

# Real-world Safety Analysis of 50,000 Patients Treated with Intracanalicular Dexamethasone Insert Using IRIS<sup>®</sup> Registry

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# Disclosures

- **Presenter:** Benjamin Xu reports research support from Ocular Therapeutix outside of the presented work.
- **Co-authors:** Srilatha Vantipalli, Dina Akasheh, Matthew Cheung, Aditi Bauskar and Rabia Gurses-Ozden are employees of Ocular Therapeutix. Michael Mbagwu, Meghan Hatfield, and Rachel Myers are employees of Verana Health.
- **Funding:** This research was supported by Ocular Therapeutix.

# Background

- Topical steroids and NSAIDs are often used to prevent and treat post-op inflammation and pain following ophthalmic surgery<sup>1</sup>
- **Intracanalicular Dexamethasone Insert (DEXTENZA [DEX])<sup>2</sup>:**
  - Hydrogel-based insert that releases dexamethasone to the ocular surface in a tapered fashion
  - Preservative-free
  - FDA-approved for the treatment of:
    - Post-op ocular inflammation and pain
    - Ocular itching associated with allergic conjunctivitis



Activates:<sup>2,3</sup>

- With moisture
- Swells to fit in the canaliculus



Releases:<sup>2,3</sup>

- Dexamethasone for up to 30 days



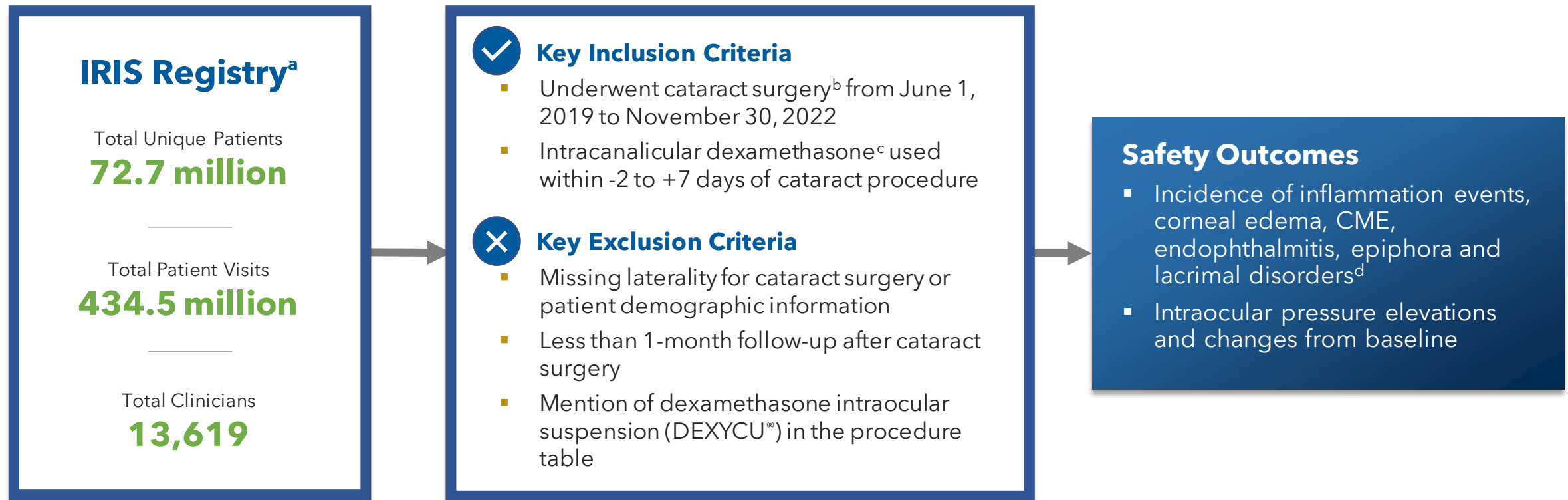
Resorbs:<sup>2,3</sup>

- Slowly through the course of treatment
- Clears via the nasolacrimal duct

**Research Question: What is the safety profile of DEX in cataract surgery patients when used in real-world clinical practice?**

# Methodology: A Retrospective Analysis of EHR Data using the Academy's IRIS Registry (Intelligent Research in Sight)

**Objective: To evaluate the incidence of safety events in 50,000 eyes who received cataract surgery and intracanalicular dexamethasone (DEX)**



