

Editorial Note on Drug Cancer

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Sometimes, existing drugs are found to have a beneficial effect against a different cancer type. Finally, new technologies and/or formulation designs can change how drugs reach cancer cells within the body, thus leading to the ability to develop a compound that may not have been possible previously.

Drug developers are creating different types of biologic medicines to treat cancer. One kind of biologic medicine is called biosimilars.

Biosimilars are a variation of drugs already approved by the FDA. They offer a growing number of new treatment options for people. They also often cost less than similar drugs.

The FDA requires a biosimilar drug to be compared with an existing one. The existing drug is called a reference drug. The biosimilar must be highly similar in structure and function and have no large differences compared to the reference drug.

Biosimilars have to meet a strict approval process by the FDA to make sure it is a safe and effective treatment option. Talk with your health care team to find out if biosimilars could be a part of your treatment plan.

Clinical trials are research studies involving volunteers. They are used to find out if a new drug is safe, effective, and better than the standard treatments. Each phase involves a larger number of people than the previous phase. It also provides more detail about the new drug's safety and effectiveness.

Clinical trials may involve hundreds or thousands of people. They usually take years to complete. But sometimes, if a small clinical trial shows very promising results, the process may be sped up.

A drug is ready for the market when it receives FDA approval. This means it can be prescribed by doctors and sold to people. But the FDA may require that the sponsor conduct more clinical trials. These are called phase IV clinical trials.

Phase IV clinical trials look for other possible side effects or confirm the benefits of the treatment. They may study the drug in different doses, new combinations, or in different schedules. They may also study the treatment in new groups of people, such as older adults or children. Or they may assess the drug's long-term effects.

Some drug makers may conduct their own phase IV clinical trials. They may do more research to get FDA approval to use the drug in a new way, such as for another type of cancer.

The FDA also monitors the safety of drugs currently on the market. They do this to make sure that drug makers report any new or serious side effects. The FDA may withdraw a drug from the market if new research shows it is not safe or effective.

This new knowledge will provide new techniques in molecular diagnosis, which will allow us to predict which in situ cancers are destined for malignant behavior, and which can be safely watched without the need for intervention. Individual patient risk for particular cancers will be accurately predictable, so that patients can alter lifestyle habits or begin other prevention strategies. Oncogenes and growth suppressor genes give us new targets to inhibit or replace. Tumor-specific kinases will meet their inhibitors. The oncologist will play a leading role in understanding, applying and interpreting this new information in the clinic—an exciting and challenging future.

Researchers are also now discovering and harnessing more advanced cell-analysis techniques that enable them to assess the biology and function of different immune subtypes. For example, a recent study harnessed the power of mathematical algorithms to produce a fluorescent cell imaging technology that provides a user-friendly way for researchers to visualize molecular pathways within cells when evaluating new drugs.

Such tools are essential for assessing the mechanistic basis behind individual patient outcomes to novel treatments such as immunotherapy, which in turn can help identify immune profiles that predict an individual patient's response – the so-called 'immune set point'.⁴ This knowledge will help drive the development of "better", more effective immunotherapies, expanding their potential for a broader range of patients and tumor types.

Conclusion

With focused efforts worldwide, our understanding of the genotypic and phenotypic biochemical differences between neoplastic and normal cells is increasing. There is therefore much hope that through further research and better understanding, small molecule drugs or biologicals that are "perfectly" selective for a particular cancer can be designed or discovered and utilized to elicit true cures.

Operations of the consolidated Group are now streamlined, and pediatric patients are assured that they will be offered the best possible trial of the Program rather than the trial preferred by a particular Group. Other types of cancer that are rare or that have consistently had suboptimal accrual in trials (e.g., lymphoma) would also likely benefit from such a consolidation.

