



TOPIC: University of Maryland, Baltimore: Master's in Pharmacometrics

COMMITTEE: Education Policy and Student Life

DATE OF COMMITTEE MEETING: June 5, 2013

SUMMARY: "Pharmacometrics is an emerging science defined as the science that quantifies drug, disease and trial information to aid efficient drug development and/or regulatory decisions. Drug models describe the relationship between exposure (or pharmacokinetics), response (or pharmacodynamics) for both desired and undesired effects, and individual patient characteristics. Disease models describe the relationship between biomarkers and clinical outcomes, time course of disease, and placebo effects. The trial models describe the inclusion/exclusion criteria, patient discontinuation and adherence...These Pharmacometric analyses are designed, conducted, and presented in the context of drug development, therapeutic and regulatory decisions. The single-most important strength of such analyses is its ability to integrate knowledge across the development program and compounds, and biology."(USFDA)

As noted in the proposal, "Graduates of the Master's in Pharmacometrics will be uniquely prepared to bridge the gap in practical knowledge of modeling and simulation (M&S) and clinical trials design and will be adept at using the state-of-the-art applications needed to make defensible drug development decisions."

Proposed to be offered as an on-line, case-study, group project – oriented program, graduates will also have the experience to more effectively interact with interdisciplinary teams and to have the benefit of a broadened exposure to international business practices.

ALTERNATIVE(S): The Regents may not approve the program or may request further information.

FISCAL IMPACT: No additional funding is necessary. The program will be supported through tuition.

CHANCELLOR'S RECOMMENDATION: That the Committee on Education Policy and Student Life recommend that the Board of Regents approve the proposal from the University of Maryland, Baltimore to offer the Master's in Pharmacometrics.

COMMITTEE RECOMMENDATION:

DATE:

BOARD ACTION:

DATE:

SUBMITTED BY: Joann Boughman 301-445-1992

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Proposal for Masters in Pharmacometrics Program

A. Centrality to institutional mission statement and planning priorities:

The proposed Masters in Pharmacometrics Program furthers the Graduate School's mission to support, promote, and facilitate excellence in graduate education by introducing the University of Maryland Baltimore to the tremendous growth potential of the field of pharmacometrics paving the way for unprecedented recognition in the pharmaceutical industry. Graduates of this program will see accelerated professional growth which follows from the case-based, practical approach of the curriculum. Poised to become leaders in their workplace and the drug development arena, graduates holding the Masters in Pharmacometrics degree will enhance the prestige of the Graduate School and inherently promote the standing of the Institution.

Independent of the constraints of international time zones and geographic barriers, the Program is entirely online, available on demand and taught by a diverse collection of senior professionals from academia, government and industry. Because all instruction and assignments are case-based, group project oriented and deliberated by peers, pharmacy education and scientific discovery are advanced.

Graduates of the Masters in Pharmacometrics will be uniquely prepared to bridge the gap in practical knowledge of modeling and simulation (M&S) and clinical trials design and will be adept at using the state-of-the-art applications needed to make defensible drug development decisions.

The educational objective of the Masters in Pharmacometrics Program is to train established professionals in the skills and knowledge needed to plan, perform and interpret pharmacometric analyses with the goal of influencing key drug development, regulatory and therapeutic decisions.

The research field around the world is intrinsically collaborative in nature underscoring the value of an online, on-demand graduate program untethered by time zones and calendar appointments. Taking full advantage of the rich body of practice-based knowledge available across the globe, instructors and students in the Masters in Pharmacometrics Program will be prepared to make meaningful dosing inferences, for example, from the intersection of drug, disease and trial data.

The Masters in Pharmacometrics Program aims to produce scientists with practical modeling and simulation skills whose research findings will ultimately inform the clinical service decisions of pharmacy practitioners. Armed with rigorous analytical skills, the newly minted Program graduates are expected to influence their drug development peers and stakeholders as these senior professionals continue their work in industry, and the regulatory and academic fields. The pharmacometric discipline is thus poised to become essentially self-perpetuating in the pharmaceutical sector and the drug development domain.

The Masters in Pharmacometrics Program also equips senior scientists to interact with interdisciplinary teams more effectively, yet also provides them with the tool kit to perform independent research. Given the global access of the Program, students' inherent communication and negotiation styles are expected to broaden with the exposure to international business practices. It follows that a healthy collegial community will be promoted.

