

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

- Widely accepted as surrogate biomarkers for disease response or progression by regulatory agencies
- Non-invasive, allowing repeated evaluations, even when a biopsy is not possible
- Reduces long-term study costs
- Shortens drug development and approval timelines

LIMITATIONS

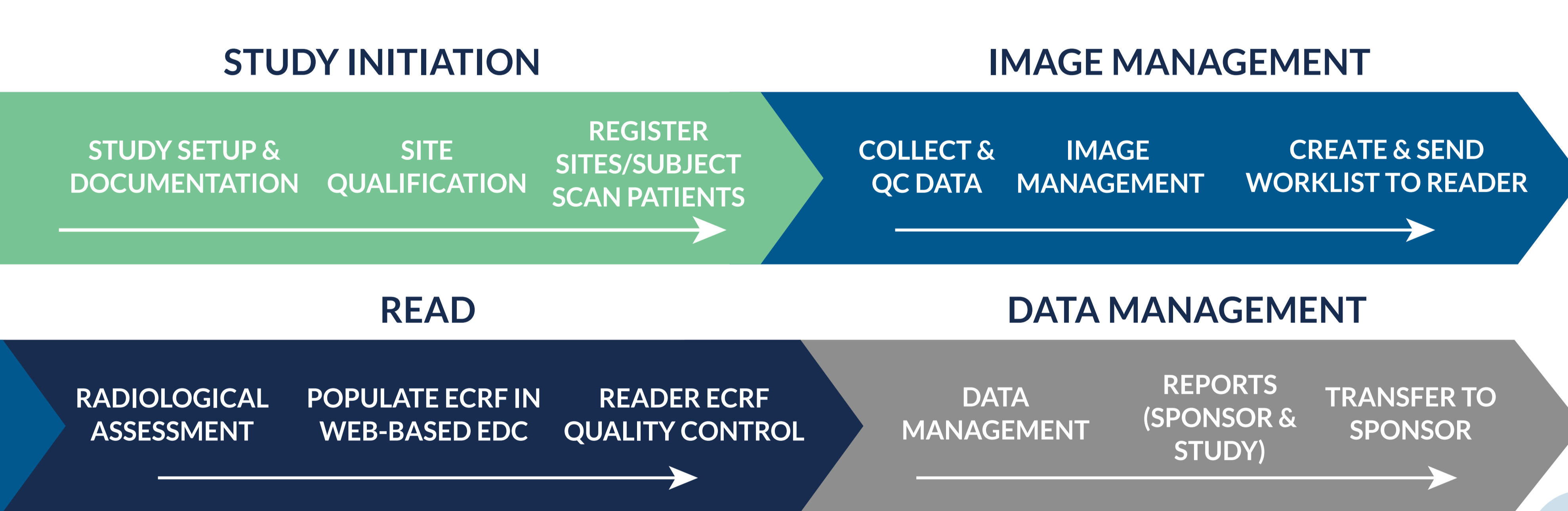
- Limited availability of sites with advanced imaging technology
- Need for fast and reliable data sharing between CRO and sponsor
- Acquisition and interpretation variability among facilities and professionals
- Critical need to standardize imaging and harmonize imaging biomarkers across sites

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.



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