

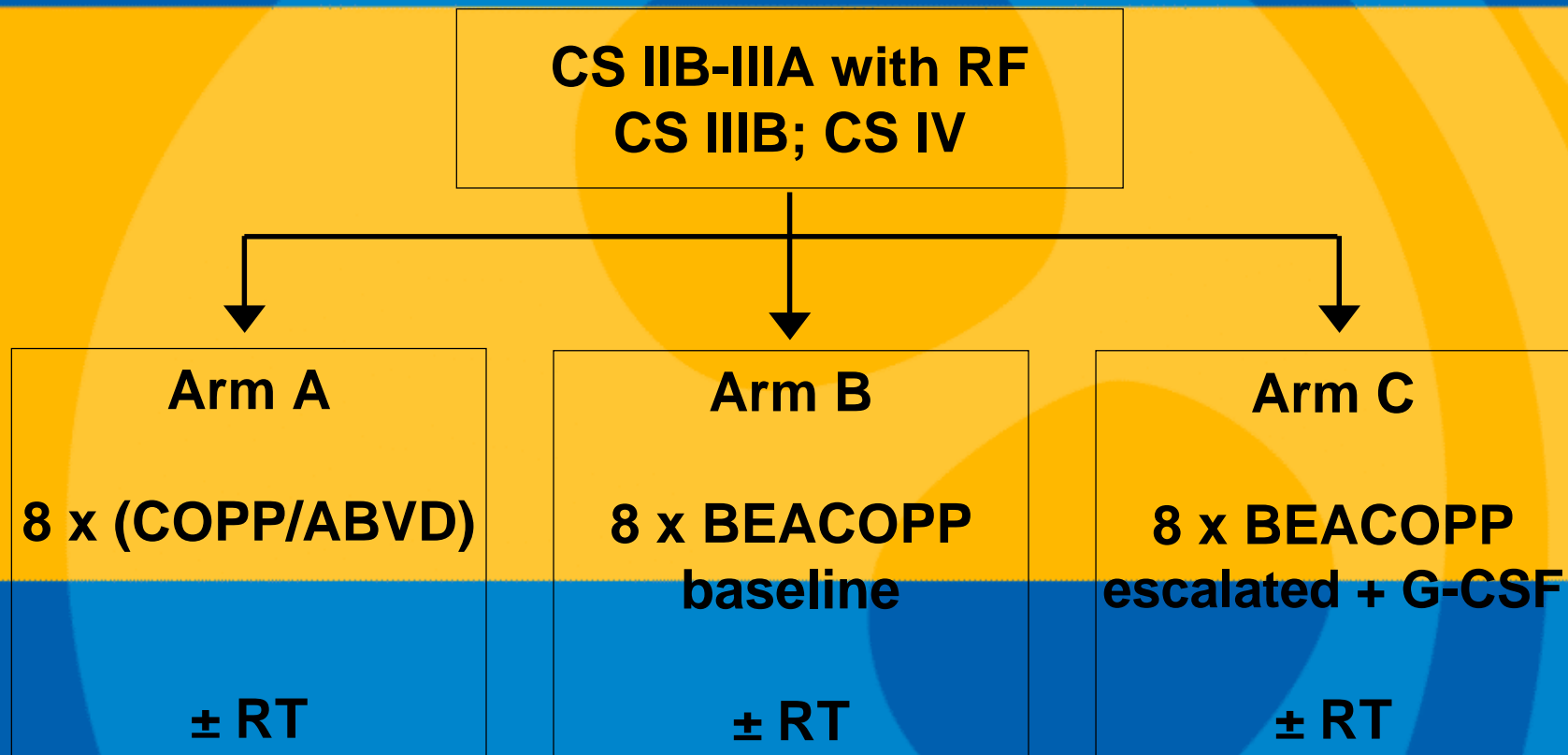
**The GHSg HD18 study
for patients with advanced stage
Hodgkin Lymphoma**

