Improvement action Plan

IRCCS SAN MARTINO-IST

<peer review visit>

Authors	
Date	
Status	

Content improvement plan:
A cancer centre may use a different lay-out for an improvement/action plan, like:

- Using the lay-out that the cancer centre uses for improvement plans,
- Using the function in the e-tool for describing improvement points/non-compliances,
- Using this template.

With regard to the content of an improvement/action plan the OECI Accreditation and Designation Group requires following items:

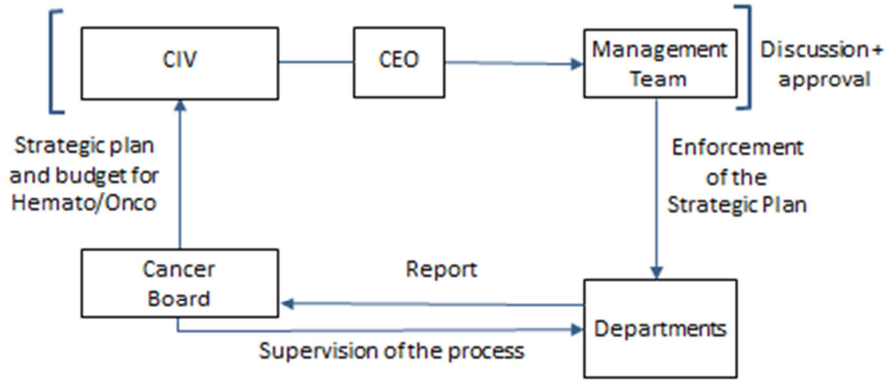
a. **Standard related to improvement/opportunity:**
b. **Opportunity:** (main opportunities)
c. **Ultimate goal (SMART formulation: specific-measurable-attainable-realistic-timely)**
d. **Actions:**
e. **Person in charge of opportunity (responsible) and who are involved**
f. **Timelines:** start – evaluation moments - final deadline
g. **Priority:** high – medium – low

To have an good overview of these items it is suggested to use underneath table.

Based upon the improvement plan the Accreditation and Designation Certificate can be awarded by the OECI Accreditation and Designation Board.

Action 1	1 General Standards - 1.1.1 Oncological policy plan and general report
Action 2	1 General Standards - 1.1.4.Cancer data registration (institutional level)
Action 3	1 General Standards - 1.4.1.Continuity of care within the cancer centre
Action 4	1 General Standards - 1.4.2.Waiting and throughput times
Action 5	1 General Standards - 1.4.4. Compliance with guidelines
Action 6	1 General Standards - 1.4.5. Tasks and responsibilities of the (oncology) nurses
Action 7	1 General Standards - 1.4.8 Referral of patients to paramedical and supportive disciplines
Action 8	1 General Standards - 1.4.9 Multidisciplinary harmonization/integrated care
Action 9	1 General Standards - 1.4.10 Selection criteria for the oncology team meeting
Action 10	1 General Standards - 1.4.11 Procedure for the oncological multidisciplinary team meetings
Action 11	1 General Standards - 1.5.1 Quality and risk management and safety requirements
Action 12	1 General Standards - 1.5.2 Quality and risk management and safety requirements
Action 13	1 General Standards - 1.5.4 Quality and risk management of research and new techniques
Action 14	1 General Standards - 1.5.6 Quality assurance in all areas (HR)
Action 15	1 General Standards - 1.5.7 Privacy, protection and personal data
Action 16	3 Care - 3.1.1 Pain service
Action 17	3 Care - 3.1.5 Psycho -oncology service
Action 18	3 Care - 3.1.8 Family involvement in care (children)
Action 19	4 Research, innovation and development - 4.1.3 Organization of clinical research
Action 20	4 Research, innovation and development - 4.1.4 Periodical policy review
Action 21	4 Research, innovation and development - 4.3.1 Means for conducting its research activities
Action 22	4 Research, innovation and development - 4.3.2 Intellectual property and innovation
Action 23	4 Research, innovation and development - 4.3.3 Biobank
Action 24	5 Teaching and continuing education - 5.4.1 Participation in teaching oncology
Action 25	5 Teaching and continuing education - 5.4.2 Types of teaching programmes provided
Action 26	5 Teaching and continuing education - 5.4.3 Types of teaching programmes organized
Action 27	6 Patient related - 6.4.1 Educational material
Action 28	6 Patient related - 6.4.2 Inform patients on admission
Action 29	6 Patient related - 6.4.4 Discharge procedure
Action 30	6 Patient related - 6.5.1 Patient satisfaction/ experiences

Action 1	Standard	1 General Standards - 1.1.1 Oncological policy plan and general report
	Opportunity	The Institute recognizes that the Oncology activity requires a more precise and dedicated governance. At present, the governance of the Cancer Center does not differ substantially from that of the remaining clinical /research activities of the Institute and most of procedures are somewhat intermingled. This organization may prevent the achievements of some of the goals set for Hematology/ Oncology. Specifically, there may be an insufficient focus on the goals to be set for the Cancer Center and/or the supervision of the actions destined to their achievement may be insufficient. Indeed, at present there is a general strategic plan for the whole Institute. This is elaborated by the Comitato di Indirizzo e Verifica (CIV) and the Management Team (Collegio di Direzione). This plan comprises also general indications on the actions to be taken for Hematology/Oncology. The Cancer Center plan (presented to OECI before the site-visit) emanates from this general plan and is in fact elaborated further by the Office of the Scientific Director. While this methodology was probably suitable for the initial phases which followed the merger, given the fact that the logistic issues were overwhelming, in the present situation a more precise and elaborated Cancer Center plan seems to be required.
	Action	To form a Cancer Board with the task of elaborating a strategic plan specific for the Cancer Center and supervising its application and accomplishments.
	Goal/ desired result	To elaborate a 5 years strategic plan which includes by the major goals to be reached. The plan should describe the vision governing the actions to be taken and propose a tentative budget. To monitor the accomplishments on a yearly basis.
	Actions description	In order to elaborate a scientifically sound strategic plan for the Cancer Center, it appears necessary to have of board of experts (Cancer Board) that determines the needs of the Cancer Center and elaborates a strategic plan also describing the means and a provisional budget for achieving the set goals. The strategic plan, together with the specific financial issues, should be presented/ discussed with CIV, the Collegio di Direzione and CEO and, once approved, will be passed to the Departments who are responsible for the plan execution. Additional duties of the Cancer Board relate to the supervision of the work done to enforce the strategic plan and of the quality of the Cancer Center performance in both the clinical and research field. Finally, the Cancer Center board also will supervise the spending of the allocated budget.

		Flow chart describing the mode of functioning of the Cancer Board 
	Who is involved and responsible for result	The Board is formed by the following members: 1. Scientific Director (chair) 2. Dean of the Medical School 3. Medical Director 4. Controller 5. Director of Department of Surgery 6. Director of Department of Hematology/Oncology 7. Director of Department of Services 8. Quality Manager 9. DMT Supervisor 10. Nurse Chief 11. Coordinator of Supportive/Palliative Care Team
	Start (date)	The board is going to be nominated in April 2015. A strategic plan is going to be prepared by October 2015
	Evaluation (date)	The mode of operating of the Board and its real effectiveness may be evaluated within 1 year, when achievements of the first year operations can be evaluated and some modifications of the strategic plan may be needed. Yearly re-evaluation are mandatory.
	Dead line (date)	The real effectiveness of the board can be observed within two years when a substantial number of actions will be accomplished. Thus a deadline can be set by April 2017.

