FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH
OFFICE OF CLINICAL PHARMACOLOGY

OFFICE OF TRANSLATIONAL SCIENCES

OFFICE OF CLINICAL PHARMACOLOGY

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CONTENTS

DIRECTOR'S MESSAGE

We recently had the opportunity to ask over 60 of our leaders, "What adjectives would you use to describe the FDA Office of Clinical Pharmacology's (OCP's) strengths?" Our staff were overwhelmingly identified as innovative, collaborative, and dedicated; attributes that have allowed us to rise to the personal and professional challenge of a lifetime, the COVID-19 pandemic. Continuing our strong tradition of rapid responses to public health crises, OCP established strike teams to address scientific and regulatory issues related to the pandemic. Internally, we established multiple, new methods to communicate the latest research, ensuring that our staffers had the necessary data and tools to make the most informed regulatory decisions.

In the midst of the pandemic, our dedicated staff members worked tirelessly to ensure the continuity of all drug development programs, research efforts, policy initiatives, and communication channels. As you will see in the following pages, we have met or exceeded our organizational, scientific, and regulatory goals for 2020. We expanded our policy fellowship program and published 6 new guidances for industry, with a major focus on the design, conduct, and interpretation of studies to assess the potential for drug-drug interactions (DDIs), a cause of preventable adverse drug events. OCP's Model-Informed Drug Development (MIDD) program brought together thought leaders from across the Agency to facilitate drug development through the use of novel approaches such as quantitative systems pharmacology (QSP), physiologically based pharmacokinetic (PBPK) analysis, and innovative population pharmacokinetic (PK) tools. We adapted quickly to the new virtual communication landscape and hosted 8 workshops/webinars on key topic areas, including assessing the proarrhythmic risk of drugs, selecting pediatric doses, developing topical drugs, determining the effects of hepatic impairment on a drug's PK, and more. Research efforts into microphysiological systems, QT prolongation, and the characterization of opioid structure and function continue to produce innovations that can further drug development and improve public health.

These are but a few examples of what our world-class workforce have been able to accomplish under immense pressure and during a time of profound public health need in the global community. I am humbled by the passion and dedication of our staff members, who bring their best to work while caring for their families and each other. It has been my honor and pleasure to work with this exceptional group of individuals this year, and I look forward to brighter days ahead.

Issam Zineh, PharmD, MPH, FCP, FCCP
Director – Office of Clinical Pharmacology

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Director - Office of Clinical Pharmacology

ORGANIZATION

OCP is a dynamic, purpose-driven organization dedicated to promoting and protecting global public health through the application of clinical pharmacology and translational medicine principles. OCP, an office within the FDA's Center for Drug Evaluation and Research (CDER) Office of Translational Sciences (OTS) super-office, is made up of over 240 pharmacologists, pharmacists, chemists, physicians, nurses, project and program managers, and administrative professionals. Our shared vision is to improve public health by building and translating knowledge of drug-response into patient-centered regulatory decisions of the highest quality.

Our mission is two-fold: 1) play a pivotal role in advancing the development of innovative new medicines by applying state-of-the-art scientific principles; and 2) promote therapeutic optimization and individualization through best practices in research, policy development, and drug evaluation throughout the product lifecycle. OCP fulfills its mission through its core functions of regulatory review, policy development and implementation, and research. Outcomes in these functional areas are enhanced by our expansive communication, stakeholder engagement, and outreach on national and international levels. We embrace our core values, stewardship, leadership, excellence, connectedness, diversity and respect, which foster a culture that empowers our staff members to translate knowledge for the benefit of patients. (See Figure 1)

