Leveraging Claims Data for Ascertaining Long-term Outcomes

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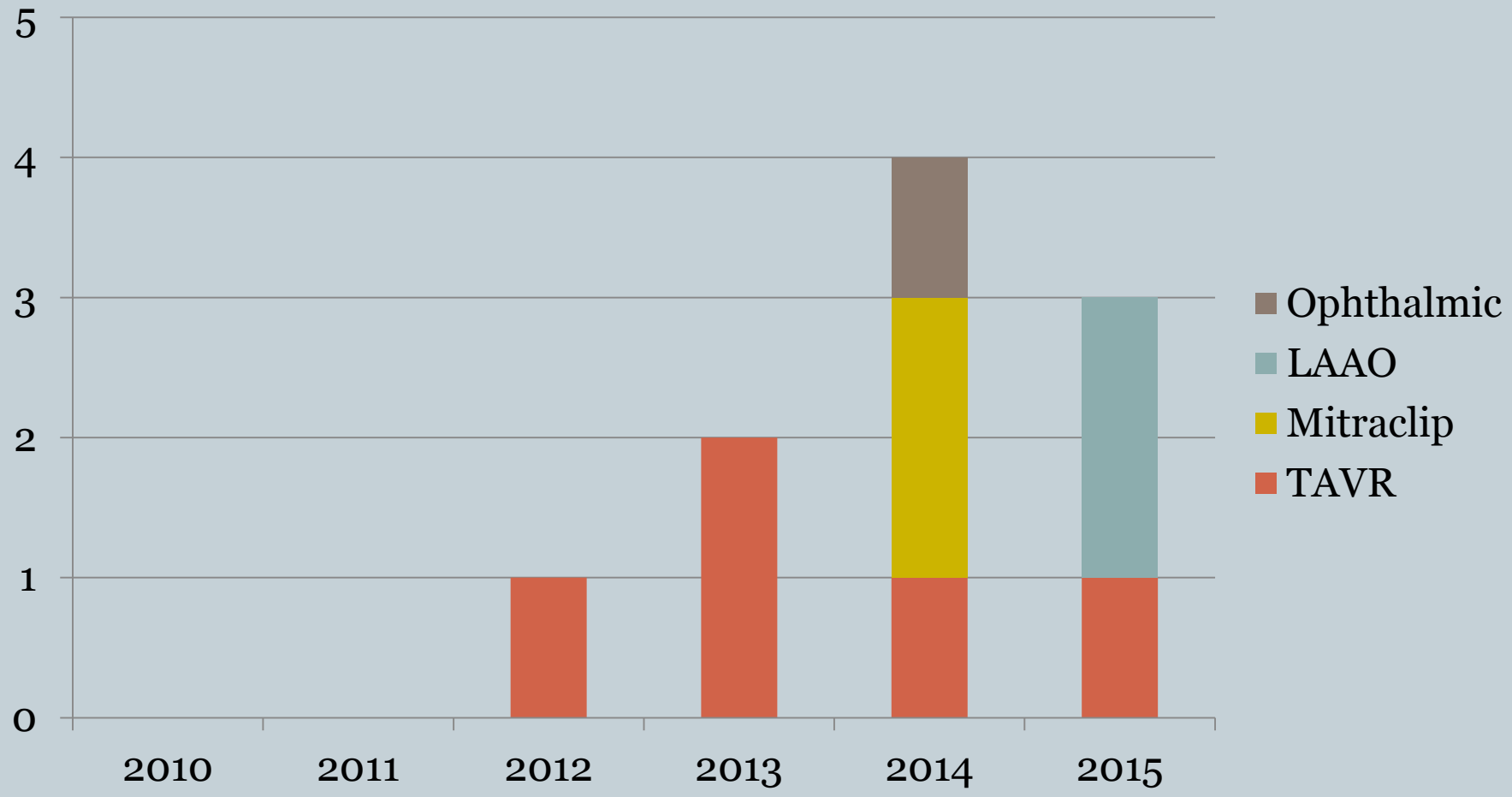
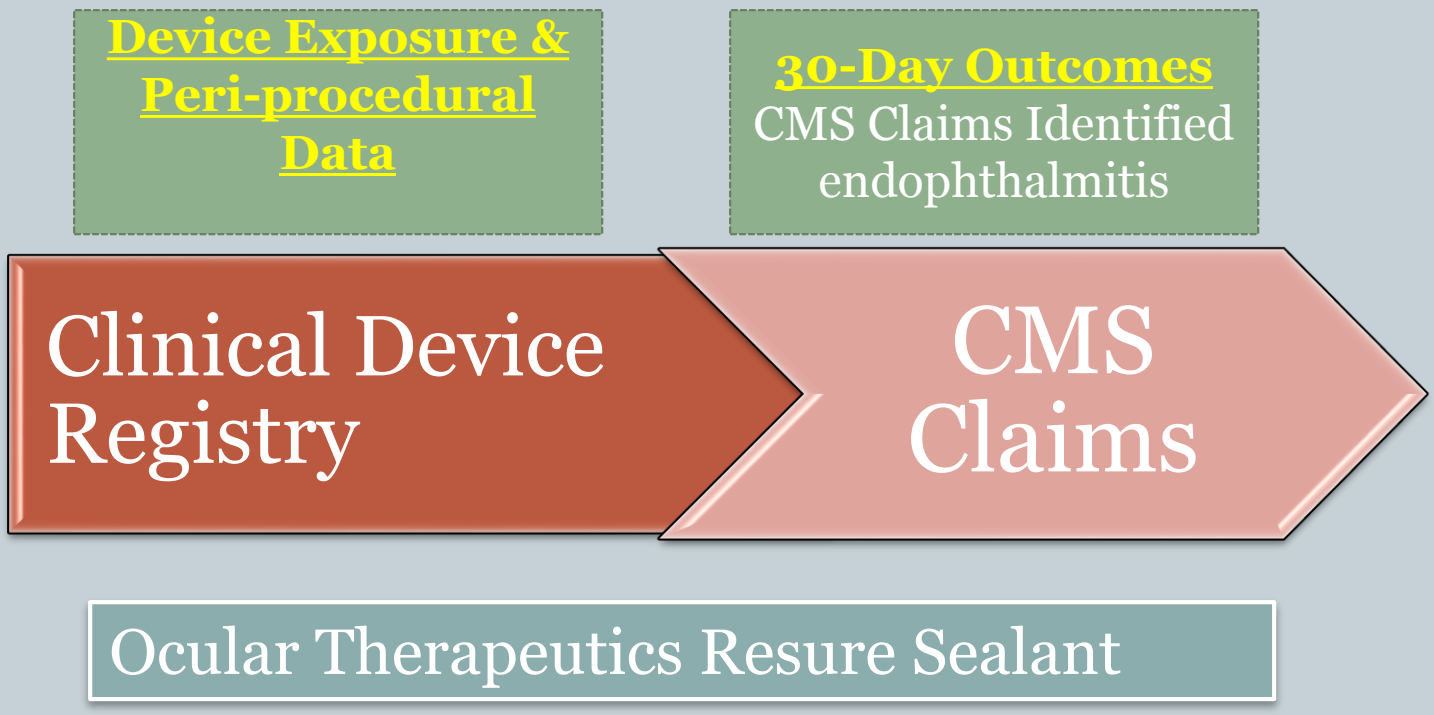
Examples of Claims Based Endpoint Ascertainment and Validation Work