	Priority - High/Med./Low	High
FUP	Progress	A CCC board has been formed (the composition is reported in the Annex).
	Status of implementation	Completed
	Results achieved	This board has discussed and elaborated a CCC strategic plan which is integral part of the hospital strategic plan. The plan which has been approved by the board of Directors and by the Management team, is now enforced in the Institute under the supervision of the CCC board

Action 2	Standard	1 General Standards - 1.1.4.Cancer data registration (institutional level)
	Opportunity	The auditors found that, although data on cancer patients (outcome, risk, mortality, etc.) were provided, the DMT were too new at the time of site visit to take actions capable of improving the clinical performances. Now, based on a larger observation period, we can state that DMT functioning is satisfactory and that actions to improve clinical performances can be taken at DMT levels. However, certain measures can help improving DMT performances.
	Action	All 9 DMTs have to produce an obligatory annual report on their activities describing information for each cancer type capable to indicate possible improvements.
	Goal/ desired result	To improve the control on the activity of the DMTs and to remodel, when necessary, the procedures employed for: • oncology care • continuous training in oncology • research activities in oncology
	Actions description	1. The DMTs have to produce an annual report containing: • Total number of patients followed by the DMT • percentage of patients discussed at the level of DMT / GIP according to DMT's rules • serious adverse events • waiting and throughput times • compliance with guidelines • outcome indicators identified through the monitoring of each clinical pathway (PDTA) and satisfaction assessment • percentage of enrolment of patients in clinical trials for each DMT • The report must be completed and forwarded to the Cancer Board by April 30th of each year. This report will be examined by CIV, Management team and, following approval, information will be spread throughout the Institute and to patient associations. 2. Further analysis of data from: • directional dashboard

		• EPR • Complication registry • DMT's activity 3. identification of opportunity and strengths by DMTs 4. definition of an annual improvement plan within the five-year strategic plan 5. approval by the CEO and Management Team 6. Information of Institute's staff and patient's associations
	Who is involved and responsible for result	DMT Cancer Board CIV CEO Management team Quality Manager
	Start (date)	This type of DMTs report/analysis will be started already in the present year, although the results should be considered rather preliminary and somewhat experimental. The deadline date for report presentation will be April 30th. The evaluations will be completed by October 30th 2015. A more precise process and evaluation will be obtained in 2016.
	Evaluation (date)	October 2015 (first) October 2016 (second)
	Dead line (date)	31st October 2016
	Priority - High/Med./Low	High
FUP	Progress	Admittedly, we have faced difficulties with one of the DMT's which is not working in a satisfactory manner. This is the only hematologic DMT, and is dedicated to lymphoproliferative disorders. Such difficulties are generated primarily by the fact that two of the Division chiefs, have retired. The new person who has been brought in from outside as replacement for the two outgoing haematologists is reorganizing a large part of the hematologic activity, including bone marrow transplant. It is expected that this DMT (and perhaps others suggested by the new hematology chief) will be working at the beginning of the fall.
	Status of implementation	60% completed
	Results achieved	Most DMT have already prepared their Annual report (namely Breast, Lung, Gynaecological, GI) while the reports of the others are in preparation and are expected to be submitted by beginning of September which is the final deadline.

Action 3	Standard	1 General Standards - 1.4.1. Continuity of care within the cancer centre
	Opportunity	The auditors team pointed out the advantages of having a Cancer Center located within a large University Hospital, particularly for the opportunity of providing a safe continuity of care. A the time of site-visit, some concern was expressed because certain initiatives were not yet fully completed. Now, we explain what has been done since and the plans for the near future.
	Action	The actions that have been or will be taken include the provision to ED physicians of the following: • information support (see attached: "Minimum Dataset about the oncological patient") related to cancer patients treated at the Cancer Center • support of a haematology consultation by a specialist on call 24 hours a day / 7 days a week • support of an oncology consultation by a specialist on call 12 hours a day / 5 days a week (fast-track oncology care)
	Goal/ desired result	To assist patients in all optimal manner in the course of oncology emergencies.
	Actions description	1. Since January 2015 ED physicians have access to the minimum dataset of each cancer patient. The dataset is based on the database that manages all the chemotherapies. This procedure is detailed in the enclosed document. 2. As described in the self-assessment (see the chapter 1.4.1.1.1. DOC ORG of the unit "Governo Clinico e Organizzazione Ospedaliera"), there is a haematology specialist, available on-site 24 hours a day. 3. Since May 1sth an oncology specialist will be available 12 hours a day / 5 days a week. According to this organisation, cancer patients are instructed by the treating oncologist to refer to the fast track first oncology aid at the IST-south first floor. The majority of emergencies are going to be treated here. For those patients presenting at the ED, the physician in charge may seek the advice of the Oncologist / Haematologist colleagues and together, these physician may make decisions regarding the subsequent patient management. The availability of the oncology specialists will be extended progressively to 6 and 7 days/week. Finally, the ED physicians will have access to new protocols with instructions for the main oncology management.
	Who is involved and responsible for result	Point 1 • Pharmacist, Head of cytostatic drugs Unit: management of the minimum dataset • Head of Emergency Department instruction on the use of information by the ED physicians and by physicians on call • Quality Manager: dissemination of the information and training on the appropriate usage of informatics tools. Point 2 • Haematologists on duty. Under supervision of Hematology Division Directors and Medical Director Point 3 • Medical Director: management of the on call rotations of oncologists to have the availability of all oncology specialists 12 hrs/5 days a week. • Head of Emergency Department: definition and implementation of the protocols for the main oncological emergencies management. • Head of Hematology / Oncology Department: instructions to the attending physicians in the oncology wards regarding the major complications/side effects and their management.
	Start (date)	Point 1: already operating

		Point 2: already operating Point 3: May 1th
	Evaluation (date)	Point 1: six months after the start (January 2015) there will be a planned assessment of the software tool utility (December 2015) Point 2: it has been satisfactorily operating since a few years Point 3: six months after the start of availability of the oncologist's consultation facility,the initiative is going to be evaluated (november 2015) according to the following criteria: • number of patients presenting to the fast track oncology ward and outcome • percentage of patients admitted to oncological ward • percentage of patients discharged and time of care administration • number of patients presenting at night and on Sunday • percentage of presentation due to serious adverse events If the results of this evaluation are satisfactory, and an appropriate need is demonstrated, then the availability can be progressively extended to 6 and thereafter 7 days/week.
	Dead line (date)	The effectiveness of the new protocols for the management of oncology emergencies can be preliminarly evaluated by November 2015. The dead-line for the whole process is December 2015.
	Priority - High/Med./Low	High
FUP	Progress	The new organization enforced following the site visit has improved the treatment of patients with oncology/hematology emergency.
	Status of implementation	80% completed
	Results achieved	The availability of the oncology/hematology consultation has resulted into a reduction of the presentation of patients to the ED. Moreover, in the case of ED presentation, the operations are facilitated by the possibility of a quick oncology/hematology consultation often resulting in the admission in the most appropriated ward. Finally, the availability of a minimum oncology/hematology data set for the patients in treatment has facilitated any action to be taken in the ED as well as in other wards.

Action 4	Standard	1 General Standards - 1.4.2. Waiting and throughput times
	Opportunity	The auditors have indicated that a more accurate control of waiting and processing times in the Cancer Center would help improving both performances and patient satisfaction.
	Action	The various steps of patients clinical pathway (PDTA) must be monitored to catch potential criticisms in waiting and throughtput times.
	Goal/ desired result	To maintain waiting/throughput times within limits indicated by guidelines.
	Actions description	The different steps of each PDTA (e.g. diagnosis, treatment, follow-up) must be monitored carefully by controller in order to assess the waiting times. The results of this analysis should be made known through the Institute intranet web. In the case of extension of the set times, the DMTs have to apply measures to correct the criticism. If the action is not sufficient, then the Management Team must suggest and possibly enforce more robust measures.
	Who is involved and responsible for result	DMT Coordinators and Supervisor Chief Nurse Controller Quality manager ICT Manager
	Start (date)	April 15th 2015
	Evaluation (date)	The first evaluation will take place after 12 months after start
	Dead line (date)	April 2016
	Priority - High/Med./Low	High
FUP	Progress	Difficulties have been recently originated from the Liguria Regione dispositions, dictating that a single monitoring procedure for all the waiting lists of the regional territory. This new disposition may generate difficulties particularly to the follow-up of the patients , who are admixed with other (no follow-up) individuals in a general waiting list which includes a variety of hospitals. Negotiations are currently under way with Liguria Regional Government in order to overcome the above difficulties.
	Status of implementation	Completed
	Results achieved	At present, monitoring of the various PDTA steps including the waiting times for certain specific tests such as TC or NMR scans are monitored by the DMT staff. Each of the DMT members is responsible for the area of specialization (i.e radiologists for radiology tests, pathologists for the pathology tests, etc.) This organization has permitted to maintain the waiting times within the internationally recognized limits. These waiting times are recorded and illustrated in the single DMT annual report.

