KOOPERATIONS
GEMEINSCHAFT
MAMMOGRAPHIE

Final Report of the Pilot Projects on Mammography Screening in Germany

GMDS Leipzig 2006

September 11th 2006

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Kooperationsgemeinschaft Mammographie

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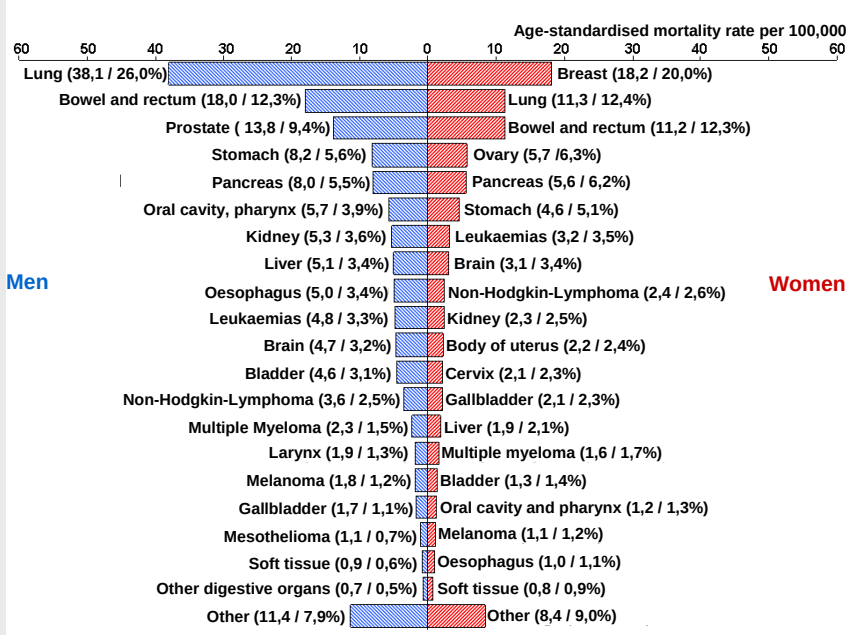
Breast Cancer in Germany



55.000 new cases per year

18.000 deaths per year

Mammography Screening

Is the only method of early detection which has been shown to achieve the goal of reducing breast cancer mortality

Quality assured mammography screening

Risk / Benefit Analysis

Greatest possible benefit

- Reduction of mortality
- Longer survival
- Less intrusive therapy
- Retention of life quality

Least possible risk

- Over-diagnosis
- Over-therapy
- False negative results
- Effects of radiation

EU-Guidelines

European guidelines for quality assurance in mammography screening

International: Netherlands, UK, France, Norway, Sweden, Luxembourg…

Introduction of the mammography screening pilot projects

1. **Resolution passed by the Bundesausschuss der Ärzte und Krankenkassen (Federal Committee of Physicians and Compulsory Health Insurance Funds) on September 12th 1996:**

   Trial and specification of the conditions for integrating mammography screening into the compulsory health insurance funds‘ programme for early detection of cancer

2. **Implementation of pilot projects:**

   Acquisition of knowledge about the conditions required for

   – the implementation of a population-based, quality-assured mammography screening based on the European guidelines (3rd ed.) and

   – how to integrate mammography screening uniformly into the early cancer detection programme of the compulsory health insurance funds in Germany

3. **Establishment of the Planungsstelle Mammographie (Association for Mammography Screening)**

   Scheduling, tendering, co-ordination and evaluation of the pilot projects. Inclusion of the experience and knowledge gained in the pilot projects into the recommendations of the Unterausschuss “Prävention” (sub-committee “Prevention”)

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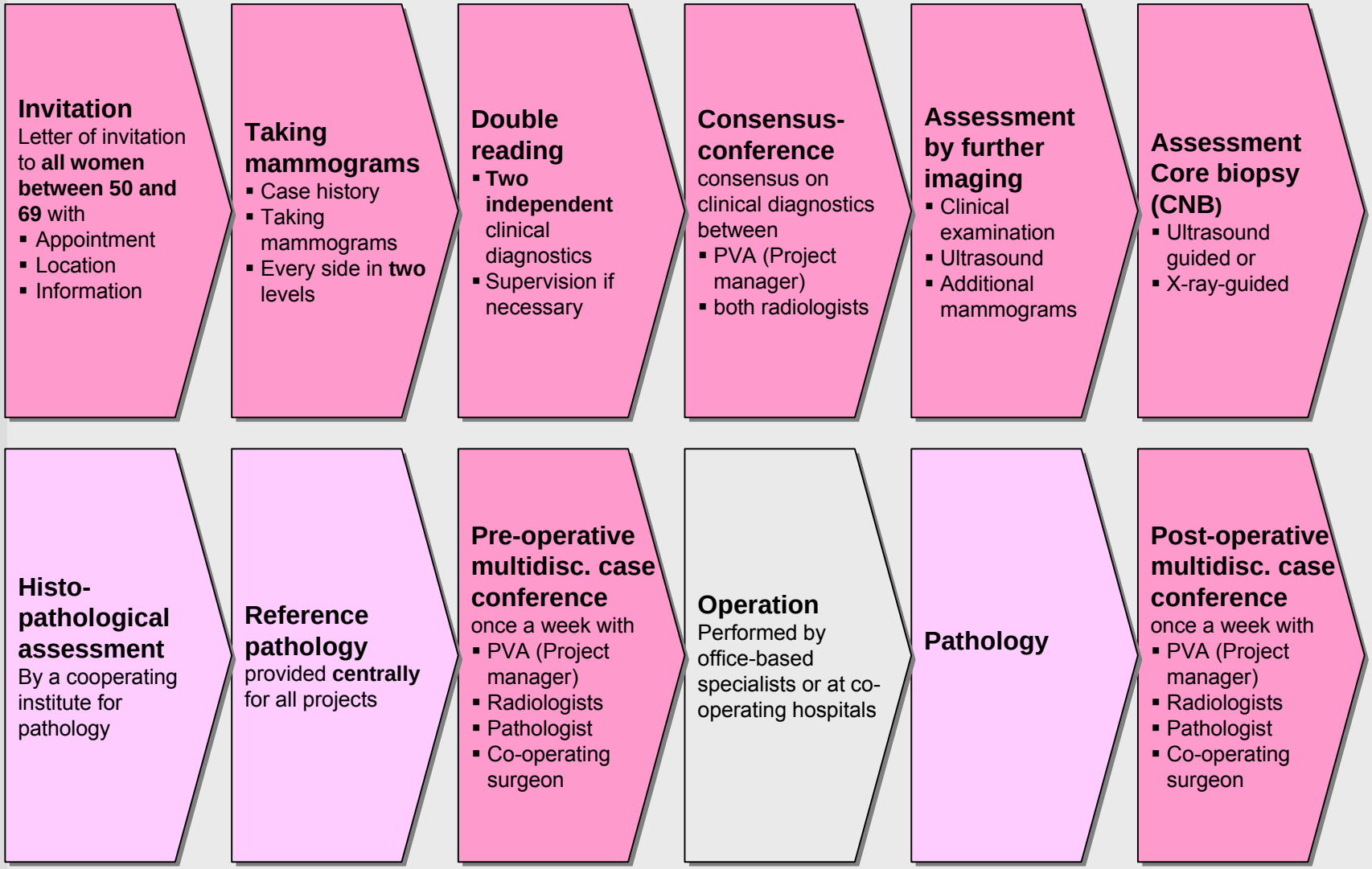
Screening in the Pilot Projects



The Pilot Projects

Bremen

- Urban region
- 540.000 inhabitants, 70.000 eligible
- Managing director: Dr. Hans Junkermann
- Operative unit: Klinikum Bremen-Mitte (Bremen Central Hospital)
- Organised with several locations:
  - 2 mammography units
  - 1 assessment unit
  - administration
- 1 co-operating institute for pathology
- Public invitation office at the Bremen Central Public Health Office
- Launch: July 2001

