



*THREAD Recognized for*

**2021**

**Customer Value Leadership**

North American

Decentralized Clinical Trials Industry

*Excellence in Best Practices*

## Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. THREAD excels in many of the criteria in the decentralized clinical trials space.

AWARD CRITERIA	
<i>Business Impact</i>	<i>Customer Impact</i>
Financial Performance	Price/Performance Value
Customer Acquisition	Customer Purchase Experience
Operational Efficiency	Customer Ownership Experience
Growth Potential	Customer Service Experience
Human Capital	Brand Equity

### *Evolving Clinical Trials Landscape*

Efforts to reduce time and cost in clinical trials over the past three decades remain ineffective despite substantial investments and various initiatives, including business process outsourcing and risk-based monitoring. Participant recruitment, data collection and analysis, patient adherence, coordination across trial sites, and logistical challenges cause critical delays in drug development and, thus, considerable monetary loss.

Paper-based data collection poses accuracy and data quality issues. Clinical trials require patient access at pre-defined times and physical presence at trial centers and hospitals to complete patient-reported outcomes (PROs). Nonetheless, patients often respond late or do not respond at all, diminishing data quality. Moreover, different collection centers have distinct approaches to collecting data, making it difficult for sponsors to utilize it systematically. This challenge calls for data collection standardization and digitalization. Emerging technologies can standardize data collection, exchange, storage, and treatment continuously, notably enhancing process efficiencies.

Patient retention is another hindrance in the clinical trials field. Inconvenient locations and strict schedules typically prompt participants to withdraw from studies. In turn, high dropout rates lead to unusable data and financial losses. The COVID-19 pandemic further highlighted the urgent need for modernization and innovation in the clinical trials market, proving traditional clinical trial models and practices ineffective and unsustainable. Indeed, there remains a pressing need to expedite clinical trials

and administer proper healthcare even during complex scenarios such as lockdowns. Therefore, providing patients with convenient times and locations can help improve retention rates.

Decentralized clinical trials (DCT) involve patients receiving healthcare at the comfort of their homes, away from clinics and hospitals, and testing new, potentially life-saving medicines. Decentralized or virtual trials are the solution the industry has been seeking and already transforming the face of clinical development in the evolving pharmaceutical (pharma) sector.

Cloud computing, an evolving regulatory framework, and consumer adoption of digital health technologies enable virtual trials to offer a more convenient and flexible approach than traditional on-site clinical trials. Most importantly, decentralized practices reduce the need for patient travel and physical presence at medical facilities, allowing completing the initial paperwork through electronic consent (eConsent) and continuing the collection of validated trial data for the remainder of the study. Increased convenience directly translates to patient empowerment, improving compliance and protocol adherence rates and yielding quicker, higher quality data. Comfort and flexibility can also impact participant recruitment rates positively and provide broader access to a diverse patient population, ensuring treatment efficacy and safety across the entire population. Furthermore, decentralized trials capture extensive data continuously, reducing data verification needs since harnessed directly from the source, speeding up the process, and significantly reducing costs.

Thus, patient-centric decentralized trials overcome the longstanding, existing challenges in the clinical trials industry by improving patient recruitment and engagement and data monitoring accuracy, leading faster to cost-effective treatments.

### ***Unique Collaborative Platform and Ecosystem Partnerships Drive Industry Excellence***

Conducting decentralized research since 2015 and headquartered in North Carolina, the United States (US), with offices around the world, THREAD provides a singular, fully configurable, and comprehensive DCT technology platform. It allows pharma and contract research organizations (CROs) to perform clinical trials virtually, starting from the planning stage, progressing to the design and launch stages, and ending finally in the close-out. A proven leader in decentralized studies, the company revolutionizes the clinical trials industry, supporting hundreds of studies with hundreds of thousands of participants available in over 50 countries.

*“THREAD’s innovations via its decentralized trials platform are sure to progress the industry to a hybrid system between a decentralized and centralized service model. Such a system is more likely to weather the disruptions caused by black swan events like emerging pandemic viruses.”*

**- Ojaswi Rana, Best Practices Research Analyst**

While still unable to replace essential centralized services completely, for instance, magnetic resonance imaging, THREAD’s innovations via its decentralized trials platform are sure to continue to progress the industry to a hybrid system between a decentralized and centralized service model. Such a system is more likely to weather the disruptions caused by black swan events like emerging pandemic viruses.

The company deploys its DCT platform using omni-channel technology to remotely reach a substantial prospective end-user base comprising of patients & caregivers, over geographically vast areas. The design

connects and serves a wide clientele, namely CROs, biopharma, life science firms, and other research organizations.