Action 5	Standard	1 General Standards - 1.4.4. Compliance with guidelines
	Opportunity	For the item 1.4.4.1.4. see point 1.1.4.Cancer data registration (institutional level)
	Action	
	Goal/ desired result	
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Dead line (date)	
	Priority - High/Med./Low	
FUP	Progress	The adherence to the guidelines is responsibility of the single DMT and such adherence (or lack of) is reported both in the summary of the single case discussion and summarized in the annual report.
	Status of implementation	Completed
	Results achieved	Clearly, there are patients for whom guidelines could not be followed at least in part, although explanations are provided in the summary of the report for the single case

Action 6	Standard	1 General Standards - 1.4.5. Tasks and responsibilities of the (oncology) nurses
	Opportunity	In Italy, the nurse training follows criteria which are somewhat different from those of other European countries. Specifically, there is not a course for nurse training in oncology; therefore the auditors have requested a particular consideration to this issue in order to optimize nurse work in the Cancer Center.
	Action	Although the general nurse training in Italy does not include an oncology subspecialty, in the past care has been taken to provide an extra – training to nurses before they are assigned to the oncology units (see “piano formativo triennale”). The Institute now admits that this may not be sufficient and hence special measures are being taken, including more detailed task descriptions to newly assigned staff and extra training in particular areas (e.g. use and administration of cytotoxic drugs, most common side/adverse events, prevention of infections, palliative care etc.).
	Goal/ desired result	• To improve nurse performances in the increasing difficult area of cancer patient treatment. • To promote/expand the role of nurses in the conduction of clinical trials providing more efficient support to medical teams. • To develop research in the field of nurse science
	Actions description	• The nurse requirements of the different hematology/oncology areas will be re-defined not only based upon nurse numbers, but also taking into account individual specialisation/skill. Training and re-training needs also will be

		considered together with the possible definition of new types of jobs. Hence, the preparation of more detailed job descriptions is required. • The DMTs are expected to cooperate in the above task, particularly identifying special steps in the PDTAs which require special skill on part of certain nurses.
	Who is involved and responsible for result	• Haematology Oncology Department Director • Human Resource Manager • Haematology/Oncology Division Directors • Palliative and supportive care team coordinator • Nurse chief • Quality manager
	Start (date)	April 1st 2015
	Evaluation (date)	This is somewhat a long term process. In fact, even if the job evaluation and the requirement for additional specialty/subspecialty training may take only a couple of months, the subsequent actions (new assignement of nurses, nurse re – training, etc.) may require up to six months. Hence, the first results may be available one year from the process start.
	Dead line (date)	April 2016
	Priority - High/Med./Low	High
FUP	Progress	A certain amount of work was carried out to define the major features required for an oncology nurse and other support people working in the supportive care team. Particularly, in the case of oncology nurses, it has been determined that master-like courses were needed in order to achieve an optimal degree of training. Such courses have been planned on paper with the cooperation with the Nurse-school of the university of Genoa. In addition to the master-like courses, research projects were presented by voluntary nurse groups. These projects are intended to investigate deeply some issues related to the functioning of oncology activity (e.g. drug administration in different day - hospital settings - haematology, oncology, ambulatory care). These groups also will propose solutions to existing problems. Subsequently, these solutions can be tested on "field". (see enclosed document)-
	Status of implementation	30 % Completed
	Results achieved	At present, financial details are being worked out and it is hoped that master-like courses can initiate in the fall. In the mean-while the office of the chief-nurse is already selecting those individuals who are considered most suitable for the job of oncology nurse. Finally, the proposal for research projects are been selected and their implementation will start in the fall.

Act	Standard	1 General Standards - 1.4.8 Referral of patients to paramedical and supportive disciplines

	Opportunity	Admittedly, in the present organization, the referral of cancer patients to palliative / supportive care physicians and even more to paramedical staff is primarily a decision of the oncologist in charge. Therefore, a more objective decision method for referral of patients should be instated, as pointed out by auditors.
	Action	Prevention of arbitrary decisions can be achieved by the use of a check list in which all the potential patient needs for supportive care are considered. The check list will be prepared by the supportive/palliative care team and is due by April 30th. The hematology/oncology specialist and nurse in charge will have the duty of filling the check-list in and enclose it within the patient chart. Moreover, the same physician/nurse will have to comply with the patient needs demonstrated by the check-list, seeking further advice and possibly treatment by the appropriate caregiver.
	Goal/ desired result	• To provide care to all of the needs of oncology/haematology patients evaluated in a holistic manner
	Actions description	• The first step is the preparation of the check list to be released to the haematology/oncology wards, DH and ambulatory care services. The check list is comprehensive of all types of supportive care available including those provided by paramedical disciplines. • The second step includes information/discussion of the check list at the DMT level. • The third step will be the enforcement of check-list compilation which is integral part of the patient chart. The attending physicians and nurses are expected to comply with the needs of patients as revealed by the check-list.
	Who is involved and responsible for result	• Check list creation: supportive and palliative care team coordinator • Check-list use enforcement: Hematology/Oncology Department Director; Hematology/Oncology Division Directors, Nurse Chief
	Start (date)	The preparation of the checklist has started March 15th and the checklist is expected to be in use within three months from the start.
	Evaluation (date)	The first evaluation will be carried out six months after the check list is routinely in use
	Dead line (date)	It is expected that two complete Deming cycles are accomplished approximately within one year.
	Priority - High/Med./Low	Med
FUP	Progress	The preparation of the checklist has been accomplished and the check list has been distributed to the clinical groups who have implemented its use (see enclosed document). In addition, the information on the checklist, together with instruction for its potential use, have been provide to the DMTs
	Status of implementation	40 % Completed
	Results achieved	A further check on the routine use of this tool, however, has demonstrated that there is no uniform or universal use of the checklist, and hence, measures are being taken to improve the issue

Action 8	Standard	1 General Standards - 1.4.9. Multidisciplinary harmonization / integrated care
	Opportunity	For the item 1.4.9.1.4. see point 4.1.3 Organization of clinical research
	Action	
	Goal/ desired result	
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Dead line (date)	
	Priority - High/Med./Low	
FUP	Progress	This issue will be dealt with at action 19
	Status of implementation	
	Results achieved	

Action 9	Standard	1 General Standards - 1.4.10 Selection criteria for the oncology team meeting
	Opportunity	There are set criteria for including patients for DMT discussion, although these criteria vary for the different DMT. While the breast and brain cancer DMT have the consolidated habit of including all cases in the discussion, in the remaining DMTs not all cases are presented and a method should be introduced to keep record of patients excluded from discussion. This will give an opportunity of improving the analysis of the patient cohort, of their features and of including these patients in subsequent discussions. Finally, this approach will provide an opportunity for a further check of morbidity/mortality.
	Action	Compilation by each DMT of a check-list reporting the major inclusion/exclusion criteria for each patients and a summary

		explaining concisely the reasons for inclusion/exclusion.
	Goal/ desired result	A more precise monitoring of diagnosis/treatment procedures for all cases presented at the Institute.
	Actions description	The check-list should report the main patient characteristics including cancer histology, grading, staging co-morbidities and the attending physician and should report clearly the reasons leading to discussion exclusion. This check-list should be compiled into two copies, one for the patient record and one for DMT files.
	Who is involved and responsible for result	DMT coordinators Quality Manager Nurse Chief
	Start (date)	The compilation of the check-list has a different degree of complexity depending upon the different DMTs. Nevertheless, it can be expected that all of these documents can be obtained from DMTs by July 2015. The use will be implemented within two months from start (October 2015).
	Evaluation (date)	The first evaluation will be carried out six months after the start of the check list usage
	Dead line (date)	It is expected that two complete Deming cycles are accomplished approximately within one year. Therefore the deadline for the whole process can be fixed for April 2017.
	Priority - High/Med./Low	Med
FUP	Progress	There been universal agreement that all the patients with a given cancer should be registered in the appropriate DMT and this registration procedure has been enforced in the single DMTs.
	Status of implementation	
	Results achieved	Different methodologies were chosen for the selection of cases to be discussed in the multidisciplinary meetings depending upon the various DMTs. For example, the breast DMT has selected to discuss briefly all cases seen by the DMT components, whereas for other DMTs (e.g. lung) only those cases considered worth discussing by the coordinators are brought to the general attention, whereas the others are just registered in the DMT cohort. However, irrespective of the methodology selected for case discussion, an information checklist is available and compiled for each patient (enclosed).

