

Sanjay K. Rai, Ph.D., Secretary of Higher Education
Maryland Higher Education Commission (MHEC)
6 N. Liberty Street, 10th Floor
Baltimore, MD 21201

November 15, 2024

Dear Dr. Rai:

On behalf of the University of Maryland, Baltimore please find attached our proposal to establish a new Academic Program, *Master of Science in Artificial Intelligence for Drug Development*, within the School of Pharmacy. This proposed academic program is being simultaneously submitted for approval to the University of Maryland Board of Regents.

The Artificial Intelligence for Drug Development (AIDD) graduate program uniquely combines interdisciplinary research and interprofessional education by integrating cutting-edge artificial intelligence (AI) technologies with pharmaceutical sciences. Through its curriculum, students gain a deep understanding of AI's role in advancing drug development, preparing them to excel in clinical care and practice by leveraging AI-driven strategies for improved patient outcomes.

AI has the potential to revolutionize the drug development process by accelerating the identification of drug candidates, predicting their efficacy and safety profiles, and optimizing clinical trial designs. A graduate program focused on advanced AI technique will attract top talent to the state, both domestically and internationally, which will ensure that Maryland remains at the cutting edge of drug development and research. This influx of skilled professionals would benefit not only the biotech sector but also Maryland's academic and healthcare communities, fostering collaborations that drive innovation and economic growth.

Should you require additional information, please contact Meghan Bruce Bojo at mbojo@umaryland.edu or 410-706-2055.

Regards,



Dr. Roger J. Ward, JD, MSL, MPA
Provost and Executive Vice President



Cover Sheet for In-State Institutions

New Program or Substantial Modification to Existing Program

| | |
|---------------------------------|-----------------------------------|
| Institution Submitting Proposal | University of Maryland, Baltimore |
|---------------------------------|-----------------------------------|

Each action below requires a separate proposal and cover sheet.

- | | |
|---|---|
| <input checked="" type="radio"/> New Academic Program | <input type="radio"/> Substantial Change to a Degree Program |
| <input type="radio"/> New Area of Concentration | <input type="radio"/> Substantial Change to an Area of Concentration |
| <input type="radio"/> New Degree Level Approval | <input type="radio"/> Substantial Change to a Certificate Program |
| <input type="radio"/> New Stand-Alone Certificate | <input type="radio"/> Cooperative Degree Program |
| <input type="radio"/> Off Campus Program | <input type="radio"/> Offer Program at Regional Higher Education Center |

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| Payment <input checked="" type="radio"/> Yes | Payment <input checked="" type="radio"/> R*STARS # JE313908 | Payment | Date |
| Submitted: <input type="radio"/> No | Type: <input type="radio"/> Check # JE313908 | Amount: 850.00 | Submitted: 10/7/24 |

| | | | |
|---|---|--------------|--|
| Department Proposing Program | School of Pharmacy | | |
| Degree Level and Degree Type | Master of Science | | |
| Title of Proposed Program | ARTIFICIAL INTELLIGENCE FOR DRUG DEVELOPMENT | | |
| Total Number of Credits | 30 | | |
| Suggested Codes | HEGIS: | CIP: 51.2006 | |
| Program Modality | <input type="radio"/> On-campus <input checked="" type="radio"/> Distance Education (fully online) <input type="radio"/> Both | | |
| Program Resources | <input checked="" type="radio"/> Using Existing Resources <input type="radio"/> Requiring New Resources | | |
| Projected Implementation Date <small>(must be 60 days from proposal submission as per COMAR 13B.02.03.03)</small> | <input checked="" type="radio"/> Fall <input type="radio"/> Spring <input type="radio"/> Summer Year: 2025 | | |
| Provide Link to Most Recent Academic Catalog | URL: https://catalog.pharmacy.umaryland.edu/ | | |

| | |
|-------------------------------------|---|
| Preferred Contact for this Proposal | Name: Meghan Bruce Bojo |
| | Title: Executive Director, Academic Administration |
| | Phone: (410) 706-2055 |
| | Email: mbojo@umaryland.edu |

| | |
|---------------------------|------------------------------|
| President/Chief Executive | Type Name: Dr. Roger Ward |
| | Signature: Date: 11/12/2024 |

| | |
|--|--|
| | Date of Approval/Endorsement by Governing Board: |
|--|--|

**A PROPOSAL FOR A NEW ACADEMIC PROGRAM at THE UNIVERSITY OF MARYLAND, BALTIMORE
SCHOOL OF PHARMACY: MASTER OF SCIENCE IN ARTIFICIAL INTELLIGENCE FOR DRUG DEVELOPMENT**

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A. Centrality to institutional mission statement and planning priorities

1. Provide a description of the program, including each area of concentration (if applicable), and how it relates to the institution's approved mission.

The University of Maryland, Baltimore (UMB) is the state's public health, law, and human services university devoted to excellence in professional and graduate education, research, patient care, and public service. As a diverse community of outstanding faculty, staff, and students, and using state-of-the-art technological support we educate leaders in health care delivery, biomedical science, global health, social work, and the law. We emphasize interdisciplinary education and research in an atmosphere that explicitly values civility, diversity, collaboration, teamwork, and accountability. By conducting internationally recognized research to cure disease and to improve the health, social functioning, and just treatment of the people we serve, we foster economic development in the city, state, and nation.

The University of Maryland School of Pharmacy is pleased to submit a proposal for a new Master of Science (MS) in Artificial Intelligence for Drug Development. To be successful, the learner must complete all required and elective coursework totaling 30 credits. This is an online program and will include synchronous (e.g., live) and asynchronous (e.g., pre-recorded) lectures, readings, and reflections, along with active learning elements, including discussion boards and individual and group assignments. The role of artificial intelligence (AI) in drug development is transformative, enhancing the capabilities of pharmaceutical leaders and researchers. The key focus of the program will be on AI-enabled Predictive Analytics. As manual analysis of expanding patient data becomes impractical, AI emerges as a powerful tool to augment existing methodologies. It has already revolutionized drug development, treatment optimization, and patient care.

In drug development, AI technologies like natural language processing and machine learning play a crucial role in accelerating processes. The AI for Drug Development program aims to equip professionals with a comprehensive understanding of AI's applications, limitations, and opportunities in pharmaceuticals. Participants explore techniques across various stages, from setting drug development strategy to clinical trial optimization, empowering them to effectively leverage AI for more efficient drug development.

This program will be offered at UMB. The eight graduate-level required courses in the program cover the principles of drug development, AI and machine learning (ML) methodology, and applications to drug development strategy, pharmacovigilance, precision medicine and clinical trial optimization. The special topics course allows the students to learn the applications of AI/ML to other areas of drug development, regulatory policies, and ethics.

The proposed degree is consistent with and will advance the mission of the University of Maryland, Baltimore. Through this new program, we will provide our students with the knowledge and skills needed to make a positive impact on communities in Maryland and beyond.

2. Explain how the proposed program supports the institution’s strategic goals and provide evidence that affirms it is an institutional priority.

The proposed Master of Science degree will advance UMB’s mission *“to improve the human condition and serve the public good of Maryland and society at-large through education, research, clinical care, and service.”* Additionally, the program contributes to the fulfillment of related strategic goals for UMB, in a number of significant ways:

- A key university strategic theme is to *“excel at interdisciplinary research and interprofessional education, clinical care and practice, and public service.”* The Artificial Intelligence for Drug Development (AIDD) graduate program uniquely combines interdisciplinary research and interprofessional education by integrating cutting-edge AI technologies with pharmaceutical sciences. Through its curriculum, students gain a deep understanding of AI's role in advancing drug development, preparing them to excel in clinical care and practice by leveraging AI-driven strategies for improved patient outcomes. Furthermore, the program's emphasis on AI's potential for accelerating drug development and enhancing pharmacovigilance aligns with the goal of serving the public by delivering safer and more effective therapeutics. It is critical to ensure this highly specialized training provides unique workforce development for Maryland, especially to ensure the skills needed for the continued growth of both the biotech industry and regulatory agencies (e.g., FDA)
- Another strategic theme of the university is *“innovative curricular and co-curricular initiatives that multiply pathways to diverse careers and leadership opportunities inside and outside of academia.”* The AIDD graduate program offers innovative coursework that combines advanced AI concepts with pharmaceutical sciences, providing students with a unique skill set for diverse career paths in academia, government, and industry. Through application-oriented learning opportunities, the program fosters leadership skills and offers pathways for students to engage in real-world drug development projects, preparing them for leadership roles. The emphasis on cutting-edge AI technologies in drug development aligns with the goal of multiplying pathways to diverse careers by equipping graduates with the expertise needed to excel in emerging fields at the intersection of AI and pharmaceuticals, and meeting workforce needs.
- And finally, the MS in AI for Drug Development will infuse innovations in instructional design throughout the curriculum, thus creating an accessible, relatable, and sustainable education program that responds to the needs and characteristics of the learner. This aligns specifically with the university’s strategic goal *“on the importance of creating accessible education for individuals already engaged in their professions and developing productive discovery-to-delivery research model that serves as a catalyst for economic development.”*

3. Provide a brief narrative of how the proposed program will be adequately funded for at least the first five years of program implementation.