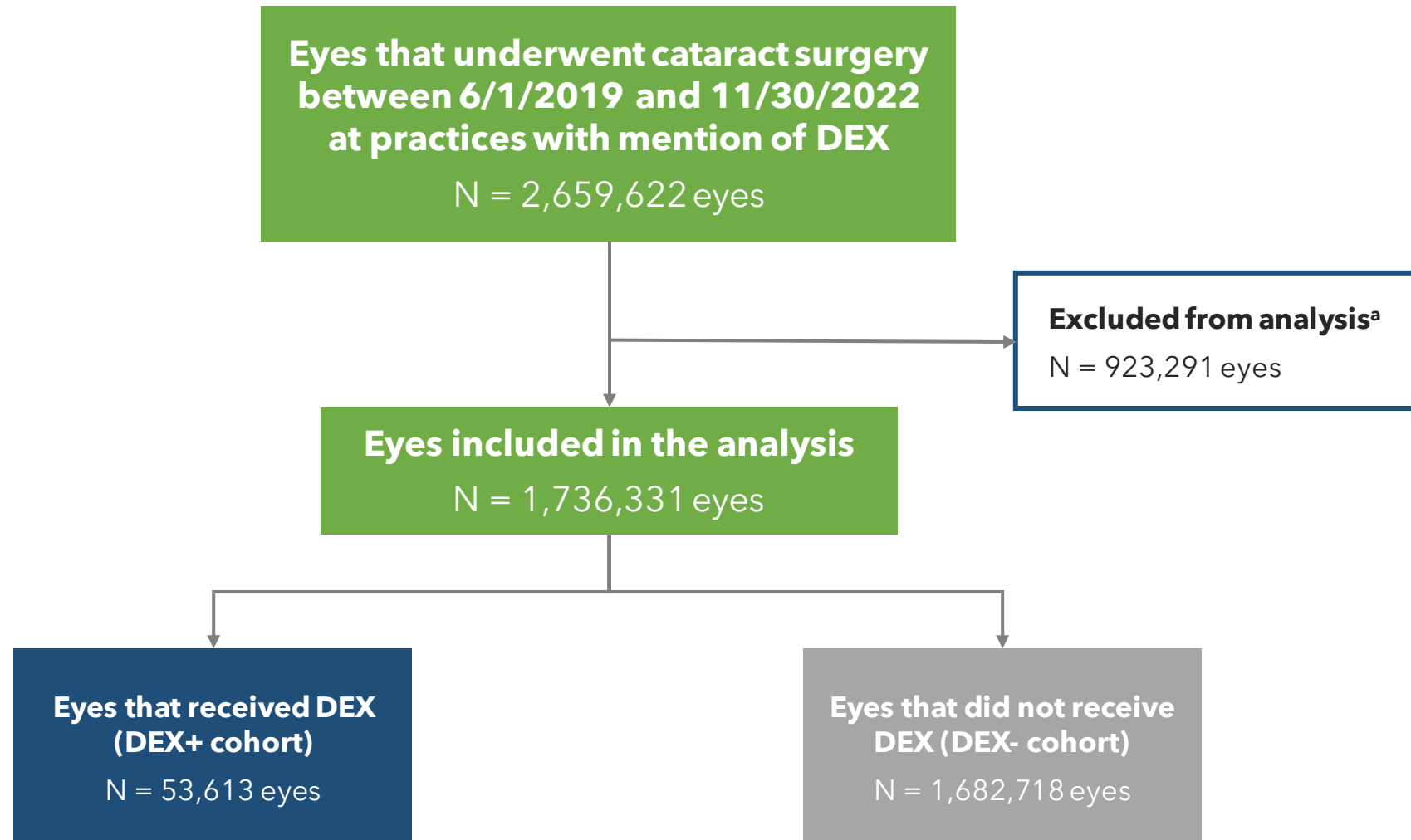
<sup>a</sup> as of October 1, 2023. <https://www.aao.org/iris-registry/data-analysis/requirements>

<sup>b</sup> defined as presence of CPT code 66984 or 66982

<sup>c</sup> defined as presence of J-code (J1096), C-code (C9048), CPT code (0356T), NDC number (70382-0204-01, 70382-204-10), or keywords indicated intracanalicular dexamethasone use (eg, "DEXTENZA", "dexamethasone, lacrimal ophthalmic insert", "intracanalicular dexamethasone", "lacrimal dexamethasone insert") in the procedural table

