



## ***Career Opportunities at the FDA***

**Dionna Green, MD and Rita Humeniuk, PhD**

Office of Clinical Pharmacology (OCP)

Office of Translational Sciences (OTS)

Center for Drug Evaluation and Research

U.S. Food and Drug Administration



**Rutgers iJOBS Seminar  
05/06/2015**



## **Outline**

- Overview of FDA
- Drug Development
- Career Opportunities for Ph.D.s, M.D.s and Engineers
- Pay and Benefits
- Professional Development & Moving Up in FDA
- Fellowships & Rotations at FDA
- Research at FDA
- Contact information



## ***CAREER OPPORTUNITIES AT THE FDA***

Rita Humeniuk, Ph.D.

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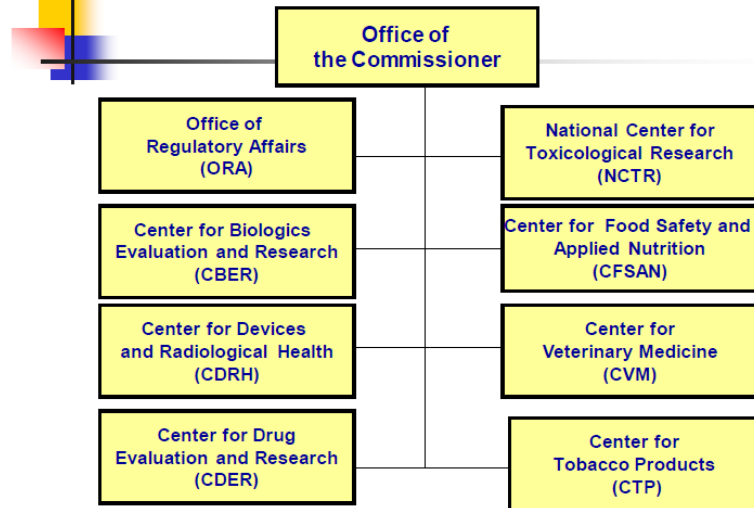


## **What does FDA do?**

- ✓ Assure the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products, medical devices, our food supply, cosmetics and radiation-emitting devices
- ✓ Regulate tobacco products
- ✓ Advance Public Health by helping speed innovations that make products more effective, safer and more affordable
- ✓ Help the public get accurate, science-based information about these products

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## Food and Drug Administration



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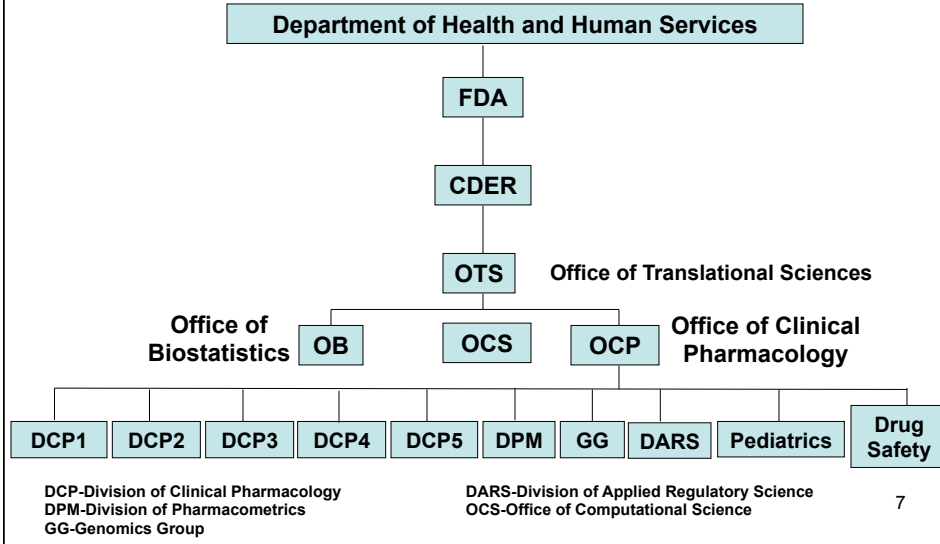
## What does CDER do?

