

## **14.2 EFFICACY DATA**

### **14.2.1.1 Sensitivity, Specificity, PPV, NPV and Accuracy: Prostate Gland -Per Patient Per Protocol Set**

## 14.2 TABLES-EFFICACY DATA

## 14.2.1 Ga-68-PSMA-11 PET/CT Ability

14.2.1.1 Sensitivity, Specificity, PPV, NPV And Accuracy: Prostate Gland-Per Patient  
Per Protocol Set

	Number of patients	Estimate	95% Confidence Interval
True Positive	135		
True Negative	0		
False Positive	0		
False Negative	4		
Sensitivity		0.971	(0.928 - 0.992)
Specificity		N/A	N/A
Positive Predictive Value		1.000	(0.973 - 1.000)
Negative Predictive Value		N/A	N/A
Accuracy		0.971	(0.943 - 0.999)

**14.2.1.2      Sensitivity, Specificity, PPV, NPV and Accuracy: Prostate Gland -Per Quadrant  
Per Protocol Set**

## 14.2 Efficacy

## 14.2.1 Ga-68-PSMA-11 PET/CT Ability

14.2.1.2 Sensitivity, Specificity, PPV, NPV And Accuracy: Prostate Gland-Per Quadrant  
Per Protocol Set

	Number of patients	Estimate	95% Confidence Interval
True Positive	345		
True Negative	42		
False Positive	28		
False Negative	141		
Sensitivity		0.710	(0.670 - 0.750)
Specificity		0.600	(0.485 - 0.715)
Positive Predictive Value		0.925	(0.898 - 0.952)
Negative Predictive Value		0.230	(0.169 - 0.290)
Accuracy		0.696	(0.658 - 0.734)

**14.2.1.3      Sensitivity, Specificity, PPV, NPV and Accuracy: Lymph Node – Per Patient  
Per Protocol Set**

## 14.2 Efficacy

## 14.2.1 Ga-68-PSMA-11 PET/CT Ability

14.2.1.3 Sensitivity, Specificity, PPV, NPV And Accuracy: Lymph Node-Per Patient  
Per Protocol Set

	Number of patients	Estimate	95% Confidence Interval
True Positive	22		
True Negative	83		
False Positive	1		
False Negative	33		
Sensitivity		0.400	(0.271 - 0.529)
Specificity		0.988	(0.965 - 1.000)
Positive Predictive Value		0.957	(0.873 - 1.000)
Negative Predictive Value		0.716	(0.633 - 0.798)
Accuracy		0.755	(0.684 - 0.827)

**14.2.1.4 Sensitivity, Specificity, PPV, NPV and Accuracy: Lymph Node -Per Patient -  
>2 mm Per Protocol Set**

## 14.2 Efficacy

## 14.2.1 Ga-68-PSMA-11 PET/CT Ability

14.2.1.4 Sensitivity, Specificity, PPV, NPV And Accuracy: Lymph Node-Per Patient- >2mm  
Per Protocol Set

	Number of patients	Estimate	95% Confidence Interval
True Positive	22		
True Negative	0		
False Positive	0		
False Negative	26		
Sensitivity		0.458	(0.314 - 0.608)
Specificity		N/A	N/A
Positive Predictive Value		1.000	(0.846 - 1.000)
Negative Predictive Value		N/A	N/A
Accuracy		0.458	(0.317 - 0.599)

**14.2.1.5      Sensitivity, Specificity, PPV, NPV and Accuracy: Lymph Node -Per Patient -  
>5 mm Per Protocol Set**

## 14.2 Efficacy

## 14.2.1 Ga-68-PSMA-11 PET/CT Ability

14.2.1.5 Sensitivity, Specificity, PPV, NPV And Accuracy: Lymph Node-Per Patient- >5mm  
Per Protocol Set

	Number of patients	Estimate	95% Confidence Interval
True Positive	20		
True Negative	0		
False Positive	0		
False Negative	9		
Sensitivity		0.690	(0.492 - 0.847)
Specificity		N/A	N/A
Positive Predictive Value		1.000	(0.832 - 1.000)
Negative Predictive Value		N/A	N/A
Accuracy		0.690	(0.521 - 0.858)

**14.2.1.6      Sensitivity, Specificity, PPV, NPV and Accuracy: Lymph Node -Per Gross  
Region (Pelvic Left/Right) Per Protocol Set**

## 14.2 Efficacy

## 14.2.1 Ga-68-PSMA-11 PET/CT Ability

14.2.1.6 Sensitivity, Specificity, PPV, NPV And Accuracy: Lymph Node-Per Gross Region (Pelvic Left/Right)  
Per Protocol Set

	Number of patients	Estimate	95% Confidence Interval
True Positive	29		
True Negative	193		
False Positive	1		
False Negative	55		
Sensitivity		0.345	(0.244 - 0.447)
Specificity		0.995	(0.985 - 1.000)
Positive Predictive Value		0.967	(0.902 - 1.000)
Negative Predictive Value		0.778	(0.727 - 0.830)
Accuracy		0.799	(0.751 - 0.846)

**14.2.1.7      Sensitivity, Specificity, PPV, NPV and Accuracy: Lymph Node -Per Sub-region  
Per Protocol Set**

## 14.2 Efficacy

## 14.2.1 Ga-68-PSMA-11 PET/CT Ability

14.2.1.7 Sensitivity, Specificity, PPV, NPV And Accuracy: Lymph Node-Per Subregion  
Per Protocol Set

	Number of patients	Estimate	95% Confidence Interval
True Positive	16		
True Negative	963		
False Positive	18		
False Negative	87		
Sensitivity		0.155	(0.085 - 0.225)
Specificity		0.982	(0.973 - 0.990)
Positive Predictive Value		0.471	(0.303 - 0.638)
Negative Predictive Value		0.917	(0.900 - 0.934)
Accuracy		0.903	(0.886 - 0.921)