U.S. FOOD & DRUG ADMINISTRATION

Office of Clinical Pharmacology

Office of Translational Sciences
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

2025 Annual Report

Contents

Director's Reflection

This year marks the 30th anniversary of the U.S. Food and Drug Administration's (FDA's) Office of Clinical Pharmacology (OCP)—three decades in which clinical pharmacology has grown from a specialized analytical discipline to a transdisciplinary, foundational pillar of regulatory decision-making at the FDA. Over these 30 years, OCP has helped shape how evidence is generated, integrated, and interpreted across the lifecycle of drug development, always with a singular aim: to ensure that patients receive therapies that are safe, effective, and appropriately used.

When OCP was established, clinical pharmacology was understood narrowly. OCP has evolved since its earliest days, cultivating not only technical rigor, but an insistence that the discipline serves decisions. Our work has consistently asked not just what the data show, but what they mean for patients, for prescribers, and for regulatory confidence.

Across three decades, OCP has played a central role in some of the most consequential evolutions in drug development and regulation. We have helped normalize routine application of model-informed drug development. We have advanced exposure-response principles to support dose optimization, labeling clarity, and pediatric extrapolation. We have brought both quantitative reasoning and mechanistic understanding to complex questions of benefit-risk, patient response variability, and scientific uncertainty—often in settings where traditional clinical trial paradigms alone were insufficient.

Just as importantly, OCP has grown in response to scientific and societal change. The last decade in particular has demanded new forms of agility: increasingly complex modalities; therapies for rare and genetically-defined diseases; accelerated development programs; and a growing expectation that regulators can assess evidence generated outside conventional randomized trials. OCP has met these challenges by expanding our methodological toolkit while remaining grounded in first principles.

Our legacy is also one of collaboration. Our staff works shoulder-to-shoulder with medical, statistical, nonclinical, and policy colleagues across Center for Drug Evaluation and Research (CDER) and the Agency, and with external partners across government, academia, and industry. Our many initiatives through the years, including those described in these pages, reflect OCP's commitment to shared problem-solving.

Equally central to OCP's 30-year story is its people. The Office has been shaped by generations of people who combined intellectual rigor with public health purpose—individuals willing to ask difficult questions, challenge assumptions, and invest deeply in mentoring those who followed. The culture they have built—one that values methodological excellence, scientific humility, and service—remains OCP's greatest asset.

Thirty years in, OCP stands as both steward and innovator: steward of a discipline that grounds drug development in quantitative and mechanistic understanding, and innovator in how that understanding is applied in the service of patients. It is a privilege to lead an office with such a distinguished legacy and such a clear sense of responsibility for the future. I am deeply grateful to the staff whose dedication makes this work possible, and I look forward with confidence to the contributions OCP will make in the decades ahead.

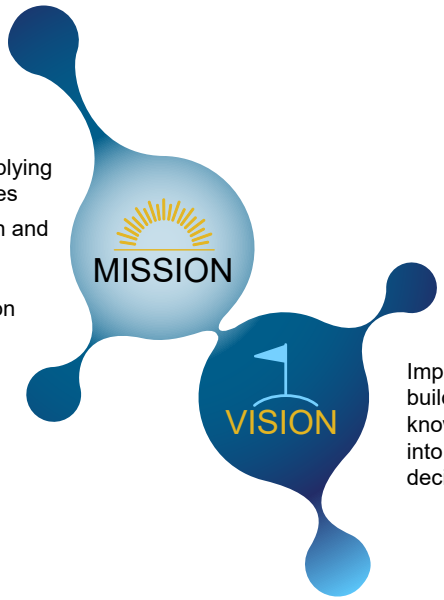
Issam Zineh
Director, Office of Clinical Pharmacology

Organization

OCP is a multidisciplinary organization within the FDA's CDER Office of Translational Sciences (OTS) that applies clinical pharmacology and translational medicine principles to achieve our mission and vision:

Advance the development of innovative new medicines by applying state-of-the-art scientific principles

Promote therapeutic optimization and individualization through best practices in research, policy development, and drug evaluation throughout the product lifecycle



Improve public health by building and translating knowledge of drug-response into patient-centered regulatory decisions of the highest quality

Comprised of over 270 professionals including pharmacologists, pharmacists, biologists, chemists, physicians, and nurses, OCP translates scientific knowledge into patient-centered regulatory decisions that ensure the safety, efficacy, and optimal use of human drug and biological products. Guided by our core values of Stewardship, Leadership, Excellence, Connectedness, and Respect, OCP leverages its multidisciplinary expertise to improve patient health outcomes through evidence-based regulatory decision-making.