- **Oversee drug development:**  
New drugs, Over-the-counter drugs, Generic drugs, Biologics, and Biosimilar products
- **Oversee post-marketing safety and promotion**
- **Oversee drug quality throughout lifecycle**
- **Promote and protect public health**

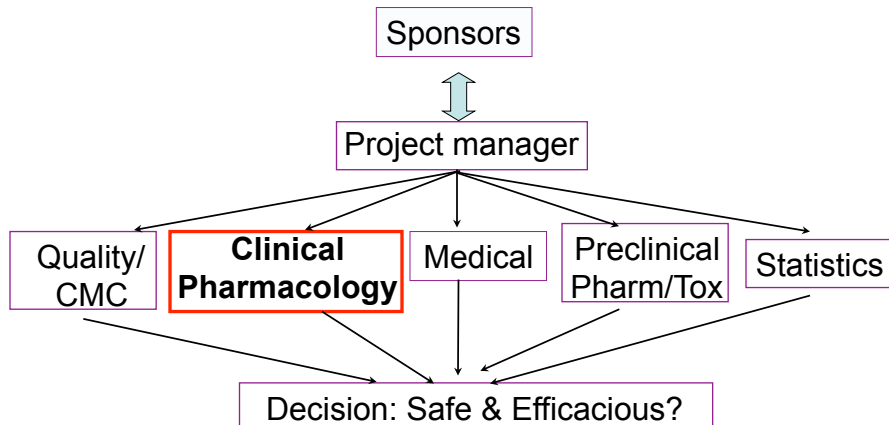
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## Office of Clinical Pharmacology (OCP)



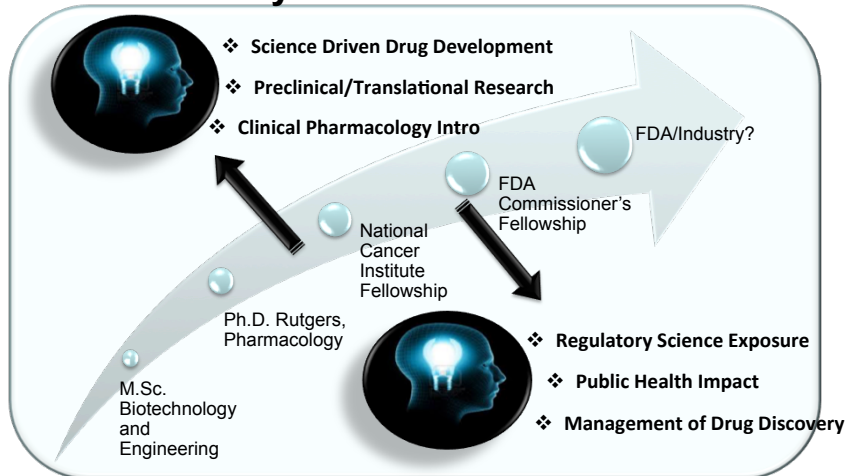
## Multi-Disciplinary Review Team



Some products may require additional disciplines such as microbiology and virology



## My Path to the FDA



Value-Driven Career Choices ... Progressive Career Pathways 9



## Career Opportunities at FDA for Ph.D.

Working at FDA	
▶	Career Descriptions
	Attorney Positions at FDA
→	Biologist Positions at FDA
→	Chemist Positions at FDA
	Consumer Safety Officer Positions at FDA
	Engineer Positions at FDA
→	Information Technology Positions in FDA
	Medical Officer Positions at FDA
→	Microbiologist Positions at FDA
→	Pharmacist Positions at FDA
→	Pharmacologist Positions at FDA
→	Statistician Positions at FDA



<http://www.fda.gov/AboutFDA/WorkingatFDA/default.htm>



### Pharmacologist Positions at FDA FDA Hiring Initiative

The Food and Drug Administration is recruiting for 1,300 medical and science positions to fill critical needs.  
More on the FDA hiring initiative

#### Description of Position

Pharmacologists at FDA in **non-laboratory settings** perform duties that include:

- reviewing and evaluating the pharmacological and toxicological data contained in New Drug Applications (NDAs) and Investigational New Drug Applications (INDAs)
- reviewing and evaluating the results of preclinical pharmacological and toxicological studies submitted in support of NDAs, INDAs, and amendments to assess the safety of drugs based on toxicity experiments conducted by the investigator (including evaluation of animal testing to ensure that animal studies support the manufacturer's claims for safety, and reviewing recommended dosage levels to determine the margin of safety for clinical use)
- preparing a comprehensive summary of data reviewed
- submitting recommendations and conclusions for approval.

