RaPTR: Registry for Real-World Radiopharmaceutical Therapy Data

Alex Heglin, DO, MHS[1] | Joshua D. Juganaru[2] | Julia K. Trigger, MS[3] | Rustain Morgan, MD[4] | Jin Cheung, MD[1]
Mehdi Djekidel, MD[5] | Orhan K. Oz, MD, PhD[1] | Anthony M. Rossi, MS[2] | Bital Savir-Baruch, MD[2]
1) UT Southwestern | 2) University of Arizona | 3) Society of Nuclear Medicine and Molecular Imaging | 4) University of Nebraska | 5) Northwell Health

Goal: The goal of the RaPTR (RadioPharmaceutical Therapy Registry) is to analyze real-world data to better understand the effects of these novel agents, establish quality performance benchmarks, develop best practices, and ultimately improve the health and quality of life of our patients.

Methods: The registry consists of two components: a cloud-based DICOM image repository (MIMCloud) and a HIPAA compliant clinical database, REDCap which is used to collect clinical data from Electronic Health Records. All data collected and stored in RaPTR is de-identified.

The clinical data in REDCap includes details on the facility and treating physician, patient demographics and medical history, disease and treatment history, on- and off-label therapy utilization if appropriate, dosimetry data, side effects and toxicities, and a patient-reported survey addressing social determinants of health **(see figure 1).**

DICOM imaging data uploaded to MIMCloud includes diagnostic scans and post-therapy administration imaging, which can be annotated for analysis. Imaging data can inform various aspects of patient selection and management including artificial intelligence algorithms for key tasks in the dosimetry workflow **(see figure 2).**

Participants can select instruments they wish to review **(as seen in figure 7**) and export their own data. A full database report may be available by submitting a research request to the RaPTR Oversight Committee. REDCap has multiple export options including (but not limited to) CSV, SPSS, PDF, and CDICS **(seen in figures 5 and 8).**

Figure 1

Data Collection Instrument	Status
Facility And Treating Physician Information	
Demographic And Medical History	
Disease Treatment History	
PSMA Treatment Information	
Side Effects/Toxicity	
Social Determinants of Health Survey	

Figure 2

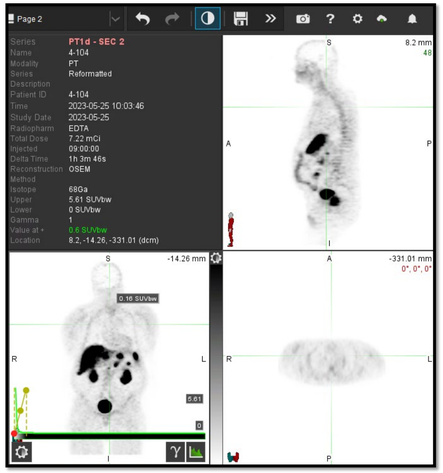


Figure 3

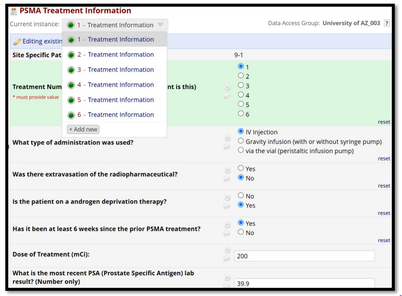


Figure 3 (above): Shows an example of a completed patient record containing ^{177}Lu-PSMA-617 therapy information. The dropdown shown in the image allows the user to enter the information after each cycle. This functionality is also available for documenting the side effects and toxicity.

Figure 4 (to the right): Shows a completed patient profile. All data collection instruments are required to be completed, except for the *Social Determinates of Health Survey*. Data administrators at the participating site can review and edit completed records as needed. To ensure the accuracy and integrity of the data, any updates to the patient records must be approved by the site's primary investigator (PI).

