



**Sino-American Pharmaceutical Professionals Association**  
***“Accelerating Pharmaceutical Growth through  
Open Innovation and Global Collaboration”***  
**August 4, 2012, Piscataway, New Jersey**

# **Science Based Regulatory Decision-Making: Recent Efforts in Clinical Pharmacology**

**Shiew-Mei Huang**  
**Deputy Director**  
**Office of Clinical Pharmacology, OTS, CDER, FDA**  
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# CDER Major priorities

- **User Fee Agreements and Implementation (PDUFA, GDUFA, BsUFA)**
- **Challenge of Globalization of Medical Products Development and Manufacture**
- **Senior Leadership Recruitment**
- **Regulatory science and drug safety continue high priorities for CDER**

# FDA on Innovation

**Our job is to enable innovation –  
but without sacrificing our high  
standards for ensuring safe,  
effective and high quality products**

*Margaret Hamburg, NEHI conference on Bridging  
the Innovation Gap, Boston, April 26, 2012*



OCTOBER 2011

www.fda.gov/Innovation

# Driving Biomedical Innovation:

## Initiatives to Improve Products for Patients



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
U.S. FOOD AND DRUG ADMINISTRATION

OCTOBER 2011

www.fda.gov/Innovation

*"America is at an important crossroads, where the science before us presents unprecedented opportunities to create new and better medical products and to promote better health for the public."*

Margaret A Hamburg, MD  
October 5, 2011

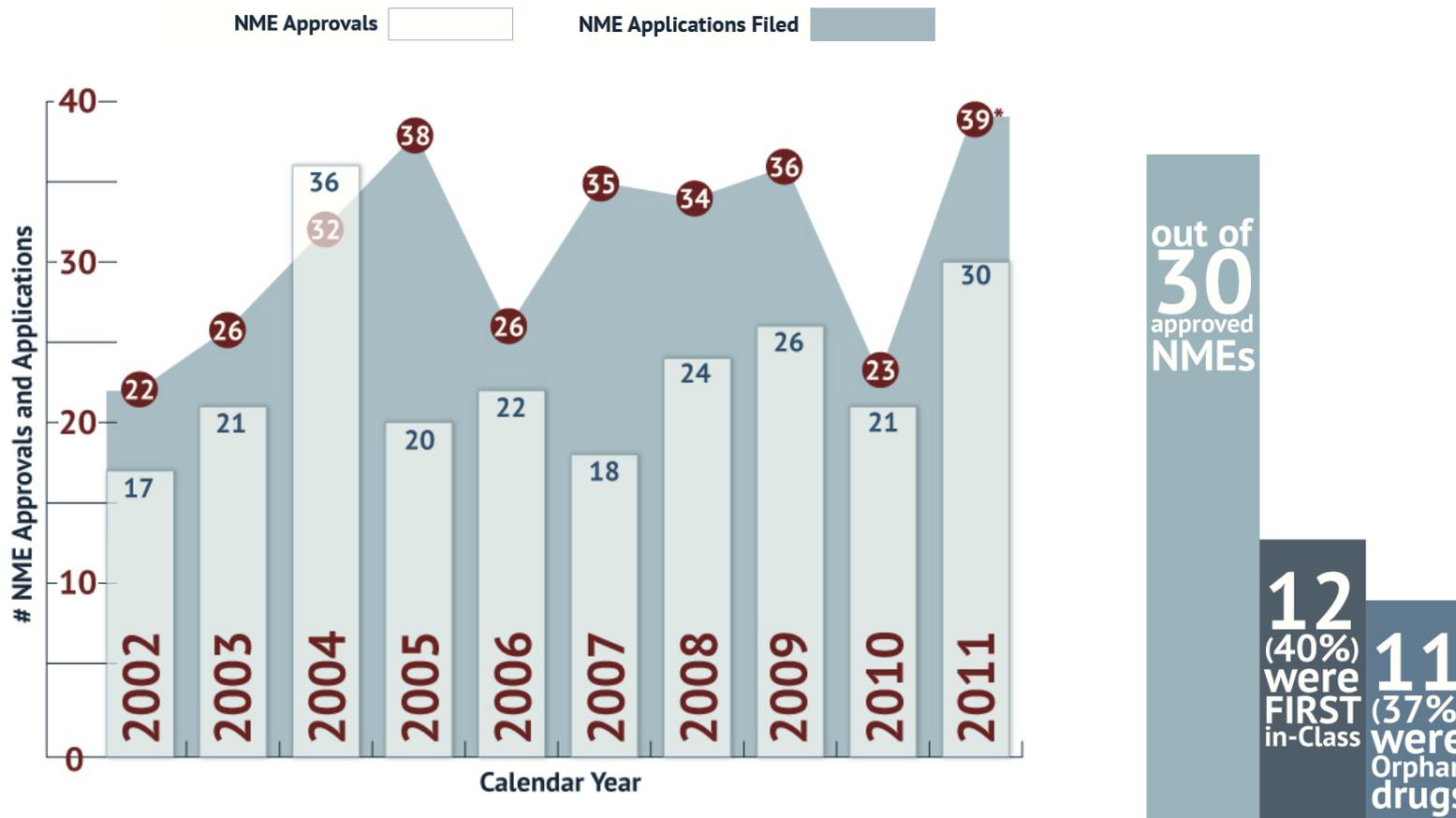
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm274333.htm>

# **Will New Scientific Discoveries Revolutionize Treatment of Disease (Soon)?**

**→ New paradigms for evaluation of  
diagnostic and therapeutic interventions  
must be developed**

- Faster**
- More efficient**
- But equally or more informative**

# In 2011, CDER approved 30 NMEs,



\*The final number of NME Applications filed in 2011 is projected, pending final validation of the data and dependent outcome of 12 applications submitted in late 2011.

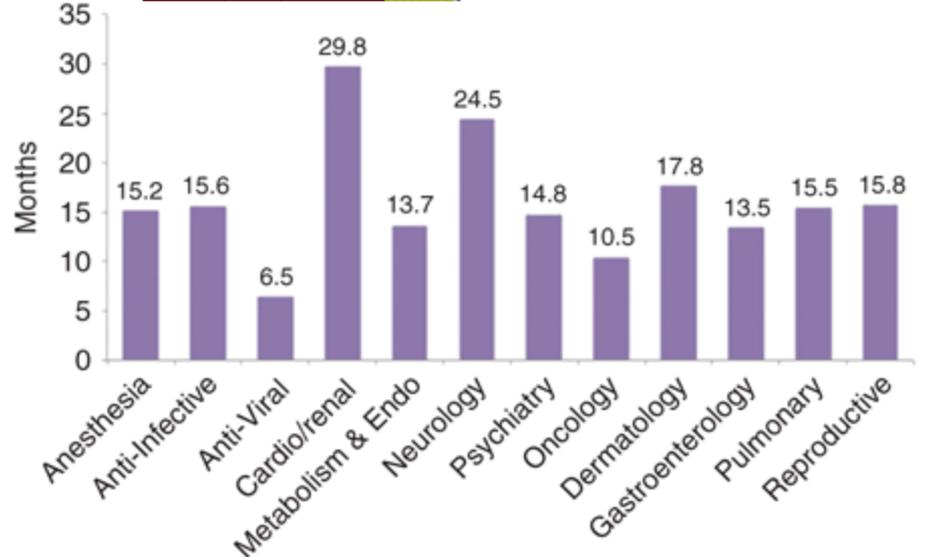
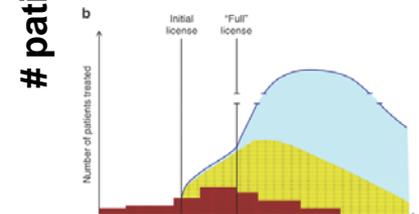
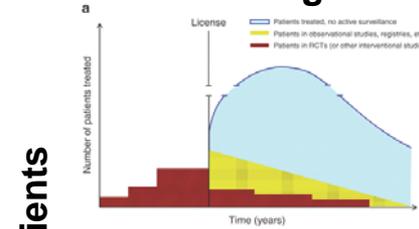
# FDA and Regulatory Science



