



# Mathematical Statisticians at FDA's Center for Drug Evaluation and Research

Thomas E. Gwise, Ph.D.

Deputy Director Biometrics V

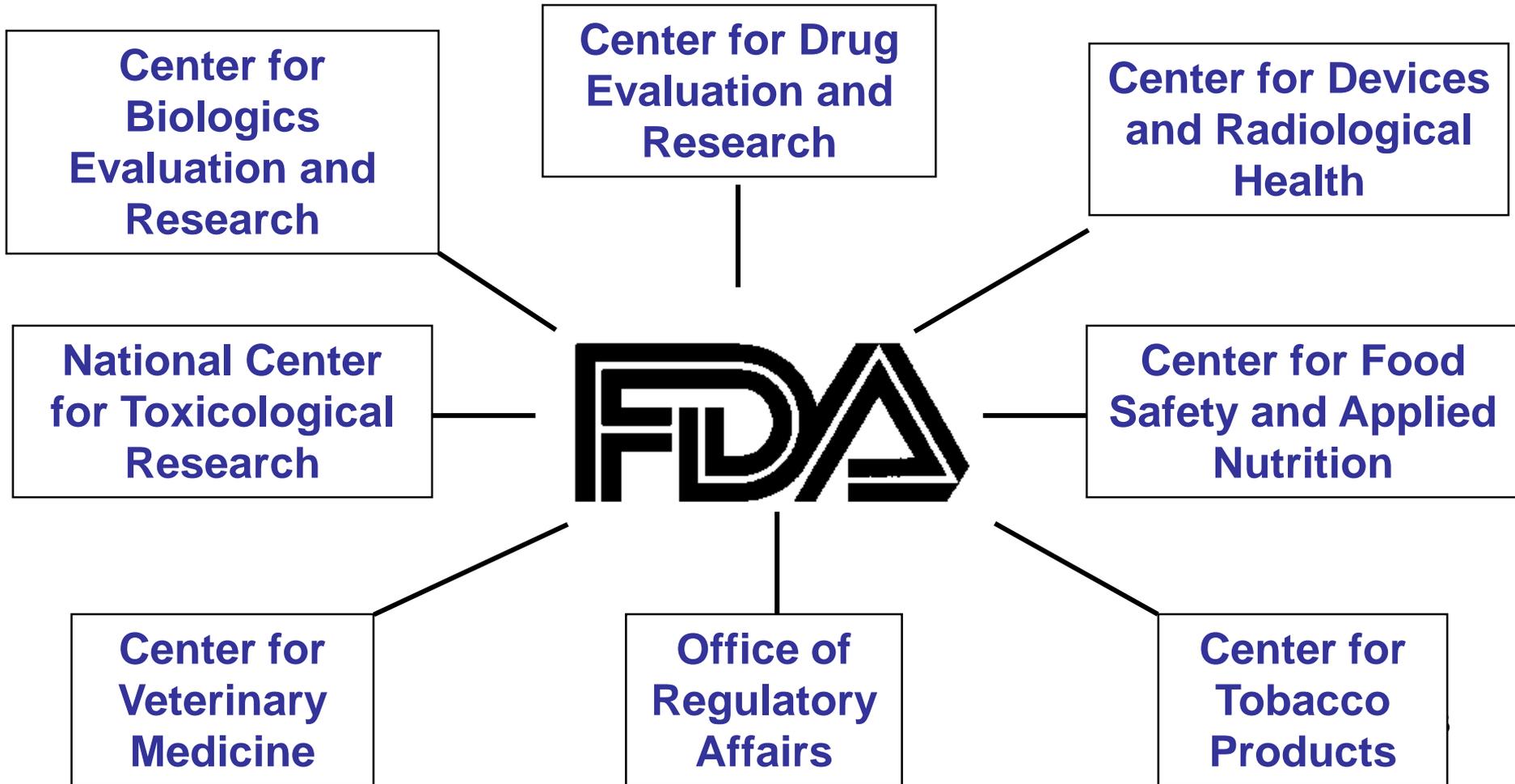
FDA/CDER/OTS/OB

# Overview

- Who is FDA
- Statisticians in FDA
- How and Why of FDA (drugs)
- Examples of our activities
  - Reviewing marketing applications
  - Research
- Hiring Process



# FDA Organization



# FDA (CDER)

- Ensures safety of food except for meat, poultry and some egg products;
- Ensures the safety and effectiveness of all drugs, biological products (including blood, vaccines and tissues for transplantation), medical devices
- Ensures the safety and effectiveness animal drugs and feed;
- Makes sure that cosmetics and medical and consumer products that emit radiation do no harm.

