



Star Clinical workflow analysis framework for SaMD

Find where a digital component fits. Before you build it.

Design your digital component around the workflow it needs to fix, not the features you want to ship.



“Standard operating procedures describe the intended pathway, not the real environment. Patient real life outside of a controlled environment includes workarounds, missing steps, environmental constraints, and changes that don’t appear in the ideal model.”



Pavel Kyrylchenko

Senior Product Manager, Star

Most OEMs know how their device performs in the clinic. Very few know what happens after the patient leaves. Adherence breaks down. Confidence erodes. Problems accumulate silently until they escalate into complications that could have been prevented.

The data that would have enabled earlier action was never captured. Not because the technology wasn't available, but because no one mapped where in the workflow it was needed.

Workflow analysis is often viewed as an implementation step, conducted after vendor selection or SaMD product concept development. This approach is too late. The Agency for Healthcare Research and Quality’s (AHRQ) Workflow Assessment for Health IT Toolkit recommends integrating workflow assessment into planning, design, implementation, and use, highlighting its impact on both clinical and administrative workflows.

Star 6-step Clinical workflow analysis

Star Clinical workflow analysis framework gives OEM product teams a structured way to answer that question. Six phases. A clear diagnostic process. One defensible product decision made before development begins.

Six phases. One defensible product decision.

Each phase builds on the last. Skipping upstream phases doesn't save time, it invalidates the decisions that follow.

1 Frame the care and business context

Define the problem space before touching solution ideas. Map the indication, care model, target population, care settings and route to market. Set a clear hypothesis for where digital value might exist, not as a roadmap, but as a claim the next phases will prove or disprove.

Core dimensions:

1. Indication and care model
2. Target population and segments
3. Care settings and transitions
4. Business model and route to market
5. Strategic hypothesis for digital value

Outputs:

1. Problem statement
2. Scope boundaries
3. Target actors and settings
4. Hypotheses to test

Consideration

Most digital health failures start here: a solution designed before the problem was understood.

2 Map the real workflow across the full ecosystem

Once the context is clearly established, begin mapping actual processes across the full ecosystem. For teams working on SaMD workflow mapping for patient and clinician adoption, this means looking beyond product use alone to understand training, monitoring, adherence, documentation, escalation, and support. A comprehensive clinical workflow map should include the patient and caregiver journey, clinician workflow, service and support processes, logistics, onboarding, commercial handoffs, and escalation paths.

Core dimensions:

1. Actors and roles
2. Tasks and decisions
3. Handoffs and escalation points
4. Tools, systems, and information objects
5. Time, place, and environment of use
6. Workarounds, delays, duplications

Outputs:

1. Current-state workflow map
2. Journey map
3. Ecosystem actor map
4. Pain-point inventory

Consideration

OEMs relying on study data and adverse event reports miss everything that happens between control points.

3 Diagnose root causes and unmet control points

Visible friction is a symptom. The failure that caused it happened earlier. Separate workflow mapping from root cause diagnosis, they are different steps. Classify each problem by gap type and determine what software can address and what requires operational change.

Use a structured diagnosis lens:

1. Visibility gap
2. Adherence /execution gap
3. Coordination /handoff gap
4. Confidence /education gap
5. Delayed response gap
6. Documentation /traceability gap
7. Incentives /ownership gap
8. Staffing /process gap

Outputs:

1. Root-cause map
2. Failure mode/friction map
3. "Digital-solvable vs non-digital" classification
4. Prioritized problem statements

Consideration

Separate problems that software can address from problems that require process redesign, training, channel changes, or service redesign. WHO's guidance is useful here: Digital can strengthen services, but it is not a substitute for a weak underlying operating model.

4 Test digital fit and solution feasibility

Not every problem qualifies for digital intervention. A problem must be: repeatable, observable, time-sensitive, linked to a decision point with a clear owner, and capable of producing a measurable outcome when resolved.

