O-1

A Systematic Survey of Two Decades of Clinical Trials in Neuroendocrine Neoplasms (NENs)

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BACKGROUND: NENs have historically been grouped homogenously in clinical trials, despite their heterogeneity. Given the adoption of an advanced pathologic classification system, dissemination of trial design recommendations from the 2011 National Cancer Institute (NCI) Neuroendocrine Tumor (NET) Clinical Trials Planning Meeting and approval of several targeted therapies over the last decade, in this analysis, we sought to assess whether there had been changes in study design, eligibility, accrual and outcomes between NEN trials which began enrollment between 2000-2009 or between 2010-2020.

METHODS: We conducted a systematic survey of completed therapeutic phase II, III NEN trials published (including abstracts) between January 1, 2000- December 31, 2020. Trials were identified through a database search of Medline, EMBASE, Web of Science, Cochrane Database of Systematic Reviews, ClinicalTrials.gov, EU Clinical Trials Register and NCI Clinical Trials. Frequencies and relative frequencies were used to describe the categorical variables; proportions between the two enrollment periods were compared using Pearson chi-squared tests.

RESULTS: Of 3243 identified studies, 119 met criteria for inclusion. Eligibility differences between the two enrollment periods are described in Table 1. With regards to design differences, trials which began enrollment after 2010

increasingly utilized progression-free survival (35% vs 18%, P = .04) and decreasingly utilized objective response rate (30% vs 53%, P = .01) as a primary endpoint compared to trials which began enrollment before. Other study characteristic differences between the enrollment periods will be detailed at the meeting.

CONCLUSION: NEN trials enrolling over the last decade have become more focused on select tumor populations. Despite this trend, 21% of studies still included all NENs. Studying novel agents in specific disease populations may further drug development in the field.

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Table 1

	Category	2000-2009 N(%)	2010-2020 N(%)	P-value
	NEN Types Specified in Inclusion Criteria			
	All NENs	34(63%)	13(21%)	<.001
	Gastrointestinal NETs	11(20%)	25(40%)	.02
	Pancreatic NETs	16(30%)	32(51%)	.02
	Neuroendocrine Carcinomas	1(2%)	11(17%)	.006
	Tumor Features Specified in Inclusion Criteria			
	Tumor Differentiation	34(63%)	59(98%)	<.001
	Ki-67 Index	5(9%)	23(38%)	<.001