IPSBI
IKATAN PROGRAM STUDI
BIOTEKNOLOGI INDONESIA

Pfizer

Outcome Report

Higher Height

Training of Trainers

October 2022

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About HigherHeight

HigherHeight by Pfizer Indonesia aims to take Indonesian medical biotechnology development to a new height through education and partnerships. The program, first and foremost, strives to foster interest and skills in medical biotechnology research in the education sector.

Launched in 2021, HigherHeight consists of the Pfizer Biotech Fellowship program targeting undergraduate and graduate students of the medical biotechnology program in Indonesia and the Training of Trainers (ToT) program targeting lecturers and researchers in the biotechnology sector.

In 2022, HigherHeight focused on the ToT, in collaboration with the Association of Indonesia's Biotechnology Program Studies (IPSBI), and supported by Tenggara Strategics, the Centre for Strategic and International Studies (CSIS), Prasetiya Mulya University and The Jakarta Post. This one-month ToT program was conducted virtually against the backdrop of the Indonesian government's focus on developing the biotechnology sector as part of its national health system transformation.

Targeting lecturers and researchers in medical biotechnology, the ToT program helps to strengthen the capacity and quality of human resources in the field. To support this objective, this year's program consisted of a series of capacity-building and knowledge-sharing sessions with medical biotechnology experts from Pfizer and reputable institutions, including the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard University.

The HigherHeight program is hoping to increase the knowledge of lecturers and researchers on the advancement of medical biotechnology in Indonesia and to provide inspiration for the development of the country's biotechnology education curriculum, ensuring the quality of research and human resources.

Program Partner

Supported By

Executive Summary

The HigherHeight program invited lecturers and researchers from universities across Indonesia to participate in a series of training and sharing sessions in an effort to strengthen the capacity and quality of human resources in Indonesia's field of medical biotechnology. A total of 29 lecturers and researchers from 16 universities across Indonesia participated in this program. The program commenced in mid-October and ended at the end of the month.

The program launch, with the overarching theme of "Turbocharging Indonesia's Medical Biotech Education" was opened by Pfizer Indonesia President Director Nora T. Siagian and Health Minister Budi Gunadi Sadikin. The launch included a panel of high-ranking experts and professionals in the field of medical biotechnology, coming from the International Pharmaceutical Manufacturers Group (IPMG) and the Information Technology and Innovation Foundation (ITIF), among others.

Included in the program was a series of ToT sessions, which focused on providing selected lecturers and researchers with training and knowledge exchange on the development of medical biotechnology. The sessions were lined up with medical biotechnology experts from Pfizer and a number of reputable institutions, including the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard University, the Analytic and Translational Genetics Unit at Massachusetts General Hospital (MGH), Harvard Medical School and Brandeis University in the United States.

The topics discussed in the program included the ethics and integrity of conducting biotechnology research; the role of demand management in the end-to-end COVID-19 vaccine supply chain; machine learning, real world data and real world evidence; advanced genomics and gene sequencing. Throughout this program, participants were given the chance to directly engage with the medical biotechnology experts through Q&As and a separate session purposely designed for the participants to discuss and raise questions with the experts.

Participating Universities

Foreword

Nora T. Siagian,
President Director of Pfizer Indonesia

As the President Director of Pfizer Indonesia, Nora T. Siagian presented her welcome speech at the launch of this year's HigherHeight program. In her speech, Nora highlighted how the HigherHeight program was in its second year, focusing on strengthening the capacity of lecturers and researchers in medical biotechnology through the ToT.

This year's program, said Nora, reached 16 universities across Indonesia and would allow lecturers and researchers in the field to exchange knowledge on various topics related to medical biotechnology. Nora further conveyed her hopes that this program could develop into a knowledge-exchange platform that is utilized to advance medical biotechnology education in Indonesia.

