Ophthalmology Experience

BioClinica has considerable experience working in a multi-study sponsor clinic model with rapid study starts. Our ophthalmic experience includes:

- Macular Degeneration
- Diabetic Retinopathy
- Macular Edema

Additionally, we have optical device experience in the following categories of studies:

- Sphere
- Presbyopia
- Custom Lens
- Toric
- Dry Eye Lens Studies

Optical Coherence Tomography (OCT)

Optical Coherence Tomography

OCT is a powerful imaging technique providing both quantitative and qualitative information about the histological details of the retina and optic nerve with a resolution of approximately 5 microns. OCT is a painless non-invasive technique, analogous to “optical ultrasound”, based on the principle of light interferometry. OCT measures either the echo time or the intensity of reflected or backscattered light from intra-retinal microstructures providing a real-time image of the microscopic retinal tissues closely reflecting histological sections of the macula and fovea.

The benefits of integrated structural imaging and functional imaging will play an increasingly important role in clinical applications. OCT optical sections visualize the succession of retinal layers and retinal pigment epithelium (RPE) and the presence of any spaces between those layers.

Indications and Potential Uses

- Age-Related Macular Degeneration (AMD)
  - Macular holes
  - Macular Puckers
- Macular edema
- Thickness of Retinal Nerve Fiber layer (RNFL) thinning – Glaucoma
- Photoreceptor Layer Thickness
- Refractive Surgery (anterior segment) (LASIK)
- Retinal Pathologic Conditions
  - Retinal thickening (measured between the inner limiting membrane and RPE)
  - Alterations of RPE frequently associated with choroidal neovascularization (CNV)

Response to Treatment

OCT examinations appear to be very useful in defining indications for modern treatments by intra-vitreous injections and the analysis of the response to treatment. Consistent OCT examinations are easy to perform with no pain and minimal discomfort. The results can be used to demonstrate complete or partial resolution or persistence of sub-retinal and/or intra-retinal fluid accumulation and cystoid edema and the various alterations of the outer retinal layers and signs in reaction to the presence of CNV.
BioClinica, Inc. is a leading global provider of integrated, technology-enhanced clinical trial services. BioClinica supports pharmaceutical and medical device innovation with:

- Imaging Core Lab services
- Electronic data capture
- Interactive voice and web response
- Clinical supply chain design and optimization solutions

BioClinica services maximize efficiency throughout all phases of the clinical trial process. With more than 2,000 successful trials to date, BioClinica has supported the clinical development of many new medicines from early phase trials through final approval.

BioClinica operates state-of-the-art, regulatory compliant imaging core labs and supports worldwide eClinical and data management services from offices in the United States and Europe.

For more information, please visit www.bioclinica.com.

Optical Coherence Tomography in Neurology

The use of OCT as an exploratory end point is growing for a number of neurological indications. The access to the optic nerve provides a unique insight into the deeper actions of the central nervous system. The optic nerve appears to reflect changes that are occurring in deeper brain tissue. Specifically, OCT is being evaluated in:

- Multiple Sclerosis
- Alzheimer’s Disease
- Neurodegenerative Diseases

Collaborative Development

BioClinica has been working with the Optic Nerve Research Center under the leadership of Dr Robert Sergott, Director of Neuro-Ophthalmology:

- The OCT Reading Center and Clinical Investigator for 12 Ophthalmic studies.
- BioClinica provides the logistics management.
- Dr. Sergott’s Team provide the consulting, QC and reads.