Regulatory Agent — Example Case Studies

One scenario per Report Hub report, showing how a customer would actually use it

The five scenarios below are illustrative composites, not real customers or real deals. Company names, asset codenames, and specific figures are invented for clarity. What's real is the report structure, the question each report answers, and the kind of finding each one surfaces — all drawn directly from how the app actually works.

Case Study 1: Academic/TTO Asset Pre-Screen

Organization	Northfield University, Office of Technology Transfer
Asset	NX-118 — a small-molecule fibrosis-pathway inhibitor discovered in a university chemistry lab
Stage	Preclinical
Report used	Academic/TTO Asset Pre-Screen

The Challenge

A TTO officer had a promising compound from a faculty lab and a decision to make: is it worth the cost of a provisional patent filing, and is there a licensing story here? Before committing budget, the office needed a fast, evidence-based read on the regulatory and competitive landscape — normally a multi-week task split between a research assistant and outside counsel.

How They Used Regulatory Agent

Entered the molecule with entity type Small Molecule and stage Preclinical, and a short free-text description of the target pathway. Ran the Academic/TTO Asset Pre-Screen report — the flagship, full-landscape view.

What the Report Surfaced

- FDA approval history for the closest comparable compounds in the same mechanistic class, establishing there was real precedent for the pathway.
- Orphan Drug Designation status on a related compound, flagging that the indication likely qualifies for orphan status — a meaningful value driver the TTO hadn't considered.
- A moderate FAERS safety signal for the class, worth flagging to the inventor early rather than discovering it during diligence with a licensee.
- Stage-appropriate IACUC/IRB oversight guidance, since the asset is still preclinical.
- Four related clinical trials in the same mechanistic space, giving a sense of how active the field already is.

The Outcome

The office had enough evidence-backed confidence in the asset's differentiation to move forward with a provisional patent filing and begin outreach to two mid-size pharma licensees — work that would previously have taken the better part of a month of manual FDA-database and literature research.

> *"One report gave us in an afternoon what used to take our team the better part of a month of manual digging."*

Case Study 2: Pre-Screen + Product Development Plan & Investor Deck (beta)

Organization	Aravel Bio (seed-stage startup)
Asset	peptide analog in development for chronic kidney disease
Stage	IND-enabling
Report used	Academic/TTO Asset Pre-Screen + Product Development Plan & Investor Deck add-on

The Challenge

A first-time founder needed a credible development roadmap and pitch materials in time for a first round of investor meetings — without the budget yet to hire a regulatory consultant just to produce a first draft.

How They Used Regulatory Agent

Ran the Pre-Screen report with entity type Peptide and stage IND-enabling, checking the "+ Also generate Product Development Plan + Investor Deck (beta)" option in the Report Hub before generating.

What the Report Surfaced

- The core Pre-Screen findings (approval precedent for the peptide class, an orphan-designation possibility worth exploring, and a read on how crowded the competitive class already is), which then fed directly into the plan and deck.
- A draft Product Development Plan (Word) laying out a phase-by-phase path forward informed by those findings.
- A draft Investor Deck (PowerPoint) built from the same run — same numbers, same findings, no separate re-entry of the asset.

The Outcome

The founder walked into the first VC meeting that same week with a professional first draft in hand, using it as a working document with advisors rather than starting from a blank page — avoiding the multi-thousand-dollar cost of commissioning an early draft from an outside consultant.

> *"We didn't have a regulatory budget yet. This got us a defensible first draft we could iterate on with our advisors instead of starting from nothing."*

Case Study 3: Asset Valuation & FTO Report

Organization	Bridgeline Capital (life-sciences VC)
Asset	ON-227 — a natural-product-derived oncology candidate under evaluation for in-license
Stage	Phase 2
Report used	Asset Valuation & FTO Report

The Challenge

The deal team needed a fast, defensible first read on how much runway and protection an in-license target actually has — market exclusivity, how it compares to similar assets historically, and whether any extra-agency regulatory hurdles change the risk picture — before committing analyst time to a full internal model.

How They Used Regulatory Agent

Entered the asset with entity type Natural Product and stage Phase 2, and ran the Asset Valuation & FTO Report.

What the Report Surfaced

- An Orphan Exclusivity Runway estimate, translating the asset's designation status into an approximate number of years of remaining market exclusivity.
- A Clinical-to-Approval Velocity benchmark, comparing how long similar natural-product oncology assets have historically taken from trial to approval.
- A Cross-Agency Regulatory Moat read confirming no DEA/NRC/USDA-EPA co-regulation applies here — a clean result that simplified one part of the risk picture.

The Outcome

The findings gave the deal team a fast, well-organized first pass to build their own valuation model on top of, and a documented basis to bring to the investment committee — without replacing the firm's own diligence process.

> *"It's not a substitute for our own diligence team, but it gave us a fast, well-organized first pass we could build our model on top of."*

Case Study 4: Competitive Intelligence & Pipeline Disruption Dashboard

Organization	Corp dev team, mid-size biotech
Asset being watched	GLX-410 — their portfolio company's lead GLP-1-class peptide for metabolic disease
Stage	Phase 3
Report used	Competitive Intelligence & Pipeline Disruption Dashboard

The Challenge

Leadership wanted a recurring pulse on who else was active in the same mechanism and indication space, without standing up a dedicated competitive-intelligence function.

How They Used Regulatory Agent

Ran the Competitive Intelligence & Pipeline Disruption Dashboard for the asset's class, repeating the run periodically as a lightweight monitoring habit.

What the Report Surfaced

- A Pre-Approval Competitive Threat Matrix showing active related trials from several distinct sponsors in the same class.
- A class-crowding signal flagged as High, prompting a closer look at differentiation strategy.
- Several orphan drug designations already granted to competitors in the same mechanistic class.
- One actively enrolling competitor trial the team had not been tracking through their usual channels.

The Outcome

Surfacing that untracked competitor trial prompted an earlier-than-planned strategy conversation with the portfolio company's leadership team, ahead of their next board meeting.

> *"It caught a competitor trial that hadn't hit our radar yet through our usual channels."*

Case Study 5: De-Risking & IND-Enabling Due Diligence Report

Organization	Series A biotech preparing an IND filing
Asset	RX-305 — a modified-nucleotide asset with a controlled-precursor manufacturing step
Stage	IND-enabling
Report used	De-Risking & IND-Enabling Due Diligence Report

The Challenge

Before finalizing the budget and timeline for their IND-enabling program, the team needed to know about any hidden regulatory or operational overhead beyond standard FDA requirements — the kind of thing that's easy to miss until it causes a delay mid-program.

How They Used Regulatory Agent

Entered the asset with its entity type and stage set to IND-enabling, including a description of the manufacturing process, and ran the De-Risking & IND-Enabling Due Diligence Report.

What the Report Surfaced

- A Specialized Overhead Risk Flag identifying a likely DEA scheduling review, triggered by a controlled-precursor keyword in the manufacturing description — a real cost and timeline factor the team hadn't yet built into their plan.
- Guidance on what that DEA overhead typically adds in licensing and recordkeeping terms, framed for a diligence/budgeting audience rather than as a compliance footnote.

The Outcome

The team built an additional two to three months and a legal/licensing line item into their IND-enabling budget proactively, instead of discovering the requirement mid-program when it would have been far more disruptive.

> *"Finding this before we broke ground on the IND program, not during it, probably saved us a quarter of lost time."*