Figure 1 | *Office of Clinical Pharmacology organization*

30 Years of OCP

OCP was formed in 1986 as the Division of Biopharmaceutics and later became the Office of Clinical Pharmacology and Biopharmaceutics before adopting its current name, the Office of Clinical Pharmacology. The office has transformed into a world-class organization of 270 scientists with comprehensive clinical pharmacology expertise.The office has achieved significant milestones in biopharmaceutics and clinical pharmacology science, including advances in bioanalysis, bioequivalence assessments, biosimilar evaluations, drug-drug interaction assessment, specialized population research, pharmacogenomics, biomarker science, and quantitative clinical pharmacology approaches. Over the past three decades, OCP has evolved from evaluating basic clinical pharmacology characteristics of drug products in the 1970s and 1980s, to individualized therapy, and to the sophisticated technology-enabled drug development approaches used today. OCP's growth has been supported by the development of regulations and guidance documents, landmark publications, and critical drug approvals that demonstrate the essential role of clinical pharmacology in modern drug regulation.

*Reflections of a Leader | **Shiew-Mei Huang***

Deputy Director (retired), Office of Clinical Pharmacology

My journey in OCP has been one of the most meaningful chapters of my professional life. After 15 years in industry, I first came to the FDA simply to join my husband but quickly discovered how much I loved being here. OCP provided an environment where I grew both personally and professionally — learning new science, starting to work out just to keep up with the pace, and finding myself energized by talented new colleagues who bring fresh perspectives every day. Some of my most memorable experiences have been working alongside regulatory thought leaders such as Dr. Robert Temple, whose kindness, knowledge, and unwavering commitment to patients deeply shaped my view of public health. I especially appreciate attending industry meetings with these leaders.

OCP has evolved into a dynamic, forward-thinking organization that embraces innovation, from quantitative methods to artificial intelligence and machine learning. The encouragement to work with external professional societies has broadened my scientific horizons and allowed me to build meaningful friendships across the field. Ultimately, choosing public health as my career was driven by the desire to have impact beyond any single company and to contribute to decisions that truly matter for patients. My time at OCP has allowed me to bring together my industry experience, my curiosity, and my commitment to service, and I remain grateful for the growth, purpose, and community it has given me.

The evolution of Office of Clinical Pharmacology

Standardizing Drug Characterization: Establishing Universal Standards for Drug Quality, Safety, and Regulatory Consistency

1970s – 1990s

Building a Foundation

- Established the Office of Clinical Pharmacology and Biopharmaceutics in 1995, creating organizational structure for the review of pharmacokinetics (PK), bioavailability, and other physiochemical drug properties
- Contributed to current statistical criteria for bioequivalence, ensuring that generic products would not produce significantly different exposure than that of the reference product
- Issued guidance to inform the preparation of the biopharmaceutics section of a New Drug Application (NDA)
- Collaborated on the scale-up and post-approval change guidances[1] [2] that describe the levels of evidence needed to modify formulation or production depending on the magnitude of change

2000s

Expansion and Refinement of Drug Characterization

- Established the Biopharmaceutics Classification System, which revolutionized biowaiver approaches by identifying products that do not have bioavailability concerns for different formulations
- Issued the original Bioanalytical Method Validation guidance, establishing expectations for assay validation and improving the reliability, consistency, and regulatory acceptance of bioanalytical data
- Developed guidance to standardize food effect evaluation, leading to better-informed labeling to enhance drug safety and efficacy

