

Offshoring Radiology for Clinical Research

By Ketan Desai

The clinical research industry is rapidly globalizing, especially in developing countries such as Brazil, China, India and Poland. Information services such as statistics and data management are moving to countries that can deliver high-quality results and lower cost.

Clinical medicine has employed offshore radiology services for at least five years, reading MRIs, CAT scans, and X-rays for U.S. hospitals, especially at night when radiology staffing in US hospitals is low.

This article describes probably the first use of offshore radiology services in a clinical trial. It is published with the generous permission of the study sponsor, who wishes to remain anonymous and keep confidential other details of the study.

Objective

This article evaluates the quality of radiology services provided by a team of radiologists based in Delhi, India for a Phase III oncology trial conducted in 2004-2005.

Materials and Methods

An international, multi-center Phase III breast cancer trial was conducted to compare standard of care with standard of care in combination with an experimental drug. One of two primary endpoints was tumor progression as assessed by primary tumor size (for tumors > 1 cm) and the presence or absence of metastasis. Tumor size was evaluated by the product of the maximum diameter of tumor in two perpendicular measurements as evaluated by radiology techniques. Up to ten lesions were measured, and the sum of the lesions was calculated. Tumors were classified based on how they changed during the study:

- **Progressive Disease.** Lesions increased in size by more than 25%, new areas of malignant disease appeared within the breast, or metastases appeared after initiation of therapy.
- **Stable Disease.** Measured lesions did not decrease in size by more than 50% or increase in size by more than 25%. No new lesions appeared.
- **Partial Response.** Lesions decreased in size by more than 50%.
- **Complete Response.** All measurable disease, signs, symptoms and biochemical changes related to the tumor disappeared.

More than 2,000 images were read from 1,026 subjects. These images included 643 mammograms, 945 chest X-rays, 1,402 CT scans of chest, abdomen and pelvis, 67 brain MRIs, 28 bone scans, and 114 skin photographs of skin lesions. The principal investigators at the study sites read the images first. Study sites then sent the images to the study sponsor, which loaded them onto its server in the U.S. Radiologists in Delhi, India read them a second time independently over a secure Internet connection. The radiologists in India were board-certified in India (but not the U.S.). The study sponsor informed FDA that the independent radiology reviews would be conducted in India; FDA did not object. Measurements, annotations and reports were made on-line. Ten percent of cases read by an

individual radiologist in India were read by another radiologist in India in a blinded, random manner to assess quality of reads and to ensure inter-reader consistency. Any differences were adjudicated and resolved.

When there was a discrepancy in the findings between the study site and the Indian radiologists, the images were sent to an independent radiologist in the U.S. to adjudicate the discrepancy. The adjudicator was not affiliated with the Indian radiologists, the study sites, or the study sponsor.

Results

Five Indian radiologists participated in the reviews. On average, each review took 1.5 hours. Scans were loaded in the U.S. by 6 pm EST (4:30 am Indian Standard Time (IST)). All readings were finished the same day by 5 pm IST (6:30 am EST next morning in the U.S.).

Perhaps because of server capacity, 6 mbps was the ideal bandwidth to read the images over the Internet; lower speeds were slower, while higher speeds were more expensive but did not decrease loading time. Broadband access was readily available, but expensive compared to rates in the US.

The cost of conducting the reviews in India was approximately 60% of the U.S. cost. 10% of the 60% was for broadband access and 50% for the services.

DICOM images were the easiest to transfer and read, but unfortunately not all images were DICOM images.

24% of images were adjudicated, at the low end of typical inter-observer variability in the U.S. of 75% to 90%.^{1,2,3} The U.S. adjudicator agreed with the Indian radiologists approximately 90% of the time, indicating an error rate by the Indian radiologists of approximately 2.4% (24% X 10%).

Conclusion

In this study, radiologists in Delhi, India read mammograms, chest X-rays, CT scans of chest, abdomen and pelvis, brain MRIs, bone scans, and skin photographs. The error rate was approximately 2.4%. Cost was about 60% of domestic U.S. costs. All images were read overnight for the U.S.-based sponsor.

References

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