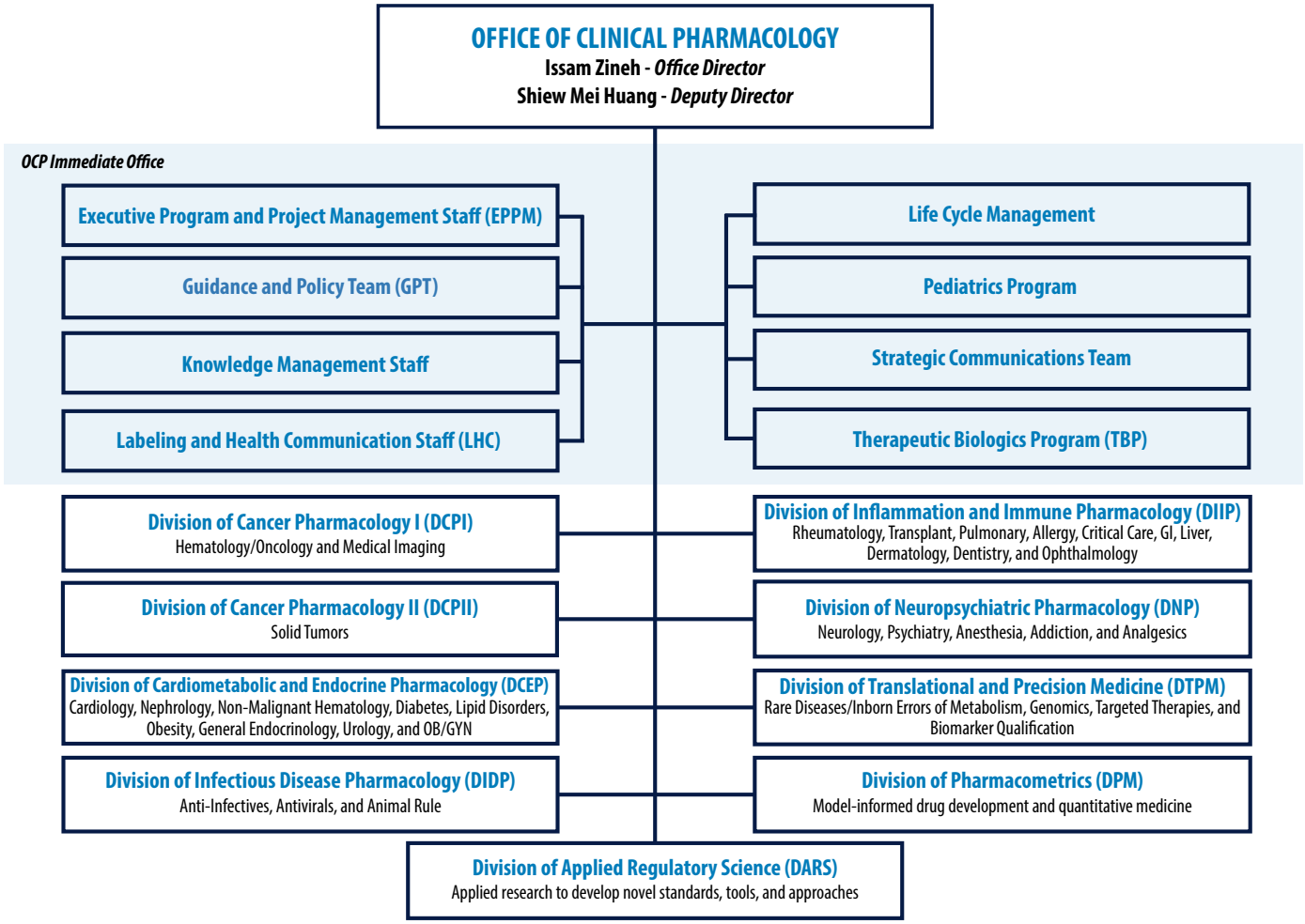
Figure 1

OCP Core Values

Last year's reorganization has continued to bring about significant organizational and regulatory synergies across the therapeutic landscape. (See Figure 2) We successfully completed the CDER New Drugs Regulatory Program modernization effort, an ongoing, multi-phase regulatory improvement initiative comprised of structural changes, process and documentation improvements, and enhancements to administrative and regulatory operations, by filling all leadership positions for our 8 review divisions. We established a new Lifecycle Management program, which will provide strategic and scientific expertise to our activities in the 505(b)2, Citizen petition, and generic drug development spaces, among other important cross-center governance activities. Our newly formed Strategic Communications Team provides direction for internal and external communications, applies traditional and innovative communication approaches, and empowers our staff members in their communication efforts to disseminate clear and meaningful information to stakeholders. In addition, we held a leadership retreat with over 60 OCP staff members to kickstart our next strategic planning effort, which will inform and guide the activities of the Office in the years to come. Our continued efforts at organizational excellence ensure better review quality and process efficiency, with a vision towards serving patients by delivering safe, effective, and high-quality drugs.

Figure 2

New Office of Clinical Pharmacology Organizational Structure



OCP REGULATORY REVIEW IN 2020

In 2020, our Agency faced an unparalleled drug development landscape and therapeutic challenges across a range of public health issues. OCP's regulatory evaluation of drugs and biologics ensures that the right drugs are administered at the right doses to the right patients at the right time in their disease process. The therapeutic challenges of 2020 were met with an efficient, multi-disciplinary, issue-based assessment strategy by our staff members. We judiciously applied clinical pharmacology principles to proposed drug development plans for investigational new drug applications (INDs), engaging drug developers and experts in multiple formats (face-to-face meetings, written responses as requested, advisory committee meetings, etc.). OCP's evaluations were also integrated into the benefit-risk assessment for new drug applications (NDAs), NDA supplements, and biologics license applications (BLAs), including 351(k) applications (i.e., biosimilars), ultimately bringing 53 safe and effective new drugs and biological products to patients.

