

OECI Accreditation and Designation User Manual V. 3.2

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Introduction to the Accreditation and Designation User Manual 3.2

Dear Colleagues,

The OECI is proud to present Version 3.2 of the OECI Accreditation and Designation User Manual, which contains the fully revised Quality Standards and Quantitative data measures for European cancer centres/institutes. The OECI A&D Programme is widely recognised as the only Cancer Accreditation Programme which includes cancer centres/institutes in almost every country in Europe. It is also the only cancer quality programme whose standards have been accredited by the International Society for Quality in Healthcare (ISQua).

Manual 3.2 is the result of a successful collaboration among the A&D Programme, OECI Members, cancer centres/institutes in the A&D Programme, and auditors involved in the peer review process. It builds on OECI's 11 successful years of experience in cancer quality systems in Europe. We thank all the experts, organisations and cancer centres/institutes who have provided insight and critique of the Standards and quantitative measures proposed in this Manual 3.2. Special thanks go to external representatives of European Cancer Organisations involved in care, research and education, namely EORTC, EONS, EACS, ECCO, ESSO, ESTRO, ESMO, Cancer Core Europe and Cancer Prevention Europe who contributed to the discussions on the revision of the Manual. Very special thanks to those organisations representing cancer patients and their caregivers – who are the real goal and purpose of the improvements in cancer diagnosis, research and treatment envisaged by these Standards - namely the European Cancer Leagues, and the European Cancer Patient Coalition. Their input has resulted in a set of Standards which set probably the highest bar of patient-centred cancer care in the world.

Manual 3.2 introduces important new standards on: molecular diagnostics, prevention, surgical oncology, radiotherapy, pathology, survivorship, palliative and supportive care. It also introduces the concept of "Core Standards" which should always be met by cancer centres/institutes, and on which evidence of compliance will always be required in a re-accreditation. A new re-accreditation process has been introduced in Manual 3.2 which will reduce the burden on cancer centres/institutes. All Standards will still need to be scored, but only new Standards, Core Standards, and those previously scored other than 'Yes' by the cancer centre/institute will require audit evidence to be uploaded (see Chapter 5.4 for details).

In this latest revision, the Designation Criteria remain largely unchanged (although definitions have been clarified), but henceforth cancer centres/institutes previously designated as "Clinical Cancer Centres" are now designated as "OECI Cancer Centres" on the grounds that many such cancer centres/institutes do have research but not at the volume of Comprehensive Cancer Centres.

We now present this set of Quality Standards which represent a true European consensus for evaluating the performance of cancer centres/institutes. They are complementary to more detailed requirements for individual tumour groups which are also needed to maintain the highest quality of cancer care. However, the uniqueness of the OECI approach is the focus on comprehensiveness: comprehensiveness in the integration of research and clinical care; comprehensiveness in relation to the whole patient journey; and comprehensiveness in the capacity of a cancer centre/institute to treat almost all cancers, and disseminate learning and expertise across cancer types as we move forward in the genomic age.

This new version will enter into force for all cancer centres/institutes applying to the Programme after 1 January 2020. Congratulations to the A&D Board and the Co-ordination Team of IKNL for their extraordinary efforts in this revision, and to the office of the OECI Director for the professional production of the outcome.

We offer these European-consensus Quality Standards for cancer centres/institutes to the cancer community, in the sincere hope that, working together towards the highest quality of cancer research, care and education in Europe, we may radically reduce death and disease caused by cancer.



Simon Oberst
Director A&D Programme



Thierry Philip OECI President



Jean-Benoit Burrion Chair A&D Programme



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A	ccreditation
and	Designation
	Programme

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. It aims to build a consensus on the best models of oncology, developing affordable and realistic solutions to combat cancer and fostering the widest deployment of oncology models to improve outcomes for patients in Europe

Background and Vision of the Accreditation and Designation Programme

The OECI launched the A&D Programme in 2002 to fulfil the following goals:

- to provide cancer patients equal access to high quality of cancer care and overcome the current differences in access to diagnostics, treatment and therapeutic options that patients experience in different parts of Europe
- to help European cancer centres/institutes implement a quality system for oncology care using the OECI standards and peer review system
- to foster and accelerate improvements in translational and clinical 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/institutes. It has been designed and developed by a wide range of European experts from European Oncology Societies and Patient Organisations, and staff from OECI members. Peer review is performed by experts from OECI cancer centres/institutes and site visits are chaired by a Director of an OECI cancer centre/institute.

What is an accreditation programme?

Accreditation is a process in which an independent organisation evaluates an institution and certifies that it meets certain quality standards. OECI has specialised its A&D Programme in multidisciplinary integrated cancer care and research, with a major focus on comprehensiveness. It is the only cancer accreditation in the world which evaluates both clinical services and research. It is also the only cancer Programme whose standards have been accredited by the International Society for Quality in Healthcare (ISQua). The domains of the A&D Programme include governance, organisational quality, patient involvement and empowerment, multidisciplinarity, prevention and early detection, all modalities of diagnosis, treatment and care, translational and clinical research, education and training.

Who should become OECI accredited and designated?

Any cancer centre/institute anywhere in the world which meets the minimum volume requirements of the A&D Programme, and provides high quality care, education and research for all major cancers. Special arrangements have to be negotiated with cancer centres/institutes outside Europe.

When should a cancer centre/institute be accredited and designated?

The aim of the A&D Programme is to stimulate cancer centres/institutes to continuously improve the quality of the total organisation, including leadership and management, and the integration of care, research and education. The OECI takes an institution-wide approach, believing that the organisation should enable individual multidisciplinary teams to improve clinical outcomes and experience for cancer patients and their caregivers. OECI has documented evidence on this subject and published a number of articles. By being accredited by OECI, a cancer centre/institute joins an important community of practice of around 50 of the leading cancer centres/institutes in Europe and abroad whose aim is to continuously improve, share best practice, respond to the needs of our patients, and benchmark our processes and outcomes to identify strengths and opportunities.

When should a cancer centre/institute be accredited and designated?

The cancer cancer centre/institute should be an established entity with a Board that oversees clinical care, research and education in cancer. The commonest reason for the OECI A&D Board to recommend a delay in starting the process is that cancer centre/institute has not yet sufficiently organised its governance in cancer or is in a process of major organisational change. The OECI self-assessment process itself is likely to take between 9 and 12 months for a first accreditation; however, the e-tool for self-assessment is easy to use and provides a comprehensive way of evaluating compliance with the quality standards. The OECI A&D Programme team establishes a precise timeline with each cancer centre/institute applying into the programme, in order to allow the necessary time for the preparation of the self-assessment, peer review, report and improvement plan.

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How does the accreditation process work?

A cancer centre/institute that wishes to become OECI accredited should contact the OECI A&D team. The cancer centre/institute should already be a member of OECI or apply immediately to become a member by contacting the OECI Liaison Office. The cancer centre/institute (Applicant Centre) then completes the Application form, and later on the fuller Designation form with a limited amount of supporting documentation. Once the Designation form has been accepted by the A&D Board, and a preliminary designation has been given, the Applicant Centre can then commence the self-assessment against the Quality Standards and the Quantitative Questionnaire in the e-tool. These are reviewed by the OECI A&D Committee and A&D Board, and a Go-decision is made when the Applicant Centre is ready for a 2-day on site peer review. The peer review is then scheduled and conducted, which results in a scoring of compliance by the audit team, and a full report with recommendations. The audit team's assessment of the strengths of the Applicant Centre are summarised, along with the opportunities for improvement which arise from the objective scoring of the questionnaires. Finally, an improvement plan is drawn up by the Applicant Centre based on the agreed list of opportunities, and agreed with the A&D Board. The certificate, according to the designation of the cancer centre/institute, is then awarded, which lasts 5 years before re-accreditation. The official certificate is handed over in a ceremony at the next OECI General Assembly (usually June each year).

OECI standards

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

Scoring system

A scoring system is included in the qualitative questionnaire. The scoring system is based on the Plan-Do-Check-Act-cycle or Deming-cycle. 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 Applicant Centre.

Designation

The OECI distinguishes two types of designation. Both types require a high degree of multidisciplinarity and high-quality cancer care, and are distinguished only by the degree of research capacity and capabilities at the cancer centre/institute. The two types are:

- OECI Cancer Centre

- OECI Comprehensive Cancer Centre

The designation criteria relating to research capacity and capabilities are used to decide the designation of the cancer centre/institute (see Appendix I).

All OECI accredited cancer centres/institutes are required to have:

- An identifiable organisational entity with a clear governance
- A direct provision of an extensive range of high quality cancer diagnostics and care tailored to the individual patient's needs
- A culture of learning and improving the professional and organisational quality of care

In addition, OECI Comprehensive Cancer Centres are required to demonstrate:

- A high level of infrastructure, expertise and innovation in cancer research, especially in translational and clinical research, but also in many cases including basic science
- Either strong University and Research Institute links, or a University partnership as part of the Comprehensive Cancer Centre
- Extensive international networking



Fig. 1 OECI Accreditation and Designation Certificate

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Accreditation and Designation Programme

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

There are ten steps in the OECI 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 the Applicant Centre to continue in the A&D Programme. For monitoring continuous and comprehensive quality improvement in the cancer centre/institute, there is a follow-up of the cancer centre/institute's improvement plan one year after certification. A detailed explanation of all steps is outlined in Chapter 5.

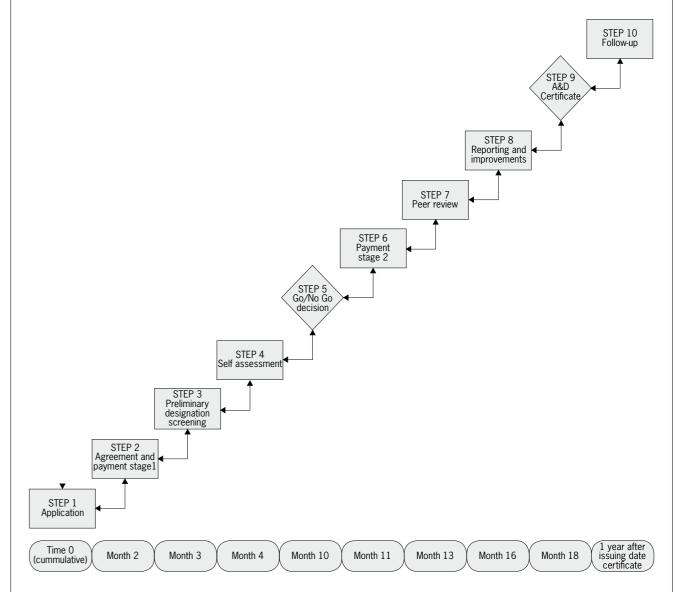


Figure 2: Timeline A&D Process

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2.1.1 General explanation of the ten steps

The OECI A&D Programme is offered by the OECI. Participation in the Programme is open only for members of the OECI. Information about membership of the OECI: **www.oeci.eu/Membership.aspx**

STEP 1: Application

The Applicant Centre applies to the Programme through the electronic application on the website https://oeci.eu/Accreditation The application will be examined by the OECI A&D Board.

STEP 2: Agreement and payment fee stage one

After approval of the application by the OECI A&D Board, the Applicant Centre receives the A&D Agreement to be signed, and the first payment order. A second payment order will follow after approval of the A&D Board for the peer review visit.

STEP 3: Preliminary designation screening

The designation screening takes place to assess the preliminary designation type of the Applicant Centre based on criteria (Appendix I). The pre-designation will be discussed in the OECI A&D Board. Both, the judgement of the Applicant Centre 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 Co-ordinator 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 may take 6-9 months.

On request of thee Applicant Centre, it is optional to invite the OECI A&D Coordinator and a Member of the A&D Board for an intermediate one day visit. The content of such visit is to discuss the progress of the self-assessment and manage the expectations of outcomes of the Programme. The costs of this visit are paid for by the Applicant Centre and will be agreed in advance.

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 advice of the analysis by the Accreditation Committee.

STEP 6: Payment fee stage two

The payment order will be sent 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 in advance of the peer review visit. The visit takes place about 3 months after finishing the self-assessment by the Applicant Centre.

STEP 8: Reporting and improvement plan

The reporting period is split into two phases. Phase 1 is the reporting by the audit team. Within 4-6 weeks the Applicant Centre receives a draft report including strengths and opportunities. Based on the draft report, the Applicant Centre formulates an improvement plan. Phase 2 is finalisation 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 months of receiving the final report including the improvement plan of the Applicant Centre. The decision is based on advice of the analysis by the Accreditation Committee. The Applicant Centre will receive the final report and a notification of OECI certification. The Certificate will be handed over during the Annual General Assembly the following June.

STEP 10: FOLLOW-UP of Accreditation and Designation Programme

One year after the issuing the certificate the cancer centre/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 cancer centre/institute should start the re-accreditation process in advance of the expiry date; OECI will send a letter to prompt this process.

The ten steps of the re-accreditation process are summarised in figure 3.

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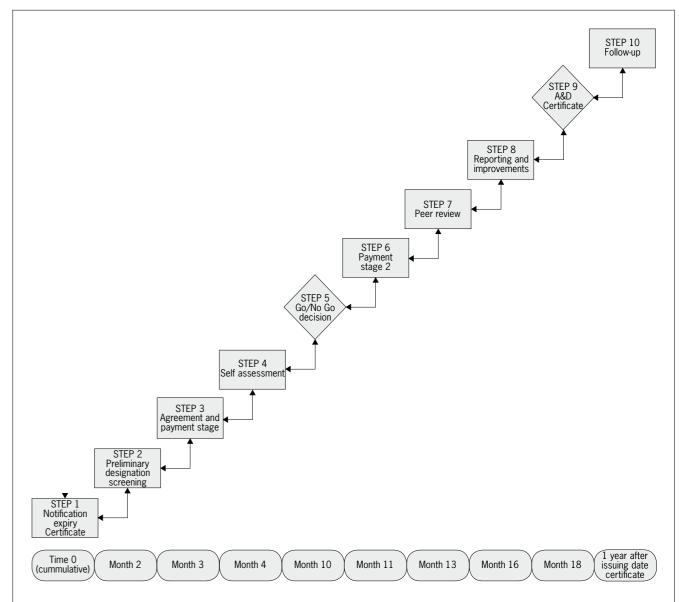


Figure 3: Timeline Re-Accreditation Process

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Accreditation and Designation Programme

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 into three parts: people and groups within the OECI, OECI auditors and the audit team, and the people involved from the Applicant Centre.

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 to be able to reduce mortality and morbidity due to cancer and increase survival and quality of life. Therefore, the model of oncology is based on a global vision of the cancer challenge which emphasises the integration of research and education with diagnosis, prevention, care and rehabilitation to promote the development of comprehensive and multidisciplinary organisation of care within cancer centres/institutes. For more information, see the OECI Statutes http://www.oeci.eu/Statutes.aspx

The structure of the OECI contains the following bodies:

- General Assembly
- Board
- President
- Manager (OECI Director)
- Coordinating Secretariat/Liaison Office
- Accreditation and Designation Programme
- Working Groups.

(see https://www.oeci.eu/Governance.aspx)

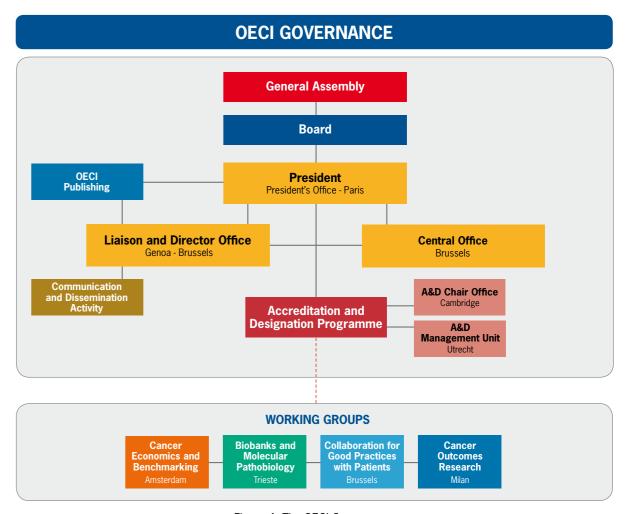


Figure 4: The OECI Governance

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3.1.1 OECI Board

The OECI Board is composed of at least the following members from OECI Full Members:

- The President, who presides the meetings of the General Assembly and the Board
- The Vice-President who shall chair all meetings in the absence of the President
- The immediate Former President
- The Executive Secretary
- At least four 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 OECI Members

A list with the names of the current OECI Executive Board members is published on:

https://www.oeci.eu/Board.aspx

3.1.2 OECI Accreditation and Designation Programme

The OECI Accreditation and Designation Programme includes:

- OECI Accreditation and Designation Board (A&D Board, 3.1.3)
- OECI Accreditation and Designation Management Unit (MU, 3.1.4)
- OECI Accreditation Committee (AC, 3.1.5)
- OECI Liaison Office (3.1.4.4)
- OECI Auditors (3.2.3)

The tasks and responsibilities of the members of those bodies are described in the following paragraphs. A list with the names of the current A&D Group members is published on: https://www.oeci.eu/Accreditation/

The OECI A&D Programme is facilitated by an online programme for self-assessment (e-tool).

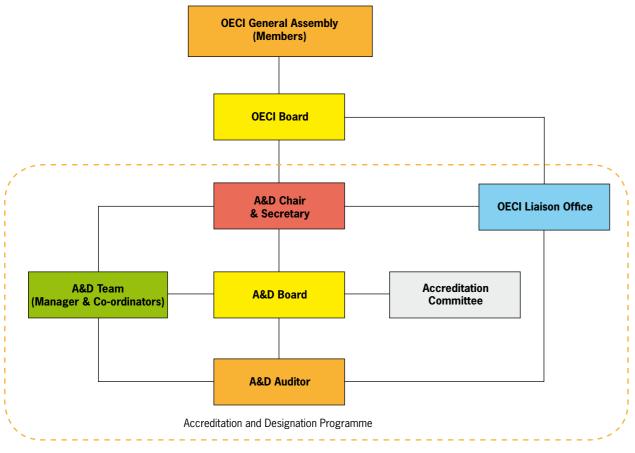


Fig. 5: OECI A&D Programme Organisational Chart

3.1.3 OECI Accreditation and Designation Board

The OECI A&D Board is composed of seven (or more) persons, from the OECI member cancer centres/institutes, including the Chairperson. External experts or representatives of other cancer organisations may be co-opted.

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3.1.3.1 Chairperson

The Chairperson leads the activities of the A&D Programme, chairing the A&D Board and representing the Programme in the OECI Board as co-opted member, if not otherwise elected.

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

3.1.3.2 A&D Board members

The requirements for the composition of the A&D Board are:

- All members of the A&D Board shall be approved by the OECI Board
- A&D Board members hold a position within the Board of Directors of an OECI Member or a position with comparable authority within an OECI member cancer centre/institute
- Other representatives as decided by the OECI Board, including patient representation
- Members are appointed for a three-year term that may be renewed for three years.

Tasks and responsibilities of the OECI A&D Board

Policy/procedures:

- Decision-making on accreditation and designation procedures and policies

A&D Programme:

- Assessing new applications of cancer centres/institutes in the A&D Programme and their preliminary designation type
- Deciding on the Go/No Go for the peer review: approve/disapprove of the self-assessment results of a cancer centre/institute as an 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 centre/institute
- Deciding on the designation type of the cancer centre/institute following the self-assessment and peer review outcomes
- Advertising and expanding the Programme in agreement with the OECI Board and in collaboration with the OECI Liaison Office

Financial:

- Assessing the income/expenditure compared to provisional budget based upon the input from the OECI Liaison Office
- Assessing annually the provisional budget and balance to be presented to the OECI Board and to the OECI General Assembly for approval.

Decision-making

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

3.1.4 OECI Accreditation and Designation Management Unit

The A&D Management Unit includes the A&D Manager, A&D Co-ordinators and A&D Secretary.

Tasks and responsibilities in relation with the A&D Programme

- Daily management of the A&D Programme
- Contact persons for all parties involved in the A&D Programme
- Coaching and advising cancer centres/institutes in all steps of the A&D Programme
- Organising and performing the peer review

3.1.4.1 OECI Coordinating Secretariat/Liaison Office

Tasks and responsibilities in relation with the A&D Programme

- Processing the A&D Agreement for new Applicant Centre:
- Sending by e-mail two copies of the A&D Agreement to the Applicant Centre to be signed by the Director (legal representative of the cancer centre/institute)
- Both copies are sent back by regular mail to the OECI Liaison Office at the address included in the agreement to be signed by the OECI Director on behalf of the OECI President
- Requesting reimbursement and payment
- Providing travelling arrangements for auditors/ OECI A&D Programme members
- Organising training courses for auditors
- Preparing all dissemination materials and certificates

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3.1.5 OECI Accreditation Committee

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

- The AC is made of up to ten persons from different cancer centres/institutes and countries
- The AC is co-ordinated by an A&D Co-ordinator of the A&D Management Unit
- Members are appointed for a three-year term that may be extended for three years
- The chair preferably works in a designated OECI CC or CCC centre
- Members have different complementing backgrounds: physicians, nurses, translational scientists, quality management, experience with industry

Profile of Accreditation Committee member: as auditors' profile, below

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 evidence 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 the final report:

- To analyse the conclusions, strengths and opportunities that are drafted by the audit team, and to advise the A&D Board on the complete final report and on the final accreditation and designation type
- The final report includes the improvement plan of the Applicant Centre.

