An Interview with
Dr. Clifford A. Hudis
CEO of ASCO and the Conquer Cancer Foundation

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Clifford A. Hudis, MD, FASCO, *is the Chief Executive Officer of the American Society of Clinical Oncology (ASCO). Previously he served for nearly two decades as the Chief of the Breast Medicine Service and Attending Physician at Memorial Sloan Kettering Cancer Center (MSKCC) in New York City where he was also a Professor of Medicine at the Weill Medical College of Cornell University. He was Co-chair of the Breast Committee of the Alliance for Clinical Trials in Oncology (formerly Cancer and Leukemia Group), Chair of the Scientific Advisory Committee of the Breast Cancer Research Foundation, a former Associate Editor of the Journal of Clinical Oncology, and the President of ASCO during its 50th anniversary year, 2013-2014.*

For almost 30 years he worked to develop more effective treatment and prevention for breast cancer. His early work focused on translating the kinetic predictions of the Norton-Simon model into more effective dose-dense adjuvant chemotherapy programs. For the past decade he has studied the interplay of inflammation, obesity, and cancer, and his group described low-grade, chronic white adipose inflammation in most overweight and obese women. Similar observations have been made in other malignancies and risk groups and these insights have been used to inform intervention studies and public policy initiatives at an international level.

This interview was conducted by Sonja V. Sorensen, MPH, Senior Director and Senior Research Scientist, Modeling and Simulation, Evidera.

Founded in 1964, ASCO is the world's leading professional organization for physicians and oncology professionals caring for people with cancer.

Its mission is conquering cancer through research, education, and promotion of the highest quality patient care.

ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds groundbreaking research and programs that make a tangible difference in the lives of people with cancer.

Before becoming CEO of ASCO, you spent 18 years at Memorial Sloan Kettering Cancer Center as Chief of the Breast Medicine Service and served on their faculty for 10 years prior to that. During your time there, how did real-world evidence and big data change your practice, and what did you learn about real-world data that has helped you in working with ASCO?

As a clinical investigator I had the opportunity to participate in a variety of research projects, including some that anticipated the modern era of "big data" such as the worldwide overviews of adjuvant therapy organized at Oxford University and the real-world data collection efforts by the National Comprehensive Cancer Network (NCCN). In different ways, these projects provided me with an early opportunity to see the promise and possibility of big data. The Oxford Overview[1], for example, allowed us to see the numerically modest but clinically important and life-saving potential of widely available post-operative systemic therapies for breast cancer. Recognizing and confirming these small effects in large populations allowed collaborators around the world to establish life-saving standards of care globally.

You were a member of ASCO's Board of Directors when it developed a vision for Cancer Care in 2030. As the new CEO, what do you hope to bring to ASCO to further this vision for evolving oncology through big data, cancer panomics, and value-based decision-making?

It is becoming clearer with every passing week that we have to begin to leverage the investment and day-to-day effort we put into assembling electronic health records to accelerate insights and the development of new knowledge. As we do this, it will be key to enable empathic caregivers to continue to exercise informed judgment for each individual patient. This is the promise of CancerLinQ[2], ASCO's dynamic learning health system connecting members' electronic health records – it will add layers and depths of insight where we lacked informative data in the past.

What other stakeholders in the industry are important to advancing the ASCO mission, and how are you looking to engage them?

Every stakeholder has a role in this effort and we want to enable more people to make faster progress controlling and curing cancer. It is that simple. Of course, this effort is ongoing, but with CancerLinQ we see that it may be possible to accelerate everyone's work by providing access to more and better data than has been available in the past. The progress we envision requires patients, healthcare providers, payers, the pharmaceutical industry, biotechnology, informaticists, and essentially everyone who contributes to care and progress in any form or fashion. Our engagement will have to be tailored and flexible to allow each to identify where they can contribute the most and provide the greatest support. Within CancerLinQ, this means we are developing opportunities for data sharing, collaboration, governance, and guidance from all quarters.

The Cancer Moonshot being led by the Vice President of the United States, Joe Biden, seems to align with many of the goals of ASCO and its members, such as improving access to treatments, early detection, and prevention. Do you see a way to contribute to this effort to achieve some of these overlapping goals?

Absolutely! Every part of currently available care can be improved by measuring and providing feedback to clinicians on what they do now. Indeed, one of the key benefits that CancerLinQ can provide is to enable our communities of caregivers around the world to deliver the optimal evidence-based care that we already know to be effective. Then we can build on that as we make technical advances in the years ahead. While we provide CancerLinQ to assist clinicians in providing today's state-of-the-art care, we are simultaneously collaborating on pilot research projects to develop even better care tomorrow.

ASCO clearly signals big data as a driver of change that will have an impact on cancer treatment in the coming decades. How do you see real-world data impacting cancer research, and do you think it will have an impact on clinical treatment beyond advancing research?

