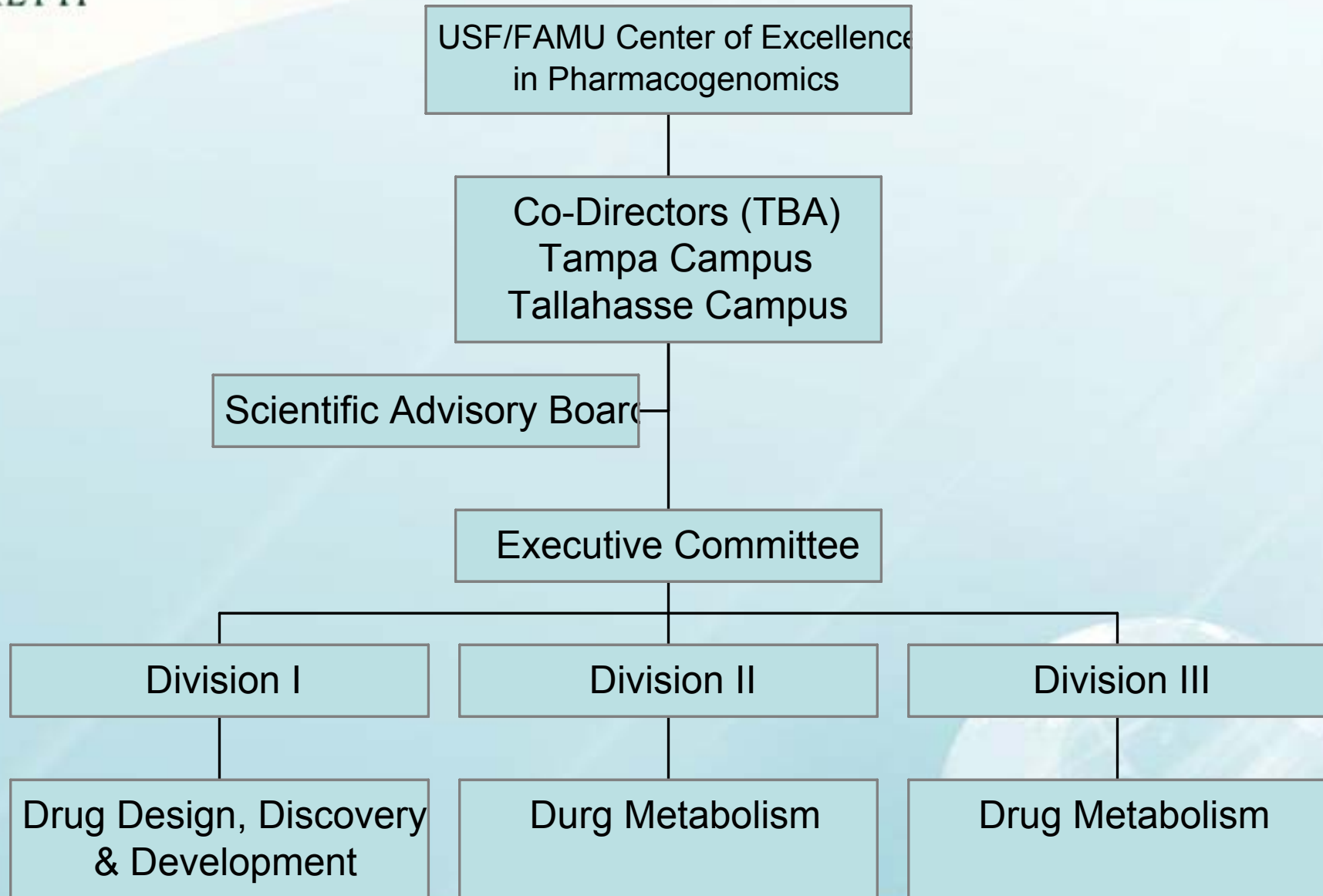


## Proposal for a Collaborative Center of Excellence in Pharmacogenomics



# Proposed Organizational Chart



# What is Pharmacogenomics ?

- the study of how genes affect an individual's response to drugs
- a revolutionary change in medicine to individualized patient care
- uses markers in the genetic code of an individual to pinpoint the bases of disease and design a ratioanle drug treatment regimen

# Key Findings from PriceWaterhouseCoopers "Personalized Medicine: The Emerging Pharmacogenomics Revolution" (2/05)

- current approaches to develop blockbuster drugs are difficult and expensive
- the pharmacogenomics era is here
- pharmacogenomics can increase a product's market
- there are immediate clinical demands for pharmacogenomic products
- pharmacogenomic tools are being developed and used in mainstream medicine
- regulatory and reimbursement structures for pharmacogenomics are currently being written
- life sciences companies are becoming more valuable
- pharmacogenomic products are finding mainstream success
- the first high-profile pharmacogenomics products are likely to be in oncology

# USF Pharmacogenomic Asset Map

- Education
  - medical students currently receive about 4 hours of didactic lecture during their second year pharmacology course
- Research
  - currently no focus areas on pharmacogenomics
- Clinical
  - USF/James Haley Pharmacogenomics Laboratory

# USF/James Haley VA Pharmacogenomics Laboratory

- currently processes 25,000 samples/day
- current genotyping analyses
  - HIV
  - HCV
  - Factor II
  - Factor V Leiden
  - CYP2D9

- HIV
  - enables targeted therapy by predicting resistance to anti-HIV medications (TRUEGENE HIV-1 Kit; Bayer Diagnostics)
- HCV
  - the hepatitis C genotype and pretreatment HCV RNA serum levels are important for estimating a patient's response to IFN-alpha (Bayer Versant LiPA analysis)

- Factor V Leiden and Factor II (prothrombin)
  - real-time PCR to detect single point mutations: G-A at position 20210 in the human prothrombin gene, and G-A at position 1691 in the human Factor V gene (LightCycler Kits for SNPs, Roche Diagnostics)
  - these are the most common genetic risk factors for thrombotic events
- CYP2D9
  - for the simultaneous detection of two major SNPs: C-T at position 430 (CYP2C9\*2), and A-C at position 1075 (CYP2C9\*3)
  - anticoagulant therapy based on genotype

# Pending USF/VA facilities

- have submitted a proposal to the VA to purchase AmpliChip, the world's first pharmacogenetic microarray-based test approved for clinical use.
- AmpliChip CYP450 provides comprehensive coverage of all genetic variations (deletions & duplications) for CYP2D6 and CYP2C19, which play a major role in the metabolism of approximately 25% of all prescription drugs.
- genotyping with AmpliChip CYP450 will be a critical tool to assist physicians in individualizing treatment selection and dosing for drugs metabolized through these genes.

# Components of a Center of Excellence in Pharmacogenomics