Additionally, Nora provided a brief introduction to Pfizer by mentioning how the company has operated in Indonesia for 53 years and established cooperation with various stakeholders, including the government, associations, communities and patient groups to create a healthier Indonesia. Nora noted that human resources were an important element for Pfizer, therefore, the company believed in building the capacity of Indonesian talent, especially in biotechnology.

Nora closed her speech by encouraging participants to collectively advance medical biotechnology and wishing the program a beneficial, as well as a positive outcome.

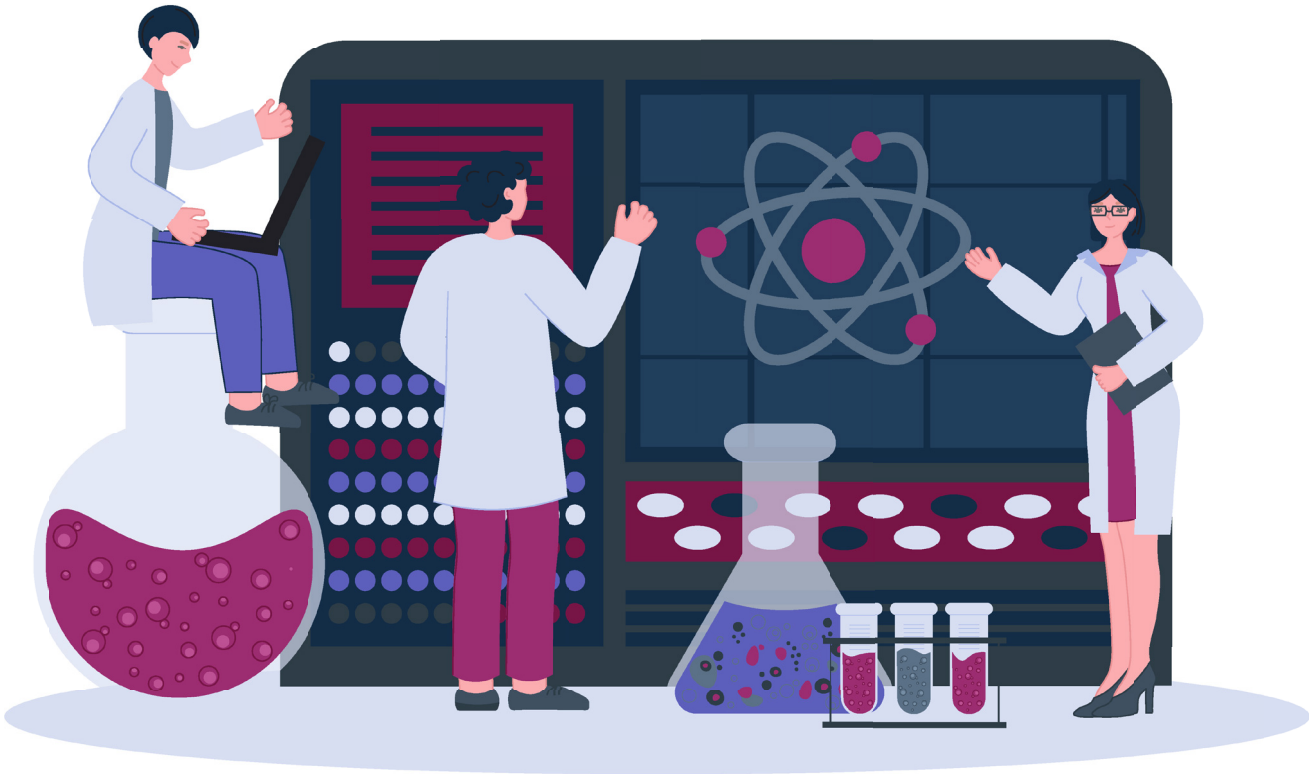
Keynote Speech

Budi Gunadi Sadikin,
Health Minister

The HigherHeight program welcomed Health Minister Budi Gunadi Sadikin, who gave his keynote speech at the launch of the program. The health minister opened his keynote speech by addressing the various breakthroughs in medical biotechnology, such as the development of drugs, therapy and detection tools. He noted that technological development has allowed the advancement of this field.

