OECI

Organisation of European Cancer Institutes

ACCREDITATION AND DESIGNATION CERTIFYING COMPREHENSIVE CANCER CARE

Accreditation and Designation

User Manual V. 2.0

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Cancer Institutes

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OECI Accreditation and Designation User Manual V. 2.0

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COOPERATION

EurocanPlatform

Introduction to the Accreditation and Designation User Manual

Dear Colleagues,

the OECI and the OECI Accreditation & Designation (A&D) Working Group are proud to present the Version 2.0 of the OECI Quality Standards and Quantitative Data Set. This new version will enter into force on January 1st 2016. As of this date, cancer centres will be evaluated according to this new Version.

This Manual is the result of a successful collaboration among the A&D Working Group, OECI Members, all participating Centres in Version 1 of the programme (2010 – 2015) and their staff, and all the auditors that have been involved, on a voluntary basis, in the peer review visits. A new set of Quality Standards have been proposed, discussed and presented, with the aim of reaching a European consensus.

We thank all individuals, Organisations and Institutes, who provided insight in the evaluation and revision of the standards and procedures. We requested their expertise and efforts to evaluate and improve the questionnaires, in the frequent rounds of input and feedback. Without their dedicated contribution, the OECI A&D Programme would not be as successful as it is today.

Special thanks also goes out to all external representatives from European cancer Organisations involved in care, research and education, namely EORTC, EONS, ESOP, EANM, ESSO, IKNL, EACR and ECL, that contributed to the open debate on the proposed revision of the Manual.

Along with the revision of the Accreditation standards, thorough work taken place on the revision and improvement of the designation criteria. Designation as OECI Clinical or Comprehensive Cancer Centre will be based, henceforth, upon more ambitious and adapted criteria. Galvanizing the OECI members towards improvement remains a distinct objective. Designation as a Clinical or a Comprehensive Cancer Centre is not a question of differing, hierarchical levels of quality, but is rather linked to the level of research activities and its integration into care. Designation criteria have not been put in place with a view to ranking the Centres, but rather as landmarks for orientating them in their quest for improvement.

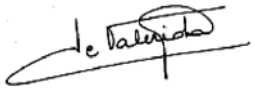
In order to evidence-base the changes in the Accreditation standards and Designation criteria, thorough scientific analysis of the results and of the data gathered through Round V1 of the programme was performed by our research team in the frame of EurocanPlatform Programme, Work Package 12. Moreover, participants in the EurocanPlatform Programme Work Package 14, dedicated to communication, have worked extensively to inform stakeholders about the A&D program and involve them in the revision process. We want to thank them, as well as the European Commission for the financial support of those Work Packages.

As the OECI strives to improve cancer care by good translational research and continuing medical education in order to offer the best available treatments to all patients, we would like to give our very special thanks to the Organisation representing all cancer patients in Europe, the European Cancer Patients Coalition “ECPC”, which has brought fundamental perspectives with regard to the revision of the Standards.

And last but not least, congratulations to the A&D Coordinating Team, to the Office of the OECI Director and to the Secretariat of the A&D Group, for the extraordinary efforts provided and for their professionalism.

Mahasti Saghatchian
OECI A&D Chair

Dominique de Valeriola
OECI President



THE OECI
Accreditation and Designation Programme and Manual

WHAT IS ACCREDITATION?

Accreditation is a process in which an independent organisation evaluates a health care provider and certifies that the provider meets certain quality standards.
The oldest accrediting organisation is the Joint Commission on Accreditation of Healthcare Organisations (JCAHO), but there are several others, in specific areas and various countries.
An accrediting organisation's survey includes an evaluation of the Centre's clinical services, as well as other aspects of the Centre's operations such as administration, personnel management and information management, research and education.
OECI has specialised its A&D programme on multidisciplinary, global and integrated cancer care and research with a major focus on comprehensiveness.

WHO SHOULD BECOME OECI ACCREDITED AND DESIGNATED?

Any OECI cancer centre that provides research, education, care services to cancer patients and that is willing to become a recognised member of our OECI cancer community.

WHY SHOULD A CANCER CENTRE BECOME OECI ACCREDITED AND DESIGNATED?

The aim of A&D programme is to stimulate cancer centres to continuously improve and/maintain the quality of the total organisation, including leadership and management, and the integration of care, research and education activities. A strong organisation may indirectly improve patient care and satisfaction. In the past few years the OECI has done research on this subject and few articles have been already published [1-2].

WHEN MUST A CANCER CENTRE BE ACCREDITED AND DESIGNATED?

The accreditation process is likely to take an average of 9 to 12 months, and longer in some cases. The increased need for accreditation will place a heavy demand on the OECI. However the cancer centre should reach a minimum level of quality and organisation in order to fulfil the process and be accepted on board the accreditation programme. The self-assessment system provides a tool for estimating the readiness of the centre.
The OECI A&D team establishes a precise timeline agreed with each cancer centre applying for the programme in order to allow the necessary time for the preparation and completion of the self-evaluation, peer-review, report and final designation.

HOW DOES THE ACCREDITATION PROCESS WORK?

The cancer centre that wishes to become OECI accredited should contact the OECI A&D team.
The cancer centre must be a member of the OECI (or apply to become a member).
The cancer centre must then review its existing services, practices, and policies and procedures to determine what changes will be required to meet the accreditation standards (self-evaluation). The centre may apply for accreditation after the changes are in place or during implementation. The cancer centre submits an application to the OECI with supporting documentation. The OECI Board and A&D Group reviews the application and documentation and conducts an on-site survey (peer review visit). Based on the submitted data and the results of the survey, the organisation will determine whether to accredit the cancer centre and the type of designation awarded. The cancer centre should then develop a plan, including a detailed timeline, for implementing the necessary changes, developing appropriate policies and procedures and training employees (improvement plan).

The core of our A&D Programme self-assessment, external peer review, designation and follow-up are the OECI Quality Standards and Quantitative Questionnaires that have been established and agreed by the OECI. These can be found in the appendix of the manual and are accessible only to our OECI members.

The full process contains 10 steps (plus the follow-up) which are described in Chapter 5:

- Step 1: Application of a cancer institute in the programme
- Step 2: Payment stage 1 fee
- Step 3: Preliminary designation screening
- Step 4: Self-assessment
- Step 5: Go/No Go decision
- Step 6: Payment stage 2 fee
- Step 7: Peer review visit and designation assessment
- Step 8: Reporting and the improvement plan
- Step 9: OECI A&D Certificate
- Step 10: Follow-up

An overview of the necessary supporting documents for the institute, auditors and OECI A&D Group are listed in Chapter 6, followed by a summary of the essential obligations and tasks of the Cancer Institute in chapter 7.

[1]Abinaya Rajan, Anke Wind, Mahasti Saghatchian, Frederique Thonon, Femke Boomsma and Wim H van Harten: Staff perceptions of change resulting from participation in a European cancer accreditation programme: a snapshot from eight cancer centres. ecancermedicalscience 9:547 - June 2015
[2]Mahasti Saghatchian, MD, MSc, Frederique Thonon, MSc, Femke Boomsma, MSc. et al.: Pioneering Quality Assessment in European Cancer Centers: a Data Analysis of the Organization for European Cancer Institutes Accreditation and Designation Program. Journal of Oncology Practice 10(5) · August 2014

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1. Introduction of the OECI A&D Programme

1. Introduction of the OECI A&D Programme

The Organisation of European Cancer Institutes

The mission of the Organisation of European Cancer Institutes (OECI) is to bring together cancer research and care institutions in Europe, in order to create a critical mass of expertise and competence. With the view of building and maintaining a consensus on the best models of oncology, developing concrete affordable and realistic solutions to effectively combat cancer and fostering the widest deployment of oncology models and solutions to improve the quality of life for the patients in Europe.

Background and Vision of the accreditation programme

The OECI launched the Accreditation Programme in 2002 to fulfil its goals:

– to provide cancer patients within Europe equal accesses to high quality of cancer care and overcome the current differences in access to diagnostics, treatment and therapeutic outcomes that patients experience in different parts of Europe
– to help European cancer institutes implement a quality system for oncology care using the OECI standards and peer review system
– to Foster and accelerate improvements in translational cancer research

Most quality assessment programmes are part of regulatory measures that are imposed by an external authority and are usually compulsory. In contrast, we have developed the OECI quality assessment programme as a supportive voluntary measure for cancer centres. It has been designed and developed internally by people from cancer centres. Peer review is performed by experts from cancer centres and visits are chaired by a director of an OECI cancer centre.

General Frame

In the A&D Programme we have developed a tool similar to other accreditation programmes in its design, with a set of quantitative and qualitative standards integrated in a database, a report and a peer review system.
The programme operates at two levels: the Comprehensive Cancer Centre and the Cancer Centre. We have developed specific criteria for each of these two types of centres. The programme includes standards and a database with a set of qualitative and quantitative data. We write an audit report and request an improvement plan for each centre, which are reviewed by the accreditation Board and then discussed with the centre.

Focus of the Accreditation Programme

The Accreditation Programme focuses on what is critical to cancer care. This includes the planning and organisation of integrated care, multidisciplinary teams and the integration and translation of clinical and basic research into care. Other key factors include education for professionals and patient experience and involvement. We are also focusing on the monitoring and organisation of quality improvement.

OECI standards

The standards describe the criteria for the organisation of cancer care, research, education and patient centeredness. The OECI Accreditation Programme is based upon the OECI standards for high qualitative cancer care. The standards are translated in two questionnaires, a qualitative and a quantitative, to assess the current quality in a cancer institute. Both are integrated in an electronic tool (e-tool) for self-assessment.

OECI peer review visit

An OECI peer review is a systematic and independent examination to determine: whether on a level of quality and the coherent results, activities correspond with the planned measures, and whether these measures are suitable and have been effectively implemented to achieve the objectives of the organization.
The peer review applies to the quality system of the organization or its elements. The added value of a peer review is that it should lead to improvement of the quality system, working process and products and services of the organization. It puts the daily routine and its results to the test of quality standards. If differences are found corrective measures are taken to upgrade the quality system. Though, it is a not solely a compulsory activity. On the other hand, a peer review does not aim to assault the quality system of the cancer institute and those responsible.

Scoring system

A scoring system is included in the qualitative questionnaire. The scoring system is based on the Plan-Do-Check-Act-circle or Deming-circle. With the scoring system it is possible to assess the stage of development for each item in the standard. After filling out all the questions, the e-tool generates the results. The results will be used for the content of the peer review as well as input for a quality improvement plan of the institute.

Designation
Two different types of cancer institute /organization are distinguished:
- **Clinical Cancer Centre** and
- **Comprehensive Cancer Centre.**

The type of cancer organization indicates the comprehensiveness of the services and the degree of specialisation.

The key word in the designation of European cancer institutes is the level of comprehensiveness of both professional infrastructure and performance. The philosophy behind comprehensiveness is:
"If all relevant competences, skills, resources and tools concerning cancer care and research are brought together and integrated, it will lead to an outcome that is larger, on the whole, than the sum of its parts" (Ringborg, 2008). Comprehensiveness, in that sense, can be seen as the new basic principle on how cancer activities institutionally should be organized.

Definitions of the designation categories are:

A Clinical Cancer Centre is an organisational entity covering a sufficient degree of all medical, surgical and radiotherapy services and a limited degree of clinical research.

Comprehensive Cancer Centre (CCC) is probably the hardest category to define as many different interpretations on a CCC already exist. Based on available information and many definitions on the concept of a CCC, the following features are considered to be essential for this particular category:
– an identifiable organizational entity with a circumscriptive governance and budget
– a highly innovative character and multidisciplinary approach using the potential of basic, translational and clinical research and clinical facilities and activities, organized in a sufficiently identifiable entity
– a direct provision of an extensive variety of cancer care tailored to the individual patient's needs and directed towards learning and improving the professional, organizational and relational quality of care
– broad activities in the area of prevention, education, and external dissemination of knowledge and innovation. In order to accentuate the differences with other cancer centres, a CCC separates itself in the following points:
  - high level of infrastructure, expertise and innovation in the field of oncology research, including translational research
  - maintenance of an extensive network including all aspects of oncology treatment and research
  - related to an academic/university centre or is an academic centre

Development the accreditation programme: Version 2 (2015 – 2020)
The first round of the OECI A&D Programme is now completed (V1, 2008 – 2014).
Twenty-nine centres participated in the programme, totally thirteen countries: Belgium (3), Denmark (1), Estonia (1), Finland (1), France (1), Germany (1), Italy (11), Lithuania (1), Norway (1), Portugal (3), Spain (1), The Netherlands (1), and United Kingdom (3).
Of note, the Italian Ministry of Health of Italy decided to fund all national cancer centres in Italy to go through the OECI Accreditation Programme over a two years period. This was a major breakthrough considering that a Member state selected a European accreditation programme for national purposes. We wish to disseminate this model to other Members States for further European harmonisation.

In 2014 the set of standards have been revised with the input of the participating centres, oncology experts, the European Cancer Patient Coalition (ECPC) and members of the European CanCer Organisation (ECCO) societies.
The content of the new questionnaires is accessible on the website:

http://oeci.selfassessment.nu/cms/node/53

On bases of the experiences and outcomes of the former A&D peer review visits of the V1 participating centres, the designation criteria have been revised as well, and approved by the A&D Board and the OECI Board (June 2015).

The second version of the programme (V2, 2015 – 2020) has been approved completely by the OECI Board and released during the OECI General Assembly in June 2015.

We hope that OECI A&D programme will continue to contribute to less fragmentation and more harmonisation across cancer centres. The aim is for centres to work more closely together, with people visiting each other's centres and learning from each other in a network that supports competition and collaboration.


OECI
Registered number OECI/EEIG B-001
CERTIFICATE OF ACCREDITATION AND DESIGNATION
OECI
hereby certifies that the
YOUR (cancer) INSTITUTE
Town - Country
meets the quality standards for cancer care and research, and it is therefore designated as:
COMPREHENSIVE Cancer Centre
Issued on: 2010-08-15
Validity date: 2012-08-15
Dominique de Valeriola
OECI President
Mahasti Saghatchian
Chair OECI Accreditation Designation Programme

Figure 1: Certificate

Accreditation and Designation User Manual

2. Timeline of the OECI A&D Process

2. Timeline of the OECI A&D Process

2.1 In ten steps to A&D Certification

It takes ten steps in the OECI Accreditation & Designation (A&D) Programme towards OECI A&D Certification. Figure 1 presents the ten steps preceded by one of the conditions for application, OECI membership. The ten steps include the essential decision moments for continuation of the institute in the programme. And, for monitoring continuous and comprehensive quality improvement in the institute there will be a follow-up of the institute's improvement plan one year after certification. A detailed explanation of all steps is outlined in Chapter 5.

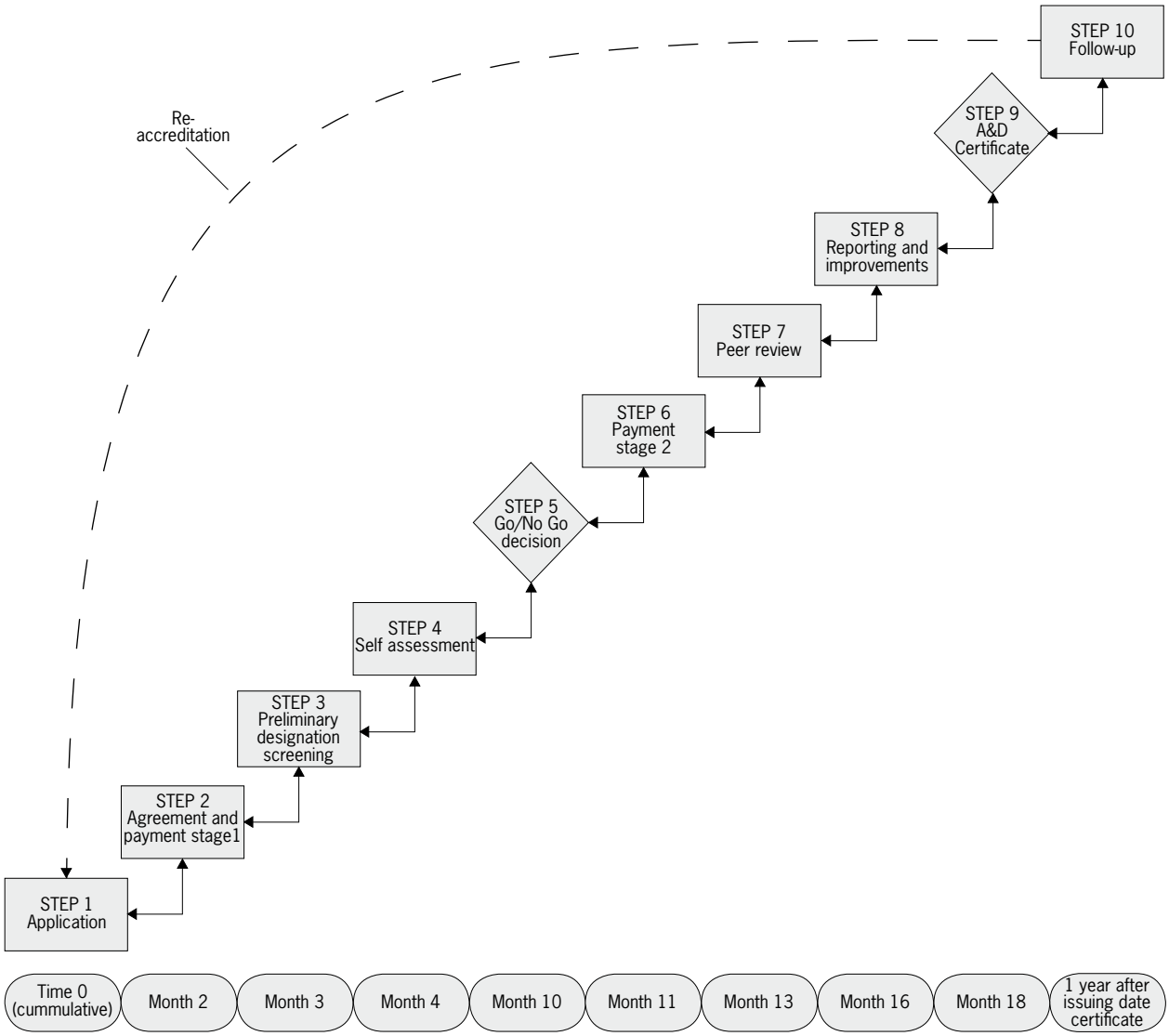

Figure 2: Timeline A&D Process

2.1.1 General explanation of the ten steps

The OECI A&D Programme is offered by the OECI. Participation to the programme is open for members of the OECI and also for non-members. Information about membership of the OECI: ***www.oeci.eu***

STEP 1: Application
The institute applies to the programme through the electronic application on the website ***http://oeci.selfassessment.nu*** . The application will be examined by the OECI Board and A&D Board.

STEP 2: Agreement and payment fee stage one
After approval of the application by the OECI A&D Board, the cancer institute receives the A&D Agreement to be signed and the first payment order. The total amount of the fee (stage one and two) differs for OECI members and non-members.

STEP 3: Preliminary designation screening
The designation screening takes place to assess the preliminary designation type of the institute based on criteria (Appendix I). The pre-designation will be discussed in the OECI A&D Board. Both, the judgement of the institute and the outcome of the pre-designation screening, are the starting point for the next steps. These steps will be explained by the A&D coordinator during a telephone/video meeting.

STEP 4: Self-assessment
The A&D Programme continues with the self assessment, including assessment of the OECI quality standards and quantitative data. The self assessment period will take 6 months.
On request of the institute, it is optional to invite the OECI A&D Coordinator and a member of the A&D Group for an intermediate visit on site. The content of such visit is to discuss the progress of the self assessment and manage the expectations of outcomes of the programme.

STEP 5: Approval of self assessment: Go / No Go
The final 'Go' or 'No Go' decision will be taken by the OECI A&D Board within 6 weeks after finishing the self assessment on advise of the analysis of the A&D Committee.

STEP 6: Payment fee stage two: amount of the fee depends on OECI membership
Non-members pay an extra €5.000. The payment order will be send after the 'Go' decision of the OECI A&D Board.

STEP 7: Peer review visit and designation assessment
An audit team will have at least 2 months to prepare the peer review in advance of the peer review visit. The visit takes place about 3 months after finishing the self assessment by the institute.

STEP 8: Reporting and improvement plan
The reporting period is split in two phases. Phase 1 is the reporting by the audit team. Within 4-6 the institute receives a draft report including strengths and opportunities. On bases of the draft report, the institute formulates an improvement plan. Phase 2 is finalization of the report by OECI including the conclusion and designation. From the peer review visit to the final peer review report, it takes about three months.

STEP 9: OECI A&D Certificate
The final accreditation and designation decision will be taken by the OECI A&D Board within two month after receiving the final report including the improvement plan of the institute. The decision is based on advice of the analysis of the A&D Committee. The institute will receive the final report and a notification of OECI certification. The Certificate will be handed over during the Annual General Assembly.

STEP 10: FOLLOW-UP of Accreditation and Designation Programme
One year after the peer review visit the cancer institute provides a written report with the progress of the goals, actions and time-schedule set in the improvement plan.

OECI Accreditation and Designation is valid for five years from the date of issue of the OECI A&D Certificate. The institute should have started a new round of the A&D programme at least 6 months before the expiring date of the Certificate.

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3. People and parties involved in the A&D Programme

3. People and parties involved in the A&D programme

This chapter explains the profiles, tasks and obligations of the people and parties involved in the OECI A&D Programme. The chapter is divided in three parts: people and groups within the OECI, OECI auditor and audit team, and the people involved from the applied cancer institute.

3.1 The OECI

The ultimate objective of the OECI-EEIG (Organisation of European Cancer Institutes-European Economic Interest Grouping) is the development of oncology in Europe for reducing mortality and morbidity due to cancer and increasing survival and quality of life of the patients. Therefore, the model of oncology must be based on a global vision of the cancer problem emphasizing the integration of research and education with diagnosis, prevention and care to promote the development of comprehensive and multidisciplinary organization within the European Cancer Institutes Statutes ***http://www.oeci.eu/Statutes.aspx***

The structure of the OECI contains the following bodies:

– General Assembly
– President
– Executive Board
– Manager (OECI Director)
– Coordinating Secretariat/Liaison Office – Working Groups and Activities

Specific tasks of the OECI Board in the A&D programme are:

1) New applications are discussed by the OECI Board
2) The final decision on certification as Clinical or Comprehensive Cancer Centre will be discussed by the OECI Board.

3.1.1 OECI Executive Board

The Executive Board (OECI Board) is composed of at least the following members:

– The President, who presides the meetings of the General Assembly and the Executive Board
– The Vice-President who shall chair all meetings in the absence of the President
– The immediate Former President
– The Executive Secretary
– Two Elected Members, one of whom serves as Treasurer
– Co-opted Members, with no voting rights, designated on the recommendation of the Board. Co-opted members need not to be representatives from Member institutions

A list with the names of the current OECI Executive Board members is published on:
http://www.oeci.eu/Board.aspx

3.1.2 OECI Accreditation and Designation Working Group

The Executive Board or the General Assembly may assign some tasks to Working Groups, as to the Accreditation and Designation Working Group. The Working Groups may include persons not belonging to the Executive Board or who do not represent Members. The Working Groups are accountable to the Executive Board or to the General Assembly for the tasks which have been entrusted to them and shall draw a report of their activities. The rules of procedure of the Working Groups are laid down in the Internal Regulation (OECI Statutes).

The OECI Accreditation and Designation Working Group (A&D Group) includes:

– OECI Accreditation and Designation Board (A&D Board, 3.1.3),
– OECI Accreditation and Designation Management Unit (MU, 3.1.4).
– OECI Accreditation and Designation Committee (AC, 3.1.5)

The tasks and responsibilities of the members of the A&D Group are described in the following paragraphs. A list with the names of the current A&D Group members is published on: ***http://oeci.selfassessment.nu***

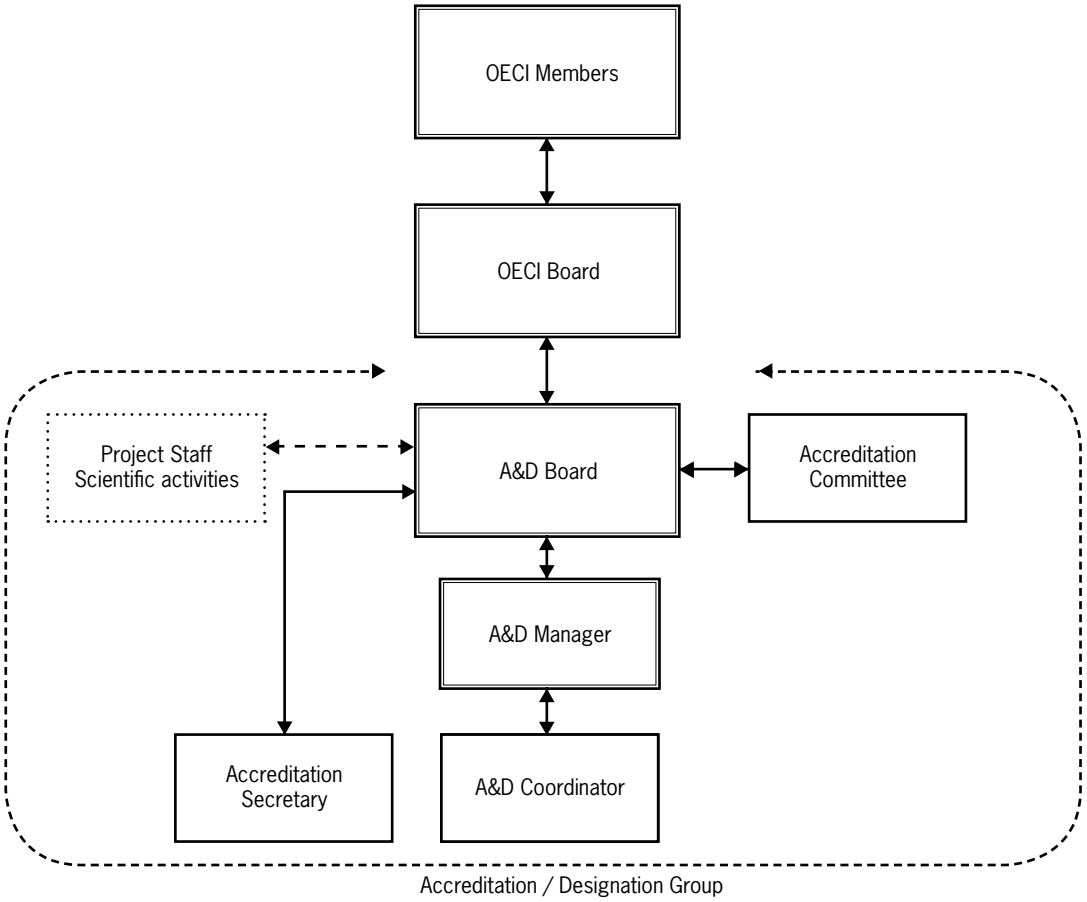


Figure 3: MT Organigram 2015

The OECI A&D Programme is facilitated by an online programme for self assessment (e-tool). The OECI has a contract with Compusense for design and administration and technical support of the self assessment e-tool

3.1.3 OECI Accreditation and Designation Board

The OECI A&D Board is composed by six (or more) persons, from the OECI member institutes, including the Chairperson.

3.1.3.1 Chairperson

The Chairperson leads the activities of the A&D Working Group, chairing the A&D Board and representing the group in the OECI Board as co-opted member.

Requirement of the Chairperson is that he/she is employed in an OECI designated Comprehensive Cancer Centre (CCC).

3.1.3.2 A&D Board members

The requirements for the composition of the A&D Board are:
– The composition of all members of the A&D Board shall be approved by OECI Board
– A&D Board members hold a position within the Board of Directors of an OECI member institute or a position with comparable authority to be decided by the OECI Board
– Legislative members are appointed for a three-year term. The term may be extended for three years.

Tasks and responsibilities of the OECI A&D Board

Policy/procedures:
– Decision making on accreditation and designation procedures and policy.

Accreditation and Designation Programme:
– Assessing new applications of cancer institutes in the A&D Programme and preliminary designation type
– Deciding on the Go/No Go for peer review: Approve/ disapprove the self assessment results of cancer institute as essential step before the programme continues with the peer review visit, deciding on the final peer review report including the improvement plan of the cancer institute

– Deciding on the designation type of the cancer institute following the self assessment and peer review outcomes
– Dealing with and solving major issues during the process of a cancer institute in the programme e.g. in case of complaints
– Advertising and expanding the programme

Financial:
– Assessing quarterly the income/expenditure compared to provisional budget on bases of the input from the OECI liaison office
– Assessing annually the balance and provisional budget

Decision making
To increase independent examinations in essential steps in the A&D Process, the A&D Board will be advised by the A&D Committee (AC) (3.1.5). The AC will propose its conclusions on the essential steps to the A&D Board as input for final decisions. The advice of the AC is not binding.

Meetings
The A&D Board meets monthly with representatives of the Management Unit by teleconference. Occasionally, the A&D Board meets in face-to-face meetings, but at least once a year during the OECI General Assembly.

The chairperson leads the activities of the A&D Working Group, chairing the A&D Board and representing the group in the OECI Board as co-opted member.

Requirement of the chairperson is that he/she is employed in an OECI designated Comprehensive Cancer Centre (CCC).

3.1.4 OECI Accreditation and Designation Management Unit

The A&D Management Unit exists of the A&D Manager, A&D Coordinators and A&D Secretary.

3.1.4.1 OECI A&D Manager

Tasks and responsibilities of the A&D Manager

– Daily management of the A&D Programme
– Contact person for all parties involved in A&D Programme
– Monitoring ongoing processes and outcomes with regard to the A&D procedures in all applied institutes
– Providing a monthly report to the A&D Board during teleconferences on:
  - new applications
  - status up-dates of institutes in the programme
  - composition of auditor teams
  - visits in institutes
– Supervising the A&D Coordinator
– Cooperation with the OECI Liaison Office on:
  - Informing approved applications to the Liaison Office: the Liaison Office will edit and send the A&D Agreement, including the first invoice to the new applicant
  - Informing the Go decision for peer review visit to the Liaison Office in order to send the second invoice
  - Informing the Liaison Office when the improvement plan of an institute has been approved by the A&D Board for certification
  - Accountancy of the A&D in collaboration with the OECI Central Office and the OECI Accountant
  - Issuing of the A&D Certificates on plate and on paper
  - Promoting the A&D through the OECI publications

3.1.4.2 OECI Accreditation and Designation Coordinator

The A&D Coordinator are supervised by the A&D Manager.

