



Summary

Over the past eight years, GAITS has quietly grown into a foundational platform for healthcare innovation programs. Today, more than 1,000 teams have used private GAITS sites, with many more using the free version at www.GAITS.org.

This scale matters, not due to volume alone, but because it creates something rare in an innovation ecosystem: a longitudinal, real-world record of how teams actually progress.

As GAITS has matured, so too has the ability to learn from the teams it serves. Importantly, this learning occurs without compromising confidentiality. All team content in GAITS remains strictly private, and no proprietary materials are ever shared across teams or programs. Insights are derived from aggregate, anonymized **patterns**, in this case, from the custom Deliverables teams create to refine their innovation journey.

GAITS: A Deliverables-Driven Platform

From the beginning, GAITS was structured around a simple principle: a project's progress is best planned and tracked through a core set of concrete deliverables. GAITS organizes the Deliverables in 10 Innovation Maturity Levels (IML's) across four Domains:

- Clinical
- Market & Business
- Regulatory
- Technology



Deliverables are specific to the type of solution. Today GAITS has 6 different Solution Types (e.g. MedTech, Digital Medicine, etc.) each with its own set of core Deliverables, with many overlapping.

Critically, GAITS allows teams to add custom Deliverables in the same framework to address project-specific needs, such as deeper technical analysis, unique workflow considerations, or specific funder requirements. This balance, structure with controlled flexibility, has allowed GAITS to evolve from a planning tool into a system that can learn from experience.

Insights from 800+ Custom Deliverables

Across more than 1,000 teams, over 800 custom Deliverables have been created. On average therefore, teams add fewer than one new custom Deliverable per project. This is a strong indicator that the existing GAITS set of core Deliverables already does an excellent job supporting the vast majority of teams.

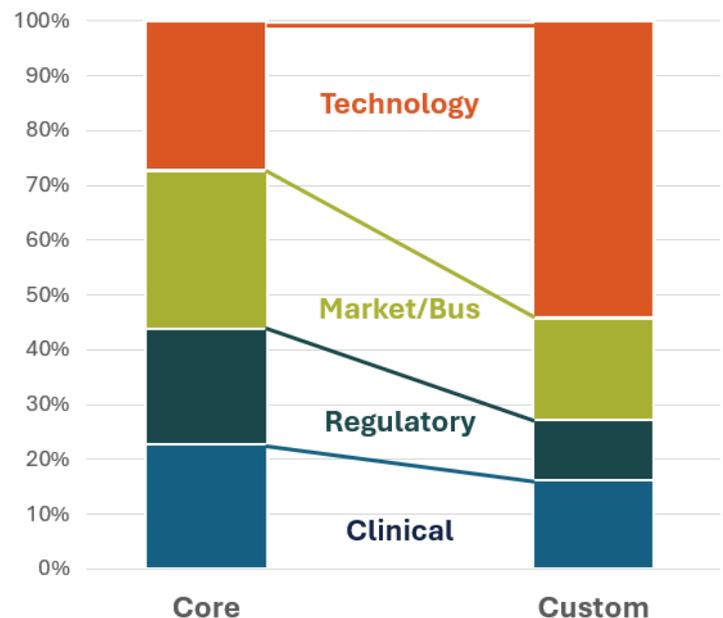
Figure 1 below shows a comparison of the proportion of Deliverables by Domain. One stacked bar is for the established set of core Deliverables used in today's 6 different Solution Types. The second stacked bar shows how the custom Deliverables are proportioned. Several patterns stand out:

- By far, most custom deliverables were created in the technology domain
- Most technology additions added granularity to existing deliverables, rather than introducing entirely new categories of work
- The fewest custom deliverables were created in the regulatory domain

The results suggest that GAITS' regulatory structure is already highly complete and well-scoped, providing teams with the discipline and clarity they need without frequent modification. This is not a surprise given the specific guidance provided by regulatory bodies.

By contrast, technical risk varies widely by solution. Teams did not indicate missing Technology categories; instead, they mostly used custom Deliverables to add project-specific depth, such as system architecture detail, integration constraints, performance limits, or scalability assumptions.

Figure 1: Proportion of GAITS Deliverables by Domain





Key Takeaways by GAITS Domain

1. Clinical

- **What teams add:** More structured deliverables around workflow fit, adoption risk, and real-world use conditions.
- **Insight:** Teams increasingly recognize that defining a clinical or user need is insufficient without understanding how solutions fit into real workflows.
- **Benefit:** Earlier identification of adoption barriers and fewer late-stage redesigns.

2. Market & Business

- **What teams add:** Deliverables clarifying buyer identity, economic value logic, pricing assumptions, and purchasing pathways.
- **Insight:** Teams often underestimate how early they must answer who pays, why, and from which budget.
- **Benefit:** Stronger commercial narratives and better alignment with funder expectations.