Although breakthroughs in medical biotechnology have greatly benefited people, Budi explained that technological advances alone are not enough to advance this field for health resilience. Budi continued by emphasizing the centrality of human resources for medical biotechnology advancement, mentioning that the field's quality of human resources is an important asset that must be collectively maintained and improved. According to Budi, quality human resources in medical biotechnology will have the capability to take advantage of technological advances and develop the field even further.

Budi closed his speech by encouraging all participants to constantly learn, take as much knowledge as possible, and share their knowledge with others. Consistency, he noted, was the rarest of all human qualities.



Seminar – Oct. 14

Turbocharging Indonesia's Medical Biotech Education: seminar

Nora T. Siagian, M.M.

Ir. Budi Gunadi Sadikin

Roy Himawan, F. Farm., Apt., M.K.M (RH)

Stephen Ezell

Dr. Listya Utami Karmawan

Inge Sanitasia Kusuma, M.M

Yalun Arifin, Ph.D

The HigherHeight program was kickstarted by a seminar titled Turbocharging Indonesia's Medical Biotech Education, which was held on Oct. 14. The hybrid seminar provided a discussion forum for academics, practitioners, researchers and government representatives on the significance of top-quality education toward achieving quality research and human resources in biotechnology. The seminar served as the foundation of the 2022 HigherHeight program.

This seminar was opened by a keynote speech from Nora T. Siagian, who addressed the aim of the program. This was followed by a keynote speech from Health Minister Budi Gunadi Sadikin about the centrality of human resources for medical-biotechnology advancement. The event continued with a panel discussion filled with high-ranking intellectuals and professionals in the field, including Inge Sanitasia Kusuma, executive director of the International Pharmaceutical Manufacturers Group (IPMG). Inge discussed the state of Indonesia's human resources and research and development in biotechnology and presented recommendations for the government, academics and the industry.

The Health Ministry's director of Pharmaceutical and Medical Device Resilience, Roy Himawan, also contributed to the panel. He discussed the government's efforts to advance biotechnology with its Biomedical and Genome Science Initiative (BGSi), which was established with the goal of boosting Indonesia into an era of biotechnology and precision medicine.

Stephen Ezell, vice president of Global Innovation Policy, at the Information Technology and Innovation Foundation (ITIF) also joined the panel discussion by proposing key innovation priorities that could support the acceleration of Indonesia's research and human resources in biotechnology, which was grounded in his review of Mexico's life-sciences ecosystem.

Listya Utami Karmawan, head of the Association of Indonesia's Biotechnology Program Studies (IPSBI), then delved into the way universities could help advance biotechnology through a penta-helix collaboration. The collaboration would entail the government, industry, community and mass media. The event ended with a Q&A session between the panelists and moderator on issues concerning medical-biotechnology education, research and human resources.

Speakers of the seminar
Keynote speaker: Nora T. Siagian, M.M., president director of Pfizer Indonesia
Keynote speaker: Ir. Budi Gunadi Sadikin, CHFC, CLU, Health Minister

Panelists:

1. Roy Himawan, F. Farm., Apt., M.K.M (RH), Director of the Pharmaceutical and Medical Device Resilience Directorate at the Health Ministry
2. Stephen Ezell, Vice President of Global Innovation Policy, the Information Technology and Innovation Foundation (ITIF)
3. Dr. Listya Utami Karmawan, Head of the Association of Indonesia's Biotechnology Program Studies (IPSBI)
4. Inge Sanitasia Kusuma, M.M, Executive Director of the International Pharmaceutical Manufacturers Group (IPMG)

Moderator: Yalun Arifin, Ph.D, a faculty member and head of Food Business and Technology at Prasetiya Mulya University, Indonesia