Tasks and responsibilities of the A&D Coordinator

– Contact person for institutes involved in A&D Programme
– Collecting, structuring and making accessible the relevant information and documentation (internal and external) on the website and e-tool
– Monitoring the ongoing processes and outcomes with regard to the A&D procedures
– Identifying improvements in the procedures, organization, e-tool and standards

Coaching and advising cancer institutes in all steps of the A&D programme:
– Processing application and designation screening
– Supervision during self assessment
– Preparation of the peer review visit with the cancer institute
– Supervision in follow-up of the peer review outcomes towards the improvement plan of an institute

Organizing and performing the peer review:
– Composing the audit team together with A&D Manager
– Providing the audit team with documents for preparing the peer review
– Organizing auditors preparation meeting
– Coordinating the peer review visit
– Coordinating the writing of the peer review report in cooperation with the audit team
– Processing the peer review report towards the final report
– Coordinating the follow-up of the cancer institute

3.1.4.3 OECI Accreditation and Designation Secretary

Tasks and responsibilities A&D Secretary
– General secretariat of the A&D Programme, under supervision of and following the instructions of the chair
– Informing the OECI A&D Group on incoming information
– Planning meetings according the availability of participants
– Booking meeting rooms, organizing lunches and coffee
– Sending the agenda and additional documentation following the input of the chair and/or manager or coordinator (at least three days in advance)
– Writing the minutes and send it to the A&D Group within one week, the Liaison Office receives the minutes of the meetings booking hotels for auditors, in cooperation with the Liaison Office

3.1.4.4 OECI Coordinating Secretariat/Liaison Office

Tasks and responsibilities in relation with the A&D Programme

– Informing the OECI A&D Group about incoming information from the OECI Board, other OECI working groups, OECI members or associations
– Processing the A&D Agreement for new applicant institutes:
  - When the application is approved by the A&D Board, the A&D manager sends a message to the Liaison Office
  - The Liaison Office edits the standardized Agreement
  - Two copies of the A&D Agreement will be send by e-mail to the institute for the signature of the Director (legal representative of the institute)
  - Both copies are send back by regular mail to the OECI Office in Brussels for a signature of the OECI President

    OECI-EEIG
    c/o Fondation Universitaire
    11 Rue d'Egmont
    1000 Brussels, BELGIUM,
  - The institute receives one copy of the signed Agreement
– Request of reimbursement and payment:
  - The A&D fee is split in two stages. The first payment order will be send by e-mail together with the A&D Agreement
  . If the applicant institute is an OECI member, the Liaison Office will also check whether the centre has paid the general OECI membership fee
  - The second payment order will be send by the OECI after the self assessment results of the institute have been approved (Go decision) by the A&D Board for the peer review on site
  - The fee shall be paid with 30 days after the issuing date of the invoice by bank transfer
  - The Liaison Office confirms payments of a centre to the A&D Manager
– Travelling arrangements for auditors/ OECI A&D Group members:
  - When the institute has the Go for the peer review visit, the Liaison Office will contact the audit team members to arrange the flight tickets in cooperation with a travel agency

- The Liaison Office has a role in authorizing travelling costs 'a priori'
- When the auditor has confirmed the travelling schedule, the Liaison Office will take care of the payment of the flight ticket directly with the travel agency
- Booking hotels for auditors will be done by the Liaison Office in cooperation with the A&D Secretary
- Accountancy of the A&D in collaboration with the OECI Central Office and the OECI Accountant

– Reimbursement of auditors and A&D Staff:
- Auditors and A&D Staff send by regular mail the original of tickets, invoices, receipts, together with an A&D expenses claim form duly signed to
  OECI Liaison Office,
  C/o SOS Europe Srl,
  Via delle Campanule 74
  16148 Genova – Italy
- An electronic copy of the A&D expenses claim form is sent by email, together with scanned copies of all the original tickets, invoices, receipts, to ***oeci@oeci.eu***
- The OECI Director authorizes the reimbursement which will be done as soon as the original documents will reach the OECI Liaison Office
- Payment will be done within 10 working days (unless absent) after receiving the original documents

– Providing twice a year a detailed overview of income/expenditure to the OECI A&D Chair and A&D Manager including follow-up of the A&D programme budget
– Proposing annually the provisional budget for the next year
– Issuing the A&D Certificates on plate and on paper
– Promoting the A&D through the OECI publications

3.1.5 OECI Accreditation and Designation Committee

The requirements for the composition of the Accreditation & Designation Committee (AC) are:

– The AC is made of up to ten persons from different cancer institutes and countries
– The members have different backgrounds related to cancer care
– The AC is coordinated by an A&D Coordinator, of the Accreditation and Designation Management Unit
– Legislative members are appointed for a three-year term. The term may be extended for three years
– The chair preferably works in a designated CCC centre
– Members have different complementing backgrounds; physicians, nurses, translational scientists, quality management, ECPC members, experience with industry

Profile of AC member (as auditors profile)

– Trained as auditor and experienced as auditor
– Accreditation knowledge and affinity
– Quality improvement attitude
– The management Board of the institute is committed to the membership
– Working as a professional
– Helicopter view
– Capacity to work in a team
– Good interpersonal properties
– Capacity to distinguish core issues and side issues, objective
– Fluently English speaking and writing
– Analytic way of thinking

Tasks and responsibilities in relation with the A&D Programme

Analysing the self assessment for advice on the Go/No Go decision:
– To analyse and examine the qualitative and quantitative self assessment reports
– To analyse the availability of the required proof documents and additional appropriate documents
– To advise the A&D Board about a Go/No Go decision with regard to the scores, notes and documents in the self assessment report

Analysing final report:
– To analyse the conclusions, strengths and opportunities that are drafted by the audit team, and to give final advice to the A&D Board about the complete final report

– The final report includes the improvement plan of the institute, this is analysed and examined to advise the A&D Board for final accreditation and final designation type
– The A&D Committee will be informed about the final decision of the A&D Board during their meetings

Meetings

Depending on the workload. Most of the contact moments are finalised by mail, and when necessary, teleconference calls take place.

A list with the names of the current A&D Committee is published on: ***http://oeci.selfassessment.nu***

3.1.6 Relations and communication between OECI Groups

The relations and communication between the OECI groups are described.

3.1.6.1 Relation/communication between the OECI A&D Group and OECI Board

The OECI Board shall take all necessary steps and make all decisions for the attainment of the goals of the OECI A&D Group.

The OECI A&D Board chair represents the group at the OECI Board as co-opted member.

– The OECI Board gives mandate for daily management to OECI A&D Group
– All standards and procedures have to be approved by the OECI Board and procedures are also signed by the OECI President
– The A&D Chair will give regular feedback to the OECI Board concerning all accreditation and designation activities. The A&D Manager will provide a quarterly report to the A&D Chair. This report can be used for giving feedback (including new applications, visited institutes, achieved accreditation etc)
– The A&D Board decides if a cancer institute will receive OECI accreditation and will give notice to the OECI Board
– The A&D Certificate will be signed by the OECI President and the chair of OECI A&D Board

3.1.6.2 Relation/communication between the OECI A&D Group and OECI Director and Liaison Office

– Contact about the annual programme General Assembly, conferences and brochures, and the annual OECI report
– Providing overview of the income/expenditure to the OECI Executive Secretary every 6 months

3.1.6.3 Relation/communication between the OECI A&D Board and OECI General Assembly

The annual General Assembly has the following powers in relation to OECI A&D Board:
– Adoption of the annual accounts
– Approval of the annual report
– Adoption of the (total) budget and plan of activities for the following year

3.1.6.4 Relation/communication between the OECI A&D Board and OECI A&D Committee

The A&D Committee has the following powers in relation to OECI A&D Board:
– Advice about the Go/No Go decision of a centre
– Advice about the final report of a centre
– Advice about the improvement plan of a centre
– Once a year there is a face-to-face meeting between the A&D Committee and A&D Board, ideally during the General Assembly

3.2 Audit team and auditors

3.2.1 OECI audit team

Composition of the audit team
The audit team typically consists of four members:
– Chair, who is also one of the auditors
– Three auditors

In an ideal situation the team consists of:
– A chair who is a director of a cancer institute
– Auditors with different positions/ functions in different fields of oncology, like: medical oncology, care, research, pathology, quality assurance
– At least one auditor who understands the language of the country where the cancer institute is situated but who is not a resident of that country
– A mix of experienced and less experienced auditors. Every team has at least two experienced auditors
– Every team consists of at least one physician and preferably one nurse
– If the visit takes place in an institute that is preliminary designated as a CCC, the chair of the audit team is employed in a CCC

An OECI A&D Coordinator will also be present during the peer review visit to coordinate the peer review activities.

Selecting an audit team
The A&D Manager and A&D Coordinator are responsible for selecting the chair and auditors of an audit team. The teams are presented to the A&D Board.
Before the audit team members get access to the self assessment information of the cancer institute:
– The particular cancer institute has expressed that there is no conflict of interest with any of the audit team members (4.1)
– Each auditor have signed a Confidentiality Agreement (doc 14) and a Conflict of Interest Form (doc 15)

3.2.2 OECI Audit team chair

The chair of the audit team has the same profile, tasks and obligations as the OECI Auditor (3.2.3). However, the chair has some specific additional obligations and tasks

Profile
– The chair is a Director of a cancer institute (or a position with comparable authority to be decided by the OECI A&D Board)
– The chair has attended the auditors training
– The chair has experienced at least one peer review as an auditor before chairing a peer review
– The chair works in a CCC, if the peer review is preliminary designated as a potential CCC

Tasks
– The chair opens the peer review visit with a presentation
– The chair has a leading role in the representation of the team
– The chair has a leading role in a balanced division of tasks in the team
– The chair has a leading role in meetings and interviews
– The chair presents the preliminary results at the end of the peer review visit
– The chair presents the preliminary designation type at the end of the peer review visit
– The chair has a leading role in the content of the report and editorial changes

3.2.3 OECI Auditor

Profile of an OECI Auditor
– Is employed by a cancer institute or hospital and is working in the specific field of oncology, for example:
– A registered as a medical specialist (medical oncologist, surgeon, radiation therapist, pathologist)
– A (quality) manager, an oncology nurse, a cancer researcher or microbiologist
– Is approved by his/her management to apply as an OECI Auditor (engagement letter)

– Has attended the OECI audit training
– Has the following skills and qualities:
  - speaks and writes fluently in English
  - has a good overview of the field of oncology in a cancer institute
  - is a team player
  - has an objective and analytic way of thinking
  - has a quality improvement attitude
  - is willing to commit time and efforts for peer review, designation screening and report:
    ◦ preparation meeting of the audit team: one day
    ◦ peer review: two days visit, one evening preparation, two days to travel. A total of four days
    ◦ reporting: two days

Tasks
The Auditor:
– Prepares the peer review visit according to the preliminary designation type
– Prepares the peer review visit by analysing the self assessment results and documents of a cancer institute
– Attends the preparation meeting of the audit team one month in advance of the peer review visit
– Attends the preparation meeting on the evening before the start of the peer review
– Performs the peer review according to the agenda and designation checklist
– Writes notes during interviews, presentations and tours
– Scores the standards as a team during the peer review visit
– Draws peer review findings as a team for the preliminary results presentation at the end of day two of the peer review: strengths and opportunities
– Processes notes in e-tool in the first week after the visit and score the standards that are reviewed
– Provides a list of strengths and opportunities chapter of the standard
– Provides a description of the checklist items for confirmation of the designation type
– Gives written response on the comments and feedback on the draft report of the cancer institute, and formulates the final strengths, opportunities and conclusions of the peer review

3.2.4 Observers in peer review visit

What is an observer?
An observer – also be called 'listener' – can be:
– A candidate chair of an audit team: a person who has participated in the auditors training to become a chair of an audit team and who joins the peer review visit to gain experience in the OECI A&D procedures
– A new person working for the OECI A&D programme e.g. PhD or coordinator
– A representative of another participating OECI centre
– Other persons related to the OECI A&D programme through participation of his/her residential centre in the programme

Objectives of an observer to attend in a peer review visit
– Learning about the OECI A&D peer review process and procedures
– Gaining experiences in the OECI A&D programme

Rules for admission of an observer in audit team
Both the auditors in the team as the observer are subjected to the following rules:
– The centre has approved the participation of the observer in the audit team by signing for the composition of the team including the observer following the OECI conflict of interest rules. The observer shall sign the conflict of interest form (doc 15)
– The observer shall sign the confidentiality agreement (doc 14)

Interference of the observer in the peer review process
There shall be no interference of the observer in the peer review process, this means that:
– The observer has no role or responsibility in the peer review process. The auditors in the audit team led by the chair are in control of the preparation and performance and results of the peer review visit
– Consequently, the observer has no role or responsibility on any decision-making related to the peer review process

Informing the participating centre of potential attendance of an observer in peer review
The potential attendance of an observer in the peer review process is a part of the OECI A&D Programme agreement, the agreement includes:
– A section in which the participating centre can approve the attendance of an observer in the audit team if above rules are met

3.2.5 Role of coordinator in the peer review visit

The coordinator plays major role throughout the whole process for an institute in the programme. The coordinator comes with the audit team in the institute for the peer review visit but is not part of the team.

The specific task of the coordinator in the peer review visit are:
– Supporting the centre during the self assessment
– Preparing the visit agenda with the centre
– Watching over the process of the visit
– Watching over the agenda and time-planning of the visit
– Watching over the content of the visits interviews with regard to the OECI standards
– Helping the team to prepare the final presentation
– Collecting the notes of the auditors and conclusions of the team in the electronic tool
– Editing the report according to the auditors input

3.3 Cancer institute

Obviously, all employees of a cancer institute are directly or indirectly involved in the Accreditation and Designation Programme, for example during the self assessment period delivering data and documents for filling out the questionnaires or during the peer review in the interviews, tours and presentations. It is also advised to involve the employees as much as possible to build commitment to the A&D Programme and encouraged the personnel to work according to the OECI standards.

Some staff members have a central role in the organisation of the programme which is outlined in this paragraph.

The specific tasks and obligations of the cancer institute are step-by-step explained in the following chapters.

3.3.1 Director cancer institute/Board of Directors

The Director/ Board of Directors of the cancer institute have a central role for the commitment of their cancer institutes in the accreditation programme. Although the A&D Coordinator will mainly relate with the contact person of the cancer institute. The Director/Board of Directors shall be involved in:
– Signing the application form with designation screening
– Discussing the preliminary designation type during the explanatory visit
– Signing the OECI A&D Programme agreement depending on the preliminary designation type (doc 6)
– Approving the peer review agenda (doc 16)
– Express a potential conflict of interests with the audit team members if necessary (4.2)

During the accreditation process of a cancer institute the Director of the institute will receive the following notifications and documents:
– Approval/disapproval of application Preliminary designation type
– Go/No Go decision for peer review visit
– Draft peer review report Final peer review report including final designation type OECI Accreditation and Designation Certificate, with agreed final designation type

3.3.2 Contact person cancer institute

During the A&D Programme the contact person of the institute communicates with people from the A&D Group concerning several issues.

With the A&D Secretary with regard to:
– Information about accommodation for peer review visit

With the A&D Coordinator with regard to:
– The application and preliminary designation screening
– Information about the programme
– Pre-designation screening result and accreditation starting point
– Periodical contact during the self assessment period
– Questions concerning the self assessment activities or questionnaires
– Organisation of the peer review visit
– Peer review agenda
– Providing feedback on the draft peer review report
– Follow-up of the A&D Programme

With the OECI Liaison Office with regard to:
– OECI membership (if the institute wants to become a member)
– A&D Agreement
– Payment of the A&D Programme fee in two stages

Accreditation and Designation User Manual

4. Confidentiality and conflict of interest

4. Confidentiality and conflict of interest

The OECI A&D Programme and the persons and parties involved are subjected to confidentiality of data, information and knowledge, and potential conflict of interests. There is a policy with regard to this confidentiality which is explained in this chapter.

4.1 Confidentiality

During the A&D Programme of a cancer institute different persons will have access to the information and data of the cancer institute. The OECI A&D Programme has developed a policy to guarantee that all persons having access to the information and data will only use them for the purpose which shall be used for: the accreditation of the cancer institute.

In accordance with OECI A&D Group policy, all information related to the accreditation of a cancer institute is strictly confidential. This includes, but is not limited to: reports of evaluation, letters, self assessment and accreditation materials, interim/annual/biennial reports, correspondence, and the content of any discussion related to the cancer institute and/or its accreditation. All requests for information related to a specific cancer institute and/or programme must be referred to OECI A&D Group, or to the respective cancer institute.

The persons who have to sign the confidentiality agreement (doc 14) are:
- Members of the OECI A&D Board
- Members of the OECI A&D Management unit
- Members of the OECI A&D Committee
- All auditors inclusive the chairs

Freedom of Information Acts which may be applicable in a given state, province, or country do not apply to OECI A&D Group confidential information related to the accreditation of cancer institutes.

4.2 Conflict of interest

All auditors have to sign the Conflict of Interest form (doc 15) for each peer review they are going to perform.

To ensure that all matters dealing with the accreditation programme of cancer institutes are conducted in an unbiased manner, the OECI A&D Group has adopted a Conflict of Interest Policy.

Criteria that may pose a conflict of interest for a candidate auditor include, but are not limited to:

1. Past or present employment at the cancer institutes being reviewed
2. Service as a consultant for the cancer institutes being reviewed
3. Graduation from the cancer institutes being reviewed
4. Membership on the advisory committee of the cancer institute being reviewed
5. Other potential conflicts of interest, such as employment of private consultants or subcontracts with a private companies etc.

It is expected that the candidate auditor communicates with the A&D Group staff for clarification of any concerns. If conflicts of interest are revealed to the entire team, and if it is agreed that the audit team member will be unbiased in evaluating the programme, it is acceptable to allow the individual to remain on the audit team.

Expressing conflict of interest by the institute
The composition of the audit team will be send to the institute to provide the opportunity to express any potential conflict of interest. In case the cancer institute has expressed any potential conflict of interest with one of the auditors in the team, the OECI A&D Board will decide whether the auditor shall be replaced by another auditor.

Accreditation and Designation User Manual

5. Ten steps A&D Process in detail

5. Ten steps A&D Process in detail

The following paragraphs describe in detail the ten steps towards the A&D Certificate and the follow-up of continuous and comprehensive quality improvements. It describes the activities and obligations of each of the parties involved in the A&D Programme.

5.1 Step 1: Application of a cancer institute in the programme

Step 1 is the application of the A&D Programme. Figure 4 shows the details in this step.

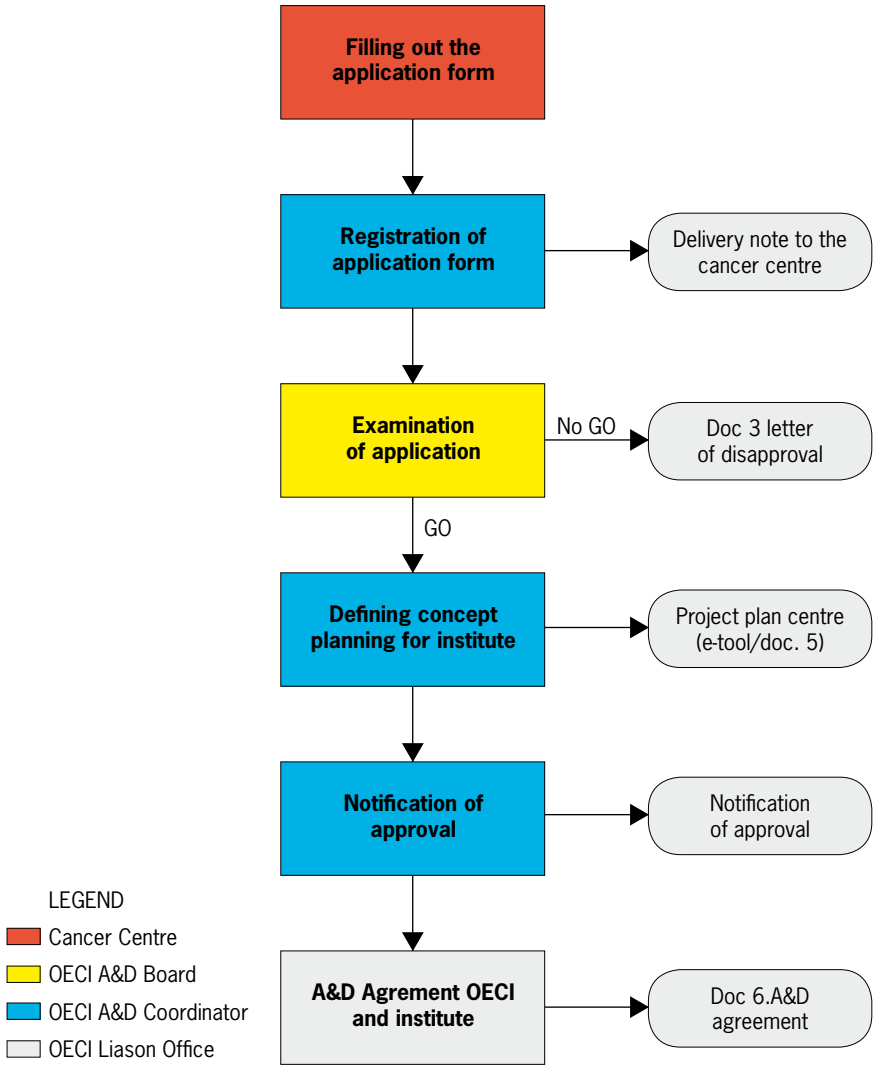


Figure 4: Step 1 Application to the A&D Programme

STEP 1: activities and responsibilities of all parties involved (figure 4)

Filling out the application form
Executor: Cancer institute
– The institute can start filling out the 'Online application form' on the website: **http://oeci.selfassessment.nu/cms/**. The institute may find in the menu the section 'How to apply?' – The page starts with a general introduction of the programme and by clicking Go to the online application form the application procedure will be explained – The institute can access the application form by choosing username and password as explained on the page The application contains questions about the preliminary designation criteria. Additional to the application form the cancer institute is requested to send a copy of the organogram of the cancer institute. On the last page of the application form, there is a button to send the application to the OECI A&D Coordinator. The approval of the Director/ Board of Directors is required for fully commitment with the programme. *Note 1: The information in the application will be copied to the OECI self assessment questionnaires at the start of the programme - after payment of stage 1 - to prevent repetition of applying information.* *Note 2: All information delivered by the cancer centre in the application form and the following stages of the OECI A&D Programme is used in a confidential way according to the OECI A&D Group policy*

Registration of application form
Executor: OECI A&D Coordinator
– The OECI A&D Coordinator receives the application form through the e-tool – The OECI A&D Coordinator sends a delivery note to the applicant institute – The OECI A&D Coordinator makes an appointment with the contact person of the institute to further discuss the process of the programme, by telephone conference

Examination of application
Executor: OECI A&D Board
– New applications are discussed in the next teleconference of the OECI A&D Board (every month) – The application is analysed according to the criteria for application as set in the application form – Also the preliminary designation items will be analysed – The A&D Board will make the conclusion of approving or disapproving the application – The conclusion by the A&D Board is send to the OECI Board for final approval **Criteria for application** Applying in the A&D Programme is a voluntary decision of the cancer institute. However, to provide the institute with a qualitative programme and to meet with the goals for accreditation and designation, there are obligations that each involved institute shall meet: – Strong commitment to quality improvement (signature of Director/ Board of Directors) – Dedicated staff (contact person, project group, all involved employees) – Stable management structure (no interim management on level of Board of Directors) – No major changes/problems (expected management change, merger, housing movements, financial crisis) – Following the steps of the A&D Programme with care and within the required timeline – Involvement in oncology research and education programmes – Provision of oncology surgery, radiation therapy and medical oncology – Cancer care is performed on an identifiable unit with an identifiable budget, management and organizational structure

Defining concept planning for institute

Executor: OECI A&D Coordinator

If the OECI A&D Board approves the institute, the A&D Coordinator will draw the planning:
- Designation screening
- Self assessment period
- Peer review: the final peer review dates are planned in alignment with the availabilities of the cancer institute and the audit team chair

This will be archived in the overall A&D Planning (doc. 41 for internal use)

Notification of approval

Executor: OECI A&D Coordinator

If an institute is approved to apply to the A&D Programme:
- The A&D Coordinator sends the notification of approval through e-mail to the Board of Directors of the institute and the contact person
- The concept planning for an explanatory telephone conference, preliminary designation screening, self assessment and peer review, is mentioned in the e-mail
- The notification e-mail is also send to the OECI Liaison Director to modify the A&D Agreement for the centre and the first invoice
- The A&D Coordinator will contact the coordinator of the cancer institute to plan a teleconference to further explain the planning and organisation of the A&D Programme

Signing contract OECI and applied institute

Executor: OECI Liaison Office

- The OECI Liaison Office sends the A&D Agreement to the institute in twofold by general mail
- Both copies shall be signed by the institute and the OECI President

5.2 Step 2: Payment stage 1 fee

After approval of the application by the OECI A&D Board, the institute receives the first invoice together with the OECI A&D Agreement.

The process and tasks of the Liaison Office and the cancer institute (see also chapter 3.1.4):
- OECI Liaison Office prepares the OECI A&D agreement
- The agreement will be send to the cancer institute for signature on two copies of the Agreement
- The institute will send by general mail the two copies of the signed Agreement to the OECI Office in Brussels
- The OECI President will sign the Agreement in twofold and send back one copy to the Director of the cancer institute
- We remind you that signing the agreement and, therefore, participation in the programme is subjected to the payment of the Accreditation and Designation fee
- The invoice for the payment of the first stage fee will be send by the OECI Liaison Office together with the Agreement
- When an OECI member applies, the OECI Liaison Office will check the status of paying the OECI membership fee. If there are outstanding payments the centre can only apply as NON-member,
- When a non OECI member applies to become member (or associate member) the OECI Liaison Office will ask to the Board the authorisation to charge an A&D fee such as the member
- The OECI Liaison Office will check any outstanding payments on the OECI membership fee
- The OECI Liaison office assesses the status of payment of the institutes and sends a confirmation of the payments to the cancer institute and A&D manager

The total fee differs for OECI members and non-members:

	Stage 1	Stage 2	Total
Clinical Cancer Centre (CICC) (member)	€ 10.000	€ 25.000	€ 35.000
Comprehensive Cancer Centre (CCC) (member)	€ 10.000	€ 25.000	€ 35.000
Reaccreditation of CICC or CCC	€ 10.000	€ 25.000	€ 35.000
CICC or CCC (non-member)	€ 10.000	€ 30.000	€ 40.000
Reaccreditation of CICC or CCC (non-members)	€ 10.000	€ 30.000	€ 40.000

Table 1: A&D fee as approved by OECI Board in December 2014

The fee of stage one is equal for all types of institutes and covers primarily the costs for application and designation screening, use of the e-tool during the self assessment period, OECI support during self assessment period, organising meetings for the A&D Committee and A&D Board for the Go decision, and labour costs of the A&D Management Unit. An intermediate visit during self assessment is not a part of the fee.

Note 1: There might be reasons for which an institute is not able to continue the A&D Programme towards the peer review visit after the self assessment, such as: 'No go decision, changes in the management of the institutes etc. One year after the payment of stage 1 an institute will be reminded of its participation in the programme. The OECI A&D Group will not return the payment of stage 1

Note 2: The application expires two years after the date of submission (date of signature of the applicant institute) on the A&D Agreement. Within these two years the cancer centre should have finished the self assessment. If the self assessment has not been finished within these two years the institute should pay the starting fee again (stage 1), before continuing in the process

Note 3: Non-members pay €5000 in addition to OECI members which is comparable with the OECI membership admission fee for new members. However, non-members do NOT have to pay the annual OECI fee on top of the A&D fee in the first year after application to the programme

After one year from the application (and at the first available OECI General Assembly) the centre has to decide whether to become a OECI Full or Associate member or not
If the centre decides not to become a member it can anyway conclude the A&D Process

Note 4: The programme will start only when stage 1 of the fee has been paid

5.3 STEP 3: Preliminary designation screening

The A&D Programme continues after the institute has paid the first stage of the A&D fee.

