

**RISK BASED MAMMOGRAPHY SCREENING  
THE TAILORED BREAST CANCER SCREENING TRIAL  
(TBST) IN ITALY**

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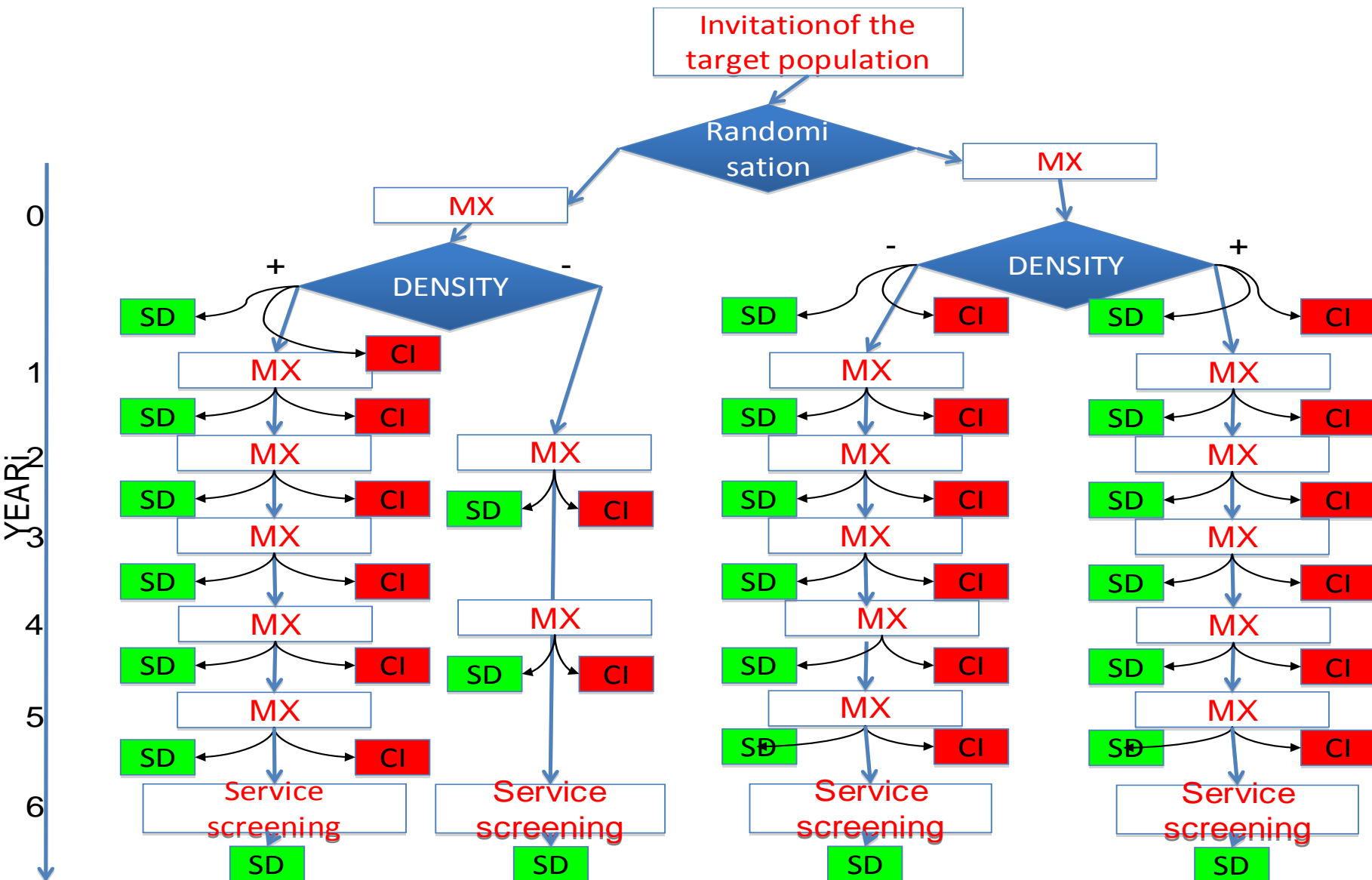
# TBST Study design

- **Cohort by birth year (45 years old)**
- **Randomisation:**
  - **1) *Annual Screening Group***, breast density is registered at screening
  - **2) *Tailored Screening Group*** breast density is registered and woman is allocated :
    - **2a) Birads 3 e 4, upper density group** , invited for annual screening
    - **2b) Birads 1 e 2, lower density group**, invited every 2 years

**At 50 years of age all women are invited in service screening (2 years interval)**

# TBST FLOW CHART

MX=DIGITAL MAMMOGRAPHY SD=SCREEN DETECTED CI=INTERVAL CANCER  
BIRADS 1-2 VS 3-4



# Short Risk Questionnaire

- **Mother or sisters, how many with breast cancer?**
- **Age at first menarch**
- **Number of children**
  
- **Age at first pregnancy?**
- **Current user of HRT?**
- **Previous breast biopsies??**
- **Smoker or ex-smoker?**
  
- **Other questionnaires on the website**

# TBST

- 2012. Pilot study is ongoing . Study design training of radiologists and study design. Initial number of women 15.000.Funding : Ministry of Health
- 2013-2016. Funding by the Ministry of health
- In the Regions where service screening starts at 45 years the cost of the study is expected minimum after the enrollment and informed consent.

