Comparison of Standard PET/CT Versus Digital PET/CT

NCT03081767

January 12, 2021

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1. PURPOSE OF THE STUDY

a. Brief Summary

This is a comparison study of two types of scanners: we want to compare the results of the standard-of-care PET/CT scanner with a new digital PET/CT scanner and we plan to do this on the same day using a single dose of a radioactive drug that is FDA-approved to be used for the PET/CT scan (FDG, NaF, DOTATATE) or radioactive drugs not FDA-approved but for which we hold INDs (Ga68 PSMA and Ga68 RM2 used in prostate cancer).

We hope to learn if the lesions seen using one standard of care scanner (PET/CT) are also seen using the novel scanner (digital PET/CT).

The goal of this study is to acquire matched sets of imaging in order to compare the standard PET/CT and digital PET/CT.

b. Objectives

Understanding the imaging characteristics of these two scanners can potentially improve the patient care, improving the image quality, by scanning the patients most suitable for the individual scanner. Understanding what patients will benefit from digital PET/CT instead of standard PET/CT will have the potential to improve patient care.

c. Rationale for Research in Humans

The scanners are designed for detection of disease in human subjects; therefore, comparing the image quality of the two requires human participants.

2. STUDY PROCEDURES

a. Procedures

Patients who are referred to Nuclear Medicine and are scheduled to undergo standard or research (68Ga PSMA or 68Ga RM2) PET/CT on the Discovery 600 or 690 scanner will be asked to have the scan repeated on the Discovery MI scanner. Conversely, patients

who are referred to Nuclear Medicine and are scheduled to undergo standard or research (68Ga PSMA or 68Ga RM2) PET/CT on the Discovery MI scanner will be asked to have the scan repeated on the Discovery 600 or 690 scanner. There will be a single injection of the PET radiopharmaceutical followed by the standard PET/CT scan and immediately after by the digital PET/CT scan. A very small amount of radiation (3 mSv) will be given by the attenuation correction CT scan in the second PET/CT.

PET/CT images will be obtained using the GE PET/CT 600 or 690 scanners (GE Healthcare) per standard oncologic protocols. In brief, PET/CT images will be acquired in 3D mode at 45-60 minutes after injection of the radiopharmaceutical. We plan to enroll 100 patients per year for both SOC and research tracers, for 3 years (total of 300 patients). The PET emission scan is corrected using segmented attenuation data of the CT scan. ToF will be used for patients with BMI>25 (on the 690 system only). The PET images are reconstructed both with a standard iterative algorithm (OSEM, two iterative steps, 28 subsets), as well as a regularized reconstruction algorithm provided by GE Healthcare. All images are reformatted into axial, coronal, and sagittal views and viewed with the software available in the Nuclear Medicine and Molecular Imaging Clinic (MIM Vista).

Immediately after completion of the standard PET/CT exam, the patients will be transferred to the adjacent digital PET/CT suite and undergo the second PET/CT image acquisition with the least delay. In brief, PET/CT images will be acquired in 3D mode. ToF is standard on the digital PET/CT system. Data driven gating will be acquired according to the vendor's protocol (once commercially available). The PET emission scan is corrected using segmented attenuation data of the CT scan. The PET images are reconstructed both with a standard iterative algorithm (OSEM, two iterative steps, 28 subsets), as well as a regularized reconstruction algorithm (Q.Clear®) provided by GE Healthcare. All images are reformatted into axial, coronal, and sagittal views and viewed with the software available in the Nuclear Medicine and Molecular Imaging Clinic (MIM Vista).

The above sequences will be done as well if the digital PET/CT is done first, followed by Discovery 600 or 690.

b. Procedure Risks

No significant risks are associated with the imaging procedures involved.

c. Use of Deception in the Study

Deception will not be used in this study.

d. Use of Audio and Video Recordings

Audio and video recording will not be used in this study.

e. Alternative Procedures or Courses of Treatment

The participant is already referred for standard or research (68Ga PSMA or 68Ga RM2) PET/CT. No other alternate procedures are available. The subject can choose not to participate in the project.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

No therapy is used in this study. The protocol will not affect any therapy the patient might receive outside this research.

g. Study Endpoint(s)

No alternative treatments are proposed.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

