# AI Vendor Pulse

An advisory briefing on AI vendors selling into pharma & biotech

ISSUE 16

**THE BLUEPRINT GOES AGENTIC — AI IN PROTOCOL DESIGN & TRIAL SIMULATION**

## QuantHealth

AI trial simulation & protocol scoring

## Biorce

AI protocol design & trial preparation

## Faro

Structured digital protocol design

## Cytel

Adaptive design & simulation software

## Evinova

AstraZeneca-built trial design & delivery

*Companies featured in this issue may include current or prospective advisory relationships of Avery & Riley. All data is publicly sourced unless otherwise noted; company-stated claims are labeled as such throughout.*

WHY THIS ISSUE EXISTS

# The blueprint is going agentic — AI now helps design the protocol

Every trial begins with a protocol, and the choices made there — endpoints, schedule of assessments, eligibility, statistical design — largely fix a study's cost, timeline and amendment risk before a site is activated. That work has lived in Word documents and statistical code. In 2026 it became a platform battleground: simulation engines, AI protocol drafters, structured-data platforms and sponsor-built toolsets. This issue maps five vendors rebuilding protocol design and trial simulation with AI.

## WHAT SENIOR LEADERS SHOULD WATCH

### 01

**Capital is moving upstream.** Biorce (~$52M Series A), Faro ($37.3M Series B) and QuantHealth ($45M Series B) each announced rounds in 2026.[1,2,3] Investors are betting design is where trial value is won.

### 02

**Sponsors are standardizing the design layer.** Bristol Myers Squibb named Faro its system of record for structured protocols,[4] and Evinova announced collaborations with Astellas, AstraZeneca and BMS.[5]

### 03

**Incumbents add AI; challengers add structure.** Cytel's East Horizon added an AI code assistant,[6] while newer entrants claim whole-protocol generation (company-stated).[7] Evidence is still thin.

# The Avery & Riley 10-stage clinical-development taxonomy

Coverage bars throughout this issue map each vendor against the ten trial-lifecycle stages below — a **directional, point-in-time read** of where a vendor appears to operate. Each lit stage is colored by **source class** — **teal** where coverage is publicly documented (named customers or third-party sources), **gold** where coverage is company-stated. This issue's cohort clusters in Plan & Design (P01–P02).

| | | | | |
|---|---|---|---|---|
| **P01** Portfolio / indication strategy | **P02** Protocol design / feasibility | **P03** Site identification / selection | **P04** Study startup | **P05** Recruitment / enrollment |
| **P06** Study conduct / execution | **P07** Monitoring / oversight | **P08** Data management / cleaning / DBL | **P09** Close-out / TMF / inspection readiness | **P10** Post-trial insights / evidence |




*Directional reads from public materials & directory review — a snapshot, not vendor-reported metrics.*

LIFECYCLE FOOTPRINT SNAPSHOT

# Where each protocol-design vendor plays in the lifecycle

| VENDOR | P01 | P02 | P03 | P04 | P05 | P06 | P07 | P08 | P09 | P10 | FOOTPRINT |
|---|---|---|---|---|---|---|---|---|---|---|---|
| QuantHealth<br>AI trial simulation & protocol scoring | ■ | ■ | | | | | | | | | 2/10 |
| Biorce<br>AI protocol design & trial preparation | | ■ | | | | | | | | | 1/10 |
| Faro<br>Structured digital protocol design | | ■ | | ■ | | | | | | | 2/10 |
| Cytel<br>Adaptive design & simulation software | | ■ | | | ■ | | | | | | 2/10 |
| Evinova<br>AstraZeneca-built trial design & delivery | ■ | ■ | ■ | | | ■ | | ■ | | | 5/10 |

■ Publicly documented (named customer / third-party) ■ Company-stated positioning

*The cohort clusters in Plan & Design (P01–P02), where the protocol is shaped before any site is activated. Footprint counts the stages a vendor is positioned to touch; it is a directional, point-in-time read, not a ranking.*

