^{68}Ga Labeled Peptide PET/CT: Current Status and Promising Developments

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October 12, 2013

MIPS
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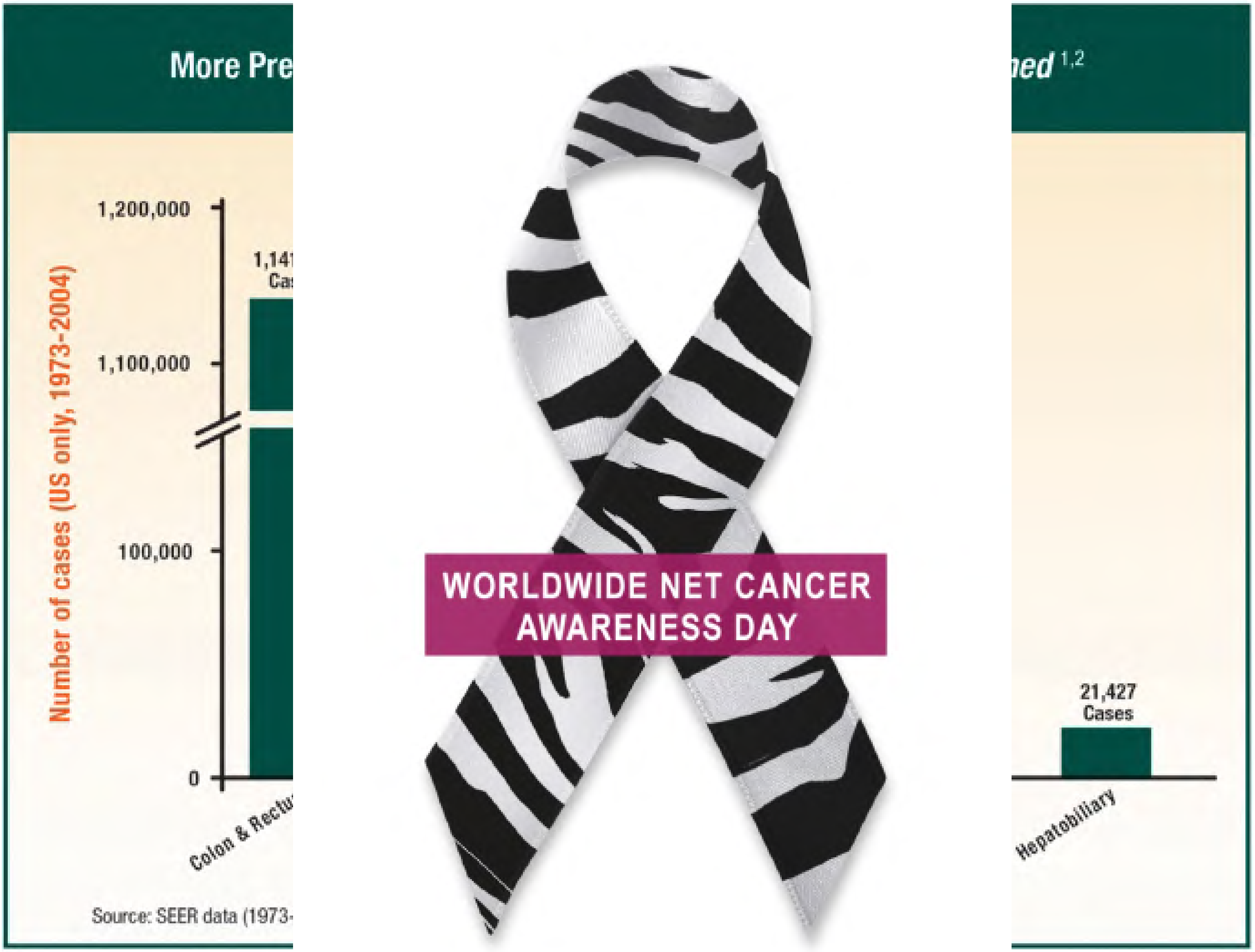
School of Medicine
Department of Radiology

