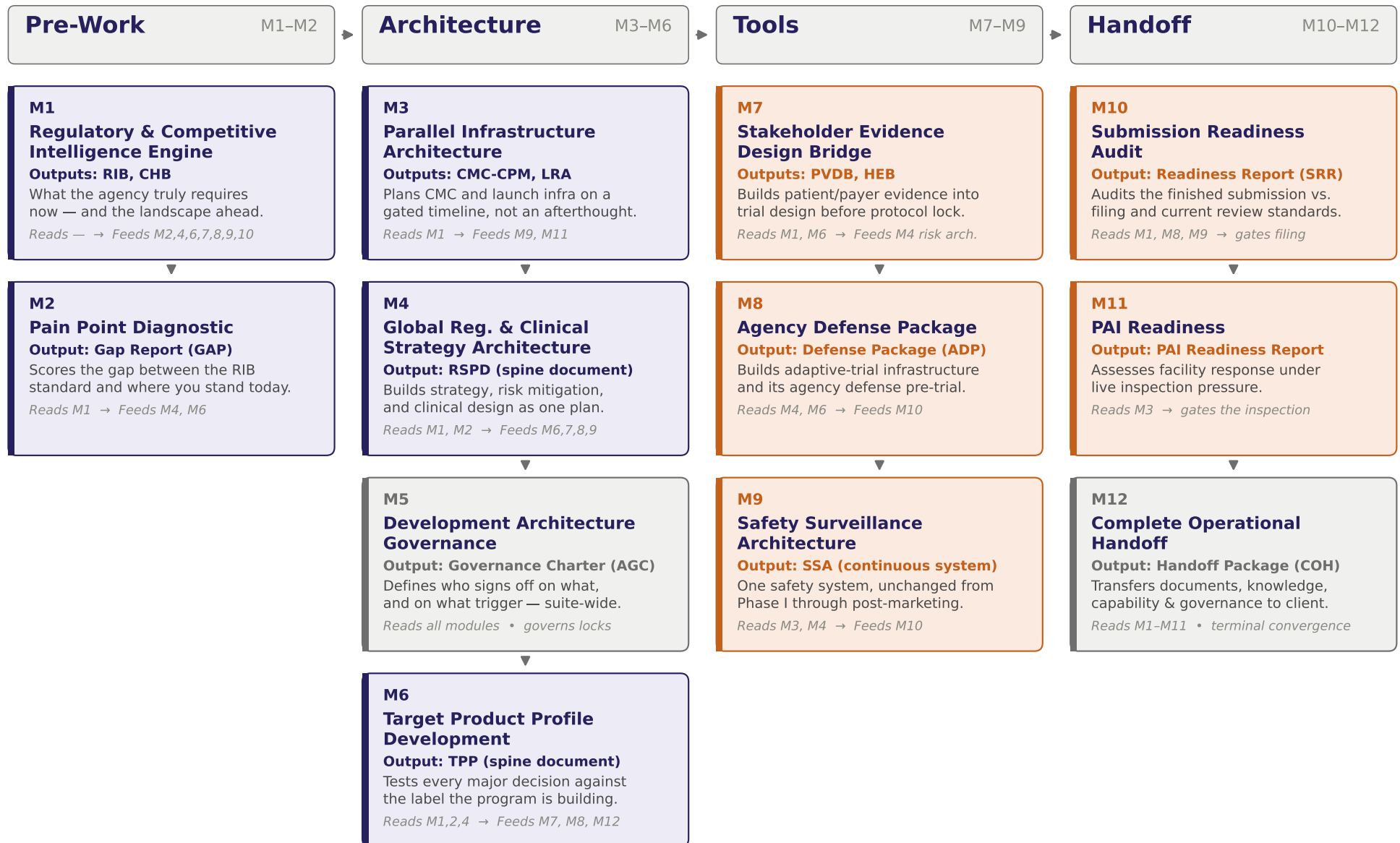


SMARTER PATH™ TO APPROVAL

Adroit-Metis LLC

Tool Workflow — modules, outputs, and how they feed into one another



● Definition — Pre-Work, Architecture

● Execution — Tools, Handoff

● Governance / convergence (M5, M12)

Illustrative workflow — architecture reference, no client data

Output Definitions — what each of the fifteen tool outputs is

Mod.	Code	Output	Definition
M1	RIB	Regulatory Intelligence Brief	Current-state view of what the agency actually requires, built from primary agency sources.
M1	CHB	Competitive Horizon Brief	Forward-projected RIB companion, forecasting the landscape at submission and approval dates.
M2	GAP	Gap Report	Scored, prioritized delta between the RIB standard and organizational readiness.
M3	CMC-CPM	CMC Critical Path Map	Gated manufacturing / analytical readiness timeline with an embedded regional heat map.
M3	LRA	Launch Readiness Architecture	Gated timeline of post-approval commercial, distribution, PV & medical-affairs infrastructure.
M4	RSPD	Regulatory Strategy & Pathway Document	Cross-agency requirements map, risk mitigation architecture, and full clinical program design.
M5	AGC	Architecture Governance Charter	Defines the Review Board's decision protocol and the Architecture Checkpoint schedule.
M6	TPP	Target Product Profile	Label-defining document the architecture converges into; tested against every major decision.
M7	PVDB	Patient Voice Design Brief	Patient engagement design and identified PRO instrument gaps, delivered pre-protocol lock.
M7	HEB	HEOR Evidence Bridge	Payer value story and the trial endpoints / comparators needed to be credible at launch.
M8	ADP	Agency Defense Package	IDMC charter, adaptation rules, SAP, and agency meeting strategy — built pre-trial.
M9	SSA	Safety Surveillance Architecture	One signal-detection and safety-database design, operated continuously from Phase I onward.
M10	SRR	Submission Readiness Report	Gap-scored audit of the submission against filing and current division review standards.
M11	PAI-R	PAI Readiness Report	Facility readiness assessment for investigator requests under live inspection pressure.
M12	COH	Complete Operational Handoff Package	Five-part transfer: documents, knowledge, capability, intelligence & governance to client.

● Definition-phase output

● Execution-phase output

● Governance / convergence output

Illustrative workflow — architecture reference, no client data