<sup>d</sup> identified by the presence of new ICD-10 codes

# Study Population

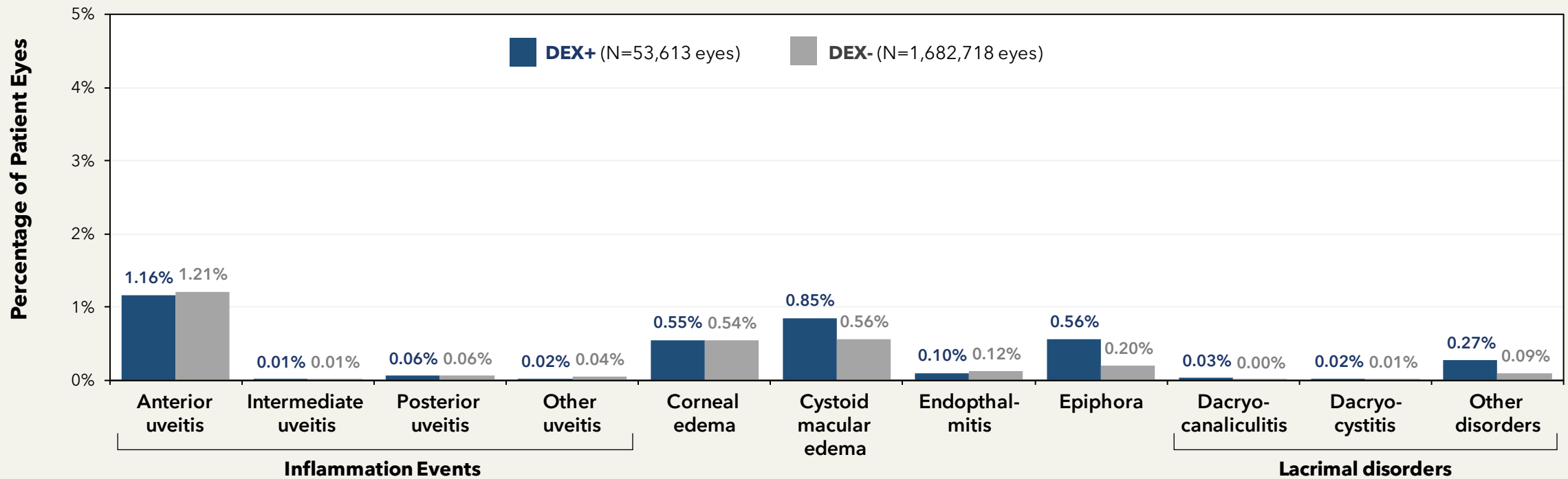


<sup>a</sup>based on exclusion criteria: 1) Missing laterality for cataract surgery 2) Missing patient demographic information 3) Less than 1-month follow-up after cataract surgery 4) Mention of dexamethasone intraocular suspension (DEXYCU®) in the procedure table

# Incidence of Postoperative Events

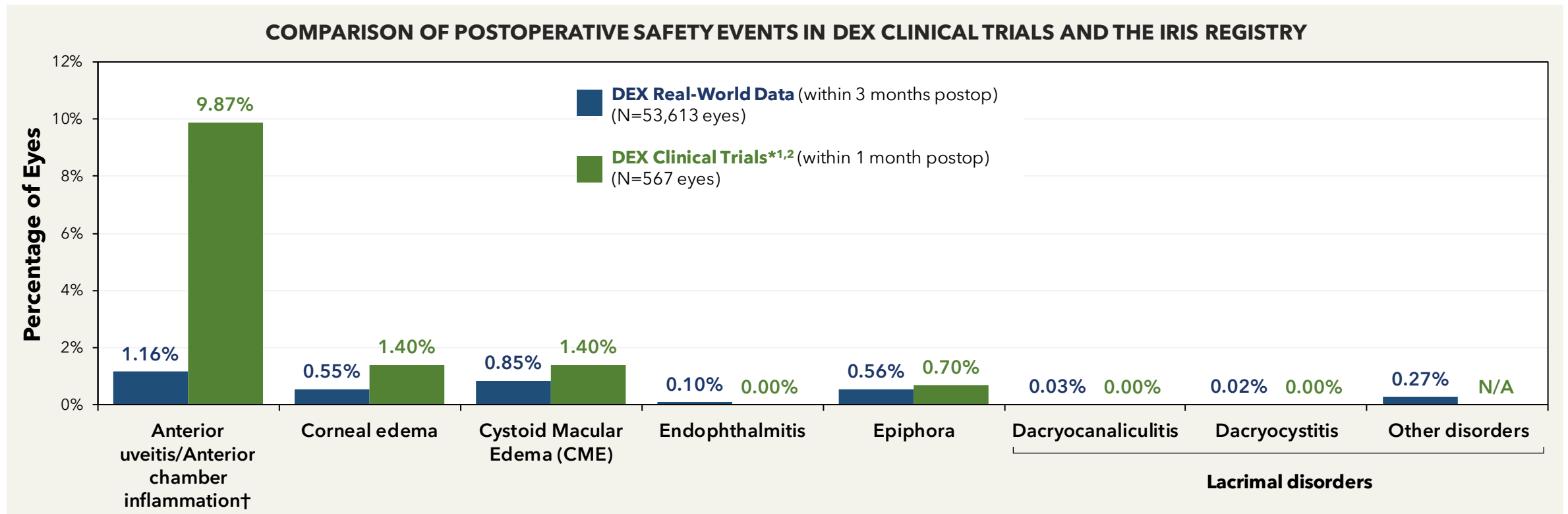
The overall incidence of post-op inflammation events was low and comparable between the DEX+ and DEX- cohorts