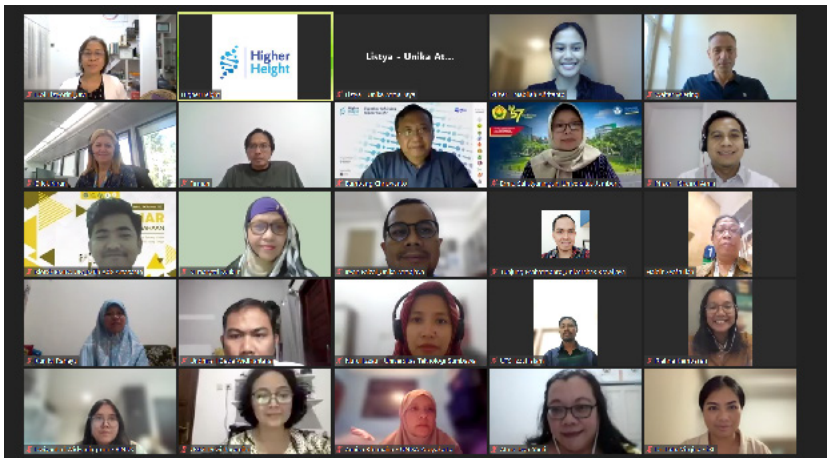
Sessions – October 18-27, 2022

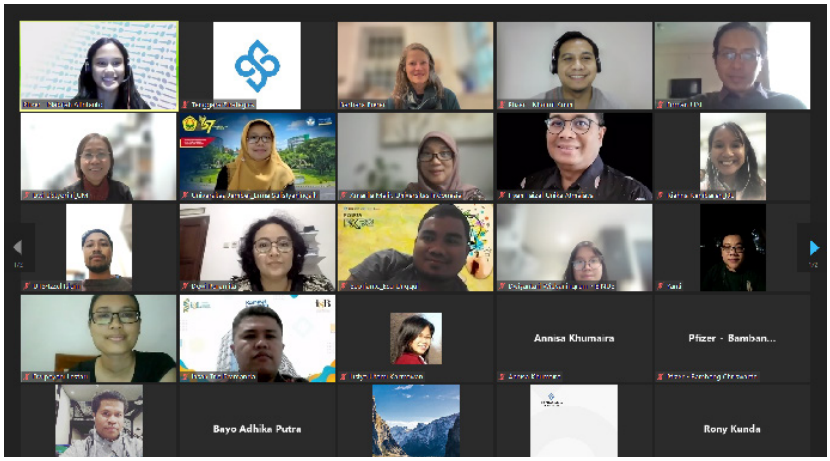
Training of Trainers

A series of capacity-building sessions for lecturers were conducted as part of the HigherHeight program, with the aim of providing training and knowledge exchange with medical biotechnology experts. The sessions saw experts from reputable institutions and Pfizer's internal experts sharing their knowledge with selected medical biotechnology lecturers.

Participants of the sessions were eager to learn about the development of medical biotechnology, ranging from the ethics and integrity of conducting biotechnology research to the discovery of biotherapeutic drugs. Through these sessions, participants had the opportunity to challenge themselves by expanding their perspectives and engage with leading intellectuals and professionals, in order to reinvigorate their knowledge and contribute to developing the curriculum of biotechnology education in Indonesia.

- The Role of Demand Management in the End-to-end COVID-19 Vaccine Supply Chain, presented by Walter Wiering
- Biotherapeutic Drug Discovery, presented by Alfredo Darmanin Sheehan
- Machine Learning, Real World Data, and Real World Evidence, presented by William Crown, PhD
- Advanced Genomics and Gene Sequencing, presented by Hailiang Huang, PhD
- Research Ethics and Integrity, presented by Barbara Bierer, MD
- Ask the Experts with Barbara Bierer, William Crown, Hailiang Huang





Sessions

The Role of Demand Management in the End-to-end COVID-19 Vaccine Supply Chain

By Walter Wiering
Brand Supply Leader

Kicking off this year's Training of Trainer program, Pfizer brand supply leader Walter Wiering shared about the role of demand management in the end-to-end COVID-19 vaccine-supply chain. Walter has worked with Pfizer for the past 10 years in several regional European and global supply-chain roles in various therapeutic areas such as oncology, rare diseases and vaccines. Therefore, he has been able to understand how supply chains differ between, for instance, how biological products versus synthesized products are managed and how the supply chains deviate.