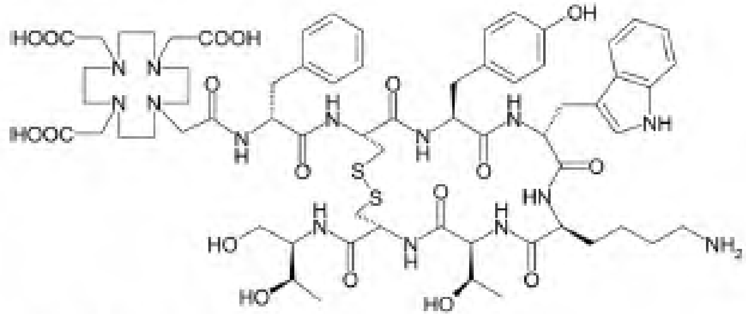
Neuroendocrine Tumors



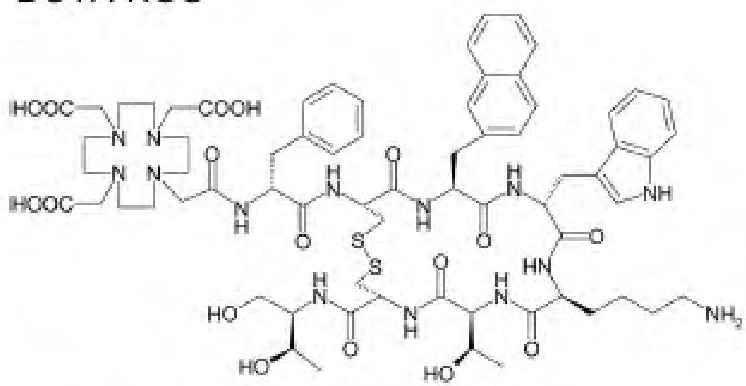
Peptide Receptor Radionuclide Imaging

- The radiolabeled peptides serve as vehicles for guiding the radioactivity to tissues expressing their corresponding receptor, in this case to cancer cells
- The peptides are specifically targeted to receptors on cancer cells
- PRRT has little or no damage to normal tissue

