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A REVIEW ON PROTEOMICS AND GENOMICS IN DRUG DISCOVERY AND DEVELOPMENT

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ABSTRACT

Genomics and proteomics are crucial in drug discovery and development, as they study the structure and function of genomes, particularly genes. The impact of genomics and pharmacogenomics on clinical medicine includes treatment interventions in cardiovascular medicine, endocrinology, and oncology. Proteomics techniques have been used to characterize rapid post-translational protein modifications in highly complex molecular signatures as important disease-related biomarkers from experimental model systems or clinical samples.

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INTRODUCTION

The drug development process is extremely complex and involves many disciplines, including structural biology, metabolomics, proteomics, and computer science, to name a few. The process of drug discovery involves candidate identification, synthesis, characterization, screening, and testing for therapeutic efficacy. The process of pre-clinical drug development begins when an active ingredient shows value in the above tests. This process is generally very time consuming and expensive. [1]

The history of drug development over the past century has been characterized by the accumulation of knowledge and technology that has enabled an increasingly detailed understanding of both targets and potential drug compounds. Targets are typically proteins that occur within the human body or come from external agents such as viruses or other pathogens. The greatest challenge for pharmaceutical researchers is to understand the complex chemical processes involved in disease processes, find the most appropriate point of intervention, and discover or develop compounds that modify the chemical process at that point. [2]

Apart from advances in technology and understanding of biological systems, drug discovery remains a long process and the rate of discovery of new treatments is low. Information about the human genome, its sequence, and its coding is said to be a potential godsend for drug discovery, virtually eliminating the therapeutic targeting bottleneck that is the limiting factor in the speed of drug discovery. You are expected to do so.

However, data shows that drug discovery projects are generally more likely to fail with new targets than with established targets. These data indicate that several ideas underlie trends in the pharmaceutical industry that began in the early 21st century and continue today, leading to increased risk aversion in target selection by multinational pharmaceutical companies. I am. The process by which a new drug is brought to market goes by many names, most commonly the development chain or "pipeline" and consists of several different phases. There are different cost estimates for each phase of the pipeline. [3]

Genomics is the science that studies the structure and function of genomes, especially genes. The genome is the complete genetic information of an organism. A genome is a collection of information that an organism can pass on to its offspring before birth. Proteomics, on the other hand, is essentially protein analysis and, until recently, could be described as a comprehensive classification of a set of techniques and bioinformatics platforms aimed at a comprehensive molecular description of the actual protein complement of a given sample. Currently, it is usually associated with systems biology. Significant advances have been made in characterizing rapid post-translational protein modifications in highly complex molecular signatures as important disease-related biomarkers from experimental model systems or clinical samples.

PRINCIPLES OF PROTEMICS AND GENOMICS

Genomics describes the discipline in genetics concerned with the study of the complete set of genes (genomes) of Organisms. The main aim of genomics is used to determine the entire DNA Sequence of organisms, fine-scale genetic mapping, studies of Intragenic phenomena. Genomics is widely used in research, medicine, biotechnology, evolutionary studies, bioengineering, etc. The study of genomics in health looks at the biological cause of disease as well as treatment options and environmental influences. Drugs in clinical development and trial can benefits from genomics technologies such as gene sequencing, statistical genetics and gene expression analysis. [4]

