

Northern California CarciNET Community



Net Cancer Day Webinar

The webinar will start shortly – Please make sure to dial in using the numbers provided or in the upper right hand side of the screen select “Switch to Interactive Meeting” to enable audio on your computer.

If you have questions you are interested in asking please send them to contactus@norcalcarcinet.org - we regret that not all will be able to be answered.

Agenda

- ✦ Survey results
- ✦ Introductions
- ✦ 3 Discussion Questions
- ✦ Questions

Northern California CarciNET Community



Patient Advocates



✦ Bill Claxton

✦ Founder of CNETS Singapore

✦ Josh Mailman

✦ President of NorCal CarciNet Community

✦ Chair of Patient Advocate Board Society of Nuclear
Medicine and Molecular Imaging

Neuroendocrine Tumor Clinics Program

Director: Thomas M. O'Dorisio

Co-Director: M. Sue O'Dorisio



- 1500 UIOWA Institutional Review Board (IRB) Registered Subjects
- **Six** dedicated NET clinics weekly, multi-disciplined with Endo-Oncology, Endocrine Surgery, GI Medical Oncology (ALL in same clinic “Pod”)
- 1,300 patient-visits yearly
- An FDA-Investigator New Drug (IND) – Two Trials with Ga⁶⁸-DOTATOC-PET (P.I. M. Sue O’Dorisio – Richard Baum, Consultant)
- An FDA-IND for large clinical trial (Phase II) with y⁹⁰-DOTATOC PRRNT, in Children, Adolescents, and Adults

Neuroendocrine Tumor Clinic

Vanderbilt University Medical Center

Leaders: Eric Liu, Ronald Walker, Jeff Clanton



- ✦ Multidisciplinary Team (weekly meetings)
- ✦ Advanced Surgical, Medical, and Imaging for Neuroendocrine
- ✦ Collaboration with European Centers
- ✦ First use of ^{68}Ga PET/CT Imaging for NET in U.S.
- ✦ Clinical Trials for NETs
- ✦ Treatment for Adults and Children



Zentralklinik Bad Berka

ENETS Center of Excellence since 2011

Richard P. Baum



- ✦ >1200 NET patients' visits/year
- ✦ 15 MDs involved directly in care of NET patients
- ✦ 500 Peptide Receptor-mediated Radionuclide Therapies (PRRT) per year
- ✦ THERANOSTICS Research Center (and THERANOSTICS School in statu nascendi)

Molecular Radiotherapy & Imaging (PET/CT Center)
specialized nuclear medicine ward, medical physics and GMP radiopharmaceutical facilities
radiopharmacy Center
Int. Medicine, Endocrinology, Gastroenterology, Oncology,
Abdominal, Thoracic, Spinal and Heart Surgery
Radiology, Interventional Radiology



PET/CT Center & NM Department

Nuclear Medicine Ward (22 beds for RN treatment)



Agenda

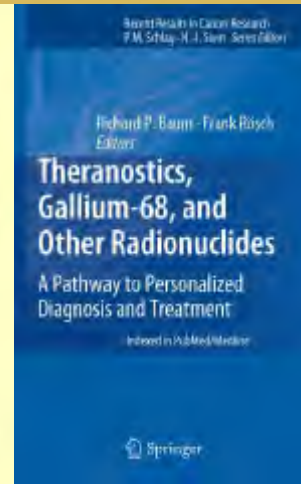
- ✦ Survey results
- ✦ Introductions
- ✦ **3 Discussion Questions**
- ✦ Questions

Northern California CarciNET Community



Question 1: Education / Knowledge Transfer

- ✦ All of your centers and staff have spent considerable amounts of time and travel to conferences and other educational events - (over a million miles this year alone) - Can you share with us some of the outcomes of these meetings and how they impact the nets community.



Vanderbilt



68Ga-DOTATATE PET Scan in Neuroendocrine Cancer

This study is currently recruiting participants.

Verified November 2012 by Vanderbilt University

Sponsor:
Vanderbilt University

Information provided by (Responsible Party):
Eric H Liu, Vanderbilt University

ClinicalTrials.gov Identifier:
NCT01396382

First received: July 11, 2011
Last updated: April 9, 2013
Last verified: November 2012
History of Changes

Clinical efficacy analysis: Change of patient's management 80 patients (2011-13)

No impact: 48% of patients

Inter-modality change: 42% (33/80)

Candidates for surgery: 15% (12/80), 2/3 UP

Not candidates for surgery: 4% (3/80), 1/9 diagnosis

Candidates for PRRT: 20% (16/80)

Not candidates for PRRT: 3% (2/80)

