OHDSI Flash Study: Keppra and Angioedema

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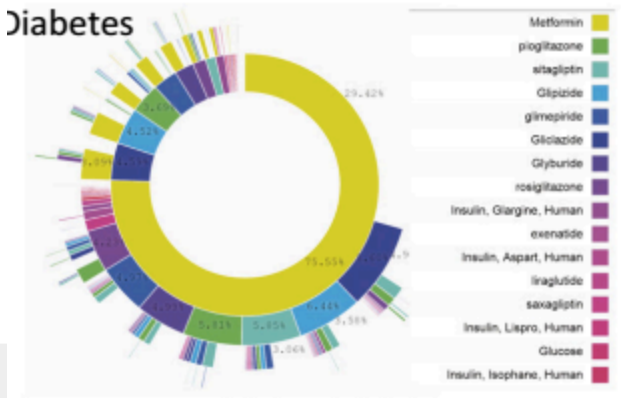
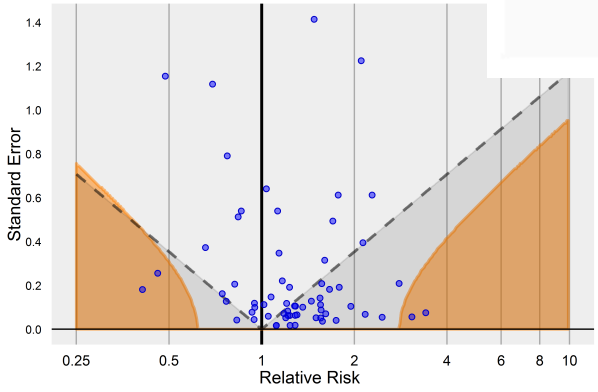
May 3rd, 2016

OHDSI Mission

To improve health, by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.

We support this mission in many ways



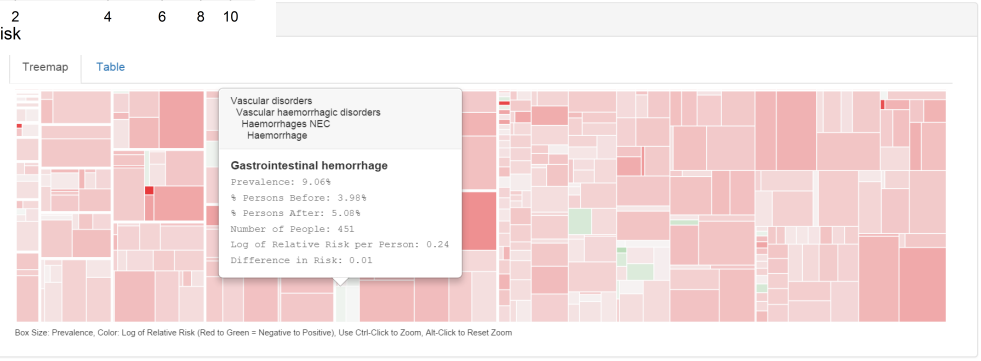


Overview | Reports

el replication - warfarin new users

	Match Rate	Matching Persons	T
Summary Statistics:	18.15%	12061	

Inclusion Rule	**% Satisfied**	**% To-Gain**
1. Prior atrial fibrillation	23.31%	71.19%
2. No prior warfarin ever	100.00%	0.00%
3. No prior dabigatran ever	98.80%	0.17%
4. No prior anticoagulants in past 183 days	98.05%	0.38%
5. No mechanical heart value or mitral stenosis	94.99%	2.23%
6. No dialysis in last 30 days	98.97%	0.39%
7. No history of kidney transplant	99.61%	0.06%
8. Not at long-term care visit	97.29%	0.70%



When duty calls…

OHDSI will answer

FDA Quarterly Reports of Potential Safety Issues

Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS) between October - December 2015

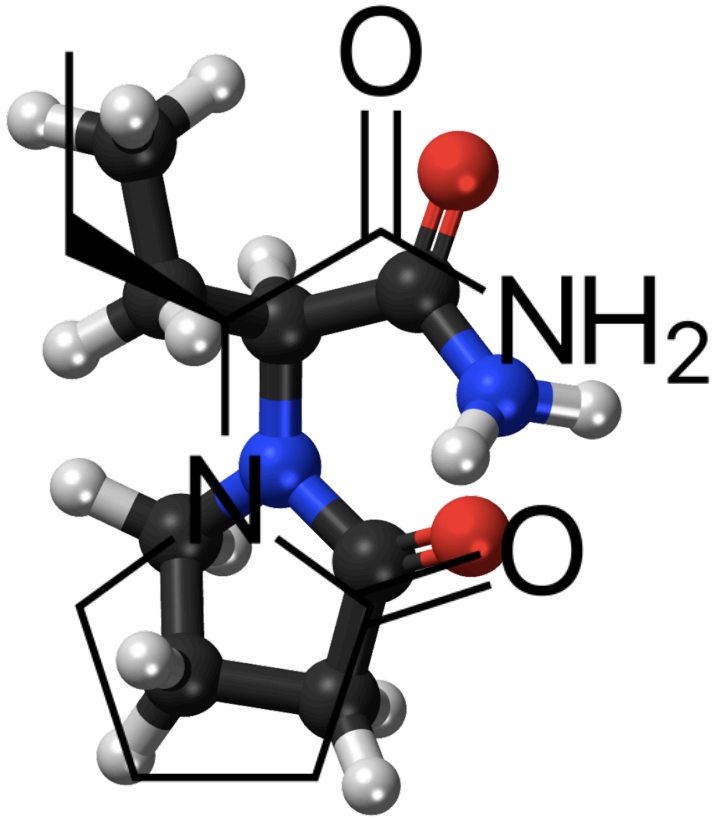
Product Name: Active Ingredient (Trade) *or* Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 31, 2016)
Keppra (levetiracetam) tablet, oral solution, injection	Angioedema	FDA is evaluating the need for regulatory action.