# Tailored breast cancer screening Trial: PI Paola Mantellini (ISPO)

- **TOSCANA**
- Istituto per lo studio e la prevenzione oncologica, Firenze (coordinating centre)
- **VENETO**
- I.R.C.S.S. Istituto oncologico veneto, Padova (regional coordination)
- Centro organizzativo screening, ULSS 4, Thiene (VI)
- Organizzazione Screening Oncologici, ULSS 13 Dolo Mirano (VE)
- **PIEMONTE**
- CPO , Torino
- **EMILIA-ROMAGNA**
- AUSL Forlì, Forlì (regional coordinating centre)
- Irst Meldola, Forlì
- Ospedale Maggiore, AUSL Bologna, Bologna

## 1 Il Tailored Breast Screening Trial (TBST): uno studio di non inferiorità finalizzato a ridurre l'impatto negativo e i costi dello screening mammografico in donne di 45-49 anni

Tailored Breast Screening Trial (TBST): a non-inferiority study to reduce screening harms  
and costs in 45-49-year-old women

TBST Working Group\*

### \*TBST WORKING GROUP

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### Radiologists of the TBST Working Group who participated in the radiological review of mammographic density

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**TBST, first round , Breast density  
Florence and Veneto Region**



# La valutazione della densità mammografica: un test di lettura

DENSITÀ	RADIOLOGO (DENSITÀ %)										
	RAD1	RAD2	RAD3	RAD4	RAD5	RAD6	RAD7	RAD8	RAD9	RAD10	RAD11
D1	25	35	29	8	61	35	18	55	36	26	31
D2	43	34	41	39	24	33	50	21	49	40	35
D3	30	19	25	46	11	18	30	19	14	19	25
D4	3	13	5	8	4	15	3	5	1	15	9
	100	100	100	100	100	100	100	100	100	100	100

**Tabella 1.** Distribuzione percentuale della densità per ciascun radiologo sul primo set di 80 mammografie.

**Table 1.** Percent density distribution by radiologist, first mammogram set.

DENSITÀ	RADIOLOGO (DENSITÀ %)										
	RAD1	RAD2	RAD3	RAD4	RAD5	RAD6	RAD7	RAD8	RAD9	RAD10	RAD11
D1	50	44	25	19	21	49	19	35	19	41	41
D2	35	41	54	66	45	35	73	44	56	39	39
D3	15	14	21	15	31	16	9	20	23	20	19
D4	0	1	0	0	3	0	0	1	3	0	1
	100	100	100	100	100	100	100	100	100	100	100

**Tabella 2.** Distribuzione percentuale della densità per ciascun radiologo sul secondo set di 80 mammografie.

**Table 2.** Percent density distribution by radiologist, second mammogram set.

Concordanza degli undici radiologi tra loro nell'attribuzione della densità

a) densità a 4 categorie:

**Kappa = 0.46 (0.41 - 0.53)**

b) densità a 2 categorie:

**Kappa = 0.68 (0.59 - 0.79)**

Concordanza categoria specifica:

<b>Densità</b>	<b>Kappa</b>	<b>Convenzionalmente:</b>
D1	0.58	0,00 - 0,20 minima
D2	0.34	0,21 - 0,40 scarsa
D3	0.46	<b>0,41 - 0,60 moderata</b>
D4	0.49	<b>0,61 - 0,80 sostanziale</b>
		0,81 - 1,00 quasi perfetta

# Florence and Veneto Region (ASL Dolo e Mirano)

	<b>Firenze</b>	<b>Veneto</b>
<b>Screened/Invited (%)</b>	<b>1538/3593 (42.81)</b>	<b>1475/3846 (41,8)</b>
<b>Study arms (Tailored vs Usual Care)</b>	<b>754/ 784 =1538 49% /51%</b>	<b>599/596 =1195 50%/50%</b>
<b>Enrolled / Exclusions after randomisation</b>	<b>1509/29</b>	<b>1195/91</b>

# Florence, by density, N =1509

	<b>Tailored (N=727)</b>	<b>Controllo (N=772)</b>
<b>Birads 1 e 2</b>	<b>546</b>	<b>581</b>
<b>Birads 3 e 4</b>	<b>191 (26%)</b>	<b>191(25%)</b>

# Veneto Region, by density

## N = 1172

	<b>Tailored (N=583)</b>	<b>Control (N=589)</b>
<b>Birads 1 &amp; 2</b>	<b>444 (76%)</b>	<b>434 (74%)</b>
<b>Birads 3 &amp; 4</b>	<b>139 (24%)</b>	<b>155 (26%)</b>

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