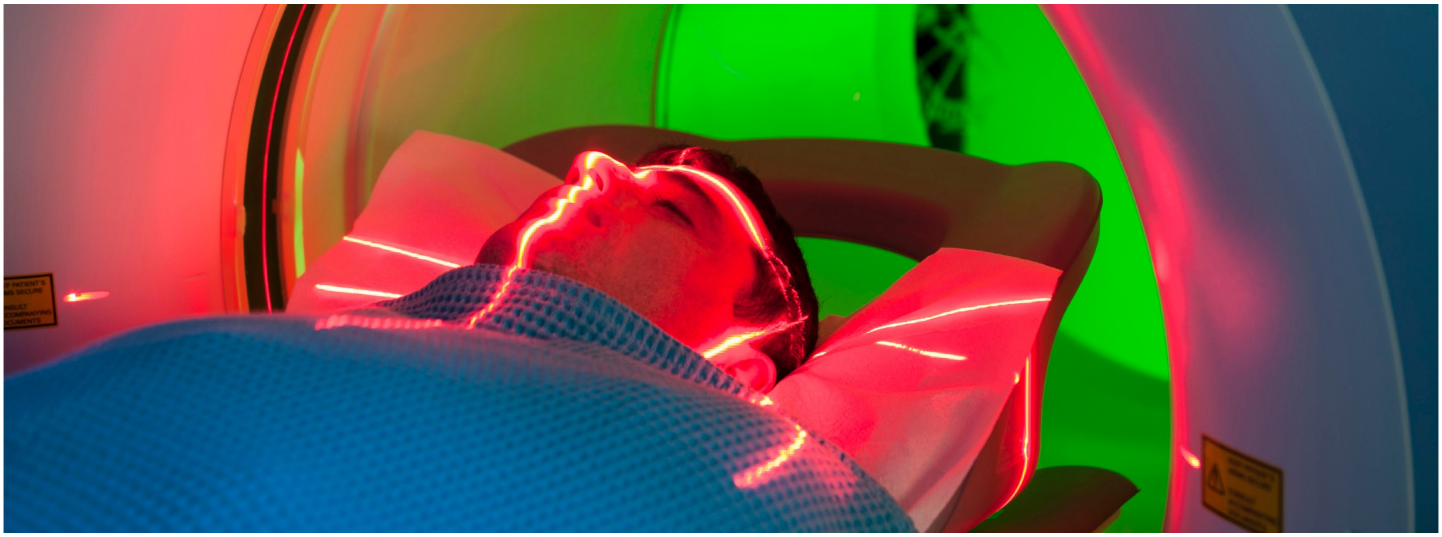
Intrinsic Imaging
www.IntrinsicImaging.com

Guidance for Sponsors
Volume 4, Issue 7 · 2026 Edition

Computed Tomography Data Acquisition in Clinical Trials

By Neal Dalrymple, M.D., Chair, Scientific Advisory Board · Updated for 2026 by Intrinsic Imaging



CT is one of the most widely used modalities in clinical trials, and a substantial literature, led by RECIST 1.1, governs how lesions are measured. Far less attention is paid to how the images are acquired, yet patient motion, scanner variability, slice thickness and contrast timing all add error to every measurement. FDA's 2018 guidance on imaging endpoint process standards makes acquisition a regulatory concern. A few basic principles, written into the protocol and imaging charter and applied consistently at every site, substantially improve data accuracy.

Computed Tomography

The use of imaging in clinical trials continues to grow, and CT is among the most common modalities. Lesion measurement is guided by established criteria such as RECIST 1.1 and, for immunotherapy, iRECIST.[1,2] Guidance on acquiring the scans, however, is often limited to the study protocol, which may not be written by a radiologist. Patient-related and technique-related variables affect image quality, and poor or variable quality increases the error in each lesion measurement, reducing the accuracy of the trial.

FDA's guidance on clinical trial imaging endpoint process standards addresses this directly. It encourages sponsors to describe in an imaging charter how sources of imaging bias and variability will be controlled, including equipment and image quality requirements and processes for acquisition, interpretation, archiving and data transfer.[3]

Adherence to the Study Protocol

When an examination is part of a clinical trial, adherence to the specified protocol is critical. In practice, the protocol may not make sense to those supervising examinations at a site if they were not involved in study design. The use or omission of intravenous or enteric contrast, or imaging in a particular phase of enhancement, may have been chosen for reasons not obvious to the site, and deviations can lead to exclusion of data or even of patients. Even well-intended protocol changes can invalidate data already collected at other sites, so revisions should be avoided unless absolutely necessary.

