

Standard Assay Development Phases

From concept to commerce



This outlines RAPIvD's standard process for taking an assay from concept to commercialisation - or any development phase(s) along the way.

Brief	● Concept generation	Objective development	R&D Services	
Phase 1	● Proof-of-principle	Concept development (wet)		
Phase 2		Optimise concept		
Phase 3	● Feasibility	Test assay (dry)		
Phase 4		Optimise assay		
Phase 5	● Optimisation	Test with real samples		
Phase 6		Optimise real samples		
Phase 7	● Realisation	Document assay standards		
Phase 8		Prototype production		
Phase 9	● Production	Technology transfer		
Phase 10		Test batch production		
Phase 11	● Testing & Validation	Design and development		
Phase 12	● Trial Manufacture	Initial production		Manufacturing & Management Services
Phase 13	● Trials	Product/Clinical trials		
Phase 14	● Regulation	Regulatory approval		
Phase 15	● Manufacture	Volume production		
Phase 16	● Commercialisation	Packaging, promotion, logistics, sales		