

Multicenter clinical registry of patients with a neuroendocrine tumor (NET) diagnosis receiving 177Lu-DOTATATE

Courtney Porfido¹, Abuzar Moradi Tuchayi², April DeMore¹, Sippy Punn¹, Emily K. Bergsland², Thomas A. Hope², Diane Reidy¹, Lisa Bodei¹, Nitya Raj¹

¹Memorial Sloan Kettering Cancer Center, New York, NY; ²The University of California, San Francisco

Background

- 177Lu-DOTATATE as treatment for advanced NETs was approved by the FDA in 2017, and the EMA in 2016
- Registry represents a compilation of clinicopathologic, epidemiologic, radiologic, and molecular data for patients receiving 177Lu-DOTATATE therapy for retrospective investigations

Methods

- Data collected/managed using REDCap (Research Electronic Data Capture) tools hosted at Memorial Sloan Kettering Cancer Center (MSK) and the University of California, San Francisco (UCSF)
- REDCap: web-based software for data capture that provides audit trails and automated exports for statistical analyses

Record ID	Demographics	Initial Diagnosis	Baseline Patient Data	Prior Treatments	Vitals And Labs	PRRT Treatment Information	Prirt Treatment	Ga-DOTATATE	Imaging	Post PRRT Response Assessment	Post PRRT Toxicities	Post Prirt Treatment	Last Follow-up Ie Death	Re-PRRT Treatment	Post Re-PRRT Toxicities
1 (MRN █████)	●	●	●	● +	● +	●	● +	● +	●	●	● +	●	●	●	●
2 (MRN █████)	●	●	●	● +	● +	●	● +	● +	●	●	● +	●	●	●	●
3 (MRN █████)	●	●	●	● +	● +	●	● +	● +	●	●	● +	●	●	●	●
4 (MRN █████)	●	●	●	● +	● +	●	● +	● +	●	●	● +	●	●	●	●
5 (MRN █████)	●	●	●	● +	● +	●	● +	● +	●	●	● +	●	●	●	●
6 (MRN █████)	●	●	●	● +	● +	●	● +	● +	●	●	● +	●	●	●	●

Fig. 1 Record Status Dashboard displaying all data collection instruments and status for each existing record

Results

	Grade at Diagnosis				Functional Status at Time of Diagnosis			Cycles of PRRT				Retreatment with PRRT (at least 1 dose)	
	Grade 1	Grade 2	Grade 3	Unknown	Yes	No	Unknown	1	2	3	4	Yes	No
Bronchial n = 30	9 (30%)	14 (47%)	4 (13%)	3 (10%)	16 (53%)	14 (47%)	0	1 (3%)	7 (23%)	5 (17%)	17 (57%)	5 (17%)	25 (83%)
Gastric n = 6	2 (33%)	4 (66%)	0	0	3 (50%)	3 (50%)	0	0	1 (17%)	1 (17%)	4 (67%)	2 (3%)	4 (7%)
Pancreas n = 183	43 (23%)	99 (54%)	28 (15%)	13 (7%)	38 (%)	139 (%)	6 (%)	17 (%)	22 (%)	21 (%)	123 (%)	29 (16%)	154 (84%)
Rectal n = 17	2 (12%)	14 (82%)	1 (6%)	0	1 (6%)	15 (88%)	1 (6%)	0	4 (24%)	2 (12%)	11(65%)	5 (29%)	12 (71%)
Small Bowel n = 166	73 (44%)	77 (46%)	4 (2%)	12 (7%)	116 (70%)	46 (28%)	4 (2%)	14 (8%)	15 (9%)	23 (14%)	114 (69%)	25 (15%)	141 (85%)
Other n = 27	10 (37%)	13 (48%)	1 (4%)	3 (11%)	9 (%)	18 (%)	0	2 (%)	3 (%)	2 (%)	20 (%)	5 (19%)	22 (81%)
Unknown n = 41	11 (27%)	22 (54%)	6 (15%)	2 (5%)	14 (34%)	24 (59%)	3 (7%)	3 (7%)	5 (16%)	3 (7%)	30 (73%)	8 (20%)	32 (80%)
Paraganglioma Pheochromocytoma n = 9	0	3 (33%)	0	6 (66%)	3 (33%)	6 (66%)	0	0 (%)	2 (22%)	0 (%)	7 (78%)	0	9 (100%)

Table 1. Overview of all current database entries, n = 479. Female n = 283 (59%), White/Caucasian n = 362 (76%)

	Somatostatin Analogue	Surgery	Liver directed therapy	Everolimus	External Beam Radiation Therapy	Capecitabine/ Temozolomide	Platinum Based Chemotherapy	Sunitinib	Immunotherapy	Other
Bronchial n = 110	22 (20%)	21 (19%)	15 (14%)	11 (10%)	14 (13%)	9 (8%)	12 (11%)	1 (1%)	1 (1%)	4 (4%)
Gastric n = 17	6 (35%)	3 (18%)	6 (35%)	0	1 (6%)	0	1 (6%)	0	0	0
Pancreas n = 593	162 (27%)	101 (17%)	89 (15%)	52 (9%)	25 (4%)	99 (17%)	33 (6%)	10 (2%)	9 (2%)	13 (2%)
Rectal n = 54	16 (30%)	8 (15%)	11 (20%)	3 (6%)	5 (9%)	2 (4%)	3 (6%)	1 (2%)	2 (4%)	3 (6%)
Small Bowel n = 427	164 (38%)	121 (28%)	73 (17%)	28 (7%)	14 (3%)	8 (2%)	5 (1%)	2 (<1%)	2 (<1%)	10 (2%)
Other n = 85	37 (44%)	13 (15%)	16 (19%)	10 (12%)	5 (6%)	5 (6%)	3 (4%)	0	2 (2%)	3 (4%)
Unknown n = 94	23 (24%)	19 (20%)	12 (13%)	6 (6%)	12 (13%)	6 (6%)	3 (3%)	0	1 (1%)	3 (3%)
Paraganglioma Pheochromocytoma n = 19	2 (11%)	7 (37%)	1 (5%)	0	4 (20%)	0	1 (5%)	1 (5%)	0	3 (16%)

