

Evinova Unified Trial Solution

Category:

Best Digital Health Solution

Company Name:

Evinova

Number of employees:

201-500

Turnover and/or Funding:

Evinova is a separate health tech company within the AstraZeneca group. AstraZeneca (AZ) originally invested in creating a portfolio of digital solutions to serve its own drug development pipeline that would improve upon the commercial options available at the time. With funding committed for the long term, in 2023 AZ established Evinova as an independent health-tech business leveraging deep experience across clinical development, digital strategy, technology, digital product development, data science and AI, measurement science, user experience design and behavioural science, to complement its scientific capability and establish a portfolio of solutions available to biopharmaceutical companies. Evinova is on track to meet \$157M Revenue this year, with 12 global contracts across life-sciences and break-even next year. Evinova provides global solutions, with Unified Trial Solution available in 57 countries (as of July 2025), including localization in China.

Product/Solution Name:

Evinova Unified Trial Solution

Corporate Name:

Evinova

Date of Approval:

2020-12-07

Indications:

Evinova's Unified Trial Solution (UTS) platform addresses needs identified through

extensive global research with patients, clinical research sites, and sponsors. UTS empowers the design and execution of innovative clinical studies that are faster and more cost-effective, while delivering an improved experience for patients and sites alongside high-quality data for sponsors.

UTS has been developed to support multiple indications, offering a flexible and scalable digital infrastructure that supports a broad range of therapeutic areas and clinical trial designs. The platform is highly configurable and has been successfully applied in many studies across oncology, respiratory, cardiovascular, metabolic, and rare disease globally, providing great flexibility to meet the specific needs of patients with these conditions and the clinical sites treating them.

Evinova has strategically partnered with indication leaders to identify key priorities that enable novel approaches with substantial benefits. These priorities have been integrated into the platform, generating significant outcomes published in Nature Medicine. Results include over 60% improvement in patient experience, six-month timeline acceleration, and 32% cost reduction.¹ The platform can be deployed for patient-centric, decentralized and hybrid trial models, effectively reaching underserved populations and those managing high-burden conditions.

Date of approval refers to date of US launch.

Therapeutic Areas:

Clinical trials often burden patients, leading to poor enrolment, high dropout rates and delayed outcomes. Evinova's Unified Trial Solution (UTS) addresses these challenges through disease-specific digital modules that enhance patient management and support. UTS improves monitoring while reducing in-person visits, enables earlier and more informed interventions and accelerates clinical assessments.

Oncology:

UTS scientifically integrates evidence-based remote patient monitoring (RPM) and symptom tracking into oncology trial workflows. Cancer treatment toxicities often affect dosing and duration, compromising clinical outcomes and patient experience. Evinova's RPM modules help sites manage serious side effects, including oral mucositis, interstitial lung disease and digestive issues. Patients receive real-time personalized guidance through the app, while clinicians receive alerts about worsening symptoms for faster intervention. These tools reduce unnecessary visits and help maintain optimal treatment doses longer, driving better outcomes. 9,000+ oncology trial patients have used UTS RPM.

Respiratory:

UTS enabled one of the fastest COPD studies ever conducted by a top 10 pharma

company. Traditional trials require monthly site visits to monitor lung function and symptoms, yet still risk missing changes in patient status-leading to longer timelines and larger participant targets.

UTS introduced at-home, coached spirometry with clinic-equivalent quality and enabled the use of CompEx-a novel, composite endpoint that integrates daily clinical indicators such as lung function, symptoms, and medication use to provide a more holistic measure of treatment effectiveness. Evinova has taken CompEx a step further by digitizing it, automating real-time data capture, calculation and visualization through UTS.

In a Phase II COPD trial, this innovation reduced the participant count from 604 to 288, halved site visits, delivered 15% cost savings and accelerated timelines by nine months. AI-driven quality checks delivered results in minutes, reducing missing data and eliminating repeat visits. The patient-centric design also enabled record-breaking recruitment-twice as fast as previous COPD studies by the sponsor.

Cardiovascular and Metabolic:

Traditional clinical trials are lengthy and resource-intensive, requiring large participant pools. UTS enables decentralized models where participants engage from home using connected devices and digital endpoints. This approach reduced clinic visits by 60% and per-patient costs by 43%, saving over \$25 million in large trials.¹ The platform's engaging interface and rich content maintain high compliance over time, addressing dropout rates that are common in long-term studies.

Rare Disease:

Patients often live far from trial sites, limiting access. UTS helps overcome this by enabling 70+% of data to be collected remotely or near the patient's home. Direct-to-patient drug delivery and simplified digital tools support up to 40% fewer site visits, broadening participation, reducing burden and improving retention.¹

All UTS modules and features are developed with therapeutic experts and clinical scientists and backed by evidence. UTS helps sponsors run faster, more inclusive trials with better outcomes for patients.

General Information File Document upload:

N/A

Background information and need for drug / device:

Traditional clinical trials are expensive, time-consuming, and inefficient. Despite the opportunity to access new medicines, fewer than 3-5% of eligible patients enrol in

clinical studies, largely due to logistical burdens like travel requirements, time commitment, and procedural complexity.² The frequent visits to research facilities disrupt participants' daily lives and severely restrict access, particularly for those in rural or underserved communities. These obstacles contribute to substantial dropout rates of 15-40%³ which frequently cause trial delays. Such delays cost pharmaceutical companies millions in unrealized revenue while postponing patient access to potentially life-saving medicines.^{4,5}

UTS was designed to address these longstanding inefficiencies. UTS is a comprehensive, end-to-end digital platform purpose-built for clinical research. Unlike many digital solutions that require the integration of disparate tools, UTS consolidates key trial functionalities such as eConsent, visit scheduling, electronic Clinical Outcome Assessments (eCOA), telehealth, home delivery, BioSample tracking, Remote Patient Monitoring (RPM), and real-time data integration into a single, unified and integrated experience for patients, sites and sponsors.

This integrated model offers distinct advantages: trial sponsors and sites benefit from reduced complexity, lower costs, and minimized vendor risk, while patients experience a more seamless, user-friendly journey. Because each module is designed to interoperate natively, UTS minimizes data duplication, reduces transcription errors, and improves overall data integrity. Additionally, multilingual support in over 115 languages and locales enables global trial deployments.

The design of UTS is grounded in ethnographic research based on over 15,000 data points from patients, caregivers, and research staff across nine countries. This deep user research informed the development of features that are not only technologically robust but also highly aligned with the real-world needs of stakeholders. Patients rate UTS a 9.1/10 on the usability of the platform.

By offering a truly unified digital platform tailored to the demands of modern clinical research, UTS simplifies operational complexity, broadens trial access, improves retention, and accelerates development timelines while upholding the highest standards of scientific rigor and regulatory compliance. It represents a major step toward a more inclusive, efficient, and patient-centric future for clinical trials.

Background File Document upload:

N/A

History of the development of the solution/product:

In 2018, AstraZeneca recognized that traditional site-based clinical trial models created

significant barriers to participation and completion, limiting the opportunity to transform trial design to accelerate the development of new medicines. The Digital Health R&D Team - now Evinova - conducted global ethnographic research that revealed a troubling reality: trial participants were overwhelmed by frequent site visits, while researchers struggled with fragmented processes and data collection inefficiencies. This critical insight catalyzed AstraZeneca's investment in digital solutions to reimagine the clinical trial experience for patients.

An analysis of 91 protocols demonstrated that up to 70% of trial procedures could be conducted remotely without compromising scientific integrity, yet the proliferation of disconnected digital tools created new complexities and added burden for participants. From this challenge emerged the concept for UTS - a clinical trial support tool that seamlessly integrates multiple connected devices into one platform, preserving data quality and patient safety while fundamentally transforming how clinical research engages with participants.

