

New drugs for a new era

Drs Gabrielle Gold-von Simson and **Ravichandran Ramasamy** discuss their new educational programme and how they are impacting the future of drug discovery



Could you briefly introduce the programme you have established, and your respective roles within it?

GGvS: The title of the programme is 'A New Era of Targeted Drug Discovery and the Path of Development: From Molecular Signaling to the Global Market and Back Again'. Its purpose is to educate students – including postdoctoral researchers, faculty, medical residents and students enrolled in MS, MD and PhD programmes – about the nuts and bolts of the drug discovery and development process, with a particular emphasis on drugs for treating diabetes, diabetic complications and obesity.

Dr Ramasamy and I are co-Principal Investigators for this National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-funded initiative. I am also Program Director as well as Director for the fall course entitled 'Drug Development in a New Era'.

Can you outline the programme's aim, and to what extent your experiences have informed the approach you have taken?

GGvS: Drug discovery and development is a broad, multidisciplinary process that integrates many components of the translational continuum, from molecular signalling pathways to public health policies and practice standards. Our goal is to implement a unique educational activity that will encompass the many essential features of this innovative process. I have conducted human drug studies, as well as dose escalation studies and other clinical trials, and this has enabled me to realise the multidisciplinary nature of this process.

RR: The main focus of my preclinical research programme has been to understand the metabolic basis of diabetic cardiovascular complications, ischaemic injury and heart failure. In this context, my work has led to the

novel finding that glucose metabolising aldose reductase is a viable therapeutic target for treating diabetic patients with heart disease. Working with human drug studies experts like Dr Gold-von Simson has made me realise the importance of developing target validated biomarkers for clinical trials.

What is it that drives your research interest in diabetes?

RR: Types 1 and 2 diabetes and the numerous complications associated with them are on the rise. There is a recognised lack both in therapies and established disease-specific biomarkers when it comes to diabetes complications. The challenge of discovering drugs for this unmet clinical need is what drives our translational research.

How has drug development changed in recent years, and how can researchers ensure it continues to improve?

RR: Drugs widely used by patients today are often perceived to have originated from innovative research breakthroughs in the scientific understanding of disease. One major difference between the way drugs are developed now and their historic emergence is the departure of the actual drug discovery and development technology from the target phenotype. Most existing drugs in longstanding clinical use (eg. penicillin) emerged essentially from phenotypic screens, and their original phenotypic effect on the target disease tends to be preserved in long-term clinical use.

GGvS: There have been many successful drug trajectories, as we are well aware, but the process is often untenable and expenses are limiting. At present, academia, industry and policy makers must act collaboratively to promote science, development and innovation in the fields of medicine and public health.

Why is the New York University School of Medicine (NYUSOM) well-positioned to implement your educational programme?

GGvS: This academic institution has excellent resources; a wide breadth of experience in curriculum development and translational research; and the ability to consistently draw from a wealth of expert faculty and advisors. In addition, NYUSOM is centrally and strategically located in New York, where we can take advantage of the many facets and experts involved in the scientific, economic and public health processes of drug development.

Which elements of this course are you most proud of, and why?

GGvS: We have built on an existing structure of courses and successfully expanded the curriculum. Our Drug Development in a New Era course had a maximum of 34 students this term, and not only did all lectures receive very high ratings, but the students' learning metrics show that they enhanced their overall knowledge base with regards to the process of drug development and marketing.

As a fledgling programme, how do you plan to expand and direct its progress in the future?

GGvS&RR: As the programme is now open at the university level, we plan to expand to offer courses and training to industry scientists, patent specialists, investors and others involved in drug development. Other courses and components will be added, such as the 'Biotechnology Industry, Structure and Strategy' course, which provides guidance on how to ensure discoveries and developments are sufficiently recognised. We will also join forces with the National Science Foundation innovation Corps (NSF i-Corps) to help broaden the focus of scientists and engineers and ensure their discoveries have greater impact in the commercial world.