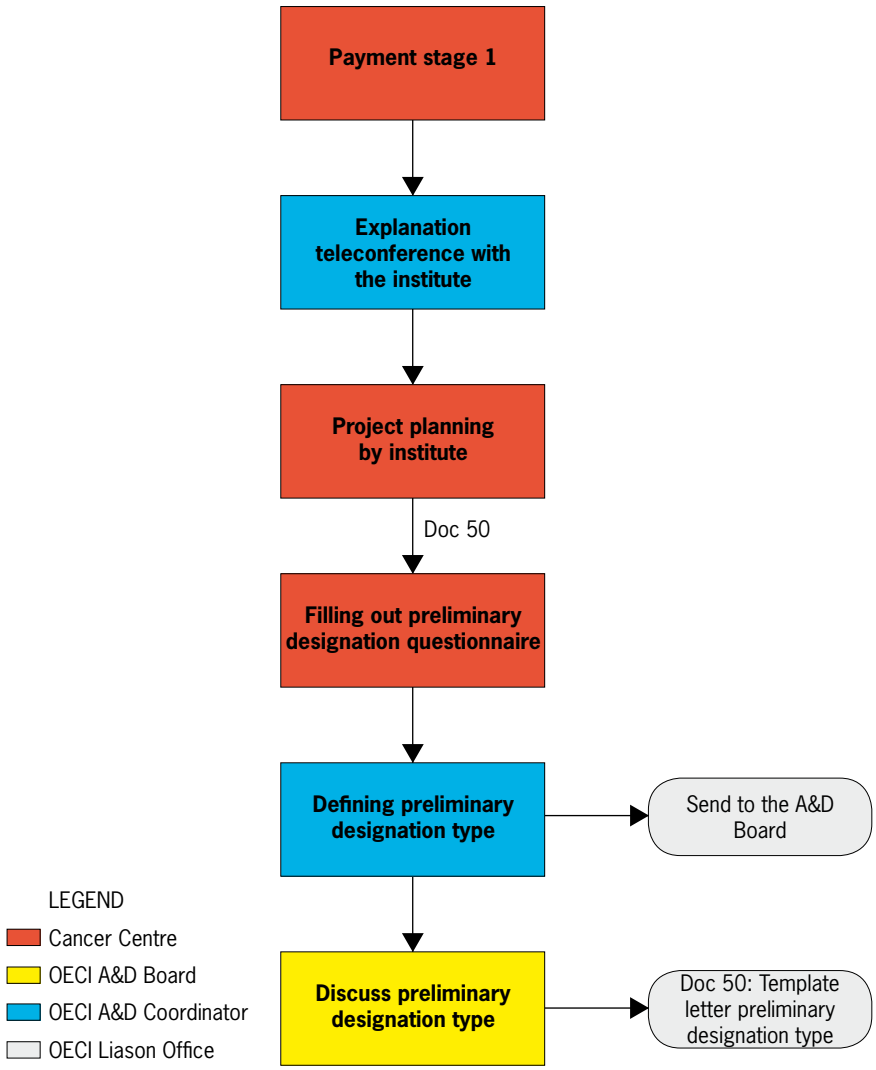


Figure 5: Step 3 preliminary designation screening

The designation screening (figure 5) takes place to assess the preliminary designation type of the institute. The preliminary designation will be discussed in the OECI A&D Board. Both, the judgement of the institute and the outcome of the preliminary designation screening, are the starting point for the next steps in programme. These steps will be explained by the A&D Coordinator during a telephone/video conference

Explanation telephone/video conference

Executor: OECI A&D Coordinator

The OECI A&D Coordinator:
- Arranges an explanatory meeting with the centre, through telephone/video conference
- Sends a meeting agenda to the cancer institute
- Sends the template project plan as an example on how to organize the preliminary designation and self assessment period in the institute

During a telephone/video meeting the A&D Coordinator will explain the following subjects:
- The accreditation and designation programme
- The preliminary designation screening. The designation type is the starting point for accreditation
- Timelines of the programme
- Access to the e-tool for the preliminary designation screening and the self assessment
- Project plan of the institute in the e-tool
- Required documents for peer review
- Obligations of the cancer institute
- Role of the OECI

The A&D Coordinator will arrange access to the preliminary designation questionnaire and the project plan.

After the explanatory telephone meeting the institute:
- Compose a project team and plan in the institute
- Will prepare and plan the preliminary designation screening and self assessment

Project group and project planning
The OECI A&D Group offers a template project plan (in available in the e-tool) containing the following items:
- Officers involved in the project group: professionals and staff from different departments
- Planning project group meetings to discuss the progress of the questionnaires
- Schedule for evaluating the progress and intermediate results to Board of Directors/Management
- Schedule and methods to inform about the progress to all professionals and staff within the institute
- Deadline for finishing the questionnaires including notes and (required) documents
- Timeline and method of informing the final results to all professionals and staff

The OECI A&D Group recommends the value of a project team and project plan to raise commitment, involvement and responsibility of professionals and staff from different departments. This may be useful in all parts of the programme:
- Answering the questions with widely accepted answers during the self assessment period
- Sharing the results of the self assessment
- Preparing the agenda for the peer review visit, it is not necessary to explain the purpose
- Giving feedback and comments to the draft peer review report
- Sharing the results from the peer review visit
- Formulating and performing actions for the improvement following the peer review results

Preparation of preliminary designation and project planning

Executor: Cancer institute

After the explanatory telephone meeting the institute:
- Sets up a project team and a institute specific project plan
- Prepares and plan the preliminary designation screening and self assessment

Project group and project planning
The OECI A&D Group offers a template project plan in the e-tool containing the following items:
- Officers involved in the project group: professionals and staff from the different departments
- Planning project group meetings to discuss the progress of the questionnaires
- Schedule for evaluating the progress and intermediate results to Board of Directors/Management
- Schedule and methods to inform about the progress to all professionals and staff within the institute
- Deadline for finishing the questionnaires including notes and (required) documents
- Moment and method of informing the final results to all professionals and staff

The OECI A&D Group recommends the value of a project team and project plan to raise commitment, involvement and responsibility of professionals and staff from different departments. This may be useful in all parts of the programme:
- Answering the questions with widely accepted answers during the self assessment period
- Sharing the results of the self assessment
- Preparing the agenda for the peer review visit; it is not necessary to explain the purpose
- Giving feedback and comments to the draft peer review report
- Sharing the results from the peer review visit
- Formulating and performing actions for the improvement following the peer review results

Designation questionnaire

Executor: Cancer institute

- After the approval of the application in the A&D Programme the institute continues with the designation screening that will be accessible as an online questionnaire in the e-tool (***http://oeci.selfassessment.nu***)
- The cancer institute can access the questionnaire with the same username and password as for the application
- The items requested for designation are a selection of the quantitative questionnaire for self assessment. The institute fills in these items only once. The numbers are automatically copied to the quantitative questionnaire
- The institute fills out all items in the designation screening questionnaire

The questionnaire request for figures of a specific year. The institute can state the year from which the figures derived. The institute should use the figures of the last completed administrative year. An exception to this rule is where is asked for figures from the last year available.

The numbers between brackets are the question numbers in the quantitative questionnaire.

Designation screening items:

- Planned annual budget for oncology health care in the year specified (Euro) (1.12.5)
- Planned annual budget for oncology research in the year specified (Euro) (1.12.5)
- Number of new patients in the cancer centre in the index year (2.1.1)
- Number of patients newly diagnosed in the index year (2.1.2)
- Number of all patients treated in the cancer centre in the index year (2.1.3)
- Number of patients on consultation for a second opinion (2.1.4)
- Number of inpatient beds + number of ambulatory beds/chairs (2.1.6)
- FTE physicians dedicated to oncology (2.2.1)
- Radiotherapy. In detail: number of linear accelerators, cobalt units, IMRT, stereotactic RT, availability of cyberknife, proton therapy, brachy therapy, other special radiation (2.9.4)
- Total FTE of employees in the cancer centre (3.1.1)
- Number of FTE surgeons. In detail: breast surgery, urologic surgery, thoracic surgery, digestive surgery, neuro-surgery, gynaecological surgery, head and neck surgery, soft tissue surgery, orthopaedic surgery, plastic and reconstructive surgery and paediatric surgery (3.1.2)
- Number of FTE from medical oncology (3.2.1)
- Number of prospective studies active (open to patient accrual) at the end of the year specified, excluding studies with no accrual (4.3.2)
- Number of studies activated in year x. In detail: Phase I, Phase II, Phase III and Phase IV (4.3.2),
- Percentage of new patients included in studies (4.3.2)
- Total research budget of the cancer institute (Euro) (4.1.1)
- Research funding sources/total amount received in year x. In detail: Number and amount of EU grants running in year x, number of EU grants coordinated in year x, public funding, charities/unrestricted grants and industrial partnership funding (4.1.2 / 4.1.3 / 4.1.4)
- Number of peer-reviewed publications per year (year x) national (4.5.1)
- Number of peer-reviewed publications per year (year x) international (4.5.1)
- Impact factor. In detail: impact factor cumulative, number of publications with impact factor > 10 (with first, second or last author), number of publications with impact factor > 10 (co-authored), number of publications with impact factor between 5 and 10 (with first, second or last author), number of publications with impact factor between 5 and 10 (co-authored) (4.4.7)

Available facilities dedicated to oncology care

Define preliminary designation type

Executor: OECI A&D Coordinator

With the data provided in the designation screening the A&D Coordinator will define the preliminary designation type for the applied institute according to the Designation Decision Schedule (Appendix I). The quantitative norms can be found in the Appendix I.

Required criteria for first selection CCC:

- Planned annual budget for oncology health care in the year specified (Euro) (1.12.5)
- Planned annual budget for oncology research in the year specified (Euro) (1.12.5)
- Number of new cancer patients per year (2.2.1)
- Total number of inpatients bed + number of ambulatory day care beds/chairs (2.1.6)
- Number of prospective studies active (open to patient accrual) at the end of the year specified, excluding studies with no accrual (4.3.2)
- Number of peer-review publications, oncology related, in the specified year: national and international (with first or last author employed by the centre) (4.5.1)
- Number of publications with impact factor > 10 (with the first, second of last author from the centre) (4.4.7)
- Number of publications with impact factor between 5 and 10 (with first, second or last author from the centre) (4.4.7)
- Centre covers radiotherapy + surgery + medical oncology

The final decision for the designation type will be checked during the peer review visit according to an additional checklist (5.7.1).

Deviation in designation judgement of the institute and the preliminary designation result
The application form for institutes includes the question to classify itself in one of the two designation types. The occurrence of a discrepancy between the judgement of the institute and the designation screening result (preliminary designation) is feasible

Discuss preliminary designation in the OECI A&D Board

Executor: OECI A&D Board

The OECI A&D Board will discuss the data provided by the cancer institute for preliminary designation and checks whether there is a deviation in designation judgement of the cancer institute and the preliminary designation result. The occurrence of a discrepancy between the judgement of the institute and the designation screening result (preliminary designation) is feasible.

The cancer institute will receive a letter with the result of the discussion of the OECI A&D Board (doc 50)

5.4 Step 4: Self-assessment

Step 4 of the A&D Programme is the self assessment of the cancer institute (figure 6).

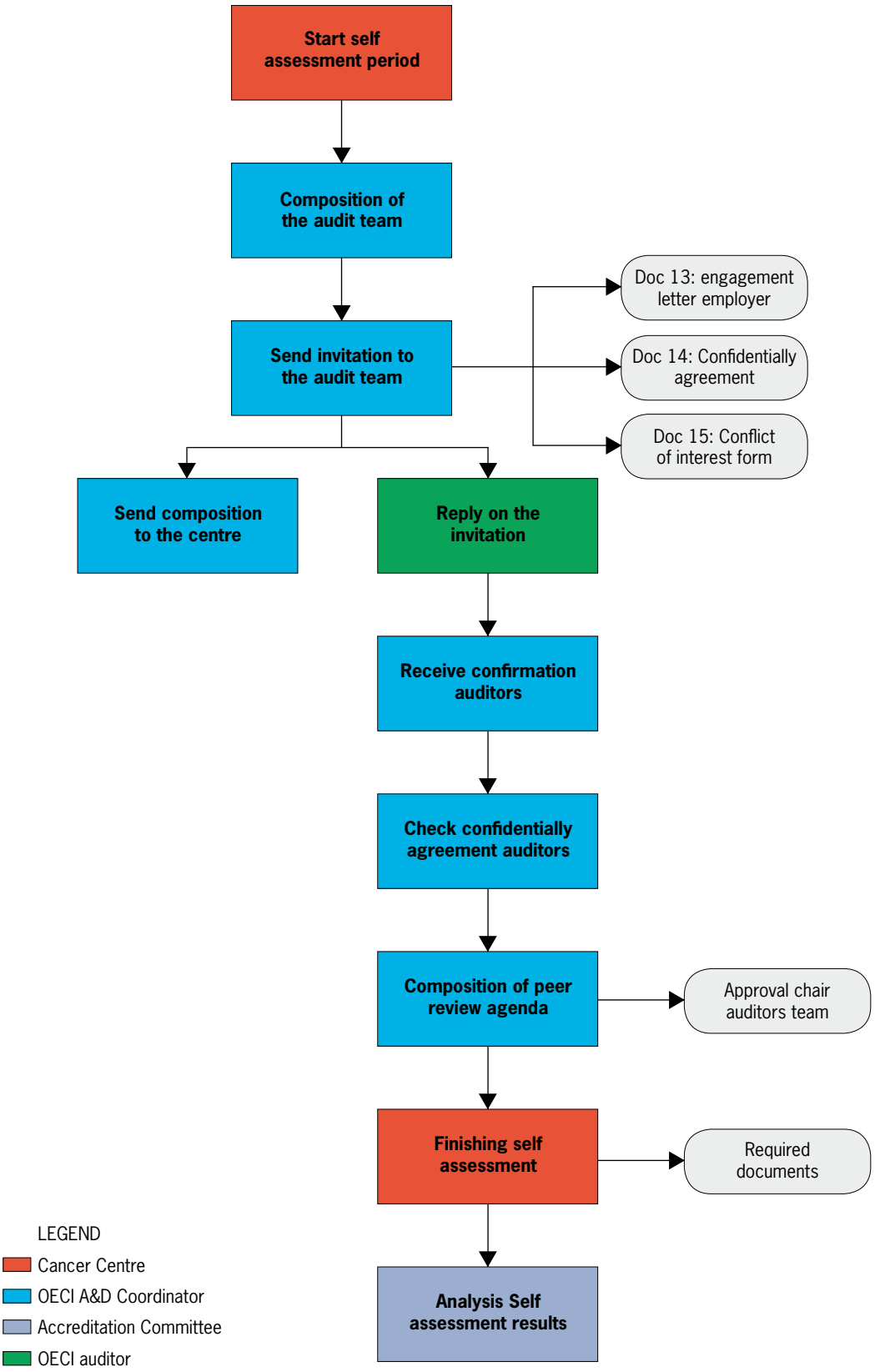


Figure 6: Step 4 Self-assessment

5.4.1 Step 4: Activities and responsibilities of all parties involved (figure 6)

Start self-assessment period

Executor: Cancer institute

- After the preliminary designation questionnaire the self assessment takes about 5 more months,
- The deadline of the self-assessment period is at least 2 weeks before the next TC of the OECI A&D Committee to prepare the Go/No Go decision for the OECI A&D Board

E-tool

- The (cancer) institute fills out the quantitative and qualitative questionnaire
- The (cancer) institute makes notes/remarks at the questions to explain the score/answers
- The (cancer) institute attaches documents (if available) to questions to support the answers
- The (cancer) institute attaches minimally the documents required by the OECI
- The (cancer) institute describes non-compliances/ improvement points in the e-tool that can be used to make an improvement plan

Progress of the self-assessment

During the self assessment period, the A&D Coordinator will contact the (cancer) institute regularly to evaluate the progress of the self assessment.
If required by the institute, it is optional that during the self assessment period the foreseen chair of the audit team and the A&D Coordinator pre-visit the institute. This pre-visit could be useful for face to face support during the self assessment and to manage expectations regarding designation and accreditation. The costs of this visit will be on account of the institute.

How to score the standards?

The score is an indicator for the stage of implementation of each item of the standard. The scoring system is based on the Plan-Do-Check-Act-circle or Deming-circle. These four stages of implementation are translated in the following possible answers:

- **Yes** means that the indicator of the standard has been implemented on a wide scale in the cancer institute and the Deming-cycle is completed at least twice (> in third cycle)
- **Mostly** means that the indicator has been implemented in most of the critical places in the cancer institute and the Deming-cycle is completed at least twice (> in second cycle)
- **Partially** means that the indicator is implemented on project bases or on a modest scale in the cancer institute or the Deming-cycle has not been completed (<Check)
- **No** means that the indicator does not get attention or there are plans to start working on the indicator (Plan)
- **Not applicable** means that the indicator is not applicable in the cancer institute

After filling out all the questions, the e-tool generates the results. The results will be used as input for the peer review as well as input for a quality improvement plan of the institute

Composition of the audit team

Executor: OECI A&D Coordinator

The OECI A&D Manager and A&D Coordinator compose the audit team for the peer review visit of the institute.

An audit team exist of:

- Chair (is also an auditor)
- Three auditors
- Coordinator

See criteria for auditors (3.2)

Send invitation audit team

Executor: OECI A&D Coordinator

The auditors will receive an invitation to perform the peer review. The letter will includes:
- Date for the preparation meeting (under reservation of a 'go' decision)
- Dates peer review (defined in alignment with the cancer institute and chair)
- Introduction of the team members
- Engagement form for management
- Explanation about potential conflict of interest from the institute. The institute may express objections against the audit team members. The audit team continues if the institute has agreed with the team

Attached to the letter are:
- Confidentiality agreement (doc 14):
  Before the first peer review of an auditor the auditor shall sign a confidentiality agreement
- Conflict of interest form (doc 15):
  Before every peer review each auditor shall sign a conflict of interest form
- Engagement form for the management of the auditors (doc 13):
  By signing the engagement form, the Management Board of the auditor provide permission and commitment to the auditor to perform the peer review

Send composition to institute

Executor: OECI A&D Coordinator

The composition of the audit team will be send to the institute to provide the opportunity to express any potential conflict of interest against one/more of the audit team members

Auditors reply on invitation

Executor: OECI Auditor

Within the timeframe set in the invitation letter, the auditors confirm to the A&D Coordinator:
- Availability on the date of the preparation meeting
- Availability on the dates of the peer review
- Doc 14: Confidentiality agreement
- Doc 15: Conflict of interest form
- Signed engagement letter from the management of the auditor

Receive confirmation from auditors

Executor: OECI A&D Coordinator

The OECI A&D Coordinator receives the confirmation from the auditors. This shall include:
- Doc 13: Signed engagement letter of management
- Doc 14: Signed Confidentiality Agreement
- Doc 15: Signed Conflict of Interest Form

Check confidentiality agreement auditors

Executor: OECI A&D Coordinator

The OECI A&D Coordinator will check if all auditors have replied a signed doc 13,14 and 15

Composition of peer review agenda

Executor: OECI A&D Coordinator

- Specify the template peer review agenda for the cancer institute
- Send concept agenda to the chair of the audit team for approval

Finishing self-assessment
Executor: Cancer institute
Within six months after the start of the self assessment period, the institute completes the questionnaires and closes the self assessment in the e-tool: – Quantitative questionnaire – Qualitative questionnaire – Notes to support scores – Requested proof documents and other proof documents attached to questions – Described non-compliance points/improvement points

Analyse self-assessment results
Executor: OECI A&D Committee
– To analyse and examine the self assessment reports before peer review – To analyse the proof documents for peer review – To analyse the results of the self assessment – To advise the Accreditation Board concerning a Go/No Go decision

5.5 Step 5: Go/No Go decision

The final Go or No Go decision will be taken by the OECI A&D Board. Before the Board takes the decision, the A&D Committee will analyse the self assessment results according to the criteria for self assessment. The Committee proposes to the A&D Board a 'Go' or 'No Go' decision.

The 'Go' decision is made at least two months in advance of the planned peer review visit.

Meaning of 'Go'
A 'Go' means that the OECI A&D Board has approved the institute for a 'Go' after the OECI A&D Committee has given their independent examination for this approval concerning the criteria:

The institute has provided convenient input of evidence and information to allow the audit team to do a reliable e peer review visit on site. The input includes:

1. All items are scored
2. The questionnaires should be useful for the auditors to prepare the audit, which means that the institute provides transparency in the available evidence (written documents) and explanations (notes):
   - Scores are justified with a note or a document with evidence, unless the score does not need explanation
   - The relevant documents/procedures/guidelines/cooperation agreements etc, that are requested in the standards are attached
   - The list of documents requested by the OECI are attached to the e-tool. If the documents are not available in English, a English summary of the documents should be provided
   - For questions scored as 'partially' or 'no' are described in a non-compliance/ improvement point

The e-tool manual for institutes explains how to put the evidence in the e-tool (doc 10 in the e-tool)

Task: Chair of the A&D Group
The Board of Directors of the institute will receive a notification letter of the Go decision (doc 36) signed by the chair of the A&D Group

Task: A&D Coordinator
The contact person of the institute will receive information about the continuation of the programme:

– Concept empty peer review agenda including the audit team (doc 16)
– Explanation on how to fill and complete the agenda
– Deadline of sending the completed agenda
– Obligations of the cancer institute for a successful peer review visit:
  - Availability of the staff involved in the peer review visit at the time and location they are expected to be present according to the agenda
  - Facilitation of the maintenance of the audit team as agreed in the A&D Programme Agreement
  - Providing permission to observe activities or procedures in the cancer institute during the peer review visit
  - On request of the OECI audit team, the institute shall provide access to all relevant locations, files and documents needed for assessment during the on-site peer review,
  - The executed language during the peer review is English. The cancer institute staff involved in interviews needs to understand and speak English. If not, the OECI requires the presence of an independent person who is able to translate

Meaning of a No go decision
Generally, it means to postpone the peer review visit. A possibility for a No Go decision is an inconvenient input for the audit team to prepare and perform the peer review in a reliable way. It might be possible that the there is a need for additional information (notes) or evidence (documents)

5.6 Step 6: Payment stage 2 fee

If the self assessment of the institute is approved for a Go the institute will receive the invoice for stage two of the A&D fee. The amount of the fee depends on the designation type of the institute.

- The OECI Liaison Office will receive a copy of the letter doc. 36 in which the Go decision by the OECI A&D Board is mentioned
- The invoice for the payment of the first stage fee will be send by the OECI Liaison Office together with the Agreement
- The OECI Liaison Office assesses the status of payment of the institutes and sends a confirmation of the payments to the cancer institute and A&D manager

The total fee differs for OECI members and non-members:

	Stage 1	Stage 2	Total
Clinical Cancer Centre (CICC) (member)	€ 10.000	€ 25.000	€ 35.000
Comprehensive Cancer Centre (CCC) (member)	€ 10.000	€ 25.000	€ 35.000
Reaccreditation of CICC or CCC	€ 10.000	€ 25.000	€ 35.000
CICC or CCC (non-member)	€ 10.000	€ 30.000	€ 40.000
Reaccreditation of CICC or CCC (non-members)	€ 10.000	€ 30.000	€ 40.000

The fee of stage two covers primarily the costs for the peer review visit, use of the e-tool, OECI support for organising the peer review, organising meetings for the A&D Committee and A&D Board decisions, and labour costs of the A&D Management Unit. A re-visit due to postponed A&D decision is not included in the fee

Note 1: The peer review can only be performed when stage 2 of the fee has been paid

5.7 Step 7: Peer review visit and designation assessment

Figure 7 shows the activities after the 'Go' decision. The audit team needs 2 months to prepare the peer review before the peer review visit can take place in month 13

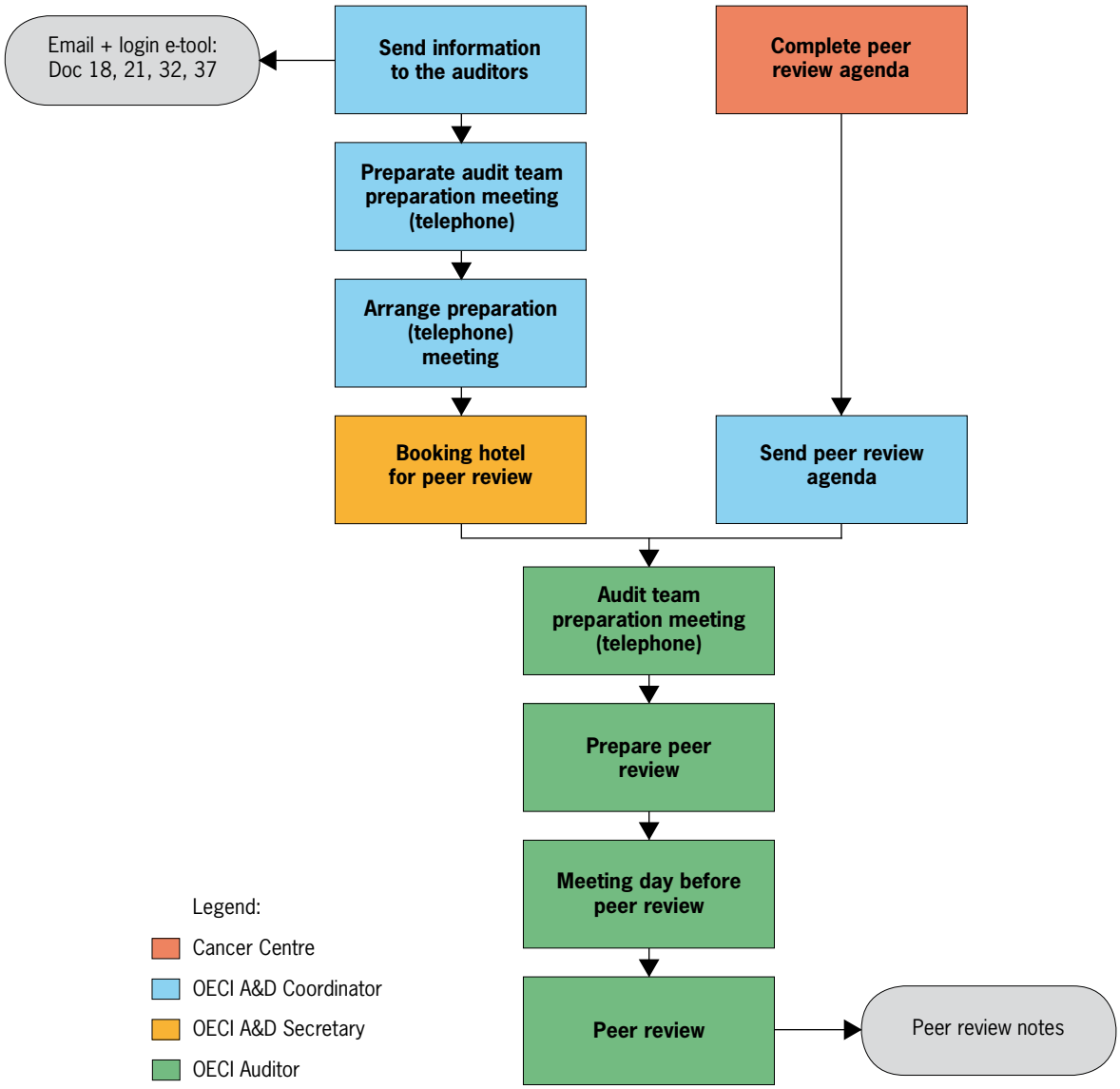


Figure 7: Step 7: Peer review visit and designation check

5.7.1 Step 7: Activities and responsibilities of all parties involved (figure 7)

Step 7 starts with parallel activities for A&D Coordinator, the auditors and the institute

Send information to auditors

Executor: OECI A&D Coordinator

The auditors receive an e-mail with a notification of the 'Go' decision of the A&D Board including information of the continuation of the accreditation programme

The e-mail contains information about:
- Preparation of the peer review
- Access to the information of the cancer institute in the e-tool
- Designation checklist (doc 34)
- Login instructions in the user manual (doc 37)
- Auditors meeting and the agenda (doc 18)
- Travel policy and coverage rules for the peer review visit (doc 32 and doc 21)

Prepare auditors team meeting

Executor: OECI Auditor

Individual preparation of the auditors team meeting include:
- Analysing the self assessment reports of the cancer institute:
  - quantitative report including: scores, notes and improvement points
  - quantitative report
- Analysing the documents the cancer institute has attached to the e-tool
- Formulation of main topics for the peer review visit
- Designation checklist (doc 34)

Booking hotel auditors meeting

Executor: OECI Secretary

The OECI secretary will book the hotel and diner for the auditors for the peer review visit

Complete peer review agenda

Executor: Cancer institute

While the audit team prepares itself for the auditors meeting, the institute defines and completes the peer review visit agenda. The concept agenda has been approved by the auditors chair during the self assessment period

The concept agenda has to be completed by the cancer institute. The auditors will have interviews with employees of the cancer institute. The institute has to provide a list of the persons from the requested departments and the location/room where the interviews will take place

Deadline of completing: 1 week before auditors preparation meeting

Send agenda's

Executor: OECI A&D Coordinator

The agenda of the preparation meeting is sent one week before the meeting, including the concept peer review agenda

Auditors team meeting, teleconference

Executor: OECI audit team

One month before the peer review the auditors prepare the peer review

Input:
- Result designation screening
- Concept peer review agenda (completed by cancer institute with interviewees and locations)
- Self assessment reports (qualitative and quantitative)
- Attached documents of the cancer institute
- Designation checklist

Content of the meeting:
- A general presentation of the accreditation programme
- An explanation of the roles and responsibilities of the auditors
- Report writing procedures
- Planning of interviews
- Content of interviews
- Follow up of the accreditation programme for the cancer institute

Every auditor makes notes during the peer review visit

Preparare peer review
Executor: OECI Auditor
Individual preparation of the peer review following appointments made in the auditors team meeting

Meeting day before peer review
Executor: OECI audit team
The evening before the peer review the auditors meet in the hotel for: – Final preparation – Extra focus on the designation type especially when the institute prefers the CCC level – Group diner

Performing peer review
Executor: OECI audit team
Performing the peer review according to the peer review agenda (doc 16) In the evening of the peer review days, the audit team will work on scoring the standards (Yes, Mostly, Partially, No)for the report and drawing the preliminary conclusions, strengths and opportunities The audit team will additionally focus on the quantitative, as in the preliminary designation screening, and qualitative criteria for designation as Comprehensive Cancer Centre: – A highly innovative character and multidisciplinary approach using the potential of basic, translational and clinical research and clinical facilities and activities, organized in a sufficiently identifiable entity [Short description] – A direct provision of an extensive variety of cancer care tailored to the individual patient's needs and directed towards learning and improving the professional, organizational and relational quality of care [Short description] – Broad activities in the area of prevention, education, and external dissemination of knowledge and innovation. In order to accentuate the differences with other cancer institutes [Short description] – The level of infrastructure, expertise and innovation in the field of oncology research [Short description] – Maintenance of an extensive network including all aspects of oncology treatment and research [Short description] **Writing notes during peer review by auditors** The notes of the interviews, tours and presentation will be processed into the e-tool by the auditors during and after the peer review. The auditors have **one week** after the peer review visit to process the notes and to provide the descriptions to support the designation type. The auditors have a personal username and password to enter the e-tool and to go to the peer review report of the institute. Auditors can process their notes in the e-tool at the same time. The answers need to provide evidence/proof for the scores given to the standard. The report needs to be: – Recognizable – Concrete – Compact – Separate minor and major points – Strength and weaknesses from appendices in text – Objective statements – Examples – Reasonable arguments for subjective statements – Unanimously agreed by the auditors team

5.8 Step 8: Reporting and the improvement plan

After the peer review visit it takes about 3 months to finish the final peer review report (figure 9).