The program will draw upon existing resources. The School of Pharmacy already has qualified faculty and offers PharmD, PhD, and Master of Science Degrees in Regulatory Science, Pharmacometrics, Palliative Care, Pharmaceutical Sciences, and Pharmaceutical Health Services Research. The school has the administrative and advising infrastructure for students.

4. **Provide a description of the institution’s commitment to:**
a) **ongoing administrative, financial, and technical support of the proposed program**
b) **continuation of the program for a period of time sufficient to allow enrolled students to complete the program.**

The School of Pharmacy has the administrative, instructional, advising, and facilities infrastructure in place to operate the program. In the event that the program is discontinued, the courses will be offered for a reasonable time period so that enrolled students can finish. The faculty and administrative infrastructure will still be in place to work with students who have not finished the program.

B. Critical and Compelling Regional or Statewide Need as Identified in the State Plan

Artificial intelligence (AI) is transforming society and work in myriad ways, and the pace of that change will continue to accelerate - unlocking new opportunities and risks for Maryland's residents, workers, and economy.¹ A graduate program focused on AI for drug development is crucial for Maryland given its strong positioning within the biotechnology and pharmaceutical industries. With companies like Emergent BioSolutions, Novavax, and AstraZeneca, and federal research organizations such as the NIH and FDA, Maryland is a key player in drug discovery. This program will solidify the state’s status as an innovation leader in life sciences and supports Maryland's broader economic development goals, which focus on promoting innovation, creating high-paying jobs, and strengthening the state's competitive edge in the life sciences sector. By offering a specialized program in AI for drug development, Maryland can further solidify its position as a hub for innovation in life sciences aligning with the Maryland State Plan for Higher Education goal three innovation, priority 8, promoting a culture of risk-taking by fostering innovation in all aspects of Maryland higher education to improve access and student success.

AI has the potential to revolutionize the drug development process by accelerating the identification of drug candidates, predicting their efficacy and safety profiles, and optimizing clinical trial designs. A graduate program focused on advanced AI technique will attract top talent to the state, both domestically and internationally, which will ensure that Maryland remains at the cutting edge of drug development and research. By training a diverse cohort of students, the program could address underrepresentation in the biotech industry, fostering diversity and inclusion within Maryland’s workforce. This influx of skilled professionals would benefit not only the biotech sector but also Maryland’s academic and healthcare communities, fostering collaborations that drive innovation and economic growth.

A graduate program in AI for drug development will create a pipeline of skilled professionals who can contribute to the growth of existing companies and the establishment of new startups in Maryland. This will lead to job creation and increased economic prosperity for the state. Collaborations with local industry partners would provide students with real-world experience and networking opportunities, enhancing their career prospects, and enriching Maryland's biotech ecosystem which aligns with priority 7, enhance the ways postsecondary education furthers lifelong learning. Maryland’s proximity to federal agencies like the FDA and NIH makes it an ideal location for a graduate program in AI for drug development. Partnerships with these agencies could offer students valuable insights into regulatory processes and access to critical resources for research.

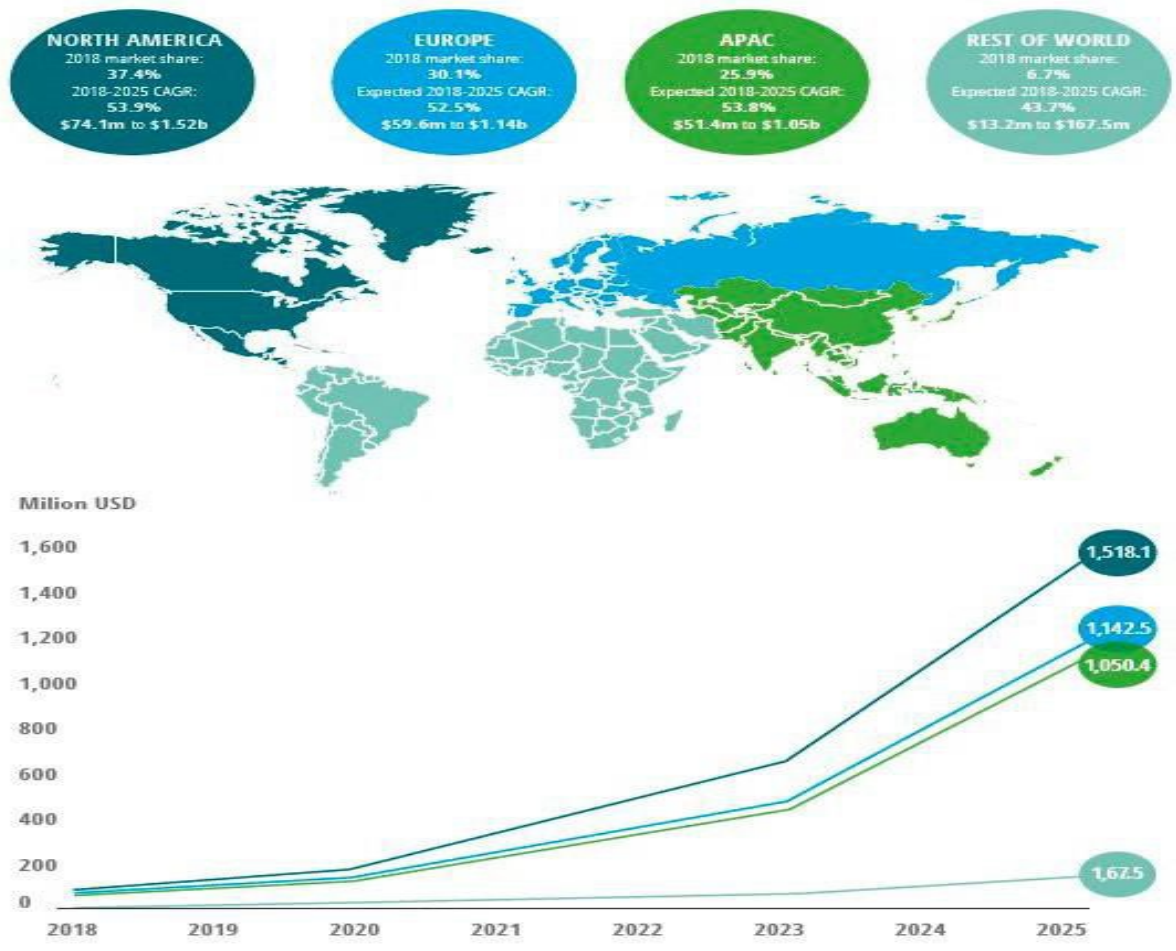
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https://governor.maryland.gov/Lists/ExecutiveOrders/Attachments/31/EO%20001.01.2024.02%20Catalyzing%20the%20Responsible%20and%20Productive%20Use%20of%20Artificial%20Intelligence%20in%20Maryland%20State%20Government_Accessible.pdf

C. Quantifiable and reliable evidence and documentation of market supply and demand in the region and state:

The following section summarizes the AI industry, including market projections, and also provides workforce needs and projections in the state of Maryland, the northeast region, and nationally.²

According to MarketsandMarkets, the market for AI in the biopharma industry is expected to increase from US\$198.3 million in 2018 to US\$3.88 billion in 2025, with a compound annual growth rate (CAGR) of 52.9 per cent. These values vary across the four regions: North America, Europe, Asia- Pacific (APAC) and Rest of World (RoW), which includes South America, Africa, and the Middle East.



Note: All dollar amounts are in US dollars. source: MarketsandMarkets, 2018.

Figure 1 Expected growth in the AI market in pharmaceutical industry, 2018-2025 (excerpt from Deloitte report “Intelligent biopharma: Forging the links across the value chain”).

