Results of the analysis of Questionnaire on cancer outcomes study proposal

A questionnaire to investigate the interest in carrying out outcomes studies in the OECI Comprehensive cancer centres (CCCs) and the availability of relevant clinical information and biorepositories, was circulated to all OECI CCCs. The present report summarises the results of this survey, and could be a basis for the common discussion on the feasibility to start collaborative outcomes studies based on CCCs.

Table 0 is the list of the 24 CCC (in 14 EU countries) which replied to the 75 total circulated questionnaires

In 19 CCCs institutional cancer registries were in place for all or for selected cancers, in 3 of them cancer registries were planned, whereas in 2 CCCs databases are available only for specific studies **(Table 1**).

Table 2 summarise the type of information available in the institutional CCCs registries: data on treatment were available in 22 CCCs registries, outcomes in 23 CCCs registries, diagnostic workup in 18 CCCs registries, and comorbidity in 15 CCCs registries.

13 CCCs registries have available information on all the variables investigated by the questionnaire (diagnostic workup, treatment outcomes and comorbidity); 4 CCCs registries have information on diagnostic workup, treatment and outcome; 2 CCCs registries had information on treatment, outcomes and comorbidity; and 3 CCCs registries on treatment and outcomes; 1 CCCs registry reported to collect only diagnostic work up and one only outcomes.

Table 3 shows that in most CCCs (17/23 CCCs that replied correctly to this question) it is possible to integrate the patient record with institutional or administrative data, in order to complete information on all the variables investigated by the questionnaire (diagnostic work up, treatment, outcomes, comorbidity, patient's life status).

Some biological banking is present (or planned) in most CCCs, for all or for selected cancers (**Table 4**).

In 20 CCCs human biospecimens are accessible for research, provided specific rules are followed (**Table 5**)**.**

Table 6 shows the constitution of biorepositories for specific outcomes studies would be feasible in most CCCs (14/24); it could be planned in 5 CCCs, in 4 CCCs some conditions could limit their feasibility.

Interest to start collaborative studies on cancer outcomes, was most frequently expressed for breast (13 CCCs), colorectal cancers (10 CCCs), for hematological malignancies (7 CCCs) , skin melanoma (6 CCCs) and prostate cancer (5 CCCs) (**Table 7**).

The last two pages summarises specific study proposals received in the questionnaires by cancer site. The study proposals have been grouped in:

1) Clinical Outcomes commonly available to population CRs (routinely or for specific studies) or provided by regional and national programmes for outcomes evaluation. Useful for benchmarking
2) Specific outcomes indicators for patterns of care (stage, treatment) and survival, with focus on:
   - novel therapies
   - ageing/ elderly ;
   - comorbidity
3) "precision medicine" indicators aimed at evaluating clinical outcomes related to histotype and molecular testing results
4) quality of life, drug safety, return to work; HTA, costs

Table 0. List of the 24 CCC (14 countries) which replied to the 75 total circulated questionnaires

Country	Comprehensive Cancer Center	Abbreviation
Austria	Comprehensive Cancer Center Graz, 8036 Graz	CCC-Graz
Belgium	AZ Groeninge, 8500 Kortrijk	AZ-Groeninge
	Institut Jules Bordet, 1000 Brussels	IJB-Brussels
	Kankercentrum Brussel, 1090 Brussels	KC-Brussel
Croatia	Klinika za tumore Klinicki bolnicki centar Sestre milosrdnice, 1000 Zagreb	KBCSM-Zagreb
Czech Republic	Masarykův onkologický ústav, 656 53 Brno	MOU-Brno
Finland	Tampereen Yliopistollinen sairaala, 33560 Tampere	Tays-Tampere
Italy	Centro di Riferimento Oncologico Istituto Nazionale Tumori, 33081 Aviano	CRO-Aviano
	IRCCS Istituto Clinico Humanitas, 20089 Rozzano -Milano	Humanitas-Milano
	Istituto Dermatologico S. Gallicano, 00144 Roma	ISG-Roma
	Istituto Nazionale Tumori Regina Elena, 00144 Roma	INTRE-Roma
	Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori-IRCCS, 47014 Meldola-Forlì	IRST-Forlì
	Ospedale San Raffaele, 20132 Milano	OSR-Milan
	IRCCS Istituto Nazionale Tumori, 20133 Milano	INT-Milano
Lithuania	National Cancer Institute, LT-08660 Vilnius	NCI-Vilnius
Norway	Oslo Universitetssykehus, 0424 Oslo	OUS-Oslo
Portugal	Instituto Português de Oncologia do Porto Francisco Gentil, E.P.E., 4200-072 Porto	IPO-Porto
	Instituto Português de Oncologia de Lisboa Francisco Gentil, E.P.E., 1099-023 Lisbon	IPO-Lisboa
Russia	Tatarstan Cancer Center, 420029 Kazan	TCC-Kazan
Slovenia	Onkološki Inštitut Ljubljana, 1000 Ljubljana	OI-Ljubljana
Spain	FUNDACIÓN INSTITUTO VALENCIANO DE ONCOLOGÍA, 46009 VALENCIA	FIVO-Valencia
The Netherlands	Erasmus MC Cancer Institute, 3015 CN Rotterdam	EMCKI-Rotterdam
	Rijnstate, 6815 AD Arnhem	Rijnstate-Arnhem
Turkey	Anadolu Sağlık Merkezi, Cumhuriyet Mahallesi 2255 Sokak No:3 41400 Gebze/Kocaeli	ASM-Gebze

