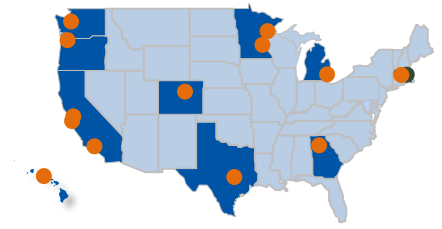
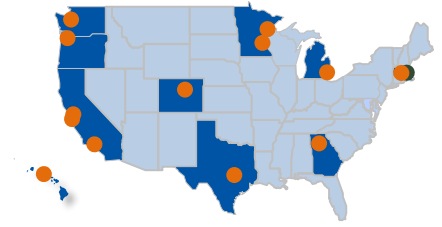


	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and Health Systems		X			
Data collection and merging datasets	X				
Regulatory issues (IRBs and consent)			X		
Stability of control intervention		X			
Implementing/Delivering Intervention Across Healthcare Organizations			X		



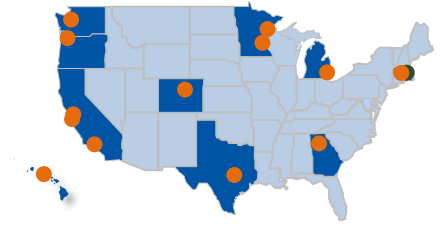
Challenges – Damage Done

- IRB review caused significant delay and waste (but less so with each iteration)
 - DSMB review caused significant delay and still causes significant waste
-



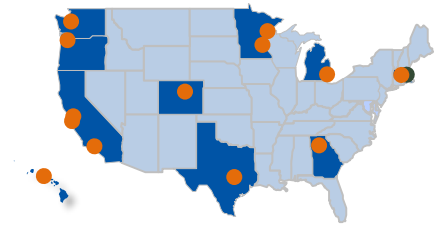
Challenges – Ongoing

- Adapting to variability in EHRs
 - Between sites
 - Within sites over time
 - Improving follow-up care in supply-constrained systems
 - “Slippage” in systematic use of outcome measures
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Challenges – Upcoming

- Re-validating outcome specifications after switch to ICD-10
 - Re-evaluating sample size in light of:
 - Switch to ICD-10 diagnoses
 - Differing event rates across sites
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Lessons

- Need clearer charter and tools for safety monitoring of pragmatic trials
 - Need more engagement with EHR vendor(s) at the beginning
 - Need guidance for reestimating (and re-estimating) sample size in PCTs
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