More than a decade ago, multimodality imaging was introduced into clinical routine with the development of the PET/CT. Since then, PET/CT has been widely accepted in clinical imaging and has emerged as one of the main cancer imaging modalities. With the recent development of combined PET/MRI systems for clinical use, a promising new PET detector technology using silicon photomultiplier tubes has become available. The combination of functional information delivered by highly sensitive novel PET detectors with the morphologic imaging of CT offers exciting possibilities for clinical applications as well as basic research. However, the differences between standard and digital PET detectors are fundamental. Digital PET/CT is expected to show advantages over standard PET/CT by decreasing required dose of PET radiopharmaceuticals, higher sensitivity and temporal resolution. However, as of now, only assumptions can be made about the future clinical role of digital PET/CT, as data about the performance of digital PET/CT in the clinical setting are still limited (1). We recently installed at Stanford University the first ever GE-made digital PET/CT worldwide and we plan to compare image quality with that from standard PET/CT as part of an investigator initiated research study.

b. Findings from Past Animal Experiments

Non-available.

4. RADIOISOTOPES OR RADIATION MACHINES

a. Standard of Care (SOC) Procedures

Identify Week/Month of Study	Name of Exam	Identify if SOC or Research
Once	standard SPECT/CT	Standard of Care
Once	digital PET/CT	Research

b. Radioisotopes

i. Radionuclide(s) and chemical form(s)

68Ga PSMA or 68Ga RM2; patients are consented separately for these studies per IRB approved protocols.

ii. Total number of times the radioisotope and activity will be administered (mCi) and the route of administration for a typical study participant.

68Ga PSMA: once, 3-5 mCi
68Ga RM2: once, 140 MBq

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).
PSMA:
Measured human dosimetry data are available from the German Cancer Research Center in Heidelberg and summarized below.

	Patient 1	Patient 2	Patient 3	Patient 4	Mean	140 MBq
Adrenals	1.34E-02	1.38E-02	1.39E-02	1.55E-02	1.42E-02	1.98E+00
Brain	9.84E-03	8.38E-03	8.54E-03	9.11E-03	8.97E-03	1.26E+00
Breasts	9.71E-03	8.41E-03	8.52E-03	9.16E-03	8.95E-03	1.25E+00
Gallbladder Wall	1.41E-02	1.48E-02	1.36E-02	1.50E-02	1.44E-02	2.01E+00
LLI Wall	1.28E-02	1.22E-02	1.21E-02	1.19E-02	1.23E-02	1.72E+00
Small Intestine	1.59E-02	1.95E-02	1.48E-02	1.49E-02	1.63E-02	2.28E+00
Stomach Wall	1.21E-02	1.19E-02	1.14E-02	1.25E-02	1.20E-02	1.68E+00
ULI Wall	2.84E-02	1.16E-01	3.91E-02	3.52E-02	5.47E-02	7.65E+00
Heart Wall	1.17E-02	1.03E-02	1.04E-02	1.13E-02	1.09E-02	1.53E+00
Kidneys	1.19E-01	2.79E-01	3.06E-01	3.42E-01	2.62E-01	3.66E+01
Liver	3.22E-02	2.87E-02	2.65E-02	3.61E-02	3.09E-02	4.32E+00
Lungs	1.09E-02	9.59E-03	9.66E-03	1.05E-02	1.02E-02	1.42E+00
Muscle	1.10E-02	1.01E-02	1.01E-02	1.06E-02	1.05E-02	1.46E+00
Pancreas	1.33E-02	1.36E-02	1.33E-02	1.49E-02	1.38E-02	1.93E+00
Red Marrow	9.36E-03	8.99E-03	8.87E-03	9.42E-03	9.16E-03	1.28E+00
Osteogenic Cells	1.53E-02	1.35E-02	1.36E-02	1.45E-02	1.42E-02	1.99E+00
Skin	9.51E-03	8.39E-03	8.48E-03	9.01E-03	8.85E-03	1.24E+00
Spleen	2.55E-02	5.61E-02	2.84E-02	6.82E-02	4.46E-02	6.24E+00
Testes	1.12E-02	9.93E-03	1.02E-02	1.02E-02	1.04E-02	1.45E+00
Thymus	1.08E-02	9.29E-03	9.43E-03	1.01E-02	9.91E-03	1.39E+00
Thyroid	1.06E-02	9.09E-03	9.25E-03	9.88E-03	9.71E-03	1.36E+00
Urinary Bladder Wall	1.22E-01	1.48E-01	1.66E-01	8.74E-02	1.31E-01	1.83E+01
Effective dose	1.83E-02	2.54E-02	2.63E-02	2.42E-02	2.36E-02	3.30E+00

