Cancer is a disease that affects all of us; we all know someone with cancer, or have been diagnosed ourselves. Total cancer deaths worldwide in 2008 were approximately 7.6 million – approximately 13% of all deaths worldwide according to the World Health Organization. Therefore, intuitively, one would think that finding cancer patients to participate in clinical trials would not be an issue. However, that’s not the case.

Given the sheer numbers of those afflicted with cancer, we tend to lose sight of the actual prevalence of the disease at a given time in a community. When spread out over a lifetime, cancer is not as common as we assume. So, when posed with the question of where to find cancer patients for clinical trials, intuitive answers will most likely fail. However, statistics can help shed light on the patient recruitment dilemma.

Consider this example based on the University of Rochester hospital where years ago I was Chief Resident in Anatomic and Clinical Pathology. In a given year, the hospital would house approximately 100,000 patients, of which 25,000 would generate a biopsy or surgical resection of some sort. Out of those 25,000 patients who received a biopsy, approximately 5,000 would result in a malignant diagnosis. So, out of 100,000 patients in a given year, only 5% were diagnosed with a malignancy, or “cancer.” Benign tumors were overwhelmingly more common. This localized example provides a good model for the overall prevalence of cancer at a given time worldwide.
Finding cancer patients becomes even more difficult when you start to break malignancies down into certain “types.” With more than 100 types of cancers, any part of the body can be affected. Also, regulatory bodies are demanding an increase in the number of trials per new drug application (NDA) filed and the number of patients required per trial. This “number of patients required per trial,” referred to as the “n,” or denominator, is the most critical factor for conducting effective studies. Increasing this denominator is the major reason that biopharmaceutical companies are looking to global patient populations.

If a study does not have a large enough population of patients, the clinical trial tends to take longer, and have less statistical power for the study, which can negatively impact the validity of results. In fact, low recruitment is a significant reason clinical trials fail or experience costly delays.

**Digital Pathology: Improving Reproducibility of Results**

A major goal of large global clinical trials is to increase the “n,” or denominator of patients included in the study to ensure scientific reliability. Structuring information in a way that is clear and reproducible is also critical for arriving at the best possible conclusion. This reproducibility of a result is important to the scientific intent of a study and can be achieved through the use of digital pathology. Digital pathology is an image-based information environment enabled by computer technology that allows for the management of information generated from a digital slide. It is enabled in part by virtual microscopy – the conversion of glass slides into interactive digital images that can be viewed, managed, and analyzed.

With these interactive digital images, scientists can not only see the image, but also maneuver around it and increase or decrease magnification. The lens used to take the digital image is like the eye of a fly with multiple facets. The lens captures a granularity of detail that is absolutely necessary to perform anatomic pathology interpretations. Plus, once the digital image is made available, it can be accessed instantly from anywhere around the globe. Digital pathology ensures portability, durability and the ability to share images instantly. While some are apprehensive to make the switch from glass slides, validation of these digital images shows that every useful microscopic detail that appears on the glass slide is reflected with fidelity in the digital image.
Digital pathology helps speed trial enrollment through quicker and more accurate target lesion identification for inclusion/exclusion of study subjects. Turnaround time can be reduced by one or two days, plus risk is reduced from not having to ship fragile glass slides, and costs are reduced because no shipping of samples is required. Overall, global consistency in data is improved due to more uniform global turnaround time from sample collection to tissue processing, as well as enabling a single reviewer, globally, to perform analysis on all slides, without concern about where in the world the slides originated.

The benefit to a clinical trial is magnified in cases where review by multiple specialists is required. Previously, either three separate slides needed to be shipped simultaneously, or a single slide needed to be shipped from one specialist to the next. Each of these approaches suffers from drawbacks in time to result, cost, and risk to the samples. Now, instead of shipping slides to one expert in Frankfurt, to a second expert in New York City, and a third expert in Los Angeles, interactive digital images can be accessed instantly by all slide reviewers. Glass slides with critical, sensitive data are no longer being shipped around the globe and then sitting on someone’s desk waiting for review. Also, storage is now in a digital archive, not in a large file cabinet.

There is no question that innovations in technology have the potential to significantly impact a number of clinical applications. However, it is not until advanced technologies are placed in the skillful hands of an experienced team of experts – in science, in process, in medicine, and logistics – that we will fully realize the value of these advances.

**Covance Opens Anatomic Pathology Lab in Singapore**

In October 2012, Covance brought its Anatomic Pathology services to its Singapore central lab. This included digital pathology services, which will reduce the need to ship samples for the studies Covance conducts for sponsors.

With digital pathology services now available in Singapore, Covance no longer needs to physically ship specimens originating in the Asia-Pacific region to our labs in Geneva or Indianapolis, which reduces turnaround time for enrollment decisions for oncology patients. In addition, by reducing the need to ship samples from Singapore, we further improve value and lower risk.
while improving milestone attainment in global studies. In fact, by processing samples and identifying target lesions in a single location, cycle time can be reduced by as much as two weeks with potential for significant cost reductions.

Digital interactive imaging represents a transformational technology, modernizing clinical trials by reducing costs, speeding enrollment decisions, and ultimately enabling clinical trial sponsors to offer improved therapies to deliver better patient care. By providing digital pathology capabilities in our labs in Indianapolis, Geneva, and Singapore, Covance now extends sponsors’ reach across the globe, providing them with uniform access to patient populations worldwide. The ability to tap a global pool of patients is a key ingredient that allows clinical trials to meet enrollment milestones, even for “hard to recruit” rare forms of cancer.

For further information about Covance’s Anatomic Pathology services, including digital pathology, please visit: http://www.covance.com/products/clinical/central-lab/laboratory-services/anatomic-pathology-histology.php

About Covance
Covance, with headquarters in Princeton, New Jersey, is one of the world’s largest and most comprehensive drug development services companies, with annual revenues greater than $1.9 billion and more than 10,000 employees in over 60 countries. Covance has the people, processes, client service, and global resource capabilities to respond to the toughest drug development challenges.

For more information about Covance, visit us online at www.covance.com.