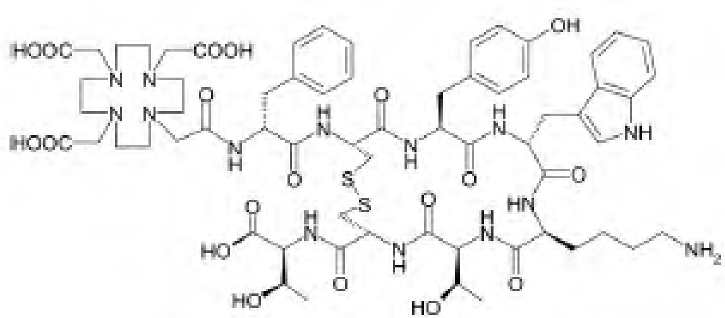
DOTA-TOC

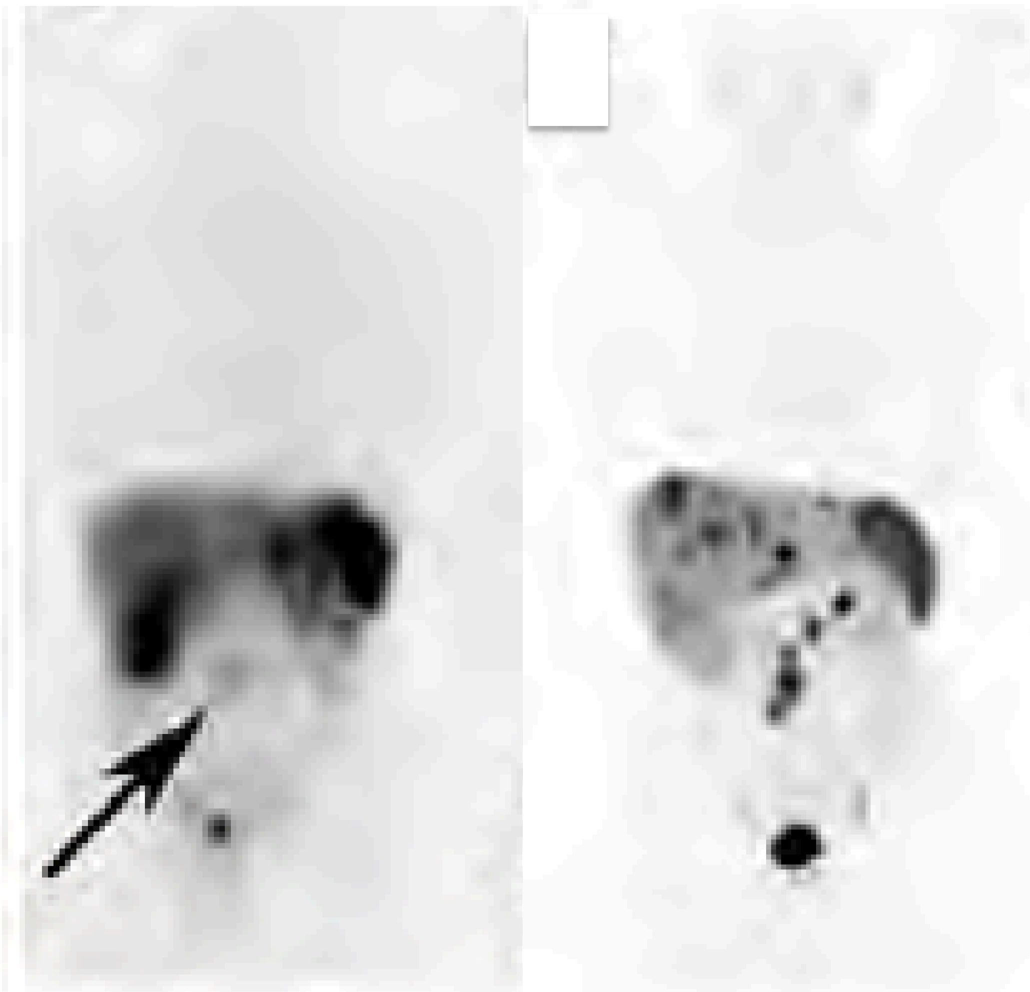


DOTA-NOC



DOTA-TATE





69 year-old man with NET. ^{111}In Octreoscan (left; current standard of care) shows a single cancer lesion (arrow), while ^{68}Ga DOTA-TATE PET (right) shows multiple lesions in the same patient.

Comparison of ^{68}Ga-DOTATOC PET and ^{111}In-DTPAOC (Octreoscan) SPECT in patients with neuroendocrine tumours

I. Buchmann · M. Henze · S. Engelbrecht ·
M. Eisenhut · A. Runz · M. Schäfer · T. Schilling ·
S. Haufe · T. Herrmann · U. Haberkorn

- ^{68}Ga DOTA TOC PET/CT is superior to ^{111}In-DTPA Octreoscan® SPECT in the detection of NET manifestations in the lung and skeleton and similar for the detection of NET manifestations in the liver and brain

- ^{68}Ga DOTA TOC PET is advantageous in guiding the clinical management

Cost comparison of ^{111}In-DTPA-octreotide scintigraphy and ^{68}Ga-DOTATOC PET/CT for staging enteropancreatic neuroendocrine tumours

Nils F. Schreiter • Winfried Brenner • Munenobu Nogami • Ralph Buchert • Alexander Huppertz • Ulrich-Frank Pape • Vikas Prasad • Bernd Hamm • Martin H. Maurer

- ^{68}Ga DOTA TOC PET/CT was considerably cheaper than ^{111}In-DTPA-octreotide with respect to both material and personnel costs

- Furthermore, by using ^{68}Ga DOTA TOC PET/CT considerably fewer additional examinations were needed reducing the consequential costs significantly

Functional Imaging of Neuroendocrine Tumors With Combined PET/CT Using ^{68}Ga-DOTATATE (Dota-DPhe^{1},Tyr^{3}-octreotate) and ^{18}F-FDG

Irfan Kayani * Jamshed B. Bomanji * Ashley Groves * Gerard Conway * Sveto Gacinovic * Thida Win * John Dickson * Martyn Caplin * Peter Joseph Ell

