

# Achieving High Quality Imaging with Perceptive after Other Providers Failed to Deliver

## Situation

An emerging biotech company turned to Perceptive Imaging after other centralized imaging providers failed to deliver reliable imaging services. They were looking for partners to help them achieve high quality imaging data to support their studies' endpoints. The studies focus on novel therapies in rare diseases, namely sickle cell disease and cerebral adrenoleukodystrophy. Both studies require qualitative assessments based on MRI images. In addition, the sickle cell disease study requires quantitative assessments based on advanced MRI techniques as well as TCD/TCDi. Taken together, study eligibility, efficacy and/or safety measurements will be supported by imaging.

The other providers couldn't manage the complexity required by the study protocols and did not act as a true partner to the biotech company. As a result, the sponsor faced numerous risks, including inconsistent, poor quality imaging, a lack of comprehensive imaging assessments/analysis, and limited scientific and operational expertise that would have impacted their development of novel compounds for the treatment of rare diseases.

## Challenges

The sponsor was not satisfied with the previous providers' scientific and operational capabilities and was concerned with the realization of the studies' endpoints:

### Imaging Quality

- ▶ Imaging Acquisition Guidelines were convoluted, without sufficient detail, and difficult for the sites to adhere
- ▶ Site qualification and image quality control was not diligently performed
- ▶ Site communication was not comprehensive

### Image Review and Analysis

- ▶ Lack of scientific and medical rigor in Independent Review Charter
- ▶ Insufficient guidance and monitoring of the independent readers

## Solution

Utilizing our scientific and medical expertise, proven processes, experienced operational management, and robust systems, Perceptive ensured a smooth transition and delivered:

### Imaging Requirements and Guidelines

- ▶ Simplified, detailed, and streamlined Imaging Acquisition Guidelines to increase compliance, ensure quality, and reduce site burden
- ▶ 3-step site qualification process, which includes understanding site capabilities, training the site staff, and requiring a test scan

- ▶ Perceptive's ongoing relationship with the sites ensured good quality image acquisition without imposing additional burden to the site or patients

#### **Independent Review Charter**

- ▶ Fully re-written comprehensive independent review charter including the MRI and TCD assessments, which enabled robust eCRFs to be developed and reviewer trainings to be conducted

#### **Consulting**

- ▶ Perceptive's scientific and medical team is available for consulting to support protocol amendments, data interpretation, and any other questions that may rise throughout the study

## **Results**

The studies are now running efficiently, and Perceptive is on track to deliver key imaging data to the sponsor in line with their studies' milestones. Feedback from the sponsor is the quality of the current imaging charter is significantly improved and they are confident that they will receive high quality imaging data to support their study endpoints.

Contact [hello@perceptive.com](mailto:hello@perceptive.com) to learn why you can rely on Perceptive Imaging to help your study succeed.



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