From initial IND submission through NDA/BLA review and the post-marketing phase, thoughtful analysis and integration of clinical pharmacology knowledge of the products we evaluate allows us to optimize dosing recommendations for patient groups, quantify risk for the products we approve, develop management strategies to lessen those risks, and expand treatment options for patients. (See Figure 3 and Table 1)

IND SPACE

- Conducted approximately 2660 IND reviews and engaged sponsors in over 1680 IND meetings throughout 2020
- Promoted the use of model-based methods to support dose selection, dose-escalation strategies, new formulations and routes of administration, and evaluation of biosimilar products
- Employed extrapolation strategies and confirmatory PK study designs to select doses for pediatric populations and support formulation bridging
- Influenced development plans and study designs through evaluation of molecular-based criteria for trial eligibility and polymorphism/genotype liability

NDA/BLA SPACE

- Used model-based analyses to evaluate and individualize dosing in diverse patient populations (e.g., pediatrics, older adults, organ impairment), predict DDI potential, support administration conditions (e.g., with food), and inform doses in complex treatment scenarios (e.g., fixed drug combinations, loading doses, dose titration)
- Formed therapeutic strategies to mitigate risk for patients due to DDIs, patient factors (e.g., age, body weight), and safety profiles (e.g., QT prolongation, laboratory abnormalities)
- Evaluated pharmacogenomic factors to support therapeutic indications and DDI management
- Supported bridging strategies underpinning effectiveness and regulatory decision-making
- Contributed to 7 advisory committee meetings, forums for scientific exchange on product-specific portfolios

POST-MARKETING

- Recommended post-marketing studies to further evaluate clinical DDI potential, PK in specific populations, safety/toxicity risk (e.g., cardiac, corneal), and formulation and administration optimization
- Expanded treatment options for patients and informed labeling for new patient populations and unmet medical needs through the application of model-based methods (e.g., E/R analyses supporting pediatric dosing and extrapolation)
- Evaluated pharmacogenomic associations to support safety-related product labeling

Figure 3

Scope of OCP Review

Table 1

OCP Review Contributions to New Molecular Entity Drug and Biological Product Approvals

Therapeutic Area	Drug Name	Primary review contribution: Influenced development plan or trial design	Optimized dosing regimen	Evaluated/ proposed bridging or extrapolation strategies	Assessed genetic factors	Mitigated risk	Other
Cardiovascular	Nexletol						
Dermatology	Klisyri						
	Winlevi						
	Xeglyze						
Gastrointestinal	Barhemsys						
	Pizensy						
Infectious Disease	Artesunate						
	Ebanga						
	Inmazeb						
	Lampit						
	Rukobia						
	Veklury						
Metabolic/ Endocrine	Dojolvi						
	Gemtesa						
	Imcivree						
	Isturisa						
	Oxlumo						
	Sogroya						
Neurology	Byfavo						
	Evrysdi						
	Nurtec ODT						
	Olinvyk						
	Ongentys						
	Tauvid						
	Viltepso						
	Vyepti						
	Zeposia						
Oncology	Ayvakit						
	Blenrep						
	Cerianna						
	Danyelza						
	Detectnet						
	Gallium 68 PSMA-11						
	Gavreto						
	Inqovi						
	Koselugo						
	Margenza						
	Monjuvi						
	Orgovyx						
	Pemazyre						
	Qinlock						
	Retevmo						
	Sarclisa						
	Tabrecta						
	Tazverik						
	Trodelvy						
	Tukysa						
	Zepzelca						
Ophthalmology	Enspryng						
	Tepezza						
	Uplizna						
Pulmonary	Orladeyo						
Rare Disease	Zokinvy						

COVID-19

On January 31, 2020, a national Public Health Emergency was declared in the United States in response to Coronavirus Disease 2019 (COVID-19), a global pandemic and international health crisis responsible for catastrophic morbidity and mortality. COVID-19 poses an unparalleled therapeutic challenge, to which OCP served a vital role in our nation's response.

OCP review activities informed dosing strategies and risk-benefit assessments for multiple COVID-19 treatment and prevention candidates under development. (See Figure 4) Specifically, our review contributions for products submitted for INDs, Emergency Use Authorization (EUA), and NDAs focused on assessing the suitability of dosing regimens, use in specific populations, and mitigating risk of drug interactions and cardiac events. OCP identified the need for studies in pediatric patients, pregnant individuals, and patients with impaired hepatic function or renal function to ultimately bring therapeutic options to the diverse patient population facing COVID-19.

