

File for application

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Standards for quality requirements

1. Breast Programs/Centers should be independent units possessing autonomous capacities.	
“Minimum New Case Volume : At least 50 cases of breast cancer should be operated in this center/program annually (with one breast surgeon); If more than one or more full time breast surgeon serves in the center/program then new breast cancer surgery number (50) should be multiplied by a surgeon number. The center/program must manage at least 100 patients with new primary breast diseases including malignant and benign lesions.”	
2. The Multidisciplinary Programs/Centers should include specialists of diagnosis and treatment disciplines and hold weekly meetings for the discussion of clinical cases.	
3. All specialists of the Breast Program/Center should undergo continuous updating training. It is highly recommended that all members of the Breast Program / Center have accredited training in Communication and Interview Skills. The quality of communication between medical staff and between the patients and physicians is considered to be a key point of the team approach and the patient should be at the center of this approach.	
In service training requirement: Updated yearly in-service training is organized by local / national and/or international organizations, and program/center should hold the proof of such trainings.	
4. The Program/ Center should have updated protocols as needed, but updating interval should not be longer than 2 years for diagnosis, treatment and monitoring of Breast Cancer.	
5. The Program/ Center should provide services in the fields of prevention, early diagnosis and treatment of breast cancer, breast pathology, genetics, physical therapy, psycho-oncology and cardio-oncology assistance, oncology nursing, and social (navigation) support. It should also provide a service for breast health, benign pathologies and follow-up.	
6.The program/center may have an affiliation with another institutes/ laboratory to provide some services that are not available in their hospital,institute, center or program	
7. A database unit should record all quality indicators. This data will be available to conduct an audit. Records of activities should be dated back for the last year (12 months) for the first accreditation process and for the last three years (36 months) for further re-accreditations	
8. Patients should be provided with oral and written information on clinical trials and all diagnostic and treatment options.	
9 Accreditation will be offered to Breast Programs/ Centers that are SIS members of national societies or individual members’ institutes affiliated to SIS.	
10. Oncologic treatment and follow-compliance data are available	

Breast Program/ Center

Components		
1. Imaging		
a. Screening mammography - (digital or analog)	YES / NO	
b. Diagnostic mammography (additional views beyond screening mammography and workup of a clinical abnormality)	YES / NO	
c. Breast ultrasound	YES / NO	
d. Breast MRI	YES / NO	
e. Tomosynthesis mammography (3D)	YES / NO	
f. Contrast Enhanced Mammography (CEM)	YES / NO	
g. Positron Emission tomography -computed tomography (PET-CT)	YES / NO	
h. Bone Scan	YES / NO	
i. CT scan	YES / NO	
j. Lymphoscintigraphy	YES / NO	
2. Needle Biopsy		
Core biopsy (Core preferred)	YES / NO	
Fine Needle Aspiration	YES / NO	
a. Palpation-guided	YES / NO	
b. Image guided – stereotactic	YES / NO	
c. Image guided – ultrasound	YES / NO	
d. Image guided – MRI	YES / NO	
e. Image guided clip insertion	YES / NO	
f. Image guided localization techniques	YES / NO	
3. Pathology		
a. Report /CAP protocols/ standardization	YES / NO	
b. Radiology-pathology correlation	YES / NO	
c. Prognostic and predictive indicators	YES / NO	
d. Somatic tests/NGS	YES / NO	
e. Circulating tumor cells (ctDNA)	YES / NO	
4. Interdisciplinary Conference and communication		
a. History and findings	YES / NO	
b. Imaging studies	YES / NO	
c. Pathology	YES / NO	
d. pre-and post-treatment interdisciplinary discussion	YES / NO	
5. Genetic Evaluation and Management		
a. Genetic risk assessment	YES / NO	
b. Genetic counseling	YES / NO	
c. Genetic (germline) testing	YES / NO	
6. Surgical Care		
a. Surgical correlation with imaging/concordance	YES / NO	
b. Pre-operative planning after biopsy for surgical care	YES / NO	
c. Breast surgery: lumpectomy/ mastectomy/ oncoplastic	YES / NO	

