

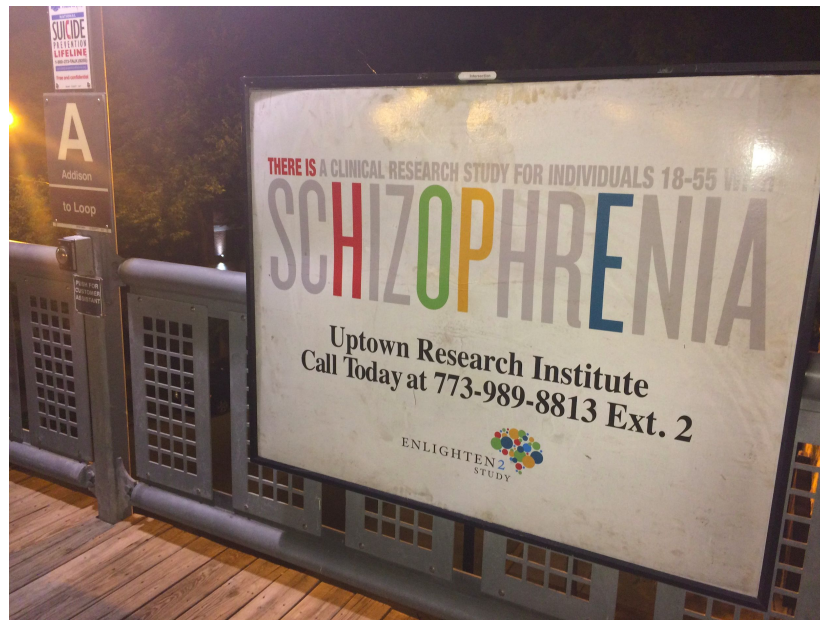
# Eligibility Patterns in Clinical Trials

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Courtney Stepien

# Patient recruitment is a barrier to clinical trial success

- 20% of suspended or terminated trials fail to recruit enough patients
- Trial recruitment is a \$2 billion industry



# Patients are interested, but trials are hard to find

Showing: 1-100 of **339** studies  studies per page

Row	Saved	Status	Study Title	Conditions	Interventions
1	<input type="checkbox"/>	Recruiting	<a href="#">Pediatric <b>ASTHMA</b>-Educator</a>	<ul style="list-style-type: none"><li><b>Asthma</b></li></ul>	<ul style="list-style-type: none"><li>Other: Pediatric ASTHMA-Educator mobile application</li></ul>
2	<input type="checkbox"/>	Recruiting	<a href="#">Pilot of Lifestyle and <b>Asthma</b> Intervention</a>	<ul style="list-style-type: none"><li><b>Asthma</b></li></ul>	<ul style="list-style-type: none"><li>Behavioral: Weight loss intervention</li></ul>
3	<input type="checkbox"/>	Recruiting <b>NEW</b>	<a href="#">Russian Severe <b>Asthma</b> Registry</a>	<ul style="list-style-type: none"><li>Severe <b>Asthma</b></li></ul>	
4	<input type="checkbox"/>	Recruiting	<a href="#">Study to Evaluate the Efficacy and Safety of Tezepelumab in Reducing Oral Corticosteroid Use in Adults With Oral Corticosteroid Dependent <b>Asthma</b></a>	<ul style="list-style-type: none"><li><b>Asthma</b></li></ul>	<ul style="list-style-type: none"><li>Biological: Tezepelumab</li><li>Other: Placebo</li></ul>

# Categorizing eligibility criteria to find similar studies

Criteria

*ETL: SQL to Mongo*

Patient does not  
currently smoke

Nonsmoker or  
ex-smoker

History of moderate to  
severe asthma

# Categorizing eligibility criteria to find similar studies

Criteria

*ETL: SQL to Mongo*

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# Categorizing eligibility criteria to find similar studies

Criteria



Clean and  
Vectorize

*ETL: SQL to Mongo*

*Word2Vec*

Patient does not  
currently smoke

[0.4, 0.5, 0.1, 0.7, ...]

