



**Professor Serke, Professor Huhn
Priv.-Doz. Martin, Professor Hoelzer
Dr. Goldschmidt, Professor Haas
HD1 1995**

**Dr. Cremer, Prof. Ho
„Triple MMM“ 2000**

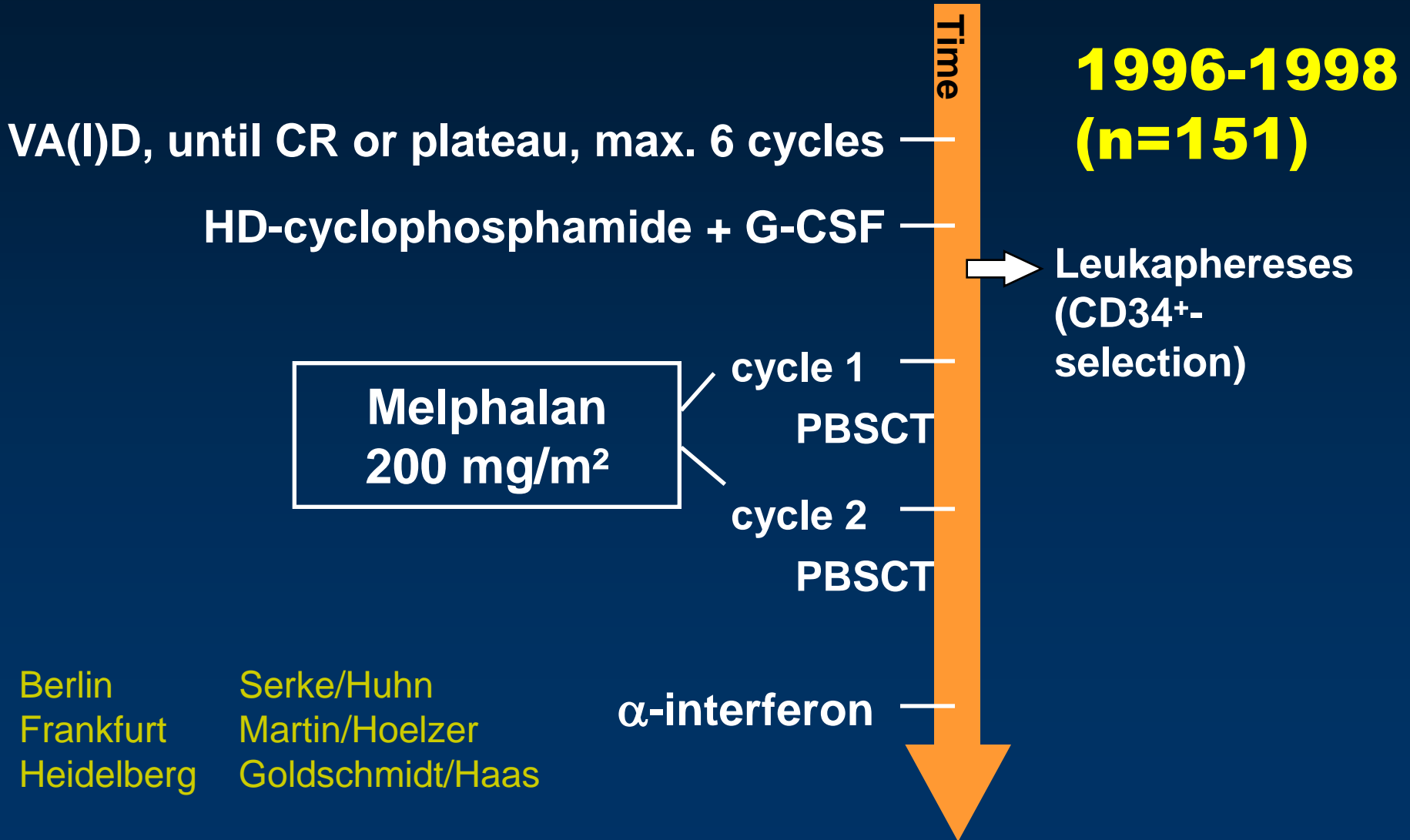


Front-Line Trials of the GMMG

- **HD1** Trial: Tandem-Transplantation 1996 – 1998 (Phase II, n=151)
- **HD2** Trial: Single- versus Double-Transplantation (Phase III, n=480) 1998 – 2001
- **HD3** Trial: Tandem-Transplantation (Germany) plus/minus Thalidomide (Phase III, GMMG n=550, HOVON n=500) 2001 – 2004
- **HO65/HD4** Trial: VAD vs. PAD, Transplantation, maintenance Thalidomide vs. Bortezomib (Phase III, GMMG n=399, HOVON=434) 2005-2008
- **MM5** Trial: VCD vs. Pad, Standard-intensification, consolidation / maintenance Lenalidomid, maintenance 2a vs. until CR (Phase III, n=504, start II/2010)



HD-1: Treatment Plan



Randomisation VID vs.
VAD

HD2 Therapy Plan

1998-2001
(n=485)