2010s – 2020s

Fine Tuning for Biological Products and Advanced Therapies

- Contributed to a comprehensive framework to assess biosimilars, supported by multiple guidances covering clinical pharmacology data, labeling, and scientific considerations
- Participated in the International Council for Harmonisation (ICH) to establish global standards for many areas: bioanalytical method validation (ICH M10), bioequivalence standard for immediate-release dosage forms (ICH M13A), and the Biopharmaceutics Classification System (ICH M9)
- Issued clinical pharmacology guidances on advanced biological products, including peptide drug products, antibody-drug conjugates, and oligonucleotide therapeutics

1 SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation
2 SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation

Individualized Therapy: Advancing Precision Medicine Through Patient-Specific Drug Optimization and Safety Assessment

1990s – 2000s

Focus on Organ Impairment and Early Precision Medicine

- Issued the original guidances on the standard evaluation of PK in patients with renal or hepatic impairment
- Ensured consistency in pharmacogenomic review activities through the formation of the Pharmacogenomics Team
- Provided expert input during development of ICH E15 to establish harmonized international definitions and terminology for pharmacogenomics

2000s – 2010s

Concentration on Safety and Specific Populations

- Led guidance efforts to ensure the safety and efficacy of drug products during pregnancy and in children by promoting rigorous study designs that account for physiological differences affecting drug exposure and response
- Made significant contributions to the creation of a comprehensive framework characterizing QT prolongation, including the issuance of the ICH E14 and S7B guidances and establishment of the Interdisciplinary Review Team for Cardiac Safety Studies

2010s – 2020s

Advancing Personalization and Enhancing Pediatric Drug Development

- Promoted systematic evaluation of how genetic differences affect drug response through new guidance
- Enhanced the consistency and scientific rigor of pediatric drug development via the ICH E11(R1) and E11A guidances as well as specialized guidances for neonates and for development of anti-seizure medications for infants and children
- Continued to strengthen the detection, prediction, and communication of safety risks by contributing to the international harmonization of drug interaction studies through ICH M12, expanding drug interaction guidances[3][4][5][6], renal impairment guidance, and modernizing QT prolongation modeling and labeling
- Transformed the Pharmacogenomics Team into the Division of Translational and Precision Medicine (DTPM) to apply clinical pharmacology principles and precision medicine strategies in all phases of drug development to maximize benefit and reduce risk to patients

3 Drug Interaction Information in Human Prescription Drug and Biological Product Labeling
4 Drug-Drug Interaction Assessment for Therapeutic Proteins Guidance for Industry
5 Clinical Drug Interaction Studies With Combined Oral Contraceptives Guidance for Industry
6 Evaluation of Gastric pH-Dependent Drug Interactions With Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications Guidance for Industry

Technology: Leveraging Computational Innovation, Data Science, and Digital Tools to Transform Drug Development and Regulatory Science

1990s
2000s

Creating a Framework for Quantitative and Mechanistic Pharmacology

- Issued multiple guidance documents[7] [8] focused on characterizing the relationships between drug exposure and the resulting clinical effects
- Established the Pharmacometrics Team to elevate model-informed evaluations of dosing, efficacy, and safety
- Initiated End of Phase 2A meetings facilitating early interaction between sponsors and FDA to discuss use of quantitative approaches to inform key drug development decisions

2010s

Applying Translational Science to Inform Drug Development

- Established the Division of Applied Regulatory Science (DARS), which applies translational approaches to meet regulatory and public health challenges
- Launched the Model Informed Drug Development (MIDD) Paired Meeting pilot to advance and integrate the development and application of models in drug development and regulatory review
- Issued guidance to enable more consistent, efficient, and transparent evaluation of physiologically based pharmacokinetics (PBPK) evidence in drug submissions

2020s

Advancing Drug Development with Quantitative Medicine

- Established the CDER Quantitative Medicine Center of Excellence (QM CoE) as a cooperative, coordinating body to spur innovation and foster comprehensive integration of quantitative medicine approaches into drug development
- Finalized guidance to standardize the design, application, and review of population pharmacokinetics (popPK) analyses
- Supported consistent adoption, application, and advancement of model-informed drug development by contributing to the development of ICH M15 and formalizing the MIDD Paired Meeting Program as a permanent opportunity