Action 10	Standard	1 General Standards - 1.4.11 Procedure for the oncological multidisciplinary team meetings
	Opportunity	The auditor team has pointed out some difficulties related to problems with the equipment which admittedly became apparent at the time of the site-visit. We are glad to inform that these problems have been satisfactorily overcome since.
	Action	
	Goal/ desired result	
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Dead line (date)	
	Priority - High/Med./Low	
FUP	Progress	As already reported, the problem were solved soon after the site visit
	Status of implementation	
	Results achieved	

Action 11	Standard	1 General Standards - 1.5.1 Quality and risk management and safety requirements
	Opportunity	As stated by the auditors team, a monitoring system of the adverse events is operating at institutional level, although some pitfalls have to be admitted and amended. Specifically, although a systematic analysis of adverse events and near misses is operated by the Quality Manager and staff, nevertheless the information obtained is not made universally known to the nurses and physicians of the Hematology/Oncology Divisions. This may be particularly true in the case of the new targeted therapies which present with a novel set of adverse events. Such information should be given and disseminated first at DMT levels and also, following appropriate analysis, at the level of patients associations. Admittedly, the present patient/relatives information also could be improved by involving the patient/relatives in the root causes investigation of most near misses or real adverse events. This goal can be obviously achieved in the absence of legal litigation
	Action	1. Improve analysis/discussion of adverse events at DMT level by implementing periodical sections for adverse events discussion (mortality/morbility approach). 2. In those cases, where litigation is not involved, the patient and / or relatives may participate to part of the analysis at point 1
	Goal/ desired result	To improve the handling of the adverse events and its prevention. To spread information on adverse events
	Actions description	Analysis of adverse events should not be limited to the Quality manager and staff and to a small number of physicians/nurses involved, but should be spread to the Hematology/Oncology nurses/physicians with involvement of patients and relatives. The

		Quality Manager has to inform the DMTs of this initiative and provide instructions regarding the methodological approach.
	Who is involved and responsible for result	Quality Manager and staff DMT coordinators Patients/relatives/patient associations Nurse Chief
	Start (date)	The above planned approach can be instated by the end of June 2015.
	Evaluation (date)	The first evaluation can be carried out after six months and the effectiveness of the initiative can be evaluated within one year.
	Dead line (date)	June 2016
	Priority - High/Med./Low	Med
FUP	Progress	A major difficulty for the implementation of this task, was that in the past, clinicians would focus primarily on the adverse events occurring in patients recruited in clinical trials. This approach was perhaps justified by the fact that adverse events occurring with drugs under investigation were more relevant, possibly more unusual and thus informative to the physicians. Therefore, these events were carefully reported and discussed within the clinical trial documents. Now, a major effort is being carried out to have the physicians focusing on all the adverse events, irrespective of whether they occur within or outside the clinical trials. These events are to be discussed within the DMTs and reported in DMTs annual report
	Status of implementation	40%
	Results achieved	So far there has been some consensus on the fact that special issues should be faced and discussed besides the adverse events. One of these relates to the use of certain therapies (procedures) in the almost end of life conditions. This issue is amenable to resolution if several physicians with different background are forced to discuss problems such as: is a bone marrow transplant in a leukemic patient with several relapses justified? Or is a forth/fifth line chemo in an elderly patient with co-morbidities required? Cases of the above type have been selected and brought to the physicians attention. It is foreseen that, at the end of this process, not only the major adverse events occurring in the DMTs will be discussed (perhaps also with the participation of patient's relatives), but also that a critical re-evaluation of procedures will be carried out in order to prevent situation leading to over-treatment or to unnecessary treatment which obviously can more easily determine adverse events

Action 12	Standard	1 General Standards - 1.5.2 Quality and risk management and safety requirements
	Opportunity	The audit team has pointed out that although there is a dashboard system for monitoring the major risk areas, nevertheless this may be insufficient for the presently required standard.
	Action	Indeed, beginning March 1st , a new dashboard has been implemented with expanded and more detailed risk description. This dashboard (enclosed) was compiled according to ISO 9001:2015 (new edition)

	Goal/ desired result	To improve the performance in the safety requirements and in the risk management.
	Actions description	A number of items were identified requiring immediate action. These items include points such as: signature of informed consent and private issue, evaluation of risk for thrombo-emorragic complication, daily monitor of pain, etc. (see enclosed form). These items have to be according to a written procedure and the results enclosed are part of BSC of each Division of the Institute.
	Who is involved and responsible for result	Quality Manager Controller
	Start (date)	March 1st 2015
	Evaluation (date)	The first evaluation will be carried out six months after the start of the new dashboard
	Dead line (date)	October 2015
	Priority - High/Med./Low	Low
FUP	Progress	As already stated, a dashboard has been implemented containing more detailed risk descriptions.
	Status of implementation	Completed
	Results achieved	The use of this dashboard has been enforced in all the institute divisions, including the hematology/oncology groups and is now part of the routine operations in the Institute

Action 13	Standard	1 General Standards - 1.5.4 Quality and risk management of research and new techniques
	Opportunity	See point 4.1.3 Improvement of Clinical Research.
	Action	
	Goal/ desired result	
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Priority - High/Med./Low	

FUP	Progress	See point 4.1.3
	Status of implementation	
	Results achieved	

Action 14	Standard	1 General Standards - 1.5.6 Quality assurance in all areas (HR)
	Opportunity	The auditors team pointed out that the evaluation methodology (enforced by a national law) in use was instated from relatively little time and hence it was difficult to evaluate its effects. Indeed, we admit that this may have represented a problem at the time.
	Action	Now, two Deming cycles have been completed and the results indicate that the methodology is suitable for staff evaluation. Notably, this methodology includes an evaluation of the training program of the single employee. Therefore, the evaluation methodology can be of help in guiding staff job assignment.
	Goal/ desired result	To use the results of staff evaluation for a more precise assignment of jobs.
	Actions description	Based upon the above results, the evaluation methodology and the results obtained can be included in the criteria used for strategic plan preparation, assignment of responsibility and decisions regarding further training.
	Who is involved and responsible for result	Cancer Center Board Management Team Human resources manager Scientific Director Medical Director
	Start (date)	Already in use.
	Evaluation (date)	Two Deming cycles accomplished.
	Dead line (date)	
	Priority - High/Med./Low	
FUP	Progress	The general evaluation procedure was enforced in the Institute a relatively short time before the site visit. Hence, it was difficult, at that time, to evaluate the validity of the proposed methodology. Now, following several Deming cycles, it can be stated that the evaluation method is working and that it is suitable to evaluate the general characteristics of physicians, nurses and also other staff components. Particularly, this methodology allows to determine the general compliance of a given individual and the diligence applied to his/her job. There is, however, a more subtle issue to be dealt with and namely the compliance of the single physicians/investigators, in carrying out the exact duty described in the jobs description of their original working contract. Such assessment should provide a more precise evaluation

		of additional qualities, such as leadership, creativity, capacity of training young people, technical skill and activity volumes.
	Status of implementation	The first item is actually completed. The second part is not yet started
	Results achieved	An action plan is now being dedicated to allow the evaluation of these more subtle features. It is planned to prepare a checklist where all the potential and expected functions of a given operator are enlisted and the actual compliance to such list is evaluated.

Action 15	Standard	1 General Standards - 1.5.7 Privacy, protection and personal data
	Opportunity	See point 4.1.3 Improvement of Clinical Research
	Action	
	Goal/ desired result	
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Dead line (date)	
	Priority - High/Med./Low	
FUP	Progress	See action 19
	Status of implementation	
	Results achieved	

Action 16	Standard	3 Care - 3.1.1 Pain service
	Opportunity	Despite the recent improvements in pain management and in pain control information, it has to be admitted that most information on the issue was given orally by physicians/nurses.
	Action	Written information on the potential pain control should be provided to patients/relatives.
	Goal/ desired result	A more precise information on pain treatment.
	Actions description	Leaflets illustrating all of the possibilities available for pain control are being prepared by the supportive and palliative care team and Quality Manager. This leaflet will be given to attending physicians and nurses in order to help the spreading information on the mode and options for pain treatment. In addition, the leaflet will be given to patient associations and made available in wards, DH and ambulatory care facilities.

	Who is involved and responsible for result	Supportive and palliative care team and Coordinator. Quality Manager.
	Start (date)	The compilations of the leaflets is being carried out since March 15th and will be completed in approximately 3 months. After the completion, the leaflets efficacy is going to be evaluated in the following 3-6 months.
	Evaluation (date)	September 2015
	Dead line (date)	December 2015
	Priority - High/Med./Low	Med
FUP	Progress	The enclosed leaflet was implemented at the end of 2015. The preparation of an improved version is currently in progress. This was stemmed from the reorganization of the oncology pain team and the subsequent re-valutation of many procedures. The new version of the leaflet is going to be placed in the intranet web mid-August and a first assessment will be available by the end of the year. .
	Status of implementation	80% completed
	Results achieved	At the end of September probably this new version of the leaflet will be available for the Haematology/Oncology wards and a general assessment can be completed by the end pf the year.