The Program offers theoretical and applied technical knowledge together with necessary business skills tailored for the pharmaceutical sector, thus preparing graduates for career success and positioning the school for a significant return on its human capital investment. Great emphasis is placed on the advantages of learning and implementing simple, persuasive and effective communication skills. Whereas, model-based drug development calls for change from current practice, the ability to communicate scientific findings well and to frame the appropriate questions can lead to business partnerships and possible philanthropic gains for the University.

B. Adequacy of curriculum design and delivery to related learning outcomes:

Through case-study based teaching, the program offers theoretical and applied technical knowledge together with necessary business skills tailored for the pharmaceutical sector. Exclusively online and available on-demand, lectures feature leaders in the field of translational medicine and pharmacometrics. Courses are designed to have a major hands-on component and promise to provide the student with a real world modeling and simulation experience.

The curriculum consists of the following courses (course descriptions are available at <http://www.pharmacy.umaryland.edu/centers/ctm/masters.html>):

Basic PKPD Modeling PHAR 602 (3 Credits)

Understanding pharmacokinetics (PK) and pharmacodynamics (PD) provides the pivotal basis for dosing and other related decisions during drug development and its use in clinic. This course will provide training in the fundamentals of PK and PD modeling and their application to decisions. Theoretical concepts pertaining to analyzing PKPD data, in an average subject, both from mechanistic and statistical points of view, will be taught. The course also includes hands-on training using standard modeling and simulation software.

Statistics for Pharmacometricians I PHAR 663 (3 Credits)

The field of pharmacometrics requires good understanding of statistical concepts. This course will provide the basic statistical principles required for a pharmacometrician. This introductory level course will strengthen the student's understanding of pharmacokinetic–pharmacodynamic modeling aspects. The course material is tailored for pharmacometricians.

Pharmacology & Therapeutics PHAR 664 (3 Credits)

Pharmacometric modeling and simulation, to a large extent, is rooted in pharmacological principles. Interpretation of modeling and simulation results for designing dosing strategies requires knowledge of therapeutics. This training also helps in designing trials to guide dosing decisions.

Intermediate PKPD Modeling PHAR 747 (3 Credits)

Conducting population analyses and interpreting complex datasets is pivotal for several decisions, such as "go-no-go" dose selection for various patients. Theoretical concepts pertaining to analyzing PKPD data, collected from several subjects, both from mechanistic and statistical points of view, will be taught. Because data from several subjects will be analyzed simultaneously, the course will include advanced modeling techniques such as nonlinear mixed effects modeling. Further, advanced modeling such as physiologically-based PK modeling and absorption-metabolism simulations will also be introduced. The course also includes hands-on training using standard modeling and simulation software.

Statistics for Pharmacometricians II PHAR 759 (3 Credits)

Understanding clinical trial data with binary, ordinal, count, and time-to-event outcomes requires specific understanding of statistical concepts. This intermediate level course will introduce application of statistical techniques like logistic regression, Poisson regression, and survival analysis. The course will also demonstrate simulation techniques associated with discontinuous outcomes. R software will be used to demonstrate the application of statistical aspects. Simulated and real data from experiments and clinical trials will be employed for practice and homework.

Strategic Communications & Negotiations PHAR 666 (2 credits)

This course will improve students' abilities to communicate strategically and to negotiate. Students will be able to identify their communication style and will learn how to compensate for any

weaknesses. Scientists in life sciences will need to work with interdisciplinary scientists with diverse backgrounds. Pharmacometrics has not reached its full potential yet and is breaking new ground. In order to influence key decisions during drug development, regulatory review or in clinics, pharmacometricians will need to communicate in a manner that is simple, persuasive, and effective. Implementation of model-based drug development calls for change from current practice, and such changes are often resisted. Scientists will need to master how to effectively negotiate amid diverse opinions to lead a team towards consensus, especially when they lack authority to implement solutions.

Dose-Response Trials PHAR 665 (3 Credits)

Knowledge of designing and analyzing dose-response is an important component of a drug development or regulatory review. Basics of the variety of dose-response designs such as parallel, cross-over, flexible-dose, titration, withdrawal, adaptive and enrichment trials will be explained. Students will perform clinical trial simulations for supporting the choice of appropriate designs and analyses. Innovative designs and data analysis make characterizing dose-response feasible within the realms of drug development. The information generated from such trials is key for both approval of new drugs as well as for drug product labeling.

