

Ophthalmic community perception of new medication needs

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Abstract

• **AIM:** To survey ophthalmologists (who have participated previously in clinical research) and ophthalmic industry professionals (who have been involved in ocular research and development) to indicate perceived needs for new pharmaceuticals in various ophthalmic subspecialties.

• **METHODS:** A prospective, industry-based survey was sent to ophthalmologists and ophthalmic industry professionals about the perceived needs for new pharmaceutical products.

• **RESULTS:** This survey was sent to 559 ophthalmic pharma professionals and ophthalmologists. We received 82 (15%) responses. The results showed that the most commonly perceived need for new pharmaceuticals were dry and wet age-related macular degeneration, glaucoma, diabetic macular edema and dry eye. There was a statistical difference found between response groups ($P < 0.0001$). Respondents indicated they would express their commitment to a new product they perceived as needed by recommending to colleagues (63%), prescribing (60%), participating as principle investigator in a related clinical trial (52%), advising the company (52%), lecturing on behalf of the product (43%), investing in the product (38%), taking no action (7%) or obtain a position in the company (1%).

• **CONCLUSION:** Ophthalmic pharma professionals and ophthalmologists perceive the greatest need for new medicines in ophthalmology to be in dry and wet age-related macular degeneration, glaucoma, diabetic macular edema and dry eye.

• **KEYWORDS:** ophthalmic; ophthalmology; ocular; eye disease; pharmaceuticals; start-up; development; needs; medication; therapies; future; new treatments

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INTRODUCTION

The development of new pharmaceutical products is important to advance ophthalmology as a medical specialty and to reduce the suffering and blindness of patients. Blindness and visual impairment affect an estimated 300-400 million people globally and around 80% of people living with blindness are aged 50 and above^[1-2]. Considering ageing populations an investment in an ophthalmic start-up may be attractive because of the potential for financial payback, perhaps as much as seven to tenfold^[3-5]. However, investing in ophthalmic start-up companies also carries risks as the overall success rate is low^[6-8].

The ophthalmic community is benefited by at least 190 companies investigating more than 436 new medications in a wide variety of therapeutic areas^[9]. As encouraging as is the number of new medications being developed, many are focused on a limited number of therapeutic areas including: wet or dry age-related macular degeneration, glaucoma or dry eye^[10-11]. Considering the extensive regulatory time and money required to develop a new medication as well as the current competitive environment having so many companies focused on so few areas, raises questions about the efficiency of resource utilization within the ophthalmic community^[10-13].

The purpose of this survey was to inquire of ophthalmologists, who have participated as investigators, and ophthalmic pharmaceutical professionals, involved in ocular research and development, their perceived needs of new medications in various ophthalmic subspecialties. We desire to assist those considering establishing new start-up companies or development plans by providing information helpful for choosing an appropriate treatment indication.

SUBJECTS AND METHODS

Two contact lists were compiled: a list of ophthalmic industry professionals who have been involved in ocular research and development; and a list of ophthalmologists who have actively participated in clinical research. The survey was developed on Survey Monkey (www.surveymonkey.com) and the link to the survey was sent *via* email. The link was sent two additional times following the initial distribution.

The survey was developed by several of the authors. Questions were based on issues derived from personal discussions with ophthalmic colleagues and based on treatments described in the medical literature. The survey questions are shown in the Figure 1.

This study adheres to the guidelines of the Declaration of Helsinki. Due to the survey design of this research project

1. Gender
 Male
 Female

2. Age
 <30
 31-40
 41-50
 51-60
 >60

3. Geographic location:
 USA - Northeast
 USA - Southeast
 USA - Midwest
 USA - Southwest
 USA - West
 Europe
 Other, please specify _____

4. Type of practice:
 General
 Subspecialty
 Cornea and external disease
 Cataract and refractive surgery
 Glaucoma
 Uveitis and ocular immunology
 Vitreoretinal diseases
 Ophthalmic plastic surgery
 Pediatric ophthalmology
 Neuro-ophthalmology
 Ophthalmic pathology
 Mixed general and subspecialty (chosen above)
 Pharmaceutical professional
 Retired doctor
 Other, please specify _____

5. How important to ophthalmology is the development of a new pharmaceutical product for each of the following disease states? Score on a scale between 0 (none needed) to 5 (pressing need).

