordance as people often stop taking their medicine simply because it is not working, makes them ill or makes things even worse than before. This has also an obvious impact on healthcare costs.
C. Commercialisation within “Health, Demographic Change and Well-being”	Enabling research and development of innovative therapies, collaborative working, as well as accessibility and affordability are key for cancer. It is imperative that academia is sufficiently resourced to undertake research in areas of a limited commercial interest such as rare cancers including paediatric cancers. Also in rare and paediatric cancers, it is critical to capitalise on the concentration of patients in expert treatment structures, such as European Reference Networks (ERNs), for research purposes, and sustainability of such research structures needs to be secured.	Based on the RARECARE (EU Health Programme project) findings, more than 4 million people in the EU are affected by rare cancers, which represent in total about 22% of all cancer cases. Rare cancers are furthermore characterised by particularly high mortality rates, which makes their human and socio-economic cost considerable despite being qualified as 'rare'. As the AG Report states, results of existing therapies for childhood cancers - that are all classified as rare, clearly fall short of society's expectations with 6,000 children still dying from cancer each year in the EU and around 70% of the survivors suffering serious long-term side effects due to treatment. Associated socio-economic challenges pertain among others to informal caring costs and challenges faced by survivors in integrating the workforce while co-existing with post-treatment effects.
D. Encouraging stronger and successful involvement of EU-13*	-	-

* Countries which have joined the EU in this millennium, i.e. Bulgaria, Croatia, Cyprus, Czechia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia.