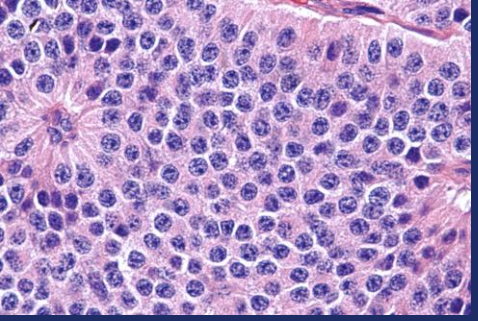
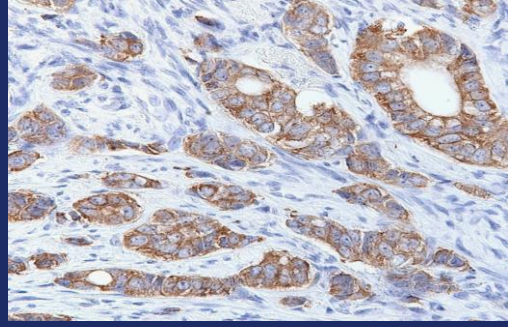
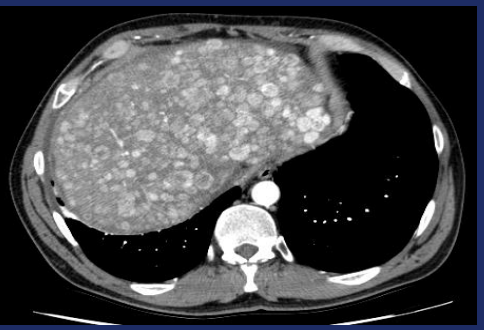


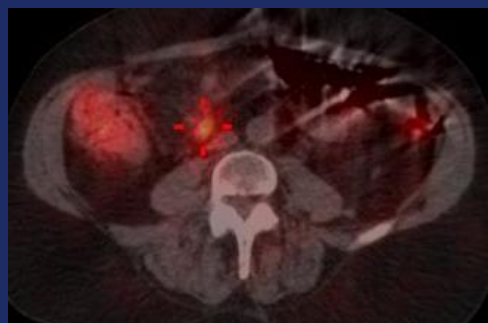


NET Trials

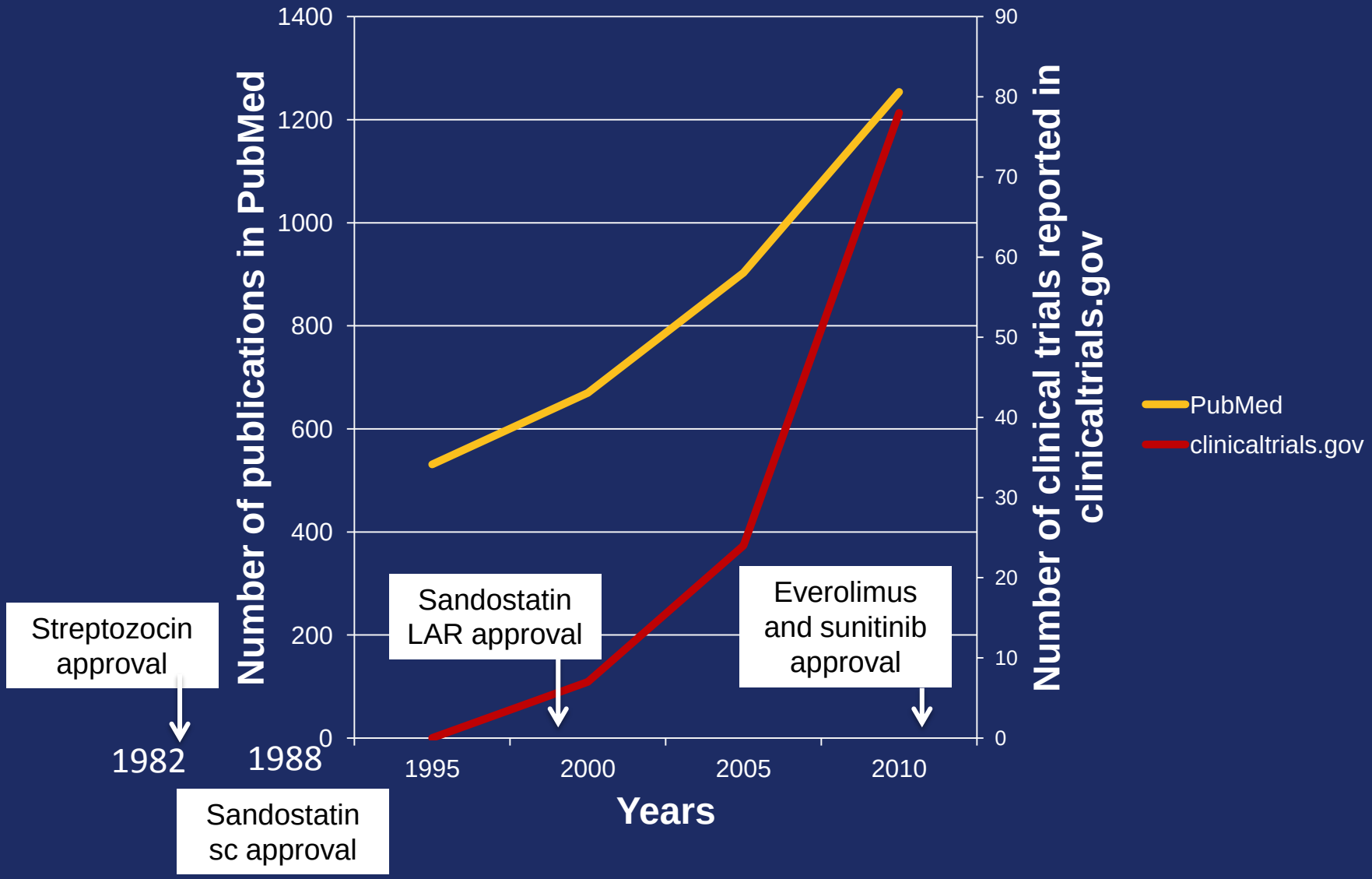
George Fisher

Stanford University





The state of NET research

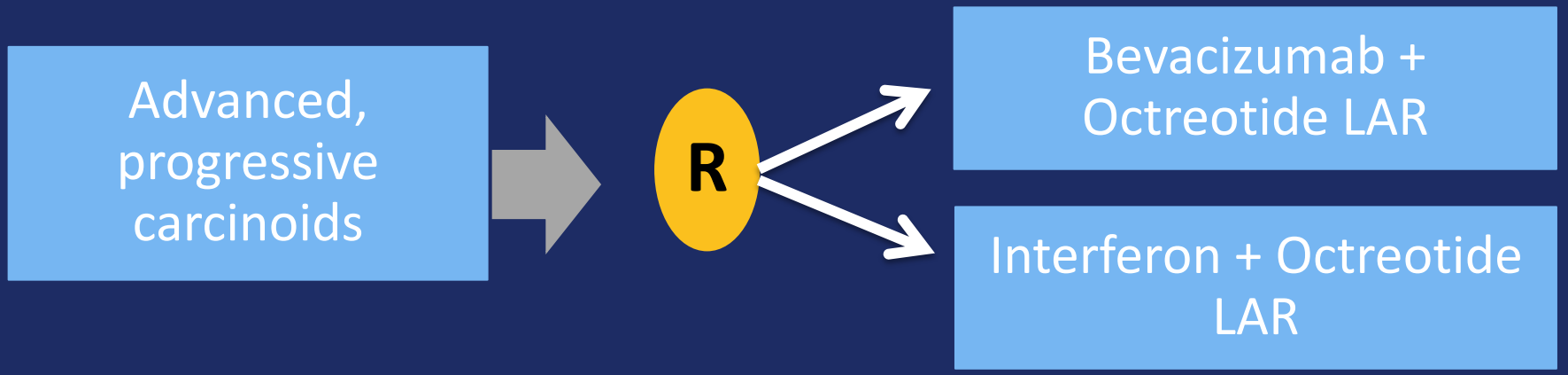


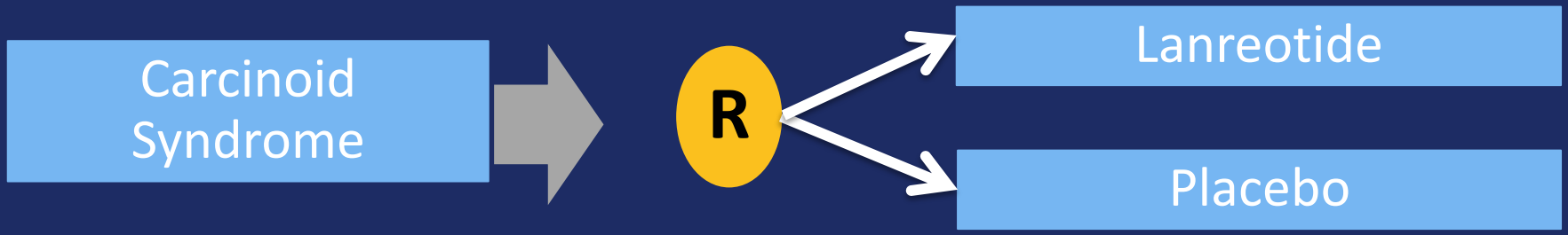
Sources of clinical trials

Investigator Initiated	Industy Initiated	Cooperative Group
• Often smaller Ph I/II • Usually available at a single academic institution • Idea is initiated by academic MD • Funding and/or drug supply from industry	• Ph I, II or III • Usually involves many sites and sometimes international • Idea is initiated by industry • Funding from pharmaceutical company	• Ph I, II or III • Sponsored by NIH /National Cancer Institute • Open at centers participating in a cooperative group (i.e. ECOG, SWOG, ALLIANCE) • Funding is federal

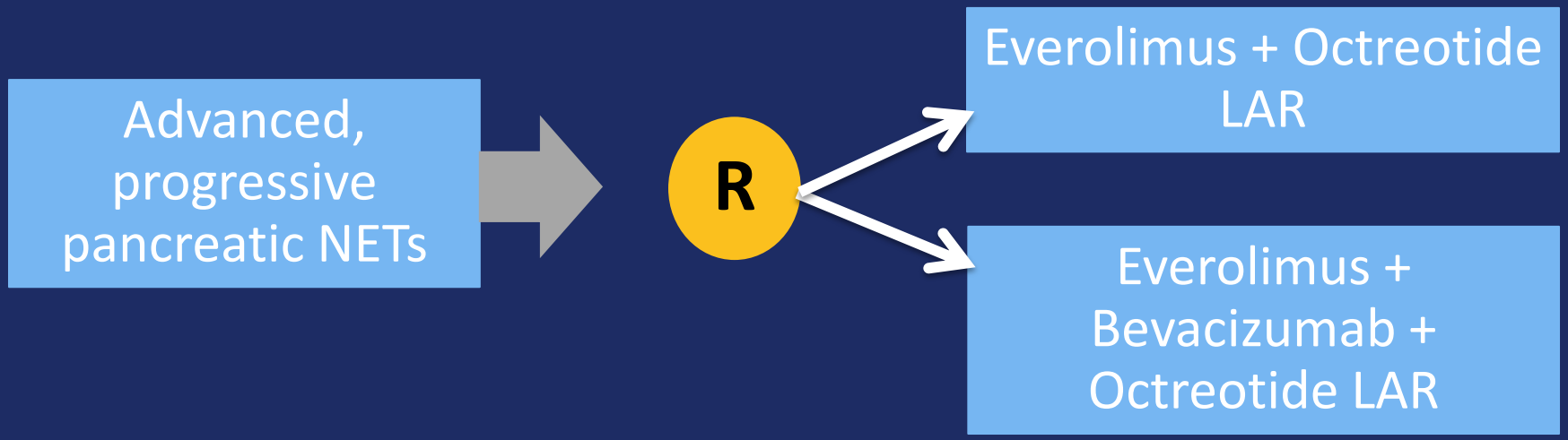
www.clinicaltrials.gov

Closed Carcinoid Trials Awaiting Results





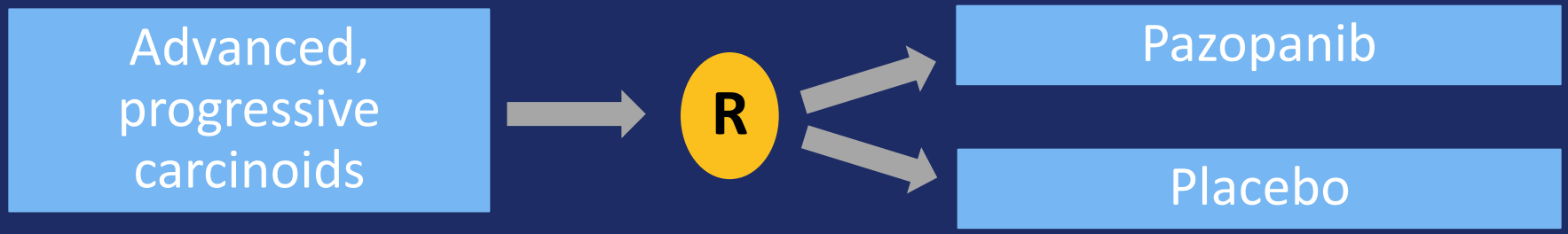
Closed PNET Trial Awaiting Results



Trials in development

What's next for carcinoid tumors?

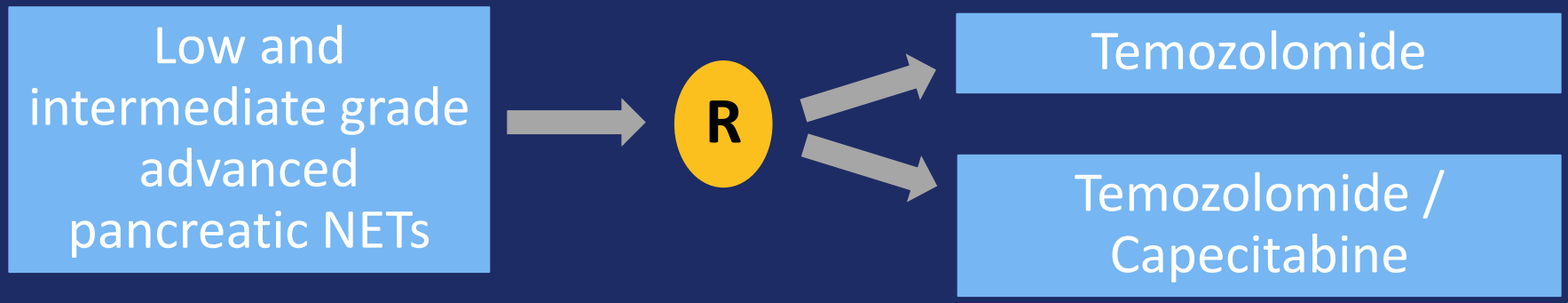
CALGB 81103 (Bergsland PI): Phase II, 1° endpoint PFS



Trials in development (2)

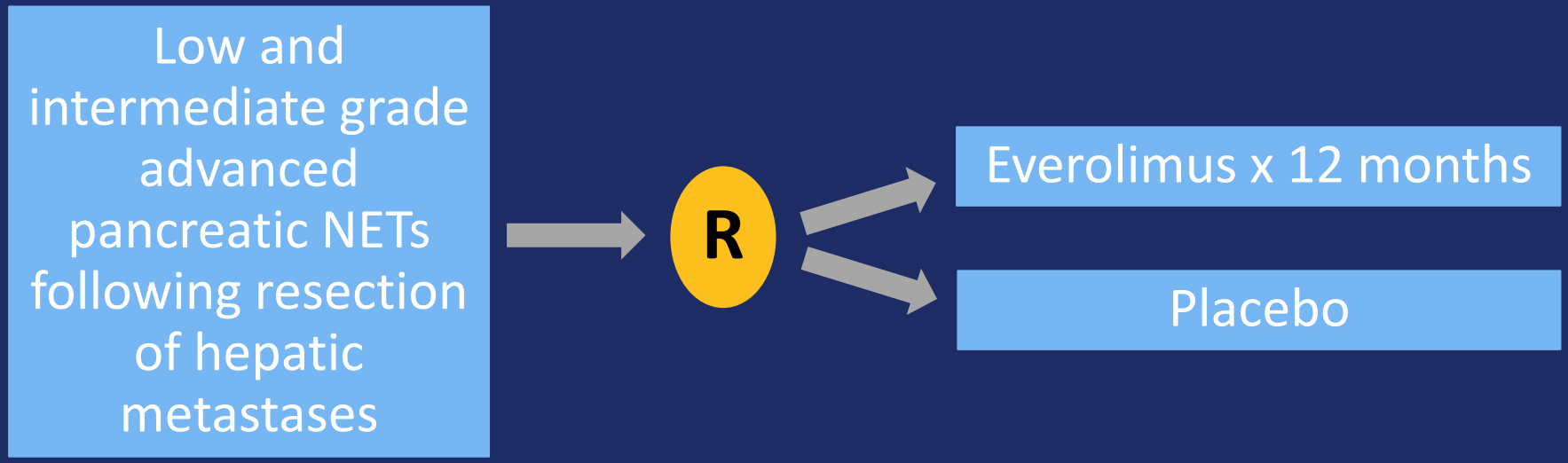
Can we define a standard cytotoxic chemotherapy for pNETs?

ECOG 2211 (Kunz PI): Phase II, 1° endpoint PFS



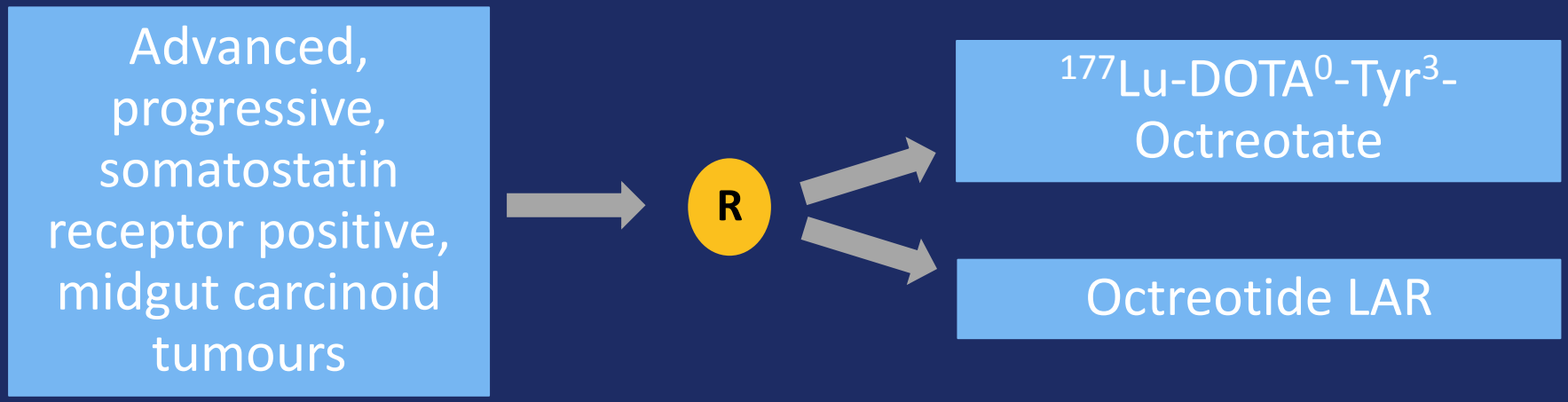
Trials in development

Is there a role for post-operative therapy in pNETs?



Trials in development

Is PRRT ever going to be available in the US?



UCSF NET Trials

- Phase II inhibitor of blood vessels, Axitinib in carcinoid
- Phase I/II inhibitor of mTOR (C223) in solid tumors
- Safety profile assessment of theraspheres for treatment of metastatic liver disease from primary NET

Stanford NET Trials

- Phase II Temodar, Capecitabine, Bevacizumab in PNET
- Phase II mTOR and PI3K inhibitor BEZ235 vs. placebo in PNET*
- Phase III ^{177}Lu-DOTA^{0}-Tyr^{3}-Octreotate vs. Octreotide in carcinoid tumors*
- Phase III Telotristat vs. Placebo for carcinoid syndrome*
- NET Registry database

* Opening soon

Cedars Sinai Trials

- Phase II: Pasireotide in NETs
- Phase I dose escalation of pasireotide in NETs
- Phase III Randomized trial of everolimus vs. placebo in carcinoid
- Phase I/II inhibitor of mTOR (C223) in solid tumors

NET Registry

- A NET Registry will allow researchers to identify connections between the molecular characteristics of tissue samples and the patient data associated with individual disease progression, and to test and validate correlation hypotheses.

Eligibility

- Possible participants must meet three criteria to be eligible for the Registry:
  - Current or past diagnosis of NET
  - 18 years of age or older
  - Adequate English proficiency to complete online consent and questionnaire or the ability to understand and the willingness to sign a written informed consent document in native language.
  - Note: You do not need to be a Stanford patient to participate

The logistics

Patient contacted to schedule meeting with research assistant prior to regular clinic visit

STANFORD UNIVERSITY – RESEARCH CONSENT FORM

Protocol Title: A registry of clinical information for patients with neuroendocrine tumors
Version number: v1.2
Protocol Director: Pamela Kunz, MD
Protocol Co Director: George Fisher, MD PhD
IRB Approval Date: 2/23/10
IRB Expiration Date: 1/31/11

Are you participating in any other research studies? _____ yes _____no

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug o… s differe… sonal doctor… th care. When … staff will follow … ithout compr…

Consent form reviewed and signed

Neuroendocrine Tumor Registry Patient Questionnaire

Page 1 of 21

Dear patient - We hope you will complete the questions on the following pages. Please try to complete all of the questions. If there are any questions that you do not understand or do not feel comfortable answering, please feel free to ask for assistance or to leave them blank. Thank you in advance for your participation. Sincerely, Your physicians, nurses and research staff in the Stanford Gastrointestinal Oncology Clinic

Patient demographic information

Study ID _____

Medical Record Number
This is an 8 digit number that may start with one or more 0s.
For example:01234567 _____

Last name _____

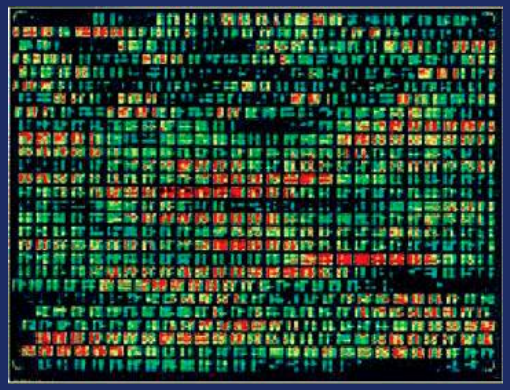
First name _____

Survey completed

Blood drawn

Future directions

- The NET Registry will connect the tumor tissue bank, databases containing clinical and epidemiologic data, clinical outcome data, and archived blood specimens.
- Will enable the rapid examination of future hypotheses and allow studies using tissue and clinical data
- The NET Registry is a tool that will lead to improved understanding of neuroendocrine tumor prevention, pathogenesis, and treatment.



Take home points

- Momentum in study of NETs
- Numerous active and developing clinical trials
- Double the accrual to trials and double the chance of finding a successful new treatment
- Participation in clinical trials is essential