² <https://www.whitehouse.gov/wp-content/uploads/2022/12/TTC-EC-CEA-AI-Report-12052022-1.pdf>

The largest future job gains are expected to be in healthcare, an industry that already has an imbalance, with 1.9 million unfilled openings as of April 2023. It is estimated that there could be demand for 3.5 million more jobs for professionals in the healthcare sector. In the areas of healthcare and STEM professionals, the backbone of pharmaceutical innovations, McKinsey reported a 83% increase in job demand.

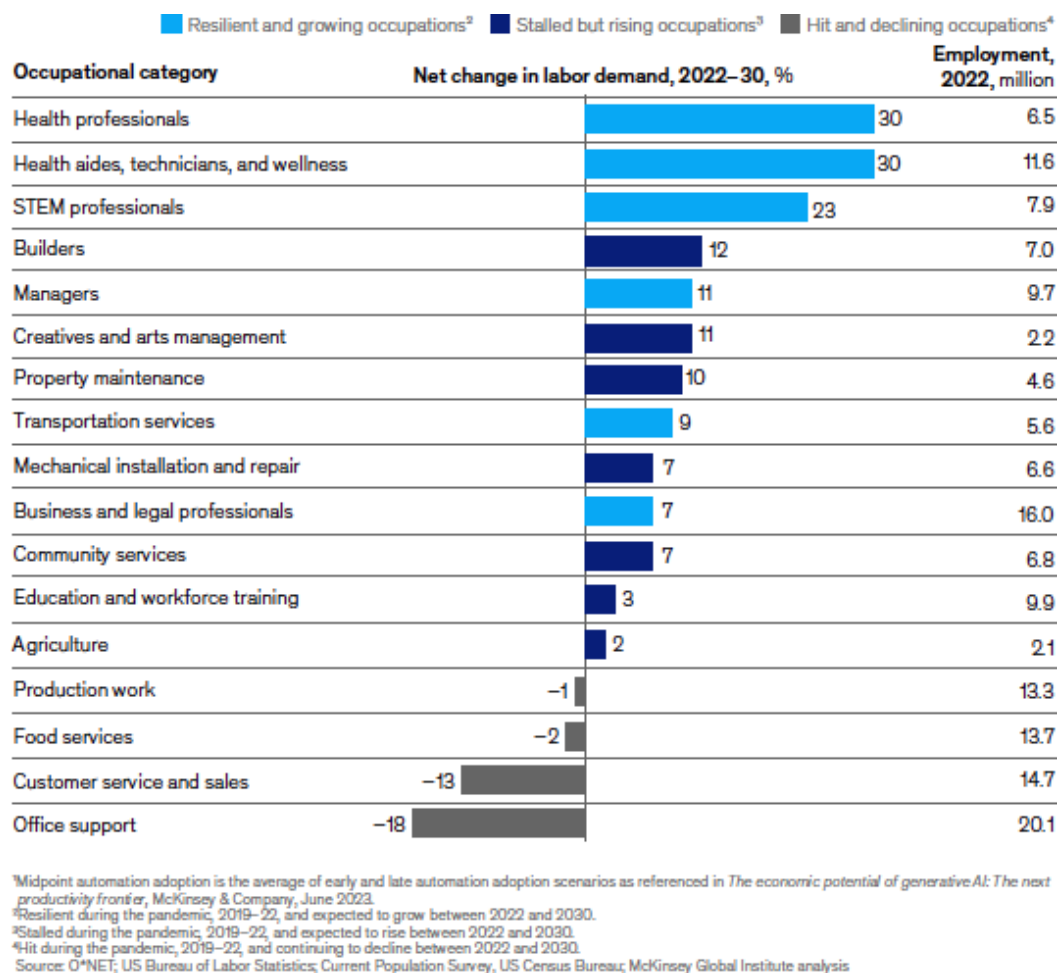


Figure 2 Estimated future US job growth by occupational category. (excerpt from McKinsey report “Generative AI and the future of work in America, July 2023”).

California accounted for almost one-fifth of all AI job postings in 2023. A small number of the states dominate AI job postings. In 2023, the Top 10 states (CA, TX, VA, NY, MA, WA, IL, FL, PA, NJ) accounted for two-thirds (67.0%) share of all AI job postings. In contrast, the bottom 10 states accounted for only 1.24% share of all AI job postings. Three factors appear to drive a state’s share of AI job postings: (a) the state’s size in terms of population and economy (e.g., CA, TX, FL, NY, IL, PA); (b) the state being the domicile for some of the world’s leading AI universities (e.g., CA, MA, NY); and (c) the state’s role as host to major AI-driven industries (e.g., CA: information services, semiconductors, biotech; NY: finance and media; and VA: defense and aerospace). Stripping out the effects of sheer size, AI Jobs Intensity (ratio of AI to all job postings) yields a different picture. Compared to the aggregated US-level AI Jobs

Intensity of 0.56%, Washington DC ranks #1 at 1.75%, followed by VA at 1.36%, with MD not too far behind at 0.83%.

| Rank | State | Value |
|------|-------|-------|
| 1 | DC | 1.75% |
| 2 | VA | 1.36% |
| 3 | WA | 1.20% |
| 4 | CA | 1.10% |
| 5 | MA | 1.02% |
| 6 | NY | 0.97% |
| 7 | MD | 0.83% |
| 8 | NJ | 0.76% |
| 9 | CT | 0.60% |
| 10 | DE | 0.58% |
| 11 | IL | 0.56% |
| 12 | TX | 0.53% |
| 13 | GA | 0.50% |
| 14 | PA | 0.50% |
| 15 | CO | 0.49% |
| 16 | RI | 0.47% |
| 17 | UT | 0.46% |
| 18 | AR | 0.45% |
| 19 | NC | 0.45% |
| 20 | MN | 0.43% |
| 21 | MI | 0.38% |
| 22 | OH | 0.34% |
| 23 | AZ | 0.33% |
| 24 | HI | 0.32% |
| 25 | OR | 0.31% |
| 26 | FL | 0.31% |

| Rank | State | Value |
|------|-------|-------|
| 27 | AL | 0.30% |
| 28 | MO | 0.29% |
| 29 | ID | 0.27% |
| 30 | VT | 0.25% |
| 31 | NE | 0.24% |
| 32 | IN | 0.22% |
| 33 | NV | 0.22% |
| 34 | NM | 0.22% |
| 35 | TN | 0.21% |
| 36 | NH | 0.20% |
| 37 | IA | 0.19% |
| 38 | WI | 0.19% |
| 39 | OK | 0.18% |
| 40 | LA | 0.17% |
| 41 | KS | 0.17% |
| 42 | MT | 0.17% |
| 43 | WV | 0.17% |
| 44 | ME | 0.16% |
| 45 | SC | 0.15% |
| 46 | KY | 0.15% |
| 47 | SD | 0.14% |
| 48 | ND | 0.13% |
| 49 | MS | 0.11% |
| 50 | WY | 0.10% |
| 51 | AK | 0.08% |

U.S. Total, AI Jobs Intensity = 0.56%

Source: UMD-LinkUp AI Maps Project

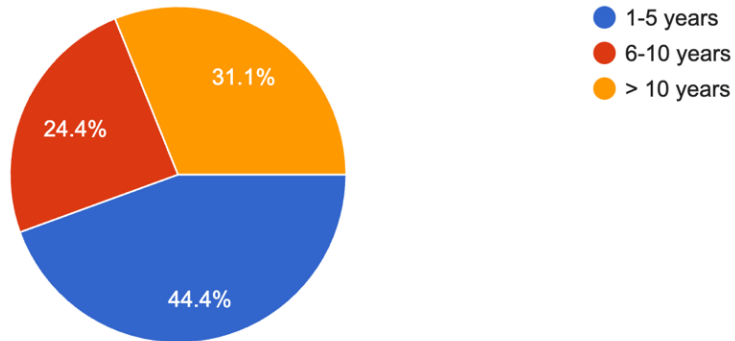
Table 1 State's AI jobs intensity (ratio of AI to all jobs postings) during Jan-Dec 2023

Education and the AI in Drug Development Workforce

University of Maryland School of Pharmacy conducted a survey among current professionals (N=43) in the pharmaceutical sector working either at a company, academic institution, or government organization. More than 80% of the professionals identified that they do not have expertise in AI but have some knowledge. A similar number opined that AI has the potential to significantly impact drug development; of which more than 40% thought AI has a transformative potential. Importantly, more than 90% recognized there is a need for professionals trained in the application of AI to drug development in the pharmaceutical industry. Almost all the survey participants indicated they prefer an online training program.

