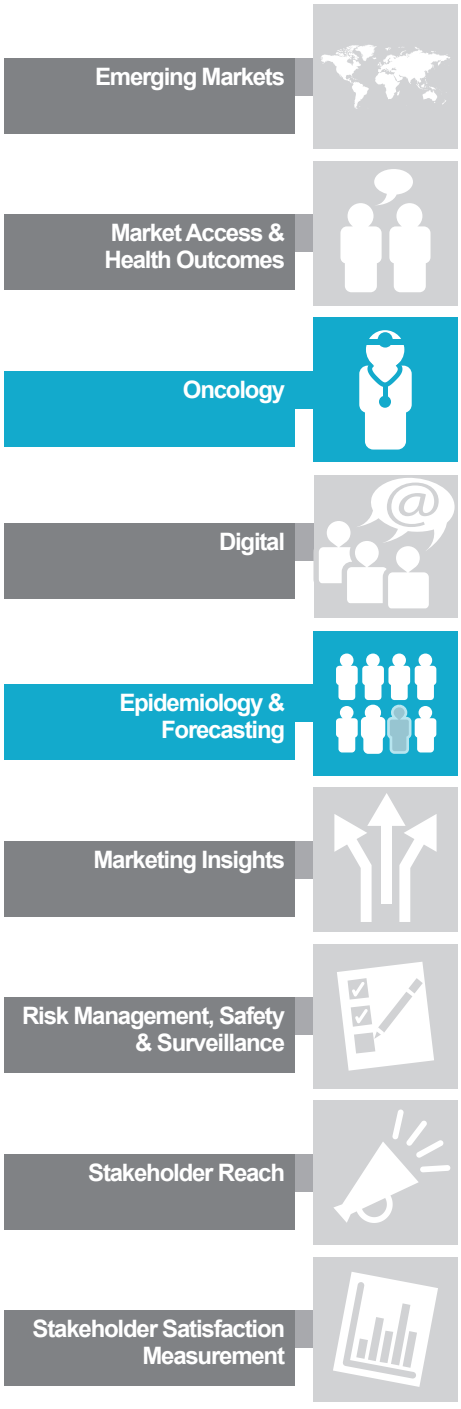
KANTAR HEALTH



Challenges and Caveats in Oncology Forecasting

Biomarkers and targeted therapies add unique challenges and implications to forecasting in the oncology market.

Kantar Health explores forecasting considerations and implications specific to oncology products. We discuss how drug use is different from other therapeutic areas and how to determine the appropriate forecasting approach. We will also explore how biomarkers and targeted therapies impact oncology forecasting. Lastly, we will address how revenue for pharma is impacted by these factors.

These topics will be covered in depth during Kantar Health's 2015 U.S. Dynamic Forecasting in the Oncology Environment Workshops. Forecasting the commercial potential in oncology markets involves some unique challenges. Determining the appropriate patient populations and their number requires reliable data sources. In-depth knowledge of definitions and of treatment paradigms are also important elements. Addressing the cascade of patients through lines of therapies can be complex. New therapies addressing various biomarkers and patient segments may mean that forecasting a single tumor type may lead to creating many different forecasts.

About the Expert

Bob Ramsey
Chief Scientific Officer

Robert Ramsey, Ph.D., is Vice President and Chief Scientific Officer at Kantar Health. Dr. Ramsey's career spans over 30 years in academia, product management, marketing, business development, and strategic planning. Dr. Ramsey has completed numerous projects for major pharmaceutical and biotechnology companies in all therapeutic areas, including cardiovascular, CNS, anti-infective, and oncology. Dr. Ramsey earned a Ph.D. in Biochemistry and an M.B.A. in International Business from Saint Louis University, and he has postdoctoral training in Neuroscience at the University of London, England. In addition, Dr. Ramsey serves on the Institutional Review Boards of Washington University Medical Center and St. Louis University Medical Center.