A list with the names of the current Accreditation Committee is published on: https://oeci.eu/accreditation

3.2 Audit team and auditors

3.2.1 OECl audit team

Composition of the audit team

The audit team consists of four to six members:

- A Chair, who is also one of the auditors
- Three to five auditors

In an ideal situation the team consists of:

- A chair who holds a position within the Board of Directors (or equivalent) of an OECI Member
- Auditors with different positions/ functions in different fields of oncology, such as: medical oncology, care, research, pathology, quality assurance
- One auditor who understands the language of the country where the Applicant Centre is situated
- If the visit takes place in a cancer centre/institute that is preliminarily designated as a CCC, the chair of the audit team is employed in a CCC

An OECI A&D Co-ordinator will also be present during the peer review visit to co-ordinate the peer review activities.

Selecting an audit team

The A&D Manager and A&D Co-ordinator are responsible for selecting the chair and auditors of an audit team in conjunction with the chair of the A&D Board.

Before the audit team members get access to the self-assessment information of the Applicant Centre:

- The Applicant Centre has expressed that there is no conflict of interest with any of the audit team members (4.1)
- Each auditor has signed a Confidentiality Agreement (Doc. 514), and a Conflict of Interest Form (Doc. 515), which needs to be signed for every audit

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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 centre/institute or holds a position within the Board of Directors (or equivalent) within this centre/institute. If the chair is retired or has accepted a position within another organisation (which is not a member of OECI), OECI may use the services of this auditor for a maximum period of four years.
- The chair has experienced at least one peer review as an auditor before chairing a review

Tasks

- The chair opens the peer review visit with a presentation
- 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 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 centre/institute and is working in the specific field of oncology, for example:
- registered as a medical specialist (medical oncologist, surgeon, radiation therapist, pathologist)
- a quality manager, an oncology nurse, a cancer researcher
- If an auditor leaves a position in a cancer centre/institute (being a member of OECI) because of retirement, or accepts a position within another organisation which is not a Member of the OECI, OECI may use the services of this auditor for a period of four years after the date of that change. In these cases, the auditor has to take out comprehensive accident and health insurance for the period of the peer review and the auditor's honorarium is paid to him or her personally. If an auditor moves to a position with another organisation which is a member of OECI, a new request of acceptance of his/her role as auditor is sent to the Legal Representative for agreement.
- Is approved by his/her management to apply as an OECI Auditor (engagement letter)
- Has attended and passed the OECI audit training programme (auditors are regarded as being "on probation" during their first OECI Peer Review)
- Has the following skills and qualities:
- speaks and writes English fluently
- has a good overview of the field of oncology in a cancer centre/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-day visit, one evening preparation, two days to travel: a total of four days
- reporting: two days

Tasks

The Auditor:

- Prepares the peer review visit by analysing the self-assessment results and documents of the cancer centre/ institute
- Attends the preparation meeting of the audit team one or two months in advance of the peer review visit (teleconference)
- 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

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- 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 centre/institute, and formulates the final strengths, opportunities and conclusions of the peer review

3.2.3.1

Honoraria and Insurance in respect of auditors

The OECI Member which releases a member of staff for the purpose of being an auditor is required to ensure that the auditor is covered by accident and health insurance for the period of the audit and to allow the auditor to render the services during working time. The employing OECI Member receives an honorarium in respect of the auditor which is currently \leqslant 500 per peer review (\leqslant 1,000 for a chair). These amounts are paid in December each year.

3.2.4 Observers in peer review visit

What is an observer?

An observer can be:

- A new person working for the OECI A&D Programme e.g. PhD or co-ordinator
- A representative of another participating OECI centre/institute, who has no conflict of interest

Objectives of an observer to attend in a peer review visit

- Learning about the OECI A&D peer review process and procedures
- Gaining experience in the OECI A&D Programme

Rules for admission of an observer in audit team

Both the auditors in the team as well as the observer are subjected to the following rules:

- The cancer centre/institute 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. 515)
- The observer shall sign the confidentiality agreement (Doc. 514)

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, performance and results of the peer review visit

3.2.5 Role of co-ordinator in the peer review visit

The co-ordinator plays a major role throughout the whole process in the A&D Programme. The co-ordinator accompanies the audit team in the institute for the peer review visit but is not part of the team.

The specific tasks of the co-ordinator in the peer review visit are:

- Supporting the Applicant Centre during the self-assessment
- Preparing the visit agenda with the Applicant Centre
- Supervising the process of the visit
- Supervising the agenda and time-planning of the visit
- Supervising the content of the visit's 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 e-tool
- Editing the report according to the auditors' input

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3.3 Applicant Centre

Obviously, all employees of an Applicant Centre are directly or indirectly involved in the A&D 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 employees as much as possible to build commitment to the A&D Programme and encourage staff 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 Applicant Centre are explained step-by-step in the following sub-chapters.

3.3.1 Legal Representative/Director Applicant Centre/ Board of Directors

The Director/ Board of Directors of the Applicant Centre has a central role in the commitment of their cancer centre/institute in the Accreditation Programme. Although the A&D Co-ordinator will mainly relate with the contact person of the Applicant Centre, the Director/Board of Directors is involved in:

- Signing the Application form
- Signing the OECI A&D Programme agreement depending on the preliminary designation type (Doc. 506)
- Expressing a potential conflict of interests with the audit team members if necessary (Chapter 4.2)

During the accreditation process the Legal Representative/Director receives the following notifications and documents:

- Approval/disapproval of application Preliminary designation type
- A&D Agreement
- Go/No Go decision for peer review visit
- Draft peer review report
- Final peer review report including final designation type OECI A&D Certificate, with agreed final designation type

3.3.2 Contact person cancer centre/institute

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

With the A&D Secretary and the OECI Liaison Office with regard to:

- Information about accommodation for peer review visit

With the A&D Co-ordinator with regard to:

- The application and preliminary designation screening
- Information about the A&D 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
- The improvement action plan
- Follow-up of the A&D Programme

With the OECI Liaison Office with regard to:

- OECI membership
- A&D Agreement
- Payment of the A&D Programme fee in two stages
- Mailing of the certificate on plate and paper

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Accreditation and Designation Programme

4. Confidentiality and conflict of interest

4. Confidentiality and conflict of interest

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

4.1 Confidentiality

During the A&D Programme of a cancer centre/institute different persons will have access to the information and data of the Applicant Centre. 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 Applicant Centre.

In accordance with OECI A&D Programme policy, all information related to the accreditation of a cancer centre/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 centre/institute must be referred to the OECI A&D Programme, or to the respective cancer centre/institute.

The persons who must sign the confidentiality agreement (Doc. 514) are:

- Members of the OECI A&D Board
- Members of the OECI A&D Management unit
- Members of the OECI Accreditation Committee
- All auditors
- Third persons, such as researchers, who are employed by an OECI Member and have been asked by OECI to analyse and publish their data. The data will be anonymous and cannot be traced back to a specific cancer centre/institute, unless the cancer centre/institute has approved that the information may be made available to the public.

As OECI builds its Quality Network around the A&D Programme, there is an increasing need for benchmarking key metrics around cancer care and research, and publishing the results of this. In doing so, there will be occasions in which OECI as lead author will wish to attribute data or results to cancer centres/institutes. If this is the case, OECI undertakes always to obtain the prior written consent of the cancer centre/institute before publishing any data of the cancer centre/institute.

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

4.2 Conflict of interest

All auditors must sign the Conflict of Interest form (Doc. 515) for each peer review they are going to perform.

To ensure that all matters dealing with the A&D Programme of cancer centres/institutes are conducted in an unbiased manner, the OECI A&D Programme 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 centre/institutes being reviewed
- 2. Service as a consultant for the cancer centre/institutes being reviewed
- 3. Graduation from the cancer centre/institutes being reviewed
- 4. Membership on the advisory committee of the cancer centre/institute being reviewed
- 5. Other potential conflicts of interest, such as employment of private consultants or subcontracts with private companies etc.

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It is expected that the candidate auditor communicates with the A&D Programme 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 A&D Programme, it is acceptable to allow the individual to remain on the audit team.

Expressing conflict of interest by the cancer centre/institute

The composition of the audit team will be sent to the Applicant Centre to provide the opportunity to express any potential conflict of interest. In case the cancer centre/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.

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Accreditation and Designation Programme

5. Ten step A&D Process in detail

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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.

$5.1~\mathrm{Step}$ 1: Application of a cancer centre/institute to the A&D Programme

Step 1 is the application to the A&D Programme. Figure 6 shows the details in this step.

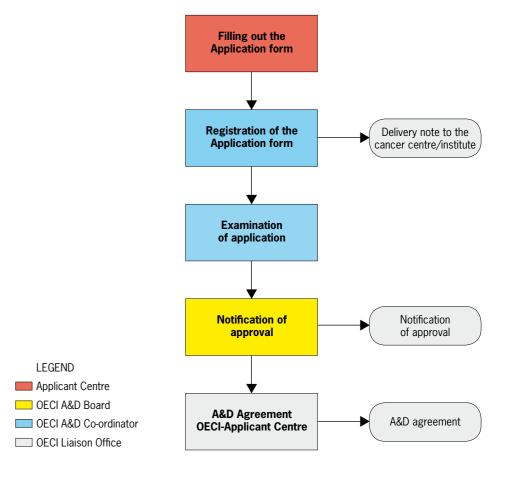


Fig. 6: Step 1 Application to the A&D Programme

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STEP 1: activities and responsibilities of all parties involved (figure 6)

Filling out the Application form

Executor: Applicant Centre

- Applications are done via the web-based e-tool which Applicant Centre can access via the OECI website.
 https://www.oeci.eu/Accreditation.
 The Applicant Centre may find general info on the application in the section 'How to apply'
- The page starts with a general introduction of the Programme. By clicking 'Go to the online Application form' (at https://oeci.exata.nl), the Applicant Centre is asked to create an account. After creating an account, the Applicant Centre receives an e-mail, asking to activate the account
- -The Applicant Centre can now access the Application form in the e-tool (oeci.exata.nl) by using the username and password for the e-tool.

The Application form contains general questions about the cancer centre/institute, such as contact details, and some additional questions to give the A&D Board an idea about the scale of activities, such as budget, number of cancer patients treated, number of physicians.

Once the Application form is finalised, the OECI A&D Management Unit will be informed and will take further action.

The approval of the Director/ Board of Directors is required for full commitment to the programme.

Note 1: The information in the application and designation phases will be copied to the OECI self-assessment questionnaires at the start of the A&D Programme - after payment of stage 1 - to prevent repetition of applying information.

Note 2: All information delivered by the Applicant Centre during all the stages of the OECI A&D Programme is used in a confidential way according to the OECI A&D Programme policy.

Registration of the Application form

Executor: OECI A&D Co-ordinator

- The OECI A&D Co-ordinator receives the Application form through the e-tool
- The OECI A&D Co-ordinator sends a delivery note to the Applicant Centre
- The OECI A&D Co-ordinator will arrange to discuss the Application form in the first planned OECI A&D Board
- The OECI A&D Co-ordinator makes an appointment with the contact person of the Applicant Centre to further discuss the process of the A&D Programme, by telephone conference

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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
- The preliminary designation items will be analysed
- The A&D Board will approve or disapprove the application

Criteria for application

Applying to the A&D Programme is a voluntary decision of a cancer centre/institute. However, to provide the Applicant Centre with a qualitative programme and to reach the Accreditation and Designation goals, there are a number of obligations that each cancer centre/institute should meet:

- Strong commitment to quality improvement (signature of Director/ Board of Directors)
- Dedicated staff (contact person, project group, all relevant employees)
- Stable management structure
- No major changes/problems (expected management change, merger, site 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 in an identifiable unit with an identifiable budget, management and organisational structure

Re-accreditation

Cancer centres/institutes who apply for re-accreditation do not need to fill out the Application form, as they have already been approved to participate in the OECI A&D Programme. They will be notified by the OECI A&D Management Unit how and when they need to apply for their re-accreditation. The re-accreditation process will start after submitting the Designation form in the e-tool.

Notification of approval

Executor: OECI A&D Co-ordinator

If the application of a cancer centre/institute is approved:

- The A&D Co-ordinator sends the notification of approval by e-mail to the Board of Directors of the Applicant Centre and the contact person
- The notification e-mail is also sent to the OECI Director to manage the A&D Agreement and the Stage 1 invoice
- The A&D Co-ordinator contacts the Co-ordinator of the Applicant Centre to plan a teleconference to further explain the planning and organisation of the A&D Programme

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5.2 Step 2: Payment Stage 1 fee

Once the OECI A&D Board approves the application (for cancer centres/institutes applying for the first time) or the OECI A&D Board approves the Designation form (for cancer centres/institutes starting their second or following re-accreditation cycles), the Applicant Centre will receive the first invoice together with the OECI A&D Agreement.

The process and tasks of the Liaison Office and the Applicant Centre (see also chapter 3.1.4):

- OECI Liaison Office prepares the OECI A&D agreement
- The agreement is sent by e-mail to the Applicant Centre for signature, together with the invoice of Stage 1 fee.
- Two copies of the signed agreement are sent back by mail to the OECI Liaison Office.
- The OECI Director, on behalf of the OECI President, signs the two copies of the Agreement and sends one copy back to the Director of the Applicant Centre.
- Signing the agreement and participation in the A&D Programme is subject to the payment of the Accreditation and Designation fee whose amount is approved by the General Assembly upon proposal of the OECI Board.
- When an OECI Member applies, the OECI Liaison Office checks the status of payment of the OECI membership
 fee and sends a confirmation to the A&D Manager; if there are outstanding payments the (re-) accreditation
 process will be halted

The total fee:

	Stage 1	Stage 2	Total
OECI Cancer Centre (CC)	€ 20,000	€ 25,000	€ 45,000
OECI Comprehensive Cancer Centre (CCC)	€ 20,000	€ 25,000	€ 45,000
Reaccreditation of CC or CCC	€ 20,000	€ 25,000	€ 45,000

Table 1: A&D fee as proposed by OECI Board and approved on June 21st 2019 by the General Assembly

The Stage 1 fee is equal for all types of Applicant Centre 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 Accreditation Committee and A&D Board for the Go decision, and labour costs of the A&D Management Unit. The costs for an intermediate visit are not included in the A&D fee.

Note 1: There might be reasons for which an Applicant Centre 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 Applicant Centre will be reminded of its participation in the A&D Programme. In this case the OECI A&D Programme will not return the payment of Stage 1.

Note 2: The application expires two years after the date of signature of the A&D Agreement. Within these two years the Applicant Centre should have finished the self-assessment. If the self-assessment has not been completed within these two years, the Applicant Centre should pay Stage 1 fee again, before continuing the process.

Note 3: The A&D Programme starts only when stage 1 of the fee has been paid.

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5.3 Step 3: Preliminary designation screening

The A&D Programme starts after the Applicant Centre has paid Stage 1 fee.

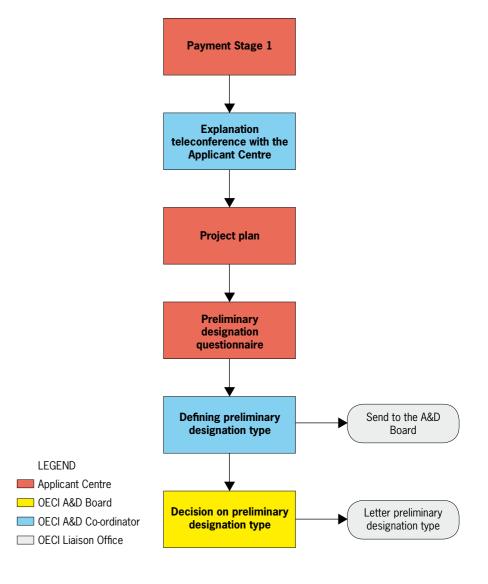


Fig. 7: Step 3 preliminary designation screening

The designation screening (figure 7) takes place to assess the preliminary designation type of the Applicant Centre. The preliminary designation is discussed by the OECI A&D Board. Both the judgement of the Applicant Centre and the outcome of the preliminary designation screening are the starting point for the next steps of the process. These steps are explained by the A&D Co-ordinator during a teleconference call.

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Explanation telephone/video conference

Executor: OECI A&D Co-ordinator

The OECI A&D Co-ordinator:

- Arranges an explanatory meeting with the Applicant Centre, through conference call
- Sends a meeting agenda to the cancer institute
- Explains the project plan (separate questionnaire in e-tool) as an example on how to organise the preliminary designation and self-assessment period in the institute

During a telephone/video meeting the A&D Co-ordinator explains the following subjects:

- The A&D Programme
- The preliminary designation screening; the designation type is the starting point for accreditation
- Timelines of the process, and what this means for the centre/institute
- Access to the e-tool for the preliminary designation screening and the self-assessment
- Project plan of the Applicant Centre in the e-tool
- Requested documents for peer review
- Obligations of the Applicant Centre
- Role of the OECI

The A&D Co-ordinator arranges the access to the preliminary designation questionnaire and the project plan in the e-tool, provides a new username and password, and arranges that the data are transferred to the new questionnaires.

Preparation of preliminary designation and project planning

Executor: Applicant Centre

After the explanatory telephone meeting the Applicant Centre

- Composes a project team in the cancer centre/institute
- Prepares and plans the preliminary designation screening and self-assessment as it was agreed in the explanatory teleconference call with the OECI A&D Co-ordinator

Project group and project planning

The OECI A&D Management Unit offers a template project plan (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 centre/ institute
- Deadline for finishing the questionnaires including notes and (requested) documents
- Timeline and method of informing the final results to all professionals and staff

The OECI A&D Programme 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

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Designation form

Executor: Applicant Centre

- After the approval of the application in the A&D Programme the Applicant Centre continues with the
 designation screening that will be accessible as an online questionnaire in the e-tool (https://oeci.exata.nl)
- The OECI A&D Management Unit provides a new e-tool account for the Applicant Centre and transfers the data from the Application form in the registration environment to the Designation form
- The items requested for designation are a selection of the quantitative questionnaire for self-assessment.
 The Applicant Centre fills in these items only once. The numbers are automatically copied to the quantitative questionnaire
- The Applicant Centre fills out all items in the Designation form

The form requests figures of a specific year. The Applicant Centre can state the year from which the figures are derived and it should use the figures of the last completed administrative year. An exception to this rule is where the standard asks for figures from the last year available.

The final decision for the designation type will be checked during the peer review visit.

Deviation in designation judgement of the centre/institute and the preliminary designation result. The Designation form asks the Applicant Centre to classify itself in one of the two designation types. It is possible that there might be a discrepancy between the judgement of the centre/institute and the designation screening result (preliminary designation).

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 Applicant Centre for preliminary designation and will check whether there is a deviation in designation judgement of the cancer institute and the preliminary designation result.

The Applicant Centre receives a communication with the results of the discussion of the OECI A&D Board (Doc. 050)

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5.4 Step 4: Self-assessment

Step 4 of the A&D Programme is the self-assessment of the Applicant Centre (figure 8).

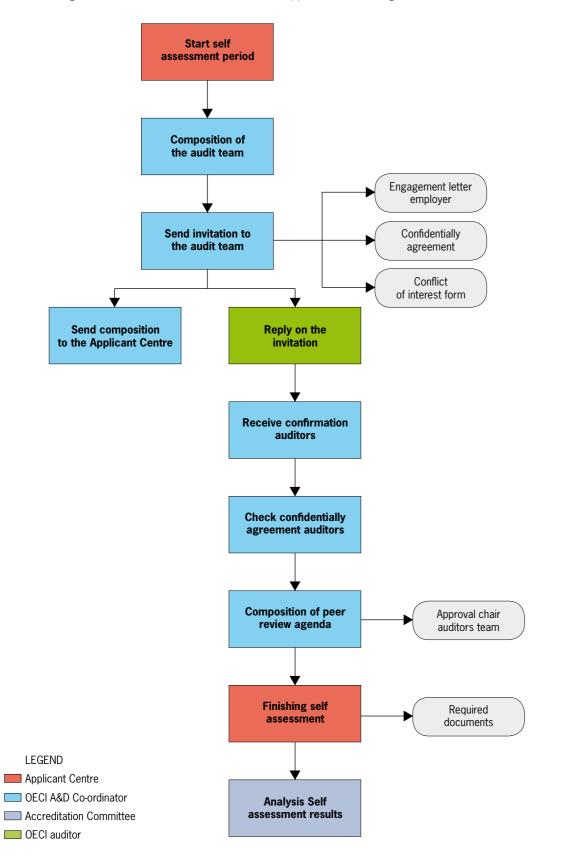


Fig. 8: Step 4 Self-Assessment

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5.4.1 Step 4: Activities and responsibilities of all parties involved (figure 8)

Start self-assessment period

Executor: Applicant Centre

- After the preliminary designation questionnaire, the self-assessment takes about 5 more months
- The deadline of the self-assessment period is at least 3 weeks before the next TC of the OECI A&D Board, to enable the Accreditation Committee to prepare the Go/No Go decision for the OECI A&D Board
- Technical review: A technical review of the draft self-assessment is carried out by A&D Co-ordinator at least two weeks before the final deadline of the OECI self-assessment. The aim of the technical review is to ensure that the self-assessment will be completed in accordance with OECI requirements and that all standards are rated. An overview is sent to the cancer centre commenting on any areas which may need addressing, no comment is made on compliance. The Applicant Centre then has time to make any necessary changes to the self-assessment prior to submission to the audit team.

E-tool

- The Applicant Centre fills out the quantitative and qualitative questionnaire
- All items requested for designation in the Designation form will be available in the quantitative questionnaire
 for the self-assessment, so that the institute fills out these items only once. When an Applicant Centre
 ascends to the next step in the accreditation process, the OECI A&D Co-ordinator will arrange that the data
 is transferred to the next questionnaire
- The Applicant Centre must make notes/remarks for all questions to explain the score/answers
- The Applicant Centre must attach documents to questions to support the answers
- The Applicant Centre additionally must attach the documents required by the OECI in the stated list of Requested Documents
- The Applicant Centre should describe non-compliances/ improvement points in the e-tool that will be used to make an improvement plan

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Start self-assesment for re-accreditation

Executor: Applicant Centre

All Standards in the Qualitative questionnaire need to be scored, but only new Standards, Core Standards, and those previously scored other than 'Yes' by the centre/institute will require audit evidence to be uploaded.

