

IMAGING CROs IN CLINICAL RESEARCH TODAY

Within the world of contract research organizations (CROs), there's a smaller, specialized group of entities known as **Imaging CROs (iCROs)**. Experts in medical imaging and its applications in clinical research, iCROs provide imaging services to sponsors and clinical CROs. They also provide a wealth of vital knowledge and insight in key areas such as site qualification for imaging purposes, standardized image acquisition, and read designs or read criteria.

Take a moment to learn more about this highly specialized and increasingly important resource for clinical operations in the 21st century.



THE GROWTH OF MEDICAL IMAGING IN CLINICAL TRIALS

1997



The US Food and Drug Administration Modernization Act (FDAMA) of 1997 created the opportunity for imaging modalities to be used as product development tools in clinical trials by allowing data generated through imaging to be included in regulatory submissions.

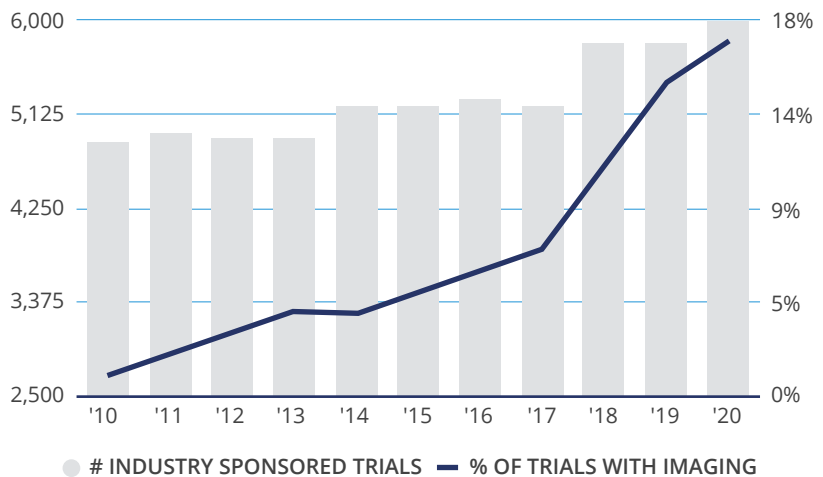
The importance of iCROs has been growing since—along with the importance of medical imaging in clinical trials.

2010 - 2020

% of Industry-Sponsored Trials Using Imaging From Years 2010 - 2020

Although the total number of industry-sponsored trials has remained much the same since 2010, the percentage of those trials using imaging has grown from 0.029% to 16.65%

0.03%
to
16.65%
growth in trials using imaging



The total number of trials has nearly doubled since 2010, but trials with imaging have increased by almost 500%.

2x
growth in total number of all trials

5x
growth in trials using imaging

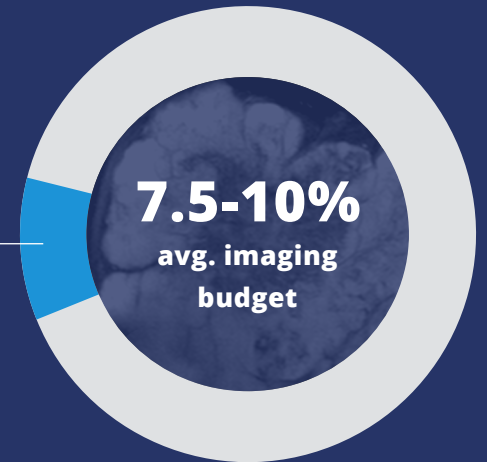
Today, imaging is involved in a wide variety of trials for a variety of purposes, including:

- + therapeutic
- + confirmation of eligibility
- + dosimetry analysis
- + safety
- + tumor response assessment
- + diagnostic
- + confirmation of progression

THE iCRO VALUE PROPOSITION: SMALL PERCENTAGE OF TRIAL BUDGET, GREAT IMPACT ON TRIAL OPERATIONS

iCRO Budget Allocation for Imaging

A CRO spends a surprisingly small percentage of a trial budget on an imaging CRO. On average, in a standard study, 7.5% to 10% of a trial budget is allocated to imaging.



● TYPICAL iCRO BUDGET ● REST OF CRO BUDGET



Benefits of Working With an iCRO

- + Image management using the newest technologies
- + Independent analysis of study data
- + Expert recommendations on read designs
- + Specialist writers for the development of imaging documentation
- + Site training for standardized image acquisition
- + Reader training for harmonized reads
- + Reader performance management for robust results
- + Regulatory support every step of the way

HOW IMAGING FITS INTO THE CLINICAL OPERATIONS WORKFLOW

The complexity of global multicentric trials using advanced imaging modalities makes it essential to develop an optimized workflow to manage every step of the process from image acquisition to interpretation. Partnering with an iCRO gives sponsors the technology and the project management services that can make this effortless and trouble-free.