Use a fit matrix with these dimensions:

1. Clinical value
2. User value and behavior fit
3. Workflow fit
4. Data availability and interoperability fit
5. Technical feasibility
6. Evidence and regulatory fit
7. Business and reimbursement fit
8. Implementation and support fit

Outputs:

1. Digital-fit scorecard
2. No-go / go / redesign decision
3. Risk assumptions
4. Dependency list

Consideration

Incorporate SaMD, CDS, usability, human factors, and evidence implications. FDA guidance makes clear that intended function and user context materially affect regulatory posture and risk.

5 Define the roles of the digital component

A digital component rarely plays a single role. It is a composition — shaped by the specific workflow failures identified upstream and the outcomes they need to produce. Those roles could be monitoring, coaching, adherence support, symptom tracking, decision support, triage, coordination, documentation, or service orchestration. Each carries a different evidence requirement, regulatory path, and infrastructure dependency.

Possible roles:

1. Monitoring
2. Coaching / education
3. Adherence support
4. Symptom tracking
5. Decision support
6. Triage / escalation
7. Communication / coordination
8. Documentation / traceability
9. Service orchestration

Outputs:

1. Role definition
2. Target users
3. Trigger points in workflow
4. High-level concept and boundaries
5. What the solution will explicitly not do

Consideration

The role should be defined by the control point it improves in the workflow, not by generic app functionality. Intended use shapes the regulatory claim and validation burden from day one. It is not a label applied after development.

6 Operationalize, commercialize, and scale

A sound digital component without a viable operating model fails in market. Selling digital alongside hardware means selling workflow value, not features. Sales teams need different messaging, different training, and explicit accountability for the digital offer.

Core dimensions:

1. Ownership model
2. Sales enablement
3. Onboarding and training
4. Service and support model
5. Channel strategy
6. Monetization / packaging
7. Evidence generation plan
8. KPI and adoption model
9. Change management

Outputs:

1. Prioritized use cases
2. Target operating model
3. Commercialization model
4. Adoption roadmap
5. KPI framework
6. Evidence roadmap

Consideration

Assigning digital to a hardware sales team with hardware KPIs is the most common commercialization failure.

From analysis to an actionable roadmap

The six phases produce workflow maps, journey maps, root cause maps, digital-fit decisions, and prioritized use cases. Turn workflow analysis into an implementation roadmap.



Anchor each use case to a validated control point

Traceability from use case back to root cause is what makes a recommendation credible – not a feature idea or a market category.



Assign an owner and a measurable outcome

Balance clinical KPIs (adherence, escalation speed, complication rate), operational KPIs (adoption, support load), and business leading indicators (retention, reimbursement). Keep the set lean – too many indicators diffuse accountability.



Sequence by infrastructure readiness

Some roles require connected device integration or EHR interoperability before they are viable. Map dependencies explicitly and sequence accordingly.



Define early performance signals

Not lagging outcomes – leading indicators that the intervention is working: fewer missed handoffs, cleaner data at transition points, faster escalation. When they move, the diagnosis was right. When they don't, revisit the root cause – not the product.

About Star

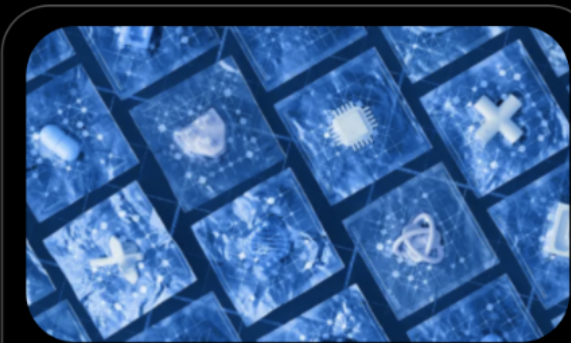
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Innovating with purpose, building with expertise

