

## EMC 16-400



### A MULTICENTER RANDOMIZED CONTROLLED TRIAL TESTING HYALURONIC ACID SPACER INJECTION FOR SKIN TOXICITY REDUCTION OF PERMANENT BREAST SEED IMPLANT (PBSI)

#### CASE REPORT FORM (CRF)

#### A MULTICENTER RANDOMIZED CONTROLLED TRIAL TESTING HYALURONIC ACID SPACER INJECTION FOR SKIN TOXICITY REDUCTION OF PERMANENT BREAST SEED IMPLANT (PBSI)

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Protocol version: Mar 2018 (version 5)

Note: this CRF was built as an e-CRF in OpenClinica

## A MULTICENTER RANDOMIZED CONTROLLED TRIAL TESTING HYALURONIC ACID SPACER INJECTION FOR SKIN TOXICITY REDUCTION OF PERMANENT BREAST SEED IMPLANT (PBSI)

### Overview of events and CRF

The CRF's are divided over the following events:

- Baseline
- Treatment
- Follow-up 2M, 6M, 1YR, 2YR, 3YR, 4YR, 5YR, 10YR
- Recurrence
- Off-study

### Randomization Form will be built separately in ALEA (\*)

This form will contain basic patient characteristics, and a selection of the eligibility criteria:

- Date of birth → calculated age,  $\geq 50$  years (yes/no)
- Surgery: BCS+ axillary lymph node dissection or BCS + sentinel lymph node biopsy, (yes/no)
- *Histological* diagnosis: IDC or DCIS, (yes/no)
- *Conditional question:*
  - o if IDC: Surgical margins clear at ink or re-excision negative (yes/no)
  - o if DCIS: Surgical margin  $\geq 2$ mm or re-excision negative (yes/no)
- Tumor size (mm),  $\leq 30$ mm (yes/no)
- Nodal status (positive/negative)
- Lymphovascular invasion (yes/no)
- Known allergy for hyaluronic acid (yes/no)
- Neo-adjuvant chemotherapy (yes/no)
- PBSI technically feasible (yes/no)
- Any other exclusion criterion (yes/no)
- Date of written informed consent

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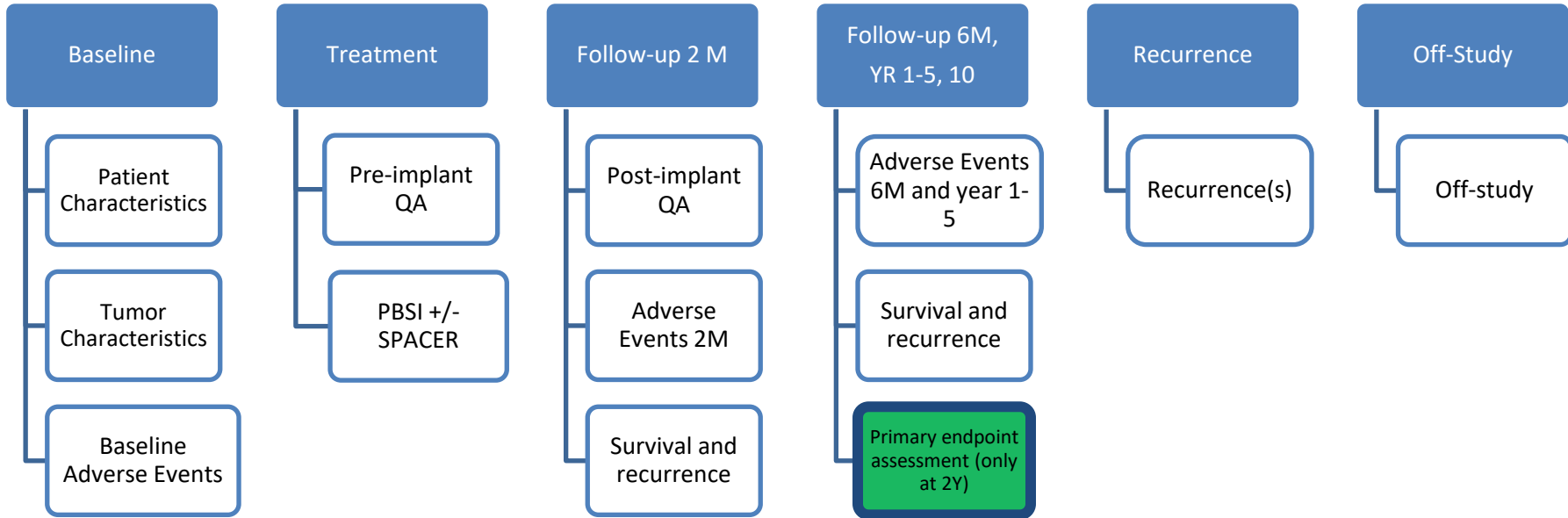
- Date of randomization
- Randomization result
- Subject IDnr