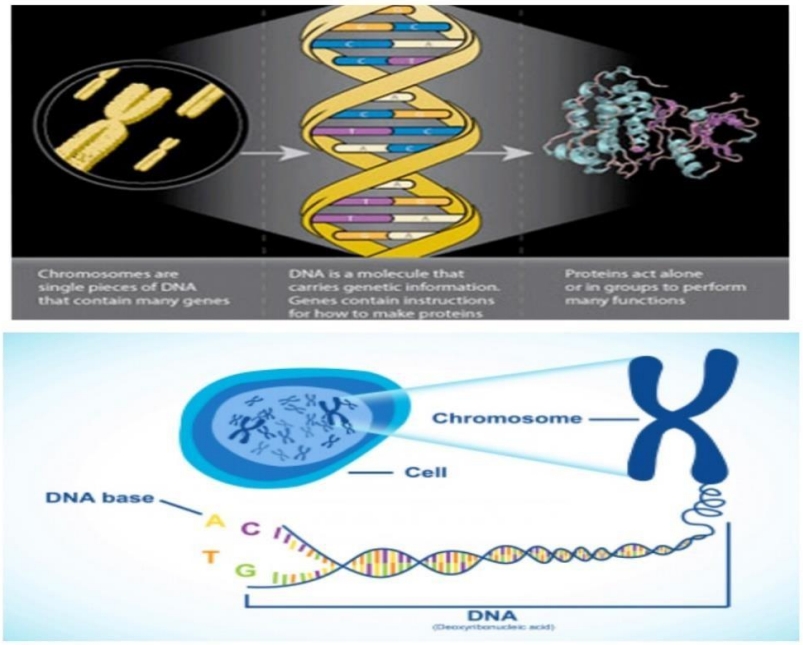


Figure No. 1: Principle of Proteomics and Genomics

Proteomics is the study of the proteome (entire set of protein produce by organism) and involves the technology used to identify and quantify the various proteins, protein-protein and protein-nucleic acid interactions within the Proteome, as well as the post-translational modifications that affect protein activity. Proteomics technology is extensively used to identify the underlying molecular mechanisms of various diseases. These can help to understand the mechanism of drug action, safety, efficacy and toxicity of drug. [5]

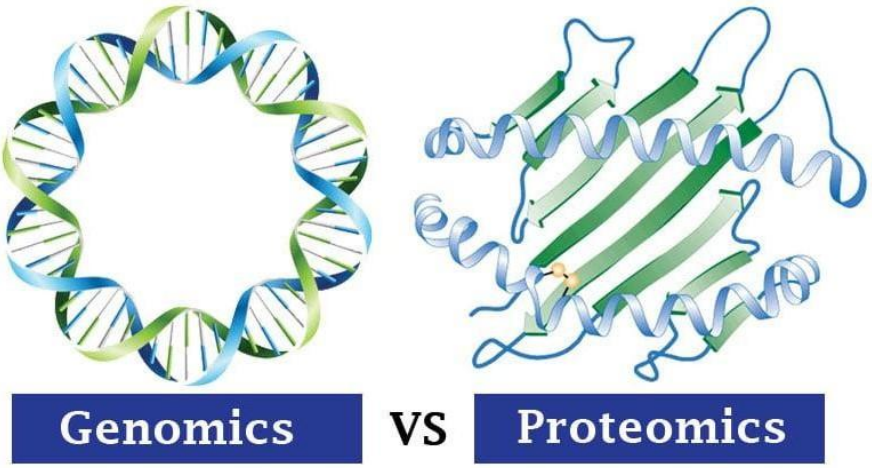
GENOME SEQUENCING AND GENOTYPING:

To better understand the potential of genomic analysis in drug development, it is necessary to outline the characteristics of three technologies currently in use: high-density genotyping of common variants (>1–5); we used genome-wide association studies (GWAS) and linkage analysis (% of allele frequencies in the population), exome sequencing, which captures about 5% of the coding sequences of the human genome, and whole-genome sequencing to estimate the human genome. Approximately 85% of the area is covered in high quality. Genome In contrast to genotyping arrays, exome and whole genome sequencing identify 4,444 specific rare disease-associated variants. This can have functional effects and cause disease. [6]

The technical characteristics of different technologies determine whether mutation discovery data can be translated into actionable information for drug development. The underlying concept is to use genomic analysis to identify “natural experiments,” or naturally occurring mutations in humans that affect the activity of specific

protein targets. Can be used to evaluate effectiveness. We aim not only to investigate the toxicity of drugs that target such proteins, but also to establish a causal relationship between target and outcome. [6]