In a **laboratory setting**, pharmacologists might:

- conduct research on the absorption and metabolism of chemicals in skin (such as colors, cosmetics, and other topically applied products)
- investigate the disposition of xenobiotics in normal and diseased animals
- investigate the effects of drugs and toxins from the molecular level to the total body response
- develop new methodology for the evaluation of chemicals, drugs, and toxins.



## Career Opportunities at FDA for Engineer

### Engineer Qualifications

- ❖ Completion of a full 4-year professional engineering curriculum leading to a bachelor or higher degree in engineering in an accredited college or university
- ❖ Knowledge of the physical and mathematical sciences underlying professional engineering
- ❖ Understanding the engineering sciences and techniques and their application to one of the branches of engineering.





## Compensation and Benefits

- GS Pay Scale

Grade	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9	Step 10
1	\$ 22,336	\$ 23,083	\$ 23,825	\$ 24,565	\$ 25,307	\$ 25,743	\$ 26,477	\$ 27,218	\$ 27,246	\$ 27,942
2	25,114	25,711	26,342	27,246	27,551	28,361	29,171	29,980	30,790	31,600
3	27,400	28,313	29,226	30,139	31,053	31,966	32,879	33,792	34,705	35,618
4	30,761	31,785	32,810	33,835	34,860	35,885	36,909	37,934	38,959	39,984
5	34,415	35,563	36,711	37,859	39,006	40,154	41,302	42,450	43,597	44,745
6	38,363	39,641	40,919	42,198	43,476	44,754	46,032	47,310	48,589	49,867
7	42,631	44,052	45,473	46,894	48,315	49,736	51,158	52,579	54,000	55,421
8	47,212	48,786	50,360	51,934	53,508	55,082	56,655	58,229	59,803	61,377
9	52,146	53,884	55,622	57,360	59,098	60,836	62,573	64,311	66,049	67,787
10	57,426	59,340	61,254	63,168	65,083	66,997	68,911	70,825	72,740	74,654
11	63,091	65,194	67,297	69,400	71,504	73,607	75,710	77,813	79,916	82,019
12	75,621	78,142	80,662	83,183	85,703	88,224	90,744	93,264	95,785	98,305
13	89,924	92,922	95,919	98,916	101,914	104,911	107,909	110,906	113,904	116,901
14	106,263	109,804	113,346	116,887	120,429	123,970	127,512	131,053	134,595	138,136
15	124,995	129,161	133,328	137,494	141,660	145,827	149,993	154,160	157,100 *	157,100 *

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[www.opm.gov](http://www.opm.gov)



### FDA Has Many Career Opportunities!

For information concerning all current FDA vacancies, please click on this link: <http://www.usajobs.gov/>. Using this site, click on "Search," select the Department of Health and Human Services/Food and Drug Administration, and search for the specific position by entering a General Service (GS) series, Occupation Type or Job Title.

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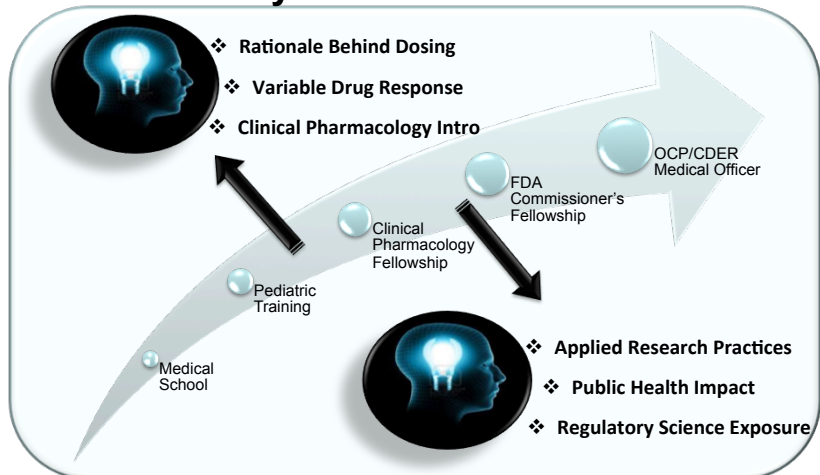
## CAREER OPPORTUNITIES AT THE FDA