d. Lymph node surgery: sentinel node/axillary dissection/ targeted axillary biopsy or dissection	YES / NO	
e. Post initial surgical correlation/treatment planning	YES / NO	
7. Plastic Surgery Consultation/Treatment		
a. Tissue expander/Implants	YES / NO	
b. Autologous breast reconstruction	YES / NO	
c. Immediate Breast reconstruction	YES / NO	
d. Delayed breast reconstruction	YES / NO	
e. Other surgeries such as lymphedema, symmetrization	YES / NO	
8. Oncology Nursing	YES / NO	
Specialist members		
1. Head of the Breast Unit, Clinical Director or Coordinator of the Breast Program/Center	YES / NO	
2. Breast surgeon	YES / NO	
3. Plastic Surgeon	YES / NO	
4. Breast radiologist	YES / NO	
5. Radiology technician	YES / NO	
6. Pathologist	YES / NO	
7. Pathology technician	YES / NO	
8. Medical oncologist	YES / NO	
9. Radiation therapy oncologist	YES / NO	
10. Radiation therapy oncology physicist/engineer	YES / NO	
11. Oncology nurse	YES / NO	
12. Navigator/social worker	YES / NO	
13. Psycho - oncologist	YES / NO	
14 Cardio-oncologist	YES / NO	
15. Physical therapist	YES / NO	
16. Genetic counselor	YES / NO	
17. Case manager/ Administrator	YES / NO	
Provided Services in breast program/center		
1. Health Education and Psycho-Social Support for patients with Breast Cancer	YES / NO	
2. Service of psychological care	YES / NO	
3. Programs for patients following breast cancer treatment (survivorship program)	YES / NO	
4. Fertility preservation program for young women with breast cancer	YES / NO	
5. Palliative Care in patients with metastatic disease	YES / NO	
6. Work in Multidisciplinary Teams	YES / NO	
7. Pathology	YES / NO	
8. Imaging Diagnosis	YES / NO	
9. Interventional Radiology	YES / NO	
10. Surgical Care (also, see below)	YES / NO	
11. Immediate or Delayed Reconstructive Surgery	YES / NO	
12. Radiation therapy	YES / NO	

13. Medical Oncology:		
Adjuvant and Neoadjuvant Chemotherapy	YES / NO	
Adjuvant and Neoadjuvant Hormonal Therapy	YES / NO	
Adjuvant and neoadjuvant Immunotherapy	YES / NO	
Hormonal therapy and Chemotherapy treatment for advanced and metastatic disease	YES / NO	
Endocrine Therapy: In patients with hormone receptor–positive invasive breast cancer, the rate of initiation of endocrine therapy should be ≥85%.	YES / NO	
Molecular Therapy/ targeted therapies	YES / NO	
Chemoprevention	YES / NO	
Cardiac support for treatment complications	YES / NO	
Neurologic support for treatment complications	YES / NO	
Hematologic support for treatment complications	YES / NO	
14. Pain management	YES / NO	
15. Assigned data management personnel	YES / NO	
16 Data collection/ tumor registry (local/national)	YES / NO	
16. Genetic Counseling	YES / NO	
17. Research: Clinical/ translational	YES / NO	
18. Continuous teaching availability for oncology staff	YES / NO	
19. Continuous Improvement of the quality of care	YES / NO	
20. Patient quality of care survey	YES / NO	

Appendix 1

Accreditation application form

Dr	
Serving as :	
Head of the Breast Program/ Center	
Coordinator of the Breast Program/Center	
Applying for the accreditation for the Breast Program / Center of:	
The HOSPITAL	
The CLINIC	
Address	
Breast program/Center phone No	
Breast Program/ Center e-mail	
Head/Coordinator's mobile phone	
Head/Coordinator's e-mail	

Requested documentation

1. Program / center certification of application by the Hospital Director/Dean/ Chief of Medical Staff	YES / NO	
2. Composition of the Breast program/center by Specialties, identifying each one of the specialists	YES / NO	
3. Certification of the specialist members	YES / NO	
4. Diagnosis and Treatment Protocols for Breast Diseases	YES / NO	
5. Non-medical personnel assigned to the Breast Program/Center. Specification of names and positions	YES / NO	
6. Specification of diagnostic imaging equipment	YES / NO	
7. Records of the care activity over the last year for the first accreditation.	YES / NO	
8. Records of scientific research and teaching activities	YES / NO	
9. Oncology nurse certification	YES / NO	
10.Data manager/ collector certification	YES / NO	