DIFFERENCE BETWEEN GENOMICS AND PROTEOMICS



Unlike the genome, which is relatively static, the proteome is not static. It is constantly changing in response to tens of thousands of intracellular and extracellular environmental signals. Proteomes vary depending on a variety of factors, including health and disease, the nature of each tissue, the stage of cell development, and the effects of drug treatments. Therefore, the proteome is often defined as "the proteins present in a sample (tissue, organism, cell culture) at a particular point in time." Proteomics is similar to genomics in many ways. Whereas genomics starts with genes and draws conclusions about their products (proteins), proteomics starts with functionally modified proteins and returns to the genes involved in their production. Sequencing of the human genome has sparked interest in proteomics. This is because while DNA sequence information provides a static snapshot of the different ways cells use proteins, the lifespan of a cell is a dynamic process. These new data are increasing interest in proteomics in science, medicine, and especially in the pharmaceutical field. [1]

TECHNIQUES OF PROTEOMICS:

Proteomics technology plays an important role in the drug development process, as most drugs target proteins or are themselves proteins. A proteomics-based approach integrates his technology, including high-throughput separation of digested proteins. Peptides by liquid chromatography (LC), peptide sequencing by mass spectrometry (MS), followed by genome database search and bioinformatics. With advances in proteomics technology, there is growing interest in using this technology to improve the drug development process. Although proteomics techniques can be classified into different types, from the perspective of the drug discovery process they can be divided into his three main classes: expression/profiling, functional and structural proteomics. [7] Different types of proteomics technologies, their advantages and disadvantages, and possible applications are listed in Table 1.

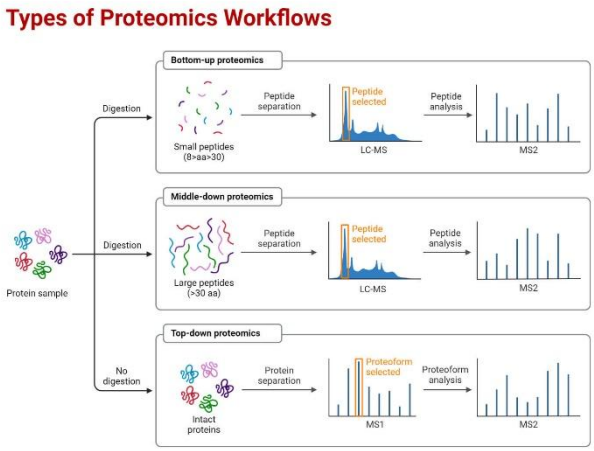


Figure No. 04: Types of Proteomics Wor'kflow

Table No. 01: Different technique in Proteomics

Techniquesin Proteomics	**Advantages**	**Limitations**	**Potential application**
Two-dimensional gelelectrophoresis (2-DGE)	Robustness, Complete proteinanalysis (including post-translational modification	Lowreproducibility, Narrow dynamic range	To assess the biologicalandhealth effects of chemicaltreatment and exposure
Massspectrometry (MS)	Robustness, accuracy, sensitivity,high throughput	Complexityof sample	Identificationof candidate biomarker/drug target
Gel-freeproteomics	**Advantages**	**Limitations**	**Potential application**
Capillary Electrophoresis-Mass Spectrometry(CE-MS)	Highsensitivity, accuracy	Limited sample volume,fluctuating migration times depending on temperaturechange	In Clinical proteomics for biomarkerdiscovery
Quantitative Proteomics	**Advantages**	**Limitations**	**Potential application**
Difference Gel Electrophoresis (DIGE)	Useful for quantitative proteomicsidentifies post-translational modifications	Sampleshavetobe fluorescently labelled	Identification of protein biomarkers by comparative protein expression profiling,appliedin clinical proteomics research

TECHNIQUES OF GENOMICS

The seven techniques are:

1. Genomic DNA Isolation
2. Separation of DNA
3. Cutting and Joining of DNA
4. Cloning and Vectors
5. Detection of Gene of Interest
6. Recombinant DNA and Cloning
7. Production of Multiple Copies of DNA Using Polymerase Chain Reaction (PCR)

Genomic DNA Isolation:

DNA was isolated by Friedrich Miescher who discovered a substance called nuclein in 1869.A method known as density gradient ultracentrifugation is used to isolate exceedingly pure forms of DNA. This involves centrifuging various cell components at a high speed of 40,000 to 70,000 rotations per minute (r.p.m.) on a gradient with variable densities (NaCl and sucrose are utilized).