Ensured adequate justification of doses and dosing regimens evaluated in clinical studies for COVID-19 therapeutics through the application of clinical pharmacology principles

- Leveraged prior clinical experience and known PK and pharmacodynamic (PD) information to predict novel safe and efficacious dosing regimens
- Assessed dosing recommendations for specific populations based on intrinsic factors, including age (i.e., pediatric patients), renal and hepatic impairment, dialysis, and body weight
- Conducted exposure/response (E/R) analyses and PK/PD modeling for efficacy and safety incorporating previous clinical experience and data from global clinical trials as they were made available
- Assessed mechanism of action, in vitro activity, neutralization assays, viral dynamics, and preclinical animal efficacy models to support regimens proposed for study
- Recommended in vitro studies to further justify treatments and dose regimens, with special consideration for predicting systemic and lung exposures (i.e., site of action)

Mitigated the risk of COVID-19 therapeutics

- Assessed the risk of cardiac toxicity to inform doses studied in clinical trials and the need for increased cardiac (i.e., ECG) monitoring
- Used modeling and simulation (M/S) to bridge previous clinical experience to inform safety of proposed dosing regimens
- Provided dosing, monitoring, and exclusion strategies to mitigate risk in clinical trials based on assessment of:
  - — DDI potential (e.g., exclusions of co-medications)
  - — Specific populations (e.g., exclusion of patients with organ impairment or certain co-morbidities)
  - — Risk of cardiotoxicity (i.e., recommended intensive QT monitoring for patients at risk) and other significant safety concerns (e.g., hypersensitivity, immunogenicity)
  - — Washout requirements for co-medications

OCP worked to enhance and enable real-time integration of data and apply novel science and technology through COVID-19 research proposals and projects. (See Research and Publications pgs. 11-12) Our collaborations across FDA and with external partners facilitated rapid advancement in:

- Defining cardiac/QTc prolongation risk assessment for combination therapies for COVID-19 using an in vitro model in combination with PK modeling
- Evaluating the DDI potential of therapeutics for COVID-19 using a liver model
- Aiding safety/toxicity assessments of hand sanitizers and potential treatment candidates for COVID-19
- Standardizing overdose labeling for approved products repurposed for COVID-19
- Leveraging an existing pharmacovigilance and overdose surveillance network to gather adverse reaction data in patients with COVID-19

Rapid communication of current regulatory science and perspectives on clinical pharmacology of COVID-19 therapeutics was achieved by enhanced internal assessment and clearance practices and dedication to getting the most current information in the public domain through peer-reviewed publications, national and international presentations, and web media. (See Research and Publications pgs. 11-12 and Outreach and Engagement pg. 13)

"Sound PK modeling and accurate in-vitro-to-in-vivo translation of data will be crucial…"

Translating In Vitro Antiviral Activity to the In Vivo Setting: a Crucial Step in Fighting COVID-19

Spotlight on CDER Science

Influenced drug development plans for COVID-19 therapeutics

- Applied model-informed methods to predict the antiviral effect of proposed treatments and explore alternative routes of administration to achieve adequate drug concentrations at the site of action
- Recommended proof-of-concept studies, dose-ranging approaches, sampling strategies to improve the utility of PK and PD/biomarker data for E/R analyses, and interim PK/PD analyses to aid in the interpretation of clinical trial results
- Evaluated routes and conditions of administration to account for variable absorption and dosing complexities, specifically in the critically ill population (e.g., nasogastric tube administration with mechanical ventilation and pH dependency)
- Conducted assessments of potential DDIs and the need for adjustments of dosing regimens in specific populations for master protocols
- Engaged international partners on dosing strategies for specific populations (e.g., pediatrics) and gained alignment on extrapolation strategies for age subsets

Figure 4

OCP Pandemic Response: Impacting COVID-19 Drug Development Through Regulatory Review

MODEL-INFORMED DRUG DEVELOPMENT

DEFINITION

MIDD is defined as the use of exposure-based, biological, and statistical models derived from preclinical and clinical data to facilitate decision-making.

MIDD has been recognized as an important facilitator of drug development by the Prescription Drug User Fee Act (PDUFA) VI, as it enables streamlined drug discovery, development, and regulatory evaluation. To facilitate safe and effective drug development, MIDD leverages a range of quantitative approaches to inform decision-making and has been routinely used to provide supportive evidence for safety and effectiveness, optimize dosing, and inform clinical trial design.