(\*) export of data any time in agreement with CTC

**PROMs will be collected in ABC Zorgmonitor: QLQ-C30/BR23, EQ-5D, BCTOS**

**Additional questionnaires not yet in Zorgmonitor: BCTOS at BL, 2M, YR1 and YR2**

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#### CRF: Patient Characteristics

[DOR]	Date of randomization	DD / MM/ YYYY
[AGE]	Age at registration	_ _ _
[ALLINCL]	Did patient meet all inclusion criteria?	_  0 =no; 1 = yes
[ALLEXCL]	Did patient meet any exclusion criteria?	_  0 =no, 1 = yes
	<i>If ALLINCL=1 or ALLEXCL=1:</i>	
[ELIGCOM]	Comments on eligibility	[FREE TEXT]
[DDIAG]	Date of first histological diagnosis	DD/ MM/ YYYY
[HEIGHT]	Height	_ _ _  cm
[WEIGHT]	Weight	_ _ _  kg
[CUPSIZE]	Breast cup size	_ _ _  (f.e. 80B)
[SMOKSTAT]	Smoking status	_  0 = never smoked 1 = former smoker 2 = current smoker 9 = unknown
[DM]	Diabetes Mellitus	_  0 = no 1 = insulin dependent 2 = not insulin dependent
[HT]	Hypertension	_  0=no; 1=yes
[CVRF]	History of MI, CVA, PAOD?	_  0=no; 1=yes
[ADJTX]	adjuvant therapy before/after PBSI	_  0 = no 1 = chemo 2 = hormone 3 = chemo+ hormone

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If ADJTX>0:

[STARTHTX]	Start date hormone therapy	DD / MM / YYYY
[STARTCTX]	Start date chemotherapy	DD / MM / YYYY
[STOPCTX]	Date of last chemotherapy	DD/ MM/ YYYY

[SURGDATE] Date of surgery: DD / MM / YYYY

[SURGTYPE] Type of surgery: |\_\_| 1 = BCS + axillary lymphnode dissection  
2 = BCS + sentinel lymphnode biopsy

[SSI] Surgical Site Infection (CDC) |\_\_| 0 = none  
1 = superficial incisional SSI  
2 = deep incisional SSI

#### CRF: Tumor Characteristics

[T]	T (NM)-classification 1997	T __
[N]	(T)N(M)-classification 1997	N __
[M]	(TN)M-classification 1997	M __

[STAGE] Clinical Stage |\_\_| 0 = stage 0  
1 = stage 1  
11 = stage 1b  
2 = stage 2a  
22 = stage 2b  
3 = stage 3a  
33 = stage 3b  
333 = stage 3c  
4 = stage 4