Andreas Engert, MD

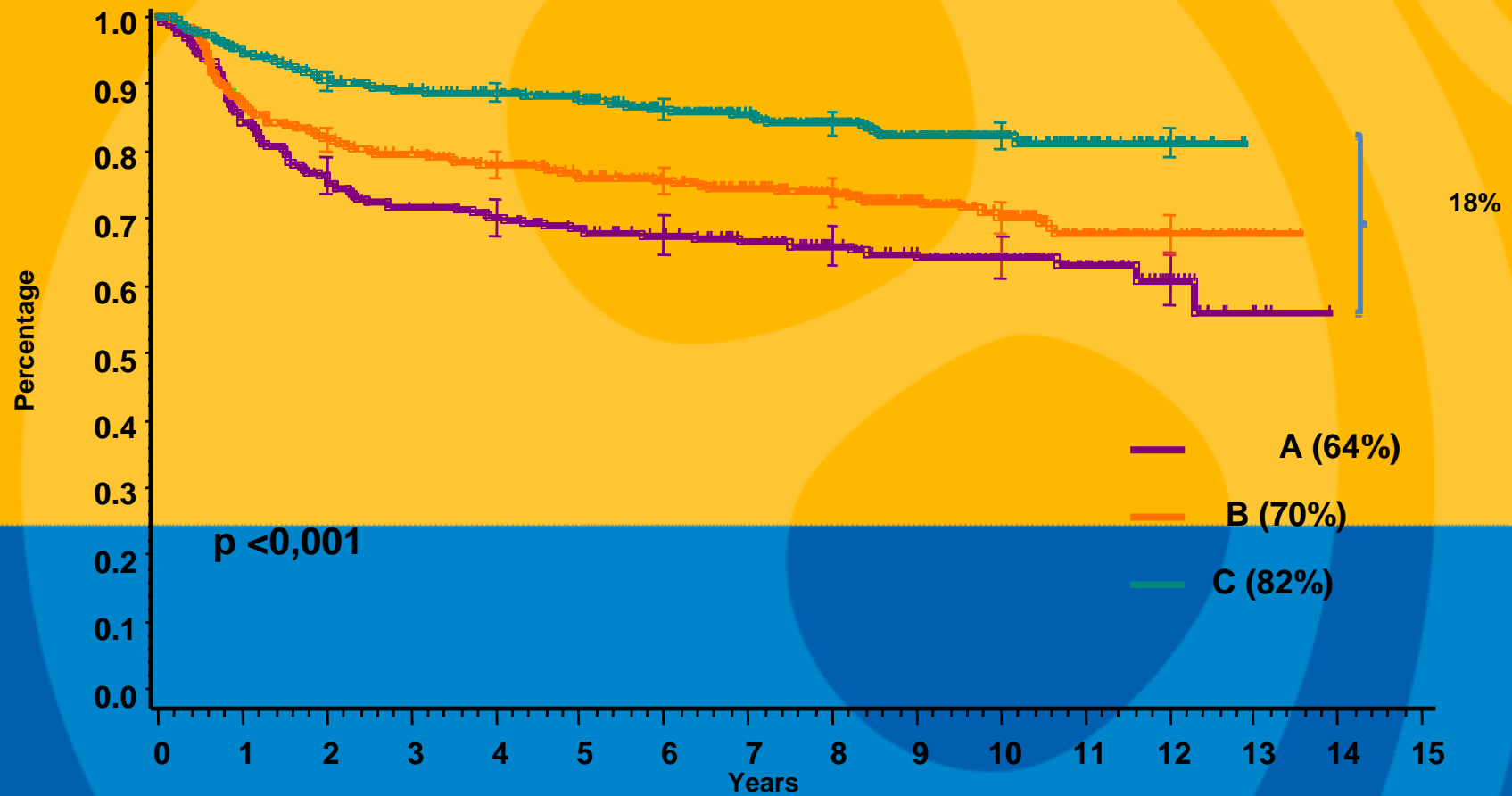
**Chairman, German Hodgkin Study Group
University Hospital of Cologne**