Action 17	Standard	3 Care - 3.1.5 Psycho-oncology service
	Opportunity	As pointed out by the auditors, there is no systematic screening for Psychology care needs of the cancer patients and patients are referred to the Psychology Service based upon physician/nurse decision.
	Action	To consider the psychological needs of all patients in a systematic manner.
	Goal/ desired result	To detect patients needing psychological support and to provide the appropriate care.
	Actions description	A check-list aimed at determining psychological needs of patients is being prepared. This will be integral part of the patients chart and its compilation by the attending physicians/nurses will be made obligatory (similar to that required for the supportive care check-list). See also General Standards - 1.4.8
	Who is involved and responsible for result	Psychology Service Director Supportive and Palliative Care team Coordinator Quality Manager Chief Nurse

	Start (date)	The preparation of the checklist has started March 15th and the checklist is expected to be in use within three months from the start.
	Evaluation (date)	The first evaluation will be carried out six months after the check list is routinely in use Two Deming cycles will be necessary to ascertain the efficacy of the approach measured in terms of number of patient referral to the Psychology Service and patient satisfaction.
	Dead line (date)	The whole process of check-list preparation, enforcement and evaluation is likely to be completed by March 2016.
	Priority - High/Med./Low	Med
FUP	Progress	Regarding this point, there was the evidence during the site visit that the psychological needs of both patients and relatives were not taken care of and especially evaluated with precision. Now checklists are available to evaluated these need for patient and relatives (particularly for young children suffering for their dying parents). These checklists are enclosed.
	Status of implementation	50% completed
	Results achieved	It should be outlined that enforcement of these checklist (and of the subsequent actions) is not universally accepted in the Institute (as well as the cooperation with the psychological team). Therefore, the quality manager and his team are now discussing with the various clinical groups/DMTs on the full implementation of this methodology.

Action 18	Standard	3 Care - 3.1.8 Family involvement in care (children)
	Opportunity	The Auditors pointed out the need to provide a psychological support to children of patients dying in the Institute. Admittedly, this problem has been only partially approached and consequently solved so far. Indeed, for patients dying in the Hospice the attending physician/nurses enquire about the family situation and need, and often they talk with the children and advice the family about further physiological support. However, there are not written procedures and the approach employed within in the Hospice is not universally used for patients dying outside Hospice.
	Action	A correct approach to the above problem is that of systematically evaluate the support need of the children of patients dying in the Institute.
	Goal/ desired result	The action has two aims: i) focusing on the needs and ii) finding out the most appropriate solution.
	Actions description	It appears that the above problems can be apparently approached and solved by: i. elaborating written procedures for physicians/nurses regarding the children support ii. these documents should not only contain advice regarding the children of dying individuals but also should deal with

		the issue of cancer as whole so that young children can be informed about the possibility that a percentage of patients with cancer diagnosis can progress from early to late stages. The attending physicians/nurse may decide regarding psychological support for children also considering the stage/prognosis of the patient/parent with cancer.
	Who is involved and responsible for result	Palliative and Supportive Care coordinator and staff Quality Manager Nurse Chief Hospice Coordinator Psycology Division Director and staff
	Start (date)	This project is going to be started April 15th. The instructions for physicians/nurses and possible leaflets for families are expected to be ready after six months.
	Evaluation (date)	Two Deming cycles after the start of the project will be required to assess the efficacy of this initiative.
	Dead line (date)	The whole process can be completed within one year from start (April 2016).
	Priority - High/Med./Low	Med
FUP	Progress	The issue has been already dealt with under action 17. Here we enclose the document related to the instructions on how to deal with children of dying patients.
	Status of implementation	50% completed
	Results achieved	Here, we should stress that the remaining problems are related with the implementation of the methodologies and with the widespread acceptance of these methodologies by the clinicians.

Action 19	Standard	4 Research, innovation and development - 4.1.3 Organization of clinical research
	Opportunity	After the site-visit, an investigation was started to ascertain whether the figures shown to the auditors were really reflecting the actual trial accrual. This analysis was promoted by the auditors perplexities regarding the percentage of patients recruited in trials. A perplexity which also was supported by the opinion of some of the in house oncologists/haematologists. Indeed, this analysis revealed that the picture provided at that time was somewhat pessimistic and we apologize for this. More in depth analysis, utilizing data from pharmacy and the controller, demonstrate that there is larger accrual of patients in the trials than declared during the site-visit. Moreover, there were pitfalls in calculating the total number of cancer patients from which the percentage of cases in trials was obtained. In the denominator of these calculations, the patients with cancers included any patient admitted who had cancer diagnosis in the whole clinical history and also patients who presented for second opinions. Nevertheless, we admit that greater care should be given to the general trials organization and point out that some inordinate procedures reflect the different approaches in use in the two Institutions before the merger.

	Action	The action suggested by the analysis of clinical research is that of bringing in a more strict supervision by the Scientific Director on clinical research.
	Goal/ desired result	To potentiate the governance, monitoring and administrating the clinical trials. Real time assessment of data.
	Actions description	It appears necessary to instate two specific actions: i. to potentiate the present clinical trial unit. The initial group of this unit has been expanded into a CRO. It is intended that this CRO manages the spontaneous (no sponsored) clinical research and reports periodically to the Scientific Director. This Unit can act as a supportive CRO for sponsored trials in which Institute Investigators are involved. Clearly, the sponsored trials may require to be referred to other CRO upon sponsor request. However, the Institute trial unit can still have supervising roles related to issues such as timing of accrual, number of patient, trial conduction, monitoring of adverse events, privacy and quality of management according to EMA regulations, etc. Importantly, this unit can collaborate with the Quality manager and staff in organizing audits to monitor the trial quality. ii. Organization of a trial managing office. This office is being formed and will have the task of following all of the aspects connected with trial administration including that of having a close cooperative working relationship with the Ethic Committee. This office will operate in close contact with the Clinical Trial Unit, the Pharmacy, DMTs and Quality Manager and will have the task of keeping record of all the trials, of their patient accrual and of the major administrative issues. Finally, the above organization will allow to have a real-time panorama of all the ongoing clinical trials. As for the issue of privacy protection, it should be pointed out that the Ethic Committee already supervises the issue in the clinical trials according to the Italian law.
	Who is involved and responsible for result	Scientific Director Clinical Epidemiology Division Director Clinical Trial Unit Chief DMTs Coordinators Centralized anti-cancer drug Unit (UFA) Chief Quality Manager Administrative Directors
	Start (date)	This operation, which is due to start April 15th, is somewhat complex. In fact, some of the needed units are already in place but require a new-organization process, while others may require up to one year to be organized and to become ready to operate.
	Evaluation (date)	Because of the above complexity, a first evaluation can take place one year after start. A second and final evaluation after another six month can provide a definitive answer on whether the new organization is suitable.
	Dead line (date)	April 2016

	Priority - High/Med./Low	High
FUP	Progress	In order to potentiate the managing of clinical research the following actions have been undertaken i) The clinical trial unit has been potentiated and has acquired the official recognition as CRO by the Italian authorities (AIFA). ii) The organization of the trial managing office is being completed (its duties/function are described below)
	Status of implementation	80% completed
	Results achieved	i) The duty of the trial managing office is that of coordinating spontaneous clinical research in the Institute and of providing organization counselling for sponsored research. In addition, this unit cooperates with the clinical trial unit manging in the supervision of trial conduct and in monitoring their progression ii) The function of the trial managing office, at the process completion, will be that of 1) keeping in contact with the sponsor for the organization of the future clinical trials and their presentation to the Regional Ethic Committee. 2) to take care of the administration of the clinical trials in coordination with the hospital administration controller 3) to keep record of the patient accrual and of the trial progression 4) to coordinate the data managers in the Institute supervision their assignment to the various ongoing trials 5) to cooperate with the Institute pharmacy for any need concerning drug supply/storage etc.