Walter shared some insights on the role of demand management as a critical success factor in the design and execution of the supply chain, as well as how demand management actually drives product availability for patients. According to him, supply chain management encompasses the planning and management of all activities involved in sourcing and procurement, product conversion, as well as all logistic management activities. Most importantly, it also included collaboration and coordination with channel partners such as suppliers, intermediaries, third-party logistic providers or service providers, and customers. In the supply chain's seven rights policy, demand management was needed to deliver the right product in the right quantity to the right customer at the right time, place, condition and cost. Walter expressed that the seven rights policies should be renamed as seven obligations because if one failed, then there would be no viable product that customers were willing to purchase. He added that it was important to note that the seven rights policy showed the criticality of demand management in securing product availability.

During his session, Walter also shared that a realistic supply chain would consist of a very complex maze of points of sale of logistic-service providers that often provided value-added services to meet local customs and legal requirements. It would also consist of multiple manufacturing sites and all material suppliers. In this way, the supply chain also would show that the demand signal did not end with predicting that end customer demand; but rather, between each of the lines that were seen represented in the supply chain network, there was a supplier-customer relationship that pictured the need to understand future demands for its product in order to ensure timely availability of their components.

Walter's presentation was followed by a Q&A session, where a participant asked about the most difficult part of working at the speed of science, such as providing the COVID-19 vaccine in a short timeframe. Walter replied by sharing that he joined the COVID-19 vaccine team in July 2020 where the phase one and two of studies had resulted in a positive outcome, the design of the manufacturing process was already well underway and being implemented. The distribution side of the vaccine was not yet designed let alone implemented, so when he joined the company did not have any idea of delivering the vaccines to the people. He continued to share that during the first year of the pandemic, all of Pfizer's colleagues and partners had had an extremely positive mindset around the purpose of why they were working on the vaccine. Since he joined the COVID-19 vaccine team, Walter revealed that every day had been a working day and that weekends no longer existed for him. However, as tiring and grueling as it was, working on the COVID-19 vaccine had been an incredible experience for him and he was proud to say that he had been a part of it, because the end result exceeded expectations.

Sessions

Biotherapeutic Drug Discovery

By Alfredo Darmanin Sheehan
Pfizer Worldwide Research Biomedicine Design (BMD) A.R. Fellow

In the next session, Pfizer Worldwide Research Biomedicine Design (BMD) A.R. Fellow Alfredo Darmanin Sheehan, provided material on biotherapeutic trends, particularly antibody-based approaches to biotherapeutic drug discovery and antibody optimization techniques. To support his material, Alfredo also presented a couple of case studies related to the development of biotherapeutic approaches and recent technologies present in antibody development, with a particular focus on COVID-19. Alfredo opened his session by mentioning his work at BMD, which focuses on the preliminary stage of early drug discovery and its optimization using a range of technologies.

Grounding his presentation with his expertise in antibody discovery, Alfredo explained that antibodies work toward specific targets, however, there are various key challenges and pitfalls as developing antibodies is not just a matter of ensuring its functionality. For one, there are challenges in its manufacturing since antibodies must meet a certain range of stability or immunogenicity before rollouts. In the case of multi-specific antibodies, they can be manufactured repeatedly depending on the targeted disease.

However, an assessment of the elements that may affect the manufacturing of antibodies are addressed in the preliminary stages of their discovery. As manufacturing is a key element in biotherapeutic drug discovery, if it cannot be developed on a reasonable scale and fit its required process, then it would become increasingly difficult to turn it into a potentially usable medicine.