Intra-modality change: 10% (8/80)

Change in surgical plans: 3.5% (3/80)

Additional PRRT: 3.5% (3/80)

Refer to endoscopic ultrasound: 3% (2/80)

Conclusions: change in patient's management

Restaging NET: 57% (40/70)

Diagnosis: 11% (1/9)

Search Orphan Drug Designations and Approvals

FDA Home Developing Products for Rare Diseases & Conditions

Return to Orphan Designation Search Page

Generic Name:	Gallium-68 (DOTA-D-Phe-Tyr3)octreotide
Trade Name:	n/a
Date Designated:	10-23-2013
Orphan Designation:	The management of neuroendocrine tumors
Orphan Designation Status:	Designated
FDA Orphan Approval Status:	Not FDA Approved for Orphan Indication
Sponsor:	Society of Nuclear Medicine & Molecular Imaging 1850 Samuel Morse Drive, Reston, VA 20190-5316



University of Iowa

Safety and Efficacy of 68Ga-DOTA-tyr3-Octreotide (GA-68)

This study is currently recruiting participants.

Verified June 2012 by University of Iowa

Sponsor:
University of Iowa

Information provided by (Responsible Party):
O'Donoghue, M S, University of Iowa

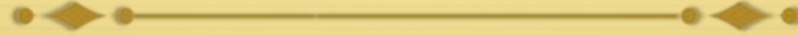
ClinicalTrials.gov Identifier:
NCT01619865

First received: June 12, 2012
Last updated: NA
Last verified: June 2012
History: No changes posted

GA-68 DOTATOC positive in only 1/22 patients presenting with symptoms / labs suggestive of elevated serotonin without diagnosis of NET (false positive)

GA-68 DOTATOC identified primary tumor in 14/20 pts with metastatic disease, 7 have gone to surgery to remove primary. 2 others confirmed by biopsy. Conventional imaging found 3.

Question 2: What is Next?



- ✦ Where are the breakthroughs coming from for NETs - what areas and what are the drivers.

Comparison of ^{177}Lu -DOTATATE and ^{177}Lu -DOTA-JR11 dosimetry

Patient with NEC (G3) of the bladder with lymphnode and uterus metastases, shows progression after surgery and treatment with Somatostatin analogues

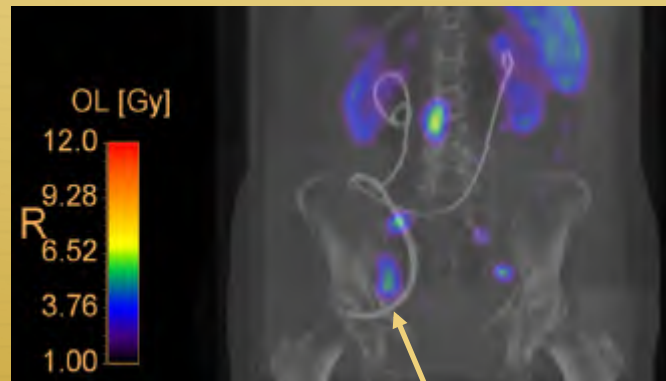
^{68}Ga -DOTA-TATE PET



Limited kidney function
Creatinine clearance: 54 ml/min
(norm 90 – 179 ml/min)



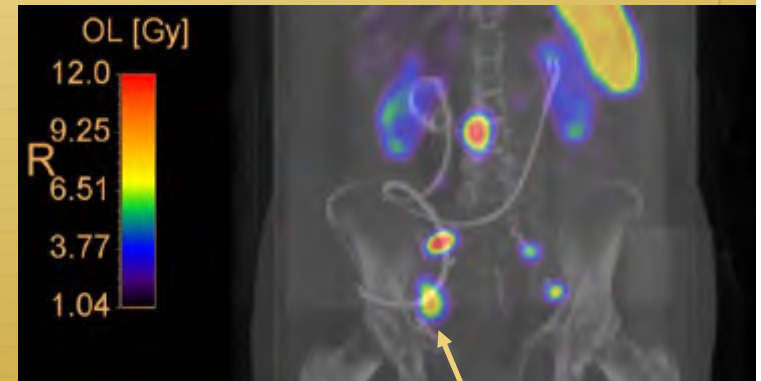
^{177}Lu -DOTA-TATE (Agonist)
Isodose curves based on
3D voxel dosimetry analysis



mean dose: 1.4 Gy/GBq
Tumor-to-kidney
dose ratio: 1.1

sst_2 affinity profile (IC_{50})
 0.7 ± 0.15 nM

^{177}Lu -DOTA-JR11 (Antagonist)
Isodose curves based on
3D voxel dosimetry analysis

