Clinical trials with recruitment

Clinical trials with recruitment

Dg.		Title	Arms
MM	R/R	Panorama 3	*Panobinostat, Bortezomib, Dexamethasone*
		AGMT – EMN-13	*Ixazomib, Thalidomid, Dexamethasone*
		PCYC-1138	*Ibrutinib, Pomalidomid, Dexamethasone*
		PCYC-1139	*Ibrutinib, Velcade, Dexamethasone*
		EMN11/HO114	*Carfilzomib, Pomalidomide, Dexamethasone*
		CA209-602	*Nivolumab, Elotuzumab, Pomalidomide, Dexamethasone*
	MT	C16021	*MLN9708 vs. placebo*

Multiple myeloma

New diagnosis

C16021 - UT

Relapsed

PCYC-1138-CA

CLBH589D2222 (Panorama3)

PCYC-1139-CA

AGMT_MM-1/EMN-13

CA209-602

EMN11/HO114 only for patients of EMN02 study

C16021

A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of Oral Ixazomib Maintenance Therapy After Initial Therapy in Patients With Newly Diagnosed Multiple Myeloma Not Treated With Stem Cell Transplantation.

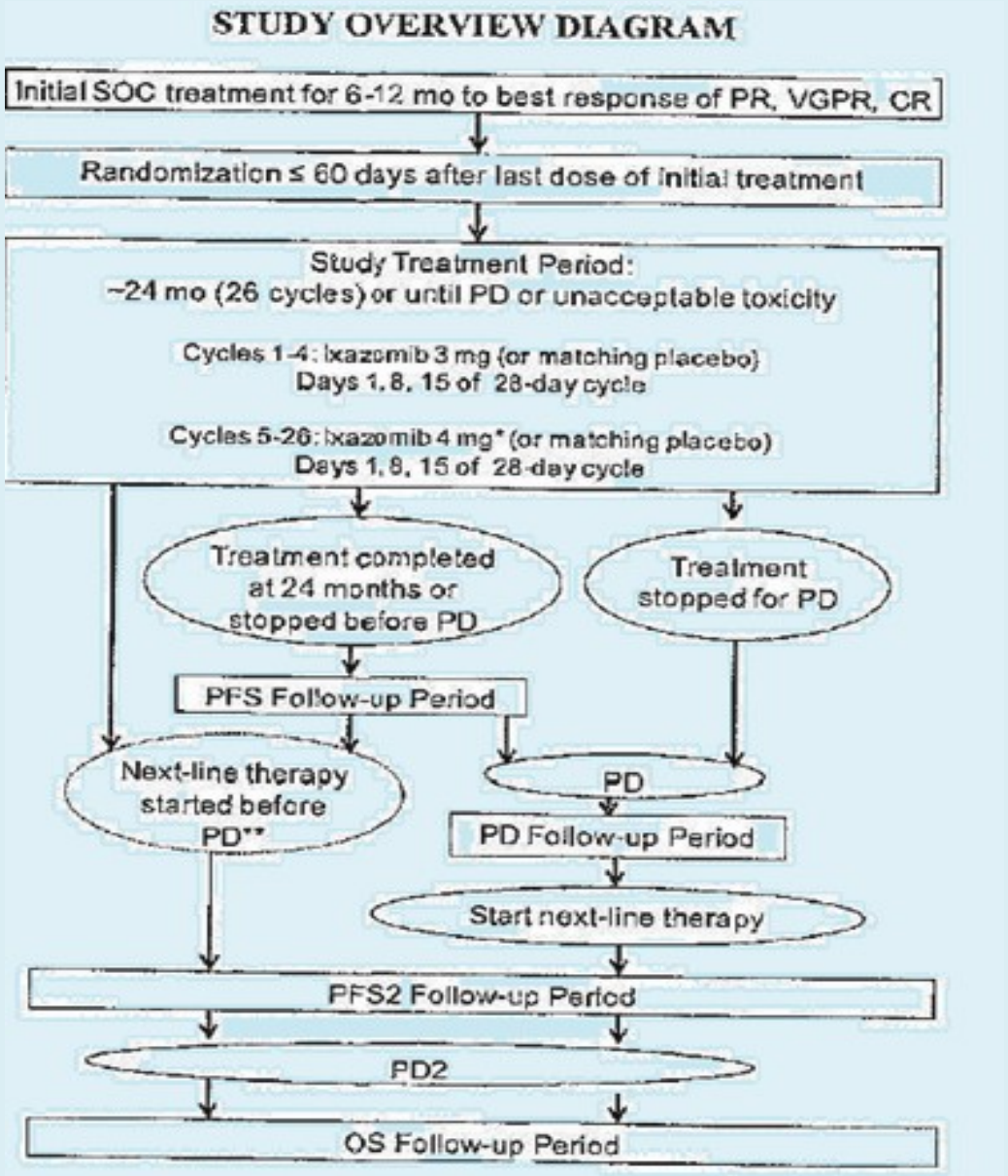
Main inclusion criteria

- completed 6 to 12 months of initial therapy with documented major response PR, VGPR, CR (maintained for 2 cycles after the M-protein nadir is reached)
- not eligible for ASCT
- ECOG 0-2

Main exclusion criteria

- relapsed/not responsive MM to initial therapy
- prior stem-cell transplantation
- radiotherapy within 14 days before randomization
- Diagnosis of Waldenstrom's macroglobulinemia, POEMS

Study design



PCYC-1138-CA

A Randomized Multicenter Study of Ibrutinib in Combination with Pomalidomide and Dexamethasone in Subjects with Relapsed/Refractory Multiple Myeloma.