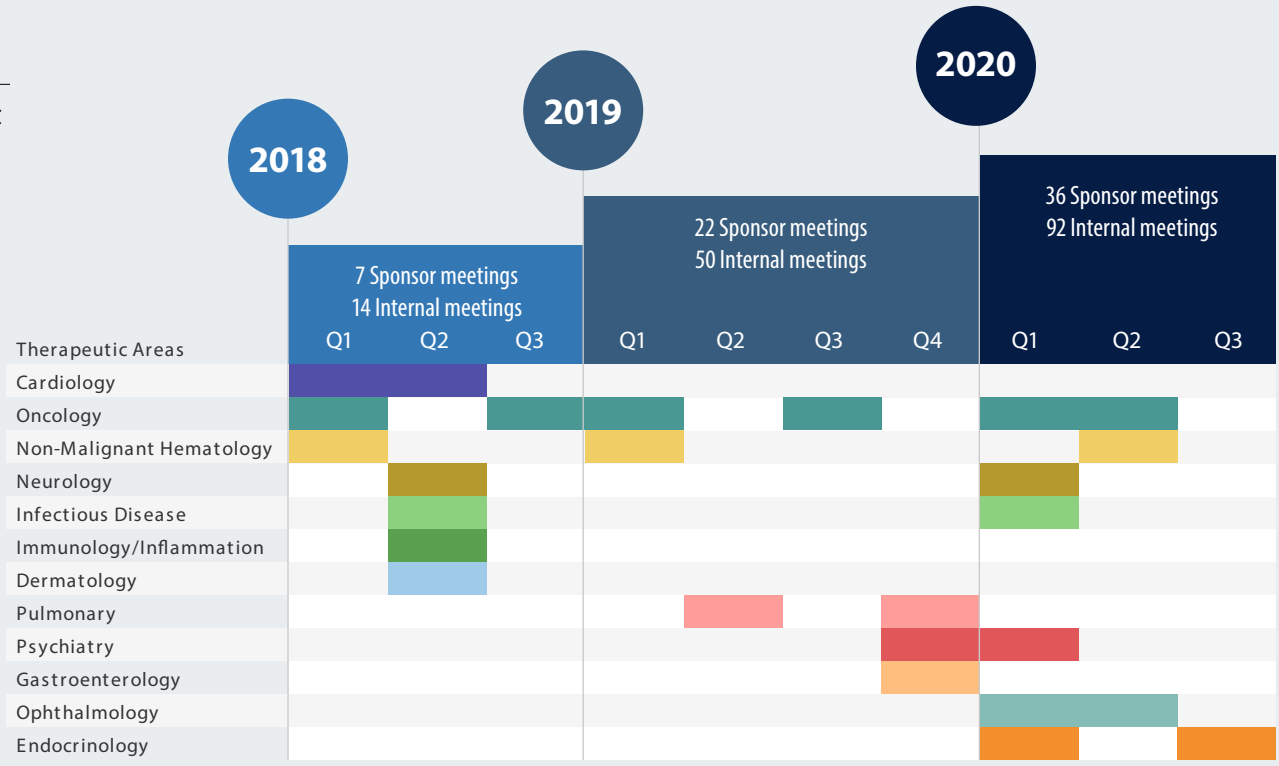
Under recent amendments to PDUFA VI, OCP has advanced the use of MIDD through policy and research, stakeholder engagement and outreach, and education. This work has had a significant impact on drug development and regulatory science, some of which has been published and presented this year. (See Research and Publications pgs. 11-12 and Outreach and Engagement pg. 13)

OCP has had a major role in the MIDD Pilot Program, a cross-center initiative that enables focused discussions between sponsors and FDA on M/S issues early in development. Since its induction in 2018, the pilot has met or exceeded its quarterly goals for granting meeting requests. Of the sponsors who have applied, 22% have submitted multiple requests for different drug programs. While the pilot granted many meeting requests in oncology, the number of therapeutic areas represented has grown over the last 3 years. (See Figure 5) For those accepted applications, FDA has conducted over 100 meetings to facilitate internal and external alignment on a variety of issues including model validation, bridging strategies between dosing schedules and administration routes, and approaches to inform patient and dose selection. This year the pilot yielded the approval of a new IV loading regimen for sotalol hydrochloride injections which reduces the length of hospitalization for patients.

If you have any questions regarding MIDD, please email *MIDD@fda.hhs.gov*.

Figure 5

Cumulative MIDD Pilot Program Meetings by Year & Expanding Therapeutic Areas Over Time



2020 was a banner year for the communication of FDA policy regarding the identification and assessment of DDIs and the conduct of studies to assess the impact of renal impairment. (See Figure 6) In addition to 6 published FDA guidances for industry, OCP also developed 18 internal policy briefs to provide best practices for the development of biosimilar biological products. OCP staff members were involved in over 58 guidance and policy working groups, providing a clinical pharmacology perspective to FDA guidances, product-specific guidances, internal policy briefs, and other policy documents to address a diverse array of diseases, drugs, devices, and biological products.

OCP's policy portfolio is informed by several information streams, including research carried out by 77 scientific and regulatory fellows. In 2020, OCP expanded its policy-driven research program to more readily identify, track, and prioritize emerging scientific topics and identify best practices and policy questions. For example, the intensive one-year OCP Policy Fellowship, instituted in 2017, has thus far successfully trained 3 individuals in regulatory science. In 2020, OCP broadened this initiative, resulting in over twice the number of applications from the year before (87 from 41) and the onboarding of 2 new policy fellows. OCP also increased the transparency and awareness of ongoing regulatory research to increase collaboration and speed the identification of scientific and regulatory issues that require policy development.

