

Center for Drug Evaluation and Safety – Data Request

COSTS

Request	Data	Unfunded	Funded
		Fees	
<input type="checkbox"/>	MarketScan Commercial Claims and Medicare Supplement data	\$2,500 (\$1250 every 6 months)	\$30,000 (not-for-profit) \$60,000 (for profit)
<input type="checkbox"/>	MarketScan Health Risk Assessment (HRA) data	\$1000 (\$500 every 6 months)	Included in above price
<input checked="" type="checkbox"/>	Medicare FFS	\$2,750 (\$1375 every 6 months)*	Left number + \$2000 one-time fee for re-use
<input type="checkbox"/>	Medicaid	\$3000 (\$1500 every 6 months)*	Left number + \$2000 one-time fee for re-use
<input type="checkbox"/>	Other Data†	CODES Voucher	\$5,000 (\$2,500 every 6 months)
<input type="checkbox"/>	Programming/Data Analysis Support	\$35-\$75 per hour, based on level of expertise required	

*If specific to Medication-related project; otherwise re-use required
 †Other Data Linked to Medicare FFS (see Medicare)

STUDY DESIGN

<input checked="" type="checkbox"/> Retrospective Cohort	<input type="checkbox"/> Time-Series Analysis
<input type="checkbox"/> Case-Control	<input type="checkbox"/> Self-Controlled Analyses _____ (Specify)
<input type="checkbox"/> Cross-Sectional	<input type="checkbox"/> Other

COHORT DISCOVERY/ENTRY

	Definition (Medication Name(s), ICD Code(s) (9 + 10), CPT Code(s))
Primary Exposure <input type="checkbox"/> Incident Use	ICD-10 Procedure Code 02L73DK
Exposure Type	<input type="checkbox"/> Fixed <input type="checkbox"/> Time-Varying
Control <input type="checkbox"/> Incident Use	No need for control at this stage
Continuous Enrollment Prior to Cohort Entry	<input type="checkbox"/> 180 days <input type="checkbox"/> 360 days <input checked="" type="checkbox"/> 365 days <input type="checkbox"/> Other:
Continuous Enrollment After to Cohort Entry	<input type="checkbox"/> None <input type="checkbox"/> 180 days <input type="checkbox"/> 360 days <input type="checkbox"/> 365 days <input checked="" type="checkbox"/> Other: at least 1 month but up to 12 months

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INCLUSION/EXCLUSION

Inclusion/ Exclusion	When Collected?	Definition: (Medication Name(s), ICD Code(s) (9 + 10), CPT Code(s), Demographic Characteristics (e.g., Age, Sex))
<input type="checkbox"/> Inclusion <input checked="" type="checkbox"/> Exclusion	<input type="checkbox"/> Prior to Cohort Entry <input type="checkbox"/> Other	Age less than 65
<input type="checkbox"/> Inclusion <input type="checkbox"/> Exclusion	<input type="checkbox"/> Prior to Cohort Entry <input type="checkbox"/> Other	

OUTCOME TYPE

Outcome Type <input type="checkbox"/> Dichotomous	<input type="checkbox"/> Diagnosis Code <input type="checkbox"/> Medication Claim
<input checked="" type="checkbox"/> Continuous	<input checked="" type="checkbox"/> Adherence <input checked="" type="checkbox"/> Utilization/Visits <input type="checkbox"/> Costs

OUTCOMES

	Definition (Medication Name(s), ICD Code(s) (9 + 10), CPT Code(s) If CPT or ICD (Specify Care Setting), Utilization/Visit Types, Cost Types)
Primary Outcome <input type="checkbox"/> Single Outcome <input type="checkbox"/> Composite	Medication use after Watchman (please see separate sheet attached), assesses use during each month after implantation
Secondary Outcomes <input type="checkbox"/> Single Outcome <input type="checkbox"/> Composite	Bleeding events prior to Watchman (see separate sheet for ICD9/10 codes)

CENSORING CRITERIA

<input type="checkbox"/> Death (if available) <input checked="" type="checkbox"/> End of Study Period <input checked="" type="checkbox"/> End of Enrollment <input checked="" type="checkbox"/> Cohort Entry + 365 Days <input type="checkbox"/> Medication Switching	Medication Discontinuation: _____ (Specify Medication) Select Grace Period: <input type="checkbox"/> 7 Days <input type="checkbox"/> 14 Days <input type="checkbox"/> 30 Days <input type="checkbox"/> 90 Days <input type="checkbox"/> 1.5xDays' Supply <input type="checkbox"/> Other Diagnosis or Procedure: _____ (Specify) Define:
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COVARIATES