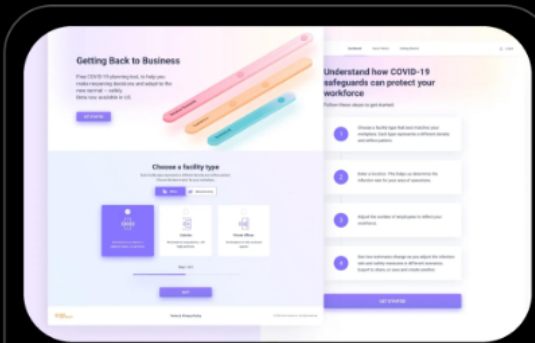
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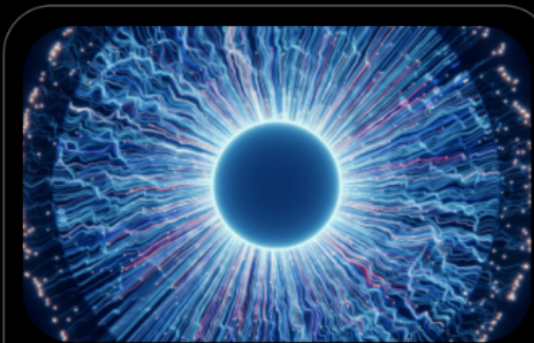
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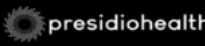
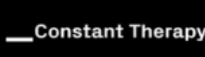
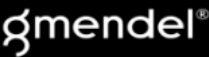
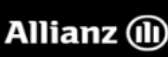
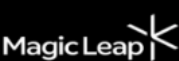


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SaMD



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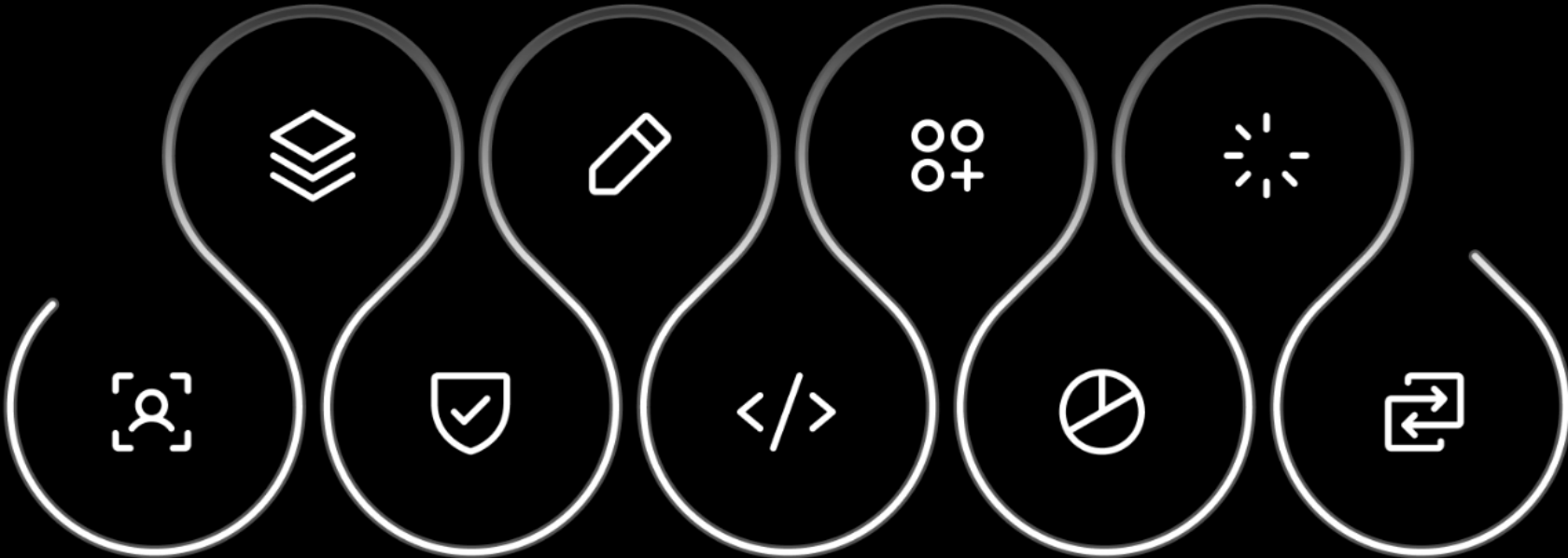
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Let's build the future of healthcare together.

Connect with us to explore how we can turn your vision into impact.



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