The reporting period is split in two phases. In week 1 to 6 the auditors are working on the draft report. This is outlined and explained in sub-process: 'Reporting by audit team' (figure 8).

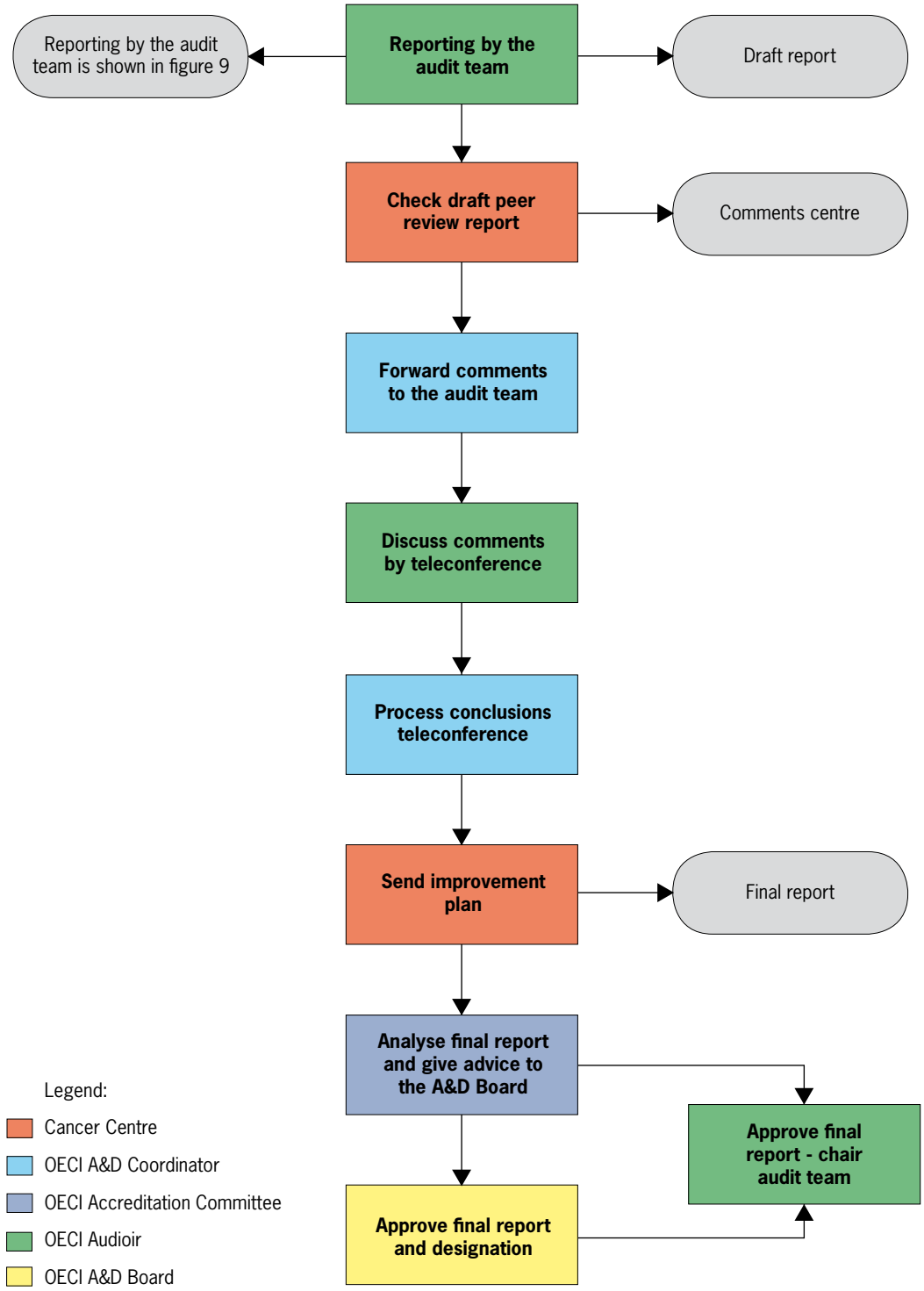


Figure 8: Step 8 Reporting

5.8.1 Week 1-6: Reporting by the auditors (figure 9)

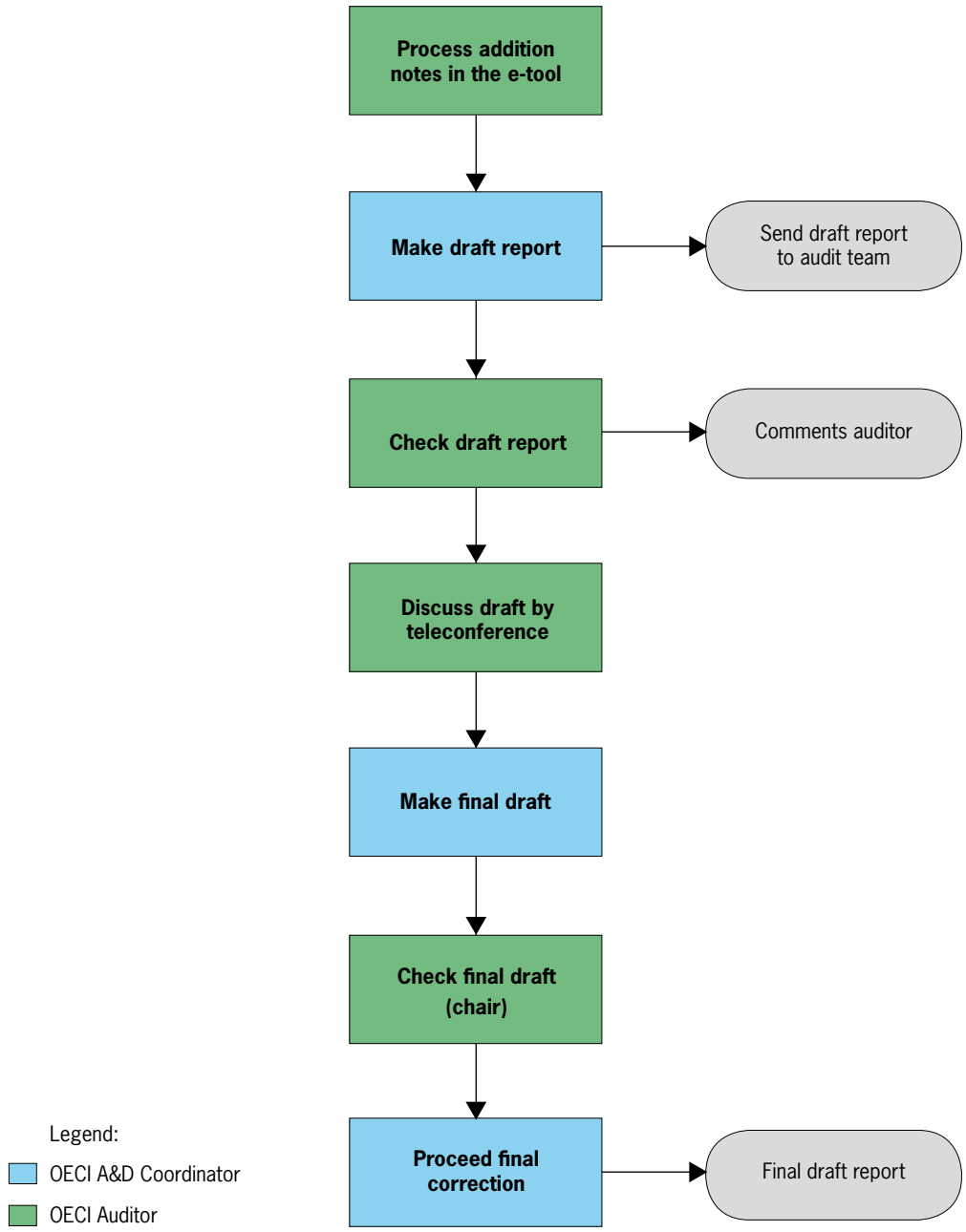


Figure 9: Week 1-6: Reporting by the auditors

Process additional notes in the e-tool
Executor: OECI Auditor
– The auditors have one week after the peer review to deliver additional scores and notes of the peer review interviews, tours and presentation in the e-tool – Auditors deliver the scores and notes in the e-tool, arranged under the appropriate standard – Auditors have one week after the peer review to deliver the short descriptions for each designation item and the final designation conclusion – The OECI Coordinator processes the notes of the peer review in the first draft of the report – The auditors are also asked to draw a list of general remarks, strengths and opportunities per chapter of the standard – The chair of the audit team is asked to write a draft final chapter with general remarks, strengths and opportunities

Make draft report

Executor: OECI A&D Coordinator

– In week 2 after the peer review the A&D Coordinator will formulate the first draft report. The A&D Coordinator:
  - Analyses the individual scores of the auditors and make a list of the deviations
  - Analyses the notes of the auditors per standard
  - Proposes the final text that supports the score of each standard
  - Makes a list of the standards that shall be discussed with the audit team
  - Adds the draft final chapter with general remarks, strengths and opportunities to be discussed with the audit team
– The A&D Coordinator sends the draft to the audit team

Check draft

Executor: OECI Auditor

The first draft of the report will be send to the audit team to analyse
– The scores of the auditors
– The proposed text per standard to support the audit team scores
– The list of standards with different findings among the auditors in the scores and notes (deviations)
– The proposed general remarks, strengths and opportunities
The auditors are requested to give feedback and comments on the draft report

Discuss draft by teleconference

Executor: OECI Chair audit team

The A&D Coordinator will discuss the draft report and feedback with the audit team by teleconference. The input of the teleconference is a list of deviations sent by the A&D Coordinator and the draft final chapter

Process the results of the audit team teleconference

Executor: OECI A&D Coordinator

The A&D Coordinator:
– Processes the conclusions of the teleconference
– Discusses the final draft with the A&D Manager

Check final draft

Executor: OECI Chair audit team

The second draft of the report will be sent to the chair to check:
– Final scores as discussed in the teleconference with the audit team
– Final text per standard that supports the audit team scores Part 2 of the report with the general findings, strengths and opportunities
– Editorial changes

Proceed final comments

Executor: OECI A&D Coordinator

The A&D Coordinator proceeds the final comments of the chair and send the final draft report latest in week 6 after the peer review to the Director and accreditation contact person of the cancer institute.

The draft is sent together with:
- Doc 41: Letter presenting the draft report
- Doc 22: Feedback and comment form
- Doc 23: Template improvement actions plan

The final draft contains:
The standards reviewed during the peer review visit with the scores of the cancer institute from the self assessment, the scores of the of the auditors and the findings of the auditors supporting the scores, the general remarks, strengths and opportunities.
The final draft does not present the final conclusion, description of the designation check findings and the designation type.

Check draft peer review report

Executor: Cancer institute

- The Director and the accreditation contact person of the institute receive the draft peer review report
- The institute distributes the draft report within the cancer institute to all involved and interested workers
- The institute is invited to check the report on textual or content inaccuracies and to collect comments and feedback on doc 22 Feedback an comment form
- After 4 weeks the contact person have collected the comments within the institute and sends the form to OECI Coordinator
- The Director and accreditation contact person of the institute receive an explanation of the minimum criteria of an improvement action plan
- Parallel to this process the institute writes the improvement plan
- Within 8 weeks after receiving the draft report, the institute sends the improvement plan to the A&D Coordinator

The general obligations for the improvement plan:
- The plan shows willingness to improve the main opportunities from the peer review report
- The plan shows a systematic approach with: opportunities/goals, actions, persons responsible, start date, evaluation date, end date and priority
- It is out of the scope of the OECI A&D Programme to give advice on how an institute approaches the actions

The plan contains the following aspects for each item for improvement. A template improvement plan is available in doc 23:

Action x	Standard	xxx
	Opportunity	
	Action	
	Goal/ desired result	
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Dead line (date)	
	Priority - High/Med/Low	

Forward comments

Executor: OECI A&D Coordinator

- The comments and feedback of the institute on the draft report will be forwarded to the audit team members
- They are requested to give their reaction on the comments by e-mail
- The institutes comments and response of the audit team members will be discussed with the audit team

Discuss comments by teleconference

Executor: OECI Chair audit team

Discuss feedback and comments of cancer institute:

- The comments and response of the auditors will be discussed in a teleconference with the audit team and the OECI A&D Coordinator
- Conclusions concerning the comments will be inserted in doc 22: Feedback and Comments form

Formulate proposal for final conclusion, description of the designation check findings and the designation type for the final report within 4 weeks

Process conclusions teleconference

Executor: OECI A&D Coordinator

The A&D Coordinator will process the conclusions of the teleconference, which includes:

- Corrections concerning the comments and feedback of the cancer institute
- The formulated final conclusion, assessment and description of the designation, proposal of designation type
- The A&D Coordinator sends this final report to the chair of the audit team for a final check

Analyse draft final report

Executor: OECI A&D Committee

The A&D Committee will receive the final report from the audit team which includes the final conclusion, strengths and opportunities, assessment and description of the designation and proposal of designation type by the audit team (chair) and improvement plan from the institute

The A&D Committee will analyse the conclusions, strengths and opportunities that are drafted by the audit team, and the improvement plan drafted by the institute. The A&D Committee gives a final advice to the A&D Board about the complete final report and proposed designation type

If the A&D Committee makes major changes in the report, the coordinator of the A&D Committee (the A&D Coordinator) will send the report for a final check to the chair of the audit team. If there are only minor changes the report will be send directly to the A&D Board for final approval

Final check

Executor: OECI Chair audit team

- If the A&D Committee has changed major parts in the report the report will be send back to the chair of the audit team
- The chair has the opportunity to check the report
- If the chair of the audit team agrees with the major changes of the A&D Committee the draft final report will be send to the A&D Board for approval

Approval final report

Executor: OECI and OECI A&D Board

Within the monthly teleconferences the OECI A&D Board discusses the final report, including the strengths, opportunities conclusions and improvement plan, to draw the final conclusion for certification as Clinical or Comprehensive Cancer Centre.

The OECI takes the final decision on the certificate

Send final report to Cancer institute
Executor: Chair A&D Group
Within 16-20 weeks after the peer review the cancer institute receives: – A letter to present the final report – The final report includes the final designation – Proposal for the A&D Certificate Based upon the final report and the improvement plan the Accreditation and Designation Certificate can be awarded by the OECI A&D Board

5.9 Step 9: OECI A&D Certificate

Within 2 months after the OECI A&D Board receives the final report and the improvement plan from the audit team, the OECI A&D Board takes the final A&D decision.

If the final report of the institute is approved by the OECI A&D Board, the institute receives the Accreditation and Designation Certificate, including the final designation. The institute receives also a letter (doc 24) stating that the institute is awarded with the Certificate.
A paper and on plate copy of the Certificate are delivered to the institute and a formal ceremony is held during the OECI General Assembly.

The A&D Certificate is valid for five years from the date of approval of the certification by the A&D Board. To maintain the A&D Certificate after these five years the institute has to start a new round A&D Programme, at least six month before the expiring date of the Certificate.

Figure 8: OECI Accreditation and Designation Certificate

5.9.1 Evaluation of the A&D Programme

Evaluation A&D Programme (figure 11 next page)
Executor: OECI A&D Coordinator and cancer centre
The A&D Coordinator will send an evaluation form to the institute 3 months after the final A&D Certification approval

Evaluation by teleconference
If required in the evaluation form, approximately five months after the final A&D Certification approval, the OECI A&D Coordinator and A&D Manager plan a teleconference to discuss the evaluation form. Representatives: – Cancer institute contact person – OECI A&D Manager – OECI A&D Coordinator

5.10 Step 10: Follow-up

There is a period of five years between the date of issue of the certification and the expiring date. Within this period the institute will work to achieve the goals of the improvement plan.

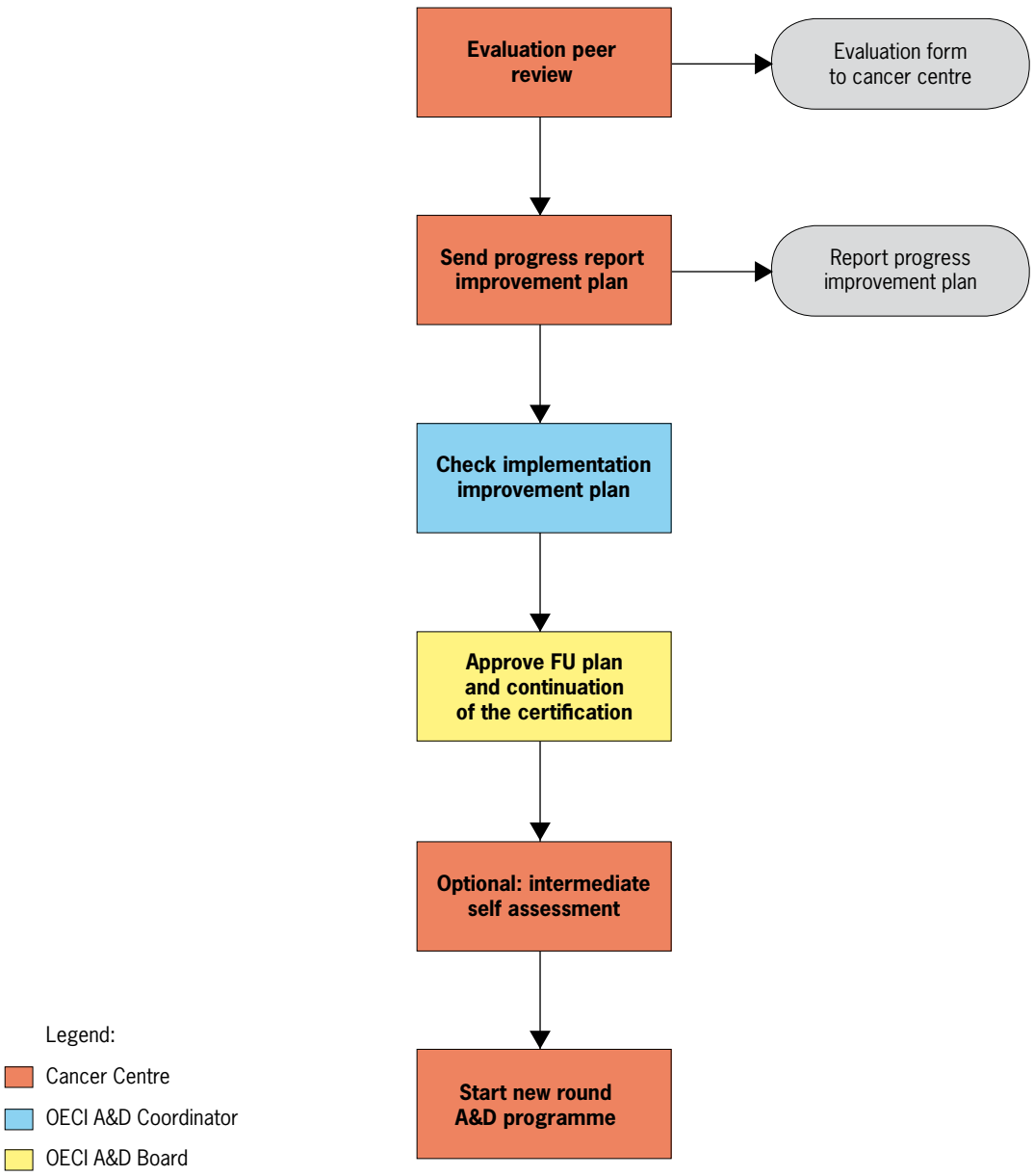


Figure 11: Step 10: Follow-up of the A&D Programme

Send progress report improvement plan

Executor: Cancer institute

One year after the peer review visit the institute reports the progress of the goals and activities set in the improvement plan to the OECI A&D Board.

The institute can add a column to the improvement plan:

Action x	Standard	xxx
	Opportunity	
	Action	
	Goal/ desired result	
	Actions description	
	Who is involved and responsible for result	
	Start (date)	
	Evaluation (date)	
	Dead line (date)	
	Priority - High/Med./Low	
	PROGRESS AFTER ONE YEAR	

Check status of implementation of improvement plan

Executor: A&D Coordinator

The A&D Coordinator will receive a report of the cancer institute with the progress of the implementation of the goals and activities set in the improvement plan. The A&D Coordinator will inform the A&D Board

Intermediate self assessment (optional)

Executor: Cancer institute

The A&D Programme fee include five years access to the self assessment e-tool
The institute has the option to perform an intermediate self assessment to measure the improvements according to the OECI Quality Standards two years after the peer review visit

Note: This intermediate self assessment will not be analysed by the OECI. It is an voluntary exercise by the institute to check improvements

Start new round A&D Programme

Executor: Cancer institute

The Certificate expires after five years from its issue. If the cancer institute wants to maintain the accreditation and designation, it needs to re-apply for a new round of the A&D Programme, at least six months before the Certificate expires

Accreditation and Designation User Manual

6. Where to find the documents needed in the programme?

6. Where to find the documents needed in the programme?

The appendix of this manual contains the documents that are useful to start up the Accreditation and Designation Programme. However, most documents are available in the e-tool.

Underneath table shows the needed and useful documents, and how to access those.

Name	Nr.	Where to find
Online application form	Doc 1	Website **http://oeci.selfassessment.nu**
Project plan for cancer institute	Doc 5	In the e-tool
Accreditation and Designation Programme Agreement	Doc 6	Managed by OECI Liaison Office
Payment order stage 1	Doc 8	Managed by OECI Liaison Office
List required documents	Doc 9	In the e-tool
E-tool user manual (institute)	Doc 10	Appendix IV and in the e-tool
Template letter for invitation of auditors	Doc 11	Managed by Management Unit
Engagement employer auditor	Doc 13	Managed by Management Unit
Confidentiality agreement	Doc 14	In the e-tool
Conflict of interest form	Doc 15	In the e-tool
Template peer review agenda	Doc 16	In the e-tool
Template auditors preparation meeting agenda	Doc 18	Managed by Management Unit
Auditors pool and planning	Doc 20	Managed by Management Unit
Reimbursement form	Doc 21	In the e-tool
Template Feedback and comments form institute	Doc 22	In the e-tool
Template improvement plan	Doc 23	In the e-tool
Template letter approval accreditation	Doc 24	Managed by Management Unit
Evaluation form audit team	Doc 26	In the e-tool
Evaluation form cancer institute	Doc 27	In the e-tool
Application form for training of auditors/ chairs	Doc 31	Website **http://oeci.selfassessment.nu**
Travel policy rules	Doc 32	In the e-tool
Template letter notification GO for peer review	Doc 36	Managed by Management Unit
Auditors e-tool user manual	Doc 37	In the e-tool
PPT peer review introduction and closing	Doc 39	Managed by Management Unit
Letter presenting draft report and request improvement plan	Doc 40	Managed by Management Unit
Planning centres	Doc 41	Managed by Management Unit
Glossary	Doc 42	In the e-tool
Letter presenting result preliminary designation screening	Doc 50	Managed by Management Unit

Accreditation and Designation User Manual

7. Overview of obligations and tasks of a cancer institute

7. Overview of obligations and tasks of a cancer institute

General obligations:
- Strong commitment to quality improvement (signature of Director/ Board of Directors)
- Dedicated staff (contact person, project group, all involved employees)
- Stable management structure (no interim management)
- No major changes/problems (expected management change, merger, housing movements, financial crisis)
- Following the steps of the A&D Programme with care and within the required timeline
- Involvement in oncology research and education programmes
- Cancer care is performed on an identifiable unit with an identifiable budget, management and organizational structure
- The institute has a preliminary designation as: Clinical Cancer Centre or Comprehensive Cancer Centre
- There is an agreement on the designation type between the OECI A&D Board and the cancer institute

Before the start of the self assessment period:
- Signing the A&D Agreement
- Paying accreditation fee Stage one
- Organizing an internal accreditation project planning and project team

Before peer review:
- Completed self assessment questionnaires; results of self assessment
- Delivering of requested documents
- Go-decision of OECI A&D Board
- Paying A&D fee stage two
- Completing the peer review agenda

During peer review:
- Facilitate the maintenance of the audit team as agreed in the audit programme
- Providing permission to observe activities or procedures in the cancer institute during on-site peer review
- On request of the OECI Auditors Team, the institute shall provide access to all relevant locations, files and documents needed for assessment during the on-site peer review
- The participants in the peer review from the institute understand and speak English
- During tour on departments and wards an independent translator needs to be available to translate the questions of auditors and answers of staff

After peer review:
- Providing feedback on the peer review report
- Delivering an improvement plan
- Delivering a report with the progress and results of the goals set in the improvement plan
- Optional: Intermediate self assessment after two years

Accreditation and Designation User Manual

8. Register

8. Register

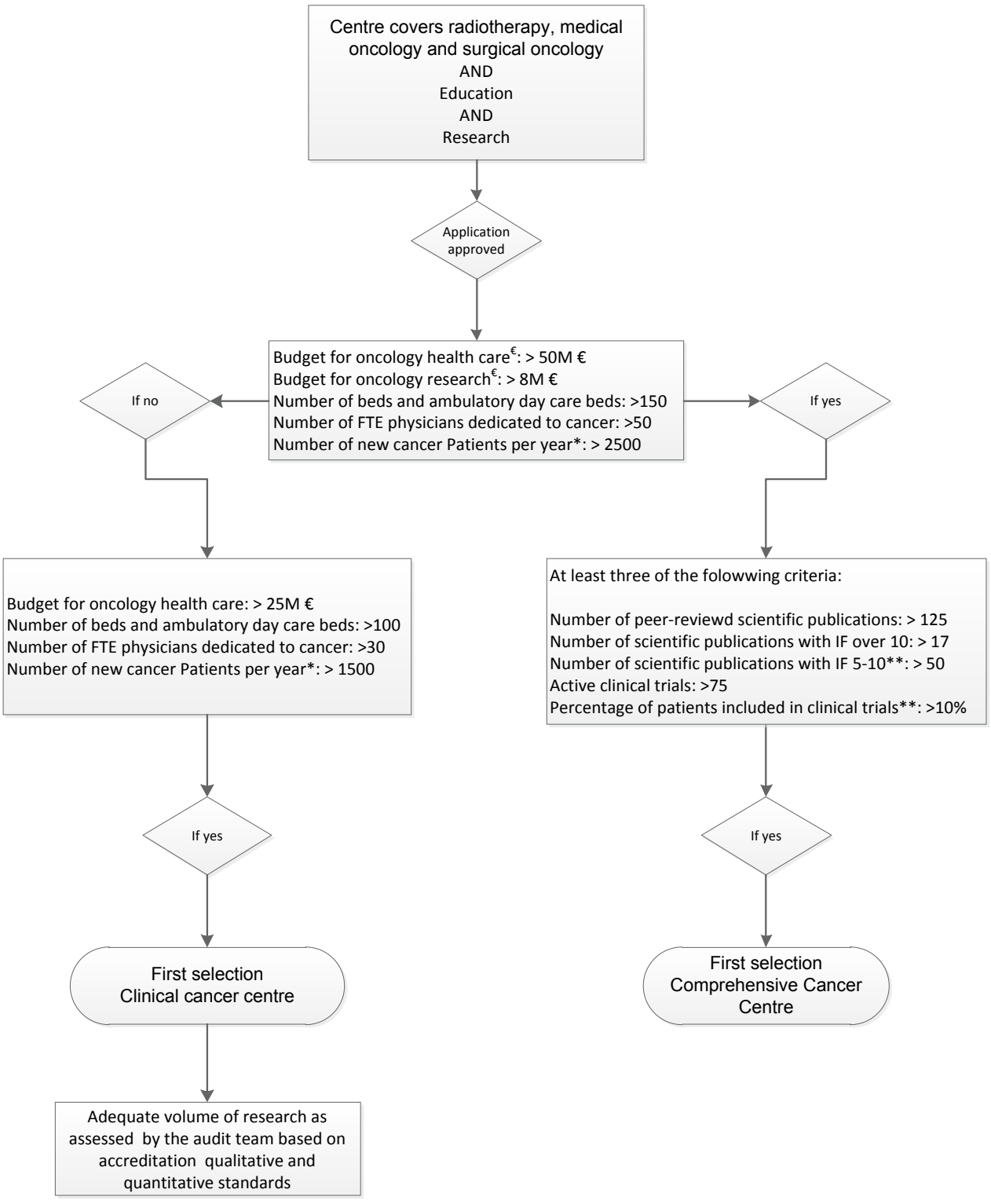
Figures

Accreditation and Designation

Appendix I

OECI Quality standards V. 2015

Designation Decision Schedule



€ *Taking into account GDP PPP (Gross Domestic Product Purchasing power parity)*

* *Number of patients with the diagnosis of cancer who are newly managed in the cancer centre in the index year. This includes new patients in the cancer centre for recurrent disease after previous treatment elsewhere. A patient with a new (second or n) cancer may be counted again. "Managed" means that the patient has been treated even partially (ex: only radiotherapy) or simply followed (no additional treatment needed) in your centre. It does not include patients just coming for a second opinion without being afterwards followed in the centre. (Generally, a patient is counted as newly diagnosed for the index year, if diagnosis was confirmed that year (usually the date of the histological/cytological report).*

** *Percentage = total number of patients enrolled on prospective clinical studies (excluding observational studies) in a index year / total number of patients diagnosed with the diagnosis of cancer who are newly managed in the cancer centre in the same index year.*

12-month reporting period

V. 2.0. 2015

Accreditation and Designation

Appendix II

OECI Quality standards V. 2015

Appendix II. OECI Quality standards V. 2015

Table of content

Centres give a score to each item of the standard. The score is a indicator for the Stage of implementation of each item of the standard. The scoring system is based on the Plan-Do-Check-Act-circle or Deming-circle.
These four Stages of implementation are translated in the following possible answers:

- **Yes** means that the indicator of the standard has been implemented on a wide scale in the cancer institute and the Deming-cycle is completed at least twice (> in third cycle),
- **Mostly** means that the indicator has been implemented in most of the critical places in the cancer institute and the Deming-cycle is completed at least once (> in second cycle),
- **Partially** means that the indicator is implemented on project bases or on a modest scale in the cancer institute or the Deming-cycle has not been completed,
- **No** means that the indicator does not get attention or there are plans to start working on the indicator,
- **Not applicable** means that the indicator is not applicable in the cancer institute.