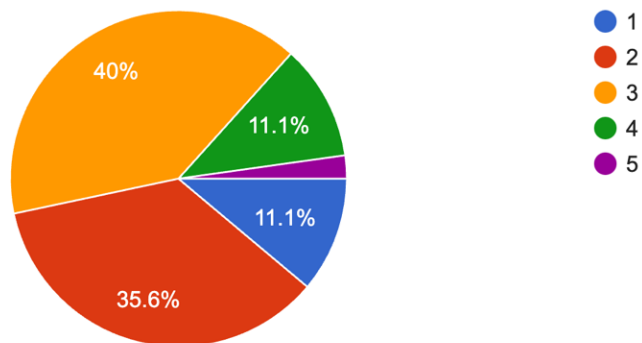
Which best describes your drug development experience?

45 responses



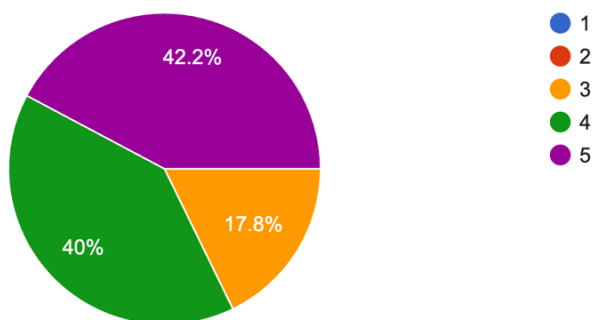
How familiar are you with artificial intelligence (AI) technologies? [1=not at all; 5=expert]

45 responses



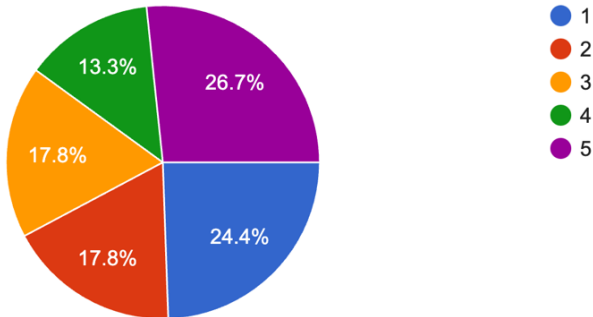
Do you believe AI has the potential to significantly impact drug development processes? [1=no potential; 5=transformative potential]

45 responses



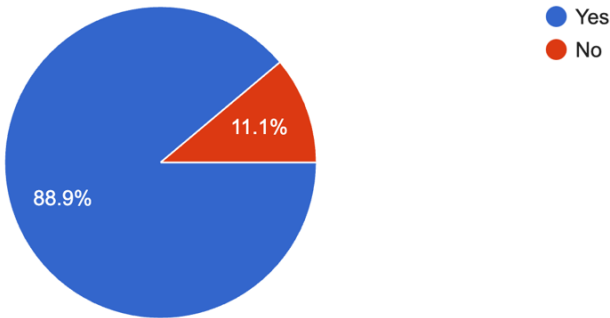
How likely are you to pursue further education in the next two years? [1=not likely; 5=very likely]

45 responses



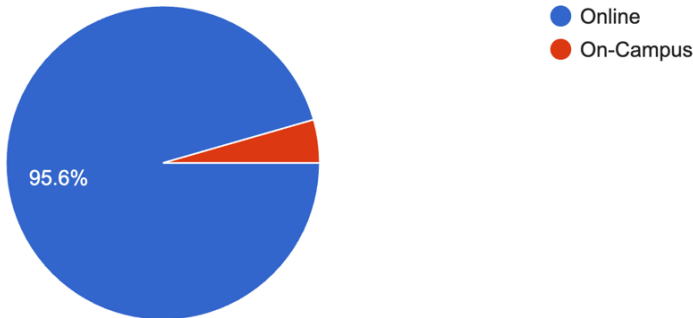
Do you think there is a need for professionals trained in the application of AI to drug development in the pharmaceutical industry?

45 responses



Would you prefer an online or on-campus program for a Masters in AI for drug development?

45 responses



D. Reasonableness of program duplication

University of Maryland School of Pharmacy conducted a careful review of AI-related programs offered by other institutions in the State of Maryland. Currently, there are no graduate programs dedicated to the application of AI for drug development. Most of the institutions offer selected courses in AI, and not full-fledged programs. Bowie State University and Morgan State University offer Master’s or Certificate programs in AI/ML. Their programs are focused on general applications of AI such as in the fields of finance, economics, engineering, and robotics. The proposed Master’s in AI for drug development is an advanced degree in a highly focused area of drug development. The following table lists related but distinctly different certificate or degree programs offered at other Maryland institutions.

| College | Program | Target Students | Comments |
|---|--|---|---|
| Bowie State University – Computer Science | Artificial Intelligence (AI) and Machine Learning (ML) For ALL for high school students. | The Department of Computer Science has a unique in this country course on AI&ML for the general public, including high school students. Participants will solve real problems in finance and economics, engineering, and healthcare. | UMB’s MS program is an advanced degree in a highly focused area of drug development. Aimed at high school students. |
| Bowie State University – Computer Science | Certificate – Database Management/Artificial Intelligence Track | The Certificate Program in Computer Science is a post-baccalaureate program designed to strengthen the expertise of professionals in key computer science areas. Graduates of the program will be better able to contribute to the increasingly technological work environment of the local economy. | UMB’s MS program is an advanced degree in a highly focused area of drug development. |
| Bowie State University – Computer Science | MS [Artificial Intelligence/Machine Learning Specialization] | Artificial intelligence (AI) includes the study of AI principles and techniques, as well as foundational material on topics such as logic, probability, and language. Topics in the AI concentration include knowledge representation and logical reasoning, robotics, machine learning, probabilistic modeling and inference, natural language processing, cognition, and applications. | UMB’s MS program is an advanced degree in a highly focused area of drug development. BSU’s MS program is more general and not specific to drug development. |
| Morgan State University – Computer Science | The Master of Science (M.S.) in Advanced Computing | The MS in Advanced Computing program preserves the core of Computer Science (CS) while possessing unique strength in emerging interdisciplinary areas in Cybersecurity, Artificial Intelligence, Data Science and Cloud Computing. | UMB’s MS program is an advanced degree in a highly focused area of drug development. MSU has one course on general principles of AI, not an entire graduate program dedicated to AI. |
| University of Maryland College Park - College of Computer, Mathematical and Natural Sciences | MS [Applied Machine Learning] | The MS in Applied Machine Learning focuses on the methods and techniques of creating models and algorithms that learn from, and make decisions or predictions, based on data. Successful graduates will apply the learned tools and techniques to a wide variety of real-world problems in areas such as marketing, finance, medicine, telecommunications, biology, security, engineering, social networking, and information technology. | UMB’s MS program is an advanced degree in a highly focused area of drug development. The UMD-College Park MS program is more general and has varied applications in multiple fields. It is not specific or focused on drug development. |

| | | | |
|--|---|--|---|
| University of Maryland College Park – Robert H. Smith School of Business | 12-month executive certificate – Data Science and Machine Learning | Executive post-graduate program certificate provides comprehensive curriculum such as inferential statistics, machine learning, predictive modeling framework to AI and business strategy and data-driven story telling. | UMB’s MS program is an advanced degree in a highly focused area of drug development. UMD-College Park certificate program is tailored for data science in general and not specific to drug development. |
| University of Maryland College Park – Robert H. Smith School of Business | 7-month professional certificate – Data Science and Business Analytics | Professional certificate program that provides comprehensive curriculum covering as inferential statistics, machine learning, predictive modeling and data- driven story telling. | UMB’s MS program is an advanced degree in a highly focused area of drug development. UMD-College Park certificate program is tailored business analytics in general and not specific to drug development. |
| University of Maryland College Park – Robert H. Smith School of Business | 7-month professional certificate – Machine Learning and Artificial Intelligence | Designed for technical professionals with a Data Analytics background who are interested in developing a 360-degree skill profile in Machine learning and Artificial intelligence. | UMB’s MS program is an advanced degree in a highly focused area of drug development. UMD-College Park certificate provides general introduction to AI and ML techniques but is not heavily focused on application-based learning within drug development. |

E. Relevance to High-Demand Programs at Historically Black Institutions (HBIs)

Bowie State University, Coppin State University, Morgan State University, and University of Maryland Eastern Shore do not offer master’s degree programs similar to our proposed program.

F. Relevance to the identity of Historically Black Institutions (HBIs)

The proposed program does not have relevance to the identity of HBIs in Maryland.