On the research side, the platform's innovative capabilities have benefited clients in shortening research study times, reaching a broader population number and diversity, growing and retaining more participants, and reducing research costs due to virtualization. For example, in 2020, Parent Project Muscular Dystrophy (PPMD), an organization leading the fight against Duchenne muscular dystrophy, witnessed phenomenal results the first year after using THREAD's decentralized platform-powered Duchenne Registry mobile application. The organization gathered massive 50% more surveys than in the previous years, collected over 1,000 additional registrants worldwide, boosted the total number of participants to more than 5,500, and recruited for 12 clinical trials.<sup>1</sup>

*"The app has played a pivotal role in PPMD's efforts to increase community engagement, encourage citizen scientists, and advance Duchenne research. THREAD's technology and partnership have allowed us to make the Registry more accessible and intuitive for everyone - including patients, caregivers, and researchers. We are blown away by the results we saw just in the first year, and we cannot wait to see our continued progress in 2021."*

*-Ann Martin, Senior Vice President, Community Research and Registry Director, PPMD<sup>2</sup>*

THREAD provides a unique collaborative platform and an additional service suite from its highly trained expert team for CROs and sponsors. The company offers training, technical support, and a LaunchKit anticipating the study's needs, launch details, and step-by-step guidance throughout the study. It also provides support services related to data audit, management, and archival over a long period, safe and secure data transference, and multi-lingual training content for handheld devices and endpoints belonging to the participants. Unlike its competitors, THREAD does not offer pre-recorded demonstrations (demos) on its platform. It opens a live platform and demonstrates its solution's depth and complexity, proving its capabilities as a clinical trial system rather than just another telehealth feature.

The company's DCT platform enables access to prospective participants and sites throughout the world. Moreover, social media platforms and partnerships organically reach a more diverse and wider population and augment participation. For instance, in April 2021, THREAD partnered with CureClick, a community-powered platform leveraging social media influencers to promote patient recruitment.<sup>3</sup>

The company's collaborative ecosystem encompasses trial sites, patient recruitment, sensor and device, and home health vendors. THREAD ensures partners' culture, vision, and mission aligns with its own. The vetting process is meticulous. It involves scoring mechanisms, scoping processes, integration practices, and term sheets followed by a measurement system analysis. Such thoroughness ensures stakeholders cover a vast geographic region and limits the total number of partners, assuring smooth governance.

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<sup>1</sup> Parent Project Muscular Dystrophy's Duchenne Registry Participant Response Rate Increases Exponentially in 2020 utilizing THREAD. (2021, January 26). *THREAD*. <https://www.threadresearch.com/press-releases/parent-project-muscular-dystrophys-duchenne-registry-participant-response-rate-increases-exponentially-in-2020-utilizing-thread>.

<sup>2</sup> Ibid.

<sup>3</sup> Parkins, K. (2021, April 7). *THREAD Q&A: bridging the gap between patients and trials with social media*. Clinical trials arena. <https://www.clinicaltrialsarena.com/accelerating-clinical-trials/thread-ceo-john-reites-on-partnering-with-cureclick-and-bridging-the-gap-between-patients-and-clinical-research/>.

In essence, the company has a hub and spoke business model and maintains both enterprise and private partnerships.

Frost & Sullivan commends THREAD for its cutting-edge offerings and innovative customer acquisition strategies.

### ***Comprehensive Offerings Catering to Customer Needs Simplify Cumbersome Processes***

Rigorous adherence to regulatory standards globally enables covering many countries, facilitating diverse populations to participate in life-saving, critical clinical trials. All in all, THREAD's unique platform empowers CROs to efficiently attain recruitment goals (scalable as per their requirements) in terms of diversity, participant numbers, and sites. It also supports the essential planning phase, thus making the study more economical, rapidly deployable, and well-planned for execution.

The company transforms participants' previously costly, tedious, and cumbersome clinical trial ordeal into a safe, trustworthy, responsive, hassle-free, convenient, and inexpensive healthcare experience. THREAD's engaging platform comes equipped with essential features incorporating robust data security measures on the participant side. The company leverages tokenization and de-identification engines to process participants' personally identifiable information (PII) as hashes over decentralized networks. Furthermore, participants' PII and protected health information are in physically different and separated locations, making them invulnerable to hacking attacks. THREAD has successfully conducted five decentralized trials with US marines,<sup>4</sup> necessitating top-notch security, a testament to its superior privacy and security levels.

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**- Ojaswi Rana, Best Practices Research Analyst**

Data security is also an essential feature for THREAD'S electronic clinical outcome assessment (eCOA) and eConsent modules. The eCOA guarantees compliance to regulatory standards during the study and improves data quality. eCOA features include a library of fully validated and licensed ePRO, eClinRO, eObsRO, ePerfRO, eDRO, 501(k) approved and CE marked sensors, surveys, electronic source forms (eSource),

electronic case report forms (eCRF). THREAD can retain more participants and sites as processes are compliant to regulatory standards, secure, reliable, convenient, inexpensive, engaging, and straightforward. The company constantly adopts the latest technology trends and innovates. In March 2021, it updated its telehealth virtual visit feature with global compliance and full configuration.<sup>5</sup>

<sup>4</sup> Stuart, S. C. (2018, September 27). 'Body Computing' Turns Healthcare Into Lifecare. *PCMag.com*. <https://www.pcmag.com/news/364036/body-computing-turns-healthcare-into-lifecare> .