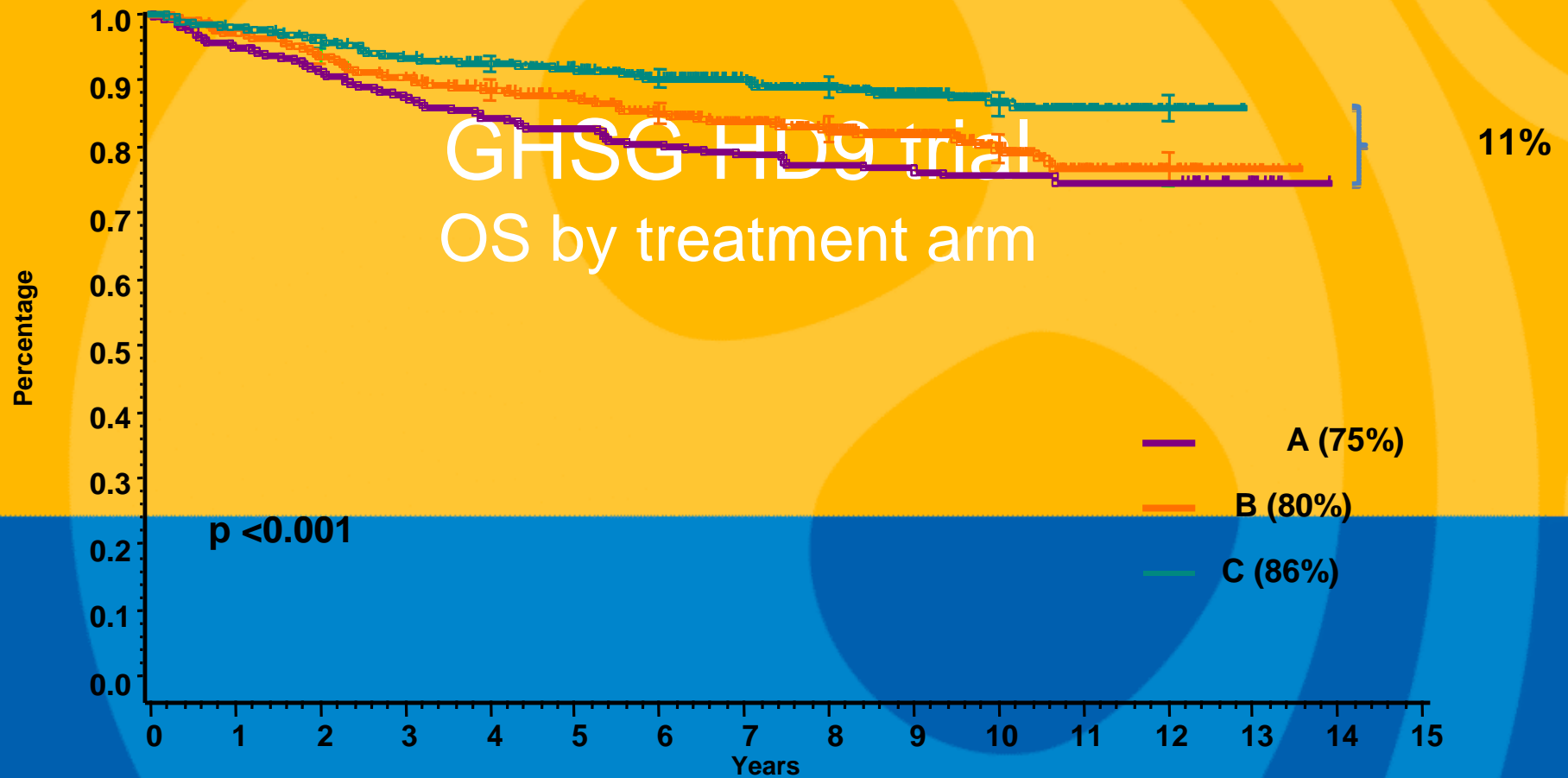
- GHS**G
Risk groups
- **Early favorable stages:** CS I/II without risk factors*
 - **Early unfavorable stages:** CS I/II with risk factors*
 - **Advanced stages:** CS III/IV; selected CS IIB

*a) large mediastinal mass; b) extranodal disease; c) high ERS; d) 3 or more areas