G. Adequacy of Curriculum Design, Program Modality, and Related Learning Outcomes

1. Describe how the proposed program was established, and also describe the faculty who will oversee the program.

The role of artificial intelligence (AI) in drug development is transformative, enhancing the capabilities of pharmaceutical leaders and researchers. The key focus of the program will be on AI- enabled Predictive Analytics. As manual analysis of expanding patient data becomes impractical, AI emerges as a powerful tool to augment existing methodologies. It has already revolutionized drug development, treatment optimization, and patient care. In drug development, AI technologies like natural language processing and machine learning play a crucial role in accelerating processes. The AI for Drug Development Program aims to equip professionals with a comprehensive understanding of AI’s applications, limitations, and opportunities in pharmaceuticals. Participants explore techniques across various stages, from setting drug development strategy to clinical trial optimization, empowering them to effectively leverage AI for more efficient drug development. Dr. Joga Gobburu is the program director for the master’s program AI in drug development and will oversee the program. Dr. Gobburu is experienced in artificial intelligence and machine learning, which he has applied to advance pharmacometrics and drug development decision-making. He is a co-founder of PumasAI Inc. and Vivpro Corporation, pioneering companies at the forefront of applying novel innovations in AI/ML to advance pharmacometrics and drug development decision-making.

2. Describe educational objectives and learning outcomes appropriate to the rigor, breadth, and (modality) of the program.

The main objective of this program is to equip students with comprehensive expertise in applying artificial intelligence to the drug development process. Students will gain both a strong theoretical understanding of AI and practical, hands-on skills with AI tools and methodologies, specifically in predictive analytics, natural language processing, and data analytics. Additionally, the program emphasizes integrating AI seamlessly into each phase of drug development, preparing students to address real-world challenges in precision medicine, regulatory intelligence, and clinical trial optimization.

The educational outcomes include:

Comprehensive Understanding of AI-enabled Solutions in Drug Development

- Provide students with a thorough theoretical foundation in artificial intelligence and its diverse applications in drug development.
- Hands-On Proficiency in AI tools and techniques
- Equip students with practical skills through hands-on experiences with AI tools, programming, and methodologies relevant to drug development. This includes application-oriented exercises in areas like natural language processing, data analytics, and machine learning geared towards Predictive Analytics.

Integration of AI into Drug Development Processes

- Foster the ability to seamlessly integrate AI technologies into various stages of drug development. This involves hands-on assignments that simulate real-world scenarios, emphasizing the predictive analytics' application of AI in tasks such as precision medicine, regulatory intelligence, and clinical trial optimization.

After completing this degree, the graduate will be able to:

1. Develop a deep understanding of artificial intelligence (AI) and machine learning (ML) principles and their applications in drug development.
2. Acquire advanced knowledge of drug development to effectively apply AI in these areas.
3. Gain proficiency in data analytics and bioinformatics techniques for analyzing large-scale biological and clinical data sets.
4. Learn to integrate AI-driven approaches into preclinical and clinical development processes, including patient selection and trial design.
5. Develop skills in regulatory intelligence specific to AI applications in drug development.
6. Collaborate with industry partners on real-world projects to gain practical experience in applying AI to drug development challenges.
7. Cultivate leadership and communication skills to effectively convey AI-driven insights to interdisciplinary teams and stakeholders.
8. Explore ethical and societal implications of AI in drug development, including privacy, bias, and transparency.
9. Prepare for diverse career paths in pharmaceutical industry, academia, regulatory agencies, and AI-driven healthcare startups.

3. Explain how the institution will:

- a) provide for assessment of student achievement of learning outcomes in the program**
- b) document student achievement of learning outcomes in the program**

The School of Pharmacy and UMB’s School of Graduate Studies have a culture and support structure to assess program educational effectiveness. An assessment committee will review each online course annually using the Quality Matters rubric. Student retention and satisfaction and faculty satisfaction will be assessed continuously. Faculty will be provided with initial and annual educational programs to continue their development as online educators.

An advisory committee that represents disciplines from all of the professional schools at UMB has been assembled and reviews and provides feedback on every aspect of program development, which will continue during implementation.

4. Provide a list of courses with title, semester credit hours and course descriptions, along with a description of program requirements

| Course # | Course Name | Course Description |
|--|---|--|
| Required Core Courses (30credits) Students take all eight courses (8/8) | | |
| AIDD 601 | Introduction to Drug Development (3 Credits) | This graduate-level course provides a comprehensive overview of the drug development process, from drug discovery to post-marketing surveillance. Students will explore the fundamental principles and practices of drug development, including regulatory requirements, preclinical and clinical testing, pharmacovigilance, and marketing approval processes. |
| AIDD 602 | AI Methodology – I (4 Credits) | The applications of Artificial Intelligence and Machine Learning (AI/ML) methodologies are ubiquitous, and the pharmaceutical industry is rapidly adapting to the AI/ML advancements in drug development. This graduate level course will provide an introductory exploration into the methodology and techniques of AI/ML. Students will learn fundamental concepts, methods, and best practices in AI/ML, including problem formulation, data preprocessing, model selection, evaluation, and interpretation. Students learn and apply supervised learning techniques in this course. Through lectures, hands-on exercises, and real-world case studies, students will gain practical skills to apply AI/ML methodologies to problems relevant to healthcare and drug development domain. The students will learn fundamentals of AI/ML programming using the open-source Python programming language |

| | | |
|----------|---|--|
| AIDD 603 | AI Methodology – II (4 Credits) | <p>This graduate level course will teach intermediate to advanced level concepts and methodology of AI/ML. Students will continue to learn advanced concepts, and best practices in AI/ML, including problem formulation, data preprocessing, model selection, evaluation, and interpretation. Students learn and apply unsupervised learning techniques and neural networks.</p> <p>Through lectures, hands-on exercises, and real-world case studies, students will gain practical skills to apply AI/ML methodologies to problems relevant to healthcare and drug development domain. The students will learn fundamentals of AI/ML programming using the open- source Python software.</p> |
| AIDD 604 | Drug Development Strategy (4 Credits) | <p>This graduate-level course provides a comprehensive overview of the strategic aspects of drug development, focusing on the critical decisions and considerations that drive successful drug development programs.</p> <p>Students will explore the key principles and practices of drug development strategy, including target product profile, regulatory strategy, market access, and lifecycle management.</p> |
| AIDD 605 | Application of AI/ML to Pharmacovigilance (4 Credits) | <p>This graduate-level course provides an in-depth exploration of the application of Artificial Intelligence (AI) and Machine Learning (ML) techniques to pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.</p> <p>Students will gain a comprehensive understanding of the role of AI/ML in improving pharmacovigilance processes, including adverse event detection, signal detection, risk management, and regulatory reporting. The course will cover fundamental concepts of AI/ML relevant to pharmacovigilance, such as data preprocessing, feature selection, model development, and evaluation.</p> |
| AIDD 606 | Precision Medicine (4 Credits) | <p>In the era of precision medicine, harnessing the power of Artificial Intelligence and Machine Learning (AI/ML) is paramount for making informed and personalized healthcare decisions. This advanced course delves into the cutting-edge methodologies and computational techniques essential for analyzing complex datasets and optimizing treatment strategies tailored to individual patients.</p> <p>Students will explore theoretical foundations and practical applications of AI/ML in precision medicine, focusing on the integration of diverse data sources including genomics and clinical outcomes. Emphasis will be placed on understanding the mechanistic insights derived from molecular data and</p> |

| | | |
|----------|---|---|
| | | integrating them with statistical models to predict patient responses and optimize treatment regimens. Hands-on sessions will provide students with proficiency in utilizing state-of-the-art AI/ML tools and software platforms for data analysis and visualization. Through case studies and real-world examples, students will develop critical thinking skills to address challenges in personalized healthcare delivery and translate research findings into clinical practice. |
| AIDD 607 | Optimizing Clinical Research (4 Credits) | AI-enabled Optimization of Clinical Research delves into the strategic integration of artificial intelligence tools to streamline and enhance various aspects of clinical research, equipping participants with the skills to optimize trial design, data management, and decision-making processes in the evolving landscape of healthcare research. This cutting-edge program is designed to equip students with the knowledge and skills to harness the power of AI/ML in clinical research settings. Across three dynamic modules, participants will explore diverse topics such as predictive modeling for treatment response, leveraging natural history data for rare diseases, and endpoint selection using digital biomarkers in decentralized clinical trials. Through engaging lectures, real-world applications, and hands-on assignments, participants will gain a deep understanding of how AI/ML techniques can revolutionize clinical research, leading to more efficient trial design, precise patient selection, and improved healthcare outcomes. |
| PHA 758 | Special Topics (3 Credits) | Special Topics will cover contemporary subjects not addressed in other courses, featuring insights from industry and government leaders through invited lectures, providing a unique and comprehensive perspective on emerging themes in the field of AI and drug development. |