Dionna Green, MD

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### My Path to the FDA



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## Career Opportunities at FDA for Physicians

### Medical Officer Qualifications

- ❖ Doctor of Medicine or Doctor of Osteopathy from an accredited school in U.S. or Canada
- ❖ Foreign medical school graduates must be ECFMG certified
- ❖ Various medical specialties accepted
- ❖ Board certification and experience conducting clinical trials are a plus (but not required)



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### • GS Pay Scale

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4	30,761	31,785	32,810	33,835	34,860	35,885	36,909	37,934	38,959	39,984
5	34,415	35,563	36,711	37,859	39,006	40,154	41,302	42,450	43,597	44,745
6	38,363	39,641	40,919	42,198	43,476	44,754	46,032	47,310	48,589	49,867
7	42,631	44,052	45,473	46,894	48,315	49,736	51,158	52,579	54,000	55,421
8	47,212	48,786	50,360	51,934	53,508	55,082	56,655	58,229	59,803	61,377
9	52,146	53,884	55,622	57,360	59,098	60,836	62,573	64,311	66,049	67,787
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## Compensation and Benefits

- Title 38 Physicians Pay
  - Pay authority intended to recruit and retain highly qualified professionals
  - Mechanism to compensate at levels comparable to private sector physicians within same locality area
  - 2-component system (Title 5 GS base pay and Title 38 market pay)
  - Physician Comparability Allowance up to \$24,000 (depending on years of federal service)
  - GS14 – GS15
- Annual leave
- Sick leave
- 10 paid federal holidays/year
- Health Insurance
- Life Insurance
- Retirement



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[www.opm.gov](http://www.opm.gov)

## How can I be part of OCP?

- Short-term internships (trainees)
- Fellowships
- Collaboration on specific projects
- Presentations/seminars

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## Work/Life Balance

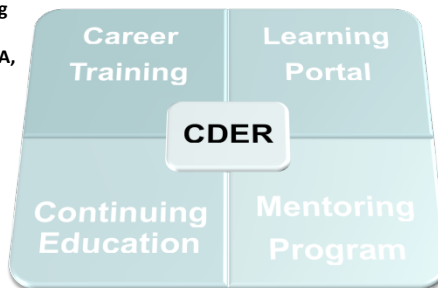


- **Alternative Work Schedules**
  - Provides schedule options other than the 8 hrs./day, 40 hrs./wk.
- **Flexible Workplace Arrangement**
  - Allows employees to work at an alternative site (e.g., home) on a recurring basis
- **Transshare Programs**
  - Offers transit subsidies to employees commuting by public transportation or vanpool
- **Voluntary Leave Transfer Program**
  - Allows employees to request donated leave to cover medical or family emergencies
- **Child Care Center**
  - Accredited center located on FDA campus that provides care for children ages 6 weeks to 5 years

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## Professional Development at FDA

- ❖ Position-specific training
- ❖ Courses in regulations governing IND, NDA, BLA, and generic drugs
- ❖ Leadership courses
- ❖ Available for MDs, PharmDs, and RNs
- ❖ Scientific Rounds, Seminars, Workshops, Journal Club, Courses
- ❖ Available all year



- ❖ HHS University
- ❖ Provides core, leadership and technical competency-based learning activities
- ❖ 1-1 mentoring
- ❖ Intended to build leadership capacity, increase job satisfaction & employee retention
- ❖ 10-month program

Committed to Providing a Continuous Learning Environment

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## Professional Development -- External

- ❖ Travel funds for 1-2 meetings/year
- ❖ Regulatory workshops

- ❖ For MDs, PharmDs, RNs
- ❖ Excused absence for clinical work, teaching, or research
- ❖ Part of official duty hours (up to 4 hrs./wk.)