Action 20	Standard	4 Research, innovation and development - 4.1.4 Periodical policy review
	Opportunity	This issue is part of the more complex issue of the Cancer Centre Governance. Indeed, we admit that it is difficult to have complete control of the research activity and of the planning of future projects in the absence of a specific strategic oncology plan and of people deputed to monitor the achievements, besides the Scientific Director.
	Action	The actions to be taken to improve the Cancer Centre governance are detailed at 1.1.1.
	Goal/ desired result	Integration of the different cancer research lines. To foster collaboration between basic science and clinical investigators.
	Actions description	As stated above, a crucial step for the above goal achievement is that of organizing a Cancer Center Board as described in a preceding section. However, some more limited actions have or can be already taken, such as that of fostering cooperation between medical oncologists and immunologists in studies on immune-potentiating monoclonal antibodies or that between molecular biologists and medical oncologists/haematologists in the targeted therapy studies.
	Who is involved and responsible for result	Scientific Director Cancer Centre Board

	Start (date)	April 15th 2015
	Evaluation (date)	April 15th 2016
	Dead line (date)	April 2016
	Priority - High/Med./Low	Med
FUP	Progress	Great effort has been placed in restructuring the governance of research and specifically of translational research. Indeed, the situation preceding the site visit period, was characterized by a great research freedom which, on one side, facilitated creativity, but on the other side, prevented cooperative efforts by more structured teams of suitable size. To this end, the research laboratory structure and hierarchy was changed in order to have more robust research groups of sufficient size and with a strong leadership.
	Status of implementation	80% completed
	Results achieved	This new organization now allows to undertake research projects of wider breath and greater ambition. A great help has also been provided by the elaboration of a strategic plan, which has set defined goals for the short/medium period to be achieved by the research groups. In order to support the validity of the above statements, we should point out that it has been possible to fund cooperative projects within the Institute involving different groups from various laboratories. These include, among others, studies on the molecular pathology of the breast and lung cancer and also epidemiology studies on the screening of high risk patients for lung cancer.

Action 21	Standard	4 Research, innovation and development - 4.3.1 Means for conducting research activities
	Opportunity	Although the accounting of research expenses is quite accurate, we must admit that some aspects of the administration of certain clinical trials may not fall under the control of the Institute Administration.
	Action	As explained in another section (4.1.3) the above pitfalls are for the great part attributable to both the insufficient functioning at present of the Clinical Trial Unit and the absence of a Clinical Trial Managing Office. The measures to obviate to these problems have been already reported. The mode of execution of these measures is already reported (see 4.1.3)
	Goal/ desired result	See 4.1.3 Improvement of Clinical Trials
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Dead line (date)	
	Priority - High/Med./Low	
F U	Progress	Admittedly at the time of the site visit, there was no clear evidence that the institute was in full control of the clinical trials administration. This pitfall is in the process of being corrected in several ways.

	Status of implementation	80% completed
	Results achieved	First, we are constructing a clinical trial managing office to be integrated with the clinical trial unit for the administration of trials, supervision of data manager and contacts with ethic-committee. Second, the software equipments for registering all the steps of any given clinical trials are being acquired and implemented. Third, negotiations with Genoa University (the end of which was been fixed for the end of July) should hopefully define the relationship between the University staff and the Institute in the responsibility of trial administration. This should conceivably bring all the control of trial administration under the responsibility of the Institute.

Action 22	Standard	4 Research, innovation and development - 4.3.2 Intellectual property and innovation
	Opportunity	The oncology research in the Institute has been focused on two major fields i.e. disease (cancer) mechanisms or drugs and biologicals clinical testing. With this research strategy, it is difficult to obtain a large patent number, since ad hoc biotechnology research is required to achieve a good performance in this field. A proof of this concept is provided by the consideration that there are patents related to tissue regeneration because of the existence in house of a research unit specialized in the field and oriented to biotechnology.
	Action	Although major changes in research strategy are not expected for the near future, nevertheless some modifications in the Institute attitude may be brought about by a new agreement with Italian Technology Institute (ITT) located in Genoa. This agreement, planned initially for neuro-sciences and neuro-rehabilitation, will lead to the construction of a jointly run laboratory within our Institute. This joint venture may produce a hopefully large number of patents (and to the exploitation of some of the existing ones) and may be extended in the future to other fields such as stem cells and/or tissue regeneration which are more related to oncology. A detailed analysis of all the above initiative goes beyond the scope of the present document.
	Goal/ desired result	Improve the number of patents and innovation in general.
	Actions description	See above. Improve cooperation with ITT, first in the area of neurosciences and subsequently in that of tissue regeneration and stem cell therapy.
	Who is involved and responsible for result	CEO Scientific Director Neuroscience Department Director
	Start (date)	Ongoing
	Evaluation (date)	June 2016
	Dead line (date)	June 2017. An increased number of patents is to be expected by this data, when the cooperation with the ITT is going to be fully operative.

	Priority - High/Med./Low	Med.
FUP	Progress	The organization which leads to the acquisition of a large patent number, is complex and requires relatively long time as already explained in the previous report. As stated in that document, there were no structures in the Institute devoted to the acquisition of patents or specialized in the biotech field, with the possible exception of the Division of Tissue Regeneration. Now, with the new re-organization of this particular sector (consequent to the retirement of Dr. R. Cancedda head of the division) this structure will be more devoted to cell oncology research.
	Status of implementation	It is possible that the goal of an increase in patent number by the summer 2017 may not be realistic.
	Results achieved	However, the new joint ventures which are being developed with the Italian Institute of Technology (IIT) may offer the opportunity of developing a more biotech and patent oriented activity. The neuroscience laboratory, which represents the first step of such joint venture, is already operating and other initiatives, particularly in the field of molecular oncology and stem cell, are now being evaluated and may lead to a substantial expansion of these joint ventures.

Action 23	Standard	4 Research, innovation and development - 4.3.3 Biobank
	Opportunity	The reorganization of biobanking is an ongoing process which has so far led to the focusing on two processes only; i.e. collection and storage of pathological tissue samples or of cells (and cell lines) and collection and storage of stem cells to be infused into bone-marrow transplant patients. The whole process is now under the control of the Blood Center Director, although the tissue acquisition part is run in close collaboration with the Pathologists.
	Action	The new organization which is focused on two major aspects of biobanking represent a great improvement over the previous situation with a number of “small” biobanks disseminated in different laboratories. Nevertheless, the present organization needs to become more robust and run with precise steps and rules.
	Goal/ desired result	Improve the collection of Pathology samples and organize the availability of these samples for both clinical and translational research.
	Actions description	Although there has been and increased collection of samples, this action will be only completed by the expansion of the pathology biobanking facilities at IST-south. This expansion is ongoing and is expected to be fully completed in November 2015. In addition, there is a team that is in charge of discussion/preparation of a SOP containing the rules that allow investigators to have access to pathological samples. The team will determine the major steps required for the control of the process. Finally, rules and means for a centralized storage and registration of samples are being instated/improved. An informed consent procedure has now been prepared and its use enforced (see enclosed document). Moreover, more detailed instructions have been delivered to DMTs, surgeons and pathologists who are urged to improve the process of tissue collection/storage.
	Who is involved and responsible for result	Director of Blood Center Pathology Directors

		Quality Manager Scientific Director
	Start (date)	The process is ongoing as specified above
	Evaluation (date)	The completion of banking facility will be obtained in the fall of the current year. At the same time all the procedures described above will be completed. A first evaluation of the whole process can be expected by April 2016, when the first Deming cycle will be done. A second Deming cycle is expected to be completed by November 2016.
	Dead line (date)	November 2016
	Priority - High/Med./Low	High
FUP	Progress	The reorganization of the biobanking actions proceeds as it was originally planned although a number of topographical changes have been brought about in order to cope with the new reorganization of the oncology pole.
	Status of implementation	50% completed
	Results achieved	First, the planned concentration of this activity under the blood centre has been accomplished at the beginning of the spring 2016. The new biobanking activities are now focused on the core business of the biobanking previously in existence in the Institute: i.e. banking of the stem cells to be used in patients bone marrow transplants, and tissue acquisition for translational studies. Clearly, the part related to pathological tissue acquisition is carried out in close cooperation with the Divisions of Pathology. Moreover, all the tissue collection and particularly cell collection carried out at the single laboratory level, has been re-classified as research activity (as indeed it is) rather than named with the “pompous” denomination of biobanking previously used by certain investigations. This laboratory activity, nevertheless, follows the rules of good laboratory practice. The newly defined biobanking activity has been initially located in the facilities of the blood centre (stem cells for transplant). This part of the activity will be moved to an entirely new building, which is expected to be ready by the beginning of 2018. The tissue acquisition activity is being carried out in the pathology division, although the final storage will be moved from the present facilities (IST-south) to new venues which are being relocated in a new ad hoc laboratory in IST –north

Action 24	Standard	5 Teaching and continuing education - 5.4.1 Participation in teaching oncology
	Opportunity	The analysis of the auditors is correct in that the hemato/oncology medical and research staff is permanently involved in teaching to both undergraduates and postgraduates. This is not the case for undergraduate courses for nurses mainly for two reasons, i) that there is no specific course for nurse oncology subspecialty and ii) the teaching of oncology to the undergraduate nurses (in the general nurse course) is primarily a duty of permanent University staff with no special connections with the Institute.
	Action	The Institute must improve the collaboration with Genova University in the implementation of Oncology teaching which should include the participation of Institute staff.