- The Applicant Centre fills out the quantitative and qualitative questionnaire (only the standards in the qualitative questionnaire indicated require notes and audit evidence to be uploaded.
- All items requested for designation in the Designation form will be available in the quantitative questionnaire
 for the self-assessment, so that the institute fills out these items only once. When an Applicant Centre
 ascends to the next step in the accreditation process, the OECI A&D Co-ordinator will arrange that the data
 is transferred to the next questionnaire
- The Applicant Centre must make notes/remarks for all questions to explain the score/answers
- The Applicant Centre must attach documents to questions to support the answers
- The Applicant Centre additionally must attach the documents required by the OECI in the stated list of Requested Documents
- The Applicant Centre should describe non-compliances/ improvement points in the e-tool that will be used to make an improvement plan

Progress of the self-assessment

During the self-assessment period, the A&D Co-ordinator will be regularly in touch with the Applicant Centre to monitor the progress of the self-assessment.

If required by the centre/institute, it is optional that during the self-assessment period the future chair of the audit team and the A&D Co-ordinator might pre-visit the Applicant Centre. This could be at the request of the Applicant Centre or because of an issue foreseen by the OECI A&D Board. This pre-visit could be useful for face-to-face support during the self-assessment and to manage expectations regarding accreditation and designation. The costs of this visit are covered by the Applicant Centre and are agreed on in advance.

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-cycle or Deming-cycle. 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/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 centre/ 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 centre/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 centre/institute

After filling out all the questions, the e-tool generates the results. The results are 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 Co-ordinator

The OECI A&D Manager and A&D Co-ordinator compose the audit team for the peer review visit of the Applicant Centre.

See criteria for auditors (3.2).

Send composition to the Applicant Centre

Executor: OECI A&D Co-ordinator

The composition of the audit team is sent to the Applicant Centre to provide the opportunity to express any potential conflict of interest against one/more of the audit team members.

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Composition of peer review agenda

Executor: OECI A&D Co-ordinator

- Specify the template peer review agenda for the Applicant Centre
- Send draft agenda to the chair of the audit team for approval

Finishing self-assessment

Executor: Applicant Centre

Within six months after the start of the self-assessment period, the Applicant Centre completes the questionnaires and finalises the self-assessment in the e-tool:

- Quantitative questionnaire
- Qualitative questionnaire
- Requested documents (required to be translated in English)
- Notes to support scores
- Requested evidence and other proof documents attached to guestions
- Described non-compliance points/improvement points

Analyse self-assessment results

Executor: OECI Accreditation Committee

- To analyse and examine the self-assessment reports before peer review
- To analyse the evidence for peer review
- To analyse the results of the self-assessment
- To advise the A&D Board concerning a Go/No Go decision

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5.5 Step 5: Go/No Go decision

The final 'Go' or 'No Go' decision is taken by the OECI A&D Board. Before the A&D Board decides, the A&D Committee will analyse the self-assessment results according to the criteria for self-assessment. The Accreditation Committee composes an advice to the A&D Board of 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 Applicant Centre for a 'Go' after the Accreditation Committee has provided their independent examination. In some cases, a 'Go' Decision is given, subject to the Applicant Centre supplying vital documentation or assurances prior to the peer review.

The Applicant Centre has provided sufficient evidence and information to allow the audit team to do a reliable peer review visit on site. The input includes:

1. All items are scored

- 2. The questionnaires are sufficient for the auditors to prepare the audit, which means that the Applicant Centre 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 requested documents, translated fully into English or provided with an extensive summary, are attached to the e-tool
- Questions scored as 'partially' or 'no' are described in a non-compliance/ improvement point

The e-tool manual explains how to put the evidence in the e-tool (Doc. 110 in the e-tool)

Task: Chair of the A&D Board

The Board of Directors of the Applicant Centre receives a notification letter of the Go decision (Doc. 616) signed by the chair of the A&D Board.

Task: A&D Co-ordinator

The contact person of the Applicant Centre receives information about the continuation of the process including:

- An empty draft of the peer review agenda including the presentation of the audit team (doc 616) for acceptance by the Applicant Centre
- Instructions on how to fill and complete the agenda
- Deadline for the submission of the completed agenda
- Requirements for the Applicant Centre to organise 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 audit team in compliance with the A&D Programme Agreement
- Providing permission to observe activities or procedures in the Applicant Centre during the peer review visit
- On request of the OECI audit team, the Applicant Centre shall provide access to all relevant locations, files and documents needed for assessment during the on-site peer review
- The language during the peer review is English. The Applicant Centre staff involved in interviews need to understand and speak English. If not, the OECI requires the cancer centre/institute to provide an independent person to translate the questions of auditors and answers of staff during the peer review visit

Meaning of a 'No Go' decision

Generally, a 'No Go' decision means that the peer review visit is postponed, e.g. because the evidence provided was not sufficient for the audit team to prepare and perform the peer review in a reliable way and that there is a need for additional information (notes) or evidence (documents).

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5.6 Step 6: Payment Stage 2 fee

If the self-assessment of the Applicant Centre is approved for a 'Go', the Applicant Centre will receive the invoice for Stage 2 of the A&D fee.

- The OECI Liaison Office receives a copy of the letter Doc. 036 in which the Go decision by the OECI A&D Board is mentioned
- The invoice for the payment of the Stage 2 fee is sent by the OECI Liaison Office.
- The OECI Liaison Office assesses the status of payment and sends a confirmation of the payments to the A&D Manager

The total fee:

	Stage 1	Stage 2	Total
OECI Cancer Centre (CC)	€ 20,000	€ 25,000	€ 45,000
OECI Comprehensive Cancer Centre (CCC)	€ 20,000	€ 25,000	€ 45,000
Re-accreditation of CC or CCC	€ 20,000	€ 25,000	€ 45,000

Stage 2 fee 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 Accreditation Committee and A&D Board decisions, and labour costs of the A&D Management Unit. A re-visit due to a postponed A&D decision, and a pre-visit arranged with the Applicant Centre are not included in these fees.

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

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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.

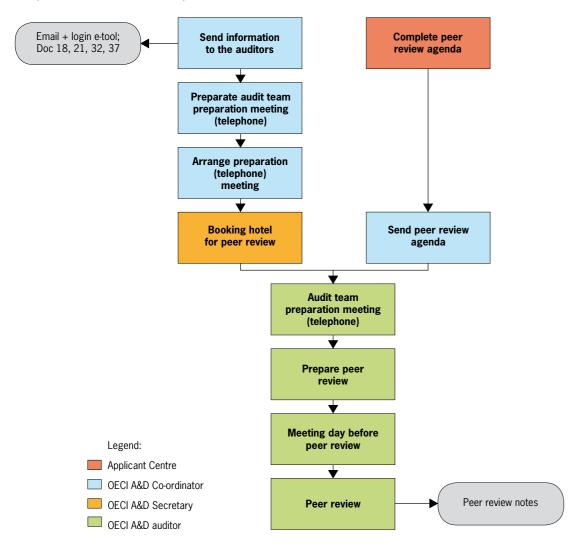


Fig. 9: Step7: Peer review visit and designation check

5.7.1 Step 7: Activities and responsibilities of all parties involved (figure 9)

Step 7 starts with parallel activities for the A&D Co-ordinator, the auditors and the cancer centre/institute. The OECI A&D Co-ordinator organises a preparation meeting with the audit team and the peer review visit in collaboration with the Applicant Centre (and the OECI Liaison Office).

Complete peer review timetable

Executor: Applicant Centre

While the audit team organises the auditor's preparation meeting, the Applicant Centre defines and completes the peer review visit agenda. The draft timetable is approved by the audit team during the preparation meeting.

The draft timetable for the peer review is completed by the Applicant Centre. During the peer review the auditors interview employees of the different departments. The Applicant Centre must provide a list of the persons from the requested departments and the location/room where the interviews may take place.

Deadline for the draft agenda: 1 week before the auditor's preparation meeting.

The draft agenda is discussed by the audit team during the preparation meeting (teleconference) and requests for changes are discussed with the cancer centre/institute (the OECI A&D Co-ordinator). Deadline final peer review agenda: 3 weeks before peer review visit.

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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 11).

The reporting period is split into two phases. In week 1 to 6 the auditors work on the draft report. This is outlined and explained in the sub-process: 'Reporting by audit team' (figure 10).

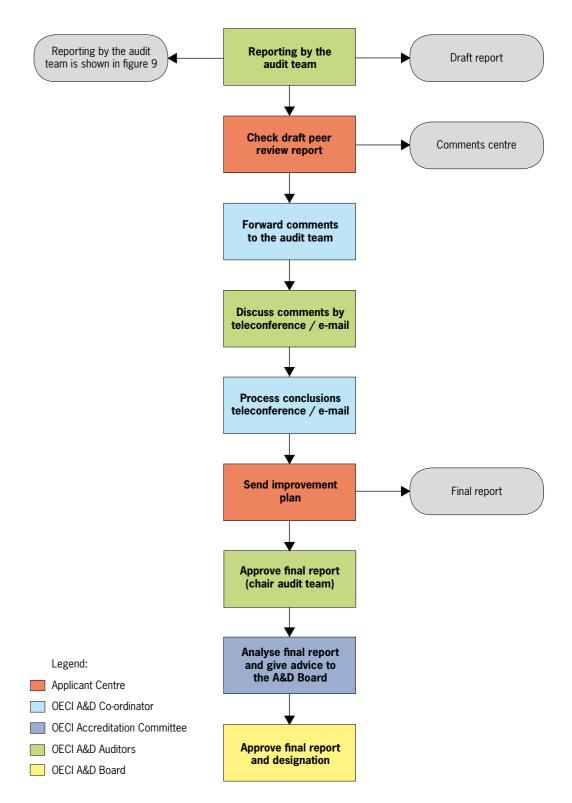


Fig. 10: Step 8 Reporting

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5.8.1 Week 1-6: Reporting by the auditors (figure 10)

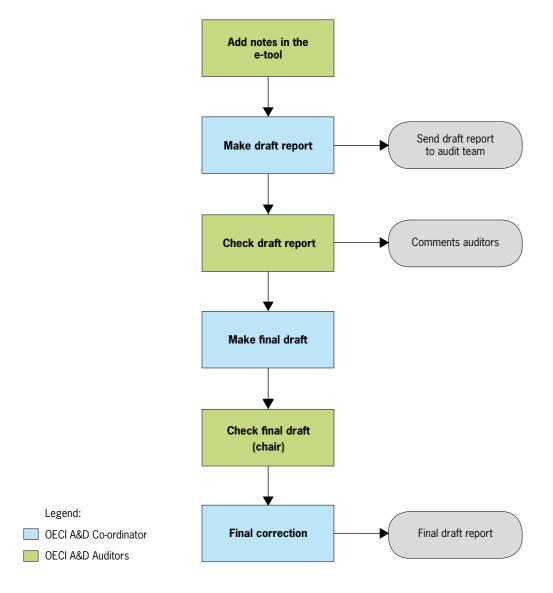


Fig. 11: Week 1-6: Reporting by the auditors

Proceed final comments

Executor: OECI A&D Co-ordinator

The A&D Co-ordinator sends the final draft report latest in week 6 after the peer review to the Director and A&D contact person of the Applicant Centre.

The draft is sent together with:

Doc. 041: Letter presenting the draft report
 Doc. 922: Feedback and comment form

Doc. 923: Template improvement actions plan

The final draft contains:

The standards reviewed during the peer review visit with the scores of the cancer centre/institute from the self-assessment, the scores 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 findings and the designation type.

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Check draft peer review report

Executor: Applicant Centre

- The Director and the accreditation contact person of the Applicant Centre receive the draft peer review report
- The Applicant Centre distributes the draft report to all involved and interested workers within the cancer centre/institute
- The Applicant Centre is invited to check the report on factual inaccuracies and to collect comments and feedback on Doc. 922: Feedback and comment form
- The contact person collects the comments within the institute and sends the form to the OECI Co-ordinator after 4 weeks
- Parallel to this process the Applicant Centre writes the Improvement Plan
- The explanation of the minimum criteria of the Improvement Plan can be found in the template document (Doc. 923)
- The Applicant Centre sends the improvement plan to the A&D Co-ordinator within 8 weeks after receiving the draft report

The general requirements 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 Applicant Centre approaches the actions

The plan contains the following aspects for each item for improvement. A template improvement plan is available in Doc. 923:

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

Forward comments

Executor: OECI A&D Co-ordinator

- The comments and feedback of the Applicant Centre on the draft report will be forwarded to the audit team members
- The audit team members are requested to provide their feedback on the comments by e-mail
- If necessary, the A&D Co-ordinator will arrange a teleconference to discuss the feedback with the audit team

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Discuss comments by teleconference or e-mail

Executor: OECI Chair/audit team

Discuss feedback and comments of the cancer centre/institute:

- The comments and response of the auditors will be discussed in a teleconference or via e-mail with the audit team and the OECI A&D Co-ordinator
- Formulate proposal for final conclusion, description of the designation check findings and the designation type for the final report within 4 weeks.

Analyse draft final report by the OECI A&D Committee

Executor: OECI Accreditation Committee

The Accreditation Committee receives 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 Applicant Centre.

The Accreditation Committee analyses the conclusions, strengths and opportunities that are drafted by the audit team, and the improvement plan drafted by the Applicant Centre. The Accreditation Committee gives a final advice to the A&D Board about the final report, improvement plan and the proposed designation type.

Approval final report

Executor: OECI A&D Board

During 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 accreditation as OECI Cancer Centre or OECI Comprehensive Cancer Centre. The A&D Board takes into account the advice from the Accreditation Committee.

The OECI A&D Board takes the final decision on the certificate.

The A&D Board may decide to postpone the certification if some major issues (e.g. strategy; governance of the cancer centre/institute) are not fulfilled. In this case the cancer centre/institute is usually given a 9-12 months period to rectify the issues.

Send final report to Applicant Centre

Executor: Chair A&D Board

Within 16-20 weeks after the peer review the cancer centre/institute receives:

- A letter to present the final report
- The final report, including the final designation
- Proposal for the A&D Certificate

Based upon the final report and the improvement plan the A&D Certificate can be awarded by the OECI A&D Board.

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5.9 Step 9: OECI A&D Certificate and final Designation

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 Accreditation and Designation decision.

The final designation is decided upon by the OECI A&D Board, taking into account the data provided by the cancer centre/institute for the peer review visit and which is confirmed during the peer review and the findings of peer review visit on the following criteria:

- 1. A highly innovative character and multidisciplinary approach using the potential of basic, translational and clinical research and clinical facilities and activities, organised in a sufficiently identifiable entity
- 2. 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, organisational and relational quality of care
- 3. Broad activities in the area of prevention, education, and external dissemination of knowledge and innovation
- 4. A high level of infrastructure, expertise and innovation in the field of oncology research
- 5. Maintenance of an extensive network including all aspects of oncology treatment and research

If the final report of the cancer centre/institute is approved by the OECI A&D Board, the cancer centre/institute will receive the A&D Certificate, including the final designation. The cancer centre/institute also receives a letter (Doc. 024) stating that it is awarded with the Certificate.

A paper and on plate copy of the A&D Certificate are delivered to the cancer centre/institute in the following month from the final decision. A copy on plate of the A&D Certificate is also held during a formal ceremony at the next annual OECI General Assembly.

The A&D Certificate is valid for five years. To maintain the A&D Certificate, the cancer centre/institute has to start a reaccreditation cycle of the A&D Programme, before the expiry date. The A&D Management Unit will prompt the cancer centre/institute to begin the re-accreditation process before the expiry of the Certificate.



OECI Accreditation and Designation Certificate

5.9.1 Evaluation A&D Process (See figure 13)

Executor: OECI A&D Co-ordinator and certified cancer centre/institute

The A&D Co-ordinator sends an evaluation form to the certified cancer centre/institute 3 months after the final A&D Certification approval. This is to obtain feedback from the cancer centre/institute on the overall process of the Programme as it affected the cancer centre/institute, so that OECl can plan continuous improvements to the A&D Programme.

Evaluation by teleconference

If requested by the certified cancer centre/institute in the evaluation form, the OECI A&D Co-ordinator and the A&D Manager plan a teleconference to discuss the evaluation form.

Representatives:

- Cancer centre/institute contact person
- OECI A&D Manager
- OECI A&D Co-ordinator

Owner:	Organisation of European Cancer Institutes – EEIG – RPM N. 0473647634	Chapter 5 Ten steps A&D Process in detail
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5.10 Step 10: Follow-up

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

Send progress report improvement plan

Executor: certified cancer centre/institute

The cancer centre/institute reports the progress of the goals and activities set in the Improvement Plan to the OECI A&D Manager **one year** after the date of the certificate.

The certified cancer centre/institute can add a column to the improvement plan:

	Standard	xxx
	Opportunity	
	Action	
Action x	Goal/ desired result	
	Actions description	
4	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 Co-ordinator

The A&D Co-ordinator receives an update from the cancer centre/institute with the progress of the implementation of the goals and activities set in the improvement plan. The A&D Co-ordinator analyses the progress and informs the A&D Board. The follow-up report will be discussed in the next monthly A&D Board meeting.

Intermediate self assessment (optional)

Executor: certified cancer centre/institute

The A&D Programme fee includes five years' access to the self-assessment e-tool

The cancer centre/institute has the option to perform an intermediate self-assessment to measure the improvements according to the OECI Quality Standards after the peer review visit.

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

Start new round A&D Programme

Executor: certified cancer centre/institute

The Certificate expires 5 years after the issuing date of the certificate.

To maintain the A&D Certificate, the cancer centre/institute has to start a re-accreditation cycle of the A&D Programme before the expiry of the A&D Certificate. The OECI Management Unit will prompt the cancer centre/institute to re-commence the process.

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Accreditation and Designation Programme

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

			,	
Owner: Status:	cer Institutes – EEIG – RPM N. 047 sels - April 9th 2019 / Consensus cor	quality standards" Brussels – April 10	± 2019	

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 A&D Programme. However, most documents are available in the e-tool.

The table below shows the needed and useful documents, and how to access them.

Name	Nr.	Where to find
Online Application form	Doc. 201	Website https://www.oeci.eu/Accreditation/
Project plan for cancer centre/institute	Doc. 205	In the e-tool
Requested documents questionnaire	Doc. 209	In the e-tool
E-tool user manual (institute)	Doc. 110	Appendix IV and in the e-tool
Template peer review agenda	Doc. 616	In the e-tool
Template Feedback and comments form cancer centre/institute	Doc. 522	In the e-tool
Template improvement plan	Doc. 523	In the e-tool
Evaluation form cancer centre/institute	Doc. 827	In the e-tool
Auditors e-tool user manual	Doc. 137	In the e-tool
Glossary	Doc. 142	In the e-tool

Owner:	Organisation of European Cancer Institutes – EEIG – RPM N. 0473647634	Chapter 6. Where to find the documents needed in the Programme?
Status:	Revised after OECl Board Brussels - April 9th 2019 / Consensus conference "Revision of the European quality standards" Brussels - April 10th 2019	Page 1 of 2
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Owner:	Organisation of European Cancer Institutes – EEIG – RPM N. 0473647634	Chapter 6. Where to find the documents needed in the Programme?
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Accreditation and Designation Programme

7. Overview of obligations and tasks of an Applicant Centre



7. Overview of obligations and tasks of an Applicant Centre

General status and eligibility:

- Strong commitment to quality improvement (signature of Director/ Board of Directors)
- Dedicated staff (contact person, project group, all involved employees)
- Stable management structure
- No major changes/problems (expected management change, merger, site 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 in an identifiable unit with an identifiable budget, management and organisational structure

Before the start of the self-assessment period:

- Signing the A&D Agreement
- Paying accreditation fee Stage 1
- Organising an internal accreditation project planning and project team

Before peer review:

- Completing the self-assessment questionnaires; results of self-assessment
- Delivering of requested documents
- Go-decision of OECI A&D Board
- Paying A&D fee Stage 2
- Completing the peer review agenda

During peer review:

- Facilitating the audit team as agreed in the A&D Programme
- Providing permission to observe activities or procedures in the Applicant Centre during on-site peer review
- On request of the OECI Audit Team, providing access to all relevant locations, files and documents needed for assessment during the on-site peer review
- Ensuring that the key participants in the peer review from the cancer centre/institute understand and speak English
- If necessary, providing the availability during tour of departments and wards of an independent 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

Owner:	Organisation of European Cancer Institutes – EEIG – RPM N. 0473647634	Chapter	7. Overview of obligations and tasks of an Applicant Centre
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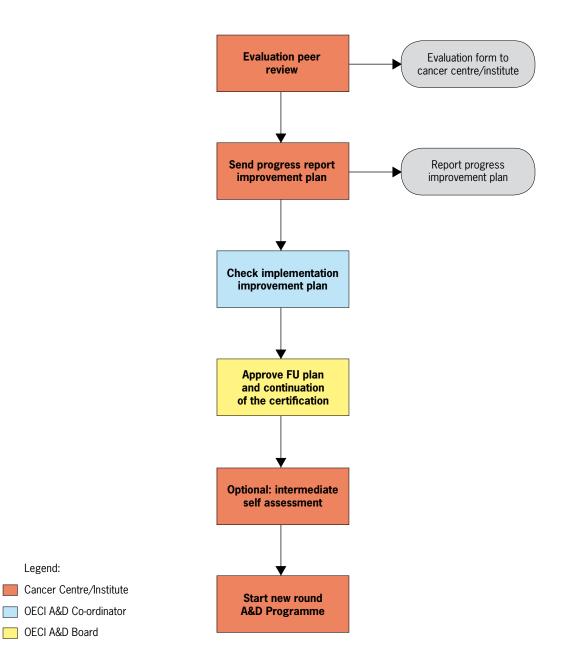


Fig. 13: Step 10: Follow-up of the A&D Programme

Owner:	Organisation of European Cancer Institutes – EEIG – RPM N. 0473647634	Chapter 7. Overview of obligations and tasks of an Applicant Centre
Status:	Revised after OECl Board Brussels - April 9th 2019 / Consensus conference "Revision of the European quality standards" Brussels - April 10th 2019	Page 2 of 2
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Accreditation and Designation Programme

Appendix I

Designation Criteria

Appendix I. OECI Quality Standards Manual 3.2

Designation Criteria

	Criteria OECI Cancer Centre	Criteria OECI Comprehensive Cancer Centre
Ger	neral Criteria	
Presence of surgical oncology, radiotherapy and medical oncology; research and education	Qualitative/quantitative assessment through accreditation	Qualitative/quantitative assessment through accreditation
Annual budget for cancer care (1.1.5)*	> 25 million Euro	> 50 million Euro
Annual budget for cancer research (1.1.5)*		> 8 million Euro
Number of cancer care inpatient beds plus the number of beds/chairs in the ambulatory day unit (2.2.1)	> 100	> 150
Number of FTE physicians dedicated to cancer (2.3.1)	> 30	> 50
Number of patients newly treated in the cancer centre/institute in the index year (2.1.1.2)	> 1500	> 2500
Extra R	esearch Criteria	
Number of peer-reviewed scientific publications (8.4.2)	> 35	> 125
Number of scientific publications with an impact factor (IF) over 10 (8.4.2)		> 17
Number of scientific publications with an impact factor (IF) between 5 and 10 (8.4.2)		> 50
Number of studies active - currently open for patient accrual (8.5.1 - Subtotal for Designation (A))	> 20	> 75
Do the above studies include Phase I trials?		Yes
The total number of patients recruited to prospective interventional clinical trials in the index year as a percentage of patients newly treated in the cancer centre/institute**		> 10%

Preliminary designation: OECI Cancer Centre / OECI Comprehensive Cancer Centre

To be designated as an OECI CCC the Centre/Institute needs to fulfil all the General Criteria and 4 out of 6 Research Criteria (at least 2 for publications and 2 for trials).