To summarize the results of the published human studies, there were no observed adverse events to the radiopharmaceutical. The measured dosimetry showed that the critical organ with 68Ga-PSMA is the spleen, followed by the stomach wall, pancreas and bladder wall. The effective dose of 68Ga-PSMA reported (0.0236 mSv/MBq) is similar to that of 68Ga-DOTA-TOC (0.023 mSv/MBq), 68Ga-DOTA-NOC (0.025 mSv/MBq), 68Ga-DOTA-TATE (0.021 mSv/MBq) and 68Ga-NOTA-RGD (0.022 mSv/MBq).

RM2:

The first-in-human study investigated the safety, tolerability, metabolism, pharmacokinetics, biodistribution, and radiation dosimetry of 68Ga-DOTA-Bombesin (BAY 86-7548). Five healthy men underwent dynamic whole-body PET/CT after an intravenous injection of 68Ga-DOTA-Bombesin (138 ± 5 MBq). Besides total radioactivity, plasma samples were analyzed by radio–high-performance liquid chromatography for metabolism of the tracer. Dosimetry was calculated using the OLINDA/EXM software. The organs with the highest absorbed doses were the urinary bladder wall (0.62 mSv/MBq) and the pancreas (0.51 mSv/MBq). The mean effective dose was 0.051 mSv/MBq. 68Ga-DOTA-Bombesin was well tolerated by all subjects. The authors concluded that the intravenously injected 68Ga-DOTA-Bombesin is safe, and rapid metabolism is demonstrated. A 140-MBq injection of 68Ga-DOTA-Bombesin results in an effective dose of 4.76 mSv after voiding at 1 hour..

Measured human dosimetry data are available from published data (30) and presented below.

The 68Ga radioactivity was rapidly excreted through the kidneys to the urinary bladder and accumulated predominantly in the pancreas and liver. Maximum peak uptake of the total injected radioactivity was seen in the urinary bladder contents and the liver, with approximately 36% and 14%, respectively.

The mean normalized number of disintegrations in units of hours of the source organs and remainder of the body are listed in Table 1. The largest mean normalized number of disintegrations for the subjects was found in the remainder tissues (0.67 h), urinary bladder contents (0.53 h), and pancreas (0.11 h).

Organ	Mean	SD	Minimum	Maximum
Heart contents	0.038	0.0052	0.029	0.043
Kidneys	0.050	0.0071	0.041	0.060
Liver	0.074	0.014	0.055	0.093
Pancreas	0.11	0.035	0.067	0.15
Red marrow	0.087	0.030	0.066	0.11
Salivary	0.0033	0.0013	0.0011	0.0044
Spleen	0.0065	0.0014	0.0040	0.0073
Stomach wall	0.012	0.0030	0.0079	0.014
Thyroid	0.0012	0.00054	0.0057	0.0018
Urinary bladder	0.53	0.050	0.47	0.59
Remainder of body	0.67	0.071	0.59	0.75

Table 1: Normalized number of disintegrations (hours) of source organs after injection 68Ga-DOTA-Bombesin.

The estimations of the absorbed doses are reported in Table 2. The organ with the highest absorbed dose was the urinary bladder wall at 0.61 mSv/MBq, followed by the pancreas at 0.51 mSv/MBq. The mean effective dose (14) was 0.051 mSv/MBq. Thus, the effective dose from a 150-MBq injected radioactivity is 7.7 mSv, which could be reduced to roughly 5.7 mSv with frequent bladder voiding (1-h voids).