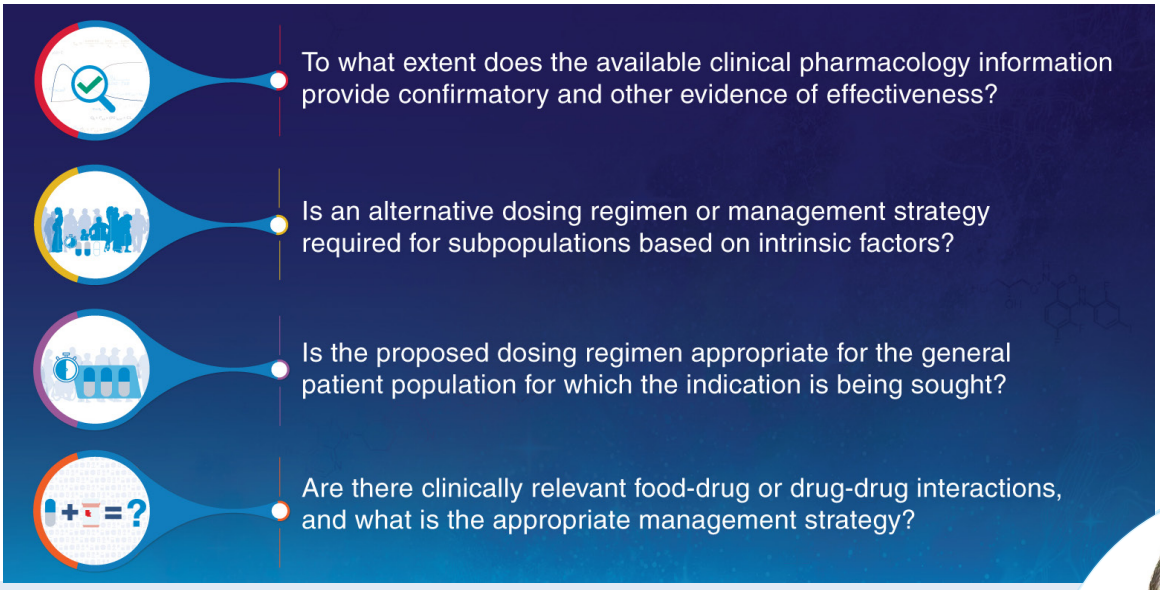
7 E4 Dose-Response Information to Support Drug Registration
8 Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications

Regulatory Evaluation

OCP's regulatory evaluation process uses an issue-based strategy that utilizes multidisciplinary clinical pharmacology knowledge to ensure approved drug and biological products are administered at the right doses to the right patients at the right time in their disease process. Through comprehensive reviews of investigational new drug (IND) submissions, NDAs, and biologics license applications (BLAs), OCP addresses the critical issues of dose selection and optimization, therapeutic individualization, and benefit/risk balance while identifying knowledge gaps and recommending studies to address them.

In 2025, OCP conducted over 6600 IND reviews and contributed to the approval of 46 safe and effective new drug and biological products. OCP additionally conducted supplemental reviews to support new indications, patient populations, formulations, and dosing regimens, and participated in thousands of drug development meetings. Through integrating clinical pharmacology findings into benefit/risk assessments, OCP directly improved patient health outcomes via evidence-based regulatory decisions informed by current science and policy.

Figure 2 | *OCP issue-based approach to drug evaluation*



Reflections of a Senior Reviewer | ***Srikanth C. Nallani***

Lead Pharmacokineticist, Division of Neuropsychiatric Pharmacology

Over the course of 22.5 years in OCP, change has been a defining characteristic. While some transformations occurred incrementally, others emerged rapidly, fundamentally altering the regulatory landscape. Throughout these transitions, the core mission has remained unwavering: advancing scientific excellence in service of public health.