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[TUMLAT]	Tumor laterality	__	1 = <i>left</i> 2 = <i>right</i>
[TUMSITE]	Tumor anatomical subsite	__	1 = <i>nipple</i> 2 = <i>central</i> 3 = <i>upper- inner quadrant</i> 4 = <i>lower- inner quadrant</i> 5 = <i>upper-outer quadrant</i> 6 = <i>lower-outer quadrant</i> 7 = <i>axillary tail</i>
[TUMORSIZE]	Tumor size	__ __	mm
[DISTSKIN]	Distance tumor to skin	__ __ __	mm
[MARGIN]	Resection margin status	__	0 = <i>tumor free at ink (IDC)</i> <i>or &gt;2mm for DCIS</i> 1 = <i>focal irradical or</i> <i>&lt;2mm for DCIS</i> 2 = <i>irradical</i> 9 = <i>unknown</i>
[HISTOL]	Histological Diagnosis	__	1 = <i>IDC</i> 2 = <i>DCIS</i> 3 = <i>IDC+DCIS</i> 4 = <i>other, .....</i>
[HISTCOM]	<i>IF HISTOL=4 please specify FREE TEXT</i>		
[TUMGRAD]	Modified Scarf-Bloom-Richardson grade	__	
[PR]	PR-receptor status	__	0 = <i>negative</i> 1 = <i>positive</i>
[ER]	ER-receptor status	__	0 = <i>negative</i> 1 = <i>positive</i>
[HER2NEU]	Her-2neu -receptor status	__	0 = <i>negative</i> 1 = <i>positive</i>
[LVI]	Lymfovascular Invasion	__	0 = <i>no</i> 1 = <i>yes</i>

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[MULTI]	multicentricity	__	0 = no 1 = yes
[EXTDCIS]	Extensive DCIS (beyond invasive tumor, or >3cm)	__	0 = no 1 = yes
[BILAT]	Bilateral breast cancer?	__	0 = no 1 = yes
[RECUR}	Recurrent breast cancer?	__	0 = no 1 = yes
[ACTOTH]	Active other cancer (defined by malignancy in <5 year?)	__	0 = no 1 = yes



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#### CRF: Baseline Adverse Events (as close as possible to start PBSI)

[AEDATE]	Date of AE assessment	DD / MM/ YYYY
[BASPAIN]	Baseline pain in breast	__  0 = none 1 = occasional and minimal, hypersensation, pruritus 2 = intermittent and tolerable 3 = persistent and intense 4 = refractory and excruciating
[BASSSI]	Baseline Surgical Site Infection	__  0 = none 1 = superficial SSI 2 = deep SSI
[BASTELEANG]	Baseline Teleangiectasia (Bentzen scale)	__  0 = none 1 = grade I – less than 1cm <sup>2</sup> 2 = grade II – 1 to 4 cm <sup>2</sup> 3 = grade III – over 4 cm <sup>2</sup>
[BASSUBINDUR]	Baseline Subcutaneous Induration	__  0 = none 1 = slight induration and loss of subcutaneous fat 2 = moderate fibrosis but asymptomatic 3 = severe induration and loss of subcutaneous tissue; field contracture 4 = necrosis
[BASPIGM]	Baseline pigmentation	__  0 = none 1 = transitory, slight 2 = permanent, marked
[OTHERAE]	Any other AE? in grid/table (multiple entries possible):	__  0=no, 1=yes *If yes, enter
	<ul style="list-style-type: none"><li>- System organ Class (conform CTCAE4/MEDRA)</li><li>- AE term (conform CTCAE4/MEDRA)</li><li>- CTC grade (1-4)</li></ul>	

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#### CRF: Pre-implant QA

##### Group: General

[PLANCT1] Date of planning CT scan DD / MM / YYYY

[PRECTV] CTV |\_\_|\_|\_|.|\_|| cc

[PREPTV] PTV |\_\_|\_|\_|.|\_|| cc

[PRESEEDNUM] Total number of seeds |\_\_|\_|\_|

[PRENEEDNUM] Total number of needles |\_\_|\_|\_|

[TOTACT] Total activity of seeds |\_\_|\_|\_|.|\_||U

[PRESKINPTV] minimal distance skin to PTV |\_\_|\_|\_|.|\_||mm

[PRESKINISO] distance between CTV isocenter and skin |\_\_|\_|\_|.|\_||mm

##### Group: DVH parameters

[PREV100] Pre-implant V100 |\_\_|\_|\_|.|\_|| %

[PREV200] Pre-implant V200 |\_\_|\_|\_|.|\_|| %

[PRED90] Pre-implant D90 |\_\_|\_|\_|.|\_|| cc

[PRESK90] Pre-implant skin isodose>90% over 1cm<sup>2</sup> |\_\_| 0=no, 1=yes

[PREDO.2] Pre-implant D0.2cc skin dose |\_\_|\_|\_|.|\_|| Gy

[PREDO.05] Pre-implant D0.05cc skin dose |\_\_|\_|\_|.|\_|| Gy

#### CRF: PBSI +/- SPACER

[PBSIDATE] Date of PBSI procedure DD / MM / YYYY

[PBSIDUR] Duration of PBSI procedure |\_\_|\_|\_|min

[PBSIDIFF] any difficulties in PBSI procedure, please specify.....