Organ	Mean	SD	Minimum	Maximum

Adrenals 0.011 0.00080 0.010 0.012
Brain 0.0056 0.00051 0.0049 0.0061
Breasts 0.0060 0.00048 0.0053 0.0064
Gallbladder wall 0.011 0.00054 0.0099 0.011
Lower large intestine wall 0.014 0.00036 0.013 0.014
Small intestine 0.010 0.00032 0.0096 0.010
Stomach wall 0.038 0.0090 0.027 0.045
Upper large intestine wall 0.0094 0.00037 0.0089 0.0098
Heart wall 0.028 0.0030 0.023 0.031
Kidneys 0.081 0.011 0.067 0.096
Liver 0.023 0.0035 0.019 0.028
Lungs 0.0071 0.00048 0.0064 0.0076
Muscle 0.0082 0.00038 0.0077 0.0086
Pancreas 0.51 0.16 0.32 0.73
Red marrow 0.013 0.0087 0.0068 0.026
Osteogenic cells 0.013 0.0051 0.0092 0.021
Salivary glands 0.022 0.0022 0.020 0.026
Skin 0.0060 0.00044 0.0055 0.0065
Spleen 0.023 0.0036 0.017 0.026
Testes 0.010 0.00045 0.0097 0.011
Thymus 0.0070 0.00055 0.0064 0.0076
Thyroid 0.027 0.011 0.014 0.039
Urinary bladder wall 0.61 0.057 0.54 0.68
Total body 0.010 0.00031 0.0098 0.011
Effective dose 0.051 0.0072 0.044 0.063
Table 2: Dose Equivalent estimates (mSv/MBq) after injection of 68Ga-DOTA-Bombesin

To summarize the results of the published human dosimetry study, there were no observed adverse events to the radiopharmaceutical. The measured dosimetry showed that the critical organ with 68Ga-DOTA-Bombesin is the urinary bladder, followed by the pancreas. The effective dose of 68Ga-DOTA-Bombesin reported (0.051 mSv/MBq) is approximately twice as much as that of 68Ga-DOTA-TOC (0.023 mSv/MBq), 68Ga-DOTA-NOC (0.025 mSv/MBq), 68Ga-DOTA-TATE (0.021 mSv/MBq) and 68Ga-NOTA-RGD (0.022 mSv/MBq)

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c. Radiation Machines – Diagnostic Procedures

i. Examination description (well-established procedures)

Immediately after completion of the standard PET/CT the subject will undergo a study scan using the Discovery PET/CT system. Similarly, if Discovery PET/CT will be used first, scan will be acquired immediately after using standard PET/CT.

Collection of the study PET/CT imaging data shall be completed up to 1 hour after completion of the standard PET/CT scan. First a CT will be done for attenuation correction. This will be followed by emission PET scan over the same regions.

ii. Total number of times each procedure will be performed (typical study participant)

Once.

iii. Setup and techniques to support dose modeling

First PET/CT: CT as ordered by referring physician, followed by emission PET
Second PET/CT: CT for attenuation correction, followed by emission PET

iv. FDA status of the machine and information on dose modeling (if procedure is not well-established)

The digital PET/CT is now FDA-approved

d. Radiation Machines – Therapeutic Procedures

i. Area treated, dose per fraction/number of fractions, performed as part of normal clinical management or due to research participation (well-established procedures)

N/A

ii. FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions (if procedure is not well-established)

N/A

5. DEVICES USED IN THE STUDY

a. IDE-Exempt Devices

IND-Exempt Device 1	
Name:	Discovery MI
Description:	Digital PET/CT scanner, that is FDA approved.

6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

a. Investigational Drugs, Biologics, Reagents, or Chemicals

Investigational Product 1	
Name:	Ga-68 PSMA
Dosage:	3-5 mCi
Administration Route:	i.v.
Investigational Product 2	
Name:	Ga-68 RM2
Dosage:	140 MBq
Administration Route:	i.v.

b. Commercial Drugs, Biologics, Reagents, or Chemicals

Commercial Product 1	
Name:	F-18 FDG
Dosage:	10-12 mCi
Administration Route	i.v.
New and different use? (Y/N)	No
Commercial Product 2	
Name:	F-18 NaF
Dosage:	5-10 mCi
Administration Route	i.v.