The numbers in bold should normally be fulfilled. Taking the extra research criteria in the round, centres/institutes with a low percentage of patient accrual to clinical trials are unlikely to be designated as an OECI Comprehensive Cancer Centre.

The number of patients with a cancer diagnosis included in prospective Phase 1, 2 and 3 clinical trials containing one or more interventions in diagnosis, treatment, follow-up or rehabilitation. Interventional means that the study contains one or more defined actions aiming to improve diagnosis, care or outcome. Studies may be single arm or multi-arm.

Patients included in clinical quality or registry studies are excluded from the Designation percentage.

Participants in cohort-based observational biomarker-driven studies are NOT included in the number forming the percentage for Designation. We do ask for the data of cohort-based observational studies (see question 8.5.1.4), provided that they concern studies with a formal PI role from the centre, and approved by scientific and ethical review committees.

^{*} Purchasing power parity measure (PPP) will be used to calculate the budget for cancer care and research (1.1.5)

^{**} The Definition should be changed into:

Accreditation and Designation Programme

Appendix II

OECI Qualitative Standards

1. Governance of the cancer centre/institute	5
2. Organisation of quality systems	7
3. Patient involvement and empowerment	10
4. Multidisciplinarity	13
5. Prevention and early detection	15
6. Diagnosis	16
7. Treatment	18
8. Research	24
9. Education and training	28

OECI Qualitative Standards Manual 3.2

How to read the document:

- Table 1 below shows the topics of all the standards in total.
- Table 2 (starting at page 4) shows all standards with the sub-questions.
- The related quantitative questionnaire is in a separate document with parallel chapter headings.

Name of chapter	Standard	Number standard
1. Governance	Structure of the cancer centre/institute – identifiable entity	1
	Structure of the cancer centre/institute – quality management	2 3
	Strategy and quality cycle of the cancer centre Financial stewardship	4
	Cooperation with universities	5
	Cooperation with external partners	6
2. Organisation	Integrated quality, risk and safety management	7
of quality systems	Quality analysis and improvement	8
or quality systems	Quality reporting	9
	Introduction of new practices	10
	Quality assurance	11
	Cancer data registration	12
	Waiting and throughput times	13
	Complications registry	14
	Technical quality of medical equipment	15
	HRM – staffing	16
	HRM – appraisal policy and support system	17
	Privacy, protection of, and access to personal data	18
3. Patient involvement		19
and empowerment	Patient education programmes	20
-	Patients' rights and preferences	21
	Patient information	22
	Informing patients about their care	23
	Informing patients on admission	24
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	Patient satisfaction/experience	26
	System for receiving and managing complaints	27
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4. Multidisciplinarity	Patient pathways	29
	Patient pathways: coordination of patients on the pathways	30
	Implementation of guidelines	31
	Electronic patients record	32
	Process of Multidisciplinary Team (MDT) meetings	33
	Multidisciplinary Team (MDT) meetings	34
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5. Prevention and	Screening and early detection	37
early detection	Oncogenetic service	38
	Cancer risk reducing strategies in the cancer centre	39

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6. Diagnosis	Radiology	40
	Nuclear medicine	41
	Logistics of scheduling diagnostic examinations	42
	Molecular diagnostics	43
	Pathology	44
	Pathology reporting	45
7. Treatment	24/7 access to specialist care within the cancer centre/institute	46
	Surgical oncology	47
	Reconstructive surgery	48
	Radiotherapy	49 50
	Radiotherapy equipment Radio-chemotherapy	51
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	Medical oncology, Anti-cancer drugs: Prescription and pharmacy preparation	
	Medical oncology, Anti-cancer drugs: Administration	55
	Nursing – Tasks and responsibilities of cancer nurses	56
	Pain service	57
	Referral to supportive disciplines	58
	Psycho-oncology	59
	Rehabilitation	60
	Social counselling	61
	Nutrition	62
	Involvement of caregivers	63
	Survivorship support	64
	Support to children and caregivers of cancer patients	65
	Palliative care team	66
	Palliative care	67
	End of life care	68
8. Research	Strategic planning for oncology research	69
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	Means for conducting research activities	71
	Periodical external site visit/review	72
	Research collaboration	73
	Scientific interaction and integration	74
	Scientific dissemination	75 76
	Research talent development Grant proposals	76 77
	Prevention and detection and handling of scientific misconduct	78
	Intellectual property and innovation	79
	Organisation of clinical research	80
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	Biobank	82
9. Education and	Analysing and providing for oncology training needs	83
training	Undergraduate academic education in oncology	84
	Postgraduate academic education in oncology	85
	5	

4 / OECI Qualitative Standards of the Accreditation & Designation Programme for Manual 3.2

Table 2: OECI A&D revised standards and sub-questions

Chapter 1: Governance of the cancer centre/institute (standards 1 to 6)

Structu	re of the cancer centre/institute – identifiable entity
Standard	d 1
The cand	cer centre/institute has an identifiable governing entity (board of directors/executive committee).
1.	CORE The cancer centre/institute has an identifiable governing entity (board of directors/executive committee) with accountability for: - strategic plan for cancer care - plan for research - quality and safety - budget

Structur	e of the cancer centre/institute - Quality management
Standard 2	
The adm	inistrative/board level of the cancer centre/institute includes quality management.
1.	CORE 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.

Strategy and quality cycle of the cancer centre/institute		
Standard 3		
A periodical planning and control cycle concerning oncology policy and strategy is present.		
1.	CORE There is a written strategic plan for the cancer centre/institute which covers at least three years, and which is formally endorsed by the board.	
2.	Each main service or department of the cancer centre/institute has an annual or multi-year plan which is consistent with the cancer centre/institute's overall strategy plan for cancer.	
3.	CORE According to the planning and control cycle the cancer centre/institute produces a (multi-)annual report which results in a quality improvement plan.	

Financial stewardship			
Standard 4			
The cancer centre/institute has processes for ensuring financial sustainability.			
1.	The cancer centre/institute defines a multi-annual budget for its activities which ensures sustainability as far as is practicable.		

Cooperation with universities		
Standard	5	
Written cooperation agreements concerning educational and research activities with at least one university are present and periodically evaluated.		
1.	CORE For training and postgraduate education activities.	
2.	CORE For research activities.	

Cooperation with external partners		
Standard	Standard 6	
There are	There are written agreements concerning the allocation of responsibilities and tasks for referrals of patients.	
1.	CORE There are written agreements or regulations, which are currently implemented, with other hospitals and cancer centres, setting out the goals for cooperation, the division of responsibilities and tasks.	
2.	There are written agreements or regulations, which are currently implemented, with special cancer care service providers for all services needed that are not directly provided by the cancer centre/institute (e.g. hospices, rehabilitation services or specialist radiology).	

Chapter 2: Organisation of quality systems (standards 7 to 18)

Integrate	Integrated quality, risk and safety management	
Standard	Standard 7	
The canc	er centre/institute has a structured policy for quality, risk and safety management.	
1.	CORE There is a quality management system based upon continuous quality improvement and risk based thinking and promoted by the line management.	
2.	The quality management system contains risk management (prospective risk assessment and prevention).	
3.	The quality management system contains safety management for patients, employees and visitors.	
4.	There is a Standard Operating Procedure (SOP) for undesirable events. This procedure is well known and accessible to all.	
5.	There are defined processes for reporting, investigating and taking action in response to safety incidents, adverse events and near misses, covering all departments.	
6.	Patients are informed of adverse events which affect them.	
7.	All activities of the cancer centre/institute follow, when applicable, the guidelines of Good Clinical Practice, good Laboratory Practice and Good Manufacturing Practice.	
8.	The cancer centre/institute has an IT, Data storage and processing system(s) which operates to Health Level 7 (HL7) standards.	
9.	There is a document management system that facilitates the retrieving and the updating of all SOPs.	
10.	CORE There is a dedicated unit or department responsible for the quality system.	

Quality a	Quality analysis and improvement	
Standard	8	
The cance	The cancer centre/institute has an integrated quality, risk, and safety management system.	
1.	CORE There is a quality, risk and safety dashboard with standardised indicators (including overall survival, patient satisfaction, patient quality of life, MDTs' activities).	
2.	This dashboard is analysed on a regular basis by senior management and acted upon.	
3.	CORE The line management of the cancer centre/institute are responsible for implementing improvements after analysing results of quality and risk and safety factors.	

Quality reporting

Standard 9

The cancer centre/institute publishes summary reports or grades from inspections and accreditations.

1. The cancer centre/institute systematically publishes on its website summary information on feedback from external quality inspections and accreditations.

Introduction of new practices

Standard 10

There is a standard process for the introduction of new practices.

1. Systematic risk assessment is performed before the introduction of a new technology or a new intervention.

Quality assurance	
Standard 11	
Quality assurance programmes (QAPs) are in place.	
1.	QAPs are part of the policy for quality and risk management covering all departments.
2.	There is a QAP for clinical research.
3.	CORE There is an internal audit system following an annual plan covering all departments.
4.	There is a programme for infection control.
5.	Infection rates are monitored.
6.	Results of the infection control programme are reported and analysed.

Cancer	Cancer data registration	
Standard	Standard 12	
Cancer pa	atient data are used for developing strategic planning and quality improvement of care processes.	
1.	CORE The number of new patients, newly diagnosed patients and treated patients by tumour type in the cancer centre/institute are available annually at the cancer centre level.	
2.	The diagnostic trends of cancer patients by tumour type/stage are known at an institutional level and reported annually to the board of the cancer centre for future planning.	
3.	The cancer centre/institute reports all new cancer patients to the regional or national cancer centre/institute registry.	
4.	The treatment trends of cancer patients by tumour type are known at the cancer centre/institute level and MDT level and reported annually to the board for future planning.	
5.	CORE The outcome data of cancer patients by tumour type are known at the cancer centre/institute and MDT level and are used by management for strategic planning or policy decisions.	

Waiting a	Waiting and throughput times	
Standard	Standard 13	
For critical	For critical stages in the care process the maximum waiting times are defined.	
1.	There are standards for the maximum waiting times between referral and first visit to outpatients' clinic or admission to the cancer centre/institute.	
2.	There are standards for the maximum waiting time between first visit and the time of definitive diagnosis.	
3.	There are standards for the maximum waiting times between definitive diagnosis and first treatment.	
4.	There is a record and continuous monitoring of the actual waiting times against the standards.	
5.	CORE If maximum waiting times are exceeded improvement actions are defined promptly.	

Complications registry		
Standard	Standard 14	
	The Board of the cancer centre/institute gets standardised reports on complications and Serious Adverse Events at regular intervals for future evaluations.	
1.	CORE The cancer centre/institute has a comprehensive system for reporting, registration and assessing complications and Serious Adverse Events.	
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 all departments and disciplines concerned.	
4.	The effect of improvement actions is measured and reported at least annually.	

Technica	Technical quality of medical equipment	
Standard	Standard 15	
Medical e	Medical equipment is safe, efficient and accurate.	
1.	There is a maintenance programme for medical equipment, including calibrations and safety checks.	
2.	Safety checks and calibrations are carried out as scheduled.	
3.	Medical devices used for diagnosis are periodically certified by an authorised authority.	
4.	The cancer centre/institute has processes to ensure that only trained and competent personnel handle specialised technical equipment (including new equipment).	

Human Resources Management – staffing	
Standard	16
Staffing levels are planned.	
1.	Staffing levels of key disciplines are planned in all clinical departments so as to ensure safety and high quality care and by reference to the guidelines or standards of professional societies or regulators, where applicable.

Human Resources Management – appraisal policy and support system		
Standard 17		
The cance	The cancer centre/institute has a comprehensive appraisal policy and support system for its staff.	
1.	CORE Regular appraisal of all staff (medical, nursing, supportive disciplines, technicians, administrative) is part of the human resources management of the cancer centre/institute.	
2.	Appraisal is done at defined intervals (preferably annually).	
3.	The results of appraisal are documented and used for individual training needs.	
4.	Every member of staff has a training record.	
5.	The cancer centre/institute ensures that all employees hold current appropriate practicing certificates.	
6.	Mental health support programmes are available to all employees.	

Privacy	Privacy, protection of and access to personal data	
Standar	Standard 18	
Written	Written procedures regarding privacy and protection of and access to personal data are present.	
1.	CORE Personal data protection is guaranteed for patients according to the General Data Protection EU Regulation (GDPR) 2016/679.	
2.	There is an institutional data protection officer.	
3.	There is a policy on access for patients to their own patient record.	
4.	The cancer centre/institute has a policy for sharing a patient health record with other health care providers for the benefits of that patient and in accordance with the privacy regulations.	
5.	There is a patient charter that is periodically evaluated and renewed.	
6.	CORE There are policies on informed consent for diagnostics, treatment and research, that meet national laws and regulations.	

Chapter 3: Patient involvement and empowerment (standards 19 to 28)

Patient involvement	
Standard 19	
It is the mission of the cancer centre/institute to encourage patient involvement in services.	
1.	CORE The cancer centre/institute involves patients and patients' voluntary organisations and support groups in the planning and organisation of services.
2.	The standard process of introducing new practices in clinical care ensures that patients are involved.
3.	There is a committee representing patients and serving as a link between the cancer centre/institute and the patients for advice and consultation.

Patient e	Patient education programmes	
Standard	Standard 20	
Patient ed	ducation programmes are in place.	
1.	There are policies in place for patient education programmes where responsibilities and accountabilities of the staff are stated.	
2.	CORE There are patient education programmes that aim at improving patient understanding of their illness, diagnosis, including information on self-care and how to manage multiple aspects of their illness or survivorship.	
3.	The cancer centre/institute makes specific provisions for access for individuals with disabilities and special needs (e.g. reduced mobility, visual and hearing difficulties).	
4.	CORE An information and support centre is available in the cancer centre/institute and easily accessible for staff, patients, family members and caregivers.	
5.	The cancer centre/institute organises public events to showcase advances in cancer research.	

Patients' rights and preferences		
Standard	Standard 21	
The cancer centre/institute has a policy on patients' preferences.		
1.	The cancer centre/institute has a policy on respecting patients' preferences (religious, cultural, social).	

Patient information		
Standard	Standard 22	
Information	on is provided to patients.	
1.	CORE The cancer centre/institute provides information material that is readable, up-to-date, appropriate and available in languages commonly spoken by the population served.	
2.	Information about diagnostic and treatment options is provided.	
3.	The information includes information about follow-up after treatment.	
4.	The information includes information about clinical trials available.	
5.	The information includes information about supportive care.	
6.	The information includes information about palliative care.	
7.	Information on relevant patients' rights is provided to patients and their caregivers.	

Informing	Informing patients about their care	
Standard 23		
	There are procedures for informing patients about the diagnostic results, treatment and follow-up, and survivorship support.	
1.	CORE There are procedures in place which specify how and by whom patients are informed about their diagnostic results, treatment options, follow-up, and survivorship support, which involve shared decision-making.	
2.	Expertise and specific training on communicating with patients and their families is available for staff.	
3.	The information communicated to the patient is recorded in the patient's record.	
4.	If patients are referred to another healthcare provider, they are informed about the continuity of their care.	
5.	Patients receive information about their contact person for all matters related to their care.	
6.	CORE All patients are given contact information of clinical staff in case of emergency.	

Informing patients on admission		
Standard 24		
Cancer pa	Cancer patients are informed about the cancer centre/institute admission and welcoming procedures.	
1.	All patients visiting the cancer centre/institute receive general information about the hospital.	
2.	Detailed information about the admission procedure is available and communicated to patients.	
3.	Information about patients' associations and about self-help and support groups is given to patients and their caregivers.	

Dischar	Discharge procedure, follow-up and survivorship care planning	
Standar	Standard 25	
Discharg	ge procedure and related care plans are defined.	
1.	CORE There is a defined discharge procedure including giving information on further treatment, follow-up, re-admission and home care.	
2.	The cancer centre/institute has processes to inform the patients' General Practitioner of a transfer of care.	
3.	The patient is provided with an individual survivorship plan which is discussed with the patient and includes details of all support services and support groups available.	
4.	The patient is provided with an individual plan for end-of-life care, which is discussed with the patient and caregivers.	

Patient s	Patient satisfaction/experience	
Standard	Standard 26	
Patients' experience of cancer care is an integrated part of the quality improvement system of the cancer centre/institute.		
1.	CORE The cancer centre/institutee has methods to regularly gather patients' experiences during outpatient and inpatient care.	
2.	CORE Satisfaction surveys are analysed, reported and acted upon through the line management of the centre.	
3.	The cancer centre/institute uses questionnaires to ascertain the perceptions of the patients' health status, level of impairment, disability and health-related quality of life (e.g. Patient-Reported Outcome Measures (PROM)).	
4	The cancer centre/institute uses questionnaires to assess the impact of the process of care on the patient's experience, e.g. communication and timelines of assistance (e.g. Patient-Reported Experience Measures (PREM)).	

System 1	System for receiving and managing complaints	
Standard	Standard 27	
The canc	The cancer centre/institute has a complaints procedure.	
1.	The cancer centre/institute has a defined complaints procedure.	
2.	CORE The cancer centre/institute has a clearly identified complaints officer or a complaints office.	
3.	The actions undertaken by the complaints officer are recorded in a file that is used to produce an annual report.	
4.	The complaints officer gives feedback on his/her findings to any member of staff who is the subject of a complaint.	

Collaboration with patient organisations		
Standard	Standard 28	
The cancer centre/institute collaborates with patient organisations.		
1.	The cancer centre/institute identifies and co-operates with existing patient organisations.	

Chapter 4: Multidisciplinarity (standards 29 to 36)

Patient I	Patient Pathways ¹	
Standard	Standard 29	
	Patient pathways are defined for all tumours and sub-types treated in the cancer centre/institute, which chart the process from patient admission up to the end of follow-up of care.	
1.	CORE There is a written patient pathway for each tumour (sub)type treated in the cancer centre/institute, except for very rare cancers.	
2.	The functions of the different disciplines involved in the diagnosis, treatment and follow-up of the patient are defined and described in the patient pathways.	
3.	Supportive and palliative care is specifically included in the patient pathways.	

Patient Pathways: co-ordination of patients on the pathways	
Standard	30
Patients h	ave co-ordination to ensure their continuity of care on the pathway.
1	CORE For every patient there is an identified co-ordinator or manager (or written process for case management) of their pathway from admission until end of follow-up, including the implementation of MDT recommendations.
2.	There are routines in place for referral and feedback amongst nursing, palliative care and supportive disciplines.
3.	There are procedures in place for informing the patients' General Practitioner about key recommendations, decisions and diagnostic and treatment results in a timely manner.

Impleme	Implementation of guidelines	
Standard	Standard 31	
	For each type of cancer, consensus has been reached among the disciplines involved about the clinical guidelines used for diagnosis, treatment and follow-up.	
1.	CORE It is formally agreed which clinical guidelines (institutional/local/regional/national/international) are used for diagnostics, treatment and follow-up.	
2.	The guidelines are easily accessible in written and/or digital form.	
3.	The guidelines are updated on a regular basis (at least every year) according to new evidence and evaluation of processes and outcomes.	
4.	It is defined who is responsible for updating and authorising the guidelines.	
5	All new clinical staff are made familiar with the guidelines relevant to their work.	
6.	There is a policy that each decision that differs from the guidelines is recorded in the patient's record.	
7.	An evaluation of deviations from the guidelines is made by the MDT at regular intervals (at least once a year).	