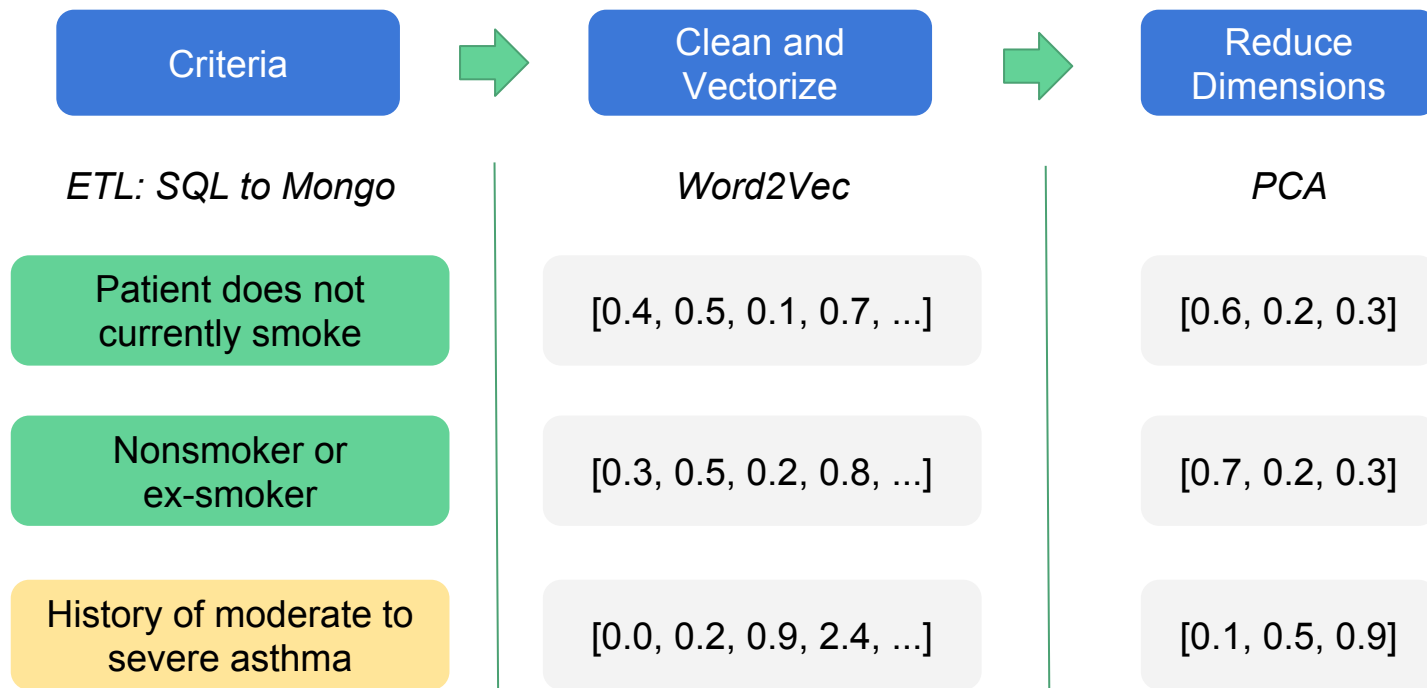
Nonsmoker or  
ex-smoker

[0.3, 0.5, 0.2, 0.8, ...]