# Authority

- 1906 Pure Food and Drug Act
  - The Jungle
  - Reactionary
- 1938 Food Drug and Cosmetic Act
  - Elixer Sulfanilamide
  - Safety
- 1962 Kefauver-Harris Amendments
  - Thalidomide
  - Effectiveness
  - Studies

# CDER Statisticians

- Review clinical trial protocols
  - Advise FDA colleagues
  - Advise drug companies
- Review approval applications
  - New Drug Application (NDA)
  - Biologic License Application (BLA)
- Associated research

# Office of Biostatistics

Director: Lisa LaVange  
Deputy Director: Ed Nevius

Associate Director: Sue-Jane Wang

Associate Director: Ram Tiwari

## Biometrics I

Director:  
James Hung  
Deputy:  
Kooros Mahjoob

Cardiovascular/  
Renal  
Team Leader (Act.):  
James Hung

Neurology  
Team Leader:  
Kun Jin

Psychiatry  
Team Leader:  
Peiling Yang

## Biometrics II

Director:  
Tom Permutt  
Deputy:  
Vacant

Anesthesia/  
Analgesia/Addiction  
Team Leader:  
Dionne Price

Metabolism/  
Endocrinology  
Team Leader:  
Vacant

Pulmonary/Allergy/  
Rheumatology  
Team Leader:  
Joan Buenconsejo

## Biometrics III

Director:  
Steve Wilson  
Deputy:  
Mike Welch

Gastroenterology/  
Inborn Errors  
Team Leader:  
Mike Welch

Dermatology/  
Dental  
Team Leader:  
Mohamed Alesh

Reproductive/  
Urological  
Team Leader:  
Mahboob Sobhan