Measured Differences: P-Value Std Diff

When Collected?	Inclusion	Definition: (Medication Name(s), ICD Code(s) (9 + 10), CPT Code(s), Demographic Characteristics (e.g., Age, Sex, Year))
<input type="checkbox"/> Prior to Cohort Entry <input checked="" type="checkbox"/> Other: on implant date	<input type="checkbox"/> Any Coding <input type="checkbox"/> 1 IPT; 2OPT <input type="checkbox"/> Other	<input checked="" type="checkbox"/> Age (Specify _____) <input type="checkbox"/> Year (Specific _____) <input checked="" type="checkbox"/> Race <input checked="" type="checkbox"/> Sex <input checked="" type="checkbox"/> Geographic Locations (Specify): Census Region <input type="checkbox"/> Charlson <input type="checkbox"/> Elixhauser
<i>One Row Per Covariate</i>		
<input checked="" type="checkbox"/> Prior to Cohort Entry <input type="checkbox"/> Other	<input type="checkbox"/> Any Coding <input type="checkbox"/> 1 IPT; 2OPT <input checked="" type="checkbox"/> Other	Bleeding events (prior to implantation) – see excel sheet either IP bleed or ED visit – exclude those that occur within 7 days of previous bleed
<input checked="" type="checkbox"/> Prior to Cohort Entry <input type="checkbox"/> Other	<input type="checkbox"/> Any Coding <input checked="" type="checkbox"/> 1 IPT; 2OPT <input type="checkbox"/> Other	Other comorbidities – see excel sheet (available on request)

Measured Differences	<input checked="" type="checkbox"/> P-Value (males versus females for baseline characteristics) <input type="checkbox"/> Std Diff
Imputation	<input type="checkbox"/> Yes (<input type="checkbox"/> Exposure <input type="checkbox"/> Outcome <input type="checkbox"/> Covariate) <input type="checkbox"/> No

CONFOUNDING REDUCTION

Type	
<input type="checkbox"/> Multivariable	
<input type="checkbox"/> PS Matching	Matching <input type="checkbox"/> 1:1 <input type="checkbox"/> Other Caliper Width <input type="checkbox"/> 0.5 <input type="checkbox"/> Other
<input type="checkbox"/> IPTW	Trimming <input type="checkbox"/>

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ANALYSIS

Type	
<input type="checkbox"/> Logistic Regression	
<input type="checkbox"/> GLM (Costs)	
<input type="checkbox"/> Linear Regression	
<input type="checkbox"/> Cox PH	<input type="checkbox"/> Check Time-Varying Assumption
<input type="checkbox"/> Poisson Regression	
<input type="checkbox"/> Other	

DATA VISUALIZATION

<input checked="" type="checkbox"/> Flow Chart	
<input checked="" type="checkbox"/> Table 1 (Compare Baseline Characteristics)	<input type="checkbox"/> Include Balance
<input type="checkbox"/> Box & Whiskers for Covariates	<input type="checkbox"/> Include Balance
<input checked="" type="checkbox"/> Primary Findings Table	<input type="checkbox"/> Number of Outcomes <input type="checkbox"/> Person-Time <input type="checkbox"/> HR / OR / RR <input type="checkbox"/> P-Value
<input type="checkbox"/> Kaplan Meier / Incidence Plot	
<input type="checkbox"/> Propensity Score Distribution	
<input checked="" type="checkbox"/> Other: data visualization for medication use and bleeding events	

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Break Down of Data Analysis Time by Graduate Student (\$35/hour Rate)

Step	Hours
Cohort Development	3
Assessment of Age and Exclusion	0.5
Continuous Enrollment determination	2
Baseline Diagnosis Codes Extraction	2
Baseline Prescription Use Extraction	3
Diagnosis Determination for Comorbidities	4
Evaluation of Primary Outcome (Abstract 1)	5
Descriptive Analysis	1
Post-hoc Analysis	1
Evaluation of Primary Outcome (Abstract 2)	6
Development of Graphs	2
Development of Tables	1
Meetings with Primary Investigator	5
Abstract Review	1
Total	36.5