- ❖ Affiliations & memberships
- ❖ Opportunities for collaborative symposiums

- ❖ Highly encouraged
- ❖ Protected time for writing/preparation available
- ❖ Opportunities for collaboration

**\*\*FDA Partnerships with Centers for Excellence  
(Georgetown University and University of Maryland)**

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## Fellowship Opportunities at FDA



- **Commissioner's Fellowship Program**
  - 2-year fellowship
  - Combines rigorous regulatory science training and a scientific, policy, or regulatory science research project
  - Graduate-level coursework
  - Applicants must have Doctoral level degree (or a Bachelor's or Master's degree in an engineering discipline)
  - Competitive salaries and travel funds
  - FDA employee
  - Benefits package (including health insurance, retirement, paid vacation leave and sick leave)
- **ORISE Fellowship**
  - Temporary appointment (limited to a total of 5 years)
  - Provides practical research training
  - Engage in scientific studies and investigations
  - Applicants can be pre-doctoral, postdoctoral, faculty, foreign national trainees, or summer research participants
  - Contractors (non-FTEs)
  - Monthly stipend (amount determined based on past experience, years in position, and scientific contributions)
  - Travel funds
  - May not include benefits package (nor earned annual or sick leave)

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## Fellowship Opportunities at FDA



- **Interagency Oncology Task Force (IOTF) Fellowship**
  - 2-5 year fellowship (depending on training track)
  - NCI, NIH and FDA joint fellowship program
  - Combines training in cancer-related scientific research and research-related regulatory review
  - Offers 4 different training tracks (oncology, clinical oncology, clinical oncology for board certified oncologists and cancer prevention fellowships)
  - Applicants must have Doctoral level degree (Ph.D., Master's degree, or equivalent)
  - Competitive salaries and travel funds
  - CRTA funding mechanism (non-FTEs)
  - Benefits package (including health insurance, paid vacation leave and sick leave)
- **Regulatory Pharmaceutical Fellowship**
  - 2 years fellowship
  - FDA-Academia-Industry joint fellowship program
  - Applicants must have PharmD degree
  - Competitive stipend and benefit package
  - Reimbursement for relocation and professional travel expenses

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<http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/default.htm>



## Student Rotation Opportunities at FDA



- **Pharmacy Student Experiential Program**
  - 4-6 week rotation
  - Provides an opportunity to become familiar with the mission, function and organizational structure of HHS, FDA, and other governmental agencies/institutions in the Washington area
  - Attend lecture series, FDA Advisory Committee hearings, and congressional hearings
  - Rotation must occur during 4<sup>th</sup> year of pharmacy school
  - Unpaid volunteer
  - Provides academic credit hours required for the PharmD degree

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<http://www.fda.gov/aboutfda/workingatfda/fellowshipinternshipgraduatefacultyprograms/pharmacystudentexperientialprogramcder/default.htm>

## CDER Science and Research Programs



## Regulatory Science Research Opportunities

- **Research Grant**
  - Critical Path Grants
  - Regulatory Science Research and Review Enhancement Grant
  - Office of Women's Health
  - Medical Countermeasure Initiative
- **Scientific Interest Group**
  - A group of volunteer members with a common interest in a particular scientific topic
  - Current SIGs in OCP include: PGx, PBPK, Geriatrics, Biologics, Transporters, Bioanalytical
- **OCP Sabbatical/Scientific Visit Program**
- **Visiting Fellows Program**
- **OCP Science Day/Presentations/Publications**



## Thank You

**Rita Humeniuk Ph.D.**

Commissioner's Fellow  
Pediatric Clinical Pharmacology Staff  
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## Food and Drug Administration

- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)**
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Tobacco Products (CTP)
- Center for Veterinary Medicine (CVM)
- National Center for Toxicological Research (NCTR)
- Office of the Commissioner (OC)
- Office of Regulatory Affairs (ORA)
- Office of Chief Counsel

[www.fda.gov](http://www.fda.gov)

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## Office of Clinical Pharmacology

