

I'm going to begin with some definitions and end with testing from the perspective of using DICOM for advanced technology clinical trials. First to acknowledge some of my colleagues and collaborators. I'm actually in the Image-guided Therapy Center, which is a component of the National Cancer Institute sponsored Advanced Technology QA Consortium, and the ATC consists of five centers including the ITC at Washington University in St. Louis, the Resource Center for Emerging Technologies in Gainesville, the RPC, the RTOG headquarters, and QARC. Advanced Technology Clinical Trials are a class of clinical trials, which involve the collection not simply of point doses but of volumetric models of patients and dosimetry. The main driving force here is the desire to link clinical radiotherapy data with clinical outcomes in a way that will allow us to evaluate the response statistics during the trial and develop and test dose-response

models after the trial. To do that, we need to collect volumetric imaging that's segmented into the target volumes and organs at risk, the registered volumetric doses, as well as fractionation information. And we need to collect that data digitally and transfer it in a common format. The ATC, and the ITC in particular, has been involved, since the beginning of the RT DICOM effort in providing digital data exchange mechanisms, and before that effort with the RTOG data exchange format. What do the data for advanced technology trials look like? Well, the primary data that we need involves dosimetric images, and in most cases that involves CT with contours that identify the target volumes, the GTV, CTV, PTV, etc., and the organs at risk associated with a particular treatment. If we're to use DICOM this will be in the form of an RT Structure Set. Also, we need a 3D dose distribution, and for that we would use the RT dose object in DICOM.

In addition to those primary data, which we use and archive and analyze and compare to clinical outcomes, we also collect a number of secondary data objects, primarily as a reality check, i.e., for QA on these primary data objects. For us that would include RT Plan (the plan specifications, the beam, geometry or source, positions and strengths), as well as dose volume histograms, and RT images to check the setup. Bruce talked about special requirements and conformance statements. He talked about DIMSE (DIMSE being the means of exchanging objects on a network). DICOM also supports a means of encoding objects as a set of files. We have structured the requirements for submission of data for advanced technology trials in terms of a set of files that are read by a program that we've developed. The behavior of that software and the requirements for the clinical trials data are embodied in a document called the ATC File

Set Reader Conformance Statement, which is available from the ATC on the ATC website. And as Bruce mentioned, there are DICOM attributes that are type 2 or 3, and that under some circumstances that information may not be provided. For clinical trials data, what we want is not the beginning of the process, the CT simulator output, for example, but rather, the record of how the patient was actually treated or was actually planned. Thus, we need the complete plan, we need the complete dose, not just the template that would contain that information. So those attributes must be provided. In addition, there are a number of special requirements for those attributes and I'll outline those very briefly for a couple of the objects. This is a fairly detailed statement and to help get people through it, we have a little more terse summary of the particular requirements in a reference guide that's also available online. I'll just go through these fairly

briefly. The way we've structured our receiving application is unlike a clinical situation where

the patient's safety is a primary issue. We tried to make our receiver as tolerant as possible and to give as much diagnostic information as possible, so as we work with vendors who are generating these data we can feed back to them and we can accept as broad a range of objects as is tolerable while maintaining the quality of data. And that has put the ATC in a good position to help in the testing. For structure sets, contours for our purposes must be planar. We need them to be defined in transverse planes and coincident positions with the images in the image set that they refer to. For external beam protocols we require that there be an external patient contour that is a skin on all axial slices. Structures need to reflect the extent of volumes that are contoured by the physician. That is, if there are target volumes that overlap the structures they must not interfere and must not "eat into" the contoured structures. And finally we're asking that

the protocol-defined names be used for the structures that are submitted. The RT dose object is actually a very versatile object. It can be used to describe point doses, isodose contours, 2D dose planes, 3D dose distributions and dose-volume histograms. For our purposes, we need the 3D dose distributions to be represented as a single object that contains multiple dose planes. There is a multi-frame mechanism within DICOM, and rather than having multiple dose planes, we're asking that the dose distribution be sent as a single, multi-frame object. Basically, all of the manufacturers have now produced implementations that can do that. A separate dose array is required for each fraction group. We want to be able to track the dates on which a particular fraction group is delivered so we can model the fractionation of the dose delivery. And so, we need a separate array for each fraction group, i.e., each set of beams or sources that are delivered

in constant proportion. The doses need to be specified as physical dose in Gray, i.e., in absolute scaling. The dose array must represent the entire meaningful dose, and so we assume that outside the dose array the dose is negligible. Finally, we want a dose volume histogram, again primarily as a QA instrument, to be submitted for the total dose plan so that we can check the scaling of the doses that are submitted in the dose array. Recently, we've allowed people to submit graphical screen captures of the DVHs so that's been of somewhat secondary importance for us. RT plan is a very complicated object, as Bruce mentioned. You saw the hierarchy and the nesting of the components of the plan. The object can represent both external beam and brachytherapy in many different treatment modalities. And this object is particularly challenging because it represents not just a record of an image that's been recorded but really a prescription,

a description of something *to be* performed. The particular requirements here are that the data element, RT Plan Geometry needs to have the value, PATIENT. I.e., for the trials that we support, we need to have plans that are based on an image set and that's what this indicates. For external-beam, 3D conformal studies, we want the beam energy, aperture and beam modifiers as a help for setup and beam weight quality assurance steps. Right now, we're not using this information for IMRT. We don't have a means of doing quality assurance based on that information. Given the variety of approaches to IMRT, we're not likely to be doing any dose recalculation from these data. For permanent-implant brachytherapy, we want to know the seed model and strength and the locations in patient space because here we do hope to do dose recalculations. Similarly for HDR, we want source geometry, i.e., dwell positions (in patient space), source strengths and dwell times. I won't say a lot about the RT Image object, because

