A-007

Self-selected and self-served
does patient-led digital enrollment predict downstream data completeness in real-world evidence studies?

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Disclosures: Derk Arts, Mariah Baltezegar, and Sebastiaan Knijnenburg are employees of Castor. Susan A. Oliveria and Christine Varner are employees of Thermo Fisher Scientific. This analysis used de-identified Castor platform operational telemetry. No external funding.

Abstract

Background: Decentralized designs increasingly use patient-led digital enrollment, where participants self-identify online, prescreen, and eConsent without investigator mediation. Whether enrollment route affects downstream data completeness and retention has not been measured at platform scale. **Objective:** Compare enrollment velocity, long-run ePRO engagement, enrolled follow-through, and retention between patient-led and site-based studies on a single platform (Castor). **Methods:** Matched retrospective study of de-identified operational data from 15,912 production studies, compared like with like on therapeutic area, design, size, time period, and survey schedule. A tiered evidence model identified 707 patient-led studies (462,812 participants) against 8,423 site-based, giving a matched set of 472 patient-led and 1,078 site-based. Patient-led classification is predominantly behavioral inference, with a confirmed 19-study subset (gold 8, silver 11) retained as a sensitivity check. Timing outcomes are reported as medians with interquartile range, other outcomes as proportions with bootstrap 95 percent confidence intervals. **Results:** Patient-led studies reached half of final enrollment in a median of 1 month versus 6 for site-based, about 6 times faster. Long-run ePRO completion converged, with no evidence of disengagement over time. Enrolled follow-through was close (0.886 versus 0.931), and 180-day retention favored site-based (0.65 versus 0.12), confounded by protocol length. **Conclusion:** Patient-led digital enrollment fills studies about 6 times faster with no long-run engagement penalty, at the cost of a shorter observed follow-up. It suits front-loaded, short-cycle real-world evidence programs.

Background and objective

Patient-led digital enrollment, where participants find a study online, check their own eligibility, and consent without a site coordinator (also called direct-to-patient), is growing in real-world evidence research. How it performs once a study is running, next to traditional site-based enrollment, has not been measured at scale, a gap in digital epidemiology. We compared the two routes across enrollment speed, long-run survey engagement, enrolled follow-through, and retention.

6x Faster

Patient-led digital enrollment fills half a study in a median of 1 month versus 6 for site-based, about 6 times faster, with no evidence of a long-run engagement penalty, at the cost of a shorter observed follow-up.

Methods

Matched retrospective study of de-identified operational data from 15,912 Castor platform studies, grouped by enrollment route and compared like with like by matching on therapeutic area, design, size, time period, and survey schedule. Patient-led studies were identified with a tiered evidence model: gold (managed landing page or eConsent, 8 studies), silver (landing-page product records, 11 studies), bronze (behavioral evidence, 688 studies). This gives 707 patient-led studies against 8,423 site-based, and a matched set of 472 patient-led and 1,078 site-based. Covariate balance held after matching.

Two cautions: about 97 percent of the patient-led arm is behavioral inference, so the 19 confirmed studies are kept as a sensitivity check. And open enrollment links create a started record for every anonymous click, so anonymous clicks are separated from enrolled participants throughout.

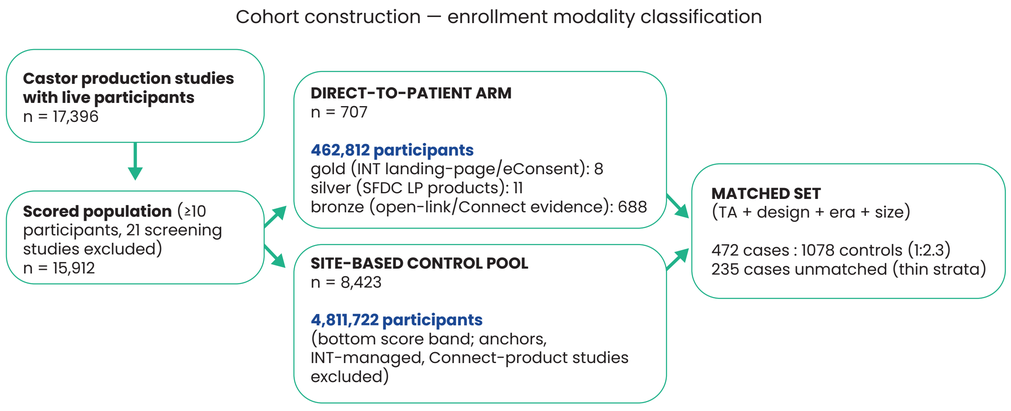
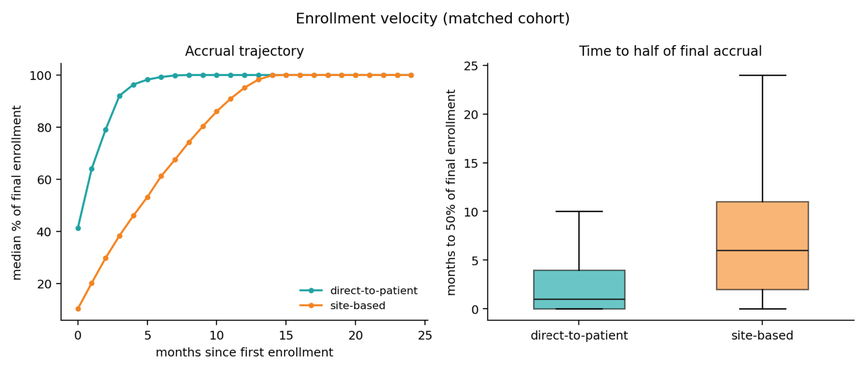


