Improving trial activation timelines: A comprehensive process improvement project

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Problem Statement

Clinical trial activation at a matrix cancer center requires complex processes with multiple stakeholders. The median trial activation time in 2021 at Sylvester was 226 calendar days, which exceeds our target of 90 days. To achieve this goal, we examined the trial activation process using a Lean Six Sigma process improvement project.
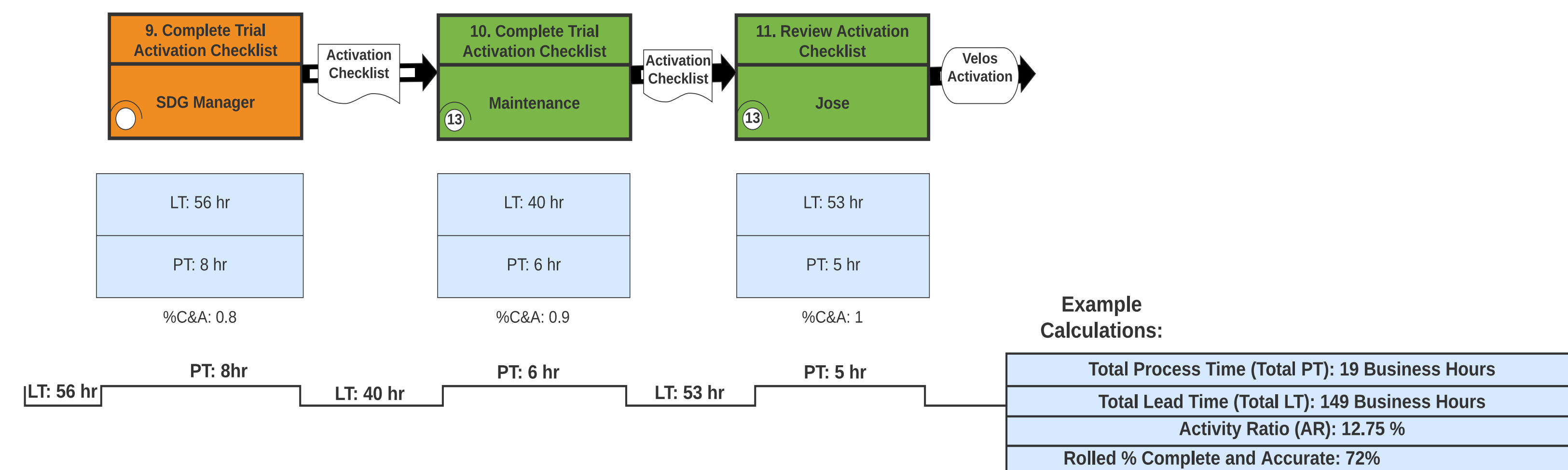
Goals