Certain achievements in regulatory science are measured not solely by product approvals, but by their direct impact on public health outcomes. The opioid crisis exemplified this principle. Working on abuse-deterrent formulations and advancing naloxone products underscored the weight and urgency of our work. Decisions were not theoretical; they shaped communities, families, and futures. This experience reinforced that clinical pharmacology extends beyond data analysis and pharmacokinetic modeling—it represents a fundamental component of public health intervention and protection.

Innovation in Regulatory Review

OCP plays a pivotal role in drug development and regulatory review through the application of quantitative methodologies, MIDD approaches, and emerging development tools, combined with deep expertise across all areas of clinical pharmacology. Staying true to our mission and vision, OCP's day-to-day work combines cutting-edge science and efficient regulatory review. Through this work, we provided essential input on clinical trial designs and dosing recommendations that keep safety and efficacy at the forefront.

Key Technical Approaches

Quantitative medicine (QM) refers to the systematic application of mathematical and statistical modeling approaches to understand drug behavior, optimize therapeutic outcomes, and support regulatory decision-making throughout the drug development lifecycle. OCP uses multiple QM approaches, including popPK, exposure-response (E-R) modeling, PBPK modeling, and quantitative systems pharmacology.

OCP leads the MIDD Paired Meeting Program to facilitate timely dialogue between sponsors and FDA to optimize MIDD strategies throughout the development process. OCP staff play pivotal roles in other innovative regulatory programs, including initiatives to advance new approach methodologies (NAMs) and to evaluate dynamic drug development tools through the Fit-for-Purpose Initiative.

In 2025, these innovative approaches were used to optimize benefit-risk profiles and improve dosing regimens for underrepresented populations, significantly impacting regulatory decision-making throughout the drug development and application review process.

Evidence of Effectiveness

Multiple clinical pharmacology approaches, including dose-response and E-R analyses and PK modeling, helped establish confirmatory evidence for numerous drug products approved in 2025 across the full spectrum of therapeutic areas. These approaches were particularly valuable for rare diseases where clinical trials are challenging. Translational analyses conducted by OCP staff inform multidisciplinary review teams as they address critical questions about the use of surrogate endpoints and biomarker translation to support efficacy determination.

Efficacy can be extrapolated from well-studied populations to less-studied populations when disease pathophysiology, clinical manifestations, treatment paradigms, and drug pharmacology are similar between groups. A common example is extrapolation of efficacy and safety from adult patients to pediatric patients, as outlined in the ICH E11A guidance. OCP staff provide key input as sponsors develop plans for extrapolation to pediatric populations and then review the data that form the foundation for extrapolation and dosing recommendations. In 2025, OCP staff supported extrapolation to adolescents, younger children, and infants, enabling significantly earlier patient access than traditional clinical investigations would allow.

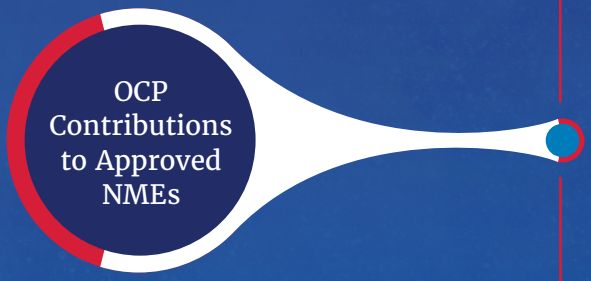
Dose Optimization and Risk Mitigation

Dose optimization has been a core function of OCP over the past three decades. During this time, our understanding of biological pathways, PK, pharmacodynamics (PD), and sources of variability significantly improved, with OCP's work directly contributing to these important advancements. This sustained focus on dose optimization continues to enhance our ability to ensure safe and effective drug dosing for patients.

