



**Introducing  
Ajoah Fink:**

**Senior  
Project  
Manager**

In August, VirtualScopics was pleased to announce the hiring of Ajoah Fink as a senior project manager. Ajoah is based in Austria and will provide dedicated project management to our international clients.

Ajoah brings a wealth of experience to the position with an extensive background in global clinical trial management. Prior to joining VirtualScopics, Ajoah held clinical trial leader and clinical trial project manager positions with global pharmaceutical companies.

With Ajoah joining our team we now have greater international coverage and experience, which has been warmly welcomed by our international clients. This hiring allows us to better meet the overall needs of our international customers, and combined with our UK staff, enables us to offer them devoted business development, site management, and project management services.

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## Ask Ed: Can imaging be used to distinguish between inflammation and disease progression in cancer trials?



**Ed Ashton, PhD  
Chief Scientific Officer  
VirtualScopics, Inc.**

This is an increasingly common question, particularly in relation to trials of immunotherapeutic agents. The two most commonly used imaging techniques in oncology trials are CT for tumor size measurement and FDG-PET for assessment of tumor metabolism. Because inflammation can cause both a transitory increase in apparent tumor size and an increase in FDG uptake due to the glucose avidity of macrophages, both of these techniques can mistake inflammation for progression. There are, however, other imaging methods that can more easily separate tumor growth from inflammation. FLT-PET, as an example, will not show an increase in tracer uptake in the presence of inflammation. If FDG- and FLT-PET are used together, cases of inflammation will show an increase in tumor size and FDG uptake with no increase in FLT uptake. Cases of tumor growth, however, will show an increase in tumor size with both FDG and FLT uptake either increasing or holding steady. Use of FLT-PET alone may also be helpful, but may result in an ambiguous result in the case where tumor size increases while FLT uptake remains unchanged.

Unfortunately, both FDG- and FLT-PET scanning are expensive and involve moderate radiation exposure (typically on the order of \$3000 - \$5000 and 5 – 7 mSv per scan). A more economical and less invasive option in this case would be to make use of a combination of dynamic contrast-enhanced (DCE) MRI for blood flow measurement with diffusion MRI. Using these techniques, we would expect inflammation to cause an increase in diffusion combined with a drop in blood flow, while disease progression should cause either no change or a decrease in diffusion combined with either no change or an increase in blood flow.

## Gadolinium-based MRI contrast agents receive new label warnings

You may have read in September that the FDA recently issued a Drug Safety Communication requiring changes in the drug label for gadolinium-based contrast agents, or GBCAs, to minimize the risk of nephrogenic systemic fibrosis, or NSF, a rare, but serious, condition associated with the use of GBCAs in certain patients with kidney dysfunction.

**To clarify, these are not new warnings, yet updates to the warnings originally issued by the FDA toward GBCAs in 2007. VirtualScopics has been advocating for the proper screening of trial subjects to assess renal function, especially in DCE-MRI studies, since the relationship between GCBAs and NSF was first reported in 2006.**

Based on the Agency's review, it was determined that the agents Magnevist, Omniscan, and Optimark are associated with a greater risk of developing NSF than other GBCAs in certain patients with kidney disease. As a result, use of these particular agents is contraindicated in patients with acute kidney injury or chronic, severe kidney disease.

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Upcoming Events

Exploratory Clinical Development World Americas 2010

Cambridge, MA
October 19-22, 2010

ACR/ARHP - Annual Meeting

Booth #1051
Atlanta, GA
November 6-11, 2010

Tumor Volume: So important we offer it free

Across the industry, the standard offering for an oncology study employing imaging is to provide 1 and 2 dimensional assessments (RECIST/WHO). VirtualScopics has advanced this offering by including 3D measurements of tumors, at no additional charge.

Study findings have suggested that tumor volumetric (3D) measurements provide a more sensitive and likely more accurate assessment of tumor burden and response to therapy. VirtualScopics was built upon this ideology.

VirtualScopics' patented technology allows us to provide precise and highly reproducible tumor volumetric measurements. Additional measurements include:

- Tumor blood flow
Tissue to blood volume
Oxygen utilization
Glucose metabolism

To learn more about the advantages of tumor volume and other assessments for your trial, contact us at:

http://www.virtualscopics.com/contact-us.aspx

Ask Jon: What criteria are used to evaluate radiographic success of a spinal fusion system?



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

The FDA released a guidance document in 2000 for the preparation of Investigational Device Exemption (IDEs) applications for spinal systems. If the goal of the system is spinal fusion, then one of the primary evaluation criteria for the study should be radiographic success of the fusion. In general, this consists of three conditions:

- Evidence of bridging bone
Translational motion less than 3mm
Angular motion less than 5°

These three criteria can be easily evaluated from anterior-posterior, lateral and flexion/extension radiographs. Due to the two-dimensional nature of radiographs, it is possible to get false positives for the presence of bridging bone. A three-dimensional CT volumetric dataset can be used to verify bridging bone. Other assessments mentioned in the guidance document, such as disc height, vertebral height and the presence of radiolucent lines may also be evaluated from the same radiographs. All of these radiographic assessments should be made by two radiologists, with a third independent radiologist brought in for cases where the first two disagree.

To learn more about VirtualScopics' spinal study solutions, join us on November 3 for a webinar presented by Jon Riek entitled "Assessing the Spine using MRI, CT and X-Ray". See registration link below.

Gadolinium warning, continued...

Patients at greatest risk for developing NSF after receiving GBCAs are those with impaired elimination of the drug, including patients with acute kidney injury, or AKI, or chronic, severe kidney disease with a glomerular filtration rate (GFR) < 30 mL/min/1.73m². Higher than recommended doses or repeat doses of GBCAs also appear to increase the risk for NSF. NSF has not been reported in patients with normal kidney function.

The label changes are intended to help ensure these drugs are used appropriately, and that patients at risk for NSF who receive GBCAs are actively monitored for the potential development of NSF. While many study teams using GBCAs already include safety precautions regarding assessment of renal function in their trial design, the revised FDA labeling will enhance and ensure the continued safe use of GBCAs.

Reminder: Fall/Autumn Educational Webinar Series continues....

Our complimentary educational webinar series continues with two offerings in October:

- Measuring Anti-TNF Therapy Using MRI—October 13 @ 9AM EST/3PM CEST and 2PM EST/9PM CEST
Measuring Fat & Muscle Using CT and MRI—October 27 @ 9AM EST/3PM CEST and 2PM EST/9PM CEST

Please register at: http://www.virtualscopics.com/webinar-registration.aspx