The overall goal is to reduce Sylvester's trial activation time to a median of fewer than 90 calendar days, which represents a 48% reduction from our 2021 median.
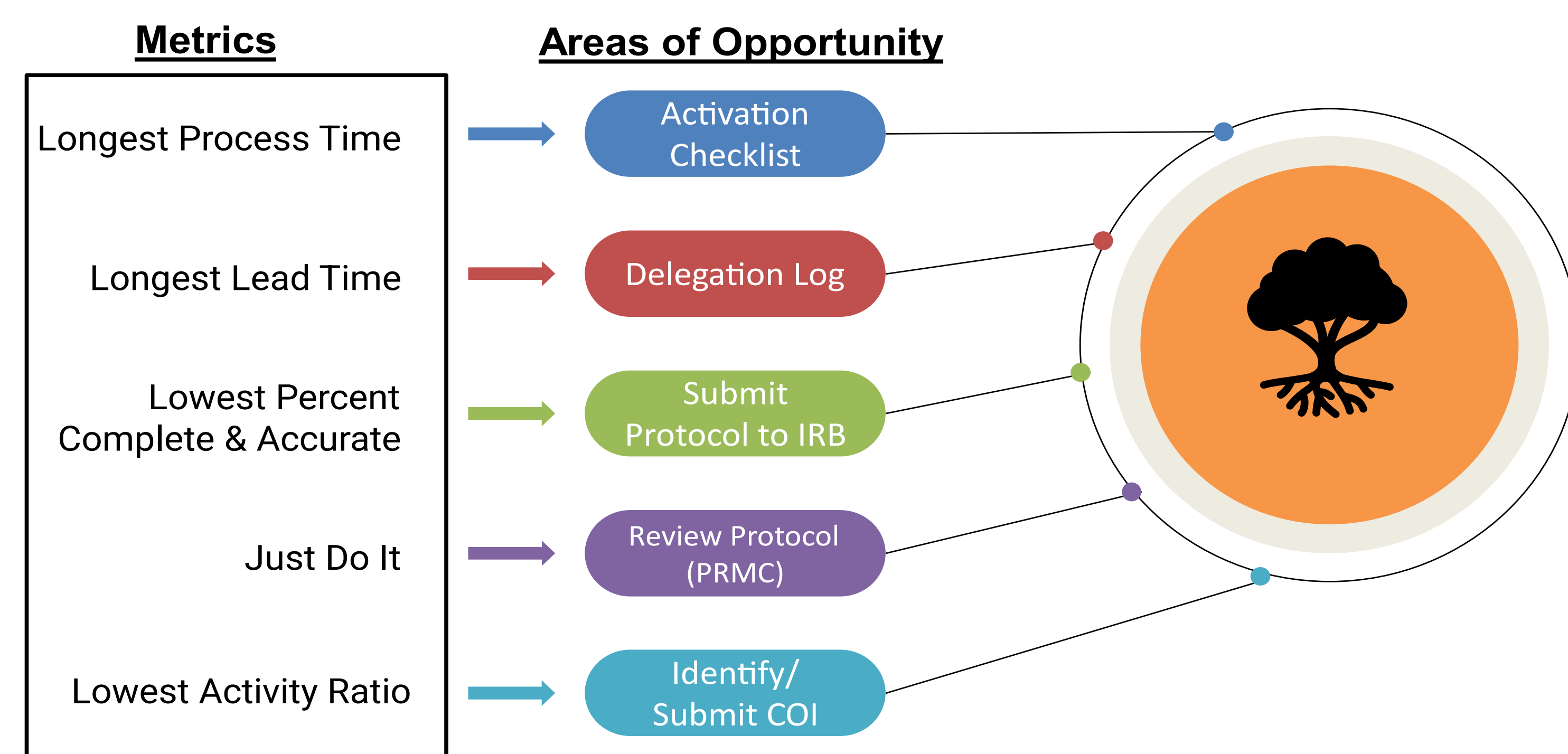
DEFINE: Current state

The deliverable was a value stream map (VSM), which provides a holistic view of our current state process by visualizing the movement of a trial from start to finish. The VSM depicted our current state, which involves 13 process blocks across the trial activation process.

Example: VSM Portion of Activation Checklist

Total Process Time (Total PT): 19 Business Hours	
Total Lead Time (Total LT): 149 Business Hours	
Activity Ratio (AR): 12.75 %	
Rolled % Complete and Accurate: 72%	