Patient-Related Variables

Relatively few patient-related variables affect the accuracy of CT data, and the most important is motion. The breath hold remains essential. Although scan times keep decreasing, a weak or breathless oncology patient may struggle to hold their breath even briefly, and language barriers can make instructions useless. Respiratory motion causes inaccurate measurements and occasionally artifactual lesions. A technologist who coaches the patient through the breath hold, or finds an interpreter, minimizes motion-related error.

Technique-Related Variables

Following the protocol should produce consistent technique, but acquisition is rarely that simple. CT scanners vary by

vendor, detector configuration and software version; most sites have several, and multicenter trials draw on widely different technology. Defining parameters that achieve comparable image quality across this range is challenging.

Dose modulation. Automated exposure control helps achieve consistent image quality across body sizes but is difficult to standardize across platforms. Radiologists and technologists must ensure it is used effectively. An off-center patient increases noise, and fast gantry rotation or table speed can prevent adequate tube current in larger patients; lower-pitch protocols give more consistent quality. Newer iterative and deep-learning reconstruction algorithms reduce noise at lower dose but change image texture, so the same reconstruction should be used throughout a patient's follow-up.

Slice thickness. Thin sections (typically 3 mm or less) allow more consistent measurement of small lesions such as lymph nodes, because slice selection is less likely to cause under-measurement. Thicker sections (5 mm) often improve conspicuity of low-contrast lesions such as liver metastases. RECIST 1.1 assumes a slice thickness of 5 mm or less.[1] These choices should be specified in the protocol; if they are not, sites should use one consistent reconstructed thickness for every examination in the study.

Contrast timing. Scan timing relative to the contrast bolus is critical to lesion conspicuity. For a patient scanned on the same scanner each time, consistency can usually be achieved by repeating the timing used at the previous examination, either a fixed delay or bolus tracking. When a patient may be scanned on several scanners, radiologists and technologists should agree on bolus timing for each so that arterial, portal venous or other phases are reproduced consistently.

Automated and AI-Assisted Measurement

Semi-automated and AI-based tools now provide two- and three-dimensional measurement of nodules, organs, lesions and lymph nodes, and their role in trials is growing. Their accuracy still depends on the acquisition variables described above: image noise affects lesion segmentation, and volumetric measurement requires isotropic or near-isotropic data to avoid error along the scan axis.

Guidance for Sponsors

Acquiring reliable CT data

- **Involve a radiologist in protocol design.** Explain the rationale for contrast, phases and parameters so sites understand and follow them.
- **Write an imaging charter.** Document acquisition, reconstruction, transfer and reading standards, as FDA recommends.[3]
- **Qualify every scanner.** Collect parameters at site start-up and check the first scans from each site.
- **Keep it consistent per patient.** Same scanner where possible, same slice thickness, reconstruction and contrast timing at every visit.
- **Monitor quality continuously.** Central quality review catches deviations early, before data are lost.
- **Read centrally.** Blinded independent central review applies RECIST 1.1 or iRECIST consistently across sites.[1,2]

Summary

CT measurements are only as good as the images they come from. Protocol adherence, attention to motion, consistent dose management, slice thickness and contrast timing, and careful use of automated tools together determine the accuracy of CT data in a clinical trial. Building these principles into the protocol and charter from the start protects the trial's endpoints.

About the Author

Dr. Neal Dalrymple wrote the original edition of this issue as Chair of the Scientific Advisory Board at Intrinsic Imaging. He received his medical degree from Tufts University School of Medicine and completed residency training in diagnostic radiology at Yale University School of Medicine, followed by a focused year in body cross-sectional imaging at Yale, during which he authored one of the 10 most cited articles in the urology literature. An expert in oncologic imaging, he has authored numerous journal articles, served on the Genitourinary Scientific Committee of the Radiological Society of North America, performed peer review for the *American Journal of Roentgenology* and *RadioGraphics*, and served as an examiner for the American Board of Radiology. He has been Vice Chairman of Radiology and Residency Program Director at the University of Texas Health Science Center at San Antonio, and is the author of the textbook *Problem Solving in Abdominal Imaging*.

References

1. Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). *Eur J Cancer.* 2009;45(2):228–247. pubmed.ncbi.nlm.nih.gov/19097774

2. Seymour L, Bogaerts J, Perrone A, et al. iRECIST: guidelines for response criteria for use in trials testing immunotherapeutics. *Lancet Oncol.* 2017;18(3):e143–e152. recist.eortc.org

3. U.S. FDA. Clinical trial imaging endpoint process standards: guidance for industry. April 2018. fda.gov

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

Contact

Intrinsic Imaging, LLC
580 Main Street, Suite 210
Bolton, MA 01740
Tel: +1 978-616-4650
Contact@IntrinsicImaging.com
www.IntrinsicImaging.com