CASE STUDY

Using DXA in Clinical Trials

SCENARIO

Several clients have sought help to understand dual-energy X-ray absorptiometry (DXA), including core labs looking to expand into the DXA market, DXA platform developers, and companies running clinical trials that include DXA readouts.

Quality Advisement

"Let's face it: In the life science industry, there's challenges at every turn.

Thankfully, Bracken's team is comprised of talent from the biggest names in pharma, digital health, medical imaging, and software to back our clients with industry knowledge and subject matter expertise.

We'll support you and your team with quality advisement to ensure you have the knowledge needed to make only the best, evidence-based decisions.

The life science markets are tough to navigate---don't go it alone.

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THE CHALLENGE

Osteoporosis clinical studies often use DXA to examine bone density in trials of drugs that could adversely affect bone, as well as studies evaluating adipose tissue and muscle, including studies of obesity, sarcopenia, and cachexia. The challenge lays in utilizing the right expertise for our clients to leverage this knowledge to correctly incorporate DXA in clinical trials.

THE STRATEGY

Thankfully, members of our group have excellent credentials qualifying them to advise on numerous DXA-related topics.

- Bracken CEO, Colin Miller, and an associate Derek Pearson wrote the book on DXA, "Clinical Trials in Osteoporosis" (2007).
- Colin has previous experience on the ultrasonic assessment of bone from his PhD thesis and continued a few years later supporting the clinical development for the FDA PMA for the Lunar Achillles ultrasound device.
- He also served on numerous clinical advisory boards using bone densitometry as a critical measurement, including as a safety signal, such as the trials of the anti-diabetic drugs rosiglitazone and canagliflozin, the anti-acne compound isotretinoin, and drugs to treat endometriosis and fibroids Eligolix or Orilissa.
- 2 DXA phantom patents are held by Colin: The bona fide phantom for bone mineral density (BMD) and the variable composition phantom (VCP) for body composition.

THE OUTCOME

Guidance has been provided on DXA to both providers and end users of DXA-based measurements who specifically sought their opinion as DXA thought leaders.

Next, we'll get into the specifics.

CASE #1
ACHIEVING DXA ANALYSIS CAPABILITIES

PROBLEM

An imaging core lab with plenty of experience in imaging for clinical trials wanted to expand into the growing DXA market though they had extremely limited experience in DXA. Both a business and a clinical perspective on the DXA market were provided to this client.

SOLUTION

A series of lectures including on-site discussions provided the underlaying concepts of DXA in clinical trials. The quantitative nature of DXA means that the machines for each clinical trial site need to be standardized using “calibration phantoms” to synchronize protocols across all sites.

Two patents related to DXA calibration phantom design (the one that has been used in more than a hundred clinical trials is the Bona Fide Phantom) were instrumental in informing the lab visit.

THE RESULT
HIGH QUALITY DXA ANALYSIS

Our client was provided with a tailored plan on how to develop the technology in-house, ensuring the client’s ability to provide high-quality DXA analysis and take advantage of this lucrative opportunity

THE RESULT
DXA READINESS FOR FUTURE APPLICATION

Analysis has allowed the company to be ready for the future, and using an ice hockey analogy from Wayne Gretzky, to play “where the puck is going to be.”

CASE #2
COMPREHENSIVE DXA KNOWLEDGE

PROBLEM

A manufacturer of DXA machines sought advice on their next round of product development. The manufacturer wanted to understand how and for what DXA might be expanded and wanted to make sure any product line extensions would be ready for users in a timely manner.

SOLUTION

We guided the client in where DXA could be used in development of future pharmaceutical products. Software types that future clinical trials are likely to want were outlined based on an understanding of how the technology could be used, in bone as well as other tissue.

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