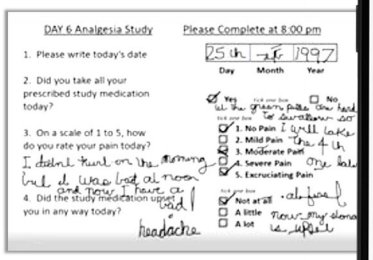
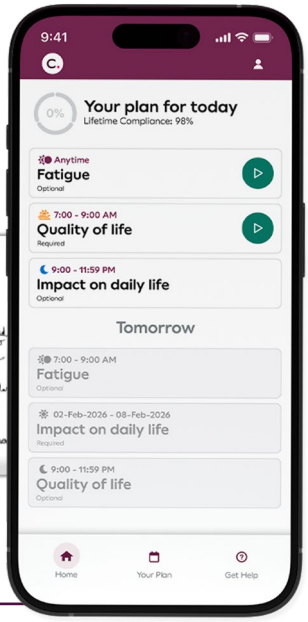
Get cost effective, higher-quality, rapid insights in early phase oncology trials

Modern methods of capturing patient data deliver benefits over paper





	Paper COA	eCOA
Data quality	✗ Falls short of regulatory standards	✓ Time-stamped, attributable data with full audit trail
	✗ Error-prone (e.g., illegible or missing data, manual transcription errors)	✓ Controlled data entry by participants and automatic transfer of data to database
	✗ 11% real compliance*	✓ 90%+ compliance*
Cost	✗ Unforeseen costs (e.g., printing, double data entry, source data verification, additional time to database lock)	✓ Predictable costs in line with early phase trial budgets
Speed	✗ Delayed access to PRO data, including patient-reported symptomatic adverse events, tolerability and compliance levels	✓ Near real-time access to help protect patient safety, quality of life, and to inform dosing decisions
	✗ Setup completed within weeks	✓ Setup can be comparable to paper
	✗ Extended timelines (e.g., shipping, manual data entry)	✓ Fast timelines with web

*Stone A, et al. 2002. Patient non-compliance with paper diaries. BMJ 2002;324:1193

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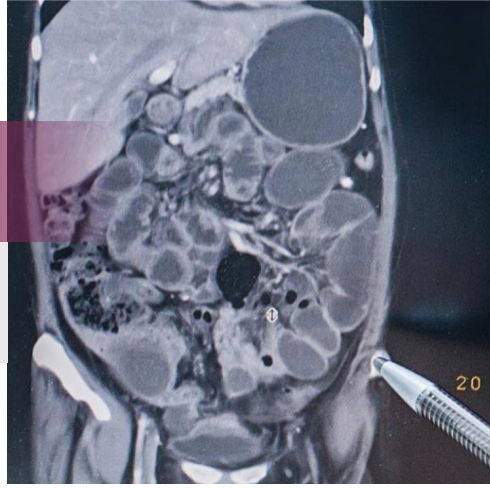
Make better early phase oncology decisions with better imaging data



Centralized imaging can enable faster go/no-go decisions vs. decentralized imaging

	Decentralized, site-driven imaging	Centralized, trial-ready imaging
Data quality	✗ Non-standardized imaging across sites limits comparability and confidence	✓ Standardized image collection across sites enables confident comparisons
	✗ Retrospective collection and analysis may delay decisions due to unresolved data quality issues	✓ Consistent, diagnostic-quality imaging with ongoing AI or expert QC with rapid query resolution
	✗ Missing data	✓ Prevention of bottlenecks with real-time flags for delayed site uploads
Cost	✗ Unforeseen costs (e.g., retrieval of data, retrospective analysis, additional time to database lock, delays moving into Phase II, inability to stop trial early to save funding)	✓ Predictable early phase budgeting and study efficiency through scalable platform design
Speed	✗ Slow deployment, with study launch potentially taking months instead of weeks	✓ Fast setup, with studies launching in as little as four weeks
	✗ Delayed access to data, including early efficacy signals	✓ Fast, informed decisions with near real-time access to image data
	✗ Delayed transition into Phase II	✓ Accelerated Phase II transition with clean, centralized, QC'd data

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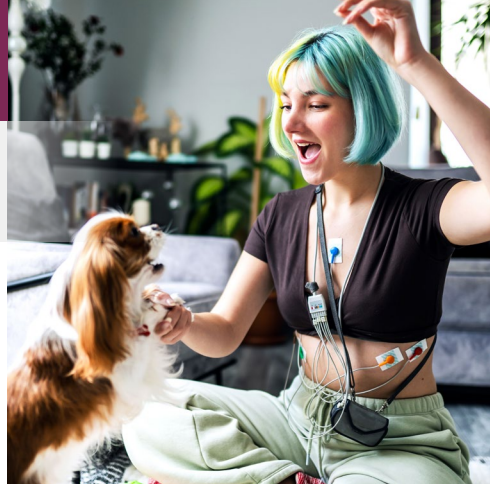
Protect patient safety and critical study timelines in early phase oncology trials



Centralized ECGs deliver benefits over site-managed ECGs

	Site-managed ECGs	Centralized ECGs
Data quality	✗ Higher risk of false-negative ECG results enable enrollment of high-risk patients	✓ Minimize false inclusions, protecting patient safety
	✗ Data variability across machines and readers	✓ Standardized machines and expert readers deliver consistent data
	✗ Data quality issues difficult to detect across large datasets of paper	✓ Data analysis issues are easier to detect and can be identified quickly
	✗ Risk of not meeting regulatory requirements	✓ Regulatory-ready data in digital XML format with a full audit trail
	✗ Challenging to retrospectively "standardize" paper data	✓ Data that is standardized as it is collected and is ready for use
Cost	✗ False-positive ECG findings lead to exclusion of otherwise eligible participants, increasing recruitment costs	✓ Minimize risk for false exclusions, enabling swift recruitment of appropriate participants
	✗ Hidden costs of manual data entry and time-consuming analysis	✓ Predictable costs of automated data workflows and AI-assisted analysis
Speed	✗ False-negative findings delay insights into safety risks	✓ Detect potential cardiotoxicity risks earlier to protect patient safety
	✗ Decentralized data extends analysis timelines	✓ Fast analysis of ECGs, with over-read data available in as little as 4 hours in a single database
	✗ Recruitment delays due to false exclusions	✓ Supports critical milestones by minimizing false exclusions

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