



Lutathera and Pluvicto Medical Events

Claire Drozd NJDEP



Claire Drozd

New Jersey Department of
Environmental Protection

Medical Event Notification

- › NJ was made aware of the occurrence of two medical events on 12/8/2022
- › Involves two licensees: Cancer Center and Nuclear Pharmacy

Preparing and Conducting Investigations

Cancer Center

- Interviewed pertinent employees
- Established timeline
- Obtained copies of relevant records
- Follow up questions and clarifications

Nucelar Pharmacy

- Interviewed pertinent employees
- Procedures and corrective actions reviewed
- Obtained copies of relevant records

Investigation Results

Timeline Established

The series of events was established and further refined with subsequent interviews.

Batch Release and Shipping Practices

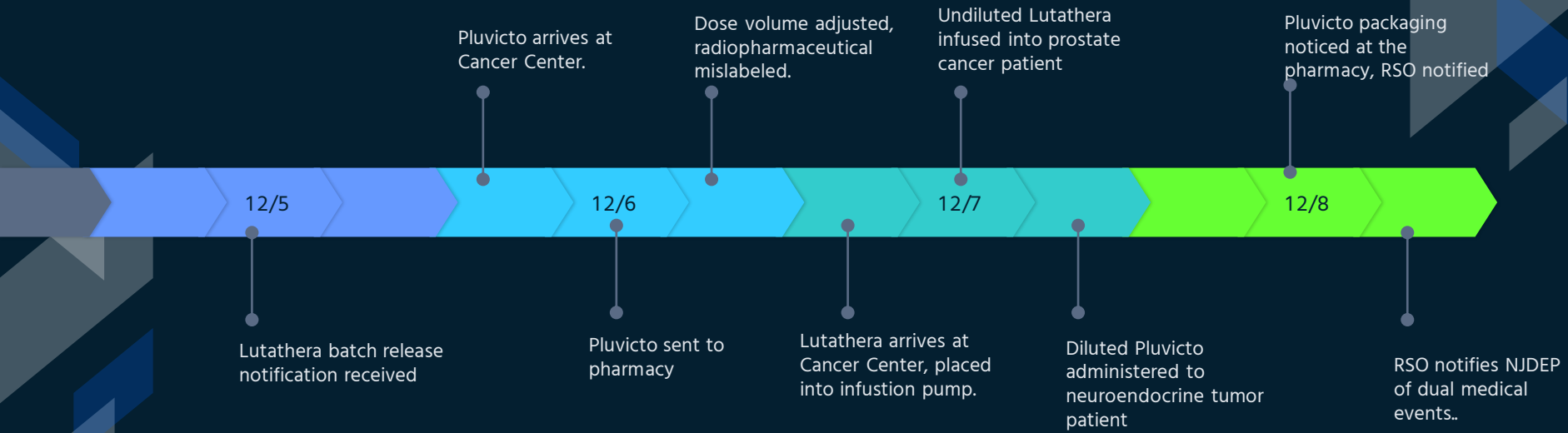
- Pluvicto release was not received before batch was already shipped to the Pharmacy
- Unique shipping practices

Circumstances

- Color of pigs were identical
- The same radionuclide is administered at the same dosage



Timeline of Events



NJDEP Evaluation

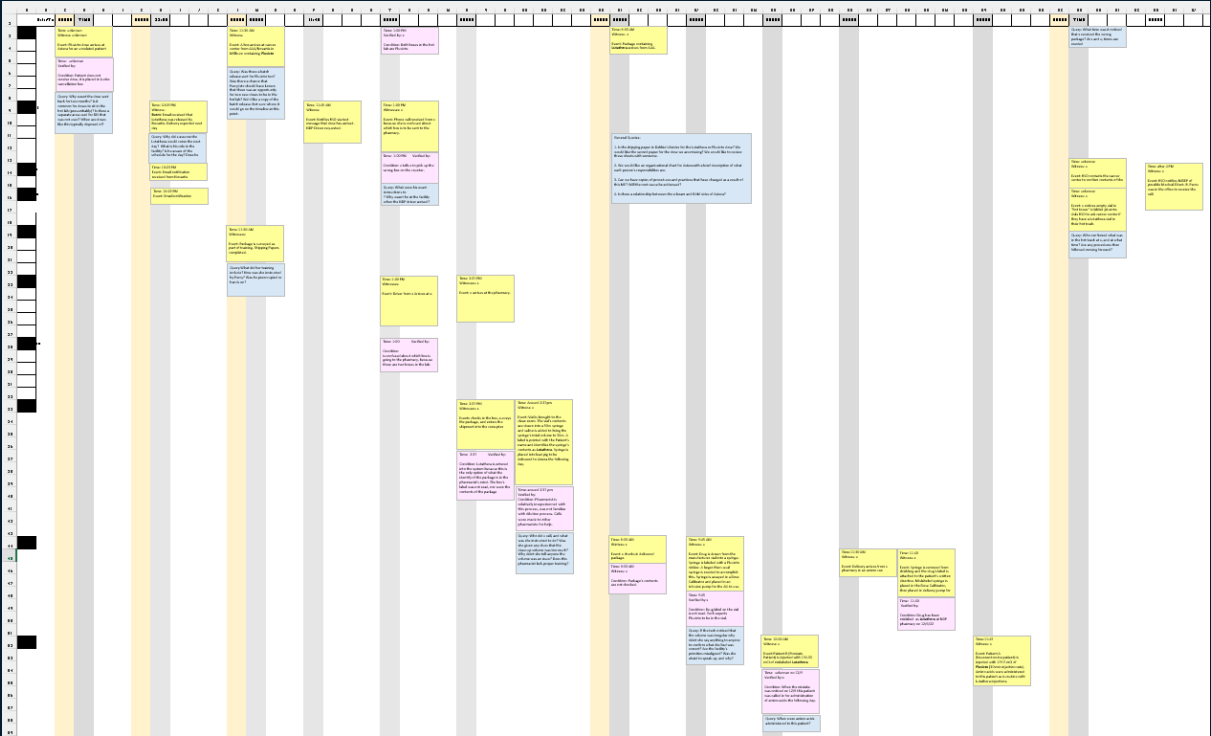
Root Cause Analysis

- Events and Conditional Factor Analysis +
- Five Why Analysis

Dose Assessment

- Facility and third-party Health Physicists analyzed dosage information to determine both patient's excess doses

Root Cause Analysis: ECFA+



Dose Assessment

		Unnecessary exposure in rem	
Drug/Patient	Critical Organ	Licensee estimate	Third Party Estimate
Pluvicto/ Patient A	Rectum	625	373
	Kidneys	475	286
	Urinary Bladder Wall	350	213
	Whole body	40	25
Lutathera/ Patient B	Spleen	627	608
	Kidneys	485 (713 without 47% reduction)	887 (no 47% reduction)
	Urinary Bladder Wall	320	314
	Whole body	40	37

Consequences

Violations were Issued

- Package intake procedures not followed
- Inaccurate radiopharmaceutical labeling

Facility's Response

- Center will not have Lu-177 patients on the same day
- Dual verifications:
 - Deliveries
 - Prior to dispensing drugs into syringes
 - AUs confirm NMT work

New Jersey's Take Aways

**Preparing for
Investigations**

Dose Assessment

National Attention

**Contact with
Manufacturer**

Training

Questions?





Claire Drozd
New Jersey Department
of Environmental
Protection

Email: Claire.Drozd@dep.nj.gov

Office: 609-984-5542

Cell: 609-712-3385