



Introducing Debra Vent:

Business Development Manager

The VirtualScopics' business development team welcomes Debra Vent who is in the process of transitioning from project management and will be servicing customers in the US eastern region and Europe. Deb has worked as a senior project manager with VirtualScopics since 2007. In that role she managed a team of 11 project managers as well as her own project portfolio.

Prior to joining VirtualScopics Deb worked in a variety of project management and technical roles with Eastman Kodak and Xerox. Deb brings a wealth of imaging and operational management expertise to her new position.

If you don't have a chance to meet with Deb over the summer there will be plenty of opportunities in September as she, along with other members of VirtualScopics, will be attending Central Labs East in Boston, the OARSI World Congress in Brussels and the ICRS World Congress in Barcelona.

Deb can be reached at
+1 585-249-6231 x355 or
debra_vent@virtualscopics.com

Deb joins a business development team that also includes:

Erik Jensen (North America)
+1 585-249-6231 x369,
erik_jensen@virtualscopics.com

Ian Marron (Europe)
+44 7864 032 091
ian_marron@virtualscopics.com

Ask Ed: How important is discordance between site and central reviews? How can discordance be minimized?



Ed Ashton, PhD
Chief Scientific Officer
VirtualScopics, Inc.

The clinical trials community has shown increasing interest in rates of discordance between site and central reviews in oncology studies recently. Before considering ways to minimize discordance, it is important to understand its sources – some of which can be addressed through training and procedure, and some of which are inherent to the review process. The first and most obvious source of discordance is simple measurement variability. Any time a physical quantity (tumor burden, weight, blood pressure, etc.) is measured more than once, whether by site and central readers or by two central readers, a certain level of variability is to be expected. The probability that this natural measurement variability will result in discordance for a particular patient depends on both the magnitude of variability and the proximity of a patient's "true" tumor burden to a decision threshold. A patient whose tumors have doubled in size is highly unlikely to produce discordant reads no matter the quality of the readers, while a patient whose tumor burden has decreased by 29%, for example, is very likely to produce discordant reads despite the best efforts of both site and central readers. Expected rates of discordance from this factor will therefore vary with reader variability, tumor growth rate, and effectiveness of therapy. Discordance may be minimized to a certain extent by ensuring that the same target lesions are selected by the site and central readers, but it cannot be eliminated entirely.

A more significant source of discordance between site and central reviewers is the clinical and other information that is available to the site reviewers. Even in cases where the protocol specifies a purely radiological review, it may be difficult for site reviewers to avoid bias due to their knowledge of the patient's clinical condition. Site reviewers are also typically less familiar with the details of the review criteria than are central reviewers, with the result that they may in some cases fail to strictly adhere to rules around treatment of non-target lesions, newly appearing lesions, etc. These issues can be partially addressed through thorough site training, but are likely to persist to a certain extent in even the best controlled trial.

Educational Webinar Series—Fall Schedule

If you missed any of our educational webinar presentations this year, you'll have another opportunity to catch them this fall. Due to their initial popularity, we will present the entire series beginning September 15 and running through December 1.

This **free** series is designed to help participants better understand the benefits of using quantitative imaging for clinical drug and device trials and will range across a variety of topics and therapeutic areas including:

- RECIST 1.0 vs. 1.1
- Functional and structural imaging in clinical trials
- Imaging for musculoskeletal diseases and devices using MRI
- Measurement of fat and muscle using CT and MRI
- Assessing intervertebral disc degeneration through MRI
- Clinical trial process flow

New for the fall we will add a 9 am EDT session to our customary 2 pm EDT session for the convenience of our international attendees.

Please follow <http://www.virtualscopics.com/webinar-registration.aspx> to register for specific webinars and times.

Click http://www.virtualscopics.com/pdf/VirtualScopics_Webinar_Schedule_2010.pdf for the complete schedule including dates and presenters.



Upcoming Events

CBI's 4th Annual Oncology Clinical Trial Summit

Vienna, VA
September 14-15, 2010

Central Labs East

Boston, MA
September 20-22, 2010

OARSI World Congress

Brussels, Belgium
September 23-26, 2010

ICRS 9th World Congress

Barcelona, Spain
September 26-29, 2010

Reproducibility: A key to your study's success

When implementing image analysis in your studies a key factor in determining a drug's effectiveness is the ability to consistently reproduce measurements throughout the trial lifecycle. Whereas current methods of image analysis can be highly variable, and thus inaccurate, VirtualScopics uses patented systems to greatly minimize variability and provide highly reproducible measurements.

VirtualScopics' methods provide several benefits:

- High level of reproducibility that can lead to reduced patient sample sizes
Greater precision leading to more confident decisions (i.e. go/no go, adaptive trials)
Higher throughput leading to increased efficiency and lower costs
Real-time reads

Contact us to learn how your trial can benefit from VirtualScopics' portfolio of image analysis services.

Ask Jon: How do you utilize MRI and CT to assess skeletal muscle volume?



Jon Riek, PhD. Chief Technical Officer VirtualScopics, Inc.

There are many conditions that may negatively influence skeletal muscle volume within the body. These include, but are not limited to, cachexia, myopathies such as muscular dystrophy or polio, atrophy from disuse, and sarcopenia. There are several potential treatments to slow or reverse the loss of muscle volume. Some of these treatments are as simple as regular exercise, while some are new drugs or biologics that are currently in development. Regardless of the method of treatment, it is important to determine its efficacy. One way to quantify the efficacy is through imaging.

MRI and CT are both viable imaging modalities when measuring muscle and fat as there is substantial contrast within the images between the muscle and fat regions. The overall rate of change in skeletal muscle volume can be approximated by looking at the change within a single region inside the body. As the thigh contains the largest skeletal muscles in the body, this is the recommended region to image. To assess the amount of muscle in the thigh it is important to choose bony landmarks at the upper and lower limits of the region to be analyzed and then to be consistent in both the imaging and the region-of-interest identification from visit to visit. Thigh muscle volume, intramuscular fat volume and subcutaneous fat volume can be assessed by separating the fat from the muscle, and then determining the boundary between the subcutaneous fat and the muscle bundle. With our experience and level of automation we have been able to achieve scan/rescan variability of approximately 1%.

Jon Riek to Present Posters at OARSI and ICRS World Congress Events

Chief Technical Officer Jon Riek will be presenting scientific posters at two important events in Europe during the month of September.

- Using T2 phantoms to obtain consistent T2 relaxation times regardless of pulse sequence will be presented at the OARSI World Congress in Brussels September 23-26, and
T2 mapping—Does the choice of imaging sequence matter when using T2 phantoms? will be presented at the World Congress of the International Cartilage Repair Society in Barcelona September 26-29.

VirtualScopics' imaging and medical experts have been busy recently presenting at various industry conferences. In May Ed Ashton lectured on quantitative MR in multi-center clinical trials at the International Society for Magnetic Resonance in Medicine (ISMRM) Annual Meeting in Stockholm. Ed also participated on a study group and presented a poster while at ISMRM. Early June saw Jon Riek present a poster at the International Workshop on Imaging Based Measures of OA in Vancouver, Canada. Rounding out our expert triumvirate was VP of Clinical Affairs Mark Tengowski presenting a poster at the recent Drug Information Association Annual Meeting. The title of Mark's poster was DCE-MRI as a predictive biomarker for tumor shrinkage: Meta-analysis of 13 clinical trials and was a compilation effort with Jon and Ed.

Congratulations to Liliana DiStabile of Thallion Pharmaceutiques Inc., winner of our Bose Headphone drawing at the DIA Annual Meeting in Washington, DC June 16.