- Mission
  - To assure the safety and effectiveness of new drugs through the evaluation of clinical pharmacology and biopharmaceutics data in support of the CDER's IND, NDA, and Biologics License Application (BLA) review programs.
  - Through research, we assure that regulatory policy and decision making are based on the best available science.
- How do we accomplish this?
  - Evaluate what the body does to the drug and what the drug does to the body
  - Understand inter-patient variabilities that relate to benefit and risk
  - Optimize dose and dose regimen to balance benefit and risk
  - Translate knowledge from NDA/BLA reviews into labeling language that is understandable and actionable
  - Conduct research to expand our knowledge of clinical pharmacology to better evaluate benefit and risk

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106189.htm>

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## OCP Strategic Plan 2010-2015

- **Demonstrate** the scientific value and clinical relevance of clinical pharmacology data analysis and interpretation
- **Focus** on continually improving the efficiency, consistency, timeliness and quality of our review process
- **Recruit** individuals with appropriate skill sets and reward them for their actions and behaviors related to the implementation of the strategic plan
- **Enhance** internal and external communication

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## Pre-IND to IND

### Industry

**Disease Targeted**



Combinatorial Chemistry  
Highthroughput Screening  
Formulations development  
Preclinical Pharmacology/  
Toxicology  
Preclinical PK/Metabolism  
In Vitro Human Metabolic  
Screening  
Pharmacogenetics  
Screening IND

### FDA/OCP

**Pre-IND meeting**



**IND: NME**

**Phase 1:  
1<sup>st</sup> time  
in humans.**

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## Phase 1 to Phase 2

### Industry

**Phase 1:  
1<sup>st</sup> time  
in humans**



**Phase 2:  
Patients**

### FDA/OCP

**Phase 1  
report**

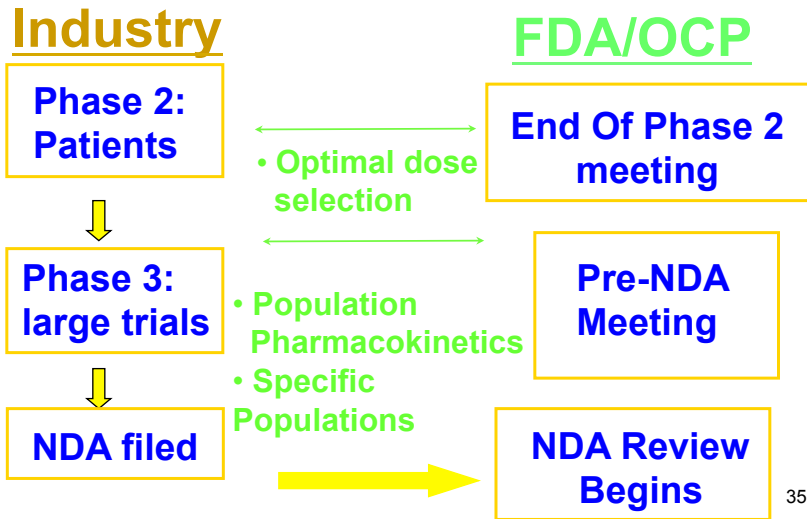
•Pharmacokinetics  
•Pharmacogenetics

**IND:  
Phase 2  
Protocol**

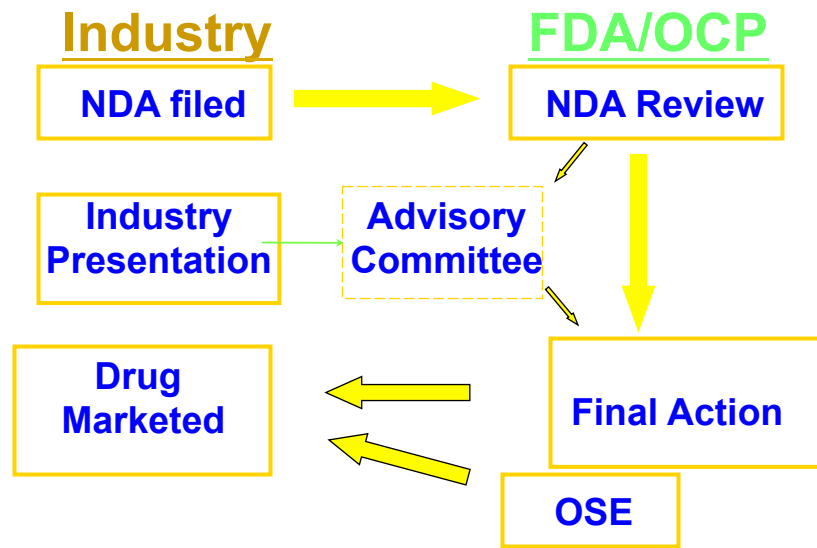
•Pharmacokinetics  
•[Pharmacogenetics]  
•Exposure-response  
•Drug interactions  
•Bioequivalence