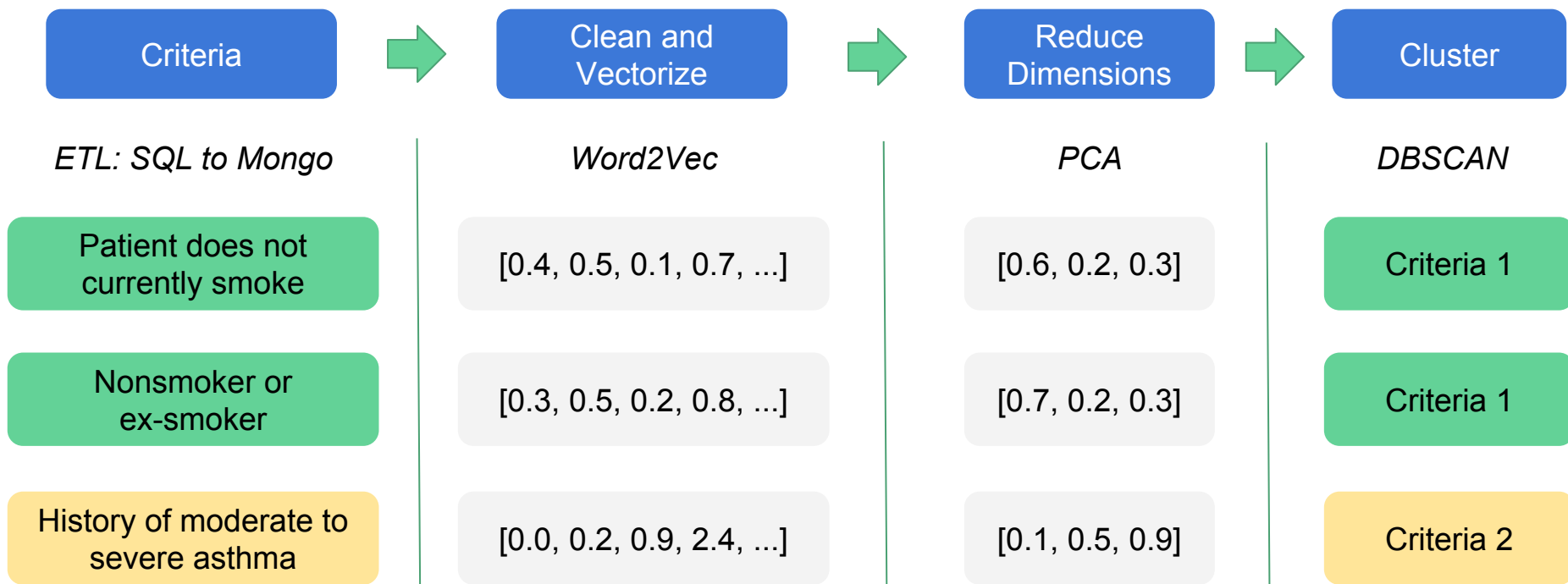
History of moderate to  
severe asthma

[0.0, 0.2, 0.9, 2.4, ...]

# Categorizing eligibility criteria to find similar studies



# Categorizing eligibility criteria to find similar studies





DBSCAN yielded 160 clusters from 11,000 criteria

### Eligibility Criteria: Visit to the ER

One asthma-related unscheduled visit to an emergency department or clinic in the past 12 months

At least one acute exacerbation of asthma in past 12 months that required a visit to the emergency department hospitalization or an unscheduled office visit for acute care and/or a course of oral steroid

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### Eligibility Criteria: Visit to the ER

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At least one acute exacerbation of asthma **in past 12 months** that required a **visit to the emergency department** hospitalization or an **unscheduled** office visit for acute care and/or a course of oral steroid