Alfredo further mentioned crucial aspects within the early stages of biotherapeutic drug discovery, as this stage is the starting point for getting a biotherapeutic drug project off the ground. The aspects include a drug-ability assessment to assess the potential and strategies of developing a specific biotherapeutic drug and ensuring that the drug has a good quality source of proteins and reagents. Alfredo emphasized that this is important to the success of developing a biotherapeutic drug.

During the Q&A session, Alfredo touched on the reasons why biotherapeutic drug discovery is advantageous over a more traditional small molecule approach. According to him, biotherapeutics offer novel approaches to developing drugs, with one key advantage being its specificity. Citing figures found in the literature, Alfredo also mentioned that the cost of developing a successful biotherapeutic drug can be significant, since the more a development process scales up, the more resources it will utilize, particularly in running clinical trials. Closing off his session, Alfredo responded to a question on COVID-19, pointing out that when variant mutations arise, they can potentially escape vaccines and antibodies. Therefore, it is important to have multiple approaches to deal with potential mutations and maximize all available tools.

Sessions

Machine Learning, Real World Data and Real World Evidence

By William Crown, PhD
Distinguished Research Scientist in the Brandeis University Heller School for Social Policy and Management

In this session, Brandeis University Heller School for Social Policy and Management distinguished research scientist William Crown, PhD discussed the use of machine learning (ML), real world data (RWD) and real-world evidence (RWE) in research. In his seminar, Dr. Crown used case studies and academic publications to present his material. The developments in data collection and AI technology were emphasized to have significant implications on business and regulatory strategies. It would also be financially prudent to utilize these same tools in research to optimize coverage and reimbursement plans in biomedicine.

Dr. Crown opens his presentation with the definition of RWD and its current applications. For some countries with nationalized healthcare, patient data is commonly collected for research purposes. Examples of the collected data could be diagnosis, symptoms, treatments, and subsequent treatment results. The data is then also categorized based on other patient data such as demographics. By utilizing large institutions, a database of RWD and RWE could be constructed for use in advanced, research. According to Dr. Crown, the amount and complexity of available data in the modern day allows for research that previously would have been considered inconceivable.

Although RWD is a powerful asset, it is also difficult to utilize. In his presentation, Dr. Crown discusses the transparency and reproducibility of RWD and RWE. He dedicates a segment of his seminar on observational study designs and time-related biases. It is critical to understand the fitness for purpose of the data, because it varies by stakeholders. Data linkages will influence the patient populations that is being represented.

During the Q&A session, all the questions were related to difficulties with Indonesian data. Difficulty in collecting patient data, unorganized datasets, and dispersed nature of databases in Indonesia due to the obstacles caused by being an archipelago. Host of the session Barbara E. Bierer, MD also asks an additional question to Dr. Crown regarding the determination of a dataset's fitness for purpose.

Dr. Crown addresses the first question regarding data collection by using existing examples. The path of least resistance to building a database is to integrate it with a national healthcare system. The alternative to this would be to do data collection on a primary basis. For the question from Barbara, Dr. Crown advises referencing how the dataset was used previously, failing that the data can be run through other processes to see how it reacts. He uses an example of a previous research he ran in which changing therapeutic care caused a big difference in the ability to draw conclusions.

One last question was asked near the end of the session. Indonesia faces unique obstacles in building a common database due to the country's nature as an archipelago. Databases end up dispersed with each institution holding onto their own set of data that is inaccessible to external parties. To answer this question, Dr. Crown brings up the option to use third party cloud services, such as Microsoft or Amazon. The total pool data can then be organized post-upload. Additionally, many of these third-party cloud services have experience working with healthcare entities and are adept at handling sensitive information such as patient privacy.

Sessions

Advanced genomics and gene sequencing

By Hailiang Huan, PhD
Assistant professor in the Analytic and Translational Genetics Unit at Massachusetts General Hospital (MGH) and Harvard Medical School.

