

Imaging is everything

Comparing imaging vendors and equipment for clinical trials

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The submission of consistent, accurate, and high-quality imaging data is spurring on the use of imaging biomarkers in biopharmaceutical and medical device trials.

Imaging centers have access to a wide array of imaging modalities and technologies for use in clinical trials. A variety of cutting-edge imaging vendors are developing technology, resulting in equipment and features that affect image quality, patient throughput, clinical workflow, and price.

The many options can make it difficult to understand a clinical trial's imaging equipment needs. A good starting point is an evaluation of several major imaging modality vendors and their technologies and products.

Magnetic resonance imaging, known popularly as MRI, and computed tomography, or CT, are the two most commonly used imaging modalities in clinical trials. Another technique, positron emission tomography, or PET, is growing in importance because it can provide researchers with metabolic data about disease status.

Each of the five major imaging industry vendors examined here — Hitachi Medical Systems America, GE Healthcare, Philips Medical Systems, Siemens Medical Solutions, and Toshiba Medical Systems — have a well-developed portfolio of imaging modalities that address a variety of clinical trial needs. All of these vendors have large research and development programs that drive innovative technology enhancements, ensuring that equipment and systems are constantly being upgraded. When evaluating imaging modalities for use in clinical trials, clinical study teams should take into account the differences among each vendor's technologies and products, and evaluate the strengths and weaknesses of their product lines.

MAGNETIC RESONANCE IMAGING

Magnetic resonance imaging uses a combination of low-frequency radio signals and magnetic fields to acquire two- and three-dimensional body images. Perhaps the most important technical aspect of the MRI scanner is the

strength of its magnet, known as field strength and measured in tesla. Magnet strength ranges between 0.2 and 3.0 tesla. Scanners with higher field strength are more expensive and produce scans with better resolution.

Most high-field MRI machines are called short-bore or closed-bore scanners because of the physical design required by the high-strength magnets. This means that the patient must lie down inside a mostly-closed tube known as a bore, a frequent cause of patient apprehension. Scanners with lower field strengths can be designed with open bores, at the expense of certain applications such as spectroscopy, biliary imaging, angiography, and other cardiac studies.

For clinical trials, it's important to look for MRI scanners with field strength high enough to provide the level of imaging detail needed for the particular study. At the same time, this should be balanced by potential problems and delays that may be caused by patient acceptance of the closed scanner.

Each vendor addresses field strength and the open/closed design question differently. For example, Hitachi is well-known for its uniquely-designed open MRI machines. Hitachi's product line is comprised primarily of open-bore scanners that use the highest magnetic field possible in an open design, ranging from 0.3 to 0.7 tesla. However, a recently-introduced open model operates at 1.5 tesla and is positioned to combine high field strength with patient comfort.

GE, Philips, and Siemens address scanner design and field strength by providing a broad range of scanners to meet a wide variety of needs. The 3.0-tesla closed scanner is considered the gold standard for applications where high image resolution is critical. A series of open scanners is available for applications where a lower field strength (0.2 – 0.7 tesla) is sufficient, as well as mid-range scanners with shorter bores.

GE and Philips have product lines that include economical open scanners with low field strength, mobile products, and high-end scanners with field strength between 1.5 tesla and 3.0 tesla. Philips has a unique, limited-availability product for clinical research. Not available commer-

cially, the 7.0-tesla scanner is the only one in the world with its field strength. This scanner is only operational at the Philips Ultra High Field Research center in Cleveland, Ohio, but installations are in process or being planned at other clinical research sites in the United States, the U.K., and Europe.

Siemens' MRI product line follows a similar strategy: economical open-bore scanners with low field strength; several 1.5-tesla models with varying footprints and levels of openness; and a high-end closed-bore model with high field strength. A product distinctive to the Siemens portfolio is a dedicated 3.0-tesla brain scanner that is optimized for high image quality and fast scanning for brain applications such as stroke, epilepsy, tumors, and multiple sclerosis. Another unique Siemens product is a 1.5-tesla hybrid scanner with shorter length and semi-open architecture that allows the patient's head to be outside of the bore, in most cases.

Toshiba developed the industry's first open MRI in 1997. The company's only product entry, an open-bore model with field strength of 1.5 tesla, is designed to strike a balance between performance and patient comfort. The Toshiba scanner is known to have a quieter magnet.

COMPUTED TOMOGRAPHY

Computed tomography uses special X-ray equipment to obtain three-dimensional images of the body. A CT scanner is typically a rotating ring of X-ray detectors that surround the patient, who must lie down in a bore. This technique is considered the gold standard for screening and diagnosis for several anatomical areas, including the lungs, chest, and abdomen.