Leukaphereses
CD34⁺-selection optional

until CR or plateau, max. 6 cycles

HD-cyclophosphamide
(ifosfamide) + G-CSF

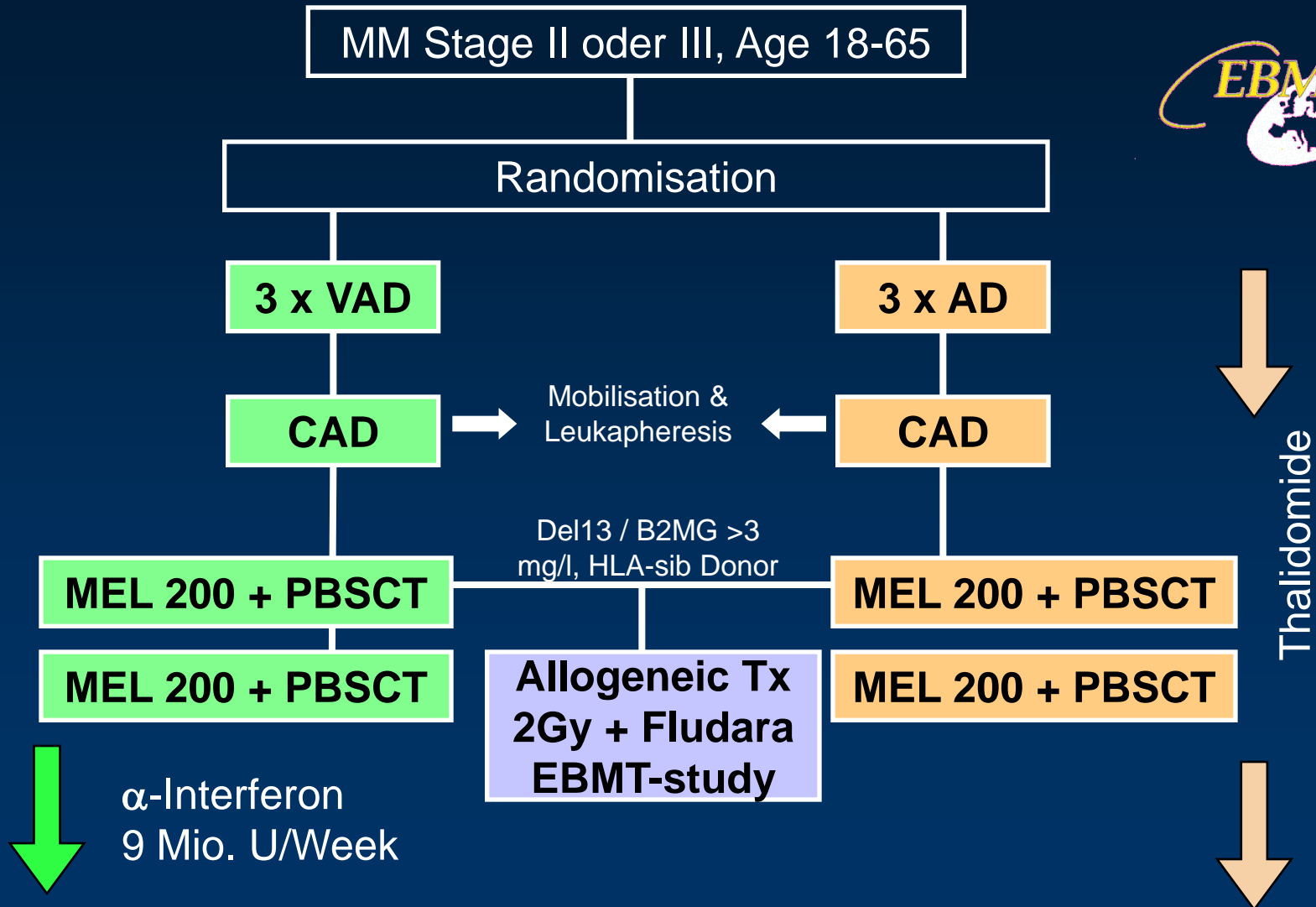
Randomisation

Melphalan
200 mg/m²
+ PBSCT

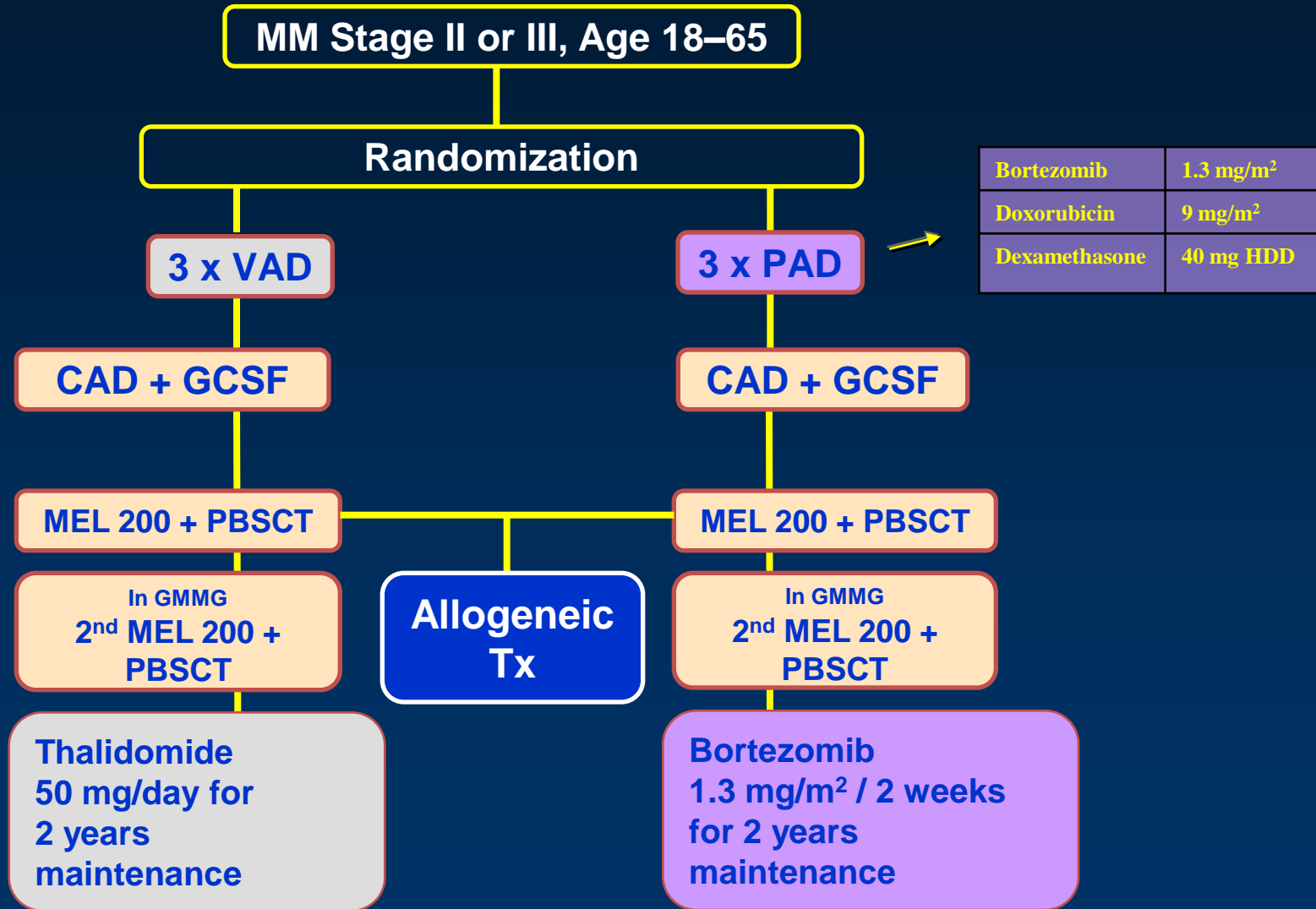
cycle 1
cycle 2
interferon- α

One cycle
interferon- α