FFTF by treatment arm





Kairos
of ancient Greece

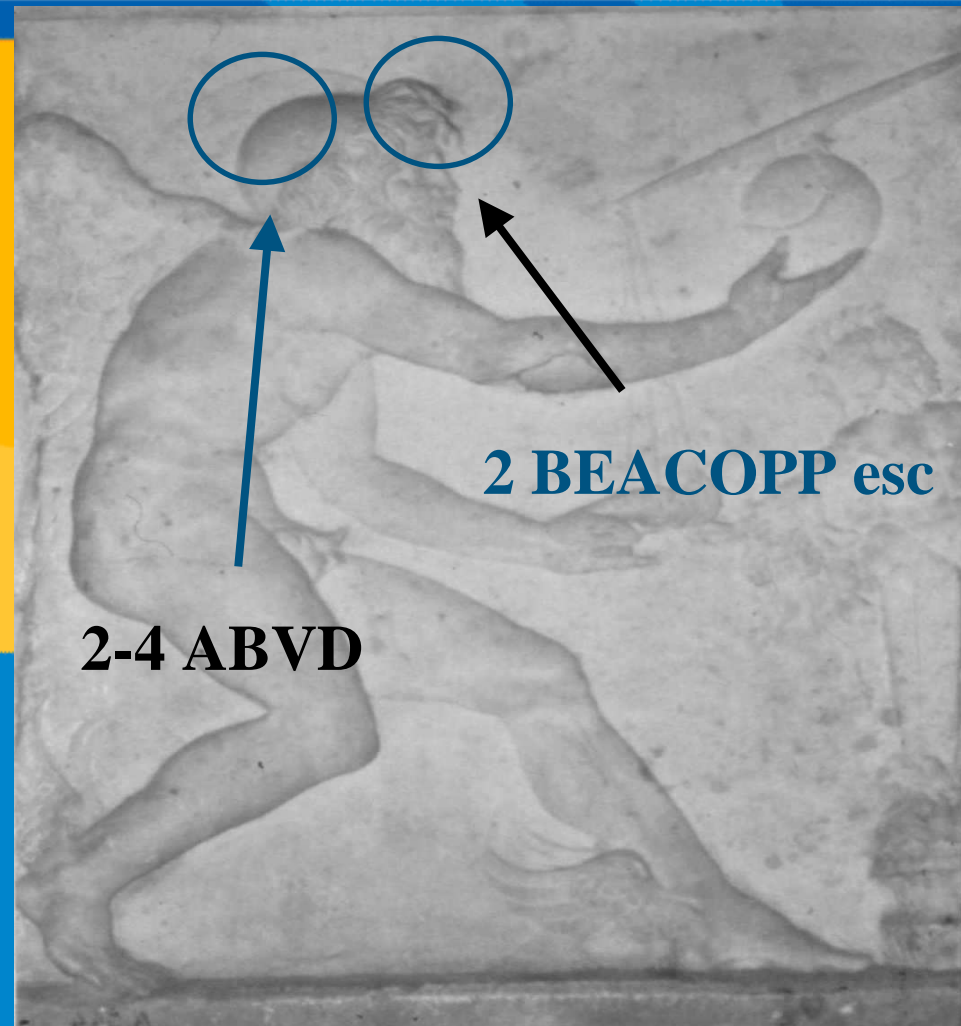
German Hodgkin Study Group
Deutsche Hodgkin Studiengruppe