Newer CT scanners with multiple rings of X-ray detectors are known as multislice scanners. An increase in the number of detectors raises the scanning speed and the number of image "slices" obtained. For routine clinical applications, 8-, 16-, and 32-slice scanners are commonly used; 64-slice scanners are most often used by major facilities for cardiovascular evaluation.

In most CT scanners, the rings of X-ray detectors are programmed to spin around the patient in a helical or spiral orientation as the patient moves through the scanner. These helical or spiral multislice scanners dramatically increase patient throughput, an important factor in clinical trial planning.

Hitachi's product line consists primarily of a 4-slice scanner for routine clinical CT applications and a 16-slice scanner expanded for angiography applications and improved workflow. The company also has a specialty scanner using cone-shaped X-ray beams that use less radiation. Unlike most CT scanners, this product permits the patient to remain in a normal seated position and is targeted at

head and neck applications.

GE's portfolio of CT scanners contains several product lines for different clinical applications and budgets, such as an economical series of single- and dual-slice scanners and a line of compact models. In addition, the company's high-end series of multislice scanners includes a wide-bore design that minimizes patient discomfort and provides highly detailed tumor delineation for oncology applications, and a whole-body system that is maximized for cardiovascular imaging.

Philips and Siemens have similar CT product offerings. With 6-, 10-, 16-, 40- and 64-slice scanners, Philips provides a variety of footprints and price points. Philips carries two specialty scanners: a wide-bore model that excels at oncology applications and enhances patient comfort, and a cardiovascular CT product touted as an accurate and more efficient alternative to invasive cardiovascular procedures.

The multislice product line offered by Siemens features 16-, 40-, 64-slice scanners, as well as an open-bore 40-slice scanner. The company offers application-based software bundles (it calls them "engines") with its CT products.

Available for oncology, neurology, cardiovascular, and acute care clinical applications, the software bundles contain automated reading and evaluation tools that are tailored to meet each area's clinical workflow needs. Siemens has recently introduced a product based on what it calls "dual source scanning," which means that it simultaneously uses two X-ray sources and two detectors. This is a breakthrough for capturing very fast body movements, such as heartbeats, at the lowest radiation dose possible.

Toshiba is well-known for its CT scanners. The company's workhorse product line has 8-, 16-, 32- and 64-slice models. Like most of the other vendors, Toshiba carries a wide-bore model that maximizes patient comfort and can image more anatomy than a traditional CT scanner because this scanner uses cone-shaped beams. This scanner provides detailed tumor delineation ideal in oncology applications.

Toshiba is developing a 256-slice CT scanner that will provide an unprecedented advancement in cardiac imaging.

POSITRON EMISSIONS TOMOGRAPHY

Positron emissions tomography uses a short-lived radioactive tracer (radio-labeled sugar) that attaches to the specific area being examined, producing a three-dimensional image of the body's functional or metabolic processes.

Like CT and MRI, PET requires the patient to lie down inside the scanner. But while CT and MRI scans provide anatomic

information, the PET scan provides researchers with metabolic data about the biochemical processes at a certain site. For this reason, PET is increasingly being used in clinical trials.

PET scans can be very useful alongside more traditional anatomic imaging data. Many vendors have developed integrated PET/CT scanner products for this reason. The two tests can be performed in sequence in a single session, and the patient doesn't have to change positions. In this way, the metabolic and anatomic images can be precisely correlated.

Hitachi's PET product line includes dedicated PET and combination PET/CT scanners. The company's PET-only machine has an upgrade path to PET/CT. Another dedicated PET offering is configured to provide the highest quality imaging for cardiology applications. Hitachi's single hybrid PET/CT device relies on a 4-slice CT scanner, suitable for routine clinical trials.

On the other hand, GE carries only hybrid PET/CT scanners. The company offers three models to fit different user needs: an entry-level model based on one of its most popular CT scanners; a small-footprint version; and a flagship model that has the highest clinical sensitivity and best image resolution.

Philips' product line includes a dedicated PET machine, available in stationary, clinical, and mobile models, and is the industry's only open PET/CT scanner. Philips pairs its dedicated PET scanner with a 16-slice CT scanner to create an open PET/CT that eases patient apprehension.

The high-quality images produced by the hybrid machine make it useful for oncology, neurology, and cardiology applications.

Siemens' PET product line consists of a single combination PET/CT machine that uses a 64-slice CT scanner. With its PET/CT scanner, Siemens offers software bundles (engines) for neurology, cardiology and oncology. Like its CT engines, the PET/CT bundles are customized to the workflow of each specific clinical application.

Toshiba does not have a PET product offering.

On the whole, the vendors and their respective products offer many options for clinical trials. In the ever-growing field of imaging biomarkers, these companies realize the importance of continuing to expand upon these products from the strengths and weaknesses standpoints, to be sure they remain relevant in their field.

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