

Panel: Lessons Learned from Conducting Clinical Trials in Pediatric Hypertension

Moderator: Jennifer S. Li MD MHS

Beverly C. Morgan Endowed Professor of Pediatrics

Professor of Medicine

Duke University School of Medicine

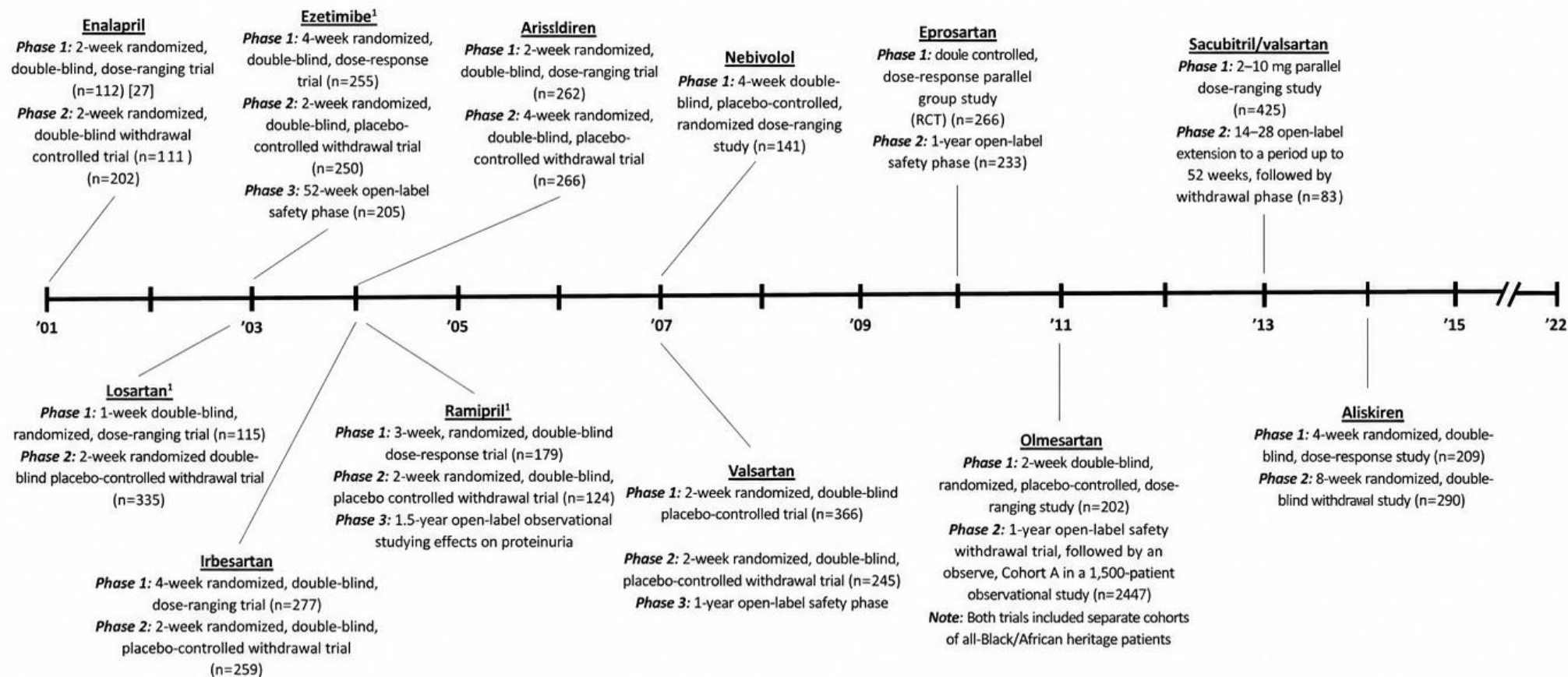


Fig. 1 Summary of drug trials that have resulted in a new labeled indication for treatment of hypertension in children and/or adolescents in the United States

Fig. 2 Antihypertensive trial designs specified in the FDA Written Request criteria

