

IMAGING CORE LAB SERVICES



Accelerating Clinical Trials:
You won't be the only one happy about that.

VirtualScopics. Advancing Medicine through Imaging.

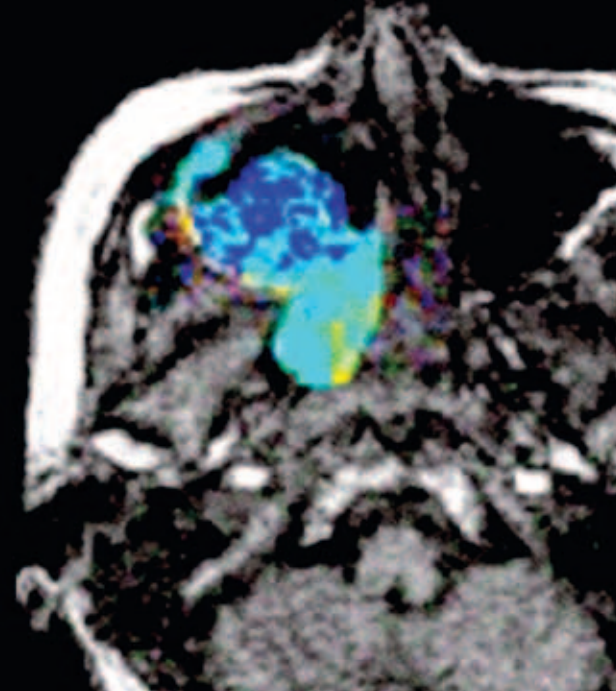
It is said that a picture is worth a thousand words. In drug development a picture could be worth millions of dollars, but more importantly, the hope for a new life.

VirtualScopics differs from other imaging core labs in that we are able to analyze scans from multiple modalities (CT, MRI, PET, X-Ray, DEXA, Ultrasound, etc.) and deliver precise, reliable data that can help you make an earlier determination of a drug's proof of mechanism, safety, and efficacy. Such information can enable you to make a more confident decision as to whether or not your study should proceed; a decision that could potentially save your company millions of dollars.

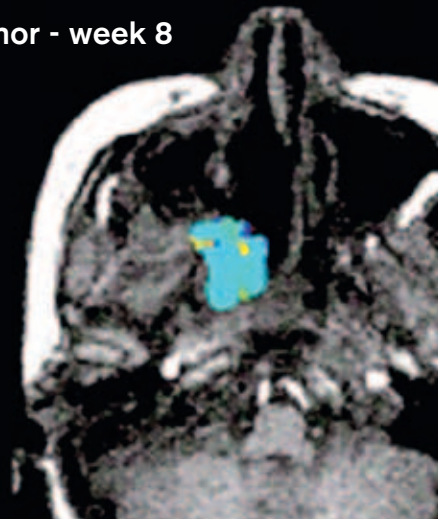
We understand what is at stake during each study – for our customers and, more importantly, those awaiting new drugs.

VirtualScopics manages the entire range of clinical trials imaging services for the majority of the leading global pharmaceutical, biotechnology and medical device companies. Yet, customers view us not as a service contractor, but as a *trusted partner*. We take a collaborative approach toward every study advising sponsors as to optimal imaging protocol design and the most beneficial course of action throughout the trial. *Our success is based upon our customers' success*; therefore, we are dedicated to managing the most effective trial to meet their goals and objectives. The advancement of medicine and its potential impact on lives is what drives the employees at VirtualScopics and our sponsors are rewarded with that personal commitment every day.

Sinus tumor - week 4



Sinus tumor - week 8



Imaging and VirtualScopics A powerful tool; an expert team.

Medical imaging can be a very powerful tool in the development of new drugs and medical devices. Based on the measurement of image-based biomarkers, imaging can provide an early proof of concept, determine safety, and confirm dosing and efficacy information. Such benefits simply cannot be gained through conventional image analysis.

In a typical oncology study employing imaging, the industry standard is to provide 1 and 2 dimensional assessments (RECIST/WHO) which measure tumor diameter. However, VirtualScopics also conducts 3D, or volumetric, measurements of tumors and we provide all assessments for the same price others charge for only 1D and 2D analysis. Depending on the study, these unique 3D measurements may include tumor blood flow, tissue to blood volume, oxygen utilization and glucose metabolism, just to name a few. Recent literature and study findings suggest that tumor volumetric measurements (i.e. 3D assessments) provide a more sensitive and likely more accurate assessment of tumor burden and response to therapy. This enables our sponsors to make faster decisions with greater confidence resulting in more efficient, cost effective, and flexible clinical trials.