Diabetes and drug development

Scientists from the School of Medicine at **New York University Langone Medical Center** are working with the next generation of translational researchers to help them effectively develop life saving drugs for the future

OWING TO SIGNIFICANT advances in modern medicine, many life altering conditions such as diabetes are no longer life shortening, and global average life expectancy is increasing every year. Historically, such progression has been achieved primarily through a retrospective approach – that is, curing a disease once it has developed. Now, however, a new age of medicine is dawning. With advances in the understanding of genetics and a more comprehensive knowledge of how diseases unfold, treatments are becoming ever more targeted and preventive.

In order to ensure the continued development of innovative new treatments, it is essential that a new generation of passionate and informed scientists step forward. With this in mind, researchers at the New York University School of Medicine (NYUSOM) within the New York University Langone Medical Center (NYULMC) have implemented an educational programme that covers key aspects of modern drug development, from gene therapy to public health policy, entitled 'A New Era of Targeted Drug Discovery and the Path of Development: From Molecular Signaling to the Global Market and Back Again'. Such programmes are gaining popularity, with similar initiatives established elsewhere, most notably within various Clinical and Translational Science Institutes (CTSI). Dr Ravichandran Ramasamy, who is the co-Principal Investigator alongside Program Director Dr Gabrielle Gold-von Simson, feels that these courses are an incredibly valuable resource for scientists at the beginning of their careers: "They will be used as a foundation upon which to build a

comprehensive curriculum in the field of drug discovery and development," she explains. "The programmes teach the core principles of drug development within the bench-to-bedside continuum." A consequence of the course's diversity is the huge range of backgrounds and levels of expertise of the people involved, from Master's students to faculty members.

SHAPING THE FUTURE

Recent research has produced promising results from clinical studies in patients with diabetes and diabetic complications such as nephropathy, retinopathy and cardiovascular disease. In response to this, and because of its funding by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a primary goal of this project has been to modify existing courses into an NIDDK-relevant educational activity that will produce professionals capable of tackling these diverse medical issues. With drug companies showing reluctance to invest in the field, NIDDK has interjected and now provides support for graduate level learners so that they can help further the promising field.

Incorporating elements of this research, the course includes advanced education on drug targeting: "We will highlight the importance of designing therapeutic interventions based on target changes during the disease; for example, some targets may be more relevant in initiation, others more in progression, and some more in failure of regression and regeneration," outlines Ramasamy. This part of the programme includes information on, and discussion of, the Diabetesity® seminar, a

The researchers have implemented an educational programme that covers key aspects of modern drug development, from gene therapy to public health policy

didactic series designed to promote discussion of ways to tackle obesity-related diabetes. In addition to understanding the biochemical implications of drug development, the course incorporates additional material geared towards industry and public health. This includes post-marketing trajectories, safety monitoring, ethics patents, and cost and investment analysis. The concept fuelling the amalgamation of the two ends of science is the idea that 'inventing' drugs is an approachable and achievable aim.

CURRENT DRUG DEVELOPMENT

A crucial aspect of this proactive attitude to medicine is the translation of ideas into practice. In addition to being a positive approach to drug development, this also provides increased impetus for the success of this education programme. It involves identifying and locating biomarkers of disease, and consequently generating molecularly targeted

therapies to use among eligible subpopulations. Despite progress in this area, breakthroughs are often hampered by public policy, safety and faulty clinical trial designs. Consequently, time from drug discovery to market is rate limiting. The ability to correctly handle such issues is a key concern when it comes to ensuring that drug development is safe and effective, therefore the course aims to teach students about these issues alongside scientific learning.

FURTHER OPPORTUNITIES

The broad and knowledgeable attitude to the pharmaceutical industry and public health sector displayed by this programme also manifests itself through further opportunities available at New York University. A good example of an additional component being implemented into the programme is the 'Biotechnology Industry, Structure and Strategy' course, which provides guidance on how to ensure discoveries and developments are sufficiently recognised.

