An Innovative Approach to Breast Cancer Research
How Susan G. Komen Tissue Bank and BioStorage Technologies are partnering to uncover causes and prevention of the disease

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Reid Graves from Pfizer discusses an innovative approach to breast cancer research with representatives from BioStorage Technologies and the Indiana University School of Medicine. The Susan G. Komen Tissue Bank, an integrated entity of the I.U. Simon Cancer Center, was created to store normal breast tissue.

Samples from the Komen Tissue Bank will help researchers understand the differences between cancerous tissue and normal tissue which could help understand the cause and prevention to the disease over time. In partnership with BioStorage, these two discuss their great synergy.

Reid speaks to Anna Maria Storniolo, the Executive Director of the Susan G. Komen Tissue Bank, and Lori Ball, Chief Operating Officer of BioStorage Technologies.
Reid: Management of research samples is vitally important to support the search for a cure to breast cancer. The Susan G. Komen Tissue Bank at the I.U. Simon Cancer Center is the only biorepository initiative worldwide that is prospectively banking healthy breast tissue from women who are not known to have breast cancer. Can you tell us a little bit about the research you are conducting and the samples you are storing?

Anna Maria: The Komen Tissue Bank was started in fact in response to a researcher’s need for normal tissue as a control in her research. We provide a variety of types of samples collected from women not known to have breast cancer. These include plasma and serum as well as DNA, and we also collect snap frozen tissue and slides from paraffin-embedded tissue. We’ve been collecting tissue on a regular basis since 2007, and we now have tissue samples from approximately 3,150 women and blood samples from over 9,000 women. These samples are available to researchers all over the world to be used in breast cancer research.

We’re structured as a clinical trial so that we’re under the regulatory purview of the Indiana University (I.U.) Institutional Review Board. This structure protects our donors as participants in human subject research. The Komen Tissue Bank stores samples in more than one location in order to protect them against unexpected disasters and to ensure the availability of the samples for future research. BioStorage Technologies is our global partner, offering us best in class sample management processes and business continuity services to support our breast cancer research initiatives.

Reid: Sample management is an area of expertise of BioStorage Technologies and, as you know, cancer is a growing area of research within the industry. So how does your company lead the industry to support the protection and storage of samples to support cancer research?

Lori: There’s twice the volume of pre-clinical and clinical products in development within oncology than any other therapeutic disease in the area in the industry. Cancer is a disease that impacts many different areas of the body, has many forms and is the largest growing area of targeted therapy development and re-generative stem-cell research. In addition, more biomarker discovery research is being conducted in oncology than any other therapeutic area. BioStorage Technologies is a provider of comprehensive sample management solutions. We have the people, process and technology expertise and capabilities to manage a broad array of sample types at a full spectrum of temperatures, from room temperature to liquid nitrogen. We manage the lifecycle of millions of samples for our clients, from collection kits for clinical trials, to sample cold-chain transport.

Our global biorepository facilities are located in North America, Europe, and Asia Pacific. Regardless of which biorepository location BioStorage Technologies stores client samples, we utilise the same processes and technology to ensure consistent integrity and optimization of the research sample assets. Many of our samples are derived from oncology studies due to the magnitude of clinical studies being conducted in this area and we are pleased to be able to support the Susan G. Komen Tissue Bank in their search for a cure to breast cancer.

Reid: How is healthy breast cancer tissue being used to support innovative research in the search for a cure for breast cancer today? What kind of research projects are being done with the samples at the Komen Tissue Bank?

Anna Maria: There are a variety of amazing research projects being conducted currently by investigators using samples from the Komen Tissue Bank. We have sent research samples to researchers all over the world, and also distributed samples to very well-respected scientists here in the US including the top tier research institutions in the country. We’ve approved 50 projects since 2009, some of the research topics which include:

- How does the normal breast change in response to normal hormonal fluctuations?
- How does the ageing process change the breast?
- How do breast cancer risk factors affect the breast on a molecular level?
- What is the difference between the same woman’s normal breast and her cancerous breast?