Hailiang Huang, an assistant professor in the Analytic and Translational Genetics Unit at Massachusetts General Hospital (MGH) and Harvard Medical School, opened his session on advanced genomics and gene sequencing by elaborating on the connection between phenotypes and diseases or disorders. Dr. Huang explained that if the format of a person's gene was pathogenic, then that person would have a disorder. On the other hand, if the gene was in a normal format, no disorder would be present in a person.

However, according to Dr. Huang, such a connection was tricky when it came to polygenic disorders because, despite a gene's pathogenic format, it did not guarantee a person would develop a disorder. The reason was that hundreds of other regulating genes may collectively confer a protective factor to reduce a person's high risk of a disorder.

Dr. Huang then touched on the Human Genome Project. As explained by Dr. Huang, the project was initiated in the United States with several other countries and aimed to sequence the human genome. With 3 billion human genome bases and an investment of US$1 per base, the project saw a total investment of US$3 billion. Though the project was a success, Dr. Huang reflected that more advanced tools were needed to further understand the "language" of DNA.

The project itself helped launch the 1000 Genomes Project, in which roughly 2,500 people were genome sequenced with 500 individuals across major ancestry groups: European, admixed American, African, East Asian and South Asian. The 1000 Genomes Project was only possible with the development of genome-sequencing technologies, such as shotgun sequencing. Dr. Huang elaborated that before the development of shotgun sequencing, DNA was sequenced in a very long stretch and then assembled. With the presence of shotgun sequencing, genomes are broken up into small pieces and sequenced individually. Assembling each of the small pieces became a challenge; however, Dr. Huang explained how the Human Genome Project provided a template to make shotgun sequencing possible.

In the Q&A session, Dr. Huang was asked whether polygenic disorders could be predicted. Dr. Huang explained that scientists and researchers working on polygenic disorders were working to use discovered genes to build a polygenic risk score, which would measure a person's likelihood of developing a disorder. However, Dr. Huang noted that to date, the polygenic risk score was not exceptionally accurate and that it would take many years for this risk score to become a tool that had clinical value for doctors. Additionally, Dr. Huang was asked about the approach to analyzing a gene's association with a disorder during genome sequencing. Dr. Huang asserted that in genome sequencing, each of its many variations did not have to be tested for a disorder since knowledge of a variation's genotype could be used to predict the genotype of other variations, resulting in an analysis of the gene's connection with a disorder without testing every variation of this gene.

Sessions

Research ethics and integrity

By Barbara E. Bierer, MD
Faculty Director, MRCT Center
Director, Regulatory Foundations, Ethics and Law Program, Harvard Clinical and Translational Science Center, Harvard Medical School
Director of Regulatory Policy, SMART IRB
Professor of Pediatrics Medicine in the Harvard Medical School

MRCT Center faculty director and Harvard Medical School professor of medicine, Barbara E. Bierer, MD discussed the importance of ethics and integrity in research. Dr. Bierer opened the seminar with a brief description of integrity, the role it plays in research and the challenges of maintaining integrity in research.

The first part of Dr. Bierer's presentation reviewed common pitfalls with which many researchers often struggle. Adherence to regulations is an important responsibility for the researcher. However, based on her experience, Dr. Bierer has found that students and professors are rarely taught the regulations or institutional policies. All institutions should have someone knowledgeable and responsible for research integrity, and researchers should know how and to whom they should be reporting misconduct.

Dr. Bierer stressed the importance of distinguishing between research misconduct and honest errors. Legally, at least according to US law, the distinguishing factor lies in the intent. An honest error can lead to publication that has an error, but misconduct must involve behavior that is knowing, reckless or intentional. Dr. Bierer then talked about a postgraduate student who plagiarized several paragraphs in a manuscript because she did not know the citation standards. This student was educated, not punished for her mistake.