Appendix 2

to be completed by the Breast Program/Center applicant

1. Head/Director of the Breast Program/Center:		
Name		
Specialty		
Mobile phone		
Member of the SIS	YES / NO	
2. The Hospital to which the Breast Program/Center belongs is under management:		
Public	YES / NO	
Private	YES / NO	
Foundation	YES / NO	
3. The Breast Program/Center incorporates services provided by different Hospitals	YES / NO	
Specify		
4. Number of Hospital beds assigned to Breast Care		
5. The Breast Program/Center has management autonomy	YES / NO	
Is under the authority of		
6. The Breast program/ center has its own designated area and is conveniently signposted in the Hospital's labeling system	YES / NO	
7. If the answer is no, specify the location		
8. The Breast Program /Center has assigned full-time staff	YES / NO	
If YES, Specify		
Specialties + Title of specialists		
Specific Training in Senology (Degree or specific courses) :		
If NO, Specify		
Part-Time shared with the service of :		
Number of staff members assigned exclusively to the Breast program/center:		
9. Number of Nurses assigned to the Breast Program/ Center		
Number of Auxiliary Staff :		
10. The Breast Program/Center has Administrative Staff	YES / NO	
11. There is a population screening program for Breast Program/ Cancer: (or participates national screening for breast cancer)		

The Breast Program/ Center is the referral center of the Screening Program	YES / NO	
The Breast Program/ Center participates in the management after screening	YES / NO	
12. Office hours of Outpatient Clinic devoted exclusively to Breast Diseases	YES / NO	
Monday	YES / NO	
Tuesday	YES / NO	
Wednesday	YES / NO	
Thursday	YES / NO	
Friday	YES / NO	
13. The Breast Program/ Center serves ONLY patients with cancer	YES / NO	
Breast Program /Center serves patients with Benign Pathology	YES / NO	
14. Number of total number of patients with benign pathology diagnosed IN the program/center over the last year (12 months)		
15. Outpatient consultation activity conducted over the last 12 months:		
Number of new patients with pathological benign		
Number of new patients with pathological malignant		
16. Schedule of operating theater devoted exclusively to Breast Surgery		
Monday	YES / NO	
Tuesday	YES / NO	
Wednesday	YES / NO	
Thursday	YES / NO	
Friday	YES / NO	

Activity; last 12 months		
1. Surgical Statistics: Number of interventions for		
Benign Diseases		
Breast Cancer		
Reconstructive Surgery by plastics surgeon		
Oncoplastic Surgery by breast surgeon		
Surgical (excisional) Biopsies		

2. Lymph node biopsies:		
Sentinel lymph node patient number		
Targeted axillary lymph node biopsy/ dissection patient number		
Axillary lymph node dissection (immediate/ delayed) patient number		
Sentinel lymph node biopsy technique:		
TC99M		YES / NO
ROLL/SNOLL		YES / NO
Targeted axillary Biopsy/Dissection	Specify the localization technique:.....	YES / NO
Dye	<i>Lymphazurin:</i> <i>Patent Blue:</i> <i>Methylene Blue:</i> <i>Indocyanine green</i> <i>Other....</i>	YES / NO YES / NO YES / NO YES / NO
Neoadjuvant	<i>Pre-treatment SLNB :</i> <i>Post-treatment SLNB :</i>	YES / NO YES / NO
Preoperative LN evaluation (frozen section) of SLN		YES / NO
Technique:	<i>Imprint :</i> <i>Freezing :</i> <i>Mixed :</i> <i>Immunohistochemistry :</i> <i>AutoAnalyzer :</i>	YES / NO YES / NO YES / NO YES / NO YES / NO
3. Diagnostic radiology statistics: Number of:		
Mammography		
Ultrasonography		
Galactography		YES / NO
Guided Biopsies (core/ FNA)		
Diagnostic MRI		
Pretreatment MRI		
High-risk or follow-up MRI		
4. New cases of Breast program/Cancer cared in the 36 months		
Stage 0		
Stage 1		
Stage II A		
Stage II B		
Stage III A		
Stage III B		
Stage III C		
Stage IV		
Recurrence Stage IV		
De Novo Stage IV		