Wiesbaden/Rhein-Taunus-Kreis

- Urban/rural region
- 456.000 inhabitants, 58.000 eligible
- Managing director: Dr. Reichel
- Operative unit: Dr. Reichel
- Organised in a single location
  - 1 Mammography unit
  - 1 assessment unit
  - administration
- 1 co-operating institute of pathology
- Own public invitation office
- Launch: July 2001

Weser-Ems

- Rural region
- 200.000 inhabitants, 22.000 eligible
- Clinical director: Dr. Gerold Hecht
- Managing director: Prof. Jensch
- Operative unit: Tumorzentrum Weser-Ems and OFFIS
- Organised with several locations:
  - 1 mobile mammogr. unit
  - 3 assessment units
  - administration
- 2 co-operating institute of pathology
- Public invitation office at OFFIS
- Launch: April 2002

Further common structures

Administrative office for the issuing of invitations

- Data imported form the municipal registration office
- Generation and mailing of the invitations (in batches to smaller sub-regions)
- Rearranging of appointments and venues
- Evaluation of participation rate

Software and Archive

- Invitation software
- Standardised electronic documentation of the examination data
- Archiving of the mammograms including client files

Technical quality assurance

- Standardised controls on the basis of the “European protocol for the quality control of the physical and technical aspects of mammography screening (EPQC, Dutch version)
- Under the leadership of the Director of the Physics Group at the RZ Nijmegen (and a medical physicist in Bremen)

Regional advisory committee

- Composition: Association of Statutory Health Insurance Physicians, Public Health Office, Chamber of Physicians, professional associations, various women’s associations and self-help groups, politicians, various institutes…
- Information campaigns
- Development of the information booklet

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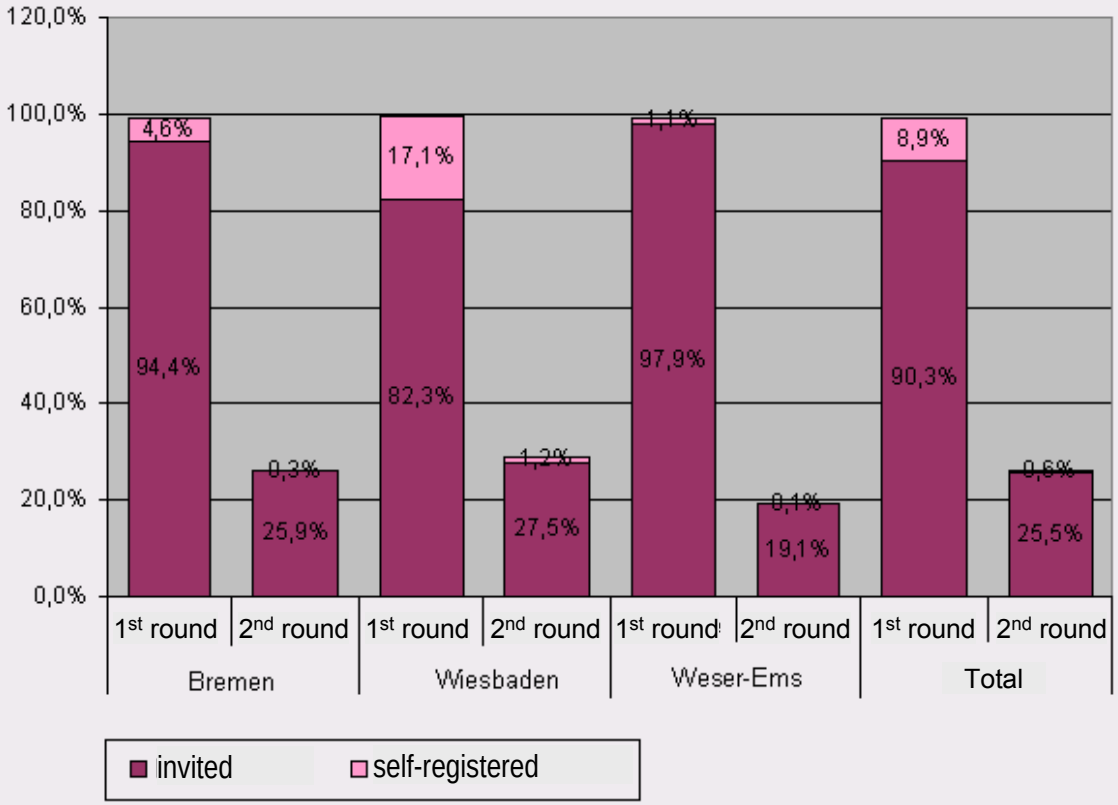
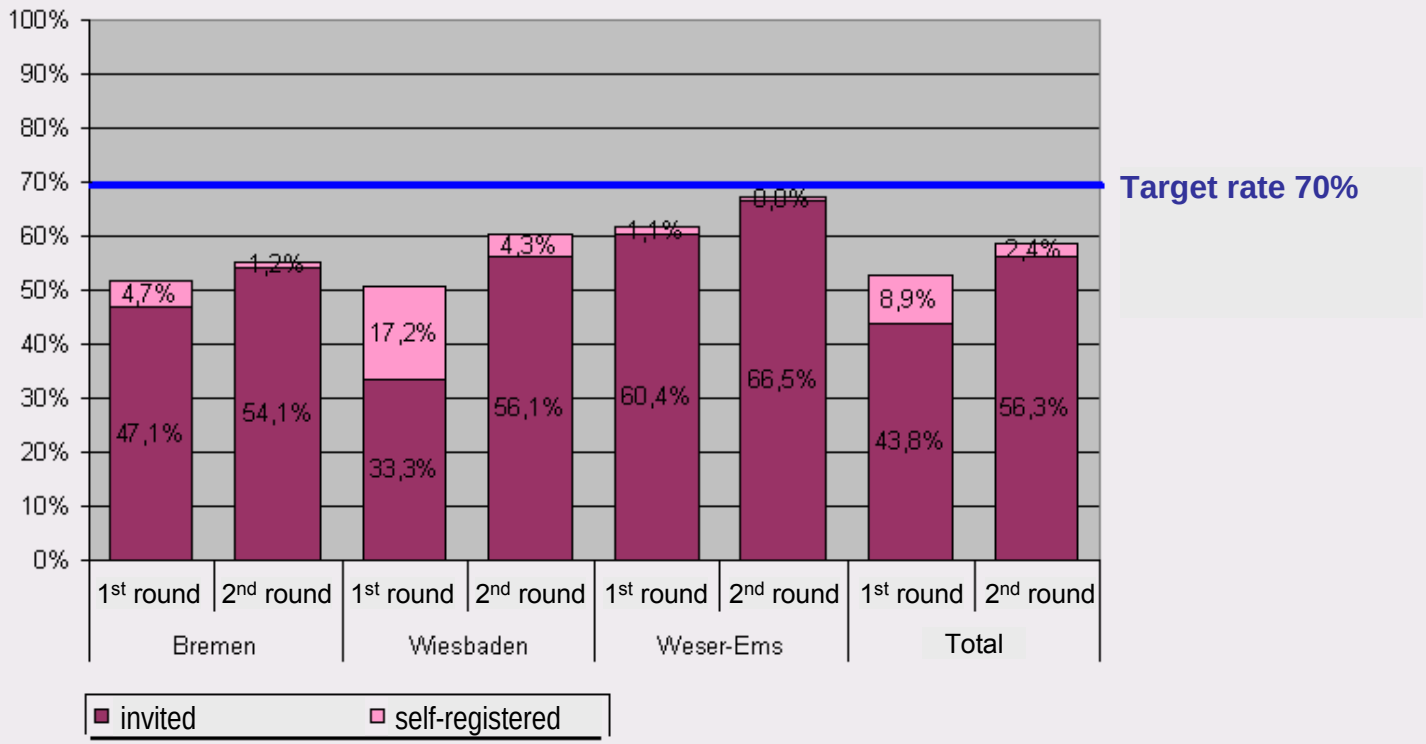
Invitation rates