POSTOPERATIVE SAFETY EVENTS WITHIN 3 MONTHS OF CATARACT SURGERY



# Real-world Postoperative Safety Events vs. Clinical Trials

Anterior uveitis and corneal edema were documented less frequently in the real world than observed in clinical trials



\* Incidences of safety events from DEX Clinical Trials were pooled from one Phase 2 (NCT01666210) and three Phase 3 (NCT02034019, NCT02089113, and NCT02736175) clinical trials in cataract surgery subjects

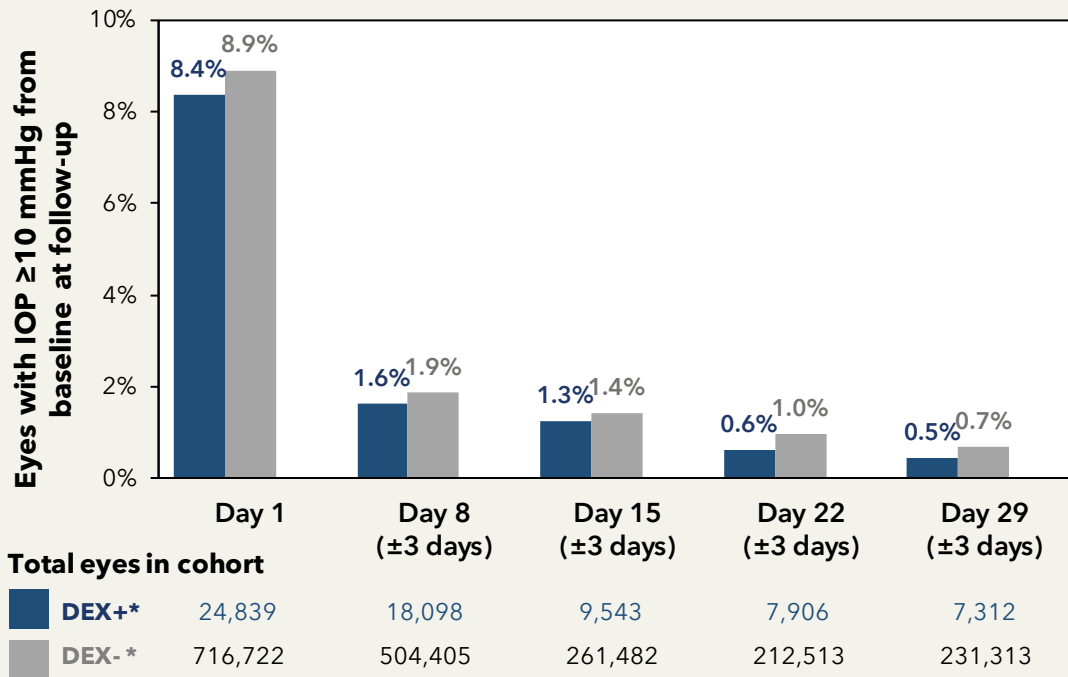
† Anterior chamber inflammation reported in DEX clinical trials included iritis and iridocyclitis

References: **1.** Walters T, et al. J Cataract Refract Surg. 2015;41(10):2049-2059. **2.** Tyson S, et al. Management of Ocular Inflammation and Pain Following Cataract Surgery with DEXTENZA, Dexamethasone Insert (0.4 mg): Pooled analysis of three Phase 3 studies. Presented at the American Society of Cataract and Refractive Surgeons. May 6, 2019. San Diego, CA.