Various cellular constituents have differential densities, causing them to migrate and ultimately halt at the gradient where their densities align with those of sucrose and NaCl. DNA is collected from the gradient tube in this manner, likewise stopping at a specific density. [8]

DNA Separation:

Due to their negative charge, DNA molecules migrate from the negative to the positive electrode in the presence of an electric field. A gel-like material is employed to facilitate the mobility of DNA under the influence of an electric current. This is a semisolid material composed of several polymers, including polyacrylamide and agarose.

The DNA molecules pass through the permeable network of fibre's that this gelling substance creates. Polyacrylamide gel is used to separate tiny DNA fragments while Agarose gel is used to separate larger DNA molecules. We refer to this process as gel electrophoresis. In gel electrophoresis, the current is conducted across the gel with the aid of a buffer. Though method is simple in separating the DNA, it needs to follow the best practice to get effective results. [9]

DNA Cutting and Joining:

The fundamental process of recombinant DNA technology is the accurate cutting and joining of DNA molecules. Restriction Enzymes are specialized enzymes that are used to cut DNA at specific locations. The ability of the restriction enzyme to identify particular DNA molecule sequences (nucleotides) and make cuts at those locations is one of its defining characteristics. They produce compatible ends of the DNA molecule by this exact cutting, which may then be linked.

The sequences that restriction enzymes may identify are referred to as palindrome sequences which are mirror images of one another. Any DNA molecule can have its two fragments joined by another enzyme after it has been cut by a restriction enzyme. [9]

Cloning and Vectors:

Cloning refers to a technique that involves the reproduction of a single molecule to produce a population of cells with identical DNA molecules. A vector is used to introduce a foreign DNA fragment and to multiply the

DNA fragment for large-scale production. Cloning machines known as vectors are able to replicate within the right host. For molecular cloning, a wide variety of vectors are employed; they include plasmids, which are circular double-stranded DNA molecules, cosmids, which are circular DNA molecules that may also be packaged into viruses, bacteriophages, which are viruses that infect various strains of bacteria.[10]

After the proper vector has been chosen, a restriction enzyme is used to cut it, exposing a location where the foreign DNA can be inserted. After that, the foreign DNA and the vector are ligated together and inserted into a host cell, where the foreign DNA and the vector can grow. To select the vector inside the host cell, various type of selectable markers are used—like antibiotic resistance etc. [10]

Detection of Gene Interest:

Southern Hybridization, Colony Hybridization, and Dot Blot are often employed methods for identifying a specific gene of interest. These techniques operate on a straightforward principle. The target is the particular DNA molecule that we are looking for.

The DNA that has been transported to the membrane serves as a replica in southern hybridization, where it is hybridized with a radiolabeled probe. Following the completion of hybridization, the membrane is cleaned using buffers to get rid of the probe's non-specific binding. After drying, the membrane is placed into an X-ray autoradiography cassette. The radioactive signal is found on the X-ray sheet following the membrane-bound probe's exposure to the X-ray film. [11]

Recombinant DNA and Cloning:

Recombinant DNA is a type of chimeric DNA molecule that includes portions of DNA from two different sources. With the aid of restriction enzymes, the DNA molecule can be precisely cut at a specific location. When a ligase enzyme joins two DNA molecules that have been cut using a specific restriction enzyme. This technique makes it possible to take any gene from any species and place this gene in any other organism or species.

Making an identical duplicate of any material is known as cloning. It is comparable to a Xerox machine in that it repeatedly prints identical copies of documents. A crucial component of recombinant DNA technology is cloning. The process of creating identical duplicates of a DNA molecule is known as cloning. [11]

Production of Multiple Copies of DNA Using Polymerase Chain Reaction (PCR):

A laboratory technique called polymerase chain reaction, or PCR for short, is used to quickly create millions to billions of copies of a particular DNA sequence in order to study it in more detail. In PCR, a section of the genome to be amplified is chosen using short synthetic DNA fragments known as primers. That segment is then amplified using numerous rounds of DNA synthesis. [11]