Plan of Study:

| Year | Semester | Course Number | Credits | Course name |
|------|----------|---------------|---------|---|
| 1 | Fall | AIDD 601 | 3 | Introduction to Drug Development |
| 1 | Fall | AIDD 602 | 4 | AI Methodology - I |
| 1 | Spring | AIDD 603 | 4 | AI Methodology – II |
| 1 | Spring | AIDD 604 | 4 | Drug Development Strategy |
| 1 | Summer | AIDD 605 | 4 | Application of AI/ML to Pharmacovigilance |
| 1 | Summer | PHAR 758 | 3 | Special Topics |
| 2 | Fall | AIDD 606 | 4 | Precision Medicine |
| 2 | Fall | AIDD 607 | 4 | Optimizing Clinical Research |

5. Discuss how general education requirements will be met, if applicable

Not applicable

6. Identify any specialized accreditation or graduate certification requirements for this program and its students.

There are no specialized accreditation or certification requirements for this program.

7. If contracting with another institution or non-collegiate organization, provide a copy of the written contract.

Not applicable

8. Provide assurance and any appropriate evidence that the proposed program will provide students with clear, complete, and timely information on the curriculum, course and degree requirements, nature of faculty/student interaction, assumptions about technology competence and skills, technical equipment requirements, learning management system, availability of academic support services and financial aid resources, and costs and payment policies.

The program will make use of established mechanisms in UMB's School of Graduate Studies and the School of Pharmacy to provide students with clear, complete, and timely information on the curriculum, course and degree requirements, nature of faculty/student interaction, assumptions about technology competence and skills, technical equipment requirements, learning management systems, availability of academic support services and financial aid resources, and costs and payment policies. For example, course materials will be available through Blackboard, a web- interface with which faculty have many years of experience, including with current programs.

Accepted students will have the background, knowledge, and technical skills needed to undertake a distance education program. Minimally, candidates for admission will possess a baccalaureate degree. Target students include health care professionals, scientists, public policy professionals, current medical cannabis professionals, or those who wish to enter this emerging field.

9. Provide assurance and any appropriate evidence that advertising, recruiting, and admissions materials will clearly and accurately represent the proposed program and the services available.

The program will be clearly and accurately described on the School of Pharmacy's website and at recruiting events. Recruitment and admissions materials about the program will represent the program and the services available (e.g., need for students to have access to computer that meets the minimum system requirements, broadband internet access, and a headset microphone for participation in web conference).

H. Adequacy of Articulation

Not applicable

I. Adequacy of Faculty Resources

1. Provide a brief narrative demonstrating the quality of program faculty. Include a summary list of faculty with appointment type, terminal degree title and field, academic title/rank, status (full-time, part-time, adjunct) and the course(s) each faculty member will teach in the proposed program.

The University of Maryland School of Pharmacy faculty are internationally recognized for their expertise across the entire life cycle of drug development and clinical care. Broad interest areas include medicinal chemistry, pharmaceuticals, pharmacology, clinical care, and pharmaceutical outcomes and policy. These faculty, whose discoveries are impacting the lives of patients around the world, routinely present at national and international conferences, and publish in high impact peer reviewed journals. Many of the faculty hold Fellow status in associations such as the American Association of Pharmaceutical Scientists, the American Chemical Society, and the American College of Clinical Pharmacy, and most serve, or have served, as consulting, associate, or principal editors of leading journals in the field, including *Pharmacology & Therapeutics*, *Journal of Experimental Medicine*, *Clinical Pharmacokinetics*, *Cancer Chemotherapy and Pharmacology*, and many others.

The Department of Pharmaceutical Sciences trains students in the design of new drugs and the study of the biological impact of these drugs in the treatment of diseases and disorders. Further divisions within the department include pharmacology, pharmacodynamics, pharmacokinetics, and pharmacogenomics. Within the Department of Practice, Sciences and Health Outcomes Research, faculty train students to perform a full range of medication decision-making functions to serve as part of the patient's health care team. In addition, faculty prepare students to improve health among diverse populations through drug-related research, education, and community outreach. Students enrolled in the proposed program will receive the highest quality education by faculty who are uniquely positioned to teach in this field.

| Faculty Members | Course(s) | Status |
|---|--|-----------|
| <ul style="list-style-type: none"> • Joga Gobburu, PhD, MBA, FAAPS, FCP, FISOP <ul style="list-style-type: none"> ○ Professor ○ Program Director, Master of Science in AI for Drug Development ○ Executive Director of Center for Translational Medicine, UMB | AIDD 601 AIDD 604 AIDD 605 PHAR 758 | Full time |
| <ul style="list-style-type: none"> • Mathangi Gopalakrishnan, MS, PhD, FCP <ul style="list-style-type: none"> ○ Program Director, Master of Science in Pharmacometrics ○ Associate Professor, Department of Pharmacy Sciences and Health Outcomes Research, University of Maryland School of Pharmacy | AIDD 602 AIDD 603 | Full time |
| <ul style="list-style-type: none"> • Allison Dunn, PharmD <ul style="list-style-type: none"> ○ Assistant Professor of Department of Pharmacy Sciences and Health Outcomes Research, University of Maryland School of Pharmacy | AIDD 606 AIDD 607 | Full time |
| <ul style="list-style-type: none"> • Tushar Nitave, MS <ul style="list-style-type: none"> ○ Adjunct Faculty, Department of Pharmacy Sciences and Health Outcomes Research, University of Maryland School of Pharmacy ○ Engineer, Vivpro Corporation | AIDD 602 AIDD 603 | Part time |

Dr. Joga Gobburu is a Professor with the School of Pharmacy and the School of Medicine at UMB. He held various positions at the US FDA between 1999 and 2011, where he played a key role in establishing the Division of Pharmacometrics and developing several policies. He is a world-recognized scientific leader in the area of quantitative disease models and their application to decisions. Dr. Gobburu is best known for transforming the field of Pharmacometrics across the world into a decision-supporting science and establishing a Pharmacometrics Fellowship program at the FDA. He received numerous FDA awards, including the Outstanding Achievement Award, and has been recognized with the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (ACCP) (2008), and the Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics in 2019. Dr. Gobburu is on the Editorial Boards of several journals and is a Fellow of ACCP, AAPS, and the International Society of Pharmacometrics. He has published over 120 papers and book chapters, and his doctoral dissertation focused on the application of Artificial Neural Networks to drug discovery and development.

Dr. Mathangi Gopalakrishnan is an Associate Professor at the Center for Translational Medicine, University of Maryland School of Pharmacy. Dr. Gopalakrishnan, trained as a quantitative clinical pharmacologist and biostatistician, possesses over 11 years of expertise employing cutting-edge quantitative methodologies, including artificial intelligence and machine learning methods. Her proficiency extends to the domains of clinical trial design and the advancement of precision therapeutics, particularly within pediatric, maternal, and critically-ill patient cohorts. She has experience applying machine learning methods for enrichment trial designs and for personalized clinical decision making. Dr. Gopalakrishnan also possesses experience in drug development strategy and is currently involved in several drug development projects including the development of artificial blood products and medical countermeasures. She has authored more than 60 peer-reviewed publications and is the recipient of American College of Clinical Pharmacy's Best teacher award in 2018. She is also the program director for the online master's program in Pharmacometrics at UMB. She obtained her master's in pharmacy from Birla Institute of Technology and Science, Pilani, India and her Ph.D. in statistics from University of Maryland, Baltimore County.

Dr. Allison Dunn is a Research Assistant Professor at the University of Maryland School of Pharmacy, specializing in the utilization of real-world evidence to inform clinical decision-making and facilitate drug development. With a background in pharmacy practice and pharmacometric modeling, Dr. Dunn aims to bridge the gap between translational research and clinical implementation. Dr. Dunn holds a dual PharmD/MS in Pharmacometrics degree from the University of Maryland School of Pharmacy, where she also completed a post-doctoral fellowship with the Center for Translational Medicine. Her work focuses on using modeling and simulation to support clinical decisions in understudied populations, particularly pediatric and elderly patients. Notable achievements include being awarded grants to leverage AI/ML methodologies to inform digoxin dosing and monitoring strategies in older adults and serving as Principal Investigator on industry projects aimed at optimizing drug development efforts. These endeavors include proving evidence of effectiveness in the face of extensive non-compliance, comprehensive characterization of exposure-response for optimal endpoint selection, and supporting regulatory efforts throughout the drug development life cycle. With memberships in prestigious organizations such as the International Society of Pharmacometrics and the American Society of Clinical Pharmacology and Therapeutics, Dr. Dunn is committed to advancing precision medicine through innovative research endeavors.