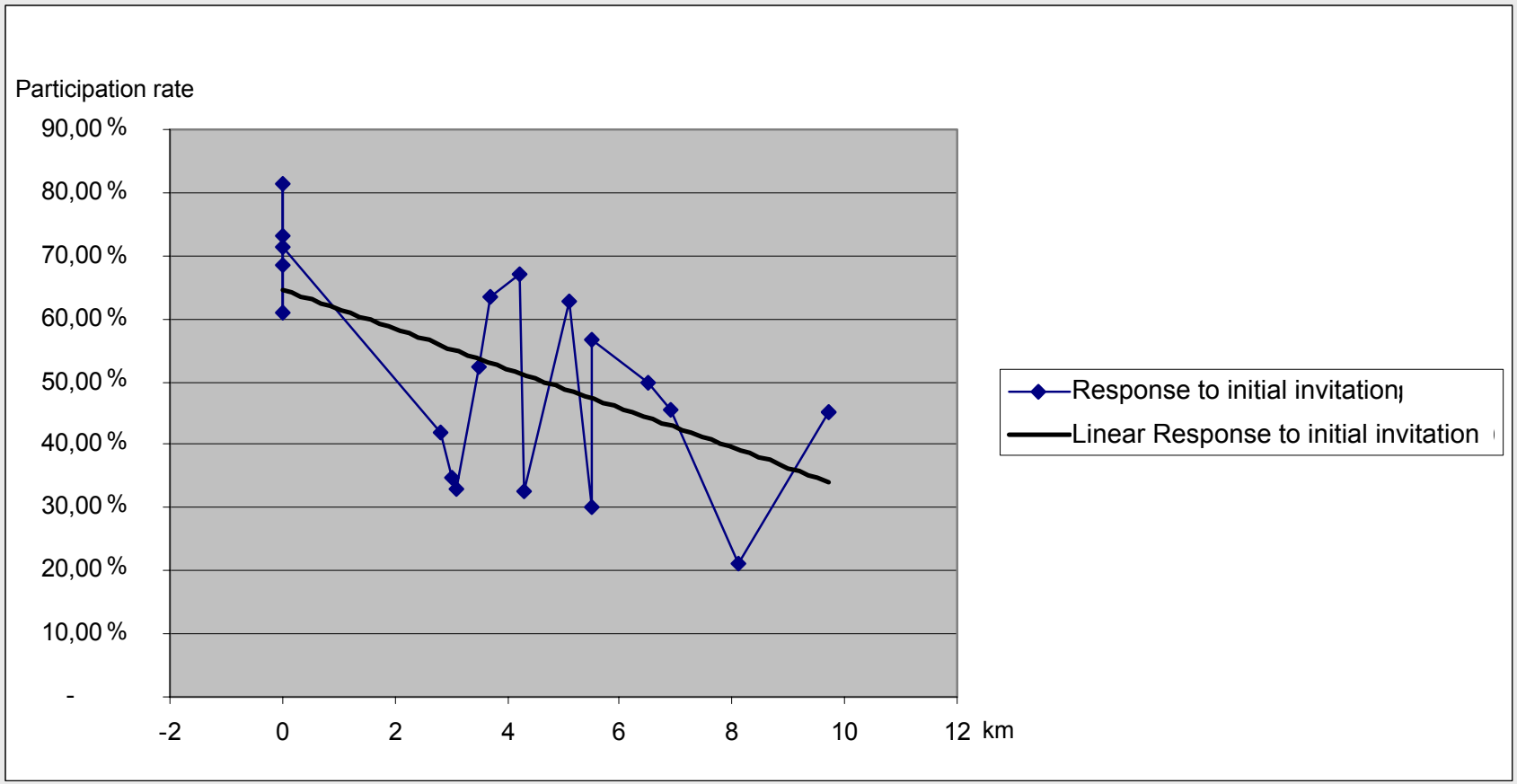


Participation rate

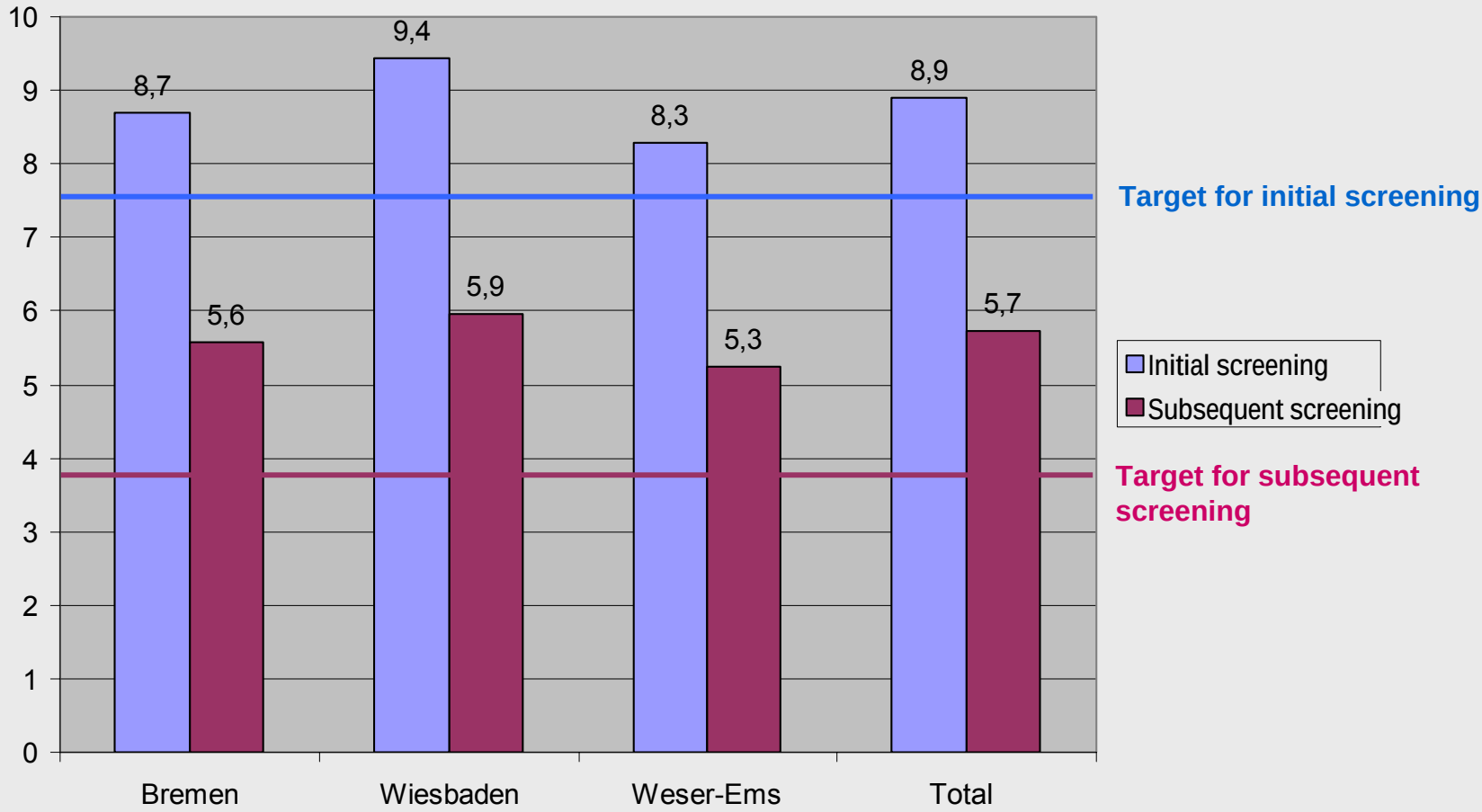


Participation in relation to distance

Weser-Ems

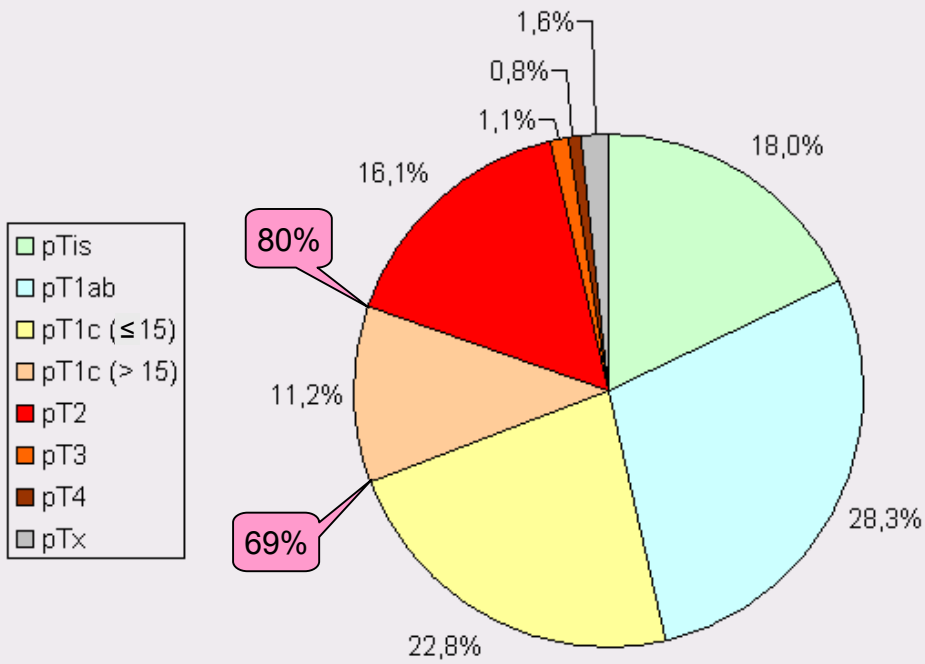


Breast cancer detection rate

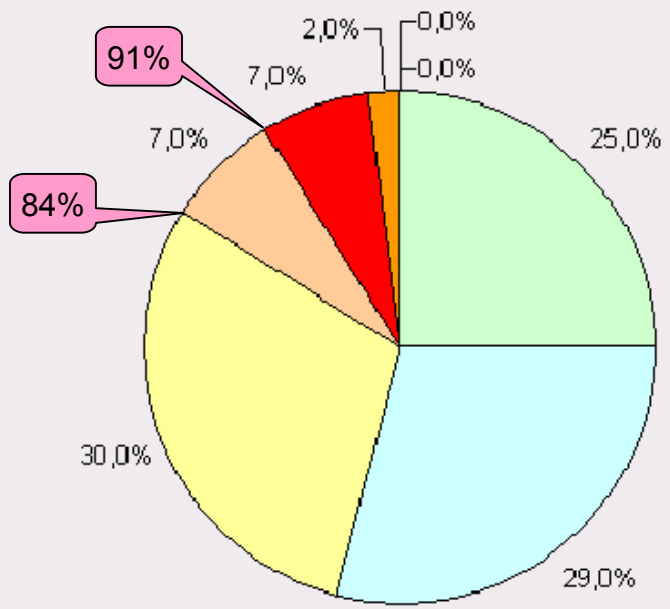


Disease Stage Distribution

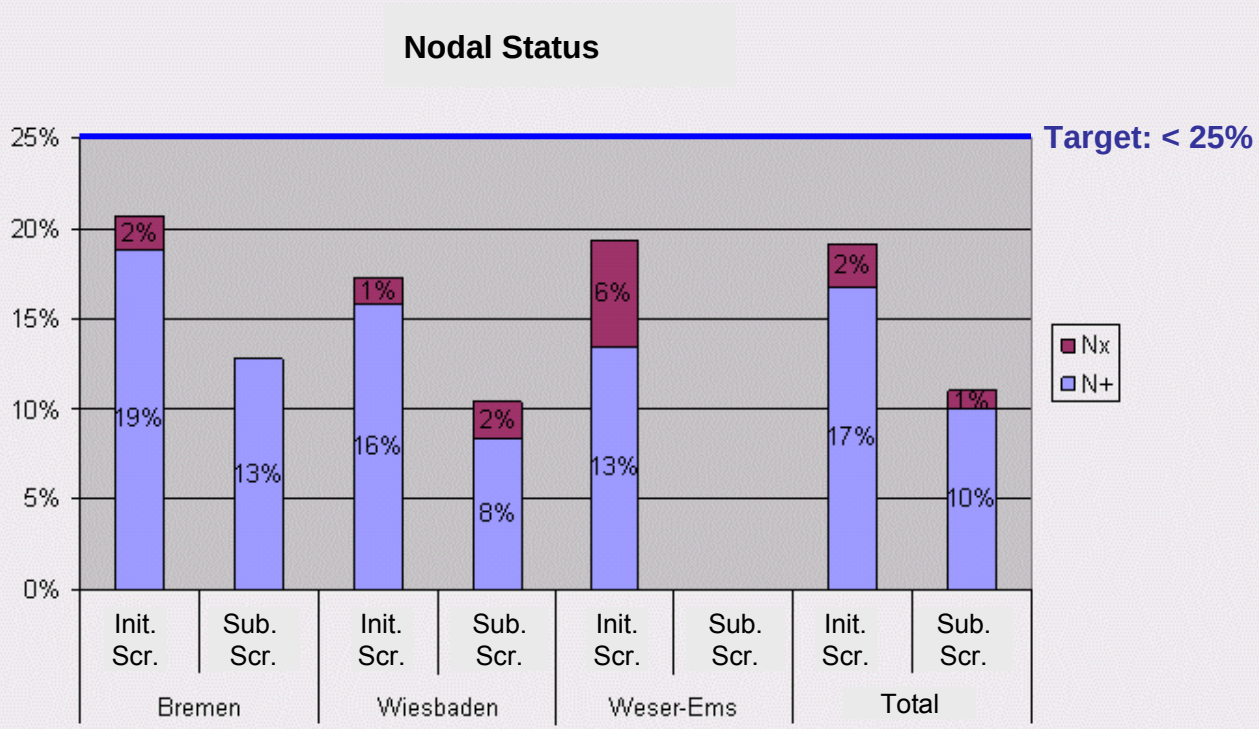
Initial Screening



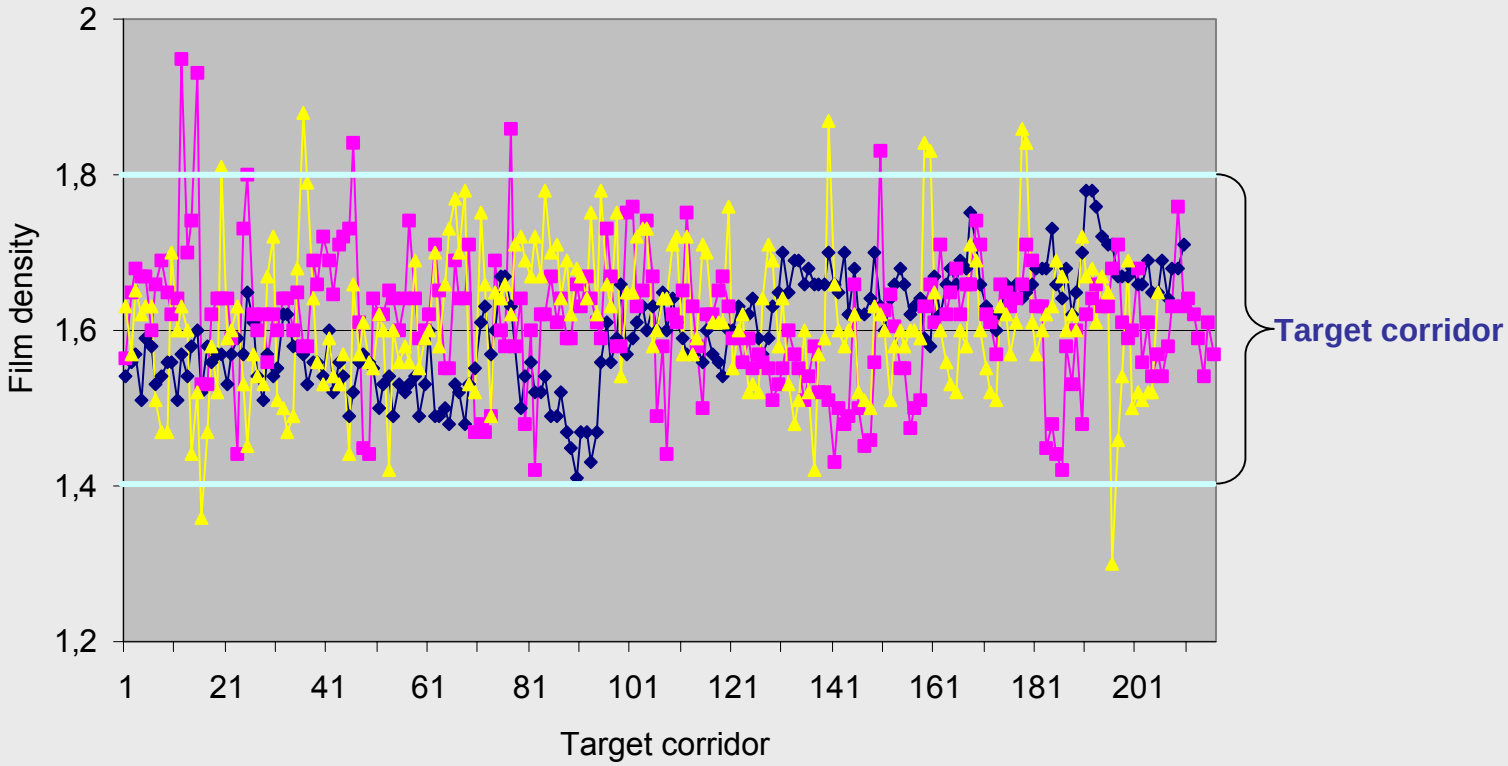
Subsequent screening



Nodal Status



Daily Technical Quality Control



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Performance indicators

indicator	Acceptable level	Desirable level	Bremen	Wiesbaden	Weser-Ems
Participation rate	> 70%	> 75%			
Initial screening			51,7%	50,5%	61,6%
Subsequent screening			55,3%	60,4%	67,2%
Repeated screening examinations	< 3%	< 1%	1,4%	2,6%	2,6%
Recall rate					
Initial screening	< 7%	< 5%	5,7%	6,2%	5,9%
Subsequent screening	< 5%	< 3%	3,8%	3,0%	2,2%
Early recall following diagnostic assesment	< 1%	0%	0,04%	0,10%	0,14%
Pre-op diagnosis of malignancy	> 70%	> 90%	94,6%	94,9%	92,5%