GHSg
www.ghsg.org



**„Catch the
moment“ ...**

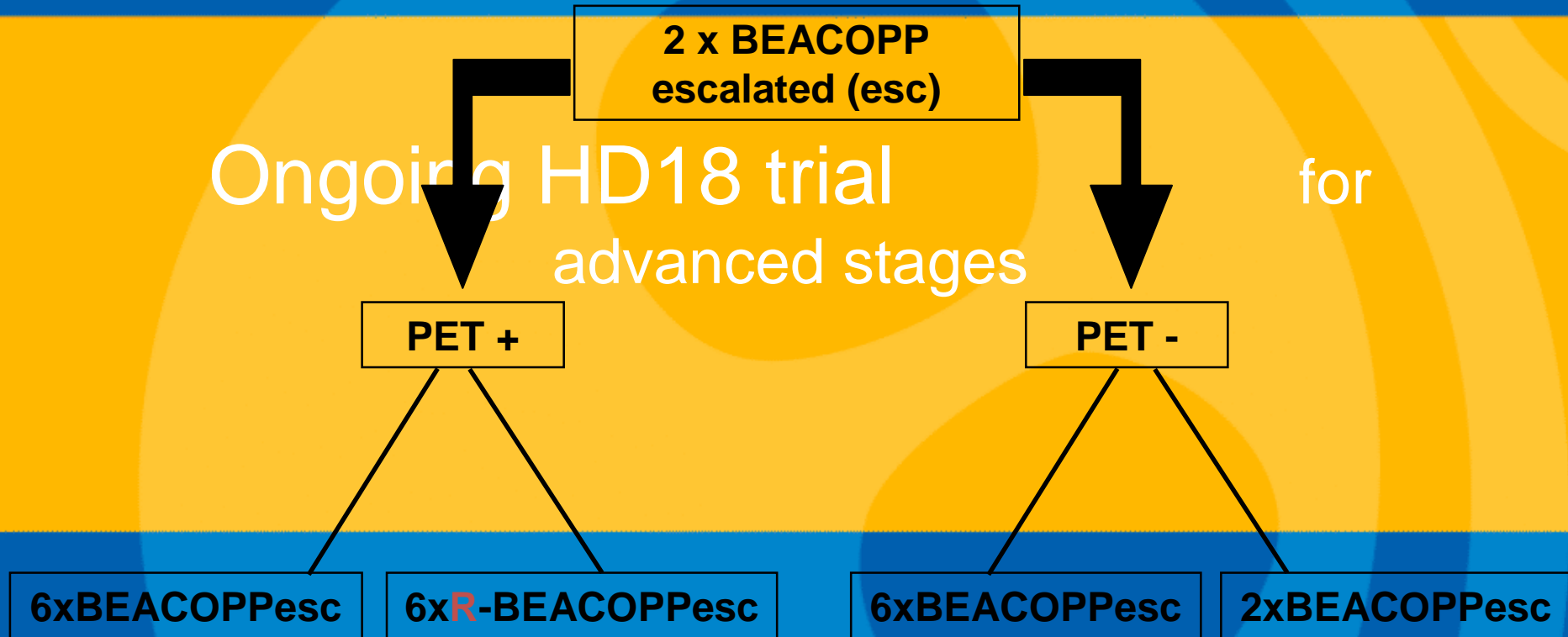
**„Catch it with the first
grip,
otherwise you loose
your chance!“**