Figure 6

Drug-Drug Interaction Guidances Published in 2020

OCP-LED GUIDANCES PUBLISHED IN 2020

- **Clinical Drug Interaction Studies – Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions (Final):** Describes clinical studies to evaluate the DDI potential of an investigational drug, including study design, interpretation, and options for managing such interactions in patients
- **In Vitro Drug Interaction Studies - Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions (Final):** Describes how to assess the DDI potential of a drug in vitro and use the results to inform clinical drug interaction studies
- **Drug-Drug Interaction Assessment for Therapeutic Proteins (Draft):** Provides a systematic, risk-based approach to determine the need for DDI studies with a therapeutic protein
- **Evaluation of Gastric pH-Dependent Drug Interactions With Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications (Draft):** Helps drug developers determine the susceptibility of an investigational drug to DDIs mediated by gastric-pH changes, characterize the effect with clinical studies, and communicate the relevant findings in the drug product labeling
- **Clinical Drug Interaction Studies with Combined Oral Contraceptives (Draft):** Helps sponsors determine the impact of co-administered drugs on the safety and efficacy of combined oral contraceptives
- **Pharmacokinetics in Patients With Impaired Renal Function – Study Design, Data Analysis, and Impact on Dosing and Labeling (Revised Draft):** Provides updated recommendations on when a standalone PK study of a drug in subjects with impaired renal function is recommended and when it may not be needed, the design of such studies, and how to analyze the data

INTERNATIONAL HARMONIZATION IN 2020

OCP involvement in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) resulted in the publication of harmonized recommendations for assessing bioequivalence (M13), biopharmaceutical classification systems (M9), and integrated nonclinical-clinical QT/proarrhythmic risk assessment (E14/S7B Q&As).

