

# What's hot and current in ophthalmology

## ... and what is missing?

30 April 2014

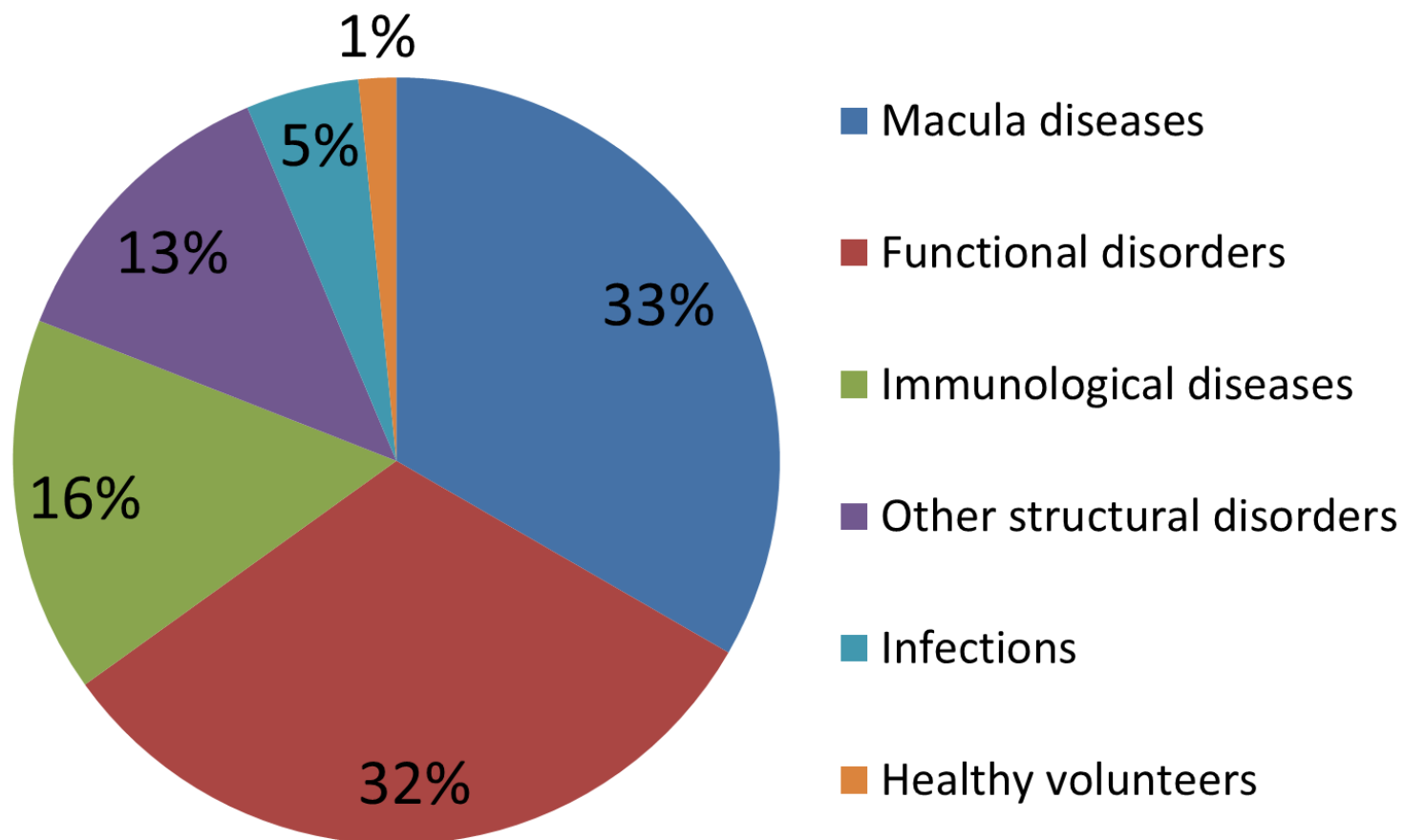


# Cross-sectional review of ophthalmology clinical trials

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- **Sources**
  - Online searches, BioPharmClinica®, clinicaltrials.gov, EU clinical trials register
- **Search criteria**
  - Ophthalmology
  - Phase 1 – 3
  - Interventional
  - Ongoing (incl. temporary halt of recruitment)
  - Date: 31st March 2014
- **Found**
  - 63 different clinical trials

