Janssen Oncology

Cancer and Cancer Research

What is Cancer?

- Cancer is not a single disease. Rather, it's a broad term for a large group of more than 200 diseases (and many more subtypes) that can affect any part of the body.[1,2]
- Cancer is the uncontrolled growth and spread of abnormal cells.[2]
  - The rapid creation of abnormal cells that invade other parts of the body, called metastasis, is a defining feature across cancers and the major cause of death.[2]

Cancer Statistics at a Glance

Approximately 14.1 million new cancer cases globally in 2012.[3]

- 7.4 million cases in men and 6.7 million in women.[3]
- The number of cancer cases is expected to increase by 70 percent to 24 million by 2035, driven largely by population growth and aging in low- and middle-income countries.[3,4,5]

Cancer is a leading cause of death worldwide,[2] accounting for 8.2 million deaths in 2012.[3]

In 2012, lung cancer was the most common cancer worldwide contributing 13 percent (1.8 million) of the total number of new cancer cases diagnosed.[3]

- The top three cancers in men are lung, prostate and colorectal cancers.
- The top three cancers in women are breast, colorectal and lung cancers.

Hematologic malignancies combined* accounted for 918,000 new cancer cases worldwide in 2012.[3]

Janssen Oncology takes an integrated, comprehensive approach to look at cancers.

In our research, we examine the ways cancer develops – and ways it may be stopped. We seek to understand the body's response to the earliest stages of disease, seeking to uncover ways to exploit natural responses to trigger the body to fight cancer.

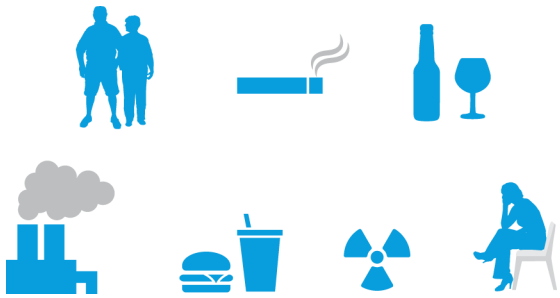
We try to identify the unique signals each cancer delivers, so that we can develop diagnostics that can pinpoint the disease in its earliest stages and monitor progress of patients' treatment more frequently and less invasively than surgical biopsies.

We look for compounds to fight disease, but seek deeper understanding of each compound's role within the treatment paradigm and ways they can be combined or better targeted to the right patient.

Using model-based development strategies, including sophisticated statistical and mathematical analysis of patient response, pharmacokinetics and toxicity, we are able to determine the most effective dose and regimen.

Together, these strategies accelerate drug development, enable efficient clinical trials that gather robust data, and speed the delivery of new therapies to the patients who need them most.

Risk Factors/Potential Causes



Global risk factors include age, tobacco use and exposure, alcohol use, unhealthy diet, air pollution, ionizing radiation and physical inactivity.[2,4]

- Tobacco use is the top global risk factor, causing 22 percent of global cancer deaths.[2]

- Chronic infections from viruses, such as hepatitis B, hepatitis C and types of human papillomavirus, pose cancer risks, especially in some developing countries.[2]

Economic Glance

Estimated total annual global economic cost of cancer ranged from US$1.16-2.5 trillion in 2010.[4]

- Of these, the estimated total cost of treatment – the economic impact associated with premature death and disability or the costs of time by caregivers or transportation to treatment facilities – was US$310 billion.[6]

Research and Progress

Key Moments in the History of Cancer

1200 BCE – Evidence suggests cancer was present in humans with the first human skeleton with metastatic cancer dating back more than 3,000 years ago

1903 – First reported successful use of radiation (brachytherapy) to treat cancer

1937 – U.S. President Franklin D. Roosevelt signed legislation establishing the National Cancer Institute

1949 – First chemotherapy drug, nitrogen mustard — the same compound used to make mustard gas in World War I (mechlorethamine) — approved by the U.S. Food & Drug Administration for cancer treatment

1971 – U.S. President Richard Nixon called for a "war on cancer," signing the National Cancer Act, which strengthened the National Cancer Institute and created the National Cancer Program

1981 – First cancer vaccine, targeting hepatitis B (the primary cause of liver cancer), approved by the U.S. Food & Drug Administration (FDA)

1997 – The FDA approved the first targeted cancer drug

2011 – In the 40 years since the signing of the National Cancer Act, the five-year survival rate for all cancers increased by more than 33 percent, with close to 12 million cancer survivors in America

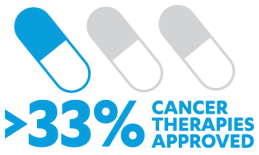
2014 – the first drug in a wave of new immuno-oncology agents approved by the FDA

Making Headway

- **Over time, both science and our understanding of cancer have evolved.**
  - Understanding how the disease evolves, the role of cancer stem cells, the tumor microenvironment, regulation of gene expression, signaling pathways, inflammation, the immune system's ability to identify tumor cells and other related biology enables the development of improved therapies, preventative options, and diagnostics.[4]
- **Advances have changed many cancers from a death sentence to a chronic, survivable disease.[17]**
  - **Survival rates of leukemia have quadrupled since 1960**;[16] survival rates for Hodgkin and Non-Hodgkin Lymphomas have doubled in the same period.[17]

- **Research has also led to increased cures in cancer patients.**
  - Today, **more than 7 out of 10 children are cured of cancer**.[19]
  - Testicular cancer, Hodgkin's lymphoma and many cases of leukemia can all be cured in adults with current treatments. Most skin cancers are cured with surgery, and cancers of the thyroid and larynx (voice box) are cured with radiotherapy. Three quarters (75 percent) of breast cancers found at an early stage are also cured.

- **Deeper understanding of the genetics of different cancers has led to improved diagnostics and targeted therapies for a variety of diseases.[20]**
  - Researchers are applying new understanding about links between chromosomes and disease to create medicines with specific targets.
  - The ability to distinguish between different sub-types of non-small cell lung cancers – squamous, adenocarcinoma and large cell – has paved the way for new, targeted treatments
  - A new generation of immuno-oncology agents has potential against several forms of cancer that resist conventional treatments.[21] In the little time this research has been underway, researchers have made great strides and as this continues, scientists aim to uncover ways to gauge patient response as well as ways to prevent metastasis.[22]
- **The fast pace of innovation, coupled with new technologies to understand genetics and the biology of cancer, has created a period of unprecedented rapid progress in cancer research.**
  - **More than one-third of all cancer therapies approved** for use in the United States have been approved in the last 10 years.[23]



  - New immuno-oncology treatments have the potential to revolutionize cancer care.[24]
  - Targeted therapies will continue to take the place of chemotherapeutic agents, transforming patterns of care and improving outcomes for patients.[25]

In 2012, the FDA created the "Breakthrough Therapy Designation" to expedite the review of drugs for serious conditions, where there is preliminary clinical evidence that the drug may provide improvement over existing therapies.[26] This and other novel regulatory pathways are creating an environment where review of breakthrough medicines may soon match the rapid pace of drug development.[27]

Yet, in spite of treatment advances, unmet needs remain.[3,28,29] This has caused a shift in cancer research from treatment to disease interception – using data gleaned from the human genome and biomarkers to predict likely disease and stop it before it even begins.

**Includes non-Hodgkin lymphoma, Hodgkin lymphoma, leukemia, multiple myeloma*
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