Figure 5

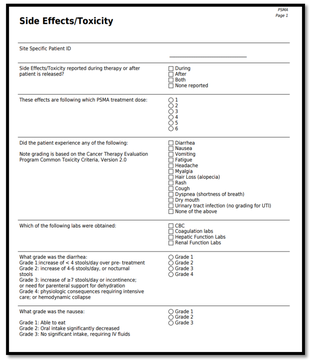


Figure 4

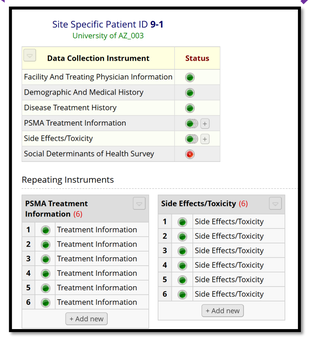
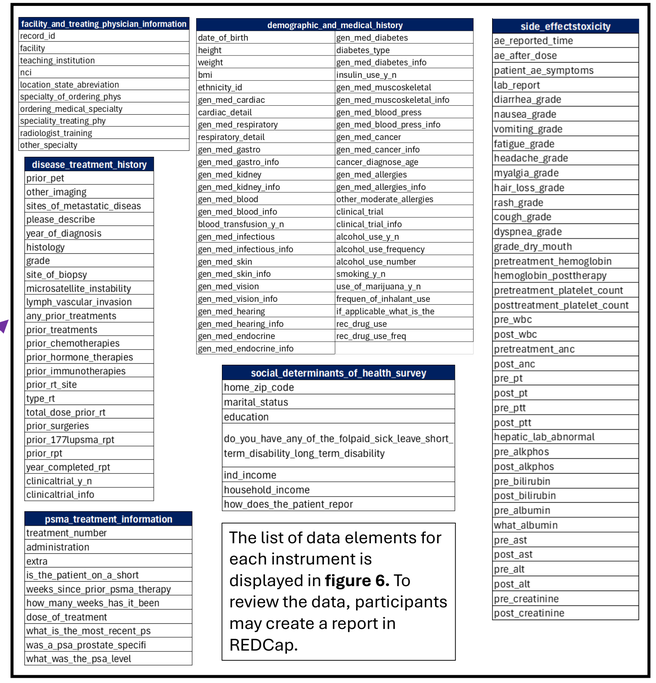


Figure 6



The list of data elements for each instrument is displayed in **figure 6.** To review the data, participants may create a report in REDCap.

Figure 7

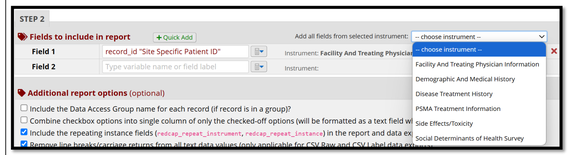


Figure 8

Site Specific Patient ID	Has it been at least 6 weeks since the prior PSMA	Dose of Treatment (mCi):	What is the most recent PSA (Prostate Specific Antigen) lab result? (Number only)	Was a PSA (Prostate Specific Antigen) lab testing done since prior	What was the PSA Level?
45901					
45901	Yes	200	39.9		
45901	Yes	200		Yes	36.8
45901	Yes	200		Yes	17.3
45901	Yes	200		Yes	11.5
45901	Yes	209.6		Yes	6.3
45901	Yes	200			

Presented in the tables below are the high-level demographic data from both ^{177}Lu-PSMA-617 and ^{177}Lu-Dotatate records.

^{177}Lu-Dotatate			
Number of Patients	**n=125**		
Female Patients	**n=63**		
Age (To comply with HIPAA regulations, RaPTR does not capture patient age above 89).	Mean = 62	SD = 13	Minimum = 27
Dosing Information	Mean = 203.7mCi	SD = 9.5	Minimum = 100.1mCi High = 217mCi
Number of Patients Per Cycle *[Cycle (n)]*	1 (132), 2 (120), 3 (112), 4 (98)		
Noted Side Effects	Fatigue, nausea, myalgia, and headache.		

^{177}Lu-PSMA-617			
Number of Patients	**n=91**		
Age (To comply with HIPAA regulations, RaPTR does not capture patient age above 89).	Mean =76	SD = 6	Minimum = 63
Dosing Information	Mean = 200.8 mCi	SD = 8.6	Minimum = 160mCi High = 217mCi
Number of Patients Per Cycle *[Cycle (n)]*	1 (91), 2 (86), 3 (73), 4 (63), 5 (49), 6 (37)		
Patients who Received 160 mCi *[Cycle (n)]*	2 (1), 3 (1), 6 (3)		
Noted Side Effects	Dry mouth, fatigue, nausea, diarrhea, rash, myalgia. n=11 experienced side effects after cycle 4.		

Results: The RaPTR and RaPTR+PLUS database modules have been built and released for Lutathera and Pluvicto, the I-131 thyroid module was added on January 30, 2025. Three pilot sites received IRB approval to participate in RaPTR+PLUS and two are actively entering data. Currently, RaPTR includes clinical data for 125 patients treated with Lutathera and 91 with Pluvicto. Imaging data has been received for Pluvicto and Lutathera patients.

Conclusion: As the use of RPTs increases with label expansions (e.g., Pluvicto), off-label indications, and new agents, multi-institutional data will be critical for refining treatment paradigms and improving patient outcomes. This robust registry will provide additional, real-world safety data and serve as an indispensable resource for physicians, technologists, and trainees.

Contact Information:
jtrigger@snmmi.org

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UT Southwestern Medical Center

Banner University Medical Center Phoenix