Benign:malignant core biopsy.					
Initial screening	(1:1)*	(0,5:1)*	1:1	0,9:1	1,2:1
Subsequent screening	(1:1)*	(0,2:1)*	0,8:1	0,5:1	0,2:1
Inadequate core biopsy	≤ 10%	< 10%	2,6%	0,6%	2,8%

* Acceptable level according to EU Guidelines for open biopsies

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Surrogate indicators

indicator	Acceptable level	Desirable level	Bremen	Wiesbaden	Weser-Ems
Breast cancer detection rate					
Initial screening	7,5	> 7,5	8,7	9,4	8,3
Subsequent screening	3,75	> 3,75	5,6	5,9	5,3
Proportion of carcinoma in situ	10 %	10 – 20%	20,2%	17,5%	20,5%
Proportion of invasive Ca ≤ 10mm					
Initial screening	≥ 20%	≥ 25%	36,0%	37,9%	25,8%
Subsequent screening	≥ 25%	≥ 30%	37,1%	38,9%	50,0%
Proportion invasive Ca < 15mm	> 50%	> 50%	62,5%	70,3%	58,1%
Proportion of node-negative Ca					
Initial screening	70%	≥ 70%	80,8%	83,9%	85,7%
Subsequent screening	75%	≥ 75%	87,2%	91,5%	100,0%
Proportion of stage II+ Ca					
Initial screening	25%	< 25 %	28,0%	24,8%	30,0%
Subsequent screening	20%	< 20%	21,3%	8,5%	0,0%