Keppra® (levetiracetam) Immediate Release

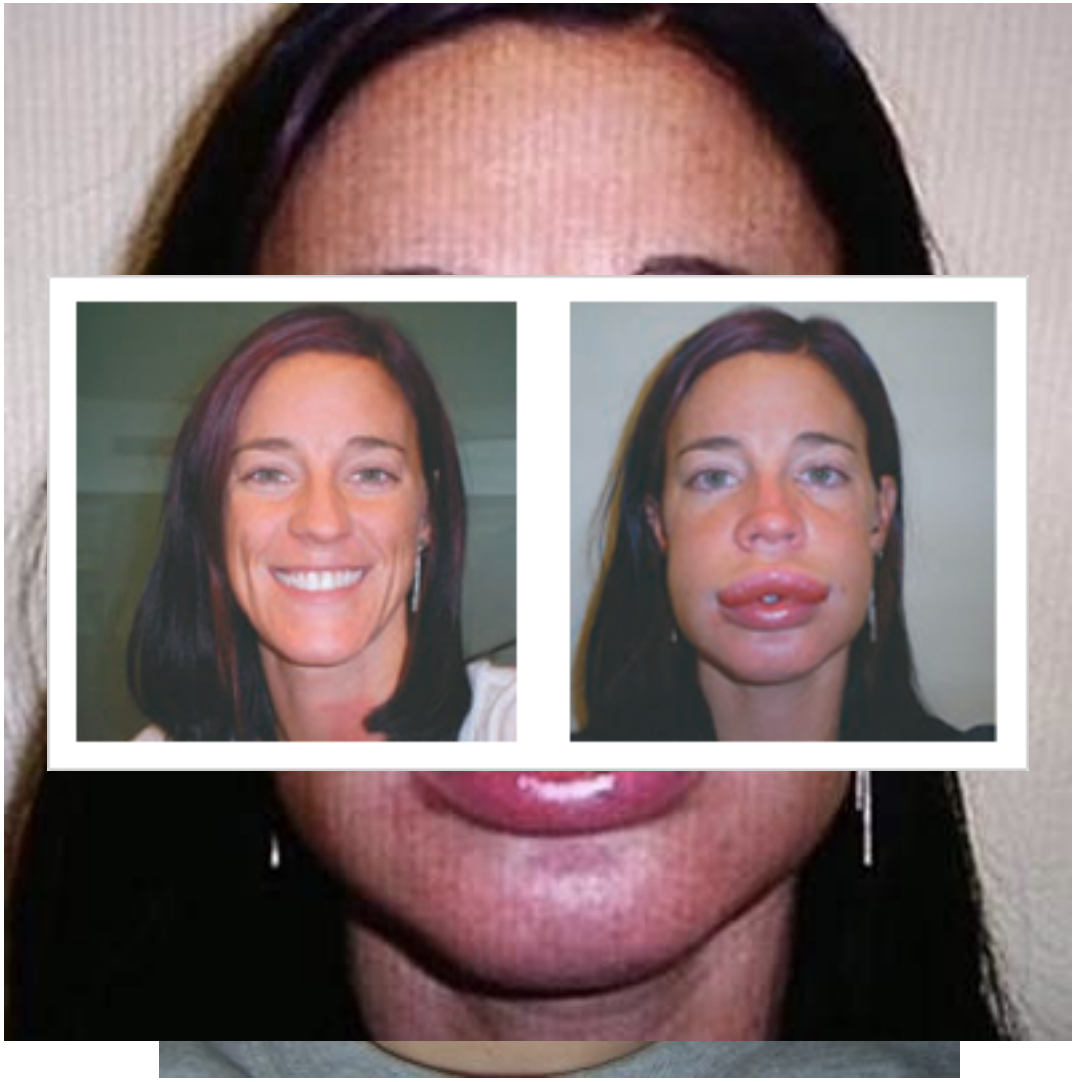
KEPPRA is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy.

KEPPRA is indicated as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy.

KEPPRA is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.