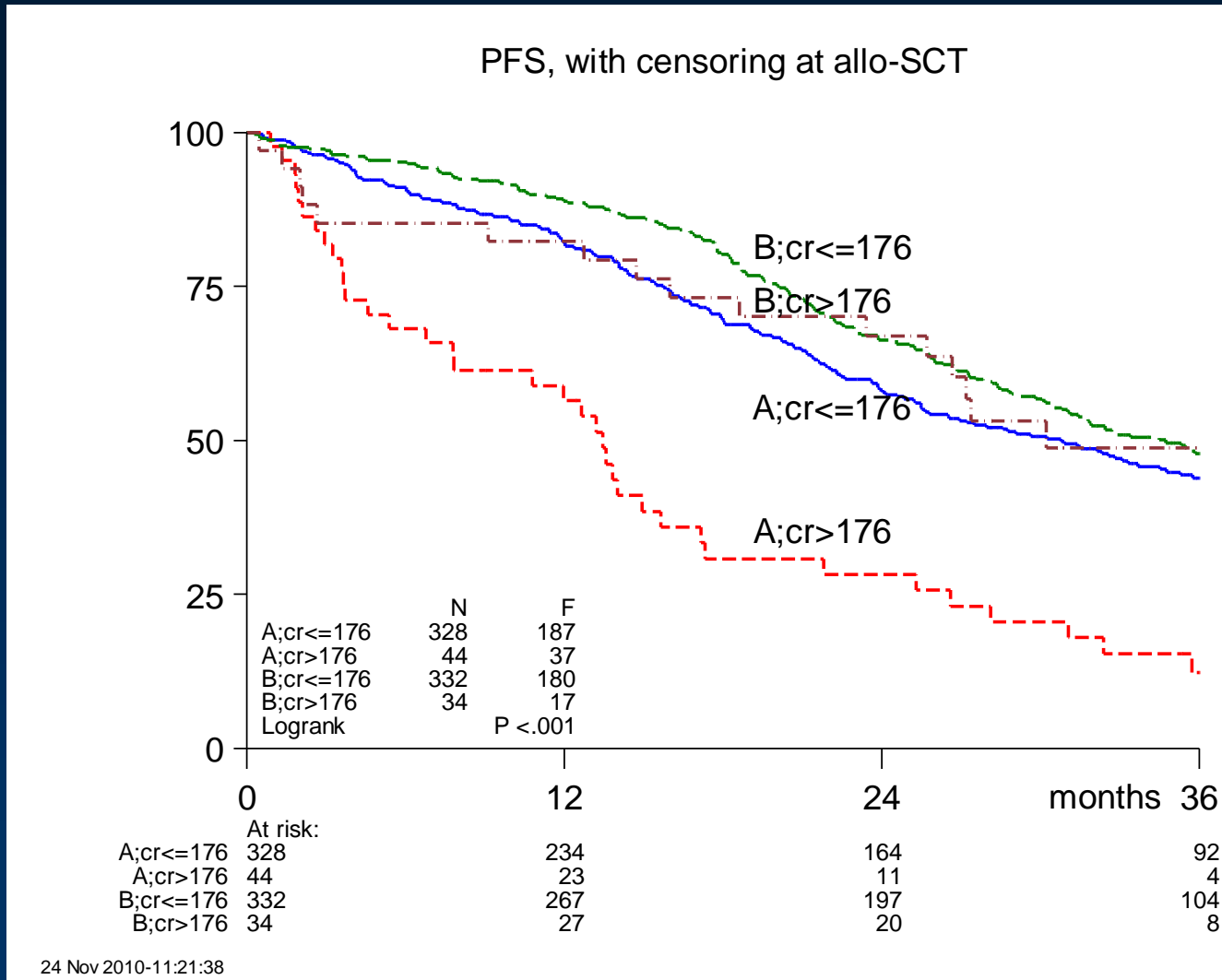
HD3/HOVON50-Studie 2001-2004



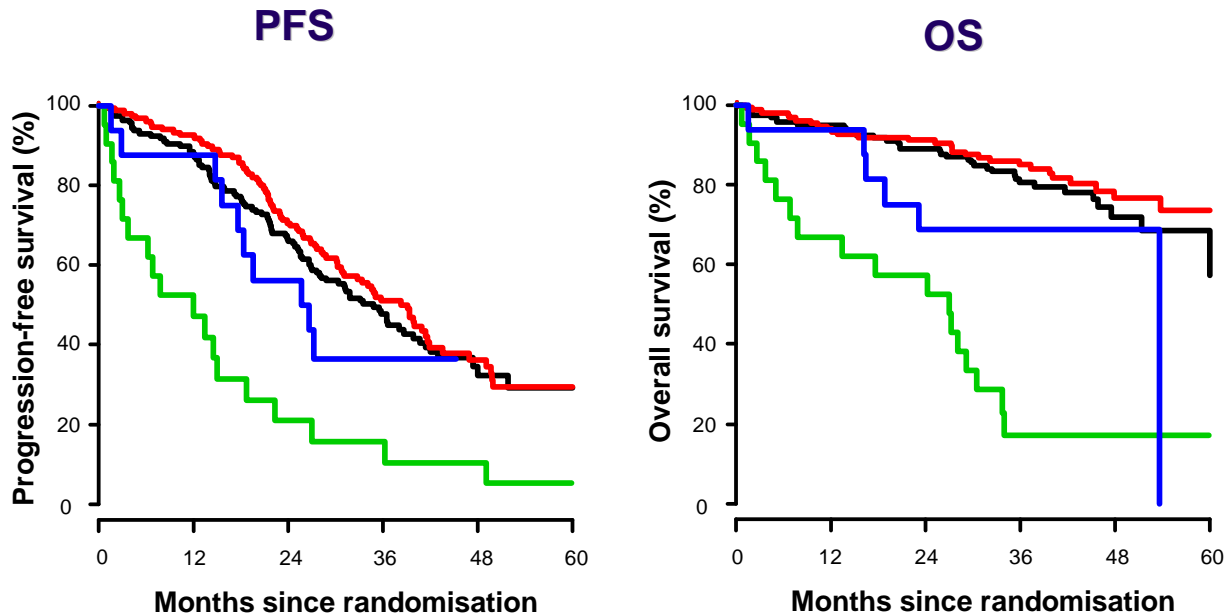
HOVON 65 MM / GMMG-HD4 Trial



HO65/HD4: Impact of kidney function



Comparison between both study arms HD4 Deletion 17p13



— del (17p), arm A (without Bortezomib) — del (17p), arm B (with Bortezomib)
— no del (17p), arm A (without Bortezomib) — no del (17p), arm B (with Bortezomib)

PAD (Vel/Dex) zur Erstlinienbehandlung von Patienten mit multiplen Myelom

„Standard für die Induktionstherapie war bislang VAD, so dass der Ersatz der ohnehin nicht sehr wirksamen Substanz Vincristin durch Bortezomib entsprechend dem GMMG/HOVON-Protokoll als neuer Standard für die Induktionstherapie anzusehen ist. Dies entspricht auch der Bewertung der deutschen Studien-gruppe GMMG.“

MDK Gutachten Prof. Heyll, August 2009



**MDK
Nordrhein**

Medizinischer Dienst der Krankenversicherung Nordrhein
Geschäftsführung: W. Machnik, PD Dr. med. H.P. Buszello

