

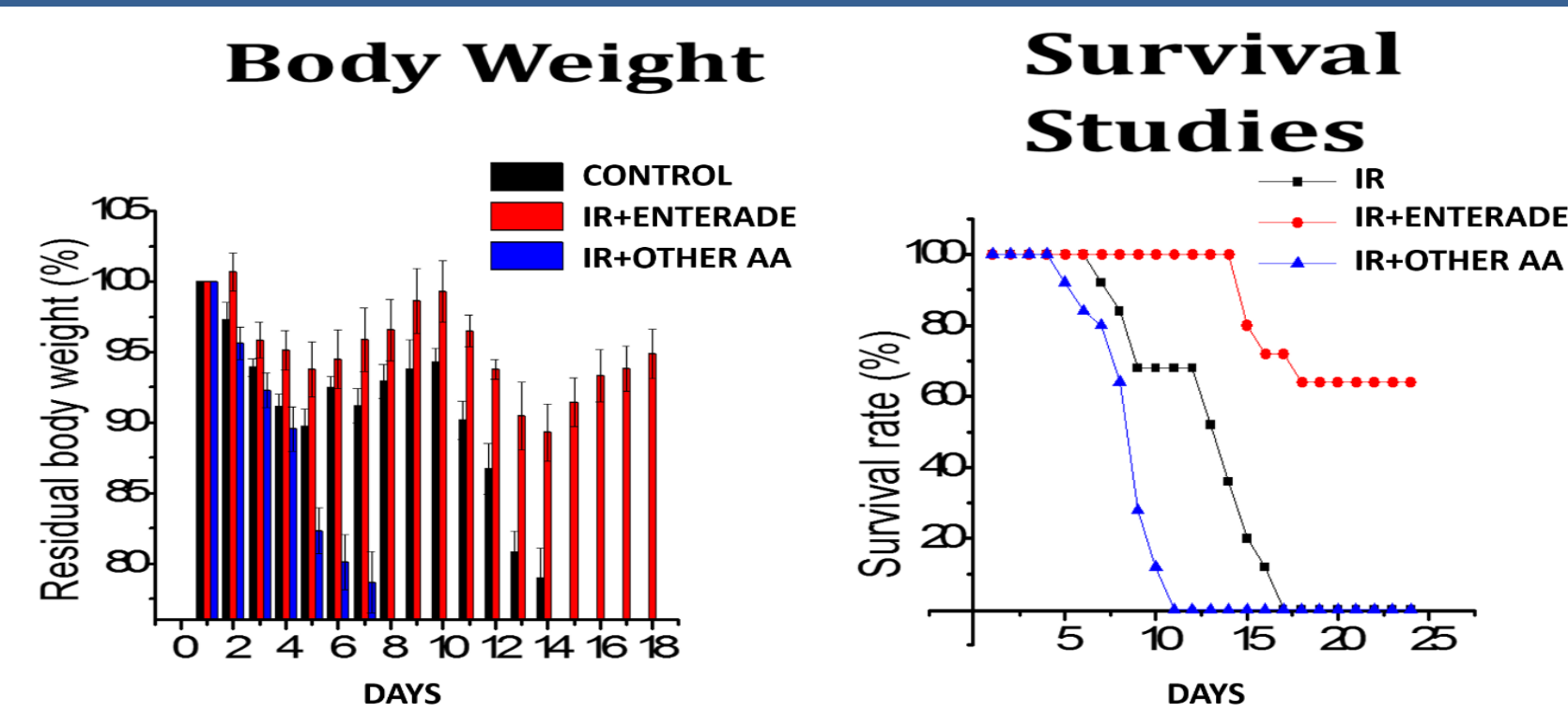
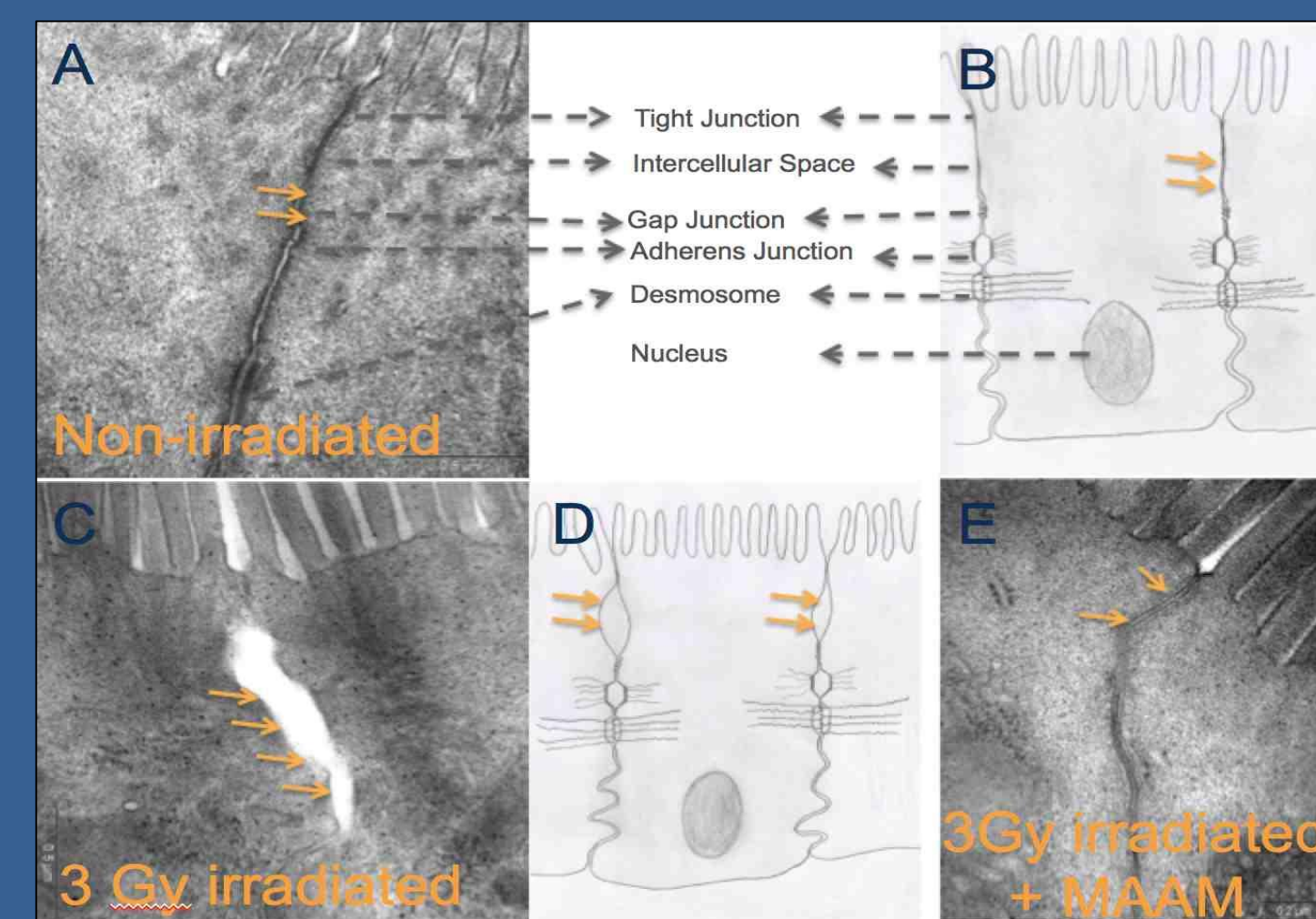
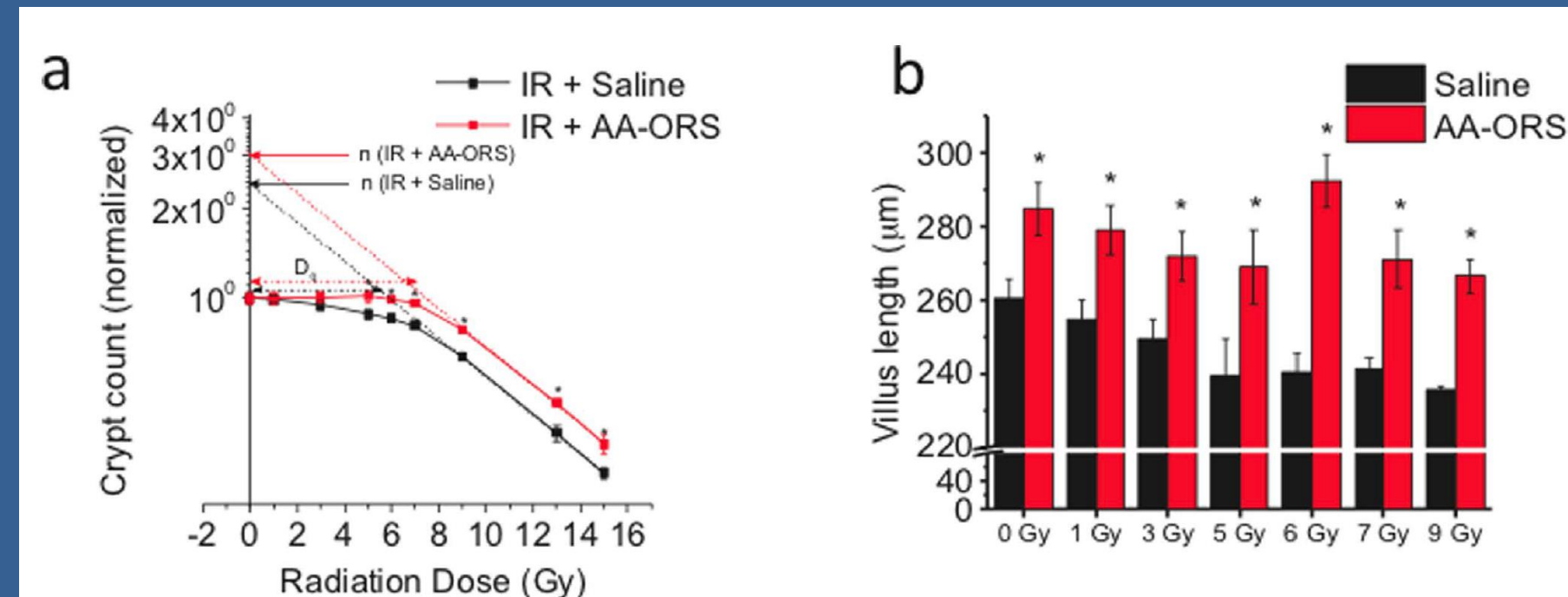
The Antidiarrheal Efficacy of a Proprietary Amino Acid Mixture (enterade®) in Neuroendocrine Tumor (NETs) Patients.