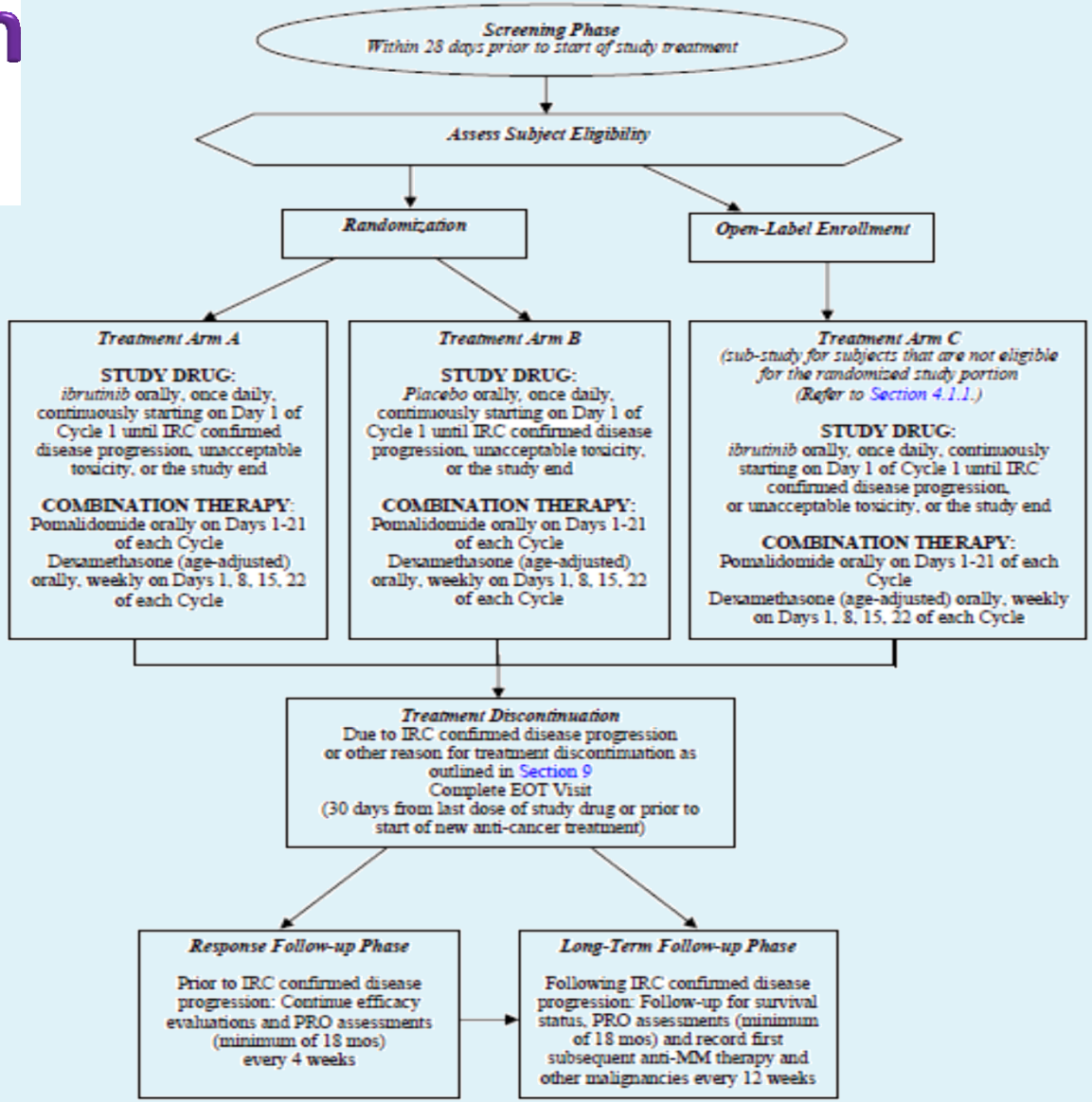
Main inclusion criteria

- relabující MM
- refrakterní MM
- nejméně 2 předchozí linie léčby MM včetně LEN a buď léčba s Bortezomibem nebo CFZ
- PD na léčbě nebo do 60 dní od ukončení léčby
- ECOG max. 2

Main exclusion criteria

- primárně refrakterní onemocnění
- předchozí léčba Pomalidomidem (výjma ramene C), BTK inhibitory
- syndrom POEM
- periferní neuropatie 2 a vyšší grade
- signifikantní GIT onemocnění

Study Design of study 2b



CLBH589D2222 (Panorama3)

A multicenter, randomized, open-label Phase 2 study evaluating the safety and efficacy of three different regimens of oral panobinostat in combination with subcutaneous bortezomib and oral dexamethasone in patients with relapsed or relapsed/refractory multiple myeloma who have been previously exposed to immunomodulatory agents.