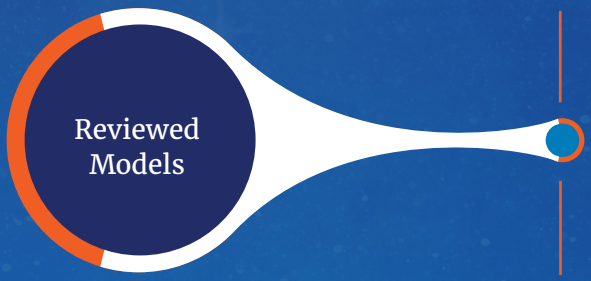
OCP conducts dose- and exposure-safety analyses that optimize dosages and minimize toxicity. Additionally, drug-drug interaction risks are mitigated through actionable labeling informed by in vitro data, clinical data, and predictive modeling. OCP also addresses dose optimization based on age, weight, organ function, and other patient factors using popPK and other modeling approaches. These methodologies, which were used for the new molecular entities (NMEs) assessed by OCP in 2025, helped identify sources of variable exposure and enabled simulations of unstudied dosage scenarios.

Review Contributions At-a-Glance

Over 6600 IND reviews
Over 580 NDA reviews
Over 230 BLA reviews
Over 160 ANDA reviews



30 NMEs: optimized dosing regimen
25 NMEs: mitigated risk
10 NMEs: assessed biomakers and PD data as evidence of effectiveness
04 NMEs: evaluated/proposed bridging or extrapolation strategies



Over 600 models reviewed
Over 200 applications contained models, including models for drug-drug interactions, organ impairment, food effects, and pediatrics

Regulatory Science Research

OCP's regulatory science research addresses challenges experienced during drug development and regulatory review. Our research activities include development of innovative tools, standards, and approaches that enable evidence-based decision-making to ensure the safety, efficacy, and quality of drug and biological products. OCP conducts pioneering research in multiple areas, including drug interactions, biomarker development, immunogenicity assessment, and precision medicine applications. Results of our research inform regulatory best practices, facilitate global harmonization, and support policy development. Application of the research findings improves risk assessment in drug development and regulatory review and enhances preparedness for responses to public health emergencies. In 2025, OCP's research resulted in peer-reviewed publications, presentations, informed advice to drug developers, and answered questions raised during regulatory review and post-approval, ensuring that advances in regulatory science translate into improved patient health outcomes and more effective therapeutic products. This link provides a list of OCP's 2025 peer-reviewed publications, many of which focus on regulatory science research initiatives and findings.

The Division of Applied Regulatory Science

OCP's DARS includes multidisciplinary teams that conduct mission-critical research to provide scientific solutions for regulatory decision-making. In 2025, DARS accelerated the integration of new science into drug review processes while expanding engagement on emerging regulatory and public health challenges. Key regulatory research priorities include developing tools to assess drug impurities, conducting research on NAMs to support regulatory review processes, studying opioid drug interactions, and optimizing opioid antagonist dosing.

DARS capabilities span both laboratory and computational research. Their laboratory research specializes in omics, bioanalysis, microphysiological systems, immunology, and electrophysiology, while in silico research is conducted by informatics and computational modeling groups. Additionally, a specialized unit designs and executes clinical studies to support regulatory assessment. In 2025, DARS applied these capabilities to conduct applied research in clinical pharmacology, systems pharmacology, chemistry, and biology. Through this comprehensive approach, DARS addressed knowledge gaps and regulatory assessment challenges, ultimately supporting FDA's mission to protect public health.

Reflections of a Senior Researcher | Donna Volpe

Pharmacokineticist, Division of Applied Regulatory Science

I was first introduced to OCP while attending OCP Science Day, shortly after I transferred to what was then known as the Laboratory of Clinical Pharmacology. I presented a poster at the meeting and received valuable insight to the scope and rigor of clinical pharmacology review. As a newcomer to clinical pharmacology, the oral presentations were particularly engaging and educational. To this day, OCP Science Day remains a valued component of my ongoing professional development and scientific engagement.

Outreach and Engagement

Clear, accurate, and timely information in the hands of healthcare providers, patients, and fellow scientists is essential for optimal drug therapy. We keep our strategic priorities of "advancing the science of translational clinical pharmacology for the benefit of patients" and "bolstering patient-centered engagement" at the forefront for all communications.

In 2025, OCP engaged the public through workshops, conferences, and webinars, which provided opportunities for information exchange and sharing of perspectives, including discussions on biological and biosimilar products, as well as NAMs for pediatric drug development. Additionally, our direct email subscription services, Clinical Pharmacology Corner and Quantitative Medicine, collectively reached over 160,000 subscribers with timely information on quantitative methods, guidance publications, and FDA events.