Interval cancer rate					
Month 0-11	30%	< 30%	30,3%	33,1%	22,8%
Month 12-23	50%	< 50%	n/a	n/a	44,4%

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Stages of Diagnosis

Screening examination including documentation of clinical abnomalities or insufficient diagnostic image quality

Interpretation of the mammograms (Double reading and consensus decision where necessary) :

a) Mammographic abnormality

b) Clinically abnormal or flaws in the diagnostic imaging quality

c) No mammographic or clinical abnormalities and no flaws in the diagnostic imaging quality

Assessment based on additional imaging

a) Image abnormal, biopsy indicated (core needle biopsy or diagnostic open biopsy)

b) Image abnormal, further assessment (other than biopsy) required

c) No imaging abnormality

Further Assessment: Biopsy (core needle biopsy or diagnostic open biopsy):

a) Malignant lesion (B5), therapy required

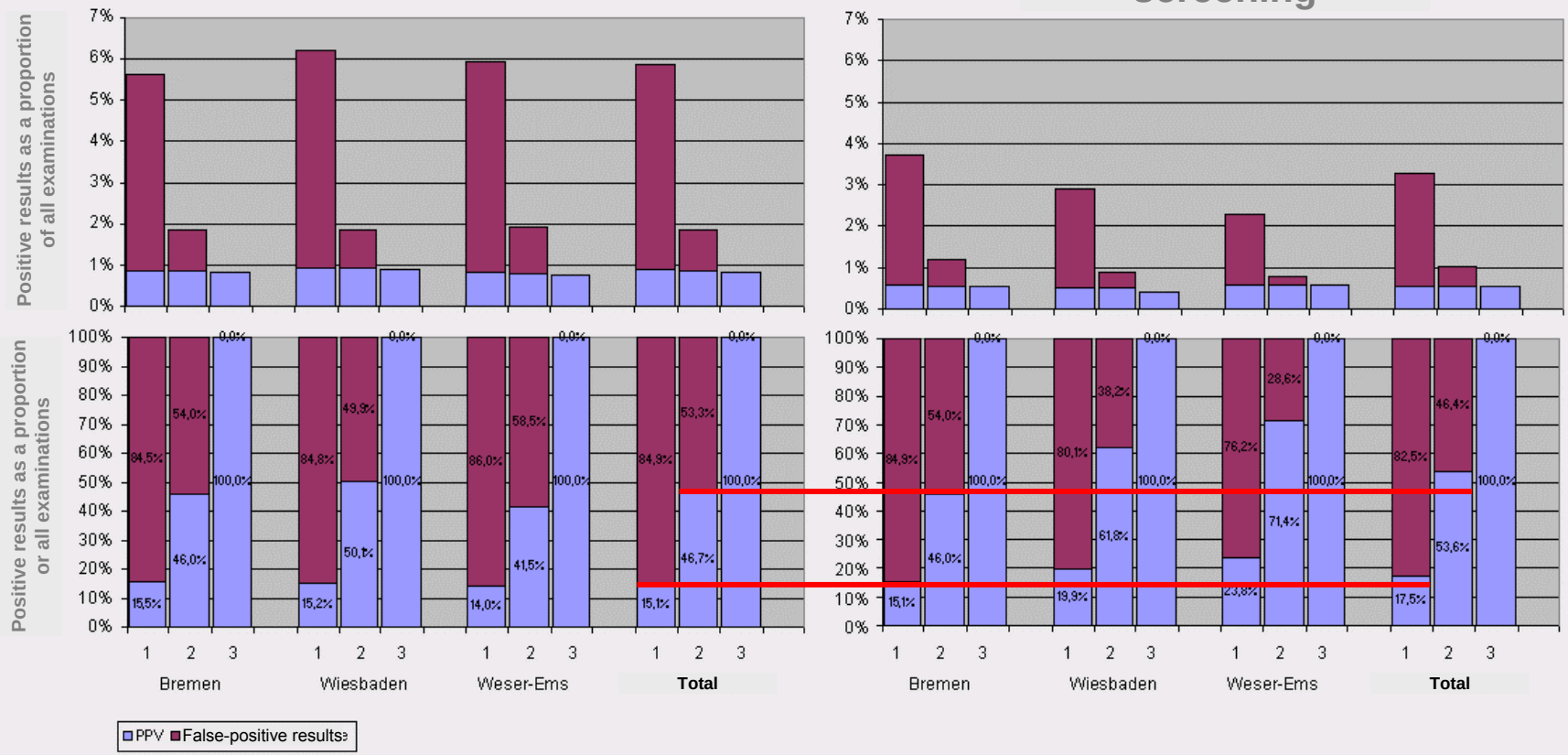
b) Lesion not definitely malignant, further assessment or therapy required