- MDEpiNet
  - Claims-based Patient Follow-up Study with DCRI
- Mini-Sentinel
  - Validated codes derived from EMR and claims against medical chart information for particular medical conditions.
  - http://mini-sentinel.org/methods/outcome_validation/default.aspx
- Observational Medical Outcomes Partnership (OMOP)
  - Established an open-source library of Health Outcomes of Interest (HOI) http://omop.org/HOI
  - Provides broad and narrow selections of diagnosis codes, combination of diagnosis codes with diagnostic or therapeutic procedures and lab values.

Postmarket Requirements Leveraging Claims



Device Exposure Registry with Claims for Longitudinal Follow-up



Validation Sub-study Nested in the Post-approval Study

Baseline – 2 years
Centrally Adjudicated Stroke Assessed Annually

3-5 years
CMS Claims Identified Stroke

Clinical Device Registry Study → Validation Sub-study → CMS Claims

Baseline – 2 years
Assess Validity of CMS Claims identified compared to centrally adjudicated

BSC Watchman Left Atrial Appendage Closure

Comprehensive/ Linked-Registry Based Surveillance

Baseline – 1 year
Clinical Outcomes at 30 days and 1 year

5 year Outcomes
all-cause mortality, neurological, and vascular outcomes

TVT-Registry
- Edwards Sapien, XT, and S3
- Medtronic Corevalve

Comprehensive/ Linked-Registry Based Surveillance

- Sponsors agree to actively participate as a stakeholder & support the operations to ensure that FDA surveillance occurs for their device
- FDA receives de-identified cumulative line-item data quarterly
- Two FDA Epidemiologists work with CMS Epidemiologists once a week analyzing TVT-R and CMS Claims Data linked data
  - ensures access to the linked data and analysis
  - FDA and CMS analyses to meet their respective public health missions

Centers for Medicare and Medicaid Services Claims Data

- Chronic Conditions Warehouse (CCW)
  - represents final actions
  - completely adjudicated
  - CCW is built upon the IDR
  - Substantial data lag ~ 1 year
- Integrated Data repository (IDR)
  - refreshed every week, but it is not final actions
  - greater information sharing
  - broader and easier access

Timely Utilization of Medicare Claims Data

- Integrated Data repository (IDR) data is refreshed every week
- Access and analyze events identified through validated claims algorithms
- Adjudicate outcomes ascertained through IDR as claims do not represent final actions
- Examine utilization of CMS Sandbox tool for analyzing IDR

Future Steps

- MDEpiNet methodology work to expand validation of claims algorithms to other disease and device areas
- Increase utilization of claims data in postmarket to enhance (and replace some) direct patient follow-up
- Expand administrative claims work and partner with private payers
- Explore leveraging of claims linked to evidence from clinical experience to support premarket decision making

Thank You