Figure F1: cohort construction and enrollment-modality classification

Enrollment fills half a study in one month, not six

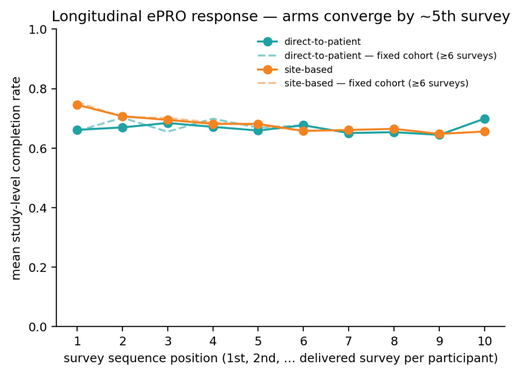
Patient-led studies reached half of their final enrollment in a median of 1 month, against 6 months for site-based. About 6 times faster. Enrollment front-loads under patient-led designs.



F5: accrual trajectory (left) and months to 50 percent of final enrollment (right).

Long-run engagement converges

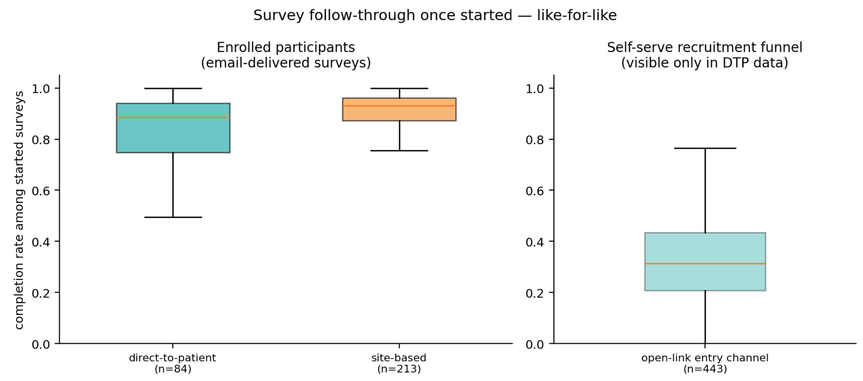
Survey completion by position converges. Site-based starts higher, at 0.75 at the first survey, and drifts to about 0.66 by the sixth. Patient-led stays roughly flat, between 0.65 and 0.68, throughout. Site coordination gives a small early bump that fades within a few months, and patient-led shows no sign of disengaging over time. This is a descriptive convergence, not a statistical equivalence and not a claim that patient-led is better.



F3: mean study-level survey completion by survey position.

A measurement point for patient-led data

Open enrollment links create a record for every anonymous click. Because site-based studies have no equivalent, any metric that pools those clicks inflates naive engagement and follow-through for the patient-led arm and understates its true performance. Within the same open-link channel, completion is similar in both arms, 0.31 and 0.17, confirming the earlier apparent gap was the channel, not the participants. Separating anonymous records from enrolled participants is necessary for a fair comparison.



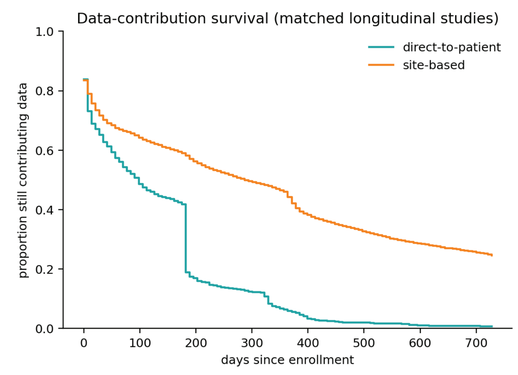
F7: follow-through among enrolled participants versus the open-link funnel.

Enrolled follow-through and after-hours use

Among enrolled participants, follow-through is close: 0.886 for patient-led and 0.931 for site-based, modestly lower for patient-led. Completions after normal working hours are near identical, **39 percent and 38 percent**, so participants use self-serve tools around their own schedules in both routes.

The honest cost: a shorter observed follow-up

Retention at 180 days favored site-based, 0.65 against 0.12 for patient-led. This is confounded by how long studies run, because patient-led protocols here are shorter and were not normalized for that, and the patient-led number is small.



F4: data-contribution survival (matched longitudinal studies).

Completeness and limitation

Raw eCRF completion is not a fair modality comparison, because patient-led studies collect through surveys, so completeness is assessed through engagement, follow-through, and retention. Main limitations: about 97 percent of the patient-led arm is behavioral inference, snapshots differ slightly in date, retention is not adjusted for protocol length, patient-led studies remain somewhat larger and more recent after matching, and enrollment speed is measured against a study's own final size.

Conclusion

In 707 patient-led studies (462,812 participants) matched to site-based studies, patient-led digital enrollment reached half of its participants about 6 times faster, with no evidence of disengaging over time once the recruitment funnel is separated from enrolled participants, at the cost of a shorter observed follow-up tied to shorter protocols. These benchmarks can inform enrollment-approach decisions when designing decentralized studies and real-world evidence programs.

Figures and estimates are provisional pending final pipeline lock and bootstrap 95 percent confidence intervals.