Ultimately, the goal here is to find the early signs of malignant transformation. Interested investigators can learn more about how to obtain samples from the Komen Tissue Bank website. The researcher’s section of the website contains a lot of important information including how to request samples, which samples are available as well as our cost recovery schedule. There is also a new tool called the ‘Virtual Tissue Bank’ which researchers can use. It is an application that allows researchers online to view data that has been generated from samples in the Komen Tissue Bank by others who have already completed their research. The raw data from these already completed experiments is uploaded to the Virtual Tissue Bank and then can be used by other investigators so that they can look at what’s been done and build upon that. Our goal is to speed up the path to a cure. The Virtual Tissue Bank’s website also provides stained images of the breast tissue as well as digital mammograms from those women who have provided them to us.

Reid: Lori, can you share with us more about how BioStorage Technologies consults with and supports research organizations in protecting their research samples? What advice would you recommend to other research organizations?

Lori: We offer teams of comprehensive solutions consultants with decades of experience working with biopharmaceutical and CRO (contract research organizations) service providers, as well as non-profit research organizations. Our experts work with our clients to provide customized sample management solutions which include off-site storage, on-site storage and a hybrid approach to storage solutions. We counsel with our clients to examine how and where they store their research samples to ensure long-term viability of their research assets. And we recommend that our clients maintain redundant storage of aliquots in different locations than the parent sample to ensure back-up protection of sample assets. It is important for research organizations to establish documented and consistent SOPs (standard operating procedures), and to ensure their processes support quick laboratory analysis of samples for fast treatment decisions while also achieving secure consolidation of parent sample inventories and resulting data for future use.

We recommend a single global database for consent in storing sample inventory and bioprocessing data. This will support research organizations in achieving optimization of research samples and faster access to best samples for specific studies. Bioprocessing of samples before they are placed in storage is also recommended which provides an understanding of the quality of the samples being stored. With the continued expansion of biomarker testing in the area of oncology, research organizations often prefer to have the sample processing and functional quality control analysis conducted on samples prior to placing them in storage.

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To support sample processing and bioinformatics for translational research, BioStorage Technologies has established a bioprocessing solutions alliance with RUCDR (Rutgers University Cell and DNA Repository) Infinite Biologics on the campus of Rutgers University to provide the most innovative and state of the art bioprocessing methods, technologies, bioinformatics and biobanking solutions to our clients.

Reid: Why did you decide to store some samples at your location and yet others at BioStorage Technologies?

Anna Maria: As we were establishing the Komen Tissue Bank, and developing our own standard operating procedures, I and the other leadership within the Komen Tissue Bank consulted with a variety of subject matter experts regarding the set-up and maintenance of a biorepository. In that process, we spoke to a member of our own external scientific advisory committee who was in fact the Head of a biorepository that had been lost to flooding during a hurricane in Houston, Texas several years ago.

This has left a lasting impression on him as hundreds of thousands of specimens were lost. He has stressed to us the importance of safeguards in the storage of our samples. It was important to diversify our storage sites so that not all samples would be lost in the event of a natural disaster. We’ve been incredibly impressed with the integrity, the safeguards and the professionalism of everyone at BioStorage Technologies and we feel very strongly that our samples are in the best hands they could be within that facility.

Reid: Lori, how are storing tissue samples unique from storing blood or other types of samples? In other words, what expertise and capabilities should organizations look for in a biorepository partner?

Lori: Well, oncology research involves patients who are very ill and they’re taking multiple medications and undergoing many different types of rapidly evolving treatments. Oncology clinical trials involve the collection of many different types of samples such as blood, tissue or cells, from many local hospitals and clinics so it can be challenging to control the quality of the storage and integrity of the samples that are managed by many different individuals at many different locations.

We recommend and provide study manuals with best-in-class sample collection and storage recommendations for research sites; tissue samples are often collected in paraffin blocks or on glass slides stored at room temperature unlike blood samples that require frozen storage temperatures of -70°C or -80°C, or even liquid nitrogen. Many research organizations store oncology tissue slides or block samples at local hospitals or clinics. Often these facilities are not well organized or experienced in sample management and may not be in the best option for long-term storage of these samples.

BioStorage Technologies offers long-term storage of these samples at our biorepository facilities and within regional storage centers through an established partnership with Iron Mountain, a leading global pathology storage and information management company. This partnership enables us to provide local storage of pathology tissue slides to research organizations who may want to maintain samples close to their research scientists and in a more regulatory compliant and best practice storage facility at a reduced cost.