5. The Center has a specific database for Breast Diseases	How many patients registered in last 36 months	YES / NO
6. Types of Quality Controls used by the Program/ Center (internal, external)		
Specify:		
7. Delays control system in the care network (Internal or external)		
For the first visit		YES / NO
For additional tests:		YES / NO
For the Histological/Cytological Report of the biopsies of the surgical specimens		YES / NO
For the beginning of treatment of Breast Cancer patients		YES / NO
For the beginning of Chemotherapy after Surgery		YES / NO
For the beginning of RT after Surgery		YES / NO
For the beginning of RT after Chemotherapy		YES / NO
8. The Breast Program/Center has electronic clinical records		YES / NO
9. The Breast Program/Center provides Breast Cancer patients with written information or Audio-Visual material on:		
Detail information about diagnostic options and complications		YES / NO
Detail information about treatment options		YES / NO
Genetic tests		YES / NO
Early Diagnosis		YES / NO
Breast Health Promotion		YES / NO
Follow up monitoring		YES / NO
Complications of breast cancer treatments		YES / NO
Contacts with Support Groups		YES / NO
Psycho-Social Support		YES / NO
Palliative Care		YES / NO
Physical therapy		YES / NO
Participation in clinical / translational trials		YES / NO
Prevention of Breast Cancer		YES / NO
10. Equipment of Imaging Diagnosis:		
Mammography guided biopsy device		YES / NO
Ultrasound guide biopsy device	-	YES / NO
MRI guided biopsy device	-	YES / NO
Nuclear medicine scanners	-	YES / NO
11. Laboratory of Pathological Anatomy:		
Uses Immunohistochemistry		YES / NO

FISH /SISH Technology		YES / NO
2 nd review of all outside pathology slides		YES / NO
Tissue handling requirements is standardized and reported on every specimen.		YES / NO
ER, PR, and HER2/neu (including FISH/SISH) testing, as much as possible, specimens should be placed in formalin within one hour after surgery. Furthermore, the breast tissue should be in contact with formalin for 6-48 hours, not to exceed 72 hours		YES / NO
Specimen Dimensions: The dimensions of the breast specimen and tumor should be reported in the x, y, and z axes, in millimeters or centimeters		YES / NO
12. Radiotherapy Equipment:		
External beam radiotherapy unit		YES / NO
Stereotactic radiotherapy/radiosurgery		YES / NO
Motion management		YES / NO
Computed tomography simulator		YES / NO
Treatment planning system		YES / NO
Mould room		YES / NO
Brachytherapy unit		YES / NO
13. For the follow-up of Breast Program/ Cancer patients:		
Protocols available and updated		YES / NO
Involved staff:	<i>Surgeons</i> <i>Gynecologists</i> <i>Medical oncologists</i> <i>RT Oncologists</i> <i>Radiologists</i> <i>Physical therapists</i>	YES / NO YES / NO YES / NO YES / NO YES / NO YES / NO
Psycho-oncology Consultation services		YES / NO
Genetic counseling for patient and family		YES / NO
Fertility preservation for young Breast Cancer patients		YES / NO
14. Additional Services provided:		
Cardio-oncology for long-term follow-up/ complications		YES / NO
Bone Mass/Scan		YES / NO
MRI for high-risk patients		YES / NO
Palliative Radiation therapy		YES / NO

Plastic Surgery for complications and lymphedema		YES / NO
Long term Psycho-oncology support for patient and family		YES / NO
Pre and post cancer treatment physical rehabilitation	=	YES / NO
15. Quality of Life surveys		
SF-36 (long or Short)		YES / NO
LYMQOL		YES / NO
Other....		YES / NO
16. Patients satisfaction is evaluated through some kind of survey		YES / NO
17 Publications and Communications of the Program/Center staff on topics related to Breast Diseases. Numbers		
Research activity (PI or Co-PI)	Last 36 months:	YES / NO
Involvement in Clinical Trials. (National and International)	Last 36 months:	YES / NO
Educational activity (Local/national. International)	Last 36 months:	YES / NO
Participation in training courses (in person/on-line)	Last 36 months:	YES / NO
Explain why if any of above answer is NO		