UTS simplifies trials for patients, sites and sponsors by integrating validated connected devices, electronic consent (eConsent), telehealth, eCOA, and digital endpoint capture into one seamless experience. UTS quickly evolved into a scalable platform supporting the entire trial lifecycle. The COVID-19 pandemic accelerated its adoption in 2020, as site closures drove the need for decentralized trials. AstraZeneca's early investment allowed rapid deployment, proving the reliability of remote data collection and uncovering additional opportunities to improve trial experiences and outcomes.

Evinova scientists developed RPM modules for the UTS platform to help sites monitor patient toxicity in real-time and alert physicians to patient symptoms so they can intervene early, preventing the escalation of certain adverse events that can impact treatment dose or duration. Evinova's RPM modules also empower patients with the resources and support to manage side effects at home, improving their overall trial experience.

Evinova's RPM incorporates advanced scientific features, including branching logic for symptom monitoring, at-home Pulse Oximetry measurements (both at rest and during exertion), alerts prompting patients to contact their care teams, and notifications for clinical sites to closely monitor critical cases. Additionally, it captures patient-reported outcomes specific to their condition, enhancing the overall management of treatment side effects. This innovative, science-backed approach supports better care for patients and improved outcomes.

Since its inception, UTS has expanded to support 3,600+ sites and is available to 40,000 patients across 57 countries, 130 languages and locales, in multiple therapy areas. New integrations with electronic health records, AI-powered symptom tracking, a single sign-on portal for sites to access clinical technology needed for a trial through the UTS platform with GenAI search capabilities and advanced analytics will further

enhance the platform.

In 2023, AstraZeneca launched Evinova, a separate digital health company, to commercialize UTS and extend its impact across the clinical research ecosystem. UTS represents a shift from traditional site-centric trials to hybrid, technology-enabled models that balance flexibility with scientific rigor. By creating a patient-centered infrastructure, Evinova is reducing trial burdens, improving patient experiences, and enabling broader participation in advancing life-changing therapies.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

UTS represents a paradigm shift in clinical research by addressing the fundamental disconnect between technological advancement and human experience. Unlike traditional approaches that simply digitize existing processes, UTS reimagines the entire clinical trial ecosystem through seamless integration of previously fragmented digital tools. This innovation eliminates the paradoxical burden created when well-intentioned technologies actually increase complexity for patients and researchers.

By enabling remote data capture while maintaining scientific integrity, UTS dramatically improves the human condition on multiple fronts. First, it democratizes clinical research participation by removing geographic, physical, and socioeconomic barriers that have historically excluded diverse populations. Second, it returns valuable time and autonomy to patients by reducing site visits and streamlining their engagement. Third, digital health technology could reduce carbon emissions by 20% by 2050.⁶ Lastly, it accelerates the development of life-saving treatments by enhancing recruitment, improving retention, managing toxicity to support improved experiences and outcomes and generating higher-quality data through real-world collection methods.

Unlike most other clinical trial technology, UTS is proven to drive improved outcomes. A Nature Medicine paper provided evidence that the implementation of digital health technology in clinical trials improves patient experience with accelerated timelines, reduced costs, and improved health outcomes.¹

As a result of these outcomes, AstraZeneca expanded its widely cited 5Rs framework for R&D productivity to include a sixth R – "right digital solution" – recognizing the essential role of digital health tools in bringing new medicines to patients faster and more effectively.

By combining science, technology, and patient insight, Evinova UTS is helping the industry modernize how patient-centric trials are run. This innovation has the potential to significantly improve the way new therapies are developed and delivered directly supporting the mission of the Prix Galien to reward advances that improve the human condition.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

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6. World Economic Forum (2022). Digital solutions can reduce global emissions by up to 20%. Here's how. Available at: <https://www.weforum.org/stories/2022/05/how-digital-solutions-can-reduce-global-emissions/>

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