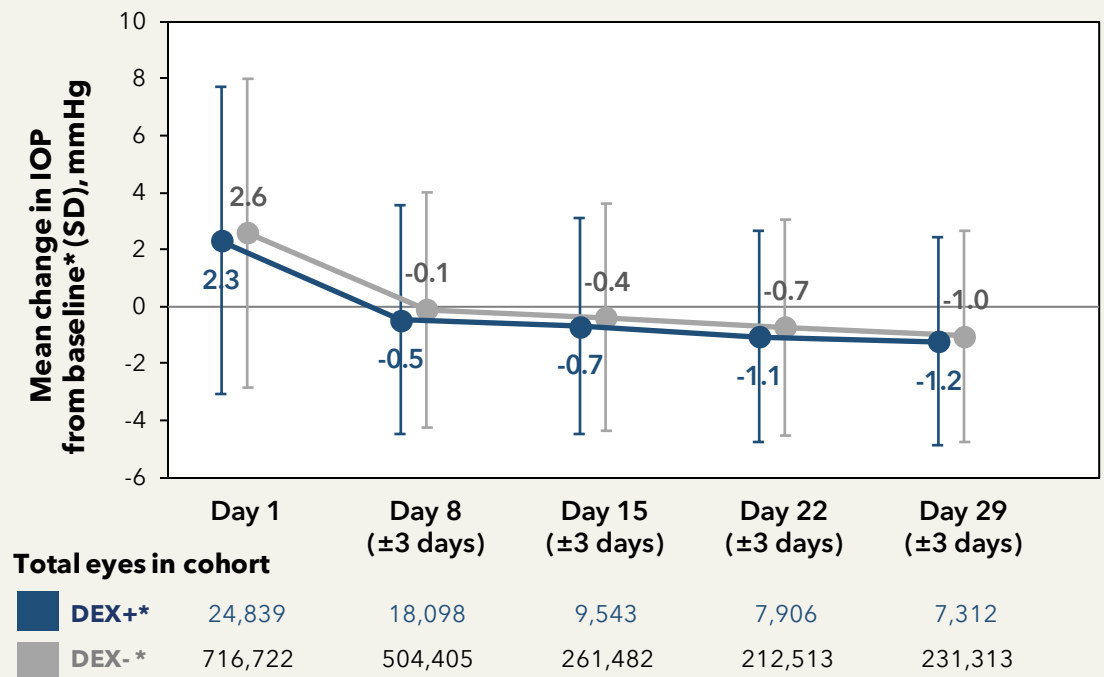
# Intraocular Pressure: Patients *without* Prior History of Glaucoma

In patients without glaucoma, rates of IOP elevation  $\geq 10$  mmHg were comparable between the DEX+ & DEX- cohort and more frequent on post-op day 1