One of the most immediate benefits of the real-world data collected by CancerLinQ is the opportunity to see if treatments work as well in "real" patients outside of

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the carefully assembled cohorts enrolled in prospective clinical trials. These trials are critical to testing and developing treatments but they don't tell us everything there is to know. For example, how does a drug, given at a particular dose and schedule in otherwise healthy 40-year-olds, really perform when administered to patients in their 70s with several common comorbidities like diabetes or hypertension? How does that data allow us to refine treatment recommendations and identify new unmet needs? At the same time it is obvious that we can't study every treatment in every conceivable subgroup and population. So, how will we go from knowing little to knowing something more, and more importantly, useful? Real-world data offers that possibility. Looked at it from another perspective, the lack of prospective controlled trials does not stop us from collecting and using data across many areas of activities outside of medicine. With the right controls and cautions it should prove to be useful in cancer care as well.

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What are you hearing from ASCO members regarding their data needs?

The needs for data are as broad as our membership and its activities. Everything from scientific analytics to benchmarking to practice management to knowledge assessments and clinical decision support. Essentially, we are looking for tools within cancer care that match those we have grown used to seeing elsewhere in our day-to-day digital lives!

What do you think are the biggest short-term obstacles for greater use of real-world data? Do you foresee any problems with greater reliance on real-world data?

The challenges are substantial and should not be minimized. Our data is only as good as it is accurate. We need to re-imagine how we support recording of data at the source by caregivers so that their workflows are improved and easier instead of interrupted and illogical. We need to make it easy to record data in an interoperable way and to reward everyone in this system for the substantial work this represents. We will also always have to maintain a healthy skepticism with regard to cause and effect as opposed to associations in the results we see from real-world data.

How can ASCO and other organizations help to promote the collection and use of data from a variety of sources, and what are your aspirations for CancerLinQ?

Here again, there is tremendous opportunity but also significant work ahead. We need to think carefully about the kind of data we need, how it is recorded and structured, who puts the data there, and how we can remove the obstacles to its use.

My aspiration is that our CancerLinQ team assembles and builds a resource that becomes a central "must-have" tool facilitating markedly more efficient and effective care while enabling faster development of ever improving treatment options.

The clinical trial landscape is changing, with earlier phase trials going to the FDA and so-called "basket trials" focusing on biomarkers rather than target organs, so what should life science companies consider when gathering evidence?

We treat cancer to achieve cures where possible and longer and better lives when a cure is not possible. This is easy to say but perhaps harder to measure than many people realize. As we divide what used to be common cancers into subtypes defined by molecular tests and treat them with more and more narrowly targeted drugs, we will need to think carefully about which surrogate endpoints are most reproducible and comparable across trials. We will have to develop tools that allow us to make indirect comparisons across studies. We will need to share toxicity and adverse event data in more efficient ways. All of this can be supported by improved interoperability of electronic records and greater data sharing.

ASCO also envisions that the value delivered by treatments, rather than their efficacy, will become the driver for oncology practices. How can life science companies support this goal?

Value and quality of care are completely intertwined. High quality care will generally be valuable and low quality care, while expensive, will not be valuable. It is critical not to lose sight of the ultimate goal: the cure and control of cancer. As we reach for that, we will have to

invest. We will have more and less expensive treatment options, and together with our patients, we will have to make decisions among many options. Value is certainly one criteria to consider in all of this but we should never lose sight of its tight link to overall quality.

How does the ASCO Value Framework[3] affect practicing clinicians as they balance cost and value considerations along with traditional safety and effectiveness considerations?

ASCO's Value Framework is a tool to enable more informed decision making at all levels of drug development and clinical care. It is meant to facilitate and inform discussions that occur and touch on challenging domains such as personal autonomy, the role of third party payers, hope for extraordinary benefit, and personal financial responsibility, among many others. It is a new and evolving tool meant to help all of society begin to grapple with a difficult and emotional issue.

Where do you see the role of patient-reported outcomes (PROs) in decision making regarding cancer treatments?

Across all of care, the patient's experience is central to determining the optimal treatment option. This is not only true when palliating a patient with an advanced and incurable disease but also when delivering curative therapy. To get this right we need much better data than has been available in the past. PROs offer the possibility of far more granular determinations of the day-to-day benefits and subjective and objective toxicities of treatment. We see the integration of PROs as critical to CancerLinQ and the drug approval and monitoring process in the years ahead.

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ASCO's vision statement predicts big changes in oncology treatment over the next 15 years. What can we expect in the next five years?

Recently, I was reminded of a description of technology change attributed to a founding father of the modern information era which said something like "technology changes less in one or two years than you expect, but much more than you expect in five or ten." I am sure I have failed to capture the phrase accurately but the concept resonates. Day by day, we see a new drug, a new biological understanding, a new technology, and we think we are seeing the small incremental steps we expect. But when we look back at five years or ten, we suddenly realize how far we have come. We saw this happen with childhood leukemia, with breast cancer and other diseases with widely available conventional treatments. More recently we have seen it happening at an accelerating pace in chronic myelogenous leukemia, multiple myeloma, melanoma, non-small cell lung cancer, and many other diseases. Each advance, in its own right, may seem to be modest or routine. But a revolution in cancer care is already underway and we will see more and more of the changes predicted for 15 years as time goes by.

REFERENCES

[1] Ingle JN. Oxford Overview. *Breast Cancer Research* 2007; 9(Suppl 2):S24. doi: 10.1186/bcr1822.

[2] http://cancerlinq.org/

[3] http://www.asco.org/practice-guidelines/cancer-care-initiatives/value-cancer-care