# Executive market map

| VENDOR | PRIMARY CATEGORY | PROBLEM(S) TARGETED | PUBLIC EVIDENCE SIGNAL |
|---|---|---|---|
| QuantHealth | Trial simulation + Katina protocol AI | Protocol-design risk: comparing many design options in silico before protocol lock. | **Simulation specialist.** $45M Series B (Aug 2026); Katina protocol AI; client count company-stated.[3,8] |
| Biorce | Aika AI protocol platform | Slow manual protocol drafting and trial preparation; late-found risks and amendments. | **Challenger.** ~$52M Series A (Feb 2026, DST Global); Aika 2.0 launch at ASCO 2026 (company-stated).[1,9] |
| Faro | Faro AI · digital protocol platform | Unstructured Word protocols; no reusable, machine-readable design data for downstream systems. | **System of record.** BMS system-of-record collaboration (Mar 2026); $37.3M Series B (Aug 2026).[2,4] |
| Cytel | East Horizon + trial-design statistics | Statistical design validity: adaptive designs, simulation and sample-size trade-offs. | **Incumbent.** East Horizon launch (Sep 2024); PE-owned since Dec 2020; AI R assistant (company-stated).[10,11] |
| Evinova | AstraZeneca-founded · Study Designer | Endpoint, schedule-of-assessments, feasibility and cost decisions made before protocol finalization. | **Sponsor-built platform.** Three external pharma collaborations (2026); Citeline data partnership; Merck KGaA (Jul 2026).[5,12] |

*Signals summarize public materials as of the cited profiles that follow; company-stated claims are labeled as such.*

# QuantHealth

LIFECYCLE FOOTPRINT 2/10

**TRIAL SIMULATION + KATINA PROTOCOL AI**

**Targets:** *Protocol-design risk — testing thousands of design choices in silico before the first patient is enrolled, rather than learning from amendments and failed trials.*

## WHAT THEY DO

- **Katina**, launched Nov 2023 as an add-on to its trial-design platform, is an AI-guided workflow that simulates very large numbers of protocol combinations and scores each protocol.[8]
- The company states 600+ trials simulated across 30 indications (company-stated), positioning simulation as a way to compare design options before commitment.[3]

## COMPANY & BACKING

- Series A in 2023 co-led by Bertelsmann Investments and Pitango HealthTech, with Accenture Ventures investing in Jan 2024.[13]
- **$45M Series B** (Aug 2026) led by Qumra Capital, with Pitango HealthTech and Sanofi Ventures among the investors.[3]
- Says 12 of the top 20 pharma companies are clients (company-stated); we found no named pharma customers in public sources.[3]

## LIFECYCLE FOOTPRINT — DESIGN-STAGE SIMULATION

P01 · P02

| P01 | P02 | P03 | P04 | P05 | P06 | P07 | P08 | P09 | P10 |
|---|---|---|---|---|---|---|---|---|---|

**$45M**[3]
Series B, Aug 2026, led by Qumra Capital

**12 of 20**[3]
Top-20 pharma companies as clients (company-stated)

**600+**[3]
Trials simulated across 30 indications (company-stated)

**SENIOR-LEADER READOUT**

A well-funded simulation specialist whose differentiator is scale of in-silico comparison. Worth a conversation for portfolio teams weighing design options before protocol lock.

Client claims are unnamed — ask for referenceable sponsors and out-of-sample validation.

*Company-stated claims summarized from public materials; not a buying recommendation.*

# Biorce

**AIKA AI PROTOCOL PLATFORM**

**Targets:** *Slow, manual protocol design and trial preparation — drafting regulator-ready protocols, anticipating risks and cutting amendments before study start.*

## WHAT THEY DO

- **Aika** is an AI platform for clinical-trial design and operations; Aika 2.0 launched at ASCO 2026 and is billed as an "operating system for clinical trials" (company-stated).[9]
- Claims regulator-ready protocols in about 90 seconds at 86% accuracy, trained on roughly one million trials (company-stated).[7]

## COMPANY & BACKING

- Barcelona-based; **~$52M Series A** announced Feb 2026 (reported as €43.8M).[1]
- Led by DST Global, with Norrsken VC, YZR Capital and Mustard Seed Maze; proceeds fund US expansion including an Austin office.[14]
- No named pharma customers, analyst recognition or acquisitions found in public sources — the evidence base is funding and company claims.

