

Auditors Session The A&D Programme 2023-25 Revision

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ACCREDITATION AND DESIGNATION PROGRAMME

Athens, 12th June 2025. 1630



DESIGNATION PROGRAMM

Standards revision process – 2023-2025

2024

 Compare all available standards world-wide

Oct 2023

- Compile ideas from auditors and centers
- Workshop in A&D board

- Thematic standards working groups with around 5 online meetings
- Commission standards in new areas, e.g. Al, molecular diagnostics, theranostics
- Conference on research standards with 70 scientific directors
- Iterative expert review
- Workshop in A&D board
- Standards Revision Conference involving professional societies: ESMO, ESTRO, ESSO, ECL, DKH, >100 individuals from 23 countries, standards approved from these professional organisations

June 2025

 Planned for finalization in OECI days in Athens





Standards revision process – key outcomes

- Updated and modernized standards
- Non-effective standards omitted and number of standards cut by a net 56 (95 deleted; 39 added)
- CC vs CCC level requirements remains roughly the same, but the level of open interventional clinical trials has been cut from 75 to 60
- CORE essential standards on governance, MDT, patient pathways have been introduced with high levels of expected compliance
- Standards 'go live' on 1 July 2025 and gradually rolled out to all 97 Centres upon reaccreditation









DESIGNATIO

New Standards - topics

- AI
- Theranostics
- Molecular diagnostics
- Interventional radiology
- Adolescents and Young Adults (AYA)
- Paediatrics (placeholder until new module)
- Strengthened Standards on Governance
- Strengthened Standards on Centres being part of Networks





1.1	CORE – Essential The cancer centre is an identifiable entity with a clear definition of entities or members comprised within the centre.
1.3	In cases where cancer centres are composed of multiple legal entities, there are formal agreements in place that define the collaboration terms between these entities.
2.5	The cancer centre governance structure includes a regular forum in which chairs of MDTs meet at least twice per year to discuss quality and strategic issues.
3.7	The formulation of the strategic plan has involved all key stakeholders, including patient representatives.
4.11	CORE There is an investment programme for all large technical equipment involved in diagnosis and treatment
6.14	CORE The cancer centre participates in a (Comprehensive) Cancer Care Network with (at minimum) accountability for shared patient pathways.
7.17	There should be a website / webpages dedicated to the cancer centre, which promotes the mission, objectives and visibility of the cancer centre to patients and the public





19.57	It is documented in which diagnostic and treatment settings a given AI application can be used.
19.58	There are processes to ensure that only trained and competent personnel use a given Al application.
19.59	There are procedures/strategies for the development of responsible AI in line with the Artificial Intelligence Act (Regulation (EU) 2024/1689) and Medical Device Regulation (Regulation (EU) 2017/745) or National equivalents
19.6	There is defined group with responsibility for establishing what procedures or strategies are used for responsible AI.





26.84	CORE The cancer centre uses PROMs for service improvement (e.g. to ascertain the perceptions of patients on their health status, level of impairment, disability, and
	health-related quality of life).

53.178	Minimum numbers of procedures are defined and implemented for complex systemic
55.176	procedures such as bone marrow transplant, CAR-T cell therapy.

	The survivorship care plan includes evaluation of individualised risks (including
66.212	familial cancers and actions such as primary / secondary prevention programme),
	rehabilitation, long-term side effects and lifestyle.







71.223	The cancer centre has a research/scientific director with a background in cancer
/1.225	research who is a member of the governing Board of the centre.
71.226	The cancer centre ensures patient and public involvement in research
73.234	The centre has policies for sharing patient level data outside the organisation
82.256	There is a Quality Assurance Programme for clinical research.





A CORE-Essential standard is a Standard, compliance with which is regarded as being essential for safe or high quality care, research or education. There are 19 CORE Essential Standards.

<u>A CORE standard</u> represents a Standard which is centrally important to the quality of either care, education or research within a cancer centre. The CORE standards generally refer to the heart of a process or system. There are 57 CORE standards.

