

FY23 FDA BAA Awards

Contract Number	Amount Obligated	Total Estimated Contract Value			Awardee Address	Description
			Center	Awardee Name		
75F40122A00018	\$252,728.90	\$252,728.90	OC	DELOITTE CONSULTING	DELOITTE CONSULTING LLP 1919 N 1919 N LYNN ST	Conversion of labeling currently not in PLR/PLLR format to PLR/PLLR format
75F40123C00060	\$468,771.00	\$468,771.00	OC	BATTELLE MEMORIAL INSTITUTE	BATTELLE/James R. Gridley 505 KING AVE COLUMBUS OH 432011268	This is a cost reimbursement contract to acquire services for Development of a Parenteral Challenge Model of Systemic Botulinum Neurotoxin Intoxication in Rabbits to Support the Advancement of Candidate Therapeutic Medical Countermeasures.
75F40123C00103	\$1,592,348.00	\$4,548,811.00	OC	STANFORD UNIVERSITY 217691	Jennifer Scerri 485 BROADWAY THIRD FLOOR REDWOOD CITY CA 94063	"Development of neuroblastoma tissue diagnostic utility through deep learning-based image analytics and targeted multiplex proteomics"
75F40123C00113	\$447,337.00	\$911,251.00	CDER	JOHNS HOPKINS UNIVERSITY	3400 N CHARLES ST, W-400 WYMAN PARK BALTIMORE MD 212182685	"Improving the Efficiency and Rigor of Pharmacovigilance at Food and Drug Administration: Developing a Cognitive Framework for Case Series Evaluation and Integrating it in the Information Visualization Platform to Support Decision-Making".
75F40123C00128	\$249,478.00	\$249,478.00	CDER	UNIVERSITY OF SOUTHERN CALIFORNIA	3720 S. Flower St. LOS ANGELES CA 900890701	Characterizing azithromycin efficacy against carbapenem-resistant Gram-negative bacteria in bicarbonate containing culture media.
75F40123C00132	\$906,628.80	\$906,628.80	CDER	UNIVERSITAT ST.GALLEN	DUFURST DUFURSTRASSE 50NST. GALLEN SG 9000	Predictive Continous Improvement Acceleration (PCIA) - Towards Performance Based Regulations and Oversight
75F40123C00133	\$441,597.00	\$441,597.00	CDRH	COLLABORATIVE COMMUNITY ON OPTHALMIC IMAGING	11190 SUNRISE VALLEY DR, STE 300 RESTON VA 20191	"Enhancing Visual Health Equity via Novel, Real-World Underserved Population Health Data Sets Utilizing Ophthalmic Imaging & Artificial Intelligence".
75F40123C00137	\$249,582.00	\$249,582.00	CDER	UNIVERSITY OF SOUTHERN CALIFORNIA	3720 S FLOWER ST FL 3 LOS ANGELES CA 90089	"Characterizing beta-lactam efficacy against metallo-beta lactamase producing bacteria in zinc-limited culture media"
75F40123C00143	\$598,674.00	\$598,674.00	CDER	UNIVERSITY OF WISCONSIN SYSTEM	750 UNIVERSITY AVE MADISON WI 537066141	"Development of In vivo Pharmacometric Approaches to Guide Antifungal Dosing and Susceptibility Breakpoint Determination for Drug Resistant Aspergillus".
75F40123C00186	\$439,681.00	\$439,681.00	CDER	APTARGROUP, INC. 1504104	APTARGROUP INC 250 N ROUTE 303 CONGERS NY 10920	"BAA RESEARCH CHALLENGES RELATED TO ENVIRONMENTALLY FRIENDLY PROPELL".
75F40123C00187	\$167,270.00	\$167,270.00	CDRH	SAGE BIONETWORKS 1236306	2901 3RD AVE STE 330 MAILSTOP M1-C108 SEATTLE WA 98121	"BraTs 2023 Data Centric Challenge
75F40123C00191	\$633,660.92	\$633,660.92	OO	THE UNIVERSITY OF LIVERPOOL	William Henry Duncan Building 6 West Derby Street Liverpool L7 8TX, United Kingdom	"Development of a rabbit model to characterise antifungal drug resistance."
75F40123C00192	\$1,211,682.00	\$655,810.00	OO	AKINA, INC	KINAM PARK 3495 KENT AVE STE A 200 WEST LAFAYETTE IN 479061074	"New PLGA analytical methods for mini-size complex long-acting injectable formulations."