Tushar Nitave holds a master's in computer science from Illinois Institute of Technology, with specialization in AI and machine learning. Currently making significant strides at Vivpro Corporation, Mr. Nitave is dedicated to integrating advanced technological solutions into drug development processes. He is a key engineer in designing AI-enabled pharmaceutical regulatory intelligence software. Mr. Nitave will be instrumental in teaching Python programming language to students.

2. Demonstrate how the institution will provide ongoing pedagogy training for faculty in evidenced-based best practices

Opportunities to improve teaching and learning in the program will be identified through a program assessment process as described in Section M. UMB's instructional design team will provide instructional training resources, support, and consultations to faculty involved with the proposed program.

Faculty teaching in this program will have access to the instructional design team available on campus to incorporate best practices when teaching in the online environment.

J. Adequacy of Library Resources

UMB's Health Sciences and Human Services Library (HS/HSL) is an excellent resource for faculty and students. The library carries a wide range of digital resources including electronic books, journals, and databases that support academic instruction, and an extensive collection of online interactive resources designed to enhance information literacy. Regular in-person and online training are available in a variety of library-related topics including, but not limited to database use, citation management, effective written communication, and research data management.

Faculty librarians provide extensive expertise supporting instruction, research, and scholarly communication through embedded instruction and personalized research consultations. The School of Pharmacy is assigned a research education and outreach librarian to support academic and research activities, who will provide support to the MS in Artificial Intelligence for Drug Development program. During the program, students will complete a variety of projects and presentations that require the review and interpretation of literature, requiring access to resources and personnel from a distance. The HS/HSL maintains proxy services to provide seamless access to electronic books, online journals, and databases from any location. Online course reserves provide an added mechanism to provide limited access to copyrighted materials licensed for instruction without requiring physical access to materials. To ensure students have the same access to personnel resources during the program, all consultation services are available both on campus and online. The program is to be implemented within existing institutional resources.

The Priddy Library at the Universities at Shady Grove (USG) provides similar workshops, training, and consultation opportunities for students on-campus. Librarians from UMB and USG regularly consult to coordinate resources and access needed to ensure students are fully supported in their academic programs at the Universities at Shady Grove.

K. Adequacy of physical facilities, infrastructure and instructional equipment

The physical facilities, infrastructure, and instructional equipment at the School of Pharmacy are adequate to initiate this program, which will leverage existing distance learning instructional technologies to support program management and curriculum delivery. Enterprise technologies supporting student information management (e.g., Ellucian Banner), Blackboard Learning Management System, and web conferencing technologies (e.g., Blackboard Collaborate and Webex) are supported collaboratively with infrastructure support provided by UMB's Center for Information Technology Services (CITS), School of Pharmacy, and School of Graduate Studies.

Infrastructure and physical facilities within the School of Pharmacy allow course faculty to create and deliver core curriculum elements from existing offices, classrooms, and dedicated studio production space. Faculty and administrative staff computers are configured to conduct web conferences and personal recordings as needed to support the delivery of courses and academic advising. For more advanced audio-visual production needs, the school houses a state-of-the-art production studio. Additional audio-visual studio space is available in the Health Science and Human Services Library for faculty and students to produce on-camera presentations. Facilities and services at the Universities at Shady Grove provide similar capabilities offering state-of-the-art classroom and meeting facilities. Faculty offices and meeting space replicate functionality at Baltimore-based facilities.

Technology application support is available through existing helpdesks and instructional design/technology staff during operating hours at UMB and USG. Additional 24/7 support is available for web conferencing technologies through existing agreements with vendors for faculty, staff, and students. Information technology staff on both campuses coordinate regularly to ensure continuity of service and infrastructure support. In addition, the Faculty Center for Teaching and Learning (FCTL) established in 2019, facilitates evidence-based teaching, learning, and evaluation practices throughout the UMB community. As a central resource for all UMB schools, the center provides support and resources for faculty to enhance their teaching and improve student learning outcomes. The center offers consultations, course design, professional coaching, and media production services, and facilitates the multidisciplinary Graduate Teaching Assistant (GTA) and Online Teaching Community (OTC) programs. The FCTL is a thriving hub of teaching excellence, offering a wide range of programs, services, and resources, and actively contributing to the scholarship of teaching and learning.

L. Adequacy of Financial Resources with Documentation

The program will be implemented within existing institutional resources. New tuition revenues coupled with reallocation of existing funds supporting the Doctor of Pharmacy Program will support the new MS in Artificial Intelligence for Drug Development Program. Fund balance will be used for one-time costs in the first year.

| MHEC FORM - Artificial Intelligence for Drug Development | | | | | |
|--|---------------------|---------------------|---------------------|---------------------|---------------------|
| Resource Categories (Note "Resources", not "Revenue") | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| 1. Reallocated Funds | \$273,856 | 0 | 0 | 0 | 0 |
| 2. Tuition/Fee Revenue (c + g) | \$470,652 | \$941,304 | \$907,686 | \$907,686 | \$907,686 |
| a. Number of F/T Students | 0 | 0 | 0 | 0 | 0 |
| b. Annual Tuition/Fee Rate (15*Credit Hour Rate) | \$16,809 | \$16,809 | \$16,809 | \$16,809 | \$16,809 |
| c. Total F/T Revenue (a x b) | \$0 | \$0 | \$0 | \$0 | \$0 |
| d. Number of P/T Students | 28 | 56 | 54 | 54 | 54 |
| e. Credit Hour Rate | \$1,121 | \$1,121 | \$1,121 | \$1,121 | \$1,121 |
| f. Annual credit hours per P/T student | 15 | 15 | 15 | 15 | 15 |
| g. Total P/T Revenue (d x e x f) | \$470,652 | \$941,304 | \$907,686 | \$907,686 | \$907,686 |
| 3. Grants, Contracts & Other External Sources (a + b + c) | \$0 | \$0 | \$0 | \$0 | \$0 |
| a. Grants | \$0 | \$0 | \$0 | \$0 | \$0 |
| b. Contracts | \$0 | \$0 | \$0 | \$0 | \$0 |
| c. Other External Sources | \$0 | \$0 | \$0 | \$0 | \$0 |
| TOTAL RESOURCES (ADD 1 - 3) | \$744,508.00 | \$941,304.00 | \$907,686.00 | \$907,686.00 | \$907,686.00 |

The unique nature of the program requires 4 FTE faculty and support staff. Ongoing expenditures include library support (curating references and materials not currently in the library), instructional design and instructional technology delivery costs, marketing and recruitment (including travel), assessment, proctors, guest lecturers and IT/software costs. There will also be a periodic need to utilize external consultants to evaluate and update the curriculum over time.

The proforma financial statement assumes tuition rates comparable to our MS Pharmacometrics Program. The program is fairly complex and will require instructional design, marketing, educational technology support, IT support, high amounts of cloud computing and cutting-edge faculty to deliver the program. The school will also incur assessment costs in keeping with its evaluation of the effectiveness of all of its programs.