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[SPACER] Spacer administered |\_\_| 0=no; 1=yes

[SPACDUR] Duration of spacer injection procedure |\_\_|\_\_|\_\_| min

[SPACMCR] Spacer administered in mediocranial quadrant of skin projection |\_\_| 0=no, 1=yes

[SPACMCA] Spacer administered in mediocaudal quadrant of skin projection |\_\_| 0=no, 1=yes

[SPACLCA] Spacer administered in laterocaudal quadrant of skin projection |\_\_| 0=no, 1=yes

[SPACLCR] Spacer administered in laterocranial quadrant of skin projection |\_\_| 0=no, 1=yes

If SPACER=1: [SPACVOL] Volume of spacer administered |\_\_|\_\_|\_\_|\_\_| cc  
(enter 9999 if not recorded)

[SPACDIFF] any difficulties in spacer injection, please specify:.....

[USSPATRANCEN] mid spacer thickness central transversal plane on ultrasound |\_\_|\_\_|. |\_\_| mm

[USSPATRANCRA] mid spacer thickness cranial transversal plane on US |\_\_|\_\_|. |\_\_| mm

[USSPATRANCAU] mid spacer thickness caudal transversal plane on US |\_\_|\_\_|. |\_\_| mm

[USSPASAGCEN] mid spacer thickness central saggital plane on US |\_\_|\_\_|. |\_\_| mm

[USSPASAGLAT] mid spacer thickness lateral saggital plane on US |\_\_|\_\_|. |\_\_| mm

[USSPASAGMED] mid spacer thickness medial saggital panel on US |\_\_|\_\_|. |\_\_| mm

[SPASUC] Spacer injection successful (>5mm in all injected quadrants) |\_\_| 0=no, 1=yes

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#### CRF: treatment pain

[PAINBAS]	Pain before procedure (baseline, LENTSOMA)	__	0-4
[PAINPBSI]	Pain during procedure (baseline, LENTSOMA)	__	0-4
[PAINPOST]	Maximum pain after procedure (1-2 d post-implant, LENTSOMA)	__	0-4

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#### CRF: Adverse Events 2 months

[2MASSDATE]	Date of AE assessment	DD / MM / YYYY
[2MPAIN]	pain in breast	__  0 = none 1 = occasional and minimal, hypersensation, pruritus 2 = intermittent and tolerable 3 = persistent and intense 4 = refractory and excruciating
[2MPAINS]	If AEPAIN>0: Was AE serious(SAE)?	__  0=no, 1=yes
[2MRED]	Redness	__  0 =none 1 = yes but no effect on ADL 2 = yes and effect on ADL
[2MREDS]	If AERED >0: Was AE serious(SAE)?	__  0=no, 1=yes
[2MPIGM]	Pigmentation	__  0 = none 1 = transitory, slight 2 = permanent, marked
[2MPIGMS]	If AEPIGM >0: Was AE serious(SAE)?	__  0=no, 1=yes
[2MSKININD]	Skin induration	__  0 = none 1 = Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up) 2 = Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL 3 = Severe induration, unable to slide or pinch skin; limiting self-care ADL 4 = Generalized
[2MSKININDS]	If AESKININD >0: Was AE serious(SAE)?	__  0=no, 1=yes

