

Expertise for biopharma

Leveraging two decades of remote radiology experience and drawing on the expertise of radiologists located across four continents, **Image Core Lab (ICL)** provides a full suite of clinical trials imaging solutions for global biopharmaceutical companies. ICL's clients are based in the US, Israel, Singapore and India.

Across speciality areas, imaging techniques have a critical role to play throughout different phases of drug development. Imaging can provide evidence about the safety and efficacy of drugs, and aid in decision-making. Conventional morphological imaging techniques and standardised response criteria based on tumour size measurements help define key study end-points. Non-invasive imaging techniques, such as computed tomography (CT), magnetic resonance imaging (MRI) and fluorodeoxyglucose positron-emission tomography (PET)/CT, can also help in generating primary, secondary and exploratory study end-points.

Value of radiology imaging biomarkers

An imaging biomarker is a biological characteristic that is detectable on an image. Imaging biomarkers are the cornerstone of modern radiology, and imaging end-points are a critical necessity for patient safety and understanding a drug's effectiveness.

They are key to making appropriate therapeutic decisions and drug evaluations, which is why they require advanced multidisciplinary expertise to provide the most accurate information possible. The two main types are:

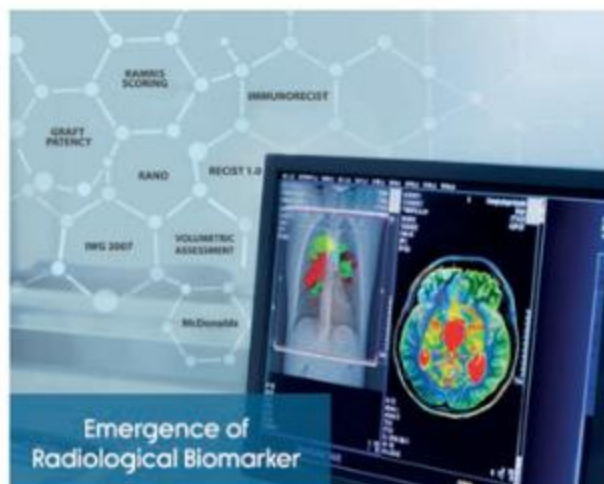
- **Anatomical or functional:** the former refers to the longest diameter of a lesion, size and so on, while the latter concerns the physiological aspects of tumours in images, and may include oxygenation levels, cellularity or vascularity.
- **Qualitative or quantitative:** 'qualitative imaging biomarker' is descriptive, while 'quantitative imaging biomarker' refers to an objectively measured parameter, such as the longest diameter of the nodule decreased by 5mm after treatment, as compared with its size before.

Unique imaging-related requirements for clinical trials

Availability of advanced imaging technologies across geographies influences site selection, especially for multicentre and multinational studies.

A lack of high-speed internet connections and corresponding software can make uploading documents and modifications in compliance with 21 CFR Part 11 difficult, thereby adversely affecting timelines and the quality of the research.

The differences in readers used by various physicians may also stand in the way of obtaining a correct reading and/or evaluation/assessment. Privacy and security concerns, due to imaging systems being connected on the cloud, as well as



Non-invasive imaging is increasingly crucial in drug development.

the GDPR guidelines in Europe, are important considerations. Finally, costs to create core laboratories equipped to handle the sophisticated imaging requirements during clinical trials are significant.

“ ICL's clinical imaging management services include training for site personnel; site management for imaging protocols; quality assurance of the captured images; quality checks for the acquired images; and expert reading, adjudication and formatted reporting until the submission of EDC. ”

Image Core Lab (ICL) has created frameworks and invested in technology that can help address the above challenges. ICL's clinical imaging management services include training for site personnel; site management for imaging protocols; quality assurance of the captured images; quality checks for the acquired images; and expert reading, adjudication and formatted reporting until the submission of EDC. In addition, ICL's investments in robust technology and security protocols – including a cloud-based server and CLINSpa, the company's

proprietary web-based platform for end-to-end management of imaging trial workflow – protect medical imaging records and facilitate easy retrieval. CLINSpa is 21 CFR and HIPAA-compliant with an FDA-approved diagnostic in-built viewer that provides end-to-end management of imaging trial workflow.

Pool of experts

ICL brings the same outstanding consistency and professionalism that the company's parent, Teleradiology Solutions, is known for. The company has a large team of radiology experts who are certified to comply with the regulatory requirements across various geographies.

The company's therapeutic expertise includes oncology, musculoskeletal, central nervous system, neuro-oncology, neuro radiology, cardiac and vascular, and thoracic and pulmonary imaging. Oncology trials are currently ICL's fastest-growing therapeutic area, with over 50% of engagements in oncology trials. ICL is also experienced in large cancer trials with irRC and RECIST 1.1 protocols.

Fellowship-trained neuroradiologists bring in subspecialty-level experience on neurodegenerative diseases such as Alzheimer's and Parkinson's, demyelinating disorders, stroke, epilepsy, neuro-oncology and post-traumatic disorders.

Analytical strength

The company's strength in cardiac MR (CMR) image analysis includes anatomic perfusion, functional imaging, graft patency and stent studies, as well as expertise in nuclear cardiology.

The highest level of expertise is provided in the evaluation of chest radiographs and high-resolution CT of pulmonary disorders, including interstitial lung disease, chronic obstructive pulmonary disease, occupational lung diseases, pulmonary thromboembolism, bronchopulmonary infections and tumours.

Success stories

ICL has played a key role in the success of several clinical trials projects. During the development of Mylan-Biocon's biosimilar for the treatment of breast cancer and stomach cancer, ICL was involved in the clinical analysis of the radiologic images to detect and quantify the radiologic response to the therapy using standardised imaging protocols. Other recent successes include the companies support in the development of a liver cirrhosis drug and a musculoskeletal drug. ■

Further information

Image Core Lab
www.imagecorelab.com



Image Interpretation Challenges In Your Clinical Trials?

Talk to us

We are Image Core Lab (ICL), a world class partner to global biopharmaceutical companies. We provide a full suite of Clinical Trials Imaging solutions to our clients based in the US, Israel, Singapore and India.

- Training of site personnel
- Site management for imaging protocols
- Quality assurance of captured images
- Quality check of acquired images
- Expert reading
- Adjudication
- Formatted reporting till the submission of EDC
- **CLINSpa** – Our proprietary, web-based platform for end-to-end management of imaging trial workflow that is 21 CFR and HIPAA compliant with FDA-approved diagnostic in-built viewer capabilities

Contact us today to speak to our experts for your next study

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