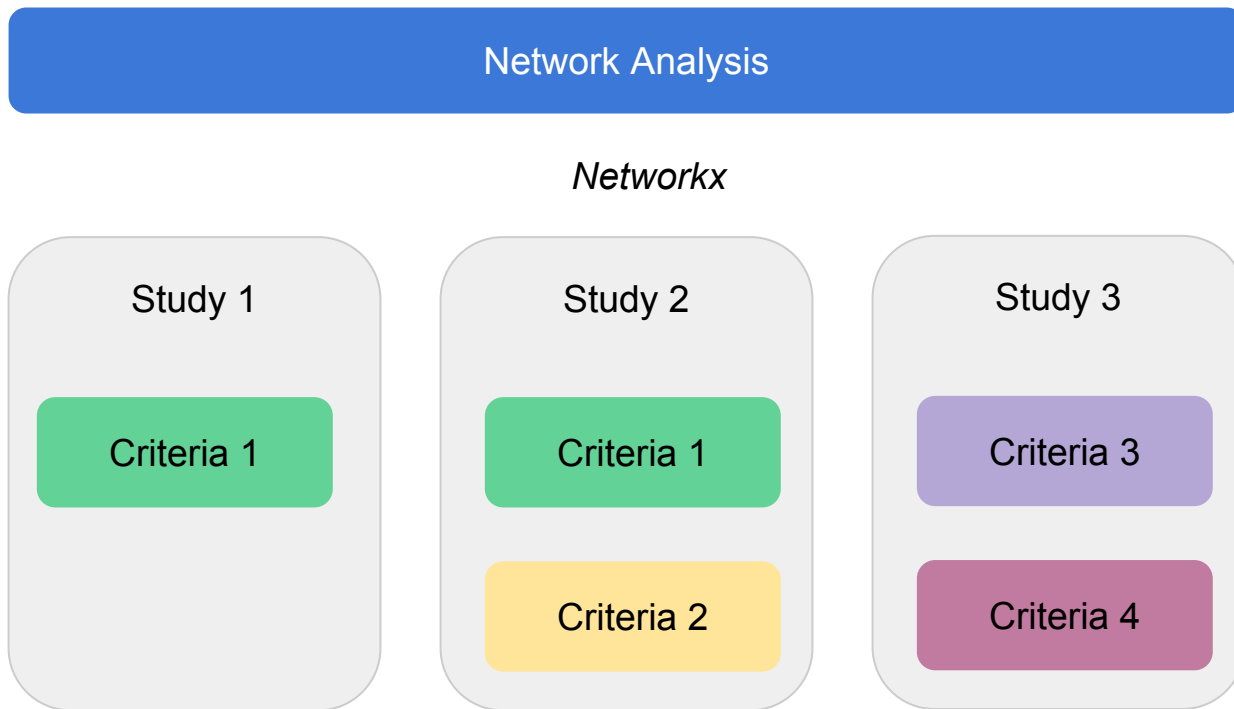
# NLP can identify similar criteria beyond just keywords