Objective: we want to encourage swift and effective improvement actions on these Standards (within 1 year):

- Centres with a score of Partially or No in 5 or more <u>CORE-Essential</u> standards are likely to have their certification delayed until compliance with a YES is achieved.
- Centres with a total of between <u>12 and 15 CORE standards</u> scored Partially or No may be considered for a delay in the Accreditation Certificate until improvement actions are implemented and demonstrated to comply with a YES in the majority of them.



CORE – Essential Standards - 1



1.1	CORE – Essential The cancer centre is an identifiable entity with a clear definition of entities or members comprised within the centre.
1.2	CORE – Essential The cancer centre has a governing entity (board of directors / executive committee) with identifiable accountability for: - strategic plan for cancer care - plan for cancer research - plan for education and training - cancer quality and safety / risk management - cancer budget
3.6	CORE - Essential There is a written strategic plan for the cancer centre which covers at least 3 years, which also states the mission and values of the centre and is formally endorsed by the board.
8.18	CORE- Essential There is a structure (department, unit) that operates a quality system based upon continuous quality improvement and safety / risk management, which is represented in the Board of the cancer centre.
11.32	CORE - Essential The cancer centre has access to a database in which all cancer patients seen or treated in the index year, and the number of patients newly treated, by tumour type, in the cancer centre are recorded.
18.56	CORE - Essential Each patient has an Electronic Patient Record which enables all relevant disciplines along the patient pathway to access the full information concerning the patient.





CORE – Essential Standards - 2



20.62	CORE - Essential
	The cancer centre has a structured process for involving patients and patients' representatives and support groups in the
	planning and organisation of services.
29.91	CORE - Essential
	There is a documented patient pathway for each tumour (sub)type, diagnosed or treated in the cancer centre, which charts the procedure from patient referral to the centre to follow-up.
31.97	CORE - Essential
	Each multidisciplinary team agrees which clinical guidelines (institutional/local/regional/national/international) are used for diagnostics, treatment, and follow-up.
32.101	CORE – Essential The cancer centre has (or in certain circumstances participates in) defined Multidisciplinary Teams covering every type of cancer diagnosed and/or treated in the centre.
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46.152	CORE - Essential
	There are arrangements or external agreements in place to provide 24/7 specialist care for patients.
54.179	CORE - Essential There is a quality assured digital system for the prescription, preparation, distribution, and administration of systemic anti- cancer therapy.





71.222	CORE - Essential
	There is a regularly updated research strategic plan covering at least 3 years, which is integrated in the overall
	strategy of the cancer centre
71.225	CORE – Essential for CCCs
	The cancer centre has research groups and output covering fundamental, translational and clinical research.
73.231	CORE – Essential for CCCs
	The cancer centre organises access to shared technological platforms for research activities.
74.235	CORE – Essential for CCCs
	An external Scientific Advisory Board (SAB) meets at regular intervals and advises the cancer centre on its cancer research strategy, organisation, infrastructure and overall performance.
76.240	CORE Essential for CCCs
	There are mechanisms in place to provide clinical staff protected time for clinical and/or translational research.
82.255	CORE - Essential
	There is a dedicated cancer trials unit.
85.270	CORE - Essential
	There is a comprehensive training programme for all staff members based on the evaluation of individual
	training needs.





- Scoring system
- Chapter Headings
- Most of the Standards with updated wording to make clearer
- Most of the Quantitative Questionnaire
- Requested Documents
- Most of the CCC Designation schedule



Innovations



- A column on "Evidence required" against every Standard
- Glossary of definitions and explanations expanded



Mechanics



- Manual 4.0 has been approved by the OECI Board
- It will apply to all applications approved after 1 July 2025





THANKS!!

- To the A&D Board
- The Coordinators
- The Accreditation Committee
- The Auditors
- The professional societies: ESMO; ESTRO; ESSO; EONS; ESO; EAPC etc
- All who participated in the Brussels Conference and the OECI Board
- SOS Europe
- The scientific directors of the Members
- Other OECI Members who commented



Discussion

