CASE STUDY

Recursion Evaluates Early-Phase Oncology Study Design to Surface Patient Burden and Enrollment Risks

Advancing protocol design with AI-generated evidence

Recursion, an AI-native clinical stage TechBio, has built its development model around large-scale biological data, AI-driven pattern recognition, and automated experimentation to discover and develop medicines more efficiently. As its clinical programs advanced, Recursion recognized the opportunity to apply that same data-first rigor to protocol optimization.

Recursion partnered with Advarra as an early adopter of its Study Design solution, powered by Braid, to leverage external operational evidence into their design process. Drawing on Advarra's longitudinal trial operations dataset, including 35,000+ studies, 170,000+ protocol-related documents, and 100,000+ amendments, Recursion could support design choices with comparable trial experience, not just limited to in-house or public datasets alone.

Assessing schedule-driven patient burden

After validating Advarra's Study Design solution in an initial rare pediatric oncology pilot, Recursion expanded its use to additional early-phase oncology trials where recruitment depended on minimizing visit and assessment burden. Advarra's proprietary dataset showed that 29% of amendments in comparable trials were schedule-driven, helping Recursion pressure-test the schedule of assessments, identify burden hotspots, and surface insights before friction affected enrollment.

> *Every design choice affects patients. Early-phase oncology studies can mean frequent visits, dense assessment days, eligibility uncertainty, and physical and emotional strain. Advarra's Study Design solution gave our teams an even deeper layer of operational evidence to evaluate where schedule of assessments, eligibility criteria, and visit burden could affect recruitment, patient experience, and site execution.*



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A CLOSER LOOK

Recursion Identified Protocol Optimization Opportunities Surfaced by Advarra Study Design

Identified concentrated visit burden within an otherwise lean schedule

The study had fewer visits and fewer total assessments than benchmarks, but burden was concentrated within visits. Across the analysis, the key friction point was 9 assessments per visit vs. a benchmark of 6, creating risk of longer visit days, site strain, and patient fatigue.

Pinpointed indication-specific criteria to support enrollment

Overall eligibility was benchmark-aligned, but restrictive creatinine clearance thresholds, GI exclusions, pancreatitis language, diabetes-related exclusions, and life expectancy requirements increased risk of screen failure, site clarification, and amendments.

Highlighted study objectives for near-term decision-making

The study exceeded benchmark objectives by 33%, creating room to defer or combine exploratory objectives that did not support near-term dose, safety, or go/no-go decisions.

Advarra links assessment complexity to amendment risk

In comparable trials, 29% of amendments were schedule-driven, helping shift the oncology early-phase review from broad “protocol simplification” to targeted burden reduction. With Advarra’s proprietary operational dataset, Study Design pinpointed where schedule design, assessment concentration, and eligibility structure would create execution risk, not just where the protocol differed from benchmarks.

The findings identified four areas where design decisions would matter most:

- Rebalance visit schedules to reduce patient and site burden
- Refine exclusion criteria affecting enrollment feasibility
- Rationalize endpoint and assessment complexity
- Preserve scientific intent while improving execution clarity

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