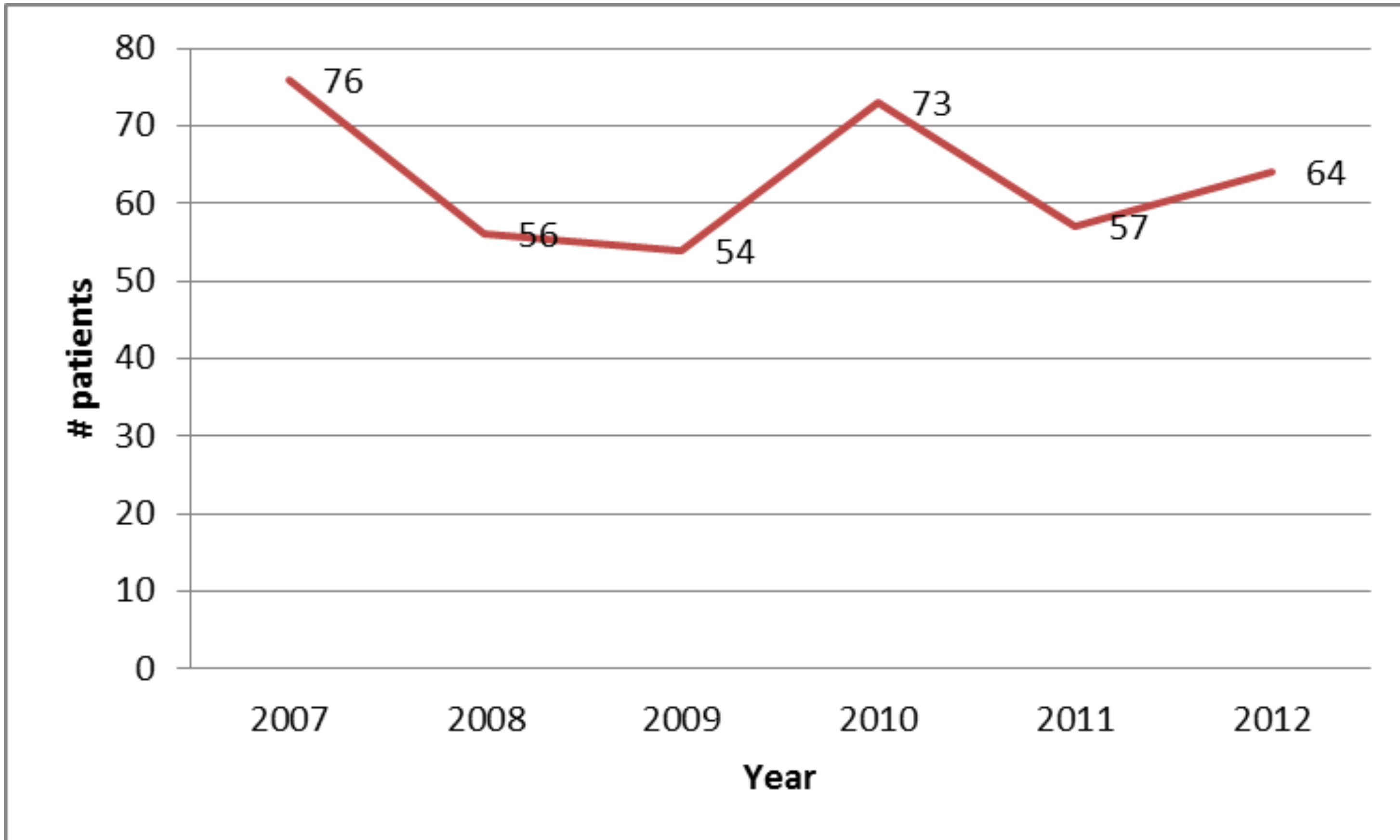
- ^{68}Ga DOTA TATE PET/CT is a useful imaging modality for NETs and is superior to ^{18}F FDG for imaging well-differentiated NET
- Functional imaging with both ^{68}Ga DOTA TATE and ^{18}F FDG has potential for a more comprehensive tumor assessment in intermediate and high-grade tumors

Why Did Stanford Get Involved?

- Luthatera® and the corresponding diagnostic ^{68}Ga DOTA TATE PET/CT are not yet widely available clinically in the United States

- In line with SHC and SoM mission:
  - ✓ Advance medicine through research and innovation
  - ✓ Provide cutting-edge therapy
  - ✓ Be a leader locally and nationally
  - ✓ Improve patient care and access to care

Yearly ^{111}In Octreoscan® Exams Done at Stanford



Financials: ^{68}Ga DOTA TATE PET/CT

Startup Costs, Year 1	
Charles River Endosafe PTS System	$5,000
Bioscan radiochemistry TLC	$25,000
Eckert & Ziegler Radiochemistry Module	$85,000
^{68}Ga Generator	$35,000
Startup Costs (Year 1)	**$150,000**

Financials: ^{68}Ga DOTA TATE PET/CT

Based upon the results of my testing and conversations with the client, I can conclude that costs included in the client's calculations tie to the documentation supplied. Furthermore, all formulae prepared by the client have been recalculated and are correctly applied to the cost calculation.