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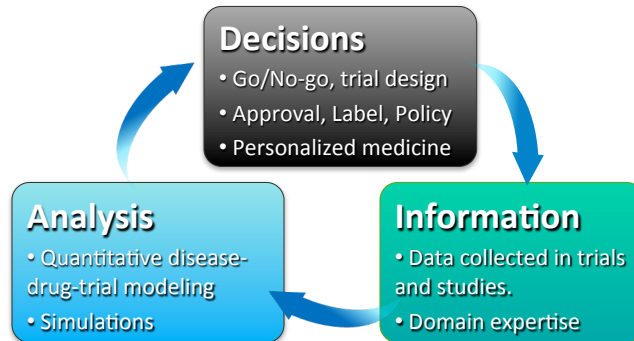
## Phase 2 to NDA



## NDA to Approval

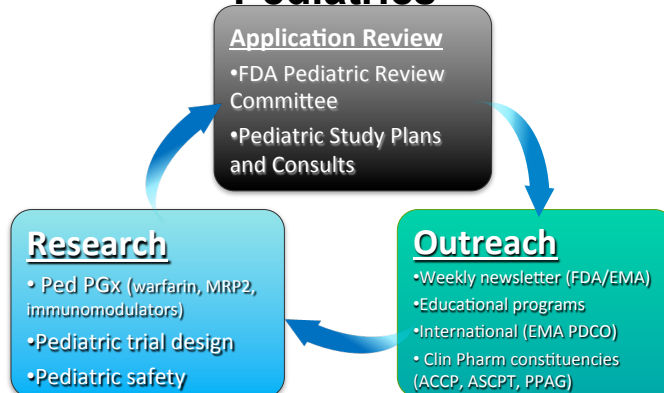


## Clinical Pharmacologists at the FDA: Pharmacometrics



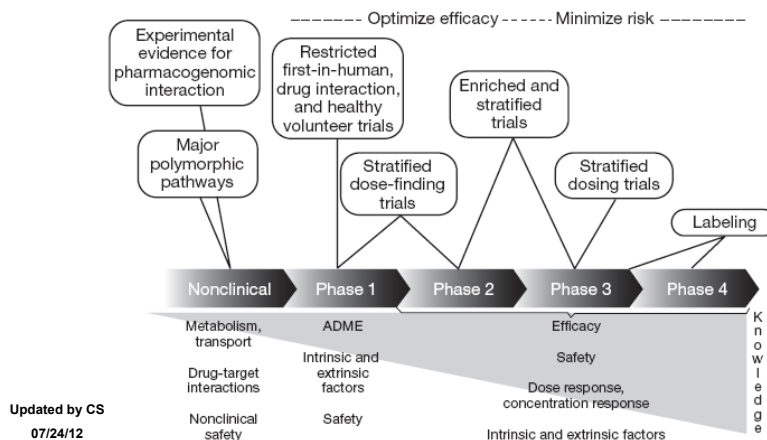
Pharmacometrics is the science of quantifying disease, drug and trial characteristics with the goal to influence drug development, regulatory and therapeutic decisions.

## Clinical Pharmacologists at the FDA: Pediatrics



Pediatric Clinical Pharmacology deals with the complex process of integrating the therapeutic considerations of pediatric disease, pediatric ontogeny, and pediatric drug development with the regulatory science behind the Pediatric Research Equity Act and Best Pharmaceuticals for Children Act.