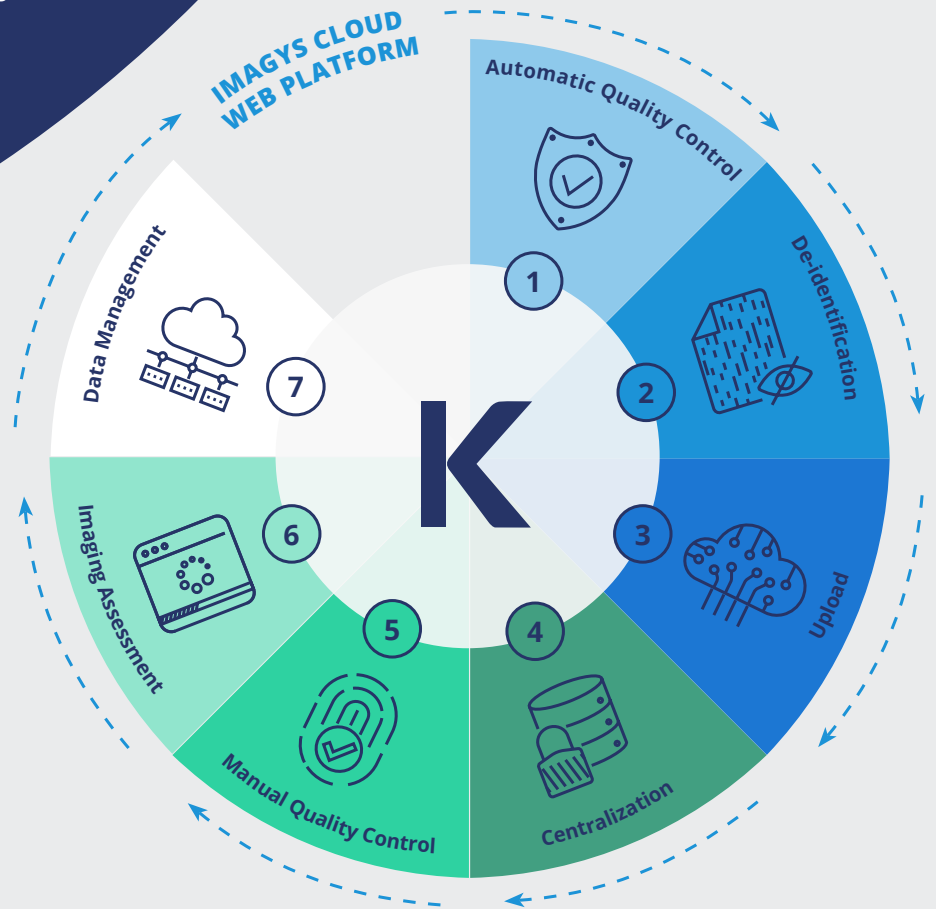
Consider our process at Keosys by way of example:

24/7 Availability

The Imagys platform is available 24 hours a day, 7 days a week from anywhere in the world. Metrics, operational and scientific dashboards, project management tools, and reports are all available in the Imagys centralized repository.

Project Management

Keosys also provides dedicated project management teams to offer guidance and support for all imaging related questions and issues throughout the trial.



To manage the workflow in clinical trials where imaging is a primary or secondary endpoint, Keosys has developed Imagys, an integrated, web-secured platform. Imagys allows for the sequential management of the imaging workflow from the first image upload to the final central independent review.

KEY TAKE AWAYS

- 1** The use of imaging in clinical trials is growing steadily
- 2** Working with an iCRO will provide sponsors with multiple benefits at a modest cost
- 3** Partnering with an iCRO makes imaging easy for any sponsor

0.03% to 16.65%

increase in trials using imaging from years 2010-2020

Imaging averages

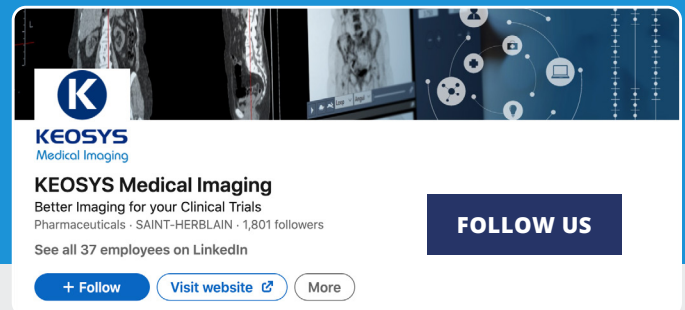
7.5% to 10%

of the total budget allotted for a clinical trial.

CONTACT KEOSYS

Connect with us on LinkedIn

We regularly share industry updates on what's going on in the medical imaging and pharmaceutical industries.



The image shows a screenshot of the KEOSYS Medical Imaging LinkedIn profile. At the top, there is a banner image featuring medical scans and a network diagram. Below the banner is the company logo, a blue circle with a white 'K', followed by the text 'KEOSYS Medical Imaging'. The profile name is 'KEOSYS Medical Imaging' with the tagline 'Better Imaging for your Clinical Trials'. Below this, it says 'Pharmaceuticals · SAINT-HERBLAIN · 1,801 followers' and 'See all 37 employees on LinkedIn'. At the bottom, there are three buttons: '+ Follow', 'Visit website', and 'More'. On the right side of the profile, there is a dark blue button with the text 'FOLLOW US' in white.

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