Multidisciplinary Meetings

In person	YES / NO
On-line	YES / NO
1. Breast Cancer Tumor Board with at least 4 different specialists:	
Weekly Frequency	
Hours invested	
Average number of cases in a week	
2. Breast Program/Center committee with the specialists and administrators meeting	
Meeting frequency	
Program update	YES / NO
3. Other committees related to breast program/center; specify	
	-

Appendix 3

Quality indicators in the clinical care for patients

The following data are objectives that the Center must achieve in the medium term and that the SIS Accreditation Committee does not consider essential at this time for granting accreditation. However, is recommended that the Center introduce them into its database to be used in the follow-up checks that the accreditation Committee conduct for all units 3-5 years after the granting of accreditation.

1. The Diagnosis of Breast Cancer should be communicated within < 5 working days after the completion of the biopsy	YES / NO	  
2. Histologic diagnosis of cancer must be prior to surgery in > 95 per cent of cases i.e. the number of surgical biopsies for Breast Cancer diagnosis is considered an exceptional practice (< 5%). Breast Cancer patients should be taken to the operating room knowing the diagnosis	YES / NO	
3. Conserving Surgery for Breast Cancer should be > 65 % for T3<	YES / NO	
4. Conserving surgery should be achieved with a maximum of 2 interventions in >95% of the patients	YES / NO	
5. Final histological assessment of margins should be carried out in 100 % of cases	YES / NO	
6. The percentage of Non-Detection of Sentinel node must be < 5%	YES / NO	
7. Appropriate lymph node number in axillary dissection is 10 or more, but should not contain less than 6 nodes	YES / NO	
8. Breast Cancers should statistically be classified using stages according to the latest AJCC or UICC classification for the Database	YES / NO	
9. Global survival and Disease-free survival should be recorded at 5 and 10 years of follow up in all cases of breast cancer	YES / NO	
10. In general, local recurrences in Conserving Surgery for invasive breast cancer at 5 years < 5%, for carcinoma in situ at 5 years <10%	YES / NO	
11. In general, local recurrences post Mastectomy within 5 years < 5%	YES / NO	
12. Regional recurrence after axillary dissection at 5 years < 5% on N +, <3% in NO	YES / NO	
13. Regional recurrence after S/T LNB at 5 years < 3%	YES / NO	
14. First visit for suspected cancer <10 working days	YES / NO	
15. First visit for benign disease < 15 days	YES / NO	

16. Histological Report after biopsy < 15 days	YES / NO	
17. Histological Report after Surgery < 15 days	YES / NO	
18. Surgical Treatment < 30 days after diagnosis or neoadjuvant systemic therapy is completed	YES / NO	
19. Beginning of Systemic therapy < 60 days after surgery	YES / NO	
20. Beginning of radiation < 8 weeks after surgery (for non-adjuvant CT patients)	YES / NO	
21. Beginning of radiation < 8 weeks after adjuvant CT		
22. Reconstructive surgery information 100% before mastectomies	YES / NO	
23. Percentage of Breast Reconstructions out of Total Mastectomies performed:		
Immediate	%	YES / NO
Deferred	%	YES / NO
24. Oncoplastic surgery during breast conserving surgery	YES / NO	
25. Establishment of a Program for Preserving Fertility in young women	YES / NO	
26. Genetic counseling for patients if appropriate	YES / NO	
27. Medical Oncology unit has automated preparation of chemotherapy system	YES / NO	
28. Medical Oncology has dedicated chemotherapy unit	YES / NO	
29. Continuous Training of the Breast Center staff in Breast Diseases. A minimum of 10 hours/year	YES / NO	
30. Radiation Oncology unit Patient care and comfort area	YES / NO	
31. Radiation therapy unit has quality assurance equipment	YES / NO	
32. Following breast-conserving surgery, the postoperative radiotherapy rate is $\geq 90\%$.	YES / NO	
33. The program/center collects 5-year survival status and recurrence data for at least 80% of treated patients.	YES / NO	
34. Patients survey on level of satisfaction with the care received	YES / NO	