NYUSOM is also involved in projects such as the National Science Foundation innovation Corps (NSF i-Corps) that aims to broaden the focus of scientists and engineers in order to allow their discoveries to have a greater impact in the commercial world. The private-public partnership being practiced by the University is vitally important in ensuring science is successfully distributed.

PAST SUCCESSES AND FUTURE POSSIBILITIES

While the range of education provided speaks for itself, NYUSOM is also ideally located to deliver the information, as it is right in the heart of the international drug industry. Its proximity to pharmaceutical giant Pfizer, as well as the New York City Department of Health, means it is exceptionally well placed to deliver an industry-gearred perspective. As a consequence, the programmes being offered are brimming with potential for all participants, and this is demonstrated by the success of the scheme so far. Gold-von Simson discloses the main achievements of the course: "Metrics show that student knowledge is increasing, learning objectives are consistently being met, and that the teaching is of high quality, reflected by excellent lecture ratings. The increased enrolment to the point of maximum capacity is also a major achievement".

With many successful courses already established within the programme, the next step is to further enhance the learning experience to be more immersive and hands on. The institution plans to use pre-established platforms such as i-Corps to achieve this through specialised training. While there are many institutions worldwide

COURSE OVERVIEW

The programme comprises smaller courses combined into a single year-long curriculum, with the goal of providing a comprehensive overview of the field of drug discovery and development, focusing particularly on drugs for treating diabetes and diabetic complications. The two key components are:

DRUG DEVELOPMENT IN A NEW ERA

- This component aims to give learners an overview of the drug development process, including everything from clinical trials and pharmacodynamics to ethics and economics
- Students will learn how to not only understand these greater processes, but also incorporate them into their own research and practice

MOLECULAR SIGNALING AND DRUG DEVELOPMENT

- In light of evolving thought about the molecular signalling pathways targeted by drugs, and the effect on the disease process as well as the disease itself, this course will educate students about molecular signalling pathways from a drug targeting perspective
- It also includes the discussion of case studies involving drugs with different developmental trajectories

that demonstrate academic excellence in the field of pharmaceuticals, it seems NYUSOM is carving out a place for itself as a truly industry-friendly university. This factor, along with the high quality of the course, is vital for ensuring that new, life changing medicines quickly and effectively reach those who need them the most.

INTELLIGENCE

A NEW ERA OF TARGETED DRUG DISCOVERY AND THE PATH OF DEVELOPMENT: FROM MOLECULAR SIGNALING TO THE GLOBAL MARKET AND BACK AGAIN

OBJECTIVE

To educate students enrolled in MS, MD and PhD programmes about all aspects of the drug discovery and development process, with a particular emphasis on drugs for treating diabetes, diabetic complications and obesity.

KEY COLLABORATORS

Dr Gabrielle Gold-von Simson, Dr Ravichandran Ramasamy, New York University (NYU) School of Medicine, USA

FUNDING

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GABRIELLE GOLD-VON SIMSON

is an assistant professor of Pediatrics and Medical Director of the Inpatient Pediatric Unit at NYULMC. She is actively involved

in teaching programmes at New York University; she is Course Director for the NYU Graduate School of Arts and Science (GSAS)'s Drug Development course, Program Director for the Health Innovations and Therapeutics Concentration, and she sits on the Program's Executive Committee. She was awarded a National Institutes of Health (NIH)-NIDDK grant to expand her educational programme in drug development for which she serves as Program Director.



RAVICHANDRAN RAMASAMY

is an associate professor of Biochemistry, Molecular Pharmacology and Medicine. He is actively involved in teaching the

NYU GSAS' Drug Development course, and mentoring PhD students and postdoctoral fellows in the Sackler graduate programme and Diabetes research centre. He is currently Principal Investigator on several peer reviewed grants from NIH. Ramasamy serves on grant review panels for various research institutions and is a editorial board member of key scientific journals.