	Goal/ desired result	Improve the participation of nurses and supportive disciplines staff from the Institute into the undergraduate teaching. Bring this aspect of the teaching more close to the everyday life of the Institute.
	Actions description	It is increasingly common that our nurse staff are requested by the University to help with the undergraduate nurse teaching (particularly for oncology and hematology) on a per year contract basis. With this type of agreement some of our nurses (including the Chief nurses) deliver lectures in the University and participate in the course running. Virtually the same organization holds true for the Institute phycologists and supportive disciplines operators, since the Institute staff is recruited into teaching by the University on a yearly basis. Clearly, the intention of the Institute is that of i) increasing the number of nurse staff involved in teaching and ii) to have University staff with nurse teaching duty becoming members of the Institute.
	Who is involved and responsible for result	Dean of Medical School Nurse Chief Scientific Director Nurse Teaching Coordinator
	Start (date)	Although the intention of an increasing involvement in teaching has been stated clearly in repeated occasions, achievements in the field depend both on the attitude of the Institute and on that of the University of Genova.
	Evaluation (date)	Not applicable
	Dead line (date)	Not applicable
	Priority - High/Med./Low	Med
FUP	Progress	The process of teaching integration between the Institute and the University of Genova medical School is continuing although the task is not easy due to the fact that teaching is a major responsibility of the University and that the Institute has a minor role. However, it should be stressed that the Institute is moving progressively to a structure/organization which is typical of a teaching hospital, where the undergraduate medical students are more involved in the everyday hospital life and the residents can be considered as hospital staff in most aspects of their duties. With this organization, all the medical staff of the hospital contributes to the training of the new doctor generation. Problems still exist for the nurse training which is taken care of by a relatively restricted number of teachers belonging to the University staff, consequently a number of Institute nurses are somewhat excluded from teaching. This problem is made even more complex if one considers that there are no subspecialties for nurses in Italy. The issue has been the focus of a major discussion with the Genoa University of Medical School and the new agreement with the University, now in preparation, is taking care of all of the aspects of the problem. (See also Action 25)
	Status of implementation	50% completed
	Results achieved	Thus, even if there is no much practical improvement so far, with the new guide lines stemmed from the agreement, we believe

		to be able to reach satisfactory solutions

Action 25	Standard	5 Teaching and continuing education - 5.4.2 Types of teaching programmes provided
	Opportunity	Italy does not have a bachelor degree in oncology nursing as correctly pointed out by the auditors. This situation can be changed only by special laws governing the University courses organization. Hence, a change of this type is absolutely out of the potential range of action of the Institute (or even of the Regional government). Nevertheless, surrogate solutions can be in part be created.
	Action	The surrogate situation is represented by the Masters in Oncology or other courses and in ECM-qualified courses. The participation of Institute staff in this from of teaching must be encouraged.
	Goal/ desired result	To increase the number of Institute staff within the faculty of Masters, ECM-courses, and PhD courses related to Oncology.
	Actions description	This plan is that of expanding the potential teaching capacity of the Institute staff to the nurse training. This implies an increase ad hoc agreement with the University of Genova.
	Who is involved and responsible for result	Dean of Medical School Undergraduate Nurse Course Coordinator MD Course Coordinator Nurse Chief Human Resources Director Scientific Director
	Start (date)	The negotiation with the University are in progress and a (positive) conclusion can be forseen by the end of the current year, when the PGI (Protocollo Generale di Intesa) is going to be presented for approval to the Regional and University Authorities.
	Evaluation (date)	Not applicable
	Dead line (date)	Not applicable
	Priority - High/Med./Low	Med
FUP	Progress	As already reported, this action was dependent upon a close collaboration between the Institute and the University of Genova. Since there are no officially recognized courses / specialization for oncology/hematology nurses in Italy, this lack of specialized training should be substituted for by the others forms of teaching such as masters, specialized courses or other ECM-qualified initiatives.
	Status of implementation	60% completed
	Results achieved	A program intended to improve this training has been planned also in cooperation with the University of Genova Medical School.

		However, the start of these initiatives is has to wait the new Protocol of Intent (PGI) between Institute and the University of Genoa is signed with the approval/supervision of the Regional Liguria authorities.

Action 26	Standard	5 Teaching and continuing education - 5.4.3 Types of teaching programmes organized
	Opportunity	As stated above the absence of certain types of teaching requires a number of surrogates, although from the organizational stand point, at present it is somewhat difficult for the Institute staff to participate in teaching and particularly in its organization. Indeed, all of the teaching falls under responsibility of the University of Genova as determined by laws and the Institute can only help/facilitate this activity as defined by the PGI (see above).
	Action	Within the above limits, the Institute will try to organize additional oncology teaching and take care of additional training/re-training of staff (see Piano Formativo 2015-16).
	Goal/ desired result	To improve the quality/quantity of teaching particularly in the field of ECM-related courses, masters, and PhD courses related to oncology.
	Actions description	The sharing of teaching activity with University of Genova, particularly for all what is related to Hematology/Oncology is one of the key point for the new PGI with the University of Genova. Since this is a matter of negotiation, the outcome is dependent also from the University of Genova attitude.
	Who is involved and responsible for result	Dean of Medical School Undergraduate Nurse Course Coordinator MD Course Coordinator Nurse Chief Human Resources Director Scientific Director
	Start (date)	The negotiations are ongoing as specified above.
	Evaluation (date)	December 2015
	Dead line (date)	December 2015
	Priority - High/Med./Low	Med
FUP	Progress	As repeatedly stated, teaching is a particular duty of the University of Genoa and, in this respect, the Institute depends upon the initiatives and course organized by the University staff. Nevertheless, two actions, which can be considered as synergistic, have been undertaken:

		i)The institute is requesting the University to consider its training/re-training needs in the planning of the teaching, and this consideration should be part of the general protocol of intent (PGI) being organized between Regione Liguria and University of Genoa medical school. ii) irrespective of the outcome of the above negotiations, the Institute is and has been organizing surrogate means which can serve the purpose of training/retraining the staff at various levels.
	Status of implementation	60% completed
	Results achieved	These initiatives include ECM-related courses, masters and also ad hoc courses on specialized issues. The summary of these activities is in the report of the Ufficio della formazione (teaching and training office) which is here in enclosed.

Action 27	Standard	6 Patient related - 6.4.1 Educational material
	Opportunity	We agree with the auditors that, although written information about cancer and cancer treatment was available, this was not located in the correct site at the time of the site-visit. We also agree that contacts with GPs were not systematic, although the Institute was sporadically involved in organizing up to date courses in Oncology for GPs. Finally, the issue of clinical trial inclusion as well as that of availability of supportive care had to be reorganized.
	Action	The above pitfalls require an improvement of the relationships with GPs together with a more accurate information of patients regarding both cancer and the means offered by the Institute for treatment and palliation.
	Goal/ desired result	Improvement of patients information and more close working relationships with GPs.
	Actions description	The location where leaflets and booklets are distributed will be expanded and spread over the IST-south buildings. Thus, besides the two patient association offices, as seen by auditors, the printed material will be distributed in the DH, in the Oncology/Surgical Oncology wards and in the ambulatory spaces. In addition, this material will be available in the surgical oncology wards of Monoblocco. Physicians will be instructed to suggest the reading of this material to the patients, while availability and the quality of this material will be improved by also using publications by Associazione Italiana di Oncologia Medica (AIOM). AIOM has made available a new set of booklets for different cancers, which are very clear and informative. The GPs coordinators (nominated by the Regional Government) will be officially involved in spreading information about cancer progress and information to GPs. Moreover, the habit of organizing ECM-courses for GPs will be resumed and expanded. Finally written material explaining what clinical trials are and the potential advantage to patients from participation is being prepared and distributed according to mode described above.
	Who is involved and responsible for result	Quality Manager Nurse Chief DMT Coordinators Patient Representatives
	Start (date)	These initiatives will be fully started in September when the present restructuring of floor 0, 1 and 2 of IST-south will be almost completed.