## Clinical Pharmacologists at the FDA: Genomics



Reference: Pharmacogenomics in the assessment of therapeutic risks versus benefits: inside the United States Food and Drug Administration; Zineh et al.; Pharmacotherapy; Aug 2011; 31(8); 729-35 39

## Clinical Pharmacologists at the FDA: Safety

- **Pharmacological mechanism guided personalized medicine**
- **Leveraging systems biology, genomics, and toxicology**
  - **Prospective prediction of drug safety signals (INDs and NDAs)**
  - **Differentiating between true and false positive safety signals**
  - **Identifying the subgroups of patients at risk**



## Career Opportunities at FDA for Physicians

### Cross-Discipline Review Teams:

- **Pre-Market**
  - Medical Officer/Physician
  - Project Manager
  - Chemist
  - Pharmacologist (Toxicologist)
  - Clinical Pharmacologist
  - Statistician
  
- **Post-Market**
  - Epidemiologist
  - Risk Management
  - Safety Evaluator

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## Career Opportunities at FDA for Physicians

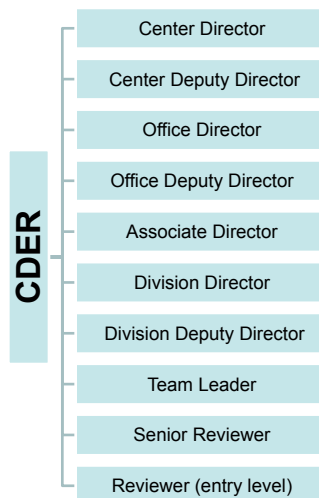
### Reviewer (Medical Officer) duties:

- Ensure all human drugs/biologics manufactured for interstate sale are effective with truthful and informative product labeling
- Evaluate data submitted by sponsors of Investigational New Drug Applications (IND), New Drug Applications (NDA), Biologic Licensing Applications (BLA), and generic drug applications to support the marketing of a drug/biologics
- Determine the scientific validity of manufacturers' tests, drug safety and efficacy claims

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## Moving Up at FDA



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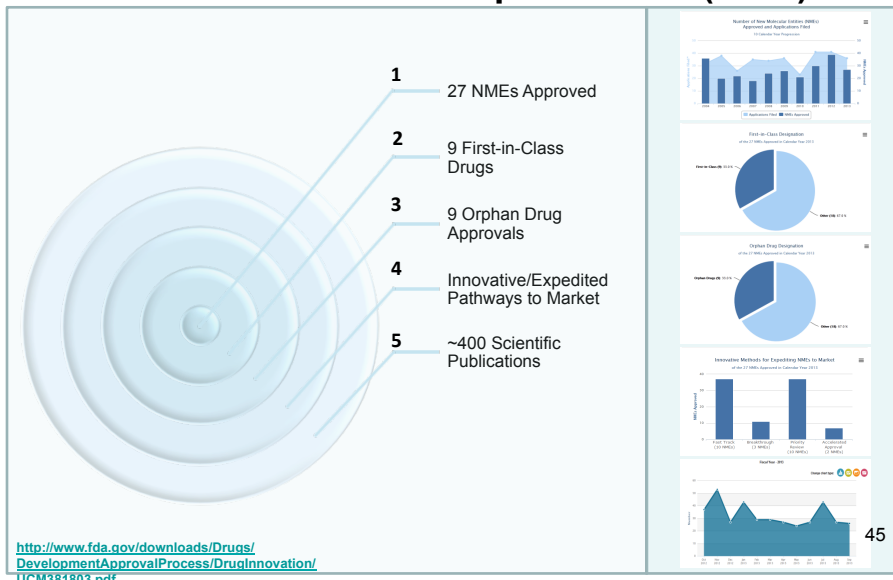


## Examples in OCP Leadership



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## Select CDER Accomplishments (2013)



## How can I be part of OCP?

- Reviewers have a variety of different backgrounds (Pharm.D., Ph.D., MD) and skill sets
- Submit a CV approximately 3-4 months before completion of degree program (ocp@fda.hhs.gov)
- Phone and/or on-site interview
- Assistance with visa processing



## Opportunities Outside OCP

- CDER/Office of New Drugs (OND)
  - Clinical reviewers
- CDER/Office of Compliance (OC)
  - Office of Scientific Investigation/Division of Good Laboratory Practice and Bioequivalence
  - Reviewers
- FDA/CDER/Office of Pharmaceutical Sciences
  - Office of Generic Drugs (OGD)
    - Reviewers