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MEDPACE

# The Key Role of Imaging in Clinical Trials

**50%** of clinical trials need imaging*

Imaging technologies, such as MRI and ultrasound, come with a number of advantages, including non-invasiveness and the potential for early outcome detection, making them promising quantitative biomarkers in the challenging process of drug development. Further support is added by the regulatory authorities, including the FDA, who have provided several guidance documents outlining the importance of imaging in clinical trials for cancer therapies as well as other indications.

## What types of imaging technologies are used in clinical trials?

- **Cross-sectional imaging techniques**, e.g. MRI, SPECT, CT
- **Ultrasound techniques**, e.g. traditional ultrasound, echocardiography
- **X-Ray-based imaging**, e.g. X-Ray scan, DXA, angiography
- **Ophthalmic imaging**, e.g. OCT, fundus photography/angiography
- **Camera-based tools**, e.g. photography, endoscopy, videography

## What are the advantages and limitations of imaging in drug development?

| ADVANTAGES | LIMITATIONS |
|---|---|
| ✓ Widely accepted as surrogate biomarkers for disease response or progression by regulatory agencies | ✗ Limited availability of sites with advanced imaging technology |
| ✓ Non-invasive, allowing repeated evaluations, even when a biopsy is not possible | ✗ Need for fast and reliable data sharing between CRO and sponsor |
| ✓ Reduces long-term study costs | ✗ Acquisition and interpretation variability among facilities and professionals |
| ✓ Shortens drug development and approval timelines | ✗ Critical need to standardize imaging and harmonize imaging biomarkers across sites |

## How to successfully implement imaging and overcome limitations?

Imaging-associated challenges can be overcome by trusting professionals at specialized CROs or Core Labs to manage and complete the imaging process according to all standards and regulatory requirements, ensuring smooth image acquisition, analysis, annotation, and transfer.

## How does Medpace Core Labs support clinical trial development?

As one of the world's top five Imaging Core Laboratories, Medpace is capable of providing the highest quality imaging endpoints for clinical trials across different therapeutic areas. The process of using imaging quantitative biomarkers is further simplified by the integrative and cloud-based systems for data management, analysis, and transfer.

**STUDY INITIATION**
STUDY SETUP & DOCUMENTATION → SITE QUALIFICATION → REGISTER SITES/SUBJECT SCAN PATIENTS

**IMAGE MANAGEMENT**
COLLECT & QC DATA → IMAGE MANAGEMENT → CREATE & SEND WORKLIST TO READER

**READ**
RADIOLOGICAL ASSESSMENT → POPULATE ECRF IN WEB-BASED EDC → READER ECRF QUALITY CONTROL

**DATA MANAGEMENT**
DATA MANAGEMENT → REPORTS (SPONSOR & STUDY) → TRANSFER TO SPONSOR

## Medpace deploys a wide range of imaging biomarkers in clinical trials across therapeutic areas

- HEMATOLOGY/ONCOLOGY
- AUTOIMMUNE DISEASES
- NEUROLOGY
- OPHTHALMOLOGY
- METABOLIC DISEASES
- RARE DISEASES
- CARDIOVASCULAR DISEASES
- MUSCULOSKELETAL DISORDERS

## CASE STUDY: An imaging success story

### Replacing invasive liver biopsy with MRI-PDFF to measure liver fat fraction in liver diseases

Proton density fat fraction (PDFF) measured by magnetic resonance imaging (MRI) is now widely accepted by the regulatory authorities as a biomarker for liver fat fraction in nonalcoholic fatty liver disease and steato-hepatitis.

**Medpace Core Labs successfully implemented a process for using MRI-PDFF in clinical trials to collect harmonized data and return validated, reliable measures for liver fat content.**

## Results:

- Consistent implementation across sites
- Harmonized data according to quality control processes
- Improved reliability of imaging endpoints
- Shorter study timelines
- Reduced cost

Medpace Core Labs provide an end-to-end suite of global imaging services to enhance and expedite biopharmaceutical and medical device development.

Integrate imaging seamlessly into your clinical trial - contact Medpace or visit their website to learn more.


**Sources:**
* Medidata
Medpace
Food and Drugs Administration
European Imaging Biomarkers Alliance - EIBALL
Quantitative Imaging Biomarkers Alliance – QIBA
Cancer Imaging
Insights into Imaging



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