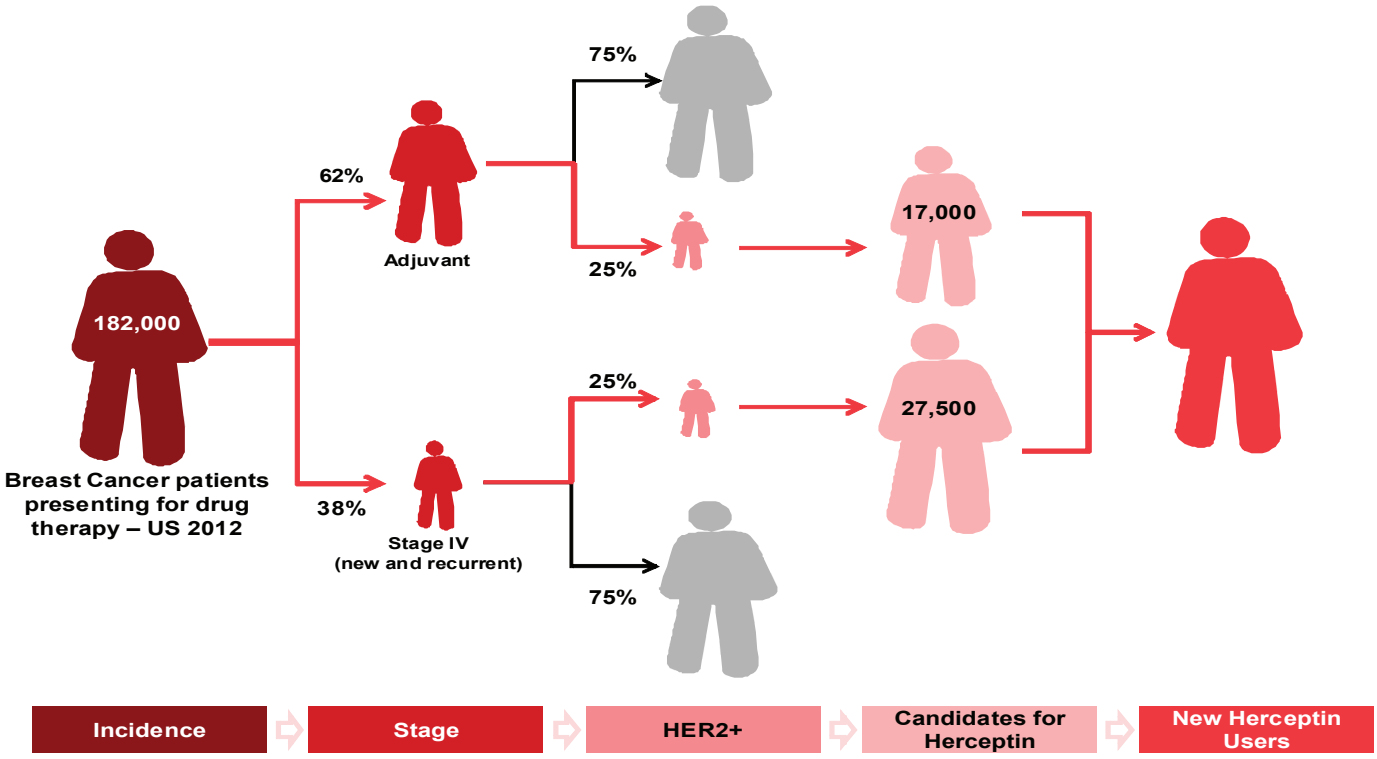
Question 1: How does oncology drug use differ from other therapeutic areas? What factors must be taken into consideration when choosing between different forecasting approaches?

Drug use in oncology varies greatly from most other therapeutic areas and often involves more drug regimens rather than single agents. While drugs for the majority of therapy areas strictly treat the respective diseases and alleviate symptoms, oncology drugs are high in toxicity due to damage to healthy cells while they work to battle existing cancer cells.

Cancer drugs primarily are used for patients with active and late stage disease when other treatments like surgery and radiation will no longer improve outcomes, though cancer drugs can be used in the adjuvant setting after surgery when patients are cancer-free in order to improve the chances of survival. Combination therapies add to the complexity of oncology drug use. In most tumor types, drugs are used in combination and may not be part of a label claim which contributes to off-label drug usage.

Patient-flow and cross-sectional forecasting approaches are utilized depending on the circumstances in which the drug is utilized. The patient-flow approach is frequently used when there is concern about reuse of the same drug in the same patient. Patient-flow models are more complex, with patients being tracked from diagnosis, through the various stages of

Figure 1: Uncover the opportunity for the breast cancer market through patient flow analysis



Source: Kantar Health CancerMPact® Patient Metrics

disease, patterns of recurrence, remission, and survival. A major concern is that, once a patient is treated with a given therapy, they are not eligible to be treated with the same therapy again. In this case, a patient-flow model is suggested, to avoid counting ineligible patients inaccurately.