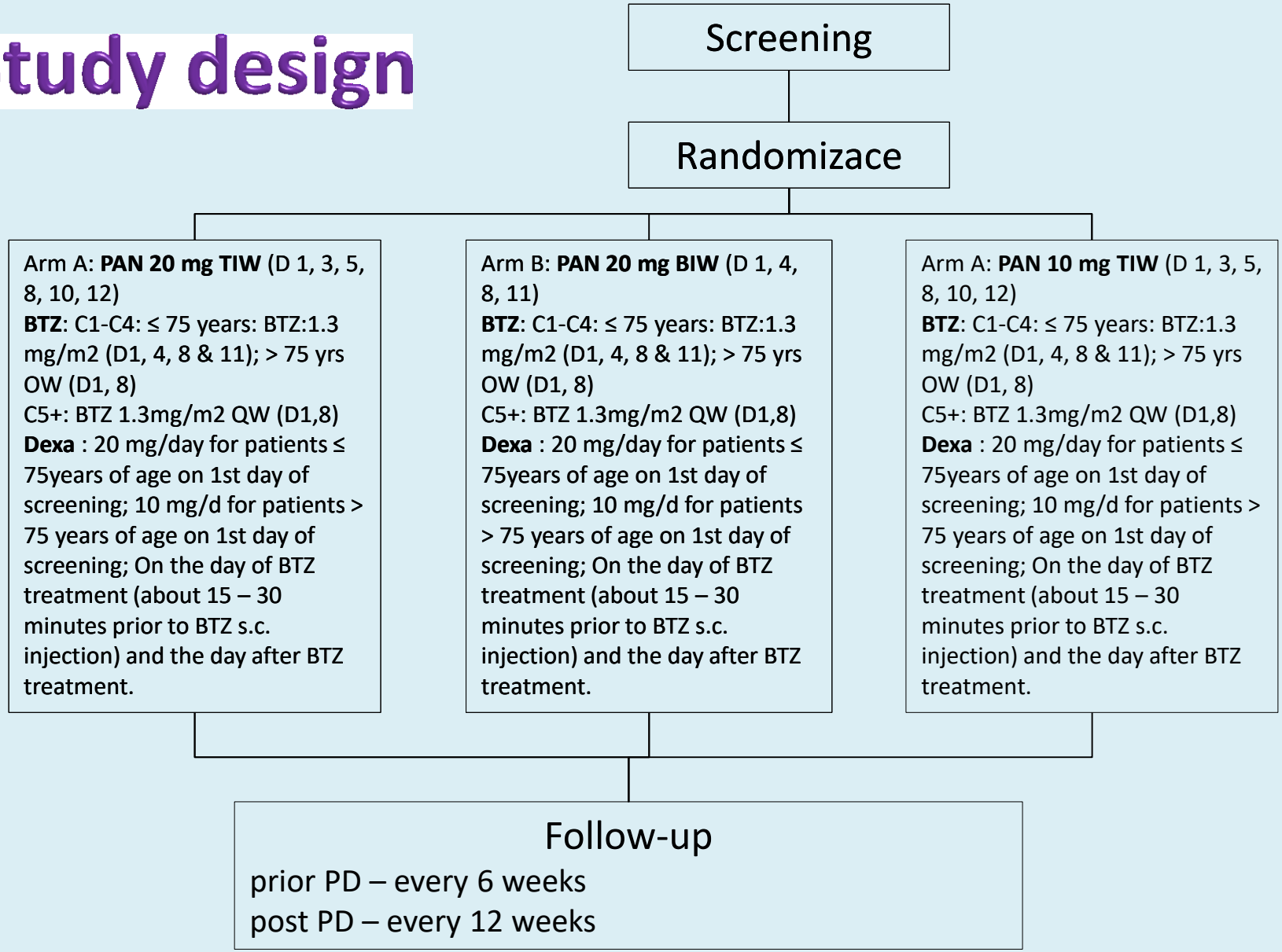
Main inclusion criteria

- relapsed or relapsed and refractory mM
- 1-3 prior lines of therapy
- measurable disease
- ECOG 0-2
- prior IMiD exposure
- laboratory values within normal range

Main exclusion criteria

- primary refractory MM
- refractory to bortezomib
- prior treatment with DAC inhibitors including Panobinostat
- diarhea grade 2 and higher
- gastrointestinal dysfunction

Study design



PCYC-1139-CA

An Open-label study of Ibrutinib in Combination with Bortezomib and Dexamethasone in Subjects with Relapsed or Relapsed and Refractory Multiple Myeloma.