**PERCENTAGE OF EYES WITH IOP  $\geq 10$  MMHG FROM BASELINE AT FOLLOW-UP**



**CHANGE FROM BASELINE IOP IN PATIENTS WITHOUT HISTORY OF GLAUCOMA**



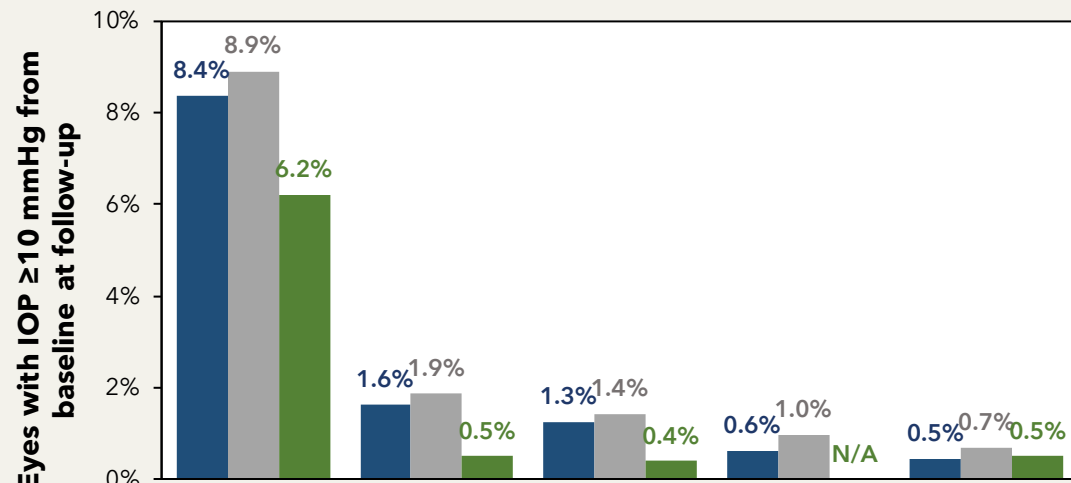
\* Baseline IOP calculated as the average of the two most recent IOP assessments up to 6 months pre-index. If only one pre-index assessment is available, that IOP measurement is the baseline IOP.



# Intraocular Pressure: Patients *without* Prior History of Glaucoma

Real-world data vs. pooled DEX clinical trial data from one Phase 2 and three Phase 3 trials

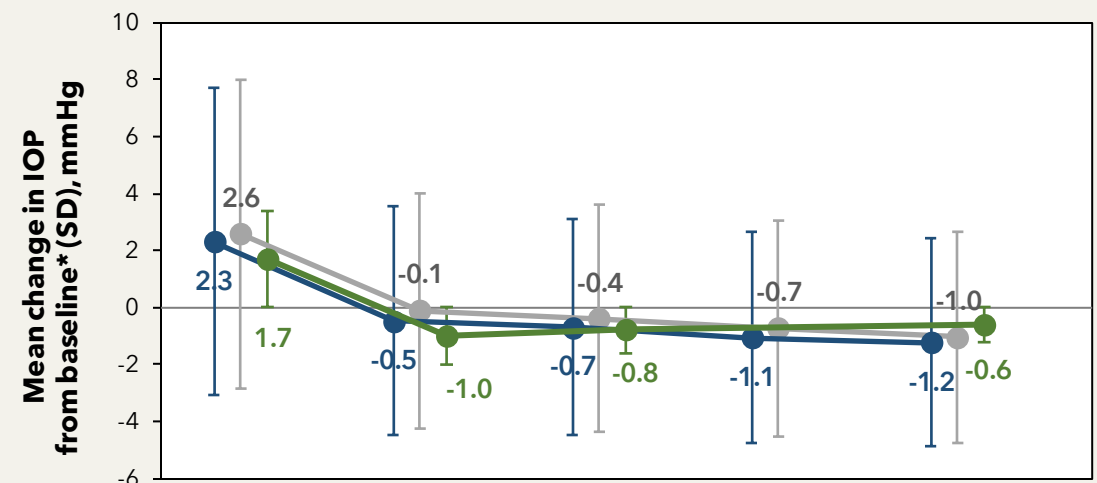
**PERCENTAGE OF EYES WITH IOP  $\geq 10$  MMHG FROM BASELINE AT FOLLOW-UP**



**Total eyes in cohort**

DEX+*	24,839	18,098	9,543	7,906	7,312
DEX-*	716,722	504,405	261,482	212,513	231,313
DEX Clinical Trials <sup>†1,2</sup>	567	565	565	N/A	562

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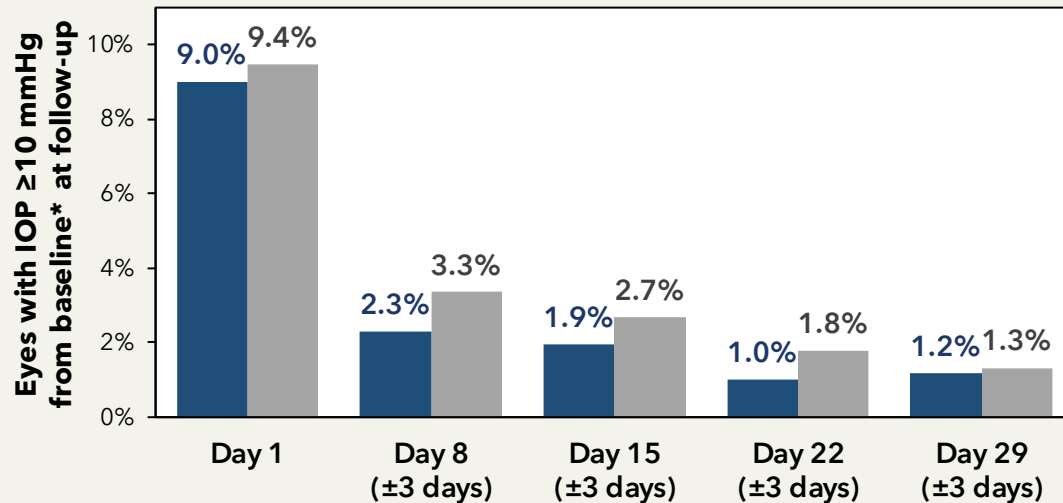
† Clinical trials of DEX excluded subjects with a history of glaucoma or ocular hypertension