## LIFECYCLE FOOTPRINT — PROTOCOL DESIGN

P02

| P01 | **P02** | P03 | P04 | P05 | P06 | P07 | P08 | P09 | P10 |
|---|---|---|---|---|---|---|---|---|---|

**~$52M**[1]
Series A, Feb 2026, led by DST Global

**90 sec**[7]
Claimed time to a regulator-ready protocol draft (company-stated)

**~1M**[7]
Trials in the claimed training base (company-stated)

**SENIOR-LEADER READOUT**

The category's newest large bet: heavy capital, bold speed claims, little public customer proof so far.

Engage as a design-partner conversation, and press for named sponsors and accuracy methodology.

*Company-stated claims summarized from public materials; not a buying recommendation.*

# Faro

**FARO AI · DIGITAL PROTOCOL PLATFORM**

**Targets:** *Protocols drafted in Word and emailed for review — replaced by structured, machine-readable designs that downstream systems and agents can reuse.*

## WHAT THEY DO

- **Study Designer** and **Protocol Library** convert protocols into reusable, USDM-aligned structured assets (company-stated).[15]
- AI agents on that structured data design studies, author documents and automate start-up (company-stated).[16]

## COMPANY & BACKING

- Formerly Faro Health (now Faro AI, Inc.); $20M round in Feb 2023 led by General Catalyst.[17]
- **$37.3M Series B** (Aug 26, 2026) co-led by Merck Global Health Innovation Fund and S32.[2]
- Mar 31, 2026: Bristol Myers Squibb to standardize on Faro as system of record for structured protocol design;[4] CDISC 2025 AI Innovation Challenge winner.[15]

LIFECYCLE FOOTPRINT — PROTOCOL DESIGN + START-UP — P02 · P04

| P01 | **P02** | P03 | **P04** | P05 | P06 | P07 | P08 | P09 | P10 |
|---|---|---|---|---|---|---|---|---|---|

**$37.3M**[2]
Series B, Aug 2026, co-led by Merck GHIF and S32

**6 of 10**[18]
Largest pharma companies using the platform (company-stated)

**$20M**[17]
Feb 2023 round led by General Catalyst

**SENIOR-LEADER READOUT**

The clearest “system of record” play in the cohort, with a named big-pharma commitment. Structure first, AI second.

Ask how structured protocols connect to your CTMS, EDC and start-up tooling.

*Company-stated claims summarized from public materials; not a buying recommendation.*

# Cytel

EAST HORIZON + TRIAL-DESIGN STATISTICS

**Targets:** *Choosing the right statistical design and assumptions before a trial runs — adaptive designs, simulation and sample-size trade-offs — with AI now helping statisticians write the code.*

## WHAT THEY DO

- **East Horizon**, launched Sep 30, 2024, is a platform for adaptive trial design and simulation, supporting R functions alongside East statistical tests.[10]
- An AI-driven R code-generation assistant sits inside East Horizon, described as producing validation-ready code (company-stated).[6] A partnership with Citeline targets enrollment planning and feasibility (company-stated).[19]

## COMPANY & BACKING

- Founded by statisticians Cyrus Mehta and Nitin Patel more than 30 years ago.[20]
- Nordic Capital and Astorg acquired Cytel from New Mountain Capital (announced Dec 21, 2020); Waltham, MA, with 1,500+ employees at the time.[11]
- The incumbent in the cohort: statistical credibility is long-standing, but we found no independent evidence on the performance of its AI features.