# Trials by indication



# Indications (1): Macula

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*Number of clinical trials:*

- All macula diseases 21
  - Choroidal neovascularisation due to macula degeneration 4
  - Dry macular degeneration 2
  - Wet macular degeneration 1
  - Macular dystrophy 2
  - Macular edema due to retinal vein occlusion 10
  - Macular edema due to diabetes mellitus 1
  - Macular teleangiectasia 1

# Indications (2): Immunological

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*Number of clinical trials:*

- All immunological diseases 10
  - Choroiditis 1
  - Neurotrophic keratitis 1
  - Immunological keratitis 1
  - Ligneous conjunctivitis 1
  - Optic nerve neuritis 2
  - Retinitis pigmentosa 3
  - Uveitis 1

# Indications (3): Structural

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*Number of clinical trials:*

- Other structural disorders 8
  - Amaurosis 3
  - Cataract 1
  - Choroidal neovascularisation due to myopia 2
  - Vitreoretinal adhesion 1
  - Retinal vein occlusion (neovascularisation) 1
  
- Infections 3
  - Bacterial infection 1
  - Viral keratitis 1
  - Non-bacterial blepharitis 1

# Indications (4): Functional

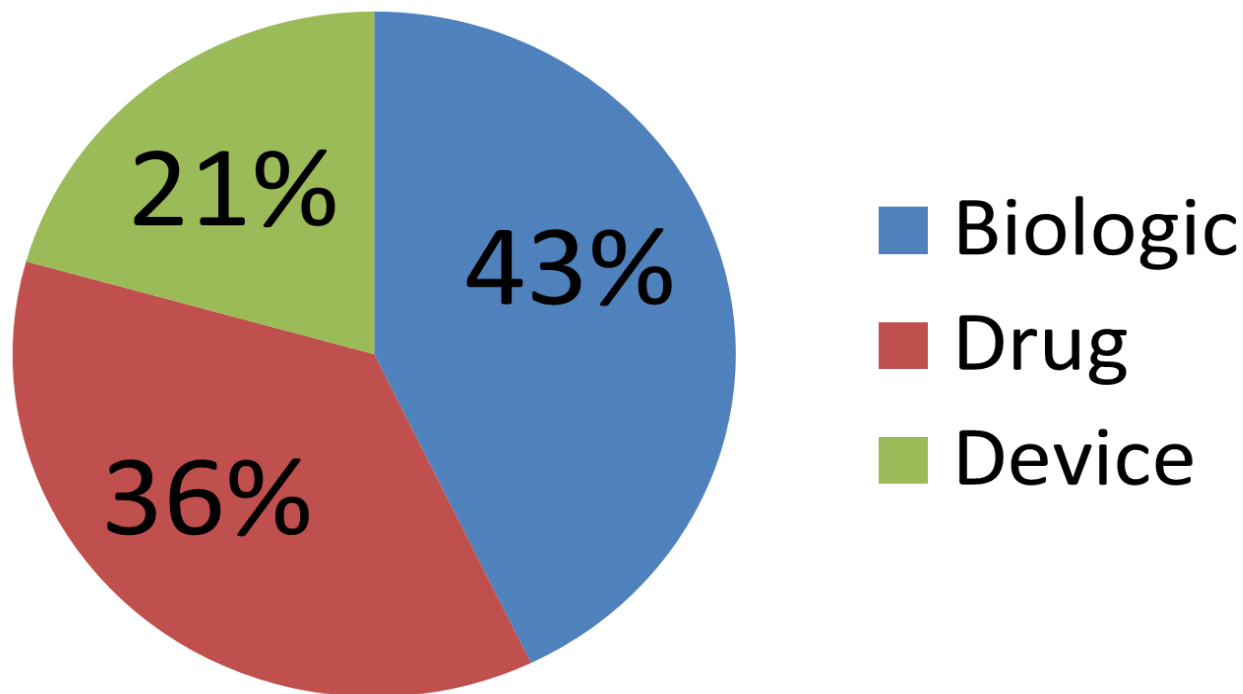
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*Number of clinical trials:*