MEASURE: Baseline with timeline
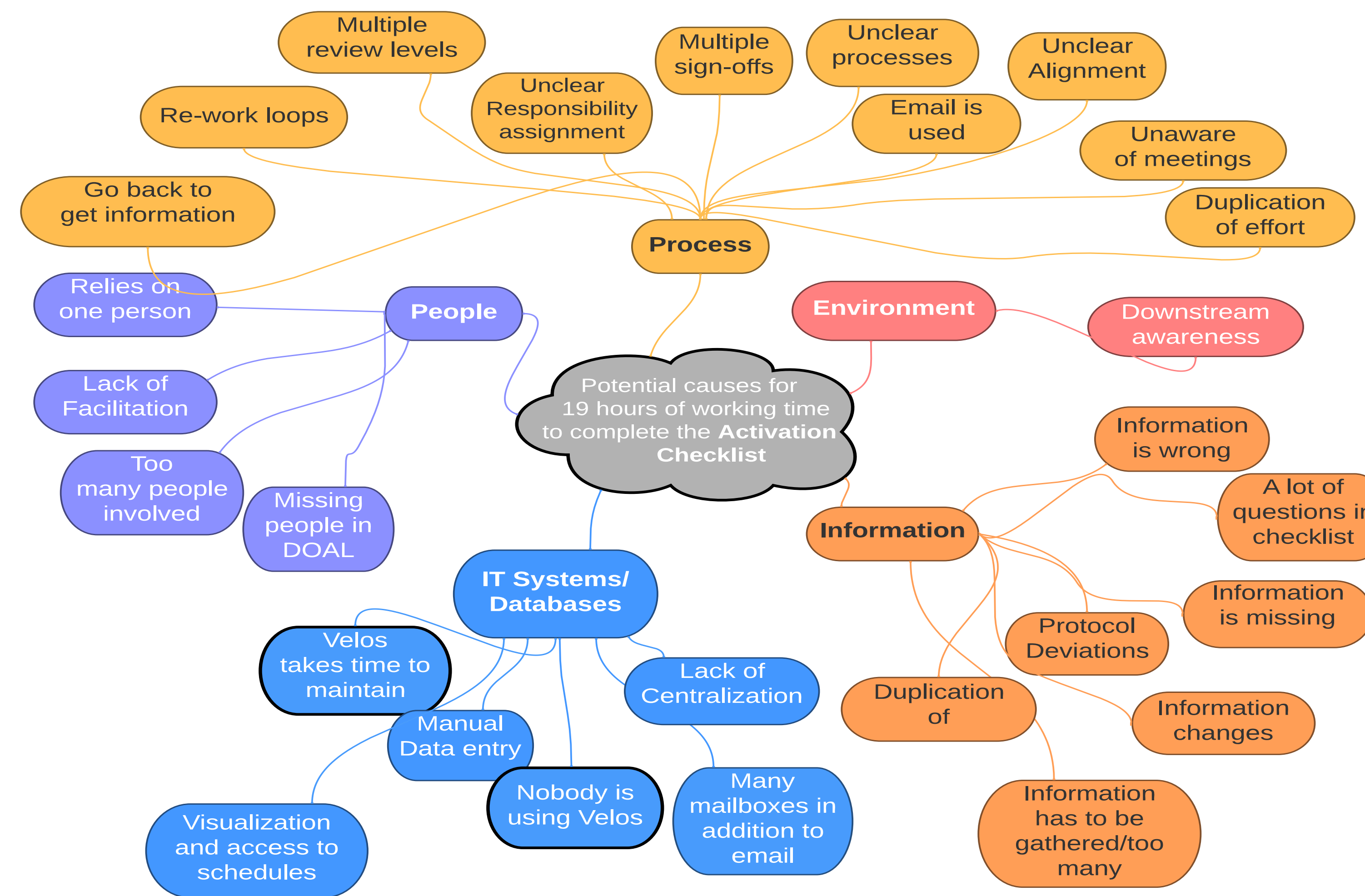
Through an analysis of our current state performance metrics, we identified multiple focus areas for the root cause analysis (RCA) phase:

Metrics
- Longest Process Time
- Longest Lead Time
- Lowest Percent Complete & Accurate
- Just Do It
- Lowest Activity Ratio

