Lecture 15. The development of new drugs by using the omics technologies.

Learning outcomes:
Explain the each step of the drug development by using different "omics" technologies, give the specific examples.

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of **drug discovery**. The entire process – from **concept** through **preclinical testing** in the laboratory to **clinical trial development**, including Phase I–III trials – to approved vaccine or drug typically takes more than a decade.
In the fields of medicine, biotechnology and pharmacology, **drug discovery** is the process by which **new candidate medications are discovered**.
In drug development, **preclinical development**, also named **preclinical studies** and **nonclinical studies**, is a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data are collected, typically in **laboratory animals**.
The main goals of preclinical studies are to determine a starting, safe dose for first-in-human study and assess potential toxicity of the product, which typically include new medical devices, prescription drugs, and diagnostics.
On average, only one in every 5,000 compounds that enters drug discovery to the stage of preclinical development becomes an approved drug.
Each class of product may undergo different types of preclinical research. For instance, drugs may undergo **pharmacodynamics** (what the drug does to the body) **(PD)**, **pharmacokinetics** (what the body does to the drug) **(PK)**, **ADME**, and toxicology testing. This data allows researchers to allometrically estimate a safe starting dose of the drug for clinical trials in humans. Medical devices that do not have drug attached will not undergo these additional tests and may go directly to **good laboratory practices (GLP)** testing for safety of the device and its components. Some medical devices will also undergo biocompatibility testing which helps to show whether a component of the device or all components are sustainable in a living model. Most preclinical studies must adhere to GLPs in ICH Guidelines to be acceptable for submission to regulatory agencies such as the Food & Drug Administration in the United States.
Typically, both in vitro and in vivo tests will be performed. Studies of drug toxicity include which organs are targeted by that drug, as well as if there are any long-term carcinogenic effects or toxic effects causing illness.
The information collected from these studies is vital so that safe human testing can begin. Typically, in drug development studies animal testing involves two species. The most commonly used models are **murine** and **canine**, although **primate** and **porcine** are also used.
Clinical trials involve three or four steps:
Phase I trials, usually in healthy volunteers, determine safety and dosing.
Phase II trials are used to get an initial reading of efficacy and further explore safety in small numbers of patients having the disease targeted by the NCE.
Phase III trials are large, pivotal trials to determine safety and efficacy in sufficiently large numbers of patients with the targeted disease. If safety and efficacy are adequately proved, clinical testing may stop at this step and the NCE advances to the new drug application (NDA) stage.
Phase IV trials are post-approval trials that are sometimes a condition attached by the FDA, also called post-market surveillance studies.

The questions for self - control:
1. Explain the each step of the drug development
2. How the "omics" technologies are used for the development of new drugs? Give the specific examples.

Recommended readings:

1. Strovel J, Sittampalam S, Coussens NP, Hughes M, Inglese J, Kurtz A, et al. (July 1, 2016). "Early Drug Discovery and Development Guidelines: For Academic Researchers, Collaborators, and Start-up Companies". Assay Guidance Manual. Eli Lilly & Company and the National Center for Advancing Translational Sciences. PMID 22553881.
2. Taylor D (2015). "The Pharmaceutical Industry and the Future of Drug Development". Issues in Environmental Science and Technology. Royal Society of Chemistry: 1–33. doi:10.1039/9781782622345-00001. ISBN 978-1-78262-189-8.
3. "The Drug Development Process". U.S. Food and Drug Administration (FDA). 4 January 2018. Retrieved 21 March 2020.
4. Emanuel EJ. "The Solution to Drug Prices". New York Times.
5. Ciociola AA, Cohen LB, Kulkarni P (May 2014). "How drugs are developed and approved by the FDA: current process and future directions". The American Journal of Gastroenterology. 109 (5): 620–3. doi:10.1038/ajg.2013.407. PMID 24796999. S2CID 205100166.