Electronic patient record	
Standard 32	
There are electronic patient records to assure the safety, timeliness and continuity of care.	
1.	CORE Each patient has an Electronic Patient Record which enables all relevant disciplines along the patient pathway to access the full information concerning the patient.

¹A patient pathway (sometimes called a "care pathway" or "clinical pathway") is a plan for decision-making and organisation of diagnostic and care processes for a well-defined group of patients in well-defined stages, beginning with first suspicion of cancer to survivorship/follow-up or end of life. This is distinct from a "care plan" which is personal to an individual patient.

Process	Process of Multidisciplinary Team (MDT) meetings	
Standard	Standard 33	
The centre	e has MDT groups covering every tumour type which follow a Standard Operating Procedure (SOP).	
1.	CORE An SOP exists for every MDT which specifies core and extended attendance from all relevant diagnostic and therapeutic disciplines, including oncology nursing and supportive care.	
2.	CORE SOPs state for each MDT whether all patients are fully discussed or listed on the agenda according to standard patient pathways following definitive diagnosis.	
3.	All patients are listed for an MDT discussion when newly managed in the centre and before any complex decision in the management of the patient (for instance regarding metastasis).	
4.	There is a defined procedure to inform the members of the MDT with sufficient notice which patients will be discussed.	
5	The inclusion of patients in clinical trials is a structured aspect of the MDT meeting.	
6.	The MDT meetings take place in a room with facilities to show the relevant results of the examinations (imaging, pathology).	

Multidis	Multidisciplinary Team (MDT) meetings	
Standard	Standard 34	
Informati	on, dissemination and access to expertise in the MDT.	
1.	The medical record of the patient is available during the MDT meeting.	
2.	The conclusions and recommendation resulting from the MDT meeting are documented in the medical record of the patient.	
3.	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 most 24 hours later.	
4.	According to a defined procedure the conclusions and recommendations resulting from the MDT are communicated to the patient for shared decision-making, in which the patient has the right to consent to or refuse a particular treatment.	
5.	Access to and information from the molecular tumour board should be made available in the MDT when relevant.	

Multidisc	Multidisciplinary Team (MDT) review	
Standard	Standard 35	
Multidisci	Multidisciplinary team (MDT) review.	
1.	CORE Every MDT meets at least twice a year in a learning event to review outcomes, quality of procedures, patient pathways and indicators, for quality improvement.	
2.	Patient pathways are updated regularly, based upon the review.	

Rare ca	incers
Standar	1 36
Manage	ment of rare cancers
1.	Procedures are in place to consult or to refer patients with rare cancers to a designated reference centre or a European Reference Network.

Chapter 5: Prevention and early detection (standards 37 to 39)

Screenin	Screening and early detection	
Standard	Standard 37	
Involveme	Involvement in screening and early detection.	
1.	The cancer centre/institute participates in regional or national screening programmes.	
2.	The cancer centre/institute participates in specific early detection programmes.	
3.	The cancer centre/institute participates in research into early detection, risk stratification and/or screening.	

Oncogenetic service	
Standard 38	
Access to an oncogenetic clinic is available.	
1.	CORE An oncogenetic clinic is available and accessible to all appropriate patients.
2.	Guidelines for referral to oncogenetic services are available.
3.	Recommendations for individuals at increased risk are based on guidelines.
4.	Psychological support is offered in the oncogenetic service.

Cancer risk reducing strategies in the cancer centre/institute Standard 39	
Cancer risk reducing strategies in the cancer centre/institute.	
1.	CORE Information is available through the cancer centre/institute on overall healthy living in the fields of: diet, smoking, alcohol, exercise, spotting signs and symptoms.
2.	CORE There is a non-smoking policy in the cancer centre/institute.
3.	All public parts of the cancer centre/institute are clearly designated smoke-free areas.
4.	CORE Support is provided to patients to quit smoking.
5.	Access to services is offered to patients to reduce alcohol intake where appropriate.
6.	Support is provided to employees to quit smoking.

Chapter 6: Diagnosis (standards 40 to 45)

Radiolog	Radiology	
Standard	Standard 40	
The radio	logy department is sufficiently staffed, resourced and effectively managed.	
1.	CORE Staffing levels of key disciplines are planned so as to ensure safety, accuracy and high quality care.	
2.	The unit has up-to-date Standard Operating Procedures which describe the imaging methods and are reviewed at least once a year.	
3.	CORE The radiologist's written report is available to the attending doctors at the latest 72 hours after the examination.	
4.	There is a record of waiting times for radiology, measured from the time of notification by the physician to the performing of the radiological examination.	
5.	The department holds learning events for quality improvement at least twice per year.	
6.	Clinical audits are carried out in accordance with national procedures.	
7.	All images (mammograms, ultrasound documentation, MRI) are stored in a digital format.	
8.	Equipment is no older than ten years.	
9.	CORE Quality control of all equipment used for imaging is routinely performed, according to the relevant national protocols and/or European guidelines.	

Nuclear	Nuclear medicine	
Standard	Standard 41	
The nucle	ear medicine department is sufficiently staffed, resourced and effectively managed.	
1.	CORE Staffing levels of key disciplines are planned so as to ensure safety, accuracy and high quality care.	
2.	The unit has up-to-date Standard Operating Procedures which describe the imaging methods and are checked at least once a year.	
3	CORE The nuclear medicine specialist's written report is available to the attending doctors at the latest 72 hours after the examination.	
4.	There is a record of waiting times for nuclear medicine, measured from the time of notification by the physician to the performing of the examination.	
5.	The department holds learning events for quality improvement at least twice per year.	
6.	Clinical audits are carried out in accordance with national procedures as required by EU COUNCIL DIRECTIVE 2013/59/EURATOM.	
7.	All images are stored in a digital format.	
8.	Equipment is no older than ten years.	
9.	CORE Quality control of all equipment used for imaging is routinely performed, according to the relevant national protocols and/or European guidelines.	

Logistics of scheduling diagnostics examinations	
Standard	42
Agreements have been reached about scheduling appointments and giving priority to urgent examinations (CT, MRI, mammography).	
1.	There is a policy for scheduling diagnostic examinations.
2.	Arrangements are in place about giving priority to urgent examinations (CT, MRI, mammography).
3.	There is a Standard Operating Procedure for keeping appointment slots available for emergencies.

Molecular diagnostics		
Standard 43		
Arrangem	Arrangements are in place for molecular diagnostics.	
1.	CORE The cancer centre/institute has a molecular diagnostics programme for the use of all tumour sub-types where clinically validated.	
2	The pathology laboratory/institute has specialists and equipment for molecular pathology for those tumour sub-types for which clinically validated tests are approved.	
3.	The molecular diagnostics laboratory works to Good Clinical Practice and Good Laboratory Practice standards.	
4.	The cancer centre/institute has a formal link with a molecular tumour board to support therapeutic decisions.	

Patholo	Pathology	
Standar	Standard 44	
The pat	hology laboratory/institute is sufficiently staffed, resourced and effectively managed.	
1.	The pathology laboratory/institute processes at least 10,000 histologies/year.	
2.	CORE The pathology laboratory/institute has sufficient Board-certified pathologists available to fulfil the requirements of each specialty served by an MDT in the centre.	
3.	A sufficient number of qualified (medical) technical assistants are on regular duty according the Good Clinical/Laboratory Practice and European/National guidelines.	
4.	CORE The laboratory has Standard Operating Procedures covering the collection, pre-analytical and analytical phases, reporting and storage of specimens of all kinds which follow international standards.	
5.	The laboratory has a recognised quality management (QM) system.	
6.	The laboratory participates regularly in quality assurance inter laboratory tests.	

Patho	Pathology reporting	
Standa	Standard 45	
Arrang	ements are in place for pathology reporting.	
1.	For frozen sections for intra-operative reports the actual time from arrival in pathology to communication of the result is recorded (guidance value maximum 30 minutes).	
2.	Standardised pathologists' reports include lymph nodes and resection margins specification, according to guidelines.	
3.	Pathologists' reports contain histological type according validated international classifications.	
4.	CORE Pathologists' reports for routine histology and immuno-histochemistry are provided within five working days of reception of the specimen.	
5.	The laboratory/institute holds oncology-focussed learning events for quality improvement at least once per year.	

Chapter 7: Treatment (standards 46 to 68)

24/7 acc	cess to specialist care	
Standard	Standard 46	
Arrangem	ents are in place for 24/7 care by specialised staff.	
1.	CORE There are arrangements in place to provide all relevant specialist care for patients 24 hours a day, every day.	
2.	CORE There is an acute oncology assessment unit particularly for patients with toxicities which operates according to Standard Operating Procedures.	
3.	The cancer centre/institute can admit patients during day and night in the event of an emergency.	
4.	Time slots for outpatient appointments are allocated according to patients' needs (e.g. longer times for new patients).	

Surgical	Surgical oncology	
Standard	Standard 47	
The surgi	cal oncology department is sufficiently staffed, resourced and effectively managed.	
1.	CORE Minimum surgical volumes per cancer surgeon are defined for each tumour type.	
2.	CORE There is 24-hour availability of surgical oncologists in all major specialties including at weekends and on public holidays.	
3.	All treatment plans and recommendations of the MDT form the basis for surgery.	
4.	If there are any deviations from the surgical treatment plan, they are recorded in the patient record and communicated appropriately to the patient and multidisciplinary team.	
5.	Technical and organisational processes for fresh tissue, frozen sections and biobanking are in place for all surgical procedures.	
6.	30-day mortality after surgery is recorded and evaluated.	
7.	Unexpected re-admissions to surgery within 90 days is recorded and evaluated.	
8.	The technical quality of surgery is regularly monitored for all procedures.	

Recons	tructive surgery	
Standard	1 48	
Reconst	Reconstructive surgery is offered to all appropriate patients.	
1.	CORE There is a full range of reconstructive surgery, immediate or delayed, including aesthetic and functional restoration surgery for all body regions.	
2.	Patient information about reconstructive surgery is proactively provided in written form and includes benefits and risks.	

Radiothe	Radiotherapy	
Standard	Standard 49	
The radio	therapy department is sufficiently staffed, resourced and effectively managed.	
1.	CORE Staffing levels of key disciplines are planned so as to ensure safety, accuracy and high quality care.	
2.	CORE The cancer centre/institute has a 24-hour on-call service outside working hours (including weekends and public holidays), if necessary through co-operation agreements.	
3.	CORE The radiotherapy department has a written contingency plan.	
4.	Each patient has a medical consultation prior to the commencement of radiotherapy.	
5.	Adequate information is provided to each patient about diagnosis and therapy planning, which includes explanation of treatment options, side effects and self-management during therapy.	
6.	The relevant radiation data (e.g. RT treatment technique, single dose, total dose, total treatment time) are recorded in line with the guidelines.	
7.	Any deviation from the dose prescribed by the physician is justified and documented.	
8.	The unit has processes for recording the complications of treatment in the patient record and at department level for quality purposes.	
9	The department holds learning events for quality improvement at least twice per year.	

Radiotherapy equipment	
Standard 50	
The radio	therapy department is sufficiently equipped and medical equipment is safe, efficient and accurate.
1.	CORE
	The radiotherapy department has at least two megavoltage linear accelerators.
2.	There is one megavoltage linear accelerator for every 350 new cancer patients per year.
3.	CORE The main radiotherapy department of the centre has sufficient linear accelerators to meet the demands of providing radiotherapy to all its patients.
4.	There is a maintenance programme for medical equipment, including calibrations and safety checks.
5.	Safety checks and calibrations are carried out as scheduled.
6.	CORE Medical devices used for treatment are periodically certified by an authorised authority.

Radio-chemotherapy		
Standard	Standard 51	
Chemo-ra	Chemo-radiation therapy follows appropriate standard procedures.	
1.	The unit has a SOP for sequential / simultaneous radio-chemotherapy.	
2.	Blood count monitoring and laboratory tests are documented during radio-chemotherapy.	
3.	The side effects of radio-chemotherapy are recorded and evaluated.	

Palliative radiotherapy	
Standard 52	
Palliative radiotherapy is offered.	
1.	In the case of patients with spinal cord compression and neurological symptoms, a plan for treatment is drawn up within 24 hours of the suspected diagnosis.
2.	In palliative radiotherapy, the therapeutic goal (local control or solely symptom alleviation) is documented.

Medical	oncology (oncology and haemato-oncology)
Standard	53
The media managed	cal oncology and haemato-oncology departments are sufficiently staffed, resourced and effectively
1.	CORE Staffing levels of key disciplines are planned so as to ensure safety and high quality care.
2.	CORE There are sufficient chairs and beds to manage patient numbers for systemic therapies.
3.	The department holds learning events for quality improvement at least twice per year.
4.	Adequate information is provided to each patient about diagnosis and therapy planning, which includes explanation of treatment options, side effects and self-management during therapy.
5.	The time between the patient consultation agreeing to the treatment plan (post MDT) and the commencement of treatment does not exceed 21 days (if there are no medical contra-indications).

Medical	Medical oncology, anti-cancer drugs: prescription and pharmacy preparation	
Standard	Standard 54	
There is a	system for the prescription, preparation and distribution of anti-cancer drugs.	
1.	CORE There is a quality assured digital system for the prescription, preparation and administration of anti-cancer drugs.	
2.	CORE There is an SOP for the prescription of anti-cancer drugs.	
3.	Anti-cancer drugs are prepared in a centralised pharmacy unit.	
4.	There are SOPs for the preparation of anti-cancer drugs in pharmacy.	
5.	Anti-cancer drugs are prepared under the direct supervision of a qualified pharmacist.	
6.	CORE A validation procedure for the whole process, including prescription, preparation, distribution and administration, is implemented.	

Medical oncology, anti-cancer drugs: administration		
Standard	Standard 55	
Administ	tering of anti-cancer drugs is controlled and effectively managed.	
1.	CORE There are SOPs for the administration of anti-cancer drugs.	
2.	Anti-cancer drugs are administered only in oncology or haemato-oncology wards (for inpatients).	
3.	There are dedicated day-care units for the administration of anti-cancer drugs.	
4.	CORE Anti-cancer drugs are administered by nurses who have completed a specific training programme for chemotherapy administration.	
5.	CORE Each patient has a medical consultation prior to the commencement of systemic therapy.	
6.	The relevant data (dosage and total treatment time) are recorded in line with the guidelines.	
7.	A specific procedure for reporting unexpected side effects of anti-cancer drugs is implemented.	
8.	Quality and risk management practices for anti-cancer drugs are regularly evaluated.	

Niversity	No. of the Land Control of	
ivursing,	Nursing, tasks and responsibilities of oncology nurses	
Standard	Standard 56	
	The cancer centre/institute employs nurses formally educated in oncology whose tasks and responsibilities are defined according to the level of their education.	
1.	For each technical, clinical or outpatient department where patients with cancer are treated, there are nurses trained in oncology.	
2.	The cancer centre/institute employs nurses with expertise in most of the tumours that are treated in the cancer centre.	
3.	The cancer centre/institute employs Advanced Practice Nurses according to the EONS definition who have acquired an expert cancer nursing knowledge base, complex decision-making skills and clinical competencies for expanded practice.	
4.	There are job descriptions including the tasks and responsibilities of cancer nurses.	
5.	Roles and responsibilities of nurses with additional expertise/focus are described (e.g. palliative care, stoma care, wound dressing, pain, social care nurses, bone marrow transplant nurses, care pathway coordinator etc.).	
6.	The nursing staff has among its members a Lead Cancer Nurse.	

Pain se	Pain service	
Standar	Standard 57	
A proto	col for pain control is implemented in the cancer centre.	
1.	CORE There is systematic screening of pain with validated assessment tools throughout the pathway of the patient.	
2.	Guidelines regarding pain treatment for patients with cancer are implemented in all relevant departments.	
3.	There is regular education for staff on pain management according to a yearly plan.	
4.	Patients and their caregivers receive verbal and written information about pain management.	
5.	CORE A defined pain team or pain specialists as part of the palliative care team are available to both in- and outpatients.	

Referral to supportive disciplines		
Standard	Standard 58	
There is a	There is a standard policy concerning access of patients to supportive disciplines.	
1.	CORE There are guidelines which define the indications for referral and the types of intervention from supportive disciplines.	
2.	In appropriate cases, supportive disciplines are regularly part of clinical sessions.	

Psycho-	Psycho-oncology	
Standard	Standard 59	
Cancer p	Cancer patients have access to psycho-oncology services.	
1.	CORE There is a psycho-oncology service with competence in oncology psychiatry and/or clinical psychology.	
2.	CORE Structured screening with validated assessment tools is systematically used.	
3.	Procedures are defined about the way to refer patients to the psycho-oncology service, including patients in psychological distress.	

Rehabilit	Rehabilitation	
Standard	Standard 60	
There is a	There is access to rehabilitation services cancer patients.	
1.	CORE There is timely access to rehabilitation services with multidisciplinary interventions for cancer patients and survivors.	
2.	There is a defined procedure for referral to cancer rehabilitation services within and outside the cancer centre/institute.	

Social co	Social counselling	
Standard	Standard 61	
Social co	Social counselling for cancer patients is provided according to guidelines.	
1.	CORE Social counselling is organised according to guidelines and is accessible for all cancer patients throughout the cancer pathway.	
2.	CORE Domains of social counselling provided include benefits advice, employment rights and housing needs.	

Nutrition	Nutrition	
Standard	Standard 62	
There is a	There is access to nutrition specialists for cancer patients.	
1.	There are screening tools which are used to identify patients who will benefit from support of nutrition specialists.	
2.	There is timely access to nutrition specialists for cancer patients throughout the patient pathway.	

Involvem	Involvement of caregivers	
Standard	Standard 63	
Arrangen	Arrangements for the involvement of caregivers are defined.	
1.	In agreement with the healthcare team, caregivers can participate in certain personal activities (e.g. meals, washing).	
2.	Each inpatient ward has a room for meetings with caregivers.	
3.	Visiting time restrictions are lifted according to the needs of the patient and caregivers, including the possibility of overnight stay of caregivers if necessary.	

Survivors	Survivorship support	
Standard	Standard 64	
Advice an	Advice and support is offered to all patients and caregivers during treatment and survivorship.	
1.	CORE Advice and support is given to patients and caregivers on prevention of recurrence and overall healthy living in the fields of: diet; exercise; spotting signs and symptoms.	
2.	Information is given to patients on relevant peer groups for patients with similar cancers.	
3.	Information and support is given to patients about the potential late effects of their cancers.	
4.	Information and support is given to patients about self management.	

Support to children and caregivers of cancer patients		
Standard	Standard 65	
Support to children and caregivers of a cancer patient is provided.		
1.	Caregivers are given specific support and advice for helping patients.	
2.	Specific support for children of cancer patients is provided by trained staff (e.g. a family therapist).	

Palliativ	Palliative care ² team	
Standard	Standard 66	
The com	The composition and tasks of the palliative care team are defined.	
1	The composition of the palliative care team is defined.	
2.	The palliative care team is led by a specialised physician in palliative medicine.	
3.	All patients referred for palliative care are discussed during scheduled meetings of the palliative care team, according to a SOP.	
4.	The palliative care team provides education and guidance of palliative care (e.g. symptom control) for patients, caregivers and health professionals.	

Palliative care ³		
Standard	Standard 67	
Palliative care is organised according to written procedures.		
1.	CORE The cancer centre/institute has a written policy which defines when and how patients are referred to specialised palliative care services as part of their care pathway.	
2.	Palliative care is specifically described in the patient pathways within the cancer centre/institute and beyond (such as primary care and hospices).	
3.	There is a help line service covering the immediate needs of palliative care patients.	

End of life care	
Standard 68	
End of Life care is appropriately and sensitively arranged according to patients' needs and wishes.	
1.	CORE There is a policy for ascertaining the wishes and preferences of patients and relatives for End of Life care.
2.	The cancer centre/institute provides information on End of Life services available both within the centre and the local community (e.g. hospices, at home services).
3.	End of Life care is a part of the care pathway of cancer patients with incurable disease offered in collaboration with palliative care providers in the community or hospice.
4.	The cancer centre/institute provides access to spiritual care and bereavement support services.

² The palliative care team should include at least palliative care physicians and specialist nurses, working with an extended team of workers from different supportive disciplines like social workers, physiotherapists and dieticians, and with pain specialists and psycho-oncologists.

³ Palliative care is 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, assessment and treatment of pain and other problems, physical, psychosocial and spiritual. Palliative care is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.

Chapter 8: Research (standards 69 to 82)

Strateg	ic planning for oncology research
Standar	d 69
The rese	earch strategy plan is regularly updated.
1.	CORE There is a regularly updated research strategic plan covering at least three years, which is integrated in the overall strategy of the cancer centre/institute.
2.	Specific aims for research performance are defined (publications, grants, innovations etc.).
3.	CORE The cancer centre/institute research performance/activity is regularly evaluated and communicated in a scientific report.
4.	CORE ⁴ The cancer centre/institute has research groups and output covering basic, translational and clinical research.

Researc	Research - Organisational structure	
Standard	Standard 70	
The organ	The organisational responsibilities within the research, innovation and development structure are clearly defined.	
1.	CORE There is a defined organisational structure specifically for research and innovation related to cancer.	
2.	The individual research group structures are clearly defined.	
3.	The qualifications and responsibilities of research group leaders are clearly defined.	
4.	The cancer centre/institute has a dedicated phase I/II clinical research unit.	