Pharmacometrics for Decision-Making PHAR 638 (3 Credits)

Knowledge of conducting pharmacometrics analysis is an important component of the drug development and regulatory project. However, integrating all the different pieces together is equally important. This course will guide students on how to frame the appropriate questions, engineer the analysis, interpret the results, and communicate to influence the decision-making process in drug development. This course integrates the essence of all the coursework in the program, and allows the students to appreciate the totality of a typical pharmacometrics project that is essential for decisions regarding new drug development.

Special Topics (Project) PHAR 758 (7 credits)

Research projects can be selected from a set of pre-defined projects provided by the Center for Translational Medicine (CTM). Students can also use projects from their organizations towards the research. The projects will need to be identified by the end of the first year. CTM staff will guide the students on these projects.

C. Critical and compelling regional or Statewide need as identified in the State Plan:

Please see Paragraph D below.

Please see Paragraph F below.

D. Quantifiable & reliable evidence and documentation of market supply & demand in the region and State:

The discipline of Pharmacometrics has seen exponential growth over the past few years as more and more pharmaceutical companies adopt model based drug development (rooted in clinical pharmacological principles) to plan and design clinical trials prospectively[1]. In recent years, the impact of pharmacometrics has increased in all facets of drug discovery, development, and innovation, because the cluster of skills that define pharmacometrics provides powerful tools to maximize the information flow between different drug development stages and delivers crucial information for rational, scientifically driven decision making throughout the drug development process [2]. The Food and Drug administration (FDA)'s critical path initiative has identified model based drug development approach critical for efficient drug development [3]. A rigorous application of pharmacometric principles in drug development is recommended by industry, academia and regulatory agencies.

This has created an increasing demand for pharmacometricians and they are highly sought after in industry, academia and by regulatory agencies. A brief survey of the PharmPK archive (<http://www.pharmpk.com/pkjob.html>), a popular discussion forum on topics of pharmacokinetics and pharmacodynamics, has on average at least 3-4 postings for pharmacometrics jobs per month in academia, industry and regulatory agencies all over the world over the last year. This information excludes other sources of pharmacometrics job postings. This number is expected to steadily increase as there is more emphasis on using pharmacometric principles for decision making in drug development. But the supply chain for trained pharmacometricians in the United States is only 5 per year [1], because of limited educational institutions to train pharmacometricians. The Masters in Pharmacometrics Program at UMB (University of Maryland, Baltimore) will strongly cater to the need for training future scientific leaders in pharmacometrics.

References:

1. Gobburu JVS. Pharmacometrics 2020. J Clin Pharmacol.2010;50(suppl 1):151S-157S.
2. Romero K, Corrigan B, Tornoe C, et al. Pharmacometrics as a discipline is entering the "industrialization" phase: standards, automation, knowledge sharing and training are critical for future success. J Clin Pharmacol. 2010;50(suppl 1):20S-31S.
- 3.<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/CriticalPathOpportunitiesReports/ucm077262.htm#toolkit> (Accessed 10/22/2012)

E. Reasonableness of program duplication:

The Masters in Pharmacometrics Program is unduplicated, unique regionally and a first of its kind. To our knowledge there are no existing programs like it internationally.

The emerging discipline of pharmacometrics along with the intrinsic demand for informed clinical trials designs has created a market for scientific leaders in the field. The Center for Translational Medicine is uniquely positioned to train future translational science researchers through the Masters in Pharmacometrics Program owing to the experienced faculty in both technical and drug development/regulatory aspects and its state-of-the-art computational infrastructure.

F. Relevance to Historically Black Institutions (HBIs)

No HBI in Maryland offers a program that is comparable to the proposed Masters in Pharmacometrics at UMB. Thus, this has no negative impact on HBIs.

G. If proposing a distance education program, please provide evidence of the Principles of Good Practice (as outlined in COMAR 13B.02.03.22C).

The Executive Masters in Pharmacometrics Program is the brain child of Dr. Joga Gobburu, an award winning scientist whose knowledge and expertise in the field is unmatched. Bringing more than a decade of knowledge and experience in the field of pharmacometrics to the Program, Dr. Gobburu was the 2008 recipient of the Outstanding Leadership Award from the American Conference on Pharmacometrics, and the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology. He is on the Editorial Boards of several journals and has published over 60 papers and book chapters.