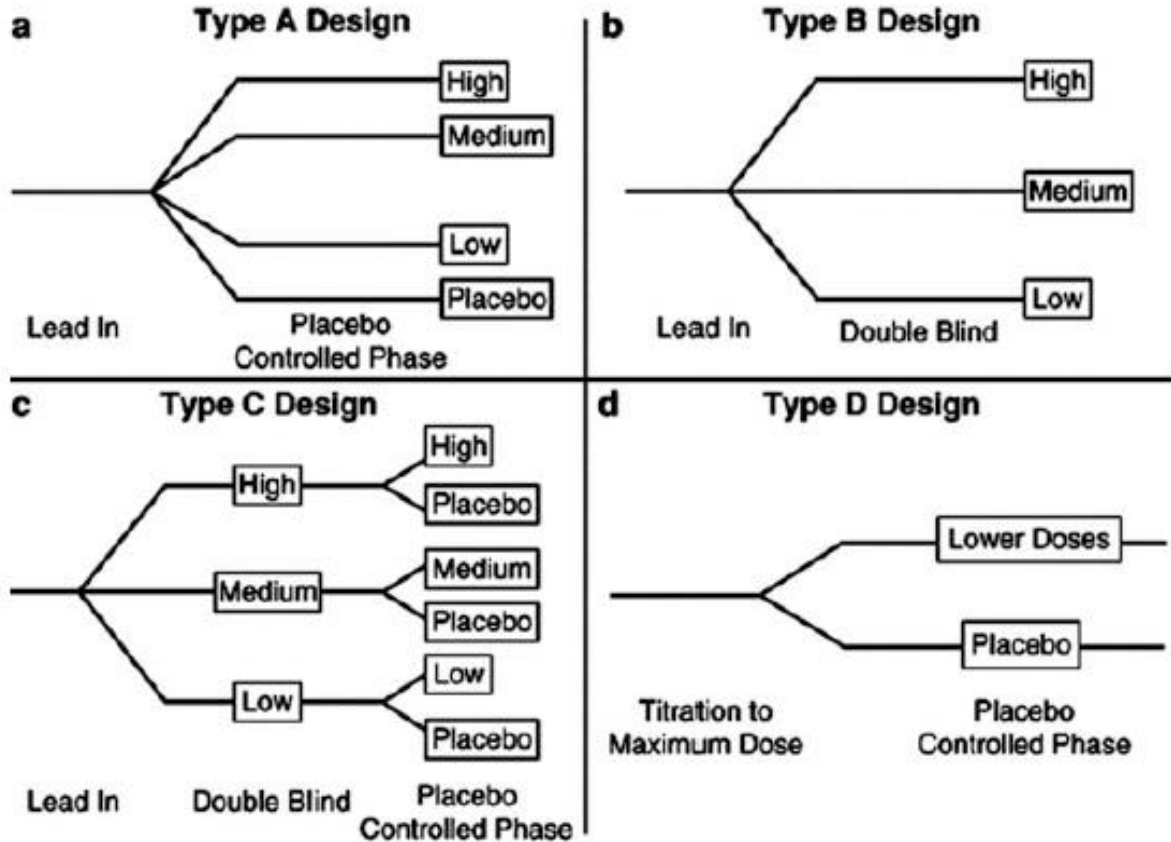


Table 1 Antihypertensive drugs studied under and FDA-issued Written Request

Drug	Trial design	Sample size	Dose response	Label change
Aliskiren	C	267	Yes	Yes
Amlodipine	C	268	No	Yes
Benazepril	D	107	No	Yes
Bisoprolol	A	94	Yes	No
Candesartan	A	240	Yes age 1–5 No age 6–17	Yes
Enalapril	C	110	Yes	Yes
Eplerenone	C	304	No	Yes (negative)
Felodipine	D	133	No	No
Fosinopril	C	253	No	Yes
Irbesartan	C	318	No	Yes (negative)
Lisinopril	C	115	Yes	Yes
Losartan	C	175	Yes	Yes
Metoprolol	A	140	No	Yes
Quinapril	A	112	No	No
Ramipril	D	219	No	No
Valsartan	C	351	No age 1–5 Yes age 6–16	Yes
Olmesartan	C	302	Yes	Yes
Sodium nitroprusside	D	63	Yes	Yes