March 2012 issue

- Adaptive licensing (MIT Center for Biomedical Innovation report)
- Analysis of FDA review division performance (Tufts Center for the Study of Drug Development)
- Development of biosimilars
- Nine papers from the FDA

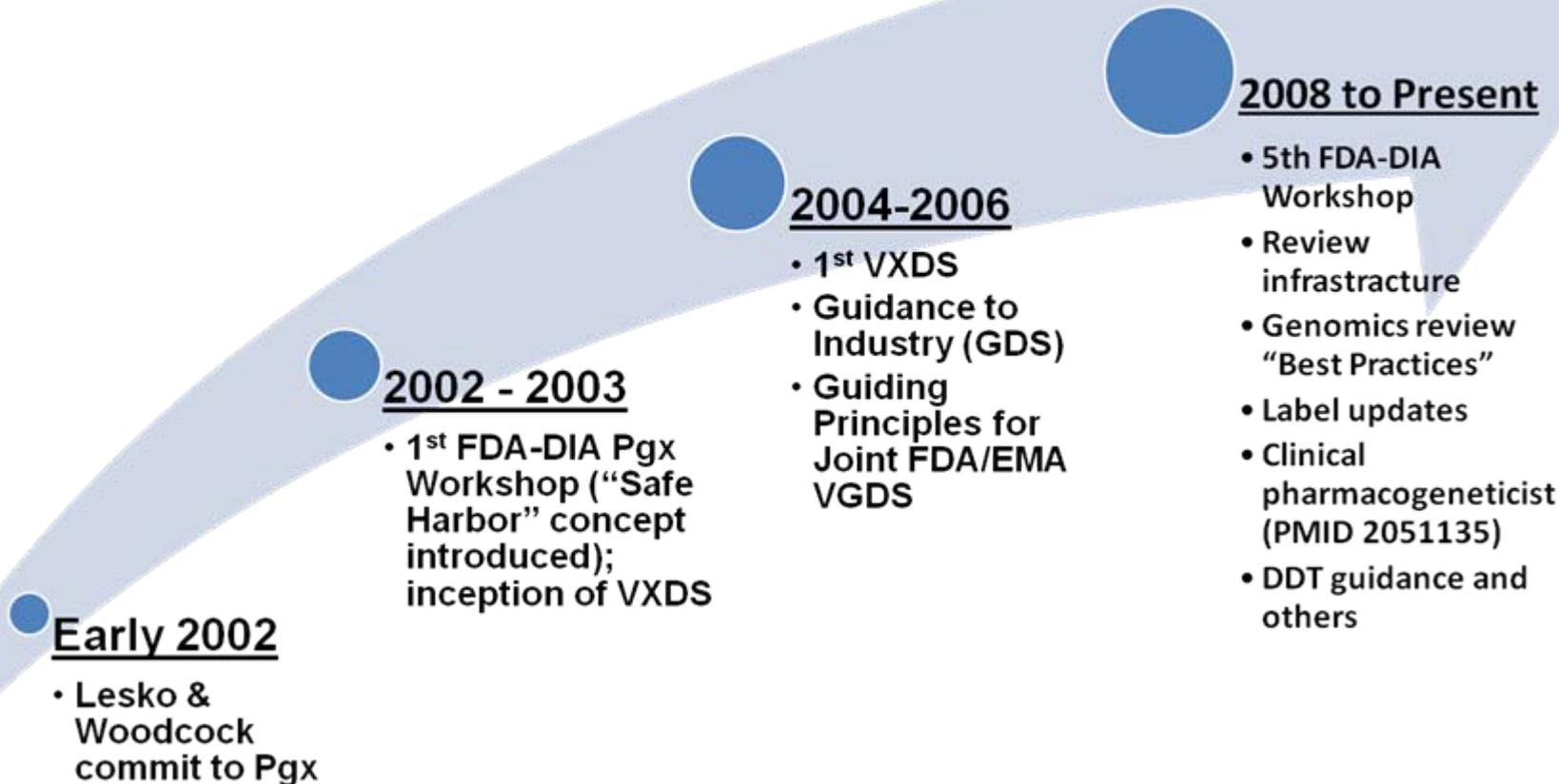
Licensing



# **Office of Clinical Pharmacology Strategic Plan**

- **OCP Review Quality & Clinical Relevance  
(patient-centric clinical pharmacology)**
- **Review Process**
- **Staff Excellence**
- **Internal Communication**
- **External Communication**

# Pharmacogenomic Efforts at the FDA



Pharmacogenomics Journal, 2002



## Guidance for Industry

### Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies

#### *DRAFT GUIDANCE*

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-301), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Lawrence Lesko at 301-796-1565 or Shiew-Mei Huang at 301-796-1541, or (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 301-827-1800, or Changting Haudenschild at 301-827-3947, or (CDRH) Frances Kalush at 301-796-5408.

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)

February 2011  
Clinical Pharmacology

## Published for public comment in February 2011

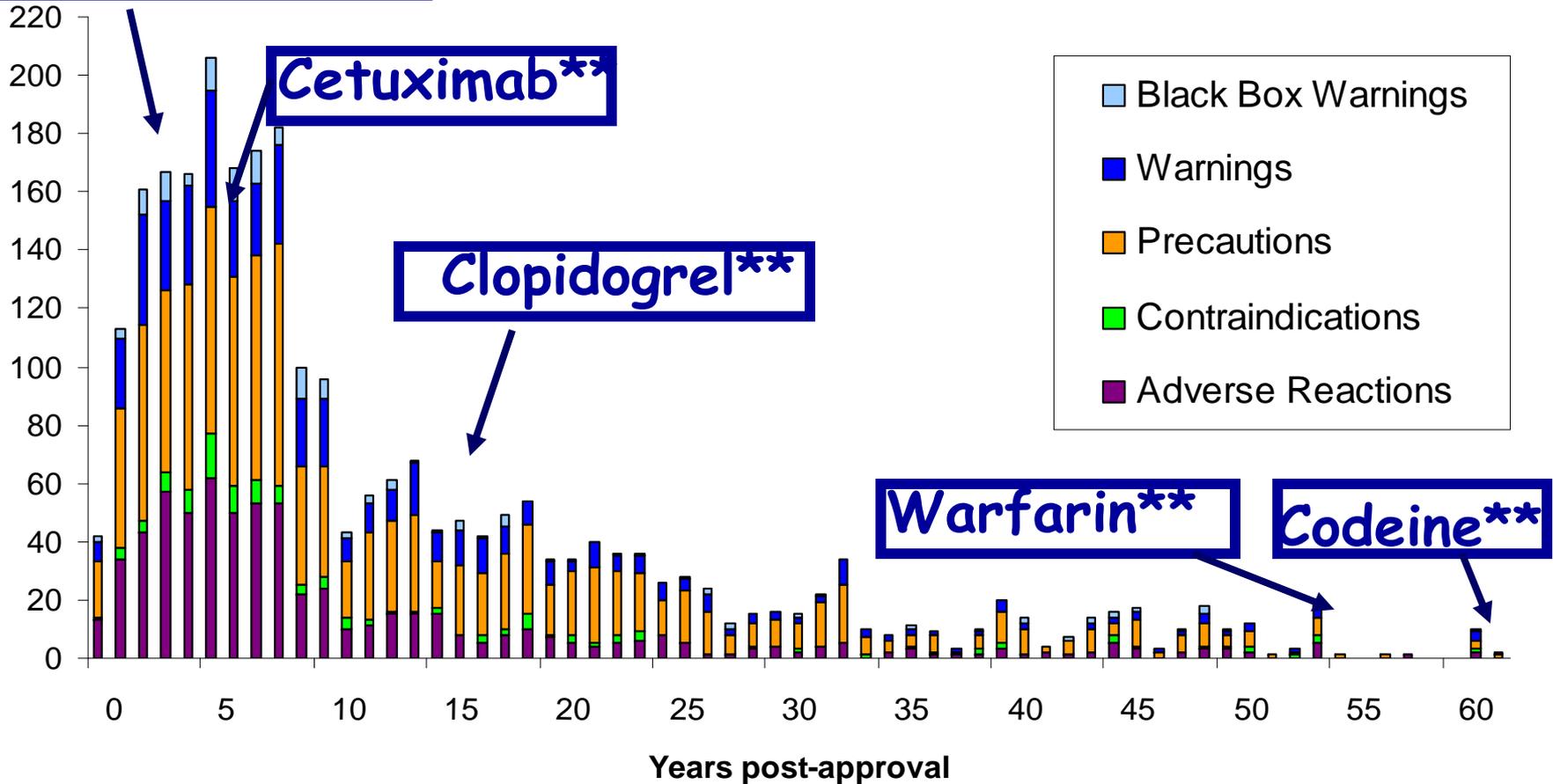
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064982.htm>

## → Included examples

# Safety-Related Labeling Changes

(changes made Oct 2002-Aug 2005, n=2645 label changes for 1601 NDA/BLA entries)

**Panitumumab\*\***



\*\*Related to pharmacogenetics

Modified from: T Mullin, CDER, Office of Planning and Analysis, OTS presentation, May 2009

**Editorial**

# Clinical Utility

*Clinical Pharmacology & Therapeutics* (2010) **88** 6, 729–733. doi:10.1038/clpt.2010.229

## What Is Clinical Utility and Why Should We Care?

L J Lesko<sup>1</sup>, I Zineh<sup>1</sup> and S-M Huang<sup>1</sup>

<sup>1</sup>Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland, USA

Correspondence: L Lesko, ([lawrence.lesko@fda.hhs.gov](mailto:lawrence.lesko@fda.hhs.gov)); I Zineh, ([Issam.Zineh@fda.hhs.gov](mailto:Issam.Zineh@fda.hhs.gov)); S-M Huang, ([ShiewMei.Huang@fda.hhs.gov](mailto:ShiewMei.Huang@fda.hhs.gov))

### State of the Art

*Clinical Pharmacology & Therapeutics* (2010) **88** 6, 765–773. doi:10.1038/clpt.2010.230

## Assessing the Clinical Utility of Diagnostics Used in Drug Therapy

J Woodcock<sup>1</sup>

<sup>1</sup>Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland, USA

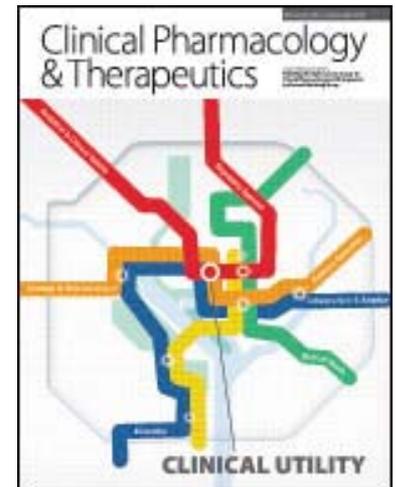
### State of the Art

*Clinical Pharmacology & Therapeutics* (2010) **88** 6, 774–778. doi:10.1038/clpt.2010.233

## Enrichment of Clinical Study Populations

R Temple<sup>1</sup>

<sup>1</sup>Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland, USA



**December 2010**

# Email Bursts

**Initiated in June 2011 (to ASCPT, ACCP, ACCPharmacy)**

**2011:**

**Boceprevir, telaprevir, crizotinib, vemurafenib, ruxolitinib, digoxin, clobazam, pimozide, asparaginase *Erwinia chrysanthemi*, zolpidem**

**2012:**

**Glucarpidase, vismodegib, ivacaftor, cisplatin, axitinib, taliglucerase alfa, pertuzumab, lorcaserin, phentermine/topiramate**

**ASCPT**American Society for Clinical  
Pharmacology and Therapeutics**UPDATES**

Advancing the science and practice of clinical pharmacology for the therapeutic benefit of patients and society

**FDA**News

### FDA Burst Email To ASCPT Members

*In cooperation with the Food and Drug Administration (FDA), and as a service to our members, ASCPT will periodically distribute information about newly approved therapies or significant changes to approved therapies. Dissemination of this information helps the FDA inform professionals in the patient care arena of recent approvals in a timely manner. Included in the email from the FDA will be a link to the product label, which will provide the relevant clinical pharmacology information on the indication, contraindications, dosing, and safety. In sending this information, ASCPT does not endorse any product or therapy and does not take any position on the safety or efficacy of the product or therapy*

\_\_\_\_\_ Taking into consideration that the higher zolpidem concentrations in women may result in more next-day residual effects, the FDA approved 1.75 mg dose in women and 3.5 mg dose for men to be taken at least 4 hours prior to awakening.

### FDA Approval of INTERMEZZO<sup>®</sup> for as-needed Treatment of Insomnia when a Middle-of-the-night Awakening is Followed by Difficulty Returning to Sleep

On November 23, 2011, the FDA approved INTERMEZZO<sup>®</sup> (zolpidem tartrate) for as-needed treatment of insomnia when a middle-of-the-night (MOTN) awakening is followed by difficulty returning to sleep. Zolpidem is a non-benzodiazepine hypnotic of the imidazopyridine class that had previously been approved for the short term treatment of insomnia characterized by difficulties with sleep initiation. Oral tablets of zolpidem tartrate have been marketed under the trade name of Ambien<sup>®</sup> since 1992 and several generic formulations are



# Guidance Update



Guidance, Compliance & Regulatory Information

- Guidances (Drugs)
- Advertising
- Bioequivalence Recommendations for Specific Products
- Biopharmaceutics
- Biosimilarity
- CMC - Microbiology (Chemistry, Manufacturing, and Controls)
- Chemistry, Manufacturing, and Controls (CMC)
- Clinical / Antimicrobial
- Clinical / Medical
- Clinical Pharmacology**
- Combination Products
- Concept Papers
- Current Good Manufacturing Practices (CGMPs)/Compliance
- Drug Safety
- Electronic Submissions
- FDAAA (Food and Drug Administration Amendments Act)
- Generics
- Good Review Practices