A patient-flow model is also best for diseases whose progression, survival, and treatment duration is expected to change over time. It is important to take these factors into consideration when deciding on a forecasting approach, and to evaluate if additional insight gleaned from a patient-flow model is worth the additional time, effort and resources, as is often the case with oncology forecasts. A cross-sectional approach may be possible if one is focusing on a single population/indication.

Question 2: What unique forecasting considerations are posed by biomarkers in oncology products?

A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. Currently, biomarkers are measured in one of two ways: on a continuum or yielding a “yes” or “no” response.

Biomarkers are becoming more prevalent in the oncology market, and can have significant impact on drug development and oncology product revenue. Many biomarkers have become part of the standard of care, including therapies for breast cancer, colon cancer, chronic myeloid leukemia (CML), non-small cell lung cancer (NSCLC), melanoma and other tumor types.

Biomarkers add complexity to oncology forecasting since populations must be precisely defined. In turn, assumptions are derived for each defined population, guiding informed decision making to uncover commercially-viable opportunities. It is important to consider that biomarkers may not always correlate in conjunction with the clinical outcome.

Accurate application is also very important. When applied incorrectly, eligible patients who could benefit may be excluded. While many perceive the benefits of biomarkers to outweigh the negatives, they may not be necessary in all cases – many drugs have been developed without the use of companion biomarkers.

Correct inclusion and application of biomarkers yields a commercial advantage.

Question 3: How do targeted therapies affect oncology forecasting?

Treatment methods for oncology vary based on the tumor type. One approach growing in popularity is the use of targeted therapies whether or not there is a corresponding biomarker. Specifically, small molecule tyrosine kinase inhibitors and monoclonal antibodies can be used as single agents or in combination with cytotoxic drugs or other targeted therapies. Although they represent the largest area of commercial growth and number of approvals in the oncology market, there is still an unmet need for targeted therapies in efforts to reduce drug toxicity.

Identifying forecasting assumptions is key in assessing the commercial potential of oncology drugs. While duration of therapy is straightforward and well defined for cytotoxic drugs, for targeted therapies, it is generally determined by progression of a disease as opposed to a set time period or number of treatment cycles. Therapies exceeding one year in duration create added complexity to forecasts as they necessitate monthly patient breakouts in place of the typical yearly forecasts, to accommodate every month past the one-year mark for the duration of the targeted therapy.

Biomarkers and targeted therapies are both largely present in the oncology marketplace, and have the potential to significantly impact pharma revenue.

Question 4: As biomarkers and targeted therapies continue to grow in the oncology market, how is revenue in pharma impacted?

Application of biomarkers has the potential to significantly benefit revenue in pharma, and also presents valid advantages to the development and marketing of oncology products. Biomarkers can be an important factor in the approval of new drugs, enabling access to indications and markets that are otherwise difficult to reach. They can improve outcomes in patient selection.

Early identification of validated biomarkers, prior to Phase III, can reduce development costs and expedite product launch. Using biomarker selection, it is likely for effective drugs in refractory settings to advance to first line in biomarker-defined populations. Biomarkers with good predictive value may facilitate premium pricing and long durations of therapy for respective oncology products, and good biomarker tests generally qualify for reimbursement.

The increasing use of targeted therapies has the potential to reshape the oncology market over the next few years, changing cancer treatment from acute to chronic. In 2013 targeted therapies represented over 70% of the global market for oncology drugs.[1] This increased presence also poses an uncertainty to the forecasted oncology market, precipitated by complications in duration of therapy.

Sources

1. Company and Analyst Reports, Sales estimates

Why Kantar Health?

Kantar Health is a leading global healthcare consulting firm and trusted advisor to many of the world's leading pharmaceutical, biotech and medical device and diagnostic companies. It combines evidence-based research capabilities with deep scientific, therapeutic and clinical knowledge, commercial development know-how, and brand and marketing expertise to help clients evaluate opportunities, launch products and maintain brand and market leadership. Our advisory services span three areas critical to bringing new medicines and pharmaceutical products to market – commercial development, clinical strategies and marketing effectiveness.

For more information, please email us at:

info@kantarhealth.com