New and different use? (Y/N)	No
Commercial Product 3	
Name:	Ga-68 DOTA TATE
Dosage:	5-7 mCi
Administration Route	i.v.
New and different use? (Y/N)	No

7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

N/A

8. PARTICIPANT POPULATION

a. Planned Enrollment

300 adult participants will be enrolled at Stanford. Participants will be clinical patients who are scheduled for a standard of care or research PET/CT.

b. Age, Gender, and Ethnic Background

All age ranges of adult population (> 18-years old) will be recruited. Both men and women will be recruited. All ethnic background will be recruited. No healthy volunteers will be recruited. Pregnant women will be excluded because pregnancy is a contraindication for a PET/CT study.

c. Vulnerable Populations

No potentially vulnerable patients will be entered into this study.

d. Rationale for Exclusion of Certain Populations

We are not excluding any minorities; we are not excluding women due to their gender, only if they are pregnant or breastfeeding, to protect the fetus or baby.

e. Stanford Populations

No laboratory personnel, employees, and/or students will be recruited for this protocol.

f. Healthy Volunteers

No healthy volunteers will be included into this study.

g. Recruitment Details

Potential participants will be identified from the PET/CT schedule in Nuclear Medicine (patients referred for standard or research PET/CT). Therefore a Waiver of Authorization for Recruitment will be applied for in the relevant section.

3 days+ in advance of scan, fellows/coordinators would identify patients that qualify based on data in the medical record.
2 days in advance, technologist or Nuc Med physician call patients to prep patients for the scan and ask whether a fellow/coordinator can contact them about the study.

1 day in advance, if they agree to be contacted, a fellow or coordinator would discuss the study with them.
Day of the scan, if they are still a candidate, fellow/coordinator will discuss further with them, answer questions, and sign informed consent.

h. Eligibility Criteria

i. Inclusion Criteria

- Patient is ≥ 18 years old at the time of the scan
- Patient provides written informed consent
- Patient is referred for standard or research (68Ga PSMA or 68Ga RM2) PET/CT
- Patient is capable of complying with study procedures
- Patient is able to remain still for duration of imaging procedure (approximately 60 minutes total for both PET/CT)

ii. Exclusion Criteria

- Patient is < 18 years old at the time of the drug administration
- Patient is pregnant or nursing

i. Screening Procedures

Patients will be identified from the PET/CT schedule in Nuclear Medicine. Therefore a Waiver of Authorization for Recruitment will be obtained in the relevant section.

j. Participation in Multiple Protocols

As part of the consent form process the patient will be asked if they are participating in a concurrent research protocol. Those enrolled in the Ga68 PSMA or Ga58 RM2 protocols will be allowed to participate.

k. Payments to Participants

Patients will be paid $[redacted] for participation in this study.
The second PET/CT will add up to 60 minutes to the patients' scheduled PET/CT visit. Given the construction delays and parking situation at Stanford, the investigators felt that the participants need to be compensated for their time and effort. We consider $[redacted] an appropriate amount given the above reasons, in line with other studies and not undue pressure on participants

l. Costs to Participants

There will be no costs for participating in this study.

m. Planned Duration of the Study

The screening part of the study will involve a phone call. This will take approximately 15 minutes. The first PET/CT will take up to 90 minutes of the subjects time. This includes 1 hour tracer uptake time and the 30 minutes scan. The second scan will take up to another 60 minutes. (iii) Analysis of the participant data may take up to 6 months.

9. RISKS

a. Potential Risks

i. Investigational devices

N/A

ii. Investigational drugs

This research study involves exposure to radiation.

The effective dose from one typical 140 MBq administration of 68Ga-PSMA is 4.36 mSv, approximately equal to 10% of the limit that radiation workers (for example, a hospital x-ray technician) are allowed to receive in one year.

The amount of radiation from one 68Ga-RM2 PET is 4.76 mSv, approximately equal to 10% of the limit that radiation workers (for example, a hospital x-ray technician) are allowed to receive in one year.

This amount of radiation involves minimal risk and is necessary to obtain the research information desired. This is captured in the ICF for the PSMA and RM2 protocols.

iii. Commercially available drugs, biologics, reagents or chemicals

The administration of the radioactive substance will feel like a slight pinprick when given by intravenous injection. The subjects will not feel anything related to the radioactivity of the substance in their body. Because the radioactivity is very short-lived, the radiation exposure is low. The substance amount is so small that it does not affect the normal processes of the body.

iv. Procedures

No procedures will be performed.

v. Radioisotopes/radiation-producing machines

Patients who are claustrophobic may feel some anxiety while positioned in the scanner. Also, some patients find it uncomfortable to hold one position for more than a few minutes.

