Clinical Trial Consultation Support Services

diagnosys
leading the wave

Ophthalmic Electrophysiology & Psychophysical Diagnostics for clinical trials

Diagnosys offers the most comprehensive hardware, software and service solutions for preclinical and clinical trials. We have supported over 100 trials during the past 30 years. Hundreds of peer-reviewed papers have been published using Diagnosys equipment.

Luxturna®, the first FDA approved gene therapy treatment for a genetic disease, used the Diagnosys*FST* to measure the efficacy of its novel therapy. Diagnosys supported Spark Therapeutics, Inc. all the way from preclinicial research to worldwide implementation for Luxturna®.

World-class capabilities for small and large Biotech and Pharma companies

We have extensive experience with both multi- and single-site studies that can range from months to years. For decades, we have worked directly with study sponsors, CROs and clinical sites.
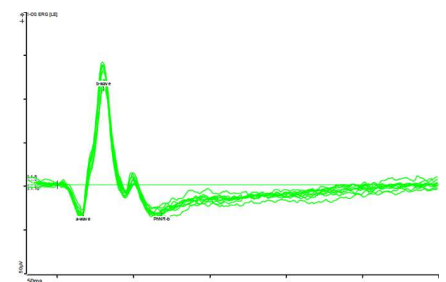
Our expertise in vision function testing

In addition to the standard electrophysiology tests, we offer psychophysical tests that can quantify visual function even when there is no discernable ERG response. We specialize in making custom protocols for testing novel therapies in both humans and animal models.

Vision function tests for all diseases and vision stages, including 'No Light Perception'

- Diagnosys*FST*
- Pupillometry
- Dark Adaptometry
- Electrically Evoked Response (EER), not available in the US
- Light Discomfort Test
- Novel ERG, mfERG, PERG and VEP options

Unmatched repeatability of ERG responses from 12 test sessions

Diagnosys Clinical Trial Package

Tests designed to measure exactly what your trial requires

Start your study off right by consulting with Diagnosys about which vision function tests are most appropriate for your study. We will then create custom protocols and manuals for it.

- **Pre study consultation**
- **Protocol customization**
- **User manual creation**
- **Customized print reports for data export**
- **Software customization**

Every site is setup exactly the same and locked in place

For each testing site, install and train staff on new protocols, then lock down the software to ensure uniformity and consistency across sites.

- **System setup**
- **Technician training**
- **Stimulator re-calibration**
- **Monthly ongoing support**

Data delivered that answers your trial's questions

Analyze the quality of data, prepare summary documents and transfer data.

- **Data collection, summary, analysis and interpretation**
- **Central upload site for trial data**
- **Backup, restore and recovery features**
- **Data and test transfer**