Figure 3 | *FDA Workshops, Conferences, and Webinars OCP Participated or Led in 2025*

Reflections of a Senior Reviewer | ***Chongwoo Yu***

Master Pharmacokineticist, Division of Cardiometabolic and Endocrine Pharmacology

OCP leads many efforts to enhance regulatory review processes and facilitate communication across offices and centers. One example is the Bioanalytical Research Scientific Interest Group (BAR SIG), established in 2011 as a dedicated forum for bioanalytical knowledge exchange and training to equip staff for regulatory decision making. Since its inception, BAR SIG has evolved into a robust multidisciplinary, cross-center collaborative network, maintaining regular participation of over 100 professionals who share cutting edge technical expertise, challenging review case examples, and identify strategic collaboration opportunities in ensuring the reliability of bioanalytical methods and data. As a founding steering committee member, I am grateful for the opportunity to serve the BAR SIG and look forward to continuous learning and collaborations!

Future Directions

Clinical Pharmacology for a Changing Landscape

As OCP enters its fourth decade, its future work will be shaped by a simple but demanding premise: the pace and complexity of therapeutic innovation will outstrip traditional evidentiary frameworks unless regulatory science evolves with equal rigor and intentionality. OCP's role in the years ahead will be to ensure that innovation in drug development is matched by innovation in how evidence is evaluated, integrated, and translated into regulatory decisions.

Strengthening Decision-Focused Quantitative and Translational Science

OCP will continue to advance clinical pharmacology as a decision-oriented discipline. This includes deepening the integration of exposure-response analyses, dose optimization strategies, and variability assessment across development programs and regulatory milestones. Future efforts will emphasize clarity around fitness for purpose: how and when quantitative analyses and mechanistic evidence meaningfully reduce uncertainty, inform benefit-risk assessments, and support regulatory actions.

Model-informed approaches will remain a central pillar of this work, with continued attention to methodological transparency, appropriate validation, and interpretability for multidisciplinary review teams. OCP will also prioritize earlier engagement in development to ensure that quantitative and translational strategies are aligned with regulatory questions from the outset.

Enabling Innovation While Safeguarding Regulatory Confidence

Emerging technologies—including advanced computational methods, artificial intelligence-enabled tools, and novel experimental systems—present significant opportunities to enhance drug development efficiency. OCP's role will be to critically evaluate these approaches through a rigorous lens: identifying where they add value, where they introduce new sources of uncertainty, and how they can be responsibly incorporated into decision-making frameworks.

This will require clear standards for evidentiary sufficiency, ongoing collaboration with internal and external scientific communities, and a continued commitment to distinguishing exploratory promise from regulatory readiness.

Addressing Increasing Therapeutic and Population Complexity

The next decade will bring continued growth in therapies targeting rare diseases, genetically-defined subpopulations, and complex biological pathways. OCP will expand its work in areas such as extrapolation, individualized dosing strategies, and the assessment of pharmacologic evidence in small or heterogeneous populations. This includes strengthening approaches to pediatric drug development, specific populations, and therapies developed under expedited programs.

OCP will also continue to refine its contributions to labeling: ensuring that the pharmacologic information remains clinically interpretable, actionable, and aligned with real-world use.

Advancing Integrated Review and Cross-Disciplinary Collaboration

Future regulatory challenges will increasingly demand integrated scientific judgment rather than siloed expertise. OCP will build on its longstanding role as a connective discipline—bridging medical, statistical, nonclinical, and policy perspectives through shared quantitative and mechanistic reasoning. Continued investment in integrated review practices, paired scientific discussions, and early cross-disciplinary engagement will remain essential to this effort.

Investing in People and the Practice of Regulatory Science

Sustaining excellence in clinical pharmacology requires sustained investment in people. OCP's future depends on cultivating a workforce that is not only technically proficient, but also fluent in regulatory context, scientific communication, and collaborative problem-solving. The Office will continue to prioritize mentorship, training, and knowledge transfer.

