

Development of a US-based, Real-world, Ophthalmology Registry Based on Automated EHR Data Extraction to Support Opportunities for Clinical and Health Economics and Outcomes Research in Eyecare

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Background

- The importance of real-world data (RWD) to inform several health-related decisions across multiple stakeholders—including regulators, payers, physicians, and patients—has never been higher:
 - However, such data are often first developed for reasons other than real-world evidence (RWE) generation (e.g., claims to support reimbursement of healthcare providers).
- Ophthalmology is one of the more challenging areas with respect to RWE generation:
 - Most care for retinal diseases in the US is rendered by ophthalmologists, who record detailed clinical information on diagnoses and symptomatology, medication(s) received, procedure(s) utilized, and response(s) to treatment(s).
 - While electronic health record (EHR) charting became broadly used in the mid-2000s as it allowed a more efficient means to maintain patients’ health information, these records are not easily accessible outside of clinic at the scale or quality required for research, and analyzing large amounts of relevant data remain challenging.
- The Vestrum Health Retinal Database®, which was created in 2013 by retina specialists around the US, was designed to provide a large-scale, rigorous, and robust source of RWD for use in RWE generation across the development lifecycle.

Objectives

- To describe development of the Vestrum Health Database, a unique source of ophthalmologic data.

Methods

Development of the Vestrum Health Database

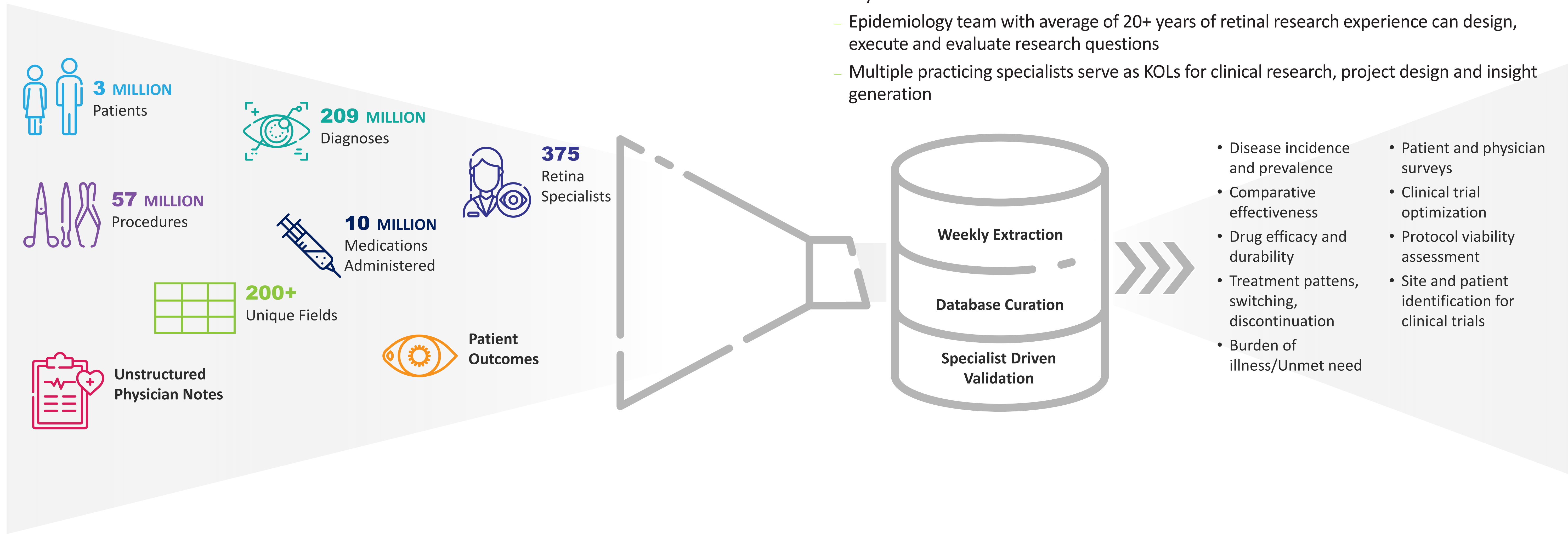
- The Vestrum Health Database comprises 75 retinal clinics and 370 practitioners who contribute de-identified and HIPAA-compliant data weekly:
 - Database spans the US (Northeast 34%, Midwest 10%, Southeast 28%, Southwest 10%, West 18%).
 - Data are tracked longitudinally by patient and eye, allowing analysis to account for bilaterality.
 - The database spans the period from 2015 to current day and is compliant with the Health Insurance Portability and Accountability Act (HIPAA) of 1996.
- The database includes:
 - Information on diseases diagnosed, treatments rendered, and progression status are collected using standardized coding (Current Procedural Terminology [CPT], International Classification of Diseases, 10th Revision, Clinical Modification [ICD-10-CM], Healthcare Common Procedure Coding System [HCPCS]).
 - Free-form notes (exam findings, imaging impressions, patient plan) are routinely entered by clinicians and scribes to inform disease progression, proposed care plan, and patients’ levels of responsiveness to treatment, and medication lists, as observed from visit to visit.
 - Key patient retina-related outcomes such as visual acuity, retinal thickness, and fluid, most of which are difficult to obtain at a scale conducive to RWE generation, are consistently populated fields that can be arrayed longitudinally to examine “disease journeys” over time.

Curation of Database

- Data are extracted weekly in collaboration with retinal clinics and EHR vendors.
- Physicians partner with Vestrum to create a unique form of data validation. Vestrum provides physicians recurring data snapshots highlighting their monthly performance, usage, and efficiency, offering quantitative support to help drive their treatment decisions. This collaboration creates an iterative data curation process in which data drive physician decisions, which in turn compels physicians towards accurate data entry and metric generation.
- The Vestrum data science team combines data from structured fields (CPT, ICD-10-CM, HCPCS) and free-form physician notes to provide a comprehensive perspective of each patient, visit over visit.

Real-world Offerings

- Given the level of rigor associated with its development and ongoing curation and evolution, the Vestrum Health Database can support a number of use cases, including but not limited to the following:
 - Near real-time (weekly) insights into the US retina market
 - Clinical trial identification and recruitment, led by Vestrum’s certified ophthalmic technicians who can access individual patient charts
 - Review of imaging studies, which can be extracted separately from EHR data collection
- Data can be accessed for research through licensing or through leveraging Vestrum’s dedicated analytics team:
 - Epidemiology team with average of 20+ years of retinal research experience can design, execute and evaluate research questions
 - Multiple practicing specialists serve as KOLs for clinical research, project design and insight generation



Conclusions

- The Vestrum Health Database provides longitudinal, near real-time insight into many retinal diseases, rendering it unique in its ability to inform the generation of rigorous RWE that can help improve care and outcomes among patients with retinal disease:
 - Existing and potential use cases include enabling clinical research, information health economics and outcomes research, and facilitating market access research on retinal treatments throughout their lifecycles.
- As the importance of RWD continues to grow, and the need of RWE to support and assess new technologies of ever-increasing complexity, the Vestrum Health Database provides a large and robust source of retina-related RWD to drive innovation, facilitate education, and enable optimal patient care.

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