Angioedema



Angioedema

- Swelling of deep layers of skin (dermis, subcutaneous tissue, mucosa, submucosa)
- Commonly around lips or eyes
- May be hereditary or allergic reaction, often due to drugs
- Most famously associated with ACE-inhibitors
  - Incidence 0.1 - 0.7%

Proposed Study

- Retrospective new-user cohort study comparing levetiracetam vs phenytoin exposure and risk of angioedema
- Use propensity scoring to match treatment and comparator cohorts. Covariates will also be included in the outcome models.
- A set of 100 negative controls has been generated (using LAERTES and clinical review) to evaluate residual bias and compute calibrated p-values.

Optional Feasiblity Scan with Calypso

Feasibility Study List Help

new feasibilty for jon duke: keppra vs. phenytoin and angioedema

Save | Import | Copy | Generate... | Delete | Show SQL

Description

Index Cohort ID:2150 **Matching Cohort ID:**2151

Index Rule | Inclusion Rules | Concept Sets | Print Friendly | Results

Source	Name		Match %	Match #	Total	Started	Duration	Status	
TRUVENCCAE	Truven CCAE (122M)	Generate	0.00%	0	56872	2016-04-21, 14:58	00:00:30	OK	Remove
TRUVENMDCR	Truven MDCR (9M)	Generate	0.00%	0	17036	2016-04-21, 14:58	00:00:29	OK	Remove
TRUVENMDCD	Truven MDCD (17M)	Generate	0.00%	0	25970	2016-04-21, 14:59	00:00:30	OK	Remove
OPTUM	Optum (41M)	Generate	0.00%	0	18779	2016-04-21, 14:59	00:00:28	OK	Remove
CPRD	CPRD (12M)	Generate	0.00%	0	10327	2016-04-21, 14:59	00:00:26	OK	Remove
PREMIER	Premier (108M)	Generate	0.00%	0	495	2016-04-21, 14:59	00:00:26	OK	Remove
JMDC	JMDC (3M)	Generate	0.00%	0	1757	2016-04-21, 14:59	00:00:26	OK	Remove

Overview | Reports

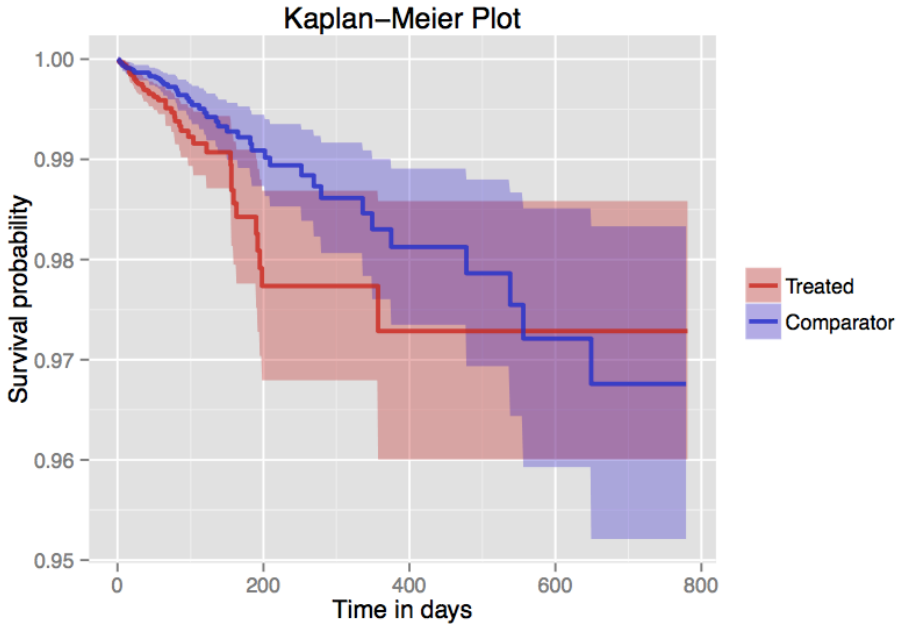
Summary Statistics:	Match Rate	Matches	Total
	0.00%	0	56,872

Inclusion Rule	N	% Satisfied	% To-Gain
1. has angioedema	213	0.37%	0.00%
2. keppra + angio	150	0.26%	0.00%
3. phenytoin + angio	60	0.11%	0.00%
4. keppra on index	44,051	77.46%	0.00%
5. Phenytoin on index	12,149	21.36%	0.00%

Population Visualization Switch to attrition view

Study R Package

- CohortMethod-based R package on GitHub
- Code will be tested and ready in ~1 week
- We will notify via forums when ready



Protocol

- Full protocol is available on the wiki
  - For those institutions requiring IRB for de-identified studies, the protocol can serve as basis

Result Dissemination

- While publication is an objective of every OHDSI study, we are also interested in the rapid dissemination of results to the community (including FDA)
- Would like to discuss people's thoughts about posting results to OHDSI website for small, targeted studies

Thanks!

forums.ohdsi.org

github.com/ohdsi/community