## Biometrics IV

Director:  
Mohammad Huque  
Deputy:  
Daphne Lin

Anti-Infective  
Team Leader:  
Thamban Valappil

Ophthalmology/  
Nonprescription  
Team Leader:  
Yan Wang

Antiviral  
Team Leader:  
Greg Soon

Special Pathogen/  
Transplant  
Team Leader:  
Karen Higgins

## Biometrics V

Director:  
Rajeshwari Sridhara  
Deputy:  
Thomas Gwise

Oncology 1  
Team Leader:  
Shenghui Tang

Oncology 2  
Team Leader:  
Kun He

Hematology  
Team Leader:  
Mark Rothmann

Medical Imaging  
Team Leader:  
Jyoti Zalkikar

## Biometrics VI

Director:  
Stella Machado  
Deputy:  
Yi Tsong

Generics  
Team Leader:  
Stella Grosser

Pharmacology/  
Toxicology  
Team Leader:  
Karl Lin

Chemistry/  
Manufacturing  
Team Leader (Act.):  
Yi Tsong

QT Studies  
Team Leader:  
Joanne Zhang

Special Projects  
Team Leader (Act.):  
Stella Machado

## Biometrics VII

Director:  
Aloka Chakravarty  
Deputy:  
Mark Levenson

Team 1  
Team Leader:  
Mat Soukup

Team 2  
Team Leader:  
Vacant

Team 3  
Team Leader (Act.):  
Mark Levenson

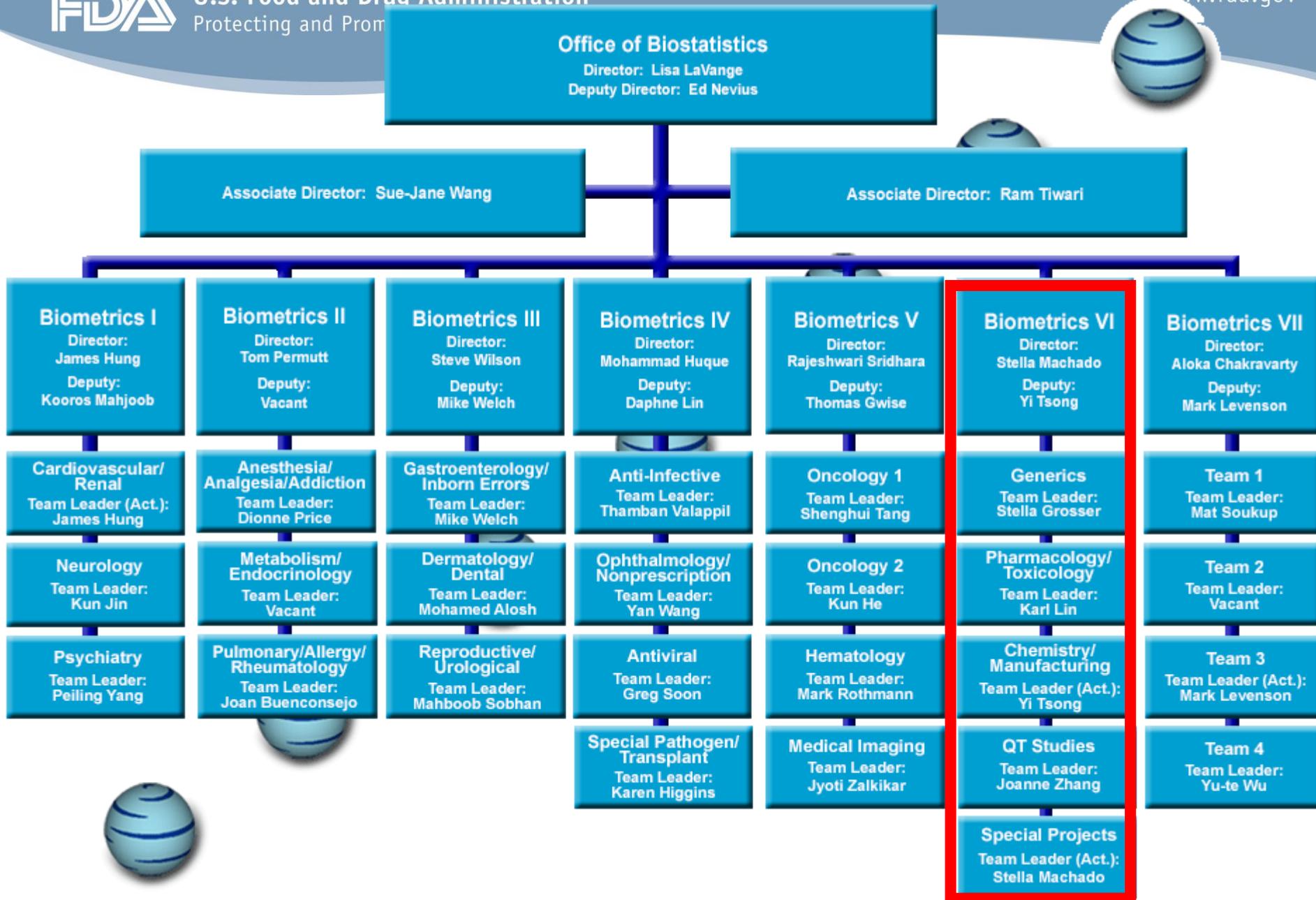
Team 4  
Team Leader:  
Yu-te Wu

# Expertise Desired

- Biostatistics or Mathematical Statistics
  - Ph.D.
- Clinical Trial Design – DoE
- Survival analysis
- Adaptive designs
- Linear models, GLMs, GEE
- Communication skills

