

ROBUST IMAGING

Realise the true potential of your next RA study. Quantitative DCE-MRI provides the next generation of markers of disease status and drug action. Bioxydyn and Imorphics offer a one-stop world-class service which combines site training, automated 3D lesion identification, automated RAMRIS-style scoring and quantification of microvascular status in inflammation.

imorphics

 bioxydyn



Robust imaging

There is a need for robust biomarkers of inflammatory disease processes

Arthritis is an autoimmune disease that results in chronic inflammation and affects primarily the synovial joints of the body. In the United States alone, 52.5 million adults have been diagnosed with some form of arthritis - this figure is expected to rise to 67 million by 2030. Current therapies aim to alleviate signs and symptoms of the disease, improve the quality of life and prevent additional structural damage. We are now in an era of biologically targeted therapies that target the autoimmune response directly and these are increasingly being developed by the pharmaceutical industry. Of the drugs that get approved, Phase III clinical trials typically represent 90 percent or more of the cost of developing an individual drug from laboratory to pharmacy. The pharmaceutical industry continues to pump more money into randomised clinical trials, but fewer drugs are being approved. Clearly, more evidence is needed to support the right drugs into late phase development.

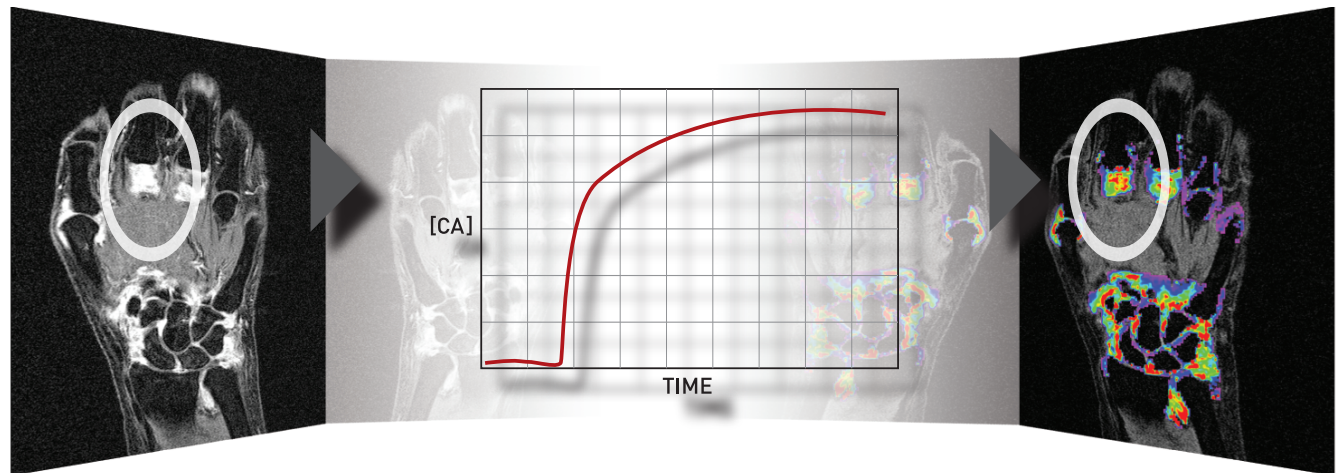
There are new challenges arising. The response of inflammatory arthritis to a wide spectrum of therapeutic strategies attests to the complexity and heterogeneity of the disease. Different types of patients, influenced by their genetic background, may respond differently to different agents. Patient stratification based on robust imaging biomarkers may direct decision-making in the choice of biologic to use in inflammatory arthritis.