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AMINO ACID ORAL REHYDRATION SOLUTION

enterade® is an amino acid-based, glucose-free medical food/beverage with electrolytes. It comprises of 5 amino acids (Valine, Aspartic Acid, Serine, Threonine, Tyrosine) selected to rebuild villi, protect the GI tract and promote hydration. It has been shown in studies with mice to mitigate radiation-induced acute gastrointestinal syndrome related to reduced electrolyte and nutrient absorption.



INTRODUCTION

Based on SEER database, gastroenteropancreatic neuroendocrine tumor (GEPNET) incidence has increased 6-fold over past 3 decades.

We conducted a retrospective chart review to evaluate antidiarrheal efficacy of enterade® in neuroendocrine tumor patients with quality of life limiting diarrhea.

METHODS

Medical records of all the GEPNET patients treated with enterade® for symptomatic diarrhea were evaluated.

Patients were treated at Markey Cancer Center between May 2017-June 2018.

DEMOGRAPHICS/RESULTS

- A total of **69 patients** were given enterade®.
- enterade® was administered as an 8oz bottle BID for 1 week.
- Antidiarrheal efficacy data was available on 41 patients.
- 15 patients had small bowel neuroendocrine tumors (NET), 5 had bronchial NETs, 2 had colorectal NETs, 3 had NETs of unknown primary, 3 had gastric NETs, 3 had pancreatic NETs and one was high grade neuroendocrine carcinoma of prostate.
- 21 patients had history of prior bowel resection either for primary neuroendocrine tumor resection or debulking.
- 25 patients were on somatostatin analogs at the time of initiation of enterade®.

Figure 1. enterade® increased crypt count & villus length following irradiation. Figure 2: Electron microscopy of ileal sections show the formation of a normal cell junction complex Figure 3. enterade® improved mouse survival and improved body weight following irradiation.