## Clinical Pharmacology

Below is a sortable listing of Clinical Pharmacology Guidances

Category	Title	Type	Date
Clinical Pharmacology	Clinical Lactation Studies--Study Design, Data Analysis, and Recommendations for Labeling (PDF - 363KB)	Draft Guidance	02/08/05
✓ Clinical Pharmacology	Clinical <u>Pharmacogenomics</u> : Premarketing Evaluation in Early Phase Clinical Studies (PDF - 531KB)	Draft Guidance	02/17/11
✓ Clinical Pharmacology	General Considerations for <u>Pediatric</u> Pharmacokinetic Studies for Drugs and Biological Products (PDF - 37KB)	Draft Guidance	11/01/98
✓ Clinical Pharmacology	Pharmacokinetics in Patients with <u>Impaired Renal Function</u> — Study Design, Data Analysis, and Impact on Dosing and Labeling (PDF - 319KB)	Draft Guidance	03/22/10
Clinical Pharmacology	Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling (PDF - 324KB)	Draft Guidance	11/01/04
✓ Clinical Pharmacology	<u>Drug Interaction</u> Studies--Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations (PDF - 827KB)	Draft Guidance	02/17/12
Clinical Pharmacology	Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications (PDF - 221KB)	Final Guidance	05/05/03
Clinical Pharmacology	Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application (PDF - 519KB)	Final Guidance	02/01/87
✓ Clinical	<u>Pharmacokinetics in Patients with Impaired Hepatic impairment</u>	Final	05/30/03

Guidance, Compliance & Regulatory Information
Guidances (Drugs)
Advertising
Bioequivalence Recommendations for Specific Products
Biopharmaceutics
<b>Biosimilarity</b>
CMC - Microbiology (Chemistry, Manufacturing, and Controls)
Chemistry, Manufacturing, and Controls (CMC)

## Biosimilarity

Below is a sortable listing of Biosimilarity Guidances.

Category	Title	Type	Date
Biosimilarity	Guidance for Industry on Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009	Draft Guidance	02/09/12
Biosimilarity	Scientific Considerations in Demonstrating Biosimilarity to a Reference Product (PDF - 576KB)	Draft Guidance	02/09/12
Biosimilarity	Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product (PDF - 432KB)	Draft Guidance	02/09/12

- Public hearing, May 11, 2012, FDA White Oak Campus  
<http://www.fda.gov/Drugs/NewsEvents/ucm265628.htm>
- DIA/FDA Workshop, September 12-13, 2012, Washington Marriott Wardman Park, Washington DC

Guidance, Compliance & Regulatory Information
Guidances (Drugs)
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<b>Biopharmaceutics</b>
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Chemistry, Manufacturing, and Controls (CMC)
Clinical / Antimicrobial
Clinical / Medical
Clinical Pharmacology
Combination Products
Concept Papers
Current Good Manufacturing Practices (CGMPs)/Compliance
Drug Safety
Electronic Submissions
FDAAA (Food and Drug Administration Amendments Act)
Generics
Good Review Practices
Industry Letters
International Conference on Harmonisation - Efficacy
International Conference on Harmonisation - Joint Safety/Efficacy (Multidisciplinary)
International Conference on Harmonisation - Quality
International Conference on

## Biopharmaceutics

Below is a sortable listing of Biopharmaceutics Guidances

Category	Title	Type	Date
Biopharmaceutics	Bioanalytical Method Validation (PDF - 63KB)	Final Guidance	05/01/01
Biopharmaceutics	Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (PDF - 519KB)	Draft Guidance	04/03/03
Biopharmaceutics	Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Data Posted on August 18, 1999 (PDF - 185KB)	Draft Guidance	04/11/03
Biopharmaceutics	Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations (PDF - 268KB)	Final Guidance	03/01/03
Bioequivalence Recommendation	Clozapine_19758 (PDF - 89KB)		
Biopharmaceutics	Topical Dermatologic Corticosteroids: in Vivo Bioequivalence (PDF - 2.6MB)	Final Guidance	06/02/95
Biopharmaceutics	Dissolution Testing of Immediate Release Solid Oral Dosage Forms (PDF - 130KB)	Final Guidance	08/01/97
Biopharmaceutics	Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (PDF - 170KB)	Final Guidance	09/01/97
Biopharmaceutics	Food-Effect Bioavailability and Fed Bioequivalence Studies (PDF - 166KB)	Final Guidance	12/01/02
Biopharmaceutics	Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro (PDF - 744KB)	Final Guidance	06/27/89
Biopharmaceutics	Statistical Approaches to Establishing Bioequivalence (PDF - 130KB)	Final Guidance	02/01/01
Biopharmaceutics	Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. (PDF - 143KB)	Final Guidance	08/01/00

**Combined guidance document for NDA submissions**

Guidance, Compliance & Regulatory Information
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Industry Letters
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International Conference on Harmonisation - Joint Safety/Efficacy (Multidisciplinary)
International Conference on Harmonisation - Quality
International Conference on

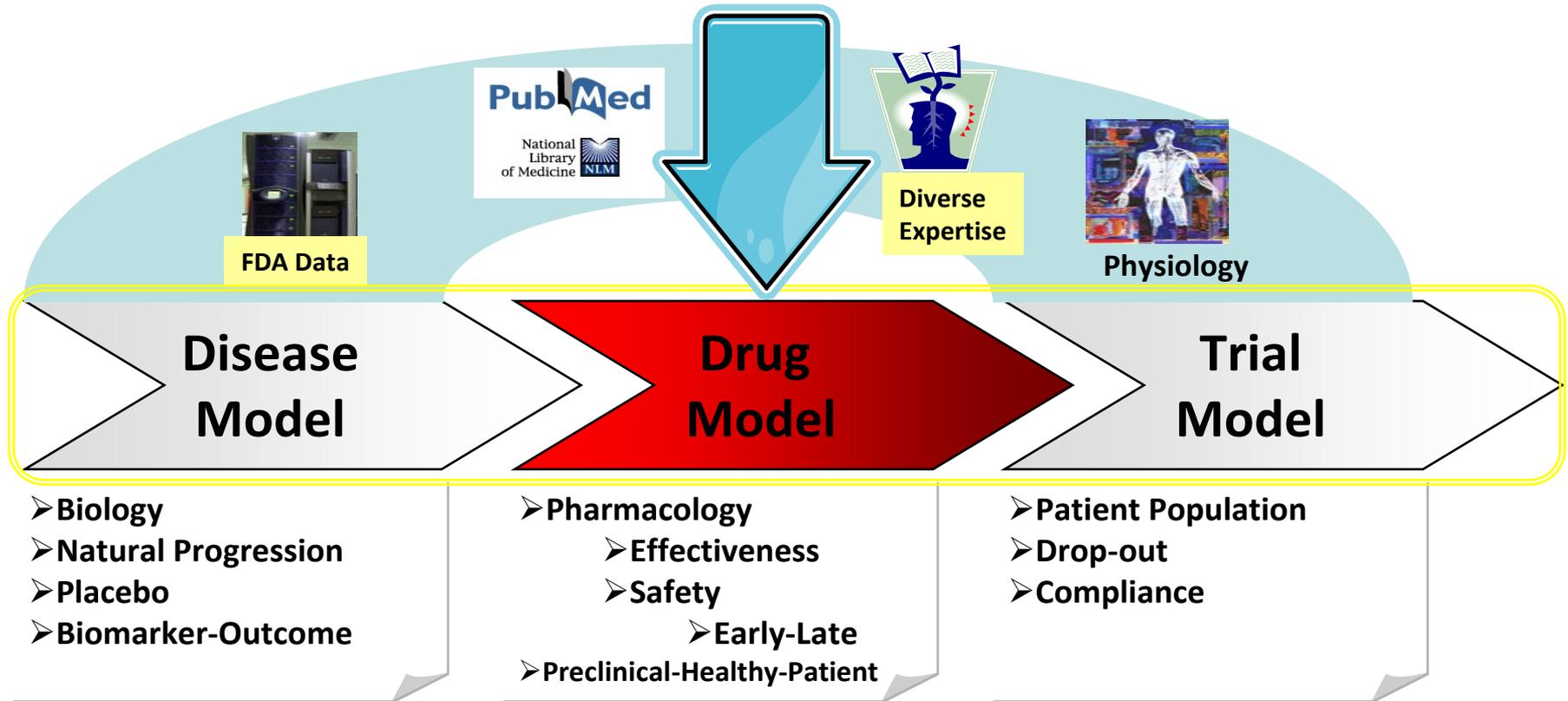
Clinical/Medical	Psychoactive Drugs in Infants and Children--Clinical Evaluation (PDF - 17.9MB)	Final Guidance	03/02
✓ Clinical/Medical	<u>Qualification Process for Drug Development Tools</u> (PDF - 190KB)	Draft Guidance	10/22
Clinical / Medical	The Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application (PDF - 417KB)	Draft Guidance	06/03
Clinical / Medical	Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment (PDF - 113KB)	Draft Guidance	11/22
Clinical/Medical	Standards for Clinical Trial Imaging Endpoints (PDF - 266KB)	Draft Guidance	08/18