The role of advanced imaging in rheumatoid arthritis

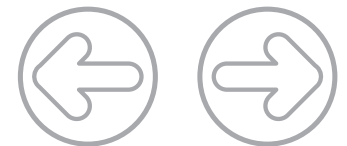
There is a need for more sensitive tools that provide insight into underlying mechanisms of drug action and efficacy. Non-invasive assessment of joint disease using magnetic resonance imaging (MRI) sheds light on disease status and the impact of therapy by providing repeatable and sensitive biomarkers of inflammation and tissue damage. The quantitative measurements provided by techniques such as dynamic contrast-enhanced (DCE) MRI enable serial assessment of changes in tissue functional status and have been shown to be sensitive to disease modifying agents.

More than just pictures

Quantitative MRI provides biomarkers of the extent and magnitude of abnormalities in tissue function. More than any other imaging modality, MRI has the ability to provide sensitive and non-invasive quantification of disease related features.



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Robust imaging in Practice

Innovative study design

Quantitative imaging measurements of the physiological effects of novel therapeutics at the microvascular level are increasingly integral to clinical trials. Whether a client is interested in looking at joint perfusion, permeability, or quantification of the RAMRIS measures - synovitis, erosion, oedema or joint space width, we have a range of quantitative image analysis technologies for use in every study of inflammatory arthritis.

We can provide expert scientific input into your study from the onset. We can advise on the best imaging technologies to use, the most appropriate imaging biomarkers and sample sizes to meet study goals.

Imaging site qualification

We understand that successful image acquisition is one of the most important aspects of an imaging study – without the best quality images the attrition rate and cost of your study will increase.

Sophisticated image analysis often requires advanced and innovative – yet robust – imaging strategies that can be standardized across a range of scanner platforms and field strengths. We send imaging experts to imaging sites to implement and test imaging protocols prior to use in the study live phase, and train radiological staff to execute the imaging protocol successfully.

Imaging handling and logistics

Fast turnaround of image QC relies on speedy image transfer from imaging site to our central analysis location. We train radiological staff in image transfer procedures and enable transfer of images immediately following a study scan.

All image transfers comply with 21 CFR 11 and HIPAA regulatory standards to ensure your images are secure.

“Unfortunately, a site visit is often an unpleasant side effect that comes with participating in medical research. However, that was not the case with Bioxydyn. They travelled great distances to visit my site for the purposes of setting up MR protocols for an upcoming study. But instead of being fatigued, I found them both to be engaging, intelligent and sincere. They are both very skilled at their work, and yet light-hearted, and that translated into a confidence that was very refreshing and enjoyable. At the end of the visit, I was actually disappointed that they were leaving.”

Bill Stuhl, Precision Imaging Centers, Jacksonville, Florida, US



Robust imaging receipt & QC

We have a team of trained imaging scientists and technicians who rigorously QC your images upon receipt. Key image parameters are automatically verified to ensure compliance to protocol and common sources of error are identified in images, if present.

We provide essential feedback regarding the quality of images within 24 hours of receipt to highlight areas of concerns according to a well-defined and thorough image QC procedure. Our strong site relationships help to resolve issues quickly and minimize loss of data.

Robust imaging biomarkers

Our high quality data input processing ensures the highest quality imaging endpoints are produced and delivered to the client. We can apply automated algorithms from our proprietary software, armed with years of peer-reviewed expert academic development and we can design and develop bespoke image analysis tools depending on your specific requirements. Every quantitative parameter produced is closely QC'd to guarantee its validity.

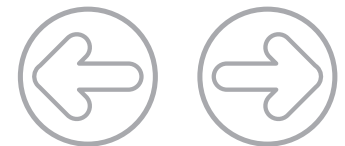
The power to make decisions

Being able to apply advanced technology in a robust, reliable and repeatable manner is challenging for multi-centre, global studies – many fail to deliver.

Our focus and effort on study design, site qualification, image receipt and rigorous QC ensures that maximum quality imaging readouts are delivered to the client, reducing overall costs from unreliable data and maximizing value.

Each study is led by scientific experts in the field, managed by meticulous project managers and delivered by trained imaging and data scientists so you can be confident that your imaging study is as valuable as you need it to be and enable you to make early go/no-go decisions about potential drug efficacy.

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Make your study picture perfect.

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