Reid: What did you learn through this process of collecting and storing these valuable research tissues that could be of value to other companies or organizations researching other types of cancer, Anna Maria?

Anna Maria: We have in fact relied heavily on best practices for biorepositories which have been issued by the National Cancer Institute’s Biorepositories and Biospecimen Research Branch as well as the International Society for Biological and Environmental Repositories. These best practices have been the backbone of our organization and I strongly recommend that anyone establishing a new biorepository look carefully at them and do as much as they can to be compliant with those best practices. We treat our samples as identically as we can and therefore try to minimize the inherent processing bias that is present in any management of biological specimens.

Reid: Lori, high quality sample management and business continuity processes are benefits that BioStorage Technologies offers to its research partners. Can you share examples of the types
of processes you have put in place within your biorepository operation to protect valuable research samples?

Lori: It is essential for companies to ensure that they’re creating business continuity plans for their sample inventories to protect their samples for future research. At BioStorage Technologies, our facilities employ freezer alarming, back-up power, data protection systems, audit trails, tracking documentation, 30-day sample holds prior to disposal, and regulatory compliant sample destruction certificates. We have also established disaster recovery procedures to maintain the safety and integrity of research samples. We recommend to our clients to check the facilities in which they’re storing their samples to ensure they are ready and have documented plans and processes for unforeseen, so we felt very fortunate to be a part of that and to be able to rescue those samples for future research.

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Reid H. Graves currently works at Pfizer as Manager, Global Master Data for the ERP program. Reid had 33 years of service at Merck with a broad range of experiences in manufacturing and packaging operations of solid dosage forms and sterile antibiotics. His experience spanned diverse functional areas including Technical Services, Quality, Supply Chain, Finance, and IT systems development. Most recently, he served as the Senior Business Lead for Supply Chain Master Data at Merck for SAP Material Master (MM) and manufacturing objects to enable an end-to-end structure of products across the global enterprise.

He was the primary architect for several custom-built web-based systems for managing Merck’s global supply chains, worldwide sales, inventory, and product cycle times. He has a Bachelor’s and Master’s degree in Biology from the College of William and Mary in Virginia.

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Dr. Storniolo is a Professor of Clinical Medicine in the Hematology/Oncology Section at the I.U. School of Medicine. Prior to coming to Indiana University in September 2000, she was an Assistant Professor of Medicine at the University of California-San Diego School of Medicine. She also served in various leadership positions at Eli Lilly and Company. And in addition to treating women with all stages of breast cancer, Dr. Storniolo is Director of the Catherine Peachey Breast Cancer Prevention Program.

Her research interests include helping to define the process by which a normal breast cell becomes cancerous. That work has led her and some very dedicated co-workers to found the Susan G. Komen Tissue Bank at the I.U. Simon Cancer Center, a biorepository of biologic specimens primarily from women who do not have breast cancer.

Reid: What has been the greatest value to your business in partnering with BioStorage Technologies?

Anna Maria: It gives me great comfort to be able to tell our donors, who are women without breast cancer coming forward to give up their time in an effort to speed the road to the cure for this horrible disease. Their samples are always processed and stored very carefully on premises at Indiana University, but we’ve gone the extra step and had some of them stored at a world-class facility. Having that available to us is literally priceless. In addition to helping store the samples; however, BioStorage Technologies have also been supportive in other ways including fundraising. They have provided volunteers and have helped raise awareness, so they’ve really become a community partner in this advocate driven project even more than simply being a business partner.

As the Chief Operating Officer, Ball leads the successful development and execution of BioStorage Technologies’ global biorepository operations and logistics expansion strategies, comprehensive sample management solutions, global strategic marketing and business development and the design and delivery of innovative technology solutions.

Ball brings over 25 years of consumer products, CRO and pharmaceutical services industry experience to BioStorage Technologies and she has a strategic role in the overall management and growth of the company. Her leadership has enabled the company to achieve year-over-year double-digit revenue growth and to increase its scale of operations through the expansion of facilities, growth in staffing and development of talent, increasing the company’s footprint into new geographies and integration of new service capabilities.