This research study involves exposure to radiation from one additional CT for attenuation correction in the digital PET/CT. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation exposure is about 3 mSv, which is approximately equal to 6% of the limit workers exposed to radiation are allowed to receive in one year. This amount of radiation involves minimal risk and is necessary to obtain the research information desired.

vi. Physical well-being

Low risk.

vii. Psychological well-being

Low risk.

viii. Economic well-being

Low risk.

ix. Social well-being

Low risk.

x. Overall evaluation of risk

Low risk.

b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

We do not anticipate hazardous situations for the subjects as a result of this protocol. However, procedures will be in place for verification of correct radiopharmaceutical dose and route of administration (i.e., each dose will be double checked for dosimetry and quality by a researcher and technologist). The Protocol Director may withdraw subjects from the study for one or more of the following reasons: failure to follow the instructions of the Protocol Director and/or study staff; determination that continuing the participation could be harmful to the subject; the study is cancelled or other administrative reasons.

The studies will be performed in a medical setting, under researchers' supervision. Crash cabinets will be available for emergencies.

All computers, external hard disks, USB thumbs, tablet computer, smart phone - any electronic devices that contain identifiable subject data - are encrypted in addition to password protected.

d. Study Conclusion

The experiment will terminate when all subjects will have the scans done.

The Protocol Director may withdraw subjects from the study for one or more of the following reasons: failure to follow the instructions of the Protocol Director and/or study staff; determination that continuing the participation could be harmful to the subject; the study is cancelled or other administrative reasons.
The studies will be performed in a medical setting, under researchers' supervision. Crash cabinets will be available for emergencies.

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

Informed consent was properly obtained, any required pre-study tests and procedures were obtained within the designated pre-treatment time interval, Eligibility criteria were accurately met, Appropriate and timely reporting of adverse events (AEs) and

serious adverse events (SAEs) to the IRB, Adherence to subject follow-up requirements.

ii. Person(s) responsible for Data and Safety Monitoring

GE is the monitoring entity because GE is the Study Sponsor. The monitoring visits will be conducted by a GE Clinical Research Associate (CRA).

iii. Qualifications of person(s) responsible for Data and Safety Monitoring

The GE Clinical Research Associate (CRA) has extensive experience in overseeing such trials.

iv. Safety Reporting

PD must notify the Sponsor and FDA of any study-related death or life-threatening event via telephone or email within 24 hours of learning of the event,
The GE Clinical Research Associate (CRA) will determine frequency of visits and meetings depending on accrual.

Data and safety monitoring activities and continuing study reviews take place until all subjects have been accrued.

v. Specific triggers or stopping rules

vi. Studies that received a rating less than satisfactory during the initial auditing review a re reviewed again by the ME on a case-by-case basis. Any follow-up recommendations such as a corrective action plan or re-auditing are based upon the results of the auditing review. For example, additional patient eligibility monitoring is performed if one or more of the patients were found to be ineligible. Findings such as the type and degree of protocol deviations or violations, unreported serious adverse events, and investigational drug medication errors may also warrant further review. A corrective action plan requires a prompt response by the PI. Once the ME determines that the corrective action plan is adequate to ensure subject safety, re-auditing is determined by the rate of subject accrual.DSMB Reporting

Internal Reporting
When the GE Clinical Research Associate (CRA) recommends suspension or study closure, they will notify principal investigators, study coordinators, and other organizations such as the IRB, as appropriate.

Confidentiality Procedures
Industry studies are considered proprietary to the sponsor. Any outcome results are strictly confidential and must not be divulged to anyone who is not a member of the sponsor monitoring entity except as specified above. The sponsor monitoring entity maintains the integrity of the data and records by keeping all source documentation in a secure locked office.

vii. Will the Protocol Director be the only monitoring entity? (Y/N)

No

viii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

No

f. Risks to Special Populations

N/A

10. BENEFITS

Understanding the imaging characteristics of the digital PET/CT scanner can potentially improve the patient care, improving the image quality, by scanning the patients most suitable for the individual scanner.

11. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.