Areas of Opportunity
- Activation Checklist
- Delegation Log
- Submit Protocol to IRB
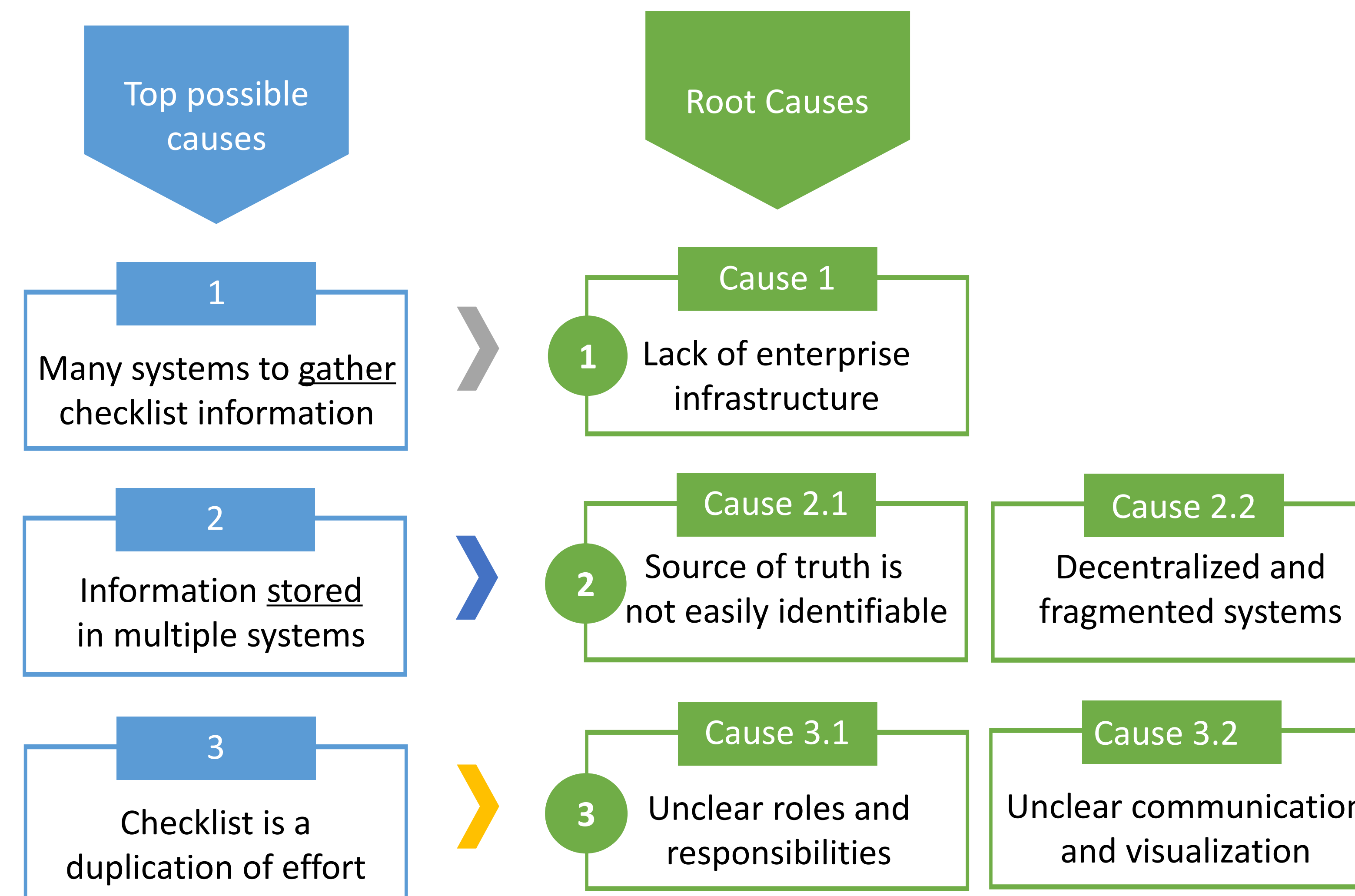- Review Protocol (PRMC)
- Identify/ Submit COI

ANALYZE: Root cause analyses (RCA)

We met with subject matter experts (SMEs) to conduct the RCA and identify pain points. We used process improvement tools such as brainstorming, multi-voting, and the Five Whys to guide the SMEs through the analysis.

Example: Brainstorming – Activation Checklist

Example: Five Whys Root Causes – Activation Checklist

Top possible causes

Root Causes

1. Many systems to gather checklist information
   → Cause 1: 1. Lack of enterprise infrastructure

2. Information stored in multiple systems
   → Cause 2.1: 2. Source of truth is not easily identifiable
   → Cause 2.2: Decentralized and fragmented systems

