

Study characteristics and considerations		Data source #6	Data source #7	Data source #11
<b>DESIGN ELEMENTS</b>				
<b>Study population</b>	<ul style="list-style-type: none"> <li>More than 5 million population (targeted 371 infants with in utero exposure to varenicline)</li> </ul>	5	5	5
<b>Treatment/exposure and comparator group(s)</b>	<ul style="list-style-type: none"> <li>Maternal prescription data linked with birth data</li> <li>In utero exposure to maternal smoking status</li> </ul>	5	5	4
<b>Primary outcomes</b>	<ul style="list-style-type: none"> <li>Mother — infant linkage</li> <li>Birth data linked to infant inpatient/outpatient diagnosis data</li> </ul>	5	5	4
<b>Secondary outcomes</b>	<ul style="list-style-type: none"> <li>Birth data linked to infant inpatient/outpatient diagnosis data</li> <li>Birth data linked to infant causes of death data</li> </ul>	5	5	4
<b>Length of follow-up and data recency</b>	<ul style="list-style-type: none"> <li>1 year after birth minimum</li> </ul>	5	5	5
<b>Confounding variables</b>	<ul style="list-style-type: none"> <li>Pregnancy data linked to maternal prescription data</li> <li>Pregnancy data linked to maternal inpatient/ outpatient diagnosis data</li> </ul>	5	5	4
<b>DATA ACCESS CONSIDERATIONS</b>				
<b>Timeline</b>	<ul style="list-style-type: none"> <li>Time to fully executed contract</li> <li>Time to data access</li> <li>Time to analyze</li> </ul>	Moderate	Fast	Moderate
<b>Contracting logistics</b>	<ul style="list-style-type: none"> <li>Cost</li> </ul>	Medium	Medium	Low
<b>FINAL DATA SOURCE SELECTION</b>		✓	✓	

#### LEGEND

5	= Many/nearly all data requirements met
4	= Several data requirements met
3	= Likely that several data requirements are met but requires further investigation
2	= Some data requirements met or unable to assess at this time
1	= Data requirements not met

**Figure S2.**  
**Case Example 2: SPIFD Step 3 heatmap retrospectively applied to varenicline pregnancy study**