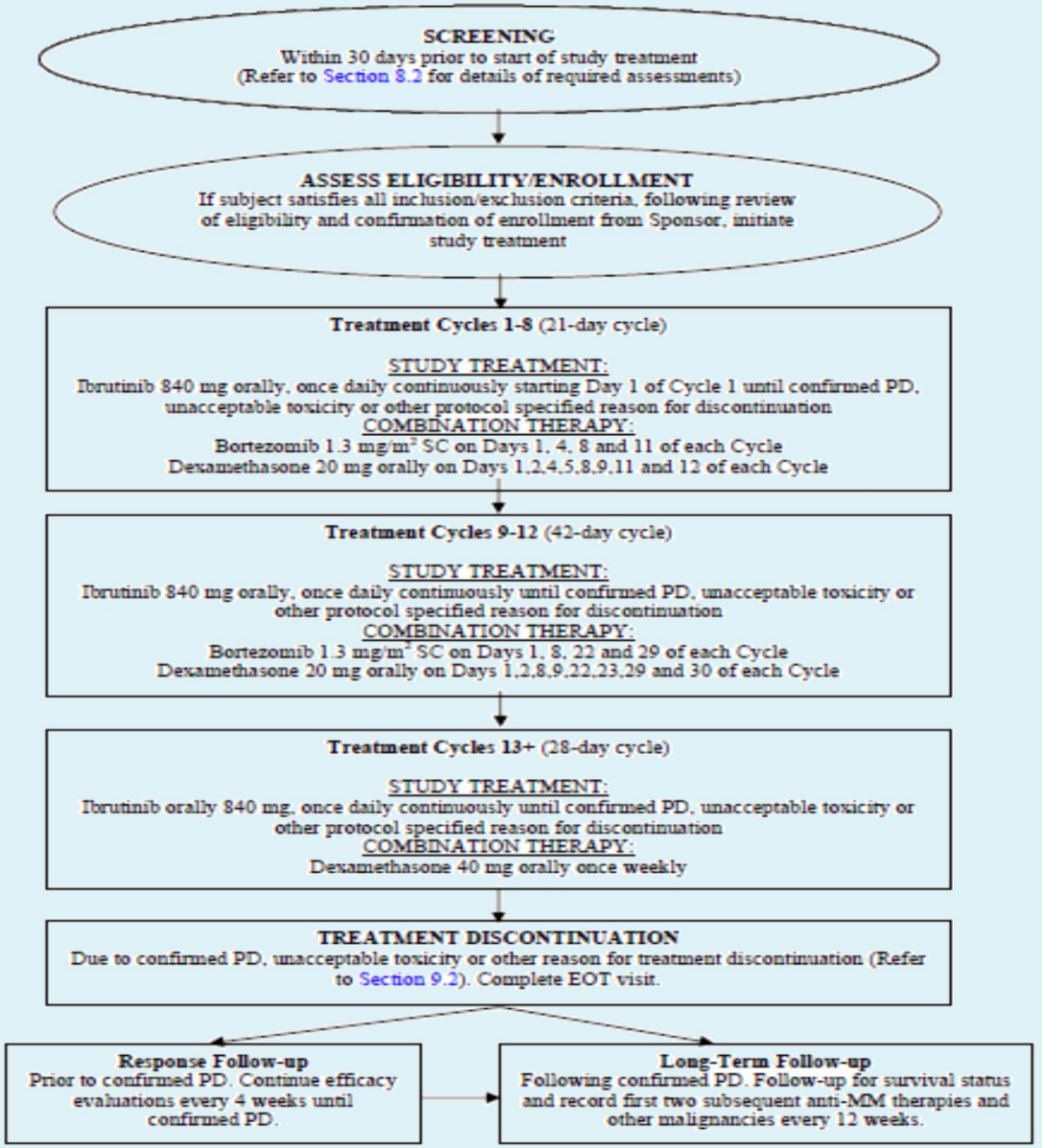
Main inclusion criteria

- relapsed MM or relapsed and refraktory MM
- prior bortezomib exposure
- received 1-3 prior lines of therapy with demonstrated PD since completion of the most recent treatment regiment
- SPEP more than 1 g/dL IgG, others more than 0.5 g/dL
- ECOG max. 2

Main exclusion criteria

- primary refraktory disease
- prior exposure to BTK inhibitors
- syndrom POEM
- prior allogeneic cell transplant
- peripheralneuropathy grade 2 or higher

Study Design



AGMT_MM-1/EMN-13

Ixazomib in Combination with Thalidomide – Dexamethasone in patients with relapsed and/or refractory multiple myeloma.