3. Checklist is a duplication of effort
   → Cause 3.1: 3. Unclear roles and responsibilities
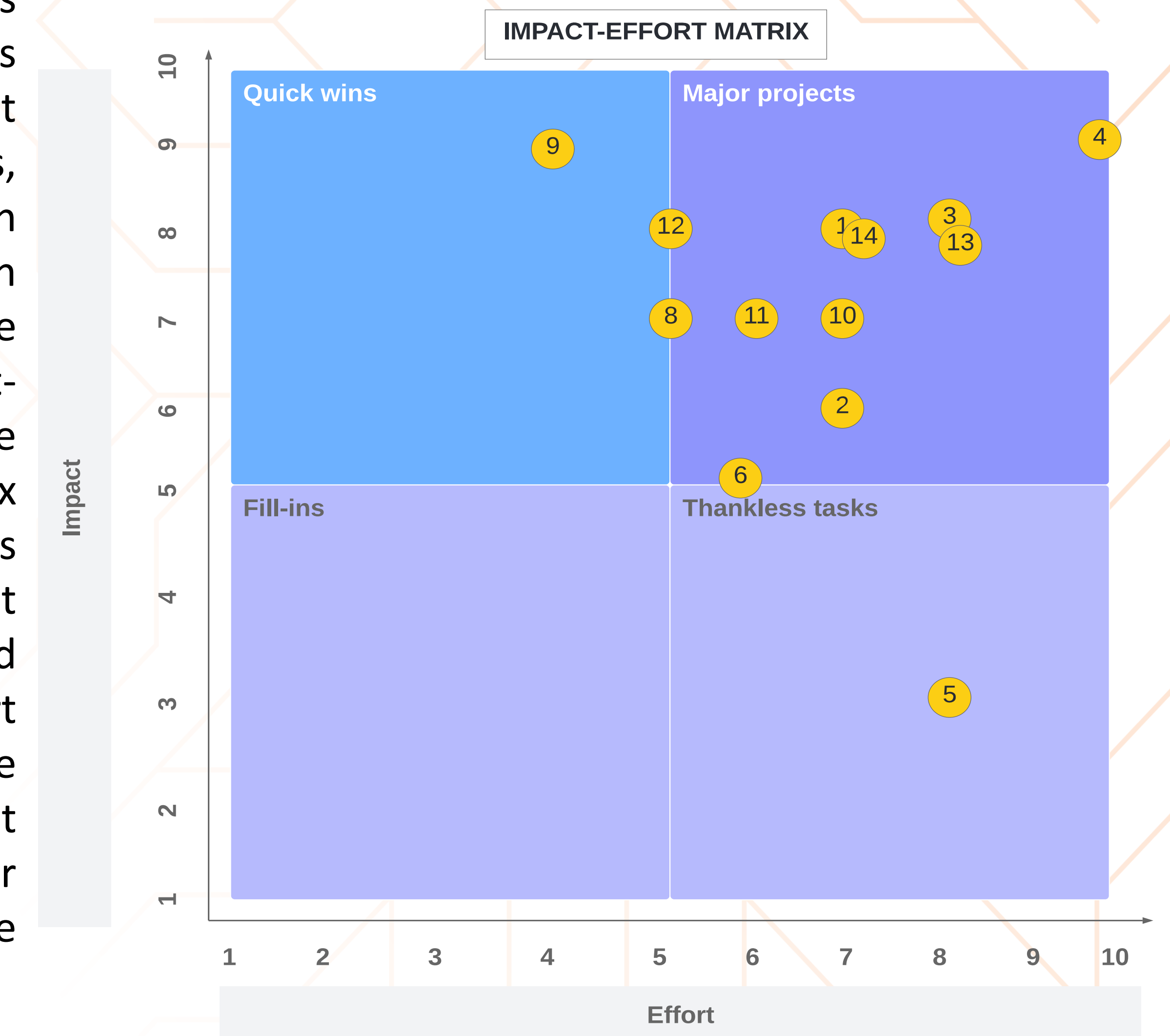   → Cause 3.2: Unclear communication and visualization

IMPROVE: Action plans

We collected 25 pages of improvement ideas from SMEs which equaled 179 individual ideas. These ideas showed distinctive patterns in the suggestions submitted to the project team. Improvements in communication, training, and standard operating procedures (SOPs) and workflows comprised more than 50% of all suggestions across the focus areas.

The root causes identified were used as a vehicle to collect improvement ideas, which were then analyzed and scored on impact and effort. The results of the impact-effort analysis were displayed in a matrix that differentiates potential solutions that have high impact and require low effort ("quick wins"), those with high impact but high effort ("major projects"), and those with low impact.

Example: Impact-Effort Matrix – Activation Checklist

PROPOSED PROJECTS

Category	Number in Matrix	Suggested Output	Score Impact - Effort
Quick Wins	9	Task list per team	9-4
Quick Wins	12	Weekly meeting with teams to discuss handoffs and progress	8-5
Quick Wins	8	Monthly meeting with teams to increase awareness of responsibilities and updates	7-5
Major projects	4	Velos as centralized system	9-10
Major projects	1	Centralized checklist that is divided by department	8-7
Major projects	3	Creating checklist in Velos status page	8-8
Major projects	13	Update workflow to include responsibility for status updates. Input statuses and show workflow in OPERA	8-8
Major projects	14	Determine segment owners and keep accountable for information	8-7
Major projects	11	Verification of data in Velos	7-6
Major projects	10	Weekly training meetings on processes	7-7
Major projects	2	Checklist divided by timepoints in OPERA	6-7

CONTROL: Future Directions (PDCA)

Sylvester plans to continue its process improvement efforts with the implementation of projects that are categorized as quick wins in the Impact-Effort Matrix. This implementation will use the Plan-Do-Check-Act approach to stimulate continuous improvement and to reduce activation times to a median of 90 calendar days.