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[2MRADDERM]	Radiation dermatitis	<input type="checkbox"/>	0 = none 1 = Faint erythema or dry desquamation 2 = Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema 3 = Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion 4 = skin necrosis/ulceration of full thickness dermis; spontaneous bleeding from involved site; (skin graft indicated)
[2MRADDERMS]	If AERADDERM >0: Was AE serious(SAE)?	<input type="checkbox"/>	0=no, 1=yes
[2MSKINTOXDIST]	Distance of clinical max skintoxicity from reference point (nipple lowerinner)	<input type="text"/>	mm
[2MSKINTOXANGLE]	Angle of clinical max skintoxicity from reference point (nipple lowerinner)	<input type="text"/>	0-360°
[2MSSI]	Surgical Site Infection	<input type="checkbox"/>	0 = none 1 = superficial SSI 2 = deep SSI
[2MSSIS]	If AESSI >0: Was AE serious(SAE)?	<input type="checkbox"/>	0=no, 1=yes
[2MOTHERAE]	Any other RT (or spacer) induced AE?	<input type="checkbox"/>	0=no; 1=yes

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If OTHERAE=yes: Enter in grid/table (multiple entries possible):

- System organ Class (drop down list conform CTCAE4/MEDRA)
- AE term (drop down list conform CTCAE4/MEDRA)
- Worst grade observed since last AE evaluation (1-5)
- Serious: yes/no

#### CRF: Post-implant QA

##### Group: general postplanning CT variables

[PLANCT2]	Date of post-implant CT scan	DD/ MM/ YYYY
[POSTCTV]	post-implant CTV	_ _ . _  cc
[POSTVOL]	post-implant treatment volume with Minimal peripheral dose (90Gy)	_ _ _ . _  cc
[POSTSEEDNUM]	Total number of seeds	_ _ _
[SEEDDISPLACED]	any seeds displaced>1 cm	_  0=no, 1=yes
[DISPSPEC]	<i>If SEEDDISPLACED =1: Specify</i>	[FREE TEXT]
[POSTVOLSKIN]	minimal distance skin to POSTVOL	_ _ . _  mm
[POSTISOSKIN]	distance between CTV isocenter and skin	_ _ . _  mm

##### Group: DVH parameters on CT

[POSTV100]	post-implant V100	_ _ _ . _  %
[POSTV200]	post -implant V200	_ _ _ . _  %
[POSTD90VOL]	post-implant D90 of skin	_ _ _ . _  cc

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[POSTSK90]	post-implant skin isodose>90% over 1cm <sup>2</sup>	__  0=no, 1=yes
[POSTD02]	post-implant D0.2cc skin dose	__ __ __ . __  Gy
[POSTD005]	post-implant D0.05cc skin dose	__ __ __ . __  Gy

#### Group: spacer measurements on CT at 2 months

[CTSPACER]	any spacer visible on CT	__  0=no, 1=yes
[CTSPACMCR]	spacer in mediocranial quadrant of skin projection	__  0=no, 1=yes
[CTSPACMCA]	spacer in mediocaudal quadrant of skin projection	__  0=no, 1=yes
[CTSPACLCA]	spacer in laterocaudal quadrant of skin projection	__  0=no, 1=yes
[CTSPACLCR]	spacer in laterocranial quadrant of skin projection	__  0=no, 1=yes

If SPACER=1:

[CTSPACVOL]	Volume of spacer on CT	__ __ __ __  cc
[CTSPATRANCEN]	mid spacer thickness central transversal plane on CT	__ __ . __  mm
[CTSPATRANCRA]	mid spacer thickness cranial transversal plane on CT	__ __ . __  mm
[CTSPATRANCAU]	mid spacer thickness caudal transversal plane on CT	__ __ . __  mm
[CTSPASAGCEN]	mid spacer thickness central saggital plane on CT	__ __ . __  mm
[CTSPASAGLAT]	mid spacer thickness lateral saggital plane on CT	__ __ . __  mm
[CTSPASAGMED]	mid spacer thickness medial saggital plane on CT	__ __ . __  mm

#### Group: gafchromic film skin dose measurement

[FILMUSED]	gafchromic film used?	__  0=no, 1=yes
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IF FILMUSED=1 than