<sup>5</sup> THREAD Launches New Telehealth Features Expanding Video and Audio Capture for Complex eCOA during Virtual Visits in Decentralized Clinical Trials. (2021, March 18). *THREAD*. [https://www.threadresearch.com/press-releases/thread-launches-new-telehealth-features-expanding-video-and-audio-capture-for-complex-ecoa-during-virtual-visits-in-decentralized-clinical-trials?utm\\_campaign=Awareness\\_PR&utm\\_term=eCOA%204.0&utm\\_content=158388623&utm\\_medium=social&utm\\_source=twitter&hss\\_channel=tw-3254745308](https://www.threadresearch.com/press-releases/thread-launches-new-telehealth-features-expanding-video-and-audio-capture-for-complex-ecoa-during-virtual-visits-in-decentralized-clinical-trials?utm_campaign=Awareness_PR&utm_term=eCOA%204.0&utm_content=158388623&utm_medium=social&utm_source=twitter&hss_channel=tw-3254745308).

THREAD's eConsent simplifies participant consent for the study, another critical step in the process for participants and research teams. eConsent eliminates cumbersome paperwork requirements, expediting study launching and helping retain more participants by reducing the engagement hurdles considerably.

Frost & Sullivan applauds THREAD's comprehensive offerings with extensive modules and features, ensuring regulatory compliance, prioritizing customer needs, and driving decentralized trials.

### ***Synergistic Acquisitions Denting the Clinical Trials Ecosystem Spur Impressive Growth***

THREAD is available in more than 50 countries supporting various DCT designs in North America, Asia Pacific, Europe, Latin America, and Africa. It plans to make its mark in every country in every language as a key goal of the company. THREAD's growth strategies go beyond extending its global footprint. THREAD is private equity-backed and has the ability to grow organically and inorganically. Apart from its comprehensive, unified platform and inclusive, representative, and large participant population, the company seeks to reduce study costs. It reallocates health source data verification (SDV) and monitoring expenditures to conducting and funding additional research, paying more to patients and sites, bringing in more protocols. While its partnerships with enterprise customers have demonstrated 20% to 25% cost savings, THREAD is working towards lowering expenses by at least 30%, revolutionizing the ecosystem. Frost & Sullivan finds THREAD's expanding geographical outreach and ground-breaking initiatives impressive.

## **Conclusion**

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The onset of the COVID-19 pandemic highlighted patient-centric decentralized clinical trials' (DCT) importance in overcoming existing industry challenges by enhancing patient recruitment and engagement, simplifying data collection, increasing monitoring accuracy, accelerating study completion, and reducing costs, considerably elevating clinical trial delivery. THREAD's singular, fully configurable, and comprehensive DCT technology platform allows its clients to perform virtual trials from the planning stage to the design and implementation stages and culminating with a successful close-out. The company offers various modules with digital features, including electronic consent, electronic clinical outcome assessment with electronic patient-reported outcomes, sensors, surveys, electronic source forms, electronic case report forms, and electronic device-reported outcomes. THREAD's products and services are compliant with regulatory standards globally and purposefully developed to simplify the clinical trial processes for its clients. The company ensures a high customer ownership level and superior service experience, thus gaining more customers. THREAD's partner ecosystem comprises selective vendors across global sites, recruitment firms, sensor and device companies, and home health providers. It continues to acquire companies with synergistic functions, broadening its capabilities.

For its promising growth potential and comprehensive customer-oriented offerings, THREAD earns Frost & Sullivan's 2021 North American Customer Value Leadership Award in the decentralized clinical trials industry.

## What You Need to Know about the Customer Value Leadership Recognition

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Frost & Sullivan's Customer Value Leadership Award recognizes the company that offers products or services customers find superior for the overall price, performance, and quality.

### Best Practices Award Analysis

For the Customer Value Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

#### *Business Impact*

**Financial Performance:** Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

**Customer Acquisition:** Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

**Operational Efficiency:** Company staff performs assigned tasks productively, quickly, and to a high-quality standard

**Growth Potential:** Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

**Human Capital:** Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

#### *Customer Impact*

**Price/Performance Value:** Products or services provide the best value for the price compared to similar market offerings

**Customer Purchase Experience:** Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

**Customer Ownership Experience:** Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

**Customer Service Experience:** Customer service is accessible, fast, stress-free, and high quality

**Brand Equity:** Customers perceive the brand positively and exhibit high brand loyalty

## About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at <http://www.frost.com>.

## The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create on-going growth opportunities and strategies for our clients is fuelled by the Innovation Generator™. [Learn more.](#)

### Key Impacts:

- **Growth Pipeline:** Continuous flow of Growth opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



## The Innovation Generator™

Our six analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

### Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