LIFECYCLE FOOTPRINT — DESIGN STATISTICS + ENROLLMENT FORECASTING

P02 · P05

| P01 | **P02** | P03 | P04 | **P05** | P06 | P07 | P08 | P09 | P10 |
|---|---|---|---|---|---|---|---|---|---|

**30+ yrs**[20]
Heritage in adaptive-design statistical software

**1,500+**[11]
Employees at the Dec 2020 PE buyout

**Sep 2024**[10]
East Horizon platform launch

**SENIOR-LEADER READOUT**

The statistical-credibility incumbent. Its AI is an assistant for statisticians — not an autonomous protocol author.

Relevant when your questions are about design validity, regulatory acceptance and simulation of adaptive designs.

*Company-stated claims summarized from public materials; not a buying recommendation.*

# Evinova

**ASTRAZENECA-FOUNDED · STUDY DESIGNER**

**Targets:** *Slow, costly, amendment-prone protocol design and trial delivery — endpoint choice, schedule of assessments, feasibility and cost estimation before the protocol is finalized.*

## WHAT THEY DO

- Launched Nov 2023 as a health-tech business within the AstraZeneca group, with three product lines: a unified trial solution, study design & planning, and portfolio management.[21,22]
- **Study Designer** covers endpoint and schedule-of-assessments planning, feasibility and costing, with multi-agent document authoring (company-stated);[12] its Cost Optimizer claims 97% cost-estimation accuracy (company-stated).[23]

## COMPANY & BACKING

- Owned by the AstraZeneca group; we found no external funding or M&A.[21]
- Feb 2026: collaborations announced with Astellas, AstraZeneca and Bristol Myers Squibb on its AI-native platform.[5] Feb 2026: Citeline Sitetrove and Trialtrove data added to Study Designer.[24]
- Jul 29, 2026: multi-year strategic partnership with Merck KGaA, Darmstadt, Germany (company-stated).[12]

## LIFECYCLE FOOTPRINT — DESIGN-TO-DELIVERY PLATFORM

P01 · P02 · P03 · P06 · P08

| P01 | P02 | P03 | P04 | P05 | P06 | P07 | P08 | P09 | P10 |
|---|---|---|---|---|---|---|---|---|---|
| ■ | ■ | ■ | | | ■ | | ■ | | |

**3**[5,12]
External pharma partners named in 2026 (BMS, Astellas, Merck KGaA)

**97%**[23]
Cost-estimation accuracy claimed for Cost Optimizer (company-stated)

**40+**[21]
Countries where the underlying tools were used (company-stated)

**SENIOR-LEADER READOUT**

The broadest footprint in the cohort and the only one born inside a pharma — a sponsor-built toolset now sold across the industry.

Ask how operational-data sharing and benchmarking are governed, and what 'AI-native' means in a validated GxP workflow.

*Company-stated claims summarized from public materials; not a buying recommendation.*

# Three patterns to carry into your diligence

## 01

### Design is becoming a data problem

Faro treats the protocol as structured data,[15] Evinova converts and benchmarks it,[12] and simulation vendors score it. Whoever holds the structured protocol becomes the anchor for everything downstream.

## 02

### Speed and accuracy claims outrun proof

The boldest numbers — 90-second protocols, 97% cost accuracy — are company-stated.[7,23] Few vendors name customers or publish out-of-sample validation. Treat claims as hypotheses to test on your own protocols.

## 03

### Sponsors, not just vendors, are shaping the category

Evinova was built inside AstraZeneca,[21] and Merck's venture arm co-led Faro's round.[2] Sponsor involvement signals demand — and raises questions about data sharing and neutrality.

THE BOTTOM LINE FOR ADOPTION

"The protocol is becoming software. Leaders who pilot this cohort on a live design problem now will shape how AI enters the most consequential document in development, before the category standardizes around someone else's format."

# From market read to executive diligence

## EXECUTIVE DILIGENCE QUESTIONS

- Which design decisions most need leverage — endpoint selection, eligibility, schedule of assessments, statistical design, or cost and feasibility?
- Can the vendor show out-of-sample validation on protocols it has not seen, and name sponsors willing to be referenced?
- How are AI-generated design outputs governed — versioning, audit trail, human sign-off, and alignment with your protocol authoring SOPs?
- Does the platform exchange structured protocol data (for example USDM) with your CTMS, EDC and start-up tools, and who owns operational data shared for benchmarking?