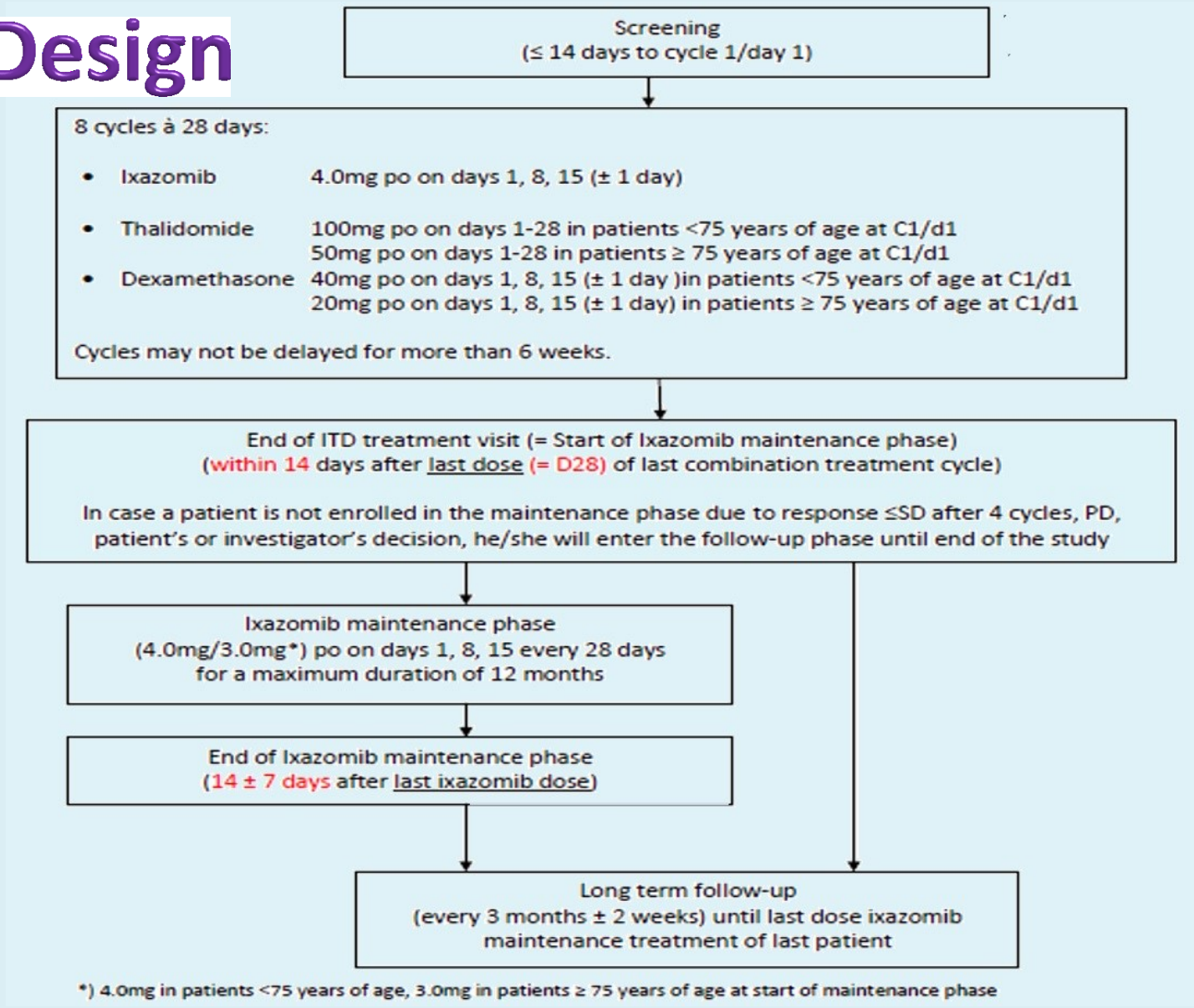
Main inclusion criteria

- relapsed or refractory MM
- at least 1 prior line of therapy
- measurable disease
- GFR nad 15 ml/min (MDRD)
- ECOG max. 2

Main exclusion criteria

- previous treatment with bortezomib nebo thalidomide within the last 3 months prior to baseline visit
- primary refractory MM
- prior treatment with Ixazomib
- neuropathy 3 and higher

Study Design



CA209-602

An Open-Label, Randomized Phase 3 Trial of Combinations of Nivolumab, Elotuzumab, Pomalidomide and Dexamethasone in Relapsed and Refractory Multiple Myeloma.