• All functional disorders	20
◦ Glaucoma	11
◦ Ocular pain	1
◦ Strabismus	1
◦ Refractive error	7
• All others	1
◦ Healthy subjects	1

# Trials by type of product

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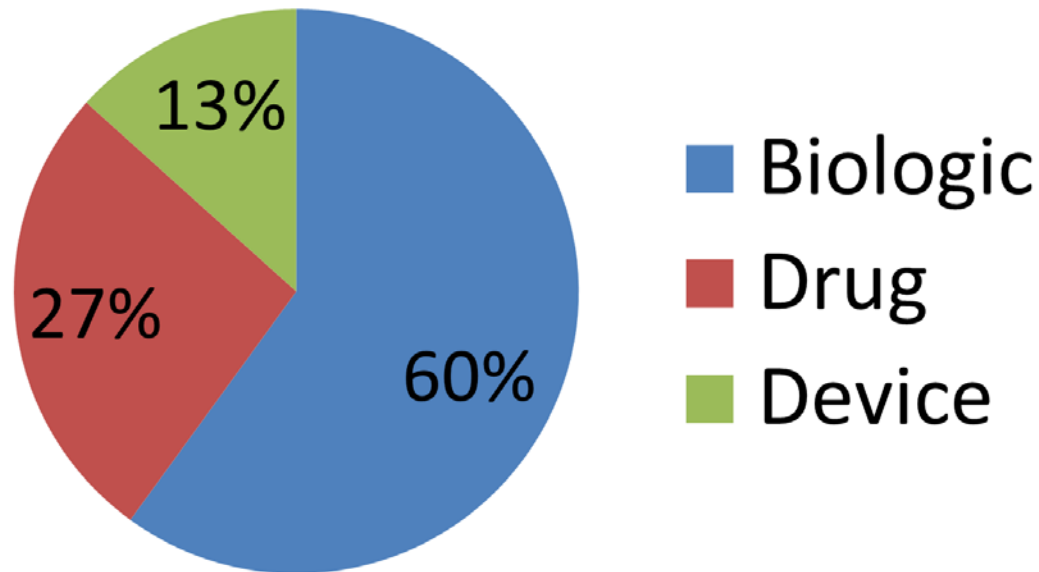


*Note: 'Drug' includes drug-eluting implants.*



# Trials by type of product - narrowed

- All trials in glaucoma are with small molecular drugs.
- All trials in refractive errors are with devices.
- ➔ The above is not surprising. If these two areas are ignored, the distribution of products is:





# Conclusions

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- Clinical research is dominated by biotechnology.
- Most research is in macula\* diseases.
- Immunological eye diseases are receiving much attention.
- In glaucoma, very few products are in new pathways (kinase inhibitors); most new products for glaucoma rely on established mechanisms.
- Some new products are tested in rare eye diseases.

*\* No surprise: The smallest part of the retina with the biggest impact on vision causes frequent problems in industrial countries.*



**But some diseases are missing ...**



# Ocular manifestations

Autoimmune disease	Frequency of ocular symptoms, main symptoms *
Rheumatoid arthritis (adult)	25% - scleritis, keratitis, conjunctivitis
Juvenile rheumatoid arthritis	80% - uveitis
Ankylosing spondylitis	25% - uveitis
Psoriatic arthritis	20% - uveitis, keratitis, conjunctivitis
Systemic lupus erythematoses	20% - inflammation of any part of the eye
Multiple sclerosis	75% - optic neuritis
Giant cell arteritis	50% - visual loss, pain
Grave's disease	50% - exophthalmos
Beçet's disease	100% - uveitis, hypopyon

Rare eye disease	Disease mechanism
Bietti's crystalline dystrophy	Linked to gene CYP4V2, related to fatty acid metabolism

\* Source: Patel et al., Am Fam Physician 2002, 66(6):991-998

# Conclusions (2)

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- Manifestations of autoimmune diseases of the eye are frequent and severe.
- ➔ But clinical trials in systemic autoimmune diseases very often do not assess ocular symptoms.
  
- The eye is more accessible than the internal organs.
- ➔ But there are no new products for ocular manifestations of autoimmune diseases.
  
- Some rare eye diseases offer new targets.
- ➔ But there is no apparent research.
  