2-4 ABVD

2 BEACOPP esc

Ongoing HD18 trial
advanced stages for

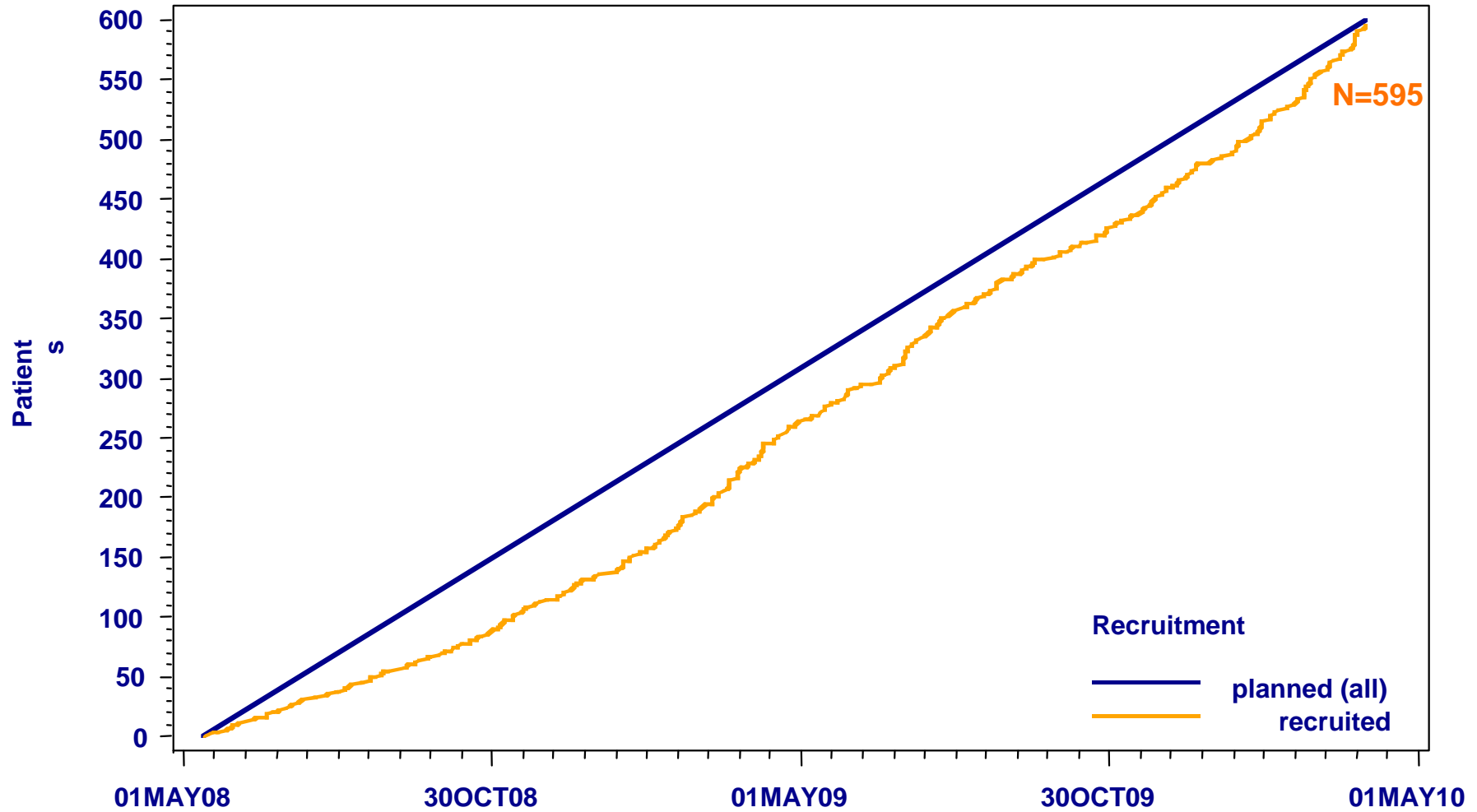


After chemo: PET; RX to PET+ res nodes >2.5 cm
PET-: Follow up

- GHSg HD18 trial
Inclusion Criteria**
- **Previously untreated HL**
 - **Histology: cHL and NLPHL**
 - **Stages III/IV; IIB with bulk or extranodal involvement**
 - **18-60 years**
 - **No composite lymphoma**
 - **No concomittant malignancy or infection**

- **Primary:** - PFS
- **Secondary:** - Acute- and late toxic Endpoints
 - OS
 - QoL
 - Rate of 2nd npl
 - CR rate
 - Rate of HL-specific mortality
 - Prognostic impact of PET2

- GHSg HD18 trial
Statistics**
- Ratio PET+/PET- of 30/70 assumed
 - PET+: $8xB.esc+R > 8xB.esc$ (317 pts needed)
 - PET-: Non-inferiority between 8x and 4xB.esc
1050 pts needed (margin 6%)
 - Adaptive design; 80% power; alpha 5%
 - Planned interim analyses: 3



PET result in 4 categories (3/09)