## Drug Development Tools:

- Patient Reported Outcomes
- Biomarker Qualification
- Animal Models and other Non-Clinical Tools



# Quantitative Disease-Drug-Trial Models

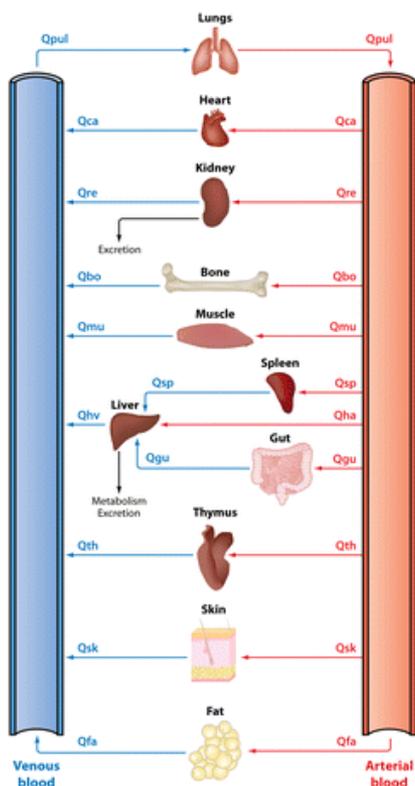


Disease-drug-trial models are mathematical representations of the time course of biomarker-clinical outcomes, placebo effects, drug's pharmacologic effects and trial execution characteristics for both the desired and undesired responses, and across experiments.

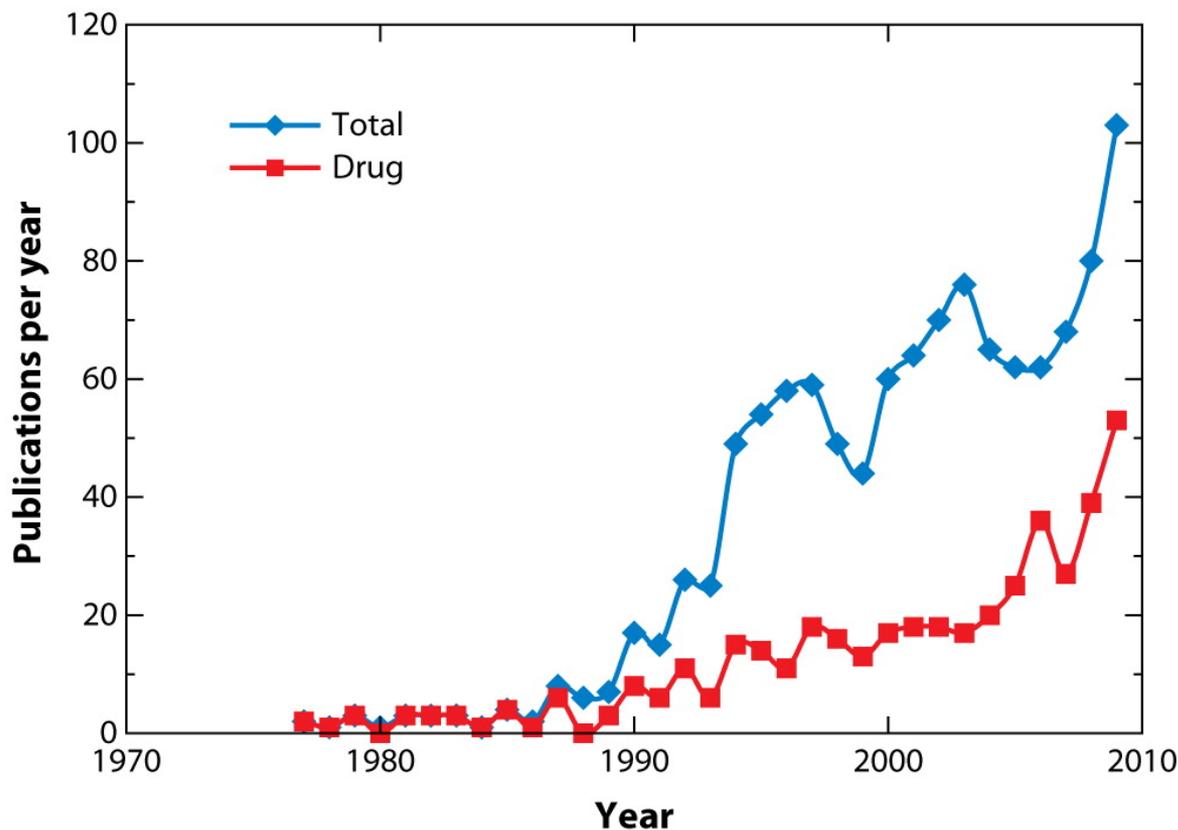


# Physiologically-based Pharmacokinetics Modeling (PBPK)

# Applications of Physiologically-Based Pharmacokinetic Modeling (PBPK)



Rowland M, et al. 2011. *Annu. Rev. Pharmacol. Toxicol.* 51:45-73



**Rowland M, Peck C, Tucker G, Physiologically-based pharmacokinetics in Drug Development and Regulatory Science *Annu Rev Pharmacol Toxicol*, 2011**



Guidance, Compliance & Regulatory Information

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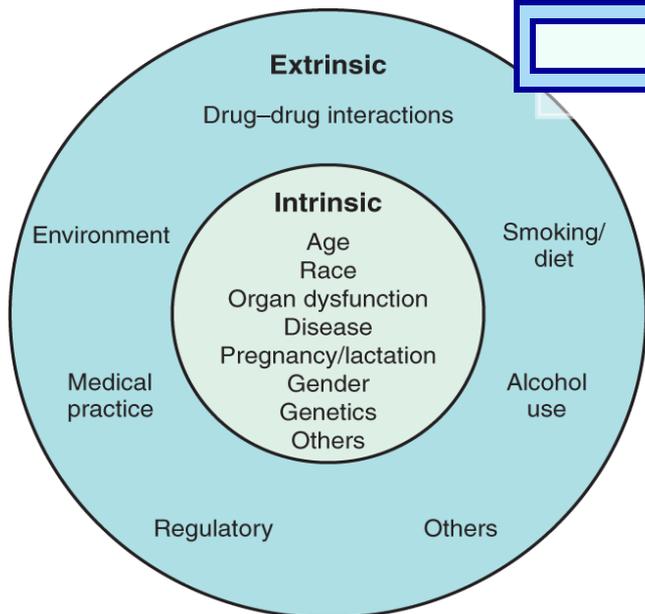
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Clinical Pharmacology	Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application (PDF - 519KB)	Final Guidance	02/01/87
Clinical	Pharmacokinetics in Patients with Impaired	Final	05/30/03