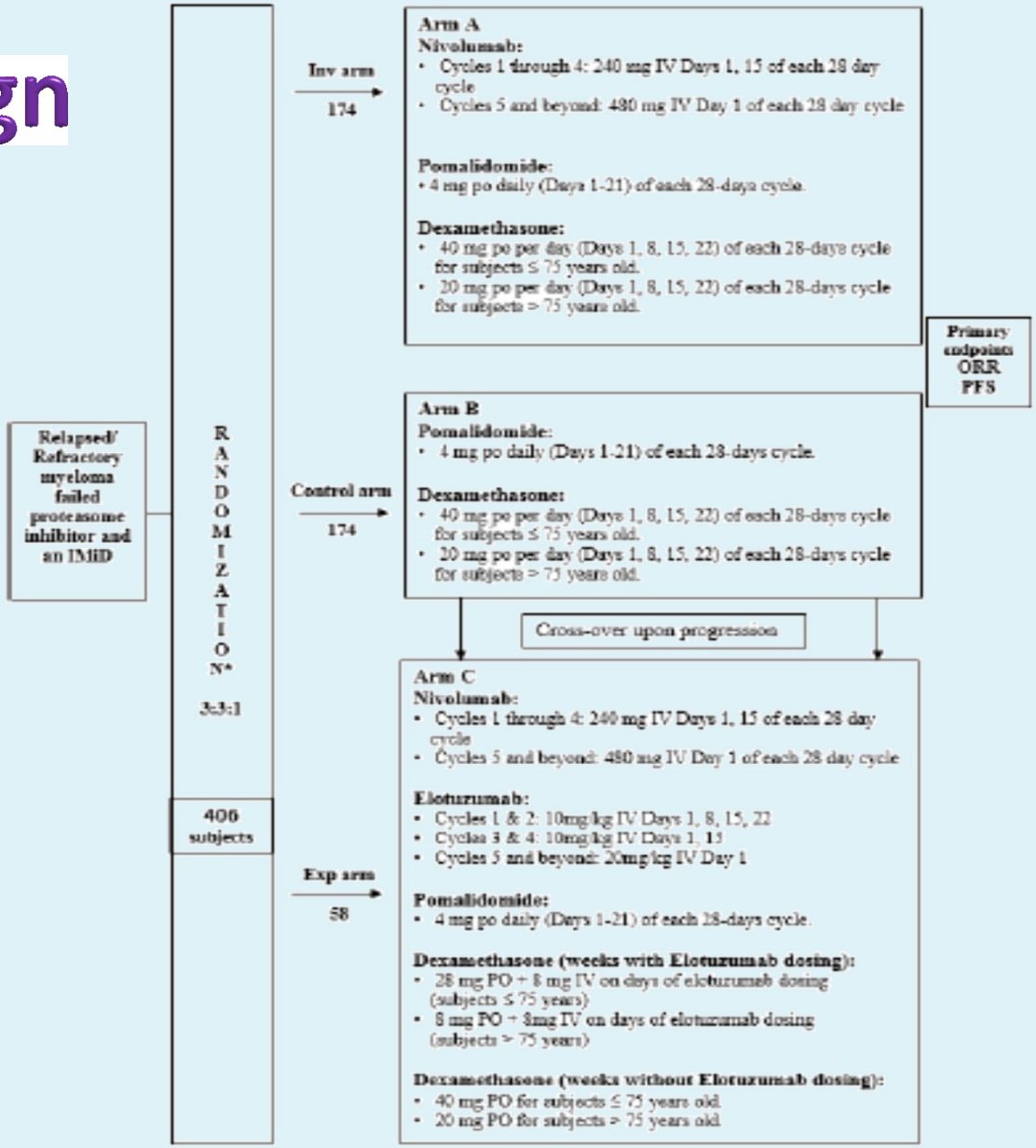
Main inclusion criteria

- „double refractory“ = refractory to PI and IMID or „relapsed nad refractory“ = previous treatment with PI or IMID, or both, but Pdwithin 6 months, and refractory to theri last treatment
- measurable disease
- 2 or more prior lines with IMID and PI

Main exclusion criteria

- solitary bone or extramedullary plasmocytoma as the only evidence of plasma cell dyscrasia
- syndrome POEM
- prior exposure nivolumab, pomalidomide, elotuzumab
- NYHA III, IV

Study Design



EMN011/HO114

Pomalidomide combined with Carfilzomib and Dexamethasone (PCd) for induction and consolidation followed by Pomalidomide combined with Dexamethason vs Pomalidomide maintenance for patients with Multiple Myeloma in progression after prior 1st line treatment with Lenalidomide and Bortezomib.

