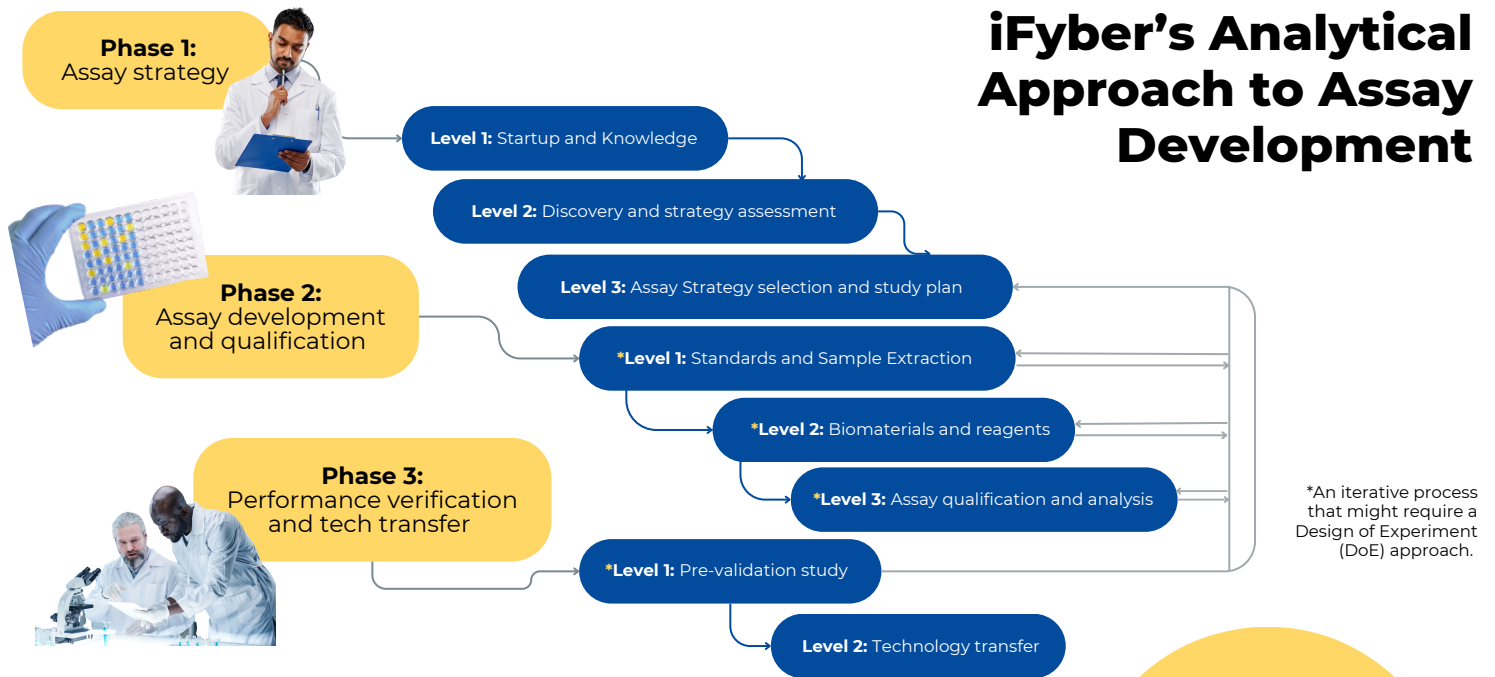


iFyber's Analytical Approach to Assay Development



Goals & Deliverables

To achieve the desired objectives, iFyber suggests a month-to-month service with predetermined key goals and deliverables for each project.

PODS (People Organization Dedication Scale)

- The next generation of FTE engagement to better address your challenges and problems.
- iFyber will deploy the PODS to perform assay development efforts.
- Integrated teams will communicate progress weekly.
- Following the initial results, propose any changes or troubleshoot discordant results.
- iFyber expects four fractional people will make up the iFyber 1+ PODS.

PODS Methodology:

1. Outline & Advise
2. Organize
3. Deploy
4. Execute
5. Report and/or Revise
6. Communicate Changes
7. Execute
8. Report and/or Revise
9. Compile and Close
10. Feedback

Goals & Deliverables

Phase	Level	Major goals and milestones	Deliverables
Phase 1: Assay strategy	L1: Startup and Knowledge	<ul style="list-style-type: none"> Assemble Team meetings and study schedules. Knowledge transfer 	<ul style="list-style-type: none"> List of priorities and goals Team meetings & study schedules
	L2: Discovery and strategy assessment	<ul style="list-style-type: none"> Evaluate and compare assay strategy options. Best option selection -out of a short list of potential strategies 	<ul style="list-style-type: none"> List of assay options rank: sample extraction methods, assay methodology, reader, and the appropriate comparison method. Best option selection with Sponsor.
	L3: Assay Strategy selection and study plan	<ul style="list-style-type: none"> Finalize requirements for the first option <ul style="list-style-type: none"> Standards Comparison method Equipment Source materials Refine study plan & schedule for phase 2 Source materials 	<ul style="list-style-type: none"> Final list of requirements for assay development (phase 2). Phase 2 proposed plan and schedule
Phase 2: Assay development and qualification	*L1: Standards and Sample Extraction	<ul style="list-style-type: none"> Prepare and validate the sample standards against the gold standard method. Compare and select the top-performing method to extract the target analyze from the DBS. 	<ul style="list-style-type: none"> List of priorities and goals Team meetings and study schedules
	*L2: Biomaterials and reagents	<ul style="list-style-type: none"> Evaluate and select biomaterials and reagents. Determine the best concentration of biomaterials and reagents. 	<ul style="list-style-type: none"> List of assay options rank: sample extraction methods, assay methodology, reader, and the appropriate comparison method. Best option selection with Sponsor.
	*L3: Assay qualification	<ul style="list-style-type: none"> Assay development and evaluation of performance. Various iterations of: <ul style="list-style-type: none"> Test Result analysis Improvement & Optimization 	<ul style="list-style-type: none"> Final list of requirements for assay development (phase 2). Phase 2 proposed plan and schedule
Phase 3: Assay performance verification & technology transfer	*L1: Pre-validation study	<ul style="list-style-type: none"> Perform a pre-validation study Data analysis 	<ul style="list-style-type: none"> Pre-validation study protocol Study report and performance evaluation
	*L2: Technology transfer	<ul style="list-style-type: none"> Prepare SOP with the best-performing assay strategy. 	<ul style="list-style-type: none"> Provide an SOP detailing materials and methods necessary to perform the assay.

Our Value Proposition

Gained value:

- The PODS program scales expertise in a time-bound, efficient way, whether it be R&D, process development, regulatory or manufacturing projects.
- Fyber's PODS will act as an extension of your R & D team
- Frequent communication and weekly meetings between the PODS and teams – reviewing tasks and data while also providing strategic advice
- Real-time project pivots – responding to mid-study data results to optimize outcomes and shorten project timeframes
- Dedicated technical team – provides the expertise needed for a specific project task/phase without the hiring commitment
- 1+ PODS can lead to more extensive and/or longer agreements to mirror company growth plans
- Scale up the work quickly, while your staff is focusing on other essential activities or aren't fully equipped

PODS Overview:

1+ PODS

1.35 FTE

10% VP

25% Director

50% Scientist

50% Associate