With regard to the application of costs associated with this IND, I can conclude that the calculation is consistent with the requirements of paragraphs (d)(1) of *Code of Federal Regulations, Title 21, Volume 5, Part 312, Section 312.8*.

This report is intended solely for the use of Stanford University in connection with its cost recovery application with the FDA and should not be used by anyone else for any other purpose.

Patricia Noll

Patricia D. Noll, CPA
Noll Accounting, LLC
September 27, 2013

Total Production Cost/Scan $\boxed{\$\ 3,408.89}$


Hochempfindlich
Elektrogeräte
LIEFERSCHEIN
PACKING LIST
Eckert & Ziegler
Eurotope
PAKLIJST
LISTE DE COLISAGE
BOLLA DI CONSEGNA
LISTA DOS VOLUMES
FØLGESEDDEL
PACKSEDEL
DOWÓD DOSTAWY
УПАКОВОЧНЫЙ ЛИСТ
Dear customer,

- Molecular imaging must be accepted as not just good science but also as central to routine patient management in personalized medicine

- There is an urgent need to reduce the cost (i.e., time and money) of developing imaging agents for routine clinical use

- The mismatch between the current regulations and personalized medicine includes molecular imaging and requires the engagement of the regulatory authorities to correct it

- Various regulatory, financial, and practical barriers that must be overcome to achieve this aim

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

"Advocates of evidence based medicine have criticized the adoption of interventions evaluated by using only observational data

We think that everyone might benefit if the most radical protagonists of evidence based medicine organized and participated in a double blind, randomized, placebo controlled, crossover trial of the parachute"

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomized controlled trials

BMJ. 2003 Dec 20;327(7429):1459-61.

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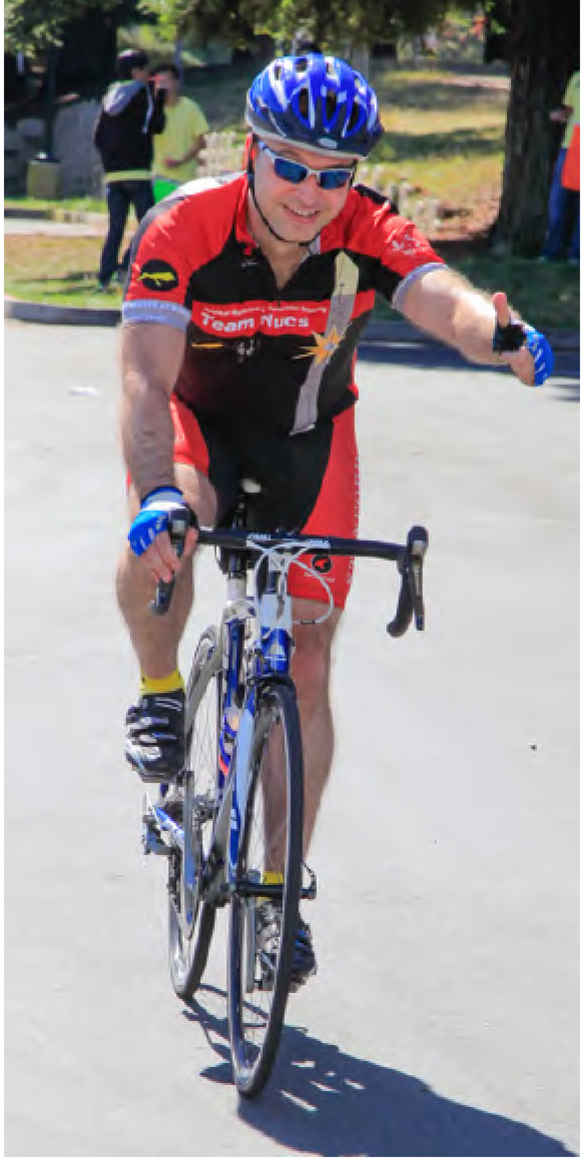

Thank you!