The online program curriculum offers introductory courses tailored for pharmacometricians that will strengthen the fundamental basic statistical principles required for a pharmacometrician. The online program also offers hands-on training using standard modeling and simulation software familiar at some level of proficiency to most program participants. Courses such as 'Pharmacometrics for Decision-Making' will guide students on how to frame the appropriate questions, engineer the analysis and interpret and communicate the results to influence the decision-making process in drug development. All of the course work in the program integrates the essence of, and allows the students to appreciate the totality of a typical pharmacometrics project that is essential for decisions regarding new drug development.

Interaction between faculty and students and among students will be frequent and collaborative using state-of-the-art web-conferencing technology and networking via email, telephone and such. Group assignments, for example, will be posted for each class cohort to discuss and critique, and grading is based on: report, discussion and confidential feedback from group members.

Students are required to pay University fees that afford them the same campus services and amenities provided to on-campus graduate students.

The Course Evaluation system of the University's Office of Academic Affairs includes early warning reports, a sentinel for early academic performance difficulty, as well as, student course evaluations used to inform course managers' decisions to modify curriculum.

H. Adequacy of faculty resources (as outlined in COMAR 13B.02.03.11).

Conceived by Dr. Joga Gobburu, PhD, FCP, MBA, a world-renowned scientific leader in the area of quantitative disease models and their application to decisions, the Program features distinguished leaders from industry, government and academia.

Dr. Gobburu is best known for transforming the field of pharmacometrics across the world into a decision-supporting science. Having joined the FDA in 1999 as a pharmacometrics reviewer, Gobburu became team leader in 2005, and director in 2007. He was appointed senior biomedical research scientist at the FDA—a rare honor—for his transformational scientific leadership. Under his direction, a Division of Pharmacometrics (DPM) was formed at the FDA and several policies were established. As part of DPM, he established a knowledge management initiative to create standardized disease databases. He also established a pharmacometrics fellowship program at the FDA.

He has received numerous FDA awards such as the Outstanding Achievement Award. In 2008, he received the Outstanding Leadership Award from the American Conference on Pharmacometrics and the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology.

Other faculty members from the School of Pharmacy and the School of Business, UM, College Park will co-teach some of the courses. The faculty are listed in the individual course descriptions.

I. Adequacy of library resources (as outlined in COMAR 13B.02.03.12).

A University Health Sciences and Human Services Library Liaison is available to assist and consult with Program faculty and staff about library services and resources. A qualified representative of the Executive Director for library resources has been engaged to meet the Program's needs. Services span orientation sessions for faculty, staff and students to acoustically-sound presentation studio time for practicing lecture recordings.

J. Adequacy of physical facilities, infrastructure and instructional equipment (as outlined in COMAR 13B.02.03.13)

Conducted entirely on-line the program will utilize Department servers for on-demand courses and instructor-student communications (Blackboard, Mediasite and such) while using Center for Translational Medicine servers for data acquisition and project reporting.

K. Adequacy of financial resources with documentation (as outlined in COMAR 13B.02.03.14)

The source of funding for the Masters in Pharmacometrics program will be reallocated funds from IMPACT: Educational Technology/AV Researches and tuition and fee revenues from students enrolled in the program. The proposed cohort of 50 part-time students per class will provide sufficient funding after the first year of the program as demonstrated in Table 1. Tuition and fees are expected to support the full costs, see Table 2, of the program after the first year.

L. Resources and expenditures

Please see Tables 1 and 2 below.

M. Adequacy of provisions for evaluation of program (as outlined in COMAR 13B.02.03.15).

The PHAR program curriculum committee reviews all courses annually.

N. Consistency with the State's minority student achievement goals (as outlined in COMAR 13B.02.03.05 and in the State Plan for Postsecondary Education).

Please see Paragraph F above.