c) No further diagnostic or therapeutic measures required

Positive Predictive Value (PPV)

Initial screening

Subsequent screening



1 – Result of consensus conference: mammogram abnormal
2 – Result of image assessment: biopsy (core needle biopsy or open biopsy) recommended
3 – Result of biopsy: result malignant (core needle biopsy B5, open biopsy positive)

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Introduction of Mammography Screening in Germany

1. **Resolution by the Bundestag (German Federal Parliament) on June 21st 2002:**

   Introduction of population-based, nation-wide mammography screening.

2. **Establishment of the Kooperationsgemeinschaft Mammographie (Coordination Office Mammography Screening) on August 1st 2003:**

   - Evaluation of the pilot projects
   - Supporting the nation-wide introduction of mammography screening
   - Establishment of national reference centres for the technical monitoring and quality assurance of the mammography units
   - Certification and re-certification of the mammography units
   - Evaluation of the quality assurance indicators and of the programme

3. **Passing of the corresponding changes to the guidelines on December 15th 2003 to take effect on January 1st 2004:**

   - Krebsfrüherkennungsrichtlinien (Section B, no. 4)
   - Bundesmantelvertrag-Ärzte und –Ärzte/Ersatzkassen (Appendix 9.2)

4. **Transfer of the pilot projects into the regular health care system**

   - Bremen and Weser-Ems in April 2005
   - Wiesbaden in March 2006

Kooperationsgemeinschaft (KoopG)

KBV

Beirat der Kooperationsgemeinscht

Vorsitzender Dr. W. Aubke (KBV)

Stelv. Vorsitzender Dr. B. Metzinger (SpiV)

AOK Die Gesundheitskasse. BKK vdak Verband der Angestellten-Krankenkassen e.V. KNAPPSCHAFT SBG IKK

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GF & Ltg. J.S. Graebe-Adelssen