| Table 2: Program Expenditures | | | | | |
|---|------------------|------------------|------------------|------------------|------------------|
| Expenditure Categories | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| 1. Faculty Expenditures (e + f) | \$586,040 | \$586,040 | \$586,040 | \$586,040 | \$586,040 |
| a. Faculty Program Director (Internal) | \$10,000 | \$10,000 | \$10,000 | \$10,000 | \$10,000 |
| b. Initial Course Development (External) | \$0 | \$0 | \$0 | \$0 | \$0 |
| c. Reallocated Faculty Salaries (Internal) | \$445,000 | \$445,000 | \$445,000 | \$445,000 | \$445,000 |
| d. Adjunct Faculty (External) | \$0 | \$0 | \$0 | \$0 | \$0 |
| e. Total Faculty Salaries | \$455,000 | \$455,000 | \$455,000 | \$455,000 | \$455,000 |
| f. Total Benefits (26.1% internal, 8.5% external) | \$131,040 | \$131,040 | \$131,040 | \$131,040 | \$131,040 |
| 2. Administrative Expenditures (b + c below) | \$52,618 | \$116,928 | \$116,928 | \$116,928 | \$116,928 |
| a. # FTE | 0.9 | 2 | 2 | 2 | 2 |
| b. Total Salary (see list) | \$37,800 | \$84,000 | \$84,000 | \$84,000 | \$84,000 |
| c. Total Benefits (39.6%) | \$14,818 | \$32,928 | \$32,928 | \$32,928 | \$32,928 |
| 3. Equipment (AV replc.) | \$17,500 | \$57,500 | \$45,512 | \$45,512 | \$45,512 |
| a. Technology (equipment, licensing, etc.) | \$10,000 | \$50,000 | \$25,512 | \$25,512 | \$25,512 |
| b. Educational Technology Allocation | \$7,500 | \$7,500 | \$20,000 | \$20,000 | \$20,000 |
| 4. Library | \$0 | \$25,125 | \$25,125 | \$25,125 | \$25,125 |
| 5. New or Renovated Space | \$0 | \$0 | \$0 | \$0 | \$0 |
| 6. Other Expenses | \$88,350 | \$155,711 | \$134,081 | \$134,081 | \$134,081 |
| a. Direct Program Expenses | \$10,000 | \$40,711 | \$50,000 | \$50,000 | \$50,000 |
| b. IT & Secure Resch Environment System | \$7,500 | \$25,000 | \$38,000 | \$38,000 | \$38,000 |
| c. Marketing Costs, Ed Technology & Assessment | \$70,850 | \$90,000 | \$46,081 | \$46,081 | \$46,081 |
| 7. Contingency Funding | \$0 | \$0 | \$0 | \$0 | \$0 |
| TOTAL EXPENDITURES (ADD 1 - 7) | \$744,508 | \$941,304 | \$907,686 | \$907,686 | \$907,686 |

M. Adequacy of Provisions for Evaluation of Program

Extensive curricular mapping has been completed to assure each terminal performance objective in Appendix A is introduced, emphasized, and reinforced through required and elective coursework. Successful completion of coursework will demonstrate student achievement of performance objectives. Best practices will be emphasized with liberal use of examples, how to operationalize these techniques, and how to assess success. Faculty will be instructed on “Standards from the QM [Quality Matters] Higher Education Rubric, Sixth Edition” including the eight standards, which cover 42 elements of assessment for an online course. An Assessment Committee will review each online course annually using this rubric to assure quality. If necessary, a corrective plan will be provided by the Assessment Committee to the Program Director. Faculty will be provided with educational programs to continue their development as online educators.

Student retention for the MS in Artificial Intelligence for Drug Development will be tracked. Both student and faculty satisfaction will be assessed after each course.

N. Consistency with the State’s Minority Student Achievement Goals

The University of Maryland, Baltimore enjoys robust cultural diversity and minority student enrollment in all academic programs. Specifically, in 2015, 43.4% of all master’s level candidates were minority students and 42.4% of students enrolled in professional practice doctorate programs were of minority status. Our university strives to make students of all cultures feel welcome, and they thrive accordingly. As stated above, per the mission statement, the University of Maryland, Baltimore “explicitly values civility, diversity, collaboration, teamwork, and accountability.”

The proposed MS in Artificial Intelligence for Drug Development program aims to address both UMB and the state’s cultural diversity goals. The program’s online delivery aims to enhance minority student access and success. Distance education uses technology to expand access and promote success for learners from diverse communities, and the flexibility inherent in online instruction meets the diverse needs of learners.

Recruitment for the MS in in Artificial Intelligence for Drug Development will include advertising and targeted recruitment to top health professional programs for African Americans (<http://www.bestcollegesforblacks.com/HEALTHPROFESSIONS.html>).

O. Relationship to Low Productivity Programs Identified by the Commission

The proposed MS in AI for Drug Development is not directly related to any identified low productivity program.

P. Adequacy of Distance Education Programs

This is an online program using Blackboard as the learning management system (LMS). Upon admission to the program, all students will be assigned to an academic advisor. All course materials will be posted in the LMS and include pre-recorded lectures, pre-recorded video interviews with experts in the field, readings, discussion boards, and links to interactive computer-based exercises. Students will have the

opportunity to participate in live, in-person sessions, as well as web conferencing, and online active-learning instruction both independently and in groups.

Many proposed program faculty have extensive teaching experience in distance education, and continued training and support will be provided to all faculty. The program will employ existing technology to produce and deliver pre-recorded lectures (e.g., recording studio), to conduct web conferences (e.g., Blackboard Collaborate) and to design and deliver active-learning instructional activities. The School of Pharmacy has been using distance education technology to deliver our PharmD program at USG for more than 10 years, and for four highly successful master's programs for more than seven years.

Performance objectives were developed, and the curriculum was designed to achieve learning outcomes via distance education modalities. Curricular mapping was structured to ensure that each terminal performance objective is introduced in one of the first four courses. Each terminal performance objective is then emphasized in one or more of the elective courses, and all objectives are reinforced in the final two required courses. The choice of electives and specialized tracks allows for self-determined learning as planned by each participant. The program will combine synchronous and asynchronous online learning, providing students with multiple opportunities for interaction with faculty. We anticipate that this program will attract students from myriad disciplines, and our faculty will also represent multiple areas of expertise in the basic and clinical sciences, policy, and administration.

All faculty teaching in this program will satisfactorily complete a training program on distance education provided by UMB's School of Graduate Studies. The faculty will collaborate and utilize the resources at the University of Maryland Faculty Center of Teaching and Learning (FCTL). The FCTL supports the UMB mission through specific efforts to sustain educational excellence, and it contributes to the UMB mission in all areas, supporting: student success, research and scholarship, educational inclusivity and diversity, assessment and efficiency, and collaboration. The FCTL partners with faculty, staff, and administrators in the curation, collaboration, and co-creation of teaching and learning resources for educational enhancement and student success. Education specialists, instructional system designers, and instructional technologists from FCTL will be working hand-in-hand with faculty to develop learning activities.

Course development will be accomplished in partnership with a program director, teaching faculty, and the instructional design team, who will ensure course materials follow best practices in online education and adult learning theory. Collectively, they will produce the following materials:

- Course-level outcomes and module level objectives
- Course syllabi and student guides that outline objectives, discussion prompts and learning activities, and resources (articles, websites, online videos)
- Assignments and assessments that measure student performance, and clear instructions for completing them
- Grading rubrics

Appendix A. Terminal Performance Objectives and Curricular Map

| Course | 601 | 602 | 603 | 604 | 605 | 606 | 607 | 75 8 | Course: | |
|--------|-----|-----|-----|-----|-----|-----|-----|---------|----------|----------------------------------|
| TPO# | | | | | | | | | MSMC | |
| 1 | I | | | I | E | E | | R | AIDD 601 | Introduction to Drug Development |
| 2 | I | I | I | | E | E | | R | AIDD 602 | AI Methodology I |
| 3 | | | | I | E | E | E | R | AIDD 603 | AI Methodology II |
| 4 | | I | I | | | | | R | AIDD 604 | Drug Development Strategy |
| 5 | | I | | | | | | R | AIDD 605 | Pharmacovigilance |
| 6 | | | | I | | | E | R | AIDD 606 | Precision Medicine |
| 7 | I | | | | | | | R | AIDD 607 | Optimizing Clinical Research |
| 8 | I | | | | | E | | R | PHAR 758 | Special Topics |
| 9 | | | | | | | E | R | | |

I = introduced; E = emphasized; R = reinforced

| | |
|-------|--|
| TPOs: | <ol style="list-style-type: none"> 1. Apply knowledge of drug development to identify key processes and decisions when developing a new treatment. 2. Apply concepts of AI/ML to real-world problems pertaining to drug development. 3. Develop monitoring plans to determine safety monitoring post-approval. 4. Apply Large Language Models (LLMs) to access key regulatory intelligence to inform development strategy. 5. Apply knowledge of AI/ML to advance precision medicine. 6. Identify key advances in AI/ML in the healthcare space. 7. Participate in health policy decision-making processes by evaluating primary literature to assist policy makers and prescribers in making well-informed decisions about AI/ML in patient care. 8. Identify areas for future research related to enrichment of clinical trials to accelerate clinical testing and protecting patients from unnecessary testing. 9. Demonstrate a commitment to excellence through continuing professional development and the education and training of data scientists, healthcare professionals, regulatory bodies, and other relevant stakeholders. |
|-------|--|