## Eligibility Criteria: Able to Use Inhalers

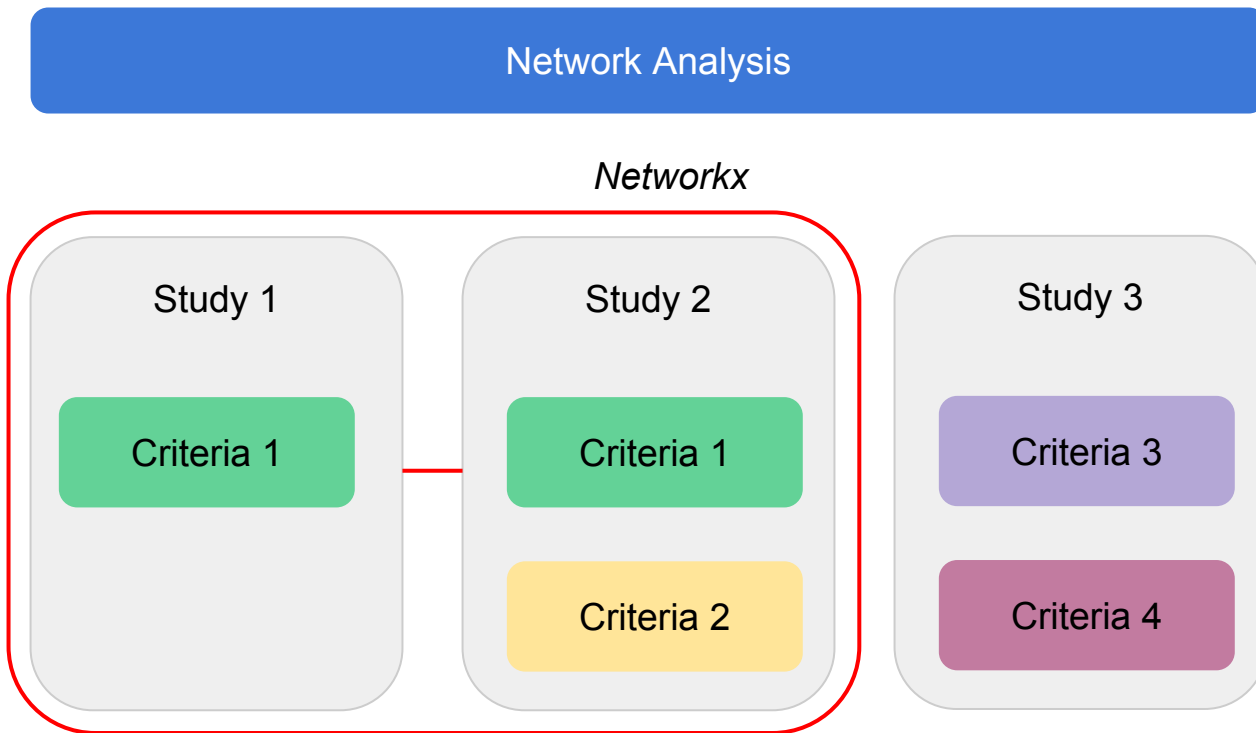
A subject must demonstrate adequate and appropriate technique for using the Diskus device

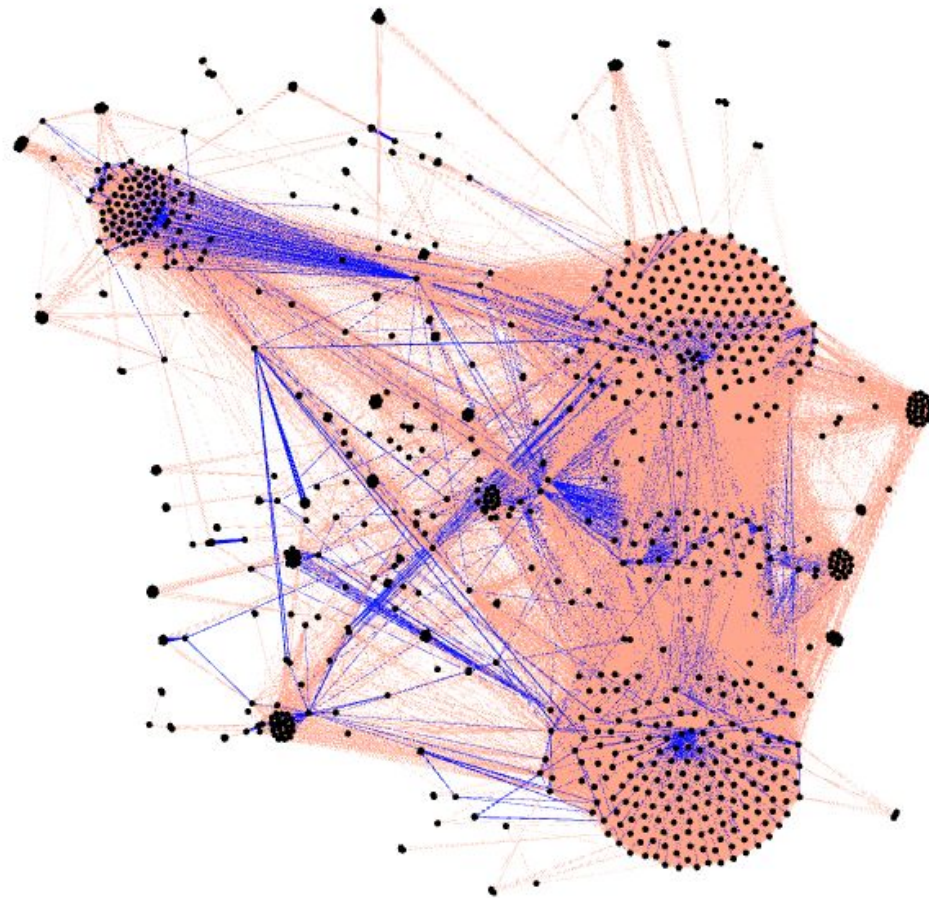
Ability to be trained in proper use of MDI with Aerochamber and Respimat