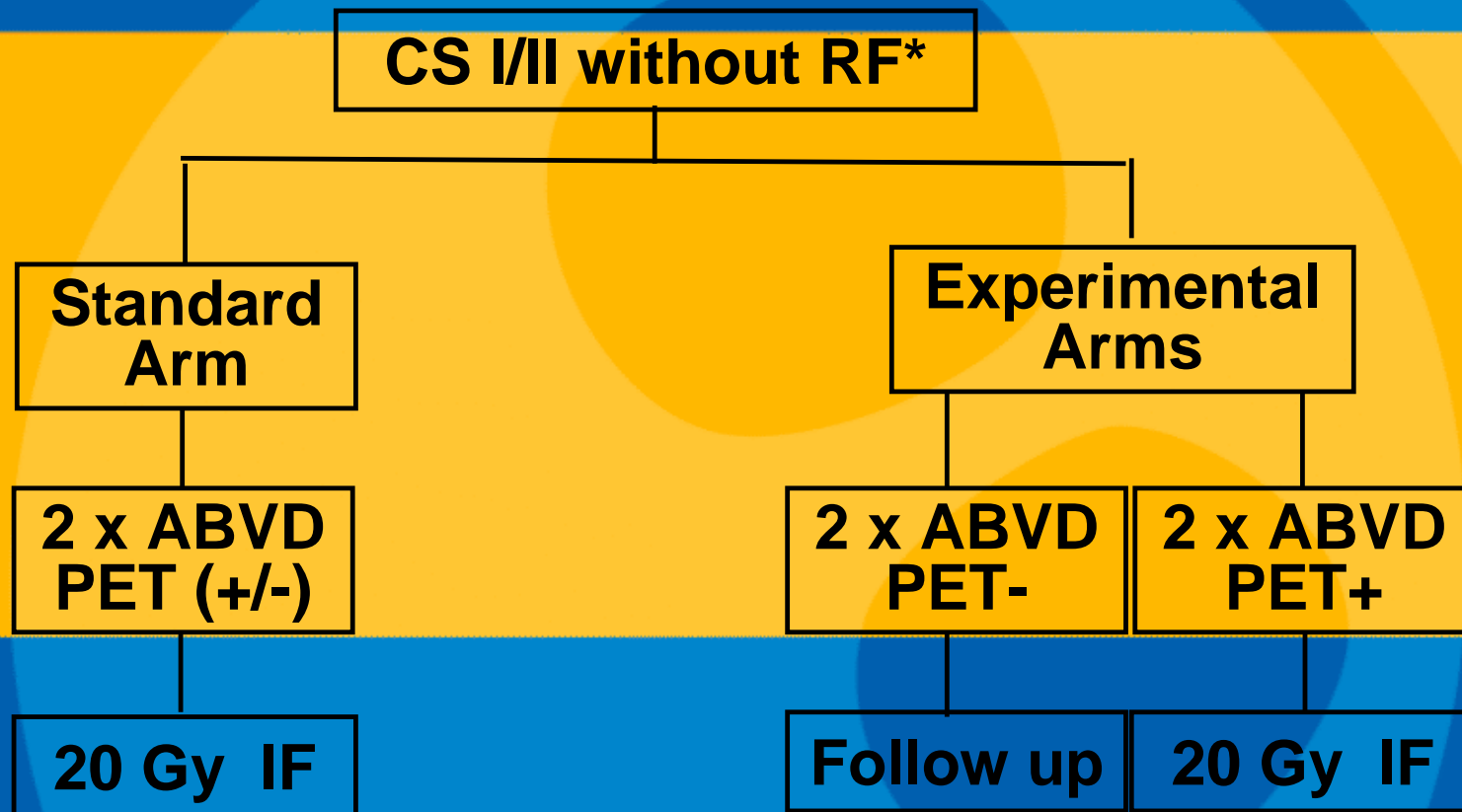
	N	%
	106	100
Score 0: No FDG avid lesions	46	43.4
Score 1: Not more than background activity of mediastinal blood pool	16	15.1
Score 2: More than background activity of the mediastinal blood pool but not more than liver	23	21.7
Score 3: More than background activity of the liver	21	19.8

PET result (9/09)

	Randomized	95% confidence interval
Total	240 100.0%	
Arm C/D (PET neg.)	142 59.2%	53.0% - 65.4%
Arm A/B (PET pos.)	98 40.8%	34.6% - 47.1%

- **The rate of PET-2 positive patients is higher than expected**
- **The statistical section of the study protocol was amended to ensure that the study objectives for both, PET positive and PET negative patients can still be met**

- GHSg HD18 trial
Summary**
- **PET-adapted design for advanced-stage HL**
 - **8xB.esc+R vs 8xB.esc in PET+ pts**
 - **8xB.esc vs 4xB.esc in PET-pts**
 - **Total of 1600 pts to be included**
 - **More PET+ pts due to more conservative approach**
 - **Study recruitment according to plan**



*a) large mediastinal mass; b) extranodal disease; c) high ERS; d) 3 or more areas