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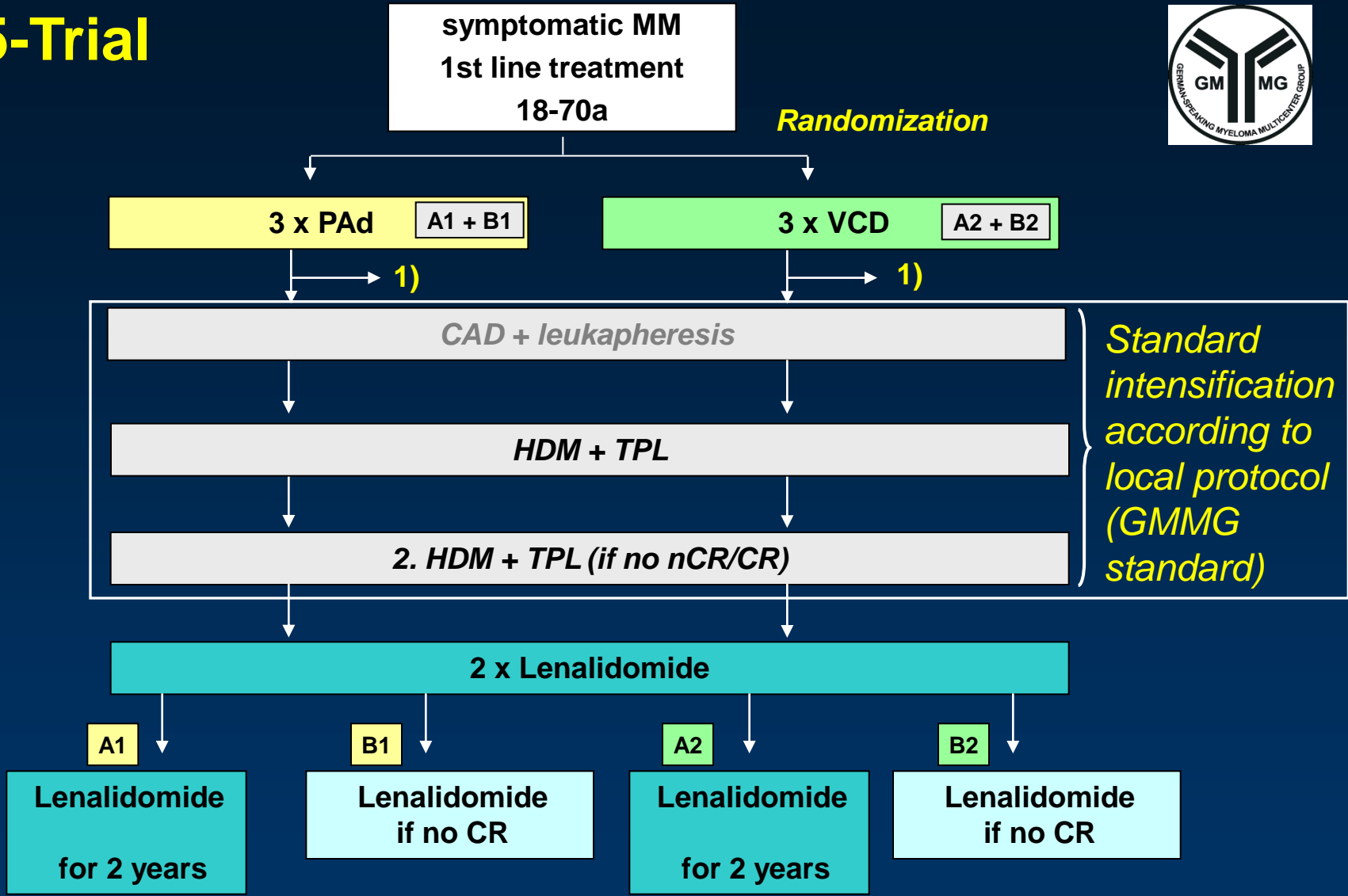
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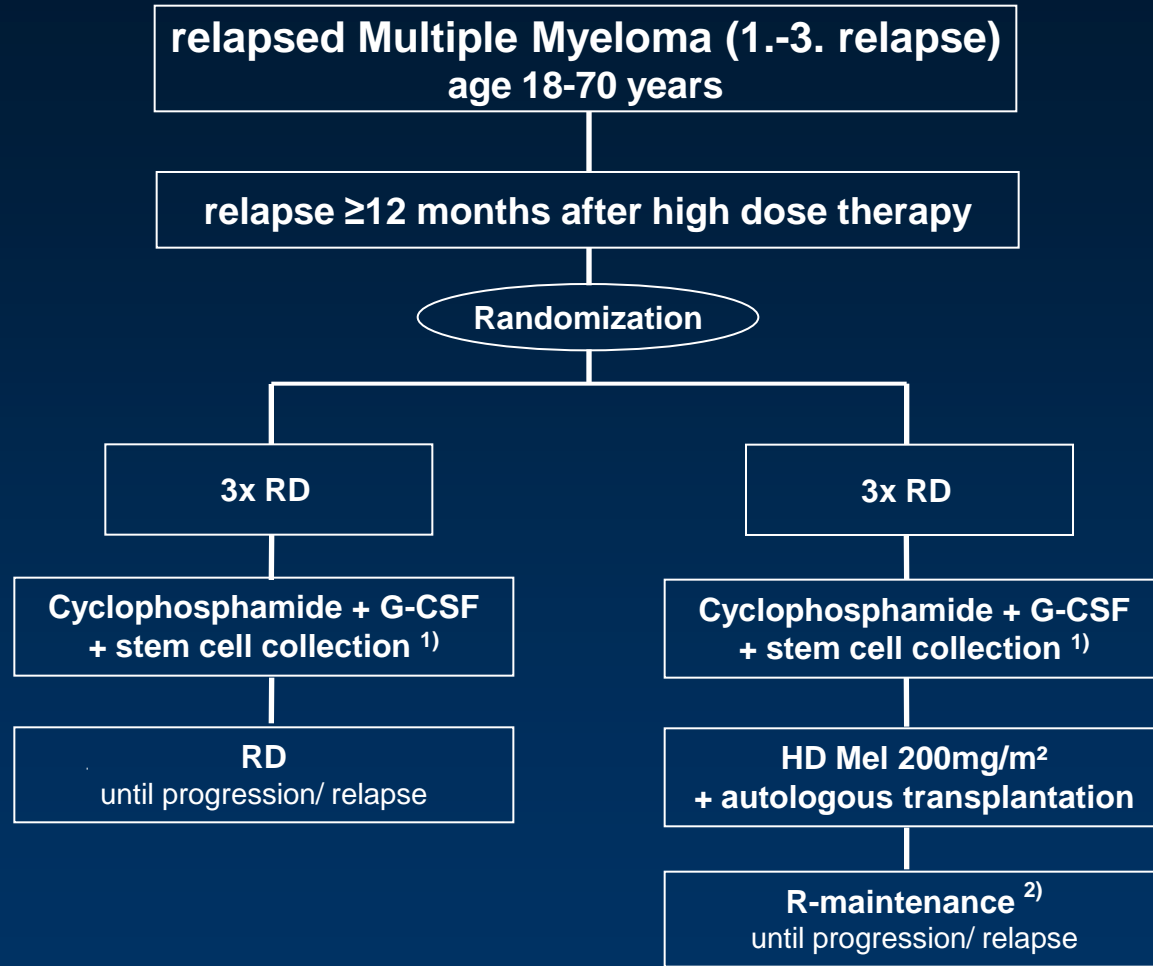
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MM5-Trial



1) High Risk Patients, optional in Phase II trial

GMMG-ReLapsE study



- 1) stem cell collection only if no useable stem cells are available from earlier mobilization
- 2) Lenalidomide (Revlimid®) maintenance therapy 10mg/day
R-Lenalidomide (Revlimid®), D-Dexamethasone, HD Mel-high dose Melphalan

GMMG-HD2, -HD3, -HD4 – Beteiligte Kliniken und Praxen

