

Current Clinical Status of Full-field Digital Mammography

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Clinical Trials for the purpose of FDA-approval

The FDA published "Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems," on June 19, 1996. This document is still available on the World Wide Web (<http://www.fda.gov/cdrh/ode/digmammo.html>). Manufacturers were required to conduct a clinical trial to show agreement between screen-film mammography and digital mammography for FDA-approved through the 510(k) or Premarket Approval (PMA) mechanism.

This guidance document indicated that the probability of a positive digital mammogram should be greater than 0.90 if the screen-film mammogram were positive and the probability of a negative digital mammogram should be greater than 0.95 if the screen-film mammogram were negative. This document estimated that approximately 520 women (260 with abnormal screen-film mammograms and 260 with normal screen-film mammograms) would be needed to achieve such an estimate of agreement. Truth about the presence or absence of cancer in the patient was not important for such a trial, only that the screen-film mammogram interpretations and the digital mammogram interpretations agreed.

Recruitment to clinical trials was begun shortly thereafter. The trials that were carried out were quite similar, as would be expected since the FDA provided a blueprint for the manufacturers to follow.

Specifically, the Fischer trial, led by Pisano, enrolled 570 women at four institutions (UNC, Thomas Jefferson, Sally Jobe Clinic in Colorado and Brook Army Medical Center). The cohorts were women with BIRAD interpretation codes 3, 4 or 5 on the diagnostic mammograms and women with symptoms.

The GE trial, led by Hendrick, enrolled 652 women at four centers (University of Colorado, University of Massachusetts, Massachusetts General Hospital and the University of Pennsylvania). The cohorts were women presenting for screening mammography and women presenting for diagnostic mammography.

The Trex trial, led by Fajardo while she was at the University of Virginia, enrolled 520 women at three centers (University of Virginia, University of California-Los Angeles, and Good Samaritan Hospital in New York). The cohorts were women with normal screening mammograms and women with abnormal screening mammograms.

All studies utilized radiologist readers interpreting the screen-film and digital mammograms of the enrolled patients and measured agreement of these readings. Trex submitted the data obtained using their protocol to the FDA in early December 1997.

Information on a Fuji agreement study protocol is not available