As well as giving a score the centre is required to support the score with a note and/or document. In the e-tool it is possible to add these documents and notes (See User Manual Appendix). As well as identifying improvement point for items that are scored with no or partially.

1. Leadership and Management of the cancer centre

1.1 Policy and organization

Topic 1: Strategic plan for oncology

Standard 1: A periodical planning and control cycle concerning oncology policy and strategy is present

		Definition	Yes	Mostly	Partially	No	n.a.*
1	A written strategic plan for the cancer centre should cover at least 3 years, and which is formally endorsed by the board is present						
2	Each main service or department of the centre has an annual or multi-year plan which is consistent with the centre's overall strategy/policy for cancer	*					
3	According to the planning and control cycle the centre produces a (multi-)annual report which results in a quality improvement plan						

* Main topics to have a strategy plan for: diagnostics, treatment, supportive care, and research.

Topic 2: Organization structure

Standard 2: The administrative/Board level of the cancer centre includes Quality Management

		Definition	Yes	Mostly	Partially	No	n.a.
1	There is an identifiable Director who has quality and risk management as his/her responsibility	*					
2	The Director who has quality and risk management as his/her responsibility is a member of the board of directors or senior management team of the cancer centre						

* Definition of risk management: Systematic identification and monitoring of risks, leading to measures preventing its occurrence or minimizing its possible effects.

Topic 3: Cooperation based on agreements with universities

Standard 3: Written cooperation agreements concerning care, educational and research activities with at least one university (hospital) are present, and periodically evaluated

		Definition	Yes	Mostly	Partially	No	n.a.
1	Care activities						
2	Training and postgraduate education activities						
3	Research activities						

Topic 4: Cooperation based on agreements with external partners

Standard 4: Written agreements are present about the allocation of tasks in the case of referrals

		Definition	Yes	Mostly	Partially	No	n.a.
1	There are written agreements with other hospitals and cancer centres setting out the goals for cooperation, the division of responsibilities, tasks and skills between the cancer institution and cooperating bodies.						
2	There are written agreements with special cancer care service providers	*					

* Examples of special cancer care service providers: radiotherapy centre, pathology, laboratory, specialized surgery unit etc.

Topic 5: Cancer data registration (institutional level)

Standard 5: Cancer patient data are used for developing strategic planning and quality improvement of care processes

		Definition	Yes	Mostly	Partially	No	n.a.
1	The number of new patients, newly diagnosed patients and treated patients in the cancer centre is available annually at institutional level						
2	The diagnostic trends of cancer patients are known on an institutional level and reported annually to the Board for future planning						
3	The treatment trends of cancer patients are known on an institutional level and reported annually to the Board for future planning						
4	The outcome trends of cancer patients are known on an institutional level and reported annually to the Board for future planning						
5	Each multidisciplinary tumour team (MDT) communicates trends in the diagnostic, treatment, outcome) data to the board in order to improve care and strategic planning						

Topic 6: Complications registry

Standard 6: A complication registry is present, accessible in all departments and used for developing improvement activities

		Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer institution has a comprehensive system for reporting, registration and assessing of complications	*					
2	The global report of complications registry data is reported to the medical management at least annually						
3	Improvement actions are developed and implemented in agreement with the all departments and disciplines concerned						
4	The effect of improvement actions are measured and reported at least annually						

* Definition complication registry: Any unintended and unfavourable event or condition during medical treatment or as a consequence of medical treatment. It seriously damaging the health of the patient with the consequence of: starting new medical treatment, changing the recent medical treatment or, irreversible damage. Complication registry can be used as a quality instrument for and by medical specialists. Complication registry offers a feasible base for reliable information. Complication registry aims to: collecting reliable information about complications, finding targets to prevent complications and, arranging a quality improvement system for prevention.

1.2 Resources and materials

Topic 7: Anti-cancer drugs, prescription, preparation and distribution

Standard 7: Written procedures are available for the prescription, preparation and distribution of anti-cancer drugs

		Definition	Yes	Mostly	Partially	No	n.a.
1	There is a written procedure for the prescription of anti-cancer drugs	*					
2	There is a written procedure for the preparation of anti-cancer drugs						
3	There is a written procedure for the distribution of anti-cancer drugs						
4	Anti-cancer drugs are prepared in a centralised unit						
5	Anti-cancer drugs are prepared under the direct supervision of a pharmacist						
6	A validation procedure for the whole process, including prescription, preparation and distribution, is implemented						

* Definition procedure: A document that describes in detail, the process or chronological steps taken to accomplish a specific task; a procedure is more specific than a policy.

Topic 8: Administration of anti-cancer drugs

Standard 8: Protocols are present for the administration of anti-cancer drugs

		Definition	Yes	Mostly	Partially	No	n.a.
1	There are protocols for the administration of anti-cancer drugs						
2	Anti-cancer drugs are administered only in specified wards (for inpatients)						
3	There is a dedicated day-care unit for the administration of anti-cancer drugs						
4	Anti-cancer drugs are administered by specially trained (oncology) nurses						
5	A specific procedure for reporting unexpected side effects of anti-cancer drugs is implemented						
6	There is a validation process for the administration of anti-cancer drugs						

1.3 Process control

Topic 9: Continuity of care within the cancer centre

Standard 9: The cancer centre has a written policy for quality and risk management and safety

		Definition	Yes	Mostly	Partially	No	n.a.
1	There are arrangements in place to provide specialist care (of medical, nursing, palliative and other supportive staff) for patients 24 hours a day, every day						
2	The cancer centre can accept patients during day and night in the event of an emergency, admit them if necessary, or refer them to another institute						

Topic 10: Waiting and throughput times

Standard 10: For critical Stages in the care process the maximum waiting- and throughput times are defined

		Definition	Yes	Mostly	Partially	No	n.a.
1	There are guidelines for each tumour type for the maximum waiting times between referral and first visit to outpatients\' clinic or admission to the cancer centre	*					
2	There are guidelines for each tumour type for the maximum waiting time between first visit and the time of definitive diagnosis						
3	There are guidelines for each tumour type for the maximum waiting times between definitive diagnosis and first treatment						
4	There is a record and continuous evaluation of the actual waiting times						
5	If maximum waiting times are exceeded improvement actions are defined promptly						

* Definition guidelines: A written document describing steps of a treatment or procedure in sufficient detail such that the treatment or procedure can be reproduced repeatedly without variation.

Topic 11: Logistics of scheduling diagnostic examinations

Standard 11: Agreements have been reached about scheduling appointments and giving priority to examinations (CT, MRI, mammography)

		Definition	Yes	Mostly	Partially	No	n.a.
1	There is a policy for scheduling examinations						
2	Agreements have been reached about giving priority to examinations (CT, MRI, mammography)						

Topic 12: Availability of guidelines

Standard 12: For each type of cancer, consensus has been reached among the disciplines involved about the guidelines used for diagnosis, treatment, follow up and research

		Definition	Yes	Mostly	Partially	No	n.a.
1	It is formally agreed which guidelines (institutional/ local/regional/ national/ international) are used for diagnostics, treatment, follow up and research						
2	The guidelines are easily accessible in written and/or digital form						
3	The guidelines are updated on a regular basis (at least every five years) according to new evidence and evaluation of processes and outcomes						
4	It is defined who is responsible for updating and authorising the guidelines.						
5	The guideline is based on a recognised and validated process						

Topic 13: Compliance with guidelines

Standard 13: Compliance with guidelines is analysed annually and reported for quality improvement in a MDT

		Definition	Yes	Mostly	Partially	No	n.a.
1	Compliance with guidelines is measured						
2	There is a policy that each decision that differs from the guideline is recorded in the patient's file						
3	Deviations from guidelines are analysed						
4	Deviations from guidelines are always discussed by the MDT						
5	A summary of deviations from guidelines is reported annually by the MDT to the medical management and discussed						

Topic 14: Tasks and responsibilities of the (oncology) nurses

Standard 14: The cancer centre employs nurses formally educated in oncology whose tasks and responsibilities are defined according the level of their education

		Definition	Yes	Mostly	Partially	No	n.a.
1	For each technical, clinical or outpatient's department where patients with cancer are treated, there are nurses trained in oncology	*					
2	The cancer centre employs nurses with expertise in most of the tumours that are treated in the cancer centre	*					
3	There are job descriptions including the tasks and responsibilities of oncology nurses						
4	Roles and responsibilities of nurses with additional expertise/focus are described (e.g. palliative care, stoma care, wound dressing.)						
5	The nursing discipline has among its members a Lead Oncology Nurse	**					

* Definition nurses with expertise:
1. Board certified nurses dedicated to oncology: at least a 3 years official nurse education.
2. Specialized nurses: Nurses with an additional official education in oncology, intensive care, palliative care, tobacco science. Acting nurses (interim) should be counted.
3. advanced nurses / clinical nurse specialists and nurse practitioners dedicated to oncology: Advanced certified nurses with a degree in Nursing Oncology (Msc. or PhD.) like clinical nurse specialists and nurse practitioners.
Standard 14.1 and 14.2 are related to specialized nurses

**Definition Lead Oncology Nurse: hierarchical nurse leader/head/director specifically dedicated to oncology nursing

Topic 15: Roles and tasks of the members of the supportive care staff

Standard 15: The roles and tasks of the supportive care staff in oncology care are described

		Definition	Yes	Mostly	Partially	No	n.a.
1	Roles and responsibilities for each of the supportive disciplines are described regarding the involvement in oncology care	*					
2	Each supportive discipline has among its members one staff-member as the contact person (referent) for oncology care						

* Supportive disciplines: Psychologists, psychotherapists, social worker, mental health worker, religious care worker. The following disciplines are also considered as supportive disciplines: Dietician, speech therapist, physiotherapist, oral hygiene employees. Note: In some countries the latter disciplines are defined as paramedic disciplines. As there is often misunderstanding about the definition of paramedic and supportive disciplines the OECI considers all above mentioned disciplines as supportive disciplines.

Topic 16: Communication between disciplines

Standard 16: Communication amongst nursing, palliative care and supportive disciplines is formalised and occurs through

		Definition	Yes	Mostly	Partially	No	n.a.
1	Consultation						
2	Data transmission of patient information						
3	Training						
4	Sharing and implementation of guidelines						

Topic 17: Multidisciplinary approach and integration

Standard 17: Multidisciplinary tumour team (MDT) organisation among disciplines involved in cancer care is formalised

		Definition	Yes	Mostly	Partially	No	n.a.
1	The MDT involved in a specific tumour type or a specific condition (e.g. pain clinic) meets on a regular basis to discuss developments in care and organisation						
2	The responsibilities of the different disciplines involved in the diagnosis of the patient are defined and described (e.g. clinical pathways)						
3	The responsibilities of the different disciplines involved in the treatment of the patient are defined and described (e.g. clinical pathways)						
4	The responsibilities of the different disciplines involved in the follow-up of the patient are defined and described (e.g. clinical pathways)						
5	The responsibilities of the different disciplines involved in the survivorship care of the patient are defined and described (e.g. care pathways)						

Topic 18: Process of multidisciplinary meetings

Standard 18: Multidisciplinary tumour team (MDT) meetings follow defined criteria

		Definition	Yes	Mostly	Partially	No	n.a.
1	All patients are discussed by the cancer centre MDT at least when first referred or before any major decision in the management of the patient						
2	There is a defined procedure to inform the members of the MDT at a proper time about which patients will be discussed						
3	The inclusion of patients in clinical trials is a structural formal aspect of the MDT meeting						
4	The medical file of the patient is available during the MDT meeting						
5	The MDT meetings take place in a room with facilities to show the relevant results of the examinations (imaging, pathology etcetera)	*					
6	The conclusions and advice resulting from the MDT meeting are documented in the medical record of the patient						
7	The conclusions and advice resulting from the MDT meeting are accessible for all physicians and other disciplines involved in the care in the medical record of the patient at the very most 24 hours						
8	According to a defined procedure, the conclusions and recommendations resulting from the MDT are communicated to the patient						
9	According to a defined procedure, decisions which deviate from the MDT conclusions are documented and explained in the patient\'s medical record, and reported back to the MDT						
10	According to a defined procedure the implementation of MDT decision recorded in the patients file is designated to a named responsible person						

* Definition MDT meetings: Tumour boards are integral to improve the care of cancer patients by contributing to the patient management process and outcomes, as well as by providing education to physicians and other staff attendance. The team exist of: medical oncologist (or equivalent), radiotherapist, imaging techniques specialist, pathologist, surgical oncologist (or equivalent). Nurses take part in the multidisciplinary meetings. Supportive care disciplines can attend the multidisciplinary meetings.
Primary objectives: ensure that all appropriate diagnostic tests, all suitable treatment options, and the most appropriate treatment recommendations are generated for each cancer patient discussed prospectively in a multidisciplinary forum. Secondary: (1) Provide a forum for the continuing education of medical staff and health professionals, (2) contribute to patient care quality improvement activities and practice audit, (3) contribute to the development of standardized patient management protocols, (4) contribute to innovation, research and participation in clinical trials, (5) contribute to linkages among regions to ensure appropriate referrals and timely consultation and to optimize patient care.

1.4 Safeguarding the quality system

Topic 19: Integrated quality, risk and safety management

Standard 19: The cancer centre has a written policy for quality and risk management and safety

		Definition	Yes	Mostly	Partially	No	n.a.
1	There is a quality management policy plan including continuous quality improvement (CQI) approach	*					
2	The quality management policy plan contains risk management						
3	The quality management policy plan contains safety management of the cancer centre and its users (patients, employees and visitors)	**					
4	There is a procedure for dealing with and reporting on Serious Adverse Events (SAE) and Sudden Unexpected Serious Adverse Reactions	***					
5	A clear process for the systematic analysis of Serious Adverse Events or Undesirable Events (e.g.: morbidity and mortality reviews) is present in each clinical and technical department						

* Definition policy plan: Documents that define the scope of an organization, explain how the goals of an organization will be achieve, and/or serve as a means by which authority can be delegated.
Definition quality management: An effective system for integrating the quality development, maintenance and quality improvement efforts of the various groups in an organization so as to enable production and service at the most economical levels which allow for full customers satisfaction.

** Definition safety management: A management function directed towards the management of safety in an organisation, containing at least: Prospective risk assessments, incidents- and complication registries, feedback of relevant analyses, improvement activities and training of staff.

*** Definition serious adverse events: Adverse advent: Any unintended or unfavourable sign, symptom, abnormality, or condition temporally associated with an intervention that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.
Definition sudden unexpected serious adverse reaction: A noxious and unintended response suspected or demonstrated to be caused by the collection or infusion of a cellular product or by the product itself.

Topic 20: Quality analysis and improvement

Standard 20: The cancer centre has an integrated quality and risk management and safety requirements system

		Definition	Yes	Mostly	Partially	No	n.a.
1	There is a quality and risk dashboard of the cancer centre, with an annual evaluation of its content	*					
2	There is a monitoring system for the technical appropriate use of diagnostic and therapeutic services						
3	There is a reporting system for near miss accidents during the use of the devices and equipment						
4	All activities of the cancer centre follow, when applicable, the guidelines of Good clinical Practice, Good laboratory Practice and Good manufacturing Practice						
5	The line management is responsible for initiating improvements after analysing results of research regarding quality and risk and safety factors						

* Definition risk dashboard: A comprehensive picture of the key regulatory and internal risks faced currently and over the period of the strategic plan. This is an internal tool which facilitates discussions on the best course of action to mitigate our key risks and assists senior management in taking decisions on priorities and resource allocation

Topic 21: Quality and risk management related to introduction of new interventions and technology

Standard 21: A policy is present for the introduction of new practices

		Definition	Yes	Mostly	Partially	No	n.a.
1	Systematic risk analysis is performed before introduction of a new technology or new interventions						
2	The SOP's are updated according to a schedule and are accessible	*					
3	The SOP includes definitions how to deal with Serious Adverse Events and Sudden Unexpected Serious Adverse Reactions related to new interventions and new technologies						
4	Patients are involved in this policy						

* Definition SOP: Standard operating procedures are defined as detailed written instructions to achieve uniformity of the performance of a specific function.

Topic 22: Quality assurance

Standard 22: Quality assurance (QA) programmes are in place

		Definition	Yes	Mostly	Partially	No	n.a.
1	Quality assurance programmes are part of the policy plan for quality and risk management	*					
2	There is a quality assurance programme in the oncology healthcare area (chemotherapy, surgery, radiotherapy) that is inline with the overall policy plan for quality and risk management						
3	Overall quality assurance programmes are developed in cooperation with involved departments						
4	There is a quality assurance programme for clinical research						
5	There is a regular internal audit system						

* Definition: the quality assurance programme is not a separate programme, but is part of the quality and risk management programme (topic 19).
Definition quality assurance (QA): he actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product or service are working as expected individually and collectively.

Topic 23: Technical quality of medical equipment

Standard 23: Medical equipment are safe, efficient and accurate

		Definition	Yes	Mostly	Partially	No	n.a.
1	There is a maintenance programme for medical equipment						
2	Safety checks have been done as scheduled						
3	Calibration of medical and technical devices and equipment (biology, pathological anatomy, imaging, functional tests) are part of the maintenance contracts						
4	Calibrations have been done as scheduled						
5	Medical and technical devices and equipment used for diagnosis are periodically certified by an authorized authority						

Topic 24: Human Resource Management

Topic 24: Quality assurance (QA) policy in human resources is defined

		Definition	Yes	Mostly	Partially	No	n.a.
1	Evaluation of all employees is part of the human resources management of the cancer centre.						
2	Evaluation of all employees is done according to defined intervals						
3	The results of evaluation are documented and used for building future strategy of the institution, with alignment of the departments						
4	Relevant training is provided to all staff according to their level of responsibility						
5	Training records of all staff are available						
6	Specific psychological support is available to all cancer centre's employees						
7	The institute ensures that all employees hold current appropriate practicing certificates the appropriate licence to practice in their daily professions						

Topic 25: Privacy, protection of personal data

Topic 25: Written procedures regarding privacy and protection of personal data are present

		Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre is committed to a secure procedure for the storage, preservation, consultation and transmission of personal data according to the national/European/international regulations						
2	There is a Patient Charter that is periodically evaluated and renewed if necessary	*					
3	Personal data protection is guaranteed through a defined procedure						
4	There is a policy on informed consent that meets national law and regulations for diagnostics and treatment and research						

* Definition patient charter: An official set of principles, a document defining the commitments of both the hospital and the patient. In this Charter the hospital commits itself to respect and to guarantee the patient's privacy.

2. Prevention and early diagnosis

2 .1 Process control

Topic 26: Organisation of patient health education

Standard 26: Involvement in patient health education is organised in co-operation with external parties

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre can demonstrate participation in patient health education and prevention initiatives/programmes in co-operations with partners						

Topic 27: Oncogenetic service

Standard 27: Access to an oncogenetic clinic is available if needed

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	An oncogenetic clinic is available and accessible to all appropriate patients						
2	Formal relationships exist between the cancer centre and reference genetic laboratories						
3	Oncogenetic counselling is offered to all appropriate patients	*					
4	Guidelines for referral to oncogentic services are available						
5	Recommendations after a oncogenetic diagnosis are based on guidelines						
6	Psychologic support is offered in the oncogenetic service						

* Definition counselling: A non-directing way of advising, that can be used to support in making difficult decisions.

Topic 28: Smoking control in the cancer centre

Standard 28: The cancer centre has a non smoking policy.

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	A non-smoking policy is clearly documented and visible						
2	Any public part of the cancer centre is clearly identified as a smoke-free area						
3	Explanations about smoking regulation in the institution are available for patients						
4	Support is provided to patients to quit smoking						
5	Support is provided to workers to quit smoking						

3. Cancer treatment and care

3.1 Process control

Topic 29: Pain service

Standard 29: A protocol for pain control is implemented in the cancer centre

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Guidelines regarding pain treatment for patients with cancer are implemented in all relevant departments.						
2	There is a pain score card as part of the guidelines.						
3	The use of the pain score card is regularly assessed						
4	There is regular education for staff on pain management according to defined intervals						
5	Patients and their families receive oral and written information about any pain management.						
6	A pain team/pain consultation provides consultation to inpatients and out-patients						
7	An oncology nurse is part of the pain team						

Topic 30: Referral to supportive care disciplines

Standard 30: Agreements have been reached within the cancer centre concerning referral of patients to support disciplines

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	It is defined for which type of clinical condition (what) related to cancer supportive disciplines are consulted						
2	It is defined in the care pathway at which moments (when) supportive disciplines are consulted						
3	A procedure about the way (how) to refer or consulting supportive disciplines is defined						

Topic 31: Palliative care team

Standard 31: The composition and tasks of the palliative care team are defined in written agreements

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The composition of the palliative care team is defined	*					
2	The palliative care team intervenes on consultation requests from all inpatients departments according to a written procedure						
3	All patient cases referred for palliative terminal care are discussed during scheduled meetings with the palliative care team						
4	Services of the palliative care team are available for outpatients through consultation and/or a help line service						
5	The palliative care team provides education for patients, families and health professionals						
6	The Leading Palliative Care Specialist (LPCS) is member of the palliative care team						

* Definition palliative care: An approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual (WHO).

Definition palliative care team: The palliative care team include at least the following disciplines: physician specialised in pain treatment, physicians including psychiatry and oncology, and a nurse. Psychology, anaesthesiology, physiotherapy, social work, general practitioner and dietician are regularly included.

Topic 32: Palliative care

Standard 32: Palliative care is organised according to written procedures

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre uses guidelines on palliative care						
2	Written procedures exist on referral of patients to palliative care						
3	Agreements exist with other (cancer) centre(s) for transferring patients at the end of their life, if necessary						
4	Services provided by the cancer centre after patients are discharged are clearly defined						
5	Information about these services are provided to all patients at the end of life, relatives and involved professionals.						
6	Structured procedures, including screening methods, are used to refer patients to the palliative care team						

Topic 33: Psycho-oncology service

Standard 33: Cancer patients have structured access to psycho-oncology services

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There is a psycho-oncology service with competence in oncology psychiatry and psychology	*					
2	Structured screening methods are used to refer patients to the psycho-oncology team						
3	Procedures about the way to refer the patients to the psycho-oncology service, including patients in psychological distress, are defined						
4	Training in detection of patients with psychological suffering or distress is provided regularly for the staff.						

* Definition psycho-oncology service: Oncological psychiatry and psychology.

Topic 34: Social counselling

Standard 34: Providing social counselling to oncology patients is organised according to a guideline or policy

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Social counselling by social workers is available and accessible for all cancer patients following a guideline or policy	*					

* Definition counselling: A non-directing way of advising, that can be used to support in making difficult decisions.

Topic 35: Involvement of relatives

Standard 35: Arrangements for involvement of relatives are defined

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	In agreement with the healthcare team, the family can participate in certain personal activities (e.g. meals, washing).						
2	Each ward offering care has a room for meeting with the relatives.						
3	Visiting time restrictions are lifted and arrangements for relatives to stay/sleep.						
4	Nurses provide education to family to help the patients						

Topic 36: Support to children and family of cancer patients

Standard 36: Support to children of a cancer patient is defined

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Staff are trained to support families whose parent has cancer according to guidelines						
2	Staff are trained to support families whose parent is dying according to guidelines						
3	Specific support is organised for children of patients						
4	Families are proactively informed on the available support						

Topic 37: Rehabilitation

Standard 37: There is access to a rehabilitation (external) unit with uni- and multidisciplinary interventions specially for cancer patients

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There is access to a functional rehabilitation department focussing on cancer patients which includes psychosocial and physical rehabilitation						
2	There is a defined procedure for referral to cancer rehabilitation within and outside the institution	*					
3	The rehabilitation unit manages and offers the physical and psychosocial rehabilitation during the cancer trajectory, including: Rehabilitation pre-treatment, during treatment, post-treatment (curative) and in the (prolonged) palliative phase						

* Definition rehabilitation: Systematic (para)medical and supportive activities aimed at improving capacities and functioning.

Topic 38: Reconstructive surgery

Standard 38: Reconstructive surgery is offered to all appropriate patients

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Reconstructive surgery is offered and accessible to all appropriate patients	*					
2	The person(s) in charge of providing information on reconstructive surgery are identified						
3	Patient information about reconstructive surgery is provided in the cancer centre						
4	This patient information includes the potential risks						
5	The potential combination of immediate reconstructive surgery during surgery is offered to the patient if appropriate.						

* Definition reconstructive surgery: The use of surgery to reconstruct damaged or malformed tissues or organs.

4. Research, innovation and development

4.1 Policy and organization

Topic 39: Strategic plan/policy for oncology research

Standard 39: The research strategy plan is regularly updated

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There is a regularly updated research strategy plan						
2	The cancer centre research performance is regularly evaluated in a (scientific) report						
3	The research vision and strategy plan are integrated into the overall strategy of the cancer centre						

Topic 40: Organizational and hierarchical structure

Standard 40: The organizational responsibilities within the research, innovation and development structure are clearly defined

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There is a defined organizational structure specifically for research, innovation and development						

Topic 41: Research collaboration

Standard 41: The cancer centre is part of a research network

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre has a strategy on collaboration and networking in research						
2	The cancer centre participates in national and international research projects						
3	The cancer centre coordinates international research projects						

Topic 42: Organisation of clinical research

Standard 42: Tasks of the clinical research management unit and institutional review board (IRB) are defined

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Standard about IRB (Institutional review board). There is an IRB to evaluate clinical trial proposals.						
2	There is a written procedure to evaluate clinical trial proposals.						
3	There is a dedicated institutional clinical research management unit						
4	The unit has an annual plan						
5	The unit provides a policy for promoting clinical trials, including public information on trial availability.						
6	The unit ensures that clinical trials are conducted according to the trial protocols						
7	The unit ensures administrative, scientific and ethical/legal review and approval of new clinical trials						
8	The unit coordinates and monitors the clinical research activities as well as their financial management.						
9	The unit keeps an up-to-date database about clinical trials						
10	The unit provides an annual report on clinical trial activities, treatment outcomes and side effects.						
11	Personal data protection is guaranteed for patients in clinical trials						

Topic 43: Scientific interaction and integration

Standard 43: Structural co-operation between researchers and clinicians is organised

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Regular briefing of research activities and results is organised through information sharing and meetings for researchers and clinicians						
2	Integration of research activities into clinical activities is organised, including opportunities for clinicians to do translational research						

Topic 44: Research talent development

Standard 44: There is a policy for research talent development

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There are policies in place for active research talent development including exchange programmes						

Topic 45: Grant proposals

Standard 45: There is a procedure for dealing with grant proposals

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There is an internal review of grant proposals before submission to the funding organization	*					
2	There is an internal evaluation of the success of the grant proposals						

* Definition: Systematic activities related to internal formal review of grant proposals to ensure adequate quality levels.

Topic 46: Prevention and detection and handling of scientific misconduct

Standard 46: There is a procedure in case of (suspected) scientific misconduct

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There is a procedure for dealing with scientific misconduct	*					

* Definition scientific misconduct: the suspicion of fraud in any part of a research project or use of material from other authors without proper citation.

4.2 Recourses and materials

Topic 47: Means for conducting research activities

Standard 47: A planning and control cycle for conducting research activities is defined

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer research budget is defined each year						
2	The cancer centre provides access to facilities for research activities						
3	The cancer centre provides resources and means for research activities						
4	Procedures for the allocation of funding for research activities are defined						
5	The use of financial resources and accounting of research activities is controlled, monitored and reported						

Topic 48: Intellectual property and innovation

Standard 48: There are policies for protection of intellectual property and innovation

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Innovation strategy is an explicit part of the strategic plan of the centre						
2	Support for protection and exploitation of intellectual property is provided						
3	Support for business development of research projects is provided						
4	There is a technology transfer service available	*					

* Definition technology transfer service: A service available for or within the organisation that focusses on comprehensive performance improvement solutions for the organisation and maintenance.

Topic 49: Biobank

Standard 49: Biobanking is subject to defined procedures

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre has a policy for biobanking patient related samples						
2	There is a SOP defining the collection, the storage, the registration and the use of the biological samples						
3	There is a centralized database of the biological material						
4	The biobank database is linked to the clinical database						

4.3 Process control

Topic 50: Scientific programme

Standard 50: A scientific knowledge transfer programme is available in the cancer centre

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There is a structured, documented and up to date scientific programme in the cancer centre through colloquia, seminars or theme-specific conferences						
2	There are procedures in place to ensure that scientific results from research community will be translated into daily practice timely; (e.g.) diagnostic tools, treatment or prevention						
3	The cancer centre supports and fosters research and innovation in the field of pain, psycho-oncology, and palliative care	*					

* Research projects with internal and external funding are provided in a list.