The goal of this session was to provide a framework for increasing research integrity and reducing research misconduct. Here Dr. Bierer emphasized the importance of cultivating a culture that values integrity within the institution. However, clear guidelines and policies need to be developed as well. Dr. Bierer used as an example of her institution, in which no policy existed for data ownership. This led to instances where some researchers would take original data with them when they left the institution.

The Q&A for this session discussed many topics, including proper data-management protocols, recent examples of unethical research in biotechnology and the growing issue of predatory journals. In the case of data management, Dr. Bierer further explored institutional protocols including the practices of meticulously backing up all data, documenting transfer by agreement that specifies who is transferring and who is accepting responsibility for them and penalties for those who misuse the data.

Dr. Bierer admits that there is no easy way to identify predatory journals, especially because there is significant effort to appear legitimate. Predatory journals will often be, in appearance, indistinguishable from legitimate journals. One must spend time critically studying their publication history, the charges for publication, the promised time for review and publication and the citation index.

Sessions

Ask the experts

Barbara Bierer

William Crown

Hailiang Huang

This year's Training of Trainers program was closed with a discussion session with MRCT Center Faculty Director, SMART IRB regulatory policy director and Harvard Medical School professor of pediatrics medicine Barbara E. Bierer, MD, assistant professor in the Analytic and Translational Genetics Unit, Massachusetts General Hospital (MGH) and Harvard Medical School Dr. Hailiang Huang and Brandeis University Heller School for Social Policy and Management distinguished research scientist Dr. William Crown. Participants were gathered to ask questions about the experts' experiences and knowledge in their respective fields.

At the beginning of the session, a participant asked about how a curriculum should be organized to be comprehensive to students, given that biotechnology is an amalgam of many different principles. Dr. Crown gave the perspective of targeted therapies. Not to mention, they are expensive to develop from a health economic standpoint and raised some severe challenges. Dr. Crown believes that understanding the dimensions of health economics of tailored therapies is important and would be a valuable addition to any curriculum. In addition to scientific chemistry and biology, the curriculum should also be focused on moving therapies into treatment and use by patients to understand the economics and how to overcome market challenges.

Dr. Huang concurred, explaining that training or education should include a wide range of topics while also delving deep for innovation in areas of given specialties. He gave an example that training in medicine should be accompanied by mathematics to help everyone be on the same page and make unique contributions. Dr. Bierer added that undergraduates should be exposed to many disciplines because it would help later when they become part of a team or pursue graduate school. Once a student identifies their passion, their field of study will provide depth to the domain. Educators, on the other hand, must remember to support the creativity of a student.

Another participant asked about the social effects of biotechnology. Dr. Bierer said that embedding ethics into any course was foundational. She continued that there was no need to be heavy-handed about ethics, but it was important to make sure that whatever was done was seen through a lens of ethical responsibility. Dr. Crown added that the issue of ethics reminded him of the issue of algorithmic bias in machine learning work. He explained that because machine learning was based on data, it reflected the pattern that was already in the data. Therefore, in the case of a situation where different segments of the population were disadvantaged in their ability to be able to access and use the healthcare system, for reasons of affordability or their physical access and proximity to medical centers, those groups would be underrepresented in the data. When the machine algorithms were developed, they would replicate those same patterns. According to Dr. Crown, if one was interested in addressing problems of underutilization and restricted access by certain groups, one needed to be aware of the challenges. Dr. Crown's example emphasizes that it was not the machine learning algorithm that was biased, but the existing patterns of bias that were in our healthcare data already.

Lastly, Dr. Huang added that ethics is a developing view rather than something static; ethics has been shaped by technology. An example of an evolving ethical perspective relates to genomics data. In many countries, genomic data are treated as not identifiable data, but we do know that everyone has a unique genetic profile (except for identical twins.) Nevertheless, we treat these data as not identifiable, because there are practically no databases that could connect genetics to one's identity. However, this might change with the national biobanks. It is possible that genetic data will be recognized as identifiable in the future. If so, the genomics-research industry will also need to change and evolve.


Higher
Height