Disease	0	1	2	3	4	5
Glaucoma						
Age-related macular degeneration WET						
Age-related macular degeneration DRY						
Dry eye						
Diabetic macular edema						
Post-op anti-inflammatory						
Anti-infective						
Presbyopia						
Uveitis						
Allergy						
Cataract						
Other, please specify						

6. If you learn of a new product for which you believe there is a pressing need, how would you express your commitment to the product? Please check all that apply.
 Recommend the product to colleagues
 Prescribe the product
 Become a Principal Investigator for a regulatory trial
 Advise the sponsoring company
 Lecture on behalf of the product
 Invest in the startup developing the product
 Take no action
 Other, please specify _____

Figure 1 Survey questions.

Institutional Review Board/Ethics Committee approval and clinical trial registration was not required.

Statistical Analysis All statistical tests were non-paired, two-sided and used a *P*-value of 0.05. The sample population was not powered statistically since the study's intent generally was a descriptive, non-comparative survey. A one-way ANOVA test was used to evaluate each comparison on this study^[14].

RESULTS

The survey link was distributed to 559 ophthalmic pharma professionals and ophthalmologists. We received 82 (15%) responses of which 21 (26%) were pharma professionals and 61 (74%) were physicians (Table 1).

The survey showed that the most commonly perceived needs (on a ranked scale of 0 to 5) were dry age-related macular degeneration with an average score of 4.5, wet age-related macular degeneration 4.0, glaucoma 3.8, diabetic macular

edema 3.8 and dry eye 3.5. There was a statistical difference found between all selections (*P*<0.0001).

Respondents indicated they would express their commitment to a new product they perceived as needed by recommending to colleagues (63%), prescribing (60%), participating as principle investigator in a related clinical trial (52%), advising the company (52%), lecturing on behalf of the product (43%), investing in the product (38%), taking no action (7%) or obtain a position in the company (1%). When the results from physicians were compared to pharma professionals there was a statistical difference across all answers (*P*=0.0006; Table 2). Generally physicians perceived more clinical needs than did pharma professionals, especially in glaucoma, age-related macular degeneration, and for anti-infectives.

DISCUSSION

This survey of ophthalmic pharma professionals and

Ophthalmic medication needs

Table 1 Survey respondent demographics *n*=82; *n* (%)

Questions	Responses
Gender	
M	66 (80)
F	16 (20)
Age (y)	
31-40	5 (6)
41-50	17 (21)
51-60	36 (44)
>60	24 (29)
Geographical region	
Northeast	11 (13)
Southeast	22 (27)
Midwest	11 (13)
Southwest	6 (7)
West	17 (21)
Europe	10 (12)
Other	5 (6)
Type of practice	
General ophthalmology	11 (13)
Mixed general ophthalmology and subspecialty	15 (18)
Subspecialty (see below)	33 (40)
Pharmaceutical professional	21 (26)
Retired doctor	2 (2)
Subspecialty area (more than one answer allowed)	
Cornea and external disease	8 (10)
Cataract and refractive surgery	15 (18)
Glaucoma	31 (38)
Uveitis and ocular immunology	1 (1)
Vitreoretinal diseases	5 (6)
Ophthalmic plastic surgery	1 (1)
Pediatric ophthalmology	1 (1)
Neuro-ophthalmology	0 (0)
Ophthalmic pathology	1 (1)

ophthalmologists showed the highest perceived needs for new ophthalmic medications were for dry and wet age-related macular degeneration, glaucoma, diabetic macular edema and dry eye. The indication of dry and wet age-related macular degeneration is not surprising because these common diseases have very few treatments to help suffering patients^[15]. In addition, diabetic macular edema and glaucoma are potentially visually disabling diseases and their treatments, while effective, are not curative and not generally sight restorative^[16-17]. Dry eye is a chronic cause of discomfort, disrupted vision and reduced quality of life in a high percentage of the population. Common treatments are palliative and can reverse the condition only to a limited extent.