Means fo	Means for conducting research activities	
Standard	Standard 71	
A planning	A planning cycle for resourcing the infrastructure of research activities is defined.	
1.	CORE The cancer research budget covering both external and internal funding for the cancer centre/institute is defined each year.	
2.	CORE The cancer centre/institute provides access to shared technological platforms for research activities.	
3.	The cancer centre/institute provides internal funding for research activities.	
4	The use of financial resources and accounting of research activities is monitored and reported.	

Periodica	Periodical external site visit/review	
Standard	Standard 72	
Periodical	Periodical external site visits of research are organised.	
1.	CORE An external Scientific Advisory Board (SAB) meets at regular intervals and advises the cancer centre/institute on its cancer research strategy, organisation, infrastructure and overall performance.	
2.	CORE The performance of each research group is externally or internally reviewed at regular intervals.	
3.	There is a periodical external site visit/review for research support facilities.	

⁴ This is only a core standard for an OECI Comprehensive Cancer Centre

Research collaboration	
Standard	73
The cancer centre/institute is part of research networks.	
1.	The cancer centre/institute supports formalised collaborations with international research organisations and networks.
2.	The cancer centre/institute co-ordinates international research projects.

Scientific	Scientific interaction and integration	
Standard	Standard 74	
There is structured co-operation between researchers and clinicians.		
1.	CORE Regular briefings on research activities, results and new opportunities are organised through information sharing and meetings for laboratory researchers and clinicians.	
2.	CORE There are funding mechanisms and/or programmes to give clinicians protected time for clinical and/or translational research.	

Scientific dissemination programme	
Standard	75
A scientifi	c knowledge transfer programme is present in the cancer centre/institute.
1.	CORE There is a structured, documented and up-to-date scientific programme in the cancer centre/institute through colloquia, seminars and theme-specific conferences.
2.	There are procedures in place to ensure that results from internal and external research are translated into new practice (e.g. diagnostic tools, treatment or prevention).

Research talent development	
Standard 76	
There is a policy for research talent development.	
1.	There is a programme in place for research talent development.

Grant proposals	
Standard 77	
There is a procedure for dealing with grant proposals.	
1.	There is an internal review of grant proposals before submission to funding bodies.
2.	There is an internal evaluation of the success of the grant proposals.
3.	CORE
	The cancer centre/institute has training programmes and supportive services for grant applicants.

Prevention and detection and handling of scientific misconduct	
Standard 78	
Conduct of research is defined by core principles of research integrity.	
1	There is a code of conduct regarding good research practices, covering the research environment, data practices and management, publication and dissemination, such as those of the European Code of Conduct for Research Integrity.
2.	There is a procedure to deal with violation of research integrity, such as research misconduct.

Intellectual property and innovation	
Standard 79	
There are policies for protection of intellectual property and innovation.	
1	Innovation strategy is an explicit part of the strategic plan of the cancer centre/institute.
2.	There are rules for ownership of intellectual property and patents.
3.	There is a unit providing support for the protection and utilisation of intellectual property (Technology Transfer Office).
4.	There is a unit (internal or external) providing support for business development arising from research.

Organi	Organisation of clinical research				
Standa	Standard 80				
Tasks c	f the Clinical Research Management unit and Institutional Review Board (IRB) are defined.				
1	CORE There is a Research Ethical Committee (internal or external) or Institutional Review Board (IRB) that evaluates ethical aspects of all research proposals on human subjects or material.				
2.	There is a scientific review board/committee that evaluates the quality, feasibility and priority of clinical trial proposals.				
3.	CORE There is an institutional clinical research management unit dedicated to cancer patients.				
4.	The unit has an annual plan for its activities.				
5.	The cancer centre/institute has a policy for promoting clinical trials, including internal and public information on trial availability.				
6.	The unit has dedicated personnel ensuring that clinical trials are conducted according to the trial protocols and Good Clinical Practice guidelines.				
7.	The unit assures the process of administrative, scientific and ethical/legal review and approval as well as the feasibility of new clinical trials.				
8.	The unit co-ordinates and monitors the clinical research activities as well as their financial management.				
9.	CORE The cancer centre/institute keeps an up-to-date database of clinical trials, including the accrual of patients.				
10.	The cancer centre/institute provides an annual report on clinical trial activities.				
11.	Personal data protection is guaranteed for patients in clinical trials according to the appropriate legislation, including GDPR.				
12.	The inclusion of a patient in a clinical trial is immediately available in the medical file of the patient, including the signed informed consent.				
13.	The institutional clinical research management unit has specific resources (expertise and financial) to manage investigator initiated trials.				

Promotio	Promotion of clinical research				
Standard	Standard 81				
The cancer centre/institute promotes and disseminates internally and externally clinical research projects and their results.					
1	The cancer centre/institute publishes the ongoing clinical research trials on its website for patients and external physicians.				
2.	2. The cancer centre/institute promotes the participation to clinical trials to the patients by mean of brochures, website, etc.				
3.	The researchers publish or participate in the publication of the results of the clinical trials, both in scientific and public papers.				
4.	4. The cancer centre/institute organises internal meetings to share the results of the clinical and translational research realised in the centre among its research community.				
5.	The results of the clinical trials are communicated on the website.				

Biobank	Biobank				
Standard	Standard 82				
Biobankir	Biobanking is conducted according to defined procedures.				
1.	The cancer centre/institute has a written policy for biobanking patient samples.				
2.	CORE There are SOPs defining the patient information, informed consent, collection, storage, registration, recovery and use of the biological samples.				
3.	3. CORE There is a centralised biobank database which provides linking to detailed clinical data.				
4.	The cancer centre/institute biobank has facilities for long-term storage of paraffin blocks for research purposes.				

Chapter 9: Education and training (standards 83 to 85)

Analysi	Analysing and providing for oncology training needs					
Standar	Standard 83					
	The cancer centre/institute analyses the specific training and continuous education needs in oncology and defines training and educational programmes.					
1.	The cancer centre/institute analyses the specific training and oncological continuous education needs of its staff regularly (preferably annually, cross reference to Chapter 2, Standard 17).					
2	CORE Relevant training is provided to all staff according to individual needs, institutional requirements, and regulatory requirements, including Good Clinical Practice and prevention and control of infections, including hand hygiene.					
3.	Based on the analysis, the institution defines an annual or multi-annual oncology training programme for physicians.					
4.	Based on the analysis, the cancer centre/institute defines an annual or multi-annual oncology training programme for researchers.					
5.	Based on the analysis, the cancer centre/institute defines an annual or multi-annual oncology training programme for nurses.					
6.	Based on the analysis, the cancer centre/institute defines an annual or multi-annual oncology training programme for supportive disciplines.					
7.	7. The centre ensures that all volunteers who work in the centre (whether with patients or not), are given appropriate training and support for their role (directly or by other bodies).					
8.	The cancer centre/institute collects and analyses feedback about the quality of the continuous professional education and training programmes.					

Undergra	Undergraduate academic education in oncology				
Standard	Standard 84				
The cance	er centre/institute provides oncology education for undergraduate degrees.				
1.	CORE The cancer centre/institute provides undergraduate oncology education.				
2.	The cancer centre/institute provides undergraduate oncology education for medical students.				
3.	The cancer centre/institute provides undergraduate oncology education for nursing students.				
4.	The cancer centre/institute provides undergraduate oncology education for supportive discipline students.				
5.	The cancer centre/institute collects and analyses feedback about the quality of the undergraduate oncology education.				
6.	The cancer centre/institute offers oncology education to medical/nursing/supportive discipline students from other countries, e.g. through exchange programmes.				

Postgra	Postgraduate academic education in oncology				
Standard	Standard 85				
The can	cer centre/institute provides oncology education of postgraduate students.				
1.	1. CORE The cancer centre/institute provides postgraduate oncology education for physicians.				
2.	CORE The cancer centre/institute provides postgraduate oncology education for nurses (including palliative care).				
3.	The cancer centre/institute provides education in oncology for supportive disciplines.				
4.	The cancer centre/institute collects and analyses feedback about the quality of the postgraduate education.				
5.	The cancer centre/institute offers oncology education to physicians/nurses/supportive disciplines from other countries, e.g. through exchange programmes and/or organisation of specific courses.				

Accreditation and Designation Programme

Appendix III

OECI Quantitative Questionnaire

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1. Governance

1.1 Management

1.1.1 Management of the cancer centre/institute

	Name	E-mail	Phone number
Chair/Director			
Medical Director			
Operations Director			
Finance Director			
Scientific Director			
Quality Director			
Nurse Director			

1.1.2 Management of the University hospital

	Name	E-mail	Phone number
Chief Executive Officer			
Finance Director			
Operations Director			
Medical Director			
Scientific Director			
Quality Director			
Nurse Director			

1.1.3 Legal representative

	Name	E-mail	Phone number
Legal Representative			

1.1.4 Administrative status

		academic	public/non profit	private
1.4.2.1	What is the most appropriate administrative status of your cancer centre/institute			

% of patients lo	ocal/regional		
% of patients n	national		
% of patients ir	nternational		
(Note: The sum	n of regional + national + international is 100%)		
Planned annual	I budget for cancer health care in the year specified (Euros	s)	
Planned annual	I budget for cancer research in the year specified (Euros)		
Planned annual	I budget for education in the year specified (Euros)		
1 9 04			
1.2 Strate			
1.2.1 Networ	king		
	Is your cancer centre/institute part of a formalised cancer network of for cancer care at regional level (please specify in notes)?	of institutions?	Yes / no
1.2.2 Europe	Is your cancer centre/institute part of a formalised cancer network of for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level? an Reference Networks (ERNs)		Yes / no Yes / no
Please specify	for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level?	ions?	Yes / no
Please specify centre/institute	for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level? an Reference Networks (ERNs) which cancer European Reference Networks (ERN) and the is a member/centre of reference:	ions?	Yes / no
Please specify centre/institute Name of ERNs Tumours for wl	for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level? an Reference Networks (ERNs) which cancer European Reference Networks (ERN) and the is a member/centre of reference:	for which families	Yes / no
Please specify centre/institute Name of ERNs Tumours for wlthat ERN	for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level? an Reference Networks (ERNs) which cancer European Reference Networks (ERN) and the is a member/centre of reference:	ions?	Yes / no
Please specify centre/institute Name of ERNs Tumours for wlthat ERN Name of ERN	for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level? an Reference Networks (ERNs) which cancer European Reference Networks (ERN) and the is a member/centre of reference: hich your centre is a centre/institute of reference within	for which families	Yes / no
Please specify centre/institute Name of ERNs Tumours for wl that ERN Name of ERN	for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level? an Reference Networks (ERNs) which cancer European Reference Networks (ERN) and the is a member/centre of reference:	for which families	Yes / no
Please specify centre/institute Name of ERNs Tumours for whithat ERN Name of ERN Tumours for whithat ERN	for cancer care at regional level (please specify in notes)? Is your cancer centre part of a formalised cancer network of instituti for cancer care at national level? an Reference Networks (ERNs) which cancer European Reference Networks (ERN) and the is a member/centre of reference: hich your centre is a centre/institute of reference within	for which families (please specify)	Yes / no

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1.2.4 Collaboration

Does your cancer centre/institute formally collaborate with: general practitioners?	Yes / no How?
Does your cancer centre/institute formally collaborate with: home care organisations?	Yes / no How?
Does your cancer centre/institute formally collaborate with: nursing homes?	Yes / no How?
Does your cancer centre/institute formally collaborate with: palliative care institutions and hospices?	Yes / no How?

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2. Organisation

2.1 Quality reporting

2.1.1 General numbers

	Number	Definition			
2.1.1.1 The size of the population served by the cancer centre/institute		There may be a range of populations, depending on the cancers concerned. If so, please give the range and details.			
2.1.1.2 Cancer patients newly treated in the index year		Definition: The number of patients with a diagnosis of cancer who are treated for the first time in the cancer centre/institute in the index year for a particular cancer, regardless of the date and place of the initia diagnosis. Treated means that the patient has gone through cancer directed treatment, regardless of type. Newly treated means the patient has never been treated before in the cancer centre/institute for the same cancer. According to this definition: a patient with a new (second or subsequent) cancer should be counted again; but a patient with a recurrent disease previously treated in the centre/institute should not be counted. The number of patients is counted, not the number of visits			
2.1.1.3 All cancer patients seen or treated in the index year		Definition: The number of unique patients with a diagnosis of cancer who are seen in person in the cancer centre/institute in the index year regardless of the date and place of initial diagnosis. This include all patients seen, including for follow up. The number of patients counted, not the number of visits.			

2.1.2 Outcomes

Specifically for the following tumours:

	breast cancer C50	lung cancer C34	male genital organs cancer: prostate C61H	cancer:	skin cancer: melanoma of the skin C43	Notes
1. % of patients with available survival data	%	%	%	%	%	

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	Notes
Do you know the recurrence status?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	
Do you have survival rates per stage (since definitive diagnosis)?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	

	Brea C50		ancer		Lung cancer C34		Male genital organs cancer: prostate C61H			Gastrointestinal cancer: colon C18			Skin cancer: melanoma of the skin C43							
Stage	ı	II	III	IV	ı	II	III	IV	ı	II	III	IV	I	II	Ш	IV	I	II	III	IV
1- year survival																				
5 - year survival																				
10 - year survival																				

2.1.3 Waiting times

	Total (oncology)	Remark
Maximum allowed waiting time (days) – as described in guidelines/regulations – from $1^{\rm st}$ contact (mail / telephone etc.) to $1^{\rm st}$ visit		Only for new patients. Visit means a face to face consultation with a physician in the centre/institute.
Actual waiting time from 1st contact (mail/telephone etc.) to 1st visit (mean, days) OR percentage compliance with the maximum allowed in the cancer centre/institute		Real waiting time between date of consultation request and date of consultation; only for new patients. Visit means a face to face consultation with a physician in the centre/institute.

	Total (oncology)	Remark
Maximum allowed waiting time (days) from $1^{\rm st}$ consultation to $1^{\rm st}$ definitive diagnosis in the cancer centre		The maximum allowed waiting time as described in the guidelines/regulations. 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 note).
Actual waiting time (mean, days, OR percentage compliance with the maximum allowed) from $1^{\rm st}$ consultation to $1^{\rm st}$ definitive diagnosis in the cancer centre		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 note).

	Surgical oncology	medical oncology	radiation therapy	Total (oncology)	Remark
Maximum allowed waiting time (days) - as described in the guidelines/regulations – from 1 st definitive diagnosis to the start treatment					The maximum allowed waiting time as described in the guidelines/regulations.
Actual waiting time (mean, days OR percentage compliance with the maximum allowed) from 1 st definitive diagnosis to the start of treatment in the cancer centre/institute					

2.1.4 Accreditations and auditing

Is your Cancer Centre/Institute accredited in the Clinical or Research domains? ²	Hospital/Clinical Care State Name of Accreditation body, date of last review, and scope of review	Research State Name of Accreditation body, date of last review				
National Accreditation bodies (statutory or voluntary)						
International Accreditation bodies						
Provide Summaries of Reports and Recommendations of all the Accreditations above as part of the Requested Documents						

² Please note that individual department certifications or accreditations are dealt with in the relevant sections of the Questionnaire below

Does your centre/institute perform internal audits on?	Yes / No	Notes
Clinical procedures		
Quality and Safety		
Clinical trials		
Other, please specifiy		

Do your MDTs/Integrated Practice Units monitor themselves according to sets of national/international Essential Requirements ³ ?	If yes, list MDT/tumour types covered
State set	

2.2 Infrastructure

2.2.1 Activity and capacity in cancer care

Inpatient Care	Medical oncology and radiotherapy	Surgical oncology	Paediatric Oncology	Haemato- oncology	Bone Marrow Transplant	Palliative Care	Total
Number of inpatient beds for overnight stays							
Number of inpatient stays in index year (visits not nights)							

Medical Oncology	Oncology	Haemato- oncology	Paediatric Oncology	Total
Number of chairs/beds for systemic therapies				
Number of day chemotherapy visits in index year				

Outpatient Visits	Oncology (for medical oncology, surgery or radiotherapy)	Haemato- oncology	Paediatric Oncology	Total
Number of outpatient visits for consultations in the index year				

2.2.2 Digital support information systems

	Yes	No
Do you have an electronic patient record?		
Do you have an electronic patient portal giving patients access to their record?		
Are clinical guidelines electronically available?		
Do you have an electronic patient tracking system? 4		
Do you have an electronic system to refer patients to the centre/institute?		
Do you have an electronic Medication Prescription and Administration System?		
Do you have technology infrastructure for cross-enterprise document sharing?		
Do you have the capability to process and exchange information and biomedical images electronically with external providers (please give details)		

2.2.3 Cancer Emergency Unit

	Yes	No
If you have an emergency facility (24/7), is there a specific procedure for cancer patients (24 hours a day)?		
Do you have a separate Cancer Assessment/Emergency Unit for patients with toxicities?		

2.2.4 Pharmacy

	Yes	No
Do you have a Pharmacy with a unit dedicated to oncology?		
Is the department certified?		
If yes, please specify according to which standard / system		
If yes, when was the last visit?		
Provide 1-page summary of Report and Recommendations		

³ For instance the European CanCer Organisation (ECCO) Essential Requirements for Quality in Cancer Care series

⁴ A patient tracking system allows a healthcare provider to log and monitor the progress of a person through the provision of care during their stay there.

2.3 Human resources

2.3.1 FTE Physicians⁵ dedicated to oncology

	Please specify the number of FTE employed by the cancer centre/institute	FTE specialist in training
Surgical oncology		
Medical oncology – solid tumours		
Haemato-oncology		
Radiation therapy		
Paediatric oncology		
Other units		
Total		

2.3.2 Specialists available in the cancer centre/institutes for Cancer Patients

	Please specify the number of FTE employed by the cancer centre/institute
Gastroenterologists	
Gynaecologists	
Haematologists	
Paediatricians	
Psychiatrists	
Anaesthesiologists	
Infectious disease specialists	
Geneticians	
Dermatologists	
Geriatricians	
Neurologists	
Intensive care specialists	
Cardiologists	
Endocrinologists	
Urologists	
Plastic surgeons	
Rehabilitation physicians	
Palliative care doctors	
Clinical pharmacologists	

2.3.3 Pathology

	Please specify the number of FTE employed by the cancer centre/institute
Pathologists ⁶	
Technicians	
Pathologists working in molecular pathology	
Technicians working in molecular pathology	
Molecular biologists	

2.3.4 Nuclear Medicine

	Please specify the number of FTE employed by the cancer centre/institute
Physicians ⁶ in nuclear medicine	
Technicians in nuclear medicine	
Medical Physicists ⁶	
Nurses in nuclear medicine	

2.3.5 Radiology

	Please specify the number of FTE employed by the cancer centre/institute
Radiologists ⁶	
Technicians in radiology	
Medical physicists ⁶	
Nurses in radiology	

2.3.6 Radiotherapy

	Please specify the number of FTE employed by the cancer centre/institute
Radiation technicians	
Medical Physicists ⁶	
Nurses in radiotherapy	
Radiobiologists	

2.3.7 Pharmacy

	Please specify the number of FTE employed by the cancer centre/institute
Oncology pharmacists ⁶	

⁵ Certified by the relevant Board or College, whether 'tenured' or not. Physicians in training are not counted.

⁶ Certified by the relevant Board or College, whether 'tenured' or not. Physicians in training are not counted.

2.3.8 Nursing

	Please specify the number of FTE employed by the cancer centre/institute
Number of Advanced Practice Nurses (EONS definition) ⁷	
Total number of cancer nurses (EONS definition) ⁸	
Number of nurses with specialisation in palliative care	
Total number of qualified nurses with only basic training	

2.3.9 Supportive disciplines

	Please specify the number of FTE employed by the cancer centre/institute regularly working with cancer patients
Dietitians / Nutritionists	
Psychologists ⁵	
Speech / swallow therapists	
Physiotherapists	
Stoma therapists	
Social workers	
Spiritual care	
Other, please specify in the notes	

2.3.10 Vacant posts

	Please specify the number or percentage of vacant posts of the following staff roles
Oncology Nurses	
Oncology surgeons	
Medical Oncologists	
Radiotherapists/ radiation oncologists	
Haemato-oncologists	
Radiologists	
Pathologists	
Oncology pharmacists	

⁷ Advanced Practice Nurse

Registered nurse who has acquired the expert cancer nursing knowledge base, complex decision-making skills and clinical competencies for expanded practice, the characteristics of which are shaped by the context and/or country in which s/he is credentialled to practice. A master's degree is recommended for entry

3 Patient involvement and empowerment

No quantitative items for this Chapter

4 Multidisciplinarity

4.1 Infrastructures for multidisciplinary care

4.1.1 Number of different MDTs

Number of different MDTs in the cancer centre/institute	

4.1.2 Multidisciplinary teams

Add list of tumours/tumour groups and the list of participants as drop-down box

1. Multidisciplinary team: Provide the name of the team

Name MDT	ICD-10 Number(s)/ cancer types covered	Frequency	List disciplines (mandatory presence (mark M) / attendance on request (matk R))	Does the team have an appointed case manager (Y/N)	Number of MDT recommendations per year	Number or percentage of patients listed but not fully discussed in MDT, per year

ICD-10: Indicate the ICD-10 number(s) of i. gastrointestinal cancer: colon C18 the cancer cases or cancer types which are discussed in the MDT gastrointestinal cancer: rectum are discussed in the MDT.