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[FILMMAX]	maximum point skindose on film	_ _ _ .  _  Gy
[FILMMAX1CM]	maximum skindose on film over at least 1cm <sup>2</sup>	_ _ _ .  _  Gy
[FILMAUC]	AUC skindose on film	_ _ _ .  _  Gy*cm
[FILMLOCDIST]	Distance of max point skindose on film from reference point (projected isocenter)	_ _ _ .  _  mm
[FILMLOCANG]	Angle of max point skindose on film from reference point (projected isocenter)	_ _ _  0-360°

#### CRF: Survival and recurrence

[FUDATE]	Date last known to be alive / date of death	DD/MM/YYYY
[SURVIVAL]	Survival status	_  1 = alive 2 = death 8 = lost to follow-up
[RADDATE]	Date last mammography or CT-scan	DD/MM/YYYY [ ]not done
[RECURR]	Any recurrent disease (not yet reported) <i>If yes, please complete the recurrence form</i>	_  0=no; 1=yes

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#### CRF: Recurrence

Please report/update all recurrences until start of a new anticancer treatment

[LREC]	<b>Local recurrence (<i>ipsilateral breast/chestwall</i>)</b>	__	0=no; 1=yes
<i>If LREC=1:</i>			
[LRECDATE]	Date of local recurrence		DD/MM/ YYYY
[LRECLOC]	Localization of local recurrence  __		1 = ipsilateral breast same quadrant 2 = ipsilateral breast other quadrant 3 = ipsilateral chest wall same quadrant 4 = ipsilateral chest wall other quadrant 5 = ipsilateral, location not documented
[LRECHIS]	Cyt/hist proof of recurrence	__	0 = no; 1=yes
[LRECPATH]	Local recurrence of disease under study confirmed by pathologist	__	0 = no, (probably) a new primary tumor 1 = yes, (probably) a local recurrence 2 = uncertain, specify
[SLRECDIA]	Comments on diagnosis	[FREE TEXT]	
[RREC]	<b>Regional recurrence (<i>ipsilateral lymphnodes/axilla</i>)</b>	__	0=no; 1=yes
<i>If RREC=1:</i>			
[RRECDATE]	Date of regional recurrence		DD/MM/ YYYY
[RRECLOC]	Localization of regional recurrence  __		1 = internal mammary chain 2 = supraclavicular area 3 = axilla
[RRECHIS]	Cyt/hist proof of regional recurrence	__	0 = no; 1=yes
[RRECPATH]	Regional recurrence of disease under study confirmed by pathologist	__	0 = no, (probably) other tumor

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[SRRECDIA]		<i>1 = yes, (probably) regional recurrence</i> <i>2 = uncertain, specify</i> [FREE TEXT]
[DMET]	<b>Distant metastases</b>	__  <i>0=no; 1=yes</i>
	<i>If DMET=1:</i>	
[DMETDATE]	Date of distant metastases	DD/MM/ YYYY
[DMETHIS]	Cyt/hist proof of distant metastases	__  <i>0 = no; 1=yes</i>
[DMETPATH]	Distant metastases from disease under study confirmed by pathologist	__  <i>0 = no, (probably) (from) other primary tumor</i> <i>1 = yes, (probably)from disease under study</i> <i>2 = uncertain, specify</i>
[DMETDIA]	Comments on diagnosis	[FREE TEXT]
[PLANTRTM]	Planned further treatment  <i>(only first anticancer treatment after PBSI)</i>	__  <i>0= none</i> <i>1= mastectomy</i> <i>2= radiotherapy</i> <i>3= chemotherapy</i> <i>4= targeted therapy</i> <i>5= combination</i>
[SPLANTRTM]	Specify: _____	[FREE TEXT]

*If locoregional or distant recurrence, follow-up local recurrence*

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#### CRF: Adverse Events 6 months and year 1-5