Topic 51: Periodical external site visit / review

Standard 51: Periodical external site visit / review in the research is organised

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	An external Scientific Advisory Board (SAB) meets at least every two years and advises the cancer centre on its (cancer) research strategy and activities						
2	There is a periodical external site visit / review, for the total research organisation						
3	There is a periodical external site visit / review, for each research group/team activities						
4	There is a periodical external site visit / review, for clinical/translational research						
5	There is a periodical external site visit / review, for research support facilities						

5. Teaching and continuing education

5.1 Policy and organization

Topic 52: Analysing oncology training needs

Standard 52: The cancer centre analyses the specific training and oncological continuous education needs to define an annual or multi-annual training programme

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre analyses the specific training and oncological continuous education needs regularly						
2	Based on the analysis, the institution defines an annual or multi-annual oncology training programme for physicians						
3	Based on the analysis, the cancer centre defines an annual or multi-annual oncology training programme for researchers						
4	Based on the analysis, the cancer centre defines an annual or multi-annual oncology training programme for nurses						
5	Based on the analysis, the cancer centre defines an annual or multi-annual oncology training programme for supportive disciplines (psychologists etc.)						
6	Based on the analysis, the cancer centre defines an annual or multi-annual oncology training programme for other disciplines (please specify in the note)						

5.2 Process control

Topic 53: Undergraduate academic education

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre provides undergraduate education for medical students						
2	The cancer centre provides undergraduate education for nursing students						
3	The cancer centre provides undergraduate education for supportive discipline students						
4	The cancer centre provides undergraduate education for other disciplines (please specify in the note)						
5	The cancer centre collects the feedback about the quality of the education						
6	The cancer centre analyses the feedback about the quality of the education						

Topic 54: Postgraduate academic certification

Standard 54: The cancer centre provides education for postgraduate certification

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre provides training for postgraduate certification for specialised physicians						
2	The cancer centre provides training for postgraduate certification for specialised nurses						
3	The cancer centre provides training for candidates (physicians /nurses/others) for higher degree (MSc, PhD, etcetera)						
4	The cancer centre collects the feedback about the quality of the postgraduate education						
5	The cancer centre analyses the feedback about the quality of the postgraduate education						

Topic 55: Education in oncology

Standard 55: The cancer centre provides or is involved in primary education in oncology

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre provides education in oncology for physicians (including palliative care and psycho-oncology)						
2	The cancer centre provides education in oncology for nurses (including palliative care and psycho-oncology)						
3	The cancer centre provides education in oncology for supportive disciplines						
4	The cancer centre provides education in oncology for other disciplines (please specify in the note)						
5	The cancer centre collects the feedback about the quality of the education						
6	The cancer centre analyses the feedback about the quality of the education						

6. Patient centeredness

6.1 Process control

Topic 56: Organisation management

Standard 56: Sustainability of and facilities for patient education

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There are policies and procedures in place for patient education programmes where responsibilities and accountabilities of the staff are stated						
2	There is an official plan for patient education programmes that aim at improving patient understanding of their illness, diagnosis, including information on how to manage multiple aspects of their illness (e.g.: side effects, disability,...). It is periodically updated (at least every 3 years)						
3	A research and information centre (e.g. Patient Library) is available for staff, patients, family members and caregivers						

Topic 57: Patients empowerment

Standard 57: It is the mission of the institute to encourage patient empowerment

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The institute involves patients and patients\'/ voluntary associations in the planning and organization of services						
2	The institute and its staff produces/provides information material that is readable, up-to-date, appropriate and available in languages commonly spoken by the population served						

Topic 58: Educational material

Standard 58: Up to date (written) educational material is provided to patients and general practitioners

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Written information on relevant aspects of oncology is provided to the patients						
2	The written information includes information about diagnostic examinations and methods of treatment						
3	The written information includes information about follow-up after treatment						
4	The written information includes information about clinical trials						
5	The written information includes information about supportive care						
6	The written information includes information about palliative care						

Topic 59: Inform patients on admission

Standard 59: Cancer patients are informed about the cancer centre admission procedures

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	Detailed updated written information about the admission procedure is available and communicated to the patient						
2	Information about patients associations and about self help groups is given during the admission procedure						

Topic 60: Patient information

Standard 60: There are agreements on informing patients about the diagnostic results, treatment and follow-up, counselling, and survivorship care

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	There are procedures in place including by whom and how patients are informed on their diagnostics, treatment and follow-up, survivorship care and counselling						
2	Expertise and if necessary specific training on communication with patients, adequate sources of information and communication strategies is available for staff						
3	The information communicated to the patient is recorded in the patient\'s record, such as information about the further treatment that can be expected, the plan of treatment, about requesting a consultation of another medical specialist, the consequence of potential side effects, the advanced care plan						
4	There is a policy on access for patients to their own patient record						
5	If patients are referred to another institution, they are clearly informed about the continuity of their care and who will be responsible for the continuation						
6	The patient receives information about the contact person for all oncology matters						
7	Patients are informed about the physician coordinating their medical management						
8	The patient receives the contact information in case of emergency						

Topic 61: Discharge procedure, follow-up and survival ship care planning

Standard 61: Policy about a discharge procedure is defined

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	A written discharge procedure is available						
2	The discharge procedure is regularly assessed according to defined intervals						
3	Information is provided to the patients about home care						
4	Information is provided to the patients about treatment and follow-up plans						
5	All information regarding above discharge information is accessible online						
6	Policies are defined about who is responsible for developing the individual survivorship care plan with the patient						
7	Patients are informed about their individual survivorship care plan						

6.2 Safeguarding the quality system

Topic 62: Patient satisfaction / experiences

ard 62: The patient's experience related to cancer care is an integrated part of the quality improvement system of the centre

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre has a survey method for obtaining the patients' opinion about their experiences during consultation						
2	The cancer centre has a survey method for obtaining the patients' opinion about their experiences during day care						
3	The cancer centre has a survey method for obtaining the patients' opinion about their experiences during hospitalisation						
4	The survey is regularly analysed						
5	The survey analyses are reported and discussed regularly in a medical and administrative setting						
6	There is a patients committee representing patients and serving as a link between the cancer centre and the patients for advisory and consultation	*					
7	The patients committee gives consultative advice about quality of services and risk management						

* Definition patients committee: A committee containing of patients which is involved in organisations decisions with direct or indirect consequences on patients care.

Topic 63: System for receiving and managing complaints

Standard 63: The cancer centre has an identified conciliator (or a conciliatory commission), for complaints related to cancer care

	Sub standards	Definition	Yes	Mostly	Partially	No	n.a.
1	The cancer centre has a clearly identified conciliator or a conciliatory commission (sometimes known as a mediator or mediation service, or as the complaints officer or complaints department)	*					
2	The conciliator replies to any request for information or complaints from the patients or their family.						
3	The actions undertaken by the conciliator are recorded in a file that is used to produce an annual report						
4	The conciliator gives feedback on his/her findings to the professional who is the subject of the complaint.						

* Definition conciliatory commission: Commission within a care institution responsible for the adoption, analysing and handling of complaints of patients and/or their families.

Accreditation and Designation

Appendix III

Quantitative Questionaire

Appendix III. Quantitative Questionaire

Table of content

1. General Questions

1.1 Cancer Centre

1.1.1 Name of the cancer centre: _____

1.1.2 Address: _____

1.1.3 Postal code: _____

1.1.4 Town/City: _____

1.1.5 Country: _____

1.1.6 Telephone: _____

1.1.7 Fax: _____

1.1.8 Internet site: _____

1.1.9 Menbership

	Yes	No
OECI (full or associate) member		

1.2 Management

1.2.1 Management of the cancer centre

Manager	Name	E-mail	Phone number
Administrative Director			
Medical Director			
Scientific Director			
Quality Director			
Nurse Director			

1.3 Management of the university hospital

1.3.1 Management of the university hospital (if the cancer centre is part of a university hospital)

Manager	Name	E-mail	Phone number
Administrative Director			
Medical Director			
Scientific Director			
Quality Director			
Nurse Director			

1.4 Project leader and survey contact person

1.4.1

	Name	Position	E-mail	Phone number
Project leader for A&D project in the cancer centre				
Contact person for the A&D surveys in the cancer centre				

1.4.2 Please specify the index year you are reporting the data on

All relevant data as reported in this questionnaire must originate in the same year: _____

1.5 Oncology activity

1.5. Number of patients newly diagnosed

Number of patients newly diagnosed in the cancer centre or elsewhere in the index year which were treated in the cancer centre* : _____

** Number of patients newly diagnosed reflects the number of patients coming to the cancer centre, not the number of visits. Generally, a patient is counted as newly diagnosed for the index year, if diagnosis was confirmed that year (usually the date of the histological/cytological report). Do not include patients with recurrent disease. Definition of "treated in the cancer centre" is that therapy planning and the main part of the therapy take place in the cancer centre*

1.6 Administrative status

1.6.1 Administrative status

	Academic	Public/non profit	Private
What is the administrative status of your cancer centre?			

1.7 Preliminary designation

1.7.1 Preliminary designation aspects

	Select the appropriate answer
Is your centre covered by the three treatment facilities surgery oncology, radiotherapy and medical oncology, and research and education ?	Yes No
Annual budget for cancer care in previous year	≤ 25 million Euro Between 25 and 50 million Euro ≥ 50 million Euro
Annual budget for cancer research in previous year	≤ 8 million Euro > 8 million Euro
Sum of the number of inpatient hospital beds plus the number of beds/chairs in the ambulatory day hospital	≤ 100 Between 100 and 150 ≥ 150
Number of FTE physicians dedicated to cancer	≤ 30 Between 30 and 50 ≥ 50
Number of new cancer patients per year*	≤1500 Between 1500 and 2500 ≥ 2500
Number of peer-reviewed scientific publications	≤ 125 > 125
Number of scientific publications with an impact factor (IF) over 10	≤ 17 > 17
Number of scientific publications with an impact factor (IF) between 5 and 10	≤ 50 > 50
Number of studies active - currently open for patient accrual	≤ 75 > 75
Does these open studies contain studies in as well as Phase I and Phase II and Phase III and Phase IV?	Yes No
Percentage of patients included in clinical trials**	≤ 10% > 10%

** Definition: The number of patients with a diagnosis of cancer who are newly managed in the cancer centre in the index year. This includes new patients managed in the cancer centre for recurrent disease after previous treatment elsewhere. A patient with a new (second or n) cancer may be counted again*
"Managed" means that the patient has been treated even partially (ex: only radiotherapy) or simply followed (no additional treatment needed) in your centre. It does not include patients just coming for a second opinion without being afterwards followed in the centre. Number of patients newly diagnosed reflects the number of patients coming to the cancer centre, not the number of visits. Generally, a patient is counted as newly diagnosed for the index year, if diagnosis was confirmed that year (usually the date of the histological/cytological report)
*** Definition: Percentage = total number of patients enrolled on prospective clinical studies (excluding observational studies) in an index year / total number of patients with a diagnosis of cancer who are newly managed in the cancer centre in the same index year*

1.7.2 Designation categories

	Clinical Cancer Centre	Comprehensive Cancer Centre (CCC)
In which category would you classify your cancer centre (based on the OECI definitions of the different categories)?		

1.7.3 Explanation

Clinical Cancer Centre is characterized as an organisational entity covering a sufficient degree of all medical, surgical and radiotherapy services and a limited degree of clinical research.

Comprehensive Cancer Centre (CCC) is probably the hardest category to define as many different interpretations on a CCC already exist. Based on available information and many definitions on the concept of a CCC, the following features are considered to be essential for this particular category:

– An identifiable organizational entity with a circumscriptive governance and budget

– A highly innovative character and multidisciplinary approach using the potential of basic, translational and clinical research and clinical facilities and activities, organized in a sufficiently identifiable entity

– A direct provision of an extensive variety of cancer care tailored to the individual patient's needs and directed towards learning and improving the professional, organizational and relational quality of care

– Broad activities in the area of prevention, education, and external dissemination of knowledge and innovation. In order to accentuate the differences with other cancer centres, a CCC separates itself in the following points:

- High level of infrastructure, expertise and innovation in the field of (translational) oncology research
- Maintenance of an extensive network including all aspects of oncology treatment and research, including translational research
- Related to an academic/university centre or is an academic centre

1.8 Networking

1.8.1

	Yes	No
Is your cancer centre part of a formalized oncology network of institutions at regional level		
Is your cancer centre part of a formalized oncology network of institutions at national level		

1.9 Collaboration

1.9.1

	Yes	No
Does your cancer centre formally collaborate with: general practitioners. If yes, please specify in the notes how.		
Does your cancer centre formally collaborate with: home care organisations. If yes, please specify in the notes how.		
Does your cancer centre formally collaborate with: nursing homes. If yes, please specify in the notes how		
Does your cancer centre formally collaborate with: structures of the local palliative care network. If yes, please specify in the notes how		

1.10 Screening and prevention

1.10.1

	Yes	No
Is your cancer centre involved in and/or participates in structured national screening programmes. If yes: please specify in the notes to what extend		

1.10.2 National screening programmes

In which national screening programmes does the institute participate?

1.10.3 Primary prevention

	Yes	No
Is your cancer centre involved in and/or participates in structures primary prevention programmes?		

1.11 Accreditation status and auditing

1.11.1

	Yes	No
Is your cancer centre general accredited by a national accreditation organisation?* If yes, specify in the note by which organization.		
Is your cancer centre accredited by another organisation on institutional level? If yes, specify in the note by which organisation		

** General means on institutional level*
*** Note: Accreditation/ certification on department/ service level is asked later on in this questionnaire*

1.11.2. Year of previous General accreditation (year and kind of accreditation programme):

Please provide the report in the requested documents questionnaire

1.11.3 Does your institute perform internal audits on

	Yes	No
Administration/organisation level		
Clinical procedures		
Quality and safety indicators		
Research SOP's		
Others (please, specify in the notes)		

1.12 Distribution areas and budget

1.12.1 Distribution areas

% regional patient's of the total number of patients*:

% national patient's of the total number of patients*:

% international patient's of the total number of patients*:

The size of the population served by the cancer centre.

1.12.2 Budget

Planned annual budget for oncology health care in the year specified (Euros): _____

Planned annual budget for oncology research in the year specified (Euros): _____

Planned annual budget for education in the year specified (Euros): _____

2 Infrastructures: cancer centre level

2.1 General numbers

2.1.1 New patients in the cancer centre

Number of new patients in the cancer centre in the index year*: _____

** Definition: First contact with at least a registered consultation within the index year, independent whether the patient has cancer or not. Technical procedures are not included. Screening consultation are not included*

2.1.2 Patients newly diagnosed

Number of patients newly diagnosed in the index year*: _____

** Definition: The number of patients with a diagnosis of cancer who are newly managed in the cancer centre in the index year. This includes new patients managed in the cancer centre for recurrent disease after previous treatment elsewhere. A patient with a new (second or n) cancer may be counted again. Reflect the number of patients coming to the cancer centre, not the number of visits. Generally, a patient is to be counted as - newly diagnosed - for the index year, if diagnosis was confirmed that year (usually the date of the histological/cytological report)*

2.1.3 Patients treated in the cancer centre

Number of all patients treated in the cancer centre in the index year*: _____

** Definition: Number of all cancer patients treated in the cancer centre in the index year. Reflect the number of patients coming to the cancer centre, not the number of visits. A patient is to be counted for the index year, if he/she was treated for a principal diagnosis of cancer between 1 January and 31 December. Do not include any patient more than once unless they have been treated for two malignancies in the index year. All patients should be counted regardless of whether they have a newly diagnosed cancer or have recurrent disease or newly appeared metastases and were referred to the cancer centre for further evaluation and primary or secondary treatment. This category excludes consultations (e.g., for service or second opinions), diagnoses at autopsy, and former patients admitted for rehabilitation purposes or treatment of some other conditions. It also excludes patient follow-up activities after treatment is completed*

2.1.4 Patients on consultation for a second opinion

Number of patients on consultation for a second opinion (any type)*: _____

** Definition: These patients are not included in the number of newly diagnosed cancer patients*

2.1.5 Number of inpatients for overnight stays

Number of inpatients for overnight stays (total oncology)* _____

**Definition: Number of hospitalisations (not the number of patients) > 1 day (without taking into account the reason of their stay). All patients are considered, whether they have cancer or not. "inpatient"= a patient hospitalized > 24 hours*

2.1.6 Number of inpatients for overnight stays

	surgery oncology	medical oncology	radiation therapy	paediatric oncology	haematology	other units	ICU	total (oncology)
Number of inpatient beds for overnight stays in the index year								
Number of outpatient visits in consultation in the index year								
Number of ambulatory day care beds and chairs in the index year								
Number of ambulatory visits for 1 day stays in the index year								

2.2 General number of staff

2.2.1

	surgery oncology	medical oncology	radiation therapy	paediatrics	haematology	other units	total (oncology)
FTE physicians dedicated to oncology (into human resources) *							
Number of FTE board certified nurses dedicated to oncology **							
Number of FTE specialized nurses ***							
FTE board certified clinical nurse specialists and nurse practitioners dedicated to oncology ****							

** Definition FTE: Full time equivalent. Encompassing clinical as well as research activities*

*** Definition: Basic/general nurse with (at least) three years official certified education. Acting nurses (interim) should be counted*

**** Definition: Nurses with an additional official education in oncology, intensive care, palliative care, tobacco science. Acting nurses (interim) should be counted*

***** Definition: Advanced certified nurses with a degree in Nursing Oncology (Msc. or PhD.)*

2.3 Waiting times in guidelines and actual waiting times

2.3.1

	surgery oncology	medical oncology	radiation therapy	paediatric oncology	haematology	other units	total (oncology)
Maximum allowed waiting time from 1st contact to 1st visit (days)*							
Actual waiting time from 1st contact to 1st visit in the cancer centre (days)**							
Maximum allowed waiting time first visit-definitive diagnose (days)***							
Actual waiting time first visit-definitive diagnose in the cancer centre (days)****							
Maximum allowed waiting time definitive diagnose – start treatment (days)*****							
Actual waiting time definitive diagnose – start treatment in the cancer centre (days)******							

**The maximum allowed waiting time as described in the adopted guidelines. Waiting time between date of consultation request by mail/telephone etc and date of consultation*

***Real waiting time between date of consultation request and date of consultation; only for new patients; Do not count technical examination as a consultation*

****The maximum allowed waiting time as described in the adopted guidelines. Definitive diagnosis may be the date of PA/lab-result OR the date of Multidisciplinary Team Meeting in which the decision was taken (please specify in the note)*

*****Real waiting time between date of consultation until the definitive diagnosis. Definitive diagnosis may be the date of lab (PA) - result OR the date of Multidisciplinary Team Meeting in which the decision was taken. (please specify in the note)*

******The maximum allowed waiting time as described in the adopted guidelines*

*******Time between the date of Multidisciplinary Team Meeting in which the decision was taken and further hospitalization (1-day or admission) OR Radiotherapy procedure. Give two figures: median and percentile 95%. Hormon-therapies are excluded. Patients with new tumours and patients relapsing/progressive disease will be considered separately*

2.4 Infrastructures: tumour organization

2.4.1 Multidisciplinary tumour teams

1	2	3	4	5	6	7	8	9	10
MDT	**Tumour types**	**Frequency**	**Duration**	**Disciplines present or on request**	**Coordinator /secretary (Y/N)**	**Nr. of MDT recommendations**	**Recommendations per year**	**MDT Recommendation pre-therapeutic (%pt)**	**MDT Recommendation post-interventional (%pi)**

1. *MDT: Provide the name of the team*
2. *Tumour types that are discussed in the team (by ICD-nr)*
3. *Frequency and when: Indicate how often the team meets (e.g. weekly, monthly, every second week, each Monday)*
4. *Duration: Indicate the duration of the MDTmeetings (e.g. 1 hour, 30 minutes*
5. *Disciplines: Select the disciplines that are present in the team as member or on request*
6. *Does the team has an appointed coordinator or secretary?*
7. *Recommendations: Indicate the average number of MDT recommendations per meeting in index year*
8. *Provide the total number of MDT recommendations in index year (a patient can appear more than once, if he/she had more than one MDT discussion and received more than one recommendation)*
9. *MDT recommendation pre-therapeutic: Indicate the percentage of MDT recommendations coming from pre-therapeutic (% pt)*
10. *MDT recommendation post-interventional: Indicate the percentage of MDT recommendations coming from post-interventional/post-operative discussions/ discussions during therapy (% pi)*

2.5 Guidelines and clinical pathways

2.5.1

Tumour type / ICD-10 numbers	Working with guidelines (institutional/ local / national/ international) ADD NAME and ORIGINE of guideline(s)	Clinical pathways available?
Tumour type / ICD-10 numbers		
Breast cancer C50		
Lung cancer C34		
Urological cancer: bladder C67		
Urological cancer: kidney C64H		
Male genital organs cancer: prostate C61H		
Male genital organs cancer: testis C62		
Male genital organs cancer: others (specify in the notes)		
Gastrointestinal cancer: oesophagus C15		
Gastrointestinal cancer: stomach C16		
Gastrointestinal cancer: colon C18		
Gastrointestinal cancer: rectum C20H		
Gastrointestinal cancer: liver C22		
Gastrointestinal cancer: pancreas C25		
Gastrointestinal cancer: others (specify in the notes)		
Gynaecological cancer: ovary C56H		
Gynaecological cancer: cervix C53		
Gynaecological cancer: endometrial C54		
Gynaecological cancer: others (specify in the notes)		
Head and neck cancer: larynx C32		
Head and neck cancer: C00-C14 (oropharynx C10, nasapharynx C11, hypopharynx C13, others)		
Head and neck cancer: thyroid C73H		
Haematological malignancies: hodgkin lymfoma C81		
Haematological malignancies: non hodgkin lymfoma C82		
Haematological malignancies: myeloma C90		
Haematological malignancies: all leukaemias		
Neuro-oncological: central nervous system C71-C72		
Neuro-oncological: others (specify in the notes)		
Paediatric malignancies: all cancers (age 0<15)		
Bone and soft tissue tumours: primary bone C40		
Bone and soft tissue tumours: soft tissue C49		
Skin cancer: melanoma of the skin C43		
Skin cancer: others C44 (please specify in the notes)		

2.5.2 Please provide a list of the existing mdt's including their members, number of meetings per period, procedures and clinical pathway

2.6 National requirements

2.6.1

	Yes/No	What is the name of the regulator?
Is your cancer centre obliged by national regulators to meet national volume criteria?*		

**Definition: In few countries health care providers (cancer centres and hospitals) are obliged by national regulators to treat a minimum number/volume of patients per cancer type per year. For example in order to be approved to provide the treatment*

2.6.2.

	Yes/No	If yes, to what definition does the obliged number refer? **
Are there specific minimum requirements for one or more of the following tumours (2.6.3)?*		

**Definition: If there are no requirements in your country the rest of the table cannot be answered*
***Definition: for example to: Minimum number of primary cases per year / Minimum number of treatments (what kind of treatment) / Other definition (please specify)*

2.6.3 Are there specific minimum requirements for the following tumours?

	Yes/No	If yes, what is the obliged minimum number for your centre?	What is the actual number in your centre?
Breast cancer C50			
Lung cancer C34			
Urological cancer: bladder C67			
Urological cancer: kidney C64H			
Male genital organs cancer: prostate C61H			
Male genital organs cancer: testis C62			
Male genital organs cancer: Others (specify in the notes)			
Gastrointestinal cancer: oesophagus C15			
Gastrointestinal cancer: stomach C16			
Gastrointestinal cancer: colon C18			
Gastrointestinal cancer:rectum C20H			
Gastrointestinal cancer: liver C22			
Gastrointestinal cancer: pancreas C25			
Gastrointestinal cancer: Others (specify in the notes)			
Gynaecological cancer: ovary C56H			
Gynaecological cancer: cervix C53			
Gynaecological cancer: Others (specify in the notes)			
Head and neck cancer: larynx C32			
Head and neck cancer: hypopharynx C13			
Head and neck cancer: oropharynx C10			
Head and neck cancer: nasopharynx C11			
Head and neck cancer: thyroid C73H			
Head and neck cancer: others (specify in the notes)			
Haematological malignancies: Hodgkin Lymfoma C81			
Haematological malignancies: Non Hodgkin Lymfoma C82			
Haematological malignancies: Myeloma C90			
Haematological malignancies: all leukaemias			
Neuro-oncological: Central nervous system C71-C72			
Neuro-oncological: Other (specify in the notes)			
Paediatric malignancies: all cancers (age 0<15)			
Bone and soft tissue tumours: primary bone C40			
Bone and soft tissue tumours: Soft tissue C49			
Skin cancer: melanoma of the skin C43			
Skin cancer: Others C44 (specify in the notes)			

2.7 Tumour treatment demand and national standards

2.7.1

What is the source of the data provided?* _____

_____

_____

** Definition: for example national cancer registry/ regional cancer registry/ hospital information system/ others*

2.7.2

Tumour type / ICD-10 numbers	Number of patients newly diagnosed*	Number of all patients treated in the cancer centre**	Number of patients who had a resection	Re-surgery within 30-days	Radiation oncology (Number of patients)	Chemotherapy (Number of patients)
Breast cancer C50						
Lung cancer C34						
Urological cancer: bladder C67						
Urological cancer: kidney C64H						
Male genital organs cancer: prostate C61H						
Male genital organs cancer: testis C62						
Male genital organs cancer: Others (please specify in the notes)						
Gastrointestinal cancer: oesophagus C15						
Gastrointestinal cancer: stomach C16						
Gastrointestinal cancer: colon C18						
Gastrointestinal cancer: rectum C20H						
Gastrointestinal cancer: liver C22						
Gastrointestinal cancer: pancreas C25						
Gastrointestinal cancer: Others (please specify in the notes)						
Gynaecological cancer: ovary C56H						
Gynaecological cancer: cervix C53						
Gynaecological cancer: endometrial C54						
Gynaecological cancer: Others (please specify in the notes)						
Head and neck cancer: larynx C32						
Head and neck cancer: hypopharynx C13						
Head and neck cancer: oropharynx C10						
Head and neck cancer: nasopharynx C11						
Head and neck cancer: thyreoid C73H						
Head and neck cancer: others (please specify in the notes)						
Haematological malignancies: Hodgkin Lymfoma C81						

Haematological malignancies: Non Hodgkin Lymfoma C82						
Haematological malignancies: Myeloma C90						
Haematological malignancies: All leukaemias						
Neuro-oncological: Central nervous system C71-C72						
Neuro-oncological: Others (please specify in the notes)						
Paediatric malignancies: all cancers (age 0<15)						
Bone and soft tissue tumours: primary bone C40						
Bone and soft tissue tumours: Soft tissue C49						
Skin cancer: melanoma of the skin C43						
Skin cancer: Others C44 (please specify in the notes)						

**Definition: The number of patients with a diagnosis of cancer who are newly managed in the cancer centre in the index year. This includes new patients managed in the cancer centre for recurrent disease after previous treatment elsewhere. A patient with a new (second or n) cancer may be counted again. Reflect the number of patients coming to the cancer centre, not the number of visits. Generally, a patient is to be counted as - newly diagnosed - for the index year, if diagnosis was confirmed that year (usually the date of the histological/cytological report). Do not include patients with recurrent disease*

***Definition: Number of all cancer patients treated in the cancer centre in the index year. Reflect the number of patients coming to the cancer centre, not the number of visits. A patient is to be counted for the index year, if he/she was treated for a principal diagnosis of cancer between 1 January and 31 December. Do not include any patient more than once unless they have been treated for two malignancies in the index year. All patients should be counted regardless of whether they have a newly diagnosed cancer or have recurrent disease or newly appeared metastases and were referred to the cancer centre for further evaluation and primary or secondary treatment. This category excludes consultations (e.g., for service or second opinions), diagnoses at autopsy, and former patients admitted for rehabilitation purposes or treatment of some other conditions. It also excludes patient's follow-up activities after treatment is completed*

2.7.3

Total number of direct reconstruction _____

Number of breast conserving reconstruction _____

2.8 Availability of outcome data

2.8.1

The objective is to check whether the centre collects the necessary data and has established a methodology and process for the calculation of these data and monitoring of the outcome of the patients. These outcome data are not meant for comparing outcome performances among cancer centres. Each centre might use different calculation methods. We require the centre to explicit clearly the calculation method used, allowing to understand which patients and which data have been used to calculate the survival outcomes; when the data is not applicable or not available, please explain the reason why

2.8.2 Follow-up data

What kind of follow-up data is available?* _____

_____

_____

Definition: Please provide information as projects (per tumour) related to collecting/ analysing follow-up data. Specify which projects / which tumours / which data is collected (for example 1 year/5 year survival).

2.8.3 Specifically for the following tumours:

	Breast cancer C50	Lung cancer C34	Male genital organs cancer: prostate C61H	Gastrointestinal cancer: colon C18	Skin cancer: melanoma of the skin C43
% patients with an available survival*					

** Definition: select all the patients in the last year available.*

2.8.4 Specifically for the following tumours:

	Breast cancer C50	Lung cancer C34 prostate C61H	Male genital organs cancer: colon C18	Gastrointestinal cancer: skin C43	Skin cancer: melanoma of the skin C43
	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
Do you know if patients are alive or not?					
Do you know the recurrent status?					
Do you have survival rates per Stage (since definitive diagnoses)?					

2.8.5 Specifically for the following tumours:

	Breast cancer C50				Lung cancer C34				Male genital organs cancer: prostate C61H				Gastrointestinal cancer: colon C18				Skin cancer: melanoma of the skin C43			
Stage	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV
1-year survival (from definitive diagnoses) (%)																				
3- year survival (from definitive diagnoses) (%)																				
5- year survival (from definitive diagnoses) (%)																				

2.9 Radiotherapy

2.9.1 Radiotherapy department

	Yes	No
Is the department certified?		

2.9.2 If yes: According to which standards/system?: _____

2.9.3 If yes: When was the last external visit?: _____

2.9.4

	Number of linear accelerators for radiation therapy	Number of cobalt units	Do you have recourses for cyberknife?	Do you have recourses for proton therapy?	Do you have other special radiation devices? (pleas specify in the notes)	Do you have brachy therapy available	Number of IMRT*	Number of stereotactic RT (single and fractionated) **
Data related to the radiotherapy department								

** Definition IMRT: Intensity Modulated Radiation Therapy, please select the patients per year*
*** Select the patients per year*

2.10.Radiology

2.10.1. Radiology department

	Yes	No
Is the department certified?		

2.10.2 If yes: According to which standards/system?: _____

2.10.3 If yes: When was the last external visit?: _____

2.10.4 Number of CT scanners: _____

2.10.5 Specify number of slices per machine : _____

2.10.6 Number of CT examinations (per year)*: _____

2.10.7 Number of patients for CT:** _____

** Definition: examination is one region*
*** Definition: patients are calculated every access*

2.10.8 Number of facilities for MRI (specify the strength and field of the techniques) : _____

2.10.9 Number of MRI examinations (per year): _____

2.10.10 Do you have special MRI techniques available? (please specify which) _____

2.10.11 Number of mammography examinations (per year): _____

2.10.12 Techniques related to the radiology department

	Yes	No
Do you have digitalized imaging (PACS)?*		
Do you have digitalized imaging (RIS)?**		

**Definition: In medical imaging, picture archiving and communication systems (PACS) are computers, commonly servers, dedicated to the storage, retrieval, distribution and presentation of images*
***Definition: A radiology information system (RIS) is a computerized database used by radiology departments to store, manipulate, and distribute patient radiological data and imagery*

2.11 Nuclear medicine unit

2.11.1 Nuclear medicine unit

	Yes	No
Is the department certified?		