→ Utility of PBPK incorporated in clinical pharmacology guidance documents

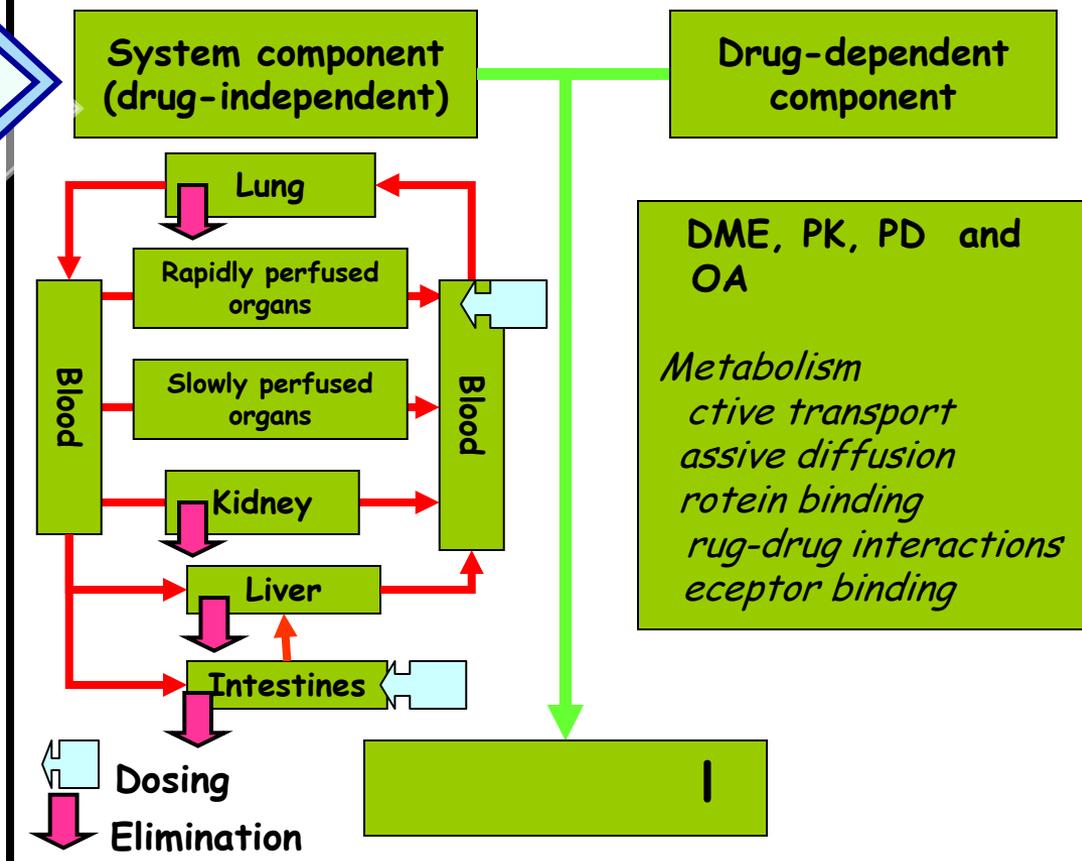
### A. Intrinsic/extrinsic Factors



*Huang and Temple, 2008*

Individual or combined effects on human physiology

### B. PBPK Model components



**Predict, Learn, Confirm**

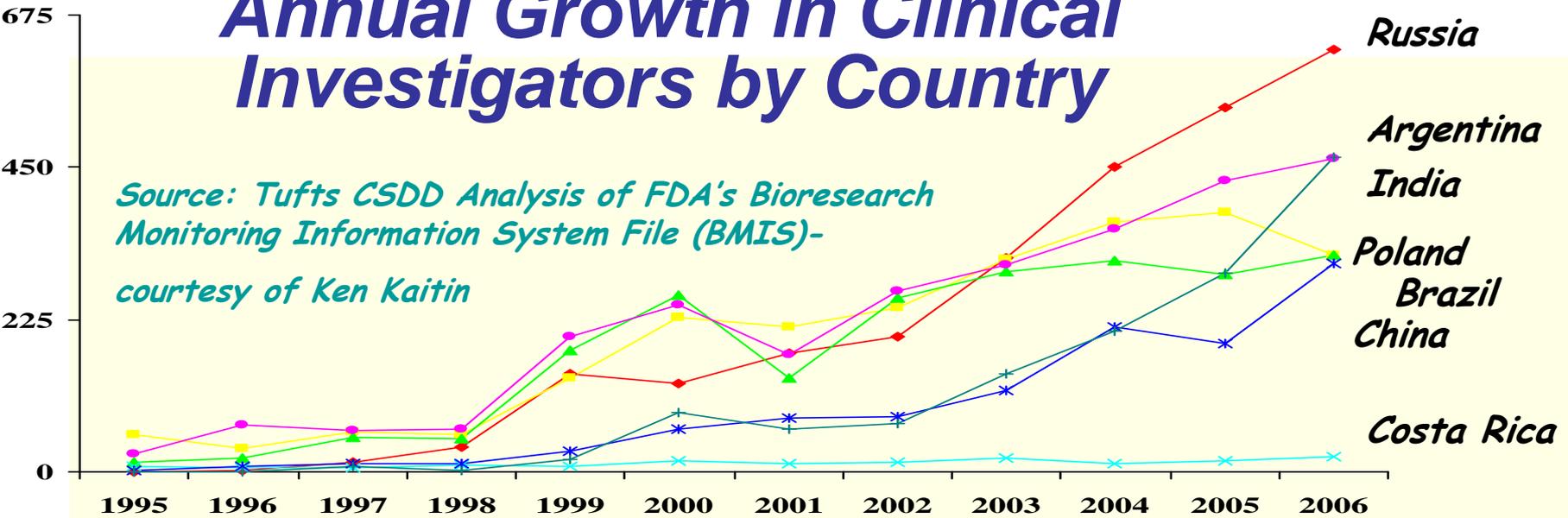
<Zhao P, Zhang L, Grillo JA, et al, Clin Pharmacol Ther, February, 2011>

<Huang S-M, Rowland M, Clin Pharmacol Ther May 2012>



# Annual Growth in Clinical Investigators by Country

Source: Tufts CSDD Analysis of FDA's Bioresearch Monitoring Information System File (BMIS)-  
courtesy of Ken Kaitin



Firms are moving operations abroad to:

- Cut costs
- Access scientific talent
- Gain knowledge of local markets

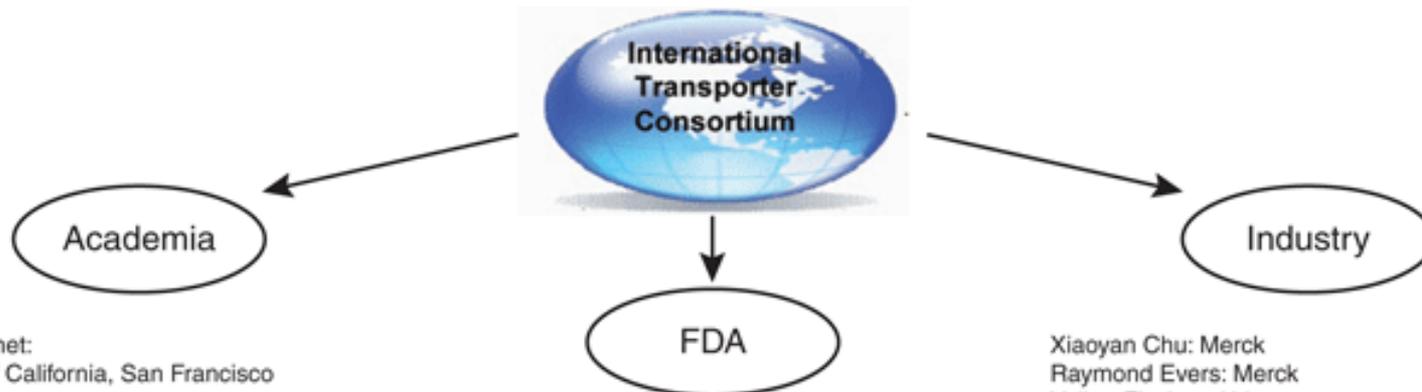
1 Tufts Center for the Study of Drug Development, Outlook 2008.  
<http://csdd.tufts.edu/InfoServices/OutlookPDFs/Outlook2008.pdf>  
2 IMS Health Forecasts 4.5-5.5 % Growth for Global Pharmaceutical Market in 2009, >\$820 B  
3 Economist, Quagmire to goldmine? 5/15/08  
- Courtesy of T Mullin, CDER, Office of Planning and Analysis

# Race and Ethnicity

Therapeutic area	Drug products: generic (brand) names	Ethnicity information
Cardiorenal	Isosorbide dinitrate–hydralazine (BiDil)	Indicated for self-identified blacks
	Angiotensin II antagonists and ACE inhibitors	Smaller effects in blacks <sup>a</sup>
Metabolic	Rosuvastatin (Crestor)	Lower dose for Asians
Hematology	Warfarin (Coumadin)	Lower dose for Asians
Neuropharmacological	Carbamazepine (Tegretol)	Box warning for Asians with variant alleles of <i>HLA-B*1502</i>

*<Huang S-M, Temple R, Clin Pharmacol Ther 84: 287-294, 2008>*

# International Transporter Consortium



Leslie Z. Benet:  
University of California, San Francisco  
Kim L.R. Brouwer:  
University of North Carolina at Chapel Hill  
Kathleen M. Giacomini:  
University of California, San Francisco\*  
Toshihisa Ishikawa: RIKEN Yokohama Institute\*  
Dietrich Keppler: German Cancer Research Center  
Richard B. Kim: University of Western Ontario  
Mikko Niemi: University of Helsinki  
Yuichi Sugiyama: University of Tokyo  
Peter. W. Swaan: University of Maryland  
Stephen H. Wright: University of Arizona

Shiew Mei Huang:  
Food and Drug Administration\*  
Lei Zhuang:  
Food and Drug Administration

Xiaoyan Chu: Merck  
Raymond Evers: Merck  
Volker Fischer: Abbott  
Katheen M. Hillgren: Lilly Research Laboratories  
Keith A. Hoffmaster: Novartis  
Caroline A. Lee: Pfizer  
Joseph W. Polli: GlaxoSmithKline  
Donald J. Tweedie:  
Boehringer Ingelheim Pharmaceuticals\*  
Joseph A. Ware: Genentech  
Maciej Zamek-Gliszczyński:  
Lilly Research Laboratories

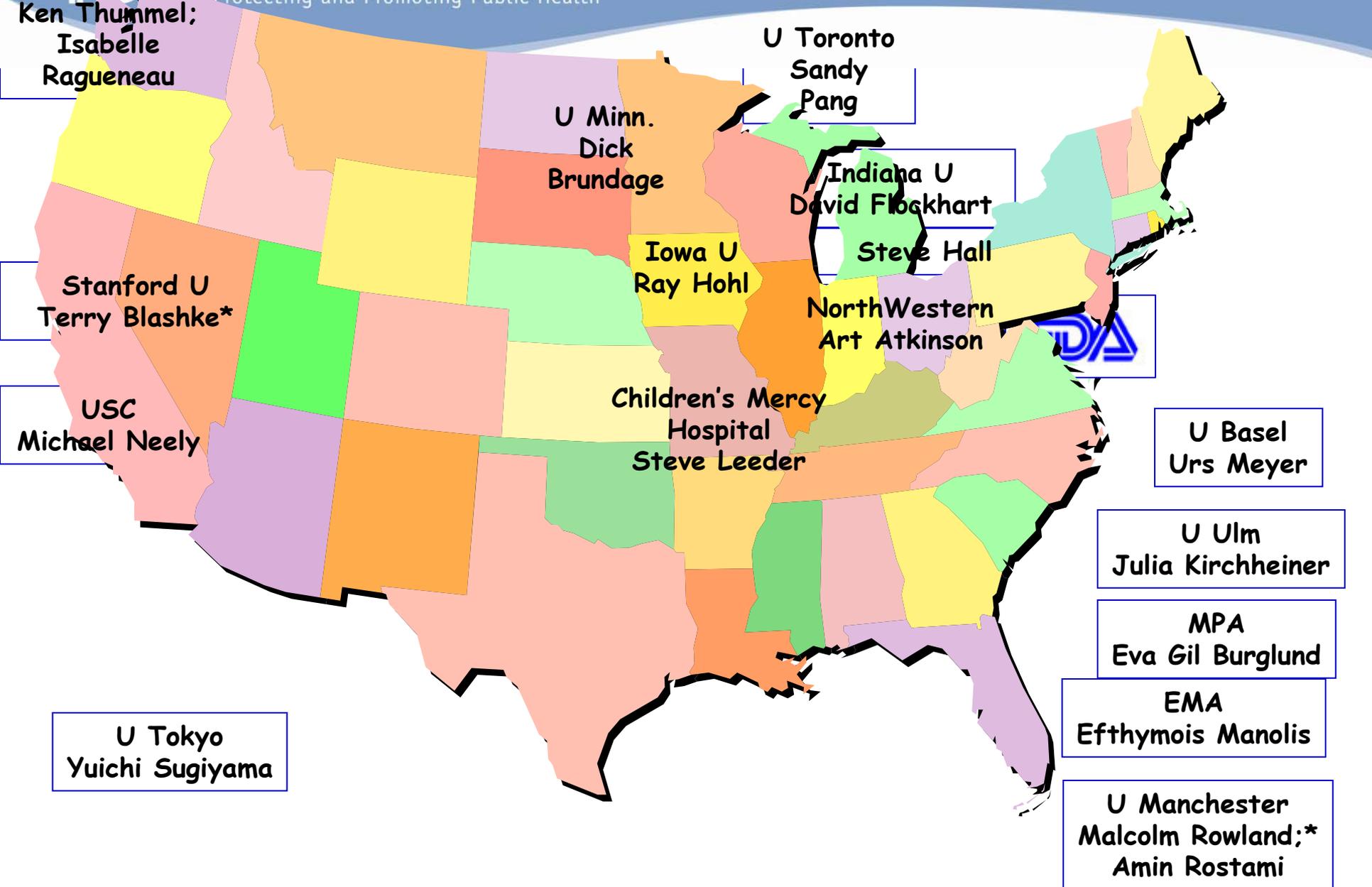
- First workshop in October 2008; whitepaper published in NRDD, March 2010;