[AEDATE]	Date of AE assessment	DD / MM / YYYY
[AETELEANG]	Telangiectasia (Bentzen scale)	<input type="checkbox"/> 0 = none 1 = grade I – less than 1cm <sup>2</sup> 2 = grade II – 1 to 4 cm <sup>2</sup> 3 = grade III – over 4 cm <sup>2</sup>
[AETELEANGS]	If AETELEANG >0: Was AE serious(SAE)?	<input type="checkbox"/> 0=no, 1=yes
[AEPAIN]	pain in breast	<input type="checkbox"/> 0 = none 1 = occasional and minimal, hypersensation, pruritus 2 = intermittent and tolerable 3 = persistent and intense 4 = refractory and excruciating
[AEPAINS]	If AEPAIN>0: Was AE serious(SAE)?	<input type="checkbox"/> 0=no, 1=yes
[AERED]	Redness	<input type="checkbox"/> 0 =none 1 = yes but no effect on ADL 2 = yes and effect on ADL
[AEREDS]	If AERED >0: Was AE serious(SAE)?	<input type="checkbox"/> 0=no, 1=yes
[AEPIGM]	Pigmentation	<input type="checkbox"/> 0 = none 1 = transitory, slight 2 = permanent, marked
[AEPIGMS]	If AEPIGM >0: Was AE serious(SAE)?	<input type="checkbox"/> 0=no, 1=yes
[AESKININD]	Skin induration	<input type="checkbox"/> 0 = none 1 = Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)

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2 = Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL  
3 = Severe induration, unable to slide or pinch skin; limiting self-care ADL  
4 = Generalized

[AESKININDS] If AESKININD >0: Was AE serious(SAE)? |\_\_| 0=no, 1=yes

[AESUBIND] Subcutaneous Induration |\_\_| 0 =none  
1 = slight induration and loss of subcutaneous fat  
2 =moderate fibrosis but asymptomatic  
3 =severe induration and loss of subcutaneous tissue; field contracture  
4 =necrosis

[AESUBINDS] If AESUBIND >0: Was AE serious(SAE)? |\_\_| 0=no, 1=yes

[OTHERAE] Any other RT (or spacer) induced AE? |\_\_| 0=no; 1=yes

If OTHERAE=yes: Enter in grid/table (multiple entries possible):

- System organ Class (drop down list conform CTCAE4/MEDRA)
- AE term (drop down list conform CTCAE4/MEDRA)
- Worst grade observed since last AE evaluation (1-5)
- Serious: yes/no

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#### CRF: Off-study

[DOFF]	Date off-study		DD / MM / YYYY
[OFFREAS]	Reason off-study	__	<i>1 = end of follow-up period, without recurrence 2 = recurrent disease 3 = start systemic/locoregional anti-cancer treatment/ breast surgery 4 = death 5 = patient withdrawal 6 = ineligibility 7 = other</i>
[SPOFFREAS]	Specify reason off-study		[FREE TEXT]
<i>If OFFREAS=3:</i>			
[CODEATH]	Cause of death	__	<i>1 = Breast cancer 2 = Concurrent disease 3 = Treatment related toxicity 4 = Other</i>
[SPCODEATH]	Specify cause of death		[FREE TEXT]
[SEEDMIGR]	Any known seed migration?	__	<i>0=no; 1=yes</i>
[MIGRSPEC]	<i>If SEEDMIGR=1: Specify</i>		[FREE TEXT]

**EMC 16-400**

**A MULTICENTER RANDOMIZED CONTROLLED TRIAL TESTING HYALURONIC ACID SPACER INJECTION FOR SKIN TOXICITY REDUCTION OF PERMANENT BREAST SEED IMPLANT (PBSI)**

**CRF: Primary endpoint assessment** (will initially be entered on paper CRF during clinical assessment, and entered in e-CRF later)

Date of assessment  DD / MM / YYYY

Physician who scored primary endpoint \_\_\_\_\_

[TELANG] Teleangiectasia (Bentzen)  |  | *0 = none*  
*1 = grade I – less than 1cm<sup>2</sup>*  
*2 = grade II – 1 to 4 cm<sup>2</sup>*  
*3 = grade III – over 4 cm<sup>2</sup>*

Evaluability of primary endpoint:  |  | *0=non-evaluable; 1=evaluable*

If non-evaluable, reason:  | Re-irradiation on ipsilateral breast/chestwall < 2 yrs post-treatment

Re-surgery on ipsilateral breast/chestwall < 2 yrs post treatment

Death < 2 yrs post treatment

Lost to follow-up < 2 yrs post treatment

other, specify

Specify [FREE TEXT]