Companion Diagnostics and Other Aspects of Personalized Medicine

Description: The focus of this report is the use of personalized medicine for pharmacological/diagnostic combinations; particularly pharmacological therapies and the diagnostic tests, which can provide information on the likelihood of a patient to respond to specific treatments.

Historically, drugs have been developed on a “one-size-fits-all” basis, but due to patients responding differently to the same drug and having potentially life threatening side effects, new therapies have been developed for approaching the treatment of diseases. Such an approach is with personalized medicine.

Personalized medicine is an all-encompassing term for focused treatments in diseases. While in some areas, personalized medicine may focus on an individual's genome in response to therapy, in others it may be broader and focus on tailoring a medical treatment to the characteristics of each patient.

Often in the form of drug/diagnostic combinations, personalized medicine is commonly used in treating breast cancer. Such an example is using estrogen and progesterone receptors, which are biomarkers, in combination with immunochemistry tests to determine an appropriate therapy. Other methods of personalized medicine for breast cancer include testing for HER2/neu overexpression as well as testing for the presence of multiple genes. With drug/diagnostic combinations, physicians can identify patients who are likely to respond to specific treatments.

With personalized medicine becoming a more effective form of treatment, more diagnostic tests are being developed to use in combination with pharmacology. Using this form of treatment, physicians not only target the proper disease with the proper therapy, but patients are also less likely to develop adverse reactions and life threatening side effects.

Main concepts of personalized medicine covered in this report include:

- Various definitions of personalized medicine
- Range of disease applications for personalized medicine
- Use of personalized medicine in research and development
- Technologies used in personalized medicine testing
- Examples of drug/diagnostic combinations currently in use
- Examples of drug/diagnostic combinations in development
- Development of diagnostic and therapeutic products
- Extensive tables which include information on diagnostic companies that market personalized medicine in vitro diagnostic tests and/or services through their own CLIA laboratory
- Survey of 157 participants (including pharmaceutical/biopharmaceutical companies, diagnostic companies, CROs, universities or research institutes, clinical/reference/hospital laboratories, among others) with experience working with personalized medicine
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