	Evaluation (date)	The results of the entire process may be seen preliminarly after one year i.e. in the spring of 2016.
	Dead line (date)	Clearly the whole operation is a multitask effort and requires a certain amount of time. It can be predicted that selection and distribution of booklets/leaflets will be completed within six months from start. The preparation of patient instructions for clinical trial will take 4-6 months. The establishment of new relationships with GPs will be a long process which presumably is going to take one year.
	Priority - High/Med./Low	Med
FUP	Progress	The patient information has been improved by a number of concerted actions: i) The number of booklets and leaflets disseminated in different sites of medical and surgical wards, oncology and hematology DH and ambulatory has been increased. In certain circumstances, specialized booklets or leaflets have been employed, such as in the case of the material used in the urology ward to explain the basic principles of pathology and surgery of this district. In addition doctors and nurses have received instruction on how to deal with the information aspects of cancer. ii) The part of the web site dedicated to patient information has been expanded. Specifically, the patient (and relatives) not only can find basic information on cancer and related problems, but there is also information on what clinical trials represent and the advantages that they may bring to patients. Also, information is provided and disseminated on the major ongoing clinical trials.
	Status of implementation	80% completed
	Results achieved	The general aim has been that of creating a stronger link between the patient and the staff so that the patients questions (and problems) could be more freely dealt with and possibly solved.

Action 28	Standard	6 Patient related - 6.4.2 Inform patients on admission
	Opportunity	As already mentioned for action 3, the criticisms of auditors regarded mainly the management of patients with oncology emergency. These criticisms have been accepted and amendment actions have been proposed in the appropriate chapter. The auditors were correct in pointing out that a more extensive information on the issue of “things to do” by patients and relatives in case of oncology emergency should be provided. This concept has been stressed here.
	Action	According to the above instruction, more extensive information regarding the management of oncology emergency should be provided to patients including notions on “what to do” and “where to go”.
	Goal/ desired result	Improve patient information on appropriateness of admission.
	Actions description	The attending oncologists/haematologists will be instructed to provide the patients with a leaflet illustrating the major possible

		complications in oncology also during chemotherapy or targeted therapies and indicating the behaviour to have and the points of contact (i.e. ED or Oncology fast-track).
	Who is involved and responsible for result	ED Director and staff Medical Director Quality Manager DMT Coordinator Nurse Chief Patient Representatives
	Start (date)	April 2015. The preparation of leaflet with take 4-6 months and another 2 months will be employed in physician/nurses information.
	Evaluation (date)	First evaluation at 6 months from start.
	Dead line (date)	April 2016
	Priority - High/Med./Low	High
FUP	Progress	There has been a general improvement represented primarily by the availability of a fast track for hematology/oncology emergencies, by a better relationship between the hematology/oncology divisions and the ER facilities and also by a generally improved information to patients on " what to do and/or where to go". Concerns still remain however, given the fact that there are no uniform procedures for handling emergencies and each group/ward has established its own methodologies for the emergencies; i.e. the lung cancer DMT has its own procedures for emergencies which are different from those followed by the Head and Neck DMT. Although some heterogeneity of procedures is dictated by differences in the specific type of pathology; nevertheless more uniformity is desirable and efforts are now placed to achieve such goal.
	Status of implementation	70% completed
	Results achieved	It is foreseen that an improved solution to the issue can be ready by the end of the year.

Action 29	Standard	6 Patient related - 6.4.4 Discharge procedure
	Opportunity	Care is taken to keep the patients informed about their clinical conditions at discharge and to provide a clean picture on "what did and will happen". In addition, information is given to the major follow-up steps and about patient association. However, criticism of the auditors related to the insufficient information about a clearly organized follow-up plan and also about the poor availability of self-help regional groups. The latter criticism related more to the regional health than to the hospital organization, although surrogate means can be provided. For the improvement of discharge methodologies, we recognize that measures could be taken and enforced.
	Action	Improve care information and support in the follow-up period in a holistic manner.

	Goal/ desired result	To obtain a more supportive assistance by both the hospital and regional environment in the post cancer treatment period.
	Actions description	First, the discharge report should be modified in order to provide extended information regarding the follow-up plan, its rationale and on "what can be reasonably expected" for the future. Second, a better relationship with GPs may contribute to improve both the post-discharge period and the follow-up efficacy. Indeed, a more motivated and involved GP may be more helpful that the hospital support in this period, and also may facilitate the management of a potential relapse. Third, although there are no self-help groups, the Institute and the patient associations may begin to organize this type of support, perhaps with the help of Regional authorities and GPs.
	Who is involved and responsible for result	Medical Director Chief Nurse DMT Coordinators Quality Manager All of them have to cooperatively provide a SOP for changing the mode of compilation of discharge report. Patient representatives, Hematology/Oncology Department Director and Hematology/Oncology Divisions Directors who have to take care of the relationships with GPs and to enforce the application of SOP. Quality Manager, Psycology Division Chief, Patients Representatives for attempts to promote the formation of support groups
	Start (date)	April 15th
	Evaluation (date)	The part which relies on the hospital action only, such as the preparation of a SOP for patient discharge, is relatively easy to both accomplish and evaluate. In contrast, the part involving the self-help group depends only for a portion by the Institute and needs both the help of GPs, the regional authorities and the community at large and hence it is more complex to be defined and run.
	Dead line (date)	With all the above caveats, nevertheless it can be predicted that the whole operation can take one year and that a preliminary evaluation of its efficacy may be expected by April 2016.
	Priority - High/Med./Low	Med
FUP	Progress	Again, for this action there has been a type of evolution which was somewhat different from that requested by the evaluators and also predicted by the managing team. Indeed, now there is a procedure for the discharge of patient which is universally employed and takes care of the information on "what to do" and "what may happen for the future". Nevertheless, this information is very specific for each DMT and hence the physician/nurse behaviour is somewhat DMT dependent with respect to this particular issue Nevertheless, additional concerns remain which are related to the role of and the help provided by the GPs. Moreover, the existence of self-help groups is still patchy in that they may be variable depending upon the various cancers; i.e. breast cancer is generally more supported that other cancer types.

		Unfortunately the solution of these issues is made complex by the combination of responsibilities involved (Regione Liguria involvement, Institute, GPs)
	Status of implementation	50% completed
	Results achieved	Efforts are now ongoing to bring about a more structured procedure governing this issue. It can be foreseen that a more defined solution will be brought about by the end of the year.

Action 30	Standard	6 Patient related - 6.5.1 Patient satisfaction/ experiences
	Opportunity	Patient satisfaction evaluation during the various steps of care is in use in the Institute and is part of the BSC. The means employed for this evaluation are provided by the Regional Health Agency and are uniform for all Regional Hospitals. Therefore, the Institute has to cope with the Regional instruction and report on the issue to the Agency according to their methodology. This holds true also for the 2014/2015 period, which the Agency intends to evaluate at the end of the current year. The auditors found that the questionnaire provided by the Agency may not be sufficient for a Cancer Center of this size. This notion was known to the Institute and discussion with the Agency have been started accordingly. However, irrespective of the negotiations with the Agency, the Institute can instate a supplementary evaluation selecting a number of items for such analysis.
	Action	To implement the present survey with new items related specifically to hematology/oncology issues.
	Goal/ desired result	To improve the knowledge of patients satisfaction.
	Actions description	A survey form should be prepared and given to patients in addition to those provided by the Regional Agency. Its use and subsequent analysis must be implemented.
	Who is involved and responsible for result	Quality Manager Nurse Chief Nurse Coordinators in the wards, DH and outpatients services DMT Supervisor
	Start (date)	The Regional survey form will be implemented with the Institute form starting from May 2016.
	Evaluation (date)	
	Dead line (date)	January 2017
	Priority - High/Med./Low	Low
FUP	Progress	A survey system has been set up and an appropriate questionnaire will be distributed soon to patients to measure the degree of their satisfaction. The questionnaire (duty approved by the CCC board) is enclosed
	Status of implementation	90% completed

	Results achieved	In November we can disseminate the new questionnaire and preliminary results can be analysed already by January 2017