- a. breast cancer C50
- b. urological cancer: bladder C67
 c. urological cancer: kidney C64H
 m. gastrointestinal cancer: Others
- e. male genital organs cancer: testis o. gynaecological cancer: cervix C53 f. male genital organs cancer: Others
- (please specify in the notes) gastrointestinal cancer: oesophagus h. gastrointestinal cancer: stomach C16
- k. gastrointestinal cancer: liver C22
- gastrointestinal cancer: pancreas
 C25 c. urological cancer: kiuliey 60411
 d. male genital organs cancer: prostate
 n. gynaecological cancer: ovary C56H
 gynaecological cancer: ovary C56H
 - p. gynaecological cancer: endometrial C54 q. gynaecological cancer: Others (please specify in the notes)
 - r. head and neck cancer: larvnx C32 s. head and neck cancer: hypopharynx
- u. head and neck cancer: nasopharynx cc. neuro-oncological: Central nervous
- v. lung cancer C34
 w. head and neck cancer: thyroid C73H
 dd. neuro-oncological: Others
 ee. paediatric malignancies: all cancers v. lung cancer C34
- x. head and neck cancer: others (please specify in the notes)
- y. haematological malignancies: Hodgkin's Lymphoma C81 z. haematological malignancies: Non-Hodgkin's Lymphoma C82
- aa. haematological malignancies: Myeloma C90 (please specify in the
- t. head and neck cancer: oropharynx bb. haematological malignancies: All

 - (age 0<15)
 ff. bone and soft tissue tumours:
 - primary boneC40
 gg. bone and soft tissue tumours: Soft
 - tissue C49 hh. skin cancer: melanoma of the skin
 - skin cancer: Others C44 (please specify in the notes)
- 2. Frequency: Indicate how often the team meets (e.g. weekly, monthly, every other day, every second week each Monday)
- 3. Define which disciplines are mandatory (M) or upon Request (R)
- a. Disciplines: Indicate the participating disciplines/ appointed f. Pathologist members of the team meetings (present / access to):
- b. Medical oncologist (or equivalent)
- Oncology Surgeon Radiotherapist/radiation oncologist
- e. Radiologist

- Nurses
- h. Physician assistant/ nurse practitioner
- Supportive care disciplines
- Pharmacist
- Plastic surgeor
- Other, (specify)
- 4. Case manager: Case Manager is sometimes called "Care Tracker", "Pathway Manager" or other term. Their responsibility is to ensure that all appropriate patients are listed for consideration in a timely manner by the MDT and that all relevant information for that case is present
- 5. Please add here the number of MDT recommendations per year
- 6. Please indicate the number or % of patients listed, that are not (fully) discussed in the MDT.

⁸ A cancer nurse is a qualified nurse who has the authority and full responsibility to provide essential nursing care to people affected by cancer. This care is based upon their evidence-based, specialised, ethical and personal knowledge and skills. Cancer nurses are fully accountable in all cancer care settings and across the care continuum for all nursing services and associated patient outcomes provided under their direction.

4.2 Clinical Guidelines and patients pathways⁹

	Name the local / national / international Clinical Guideline that the centre/institute uses for each cancer type and provide source or link	Are Patient pathways documented? (Y/N)
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, nasopharynx C11, hypopharynx C13, others)		
Head and neck cancer: thyroid C73H		
Haematological malignancies: Hodgkin's Lymphoma C81		
Haematological malignancies: Non-Hodgkin's Lymphoma 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)		

⁹ **A patient pathway** is a plan for decision-making and organisation of diagnostic and **care** processes for a well-**defined** group of patients in well-**defined** stages, beginning with first suspicion of cancer to survivorship/follow-up or end of life. This is distinct from a "care plan" which is personal to an individual patient.

4.3 Tumour treatment demand and national standards

4.3.1 Tumour type / ICD-10 numbers

Tumour	Number of newly patients treated in the index year	Number of (Number of patients)	Re-surgery within 30-days (Number of patients, or percentage)	Radiation oncology (Number of patients per year)	Systemic therapy (Number of patients per year)
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: thyroid C73H					
Head and neck cancer: others (please specify in the notes)					
Haematological malignancies: Hodgkin's Lymphoma C81					
Haematological malignancies: Non-Hodgkin's Lymphoma C82					
Haematological malignancies: Myeloma C90					
Haematological malignancies: All leukaemias					

Tumour	Number of newly patients treated in the index year ¹⁰	Number of (Number of patients)	Re-surgery within 30-days (Number of patients, or percentage)	Radiation oncology (Number of patients per year)	Systemic therapy (Number of patients per year)
Neuro-oncological: Central nervous system C71-C72					
Neuro-oncological: Others (please specify in the notes)					
Paediatric malignancies: all cancers (age 0<18)					
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)					

¹⁰ Definition: The number of patients with a diagnosis of cancer who are treated for the first time in the cancer centre/institute in the index year for a particular cancer, regardless of the date and place of the initial diagnosis. TREATED means that the patient has gone through cancer-directed treatment, regardless of type. NEWLY treated means the patient has never been treated before in the cancer centre/institute for the same cancer. According to this definition: a patient with a new (second or subsequent) cancer should be counted again; but a patient with a recurrent disease previously treated in the centre/institute should not be counted. The number of patients is counted, not the number of visits.

5 Prevention and early detection

No quantitative items for this Chapter

6 Diagnosis

6.1 Radiology

Certification: 6.1.1 - 6.1.5 6.1.1 Is the department certified? 6.1.2 If yes, please specify according to which standard / system (International) 6.1.3 If yes, please specify according to which standard / system (National) 6.1.4 If yes, when was the last visit? 6.1.5 Provide 1-page summary of **Report and Recommendations** 6.1.6 Data related to the radiology department Number of CT scanners Number of slices per machine Number of CT examinations per year Number of facilities for MRI (specify the strength and field of the techniques) Number of MRI examinations (per year) Number of mammography (please specify analogic mammography or digital) Number of mammography examinations (per year) 6.1.7 Waiting and turnaround times Mean waiting time (days) for routine diagnostic CT/MRI scan

6.1.8 Availability of techniques related to the radiology department and interventional radiology

Mean turnaround time for radiology reports (from scan to report, fractions of days)

Availabliltiy of techniques related to the radiology department and interventional radiology	Yes / No	Notes
Digitalised imaging (PACS)		
Digitalised imaging (RIS)		
Resources for diagnostic interventional techniques (e.g. Ultrasound and CT guided biopsies, E/S fine needle biopsy, Vacuum-assisted breast biopsy (V.A.B.B.))? (please specify in the notes)		
Angiography		

5.2 Nuclear Medicine			
ertification: 6.2.1 – 6.2.5			
2.1 Is the department certified?	?		
2.2 If yes, please specify accor standard / system (Internat			
.2.3 If yes, please specify accor standard / system (Nationa			
.2.4 If yes, when was the last vis	it?		
.2.5 Provide 1-page summary of Recommendations	f Report and		
2.6 Data related to Nuclear me	dicine		
Facilties related to Nuclear Medicine	Yes / No	Specify how many facilities	How many scans per year
PET Scan		lacinues	
PET CT			
PET/MRI			
Radionuclide treatment facilities			
SPECT			
SPECT CT			
Sentinel node scintigraphy			
Bone scintigraphy			
.2.7 Waiting and turnaround time	es		
lean waiting time (days) for routine c can			
lean turnaround time for NM reports eport, fractions of days)	(trom scan to		

6.2 Nuclear Medicine

6.3.8 Molecular tests used as Standard of Care

Molecular tests used as Standard of Care	Number performed per year
KRAS	
EGFR	
ALK	
ROS	
HER2 status	

6.3.9 Waiting and turnaround times

Specify the mean time from reception of
routine histological samples to production
of the Pathologist's Report (days)

7 Treatment

7.1 Surgical oncology

Certification: 7.1.1 – 7.1.4

7.1.1 Is the department certified?

7.1.2 If yes, please specify according to which standard / system

7.1.3 If yes, when was the last visit?

7.1.4 Provide 1-page summary of Report

7.1.5 Specialisation of surgeons (FTE)

and Recommendations

Tumour	No of surgeons (FTE)
Breast surgery	
Urological surgery	
Thoracic surgery	
Digestive surgery	
Neurosurgery	
Gynaecological surgery	
Head and neck surgery	
Soft tissue surgery	
Orthopaedic surgery	
Oncoplastic surgery	
Paediatric surgery	

7.1.6 Data related to the surgical oncology department - techniques

Techniques	Yes / No	Notes
Robotic surgery is used in the cancer centre/institute (if yes, please make a note for which tumours it is used)		
The centre/institute uses image guided surgery (please specify)		
The cancer centre/institute offers spinal decompression surgery for vertebral metastases on an emergency 24/7 basis		

7.1.7 Data related to the surgical oncology department - complications

Complications	Yes / No	Notes
The number and nature of complications is reported and monitored for all types of cancer surgery		
The number and nature of complications is reported and monitored for all cancer surgeons		

The number and nature of complications is reported and monitored for all cancer surgeons		
7.1.8 30-day mortality after open and robotic surger	у	Specify mean percentage over 1 to 3 years
Lung cancer C34		
Gastrointestinal cancer: oesophagus C15		
Gastrointestinal cancer: stomach C16		
Gastrointestinal cancer: liver C22		
Gastrointestinal cancer: pancreas C25		
Male genital organs cancer: prostate C61H		
Neuro-oncological surgery		
7.1.9 Waiting times		
When surgery is next treatment, median waiting time between the Decision to Treat agreed by the patient and the surgical operation (days) for:		
Invasive Breast cancer		
Pancreatic cancer		
Prostate cancer (robotic or open)		
7.1.10 Outcome measure		
% of patients with unexpected re-admission to surgical ward within 90 days of surgery with curative intent for:		
Rectal cancer		
Lung cancer		

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Z.2.1 Is the department certified? Z.2.2 If yes, please specify according to which standard / system (International) Z.2.3 If yes, please specify according to which standard / system (National) Z.2.4 If yes, when was the last visit? Z.2.5 Provide 1-page summary of Report and Recommendations	
.2.2 If yes, please specify according to which standard / system (International) .2.3 If yes, please specify according to which standard / system (National) .2.4 If yes, when was the last visit? .2.5 Provide 1-page summary of Report	
standard / system (International) 2.3 If yes, please specify according to which standard / system (National) 2.4 If yes, when was the last visit? 2.5 Provide 1-page summary of Report	
standard / system (National) 2.4 If yes, when was the last visit? 2.5 Provide 1-page summary of Report	
2.5 Provide 1-page summary of Report	
2.6 Data related to the radiotherapy department – treatment machines Number and specification of treatment machines Number Notes / speci	ification
Fotal MegaVoltage units	
inear accelerators	
inear accelerators with IMRT/VMAT	
inear accelerators with IGRT	
Linear accelerators with SBRT/SRS	
Other treatment machines (e.g. orthovoltage units, proton/carbon facilities, dedicated SRS units, cobalt units)	
Brachytherapy units	

7.2.8 Data related to the radiotherapy department – facilities / techniques

Facilities / techniques	Yes / No	Notes
Do you have 3D conformal radiotherapy?		
Do you provide radiosurgery?		
Do you have proton therapy on site?		
Do you have other special radiation devices?		
Does the centre use respiratory motion management?		
Does the centre use adaptive radiotherapy?		
Does the unit use conventional simulation or virtual simulation for treatment planning?		
Does the unit have CT planning?		
Does the unit have IMRT radiotherapy planning system?		
Does the unit have access to magnetic resonance for radiotherapy treatment planning?		
Does the unit have access to PET CT treatment planning?		

7.2.9 Waiting time

Mean waiting time (days) between patient	
consultation agreeing to the treatment plan	
(post MDT) and the commencement of treatment	

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7.3 Haemato-oncolog	gy/Bone Marrow	Transplants
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Certification: 7.3.1 – 7.3.4				
7.3.1 Is the department certified?				
7.3.2 If yes, please specify according to whe standard / system (International)	7.3.2 If yes, please specify according to which standard / system (International)			
7.3.3 If yes, when was the last visit?				
7.3.4 Provide 1-page summary of Report and Recommendations				
7.3.5 Facilities				
Facilities	On site: Yes / No	Notes		
Transfusion Unit				
Bone marrow / stem cell bank				
Cytopheresis				
Cellular therapy unit with GMP				
Quality vigilance system				
Special techniques, please specifiy in notes				
7.3.6 Data related to the haemato-oncolog Number of laminar flow rooms	y department			
Number of sterile rooms				
Please specify the number of bone marro stem cell transplants per year for allogen stem cell				
Please specify the number of bone marro stem cell transplants per year for autolog bone marrow	•			
Please specify the number of bone marro stem cell transplants per year for autolog stem cell				

7.4 Palliative care / end of life care

7.4.1 MDT Palliative care team	
How often does the palliative care team	
or MDT meet to discuss palliative patients?	

7.4.2 Presence of disciplines in palliative care MDT

The following disciplines are present during the MDT meeting for palliative care

Specialist	Mandated (M)	Upon request (R)	Not at all
Physician with a specialisation in palliative care			
Medical oncologist			
Nurse with a specialisation/certification in palliative care			
Physician specialised in pain treatment			
Neurologist			
Lung physician			
Radiotherapist			
Psychologist or Psychotherapist			
Psychiatrist			
Pharmacist			
Social worker			
Spiritual care			
Physiotherapist			
Dietitian			
Other professionals, please specify in notes			

8 Research

8.1 Research funding

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

8.1.1 Funding sources

Total cancer research funding by external competitive sources	
Total cancer research funding by other sources such as core or government funding (please specify)	
Total cancer research funding from internal resources of the centre/institute	
Grand total of Cancer Research Funding for the year	
8.1.2 EU grants running	
Total number of running EU grants in the centre/institute	
Value (Euros) of EU grants running in the centre/institute	
Total number of running EU grants coordinated by the centre/institute	
Value (Euros) of EU grants (all partners) in projects coordinated by the centre/institute	
8.1.3 Other international grants running	
Total number of other running international Grants	
Value (Euros) in centre/institute from other international grants	
Total number of other running international grants coordinated by the centre/institute	
Value (Euros) (to all partners) in other international	

8.2 Research groups

8.2.1 Please provide a list of research groups working predominantly or wholly on cancer in the cancer centre/institute

8.2.2 Listing of research groups

Name research group	Topic research group	Type of research	Average FTE of group (including PhDs)
<name 1="" group="" research=""></name>			

8.3 Research structures

8.3.1 Research structures

	Yes	No	Not applicable
Do you have partnerships with companies related to research and innovation If yes specify in the notes			
Do you have a unit of epidemiology?			
Do you have a unit of health economics?			
Do you have a bioinformatics unit			

8.4 Research output

	*	
8.4.1	Innovations over the last 5 years	
	Number of patents over the last 5 years	
	Number of patent applications	
	Number of Declarations of Invention (DOFI's)	
8.4.2	Peer reviewed publications	
	Number of international peer-reviewed publications (in the year specified) with first, second or last author from the centre/institute	
	Total Number of international peer-reviewed publications per year (in the year specified)	
	Number of publications with impact factor 5 - 10 with first, second or last author from the centre/institute	
	Total number of publications with impact factor 5 - 10	
	Number of publications with impact factor > 10 with first, second or last author from the centre/institute	
	Total number of publications with impact factor > 10	
	Impact factor cumulative	

8.5 Clinical research activity

8.5.1 Clinical Trials

Total number of accruing multi-centre trials with international participation	
Total number of accruing multi-centre trials with Principal Investigator (co-ordinating) from the cancer centre/institute	
Number of new investigator-initiated multi-centre trials started in the year with PI co-ordination from the cancer centre/institute	
Number of accruing prospective studies sponsored by industry	
Number of accruing prospective studies academically initiated	
Total number of trials in follow up (closed to recruitment)	

	Open Studies	Number of Accruing studies	Number of patients included in the year
Prospective interventional	Phase I and Phase IIa trials		
trials	Phase IIb trials		
	Phase III trials		
	Subtotal for Designation (A)		
	Observational or cohort studies testing with biomarker-based patient selection (see definition)		
Other trials	Phase IV "real life" trials		
	Retrospective registry or quality studies		
	Other studies (e.g. population or GWAS studies)		
	Grand total		

Percentage of newly-treated patients included in prospective interventional clinical trials in the index year (A)/2.1.1.2

Note: the denominator for this is at 2.1.1.2

Definitions:

Accrual into prospective interventional clinical trials	The number of patients with a cancer diagnosis included in prospective Phase 1, 2 and 3 clinical trials containing one or more interventions in diagnosis, treatment, follow-up or rehabilitation. Interventional means that the study contains one or more defined actions aiming to improve diagnosis, care or outcome. Studies may be single arm or multi-arm. Patients included in clinical quality or registry studies are excluded from the Designation percentage. Participants in cohort-based observational biomarker-driven studies are NOT included in the number forming the percentage for Designation. We do ask for the data of cohort-based observational studies (see question 8.5.1.4), provided that they concern studies with a formal PI role from the centre, and approved by scientific and ethical review committees.
Percentage of patients included into clinical trials	Definition: Number of included patients as defined above as a percentage of number of newly treated cancer patients in the index year (as counted in 2.1.1.2).

8.5.2 Certification of Clinical Trials Unit	
Is the department certified?	
If yes, please specify according to which standard / system	
If yes, when was the last visit?	
Provide 1-page summary of Report and Recommendations	
8.5.3 Clinical Trials Unit	
Total FTE of study nurses	
Total FTE of study co-ordinators	
Total FTE bioinformaticians and statisticians	
Other (please specify in notes) Please specify FTE	
8.6 Human Resources in Cancer Re8.6.1 Total number of FTE dedicated to cancer resea	
Total number of senior (independent) researchers (FTE)	
Total number of postdocs (FTE)	
Total number of PhDs (FTE)	
Total number of technical staff (FTE)	
Total number of administrative staff (FTE)	
Total FTEs of medical doctors' time in oncology/haematology/surgery with a formalised allocation to research	
Total FTEs of MD pathologists and radiologists with a formalised allocation to research	
Grand Total	

Yes / no

8.7 Biobank

Certification: 8.7.1 – 8.7.5

8.7.1. Is the department certified?

8.7.3 If yes, when was the last visit?

Recommendations.

Standards.

8.7.6 Data related to the biobank

8.7.2 If yes, please specify according to which standard / system.

8.7.4 Provide 1-page summary of Report and

8.7.5 The cancer centre/institute biobank follows

governing the collection and storage of biomaterials, such as ISO 20387: 2018

Common Minimum Technical Standards.
The cancer centre/institute biobank follows the WHO/IARC Common Minimum Technical

Number of frozen tumour sections stored

Number of FFPE tumour sections stored

Number of frozen normal tissue stored

Number of FFPE normal tissue stored

Number of blood/plasma specimens stored

the latest national and international standards

Biotechnology - Biobanking; and the WHO/IARC

9 Education and training

9.1 Education

9.1.1 Availability of cancer education courses¹¹ organised by the cancer centre/institute

	Educational courses including summer schools organised by the cancer centre/institute on site	Number per year
	with local audience	
	with (inter)national audience	

9.1.2	International Conferences organised by
	the cancer centre/institute on aspects
	of cancer research

Number of international conferences organised by the centre/institute per year

9.1.3 Number of students and professors

Number of medical students in oncology training on site per year	
Number of MD graduates under specialist training in all fields of oncology	
Number of nurses under specialist training per year in all fields of oncology	
Number of new PhD students per year (average last years) (medical, nurses, and researchers,) in all fields relating to oncology	5
Number of PhD theses per year (average last 5 years) in all fields related to oncology	

9.1.4 Formalised exchange programmes and continuous education

Number of University Professors and lecturers

at the centre in all fields of oncology (excluding

visiting professors)

Formalised exchange programmes	Yes	No
Do you have exchange programmes at national level?		
Do you have exchange programmes at international level?		
Do you have training programmes for managers?		

10 General

10.1 Cancer Centre/Institute

tre/institute	
	Full or Associate
e data	
ed year to start the A&D	
in which you would like to place	
nying the Application form	
cer centre/institute	
ease add the organogram	
	e data ed year to start the A&D in which you would like to place nying the Application form cer centre/institute

10.2.1 Criteria for application

Criteria for application	Yes	No
Strong commitment to quality improvement in oncology evidenced by the signature of Director of the Cancer Centre/Institute		
Dedicated staff to be involved in the A&D Programme (contact person, project leader and group, involved all employees)		
Stable management structure (no extensive interim management)		
No major structural changes (e.g. merger)		
The Cancer Centre/Institute is an identified entity with a Board, clear management, and an organisational structure		
Awareness of the OECI User Manual to follow the steps of the A&D programme with care and within the required timeline		
Does your centre/institute include the three main modalities of treatment (surgery oncology, radiotherapy and medical oncology), and research and education?		

¹¹ A course is not a single event or conference. It should entail more than 4 sessions. A "summer school" lasting several days should be included

10.3 Designation category

10.3.1 Designation

		OECI Comprehensive Cancer Centre	OECI Cancer Centre
1.4.1.1	In which category would you classify your cancer centre/institute (based on the OECI definitions of the different categories)		

OECI definitions of different categories:

- An OECI Cancer Centre (CC) is characterised as an organisational entity covering a sufficient degree of high quality medical, surgical and radiotherapy services and a degree of clinical research.
- An OECI Comprehensive Cancer Centre (CCC). The following features are considered to be essential
 for this particular category:
 - An identifiable organisational entity with a clear governance and budget
 - A highly innovative character and multidisciplinary approach using the potential of basic, translational and clinical research and clinical facilities and activities
 - A direct provision of an extensive scope of cancer care tailored to the individual patient's needs and directed towards improving the quality of care
 - Broad activities in the area of prevention, education, and external dissemination of knowledge and innovation. A CCC should have:
 - o A high level of infrastructure, expertise and innovation in the field of cancer research, including translational and clinical research
 - o An extensive network including all aspects of cancer treatment and research
 - o Full integration between hospital care and cancer research, linked to one or more universities.