Looking Ahead

In the years to come, OCP will remain guided by the principles that have defined its first thirty years: scientific rigor, transparency, and public health purpose. As therapies grow more complex and development paradigms continue to evolve, the need for sound clinical pharmacology, anchored in quantitative and mechanistic understanding and regulatory judgment, will only deepen.

OCP enters its next chapter not with a fixed endpoint, but with a clear orientation: to meet change with discipline, to evaluate innovation with care, and to ensure that regulatory decisions remain grounded in evidence that serves patients.

Appendix: OCP Contributions to Novel Drug and Biological Product Approvals

Therapeutic Area	Drug Name	Active Ingredient	Primary Review Contribution			
			Evaluated/ proposed bridging or extrapolation strategies	Mitigated risk	Optimized dosing regimen	Provided evidence of effectiveness (confirmatory and other evidence)
Cardiology | Hematology | Nephrology	Myqorzo	*aficamten*		●	●	
	Qfitlia	*fitusiran*		●	●	
	Voyxact	*sibeprenlimab*		●	●	
	Wayrilz	*rilzabrutinib*		●	●	
	Yartemlea	*narsoplimab-wuug*	●	●	●	
Infectious disease	Blujepa	*gepotidacin*		●		●
	Enflonsia	*clesrovimab-cfor*			●	●
	Nuzolvence	*zoliflodacin*	●	●	●	
Inflammation | Immunology | Dermatology	Andembry	*garadacimab-gxii*		●		
	Anzupgo	*delgocitinib*		●		
	Brinsupri	*brensocatib*	●	●	●	
	Dawnzera	*donidalorsen*			●	●
	Ekterly	*sebetralstat*		●	●	●
	Exdensur	*depemokimab-ulaa*	●	●	●	
	Jascayd	*nerandomilast*		●	●	
	Nereus	*tradipitant*		●		
	Rhapsido	*remibrutinib*		●	●	
Metabolic | Endocrine	Forzinity	*elamipretide*		●	●	
	Lerochol	*lerodalcibep-liga*		●	●	
	Lynkuet	*elinzanetant*		●	●	
	Palsonify	*paltusotine*		●	●	
	Redemplo	*plozasiran*		●	●	
	Vanrafia	*atrasentan*		●	●	

Products with minimal to no systemic availability are not listed [Cardamyst (etripamil), Tryptyr (acoltremon) and Vizz (aceclidine)].

Therapeutic Area	Drug Name	Active Ingredient	Primary Review Contribution			
			Evaluated/ proposed bridging or extrapolation strategies	Mitigated risk	Optimized dosing regimen	Provided evidence of effectiveness (confirmatory and other evidence)
Neurology | Psychiatry	Imaavy	*nipocalimab-aahu*	●			●
	Journavx	*suzetrigine*		●	●	
Oncology	Avmapki Fakzynja Co-Pack	*avutometinib; defactinib*		●	●	
	Datroway	*datopotamab deruxtecan-dlnk*		●	●	
	Emrelis	*telisotuzumab vedotin-tllv*		●	●	
	Gomekli	*mirdametinib*		●	●	
	Grafapex	*treosulfan*	●	●	●	
	Hernexeos	*zongertinib*			●	●
	Hyrnuo	*sevabertinib*		●	●	
	Ibtrozi	*taletrectinib*		●	●	
	Inluriyo	*imlunestrant*		●	●	
	Keytruda Qlex	*pembrolizumab & berahyaluronidase alfa-pmph*			●	
	Komzifti	*ziftomenib*		●	●	
	Lynozyfic	*linvoseltamab-gcpt*		●	●	
	Modeyso	*dordaviprone*		●	●	
	Penpulimab-kcqx	*penpulimab-kcqx*	●		●	
	Romvimza	*vimseltinib*		●	●	
	Zegfrovy	*sunvozertinib*			●	
Rare Diseases	Kygevvi	*doxecitine & doxribtimine*			●	
	Sephience	*sepiapterin*		●	●	●

Products with minimal to no systemic availability are not listed [Cardamyst (etripamil), Tryptyr (acoltremon) and Vizz (aceclidine)].

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