Table 2. Treatment landscape prior to 177Lu-DOTATATE therapy. N calculated by sum of all treatments per patient

Fig. 2 REDCap data entry form for PRRT dosing

Fig. 3 REDCap data entry form for radiographic response to PRRT

Figure 2 shows the REDCap data entry form for PRRT dosing, including fields for Record ID, Date of PRRT treatment, Administered therapy, Route of administration, Administered activity, Dose Level, Did the patient develop toxicities during or immediately after PRRT?, Form Status, and Complete?.

Figure 3 shows the REDCap data entry form for radiographic response to PRRT, including fields for Record ID, Start/End dates, How many cycles of PRRT did the patient complete?, Was there concern for pseudoprogression after treatment?, What was the patient's best radiographic response by report (as seen any modality?), Date of best radiographic response, Was there POD?, Date of POD, What type of imaging was progression documented on?, and If patient received fewer than 4 doses of PRRT, what was the reason for discontinuation?.

Patient Journey

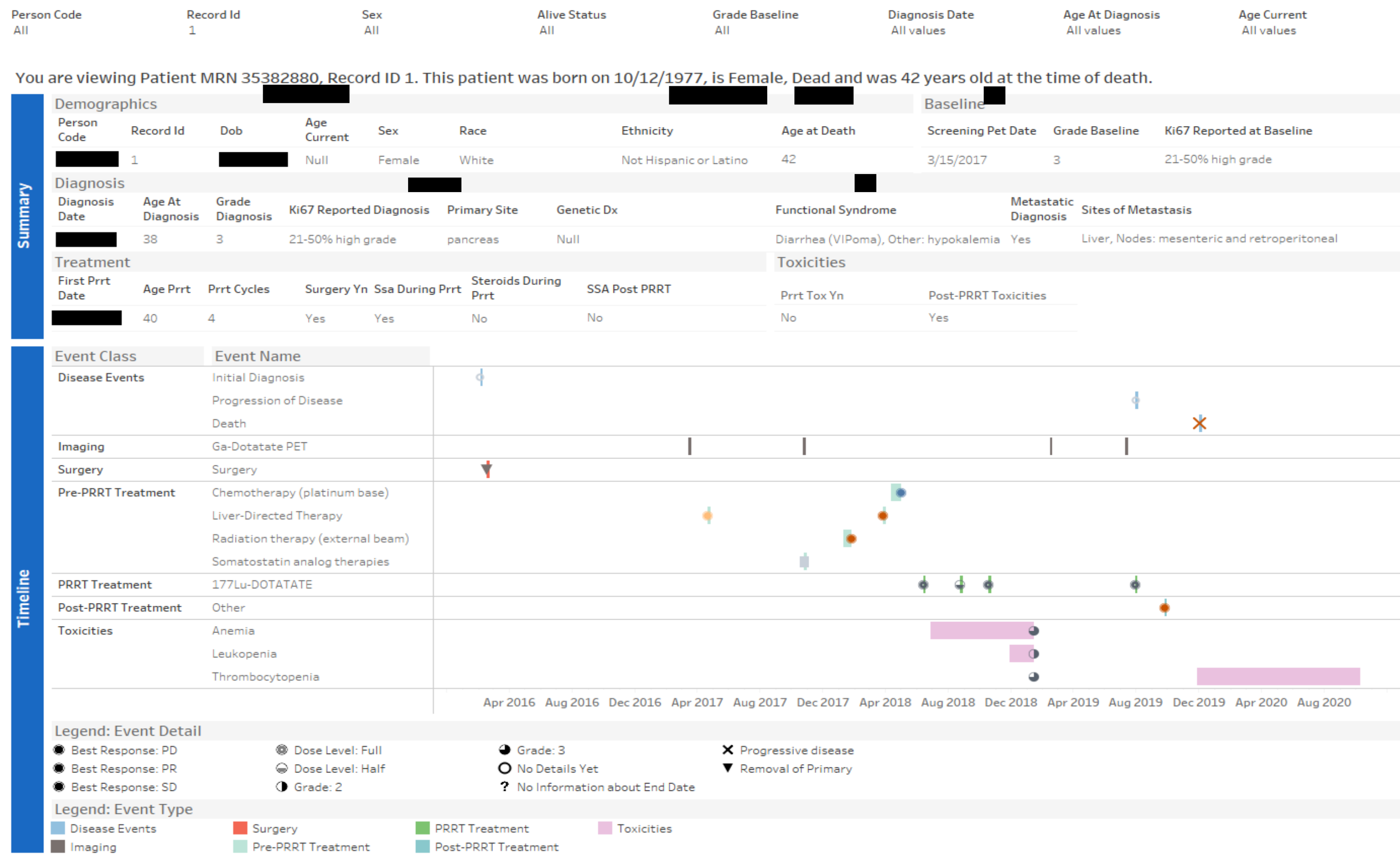


Fig. 4 Tableau dashboard for single patient record

Conclusion

- A powerful tool for answering preliminary questions to feed prospective research
- Built-in functionality allows data to be shared easily across institutions
- Registry allows us to comprehensively capture the treatment course of NET patients