O. Relationship to low productivity programs identified by the Commission:

Not applicable.

| Pharmacometrics Master's Program | | | | | | |
|---|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|--|
| TABLE 1: RESOURCES | | | | | | |
| Resource Categories | Year 1 FY 14 | Year 2 FY 15 | Year 3 FY 16 | Year 4 FY 17 | Year 5 FY 18 | |
| 1. Reallocated Funds Note 1 | \$9,000 | | | | | |
| 2. Tuition/Fee Revenue (C + G Below) | \$515,400 | \$566,940 | \$566,940 | \$566,940 | \$566,940 | |
| a. # F T Students | 0 | 0 | 0 | 0 | 0 | |
| b. Annual Tuition/Fee Rate | \$10,308 | \$10,308 | \$10,308 | \$10,308 | \$10,308 | |
| c. Annual Full Time Revenue (A X B) | \$515,400 | \$566,940 | \$566,940 | \$566,940 | \$566,940 | |
| d. # Part Time Students | 50 | 55 | 55 | 55 | 55 | |
| e. Credit Hour Rate | | | | | | |
| f. Annual Credit Hours | | | | | | |
| G. Total Part Time Revenue (d X e X f) | | | | | | |
| 3. Grants, Contracts & Other External Sources | \$0 | \$0 | \$0 | \$0 | \$0 | |
| 4. Other Sources | \$0 | \$0 | \$0 | \$0 | \$0 | |
| Total (Add 1-4) | \$524,400 | \$566,940 | \$566,940 | \$566,940 | \$566,940 | |
| Note 1 Reallocated funds are state appropriations supporting faculty effort & staff for the 1st year | | | | | | |
| IMPACT: Educational Technology/AV Resources will be stretched. | | | | | | |
| Faculty productivity should not be adversely impacted (several will be involved). | | | | | | |
| Note 2 Tuition Revenue Exclude Fees that go to the campus | | | | | | |

¹ Whenever reallocated funds are included among the resources available to new programs, the following information must be provided in a footnote: origin(s) of reallocated funds, impact of the reallocation on the existing academic program(s), and manner in which the reallocation is consistent with the institution's strategic plan.

² This figure should be a realistic percentage of tuition and fees which will be used to support the new program. Factors such as indirect costs linked to new students and the impact of enrolling continuing students in the new program should be considered when determining the percentage.

³ Whenever external funds are included among the resources, the following information must be provided in a footnote: source of the funding and alternative methods of funding the program after the cessation of external funding.

| TABLE 2: EXPENDITURES | | | | | |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Expenditure Categories | Year 1 FY 14 | Year 2 FY 15 | Year 3 FY 16 | Year 4 FY 17 | Year 5 FY 18 |
| 1. Total Faculty Expenses (b + c below) | \$412,650 | \$412,650 | \$412,650 | \$412,650 | \$412,650 |
| a. # FTE | 2.54 | 2.75 | 2.75 | 2.75 | 2.75 |
| b. Total Salary | \$330,120 | \$330,120 | \$330,120 | \$330,120 | \$330,120 |
| c. Total Benefits | \$82,530 | \$82,530 | \$82,530 | \$82,530 | \$82,530 |
| 2. Total Administrative Staff (b + c below) | \$10,500 | \$10,500 | \$10,500 | \$10,500 | \$10,500 |
| a. # FTE | 0.20 | 0.20 | 0.20 | 0.20 | 0.20 |
| b. Total Salary | \$8,400 | \$8,400 | \$8,400 | \$8,400 | \$8,400 |
| c. Total Benefits | \$2,100 | \$2,100 | \$2,100 | \$2,100 | \$2,100 |
| 3. Total Support Staff Expenses (b + c below) | \$54,250 | \$54,250 | \$54,250 | \$54,250 | \$54,250 |
| a. # FTE | 0.75 | 0.75 | 0.75 | 0.75 | 0.75 |
| b. Total Salary | \$38,750 | \$38,750 | \$38,750 | \$38,750 | \$38,750 |
| c. Total Benefits | \$15,500 | \$15,500 | \$15,500 | \$15,500 | \$15,500 |
| Graduate Teaching Assistant Support | \$0 | \$28,000 | \$28,000 | \$28,000 | \$28,000 |
| 4. Equipment | | | | | |
| 5. Library | | | | | |
| 6. New or Renovated Space | | | | | |
| 7. Other Expenses | \$47,000 | \$61,540 | \$61,540 | \$61,540 | \$61,540 |
| Total (Add 1-7) | \$524,400 | \$566,940 | \$566,940 | \$566,940 | \$566,940 |
| Excess Revenues over Expenditures | \$0 | \$0 | \$0 | \$0 | \$0 |