- ➔ **Maybe it's time for a fresh look at forgotten or rare eye diseases?**



# How can we help you?

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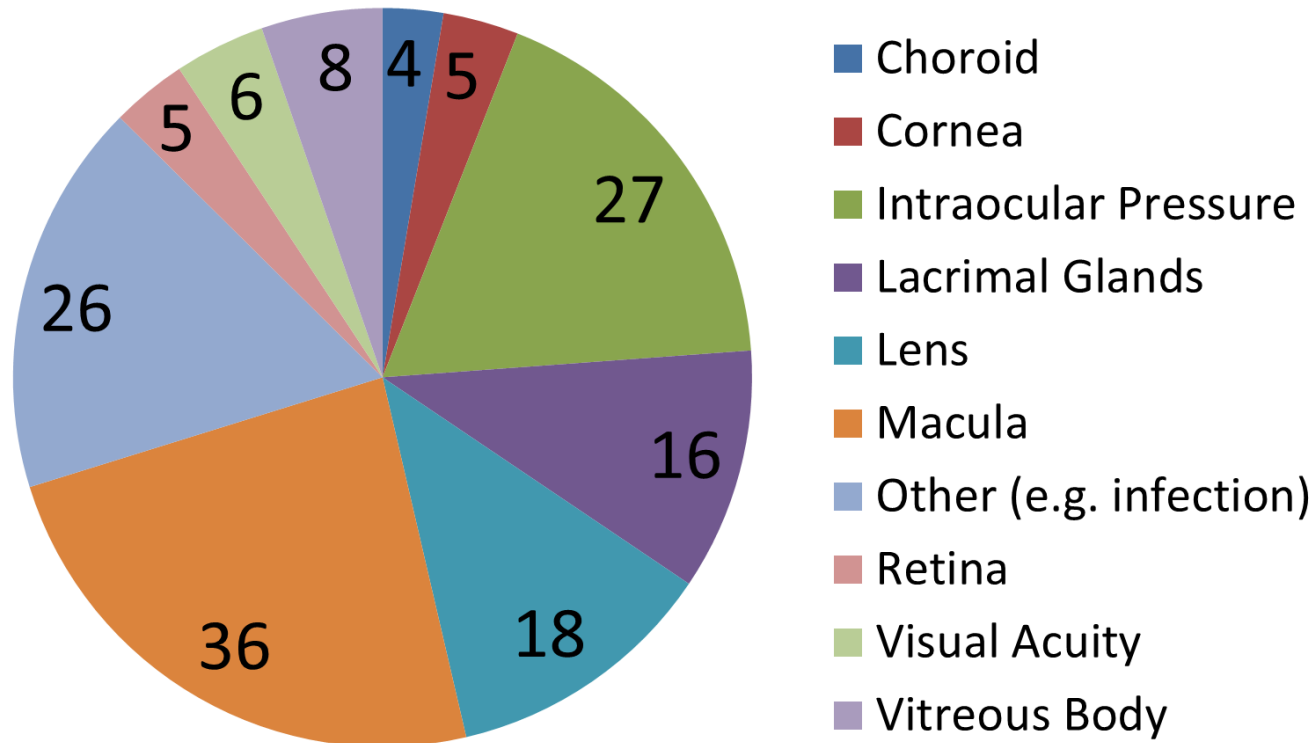
- If you want to take a new look at ocular manifestations of autoimmune diseases, we can help you with:
  - **Our vast combination of experience and research** in eye diseases, autoimmune diseases and in rare diseases
  - **Dual indication studies** involving feasibility, site identification, practical study scenario, logistics and performance
  - **Smarter statistical analysis** of autoimmune disease data, taking eye symptoms into account
    - Gatekeeping Procedure, A-priori Ordered Hypotheses, Pre-specified Sub-study, Stratified Randomisation, or other
  - **Smarter protocols** in autoimmune diseases with special consideration of eye symptoms
  - **Sophisticated treatment protocols** in the specific indication of autoimmune eye diseases, combining systemic background treatment with specific eye treatment



# SynteractHCR experience in ophthalmology

# All around the eye ball

SynteractHCR has conducted more than 150 clinical trials in ophthalmology, categorized below by the affected eye area:







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