VirtualScopics' in-house imaging scientists, radiologists and technologists have the breadth of knowledge to direct our customers as to the best use of imaging and novel biomarkers for their trial. Our Chief Scientific Officer, Ed Ashton Ph.D., Chief Technical Officer, Jon Riek Ph.D., and Vice President of Clinical Affairs, Mark Tengowski DVM, MS, Ph.D., boast nearly 50 years of combined experience in clinical and imaging research. They consult with sponsors at trial inception to help establish an effective and successful imaging protocol for the sponsor's compound. More importantly, they are available for consultation throughout the duration of a sponsor's trial. Customers often cite our consultative approach and the accessibility to our subject matter experts as important reasons for choosing us as their imaging core lab.



Dr. Jonathan Riek, Chief Technical Officer,
VirtualScopics employee since 2001

The promise of reproducibility

Current methodologies for image analysis can be time-consuming, inaccurate and highly variable. Even when the exact same data is being repetitively measured, results can vary from measurement to measurement, technologist to technologist and radiologist to radiologist. Our patented, semi-automated methods minimize much of this variability, providing highly reproducible measurements throughout the trial lifecycle. Published studies have shown that our semi-automated processes consistently yield a lower coefficient of variation than manual techniques.

VirtualScopics' methods provide several significant benefits:

- Higher level of measurement reproducibility that can lead to reduced sample sizes
- Less dependence on a single external expert reader who may have conflicting priorities as it relates to your study, allowing flexibility and reduced costs
- Greater precision leading to more confident decisions
- Higher throughput leading to increased efficiency and lower costs
- Real-time reads

Not Just A Job, It's A Mission

The staff at VirtualScopics sees their work as more of a mission than a job. Many staff members have chosen employment at VirtualScopics based upon personal experiences with cancer and other diseases. In fact, the entire VirtualScopics family was affected by the passing of a longtime colleague in 2009. For these reasons we are committed to the advancement of medicine to better the lives of others.

Our Mission:

To improve the lives of those impacted by disease and disability.



VirtualScopics' people make the difference.

When we surveyed our customers recently they said our technology makes us unique, but it is our people who make us special. Our imaging experts possess a wealth of experience to help design the most effective study, while our project teams display the energy and professional dedication to ensure each study runs according to protocol. Operationally, our teams possess the *creativity, flexibility and expertise to design personalized solutions* to meet our customers' goals and objectives. But what truly sets us apart is the internal motivation of our employees and the pride they take in helping customers affect the lives of those in need.

Our Commitment:

To provide accessible, accurate, and reliable analysis in a way that facilitates and adapts to our clients' needs to progress their clinical trials at the fastest possible pace.



Debra Vent, Business Development Manager,
VirtualScopics employee since 2007

Central Read Efficiencies

VirtualScopics built its strong scientific reputation in early phase studies, but our focus on operational platforms (**all 21 CFR Part 11 Compliant**) has led our customers to increasingly select us as their preferred imaging provider for late phase trials. Our adherence to the methodologies of Lean Six Sigma have allowed us to be more flexible, efficient and readily scalable to manage any size project. We have a proven track record of delivering accurate and on-time deliveries. Our relentless commitment to improvement enables us to tightly manage costs and reduce waste – benefits we pass on to our customers.

We have structured our operations around a rolling read strategy as opposed to the batch read system prevalent in our industry. An imaging provider conducting batch reads will collect data, hold it and then analyze it all at once prior to a milestone delivery date. Conducting rolling reads allows us to analyze images as we receive them giving us tighter quality control while making us more nimble and fluid; we are always prepared to deliver study data whether it is a special needs request, interim database upload or final database lock.

Likewise, conducting rolling reads gives our sponsors greater flexibility during studies. Since we provide bi-weekly data deliveries throughout the life of a study, as opposed to only at milestone dates, sponsors have earlier access to data that may enable them to make critical changes mid-study. Providing sponsors with greater confidence in their active decision making during early phases can be a key to helping reduce late stage attrition.



Therese Crilly, Image Technologist,
VirtualScopics employee since 2002
Larry Molinelli, Image Processing
and Analysis Manager,
VirtualScopics employee since 2001

Worry-Free Clinical Trials

This industry is fraught with high risk and high reward projects. Clinical studies require large investments in both human capital and financial resources by trial sponsors, thereby placing study teams under great stress to run efficient trials. VirtualScopics' attitude is that working with an imaging core lab should reduce your stress, not increase it. For this reason we provide our customers with **worry-free trial management**.