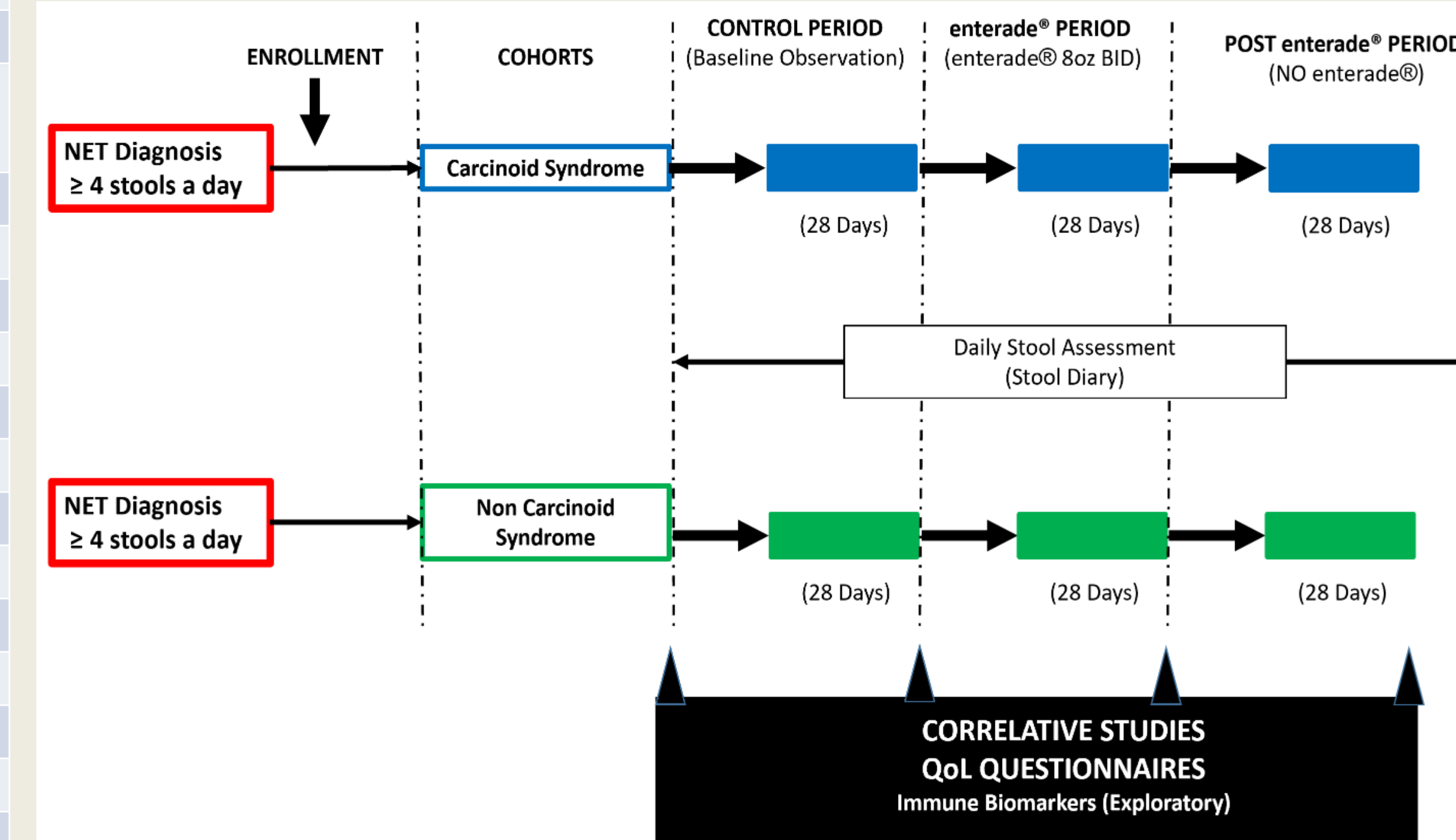
Pt #	Type of NET	SSA?	Baseline BM Frequency	Post enterade® BM Frequency
1	pancreatic NET	No	6	3
2	midgut NET	Yes	9	5
3	gastric NET	No	7	2
4	bronchial NET	Yes	8	3
5	bronchial NET	No	7	2
6	NET of unknown primary	Yes	7	2
7	bronchial NET	Yes	5	0
8	metastatic prostatic NEC	No	3	1
9	midgut NET	No	4	2
10	midgut NET	Yes	5	1
11	midgut NET	Yes	3	2
12	metastatic pulmonary NET	No	20	0
13	midgut NET	Yes	3	0
14	mixed colonic/cecal adenocarcinoma	No	15	3
15	bronchial NET	No	5	3
16	midgut NET	Yes	8	1
17	pancreatic NET	Yes	5	4
18	midgut NET	Yes	9	4
19	Bronchial NET	No	6	3
20	midgut NET	No	7	3
21	midgut NET	Yes	5	2
22	midgut NET	Yes	8	2
23	Gastric NET	Yes	8	4
24	midgut NET	Yes	10	5
25	midgut NET	No	20	2
26	pancreatic NET	No	10	0
27	NET of unknown primary	Yes	3	2
28	pancreatic NET	Yes	5	1
29	midgut NET	Yes	5	1
30	Duodenal NET	No	5	4
31	Bronchial NET	Yes	4	2
32	midgut NET	Yes	15	4
33	midgut NET	Yes	8	6

Table 1. Stool frequency pre and post enterade®. Data for 33 responders to enterade® as of June 2018.

RESULTS/CONCLUSIONS

- 33 out of 41 (80%) patients reported subjective improvement in diarrheal symptoms (Table 1)**
- 51% (21/41) reported more than 50% reduction in diarrhea frequency.**
- A prospective Phase II study (NCT03722511) of enterade in neuroendocrine tumor patients with quality of life limiting diarrhea is starting Q4 2018.**

PROSPECTIVE PHASE 2 STUDY



REFERENCES

Yin L, Vijaygopal P, Menon R, Vaught LA, Zhang M, Zhang L, Okunieff P, Vidyasagar S. An amino acid mixture mitigates radiation-induced gastrointestinal toxicity. *Health Phys.* 2014 Jun; 106(6):734-44.

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