

EXPERTISE

Ophthalmology





SMALL DISCIPLINE - BIG IMPACT

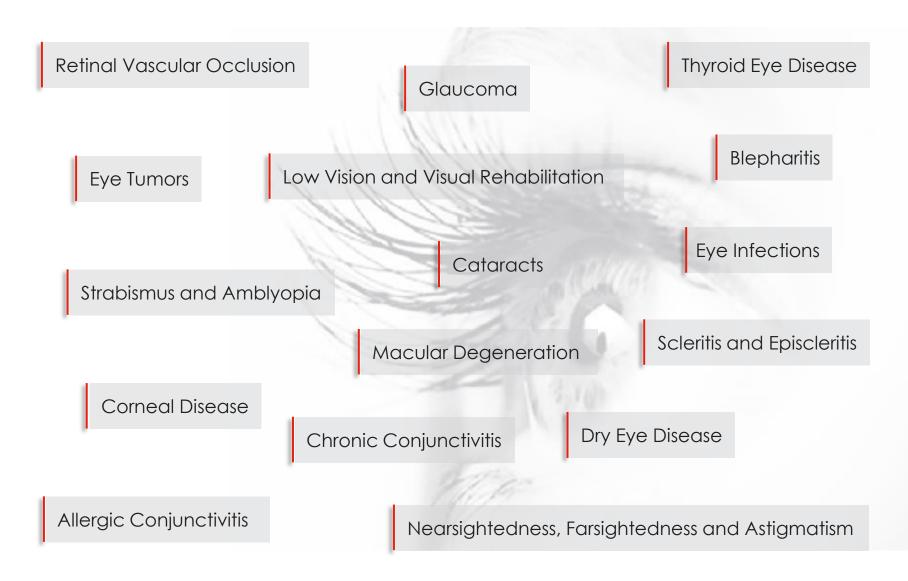


OPHTHALMOLOGY

- Rapidly growing discipline
- Multifaceted patient populations
- Wide range of acute and chronic diseases
- Unmet medical needs
- Insight into internal and neurological conditions

VARIETY OF EYE DISORDERS





MORE THAN MEETS THE EYE



- Optic neuritis
- Blurred vision
- Retinal nerve fiber layer thinning
- → e.g. Multiple sclerosis
- → e.g. Parkinson's disease
- → e.g. Alzheimer's disease

CHARACTERISTIC SIGNS

concomitant & significant

NEUROLOGICAL DISEASES



INTERNAL DISEASES

visible & assessable

EYE DIAGNOSTICS

- Arteriolar thinning, retinal crossing signs
- Soft and hard exudates, neo-proliferations
- Arterial hypertension, cardiovascular diseases
- → Diabetes mellitus, metabolic syndrome

EYE-OPENING PARAMETERS FOR CLINICAL RESEARCH



FUNCTIONAL MARKERS

(routine technologies)

- Visual acuity
- Contrast vision
- Contrast sensitivity
- Visual field

PATIENT-REPORTED OUTCOMES

- NEI VFQ-25
- QoL
- EQ-5D

- SF-36
- Glaucoma Utility Index

MORPHOLOGICAL MARKERS

(more specialized technologies)

- RNFL thickness (OCT)
- Foveal thickness (OCT)
- Optic disc assessment
- Lesion size (CNV, GA, etc.)
- 'Flicker-light' induced retinal vasodilatation
- Retinal beta-amyloid accumulation

OUR SERVICES



TAILORED TO YOUR NEEDS

INNOVATIVE CONCEPTS



- clinical trials
- value dossier
- non-interventional studies



- drugs
- medical devices



- involvement of an experienced ophthalmologist at every step
- medical advising
- study planning
- cooperation with an established
 tele-ophthalmological network
 (talkingeyes&more®)

RELIABLE SERVICE



medical writing



regulatory



project management



quality assurance



biostatistics



vigilance



data management



OUR EXPERIENCE (I)



Clinical Studies (n = 13)

Eye infection following cataract surgery: phase IV

Eye irritation: phase IV

Visual performance: phase IIIb/IV

Choroidal neovascularisation: phase III

Epithelial keratitis herpetica: phase III

Eye infection: phase I

Eye infection following cataract surgery: phase III

Choroidal neovascularisation: phase III

Eye infection following cataract surgery: phase IV

Eye infection: phase I

Eye infection: phase I

Neovascular (wet) age-related macular degeneration: phase III

Allergic conjunctivitis: phase III

OUR EXPERIENCE (II)



Non-interventional Studies (n = 8)

Other Projects (n = 3)

Glaucoma and dry eye

High intraocular pressure and glaucoma

Glaucoma

Allergic conjunctivitis

Eye infection following cataract surgery

Glaucoma

Eye infection

Ocular hypertension, open-angle glaucoma

Eye conditions in kids: literature research and analysis

Glaucoma: publication service

Ophthalmology: site recruitment and feasibility



Your personal contact:



Dr. med. Christoph Engler, FEBODeputy Head of Medical Advising and Clinical Safety Fellow of the European Board of Ophthalmology c.engler@gkm-therapieforschung.de

GKM Gesellschaft für Therapieforschung mbH

Lessingstraße 14 D-80336 München Phone +49 (0)89 20 91 20-0 Fax +49 (0)89 20 91 20-30 www.gkm-therapieforschung.de