3. Regulatory

- **What teams add:** Very few new deliverables.
- **Insight:** The low volume of custom deliverables indicates that GAITS' Regulatory & Evidence structure already captures the critical work required for most teams.
- **Benefit:** Consistent regulatory planning, disciplined claims, and reduced downstream risk.

4. Technology

- **What teams add:** Project-specific extensions to existing deliverables, adding technical depth rather than new categories.
- **Insight:** Technical uncertainty varies widely by solution; teams value the ability to increase granularity without redefining the framework.
- **Benefit:** Stable structure with flexible depth—supporting both simple and technically complex projects.

Suggested New Core GAITS Deliverables:

The appendix provides a concise, evidence-based summary of proposed new and modified core GAITS Deliverables. All insights are derived from aggregate patterns and anonymized structure, not from sharing, exposing, or reusing any team's content.

For each Deliverable, the appendix specifies the domain, IML, status (new or modified), the “what, why, and how” instructions and the rationale for inclusion, explicitly noting which existing Deliverables are refined when applicable.



Conclusion

GAITS began as a guidance and tracking platform, designed to help teams understand and track what work needed to be done and in what sequence as projects matured. Over time, as thousands of innovators have used the platform, GAITS has a robust, structured data repository that reflects how real projects progress across clinical, market, regulatory, and technology domains.

Looking ahead, GAITS is well positioned to emerge as a true learning environment. As AI tools become more capable, we envision that the platform's growing longitudinal record will enable better pattern recognition, earlier identification of risk, and more adaptive guidance, while preserving full data privacy. In this way, GAITS will continue to increase in value over time, learning from teams' experiences without ever appropriating it, while supporting teams, mentors, and program managers with increasingly evidence-informed insight.

GAITS is not just supporting innovation, it is learning from it.



Appendix: Proposed New or Modified Deliverables

The following proposed new or updated GAITS Deliverables are informed by patterns observed in custom deliverables created to date.

Deliverable Name	Domain	Level	Status	What	Why	How	Rationale for Change
Workflow Adoption Risk Assessment	Clinical	2	New	A structured assessment of how the solution fits into real clinical or operational workflows, including handoffs, exceptions, and behavior change requirements.	To identify adoption and workflow risks early, before pilots or broader deployment lock in assumptions that are hard to change.	Describe where the solution enters existing workflows, who must change behavior, what happens in edge cases, and where adoption could realistically fail.	Teams repeatedly created ad hoc adoption analyses after mentor or pilot feedback, indicating this risk is often under-addressed early.
Economic Buyer & Budget Owner Mapping	Market & Business	3	New	A clear mapping of users, champions, economic buyers, and the specific budget expected to fund adoption.	To ensure the solution is aligned with real purchasing decisions, not just user enthusiasm or clinical interest.	Identify who uses the product, who influences the decision, who approves the purchase, and which budget line is impacted.	Many teams added custom Deliverables to clarify who actually pays, often after investor or procurement pushback.
Procurement Pathway Assumptions	Market & Business	4	New	A documented set of assumptions about how the solution will move through purchasing, contracting, and approval processes.	To anticipate procurement friction and prevent stalled pilots or delayed commercialization.	Outline expected approval steps, decision gates, stakeholders involved, dependencies, and	Teams often introduced this analysis only after encountering unexpected procurement barriers, revealing a

Learning from GAITS' Custom Deliverables



Deliverable Name	Domain	Level	Status	What	Why	How	Rationale for Change
Claim–Evidence Alignment Matrix	Regulatory	2	Modified (<i>Regulatory Strategy Overview</i>)	A structured mapping of external-facing product claims to the evidence required to support them at the current stage.	To maintain credibility by ensuring claims are supported by appropriate evidence and are staged realistically over time.	assumed cycle times. List key claims, identify required evidence for each, and explicitly defer claims not yet supportable.	common late-stage blind spot. While few regulatory custom Deliverables exist overall, this pattern recurred when teams needed stronger claim discipline.
System Architecture & Integration Map	Technology	2	Modified (<i>Technical Feasibility Assessment</i>)	A clear representation of system components, integrations, data flows, and external dependencies.	To surface technical integration and dependency risks before architecture decisions become difficult to reverse.	Create a visual or structured map showing system boundaries, interfaces, data sources, and constraints.	This was the most common Technology-domain customization, indicating teams need more architectural clarity early.
Scalability & Performance Constraints Analysis	Technology	4	New	An explicit analysis of performance limits, scalability assumptions, reliability requirements, and resource constraints.	To ensure the solution can realistically scale without failure as adoption increases.	Identify bottlenecks, scaling thresholds, performance assumptions, and conditions under which the system may break.	Teams often added this analysis late, after architecture was locked, leading to avoidable rework and risk.