Although there are limited studies similar study to ours regarding perceived therapeutic needs in ophthalmology^[8,11]. We found several online surveys sponsored by ophthalmic societies that included devices as well. The Fight for Sight

Table 2 Comparisons between physician and pharma professional responses for area of perceived need and how they would express their commitment to chosen need *n* (%)

Parameters	Physicians (<i>n</i> =61)	Pharma professionals (<i>n</i> =21)
Indication of perceived need		
Glaucoma	28 (46)	1 (5)
Wet age-related macular degeneration	28 (46)	5 (24)
Dry age-related macular degeneration	40 (66)	10 (48)
Dry eye	13 (21)	4 (19)
Diabetic macular edema	16 (26)	7 (33)
Postop. anti-inflammatory	0 (0)	0 (0)
Anti-infective	10 (16)	1 (5)
Presbyopia	14 (23)	3 (14)
Uveitis	7 (11)	3 (14)
Allergy	2 (3)	1 (5)
Cataract	9 (15)	3 (14)
How would you express your commitment to the product?		
Recommend the product to colleagues	47 (77)	5 (24)
Prescribe the product ^a	49 (80)	N/A
Become a principle investigator in a clinical trial ^a	43 (70)	N/A
Advise the sponsoring company	34 (56)	10 (48)
Lecture on behalf of the product	33 (54)	2 (10)
Invest in the product startup	22 (36)	9 (43)
Take no action	1 (2)	5 (24)
Obtain a position in the company	0 (0)	1 (5)

^aThese choices were excluded from the analysis since it applied only to practicing physicians.

Survey of health professionals and patients also indicated age-related macular degeneration and glaucoma, but added cataract, corneal diseases and childhood disorders^[18]. The National Eye Institute Panel of ophthalmic experts also noted a similar top five list as the Fight for Sight Survey^[19]. And there have been reports discussing the need for new retinal disease and dry eye treatments^[20-21]. Our survey differed in that our therapies were limited to: practitioner and pharma professional respondents. Device and pediatric treatments were not offered as a choice in our survey.

Interestingly, the therapeutic areas indicated by survey respondents as having the greatest therapeutic need generally match the areas where the pharmaceutical companies are developing new treatments. In a recent study it was found that approximately 59% (257/436) of the new medicines being developed were in age-related macular degeneration (both types), glaucoma, dry eye and diabetic macular edema^[9]. In addition, the internal development goals of a number of large pharma companies also follow in these areas (William Stewart, personal communication, PRN, USA).

However, the results of this survey for less needy areas, compared to the number of pharmaceutical companies developing

medicines under each therapeutic area by our internal data, appeared to diverge. Respondents indicated that even therapeutic areas perceived as requiring less assistance still had a reasonably high needs level (2.2-3.2 for cataract, uveitis, presbyopia, anti-infective and post-operative inflammatory conditions, on a ranked scale of 0 to 5). However, the associated decrease in the number of companies making new products in the perceived less needy areas is much greater^[9].

The reasons for this disparity are not known. However, selecting the indication best suited to a medicine under development is a complicated process which includes assessing not only physicians' patients' perceived needs, but the required regulatory pathway, route of delivery, total costs and time involved, potential treatment population and market penetration of this patient group and associated reimbursement^[6]. Consequently, the disparity in the number of medicines being developed between the areas of the greater to lesser perceived needs could be due to the other development factors mentioned above and may be deserving of future research.

Nonetheless, this disparity between perceived need and the number of products currently being developed could point to the utility of new companies to examine, early in the development process, at least the perceived needs of physicians and the competitive environment to better help guide the therapeutic indication choice.

When the expression of commitment for physicians was compared to pharma professionals, generally physicians statistical indicated more potential commitment to a new needed product. The reason for this finding is unclear. Physicians would have the advantage of perceiving needs from a patient based level which may heighten commitment. In contrast, a pharma professional might be in a lesser position to express sometimes of commitment to a new medicine such as lecturing.

This survey showed that ophthalmic pharma professionals and ophthalmologists perceive the greatest need for new medicines in ophthalmology to be in dry as well as wet age-related macular degeneration, glaucoma, diabetic macular edema and dry eye. More research is needed generally regarding the best way to utilize start-up funds and personnel talent to most efficiently and profitably develop new medications for ophthalmic patients.

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