TYPES OF GENOMICS

Functional Genomics

Functional genomics involves examining the roles of genes and their products within an organism, with a focus on gene transcription, translation, and protein interactions. Unlike genomics and proteomics, it emphasizes gene expression and regulation at transcriptional or post-transcriptional levels. By profiling mRNA expression, functional genomics reveals the transcriptome under specific conditions, identifying co-regulated genes forming regulons with shared functions. Microarrays, beyond gene expression studies, aid in diverse applications such as mapping transposon insertion sites to identify essential genes, as demonstrated by Sassetti et al. in their method for mycobacteria gene identification. [12]

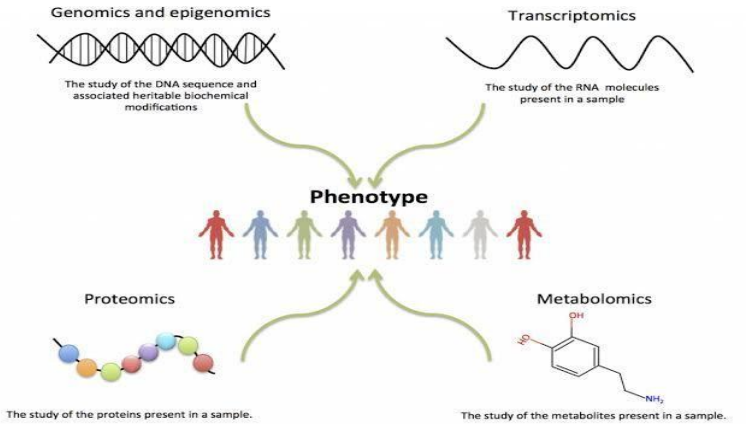


Figure No. 05: Functional Genomics

Structural Genomics:

Structural genomics, a subset of genomics, concentrates on characterizing the structures within a genome. This knowledge is valuable for manipulating genes and DNA segments in species. For instance, understanding a gene's location in the genome is crucial for successful cloning, and comprehending its composition aids in grasping its function and potential modifications for practical purposes, such as enhancing health. Structural genomics encompasses the three- dimensional structures of all proteins encoded by a genome, which is known as structural proteomics when focusing specifically on proteins. The field employs experimental and computational methods to examine the entire genome's structure, aiming to determine the structure of every protein encoded by it, unlike traditional structural prediction, which focuses on individual proteins. [13]

Figure No. 06: Structural Genomics

Comparative Genomics

Comparative genomics is a field of biological research in which the genomic features of different organisms are compared. The major principle of comparative genomics is that common features of two organisms will often be encoded within the DNA that is evolutionarily conserved between them. Therefore, comparative genomic approaches start with making some form of alignment of genome sequences and looking for orthologous sequences (sequences that share a common ancestry) in the aligned genomes and checking to what extent those sequences are conserved. [14]

OBJECTIVE OF GENOMICS

1. As the protein structure and function are closely linked, the importance of structural genomics in understanding the function paramount.
2. Structural genomics can also provide insight in dynamic properties such as protein folding and identify possible targets that may be used for drug discovery. [14]

TYPES OF PROTEOMICS

Expression proteomics:

Expression proteomics, a cutting-edge approach, investigates both quantitative and qualitative aspects of protein expression. Its primary goal is to delineate the variations in protein expression between conditions, such as patients and controls, pinpointing disease-specific proteins and novel components in signal transduction pathways. Typically, expression proteomics experiments analyse protein expression patterns across diverse cells. For instance, comparing protein levels in a tumour tissue sample to a normal tissue sample allows the identification of variations using techniques like 2-DE and MS. These methods help detect differences in protein expression, whether present or absent, providing valuable insights into disease-related protein profiles. [15]

Structural proteomics:

In structural proteomics, techniques like nuclear magnetic resonance (NMR) spectroscopy and X-ray crystallography play a pivotal role in elucidating the three-dimensional structure and intricate details of functional proteins. These methods are instrumental in identifying protein interactions within various cellular components, including membranes, organelles, and ribosomes. One notable application of structural proteomics is the investigation of complex structures like the nuclear pore complex. This exemplifies how these techniques contribute to unraveling the structural intricacies of proteins, providing valuable insights into their functional roles and interactions within cellular environments. [15]

Functional proteomics:

This branch of proteomics delves into understanding protein functions and molecular mechanisms within cells, emphasizing the exploration of protein interactions with various partners. It specifically investigates how an unknown protein interacts with members of a specific protein complex associated with a particular cellular process, shedding light on the protein's biological role. Moreover, uncovering in vivo protein-protein interactions contributes to comprehensive insights into cellular signalling pathways, enriching our understanding of complex cellular processes. [15]

Genetic deficiency:

Genetic mutations, sometimes known as alterations to DNA, are the cause of genetic diseases also known as genetic disorders. Since genetic mutations are mostly transmitted from one's parents, you may receive them from one or both of them. Genetic mutations, however, can happen randomly or in response to external stimuli. This implies that a genetic mutation might be present in a child at birth even though neither parent has the mutation themselves. This implies that a genetic mutation may be present in a child at birth even though neither parent has the mutation. This is referred to as a de novo instance of the illness. While the majority of genetic mutations are benign and do not cause disease, some can lead to hereditary illnesses that have an impact on human health. [15]

ROLE OF GENOMICS AND PROTEOMICS

Genomics and proteomics play significant parts in medicate disclosure by giving profitable data around the hereditary and atomic viewpoints of infections, as well as potential targets for restorative intercession. Here are the parts of genomics and proteomics in medicate disclosure. [16]

1. Target Identification and Validation:

Genomics: Genomic ponders offer assistance distinguish qualities related with particular infections or conditions. This data is vital for understanding the basic atomic components of maladies.

Proteomics: Proteomic examinations can approve potential restorative targets by examining the expression and action of proteins related with illness pathways. Recognizing proteins that play key parts in malady forms makes a difference prioritize targets for sedate improvement.

2. Biomarker Discovery:

Genomics: Genomic data makes a difference distinguish hereditary markers or transformations related with infection vulnerability or movement.

Proteomics: Proteomic profiling can distinguish particular proteins or designs of protein expression that serve as biomarkers for infection conclusion, forecast, and observing treatment reactions.

3. Drug Screening and Development:

Genomics: Understanding the hereditary premise of maladies empowers the advancement of focused on treatments that particularly address the basic hereditary variables.

Proteomics: Proteomic thinks about help in recognizing and characterizing potential medicate targets among proteins. Furthermore, proteomics makes a difference evaluate the impacts of drugs on protein expression and alterations.

4. Personalized Medicine:

Genomics: Genomic information can be utilized to stratify persistent populaces based on their hereditary profiles, permitting for the advancement of personalized treatment plans.

Proteomics: Proteomic data can complement genomic information in fitting treatment approaches, as protein expression levels and adjustments may shift among people.

5. Understanding Disease Mechanisms:

Genomics: Genomic considers give experiences into the hereditary premise of maladies, making a difference analysts get it the atomic instruments fundamental different conditions.

Proteomics: Proteomic examinations contribute to a more comprehensive understanding of malady components by uncovering the energetic changes in protein expression, post-translational alterations, and protein-protein intuitive.

6. Toxicity Assessment:

Genomics: Genomic data can be utilized to anticipate potential poisonous quality issues by distinguishing qualities related with antagonistic sedate responses.

Proteomics: Proteomic profiling makes a difference evaluate the effect of drugs on protein expression and adjustments, contributing to the recognizable proof of potential poisonous impacts.

7. Drug Resistance Studies:

Genomics: Genomic considers are vital for understanding the hereditary premise of sedate resistance and distinguishing transformations which will bestow resistance to certain medications.

Proteomics: Proteomic examinations can uncover changes in protein expression and alterations related with medicate resistance, giving experiences into elective treatment procedures.

