FDA REQUESTS REGULATORY AUTHORITY FOR LABORATORY-DEVELOPED TESTS

Cause Map

"Laboratory developed tests (LDTs) serve an increasingly important role in health care today. They also have become significantly more complex and higher risk, with several notable examples of inaccurate tests placing patients at otherwise avoidable risk."

"Despite the contention from some that "CLIA (Clinical Laboratory Improvement Amendments) is enough," all of the tests described as problematic in this report were offered from laboratories following the minimum requirements of CLIA."

- "The Public Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies"

1 Problem

What	Problem(s)	Request for FDA regulatory oversight
When	Date	Report released November 16, 2015
	Different, unusual, unique	LDTs not required to be regulated by FDA
Where	Facility, site	Diagnostic laboratories
	Unit, area, equipment	Diagnostic testing
	Task being performed	Laboratory-developed tests (LDTs)

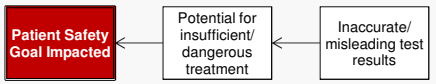
Impact to the Goals

Patient Safety	Insufficient treatment for life-threatening disease
	Potential to undergo dangerous procedures
Employee Safety	?
Environmental	?
Compliance	None; not required to be regulated
Patient Services	Threat to scientific integrity of clinical trials
Schedule/ Operations	?
Property/ Equipment	?
Labor/ Time	?

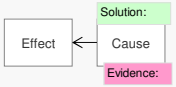
Frequency	31 warning letters to test manufacturers in 2014

2 Analysis

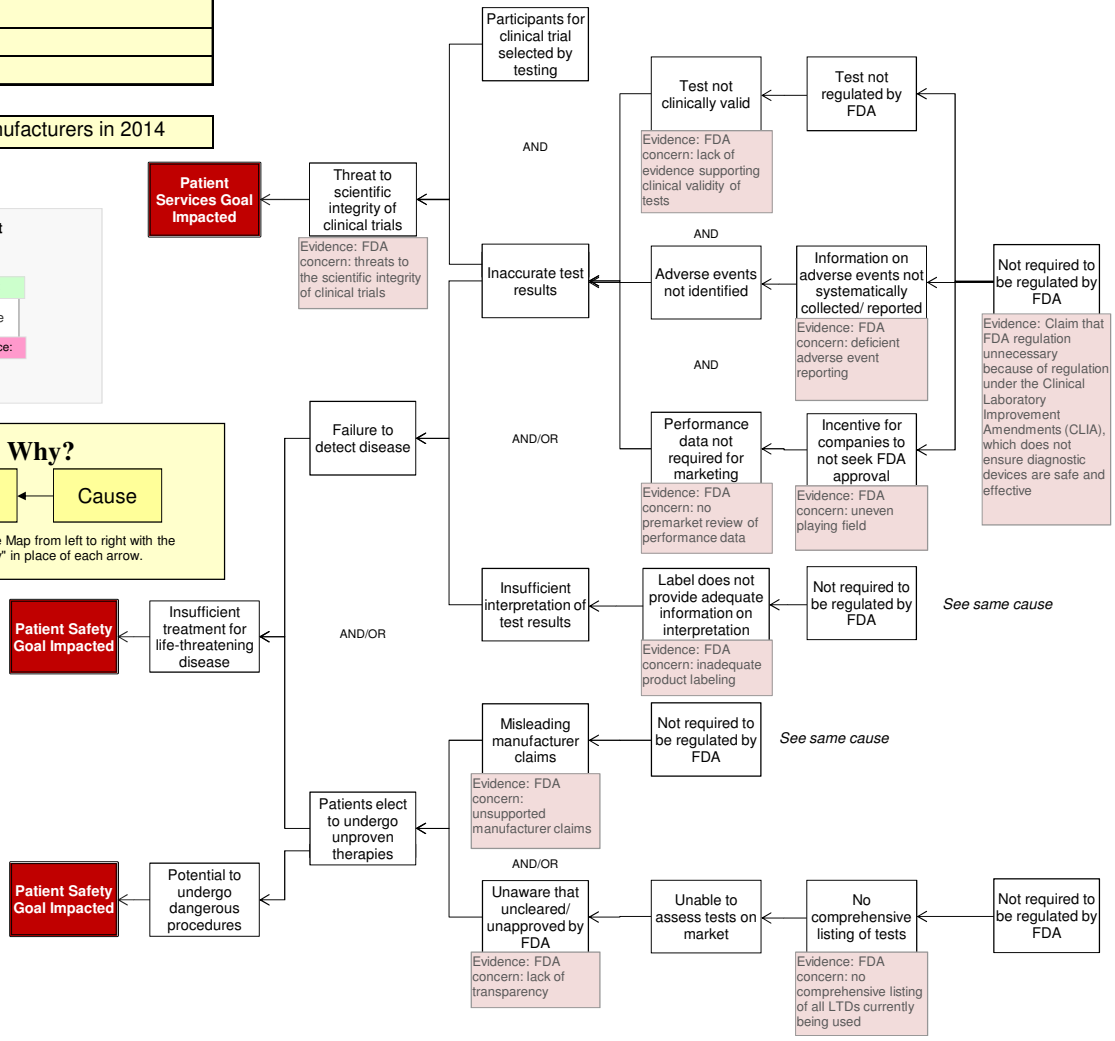
Basic Level Cause Map - Start with simple Why questions.



Basic Cause-and-Effect



More Detailed Cause Map - Add detail as information becomes available.



Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.

CAUSE MAPPING

Problem Solving • Incident Investigation • Root Cause Analysis

Step 1	Problem	What's the Problem?
Step 2	Analysis	Why did it happen?
Step 3	Solutions	What will be done?

For a free copy of our Root Cause Analysis Template in Microsoft Excel, used to create this page, visit our web site.

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