## SUGGESTED CATEGORIES FOR FUTURE ISSUES

- Site payments & clinical trial budgeting
- Regulatory information management (RIM)
- Manufacturing, CMC & supply-chain AI
- Biostatistics & statistical computing environments
- Imaging & central-read endpoints

**Source standard.** All data is publicly sourced unless otherwise noted. Company-stated claims are labeled as such and summarized from public materials; they are not independently validated performance guarantees.

# References

*Numbered by first appearance in the body; each entry links to its source. Sources identified via public search; vendor claims not independently validated.*

1 EU-Startups (Feb 2026) — Barcelona-based Biorce closes €43.8M Series A to accelerate AI-driven clinical trials.

2 Fortune / press release (Aug 26, 2026) — Faro Series B ($37.3M), co-led by Merck Global Health Innovation Fund and S32.

3 Globes (Aug 4, 2026) — QuantHealth $45M Series B led by Qumra Capital; investors; “12 of top 20” pharma clients and 600+ trials simulated (company-stated).

4 Faro release via AM920 (Mar 31, 2026) — Bristol Myers Squibb to standardize on Faro as system of record for structured protocol design.

5 Fierce Biotech (Feb 2026) — Evinova expands AI development partnerships with Astellas, AstraZeneca and Bristol Myers Squibb.

6 Cytel — AI-driven R code generation assistant in East Horizon (company-stated).

7 MedPath — Biorce raises $52.5M Series A; 90-second protocol draft, 86% accuracy, ~1M trials of training data (company-stated).

8 HIT Consultant (Dec 1, 2023) — QuantHealth launches Katina AI-powered trial-optimization platform.

9 Biorce — Aika 2.0 launch at ASCO 2026 (company-stated).

10 Observer-Reporter / GlobeNewswire (Sep 30, 2024) — Cytel launches East Horizon for adaptive trial design and simulation.

11 Nordic Life Science — Nordic Capital and Astorg acquire Cytel from New Mountain Capital (announced Dec 21, 2020); 1,500+ employees.

12 BioSpace (Jul 29, 2026) — Evinova–Merck KGaA strategic partnership; Study Designer capabilities (company-stated).

13 Pulse 2.0 — QuantHealth funding from Accenture Ventures and other investors (Series A).

14 Tech Funding News — Biorce raises $52M Series A (lead DST Global; other investors; US expansion).

15 Newswire — Faro wins CDISC 2025 AI Innovation Challenge for Protocol Library (Sep 29, 2025); USDM-aligned protocol assets.

16 The SaaS News — Faro raises $37.3M Series B; agents to design studies, author documents and automate study start-up (company-stated).

17 HIT Consultant (Feb 8, 2023) — Faro Health secures $20M led by General Catalyst.

18 Pulse 2.0 — Faro AI Series B; platform used by 6 of the world’s 10 largest pharma companies (company-stated).

19 Citeline — Cytel partnership for enrollment planning and feasibility (joint announcement; company-stated).

20 Nordic Capital — press release on Nordic Capital and Astorg investing in Cytel; founders Mehta and Patel, “over 30 years ago.”

21 AstraZeneca (Nov 2023) — launch of Evinova health-tech business; tools used in 40+ countries (company-stated).

22 TechTarget — AstraZeneca launches Evinova: unified trial solution, study design & planning, portfolio management.

23 Evinova — Study Designer Cost Optimizer brochure; “97 percent” cost-estimation accuracy (company-stated).

24 Life Sciences Europe (Feb 2026) — Evinova–Citeline partnership: Sitetrove and Trialtrove data in Study Designer.

*Disclosure: Companies featured in this issue may include current or prospective advisory relationships of Avery & Riley. Lifecycle-footprint and source-class reads use Avery & Riley’s vendor framework compiled from public materials; they are a snapshot of the latest publicly known data and may change as vendors ship or reposition capabilities. This is not a ranking and not a buying recommendation.*