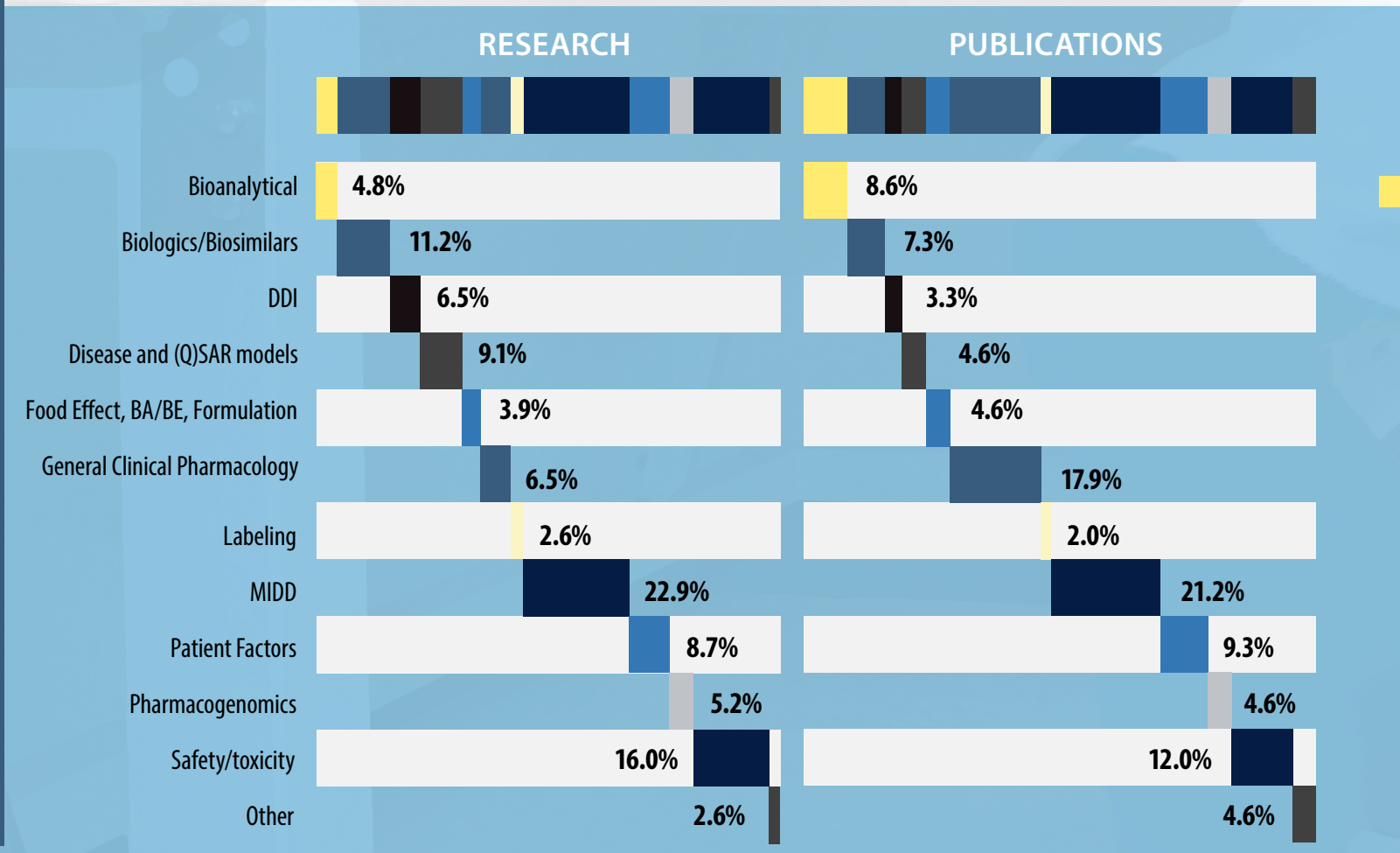
RESEARCH AND PUBLICATIONS

Regulatory research is critical to advancing the science to facilitate both regulatory review and policy. OCP has also used research to address urgent public health needs this year including the COVID-19 outbreak and the opioid crisis. Through frequent publication in peer-reviewed journals, our staff members share important research outcomes and give insight into regulatory thinking. This year, OCP engaged in 231 research projects and published 151 papers covering a wide range of topics in clinical pharmacology and translational science. (See Figure 7) Our robust research fellowship program offered unique development opportunities to 77 new scientists and enriched OCP regulatory research activities across analytical, laboratory, policy, and review domains.

OCP's Division of Applied Regulatory Science (DARS) used translational approaches such as in vitro and in vivo laboratory methods, experimental medicine, and in silico computational modeling and informatics to meet challenges in drug development, regulatory review, and emergent public health needs. For more details on our dedicated research division, visit the DARS website. (https://go.usa.gov/xAH6Z)

Figure 7

OCP Research and Publication Focus Areas in 2020



NOTABLE OCP PUBLICATIONS IN 2020

COMMUNICATING SCIENCE TO IMPROVE PUBLIC HEALTH

COVID-19

- Connecting Hydroxychloroquine In Vitro Antiviral Activity to In Vivo Concentration for Prediction of Antiviral Effect: a Critical Step in Treating COVID-19 Patients (PMID: 32435791)
- Dose Selection in a Pandemic: a Framework Informed by the FDA Animal Rule (PMID: 33201590)
- Immunomodulatory Therapeutic Proteins in COVID-19: Current Clinical Development and Clinical Pharmacology Considerations (PMID: 32779201)
- Translating In Vitro Antiviral Activity to the In Vivo Setting: a Crucial Step in Fighting COVID-19 (Spotlight on CDER Science article; https://go.usa.gov/xA4jP)

SAFETY

- Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: a Randomized Clinical Trial (PMID: 31961417)
- Evaluating Kratom Alkaloids Using PHASE (PMID: 32126112)
- Predicting Potential Adverse Events Using Safety Data from Marketed Drugs (PMID: 32349656)
- Regulatory Efforts to Facilitate Evaluation and Clinical Management of Drug-Drug Interaction Risks (PMID: 32721040)
- Skin Cancer Prevention and Sunscreen Safety: Commentary on American Society of Clinical Oncology Policy Statement on Skin Cancer Prevention (PMID: 32603257)

SPECIFIC POPULATIONS

- Assessment of Similarity in Antipsychotic Exposure-Response Relationships in Clinical Trials Between Adults and Adolescents With Acute Exacerbation of Schizophrenia (PMID: 31994186)
- Does Hepatic Impairment Affect the Exposure of Monoclonal Antibodies? (PMID: 31899819)
- Geriatrics 2030: Developing Drugs to Care for Older Persons - a Neglected and Growing Population (PMID: 31667834)
- Scientific and Regulatory Considerations for an Ontogeny Knowledge Base for Pediatric Clinical Phar 31983072)
- The RACE to Develop New Targeted Therapies for Children With CNS Tumors (PMID: 32638364)

OCP RESEARCH AT A GLANCE

$16.4M 2020 research budget (approximate)

77 Research fellows in 2020

10 Average number of OCP publications per month in 2020

"Our goal is to move new science into the drug review process and close the gap between scientific innovation and drug review. "

David Strauss, M.D., Ph.D., Director

OCP Division of Applied Regulatory Science

OUTREACH AND ENGAGEMENT

In 2020, connectedness with our stakeholders was both more important and more challenging than ever. However, OCP adapted quickly to the new landscape, engaging collaborators domestically and internationally through virtual workshops and webinars, consortia and working group meetings, and presentations on an array of clinical pharmacology topics. OCP staffers ensured the continuation of our robust training and education programs, adapting student and policy fellowships to an all-virtual environment and increasing leadership in professional societies and committees.

