



CONSULTING SERVICES

Defining and developing imaging strategies in a clinical development program

Protocol development

- ◆ Optimal imaging endpoints
- ◆ Imaging charter development

Site selection & qualification

Site investigator and blinded reader training: BRITI

Blinded reading strategies

Post-approval data mining and marketing support

Expert panels

Support for regulatory meetings (pre IND, pre NDA, SPA etc) and regulatory submissions (IND, NDA, etc)

Preparation and review of study reports, publications, and expert reports

RadMD's expertise lies in our ability to construct and implement unique and customized medical imaging solutions. The founders of RadMD have over 25 years of combined experience in both diagnostic and therapeutic clinical development

TRAINING THROUGH BRITI

BRITI (Blinded Reader & Investigator Training Institute) provides standardized training for imaging in clinical trials

Training is primarily web-based; onsite or webinar options are available

Each training module consists of audiovisual lecture plus multiple choice test. Certification of completion is available.

Basic modules include imaging in clinical trials, and advanced modules on all image major evaluation criteria (RECIST, Cheson, etc.)

Study-specific and other customized modules

- ◆ Preparation and attending investigator meeting
- ◆ Post-investigator meeting online training is available throughout the study period

Standardized training is a regulatory requirement, and only BRITI provides targeted training on imaging in clinical trials. Only BRITI offers category I CME certification courses, improving training compliance, reducing site data variability, resulting in overall robust site data.

EXPERT SOURCING

Sourcing and managing of blinded readers and other experts for clinical trials

Database of over 600 pre-qualified, vetted specialists

Experts include radiologists, cardiologists, oncologists, pathologists, medical physicists, and others; backup experts always provided

Readers available in all geographic locations: N. & S.America, EU, Asia

Readers pre-trained through BRITI

One stop shop reduces blinded read timeline through improved reader availability and management

Readers available for safety, efficacy, inclusion evaluations and confirmation of disease progression

24 hour read turnaround available for enrollment evaluations

Turn-key management of readers (contracts, training, logistics, etc.) allows sponsor to focus on key competencies, increasing overall efficiency in blinded read process, reducing costs, and saving time.

The founders of RadMD, Kohkan Shamsi, MD,PhD and Rick Patt, MD are radiologists with a unique combination of drug development, regulatory, academic, and clinical expertise. They have strong relationships with key academic and industry opinion leaders, sponsors, CRO's and ICRO's. It is their unique experience and knowledge which serves as the intellectual base and drives the value of RadMD.