# Network analysis using shared criteria across studies



# Network analysis using shared criteria across studies





— More shared  
eligibility criteria

— Fewer shared  
eligibility criteria

● Study

# What if a patient qualifies for Study 1 but can't enroll?

Study 1	Study 2
<p>"Male or female adult subjects", "Age <math>\geq 18</math> and <math>\leq 65</math> years", "Body mass index (BMI) <math>\geq 18.5</math> and <math>\leq 32.0</math> kg/m<sup>2</sup>", "Non-smokers (within the last 5 years)", "Signed and dated written informed consent prior to admission to the trial in accordance with Good Clinical Practice (GCP) and the local legislation", "Proper use of RMT and MDI", ... exposure to at least one of the following: cold, exercise, dry air, smoke, dust, allergens", "Positive methacholine challenge test reflecting mild to moderate bronchial hyperreactivity (PC20: 0.25-4.0 mg/mL) performed within two weeks prior randomization (at visit 1 or between visit 1-2)"</p>	<p>"Males and females aged 18 to 65 years inclusive.", "Body mass index within the range 18.5-37.0 kilograms/metre<sup>2</sup> (kg/m<sup>2</sup>).", "An established clinical history of Asthma in accordance with the definition by the GINA Guidelines [GINA, 2006]. Subjects should have at screening or within the last year documented reversibility (<math>&gt;12\%</math>) to short acting bronchodilator, or positive methacholine challenge, or positive histamine challenge (PC20 <math>&lt;8</math>mg/ml).", "Subject with moderate to severe asthma with forced expiratory volume in one second..."Signed and dated written informed consent is obtained from the subject"</p>

# NLP and network analysis allows for quick evaluation

Study 1	Study 2
<p>"Male or female adult subjects", "Age <math>\geq 18</math> and <math>\leq 65</math> years", "Body mass index (BMI) <math>\geq 18.5</math> and <math>\leq 32.0</math> kg/m<sup>2</sup>", "Non-smokers (within the last 5 years)", "Signed and dated written informed consent prior to admission to the trial in accordance with Good Clinical Practice (GCP) and the local legislation", "Proper use of RMT and MDI", ... exposure to at least one of the following: cold, exercise, dry air, smoke, dust, allergens", "Positive methacholine challenge test reflecting mild to moderate bronchial hyperreactivity (PC20: 0.25-4.0 mg/mL) performed within two weeks prior randomization (at visit 1 or between visit 1-2)"</p>	<p>"Males and females aged 18 to 65 years inclusive.", "Body mass index within the range 18.5-37.0 kilograms/metre<sup>2</sup> (kg/m<sup>2</sup>).", "An established clinical history of Asthma in accordance with the definition by the GINA Guidelines [GINA, 2006]. Subjects should have at screening or within the last year documented reversibility (<math>&gt;12\%</math>) to short acting bronchodilator, or positive methacholine challenge, or positive histamine challenge (PC20 <math>&lt;8</math>mg/ml).", "Subject with moderate to severe asthma with forced expiratory volume in one second..." "Signed and dated written informed consent is obtained from the subject"</p>



# The NLP/clustering/network approach beyond trials

- Market segmentation
  - Product reviews
  - Novel markets

# Thank you!

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courtneystepien