75F40123C00196	\$552,931.00	\$876,368.00	CDER	VIRGINIA COMMONWEALTH UNIVERSITY 164539	VIRGINIA COMMONWEALTH UNIVERSITY RICHMOND VA 23298-0568	"In Vitro and In Vivo Assessment of Buprenorphine Extended Release Injections for Generic Product Equivalence "
75F40123C00199	\$2,949,902.00	\$2,949,902.00	OC	MCKESSON SPECIALTY HEALTH PHARMACEUTICAL & BIOTECH SOLUTIONS LLC	BIOTECH SOLUTIONS LLC 10101 WOODLOCH FOREST DRIVE THE WOODLANDS TX 77380	"Leveraging Real-World Data (RWD) to Investigate the Natural History of Rare Cancers Treated in the US Community Oncology Setting to Provide Clinical Context to Inform Future Research"
75F40123C00201	\$687,062.00	\$687,062.00	CDER	UNIVERSITY OF SYDNEY 1618776	NICOLEMAKOVINEY, LEVEL 3, ADMINISTRATION BUILDING F23, THE UNIVERSITY OF SYDNEY NSW 2006	Development of a laser-based testing platform for generic dry powder inhaler DPI evaluation and in-silico model validation".
75F40123C00211	\$437,576.00	\$1,721,851.00	CDER	TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK	722 W 168TH STREET 4TH FLOOR NEW YORK NY 100323702	"Health and Neurodevelopmental Outcomes in Infants at Risk for Neonatal Opioid Withdrawal Syndromes (NOWS): Effects of Timing and Duration of Prenatal Opioid Exposure (POE) & Postnatal Management with Eat2Sleep-Console (ESC)."
75F40123C00213	\$324,472.00	\$964,769.00	CDER	RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY	3 RUTGERS PLAZA NEW BRUNSWICK NJ 089018559	"Role of excipients and excipient substitution in topical semi-solid formulations and their effect on product performance and quality".
75F40123P00138	\$21,480.00	\$748,888.56	CDRH	ARRAY STAR INC 1365876	9430 KEY WEST 9430 KEY WEST AVE, STE 128 ROCKVILLE MD 208506345	Transfer RNA Sequencing (tRNAs) Service
75F40123C00185	\$399,988.00	\$399,988.00	CDER	MONASH UNVIERSITY 1635407	DAVID ROBSON MONASH UNIVERSITY WELLINGTON R WELLINGTON RD CLAYTON VIC 316	Bridging the gap between urinary tract infection pharmacokinetic/pharmacodynamic in vitro models and the optimization of antibiotic selection, dosing strategies, clinical breakpoints, and novel drug development."
75F40123C00195	\$523,227.89	\$523,227.89	CDER	AMERICAN COLLEGE OF EMERGENCY PHYSICIANS	4950 West Royal Lane, Irving TX 75063-2524	"Naloxone Usage, Safety, And Efficacy in Prehospital Environment for Conventional and Emerging Synthetic Opioids and Other Co-mixtures"
75F40123C00184	\$996,392.00	\$4,553,525.00	CDER	AMERICAN COLLEGE OF MEDICAL TOXICOLOGY INC 429654	AMERICAN COLLEGE OF MEDICAL TOXICOL 5431 E CHERYL DR PARADISE VALLEY AZ 85253	"Real-world Examination of Naloxone d for Drug Overdose Reversal (RENDOR)"

75F40123C00198	\$190,246.00	\$518,363.00	CDRH	PPD DEVELOPMENT, LP 1228530	PPD DEVELOPMENT LP 929 N FRONT ST WILMINGTON NC 28401	"Assessing , Clinical Site Readiness: A Framework to Support Enrollment of Under-Represented Minorities in Medical Device Clinical Trials
75F40123C00204	\$119,006.00	\$507,625.00	CDER	THE CORPORATION OF MERCER UNIVERSITY 292546	THE CORPORATION OF MERCER UNIVERSIT 1501 MERCER UNIVERSITY DR MACON GA 31207	"In vitro tests to support bioequivalence determination when generic dermatological formulation has differences from the brand product formulation".
75F40123C00140	\$263,016.10	\$263,016.10	OO	INSTITUTE FOR CLINICAL PHARMACODYNAMICS	242 BROADWAY STE 101 , SCHENECTADY NY 12305	"Development of Modernized Susceptibility Guidance for Ampicillin and Vancomycin for Enterococcus Species Using Pharmacometric Approaches".
75F40123C00197	\$1,151,037.00	\$1,151,037.00	CDER	THE REGENTS OF THE UNIVERSITY OF MICHIGAN	1058 WOLVERINE TOWER - DRDA 3003 S. STATE ST. ANN ARBOR MI 481091274	"Seamless Design for Multicomponent Endpoints for Drug , Development in Rare Diseases".