Table 1. Number of institutional cancer registries in place or planned

Yes, for all cancers n=11	OI-Ljubljana ASM-Gebze AZ-Groeninge Humanitas-Milano IJB-Brussels IPO-Lisboa IPO-Porto IRST-Forlì MOU-Brno Tays-Tampere TCC-Kazan	
Yes, for selected cancers n=8	KBCSM-Zagreb OSR-Milan Rijnstate-Arnhem NCI-Vilnius EMCKI-Rotterdam KC-Brussel OUS-Oslo INT-Milano	breast and colon, acute leukemias, myelodysplastic syndromes,head, neck cancer, oesophago-gastric
Not presently, but planned n=3	INTRE-Roma ISG-Roma CRO-Aviano	
No, databases are available only for specific studies n=2	CCC-Graz, FIVO-Valencia	

Table 2. Information available from in place or planned institutional cancer registries

Diagnostic work-up	Treatment	Outcomes	Comorbidity	Number CCCs
X	X	X	X	13
X	X	X		4
	X	X	X	2
	X	X		3
X				1
		X		1
18	22	23	15	

Table 3. Institutional or administrative data available to integrate clinical patients records

Diagnostic work-up	Treatment	Outcomes	Comorbidity	Patient's life status	N. institutes
X			X		1
X	X	X	X		1
X	X	X	X	X	17
X	X	X		X	3
	X				1
	X	X			1
22	23	23	19	20	

Table 4. Number of CCCs with biological bank

Yes, for all cancers	9
Yes, for selected cancers -breast and colon -breast -hematological, prostate, ovarian cancer. Biobank starting/started recently for all cancer -breast cancers, sarcomas, thymomas are "biobanked" for each type of bio-specimen (fixed/fresh tissue/ blood/plasma/serum). Expansion to other cancers for the biological fluids is in progress. -acute leukemias, myelodysplastic syndromes, multiple myeloma -head and neck cancer (and many others …) -?leukemia not specified (4)	**11**
Not presently, but in the future -histological and cytological units from all patients; freezes blood from colorectal cancer patients -bank of cytological sample	**2**
Not at all nor planned	**2**

Table 5. Number of CCCs with the possibility to access existing biorepositories for studies on outcomes

Yes	**12**
Yes, if/conditional to consent by ethical committee, collaboration with local researchers, project prioritization, specific rules for the access	**8**
data processing must be done locally, all the information is only in the national language	**1**
Not available now	**1**
No	**2**

Table 6.

Number of CCCs where it would be feasible to plan the constitution of biorepositeries specifically for outcome studies

YES, for all or specific cancers	**14**
Yes for selected cancers, but limitations (adequate funding, specific projects validity and competition with other ongoing projects...)	**4**
Not presently, but could be planned	**5**
No	**1**

Table 7.

Would you be in favour to start collaborative studies on cancer outcomes, establishing cohorts of cancer patients treated at CCCs, to be followed up?

YES:

Breast	KBCSM-Zagreb, TCC-Kazan, Rijnstate-Arnhem, MOU-Brno, Humanitas-Milano, INTRE-Roma, IPO-Porto, IPO-Lisboa, NCI-Vilnius, Tays-Tampere, CRO-Aviano, IRST-Forlì, INT-Milano	**13**
Colon & rectum	KBCSM-Zagreb, TCC-Kazan, MOU-Brno, Humanitas-Milano, INTRE-Roma, OSR-Milano, IPO-Lisboa, Tays-Tampere, IRST-Forlì, INT-Milano	**10**
Hematological (Acute leukemia, CLL, MDS, Lymphomas)	Humanitas-Milano, IRST-Forlì, OSR-Milano, CRO-Aviano IPO-Porto, AZ-Groeninge, INTRE-Roma,	**7**
Skin & Melanoma	IRST-Forlì, ISG-Roma, INTRE-Roma, IPO-Porto, IPO-Lisboa, INT-Milano	**6**
Prostate	Rijnstate-Arnhem, IPO-Porto, Tays-Tampere, CRO-Aviano, Tays-Tampere	**5**
Stomach	MOU-Brno, OSR-Milano, EMCKI-Rotterdam, IRST-Forlì	**4**
Lung	Rijnstate-Arnhem, INTRE-Roma, IPO-Porto, NCI-Vilnius	**4**
Sarcoma	KBCSM-Zagreb, TCC-Kazan, MOU-Brno, INTRE-Roma	**4**
Liver	Humanitas-Milano, INTRE-Roma, OSR-Milano	**3**
uro-gynecology	INTRE-Roma, NCI-Vilnius, IRST-Forlì	**3**
Uterus/endometrium/cervix	MOU-Brno, INTRE-Roma, Tays-Tampere	**3**
Esophagus	OSR-Milano, EMCKI-Rotterdam, IRST-Forlì	**3**
head and neck	AZ-Groeninge, INTRE-Roma, EMCKI-Rotterdam	**3**
neuroendocrine	TCC-Kazan, INTRE-Roma	**2**
CNS	INTRE-Roma, Tays-Tampere	**2**
Pancreas	AZ-Groeninge, INTRE-Roma	**2**
Ovary	MOU-Brno, Tays-Tampere	**2**
Kindey	MOU-Brno, INTRE-Roma	**2**
Bladder	INTRE-Roma, OSR-Milano	**2**
rare cancers (unspecified)	IJB-Brussels, ISG-Roma	**2**
Pleura	INTRE-Roma	**1**
Thyroid	INTRE-Roma	**1**
Thymus	INTRE-Roma	**1**
Testis	AZ-Groeninge	**1**
osteoncology	IRST-Forlì	**1**
Torax	IRST-Forlì	**1**

rare cancers (unspecified)	IJB-Brussels, ISG-Roma	**2**

Proposals of outcomes studies

1) Clinical Outcomes commonly available to population CRs (routinely or for specific studies) or provided by regional and national programmes for outcomes evaluation. Useful for benchmarking

Practically all cancers: Breast, Endometrium, Cervix, Lung, Pleura, Thyroid, Thymus, Lymphomas, Kidney, Urinary Bladder, Colon, Rectum, Liver, Pancreas, Melanoma, Sarcoma, Head and Neck tumors, Central Nervous System, Neuroendocrine Tumors.	Number surgeries for lung, colon etc.; perioperative (30-days) mortality; re-operation of conservative BC surgery after 30/60 days of 1st surgery)... Hospital volume where first treatment were done: number for specific cancer

2) Specific indicators for patterns of care (stage, treatment) and survival, with focus on:
- novel therapies; ageing/ elderly ; comorbidity

cancer types in which one modality has a major impact on cure rate	pancreatic cancer (surgery), advanced H&N (radiotherapy), testicular cancer (chemotherapy), aggressive lymphoma (chemotherapy) etc... Develop a robust methodology to correct for comorbidity, especially if the aim is to benchmark between CCC's
Breast, colorectal, kidney, sarcomas, stomach, uterine, ovarial cancers..	Survival. Methods of treatment / surgery, radiotherapy, systemic therapy. The percentage of ppt. receiving modern - targeted therapies, etc.
Prostate, breast, leukemias, non-Hodgkin lymphomas	stage at presentation; time from symptoms to diagnosis to outcome; ageing and outcomes
Liver, Bile ducts, gallbladder (hepatocellular carcinoma, cholangiocarcinoma, liver adenoma)	Response to chemotherapy, features of liver failure, liver regeneration, injury following ischemia/reperfusion, frequency and effects of laparoscopic surgery
esophagus, stomach, colon, rectum	morbidity, mortality, outcome, survival
oesophagus and stomach	recurrence after surgery, role of adjuvant treatment, survival after metastasectomy
Rare tumors (to be specified)	Therapeutic management of rare tumors and outcomes (some tumors to be specified)

1) 3) "precision medicine" indicators aimed at evaluating clinical outcomes related to histotype and molecular testing results

colorectal, breast sarcoma	tumour heterogeneity, response to therapy, immunology
acute leukemias, myelodysplastic syndromes	outcome of elderly patients after intensive treatments, outcome of very poor (genetic) risk acute myeloid leukaemias after intensive treatment and transplantation
CLL	Subclonal composition in CLL patients treated with chemoimmunotherapy and novel agents; disease characteristics in different compartments (peripheral blood, lymph nodes and bone marrow) in patients treated with novel agents.
All gastro-Intestinal tract, Breast cancer, melanoma	Expression of biomarkers related to outcomes of immunotherapy
neuroendocrine cancers, sarcomas	How common is mutation c-kit an others for

	neuroendocrine tumors, biomarkers of neuroendocrine tumors
prostate cancer, gynecological cancers, Lung, breast,	Circulating biomarkers, using plasma for liquid biopsies

4) quality of life, drug safety, return to work; HTA, costs

Prostate, CNS	Health-related quality of life, functional capacity, return to work, specific symptoms, patient satisfaction
Breast, melanoma, lung, prostate and chronic lymphocytic leukemia (CLL)	Safety, effectiveness, quality of life and cost of new technologies