References: 1. Walters T, et al. J Cataract Refract Surg. 2015;41(10):2049-2059. 2. Tyson S, et al. Management of Ocular Inflammation and Pain Following Cataract Surgery with DEXTENZA, Dexamethasone Insert (0.4 mg): Pooled analysis of three Phase 3 studies. Presented at the American Society of Cataract and Refractive Surgeons. May 6, 2019. San Diego, CA.

# Intraocular Pressure: Patients with Prior History of Glaucoma

In eyes with pre-existing glaucoma, proportions of IOP elevations and mean IOP were similar in DEX+ and DEX- eyes throughout the first postoperative month

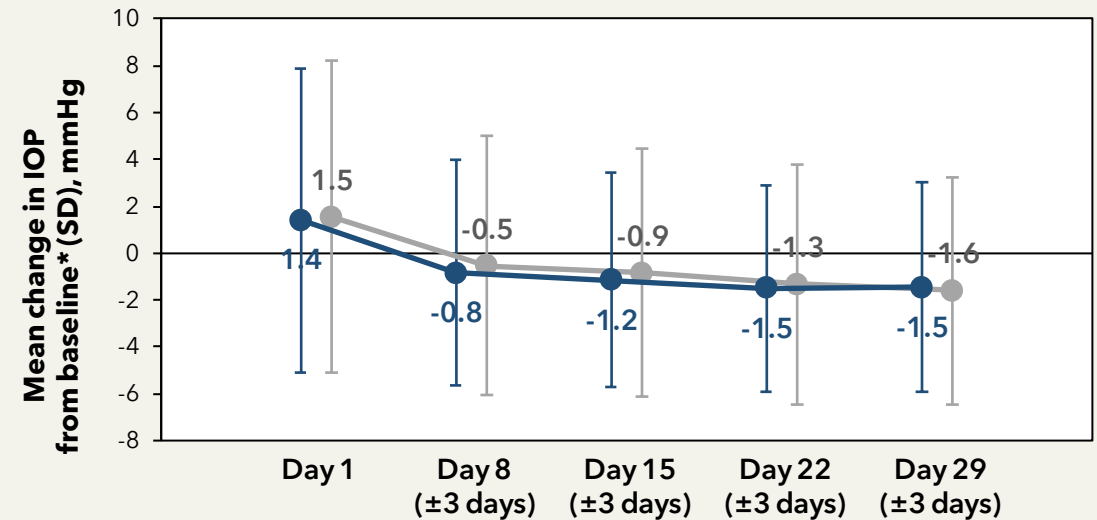
**PERCENTAGE OF EYES WITH IOP  $\geq 10$  MMHG FROM BASELINE AT FOLLOW-UP**



**Total eyes in cohort**

<b>DEX+</b>	8,011	6,153	3,370	2,824	2,556
<b>DEX-</b>	246,898	182,182	99,744	83,092	86,868

**CHANGE FROM BASELINE IOP IN PATIENTS WITH HISTORY OF GLAUCOMA**



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# Conclusions

- This study represents the largest analysis of patients who received intracanalicular dexamethasone insert, encompassing over 50,000 eyes
- Incidence of inflammation events, corneal edema, CME, endophthalmitis, epiphora, lacrimal disorders in DEX treated eyes were low (<2%)
- The proportion of eyes with IOP elevations  $\geq 10$  mmHg was comparable in between DEX+ and DEX- eyes, irrespective of any prior glaucoma history
- Real-world treatment data of DEX utilization in cataract surgery patients offers insights into its post-market safety profile