At study inception, a critical sponsor concern is whether their imaging sites will be ready for **First Patient First Visit**. VirtualScopics commits to having sites qualified, trained and ready to accept their first patient. Our site management team coordinates with the study team and, based on their timelines, will prioritize site initiation. We will then provide a site questionnaire, assess pre-qualification and conduct image initiation with the site.

Communication between our teams is the key to avoiding costly delays. Thus, we provide sponsors with real-time site status reports. By utilizing our proprietary software tracking system, SMART (Site Management Automated Reports and Tracking), we identify which sites have completed the qualification process and are ready for first visit, as well as those who have been non-compliant or unresponsive. We provide these weekly reports to keep the study teams informed on the status of site readiness.



Our site management, incoming image processing and project management teams utilize SMART to provide sponsors with **real-time reports** throughout the life of their project and to give them **transparency** into all of our site communications, incoming package receipts, and subject tracking.

SMART Tracking Reports

Package Report: Each package, whether electronic or hard copy, is immediately logged into SMART upon receipt. Incoming Image Processing then conducts a quality inspection of all materials to confirm quality and compare the current image to baseline. If there are any concerns with the image they will immediately contact the site to resolve the issue.

Subject Tracking Report: This report tracks the receipt of timepoints and forecasts the expected dates of future timepoints. We use this report to identify late or missing data so we can proactively initiate site queries to obtain the data.

Communication Log: This log tracks every communication we make with a site from qualification through the maintenance phase of the study. These reports are provided per site/per project.

We work tirelessly on site follow-up because we realize delays are unacceptable. The data we provide is critical to our customers and we appreciate the importance of meeting their timelines, whether it's a monthly data delivery, an interim database upload or final database lock. In fact, only VirtualScopics will guarantee quality, on-time deliveries (see **Our Promise** at www.virtualscopics.com).

We are expertly skilled at working with sites to qualify equipment, accelerate image retrieval to minimize delays, and verify data to minimize acquisition errors. This results in cost efficiencies and expedites timelines for our customers. **Our focus on managing trial details allows sponsors to focus on their expertise – drug and device development.**

A world map with a dark blue background and white outlines of continents. Numerous small orange dots are scattered across the map, representing clinical imaging sites. The dots are most densely clustered in North America and Europe, with smaller clusters in Latin America, India, and the Asia-Pacific region. There are also a few dots in Africa and Australia.

Global Solutions

Increasingly, pharmaceutical, biotechnology and medical device companies are looking to new, emerging markets to conduct studies: Latin America, Eastern Europe, India, and the Asia-Pacific region. VirtualScopics is already there. We have conducted clinical trials worldwide, qualifying, initiating and training nearly **2,000 unique clinical imaging sites** in over **40 countries** across **6 continents**.

Our senior project managers and site management technologists are regularly criss-crossing the globe to attend investigator meetings and conduct on-site assessments and trainings. With staff based in the US and Europe, we are able to effectively manage global studies.



Areas of Expertise:

Musculoskeletal Research

Our proprietary algorithms help isolate selected tissues to precisely quantify erosions, joint space and inflammation. Computer-aided approaches provide precise measurement of cartilage, bone, and other structures.

Medical Device Research

We can assess both the structural and compositional qualities of biologics and devices used in cartilage repair. Additionally, our image analysis provides a non-invasive assessment of compounds, biologics and devices for prostheses, new bone growth and intervertebral disc repair.

Oncology Research

Our semi-automated approach provides highly reproducible measurements of both structural and functional tumor endpoints.

Neurological Research

We provide precise, automated and reproducible quantification of brain volume, parenchymal fraction, white matter lesions and more.

Cardiovascular Research

We provide expertise across multiple imaging modalities, including ultrasound, CT and multiple pulse sequence MRI.

Muscle Wasting

VirtualScopics is helping to analyze muscular changes that occur as a result of cancer or other debilitating diseases. Our novel endpoints and ability to segment muscles, fat, bone and vessels precisely measure muscle growth or atrophy.

Pulmonary Research

We can measure Chronic Obstructive Pulmonary Disease by using CT to provide a non-invasive anatomic assessment and a densitometry map of the lungs.