- Second workshop in March 2012
- Whitepapers being prepared
- Expand to include other regulatory agencies

<http://www.nature.com/clpt/journal/v87/n1/full/clpt2009236a.html>



# 2006-2011 OCP "Sabbatical"



# Research and Collaborations

- **Center for Excellence in Regulatory Science/Innovation (CERSI)**
  - **University of Maryland**
  - **Georgetown University**
- **Medical Countermeasures Initiative (MCMi)**  
<http://www.fda.gov/EmergencyPreparedness/MedicalCountermeasures/default.htm>
  - **various grants**
- **Critical Path Projects; Regulatory Science Research grants; Office of Women's Health grants**
- **Other research projects**
  - **knowledgebase development**
  - **iTool development**

Kari M. Morrissey<sup>1</sup>, Chris Wen<sup>1</sup>, Susan J. Johns<sup>2</sup>, Shiew-Mei Huang<sup>3</sup>, Lei Zhang<sup>3</sup>, Kathleen M. Giacomini<sup>1</sup>

<sup>1</sup> Department of Bioengineering and Therapeutic Sciences and <sup>2</sup> Pharmaceutical Chemistry, University of California, San Francisco, CA

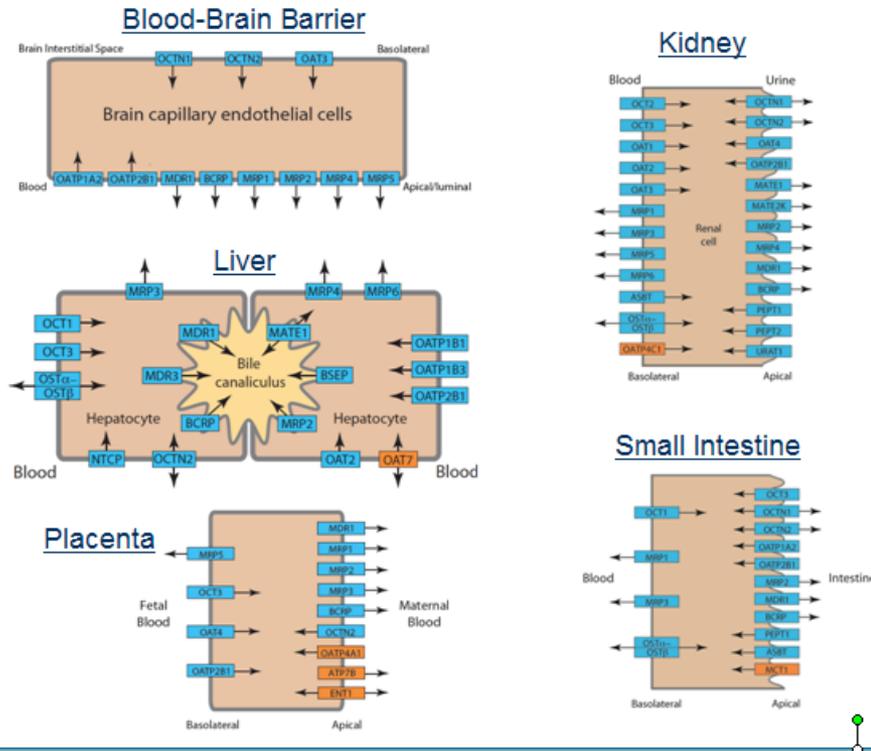
<sup>3</sup> Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD

## ABSTRACT

Drug transporters are key determinants of absorption, distribution and elimination of many drugs and appear to play important roles in therapeutic and adverse drug effects. Though a large body of data are available on drug transporters, there are few databases that inform drug developers, regulatory agencies and academic scientists about transporters important in drug action and disposition. We have selected 31 drug transporters from the ATP-Binding Cassette (ABC) and Solute Carrier (SLC) transporter superfamilies and compiled primary literature on their expression levels, subcellular localization, inhibitors, substrates and clinical drug-drug interactions. This project is supported by the FDA Critical Path to build a public drug transporter database to serve as a central resource for information needed by the scientific community on important drug transporters.

## DATABASE SCREENSHOTS

### Drug Transporters in Selected Organs & Direction of Transport



### Representative Screenshot of data for each transporter

**ABCB1**  
ATP-binding cassette, subfamily B, member 1  
Gene ID: 10245  
Accession: U08250.1  
Protein ID: P13503  
Molecular Weight: 98,800  
Isoelectric Point: 5.5  
Subcellular Localization: Plasma Membrane  
Tissue Expression: Liver, Kidney, Intestine, Placenta  
Drug Interactions: ABCB1 is a substrate for ABCB1, ABCB2, ABCB3, ABCB4, ABCB5, ABCB6, ABCB7, ABCB8, ABCB9, ABCB10, ABCB11, ABCB12, ABCB13, ABCB14, ABCB15, ABCB16, ABCB17, ABCB18, ABCB19, ABCB20, ABCB21, ABCB22, ABCB23, ABCB24, ABCB25, ABCB26, ABCB27, ABCB28, ABCB29, ABCB30, ABCB31, ABCB32, ABCB33, ABCB34, ABCB35, ABCB36, ABCB37, ABCB38, ABCB39, ABCB40, ABCB41, ABCB42, ABCB43, ABCB44, ABCB45, ABCB46, ABCB47, ABCB48, ABCB49, ABCB50, ABCB51, ABCB52, ABCB53, ABCB54, ABCB55, ABCB56, ABCB57, ABCB58, ABCB59, ABCB60, ABCB61, ABCB62, ABCB63, ABCB64, ABCB65, ABCB66, ABCB67, ABCB68, ABCB69, ABCB70, ABCB71, ABCB72, ABCB73, ABCB74, ABCB75, ABCB76, ABCB77, ABCB78, ABCB79, ABCB80, ABCB81, ABCB82, ABCB83, ABCB84, ABCB85, ABCB86, ABCB87, ABCB88, ABCB89, ABCB90, ABCB91, ABCB92, ABCB93, ABCB94, ABCB95, ABCB96, ABCB97, ABCB98, ABCB99, ABCB100

**Expression Data**  
Kidney - RNA-Sequencing  
Bar chart showing relative expression of ABCB1 in kidney tissue across various conditions.

**Kidney - Quantitative PCR**  
Bar chart showing relative expression of ABCB1 in kidney tissue across various conditions.

**REFERENCES**  
1. <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>  
2. Nishimura M, Naito S. Drug Metab Pharmacokin. 2005 Dec;20(8):452-77  
3. International Transporter Consortium. Nat Rev Drug Discov. 2010 Mar;9(3):215-36. Review.

<http://bts.ucsf.edu/fdatransporter/>

# Summary- priorities

- **OCP reviews follow “patient- centric” clinical pharmacology**
  - Alignment with CDER/FDA priorities
  - User Fee Agreements Implementations
  
- **Regulatory science, staff excellence, communications high priorities**
  - Collaborations with other regulatory agencies
  - Collaborations with academic, industry, and other government scientists (consortia)
  - Continuation of academic visits, publications, presentations

# Office of Clinical Pharmacology (OCP)/OTS





## References

**FDA Drug Development and Drug Interactions Website:**

*<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm080499.htm>*

**Genomics at the FDA:**

*<http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/default.htm>*

**Drugs@FDA:**

*<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>*

**Clinical Pharmacology Guidance for industry:**

*<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064982.htm>*