10.4 Signature for acceptance of the application by the Board of Directors of the cancer centre/institute

Name of the Director	
Date of signature	
Place	
Signature	

10.5 Preparation for peer review

10.5.1 Project leader and Survey contact person

	Name	Position	Email	Phone number
Project leader for A&D accreditation in the Cancer Centre/Institute				
Contact person for the A&D accreditation in the cancer centre/institute				

10.5.2 Project plan (part of the pre-designation phase)

Owner of the project – Supervising Body	
Start date OECI A&D Programme	
What is (are) the motive(s) for starting the project?	
Which goal(s) would you like to achieve? (Try to define according to the SMART - method: Specific, Measurable, Achievable, Realistic, Time-related)	

Steering committee	е			
Is there a steering	committee?			
Composition of the	project team	ı		
	Name / email / phone		Position / function	Responsibilities
Project leader in the centre				
Secretary:				
Member:				
Member				
etc				
Planning of the pro	ject			
Number of planned meetings	l internal			
Planned self-assess period (6 months)	sment			
Date of 1 st evaluati OECI Coordinator	ion with			
Date of 2 nd evaluat OECI Coordinator	ion with			
Date of 3 rd evaluati OECI Coordinator	ion with			
Date of Go/ no-go	decision			
Planned peer review	w date			
Planned end date				

Communication: reporting method		
То:	When/time	Method
Owner ¹¹		
Board of the centre		
Steering committee		
Project team		
Quality committee		
Others:		
Staff		
Patients		
Communication of the final self assessmen	nt results	
To:	When/time	Method
Board of the centre/institute, steering committee, project team, Quality committee, staff		
Which extra means are necessary? Time c	onsidered needed	
Project leader		
Time project members (for each person)		
Time participants		
Financial means		
Other resources (e.g. training/education, meeting costs)		

Accreditation and Designation Programme

Appendix IV

Requested documents

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3.	Research	68
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¹¹ Council or Supervising bod

How to read the document:

The documents requested in the Requested Documents questionnaire support the OECI Quality Standards. The requested documents provide essential information for the audit team and therefore need to be translated into English, either fully or in the form of a summary.

1. Governance

1.1 Management

- 1.1.1 Mission statement and vision
- 1.1.2 Organogram of the cancer centre/institute
- 1.1.3 Organogram of the research organisations within the cancer centre/institute
- 1.1.4 List of key staff members Include heads of departments/services/units/programmes

1.2 Strategy

- 1.2.1 Overall strategy of the centre/institute
- 1.2.2 Oncology strategic plan

Fully translated, including planned activities, developments and priorities for cancer care, research, and education

1.2.3 Annual or multi-Annual Report

Fully translated, covering the entire cancer centre/institute

1.2.4 Annual or multi-Annual Oncology Report (if the centre/institute is part of a University or General Hospital)

2. Organisation

2.1 Quality

- 2.1.1 System descriptions for risk management, safety management and patient safety management
- 2.1.2 The latest Quality Improvement Report
- 2.1.3 Quality cancer performance indicator sets

2.2 Accreditation and auditing

- 2.2.1 Reports from other (external) accreditations / audits / visits Summaries of reports from other external accreditations / audits Improvement points are required to be translated into English
 - 1. Hospital (general)
 - 2. Pharmacy
- 2.2.2 Previous improvement plan including the follow-up of OECI A&D visit Only for cancer centres/institutes in the re-accreditation process

3. Patient involvement and empowerment

3.1 Results of patient satisfaction surveys

3.1.1 The latest results of patient satisfaction surveys for inpatients, outpatients and day care Summary, with results and improvement points translated into English

3.2 Patient information brochures

- 3.2.1 Overview of the titles of the patient information brochures
- 3.2.2 Some examples of information brochures, for instance information on admission and treatments

Requested documents of the Accreditation & Designation Programme for Manual 3.2 / 67

4. Multidisciplinarity

4.1 Multidisciplinary teams (MDTs)

4.1.1 MDT procedures

Standard procedures across all MDTs fully translated into English

4.1.2 Three examples of tumour-specific MDT procedures in English

5. Prevention and Early Detection

6. Diagnosis

6.1 Accreditations

- 6.1.1 Reports from other (external) accreditations / audits / visits
 Summaries of reports from other (external) accreditations. Improvement points
 are required to be translated into English
 - 1. Radiology department
 - 2. Nuclear Medicine department
 - 3. Pathology department

7. Treatment

7.1 Guidelines and patient pathways

7.1.1 Three examples of patient pathways (see definition) translated into English

7.2 Accreditations

7.2.1 Reports from other external accreditations / audits Summaries of reports from other external accreditations. Improvement points are required to be translated into English

- 1. Surgical oncology
- 2. Radiotherapy department
- 3. Cell Transplant/Therapy Unit

8. Research

8.1 Strategic plan for oncology research

8.1.1 Current strategic plan for research Fully translated

8.2 Scientific Report of the centre

8.2.1 Latest scientific report

Fully translated latest scientific report that describes the research activities related to cancer centre/institute

8.3 Reviews by external bodies

- 8.3.1 Latest review/report on research at the centre/institute by international review bodies (e.g. European Academy of Cancer Sciences' Designation of Research Excellence)
- 8.3.2 Latest review/report on research at the centre by the Scientific Review Board of the centre
- 8.3.3 Latest review/report on key institutes/units by national review bodies.

8.4 Research output

8.4.1 List of publications contributed to by authors at the centre/institute in the last 3 years Underline the authors of your institute, add the impact factor, and put them in order from highest to lowest impact factor for **each of the 3 years**.

9. Education and Training

10. General

10.1 Peer review objectives

The goals your centre/institute would like to achieve, which are described in the project plan. Which goal(s) would you like to achieve? Define the goals according to the SMART-method: Specific, Measurable, Achievable, Realistic, Time-related

10.2 Geographic and demographic location

Describe the geographic and demographic location of your centre/institute, including the population served for various cancer types

10.3 Explanation of the national healthcare system

Summary of the national healthcare system. Include for example important national authorities, health insurance

10.4 Explanation of the education of medical specialists

10.5 Explanation of the education of nurses

Generally, and specifically for oncology nurses

Accreditation and Designation Programme

Appendix V

User Manual e-tool for cancer centres/institutes

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User manual

Preface

Questions concerning the use of this tool may be directed to the OECI A&D Co-ordinators:

Willien Westerhuis:

email: accreditation@oeci.eu

Harriët Blaauwgeers:

email: accreditation@oeci.eu

Logging in

Usernames and passwords will be provided by the administrator in advance.



Home screen

After logging into the application the Home page will be shown.



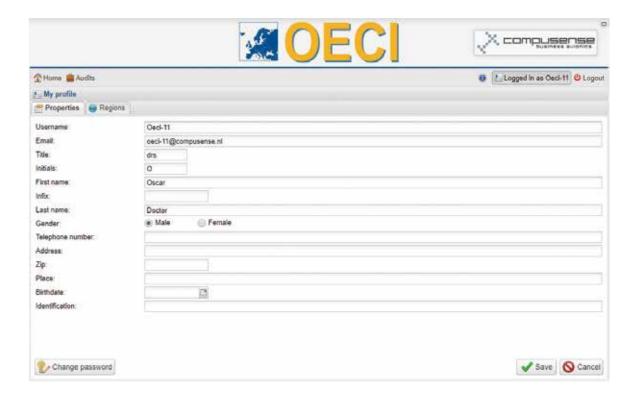
On the homepage you will find general information and a list of documents and manuals.

Change your password and contact info

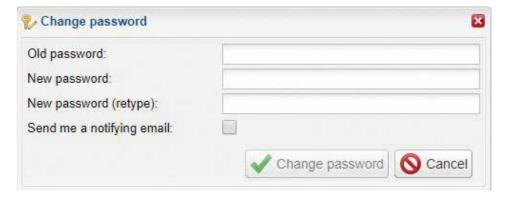
To change your password and contact info click on the 'Logged in as...' button at the top right of your screen



You can also add or change other personal information to your profile on this page. Please note that this information is only used in e-mails send to you to appropriately contact you.



To change your password press "Change password" at the bottom on the left.



Option Audits

Clicking on the Audits button will take you to the overview of the audits that you are involved in. The summary tab shows the dates involved in the preparation and the planned date of the visit.



The option 'Question lists' shows an overview of the question lists that need to be filled out by the centre/institute in preparation of the peer review. These question lists need to be filled out once for the entire cancer centre/institute unless this has been arranged in another way. Depending on the step in the accreditation process, there will be one or several questionlists.

An accreditation project will usually start with an application form and will be expanded as the project evolves. You may come across the following question lists:

- OECI Application form
- OECI Designation form
- OECI Project plan
- OECI Qualitative Questionnaire
- OECI Quantitative Questionnaire
- Requested Documents



Select one of the questionnaires in the screen on the right. A red button indicates that this questionnaire has not been dealt with. An orange button indicates that progress has been made but the questionnaire is not yet complete. A green button indicates that all questions have been answered, the progress bar should show 100%.

A questionnaire can be opened by double-clicking on the line or by single-clicking and pressing "Open" in the button ribbon.

All questionnaires are made up as follows:



Question overview:

On the left is the list of the different chapters and standards in the questionnaire. In front of the Standard titles are different icons:

This standard has not been started yet

This standard has been started but is not finished

This standard is completed

If a question is marked, the Standard turns red:



Navigation:

The question overview and the navigation buttons allow you to find your way through the Standards. Moving from one standard to another will automatically save any changes that have been made to the page, both answers and notes.

Questions:

Questions contain the following buttons:



If you want to come back to a certain question you have the option of marking it.



To delete any answer click this button, this also deletes any notes.

Saving and closing the questionnaire:

The questionnaire can be saved by either navigating among different standards (as described above) or by pressing the "Save" button at the bottom of the screen:



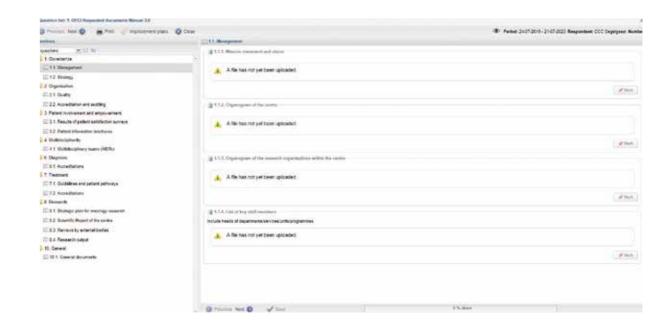
To correctly close the questionnaire, enabling you to continue working on it at a later time, click the "Close" button at the top of the screen:



A brief overview of the different questionnaires: will follow in the next chapters.

Requested documents

This questionnaire allows the centre to supply the requested documents which need to be translated into English. The standards are listed on the left, uploading is facilitated on the right.



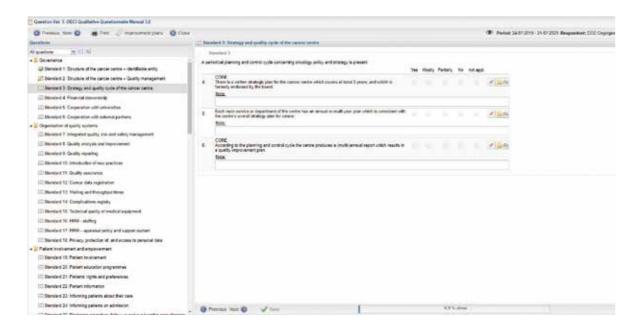
Uploading documents

By clicking 'Upload file' a new window appears in which you can write a description and browse your computer for the file you wish to upload.



Qualitative Questionnaire

The qualitative questionnaire consists of 85 standards. Each standard can have one or more substandards that deal with certain aspects of the standard.



- Clicking this icon allows you to upload files for this question and to view uploaded files.
- This Icon indicates that no files have been uploaded yet.
- This Icon indicates that one or more files have been uploaded.
- If you do not comply to a standard this is where you can view and add tasks.

Tasks can also be viewed on the homepage by clicking the 'Tasks' button in the main menu.



Quantitative Questionnaire

The quantitative questionnaire consists of the questions that need to be filled out in the different steps that lead to the approval to start with the self assessment, these steps are:

- 1. Application
- 2. Application & Designation
- 3. Self assessment

In steps 2 and 3, the answers to the questions from the previous questionnaire will be transferred to the following questionnaire and new questions will be added. This is to prevent that an organisation will have to fill out the same question two or three times.

The quantitative questionnaire consists of different types of questions, some are open, some are closed, others require figures (fte etc.) and some are tables that need to be populated with a mix of types.

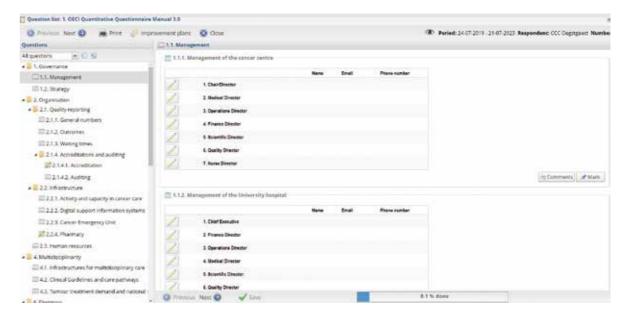
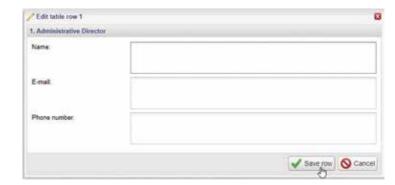


Table questions are answered by clicking the pencil icon.



This opens a window where you can give your answers, clicking 'Save row' saves your answers:

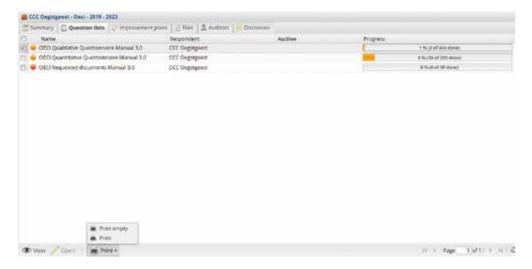


Project plan

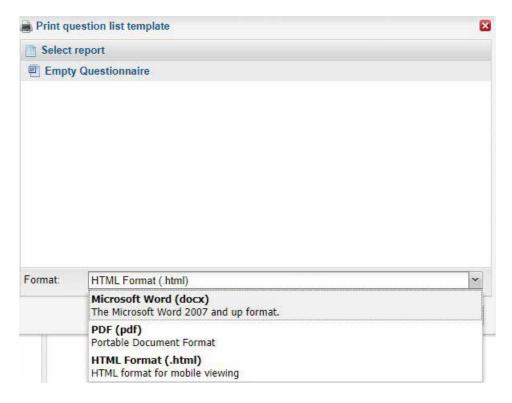
The structure of the Project plan questionnaire is similar to the Qualitative questionnaire, also a mix of question types.

Printing questionnaires

The questionnaires can be printed and downloaded as follows:

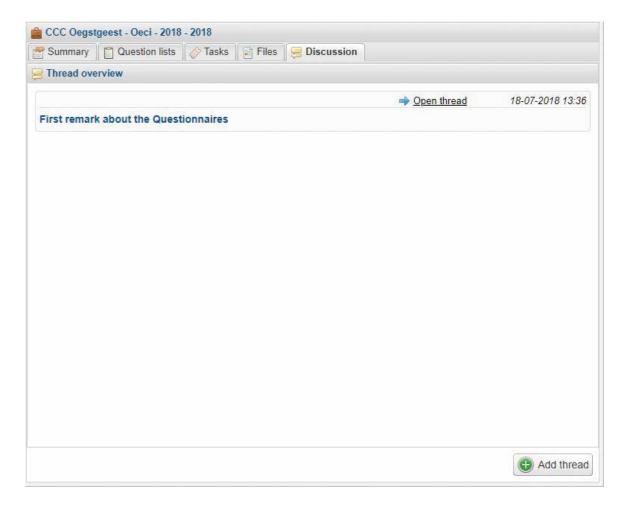


In question lists select the questionnaire which you would like to print and click on "Print" at the bottom of the screen. This opens a new window which allows you to select the format in which you would like to print/download/open the report.



Discussions

This application allows a discussion among group members. Posts made here are visible to all group members.



Click on "Question lists", and click on the tab for "Discussion".

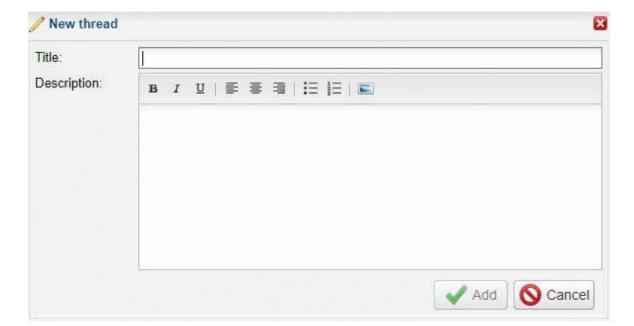
You may partake in discussions that have already started by other members or start a new discussion. To respond to an existing discussion open the thread by clicking on it.



To start a new discussion click on the button "Add thread":



Clicking this button opens the window where you can write the title of your thread and the first content:



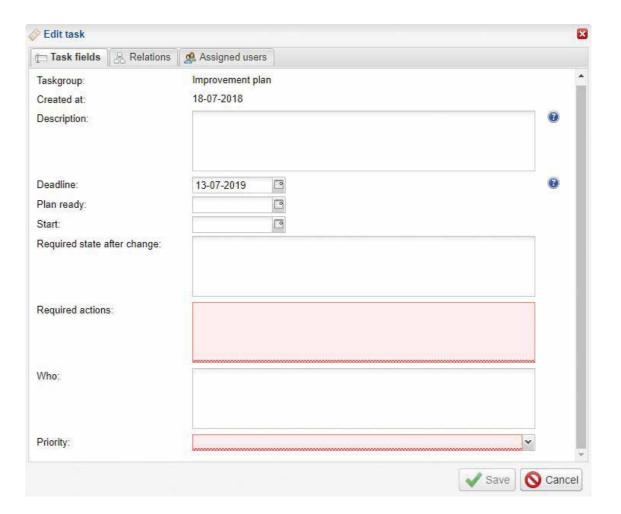
Improvement plan

Specifically in the Qualitative questionnaire there is a possibility to specify improvement points. The application gives a suggestion that, if a question is scored with Partially or No, you can specify how this can be improved.

	Yes	Mostly	Partially	No	not appl.	
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. Note:	0	0		0	0	*2
or answer does not meet the requirements, click here to view the task for improvement						
There are written agreements with special cancer care service providers.	0	0		9	0	* 0

To do this click on the line with the warning.

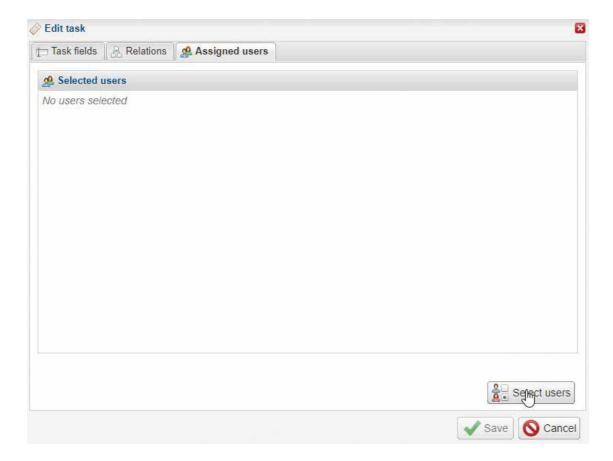
A dialog will start where you can describe the improvement point.



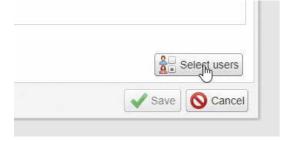
Mandatory fields are Required action and priority, these are red.

The Relations tab provides information about the origin of the Improvement point (e.g. Question, Questionlist), these can not be changed.

On the Assigned users tab you can assign the Improvement point to a user of the application.

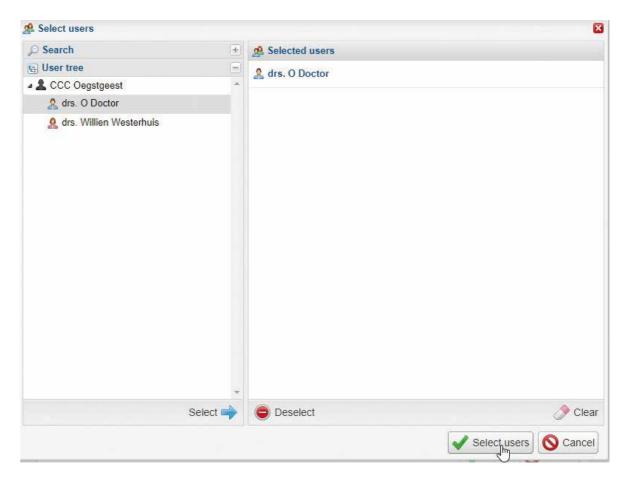


Press "Select users" to open the user list.



From the user tree you can select one or more of the users in your centre by selecting them and clicking





If you have finished with your selection press Select users to confirm.

When the selected users log in they will find the actions in a to do list.

As an alternative you can specify the respondents to the Improvement point in the textbox 'Who' on the Task fields tab of the Improvement point.

Who:

Closing the questionnaires

There is no need to close the questionnaires when they are completed. However, if you wish to close it to prevent further editing go to the Audits screen and select "Question lists".

Select the questionnaire you wish to close by single-clicking it. Then select "Actions" at the bottom and "Finalise".

A warning will appear asking you to confirm the action, after closing it no changes can be made to this questionnaire.



The OECI A&D Co-ordinator will contact you on how to proceed.

OECI-EEIG

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