requirements are very protocol-specific and it's not central to our QA process. RT Image objects can be used for DRRs, and for digital simulator or verification images. And since RT Images are divergent images that can be tied to beam geometry, i.e., to specific beams, they're preferred to Secondary Capture, which is a more generic ("screen grab") image modality in DICOM, or Computed Radiography. So, how do you know if your treatment planning system is capable of sending data for advanced technology clinical trials? Well, we've tried to provide a list of those systems for which we have done testing, and that's available on our website, at <http://atc.wustl.edu>. We provide a list of those systems for which we have received data successfully for the clinical trials that we support. Since this is an advertisement that you can use these systems, we've tried to be fairly stringent in requiring that a treatment planning system is listed here only after we've received a complete, protocol-compliant submission that meets the

clinical trials protocol requirements from real clinical users. More recently, we've had to be more careful in saying that the system must be *released* software, because there have been issues of getting data to test from early versions of software that were not generally available. On the right-hand side of this slide you see the dates for ATC Compliance of the four treatment planning systems that export DICOM. And you'll note that they have all been approved within the last year. In fact, a year ago, at the AAPM DICOM symposium, I said that there were no ATC-compliant treatment planning systems. I'm happy to say that that situation has changed. In fact, in addition to those four treatment planning systems, there are eight other treatment planning systems that are "works in progress" at various stages and some of them are getting very close to what we informally refer to at the Image-guided Therapy Center as "vendor-complete", that is

ready to test by users. In addition, there are 40 institutions that have been credentialed that are now able to submit data to us for trials using DICOM. Some of these for more than one protocol, and some with multiple treatment planning systems. We've received almost 200 submissions of DICOM data, 123 of those were "dry runs", i.e., test submissions. And you can see that for these 40 institutions, even if they have multiple treatment planning systems, this is an iterative process because multiple submissions are sometimes required to correct problems. We have 50 protocol case data sets on RTOG protocols that have been submitted using DICOM, and 21 phantom studies which are used as a credentialing vehicle to submit the dose distributions for comparison to TLD measurements at the Radiological Physics Center. I want to shift gears now to .testing, to what has been called the DICOM "connectathon". Last Fall at ASTRO, a group of

us primarily in DICOM Working Group 7, with Bruce representing the AAPM and my representation of the ATC, made plans to see what we could do to begin testing and demonstrating the use of RT objects. And this year's demonstration is the first phase of that process. What we decided to do was to come up with a modest test suite, in this case, two data sets, that would be distributed as a starting point. We would give instructions to treatment planning vendors. (We did that in April at the DICOM workshop that was held in St. Louis at the ITC.) We gave plan specifications and we asked the vendors to import the images and structure sets, create the plans and export as many as possible of the DICOM RT objects that are listed here. We asked the vendors to submit them to us by about a month before AAPM so that we could iterate with them and we could evaluate the data and display them here. And in fact,

they are on display in the exhibit hall at the ATC booth. The two data sets that we started with were a 3D CRT prostate case based on RTOG protocol 0126, and an IMRT nasopharynx case based on RTOG protocol 0225. We de-identified them, we made attempts to facilitate their import by removing the private attributes that Bruce was describing in order to avoid problems with the import, and made sure that the structure sets axial positions coincided with the CT images. One of the things we didn't check, and it caused grief to at least one of the vendors, was that one of the data sets (the prostate case) had irregularly spaced CT slices (with some 3-mm and some 5-mm cuts). That turned out to be an issue. I have to give credit, a lot of credit, to Dr. John Matthews at ITC who iterated with a number of the vendors. In fact, one of the vendors sent ten submissions.) John evaluated those data and reported back to them and gave them

access to display their data sets using our web-based Remote Review Tool. Briefly, one of these is shown here as an example here. The prostate case has 97 CT slices and ten structures. We gave some dosing prescription guidelines, we suggested a six-field conformal plan, and gave some normal structure tolerance data. We got submissions from eight manufacturers (that would include twelve treatment planning systems). Nine of those included all of our primary data: the CT Image, RT Structure Set, RT Plan, and RT Dose (the 3D dose array). We got partial data sets from three other systems. As I said, you can come down and see in the exhibit hall, in booth 1634 next to AAPM, a display of those data sets that were submitted. Here are some tools that we used and have been of great value, not only the review of protocol data by the study chairs, but also to the vendors. There's the Remote Review Tool which is a web-based display of the

images, the structure contours and isodoses. that you can see at our booth. In addition, we've started to use a PC-based tool developed by Dr. Joe Deasy and co-workers at Washington University called CERR. As I mentioned before, the export of a complete set of DICOM objects was envisioned as the first phase of this demonstration. What we're hoping to do is build on that using the data that we've collected this year as the starting point of a library to allow vendor-to-vendor testing of interoperability of those data sets and demonstrate that next year at the 2005 AAPM meeting. And we're still working out the details, but hopefully there will be some exchange using either media exchange or network exchange next year. So in summary, the last twelve months have seen really significant progress. DICOM is now a viable format for advanced technology clinical trials, and hopefully that translates into clinical usefulness as well.

The ATC Conformance Statement is a profile for using the RT objects in clinical trials. The Image-guided Therapy Center provides assistance to vendors. The process of the "connectathon", the DICOM demonstration, has really been valuable and has pushed forward the process of implementation for a number of vendors. And we hope that the data we've collected this year will be a good starting point for import testing next year.