REFERENZZENTRUM MAMMOGRAPHIE BERLIN

Ltg. Dr. L. Regitz-Jedermann

REFERENZZENTRUM MAMMOGRAPHIE BREMEN

Ltg. Dr. G. Hecht

REFERENZZENTRUM MAMMOGRAPHIE MÜNCHEN

Ltg, Prof. Dr. S. Heywang-Köbrunner

REFERENZZENTRUM MAMMOGRAPHIE MÜNSTER

Ltg. Prof. Dr. W. Heindel

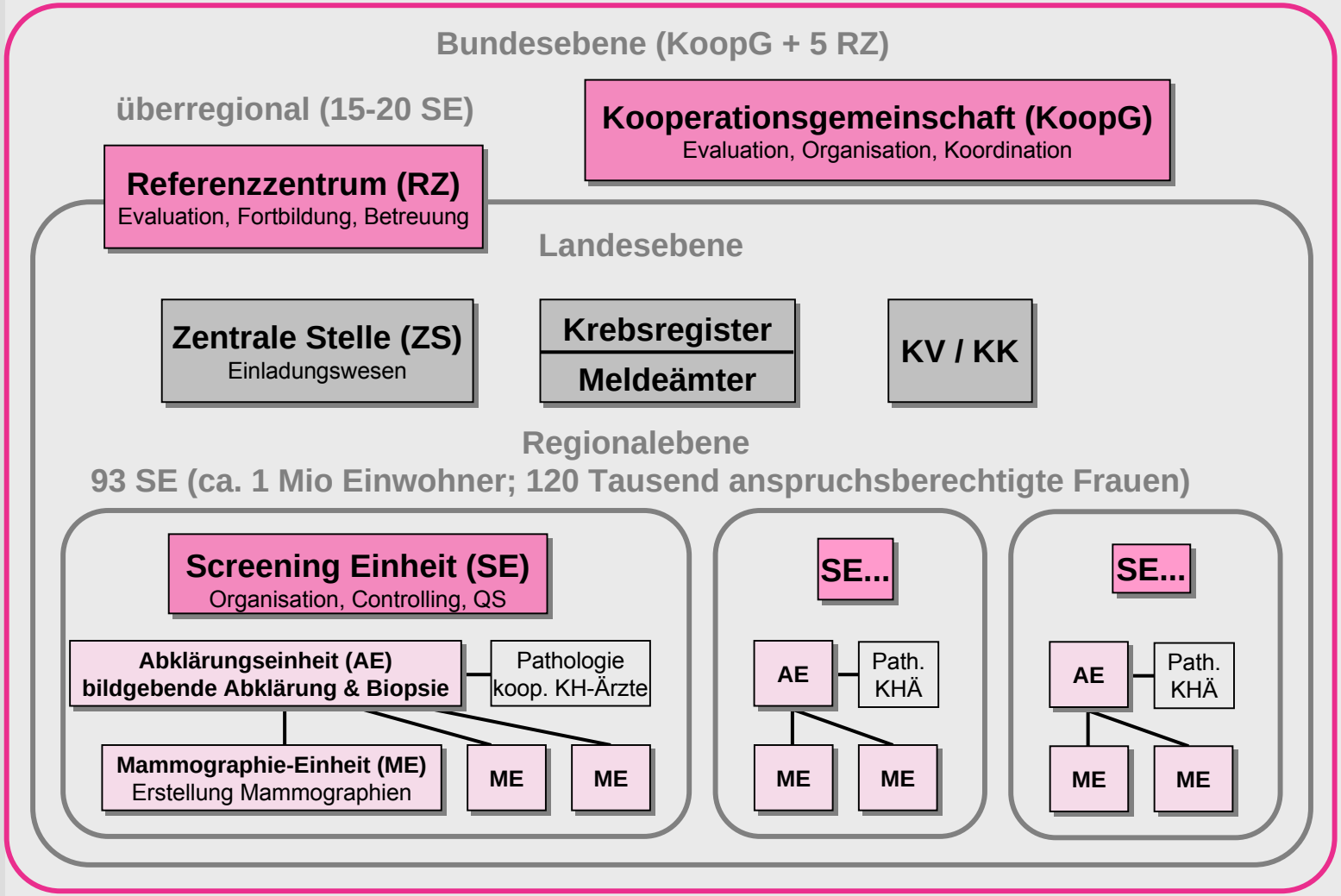
REFERENZZENTRUM MAMMOGRAPHIE SÜDWEST

Ltg. Dr. K. Bock

REFERENZZENTRUM MAMMOGRAPHIE WIESBADEN

Ltg, Dr . M. Reichel

Makrostrukturen im deutschen Mammographie Screening



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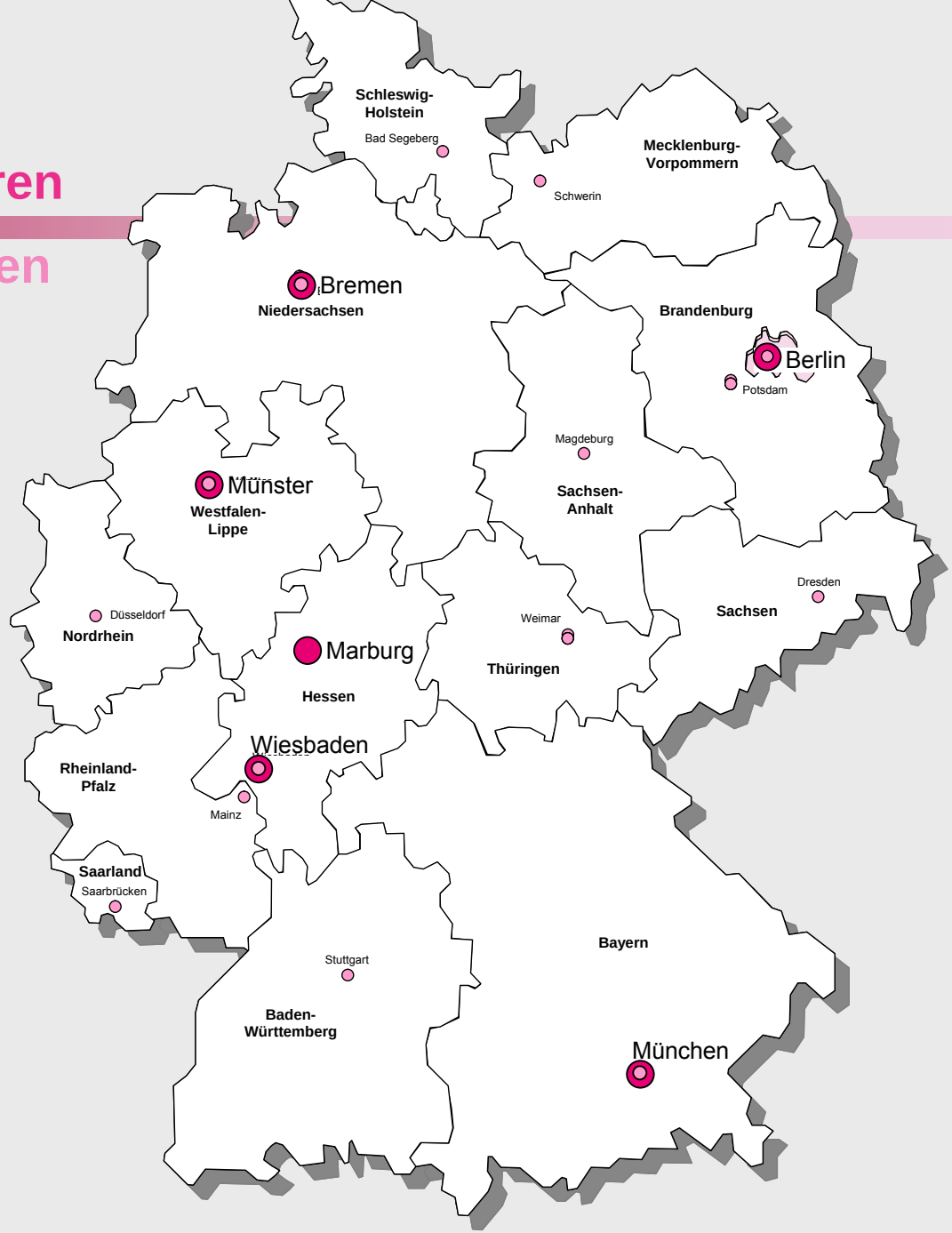
Standorte Referenzzentren

Standorte Zentrale Stellen

Zentrale Stelle	Lädt ein nach	
ZS Berlin	Berlin 01	
ZS Bremen	Bremen Nie Nordwest Hannover Nie Nord	Nie Süd Nie Ost Nie Mitte
ZS Düsseldorf	Düsseldorf Köln linksrh. Köln rechtsrh.	Krefeld Wuppertal
ZS München	Mit.Franken-Ld.	München-Süd
ZS Münster	Münster Nord Münster Süd Dortmund Bielefeld Gelsenkirchen Steinfurt/Borken	Herford/ Minden Lippe Paderborn/ Lippstadt Unna Herne
ZS Schwerin	Greifswald	
ZS Wiesbaden	Wiesbaden Darmstadt	Marburg Fulda



● Referenzzentrum

○ Zentrale Stelle

Zuordnung der Referenzzentren

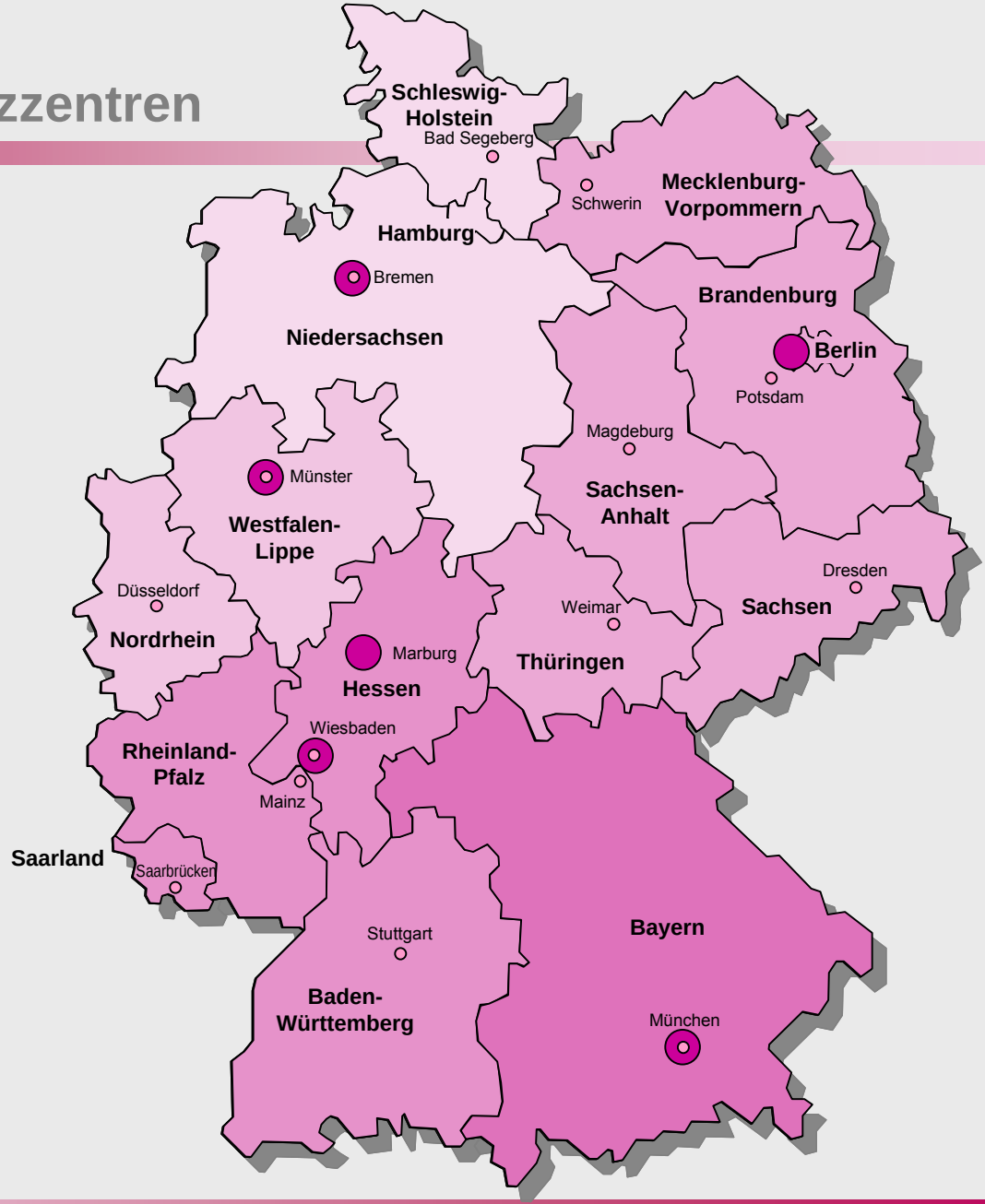
Referenzzentrum Bremen
– Dr. med. Gerold Hecht