APPLICATION OF GENOMICS

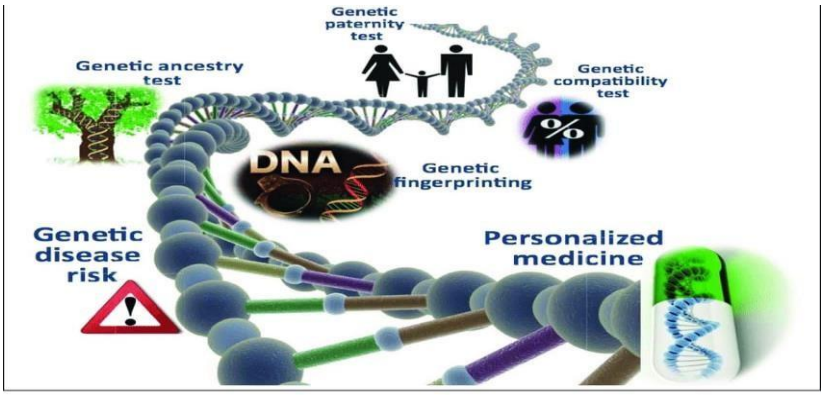


Figure No. 07: Applications of Genomics

Human Health and Medicine:

In arrange to create customized treatment procedures and comprehend the hereditary underpinnings of human clutters, genomics is basic to human wellbeing and pharmaceutical. It makes it conceivable to discover hereditary varieties that cause illnesses, discover unused restorative targets, and make symptomatic tests. Pharmacogenomics, which tries to customize pharmacological treatments based on a person's hereditary composition, benefits from genomics as well. [17]

Agriculture and crop improvement:

The consider of plant and creature genomes made conceivable by genomics has changed agrarian strategies. It helps in finding the qualities in charge of alluring characteristics counting abdicate, malady resistance, and supplement substance. Through marker-assisted breeding, which includes choosing prevalent plant assortments and raising agrarian efficiency, genomic methods back edit change.[17]

Forensic Science:

Genomic innovation has changed scientific examinations by making it conceivable to distinguish and profile individuals based on their DNA. Genomic examination is utilized to progress the exactness and constancy of legal science methods such as DNA fingerprinting, connection testing, and criminal examinations.[17]

Identification and diagnosis of genetic Disease:

Genomic advances are progressively being utilized to get it the commitment of both uncommon and common hereditary components to the improvement of common maladies, such as tall blood weight, diabetes and cancer.

Infectious diseases:

Sequencing the genomes of microorganisms which cause human disease can recognize the precise life form causing indications, offer assistance to follow the cause of irresistible flare- ups, and grant data as to which anti-microbials are most likely to be successful in treatment. [17]

Prenatal diagnosis and testing:

Hereditary illnesses are regularly destroying and may cause critical inability and indeed passing in childhood. Pre-birth conclusion of hereditary maladies permits guardians to create choices approximately whether to proceed with the pregnancy or to permit early conclusion and conceivable treatment in utero or at birth. While past approaches to pre-birth conclusion may put the pregnancy at hazard, unused strategies utilizing genomic innovation can see straightforwardly at the DNA of the hatchling from a maternal blood test, without expanding the risk of premature delivery – this can be known as non-invasive prenatal testing. The utilize of NGS and cluster innovation in pre-birth tests is additionally on the increment to move forward symptomatic yields in a pregnancy.

APPLICATION OF PROTEOMICS

Personalized medicine:

Fitting malady treatment to each persistent based on their hereditary and epigenetic cosmetics, so as to move forward adequacy and diminish unfavorable impacts. Whereas genomics and transcriptomics have been the most center of such thinks about to date, proteomics information will likely include a encourage measurement for patient-specific administration.[17]

Drug discovery and development:

Distinguishing potential medicate target, analyzing sedate capacity of chosen protein targets, and creating drugs pointed at candidate helpful protein target. (eg Hepatocellular carcinoma)[17]

Agriculture:

Investigation of plant pathogen interaction, crop engineering for increased resilience to .eg flooding and other environmental stresses.

Food Science:

It improves the nutritional value of food, food safety allergen detection and quality control.

CONCLUSION

In this review, new drug development and clinical trial designs using genomic and proteomic information are discussed. New gene targets for therapeutic intervention only provide a starting point in the long and difficult process of drug discovery. However, genomics will have an important impact in the later stages of drug development, especially in providing an understanding of the molecular nature of diseases and of the responses, both desirable and adverse to drugs. The genomics revolution has impacted very positively upon these issues and now has a powerful new partner in proteomics. The two most important needs for this type of technology are to find more effective biomarkers for disease detection and discover proteins to which therapeutic drugs can be targeted.

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