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B. v. Treskow

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M. Schumacher

German Hodgkin Study Group
(GHSg)

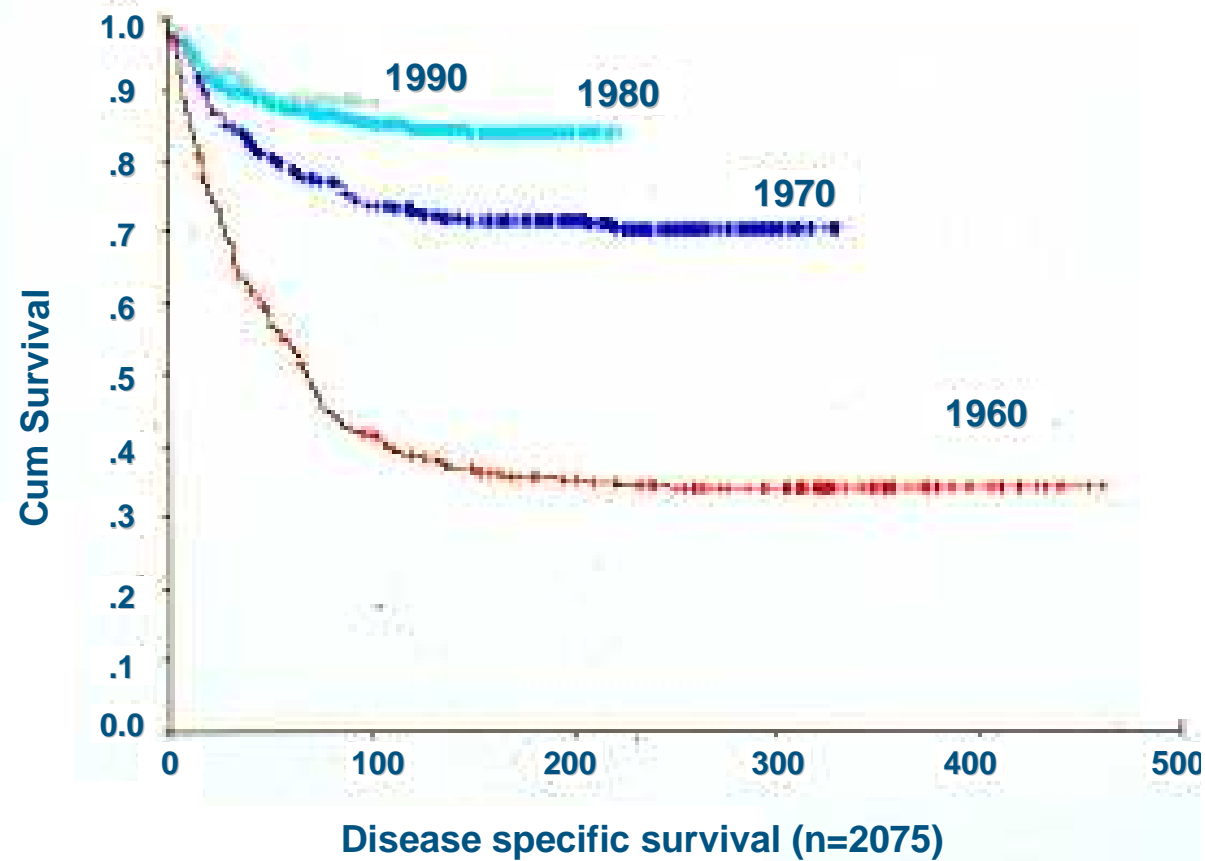


8th International Symposium
**on Hodgkin
Lymphoma**
Cologne, Germany

German Hodgkin Study Group
www.hodgkinsymposium.org

October 23–26, 2010
Gürzenich, Cologne

German Hodgkin Study Group
Deutsche Hodgkin Studiengruppe
by decades (Vancouver)





Recruitment into phase III (1st line)

1978 - 88	HD 1 - 3	506
1988 - 94	HD 4 - 6	2035
1994 - 98	HD 7 - 9	2865
1998 - 02	HD10-12	3948
2003 - 08	HD13-15	5171
2008 -	HD16-18	625
Total		15150