2.11.2 If yes: According to which standards/system?: _____

2.11.3 If yes: When was the last external visit?: _____

2.11.4 Which facilities related to nuclear medicine are available?

	on site	access to (please specify the referral)	not available
PET scan facilities			
Pet CT/MRI facilities			
Radio nuclide treatment facilities (please specify)			
SPECT			
SPECT CT			
Sentinel node			

2.12 Laboratory

2.12.1 Laboratory

	Yes	No
Is the department certified?		

2.12.2 If yes: According to which standards/system?:

_____

2.12.3 If yes: When was the last external visit?:

_____

2.12.4

	on site	access to (please specify the referral)	not available
Do you have a cytology laboratory?			
Do you have a histopathology laboratory?			

2.12.5

If 2.12.4 is answered with on site, are the techniques below available?

	Yes	No
Immunofluorescence techniques		
Histochemistry		
Techniques for molecular pathology		
Cytogenetics*		
Electronic microscopy		

** Definition: Molecular biology is research focused on molecules involved in cellular processes*

2.12.6

	FNA by cytology	gynaecological by cytology	by biopsy (by needle)	on large pieces of excision
Please specify the number of samples for tumour pathological diagnosis per year at your cancer centre				

2.13 Haematology unit

2.13.1 Haematology unit

	Yes	No
Is the department certified?		

2.13.2 If yes: According to which standards/system?: _____

2.13.3 If yes: When was the last external visit?: _____

2.13.4

	on site	access to (please specify the referral)	not available
Do you have a transfusion centre?			
Do you have a bone marrow / stem cell bank?			
Do you do cytapheresis?			
Do you have a cellular therapy unit with GMP?			
Do you have a quality vigilance system*			
Do you have special techniques (please specify in the note)			

** Definition: The principal purpose of the Medical Device Vigilance System is to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Therefore, the Medical Devices Directives provide that adverse incidents are evaluated and, where appropriate, information is disseminated in the form of a National Competent Authority Report (NCAR) with the objective of preventing repetition of such incidents through the adoption of appropriate field safety corrective actions*

2.13.5 Number of laminar flow rooms:

2.13.6

	allogenic stem cell	autologous bone marrow	autologous stem cell
Please specify the number of bone marrow /stem cell transplants per year			

2.14 Composition of oncology Multidisciplinary team

2.14.1 The following disciplines are present during the MDT meeting for each tumour type.

	Yes	No
Medical oncologist (or equivalent)		
Surgical oncologist		
Radiotherapist		
Radiologist		
Pathologist		
Nurses		
Physician assistant/nurse practitioner		

2.14.2 Specify other members:

	Yes	No	On Request
Supportive care disciplines			
Pharmacist			
Plastic surgeon			
Other			

2.14.3 Please specify the availability of gynaecologist/ lung specialist/ urologist/ dermatologist/ haematologist/ neurologist for organ specific multidisciplinary team meetings.

2.15 Composition of palliative care team

2.15.1 How often does the palliative care team meet to discuss palliative patient's? : _____

2.15.2 The following disciplines are present during the MDT meeting palliative care.

	Yes	No
Physician with a specialization in palliative care, full or most of the time dedicated to palliative care		
Nurse with a specialization - certification in palliative care, full or most of the time dedicated to palliative care		
Medical oncologist		

2.15.3 Specify other members

	Yes	No	On Request
Physician specialised in pain treatment			
Neurologist			
Lung physician			
Radiotherapist			
Psychologist or psychotherapists			
Psychiatrist			
Pharmacist			
Social worker			
Spiritual care			
Physiotherapist			
General practitioner			
Dietician			
Other professionals (please, specify in the notes)			

2.16 Other facilities

2.16.1

	on site	access to (please specify the referral in the notes)	not available
Do you have a central pharmacy?			
Do you have an emergency facility (24/7)?			

2.16.2 Number of active operating theater sessions in the index year (specific to oncology surgery): _____

3 Human resources

3.1 Human resources

3.1.1

	FTE
Total FTE of employees in the cancer centre	
Total FTE nurses with basic training*	
Total FTE nurses certified in oncology**	
Total FTE advanced nurses***	

** Definition: Basic/general nurse with (at least) three years official certified education. Acting nurses (interim) should be counted*
*** Definition: Basic nurse + qualification of at least one year training in oncology*
**** Definition: Advanced certified nurses with a degree in Nursing Oncology (Msc. or PhD.)*

3.1.2 Human resources: Cancer Surgeons

	Please specify the number of FTE surgeons
Total number of FTE cancer surgeons	
Breast surgery	
Urologic surgery	
Thoracic surgery	
Digestive surgery	
Neurosurgery	
Gynaecological surgery	
Head and neck surgery	
Soft tissue surgery	
Orthopaedic surgery	
Plastic and reconstructive surgery	
Paediatric surgery	

3.2 Human resources: Physicians specialities

3.2.1

	Please specify the number of FTE surgeons
Gastro enterologists	
Pneumonologists/respiratory physicians	
Gynaecologists	
Haematologists	
Paediatricians	
Psychiatrists	
Anaesthesiologists	
Infectious disease specialists	
Geneticians	
Dermatologists	
Pharmacist	
Geriatricians	
Neurologists	
Intensive care specialists	
Medical oncologists	
Cardiologists	
Endocrinologists	
Urologists	
Rehabilitation physician / palliative care doctor	
Clinical pharmacologist	

3.3 Human resources: Supportive disciplines

3.3.1 Pathology

	Please specify the number of FTE
Technicians	
Pathologists	
Molecular biologists	
Technicians working in molecular PA	
Pathologists working in molecular PA	

3.3.2 Nuclear medicine

	Please specify the number of FTE
Technicians in nuclear medicine	
Physicians in nuclear medicine	
Physicists/engineers	
Nurses in nuclear medicine	

3.3.3 Radiology

	Please specify the number of FTE
Radiologists	
Technicians in radiology	
Nurses in radiology	
Physicist	

3.3.4. Radiotherapy

	Please specify the number of FTE
Radiation oncologists	
Radiation technicians in radiotherapy	
Nurses	
Physicist/engineers	
Radiobiologists	

3.3.5 Pharmacy

	Please specify the number of FTE
Onco Pharmacist	

3.3.6 Supportive care

	Please specify the number of FTE
Dieticians/nutricians	
Psychologists	
Ergotherapists	
Speech/swallow therapists	
Physiotherapists	
Stoma therapists	
Social workers	
Other (please specify in the notes)	

4 Research

4.1 Research budget including basic/clinical/translational

Research funding sources/total amounts received (in the year)

4.1.1 Total research budget cancer centre in Euros:

4.1.2

	Number EU grants	Amount of grants in Euros
EU grants running		
EU grants coordinated		

4.1.3

	Number of EU grants running in Euros	Number of EU grants coordinated in Euros	Total amounts in Euros
Research funding received in the index year relevant to oncology			

4.1.4

	Public funding in Euros	Charities/unrestricted grants in Euros	Industrial partnership funding in Euros
Research funding received in the index year relevant to oncology			

4.2 Research groups

4.2.1 Research groups

Research group	Programmes	Composition of the group	FTE per group	Does the team have an appointed coordinator/secretary (Y/N)

4.2.2 List of core facilities

Core facility	Type	Nr

4.2.3 Please specify the number of FTE dedicated to oncology research

Type	Nr of FTE
Total FTE of researchers	
Senior scientist	
Post docs	
Fellows	
PhD	
Nurses	
Technicians	
Number of clinicians with laboratory sessions	
Total administrative support FTEs for research	

4.3 Clinical research

4.3.1 Number of retrospective studies initiated within the index year:

4.3.2 Number of prospective studies active at the end of the index year

	Number of studies	Patients newly included***
Count Phase I + Phase I-II*		
Count Phase II + Phase II-III**		
Count Phase III		
Count Phase IV		
Total		
Percentage of new patients included in studies***	x	

**Phase I must be counted once*
***Phase II must be counted once*
**** Definition: include the new patients (new diagnosed and new referred), exclude the follow-up patients. Percentage = total number of patients enrolled on prospective clinical studies (excluding observational studies) in an index year / total number of patients with a diagnosis of cancer who are newly managed in the cancer centre in the same index year*

4.3.3 Number of prospective studies initiated within the index year

Investigator/study type (legally responsible of the study)	Number
Local	
External participation national	
External participation international	
Not industry sponsored	
Industry	
Number of collaborative studies with chief investigator from the institution	

4.4 Research structures

	Yes	No	not applicable
Do you have a private partnership with companies related to research and innovation (if yes, please specify in the notes)			
Do you have a unit of epidemiology?			
Do you have a unit of health economics?			
Do you have a bio-informatics unit?			
Do you have a clinical data registry?			

4.5 Research output

Type	Number
Number of patents over the last 5 years	
Number of peer-reviewed publications per year (in the year specified) national	
Number of peer-reviewed publications per year (in the year specified) international	
Impact factor cumulative	
Number of publications with impact factor > 10 with first, second or last author from the centre	
Number of publications with impact factor > 10 co-authored by the centre	
Number of publications with impact factor between 5 and 10 with first, second or last author from the centre	
Number of publications with impact factor between 5 and 10 co-authored by the centre	

5 Education

5.1 Education

5.1.1 Availability of education courses organized by the centre

	with local audience	with national audience	with international audience
Educational courses organized by the cancer centre on site			

5.1.2 Number of students and professors

	Amount
Number of medical students in oncology training on site per year	
Number of graduate/postgraduate/under specialist training persons in all fields directly related to oncology students	
Number of nurses under specialist training per year in all fields directly related to oncology	
Number of nurses students per year in all fields directly related to oncology	
Number of new PhD students per year (average last 5 years) (medical, nurses, researchers, ..) in all fields directly related to oncology	
Number of PhD theses per year (average last 5 years) in all fields directly related to oncology	
Number of University - Faculty Professors and lecturers employed by the centre, in all fields directly related to oncology (excluding associate professors)	

5.1.3 Formalized exchange programmes

	Yes (please specify in the notes if they are formalized?	No
Do you have exchange programmes at national level		
Do you have exchange programmes at international level		
Do you have patient education programmes		
Do you have education programmes for managers		
Do you have continuous medical education (CME) programme		

5.2 Analysis

5.2.1 Digital support information systems

	Yes	No
Do you have an electronic patient record?		
Do you have an electronic patient portal?		
Do you have electronic practice guidelines available?		
Do you have an electronic patient pathway tracking system?		
Do you have an electronic patient referral system shared with external care providers?		
Do you have an Electronic Medication Prescription System?		
Do you have an internet technology (IT) infrastructure for cross-enterprise document sharing?		

Accreditation and Designation

Appendix IV

E-tool user manual for institutes

Appendix IV. E-tool user manual for institutes

Doc 10: User manual OECI electronic tool for OECI centres

1. How to work with the e-tool?

1.1 Log in

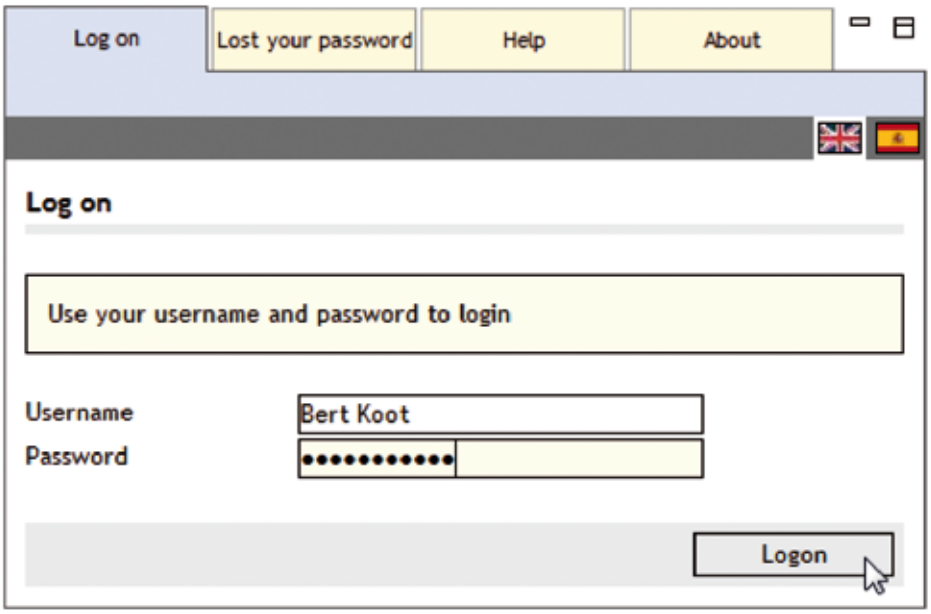
Go to: ***http://oeci.selfassessment.nu*** to visit the OECI Accreditation & Designation website with all information concerning the programme.

Click the button "Go to the e-tool" to go to the log-in screen of the e-tool application.

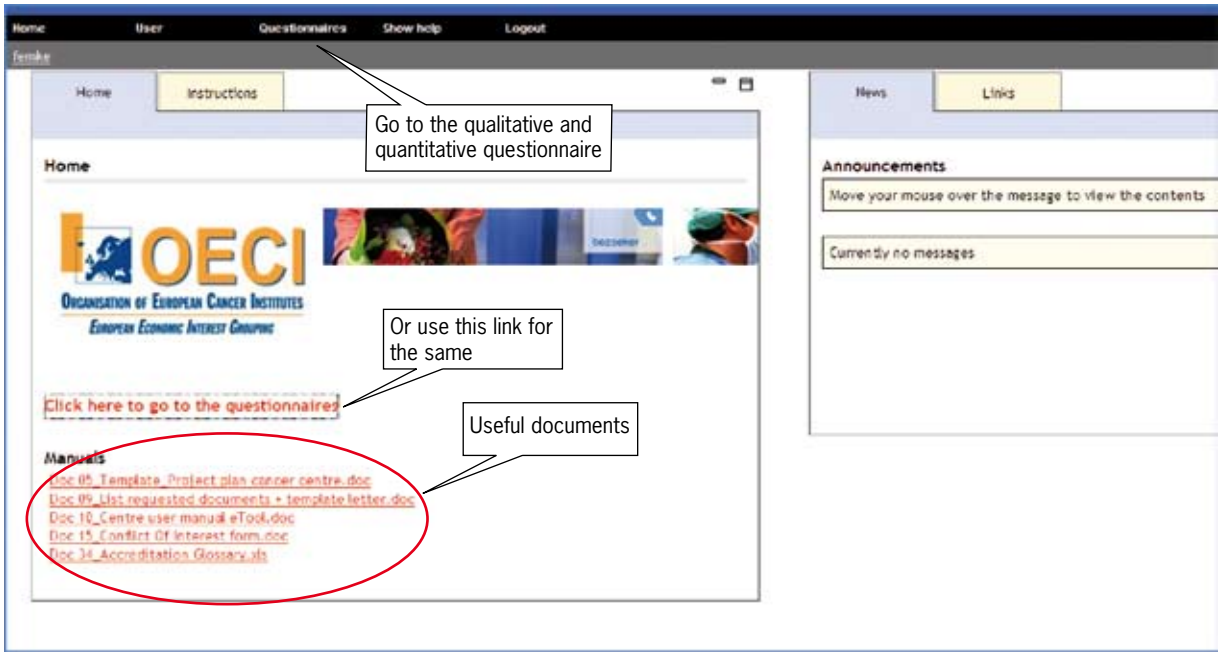
Or directly to the e-tool log in screen via ***http://oeci.selfassessment.nu/compass/user***

Save this address in your favourites to make it easier for the next time to log-in.

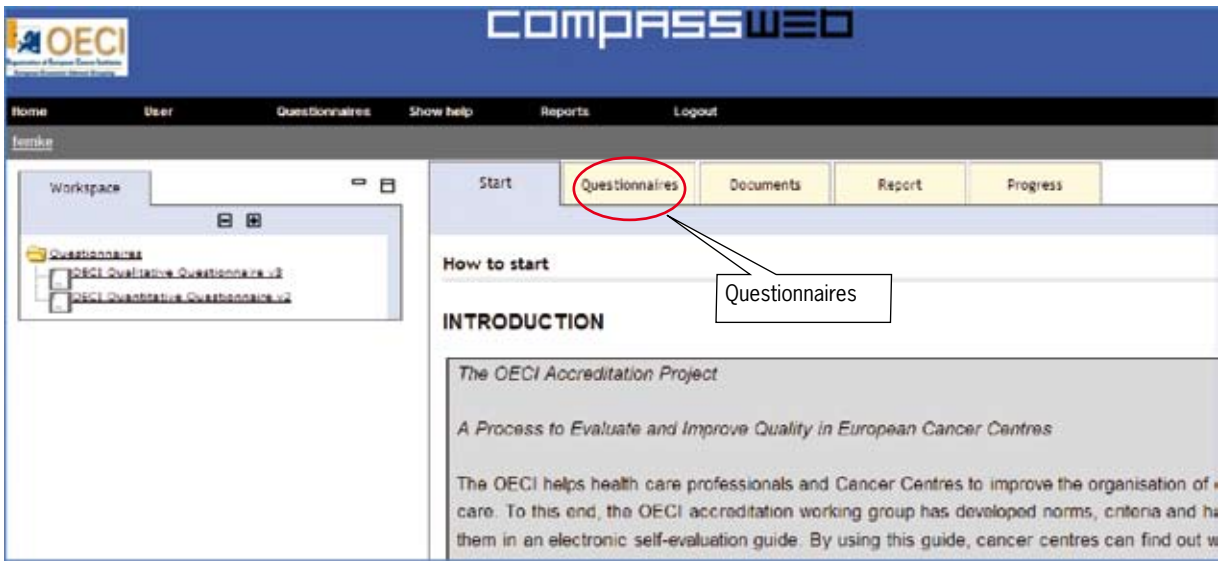
In the log in screen you can use your username and password to enter the e-tool application.



When logged in you will enter the e-tool in the following screen.



If you go to the questionnaires the following screen appears.

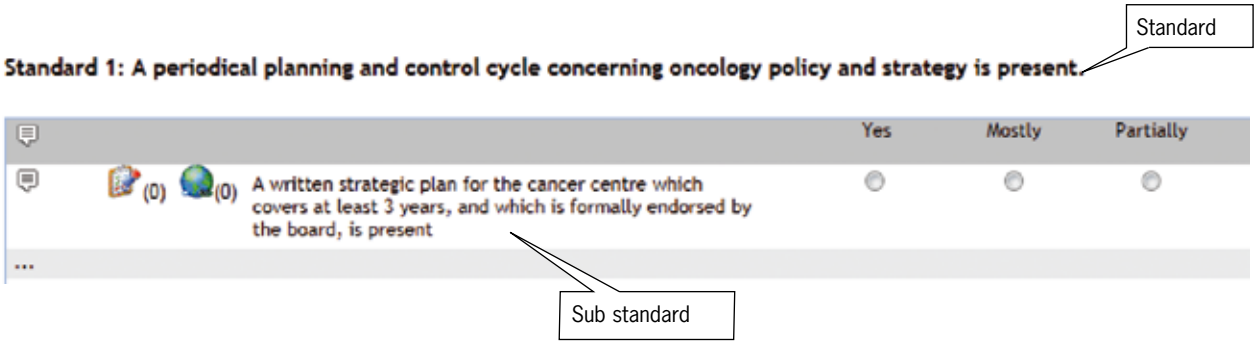


1.2 Three steps to fill out the qualitative questionnaire

1.1.2 Step 1: Give a score to all items in the questionnaire

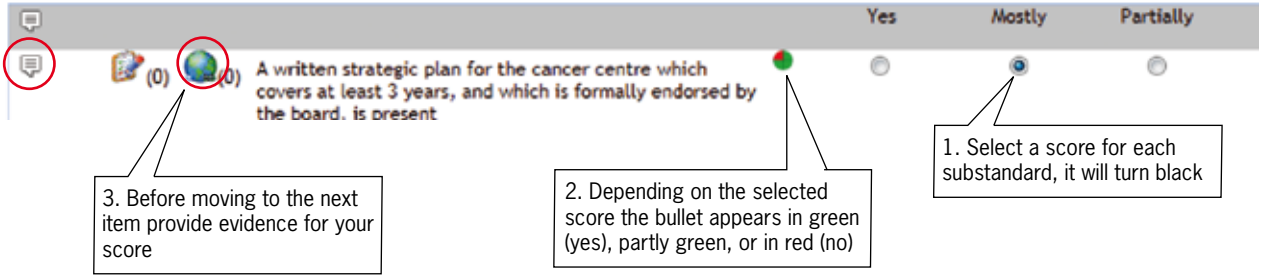
The quality questionnaire consists of:

Chapters	Domains	Standards 63	Sub standards/questions, Total 274 (100%)
Chapter 1	Leadership and management of the cancer centre	25	112 (41%)
1	Policy and organisation	6	19
2	Resources and materials	2	12
3	Process control	10	46
4	Safeguarding the quality system	7	35
Chapter 2	Prevention and early diagnoses	3	12 (4%)
1	Process control	3	12
Chapter 3	Cancer treatment and care	10	43 (16%)
2	Process control	10	43
Chapter 4	Research, innovation and developments	13	45 (16%)
1	Policy and organisation	8	24
2	Resources and materials	3	13
3	Process control	2	8
Chapter 5	Teaching and continuing education	4	23 (8%)
1	Policy and organisation	1	6
2	Process control	3	17
Chapter 6	Patient centeredness	8	39 (14%)
1	Process control	6	28
2	Safeguarding the quality system	2	11



Possible scores
The score is a indicator for the Stage of implementation of each item of the standard. The scoring system is based on the Plan-Do-Check-Act-circle or Deming-circle. These four Stages of implementation are translated in the following possible answers:

- **Yes** means that the indicator of the standard has been implemented on a wide scale in the cancer centre and the Deming-cycle is completed at least twice (in third cycle)
- **Mostly** means that the indicator has been implemented in most of the critical places in the cancer centre and the Deming-cycle is completed at least once (in second cycle)
- **Partially** means that the indicator is implemented on project bases or on a modest scale in the cancer centre or the Deming-cycle has not been completed (<Check)
- **No** means that the indicator does not get attention or there are plans to start working on the indicator (Plan)
- **Not applicable** means that the indicator is not applicable in the cancer centre



1.2.2 Step 2: Provide evidence for the given score

Provide the evidence through:

A. Attaching a document to a specific question in the e-tool that provides the evidence OR

B. Referring to a document that is already attached in an earlier item OR

C. Adding a note to justify the score if there is no document available AND

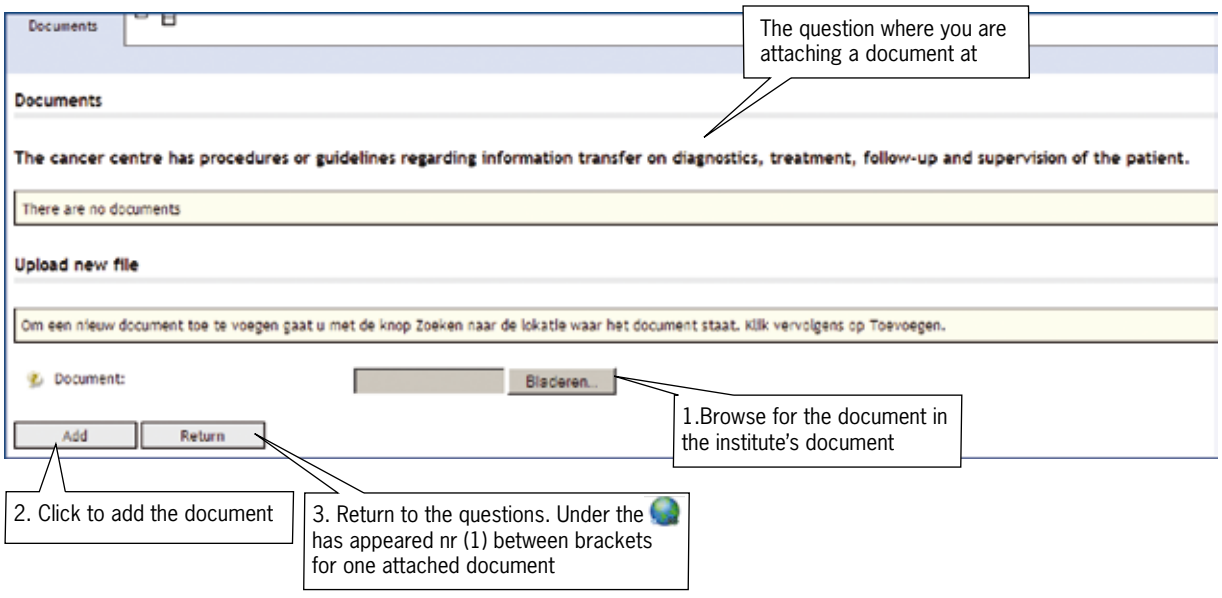
D. Adding the requested documents.

A. How to attach a document to a specific question?

Many questions are related to documents that are possibly available in the cancer institute. If there is a such a question please add the document.

NOTE: These documents do not need to be translated in English. However, the OECI advices to add a short explanation of the content of the attached document in English and/or refer to the page where the evidence for the specific question is given.

Click on the globe icon and the following screen appears:



To get an overview of the specific questions that contain a document you close the questionnaire and clicking the icon in the table under evidence.

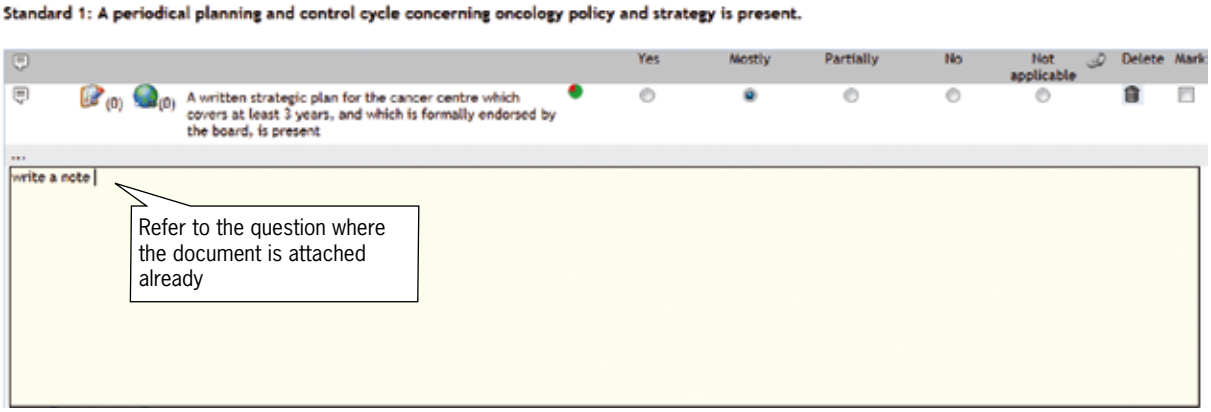
B. How to refer to a document that is already attached?

When a question is related to an existing document in the cancer institute that has been uploaded elsewhere in the questionnaire, it is wise to refer to the question where it has been uploaded already, rather than upload it again.

Click on the note box icon. A note box appears under the specific question.

To close the box: just click with your mouse somewhere on the page.

If there is a note in the note box, the icon will be changed with bold lines:



C. How to add a note to justify the score?

When to add a note:

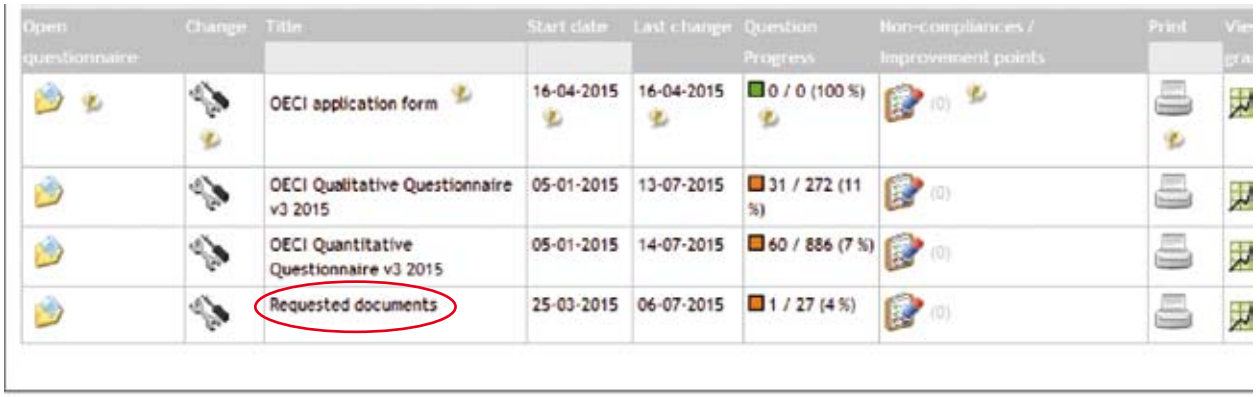
- Add least add a note to a question that has been scored with “partially” or “no” AND
- Add a note if there is no document that can provide evidence for the given score or the document/ policy/ procedure is not available.

Please justify the given score by putting a note in the note box (as explained above).

It is also possible that the centre cannot answers the question literally, for example because the centre is not responsible for the standard questioned, please also use the note box to explain this issue.

