



Excellence in Clinical Endpoint Committees

Transforming images into information.
Turning information into knowledge.
Mapping Life Pixel by Pixel.™

Many clinical trials incorporate evaluation of endpoints for either efficacy or safety, by independent adjudication committees. Efficacy committees, or Clinical Event Committees (CEC), are comprised of physicians with expertise in the relevant therapeutic area. The CEC will review all relevant data, to provide an independent, blinded determination of trial endpoints or events.

Historically most adjudication work has been performed in the academic sector, in a paper based environment. A paper based environment relies on evaluation of paper CRFs, listings, videotapes, or films and does not allow simultaneous project tracking nor provide an optimal audit environment. Despite high level physician expertise, the conduct of the committee can be affected by lack of real time access to all data in an electronic manner and the ability to easily identify multiple data.

Advantages of the Electronic Elements of the ICON Medical Imaging Adjudication Solution:

- Eliminates the need for copying, overnight couriers and tracking of paper and film data
- Significant reductions in data loss
- Reliable, secure audit trails
- Enhancement of committee function due to superior organization of data
- Improved ability to track your study's progress and meet your strict guidelines
- Lower costs with MIRA's™ ability to interface directly with various EDC systems as well as programmed SAS input
- Secure remote access to ICON Medical Imaging's MIRA™ system

The ICON Medical Imaging Approach

ICON Medical Imaging has over 20 years of experience in the use of medical imaging in Cardiovascular, Oncology, Neurology, and Medical Device clinical trials. ICON Medical Imaging has provided adjudication services in a wide variety of therapeutic and diagnostic areas.

ICON Medical Imaging possesses the ability to collect digital image data and convert the various image types into a standard digital format for inclusion in the adjudication database. This data is then entered into MIRA™, a database driven information management system with the ability to distribute, view, and interpret a variety of information “objects”.

Use of MIRA™ offers:

- A secure electronic platform that ensures 21 CFR Part 11 compliance
- Centralized collection of all data
- The ability to logically organize data based on permission based access as determined by the eCRF
- 24/7 online access for independent review
- The ability to identify reader discordance and programmatically drive re-read or face-to-face consensus
- Real-time project tracking
- Audit trails of the data reviewed by the adjudicator

How the ICON Medical Imaging Adjudication System Works:

A typical endpoint Adjudication committee consists in the initial step of with independent physicians. Each physician completes an eCRF. These eCRFs are programmatically compared. If there is concordance, the outcome of the event is considered final and ready for transfer. If there is discordance, there is a second step in which the event is reviewed by an additional group of physicians who adjudicate in further review. The complexity of this process and the amount of data reviewed provides a clear rationale for the ICON Medical Imaging Adjudication Solution.

ICON Medical Imaging’s superior technology coupled with the prior Clinical, Regulatory and Adjudication experience of our senior staff as well as access to our expert panel of physicians is unmatched in the marketplace.

To learn how ICON Medical Imaging’s adjudication services can be custom created for your needs, contact us to schedule a meeting today!

For more information, please contact:

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