Our communication and outreach efforts span the globe, with the aim of advancing the clinical pharmacology enterprise in three critical areas: (1) generating efficacy and safety data to facilitate drug development, (2) optimizing dosing for individual patients to maximize benefit and minimize risk; and (3) enabling access to medications worldwide through global partnerships. (See Figure 8)

Figure 8

OCP's Outreach and Communication Efforts Across the Global Clinical Pharmacology Enterprise

	DRUG DEVELOPMENT BUILD UPON DISCOVERIES TO GENERATE NECESSARY EFFICACY/SAFETY DATA	MEDICATION THERAPY MANAGEMENT INDIVIDUALIZED PHARMACOTHERAPY FOR PATIENTS IN THE HEALTHCARE SETTING	GLOBAL PUBLIC HEALTH LEVERAGE ADVANCES IN CLINICAL PHARMACOLOGY TO TRANSFORM THE HUMAN CONDITION
PRESENTATIONS (N = 135)	**75**	**37**	**23**
GUIDANCE WORKING GROUPS (WGs) (N = 58)	**37**	**15**	**6**
SCIENTIFIC & REGULATORY WGs/CONSORTIA (N = 85)	**43**	**34**	**8**

Reference: PMID: 31675100

2020 OCP OUTREACH AT A GLANCE

WORKSHOPS

- Topical Drug Development - Evolution of Science and Regulatory Policy Part 2 (FDA/M-CERSI)
- 3D Cell Culture Models for Drug Pharmacokinetic, Safety, and Efficacy Assessment (FDA/M-CERSI)
- Assessing Changes in Pharmacokinetics of Drugs in Liver Disease (FDA/M-CERSI)
- Pediatric Dose Selection (FDA/M-CERSI)

WEBINARS

- Labeling Made Simple: The How, What, and Where of Drug Interactions in Prescribing Information (FDA Drug Topics Webinar)
- New Approaches for an Integrated Nonclinical-Clinical QT/Proarrhythmic Risk (CDER Small Business and Industry Assistance (SBIA)/ICH Webinar)
- Regulated Bioanalysis Workshop: Current Requirement and Expectations (CDER SBIA Webinar)
- Updates on FDA's Drug-Drug Interaction Final Guidances (CDER SBIA Webinar)

ENGAGEMENT

- OCP Clinical Pharmacology Corner newsletter subscription service conveying timely information on NDA/BLA approvals, policy updates, events, and notable scientific topics to 78,500 subscribers
- 'Cluster' meetings with other regulatory agencies to identify gaps and harmonize approaches
- PEDSCLIPS Pediatric Clinical Pharmacology Weekly Newsletter disseminated FDA-wide and to regulatory agencies internationally (European Medicines Agency and Pharmaceuticals and Medical Devices Agency)

2021 OUTLOOK

This year has challenged us personally and professionally, and here at the end of 2020, we begin to see a light at the end of the tunnel and a return to "normal" life. Times such as these offer an incredible opportunity for reflection. What worked well and got us through these difficult times? And how do we ensure our continued readiness for the future? In November of 2020, we held an OCP Leadership Retreat to provide insights into the current state of clinical pharmacology from a diverse group of collaborators, understand how strategic planning can help our Office continue to grow, and brainstorm how to engage our OCP staff members and those impacted by our work in this critically important process. Our upcoming Strategic Plan will be our playbook, guiding initiatives that will keep us responsive and adaptable and ensure that our work has the maximum positive impact on the health and lives of the public.

At the same time, we will continue to move forward on mission-critical initiatives in OCP, including advancing MIDD, research and consults to address the ongoing opioid epidemic and sunscreen initiatives, pharmacogenomics to further personalized medicine, guidances and policies to articulate best practices in clinical pharmacology, and robust communication channels to ensure our partners can make informed decisions based on the latest scientific and regulatory information. These efforts will be supported by continued improvements to our program management processes, successful completion of the CDER Reorganization, and programmatic enhancements such as the creation of a Lifecycle Management team to provide strategic and scientific direction to our activities in the 505(b)2, Citizen petition, and generic drug development guidance spaces.

OCP rose to the challenge in 2020. In a year when staying connected was difficult, and at times seemed impossible, we provided experiential opportunities to students and trainees remotely, became leaders in professional organizations, presented at numerous virtual workshops and seminars, and continued to produce high-quality publications. We look forward to 2021 to ensure that OCP remains first-in-class in all aspects of our work to advance public health and improve the lives of all.

Examples presented in this Annual Report are illustrative and are not a comprehensive representation of 2020 information. For detailed information on the content of this report or our Office's other activities, please contact *ocp@fda.hhs.gov*.

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