Bioinformatics and the Pharmaceutical industry

Introduction:

Bioinformatics is a scientific sub-field that involves using computer technology to collect, store, analyze and spread biological data and information, such as DNA and amino acid sequences or annotations about those sequences. Scientists and clinicians use databases that organize and index such biological information to increase our understanding of health and disease and, in certain cases, as part of medical care.

Bioinformatics and drug discovery:

Drug discovery is the step-by-step process by which new candidate drugs are discovered. Traditionally, pharmaceutical companies follow well-established pharmacology and chemistry-based drug discovery approaches and face various difficulties in finding new drugs (Iskar et al. 2012). In the highly competitive pharmaceutical industry, the first company to patent a new chemical entity (NCE i.e., new drug candidate) for a specific treatment takes all the spoils, leaving other competitors to mostly wait for patent expirations (Iskar et al. 2012). Nowadays, therefore, pharmaceutical companies invest heavily

in all those approaches that show potential to accelerate any phase of the drug development process (Whittaker 2003).

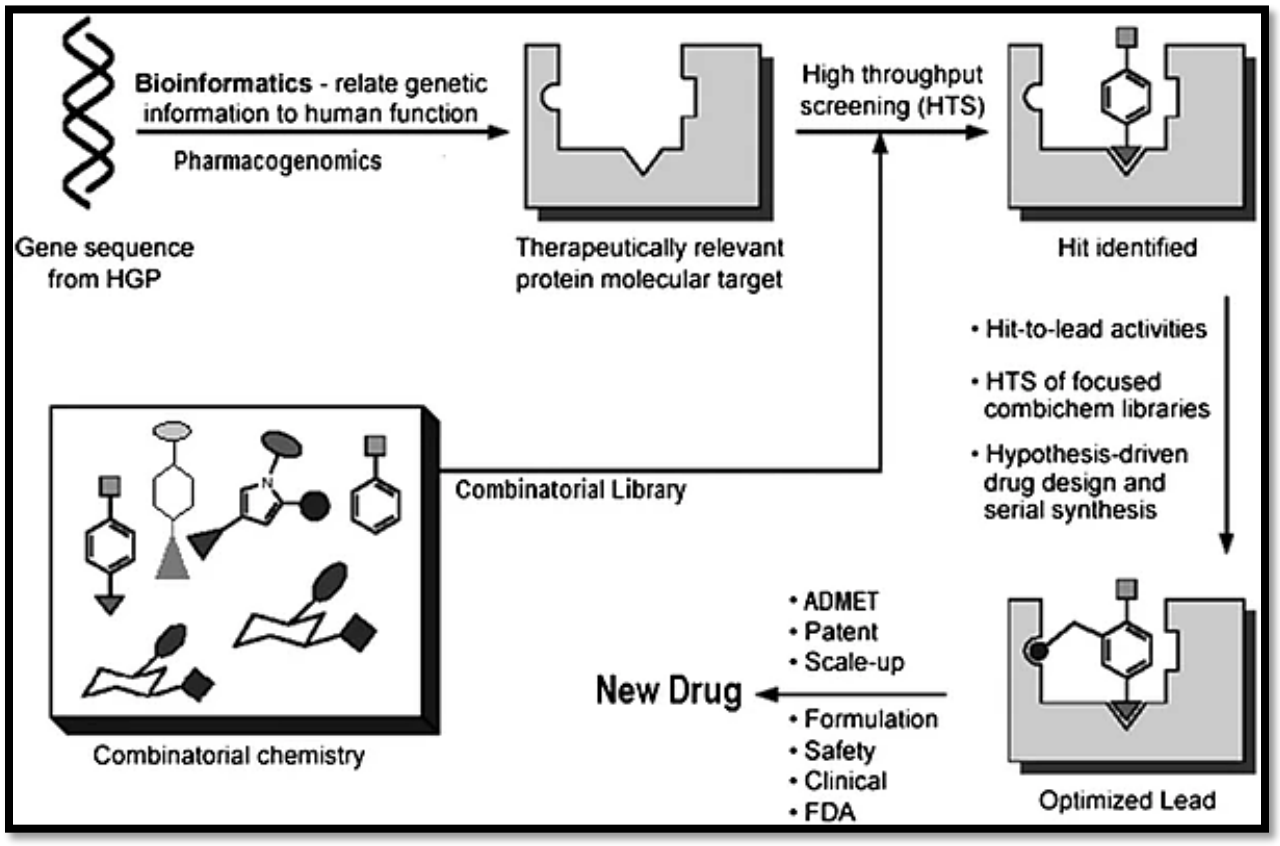
Drug target identification:

One of the major thrusts of current bioinformatics approaches is the prediction and identification of biologically active candidates (Whittaker 2003), and mining and storage of related information. Drugs are usually only developed when the drug target for drug discovery is increasing exponentially. Mining and warehousing of the human genome sequence using bioinformatics has helped to define and classify the nucleotide compositions of those genes, which are responsible for the coding of target proteins, in addition to identifying new targets that offer more potential for new drugs (Chen and Chen 2008; Katara et al. 2011).

Drug target validation:

Bioinformatics also provide strategies and algorithm to predict new drug targets and to store and manage available drug target information. After the discovery of "potential" drug targets, there is an interest (Yamanishi et al. 2010). The establishment of such a key association provides justification for the drug development process. This process, known as target validation, is an area where bioinformatics is playing a significant role. Drug target validation helps to moderate the potential for failure

in the clinical testing and approval phases (Ratti and Trist 2001; Gilbert et al. 2003; Whittaker 2003).



Clinical stage:

The clinical stage in drug development is when researchers administer the drug to human volunteers in clinical trials. There are 3 phases of clinical trials, and each has a different aim.

Phase 1 trials is to assess what dose of the drug the human body can tolerate and may assess an element of drug effectiveness.

Phase 2 trails test the drug in the relevant patient population (exceptions are oncology drugs and orphan disease therapeutics). Often there are 2 parts to this trial: Phase 2a and

Phase 2b. In these cases, Phase 2a trials test a smaller number of patients. It is common for multiple Phase 2 trials to run simultaneously, testing various clinical indications, combinations, or formulations of the drug.

Finally, **Phases 3** trials. In these trials, researchers compare the trial drug to current drugs already available to treat the same condition. The trial drug must be better than the current drugs available to pass Phase 3. For example, the new drug must be more effective or have less side effects.

How bioinformatics benefits the pharmaceutical industry at the clinical stage:

Phase 1,2 and 3 all generate data, often in vast amounts. This is where bioinformatics comes in. Bioinformatics analyses can be applied to data from primary outcomes as well as each of the following data which can be generated during clinical trials:

- Genotype Data
- Demographic Data
- Gene expression Data
- Clinical Phenotypes
- Clinical Chemistry
- Immunohistochemistry (IHC)
- Flow Cytometry
- Haematological tests
- Human leukocyte antigen (HLA) typing
- Cytokine profiling
- Pharmacokinetic/ pharmacodynamic measurements

Applying bioinformatics approaches to clinical trial data ensures we reveal all the key insights in the data. In turn, these insights can inform the next steps and ensure maximum returns on investment in pharmaceutical research.

References:

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