Pre-Study Services

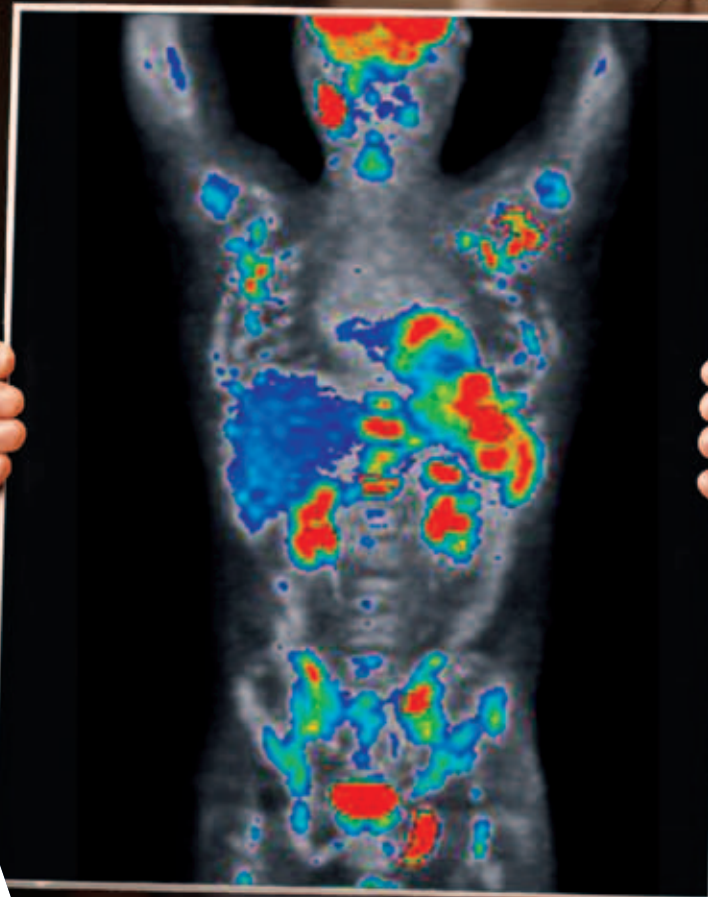
- Modality selection - CT, PET, MRI, X-Ray, Ultrasound, DEXA
- Standardization across global imaging sites
- Clinical protocol design, including image-based biomarker selection
- Independent review charter development (Imaging charter)
- Special protocol assessment (SPA) development
- Statistical analysis plan development
- Imaging site qualification, initiation and training
- Method, proof-of-concept and pilot studies
- Support at regulatory meetings

Study Services

- Ongoing image site management
- Image data quality control and inspection
- Regulatory-compliant image data management
- State-of-the-art image analysis techniques
- Traditional image-based biomarkers
- Novel quantitative biomarkers
- Image data results delivered to your specifications
- Medical and scientific reports

Post-Study Services

- Secure image data management and archiving
- Statistical analysis and mining of image data
- 3D & 4D visualization of results
- Image data regulatory submissions
- Rescue studies - strategic solutions and proven adaptability to ensure project completion



Dr. Ed Ashton, Chief Scientific Officer,
VirtualScopics employee since 2001

The Benefits of VirtualScopics.

Broad therapeutic area expertise

Oncology, Musculoskeletal, Cardiovascular, Central Nervous System.

Collaborative process

Unlike competitors, our imaging experts are in-house and available for consultation from initial protocol design through each stage of a study ensuring sponsors conduct a well-structured trial.

Highly precise analysis

Our analyses are based on quantifiable image-based biomarkers instead of subjective endpoints.

Exceptional reproducibility

Our patented algorithms consistently return the same results from the same image minimizing reader variability.

Smaller sample sizes/Shorter trials

Greater confidence in results gained from very precise measurements allow trials to proceed with a reduced number of subjects, moving a trial forward faster towards completion.

Cost savings

By providing real-time, reliable information our sponsors are able to arrive at pivotal decisions faster and with more confidence.

Fast service

Critical customer requests can be turned around within 24 hours where other core labs take weeks or months.

End-to-end services

From development of clinical protocol, to imaging site initiation and training, to delivery of results, to regulatory requirements, we provide a seamless solution.

Critical information/Detailed information

VirtualScopics provides more comprehensive 3-D and 4-D image analysis in addition to the industry standard 1-D and 2-D measurements.

Adaptive trial design

The rapid delivery of detailed results provides sponsors the flexibility to conduct adaptive trials which can result in cost efficiencies and quicker, more dynamic studies.

Multi-disciplinary approach

Radiology, radiological technicians, imaging science, software and project management are all in-house enabling us to tailor studies to meet sponsors' specific goals.

500 Linden Oaks
Rochester, NY 14625 USA
P +1.585.249.6231
F +1.585.218.7350
info@virtualscopics.com
www.virtualscopics.com



In memory of
Joerg Batterman
1964–2009