Referenzzentrum Berlin
– Dr. Lisa Regitz-Jedermann

Referenzzentrum Münster
– Prof. Dr. med. Walter Heindel

Referenzzentrum Süd-West
a) Wiesbaden – Dr. med. Margrit Reichel
b) Marburg – Dr. med. Karin Bock

Referenzzentrum München
– Prof. Dr. med. S. H. Heywang-Köbrunner



○ Zentrale Stelle ● Referenzzentrum

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Stand Einführung

	SE gesamt	SE in 2005 gestartet	SE im Quartal I 2006 gestartet	SE Start im Quartal II 2006 erwartet	SE Start im Quartal III 2006 erwartet	SE Start im Quartal VI 2006 erwartet	SE Start in 2007 Quartal I	SE Start in 2007 Quartal II	SE Start in 2007 Quartal III	SE Start in 2007 Quartal IV	
KV Westfalen-Lippe	13	3	4	3	1	1	1				WL
KV Bremen + Niedersachsen	1+8	2	1	2	1		2				N
KV Bayern	14	1	-	-	1	7	5				BAY
KV Nordrhein	9		1	3	2	3					NO
KV Hessen	6		1	2		2	1				H
KV Meck.-Vorpom.	4			1	1	2					MV
KV Berlin	4				1	1	1	1			BER
KV Baden-Württemberg	10					3	2	5			BaWü
KV Thüringen	2					1	1				T
KV Rheinland-Pfalz	4						3		1		RLP
KV Schleswig-Holstein	4						4				S-H
KV Hamburg	2						2				HH
KV Saarland	1						1				SAA
KV Brandenburg	2							2			BBG
KV Sachsen	5								5		S
KV Sachsen-Anhalt	4									4	S-A
Zuwachs SE	93	6	7	11	7	20	23	8	6	4	
Zuwachs in Prozent	100%	6,45%	7,53%	11,83%	7,53%	21,51%	24,73%	8,60%	6,45%	4,30%	
SE kummuliert		**[6]**	**[13]**	**[24]**	**[32]**	**[51]**	**[75]**	**[82]**	**[88]**	**[93]**	
Flächendeckung		**6%**	**14%**	**26%**	**33%**	**55%**	**80%**	**88%**	**95%**	**100%**	
						(optimistisch geschätzt)					

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Flächendeckendes Screening

Westfalen-Lippe – ab IV. Quartal 2006

Mecklenburg-Vorpommern – ab IV. Quartal 2006

Bayern – ab I. Quartal 2007

Niedersachsen – ab I. Quartal 2007

Nordrhein – ab I. Quartal 2007

Hessen – ab I. Quartal 2007

Thüringen – ab I. Quartal 2007

Rheinland-Pfalz – ab I. Quartal 2007

Saarland – ab I. Quartal 2007

Berlin – ab II. Quartal 2007

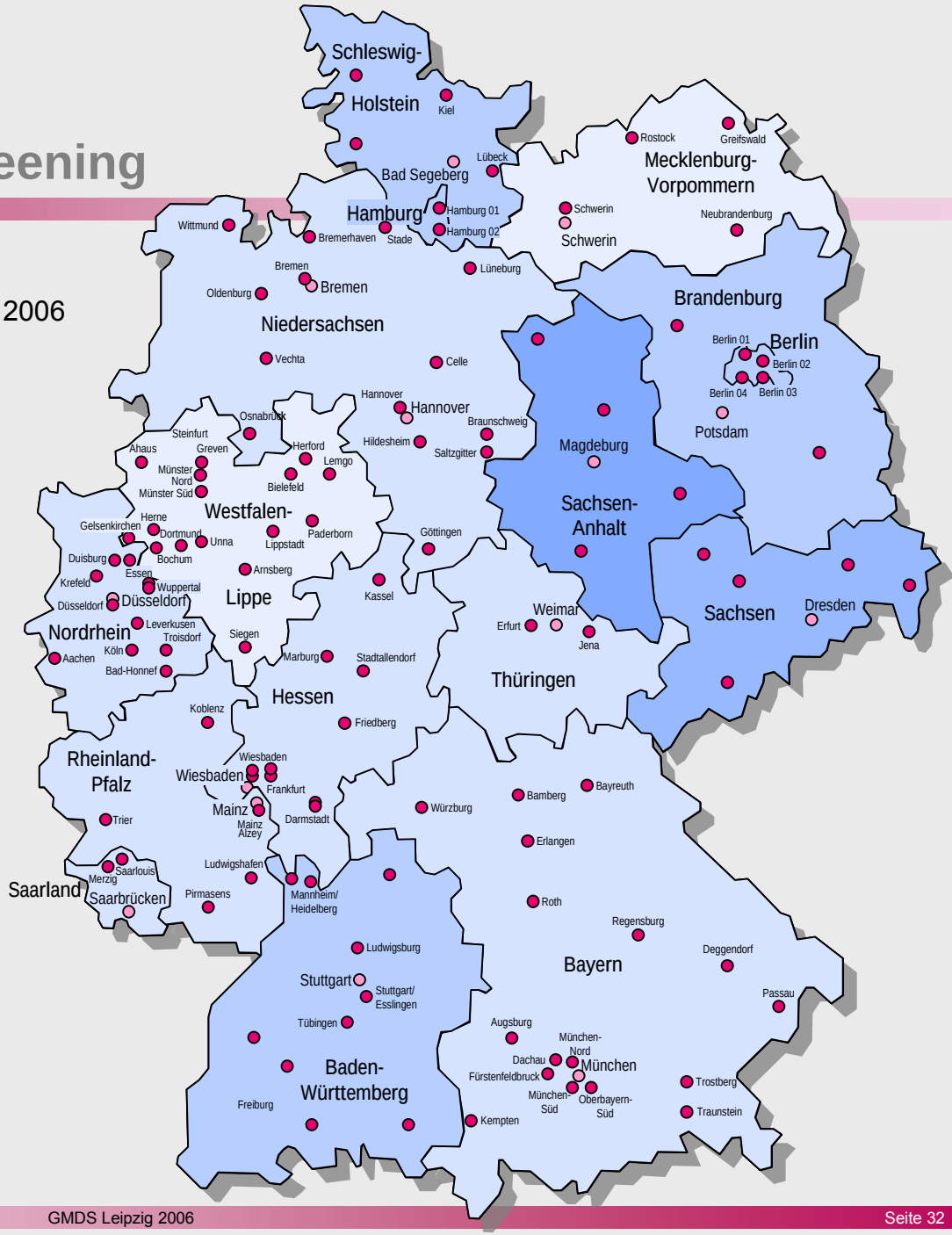
Baden-Württemberg – ab II. Quartal 2007

Schleswig-Holstein – ab II. Quartal 2007

Brandenburg – ab II. Quartal 2007

Sachsen – ab III. Quartal 2007

Sachsen-Anhalt – ab IV. Quartal 2007



○ Sitz der KV, bzw. Zentrale Stelle

● Screening-Einheit

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Thank your for your attention