75F40123C00202	\$811,680.97	\$811,680.97	CDRH	RESEARCH TRIANGLE INSTITUTE 105107	RESEARCH TRIANGLE INSTITUTE 30 , 3040 E CORNWALLIS RD , RESEARCH TRIANGLE PARK NC 2770	"Patient Experience and Preference Research to Genitourinary Syndrome of Menopause"
75F40123C00183	\$748,779.00	\$748,779.00	CDRH	DUKE UNIVERSITY 132317	OFFICE OF SPONSORED PROGRAMS 2200 WEST MAIN STREET SUITE 300 DURHAM NC 27705	"Meaningful Changes in Patient Reported Outcomes – Identifying Changes That Matter to Patients".
75F40123C00138	\$748,888.56	\$1,206,589.24	CDRH	DUKE UNIVERSITY	0 DUKE UNIVERSITY DURHAM NC 277088990	"Quantifying patient priorities for clinical evidence on the impact of osseointegrated limb prostheses."
75F40123C00209	\$1,567,108.00	\$1,567,108.00	CDER	DUKE UNIVERSITY 132317	2200 W MAIN ST DURHAM NC 27705	"Medicare Advantage for Real World Evidence in Cardiovascular Disease"
75F40123C00208	\$500,000.00	\$800,000.00	OC	THE RESEARCH FOUNDATION OF STATEUNIV. OF NY 117615	RESEARCH FOUNDATION FOR THE STATE U 4400 VESTAL PKWY E BINGHAMTON NY 13902	"build human lactation PBPK 0.00 +models
75F40123C00118	\$303,245.00	\$1,530,889.00	CDER	UNIVERSITY OF CONNECTICUT 297690	UNIVERSITY OF CONNECTICUT 438 438 WHITNEY RD EXTENSION UNIT 1133 STORRS CT 06269	"Investigating the Impact of API Purity, Excipient Source and Manufacturing Process on Performance and Quality of Complex siRNA Lipid Nanoparticles"
75F40123C00188	\$845,834.00	\$845,834.00	CDRH	RESEARCH TRIANGLE INSTITUTE 105107	3040 East Cornwallis Rd PO BOX 12194 RESEARCH TRIANGLE PARK NC 27709	"Project Titled Incorporating Patients' Experiences and Prioritization of Treatment Outcomes into Regulatory Decision Making for Medical Devices: Application of Patient Experience and Preference Research to Tricuspid Valve Disease"
75F40123C00200	\$1,928,198.00	\$4,714,475.00	CBER	MASSACHUSETTS INSTITUTE OF TECHNOLOGY	VIVIAN M HOLMES 77, MASSACHUSETTS AVE NE18-901 , CAMBRIDGE MA 02139	"Mechanistic Modeling and Process Analytical Technology for Exosome Production".
75F40123C00205	\$415,700.00	\$415,700.00	CDER	UNIVERSITY OF EASTERN FINLAND 1642371	Arto Urtti PL 1627 KUOPIO 70211	"Understanding Preservative Effects on Bioequivalence of Topical Ocular Product"
75F40123C00210	\$555,292.00	\$1,233,980.00	CDER	KAISER FOUNDATION HOSPITALS 157119	1 KAISER PLAZA 22ND FLOOR OAKLAND CA 94612	Reducing the Use and Harms of Benzodiazepine Treatment through Health Systems Interventions
75F40123C00142	\$248,198.00	\$248,198.00	CDER	University of Connecticut	438 whitney RD Extension Unit 1133 , Storrs CT 06269	"Impact of API CQAs on In Situ Forming Implants and Understanding In Vitro and In Vivo Performance Differences".
75F40123C00072	\$179,898.00	\$950,450.00	CDER	CFD Research Corporation	6820 Moquin Drive HUNTSVILLE AL 358062923	An CFD_PBPK Framework for Supporting Bioequivalence Evaluation of Ophthalmic Drugs Used FY23 funds for applications from FY22 BAA soliciatation
75F40123C00207	\$400,000.00	\$798,000.00	CDER	CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM	401 W 15TH ST STE 800 AUSTIN TX 78701	CDMH Phase III to Extend the Value of Common Data Model Harmonization and FHIR in the Generation of Clinical Evidence from Real World Data Sufficient to Support Regulatory Use Used FY23 funds for applications from FY22 BAA soliciatation
75F40123C00039	\$594,609.00	\$1,429,670.00	OC	Battelle Memorial Institute	505 KING AVE COLUMBUS OH 432011268	Development of a Ferret Nerve Agent Exposure Model For Chemical Warfare Agent Countermeasue Evaluation Used FY23 funds for applications from FY22 BAA soliciatation
	\$26,123,205.14	\$43,690,919.38				
	Total Obligated in FY23	Total Contract Values				