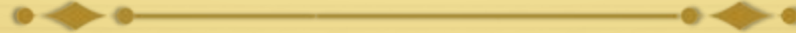


mean dose: 5.7 Gy/GBq
Tumor-to-kidney
dose ratio: 2.5

sst_2 affinity profile (IC_{50})
 1.5 ± 0.4 nM

Courtesy Damian Wild

Question 3: When to search for more expertise

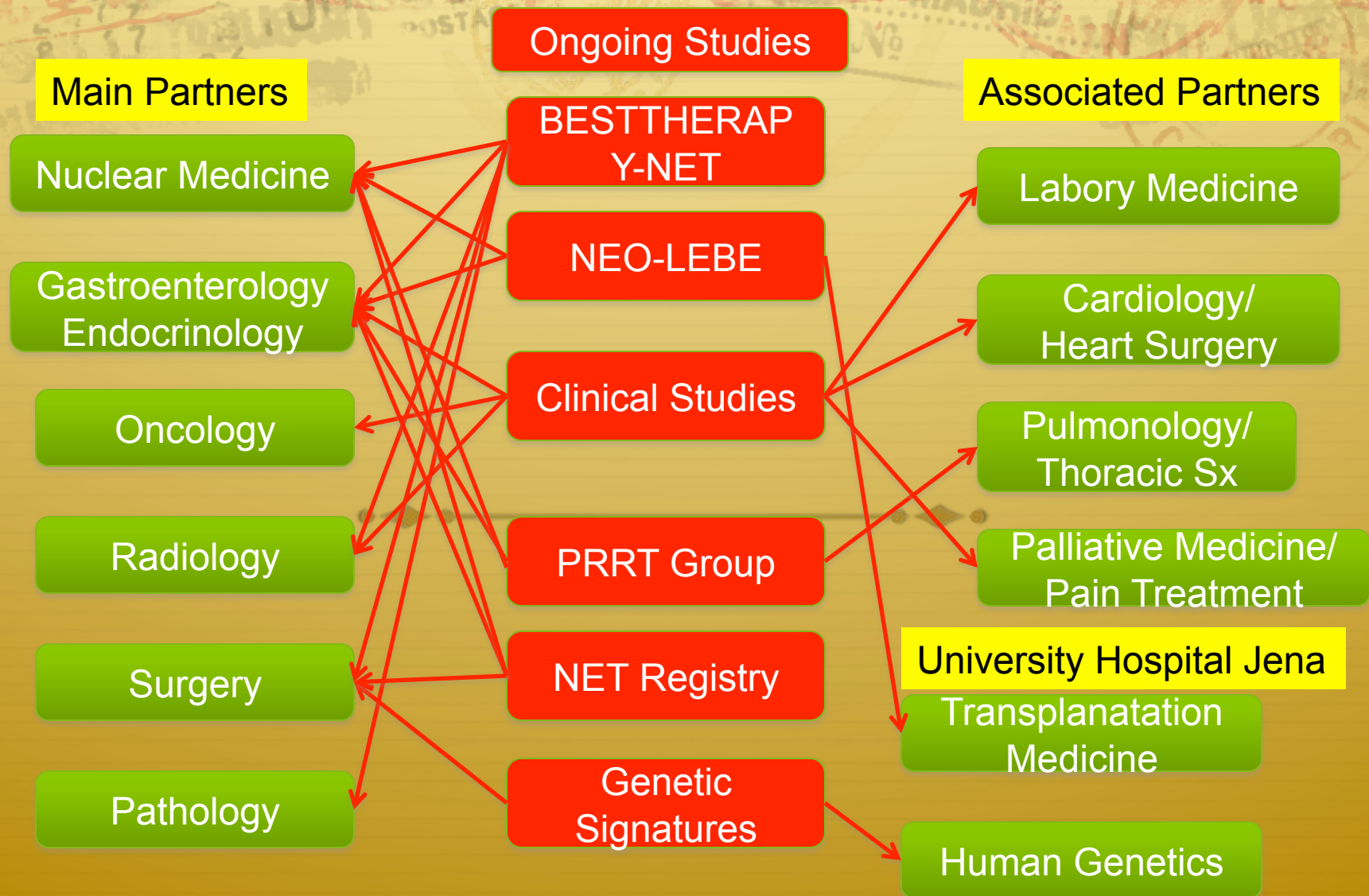


- ✦ From a clinicians view what factors should patients weigh when selecting a center for care - when do they need to consider traveling

ENETS Center of Excellence Structure



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