D. How to add the documents requested by the OECI?

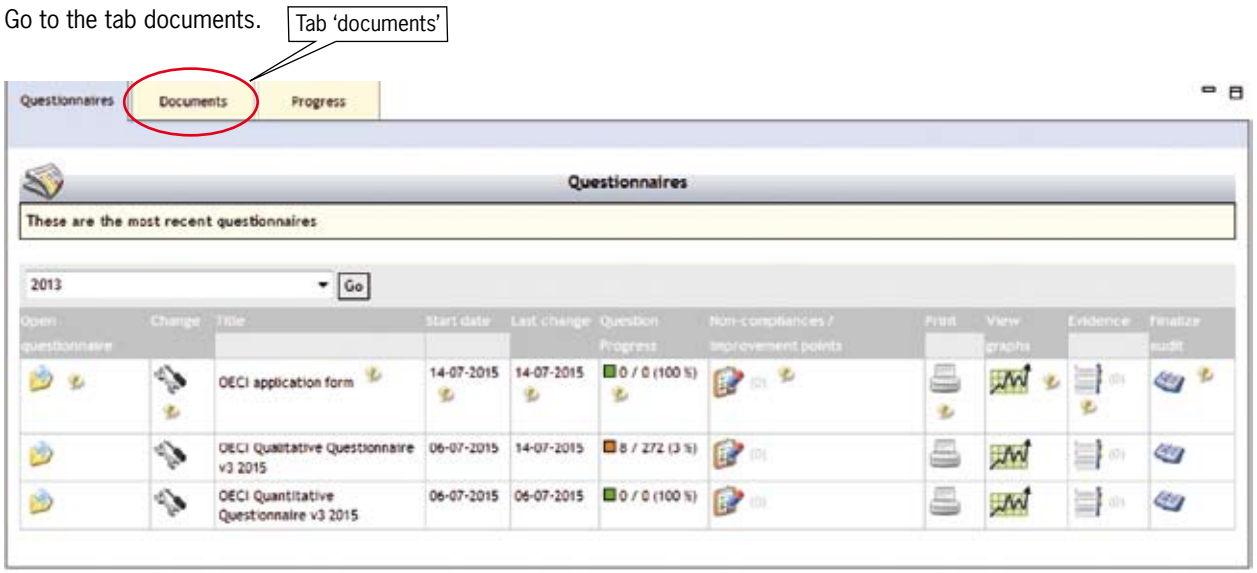
The requested documents are listened in a separate questionnaire named ‘requested documents’.



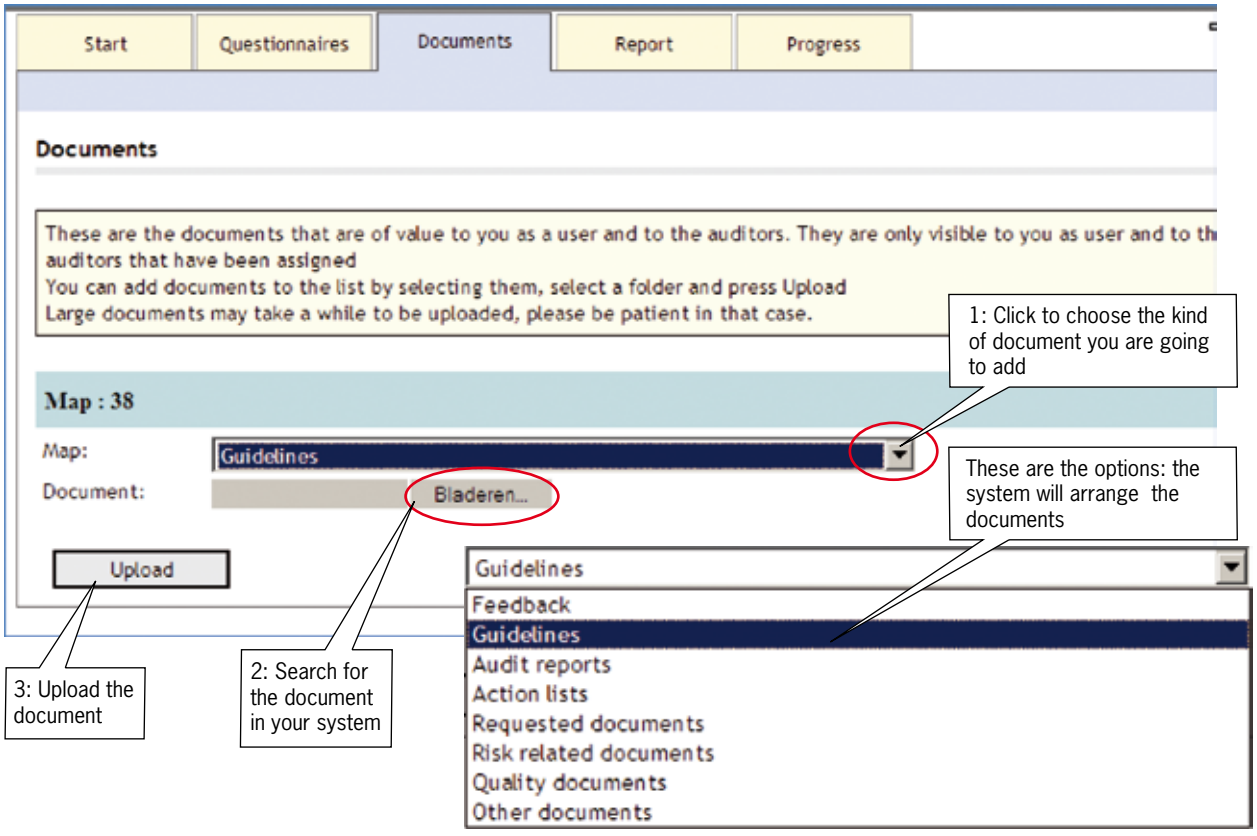
E. How to add additional documents, for example, requests during the peer review visit

When you log in to the e-tool you will see the following screen with above the two questionnaire some tabs. In underneath figure the tab that is blue: 'Questionnaires' is open.

Go to the tab documents.



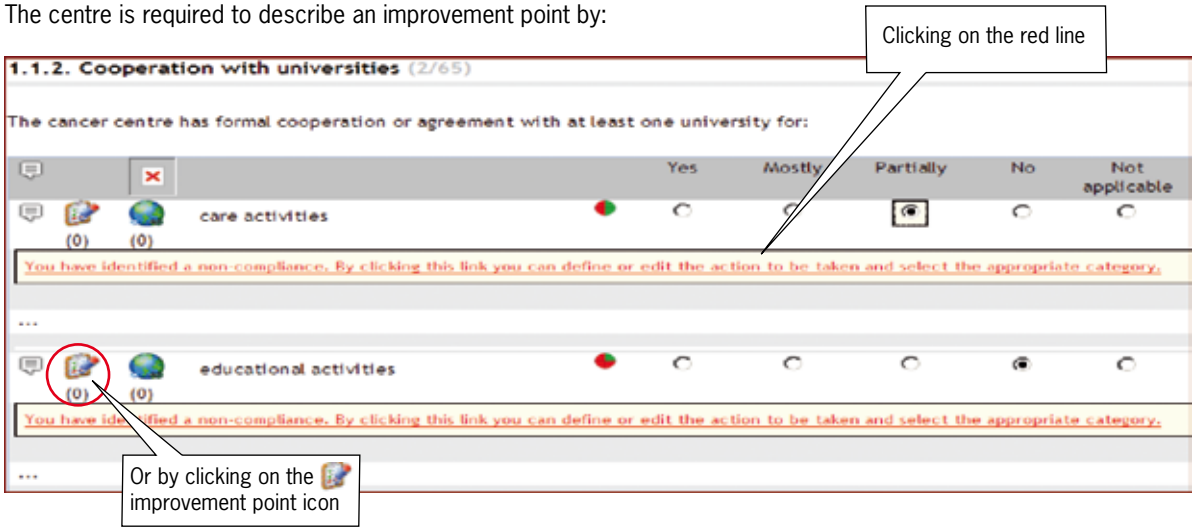
The following screen will appear. Follow step 1, 2 and 3.



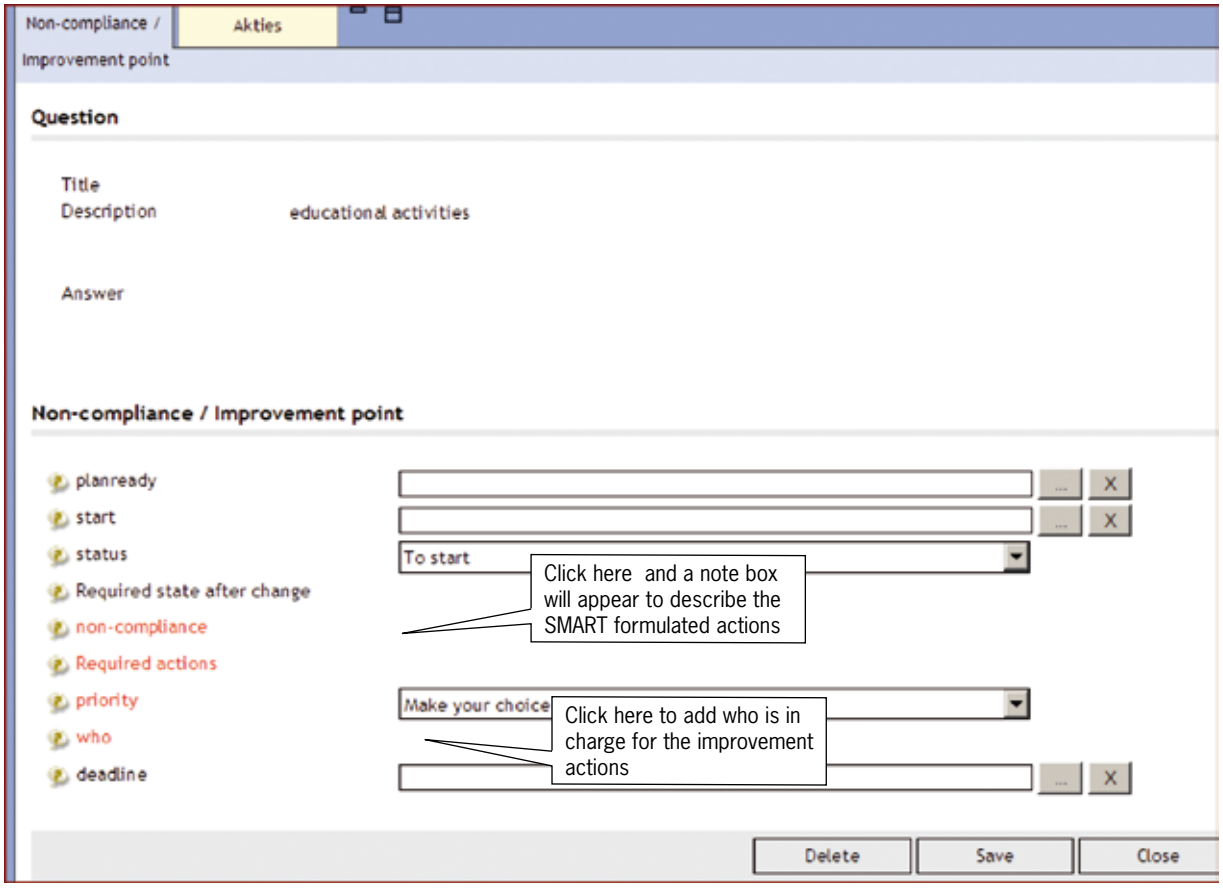
1.2.3 Step 3: Add a non-compliance/improvement point

If you have scored a question with 'partially' or 'no' a red sentence appears under the question that a non-compliance point has been identified. This means that (quality) improvement can be made regarding this sub standard by the centre

The centre is required to describe an improvement point by:

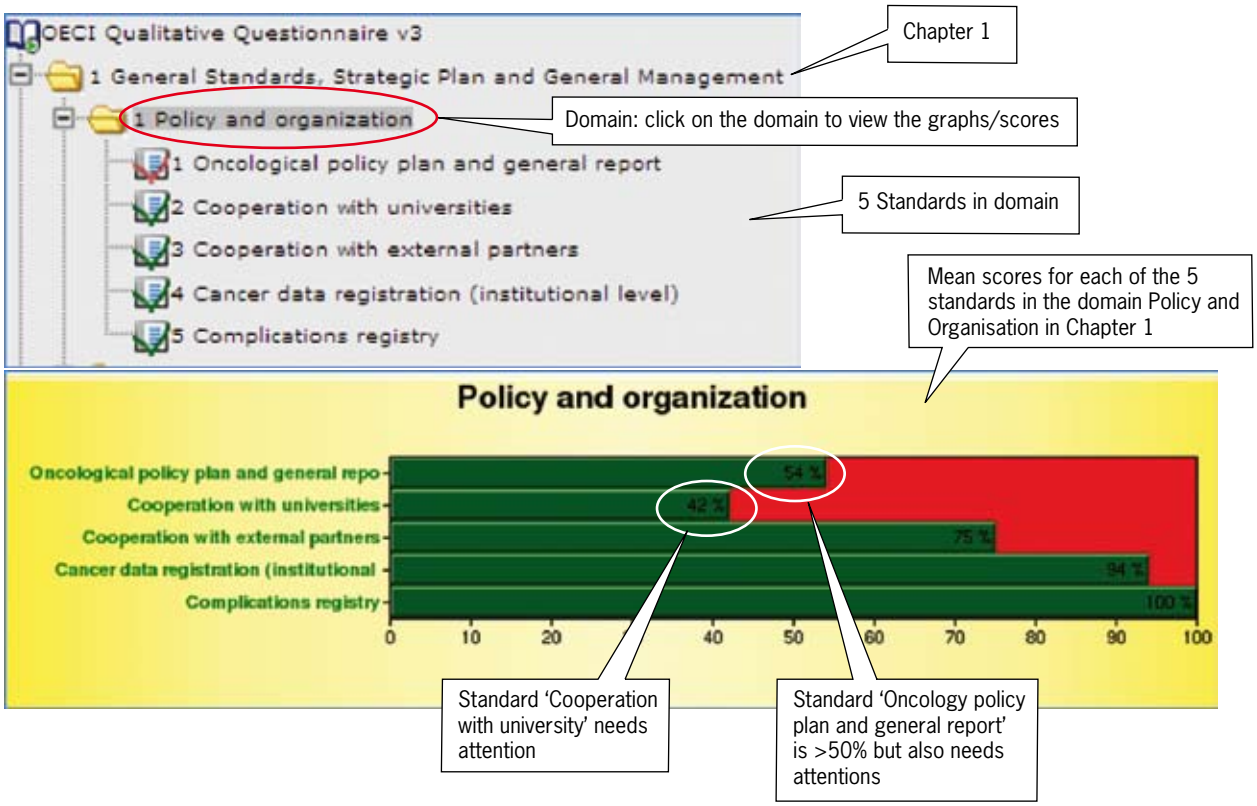


Click on 'Save and new entry' in the screen that appears and fill in the items for the improvement:



1.2.4 How to check the level of quality the centre has achieved per standard

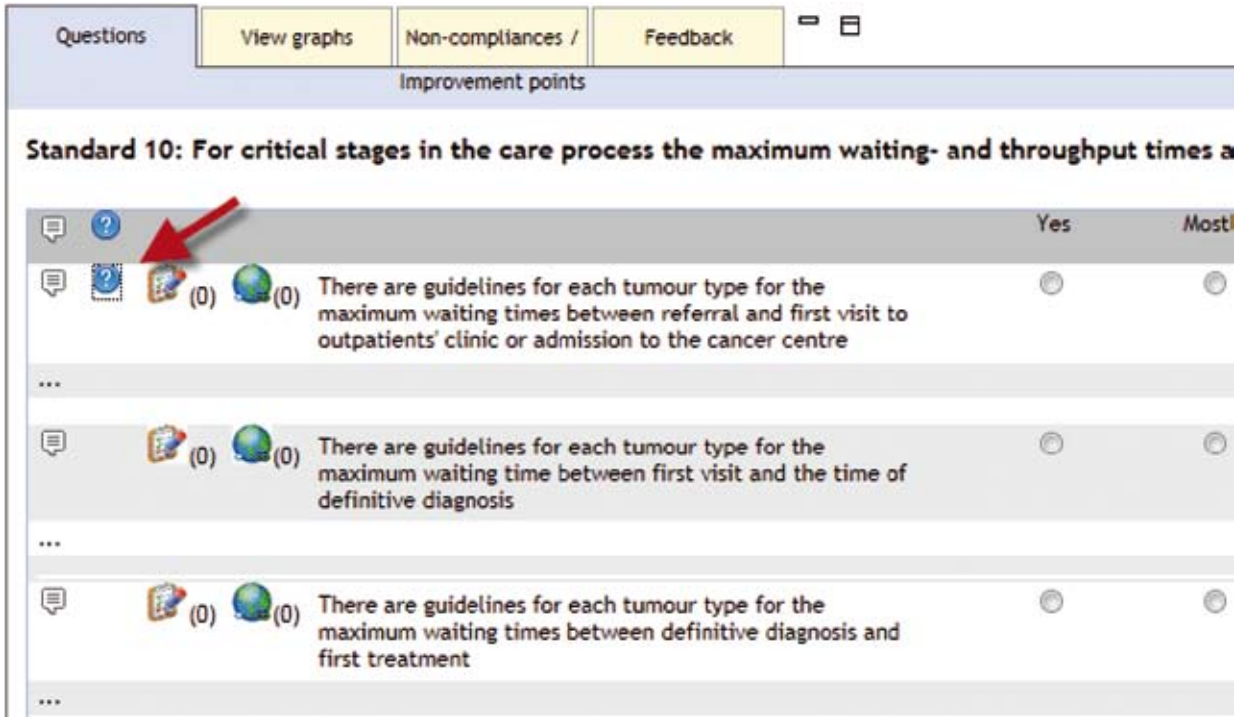
- Open the qualitative questionnaire
- Open the show tree



1.2.5 Close the questionnaire if you will not change or add something more

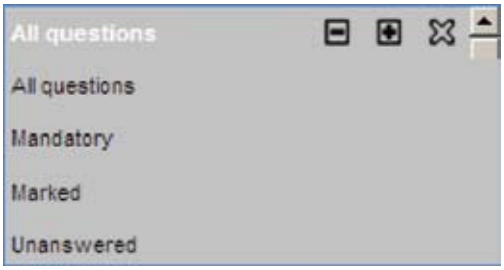
1.2.6 Definitions

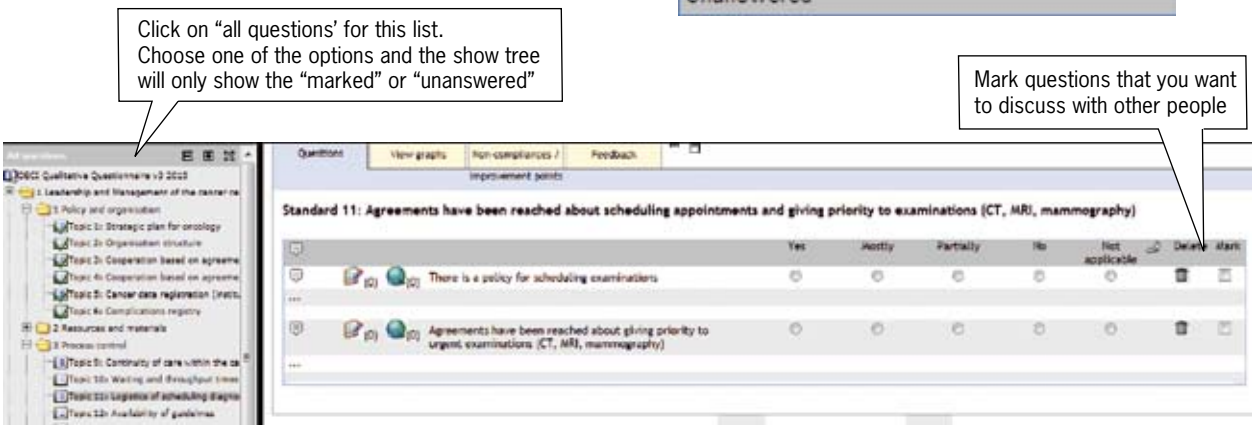
If you click on the blue question mark , the definition or definitions of the standard or substandard will appear. You can use as well as the mouse over or the double click.



1.2.7 Other options

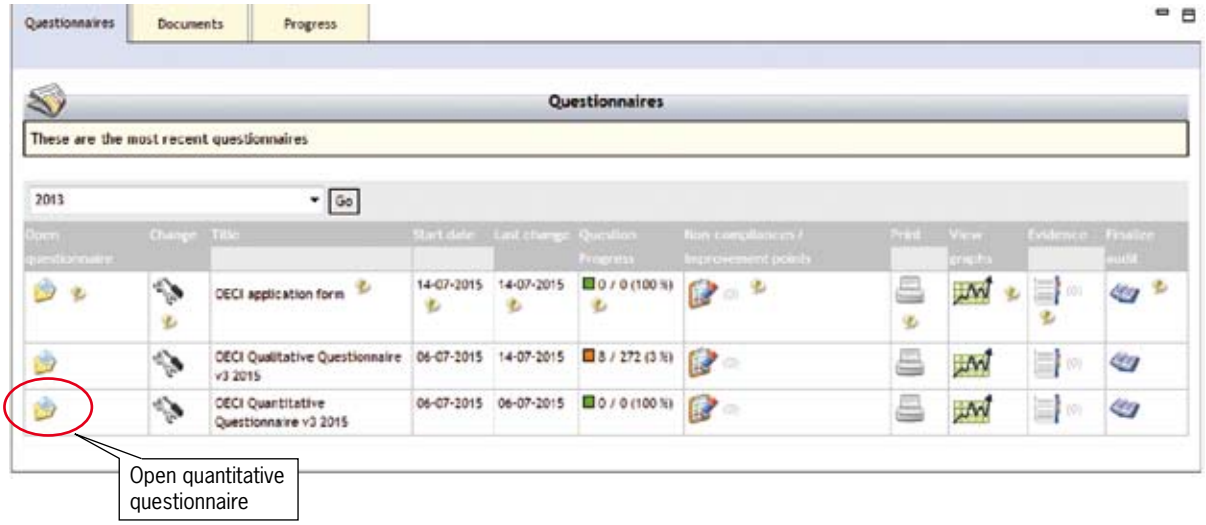
- Mark questions to discuss in project group meetings
- Make a note for other people working in the questionnaire
- Show only the marked or unanswered questions

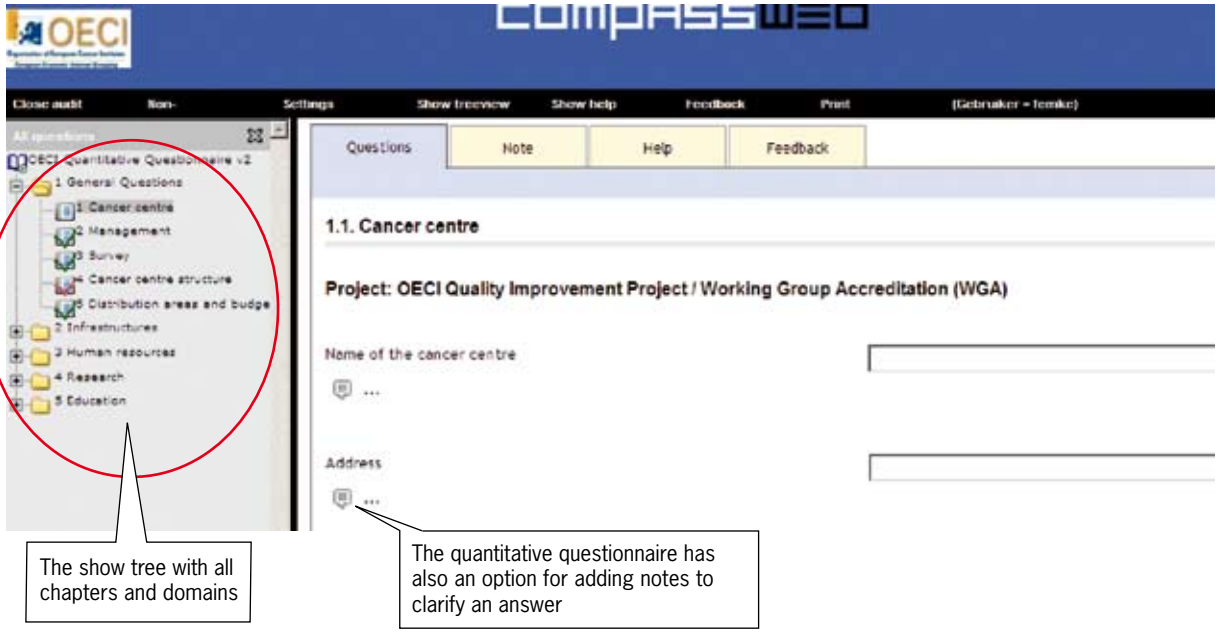




2. Quantitative questionnaire

2.1 Quantitative questionnaire





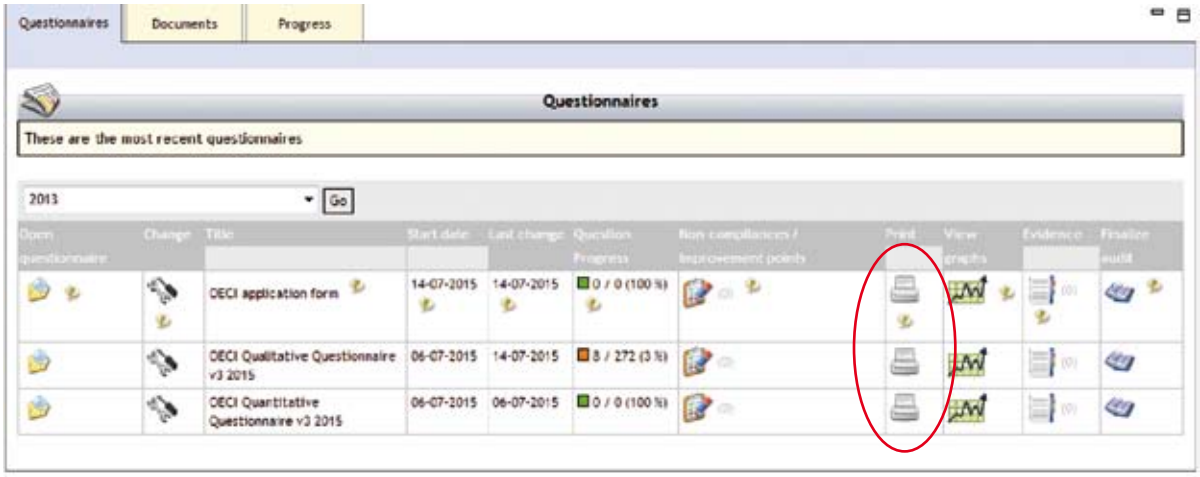
2.2 Suggestions

Make a distinction between 'something is not present' or 'data not available'. If your institute has, for example, no gynaecologists (3.2.1 quantitative questionnaire), enter a '0' in the box. If it is not possible to identify the numbers, please enter a '-' in the box. Explain in the notes why the numbers are not possible to identify.

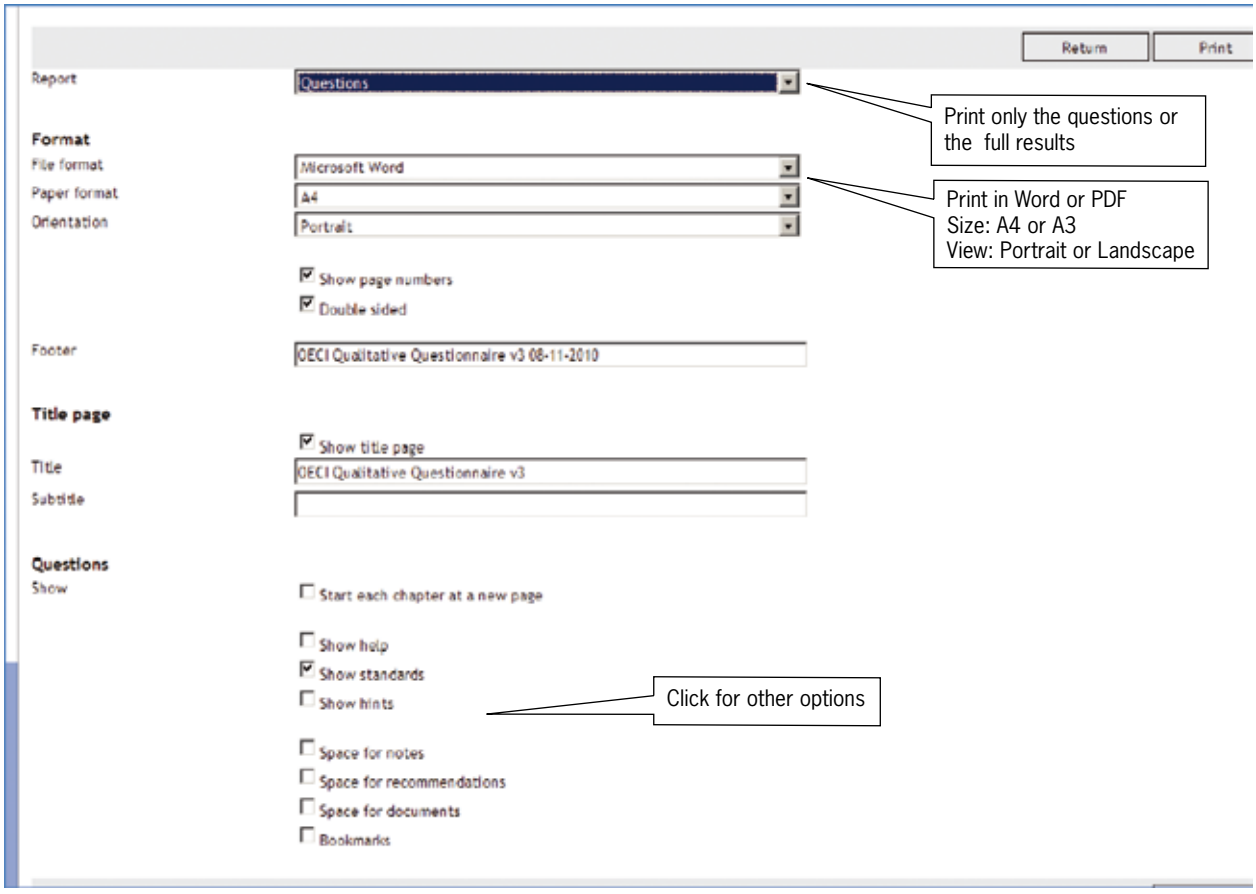
Make use of the 'next' and 'previous' buttons below every standard, to continue to the next standard.

Data is auto saved in 150 seconds and when you use the 'next' and 'previous' buttons or show tree. Avoid the buttons of your web browser, because this does not guarantee that your data is saved. It is not possible to work with more than one person at the same time with the same account / username.

3. Print the questions and/or the results in a report



The following screen appears with several options.



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