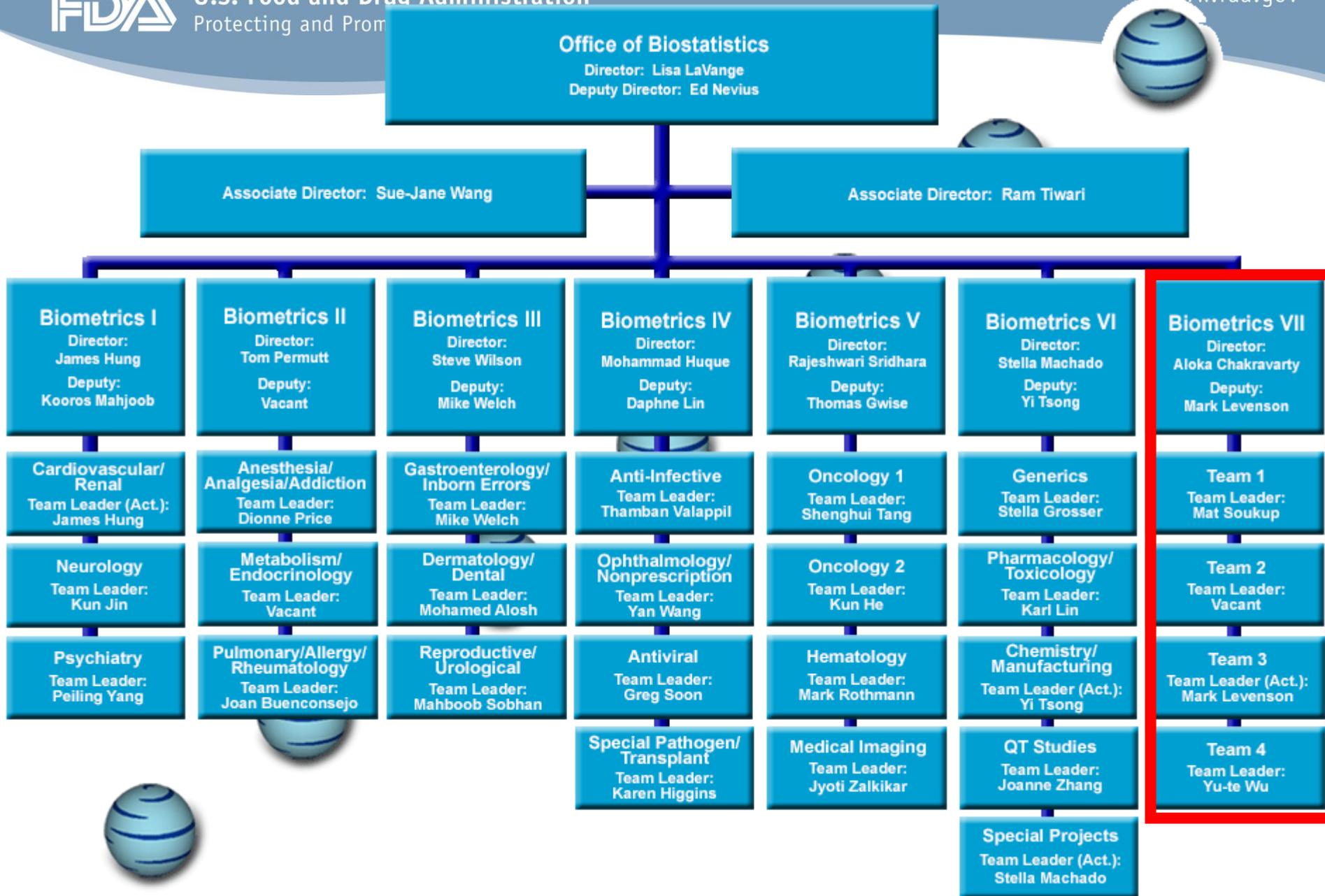
# Biometrics V (Oncology)

Drug	Indication
<a href="#"><u>Pomalyst</u></a>	multiple myeloma
<a href="#"><u>Kadcyla</u></a>	HER2-positive, late-stage breast cancer.
<a href="#"><u>Lymphoseek</u></a>	helps doctors locate lymph nodes in patients with breast cancer or melanoma
<a href="#"><u>Dotarem</u></a>	magnetic resonance imaging (MRI) of the brain
<a href="#"><u>Xofigo</u></a>	late-stage castration-resistant prostate cancer
<a href="#"><u>Tafinlar</u></a>	melanoma
<a href="#"><u>Mekinist</u></a>	melanoma
<a href="#"><u>Gilotrif</u></a>	late stage non-small cell lung cancer (NSCLC)
Vizamyl	imaging of the brain (for beta amyloid related to AD)



# Biometrics VI (Non-Clinical)

- Chemistry
- Quality control
- Toxicity
- Manufacturing
- Generic drug applications



# Biometrics VII (Safety)

- **Focus** on the **quantitative** assessment of safety
  - Development phase of product development
  - Pre-market risk assessment
  - Post-market risk assessment
  
- **Expertise** in areas **unique** to the safety assessment
  - Meta-analysis
  - Randomized trials primarily to evaluate safety
  - Design and analysis of observational studies
  - Graphical and computational methods
  - Analyses of registry and health care databases
  
- **Experience** in working across **multiple** divisions
  - Application of prior experience to new situations

# Research

- Related to regulatory work
- Regulatory and Science Review Enhancement (RSR)
- Examples
  - Surrogate endpoints (pCR project)
  - Image reading variability and PFS

# Surrogate Endpoint

- Lab measurement or physical sign substituted for a clinically meaningful endpoint
- “True EP” untenable; too time consuming
- Examples:
  - Cholesterol in CAD (MI, Survival)
  - Viral load in HIV (survival)

# Hiring

- Apply through USA jobs (US citizens only)
- Apply to our office directly
  - Posting at Amstat News, JSM, Now...
  - US permanent residents (Staff fellows)
  - Other non-citizens (as allowed by statute)
    - Dr. S. Edward Nevius  
Bldg 21, room 3550, 10903 New Hampshire Ave  
Silver Spring, MD 20993  
[SEdward.Nevius@fda.hhs.gov](mailto:SEdward.Nevius@fda.hhs.gov)



**Thank you**