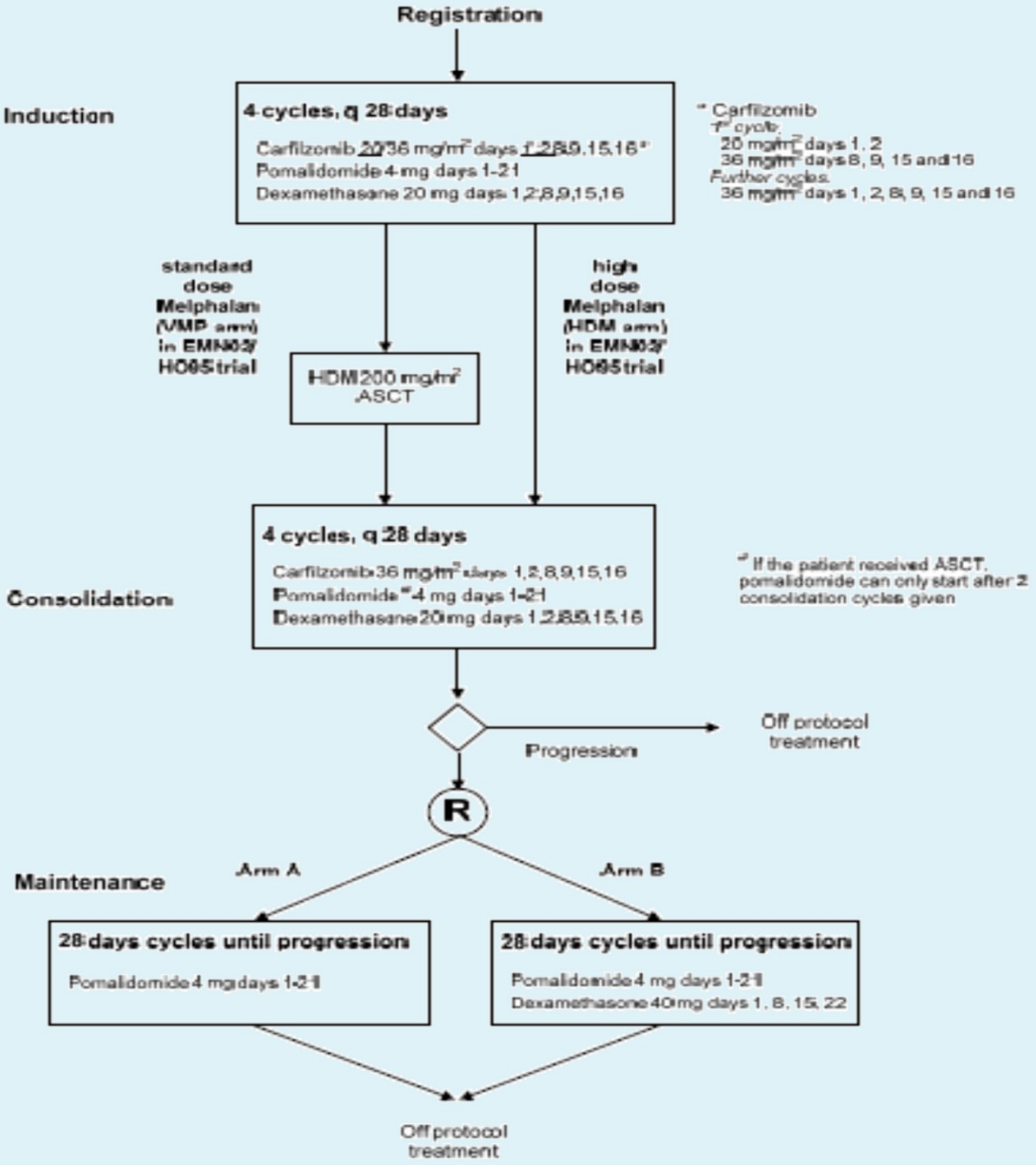
Main inclusion criteria

- included in EMN02 trial
- measurable disease
- documented PD or refractory MM as per IMWG criteria
- WHO 0, 1, 2

Main exclusion criteria

- recieved more than 1 line of therapy, except local radiotherapy
- syndrome POEM
- previous therapy with pomalidomide or carfilzomib
- LVEF no higher than 40 %
- NYHA III or IV

Study Design



Thank you.